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INSTRUCTIONS FOR USE
HiResolution™ Bionic Ear System

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The HiResolution Bionic Ear System is a cochlear implant designed to provide useful hearing to individuals with severe-to-profound hearing loss. It consists of internal and external components. The internal components include a receiver (HiRes 90K™ or HiRes 90K™ Advantage) and an electrode array that are implanted surgically under the skin behind the ear. The external components include a sound processor (body-worn or ear-level), a headpiece, and a cable. The system converts sound into electrical energy that activates the auditory nerve. The auditory nerve then sends information to the brain, where it is interpreted as sound.

The HiRes 90K™ or HiRes 90K™ Advantage is the cochlear implant provided by Advanced Bionics. The reciever stimulator encapsulates the electronics into a titanium casing, the antenna coil allows for forward and backward telemetry between the implant and the external parts. The antenna coil also includes a magnet in order to retain the external headpiece.

The electrode array is connected to the implant through the electrode lead. There is a choice of 3 electrode arrays each with16 contacts: HiFocus™ Mid-Scala (Advantage only), HiFocus™ 1j, and HiFocus Helix™.

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 or severe-to-profound unilateral hearing loss.
- 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.
- Severe-to-profound bilateral sensorineural deafness or severe-to-profound unilateral hearing loss.
- 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; tympanic membrane perforations associated with recurrent middle ear infections.

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) which 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 Advanced B ionics 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.

- ***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™ or HiRes 90K™ Advantage 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 radio-frequency 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.

- ***Diagnostic Ultrasound Energy*** must not be used in the area of 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.

- ***Magnetic Resonance Imaging Testing:*** MRI testing for the HiRes 90K Advantage cochlear implant, was performed according to two configurations: with the internal magnet in place and with the internal magnet removed. These tests were performed 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. MRI safety at higher energy levels has not been tested.
  - Select MRI imaging parameters to ensure a specific absorption rate (SAR) less than 1.0 W/kg in the head.
  - Carefully perform continuous verbal and visual monitoring of the patient throughout the MRI procedure

MRI Warnings

MRI is contraindicated except under the circumstances described below. Do not allow patients with a HiRes 90K Advantage cochlear implant to be in the area of an MRI scanner unless the following conditions have been met:
- The bandaging protocol recommended by Advanced Bionics is followed when the patient undergoes an MRI procedure with the magnet left in place or,
- the internal magnet is surgically removed and possibly replaced with the Magnet Insert Dummy before the patient undergoes an MRI procedure.
- The external sound processor and headpiece are removed before entering a room where an MRI scanner is located.

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

In EU (European Union): Medical personnel must contact Advanced Bionics Technical Support prior to MRI procedure for completion of the "MRI Examination Request Form," for review of the technical specifications of the specific MRI equipment and for additional guidelines.

MRI testing performed for the HiRes 90K Advantage cochlear implant indicated that image shadowing may extend as far as 70 cm^2 (with the magnet removed) and 210 cm^2 (with the magnet in place) from the implant resulting in loss of diagnostic information in the implant vicinity. The extent of the shadowing may be minimized by adjusting the signal parameters.

MRI testing of the HiRes 90K Advantage cochlear implant with the internal magnet in place is only available in markets where regulatory approval has been received. Contact your Advanced Bionics representative for more information.

PRECAUTIONS:

- **Electrostatic Discharge (ESD):** It is known that static electricity can potentially damage sensitive electronic components such as the ones used in the 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 hand-held 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.

- **Change of Performance:** If you notice a change of performance with the device, please contact your caregiver for assessment. If necessary, you can fill out a complaint form and return it to Advanced Bionics.

CLINICAL STUDIES:

PERFORMANCE DATA

The HiRes 90K or HiRes 90K Advantage implant supports the HiResolution family of sound processing strategies including HiRes, HiRes with Fidelity 120 (HiRes 120), and ClearVoice.

HiRes and HiRes 120 Sound Processing

A clinical study was conducted in 50 adults implanted with a CII/HiRes 90K device who used a Harmony processor to document the benefits of HiRes 120 and HiRes sound processing. Performance with HiRes was assessed at the baseline visit and compared with HiRes 120 performance after three months of listening experience. Subsequently, subjects were refit and retested with HiRes. Results showed equivalent mean CNC word recognition scores for the two strategies. The mean HINT sentence perception scores in quiet and noise were significantly higher for HiRes 120 compared to baseline with HiRes. For HINT sentences in noise, the mean scores for HiRes 120 were significantly higher than scores after subjects were refit with HiRes.

Table 1

Mean Speech Scores for HiRes and HiRes 120

Sound Processing Group	HiRes	HiRes 120	HiRes
Test Interval	Baseline	3 Months	3 Months
CNC Words	63	65	63
HINT Sentences in Quiet	88	93*	91
Hint Sentences in Noise (+8 dB SNR)	64	70**	65

* HiRes 120 score significantly different from baseline HiRes score ($p<.05$)
** HiRes 120 score significantly different from baseline and 3-month HiRes scores ($p<.05$)

Forty-three of 50 subjects (86%) preferred HiRes 120 over HiRes. Subjects rated strength of preference for the two strategies on a scale from 1 (weak preference) to 10 (strong preference). The mean strength of preference for the 43 subjects who preferred HiRes 120 was 7.9 (range: 1-10). The strength of preference was rated as 8 or higher by 26 of the 43 subjects, and 16 of the 43 subjects rated their preference as 10 (strong preference). For the 7 subjects who preferred HiRes, the mean strength of preference was 4.4 (range: 1-9).

