



**CAUTION:** Federal law restricts this device to sale, distribution and use by or on the order of a physician. For use in children, Federal law restricts this device to sale, distribution and use by or on the order of a physician who is trained in the pediatric implantation procedures for the HiRes 90K Cochlear Implant.

This device is protected under one or more of the following U.S. Patents: 3,751,605, 3,752,939, 4,400,590, 4,405,831, 4,495,917, 4,686,765, 4,721,551, 4,819,647, 4,837,049, 4,969,468, 4,991,582, 4,931,795, 4,990,845, RE. 22,170. Other U.S. and /or foreign patents may be pending.

Federal Express and FedEx are registered trademarks of Federal Express Corporation.

HiFocus and Advanced Bionics are registered trademarks of Advanced Bionics in the United States and other countries. HiRes 90K and SoundWave are trademarks of Advanced Bionics.

Names of products mentioned herein are used for identification purposes only and may be trademarks and/or registered trademarks of their respective company.



Authorized to affix the CE mark in 2004.

#### Headquarters

Advanced Bionics LLC  
12740 San Fernando Road  
Sylmar, CA 91342  
(800) 678-2575 in U.S. and Canada  
(661) 362-1400  
(661) 362-1500 Fax

#### Europe

Advanced Bionics SARL  
76, rue de Battenheim  
68170 Rixheim, France  
+33 (0) 3-89-65-98-00  
+33 (0) 3-89-65-50-05 Fax

#### Latin America

Advanced Bionics  
25129 Rye Canyon Loop  
Valencia, CA 91355, USA  
(661) 362-1840

#### Asia-Pacific

Advanced Bionics Asia-Pacific Limited  
Suite 4203, 42/F Tower One  
Lippo Centre, 89 Queensway  
Hong Kong  
852-2526-7668



# HiRes 90K<sup>®</sup>

Surgeon's Manual for the  
HiFocus<sup>®</sup> Helix and  
HiFocus<sup>®</sup> 1j Electrodes



## Acknowledgements

This manual represents hundreds of hours working with the surgical aspects of implanting HiRes 90K®, the HiFocus Helix® and HiFocus®1j electrodes. As with any project of this size, we are grateful to the fine surgeons and operating room professionals we have worked with and who have made valuable contributions to this manual with their insights and observations.

We want to acknowledge the following individuals for their contributions and guidance:

David Schramm, MD, FRCSC, FACS  
Cochlear Implant Centers  
University of Ottawa  
Ottawa, Ontario, Canada

Loren Bartels, MD, FACS  
Tampa Bay Hearing & Balance Center  
Tampa, Florida, U.S.A.

## Contributors

Jorge Almario, MD, Bogotá, Colombia  
Manohar Bance, MD, FRCSC, Halifax, Nova Scotia, Canada  
Jose Fayad, MD, FACS, Los Angeles, California, U.S.A.  
Eric Kraus, MD, FACS, Greensboro, North Carolina, U.S.A.  
Jose Lora, MD, Bogotá, Colombia  
William Luxford, MD, FACS, Los Angeles, California, U.S.A.  
Ralph A. Nelson, MD, FACS, and Dr. Nelson's *Temporal Bone Surgical Dissection Manual*, House Ear Institute, Los Angeles, CA 90057, U.S.A.  
Lorne Parnes, MD, FRCSC, London, Ontario, Canada  
Jose Prieto, MD, Bogotá, Colombia  
Peter Roland, MD, Dallas Texas, U.S.A.  
P. Ashley Wackym, MD, FACS, Milwaukee, Wisconsin, U.S.A.









# Table of Contents

Labeling .....	1
<b>1. Introduction .....</b>	<b>3</b>
HiRes 90K Components and Features .....	3
HiRes 90K Implant Description .....	3
HiRes 90K Surgical Tool Kit, CI-4500 .....	5
HiRes 90K Packaging and Handling .....	6
<b>2. Preoperative Considerations .....</b>	<b>13</b>
Ear Selection .....	13
Imaging .....	13
<b>3. Initial Surgical Procedures .....</b>	<b>15</b>
Preparation and Implant Positioning .....	15
Incision .....	16
Conventional Incision Approach .....	17
Minimal Incision Approach .....	23
Cochleostomy .....	30
Procedures Before Device Placement .....	31
<b>4. HiRes 90K Fixation .....</b>	<b>33</b>
HiRes 90K Implant Fixation .....	33
<b>5. HiFocus Helix Electrode .....</b>	<b>35</b>
HiFocus Helix Electrode Description .....	35
HiFocus Helix Electrode Specifications .....	36
HiFocus Helix Electrode Insertion Tool - Stylet Assembly and Handle .....	37
How the HiFocus Helix Electrode Insertion Tool Works .....	39
Single-Use HiFocus Helix Tools .....	40
HiRes 90K with HiFocus Helix Electrode Equipment Requirements .....	41
HiRes 90K Surgical Mock-up, CI-4425 .....	43
HiRes 90K Surgical Tool Kit, CI-4500 .....	43
HiFocus Helix Electrode Instrument Kit, CI-4501 .....	44
HiRes 90K with Helix Electrode Surgical Equipment Sterilization Guidelines .....	46
HiFocus Helix Electrode - Facial Recess .....	47
HiFocus Helix Electrode - Cochleostomy .....	47
HiFocus Helix Electrode Insertion .....	48
Mount the Stylet Assembly into the Handle .....	49
Prepare for Electrode Insertion - Orient the Insertion Tool .....	51
Position the Stylet Guide-Footpad and Insert the HiFocus Helix Electrode Array .....	52
Withdraw the Electrode Insertion Tool .....	55
Reloading the HiFocus Helix Electrode Array .....	56
Determine HiFocus Helix Electrode Insertion Depth .....	60
Pack the Cochleostomy .....	60

