Surgeon's Manual for the

HiRes™ Ultra 3D

Cochlear Implant with the HiFocus™ SlimJ and HiFocus™ Mid-Scala Electrodes

Advanced Bionics

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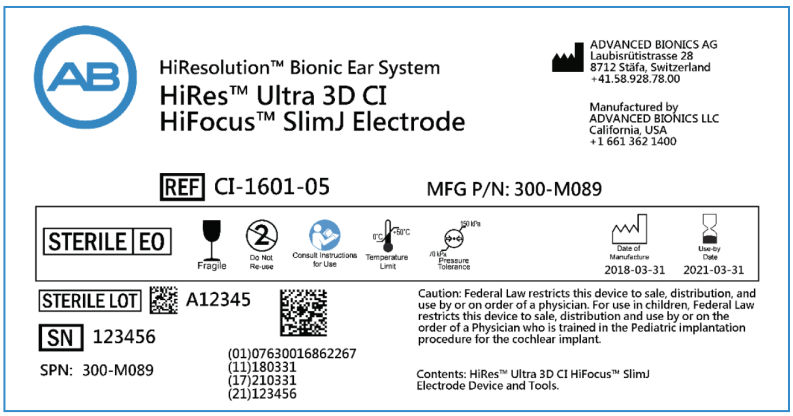
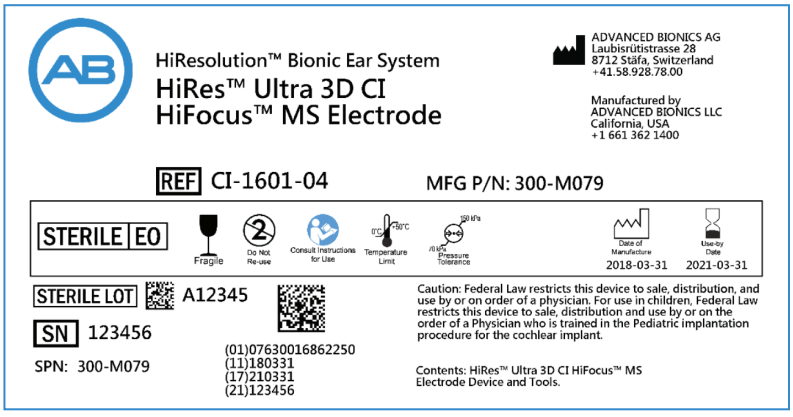
Labeling

Below is a sample of the device label for the HiRes™ Ultra 3D Cochlear Implant with HiFocus™ SlimJ Electrode.



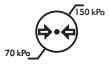
The maroon "SJ" sticker on the packaging identifies the HiFocus SlimJ electrode.

Below is a sample of the device label for the HiRes™ Ultra 3D Cochlear Implant with HiFocus™ Mid-Scala Electrode, also listed as HiFocus™ MS Electrode.



The orange "MS" sticker on the packaging identifies the HiFocus Mid-Scala electrode.

The symbols used on the labeling and their meanings are as follows:

CAUTION: Federal law restricts this device to sale, distribution, and use by or on the order of a physician.	
	Model number
	Serial number
	Date of manufacture
	Manufacturer
	Sterile Lot Number
	Ethylene oxide sterilized
	Use By Date
	Suitable for atmospheric range between 70 kPa and 150 kPa, which is equivalent to altitude 3000 m above sea level and 5 m depth underwater.
	Temperature product should be stored at
	See instructions for use
	Fragile
	Single-use only, do not resterilze product
	MR Conditional: Specific circumstances are required for the patient to undergo an MRI procedure with this device in place. See complete Instructions for Use for details
	Unique Device Identifier

Introduction

This manual describes the HiRes™ Ultra 3D Cochlear Implant with the HiFocus™ SlimJ and HiFocus Mid-Scala electrodes, and the procedures associated with its implantation in both children and adults. Refer to the implant Instructions for Use, for warnings, contraindications, precautions and information on the system.

Prior to implantation of the HiRes Ultra 3D implant and the electrode, it is highly recommended that the surgeon receive training through Advanced Bionics or a medical professional experienced with the device. Please contact your Advanced Bionics representative for further information.

HiRes Ultra 3D Implant Description

The HiRes Ultra 3D implant, also referred to as an Implantable Cochlear Stimulator, or ICS, is composed of materials that have been thoroughly tested for biocompatibility. The implant includes a magnet and electronics.

The implant electronics are contained within a hermetically sealed titanium case with a removable magnet and telemetry coil attached and encased in silicone. The overall dimensions are 25 mm wide at the case, 28.5 mm wide at the antenna by 56.2 mm in length.

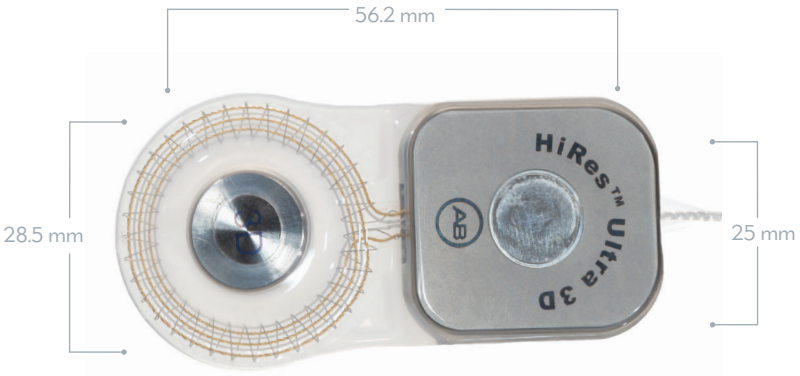


Figure 1-1.
HiRes Ultra 3D implant overall dimensions.

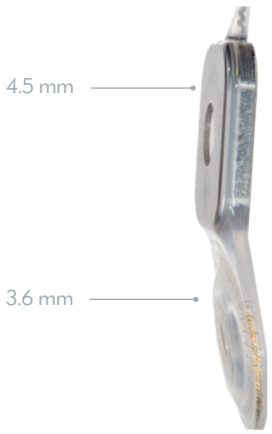


Figure 1-2.
HiRes Ultra 3D side dimensions.

The HiRes Ultra 3D System also features bi-directional telemetry. This allows the clinician to verify the integrity of the implanted electronics before, during, and any time after surgery. Information is sent from the implant back to the external components through the same inductive coupling that allows the sound signal to be transmitted from the external components to the implant.

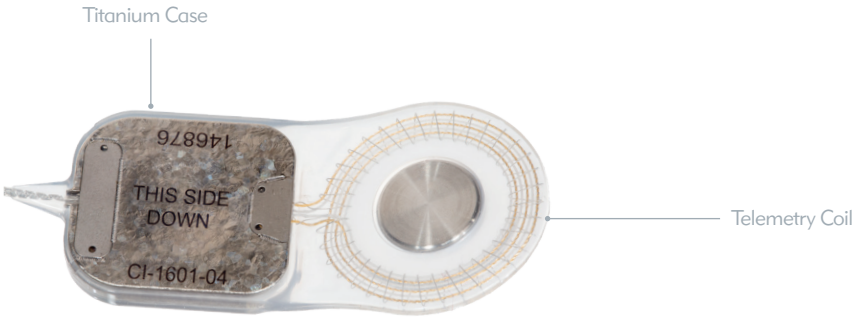


Figure 1-3.
HiRes Ultra 3D implant, reverse back.

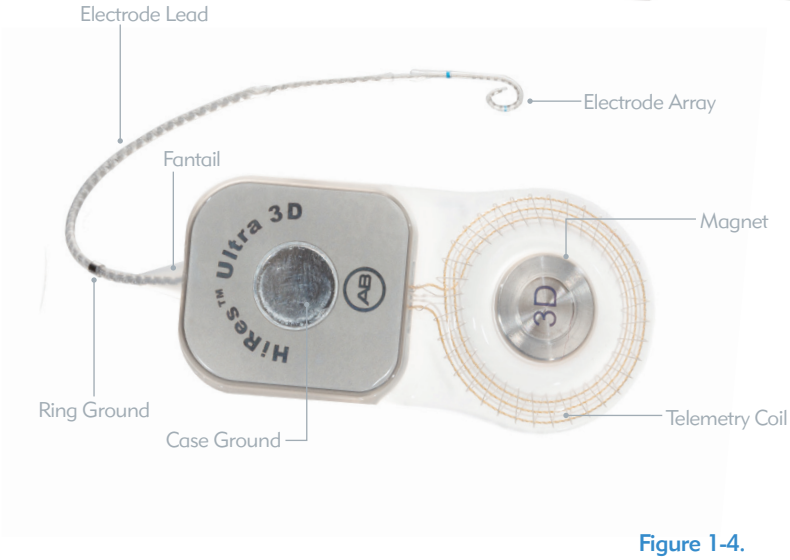


Figure 1-4.
HiRes Ultra 3D implant with HiFocus SlimJ and HiFocus Mid-Scala electrode arrays.

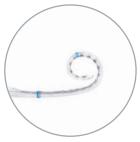


Figure 1-5A.
HiFocus Mid-Scala electrode array

Figure 1-5B.
HiFocus SlimJ electrode array.

Implant Specifications

Electronic Technical Specifications	
Information Update Rate	90 kHz
Stimulation Rate	Up to 83,000 pps (software limited)
Independent Output Circuits	16
Spectral Bands	Up to 120 sites of stimulation (software limited)
Communication Link	Bi-directional inductive link
IntelliLink™ Safety Feature	Implant and processor association
Diagnostics	Neural response imaging (NRI), impedance measurements, ESRT, integrity testing
ADC Resolution Sampling Rate	Resolution: 9 bits
	Sampling Rate: 25 KHz
Pulse Amplitude	0-2040 µA
Pulse Width	10.78-229 µS
Impedance Accuracy	2.5 kohm
Stimulation Configuration	Monopolar

Implant Materials and Dimensions	
Titanium Case	4.5 mm thick
Housing	25/28.5 mm x 56.2 mm flexible silicone
Weight	11 grams
Volume	4800 mm^3 (Housing and Telemetry Coil)
Magnet	Can be left in place for 1.5T and 3.0T MRI scans See MRI Safety Information document
Telemetry Coil	Gold-braided wire and platinum-shield wire in flexible silicone Reinforced with high-density polymer fiber
Ground	2 – Case Ground and Ring Ground
Impact Resistance Value	Exceeds the impact requirements specified in EN45502-2-3:2010
Pressurized Environment Information	Can withstand a pressure up to a depth of 42m under water (138 feet) or a gauge pressure of 4ATM (413 kPa)
Electrode Technical Specifications	
HiFocus Electrodes	HiFocus SlimJ HiFocus Mid-Scala
Electrodes	16 platinum contacts
	Platinum–iridium wires
	Flexible silicone carrier
	Integrated ground on lead (Ring Ground)
Minimum Exposed Contact Area	0.12 mm^2
Contact Spacing	HiFocus SlimJ 1.3 mm HiFocus Mid-Scala 0.975mm
Active Length	HiFocus SlimJ ~20 mm HiFocus Mid-Scala ~15 mm
Insertions	3 Maximum (for both HiFocus SlimJ and HiFocus Mid-Scala)
Forceps	Yes – Optional (for HiFocus SlimJ)
Insertion Tool	Yes – Optional (for HiFocus Mid-Scala)
Reloadable	Yes - 2 Maximum (for HiFocus Mid-Scala)

HiRes Ultra Reusable Surgical Tool Kit, CI-4509

The HiRes Ultra Reusable Surgical Tool Kit includes tools and templates for placement of the HiRes Ultra implant package (Figure 1-6). **These tools must be sterilized prior to use. See the *"Guide for Reprocessing HiRes Ultra Reusable Tools"* provided in the kit.**

The kit contains the following tools and templates:

- Two HiRes Ultra BTE Templates, CI-4421
- Two HiRes Ultra Recess Gauges, CI-4331
- Two HiRes Ultra Coil Gauges, CI-4341

Figure 1-6.
HiRes Ultra Reusable Surgical Tool Kit, CI-4509

Figure 1-7.
Contents of the HiRes Ultra Reusable Surgical Tool Kit, CI-4509.

HiRes Ultra 3D Implant Packaging and Handling

One sterile, silicone, single-use HiRes™ Ultra Mock-up, CI-4426, is provided with the HiRes Ultra 3D Implant, CI-1601-04, located in a separate pre-sterilized peel pack inside the packaging (Figures 1-8A).

Figure 1-8A.
HiRes Ultra Mock-up provided with the implant package.

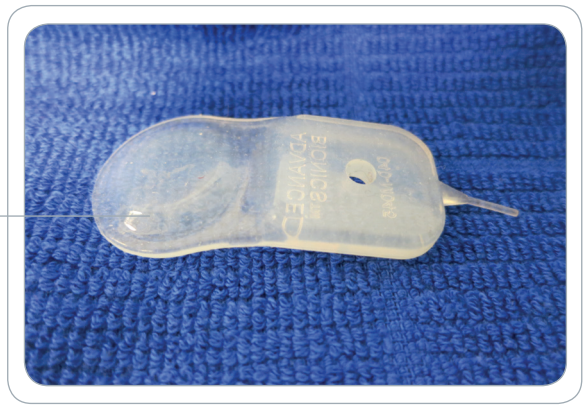


Figure 1-8B.
HiRes Ultra Mock-up, CI-4426

It is important to understand the different levels of HiRes Ultra 3D implant packaging, both sterile and non-sterile, in order to appreciate the care that must be taken in opening the packaging and removing the implant device from its tray.

There are four levels of packaging: 1. the sleeve, 2. the outer box, 3. the outer tray, and 4. the inner sterile tray.

The HiRes Ultra 3D implant packaging contains a sleeve with labeling that indicates the following:

- Implant serial number
- Model number
- Sterilization lot number
- Sterilization expiration date
- Date of manufacture
- Basic handling information
- Electrode Type

An explanation of the product labeling is presented in the Labeling section. This labeling is included on the three outer levels of packaging. The sleeve is non-sterile and is used for handling and shipping (Figure 1-9A).

The tamper-proof seals must be broken to access the outer box. The outer box is also non-sterile and has a pre-formed liner that supports the sterile outer tray contained within (Figure 1-9B).

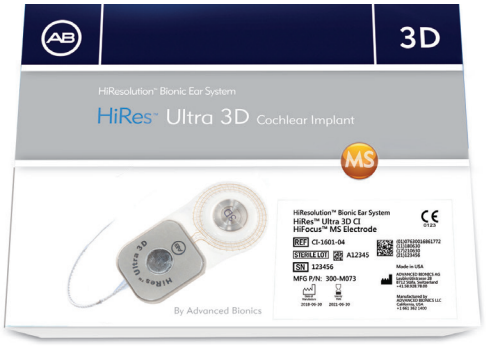


Figure 1-9A.
Implant Package sleeve.

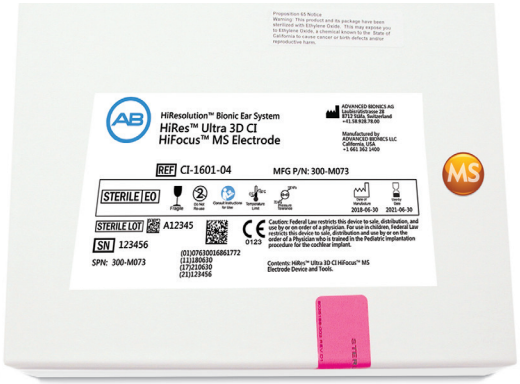


Figure 1-9B.
Implant Package outer box.

The tamper-proof seals on the *outer* box must be broken to access the *outer* tray. The *outer* tray may be handled in a non-sterile environment **(Figure 1-9C)**.

When you are ready to use the implant, slowly peel back the cover of the *outer* tray to access the *inner* sterile tray. The sterile tray must be handled within a sterile field. Extra care in handling the HiRes Ultra implant outer and inner trays in the operating room is essential to avoid the buildup of static charge on the implant **(Figure 1-9D)**.

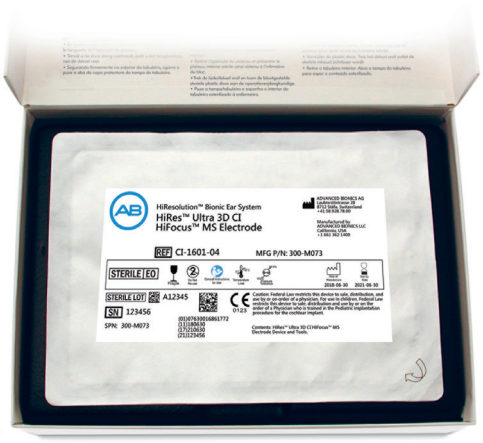


Figure 1-9C.
Implant Package, outer tray.

Figure 1-9D.
Implant Package, inner tray.

CAUTION: Peeling the cover off the outer or sterile tray too quickly or sliding the HiRes Ultra 3D implant device package across a table can increase static charge buildup.

To avoid static charge buildup, use the following method when removing the implant from its sterile inner package:

- Slowly lift and peel open a corner of the inner sterile tray and pour in sufficient sterile saline to flood and cover the implant device (Figures 1-10A-D).

Figure 1-10A.
Slowly open the HiRes Ultra 3D implant device outer tray package. Lift the sterile tray package out.

Figure 1-10B.
Flood the sterile tray package with saline and slowly lift the top cover off the sterile tray.

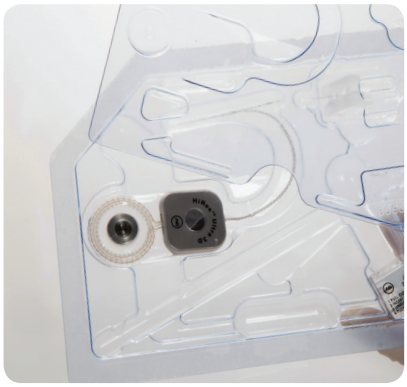


Figure 1-10C.
Remove the plastic lid frrom the sterile tray

Figure 1-10D.
The HiRes Ultra 3D implant is ready for the surgeon. (HiFocus Mid-Scala electrode, with reloading tool and stylet shown).

Following is an alternate method for opening the HiRes Ultra 3D implant package (Figure 1-11A-G).

- Place the inner sterile tray in a bath of sterile saline and slowly lift the top of the tray off to open the package.

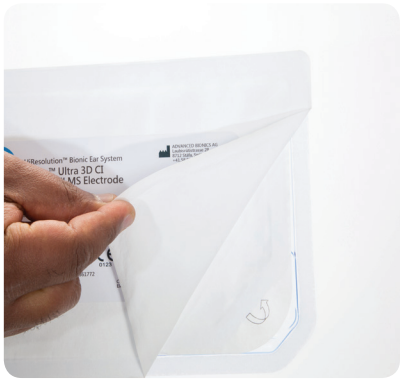


Figure 1-11A.
Slowly open the outer tray package.

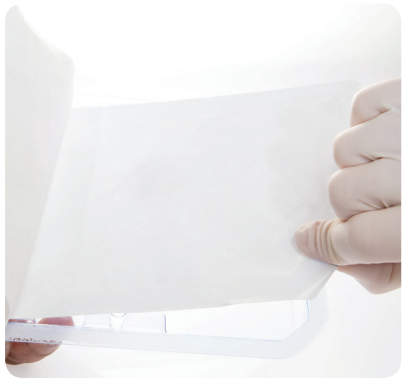


Figure 1-11B.
Lift out the inner sterile tray package.

Figure 1-11C.
Submerge the inner sterile tray package in a basin filled with sterile saline.

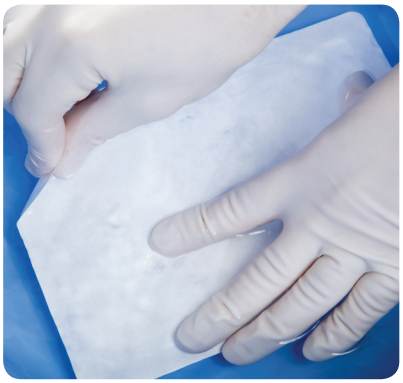


Figure 1-11D.
Slowly lift the top cover off the sterile tray package to flood the inner tray with saline.

Figure 1-11E.
Slowly open the inner sterile tray package.

Figure 1-11F.
Remove the inner sterile tray package cover.

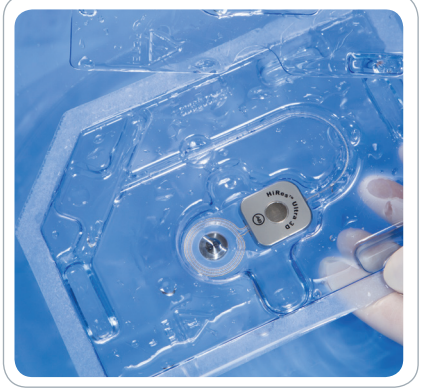


Figure 1-11G.
Lift the plastic lid, covering the tools and implant, out of the sterile tray (HiFocus Mid-Scala electrode, with reloading tool and stylet shown).

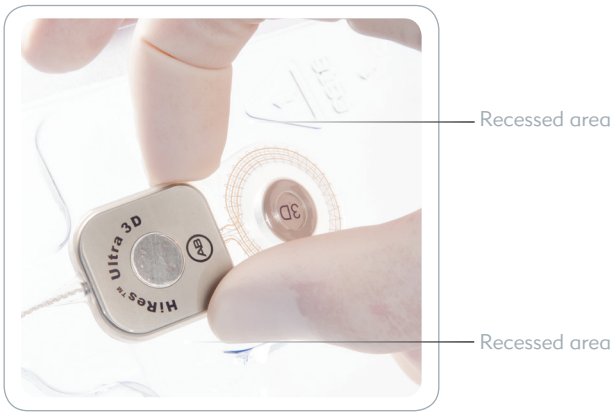


Figure 1-12.
The implant tray includes a recessed area on either side of the device that allows the implant to be picked up easily.

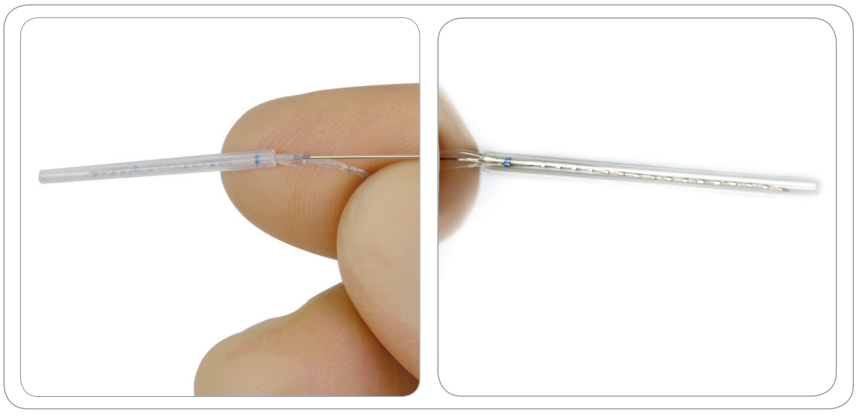


Figure 1-13.
Receive the HiRes Ultra 3D with HiFocus Mid-Scala electrode for implantation.

Figure 1-14
Receive the HiRes Ultra 3D with HiFocus SlimJ electrode for implantation.

CAUTION: Switch to a backup device if any damage to the device is noted during surgery.

