Nasal Implants for Nasal Vestibular Lateral Wall Stenosis or Collapse

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DESCRIPTION

Vestibular stenosis or collapse of the internal valves may be a cause of nasal obstruction. The nasal valve refers to tissue that acts as a bridge between the bony skeleton and the nasal tip and can account for approximately half of the total airway resistance of the entire upper and lower respiratory tract. Nasal valve compromise may account for nasal airway obstruction. The causes of internal nasal valve obstruction may include previous surgery, trauma, facial paralysis, and cleft lip nasal deformities. The nasal valve has internal and external components. The internal nasal valve is the narrowest portion of the nasal cavity and compromise of these components of the valve may create symptoms of nasal obstruction. Deformities of the adjacent nasal septum or loss of anatomic support structures can predispose the valve to collapse or narrowing, which may cause airway obstruction. The upper lateral cartilage at its junction with the septum may be thickened, twisted, or concave because of weakness, trauma, or prior surgery.

The external valve is a laterally based space that is surrounded by the anterior nasal opening in the skull, the upper lateral cartilage and lower lateral cartilage attachments and the caudal septum.

Nasal Obstruction
Nasal obstruction is defined clinically as a patient symptom that presents as a sensation of reduced or insufficient airflow through the nose. Commonly, patients will feel that they have nasal congestion or stuffiness. In adults, clinicians focus the evaluation of important features of the history provided by the patient such as whether symptoms are unilateral or bilateral. Unilateral symptoms are more suggestive of structural causes of nasal obstruction. A history of trauma or previous nasal surgery, especially septoplasty or rhinoplasty, is also important. Diurnal or seasonal variation in symptoms is associated with allergic conditions.

Etiology
Nasal obstruction associated with the external nasal valve is commonly associated with post-rhinoplasty or traumatic sequelae and may require functional rhinoplasty procedures. A common cause of internal nasal valve collapse is a septal deviation. Prior nasal surgery, nasal trauma, and congenital anomaly are additional causes.

Pathophysiology
The internal nasal valve, bordered by the collapsible soft tissue between the upper and lower lateral cartilages, the anterior end of the inferior turbinate, and the nasal septum, forms the narrowest part of the nasal airway. During inspiration, the lateral wall cartilage is dynamic and draws inward toward the septum and the internal nasal valve narrows providing protection to the upper airways. The angle at the junction between the septum and upper lateral cartilage is normally 10° to 15° in white populations. Given that the internal nasal valve accounts for at least half of the nasal airway resistance; even minor further narrowing of this area can lead to symptomatic obstruction for a patient. Damaged or weakened lateral nasal cartilage will further decrease airway capacity of the internal nasal valve area, increasing airflow resistance and symptoms of congestion.

Physical Examination
A thorough physical examination of the nose, nasal cavity, and nasopharynx is generally sufficient to identify the most likely etiology for the nasal obstruction. Both the external and internal nasal valve areas should be examined. The external nasal valve is at the level of the internal nostril. It is formed by the caudal portion of the lower lateral cartilage, surrounding soft tissue and the membranous septum.

The Cottle maneuver is a test of nasal valve integrity. It can be performed by retracting the cheek laterally, pulling the upper lateral cartilage away from the septum and widening the internal nasal valve angle. If the patient's symptoms are relieved with this maneuver, it suggests that the cause of the nasal airway obstruction is related to the nasal valve area (e.g., dorsal septal deviation, lack of upper lateral cartilage integrity). Another technique to evaluate the nasal valves involves using an object (e.g., cotton swab or nasal speculum) to lateralize the upper lateral cartilage from inside the nose, and the patient is

asked if their symptoms are improved. This technique allows direct observation of the nasal valve area as it widens.

Treatment
Treatment of symptomatic nasal valve collapse includes the use of non-surgical interventions such as the adhesive strips applied externally across the nose (applying the principle of the Cottle maneuver) or use of nasal dilators, cones, or other devices that support the lateral nasal wall internally (applying the principle of the modified Cottle maneuver).

