Medical Coverage Policy

Effective Date.....5/15/2026
Next Review Date.....5/15/2027
Coverage Policy Number..... 0119

Partial Rhinectomy, Rhinoplasty, Vestibular Stenosis Repair and Septoplasty

Table of Contents

Related Coverage Resources

Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation
Gender Dysphoria Treatment
Orthognathic Surgery
Surgical Treatments for Obstructive Sleep Apnea

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 Medical Coverage Policy addresses partial rhinectomy, rhinoplasty, vestibular stenosis repair, absorbable nasal implants (e.g., Latera), radiofrequency of nasal valve (e.g., VivAer Stylus), and septoplasty procedures for nasal airway obstruction and other otolaryngologic conditions, including cleft lip and cleft palate repair.

Coverage Policy

Partial Rhinectomy

Coverage for partial rhinectomy varies across plans and may be subject to the provisions of a cosmetic and/or reconstructive surgery benefit. Refer to the customer's benefit plan document for coverage details.

Partial Rhinectomy is considered medically necessary for ANY of the following indications:

- Malignant neoplasm of the nasal structures that cannot be adequately treated by less invasive surgical procedures or non-surgical interventions
- Extensive benign tumor or lesion causing functional impairment (e.g., airway obstruction, significant nasal deformity, or chronic recurrent infection) unresponsive to, or unsuitable for conservative medical treatment
- Severe nasal trauma resulting in irreparable damage to nasal structures requiring partial removal for restoration of function or form
- Chronic infection unresponsive to appropriate medical treatment

Partial rhinectomy performed solely for cosmetic enhancement or patient preference, without clinical or functional justification as outlined above, is considered not medically necessary and is not covered.

Rhinoplasty & Vestibular Stenosis Repair

Coverage for rhinoplasty varies across plans and may be subject to the provisions of a cosmetic and/or reconstructive surgery benefit and may be governed by state and/or federal mandates. Refer to the customer's benefit plan document for coverage details.

Rhinoplasty is considered medically necessary for ANY of the following indications:

- Correction or repair of a nasal deformity secondary to a cleft lip/palate or other severe congenital craniofacial deformity (e.g., maxillonasal dysplasia, Binder's syndrome, facial clefts) in a child five years of age or younger.
- Correction or repair of a nasal deformity secondary to a cleft lip/palate or other severe congenital craniofacial deformity (e.g., maxillonasal dysplasia, Binder's syndrome, facial clefts) in a child that is six years of age or older that is causing a functional impairment (i.e., nasal obstruction, inadequate airflow, feeding difficulties) when BOTH of the following criteria are met:
    - photographic evidence of the anatomical abnormality including frontal, lateral and worm's eye view (e.g., nasal base)
    - the functional impairment is expected to be resolved by the rhinoplasty

- Correction or repair of a nasal deformity secondary to trauma that is causing a functional impairment (i.e., nasal obstruction, inadequate airflow) and ALL of the following criteria are met:
    - photographic evidence of the anatomical abnormality including frontal, lateral and worm's eye view (e.g., nasal base)
    - the functional impairment has either not resolved after previous septoplasty/turbinectomy or would not be expected to resolve with a septoplasty/turbinectomy alone
    - the functional impairment is expected to be resolved by the rhinoplasty

Vestibular stenosis repair is considered medically necessary when there is chronic nasal obstruction due to vestibular stenosis (i.e., collapsed internal valves) and there is demonstration of improvement of the airway by EITHER of the following methods:

- Cottle maneuver
- lateralization of the upper lateral cartilage from inside the nose with an object (e.g., cotton swab or nasal speculum)

Each of the following procedures is considered experimental, investigational and unproven:

- repair of nasal valve collapse with absorbable nasal implant(s) (e.g., Latera®)
- radiofrequency of nasal valve for the treatment of nasal airway obstruction (e.g., VivAer® Stylus)

Rhinoplasty or vestibular stenosis repair when performed for EITHER of the following indications is considered cosmetic in nature and/or not medically necessary:

- solely for the purpose of changing appearance
- as a primary treatment for an obstructive sleep disorder when the above criteria for approval have not been met

Septoplasty

Septoplasty is considered medically necessary when performed for ANY of the following indications:

- nasal breathing difficulty or mouth breathing due to septal deviation or deformity
- recurrent epistaxis related to a septal deformity
- performed in association with a covered cleft lip or cleft palate repair

- obstructed nasal breathing due to septal deformity or deviation that is interfering with the effective use of medically necessary continuous positive airway pressure (CPAP) for the treatment of an obstructive sleep disorder (i.e., obstructive sleep apnea with an apnea/hypopnea index [AHI] ≥ 15 as documented by polysomnography or home/portable sleep study)

Septoplasty for any indication not listed above is not medically necessary.

Balloon dilation septoplasty for treatment of septal deviation is considered experimental, investigational and unproven.

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.

Partial Rhinectomy

Considered Medically Necessary only when coverage for the service is available and when criteria in the applicable policy statements listed above are met. Benefit exclusions and limitations may apply:

CPT®* Codes	Description
30150	Rhinectomy; partial

Rhinoplasty

Considered Medically Necessary only when coverage for the service is available and when criteria in the applicable policy statements listed above are met. Benefit exclusions and limitations may apply:

CPT®* Codes	Description
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies

Vestibular Stenosis Repair

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)

Considered Experimental, Investigational and Unproven:

CPT®* Codes	Description
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)
30469	Repair of nasal valve collapse with low energy, temperature controlled, (i.e., radiofrequency) subcutaneous/submucosal remodeling

Septoplasty

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
30620	Septal or other intranasal dermatoplasty (does not include obtaining graft)

Considered Medically Necessary when submitted with a medically necessary procedure:

CPT®* Codes	Description
20912	Cartilage graft; costochondral
21209	Osteoplasty, facial bones; reduction
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
21235	Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)

Considered Experimental/Investigational/Unproven when used to report balloon dilation septoplasty:

CPT®* Codes	Description
30999	Unlisted procedure, nose

General Background

Partial Rhinectomy

Rhinectomy is a surgical procedure to remove all or part of the nose. When part of the nose is removed, it is called partial rhinectomy. Partial rhinectomy involves the surgical removal of a portion of the external nose and may include skin, cartilage and possibly bone, depending on the extent of the disease. This procedure is typically performed to excise malignant or extensive benign tumors, or to address severe trauma, with a goal of disease control and functional preservation. Reconstruction may be necessary to restore nasal form and function. Partial rhinectomy is indicated for: malignant tumors (e.g., squamous cell carcinoma or melanoma) where excision is necessary for disease control; extensive benign tumors that cause functional impairment (e.g., airway obstruction) and are unresponsive to conservative treatments; or severe nasal trauma resulting in nonviable tissue requiring surgical removal. Prior to considering partial rhinectomy, less invasive treatments should be evaluated (Hosal, et al., 2018). Medical management for benign conditions include options like medications or minor surgical interventions. In certain malignancies, radiation may be considered as an alternative or adjunct to surgery. Partial rhinectomy is typically reserved for cases where conservative measures are ineffective or inappropriate.

U.S. Food and Drug Administration (FDA)

Partial Rhinectomy is considered a surgical procedure and does not require FDA review or approval.

Literature Review
Partial rhinectomy is considered a standard of care in select individuals with malignant neoplasm of the nasal structures, extensive benign tumor or lesion, severe nasal trauma, and chronic infection (Hosal, et al., 2018).

Rhinoplasty and Vestibular Stenosis Repair

Rhinoplasty is a surgical procedure that reshapes, repairs, or reconstructs the internal and external structures of the nose. Indications for surgery include correction or repair of a nasal deformity secondary to a cleft lip/palate or other severe congenital craniofacial deformity in select patients, as well as correction or repair of a nasal deformity secondary to trauma that is causing a functional impairment. The Cottle maneuver and modified Cottle maneuver should be used in the evaluation of nasal valve compromise. Functional septorhinoplasty is considered the gold standard for management when nasal airway obstruction is due to structural abnormalities (septal deviation or nasal valve compromise). Functional septorhinoplasty encompasses multiple surgical techniques (open and closed; and using grafting, as needed) selected according to the etiology of the obstruction. Vestibular stenosis repair may also be performed in the presence of vestibular stenosis. Alternatives include septoplasty alone for isolated septal deviation. The nonsurgical management of nasal valve compromise includes external and internal nasal dilators. Absorbable nasal implants or temperature-controlled radiofrequency have also been proposed as minimally invasive treatments for nasal valve compromise. (Fuller, et al., 2026; Walker and Toriumi, 2026; ACPA, 2024).

U.S. Food and Drug Administration (FDA)

Rhinoplasty and vestibular stenosis repair are considered surgical procedures and do not require FDA review or approval.