Preoperative Considerations

Ear Selection

Based on both medical and audiological findings, the surgeon and audiologist together determine the ear most appropriate for implantation. The following hierarchy of considerations is recommended.

- **Cochlear patency and the scala tympani:** The ear with the least cochlear ossification and the most normal-appearing scala tympani, according to radiographic evidence, is given primary consideration and takes precedence over other factors. *Magnetic resonance imaging may be used if necessary to determine the degree of cochlear patency (see Instructions For Use for more information).*
- **Duration of hearing loss:** If one ear has sustained deafness for a longer period of time than the other ear, the ear with the most recent onset of deafness is usually selected.
- **Age at onset of deafness:** In adults, ears that are prelingually or congenitally deafened generally should not be implanted. In children, ears that have been prelingually or congenitally deafened may be implanted.
- **Electronystagmography:** May be used in adults to determine vestibular function of both ears.
- **Patient preference:** If both ears are equivalent in all regards, the patient's or parents' preference should be the determining factor in selecting the ear for implantation.

Imaging

CT (Computerized Tomography) should be used to obtain a cross-sectional view of the left and right cochlea, mastoid cavity, and other critical landmarks (i.e., jugular bulb, internal auditory canal and sigmoid sinus) **(Figure 2-1)**. Selection of the ear to be implanted should consider any structural abnormality and/or ossification found through radiographic procedures. In some patients, Magnetic Resonance Imaging (MRI) may be helpful in identifying congenital malformations, fibrosis, or early stages of ossification within the scala tympani **(Figure 2-2)**.

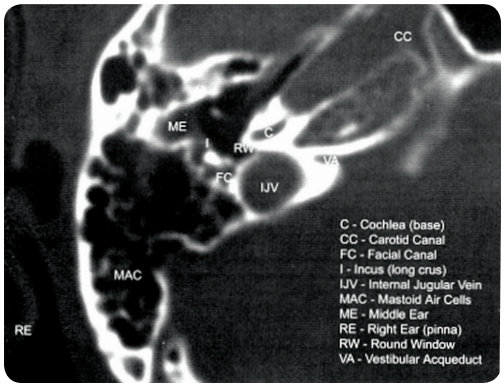


Figure 2-1.
CT Scan, Right Ear (axial view).

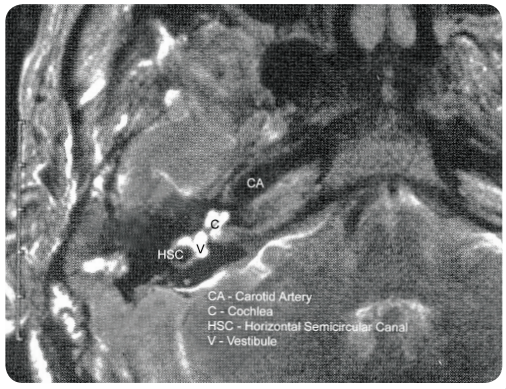


Figure 2-2.
MRI Scan, Right Ear (axial view).

Initial Surgical Procedures

Surgical implantation of the HiRes Ultra 3D implant typically takes from two to three hours, depending on the anatomical features encountered in each patient. The surgery is performed under general anesthesia following routine preparatory procedures and preoperative medication. Surgeons typically elect to utilize perioperative systemic antibiotics. The transmastoid facial recess approach is used to expose the basal scala tympani for insertion of the electrode array.

Surgeons are encouraged to utilize facial nerve monitoring in order to reduce the potential for facial nerve injury.

Preparation and Implant Positioning

The patient is placed in the supine position. The scalp is shaved and prepped to accommodate the incision. To ensure integrity of the operative field, drapes are secured into position. Accurate placement of the incision and the device is accomplished with use of the BTE (Behind-the-Ear) Template. It is vital that additional space is left between the pinna and the implant to permit the use of the BTE sound processor.

The implant should be placed on a flat and smooth surface. Usually, the device is placed between 45° and 60° to the temporal line (Figure 3-1). Care should be taken as skin erosion or implant migration/extrusion may occur if positioning of the device interferes with use of the BTE processor and headpiece. If the implant cannot be completely supported by bone in a conventional position, a more vertical or oblique placement of the device should be considered. The position of the implant should be determined as closely as possible prior to making the skin incision. Rotation of the implant from a horizontal to a more vertical position may require modification of the "typical" incision.

Using the BTE Template, mark the location on the skin where the back edge of the BTE package will be. This will be used as a guide during the initial phases of location and creation of the incision (Figure 3-2).

Figure 3-1.
A typical implant position.

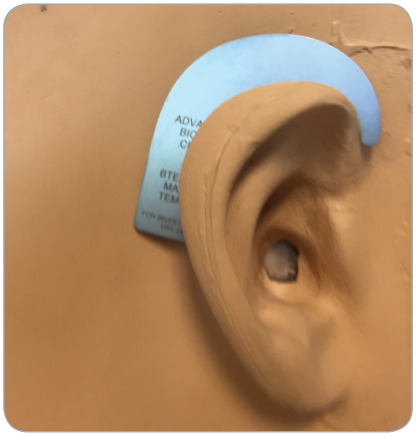


Figure 3-2.
Use the HiRes Ultra BTE Template, CI-4421, to mark the location for the receiver package.

Use the Coil Gauge to locate the edge of the titanium case at the mark left in the previous step (Figures 3-3, 3-4). Ensure implant will not be under the BTE Template. Use a marker and create dot through hole in Coil Gauge.

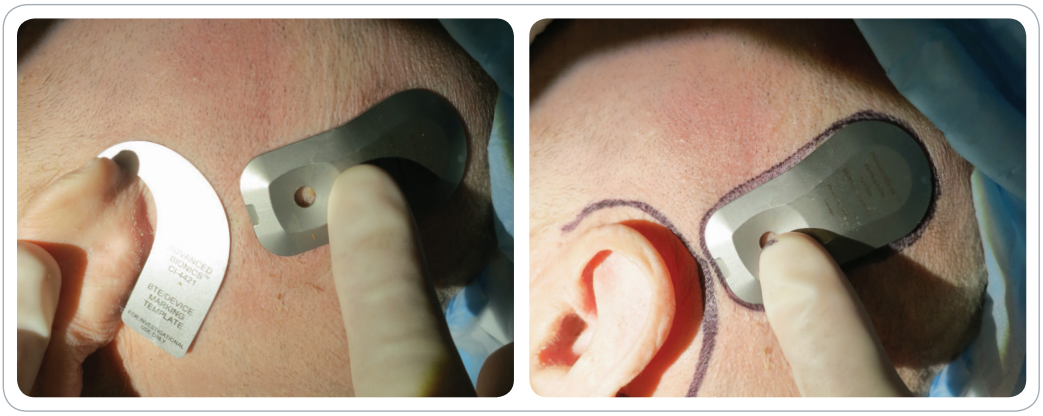


Figure 3-3.
Place the HiRes Ultra Coil Gauge, CI-4341, in a position where the electrode lead exits toward the proposed mastoidectomy location.

Figure 3-4.
Use the HiRes Ultra Coil Gauge, CI-4341, to draw an outline. Mark skin through hole.

Incision

Using a marker, draw an incision line with sufficient clearance to allow for some change of position if necessary. Some surgeons choose to inject a local anesthetic with epinephrine along the incision line. The following should be considered:

- The implant must not lie under the pinna. Space between the pinna and the implant receiver should be allowed to permit the comfortable use of the BTE sound processor.
- The incision line should be at least 1.5 cm away from the implant to minimize the risk of device extrusion or postoperative infection.
- The scalp incision should be kept within the hairline, if possible.
- The length of the incision, as well as the location of the incision itself, are decisions each surgeon must consider.

Two frequently used incision lines are illustrated in Figure 3-5.

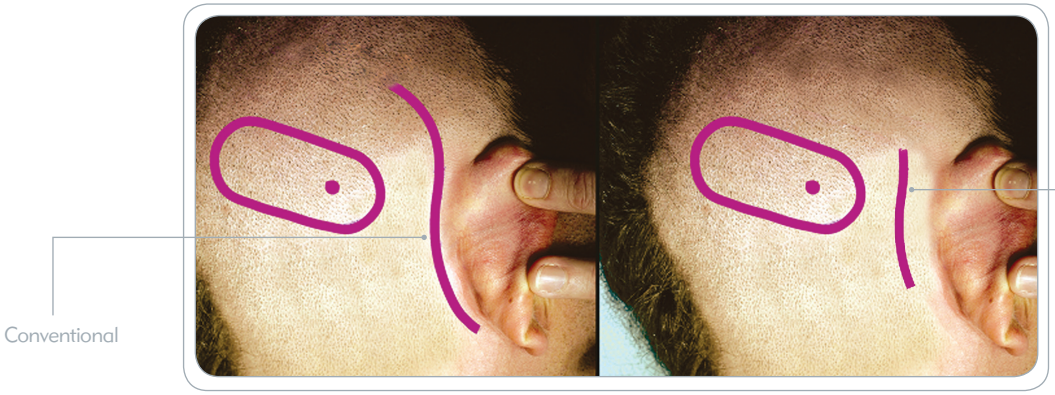


Figure 3-5.
Typical incision lines.

The length of the incision line will be determined by the surgeon and may range from a 4-6 cm-long incision behind the pinna to a 15 cm (conventional) postauricular incision that extends posterosuperiorly on the scalp. Incision is typically 2 mm to 10 mm behind the Sulkus.

Keep the following key recommendations in mind:

- Place the receiver package to match location marked on skin.
- The implant is usually placed between 45° and 60° to the temporal line, although some cases may warrant a more vertical implant placement.
- Maintain adequate visibility and access for developing the required ramped recess.
- The optional use of sutures-to-bone can provide additional fixation for the implant..

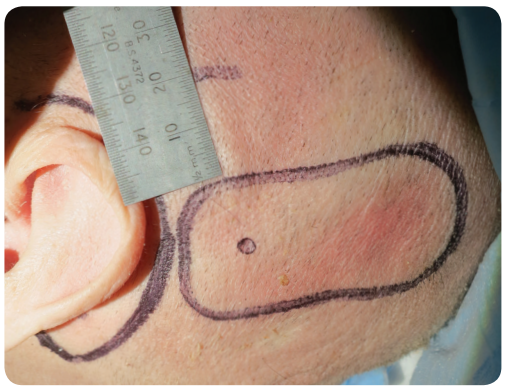


Figure 3-6.
The incision line should be at least 1.5 cm away from the implant.

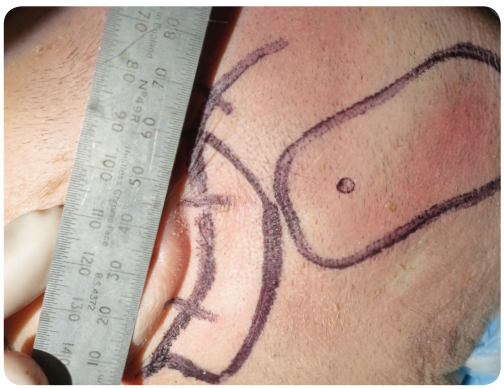


Figure 3-7.
Completed incision line. The scalp incision may be extended posterior-superiorly if it is necessary to thin the scalp flap.

Most surgeons choose to inject local anesthetic along the incision line.

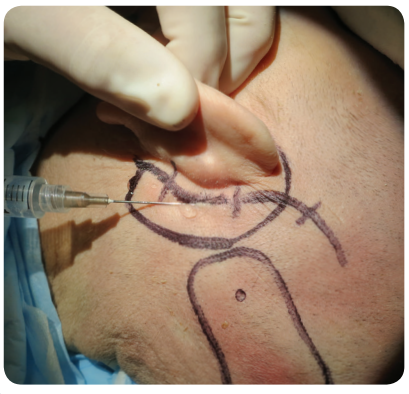


Figure 3-8.
Inject with a local anesthetic.

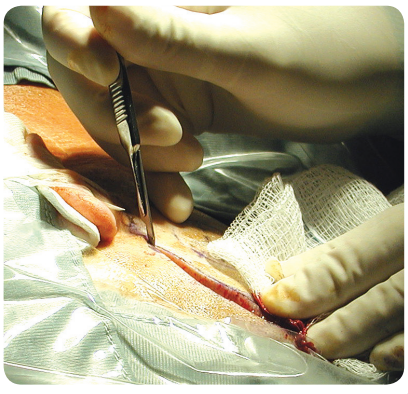


Figure 3-9.
Incision.

In developing the skin flap, keep the following points in mind:

- Maintain hemostasis with skin clips, sutures, and/or electrocautery **(Figure 3-10)**.

CAUTION: Monopolar electrocautery must not be used when a patient has a cochlear implant in the opposite ear or during surgery once the implant is placed. For the use of bipolar electrosurgical equipment, the probe tips must not contact the implant and should be kept more than 1 mm (0.04 in) from the implant.

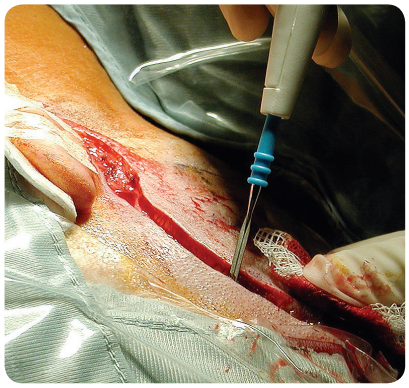


Figure 3-10.
Use electrocautery to control bleeding.

- Retain some muscle or fascia tissue for later packing of the cochleostomy site.
- A 5-7 mm skin flap is recommended. However, the system functionality of the implant/headpiece has been confirmed up up to a 10 mm range. Modification of the skin flap is at the discretion of the surgeon.
- Develop an anteriorly based pericranial flap splitting the fascia to provide additional protection for the implant. In young children, the skin/scalp flap typically is lifted as one layer. Prior to determining the length of the incision, the surgeon may wish to determine the thickness of the scalp flap at the site of the magnet telemetry coil.

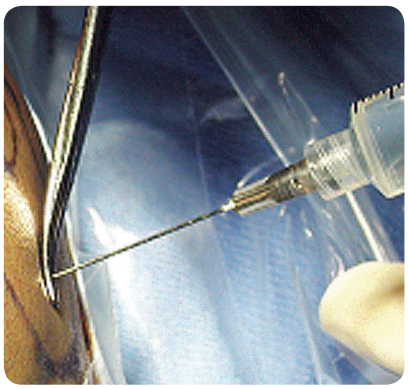


Figure 3-11.
Needle-syringe and hemostat through scalp flap at magnet site.

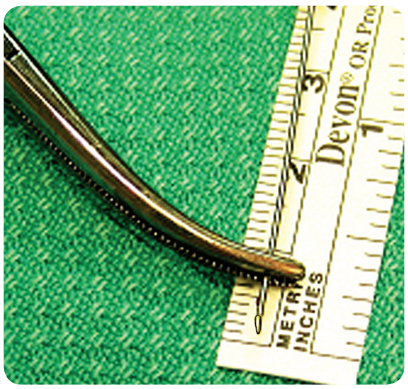


Figure 3-12.
Needle-syringe and hemostat adjacent to ruler to determine scalp thickness.

A conventional incision is recommended if the scalp flap needs to be thinned to 5-7 mm. Prior to using a minimal incision approach, the surgeon may need to verify the thickness of the scalp flap over the magnet telemetry coil.

A periosteal flap is created to cover the mastoid cavity opening.

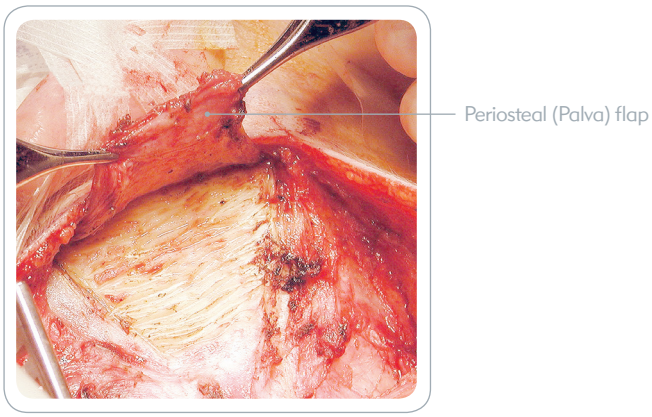


Figure 3-13.
Periosteal (Palva) flap to cover the mastoid cavity opening.

In children, where the postauricular flap is already thin, it is important to maintain the temporalis fascia and muscle as part of the posterior scalp flap. Typically, the entire scalp flap is elevated in one layer.

Modified Cortical Mastoidectomy

A modified cortical mastoidectomy is performed, and the middle ear and round window are exposed via the facial recess. The mastoid bone is excavated until an entrance can be made into the middle ear behind the posterior canal wall at the site of the facial recess. The edges of the mastoid cavity should not be saucerized. Bony overhangs are left superiorly, posteriorly and inferiorly to aid in retention of the coiled electrode lead.

When performing the cortical mastoidectomy in children, it is important to enlarge the cavity inferiorly to adequately accommodate the coiled electrode lead.

The facial recess is a triangular space bounded by the incus buttress superiorly, the facial nerve posteriorly, and the chorda tympani nerve anteriorly **(Figure 3-14)**.

Exposure of the middle ear through the facial recess should allow visualization of the round window **(Figure 3-15)**.

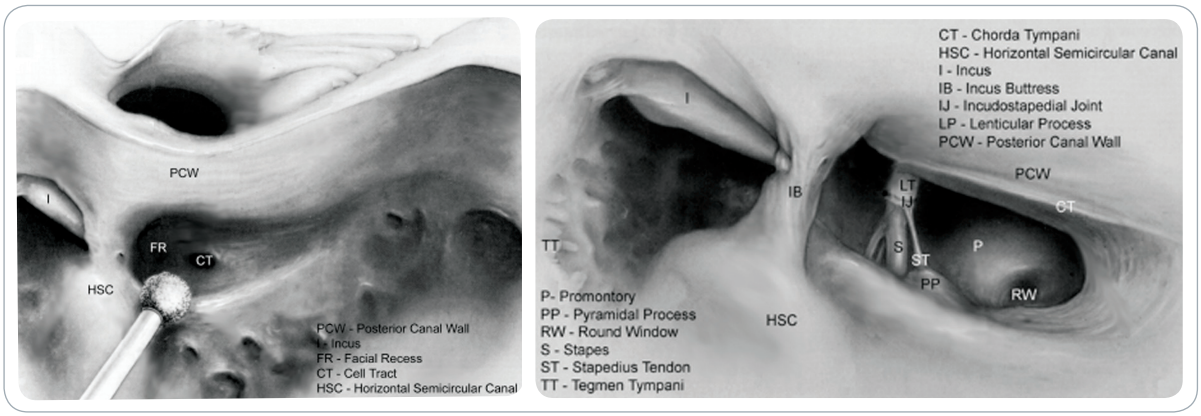


Figure 3-14.
Developing the facial recess. Right ear.

Figure 3-15
Exposure of the middle ear through the facial recess. Right ear.

The facial recess must be sufficient to accommodate the HiFocus electrode array being used.

After accessing the round window or cochleostomy site, surgeons typically keep the cochlea sealed while drilling a ramped recess and channel. Opening the cochlea after the Implant Placement and Stabilization steps in the following section helps to minimize bone dust and blood intrusion into the cochlea.

It is important to keep in mind that the implant should be placed so that there is sufficient distance from the mastoid cavity to accommodate the bony channel for the electrode fantail and proximal electrode lead including the Ring Ground (Figure 3-16).

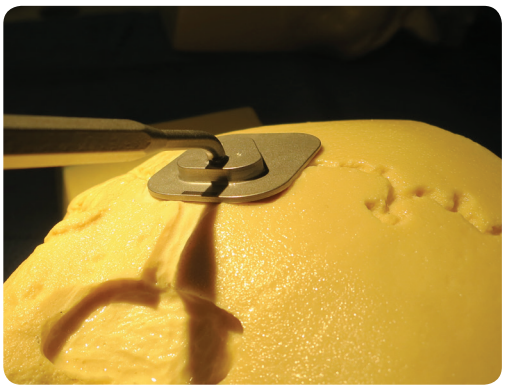


Figure 3-16.
Completed channel for the fantail and electrode lead.

Implant Placement and Stabilization

Ramped Recess and Suture Fixation

This alternate implant placement method includes the option of using sutures for additional fixation. The implant and electrode fantail must not be susceptible to movement along the surface of the skull. Thus the following steps are recommended:

Step 1: Locate and mark a ramped recess

Step 2: Verify sufficient skin-flap pocket space for the implant

Step 3: Drill a ramped recess for the titanium case

Step 4: Drill a straight channel for the electrode fantail and lead including the Ring Ground, below the lateral surface of the skull

Step 5: Drill tie-down holes for the implant

Step 6: Secure the Implant

Step 7: Open the round window or cochleostomy

Variables in the technique may be a consideration by surgeons and therefore each surgeon must consider how their particular modification(s) influences the successful long term implant longevity and reliability thus minimizing patient complications including replacement and/or revision. A goal of any effort to provide device stabilization is to provide mechanical stabilization, not soft tissue stabilization only.

CAUTION: Prior to placing the implant in the patient, ensure that electrocautery has been discontinued.

A ramped recess for the titanium case, a channel for the electrode fantail and lead, including the Ring Ground, as well as suture tie-down holes should be drilled in order to stabilize and protect the implanted device.

It is important to keep in mind that the implant should be placed so that there is sufficient distance from the mastoid cavity to accommodate the bony channel for the electrode fantail and proximal electrode lead including the Ring Ground **(Figures 4-1, 4-2)**.

CAUTION: Care should be taken to minimize bending, twisting or elongation of the fantail/lead/Ring Ground region during fixation of the device and subsequent placement of the electrode. Excessive manipulation may lead to damage to the electrode lead wires.

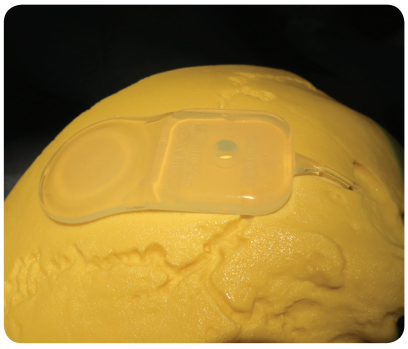


Figure 4-1.
Electrode fantail exit region.

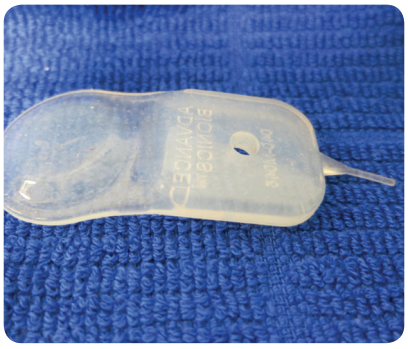


Figure 4-2.
HiRes Ultra Mock Up (Located in separate pre-sterilized peel pack inside implant packaging). Note short silicone lead exit.

Step 1: Locate and mark a ramped recess for the titanium case.

Locate the bone directly under the skin/muscle flap where the front (anterior/inferior) edge of the implant location was previously drawn on the skin. Mark the bone at this location.

An optional method is to measure 3.5 cm from the posterior canal wall (typical distance for adults – young pediatric patients will be closer) and mark the bone.

