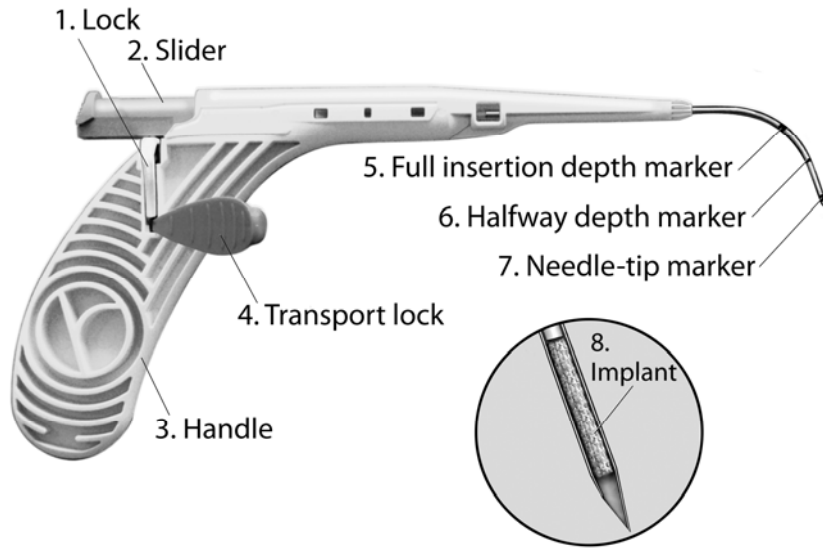


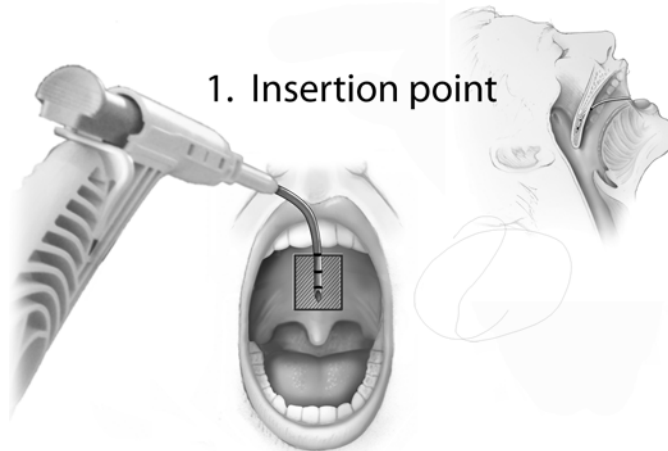
**FIGURE 1**  
Delivery Tool and Implant



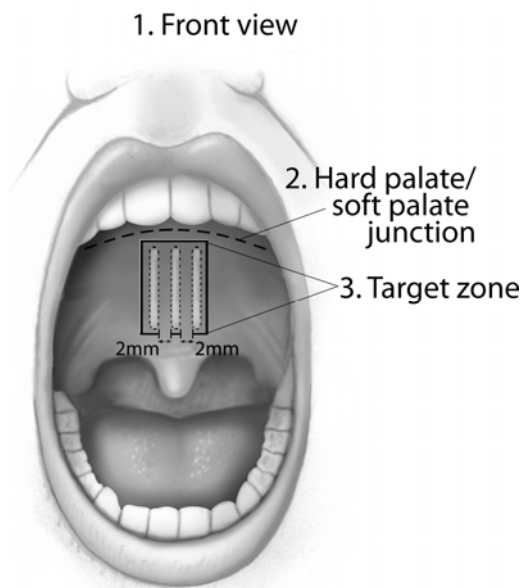
**FIGURE 2**  
Removing the transport lock



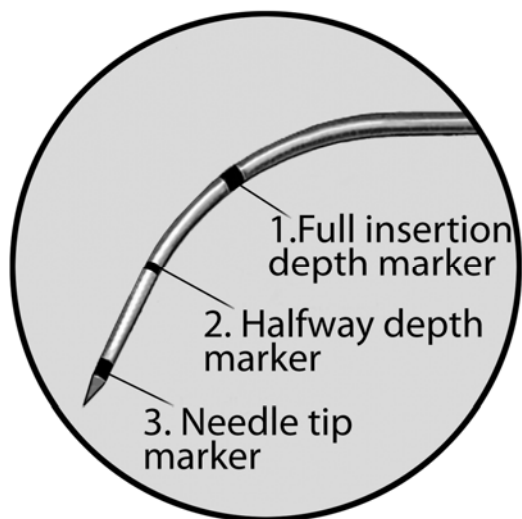
**FIGURE 3**  
Determining an insertion point (illustration of midline placement)



