

Elevo® Snoring Intervention Set

**Implantable Portion Comprised of PDO
(Polydioxanone)**

Synthetic Absorbable Suture Implant
Integrated Suture Delivery Needle and Handle
Pilot Hole Initiation Tool (PHIT™)

INSTRUCTIONS FOR USE

Each Elevo® suture implant comprised of PDO is provided pre-loaded into the Suturing Needle Delivery Device. The bi-directional barbs allow for implant of the suture without the need for surgical knots and the Suturing Needle Delivery Device eliminates the need for a swaged needle.

The Elevo® suture implant is comprised of polydioxanone. Polydioxanone has been found to be non-antigenic and to elicit only a slight tissue reaction during absorption. It degrades into two substances which are both endogenous to the body: (1) lactic acid and (2) water.

The Elevo® Set contains a fourth component called the Pilot Hole Initiation Tool (PHIT). The PHIT is distinguished from the three implant tools by its colorless handle. The purpose of the PHIT is to provide you with the procedural option of creating a small pilot hole to facilitate implant of the Elevo® suture. The pilot hole may alleviate premature de-coupling of the Elevo® suture during the implant step of the procedure.

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.

PRECAUTIONS

The Elevo® Kit Snoring Intervention Device is not to be used in the treatment of obstructive sleep apnea.

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® Kits only until their printed expiration date.

Store unopened Elevo® Kits in a cool place (e.g., an office that has consistent air conditioning, including on weekends) and out of direct sunlight. Storing Elevo® Kits in an office in which air conditioning is turned off on weekends may shorten shelf life and is not recommended.

S.I.LE.N.C.E. CLINICAL STUDY

The Elevo® Kit Snoring Intervention Device was clinically evaluated in fifty-two (52) human subjects during the S.I.LE.N.C.E. (Snoring Intervention via **E**levoplasty in a **N**on-surgical Clinical Environment) Study sponsored by Zelegent, Inc. Of these study Subjects, thirty-one (31) began the clinical study with a Baseline Apnea Hypopnea Index (AHI) of 5 or below (Primary Snoring). These patients experienced a mean 24.5% reduction in Snoring Visual Analog Scale (VAS) at 30 days, 33.6% mean reduction at 90 days, and 27.3% mean reduction at 180 days.

Subset Analysis: 31 Patients Who Began the Study with Baseline AHI of 5 or Below	
Day 30 reduction in Snoring VAS	24.5%
Number of patients' bed partners' reporting Day 30 results	31
Day 90 reduction in Snoring VAS	33.6%
Number of patients' bed partners' reporting Day 90 results	27
Day 180 reduction in Snoring VAS	27.3%
Number of patients' bed partners' reporting Day 180 results	27

ADVERSE EVENTS / COMMON TREATMENT EVENTS

Minor Bleeding
Mild Pain or Discomfort
Palate Swelling
Palpable Suture
Dysphagia

EPWORTH SLEEPINESS SCALE (ESS)

Using anchor-based methods, the MCID (Minimum Clinically Important Difference) for improvement of the ESS lies between -2 and -3. ESS change of 1.57 in the clinical study was observed even though this was not clinically significant.*

** Suhani Patel, Samantha SC Kon, Claire M Nolan, Anita K Simonds, Mary J Morrell, William D-C Man, Ruth E Barker: Minimally clinically important difference of the Epworth Sleepiness Scale. European Respiratory Journal Sep 2017, 50 (suppl 61) PA330; DOI: 10.1183/1393003.congress-2017.PA330*

DESCRIPTION OF ELEVOPLASTY® PROCEDURE

Elevoplasty® is a minimally-invasive physician's office intervention to treat patients that present with mild to moderate snoring. It works by shortening and stiffening the soft palate. Elevoplasty® is accomplished by way of a custom designed resorbable suture implant that works similarly to standard barbed sutures in plastics procedures. Its barb configuration and length are optimized for simple deployment and for providing tissue apposition specifically in the soft palate.

PRE- ELEVOPLASTY® HOME SLEEP STUDY

If your patient has not recently had an in-lab sleep study, Zelegent, Inc. recommends that candidates for Elevoplasty® undergo a diagnostic home sleep study prior to the Elevoplasty® procedure. The resulting report generated by the data collected allows you to evaluate snoring sound, pulse oximetry, respiration effort, and respiratory flow via pressure and body position. The sleep study results will assist you in diagnosing, or ruling out, many types of sleep disorders including the presence and severity of obstructive sleep apnea. Ruling out moderate or severe sleep apnea is recommended. See Precautions on previous page.

