The HIRESolution Bio 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 HiFocus™ Stim electrode and either the HiFocus™ Silk electrode or the HiFocus™ Mid-Scale (MS) electrode array that are implanted surgically under the skin of the patient. 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 stimulates the auditory nerve. The auditory nerve then sends information to the brain, where it is interpreted as sound.

INDICATIONS: The HIRESolution Bio Ear System is intended to resolve level of hearing impairment in adults and children with single or bilateral severe-to-profound sensorineural hearing loss due to irreversible neural damage.

CONTRAINDICATIONS: Deafness due to lesions of the acoustic nerve or obstruction of the internal auditory canal. UNILATERAL: Contraindications apply to the side with a hearing disorder. Bilateral: Contraindications apply to each side independently. 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.

1. Precautions before entering the area of an MRI scanner:

- 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 use of hearing aids for children < 4 years of age, lack of benefit is defined as a failure to reach developmental milestones, or not exceeding the norms defined by equivalent responses in terms of gain or in quiet or to environmental sounds measured using the Infant-Toddler Hearing Assessment Test (IT-HAT) or normal hearing children of the same age.
- Thrombosis may not be avoided. High currents induced into the electrode can cause tissue damage to the cochlear tissues or permanent damage to the implant.
- The recommended minimum duration of time post implant surgery prior to undergoing any MRI scan is 2 to 4 weeks in order to allow any inflammation to subside.

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:

- Maximum MR system reported, head averaged SAR of ≤ 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.

0.3 W/kg at 1.5T (Normal Operating Mode) for quadrature transmit RF body coils.

The 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.

3. Cut a piece of the Coach bandage that is long enough to wrap around the head once.

4. Place this piece around the head, so that the bandage covers the patient head piece. Make this wrap tight

5. Outline the position of the headpiece on the bandage using a marker or pen.

6. Open the Coach bandage roll. Unroll the remaining bandage roll and wrap the bandage around the headpiece. Continue wrapping the bandage around the headpiece, ending at the marked head circumference. Make this wrap tight.

7. Slide the MRI Antenna Coil Cover under the bandage, lining it up with the marked head circumference.

8. Place the patient's head inside the antenna coil cover. Please note that the MRI Antenna Coil Cover, CI-7521, and bandaging supplies must be kept for removal instructions.

9. After completing the bandaging process, your patient will be instructed to hold or cover their head to avoid the risk of losing control or distraction.

In rare cases, an MRI scan is not recommended if the patient has a fever.

PRECAUTIONS:

- Electromagnetic Discharge (ESD): It is known that static electricity can potentially damage the external components of the cochlear implant system. Care should be taken to avoid situations in which high levels of static electricity can be generated. Medical personnel should be provided in the vicinity of the system. If static electricity is present, static electrical potential of the cochlear implant recipients can safely be reduced by the patient touching the examination room wall or person or his fingers to that person or object contacting the implant system.

- Digital Cellular Phones: Using or being in close vicinity to someone using digital cellular phones may cause interference with the system. If such interference occurs, patients should immediately stop using the phone before proceeding to the MRI. If interference is noted before purchasing a digital cellular phone, patients should evaluate whether it will be safe to use the phone while wearing the implant system.

- Ingrained bandaging technique: The external components of the implant system contain small parts that may I be harmful if swallowed.
Device-Related Complications

Two patients (2/80, 2.5%) experienced device failures that required device replacement. Both patients involved a complete failure of the CII device and the study, and the other patient required a device replacement.

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

HiResolution Sound Processing was offered by the CII Bionic Ear implant to differ from its previous stimulation waveform. The CII device was configured to use the HiRes waveform, which included 80 independent channels.

CII Bionic Ear Stimulation Waveform

The CII Bionic Ear stimulation waveform was designed to provide a more natural sound experience. It included multiple frequency bands and was capable of reproducing speech in multiple environments.

HiFocus Electrode

The HiFocus Electrode was a pre-shaped electrode that was specifically designed for use in conjunction with the HiFocus Ultra implant. It was intended to improve speech clarity and reduce side effects.

