INSTRUCTIONS FOR USE

HiResolution™ Bionic Ear System

This document is applicable to the United States.

For more information contact

Advanced Bionics AG
Laubisrütistrasse 28
8712 Stäfa, Switzerland
+41.58.928.78.00

Manufactured by:
Advanced Bionics, LLC
California, USA
+1.661.362.1400

www.advancedbionics.com

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 the HiRes™ Ultra receiver and either the HiFocus™ SlimJ electrode or the HiFocus™ Mid-Scala (MS) 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.

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 HL).
- 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 HL).
- 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 Bionics 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 Ultra 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 for the implant and securely stabilizing the device in place are critical elements of the surgical procedure.**
- **Electrosurgical instruments** must not be used. 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. 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.
- **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 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.
- **MRI Safety Information:**

Testing has demonstrated that the HiRes Ultra cochlear implant is MR Conditional. Unilateral and bilateral recipients with this device can be safely scanned in an MR system meeting the following conditions:

3.0T with the magnet removed
- The internal magnet must be removed. See the "*Surgeon Manual for the HiRes Ultra Cochlear Implant*" for removal instructions.
- The external sound processor and headpiece are MR Unsafe and must be removed before entering a room containing an MR scanner.
- Horizontal closed bore scanners with a static magnetic field of 3.0T
- Maximum spatial field gradient of 2,000 Gauss/cm (20 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg at 3.0T (Normal Operating Mode) for quadrature transmit RF body coils
- Maximum MR system reported, head averaged SAR of ≤ 2.6 W/kg at 3.0T (Normal Operating Mode) for quadrature transmit RF head coils
- RMS gradient field of 30 T/s and peak gradient field of 150 T/s

Under the scan conditions defined above the HiRes Ultra implant is expected to produce a maximum temperature rise of <3°C after 15 minutes of continuous 3.0T scanning.

In MRI testing of unilateral and bilateral recipient conditions, respectively, the image artifact caused by the device extends from the HiRes Ultra implant approximately 5 cm using a spin echo pulse sequence in a 3.0T scanner with the temporary non-magnetic plug in place. These artifacts may result in a loss of diagnostic information in the implant vicinity

The recommended minimum duration of time post implant surgery prior to undergoing an MRI scan is 2 to 4 weeks in order to allow any inflammation to subside.

An MRI scan is not recommended if the patient has a fever.

1.5T with the magnet removed
- The internal magnet must be removed. See the "*Surgeon Manual for the HiRes Ultra Cochlear Implant*" for removal instructions.
- The external sound processor and headpiece are MR Unsafe and must be removed before entering a room containing an MR scanner.
- Horizontal closed bore scanners with a static magnetic field of 1.5T.
- Maximum spatial field gradient of 2,000 Gauss/cm (20 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg at 1.5T (Normal Operating Mode) for quadrature transmit RF body coils.
- Maximum MR system reported, head averaged SAR of ≤ 3.2 W/kg at 1.5T (Normal Operating Mode) for quadrature transmit RF head coils
- RMS gradient field of 30 T/s and peak gradient field of 150 T/s.

Under the scan conditions defined above the HiRes Ultra implant is expected to produce a maximum temperature rise of <3°C after 15 minutes of continuous 1.5T scanning.

In MRI testing of unilateral and bilateral recipient conditions, respectively, the image artifact caused by the device extends from the HiRes Ultra implant approximately 3 cm and 4 cm using a gradient echo pulse sequence in a 1.5T scanner with the temporary non-magnetic plug in place. These artifacts may result in a loss of diagnostic information in the implant vicinity.

The recommended minimum duration of time post implant surgery prior to undergoing an MRI scan is 2 to 4 weeks in order to allow any inflammation to subside.

An MRI scan is not recommended if the patient has a fever.

1.5T with the magnet in place
- The external sound processor and headpiece are MR Unsafe and must be removed before entering a room containing an MR scanner.
- A bandage must be applied using the bandaging protocol below.
- Horizontal closed bore scanners with a static magnetic field of 1.5T.
- Maximum spatial field gradient of 2,000 Gauss/cm (20 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg at 1.5T (Normal Operating Mode) for quadrature transmit RF body coils.
- Maximum MR system reported, head averaged SAR of ≤ 3.2 W/kg at 1.5T (Normal Operating Mode) for quadrature transmit RF head coils.
- RMS gradient field of 30 T/s and peak gradient field of 150 T/s.

Under the scan conditions defined above the HiRes Ultra implant is expected to produce a maximum temperature rise of <3°C after 15 minutes of continuous 1.5T scanning

In MRI testing of unilateral and bilateral recipient conditions, respectively, the image artifact caused by the device extends from the HiRes Ultra implant approximately 8 cm using a gradient echo pulse sequence and >9.5 cm using a spin echo or gradient echo pulse sequence in a 1.5T scanner with the magnet in place. These artifacts may result in a loss of diagnostic information in the implant vicinity.

The recommended minimum duration of time post implant surgery prior to undergoing an MRI scan is 2 to 4 weeks in order to allow any inflammation to subside.

An MRI scan is not recommended if the patient has a fever

Please note that the MRI Antenna Coil Cover, CI-7521, and bandaging supplies must be on hand at the time of the MRI procedure. Please contact Advanced Bionics at customerservice@advancedbionics.com or 1-877-829-0026 prior to the MRI procedure to request these supplies.

Caution: The bandaging protocol with use of the MRI Antenna Coil Cover was developed and approved to prevent magnet displacement and counteract magnet torque during a 1.5T MRI procedure, but some discomfort and pain at the implant site may still be experienced. Please consult with your physician if this is an issue.

Caution: If discomfort persists following an MRI, please notify your physician.

Caution: Failure to secure the MRI Antenna Coil Cover and internal magnet in place during MRI may result in magnet displacement or the need for surgical revision.

Caution: Please consult with your physician prior to MRI to determine if the benefits of MRI are worthwhile over other imaging techniques.

Bandaging Protocol for 1.5T MRI with the magnet in place.
Before entering the area of an MRI scanner:

1. Place patient in sitting position to allow access to the implant site.

Secure MRI Antenna Coil Cover over implant magnet site:

2. Place the patient headpiece (with cable removed) over the implant site. The magnets will hold the headpiece in place.
3. Cut a piece of the Coach bandage that is long enough to wrap around the head once.
4. Wrap this piece around the head, so that the bandage covers the patient headpiece. Make this wrap tight.
5. Outline the position of the headpiece on the bandage using a marker or pen.
6. Slip out the patient headpiece, but keep the bandage in place.
7. Slide the MRI Antenna Coil Cover under the bandage, lining it up with the marked outline of the headpiece.

Measure head size and bandage length needed for compression wrapping:

8. Take the remaining Coach bandage roll and wrap the bandage around the head once, without stretching.
9. Mark the location on the bandage that is one full wrap around the head. This is the head circumference.
10. Unwrap the piece of bandage with the marked head circumference, and place it on a flat surface.
11. Unroll the remaining bandage roll.
12. Fold over the bandage start and crease at the marked head circumference.
13. Cut or tear the remaining bandage where it overlaps with the bandage start. The resulting bandage piece length is twice the head circumference.

Apply compression bandaging:

14. Wrap this cut piece, this time very tightly, by stretching the marked line an additional half turn around the head. This ensures 150% extension of the bandage.
15. Continue wrapping the bandage at 150% extension for an additional 1.5 turns, resulting in 3 full turns total.

For additional information regarding the use of an MRI scanner with a HiRes Ultra device, please contact Advanced Bionics Technical Support at technicalservices@advancedbionics.com, 1-877-454-5051, or visit www.advancedbionics.com/mri.

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.
- **Electromagnetic Interference:** RF workers may be exposed to higher interference. In the presence of high intensity EMI you may experience loss of sound. If this occurs, move from the area or temporarily discontinue use of the system by removing the headpiece.
- **Electromagnetic Sources:** It is advised to maintain a minimum distance of 30 cm (12 in) from electromagnetic emitters such as RFID, and metal detectors. It is advised to maintain a minimum distance of 50 cm (20 in) from an electronic article surveillance emitter.
- **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.

ADDITIONAL INFORMATION:

Electromagnetic Interference:

The HiRes Ultra implant employs an intermittently keyed back telemetry transmitter that uses a frequency modulated 10.7 MHz signal. This is a near field inductively coupled technology.