**FIGURE 4**  
Target zone for midline and lateral Implant placements

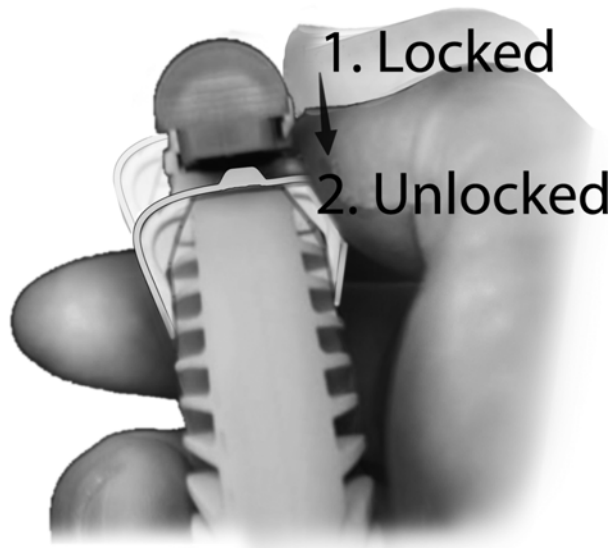


**FIGURE 5**  
Needle Detail



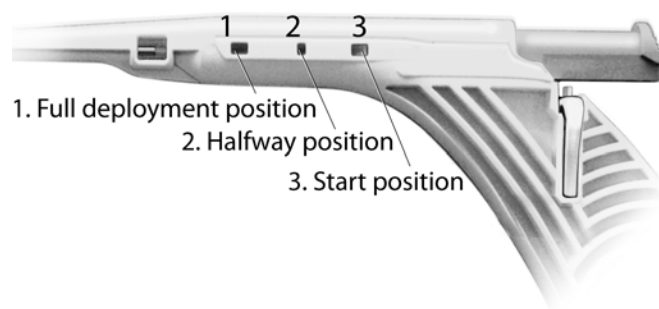
**FIGURE 6**

Moving from the locked to unlocked position



**FIGURE 7**

Slider in the start position



### **Intended Use/ Indications For Use**

The Pillar® System (“System”) is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals, and for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (Obstructive Sleep Apnea).

Indications for use of the System include: symptomatic, habitual, social snoring due to palatal flutter or upper airway obstruction caused by the soft palate.

This system is labeled for use by physicians only.

### **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 <25mm.
- Under the age of 18.
- Do not use substances that are incompatible with any of the product’s components (see Product Description/Components section).

## **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:
- Difficulty swallowing
- Erosion of Implant
- Gastro-intestinal obstruction
- Implant aspiration
- Implant rejection
- Implant migration
- Infection
- Mucosal edema
- Partial/full extrusion of Implant\*
- Sore or scratchy throat
- Voice/taste change
- Allergic reaction to Implant material
- Foreign body sensation

\*Partial extrusions of the Implant did occur during clinical studies, and patients should be informed of this potential complication.

## **Product Description/ Components**

The System consists of a Delivery Tool and an Implant (Figure 1). The Delivery Tool comes preloaded with the Implant. The Implant is a braided segment of polyester filaments intended for permanent implantation. The Implant is approximately 0.7 inches (18mm) in length and has an approximate outer diameter of 0.08 inches (2 mm). The Delivery Tool consists of a handle and 14- gauge needle. The needle is inserted into the soft palate; the Implant is deployed by advancing the slider; and the Delivery Tool is removed. The Delivery Tool is disposable.

## **Clinical Considerations**

The following factors may affect the overall success of the Implant:

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

**The System has been shown to be clinically effective in patients with a Body Mass Index (BMI) less than or equal to 30 kg/m<sup>2</sup>.**

Additionally, prior to the procedure it is recommended the following evaluations be considered to confirm that palatal flutter is the main contributor to the patient's snoring or that the palate is a contributor to the patient's OSA:

- Complete physical examination
- Nasopharyngeal, hypopharyngeal, and oral cavity examinations
- Mallampati classification
- General assessment of the thickness of palatal and pharyngeal mucosa tissues
- Sleep study
- Sound description (simulated snoring)

Clinical long-term success with the Implant has not been established.

In order to minimize the chance of infection, it is recommended that an appropriate antiseptic oral rinse, (e.g. chlorhexidine gluconate 0.12% - 0.2%) be used preoperatively and an appropriate broad spectrum antibiotic be given both pre- and post-operatively. A suitable analgesic is also suggested to manage discomfort in the immediate post-operative period.

During the procedure an appropriate local anesthetic should be used to infiltrate the soft palate tissue in the area where the Implants will be placed. The anesthetic may swell the tissue. Care should be taken to avoid superficial placement that may lead to partial extrusion.

**Note: 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.**

### **Preparations For Use**

Read all instructions carefully prior to using the System. The System is supplied sterile and intended for single use only. Inspect the package and the System for damage prior to use. If there is a breach to the package or if the System is damaged DO NOT USE. Immediately return the defective package/ System to the Company for replacement.

