Medical Coverage Policy

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Coverage Policy Number..... 0068

Tissue-Engineered Skin Substitutes

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only

be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses tissue engineered skin substitutes and the various proposed indications for their use in multiple conditions.

Coverage Policy

Each of the following skin grafts is considered medically necessary for wound coverage:

- autologous skin graft (CPT® Codes 15150-15157)
- unprocessed allogeneic human, cadaver skin graft (CPT® Codes 15271-15278)
- unprocessed xenogeneic pig skin graft (CPT® Codes 15271-15278)

Each of the following products is considered medically necessary as indicated:

Covered Indication - Breast Reconstruction			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
AlloMax™	15777	C1781	Considered medically necessary when used in association with a covered, medically necessary breast reconstruction procedure.
Cortiva®	15777	C9399	
Dermacell®	15777	Q4122	
FlexHD® Acellular Hydrated Dermis	15777	Q4128	
GalaFLEX® Scaffold GalaFLEX 3D Scaffold GalaFLEX 3DR Scaffold GalaFLEX LITE™ Scaffold	15777	C9399	
Avance® Nerve Graft	64912 64913	C9399	Considered medically necessary when used in association with mastectomy or breast reconstruction procedures when nerves cannot be preserved.

Covered Indication - Burn wounds			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
Biobrane	15271-15278 C5271 C5273 C5275	C9399	Considered medically necessary when used for temporary covering of a partial-thickness freshly debrided or excised burn wound
Biobrane-L	15271-15278 C5271 C5273 C5275	C9399	Considered medically necessary when BOTH of the following criteria are met: • temporary covering of a partial-thickness freshly debrided or excised burn wound • adjunct to meshed autograft
Epicel	15150-15157 C5271 C5273 C5275	C9399	Considered medically necessary when used according to the U.S. Food and Drug Administration (FDA)-approved Humanitarian Device Exemption (HDE) for an individual with deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30%

Covered Indication - Diabetic Foot Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
Actigraft®	15271-15278	C9399	Considered medically necessary when ALL of the following criteria are met: • partial or full-thickness diabetic foot ulcer of greater than four weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to five applications • additional applications up to a maximum of eight in 12 weeks are considered medically necessary when there is evidence of wound healing (e.g., signs of epithelialization and reduction in ulcer size)

Covered Indication - Diabetic Foot Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
AlloPatch Pliable®	15275-15278	Q4128	Considered medically necessary when ALL of the following criteria are met: • full-thickness diabetic foot ulcer of greater than six weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to five applications • additional applications up to a maximum of eight in 12 weeks are considered medically necessary when there is evidence of wound healing (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
AmnioBand®	15275-15278	Q4151 Q4168	Considered medically necessary when ALL of the following criteria are met: • full-thickness diabetic foot ulcer of greater than six weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply:

Covered Indication - Diabetic Foot Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			• initial treatment is limited to five applications • additional applications up to a maximum of eight in 12 weeks are considered medically necessary when there is evidence of wound healing (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Dermacell AWM® For Breast Reconstruction see CP 0178	15275-15278	Q4122	Considered medically necessary when ALL of the following criteria are met: • partial or full-thickness diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, treatment is limited to a total of two applications. Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
EpiFix® Amniotic Membrane	15275-15278	Q4186	Considered medically necessary when ALL of the following criteria are met: • partial or full-thickness, diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70

Covered Indication - Diabetic Foot Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to four applications • additional applications up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Grafix® GRAFIX DUO	15275-15278	Q4132 Q4133 Q4392	Considered medically necessary when ALL of the following criteria are met: • partial or full-thickness diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to five applications • additional applications up to a maximum of six in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Kerecis Omega3 Marigen Shield	15271-15278	A2019	Considered medically necessary when ALL of the following criteria are met:

Covered Indication - Diabetic Foot Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			• partial or full-thickness diabetic foot ulcer of greater than four weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to five applications • additional applications up to a maximum of 12 in 12 weeks are considered medically necessary when there is evidence of wound healing (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Kerecis® Omega3 Wound	15271-15278	Q4158	Considered medically necessary when ALL of the following criteria are met: • partial or full-thickness diabetic foot ulcer of greater than four weeks duration for which standard therapy has failed • type I or type II diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to five applications • additional applications up to a maximum of 12 in 12 weeks are considered medically necessary when there is evidence of wound healing (e.g., signs of epithelialization and reduction in ulcer size)

Covered Indication - Diabetic Foot Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Oasis® Wound Matrix Oasis® Ultra Tri-Layer Matrix	15275-15278	Q4102 Q4124	Considered medically necessary when ALL of the following criteria are met: • partial or full-thickness, diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to four applications • additional applications up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.

Covered Indication - Venous Stasis Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
AmnioBand®	15271-15278	Q4151 Q4168	Considered medically necessary when BOTH of the following criteria are met: • partial- or full-thickness venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the

Covered Indication - Venous Stasis Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to five applications • additional applications up to a maximum of 12 in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
EpiFix® Amniotic Membrane	15271-15278	Q4186	Considered medically necessary when BOTH of the following criteria are met: • partial- or full-thickness venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to four applications • additional applications up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.

Covered Indication - Venous Stasis Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
Grafix® GRAFIX DUO	15271-15278	Q4132 Q4133 Q4392	Considered medically necessary when BOTH of the following criteria are met: • partial- or full-thickness venous stasis ulcer of greater than four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to five applications • additional applications up to a maximum of six in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size) Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.
Oasis Wound Matrix Oasis® Ultra Tri-Layer Matrix	15271-15278	Q4102 Q4124	Considered medically necessary when BOTH of the following criteria are met: • partial or full-thickness, lower extremity venous stasis ulcer of four weeks duration for which standard wound therapy has failed • treated lower extremity has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, the following conditions of coverage apply: • initial treatment is limited to four applications • additional applications up to a maximum of four in 12 weeks are considered medically necessary when evidence of wound healing is present (e.g., signs of epithelialization and reduction in ulcer size)

Covered Indication - Venous Stasis Ulcers			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			Additional applications beyond 12 weeks are considered not medically necessary regardless of wound status.

Covered Indication - Dural repair			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
Biodesign® Dural Graft	No specific code	C1763	Considered medically necessary when used in association with a covered, medically necessary skull or spine procedure.
Duraform™	No specific code	C9399	
DuraGen®	No specific code	C9399	
Dura-Guard	No specific code	C1763	
DuraMatrix™	No specific code	C9399	
Durepair Dura Regeneration Matrix®	No specific code	C9399	
Lyoplant®	No specific code	C1763	
SYNTHECEL™ Dura Repair	No specific code	C1781	

Covered Indication - Paraesophageal/hiatal hernia repair			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
Phasix™ ST Mesh	15271-15278	C1781	Considered medically necessary when used in association with a covered, medically necessary hiatal hernia repair when **ANY** of the following criteria are met: • the crural fibers are disrupted during dissection • the hernia defect is large (defined as: ≥ 30-50% of the stomach herniates into the thoracic cavity **OR** hiatal surface area of >5 cm^2) • crural closure is tenuous
GORE® BIO-A® Tissue Reinforcement	15777 17999	C1781	

Covered Indication - Paraesophageal/hiatal hernia repair			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
			• crural closure is under tension

Covered Indication –Peripheral Nerve Repair			
Skin Substitute	**Application CPT®/HCPCS Codes**	**Product HCPCS Codes**	**Criteria**
Avance Nerve Graft	64912 64913	C9399	Considered medically necessary for peripheral nerve gap repair in digital nerves when direct repair is not feasible.

Each of the products listed above for ANY unlisted indication is considered not medically necessary.

Each of the following products listed below is considered experimental, investigational, or unproven for ANY indication:

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
Absolv3 Membrane	Wound care	15271-15278	Q4401
AC5® Advanced Wound System	Wound healing	15271-15278	A2020
A/C Wrap™	Wound care	15271-15278	Q4422
Acelagraft®	Wound care	15271-15278	Q4395
Acesso TrifACA	Wound care	15271-15278	Q4386
Actishield™ Amniotic Barrier Membrane	Soft and/or hard tissue repair	15271-15278	C9399
Actishield™CF Amniotic Barrier Membrane	Soft and/or hard tissue repair	15271-15278	C9399
ActiveBarrier®	Wound care	15271-15278	C9399
ActiveMatrix® flowable	Connective tissue repair	No specific code	C9399
Adherus Dural Sealant®	Dural repair	No specific code	C9399
Affinity	Wound care	15271-15278	Q4159

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
AlloMend® Acellular Dermal Matrix	Soft tissue repair	No specific code	C1762
Allopatch HD™	Tendon augmentation	No specific code	Q4128
Allowrap™ DS and Dry	Wound care	15271-15278	Q4150
AmchoMatrixDL	Wound care	15271-15278	Q4410
AmnioAMP-MP™	Wound care	15271-15278	Q4250
AmnioBand® Particulate	Wound care	15777	Q4168
Amnio Burgeon Dual-Layer Membrane	Wound care	15271-15278	Q4365
Amnio Burgeon Membrane and Hydromembrane	Wound care	15271-15278	Q4363
Amnio Burgeon XPlus Membrane and XPlus Hydromembrane	Wound care	15271-15278	Q4364
AmnioCare®	Tendon/nerve repair	No specific code	C9399
AmnioClear®	Wound care Surgical barrier	15271-15278	C9399
AmnioClear LTC flowable	Knee pain and inflammation	No specific code	J3590
AMNIOCORD®	Wound care	15271-15278	C9399
AmnioCore™	Wound care	15271-15278	Q4227
Amniocyte™ Flowable Matrix	Connective tissue repair	No specific code	J3590
AmnioEffect™	Wound care Surgical barrier	15271-15278	C9399
AmnioExCel/AmnioExcel Plus/BioDExCel™	Wound care Soft tissue repair	15271-15278	Q4137
Amniofix® Amniotic Membrane	Tendon/nerve repair	No specific code	C9399
Amniofix® Injectable	Tendon repair Soft tissue repair	No specific code	J3590
AmnioHeal® Plus	Wound care	15271-15278	C9399
Amnio-Maxx	Wound care	15271-15278	Q4239
AmnioMatrix®	Wound care Soft tissue repair	15271-15278	Q4139
AmnioMatrixF4X	Wound care	15271-15278	Q4411

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
AmnioPro Membrane	Wound care	15271-15278	C9399
Amniorepair/Altiply	Wound care	15271-15278	Q4235
Amnios®/Amnios® RT	Wound care	No specific code	C9399
Amniovo™	Soft tissue repair Tendon repair	No specific code	C9399
Anu RHEO™	Connective tissue repair	No specific code	C9399
Apollo FT	Wound care	15271-15278	Q4385
Artacent® ac, powder	Wound care	No specific code	Q4189
Arthrex Amnion™ Matrix	Orthopedic barrier or wrap	No specific code	C1762
Arthrex Amnion™ Viscous	Orthopedic barrier or wrap	No specific code	J3590
ArthroFlex™ (FlexGraft®)	Shoulder reconstruction Achilles tendon repair	No specific code	Q4125
ARTIA™ Reconstructive Tissue Matrix	Soft tissue repair	No specific code	C1763
Avive+ Soft Tissue Matrix	Soft tissue barrier	No specific code	C9399
AxoGuard® Nerve Connector	Peripheral nerve repair	64999	C1763
AxoGuard® Nerve Protector	Peripheral nerve repair	64999	C1763
Axolotl Ambient™	Soft tissue repair	No specific code	Q4215
Axolotl Cryo™	Soft tissue repair	No specific code	Q4215
Axolotl DualGraft™	Soft tissue repair	15271-15278	Q4332
Axolotl Graft™	Soft tissue repair	15271-15278	Q4331
Axolotl Graft™ Ultra	Wound care	15271-15278	Q4383
BellaDerm® Acellular Hydrated Dermis	Integumental tissue repair Soft tissue repair	15778	C9399
BioDfence™	Surgical wrap/barrier Tendon repair	No specific code	Q4140
BioDfence™ DryFlex	Surgical wrap/barrier Tendon repair	No specific code	Q4138
Biodesign Anal Fistula Plug (AFP)	Anal and rectal fistula repair	46707	C1763

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
Biodesign® Fistula Plug Set	Recto-vaginal fístula repair	No specific code	C1763
Biodesign® Hiatal Hernia Graft	Hernia repair	No specific code	C1781
Biodesign® Inguinal Hernia Graft	Hernia repair	No specific code	C1781
Biodesign® Otologic Repair Graft	Otologic repair	No specific code	C1763
Biodesign® Peyronie's Repair Graft	Urological deficits	15778	C1763
Biodesign® Rectopexy Graft	Rectal prolapse/rectal intussusception	No specific code	C1763
Biodesign® Sinonasal Repair Graft	Wound care	No specific code	C1763
BioFix®	Wound care	15271-15278	C9399
BioLab Tri-Membrane Wrap Flow™	Wound care	15271-15278	Q4423
CardioCel®	Pericardial closure Cardiac and vascular defect repairs	No specific code	C9399
CardioGRAFT-MC™ Decellularized Pulmonary Patch Graft	Repair of right ventricular outflow tract	No specific code	C9399
carePATCH	Burn care Wound care	15271-15278	Q4236
Clarix 100	Surgical covering/wrap/barrier	No specific code	Q4156
Clarix Cord 1K	Surgical covering/wrap/barrier	No specific code	Q4148
Clarix® Regenerative Matrix	Surgical covering/wrap/barrier	No specific code	C9399
Clarix® Flo	Integumental tissue repair	No specific code	Q4155
Cocoon membrane	Wound care	15271-15278	Q4264
Coll-e-Derm	Soft tissue repair	15271-15278	Q4193
Cogenex Amniotic Membrane	Burn care Wound care	15271-15278	Q4229
Complete™ FT	Wound care	15271-15278	Q4271
Complete™ SL	Wound care	15271-15278	Q4270
Coretext and Protext	Tissue repair	No specific code	Q4246
CorMatrix® ECM® for Cardiac Tissue Repair	Intracardiac patch	No specific code	C9399

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
CorMatrix® ECM® for Carotid Repair	Carotid artery repair	No specific code	C9399
CorMatrix® ECM® for Pericardial Closure	Pericardial repair	No specific code	C9399
Creos™ Xenoprotect	Bone and tissue regeneration	No specific code	C9399
CryoMatrix®	Connective tissue repair	No specific code	C9399
CryoSkin®	Wound care	15271-15278	C9399
CTM Flow	Soft tissue repair Connective tissue repair	15271-15278	C1762
CTM Thick	Soft tissue repair Connective tissue repair	15271-15278	C1762
CuraMatrix	Wound care	15271-15278	Q4440
Cygnus®	Wound care Nerve wrap	15271-15278 64999	Q4170
CYGNUS Solo	Wound care	15271-15278	Q4413
Cytal®	Wond care	15271-15278	Q4166
DermaBind SL DermaBind SL N DermaBind SL X	Wound care	15271-15278	Q4428
DermaPure™	Wound care	15271-15278	Q4152
DermaSpan™	Wound covering Tendon repair	15271-15278 15778	Q4126
Dual Layer Amnio Burgeon X-Membrane	Wound care	15271-15278	Q4366
Dual layer impax membrane	Wound care	15271-15278	Q4262
DuraSeal® Dural Sealant System	Dural repair	No specific code	C9399
DuraSeal® Exact Spine Sealant System	Dural repair	No specific code	C9399
DuraSorb® Monofilament Mesh/ Polydioxanone Surgical Scaffold™	Soft tissue reinforcement	No specific code	C1781
Endoform Dermal Template™	Wound care	15271-15278	C9399

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
EpiBurn®	Wound care	15271-15278	C9399
EPICORD®	Wound care	15271-15278	Q4187
EPIXPRESS™	Wound care	15271-15278	Q4361
Esano™ A	Wound care	15271-15278	Q4272
Esano™ AAA	Wound care	15271-15278	Q4273
Esano™ AC	Wound care	15271-15278	Q4274
Esano™ ACA	Wound care	15271-15278	Q4275
Essence Acellular Dermal Matrix	Soft tissue reinforcement	15777	C1762
FloGraft™ flowable	Tendonitis Soft tissue trauma	No specific code	C9399
Fortaderm™/PuraPly™	Wound care	15271-15278	Q4195
Fortiva® Porcine Dermis	Soft tissue reinforcement	15778	C1763
Gentrix®	Soft tissue reinforcement	No specific code	C1763 C1781
GORE® BIO-A® Fistula Plug	Anorectal fistulas	46707	C1781
GraftJacket® Xpress	Wound care	No specific code	Q4113
GrowFX® Connective Tissue Matrix	Soft tissue reinforcement	15271-15278	C1762
Guard AC - Amniotic Allograft	Wound care	15275-15278	C9399
Helicoll™	Wound care	15271-15278	Q4164
HydroFix® Vaso Shield	Vessel guard	No specific code	C9399
InnovaMatrix® FD	Wound care	15271-15278	A2039
Integra™ Flowable Wound Matrix	Wound care	No specific code	Q4114
Integra® Reinforcement Matrix	Soft tissue reinforcement	No specific code	C1763
InteguPly	Tendon repair Wound care	15271-15278	Q4126
MatriStem®	Wound care	15271-15278	Q4118
Matrix HD™	Wound care Tendon repair	15271-15278	Q4345

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
Membrane Graft™	Wound care	15271-15278	Q4205
Membrane Wrap™	Wound care	15271-15278	Q4205
Membrane Wrap Flow™	Wound care	15271-15278	Q4418
MemoDerm™	Wound care Tendon repair	15271-15278	Q4126
Miamnion®	Wound care	No specific code	C9399
Microlyte® Matrix	Wound care	15271-15278	A2005
MiroFlex® (formerly Miromesh®)	Soft tissue reinforcement	No specific code	C9399
Myriad Matrix™	Wound care	15271-15278	C9399
Myriad Morcells™	Wound care	15271-15278	A2033
Natalin®	Wound care	15271-15278	Q4396
NeoMatriX®	Wound care	15271-15278	A2021
NeoStim DL	Wound care	15271-15278	Q4267
NeoStim Membrane	Wound care	15271-15278	Q4266
NeoStim TL	Wound care	15271-15278	Q4265
NeoThelium FT	Wound care	15271-15278	Q4387
NeoThelium 4L	Wound care	15271-15278	Q4388
NeoThelium 4L+	Wound care	15271-15278	Q4389
Neox® 100	Wound care	15271-15278	Q4156
Neox® 1K Neox RT	Wound care	15271-15278	Q4148
Neox® Flo	Wound care	No specific code	Q4155
NeuraGen® Nerve Guide	Peripheral nerve repair	64910	C9352
NeuraWrap™ Nerve Protector	Peripheral nerve repair	64999	C9353
NeuroFlex™	Peripheral nerve repair	64999	C9399
Novafix® DL	Wound care	15271-15278	Q4254

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
NuCel™	Wound care	No specific code	C9399
NuForm	Wound care	15271-15278	Q4420
NuShield™ Orthopaedics	Tendon repair	No specific code	Q4160
NuShield™ Spine	Dura repair	No specific code	Q4160
Oasis® Burn Matrix	Burn wounds	15271-15278	Q4103
Orcel®	Burn wounds	15271-15278	C9399
Orion Amniotic Membrane	Wound covering	15271-15278	Q4276
OrthADAPT™ Bioimplant	Soft tissue reinforcement	15777 15778 17999	C1781
OsseoGuard®	Oral defects	15275-15278	C9399
Ovation®	Wound healing	15271-15278	C9399
OviTex®	Soft tissue reinforcement Breast reconstruction	No specific code	C1781
PalinGen® Flow	Soft tissue repair	No specific code	Q4174
PalinGen® Membrane, PalinGen® HydroMembrane, PalinGen® Xplus, PalinGen® Xplus HydroMembrane	Soft tissue repair	No specific code	Q4173
Paraderm™ Dermal Matrix	Integumental tissue repair	No specific code	C9399
Peri-Guard® Repair Patch	Soft tissue repair Pericardial and intracardiac repair	No specific code	C1763
Peri-Strips® Dry with Veritas Collagen Matrix	Staple line reinforcement	No specific code	C9399
Permacol™	Soft tissue reinforcement/repair	15777 17999	C9364
Phasix Mesh	Soft tissue reinforcement/repair	15271-15278 15778 C5271 C5278	C1781
Phasix™ Plug and Patch	Soft tissue reinforcement/repair	15271-15278	C1781

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
		15778	
PhotoFix® Decellularized Bovine Pericardium	Vascular repair	No specific code	C1763
Polygon3 Membrane	Wound care	15271-15278	Q4400
Preclude® Pericardial Membrane	Pericardial repair	No specific code	C9399
Preclude® Vessel Guard	Vessel covering	No specific code	C9399
Pretect	Wound care	15271-15278	Q4438
Pro3™ Amniotic Fluid	Wound care	No specific code	J3590
Pro3™ Membrane	Wound care	15271-15278	C9399
Proceed® Surgical Mesh	Hernia repair	No specific code	C9399
ProgenaMatrix™	Wound care	15271-15278	Q4222
ProLayer Acellular Matrix	Wound care	15271-15278 15778	C9399
ProLayer Xenograft	Soft tissue repair	15778	C9399
ProMatrX™	Wound care	No specific code	Q4174
Promote™ Amnio-Frt™	Wound care	15271-15278	C9399
Promote™ Amnio F™	Wound care	15271-15278	C9399
Promote AmnioStrip®	Wound care	15271-15278 15778	C9399
Puracol®	Wound care	15271-15278	C9399
PuraPly® Wound Matrix	Wound care	15271-15278	Q4195
PuraPly® Antimicrobial/PuraPly® AM	Wound care	15271-15278	Q4196
PX50®/PX50® Plus	Damaged or inadequate tissue repair	No specific code	C9399
RECELL® Autologous Cell Harvesting Device	Burn Care	15011-15018	C8002
REGENETEN Bioinductive Implant	Tendon repair	No specific code	C1763

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
Renati AC Membrane	Wound care	15271-15278	Q4436
Renuva® Allogrft Adipose Matrix	Reconstructive surgery Breast reconstruction	No specific code	J3590
Repliform™	Integumental tissue repair	No specific code	C1762
Restore® Orthobiologic Soft Tissue Implant	Soft tissue reinforcement	17999	C1763
Restorigin™ Amniotic Fluid	Wound care	No specific code	Q4192
Revita	Wound care	15271-15278	Q4180
REVIVAL™ AC	Wound care	15271-15278	Q4437
Revive FT	Wound care	15271-15278	Q4424
Seamguard® Staple Line Reinforcement	Staple line reinforcement	No specific code	C9399
Simpliderm™	Soft tissue reinforcement/repair Breast reconstruction	15777	C9399
SJM™ Pericardial Patch with EnCap™ AC Technology	Pericardial repair	No specific code	C9399
SomaGen® Meshed Tissue	Wound care	15271-15278	C9399
SportMesh™	Soft tissue reinforcement	15777 17999	C1781
SteriShield™	Soft tissue reinforcement/repair	15777 15778 17999	C9399
Strattice™ Reconstructive Tissue Matrix	Soft tissue reinforcement/repair	15777 17999	Q4130
Stravix ™	Integumental tissue repair	15778	Q4133
Summit AAA	Wound care	15271-15278	Q4397
Summit AC	Wound care	15271-15278	Q4398
Summit FX	Wound care	15271-15278	Q4399
SurGraft AC	Wound care	15271-15278	Q4393
SurGraft ACA	Wound care	15271-15278	Q4394

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
SurGraft® FT	Wound care	15271-15278	Q4268
SurGraft TL®	Wound care	15271-15278	Q4263
SurGraft® XT	Wound care	15271-15278	Q4269
SurgiMend®	Breast reconstruction	15777	C9358 C9360
tarSys™	Eyelid reconstruction	15275	C9399
TEXAGEN Amniotic Membrane Allograft	Wound care	15271-15278	C9399
TissueMend	Soft tissue repair Tendon repair	No specific code	C1781
Tornier® BioFiber Absorbable Biological Scaffold	Soft tissue reinforcement/repair	15777 15778 17999	C1781
Tornier® Collagen Coated BioFiber Scaffold	Soft tissue reinforcement/repair	15777 15778 17999	C1781
TranZgraft	Tendon repair	15271-15278	Q4126
Tutopatch® Bovine Pericardium	Soft tissue reinforcement/repair	15777 17999	C1781
Tutoplast® Pericardium Allograft/Tutoplast Processed Pericardium	Soft tissue reinforcement/repair	15271-15278	C1762
Unite® Biomatrix	Wound care	15271-15278	C9399
VascuCel®	Vascular patch	No specific code	C9399
Vascu-Guard®	Peripheral vascular reconstruction	No specific code	C9399
VersaShield™	Wound care Soft tissue covering	15271-15278	C9399
Viaflow™/Viaflow C	Connective tissue repair	No specific code	C1781
VIAGENEX™ Matrix Amnion Allograft	Soft tissue covering Wound covering	15271-15278	C9399
VIAGENEX™ Max Umbilical Cord Membrane	Soft tissue covering Wound covering	15271-15278	C9399
VNEW™ Precut Shaped Decellularized Dermal Allograft	Integumental tissue repair	No specific code	C1762
WoundEx® Membrane	Wound care	15271-15278	Q4163
WoundEx® Flow	Integumental tissue repair	No specific code	Q4162

Not Covered Products	Reason(s) for Request (this list may not be all inclusive)	Application CPT/HCPCS Codes	Product HCPCS Codes
Xcellerate	Burn care Wound care	15271-15278	Q4234
XCelliStem® Wound Powder	Wound care	No specific code	A2004
XenMatrix™ Surgical Graft	Soft tissue reinforcement/repair	15777 17999	C1781
XenoSure® Biologic Patch	Cardiac reconstruction/repair Vascular reconstruction/repair	No specific code	C1781
XWrap®	Wound care	15271-15278	Q4204
XWrap® Dual	Wound care	15271-15278	Q4358
XWrap® Plus	Wound care	15271-15278	Q4357
Zenith™ Amniotic Membrane	Burn care Wound care	15271-15278	Q4253

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Covered Tissue Engineered Skin Substitutes Application and Product Codes

Considered Medically Necessary when criteria in the applicable policy statement listed above are met and when used to report the application and/or the product of a covered skin substitute:

CPT®* Codes	Description
15150	Tissue cultured skin autograft, trunk, arms, legs; first 25 sq cm or less
15151	Tissue cultured skin autograft, trunk, arms, legs; additional 1 sq cm to 75 sq cm (List separately in addition to code for primary procedure)
15152	Tissue cultured skin autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15155	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 25 sq cm or less

CPT®* Codes	Description
15156	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; additional 1 sq cm to 75 sq cm (List separately in addition to code for primary procedure)
15157	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk) (List separately in addition to code for primary procedure)
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
64912	Nerve repair; with nerve allograft, each nerve, first strand (cable)
64913	Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)

HCPCS Codes	Description
A2019	Kerecis omega3 marigen shield, per square centimeter
C1763	Connective tissue, non-human (includes synthetic)
C1781	Mesh (implantable)

HCPCS Codes	Description
C5271	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area (Code deleted 12/31/2025)
C5273	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children (Code deleted 12/31/2025)
C5275	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area (Code deleted 12/31/2025)
C9399††	Unclassified drugs or biologicals
Q4100††	Skin substitute, not otherwise specified (Code deleted 12/31/2025)
Q4102	Oasis Wound Matrix, per square centimeter
Q4106	Dermagraft, per square centimeter (Code deleted 12/31/2025)
Q4122	Dermacell, Dermacell AWM or Dermacell AWM Porous, per square centimeter
Q4124	Oasis Ultra Tri-layer Wound Matrix, per square centimeter
Q4128†	FlexHD, Allopatch HD, per square centimeter
Q4132	Grafix core and GrafixPL core, per square centimeter
Q4133	Grafix prime, GrafixPL prime, stravix and stravixpl, per square centimeter
Q4151	Amnioband or guardian, per square centimeter
Q4158	Kerecis Omega3, per square centimeter
Q4168	AmnioBand, 1 mg
Q4186	Epifix, per square centimeter
Q4392	Grafix duo, per square centimeter

†Note: Considered Experimental/Investigational/Unproven when used to report Allopatch HD

††Note: The TYRX™ Absorbable Antibacterial Envelope and the Elupro™ Antibiotic-Eluting Bioenvelope are considered integral to the primary procedure and not separately reimbursable.

Not Covered Tissue Engineered Skin Substitutes Application and Product Codes

Considered Not Medically Necessary when used to report a tissue-engineered skin substitute not covered in the policy statement above:

HCPCS Codes	Description
C1781	Mesh (implantable)
C9399	Unclassified drugs or biologics
Q4100	Skin substitute, not otherwise specified (Code deleted 12/31/2025)

Considered Experimental/Investigational/Unproven when used to report RECELL® Autologous Cell Harvesting Device:

CPT®* Codes	Description
15011	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less

CPT®* Codes	Description
15012	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin
15014	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)
15015	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less
15016	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)
15017	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less
15018	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)

HCPCS Codes	Description
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)

Considered Experimental/Investigational/Unproven when used to report a tissue-engineered skin substitute not covered in the policy statement above:

CPT®* Codes	Description
15778	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (i.e., external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
46707	Repair of anorectal fistula with plug (eg: porcine small intestine submucosa [SIS])
64910	Nerve repair; with synthetic conduit or vein allograft (eg, nerve tube), each nerve
64999	Unlisted procedure, nervous system

HCPCS Codes	Description
A2004	Xcellistem, 1 mg
A2005	Microlyte matrix, per square centimeter
A2020	Ac5 advanced wound system (ac5)
A2021	Neomatrix, per square centimeter

HCPCS Codes	Description
A2033	Myriad morcells, 4 milligrams
A2039	Innovamatrix fd, per square centimeter
C1762	Connective tissue, human (includes fascia lata)
C1763	Connective tissue, non-human (includes synthetic)
C1781	Mesh (implantable)
C9352	Microporous collagen implantable tube (NeuraGen Nerve Guide), per centimeter length
C9353	Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per centimeter length
C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9364	Porcine implant, Permacol, per square centimeter
C9399††	Unclassified drugs or biologics
J3590	Unclassified biologics
Q4100††	Skin substitute, not otherwise specified (Code deleted 12/31/2025)
Q4103	Oasis Burn Matrix, per square centimeter
Q4113	GraftJacket Xpress, injectable, 1 cc
Q4114	Integra Flowable Wound Matrix, injectable, 1 cc
Q4118	Matristem micromatrix, 1 mg
Q4125	Arthroflex, per square centimeter
Q4126	Memoderm, dermaspan, tranzgraft or integuply, per square centimeter
Q4128†	FlexHD, Allopatch HD, per square centimeter
Q4130	Strattice TM, per square centimeter
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per square centimeter
Q4138	Biodfense dryflex, per square centimeter
Q4139	Amniomatrix or biodmatrix, injectable, 1 cc
Q4140	Biodfense, per square centimeter
Q4148	Neox cord 1K, Neox cord RT, or Clarix cord 1K, per square centimeter
Q4150	AlloWrap DS or dry, per square centimeter
Q4152	DermaPure, per square centimeter
Q4155	Neoxflo or clarixflo, 1 mg
Q4156	Neox 100 or Clarix 100, per square centimeter
Q4159	Affinity, per square centimeter
Q4160	NuShield, per square centimeter
Q4162	Woundex flow, BioSkin flow 0.5 cc
Q4163	Woundex, BioSkin per square centimeter
Q4164	Helicoll, per square centimeter
Q4166	Cytal, per square centimeter
Q4168	AmnioBand, 1 mg
Q4170	Cygnus, per square centimeter
Q4173	PalinGen or PalinGen XPlus, per square centimeter
Q4174	Palingen or ProMatrX, 0.36 mg per 0.25 cc
Q4180	Revita, per square centimeter
Q4187	Epicord, per square centimeter
Q4189	Artacent ac, 1 mg
Q4192	Restorigin, 1 cc
Q4193	Coll-e-derm, per square centimeter

HCPCS Codes	Description
Q4195	Puraply, per square centimeter
Q4196	Puraply am, per square centimeter
Q4204	Xwrap, per square centimeter
Q4205	Membrane graft or membrane wrap, per square centimeter
Q4215	Axolotl ambient or axolotl cryo, 0.1 mg
Q4222	Progenamatrix, per square centimeter
Q4227	Amniocore, per square centimeter
Q4229	Cogenex amniotic membrane, per square centimeter
Q4234	Xcellerate, per square centimeter
Q4235	Amniorepair or Altiply, per square centimeter
Q4236	Carepatch, per square centimeter
Q4239	Amnio-maxx or amnio-maxx lite, per square centimeter
Q4246	Coretext or Protext, per cc
Q4250	Amnioamp-MP, per square centimeter
Q4253	Zenith amniotic membrane, per square centimeter
Q4254	Novafix DL, per square centimeter
Q4262	Dual layer impax membrane, per square centimeter
Q4263	Surgraft tl, per square centimeter
Q4264	Cocoon membrane, per square centimeter
Q4265	Neostim tl, per square centimeter
Q4266	Neostim membrane, per square centimeter
Q4267	Neostim dl, per square centimeter
Q4268	Surgraft ft, per square centimeter
Q4269	Surgraft xt, per square centimeter
Q4270	Complete sl, per square centimeter
Q4271	Complete ft, per square centimeter
Q4272	Esano a, per square centimeter
Q4273	Esano aaa, per square centimeter
Q4274	Esano ac, per square centimeter
Q4275	Esano aca, per square centimeter
Q4276	Orion, per square centimeter
Q4331	Axolotl graft, per square centimeter
Q4332	Axolotl dualgraft, per square centimeter
Q4345	Matrix hd allograft dermis, per square centimeter
Q4357	Xwrap plus, per square centimeter
Q4358	Xwrap dual, per square centimeter
Q4361	Epiexpress, per square centimeter
Q4363	Amnio burgeon membrane and hydromembrane, per square centimeter
Q4364	Amnio burgeon xplus membrane and xplus hydromembrane, per square centimeter
Q4365	Amnio burgeon dual-layer membrane, per square centimeter
Q4366	Dual layer amnio burgeon x-membrane, per square centimeter
Q4383	Axolotl graft ultra, per square centimeter
Q4385	Apollo ft, per square centimeter
Q4386	Acesso trifaca, per square centimeter
Q4387	Neothelium ft, per square centimeter
Q4388	Neothelium 4l, per square centimeter
Q4389	Neothelium 4l plus, per square centimeter
Q4393	Surgraft ac, per square centimeter

HCPCS Codes	Description
Q4394	Surgraft aca, per square centimeter
Q4395	Acelagraft, per square centimeter
Q4396	Natalin, per square centimeter
Q4397	Summit aaa, per square centimeter
Q4398	Summit ac, per square centimeter
Q4399	Summit fx, per square centimeter
Q4400	Polygon3 membrane, per square centimeter
Q4401	Absolv3 membrane, per square centimeter
Q4410	Amchomatrixdl, per square centimeter
Q4411	Amniomatrixf4x, per square centimeter
Q4413	Cygnus solo, per square centimeter
Q4418	Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4420	Nuform, per square centimeter
Q4422	A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)
Q4423	Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4424	Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4428	Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4436	Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4437	Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)
Q4438	Pretect, per square centimeter (add-on, list separately in addition to primary procedure)
Q4440	Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)

†Note: Considered Experimental/Investigational/Unproven when used to report Allopatch HD

††Note: The TYRX™ Absorbable Antibacterial Envelope and the Elupro™ Antiobiotic-Eluting Bioenvelope are considered integral to the primary procedure and not separately reimbursable.

General Background

Skin Substitutes
Skin substitutes can be comprised of biologic, synthetic, or biosynthetic materials. Biologic skin substitutes can refer to skin that is harvested from a donor site and transplanted into the recipient site. Also called biological tissue, these skin substitutes can be an autograft, allograft, or xenograft. Autograft skin substitutes are harvested from another location of the patient's body. Allografts are harvested from a donor of the same species, and xenografts are derived from a

different species such as porcine, bovine or piscine. These products may provide temporary coverage of the wound or may be resorbed and become a permanent part of the body. Skin substitutes ideally possess the composition and function of skin or have the potential to allow the body to heal itself (Shahrokhi, 2025).

Autologous Skin Grafts and Cadaver-Derived Skin Grafts
Autologous skin grafts and the use of fresh, unprocessed allogeneic cadaver-derived skin grafts are established procedures for wound care. Autologous skin grafts, or autografts, refer to tissue transplanted from one location to another in the same individual. Autografts are referred to as partial-thickness or split-thickness graft. Autografts are ideal because there is no risk of rejection. In some cases, the area of healthy skin available for harvesting may be inadequate to cover the wound area. In these cases, the best choice is human skin taken from human cadavers, consisting of both epidermal and dermal skin layers. These unprocessed, allogeneic cadaver-derived skin grafts (allografts or homograft) are used for temporary coverage of excised wounds. Cadaver skin grafts may be kept fresh for up to 14 days or may be cryopreserved or glycerol-preserved (GPA). Unprocessed cadaveric skin is a widely used skin substitute. Fresh pig's skin that has been specially treated and contains only the dermis layer has been used for coverage of partial thickness burns and excised wounds prior to grafting. There are various ways to sterilize and preserve pigskin. In general, the pigskin is treated with a solution (e.g., providine-iodine), placed in normal saline with an antibiotic, soaked in a solution to sterilize it, rinsed and refrigerated or frozen. Fresh skin stored in normal saline is viable for up to 72 hours. When autografts, unprocessed human cadaver skin or unprocessed pig's skin graft are not available, tissue-engineered skin substitutes which include processed human cadaver skin and pig skin may be an option (Shahrokhi, 2025; Ahmad et al., 2010; Ge et al., 2010). PureSkin™ is an example of an allograft that is available in fresh configuration or cryopreserved from, meshed and non-meshed. PureSkin is primarily used in burn patients to advance wound healing when autografting is not feasible (Allosource, 2022). Maxxeus is a provider of a cryopreserved allograft for burn care (Maxxeus, 2025).

Tissue-Engineered Skin Substitutes
Tissue-engineered skin substitutes (i.e., human skin equivalents [HSE]), also referred to as artificial skin, are bioengineered skin products and may be either acellular or cellular. Acellular (i.e., cadaveric human dermis with cellular material removed) products contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. The construction of the matrix allows easy access by host cells during the healing process. Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within a matrix may be allogeneic (i.e., obtained from another individual) or autologous (i.e., obtained from the same individual). Some products are derived from other species (e.g., bovine, porcine) and are referred to as a xenograft. Skin substitutes are generally comprised of epidermal cells, dermal cells or may be composites (i.e., a combination of dermal and epidermal). The substitutes can be used as either temporary or permanent wound coverings (Ho, et al., 2005; Sibbald, et al., 2005).

Tissue source and different tissue-processing methodologies impact the physical properties, mechanical properties and host-implant interactions of these extracellular matrix (ECM) derived implants (Cornwell, et al., 2009). Processing of ECM–based biomaterials varies among soft tissue substitutes and may result in clinically meaningful differences between products. Manufacturing processes may include different chemical washes and rinses; some products undergo crosslinking, while others are dried or lyophilized, and a range of sterilization methods may be used. Any one or combination of these processing steps may alter the composition and structural characteristics of the resulting ECM-based material. In addition, specific parameters within the same processing method may differ across products. For example, variations in freezing times and temperatures during lyophilization may affect ice-crystal formation, leading to differences in pore size and

material porosity. As a result, ECM-based products cannot be assumed to be clinically equivalent and must be evaluated on an individual product basis, considering final composition, physical and mechanical properties, and host–implant interactions.

Skin substitutes have been proposed for the treatment of multiple conditions including burns (including acute or reconstructive), breast reconstruction, chronic wounds such as venous status ulcers and diabetic foot ulcers unresponsive to standard therapy, and duraplasty.

During breast reconstruction, acellular dermal skin substitutes (i.e., AlloDerm, AlloMax) are primarily used in the setting of tissue expander and breast implant reconstruction. Patients should be in overall good health and have no underlying condition that would restrict blood flow or interfere with the normal healing process (e.g., uncontrolled diabetes, hypertension, previous surgery). These matrixes may be indicated when there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required, as may be the case in a very thin patient; if there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; or if there is a need to re-establish the inframammary fold and lateral mammary fold landmarks. When used in appropriate candidates, these skin substitutes are proposed to improve control over placement of the inframammary fold and final breast contour, enhance use of available mastectomy skin, reduce the number of expander fills necessary, reduce time to complete expansion and eventual implant exchange, potential improved management of a threatened implant, reduce the need for explantation and the potential for reduction in the incidence of capsular contracture. However, there are ongoing concerns regarding the increased risk of seroma and infection, a higher risk of an implant having to be removed, and tissue flap death.

A chronic wound is defined as a wound that does not heal in the time expected based upon the patient's age, comorbidities, and wound etiology. A wound that has not healed within 30 days to three months is considered chronic. Different types of chronic wounds include lower extremity diabetic neuropathic ulcers, venous ulcers and burn wounds. Treatment depends on the type of wound, wound location, and wound size. The wound should be free of infection, coagulum, sinus tracts, tunnels, cellulitis, eschar and necrotic tissue. There should be no exposure of joints, tendons, ligaments or bone. Adequate blood supply to the affected area should be evidenced by a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70.

Standard wound therapy for a foot ulcer in a type 1 or type 2 diabetic includes avoidance of mechanical stressors on the ulcerated extremity (i.e., off-loading), wound cleansing and debridement, management of infection with antibiotic therapy and application of saline-soaked gauze. It is essential that routine medical management of diabetes and the presence of a hemoglobin A1C (HbA1C) of less than 12% be achieved to maximize complete healing of the wound.

The mainstay of conventional wound therapy for lower extremity venous stasis ulcers is compression therapy (e.g., compression stockings, Unna boots, elastic wraps). Surgical debridement of the wound, zinc paste gauze and non-weight bearing regimens may also be used. Skin substitutes may be indicated for the treatment of a wound that is not healing in response to conventional therapy. The underlying medical condition, such as hypertension, should be adequately managed to foster complete healing. To date, evidence is lacking supporting superiority of one product over another for the treatment of lower extremity wound therapy.