WIRELESS COMMUNICATION BETWEEN PROCESSOR AND IMPLANT:

The external headpiece coil and implant are an induction coupled device, and as such require proximity less than approximately 12 mm to provide power and signal to the implant. Power is transferred at 49 MHz and rectified by the implant, and telemetry is encoded at a data rate of 1.11 megabits per second utilizing power signal coding either OOK (On / Off keyed) or ASK (Amplitude Shift Keying) with parity. Power requirements vary among patients due to coil spacing, alignment and other factors, ranging from ~1mW to ~40mW for 100% coverage (including all strategies). Note that this is the RF output power delivered to UHP (headpiece). The HiRes Ultra implant employs an intermittently keyed back telemetry transmitter that uses a frequency modulated 10.7MHz signal. This is a near field inductively coupled technology.

CLINICAL STUDIES:

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

Safety Results:

The HiRes Ultra implant is a repackaging of the commercially available HiRes 90K and HiRes 90K Advantage implantable electronics into new housing to reduce the size of the implanted components and to simplify the surgical procedure. A clinical study of the HiRes 90K was conducted with the HiFocus Electrode. Clinical data from 41 HiRes 90K patients (37 adults and 4 children) implanted with the HiFocus Electrode in Canada and Europe indicated no safety concerns with the new smaller implant. A subsequent clinical study was conducted with the HiRes 90K and the HiFocus Helix Electrode in adults only. The Helix is a modification of the HiFocus Electrode that is highly pre-curved for close modiolar placement. Clinical data from 22 adults implanted with Helix in Canada and Europe indicated no safety concerns with the Helix Electrode. The Helix was approved for children, 12 months through 17 years of age, without clinical data because Helix design is only a minor modification to the HiFocus Electrode, and because adult safety results could be generalized to the pediatric population given that the cochlea is adult-sized at birth. The following adverse events occurred.

HiRes 90K with HiFocus Electrode

Leakage of Cerebrospinal Fluid during Surgery: One adult patient with a cochlear anomaly experienced moderate leakage of cerebrospinal fluid. No further leakage occurred following routine packing of the cochleostomy.

Complications at the Implant or Magnet Site: Complications occurred at the implant incision site during the immediate postoperative period in three patients (two adults and one child). The symptoms resolved in two patients (one adult and the child) and are resolving in the third patient following antibiotic treatment. Two patients experienced complications at the magnet site that resolved in one of the patients. Device removal was ultimately required in the other patient because a pressure ulcer developed, resulting in protrusion and subsequent removal of the magnet. The patient will be reimplanted in the same ear following resolution of the ulcer.

Vestibular Effects: One elderly patient with a history of significant episodes of imbalance and numerous other medical problems reported severe vestibular symptoms postoperatively that have resolved.

Tinnitus: Two patients reported postoperative tinnitus. One patient, whose symptoms resolved, also experienced the symptoms preoperatively. The other patient had no history of preoperative tinnitus and has not yet been seen for the next follow-up evaluation.

No device failures or major device malfunctions occurred in this study group.

HiRes 90K with HiFocus Helix Electrode

There were no significant surgical or medical complications in the 22 patients implanted with the HiRes 90K with Helix Electrode. Surgeon feedback via a questionnaire revealed no major surgical handling or placement concerns with the Helix. Eighteen patients with data at initial device fitting indicated that thresholds, most comfortable listening levels, and dynamic ranges were as expected. There were no major device malfunctions or failures.

In summary, the incidence of medical and surgical complications for the HiRes 90K with HiFocus Electrode, and for the HiRes 90K with HiFocus Helix Electrode, were comparable to that observed in the CII-HiRes IDE clinical trial.

Efficacy Results:

HiRes 90K with HiFocus Electrode: The HiRes 90K is a repackaging of the CII implant electronics and delivers the same stimulation strategies and programming parameters as the CII. Because the electronics of the HiRes 90K implant are essentially the same as those of the CII implant, patient outcomes with the HiRes 90K were expected to be similar to those obtained with the CII implant.

To verify that outcomes were similar between implant packages, clinical data were collected from 41 HiRes 90K patients (37 adults and 4 children) in Canada and Europe. The results demonstrated that HiRes 90K speech-perception benefit was similar to the benefit shown during the clinical trial of the CII with HiResolution Sound (HiRes™) processing, as well as to the benefit experienced by patients participating in an ongoing post-market surveillance study of the CII and HiRes sound processing.

A subset of adult patients with the HiRes 90K were matched to a subset of adult patients who participated in the CII HiRes IDE clinical trial on the basis of one-month word recognition abilities (CNC scores). Speech-perception results for the HiRes 90K subset after one month (n = 23) and three months (n = 13) were similar to those of the matched patients in the CII HiRes IDE (n = 23). The distribution and range of benefit for the subset of HiRes 90K patients and the matched group of CII-HiRes IDE patients were indistinguishable across test measures and time. In addition, the distribution and range of benefit for the subset of HiRes 90K patients was similar to that of 20 consecutively implanted adults with follow-up results in the ongoing postmarket study of the CII and HiRes sound processing. Thus, these results indicate that the efficacy of the HiRes 90K and CII are comparable.

In summary, the clinical comparability of safety and efficacy between the HiRes 90K and the CII precluded the need for a separate clinical trial of the HiRes 90K device in the United States.

Mean speech-perception scores for low, medium, and high performers at one and three months postimplant for the HiRes 90K adults, the matched group of CII IDE adults, and adults in the ongoing HiRes postmarket study.

CNC Words One Month			
Performance Group	90K	CII IDE	PMS
Low (<20%)	5%	5%	2%
Moderate (20-40%)	26%	26%	27%
High (>40%)	53%	53%	42%
n	23	23	20

CNC Words Three Months			
Performance Group	90K	CII IDE	PMS
Low (<20%)	5%	10%	5%
Moderate (20-40%)	27%	28%	27%
High (>40%)	60%	49%	49%
n	13	13	13

Hint Sentences in Quiet: One Month			
Performance Group	90K	CII IDE	PMS
Low (<40%)	15%	11%	9%
Moderate (40-70%)	54%	52%	57%
High (>70%)	89%	89%	82%
n	23	23	20

Hint Sentences in Quiet: Three Months			
Performance Group	90K	CII IDE	PMS
Low (<40%)	10%	17%	18%
Moderate (40-70%)	56%	48%	55%
High (>70%)	92%	82%	84%
n	13	13	13

Hint Sentences in Noise (+10 dB SNR): One Month			
Performance Group	90K	CII IDE	PMS
Low (<40%)	9%	5%	11%
Moderate (40-70%)	46%	56%	61%
High (>70%)	95%	72%	86%
n	23	22	18

Hint Sentences in Noise (+10 dB SNR): Three Months			
Performance Group	90K	CII IDE	PMS
Low (<40%)	11%	13%	18%
Moderate (40-70%)	50%	43%	47%
High (>70%)	82%	76%	NA
n	13	12	11

HiRes 90K with HiFocus Helix Electrode

Speech-perception results from adults using the HiRes 90K and HiFocus Helix Electrode who have reached the one-month (n = 19) and three-month (n = 10) post-implant intervals were comparable to results from adults in the CII-HiRes IDE clinical trial.

Mean Speech-Perception Scores for Adults Using the HiRes 90K and HiFocus Helix Electrode

	CNC Words		HINT in Quiet		HINT in Noise	
Test Interval	1 Month	3 Months	1 Month	3 Months	1 Month	3 Months
Mean	42.0%	45.9%	69.5%	76.3%	34.0%	52.3%
St Dev	23.9%	20.9%	30.1%	23.8%	26.2%	26.9%
N	18	10	19	10	19	10

CLINICAL STUDIES: CII and CI Devices

Clinical trials have been conducted with two previous CLARION cochlear implant systems: the CLARION CII Bionic Ear ("CII") with HiResolution Sound Processing (HiRes) and the first-generation CLARION implant ("CI") and its corresponding sound-processing strategies. A clinical trial of the CII implant was conducted in adults with postlingual onset of severe-to-profound hearing loss. Clinical trial results for children, 12 months through 17 years of age, were obtained with the first-generation CI implant. A clinical trial of the CII with HiRes sound processing was not conducted in children.

During the clinical trials, the HiFocus Electrode was implanted with an ancillary component called the Positioner. With the CI implant, the Positioner was inserted behind the electrode array for the intended purpose of placing the electrode closer to the auditory nerves. A modified design was used with the CII Bionic Ear implant in which the Positioner was attached to the electrode to simplify the surgical procedures. Comparison of safety and efficacy data showed that electrode type (with Positioner inserted separately or attached to the electrode) had no significant effect on safety or efficacy results.

