

What is Nasal Airway Obstruction?

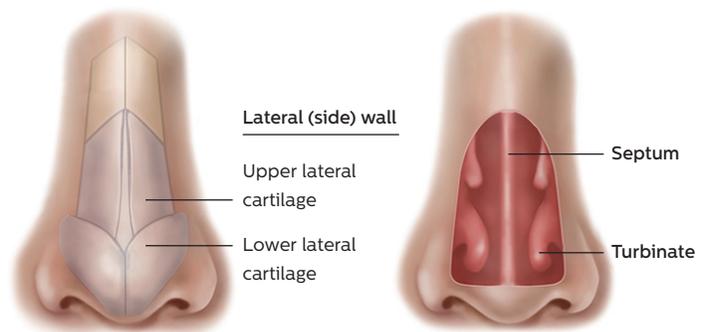
Nasal breathing normally delivers 70% of airflow to the lungs.⁽¹⁾ More than 20 million Americans suffer from nasal airway obstruction (NAO), which limits airflow through the nose with significant quality of life consequences.⁽²⁾ Symptoms may include:

- Difficulty breathing at rest and/or while exercising
- Reduced sleep time or sleep quality
- Reduced daytime productivity

What causes Nasal Airway Obstruction?

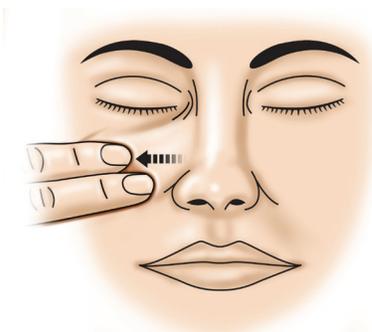
Even slight narrowing of the nasal passage can lead to significant reduction in airflow.⁽³⁾ Structural blockages in three areas are common:

- 1. Lateral (side) wall:** The upper/lower cartilage in the side of your nose can flex or collapse inward when you breathe.
- 2. Septum:** The cartilage wall between the nostrils can bend and block the nasal passage.
- 3. Turbinates:** Ridges of bone and tissue inside your nose can limit airflow when enlarged.



Is lateral wall collapse contributing to my Nasal Airway Obstruction?

Your doctor can determine the cause of your NAO. If your symptoms improve when you wear nasal strips, or when you perform a simple breathing test called the Cottle Maneuver (see illustration below), you may benefit from support for your lateral wall.

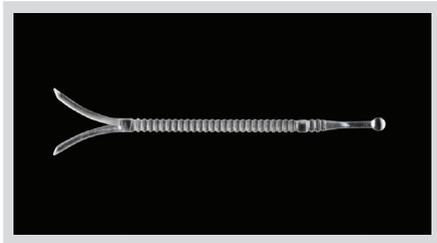


COTTLE MANEUVER: Does your breathing improve when you pull on your cheek to hold your nostril to the side? If yes, talk to your doctor about options to support your lateral cartilage, which may include the LATERA™ implant.

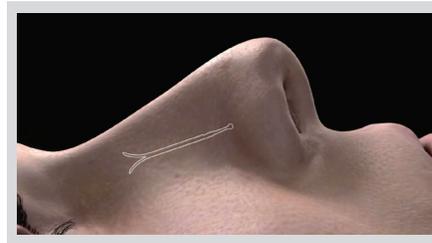
The LATERA implant is a minimally invasive option for supporting upper and lower lateral wall cartilage in your nose.

How does LATERA work?

The LATERA Absorbable Nasal Implant is used to support upper and lower lateral cartilage in your nose. It is placed inside the nasal wall in a minimally invasive way. Supporting the cartilage in this manner may reduce nasal airway obstruction symptoms and help patients breathe better. The LATERA implant is made of a material that absorbs over a period of approximately 18 months, so can deliver support without limiting future treatment options.



LATERA Implant



Implant is placed under the skin at the location shown

What have patients experienced with the LATERA implant?

LATERA showed significant quality of life improvement for nasal obstruction patients with lateral wall or nasal valve collapse. While individual results may vary, LATERA patients saw the following improvements in:⁽⁴⁾

- Reduced nasal congestion or stuffiness
- Less trouble breathing through the nose
- Improved ability to get enough air through the nose during exercise or exertion
- Reduced nasal blockage or obstruction
- Less trouble sleeping

Patients experienced a reduction in nasal obstruction symptoms of 56% at 6 months, as measured by the NOSE survey.^(5,6) Patients got these results without negative cosmetic effects. Risks included temporary symptoms such as:

- Mild bruising and inflammation
- Awareness of the implant
- Mild pain or irritation

Other risks related to the LATERA implant include: discomfort, infection, reaction to material, and device retrieval.

Talk to your doctor about your nasal obstruction to find out if LATERA could be right for you.

INDICATIONS FOR USE: The LATERA Absorbable Nasal Implant is indicated for supporting upper and lower lateral nasal cartilage. CAUTION: Rx only.

References

- <http://www.entnet.org/content/your-nose-guardian-your-lungs>
- <http://www.entnet.org/content/stuffy-nose>
- http://care.american-rhinologic.org/snoring_nasal_congestion

- 1) Crawford-Brown, Theoretical and Mathematical Foundations of Human Health Risk Analysis; 1997.
- 2) Stewart et al Intl J Gen Med 2010; Rhee et al JAMA Facial Plast Surg 2014. Nasal Obstruction Symptom Evaluation (NOSE) survey is a quality of life survey supported by the AAO Consensus Statement. Otolaryngology–Head and Neck Surgery: 162 STEWART et al February 2004.
- 3) Wever, The Nasal Airway: A Critical Review; Facial Plast Surg 2016;32:17–21. Camacho et al, The Effect of Nasal Surgery on Continuous Positive Airway Pressure Device Use and Therapeutic Treatment Pressures: A Systematic Review and Meta-Analysis; SLEEP, Vol. 38, No. 2, 2015. Lin, Meyers, et al, Nasal Aerodynamics.
- 4) Data are individual results for a single site in the Spirox study, in 21 patients at 6 months.
- 5) Data on file from a 30-patient Spirox clinical study conducted in Germany, in patients with confirmed nasal valve collapse as a primary factor for their nasal airway obstruction. Patients were 60% female, aged 24-77, 93% Caucasian. Study follow-up is ongoing. <https://clinicaltrials.gov/ct2/show/NCT02188589?term=spirox>
- 6) Nasal Obstruction Symptom Evaluation (NOSE) survey is a quality of life survey supported by the AAO Consensus Statement. Otolaryngology–Head and Neck Surgery: 162 STEWART et al February 2004.