The use of dural grafts in cases where dural closure is difficult has been described as standard of care for many spine and skull-based procedures in medical textbooks (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015). Circumstances in which a surgeon may need to use a dural graft include decompressive

craniectomies for brain swelling, treatment of meningiomas, posterior fossa decompression of Chiari malformation, and skull-based procedures including but not limited to encephaloceles and posterior fossa cases.

There are four types of hiatal hernias and can range from a small sliding hiatal hernia to a large paraesophageal hernia (PEH) (Rosen and Blatnik, 2024; Yates and Oelschlager, 2022). Hiatal hernias are classified into four types based on their anatomical features, three of which are paraesophageal hernias (PEH).

- Type I (sliding hernia) involves displacement of the gastroesophageal junction (GEJ) above the diaphragm, with the gastric fundus remaining below the GEJ.
- Type II (true PEH) is rare and results from a defect in the phrenoesophageal membrane, allowing the gastric fundus to herniate adjacent to the esophagus while the GEJ remains in the abdomen.
- Type III (mixed PEH) is the most common PEH, characterized by both the GEJ and gastric fundus herniating into the mediastinum, with the fundus positioned above the GEJ.
- Type IV PEH is a Type III hernia with additional herniation of another organ—most commonly the colon, but potentially the spleen, pancreas, or small intestine. Herniation of omentum alone does not qualify as Type IV.

Surgical management is indicated when medical management fails to control symptoms or when there is a complication (e.g., bleeding, obstruction, or gastric volvulus). Symptoms of a hiatal hernia can include gastroesophageal reflux, dysphagia, regurgitation, anemia, dyspnea, epigastric or abdominal pain. Medical textbooks describe certain scenarios when a hiatal hernia would be unable to be primarily closed and the use of Phasix ST mesh or Gore Bio A mesh would be appropriate to use (Michaels and Pappas, 2025; Ferguson, 2024; Plumblee et al., 2024; Dunn et al., 2022; Yates and Oelschlager, 2022). Scenarios when the use of Phasix ST or Gore Bio A is indicated include when the crural fibers are disrupted during dissection, the hernia defect is large, crural closure is tenuous, or the crural closure is under tension. The objective definition of a large hiatal hernia is greater than (or equal to) 30-50% of the stomach herniates into the thoracic cavity or a hiatal surface area of >5 cm^2 (Tam, et al., 2016).

The routine use of mesh during paraesophageal hernia repair (PEHR) is not recommended. Studies report conflicting results with small patient populations (n=50-144) and short-term follow-ups (90 days to 17 months) and have primarily been in the form of prospective observational and retrospective reviews (Ukegjini et al., 2023; Aiolfi et al., 2021; Abdelmoaty et al., 2020; Panici Tonucci et al., 2020).

U.S. Food and Drug Administration (FDA)

Depending on the purpose of the product and how it functions, skin substitutes are regulated by the FDA premarket approval (PMA) process, 510(k) premarket notification process, or the FDA regulations for banked human tissue.

Products that are classified by the FDA as an interactive wound and burn dressing are approved under the PMA process as a class III, high-risk device and require clinical data to support their claims for use. These devices may be used as a long-term skin substitute or a temporary synthetic skin substitute. They actively promote healing by interacting directly or indirectly with the body tissues. Examples of these devices include Dermagraft® (Organogenesis, Canton, MA).

Other wound care devices are approved by the 510(k) process, and their primary purpose is to protect the wound and provide a scaffold for healing. They may or may not be integrated into the body tissue. Some devices are rejected by the body after approximately ten days to several weeks and removed prior to definitive wound therapy or skin grafting. Oasis® Wound Matrix (Cook Biotech, Inc., West Lafayette, IN) is an example of these devices.

Donated skin that requires minimal processing and is not significantly changed in structure from its natural form is classified by the FDA as banked human tissue, is not considered a medical device, and does not require PMA or 510(k) approval. Donated skin is regulated by the American Association of Tissue Banks (AATB) and the FDA guidelines under section 361 of the Public Health Service (PHS) Act for the manufacture of human cells, tissues, and cellular and tissue-based products (HCT/Ps). AATB oversees a voluntary accreditation program, and the FDA focuses on preventing the transmission of communicable diseases by requiring donor screening and testing. Establishments that manufacture HCT/Ps must register with the FDA and list each cell or tissue produced (FDA, 2021). An example of a banked human tissue product is AlloDerm, an acellular dermal matrix.

In April 2024, the FDA updated a July 2020 and June 2021 consumer alert on regenerative medicine therapies. These products require FDA licensure/approval to be marketed to consumers. These unapproved products include stem cells, stromal vascular fraction (fat-derived cells), umbilical cord blood and/or cord blood stem cells, amniotic fluid, Wharton's jelly, ortho-biologics, and exosomes. The warning included the statement that regenerative medicine therapies have not been approved "for the treatment of any orthopedic condition, such as osteoarthritis, tendonitis, disc disease, tennis elbow, back pain, hip pain, knee pain, neck pain, or shoulder pain."

Skin Substitutes

The safety and efficacy of the skin substitutes listed below are supported by the evidence in the published peer-reviewed scientific literature and/or are established treatment options for the discussed indications.

Actigraft®

Actigraft (RedDress®, Ponte Vedra Beach, FL) is a regenerative wound care product intended to be used at point-of-care that creates in vitro blood clots from a patient's whole blood. In 2023, the product became known as ActiGraft^{PRO}. It is proposed that applying the blood clot to the site of the wound recreates the natural wound healing environment and promotes the body's own healing process. ActiGraft is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, diabetic ulcers, and mechanically or surgically debrided wounds (RedDress, 2026; CMS, 2021). The RD2 system (a peripheral blood processing device for wound management) received 510(k) approval (BK190349) on Nov 8, 2019. The RD2 System is a kit that contains three components for drawing and handling autologous blood and allowing it to clot in a controlled manner to form the provisional wound matrix. The system includes blood withdrawal kit, coagulation initiator component, and a clotting tray containing coagulation accelerator. On March 3, 2020, the RD2 System received an additional 510(k) clearance (BK200464). The RD2 Ver.02 System received 510 (k) (BK210570) on June 22, 2021. The indications for use remained the same. Studies are in the form of case studies and one large, randomized control trial that demonstrated faster healing of wound closure in diabetic foot ulcers when compared to standard of care.

Snyder et al. (2024) conducted a multicenter randomized control trial across 16 sites in three countries to evaluate the safety and efficacy of autologous whole blood clot (AWBC) (ActiGraft^{PRO} system) combined with standard of care (SOC) (n=59) when compared to SOC alone (n=60) in the treatment of hard-to-heal diabetic foot ulcers (DFUs). The objective of the study was to compare complete wound healing at twelve weeks. One hundred nineteen individuals met inclusion criteria. Selection criteria included: age ≥ 18 years; type 1 or type 2 diabetes, DFU of ≥ 30 days duration with failure to treatment; DFU > 1 cm^2 but < 28 cm^2 ; no signs of infection, HBA1C ≤ 12%; and adequate circulation to index limb (transcutaneous oxygen pressure test ≥ 30mmHg, ABI ≥ 0.7 and ≤ 1.2, triphasic or biphasic Doppler arterial waveform at the ankle of affected leg, toe brachial index > 0.6). Following a two-week screening period in which DFUs were treated with offloading and moist wound care, patients were randomized to SOC alone or AWBC

plus SOC. Both AWBC and SOC groups were treated weekly. The primary outcome of the study was to compare complete wound healing at twelve weeks. Wounds were defined as healed if there was complete (100%) re-epithelialization without drainage or need for dressing. Secondary outcomes were time to heal and percentage area reduction (PAR) at four and eight weeks. A total of 22 individuals (18%) discontinued the study. In the AWBC group, 12 individuals discontinued the study: four withdrew consent, three had a significant adverse event, one had an adverse event, one was lost to follow-up, two were non-adherent with study protocol, and one died. In the control group, 10 individuals discontinued the study: three were non-adherent with study protocol, one was lost to follow-up, three had an adverse event, one had a significant adverse event, one was discontinued at the investigator's discretion, and one withdrew consent. Overall, better outcomes were reported in the AWBC plus SOC group. AWBC treatment resulted in higher healing rate compared to control group in the intention-to-treat (ITT) population (41% [24/59] versus 15% [9/60], respectively; p=0.002) and per-protocol (PP) population (51% [24/47] versus 18% [9/49], respectively; p=0.0075). The analysis of mean time to healing at 12 weeks in the ITT group was determined to be 70.6 days in the AWBC group and 79.2 days for the control group. In the PP group, mean time to healing at 12 weeks was 68.4 days in AWBC group and 78.7 days for control group. The weekly PAR did not show a statistically significant difference between treatment groups. The number of treatments in the AWBC group was 7.4 ± 2.8. There were no treatment related adverse events (AE). There were wound related AE in both groups: 21 in 19 individuals in AWBC group and 23 in 15 individuals in control group. Wound related adverse events in both groups included wound inflammation, wound infection, cellulitis, and osteomyelitis. Author noted study limitations included being conducted during the COVID-19 pandemic affecting recruitment and patient adherence. Actigraft demonstrated faster healing of wound closure in DFU when compared to standard of care.

AlloMax™
AlloMax Surgical Graft (Bard Davol, Inc. Warwick, RI) is an acellular non-cross-linked human dermis allograft. Because AlloMax is a natural human product, it is classified as banked human tissue and does not require FDA approval. It is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. The AlloMax Surgical Graft for Breast Reconstruction (previously marketed as NeoForm™) is proposed for post-mastectomy breast reconstruction and is an established skin substitute for this indication.

The AlloMax Surgical Graft for Hernia and Abdominal Wall Repair is proposed for hernia or other complex abdominal wall repairs when a synthetic prosthesis is contraindicated or inappropriate. There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of AlloMax for hernia and abdominal wall repair. Studies have primarily been in the form of case reports for hernia repair (e.g., hiatal hernia, incisional hernia) and abdominal wall reconstruction

AlloPatch® Pliable
AlloPatch® Pliable (Musculoskeletal Transplant Foundation [MTF Biologics], Edison, NJ) is an acellular allogenic human dermal graft designed to support host tissue remodeling. AlloPatch Pliable is used as a wound care scaffold for the replacement of damaged or inadequate integumental tissue. Regulated under the FDA Human cells, tissues, and cellular and tissue-based products, the graft is proposed for the treatment of acute traumatic wounds such as burns and penetrating trauma, surgical skin cancer wounds and scar revisions. Indications for the treatment of chronic wounds include diabetic foot ulcers, venous ulcers, pressure/decubitus ulcers and vascular arterial ulcers. It is a pre-hydrated matrix that comes in four sizes from 1.5 x 1.5 cm to 4 x 8 cm. (MTF Biologics, 2025).

Zelen et al. (2017) conducted a multicenter, randomized controlled trial to investigate the effectiveness of AlloPatch Pliable plus standard of care (SOC) (n=20) compared to SOC alone

(n=20) in the treatment of nonhealing diabetic foot ulcers (DFUs). The objective of the study was to compare complete wound healing at six weeks and twelve weeks. Selection criteria included: age ≥ 18 years; type 1 or type 2 diabetic, DFU of ≥ 4 weeks duration with failure to treatment; DFU ≥ 1 cm^2; no signs of infection, HBA1C < 12%; adequate circulation within past 60 days; dorsum transcutaneous oxygen test ≥ 30 mmHg; and ABI ≥ 0.7 and ≤ 1.2. Following a two-week screening period in which DFUs were treated with offloading and moist wound care, patients were randomized to SOC alone or AlloPatch plus SOC applied weekly for up to 12 weeks. Patients whose index wound had not healed greater than 20% at two weeks were randomized to the AlloPatch plus SOC or SOC alone group. Wounds were defined as healed if there was complete (100%) re-epithelialization without drainage or need for dressing. For patients in the SOC group, daily dressing changes with a collagen alginate were performed weekly. Overall, significantly better outcomes were reported in the AlloPatch plus SOC group. At six weeks 65% of patients treated with AlloPatch had healed compared with 5% of DFUs in the SOC alone group. Mean time to heal at six weeks was 28 days vs. 41 days in the SOC group. Ten patients from the SOC group (50%) and one patient from the graft group (5%) exited from the study at six weeks per protocol because their wounds failed to reduce by at least 50%. At 12 weeks 80% of the study group and 20% of the SOC group had healed (p=0.00036). Mean time to healing at 12 weeks was 40 days in the AlloPatch group and 77 days in the SOC group (p=0.00014). The mean number of grafts used to achieve closure was 4.7 per wound. Adverse events in both groups were related to foot infections, and none were attributed to the use of the graft. Limitations of the study include the small patient population, short-term follow-up and a larger mean wound area in the AlloPatch group (4.7 cm^2) compared with the SOC group (2.7 cm^2).

AmnioBand® or Guardian
AmnioBand or Guardian (MTF Biologics, Edison, NJ), is an allograft made of human amnion and chorion and proposed as a covering for internal and external wounds. The product is regulated by the American Association of Tissue Banks (AATB) and the FDA guidelines for banked human tissue. Although marketed under two different names, the products are exactly the same. The membrane is hydrophilic and can be used in a hydrated or dehydrated state. AmnioBand Membrane is used as a wound care scaffold for the replacement of damaged or inadequate integumental tissue such as diabetic foot ulcers, venous leg ulcers, pressure ulcers, or for other homologous use. AmnioBand comes in 13 sizes (MTF Biologics, 2025; Centers for Medicare and Medicaid, 2014).

Serena, et al. (2022) conducted a multicenter, randomized control trial to evaluate the safety and efficacy of weekly (n=20) and biweekly (every two weeks) (n=20) applications of AmnioBand plus standard of care compared to standard of care alone (n=20) on chronic venous leg ulcers (VLU). Standard of care included the cleaning and debriding of the study ulcer, application of multilayer compression bandaging, and instructions to keep leg elevated and bandage dry. Inclusion criteria included: age ≥ 18 years; ankle brachial index (ABI) >0.75 or skin perfusion pressure (SPP) >30 mmHg or transcutaneous oximetry measurement (TCOM) >30 mmHg; VLU wound area ≤ 2 cm^2 but < 20 cm^2 of a duration longer than one month that extended through the full thickness of the skin but not down to the muscle, tendon, or bone; study ulcer with a clean, granulating base with minimal adherent slough and treated with compression therapy for a minimum of 14 days prior to randomization. Patients were excluded if the ulcer was infected, suspicious for cancer, caused by a condition other than venous insufficiency, required treated by negative-pressure wound therapy or hyperbaric oxygen therapy or had previously been treated with cellular and/or tissue-based products. Patients were also excluded if they had a history of HIV/AIDS, drug or alcohol abuse, radiation therapy at the ulcer site, ulcers on the dorsum of the foot or with ≥ 50% of the ulcer below the malleolus, pregnant or breastfeeding, diabetes with HbA1c >12.0 within the past 90 days, renal dysfunction with serum creatinine levels ≥ 3.0 mg/dl within the last 90 days, used tobacco within the last 30 days or had a history of liver disease with active cirrhosis. The primary endpoint was the proportion of ulcers achieving complete closure (defined as macroscopic wound

closure at 12 weeks) using the Silhouette three-dimensional laser camera system by Aranz Medical (Christchurch, New Zealand). Secondary endpoints included the proportion of ulcers achieving 40 percent area reduction at four weeks and the incidence of adverse events. At 12 weeks, complete healing occurred in 75% (15/20) of the weekly AmnioBand treatment group and in 75% (15/20) of the biweekly AmnioBand treatment group compared to 30% (6/20) of the SOC group (p=0.001). The percentage of ulcers achieving 40 percent area reduction at four weeks, was 65% (13/20) in SOC group, 80% (16/20) in the weekly AmnioBand group, and 70% (14/20) in the biweekly AmnioBand group. Thirty-eight adverse events occurred including nine serious adverse events. The most common types of adverse events were wound-related infections and formation of a new ulcer. None of the events were related to the study allograft or procedure. There were no amputations or deaths. An author noted limitation was the lack of blinding of patients and investigators to the treatment received. The application of AmnioBand (either weekly or biweekly) in conjunction with standard of care improved outcomes in the treatment of venous leg ulcers when compared to standard of care alone.

DiDomenico et al. (2016) conducted a multi-center, randomized controlled trial to compare AmnioBand (n=20) to standard of care (SOC) (n=20) in facilitating wound closure in nonhealing diabetic foot ulcers (DFUs). Included patients were age ≥ 18 years, type 1 or type 2 diabetic, had at least one unhealed neuropathic DFU ≥ 1 cm^2 with no sign of infection, had an HBA1c < 12%, and had failed conservative therapy for at least four weeks. Patients also had adequate circulation to the affected extremity within 60 days of the study, as demonstrated by dorsum transcutaneous oxygen test ≥ 30 mm Hg; or ABI with results of ≥ 0.7 and ≤ 1.2; or Doppler arterial waveforms, which were triphasic or biphasic at the ankle of the affected leg. SOC included: off-loading, appropriate debridement, and moist wound care. During a two-week screening period, patients were treated with SOC. During the screening period, wounds were assessed and measured weekly, and debridement was performed as necessary. If the index wound did not reduce by more than 20% in size at the end of the screening period, the patient was randomized to SOC or AmnioBand + SOC. Following randomization, each patient was treated weekly during the study period until the index wound closed or for 12 weeks. Wounds were defined as healed if complete (100%) epithelialization occurred without drainage and need for dressing. At six weeks, mean time to healing with AmnioBand was 30 days vs. 40 days with SOC (p=0.00073) and 70% (14/20) of the AmnioBand group healed compared with 15% (3/20) of DFUs treated with SOC alone. At six weeks eight SOC patients and one AmnioBand patient were withdrawn from the study because their wounds failed to reduce in area by at least 50%. Two DFU in the SOC group reopened after initial closure. Twelve weeks following treatment, 85% (17/20) of the AmnioBand patients were healed compared with 25% (5/20) in the SOC group. The mean time to heal was 36 days for AmnioBand and 70 days for SOC. The mean number of grafts used at 12 weeks was 3.8 (median 3.0). Four adverse events involved foot infection but were not found to be related to the graft. Limitations of the study include small patient population, short-term follow-up; and mean wound size at randomization was larger in the SOC group (3.3 vs. 2.0 cm^2).

Avance® Nerve Graft

Peripheral nerve damage resulting from traumatic injury or surgery requires closing to prevent loss of sensation and motor function. Bridging a nerve defect with an autologous nerve graft of a non-essential nerve is a well-established option, bu-t harvesting a graft of adequate length and diameter is not always feasible. In addition, this method is often associated with significant donor site morbidity. Alternatives to autologous grafts include synthetic conduits and processed nerve allografts.

Avance Nerve Graft (AxoGen, Inc., Alachua, FL.) is acellular, processed human peripheral nerve tissue proposed as an alternative to autologous grafts for the surgical repair of severed peripheral nerve discontinuities (breaks in the pathway of sensory nerves). The device maintains a 3-dimension scaffold intended to support cell migration and tissue regeneration. On December 3,

2025, Avance was approved via the Biological License Application (BLA) pathway for sensory nerve discontinuities of ≥ 25mm in adult and pediatric patients ≥ one month. Under the Accelerated Approval pathway, Avance was also approved for larger sensory nerve discontinuities (>25mm), motor, and mixed nerve discontinuities. Avance was previously regulated by the FDA Human Cellular and Tissue-based Products and the guidelines of the American Association of Tissue Banks (AATB). It is available in 16 sizes consisting of four diameter ranges in lengths of 15 mm, 30 mm, 50 mm and 70 mm (Axogen, 2026).

Isaacs et al. (2023) conducted a multicenter randomized controlled trial comparing conduits versus decellularized nerve allograft for digital nerve repairs (n=220). Patients presenting with suspected acute or subacute (less than 24 weeks old) digital nerve injuries were recruited to participate at 20 medical centers within the United States. Individuals were stratified to short (5-14 mm) and long (15-25 mm) gap sub-groups and randomized 1:1 to repair with either a commercially available processed nerve allograft (Avance) or a bovine collagen conduit. Baseline and outcomes assessments were obtained either before or immediately following surgery and were planned at 5, 6, 9, and 12 months after surgery. Both assessors and patients were blinded to the treatment arm. A total of 183 patients completed an acceptable last evaluation visit (at least six months and not more than 15 months post-repair). For the short-gap repair group average static two-point discrimination was 7.3 ± 2.8 mm for PNA and 7.5 ± 3.1 for conduit repairs at the last follow-up. Static two-point discrimination is a key measure of digital nerve integrity, sensory recovery after nerve repair, and localization and tactile discrimination ability. For the long-gap group, average static two-point discrimination was significantly lower, at 6.1 ÷ 3.3 mm for PNA, indicating better sensory recovery, compared with 7.5± 2.4 mm for conduit repairs. Normal sensation, based on the American Society for Surgery of the Hand scale, was achieved in 40% of PNA long gap repairs, compared to 18% observed in long conduit patients. Long gap conduits had more clinical failures (lack of protective sensation) than short gap conduits. The authors concluded that although supporting similar levels of nerve regeneration for short gap length digital nerve repairs, PNA was clinically superior to conduits for long gap reconstructions.

Zhang et al. (2023) published a systematic review and meta-analysis of 66 studies (n=2,446). to compare the outcomes of various finger nerve surgeries and to identify factors associated with postsurgical outcomes. Data was analyzed across multiple surgical techniques: end-to-end neurorrhaphy, autologous nerve grafts, autografts (vein grafts, muscle-in-vein grafts), allografts, artificial nerve conduits (collagen or PGA tubes, and end-to-side neurorrhaphy. Primary sensory outcomes were measured using static two-point discrimination (S2PD), moving two-point discrimination (M2PD), Semmes-Weinstein monofilament testing (SWMF), and Modified Highet Scale (graded sensory recovery). The highest S2PD score was achieved using a PGA conduit; while the best M2PD score was achieved with neurorrhaphy. End-to-side neurorrhaphy achieved the best excellent-good rate according to the Highet classification. Autologous nerve graft resulted in good-excellent recovery based on the SWMF. Factors influencing recovery included age, nerve gap length and injury type. Younger patients had improved recovery, with children outperforming adults. Larger nerve gaps resulted in poorer recovery, and sharp injuries generally recovered better than crush injuries, especially with direct neurorrhaphy. Autograft repairs had the highest complication rates, likely due to donor site morbidity. Allografts and conduits had fewer complications. The authors concluded that results of surgical treatment of digital nerve injury are generally satisfactory, although no nerve repair method has absolute advantages. Various factors, particularly the gap size of the nerve defect, should be considered.

A systematic review and metanalysis was conducted by Lans et al. (2022) to compare the meaningful recovery rates and postoperative complications following autograft, allograft, and conduit repairs in nerve gaps greater than 5 mm and less than 70 mm. The analysis included 35 studies; 1559 nerve repairs. Included studies must have reported nerve injury type (sensory, mixed, or motor); nerve repair type (autograft, allograft [Avance Nerve Graft], or conduit); gap

length where the nerve repair could be categorized as short gap (>5 to30 mm) so only commercially available conduits would be evaluated); or long gap (>30 to 70 mm) so that only commercially available allograft would be evaluated. Outcomes were reported using static two-point discrimination (S2PD), Semmes-Weinstein monofilament (SWMF) testing and/or Medical Research Council Classification (MRCC), such that meaningful recovery rates could be determined. There was no significant difference between autograft (n=670) and allograft (n=711) in meaningful recovery (MR) rates for sensory and motor function for both short and long gaps. MR rates for autograft (81.6%) and allograft (87.1%), however, were significantly higher compared with conduits (62.2%) ($p<0.05$) in sensory short-gap repairs. Complication rates in terms of pain were comparable for autograft and allograft but higher for conduits. The authors concluded that the literature demonstrated comparable rates of MR between autograft and allograft, regardless of gap length or nerve type, while MR rates were lower in conduit repairs.

Herman and Ilyas (2019) conducted a systematic review and meta-analysis to compare safety and effectiveness of direct repair (neurorrhaphy), autograft, allograft, and conduit repair in digital nerve repair. A total of fifteen studies were included: four on neurorrhaphy (three prospective [n=12–81], one retrospective [n=63]); four on allograft repair (three prospective [n=5–72], one retrospective [n=24]); six on autograft repair (five prospective [n=15–31], one retrospective [n=15]) and five on conduit repair (three prospective [n=7–35], two retrospective [n=12–16]). Inclusion criteria were observational cohort studies and randomized control trials on patients undergoing surgery for digital nerve lesions that reported a minimum of two of the following outcome measures: static 2-point discrimination (S2PD), moving 2-point discrimination (M2PD), Semmes-Weinstein monofilament testing (SWMF), and complication rates. Studies were excluded if they included pediatric patients, peripheral nerves other than the hand, or used other surgical repair techniques. The mean length of follow up varied: neurorrhaphy (13.3 months), allograft repair (9.4 months), autograft repair (23.2 months), and conduit repair (21.1 months). Static 2-point discrimination outcomes: neurorrhaphy 15% < 6mm (excellent), 60% 6–15mm (good), 24% > 15mm (poor); allograft 23% < 6mm, 57% 6–15 mm, 20% > 15 mm; autograft 28% < 6mm, 67% 6–15 mm, 5% > 15mm; and conduit 19% < 6mm, 59% 6–15 mm, 22% > 15 mm. The autograft repair was statistically superior to allograft ($p<0.001$), conduit ($p<0.005$), and neurorrhaphy ($p<0.0001$). Moving 2-point discrimination outcomes are as follows: neurorrhaphy 67% < 3mm (excellent), 25% 4–7 mm (good), 8% > 7mm (poor); allograft 2% < 3mm, 88% 4–7 mm, 10% > 7mm; conduit 0% < 3 mm, 67% 4–7 mm, 33% > 7 mm. There was no statistical difference between direct repair and allograft repairs ($p=.60$), however both were statistically superior to conduit repair ($p<0.0001$). SWMF outcomes: neurorrhaphy 17% normal sensation, 41% diminished light touch; allograft 18% normal sensation, 51% diminished light touch; autograft 10% normal sensation, 85% diminished light touch; and conduit 7% normal sensation, 40% diminished light touch. Allograft adverse events included prolonged pain, effusion or wound exudate greater than two weeks. Autograft complications were reported as donor site complications. Conduit repair adverse events included infection and prolonged pain. No adverse events were reported for neurorrhaphy. Limitations of the study include heterogeneity of the studies, inclusion of retrospective study designs, and small patient populations.

Mauch et al. (2019) conducted a systematic review of the literature to compare the safety and efficacy of nerve autografts, processed nerve allografts (PNA) and conduits to primary repair (PR). Four studies were identified using autografts including one comparative study (n=12), two observational studies (n=11, n=15), and one retrospective review (n=14). Four PNS studies included: one observational study (n=14), one pilot study (n=14), one retrospective comparative study (n=24), and one case series (n=5). There were five studies identified on nerve conduit reconstruction including two prospective cohort studies (n=40, n=12), two prospective observational studies (n=9, n=19) and one pilot study (n=14). Seven retrospective reviews (n=15-150) on PR were included. Studies on traumatic digital nerve injuries repaired with PR, nerve autograft, PNA, or nerve conduit were included. Studies were excluded if they were prior to

1990, had follow-ups less than six months, were case reports, or on PNA that were not commercially available. Primary outcomes measured included: static 2-point discrimination (S2PD), the British Medical Research Council Scale (BMRC), or Semmes-Weinstein (SW). Static 2-point discrimination measures the ability to localize two points of pressure on the skin and identify them as discrete sensations. Normal is less than 6 mm, fair 6–10 mm, poor 11–15 mm, protective- one point perceived, anesthetic- no points perceived. The British Medical Research Council Scale is as follows: S0: absence of sensibility in the autonomous area; S1: recovery of deep cutaneous pain sensibility within the autonomous area of the nerve; S2: recovery of some degree of superficial cutaneous pain and tactile sensibility within the autonomous area of the nerve; S3: return of superficial cutaneous pain and tactile sensibility throughout the autonomous area, with disappearance of any previous overresponse; S3+: return of sensibility as in S3; in addition, there is some recovery of 2-point discrimination within the autonomous area (7–15 mm); S4: complete recovery (2-point discrimination, 2–6 mm). The Semmes Weinstein Monofilaments are a discriminative test used to assess the threshold stimulus necessary for perception of light touch to deep pressure. Follow up ranged from 12–42 months. Results of the S2PD in the autografts studies reported < 15 mm (64–100%) and 0-36% reported > 15 mm. Two studies reported a mean of 5.92 mm and 7.06 mm. All PNA studies reported S2PD < 15 mm. Two studies reported 80% and 83% S2PD < 6 mm. The nerve conduit studies reported 63%–100% of patients with S2PD < 15 mm, the mean ranged from 5.2 mm to 8 mm. A S2PD > 15 mm occurred in 0%–38% of patients. The primary repair group reported 30%–100% S2PD < 15mm with a mean of 8.9 and 10.6 mm. Between 9%–70% reported S2PD > 15 mm. Autograft studies reported 75%–100% regained BMRC S3+ or above. Sensibility of S2 or # occurred in 6%–16%. No return in sensation was reported in 6%–8%. The PNA group reported 84%–100% with S3+ or S4. BMRC S1, S2, or S3 was reported in 16%, S0 0%. In the nerve conduit studies, BMRC of S3+ or S4 was reported in 75%–78%. Complete loss of sensation was reported in 17–22% with 0–8% returning to S2. Primary repair reported 0–2% with no return of sensation, 0–68% between S1–S3, and 30–100% with S3+–S4. The SW results in the autograft group reported 86–100% with normal or diminished light touch and 0–13% with diminished protective sensation. No reports of loss of protective sensation or anesthetic sensation. The PNA group reported 0–78% with normal sensation or light touch, 6–60% diminished protective sensation, and 0–40% with loss of protective sensation. One study reported 17% anesthetic sensation. In the nerve conduit studies, 36–78% reported diminished light touch, 22–54% diminished protective sensation or loss of protective sensation and 0–22% with anesthetic sensation. Only two studies in the PR group reported SW outcomes: 0% and 5% anesthetic sensation, 23% and 37% diminished protective sensation or loss of protective sensation, and 63% and 72% with diminished light touch or normal sensation. Adverse events include infection (two in PNA and one in nerve conduit) and neuromas (four in autograft and two in PR group). The nerve conduit studies reported two amputations, one extrusion, and seven removals. Study limitations include heterogeneity of the studies, inclusion of registry data, retrospective reviews, a case series, small patient populations and short term follow up.

The published peer-reviewed evidence demonstrates that while sensory and motor function recovery rates using processed nerve allograft and autograft are comparable for peripheral nerve gap repair, repair using processed nerve allograft avoids potential donor site morbidity. The available evidence also indicates that meaningful recovery rates are lower for synthetic conduits, especially for long gap reconstructions.

Biobrane®/Biobrane®-L
Biobrane/Biobrane-L (Smith & Nephew, Inc., Largo, FL) are synthetic, bilaminate, collagen-based composites. Under the FDA PMA approval, Biobrane is indicated for use as a temporary covering of partial-thickness, freshly debrided or excised burn wounds in the absence of coagulum, eschar and necrotic tissue (Smith & Nephew, 2026). Biobrane-L is also a temporary covering used as an adjunct until autografting is clinically appropriate. Biobrane L is a less complex nylon fabric for use

when less aggressive adhesion is needed. Randomized controlled trials and retrospective reviews support the safety and effectiveness of Biobrane for the treatment of partial-thickness burns (Lang, et al., 2005; Lal, et al., 2000).

Biobrane has also been proposed for the treatment of toxic epidermal necrolysis, paraneoplastic pemphigus, dermabrasion, skin graft harvesting, laser resurfacing, and other types of chronic wounds that cannot be immediately closed (e.g., open sternotomy, venous ulcers), but there is insufficient evidence to support Biobrane for these indications (Whitaker, et al., 2008).

Biodesign® Dural Graft
Biodesign® Dural Graft (Cook Medical, Bloomington, IN) is a porcine, small intestinal submucosa (SIS), bioabsorbable, extracellular collagen matrix. It is FDA 510(k) approved for use as a dura substitute for the repair of dura mater (K131015). The FDA approval was based on predicate devices and an animal study. The matrix is available in four sizes (2x3 cm, 4x7 cm, 7x10cm, 7x20 cm) (Cook Medical, 2026; FDA. 2013). Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

Cortiva®
Cortiva (Evergen processed by RTI Surgical, Alachua, FL) is a non-crosslinked, cadaveric human acellular dermal matrix processed by Tutoplast technology using low-dose gamma irradiation. The matrix is FDA regulated as human cell, tissue, and cellular and tissue-based product (361 HCT/P) and proposed for the repair, replacement, reconstruction or augmentation of soft tissue, including supplemental support and reinforcement of soft tissue in breast reconstruction and hernia repair. There are three products: Cortiva, Cortiva 1.0 mm and Cortiva 1 mm tailored allograft dermis. The matrixes are offered in regular and 1 mm thicknesses and supplied in a range of sizes from 2x4 cm to 16x20 cm (Evergen, 2026; CMS, 2015). Studies investigating the clinical outcomes of Cortiva are primarily in the form of retrospective reviews with short-term follow-ups (Keifer, et al., 2016; CMS, 2015). Cortiva has evolved into an acceptable tissue substitute for breast reconstruction and a randomized controlled trial with short-term follow-up reported that outcomes with Cortiva were not inferior to outcomes using AlloDerm. There is insufficient evidence in the published peer-reviewed literature to support the clinical effectiveness of Cortiva for all other indications.

Parikh, et al. (2018) reported the outcomes of a phase 2 randomized controlled trial that compared outcomes following breast reconstruction surgery using Cortiva 1 mm allograft or AlloDerm Ready to Use (RTU) regenerative tissue matrix. The 16x8 cm graft was used as a sling to support tissue expanders placed in the submuscular location in one study arm, and prepectoral reconstructions with tissue expanders (TEs) or direct-to-implants (DTI) in a second study arm. The interim analysis of the submuscular reconstruction group is reported herein. Breasts reconstructed with AlloDerm RTU (n=17 patients; 28 breasts) or Cortiva 1 mm (n=17 patients; 31 breasts) submuscular TE, completed the interim analysis. During the study a significant shift to prepectoral reconstructions was noted and the prepectoral arm of the study was added to optimize enrollment rates. Patients who underwent prepectoral breast reconstruction with either DTI or TE supported by a 20x16 cm ADM sheet were compared in a separate study arm. The decision to proceed with prepectoral or submuscular reconstruction with either a TE or DTI was determined preoperatively. Female patients, aged 22–70 years old, undergoing immediate prosthetic reconstruction following therapeutic or prophylactic skin- or nipple-sparing mastectomy with a body mass index (BMI) less than 36 kg/m^2 were included. Excluded patients were those who were pregnant or breastfeeding immediately before mastectomy. The primary outcome measure was premature explantation of the TE before exchange, or unintended explantation of a DTI reconstruction during the first three months postoperatively. Secondary outcome measures

included other complications (e.g., seroma, cellulitis, wound or ADM dehiscence, skin flap necrosis). Patients undergoing TE placement in either study arm were followed until there was TE exchange with an implant, flap, or both, or there was premature removal of the device. Patients undergoing DTI reconstruction were followed for at least three months following surgery. Patients undergoing reoperation of the surgical site without device exchange or removal were kept in the study. Patients underwent planned exchange of TEs for implants or flaps within 145.6 ± 51.6 days in the AlloDerm group and 167.0 ± 61.5 days in the Cortiva 1 mm group (p=0.27), not statistically significant. Most patients were exchanged with breast implant alone, but 14.3% in the AlloDerm group and 26.6% in the Cortiva group (p=0.25) received an autologous flap, not statistically significant. There was no significant difference between the group in integration of the ADM to the mastectomy flap (p=0.69), in drain removal between the groups or in physical well-being, or satisfaction with information or plastic surgeon. A significant difference was seen in detectable seroma in the AlloDerm (n=3) vs. the Cortiva group (n=0). Premature explantation was performed in no Alloderm breast vs. one breast with Cortiva. The initial size of the TE selected was significantly larger in patients reconstructed with Cortiva 1 mm (p=0.02). The AlloDerm RTU group was comprised of a significantly higher proportion of patients who had never smoked (p=0.009). This interim analysis of submuscular reconstructions patients revealed no evidence of inferiority of outcomes of AlloDerm vs. Cortiva. Limitations of the study include the small patient population and short-term follow-up.

Dermacell®
Dermacell (LifeNet Health®, Virginia Beach, VA) is an acellular human dermis allograft collagen scaffold proposed for the treatment of soft tissue injury including second- and third-degree burns, breast reconstruction, chronic non-healing wounds, dehisced wound sites and cosmetic reconstruction after traumatic burn injuries. Dermacell AWM is proposed for the treatment of chronic wounds including diabetic foot ulcers (DFUs), venous stasis ulcers (VSUs), arterial ulcers, pressure ulcers, dehisced surgical wounds, and traumatic burns. Dermacell AWM can be used over exposed tendon, bone, joint capsule, and muscle. The Matrix in available in 2X2 cm – 4X8 cm unmeshed and 2X2 cm – 8X12 cm meshed. There is also an AWM porous matrix (LifeNet Health, 2026).

LifeNet Health is registered with the FDA as an establishment producing tissue- and cellular-based products. Matracell® is a patented process that removes > 97% of donor DNA that renders Dermacell acellular. Terminal sterilization is performed by low dose gamma irradiation. The evidence in the published peer-reviewed literature supports Dermacell for the treatment of diabetic foot ulcers. The use of Dermacell for breast reconstruction has evolved into an accepted standard of practice.

Dermacell has been proposed for the treatment of large, complex diabetic foot ulcers (DFUs) that probed to tendon or bone. Studies are primarily in the form of case series with small patient populations (n=47) (Cazzell, et al., 2019). Evidence supporting Dermacell for the treatment of complex DFUs and all other indications is lacking.

Diabetic Foot Ulcer: Evidence in the published peer-reviewed literature support Dermacell for the treatment of partial and full-thickness diabetic foot ulcers. Walters et al. (2016) conducted a multicenter, randomized controlled trial (n=168) to compare the safety and efficacy of Dermacell (n=53) to conventional therapy (n=56) and to Graftjacket (n=23) in a 2:2:1 ratio. The primary endpoint was assessment of complete reepithelialization with no drainage or dressing requirements with confirmation at two consecutive follow-up visits two weeks apart. The healing rate of wounds at 16 weeks and the percentage of reduction in wound size from baseline were also assessed. Patients were included in the study if they met the following had a single, full-thickness target DFU, Wagner grade 1 or 2, a wound area ≥ 1 cm^2 or ≤ 25 cm^2, wound depth ≤ 9 mm, and adequate circulation to the affected area. Adequate circulation within the past 60 days

was defined as transcutaneous oxygen measurement of 30 mm Hg or more at the dorsum of the foot; ankle-brachial index ranging from 0.8 to 1.2; and/or at least biphasic Doppler arterial waveforms at the dorsalis pedis and posterior tibial arteries. At 16 weeks, the Dermacell arm had a statistically significant higher proportion of completely healed ulcers compared to conventional care (p=0.0385) and a nonsignificantly higher proportion than the Graftjacket group (p=0.1149). The Dermacell arm showed a greater average percent reduction in wound area than conventional care (p=0.0791) and Graftjacket (p=0.0762), but the difference was not significant. The use of the second application was at the investigator's discretion. Severe adverse events were similar among the three groups. Limitations of the study included the small patient population, short-term follow-up and the number of patients lost to follow-up (31%).

Breast Reconstruction: Although the evidence supporting Dermacell for breast reconstruction is primarily in the form of case series and retrospective reviews, outcomes reported a significant improvement in time to drainage removal and fewer "red breast" episodes compared to AlloDerm (Pittman, et al., 2016). Zenn et al. (2016) reported that Dermacell was as good as AlloDerm RTU in the occurrence of postoperative infection, implant loss, seroma and hematoma. Other studies have also reported favorable outcomes with Dermacell (Chang and Liu, 2017; Bullocks, et al., 2014; Vashi, 2014). Therefore, Dermacell has evolved into an accepted skin substitute for breast reconstruction.

Duraform™
Duraform Dural Graft Implant (Codman & Shurtleff, Inc., Raynham, MA) is a collagen-based biocompatible implant from processed bovine tendons approved by the FDA 510(k) process for "use in procedures where the repair or substitution of the patient's dura mater is needed (FDA, 2004). The overlay is proposed to prevent spinal fluid leakage. Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

DuraGen®
DuraGen (Integra LifeSciences, Princeton, NJ) is a family of collagen absorbable implants or onlay grafts proposed for repair of dural defects. The grafts are made from bovine Achilles tendon. The DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and the Integra™ SpinalMend™ Dural Regeneration Matrix are FDA 510(k) approved "as a dura substitute for the repair of dura mater" (Integra LifeSciences, 2026; FDA, 2010). Studies are primarily in the form of case reports and retrospective reviews. Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

Williams et al. (2013) conducted a randomized controlled trial (n=34) to compare the efficacy of DuraGen (n=16), a sutureless device to Dura-Guard (n=18), a suturable device. The objective of the study was to determine if suturing the dural patch was essential for reduction of complications or whether sutureless patches correlated to worse outcomes. The authors also completed a cost analysis. Subjects were aged 18 years and older with a clinical diagnosis of Chiari Malformation I (CM I). Follow-up occurred for three months. Postoperatively, there were no significant differences in complications, pseudomeningocele, meningitis, CSF leak, readmissions or emergency room visits, and no patients had a wound infection. SF-36 Quality of Life Questionnaire scores showed no significant differences in patient's physical health ($p<0.005$) and function ($p<0.005$) were significantly improved. All patients showed a significant improvement in their outcome response (p=0.0112). Limitations of the study include the small patient population and short-term follow-up.

