

# The Foundation of Better Hearing AB IMPLANTABLE TECHNOLOGY





As surgeons, you want the best for your patients.

That's why

**Advanced Bionics** 

developed the most advanced and comprehensive cochlear implant technology in the world.



# HiRes Implantable Technology THE FOUNDATION OF BETTER HEARING

- Current steering to provide the best quality of sound possible
- Independent current sources for variety of stimulation strategies for better hearing performance



## HiRes Ultra Cochlear Implant Family DESIGNED FOR OPTIMAL HEARING EXPERIENCE

- Low profile for a discreet solution
- High-impact resistance for everyday activities
- MRI conditional: pain free and hassle free



## HiFocus Electrode Family CHOICE WITH UNCOMPROMISED PERFORMANCE

- Optimal spiral ganglion coverage with preservation of intracochlear structures
- Asymmetric design for smooth insertion
- Choice based on surgical approach and patient's anatomy



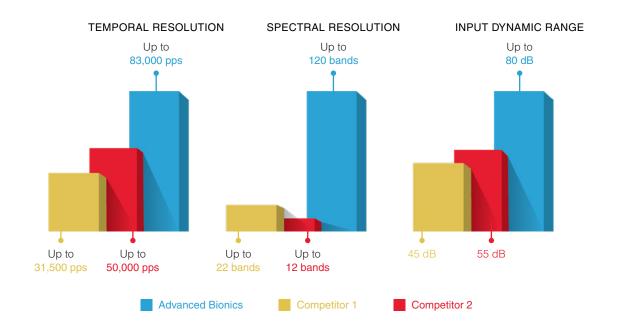
# The AIM System FAST, OBJECTIVE, CONVENIENT

- Real-time monitoring of patient's cochlear function during surgery
- Automated objective audiometry

# Implantable Technology The Foundation of Better Hearing

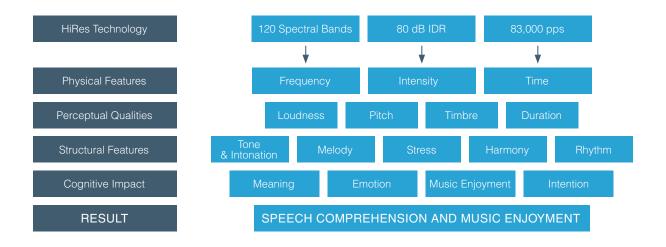
The HiRes<sup>™</sup> Ultra cochlear implant from Advanced Bionics (AB) consists of forward-thinking technologies that work together to provide the best CI based hearing possible. It is the capability and unsurpassed digital processing power that sets HiRes Ultra apart from other cochlear implants.

HiResolution implantable technology is the foundation for optimal hearing. The quality of the sound delivered by a cochlear implant system is a direct result of how well the system captures and delivers the details of sound. The HiRes Ultra cochlear implant was designed to deliver all of the loudness, pitch, and timing information that is essential for natural sound perception and appreciation of music: it automatically encodes the widest range of intensities (up to 80 decibels); it is capable of delivering frequency information to 120 cochlear sites of stimulation using a patented delivery method called current steering; it provides up to 83,000 updates per second.<sup>1</sup>



## Access to Speech and Music

AB patients can use fine spectral and temporal information to hear details of sound, enabling them to better understand tonal information in speech and to enjoy music.<sup>6,7,8</sup> An adult will have the best opportunity to reconnect with the hearing world; a child can have access to the best speech and language development possible.<sup>9,10,11</sup>

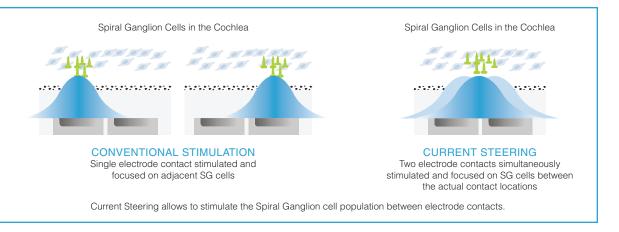


## Bidirectional Communication Link Between Implant and Sound Processor

All Advanced Bionics patients or their caregivers can be confident that the implant is functioning properly and that they can benefit from all features of our technology thanks to the proprietary Bidirectional Inductive Communication Link that relays information about the implant's functional status in real time back to the sound processor. The implant together with the sound processor build a closed loop that ensure proper functioning of the system.