Literature Review

Septorhinoplasty is considered the gold standard for correction or repair of a nasal deformity causing a functional impairment due to nasal airway obstruction in select individuals. Vestibular

stenosis repair may also be performed in the presence of vestibular stenosis. Rhinoplasty and septorhinoplasty are also considered standard of care procedures for nasal deformity secondary to a cleft lip/palate or other severe congenital craniofacial deformity in select individuals (Fuller, et al., 2026; Walker and Toriumi, 2026; ACPA, 2024; AAO-HNS, 2017; AAO-HNS, 2010).

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): AAO-HNS (2017) published a clinical practice guideline regarding improving nasal form and function after rhinoplasty that states:

- "Statement 3: Nasal Airway Obstruction: The surgeon, or the surgeon's designee, should evaluate the rhinoplasty candidate for nasal airway obstruction during the preoperative assessment. Recommendation based on observational studies, with a preponderance of benefit over harm."
- "The purpose of this statement is to provide guidance to clinicians regarding the preoperative evaluation of the rhinoplasty patient for nasal airway obstruction. Evaluation of both function and form is critical in the preoperative workup of the rhinoplasty patient."
- "Patients presenting with symptoms of nasal congestion, described as fullness or obstruction leading to reduced airflow, are commonly encountered in clinical practice. Most causes of nasal congestion are attributed to rhinitis and rhinosinusitis. Alternatively, anatomic variation (congenital malformation, trauma, etc) of nasal structures (nasal bones and cartilage) may lead to nasal obstruction and resultant airflow compromise. A comprehensive history with respect to nasal breathing is necessary. Clinicians should document whether it is one or both sides that are congested and at what time of the day this occurs."
- "Septoplasty can improve the nasal airway; therefore, a thorough evaluation of the septum preoperatively is critical, as it is a common cause of nasal obstruction. Enlarged inferior turbinates, as seen in allergic rhinitis, may also be a frequent contributor to nasal airway obstruction, and evaluation of these structures should be included in the preoperative physical examination, as listed in Table 6."
- "Surgery to correct nasal valve collapse can also improve the nasal airway; therefore, evaluating the internal nasal valve and external nasal valve areas are important, especially among patients complaining of nasal congestion prior to rhinoplasty. Techniques such as static and dynamic inspection, the modified Cottle maneuver (as depicted in Figure 5), and palpation can augment the physical examination. Furthermore, the rhinoplasty surgeon should be cognizant of the dynamic nature of the operation and consider how attempts to alter the aesthetic appearance of the nose may affect nasal airway obstruction. For example, careful evaluation of the strength of the nasal tip and lower lateral cartilages is important, as too much resection in the setting of weak cartilage can lead to postoperative nasal obstruction. The preoperative examination should identify potential intraoperative areas for concern and inform the surgeon as he or she develops an outline of the operation."

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): AAO-HNS (2010) conducted a systematic review of the literature and published clinical consensus statements regarding the diagnosis and management of nasal valve compromise including:

- "NVC [nasal valve compromise] is a distinct clinical entity for patients who present with symptomatic nasal airway obstruction."
- "NVC can be caused by a high septal deviation."
- "The main symptom of NVC is decreased nasal airflow as reported by the patient."
- "NVC can adversely affect sleep."

- "Abnormalities of the lateral nasal wall related to weak or malformed upper lateral and/or weak lower lateral cartilages can be diagnosed by the clinician on physical exam."
- "Subjective improvement in nasal airflow during a Cottle maneuver (manual lateral retraction of the cheek) or manual intranasal lateralization of the lateral nasal wall is consistent with NVC."
- "Audible in combination with subjective improvement in nasal airflow during a Cottle maneuver (manual lateral retraction of the cheek) or manual intranasal lateralization of the lateral nasal wall is consistent with NVC."
- "Photography is useful for documenting an external nasal deformity that may be consistent with NVC."
- "A trial of adult nasal strips (e.g., Breathe Right Strips) is useful for confirming the diagnosis of NVC."
- "In some cases, septoplasty with or without turbinate surgery can treat NVC without surgery to support the lateral nasal wall/alar rim."
- "Adult nasal strips (e.g., Breathe Right Strips) can be used therapeutically for NVC for some patients."
- "Nasal stents or cones can be used therapeutically for NVC for some patients."

Repair of Nasal Valve Collapse with Absorbable Nasal Implant(s) (e.g., Latera)

Absorbable nasal implants (e.g., Latera) have been proposed as a minimally invasive procedure for the repair of nasal valve collapse. Nasal airway obstruction from nasal valve collapse limits airflow through the nose and may result in reduced quality of life (QOL). Absorbable nasal implants are intended as an alternative to temporary nonsurgical therapies (e.g., external nasal dilating strips, nasal cones) and more invasive surgical treatments requiring general anesthesia. During the procedure, the implant is inserted into the nose under local anesthesia. The implant is intended to support the upper and lower lateral nasal cartilage, reduce nasal airway obstruction, increase nasal airflow, and be replaced with fibrous collagen to provide ongoing support, as the implant is absorbed over 18 to 24 months (Stryker, 2026; Bikhazi, 2021).

U.S. Food and Drug Administration (FDA)

On June 23, 2016, the Latera Absorbable Nasal Implant (Stryker) (previously Spirox, Inc.) received FDA 510(k) clearance as a Class II device. "The Spirox Latera Absorbable Nasal Implant is indicated for supporting nasal upper and lower lateral cartilage" (FDA, 2025).

Device or Product	Identifier	Manufacturer
Latera Absorbable Nasal Implant	K161191	Spirox, Inc.

*FDA product codes: NHB

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

There is currently insufficient high-quality evidence in the published, peer reviewed literature to support the safety and efficacy of absorbable nasal implants (e.g., Latera) for repair of nasal valve collapse. Existing systematic reviews are constrained by the limitations of the available studies, which weaken the strength of the conclusions.

Bikhazi et al. (2021) reported long-term follow-up results from the treatment and crossover arms of a randomized controlled trial (RCT) of an absorbable nasal implant for dynamic nasal valve collapse. Three-month results were previously reported by Stolovitzky et al. (2019) and discussed below. A total of 137 participants (71 treatment and 66 sham) were enrolled and treated in the original randomized cohort. Cross-over was offered to qualified sham participants at three months post implant. The forty remaining sham participants underwent a crossover procedure, resulting in 111 total participants in the combined treatment and crossover arms for long-term follow-up. Of the 111 participants implanted, 88 completed the 12-month visit and 68 completed the 24-month visit. Inclusion criteria were comprised of a baseline Nasal Obstruction Symptom Evaluation (NOSE) score ≥ 55 and a positive modified Cottle maneuver. Additionally, participants were required to have documentation of lack of benefit or tolerability of at least 4 weeks of conservative medical management (e.g., nasal steroids or antihistamines). Participants were excluded if they required concurrent nasal procedures or had undergone endoscopic sinus surgery, septoplasty, inferior turbinate reduction, or rhinoplasty within 6 months before enrollment. External nasal dilators were not permitted during the study. Primary outcome measures included improvement in nasal obstruction (NOSE) scores and nasal airflow. A responder was defined as a participant with at least one NOSE class improvement or a NOSE score reduction of ≥ 20% compared with baseline. Secondary measures addressed patient satisfaction, QOL, and improvement in sleep quality via the Epworth Sleepiness Scale (ESS). The mean participant reported visual analog scale (VAS) reduction was ≥ 29.7 points and statistically significant ($p < 0.001$) at all time points. The worst-case analysis resulted in lower NOSE responder rates and changes from baseline, especially at the 18-month and 24-month visits, where there were more missing values. The authors assumed no change from baseline for all missing values and the NOSE responder rates at 18-months and 24-months, respectively, were 61.1% (95% confidence interval [CI], 51.3%, 70.3%) and 55.0% (95% CI 45.2%, 64.6%). They determined the mean change from baseline remained statistically significant at −27.3 at 18-months and −23.9 at 24-months (both $p<0.001$). The mean baseline ESS value for the whole participant cohort was within the normal range (ESS ≥10). While the changes in scores were statistically significant ($p<0.001$), the clinical impact was unclear. The authors suggested reduction in nasal symptoms possibly reduced daytime sleepiness for participants who had problems with sleep quality. A total of 34 device/procedure-related adverse events were reported in 26 participants. The most common adverse events reported among the 111 participants included: implant migration/retrieval (9%); pain or discomfort (4.5%); bumps on nose (3.6%); and foreign body sensation (3.6%). Five participants underwent re-implant after device extrusion at a median of 21 days (range 0 to 133 days) after the initial placement. All device/procedure related adverse events were considered mild to moderate in severity and resolved without clinical sequelae or were ongoing but stable at study completion. Study limitations included the lack of long-term follow-up of the control arm, significant loss of study participants to follow-up at 18 and 24 months, lack of objective assessment of nasal valve collapse and uneven distribution of participants of varying race or ethnicity. The authors concluded that the Latera absorbable implant was a safe and effective in-office treatment option for dynamic nasal valve collapse in participants with severe to extreme nasal obstruction, with maintained symptom improvement at 24 months post placement.