The CLARION CII Bionic Ear implant is no longer being distributed with the Positioner, and the Harmony HiResolution Bionic Ear System does not include a Positioner. Data obtained from HiFocus and HiRes clinical trial patients who did not receive the Positioner (20 adults and 37 children), and retrospective data from other patients implanted with HiFocus Electrode without the Positioner (from Advanced Bionics patient registry, 33 adults and 45 children) indicate that there are no unusual safety and efficacy concerns associated with absence of the Positioner. (Patients were intended to receive a Positioner but, in most cases, cochlear anomalies and conditions encountered at the time of surgery precluded its use.) Specifically, the incidence of medical/surgical or device related complications is similar to HiFocus clinical trial patients implanted with a Positioner. Moreover, efficacy results from No-Positioner patients are indistinguishable from HiFocus clinical trial patients implanted with a Positioner, thereby indicating that there is no systematic reduction in efficacy associated with absence of the Positioner. Similar to all clinical trial populations, patients implanted without the Positioner derived clinical benefit from their implants consistent with their demographics at the time of implantation. However, the independent effect of the Positioner has not been established. Postmarket study is currently underway.

Safety Results in Adults

Patients received the CII Bionic Ear implant, which was initially approved for commercial distribution when programmed to operate as the first-generation CI implant. A subsequent clinical trial was conducted to evaluate the software that enables HiResolution sound processing and signal delivery capabilities of the CII Bionic Ear implant.

Safety data are based on 80 adults implanted in North America with the CII Bionic Ear implant (HiFocus Electrode with attached Positioner) during the clinical trial. The following adverse events occurred in relation to the use of the device.

Medical/Surgical Complications

- Vestibular Effects: Five patients (5/80, 6.3%) reported vestibular symptoms (dizziness and or spinning sensation) after surgery. Two of the five patients also experienced those symptoms preoperatively. Symptoms are improving in one patient, while no further reports have been received for the second patient who experienced severe symptoms approximately six months post-implant. Three of the five patients had no symptoms preoperatively. Two patients had mild symptoms that have resolved, and the third patient had severe symptoms with current status unknown because the patient withdrew from the study.
- Tinnitus: Thirty-eight patients (38/80, 47.5%) experienced tinnitus preoperatively in the ear to be implanted. No postoperative tinnitus was reported by 35 of these patients (35/38, 92.1%). The status is unknown in the remaining patients because they withdrew from the study following surgery.
  Forty-two patients (42/80, 52.5%) reported no preoperative tinnitus in the implant ear. Three patients (3/42, 7.1%) reported tinnitus postoperatively. The symptoms were initially reported as severe in one of the patients but resolved. The symptoms also resolved in another patient and are reported as intermittent in the third patient.
- Facial Nerve Involvement: Two patients (2/80, 2.5%) demonstrated post operative facial nerve paralysis and were treated with steroids and antiviral medication. Symptoms are partially resolved in one patient with no further reports received on the second patient. One patient (1/80, 1.3%) experienced facial nerve stimulation that is controlled with device programming.
- Postoperative Complications at Surgical Site: Four patients (4/80, 5.0%) experienced inflammation at the surgical site that resolved with topical antibiotics. One of these patients also experienced an infection in the external auditory canal which is resolving following antibiotic treatment. Another patient (1/80, 1.3%) experienced redness and swelling at the surgical site following trauma that resolved without medical intervention. One patient (1/80, 1.3%) experienced superficial skin sloughing with unknown resolution because the patient withdrew from the study.
- Electrode Displacement: One patient (1/80, 1.3%), who had a partial insertion of the electrode array during the initial surgery because of extensive cochlear ossification, required revision surgery because the non-inserted portion of the array appeared to have migrated into the middle ear space. During revision surgery, it was noted that the part of the array originally inserted into the cochlea was still in place, and thus, the array was not repositioned or removed. Because the patient derived limited benefit from the original device, the contralateral ear was reimplanted. The patient only uses the second device.

Device-Related Complications

Two patients (2/80, 2.5%) experienced device failures that required device replacement. One patient withdrew from the study and the other patient derives comparable benefit from the replacement device.

HiResolution Sound Processing (HiRes), Stimulation Waveform, Number of Electrode Contacts, and Stimulation Rate.

HiResolution Sound Processing offered by the CII Bionic Ear implant is different from the sound-processing strategies implemented by the earlier-generation CI implant, which had 8 independent output circuits and 16 contacts on the electrode array. In contrast, the CII has 16 independent output circuits to deliver information to 16 contacts on the electrode array.

For HiRes sound processing in the clinical trial, all 16 independent output circuits and all 16 electrode contacts were used, thereby doubling the number of independent pathways for conveying frequency information to the auditory nerve. HiRes sound processing also delivered pulses at high stimulation rates on each contact. High stimulation rates are intended (1) to represent the fine timing information in the sound signal and (2) to induce a more natural pattern of responses in the hearing nerve, which may convey more information about sound to the brain.

During the clinical trial, the CII was initially programmed to operate like a CI device using conventional sound processing strategies (SAS, MPS, or CIS) and patients were evaluated after three months using these strategies. Patients then switched to HiRes sound processing and were evaluated after three months of HiRes use. When programmed with HiRes sound processing during the clinical trial, all patients used pulsatile stimulation with monopolar coupling of the 16 electrode contacts. The number of contacts used, the pulse width and grouping of contacts all determined the stimulation rate (pulses per second per contact) used by each patient.

Fifty-one of the 80 patients reached the six-month CII Bionic Ear clinical trial test interval (three-month HiRes interval). The number of stimulation contacts used and the rate of stimulation are summarized in the table below. Notably, 92% of the patients used 13 or more contacts, thereby giving them access to the greater independent spectral resolution provided by the 16 output circuits. Seventy-five percent of patients used stimulation rates exceeding 2900 pulses per second per contact. Such high stimulation rates are designed to induce a more natural response pattern in the hearing nerve than the lower rates used in earlier generation cochlear implants.

HiRes Stimulation Parameters for Adult Patients (n = 51)

Number of Stimulation Contacts	< 2900 pps per contact	2900-5000 pps per contact	> 5000 pps per contact	Total
6	2%		2%	4%
8			2%	2%
10		2%		2%
13	4%	4%		8%
14	2%	8%	4%	14%
15	2%	2%	2%	6%
16	15%	41%	8%	64%
Total	25%	57%	18%	

HiRes Efficacy Results in Adults

Efficacy results are based on data from 51 of the 80 patients who had reached the six-month test interval. Patients were initially fit with previous-generation (conventional) sound processing strategies and evaluated after three months of use, after which they were fit with HiRes sound processing and again evaluated after three months of use (approximately six months of device experience). Word recognition, easy sentence recognition, and difficult sentence recognition in quiet and noise (all without lipreading) were evaluated after six months of device use (three months of HiRes use).

The mean age at implant for the 51 postlingually deafened adults was 55 years. Mean duration of severe-to-profound hearing loss was 12 years.

Word Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of HiRes Use): Consonant-Nucleus-Consonant (CNC) Words

Mean	Median	Standard Deviation	Range	n
50%	48%	25%	0-94%	51

After six months of implant use (three months HiRes use):

- Almost half (25/51, 49%) recognized 50% or more of these difficult words.
- Over one-third (20/51, 39%) of the adults recognized 60% or more of the words.

Easy Sentence Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of HiRes Use): CID Everyday Sentence Test

Mean	Median	Standard Deviation	Range	n
84%	95%	26%	0-100%	51

After six months of implant use (three months HiRes use):

- Ninety percent of the adults (46/51) recognized 50% or more of the words.
- Three quarters of the adults (38/51, 75%) recognized 80% or more of the words.

Difficult Sentence Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of HiRes Use): Hearing in Noise Test (HINT)

Mean	Median	Standard Deviation	Range	n
80%	89%	25%	0-100%	51

After six months of implant use (three months HiRes use):

- Ninety percent of the adults (46/51) recognized 50% or more of the words.
- Two thirds of the adults (32/51, 63%) recognized 80% or more of the words.

Difficult Sentence Recognition with Background Noise, Hearing Only (no lip reading) After Six Months of CLARION Use (Three Months of HiRes Use): Hearing in Noise Test (+10 dB signal-to-noise ratio)

Mean	Median	Standard Deviation	Range	n
61%	65%	28%	0-100%	51

After six months of implant use (three months HiRes use):

- More than two thirds of the adults (35/51, 69%) recognized 50% or more of the words in this difficult listening situation.
- Almost one-third of the adults (16/51, 31%) recognized 80% or more of the words in this difficult listening situation.