## Current Steering: Hear the Most Subtle Pitch Changes

The number and placement of the actual electrode contacts should not determine the pitch differences a patient can detect. Under software control, the 16 independent current sources of the AB implant can steer stimulation to 120 separate locations along the cochlea, thereby increasing the amount of frequency information that can be delivered.<sup>2</sup> Patients may take advantage of this enhanced spectral information to hear more pitches, which can improve speech understanding in noise, music appreciation, and tonal language perception.<sup>3,4,5</sup> In fact, independent researchers have shown that AB cochlear implant patients have a potential total number of spectral bands (distinct pitches) across the electrode array of up to 451 with current steering technology.<sup>6</sup>



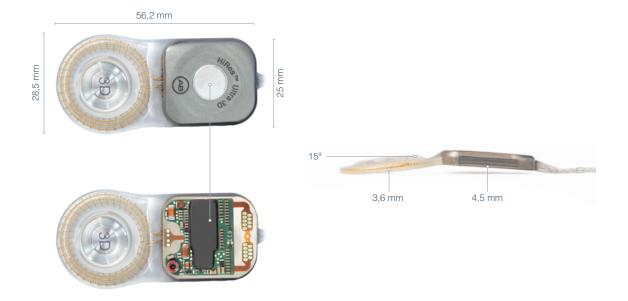


## HiRes Ultra Cochlear Implant Family

The HiRes™ Ultra cochlear implant family was developed in collaboration with leading cochlear implant surgeons to meet the needs of surgeons and their patients.

## LOW PROFILE

To make insertion easy and to provide flexibility for surgeons, the implant family is designed for surface mount or shallow 1 mm ramped recess, requiring minimal drilling to reduce surgery time. The thin profile (4.5 mm) and small footprint offer a discreet solution once implanted, making it suitable for both adults and children.



#### HIGH IMPACT RESISTANCE

The HiRes Ultra implant family exceeds the industry standard for impact resistance<sup>12,13,14</sup> and allows patients to participate in everyday activities and sports without worry. The latest version (V2) of the HiRes Ultra cochlear implant family is highly reliable and durable.<sup>15,16,17</sup>

## MRI CONDITIONAL

The standard HiRes Ultra implant is approved for 1.5T MRI with the magnet in place—ready for the most widely recognized standard of care MRI procedure. A simple head bandage procedure utilizing an Antenna Coil Cover is all that is required if a patient needs to undergo MRI imaging—no surgical procedure is necessary. And if a high resolution 3T MRI scan is required, the standard HiRes Ultra CI is approved for 3T MRI following the simple magnet removal procedure.

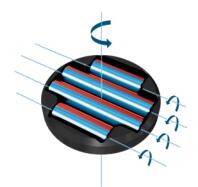
## Multi-magnet assembly of HiRes Ultra 3D Implant

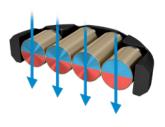
#### HASSLE FREE MRI

We at Advanced Bionics believe that an MRI procedure should be hassle free for you and your patients. The new, innovative multi-magnet assembly in the HiRes Ultra 3D CI provides 3D magnetic field alignment that allows adult and pediatric users to safely undergo high-resolution imaging, such as 3.0 Tesla MRIs, without any preparation, surgery or head bandaging. This unique multi-magnet assembly is composed of four individual magnets that work to provide alignment to the 3D MRI field. If diagnostic procedures require a reduced-image artifact range, the multi-magnet assembly can be easily removed and replaced with a nonmagnetic spacer through a small incision made prior to an MRI.

## PAIN FREE

Going into an MRI tube is stressful, especially for your young patients. Our HiRes Ultra 3D cochlear implant requires no restriction on head orientation during an MRI, ensuring your patient a truly stressfree MRI experience. The smooth movement of multi-magnet assembly generates such low torque that adults and pediatric recipients feel no pain or discomfort due to magnetic pulling during a high-resolution imaging MRI. The design of the HiRes Ultra 3D CI was demonstrated to be not prone to the risk of magnet dislocation and generate the least torque in a comparative study with different manufacturers.<sup>18</sup>







Four magnetic rods in a frame, allowing rotations in 3 dimensions

## UNINTERRUPTED HEARING

Eliminating the lengthy preparation procedures for a CI patient before an MRI saves time and hassle for you and for your patients. With the HiRes Ultra 3D, you don't need any special preparation for an MRI other than to ask your patients to take off their processor. When the scan is done, all they have to do is put their processor back on to return to hearing. With the HiRes Ultra 3D cochlear implant we provide your patients with uninterrupted hearing, which reduces the stress particularly with kids, who then have the ability to hear their parents right before and after the MRI scan.





