Medtronic News

# Meta-Analysis Demonstrates Efficacy of Pillar Procedure for the Treatment of Snoring and Mild to Moderate Obstructive Sleep Apnea

*Authors Reach Conclusions After a Meta-Analysis of 7 Clinical Studies for Snoring, and 7 Studies for OSA*

MINNEAPOLIS - Feb. 27, 2013 - In a meta-analysis of seven studies published in the January issue of *Laryngoscope,* Ji Ho Choi, M.D., Ph. D., and coauthors conclude that the Medtronic Pillar Procedure significantly reduced snoring loudness and mild-to-moderate obstructive sleep apnea (OSA).

The Medtronic Pillar Procedure was cleared by the Food and Drug Administration (FDA) as a treatment for snoring in 2002 and for mild-to-moderate OSA in 2004. A minimally invasive, tissue-sparing procedure, doctors perform the Pillar Procedure as an alternative to more invasive surgical procedures to remove obstructive tissues in the upper airway that contribute to snoring and OSA.

Choi and his colleagues write, "Various surgical procedures on the upper airway have been attempted for snoring and OSA. Yet their effect remains equivocal. This is mainly because of a shortage of evidence on the surgical results and the absence of definitive criteria about surgical success."

For their analysis of the effect of the Pillar Procedure on snoring, Choi and his colleagues used seven case-controlled studies, with a total enrollment of 174 subjects. These studies all used the post-procedure Visual Analogue Scale (VAS) score compared to the pre-procedure score as their primary outcome measure. VAS is a measure of snoring intensity. The meta-analysis results indicate that the Pillar implant reduced snoring sound significantly as compared to preprocedure values with a standardized mean difference of -0.591 ($p<0.001$).

Study authors also analyzed the efficacy of the Pillar procedure as a single surgical procedure for the treatment of mild to moderate OSA. The seven selected studies included five case series and two placebo-controlled trials. The total number of subjects enrolled in the seven studies was 363, of which 76 were in placebo control groups.

The primary OSA outcome measures for the seven selected studies included the Epworth Sleepiness Scale (ESS), and the Apnea-Hypopnea Index (AHI).

The ESS is a questionnaire completed by each person who self-identifies his or her likelihood of falling asleep during the day in eight different situations. AHI is a measure of the mean number of times a person experiences an episode of apnea or hypopnea (partial or complete blockage of the airway) during an hour of sleep. The results of the meta-analysis indicate that the Pillar implant significantly reduced ESS as compared to preprocedure values with a standardized mean difference of -0.481 ($p<0.001$), and significantly reduced AHI as compared to preprocedure values with a standardized mean difference of -0.378 ($p=0.002$).

The authors' study, "Efficacy of the Pillar Implant in the Treatment of Snoring and Mild-to-Moderate Obstructive Sleep Apnea: a Meta-Analysis," can also be read online at www.laryngoscope.com.

About The Medtronic Pillar Procedure

The Pillar® Procedure is a method for stiffening the soft palate to address tissue vibration and collapse that can block the upper airway and contribute to snoring and mild to moderate OSA. A specially trained surgeon places small implants into the soft palate. Over time, the implants work with the body's natural fibrotic response to add structural support (stiffen) the soft palate. This structural support helps to reduce the tissue vibration that can cause snoring. In July 2012, the FDA cleared new labeling information for the Pillar Palatal Implant system that allows surgeons to use up to five Pillar Implants specifically for snoring. For

more information, visit www.PillarProcedure.com
www.medtronicsleep.com

About Medtronic Surgical Technologies
The Surgical Technologies business develops products and procedural solutions for surgical applications that include: neuro spine, cranial and orthopedics; ear, nose and throat; and surgical oncology. Surgical Technologies designs, develops, manufactures and supports healthcare providers with advanced surgical navigation and imaging solutions, powered surgical tools and systems, intraoperative nerve monitoring devices, advanced energy-based devices for hemostatic sealing and tissue dissection, and implantable devices for hydrocephalus management.

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Medtronic, Inc. (NYSE: MDT) (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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