Kim et al. (2020) reported on a systematic review with meta-analysis to determine the efficacy of a bioabsorbable nasal implant for treating nasal obstruction caused by lateral wall insufficiency. Five studies (n=396) were included in the systematic review. Studies that scored endoscopic lateral wall movement and nasal obstruction related to QOL postoperatively before and after bioabsorbable nasal implants, and those that compared the outcomes of nasal implants (treatment group) with outcomes of sham surgery (control group), were included in the analysis. The systematic review found that bioabsorbable nasal implants significantly reduced endoscopic lateral wall motion compared to pretreatment values and improved QOL at 12 months postoperatively. Most adverse effects following the nasal implant, such as skin or mucosal reaction, infection, or implant retrieval, were reported with a 5% incidence rate. All adverse outcomes were resolved

without significant sequelae. Compared with sham surgery, bioabsorbable nasal implants significantly improved disease specific QOL. The authors concluded that bioabsorbable nasal implants may reduce nasal wall movement and subjective symptom scores compared to preoperative status. However, more RCTs must be conducted to further verify the effectiveness of bioabsorbable nasal implants. The authors noted that larger comparative studies or well-designed RCTs with outcomes based on validated patient-reported outcome measures are still required to provide more definitive recommendations.

Sidle et al. (2020) conducted a prospective, multicenter, nonrandomized study to examine 12-month outcomes for in-office treatment of dynamic nasal valve collapse with a bioabsorbable implant. The study included 166 participants with severe-to-extreme class of NOSE scores that were treated with a bioabsorbable implant (Latera) to support the lateral wall, with or without concurrent inferior turbinate reduction (ITR), in an office setting. NOSE scores and VAS were measured at baseline and at 1, 3, 6, and 12 months postoperatively. The lateral wall insufficiency score was determined by independent physicians observing the lateral wall motion video. One hundred and five participants were treated with implant alone, whereas 61 had implant + ITR. Thirty-one participants reported 41 adverse events, all of which resolved with no clinical sequelae. There was reduction in NOSE scores throughout 12 months postoperatively (77.4 ± 13.4 baseline versus 36.2 ± 22.7 at one month postoperatively, 33.0 ± 23.4 at 3 months, 32.1 ± 24.6 at six months, and 30.3 ± 24.3 at 12 months; $p<0.001$). There was significant reduction in VAS scores postoperatively (69.7 ± 18.1 baseline versus 31.3 ± 27.1 at 12 months postoperatively, $p<0.001$). The results were similar in participants treated with implant alone and those treated with the implant + ITR. Consistent with participant-reported outcomes, postoperative lateral wall insufficiency scores were demonstrably lower (1.42 ± 0.09 and 0.93 ± 0.08 pre- and postoperatively, $p< 0.001$). Author noted study limitations include the single-arm study design lacking a randomized controlled comparison and limited 12-month follow-up.

Stolovitzky et al. (2019) conducted a prospective, multicenter, single-blinded RCT to evaluate a minimally invasive procedure addressing dynamic nasal valve collapse with a bioabsorbable implant (Latera) to support the lateral nasal wall. The study included 137 participants randomized into two arms: treatment arm (70 participants) and sham control arm (67 participants). Participants in the active treatment arm received the implant, delivered using a cannula inserted into the nasal lateral wall, and those in the sham control arm had an identical cannula inserted into the nasal lateral wall but received no implant. Outcome measures were followed through three months after the procedure. The primary endpoint was the responder rate (percentage of participants with reduction in clinical severity by ≥ one category or ≥ 20% reduction in NOSE score. At three months (127 participants included in the final analysis: 63 treatment; 64 sham control), responder rate was higher for the treatment arm compared to the control (82.5% versus 54.7%, $p=0.001$). Participants in the treatment arm also had a significantly greater decrease in NOSE score (−42.4 ± 23.4 versus −22.7 ± 27.9, $p<0.0001$) and significantly lower VAS scores (−39.0 ± 29.7 versus −13.3 ± 30.0, $p<0.0001$) than the sham control arm. Seventeen participants reported 19 procedure/implant-related adverse events, all of which resolved with no clinical sequelae. The study is limited by short follow-up (three months) and single-blind design. Participants were blinded, but physicians were aware of the assignment, which may have introduced risk of bias.

Stolovitzky et al. (2018) reported on a multicenter, nonrandomized, single-blind study that examined six-month outcomes for treatment of lateral nasal wall insufficiency with a bioabsorbable implant. The study included 101 patients with severe-to-extreme class of NOSE scores. The patients were treated with a bioabsorbable implant designed to support the lateral wall, with or without concurrent septoplasty, and/or turbinate reduction procedures. NOSE scores and VAS were measured at baseline and 1, 3, and 6 months postoperatively. The lateral wall insufficiency score was determined by independent physicians observing the lateral wall motion

video. Forty-three patients were treated with implant alone, and 58 with adjunctive procedures. Seventeen patients reported 19 adverse events, which resolved with no clinical sequelae. Patients showed reduction in NOSE scores at 1, 3 and 6 months postoperatively (79.5 ± 13.5 preoperatively, 34.6 ± 25.0 at one month, 32.0 ± 28.4 at three months, and 30.6 ± 25.8 at six months postoperatively; $p<0.01$ for all). Reduction was noted in VAS scores postoperatively (71.9 ± 18.8 preoperatively, 32.7 ± 27.1 at 1 month, 30.1 ± 28.3 at 3 months, and 30.7 ± 29.6 at 6 months postoperatively; $p<0.01$ for all). These results were similar in patients treated with the implant alone compared to those treated with the implant and adjunctive procedures. Consistent with patient-reported outcomes, postoperative lateral wall insufficiency scores were demonstrably lower (1.83 ± 0.10 and 1.30 ± 0.11 pre- and postoperatively; $p< 0.01$). Limitations of the study include nonrandomized, single arm study design with short-term follow-up.

San Nicoló et al. (2018) reported on follow-up of the study below (San Nicoló, et al., 2017) to assess whether the safety and effectiveness of the implant persisted in these patients for 24 months after the procedure. Patients were followed through 24 months post-procedure. The mean preoperative NOSE score was 76.7 ± 14.8, with a range of 55 to 100. At 24 months, the mean score was 32.0 ± 29.3, reflecting an average within-patient reduction of -44.0 ± 31.1 points. There were no device-related adverse events in the 12 to 24 months period. There were five patients who exited the study prior to the 24-month follow-up.

San Nicoló et al. (2017) reported on a prospective, single cohort, nonrandomized study that evaluated the safety and effectiveness of an absorbable nasal implant with 12 months follow-up. The study included 30 patients with NOSE score ≥ 55 and isolated nasal valve collapse. Fourteen cases were performed in an operating suite under general anesthesia. Sixteen cases were performed in a clinic-based setting under local anesthesia. Fifty-six implants were placed in 30 patients. The mean preoperative NOSE score was 76.7 ± 14.8, with a range of 55 to 100. At 12 months, the mean score was 35.2 ± 29.2, reflecting an average within-patient reduction of -40.9 ± 31.2 points. The majority (76%) of the patients were responders, defined as having at least one NOSE class improvement or a NOSE score reduction of at least 20%. There were no adverse changes in cosmetic appearance at 12 months post-procedure. Three implants in three patients required retrieval within 30 days post-procedure and resulted in no clinical sequelae. This study is limited by the small number of patients, lack of a comparator, and lack of randomization.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): AAO-HNS (2023) published a position statement regarding nasal valve repair that states:

- "The American Academy of Otolaryngology-Head and Neck Surgery recognizes surgical repair of the nasal valve as a distinct surgical procedure that can improve nasal obstruction symptoms for appropriately selected patients with nasal valve collapse."
- "The treatment of nasal valve dysfunction may involve techniques that include cartilage grafting and open surgical repair, suture suspension techniques, and implants or radiofrequency treatment aimed at stabilizing the nasal valve. Surgical repair of the nasal valve can be performed as a standalone surgical procedure or in conjunction with other procedures to improve nasal obstruction. These may include septoplasty, turbinate reduction, endoscopic sinus surgery, among others. These procedures, such as septoplasty, may be complementary to nasal valve repair, but are not effective substitutes as they do not address nasal valve dysfunction. When feasible, surgical treatment to address all contributing anatomic sites should be performed concomitantly, based on patient and physician shared decision making. Requiring septoplasty and/or turbinate surgery prior to nasal valve surgery is not recommended, as this may lead to unnecessary increases in surgical encounters."