## Electrodes Designed for Choice: Without Compromise

The HiRes Ultra implant offers two electrode designs, the straight HiFocus™ SlimJ electrode and the precurved HiFocus™ Mid-Scala electrode, to offer the surgeon a choice based on their practice preferences and the patient's anatomy. Both electrodes share the HiFocus design elements.

HiFocus electrode contacts are encased in a slim flexible tapered silicone carrier to minimize insertion forces and damage to cochlear structures during surgery. HiFocus electrodes are designed with balanced stiffness, which allows for easy insertion within the scala tympani while making it less prone to bend upwards towards the basilar membrane and translocate. By minimizing cochlear disruption, HiFocus electrodes offer an increased opportunity for better hearing outcomes. 22,23



HiFocus SlimJ electrode

A lateral wall electrode designed for confidence of insertion



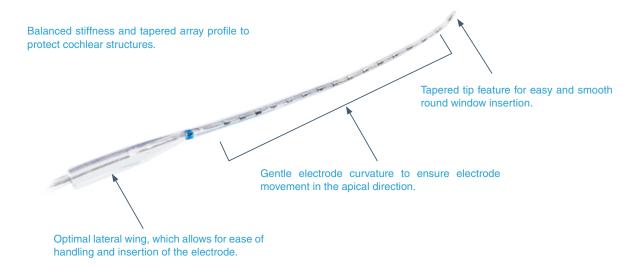
HiFocus Mid-Scala electrode

A pre-curved mid-scala electrode designed for consistency of placement

The HiFocus SlimJ or HiFocus Mid-Scala electrode provide the surgeon with maximum surgical flexibility based upon surgical preference while maintaining patient performance.<sup>20,21,22</sup>



The HiFocus SlimJ electrode is the latest approved lateral wall electrode technology, **designed for confidence of insertion with proven structure and hearing preservation.**<sup>20,24</sup> It is offered as a straight electrode with a gentle curvature, designed to be easily and smoothly inserted by freehand technique or with forceps. The main benefit of the gentle curvature next to easy insertion is to ensure electrode movement in the apical direction.



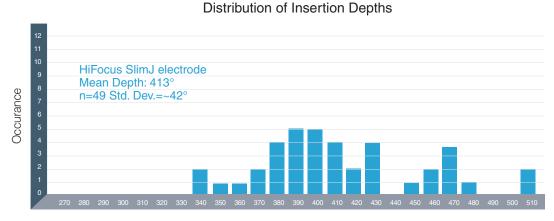
## **CONFIDENCE OF INSERTION**

Key to the design are the elements that allow a surgeon to easily handle the electrode in the surgical space and insert with minimal trauma to the delicate cochlea structures. The SlimJ electrode has been designed to have balanced stiffness and flexibility to offer smooth insertion and protect cochlear structures. The wing feature allows for the best possible visualization of the cochlea, and precise control of the angle and speed of insertion. It provides an easy area for a surgeon to hold and control the electrode, even into the facial recess.

The HiFocus SlimJ electrode can be introduced into the cochlea by a surgeon's preferred approach—by using round window, extended round window, or small cochleostomy, requiring only a 0.8 mm opening. The tip feature is intended to ease the insertion through the round window. The HiFocus SlimJ electrode can be inserted and reinserted up to three times.