Coil the Electrode Lead .....	61
Imaging .....	62
HiFocus Helix Insertion Sequence .....	62
HiFocus Helix Reloading Sequence .....	62
<b>6. HiFocus 1j Electrode .....</b>	<b>63</b>
HiFocus 1j Electrode Description .....	63
HiFocus 1j Electrode Specifications .....	63
HiFocus 1j Electrode Insertion Tool and Tube .....	64
HiRes 90K with 1j Electrode Equipment Requirements .....	65
HiRes 90K Surgical Mock-up, CI-4425 .....	66
HiRes 90K Surgical Tool Kit, CI-4500 .....	67
HiFocus 1j Electrode Instrument Kit .....	68
Using the Metal Insertion Tube, AB-6135 .....	69
HiRes 90K with HiFocus 1j Electrode Equipment Sterilization Guidelines .....	70
HiFocus 1j Electrode Insertion .....	71
Mate the Insertion Tube to the Electrode Insertion Tool .....	71
Rotate the Insertion Tube Slot Toward the Modiolus .....	71
Verify the Orientation of the Electrode Array .....	72
Position the Insertion Tube and Insert the Electrode HiFocus 1j Array .....	73
Remove the Electrode Insertion Tool .....	73
If It Becomes Necessary to Reload the HiFocus 1j Electrode Array into the Insertion Tube .....	74
Following Removal of the Electrode Insertion Tool .....	75
Pack the Cochleostomy .....	75
Coil the Electrode Lead .....	76
Imaging .....	76
<b>7. Closing Procedures .....</b>	<b>77</b>
Testing .....	77
Suturing .....	77
Mastoid Dressing .....	77
Drains .....	77
Imaging .....	77
<b>8. Special Handling .....</b>	<b>79</b>
Ordering the HiRes 90K with HiFocus Helix or HiFocus 1j Electrode .....	79
Surgeon's Tools—Ordering Information .....	79
Surgeon's Tools needed when implanting the HiRes 90K with the HiFocus Helix Electrode, CI-1400-02H .....	79
Surgeon's Tools needed when implanting the HiRes 90K with the HiFocus 1j Electrode, CI-1400-01 .....	80
Handling .....	81
Shelf Life .....	81
Sterilization .....	81
Sterilization of the Single-Use HiRes 90K Plastic Mock-up, CI-4425 .....	81
Decontamination and Resterilization of the Advanced Bionics Surgical Tools .....	81
Decontamination and Resterilization of the HiFocus 1j Electrode Insertion Tool .....	82
Storage .....	83
Explant of the HiRes 90K .....	83









## Labeling

Below is a sample of the HiRes 90K with Helix Electrode implant device labeling:

		<p>MANUFACTURED BY ADVANCED BIONICS® LLC 12740 San Fernando Rd Sylmar, CA 91342 USA (+1) 818-362-7588</p>									
<p>HiResolution® Bionic Ear System <b>HiRes 90K® Cochlear Implant</b> with the <b>HiFocus® Helix Electrode</b> Model CI-1400-02H</p>		<p>ADVANCED BIONICS SARL 76 Rue de Battenheim 68170 Rixheim, France +33 (0) 3 89 65 98 00</p>									
STERILE	EO				0°C		+50°C		XXXXX		20yy-mm
SN	XXXXX	<p>Caution: Federal Law restricts this device to sale, distribution, and use by or on order of a physician. For use in children, Federal Law restricts this device to sale, distribution and use by or on the order of a Physician who is trained in the Pediatric implantation procedure for the cochlear implant.</p>		<p>Contents: HiRes 90K Cochlear Implant Device and Literature.</p>							
STERILE LOT	XXXXX	XXXXX									
				0123							

PLEASE NOTE: HiFocus® Helix Electrode text in **BLUE**









Below is a sample of the HiRes 90K with 1j Electrode implant device labeling:

		<p>MANUFACTURED BY ADVANCED BIONICS® LLC 12740 San Fernando Rd Sylmar, CA 91342 USA (+1) 818-362-7588</p>									
<p>HiResolution® Bionic Ear System <b>HiRes 90K® Cochlear Implant</b> with the <b>HiFocus® Electrode</b> Model CI-1400-01</p>		<p>ADVANCED BIONICS SARL 76 Rue de Battenheim 68170 Rixheim, France +33 (0) 3 89 65 98 00</p>									
STERILE	EO				0°C		+50°C		XXXXX		20yy-mm
SN	XXXXX	<p>Caution: Federal Law restricts this device to sale, distribution, and use by or on order of a physician. For use in children, Federal Law restricts this device to sale, distribution and use by or on the order of a Physician who is trained in the Pediatric implantation procedure for the cochlear implant.</p>		<p>Contents: HiRes 90K Cochlear Implant Device and Literature.</p>							
STERILE LOT	XXXXX	XXXXX									
				0123							

PLEASE NOTE: HiFocus® 1j Electrode text in **GREEN**

## Labeling

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

<b>CAUTION:</b>	Federal law restricts this device to sale, distribution, and use by or on the order of a physician.	
	European Community Mark of Conformity. Authorized to affix the CE Mark in 2004	 Expiration of product
<b>REF</b>	Model number	 Temperature product should be stored at.
<b>SN</b>	Serial number	 See instructions for use
	Date of manufacture	 Fragile
	Ethylene oxide sterilized	 Single-use only, do not resterilize product.

# 1. Introduction

This manual describes the HiRes 90K® Implant, the HiFocus Helix®, HiFocus® 1j electrodes, and the procedures associated with their implantation in both children and adults. Refer to document number, 9055522-001, "Package Insert", for warnings, contraindications, precautions and information on the system.

Prior to implantation of the HiRes 90K 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 90K Components and Features

This section describes components of the system that are related to surgical implantation of HiRes 90K, including the implant and HiFocus Helix and HiFocus 1j electrode arrays.

## HiRes 90K Implant Description

The HiRes 90K 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 silastic. The overall dimensions are approximately 28 mm wide by 56 mm in length.

Figure 1-1. HiRes 90K implant overall dimensions.