Sound-Processing Preference

A preference questionnaire was completed by 50 of 51 patients after six months of implant use (three months of conventional sound processing and three months of HiRes use).

- 90% (45/50) of the patients preferred HiRes sound processing to conventional sound processing.
- Patients showed a stronger preference for HiRes sound processing than for conventional sound processing. On a scale of 1 (weak preference) to 10 (strong preference), the mean preference rating for the patients who preferred HiRes sound processing was 8.5 (range 4-10) compared with a mean rating of 5.3 for the patients who preferred conventional sound processing (range 1-8).
- Of the 45 patients who preferred HiRes sound processing:
  - 91% reported that the quality of speech was better
  - 84% reported that speech was easier to understand in a quiet situation while conversing with one person
  - 80% reported that they were better able to converse on the telephone
  - 78% reported that speech was easier to understand while conversing in a small group
  - 71% reported that speech sounded more natural
  - 60% reported music sounded better
  - 47% reported that speech was easier to understand in noise

At the 12-month follow-up visit, three of the five patients who initially preferred conventional sound processing stated a preference for HiRes. Thus, 96% (48/50) of the patients preferred HiRes sound processing to conventional sound processing.

Pre-Implant to Post-Implant Improvement after Six Months of CLARION Use

Word recognition, easy sentence recognition, and difficult sentence recognition in quiet and in noise (all without lipreading) were evaluated preoperatively with hearing aids and after six months of CLARION use (3 months of HiRes use). A positive difference between post-implant and pre-implant scores was considered a clinically significant improvement if the difference equaled or exceeded 20%. Similarly, a decrease between pre- and post-implant scores that equaled or exceeded 20% was considered a clinically significant decrement. A difference between the pre- and post-implant scores less than 20% was considered no change in performance.

	Significant Improvement (%, n)	No Change	Significant Decrease (%, n)	Could Not Calculate(n)*
CNC Words	85% (40/47)	15% (7/47)	0% (0/47)	4
CID Sentences	90% (43/48)	8% (4/48)	2% (1/48)	3
HINT Sentences in Quiet	94% (48/51)	6% (3/51)	0% (0/51)	0
HINT Sentences in Noise	84% (36/43)	16% (7/43)	0% (0/43)	8

* Either pre- or postoperative score not available.

All but two patients showed clinically significant improvement on one or more of the speech measures. One of the two patients showed a significant decrement on CID sentences, with non-significant improvement on the other three tests. The decrease in CID sentence recognition ability does not reflect a decrement in performance of the implanted ear, but the absence of the contribution of the non-implanted ear, which likely augmented preoperative performance. The other patient is elderly, has a long duration of deafness, and has only a partial insertion of the electrode because of cochlear ossification.

Improvement from Conventional Sound Processing to HiResolution Sound Processing

Word recognition, easy sentence recognition, and difficult sentence recognition in quiet and in noise (all without lipreading) were evaluated after using conventional sound processing strategies for three months and after using HiRes sound processing for three months. The mean improvement in performance from conventional sound processing to HiRes sound processing was statistically significant on all measures, although the study design does not allow determination of whether HiRes sound processing was solely responsible for the improvement.

CLINICAL STUDIES: HiRes Fidelity 120™ (for S and P)

The flexibility of the HiResolution Bionic Ear System's electronics platform (CII and HiRes 90K implants) allows for the continued evolution of sound processing, giving patients access to new features through software upgrades. An optional feature, HiRes Fidelity 120, implements active current steering. In theory, active current steering may deliver added spectral information between adjacent pairs of electrodes through accurately weighted simultaneous stimulation of each electrode in the pair during each processing cycle.

HiRes Fidelity 120 has the potential to choose from 120 unique spectral bands for stimulation, if all 16 electrodes are enabled. A spectral band is derived by filtering the input acoustic signal and assigned to a discrete address or location along the electrode array for stimulation. Each electrode in the pair defines a frequency boundary for the assigned spectral bands. A spectral band for each electrode pair is chosen from eight available spectral bands during each processing cycle. Therefore, for each stimulation cycle across the entire electrode array, a maximum of 15 spectral bands may be selected for stimulation from a total of 120 spectral bands (8 spectral bands x 15 output channels = 120 spectral bands). Each electrode or electrode pair can be stimulated simultaneously or sequentially. All enabled electrodes are stimulated in every processing cycle thereby delivering the captured spectrum in each cycle through the electrode array.

Programming HiRes with HiRes Fidelity 120

(Not Programmable with the HiRes Auria™ Processor)

In the United States of America (USA), only adults (with postlingual onset of severe or profound hearing loss) with at least 3 months experience with HiRes and who have the cognitive ability to choose the sound processing options can be provided with the HiRes Fidelity 120. All the other patients are to be fit with HiRes (HiRes-S or HiRes-P) programs only.

A clinical study of HiRes Fidelity 120 was conducted in two phases. In Phase I, 37 adults who had been implanted with CII or HiRes 90K implants were tested with original HiRes and then again after using HiRes Fidelity 120 for one month. Two subjects had bilateral implants and were evaluated separately in each ear. Average duration of implant use was 3.0 years at the time of the study. In Phase II, 26 adults who had been implanted with CII or HiRes 90K implants were tested with original HiRes and then again after using HiRes Fidelity 120 for three months. Average duration of implant use in the second group was 2.6 years at the time of the study.

Safety Results

Because the clinical study was conducted with adults who had been implanted previously, no medical/surgical complications were reported. One Phase II subject experienced dizziness that was unrelated to the device. Two other Phase II subjects reported unpleasant sound sensations after being fit with HiRes Fidelity 120 that were resolved through reprogramming.

Efficacy Results

Phase I

In Phase I, HiRes Fidelity 120 benefit was assessed using speech recognition measures and sound/music quality ratings. Subjects were tested at baseline with original HiRes and one month after using HiRes Fidelity 120. (AzBio sentence recognition in quiet was tested at two levels, 55 and 65 dB SPL. AzBio sentence recognition in noise was tested with two noise types, speech-spectrum noise and multi-talker babble.)

Summary of Phase I Speech Perception Results for HiRes (Baseline) versus with HiRes Fidelity 120 (One Month).

	CNC Words		AzBio in Quiet (55 dB SPL)		AzBio in Quiet (65 dB SPL)	
Test Interval	HiRes (Baseline)	HiRes Fidelity 120 (1 Month)	HiRes (Baseline)	HiRes Fidelity 120 (1 Month)	HiRes (Baseline)	HiRes Fidelity 120 (1 Month)
Mean	59.8%	69.7%	74.3%	77.4%	77.7%	82.2%
St Dev	20.9%	19.9%	23.0%	20.6%	22.2%	18.8%
Range	8-92%	22-96%	14-99%	9-100%	17-99%	14-100%
n*	34	35	32	34	35	35

	AzBio in Noise (Speech Spectrum)		AzBio in Noise (Multi-Talker Babble)	
Test Interval	HiRes (Baseline)	HiRes Fidelity 120 (1 Month)	HiRes (Baseline)	HiRes Fidelity 120 (1 Month)
Mean	64.1%	67.2%	58.4%	57.5%
St Dev	24.5%	24.0%	19.7%	24.9%
Range	5-96%	9-97%	18-88%	1-97%
n*	29	31	34	34

*All subjects did not provide data at all intervals. The maximum number of data points at any one interval could be 36 (32 subjects with unilateral implants and 2 subjects with bilateral implants).

Number of Phase I Subjects showing Clinically Significant Improvement or Decrement in Speech Perception Scores between Baseline with HiRes and One Month with HiRes Fidelity 120.

Speech Recognition Measure	Significant Improvement (≥20%)	Significant Decrease (≥ 20%)	No Change
CNC words	7/33 (21%)	0/33 (0%)	26/33 (79%)
AzBio in Quiet (55 dB SPL)	4/32 (13%)	2/32 (6%)	26/32 (81%)
AzBio in Quiet (65 dB SPL)	5/35 (14%)	1/35 (3%)	29/35 (83%)
AzBio in Noise (Speech Spectrum)	3/29 (10%)	3/29 (10%)	23/29 (79%)
AzBio in Noise (Multi-Talker Babble)	3/34 (9%)	3/34 (9%)	28/34 (82%)

Twenty subjects reported a preference for either HiRes processing or HiRes with Fidelity 120 at the one-month evaluation. Of the 20 respondents, 15 (75%) preferred HiRes Fidelity 120, whereas five (25%) preferred original HiRes.