Severe cases of obstruction result from nasal valve deformities are treated with surgical grafting to widen and/or strengthen the valve. Common materials include cartilaginous autografts and allografts, as well as permanent synthetic grafts. Cartilage grafts are most commonly harvested from the patient's nasal septum or ear.

Nasal Implants
The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction.

The Latera implant is designed to support the lateral nasal cartilage. It is intended to treat nasal valve collapse, which may lead to nasal obstruction and difficulty breathing. According to the vendor, it is endoscopically placed inside the nasal wall in a minimally invasive procedure by otolaryngologists or plastic surgeons using the manufacturer provided accessory delivery device. The implant is intended to support the nasal cartilage and potentially reduce the symptoms of airway obstruction. It is composed of poly (l-lactic acid) (PLLA) and poly (dlactic acid) (PDLA) copolymer materials and is designed to be absorbed by the body within approximately 18 months after implantation.

Clinical Context and Therapy Purpose
The purpose of insertion of an absorbable nasal valve implant in patients who have symptomatic nasal valve obstruction due to nasal valve collapse (NVC) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is adults who have severe symptomatic nasal obstruction symptoms due to the internal (also known as zone 1) NVC. NVC is one of the recognized structural causes of obstructed breathing and congestion, and the diagnosis is primarily clinical. NVC may be unilateral or bilateral and is typically constant with each inspiration. The condition may occur in association with prior trauma or rhinonasal surgery. The evaluation consists of clinical history to elicit alternative causes or co-occurring conditions such as obstructive sleep apnea or medication use. In addition to examination of the head and neck, the Cottle maneuver or modified Cottle maneuver (previously described) is used to rule-in NVC. Anterior rhinoscopy and nasal endoscopy are used and rule out structural abnormalities such as septal deviation or mucosal conditions such as enlarged turbinates. Radiographic studies are not generally indicated.

Interventions
The therapy being considered is a unilateral or bilateral insertion of an absorbable nasal implant into the lateral nasal wall. The product is predominantly cylindrical in shape with a diameter of 1 mm and an overall length of 24 mm with a forked distal end for anchoring into the maxillary periosteum. It is composed of poly (L-lactide-*co*-D-L-lactide) 70:30 copolymer, which is absorbed in the body over approximately 18 months. It is packaged with a 16-gauge insertion device. The available product information describes the integrity of the implant to be maintained for 12 months after implantation while a fibrous capsule forms around the device. A remodeling phase where collagen replaces the implant within the capsule persists through 24 months and is the purported mechanism of support for the lateral nasal wall support.

Comparators
The following therapies and practices are currently being used to treat NVC: nonsurgical treatments include the use of externally applied adhesive strips or intranasal insertion of nasal cones. The basic mechanism of action of these treatments is to widen the nasal valve and permit increased airflow. Surgical grafting using either autologous cartilage (typically from the nasal septum, ear, or homologous irradiated rib cartilage) or a permanent synthetic implant may be performed to provide structural support to the lateral wall support defect.

Outcomes
The general outcomes of interest are a change in symptoms and disease status, treatment-related morbidity, functional status, and change in the quality of life (QOL). The Nasal Obstruction Symptom Evaluation (NOSE) score is an accepted symptom questionnaire for research purposes. The score can also be stratified to indicate the degree of severity of the nasal obstruction symptoms. The insertion of the absorbable implant is performed under local anesthesia and the adverse event profile includes mild pain, irritation, bruising and inflammation, awareness of the presence of the implant, infection, and the need for device retrieval prior to complete absorption.

Review of Evidence
Hayes Evolving Evidence Review completed March 2022 regarding absorbable nasal implant (Latera, Stryker) for the treatment of nasal valve collapse, while the clinical evidence may show promise in suggesting absorbable nasal implants are associated with reduction in nasal airway obstruction symptoms and pain, the current peer reviewed medical literature is of generally very poor quality and the studies do not include control groups to allow conclusions as to whether absorbable nasal implants have a clinical performance that is better, worse or similar to other treatments such as nonabsorbable nasal implants.