HiFocus Ultra Implant

The HiFocus Ultra Implant was a new design that included a smaller, more compact device. It was intended to improve patient comfort and reduce device visibility.

Performance Results

Performance results were comparable between the HiRes and HiFocus devices, with slight differences in speech perception scores.

Safety Results

Safety results were comparable between the HiRes and HiFocus devices, with slight differences in incidence rates of minor complications.

Conclusion

The study demonstrated that the HiFocus Electrode and HiFocus Ultra implant were safe and effective for use in patients with bilateral hearing loss. The device showed promising results in improving speech perception and reducing side effects.
During the clinical trial, the CI was initially programmed to operate like a CI device using conventional sound processing strategies (SAS, MPS, or CIS) and patients were evaluated three months later. These patients then switched to HiRes sound processing and were evaluated after three months of HiRes use. When programmed with HiRes and 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 determined the stimulation rate (pulses per second) 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 varied from 50% of 80% in 96.5% of the whole patient population. Ninety-two of the patients used 13 or more contacts, thereby giving them access to the greater number of stimulation contacts used by each patient.

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.

**HIF Res Efficacy Results in Adults**

Efficacy results are based on data from 51 of the 80 patients who had reached the six-month clinical test interval. The calculation was done 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 was defined as the percentage of correct word recognition in quiet and noise (all without lipreading) 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)**

<table>
<thead>
<tr>
<th>Test</th>
<th>n</th>
<th>Mean</th>
<th>Median</th>
<th>25%</th>
<th>0%–94%</th>
<th>Range</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC W</td>
<td>65</td>
<td>85%</td>
<td>84%</td>
<td>75%</td>
<td>0%–47%</td>
<td>100-100</td>
<td>51</td>
</tr>
<tr>
<td>CID S</td>
<td>90%</td>
<td>94%</td>
<td>85%</td>
<td>0%–47%</td>
<td>100-100</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>HINT S</td>
<td>94%</td>
<td>65%</td>
<td>55%</td>
<td>0%</td>
<td>65%</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

**Difficult Sentence Recognition in Quiet, Hearing Only (No Lipreading) After Six Months of CLARION Use (Three Months of HiRes Use)**

<table>
<thead>
<tr>
<th>Test</th>
<th>n</th>
<th>Mean</th>
<th>Median</th>
<th>25%</th>
<th>0%–100%</th>
<th>Range</th>
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<td></td>
</tr>
<tr>
<td>HINT S</td>
<td>94%</td>
<td>65%</td>
<td>55%</td>
<td>0%</td>
<td>65%</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test</th>
<th>AdLib in Quiet (Speech Spectrum)</th>
<th>AdLib in Quiet (Multi-Talker Babble)</th>
<th>AdLib in Noise (HiRes)</th>
<th>AdLib in Noise (HiRes Fidelity 120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC W</td>
<td>77% (21)</td>
<td>30% (0)</td>
<td>26% (73)</td>
<td>33%</td>
</tr>
<tr>
<td>CID S</td>
<td>43% (12)</td>
<td>20% (6)</td>
<td>24% (61)</td>
<td>31%</td>
</tr>
<tr>
<td>HINT S</td>
<td>51% (14)</td>
<td>10% (3)</td>
<td>35% (90)</td>
<td>25%</td>
</tr>
<tr>
<td>HINT S in Noise</td>
<td>30% (10)</td>
<td>10% (3)</td>
<td>35% (90)</td>
<td>25%</td>
</tr>
</tbody>
</table>

**Performance of Patients with HiRes Fidelity 120**

Both patients who 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 programming.

**Efficacy Results**

In Phase I, HiRes Fidelity 120 benefit was assessed using speech perception measures at conversational level and the results were compared with those obtained at baseline in the original HiRes and one month after using HiRes Fidelity 120. (AdLib sentence recognition in quiet was tested in two levels, 55 and 65 dB SPL. AdLib sentence recognition in noise was tested in two noise types, speech-spectrum noise and multitalker babble.)

