

Elevate the palate.
Alleviate snoring.^{1,2}



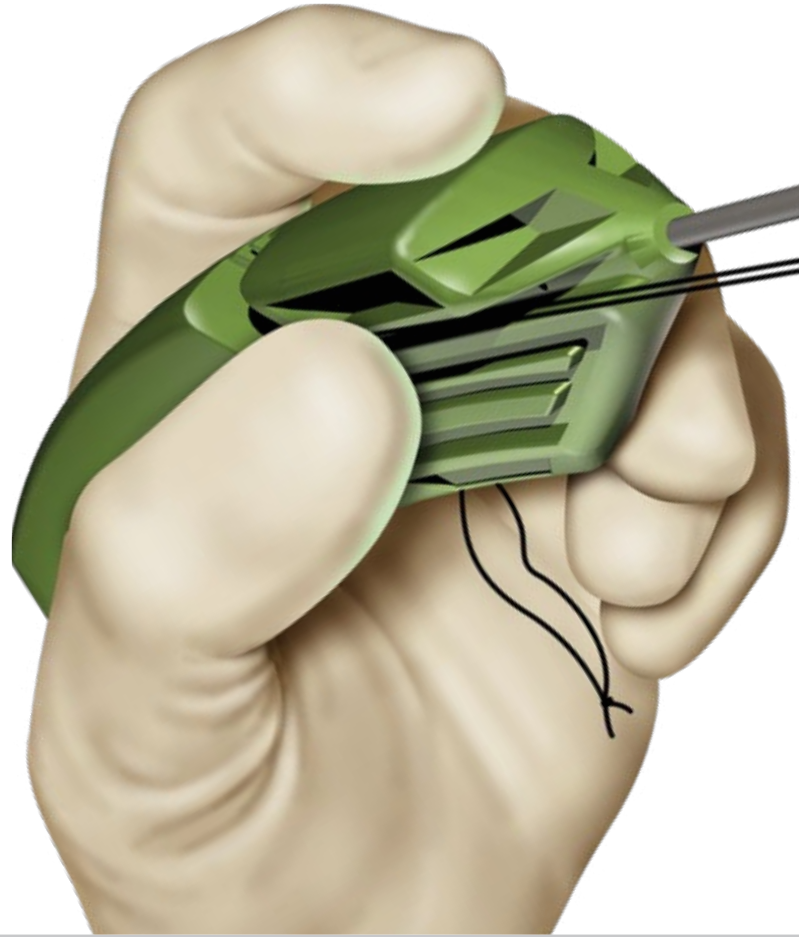
Elevo[®]

SNORING INTERVENTION SET



Manufactured by **Zelegent[®]**

What is the Elevo Snoring Intervention Set?





Created by Zelegent, Inc. and distributed by Cook Medical, the Elevo Snoring Intervention Set is a product designed to enhance patient treatment for snoring. The set is used to perform Elevoplasty®, a procedure that provides lift and stiffening to the soft palate through the placement of three bi-directional, barbed resorbable suture implants.

The concept of the set was developed by Drs. Yosef P. Krespi and David O. Volpi. Their goal was to develop a

minimally invasive procedure which could be performed by sleep specialty otolaryngologists to treat snoring at the palatal level without the need for invasive surgery.

The Elevo Snoring Intervention Set is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals. It is indicated for symptomatic, habitual, and social snoring due to palatal flutter.