In 2021, Bikhazi et. al. reported on the long-term follow-up from the treatment and crossover arms of randomized controlled trial of an absorbable nasal implant for dynamic nasal valve collapse. Participants were adults with severe/extreme nasal airway

obstruction primarily due to nasal valve insufficiency who had implant placement. Follow-up visits were at 3,6,12,18, and 24 months post implant. Visits included collection of the following patient-reported outcome measures: nasal obstructive symptom evaluation (NOSE), nasal obstruction visual analog scale (VAS), and the Epworth Sleepiness Scale (ESS). Adverse events were evaluated at each visit. One-hundred-eleven participants with implants were followed. Of the 111, 90 completed the 12-month visit and 70 completed the 24-month visit. NOSE responder rates are greater than 80% at all follow-ups through 24months. Mean reduction from baseline in NOSE scores is $\geq$30 points and statistically significant ($p<0.001$) at all timepoints through 24 months. Mean VAS score reduction is $\geq$ 29.7 points and statistically significant ($p <0.001$) at all time points. The subgroup of participants with baseline ESS values >10 experienced statistically significant ($p <0.001$) and clinically meaningful reductions at all postimplant periods, suggesting that the reduction in nasal symptoms may reduce daytime sleepiness for patients who have problems with sleep quality. No serious device-procedure-related adverse events were reported. Implant migration/retrieval rate was 4.5% (10/222) of total implants or 9% of participants (10/111). Limitations related to this study include the lack of long-term follow-up of the control arm, significant loss of study participants to follow-up at 18 and 24 months, and a lack of objective assessment of nasal valve collapse. The loss of treatment participants at 18 and 24 months, which was due in part to the coronavirus-19 pandemic of 2020, also presented a limitation to the study. Finally, a notable limitation of this study is an uneven distribution of participants of varying race or ethnicity. While the enrolled population of non-White participants was low at 14%, significant attempts were made in the study design to find a diverse population, such as the inclusion of 10 clinical sites across multiple geographies. While all attempts to find a diverse population were made, inherent bias toward White participants may exist. Previous studies have demonstrated racial differences in nasal anatomy that may contribute to underrepresentation of some ethnic groups.

In 2021, Olson et. al. compared absorbable nasal implants versus functional rhinoplasty for nasal obstruction. Two groups were analyzed for the study. One group had surgery which included the implant, septoplasty, and inferior turbinate submucous reduction and the other group had a variety of functional rhinoplasty techniques for lateral wall insufficiency in addition to septoplasty and inferior turbinate submucous reduction. NOSE and SNOT-22 were used to demonstrate pre- and post-operative changes. Ninety total patients were identified. Fifty patients underwent insertion of an absorbable nasal implant and 40 underwent a traditional open technique to stabilize the LNW. For the implant group the mean NOSE score was 63.4 (SD 24) and post-operative was 22.9 (SD 19.9), in addition, the SNOT-22 score was 38.8 (SD 19.8) and post-operative was 18.5 (SD 15.2). For the open rhinoplasty group, the mean NOSE score was 57.9 (SD 23.2) and post-operative was 17.6 (SD 16.4). The SNOT-22 score was 33.6 (SD 14.9) and post-operative score was 11.5 (SD 15.2) The delta between pre- and post-operative NOSE and SNOT-22 test were not different at an average of 3.95 months post-operatively between the groups (NOSE, $P = 0.94$ and SNOT-22, $p = 0.53$). Limitations of this study include: The difficulty in determining what was the patient's main driver of nasal obstruction was

upon presentation which is not an uncommon problem in evaluating patients with nasal obstruction related to multiple structural etiologies. A second limitation of the study is some of the open techniques, such as LCSGs, support of the LNW is usually accomplished by lateralization of the nasal wall, and perhaps in these patients their improvement was secondary to this mechanism. Although the end outcome of the LCSG is improvement in the LNW pathology, it may have led this subgroup to have a more robust response in comparison. Furthermore, the study did not follow individuals for longer than 6 months which calls into question whether the effect demonstrated in patient-reported outcome measures will be persistent after the implant is absorbed (approximately 18 months). Other limitations included the retrospective nature of this study. Ideally, a prospective study of patients with just LNW collapsibility compared to patients undergoing an isolated open technique to the LNW would be undertaken. Of course, this type of study is challenging at best without a multi-center collaboration given the relative rare nature of isolate LNW collapse. Finally, the age and gender differences between the two groups should be considered, with the implant group being older and predominately male, however conclusions regarding the effect of this on the study outcomes are unlikely to be definitive.