Dura-Guard®
Dura-Guard (Baxter, Deerfield, IL) is prepared from a bovine pericardium cross-linked with glutaraldehyde. It is a membranous implant sutured to the surrounding dura. The device is FDA 510 (k) approved for closure of dura mater during neurosurgical procedures. The product is available in five different sizes (FDA, 1998). As noted above in DuraGen, Williams et al. (2013) compared DuraGen to Dura-Guard and found no significant differences between the products. Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

DuraMatrix™
DuraMatrix Collagen Dura Substitute Membranes and DuraMatrix-Onlay™ (Stryker, Portage, MI) are resorbable matrices made from collagen derived from bovine Achilles tendon. The devices are FDA 510(k) approved for "use as a dural substitute for the repair of dura mater" (FDA, 2006). The membrane can be applied either as an inlay or sutured in place (Stryker, 2026). Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

Durepair® Dura Regeneration Matrix
Durepair Dura Regeneration Matrix (Integra LifeSciences, Princeton, NJ) is a biological fetal bovine collagen implant that is FDA 510(k) approved for the repair of defects in the dura mater. The scaffold is proposed to prevent cerebrospinal fluid leakage and allow healing of openings in the dura by the ingrowth of fibroblasts and blood vessels on the scaffold (FDA, 2004). Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

Epicel
Epicel (Vericel Corporation, Cambridge, MA) is a cultured epidermal autograft (CEA) that is FDA approved under the HDE process for patients who have deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30% (Vericel Corporation, 2025). It may be used in conjunction with split-thickness autografts or alone in patients for whom split-thickness autografts may not be an option (FDA, 2007). Epicel is FDA approved as a Humanitarian Device Exemption (HDE) device. Prospective comparative studies and case series support Epicel for the treatment of burns (Carson, et al., 2003; Munster, 1996).

Epifix®
EpiFix Amniotic Membrane Allograft (MiMedx Group, Kennesaw, GA) is a placental tissue allograft composed of dehydrated human amnion/chorion membrane (DHACM) processed by a patented Purion® Process. These processes are regulated by the FDA regulations and American Association of Tissue Banks (AATB) standards. EpiFix is proposed to promote cellular migration to enhance soft tissue repair in acute and chronic wounds free of necrotic tissue and infection; partial- and full-thickness wounds; venous, diabetic, pressure, and chronic vascular ulcers; trauma wounds, including burns; and surgical wounds. EpiFix membranes/sheets come in a variety of sizes (MiMedx, 2026). Randomized controlled trials support EpiFix for the treatment of diabetic foot ulcers and venous status ulcers. Studies reported significantly greater reduction in wound size and faster healing time (Bianchi, et al., 2017; Zelen, et al., 2016; Zelen, et al., Feb 2014; Serena, et al., 2014; Zelen, et al., Apr 2014; Zelen et al., 2013). EpiFix® also comes in a micronized powder.

Evidence for the effectiveness of EpiFix for all other indications and EpiFix Micronized Powder for all indications is lacking.

FlexHD® Acellular Hydrated Dermis: FlexHD Acellular Hydrated Dermis (Musculoskeletal Transplant Foundation, Edison, NJ and Ethicon Inc., Somerville, NJ) is a matrix derived from donated human allograft skin. The product is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. The dermis is indicated for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects. FlexHD is available in multiple sizes. Case series and retrospective reviews support the safety and efficacy of FlexHD for use during postmastectomy breast reconstruction. FlexHD is an established skin substitute for this indication (Liu, et al., 2014; Seth, et al., 2013; Seth, et al., 2012; Brooke, et al., 2012; Rawlani, et al., 2011; Cahan, et al., 2011; Topol, et al., 2008).

The implantation of FlexHD has also been reported to aid in the rehabilitation of patients with empty nose syndrome in an attempt to provide resistance for breathing and decrease the sensation of suffocation (Chhabra and Houser, 2009). Data supporting the safety and efficacy of FlexHD for other indications from published clinical trials are lacking. Studies have primarily been in the form of retrospective reviews and case series with small patient populations.

Bochicchio et al. (2013) conducted a prospective quasi-experimental time-interrupted series to evaluate the incidence of hernia recurrence in traumas or emergency surgical patients who were implanted with AlloDerm (n=55) or FlexHD (n=35). Patients had a large (> 200 cm^2) complicated symptomatic (pain, discomfort) ventral hernia as result of surgery. The primary outcome was hernia recurrence (true or functional) at one year. By year one, all AlloDerm patients requested and required a second hernia repair. The mean hernia size in the AllloDerm patients was 402 cm^2 and the mean mesh size used to repair the defect was 318 cm^2. Twelve of these patients were found to have intraoperative contamination at their first hernia repair operation and 33 had significant laxity (functional hernia recurrence) by six months postoperatively. A total of 17 patients had developed a functional recurrence by the one-year follow-up and five were diagnosed with a true recurrence confirmed at the time of the second hernia operation. AlloDerm complication ns included five seromas, seven intra-abdominal abscesses and two enterocutaneous fistulas. In the FlexHD group, mean hernia size was 388 cm^2 and the mean size of the mesh used to repair the defect was 389 cm^2. At the one-year follow-up, three patients had a true hernia recurrence (i.e., through the mesh or through the mesh/fascial interface) and eight had significant laxity (functional hernia recurrence). Of the 11 patients, six patients with functional hernia underwent repair. Complications in the FlexHD group included ten wound infections, two enterocutaneous fistulas, three intra-abdominal abscesses and three seromas. The difference in the groups in complications was not significant. All AlloDerm patients required a second hernia operation vs. 31% of FlexHD patients. Three of ten FlexHD patients vs. all AlloDerm patients in the underlay arm group suffered recurrence by one year ($p<0.001$). The lowest recurrence rate was in the FlexHD overlay group (2/23) as compared to Alloderm (13/13) group ($p<0.001$). Overall, recurrence rates were significantly greater in all three AlloDerm technique groups at one year. The authors concluded that FlexHD appeared to have reduced the recurrence and laxity rates while maintaining a similar complication profile when compared with AlloDerm. Limitations of the study include: the variation in surgical techniques within and between the groups, short-term follow-up, small patient population, and the study design having occurred during different time periods.

GalaFlex® Scaffold/GalaFLEX Mesh: GalaFlex (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) is a sterile, knitted, resorbable mesh, constructed of non-dyed monofilament fibers made from poly-4-hydroxylbutyrate (P4HB) (BD, 2026). P4HB, a proprietary product, is produced from a naturally occurring monomer (small molecule that reacts with a similar molecule to form a larger molecule) and is processed into monofilament fibers and knitted into a surgical fold. It is provided in single sheets of varying widths, lengths and shapes, and may also be cut to the shape or size desired for a specific application (BD, 2026). According to the FDA 510(k) approval,

GalaFLEX Mesh is indicated for use as a transitory scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome including reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction (Williams, et al., 2016; FDA, 2014). Although the published literature investigating Galaflex in breast reconstruction is primarily in the form of retrospective reviews and case series with small patient populations (n=11-62) and short-term follow-ups (12 months) (Adams, et al., 2018; Nair et al., 2018; Adams, et al., 2016), it has evolved into a standard of care (Movassaghi and Stewart, 2024; Frey and Choi, 2020).

Mallucci and Bistoni (2022) conducted an observational study of 100 consecutive patients to evaluate the efficacy and range of indications of P4HB (Galaflex) in aesthetic breast surgery with a focus on long-term outcomes in mastopexy. All patients were female with a mean age of 43.3 years (range 20 to 79 years) and a mean body mass index of 23.6 (range 19.2-32.4). Follow up ranged from 6–36 months with a median of 14 months. The most common indications were for mastopexy alone, augmentation/mastopexy, and secondary correction of implant malposition, including bottoming out, symmastia, and prevention of implant rotation. To evaluate lower pole stability in patients who received a mastopexy, the author employed a simple photographic linear analysis tool involving a three-quarter profile image of the breast to compare images preoperatively and postoperatively. The lower pole stretch was determined by measuring lower pole descent and arc length increase. Lower pole descent was defined as the percentage increase in vertical length between the nipple and the inframammary fold (IMF) taken at two postoperative time points of six weeks and one year. Arc length increase was defined as the percentage increase in the curvilinear distance from the nipple to the IMF utilizing the same time points. In all cases, the increase in arc length slightly exceeded the decent of the IMF indicating very little change in lower pole stretch between six weeks and one year postoperatively. There were two adverse events: an infection 14 days post-surgery in a 79-year-old patient for a secondary revision augmentation mastopexy and an acute seroma in a patient for primary augmentation/mastopexy which occurred post gym activity five days after surgery. There were no cases of extrusion, no red breast, no pure scaffold infections, and no complaints about palpability of the scaffold. The study demonstrated the use of Galaflex in breast surgery gave stability to the lower pole over time for mastopexies and implant mastopexies and was successful in correcting many secondary defects.

Sigalove et al. (2022) conducted a retrospective review of consecutive patients (n=263) to evaluate the safety of using Galaflex and AlloDerm (n=135, 250 breasts) versus AlloDerm alone (n=128, 249 breasts) in immediate, expander-implant, prepectoral breast reconstruction. Excluded were patients who underwent delayed, single-stage, revision, or hybrid autologous-prosthetic reconstruction. Primary outcome measured was the complication rate. Follow up for the Galaflex-AlloDerm group was an average of 15 ± 7.8 months and the AlloDerm alone group follow up was an average of 41.9 ± 12 months. Rate of any complication was 6.4% (16 breasts) in the Galaflex-AlloDerm group and 7.6% (19 breasts) in the AlloDerm alone group. Complication type in the Galaflex-AlloDerm group versus (vs) the AlloDerm alone group included surgical site infection (five breasts vs four breasts), skin necrosis (three breasts vs 13 breasts), seroma (eight breasts vs seven breasts), wound dehiscence (two breasts vs five breasts), prothesis exposure (four breasts vs three breasts), return to operating room (13 breasts vs nine breasts), prothesis loss (eight breasts vs four breasts), and capsular contracture (two breasts vs two breasts). Author noted limitations include retrospective study design and short term follow up. The complication rate of Galaflex and Alloderm in in two-stage, prepectoral breast reconstruction was similar to the complication rate of Alloderm alone.

GalaFLEX 3DR Scaffold, GalaFLEX 3D Scaffold: GalaFORM 3D Scaffold (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) is a bioresorbable surgical mesh made from the biologically derived poly-4-hydroxybutyrate (P4HB) used in plastic and reconstructive surgery. After implantation, the scaffold slowly bioresorbs while tissue grows into the scaffold. According to the

FDA 510(k) approval, GalaFORM 3D scaffold is indicated for use "as a bioresorbable scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction. GalaFORM 3D scaffold is also indicated for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result". GalaSHAPE 3D is approved for the same indications and now known as GalaFLEX 3D (BD, 2026; FDA, 2017; FDA, 2016; FDA 2014). The Galatea products are available in various sizes in oval, rectangular, triangular, circular shapes and can be custom made.

GalaFLEX has been proposed for use in high-risk ventral and incisional hernia repair. There is insufficient evidence to support the safety and efficacy of GalaFLEX for high-risk ventral and incisional hernia repair.

GalaFLEX Lite™ Scaffold: GalaFLEX Lite Scaffold (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) is a bioabsorbable surgical mesh manufactured from poly-4-hydroxybutyrate (P4HB), a biologically derived polymer which is extruded into monofilament fibers and knitted into a surgical scaffold. P4HB is absorbed by the body through a process of hydrolysis and hydrolytic enzymatic digestion, typically within 18-24 months. It received FDA clearance as a class II medical device via the 510(k) pathway. The P4HB material is identical to the predicate device, TephaFLEX Light Mesh and the reference device, Phasix Mesh in terms of formulation and the manufacturing processes. Phasix Mesh is used as a reference device since the specifications of the GalaFLEX Lite Scaffold device are being harmonized with the BD P4HB product line, following the acquisition of Tepha, Inc. by BD in 2021. GalaFLEX Lite Scaffold is intended to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result (FDA, 2023, 2024).

GORE® BIO-A® Tissue Reinforcement
GORE BIO-A Tissue Reinforcement (Gore Medical, Flagstaff, AZ) is a synthetic bioabsorbable copolymer fiber (polyglycolic acid:trimethylene carbonate [PGA:TMC]), gradually absorbed by the body and proposed for soft tissue reinforcement. The product is FDA 510(k), Class II, approved for use in the reinforcement of soft tissue including hernia repair, muscle flap reinforcement, perforated tissue repair and general tissue reconstruction. Six sizes are available (7x10 cm, 8x8 cm, 9x15 cm, 10x30 cm, 20x20 cm, 20x30 cm) (Gore Medical, 2026; FDA, 2012).

Medical textbooks describe certain scenarios when a hiatal hernia would be unable to be primarily closed and the use of Phasix ST mesh or Gore Bio A mesh would be appropriate to use (Michaels and Pappas, 2025; Ferguson, 2024; Plumblee et al., 2024; Dunn and Houghton, 2022; Yates and Oelschlager, 2022). Scenarios when the use of Phasix ST or Gore Bio A is indicated include when the crural fibers are disrupted during dissection, the hernia defect is large, crural closure is tenuous, or the crural closure is under tension. The routine use of mesh during paraesophageal hernia repair (PEHR) is not recommended.

GORE® BIO-A® Tissue Reinforcement– Other Indications
The safety and efficacy of this product for other indications have not been established. Studies are primarily in the form of retrospective reviews, case reports and case series with small patient populations and short-term follow-up (Smith and Slater, 2021).

Rosen et al. (2017) conducted a multicenter prospective observational study (n=104) to evaluate the use and performance of Gore Bio-A Tissue Reinforcement. Adult patients with incisional hernias of ≥ 9 cm^2, undergoing a planned single-staged repair of a ventral/incisional hernia with

an operation classified by Centers for Disease Control (CDC) wound criteria as a clean-contaminated or contaminated wound were eligible for study enrollment. The CDC wound classification showed 77% of wounds were contaminated and 23% were clean-contaminated. Patients were enrolled if a single unit of the Mesh could adequately reinforce the midline fascial closure with at least four centimeters of lateral overlap. The biosynthetic mesh was placed as a sublay in either the intraperitoneal or retrorectus position, based on the discretion of the surgeon, to reinforce midline fascial closure. The primary outcome measure was the rate of hernia recurrence based on physical examination at the two-year follow-up. Hernia recurrence was defined as a new hernia within seven centimeters of the repair, and categorized as midline, at the stoma site, or both. Secondary outcomes included incidence of wound events and quality-of-life assessments. Recurrent herniation occurred in 16 patients (17%) at the 2-year follow-up. The recurrence rate was significantly higher in patients with mesh placement in the intraperitoneal position (40%; 4/10) versus placement in the retrorectus position (13%; 12/94) ($p=0.0451$). Time to recurrence was shorter in patients with postoperative infection ($p=0.0098$) than those without and those with parastomal compared with midline hernia recurrences ($p<0.0001$). Overall patients reported significant sustained improvement in physical health of the two-year follow-up period ($p<0.05$). There were nine superficial surgical site infections that resolved with oral or intravenous antibiotics. Of the ten deep surgical site infections, six required percutaneous drainage alone, three underwent minor operative debridement and one underwent wide wound debridement with partial mesh excision. Additional wound events included development of a postoperative seroma (n=6). Three required percutaneous drainage and eventually resolved. Two postoperative bowel obstructions occurred in patients with mesh placed in the retrorectus position. Author-noted limitations of the study included: the selected study format of a longitudinal observational study potentially limited the ability to apply the results; lack of a control group and randomization; short-term follow-up; diversity of hernia sizes; heterogeneity of the patient population and surgical procedures performed; inherent limitations of outcomes researched (e.g., quality-of-life indices) in patients with complex ventral hernia repair; lack of post-operative computerized tomogram; and lack of generalizability. Additional studies are needed to establish the clinical effectiveness and safety of Gore Bio-A Tissue Reinforcement for this indication.

Grafix®
Grafix Cryopreserved Placental Membrane (Osiris Therapeutics, Inc., Columbia, MD is a subsidiary of Smith & Nephew) is a cryopreserved, human placental, extracellular matrix, amnion or chorion collagen rich, that includes growth factors and mesenchymal stem cells (MSC). The product is proposed for the treatment of acute and chronic wounds including diabetic foot ulcers, venous leg ulcers, pressure ulcers, deep tunneling wounds, burns, pyoderma gangrenosum, epidermolysis bullosa, surgical incisions, and surgical dehiscence. Grafix is regulated by the FDA as banked human tissue and Osiris is accredited by the American Association of Tissue Banks (AATB). Grafix Core is a chorion matrix and Grafix Prime is an amnion matrix. GrafixPL Prime and GrafixPl Core are also other configurations of the Grafix products intended for the same use. Grafix PL Membrane is lyopreserved and stored at room temperature (Smith and Nephew, 2026). GRAFIX DUO is a sterile, dual-layered, dehydrated, amniotic membrane-based skin substitute product. It is supplied in a variety of five sizes and is packaged within a heat-sealed pouch contained within a tertiary box.

Multicenter randomized controlled trials and technology assessments have reported that Grafix significantly improves overall wound healing and shortens the time to wound healing for partial and full-thickness diabetic foot ulcers and has evolved into an accepted treatment option for a select subgroup of patients (Ananian, et al., 2018; Lavery, et al., 2014). However, there is insufficient evidence to support the effectiveness of Grafix for complex diabetic foot ulcers including exposure of muscle, tendon, fascia, bone and/or joint capsule.

Published clinical trials have reported completed and faster healing of venous leg ulcers (VLUs) when Grafix was used as an adjunctive therapy with standard wound therapy (SWT) compared to SWT alone.

Farivar et al. (2019) conducted a prospective case series to evaluate the effectiveness of Grafix for the treatment of venous leg ulcers (VLU) (n=21 patients; 30 VLUs). Inclusion criteria were: presence of superficial or deep venous reflux confirmed by duplex ultrasound; active chronic VLU that failed standard wound care therapy; no evidence of active or ongoing wound or systemic infections; no evidence of limb ischemia (ankle-brachial index <0.8); and not immunosuppressed (i.e., human immunodeficiency virus infection, organ transplant recipients, receiving chronic steroid therapy). Ten of the patients had diabetes. The primary outcome measure was complete closure of the index wound. Secondary end points were the percentage change in total ulcer area during the follow-up period and reduction in wound area with application of Grafix. Patients who did not heal after 12 weeks of standard wound therapy (SWT) began receiving SWT and one application of Grafix per week for up to 12 weeks. If the percentage take of the graft was <50%, another application to the ulcer site was applied. Ulcer sites with percentage take >50% did not undergo another application on that follow-up visit. No patient received more than 12 applications. After a mean follow-up of 10.9 weeks, mean wound size was significantly reduced with Grafix therapy (p=0.002). Of the VLUs that failed SWT, 53% (16/30) healed completely with the addition of Grafix with a mean treatment time of 10.9 weeks. Of the remaining VLUs that did not achieve complete wound closure, 57% (8/14 limbs) had >50% wound area reduction. On average, 79.2% wound surface area reduction was achieved with Grafix compared with 29.2% SWT only (p<0.001). Patients received a mean 7.2 applications of Grafix and no ulcers recurred during the 12 weeks following healing. Limitations of the study include lack of a comparator and the small patient population.

Additional case series (Reyzelman, et al., 2019) and retrospective reviews have reported 47%–67.6% complete closure within 12 weeks when Grafix therapy was combined with standard wound therapy (Ananian, et al., 2019; D'Costa and Kurtzl., 2018, Smedley, et al., 2016; Regulski, et al., 2013).

Grafix has been proposed for the treatment of chronic, complex diabetic foot ulcers including exposure of muscle, tendon, fascia, bone and/or joint capsule. There is insufficient evidence to support the effectiveness of Grafix for complex diabetic foot ulcers. In a multicenter, prospective case series (n=31), Frykberg et al. (2016) evaluated the safety and efficacy of viable cryopreserved human placental (vCHPM) (GrafixCore) for the treatment of chronic complex diabetic foot wounds with exposed bone and tendon. Type 1 and type 2 diabetics, age 18–85 years, with a complex diabetic foot wound ≤15 cm in longest diameter were included. The wound extended through the dermis into the subcutaneous tissue with exposed muscle, tendon, fascia, bone and/or joint capsule. Vascular parameters included: ankle-brachial index (ABI) ≥0.5 and ≤1.2 or toe systolic pressure ≥40 mmHg or transcutaneous tissue oxygen tension (tcpO2) >30 mmHg or skin perfusion pressure of >30 mmHg. The patients had significant comorbidities (hypertension, current or former smoker, heart disease and/or partial food amputation). Three patients had end-stage renal disease and were on hemodialysis. The primary endpoint was 100% granulation (i.e., complete coverage of the exposed tendon and/or bone with collagen-rich connective tissue) of the index wound by 16 weeks after the initial application of GrafixCore. Standard wound care (cleansing, debridement, absorptive foam dressings, off-loading devices) was also performed before and after application. Patients were treated with a weekly application of the graft for up to 16 weeks. If 100% granulation was achieved prior to 16 weeks, the patients continued to receive weekly applications until complete wound closure occurred for up to a maximum of 16 applications. By week 16, 96.3% of patients achieved 100% granulation of the index wound. An average of 6–8 applications was required. In addition, 59.3% of patients achieved complete wound closure (100% reepithelialization*)* with an average of nine applications

without the need for further amputation or surgical intervention. No adverse events related to the graft were reported. The authors noted that this was the first prospective study reporting outcomes for viable cryopreserved human placental for the treatment of complex diabetic foot ulcers. The incidence of amputation in this study group was 6.5%. Twenty-seven patients completed the study. Additional studies with larger patient populations are needed to validate the effectiveness of skin substitutes for complex diabetic foot wounds.

Kerecis® Omega3 MariGen™/ Kerecis® Omega3 Marigen® Shield
Kerecis Omega3 MariGen wound dressing (Kerecis Ltd., Reykjavik, Iceland), also known as Kerecis MariGen or Kerecis Omega3 Wound, is a processed, fish (piscine) dermal matrix composed of fish collagen. Variations of Kerecis MariGen include Kerecis MariGen Micro and MariGen Expanse. MariGen Micro consists of small units of fragmented fish skin intended to cover uneven and irregular wound spaces. MariGen Expanse is designed to cover large wounds of 100 cm^2 or larger. Kerecis Omega3 Wound (formerly Marigen Wound) is FDA 510(k) (K132343) approved for the treatment of partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, draining wounds and trauma and surgical wounds. MariGen Wound Extra is FDA 510(k) (K190528) approved for the same indications. It is supplied as a meshed sheet ranging in sizes up to 20 x 30 cm.

Kerecis® Omega3 Marigen® Shield received FDA 510(k) clearance (K213231) on June 29, 2022. MariGen Shield is a bilayer of processed resorbable acellular fish dermal matrix skin substitute adhered to a thin, transparent, porous, soft silicone layer. The silicone layer is a transparent polyurethane film single-coated with soft, medical grade silicone that is attached to the scaly side of the fish dermal matrix. The silicone layer is porous, soft and conformable to the wound surface which can be peeled off as the fish dermal matrix is resorbed. It is indicated for the management of wounds. As part of the processing of Kerecis products, cells and antigenic materials are extracted. The fish skin is derived from cod farmed in the North Atlantic Ocean. Kerecis Omega3 serves as a scaffold for revascularization and repopulation by the patient's cells and is converted into living tissue. In comparison to human skin substitutes, Kerecis Omega3 contains omega3 polyunsaturated fatty acids. In comparison to porcine grafts, fish skin is proposed to have lower risk of disease.

Kerecis SecureMesh is FDA 510(k) (K153364) approved for use as a prosthesis when staple line reinforcement is needed in surgical repair of soft tissue deficiencies using surgical staplers. It can be used for reinforcement of staple lines during lung, bariatric, gastric, colorectal and other surgeries. Kerecis Gingiva Graft is FDA 510(k) (K192612) approved for localized gingival augmentation to increased keratinized tissue around teeth or implants. Kerecis Reconstruct (also known as Kerecis Omega3 SurgiBind) is FDA 510(k) (K202430) approved for use for implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

Kerecis Ltd distributes additional products which are available in various countries and may have different names. These other products include: Kerecis® SurgiClose™, Kerecis® SurgiClose Micro™, Kerecis GraftGuide™, GraftGuide™ Micro, and GraftGuide™ Mano. The various products are indicated for use as a wound covering for burns, chronic wounds, surgical repairs, and traumatic wounds. Additional products under development include: Kerecis Omega3 Dura for reconstruction of dura mater, Kerecis Omega3 Hernia for abdominal repair, and Kerecis Omega3 Pectus for breast reconstruction. These additional products are not FDA approved and are in various stages of development (Kerecis, 2025; FDA, 2021, 2020, 2019, 2016, 2013).

Kerecis Omega3 Wound products are supported by randomized controlled trials (n=102-255) (Dardari et. al., 2024; Lantis et al. 2023) for the treatment of non-healing diabetic foot ulcers. Compared to standard wound care, more patients healed within 6-12 weeks with Kerecis Omega3

Wound products. Other studies are primarily in the form of small randomized control trials, case series, retrospective reviews and case reports with small patient populations (n=5–85) with short-term follow-up (28 days to 12 weeks) (Kim, et al., 2021; Lullove, et al., 2021; Badois, et al., 2019; Kirsner, et al., 2019; Michael, et al., 2019; Woodrow, et al., 2019; Dorweiler, et al., 2018; Yang, et al., 2016; Baldursson, et al., 2015; FDA. 2013).

Dardari et. al., (2024) conducted a randomized control trial to compare the safety and effectiveness of fish skin graft (FSG) (n=129) to standard of care (SOC) (n=126) in the treatment of diabetic foot ulcers that penetrate to the bone, joint, or tendon. Included individuals were age ≥ 18 years, diagnosed with diabetes mellitus, with a lower limb wound below the malleolus penetrating to tendon or capsule (University of Texas Wound Classification System Grade [UT grade] 2) or to the bone or joint (UT grade 3) present for ≥ one month or with open amputation wounds. Additionally, nonischemic to moderately ischemic wounds with an ankle to brachial systolic pressure index (ABPI) of a minimum of 0.6 were included. Exclusions included active, unmanaged osteomyelitis; immune deficiency or autoimmune disease; had undergone arterial reconstruction within the previous month; were receiving treatment with systemic glucocorticoids or other treatments known to delay wound healing; pregnant, breastfeeding or plans to become pregnant; or had a known allergy to fish. All patients underwent surgical wound debridement in week one and were required to offload. All patients were actively treated for 14 weeks with follow-up continuing until week 24 or wound closure. The intervention group received an application of intact fish skin graft weekly for six weeks, then every other week on weeks 8, 10, 12, and 14. Standard of care group received wound cleansing with isotonic saline, running water, and neutral soap followed by the application of any of the following dressings: hydrocolloid, alginate, hydrocellular, charcoal, silver, petrolatum gauze, or pressure dressing. The primary outcome measure was the percentage of wounds with complete closure by 16 weeks. Wounds were defined as healed if complete (100%) epithelialization occurred without drainage and need for dressing. Secondary outcomes were the percentage of wounds closed at weeks 20 and 24 and time to healing. At 16 weeks, 44% of FSG and 26% SOC achieved complete wound healing ($p<0.001$). Healing at 20 weeks occurred in 46% of FSG and in 32% SOC. At 24 weeks, 55% FSG and 38% SOC were healed. Mean time to healing for FSG was 17.3 weeks and 19.4 weeks for SOC. Most common adverse event was primary wound infection occurring in 30.2% (n=39) of FSG and 24.6% (n=31) of SOC group. One study limitation is the variability of in selection of standard of care dressings which denotes there is no universally accepted standard treatment. The results of this study indicated that intact fish graft had higher rates of healing of diabetic foot ulcers that penetrate to the bone, joint, or tendon than standard of care.

Lantis et al. (2023) conducted a randomized control trial to investigate the safety and efficacy of fish skin graft (FSG) (n=51) to standard of care (SOC) of collagen alginate therapy (CAT) (n=51) in the treatment of diabetic foot ulcers (DFUs). The objective of the study was to compare complete wound healing at twelve weeks. Selection criteria included: DFU extending through the dermis but not into tendon, muscle, or bone; DFU of ≥ 4 weeks duration up to one year; DFU ≥ 1 cm^2 to 25 cm^2; HBA1C < 12%; adequate perfusion within six months of randomization as measured by dorsal transcutaneous oxygen measurement or skin perfusion pressure greater than 40 mm Hg, ankle-brachial index between 0.7 and 1.3, or toe-brachial index of 0.6. Individuals were excluded if index ulcer was on the posterior heel, on renal replacement therapy, or had a serum creatinine level greater than 3.0 mg/dL. Following a two-week pretreatment period in which DFUs were treated with sharp debridement, moist wound care (i.e., application of CAT, soft roll, and a compressive dressing to the ulcer), and offloading with a walking boot, patients were randomized to CAT alone three times a week or FSG applied weekly for up to 12 weeks. The primary outcome of the study was the comparison of the proportion of index ulcers healed at 12 weeks. Wounds were defined as healed if there was complete (100%) re-epithelialization without drainage or need for dressing. Secondary outcomes included time to healing (for DFUs that healed) and mean percentage wound area reduction (PAR) at 12 weeks. Diabetic foot wounds

treated with FSG were significantly more likely to achieve closure than those managed with CAT (intention to treat [ITT]: 56.9% vs 31.4%; p=0.0163). The mean PAR at 12 weeks was 86.3% for FSG vs 64.0% for CAT (p=0.0282). Adverse events in both groups were related to infection of the index ulcers (FSG n=1; CAT n=5). Limitations of the study include the small patient population, short-term follow-up and lack of variety of DFUs and comorbidities.

Lullove et al (2021) conducted a randomized control trial to evaluate the safety and efficacy of Kerecis Omega3 in the treatment of diabetic foot ulcers. Included in the study (n=49) were adults ≥18 years or older with diabetic foot ulcers (DFUs) for a minimum of four weeks who demonstrated adequate renal function and perfusion to affected extremity. The DFU could be through the dermis but not into tendon, muscle, or bone with the index ulcer size of ≥1cm² and ≤25cm². Patients were excluded if they were being treated with systemic antibiotics at time of randomization; had an ulcer on heel; were on any investigational drug or therapeutic device within 30 days preceding study visit; had received a biomedical or topical growth factor for wound within the previous 30 days; were pregnant or breastfeeding; had a HbAic >12.0; or end-stage renal disease as evidenced by a serum creatinine ≥3.0 mg/dL within the previous six months. No significant difference was noted between the study groups in terms of demographics, renal function, or blood glucose. All patients were first treated with standard of care (SOC) (offloading, appropriate debridement, and moist wound care) for a 2–week screening period then randomized to SOC plus fish skin graft (n=25) applied weekly for up to 12 weeks or SOC using collagen alginate dressing (n=24) applied weekly by investigator and three times weekly by patient/caregiver. Primary outcome was the percentage of wounds closed at 12 weeks. Secondary outcome measures included time to heal (for DFUs that healed) and wound area reduction by percentage at 12 weeks. Percentage of wounds healed at 12 weeks was 67% (16/24) for fish skin group and 32% (8/25) in SOC group. Time to closure was six weeks for both groups. Percentage of area reduction at six weeks was 72.8% for fish skin and 41.2% for SOC. Percentage of area reduction at 12 weeks was 97.3% fish skin and 76.8% SOC. Adverse events included mild erythema and irritation which was experienced by both groups. Study limitations included small patient population.

Lyoplant®
LyoPlant (Aesculap® Inc., Center Valley, PA) is a pure collagen implant that is produced from bovine pericardium and proposed for substitution and enlargement of connective tissue structures in neurosurgery (e.g., covering for cerebral and cerebellar dura defects; cerebral decompression surgery; covering spinal dura defects; spinal compression surgery). Lyoplant is FDA approved for neurological procedures for soft tissue reconstruction of damaged, impaired or missing tissue (Aesculap, Inc., 2025; FDA, 1997). Lyoplant Onlay is FDA 510(k) approved as a dura substitute for the repair of the dura mater and is a biological, collagen-based absorbable dura substitution consisting of a bilayer membrane. The onlay is proposed to help prevent cerebrospinal fluid (CSF) leakage. It can be sutured in place as needed and is gradually broken down and replaced by the body's connective tissue. The Onlay comes in five sizes ranging from 1x1 cm to 4x5 cm (Aesculap, Inc., 2025; FDA, 2013). Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

Oasis® Wound Matrix
Oasis Wound Matrix (Cook Biotech Inc., West Lafayette, IN) is a porcine-derived, acellular collagen matrix. Oasis matrix products are manufactured by Cook Biotech and distributed by Smith and Nephew (Smith and Nephew, 2025). Oasis is 510(k) FDA approved for the management of partial and full thickness wounds including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations,

second-degree burns, skin tears), and draining wounds (FDA, 2006). The Oasis Ultra Tri-Layer Matrix incorporates three layers of the same structural components as the single layer matrix and is used in the treatment of larger wounds.

Oasis is an established treatment option for partial or full-thickness diabetic foot ulcers of greater than four weeks duration. The diabetic patient should be participating in ongoing medical management and have an A1C of less than 12%. Oasis may also be used to treat venous stasis ulcers of one month duration that do not respond to standard wound care. The ulcer should be free of sinus tracts, tunnels, cellulitis, eschar and necrotic tissue. Viable tissue around the edges of the ulcer and the presence of adequate arterial blood supply therapy (i.e., palpable pedal pulse or an ankle-brachial index [ABI] of ≥ 0.70) are necessary for healing to occur.

Randomized controlled trials and case series support Oasis for the treatment of chronic partial- and full-thickness lower extremity venous or diabetic foot ulcers when conventional wound therapy fails. The studies compared Oasis to standard wound therapy, Regranex Gel or hyaluronic acid dressing. Treatment with Oasis resulted in better outcomes and lower recurrence rates (Romanelli, et al., 2010; Romanelli, et al., 2007; Niezgoda, et al., 2005; Mostow, et al., 2005; Demling, et al., 2004).

Phasix™ ST Mesh
Phasix™ ST Mesh (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) combines the monofilament resorbable Phasix mesh with a hydrogel barrier using Sepra technology. Phasix ST Mesh is coated on the PGA surface with a resorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel (FDA, 2016). According to the manufacturer, the hydrogel barrier minimizes tissue attachment to the visceral side of the mesh for intraabdominal placement (BD, 2026). Phasix ST mesh received FDA 510(k) approval (K143380) and is indicated for the use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias (FDA, 2016).

Meta-analyses, observational studies, observational cohort studies and retrospective reviews support the use of Phasix ST for the use in paraesophageal/hiatal hernia repair (Aiolfi, et al., 2025; Ganam, et al., 2025; McKay, et al., 2025; Fair, et al., 2024; Panici Tonucci et al., 2024; Konstantinidis and Charisis, 2023; Ukegjini et al., 2023; Aiolfi, et al., 2021; Abdelmoaty, et al., 2020; Panici Tonucci, et al., 2020). Medical textbooks describe certain scenarios when a hiatal hernia would be unable to be primarily closed and the use of Phasix ST mesh or Gore Bio A mesh would be appropriate to use (Michaels and Pappas, 2025; Ferguson, 2024; Plumblee et al., 2024; Dunn and Houghton, 2022; Yates and Oelschlager, 2022). Scenarios when the use of Phasix ST or Gore Bio A is indicated include when the crural fibers are disrupted during dissection, the hernia defect is large, crural closure is tenuous, or the crural closure is under tension. The routine use of mesh during paraesophageal/hiatal hernia repair (PEHR) is not recommended.

Although the use of Phasix ST Mesh has been explored for other indications, including routine use in ventral hernia repairs, as well as use in incisional hernia repair and abdominal wall reconstruction (Layer et al., 2022; Hope et al., 2021; and Bueno-Lledo et al., 2020) the current published evidence does not support the use of Phasix ST Mesh for indications other than when used in association with a covered, medically necessary hiatal hernia repair with specific complicating factors.

SYNTHECEL™ Dura Repair
SYNTHECEL Dura Repair (DePuy Synthes, West Chester, PA) SYNTHECEL™ Dura Repair is composed of biosynthesized cellulose and water and constructed of non-woven, interconnected cellulose fibers. It is proposed to function as a mechanical layer which protects and repairs the

dural defect while preventing further CSF leakage. It is non-resorbable. SYNTHECEL Dura Repair is intended for use as a dura replacement for the repair of dura mater in adults. SYNTHECEL Dura Repair received FDA 510(k) approval on Dec 16, 2013 (K131792). It is available in various t sizes (DePuy Synthes, 2026; FDA, 2013). Medical textbooks support the safety and effectiveness of dural grafts for use in skull or spine procedures in cases where dural closure is difficult (Godil and Schwartz, 2023; Timmons, 2023; Asthagiri et al., 2022; Citardi and Fakhri, 2021; Jandial, 2020; Batzdorf, 2015).

Other Skin Substitutes

Additional skin substitutes have been proposed for the treatment of multiple conditions as discussed below, but the evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of the use of these substitutes for any indication. The number of available studies is limited and involves small, heterogeneous patient populations, short-term follow-ups, minimal comparisons to the established treatment method for the condition, and/or lack of a control group. In some cases, reported outcomes are inconsistent, and a consensus on patient selection criteria and the appropriate surgical approach and techniques that should be used have not been established.

Absolv3 Membrane

Absolv3 Membrane (Amnio Technology, LLC, Phoenix, AZ) is an amniotic/chorionic/amniotic membrane proposed for use as a wound covering and to act as a barrier for full and partial-thickness, chronic and acute wounds. Absolv3 Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a covering or barrier and to protect the wound (CMS, 2025). It is applied per square centimeter based on wound size. There is insufficient evidence to support the safety and effectiveness of Absolv3 Membrane for any indication.

AC5® Advanced Wound System

AC5® Advanced Wound System (Arch Therapeutics, Inc., Framingham, MA) is a topical gel that is made up of synthetic, biocompatible and resorbable peptides. Once reconstituted and applied, the gel self-assembles into a nanofiber network which resembles the construct of the extracellular matrix. AC5 is completely non-animal and non-plant derived, and contains no preservatives (Arch Therapeutics, 2026). It is intended for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds. AC5 Topical Gel received FDA 510(k) clearance on December 14, 2018 (K182681) with a subsequent 510(k) issued on March 11, 2020 (K190129) to add an additional manufacturing process and manufacturer (CMS, 2022). AC5 is provided in a vial containing lyophilized peptide, which must be reconstituted using sterile water prior to use. The kit includes: one 3 mL syringe with Luer-Lok tip; one vial of lyophilized peptide; one vial of sterile water for injection; USP two 18-gauge, 1.5-inch needles; one 18-gauge 11.5-inch blunt fill needles; and two alcohol prep pad wipes (CMS, 2022). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of AC5 Advanced Wound System for any indication.

A/C Wrap™, BioLab Tri-Membrane Wrap Flow™, Membrane Wrap Flow™

A/C Wrap™ (BioLab Holdings, Mesa, AZ) is human dual-layer amnion and chorion allograft. BioLab Tri-Membrane Wrap Flow™ is a human amnion tri-layer allograft. Membrane Wrap Flow™ is a human amnion-amnion fenestrated dual-layer allograft. These products are indicated for chronic and acute wounds. A/C Wrap, BioLab Tri-Membrane Wrap Flow, and Membrane Wrap Flow are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "cover" and "barrier" (CMS, 2025). The route of administration is topical, applying the product on the wound base. The products are available in various sizes to be used by the clinician. There is

insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of A/C Wrap, BioLab Tri-Membrane Wrap Flow, or Membrane Wrap Flow for any indication.

Acelagraft®
Acelagraft® (Celularity Inc., Florham Park, NJ) is a bilayered, decellularized, dehydrated human amniotic membrane allograft. It is proposed for use as a covering for surgical sites, partial- and full-thickness wounds, acute and chronic wounds, including traumatic wounds, burns, diabetic, venous, arterial, and pressure ulcers, and wounds with exposed tendon, muscle, or bone. It is purported to act as a cover and protect damaged tissue by providing a barrier and preserving the wound environment. Acelagraft is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "covering, wrap or barrier to partial- and full thickness, acute and chronic wounds" (CMS, 2025). It is applied per square centimeter based on wound size and the sheets may be trimmed to size. It is supplied in a sterile double-peel, single-use pouch in various sizes with a shelf-life of 10 years when stored at room temperature. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Acelagraft for any indication.

Acesso TrifACA
Acesso TrifACA (Dynamic Medical Services LLC dba Acesso Biologics) is a full-thickness amnion/chorion/amnion membrane. It is a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue. Acesso TrifACA is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier and provides protective coverage to acute and chronic wounds" (CMS, 2025). There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Acesso TrifACA for any indication.

Actishield™ and Actishield™CF Amniotic Barrier Membranes
Actishield™ and Actishield™CF Amniotic Barrier Membranes (Stryker, Portage, MI) are biologic allografts derived from dehydrated human amniotic tissue. Actishield is a chorion based membrane and Actirshield CF is amnion only. It is proposed for soft and/or hard tissue repair. These products are processed in accordance with FDA requirements for Human Cellular and Tissue based Products (HCT/P) (21 CFR Part 1271), State regulations, and the Standards of the American Association of Tissue Banks (AATB). They are available in two thicknesses in the following sizes: 2cm x 4cm, 4cm x 4cm and 4cm x 8cm (Stryker, 1998-2026). There is insufficient evidence to support the safety and efficacy Actishield and Actishield CF Amniotic Barrier Membranes for soft and/or hard tissue repair. Studies are in the form of case studies.