An additional option is to place the skin tissue back into the original location (pulling the skin incision together) and then place a very small sterile needle through the skin at the location of the front (anterior/inferior) edge of the implant and onto the underlying periosteum/bone. Once located mark the site on the periosteum/bone.

Step 2: Verify sufficient skin-flap pocket space for the implant.

Use the HiRes Ultra Coil Gauge, CI-4341, and/or the silicone HiRes Ultra Mock Up, CI-4426 (located in a separate pre-sterilized peel pack inside the implant packaging), to verify that there is sufficient space to place the coil/antenna end of the implant in the pocket under the skin/muscle flap.

Be careful to ensure there is no pressure or resistance to sliding in the Coil Gauge or silicone Mock Up into position.

Create a pocket for the device sufficient to place the proximal end (lead exit or anterior/inferior portion) of the coil gauge or silicone mock up sufficiently under the skin flap to find the mark from the previous step. This provides adequate distance to ensure proper device positioning versus the external processor and headpiece.

Draw or mark the length of the proximal end (lead exit or anterior/inferior portion). This creates important information for the following step. If using the Coil Gauge mark the location of the electrode fantail portion toward the mastoidectomy. If using the silicone Mock Up mark the outer shape of the electrode fantail exit toward the mastoidectomy.

NOTE: It is recommended that the Ring Ground on the lead is placed on the bone to ensure proper contact with the soft tissue. The Ring Ground is used to conduct objective measures.

Once located and confirmed remove the Coil Gauge or silicone Mock Up.

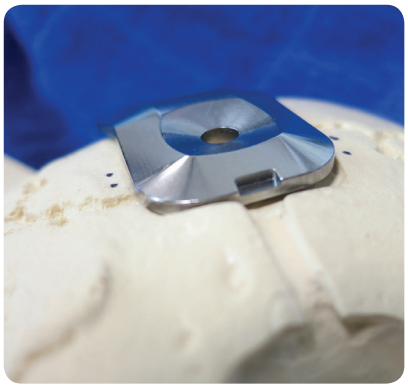


Figure 4-3.
HiRes Ultra Coil Gauge, CI-4341 Electrode Fantail exit width is marked in center of gauge.

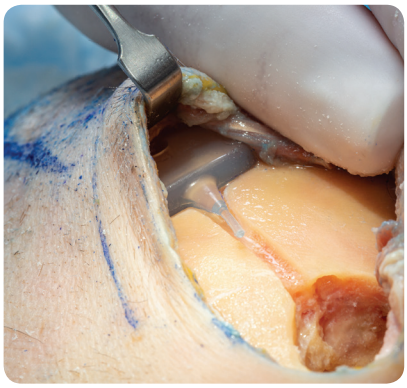


Figure 4-4.
HiRes Ultra Mock Up (Located in separate pre-sterilized peel pack inside implant packaging). **Note** short silicone lead exit.

Step 3: Drill a ramped recess for the titanium case.

Using the HiRes Ultra Recess Gauge, CI-4331, place it on the bone in the location previously determined by lining up the proximal (anterior/inferior) edge on the previously drawn line. It is important to maintain it parallel to the line and to be within the width of the line.

This allows the ramped recessed bed to be in the correct orientation for proper alignment based on the pocket created for the coil/magnet location.

Once located draw a line along both sides of the HiRes Ultra Recess Gauge, CI-4331, and along the front if necessary. Mark the location of the electrode fantail exit if not already accomplished.

Figure 4-5.
Drawing line on sawbone.

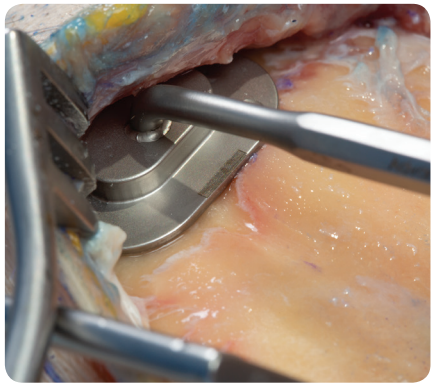


Figure 4-6.
Drawing line on skull.

The HiRes Ultra Recess Gauge, CI-4331, is 1 mm thick at the anterior/inferior edge and tapers away in the posterior/superior direction. This will allow creation of a ramped recess not exceeding 1 mm thickness.

In some situations, especially the young pediatric patients, the maximum recess will be less than 1 mm. In these patients, extreme care must be taken to avoid injuring the dura while creating the recess and tie-down holes. Some surgeons may wish to expose dura with a diamond burr around the anterior/inferior end of the recess.

NOTE: The dimensions of the HiRes Ultra Recess Gauge, CI-4331, is slightly larger than the titanium case of the implant.

Failure to create a recess in the mastoid cortex may also cause a slightly higher device profile or allow the implant to migrate, potentially leading to (but not limited to) device extrusion, patient pain, electrode array backing out of the cochlea or skin flap erosion.

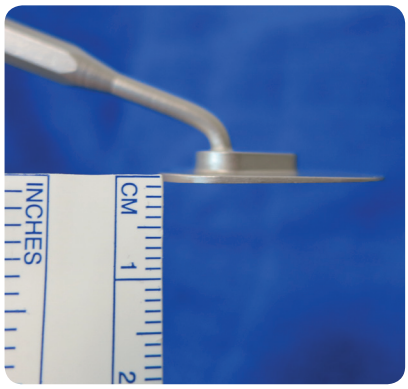


Figure 4-7.
HiRes Ultra Recess Gauge side view (with measurement in mm).

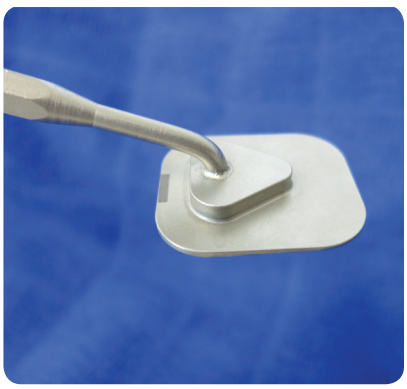


Figure 4-8.
HiRes Ultra Recess Gauge and Electrode Fantail Exit identified.

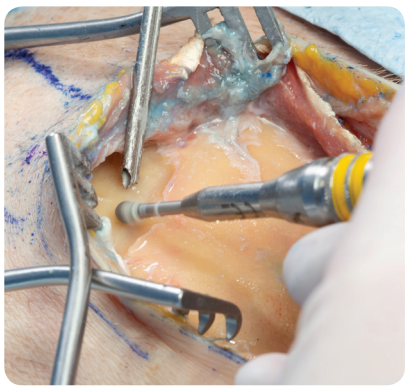


Figure 4-9.
Ramped recess bed.

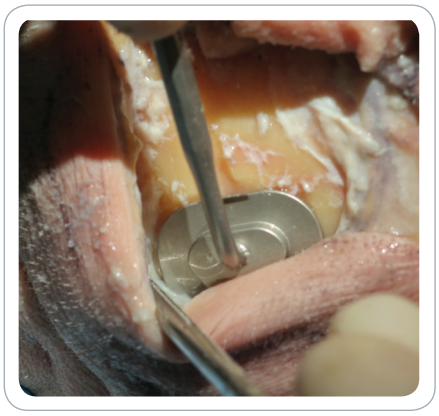


Figure 4-10.
HiRes Ultra Recess Gauge Verifying Dimensions of Recess.

Step 4: *Drill a channel for the electrode fantail and lead.*

To secure and protect the electrode fantail and electrode lead (including the Ring Ground) as it exits the implant, a straight channel or groove should be created between the implant and the mastoid cavity. Additionally, slight undercuts of this channel, as it enters the mastoid cavity can also aid in securing the coiled lead.

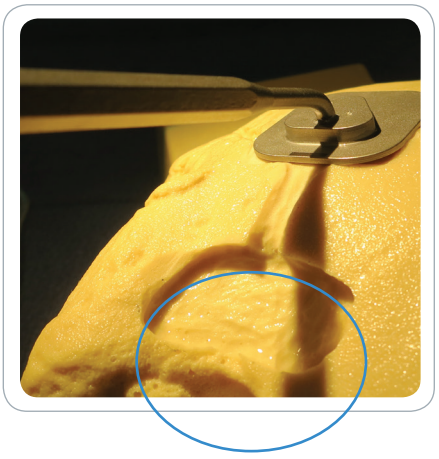


Figure 4-11.
Undercut channel end into the mastoid cavity.

Step 5: *Drill tie-down holes for the implant*

The optional use of sutures-to-bone can provide additional fixation for the implant. After seating the implant in its ramped recess, the device should be secured with non-absorbable sutures to bone. Tie-down holes should be drilled so that the sutures can be placed across approximately 1/3 to 1/2 of the distance from the anterior/inferior (electrode lead exit end) titanium case portion of the implant.

CAUTION: The suture shall not be placed directly over the fantail portion of the electrode lead. Damage can occur to the electrode lead wires or attachment location into the implant.

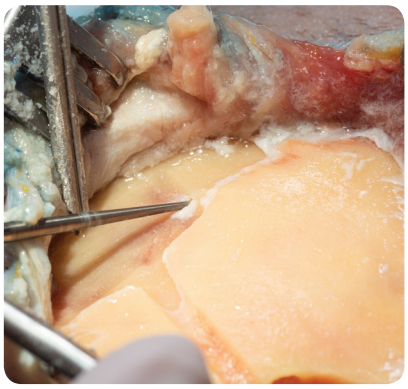


Figure 4-12.
Classic two holes.

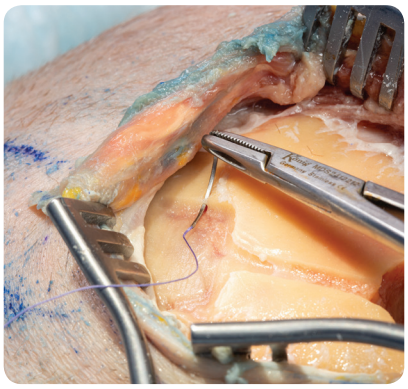


Figure 4-13.
Single hole through the side wall.

Step 6: Secure the Implant

Implant Fixation

The implant and electrode fantail must be fit securely within the ramped recess and channel previously created. The implant should be stable and sufficiently recessed to avoid a high profile. This is important in order to minimize damage to the electrode lead wires. Stabilization of the implant receiver also reduces the possibility of postoperative receiver migration, extrusion, and/or skin-flap erosion. It is best to secure the implant in place prior to insertion of the electrode array because it allows for easier handling of the electrode insertion tool.

Place sutures into position before placing the implant into the ramped recess.

CAUTION: While placing the implant into position, ensure that the electrode array is also guided into position. For the HiFocus Mid-Scala electrode, additional care should be taken when guiding the electrode due to the presence of the (stiff) stylet and any resulting elongation/twisting of the electrode lead.

CAUTION: Care should be taken to minimize bending, twisting or elongation of the fantail/lead/Ring Ground region during fixation of the device. Excessive manipulation may lead to damage to the electrode lead wires.

Using the tie-down holes previously drilled, sutures are placed across the titanium case portion of the implant. Suturing directly on any portion of the electrode lead or fantail must be avoided.

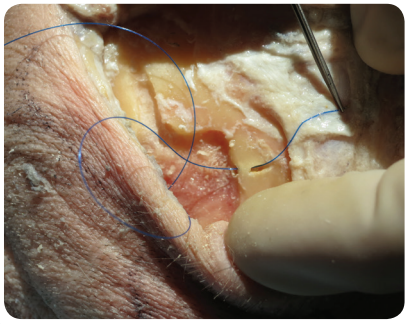


Figure 4-14.
Placing sutures.

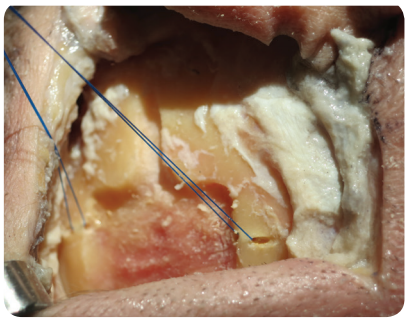


Figure 4-15.
Sutures in place.

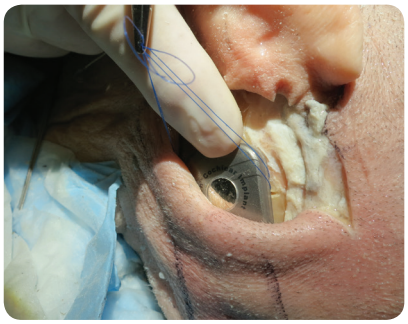


Figure 4-16.
Slide the implant under the suture.

Verify that suture knots are placed to the side of the implant. Any excess suture, after being trimmed, should be kept from potentially irritating the skin flap.

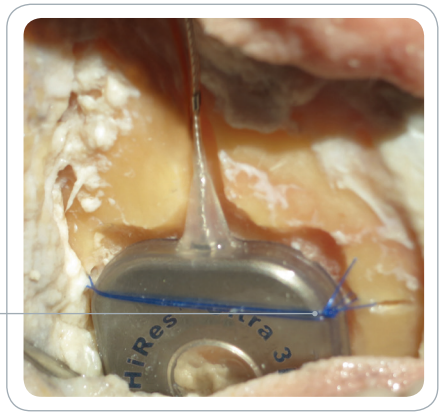


Figure 4-17.
HiRes Ultra 3D implant suture in place. **Note** the implant, electrode fantail, and Ring Ground are fit securely within the ramped recess and channel, and the suture knots are at the side of the implant.

Step 7: Open the round window or cochleostomy

Round Window Membrane Approach

The HiFocus SlimJ and HiFocus Mid-Scala arrays can be inserted through a conventional cochleostomy, the round window or a modified (extended) round window approach.

> **CAUTION:** If the diameter of the conventional cochleostomy, round window or a modified (extended) round window approach is not the required 0.8 mm minimum size, pressure can be exerted on the electrode array during insertion. This pressure can cause damage to the electrode array or result in an incomplete insertion.

Prior to insertion of the electrode, any bony lip covering the round window niche must be removed in order to expose the round window membrane **(Figure 4-18)**. Care must be taken to avoid damage to the round window membrane until entry into the scala tympani is desired.

Cochleostomy

Using a rotating micro bur, a fenestra is created into the basal scala tympani just inferior and slightly anterior to the round window membrane leaving minimal bone between the round window membrane and cochleostomy, exposing the first turn of the cochlea, and avoiding the hook region **(Figure 4-19)**.

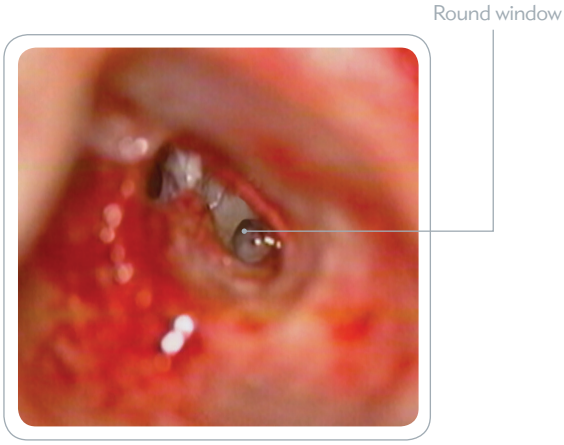


Figure 4-18.
Clearly expose the round window. Right ear.

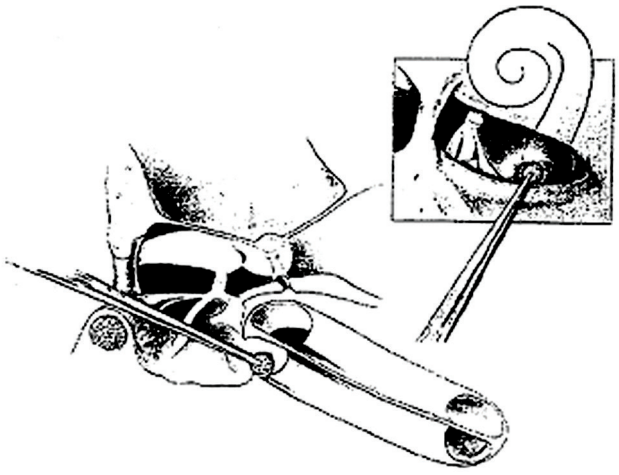


Figure 4-19.
Cochleostomy drilling. Right ear.

If a *soft* cochleostomy approach is elected, the surgeon will use a micro bur to remove the bone and open the cochlear endosteum with a fine pick and other instructions.

Exposure of the scala tympani may reveal ossification, requiring removal with a drill in order for electrode insertion to proceed. In a partially ossified cochlea, it may be necessary to drill more extensively before a patent channel is encountered. The first turn of the scala tympani is readily seen if the cochlea is not ossified.

CAUTION: If the diameter of the cochleostomy is too small, pressure can be exerted on the electrode itself at the time of insertion. This pressure can result in electrode array damage or an incomplete insertion.

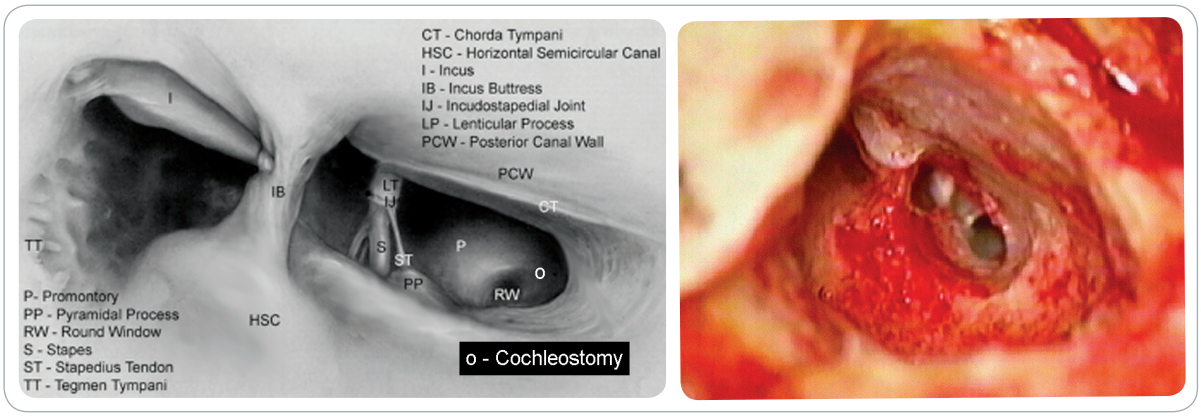


Figure 4-20.
Drill the cochleostomy just anterior and inferior to the round window. Right. ear.

Figure 4-21.
Completed cochleostomy. Right ear.

HiFocus™ SlimJ Electrode

HiFocus SlimJ Electrode Description

In describing the electrode and insertion procedure, the distal and proximal locations are in reference to the surgeon's hand.

The HiFocus SlimJ Electrode consists of an electrode lead, and HiFocus SlimJ Electrode array. The electrode contacts, composed of platinum, and the wires, composed of platinumiridium alloy, are housed in a silicone carrier and extend from the titanium case of the HiRes Ultra 3D. The HiFocus SlimJ intracochlear electrode array is 23 mm in length (from blue marker to distal tip) and is designed to be inserted approximately 420° into a normal patent cochlea. The array consists of 16 planar contacts arranged along the medial (or inside) surface of the electrode array for stimulation of discrete segments of the cochlea. The electrode contacts are numbered 1 through 16 from apex to base.

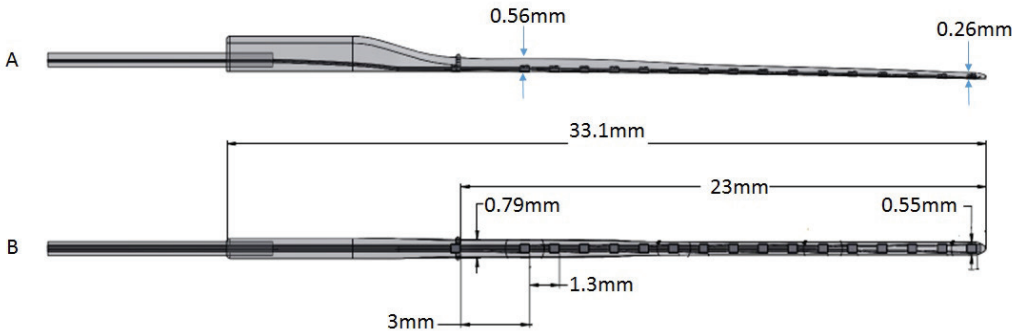


Figure 5-1.
HiFocus SlimJ Electrode: A – front view; B – bottom view.

There is one blue marker on the electrode array, positioned proximal to the 16th contact. The blue marker is placed adjacent to a raised feature on the electrode silicone carrier.

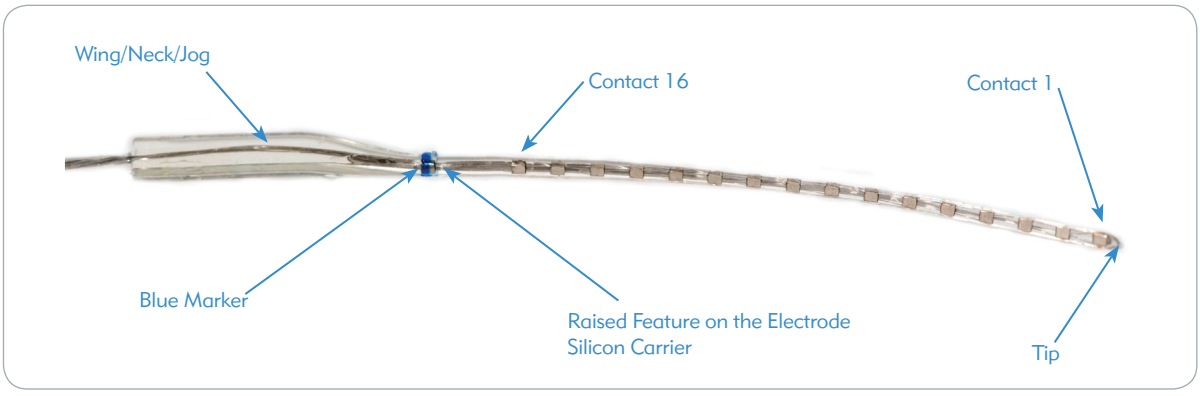


Figure 5-2
Features of the HiFocus SlimJ Electrode

The 'wing' refers to the jog (Figure 5-2) at the proximal end of the electrode array at the transition to the electrode lead. It is intended to offer a section of the lead/array for forceps/surgical tool use to allow insertion of the array. The lead, which extends from the fantail, refers to the silicone carrier in which the electrode wires are enclosed.

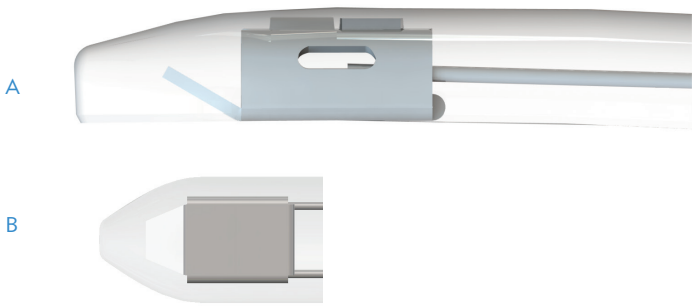


Figure 5-3.
A) Side View and B) Bottom View of the Tip Feature.

