The Harmony™ HiResolution® Bionic Ear System is a cochlear implant designed to provide access to the auditory environment for individuals who have severe-to-profound sensorineural hearing loss. It consists of internal and external components. The internal components include a receiver-stimulator (HiRes® 90K) and electrode arrays (HiFocus® or HiFocus Helix® Electrodes). The external system includes a body-worn processor (HiFocus®), 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 Harmony HiResolution® Bionic Ear System is intended to restore a level of auditory sensation to individuals with severe-to-profound sensorineural hearing loss. This condition can occur if the electrode is not inserted properly.

- age of 18 years or older
- severe-to-profound bilateral sensorineural hearing loss of ≥ 70 dB HL
- postlingual onset of hearing loss
- limited benefit from appropriately fitted hearing aids, defined as scoring ≤ 80% on a test of speech reception (BNT Sentence Test).

### Children

- 12 months through 17 years of age
- hearing loss of at least 60 dB HL
- use of appropriately fitted hearing aids for at least 6 months in children 2 through 3 years of age
- minimum duration of hearing aid use or wear should be ≥ 12 months in children 4 through 7 years of age
- individual must be able to cooperate with the test
- individual must be able to understand and follow the examiner

### Contraindications

- History of meningitis
- Central auditory pathway; active external or middle ear infections; cochlear Deafness due to lesions of the acoustic nerve or congenital abnormalities of the cochlea (innner ear) which predispose them to meningitis or significant bone deafness (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 health conditions. Physicians or patientsshould refer to the applicable authorities for this information.

### Aftercare

- The HiFocus Helix Electrode is intended for use with the Modular HiRes 90K with Helix Electrode. Clinical data from 41 HiRes 90K patients (37 adults and 4 children) in Canada and Europe indicated no safety or efficacy concerns. The symptoms resolved in two patients (one adult and the child) who were implanted with the HiRes 90K with HiFocus Electrode. Surgeon feedback via a postimplantation questionnaire revealed no major surgical handling or placement concerns with the Helix. Eighteen patients with a device for either navigation or a11:24 AM

### Side Effects

- Dizziness
- Headache
- Tinnitus
- Electromagnetic interference
- Sensory nervousness
- Excessive sound processing
- Device malfunction

### Warnings

- Electrical 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 determined. Although the percentage of deaf patients may have congenital abnormalities of the cochlea (inner ear) which predispose them to meningitis or significant bone deafness.

### Instructions

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

### Use of Cochlear Implants

- Failure to use the implant system can result in loss of hearing due to the cochlea or permanent damage to the implant.

### Image

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- FAX: 913-217-5601
- EMAIL: info@advancedbionics.com
- WEB: www.advancedbionics.com

### Services

- Biostats
- Biostats Asia-Pacific
- Biostats Asia-Pacific
- Biostats Asia-Pacific

### Contacts

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- Advanced Bionics SAEL 1001 Stirling Road, Santa Clara, CA 95054 U.S.A.
- www.advancedbionics.com
- Email: asiapacific@advancedbionics.com
- Telephone: (661) 362-1500
- Fax: (661) 362-1500

### References


### Safety

- 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 CI-BIIDE clinical trial.

### Efficacy Results

- In summary, the clinical comparability of safety and efficacy between the HiRes 90K with HiFocus Electrode, and the HiRes 90K with HiFocus Helix Electrode, were comparable to that observed in the CI-BIIDE clinical trial.
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 BIE adults, and adults in the ongoing HiRes postmarket study.

