

Post-Market Clinical Investigation of the IotaSOFT Insertion System

NCT06664697

Status RECRUITING
Sponsor IotaMotion, Inc.
Enrollment 50 participants

Key Eligibility Criteria

Inclusion (6)

- Candidates with sensorineural hearing loss who received or will receive unilateral or bilateral cochlear implantation according to indications for use with FDA approved cochlear implant devices, as listed below:
 - Advanced Bionics HiFocus SlimJ
 - Cochlear Slim Straight
 - MED-EL Flex 24 and 28
 - Age 12 years or older at the time of CI surgery.
- ... and 1 more (see full listing online)

Exclusion (12)

- Prior cochlear implantation in the ear to be implanted.
 - Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array or present an increased risk of aberrant insertion.
 - Craniofacial abnormality, temporal squamosal skull thickness less than 3mm, major cochlear lesions (e.g., fibrosis, fracture, or ossification), or cochlear malformations.
 - Deafness due to lesions of the acoustic nerve or central auditory pathway.
 - Diagnosis of auditory neuropathy.
- ... and 7 more (see full listing online)

Locations (3 total)

Indiana University, Indianapolis, Indiana, United States
University of Iowa, Iowa City, Iowa, United States
Oregon Health and Sciences University, Portland, Oregon, United States