- "Nasal valve repair in appropriately selected patients is effective for symptom relief and quality-of-life improvement. When nasal valve dysfunction is diagnosed, conservative therapy may include nasal cones or external nasal dilator adhesive strips. However, these are not feasible for around the clock use and are not viewed as a viable long-term treatment. Medical treatment (i.e., intranasal steroids), may address inferior turbinate hypertrophy. This treatment does not address the majority of the anatomic components of the nasal valve. Therefore, medical treatment is not recommended as a means of addressing nasal valve dysfunction."
- "The nasal valve may be stabilized using office-based treatments, such as implants or radiofrequency treatment. For patients who require anatomic widening and definitive stabilization of the nasal valve, surgical treatment of nasal valve collapse, along with treatment of other possible causes of nasal airway obstruction, is required to optimize patient outcomes. Failure to perform nasal valve repair, when indicated, is a common cause of incomplete symptom resolution for patients with nasal obstruction and nasal valve dysfunction."

American Rhinologic Society (ARS): ARS (2022) published a position statement regarding bioabsorbable nasal implants that stated:

- "The American Rhinologic Society (ARS) supports the use of a bioabsorbable nasal implant to treat nasal obstruction due to nasal valve collapse (CPT code 30468). This procedure should not be considered experimental, but should be considered as an effective option in treating nasal valve collapse and improving patient quality of life in those suffering from nasal airway obstruction due to nasal valve collapse based on the following data.
- Nasal valve collapse is a common finding in otolaryngology practices evaluating patients for nasal obstruction. In a study by Clark, et al, the authors identified a prevalence of 73% of nasal valve collapse in patients (n=1906) identified as having severe or extreme nasal airway obstruction based on a validated survey of nasal obstruction. Traditional methods to address nasal valve collapse involve an open septorhinoplasty approach with the placement of various cartilage grafts. There are currently bioabsorbable implants in the market that represent an alternative approach to treat the problem of nasal valve collapse. Initial studies in humans demonstrated safety and tolerance of the device as well as efficacy for the treatment of nasal airway obstruction via the absorbable implant for support of the lateral nasal cartilages through 18 months post-procedure. These data were further supported prospectively to the 6-month mark, demonstrating improvement in NOSE survey scores and sustained safety profile of the absorbable implant. Furthermore, in a randomized control trial comparing the bioabsorbable implant to a sham control procedure, patients in the treatment arm demonstrated a significantly greater decrease in NOSE score and significantly lower visual analogue scale (VAS) scores compared to patients in the sham control group.
- Given these data on safety and efficacy, the ARS supports the use of a bioabsorbable implant to treat patients presenting with nasal airway obstruction due to nasal valve collapse. We do not consider absorbable implants to be experimental and urge all payors to support the use of absorbable nasal implants in the treatment of patients with nasal valve collapse."

Radiofrequency of Nasal Valve for the Treatment of Nasal Airway Obstruction (VivAer Stylus)

Radiofrequency remodeling of the nasal valve, (e.g., VivAer Stylus), also referred to as temperature-controlled radiofrequency (TCRF) treatment, has been proposed to address nasal airway obstruction secondary to nasal valve collapse. TCRF device treatment is intended as an alternative or adjunct to current treatment options including temporary nonsurgical therapies

(e.g., external nasal dilating strips, internal nasal dilators) and more invasive surgical treatments requiring general anesthesia. During the incisionless, minimally invasive procedure, the TCRF device is inserted into the nose and radiofrequency energy is administered to the targeted zones (e.g., mucosal tissue near the caudal end of the upper lateral cartilage, head of the inferior turbinate, septal swell body). TCRF is intended to tighten and remodel subcutaneous and submucosal tissue that's contributing to the nasal airway obstruction (Aerin Medical Inc., 2026; Yao, 2023).

U.S. Food and Drug Administration (FDA)

On April 13, 2020, the VivAer Stylus (Aerin Medical, Inc.) received FDA 510(k) clearance as a Class II device. "The VivAer® Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area" (FDA, 2025).

Device or Product	Identifier	Manufacturer
VivAer Stylus	K200300	Aerin Medical, Inc.
VivAer ARC Stylus	K172529	Aerin Medical, Inc.

*FDA product codes: GEI

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

There is currently insufficient high-quality evidence in the published, peer reviewed literature to support the safety and efficacy of radiofrequency of the nasal valve (e.g., VivAer Stylus) for the treatment of nasal airway obstruction. Existing systematic reviews are limited by the absence of prospectively registered protocols, incomplete transparency in study selection, heavy reliance on non-randomized and single-arm studies, high and unexplained heterogeneity, insufficient integration of risk-of-bias assessments into quantitative syntheses, and pervasive industry involvement; which weaken the strength of the conclusions (Han, et al., 2024; Kang, et al., 2024; Casale, et al., 2023). Although non-systematic evidence includes a sham controlled randomized trial demonstrating a treatment effect, the existing, peer reviewed literature is limited due to concerns regarding risk of bias related to single blinding and crossover design, substantial heterogeneity across supporting observational studies, short-term follow-up for non-comparative studies, inconsistent reporting across studies, self-reported outcome measures, and limited independent replication of outcomes. Additional well-designed, independently conducted randomized controlled trials—with clearly defined populations, appropriate comparators, adequate follow-up, and transparent reporting are needed (Han, et al., 2025; Yao, et al., 2025; Silvers, et al., 2024; Yao, et al., 2023; Jacobowitz, et al., 2022; Han, et al., 2022; Ephrat, et al., 2021; Silvers, et al., 2021; Yao, et al., 2021; Brehmer, et al., 2019; Jacobowitz, et al., 2019).

Han et al. (2024) conducted a systematic review and meta-analysis to compare treatment effect sizes after TCRF treatment of the internal nasal valve alone (i.e., not including turbinate treatment) and functional rhinoplasty surgery. The systematic review included 68 studies involving 6519 adult individuals. Of the 68 studies, five studies involved TCRF treatment (VivAer) (318 individuals) and 80 studies involved functional rhinoplasty (6201 individuals). Inclusion criteria included studies of adults with a baseline NOSE score ≥ 45 who underwent TCRF treatment of the

nasal valve or functional rhinoplasty (primary or revision), with or without concomitant procedures, including septoplasty and turbinate treatment. Studies with less than 10 individuals, non-validated NOSE scale instruments, follow-up less than 3 months or more than 12 months, pediatric populations, septoplasty only, reduction rhinoplasty, maxillary surgery (e.g., maxillary expansion), maxillomandibular advancement, stents only, implants, caudal septal deviation or tip-focused focus procedures, or ambiguous NOSE score data or follow-up timeframe were excluded. Outcomes of interest included weighted mean difference (WMD) in NOSE score between baseline, 3, 6, and 12 months post-procedure. The study results revealed that across all analyses, pooled effect sizes for both TCRF and functional rhinoplasty were comparable. The WMD in NOSE score between baseline at 12 months was −48.8 (95% CI, −56.9 to −40.7, I2=67.9%) for TCRF treatment and −47.7 (95% CI, −51.1 to −44.4, I2= 90.0%%) for functional rhinoplasty. The systematic review did not extract or report adverse-event data from the studies included in the meta-analysis. The authors concluded that TCRF treatment of the internal nasal valve for nasal valve dysfunction was associated with sustained effects comparable to functional rhinoplasty addressing the nasal valve only, rhinoplasty without concomitant turbinate treatment, and all rhinoplasty. Study limitations noted by the authors include high heterogeneity across studies, moderate to poor quality included studies, focus on NOSE scores as an outcome measure, imbalance of datapoints when comparing TCRF treatment with all functional rhinoplasty procedures, follow-up limited to 12 months due to fewer available studies with longer follow-up, and the potential inclusion of individuals with less than moderate nasal obstruction despite the NOSE ≥ 45 requirement. (This systematic review includes the following studies summarized individually below: Han, et al., 2022; Ephrat, et al., 2021; Yao, et al., 2021; and Brehmer, et al., 2019.)

Kang et al. (2024) conducted a systematic review and meta-analysis to evaluate the efficacy of TCRF treatment in improving nasal obstruction by correcting nasal valve collapse. The systematic review included eight prospective studies involving 451 participants. Three studies were randomized. Use of the VivAer device for treatment was specified in all but one study. Studies meeting the following criteria were included in the systematic review: participants seeking improvement in nasal airway function due to severe obstruction and reporting NOSE scores greater than 55. Studies employing only VAS, duplicates, and studies without quantifiable data were excluded. Additionally, studies that involved participants who underwent other surgeries, e.g., turbinoplasty or septoplasty, were excluded, except for one study of 22 participants whose surgery was determined to not affect the lateral nasal wall. Outcomes of interest included QOL and nasal obstruction scores before and after treatment. Follow-up extended to 24 months. The study results revealed that participants who underwent treatment reported significantly enhanced QOL at 24 months when compared to pretreatment scores. After treatment, the rate of clinical improvement was 82% and the rate of positive response was 91%. Disease-specific QOL, assessed by NOSE score, also significantly improved. A meta-analysis of adverse effects was not performed as reporting of these events was noted to be sparse in the included studies. The authors concluded that nasal obstruction symptom scores demonstrated significant improvement 24 months after TCRF treatment when compared to baseline. However, the authors also noted that only one of the included studies was a comparative study with a sham group. Therefore, it was not possible to determine whether TCRF treatment was the best option for improving nasal obstruction by correcting nasal valve collapse. Additional RCTs are needed to substantiate efficacy. Study limitations noted by the authors include meta-analysis restricted to total NOSE scores and not individual NOSE score item due to limited data in the available studies, lack of studies with a control group undergoing sham treatment, small number of studies and targeted populations, demographic homogeneity, limited control of concomitant medications, exclusion of cases requiring additional surgery, uninvestigated alternative causes of obstruction, and potential conflicts of interest in the majority of included studies. (This systematic review includes the following studies summarized individually below: Han, et al., 2022; Ephrat, et al., 2021; Silvers, et al., 2021; Brehmer, et al., 2019; and Jacobowitz, et al., 2019.)