ClearVoice

A clinical study was conducted in 46 adults who had at least six months experience with HiRes 120 sound processing and at least moderate speech perception abilities to investigate the benefits of ClearVoice. ClearVoice has three adaptive gain settings that allow individuals to select the setting that provides the best hearing—Low, Medium, and High. A two-week randomized, crossover design was used to evaluate ClearVoice-Medium and ClearVoice-High. ClearVoice-Low was evaluated acutely during an initial test session. Speech benefit was compared for ClearVoice vs. HiRes 120 without ClearVoice (Control) using the AzBio sentence test.

Speech understanding in speech-spectrum noise was significantly better with ClearVoice- Medium and ClearVoice-High compared to the Control ($p < .0001$). ClearVoice-Medium significantly improved speech understanding in multi-talker

babble (p< .02). Speech understanding was no worse than the Control when listening in quiet for both ClearVoice Medium and ClearVoice High (p < .0001). Speech understanding with ClearVoice-Low was no worse than the Control in quiet, in speech-spectrum noise, and in multi-talker babble (p <.001).

Table 2

Mean AzBio Sentence Scores for HiRes 120 with and without ClearVoice

Study Group	Control	ClearVoice Low	Control	ClearVoice Medium	Control	ClearVoice High
Quiet	87.3	87.8	88.6	88.3	86.8	87.7
Speech-Spectrum Noise	48.0	55.6	49.5	58.2	47.7	58.3
Multi-Talker Babble	42.8	47.2	44.9	48.1	44.9	46.2

Preference ratings indicated that 42 out of 45 subjects (93%) preferred ClearVoice to the Control for everyday listening (one subject did not complete the questionnaire). The mean strength of preference for the 42 subjects who preferred ClearVoice was 7.9 (1 = weak preference, 10 = strong preference). Of the 42 subjects preferring ClearVoice, 22 indicated they would use it all of the time, 17 indicated they would use it most of the time, and 3 indicated they would use it some of the time. Of the 3 subjects preferring the Control, all indicated they would use ClearVoice some of the time.

ClearVoice is not approved for pediatric use in the United States.

ClearVoice is only available in markets where ClearVoice has received regulatory approval. Contact Advanced Bionics for more information.

For additional information about the clinical studies and clinical results including safety and efficacy, please contact your AB representative.

POSSIBLE ADVERSE EVENTS: The following risks associated with cochlear implantation and ear surgery also can occur.

- Implant patients incur the normal risks of surgery and general anesthesia.
- Major ear surgery may result in numbness, swelling or discomfort about the ear, disturbance of taste or balance, or neck pain. If these events occur, they are usually temporary and subside within a few weeks of surgery.
- Rarely, cochlear implantation may cause a leak of the inner ear fluid, which may result in meningitis.
- During the surgery, it is a rare possibility that the facial nerve could be injured resulting in a temporary or permanent weakening or full paralysis on the same side of the face as the implant.
- During the surgery, there is a rare possibility that cerebrospinal fluid leakage or perilymph fluid leakage could occur.
- As a result of the surgery, it is possible that dizziness, tinnitus, or vertigo may result. If these events occur, they are usually temporary and subside over time.
- The presence of a foreign body may cause irritation, inflammation, or skin breakdown and may require additional medical treatment or removal of the internal device.
- Skin infection in the area of the implant may require additional medical treatment or removal of the internal device.
- There is a possibility that the electrode or device may migrate requiring additional medical treatment or removal of the internal device to address any resulting injury.

PATIENT COUNSELING INFORMATION

Prospective cochlear implant candidates must be counseled appropriately on expected outcomes prior to surgery. Patients demonstrate a range of cochlear implant benefit.

Although it is not possible to predict post-implant performance preoperatively for individual patients, research and clinical experience have shown that age at implant, duration of severe-to-profound hearing loss, and preoperative speech perception skills have a significant effect on post-implant performance.

Ear selection for implantation is left to the discretion of the patient, surgeon, and audiologist. There is no consensus in the field regarding implantation of the better versus poorer ear. If the poorer ear is implanted, patients should be counseled that postoperative performance ear may not equal that of the better non-implanted ear, especially if there also is long duration of deafness and negligible residual hearing preoperatively.

Communication mode (oral versus total communication) and the patient's auditory environment can affect outcomes in children. Implant-center professionals should counsel parents about the impact of communication mode and auditory environment on potential implant benefit in the pediatric population.

TELEMETRY: The HiResolution Bionic Ear System incorporates bi-directional telemetry that verifies system function and continuously monitors the system during normal use.

STORAGE: The HiResolution Bionic Ear System should be stored at temperatures in the range of 0° to 50° Centigrade (32° to 122° Fahrenheit).