### **Cautions**

1. Single use only. Do not resterilize.
2. Sterile conditions should be maintained at all times while handling the System.
3. Open or damaged product should not be used due to potential non-sterile conditions.
4. Implant should not be removed from needle and/or modified prior to use.
5. Delivery Tool handle and needle should not be modified prior to use.
6. Do not use excessive force during needle insertion, Implant deployment, or Delivery Tool removal.
7. If the Implant is ejected from the needle prior to placement, discard the Implant and Delivery Tool.
8. After use, all components should be treated as biologically hazardous waste during disposal.
9. Product that is damaged, or where the sterility has been compromised, needs to be returned — contact the Company for detailed instructions.
10. Should the Implant require removal or the patient request removal, a minimally invasive surgical procedure is required.

11. 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.

## Placement Technique

Locating the Insertion Point:

1. Remove the transport lock (blue tab) by grasping the blue tab and pulling the lock away and out of the handle (Figure 2).
2. Remove the protective cap from the Delivery Tool needle using aseptic technique.
3. The marking on the needle farthest from the needle tip is the “full insertion depth marker” (see detail in Figures 1 and 5). Using the hard palate/soft palate junction as a landmark, place the Delivery Tool needle near the soft palate, without touching it, and approximate the position of the “full insertion depth marker” just distal to the landmark (Figure 3). With the needle placed in this manner, the “full insertion depth marker” denotes the proper insertion point.
4. The Target Zone for midline and lateral Implant placement is within the area as shown in Figures 3 and 4.
5. All three (3) Implants must be placed parallel within the Target Zone approximately 2mm apart from one another as shown in Figure 4. The needle should be used as a gage, as the needle width is approximately 2mm. Implants shall be placed in this arrangement regardless of palate width and size. Implants should be placed as close to the junction of the hard palate and soft palate as possible. Avoid placement of any part of the Implant at the base of the uvula.

**Warning: Avoid inserting into the uvula or too far laterally as the palate is usually thinner in this area and subsequent partial/full extrusion of the Implants may occur.**

## Insertion Technique

6. 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.**

After determining an insertion point and confirming that the slider is in the locked position, insert the needle through the submucosal tissue layer into the muscle. Continue needle advancement in an arcing motion up to the “full insertion depth marker.” This marker needs to remain visible.

Ensure that the needle does not exit any portion of the soft palate and become exposed.

**Caution: If the needle tip pierces the back of the soft palate, remove the needle from the tissue and determine a different insertion point. DO NOT reposition the needle in the original penetration site.**

**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.**

7. Unlocking the Slider

Unlock the slider by applying downward pressure to the arms of the lock just beneath the slider and the back of the handle (see Figure 6). You may hear an audible “click” or receive tactile feedback indicating the slider is unlocked.

## 8. Deploying the Implant

*Step 1:* Begin deploying the Implant by advancing the slider from the start position. Stop advancing the slider when it reaches the halfway deployment position—you may hear an audible “click” and receive a tactile feedback indicating the halfway deployment position. Additionally, viewing the side of the Delivery Tool will indicate the slider position (see Figure 7).

*Step 2:* Withdraw the needle until the halfway depth marker is visible on the needle.

*Step 3:* When the halfway depth marker on the needle is visible, continue advancing the slider until it comes to a stop at the full deployment position.

**NOTE: When advancing the slider into the full deployment position, the contact of the Implant with tissue at the distal end of the needle track may result in a feeling of resistance and naturally cause the needle tip to push up or out.**

*Step 4:* After the Implant is fully deployed, withdraw the needle from the palate following the insertion path (move the handle in an arcing fashion).

DO NOT remove the needle from the palatal tissue until the slider is fully advanced. The Implant is now correctly deployed and the green deployment assembly should be visible in the needle tip.

**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.**

9. Inspect the needle insertion site. If a portion of the Implant is exposed, it may be gently removed with forceps to mitigate the risk of infection or extrusion.
10. Inspect the dorsal (nasal) surface of the soft palate. If the Implant is visible, it must be removed.

## Storage

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 prior to the expiration date on the package label.

## Customer Service Information

For further information regarding the use of this product or to report any problems, please contact Medtronic Xomed using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

## LIMITED WARRANTY

A. This LIMITED WARRANTY provides assurance for the customer who purchases a Medtronic Xomed Product (hereinafter the “Product”) that should the Product fail to function to Medtronic Xomed’s published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product, 90 days from date of shipment for refurbished or used Product), Medtronic Xomed will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing

the Product directly from Medtronic Xomed or from its affiliate or its authorized distributor or representative.

B. To qualify for this LIMITED WARRANTY, the following conditions must be met:

- (1) The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
- (2) The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
- (3) Medtronic Xomed must be notified in writing within thirty (30) days following discovery of a defect.
- (4) The Product must be returned to Medtronic Xomed within thirty (30) days of Medtronic Xomed receiving notice as provided for in (3) above.
- (5) Upon examination of the Product by Medtronic Xomed, Medtronic Xomed shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Xomed or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

C. This LIMITED WARRANTY is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic Xomed be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.