Casale et al. (2023) aimed to assess the efficacy the novel VivAer radiofrequency device to treat nasal obstruction through a systematic review and meta-analysis. The duo reviewed literature published through December 2021. Prospective or retrospective studies on patients seeking treatment for nasal obstruction due to nasal valve collapse with high NOSE scores (more than 55) were eligible for review. Four studies (218 patients aged 19-83 years of age) met the inclusion criteria and treated the nasal valve regions bilaterally. Studies were not eligible if patients underwent additional procedures such as septoplasty, turbinoplasty, rhinoplasty, and orthognathic surgery. In addition, studies were excluded from analysis if they did not clearly report outcomes of interest with quantifiable data or if data could not be extracted or outcomes calculated from published results. The primary outcome consisted of NOSE questionnaire results, representing the disease-specific QOL reported by patients, comparing pre-treatment and post-treatment values during the follow-up period. Severity was classified as follows: mild (5–25 points), moderate (30–50 points), severe (55–75 points), or extreme (80–100 points). Comparisons were analyzed between pretreatment and post-treatment values, and/or between post-treatment and control (sham) outcomes during the follow-up period. Follow-up was three months. After bilateral treatment, the NOSE score was reduced at three months postoperatively. Minor adverse events were reported in the included studies, and two showed no complications. None of the studies reported changes in the external appearance of the nose. Three months after treatment, NOSE scores reduced significantly (pre-treatment: 76.16 ± 6.39; post-treatment: 31.20 ± 2.73; MD: 46.13; 95% CI 43.27–48.99) with moderate heterogeneity (IF = 70.1%). In the only randomized controlled study, the active group showed significantly better results than control group 3 months after treatment (active group from 76.7 ± 12.6 to 34.4 ± 24.8 vs control group from 78.8 ± 14.3 to 62.0 ± 29.04). Given the moderate heterogeneity of the results and the limited number of studies investigating small populations with short follow-up periods, the outcomes of this review must be considered with caution. The authors noted the risk of bias ranged from moderate to serious. The authors concluded the radiofrequency treatment using the VivAer device could be useful for treating nasal valve collapse and significantly improved subjective breathing symptom scores. Further studies on a large scale are needed to confirm these results.

Silvers et al. (2021) conducted a prospective, multicenter, single-blinded, RCT comparing TCRF device treatment of the nasal valve (n=77) for nasal airway obstruction against a sham procedure (n=41). Inclusion criteria included: age 18 to 85 years; seeking treatment for nasal obstruction; a baseline NOSE scale score ≥55, nasal valve collapse as the primary or a significant contributor to the nasal obstruction; a positive response to a temporary nasal dilation measure, such as the modified Cottle maneuver; and patient dissatisfaction with medical management. Key exclusion criteria included: previous surgery of the lateral nasal wall; a severe case of septal deviation; turbinate hypertrophy; polyps; or ptotic nose tip believed to be the primary contributor to the nasal obstruction symptoms and warranting surgical intervention. After administration of topical and local anesthesia, intervention patients were treated bilaterally with the VivAer Stylus on up to four non-overlapping areas of the nasal mucosa at the junction of the upper and lower lateral cartilage on the lateral nasal wall. For the sham procedure, the stylus was applied in the same manner but without radiofrequency energy delivery, while audible tones mimicking activation of the Aerin Console were played. Patients were assessed at intervals with a physical and endoscopic exam, NOSE scale score, a 100-mm ease-of-breathing VAS, and a 100-mm VAS for nasal pain. Results are through three months, but the trial is planned to continue with follow-up through two years. At baseline, patients had a mean NOSE-scale score of 76.7 (95% CI, 73.8 to 79.5) and 78.8 (95% CI, 74.2 to 83.3) (p=0.424) in the active treatment and sham-control arms, respectively. At three months, the responder rate was significantly higher in the active treatment arm (88.3%, 95% CI, 79.2% to 93.7% versus 42.5%, 95% CI, 28.5% to 57.8%; p<0.001). The active treatment arm had a significantly greater mean decrease in NOSE-scale score (mean, -42.3, 95% CI, -47.6 to -37.1 versus -16.8, 95% CI, -26.3 to -7.2; p<0.001). Three adverse events related to the device and/or procedure were reported, and all resolved. This study is

limited by physicians not blinded, which could have caused bias, medication use was not dictated by the protocol, which could have impacted results, and short-term follow-up. Han et al. (2022) reported on the 12-month outcomes from this same study. The study included 108 participants who ultimately received active temperature-controlled radiofrequency treatment: 77 in the index active-treatment arm and 31 who crossed over from the sham arm after the 3-month primary endpoint. Of note, two participants who crossed over were later determined to be ineligible, but were still included in data analysis. Eleven participants were reported lost to follow-up or withdrew after either the index or crossover active treatment. Nine participants exited from the trial to undergo an additional nasal procedure to address turbinate hypertrophy and/or sinus disease after active treatment. At 12-months, the results for 88 participants were analyzed. The NOSE Scale score improved from baseline (mean change, -44.9 [95% CI, -52.1 to -37.7]). The responder rate was 89.8% (95% CI, 81.7% to 94.5%). No device/procedure-related serious adverse events were reported. Eight adverse events in seven participants were designated with at least a possible relationship to either the device or procedure (e.g., intraprocedural vasovagal reaction, nasal congestion, intermittent headache, and nasal bleeding). Study limitations noted by the authors include non-standardized concomitant medication and the potential for some confounding effect on symptom relief, 12 month follow-up, participant selection was restricted to nasal valve collapse as the primary driver of symptoms, and limited racial diversity. Of note, the crossover study design complicates long-term comparative inference versus sham. Silvers et al. (2024) published outcomes extending to two years for 71 participants. The responder rate was sustained through two years. The NOSE score treatment effect at 3 months ($p<0.001$) was sustained through 2 years ($p<0.001$). These data represent 53.6% and 54.7% improvement from baseline at 3 months and 2 years, respectively. No new adverse events related to the TCRF device/procedure were reported. The authors note the following as limitations: long-term follow-up was single arm; medication/nasal dilator use was not dictated by the protocol; lack of heterogeneity in the study population (predominantly White). Subpopulation analyses were exploratory and authors acknowledged a need for future studies focusing on discreet subpopulations in determining optimal TCRF treatment protocols to address nasal airway obstruction in specific patient populations. Han et al. (2025) reported outcomes of the original trial by Silvers et al. (2021) extending to three-years in 54 individuals. The baseline mean NOSE score was 76.3% (95% CI, 73.6 to 79.1), and three-year NOSE score treatment effect was -49.4 (95% CI, -56.5to -42.4; $p<0.001$), a 64.7% improvement from baseline. Most participants reported significant improvement in sleep post-treatment compared to baseline. This study includes significant limitations. There was a high crossover rate and a high rate of attrition; approximately 50% of the enrolled trial participants were lost to follow-up. In addition, sleep improvement was measured using the ESS, a self-reported questionnaire; CPAP data was not captured between the initial procedure and three-year follow-up, calling into question the benefit of TCRF in OSA patients. Use of nasal medication was not an enrollment criterion throughout the study, which could have had a confounding effect on symptoms. Of note, the study was funded by Aerin Medical, Inc.