In 2021, Sidle et. al. reported outcomes after treatment of nasal valve collapse with a bioabsorbable nasal implant. It involves two prospective, multicenter, post-market studies evaluating long-term effectiveness of the LATERA implant for severe to extreme nasal obstruction. Participants underwent implant alone or with concomitant inferior turbinate reduction (ITR) and/or septoplasty. Outcome measures included the change from baseline Nasal Obstruction Symptom Evaluation (NOSE) scores, NOSE responder rates, visual analog scale (VAS) scores, and adverse events. A total cohort of 277 participants (109 implants only, 67 implants + ITR, 101 implants + septoplasty +ITR) enrolled at 19 U.S. centers was available for analysis with 177 participants (69 implants only, 39 implants + ITR, 69 implants + septoplasty + ITR) available at 2 years. The mean changes from baseline in NOSE scores and VAS scores were statistically significant ($p<0.001$) at all follow-up periods. The baseline NOSE score of 77.8 $\pm$ 13.6 was improved to 24.2 $\pm$ 23.6 at 24 months. Greater than 90% of participants were NOSE responders across all follow-up periods, 6.1% withdrew for lack of treatment effect. The baseline VAS score of 66.718.8 was improved to 21.1$\pm$23.9 at 24 months. There were no serious adverse events related to the device or implant procedure. Implant retrieval rate was 4.0% (22/543 implants). Nonserious adverse events were mild to moderate in severity, typically occurred within 6 months of implant, and resolved or were stable. Significant reductions in NOSE and VAS scores and high responder rates from our large population of patients with nasal obstruction who had nasal valve implants confirm sustained effectiveness at 24months after treatment. Study limitations include lack of control group and the initial study design only included follow-up through 12-months. The long- term follow- up amendment required additional consent and resulted in some loss to follow-up at long-term visits. Additionally, two patients were withdrawn due to implant retrieval before any follow-up data were obtained. To address this limitation, a worst-case sensitivity analysis was performed.

Kim et. al. (2020) reported on a systematic review with meta-analysis to determine the efficacy of bioabsorbable nasal implant for treating nasal obstruction caused by lateral wall insufficiency (LWI). Five studies (n=396) were included in the study. Studies that scored endoscopic lateral wall movement and nasal obstruction related to quality of life (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 study found that bioabsorbable nasal implants significantly reduced endoscopic lateral wall motion compared to pretreatment values and also 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 randomized clinical trials must be conducted to further verify the effectiveness of bioabsorbable nasal implants. The authors noted that larger comparative studies or well-designed randomized clinical trials 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 (NVC) with a bioabsorbable implant. The study included 166 patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (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 Visual Analog Scale (VAS) were measured at baseline and one, three, six, and 12 months postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video. One hundred five patients were treated with implant alone, whereas 61 had implant + ITR. Thirty-one patients 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 vs. 36.2 ± 22.7 at 1 month postoperatively, 33.0 ± 23.4 at 3 months, 32.1 ± 24.6 at 6 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 vs. 31.3 ± 27.1 at 12 months postoperatively, $P<0.001$). The results were similar in patients treated with implant alone and those treated with the implant + ITR. Consistent with patient-reported outcomes, postoperative LWI scores were demonstrably lower (1.42 ± 0.09 and 0.93 ± 0.08 pre- and postoperatively, $P < 0.001$). The authors note that limitations of this study include that this a single-arm study comparing pre- and posttreatment measurements of symptoms and that a future randomized controlled study should be considered to further examine the device efficacy. The study was limited to 12- months and additional follow-up out to 24-months would be beneficial.

