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\$10,000 "Use it!" Lemelson-MIT Student Prize
Undergraduate Team Winner

N-Stent: Daily-Wear Nasal Breathing Aid

The Challenge: Chronically restricted nasal breathing is one of the most commonly reported complaints to ENTs (Ear, Nose, and Throat specialists)¹. In fact, over 40 million Americans suffer nasal airway obstruction resulting from septal deviation, nasal valve collapse, and other anatomical conditions that block or limit airflow². Nasal obstruction significantly impacts quality of life, as it presents a constant bother and source of embarrassment, causes reliance on mouth breathing, leads to difficulty sleeping and habitual snoring, and limits endurance during physical activity².

Slight dilation of the nasal passages counteracts nasal obstruction at its source and reverses symptoms in 89% of those afflicted³. Roughly 125,000 sufferers per year in the U.S. – far less than one percent of the total sufferers – undergo nasal reconstruction to permanently open the airways⁴. After a painful, yearlong recovery, up to 20% of the patients who opted for surgery report unimproved or worsened symptoms⁵. Millions of sufferers view this invasive option as too extreme of a solution for their symptoms.

Breathe Right strips and other over-the-counter nasal dilators better fit sufferers' preferences for treatment, as they instantly reproduce the effects of surgery without the risk and inconvenience⁶. However, customers find that these sleep aids are too uncomfortable and too visible to wear in public. Although the mechanism for reversing nasal obstruction is straightforward, there is no viable alternative to surgery.

¹ Stewart M, Ferguson BJ, Fromer L. Epidemiology and burden of nasal congestion. *Int J Gen Med*. 2010;3:37-45.

² Miman MC, Deliktas H, Ozturan O, et al. Internal nasal valve: revisited with objective facts. *Otolaryngol Head Neck Surg*. 2006;134:41-47.

³ Camacho, M., Zaghi, S., Certal, V. et al., 2016, "Predictors of Nasal Obstruction: Quantification and Assessment Using Multiple Grading Scales," *Plastic Surgery International*, vol. 2016, Article ID 6945297, 9 pages: doi:10.1155/2016/6945297.

⁴ "2016 Plastic Surgery Statistics Report." American Society of Plastic Surgeons, n.d. Web.

⁵ Schlosser, R.J. and Park, S. S., 1999, "Surgery for the Dysfunctional Nasal Valve." *Archives of Facial Plastic Surgery* 1, no. 2: 105. doi:10.1001/archfaci.1.2.105.

⁶ Kiyohara, N., 2016, "A Comparison of Over-the-Counter Mechanical Nasal Dilators." *JAMA Facial Plastic Surgery* 18, no. 5: 385. doi:10.1001/jamafacial.2016.0291.

The Solution: The AssistENT team invented N-Stent, a comfortable and discreet nasal dilator that immediately improves breathing upon insertion without the risk and inconvenience of surgery or the social stigma and discomfort of existing sleep aids. The device is worn entirely inside the nose with no visible components, enabling users to wear the device confidently in public to aid their breathing throughout the day. N-Stent is made of soft, form-fitting materials that enhance comfort and grip the nasal cavity to safely remain in position. Rather than undergo invasive nasal reconstructive surgery, users will simply deploy the device in the nose to breathe better instantly. With its ease of use and ability to be worn with little or no detection, N-Stent is comparable to the use of contact lenses by those with impaired vision.

N-Stent is a tapered silicone stent consisting of two flexible beams bridging two soft pads, whose shape closely follows the nasal passage anatomy. When deployed, one pad grips the nasal septum (middle bridge of the nose) and the other presses against the lateral nasal wall (outer wall of the nose) to dilate the passage. The bending beams supply this dilation force and form a nozzle that allows for drastically improved airflow.

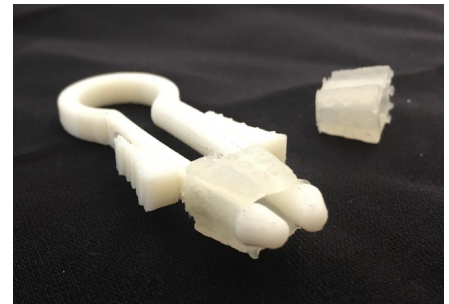


Figure 1: The N-Stent applicator with dilator (left) and single dilator (right).

There are several unique components compared to existing nasal dilators. N-Stent is:

- (1) Discreet:** N-Stent is entirely internalized within the nose, so individuals can use the device in public undetected.
- (2) Effective:** By specifically targeting the part of the nose where obstruction occurs, the device counteracts the obstruction directly at its source to achieve better results without excessive pressure that would cause discomfort or noticeably deform the nose.
- (3) Comfortable:** N-Stent's skeleton is coated in soft silicone that conforms to the nasal passage to distribute pressure evenly, making it wearable all day.
- (4) Easy to Use:** N-Stent has an applicator that facilitates the dilator's insertion into the proper position and allows for fast, easy removal.

N-Stent prototypes have been tested to ensure that they provide users with an experience that is both comfortable and effective. They have also been evaluated for degree of improved nasal airflow during peak breathing, and stability testing was conducted using a nose model and sneeze simulator.

Commercialization: A provisional patent has been filed for N-Stent and the product will be eligible for sale over-the-counter. The team has partnered with a certified manufacturer to develop injection tooling and packaging processes to create their inventory, emphasizing the use of recycled materials, including depolymerized silicones.

The team hopes to sell and distribute N-Stent directly to consumers online. The product also could be sold in brick-and-mortar pharmacies where existing nasal dilators are commonly available. A pair of N-Stent dilators will be priced at around \$4, and at the expected year one

production volume, each pair will be manufactured for about \$0.15. Since each pair is recommended for ten uses, the customer pays about \$0.40 per day for N-Stent. In comparison, Breathe Right comes to a price of \$0.35 per single-use strip, and a typical reusable sleep aid nasal dilator costs users \$0.72 per day. N-Stent's competitive pricing will reduce barriers to entry and growth within the market.

In addition to direct-to-consumer and retail sales, by leveraging their existing relationships with key opinion leaders in the medical community, the team will provide samples to general practitioners, ENTs, dentists, and sleep specialists at partner hospitals and clinics. Medical professionals will be able to size patients for dilators in-office and instruct them in proper device care and use. This channel will legitimize N-Stent as a valuable technology that is trusted by physicians and surgeons, promoting trial and adoption among sufferers.