The Tip feature is intended to aid the insertion of the electrode through the round window membrane.

The total electrode lead and fantail length is approx. 76.6 mm. This includes the distal, thin portion of the lead up to the 'wing' feature, which allows for better visualization during Ring Ground array implantation.

HiFocus SlimJ Electrode Specifications

(Approximate Measurements)	
Electrode array dimensions at contact #1 (distal) (w x h)	0.55 x 0.26 mm
Electrode array dimensions at contact #16 (proximal) (w x h)	0.76 x 0.56 mm
Electrode array dimensions at the point of typical cochleostomy	0.79 x 0.61 mm
Total length of active contacts (distance that the electrode contacts are spread over)	20 mm
Spacing between active contacts (distance from midpoint of one contact to midpoint of neighboring contact) – contacts are evenly spaced	1.3 mm
Distance between blue marker and proximal stimulating contact (contact#16)	3 mm
Length of wing (distance from lead to blue marker)	10 mm
Cochleostomy diameter	0.8 mm
Distance of electrode lead from device fantail to wing	76.6 mm
Distance of electrode lead from device fantail to blue marker	86.6 mm
Approximate angular insertion following full electrode insertion	~420°
Total length of electrode array (distance from distal electrode array tip to blue marker)	23 mm

HiFocus SlimJ Electrode Equipment Requirements

At the time of each surgery, Primary and Back-up Implants, CI-1601-05 should be present in the operating room. The implant with the lower serial number should be used as the primary device. The implant is delivered sterile.

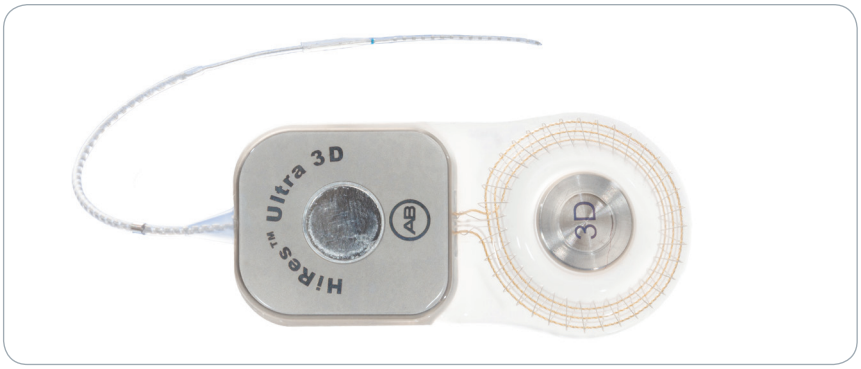


Figure 5-4.
HiRes Ultra 3D with HiFocus SlimJ electrode.

The HiFocus Electrode Forceps Kit, CI-4350-02, may be ordered separately as a forceps option alongside standard surgical forceps. Forceps, standard surgical forceps or the HiFocus Electrode Forceps in the HiFocus Electrode Forceps Kit, aid in the insertion of the HiFocus SlimJ electrode.

The following tools must be sterilized prior to use. See the *"Guide for Reprocessing HiRes Ultra Reusable Tools"* and *"Guide for Reprocessing HiFocus Electrode forceps"*, provided in the respective kits.

HiRes Ultra Reusable Surgical Tool Kit, CI-4509

Figure 5-5.
HiRes Ultra Reusable Surgical Tool Kit.

HiFocus Electrode Forceps, CI-4350

The HiFocus Electrode Forceps provided in the HiFocus Electrode Forceps Kit, CI-4350-02, can be used for the insertion of the electrode.

Figure 5-6.
HiFocus Electrode Forceps.

The following tools and gauges can also be used to aid insertion of the HiFocus SlimJ Electrode:

HiFocus Mid-Scala Cochleostomy Gauge, CI-4347

The cochleostomy gauge can be used to verify the minimum recommended cochleostomy size. The cochleostomy technique and size recommendations, in case of HiFocus SlimJ, are the same as for HiFocus Mid-Scala.

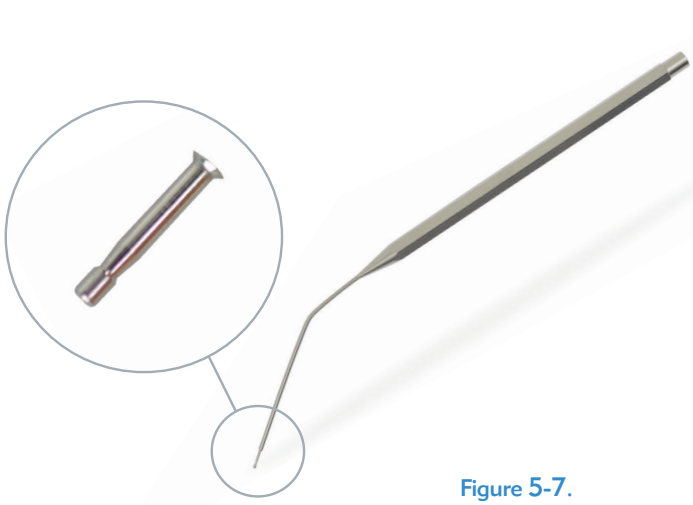


Figure 5-7.
HiFocus Mid-Scala Electrode Cochleostomy Gauge.

HiFocus Mid-Scala Claw Tool, CI-4254

The Claw Tool can be used with HiFocus SlimJ to stabilize the electrode during and/or following insertion and may help prevent buckling/movement of the electrode.

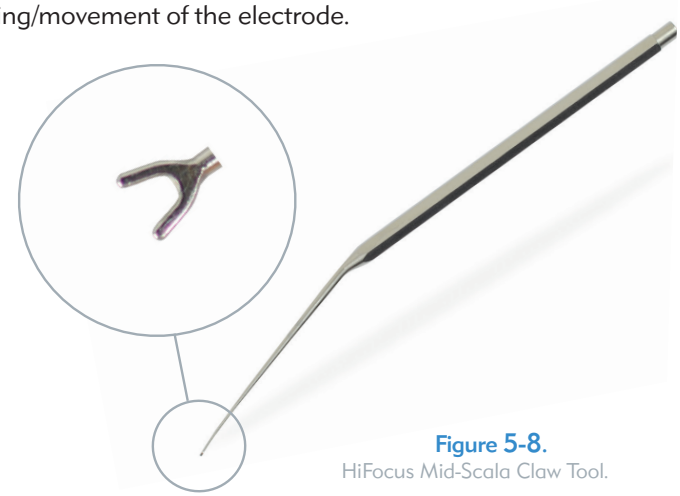


Figure 5-8.
HiFocus Mid-Scala Claw Tool.

HiFocus SlimJ Electrode Depth Gauge, CI-1605

The HiFocus SlimJ Electrode Depth Gauge is a single-use, EO-sterilized instrument that matches the HiFocus SlimJ electrode profile. The HiFocus SlimJ Electrode Depth Gauge is intended to be used by the surgeon to determine the patency of suspected occluded cochlea prior to insertion of the HiFocus SlimJ electrode. It is inserted into the cochleostomy in the same manner as the HiFocus SlimJ electrode.

WARNING

- **The HiFocus SlimJ Electrode Depth Gauge should not be resterilized or reused.**
- **Do not use if the sterile packaging is damaged.**
- **The HiFocus SlimJ Electrode Depth Gauge should not be used as a stent in the patient.**

The safety of performing MRI with the Depth Gauge in the patient has not been established. Do not perform MRI with the HiFocus SlimJ Electrode Depth Gauge in the patient.

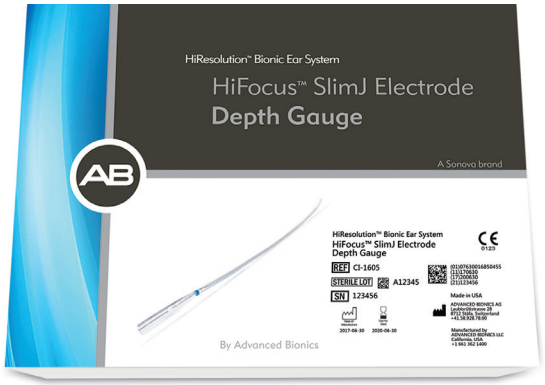


Figure 5-9A.
HiFocus SlimJ Electrode Depth Gauge package CI-1605.

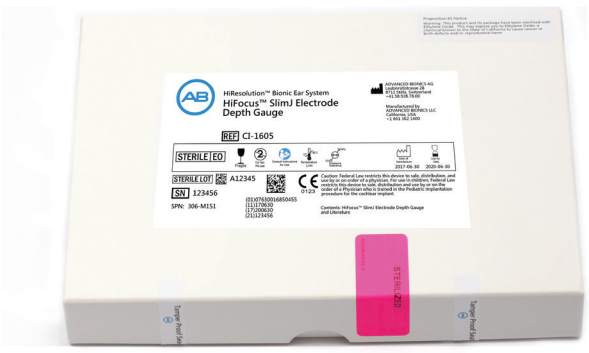


Figure 5-9B.
HiFocus SlimJ Electrode Depth Gauge Outer Box.

HiFocus SlimJ Electrode – Insertion into the Cochlea

The surgical approach/technique for insertion of the HiFocus SlimJ Electrode is free-hand insertion utilizing a cochleostomy, round window membrane or (modified/extended) round window. The free-hand approach uses a standard surgical forceps or HiFocus Electrode Forceps to insert the electrode into the cochlea. A cochleostomy approach is assumed to be the traditional inferior and slightly anterior anatomical position in relation to the round window membrane. A round window approach is assumed to be a cut or lifting of the round window membrane, with removal of the round window overhang to gain sufficient access to the membrane itself for insertion. A modified/extended round window approach is assumed to involve extending the round window itself. Any approach should ensure good visualization of the round window and good visibility of the surgical space.

The cochlea opening must be sufficiently sized to accommodate the HiFocus SlimJ Electrode array. Use the HiFocus Mid-Scala Electrode Cochleostomy Gauge, CI-4347, to check for minimum diameter of 0.8 mm. Alternately, an 0.8mm or 1.0mm Burr can be used to check for minimum diameter of 0.8mm. The distal tip of the HiFocus Mid-Scala Electrode Cochleostomy Gauge should easily fit into the cochleostomy, round window or modified/extended round window. The appropriate cochlea opening will facilitate a smoother/easier insertion of the electrode.

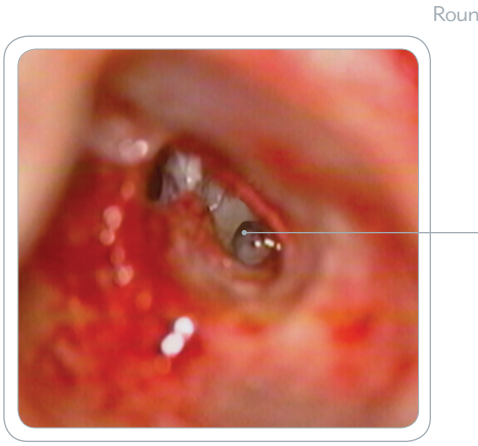


Figure 5-10A.
Clearly expose the round window. Right ear.

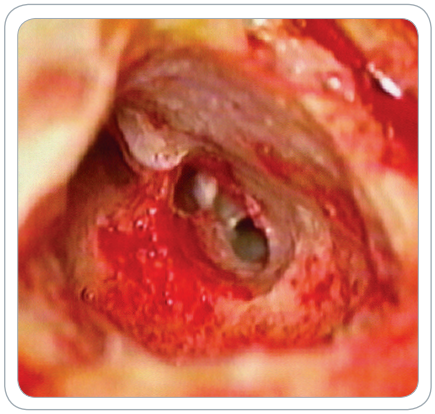


Figure 5-10B.
Completed cochleostomy. Right ear.

CAUTION: If the diameter of the cochlea opening is not the required 0.8 mm minimum size, pressure can be exerted on the electrode array during insertion. This pressure can cause damage to the electrode or result in an incomplete insertion.

HiFocus SlimJ Electrode Insertion—Free Hand Technique with Forceps

After the HiRes Ultra 3D implant has been secured, the HiFocus SlimJ Electrode is inserted into the cochlea through the cochlea opening: either cochleostomy; round window; or modified/extended round window. The HiFocus SlimJ Electrode is protected in the packaging by protective tubing. The following section outlines the steps that can be performed to ensure successful HiFocus SlimJ Electrode insertion.

While holding the electrode at the 'wing' feature, proximal to the protective tubing, remove the protective tubing from the HiFocus SlimJ Electrode.

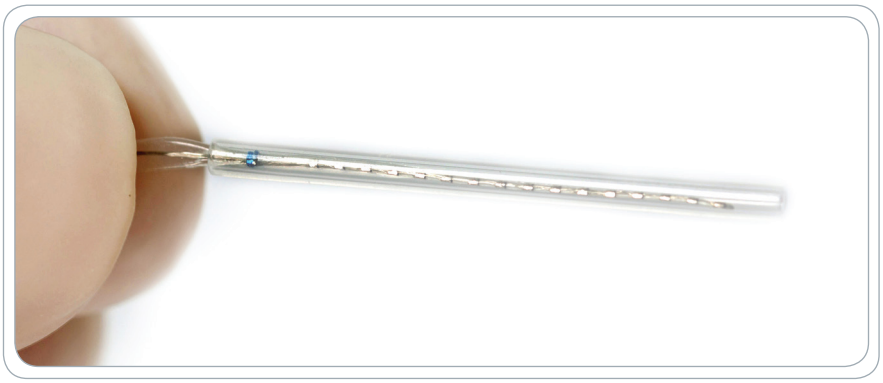


Figure 5-11.
HiFocus SlimJ Electrode shown with the protective tubing.

Figure 5-12.
Removing the protective tubing from the HiFocus SlimJ Electrode.

Using the HiFocus Electrode Forceps or standard surgical forceps or similar, grasp the HiFocus SlimJ Electrode array at the 'wing' feature (proximal from the blue marker) proximal to the electrode array contacts.

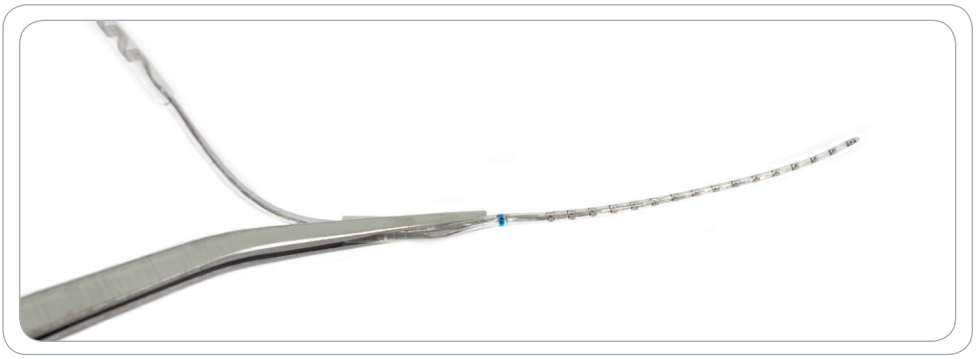


Figure 5-13.
Grasp the HiFocus SlimJ Electrode array at the 'wing' feature of the electrode array.

Ensure that the electrode contacts of the HiFocus SlimJ Electrode array face superiorly, toward the modiolus. The orientation (superiorly) of the electrode contacts indicates the direction that the array will conform along the lateral wall, when it is inserted into the cochlea. It is essential that the electrode contacts of the HiFocus SlimJ Electrode be positioned correctly in relation to the modiolus.

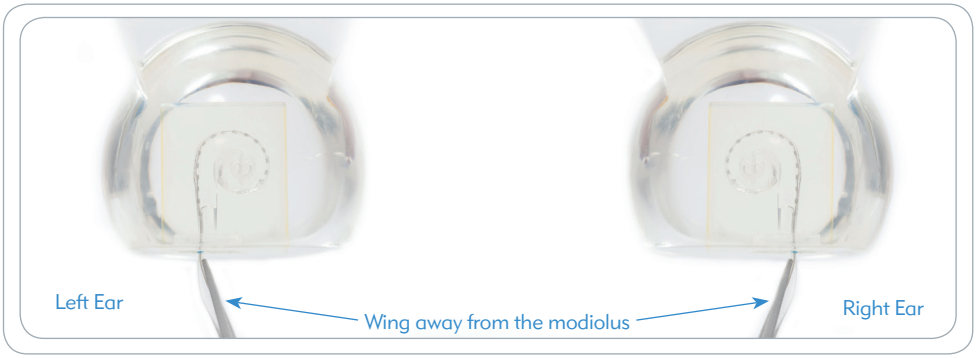


Figure 5-14.
HiFocus SlimJ Electrode orientation for left and right ears.

Insert the electrode into the cochlea. Continue to advance the electrode array, while holding the 'wing' feature until the blue marker is positioned at the cochleostomy.

WARNING: Avoid excessive force in order to prevent damage. Discontinue electrode insertion if resistance is met. Determine the cause of the resistance before continuing. Once the cause has been determined and corrected, you can attempt reinsertion of the electrode.

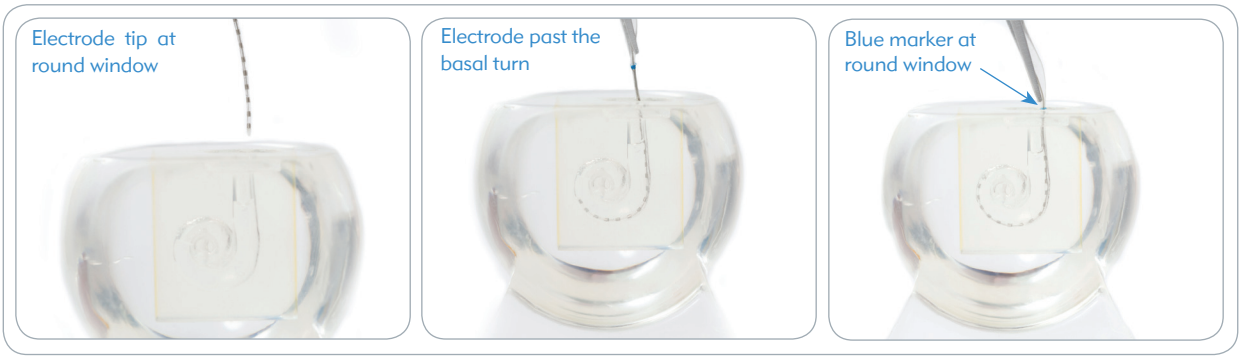


Figure 5-15
Insert the HiFocus SlimJ Electrode array using the free-hand approach. HiFocus SlimJ Electrode array inserted into the cochlea, right ear.

When the blue marker of the HiFocus SlimJ Electrode array is positioned at the cochleostomy, release the forceps from the 'wing' feature and remove.

Following insertion, visualize the cochleostomy site. The blue marker typically lies at the cochleostomy with the most proximal stimulating contact approximately 3 mm inside the cochlea. The HiFocus SlimJ Electrode array is designed to be typically inserted a full turn and a quarter into the cochlea.

The cochlea opening around the electrode should be packed with fascia.

Imaging

Intraoperative X-rays are recommended to verify electrode placement.

Reinsertion of the HiFocus SlimJ Electrode

CAUTION: We recommend that the HiFocus SlimJ Electrode be reinserted only two times for a total of three insertion attempts.

Electrode reinsertion should take place only if:

- The electrode met resistance during insertion and did not achieve a full insertion due to an undersized cochleostomy. Before reinserting the electrode, correct the dimensions of the cochleostomy.
- The electrode is pulled partially out of the cochlea and cannot be returned to its original position.

Pack the Cochleostomy

To secure the HiFocus SlimJ Electrode in place, fascia or muscle should be well packed around the cochleostomy site.

NOTE: Pack completely around the electrode array.

Coil the Electrode Lead

Once the HiFocus SlimJ Electrode array has been secured at the cochleostomy site, the excess electrode lead is coiled inside the mastoid cavity. Use the mastoid cavity bony overhangs to retain the coiled lead in position.

NOTE: While coiling the excess electrode lead into the mastoid cavity, some rotation of the electrode array outside the cochleostomy may be observed. This is a normal characteristic due to the rotational effect from the coiling.

HiFocus Mid-Scala Electrode

HiFocus Mid-Scala Electrode Description

The HiFocus Mid-Scala Electrode consists of an electrode lead and HiFocus Mid-Scala Electrode array. The electrode contacts, composed of platinum, and the wires, composed of platinum-iridium alloy, are housed in a silicone carrier and extend from the titanium case of the HiRes Ultra. The HiFocus Mid-Scala intracochlear electrode array is 23.7 mm in length (from neck/"jog" to distal tip) and is designed to be inserted approximately 18.5 mm into a normal patent cochlea. The array consists of 16 planar contacts arranged along the medial (or inside) surface of the electrode array for stimulation of discrete segments of the cochlea. The electrode contacts are numbered 1 through 16 from apex to base.

There are two blue markers on the electrode array. One marker is positioned between the 5th and 6th contact from the end of the array (the "distal" marker). The other marker is positioned proximal to the 16th contact. This "proximal" marker is placed adjacent to a raised ring on the electrode silicone carrier.

The "neck" refers to the jog at the proximal end of the electrode array at the transition to the electrode lead. The lead, which extends from the fantail, refers to the silicone carrier in which the electrode wires are enclosed.

The total electrode lead and fantail length is 80 mm. This includes the distal, thin portion of the lead, which allows for better visualization during Ring Ground array insertion.

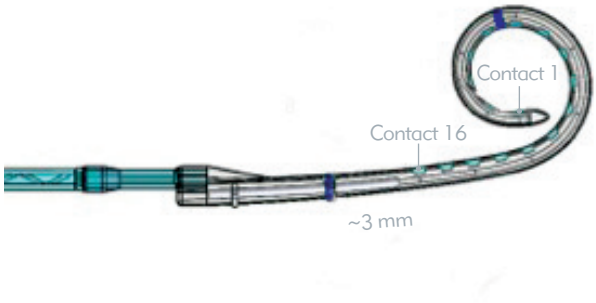


Figure 6-1.
HiFocus Mid-Scala Electrode.

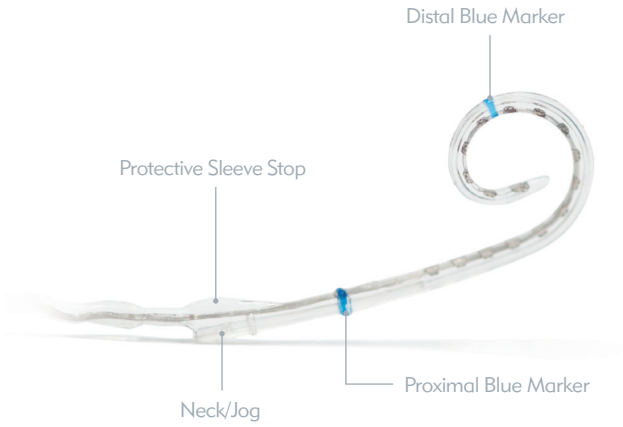


Figure 6-2.
Distal and Proximal Markers on the HiFocus Mid-Scala Electrode.