INSTRUCTIONS FOR USE

1. Request that the patient sit comfortably in your examination chair and open his/her mouth.
2. Use a standard purple/blue marker to mark the location of the three pilot holes before making them. The optimal location for each of these three marks is just distal to the hard/soft palate junction. Use a topical lidocaine spray on the patient's soft palate, then inject the patient's soft palate with 1-3 small doses of lidocaine through a 25-gauge bent-tip hollow needle. **Inject lidocaine conservatively** - the total cumulative lidocaine injection should not exceed 1.5 cc, and optimally should be less than 1.0 cc. The purpose of this recommended limit on lidocaine injection is to avoid hydro-dissection. If hydro-dissection occurs secondary to too much injected lidocaine, the Elevo® suture implants may have less ability to grip tissue after implantation.
3. Open the outer opaque foil pouch to reveal the Elevo® Set. Open the transparent (Tyvek/Poly) pouch and place the white card stock packaging onto a sterile or semi-sterile procedure tray. Lift the two exposed white tabs. The front protective arch of the packaging will pop up revealing the three pre-loaded Elevo® Suturing Needles (green handles) and the Pilot Hole Initiation Tool (colorless handle).

4. Visually confirm that each suture implant is pre-loaded before beginning Elevoplasty®

NOTE: PHYSICIAN / USER RE-LOAD OF SUTURE IMPLANT

*If the suture has been unseated from its implant-ready status you will need to “re-load” the suture prior to deployment. Hold the Elevo® suture and maneuver the needle tip so that it enters the distal loop of the implant (the distal end is opposite from the disposable tension suture). The proximal end of the suture – the long “disposable tension suture”– is held back and wrapped through the suture cleat of the Suture Delivery Handle, which is a small knob on the upper surface of the tool that is designed to maintain tension in the suture (see **FIGURE A**). The distal barbs of the suture should lay along the dorsal surface at the distal end of the curved needle when properly placed. The proximal (reverse) barbs should lay in the dorsal needle slot, thereby not visible and shielded from the tissue. If desired, advanced users may hold the disposable tension suture against the dorsal surface of the handle with your index finger rather than placing it in the cleat, to facilitate one-hand deployment.*

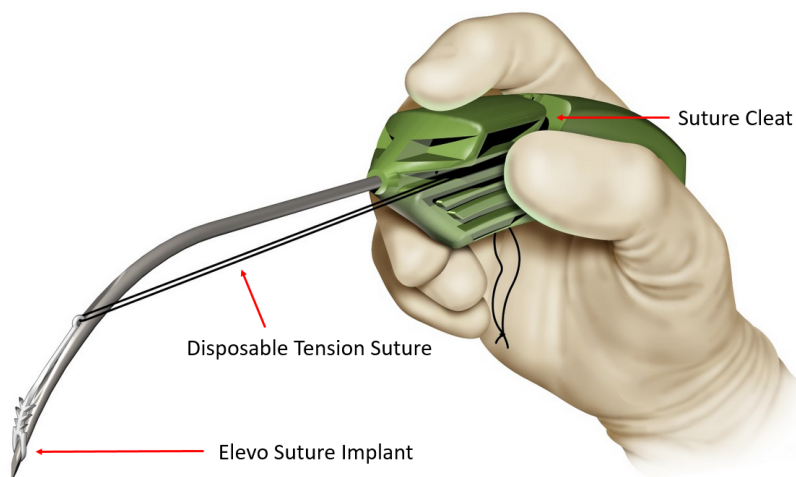


FIGURE A

5. Allow approximately 10 minutes for the lidocaine to take effect, and inform the patient that the procedure is about to begin. Using the PHIT you may now prepare the three points of entry in the patient's soft palate by piercing them – creating pilot holes. Pierce the fascial layer of the soft palate using the PHIT on or near the three marks you made in Step 2. Insert the tip of the PHIT approximately one-third as deep as your intended depth for the Elevo® suture in the three previously marked points (see STEP 2) that you plan to use for deployment. Remove the PHIT by gently pulling it backward in the same arc that it took to enter the tissue. **The target zone for the points of entry should be approximately 5-6 mm distal (posterior) to the hard/soft palate junction.** If you choose to make one pilot hole at a time before inserting each Elevo suture implant, take care to avoid touching the tip of the PHIT to other surfaces between uses.