ActiveBarrier®/ActiveMatrix®
ActiveBarrier (Skye Biologics, Inc., Redondo Beach, CA) is a dehydrated amniotic membrane proposed as a wound covering for acute, chronic or surgical wounds. The product is available in two thicknesses (Skye Biologics, 2025). ActiveBarrier 200 is a thick, chorion-based product available in five sizes (2x2cm, 2x4cm, 4x4cm, 4x6cm, 4x8cm). ActiveBarrier 2000 is the thickest form (2000 microns), is suturable and comes in seven sizes. ActiveMatrix is a decellularized allograft derived from human placental connective tissue. It is intended to replace or supplement damaged or inadequate connective tissue. ActiveMatrix is in a flowable form and comes in 0.5 cc, 1.0 cc, 1.5 cc and 2.0 cc size. These products are regulated under the FDA 21 CFR Part 1271, section 361 as HCT/Ps (Human Cells, Tissues, and Cellular or Tissue-Based Products) and an AATB accredited tissue bank. There is a lack of evidence in the published, peer-reviewed literature to support the effectiveness of these products.

Adherus Dural Sealant®

The Adherus Dural Sealant system (manufactured by HyperBranch Medical Technology, Inc., Durham, NC distributed by Stryker) is a synthetic hydrogel sealant proposed for use as an adjunct to standard methods of dural repair (e.g., sutures) to prevent spinal fluid leakage in cranial and spinal surgery. The sealant is also proposed to minimize dural adhesions and scarring. It is designed for neurosurgical procedures when only a small amount of material is required to close a durotomy. The product comes in a syringe and is reconstituted prior to use. The hydrogel is absorbed by the body over a 90 day period as healing occurs. Adherus™ sealants also include the Adherus AutoSpray Dural Sealant. Adherus autospray dural sealant received PMA FDA approval on March 30, 2015. It is proposed for use in patients 13 years of age and older, as an adjunct to standard methods of dural repair, such as when using sutures, to provide watertight closure during cranial procedures (Stryker, 2025; FDA, 2015).

Affinity®
Affinity (Organogenesis, Inc., Birmingham, AL) is an amniotic membrane allograft proposed for wound repair and healing. The device is comprised of the amniotic epithelial layer, amniotic basement membrane, and amniotic stroma. The membrane contains collagen, hyaluronic acid; proteins, growth factors, tissue inhibitors and multipotential cells. The intended use includes acute and chronic wounds, including neuropathic ulcers, venous stasis ulcers, pressure ulcers, burns, post-traumatic wounds and post-surgical wounds. Affinity is available in 1.5X 1.5cm and 2.5X2.5 cm sizes (Organogenesis, 2021-2025; Centers for Medicare and Medicaid [CMS], 2014). There is insufficient evidence in the peer-reviewed literature to support the safety and effectiveness of Affinity. One study compared the use of Affinity to standard of care in the treatment of 76 patients with diabetic foot ulcers (Serena, et al., 2020).

AlloMend®
AlloMend® Acellular Dermal Matrix (ADM) (Allosource®, Centennial, CO) is decellularized donated human dermal tissue and classified as banked human tissue by the FDA because it is minimally processed and not significantly changed in structure from the natural material. It is proposed to replace or repair integumental soft tissues compromised by disease, injury or surgical procedures (Allosource, 2022). It is available in a variety of square/rectangle sizes and thicknesses. Evidence is lacking in the published peer-reviewed literature to support the clinical effectiveness of AlloMend ADM for any indication.

Allopatch HD™
Allopatch HD (Conmed, Utica, NY) is an extracellular matrix (ECM) scaffold derived from human allograft skin for tendon augmentation. The Musculoskeletal Transplant Foundation (MTF), which acquires and processes the tissue, is registered with the FDA (Conmed, 2026). The graft comes in multiple sizes and thickness. There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of Allopatch HD.

AlloWrap™
AlloWrap DS (double-sided) and Dry (Allosource, Centennial, CO) are wound coverings made of two layers of amniotic membrane processed with a proprietary technology. The implant is derived from scheduled and serological screened cesarean sections and provided by Organ Procurement Organizations. Donated skin is regulated by the American Association of Tissue Banks (AATB) and the FDA guidelines for banked human tissue. The product can be wrapped around tissue or placed as an onlay cover. AlloWrap DS is packaged wet and proposed for surgical application to skin with most wound responding with one application. AlloWrap DS comes in four sizes. AlloWrap Dry is surgically applied, comes in two difference sizes and proposed for a variety of procedures as a wound cover or barrier. AlloWrap DS and AlloWrap Dry are also referred to as AlloWrap Natural Wound Cover (AlloSource, 2022). There is insufficient evidence to support the effectiveness of AlloWrap.

AmchoMatrixDL
AmchoMatrixDL (Cellution Biologics Inc., Roswell, GA) is a minimally manipulated, dehydrated, dual-layer amnion membrane allograft this is proposed for homologous use by acting as a barrier and providing protective coverage from the surrounding environment for acute and chronic wounds. Smaller sizes can be applied as a cover to the ocular surface following repair or reconstruction procedures. AmchoMatrixDL is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a covering or barrier (CMS, 2025). It is applied per square centimeter based on wound size. There is insufficient evidence to support the safety and effectiveness of AmchoMatrixDL for any indication.

AmnioAMP-MP™
AmnioAMP-MP (CellGenuity, Grapevine, TX) is a decellularized dehydrated human amniotic membrane indicated for the management of partial and full-thickness acute and chronic wounds including burns, diabetic wounds, venous wounds, arterial wounds, pressure wounds and wounds with exposed tendon, muscle, and bone. AmnioAMP-MP is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 (CellGenuity, 2022). The AmnioAMP-MP allograft is available in single and dual layers in multiple following sizes (CMS, 2020). There is a lack of evidence in the published, peer-reviewed literature to support the effectiveness of this product.

AmnioBand Particulate
AmnioBand Particulate is a lyophilized (freeze-dried) placental matrix in particulate form, aseptically processed to preserve the tissue's natural cytokines and tissue matrix. The Particulate is intended to be used as a wound care scaffold for the replacement of damaged or inadequate integumental tissue, such as diabetic foot ulcers, venous leg ulcers, pressure ulcers, or for other homologous use, particularly irregularly-shaped or crevassing wounds. AmnioBand Particulate is available in a variety of masses, ranging from 40 mg to 160 mg (CMS, 2016). There is insufficient evidence to support the safety and efficacy of the Amnioband products.

Amnio Burgeon Membrane and Hydromembrane , Amnio Burgeon XPlus Membrane and XPlus Hydromembrane, Amnio Burgeon Dual-Layer Membrane and the Dual Layer Amnio Burgeon X-Membrane
Amnio Burgeon Membrane and Hydromembrane , Amnio Burgeon XPlus Membrane and XPlus Hydromembrane, Amnio Burgeon Dual-Layer Membrane and the Dual Layer Amnio Burgeon X-Membrane (One BioTech LLC., West Palm Beach, FL) are amniotic membrane products used as a wound covering and to act as a barrier for full and partial-thickness, chronic and acute wounds. The products are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 (CMS, 2024). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Amnio Burgeon Membrane and Hydromembrane , Amnio Burgeon XPlus Membrane and XPlus Hydromembrane, Amnio Burgeon Dual-Layer Membrane and the Dual Layer Amnio Burgeon X-Membrane for any indication.

AmnioCare®, AmnioMatrix®, and FloGraft™
AmnioGenic Therapy™ (Applied Biologics™ LLC. Phoenix, AZ) includes various amniotic membrane products proposed for various indications. These products are regulated by the FDA guidelines for banked human tissue. AmnioMatrix® is a cryopreserved, allograft liquid wound covering and is most commonly used as a filling agent for soft tissue injuries, hollow regions of bone, and as an anti-inflammatory wound dressing. Other proposed uses include the treatment of skin and soft tissue ulcerations, plantar fasciitis, muscle tears, repetitive motion/overuse injuries, tendinopathies, bone injuries resistant to healing, arthritis, and failed back surgery syndrome due to epidural scar formation. AmnioGenic Therapy™ amniotic products also include AmnioCare®

which is a patch proposed as a wound covering for tendons and nerves at the surgical site. FloGraft™, a cryopreserved tissue matrix, is proposed for use as a soft tissue defect filler. FloGraft is proposed for the treatment of tendinitis, tendinosis, soft tissue trauma and defects, plantar fasciitis, Charcot, ligament tears and strains and other orthopedic injuries. Studies are primarily in the form of case reports and case series with small patient populations (n=≤20). There is insufficient evidence in the published peer reviewed literature to support the safety and efficacy of AmnioGenic Therapy or amniotic membrane for these indications.

AmnioClear®/AmnioClear LTC
AmnioClear (Liventa Bioscience, formerly AFCell Medical, West Conshohocken, PA) is a placental amnionic membrane consisting of amnion and chorion. The product is proposed for the treatment of difficult to heal wounds or as a protective barrier in surgical procedures. Liventa is partnered with the Musculoskeletal Transplant Foundation (MTF) for allograft procurement and processing. AmnioClear is available in four sizes (2x2 cm, 4x4 cm, 4x6 cm, 1 cm disks). Liventa also offers AmnioClear LCT (loose connective tissue) which is a flowable, injectable amniotic allograft for knee pain and inflammation secondary to osteoarthritis. Its use is intended for supplementing synovial fluid in articulating joints. The product is not FDA approved (CMS, 2015). There is a lack of data in the peer-reviewed literature to support the safety and efficacy of these products.

AMNIOCORD®
AMNIOCORD (MIMEDX Group, Inc., Marietta, GA) is a dehydrated human umbilical cord allograft. It is proposed to be used as a protective barrier for wounds. AMNIOCORD is processed using PURION, a unique patented method for placental allografts that is in accordance with the American Association of Tissue Banks (AATB) standards (MIMEDX Group, 2026). There is insufficient evidence in the published peer-reviewed literature supporting the safety and effectiveness of AMNIOCORD.

AmnioCore™
AmnioCore (Stability Biologics®, Nashville, TN; also distributed by Innovasis® Inc., Salt Lake City, UT), is a dual layer amniotic tissue allograft available in multiple formats. The allograft is a non-viable cellular amniotic membrane, particulate or fluid that contains multiple extracellular matrix proteins, growth factors, cytokines and other specialty proteins present in amniotic tissue. AmnioCore is intended for homologous use in the treatment of acute and chronic wounds to reduce scar tissue formation, modulate inflammation, provide a barrier and enhance healing. The Innovasis AmnioCore Product Line is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps). Innovasis, Inc. is registered with the FDA for tissue storage and distribution. Stability Biologic is registered with the FDA for tissue processing and is accredited by the American Association of Tissue Banks (AATB). AmnioCore membrane is supplied in multiple sizes. AmnioCore particulate volume sizes include: 20 mg, 40 mg, 100 mg, 160 mg. AmnioCore Flow is available in 0.50 ml, 1.0 ml, 2.0 ml, and 4.0 ml (Stability Biologics, 2025; Centers for Medicare & Medicaid Services (CMS), 2020). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of AmnioCore products for any indication.

Amniocyte™ Flowable Matrix
Amniocyte Amniotic Fluid Allograft Suspension (Stemcellife Corporation, Newport Beach, CA) is an injectable amniotic fluid matrix intended to supplement or replace damaged or inadequate connective tissue. Amniocyte is processed from donated human tissue from full term, c-section deliveries in accordance with the FDA and the American Association of Tissue Banks (AATB) standards and is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/ P) under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. The fluid is proposed to have similar characteristics as the synovial fluid present in the joints and processed to preserve the cytokines, growth factors and proteins in amniotic fluid for homologous use. Proposed

treatment indications include: large joints (knee, hip, shoulder & ankle), chronic partial rotator cuff tears, persistent partial tendon tears (tennis elbow), plantar fasciitis/bone spurs, quadriceps and patellar tendon tears, muscular tears, meniscus tears, cartilage tears, intervertebral disc and spinal facet joints, and radicular and sacroiliac nerves. There is insufficient evidence in the published peer-reviewed literature to support the effectiveness of Amniocyte products.

AmnioEffect™
AmnioEffect™ (MiMedx, Marietta, GA) is a lyophilized human placental-based allograft membrane that includes amnion, intermediate layer, and chorion. It is proposed to provide a semi-permeable protective barrier that supports the healing cascade and protects the wound bed to aid in the development of granulation tissue (MiMedx, 2026). The product is classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of AmnioEffect for any indication.

AmnioExCel®/AmnioExcel Plus/BioDExCel
AmnioExCel or BioDExCel™ (Integra LifeSciences, Princeton, NJ) is a non-crosslinked, dehydrated, human amniotic extracellular matrix that acts as a scaffold for cellular attachment. AmnioExCel and AmnioExcel Plus are FDA-registered devices regulated as a human tissue products. Proposed applications include: wound covering for acute and chronic wounds including diabetic ulcers, venous and arteria ulcers, pressure ulcers, traumatic injuries, burns, surgical wounds), ridge augmentation, soft tissue repair, periodontal defects, boney defects and sinus coverage. AmnioExcel and AmnioExcel Plus are available in multiple sizes (Integra, 2026). There is insufficient data in the published clinical trials to support the safety and efficacy of AmnioExCel or AmnioExcel Plus.

Snyder et al. (2016) conducted a multicenter, randomized controlled trial to evaluate the safety and efficacy of AmnioExcel plus standard of care (SOC) (DAMA+SOC) (n=15) vs SOC alone (n=14). Patient characteristics included: type 1 or type 2 diabetics; with one or more Wagner grade 1 or superficial 2 foot ulcer, measuring between 1–25 cm^2 in area, presenting for more than one month with no signs of infection/osteomyelitis; ABI > 0.7; HbA1c < 12%; and serum creatinine < 3.0 mg/dL. The primary outcome measure was the proportion of subjects who achieved complete wound closure prior to or on week six after initiation of treatment. Following a two-week screening period, subjects received treatment for six weeks or until complete reepithelialization without drainage or need for dressings (complete wound closure) occurred. SOC included debridement of necrotic/nonviable tissue and hemostasis, moist wound dressings, offloading where appropriate, infection surveillance, and weekly dressing changes, inspection, and debridement, and in the study group application of DAMA. A nonadhesive dressing and compression bandage were also applied. DAMA application was determined by the investigator based on ulcer appearance and clinical judgment. The study group received a mean 4.3 ± 1.7 pieces of DAMA applied weekly. A total of 33% of DAMA+SOC subjects achieved complete wound closer at or before week six compared to 0% of SOC subjects (p=0.017). DAMA patients achieved significantly faster wound closure compared to SOC alone (p<0.0001). There was no significant difference in adverse events (infection, bleeding, osteomyelitis). The authors noted that although the study suggested that DAMA is safe and effective in the treatment of DFUs, additional research is needed. Limitations include: subjects lost to follow-up (n=4 in each group); small patient population and short-term follow-up.

AmnioFix® Amniotic Membrane
AmnioFix (MiMedx Group, Kennesaw, GA) is an amniotic membrane extracellular collagen allograft comprised of an epithelial layer and two fibrous connective tissue layers with growth factors. It is available in sheet, fenestrated, and wrap configurations in a variety of sizes. The products are

proposed to provide a protective barrier to wounds and the wrap is proposed for nerve and tendon protection to enhance healing. The product is classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271). AmnioFix injectable which is a powder form is proposed for the treatment of tendon and soft tissue injuries, patellar tendon inflammation, tendonitis, tendinosis, plantar fasciitis, tennis elbow, ulcer perimarginal and intramarginal adjuctive use, bursitis, neuritis and capsulitis. There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of Amniofix products.

Cazzell et al. (2018) conducted a multicenter, randomized controlled trial (n=145) to investigate the safety and effectiveness of a micronized dehydrated human amnion/chorion membrane (dHACM) injection (Amniofix) for the treatment of plantar fasciitis (PF). Inclusion criteria were: age 21 to < 80 years; confirmed diagnosis of PF for 1–18 months; VAS pain sale of ≥ 45 at time of randomization; and had undergone conservative treatment for ≥ 30 days (rest, ice, compression, and elevation [RICE]; stretching exercises; nonsteroidal anti-inflammatory drugs [NSAIDs] and/or orthotics). Patients were excluded if they had trauma or previous surgery to the affected area; bilateral PF; prior use of lower limb injection therapy; diabetes and multiple other comorbidities and contraindications. Patients were randomized to receive one injection of Amniofix (n=73) or sodium chloride placebo (n=72). The primary outcome was the mean change in the visual analog scale (VAS) score between baseline and three months post-injection. Secondary outcome was mean change in Foot Function Index–Revised (FFI-R) score between baseline and three months follow-up. Overall, at the 3-month follow-up, 60 subjects in the treatment group compared to 34 control subjects reported at least a 50% reduction in VAS scores from baseline. VAS scores in the treatment group were 76% lower compared with a 45% reduction in mean VAS scores for controls ($p<0.0001$). Compared to baseline the FFI-R scores for treatment subjects showed a significant mean reduction ($p=0.0004$) of 60% compared to a 40% reduction in the control group at the 3-month follow-up. Control group subjects reported a reduction in pain and improved function over time. No serious adverse events were related to the study. Two cases of post-injection pain at the injection site and one case of post-injection itching were considered normal events. Limitations of the study include the small patient population and short-term follow-up. It is unknown if additional injections would be effective for persistent symptoms. Three Amniofix and two control subjects did not complete the three month follow-up and the last observation data was carried forward to the three-month analysis.

Zelen et al. (2013) conducted a feasibility single-center randomized controlled trial to examine the effectiveness of AmnioFix injectable amniotic membrane for the treatment of refractory plantar fasciitis (n=45). Recruited patients were 18 years or older and were recalcitrant to three of the following treatments: rest, ice, compression, and elevation (RICE); corticosteroid injection; stretching exercises; nonsteroidal oral anti-inflammatory agents; and orthotics. Patients were randomized to standard care, 2 cc injection of 0.5% Marcaine plain, then 1.25 cc saline (controls) or 0.5 cc AmnioFix, or 1.25 cc AmnioFix (n=15 per group). Follow-ups occurred for eight weeks. At one week significant improvement in plantar fasciitis symptoms was observed in patients receiving Amniofix injection compared to those receiving saline injections. There was a significant improvement in the American Orthopedic Foot and Ankle Society (AOFAS) Hindfoot scores at one week and at eight weeks follow-up in each group ($p<0.01$, each). The significant difference was greater in the AmnioFix groups vs. control ($p<0.001$). No significant differences in outcomes were noted in those who received 0.5 cc Amniofix vs. 1.25 cc. Overall, at weeks 1–8, AmnioFix subjects demonstrated statistically significantly lower median Wong–Baker FACES pain scores scores compared to the control group ($p<0.001$). No adverse events related to AmnioFix were reported. Limitations of the study include the short-term follow-up and small patient population.

AmnioHeal® Plus

AmnioHeal® Plus (Tides Medical, Lafayette, LA) is a dehydrated amniotic membrane graft proposed to stimulate wound healing and to reduce inflammation and the formation of scar tissue. It is proposed as a covering for chronic wounds (e.g., diabetic, pressure and venous status ulcers; burns) and numerous surgical applications (e.g., podiatric, urological, spinal, plastic/reconstructive, vascular, orthopedic, ophthalmic). AmnioHeal Plus is regulated under the FDA 21 CFR Part 1271, section 361 as HCT/Ps (Human Cells, Tissues, and Cellular or Tissue-Based Products). It is available in eight sizes (Tides Medical, 2025). There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of AmnioHeal Plus.

Amnio-Maxx™
Amnio-Maxx™ (Royal Biologics, Hackensack, NJ) is a family of amnion products proposed for numerous indications. Amnio-Maxx is a dual layered, dehydrated, amniotic tissue membrane graft. The allograft is proposed for used as a chronic wound covering or an anatomical (soft tissue) barrier and used for chronic non-healing wounds (e.g., diabetic foot ulcers and venous leg ulcers) (CMS, 2020). The Amnio-Maxx Lite is a single layer version. Amnio-Maxx DL is a dual layer amnion allograft derived from the amnion layer of the placental membrane. Amnio-Maxx UC is a maximum natural thickness allograft derived from the umbilical cord and has the ability to be sutured. Amnio-Maxx is processed in accordance with FDA regulations and AATB standards. Amnio-Maxx DL sizes include: 2x3 cm, 4x4 cm, 4x6 cm, 4x8 cm. Amnio-Maxx UC sizes are 3x6 cm and 3x8 cm (Royal Biologics, 2025). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Amnio-Maxx for all indications.

AmnioMatrixF4X
AmnioMatrixF4X (Cellution Biologics Inc., Roswell, GA) is a minimally manipulated, dehydrated, four-layer amnion membrane allograft that is intended for homologous use by acting as a barrier and providing protective coverage from the surrounding environment for acute and chronic wounds such as partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. AmnioMatrixF4X is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a covering or barrier for acute and chronic wounds (CMS, 2025). It is applied per square centimeter based on wound size. There is insufficient evidence to support the safety and effectiveness of AmnioMatrixF4X for any indication.

AmnioPro Membrane
AmnioPro Membrane (Human Regenerative Technologies [HRT®], LLC, El Segundo, CA) is a human amniotic tissue allograft, consisting of dehydrated and decellularized human amniotic membrane. The Membrane is processed with HRT's proprietary HydraTek® technology. AmnioPro thin membrane is designed as a single layer wound covering for common wounds and AmnioPro thick membrane is designed as a thicker single layer wound covering for deeper wounds where tissue bulk is required. It is intended to be used as a wound covering and is surgically applied to the skin in the treatment of chronic acute and surgical wounds. HRT® is accredited by the American Association of Tissue Banks® (AATB). Both products are available in the following sizes: 10mm, 12mm, 15mm, 1x1cm, 1.5x2cm, 2x2cm, 2x4cm, 4x4cm, 4x6cm, and 4x8cm. Amniopro flow is the fluid form of the placental matrix (CMS, 2015). Product information on Bioskin, Bioskin Flow, Biorenew, Biorenew Flow, Amniogen-45, Amniogen-200, Amniogen-A and Amniogen-C was not available at the time of the update of this policy. Per CMS (2017) the following products have been discontinued AmnioGen-A, Amnio Gen-C, BioRenew Flow, and AmnioPro Flow.

Amniorepair and AltiPly®
Amniorepair and AltiPly® (Zimmer BioMet Warsaw, IN) are lyophilized placental membrane allografts proposed for use as a biological barrier or wound cover proposed to form a protective cover for acute and chronic wounds. Amniorepair and AltiPly are human cellular and tissue based

products per 21 CFR Part 1271 (CMS, 2020). They are supplied in sizes ranging from 2x2 cm to 4x6 cm (Zimmer BioMet, 2026). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Amniorepair or AltiPly for all indications.

Amnios®/Amnios® RT
Amnios® and Amnios® RT (Sapient Medical, Lewisville, TX) are liquid tissue allografts derived from human amniotic fluid proposed for topical application as a wound covering. These products are processed and prepared by Texas Human Biologics in accordance with FDA requirements for Human Cellular and Tissuebased Products (HCT/P) (21 CFR Part 1271), State regulations, and the Standards of the American Association of Tissue Banks (AATB). The allografts are proposed for use for different types of surgical procedures, independently or in combination with autologous tissue or other forms of allograft tissue. Amnios is a cryopreserved liquid and Amnios RT is an acellular ambient temperature liquid amnion (Sapient Medical, 2022). Evidence supporting the safety and clinical effectiveness of Amnios is lacking.

Amniovo™
Amniovo (Reign Medical Irvine, CA) is a composite amniotic tissue membrane processed through the proprietary Purion® Process. It is proposed for use in surgical, soft tissue, tendon, and nerve applications to reduce scar tissue formation, reduce inflammation in the surgical site, enhance healing, and act as a barrier. Amniovo is available in sheet/membrane, particulate, and wrap configurations and in in four different thicknesses: Amniovo Solo, Amniovo Dual, Amniovo Matrix, and Amniovo Max. The sheet/membrane sizes are 2x2 cm, 2x4 cm, 4x4 cm, and 4x6 cm. The particulate is available in 20 mg, 40 mg, 100 mg, and 160 mg preparations (Reign Medical, 2023). There is insufficient evidence in the published peer-review literature to support the safety and clinical effectiveness of Amniovo.

Anu RHEO™
Anu RHEO (Anu Life Sciences, Sunrise, FL), previously Regen Anu Rheo, is an amniotic fluid matrix proposed to supplement or replace damaged or inadequate connective tissue such as synovial fluid in joints and to prevent scarring, adhesion and inflammation The Anu RHEO+ preparation contains Wharton's jelly. Wharton's jelly is a mucous tissue within the umbilical cord that protects and insulates blood cells made from mucopolysaccharides such as hyaluronic acid and chondroitin sulfate. Anu Rhea is minimally manipulated and falls under the FDA 361 status. Rheo Plus™ comes in 1 cc and 2cc vials (HNM Medical, 2017). There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of Anu Rheo.

Apollo FT
Apollo FT (Dynamic Medical Services LLC dba Acesso Biologics) is a full-thickness amnion/chorion membrane. It is designed for single use as a sterile, dehydrated, resorbable allograft derived from donated human placental birth tissue (CMS, 2025). Apollo FT is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier." There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Apollo FT.

Artacent™ AC Powder
Artacent AC powder is a dehydrated, micronized particulate processed from human chorioamniotic membrane, submucosa of human placenta. The product contains growth factors proposed to promote wound healing. Once applied, the particulate integrates with the surrounding native tissues with the purpose of stimulating wound healing. The powder is applied directly onto the wound bed and is supplied in 20 mg, 25 mg, 40 mg, 50 mg, 100 mg, 125 mg, 140 mg and 200 mg vials. Evidence supporting the safety and efficacy Artacent AC powder is lacking.

Arthrex Amnion™ Matrix and Viscous

Arthrex Amnion Matrix and Viscous (Arthrex, Inc., Naples, FL) are amnion matrices proposed to be rich in growth factors and contain regenerative properties that maintain natural healing properties of amnion. The products are proposed as an anatomical barrier or wrap in the treatment of orthopedic conditions to strengthen repair of the wound and prevent adhesions. The Matrix is available as Amnion Thin in eight sizes (2x2 cm, 2x3 cm, 3x3 cm, 4x4 cm, 4x6 cm, 4x8 cm, 7x7 cm, 2x12 cm) and Amnion Matrix Cord in sizes 2x2cm, 2x3 cm, 3x3 cm, 3x4 cm, 3x6 cm, and 3x8 cm (Arthrex Inc., 2026). The Arthrex Amnion Matrix Flowable in available in 0.5 cc, 1.0 cc, and 2.0 cc vials. Data supporting the safety and efficacy of these products is lacking.

ArthroFlex™ Acellular Bio-Implant for Soft Tissue Repair
ArthroFlex or FlexGraft® (Arthrex, Inc., Naples, FL) is a decellularized human allograft dermis implant proposed for soft tissue repair including shoulder reconstruction, fat pad repair of the foot and Achilles tendon repair. The allograft is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. Based on the size and thickness the product may be referred to as Aflex100, Aflex101, Aflex103, Aflex 150, or Aflex200, Aflex201, Aflex301, Aflex400, Aflex 401, Aflex500 (Arthrex, Inc, 2026).

Data in the published peer-reviewed scientific literature supporting the safety and effectiveness of Arthroflex are lacking. Studies are primarily in the form of retrospective reviews, case reports and case series with small patient populations (n=9–30) and one to two years follow-up (Denard, et al., 2018; Pennington, et al., 2018; Hirahara, et al., 2017).

ARTIA™ Reconstructive Tissue Matrix: ARTIA Reconstructive Tissue Matrix, also called ARTIA Tissue Matrix, and ARTIA Tissue Matrix-Perforated (Allergan Aesthetics, an AbbVie company, North Chicago, IL) is a surgical mesh derived from porcine skin that is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers (Allergan Aesthetics, 2025). The Matrix is FDA 510(k) approved "for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement in plastic and reconstructive surgery" (FDA, 2017). ARTIA was originally developed by LifeCell Corporation and is currently distributed by Allergan Aesthetics. There is insufficient evidence to support the safety and efficacy of ARTIA Reconstructive Tissue Matrix for any indication.

Avive+ Soft Tissue Matrix
Avive+ Soft Tissue Matrix (Axogen, Alachua, FL) is a minimally processed human umbilical cord membrane proposed for use as a homologous, resorbable soft tissue covering to separate tissue layers. It is intended for use during nerve surgeries to separate certain tissues for the purpose of reducing inflammation and scar formation. The membrane is thicker than placental amnionic products due to the thickness of the umbilical cord. It may be sutured or secured or laid across the tissue. Avive Soft Tissue Membrane had been reported to be processed and distributed in accordance with US FDA requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, US State regulations and the guidelines of the American Association of Tissue Banks (AATB) (Axogen, 2026). There is insufficient evidence to support the effectiveness of Avive. Studies have primarily been in the form of case reports.

AxoGuard® Nerve Connector
AxoGuard Nerve Connector is a surgically implanted porcine submucosa extracellular matrix (ECM) proposed for the protection and isolation of injured nerves to prevent soft tissue attachment. It is proposed for reinforcement during nerve reconstruction and as a wrap for a partially severed or compressed nerve. The product is manufactured at Cook Biotech (West Lafayette, IN) and sold by Axogen Inc. (Alachua, FL). AxoGuard is FDA 510(k) approved as Surgisis® Nerve Cuff produced by Cook Biotech, Inc. The FDA intended use is "for the repair of peripheral nerve discontinuities

where gap closure can be achieved by flexion of the extremity". The Nerve Connector is proposed as an alternate to suturing and the Nerve Protector is proposed for wrapping and protecting injured peripheral nerves. Both products come in numerous sizes (Axogen Inc., 2026; Cook Biotech, 2025; FDA, 2003). There is insufficient evidence to support the safety and efficacy of AxoGuard. Studies are primarily in the form of case reports and retrospective reviews with small patient populations (Salomon, et al., 2016; Papatheodorou, et al., 2015).

AxoGuard® Nerve Protector
AxoGuard Nerve Protector (AxoGen, Inc., Alachua, FL) is a porcine submucosa extracellular (ECM) matrix which is surgically implanted to protect injured nerves and to reinforce the nerve reconstruction while preventing soft tissue attachments. Per the manufacturer, the nerve protector separates and protects the nerve from surrounding tissue during the healing process. The patient's cells incorporate into the matrix to remodel and form new tissue. It is proposed for injured nerves up to 40 mm. AxoGuard Nerve Protector was FDA 510(k) approved as a nerve cuff (Cook Biotech, Inc. West Lafayette, IN) "indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity (Axogen, 2026; FDA, 2014). There is insufficient evidence to support the safety and effectiveness of AxoGuard Nerve Protector. Studies are primarily in the form of retrospective reviews, case reports and case series with small patient populations (n=12) investigating the use of Axoguard in lingual nerve surgery and cubital tunnel syndrome (Wilson, et al., 2017; Theberge and Ziccardi, 2016; Papatheodorou, et al., 2015).

Axolotl Products
Axolotl Ambient™ (Axolotl Biologics, Inc., Phoenix, AZ) is a liquid allograft derived from the amniotic components of the placenta. The product is proposed for soft tissue repair and reconstruction. It contains growth factors and cytokines such as epidermal growth factor (EGF), vascular endothelial growth factor (VEGF), transforming growth factor – beta (TGF-ß), and Interleukin-10 (IL-10). Axolotl Ambient is currently being investigated as an Investigational New Drug product by the FDA (Axolotl Biologics, 2024). Proposed indications by the manufacturer include the treatment of tendinitis, bursitis, plantar fasciitis, ruptured achilles tendon, osteo-chondral defects, labral tears of the shoulder and hip, flexor tendon repair, and osteoarthritis, Axolotl Ambient is also proposed for pain management associated with hip abductor/adductor tears, knee injections, rotator cuff lesions, epicondylitis (tennis elbow), hamstring strains/tears, chronic non-healing wounds, and ankle sprain (CMS, May 2019).

Axolotl Graft™ is a dehydrated human amnion membrane allograft (dhAM) also derived from the amniotic components of the placenta and proposed for soft tissue repair and reconstruction. It is classified as minimally manipulated under FDA regulation 21 CFR Part 1271 and section 361 of the PHS. The Biologix proprietary BioSym™ process is used to manufacture the graft. The product is proposed to create a natural 3-D extracellular matrix scaffold for cellular attachment to promote cell migration and proliferation. Axolotl Graft is available in a 4x4 cm size. The Axolotl DualGraft is a bi-layered form of the product and is available in 1x2 cm, 2x2 cm, 2x4 cm, 4x4 cm, 4x6 cm, and 4x8 cm sizes (Axoloti Biologics, 2024).

Axolotl Graft™ Ultra is a resorbable, chorion-free, single-layer, cross-linked human amnion allograft. It is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "wound covering" and to act as a "barrier" (CMS, 2025).

There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of the Axolotl products.

BellaDerm® Acellular Hydrated Dermis

BellaDerm Acellular Hydrated Dermis (Musculoskeletal Transplant Foundation [MTF Biologics], Edison, NJ) is a human allograft minimally processed to remove epidermal and dermal cells. The process used to prepare the dermis is intended to preserve the extracellular matrix resulting in an allograft that serves as a framework to support cellular repopulation and vascularization at the surgical site. The production of the Dermis is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. BellaDerm is proposed for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects. Per the manufacturer, BellaDerm is specifically for cosmetic use. BellaDerm is available in various sizes (MTF Biologics, 2025).

There is insufficient evidence to support the safety and efficacy of BellaDerm Acellular Hydrated Dermis. Studies have primarily been in the form of animal studies, retrospective reviews, and case series with small patient populations and short-term follow-ups for lower eyelid retraction (Scruggs, et al., 2015) and phalloplasty for penis girth augmentation (Solomon, et al., 2013).

BioDfence™/BioDfence™ DryFlex
Integra LifeSciences (Princeton, NJ) provides products that are proposed for use as physical barriers between the dura and soft tissue of the paraspinal muscles to reduce fibroblast infiltration into the epidural space and postoperative scarring. The products are human amniotic tissue allografts that are resorbed into the body during healing. They are regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. BioDfactor is a cryopreserved liquid form of the allograft extracellular matrix and comes in 0.25 ml, 0.5 ml and 1.25 ml. BioDfence Resorbable Adhesion Barrier comes in sheets 1x2 cm, 2x2cm, 2x6 cm and 4x4 cm. BioDfence DryFlex comes in sheets 2x3 cm, 2x6 cm, 4x4 cm and 4x8 cm. BioDRestore Elemental Tissue Matrix is an amniotic flowable tissue allograft proposed for soft tissue repair to reduce pain and inflammation. It is proposed for use with soft tissue injuries, tendonitis, plantar fasciitis, inflamed nerves, muscle tears and repetitive motion injuries. This product is offered 0.5 cc, 1.0 cc and 2.0 cc sizes. BioDFence G3 is a multilayer amnion and chorion allograft that is available in multiple sizes (Integra LifeSciences, 2026).

There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of these products.

Biodesign® Anal Fistula Plug (AFP™)
The Biodesign Anal Fistula Plug AFP (Cook Medical Bloomington, IN) is a porcine-based acellular matrix and is contraindicated in patients who are sensitive to porcine materials (Cook Medical, 2026). The Surgisis AFP (i.e., SIS Fistula Plug) received 510(k) approval (K050337) from the FDA in March 2005 for "implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal, and enterocutaneous fistulas."

Evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of the Surgisis AFP. Studies have primarily been in the form of case series and retrospective reviews with small, heterogeneous patient populations, and short-term follow-ups (Schwandner, et al. 2009; Zubaidi and Al-Obeed, 2009; Garg, 2008; Ky, et al., 2008; Schwandner, et al., 2008; Thekkinkattil, et al., 2008). Randomized controlled trials have reported no significant difference with the use of Surgisis AFP or worse outcomes. Appropriate candidates for AFP have not been established. Outcomes varied based on the type of fistula, the presence of single vs. multi-track fistula, and whether or not the patient had undergone previous fistula surgical procedures. Poorer results were reported in patients who were smokers, diagnosed with diabetes, and/or had Crohn's disease. Failure rates were reported as high as 59% and recurrence rates as high as 75%. Some studies reported a decline in the success rate over time. One of the most common reasons for failure was due to plug expulsion. Studies also reported the occurrence of postoperative sepsis as high as 89%.

Jayne et al. (2021) conducted a multicenter randomized controlled trial comparing safety, efficacy, and cost-effectiveness of the Surgisis anal fistula plug with other surgical treatments (surgeon's preference) for the treatment of transsphincteric anal fistula. Participants (n=304) were randomized to either the fistula plug (n=152) or surgeon's preference (n=152) (advancement flap, cutting seton, fistulotomy, Ligation of the Intersphincteric Fistula Tract procedure). Participant median age was 45.1 years with 55% being males. No difference in co-morbidity between the groups. At the 12 month follow up, there were no significant differences in faecal incontinence quality of life (FIQoL) scores between the two groups and clinical fistula healing was similar between the two groups: 54% fistula plug and 55% surgeon's preference. No significant difference in fecal incontinence rates (p=0.48). Infective complication rate was 50% in fistula plug group versus 38% in the surgeon's preference group at 12 months. Author noted study limitations include the small patient population and short-term follow-up.

van Koperen et al. (2011) conducted a double-blinded, multicenter, randomized controlled trial to compare Surgisis Anal Fistula Plug (n=31) to a mucosal advancement flap (n=29) for the treatment of cryptoglandular high transsphincteric perianal fistulas. At the 11-month median follow-up, the recurrence rate was not significantly different (p=0.126) between the two groups with fistula plug patients and 15 mucosal advancement flap patients experiencing recurrence. There were also no significant differences in postoperative pain, pre- and postoperative incontinence scores, soiling and quality of life. There were no intraoperative complications and one postoperative complication in a fistula plug patient and two complications in advancement flap patients. Limitations of the study include the small patient population and short-term follow-up.

In a randomized controlled trial, Ortiz et al. (2009) compared the outcomes of Surgisis AFP (n=16) to endorectal advancement flap (ERAF) (n=16) for the treatment of patients with high fistula in ano of cryptoglandular etiology. Sixteen patients had previously undergone ERAF. Recruitment was stopped because of the high recurrence rate following AFP. Follow-up evaluations were performed by an independent observer for up to one year postoperatively. Within the first postoperative year, a statistically significant difference was seen in 12 AFP patients who had fistula recurrence compared to two ERAF patients (p<0.001). Nine of 16 patients who had undergone previous surgery, experienced fistula recurrence, and eight of the nine were in the AFP group. Postoperatively, one AFP patient experienced recurrence with abscess, three had plug dislodgement, and eight had persistent leakage around the plug. Two ERAF patients experienced recurrences. In this study, AFP was associated with a low rate of healing especially in patients with previous fistula surgery.

Biodesign® Fistula Plug Set

Biodesign Fistula Plug Set, previously Biodesign (Surgisis) RVP Recto-Vaginal Fistula Plug (Cook® Medical, Bloomington, IN) is a surgical mesh skin substitute manufactured from porcine small intestinal submucosa (Cook Medical, 2026). It is supplied in a tapered configuration with a button to allow increased retention. The button eventually falls off leaving the plug to seal the opening between the rectum and the vagina. The Plug is FDA-510(k) approved for "implantation to reinforce soft tissue for repair of recto-vaginal fistulas or anorectal fistulas." (FDA, 2006). The predicate device is the original SIS Fistula Plug 510(k) (K050337), cleared for marketing by the Food and Drug Administration on March 9, 2005. There is insufficient evidence in the published peer-reviewed scientific literature to establish the safety and efficacy of Surgisis RVP. Studies are primarily in the form of case series with small patient populations and short-term follow-ups (1–21 weeks). Failure rates were as high as 65% due to dislodgement of the plug (Gonsalves, et al., 2009).

Biodesign® Hiatal Hernia Graft

Biodesign Hiatal Hernia Graft is derived from a porcine source and proposed for implantation to reinforce soft tissue where weakness exists including paraesophageal/hiatal hernias (Cook Medical, 2026). Per the FDA 510(k) (2006) approval for SIS Hernia Repair Device and Surgisis Gold Hernia Repair Graft, the devices are "intended to be implanted to reinforce soft tissue where weakness exists. Indications for use include the repair of a hernia and body wall defect." There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of Surgisis Hiatal Hernia Graft. Studies are primarily in the form of case reports, retrospective reviews and case series with small patient populations (n=5-6) and short-term follow-ups, reporting a high hernia recurrence rate.

Oelschlager et al. (2006) conducted a randomized controlled trial to compare the outcomes of paraesophageal hernia repair with primary repair (n=57) to primary repair with Surgisis (n=51). At the six-month follow-up, four SIS patients and 12 primary repair patients developed a recurrent, >2-centimeter hernia (p=0.04). There were no significant differences in operative times and perioperative complications. Both groups experienced significant improvement in heartburn, regurgitation, dysphagia, chest pain, early satiety, postprandial pain and improved quality of life symptoms following surgery with no significant differences between the groups. Limitations of the study include the small patient population, short-term follow-up and the lack of follow-up data on 18 patients (i.e., seven incomplete questionnaire data and eleven did not have an x-ray).

Biodesign® Inguinal Hernia Graft
The Biodesign Inguinal Hernia Graft (SIS Hernia Repair Device, Surgisis Gold Hernia Repair Graft) (Cook® Medical, Bloomington, IN) is a porcine derived device (Cook Biotech, 2026). Per the FDA 510(k) (2006) approval for SIS Hernia Repair Device and Surgisis Gold Hernia Repair Graft, the device is "intended to be implanted to reinforce soft tissue where weakness exists. Indications for use include the repair of a hernia and body wall defect." There is insufficient data from clinical trials to support the efficacy of this matrix. Studies are primarily in the form of case reports and case series with small patient populations (n=5-67) and short-term follow-ups.

