

The Pillar[®] System

Palatal Implants

INSTRUCTIONS FOR USE

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

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. **The 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.

POTENTIAL COMPLICATIONS

There have been no reported major complications as a result of the Pillar Procedure. The reported rate for all complications is less than 1%.

Since the Pillar Procedure does not involve removing or destroying tissue, the risk of complication is low. With approximately 30,000 Pillar Procedures performed worldwide, the most commonly reported complication is a partial extrusion. A partial extrusion occurs when the implant is placed too shallow or too deep, and the tip of the implant protrudes through the surface of the soft palate tissue. If a partial extrusion occurs, the physician should remove the implant and replace it with a new implant.

Other potential complications that may occur include:

(Most complications are temporary and resolve within 24 to 72 hours.)

- Sore or scratchy throat
- Voice/taste change
- Foreign body sensation
- Mucosal edema (swelling)
- Infection
- Allergic reaction to Implant material
- Implant migration

Patients who have questions about the Pillar Procedure are encouraged to talk to their doctor.