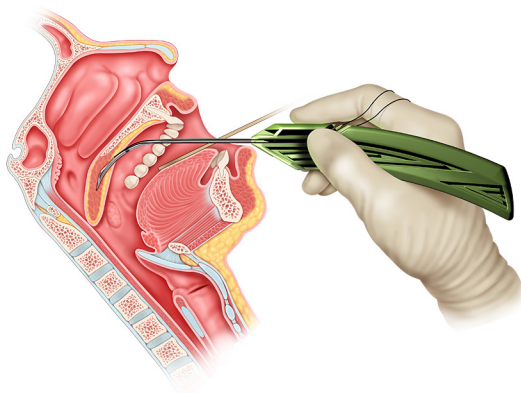


FIGURE B

6. Now pick up one of the three pre-loaded Elevo® suturing needles and insert the tip into the patient's soft palate, taking advantage of one of the three pilot holes you created with the PHIT in Step 5. Applying consistent pressure, advance the tip of the suture delivery device in a gentle arc motion (see **FIGURE B**) deeper through the levator palatine muscles until it is near the posterior end of the soft palate (the uvula). **The key to this deployment is to make the motion *continuous* - without reversing direction.**

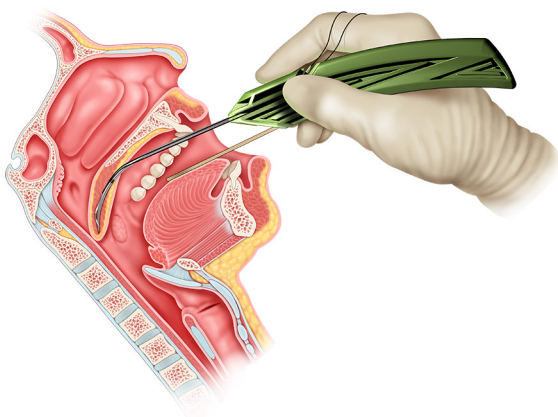


FIGURE C

7. Advance the tip distally until it has traveled approximately 25-30 mm through the soft palate to an area approximately 8-10 mm from the distal ridge of the soft palate (see **FIGURE C**). Do not be afraid to over-insert. The key to optimal deployment is to insert in one continuous motion, without hesitating, and continuing all the way until the depth insertion marker is fully submerged. Once full depth of deployment has been achieved, hold the green handle steady and release the tongue depressor from your non-dominant hand, so that this hand can be used to release the black disposable tension suture from the dorsal handle cleat -- releasing the proximal end of the disposable tensioning suture from the handle.

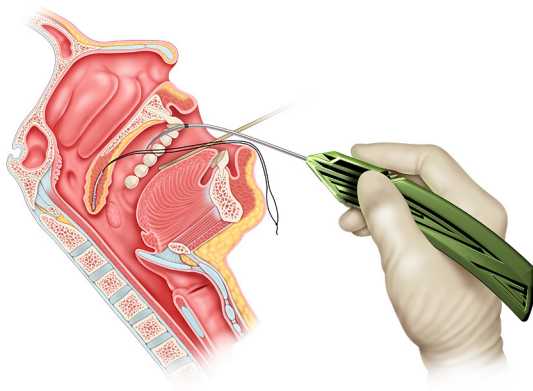


FIGURE D

8. Once the disposable tension suture is lying loose and disconnected from the handle (see **FIGURE D**), reverse direction and retract the needle (using the handle) out of the soft palate in a backward re-tracing of the simple arc motion that was just completed. This should result in the resorbable barbed suture implant being left in place in the soft palate, with both sets of barbs engaged in tissue and the disposable tension suture protruding out of the patient's palate and mouth (see **FIGURE E**). If the proximal end of the Elevo® implant appears in the entry hole as the needle is being withdrawn (sometimes due to partial adherence of the implant to the metal of the needle), you may use a wooden tongue depressor or metal forceps to gently hold back the implant while you are withdrawing the needle.

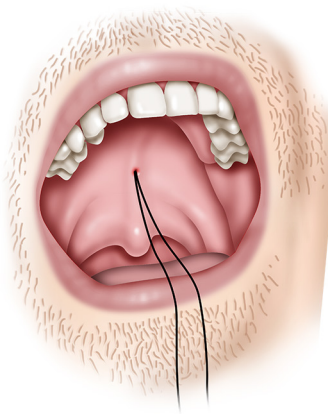


FIGURE E

9. Repeat this piercing-and-pulling out procedure with the two remaining Elevo® suture implants included in the Elevo® Set.

PROCEDURAL NOTE

The exact orientation of the suture implant is less important than the goal of deploying the sutures all the way i.e., past the depth insertion marker, before cutting the disposable tension suture.