#### **OPTIMAL SPECTRAL COVERAGE**

A marker on the electrode array provides visual indication of insertion depth — the 23 mm indicator represents approximately 420° in a standard cochlea, covering the main spiral ganglion population<sup>23</sup> to provide optimal spectral coverage without increasing the risk of trauma or perceptual distortions reported with deeper insertions.<sup>26,27,28</sup>



Insertion Depth (° re: RW)

Results from Rivas et al. shows an insertion depth of 413°.20

#### COCHLEAR STRUCTURE PRESERVATION

Cochlear structure preservation allows for the best possible hearing outcomes in patients. Studies have shown that patients may perform better when cochlear structures are undamaged by the electrode insertion. 19,22,23,25 Recent evidence has demonstrated that the insertion of HiFocus SlimJ in combination with ECochG measurement may be accountable for the encouraging hearing preservation in most of the patients. 1



Histology showing HiFocus SlimJ electrode ideally positioned in the Scala Tympani (Eshraghi Scale '0')<sup>20</sup>



The HiFocus Mid-Scala electrode is the smallest styleted precurved electrode designed for consistency of placement in the scala tympani to avoid and protect the delicate cochlea structures.



## CONSISTENCY OF PLACEMENT

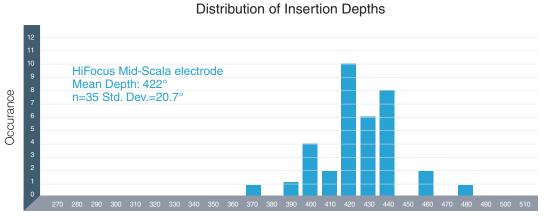
Key to the design are the precurved shape, allowing the HiFocus Mid-Scala electrode to be inserted consistently with minimal cochlea trauma,<sup>21</sup> a Straight Tip region to avoid tip fold overs, and if desired, the electrode can be loaded on a dedicated insertion tool to support a controlled insertion.

The HiFocus Mid-Scala electrode can be introduced into the cochlea by a surgeon's preferred approach—freehand or by use of the insertion tool. It can be inserted through the round window, extended round window, or small cochleostomy approach, requiring only a 0.8mm opening. The tip feature is intended to ease the insertion through the round window

The distal blue marker can be used to ensure the electrode is properly positioned prior to the off stylet technique, thus avoiding tip fold over issues. The proximal blue marker provides a visual indication of a 'full' insertion depth—representing approximately 420° angular insertion in a standard cochlea, covering the main spiral ganglion population<sup>25</sup> for optimal spectral coverage. The HiFocus Mid-Scala electrode can be inserted and reinserted up to three times.

## **OPTIMAL SPECTRAL COVERAGE**

The length and curvature of the HiFocus Mid-Scala allows for proven consistency of full spectral coverage of approximately 420° insertion depth signifying coverage of main Spiral Ganglion cell population<sup>25</sup> with a **tight standard deviation of 20.7**° without increasing the risk of trauma or perceptual distortions reported with deeper insertions.<sup>26,27,28</sup>

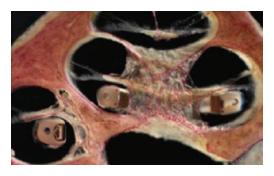


Insertion Depth (° re: RW)

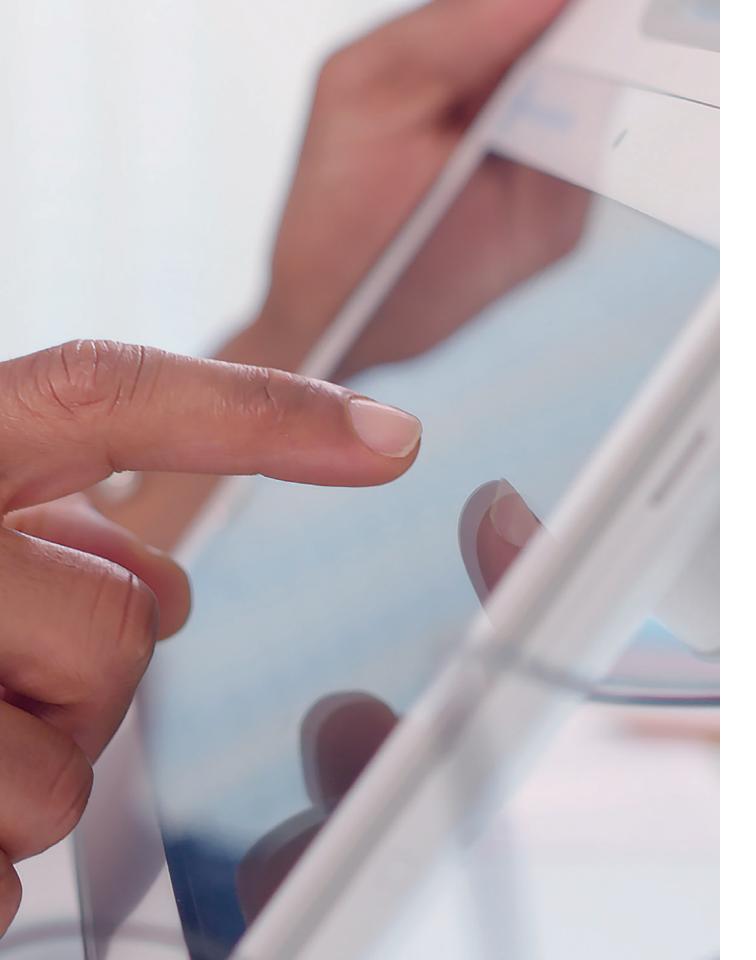
Graph showing angular insertion depths of HiFocus Mid-Scala across 35 samples<sup>17</sup>