Yao et al. (2021) conducted a prospective, single-arm, open-label, multi-institutional study to evaluate the effectiveness of a low-power TCRF procedure to treat the nasal valve and measure symptomatic improvement in patients diagnosed with nasal airway obstruction due to nasal valve collapse. Inclusions criteria included: age 18 years or older; NOSE Scale score ≥ 60; nasal valve was a primary or significant contributor to the patient's nasal obstruction as determined by the study investigator (based on clinical presentation, physical examination, nasal endoscopy); positive response to external nasal dilator strips (e.g., Breathe Right® Strips), Q-Tip test (manual intranasal lateralization), use of nasal stents, or Cottle’s Maneuver (manual lateral retraction of the cheek). Key exclusion criteria included: prior surgical treatment of the nasal valve within six months; rhinoplasty, septoplasty, inferior turbinate reduction or other surgical nasal procedures within three months prior; anatomy that required an adjunctive surgical nasal procedure on the same day or three months after the study procedure; medical conditions which, in the opinion of the treating physician, would predispose the patient to poor wound healing or increased surgical

risk. One hundred twenty-two patients underwent radiofrequency procedure with stylus was placed on the lateral wall of the nasal valve and treatment was applied to the mucosal tissue near the caudal end of the upper lateral cartilage at non-overlapping loci. NOSE scale total scores at three months post-procedure were significantly improved relative to baseline, from 80.3 (± 12.6; range: 60-100) to 32.9 (± 24.2; range: 0-100), p<0.001. At baseline, 100% of patients' total NOSE scale scores were in the 'extreme' (score of 80-100) or 'severe' (55-75) categories. At three months post-procedure this decreased to 18.5%. At the three-month visit, 91.6% of the patients had either a 20% improvement in NOSE scale total score relative to baseline or at least one severity category improvement. Ten adverse events that were considered related to the device or study procedure occurred, and all resolved during the study period. The study is limited due to lack of control group and short follow-up period. Yao et al. (2023) published outcomes extending to two-years (n=91). The adjusted mean change in score at 2-years was 45.8 (p < 0.001). The 2-year responder rate was 90.1%. Significant and sustained symptom improvement was achieved in subpopulations based on sex, age, body mass index, baseline nasal airway obstruction severity, nasal surgery history, nasal valve collapse mechanism, septal deviation, and other anatomic contributors of nasal airway obstruction. No serious adverse events with a relationship to the study device and/or procedure were reported. The authors acknowledged limitations of this study which included: study design (non-blinded, single-arm studies); limitation of treatment to the internal nasal valve only (the TCRF device is indicated for treatment of soft tissues such as inferior turbinates and septal swell bodies, and the results of this present study may not represent the total effect that that may be achievable using TCRF in a comprehensive nasal airway obstruction treatment protocol); lack of heterogeneity in the study population. The study population was predominantly White, which limited the analysis of outcomes in patient populations with different races and ethnicities, who may have meaningful differences in nasal anatomy. Yao et al. (2025) reported 36-month follow-up results from the original study by Yao et al. (2021). Of the 122 participants who were enrolled and treated in the primary study, 66 agreed to participate through 36-months, 16 declined to participate, four were lost to follow-up after the 24-month visit, four could not be reached after agreeing to participate, and one patient died. This death was determined to be unrelated to the device or procedure. In-person follow-up occurred at three months. Subsequent visits were conducted remotely. The study results revealed that compared to baseline, there was a 52.6% decrease in NOSE score at 36-months (<0.001). Additionally, the responder rate was 83.3% at 36-months. A post hoc sensitivity analysis of the treatment response for all participants from the time of enrollment was 73.9%. It was also observed that many participants stopped or reduced their dose of antihistamines (34.6%), leukotriene inhibitors (58.3%), decongestants (50%), and steroid nasal sprays (57.7%), during the study. There were no device or procedure-related adverse events or serious adverse events reported between 24 and 36 months. Study limitations noted by the authors include the single-arm open-label design, absence of in-person nasal examinations beyond 3 months, non-restricted medication use, high participant attrition, and lack of objective physiologic measures. Of note, the study was funded by Aerin Medical, Inc.

Brehmer et al. (2019) conducted a prospective, nonrandomized study to evaluate the safety and efficacy of the VivAer system for the treatment of narrowed nasal valves and to measure changes in the symptoms of nasal obstruction and snoring. The study involved 31 patients presenting with symptoms of nasal obstruction and snoring. Thirty days after the treatment, patients completed two questionnaires measuring nasal obstruction and snoring, NOSE and the Snore Outcomes Survey (SOS). The patients´ satisfaction with the treatment was assessed 90 days after the intervention by means of a 10-point Likert scale. In all patients, an improvement was observed in nasal breathing measured by NOSE score, sleep quality by SOS questionnaire, and QOL as measured by EQ-5D and SNOT-22. The study is limited by the small number of participants, the lack of randomization, control group and comparator, and by the short follow-up period.

Jacobowitz et al. (2019) reported on a prospective, nonrandomized, multicenter case series to assess the safety and effectiveness of in-office bipolar radiofrequency treatment of nasal valve obstruction. The study included 50 patients with a NOSE score ≥60 and clinically diagnosed with dynamic or static internal nasal valve obstruction as primary or significant contributor to obstruction and were required to have a positive response to nasal mechanical dilators or lateralization maneuvers. Bilateral radio-frequency treatment was applied intranasally using a novel device (Aerin Medical's VivAer Stylus), under local anesthesia in a single session. Safety and tolerance were assessed by event reporting, inspection and VAS for pain. Efficacy was determined using the NOSE score and patient-reported satisfaction survey at 26 weeks. No device or procedure-related serious adverse events occurred. Soreness, edema, and crusting resolved by one month. The mean baseline NOSE score was 79.9 (SD 10.8, range 60-100), and all had severe or extreme obstruction. At 26 weeks, mean NOSE score was 69% lower at 24.7 ($p<0.0001$) with 95% two-sided confidence intervals 48.5 to 61.1 for decrease. The decrease in NOSE score did not differ significantly between patients who did or did not have prior nasal surgery. Patient satisfaction mean by survey was 8.2 of 10. The study is limited by the small number of patients, lack of randomization, uncontrolled and lack of comparator, and short-term follow-up. Ephrat et al. (2021) reported on these outcomes to 24 months in 39 participants. Clinically significant improvement from baseline in NOSE Scale score change demonstrated at six months ($p < 0.0001$) was maintained through 24 months ($p<0.0001$). Responders (≥15-point improvement) consisted of 92.3% of participants at six months and 97.2% at 24 months. Responses to the QOL questions also showed improvement in patients' QOL. Jacobowitz et al. (2022) reported on results that extended out to 48 months. Extended follow-up assessments included use of the validated NOSE score, completed in person, by telephone, or through mail at 36 and 48 months post-procedure (n=28). Compared with baseline, total NOSE scores significantly improved after treatment and were maintained throughout the 48 months. NOSE scores decreased from 81.0 (±9.9) at baseline to 25.7 (±19.1) after 48 months (68.3% change) ($p<0.001$). Mean NOSE domain scores showed sustained improvement through 48 months, including patients with NOSE scores in the "extreme" (score of 80-100) or "severe" (score of 55-75) categories at baseline. At 48 months, 67.9% of patients had severity scores in the "no problems" or "mild" categories, 21.4% were in the "moderate" and 10.7% were in the "severe" categories, and none in the "extreme" category, representing significant changes in the proportion of patients in each category ($p<0.001$). Based on a ≥15-point improvement on the NOSE score scale, 93.1% (27 of 29), 96.3% (26 of 27), 96.6% (28 of 29), 100% (27 of 27), 92.9% (26 of 28), and 96.4% (27 of 28) of patients were considered responders at the 6-, 12-, 18-, 24-, 36-, and 48-month follow-up times, respectively. This study was limited by its use of a single-arm design without randomized control, no control of medication usage, and small population size. Two nonparticipants were known to have undergone subsequent surgery for nasal obstruction and it is possible that the effectiveness declined in the extended follow-up nonparticipants. The authors conclude that significant and sustained improvements in symptoms of nasal airway obstruction were shown through 4 years following treatment of nasal valve collapse via a single TCRF procedure.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): AAO-HNS (2023) published a non-evidence based position statement regarding nasal valve repair that states:

- "The American Academy of Otolaryngology-Head and Neck Surgery recognizes surgical repair of the nasal valve as a distinct surgical procedure that can improve nasal obstruction symptoms for appropriately selected patients with nasal valve collapse."
- "The treatment of nasal valve dysfunction may involve techniques that include cartilage grafting and open surgical repair, suture suspension techniques, and implants or radiofrequency treatment aimed at stabilizing the nasal valve. Surgical repair of the nasal

valve can be performed as a standalone surgical procedure or in conjunction with other procedures to improve nasal obstruction. These may include septoplasty, turbinate reduction, endoscopic sinus surgery, among others. These procedures, such as septoplasty, may be complementary to nasal valve repair, but are not effective substitutes as they do not address nasal valve dysfunction. When feasible, surgical treatment to address all contributing anatomic sites should be performed concomitantly, based on patient and physician shared decision making. Requiring septoplasty and/or turbinate surgery prior to nasal valve surgery is not recommended, as this may lead to unnecessary increases in surgical encounters."