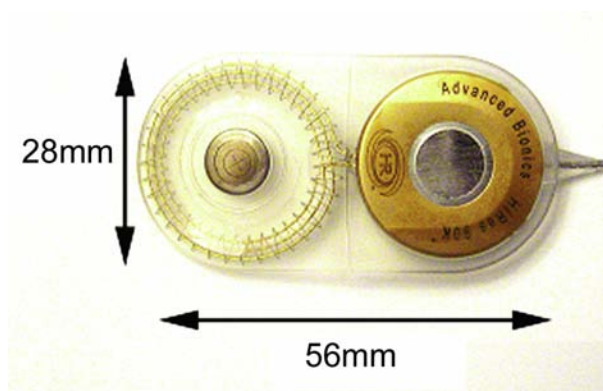
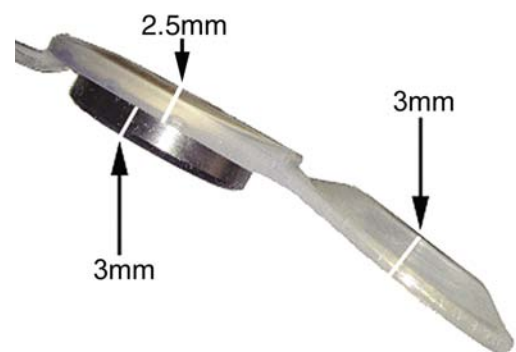


Figure 1-2. HiRes 90K side dimensions.



The HiRes 90K 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 90K Implant, reverse back.

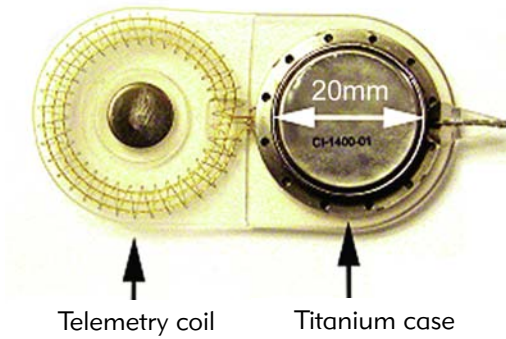


Figure 1-4. HiRes 90K implant with Helix Electrode array.

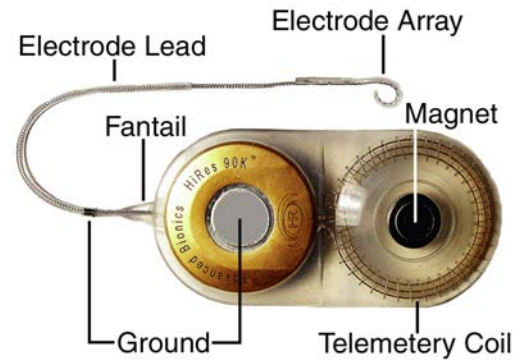
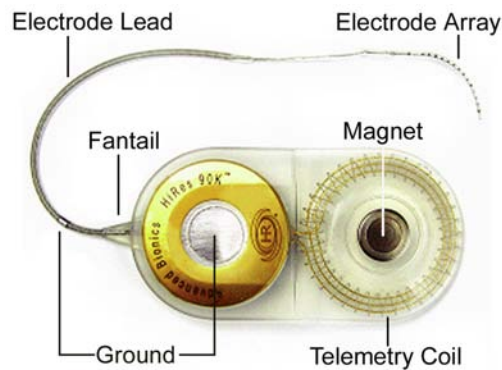


Figure 1-5. HiRes 90K implant with 1j Electrode array.



## HiRes 90K Implant Specifications

Information Update rate	90kHz
Stimulation rate	83 kHz with current software
Independant output circuits	16
Information channels	16 with current software
Programmable memory registers	256
Diagnostics	Neural Response Imaging
Telemetry	Bi-directional communication link

### Electronic Platform

Titanium case	5.5 mm total profile, 2.5 mm above bone profile with 3 mm bone bed depth
Magnet	Removable magnet for MRI
Housing	28 mm x 56 mm flexible silicone
Weight	12 grams

### Implant Packaging

## HiRes 90K Surgical Tool Kit, CI-4500

The HiRes 90K Surgical Tool Kit, CI-4500, includes tools and templates for placement of the HiRes 90K implant package (Figure 1-6).

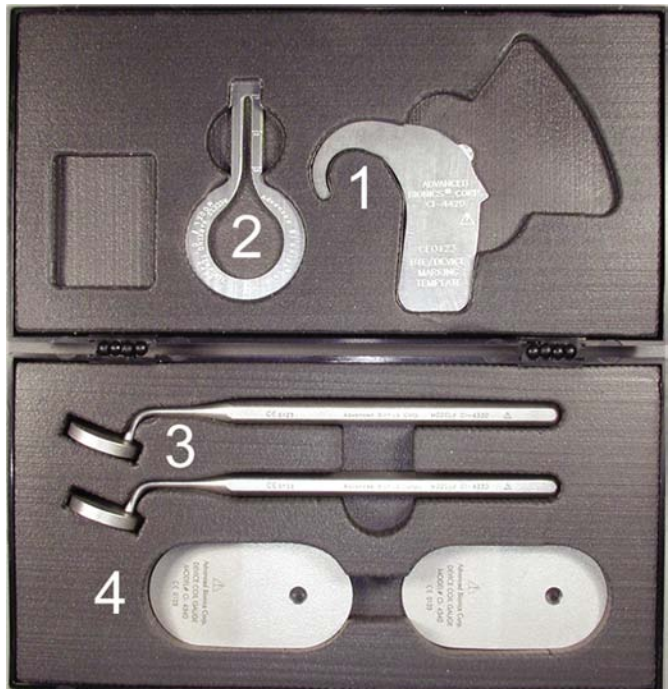
The HiRes 90K Surgical Tool Kit, CI-4500, contains the following tools and templates:

- Two BTE (Behind-the-Ear) Device Marking Templates, CI-4420, (Figure 1-7, [1]).
- Two Recess Marking Templates, CI-4430, (Figure 1-7, [2]).
- Two Recess Gauges, CI-4330, (Figure 1-7, [3]).
- Two Device Coil Gauges, CI-4340, (Figure 1-7, [4]).