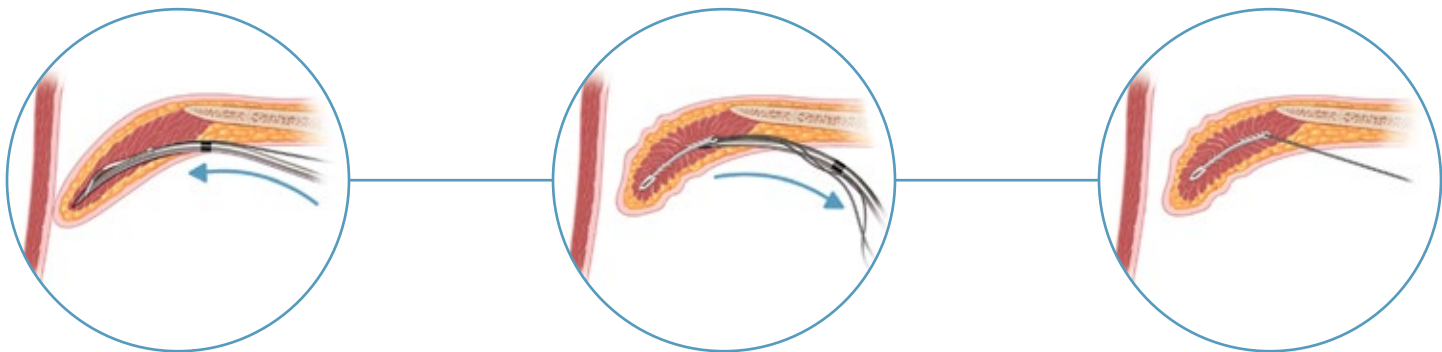
Elevo and Elevoplasty are registered trademarks of Zelegent, Inc.

Elevoplasty procedure

Elevo's delivery system allows the placement of bi-directional, barbed suture implants that provide lift to the soft palate. As the suture implants are resorbed over time, the soft palate is stiffened. Due to this lifting and stiffening action created in the soft palate, patients experienced a 30.3% reduction in sVAS at 180 days post-procedure.¹

30.3%
reduction
in sVAS

at 180 days post-procedure



Sleep outcome measurements resulting from the S.I.L.E.N.C.E. clinical trial

Epworth Sleepiness Scale

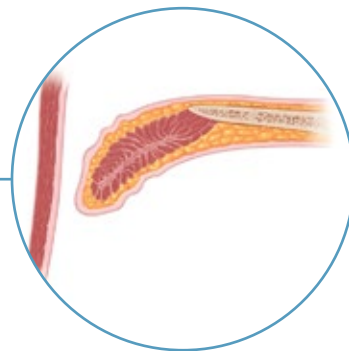
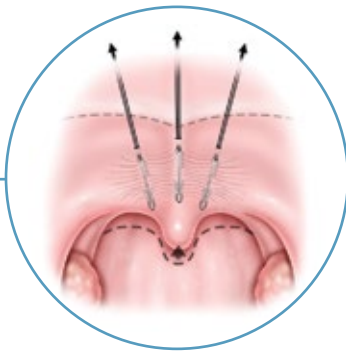
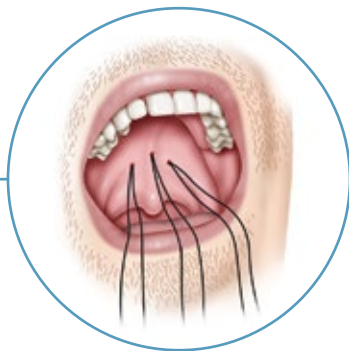
The mean score decreased from 6.63 at baseline to 4.63 at 180 days post-procedure ($p < .01$).

Pittsburgh Sleep Quality Index

The mean score decreased from 7.04 at baseline to 5.51 at 180 days post-procedure ($p < .001$).

SNAP home sleep test

The snoring loudness ratio measurements decreased, though this was not deemed statistically significant.



Set components

Elevo Snoring Intervention Set

The Elevo Snoring Intervention Set includes one PHIT and three snoring intervention devices.



Pilot hole initiation tool (PHIT™)

Creates a single hole used for both entry and exit of the delivery tool.