Ansaloni et al. (2009) conducted a blinded, randomized controlled trial to compare the safety and efficacy of the use of Inguinal Hernia Matrix (SIHM) (n=35) to polypropylene mesh (n=35) in Lichtenstein's repair of noncomplicated, primary inquinal hernias in men. The primary endpoint was the degree of postoperative pain using a visual analogue scale or a simple verbal scale. The investigators were unaware of the mesh used. The first 24 postoperative hours a significant number of patients in the SIHM group developed self-subsiding hyperpyrexia (temperature > 38) compared to the polypropylene group ($p<0.05$). During the three year follow-up period, a significant decrease in the incidence of postsurgical pain was not seen in the SIHM group, but a significantly lower degree of pain was detected at rest and on coughing at 1, 3, and 6 months, on movement at 1, 3, and 6 months and 1, 2, and 3 years, and use of pain medication at 1, 3, and 6 months ($p<0.05$, each). No significant differences were noted in pain localization and irradiation. One recurrence was noted in the polypropylene group. Both groups experienced hematomas and seromas that resolved without treatment within the first three postoperative months. The SIHM group had a trend in higher incidence of complications (especially seromas) but compared to the polypropylene group the difference wasn't significant. The authors noted that their sample size was "too small to prove absolute efficacy in terms of low recurrence rate". Additional prospective studies are needed to establish the safety and efficacy of Inguinal Hernia Matrix.

Biodesign® Otologic Repair Graft
Biodesign® Otologic Repair Graft (Cook® Medical, Bloomington, IN) is a porous biomaterial composed of laminated extracellular collagen matrix derived from porcine small intestinal submucosa (SIS) (Cook Medical, 2026). It is FDA 510(k) approved "for use as an implant material to aid in surgical repairs and as an adjunct to aid in the natural healing process in various otologic procedures, including but not limited to myringoplasty and tympanoplasty." Biodesign is available

in various sizes (Cook Medical, 2026; FDA 2015). Data supporting the safety and effectiveness of the Biodesign Otologic Repair Graft is lacking. A single retrospective review was identified with a small patient population (n=55) and short-term follow-up (four weeks) (Wang and Isaacson, 2020).

Biodesign® Peyronie's Repair Graft
Biodesign Peyronie's Repair Graft (Cook® Biotech, Inc., West Lafayette, IN) is FDA 510(k) approved for implantation to reinforce soft tissue. Per the manufacturer the Graft is intended for use in urological anatomy including repair of tunica albuginea defects and Peyronie's disease. The Graft is proposed to provide strength and flexibility for reinforcement and correction of penile curvature and once sutured in place the body completely remodels Biodesign into vascularized tissue. Biodesign is derived from a porcine source and is available in 4x10 cm and 7x10 cm sizes (FDA, 2016). Data supporting the safety and effectiveness of the Biodesign Peyronie's Repair Graft is lacking. Studies are primarily in the form of retrospective reviews and case series with small patient populations and short-term follow-ups. There are conflicting outcomes regarding the clinical effectiveness of these grafts in the treatment of Peyronie's disease and tunica albuginea defects (Cosentino, et al., 2016; Knoll, 2007; Santucci and Barber, 2005).

Biodesign® Rectopexy Graft
Biodesign Rectopexy Graft (Cook® Medical, Bloomington, IN) is a porcine derived, non-cross linked, dried multi-layered small intestinal submucosa (SIS) sheet. Biodesign Rectopexy Graft is proposed to reinforce soft tissue where weakness exists in the gastroenterological anatomy including transabdominal repair of colon and rectal prolapse (Cook Medical, 2026). The product received FDA 510(K) approval on May 6, 2016, as Biodesign Sling, Biodesign Plastic Surgery Matrix, Biodesign Anal Fistula Plug (K161221). The three devices were bundled under the same 510(k) submission because the devices share many of the same technological characteristics: composed of porcine small intestinal submucosa (SIS), packaged in a Tyvek/PE pouch, labeled with a shelf-life of 18 months, and sterilized using ethylene oxide. The only differences between the three devices are the indications (and associated labeling) and the dimensional specifications (specific to the indication and anatomic requirement for each device) (CMS, 2016). The Biodesign Sling FDA indication for use: for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy including but not limited to the following procedures: transvaginal repair of stress urinary incontinence, such as pubourethral support and bladder support, and transabdominal repair of apical vaginal prolapse, colon and rectal prolapse, and sacrocolposuspension. Per the manufacturer, the rectopexy graft and sling are the same product, just renamed. There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of Biodesign Rectopexy Graft. Studies have primarily been in the form of retrospective reviews (Brunner, et al., 2018; Albayati, et al., 2017; Evans, et al., 2015; Ogilvie, et al., 2014).

Biodesign® Sinonasal Repair Graft
Biodesign Sinonasal Repair Graft (Cook® Medical, Bloomington, Indiana) is a bioabsorbable, small intestinal submucosa (SIS), extracellular collagen membrane matrix derived from a porcine source (Cook Medical, 2026). The Graft is FDA 510(k) approved "to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use where an open wound dressing material is required in the nasal and/or sinus cavities following nasal and/or sinus surgery where separation of tissues or structures is desired". Biodesign Sinonasal Repair Graft is available in 1x2 cm, 2x3 cm, 4x7 cm and 7x10 cm sizes (Cook Medical, 2026). Data supporting the safety and efficacy of Biodesign Sinonasal Repair Graft are lacking. The clinical utility of this Graft has not been established. Studies are primarily in the form of retrospective reviews or small case series (n=10-11) (Membreno et al., 2021; Ambro et al., 2003).

BioFix® Amniotic Membrane Allograft
BioFix Amniotic Membrane Allograft (Integra LifeSciences, Princeton, NJ) represents a group of three products: BioFix, BioFix Plus and BioFix Flow. BioFix and BioFix Plus are derived from human placental tissue. The tissue is dehydrated and decellularized using a proprietary HydraTek® Technology. The products are proposed for the treatment of ulcers, burns, chronic wounds, dermal lesions, surgical wounds, voids and tissue defects. BioFix Flow is a placental tissue matrix allograft and is intended for use as a connective tissue matrix. There is insufficient evidence to support the effectiveness of the BioFix products. The BioFix Amniotic Membrane Allograft is not currently available as the product has been retired (WoundReference Inc, 2026).

CardioCel®
CardioCel (LeMaitre Vasular, Inc., Burlington, MA; developed by Admedus Innovative Health Solutions, Minneapolis, MN acquired by Anteris Technology, Eagan, MN) is an acellular, collagen cardiovascular patch prepared from glutaraldehyde-crosslinked bovine pericardium using a patented ADAPT® process. The rights to CardioCel were sold to Genpharm in 2019 while Anteris retained the propriety ADAPT technology. The product is FDA 510(k) approved for "use as a patch in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing" (LeMaitre Vascular, Inc., 2026). It is supplied in three sizes: 4x4 cm, *5*x8 cm and 14x7 cm (LeMaitre Vascular, Inc., 2026; FDA, 2014).

To date, studies are primarily in the form of animal studies, case series with small patient populations and retrospective reviews (van Beynum, et al., 2021; Bell, et al., 2019; Neethling, et al., 2013). One case series (n=30) (Neethling, et al., 2013) evaluated pediatric patients who underwent surgery utilizing CardioCel for a wide range of congenital heart deformities. Follow-ups were reported for 12 months with 19 patients followed for 36 months. At 36 months there was no evidence of device calcification, infection, thromboembolic events or device failure on echocardiographic data. According to the authors, it is evident from the literature that the ideal prosthetic material for congenital heart deformity repair has not been established. Additional studies with larger, heterogeneous patient populations and long-term follow-ups are needed to support the safety and efficacy of CardioCel.

CardioGRAFT-MC™ Decellularized Pulmonary Patch Graft (previously known as MatrACELL™ Decellularized CardioGRAFT)
The CardioGRAFT-MC™ Decellularized Pulmonary Patch Graft (LifeNet Health, Virginia Beach, VA) is composed of human, cryopreserved, decellularized, pulmonary artery tissue. It is FDA 510(k) approved for repair of the right ventricular outflow tract (FDA, 2008). The patch is available as a thin or thick graft, 2.5–5.0 cm in width and 3.0–8.0 cm in length, or as a hemi pulmonary artery in sizes that vary by donor (LifeNet Health, 2026). There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of the MatrACELL Patch. Studies are primarily in the form of retrospective reviews (Hopkins, et al., 2014; Lofland et al., 2012).

carePATCH
carePATCH (Tiger BioSciences, Conshohocken, PA) is a dehydrated amniotic membrane allograft proposed for the treatment of non-healing wounds and burn injuries. The dosage for carePATCH amniotic membrane allograft is per square centimeter and available in absorbable and non-absorbable suture material and/or tissue adhesives. The allograft is supplied in sizes varying from 2x2 cm to 4x8 cm (Tiger BioSciences, 2026; CMS, 2020). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of carePATCH for all indications.

Clarix® Surgical Matrix

Clarix Surgical Matrix (BioTissue, Inc., Miami, FL) is an amniotic membrane/umbilical cord product processed by Amniox's patented Cryotek™ Process that utilizes a deep-freezing technique (cryopreserved) to preserve the membrane. The membrane is proposed for surgical covering, wrap or barrier. Based on the size of the membrane, it comes in two different products. Clarix is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. There are two preparations of the matrix based on the thickness and size: Clarix 1K (five sizes) and Clarix 100 (three sizes) (BioTissue, Inc., 2026). An additional product is Clarix Cord RT (CMS, 2017). There is insufficient evidence in the published peer-reviewed literature to support the efficacy of Clarix. Studies are primarily in the form of case reports.

Clarix™ Flo
Clarix Flo (BioTissue, Inc., Miami, FL) is the particulate form of Clarix. It is also comprised of amniotic membrane and umbilical cord products. Clarix is proposed as a replacement or supplement for damaged or inadequate integumental tissue. The product comes in 25 mg, 50 mg and 100 mg sizes. The data supporting the clinical utility of Clarix Flo is lacking.

Cocoon Membrane
Cocoon Membrane (Pinnacle Transplant Technologies) is a human-derived amnion allograft that is a minimally manipulated placental membrane used as a wound covering and barrier. It is intended to serve as a covering and barrier for full and partial-thickness, chronic, and acute wounds. The product is classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Cocoon Membrane for all indications.

Coll-e-Derm
Coll-e-Derm (Parametrics Medical, Leander, TX) is a human-derived dermal allograft comprised of collagen, elastin and proteoglycans which are proposed to allow cellular regeneration upon implantation. The product is placed over a wound and may be sutured when necessary. Per CMS the use of Coll-e-Derm is restricted to the "replacement of damaged or inadequate homologous tissue" and the repair of soft tissue defects in those with "chronic, non-infected, full-or partial thickness diabetic or venous insufficiency ulcers". Use is also proposed for second or third degree burns. There are three patches: Coll-e-Derm patch, thin (0.05 – 1 mm thickness); Coll-e-Derm patch, medium (1-2 mm thickness); and Coll-e-Derm patch, thick (≥ 2 mm thickness). All are available in 5x4 cm, 7x5 cm, 10x5 cm, 16x8 cm and 20x8 cm sizes. The Coll-E-Derm patch, thick, SCR (2.75 – 3.25 mm thickness) comes in 5x4 cm and 7x5 cm. Parametrics is accredited by the American Association of Tissue Banks (AATB) and complies with the AATB Standards for Tissue Banking (Parametrics Medical, 2025; CMS, 2018). Data supporting the safety and effectiveness of Coll-e-Derm is lacking.

Cogenex
Cogenex amniotic membrane (Stimlabs LLC., Roswell, GA) is a minimally manipulated amniotic membrane allograft that offers protection from surrounding environment in reparative and reconstructive procedures. These procedures include but are not limited to chronic wound repair, urologic and gynecological surgeries, and burn wound reconstruction. The product is regulated under section 361 of the Public Health Service Act. Cogenex Amniotic Membrane is available wet or dry in various sizes (Stimlabs LLC, 2026; CMS, 2020). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Cogenex amniotic membrane for all indications.

Complete FT/ Complete SL
Complete™ SL (Advanced Solution, Carlisle, PA) is a single layer amnion derived allograft and Complete™ FT is a full thickness amnion-chorion derived allograft. Each product is intended to

serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. Complete™ SL and Complete™ FT are applied directly to the wound, adheres to the wound bed without fixation, is fully resorbable and does not have to be removed from the wound bed. The products are classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Complete SL and Complete FT for all indications.

Coretext™ and Protext™
Coretext™ and Protext™ (Regenative Labs, Gulf Breeze, FL) are both Wharton's jelly products or human umbilical cord product. The products are proposed to reduce scarring, fibrosis and adhesions in surgical and wound sites, specifically for muscle and cartilage tears and to aid in the repair of damaged tissue. The products are applied directly to the defect using a syringe. The cell sorter used in the preparation of Protext is 300 um mesh and 200 um for CoreText. CoreText and ProText are regulated by the FDA as a human tissue product subject to Section 361 of the Public Service Act and 21 CFR 1271 (Regenative Labs, 2026). Coretext is available as Coretext 1000 or Coretext 2000 (CMS, 2020). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Coretext or Protext for all indications.

CorMatrix®
CorMatrix ECM® products (CorMatrix, Inc. Roswell, Georgia) are porcine, small intestinal submucosa (SIS) extracellular matrix (ECM). There are three CorMatrix FDA approved products. The CorMatrix ECM® for Pericardial Closure is FDA 510(k) approved as a pericardial patch for the "reconstruction and repair of the pericardium" (FDA, 2005). The CorMatrix ECM Patch for Cardiac Tissue Repair is FDA 510(k) approved for "use as an intracardiac patch or pledget for tissue repair (i.e., atrial septal defect [ASD], ventricular septal defect [VSD], etc.) and suture-line buttressing (FDA, 2007). The CorMatrix ECM for Carotid Repair received FDA 510(k) approval in July of 2011. This patch is "intended for use as a patch material for vascular reconstruction and repair of the carotid artery, including patch closure following carotid endarterectomy and suture line buttressing and will be available to repair the carotid artery including patch closure following endarterectomy procedures" (FDA, 2011).

There is a paucity of evidence supporting the safety and effectiveness of the CorMatrix products. Published studies are primarily in the form of case reports, case series and retrospective reviews with small, heterogeneous patient populations and short-term follow-ups (Woo, et a., 2016). Outcomes have been conflicting regarding the clinical effectiveness and complications following implantation of Cormatrix.

Mosala et al. (2016) conducted a systematic review to evaluate CorMatrix for cardiovascular surgeries. A total of 47 articles were included. Twenty studies were animal studies. Two human studies investigated CorMatrix for pericardial reconstruction and vascular repair at different sites. Eleven studies used CorMatrix at intracardiac sites for various indications. Several case reports for various conditions were also included. CorMatrix has been used in congenital cardiac and vascular surgery, pericardial reconstruction, valve reconstruction in adults and children, endocarditis, acquired vascular defects at different sites and for repair of damaged myocardium after infarction. Overall, patient populations have been small (n=2–57) with short-term follow-ups. There are few reports of complications when used in the low-pressure conditions, usually extracardiac environment (i.e. veins). However, when used at higher pressure intracardiac sites such as the aortic valve or in semilunar valves, more complications have been reported. Data also suggested that CorMatrix may cause significant inflammatory reactions. Due to the heterogeneity of the studies, retrospective study designs and lack of a comparator the safety and effectiveness of CorMatrix has not been established.

Creos™ Xenoprotect
Creos Xenoprotect (Nobel Biocare®, Zurich, Switzerland) is a resorbable, non-chemically cross-linked porcine collagen. It is proposed for guided bone regeneration (GBR) and guided tissue regeneration (GTR) dental procedures. The membrane was FDA 510(k) approved in 2013 as Matricel Dental Barrier Membrane (Matricl GmbH, Germany) for "use during the process of guided bone regeneration and guided tissue regeneration" for multiple conditions. Creos is proposed to add stability and protection to grafted dental sites. Creos comes in three sizes: 5x20 mm, 25x30 mm and 30x40 mm (Nobel Biocare, 2026). There is insufficient evidence to support the safety and effectiveness of Creos. The limited number of studies have investigated Creo for immobilizing bone augmentation material during horizontal guided bone regeneration (GBR) procedures and guided bone regeneration at dehisced implant sites involving small patient populations and short-term follow-ups. Studies comparing collagen membrane to no membrane are lacking (Wessing, et al., 2017; Wessing, et al., 2016).

CryoMatrix®
CryoMatrix (Skye® Biologics, Inc., Redondo Beach, CA) is a cryopreserved, placental connective tissue matrix, proposed for surgical use to supplement or replace damaged or inadequate connective tissue. The tissues are collected, processed, stored and distributed in compliance with FDA regulations governing Human Cells, Tissues, and Cellular or Tissue-Based Products. The matrix is a flowable graft supplied in 0.5 cc, 1.0 cc, 1.5 cc and 2.0 cc vials. There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of CryoMatrix.

Cryoskin®
Cryoskin (Altrika Ltd, Sheffield, United Kingdom) is a frozen mono-layer sheet of undifferential allogenic keratinocysed attached to a silicone backing. The product includes growth factors and cytokines. It is proposed as a treatment option for burns and hard to heal wounds or as an adjunct to meshed grafting to enhance closure and reduce scarring. It has also been used as a covering for donor sites. Altrika is licensed by the UK Medicines and Healthcare Products Regulatory Agency (MHRA). Per the manufacturer Cryoskin is available as an unlicensed medicine under specific circumstances. It is also available in a spray form from Regenrys Ltd. (Sheffield, United Kingdom) who acquired Altrika. Data supporting the safety and efficacy of Cryoskin are lacking.

CTM Flow and CTM Thick
CTM Flow and CTM Thick (CTM Biomedical, LLC., Toronto, ON) are human placental allografts for surgical use. CTM Flow is a connective tissue implant and CTM Thick is an extracellular matrix implant. The products are proposed to cover or protect tissues intra-operatively and to augment or replace damaged or inadequate connective tissue. CTM Flow comes in various sizes from 1.0 cc to 10.0 cc and CTM Thick sizes range from 2 x2 cm to 4 x 7 cm. There is insufficient evidence in the published peer-reviewed literature supporting the safety and effectiveness of CTM Flow and CTM Thick.

CuraMatrix
CuraMatrix (Xtant Medical, Belgrade, MT) is a dehydrated, textured, single-layer amniotic membrane obtained from healthy deliveries following informed consent. It is intended to serve as a barrier and provide protective coverage from the surrounding environment when topically applied to chronic and acute wounds. CuraMatrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier" and "to provide protective coverage from the surrounding environment (CMS, 2025). CuraMatrix is available in a variety of sizes. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of CuraMatrix for any indication.

Cygnus®/CYGNUS Solo
Cygnus products (Vivex® Biologics, Miami, FL) are amniotic tissue matrixes obtained from umbilical cord and are proposed to support healing without adhesion or scar formation. The products are proposed for use as an adhesion barrier, wrap, patch, protection bandage, nerve wrap, and reconstruction patch for various applications (e.g. neurosurgery, burn care, urology, dermatology). Cygnus products include Cygnus Solo™, Cygnus Max™, and Cygnus Max XL. Cygnus Solo is a single layer amnion that is proposed for use as a soft tissue barrier and wound covering (CMS, 2025). Cygnus Max is the maximum thickness graft (eight times thicker than traditional amnion) with a high concentration of growth factors. The Max can be sutured. Cygnus Max XL is fenestrated. The products are processed in accordance with the FDA regulations for tissues and biologics and the American Association of Tissue Banks (AATB) standards and come in multiple sizes from 2x2 cm to 7x7 cm and three thicknesses (Vivex Biologics, 2026; CMS, 2023). Evidence in published peer-review literature supporting the safety and efficacy of Cygnus products is lacking.

Cytal®
Cytal Wound Matrix (Integra, Columbia, MD) is a porcine extracellular matrix (urinary bladder matrix) proposed for wound care. The Matrix is FDA 510(k) approved "for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds". Cytal is available as 1-layer, 2-layer (meshed), 3-layer and 6-layer sheets in a 10x15 cm size. Cytal Wound Matrix 1-Layer and 2-Layer are also marketed as MatriStem® Wound Matrix and Multilayer Wound Matrix. There is also a product labeled Cytal Burn Matrix available in 5x5 cm, 7x10 cm, and 10x15 cm sizes (Integra, 2026; CMS, 2016; FDA, 2015). There is insufficient evidence to support the safety and efficacy of Cytal for all indications.

DermaBind SL N
DermaBind SL N (HealthTech Wound Care, Salt Lake City, UT) is a dehydrated human single-layer amnion membrane. It is a wound covering designed for application directly to acute and chronic wounds. DermaBind SL N is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "wound covering" and "to protect those wounds from the environment" (CMS, 2025). Other configurations include DermaBind SL and DermaBind SL X. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of DermaBind SL N for any indication.

DermaPure™
DermaPure (Tissue Regenix Group [TRG], San Antonio, TX) is a decellularized, human dermis allograft donated from human tissue intended for transplant. The dermis is produced using dCELL® proprietary technology, removes all cells and DNA and acts as a scaffold for cell growth. The implant becomes integrated into the host tissue. DermaPure is proposed as a covering for difficult or hard to heal, acute and chronic wounds. Donated tissue is processed in accordance to the standards of the American Association of Tissue Banks. DermaPure comes in multiple sizes (TRG, 2026). There is insufficient evidence to support the clinical utility of DermaPure for the treatment of wounds. Published studies are primarily in the form of a pilot study with a small patient population (n=20) who had 70% venous ulcers (Greaves, et al., 2013).

DermaSpan™
DermaSpan (Zimmer Biomet, Warsaw, IN) is an acellular dermal matrix derived from allograft human skin. The product is regulated by the FDA's American Association of Tissue Banks and

regulatory process for testing and donor screening and prepared by a Biologics proprietary process. DermaSpan is proposed for repair or replacement of damaged or inadequate integumental tissue (wound coverage), and as supplemental support, protection, reinforcement or covering of tendons (Zimmer BioMet, 2026). There is insufficient evidence to support the safety and efficacy of DermaSpan.

Dual Layer Impax Membrane
Dual Layer Impax Membrane (Legacy Medical Consultants, Fort Worth, TX) is a sterile dehydrated dual layered human amniotic membrane allograft. It is intended to serve as a barrier or cover for acute and chronic wounds and for use as a barrier to protect wounds from the surrounding environment. The product is classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271). There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of Dual Layer Impax™ Membrane for any indication.

DuraSeal® Dural Sealant System
The DuraSeal Dural Sealant System (Integra Lifesciences, Princeton, NJ) consists of synthetic absorbable sealant materials and an applicator used to apply the sealant to an incision site. The sealant is approved by the FDA premarket approval (PMA) process "for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure. DuraSeal should only be used with autologous duraplasty." The sealant is composed of a polyethylene glycol (PEG) ester solution and a trilysine amine solution that are mixed together to form a gel (Integra Lifesciences, 2026). The gel is applied to the suture site to prevent cerebrospinal fluid leakage and is proposed to be absorbed in four to six weeks (FDA, 2009; FDA, 2005).

Osbun et al. (2012) conducted a multicenter, randomized controlled trial to assess the safety and efficacy of DuraSeal Dural Sealant System (n=120) compared to a control group treated with standard procedure based on the surgeon's judgment (e.g., application of additional sutures; soft tissue patches from muscle, pericardium or fascia; vascularized grafts of muscle and pericranium; off-label use of various biological products including fibrin glues, gelatin and collagen sponges, dural substitutes, and/or hemostatic agents) (n=117). Patients underwent infratentorial or supratentorial procedures. There were significant differences in sealing methods between the two approaches. Some patients in both groups required autologous duraplasty. There were no significant differences between the groups in neurosurgical complications, reoperation/unplanned interventions, surgical wound complications, central nervous system events, cerebral spinal fluid leaks or surgical site infections within the first 30 postoperative days. The authors noted that a limitation of the study included a significantly greater number of infratentorial procedures were performed in the control group (p=0.04). Other limitations include the use of two different surgical approaches and the short-term follow-up. Additional randomized controlled trials are needed to validate the safety and efficacy reported in this study.

DuraSeal® Exact Spine Sealant System
DuraSeal Exact Spine Sealant System (Integra Lifesciences, Princeton, NJ) is FDA PMA approved "for use as an adjunct to sutured dural repair during spinal surgery to provide watertight closure" to prevent CSF leakage through the suture pinholes and gaps between stitches. The system is composed of two solutions, a PEG ester solution and a Trilysine amine solution. When mixed together, the precursors polymerize to form the hydrogel sealant (Integra Lifesciences, 2026). The sealant is sprayed or layered on the sutured site. Since the sealant is more than 90% water, it is absorbed within four to eight weeks following surgery. The hydrogel may swell up to 50% of its size in any dimension (FDA 2009).

Kim and Wright (2011) conducted a multicenter, randomized controlled trial to assess the safety and efficacy of DuraSeal Spinal Sealant (n=102) compared to standard methods (n=56) (control

group). Examples of control group procedures included sutures or sutures plus fibrin glue. Postoperative follow-ups occurred at 30 and 90 days. Nine patients required a second application of DuraSeal for continued leakage on Valsalva. In the control group, 20 patients had a nonwatertight closure and 16 received no further treatment per the surgeon's discretion. Patients treated with DuraSeal had a significantly higher rate of watertight closure compared to the control group ($p<0.001$). No statistically significant differences were reported in postoperative cerebrospinal fluid leakage (CSF) ($p=1.00$), infection, and wound healing. No neurologic deficits were seen attributable to the sealant. Study limitations noted by the authors included the choice of the intraoperative watertight dural closure with Valsalva as the primary end point instead of postoperative CSF leak and in the control group some investigators chose not to attempt second treatment method per protocol but instead used another adjunctive therapy. Other limitations of the study are the unequal number of patients in the groups and the short-term follow-up. Additional studies are needed to support the safety and efficacy of DuraSeal Spinal Sealant.

DuraSorb® Monofilament Mesh/ Polydioxanone Surgical Scaffold™
DuraSorb® Monofilament Mesh/ Polydioxanone Surgical Scaffold™ (Integra LifeSciences, Princeton, NJ) is a resorbable, colorless, monofilament knit surgical mesh made entirely of uncolored and undyed polydioxanone (PDO) thread. Polydioxanone Surgical Scaffold is proposed for use in reinforcement of soft tissue where weakness exists. On August 1, 2018, 510(k) approval (K181094) was given to Polydioxanone Surgical Scaffold™. It is manufactured in three rectangular shapes: 6x16 cm, 10x25 cm, and 20x25 cm. According to the manufacturer's Instructions for Use, DuraSorb has not been studied for use in the repair of direct inguinal hernias, intraperitoneal use, urogynecological use, contaminated and/or infected wounds, tendon repair or in breast reconstructive surgeries (Integra LifeSciences, 2026). Evidence is lacking in the published peer-reviewed literature to support the clinical effectiveness of DuraSorb Monofilament Mesh/Polydioxanone Surgical Scaffold for any indication.

Endoform Dermal Template™
Endoform Dermal Template (Aroa Biosurgery Limited, San Diego, CA) is an ovine (sheep)-derived extracellular matrix that is FDA 510(k) approved for single use in the treatment of "partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree bums; and skin tears) and draining wounds" (FDA, 2010). Endoform is prepared from propira submucosa of ovine forestomach tissue. The dressing contains 90% natural collagen and 10% extracellular matrix. The template is a temporary matrix that is completely replaced by the patient's own tissue over time and is proposed to be effective for up to seven days. There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of Endoform. Studies are primarily in the form of retrospective reviews with small patient populations and heterogeneitity of wound types (e.g., diabetic foot ulcers, venous leg ulcers, heel pressure ulcers) (Ferreras, et al., 2017; Lullove, 2017; Bohn and Gass, 2014).

EpiBurn®
EpiBurn (MiMedx, Marietta, GA) is a bioactive, dehydrated human amnion/chorion membrane (dHACM) proposed for the treatment of wounds to promote healing, act as a barrier membrane, reduce scar tissue and prevent inflammation. The Membrane has multiple layers including a layer of epithelial cells, a basement membrane, and an avascular connective tissue. EpiBurn is proposed for the treatment of partial and full-thickness burns, surgical debridement and donor sites. EpiBurn is processed from human tissue according to the Food and Drug Administration (FDA) regulations and the American Association of Tissue Banks (AATB) standards, and is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) under Section 361 of the Public Health Service Act. The Membrane is available in 6x6 cm, 9x7 cm and 7x15 cm sizes. Evidence supporting the use of EpiBurn for any indication is lacking.

EPICORD®
EPICORD (MiMedx Group, Kennesaw, GA) is a minimally manipulated, dehydrated, human umbilical cord allograft for homologous use. It is comprised of the protective elements of the umbilical cord with a thin amnion layer and a thicker Wharton Jelly mucopolysaccharide component. It is proposed for the treatment and management of chronic and acute wounds, burns and as a natural biological barrier to protect tendons. EPICORD is processed from human tissue according to the American Association of Tissue Banks (AATB) standards, and is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) under Section 361 of the Public Health Service Act. It is available in various sizes (Mimedex, 2026; CMS, 2016). Evidence supporting the safety and effectiveness for EPICORD for all indications is lacking.

Tettelbach et al. (2018) conducted a multicenter, randomized controlled trial to investigate the safety and efficacy of EpiCord (n=101) compared to an alginate wound dressing (control group) (n=54) for the treatment of diabetic foot ulcers (DFU). Inclusion criteria were a confirmed diagnosis of Type 1 or Type 2 diabetes and a 1–15 cm^2 ulcer located below the ankle for at least 30 days that had undergone debridement. The control group had an alginate dressing applied (excluding silver and collagen), covered by a non-adherent silicone dressing and an absorbent hydropolymer secondary dressing. The 18-week study period included a two-week run-in phase in which the DFU was treated with moist dressings and offloading. If the DFU did not reduce by at least 30% from baseline, subjects were randomized 2:1 into the EpiCord or control group, respectively. The run-in period was followed by a 12-week treatment phase and final follow-up at week 16. EpiCord was applied weekly following debridement. The primary outcome measure was the percentage of subjects in the intention to treat (ITT) population with complete wound closure of the study ulcer within 12 weeks of treatment. Secondary outcomes included 12-week healing rates in subjects who completed the study per protocol and wounds that were determined to have received consistent, adequate debridement. Complete healing was defined as 100% epithelialization of the wound. Data were analyzed in an intent-to-treat (ITT) population. Analysis was also conducted on subjects (n=134) who completed the study per protocol (PP) (EpiCord, n=86; alginate, n=48) and subjects who received adequate debridement (EpiCord, n=67, alginate, n=40). 12-week outcomes included the following:

- ITT analysis showed that significantly more DFUs treated with EpiCord (71/101; 70%) healed compared to subjects treated with alginate dressings (26/54; 48%) (p=0.0089).
- Healing rates at 12 weeks for subjects treated PP showed significantly better healing rates with EpiCord (70/86; 81%) than alginate-treated subjects (26/48; 54%) (p=0.0013).
- Significantly more EpiCord-treated subjects who received adequate debridement (64/67; 96%) completely healed compared to the control group (26/40; 65%) (p<0.001).
- In the ITT population, DFUs that received adequate debridement healed completely with EpiCord (64/67; 96%) compared with the control group (26/40; 65%) (p<0.0001).

At the 16-week follow-up significantly more ulcers treated with EpiCord were healed compared with control group in the ITT population (p=0.0199). For subjects completing the study per protocol more EpiCord-treated ulcers (73/86; 85%) were healed compared to the control group (29/48; 60%). The median number of EpiCord allografts applied per healed wound was seven (range 2-12). There were no reported adverse events related to EpiCord or alginate dressings. Limitations of the study include the small patient population, short-term follow-up and 2:1 randomization. The authors noted that this is the first randomized controlled trial to examine the safety and efficacy of an allograft derived from umbilical cord as a treatment for chronic DFUs. Additional studies are indicated to support the clinical effectivenss of EpiCord.

EPIXPRESS™
EPIXPRESS™ (MiMedx Group, Inc., Marietta, GA) is a lyophilized human placental-based allograft that includes the amnion layer, intermediate layer, and chorion layer (MiMedx Group, Inc., 2026). EPIXPRESS is intended for use as a barrier to provide a protective environment in acute and

chronic wounds and is supplied in various sizes. EPIXPRESS is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 (CMS, 2024). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of EPIXPRESS for any indication.

Esano™ A, Esano™ AAA, Esano™ AC, Esano™ ACA
Esano™ (Evolution Biologyx™, LLC., Center Valley, PA) family of products are comprised of decellularized, dehydrated human amniotic membrane allografts. Esano A is a single layer sheet, Esano AAA is a tr-layer with a preserved natural epithelial basement membrane and an intact extracellular matrix structure, Esano AC is a dual-layer, and Esano ACA is a triple layer amnion/chorion/amnion allograft. The products are proposed for use as a cover or barrier for acute and chronic wounds and to provide protective coverage from the surrounding environment for acute and chronic wounds. Esano products are applied directly to the wound, adheres without fixation, and are available in various sizes. The products meet the criteria for FDA regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271 (CMS, 2023). There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of these products.

Essence Acellular Dermal Matrix
Essence Acellular Dermal Matrix (ADM) (Bimini Health Tech, Plano, TX) is a terminally sterilized acellular dermal matrix derived from human cadaveric dermis. It is proposed for plastic and reconstructive surgery procedures. Essence Acellular Dermal Matrix (ADM) implants are regulated as 361 Human Cell and Tissue Products (HCT/Ps) as defined in US FDA 21 CFR 1271, and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician) (Bimini Health Tech, 2026). Essence is available in two thicknesses and multiple shapes and sizes. There is insufficient evidence to support the safety and efficacy of Essence Acellular Dermal Matrix for any indication.

FloGraft™
See the AmnioCare®, AmnioMatrix®, and FloGraft™ information above.

Fortaderm™/PuraPly™: See PuraPly

Fortiva® Porcine Dermis
Fortiva porcine dermis (also known as Tutoplast porcine dermis) (RTI Surgical, Inc., Alachua, FL) is a non-crosslinked acellular porcine dermal matrix. Fortiva is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. The implant is indicated for use in repairing hernias and/or body wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome. Fortiva porcine dermis (also known as Tutoplast porcine dermis) received FDA 510(k) clearance (K142070) Oct 27, 2014 (FDA, 2014). The product is available in a range of sizes up to 35cm x 35cm. There is insufficient evidence to support the safety and efficacy of Fortiva porcine dermis for soft tissue reinforcement.

Gentrix®
Gentrix Surgical Matrix products (Integra LifeSciences, Princeton, NJ Acell, Inc., Columbia, MD) are engineered using Integra's proprietary MatriStem UBM (Urinary Bladder Matrix) technology (Integra LifeSciences, 2026). Gentrix was previously marketed as Matristem. In 2017 Acell announced that all products previously marketed under Matristem were being rebranded to Gentrix Surgical Matrix to differentiate Acell’s surgical products from their wound management products. In 2021, ACell was acquired by Integra LifeSciences. Gentrix Surgical Matrix 2-layer, 3-layer, 6-layer, and 8-layer are FDA 510(k) approved for “implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive

surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair". The Gentrix™ Surgical Matrix Thick and Gentrix Surgical™ Matrix Extend are also FDA 510(k) approved for the same indications. Per the manufacturer's website the surgical products include Gentrix Surgical Matrix Thin, Gentrix Surgical Matrix, Gentrix Surgical Matrix Plus, Gentrix® Surgical Matrix Thick (Integra LifeSciences, 2026). There is insufficient evidence to support Gentrix for any indication. Studies are primarily in the form of retrospective reviews.

GORE® BIO-A® Fistula Plug
The GORE BIO-A Fistula Plug (Gore Medical, Flagstaff, AZ) is FDA approved as a Class II, 510(k) synthetic bioabsorbable scaffold intended for use in the reinforcement of soft tissue for repair of anorectal fistulas. It is a surgical mesh supplied in a preformed three-dimensional shape (disk with attached tubes) and comprised of a porous structure of synthetic bioabsorbable PGAP:TMC copolymier fiber, degraded via a combination of hydrolytic and enzymatic pathways. Cell migration into the scaffold and tissue is generated as the body gradually absorbs the synthetic material (FDA, 2009). There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of this device. Studies are primarily in the form of case reports, retrospective reviews and case series with small patient populations and short-term follow-up.

Narang et al. (2016) conducted a systematic review of the literature to evaluate the safety and efficacy of GoreBio-A synthetic plug for the treatment of anal fistula. Six studies (n=221) met inclusion criteria and were included in the analysis, data extraction (n=187) and data synthesis. Studies of adult patients undergoing treatment for simple or complex fistulas with the Gore fistula plug regardless of etiology or pathological anatomy were included. Most fistulas were cryptoglandular and others were due to surgical trauma, Crohn's disease or HIV infection. Three studies were prospective in design and three were retrospective. No randomized controlled trials were found. Subject ages ranged from 19–82 years. Follow-ups ranged from 2–19 months. Thirteen patients (5.9%) were lost to follow-up and 21 (9.5%) underwent alternative treatment. Fistula healing rates ranged from 15.8%–72.7%. Early or delayed plug extrusion occurred in 16/187 patients (8.5%). Limitations of the studies included: small patient population, lack of randomized or comparative study design, and heterogeneity of etiologies and follow-up protocols. Due to the low quality of evidence, conclusions regarding the effectiveness of the Gore Bio-A fistula plug and improved clinical outcomes could not be made.

GraftJacket® Xpress
GraftJacket Xpress a flowable soft-tissue scaffold, is a powdered form of the GraftJacket tissue matrix. Using saline, it is reconstituted and injected into a wound. The scaffold is proposed for filling deep tunneling-type chronic wounds such as those found in chronic diabetic foot ulcers. The skin substitute is packaged in a syringe and intended for one time use (WoundReference, 2026). This product is regulated by the FDA as human tissue for transplantation. There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of GraftJacket Xpress. Studies have primarily been in the form of retrospective reviews with small patient populations and short-term follow-ups (Brigido, et al., 2009).

GrowFX® Connective Tissue Matrix
GrowFX Connective Tissue Matrix (Regenerative Sciences) is a connective tissue flowable matrix derived from placental tissue composed of amniotic tissue and membrane and is chorion-free. It is proposed for homologous use to fill space and provide support. GrowFX product donor tissues are procured in the US and are processed aseptically in accordance with current Good Tissue Practice (cGTP) and current Good Manufacturing Practice (cGMP) standards. Communicable disease testing is performed by a Food and Drug Administration (FDA) registered and Clinical Laboratory Improvement Amendments (CLIA) laboratory. GrowFX Connective Tissue Matrix comes in various

volumes ranging from 0.25 cc to 2.0 cc (Regenerative Sciences, 2024). There is insufficient evidence in the published peer-reviewed literature supporting the safety and effectiveness of GrowFX Connective Tissue Matrix.

Guard AC - Amniotic Allograft
Guard AC - Amniotic Allograft (OrthoNovis, Inc., Palm Coast, FL) is a dehydrated amniotic membrane sheet produced using minimal manipulation. It is proposed for use as a protective covering and in wound management (OrthoNovis, 2026). OrthoNovis products are processed and registered in compliance with all current Good Tissue Practices as mandated by the FDA and AATB and regulated under Section 361 of the Public Health Service Act. There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Guard AC - Amniotic Allograft products for any indication.

Helicoll®
HeliColl (EnColl Corporation, Fremont, CA) is a semi-occlusive, self-adhering, acellular, Type- 1 collagen graft proposed for wound care (EnColl, 2026). It is derived from a bovine or ovine source. The product is FDA 510(k) approved for topical wound management including: partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence). It was approved as a predicate device to existing similar products. According to Encoll, healing occurs within 1–4 applications. HeliColl comes in multiple sizes ranging from 1 square cm to 50 square cm (WoundSource, 2025; Dhanraj, 2015; FDA, 2004). Data supporting the safety and efficacy of HeliColl is lacking.

HydroFix® Vaso Shield
HydroFix Vaso Shield (the "Vaso Shield") (MiMedx® Group, Inc., Marietta, GA) is a vessel guard made of hydrogel material using proprietary technology. Protection of veins and arteries is a common issue associated with many types of surgeries. Protection of the aorta, vena cava, iliac vessels and other anatomy is particularly important in anterior spine surgery. HydroFix® Vaso Shield was designed to help physicians protect vessels during anterior vertebral surgery. The Shield is FDA 510(k) approved "as a cover for vessels during anterior vertebral surgery". Intended uses include fusion surgery, adjacent level surgery, artificial disc implantation, implant or hardware removal, trauma, and vascular surgery in the spine (FDA, 2011). Data in the form of clinical trials supporting the safety and effectiveness of HydroFix are lacking.

InnovaMatrix® FD
InnovaMatrix® FD (Convatec Triad Life Sciences, LLC, Bridgewater, NJ) is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material and composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans. InnovaMatrix FD is proposed for management of a variety of wounds such as pressure ulcers, diabetic ulcers, vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds and draining wounds (CMS, 2025). InnovaMatrix FD received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on July 26, 2024 (K241866) (FDA, 2024). InnovaMatrix FD is produced in sheet form in a variety of sizes up to 25 square centimeters. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of InnovaMatrix FD for any indication.

Integra™ Flowable Wound Matrix
Integra Flowable Wound Matrix (Integra Lifesciences, Princeton, NJ) is a granulated, acellular bovine tendon collagen and glycosaminoglycan device that is 510(k) FDA (K072113) approved for the treatment of advanced wound care. The granulates are reconstituted with saline to form a gel-like substance. The Matrix is considered "substantially equivalent in function and intended use to

Integra Matrix Wound Dressing" and is approved for the treatment of "partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds" (Integra LifeSciences, 2026; FDA, 2007). The skin substitute is packaged in a syringe and intended for one time use. There is insufficient evidence in the published peer-reviewed scientific literature supporting the efficacy of Integra Flowable Wound Matrix.