Phase II
In Phase II, HiRes Fidelity 120 benefit was assessed using speech recognition measures, sound/music quality ratings, and questionnaires. Subjects were tested at baseline with original HiRes and at three months after using HiRes Fidelity 120. Speech results showed equivalent performance on word recognition (CNC word test) and sentence recognition in noise. (Sentence recognition in noise was tested two ways. First, HINT sentences were presented at 60 dB SPL using a fixed signal-to-noise ratio of +8 dB. These results are presented as percent correct. Second, the noise level was fixed and the HINT sentence level was varied until the subject achieved a 50% correct score. These results are presented as the SNR in dB. A lower SNR indicates better performance.)

Summary of Phase II Speech Perception Results for HiRes (Baseline) versus HiRes Fidelity 120 (3 Months).

	CNC Words		HINT in Quiet	
Test Interval	HiRes (Baseline)	HiRes 120 (3 Months)	HiRes (Baseline)	HiRes 120 (3 Months)
Mean	56.8%	58.7%	83.8%	89.4%
St Dev	25.0%	22.5%	20.2%	13.6%
Range	10-92%	20-96%	36-100%	62-100%
N	26	26	26	26

	HINT in Fixed Noise (+8 dB SNR)		HINT Adaptive	
Test Interval	HiRes (Baseline)	HiRes 120 (3 Months)	HiRes (Baseline)	HiRes 120 (3 Months)
Mean	57.6%	62.2%	6.8 dB	6.3 dB
St Dev	32.3%	32.1%	4.4 dB	5.3 dB
Range	7-100%	4-99%	2.2-18.2 dB	0-19.4 dB
N	26	25*	18^	18^

*One subject had no three-month data.
^The HINT adaptive test was not administered to all subjects at all visits either because the subject did not achieve criterion performance on the HINT in quiet or because the clinician failed to administer the test.

Number of Subjects showing Clinically Significant Improvement or Decrement in Speech Perception Scores between Baseline with HiRes and 3 Months with HiRes Fidelity 120.

Speech Recognition Measure	Significant Improvement (≥ 20%)	Significant Decrease (≥ 20%)	No Change
CNC words	1/26 (4%)	1/26 (4%)	24/26 (92%)
HINT in Quiet	4/26 (15%)	1/26 (4%)	21/26 (81%)
HINT in Fixed Noise*	5/25 (20%)	1/25 (4%)	19/25 (76%)

*One subject had no three-month data.

Preference ratings indicated that 20 out of 26 subjects (77%) preferred HiRes Fidelity 120 over HiRes. The mean strength of preference for the 20 subjects who preferred HiRes Fidelity 120 was 8.3 (1 = weak preference, 10 = strong preference). The strength of preference was rated as 8 or higher by 14 of the 20 subjects and 11 of them rated it as 10 (strong preference).

In summary, the objective speech perception data showed that the majority of subjects in both studies had equivalent performance to the standard HiRes strategy, with a smaller proportion demonstrating a clinically significant improvement with HiRes Fidelity 120 and an even smaller proportion demonstrating a clinically significant decrease in performance. Moreover, both performance improvement and decrement was subject, stimuli and noise background specific. Nevertheless, the potential benefit of HiRes Fidelity 120 over standard HiRes, regardless of speech outcomes, was evidenced by the overall preference for HiRes Fidelity 120 in both studies, and, also by the strength of preference reported by subjects in the Phase II study (Phase I: preference @ 1-Month = 75%; Phase II: preference @ 1-Month = 88%, strength rating = 7.8; Phase II preference @ 3-Month = 77%, strength rating = 8.3). Importantly, these ratings indicated that the majority of subjects preferred using HiRes Fidelity 120 for listening to music and environmental sounds, as well as speech. Overall results indicated that HiRes Fidelity 120 is a viable, optional programming feature for some CII and HiRes 90K adults in a variety of listening environments.

CLINICAL STUDIES: ClearVoice
ClearVoice is a new feature designed to improve listening in challenging everyday listening environments for users of HiRes Fidelity 120 sound processing. ClearVoice adapts automatically to enhance speech understanding in certain noisy environments, such as where there is fan noise or road noise while riding in a car. ClearVoice also may be effective in a cafeteria or restaurant so that a nearby talker may be understood better. In quiet environments, ClearVoice is designed to have no impact on speech understanding.

A clinical study was conducted in 46 adults who had at least six months experience with HiRes Fidelity 120 sound processing and at least moderate speech perception abilities to investigate the safety and efficacy 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. These two gain settings were evaluated chronically to allow subjects the opportunity to use ClearVoice in a variety of everyday situations. Subjects used each gain setting alone for two weeks, then were fit with three programs [HiRes Fidelity 120 without ClearVoice (Control), ClearVoice Medium, ClearVoice High] for one week, after which they completed a questionnaire. ClearVoice Low was evaluated acutely by all subjects during an initial test session. Scores on the AzBio sentence test were compared between ClearVoice and the Control in quiet, in speech-spectrum noise, and in multi-talker babble at each test session. For testing with each type of noise, the signal-to-noise ratio (SNR) was adjusted individually for each subject while using the Control to yield a score approximately half of the score in quiet in order to provide headroom to evaluate any advantage provided by ClearVoice.

Safety Results
The primary safety objective was to demonstrate that speech understanding with ClearVoice Medium or ClearVoice High was no worse than the Control in quiet. Results showed that speech understanding was no worse than the Control when listening in quiet for both ClearVoice Medium and ClearVoice High ($p < .0001$). The secondary safety objective was to demonstrate that speech understanding with ClearVoice Low was no worse than the Control in both quiet and noise. Results showed that speech understanding with ClearVoice Low was no worse than the Control in quiet, in speech-spectrum noise, and in multi-talker babble ($p < .001$). No device-related adverse events occurred during the study.

Efficacy Results
The primary efficacy objective was to demonstrate that ClearVoice improved speech perception in steady-state noise, which is representative of the type of noise from a fan or when in a car. For ClearVoice Medium and ClearVoice High, results showed that speech understanding in speech-spectrum noise was significantly better with ClearVoice compared to the Control ($p < .0001$). The secondary efficacy objective was to demonstrate that ClearVoice was no worse (or better) than the Control for understanding speech in multi-talker babble, which is representative of listening in environments like restaurants. Results indicated that ClearVoice Medium significantly improved speech understanding in multi-talker babble ($p < .02$). Gender analyses revealed a difference in benefit for ClearVoice Medium in multi-talker babble ($p = .0589$) with women experiencing greater benefit ($p = .0007$) than men ($p = .55$) when analyzed separately. ClearVoice High provided speech understanding in multi-talker babble that was no worse than with the Control ($p < .0001$).

Summary of Sentence Perception Results for ClearVoice and Control in Quiet, Speech-Spectrum Noise (SSN), and Multi-Talker Babble (MTB).

	Control	Clear-Voice Low (Safety)	Control	Clear-Voice Medium	Control	Clear-Voice High
Quiet (Safety)						
Mean (%)	87.3	87.8	88.6	88.3	86.8	87.7
Stand Dev (%)	8.1	9.5	9.4	9.8	11.6	10.7
Range (%)	65.5 - 99.5	61.0 - 99.5	61.0 - 99.5	51.5 - 100.0	47.5 - 99.0	46.5 - 99.5
n	46	46	46	46	46	46
SSN (Efficacy)						
Mean (%)	48.0	55.6	49.5	48.2	47.7	58.3
Stand Dev (%)	10.9	10.8	13.0	14.0	15.0	14.5
Range (%)	31.5 - 81.0	35.5 - 85.0	25.5 - 88.5	24.0 - 96.5	2.0 - 80.0	18.5 - 88.0
n	46	46	46	46	46	46
MTB (Efficacy)						
Mean (%)	42.8	47.2	44.9	48.1	44.9	46.2
Stand Dev (%)	8.2	10.4	12.9	13.1	14.7	14.1
Range (%)	30.5 - 64.5	27.5 - 71.0	14.5 - 78.5	13.0 - 70.5	5.5 - 77.0	4.5 - 70.5
n	46	46	46	46	46	46

As with all sound processing strategies, individual subjects experienced different degrees of benefit from each ClearVoice setting. However, the proportion of subjects showing improved sentence scores with ClearVoice when listening in speech-spectrum noise (exceeding the critical difference score of 8.9%) was significantly greater than the proportion of subjects experiencing a decrement in scores for both ClearVoice Medium and ClearVoice High ($p < .0001$).

Number of Subjects Showing a Significant Improvement or Decrement (≥ 8.9%) in Sentence Perception Scores between ClearVoice and Control.

