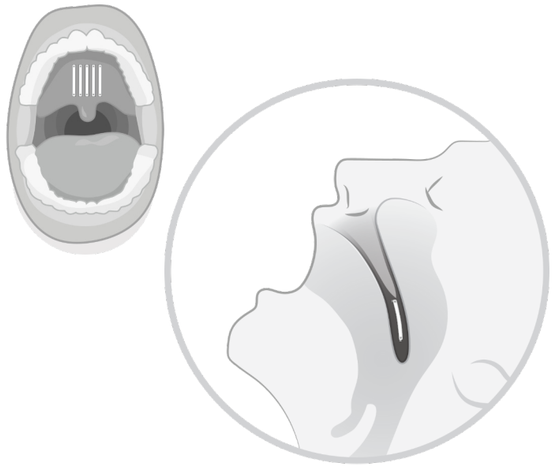
THE SERENE SLEEP PALATAL IMPLANT SYSTEM

INSTRUCTIONS FOR USE

DEVICE INFORMATION

INTENDED USE / INDICATIONS FOR USE

The Serene Sleep Palatal Implant System ("System") is intended for use in stiffening the soft palate tissue, which may reduce the severity of symptomatic, habitual, and social snoring due to palatal flutter in some individuals and reduce the incidence of airway obstructions in patients suffering from mild to moderate OSA (Obstructive Sleep Apnea).



DEVICE AND PROCEDURAL EXPECTATIONS

- This is a single-use device
- Each individually packaged device will be used to place one (1) Implant
- An individual patient will require 3+ Implants depending on anatomy
- The Implant stiffens the soft palate tissue by two (2) methods of action:

1. Directly stiffening the tissue
2. Promoting a fibrotic response in the tissue, inducing the encapsulation of the Implants with stiff scar tissue while also allowing that scar tissue growth to bridge between individual Implants and between the Implant ends and the hard palate tissue

- Due to method of action of Implants, patients may need to wait up to 3-12 months to see full effects
- Implant positioning and deployment technique is key to efficacy

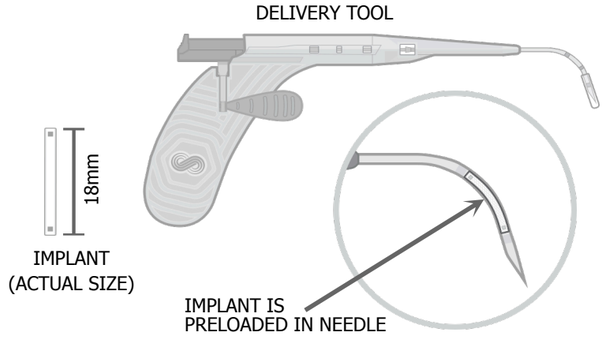
CAUTION: Not everyone is a suitable candidate for this procedure, carefully follow patient selection guidelines prior to prescribing this treatment.

Prior to prescribing the procedure, palatal flutter should be identified to be the main contributor to the patient's snoring or palate collapse should be identified as a contributor to the patient's OSA. Completion of the following evaluations is recommended:

- Complete physical examination
- General assessment of the thickness of palatal and pharyngeal mucosa tissues
- Nasopharyngeal, hypopharyngeal, and oral cavity examinations
- Mallampati classification and/or Friedman Tongue Position and Tonsil Grade
- Sleep study

PRODUCT DESCRIPTION & COMPONENT OVERVIEW

The System consists of a Delivery Tool and an Implant. The System is packaged sterile with the Implant preloaded into the needle of the Delivery Tool.



The Delivery Tool consists of a handle and 14-gauge needle. The needle is inserted into the soft palate, and the Implant is deployed by advancing the handle slider while the needle is retracted from the soft palate, leaving the Implant embedded in the tissue. The Delivery Tool is disposable.

The Implant is a short braided length of polyester (PET polyethylene terephthalate) yarns intended for permanent implantation. The Implant has a length of approximately 0.7 inches (18 mm) and an effective outer diameter of approximately 0.063 inches (1.6 mm).