Campitiello et al. (2017) conducted a randomized, placebo-controlled trial to evaluate the efficacy of Integra Flowable Wound Matrix (n=23) compared with a wet dressing (n=23) for the treatment of diabetic foot ulcers (DFUs) with irregular geometries (tunneling or cavity lesions). Inclusion criteria were diabetic patients, age > 18 years, who had Grade 3 Wagner classification DFUs with an ankle-brachial index (ABI) of ≥ 0.5. Antibiotic therapy was started 7–10 days prior to surgery and continued until the wound had healed. The primary objective of the study was to determine the percentage of patients with wound closure (100% re-epithelialization). Secondary outcome measures included the time to healing and safety (number of major amputations and hospitalizations). Wounds were cleaned and necrotic tissue was removed until normal healthy tissues appeared. After mixing the dry granular collagen with saline solution, the matrix was applied to the lesion, until completely filled. The edge of the wound was sutured. Wounds in the control group were covered with a sterile saline-moistened gauze before the dressing was applied. Compression dressings and offloading devices were used by both groups. Patients were followed until complete wound healing had occurred or for up to six weeks. Healing was determined by clinical examination and complete healing was defined as 100% re-epithelialization in the absence of discharge. At six weeks, complete healing had occurred in significantly more Integra patients (n=20; 86.95%) than control group patients (n=12; 52.17%) (p=0.001). Healing time was significantly shorter in the study group, where the surgical breach was closed by primary intention compared to the control group, where the surgical breach healed by secondary intention. The biomaterial allowed closure of wound by primary intention, reducing the healing time. Minor amputations were performed in nine study group subjects and eight control group subjects. Major amputations (p=0.0019) and re-hospitalization rates (p=0.028) were significantly less in the Integra group. Limitations of the study include the small patient population and short-term follow-up. The authors concluded that additional studies are needed with large patient populations and long-term follow-up to validate these findings.

Integra® Reinforcement Matrix
Integra Reinforcement Matrix (Integra LifeSciences, Princeton, NJ) is an acellular porcine dermal matrix proposed for use in the reconstruction of soft tissue deficiencies. Per Lifesciences, the matrix is "intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Integra Reinforcement Matrix is not intended to replace normal body structure or provide full mechanical strength. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair". The Integra Reinforcement Matrix is available in 4x7 cm and 5x10 cm. There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of this matrix.

IntéguPly
Integuply (Berkeley Biologics, Richmond, CA) is a dual-sided, human acellular collagen matrix proposed for the treatment of sports related injuries, including tendons and ligaments. The epidermis and all viable cellular components are removed from the collagen matrix during processing. The dermal side is proposed to host tissue vascularization and cellular incorporation. The tissue preparation is compliant with the FDA, AATB and state regulatory requirements

(Berkeley Biologics, 2026). There is insufficient evidence published in the peer-reviewed literature to support the safety and effectiveness of Integuply.

MatriStem® (Gentrix®)
MatriStem (Acell®, Inc., Columbia, MD), also called urinary bladder matrix (UBM), is an acellular device derived from the urinary bladder of pigs. The matrix is FDA 510(k) approved for the "management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, skin tears) and draining wounds" (FDA, 2009). The matrix is resorbed and replaced with new tissue. MatriStem has also been proposed for the treatment of alopecia. Product types include the MatriStem Wound Matrix; MatriStem Multilayer Wound Matrix (meshed sheets); MatriStem Pelvic Floor Matrix (surgical sheets); MatriStem Plastic Surgery Matrix; MatriStem Surgical Matrix RS, PSM, PSMX, & Thick (surgical sheets; MatriStem Burn Matrix; and MatriStem Hernia Matrix. The MatriStem MicroMatrix® consists of micronized particles that are sprinkled onto the wound and covered with a moist dressing. MatriStem Wound Matrix and Multilayer Wound Matrix are also marketed as Cytal Wound Matrix 1-Layer and 2-Layer (Integra LifeSciences, 2026). In 2017 Acell announced that all products previously marketed under Matristem were being rebranded to Gentrix Surgical Matrix for soft tissue repair to differentiate Acell's surgical products from their wound management products Cytal and MicroMatrix.

Matristem has been proposed for the treatment of diabetic foot ulcers, pilonidal wounds, anal fistulas, burns, septal ulceration and perforation, esophagojejunal anastomotic leaks after total gastrectomy for malignancy and venous status and decubitus ulers. Studies investigating Matristem for these conditions are primarily in the form of retrospecitive review with small patient populations (Geiger, et al., 2016; Kraemer, et al., 2016). There is insufficient evidence to support Matristem for these conditions.

Frykberg et al. (2016) conducted a multicenter randomized controlled trial (n=56) to compare the treatment of non-healing DFUs with both MatriStem MicroMatrix (MSMM) and MatriStem Wound Matrix (MSWM) (porcine-derived) (n=27) to ulcers treated with Dermagraft (DG) (n=29) (living skin substitute). Prior to study initiation, patients participated in a four-week screening phase during which they received physician-selected standard of care (e.g., debridement, saline irrigation, primary dressing, offloading boot). Following the screening phase, patients with DFUs that decreased in size by ≤ 30% or increased by ≤ 50% and met other inclusion criteria were enrolled in the study. Other inclusion criteria included: ulcer present for ≥ 4 weeks and extended through the dermis and into the subcutaneous tissue without muscle, tendon, bone or joint capsule exposure; HbA1c <12%; wound free of necrotic debris following debridement and appeared to have healthy vascularized tissues; and Doppler measured ankle-bronchial index (ABI) of ≥ 0.7 after 10 minutes rest. Once granulation began to occur on the wound bed, only MSWM was applied. The matrix was applied weekly until wound closure (complete re-epithelialization with no drainage, no dressing required) or until the patient had received one application per week without wound closure, whichever came first, up to a maximum of eight applications. Following complete wound closure, patients returned for a six-month follow-up visit to assess for ulcer recurrence. There were no statistically significant differences between the two groups in the following: complete wound closure at day 56 (p=0.244), change in wound size over eight-week treatment period (p=0.762); complete wound closure at day 70 (p=0.768); or mean time to closure (p=0.523). At the end of treatment, the MS group reported statistically significant improvement in quality of life compared to the DG group (p=0.004 to 0.049). There was no statistically significant difference in wound recurrence at the six-month follow-up (n=10). One MS-treated patient and two DG treated patients had ulcer recurrence. There was no significant difference in adverse events between the two groups. Limitations of the study include the small

patient population and the manual nature of the data collection tracing the wounds to a Visitrak system.

Matrix™ HD
Matrix HD (Royal Biologics, Hackensack, NJ), an acellular allograft human dermis of collagenous connective tissue, is proposed to support cellular revascularization and repopulation by the host tissue. Regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue, the matrix has been used as a wound covering in diabetic ulcers, Charcot foot ulcers, venous ulcers, trauma wounds, pressure sores/ulcers, partial and full thickness wound and surgical wounds (Royal Biologics, 2025). Evidence supporting the safety and efficacy of Matrix HD from published clinical trials is lacking.

Membrane Wrap™, Membrane Graft™
Membrane Wrap (BioLab Holdings Inc. Mesa AZ) is a dual-layered dehydrated human amnion membrane allograft composed primarily of a connective tissue matrix. It is proposed to be minimally manipulated, preserving the natural growth factors and cytokines that are present in amniotic tissue. The product is proposed for chronic and post-surgical wound healing including the treatment of non-healing acute and chronic wounds (diabetic, venous, mixed, venous-arterial, pressure ulcers), complex and /or open surgical wounds and burns, for children and adults. Available in various sizes (BioLab Holdings, 2025). Membrane Graft is a similar product by BioLab proposed for the same indications (CMS, May 2019). There is insufficient evidence to support the clinical effectiveness of these products.

MemoDerm™
MemoDerm (Stryker Sports Medicine) is a sterile acellular dermal matrix derived from human allograft skin tissue and is regulated by AATB and FDA requirements for tissue processing. The matrix is proposed for use in various orthopedic procedures involving rotator cuff, anterior shoulder capsule, flex/extension tendon, ulnar collateral ligament, Achilles tendon, or lateral ankle complex, as well as for treatment of chronic diabetic foot ulcers (WoundReference, 2026). There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of Memoderm.

Miamnion®
Miamnion® (Vivex Biologics, Atlanta, GA) is an amnion tissue allograft that is processed in accordance with FDA regulations and AATB standards. It is proposed for use as a soft tissue barrier and wound covering in the following clinical applications: spine and neurosurgery, foot and ankle, wound care, burn care, and dermatology (Vivex Biologics, 2026). The sizes available vary in thickness. Evidence is lacking in the published peer-reviewed literature to support the clinical effectiveness of Miamnion for any indication.

Microlyte® Matrix
Microlyte® Matrix (Imbed Biosciences, Inc., Madison, WI) is a synthetic, bioresorbable wound matrix composed of a resorbable polymer–polyvinyl alcohol (PVA) and contains bacteria-killing antimicrobial silver (Imbed Biosciences, 2026). It is proposed for the management of: wounds, partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second-degree burns, abrasions and lacerations, donor sites and surgical wounds, and may be used over debrided and grafted partial thickness wounds. Microlyte Matrix received FDA 510(k) (K153756) approval in 2016 (FDA, 2022). Microlyte Matrix is available in various sizes. Evidence in the published peer-reviewed literature consists of a prospective pilot study (Manning, et al., 2020) and case reports on the manufacturer's website and is insufficient to support the clinical effectiveness of Microlyte Matrix for any indication.

MiroFlex® (formerly Miromesh®)

MiroFlex (formerly known as Miromesh®) (Reprise Biomedical, Plymouth, MN; Miromatrix Medical, Inc., Eden Prairie, MN) is a non-crosslinked, acellular surgical mesh derived from whole, compressed porcine livers for the reinforcement of soft tissue. Proposed indications include hernia repairs, and reinforcement in plastic and reconstructive surgery. MiroFlex uses a perfusion decellularization as opposed to an immersion decellularization technology to remove cells from the mesh. Miromesh sales and manufacturing will be managed by Reprise Biomedical (Reprise Biomedical, 2024; FDA, 2014). The mesh is available in various sizes. Studies investigating the safety and effectiveness of Miromesh include a retrospective review for patients who underwent hernia repair and a case series for repair of esophageal hernia (Rosen, et al., 2019)

Rosen et al. (2019) conducted a multicenter prospective single arm study (n=41) evaluating the outcomes of MiroMesh when used for repair of a symptomatic paresophageal hernia. Inclusion criteria were: adults age 18–80 years; candidate for elective laparoscopic paraesophageal hernia repair; > 5 cm hiatal hernia in axial/vertical dimension; evidence of Type II or III paraesophageal hernia; and committment to not smoking for at least four weeks prior to procedure. Subjects were excluded if they had undergone prior esophageal or gastric surgery; had a sensitivity to porcine material; were immunocompromised (i.e., HIV, post-organ transplant, on chemotherapy); required emergent surgery for acute gastric volvulous or strangulation; had a BMI ≥ 40; life expectancy < 2 years; and/or had an associated GI disease that required extensive medical or surgical intervention (e.g., Crohn's Disease) that might interfere with quality of life assessment. The primary endpoint of the study was hernia recurrence that required surgical re-intervention at two years postoperate due to symptoms or adverse events. The secondary endpoints included: radiologic recurrence, symptomatic improvement, quality of life, adverse events and perioperative outcomes. All patients underwent a laparoscopic transabdominal approach with no conversions to an open procedure. Twenty-seven patients completed the two-year follow-up. Radiologic evaluation demonstrated hiatal hernia recurrences in three patients who did not require surgical reintervention. GERD HRQL scores were significantly improved from baseline to two years follow up (19.3 to 3.8) ($p<0.0001$). At the two-year follow-up 89% of patients reported satisfaction with their condition vs. 17.9% preoperatively. Results of the SF-36 questionnaire showed that quality of life was significantly improved at all time points with overall quality of life improvement seen at 24 months compared to baseline. There were no major intraoperative complications reported. Eighteen postoperative adverse events included four serious events that were not related to the mesh. Limitations of the study include the lack of a comparator, small patient population, number of patients lost to follow-up and the short-term follow-up. Randomized controlled trials with large patient populations and long-term follow-up are needed to validate the results of this study.

Myriad Matrix™ and Myriad Morcells™

Myriad Matrix™ (Aroa Biosurgery Limited, San Diego, CA) is a soft tissue bioscaffold engineered extracellular matrix (ECM) derived from ovine (sheep) forestomach tissue. Myriad Morcells™ is the powdered form of Myriad Matrix. Myriad Matrix™ is proposed for use in the management of the following wounds: partial and full-thickness wounds, ulcers (pressure, venous, diabetic, chronic vascular), tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds (Aroa Biosurgery, 2026). Aroa received FDA 510(k) clearance (K171231) for Myriad Matrix in June 2017. It is available in 5x5cm, 7x10 cm, 10x10cm, 10x20cm, and 20x20 cm sizes. Evidence in the published peer-reviewed literature consists of case series (Chaffin, et al., 2021; Desvigne, et al., 2021; Bohn and Chaffin, 2020) and is insufficient to support the clinical effectiveness of Myriad Matrix for any indication.

Myriad Morcells™ is the powdered form of Myriad Matrix (Aroa Biosurgery, 2026). Myriad Morcells is intended for use in certain acute and chronic wounds, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. Myriad

Morcells™ is the proprietary (brand) name of the technology, which received 510(k) clearance (K200502) on March 31, 2021, under the device name "Myriad Particles." Upon commercialization, the proprietary name "Myriad Morcells™" was added to the device through an update to the FDA Establishment Registration & Device Listing Database. Myriad Morcells is currently available in a range of sizes, from 200 mg to up to 2000 mg (Aroa Biosurgery, 2026). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Myriad Morcells for any indication.

Natalin®
Natalin® (Celularity Inc., Florham Park, NJ) is a tri-layer, decellularized, dehydrated human amniotic membrane allograft that is terminally sterilized with e-beam irradiation. It is proposed for use as a wound covering or surgical barrier for acute and chronic wounds, including diabetic, venous, arterial, and pressure ulcers, burns, surgical sites (including Mohs), and complex wounds with exposed structures (tendon, bone, muscle). Natalin is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "covering, wrap or barrier to partial- and full-thickness, acute and chronic wounds" (CMS, 2025). Natalin is applied based on wound size; customizable and measured per square centimeter, and is available in single-use, sterile, dehydrated sheets in sealed, double-peel pouches ranging in various sizes. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Natalin for any indication.

NeoMatriX® Wound Matrix
NeoMatriX® Wound Matrix (NeXtGen™ Biologics, Alachua, FL) is a wound covering derived from the dermal extracellular matrix of axolotl (salamander). It is proposed to support in the healing of chronic and hard-to-heal wounds. In 2018, NeoMatriX Wound Matrix received FDA 510(k) approval (K181330) for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. The product was modified and received an additional FDA 510(k) approval in 2021 (K210024) due to changes in the manufacturing process. There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of NeoMatriX for any indication.

NeoStim Membrane/NeoStim DL/NeoStim TL
NeoStim (Acesso Biologics, Las Vegas, NV) are a family of dehydrated amnion membrane allografts derived from donated human amniotic membrane. NeoStim Membrane is a single layer, NeoStim DL is a double layer, and NeoStim TL is a triple layer dehydrated amnion membrane allograft (Acesso Biologics, 2026). The products are proposed to serve as a barrier or provide a protective coverage from the surrounding environment for acute and chronic wounds such as: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds and trauma wounds. The product is applied directly to the wound, adheres to the wound bed without fixation and it is fully resorbable. The products are classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of NeoStim products for all indications.

NeoThelium FT, NeoThelium 4L, and NeoThelium 4L+
NeoThelium FT, NeoThelium 4L, and NeoThelium 4L+ (Neostim, LLC dba NSM Biologics) are derived from donated human placental birth tissue. Thelium FT allograft is a full-thickness amnion/chorion membrane, indicated as a sterile, single-use, dehydrated resorbable allograft. Thelium 4L membrane is a full-thickness amnion/chorion/chorion/amnion allograft. NeoThelium 4L+ membrane is a full-thickness quad-layer chorion/ amnion/amnion/chorion allograft. The

products are proposed for use as a barrier and to provide protective coverage from the surrounding environment to acute and chronic wounds. They are single use, dehydrated resorbable allografts intended to be applied topically over the wound. NeoThelium FT, NeoThelium 4L, and NeoThelium 4L+ products are each regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier and provides protective coverage to acute and chronic wounds" (CMS, 2025). There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of NeoThelium FT, NeoThelium 4L, or NeoThelium 4L+.

Neox 1K/Neox 100/Neox RT
Neox products (BioTissue, Inc., Miami, FL) are amniotic membrane and umbilical cord grafts proposed for use as a wound covering for dermal ulcers and defects. The products, classified as human tissue and cell-based products regulated by the AATB, are prepared using the Cryoteck™ process. They are proposed for single use as a surgical covering, wrap or barrier. Neox 1K is cryopreserved, ultra-thick allograft, Neox 100 is also cryopreserved and thinner than Neox 1K, and Neox RT is a hydrated shelf stable ultra-thick human amniotic membrane allograft. Studies are primarily in the form of case reports and retrospective reviews with small patient populations (Caputo, et al., 2016; Raphael, 2016).

Caporusso, et al. (2025) conducted a randomized controled trial to compare safety and efficacy of Neox 1K plus standard of care with standard of care alone in complex diabetic foot ulcers (DFUs) with exposed bone, tendon, muscle and/or joint capsule and controlled osteomyelitis. A total of 220 eligible patients were enrolled and randomized to receive either Neox 1K plus standard of care (SOC) (n=118) or SOC alone (n=102). Standard of care consisted of debridement, bone resection, wound dressings, offloading, and a 6-week course of systemic antibiotics. Neox 1K was applied at baseline and reapplied at a minimum of 4-week intervals if healing was stalled throughout a 16-week treatment period, for a maximum of four applications. At 26 weeks, complete wound healing was achieved in 139 patients in the intent-to-treat population, with healing rates of 66.1% in the Neox 1K group and 59.8% in the SOC group (p=0.40). Patients treated with Neox 1K required a mean of 1.67 ± 0.87 applications to achieve wound closure. By 50 weeks, complete healing was observed in 77.1% of patients receiving Neox 1K compared with 71.6% of those receiving SOC (p=0.29). Adverse event rates were similar between treatment groups (89.8% for Neox 1K and 87.3% for SOC). Overall, no statistically significant differences were observed between the Neox 1K and SOC groups in healing outcomes or adverse event rates at any assessed time point. **LOE 2**

Neox® Flo
Neox Flo (Amniox Medical™, Marietta, GA) is the particulate form of Neox 100 and is also made from human placental tissue including amniotic membrane and umbilical cord tissues. The product is proposed for managing complex wounds and tunneling anatomies. It contains growth factors, cytokines and proteins and is FDA-regulated as a Human Cell, Tissue, and Cellular and Tissue-Based Product. There is insufficient data to support the clinical utility of Neox Flo. The product is no longer available and has been retired (WoundReference, 2026).

NeuraGen® Nerve Guide and NeuraWrap™ Nerve Protector
NeuraGen Nerve Guide (Integra Life Sciences, Princeton, NJ) is an absorbable, Type I collagen tubular matrix designed for peripheral nerve repair. The collagen tube is proposed to act as an interface between the nerve and surrounding tissue to promote healing across a nerve gap, therefore, replacing the need for a nerve graft. The NeuraWrap Nerve Protector is also an absorbable collagen implant that is proposed to provide an encasement and protection for injured peripheral nerves to isolate the nerve during the healing process (Integra LifeSciences, 2026). NeuraGen Nerve Guide is FDA 510(k) approve "for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity". NeuraWrap is 510(k) approved "for the

management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue".

There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of NeuraGen and NeuraWrap. Studies are primarily in the form of case series and retrospective reviews with small patient populations.

Neuroflex™
Neuroflex (Collagen Matrix, Inc. Oakland, NJ) is a flexible, resorbable, type 1 collagen nerve cuff that is proposed to provide an encasement for peripheral nerve injuries and protection of the neural environment. It allows repair without tension of peripheral nerve discontinuities of less than three centimeters. Nerve gaps may occur in crushing injuries; penetrating injuries such as lacerations, stabbings, fractures; failed primary repairs; and oncology related excisions. When hydrated the cuff becomes a flexible collagen conduit with a proposed kink-resistant property. It is designed to be an interface between the nerve and surrounding tissue to prevent ingrowth of scar tissue. The cuff may be placed at the terminal end of a nerve in an effort to prevent formation of a neuroma. Neuroflex is FDA 510(k) approved as a nerve cuff used "for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve in the foot to reduce the formation of symptomatic or painful neuroma". It is proposed for severed injuries where there is a gap across the joint. The product comes in six 2.5 cm lengths with an inner diameter of 2.0 mm to 6.0 mm (Stryker, 2026; FDA, 2014 [K131541]).

Neuroflex is marketed as part of a peripheral nerve portfolio by Stryker Orthopedics (Mahwah, NJ). Data investigating the safety and effectiveness of these collagen nerve matrixes are lacking. Studies are primarily in the form of animal studies, case reports and retrospective reviews with small patient population used in a variety of different procedures.

Novafix® DL
Novafix DL (Triad Life Sciences®, Inc., Memphis, TN) is a dehydrated human amnion chorion membrane allograft indicated for wound management including partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds, (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds (CMS, 2020). There is a lack of evidence in the published, peer-reviewed literature to support the effectiveness of this product. The product is no longer available and has been retired (WoundReference, 2026).

NuCel™
NuCel (Organogenesis Inc., Canton, MA) is a cryopreserved amniotic suspension allograft derived from human amnion and amniotic fluid. The product is mixed with the patient's own blood or sterile saline and applied to the site. Nucel suspension is available in small, medium, large and extra-large sizes. Due to the lack of evidence in published clinical trials, the safety and efficacy of NuCel products have not been established. Studies are primarily in the form of case series with small patient population (Anderson, et al., 2014).

NuForm™
NuForm™ (Organogenesis Inc., Canton, MA) is a human allograft tissue product composed of amnion and chorion, derived from donated birth tissue, that is meshed to allow for better conformability and drainage of exudative wounds. It is intended as a protective barrier in the management of a variety of partial- and full-thickness acute and chronic wounds, such as dermal ulcers, and wounds with exposed tendon, muscle, joint capsule, and bone, as well as use during surgical procedures. NuForm is regulated as a human cell, tissue, or cellular or tissue-based

product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a protective barrier (CMS, 2025). It is dehydrated and provided sterile for individual, single use and available in multiple sizes based on wound size. There is insufficient evidence to support the safety and effectiveness of NuForm for any indication.

NuShield™
NuShield (Organogensis; Canton, MA) is a dehydrated placental allograft that retains all layers of the amnio/chorion membrane (Organogensis, 2025). NuShield is proposed for use as a protective barrier and extracellular matrix (ECM) scaffold to support healing in a variety of wounds. Due to the lack of evidence in published clinical trials, the safety and efficacy of NuShield has not been established.

Oasis® Burn Matrix
Oasis Burn Matrix (Cook BioTech, Inc., West Lafayette, IN) is a porcine-derived acellular collagen matrix that is FDA 501(k) approved under the Oasis Wound Matrix device approval. Oasis matrix products are manufactured by Cook Biotech and distributed by Smith and Nephew (Smith and Nephew, 2025). The Burn Matrix is indicated for the treatment of partial-thickness burns. It is not indicated for the treatment of third-degree burns (FDA, 2006). There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of Oasis Burn Matrix for the treatment of burns. Studies have primarily been in the form of case reports.

OrCel™
OrCel (Forticell Bioscience, Inc., New York, NY) is an allogeneic, bilayered cellular matrix, Type I bovine collagen sponge with FDA PMA approval for the treatment of split-thickness donor site wounds in burn patients. There is limited evidence to support the efficacy of Orcel compared to the standard of care for the treatment of split-thickness donor sites. Therefore, OrCel is considered investigational for this indication. FDA-HDE approval (H990013) was granted for OrCel for use as an adjunct in the treatment of mitten-hand deformity surgery of epidermolysis bullosa. Published studies are in the form of case series with small patient populations (n=7). There is insufficient evidence to support the use of Orcel for any indication.

In a matched-pairs study conducted by Still et al. (2003), the use of OrCel was compared to treatment with Biobrane L. Eighty-two severely burned patients each had two designated split-thickness donor sites of equivalent surface area and depth. Sites were randomized to receive a single treatment of either OrCel or the standard dressing, Biobrane-L. Sites were evaluated for wound closure. The researchers found a statistically significant decrease in healing time with the use of OrCel compared to Biobrane L. There was a decrease in scarring associated with the use of OrCel, although it was not statistically significant. Additional clinical trials are needed to validate the findings of this study.

Orion Amniotic Membrane
Orion Amniotic Membrane (Legacy Medical Consultants, LLC., Fort Worth, TX) is a sterile dehydrated dual layered human amniotic membrane allograft (Legacy Medical Consultant, 2025). It is proposed for use as a barrier or cover for acute and chronic wounds and for use as a barrier to protect wounds from the surrounding environment. The product meets the criteria for FDA regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271 (CMS, 2023). Orion Amniotic Membrane is available in multiple sizes (Legacy Medical Consultants,2025). There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of this product for any indication.

OrthADAPT™ Bioimplant
OrthADAPT Bioimplant (Pegasus Biologics, Inc., Irving, CA) is a decellularized, biologic scaffold made from equine pericardium (xenograft). It is FDA 510(k) approved "to reinforce soft tissue

including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement and other reconstructive procedures. The device is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons" (FDA, 2007; Coons and Barber, 2006). There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of this product for any indication.

OsseoGuard®
The OsseoGuard Membrane (ZimVie, Palm Beach Gardens, FL) is a protective barrier made from bovine Type I Achilles tendon collagen proposed for the regeneration of hard and soft tissue in various dental defects including: localized ridge augmentation/future site preparation, peri-implant bone defects, extraction sockets, bone regeneration after root resection and sinus window coverage. The OsseoGuard Flex® Membrane is a resorbable collagen matrix made from Type I and Type III bovine dermis collagen. It is intended for use in oral surgical procedures as a resorbable membrane for: peri-implant defects in immediate or delayed extraction sockets, localized and alveolar ridge reconstruction, filling of bone defects, guided bone regeneration in dehiscence defects, and guided tissue regeneration in periodontal defects (ZimVie, 2026). OsseoGuard Flex™ Membrane is proposed for use in defects in which more drapability is indicated. Data are primarily in the form of case series with small patient populations and case reports and insufficient to establish the safety and efficacy of these products.

Ovation®
Ovation (Osiris Therapeutics, Inc. Columbia, MD is a subsidiary of Smith and Nephew), an allograft product, is an injectable cellular repair suspension proposed for tissue repair. The product is regulated by the FDA under regulations for human cell, tissues and cellular and tissue-based products. Ovation is a three-dimensional collagen scaffold proposed to enhance wound healing. There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of Ovation.

OviTex®
OviTex® (TELA Bio®, Inc., Malvern, PA) is a reinforced tissue matrix composed of interwoven biologic material derived from ovine rumen and polymer reinforcement (TELA Bio, 2026). The polymer fiber is available in resorbable or permanent variations. It is proposed for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome. The OviTex portfolio of products includes: OviTex Core, a four layer device not intended for intraperitoneal placement; OviTex 1S, a six layer device with smooth external layers suitable for intraperitoneal placement; OviTex 2S, an eight layer device with two smooth external layers suitable for intraperitoneal placement; OviTex LPR, a four layer device with a smooth side suitable for laparoscopic and robotic-assisted intraperitoneal placement; and OviTex PRS, a two or three layer device available in four shapes for plastic and reconstructive surgery. In order to achieve better fluid management, tissue integration, and directional flexibility, OviTex PRS was designed with micropores, macropores, and stents to address soft tissue repair in plastic and reconstructive surgery. OviTex received FDA 510(k) (K141053) as Ovine Tissue Matrix (OTM) in 2014 (FDA, 2022). It is available in various sizes. Evidence in the published peer-reviewed literature consists of an observational study (DeNoto, et al., 2021), retrospective review (Sweitzer, et al., 2024) and case series (Parker, et al., 2020; Sawyer, 2018) and is insufficient to support the clinical effectiveness of OviTex for any indication.

Sweitzer et al. (2024) conducted a retrospective review of consecutive patients to evaluate the safety and efficacy of 2-stage, immediate tissue expander breast reconstruction using either

Alloderm and Cortiva (human acellular dermal matrices [ADM]) (n=42) or Ovitex (ovine extracellular matrices [ECM]) (n=85) by a single surgeon from 2018 to 2023. Individuals with direct to implant or who underwent radiation treatment were excluded. Primary outcomes measured were any and all possible complications in each group. Follow up started at the time of mastectomy and continued for 920 days ± 708 days in ADM group and 848 days ± 293 days in ovine ECM group. Reconstructive success or failure was defined as the likelihood the patient achieved a permanent implant and was similar between the two groups (p=0.066). Major complications requiring a return to the operating room (RTOR) included hematoma (ADM n=1 [1.2%]; ovine ECM n=9 [5.5%]), seroma (ADM n=4 [4.9%]; ovine ECM n=3 [1.8%]), infection (ADM n=1 [1.2%]; ovine ECM n=3 [1.8%]), mastectomy flap necrosis (ADM n=6 [7.4%]; ovine ECM n=4 [2.5%]; implant loss (AMD n=7 [8.6%]; and implant replacement (initial RTOR) (ADM n=5 [6.2%]; ovine ECM n=11 [6.7%]). There was no statistically significant difference in complications requiring RTOR between human ADM (14.8%) or ovine ECM (12.7%) (p=0.31). Minor complications treated as outpatient included seroma, cellulitis and mastectomy flap necrosis and were not statistically different (p=0.31) between the two groups. Study limitations include retrospective study design and single surgeon at a single institution. When comparing the use of Ovitex to Alloderm and Cortiva in 2-stage expander implant breast reconstruction, outcomes were similar.

PalinGen®
There are four PalinGen products (Amnio Technology, LLC., Phoenix, AZ), PalinGen Membrane, PalinGen HydroMembrane, PalinGen Xplus and PalinGen Xplus HydroMembrane (Amnio Technology, 2024). The products are made from placental amniotic tissue and proposed for use as a wound covering following various procedures (e.g., orthopedic surgeries and injuries, nerve wrapping, spinal surgery, general surgery, burns and wounds). The tissue is designated for human homologous allograft use under FDA regulations and processed, cleansed, and packaged at an AATB accredited tissue bank. PalinGen Flow is available in 0.25 ml, 0.50 ml, 1.00 ml, and 2.00 ml sizes. A wet form of PalinGen, the Xplus Hydro Membrane, is also available. The Membranes come in ten sizes and can be customized (Amnio Technology, 2024). There is insufficient evidence in the published studies to support the effectiveness of these products for their proposed use.

Paraderm® Dermal Matrix
Paraderm Dermal Matrix (Paragon® 28, Englewood, CO) is a patent pending, minimally manipulated human collagen matrix that is proposed to promote cellular infiltration and proliferation as an integumentary augmentation. The product is obtained through the University of Miami Tissue Bank. Paragon 28 is a company established for the orthopedic foot and ankle market. The Matrix is provided in a variety of sizes and thicknesses (Paragon 28, 2026). There is insufficient evidence to support the safety and effectiveness of this matrix.

Peri-Guard® Repair Patch
Peri-Guard Repair Patch (Peri-Guard) (Baxter, Deerfield, IL) is prepared from bovine pericardium cross-linked with glutaraldehyde and manufactured with Synovis' exclusive Apex Processing®. Per the FDA 510(k) approval, Peri-Guard is "intended for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric binding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias). Peri-Guard is also intended for use as patch material for intracardiac defects, great vessel, septal defect and annulus repair, and suture-line buttressing. Supple Peri-Guard Patch is a similar product proposed for procedures that require a more flexible and compliant patch (FDA, 2012).

There is insufficient evidence in the peer-reviewed literature to support Peri-Guard Repair Patch for any indication. Studies evaluating the Patch include case reports, case series and retrospective

reviews with small patient populations (n=5–92). Reported uses of the Patch included post-mastectomy breast reconstruction, chest wall reconstruction (e.g., due to secondary incisional herniation development following lung transplantation or malignant disease with chest wall infiltration) and diaphragmatic repair.

Peri-Strips Dry with Veritas Collagen Matrix
Peri-Strips Dry with Veritas Collagen Matrix (Baxter, Deerfield, IL) is a proposed staple line reinforcement used with a surgical stapler (Baxter, 2026). The device is composed of two primary components: the Peri-Strips Dry plastic mounting unit and the PSD Gel. The mounting unit has two strips of dehydrated bovine pericardium on each side of a foam spacer by the plastic mounting unit. The PSD adhesive hydrogel is placed on the strips to create a temporary bond between the strips and the surfaces of a surgical stapler and also promotes rehydration of the strips. The stapler is positioned on the tissue to be excised, fired, and removed.

Peri-Strips Dry with Veritas is FDA 510 (k) approved for the following indications: 1) "as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed; 2) for reinforcement of staple lines during lung and bronchus resections and during bariatric surgical procedures; 3) for reinforcement of staple lines during gastric, small bowel, mesentery, colon, and colorectal procedures; 4) for reinforcement of suture lines and staple-lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery"

There is insufficient evidence to support the safety and effectiveness of Peri-Strips Dry.

Stamou et al. (2011) conducted a prospective comparative study (n=187) to determine if staple-line reinforcement with Peri-Strips Dry (PSD) reduces surgical complications of laparoscopic sleeve gastrectomy. Group A (n=96) received PSD and group B (n=91) did not receive PSD. Reinforcement with PSD significantly reduced the occurrence of bleeding from the staple line (p=0.012) and intra-abdominal collections (p=0.026). The leak rate was not significantly different between the two groups. Patients in group A required fewer days of hospitalization than group B (481 days vs. 524 days). Two leaks were observed in group A, one due to malfunction of the stapling device. In group B, three patients required transfusion. Number of stapler loads was 5–8 per operation. Limitations of the study include the small patient population, lack of randomization, and allocation primarily determined by insurance coverage and product availability.

Angrisani et al. (2004) conducted a randomized controlled trial to compare extraluminal bleeding with (group A) (n=50) or without (group B) (n=48) staple-line reinforcement with Peri-Strips Dry during laparoscopic Roux-en-Y gastric bypass in morbidly obese patients. Outcome measures included: mortality, intraoperative and postoperative complications, operating time, number of hemostatic clips used, and blood transfusion. There were no recorded incidents of intra- or postoperative mortality and no patients were re-operated or transfused because of extraluminal bleeding. Intra-operative methylene blue test was positive in six group B patients compared to zero group A patients ($p<0.001$). The mean number of clips ($p<0.001$) and operating time ($p<0.01$) were significantly lower in group A. Conversion to laparotomy was required in one group A patient and two group B patients. No adverse clinical or surgical event was related to Peri-Strip. A limitation of the study is the small patient population and lack of reporting of inclusion and exclusion criteria.

Miller et al. (2001) conducted a two-center, randomized controlled trial (n=80) to determine if Peri-Strip used as a buttress along the lung staple line would decrease air leaks and hospital stays after lobectomy and segmentectomy. Patients were randomized to Peri-Strip (n=40) or no Peri-Strip (n=40). There were no statistical differences in the mean intensive care unit length of stay (p=0.09), number of days with a chest tube (p=0.6), or total length of stay (p=0.24). Patients

treated with Peri-Strip had a 2 day mean duration of air leak and 5.9 day mean time to chest tube removal compared to three days and 6.3 days, respectively, for patients without Peri-Strip.

Stammberger et al. (2000) conducted a three-center randomized controlled trial to compare the effects of Peri-Strips Dry (PSD) (n=32) vs. no PSD (control group) (n=33) to reduce air leaks and shorten hospital length of stay on patients who underwent bilateral lung volume reduction surgery by video-assisted thoracoscopy using endoscopic staplers for severe emphysema. Number of cartridges used in the treatment group ranged from 8–24 and 10–26 in the control group. The median duration of air leaks ($p<0.001$) and the median drainage time ($p<0.045$) was significantly shorter in the PSD group. Four patients in the non-PSD group and three PSD patients required reoperation for persistent air leak and pneumothorax. There was no significant difference between the groups in the length of hospital stay. In three patients, PSD detached from the stapler before it was fired. Limitations of the study include the small patient population, short-term follow-up and heterogeneous emphysema morphology.

Permacol™
The Permacol Crosslinked Porcine Dermal Collagen Surgical Mesh (Medtronic, Minneapolis, MN), a xenograft, is a fibrous flat sheet comprised of acellular porcine dermal collagen and elastin (Medtronic, 2026). It is 510(k) FDA approved for "use to provide soft tissue repair or reinforcement in plastic and reconstructive surgery of the face and head" (FDA, 2002). Permacol is also proposed for use in inguinal hernia repair, abdominal wall repair, and colorectal surgery. In 2004, 510(k) FDA approval was given for Permacol® Surgical Implant "for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal wall defects and hernias, including but not limited to parastomal hernias. The Permacol® Surgical Implant T-piece is shaped for use in rectal intussusception repair, and the Permacol® Surgical Implant Rectocele-pieces are shaped for use in rectocele repair (FDA, 2005). Other Permacol products include ENDURAGen™ (distributed by Porex Corporation, Newnan, GA) specifically indicated for plastic and reconstructive surgery of the head and face, and Permacol™ Biologic Implant (distributed by Covidien, Mansfield, MA), a biologic mesh for hernia repair. The Permacol™ Injection agent is also available from Covidien.

The application of Permacol products has been investigated for multiple conditions including: various types of hernia repairs, rectocele repair, Frey's syndrome, nasal septal perforation, fecal incontinence, lip augmentation; facial augmentation; nasal wall deformity; orbital floor implants; as a substitute for tendon graft to repair rotator cuff tears; abdominal compartment syndrome; inquinal, Littre's, and paraesophageal hernia repairs; hernias in contaminated fields; complex abdominal wall repair; perianal fistulas; various urological, gynecological and plastic surgery indications and urodynamic stress incontinence (Dirani, et al., 2021; Vollebregt, et al., 2021; Sileri, et al., 2012; Wahed, et al., 2012; Bachman and Ramshaw, 2008; Hammond, et al., 2008; Hsu, et al., 2008; Papadogeorgakis, et al., 2008; Teicher, et al., 2008; Shaikh, et al., 2007). Case series, case reports and retrospective reviews with small patient populations (n=15-86) and short-term follow-ups lack the data needed to support the efficacy of Permacol in the treatment of these conditions.

Gossetti et al. (2021) conducted a prospective multicenter study to evaluate the safety and efficacy of the biologic surgical implant, Permacol, in the surgical treatment of complex abdominal wall reconstruction (CAWR) in adult patients (n=114) through 36 months postoperatively. Patients had a mean age of 60.8 ± 12.2 (29–87) years, 58.8% male, with a mean BMI of 31.2 ± 6.0 (18.7–45.4) kg/m^2. At 24 months, the cumulative hernia recurrence rate was 18.7% (17/91) and 22.4% (19/85) at 36 months. Reoperation for hernia repair within 36 months occurred in 12 (14.1%) patients. Patients reported improvement in the Carolina comfort scale (CSS) measures of severity of pain, sensation of mesh, and movement limitations between 6- and 36- months post-

surgery. Adverse events included 13 (11.3%) dehiscences, 11 (9.6%) wound infections, 11 (9.6%) seromas, four (3.5%) hematomas and one stoma site pain. Study limitations include small patient population, short term follow up, and lack of a comparator.

Maeda et al. (2013) conducted a systematic review investigating perianal injectable bulking agents for the treatment of fecal incontinence. Two randomized controlled trials using Permacol injection agent with a total of 12 patients were identified. There is insufficient data to support Permacol for the treatment of fecal incontinence.

Bano et al. (2005) conducted a randomized controlled trial to compare the use of Permacol injection (n=25) to silicone injection (Macroplastique) (n=25) in the treatment of urodynamic stress incontinence in women. Following injection, two women treated with Permacol had urinary retention requiring catheterization for one week compared to three women in the Macroplastique injection group requiring catheterization for 24 hour to three days. Regarding pad loss at six months, 15 Permacol patients remained dry (62.5%), seven were unchanged, one was worse and one relapsed. In the Macroplastique group, nine were dry, seven were unchanged, five were worse and two relapsed. Fourteen Permacol patients had a reduction in the Stamey scoring system and 14 in the King's College Hospital Quality of Health Questionnaire scores compared to ten and seven, respectively, in the Macroplastique.

Phasix Mesh™
Phasix™ Mesh (Davol, Inc., Warwick, RI) is a knitted monofilament mesh scaffold using Poly-4-hydroxybutyrate (P4HB), a biologically derived, fully resorbable material. The Mesh is FDA 510(k) approved and "indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result" (FDA, 2016, FDA, 2015).

There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of Phasix mesh for any indication. Studies report conflicting results with small patient populations (n=15-215) and most are limited to short term follow-ups (48 days to 43 months) and have primarily been in the form of prospective observational and restrospective reviews (Charleux-Muller, et al., 2021; Christopher, et al., June, 2021; Christopher, et al., Aug 2021; Christopher, et al., Dec 2021; Claessen, et al., 2021; Faulkner, et al., 2021; Levy, et al., 2021; van Driel, et al., 2021; van Rooijen, et al., 2021; Vauclair, et al., 2021; Aldohayan, et al., 2020; Rognoni, et al., 2020; Roth, et al., 2020; van Rooijen, et al., 2020; Yu, et al., 2019).