HiFocus Mid-Scala Electrode Specifications

(Approximate Measurements)	
Electrode array dimensions at contact #1 (distal)	0.5 x 0.5 mm
Electrode array dimensions at contact #16 (proximal)	0.7 x 0.7 mm
Electrode array dimensions at the point of typical cochleostomy	0.7 x 0.7 mm
Total length of active contacts (distance that the electrode contacts are spread over)	~15 mm
Spacing between active contacts (distance from midpoint of one contact to midpoint of neighboring contact) – *contacts are evenly spaced*	0.975 mm
Distance between proximal marker and proximal stimulating contact (contact #16)	3 mm
Distance between Neck/Jog (proximal end of electrode array) and proximal non-stimulating marker contact	5.4 mm
Required facial recess width	≤2 mm
Cochleostomy diameter, round window or modified (extended) round window (round)	0.8 mm
Distance of electrode lead from device fantail to proximal Neck/Jog	80 mm
Distance between electrode array (distal) tip and distal (blue) marker	5.4 mm
Distance between electrode array (distal) tip and proximal (blue) marker – *distance the electrode array extends into the cochlea following insertion*	18.5 mm
Approximate angular insertion following full electrode insertion	420°
Total length of electrode array (distance from distal electrode array tip to proximal Neck/Jog)	23.7 mm

The HiFocus Mid-Scala Electrode array is preloaded onto a Stylet in the sterile implant tray. It is housed in a Protective Sleeve **(Figure 6-3)**.

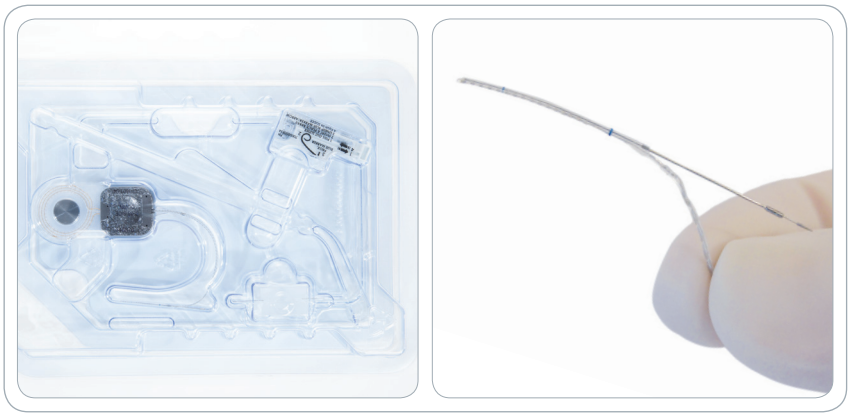


Figure 6-3.
HiRes Ultra 3D with HiFocus Mid-Scala Electrode in sterile tray.

Figure 6-4.
HiFocus Mid-Scala/Stylet Assembly with the Protective Sleeve removed.

HiFocus Mid-Scala Electrode/Stylet and Insertion Tool

The HiFocus Mid-Scala Electrode can be inserted into the cochlea using the Stylet for a free-hand approach or the Electrode Insertion Tool may be used to assist the surgeon **(Figure 6-5)**.

Figure 6-5.
HiFocus Mid-Scala Electrode/Style Assembly loaded on Electrode Insertion Tool.

In describing the Stylet and Electrode Insertion Tool, the distal and proximal locations are in reference to the surgeon's hand.

The tools contained within the sterile tray are single-use, disposable surgical instruments.

HiRes Ultra 3D HiFocus Mid-Scala (CI-1601-04) Single-Use, Disposable Tools

NOTE: The HiRes Ultra 3D HiFocus Mid-Scala array is pre-loaded on a Stylet and can be inserted manually as described in this document.

The following single-use, disposable HiFocus Mid-Scala tools are included in the sterile tray:

- HiFocus Mid-Scala Electrode Reloading Tool
- HiFocus Mid-Scala Electrode Stylet (back-up)

Single-Use, Disposable HiFocus Mid-Scala Insertion Tool (CI-4207)

NOTE: The HiFocus Mid-Scala Insertion Tool is provided in a separate package and must be ordered separately.

NOTE: Use of the HiFocus Mid-Scala Insertion Tool is optional. The HiFocus Mid-Scala array is pre-loaded on a Stylet and can be inserted manually as descibed in this document.

The single-use, disposable HiFocus MS Insertion Tool is included in a sterile tray.

HiFocus MS Insertion Tool Kit (CI-4507)

NOTE: The HiFocus Mid-Scala Insertion Tool Kit is provided in a separate package and must be ordered separately.

NOTE: Use of the HiFocus Mid-Scala Insertion Tool Kit is optional. The HiFocus Mid-Scala array is pre-loaded on a stylet and can be inserted manually as descibed in this document.

The following single-use, disposable HiFocus Mid-Scala tools are included in the sterile tray **(Figure 6-6)**:

- HiFocus Mid-Scala Electrode Insertion Tool
- HiFocus Mid-Scala Electrode Reloading Tool
- HiFocus Mid-Scala Electrode Stylet (back-up)

Figure 6-6.
HiRes Mid-Scala Insertion Tool Kit Sterile Tray

HiFocus Mid-Scala Insertion Tool Kit Packaging and Handling

There are four levels of packaging: 1. the sleeve, 2. the outer box, 3. the outer tray, and 4. the inner sterile tray.

The HiFocus MS Insertion Tool Kit packaging contains an sleeve with labeling that indicates the following:

- Model number
- Lot Number
- Sterilization lot number
- Sterilization expiration date
- Date of manufacture
- Basic handling information

An explanation of the product labeling is presented in the Labeling section. This labeling is included on the three outer levels of packaging. The sleeve is non-sterile and is used for handling and shipping (Figure 6-7A). In the operating room, the tamper-proof seals must be broken to access the outer box. The outer box is also non-sterile and has a pre-formed liner that supports the sterile outer tray contained within (Figure 6-7C).

Figure 6-7A.
HiFocus Mid-Scala (MS) Insertion Tool Kit Package, CI-4507

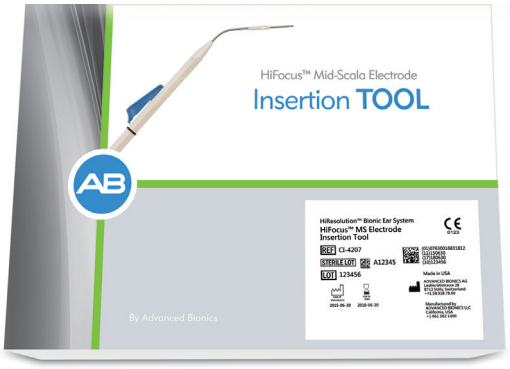
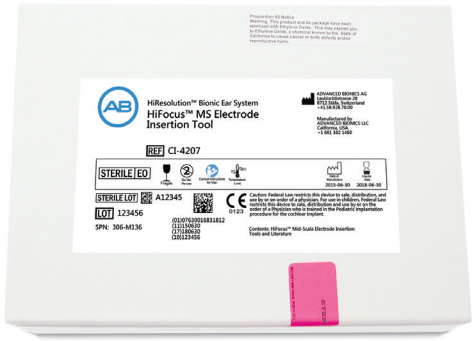


Figure 6-7B.
HiFocus Mid-Scala (MS) Insertion Tool Package CI-4207

Figure 6-7C.
HiFocus Mid-Scala Insertion Tool Package, outer box.



The tamper-proof seals on the *outer* box must be broken to access the *outer* tray. The *outer* tray may be handled in a non-sterile environment.

When you are ready to use, slowly peel back the cover of the *outer* tray to access the *inner* sterile tray. The sterile tray must be handled within a sterile field, (Figure 6-7D, 6-7E).

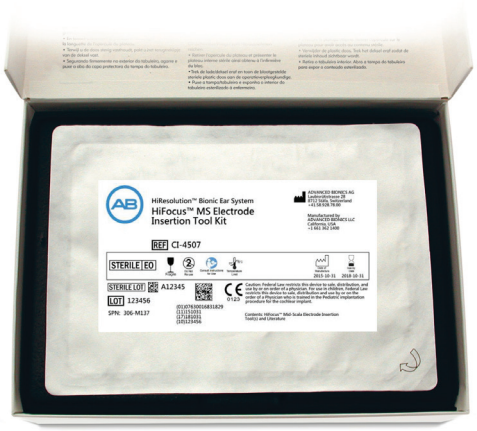


Figure 6-7D.
HiFocus Mid-Scala Insertion Tool kit Package, outer tray

Figure 6-7E.
HiFocus Mid-Scala Insertion Tool kit Package, inner tray.

HiFocus Mid-Scala Electrode Equipment Requirements

At the time of each surgery, the following equipment should be present in the operating room:

- Primary and Back-up Implants, CI-1601-04: The implant with the lower serial number should be used as the primary device. The implant is delivered sterile **(Figures 6-8-6-11)**.

Figure 6-8.
Implant Sleeve with HiFocus Mid-Scala Electrode.

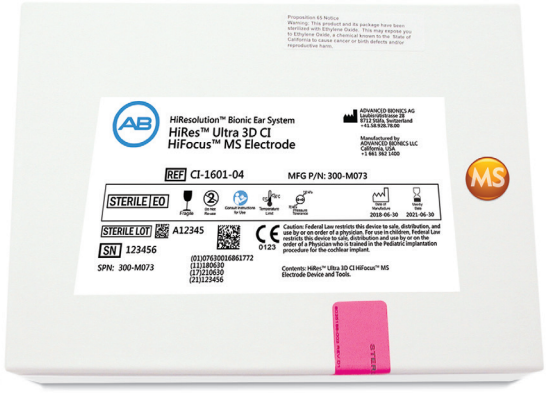


Figure 6-9.
Outer box for implant with HiFocus Mid-Scala Electrode.

Figure 6-10.
Contents of outer box for implant with HiFocus Mid-Scala Electrode, showing sterile package, HiRes Ultra Mock-up, literature package and device labels.

Figure 6-11.
Sterile package for implant with HiFocus Mid-Scala electrode, opens to reveal sterile tray.

The following tools must be sterilized prior to use. See the *"Guide for Reprocessing HiRes Ultra Reusable Tools"* provided in the kit. (Figure 6-12):

HiRes Ultra Reusable Surgical Tool Kit, CI-4509

Figure 6-12.
HiRes Ultra Resusable Surgical Tool Kit, CI-4509

The following tools must be sterilized prior to use. See the *"Instructions for Cleaning and Sterilization"* provided in the HiFocus™ Mid-Scala Electrode Instrument Kit (Figures 6-13A-B):

HiFocus Mid-Scala Electrode Instrument Kit, CI-4508.

Figure 6-13A.
HiFocus Mid-Scala Electrode Instrument Kit, CI-4508.

Figure 6-13B.
HiFocus Mid-Scala Electrode Instrument Kit contains Two (2) HiFocus Mid-Scala Cochleostomy Gauges and Two (2) Claw Tools.

HiFocus Mid-Scala Electrode Instrument Kit, CI-4508

The HiFocus Mid-Scala Electrode Instrument Kit, CI-4508, includes the following tools and gauges for insertion of the HiFocus Mid-Scala Electrode:

Two Cochleostomy Gauges, CI-4347, labeled "0.8 mm": The cochleostomy gauge can be used to verify the minimum recommended cochleostomy or round window size **(Figure 6-14)**.

Two Electrode Claw Tools, CI-4254. The Electrode Claw Tool can be used to stabilize the electrode during and/or following insertion or to push the array in during freehand insertion **(Figure 6-15)**.

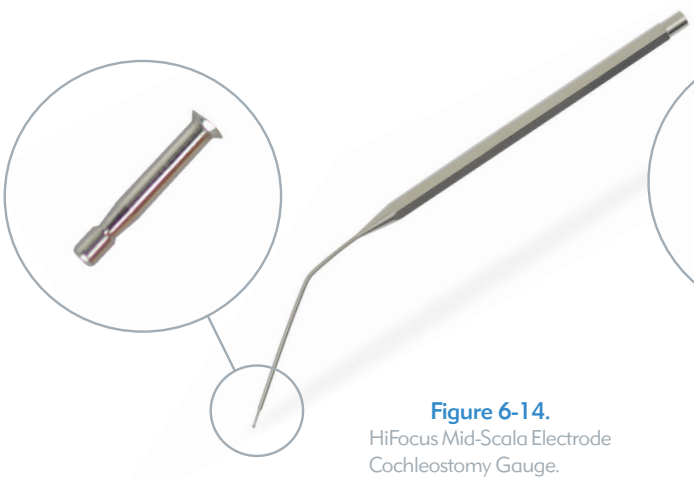


Figure 6-14.
HiFocus Mid-Scala Electrode Cochleostomy Gauge.

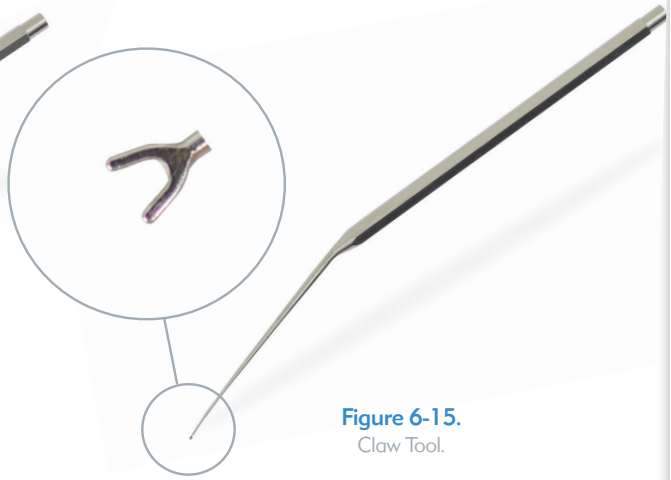


Figure 6-15.
Claw Tool.

HiFocus Mid-Scala Electrode – Cochleostomy

The cochleostomy must be sufficiently sized to accommodate the HiFocus Mid-Scala Electrode array. Use an 0.8 mm or 1.0 mm Burr, to check for minimum diameter of 0.8 mm.

The HiFocus Mid-Scala Electrode can be inserted through a conventional cochleostomy, the round window, or a modified (extended) round window approach **(Figure 6-16)**. The term cochleostomy shall be used to cover all variations.

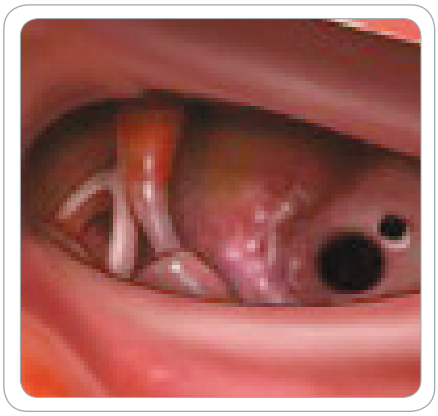


Figure 6-16.
Typical cochleostomy placement and dimensions.

CAUTION: If the diameter of the cochleostomy is not the required 0.8 mm minimum size, pressure can be exerted on the electrode array during insertion. This pressure can cause damage to the electrode array or result in an incomplete insertion.

HiFocus Mid-Scala Electrode Insertion—Free Hand Technique with the Stylet

After the HiRes Ultra 3D implant has been secured, the HiFocus Mid-Scala Electrode is inserted into the cochlea through the cochleostomy previously created. The HiFocus Mid-Scala Electrode is pre-loaded onto the Stylet. The following section outlines the steps that can be performed to ensure successful HiFocus Mid-Scala Electrode insertion.

While holding the electrode at the neck/"jog" region, proximal to the protective sleeve, remove the protective sleeve from the HiFocus Mid-Scala Electrode. Avoid grasping the Stylet **(Figure 6-17)**.

Using jeweler's forceps or a similar instrument, grasp the HiFocus Mid-Scala Electrode array near the neck/"jog" region (proximal from the blue marker) **(Figure 6-18)**.

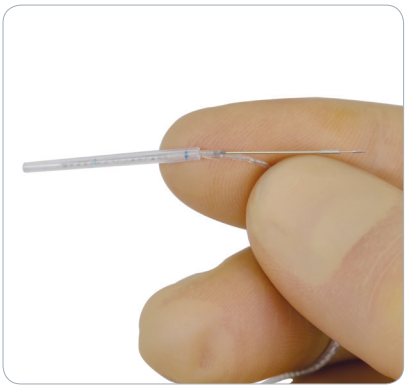


Figure 6-17.
HiFocus Mid-Scala Electrode/Stylet Assembly shown with the Protective Sleeve.

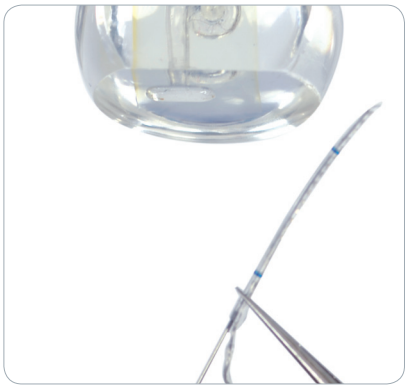


Figure 6-18.
Grasp the HiFocus Mid-Scala Electrode array near the neck/"jog" region of the electrode array.

Ensure that the electrode contacts of the HiFocus Mid-Scala Electrode array face superiorly, toward the modiolus, and that the distal blue marker (between the 5th and 6th contacts) is positioned at the cochleostomy. The orientation (superiorly) of the electrode contacts indicates the direction that the array will 'curl' when it is released/expelled off the Stylet. It is essential that the HiFocus Mid-Scala Electrode be released off the Stylet so that the electrode array curves around the basal turn of the cochlea.

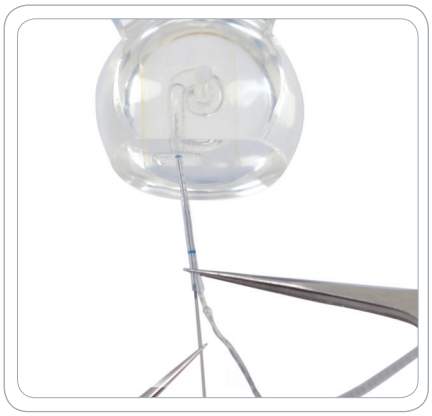


Figure 6-19.
Grasp the distal jog of the electrode and proximal end of the stylet.

Using another pair of jeweler's forceps or similar instrument, grasp the Stylet toward its proximal end and, using the distal pair of forceps, advance the electrode array off the Stylet **(Figures 6-19, 6-20)**.

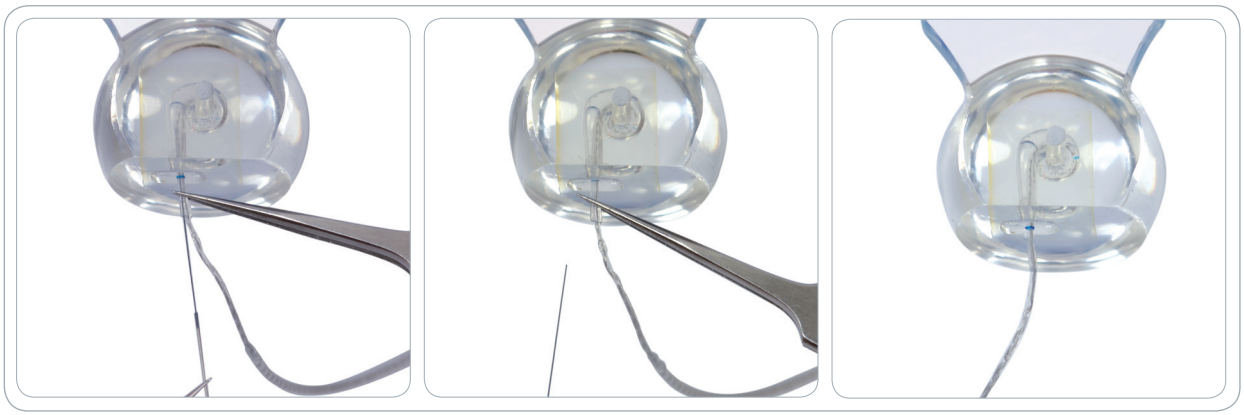


Figure 6-20.
Insert the HiFocus Mid-Scala Electrode array using the free-hand approach.
HiFocus Mid-Scala Electrode array inserted into the cochlea, right ear.

The Stylet must be held in a stable position and should not be advanced or pulled out until the array is fully inserted. Holding the Stylet in a stable position will ensure that the HiFocus Mid-Scala Electrode can be easily advanced from the Stylet and into the cochlea. Continue to advance the electrode array, while holding the Stylet in a stable position until the proximal blue marker is positioned at the cochleostomy.

WARNING: Avoid excessive force in order to prevent damage. Discontinue electrode insertion if resistance is met. Determine the cause of the resistance before continuing. Once the cause has been determined and corrected, reload the electrode array as noted in the section *Reload the HiFocus Mid-Scala Electrode Array on the Stylet*.

WARNING: At no time shall the array with stylet be fully inserted into the cochlea. The array must be inserted as noted, not allowing the stylet to insert deeper than the basal turn.

When the proximal blue marker of the HiFocus Mid-Scala Electrode array is positioned at the cochleostomy, use the Claw Tool, or similar instrument, to stabilize the electrode array in place while withdrawing the remaining part of the Stylet from the electrode array.

Following removal of the Stylet, visualize the cochleostomy site. The proximal blue marker typically lies at the cochleostomy with the most proximal stimulating contact approximately 3 mm inside the cochlea. The HiFocus Mid-Scala Electrode array is typically inserted a full turn and a quarter into the cochlea.

Figure 6-21.
HiFocus Mid-Scala Electrode orientation for left and right ears.

Imaging

Intraoperative X-rays are recommended to verify electrode placement **(Figure 6-22)**.

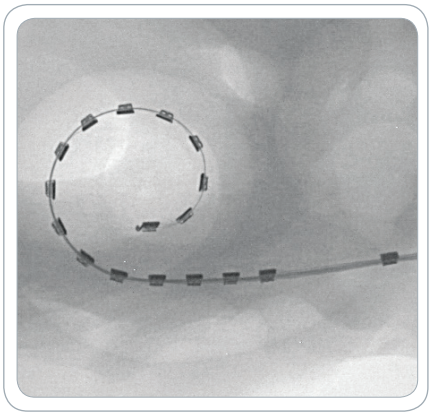


Figure 6-22.
HiFocus Mid-Scala electrode, Intraoperative X-ray

Reload the HiFocus Mid-Scala Electrode Array on the Stylet

CAUTION: We recommend that the HiFocus Mid-Scala Electrode be reloaded only two times for a total of three insertion attempts. If a third reload of the HiFocus Mid-Scala Electrode array is necessary, use the back-up unit.

CAUTION: When reloading the HiFocus Mid-Scala Electrode care should be taken to minimize elongation/twisting of the lead body.

WARNING: If at any time and for any reason the stylet extends outside the distal tip of the array, the back-up HiRes Ultra implant must be used.

Electrode reloading and reinsertion should take place only if:

- The electrode met resistance during insertion and did not achieve a full insertion due to an undersized cochleostomy. Before reinserting the electrode, correct the dimensions of the cochleostomy.
- More than two electrode contacts have been expelled off the Stylet prior to insertion.
- The electrode is pulled partially out of the cochlea and cannot be returned to its original position.