10. Once all implants have been placed the disposable tension suture ends will protrude from the patient's mouth (see **FIGURE F**). If you feel that some pulling has not already occurred by the act of withdrawing the needle, gently pull on each disposable tension suture (see **FIGURE G**). The pulling motion should cause a mild tissue apposition ("accordion-ing") of the soft palate. The proximal barb row will engage with the tissue and act like a gentle ratchet. The suture implant should slightly raise, shorten, and stiffen the soft palate. One to four millimeters (1-4 mm) of "lift" is the goal. Note that because the soft palate is in continual motion, combined with the shape of the anatomy, the amount of lift may be difficult to immediately visualize. Some degree of lift may also occur in the days or weeks after the procedure as the motion of the tissue continues to interact with both sets of barbs of the three implants.

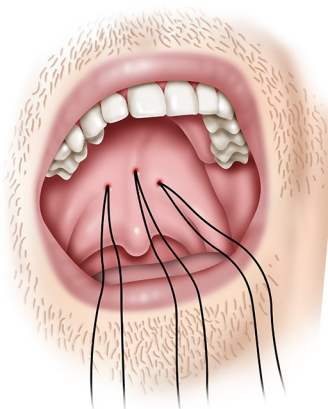


FIGURE F

11. Cut the extending disposable tension sutures with scissors (see **FIGURE H**). This action may cause the suture implants to retract slightly into the tissue, ensuring that the suture does not protrude and result in tongue-mediated awareness for the patient. Mild retraction into the tissue will also serve as a barrier to infection as the implant becomes imbedded. If any of the Elevo® suture implants protrude after cutting the disposable tension suture, use a pair of forceps or a mosquito tool to gently tuck the suture back into the tissue. Tucking the suture implant back in is preferable to cutting off part of the implant because the more barbs that are left in the patient, the greater the ability of the suture implant to create lift over time.

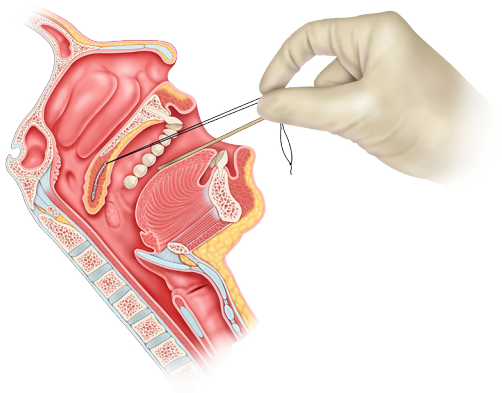


FIGURE G

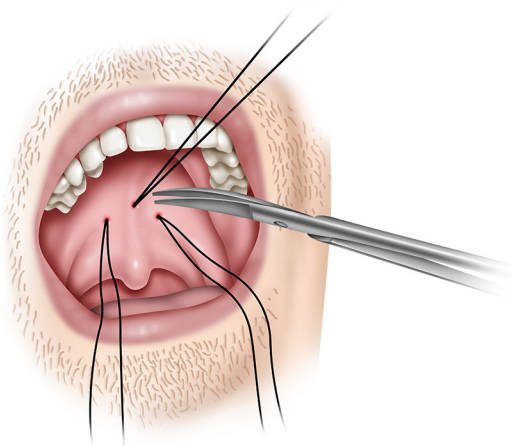


FIGURE H

12. Advise the patient that the Elevoplasty® procedure is complete, and that he/she can expect a sore throat sensation for the next 2-3 days. Recommend that spicy or acidic foods and alcohol be avoided for a few days. Instruct the patient to re-contact you in the event of severe pain, protruding suture implant, visible swelling or hematoma.

– END OF ELEVO® SET INSTRUCTIONS FOR USE –

STERILITY

The Elevo® Set comprised of three PDO suture implants pre-loaded on suturing needles and the Pilot Hole Initiation Tool, is sterilized by ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Do not use after expiration date.

HOW SUPPLIED

The Elevo® suture implant is provided in a single-use bi-directional barbed configuration. The Suture Delivery Needle Handle is preloaded with the suture implant and the disposable tension suture. Three (3) Elevo® suture implants pre-loaded on three suturing needles and one (1) Pilot Hole Initiation Tool (PHIT) are supplied in each Elevo® Set.

SYMBOLS USED FOR LABELING



Catalog Number



Read Instructions for Use



Do Not Reuse



Use By Date



Sterilized Using Ethylene Oxide



Do Not Resterilize



Batch Code



Manufactured by Zelegent, Inc.



Do Not Use if Package is Damaged



Quantity in a box.

Rx ONLY

Rx Only.

The mini-facelift for the soft palate™

Part Number: 50007 Revision C
December 31, 2019

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