**Number of Phase I Subjects Showing Clinically Significant Improvement or Decrement in Speech Perception Scores Between Baseline and HiRes and One Month with HiRes Fidelity 120**

<table>
<thead>
<tr>
<th>Test</th>
<th>AdLib in Quiet (Speech Spectrum)</th>
<th>AdLib in Quiet (Multi-Talker Babble)</th>
<th>AdLib in Noise (HiRes)</th>
<th>AdLib in Noise (HiRes Fidelity 120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC W</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
</tr>
<tr>
<td>CID S</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
</tr>
</tbody>
</table>

**AdLib in Noise (Speech Spectrum)**

<table>
<thead>
<tr>
<th>Test</th>
<th>AdLib in Quiet (Speech Spectrum)</th>
<th>AdLib in Quiet (Multi-Talker Babble)</th>
<th>AdLib in Noise (HiRes)</th>
<th>AdLib in Noise (HiRes Fidelity 120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC W</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
</tr>
<tr>
<td>CID S</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
</tr>
</tbody>
</table>

**AdLib in Noise (Multi-Talker Babble)**

<table>
<thead>
<tr>
<th>Test</th>
<th>AdLib in Quiet (Speech Spectrum)</th>
<th>AdLib in Quiet (Multi-Talker Babble)</th>
<th>AdLib in Noise (HiRes)</th>
<th>AdLib in Noise (HiRes Fidelity 120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC W</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
</tr>
<tr>
<td>CID S</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
</tr>
</tbody>
</table>

**AdLib in Noise (Speech Spectrum)**

<table>
<thead>
<tr>
<th>Test</th>
<th>AdLib in Quiet (Speech Spectrum)</th>
<th>AdLib in Quiet (Multi-Talker Babble)</th>
<th>AdLib in Noise (HiRes)</th>
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<td>3/34 (9)</td>
<td>3/34 (9)</td>
<td>3/34 (9)</td>
</tr>
<tr>
<td>CID S</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
<td>2/34 (6)</td>
</tr>
</tbody>
</table>
Preference ratings indicated that 20 out of 26 subjects (77%) preferred HiRes Fidelity over the SNR in dB. A lower SNR indicates better performance.)

In summary, the objective speech perception data showed that the majority of subjects in both studies had equivalent performance to the standard HiRes strategy preference. Mean differences in sentence scores were 0.8% for all three test conditions (p < .0001), which 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 III study (Phase II: 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 CI users and HINT 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 a user’s listening environment, as well as to the user’s personal listening preferences, in order to provide a natural-sounding conversational voice, as well as to provide a comfortable listening experience. The voice is clear, as well as to the user’s natural voice tone and level. ClearVoice has three settings that allow individual users to select the setting that provides the best fit. These three settings are: Low, Medium, and High. A two-week randomized, crossover design was used to compare performance with HiRes Fidelity 120 Baseline and HiRes Fidelity 120 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 solely by all subjects in each of the length of the study. Scores on the ADHS 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.

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

In summary, the clinical data demonstrated that that ClearVoice is effective for enhancing speech understanding in certain noisy environments without compromising comfort, with a demonstrated in decreasing in 81% to 76% of subjects, with a difference in improvement across the HiRes Optima and HiRes Fidelity 120 sentence scores in quiet of 1.9 dB in favor of HiRes Fidelity 120 while improving battery life in users of the HiResolution Bionic Ear System (HiResMatrix™). To verify the noninferiority of HiRes to HiRes Optima, a clinical trial was conducted in 36 adults who were bilateral or unilateral users of a CI and HI/DK device (minimum of one year of use in one ear implanted) and who demonstrated at least minimal speech perception scores. Subjects were randomized to either HiRes Optima or HiRes Fidelity 120 for one week, after which they used the opposite device for one week. A follow-up visit was conducted to assess 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 ClearVoice was at least as good as, and not worse than, with HiRes Fidelity 120 without ClearVoice. The primary objective was to demonstrate that speech understanding with ClearVoice was at least as good as, and not worse than, with HiRes Fidelity 120 without ClearVoice. The secondary objective was to demonstrate that speech understanding with ClearVoice was no worse than the Control in both conditions. The results showed that speech understanding in multi-talker babble was significantly better than the Control for everyday listening. The mean strength of preference for the 42 subjects preferring ClearVoice, 22 indicated they would use it all the time every day. The 3 subjects who did not prefer ClearVoice used it some of the time. Of the 3 subjects preferring the Control, all indicated they would use it 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 (54%), conversing in a group of people. Seventeen percent (17%) of subjects indicated that ClearVoice was helpful while listening in challenging situations worse, less time, and less stressful.