Figure 1-6. HiRes 90K Surgical Tool Kit, CI-4500.



Figure 1-7. HiRes 90K Surgical Tool Kit, CI-4500, contents: (1) BTE (Behind-the-Ear) Device Marking Templates, CI-4420, (2) Recess Marking Templates, CI-4430, (3) Recess Gauges, CI-4330, (4) Device Coil Gauges, CI-4340.



## HiRes 90K Implant Packaging and Handling

One sterile, single-use HiRes 90K Surgical Mock-up, CI-4425, is provided with the *primary* HiRes 90K Implant, CI-1400-02H or CI-1400-01 (Figures 1-8, 1-9).

Figure 1-8. HiRes 90K Surgical Mock-up provided with the implant package.

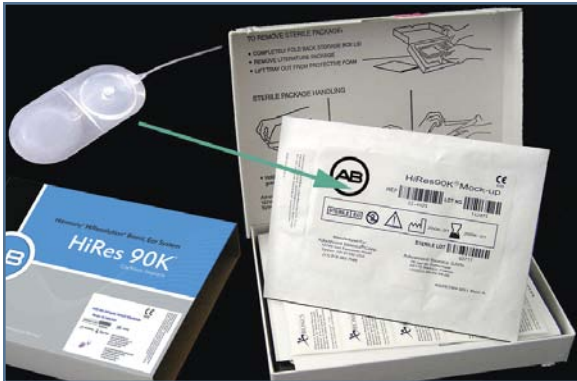


Figure 1-9. HiRes 90K Surgical Mock-up, CI-4425.



It is important to understand the different levels of HiRes 90K 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 *outer sleeve*, (2) the *inner box*, (3) the *outer tray*, and (4) the *inner tray*.

The HiRes 90K implant packaging contains an outer sleeve with labeling that indicates the following:

- Implant serial number
- Model 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 outer sleeve is non-sterile and is used for handling and shipping (Figure 1-10A).

In the operating room, the tamper-proof seals must be broken to access the inner box. The inner box is also non-sterile and has a pre-formed liner that supports the sterile outer tray contained within (Figure 1-10B).

Figure 1-10A. Implant Package, HiFocus Helix Electrode, outer sleeve.



Figure 1-10B . Implant Package, HiFocus Helix Electrode, inner box.



The tamper-proof seals on the *inner* box must be broken to access the sterile *outer* tray. The *outer* tray may be handled in a non-sterile environment (Figure 1-10C).

When you are ready to use the HiRes 90K implant, slowly peel back the cover of the *outer* tray to access the sterile *inner* tray. The *inner* tray must be handled within a sterile field. Extra care in handling the HiRes 90K implant outer and inner trays in the operating room is essential to avoid the build-up of static charge on the implant (Figure 1-10D).

Figure 1-10C. Implant Package, HiFocus Helix Electrode, outer tray.



Figure 1-10D. Implant Package, HiFocus Helix Electrode, inner tray.



**CAUTION:** Peeling the cover off the sterile outer or inner tray too quickly or sliding the HiRes 90K implant device package across a table can increase static charge buildup.

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

- Slowly lift and peel open a corner of the sterile inner tray and pour in sufficient sterile saline to flood and cover the implant device (Figures 1-11A-D).

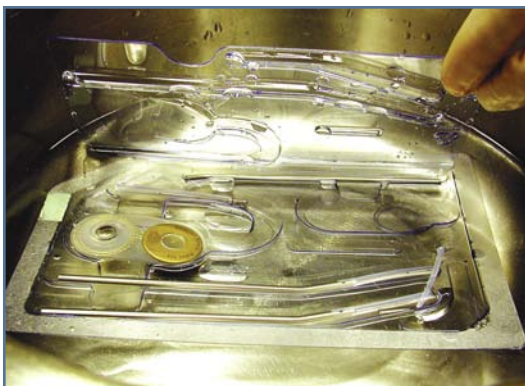
*Figure 1-11A. Slowly open the HiRes 90K implant device outer tray package. Lift the inner tray package out.*



*Figure 1-11B. Flood the inner tray package with saline and slowly lift the top cover off the inner tray.*



*Figure 1-11C. Remove the plastic lid from the inner tray (HiRes 90K with HiFocus Helix electrode).*



*Figure 1-11D. The HiRes 90K implant with HiFocus Helix electrode is ready for the surgeon.*

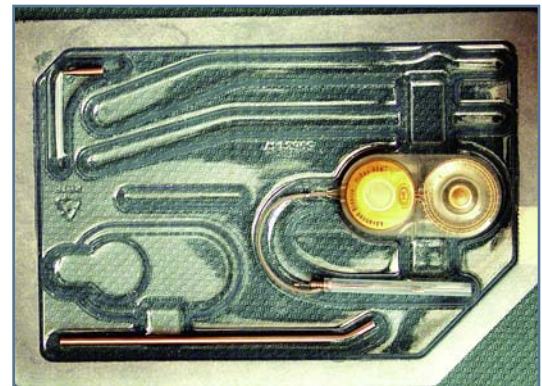
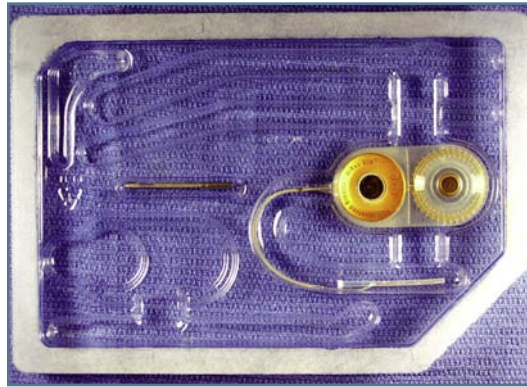


Figure 1-11E. The HiRes 90K implant with HiFocus 1j electrode is ready for the surgeon.