### CII Words One Month

<table>
<thead>
<tr>
<th>Performance Group</th>
<th>HiRes 90K</th>
<th>CII BIE</th>
<th>PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (&lt;25%)</td>
<td>26%</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>Moderate (25-45%)</td>
<td>26%</td>
<td>26%</td>
<td>27%</td>
</tr>
<tr>
<td>High (&gt;45%)</td>
<td>33%</td>
<td>33%</td>
<td>31%</td>
</tr>
</tbody>
</table>

### CII Words Three Months

<table>
<thead>
<tr>
<th>Performance Group</th>
<th>HiRes 90K</th>
<th>CII BIE</th>
<th>PMS</th>
</tr>
</thead>
<tbody>
<tr>
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<td>28%</td>
</tr>
<tr>
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<td>30%</td>
<td>29%</td>
<td>30%</td>
</tr>
<tr>
<td>High (&gt;45%)</td>
<td>38%</td>
<td>38%</td>
<td>37%</td>
</tr>
</tbody>
</table>

### CII Sentence in One Month

<table>
<thead>
<tr>
<th>Performance Group</th>
<th>HiRes 90K</th>
<th>CII BIE</th>
<th>PMS</th>
</tr>
</thead>
<tbody>
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<td>31%</td>
</tr>
<tr>
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<td>33%</td>
<td>32%</td>
<td>32%</td>
</tr>
<tr>
<td>High (&gt;45%)</td>
<td>40%</td>
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<td>40%</td>
</tr>
</tbody>
</table>

### CII Sentence in Three Months

<table>
<thead>
<tr>
<th>Performance Group</th>
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<th>PMS</th>
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<tr>
<td>Moderate (25-45%)</td>
<td>40%</td>
<td>39%</td>
<td>39%</td>
</tr>
<tr>
<td>High (&gt;45%)</td>
<td>50%</td>
<td>50%</td>
<td>50%</td>
</tr>
</tbody>
</table>

### HiRes Sentence in One Month

<table>
<thead>
<tr>
<th>Performance Group</th>
<th>HiRes 90K</th>
<th>CII BIE</th>
<th>PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (&lt;25%)</td>
<td>34%</td>
<td>33%</td>
<td>33%</td>
</tr>
<tr>
<td>Moderate (25-45%)</td>
<td>34%</td>
<td>34%</td>
<td>34%</td>
</tr>
<tr>
<td>High (&gt;45%)</td>
<td>42%</td>
<td>41%</td>
<td>41%</td>
</tr>
</tbody>
</table>

### HiRes Sentence in Three Months

<table>
<thead>
<tr>
<th>Performance Group</th>
<th>HiRes 90K</th>
<th>CII BIE</th>
<th>PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (&lt;25%)</td>
<td>42%</td>
<td>41%</td>
<td>41%</td>
</tr>
<tr>
<td>Moderate (25-45%)</td>
<td>42%</td>
<td>42%</td>
<td>42%</td>
</tr>
<tr>
<td>High (&gt;45%)</td>
<td>50%</td>
<td>49%</td>
<td>49%</td>
</tr>
</tbody>
</table>

### HiFocus Electrode Electrode Contacts and Stimulation Rate

- **Number of Contacts (1-38)**
  - **Stimulation Rate**
    - Low (≤25%): 2900-5000 pps per contact
    - Moderate (25-45%): >5000 pps
    - High (>45%): >5000 pps

### CIIIE Adults

- **Ninth CIIIE Adults**
  - **Mean Speech Perception Scores**
    - Low (≤25%): 26%
    - Moderate (25-45%): 26%
    - High (>45%): 33%

### HiFocus Electrode Helix Electrode

- **Speech-perception scores from adults using the HiRes 90K and HiFocus Helix Electrodes who have reached the one-month (n = 31) and three-month (n = 10) postimplant intervals were comparable to results from adults in the CII BIE and HiRes 90K clinical trials.

