



## Warnings and Precautions

### Warnings

Bacterial meningitis has been reported in users of the system and other cochlear implants, especially in children under the age of 5. The cause of meningitis in these cases has not been established. A small percentage of deaf patients may have congenital abnormalities of the cochlea (inner ear) that predispose them to meningitis even prior to implantation. Patients who become deaf as a result of meningitis are also at increased risk of subsequent episodes of meningitis compared to the general population. Other predisposing factors may include young age (<5 years), otitis media, immunodeficiency, or surgical technique. The cochlear implant, because it is a foreign body, may act as a nidus for infection when patients have bacterial illnesses.

The incidence rate, although low, appears to be higher than the age-adjusted rate for the general population. The fatality rate as a result of meningitis also appears to be higher. Adequate epidemiological data are not available to determine whether the incidence and fatality rates are, in fact, definitively different from the general population, whether there are special risk factors in the cochlear implant population, or whether different cochlear implant models pose different risks.

Adults and parents of children who are considering a cochlear implant or who have received cochlear implants should be advised of the risk of meningitis. They should also be informed of the availability of vaccines that have been shown to substantially reduce the incidence of meningitis in the general population resulting from the organisms that commonly cause bacterial meningitis (*Streptococcus pneumoniae*, *Haemophilus influenzae*, *Meningococcus*). National health agencies frequently provide updated information on the safety and utility of specific vaccines and offer recommendations reflecting local or regional conditions. Physicians or patients should refer to the applicable authorities for this information. These vaccines can be administered by pediatricians, primary care/family physicians, and infectious disease specialists.

Adults and parents of children who have received cochlear implants should be counseled on the symptoms of meningitis, the need to seek immediate medical care if any symptoms appear, and the need to advise the treating physicians of the presence of the cochlear implant and of the possibility of increased risk of meningitis associated with implant. They should also be counseled to obtain medical care at the first signs of otitis media.

- Extreme direct pressure on the implanted device, up, down, left or right may cause the implant to move and possibly dislodge the electrode array.
- A direct impact to the implant site may damage the implant and result in its failure to function. There have been instances of Clarion® device failure as a result of a child hitting his/her head at the site of the implanted device. None of these reported incidents have resulted in a concussion or fracture of the skull. In all cases, the failed device was explanted and a new device reimplanted with no further complications.
- The long term effects of chronic electrical stimulation are unknown. Clinical experience with the system since 1991 has shown no adverse effects of chronic electrical stimulation on patient performance, electrical thresholds, or dynamic range.

- **Magnetic Resonance Imaging Testing:** The HiRes 90k cochlear implant, with the internal magnet removed, has been tested with MRI machines having a 1.5 Tesla static field, with a 64 MHz RF pulsed field, and a 0.3 Tesla static field, with a 12 MHz RF pulsed field, with the following results:
  - The diagnostic image in situ will be distorted. With worst-case scan parameters, an image shadow around the implant area was produced. The image distortion was largest in the axial scans. The MRI static field exerts a small force on the implant.

### **MRI Guidelines**

- Use only MRI systems operating at a static magnetic field strength of 0.3 Tesla or 1.5 Tesla.
- Select MRI imaging parameters to ensure a specific absorption rate (SAR) of less than 1.0 W/kg in the head.
- Carefully perform continuous verbal and visual monitoring of the patient throughout the MRI procedure.

### **Warnings**

- The HiRes 90k is designed with a removable magnet to allow for MRI scans. The HiRes 90k is MRI safe at 0.3 Tesla. MRI safety at higher energy levels has not been tested.
- The magnet must be surgically removed before the patient undergoes an MRI procedure.
- Patients must also remove their sound processor and headpiece before entering a room where an MRI scanner is located.

For additional information regarding the use of an MRI scanner with a HiRes 90k device, please contact Advanced Bionics Technical Support.

- Electrode displacement can occur if the electrode is not inserted properly. Surgeons should be proficient in the use of the electrode insertion tool. Failure to follow the recommended surgical procedure for placement and stabilization of the HiRes 90K implant increases the risk of device migration or extrusion and of damage resulting from impact trauma, including breakage of the electrode lead wires. Creating a recessed bed or well for the implant and securely stabilizing the device in place with sutures are critical elements of the surgical procedure.
- Electrosurgical instruments must not be used within the vicinity of the implant or electrode. Electrosurgical instruments are capable of producing radiofrequency voltages of such magnitude that a direct coupling might occur between the cautery tip and the electrode. Induced currents could cause damage to the cochlear tissues or permanent damage to the implant.
- Diathermy must never be applied over the implant or electrode. High currents induced into the electrode can cause tissue damage to the cochlea or permanent damage to the implant.
- Electroconvulsive therapy must never be used on a cochlear implant patient. Electroconvulsive therapy may cause tissue damage to the cochlea or permanent damage to the implant.
- Ionizing Radiation Therapy cannot be used directly over the implant as it may damage the device.
- The effects of cobalt treatment and linear acceleration techniques on the implant are unknown.
- Insertion of a cochlear implant electrode will likely result in the loss of any residual hearing in the implanted ear.

## Precautions

- **Electrostatic Discharge (ESD).** It is known that static electricity can potentially damage sensitive electronic components such as the ones used in a cochlear implant system. Care should be taken to avoid situations in which high levels of static electricity are generated. More information is provided in the user manuals of the system. If static electricity is present, static electrical potential of the cochlear implant recipients can safely be reduced by the patients touching any person or object with their fingers prior to that person or object contacting the implant system.
- **Digital Cellular Phones.** Using or being in close vicinity to someone using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone. Before purchasing a digital cellular phone, patients should evaluate whether it will interfere with their system. No such interference has been noted with cellular phones using analog technology.
- **Ingestion of Small Parts.** The external components of the implant system contain small parts that may be harmful if swallowed.
- **Airport/Security Metal Detectors.** Metal detectors, x-ray machines, and security scanners will not damage the implant or sound processor. However, individuals with a cochlear implant should be advised that passing through security metal detectors may activate the detector alarm. It is advised that patients carry their "Patient Emergency Identification Card" with them at all times. Cochlear implant users also might hear a distorted sound caused by the magnetic field around the security scanner door or handheld scanning wand. Turning the sound-processor volume down before passing through security screening will ensure that those sounds, if they occur, are not too loud or uncomfortable.
- **Use of Another Person's Sound Processor.** Implant recipients should use only the sound processor that has been specifically programmed for them by their clinician. Use of a different sound processor may be ineffective in providing sound information and may cause physical discomfort.
- **Physical Activity.** When engaging in physical activities that include the possibility of trauma or impact, precautions should be taken, such as wearing a protective helmet, to reduce the risk of damage to the internal device.