An Electrode Reloading Tool is included in the sterile tray with the HiRes Ultra with HiFocus Mid-Scala Electrode **(Figure 6-23)**.

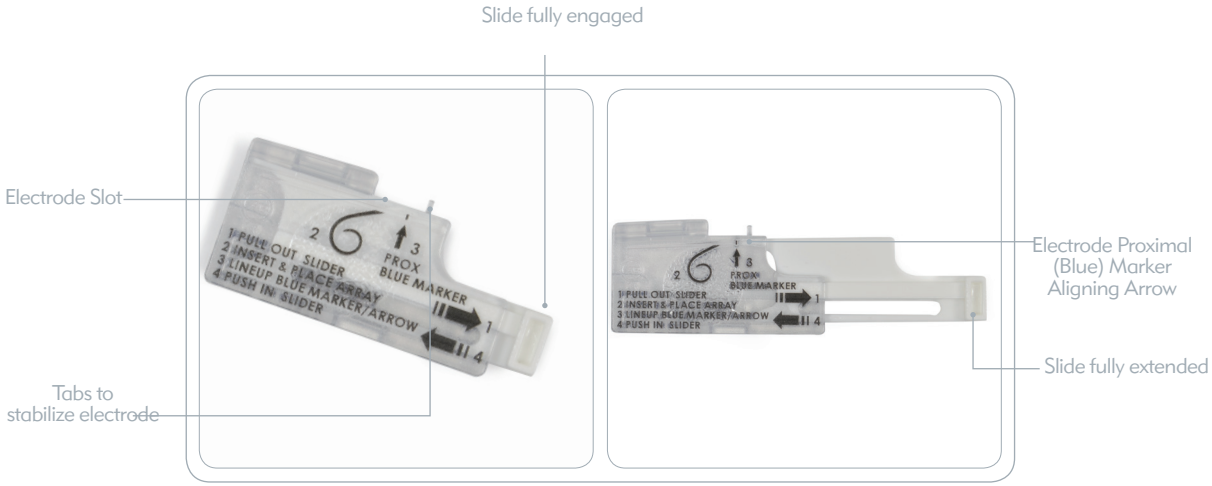


Figure 6-23.
Features of the HiFocus Mid-Scala Electrode Reloading Tool.

When preparing to reload the HiFocus Mid-Scala Electrode array, wet the electrode array and Electrode Reloading Tool with sterile saline. This will provide lubrication.

1. Obtain the Electrode Reloading Tool from the sterile, inner tray **(Figure 6-24)**.

Figure 6-24.
HiFocus Mid-Scala Electrode Reloading Tool.

2. Pull the Electrode Reloading Tool slide as far as the tool will allow **(Figure 6-25)**.

Figure 6-25.
Pull the Reloading Tool slide out as far as tool will allow.

3. Place the HiFocus Mid-Scala Electrode array into the Reloading Tool as shown (Figure 6-26).

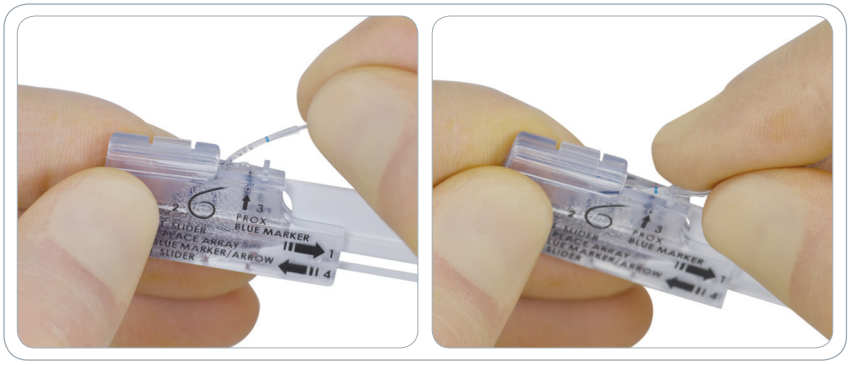


Figure 6-26
Place the HiFocus Mid-Scala Electrode array into the electrode slot of the Reloading Tool.

4. Align the Proximal Blue Marker with the Arrow Mark on the Reloading Tool as shown and lightly press the proximal end of the HiFocus Mid-Scala Electrode array into the Reloading Tool tabs (Figure 6-27).

Figure 6-27.
Align the Proximal Blue marker and proximal end of the HiFocus Mid-Scala Electrode array.

5. Slowly engage the Slide mechanism back into the Reloading Tool until the HiFocus Mid-Scala Electrode is fully extended and straight (Figure 6-28).

6. The Slide mechanism should stop automatically. You may notice that there is a gap between the handle of the Slide mechanism and the body of the Reloading Tool. This gap is normal and is designed to prevent damage to the electrode lead.

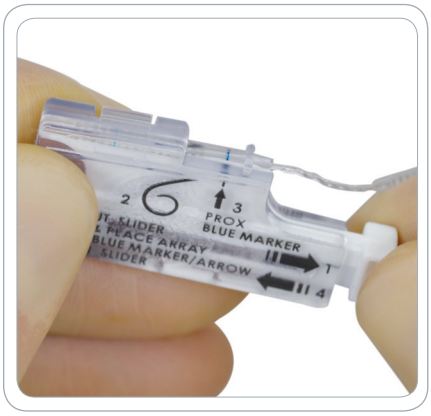


Figure 6-28.
Reloading Tool with slide fully engaged.

7. Locate the Stylet hole of the HiFocus Mid-Scala Electrode array as shown (Figure 6-29).

Figure 6-29.
Stylet located in Stylet hole of electrode array.

8. Introduce the HiFocus Mid-Scala Stylet into the Stylet hole of the HiFocus Mid-Scala Electrode array (Figure 6-30).

9. Continue to slide the stylet into the hole of the HiFocus Mid-Scala Electrode array until the proximal portion of the stylet base just engages the opening of the stylet hole. The stylet base is the larger diameter portion of the stylet.

Figure 6-30.
Slide the Stylet into the hole of the HiFocus Mid-Scala Electrode array.

10. Keeping the Slide fully engaged, gently grip the proximal part of the Stylet and the electrode lead as shown, and lift the Stylet / Electrode Assembly out of the Tabs (Figure 6-31).

Figure 6-31.
Lift the Stylet/Electrode Assembly out of the Tabs.

11. Remove the Stylet / Electrode Assembly from the Reloading Tool as shown (Figure 6-32).

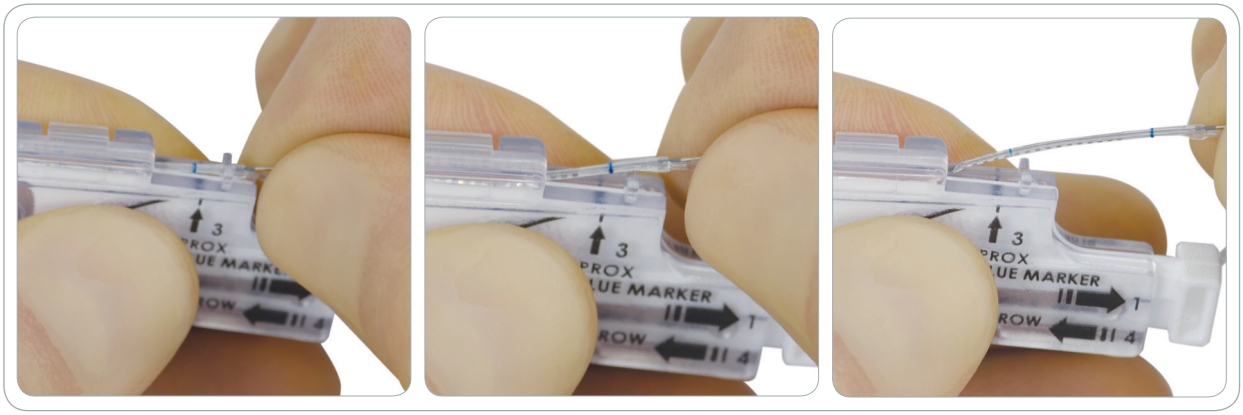


Figure 6-32.
Remove the Stylet/Electrode Assembly from the Reloading Tool.

12. Verify that the HiFocus Mid-Scala Electrode array is completely loaded on the Stylet. There should be minimal 'hooking' of the distal tip of the HiFocus Mid-Scala Electrode (Figure 6-33).

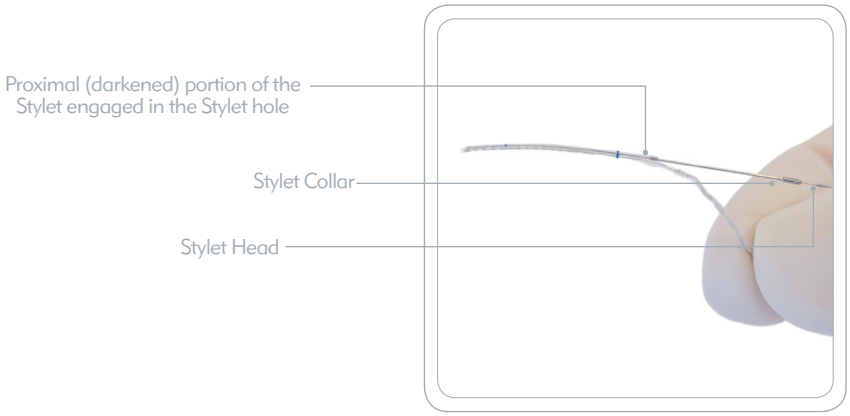


Figure 6-33.
Verify that the HiFocus Mid-Scala Electrode is fully loaded onto the Stylet.

HiFocus Mid-Scala Electrode Insertion—Using the Insertion Tool

After the HiRes Ultra 3D implant has been secured, the HiFocus Mid-Scala Electrode is inserted into the cochlea through the cochleostomy previously created. The electrode is pre-loaded onto the Stylet. Obtain the HiFocus Mid-Scala Electrode Insertion Tool **(Figure 6-34)** from the sterile tray of the separate HiFocus Mid-Scala Insertion Tool Kit (CI-4507). A Protective Tube is used to protect the Electrode Orientation Tube **(Figure 6-35)**.

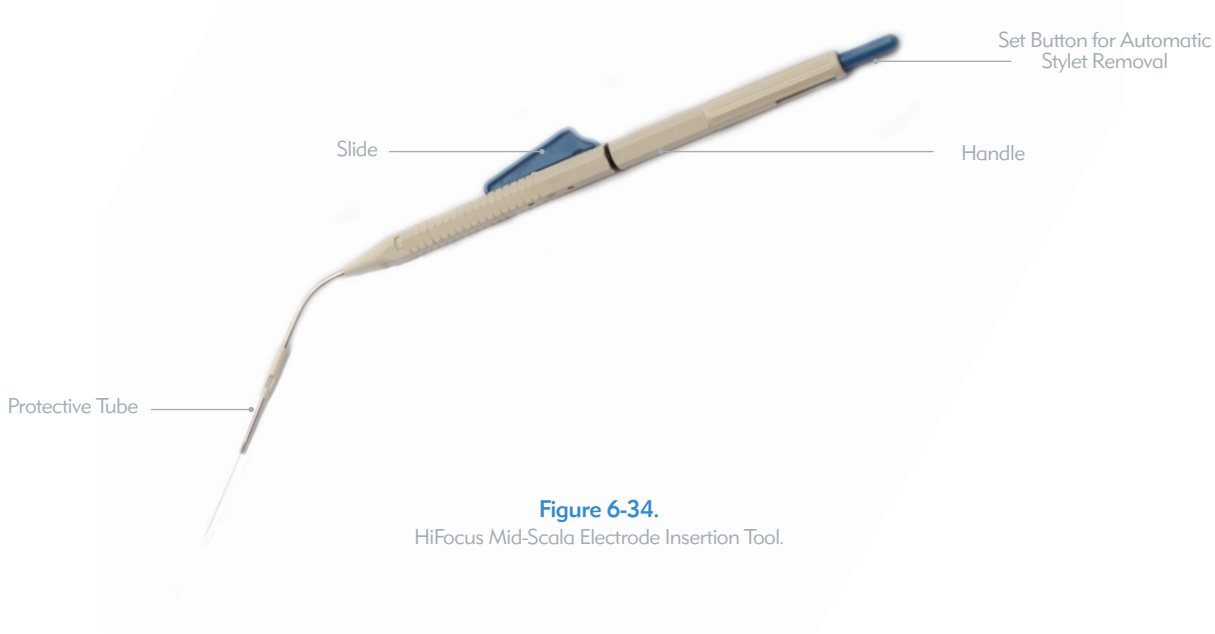


Figure 6-34.
HiFocus Mid-Scala Electrode Insertion Tool.

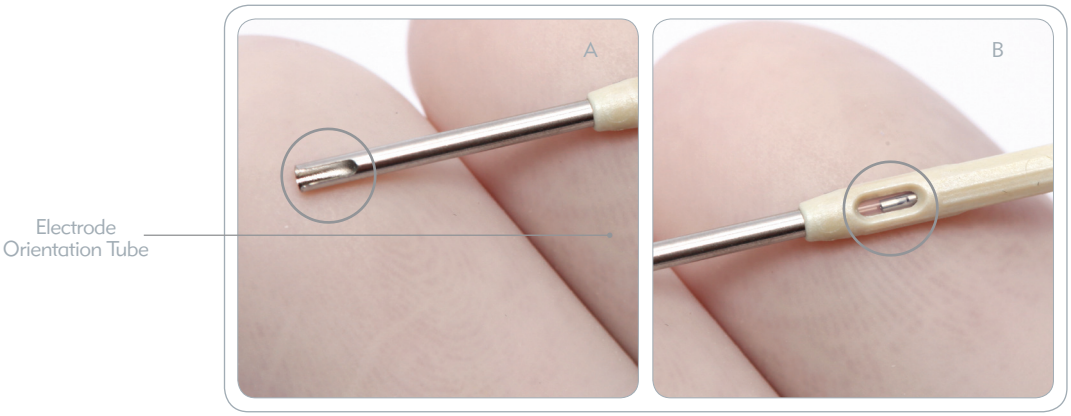


Figure 6-35.
Electrode Orientation Tube showing **a)** the Slot/"Key" and **b)** the Stylet Locking Viewing Window.

The following section outlines the steps that can be performed to ensure successful HiFocus Mid-Scala Electrode insertion.

Prepare the HiFocus Mid-Scala Electrode Insertion Tool

1. Obtain the HiFocus Mid-Scala Insertion Tool Kit (CI-4507).

2. Remove the HiFocus Mid-Scala Electrode Insertion Tool from the tray.

3. Remove the Protective Tube from the Electrode Insertion Tool as shown in **Figure 6-36**.

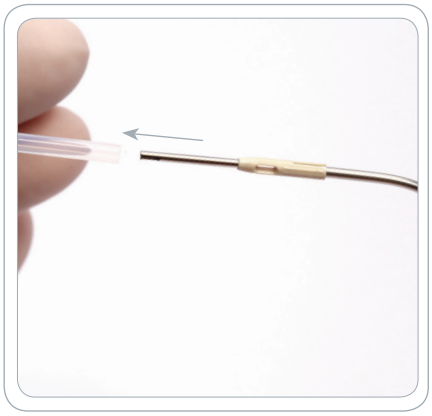


Figure 6-36.
Remove the Protective Tube from the Electrode Orientation Tube.

4. Retract the slide of the Electrode Insertion Tool as shown in **Figure 6-37**.

Figure 6-37.
Retract the Slide of the Electrode Insertion Tool.

5. Set the Automatic Stylet Reset mechanism by pushing the button (at the proximal end of the Electrode Insertion Tool handle) as shown in Figure 6-38.

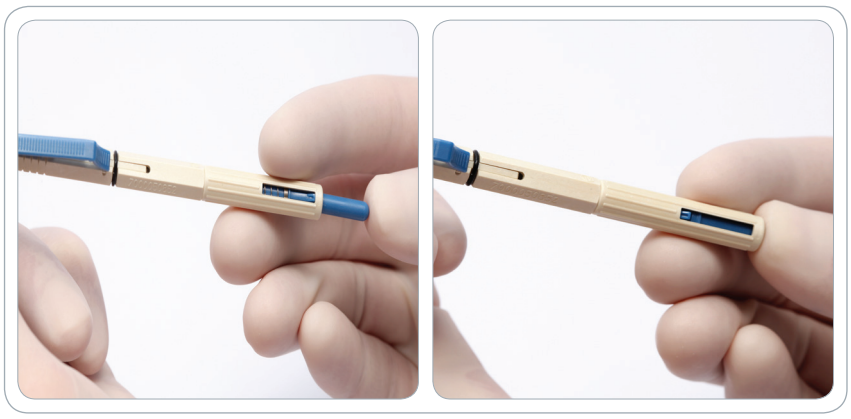


Figure 6-38.
Set the Automatic Stylet Reset Mechanism.

6. Hold the HiFocus Mid-Scala Electrode by the Protective Sleeve. Avoid grasping the Stylet. Do not remove the Stylet from the HiFocus Mid-Scala Electrode array (Figure 6-39).

NOTE: The electrode 'jog' and the Stylet head.

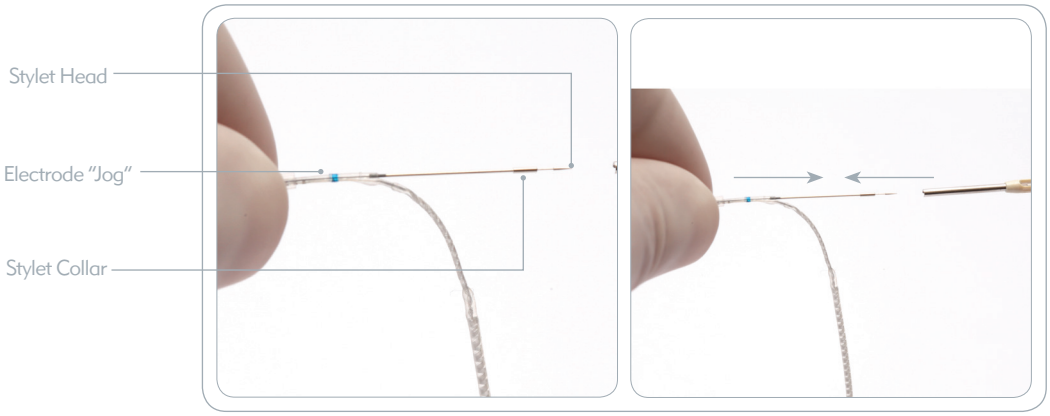


Figure 6-39.
Hold the HiFocus Mid-Scala Electrode by the Protective Sleeve.

Figure 6-40.
Align the Electrode "Jog" of the HiFocus Mid-Scala Electrode to the Engagement Slot of the Electrode Orientation Tube.

7. Align the electrode 'jog' to the engagement slot on the electrode orientation tube so that the Stylet will go straight in as shown in Figure 6-40.

8. Insert the Stylet Head into the HiFocus Mid-Scala Electrode Insertion Tool and advance the Stylet, keeping the "jog" aligned with the Slot. Some resistance may be felt as the Stylet Collar enters the Electrode Orientation Tube **(Figure 6-42)**.

NOTE: The drawing below in **Figure 6-41** showing the HiFocus Mid-Scala Electrode/Stylet Assembly oriented prior to engagement.

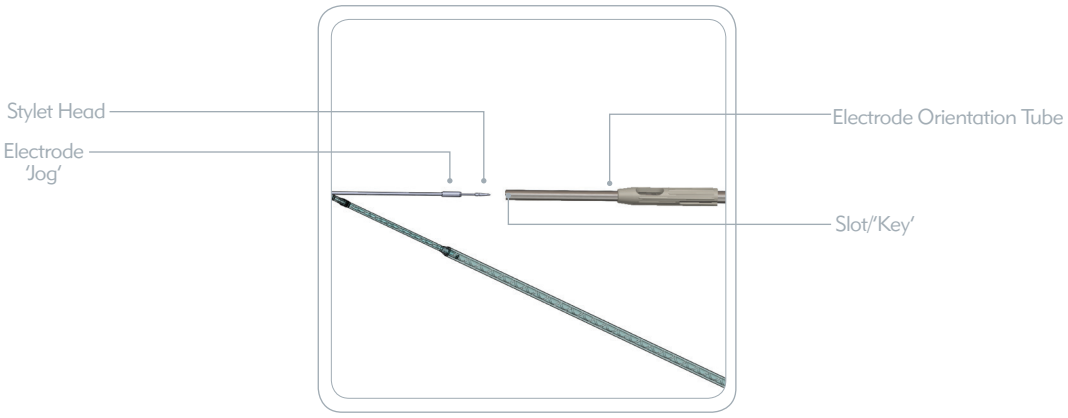


Figure 6-41.
Drawing of the HiFocus Mid-Scala Electrode/ Stylet Assembly oriented prior to engagement.

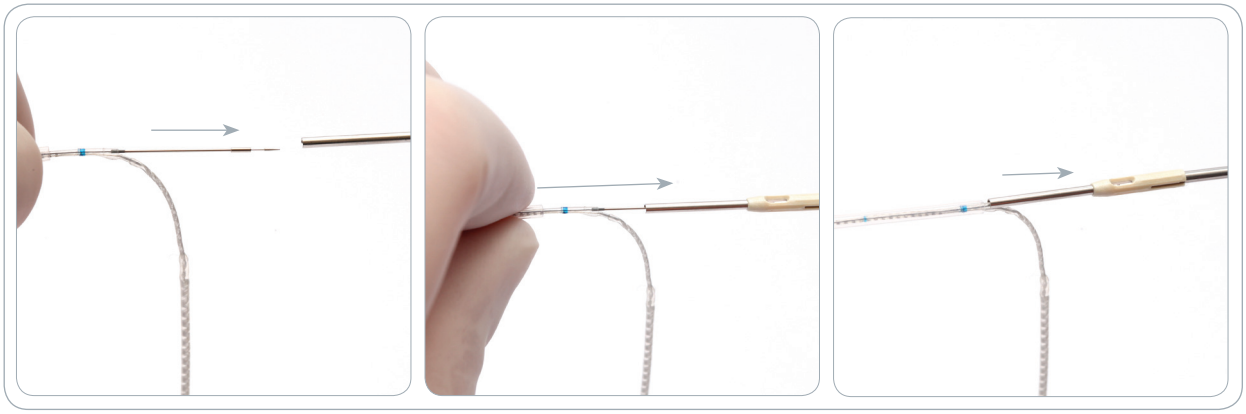


Figure 6-42.
Insert the Stylet into the Electrode Insertion Tool.

This graphic below in Figure 6-43 shows the Stylet prior to engagement of the stylet head into the locking mechanism.

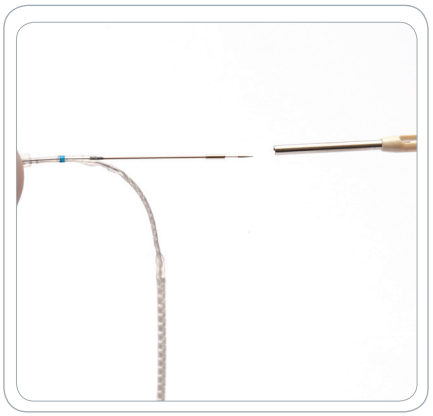


Figure 6-43.
Stylet head prior to engagement into the locking mechanism.

