Center for NEUROSCIENCES

EAR & HEARING
Otology I Neurotology I Audiology

Date:
Patient Name:
Account Number:
DOB:

CONSENT FORM

Envoy Esteem Hearing Implant Surgery
□ RIGHT EAR
□ LEFT EAR

The Esteem® implant procedure is a middle ear surgery, and the risk of a potential revision procedure after a middle ear surgery, including the implant of the Esteem® system may be as high as 7%. The revision rate for the subjects enrolled early in this clinical trial was 5% with an additional 2% explant rate.

The potential risks and discomforts associated with the operative procedure are similar to those for standard mastoid operations. Risks include but are not limited to the following:

- Bleeding
- Cerebrospinal fluid (fluid that surrounds the brain) leak and meningitis (brain infection)
- Damage to the Chorda Tympani branch of the facial nerve which may result in temporary or permanent taste disturbances
- Death
- Development of ear ringing (tinnitus) or an increase in ringing that was already present before the operation
- Drainage from ear canal
- Eardrum perforation/hole
- Hematoma/blood clot
- Infection of the ear
- Jaw soreness or stiffness
- Partial or complete one-sided facial paralysis or stimulation
- Partial or total loss of remaining hearing on implanted ear due to surgical procedure
- Physical breaking or dislocation of the middle ear bones
- Post-operative pain (everyone has discomfort after surgery for which we prescribe pain medication)
- Temporary external ear or incision numbness
- Transient or prolonged dizziness or vertigo
- Widening and thickening of the scar behind the ear (there is a small scar in every patient)
- Transient or prolonged ringing (tinnitus) in the operated ear

There may be some potential risks and complications that are possible due to the implantation and use of the Esteem® System. These risks include but are not limited to the following:

- Amplification of body sounds such as chewing or swallowing
- Head vibrations
- Decay of soft tissue or bone resulting in the body's rejection of the device
- Device failure/malfunction
- Dizziness when test vibrations are delivered to the stapes (middle ear bone)
- Feedback/whistling or squealing from the device
- Fibrotic growth/keloid formation (growths around the scar tissues or around the device)
- Infection of the Sound Processor pocket
- Injury to the middle ear bones because of physical contact with the Sensor/Driver portion of the device
- Loss of attachment of leads from the Sound Processor or the transducers requiring revision surgery

- Noise, distortion, or poor fidelity
- Non-implant of the device due to fit or function of the device
- Partial or total loss of remaining hearing on implanted ear due to device failure
- Stimulation of the chorda tympani branch of the facial nerve
- Stimulation of the facial nerve
- Subluxation of the stapes during revision or explantation of the Esteem® System
- Transient or permanent injury to the hearing (auditory) nerve of the test ear with subsequent hearing loss due to the physical vibration of the stapes by the Driver portion of the device
- Accumulation of air under the scalp around the Sound Processor due to inadvertent nose blowing after the operation

Potential risks to the ear include infection of the ear. Risks specific to the middle ear include but are not limited to the following:

- Fullness or stuffy sensation in the ear
- Middle ear infection
- Ossicular necrosis or deterioration of the middle ear bones over time
- Hearing loss
- Reconstruction of the bony ossicular chain due to resection of the long process (arm) of the incus bone

Potential risks of cochlear damage include but are not limited to the following:

- Damage to the cochlea (inner ear) due to excessive pressure from the Esteem System
- Damage to the cochlea (inner ear) associated with performing intra-operative testing
- Excessive electrical stimulation from the device of the inner ear
- Excessive vibration of the inner ear
- Hearing loss secondary to other risks to the inner ear
- Insufficient stimulation of the inner ear

Potential risks associated with anesthesia include but are not limited to the following:

- Neurological complications due to an increase in general anesthesia time above that normally associated with mastoid surgery
- Reaction to anesthesia
- Allergic reactions

Potential risks associated with a second surgical procedure (a transcanal middle ear surgery) include but are not limited to the following:

- Disruption of the Sensor when lifting the eardrum
- Drainage from the ear canal
- Infection
- Injury to the nerve for taste (chorda tympani nerve) causing a temporary or permanent taste disturbance
- Pain from the surgical procedure
- Immediate or delayed hole(s) in the eardrum (perforation(s))
- Reaction to anesthesia
- Stiffening of the eardrum

By signing below, I acknowledge that my physician and his staff have made themselves available to answer my questions. In addition to verbal counseling during my visit(s) with personnel from Ear & Hearing at Center for Neurosciences, I have read, understand, and have carefully considered the risks and complications of this operation, and I accept them. There were no barriers to effective communication.

Patient Signature: _____ Date: _____

Provider/Representative Signature: _____ Date: _____

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