ClearVoice Setting	Significant Improvement (≥ 8.9%)	Significant Decrement (≥ 8.9%)	No Change
Medium			
Speech-Spectrum Noise Multi-Talker Babble	23/46 (50.0%) 12/46 (26.1%)	1/46 (2.2%) 4/46 (8.7%)	22/46 (47.8%) 30/46 (65.2%)
High			
Speech-Spectrum Noise Multi-Talker Babble	29/46 (63.0%) 9/46 (19.6%)	1/46 (2.2%) 4/46 (8.7%)	16/46 (34.8%) 33/46 (71.7%)

Subjective questionnaire data supported the speech perception results. Preference ratings indicated that 42 out of 45* subjects (93%) preferred ClearVoice to the Control for everyday listening. 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.

All 46 subjects reported that ClearVoice was helpful for listening in a car and approximately three-quarters of them reported that ClearVoice was helpful while conversing at a party or restaurant (35/46), conversing in a group of people (33/46), or while watching TV or listening to talk radio (33/46). Ninety-one percent (42/46 or 41/45) of the subjects indicated to some degree that ClearVoice makes listening in challenging situations easier, less tiring, and less stressful.

Three subjects commented on specific individual situations where it had been difficult to hear with ClearVoice. Nonetheless, 2 of them preferred ClearVoice to the Control and indicated they would use ClearVoice some or most of the time. The other subject preferred the Control but indicated that ClearVoice would be used some of the time.

In summary, the clinical data demonstrated that that ClearVoice is effective for enhancing speech understanding in certain noisy environments without compromising speech understanding in quiet. The preference data indicated that a large majority of subjects (93%) preferred ClearVoice to the Control in everyday environments, and all subjects (100%) indicated they would use ClearVoice for some percentage of time every day. Therefore, ClearVoice is an effective optional programming feature for everyday listening for users of HiRes Fidelity 120 sound processing.

* One subject did not use the Control during the last week of the study. Therefore, strategy preference and strength of preference are not included for this subject.

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.

CLINICAL STUDY: HiRes™ Optima Sound Processing
HiRes Optima is a sound processing strategy designed to provide the same benefits as HiRes Fidelity 120 while improving battery life in users of the HiResolution Bionic Ear System (HiResolution system). To verify the non-inferiority of HiRes Optima to HiRes Fidelity 120, a clinical study was conducted in 36 adults who were unilateral or bilateral users of a CII/HiRes 90K device (minimum of one year of use in each ear implanted) and who demonstrated at least moderate speech perception abilities. Subjects used either HiRes Optima or HiRes Fidelity 120 for one week, after which they used the opposite strategy for one week (randomized crossover design). Subjects completed an acceptability questionnaire after using HiRes Optima. Battery life was tracked throughout the study.

Efficacy Results
The efficacy objectives were to demonstrate that speech understanding with HiRes Optima was no worse than with HiRes Fidelity 120 in quiet, in speech spectrum noise, and in multi-talker babble. Non-inferiority statistical analyses demonstrated that sentence recognition with HiRes Optima was not inferior to HiRes Fidelity 120 in all three listening conditions ($p < .0001$).

Summary of Sentence Perception Results for HiRes Optima and HiRes Fidelity 120 in Quiet, Speech-Spectrum Noise (SSN), and Multi-Talker Babble (MTB)

	HiRes Optima	HiRes Fidelity 120
Quiet		
Mean (%)	88.5	88.3
Standard Deviation (%)	12.43	11.15
Range (%)	55-99	46.5-100
n	36	36
SSN		
Mean (%)	64	61.2
Standard Deviation (%)	18.11	18.98
Range (%)	29-93.5	17-89
n	36	36
MTB		
Mean (%)	70	67.8
Standard Deviation (%)	16.53	17.13
Range (%)	37-96.5	26-92.5
n	36	36
Standard Deviation (%)	18.11	18.98
Range (%)	29-93.5	17-89
n	36	36

High correlations between HiRes Optima and HiRes Fidelity 120 sentence scores in quiet and in noise indicate that individual subjects attained similar scores with both strategies. As with all sound processing strategies, individuals experienced different degrees of benefit from HiRes Optima and HiRes Fidelity 120. For all three test conditions, the proportion of subjects showing improved scores with HiRes Optima was not significantly different from the proportion of subjects showing decreased scores with HiRes Optima, further demonstrating that HiRes Optima provides benefit that is comparable to HiRes Fidelity 120.

Pearson Product-Moment Correlations between HiRes Optima and HiRes Fidelity 120 Sentence Perception Scores in Quiet, Speech-Spectrum Noise (SSN), and Multi-Talker Babble (MTB)

	Quiet	SSN	MTB
r	.87	.90	.92

Number of Subjects Showing a Significant Improvement or Decrement (≥ 8.9%) in Sentence Perception Scores between HiRes Optima and HiRes Fidelity 120

	Improvement with HiRes Optima (≥ 8.9%)	Decrement with HiRes Optima (≥ 8.9%)	No Change
Quiet	0/36 (0%)	3/36 (8.3%)	33/36 (91.7%)
SSN	10/36 (27.8%)	3/36 (8.3%)	23/36 (63.9%)
MTB	6/36 (16.7%)	2/36 (5.6%)	28/36 (77.8%)

Questionnaire Results
All participants (100%) reported that HiRes Optima was an acceptable sound-processing strategy for everyday use. Twenty-six subjects (72%) indicated they would use HiRes Optima all of the time, while 10 subjects (28%) indicated they would use HiRes Optima most or some of the time.

Battery Life
Average battery life improvement was 53%, ranging from 25% to 109% for individual Harmony processors.
In summary, the clinical data demonstrated that HiRes Optima provides speech perception benefit that is no worse than HiRes Fidelity 120, while at the same time offering improved battery life. All subjects (100%) indicated that HiRes Optima is acceptable for everyday listening.

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

CLINCIAL STUDIES: Safety and Efficacy Data in Children
Pediatric safety and efficacy data are based on clinical trial results obtained with the first-generation CLARION implant (CI) and electrode technology and HiFocus Electrode with Positioner. Two consecutive clinical trials were conducted in the pediatric population with CLARION CI HiFocus I Electrode with Positioner: (a) children implanted between 18 months and 17 years of age, and (b) children implanted between 12 months and 17 months of age.

Pediatric safety and efficacy data are based on clinical trial results obtained with the previous-generation device and electrode technology√-CLARION CI with HiFocus I Electrode with Positioner–which was the predecessor to the CII HiFocus II Electrode. The HiFocus II Electrode is a design change in which the Electrode Positioner is attached to the HiFocus I Electrode, a modification made to streamline and simplify the surgical procedure. The HiFocus II Electrode was evaluated with the CLARION CI device only in postlingual adults, and a clinical trial was not conducted in the pediatric population. Two consecutive clinical trials were conducted in the pediatric population with CLARION CI HiFocus I Electrode with Positioner: (a) children implanted between 18 months and 17 years of age, and (b) children implanted between 12 months and 17 months of age.

Safety Results: Children Implanted Between 18 Months and 17 Years of Age
Safety results are based upon data from 150 children implanted in North America with the CLARION CI implant and HiFocus Electrode with Positioner. Among this group, the following adverse events occurred in relation to the use of the device.

Medical/Surgical Complications

- Vestibular Effects: Two patients (2/150, 1.3%) experienced postoperative vestibular symptoms. One patient experienced balance problems immediately following surgery. Another patient experienced minor positional vertigo. Symptoms resolved in both patients without medical intervention.
- Tinnitus: One patient (1/150, 0.7%) reported mild tinnitus in the implanted ear on several occasions following surgery. The tinnitus resolved without medical intervention.
- Facial Nerve Involvement: One patient (1/150, 0.7%) experienced facial nerve weakness and ear pain 6 days after surgery which resolved following medical treatment.
- Postoperative Complications at Surgical Site: Three patients (3/150, 2.0%) experienced a complication at the surgical site. Two patients experienced infection which resolved in one patient following medical treatment. The infection in the other patient did not respond to medical treatment and required surgery to replace the device. The patient was reimplanted without incident. Another patient experienced a hematoma at the surgical site following head trauma. The hematoma resolved following treatment and the device continues to function normally.
- Electrode Displacement: One patient (1/150, 0.7%) experienced electrode displacement due to excessive intracochlear bone growth (ossification) and required reimplantation. The device was explanted and the patient was reimplanted without incident.