9. Insert the Stylet fully until a slight "click" is heard or a hard stop is felt. The Stylet head should now be locked into the electrode insertion tool locking mechanism. This should be confirmed by viewing the locking mechanism under the microscope as shown in Figure 6-44.

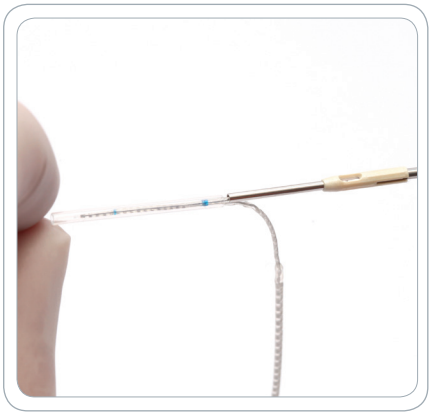


Figure 6-44.
HiFocus Mid-Scala Electrode/Stylet Assembly fully engaged in Electrode Orientation Tube of Electrode Insertion Tool.

CAUTION: Failure to confirm the Stylet head completely engaged in the locking mechanism could lead to incomplete insertion or inability to insert electrode array.

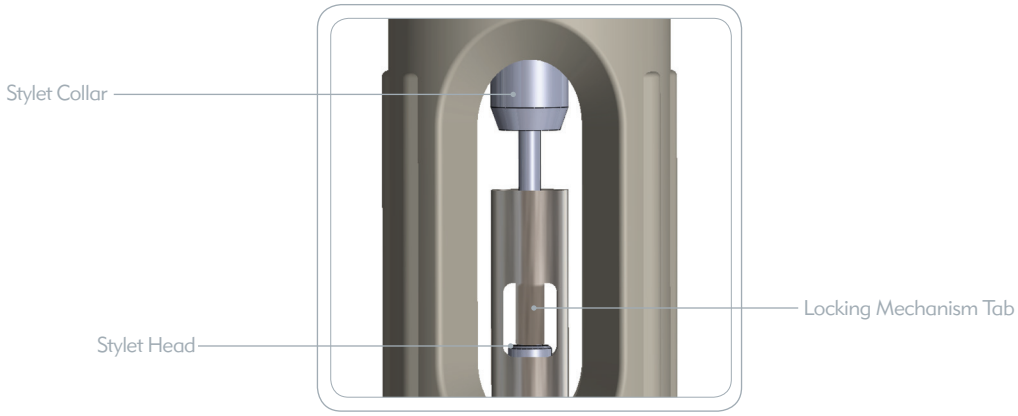


Figure 6-45.
Stylet head fully beyond locking mechanism tab.

The Stylet Head should be *fully* beyond the Locking Mechanism Tab, and the Stylet Collar should be visible in the Stylet Locking Viewing Window **(Figure 6-45)**.

10. Remove the Protective Sleeve from the Electrode taking care not to pull the electrode off the Stylet as shown in **Figure 6-46.** The Electrode Insertion Tool is now ready to be used.

CAUTION: Once the Stylet is locked into the Electrode Insertion Tool it cannot be removed.

If required, the Electrode can be reloaded onto the Stylet engaged in the Electrode Insertion Tool, or onto the spare Stylet provided in the implant package, by using the Electrode Reloading Tool.

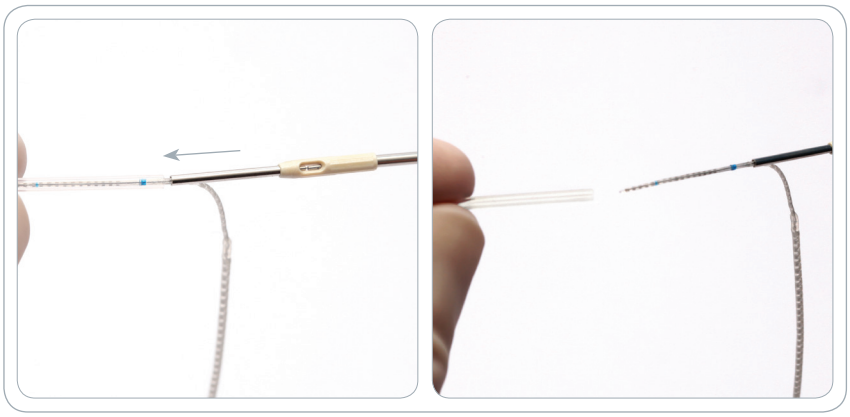


Figure 6-46.
Remove the protective Sleeve from the HiFocus Mid-Scala Electrode.

Check to ensure that the electrode contacts of the HiFocus Mid-Scala Electrode array face superiorly towards the modiolus (Figure 6-47). Rotate the orientation tube to the appropriate position. The orientation of the electrode array contact pads to the modiolus indicates the direction that the electrode array will "curl" when the array is expelled off the Stylet.

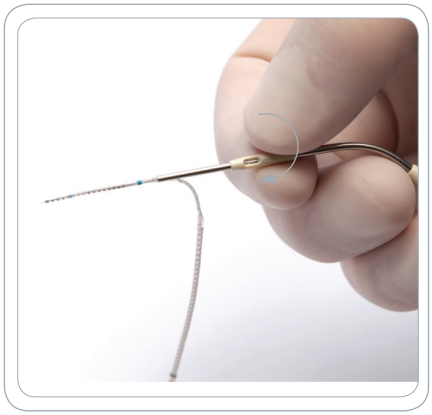


Figure 6-47.
Rotate the Electrode Orientation Tube so that the electrode contacts face superiorly towards the modiolus.

It is essential that the HiFocus Mid-Scala Electrode be released off the Stylet so that it curves around the basal turn of the cochlea.

11. Position the HiFocus Mid-Scala Electrode array until the distal blue marker (between the 5th and 6th contacts) is positioned at the cochleostomy (Figure 6-48). This ensures that the tip of the HiFocus Mid-Scala Electrode is sufficiently advanced into the cochlea. Do not advance the Insertion Tool any further.

Figure 6-48.
Position the Insertion Tool/HiFocus Mid-Scala Electrode array until the Distal Blue marker is positioned at the cochleostomy.

*When preparing for electrode insertion, keep in mind that the HiFocus Mid-Scala Electrode Insertion Tool must now be held in a **stable** position and should not be advanced or withdrawn* (Figure 6-49).

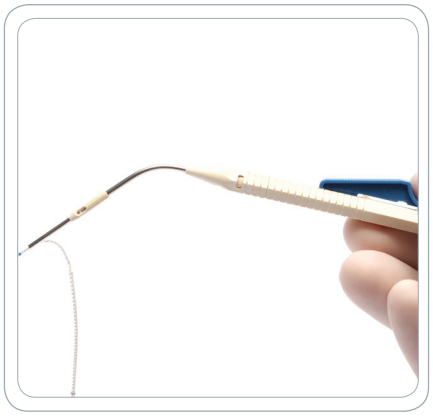


Figure 6-49.
Hold the HiFocus Mid-Scala Electrode Insertion Tool in a stable position.

12. Holding the Insertion Tool in a stable position will ensure that the HiFocus Mid-Scala Electrode can be easily advanced off the Stylet and into the cochlea up until the proximal blue marker is positioned at the cochleostomy. To advance the HiFocus Mid-Scala Electrode gently off the Stylet, push the Slide forward on the Insertion Tool.

CAUTION: Failure to maintain the HiFocus Mid-Scala Electrode Insertion Tool stable may result in an incomplete insertion, array foldover or incorrect electrode array placement.

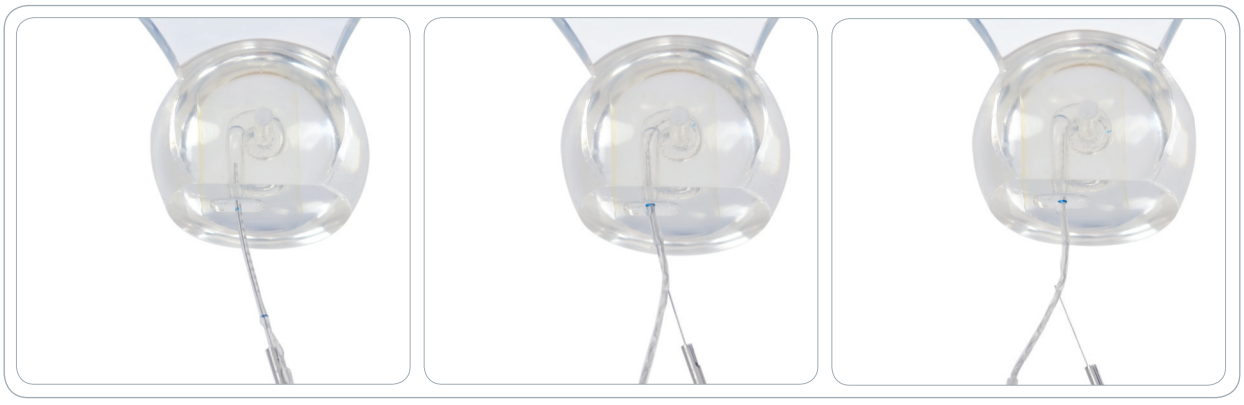


Figure 6-50.
Insert the HiFocus Mid-Scala Electrode using the Electrode Insertion Tool. **Note:** maintain stable Electrode Insertion Tool position during array insertion.

WARNING: Avoid excessive force in order to prevent damage. Discontinue electrode insertion if resistance is met. Determine the cause of the resistance before continuing. Once the cause has been determined and corrected, reload the electrode array as noted in the section *Reload the HiFocus Mid-Scala Electrode Array on the Stylet—When the Stylet Has Already Been Loaded on the Insertion Tool.*

WARNING: If at any time and for any reason the stylet extends outside the distal tip of the array, the Back-Up HiRes Ultra 3D Implant must be used.

13. If the Insertion Tool has remained in a stable position during Ring Ground insertion, the proximal blue marker should be visualized at the cochleostomy once the Slide has traveled until resistance is met **(Figure 6-51)**.

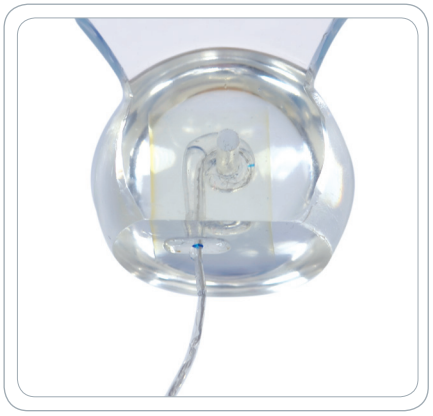


Figure 6-51.
Proximal Blue Marker at the cochleostomy.

If the Insertion Tool Slide is advanced further, the Stylet will automatically retract from the electrode array. With the Stylet withdrawn from the electrode, a Claw Tool, or similar instrument, may now be used to stabilize the electrode array in place while the Insertion Tool is withdrawn from the surgical space **(Figure 6-52)**.

NOTE: If the Proximal Blue Marker is at the cochleostomy and the Stylet has not automatically retracted, or if resistance is felt prior to the Proximal Blue Marker being at the cochleostomy and you wish to either leave the electrode in place or remove it to attempt reinsertion, you will need to manually disengage the Stylet from the electrode. To do so, use a Claw Tool or similar instrument to stabilize the electrode while the Insertion Tool is withdrawn.

Figure 6-52.
Stabilize the HiFocus Mid-Scala Electrode array.

14. Following removal of the Stylet, visualize the cochleostomy site. The proximal blue marker typically lies at the cochleostomy with the most proximal stimulating contact approximately 3 mm inside the cochlea.

The HiFocus Mid-Scala Electrode array is typically inserted a full turn and a quarter into the cochlea **(Figure 6-53)**.

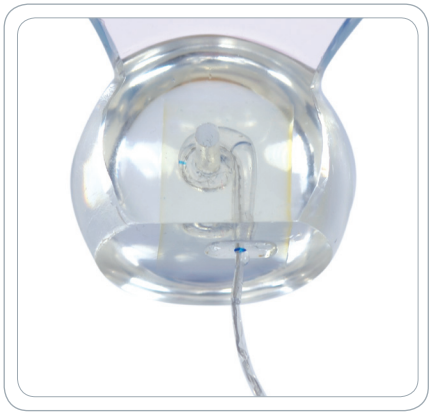


Figure 6-53.
HiFocus Mid-Scala Electrode array inserted into a cochlea, right ear.

15. If the proximal blue marker is not visible, retract the array to the level of the cochleostomy. if the proximal blue marker is outside the cocheiostomy, use the Electrode Claw Tool, CI-4254 (or similar instrument) to ease the electrode array in until the proximal blue marker is at the level of the cochleostomy.

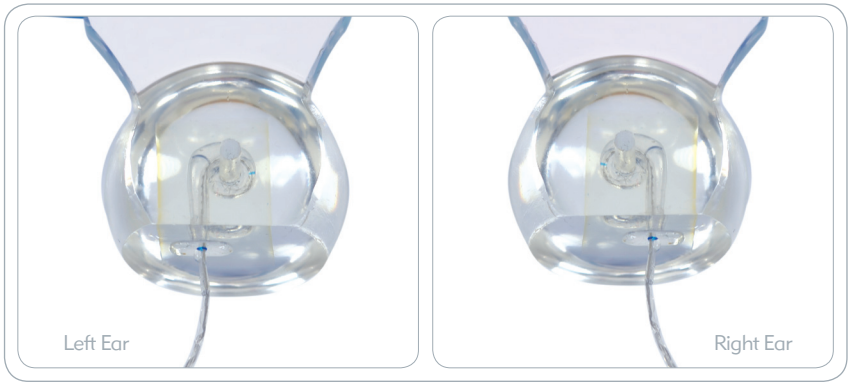


Figure 6-54.
Electrode contacts facing superiorly towards the modiolus.

WARNING: The Stylet must not be left in the array at the completion of insertion whether the array is fully or partially inserted.

Imaging

Intraoperative X-rays are recommended to verify electrode placement **(Figure 6-55).**

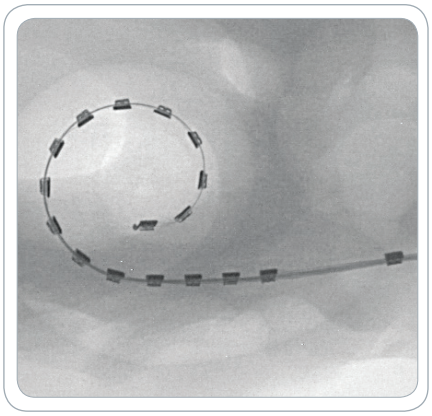


Figure 6-55.
HiFocus Mid-Scala electrode, Intraoperative X-ray.

Reloading When the Stylet Has Already Been Loaded on the Insertion Tool

CAUTION: We recommend that the HiFocus Mid-Scala Electrode be reloaded only two times for a total of three insertion attempts. If a third reload of the HiFocus Mid-Scala Electrode array is necessary, use the back-up unit.

CAUTION: When reloading the HiFocus Mid-Scala Electrode care should be taken to minimize elongation/twisting of the lead body.

Electrode reloading and reinsertion should take place only if:

- The electrode met resistance during insertion and did not achieve a full insertion due to an undersized cochleostomy. Before reinserting the electrode, correct the dimensions of the cochleostomy.
- More than two electrode contacts have been released off/expelled off the Stylet prior to insertion.
- The electrode is pulled partially out of the cochlea and cannot be returned to its original position.

An Electrode Reloading Tool is included in the sterile tray **(Figure 6-56)**.

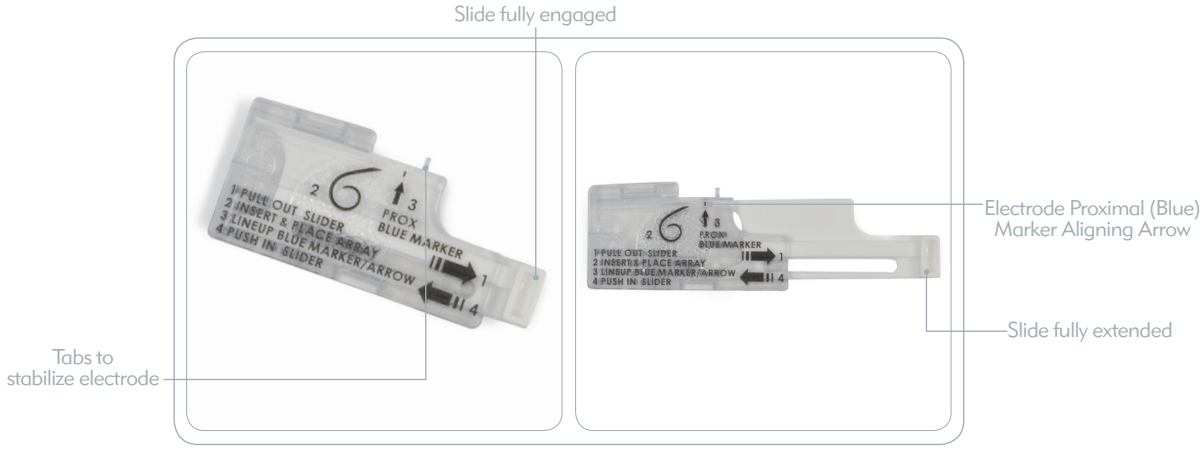


Figure 6-56.
Features of the HiFocus Mid-Scala Electrode Reloading Tool.

When preparing to reload the HiFocus Mid-Scala Electrode array, wet the electrode array and Electrode Reloading Tool with sterile saline. This will provide lubrication.

Prepare the HiFocus Mid-Scala Electrode on the Stylet

1. Obtain the Electrode Reloading Tool from the sterile, inner tray **(Figure 6-57)**.

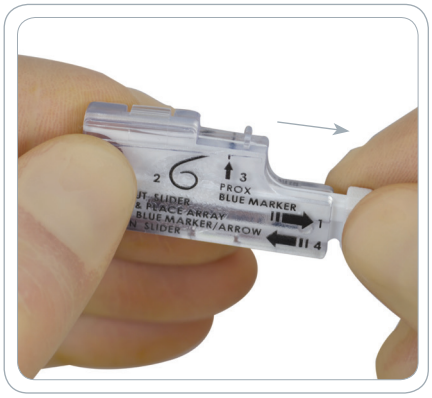


Figure 6-57.
HiFocus Mid-Scala Electrode Reloading Tool.

2. Pull the Electrode Reloading Tool Slide as far as the tool will allow **(Figure 6-58)**.

Figure 6-58.
Pull the Reloading Tool Slide out as far as tool will allow.

3. Place the HiFocus Mid-Scala Electrode array into the Reloading Tool as shown in Figure 6-59.

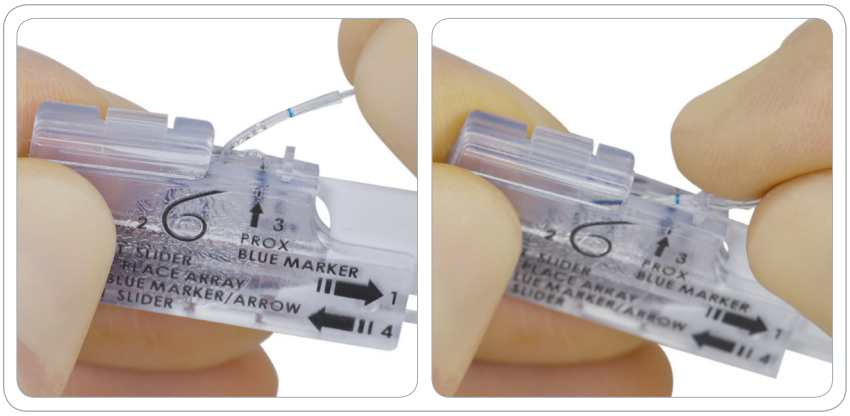


Figure 6-59.
Place the HiFocus Mid-Scala Electrode array into the Electrode Slot of the Reloading Tool.

4. Align the Proximal Blue Marker with the Arrow Mark on the Reloading Tool as shown and lightly press the proximal end of the HiFocus Mid-Scala Electrode array Reloading Tool Tabs (Figure 6-60). The Protective Sleeve Stop should be behind the Tabs to stabilize the electrode.

Figure 6-60.
Align the Proximal Blue marker and proximal end of the HiFocus Mid-Scala Electrode array.

5. Slowly engage the Slide mechanism back into the Reloading Tool until the HiFocus Mid-Scala Electrode is fully extended and straight (Figure 6-61).

Figure 6-61.
Reloading Tool with slide fully engaged.

6. The Slide mechanism should stop automatically. You may notice that there is a gap between the handle of the Slide mechanism and the body of the Reloading Tool. This gap is normal and is designed to prevent damage to the electrode lead.

Prepare the HiFocus Mid-Scala Electrode Insertion Tool

1. Retract the Electrode Insertion Tool Slide until a hard stop or slight "click" is felt (Figure 6-62).

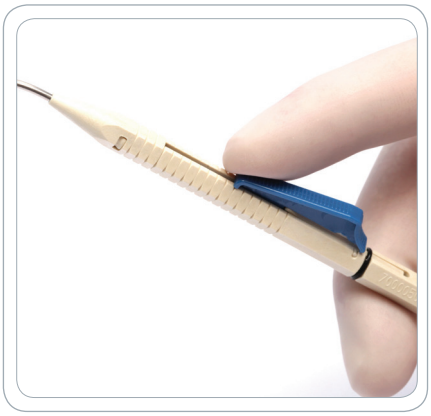


Figure 6-62.
Retract the Slide of the Electrode Insertion Tool.

2. Set the Automatic Stylet Reset mechanism. Press the Set Button (at the proximal end of the Electrode Insertion Tool handle) as shown in **Figure 6-63.**

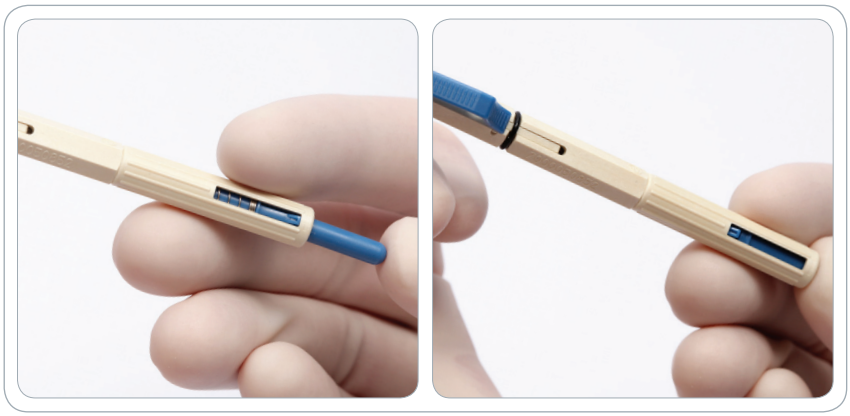


Figure 6-63.
Set the Automatic Stylet Reset Mechanism.

3. The Ejector Tube is now fully retracted into the Electrode Orientation Tube, and the Stylet is fully extended out of the Insertion Tool.

Figure 6-64.
Stylet loaded into Electrode Insertion Tool.