Roth et al. (2022) published sixty-month follow-up of a prospective multicenter study of Phasix Mesh for primary ventral or incisional or multiply recurrent hernia repair in a cohort at risk for complications (n=121). Fifty-four patients (44.6%) completed the 60-month follow-up. There were no mesh-related complications identified beyond the early postoperative period, and no mesh infections or mesh-related complications during the study period. The authors acknowledged, however, that the ability to draw definitive conclusions regarding long-term mesh-related complications is limited due to the relatively low number of patients completing the 60-month follow-up. **LOE: 3**

Morrison et al. (2022) conducted a retrospective single-center case series to examine long-term outcome data and directly compare hernia recurrence of ventral hernia repair with biosynthetic mesh (i.e., Phasix) versus synthetic mesh. Clinical outcomes did not vary significantly between the two groups other than the in the frequency of seroma formation; 17 patients (16.8%) in the biosynthetic mesh group compared to 31 patients (9.2%) in the synthetic mesh group. The authors noted that a low percentage of postoperative seromas are symptomatic or require intervention, however. There was no significant difference in hernia recurrence between the two

groups; both mesh types had recurrence-free survival rates of approximately 72%. The authors noted that future studies are needed that control for wound classification and hernia repair techniques to further define the advantages and disadvantages of these biomaterials. **LOE:4**

Phasix™ Plug and Patch
Phasix™ Plug and Patch (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) is a fully resorbable monofilament knitted mesh constructed of monofilament Poly-4-Hydroxybutyrate (P4HB) which is pre-formed into a three-dimensional (cone shape) configuration constructed of a fluted outer layer and multiple inner layers (petals) of mesh attached at the tip. The Phasix™ Plug and Patch is FDA 510(k) approved for reinforcement of soft tissue where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects. The device is proposed to support host tissue formation at the repair site and gradually degrade via hydrolysis within 12 to 18 months or until fully resorbed. Phasix Plug and Patch come in four sizes: 2.5x3.6 cm, 3.3x4.1 cm, 4.1x4.8 cm, 3.8x5.1 cm (BD, 2026; FDA, 2012). There is insufficient evidence in the published peer-reviewed literature to support the efficacy of this product.

PhotoFix® Decellularized Bovine Pericardium
PhotoFix Decellularized Bovine Pericardium (Artivion, Inc. formerly CryoLife®, Kennesaw, GA) is a cardiovascular patch prepared from bovine pericardium which is stabilized using a dye-mediated photo oxidation process, using ethylene oxide and sterilized using aseptic processing techniques. The photooxidation process creates crosslinks in the bovine tissue. No aldehyde chemistry is used during any phase of manufacturing including the tissue fixation or sterilization processes (Artivion, 2026; FDA, 2017). It is proposed for intracardiac repair, great vessel repair, suture line buttressing, pericardial closure and vascular repair and reconstruction of the carotid, iliac, femoral, tibial blood vessels and arteriovenous access revisions. PhotoFix Decellularized Bovine Pericardium received FDA 510K approval on March 9, 2017 (K162506). It is supplied in the following sizes: 1cm x 1cm, 4cm x 4cm, 6cm x 8cm, 8cm x 14cm, 10cm x 16cm, 14cm x 16cm (FDA, 2017). There is insufficient evidence in the peer-reviewed literature to support Photofix bovine pericardium patch for any indication. Studies are primarily in the form of retrospective reviews (Baird et al, 2017; Majeed et al, 2016).

Polygon3 Membrane
Polygon3 Membrane (Amnio Technology, LLC, Phoenix, AZ) is a dehydrated human allograft derived from the placenta, consisting of two layers of amniotic membrane with a chorionic layer in the middle. It is intended for use in all ages of individuals with non-healing acute and chronic wounds (diabetic, venous, mixed venous-arterial, pressure ulcers), complex and/or open surgical wounds. Polygon3 Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a covering or barrier and to protect the wound (CMS, 2025). It is applied per square centimeter based on wound size. There is insufficient evidence to support the safety and effectiveness of Polygon3 Membrane for any indication.

Preclude® Pericardial Membrane
Preclude Pericardial Membrane (Gore Medical, Flagstaff, AZ) is FDA 510 (k) approved for the reconstruction or repair of the pericardium. The membrane is a biocompatible, expanded polytetrafluoroethylene and is proposed for use with left ventricular assist devices and artificial hearts. Preclude is available in three sizes and lengths (Gore, 2026). There is insufficient evidence to support the safety and efficacy of Preclude. The manufacturer's information warns that the safety and efficacy of Preclude Pericardial Membrane in preventing adhesion formation between tissues or between tissue and a mechanical circulatory assist device has not been proven. Clinical trial data are currently unavailable.

Preclude® Vessel Guard

Preclude Vessel Guard (Gore Medical, Flagstaff, AZ) is an FDA 510(k), Class II approved device which was submitted to the FDA as a proposal for a new indication for the Gore Acuseal Cardiovascular Patch. The new indication is marketed under the name of Gore Preclude Vessel Guard. The Vessel guard is FDA approved "as a cover for vessels following anterior vertebral surgery to reduce the risk of potential vessel damage during a revision surgery by providing a plane of dissection". The device is made of polytetrafluoroethylene (fluoropolymer (ePTFE and fluoroelastomer). The Guard is proposed to reduce the risk of potential vessel damage during reoperations and revision surgeries by allowing a clear plane of dissection and facilitating retraction of a vessel to minimize tissue attachment. Preclude Vessel Guard is proposed for the following surgical indications: lumbar interbody fusion, adjacent level disc treatment, total disc replacement, hardware removal, instrumented scoliosis reconstruction, corpectomy for tumor or trauma, open vascular treatment, and also staged procedures or reoperations for any of these procedures. Two sizes are available (5x6 cm, 6x10 cm). There is insufficient evidence in the published clinical studies to support the safety and efficacy of the Preclude Vessel Guard.

Pretect
Pretect (Stimlabs LLC, Roswell, GA) is a dehydrated human amniotic membrane obtained from donated placental tissue. The product is intended for use as a barrier membrane or protective wound covering to protect wounds from the surrounding environment and is indicated for use over acute and chronic wounds, such as dermal wounds and surgical defects. Pretect is not intended for use in pediatric populations or for ocular use. Pretect is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier membrane or wound covering" and "not intended for wound healing" (CMS, 2025). Pretect is offered in a variety of sheet sizes. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Pretect for any indication.

Pro3™
The Pro3™ products (Paragon 28, Inc., Englewood, CO) include the Pro3™-F (frozen) and Pro3™-FA (ambient) liquid matrix allografts derived from amniotic fluid. Pro3 amniotic fluid is proposed for use in joint capsules to provide shock absorption, lubrication, and joint stability. Pro3-Placenta Amniotic Placental Membrane and Pro3-Cord Amniotic Umbilical Cord Membrane are tissue matrixes proposed for use as therapeutic grafts for multiple indications including wound care; burn care; oral surgery; urological wrap; and spinal and neurosurgery adhesion barrier, wrap and patch (Paragon 28, 2026). The Pro3 Placental Membrane is a thin graft available in 2x3 cm, 4x4 cm, 4x8 cm, 7x7 cm, and 2x12 cm sizes. The Pro3 Cord Membrane is eight times thicker than the Membrane and available in 2x3 cm and 3x6 cm sizes (Paragon 28, 2026). There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of the Pro3 products.

Proceed® Surgical Mesh
Proceed® Surgical Mesh (Ethicon Inc., Somerville, NJ) is a laminate mesh designed for the repair of hernias and other fascial deficiencies. The mesh is comprised of an oxidized regenerated cellulose (ORC) fabric, and Propolene™ Soft Mesh, a nonabsorbable polypropylene mesh, which is encapsulated by a polydioxanone polymer. The polypropylene mesh side allows for tissue ingrowth and the ORC side is proposed to provide a bioresorbable layer to physically separate the polypropylene mesh from underlying tissue and organ surfaces to minimize tissue attachment to the mesh during healing. Proceed is FDA 510(k) approved "for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The mesh is available in a variety of shapes and sizes (Ethicon Inc., 2025; FDA, 2016).

There is insufficient evidence in the published peer-reviewed literature to support Proceed Surgical Mess for any indication. The evidence is primarily in the form of animal studies, retrospective

reviews, feasibility studies and small case series (n=22-36) with short-term follow-up (1–36 months) (Bhanot, et al., 2013; Eltayeb, et al., 2013; Rosenberg, et al., 2008).

ProgenaMatrix™
ProgenaMatrix (ProgenaCare, Marietta, GA) is a hydrated keratin wound matrix manufactured from human keratin and other proteins extracted from human hair. ProgenaMatrix is FDA 510(k) approved as a dressing for the treatment of "dry and exuding partial and full thickness wounds such as: pressure (stage I-IV) and venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, donor sites and grafts, first and second-degree burns, superficial injuries, cuts, abrasions and surgical wounds". It is not intended to be used for the treatment of third-degree burns. The Matrix is applied directly to the wound bed following debridement. It is available in 2x2 cm, 4x4 cm, 6x6 cm, 10x10 cm, and 12x12 cm sizes (CMS, 2019; FDA, 2019). There is insufficient evidence in the peer-reviewed literature to support the safety and effectiveness of ProgenaMatrix.

ProLayer®
ProLayer Acellular Dermal Matrix (manufactured by AlloSource, Centennial, CO; distributed by Stryker Corp., Mahwah, NJ) is a human allograft with a three-dimensional collagen elastin matrix proposed to allow cells to infiltrate and repopulate for revascularization and remodeling of wounds. ProLayer is proposed for use for a variety of clinical applications including wound coverage, tendon augmentation, and surgical closure. The matrix is available in 13 sizes ranging from 2x4 cm to 6x12 cm in 1.0- 3.3 mm thickness. ProLayer Xenograft is an acellular porcine dermal matrix proposed for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue (Stryker, 2026). There is insufficient evidence to support the safety and efficacy of Prolayer and ProLayer Xenograft. Available data are primarily from animal studies.

ProMatrX™
ProMatrX ACF (Amino Regen Solutions, Las Vegas, NV) is a human liquid allograft comprised of amnion and amniotic fluid and proposed for the repair and healing of wounds. The product contains growth factors, cytokines, amino acids, carbohydrates, hyaluronic acid, and extracellular matrix (ECM) proteins. ProMatrX™ ACF is manufactured and regulated for human homologous allograft use under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. It is processed and packaged at an FDA registered and American Association of Tissue Banks (AATB) accredited facility. ProMatrX may be applied topically or implanted for wound care and may be diluted to any ratio (1:1 recommended). The prescribed dosage varies by the size of the wound. Typical doses range from 0.25 cc to 4.0 cc, depending on the size, depth and type of wound. The product is supplied in liquid form in vials containing 0.25 cc, 0.5 cc, 1 cc, 2 cc, and 4 cc (CMS 2016). There is insufficient evidence in the published peer reviewed literature to support the safety and efficacy of ProMatrX.

Promote™ Amnio-FRT™ or Promote™ Amnio F™
Amnio FRT (AllianceSpine™, San Antonio, TX) is a flowable tissue allograft derived from human amniotic fluid. Amnio F is a cryopreserved allograft derived from human amniotic fluid. The products are proposed for use as a topical application over wounds. Collection of the donor placental tissue is performed and processed in accordance with the standards and guidelines established by the American Association of Tissue Banks (AATB). Both Amnio F (2.0 mL) and Amnio FRT (0.5 mL, 1 mL, 2 mL) come in liquid format. There is insufficient evidence to support the safety and efficacy of Promote Amnio-FRT or Promote Amnio F for wound healing.

Promote AmnioStrip®
Promote AmnioStrip (AllianceSpine™, San Antonio, TX) is a placental tissue product supplied as a dual layer amnion patch for wound management. It is proposed to reduce scarring of dermal and

subcutaneous wounds, reduce dural and nerve root adhesions, prevent adhesions to implanted hardware and in tendon grafts. Promote Amnio Strip is processed in accordance with the safety guidelines provided by the U.S. Food and Drug Administration (FDA) Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271) and the standards from the American Association of Tissue Banks (AATB). The product is available in the following sizes: 3cm x 3cm, 4cm x 4cm, 4cm x 6cm (AllianceSpine, 2025). There is insufficient evidence to support the safety and efficacy of Promote AmnioStrip for wound management.

Puracol®
Puracol, Puracol Plus and Puracol Plus Ag (Medline Industries, Inc., Mundelien, IL.) are type I bovine 100% collagen wound dressings. The dressings are proposed for the treatment of partial- and full-thickness wounds, pressure ulcers, venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first- and second-degree burns, donor sites and other bleeding surface wounds, abrasions, trauma wounds, dehisced wounds, and/or surgical wounds. Puracol is a primary wound dressing proposed for all drainage types. Puracol Plus is proposed for chronic or stalled wounds. Puracol Plus Ag with silver chloride is proposed for stalled wounds when the antimicrobial properties of silver are desired. Puracol Plus Ag is FDA 510(k) approved for the management of wounds. These products are offered in 2x2 cm, 4x4 cm and 8x8 cm sizes and as a 1x8 cm rope. The rope configuration is proposed for tunneling wounds. Puracol Ultra Powder is a filler that absorbs the wound's fluids to form a gel-like barrier to protect the wound bed. The powder is proposed for the treatment of irregular shaped wounds and is available in a 1G pouch (Medline, 2026; FDA, 2008). There is insufficient evidence to support the Puracol products for the treatment of wounds. Studies are primarily in the form of case reports and small case series (n=5).

PuraPly™ (previously Fortaderm™)
Fortaderm Wound Dressing (PuraPly) and Fortaderm Antimicrobial Wound Dressing (PuraPly Antimicrobial Wound Matrix) (Organogenesis, Inc., Canton, MA) were FDA 510(k) approved in 2001 and 2005, respectively. Fortaderm Wound Dressing (PuraPly wound matrix) is a single-layer fenestrated porcine allograft. The FortaDerm Antimicrobial Polyhexamethylene Biguanide Hydrochloride (PHMB) is FDA approved for the management of wounds and as an effective barrier to resist microbial colonization within the dressing and reduce microbes penetrating through the dressing. Both PuraPly products are proposed for the management of partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds and draining wounds (Organogenesis, 2025. Per the FDA, PuraPly is the proprietary name for FortaDerm (CMS, 2014; FDA, 2005; FDA 2001).

PuraPly AM is a five-layer fenestrated and cross-linked sheet of porcine collagen, coated with polyhexamethylene biguanide hydrochloride (PHMB) which is proposed to resist microbial colonization and reduce microbial penetration within the matrix. The product is supplied in sheet form (Organogenesis, 2025; CMS, 2018). There is insufficient evidence in the peer-reviewed literature to support the clinical utility of the PuraPly products.

PX50®/PX50® Plus
PX50/PX50 Plus (Skye Biologics, Inc., Redondo Beach, CA) are products made from human tissue allografts derived from decellularized particulate placental, connective tissue matrix. The matrix includes extracellular components, growth factors and collagen scaffolds. PX50 and PX50 Plus are proposed for the treatment of acute or chronic tendon or muscular injuries. PX50 is a ready-to-use flowable matrix and PX50 Plus is a cryopreserved form that must be kept frozen until used. Both preparations come in a 0.5 cc size. Sky Biologics also offers additional products in larger sizes for more complex injuries. There is insufficient evidence in the peer-reviewed literature to support the

effectiveness of PX50 or PX50 Plus. Studies are primarily in the form of small (n=10) retrospective reviews (Lullove, 2015).

RECELL® Autologous Cell Harvesting Device

The RECELL® Autologous Cell Harvesting Device (Avita Medical, Valencia, CA) is a sterile, single use, stand-alone, battery powered cell separation device operated by an appropriately licensed healthcare professional at the patient's point of care (Avita Medical, 2026). It is used to prepare autologous Regenerative Epidermal Suspension (RES®) for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. The device enables the processing of a small, thin split-thickness skin sample 0.006-0.008 inch (0.15-0.20 mm) in depth to prepare a cell population in suspension for immediate delivery onto a prepared wound surface. The user can enzymatically and mechanically process a small skin sample to produce RES. Processing tools provided with the device include off-the-shelf syringes, scalpels, and fill needles. The device also includes nozzles that attach to syringes and can be used to aerosolize the cell suspension onto the wound. The proprietary RECELL Enzyme is reconstituted with sterile water (included) and used to facilitate disaggregation of cells from the harvested donor skin. A buffer solution is also provided to suspend the disaggregated cells for delivery to the prepared wound site. No cell culturing processes are involved in the procedure. The resulting suspension of cells comprises a mixed population predominantly of keratinocytes and fibroblasts. The presence of viable melanocytes has also been demonstrated. The RECELL Autologous Cell Harvesting Device received FDA Premarket Approval (PMA) on 09/20/2018 for treatment of acute thermal burns in adults and the indication was expanded in 2021 for use in combination with meshed autografting for acute full- thickness thermal burn wounds in pediatric and adult patients (PMA Number: BP170122) (FDA, 2022). There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of the RECELL Autologous Cell Harvesting Device for the treatment of burns. Studies have primarily been in the form of case reports and one small randomized control trial (Holmes, et al., 2019)

Bairagi et al. (2021) conducted a systematic review and meta-analysis of randomized control trials to evaluate the efficacy of autologous skin cell suspensions (ASCS) on the re-epithelialization of partial thickness burn injuries and skin graft donor site wounds (DSW). Five studies (n=347) were located: two studies on adults (n=183) and one study on children with burn wounds (n=13), and two studies on adults with donor site wounds (n=151). Studies were included if they were on humans with partial thickness burn injuries and split-thickness skin graft donor site wounds. The intervention was autologous skin cell suspension prepared with the RECELL autologous cell harvesting device. The non-cultured mixture of epithelial cells was used in suspension format as a spray or droplet application in the wound management for treatment of burn wounds or split-thickness skin graft donor sites. Comparators included standard of care dressings/treatment with or without a skin graft. Primary outcome measured was wound time to re-epithelialization (TTRE). Secondary outcomes measured included pain, scar sensitivity (itch, tightness), scar characteristics (pigmentation, thickness), scar specific health related quality of life, infection and need for additional surgery. Length of follow up ranged from 12–52 weeks. Two studies reported on the use of ACSC in adult burn wound re-epithelialization compared to control group and had different methods of reporting the results. One study reported ASC had a reduced percentage of re-epithelialization (standardized mean difference [SMD] -0.27, [95% CI: -0.57, 0.03]). The second study reported ASCS increased the TTRE (SMD 0.50, [95% CI: 0.06, 0.94]). However, the time to re-epithelialization was decreased (SMD -1.75, [95%CI: -3.45, -0.05]) in pediatric BW, when ASCS was compared to control group. In adults DSW, ASCS significantly reduced time to re-epithelialization compared to the control group (SMD -5.71, [95% CI: -10.61, -0.81]). Pain was reported using the Visual Analogue Scale (0-100 VAS) in adults and age-appropriate scales for the children, either the Children and Infant's Post-operative Pain Scale (CHIPPS, 0-23 months), Face, Legs, Activity, Cry and Consolability Scale (FLACC, 2-7 years), or the Revised Faces Pain Scale

(FPS-R, older children). Adult BW pain was reduced when treated with ASCS (SMD -0.62, [95% CI: -0.90, -0.35]). One study on adult DSW reported reduced pain when treated with ASCS (SMD -6.80, [95% CI: -7.30, -6.30]) and a second study reported low pain scores in both ASCS (median 1.7, IQR 1.3-2.1) and control (median 1.6, IQR 1.3-2.3) groups and not significantly different (p< 0.444). Pain in children with BW was reduced (SMD -0.24 [95% CI: -1.56, 1.08]) when treated with ASCS. Itch was reported in two studies. Adult BW reported no difference in incidence of itch between ASCS and control groups. Adult DSW reported no difference in itch intensity between ACSC and control. When compared to the control group, adult BW treated with ACSC (OR 1.52 [95% CI: 0.25, 9.27]) had 52% higher odds for surgical wound infection when compared to control. Conversely, adult DSW had 81% lower odds of cellulitis when treated with ASCS (OR 0.19, 95% CI: 0.01 to 4.11). Pediatric BW treated with ASCS had higher odds of sepsis and surgical wound infection (OR 3.00 [95% CI: 0.09, 95.17]) compared to control. Need for further surgery increased for BW patients treated with ASCS by 38% (OR 1.38 [95% CI: 0.46, 4.18]). Pediatric BW patients had 96% lower (OR 0.04 [95% CI: 0.00, 1.25) odds of needing another surgery when treated with ASCS compared to control. The authors reported the certainty of evidence was very low. Author noted study limitations included small number of studies, small sample size of studies, varied measurement of outcomes, and most studies were completed on adults which cannot be directly applied to children. Due to the low certainty of evidence, no conclusions can be drawn about the role of ASCS in partial thickness burn injury management.

A search of UpToDate and medical textbooks located several references describing the use of RECELL autologous cell harvesting procedure as a spray to cover a burn wound; however, no references were located to indicate that RECELL autologous cell harvesting procedure/device has become a generally accepted/standard of care (SOC) procedure in the management of thermal burns.

REGENETEN Bioinductive Implant

REGENETEN Bioinductive Implant (Smith & Nephew, Inc., Largo, FL) is a resorbable type I collagen matrix derived from highly purified bovine Achilles tendon. The REGENETEN Bioinductive Implant System (Smith & Nephew) is the new marketed name of the Rotation Medical Rotator Cuff System (Rotation Medical which was acquired by Smith & Nephew in October 2017). Rotation Medical Inc received FDA 510(k) approval (K140300) on March 24, 2014, for marketing the device with trade name: Collagen Tendon Sheet, common name: Tendon Protector, under the surgical mesh classification, class II device. A subsequent FDA 510(k) (K222501) was approved on May 11, 2023, for the Regeneten Bioinductive Implant for the same indication/intended use (FDA, 2023). The implant is proposed for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue (FDA, 2023; FDA, 2014). There is insufficient evidence in the peer reviewed published literature regarding the long-term outcomes, safety, and efficacy of Regeneten Bioinductive Implant in tendon repair to support the effectiveness of this product for any indication.

Ruiz Ibán et al. (2023) conducted a randomized controlled trial (RCT) (n=124) to evaluate the healing rate of the addition of a bioinductive collagen implant (BCI) compared to no implant in rotator cuff repair. Patients were randomized to either arthroscopic posterosuperior rotator cuff tear transosseous equivalent (TOE) repair performed alone (Control group – n=62) or with BCI applied over the TOE repair (BCI group – n=60). The primary outcome was the retear rate (defined as Sugaya 4-5) determined by MRI at 12 months of follow-up (n=122). Study results demonstrated a reduced retear rate (8.3% [5/60] in the BCI group vs 25.8% [16/62] in the Control group, (p=0.010); relative risk of retear of 0.32 [95% confidence interval 0.13-0.83]). Sugaya grade was also better in the BCI group (p=0.030). There were complications in 10 subjects, five having major complications. A total of two subjects (one from each group,1.6% of total) had postoperative deep infections requiring surgical debridement (the BCI implant was left in place in the BCI case), and prolonged antibiotic treatment. At 12-months, there were no

differences between groups in clinical outcomes or in complication rates. Additional well-designed RCTs are needed to establish the role of this bioinductive collagen implant (i.e., Regeneten) in the treatment of rotator cuff repair.

Renati AC Membrane
Renati AC Membrane (Pinnacle Transplant Technologies, Phoenix, AZ) is a dehydrated resorbable allograft derived from donated human placental birth tissue (amniotic membrane). It is intended for use as a wound covering and acts as a barrier for full and partial-thickness, chronic and acute wounds. Renati AC Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "wound covering" and "to act as a barrier to protect the wound" (CMS, 2025). The product is available in multiple sizes. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Renati AC Membrane for any indication.

Renuva® Allograft Adipose Matrix
Renuva® Allograft Adipose Matrix (MTF Biologics, Edison, NJ) is an injectable allograft adipose matrix processed from human adipose tissue. According to the manufacturer's Instructions for Use, it is proposed for the replacement of damaged or inadequate integumental adipose tissue matrix in areas of the body where native fat would exist and for the reinforcement or supplemental support in underlying adipose tissue matrix as the result of damage or naturally occurring defects (MTF Biologics, 2025). Renuva Allograft Adipose Matrix is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps). It is available in 1.5cc and 3cc. Evidence in the published peer-reviewed literature consists of an observational study (Gold, et al., 2020) and is insufficient to support the clinical effectiveness of Renuva Allograft Adipose Matrix for any indication.

Repliform ™
Repliform Tissue Regeneration Matrix (Boston Scientific, Marlborough, MA) is a non-crosslinked acellular human dermal allograft. Repliform Matrix is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. All tissue is processed and provided in accordance with the FDA's requirements for banked human tissue (21 CFR Part 1271) and Standards for Tissue Banking of the American Association of Tissue Banks (AATB). Repliform is proposed for the repair or replacement of damaged or inadequate integumental tissue as in the treatment of urinary incontinence, to repair enteroceles, rectoceles and/or cystoceles and for pelvic floor reinforcement or other conditions resulting from inadequate or damaged integumental tissue. The graft is available in seven sizes ranging from 2x4 cm to 6x12 cm. There is insufficient evidence to support the clinical effectiveness of Repliform. Studies are primarily in the form of retrospective reviews and case series with short-term follow-ups investigating Repliform for rectocele repair and transvaginal slings for stress urinary incontinence (Marinkovic, et al., 2016; Crivellaro, et al., 2004). Randomized controlled trials comparing Repliform to standard therapy used in these procedures are needed to further evaluate the safety, efficacy, long-term outcomes and complications of this matrix.

Restore® Orthobiologic Soft Tissue Implant
Restore Orthobiologic Soft Tissue Implant (DePuy Orthopaedics, Inc., Warsaw, IN) is an FDA 510(k) porcine small intestinal submucosa (SIS) device. Per the FDA it is "intended to reinforce soft tissue where weakness exists, specifically for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patella, Achilles, biceps, quadriceps, and other tendons." It may also be used during general tissue reconstruction of the periosteum. The device is proposed to be reabsorbed and replaced by the patient's own tissue (FDA, 2007). There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of Restore. Published studies consist primarily of case reports and in vitro studies. One randomized controlled trial (Bryant et al., 2016) concluded that it

is unlikely that the use of SIS with a standard rotator cuff repair offers better outcomes for patient with a moderate to large rotator cuff tear than surgery without SIS.

Bryant et al. (2016) conducted a pilot randomized controlled trial (n=62) to compare the effectiveness of rotator cuff repair with (n=34) and without (n=28) the use of a porcine small intestine submucosa (SIS) for patients with moderate to large rotator cuff tears. For patients randomized to receive the SIS, a Restore Orthobiologic Implant was extended over the repaired rotator cuff tendon and the tuberosity to which the tendon was attached and then sutured in place. The primary outcome was whether or not the patient had failed the procedure. Patients underwent standardized magnetic resonance arthrography (MRA) of the rotator cuff one year postoperatively to determine whether the defect had healed and, if it had not healed completely, whether the remaining full-thickness defect had increased by > 5 mm in any dimension from the immediate postoperative appearance. If such a defect was detected, the repair was classified as having failed. Secondary outcomes included pain, range of motion and quality of life. At the one-year follow-up the overall rate of failure was just under 60%. There was no significant difference in the absolute risk of failure between the two groups (p=0.33) or for any of the patient-reported outcomes at one year. Differences between groups in self-reported outcomes were consistently in favor of the control group, but the difference was small. There was no statistically significant difference (p=0.50) between groups in the number of days to being narcotic and pain free. From the SIS group, one patient experienced a deep infection six weeks postoperatively that required surgical washout and one patient experienced a rupture of the biceps tendon 12 months postoperatively that required surgical repair. Two patients experienced transient slight fever and warmth around the wound at week six. In the control group, one patient required a revision at 18 months; one required manipulation of the shoulder joint at 3 and 12 months postoperatively and one patient had a superficial wound infection. Limitations of the study include small patient population; number of patients lost to follow-up (n=7), six patients did not undergo preoperative MRI; six patients did not undergo postoperative MRA; variety of tear sizes, muscle atrophy, fatty infiltration, and reparability (i.e., medialization or remaining defect); and short-term follow-up. Additional data with large populations and long-term follow-ups are needed to establish the clinical utility of Restore Orthobiologic Implant for this indication. The authors concluded that it is unlikely that the use of SIS with a standard rotator cuff repair will offer superior outcomes to patients with a moderate to large rotator cuff tear.

Restorigin™
Restorigin Amniotic Fluid Therapy (AFT) (Parametrics Medical, Leander, TX) is processed in accordance with the United States Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB) standards. Restorigin Amniotic Fluid is a multipurpose, frozen allograft derived from amniotic fluid and contains growth factors and cytokines. The amniotic fluid is proposed to enhance healing when injected at the site of injury. Restorigin Amniotic Fluid Therapy (AFT) is applied directly at the site of injury, inflammation and pain. Available sizes include 0.25 ml, 0.5 ml, 1.0 ml and 2.0 ml. There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of Restorigin Amniotic Fluid Therapy.

Revita
Revita (StimLabs, LLC., Roswell, GA) is a lyophilized dehydrated human placental membrane allograft (StimLabs, 2026). The Clearify™ processing method is used to preserves all three layers of the amniotic membrane. Clinical applications are proposed for acute and chronic wound care. Data supporting the safety and effectiveness of Revita are lacking.

REVIVAL™ AC
REVIVAL™ AC (Samaritan Biologics LLC, Cordova, TN) is a dehydrated allograft derived from donated human amnion chorion membrane. It is Intended to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. REVIVAL AC

is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier" or "cover for acute and chronic wounds" (CMS, 2025). The graft is intended for external application, does not have to be removed from the wound bed, and can be reapplied as needed. There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of REVIVAL AC for any indication.

Revive FT
Revive FT (Acesso Biologics LLC dba Dynamic Medical Services, Las Vegas, NV) is a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue. Revive FT is a full-thickness amnion/chorion membrane. It is intended for use as a protective wound covering and barrier in acute and chronic wounds. Revive FT is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier" or "cover" (CMS, 2025). There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Revive FT for any indication.

Seamguard® Staple Line Reinforcement Material
Seamguard Staple Line Reinforcement Material (Gore Medical, Flagstaff, AZ) is a bioabsorbable membrane of synthetic polyglycolic acid and trimethylene carbonate copolymer for use in surgical staplers. The material is FDA 510(k) approved for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed (e.g., hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures) (Gore Medical, 2026; FDA, 2005).

There is insufficient evidence to support the use of Seamguard for staple line reinforcement. A randomized controlled trial (Senagore, et al., 2014) compared outcomes with Seamguard vs. no reinforcement (n=258) with a colorectal, coloanal, or ileoanal anastomosis. The study was terminated at the first planned interim analysis because of insufficient power to detect an intergroup difference in anastomotic leak rate between the two groups.

SimpliDerm™
SimpliDerm™ (Elutia formerly Aziyo Biologics, Silver Spring, MD) is a pre-hydrated human acellular dermal matrix minimally processed to remove epidermal and dermal cells and then preserved in an irradiation protection solution. The process utilizes a proprietary and patented technology to preserve the remaining bioactive components and extracellular matrix of the dermis. It is proposed for the repair or replacement of damaged or insufficient integumental tissue and for the repair, reinforcement, or supplemental support of soft tissue defects or any other homologous use of human integument (Elutia, 2025). The product is classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271). It is available in both Ellipse™ and rectangular sizes. There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of Simpliderm (Hydrated Acellular Dermal Matrix) for any indication. Studies have primarily been in the form of retrospective reviews (Tierney, et al., 2022) or case series (Gardner, et al., 2023; Tierney, et al., 2021).

SJM™ Pericardial Patch with EnCap™ AC Technology
SJM Pericardial Patch with EnCap™ AC Technology is a glutaraldehyde bovine pericardial patch (Glycar, Inc., Dallas, TX) with anti-calcification treatment that is proposed to enhance tissue healing and long-term tissue stability. The product was FDA approved under the trade name "glycar pericardial patch" as a 510(k) Class III device (K963967). The intended uses include pericardial closure, peripheral vascular reconstruction and repair, and cardiac and great vessel

reconstruction and repair. Cardiac and vascular repairs may include annular reconstruction, endocarditis leaflet repairs, septal defect repairs, and aortic root enlargement. The patch is provided in various sizes. Published clinical trials supporting the safety and effectiveness of SJM are lacking.

SomaGen® Meshed Tissue
SomaGen® Meshed Tissue (MTF Biologics, Edison, NJ) is an acellular human reticular dermal allograft that is processed in accordance with FDA regulations and AATB standards. It is proposed to be used as a wound care scaffold for the replacement of damaged or inadequate integumental tissue for a variety of large and complex wounds such as diabetic foot ulcers, venous leg ulcers, pressure ulcers, or for other homologous use. The product is available in the following sizes: 8cm x 9cm, 10.5cm x 13.5cm, 13cm x 17cm, and 17cm x 28cm (MTF Biologics, 2025). Evidence is lacking in the published peer-reviewed literature to support the clinical effectiveness of SomaGen Meshed Tissue for any indication.

SportMesh™
SportMesh (Biomet Sports Medicine, Warsaw, IN) is a synthetic device made from Artelon® (Artimplant, AB, Vastra Frolunda, Sweden) fibers. The device is a biodegradable temporary scaffold that is proposed to allow the body's cells to regenerate and heal. SportMesh is FDA 510(k) approved for "use in general surgical procedures for reinforcement of soft tissue where weakness exists" and "for reinforcement of soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery" (FDA, 2006). A second product, SportsMesh or Artelon Tissue Reinforcement mesh, is also FDA 510(k) approved based on the SportMesh predicate device for the same indications. Data supporting the safety and efficacy of SportMesh is lacking. Studies have primarily been in vitro or in the form of case reports with small patient populations (n=4) and short-term follow-ups (i.e., two weeks) (Huss, et al., 2008).

SteriShield™
SteriShield and SteriShield II (enovis, Wilmington, DE) are constructed from amniotic membrane and proposed as a wound covering, nerve protector, barrier for scar tissue adhesion, cover for implanted hardware and for use in various surgical procedures including bariatric surgery, orthopedic surgery and dental surgery. The products are processed in accordance to the FDA guidelines for banked human tissue and the American Association of Tissue Banks. SteriShield is a single layer preparation that comes in four sizes and SteriShield II is a dual layer patch that comes in eight different sizes. There is insufficient evidence to support SteriShield for these indications.

Strattice™ Reconstructive Tissue Matrix
Strattice Reconstructive Tissue Matrix (Allergan™, Parsippany, NJ [formerly LifeCell™ Corporation, Branchburg, NJ]), a surgical mesh, is an acellular, xenographic tissue matrix derived from porcine dermis. It is FDA 510(k) approved as LTM-RC surgical mesh "for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. The implant is intended for the reinforcement of soft tissues repaired by sutures or suture anchors, during rotator cuff surgery. Indications for use also include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome" (Allergan, 2025; FDA, 2007). The Matrix is also available in a perforated form. There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of Strattice for any indication.

Breast reconstruction: Life Cell Corporation has proposed Strattice for use during postmastectomy breast reconstruction to support medial repair for breast pocket size and position. In June 2015 the FDA issued a warning letter to LifeCell Corporation stating that the FDA approval for Strattice did not include the use of Strattice for breast reconstruction. Per the FDA, this

indication falls outside of the intended use "because surgical mesh has not been cleared or approved for use in breast reconstructive surgery applications". The FDA requested that Life Cell "immediately cease activities that result in the misbranding or adulteration of the Strattice Reconstructive Tissue Matrix" for breast reconstruction.

Abdominal Wall Defect: Zerbib et al. (2015) conducted a prospective study (n=18) to evaluate the long-term outcomes of Strattice when used as a reinforcement for infected, abdominal wall defects. Subjects had an abdominal wall defect with enterocutaneous fistula or infected prosthetic mesh, considered to be grade IV. The primary outcome measure was the hernia recurrence rate. Follow-ups ranged from 3–22 months (median, 13 months). Length of hospitalizations ranged from 4–56 days (median, 13 days). Fourteen patients were evaluated. Postoperative complications included skin dehiscence (n=3), wound infection (n=2), skin necrosis (n=1), and seroma (n=2). At the last follow-up, six patients (43 %) experienced abdominal wall defect recurrence, three mesh infections and three enterocutaneous fistula patients. After 13 months of follow-up, 57% of patients had a clean and solid abdominal wall. No mesh exposition was observed and no Strattice removals were performed. Limitations of the study include the small patient population, short-term follow-ups, patients lost to follow-up and lack of a comparator.

Abdominal Wall Ostomy: Fleshman et al. (2014) conducted a multicenter, randomized controlled (n=113) to assess the safety and efficacy of Strattice dermal matrix for parastomal reinforcement in patients undergoing standard end-stoma reconstructions for permanent abdominal wall ostomy. Strattice was applied in the study group (n=55) but not in the control group (n=58). The primary outcome measure was the occurrence of parastomal hernia by the 24-month follow-up. Secondary outcome measures included a comparison of early (≤30 days) and late (>30 days) stoma-related complication, as well as quality-of-life measurements. At the 24-month follow-up, there was no significant difference in the incidence of parastomal hernias between the two groups, intraoperative complications and blood loss and quality of life scores. Strattice did not significantly reduce the incidence of parastomal hernia. Limitations of the study include the inclusion of ileostomy and colostomy patients, heterogeneity of operative procedures and loss of patients to follow-up (n=12).

Hernia Repair: Bellows et al. (2014) conducted a randomized controlled trial to evaluate the safety and efficacy of Strattice (n=84) vs. UltraPro (Ethicon, Semerville, NJ) (n=88) when used in a Lichtenstein's tension-free hernioplasty. Ultrapor is a lightweight, partially abosorbable, polypropylene mesh. Subjects were adult males, age ≥ 18 years, with a primary, unilateral, non-emergent inguinal hernia. The hernia types were indirect (54 %), direct (31 %), pantaloon (14 %), and other (1 %). Data reported herein are the three-month follow-up results of an ongoing 24-month study. The primary endpoint is resumption of activities of daily living (ADL) at the one-year follow-up. Secondary outcome measures include long-term pain (persistent groin pain or discomfort affecting ADLs for more than three months postoperatively), postoperative complications, and incidence of recurrence. The average mesh size was significantly larger in the Ultrapro group ($p=0.002$). The mean surgical time was significantly less in the Ultrapro group ($p=0.02$). There were no significant differences between the two groups in duration of hospitalization. Six patients in the UltraPro group vs. three in the Strattice group had an overnight stay. At the three-month follow–up, there were no statistically significant differences in the occurrence or type of wound complications ($p=0.069$), restrictions of ADL, postoperative groin pain ($p=0.25$), and C-reactive protein level. There was significantly less pain reported in the first three postoperative days in the Strattice group ($p<0.05$) and no hernia recurrences. However after the first three days there was no reported advantage of Strattice in terms of chronic pain. There was no advantage to using Strattice over the synthetic mesh. Limitations of the study include the short-term follow-up, heterogeneity of hernia types and absence of female patients.

Itani et al. (2012) conducted the Repair of Infected or Contaminated Hernias (RICH) prospective, multicenter study (n=80) to evaluate the clinical outcomes of open repair of ventral incisional hernia of contaminated abdominal defects using Strattice. Patients were age ≥ 18 years with hernias ≥ 9 centimeters^2 (cm^2) and reparable using a single sheet (up to 20 X 20 cm) of Strattice. Hernia defects were 'clean-contaminated' (n=39), 'contaminated' (n=39), or 'dirty' (n=2), and the defects were classified as grade 3 (n=60) or grade 4 (n=20). The midline was restored, and primary closure was achieved in 64 patients; the defect was bridged in 16 patients. Strattice was placed in the retrorectus or intraperitoneal space as an underlay and as an on-lay in three patients. The primary outcome was the incident of wound events (e.g., inflammation, seroma, hematoma, dehiscence, reoperation). At 24 months postoperative, 95 wound events were experienced by 53 patients including 22 seromas. There were 28 unique, infection-related events in 24 patients. There were 15 hernia recurrences at 12 months and 22 at 24 months. Seven patients underwent repair within the study period. Limitations of the study include the small heterogeneous patient population, short-term follow-up and lack of a comparator.

Stravix™
Stravix (Osiris Therapeutics, Inc., Columbia, MD, a subsidiary of Smith & Nephew, Andover, MA) is a cryopreserved human placental tissue comprised of umbilical amnion and Wharton's jelly, a gelatinous substance within the umbilical cord. Stravix retains the extracellular matrix, growth factors, and endogenous neonatal mesenchymal stem cells, fibroblasts, and epithelial cells. The product is proposed as a surgical covering or wrap for damaged or inadequate integumental tissue. The matrix is available in 2x2 cm, 2x4 cm and 3x6 cm sizes (Smith & Nephew, 2026). There is insufficient evidence to support the safety and effectiveness of Stravix.

Summit AAA/Summit AC/Summit FX
Summit AAA (Legacy Medical Consultants, LLC, Fort Worth, TX) is a triple-layer graft consisting of amnion/amnion/amnion membrane, Summit AC is a dual-layer amnion/chorion membrane allograft, and Summit FX is a fenestrated dual-layer amnion/amnion membrane allograft. The products are single use, dehydrated, resorbable allografts derived from donated human placental birth tissue. Summit AAA, Summit AC, and Summit FX are proposed for use as a protective wound covering and barrier in acute and chronic wounds and are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "covering or barrier" (CMS, 2025). There is insufficient evidence in the peer-reviewed literature to support the clinical effectiveness of Summit AAA, Summit AC, and Summit FX for any indication.

SurGraft® FT/SurGraft® TL/ SurGraft® XT/ SurGraft AC/SurGraft ACA
SurGraft (Surgenex®, LLC, Scottsdale AZ) Allograft Membranes are dehydrated, terminally irradiated amnion derived membranes that are available in multiple configurations and sizes. SurGraft is a single layer, SurGRaft XT is a dual layer, and Surgraft TL is a triple layer amnion derived allograft (Surgenex, 2026). SurGraft FT is a full thickness dehydrated amniotic and chorionic tissue allograft derived from donated human amniotic and chorionic membrane. SurGraft AC is a dehydrated dual-layer amnion chorion membrane allograft and SurGraft ACA triple-layer amniotic/chorionic/amniotic membrane allograft. Each product is proposed for the treatment of non-healing wounds and burn injuries. SurGraft Allograft Membranes are proposed for use in patients with acute or chronic wounds, including chronic, non-infected, diabetic foot ulcers; chronic, non-infected, partial or full-thickness diabetic foot skin ulcers (due to venous insufficiency); pressure ulcers; and surgical wounds and burns which have not adequately responded to conventional therapy." Data supporting the clinical effectiveness of SurGraft Allograft Membranes are lacking.