Following is an alternate method for opening the HiRes 90K implant package (Figure 1-12A-H).

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

Figure 1-12A. Slowly open the outer tray package.



Figure 1-12B. Lift out the inner tray package.

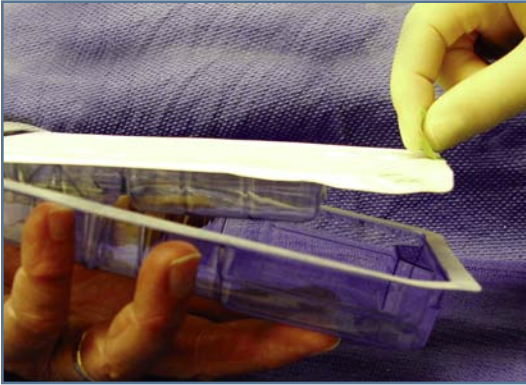


Figure 1-12C. Submerge the inner tray package in a basin filled with sterile saline.



Figure 1-12D. Slowly lift the top cover off the inner tray package to flood the inner tray with saline.



Figure 1-12E. Slowly open the inner tray package.

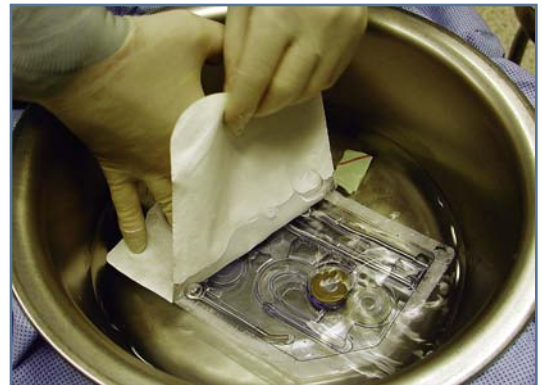


Figure 1-12F. Remove the inner tray package cover.



Figure 1-12G. Lift the plastic lid, covering the tools and implant, out of the inner tray (HiRes 90K with HiFocus Helix electrode).

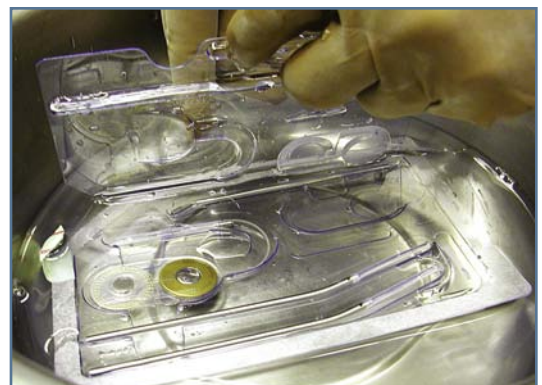


Figure 1-12H. The HiRes 90K implant with HiFocus Helix electrode is ready for the surgeon.

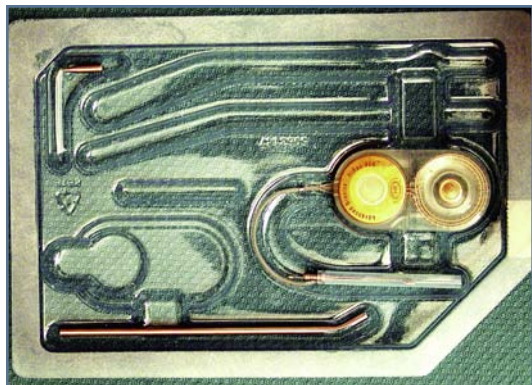


Figure 1-12I. The HiRes 90K implant with HiFocus 1j electrode is ready for the surgeon.

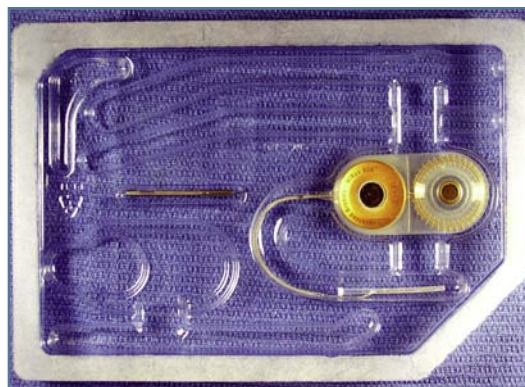


Figure 1-13. Prepare the implant for the surgeon (HiRes 90K with HiFocus Helix electrode).



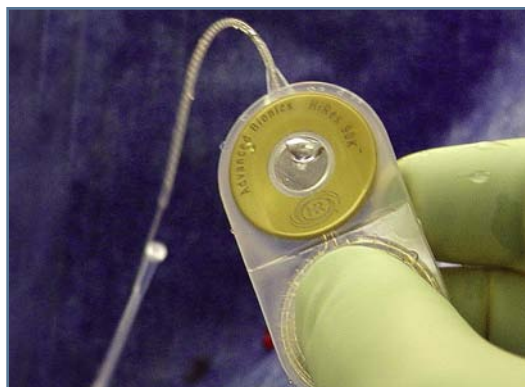
Figure 1-14. The implant tray includes a recessed area on either side of the device that allows the implant to be picked up easily.



Figure 1-15. Receive the HiRes 90K with HiFocus Helix electrode for implantation.



Figure 1-16. Receive the HiRes 90K with HiFocus 1j electrode for implantation.



Note: For information on the HiFocus Helix and HiFocus 1j Electrodes, see the appropriate section.



# 2. 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 package insert 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 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 2-1. CT Scan, Right Ear (axial view).