Device-Related Complications

- One patient (1/150, 0.7%) experienced a device failure as a result of electrode breakage and required surgery to replace the device. The patient was reimplanted without incident.

Efficacy Results: Children Implanted Between 18 Months and 17 Years of Age
Efficacy results are based on 52 of the 150 children with six-month follow-up data. Children were implanted with the CLARION CI implant with HiFocus Electrode with Positioner.

Because of developmental differences in cognitive and linguistic skills, children were classified into two groups by age at time of implant: (1) children between 18 months and 3 years 11 months of age (n = 25), and (2) children 4 years of age and older (n = 27). For both age groups, parental ratings of the child's response to sound in everyday listening situations [Meaningful Auditory Integration Scale (MAIS) or Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)] were made pre-implant with hearing aids and at six months post-implant. For the older group, closed-set and open-set word recognition also were evaluated pre-implant with hearing aids and at six months post-implant using monitored live voice (70 dB SPL). Effectiveness was assessed by comparing post-implant scores after six months of device use to pre-implant scores on each test.

A positive difference between post-implant and pre-implant scores was considered a clinically significant improvement if the difference equaled or exceeded 20%. Similarly, a decrease between pre-implant and post-implant scores that equaled or exceeded 20% was considered a clinically significant decrement. A difference between the pre-and post-implant scores less than 20% was considered a non-significant change in performance because of the long-time course over which auditory skills emerge in children.

Children 18 Months to 3 Years 11 Months of Age

Response to Sound in Everyday Situations After Only Six Months of Device Use

Test: Meaningful Auditory Integration Scale (MAIS) or Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)

During a structured interview, parents rated the frequency of occurrence of 10 auditory behaviors using the scale: 0 (never), 1 (rarely), 2 (occasionally), 3 (frequently), 4 (always). Composite scores (sum of 10 items divided by the total number of possible points) were calculated.

Mean	59%	Significant Improvement(%, n)	82% (18/22)
Median	66%	Non-Significant Improvement(%, n)	14% (3/22)
S.D.	30%	No Change(%, n)	0% (0/22)
Range	0-98%	Non-Significant Decrement(%, n)	5% (1/22)
n	22*	Significant Decrement(%, n)	0% (0/22)

* Three children did not have six-month scores.

- Approximately one-third (7/22, 32%) of the children attained a composite score of 80% or higher after six months of device use.
- Results also were analyzed for the percentage of children who "frequently" or "always" demonstrated a specific auditory behavior.
- Preoperatively with hearing aids only, 4% (1/25) of the children frequently or always responded to their name in quiet. Postoperatively with the implant, 73% (16/22) of the children frequently or always responded to their name in quiet.
- Preoperatively with hearing aids only, 4% (1/25) of the children frequently or always responded to environmental sounds. Postoperatively with the implant, 68% (15/22) of the children frequently or always responded to environmental sounds.
- Preoperatively with hearing aids only, 8% (2/25) of the children frequently or always differentiated between speech and non-speech sounds. Postoperatively with the implant, 68% (15/22) of the children frequently or always differentiated between speech and non-speech sounds.

Children 4 Years of Age and Older

Pre-Implant to Post-Implant Improvement in Individual Patients

All children 4 years of age and older showed clinically significant improvement on one or more of the efficacy measures.

Response to Sound in Everyday Situations After Only Six Months of Device Use

Test: Meaningful Auditory Integration Scale (MAIS)

During a structured interview, parents rated the frequency of occurrence of 10 auditory behaviors using the scale: 0 (never), 1 (rarely), 2 (occasionally), 3 (frequently), 4 (always). Composite scores (sum of all 10 items divided by total number of possible points) were calculated.

Mean	71%	Significant Improvement (%, n)	76% (19/25)**
Median	71%	Non-Significant Improvement(%, n)	16% (4/25)**
S.D.	19%	No Change (%, n)	4% (1/25)**
Range	38-100%	Non-Significant Decrement (%, n)	4% (1/25)**
n	26*	Significant Decrement (%, n)	0% (0/25)**

* One child did not have a six-month score.
** Two children did not have preoperative or six-month scores.

- More than one-third (10/26, 38%) of the children attained a composite score of 80% or higher.

Results also were analyzed for the percentage of children who "frequently" or "always" demonstrated a specific auditory behavior.

- Preoperatively with hearing aids only, 23% (6/26) of the children frequently or always responded to their name in quiet. Postoperatively with the implant, 88% (23/26) of the children frequently or always responded to their name in quiet.

- Preoperatively with hearing aids only, 23% (6/26) of the children frequently or always responded to environmental sounds. Postoperatively with the implant, 85% (22/26) of the children frequently or always responded to environmental sounds.
- Preoperatively with hearing aids only, 31% (8/26) of the children frequently or always differentiated between speech and non-speech sounds. Postoperatively with the implant, 81% (21/26) of the children frequently or always differentiated between speech and non-speech sounds.

Closed-Set Word Recognition in Quiet, Hearing Only (no lipreading) After Only Six Months of Device Use

Test: Early Speech Perception (ESP) Test (Monosyllable Word Identification Subtest)

Mean	60%	Significant Improvement(%, n)	50% (13/26)
Median	71%	Non-Significant Improvement(%, n)	4% (1/26)
S.D.	37%	No Change(%, n)	19% (5/26)
Range	8-100%	Non-Significant Decrement(%, n)	19% (5/26)
n	26*	Significant Decrement(%, n)	8% (2/26)

* One child did not have a six-month score.

- Approximately one-third (9/26, 35%) of the children recognized 90% or more of the closed-set words.

Open-Set Phoneme Recognition in Quiet, Hearing Only (no lipreading) After Only Six Months of Device Use

Test: Phonetically Balanced-Kindergarten Word Test (scored for phonemes correct)

Mean	37%	Significant Improvement(%, n)	49% (11/23)**
Median	33%	Non-Significant Improvement(%, n)	26% (6/23)**
S.D.	31%	No Change(%, n)	26% (6/23)**
Range	0-90%	Non-Significant Decrement(%, n)	0% (0/23)**
n	24*	Significant Decrement(%, n)	0% (0/23)**

* Three children did not have six-month scores.
** Four children did not have either preoperative or six-month scores.

- One-third (8/24, 33%) of the children recognized 60% or more of the phonemes in words after six months of device use.

Open-Set Word Recognition in Quiet, Hearing Only (no lipreading) After Only Six Months of Device Use

Test: Phonetically Balanced-Kindergarten Word Test (scored for words correct)

Mean	23%	Significant Improvement(%, n)	28% (7/25)
Median	16%	Non-Significant Improvement(%, n)	40% (10/25)
S.D.	26%	No Change(%, n)	32% (8/25)
Range	0-100%	Non-Significant Decrement(%, n)	0% (0/25)
n	25*	Significant Decrement(%, n)	0% (0/25)

* Two children did not have six-month scores.

- Slightly more than one-fourth (7/25, 28%) of the children recognized 48% or more of these difficult words.

Stimulation Strategy and Pulse Rate

Several sound-processing strategies are implemented with the CLARION CI implant and HiFocus Electrode. There are 8 independent output circuits and 16 electrode contacts in the cochlea. In the Simultaneous Analog Strategy (SAS), the 16 electrode contacts are bipolar coupled and analog waveforms are delivered to the resulting 8 channels simultaneously. In the Continuous Interleaved Sampler (CIS), monopolar coupling (even or odd) is used and pulsatile waveforms are sent to the resulting 8 sites sequentially. In the Multiple Pulsatile Sampler (MPS), pulsatile waveforms are sent to two electrodes at the same time (partially simultaneous stimulation). The table below indicates the strategies, the number of channels, and the stimulation rates (for pulsatile strategies only) used by the 52 children. Approximately two-thirds of the children used SAS with 7 or 8 channels. The remaining patients used pulsatile stimulation with 7 or 8 channels.