CONSIDERATIONS

CONTRAINDICATIONS

The System should not be used in the treatment of patients…

- Whose soft palate length, as measured from the hard palate junction to the base of the uvula, is shorter than 25 mm
- Under the age of 18

PATIENT SELECTION

Palatal Implants have historically been shown to be clinically effective in patients with…

- A Body Mass Index (BMI) less than or equal to 30 kg/m²
- A tonsil grade less than or equal to 2
- A Friedman Tongue Position of I or II

Use of the System to treat patients with palatal-based snoring and/or palatal collapse OSA who do not fall who DO NOT fall within the above requirements may limit the success of the treatment.

PHYSICIAN TRAINING

Physicians preparing to offer this procedure to their patients for the first time must notify Serene Sleep of their intent to offer the procedure. Serene Sleep will in turn supply devices and other materials for training and familiarization. Training may consist of:

- Deployments of the Implant from the Delivery Tool outside of tissue (real or facsimile)
- Deployment of the Implant from Delivery Tool into transparent facsimile tissue
- Deployment of the Implant from the Delivery Tool into a synthetic cadaver / representative mouth model

Physicians may also submit a request to Serene Sleep at any point for training materials to re-familiarize themselves with the device or refresh their understanding outside of patient procedures.

POTENTIAL COMPLICATIONS

Use of the System involves potential risks normally associated with the use of any implanted device, including but not limited to those listed below:

- Allergic reaction to Implant material
- Difficulty swallowing
- Erosion of Implant
- Extrusion of Implant either partial or full
- Foreign body sensation
- Gastro-intestinal obstruction
- Implant aspiration
- Implant rejection
- Implant migration
- Infection
- Mucosal edema
- Throat irritation
- Voice/taste change

Mild pain may persist for 1–3 days post-procedure and usually improves quickly; most patients manage discomfort with acetaminophen alone. NSAIDs, aspirin, supplements, mouthwashes and lozenges should be avoided for one week, and ice chips in the mouth may be used for relief. Stick to soft or cool foods for a few days and limit strenuous activity for a week.

WARNINGS AND PRECAUTIONS

- Clinical long-term success with the Implant has not been established.
- To minimize the chance of infection, it is recommended to use an appropriate antiseptic oral rinse (e.g., chlorhexidine gluconate 0.12% - 0.2%) pre-operatively and administer an appropriate broad-spectrum antibiotic both pre- and post-operatively. A suitable analgesic is also suggested for managing discomfort in the immediate post-operative period.
- During the procedure, use an appropriate local anesthetic injected at each insertion site to infiltrate the soft palate tissue along the profile where each Implant will be placed. The anesthetic may cause tissue swelling. Care should be taken to avoid superficial Implant placement that may lead to partial extrusion. Recommended anesthetic consists of Lidocaine 1% combined with Epinephrine 1:100,000
- Patients exhibiting a significant gag reflex may adversely affect the Implant placement procedure. Therefore, mild sedation may be indicated to minimize the patient's gag reflex.

CAUTION: Ensure that applied anesthetic DOES NOT promote full loss of muscle tension, as tactile distinction between muscular and mucosal tissue facilitates proper placement of Implant

CAUTIONS

- Single use only. Do not resterilize.
- Implant should not be removed from the needle and/or modified prior to use.
- Delivery Tool handle and needle should not be modified prior to use.
- Do not use excessive force during needle insertion, Implant deployment, or Delivery Tool removal.
- If the Implant is ejected from the needle prior to placement, discard the Implant and Delivery Tool.
- After use, all components should be treated as biologically hazardous waste during disposal.
- Product that is damaged, or where the sterility has been compromised, needs to be returned — contact the Company for detailed instructions.
- Should the Implant require removal or the patient request removal, a minimally invasive surgical procedure is required. To remove an Implant, make a single incision over the Implant site and carefully extract the Implant using clean, sterile forceps. Dispose of the removed Implant appropriately and apply a suture if needed. Ensure the incision has fully healed before considering replacement of the Implant.
- The insertion of the Implant should only be undertaken by those physicians who have a comprehensive knowledge of the indications, techniques, and risks of the procedure
- Serene Sleep Palatal Implants are intended to be permanent, but device has not been clinically validated for long term use

OTHER

The following factors may affect the overall success of the treatment for a given patient:

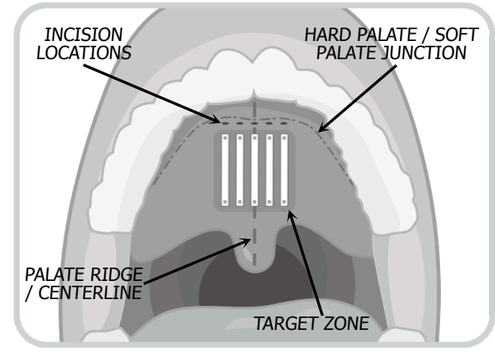
- Alcohol consumption
- Allergies
- Autoimmune deficiency
- Body weight gain
- Diabetes
- Drug use such as antihistamines, tranquilizers, and sleeping aids
- Partner expectations
- Pharyngeal anatomy
- Poor health/healing
- Sleeping body position
- Smoking

PROCEDURE

SETUP INSTRUCTIONS

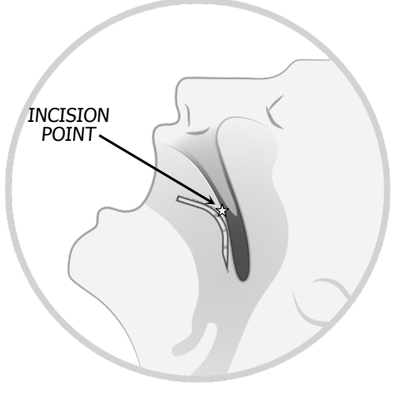
Read all instructions carefully prior to using the System.

- The System is supplied sterile and intended for single use only. Carefully inspect the packaging and the System for damage upon receipt of delivery and again prior to use. If there is a breach in the package or if the System is damaged, DO NOT USE. Return the defective package/System immediately and contact the Company for replacement.
- The System must be handled with sterile gloves

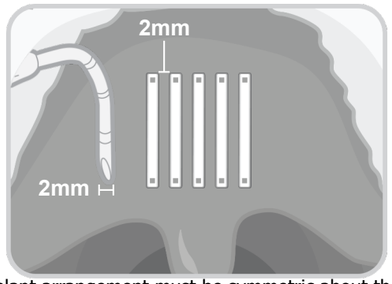


DETERMINING IMPLANT POSITIONING

1. Identify the the midline of the soft palate and point at which the midline meets the hard palate. Just distal to this point is the needle incision point for the placement of the first Implant (Implants should be placed as close to the hard palate as possible).



2. Without contacting the needle with the tissue place the Delivery Tool up to the soft palate such that the "full insertion depth marker" is aligned with the insertion point and the needle is aligned with the midline of the soft palate. Verify that the tip of the needle does not extend within ~5mm of the start of the uvula.
3. Work laterally outwards from the first Implant location and insertion point to determine placement for subsequent Implants. Continue to use the midline of the soft palate as a reference and plan to place subsequent Implants parallel to the first with 2 mm spacing between (the width of the Delivery Tool needle can be used as a guide to approximate a 2 mm distance). Insertion points for subsequent Implants will continue to be just distal of the junction point between the hard palate and the imaginary line positioned at a 2 mm parallel distance from the last Implant location.

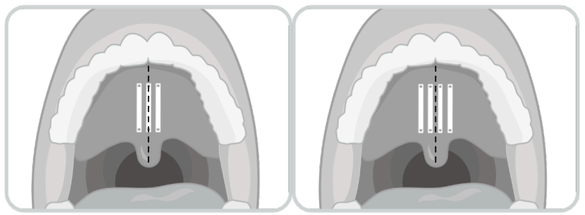


The full Implant arrangement must be symmetric about the midline. If an even number of the Implants is to be used, position the first two (2) Implants so they evenly straddle the midline with a 2 mm spacing between them

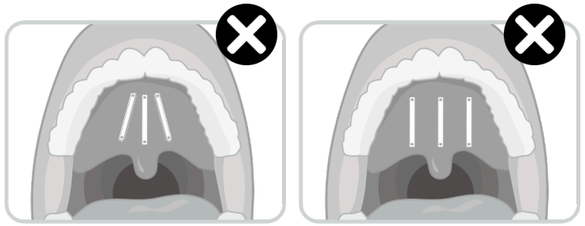
NOTE: This 2 mm parallel spacing arrangement MUST be maintained regardless of palate width and size.

4. Once the insertion locations for subsequent Implants have been determined, repeat step 2 for each Implant to ensure that the tip of the needle does not extend within ~5 mm of the end of the soft palate.