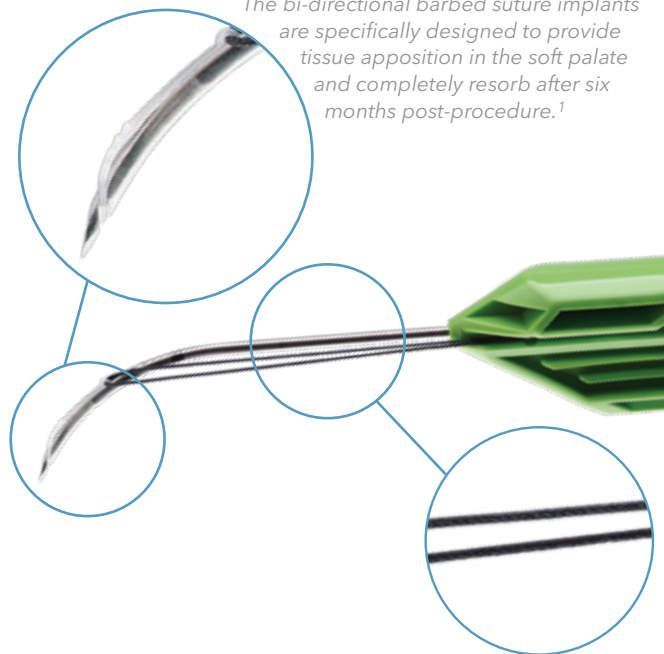
The PHIT does **not** include:

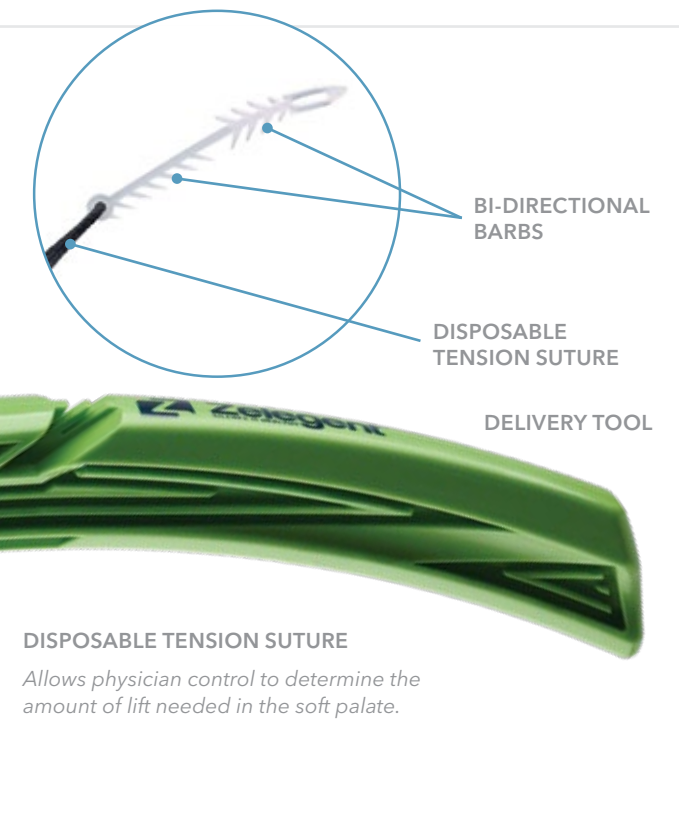
- Depth insertion marker
- Ventral divot
- Dorsal slot
- Resorbable suture implant

Elevo Snoring Intervention Device

ELEVO RESORBABLE SUTURE IMPLANT

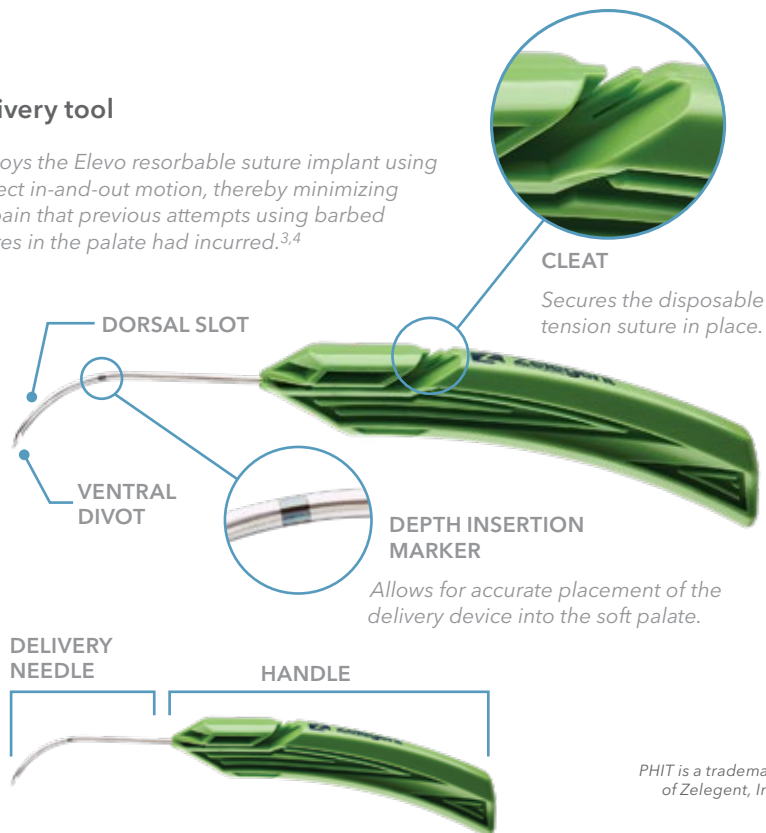
The bi-directional barbed suture implants are specifically designed to provide tissue apposition in the soft palate and completely resorb after six months post-procedure.¹





