Sonitus Medical Announces Affirmative Update Regarding Bone Conduction Oral Appliances in American Academy of Otolaryngology-Head and Neck Surgery Policy Statement on Implantable Hearing Devices

The Associated Press

Sonitus Medical, Inc., a medical device company that manufactures the world's first and only non-surgical and removable hearing device to transmit sound via the teeth, announced today that the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) approved a policy statement on implantable hearing devices that includes placement of a bone conduction oral appliance as an acceptable procedure for the relief of appropriate indications (e.g., Single Sided Deafness or Conductive Hearing Loss) when performed by a qualified health care professional. Since hearing aids are medically inappropriate for patients suffering with Single Sided Deafness and Conductive Hearing Loss, the Academy's decision to recognize an intra oral prosthetic hearing device offers these patients a non-surgical and cost-effective treatment option.

"We are delighted that the AAO-HNS Board of Directors has acknowledged the clinical safety and efficacy of an oral appliance for treatment of single sided deafness and conductive hearing loss in its policy statement library," said Amir Abolfathi, CEO of Sonitus Medical.

"This positive action by such a prestigious professional organization is an important product milestone and promises to be very beneficial as we actively pursue securing a broad-based reimbursement for SoundBite Hearing System." An innovation in hearing loss technology, SoundBite transmits sound using the well-established principle of bone conduction. Unlike predecessor prosthetic devices that reroute sound through skull bones, SoundBite places a custom fabricated transducer on the tooth, thereby eliminating the need to surgically implant a post in the skull. In this way, SoundBite eliminates the surgical costs and potential complications of the implant by using the tooth as a "naturally osseointegrated" post.

The SoundBite system comprises two parts. The first component is a removable in-the-mouth (ITM) appliance, which is custom made for each patient to fit on either the upper left or right back teeth. The ITM transducer produces vibrations that allow sound to reach the cochleae via bone conduction. The second component is a small digital signal processor unit worn behind the ear (BTE), which picks up the sound and wirelessly transmits the signal to the ITM. The ITM does not require modification to the teeth, and an oral exam is conducted by a medical professional prior to use of SoundBite. SoundBite is removable, with normal daily functions such as talking and eating attainable with the device in place.

AAO-HNS Implantable Hearing Devices Policy Statement The AAO-HNS policy statement, which was originally adopted in 1986 and has gone through periodic revisions (the most recent in 1/2013), addresses implantable hearing devices that can be used as part of a procedure to provide relief of hearing impairment.

The American Academy of Otolaryngology-Head and Neck Surgery, Inc. considers the implantation of a percutaneous or transcutaneous bone conduction hearing device, placement of a bone conduction oral appliance, and implantation of a semi-implantable hearing device or totally implantable hearing device to be acceptable procedures for the relief of hearing impairment when performed by, or in collaboration with, a qualified otolaryngologist-head and neck surgeon. Use of any device must adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the Food and Drug Administration in the United States and other similar regulatory agencies in countries other than the United States.

Important AAO-HNS/F Disclaimer Notice Policy statements are approved by the American Academy of Otolaryngology-Head and Neck Surgery, Inc. or Foundation (AAO-HNS/F) Boards of Directors and are typically generated from AAO-HNS/F committees. Once approved by the Academy or Foundation Board of Directors, they become official policy statements and are added to the existing policy statement library. In no sense do they represent a standard of care. The applicability of policy statements as guidance for a procedure must be determined by the responsible physician in light of all the circumstances presented by the individual patient. Adherence to these clinical policy statements will not ensure successful treatment in every situation. As with all AAO-HNS/F guidance, this policy statement should not be deemed inclusive of all proper treatment decisions or methods of care, nor exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results.

About SoundBite
SoundBite hearing system is the world's first and only non-surgical and removable hearing solution that imperceptibly transmits sound via the teeth to help people with Single Sided Deafness or Conductive Hearing Loss rejoin the conversation of life.

The SoundBite prosthetic device currently has FDA 510(k) clearance to treat single sided deafness and conductive hearing loss, and mixed hearing loss, along with CE Mark certification. To learn more about the SoundBite Hearing System, please visit http://www.soundbitehearing.com.

About Sonitus Medical
Sonitus Medical Inc. is a privately held medical device company that markets the SoundBite hearing system, the world's first hearing and communication solution that imperceptibly transmits sound via the teeth. Relying on the principle of bone conduction, this nearly invisible ITM (in-the-mouth) hearing device is a simple and non-invasive hearing and communication platform. Intended future applications include indications for hearing disorders such as mixed hearing loss and tinnitus, as well as consumer and covert communications. Founded in June 2006, Sonitus

Medical is headquartered in San Mateo, California. To learn more, please visit http://www.sonitusmedical.com.

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