IMPLANT CONFIGURATION



- Implant arrangement, regardless of the quantity of Implants used, must be symmetric about the center line of the palate

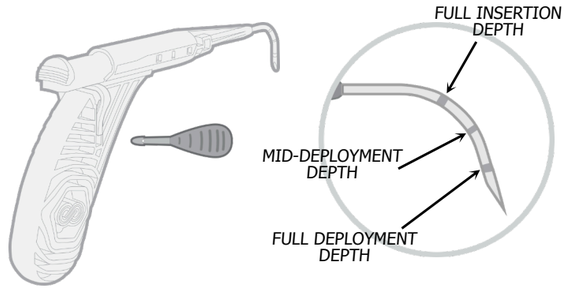


- All Implants must be positioned parallel to each other spaced approximately 2mm (~1 needle width) a part from each other

WARNING: DO NOT position the Implants at an angle or space them more than 2 mm apart from each other.

PREPARATION FOR USE

1. Remove the protective needle cap from the Delivery Tool needle using aseptic technique.
2. Remove the blue pull tab from the System by grasping the tab and pulling it away and out of the handle.
3. Identify the 3 markings on the Delivery Tool needle.

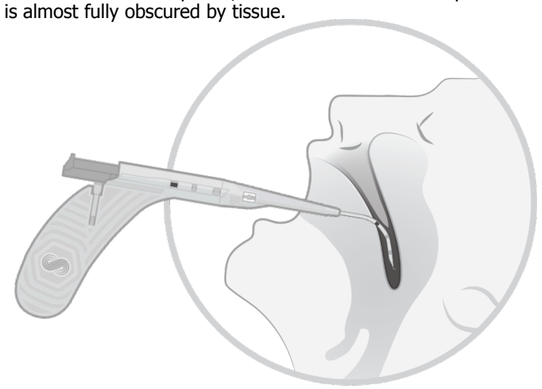


NEEDLE INSERTION

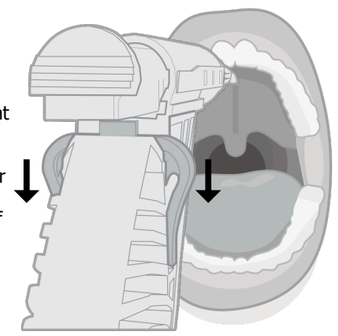
CAUTION: If the Implant is exposed at any time prior to needle insertion, discard the device.

CAUTION: Ensure that the slider is not advanced during needle insertion in order to avoid premature exposure of the Implant

1. Insert needle
   After determining the appropriate positioning for the insertion point and confirming that the safety clip is still in its engaged position, insert the needle through the sub-mucosal tissue layer into the muscle. The initial trajectory should be guided by the boundary of the hard palate. Continue needle advancement in an arcing motion to follow the profile of the soft palate, aiming to keep the needle moving along the mid-plane of the tissue, parallel to the midline of the palate, until the "full insertion depth marker" is almost fully obscured by tissue.

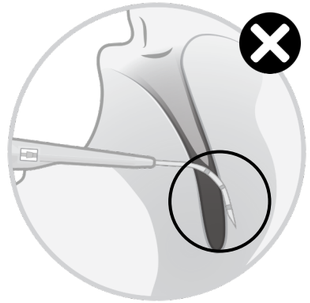


2. Disengage the safety clip by applying downward pressure to the top of the clip just below the slider at the back of the handle. When the clip is disengaged, you may hear and audible 'click' or receive tactile feedback of the clip snapping into position.



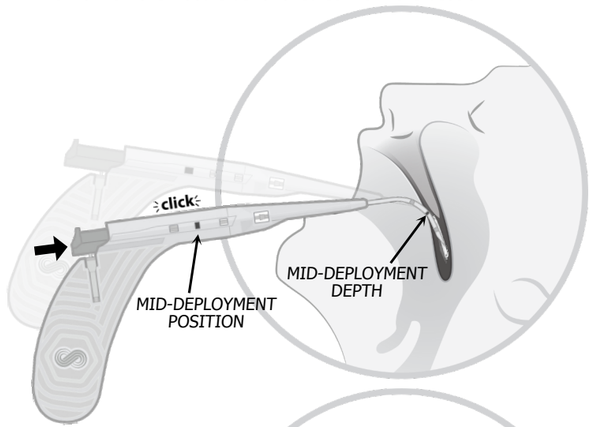
WARNING: Ensure that the needle does not pierce/exit any portion of the tissue and become exposed.