- "Nasal valve repair in appropriately selected patients is effective for symptom relief and quality-of-life improvement. When nasal valve dysfunction is diagnosed, conservative therapy may include nasal cones or external nasal dilator adhesive strips. However, these are not feasible for around the clock use and are not viewed as a viable long-term treatment. Medical treatment (i.e., intranasal steroids), may address inferior turbinate hypertrophy. This treatment does not address the majority of the anatomic components of the nasal valve. Therefore, medical treatment is not recommended as a means of addressing nasal valve dysfunction."
- "The nasal valve may be stabilized using office-based treatments, such as implants or radiofrequency treatment. For patients who require anatomic widening and definitive stabilization of the nasal valve, surgical treatment of nasal valve collapse, along with treatment of other possible causes of nasal airway obstruction, is required to optimize patient outcomes. Failure to perform nasal valve repair, when indicated, is a common cause of incomplete symptom resolution for patients with nasal obstruction and nasal valve dysfunction."

Septoplasty

Septoplasty is a surgical procedure to correct symptomatic nasal airway obstruction with a deviated nasal septum. However, more complicated septal repairs may require septorhinoplasty. Septoplasty is also used for recurrent epistaxis related to a septal deformity. Though, topical moisturization and nasal humidification may also be effective in preventing epistaxis. Nasal airway obstruction is associated with poor sleep quality, snoring, and obstructive sleep apnea (OSA). While nasal surgical procedures alone are unlikely to significantly improve the symptoms of OSA, septoplasty may improve nasal patency, help restore physiologic breathing, and increase continuous positive airway pressure (CPAP) adherence for previously intolerant individuals. Septoplasty is also indicated when performed in association with a covered cleft lip or cleft palate repair. (Fuller, et al., 2026; Kuan, et al., 2026; Sarber, et al., 2026; ACPA, 2024; AAO-HNS, 2015).

U.S. Food and Drug Administration (FDA)

Septoplasty is considered a surgical procedure and does not require FDA review or approval.

Literature Review

Septoplasty is considered a standard of care in select individuals with nasal breathing difficulty or mouth breathing due to septal deviation or deformity, recurrent epistaxis related to a septal deformity, or obstructed nasal breathing due to septal deformity or deviation that has proved poorly responsive to medical management and is interfering with the effective use of medically necessary continuous positive airway pressure (CPAP) for the treatment of an obstructive sleep disorder. Septoplasty is also considered a standard of care when performed in association with a covered cleft lip or cleft palate repair (Fuller, et al., 2026; Kuan, et al., 2026; Sarber, et al., 2026; ACPA, 2024; AAO-HNS, 2015).

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): AAO-HNS (2015) conducted a systematic review of the literature and published clinical consensus statements regarding septoplasty with or without inferior turbinate reduction including:

- "Septoplasty can improve continuous positive air pressure tolerance for patients with sleep apnea and a deviated septum."
- "Septoplasty may be useful in managing epistaxis."
- "Septoplasty can improve quality of life for patients with septal deviation."
- "Septoplasty can improve outcomes of sinus surgery when the septum is contacting the middle turbinate and obstructing the drainage of the ostiomeatal complex."

American Cleft Palate-Craniofacial Association (ACPA): ACPA (2024) parameters of care for the evaluation and treatment of individuals with cleft lip/palate and/or other craniofacial conditions notes:

- "Depending on the severity of the cleft lip, primary rhinoplasty with or without limited septoplasty should be performed at the time of the primary cleft lip surgery to address nasal distortion."
- "Optimization of the nasal airway may have benefits to oral hygiene (i.e. reducing mouth breathing) and reduce risks of obstructive sleep apnea (see Sleep Health and Hygiene and Airway and Breathing)."
- "Definitive septorhinoplasty should await skeletal maturity. If orthognathic surgery is indicated, septorhinoplasty is usually undertaken afterwards to avoid nasal changes that may occur with jaw surgery."
- "Septorhinoplasty may involve addressing septal deviation and other measures to reduce nasal airway obstruction."

Balloon Dilation Septoplasty for Treatment of Septal Deviation

Septoplasty is a standard of care surgical procedure to correct symptomatic nasal airway obstruction with a deviated nasal septum. However, more complicated septal repairs may require septorhinoplasty. Balloon dilation septoplasty, also referred to as balloon-assisted endoscopic septoplasty, has been proposed as a less invasive and alternative treatment for septal deviation. During the procedure, a nasal balloon is endoscopically positioned and sequentially inflated to apply hydrostatic pressure and mobilize the septal cartilage and bone toward the midline without cutting (Fuller, et al., 2026; Dillard, et al., 2025).

U.S. Food and Drug Administration (FDA)

Balloon dilation septoplasty devices for treatment of septal deviation are considered Class I medical devices and are regulated by the FDA via the 510(k) pathway.

According to the manufacturer of the ClearPath Nasal Balloon System (ClearPath, 2025):

- "The ClearPath Nasal Balloon System is a minimally invasive device designed to provide precise nasal dilation, helping surgeons address nasal obstructions and improve patient outcomes."
- "ClearPath is intended for patients aged 17 and older to address nasal obstructions by dilating the inferior turbinate and nasal septum."

- "ClearPath is intended for patients aged 17 and older to address nasal obstructions by dilating the inferior turbinate and nasal septum."
- "ClearPath is effective for treating nasal obstructions, septal deviations, turbinate hypertrophy, and conditions requiring increased nasal space for endoscopic procedures."

The ClearPath Nasal Balloon System was cleared by the FDA as the Dillard Nasal Balloon Catheter (Intuit Medical Products, LLC).

Device or Product	Identifier	Manufacturer
Dillard Nasal Balloon Catheter	K181546	Intuit Medical Products, LLC

*FDA product code: LRC

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

There is a lack of high-quality evidence in the published, peer reviewed literature to support the safety and efficacy of balloon dilation septoplasty for septal deviation.

For information on balloon sinus ostial dilation (balloon sinuplasty) and eustachian tube balloon dilation (ETBD) procedures, refer to the Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation Medical Coverage Policy (Coverage Policy Number: 0480).

Septoplasty and Rhinoplasty for Obstructive Sleep Apnea (OSA)

There is insufficient literature found to support the efficacy of septoplasty and rhinoplasty as a primary treatment for obstructive sleep apnea (OSA), either performed alone or routinely as part of another procedure such as uvulopalatopharyngoplasty (UPPP). However, septoplasty may improve nasal patency, help restore physiologic breathing, and increase CPAP adherence for previously intolerant individuals (Sarber, et al., 2026).

Professional Societies/Organizations

American Academy of Sleep Medicine (AASM): According to the AASM recommendations (Kapur, et al., 2017; AASM, 1999), OSA severity is determined by the severity of daytime sleepiness and of sleep-related obstructive breathing based on overnight monitoring. A severity level is specified for each component. The diagnosis of moderate OSA would include:

- Sleepiness: Unwanted sleepiness or involuntary sleep episodes occur during activities that require some attention, such as concerts, meetings, or presentations. Symptoms produce moderate impairment of social or occupational function.
- Sleep related obstructive breathing events: ≥ 15 and ≤ 30 events per hour.

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.

References

1. Aerin Medical Inc. Aerin Medical - VivAer. 2026. Accessed January 5, 2026. Available at URL address: https://vivaer.com/hcp/

2. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Clinical Practice Guideline: Improving Nasal Form and Function after Rhinoplasty. 2017. Accessed January 5, 2026. Available at URL address: https://www.entnet.org/quality-practice/quality-products/clinical-practice-guidelines/

3. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Clinical consensus statement: Diagnosis and management of nasal valve compromise. 2010. Accessed January 5, 2026. Available at URL address: https://www.entnet.org/quality-practice/quality-products/expert-consensus-statements/

4. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Expert Consensus Statement. Clinical Consensus Statement. Septoplasty with or without Inferior Turbinate Reduction. 2015. Accessed January 5, 2026. Available at URL address: https://www.entnet.org/quality-practice/quality-products/expert-consensus-statements/

5. American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Position Statement: Nasal Valve Repair. March 22, 2023. Accessed January 5, 2025. Available at URL address: https://www.entnet.org/business-of-medicine/position-statements/

6. American Academy of Sleep Medicine (AASM). Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep. 1999 Aug 1;22(5):667-89.

7. American Cleft Palate-Craniofacial Association (ACPA). Parameters of Care for Evaluation and Treatment of Individuals with Cleft Lip/Palate and/or Other Craniofacial Conditions. 2024. Accessed January 5, 2026. Available at URL address: https://acpacares.org/parameters-of-care/

8. American Rhinologic Society (ARS). ARS Position Statement: Bioabsorbable Nasal Implants. January 2022. Accessed January 5, 2026. Available at URL address: https://www.american-rhinologic.org/position-statements

9. Bikhazi N, Ow RA, O'Malley EM, Perkins N, Sidle DM, Stolovitzky P. Long-Term Follow-up from the Treatment and Crossover Arms of a Randomized Controlled Trial of an Absorbable Nasal Implant for Dynamic Nasal Valve Collapse. Facial Plast Surg. 2022 Oct;38(5):495-503.

10. Brehmer D, Bodlaj R, Gerhards F. A prospective, non-randomized evaluation of a novel low energy radiofrequency treatment for nasal obstruction and snoring. Eur Arch Otorhinolaryngol. 2019;276(4):1039–1047.