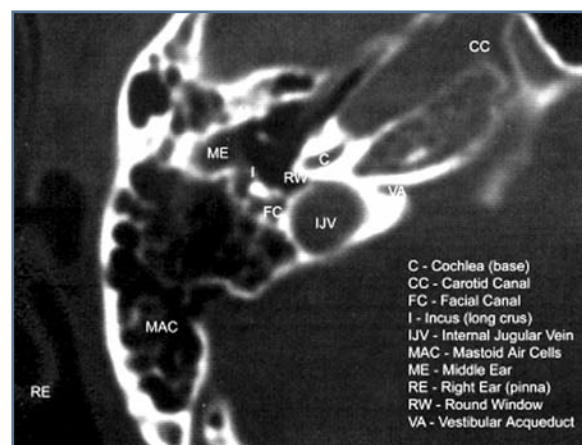
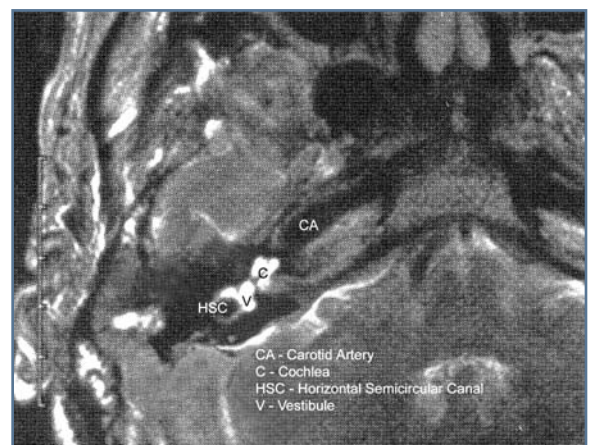


Figure 2-2. MRI Scan, Right Ear (axial view).





# 3. Initial Surgical Procedures

Surgical implantation of the HiRes 90K implant and HiFocus Helix electrode system 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.

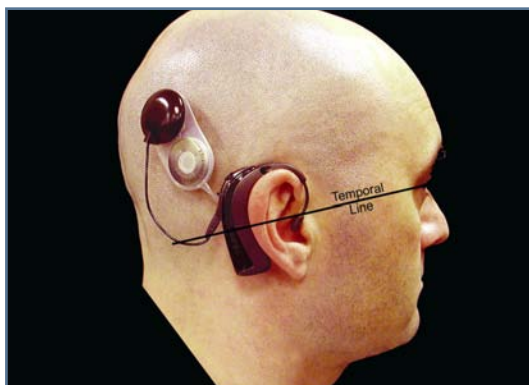
## Preparation and Implant Positioning

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) Device Marking Template, CI-4420. 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 requires a modification of the "typical" incision.

Using the BTE Device Marking Template, CI-4420, 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.*

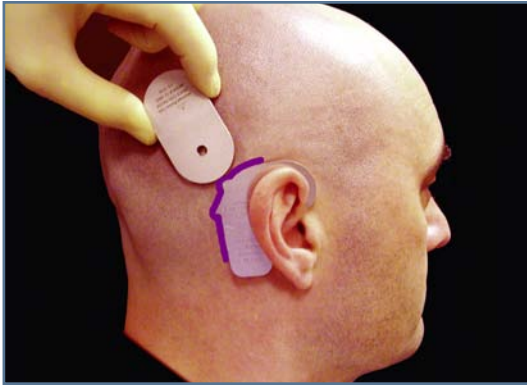


*Figure 3-2. Use the BTE Device Marking Template, CI-4420, to mark the location for the back of the receiver package.*

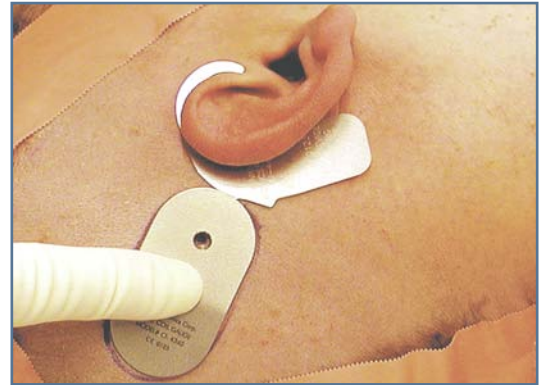


Use the metal HiRes 90K Coil Gauge, CI-4340, to locate the edge of the titanium case at the mark left in the previous step (Figure 3-3).

*Figure 3-3. Place the HiRes 90K Coil Gauge, CI-4340, in a position where the electrode lead exits toward the proposed mastoidectomy location.*



*Figure 3-4. Use the HiRes 90K Coil Gauge, CI-4340, to draw an outline*



## Incision

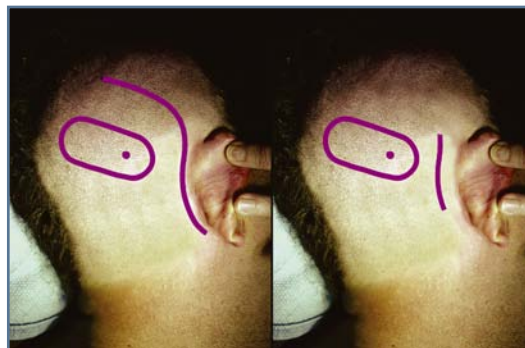
Using a marker, draw an incision line with sufficient clearance to allow for some change of position if necessary. Some surgeons choose to inject a local anesthetic with epinephrine along the incision line.

Incision location should consider the following:

- 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: conventional (left); minimal (right).*



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

Keep the following key recommendations in mind:

- Place the receiver package a minimum of 3.5 cm from the posterior external auditory canal wall.
- 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 recessed well.
- Use non-absorbable sutures-to-bone to secure the device in place.

## Conventional Incision Approach

A *conventional* incision approach is described as follows:

Using a marker, draw an incision line with sufficient clearance to allow for some change in position if necessary (Figure 3-6). The incision line should be kept within the hairline and should be a minimum of 1.5 cm away from the planned location of the implant (Figure 3-7).

