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Otolaryngology
Head And Neck Surgery
Facial Plastic Surgery
Allergy, Asthma, Immunology

Pillar[®] Procedure Patient Consent Form

Introduction

The PILLAR[®] PROCEDURE is designed to reduce airway obstruction, a leading cause of sleep apnea, which occurs when breathing temporarily stops during sleep, and to reduce the instability in the soft palate tissue that can cause snoring.

The PILLAR PROCEDURE combines the use of three tiny inserts that are placed in your soft palate, the back portion of the roof of your mouth. The inserts support and stiffen the palate. This supporting and stiffening of the soft palate should last as long as the inserts are in place.

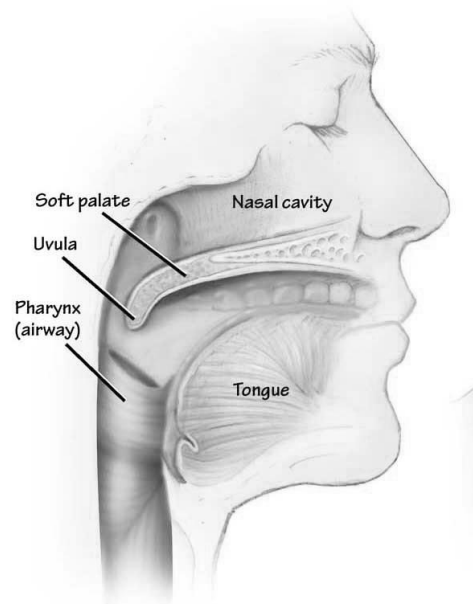
The Food and Drug Administration (FDA) regulates the manufacture and use of The PILLAR PROCEDURE in the US. The PILLAR PROCEDURE has been reviewed and cleared by the FDA for both obstructive sleep apnea and disruptive snoring.

This Patient Consent Form generally describes the PILLAR PROCEDURE and outlines certain risks and possible benefits. Before electing to undergo the PILLAR PROCEDURE, you must discuss the potential risks, complications, and post-procedure recovery with your physician. You are encouraged to ask questions at any time about the PILLAR PROCEDURE or about any statements made in this form.

What Causes Sleep Apnea and Snoring?

The noisy sounds of snoring occur when the airflow through the passages at the back of the mouth and throat causes instability in the soft palate tissue. The instability then causes these tissues to vibrate, which results in snoring sounds. Studies estimate that the soft palate contributes, entirely or in part, to 90% of all snoring.

As throat muscles relax during sleep, unsupported tissues in the back of the mouth (soft palate) and throat (pharynx) may collapse reducing the size of or blocking the airway. Airflow through the passages at the back of the mouth and throat create instability in soft palate tissue, causing these tissues to vibrate. This vibration results in the snoring sound.



In the case of sleep apnea, the airway is blocked when the palate collapses and blocks the airway during sleep. This can occur hundreds of times during the night.

Treatment Overview

After first numbing the area with a local anesthetic, your physician will place three tiny inserts in your soft palate using a specially designed Delivery Tool. The inserts are made of a braided polyester material that has been used for many years in implantable medical products.

After the inserts are placed, they should be invisible in the soft palate.

Some Individuals Require Treatments in Addition to the PILLAR PROCEDURE

The PILLAR PROCEDURE is effective in reducing airway obstruction caused by instability in the soft palate tissues. In addition to the palate, tongue size, enlarged tonsils, a large uvula (the soft tissue structure that hangs from the back of your mouth), and/or nasal obstruction can all contribute to obstructive sleep apnea (OSA) and snoring. Your physician will examine your airway to determine if other obstructions, in addition to the palate, contribute to your condition. If necessary, your physician will develop a plan to perform additional procedures to address these obstructions.

Post-Procedure Expectations

The procedure usually causes minimal discomfort and recovery time is short for most patients. Most patients resume a normal diet and activities the same day.

Pain and swelling are usually minimal. Most patients use only an over-the-counter pain reliever to treat discomfort. Over time, the inserts create a stiffening response in the tissue, which further supports the soft palate.

Possible Benefits

In most cases, patients soon report a noticeable reduction in snoring. In clinical studies, apnea and hypopnea events/hours of sleep, daytime sleepiness, and snoring were significantly reduced in patients with mild to moderate sleep apnea.

Potential Complications

Use of the PILLAR PROCEDURE involves potential risks including, but not limited to, those listed below. For more information about the following potential complications, please ask your physician:

- 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

Other Considerations

Even after treatment, you may have the same symptoms you are having now.

Because the PILLAR PROCEDURE is a relatively new procedure, the long-term effects and consequences of the procedure have not been fully determined.

CONSENT FOR THE PILLAR PROCEDURE

1. I have read this Patient Consent Form in its entirety.
2. I have discussed it with my physician and have been given the opportunity to ask questions. All of the questions that I have asked have been answered to my satisfaction. I understand how the PILLAR PROCEDURE is performed and acknowledge its potential complications and risks.
3. I understand that:
 - a. The U.S. Food and Drug Administration (FDA) regulates the manufacture and use of the PILLAR PROCEDURE for mild to moderate sleep apnea and snoring.

Alternative therapy and/or treatments to the PILLAR PROCEDURE include:

CPAP: (Continuous Positive Airway Pressure) A tight-fitting mask is placed over the nose and air – under pressure – is pushed into your airway while you sleep;

LAUP: (Laser-Assisted Uvulopharyngoplasty) A surgical procedure surgery to remove tissue from the back of the throat using a laser knife;

UPPP: (Uvulopalatopharyngoplasty): A surgical procedure that involves the removal of soft palate tissue, the uvula and/or tonsils to open the airway; and

RF Ablation (Radiofrequency): Thermal heat is applied to the palate to create scarring, which should stiffen the palate.

- b. The results of the PILLAR PROCEDURE cannot always be predicted. The safety and efficacy of the PILLAR PROCEDURE cannot be guaranteed. I may still need to pursue additional sleep apnea treatment options.
- c. The PILLAR PROCEDURE is not risk-free. Potential complications, as described in this consent form, are possible.
- d. My decision to undergo the PILLAR PROCEDURE is voluntary. I understand that, I may withdraw my consent at any time prior to the procedure.

I consent to undergo the PILLAR PROCEDURE:

Patient Signature / Date / Time

Patient Printed Name

Witness Signature / Date / Time

Witness Printed Name

Physician Signature / Date / Time

Physician Printed Name

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