HANDLING: The HiRes 90K or HiRes 90K Advantage implant package should be handled with care. An impact that damages the storage pack also could rupture the sterile packaging.

SHELF LIFE: A Use Before date is stamped on the packaging and is based on the date of the original sterilization.

STERILIZATION: The HiRes 90K or HiRes 90K Advantage implant is supplied in ethylene oxide sterile packaging with indicators of sterilization. Sterile packs should be inspected carefully to confirm that they have not been ruptured. Sterility cannot be guaranteed if the sterile package is damaged or opened. If the sterile pack of the HiRes 90K or HiRes 90K Advantage is damaged, the device must not be used. If the sterile packaging of the HiRes 90K or HiRes 90K Advantage has been opened, the cochlear implant cannot be resterilized by either the customer or Advanced Bionics.

COMPATIBILITY: The following table displays the compatibility between products in the HiResolution Bionic Ear System family and/or previous generation product.

	Implant Type				
Processor Type		*C1*	*CII*	*HiRes 90K*	*HiRes 90K Advantage*
	Naída CI[1]	-	✓[5]	✓[5]	✓[5]
	Neptune	-	✓[1]	✓[1]	✓[1]
	Harmony	✓[2]	✓[3]	✓[3]	✓[1]
	Auria	-	✓[3]	✓[3]	✓[1]
	Platinum Sound Processor (PSP)	✓[4]	✓	✓	✓[1]

[1] Naída CI is only available in markets where Naída CI has received regulatory approval. Contact Advanced Bionics for more information.
[1] Requires SoundWave 2.1 or later
[2] Requires SoundWave 2.0 or later
[3] Requires SoundWave 1.4 or later
[4] Requires SClin2000 and CPI-II
[5] Requires SoundWave 2.2 and CPI-3

INFORMATION FOR USE AND REQUIRED TRAINING: A Surgeon's Manual and a video describing the surgical procedure and insertion of the electrode are provided to all physicians prior to implantation. Physicians must be well versed in mastoid surgery and the facial recess approach to the round window. Advanced Bionics conducts periodic training courses on the recommended surgical procedure to implant HiRes 90K or HiRes 90K Advantage and strongly recommends that surgeons who implant adults receive training.

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All physicians implanting the HiRes 90K or HiRes 90K Advantage in children must be trained in the implantation procedure. Failure to obtain the appropriate training will result in a higher incidence of surgical and medical complications.

Surgeons should work with an audiology professional who has been trained fully on the proper fitting and adjustment of the system.

Device and Fitting Manuals are provided to all clinical centers with the Clinician's Programming System. Audiologists must be highly skilled in administering test procedures used to determine cochlear implant candidacy. They should be knowledgeable about state-of-the-art hearing aid technology and fitting procedures. In addition, at least one audiologist from a clinical center should be fully trained and qualified in the fitting of the Advanced Bionics cochlear implant in both adults and children. Advanced Bionics conducts periodic training courses for audiologists and strongly recommends that audiologists attend a training course. Failure to obtain the appropriate training will result in less-than-optimal patient performance.

Sound processor user guides are provided to all HiResolution Bionic Ear System recipients upon delivery of the system. Patient counseling materials are made available to all implant centers upon request. These materials provide detailed information about the system, indications for use, benefits, risks, and what is involved in patient selection, surgery, and follow-up procedures.

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician. For use in children, federal law restricts this device to sale, distribution and use by or on the order of a physician who is trained in the pediatric implantation procedures for the HiResolution Bionic Ear System.

HiRes 90K Advantage and HiFocus Mid-Scala are only available in markets where HiRes 90K Advantage and HiFocus Mid-Scala have received regulatory approval. Contact Advanced Bionics for more information.

REF	
CI-1500-04	HiRes90K™ Advantage with HiFocus Mid-Scala Electrode
CI-1500-01	HiRes 90K™ Advantage with HiFocus 1j Electrode
CI-1500-02H	HiRes 90K Advantage with HiFocus Helix Electrode
CI-1410	HiRes 90K Magnet Insert Dummy
CI-1412	HiRes 90K Replacement Magnet
CI-4254*	Electrode Claw Tool
CI-4252	Electrode Claw Tool (for HiFocus 1j and HiFocus Helix)
CI-4330	Recess Gauge for HiRes 90K
CI-4340	Coil Gauge for HiRes 90K
CI-4347*	HiFocus Mid-Scala Cochleostomy Gauge
CI-4345	Helix Cochleostomy Sizing Gauge
CI-4420	BTE/ICS Template for HiRes 90K
CI-4425	HiRes 90K Mock Up
CI-4430	Recess Marking Template for HiRes 90K
CI-4500	HiRes 90K Surgical Tool Kit
CI-4508*	HiFocus Mid-Scala Electrode Instrument Kit
CI-4501	Helix Electrode Instrument Kit
CI-8160	HiRes 90K Surgeons Kit
CI-4507	HiFocus Mid-Scala Electrode Insertion Tool Backup Kit
MMT-6111	Electrode Insertion Tool
MMT-6135	Slotted Electrode Insertion Tube

* Not FDA Approved