11. Casale M, Moffa A, Giorgi L, Pierri M, Lugo R, Jacobowitz O, Baptista P. Could the use of a new novel bipolar radiofrequency device (Aerin) improve nasal valve collapse? A systematic review and meta-analysis. J Otolaryngol Head Neck Surg. 2023 Jun 22;52(1):42.

12. ClearPath. Frequently asked questions. 2025. Accessed January 5, 2025. Available at URL address: https://www.clearpathnasal.com/faqs

13. Corey CL, Most SP. Treatment of nasal obstruction in the posttraumatic nose. Otolaryngol Clin North Am. 2009 Jun;42(3):567-78.

14. Dillard DJ, Koudouovoh C, Lee V, Barnes C, Su R, Fortson JK. Outcomes of force-directed balloon-assisted endoscopic septoplasty: a retrospective analysis with a new technique and device. Organization for Research in Otolaryngology. 2025. Available from: https://www.oromed.org/post/outcomes-of-force-directed-balloon-assisted-endoscopic-septoplasty-a-retrospective-analysis-with-a

15. Ephrat M, Jacobowitz O, Driver M. Quality-of-life impact after in-office treatment of nasal valve obstruction with a radiofrequency device: 2-year results from a multicenter, prospective clinical trial. Int Forum Allergy Rhinol. 2021 Apr;11(4):755-765.

16. Fuller JC, Burks CA, Lindsay RW. Functional rhinoplasty. In: Francis HW, Haughey BH, Hillel AT, Lesperance MM, Lund VJ, Park SS, Robbins KT. Cummings Otolaryngology. Eighth Edition. Philadelphia: Elsevier; 2026. 33, 539-552.e2

17. Han JK, Perkins J, Lerner D, Yim MT, Ishii LE. Comparison of nasal valve dysfunction treatment outcomes for temperature-controlled radiofrequency and functional rhinoplasty surgery: a systematic review and meta-analyses. Rhinology. 2024 Jun 1;62(3):258-270.

18. Han JK, Rosenthal JN, McDuffie CM, Yen DM, Bikhazi NB, Kakarlapudi VV, Silvers SL. Temperature-Controlled Radiofrequency Treatment of the Nasal Valve in Patients With Nasal Obstruction: Long-Term Outcomes. Otolaryngol Head Neck Surg. 2025 Apr;172(4):1214-1223.

19. Han JK, Silvers SL, Rosenthal JN, McDuffie CM, Yen DM. Outcomes 12 Months After Temperature-Controlled Radiofrequency Device Treatment of the Nasal Valve for Patients With Nasal Airway Obstruction. JAMA Otolaryngol Head Neck Surg. 2022 Oct 1;148(10):940-946.

20. Hosal SA, Aydin, C. Rhinectomy. In: Myers EN, Snyderman CH. Operative Otolaryngology Head and Neck Surgery. Third Edition. Philadelphia, PA: Elsevier; 2018. 101, 674-680.

21. Hwang PH, Lin B, Weiss R, et al. Cryosurgical posterior nasal tissue ablation for the treatment of rhinitis. Int Forum Allergy Rhinol. 2017;7(10):952-956.

22. Jacobowitz O, Driver M, Ephrat M. In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device. Laryngoscope Investig Otolaryngol. 2019;4(2):211–217.

23. Jacobowitz O, Ehmer D, Lanier B, Scurry W, Davis B. Long-term outcomes following repair of nasal valve collapse with temperature-controlled radiofrequency treatment for patients with nasal obstruction. Int Forum Allergy Rhinol. 2022 Nov;12(11):1442-1446.

24. Jang YJ, Kwon M. Modified extracorporeal septoplasty technique in rhinoplasty for severely deviated noses. Ann Otol Rhinol Laryngol. 2010 May;119(5):331-5.

25. Kang YJ, Kim DH, Stybayeva G, Hwang SH. Effectiveness of Radiofrequency Device Treatment for Nasal Valve Collapse in Patients With Nasal Obstruction. Otolaryngol Head Neck Surg. 2024 Jan;170(1):34-44.

26. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017 Mar 15;13(3):479-504.

27. Kim DH, Lee HH, Kim SH, Hwang SH. Effectiveness of using a bioabsorbable implant (Latera) to treat nasal valve collapse in patients with nasal obstruction: systemic review and meta-analysis. Int Forum Allergy Rhinol. 2020 Jun;10(6):719-725.

28. Kuan EC, Palmer JN, Rimmer J. Epistaxis. In: In: Francis HW, Haughey BH, Hillel AT, Lesperance MM, Lund VJ, Park SS, Robbins KT. Cummings Otolaryngology. Eighth Edition. Philadelphia: Elsevier; 2026. 46, 749-761.e4.

29. San Nicoló M, Stelter K, Sadick H, Bas M, Berghaus A. A 2-Year Follow-up Study of an Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg. 2018 Oct;34(5):545-550.

30. San Nicoló M, Stelter K, Sadick H, Bas M, Berghaus A. Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg. 2017 Apr;33(2):233-240.

31. Sarber KM, Lam DJ, Ishman SL. Sleep apnea and sleep disorders. In: In: Francis HW, Haughey BH, Hillel AT, Lesperance MM, Lund VJ, Park SS, Robbins KT. Cummings Otolaryngology. Eighth Edition. Philadelphia: Elsevier; 2026. 14, 216-236.e4.

32. Sidle DM, Stolovitzky P, Ow RA, Silvers S, Matheny K, Bikhazi N, et al. Twelve-month outcomes of a bioabsorbable implant for in-office treatment of dynamic nasal valve collapse. Laryngoscope. 2020 May;130(5):1132-1137.

33. Silvers SL, Rosenthal JN, McDuffie CM, Yen DM, Han JK. Temperature-controlled radiofrequency device treatment of the nasal valve for nasal airway obstruction: A randomized controlled trial. Int Forum Allergy Rhinol. 2021;11(12):1676-1684.

34. Silvers SL, McDuffie CM, Yen DM, Rosenthal JN, Davis SE, Han JK. Two-year outcomes of radiofrequency device treatment of the nasal valve for nasal airway obstruction. Rhinology. 2024 Jan 13.

35. Stolovitzky P, Senior B, Ow RA, Mehendale N, Bikhazi N, Sidle DM. Assessment of bioabsorbable implant treatment for nasal valve collapse compared to a sham group: a randomized control trial. Int Forum Allergy Rhinol. 2019 Aug;9(8):850-856.

36. Stolovitzky P, Sidle DM, Ow RA, Nachlas NE, Most SP. A prospective study for treatment of nasal valve collapse due to lateral wall insufficiency: Outcomes using a bioabsorbable implant. Laryngoscope. 2018 Nov;128(11):2483-2489.

37. Stryker. LATERA® absorbable nasal implant system. 2026. Accessed January 5, 2026. Available at URL address: https://www.stryker.com/us/en/ent/products/latera-absorbable-nasal-implant-system.html

38. U.S. FDA 510(k): U.S. Food and Drug Administration (FDA). 510(k) premarket notification database. Product code(s): LRC, GEI, NHB. Page Last Updated: January 5, 2026. Accessed January 5, 2025. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

39. Walker BA, Toriumi DM. Primary rhinoplasty. In: In: Francis HW, Haughey BH, Hillel AT, Lesperance MM, Lund VJ, Park SS, Robbins KT. Cummings Otolaryngology. Eighth Edition. Philadelphia: Elsevier; 2026. 31, 494-519.e2

40. Yao WC, Ow RA, Barham HP. Temperature-Controlled Radiofrequency Treatment of the Nasal Valve and Nasal Airway Obstruction: Early Results of a Prospective, Multi-Center Study. J Otolaryngol Rhinol. 2021, 7:105.

41. Yao WC, Pritikin J, Sillers MJ, Barham HP. Two-year outcomes of temperature-controlled radiofrequency device treatment of the nasal valve for patients with nasal airway obstruction. Laryngoscope Investig Otolaryngol. 2023 Jun 15;8(4):808-815.

42. Yao WC, Ow R, Sillers MJ, Nachlas NE, Johnson CD, Ehmer D, Pritikin J, Barham HP. Three-Year Outcomes After Temperature-Controlled Radiofrequency Treatment of Nasal Airway Obstruction. OTO Open. 2025 Apr 7;9(2):e70111.

Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Revised policy statement for rhinoplasty. • Revised policy statement for septoplasty.	5/15/2025
Focused Review	• Removed requirement for recent trial of conservative treatment prior to Septoplasty.	10/15/2025
Annual Revision	• Added policy statement for partial rhinectomy. • Removed policy statements related to RhinAer and Clarifix.	9/15/2025
Annual Revision	• No clinical policy statement changes.	5/15/2024
Focused Review	• Updated to new template and formatting standards	11/12/2023