



Indications and Contraindications

Indications

The HiResolution Bionic Ear System is intended to restore a level of auditory sensation to individuals with severe-to-profound sensorineural hearing loss via electrical stimulation of the auditory nerve.

Adults

- 18 years of age or older
- Severe-to-profound, bilateral sensorineural hearing loss (>70 dB)
- Postlingual onset of severe or profound hearing loss
- Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences)

Children

- 12 months through 17 years of age
- Profound, bilateral sensorineural deafness (>90 dB)
- Use of appropriately fitted hearing aids for at least 6 months in children 2 through 17 years of age, or at least 3 months in children 12 through 23 months of age. The minimum duration of hearing aid use is waived if x-rays indicate ossification of the cochlea
- Little or no benefit from appropriately fitted hearing aids
- In younger children (<4 years of age), lack of benefit is defined as a failure to reach developmentally-appropriate auditory milestones (such as spontaneous response to name in quiet or to environmental sounds) measured using the Infant-Toddler Meaningful Auditory Integration Scale or Meaningful Auditory Integration Scale or <20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test) administered using monitored live voice (70 dB SPL)
- In older children (>4 years of age), lack of hearing aid benefit is defined as scoring <12% on a difficult open-set word recognition test (Phonetically Balanced-Kindergarten Test) or <30% on an open-set sentence test (Hearing in Noise Test for Children) administered using recorded materials in the soundfield (70 dB SPL)

Contraindications

Deafness due to lesions of the acoustic nerve or central auditory pathway; active external or middle ear infections; cochlear ossification that prevents electrode insertion; absence of cochlear development; and tympanic membrane perforations associated with recurrent middle ear infections.