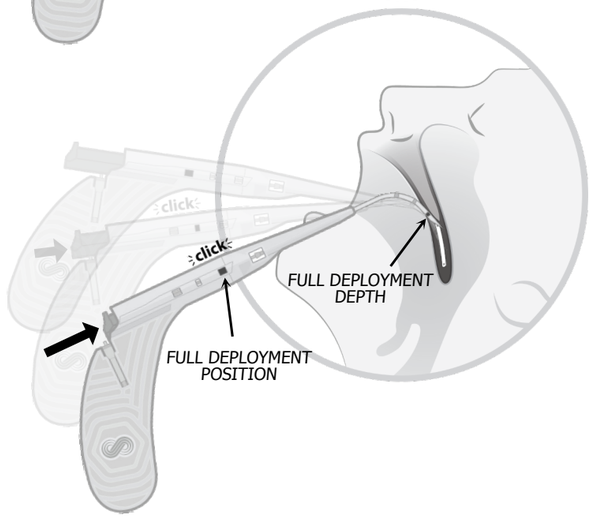
WARNING: Attempting to place the Implant into a pathway that has a breach on the nasopharyngeal aspect of the palate may result in extrusion of the Implant.



IMPLANT DEPLOYMENT

1. Begin deploying the Implant by **SLOWLY** advancing the slider from the start position while simultaneously retracting the needle. When the slider reaches the "mid deployment position", there will be an audible and tactile 'click' to indicate the position. The coordinated needle retraction should occur such that this first click corresponds with the visibility of the "mid deployment depth marker" on the needle as it revealed from the tissue.

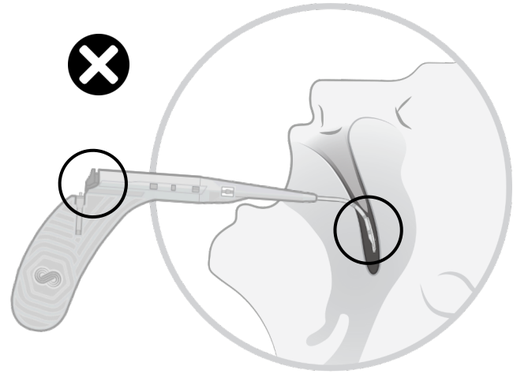




2. Continue **SLOWLY** advancing the slider and simultaneously retracting the needle. When the slider reaches the "full deployment position" there will be another audible and tactile 'click'. The coordinated needle retraction should occur such that this second click corresponds with the visibility of the "full deployment depth marker" on the needle as it is revealed from the tissue. At this point, the Implant is fully deployed from the needle.
3. Once the Implant is fully deployed, withdraw the needle from the palate following the the insertion path.

WARNING: DO NOT remove the needle from the palatal tissue until the slider is fully advanced.

WARNING: DO NOT depress the slider without also retracting the needle from the tissue in a coordinated fashion. This may lead to improper Implant positioning and Implant extrusion.



INSPECTION

1. Inspect the needle insertion site and the dorsal (nasal) surface of the soft palate. If the Implant is exposed or visible, it must be removed. Use forceps to gently remove the Implant from the tissue.

WARNING: If the Implant is visible, it has been placed too superficially and must be removed and replaced with a new Implant. Implants placed too superficially may result in partial or full extrusions. DO NOT reposition the needle in the original penetration site.

DISPOSAL

1. Once the Implant has been deployed, properly dispose of the Delivery Tool and all its components. DO NOT attempt to reload or reuse a Delivery Tool.
2. If an Implant was removed from the tissue following placement for any reason, dispose of the Implant. DO NOT attempt to reuse an Implant.

ADDITIONAL INFORMATION

Store the System at room temperature. Do not expose it to organic solvents, ionizing radiation, or ultraviolet light. Rotate inventory to ensure that the Systems are used before the expiration date on the package label.

MANUFACTURED BY
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INSTRUCTIONAL-070-01 PALATAL IMPLANT SYSTEM IFU