SurgiMend®

SurgiMend or SurgiMend Collagen Matrix (Integra LifeSciences, Princeton, NJ) is an acellular dermal tissue matrix derived from fetal or neonatal bovine dermis. The matrix acts as a scaffold that is progressively integrated, remodeled, and replaced by the functional host tissue. Approved as a Class II, FDA 510(k) device, SurgiMend is "intended for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damage or ruptured soft tissue membranes" specifically for plastic and reconstructive surgery, muscle flap reinforcement, and hernia repair (e.g., abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, incisional) (FDA, 2009). SurgiMend Collagen Matrix is available in 1.0, 2.0, 3.0 4.0 mm thicknesses and multiple sizes up to 25x40 cm. SurgiMend-e is a collagen matrix specifically designed for application in ventral hernia repair and is available in 3 mm and 4 mm thicknesses and one size, 10x25X3 mm. SurgiMend PRS, a pure collagen product, is designed for plastic and reconstructive surgery and is available in multiple shapes, sizes and thicknesses (Integra LifeSciences, 2023).

Historically, TEI Biosciences Inc. had marketed SurgiMend for breast reconstruction. In May 2015, the FDA issued TEI Biosciences Inc. a warning letter stating that TEI did not have FDA clearance or approval to market SurgiMend for breast reconstruction. Per the FDA, this indication falls outside of the intended use "because surgical mesh has not been cleared or approved for use in breast reconstructive surgery applications". The FDA requested that TEI Biosciences Inc. "immediately cease activities that result in the misbranding or adulteration of SurgiMend" for breast reconstruction (FDA, 2015).

Studies, primarily in the form of case reports and retrospective reviews, have evaluated SurgiMend for the treatment of necrotic heel decubitus ulcers; repair of recurrent ventral hernia, enterocutaneous fistula, Achilles tendon, rupture of tibialis anterior tendon, posterior tibiotalar ligament, damaged cartilage; tendon-lengthening procedures; foot and ankle tendon reattachment procedures; and to promote biologic regeneration of tendon tissue around a supporting suture to prevent a large tissue gap (Cromwell, et al., 2009). Although not FDA approved for breast reconstruction, some studies have evaluated SurgiMend for this indication (Wazir, 2022; Butterfield, et al., 2013; Gaster, et al., 2013; Ohkuma, et al., 2013; Endress, et al., 2012; Craft, et al., 2011). There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of SurgiMend for all indications.

tarSys™
tarSys (IOP Inc., Costa Mesa CA), also called Surgisis Ocular Graft, is a porcine small intestinal submucosa (SIS). The graft is FDA 510(k) approved for "implantation to reinforce and support the reconstruction of the soft tissue of the eyelid" (FDA, 2005). Studies are primarily in the form of case reports and retrospective reviews of 2-37 patients (Kim, et al., 2014; Liao and Wei, 2013). There is insufficient evidence to support tarSys for eyelid reconstruction.

TEXAGEN™ Amniotic Membrane Allograft
TEXAGEN™ Amniotic Membrane Allograft (Sanara MedTech Inc., Fort Worth, TX) is a semi-transparent, collagenous membrane derived from the amnion and chorion layers of the amniotic sac. It is proposed for use as a soft tissue barrier and wound covering. The product is classified as a human tissue and cell-based product regulated by the American Association of Tissue Banks (AATB) and in compliance with U.S. FDA regulations (21 CFR 1271) (Sanara MedTech, 2026). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of TEXAGEN Amniotic Membrane Allograft for any indication.

TissueMend Soft Tissue Repair Matrix
TissueMend Soft Tissue Repair Matrix (Stryker, Portage, MI), an acellular bovine collagen matrix, is 510(k) FDA approved for "reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons" (Stryker, 2026; FDA, 2006). It is a remodelable scaffold replaced by

the patient's own soft tissue during the healing process (Coons and Barber, 2006). Data from clinical trials to establish the efficacy of this matrix are lacking.

Tornier® BioFiber™ Scaffold and Tornier® Collagen Coated BioFiber Scaffold
There are two Tornier BioFiber Scaffolds (Tornier, Inc. Edina MN). The Tornier Collagen Coated BioFiber Scaffold is a bi-layer, synthetic absorbable reinforced woven fabric made from P4HB (poly 4-hydroxybutyrate) fibers (HealthManagement, 2026). The device is FDA 510(k) approved for "use where temporary wound support is required to reinforce soft tissues where weakness exists or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result". The 510(k) FDA approved predicate device is the BioFiber Absorbable Biological Scaffold for soft tissue repair and reinforcement. BioFiber is an orthopedic absorbable polymer soft tissue scaffold proposed for reinforcement of suture-tendon interface and tendon repair. Biofiber is proposed for a wide range of orthopedic indications including repairs of the shoulder, knee, hip, and foot/ankle (FDA, 2012). There is insufficient evidence supporting the safety and efficacy of the Tornier BioFiber Scaffolds.

TranZgraft
TranZgraft (Berkeley Biologics, Richmond, CA) is a sports graft proposed for the treatment of sports related injuries, including tendons and ligaments. The human tissue preparation is compliant with the FDA, AATB and state regulatory requirements (Berkeley Biologics, 2026). There is insufficient evidence published in the peer-reviewed literature to support the safety and effectiveness of TranZgraft.

Tutopatch® Bovine Pericardium
Tutopatch Bovine Pericardium (RTI Surgical, Inc., Alachua, FL) is a solvent-dehydrated gamma irradiated bovine pericardium mesh consisting of collagenous connective tissue with multidirectional fibers. The product is FDA 510(k) approved as a Class II surgical mesh indicated for the reinforcement of tissue during general and plastic surgery repair. It is intended for use "to reinforce soft tissue where weakness exists in general and plastic surgery applications and is indicated for pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which includes: gastric banding, muscle flap reinforcement, repair of rectal prolapse using an abdominal approach (excluding rectocele), reconstruction of the pelvic floor using an abdominal approach (excluding transvaginal repair of pelvic organ prolapse), and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, ventral, scrotal, and umbilical)". The mesh is available in 6x8 cm, 6x18 cm, 8x11 cm, 8x14 cm, 8x16 cm, 8x18 cm, 10x12.5 cm, 10x16 cm, 12x12 cm, 12x16 cm, and 14x20 cm. sizes. The product is also available in an oval fenestrated mesh design, Tutomesh® Fenestrated Bovine Pericardium is available in 10x16 cm and 13x22 cm. (FDA, 2012). There is insufficient evidence in the published peer-reviewed literature supporting the safety and effectiveness of Tutopatch Bovine Pericardium and Tutomesh.

Tutoplast® Pericardium Allograft/Tutoplast Processed Pericardium
Tutoplast® Pericardium Allograft, also known as Tutoplast Processed Pericardium (Coloplast Corp, Minneapolis MN) is a dehydrated, processed pericardium from donated human tissue (Coloplast Corp, 2026). According to the product's Instructions for Use, the implant is preserved using the Tutoplast tissue sterilization process. It is proposed to retain the three-dimensional collagen structure responsible for the multidirectional, mechanical properties of the original pericardium tissue. Tutoplast Processed Pericardium is regulated as a 361 human cell and tissue product (HCT/P) as defined in USFDA 21 CFR 1271 and is restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). The product is available in various sizes. There is insufficient evidence in the published peer-reviewed literature supporting the safety and effectiveness of Tutoplast® Pericardium Allograft or Tutoplast Processed Pericardium.

Unite® Biomatrix
Unite Biomatrix (Synovis®, Irvine, CA) is a non-reconstituted collagen xenograft derived from native equine pericardium. The matrix is FDA 510(k) approved "for the management of moderately to severely exudating wounds, including: partial and fill thickness wounds, draining wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (e.g., abrasions, lacerations, partial thickness [second degree] burns, skin tear, surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced surgical incisions) (FDA, 2011). Because studies are primarily in the form of case reports, there is insufficient data to support the safety and efficacy of Unite Biomatrix.

VascuCel®
VascuCel® (LeMaitre Vascular, Inc., Burlington, MA) is a bovine pericardial patch prepared from glutaraldehyde-crosslinked bovine pericardium using the ADAPT® TEP technology. VascuCel is proposed for use as a patch in great vessel repair, peripheral vascular reconstruction and suture line buttressing. VascuCel received FDA 510(k) (K162579) approval on Oct 14, 2016. The predicate device was CardioCel. There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of VascuCel for any indication. Articles are in the form of animal studies, case series and retrospective reviews for the predicate device.

Vascu-Guard®
Vascu-Guard (Baxter, Deerfield, IL) is a bovine pericardium cross-linked matrix with glutaraldehyde. It is 510(k) FDA approved as an intracardiac patch and proposed for use in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda and tibial blood vessels and arteriovenous access revisions. It is available in various sizes (Baxter, 2026). Vascu-Guard may be sutured, clipped, or stapled to the edge of the host tissue or vessel. There is insufficient evidence in the published peer-reviewed literature supporting the safety and efficacy of Vascu-Guard. Studies are primarily in the form of retrospective reviews.

VersaShield™
VersaShield (Orthofix® International, Lewisville, TX) is a human placental amniotic membrane proposed for the treatment of interior or exterior wounds (including covering surgical sites) or as a soft tissue covering or a protective barrier. The dehydrated allograft contains an amnion and chorion layer, as well as four different extracellular matrix proteins and numerous growth factors. VeraShield is regulated by the FDA as a Human Cellular and Tissue Product and processed by the Musculoskeletal Transplant Foundation (MTF). The membrane is available in five sizes (2x2 cm, 4x4 cm, 4x6 cm, 3x4 cm, 3x8 cm) (Orthofix, 2026). There is insufficient evidence in the published clinical trials to support the efficacy of VeraShield for any indication.

ViaFlow™/ViaFlow™ C
ViaFlow Placental Tissue Matrix and ViaFlow C Flowable Placental Tissue Matrix (Stryker Corp., Mahwah, NJ) are premixed, flowable, tissue matrix allografts made from human placental tissues. Vialfow is proposed for homologous use to supplement or replace damaged or inadequate connective tissues. The matrix is injected into the target using a 23G needle. The two available configurations are ambient temperature (ViaFlow) and cryopreserved (ViaFlow C) (Stryker, 2026). ViaFlow Flowable Placental Tissue Matrix is available in 0.5 cc, 1.0 cc and 2.0 cc and ViaFlow C is available in 1.0 cc. All tissues are collected, processed, stored, and distributed in compliance with FDA regulations governing HCT/Ps. There is insufficient evidence available to make informed decisions regarding either safety or clinical effectiveness of ViaFlow and ViaFlow C.

VIAGENEX™ Max Umbilical Cord Membrane and VIAGENEX™ Matrix Amnion Allograft
VIAGENEX™ Max Umbilical Cord Membrane and VIAGENEX™ Matrix Amnion Allograft (Vivex Biologics, Atlanta, GA) are a family of amniotic allografts. The products are proposed for use as a

soft tissue barrier and wound covering. The products are processed in accordance with the FDA regulations for tissues and biologics and the American Association of Tissue Banks (AATB) standards (Vivex Biologics, 2026). VIAGENEX products are available in multiple sizes. There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of VIAGENEX products for any indication.

VNEW™ Precut Shaped Decellularized Dermal Allograft
VNEW™ Precut Shaped Decellularized Dermal Allograft (ARMS Medical, Fort Lauderdale, FL) is a decellularized human dermal allograft. According to the manufacturer's website, VNEW is available in precut anatomical shapes. VNEW is produced from donated human tissue intended for transplant using a proprietary process called dCELL technology. dCELL technology is proposed to remove >99% of DNA content while maintaining an intact ECM including key collagen proteins, vascular channels, key proteoglycans and glycosaminoglycans. VNEW's proposed use is to provide reinforcement, repair, or replacement of damaged or inadequate or inadequate integumental tissue or for other homologous uses of human integument. The product is proposed for use in urogynecology, gynecology, urology, and colorectal surgeries. All tissue is recovered, processed, stored, and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB) and U.S Federal Regulations CFR 21 part 1270 and 1271. There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of VNEW Precut Shaped Decellularized Dermal Allograft.

WoundEx® Membrane and WoundEx® Flow
WoundEx Membrane (CarePath Biologics, LLC) is a dehydrated amniotic membrane proposed as a wound covering for chronic and acute wounds. It can be applied dry or pre-moistened and does not require sutures or fixation. The product is regulated by the FDA under the Human Cells, Tissues, and Cellular or Tissue-Based Products regulations and is obtained from an AATB accredited tissue bank. WoundEx is available in four sizes (1x1 cm, 2x2 cm, 2x4 cm, 4x4 cm, 4x6 cm). WoundEx Flow is a placental connective tissue matrix in flowable form proposed to replace or supplement damaged or inadequate integumental tissue. The liquid contains the complete placental tissue matrix with growth factors and collagen scaffold. The flowable product is available in 0.5 cc and 1.0 cc sizes. Published studies supporting the safety and effectiveness of these products are primarily in the form of retrospective reviews with small patient populations (n=20) (Lullove, 2017).

XCellerate™
XCellerate™ (Precise Bioscience, Hinsdale IL) is a lyophilized amniotic membrane allograft proposed for the treatment of non-healing wounds and burn injuries (Precise Bioscience, 2026). XCellerate is a human cellular and tissue-based product. XCellerate is provided in the following sizes: 2x2 cm, 2x4 cm, 4x4 cm, 4x7 cm and 6 mm, 9 mm, 12 mm discs (CMS, 2020). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of XCellerate for any indication.

XCelliStem® Wound Powder
XCelliStem® Wound Powder (Stemsys® Bio, Sunrise, FL) is an extracellular matrix composed of porcine collagen that is designed to break down rapidly after application to the wound site to promote host site remodeling and regeneration (Stemsys Bio, 2025). It is proposed for the management of wounds including: partial and full-thickness wounds, pressure ulcers, diabetic ulcers, venous ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds. XCelliStem Wound Powder received FDA 510(k) (K172593) approval in 2018 (FDA, 2022). Evidence in the published peer-reviewed literature to support the clinical effectiveness of XCelliStem Wound Powder for any indication is lacking.

XenMatrix™ Surgical Graft
XenMatrix (Becton, Dickinson and Company [BD], Franklin Lakes, NJ) is an acellular non-crosslinked regenerative porcine collagen matrix proposed for hernia and abdominal wall repair. The grafts are created using a patented AquaPure™ Process that removes the cells, leaving an open collagen scaffold. Brennan Medical received FDA 510(k) approval for porcine dermal matrix "intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. XenMatrix is specifically indicated for: plastic and reconstructive surgery; muscle flap reinforcement; hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias; suture-line reinforcement; reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Porcine Dermal Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar Achilles, biceps, quadriceps, or other tendons (BD, 2026; FDA, 2011). Clinical trials with data supporting the safety and efficacy of XenMatrix are lacking. Studies are primarily in the form of retrospective reviews and in vitro studies.

XenoSure® Biologic Patch (formerly PeriPatch)
XenoSure Biologic Patch (LeMaitre Vascular, Inc., Ontario, Canada), a processed bovine pericardial patch was FDA approved as PeriPatch™ (PM Devices Inc., British Columbia, Canada). The device is intended for use as a surgical patch for cardiac and vascular reconstruction and repair as well as soft tissue repair and reinforcing suture lines during general surgical procedures. Per LeMaitre, applications include carotid endarterectomy, iliac artery stenting, femoral, renal and tibial patching, profundaplasty, and arteriovenous access revisions (LeMaitre Vascular, 2026; FDA, 2004). There is insufficient evidence to support the safety and efficacy of Xenosure.

Xwrap®
Xwrap (Applied Biologics, LLC, Scottsdale, AZ) is a chorion-free, amniotic, non-crosslinked soft-tissue wound covering which acts as a natural scaffold for cellular migration, attachment, and proliferation. The covering is regulated by the FDA Center for Biologics Evaluation and Research (CBER) which regulates HCT/Ps under 21 CFR Parts 1270 and 21 CFR Part 1271 and Section 361 of the Public Health Service Act. Xwrap is indicated for homologous use as a barrier or protective covering for tissue repair and reconstruction sites. No suturing is required for application. The product is also available in Xwrap dual and Xwrap plus. Xwrap dual is a double layer, chorion-free amniotic membrane allograft and Xwrap Plus is a single layered, chorion free membrane allograft. Available sizes range from 2x2 cm to 4x8 cm (Applied Biologics, 2026; CMS, 2018). There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of the Xwrap line of products.

Zenith™ Amniotic Membrane
Zenith™ Amniotic Membrane (Legacy Medical Consultants, Houston, TX) is a dehydrated amniotic membrane allograft. It is proposed for use as a barrier and covering for acute and chronic non-healing wounds and burn injuries. It is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) under Section 361 of the Public Health Service Act. Zenith Amniotic Membrane allograft is available in multiple sizes ranging from 2x2 cm to 15x20 cm (Legacy Medical Consultants, 2025; CMS, 2021). There is insufficient evidence in the published peer-reviewed scientific literature to support the efficacy of Zenith Amniotic Membrane for all indications.

Literature Review – Systematic Reviews and Meta-Analysis
Abdominal Wall Reconstruction: Following a systematic review of 40 studies (37 retrospective reviews), Janis et al. (2012) concluded that there is a lack of high-level data to define the precise role of acellular dermal matrix and guidelines for its use for abdominal reconstruction guidelines.

Hernia recurrence, the primary outcome measure, ranged from 0–80%. Limitations of the studies included small, heterogeneous patient populations (n=5–240); short-term follow-ups (0–68 months); heterogeneity in surgical techniques; variable starting points of the studies; wide variety of clinical indications for reconstruction (e.g., ventral hernia; incisional hernia, abdominal compartment syndrome, tumor resection, fascial defects, contaminated abdominal wall); variety of positions of matrices; conflicting reports regarding superiority of underlay vs. overlay techniques; variety in the number of matrix layers used; and use of matrices in combinations with other techniques making it difficult to evaluate the benefit of the matrix alone.

Zhong et al. (2011) conducted a systematic review to evaluate the evidence on acellular dermal matrix (ADM) used during abdominal wall reconstruction. Thirty case series (n=4) and retrospective reviews (n=26) met inclusion criteria. No randomized controlled trials or systematic reviews were found. Studies included the use of porcine acellular dermal matrix and human acellular dermal matrix. The outcomes studied included hernia recurrence, abdominal wall laxity, delayed wound healing, infection and seroma. The incidence of postoperative/recurrent hernia ranged from 0%–80%, and the incidence of abdominal wall laxity was largely unreported. Delayed healing occurred in up to 64% of patients with infection-related complications (e.g., surgical site infections, cellulitis, deep/intrabdominal abscesses) reported as high as 40%. Types of ADM, technique, and types of fascia repair and suture used varied. The authors concluded that there was a paucity of high-level evidence comparing ADM with other methods interfering with the ability of physicians to make data-driven recommendations on clinical indications, surgical techniques and outcomes following ADM assisted abdominal wall reconstruction.

Amniotic Allografts for Use in Bariatric and Gynecological Procedures: Abstracts included a Cochrane review (Bosteels, et al., 2017) on anti-adhesion therapy following operative hysteroscopy for treatment of female subfertility. Studies using human amniotic membrane grafting vs. no grafting were included. The authors concluded that the clinical effectiveness of anti-adhesion treatment for improving key reproductive outcomes or for decreasing intrauterine adhesions (IUAs) following operative hysteroscopy in subfertile women remained uncertain. A pilot randomized controlled trial (n=45) of women with severe adhesions allocated the women to one of three groups—insertion of intrauterine balloon only, fresh amnion graft or dried amnion graft. Outcomes were significantly better with amnion graft that intrauterine balloon alone (p=0.003) and outcomes were better with fresh amnion than with dried amnion (p=0.01). Additional studies with larger patient populations are needed to validate the effectiveness of amniotic graft for this indication. No evidence was found to support the use of amniotic membrane in bariatric surgery.

Dural Sealants: Kinaci et al. (2018) conducted a systematic review of the literature to evaluate the efficacy of dural sealants in preventing cerebrospinal fluid (CSF) leakage following cranial surgery. Studies describing regular cranial procedures combined with the use of any dural sealant reporting CSF leakage were included. The primary outcome measure was CSF leakage of any origin. Secondary outcomes were incidental leakage through the skin, pseudomeningocele formation (subcutaneous or epidural collection of CSF) and surgical-site infection. Twenty studies (n=3682 procedures) met inclusion criteria and were primarily in the form of retrospective reviews and case series. Ten comparative studies (n=2321), including three randomized controlled trials, comparing sealant vs no sealant were included in the meta-analysis. There was no significant difference between the two groups in CSF leakage. Meta-analyses for secondary outcomes showed no significant difference between the number of incisional CSF leakage or in the pseudomeningocele formation. Surgical-site infection was seen less in the sealant group than the control group. The number of patients with surgical-site infection in the sealant group was 10 of 1006 (1.0%) versus 60 of 1062 (5.6%) in the control group. Overall, adverse events were not reported and when they were, the direct relationship between sealant use and adverse event was not objectively confirmed. Author-noted limitations of this systematic review included: lack of randomized controlled trials; patients receiving rescue therapy in the control group with other

types of sealants or grafts to obtain watertight closure were not excluded; high risk of bias in the comparative cohort studies; heterogeneity of the patient populations and sealants used; variation in the number of CSF leakages; and differentiation in leakage between supra- and infratentorial craniotomies could not be made. The authors concluded that studies with greater methodologic quality, including randomized controlled trials are warranted.

Fibrin Sealants: Esposito et al. (2016) conducted a systematic review of the literature to investigate the safety and efficacy of fibrin sealants that are used as dural sealants to prevent and/or treat cerebrospinal fluid leaks. Thirty-two studies enrolled 2935 patients who were exposed to fibrin sealant. Seven studies that only included safety data were included and used for safety analysis. Three studies were randomized controlled trials. The remaining studies were prospective case series and retrospective reviews. The studies investigated fibrin glue for the treatment of acute intraoperative CSF leaks, prevention of postoperative CSF leaks, and treatment of persisting CSF leaks. Overall, few or no adverse events were reported in most of the studies. Limitations of the studies included: limited number of randomized controlled trials, heterogeneity in the definition of postoperative CSF leak; limited number of studies (n=2) that discussed fibrin sealants for persistent CSF leaks; variations in surgical technique; variety of fibrin glues that were used did not allow comparison of products; heterogeneity in patient populations (e.g., age, sex, race, medical condition); and variation in use of secondary treatments (i.e., medical therapies, interventional strategies). Due to the limitations of the studies, firm conclusions could not be made regarding the benefit of fibrin sealants. Well-designed and powered randomized clinical trials are needed to support the safety and establish the efficacy of these sealants.

Fistula Plugs: Nasseri et al. (2016) conducted a systematic review to evaluate the evidence on the efficacy of fistula plugs (AFPs) in treating fistula-in-ano in patients with Crohn's disease. Twelve studies met inclusion criteria. Eight were nonrandomized prospective and four were retrospective reviews. A total of 84 patients (n=1–20 per study), age 18–72 years (median 45 years) and follow-up of 3–24 months (median nine months) were included in the analysis. The total success rate (i.e., closure of the fistula tract) was achieved by 49/84 patients. Two out of five patients had success with recurrent fistula., The overall success rate with Surgisis was 48/80 and one out of four patients for Gore Bio-A. Five studies reported a recurrence rate of 13.6% (3/22 patients). The authors were unable to draw firm conclusions due to the limitations of the studies. The procedure appeared safe with little morbidity and low risk of incontinence. Limitations of the studies as noted by the authors included; heterogeneity of study design; small patient population; lack of statistical significance in outcomes; grouping of fistulas in Crohn's disease with other types of anal fistulas introducing ambiguity; short-term follow-up and heterogeneity of follow-up times; and various confounding factors (e.g., use of steroids or immunosuppressants, previous use of seton stitch to aid in healing and variation in surgical technique) and lack of reporting of these factors. The authors noted that the outcomes may have been worse if longer follow-ups had been reported and that it was unclear whether failure occurred as a result of technical error or owing to the pathology of the fistula despite use of the correct surgical technique.

In a systematic review, O'Riordan et al. (2012) identified 56 articles that investigated anal fistula plugs for the treatment of Crohn's (n=42) and non-Crohn's disease (n=488). Eight studies were retrospective, ten were prospective cohorts, and two were randomized controlled trials. Patient population ranged 4–60 patients. Included studies involved patients with and without Crohn's disease that could be differentiated and a mean or median follow-up of three months or greater. The longest follow-up was 24.5 months. Patients with rectovaginal, anovaginal, rectourethral, or ileal-pouch vaginal fistulas were excluded. Overall, plug extrusion rate was 8.7% (n=46). In patients with non-Crohn's disease, fistula closure ranged from 0.2–0.86. The overall success rate for patients with Crohn's was 54.8% (23 of 42 patients) and 54.3% of patients (265 of 488 patients) without Crohn's. Limitations of the study included: heterogeneity of operative technique,

perioperative care; operative position, and anesthesia type; and the retrospective and non-comparative study designs.

Hernia Repairs: Trippoli et al. (2018) conducted a systematic review of the literature to evaluate the differences in various biological products for the treatment of primary and incisional ventral hernias. Included studies met the following criteria: treatment of primary and incisional abdominal hernia; mesh derived from porcine dermis or porcine intestinal submucosa or bovine pericardium or bovine or fetal dermis; may or may not involve "cross-linking of collagen"; end-point was 30-day follow-up of surgical site infection and/or relapse rate after follow-up of at least 12 months. The five available biological meshes of porcine derivative available in the market at the time of the analysis were Strattice, Permacol, Fortiva, Surgisis, and Xenmatrix. The four available bovine meshes were Peri-guard, Veritas, Bioripar and Tutomesh. Eleven trials that evaluated five meshes met inclusion criteria. Nine studies were single-arm (prospective or retrospective), and two studies were based on a comparative design. The meshes included in the studies were: Permacol (n=706), Strattice (n=324), Surgisis (n=44), Tutomesh (n=38) and Xenmatrix (n=22). No published studies were found investigating Fortiva, Veritas, Bioripar and Tutomesh. Among all comparisons carried out within these biological meshes, one significant difference was found. Permacol (a crosslinked mesh) showed a lower recurrence rate at 12 months than Strattice (a non-cross-linked mesh) (p=0.001), suggesting that crosslinking may strengthen a mesh. Overall the studies generally showed a poor methodological quality. There was wide variability in the surgical wound infections between studies and the 12-month relapse rates (n=4 studies). Additional author-noted limitations of the studies included the limited available clinical information, small patient populations, short-term follow-ups, and uncontrolled study designs. Other limitations are the heterogeneity of the wound types and retrospective study designs. In conclusion, there is insufficient evidence in the published literature to support the use of biological mesh for hernia repair. Data do not indicate if a porcine vs. bovine or cross-linked vs non-crosslinked mesh should be used. Patient selection criteria have not been established.

In a 2014 systematic review, Cross et al. reported that the data for biological mesh products in ventral hernia repair in contaminated fields were limited. Sixteen studies (n=554) met inclusion criteria. All of the studies were case series with the largest patient population being 116. Six different mesh products were used. The authors recommended that caution be used when considering the use of biological meshes because there is a paucity of controlled trials and none of the products are FDA approved for this indication.

Ferzoco (2013) conducted a systematic review to assess outcome in patients who underwent repair of contaminated or infected ventral incisional hernias using a biologic mesh. The eleven studies that met inclusion criteria used the following products: AlloDerm (n=7), Surgisis (n=2); CollaMend (n=2), Permacol (n=2), Strattice (n=1), and Veritas (n=1). All studies were retrospective chart reviews and included a total of 677 patients. Reported hernia recurrence varied widely and ranged from 0%–50%. Wound dehiscence rates varied from 0%–35.5% and mesh explantation ranged from 0%–23%. Occurrence rates for seroma, fistula, evisceration, intrabdominal bleeding, repeat surgery, and hematoma were typically not reported. The most commonly reported reasons for a secondary surgical procedure included repair of recurrent hernia, mesh removal, drainage of seroma, and drainage of surgical site abscess. Prospective studies are needed to investigate the efficacy of biologic mesh in the treatment of infected ventral incisional hernias.

Beale et al. (2012) conducted a systematic review to evaluate the use of biological mesh in the repair of ventral hernias in adults. Twenty-nine studies met inclusion criteria (n=1257). Four studies used Permacol (n=64), three used Surgisis (n=87) and 23 used AlloDerm (n=1106). Primary outcomes were hernia recurrence and surgical site occurrences (hematoma, seroma, wound infection, dehiscence or graft removal). There was a 20.8% AlloDerm, 10.9% Permacol and

8.0% Surgisis recurrence rate and a 31.4% AlloDerm, 25% Permacol and 40.2% Surgisis surgical site occurrence rate (e.g., hematoma, seroma, wound, infection, dehiscence, or need for graft removal). The authors noted that it was difficult to identify a uniformly accepted technique for the placement of the biologic mesh. Limitations of the studies included: retrospective study design (n=27 studies), heterogeneity of surgical technique and placement of the product, lack of reporting of hernia recurrence and complication rates, paucity of data and older studies. Well designed, prospective randomized controlled trials with large patient populations and long-term follow-up are needed to evaluate biological mesh for ventral hernia repair.

Kissane and Itani (2012) conducted a systematic review to evaluate acellular dermal matrix for complex ventral incisional hernia repair. Eight single center studies (n=635) met inclusion criteria and used either AlloDerm (n=461), Surgisis ("Sis-ECM" mesh) (n=91) or Strattice (n=80). One study was prospective and used Strattice in a one-stage repair of infected or contaminated hernias. Seven studies were retrospective in design. There was a recurrence rate of 21 percent after 25.8 months with the highest rate being in the AlloDerm patients. Total percentage of complications (e.g., wound-related, eventration, mesh rejection) in the AlloDerm hernia repairs was 40.4 percent. Other complications included: seroma formation, postoperative peritonitis, subfascial abscesses, intraabdominal hematoma, and mesh reaction. Because of the heterogeneity of the patient population, ventral incisional hernia grades, type of meshes used, surgical techniques, and length of follow-up, a meta-analysis could not performed. Other limitations of the studies included: minimal reporting of patient inclusion criteria and demographics; diverse patient comorbidities; retrospective study designs; lack of controls; and short-term follow-up (mean 25.8 months).

Smart et al. (2012) conducted a systematic review to assess the clinical outcomes of biological meshes used in abdominal wall hernia repairs. Forty-five randomized controlled trials, case series and retrospective reviews met inclusion criteria including: 23 studies on AlloDerm, seven on Surgisis, ten on Permacol and seven on other meshes. Most articles were retrospective reviews or uncontrolled prospective case series with small heterogeneous, patient populations, poorly described methodology and short-term follow-ups (3–52 months). AlloDerm recurrence rates ranged from 0%–100% and were inferior compared to polypropylene and Surgisis. In infected fields, recurrence rates were high at short and medium-term follow-up. Concerns were reported regarding bulging at the repair site and stretching of the graft. "There is little evidence to support the use of AlloDerm in most of the situation where a biological mesh is indicated." The recurrence rates with Permacol were 0%–15%. Outcomes in Permacol studies were conflicting and "important methological weaknesses exist" representing a low level of evidence. Outcomes with Surgisis were also conflicting. Some studies reported a recurrence rate of 0%–5.3% regardless of whether the surgery was performed in a clean or infected field, while other studies reported a recurrent rate as high as 39% in dirty fields. One study was terminated early due to the high recurrence rates in a Surgisis group with clean cases. According to the authors, insufficient or minimal data in the form of retrospective reviews were found for Veritas, Xenmatrix, CollaMend and Strattice and only case reports were found for Allomax, FlexHD, FortaGen, Peri-Guard, SurgiMend and Tutopatch.

Hyaluronic Acid: Shaharudin et al. (2016) conducted a systematic review to assess the evidence on the effectiveness of hyaluronic acid (HA) compared to placebo or other agents for promoting chronic wound healing. Nine randomized controlled trials (n=865) met inclusion criteria. The authors noted that there was better quality of evidence for mixed arterial and venous ulcers than for venous leg ulcers and diabetic foot ulcers. Overall, the studies provided little evidence regarding the claimed effects of HA for this indication. Some mixed evidence suggested that HA reduced the intensity of pain for mixed arterial and venous ulcers. There is insufficient evidence to support the use of HA for the treatment of chronic wound healing.

Laryngotracheal and Pharyngeal Reconstruction: Hui et al. (2017) conducted a systematic review to evaluate the safety and efficacy of acellular dermal matrices in laryngotracheal and pharyngeal reconstruction. Eleven studies (n=170) including three retrospective review, five case series and three case reports met inclusion criteria. Eight studies reported on ADM use in oncological reconstruction. Seven studies used AlloDerm, three studies used Heal-All Oral Biofilm (Zhenghai Biotech, Yantai, China) and one case report used Permacol. Follow-ups varied from two weeks to 42 months. The methodology of the studies was poor. Other limitations included the small patient populations, and heterogeneity of surgical procedures and diagnosis. Overall, the studies provided incomplete descriptive detail concerning peri-operative radiation dosing and scheduling, the surgeon's experience using dermal grafts, graft thickness, and defect size. The authors stated that due to the limited number and heterogeneity of the cases, conclusions could not be made regarding the impact of acellular dermal matrix use on post-operative stricture and stenosis rates in tracheal or pharyngeal reconstruction.

Orthopedic Sports Medicine: Riboh et al. (2016) conducted a systematic review of the literature to assess the evidence for amniotic membrane products used in orthopedic sports medicine. Eighty articles were considered relevant to the study. Fifty-five of the articles were narrative and 25 articles described preclinical and clinical trials of amniotic products for orthopedic sports medicine. The primary indications being explored included: cartilage restoration, ligament and tendon healing, nonoperative treatment of knee osteoarthritis, and plantar fasciitis. Due to the low quality of the studies, a systematic review summary and meta-analysis for the use of these products for this indication could not be conducted. According to the authors the current body of evidence is heavily biased toward in vitro and animal studies, with little to no human clinical data.

Tendon and Ligament Repairs: Chen et al. (2009) conducted a systematic review of biological and synthetic scaffolds used for tendon and ligament repairs. Out of 378 identified articles, 47 clinical trials met inclusion criteria. Of the 47 articles, 16 clinical trials included four commercial biological scaffolds (i.e., five included the use of Restore, six used GraftJacket, four used Zimmer (formerly Permacol), and one study included both Restore and GraftJacket. After a review of the data, the authors reported the following:

- Restore – "Restore or scaffolds from small intestine submucosal are ineffective in the reinforcement of large rotator cuff tears and currently not recommended for use in cuff tendon repair." They identified other scaffolds made from small intestine submucosal (i.e. Oasis, Surgisis, and CuffPatch™ [Organogenesis, Inc., Canton, MA]) and stated that "extra care should be taken to monitor adverse events when applied in patients."
- GraftJacket – "Satisfactory results have been described using GraftJacket for skin lesion and abdominal wall repair". No reports of inflammatory response, edema or postoperative infection have been reported, and patients seemed to tolerate it well. However, recurrent tears were noted in 30% of patients in two studies.
- Zimmer (Permacol) – Two retrospective reviews (n=10 each) reported increased pain relief and range-of-motion following implantation, but two other smaller studies reported recurrent tears, aggravated pain and decrease range-of-motion. Foreign body reaction was noted in several of the patients.
- TissueMend – No published animal or clinical studies were found. They noted that TissueMend has been reported to contain higher genetic materials compared to other products which raise concern re human application.
- OrthADAPT – No published animal or clinical studies could be found

According to Chen et al., the studies in this systematic review were primarily in the form of case reports, case series, or retrospective reviews and limited by small patient populations (n=1–30), short term follow-ups (3 months–5 years) and lack of comparison to established methods of treatment. One of the major concerns with these products is biocompatibility and inflammatory

response associated with foreign body rejection. The authors also noted that many scaffolds were FDA approved without proper animal studies or evidence-based clinical trials.

Professional Societies/Organizations
American Society of Colon and Rectal Surgeons
In 2016, the American Society of Colon and Rectal Surgeons published clinical practice guidelines for the management of anorectal abscess, fistula-in-ano, and rectovaginal fistula (Vogel, et al., 2016). The guidelines state that the fistula plug is a relatively ineffective treatment for fistula-in-ano. The guidelines did not include the use of collagen plug for rectovaginal fistulas as they state the success of this intervention has proven to be prohibitively poor.

New England Regional Society of the American Society of Colon: Based on data from a prospective, multicenter registry of 245 patients who underwent surgical intervention for anal fistula, the New England Regional Society of the American Society of Colon and Rectal Surgeons (Hyman, et al., 2009) reported that the best healing rates occurred following fistulotomy (87%) and the worse healing rates occurred following anal fistula plug (32%) (p=0.001). They stated that randomized controlled trials comparing various treatment options for anal fistulas "are clearly needed."

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES): The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) (Daly, et al., 2024) guidelines for hiatal hernia repair are based on a systematic review of the evidence in the published peer-reviewed scientific literature. One objective was to assess the benefits and harms associated with the surgical management options of using mesh versus no mesh. Large hiatal hernias were defined as those measuring >2 cm in any direction. The guideline panel deferred making a recommendation on the routine use because the evidence was lacking. They concluded that the use of mesh must be a joint decision between surgeon and patient; large, well designed randomized control trials comparing type of mesh used and orientation of the mesh are required to better establish the safety and long-term outcomes of mesh use at the hiatus.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

There is a lack of literature addressing health care disparities in the use of skin substitute grafts for diabetic foot ulcers (DFUs) and venous stasis ulcers (VSUs) specifically. There are higher rates of diabetes in some racial and ethnic groups and groups with lower socioeconomic status (Center for Disease Control [CDC], 2024). Among U.S. adults aged 18 years or older, age-adjusted data for 2019–2021 indicated for both men and women, prevalence of diagnosed diabetes was highest among American Indian and Alaska Native adults (13.6%), followed by non-Hispanic Black adults (12.1%), adults of Hispanic origin (11.7%), non-Hispanic Asian adults (9.1%) and non-Hispanic White adults (6.9%). For both men and women, prevalence was higher among adults living in nonmetropolitan areas compared to those in metropolitan areas. According to the CDC, there is a

high rate of diabetes in individuals who live in the part of the United States known as Appalachia who have less access to health care compared to other parts of the country.

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Removed Acuseal Cardiovascular Patch, Alloderm, AmnioMTM Injectable, AmnioPro Flow, Apligraf, BioDfactor™, BioDRestore flowable, BioNextPatch, CellerateRX®, Conexa™, Dermagraft, dermamatrix, Integra™ Bilayer Matrix Wound Dressing, Integra Dermal Regeneration Template, Integra Matrix, Neoform™ Dermis, Neox®	4/15/2026

	Wound Matrix, NeuroMatrix™, NeuroMend Collagen Nerve Wrap, Nucel Bioactive Amniotic Suspension, Preclude Dura Substitute, RX Flow, Rx Membrane, SERI Surgical, Suprathel, TenoGlide, Transcyte, Veritas Collagen Matrix, Xceed™, Xenform Soft Tissue Repair Matrix (discontinued and/or no longer available or no longer managed) • Added Galaflex Lite to existing coverage statement • Added coverage for Avance nerve graft • Added the following products to EIU policy statement: A/C wrap, AMNIOCORD, Biolab membrane wrap flow, Biolab tri-membrane wrap flow, CTM Flow, CTM Thick, Curamatrix, Dermabind sl n or dermabind sl + or dermabind sl x, Essence Acellular Dermal Matrix, GrowFX Connective Tissue Matrix, Pretect, Revive ft, Renati ac membrane, Revival ac, Tutoplast® Pericardium Allograft/Tutoplast Processed Pericardium	
Focused review	• Removed Marigen™ Pacto from coverage statement • Added the following products to EIU policy statement: Absolv3 Membrane, AmchoMatrixDL, AmnioMatrixF4X, CYGNUS Solo, NuForm, Polygon3 Membrane, Summit AC, Summit FX • Differentiated Phasix and Phasix ST in coverage statement and in background	1/15/2026
Focused review	• Added policy statement to cover Marigen™ Pacto for diabetic foot ulcers • Added policy statement to cover GRAFIX DUO for diabetic foot ulcers and venous stasis ulcers • Added definition of large hiatal hernia to coverage statement for clarification • Added the following to EIU policy statement: Acelagraft, Acesso TrifACA, AmnioPlast Double, Apollo FT, Axolotl Graft™ Ultra, InnovaMatrix® FD, Natalin®, NeoThelium FT, NeoThelium 4L, and NeoThelium 4L+, Summit AAA, SurGraft AC, SurGraft ACA	10/15/2025
Focused review	• Added Allomend and VNEW to EIU policy statement. • Clarified Phasix ST mesh is the appropriate type of Phasix mesh for use in paraesophageal/hiatal hernia repair	8/15/2025
Annual review	• Added policy statement to cover Galaflex for breast reconstruction	3/15/2025

	• Added policy statement to cover Actigraft and Kerecis for diabetic foot ulcers • Added policy statement to cover multiple products for dural repair • Added policy statement to cover Phasix ST mesh and Gore Bio A for paraesophageal/hiatal hernia repair • Added policy statement to cover Alloderm for use in parotidectomy • Removed Symbotex from the policy • Added multiple new CPT codes for products that are EIU • Removed policy statements for numerous products	
Focused review	• Added policy statement of noncoverage for XWrap	3/15/2025
Focused review	• Revised policy statement to increase the number of initial applications that are allowed for venous stasis ulcers • Added policy statement of noncoverage for Membrane Wrap and Membrane Graft	1/15/2025
Focused review	• Added new CPT code for Matrix HD. This product is listed as EIU.	10/16/2024
Focused review	• Revised policy statement to increase the number of initial applications that are allowed for diabetic foot ulcers	6/15/2024
Annual review	• Revised noncoverage policy statement • Removed policy statements for numerous products	3/15/2024