### Mean Speech Perception Scores for Adults Using the HiRes 90K and HiFocus Helix Electrodes

<table>
<thead>
<tr>
<th>Test Interval</th>
<th>HiRes 90K</th>
<th>HiFocus Helix</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 months</td>
<td>30%</td>
<td>29%</td>
</tr>
<tr>
<td>18 months</td>
<td>30%</td>
<td>28%</td>
</tr>
</tbody>
</table>

### HiRes Bionic Ear Systems

- **HiRes 90K HiFocus Electrode**
  - **Median Speech-Perception Scores for Adults Using the HiRes 90K and HiFocus Electrode**
    - Low (≤25%): 26%
    - Moderate (25-45%): 26%
    - High (>45%): 33%

### HiFocus Electrode

- **HiFocus Electrode**
  - **Median Speech-Perception Scores for Adults Using the HiFocus Electrode**
    - Low (≤25%): 34%
    - Moderate (25-45%): 34%
    - High (>45%): 42%

### HiRes Efficacy Results in Adults

Efficacy results are based on data from 51 of the 80 patients who had reached the ten-month (±3 months) postimplant. Patients were initially fit with previous-generation (conventional) sound processing strategies and evaluated after three months of use, after which they underwent a switch to HiRes Sound Processing and evaluated after three more months of use (approximately six months of device experience). Word recognition scores were obtained, and device_sensitivity recognition in quiet and noise (all without lipreading) were evaluated after six months of device use (three months of HiRes use).

### HiRes Resolution Sound Processing (HiRes)

HiResSound 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.

### HiRes Efficacy Results in Adults

- **Word Recognition in Quiet, Hearing Only (no lipreading)** After Six Months of CLARION Use (Three Months of Bionics Use) (Conventional NICI Consonant (CNC) Words)
  - **Mean**
    - Low (≤25%): 49%
    - Moderate (25-45%): 61%
    - High (>45%): 79%
  - **Range**
    - Low (≤25%): 39-59%
    - Moderate (25-45%): 51-82%
    - High (>45%): 70-89%

### Difficult Sensation Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of Bionics Use)

Difficult Sensation Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of Bionics Use) Hearing in Noise (HINT)

- **Mean**
  - Low (≤25%): 80%
  - Moderate (25-45%): 85%
  - High (>45%): 90%
- **Range**
  - Low (≤25%): 60-100%
  - Moderate (25-45%): 75-100%
  - High (>45%): 85-100%

### Difficult Sensation Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of Bionics Use)

Difficult Sensation Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of Bionics Use) Hearing in Noise (HINT)

- **Mean**
  - Low (≤25%): 80%
  - Moderate (25-45%): 85%
  - High (>45%): 90%
- **Range**
  - Low (≤25%): 60-100%
  - Moderate (25-45%): 75-100%
  - High (>45%): 85-100%
All but two patients showed clinically significant improvement on one or more of the speech measures (HINT word recognition and AzBio sentence recognition in noise) postoperatively. A significant decrement in CIDs sentence scores, with non-significant improvement on the other three tests. The decrease in CIDs sentence recognition ability (as reflected by a decrease in performance of the implanted ear, but the absence of the contribution of the non-implanted ear, which likely augmented performance. The other patients, however, has an elderly duration of deafness, and has only a partial insertion of the electrode because of avulsion or severe atrophy of auditory nerve.

**Improvement from Conventional Sound Processing to HiResSound Solution Processing**

Word recognition, easy sentence recognition, and difficult sentence recognition in quiet and in noise (all with lipreading) were evaluated after using conventional sound processing strategies for three months and after using HiRes sound processing. Before the HiRes sound processing, the mean preoperative score on the AzBio in quiet was 83% for all patients.

In the active current setting may deliver additional 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 for each electrode is chosen from eight available spectral bands during each processing cycle. Therefore, for each stimulation cycle across the entire electrode array, a minimum of 15 spectral bands may be selected for stimulation from a total of 120 spectral bands (8 x 15 output channels = 120 spectral bands). Each electrode on a pair performs in a 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.

A clinical study of HiRes Fidelity 120 was conducted in two phases. In Phase I, 37 adults who had been implanted with CI 90K or HiRes 90K implants were tested with original electrodes 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 5.8 years at the time of the study. In Phase II, 26 adults who had been implanted with HiRes Fidelity 120 were tested with original electrodes 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.