## COCHLEAR STRUCTURE PRESERVATION

The shape of the HiFocus Mid-Scala places the electrode within the scala tympani, close to the spiral ganglion cells for maximum performance. The electrode dimensions easily fit within the scala tympani which has been shown to protect the delicate structures of the cochlea whilst avoiding damage to the modiolus, osseous spiral lamina and the basilar membrane. HiFocus Mid-Scala, being located central to perimodiolar, has an ideal basal placement for high frequencies.



Histology showing HiFocus Mid-Scala electrode ideally positioned in the middle of the scala tympani.





## The AIM System: Fast, Objective, Convenient

The AIM<sup>TM</sup> System was developed to help you better serve your cochlear implant patients with real-time ECochG measurement of cochlear functioning during electrode insertion, automated objective audiometry, and an objective measurements suite including Impedances, NRI, and eSRT.

#### REAL-TIME MEASUREMENT DURING CI SURGERY

The AIM System uses the implant to measure electrocochleography, or ECochG, potentials generated by the inner ear and the auditory nerve in response to acoustic stimuli. This continuous and real-time measurement during electrode insertion provides invaluable feedback. Studies suggest that ECochG measurement can be used to optimize the insertion of a lateral wall electrode and real time monitoring is the most effective approach for preservation of available hearing.<sup>24,31,32</sup>



## **AUTOMATED OBJECTIVE AUDIOMETRY**

Post-op, the AIM System continues to provide benefit. At the click of a button, it can perform objective audiometry from 125 Hz to 4000 Hz in seconds. This objective measurement requires no patient collaboration, helping you get the best possible results with all your patients. Studies indicate ECochG thresholds are positively correlated with behavioral audiometry thresholds (r=0.83;  $\pm 5-10$  dB).  $^{33,34,35}$ 

## COMPREHENSIVE OBJECTIVE MEASUREMENTS SUITE

Designed for intra-operative and post-operative clinical use, AIM can perform quick NRI, ESRT, Impedance measurements. Just like objective audiometry, these measures can also be conducted without patient interaction. The modern and intuitive user interface makes the AIM system easy to use by any trained healthcare professional. When the testing is done, the data can be exported, reviewed, or shared easily.

<sup>\*</sup> Product use and indication may vary. Please contact your local AB representative for regulatory approval and availability in your region.

# POWERFUL CONNECTIONS START HERE

Life is full of amazing moments. Moments that inspire, exhilarate, and connect, and your patients want to actively enjoy all of life's moments.

For over 25 years, Advanced Bionics has been the cochlear implant innovation leader. Now, in partnership with Phonak, one of the world's leading providers of hearing aid solutions, we are introducing our most advanced cochlear implant yet—Naída™ CI M sound processor, and the world's first CI solution dedicated to children and their needs—Sky CI™ M sound processor.

Leveraging the power of Phonak's Marvel Platform, Naída CI M and Sky CI M offer your patients a customizable hearing solution that is designed specifically for their unique journey—from baby to teen to adult, whether that's at work, at play, or while traveling.

With Naída CI M and Sky CI M, we welcome you and your patients to a world of powerful connections, today and into the future.



NAÍDA CI M SKY CI M







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