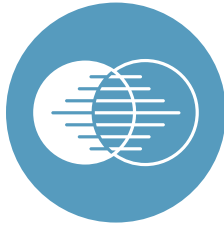
Delivery tool

Deploys the Elevo resorbable suture implant using a direct in-and-out motion, thereby minimizing the pain that previous attempts using barbed sutures in the palate had incurred.^{3,4}



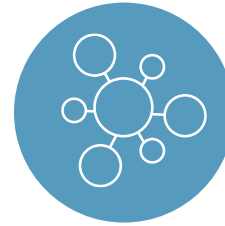
PHIT is a trademark of Zelegent, Inc.

Resorbable material



Resorption

The suture implant is completely resorbed into the body within six months post-procedure.¹



Composition

The suture implant is comprised of polydioxanone, which has been found to be nonantigenic and degrades into two substances that are both endogenous to the body: lactic acid and water.⁵

Office-based approach

Elevoplasty is a minimally invasive procedure that provides lift and stiffening to the soft palate to aid in the treatment of snoring. This procedure can be performed under local anesthesia in an office setting without the need for surgery.

Elevoplasty is the next step
in the office-based treatment
of primary snoring





To learn more about Elevo and Elevoplasty,
visit **cookmedical.com/elevo**.



To contact a sales representative, email
cookOHNS@cookmedical.com.



For news and updates, follow us
on Twitter **[@cookOHNS](https://twitter.com/cookOHNS)**.

Elevo® Snoring Intervention Set

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

INDICATIONS FOR USE: The Elevo® Snoring Intervention Set is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals.

WARNINGS: Do not resterilize. Dispose of used Elevo® suturing needles in a sharps container similar to any other medically-used sharp device. Retain opened, unused Elevo® Sets only until their printed expiration date. • Store unopened Elevo® Sets in a cool place (e.g., an office that has consistent air conditioning, including on weekends) and out of direct sunlight. Storing Elevo® Sets in an office in which air conditioning is turned off on weekends may shorten shelf life and is not recommended.

PRECAUTIONS: The Elevo® Snoring Intervention Set is not to be used in the treatment of obstructive sleep apnea.

ADVERSE EVENTS / COMMON TREATMENT EVENTS: Minor Bleeding • Mild Pain or Discomfort • Palate Swelling • Palpable Suture • Dysphagia

See instructions for use for full product information.

AB_50006_REV1

References

1. Elevo Kit Snoring Intervention Device. Premarket notification 510(k) K181107.
2. Indications for Use: The Elevo Kit Snoring Intervention Device is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals.
3. Mantovani M. The ENT's role in sinus lift management doesn't need misleading messages. *Acta Otorhinolaryngol.* 2012;32(6):404.
4. Murphey AW, Nguyen SA, Fuller C et al. TranQuill sling snoreplasty for snoring: a single-arm pilot study for safety and effectiveness. *Laryngoscope.* 2016;126(1):243-248.
5. Mahadevappa Y, Arhuman A, Ravindra R. Polymer synthesis and processing. *Natural and Synthetic Biomedical Polymers.* 2014;1-31.