*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 posterosuperiorly if it is necessary to thin the scalp flap to 5-7 mm.*

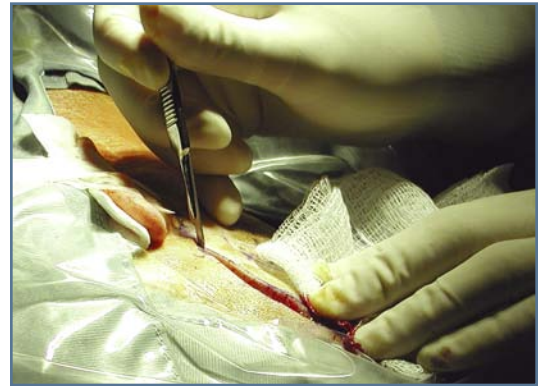


Most surgeons choose to inject local anesthetic along the incision line (Figure 3-8).

*Figure 3-8. Inject with a local anesthetic.*



*Figure 3-9. Incision.*

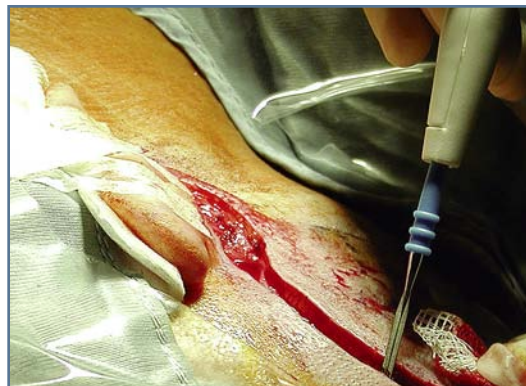


In developing the skin flap keep the following points in mind:

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

**NOTE:** Monopolar electrocautery must not be used once the implant is placed in the sterile operative field.

*Figure 3-10. Use electrocautery to control bleeding.*



- Retain some muscle or fascia tissue for later packing of the cochleostomy site.
- Maintain a scalp flap thickness of approximately 5 mm. The flap should not exceed 7 mm.
- 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.

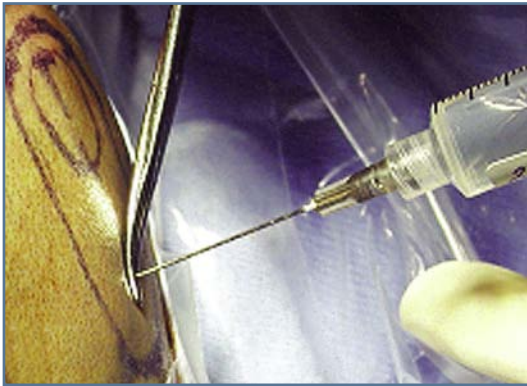


Figure 3-12. Needle-syringe and hemostat adjacent to ruler to determine scalp thickness.



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 needs to be assured that the thickness of the scalp flap over the magnet telemetry coil does not exceed 7 mm.

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

Figure 3-13. Skin flap thickness can be quickly assessed by comparing the thickest portion of the Device Coil Gauge, CI-4340, (approximately 5 mm) to the thickness of the skin/muscle flap.

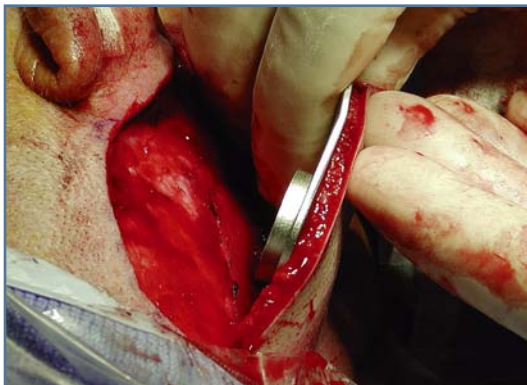
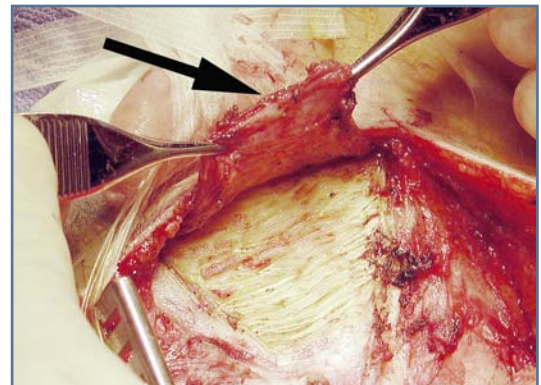


Figure 3-14. Periosteal (Palva) flap (arrow) to cover the mastoid cavity opening.



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. The entire scalp flap is elevated in one layer.

A 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 electrode lead.

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

The facial recess is a triangular space bounded by the short process of the incus superiorly, the facial nerve posteriorly, and the chorda tympani nerve anteriorly (Figure 3-15).

Exposure of the middle ear through the facial recess should allow visualization of the round window (Figure 3-16).

Figure 3-15. Developing the facial recess. Right ear.

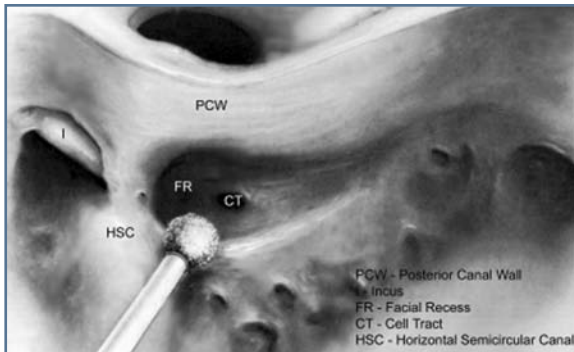
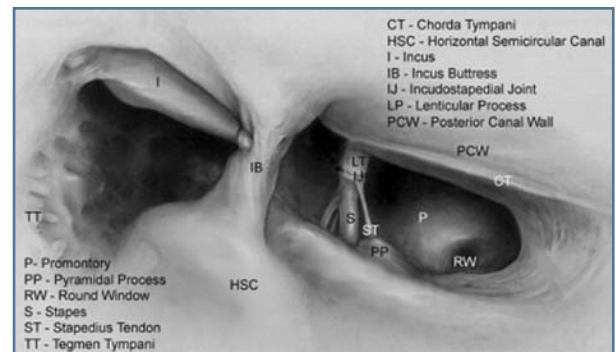


Figure 3-16. Exposure of the middle ear through the facial recess. Right ear.