Stolovitzky et. al. (2019) conducted a prospective, multicenter, single-blinded randomized controlled trial to evaluated minimally invasive procedure addressing dynamic nasal valve collapse (NVC) with a bioabsorbable implant (Latera) to support the lateral nasal wall. The study included 137 patients randomized into two arms: treatment arm (70 patients) and sham control arm (67 patients). Patients 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 patients with reduction in clinical severity by ≥1 category or ≥20% reduction in Nasal Obstruction Symptom Evaluation [NOSE] score). At three months (27 patients included in the final analysis: 63 treatments; 64 sham control) responder rate was higher for the treatment arm compared to the control (82.5% vs 54.7%, $p = 0.001$). Patients in the treatment arm also had a significantly greater decrease in NOSE score ($–42.4 \pm 23.4$ vs $–22.7 \pm 27.9$, $p < 0.0001$) and significantly lower visual analogue scale (VAS) scores ($–39.0 \pm 29.7$ vs $–13.3 \pm 30.0$, $p < 0.0001$) than the sham control arm. Seventeen patients reported 19 procedure/implant-related adverse events, all of which resolved with no clinical sequelae. The study is limited to the short follow-up time of three months and that the study is single blinded which all patients 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-blinded 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 Nasal Obstruction Symptom Evaluation (NOSE) scores. The patients were treated with a bioabsorbable implant designed to support lateral wall, with or without concurrent septoplasty and/or turbinate reduction procedure(s). NOSE scores and visual analog scale (VAS) were measured at baseline and one, three, and six months postoperatively. The Lateral Wall Insufficiency (LWI) 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 one, three, and six months postoperatively (79.5 ± 13.5 preoperatively, 34.6 ± 25.0 at 1 month, 32.0 ± 28.4 at 3 months, and 30.6 ± 25.8 at 6 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 LWI 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 Nicolo et. al. (2018) reported on follow-up of the above study (San Nicolo, et al., 2017) to assess whether the safety and effectiveness of the implant persist in these patients for 24-months after the procedure. Subjects were followed up 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 subjects who exited the study prior to the 24-month follow-up.

San Nicolo 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 subjects with Nasal Obstruction Symptom Evaluation (NOSE) score 55 and isolated NVC; 14 cases were performed in an operating suite under general anesthesia and 16 cases were performed in a clinic-based setting under local anesthesia. Fifty-six implants were placed in 30 subjects. 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 subjects 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 subjects required retrieval within 30 days post-procedure and resulted in no clinical sequelae. This study is limited by the small number of subjects, lack of a comparator and lack of randomization.

Summary of Evidence
Based on review of the peer reviewed medical literature the evidence includes symptomatic reviews, randomized and nonrandomized controlled trials. While the evidence may show promise related to absorbable nasal implants (e.g., Latera Absorbable Nasal Implant) to repair nasal valve stenosis and collapse larger comparative studies or well-designed randomized clinical trials with outcomes based on validated patient-reported outcome measures are still required to provide more definitive recommendations. Twenty-four-month follow-up has been reported in the 3 multicenter cohort studies. Loss to follow-up was high, although sensitivity analysis with a worst-case scenario supported an improvement in symptoms at 24 months. As reported, adverse events appeared to be mild in severity and self-limiting, but still appeared common. In the larger cohorts, device retrievals or extrusions occurred in 4% of patients. The need for device retrievals appears to occur early in the course of follow-up (1 month); suggesting technical experience limitations on the part of the operator or inappropriate patient selection. No studies have been identified that compared insertion of an implant with inferior turbinate reduction and/or septoplasty. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
In 2010, a consensus panel was convened by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) to create a clinical consensus statement for the diagnosis and management of nasal valve compromise (NVC). The statement included:

- NVC is a distinct clinical entity for patients who present with symptomatic nasal airway obstruction and is best evaluated with history and physical examination findings.
- Audible 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
- Endoscopy and photographs may useful, but are not routinely indicated
- Radiographic studies are not useful in evaluating NVC
- Nasal steroid medication is not useful for treatment of NVC in absence of rhinitis
- mechanical treatments (e.g., nasal strips, stents, or cones) may be useful in selected patients
- Surgical treatment is the primary mode of treatment of NVC. The panel met consensus that surgical procedure that is targeted to support the lateral nasal wall/alar rim is a distinct entity from procedures that correct a deviated nasal septum or hypertrophied turbinate.