Number of Channels	SAS		CIS		MPS	
	Analog	Percentage of Users	Pulses per Second per Channel	Percentage of Users	Pulses per Second per Channel	Percentage of Users
3	Continuous Simultaneous Stimulation		2167		3250	
4			1625		3250	
5			1300		2167	
6			1083		2167	
7		8%	929		1625	2%
8		56%	813	15%	1625	19%
Total		64%		15%		21%

Safety Results: Children Implanted Between 12 Months and 17 Months of Age
Safety results are based on 29 children implanted between 12 and 17 months of age in North America with the CLARION CI implant and HiFocus Electrode with Positioner. The following adverse events occurred:

Medical/Surgical Complications

- Leakage of Cerebrospinal Fluid during Surgery: Three children (3/29, 10.3%) with malformed cochleae experienced leakage of cerebrospinal fluid during surgery. Routine packing terminated the leaks. One patient also required a lumbar drain and two additional days of hospitalization for observation. All three patients stabilized after surgery and no further complications were reported.
- Middle Ear Complications: Two patients (2/29, 6.9%) had acute ear infections at six months postimplantation that resolved after antibiotic treatment. One patient (1/29, 3.4%) had a small dry perforation of the tympanic membrane 12 months after implantation. No further complications were reported for the three patients.
- Electrode/Device Displacement: Two patients (2/29, 6.9%) experienced migration of the electrode or receiver/stimulator. One patient experienced device migration due to head trauma resulting from a fall seven months following surgery. The receiver/stimulator was repositioned surgically without disturbing the electrode array or requiring device replacement. The other patient was reimplanted without incident after demonstrating unusual responses to sound six weeks after initial stimulation. The electrode had migrated partially and was kinked due to unknown cause.

Device-Related Complications

- No device failures or major device malfunctions among this study group.

Efficacy Results: Children Implanted Between 12 Months and 17 Months of Age
Results from 20 of 29 children who had reached the six-month test interval were used to determine the effectiveness of the CLARION CI HiFocus I Electrode with Positioner in children 12-17 months of age. Parental ratings of the child's response to sound in everyday listening situations [Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)] were made pre-implant with hearing aids and at six months post-implant. Effectiveness was assessed by comparing post-implant scores after six months of device use to pre-implant scores. A positive difference between post-implant and pre-implant scores was considered a clinically significant improvement if the difference exceeded 20%. Similarly, a decrease between pre-implant and post-implant scores that exceeded 20% was considered a clinically significant decrement.

Response to Sound in Everyday Situations After Only Six Months of Device Use
Test: Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)

During a structured interview, parents rated the frequency of occurrence of 10 auditory behaviors using the scale: 0 (never), 1 (rarely), 2 (occasionally), 3 (frequently), 4 (always). Composite scores (sum of all 10 items divided by the total number of possible points) were calculated.

Mean	70%	Significant Improvement(%, n)	95% (19/20)
Median	75%	Non-Significant Improvement(%, n)	5% (1/20)
S.D.	22%	No Change(%, n)	0% (0/20)
Range	15-95%	Non-Significant Decrement(%, n)	0% (0/20)
n	20	Significant Decrement(%, n)	0% (0/20)

- More than one-third (8/20, 40%) of the children attained a composite score of 80% or higher after six months of device use.

Results also were analyzed for the percentage of children who "frequently" or "always" demonstrated a specific auditory behavior.

- Preoperatively with hearing aids only, 15% (3/20) of the children frequently or always showed a change in their vocalizations. Postoperatively with the implant, 100% (19/19) frequently or always showed a change in their vocalizations.
- Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always responded to their name in quiet. Postoperatively with the implant, 84% (16/19) of the children frequently or always responded to their name in quiet.
- Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always responded to their name in noise. Postoperatively with the implant, 68% (13/19) of the children frequently or always responded to their name in noise.
- Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always responded to environmental sounds. Postoperatively with the implant, 74% (14/19) of the children frequently or always responded to environmental sounds.
- Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always recognized sounds in the environment. Postoperatively with the implant, 68% (13/19) of the children frequently or always responded spontaneously to everyday sounds.
- Preoperatively with hearing aids only, 5% (1/20) of the children frequently or always differentiated between speech and non-speech sounds. Postoperatively with the implant, 74% (14/19) of the children frequently or always differentiated between speech and non-speech sounds.

Stimulation Parameters

Several sound-processing strategies are implemented with the CLARION CI implant and HiFocus Electrode with Positioner. There are 8 independent output circuits and 16 electrode contacts in the cochlea. In the Simultaneous Analog Strategy (SAS), the electrodes are bipolar coupled and analog waveforms are delivered to the resulting 8 sites simultaneously. In the Continuous Interleaved Sampler (CIS), monopolar coupling (even or odd) is used and pulsatile waveforms are sent to the resulting 8 sites sequentially. In the Multiple Pulsatile Strategy (MPS), pulsatile waveforms are sent to two electrodes at the same time (partially simultaneous stimulation). Two thirds of the very young children (13/20) used analog stimulation and one third (7/20) used pulsatile stimulation. All children used 6-8 channels.

Stimulation Parameters for Children 12-17 Months of Age (n = 20)

Number of Channels	SAS		CIS		MPS	
	Analog	Percentage of Users	Pulses per Second per Channel	Percentage of Users	Pulses per Second per Channel	Percentage of Users
3	Continuous Simultaneous Stimulation		2167		3250	
4			1625		3250	
5			1300		2167	
6		5%	1083		2167	
7			929	5%	1625	5%
8		60%	813	10%	1625	15%
Total		65%		15%		20%

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 Ultra 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 Ultra 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.

PRESSURIZED ENVIRONMENT INFORMATION: The HiRes Ultra Implant can withstand a pressure up to a depth of 42m under water (138 feet) or a gauge pressure of 4ATM (413 kPa).

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

Table 1

		Implant Type				
		C1	*CII*	*HiRes 90K*	*HiRes 90K Advantage*	*HiRes Ultra*
Processor Type	*Naída CI*	-	✓[5]	✓[5]	✓[5]	✓[6]
	Neptune	-	✓[1]	✓[1]	✓[1]	✓[6]
	Harmony	✓[2]	✓[3]	✓[3]	✓[3]	✓[6]
	Auria	-	✓[3]	✓[3]	-	-
	Platinum Sound Processor (PSP)	✓[4]	✓	✓	✓	✓[6]

[1] Requires SoundWave 2.1 or later
[2] Requires SoundWave 2.0 or later
[3] Requires SoundWave 1.4 or later
[4] Requires SClin2000
[5] Requires SoundWave 2.2 or later
[6] Requires SoundWave 2.3 or later

Table 2

		Implant Type				
		C1	*CII*	*HiRes 90K*	*HiRes 90K Advantage*	*HiRes Ultra*
Software Type/Version	*SClin2000*	✓	✓	-	-	-
	SoundWave (versions 1.x)	-	✓	✓	-	-
	SoundWave 2.0	✓[1]	✓	✓	-	-
	SoundWave 2.1	✓[1]	✓	✓	✓[2]	-
	SoundWave 2.2	✓[1]	✓	✓	✓	-
	SoundWave 2.3	✓[1]	✓	✓	✓	✓
	SoundWave 3.0	✓[1]	✓	✓	✓	✓
	SoundWave 3.1	✓[1]	✓	✓	✓	✓

[1] Only on Harmony
[2] Recognized but not selectable from Implant Type list

Table 3

		Processor Type				
		Naída CI	*Neptune*	*Harmony*	*Auria*	*PSP*
Headpiece Type	*Universal Headpiece (UHP)*	✓	✓	✓	✓	✓
	AquaMic	✓	✓	-	-	-
	HR 90K Auria Headpiece	-	-	✓	✓	-
	Platinum Headpiece	-	-	✓	✓	✓

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 Ultra and strongly recommends that surgeons who implant adults receive training.

All physicians implanting the HiRes Ultra 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.

REF	
CI-1600-04	HiRes™ Ultra CI HiFocus™ MS Electrode
CI-1600-05	HiRes™ Ultra CI HiFocus™ SlimJ Electrode
CI-4509	HiRes™ Ultra Reusable Surgical Tool Kit
CI-4331	HiRes™ Ultra Recess Gauge
CI-4341	HiRes™ Ultra Coil Gauge
CI-4421	HiRes™ Ultra BTE Template
CI-1418	HiRes™ Ultra Magnet Tool Kit
CI-4348	HiRes™ Ultra Magnet Insertion Tool
CI-4349	HiRes™ Ultra Magnet Pusher Tool
CI-1413	HiRes™ Ultra Replacement Magnet
CI-1411	HiRes™ Ultra Temporary Non Magnetic Plug
CI-4426	HiRes™ Ultra Mock Up
CI-4508	HiFocus™ Mid-Scala Electrode Instrument Kit
CI-4254	HiFocus™ Mid-Scala Claw Tool
CI-4347	HiFocus™ Mid-Scala Cochleostomy Gauge
CI-4507	HiFocus™ MS Electrode Insertion Tool Kit
CI-4207	HiFocus™ MS Electrode Insertion Tool
CI-1605	HiFocus™ SlimJ Electrode Depth Gauge
CI-4350-02	HiFocus™ Electrode Forceps Kit