4. Orient the Slot of the Electrode Orientation Tube to the "jog" of the HiFocus Mid-Scala Electrode **(Figure 6-65)**.

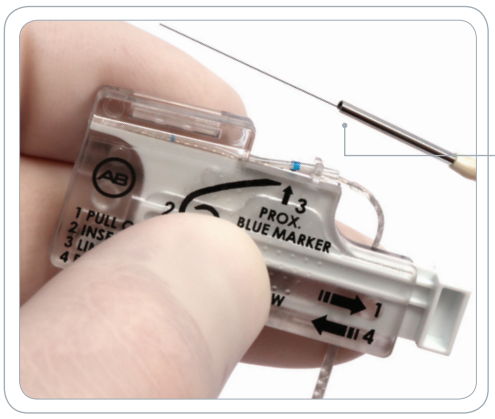


Figure 6-65.
Orient the Slot of the Electrode Orientation Tube to the "jog" of the HiFocus Mid-Scala Electrode.

5. Locate the Stylet hole of the HiFocus Mid-Scala Electrode array.

6. Introduce the HiFocus Mid-Scala Stylet into the Stylet hole of the HiFocus Mid-Scala Electrode array as shown in **Figure 6-66**.

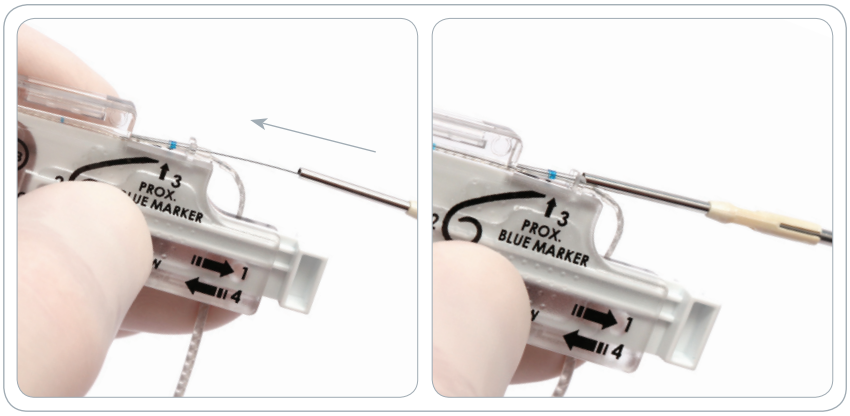


Figure 6-66.
Introduction of HiFocus Mid-Scala Stylet into the Stylet hole.

7. Continue to slide the Stylet into the hole of the HiFocus Mid-Scala Electrode array until the "jog" of the electrode is positioned within the Slot ("key") section of the Orientation Tube **(Figure 6-67)**. The end of the Orientation Tube should almost touch the Tabs of the Reloading Tool.

Figure 6-67.
Electrode array "jog" is positioned into the Slot of the Orientation Tube.

8. With the Slide of the Reloading Tool engaged, gently lift the Insertion Tool to disengage the HiFocus Mid-Scala Electrode from the Tabs of the Reloading Tool. Remove the HiFocus Mid-ScalaElectrode/Stylet Assembly from the Reloading Tool **(Figure 6-68)**.

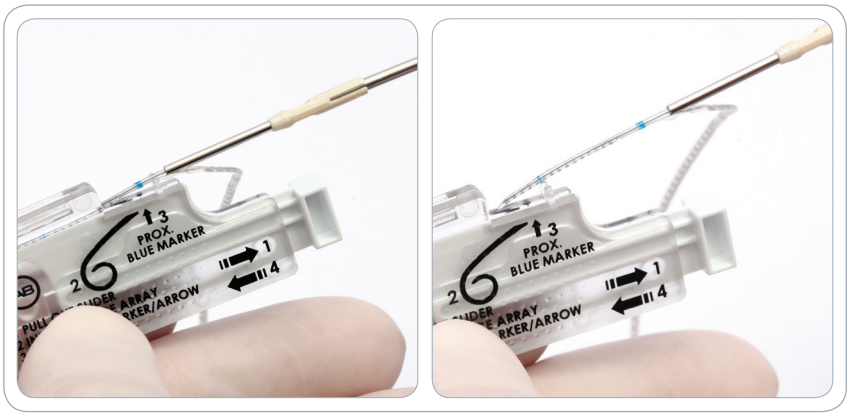


Figure 6-68.
Remove the HiFocus Mid-Scala Electrode/ Stylet Assembly from the Reloading Tool.

9. Verify that the HiFocus Mid-Scala Electrode array is completely loaded on the Stylet (Figure 6-69).

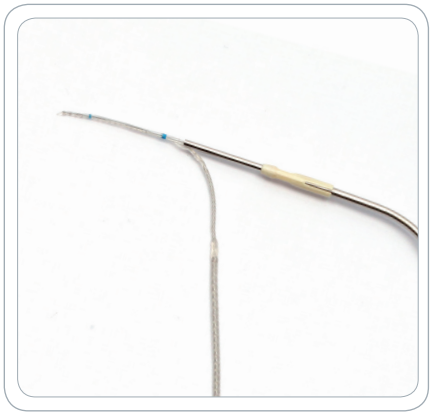


Figure 6-69.
HiFocus Mid-Scala Electrode fully loaded on the Stylet, loaded into the Insertion Tool.

Pack the Cochleostomy

To secure the HiFocus Mid-Scala Electrode in place, fascia or muscle should be well packed around the cochleostomy site.

NOTE: Pack completely around the electrode array.

Coil the Electrode Lead

Once the HiFocus Mid-Scala Electrode array has been secured at the cochleostomy site, the excess electrode lead is coiled inside the mastoid cavity. Use the mastoid cavity bony overhangs to retain the coiled lead in position.

NOTE: While coiling the excess electrode lead into the mastoid cavity, some rotation of the electrode array outside the cochleostomy may be observed. This is a normal characteristic due to the rotational effect from the coiling.

Closing Procedures

Testing

Intraoperative testing of the HiRes Ultra 3D is an option implant centers may wish to perform. Software used in patient programming can also be utilized intraoperatively to test a wide range of functions, including electrode impedance measurements and Neural Response Imaging (NRI). It is up to each implant center to decide if testing intraoperatively is to be performed. Contact Advanced Bionics for specific instructions and guidance if this option is selected.

Suturing

The scalp wound is closed in layers using sutures or staples.

Mastoid Dressing

A compression dressing is applied. The patient is usually discharged on the first postoperative day and sutures/staples are typically removed seven to ten days following surgery. There are various methods of compression dressing and it is up to the surgeon as to which method is selected.

Drains

Some surgeons may place a closed suction drain in the posterior aspect of the wound. It is usually removed 24 hours after surgery and a mastoid pressure dressing is reapplied. However, in the patient with congenital malformation of the cochlea and Cerebro Spinal Fluid (CSF) leak at the cochleostomy site, it may not be recommended to use a post-auricular wound drain.

Imaging

Intraoperative X-rays are recommended to verify electrode placement.

MRI Safety Information

Testing has demonstrated that the HiRes Ultra 3D Cochlear Implant is MR Conditional. Unilateral and bilateral recipients with this device can be safely scanned in an MR system meeting certain conditions.

For information regarding the use of an MRI scanner with a HiRes Ultra 3D device, refer to the MRI Safety Information booklet or contact Advanced Bionics Technical Support at technicalservices@advancedbionics.com, 1-877-454-5051, or visit www.advancedbionics.com/mri

Magnet Removal/Replacement Using Common OR Tools

The House Ear Elevator, Freer Elevator, and the cerumen curette are common OR tools that can be used for magnet removal and replacement. Ensure that these or similar tools are sterilized and available for the magnet removal and replacement procedures.

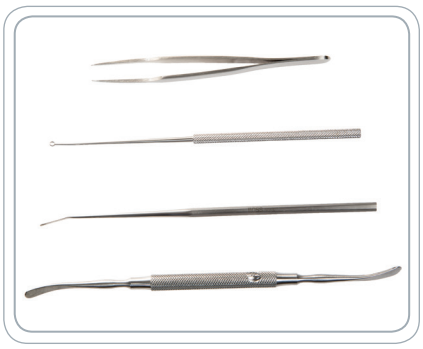


Figure 7-1.
The OR tools should be sterilized prior to procedure.

Components Required

- HiRes Ultra 3D Replacement Magnet (CI-1419)
- HiRes Ultra 3D Temporary Non-Magnetic Plug (CI-1420)
- Patient Headpiece
- Marking Pen

NOTE: The HiRes Ultra 3D Replacement Magnet and HiRes Ultra 3D Temporary Non-Magnetic Plug are non-reusable, single use sterile components.

Prior to preparing the sterile surgical site place the patient's headpiece over the coil/magnet portion of the implant.

Verify that the headpiece attracts appropriately magnetically.

Decide on location for an incision to gain access to the implant. This incision should be 1 centimeter away from the patient's headpiece either to the side of the implant or behind the implant.

Once the location is determined draw the incision location with a marking pen.

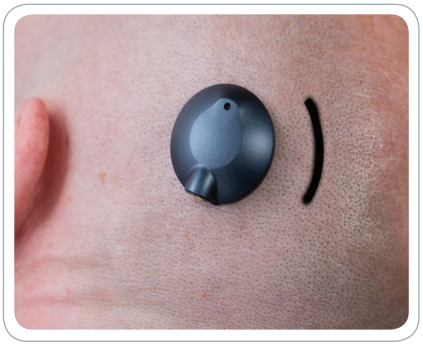


Figure 7-2.
BTE and receiver package sites drawn with incision location.

This location needs to remain visible after preparations for creating a sterile field including any hair removal.

NOTE: If marked location is not maintained for any reason, the patient's headpiece can be placed in a sterile bag and placed over the coil/magnet site and the incision location can be re-established.

CAUTION: Monopolar electrocautery must not be used. For the use of bipolar electrosurgical equipment, the probe tips must not contact the implant and should be kept more than 1 mm (0.04 in) from the implant.

Create an incision to gain access to the receiver package. Typically the fibrous capsule is accessed and the fibrous tissue lifted away from the silicone portion of the coil/magnet prior to cutting open.

Open the fibrous capsule to gain visualization of the magnet pocket location on top of the receiver package coil/magnet region.
Extend the skin incision and fibrous capsule as necessary to gain sufficient access to remove the magnet.

CAUTION: Careful handling is required as the silicone pocket can be easily damaged by sharp instruments, forceps and similar instruments. Use microscope to access and visualize the fibrous tissue, receiver package and silicone aspects of the magnet pocket.

Magnet Removal

Ensure the magnet pocket site has sufficient fluid (water) to provide lubrication.

Slide the distal end of the House Ear Elevator or similar tool under the far side of the magnet pocket lifting the silicone lip **(Figure 7-3)**.

Figure 7-3.
Hold House Elevator with angle facing downward.

Now slowly flip the magnet out of the pocket by tilting the instrument on its side as shown. The magnet is attracted to the instrument so it is automatically retained on the tool **(Figure 7-4)**.

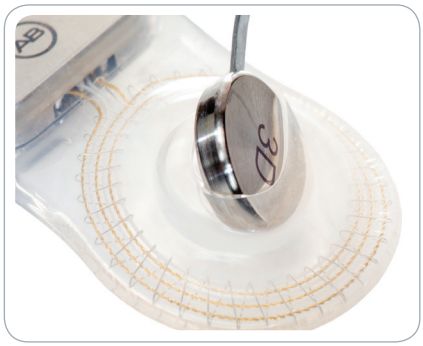


Figure 7-4.
House Elevator "flipping" magnet out of magnet pocket.

Remove the magnet from the instrument by sliding off sideways (less magnetic attraction) **(Figure 7-5)**.

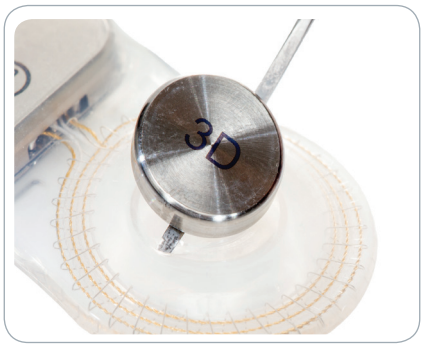


Figure 7-5.
Magnet removed.

Magnet Installation

NOTE: The magnet is lasermarked as shown with the letters "3D" on one face. The letters "3D" may face in or out.

Figure 7-6.
Magnet almost "Loaded" for placement.

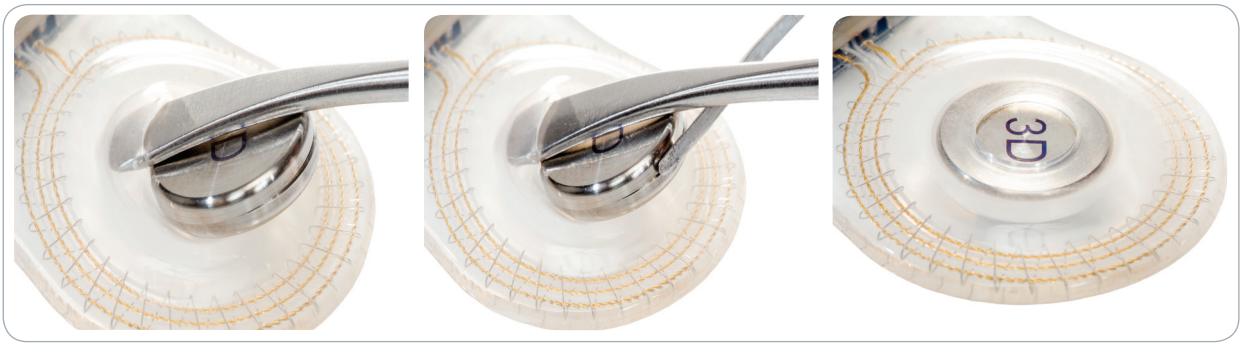


Figure 7-7.
Place Freer Elevator under distal silicone lip.

Figure 7-8.
Freer Elevator tool holding magnet in position as House Elevator tool is used to push the magnet into the silicone pocket.

Figure 7-9.
Magnet Silicone Pocket Inspected – No Damage Verified (torn or split silicone is obvious).

Temporary Non-Magnetic Plug Installation

There are two options in which the magnet can be removed and replaced with a Temporary Non-Magnetic plug. The first is prior to the implantation of the receiver package and the other is after implantation.

Both scenarios are described below:

Temporary Non-Magnetic Plug Installation Procedure Prior to Implantation

Place the receiver package in the sterile field on a non-magnetic flat surface and ensure the device has fluid over the site of the magnet pocket region. Fluid provides lubrication to aid in magnet removal and Temporary Non-Magnetic plug reinstallation.

Temporary Non-Magnetic Plug Installation Procedure After Implantation

CAUTION: Monopolar electrocautery must not be used. For the use of bipolar electrosurgical equipment, the probe tips must not contact the implant and should be kept more than 1 mm (0.04 in) from the implant.

Remove the magnet as previously described.

CAUTION: Careful handling is required as the silicone pocket can be easily damaged by sharp instruments, forceps, and similar instruments.

The House Ear Elevator, Freer Elevator, cerumen curette, and forceps are common OR tools that can be used for insertion and removal of the Temporary Non-Magnetic plug. Ensure that these or similar tools are sterilized and available for the Temporary Non-Magnetic plug removal and replacement procedures.

Obtain a sterile Temporary Non-Magnetic Plug from the sterile packaging.

Ensure sterile water or sterile saline is in the magnet pocket and applied to the adjacent area.

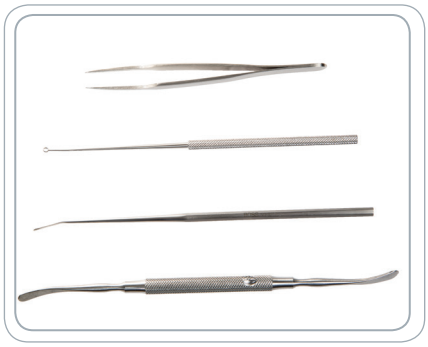


Figure 7-10.
The OR tools should be sterilized prior to procedure.

Slide the distal end of the Freer Elevator under the far side of the magnet pocket lifting the silicone lip. Using forceps or fingers, place the Temporary Non-Magnetic Plug into the silicone magnet pocket and slide the distal side under the silicone lip **(Figure 7-11)**. Move side to side and in a proximal direction to ease the lip over the Temporary Non-Magnetic Plug. Or Place the Freer Elevator, House Elevator, or Cerumen Curette under the silicone lip (between the Temporary Non-Magnetic Plug and the silicone lip) and slide around in a circular fashion until the silicone lip is completely over the Temporary Non-Magnetic Plug **(Figure 7-12)**. Use a gimmick (house elevator or a cerumen curette) to encourage the silicone lip over the remaining Temporary Non-Magnetic plug. Use short 1-2 mm movements and proceed side to side, if needed.

NOTE: Since the Temporary Non-Magnetic plug does not have any magnetic attraction there are no orientation marks on it. Either side can face up.

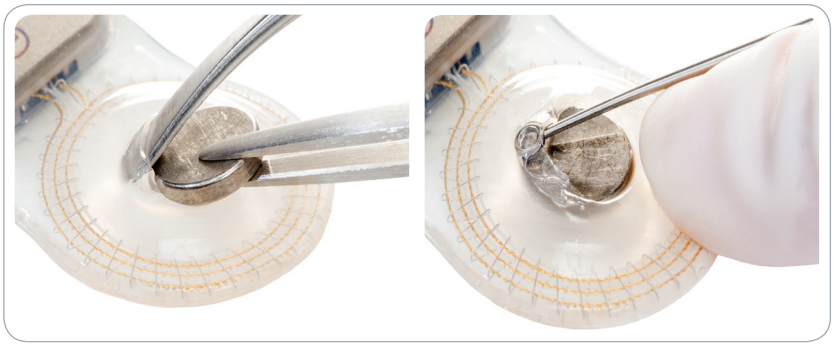


Figure 7-11.
Inserting Temporary Non-Magnetic Plug using Freer Elevator and forceps.

Figure 7-12.
Inserting Temporary Non-Magnetic Plug using House Elevator and forceps.

Ensure no damage to the silicone lip prior to proceeding to closure.

Figure 7-13.
Magnet Silicone Pocket Inspected – No Damage Verified (torn or split silicone is obvious).

Special Handling

Ordering the HiRes Ultra 3D Cochlear Implant

The following chart lists part number information for ordering the HiRes Ultra 3D.

Description	Part No.
HiRes Ultra 3D CI HiFocus SlimJ electrode	CI-1601-05
HiRes Ultra 3D CI HiFocus MS electrode	CI-1601-04

Surgeon's Tools — Ordering Information

The following charts identify the surgeon's tools used when implanting the HiRes Ultra 3D.

NOTE: A single-use, sterile silicone HiRes Ultra Mock Up, CI-4426, is included with the HiRes Ultra 3D implant.

HiRes Ultra Reusable Surgical Tool Kit, CI-4509

These tools must be sterilized prior to use. See the *"Guide for Reprocessing HiRes Ultra Reusable Tools"* provided in the kit.

Description	Part No.	Qty
HiRes™ Ultra Recess Gauge	CI-4331	2
HiRes™ Ultra Coil Gauge	CI-4341	2
HiRes™ Ultra BTE Template	CI-4421	2

HiRes Ultra 3D with HiFocus SlimJ – Surgical instruments

Description	Part No.
Kit HiFocus Electrode Forceps*	CI-4350-02
HiFocus SlimJ Electrode Depth Gauge	CI- 1605

The HiFocus Electrode Forceps must be sterilized prior to use. See the "Guide for Reprocessing HiFocus Electrode Forceps" provided in the kit.

The following tools can be used with both the HiFocus SlimJ and HiFocus Mid-Scala electrodes

HiFocus Mid-Scala Electrode Instrument Kit, CI-4508

These tools must be sterilized prior to use. See the *"Guide for Reprocessing HiRes Ultra Reusable Tools"* provided in the kit.

Description	Part No.	Qty
HiFocus™ Mid-Scala Cochleostomy Gauge	CI-4347	2
HiFocus™ Mid-Scala Claw Tool	CI-4254	2

HiRes Ultra 3D with HiFocus Mid-Scala – Surgical instruments

HiFocus MS Electrode Insertion Tool, CI-4207

Description	Qty
Insertion Tool	1

HiFocus MS Electrode Insertion Tool Kit, CI-4507

Description	Qty
Insertion Tool	1
Stylet	1
Reloading Tool	1

Handling

Severe impact could damage the storage pack which may, in turn, rupture the sterile packaging. The implant should be treated with the same care and attention appropriate for any implantable medical device.

Neither the implant nor the Electrode Insertion Tool are intended to tolerate a drop onto a hard surface. If the implant falls onto a hard surface, it must be returned to Advanced Bionics and the backup implant must be used. The returned device should be accompanied by a detailed description of the impact that caused the return.

Shelf Life

A *Use Before* date is noted on the packaging and is based on the date of the original sterilization.

Sterilization

The HiRes Ultra 3D implant and HiFocus electrode device are supplied in ethylene oxide sterilized packaging with indicators of sterilization. Sterile packs should be carefully inspected to confirm that they have not been ruptured. Any devices found in ruptured packages should not be used and should be returned to Advanced Bionics.

Storage

HiRes Ultra 3D implants should be stored where temperatures do not exceed 50°C/122°F nor fall below 0°C/32°F.

Explant of the HiRes Ultra

All explanted devices should be returned to Advanced Bionics. All contaminated parts must be returned in the Cochlear Implant Explant Return Kit, 305-M078, in accordance with International Air Transport Association (IATA) rules. Please contact Advanced Bionics for further information.

Product Compatibility Tables

Table 1

Processor Type	Implant Type					
	C1	CII	HiRes 90K	HiRes90K Advantage	HiRes Ultra	HiRes Ultra 3D
Naída CI	–	✓[5]	✓[5]	✓[5]	✓[6]	✓[7]
Neptune	–	✓[1]	✓[1]	✓[1]	✓[6]	✓[7]
Harmony	✓[2]	✓[3]	✓[3]	✓[1]	✓[6]	✓[7]
Auria	–	✓	✓	–	–	–
Platinum Sound Processor (PSP)	✓[4]	✓	✓	✓[1]	✓[6]	✓[7]

References: [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. [7]Requires SoundWave 3.1 or later and CPI-3.

Table 2

Software Type/Version	Implant Type					
	C1	CII	HiRes 90K	HiRes 90K Advantage	HiRes Ultra	HiRes Ultra 3D
SClin2000	✓	✓	–	–	–	–
SoundWave 1.0 (or later)	–	✓	✓	–	–	–
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]	✓	✓	✓	✓	✓

References: [1]Only on Harmony. [2]Requires SoundWave 2.1.13 or later.

Table 3

Headpiece Type	Processor Type				
	Naída CI	Neptune	Harmony	Auria	PSP
Concave UHP	✓	✓	✓	✓	✓
Universal Headpiece (UHP)	✓	✓	✓	✓	✓
AquaMic	✓[1]	✓	–	–	–
HR 90K Auria Headpiece	–	–	✓	✓	–
Platinum Headpiece	–	–	✓	✓	✓
UHP 2.0	✓	✓	✓	–	✓
UHP 3D	✓	✓	✓	–	✓
AquaMic™ 3D	✓[1]	✓	–	–	–

References: [1] Requires AquaCase™ Container

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For information on additional AB locations, please visit
AdvancedBionics.com/contact

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