Regulatory Status
June 2016, the Spirox Latera Absorbable Nasal Implant System (Spirox, Menlo Park, CA) received 501(k) clearance intended to support cartilage in the nasal lateral wall.

The System consists of the Latera Absorbable Nasal Implant (Implant) and Accessory Delivery Device (Delivery Device). The Implant is composed of a PLLA-PDLA copolymer that is predominantly cylindrical in shape with an approximate diameter of 1mm and overall length of 24mm. The distal end of the Implant is forked to facilitate anchoring during implantation and the proximal end is narrower for increased flexibility. The disposable Delivery Device is comprised of a non-patient contacting handle assembly and a medical grade stainless steel 16-gauge delivery cannula. The Delivery Device enables placement of the Implant in a minimally invasive manner.

PRIOR APPROVAL

Not applicable.

POLICY

- **See Related Medical Policies**
  - 07.0.31 Balloon Dilation (BOD)/Balloon Sinuplasty for the Treatment of Chronic and Recurrent Rhinosinusitis as a Stand-Alone Procedure or as an Adjunctive Procedure to Functional Endoscopic Sinus Surgery (FESS)
  - 07.01.82 Steroid-Eluting Sinus Stents and Implants

The use of absorbable nasal implants, including but not limited to Latera Absorbable Nasal Implant to repair nasal valve stenosis or collapse is considered **investigational** for

all indications, because the evidence is insufficient to determine the effects of the technology on health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 30468 Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) (Latera Absorbable Nasal Implant)
- 30999 Unlisted procedures, nose (*May be utilized for Latera Nasal Implant)*

SELECTED REFERENCES

- UpToDate. Nasal Obstruction: Diagnosis and Management. Neil Bhattacharyya M.D., FACS. Topic last updated January 11, 2022
- UpToDate Etiologies of nasal symptoms: an overview. Marilene B. Wang M.D., Topic last updated August 17, 2021
- Corey J, Pallanch J. Evaluation of Nasal Breathing Function with Objective Airway Testing. Otolaryngology: Head & Neck Surgery, 5th ed. Mosby, Inc. an Imprint of Elsevier; 2010.ch 42
- 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
- San Nicolo 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
- San Nicolo 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
- 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
- Spirox Latera Absorbable Nasal Implant (website). Available at ent.stryker.com/physician-resources/clinical-studies-trials/nasal-implant
- 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
- 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
- U.S. Food and Drug Adminstration (FDA). 510 (k) approval K161191. Latera Absorbable Nasal Implant. June 23, 2016. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161191.pdf

- Sidle D, Stolovitzky, O'Malley E, et. al. Bioabsorbable implant for treatment of nasal valve collapse with or without concomitant procedures. Open Access. Published on line 2021-04-14
- Hayes Inc. Evolving Evidence Review: Absorbable Nasal Implant (Latera, Stryker) for the Treatment of Nasal Valve Collapse. March 2022
- Olson M and Barrea J. A comparison of an absorbable nasal implant versus functional rhinoplasty for nasal obstruction. American Journal of Otolaryngology Head and Neck Medicine and Surgery 42 (2021) 103118
- Bikhazi N, Ow R, O'Malley E, et. al. 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. Published online 2021-12-29

POLICY HISTORY		
Date	**Reason**	**Action**
October 2022	Annual Review	Policy Renewed
March 2022	Interim Review	Policy Revised
October 2021	Annual Review	New Policy Created and Content Moved and Revised

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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