These results are consistent with previous studies, and further demonstrating that HiRes Optima provides benefit that is comparable to HiRes Fidelity 120.
Conducted in the pediatric population with CLARION CI HiFocus I Electrode with Positioner—which was the predecessor to the CII HiFocus—

Efficacy: Children Implanted Between 18 Months and 17 Years of Age

Efficacy results based on 32 of 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 = 75).

During a structured interview, parents rated the frequency of occurrence of 10 auditory abilities for their child (Table 14).

Mean 95% Significant Improvement(%, n) 82% (18/22)

Range 0%–96% Non-Significant Decrement(%, n) 0% (2/22)

One child did not have a six-month score.

* Two children did not have preoperative or six-month scores.

Results also were analyzed for the percentage of children who “frequently” or “always” differentiated between speech and non-speech sounds. Postoperatively with the implant, 85% (22/26) of the children frequently or always responded to environmental sounds.

Mean 16% Significant Improvement(%, n) 50% (13/25)

Range 0%–100% Non-Significant Decrement(%, n) 4% (1/25)**

* Three children did not have six-month scores.

** Slightly more than one-month (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 input circuits and 16 electrode contacts in the cochlea. The stimulation rates used by the 52 children. The 52 children used 16 channels, and the stimulation rates (for pulsatile strategies only) used by the 52 children. Approximately one-third (9/26, 35%) of the children recognized 90% or more of the phonemes in continuous speech. Postoperatively, the implant, 81% (21/26) of the children frequently or always responded to environmental sounds.

Mean 60% Significant Improvement(%, n) 40% (10/25)

Range 0%–100% Non-Significant Decrement (%, n) 0% (0/25)

* Two children did not have six-month scores.

Medical/Surgical Complications

• Severe Aural Trauma: Two patients (2/150, 1.3%) experienced postoperative aural trauma. One patient experienced persistent pain and distress due to foreign body sensation. Symptoms resolved in both patients without medical intervention.

• Trauma: One patient (1/150, 0.7%) reported mild trauma in the implanted ear on external examination. No complaints or complications followed in this patient following treatment.

• Facial Nerve Involvement: One patient (1/150, 0.7%) experienced facial nerve weakness and arm pain 6 days after surgery which resolved following medical treatment.

• Pulsatile 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 require medical treatment and required surgery to replace the device. The patient was reimplanted without incident.

Children 4 Years of Age and Older

Predominantly Implanted in Healthy Patients

All children 4 years of age and older showed clinically significant improvement on one or more of the efficacy measures.
RESULTS
Children Implanted Between 12 Months and 17 Months of Age
A total of 20 children were enrolled in the study. The device was used to determine the effectiveness of the CLARION CI HiFocus™ I Electrode with children in 12-17 months of age. Parental consent for the child’s response to sound in everyday listening situations (Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)) were examined 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 change if the difference exceeded 20%. Similarly, a decrease between postimplant and pre-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)

POSSIBLE ADVERSE EVENTS: The following risks associated with cochlear implantation and use may occur:

• Implant patients incur the normal risks of surgery and general anesthesia.
• Motor vehicle or traffic accident while wearing the device could result in serious injury.
• No device failures or major device malfunctions among this study group.
• Skin infection in the area of the implant may require additional medical treatment or removal of the internal device.

Efficacy Results: Children Implanted Between 12 Months and 17 Months of Age

A total of 20 children were enrolled in the study. The device was used to determine the effectiveness of the CLARION CI HiFocus™ I Electrode with children in 12-17 months of age. Parental consent for the child’s response to sound in everyday listening situations (Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)) were examined 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 change if the difference exceeded 20%. Similarly, a decrease between postimplant and pre-implant scores that exceeded 20% was considered a clinically significant decrement.

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