**Efficacy Results**

Phase I

HiRes Fidelity 120 benefited as assessed using speech recognition measures and sound/music quality ratings. Subjects were tested at baseline with original electrodes and one month after using HiRes Fidelity 120. (AzBio sentence recognition in quiet was tested at two levels, 35 and 48 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 Baseline versus HiRes Fidelity 120 (One Month)**

<table>
<thead>
<tr>
<th>Test</th>
<th>AzBio in Quiet (Multi-Talker Babble)</th>
<th>AzBio in Noise (Multi-Talker Babble)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC words</td>
<td>53/51 (25%)</td>
<td>53/51 (25%)</td>
</tr>
<tr>
<td>Significant Decrease (&gt; = 20%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Quiet</td>
<td>4/26 (15%)</td>
<td>4/26 (15%)</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Fixed Noise</td>
<td>5/26 (20%)</td>
<td>5/26 (20%)</td>
</tr>
<tr>
<td>Significant Decrease (&gt; = 20%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Preference Ratings**

Ratings indicated that 20 out of 26 subjects (77%) preferred HiRes Fidelity 120 over HiRes. The mean strength of preference for the 26 subjects who preferred HiRes Fidelity 120 was 3.11 (moderate preference), while the 10 who preferred HiRes stated a preference for HiRes Fidelity 120 over all HiRes. The strength of preference was rated at 8 or higher by 14 of the 26 subjects and 11 of them rated it at 10 (strong preference).

In summary, the subjective 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 specific 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 @ 8-Month = 75%, Phase II preference @ 10-Month = 80%, strength rating = 7.8). Phase II preference @ 3-Months = 77%, strength rating = 8.3). Importantly, these ratings indicated that the majority of subjects preferred using Hi

**Summary of Phase II Speech Perception Results for Baseline (Baseline) versus HiRes Fidelity 120 (3-Month)**

<table>
<thead>
<tr>
<th>Test</th>
<th>HiRes (Baseline)</th>
<th>HiRes Fidelity 120 (3-Month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC words</td>
<td>16/14 (71%)</td>
<td>16/14 (71%)</td>
</tr>
<tr>
<td>Significant Increase (&gt; = 20%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Quiet</td>
<td>4/26 (15%)</td>
<td>4/26 (15%)</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Fixed Noise</td>
<td>5/26 (20%)</td>
<td>5/26 (20%)</td>
</tr>
<tr>
<td>Significant Decrease (&gt; = 20%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Summary of Phase III Speech Perception Results for Baseline (Baseline) versus HiRes Fidelity 120 (6-Month)**

<table>
<thead>
<tr>
<th>Test</th>
<th>HiRes (Baseline)</th>
<th>HiRes Fidelity 120 (6-Month)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNC words</td>
<td>15/13 (75%)</td>
<td>15/13 (75%)</td>
</tr>
<tr>
<td>Significant Increase (&gt; = 20%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Quiet</td>
<td>4/26 (15%)</td>
<td>4/26 (15%)</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Fixed Noise</td>
<td>5/26 (20%)</td>
<td>5/26 (20%)</td>
</tr>
<tr>
<td>Significant Decrease (&gt; = 20%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Perception Measure</th>
<th>Significant Improvement (&gt; = 20%)</th>
<th>Significant Decrease (&gt; = 20%)</th>
<th>No Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>AzBio in Quiet (Multi-Talker Babble)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AzBio in Noise (Multi-Talker Babble)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CNC words</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Quiet</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HINT in Fixed Noise</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Safety Results**

Because the clinical study was conducted with adults who had been implanted previo- ously, no medical history or audiometric test results were reported. One Phase II subject experi- enced dizziness that was unrelated to the device. Two other Phase II subjects reported mild to severe hearing phantom sensations while being fit with HiRes Fidelity 120 that were resolved through reprogramming.

