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Independent Study Shows Esteem® Provides Significant Improvements in Hearing for Patients

Results Published in The Journal of Laryngology & Otology Support Use of Active Middle Ear Implants in Patients with Moderate-to-Severe Sensorineural Hearing Loss Who Have Struggled with Hearing Aids

WHITE BEAR LAKE, Minn. – March 23, 2021 – Envoy Medical® Corporation, a hearing health company focused on providing innovative technologies across the hearing loss spectrum, today announced that an independent study <u>published online</u> in *The Journal of Laryngology & Otology* found that the fully implanted Esteem® osseointegrated active middle ear implant (AMEI) showed statistically significant improvements in post-operative hearing results. The study also reinforced the safety and efficacy of the Esteem® for patients with moderate-to-severe sensorineural hearing loss who have failed to benefit from traditional amplification like hearing aids.

The Esteem osseointegrated AMEI was used in all study patients and this device is the first and only fully implanted AMEI approved by the Food and Drug Administration. The study, "Totally implantable active middle-ear implants: a large, single-surgeon cohort," represented a large, retrospective, single-surgeon experience which demonstrated that the AMEI provided an overall significant improvement in pure tone average (PTA) and word recognition score at a hearing level of 50 dB.

"These study results provide further evidence to support the use of fully implanted active middle ear implants such as the Esteem for patients with moderate-to-severe sensorineural hearing loss who are unable to use or do not benefit from hearing aids," said William McFeely, M.D., study author and otolaryngology specialist at North Alabama ENT Associates. "Large studies of patient outcomes with AMEI are still lacking largely due to the lack of insurance coverage, so patients who may benefit from these devices may not be offered an AMEI as a treatment option. However, many patients with hearing loss haven't found hearing aids to be an optimal choice and are still searching for alternatives; AMEIs such as the Esteem represent an excellent alternative."

This retrospective review was performed on 116 implants placed between November 2011 and August 2016 and included many patients who reported subjective suboptimal performance with traditional amplification and a lack of desire to continue using hearing aids. In addition to the statistically significant improvements in PTA and word recognition score, other key findings from this study included:

- Active middle ear implants are a safe and effective option for patients with sensorineural hearing loss who have struggled with traditional hearing aids and are good surgical candidates
- Although technically demanding, implantation is readily learned by an experienced otological surgeon
- Complication rates are low
- Further high quality, prospective data are needed to establish superiority of active middle ear implants compared with traditional hearing aids

"We welcome the results of this retrospective study in demonstrating the benefit of a fully implanted active middle ear implant, and hope it helps more people understand that hearing aids and cochlear implants are not the only two options for people with sensorineural hearing loss," said Brent Lucas, CEO of Envoy Medical. "There are over 48 million Americans with hearing loss of varying types and degrees – we think hearing professionals and their patients benefit from having more tools in their toolbelt. We support people with hearing loss and other advocates who continue to lobby Congress for better access to treatments that improve hearing health."



Specialty hearing implants like the Esteem hearing implant are not covered by Medicare or Medicaid because they are incorrectly classified as a hearing aid.

About the Fully Implanted Esteem® Osseointegrated Active Middle Ear Implant

The fully implanted Esteem® osseointegrated active middle ear implant (AMEI) is the only FDA approved, completely internal hearing device designed to improve the hearing of adults diagnosed with moderate to severe sensorineural hearing loss. Instead of a microphone, the Esteem osseointegrated AMEI uses a novel sensor to leverage the natural anatomy of the ear to capture sound and convert it into electrical signals that are used by the implant to address hearing loss. The Esteem hearing implant is invisible and offers true 24/7 hearing, removing many limitations of hearing aids. Esteem is available in the U.S. It is not currently covered by Medicare or Medicaid, and is not widely covered by private insurers. To learn more about Esteem, visit https://www.envoymedical.com/middle-ear-implants.

About Envoy Medical Corporation

Envoy Medical Corporation, headquartered in White Bear Lake, Minnesota, is a privately held hearing health company focused on providing innovative technologies across the hearing loss spectrum. Envoy Medical has pioneered one-of-a-kind, fully implanted devices for hearing loss, including its fully implanted Esteem® osseointegrated active middle ear implant, commercially available in the U.S. since 2010, and the fully implanted Acclaim® cochlear implant, an investigational device. Envoy Medical is dedicated to pushing hearing technology beyond the status quo to improve access, usability, compliance and ultimately quality of life. For more information, please visit: www.envoymedical.com.

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