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#### **8.4**

##### **Vibrant Soundbridge clinical investigations: expanding indications for use**

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**Purpose/Material:** The Vibrant Soundbridge is a partially implantable “direct-drive” hearing system for the treatment of hearing loss and is currently indicated for use in adults who have mild-to-severe sensorineural hearing loss. Recently, the device has been applied to persons with mixed and conductive hearing losses to provide amplification to residual sensorineural hearing. In order to appropriately place the device in disordered and malformed ears, the manner and/or location of placement of the device is altered, and, in some cases, the device is used in conjunction with commercially available, passive middle ear prostheses. The objective of these studies is to evaluate expanding indications for use of the Vibrant Soundbridge to include persons with conductive and mixed hearing losses.

**Methods:** Subjects were implanted with the Vibrant Soundbridge implantable hearing aid, using either the Vibroplasty or Round Window Vibroplasty surgical technique. A single-subjects, repeated measures design is used to evaluate the safety and efficacy of the Vibrant Soundbridge in persons with conductive and mixed hearing losses.

**Results:** An overview of the study and its procedures, as well as preliminary results, will be presented.