**Efficacy Results**

Phase I

Phase I, HiRes Fidelity 120 benefited as assessed using speech recognition measures and sound/music quality ratings. Subjects were tested at baseline with original electrodes and one month after using HiRes Fidelity 120. (AzBio sentence recognition in quiet was tested at two levels, 35 and 48 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 Baseline (Baseline) versus HiRes Fidelity 120 (One Month)**

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<th>HiRes Fidelity 120 (One Month)</th>
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<tr>
<td>Significant Increase (&gt; = 20%)</td>
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</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
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</tr>
<tr>
<td>HINT in Quiet</td>
<td>4/26 (15%)</td>
<td>4/26 (15%)</td>
</tr>
<tr>
<td>Speech Recognition</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
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<td>5/26 (20%)</td>
<td>5/26 (20%)</td>
</tr>
<tr>
<td>Significant Decrease (&gt; = 20%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Perception Measure</th>
<th>Significant Improvement (&gt; = 20%)</th>
<th>Significant Decrease (&gt; = 20%)</th>
<th>No Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>AzBio in Quiet (Multi-Talker Babble)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AzBio in Noise (Multi-Talker Babble)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CNC words</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
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<td>0</td>
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</tr>
<tr>
<td>HINT in Quiet</td>
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</tr>
<tr>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Hillys Fiddle 120 for listening to music and environmental sounds, as well as speech. The adults (218/300) and children (29/1120) were a selected, optional pro-
gramming frame for some CIH and Hillys 90k adults in a variety of living en-
vironments.

Safety and Efficacy Data in Children

Pediatric safety and efficacy data are based on clinical trial results obtained with
the previous-generation device and electrode technology CI/HiFocus Implant with
HiFocus II electrode, which was the predecessor to the CI/HiFocus II Implant. The
HiFocus II Implant is a change in design in which the electrode Positioner is
attached to the HiFocus II Electrode, a modification made to streamline and
simplify the surgical procedure. The HiFocus II Electrode was evaluated with the
CI/HiFocus II device only in postlingual adults, and a clinical trial was not con-
ducted in the pediatric population. Two consecutive clinical trials were
conducted in the pediatric population with CI/HiFocus II Implant with
HiFocus II Electrode. During a structured interview, parents rated the frequency of occurrence of 10 auditory behaviors using the scale: 0 (none), 1 (rarely), 2 (occasionally), 3 (frequently), 4 (always). Composite scores (sum of 10 items divided by the total number of possible points) were calculated.

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>S.D.</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>82%</td>
<td>82%</td>
<td>12%</td>
<td>0% – 22%</td>
</tr>
<tr>
<td>8%</td>
<td>8%</td>
<td>22%</td>
<td>0% – 22%</td>
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</table>

**Three children (4%) had no postoperative scores.

**Approximately one-third (2/3, 33%) of the children attended a composite score of 80% or higher six months after device use.

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

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

**One child did not have any postoperative scores.

**One child did not have either preoperative or six-month scores.

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

**Three children did not have six-month scores.

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

**One child did not have any postoperative scores.

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

**Three children did not have six-month scores.

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

**One child did not have any postoperative scores.

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

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

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

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

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

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

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

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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 1 Electrode with Positioner in children 12-17 months of age. Prevalent ranges 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)

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

- **Prospective with hearing aids only**: 83% (16/19) of the children frequently or always showed a change in their vocalizations.
- ** Prospectively with hearing aids and postoperative performance ear may not equal that of the better non-implanted ear, perception skills have a significant effect on post-implant performance. Ear duration of severe-to-profound hearing loss, and preoperative speech
- **Prospective with hearing aids only**: 20% (4/20) of the children frequently or always showed a change in their vocalizations. 100% (19/19) frequently or always showed a change in their vocalizations.
- **Prospective with hearing aids only**: 5% (1/20) of the children frequently or always showed a change in their vocalizations.

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

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Prospective cochlear implant candidates must be counseled appropriately on the proper fitting and adjustment of the system. Device and Fitting Manuals are provided to all clinical centers with the Clinic’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 CLARION 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 a higher incidence of surgical and medical complications.

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