The facial recess must be sufficient to accommodate the Helix Stylet Assembly and its footpad that will be stabilized on the inferior lip of the cochleostomy or the insertion tube of the HiFocus 1j electrode.

A recessed well for the titanium case, a channel for the electrode fantail and lead, 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 (Figure 3-17).

Figure 3-17. Completed channel for the fantail and electrode lead.



The implant and electrode fantail must not be susceptible to movement along the surface of the skull. Such movement could produce a differential stress on the electrode fantail, leading to damage of the electrode wires. The following four steps are recommended:

**Step 1:** Locate and drill a recessed well for the titanium case.

Using the Recess Marking Template, CI-4430, place the distal end (or tip) at the posterior canal wall. Orient the template to locate the planned recessed area that will be a minimum of 3.5 cm from the posterior canal wall. Draw or mark the shape of the inside edge of the template and establish the location to be drilled.

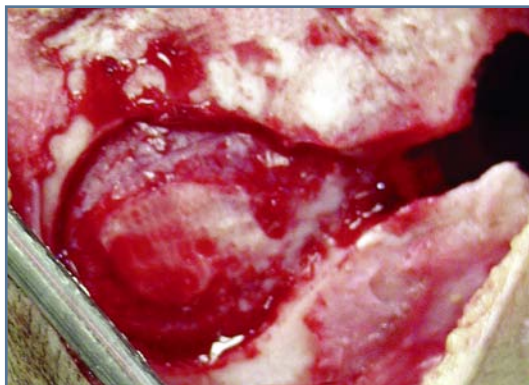
In children and some adults, the thickness of the skull will be less than 3 mm. In these patients, extreme care must be taken to avoid injuring the dura at the base of the recessed bed. Some surgeons may wish to expose dura with a diamond bur around the circumference of the base of the recessed bed creating a bony *island* to protect the dura.

The well should have sufficient depth to accommodate the titanium case and is checked by using the Recess Gauge, CI-4330.

**NOTE:** The diameter of the Recess Gauge, CI-4330, is slightly larger than the titanium case of the implant to ensure that the case will fit.

Failure to create a recessed well or bone bed in the mastoid cortex may also cause a high device profile or allow the implant to migrate, potentially leading to extrusion or skin flap erosion.

*Figure 3-18. Dura exposed around the circumference of the base of the recessed bed creating a bony island to protect the dura (pediatric patient).*



*Figure 3-19. Determine the placement of the recessed well/bone bed using the Recess Marking Template, CI-4430. The tip of the template is placed at the posterior edge of the external auditory canal.*

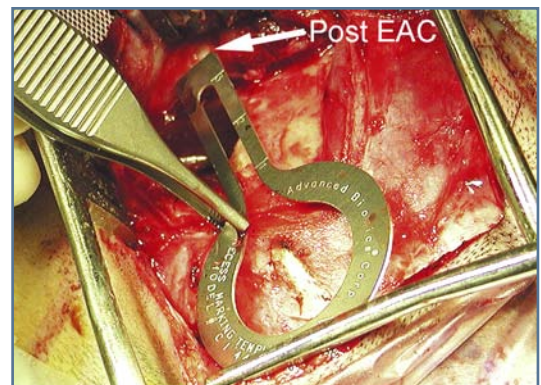


Figure 3-20. Use the Recess Gauge, CI-4330, to size the recessed well.

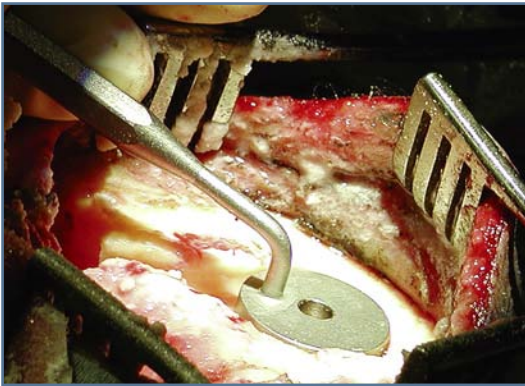
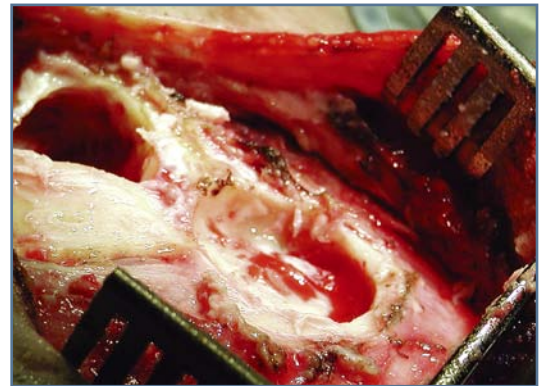


Figure 3-21. Drilled recessed well.



**Step 2:** Drill a channel for the electrode fantail and lead.

To secure and protect the electrode fantail as it exits the implant, a channel or groove should be created between the implant and the mastoid cavity. Additionally, slight undercuts of this channel particularly on the inferior edge, as it enters the mastoid cavity, can also aid in securing the coiled lead (Figure 3-22).

**Step 3:** Verify sufficient space under the skin muscle flap for the implant.

Use the metal Device Coil Gauge, CI-4340, and/or the plastic HiRes 90K Surgical Mock-up, CI-4425, 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 the plastic Surgical Mock-up or Device Coil Gauge into position. Allow the titanium case portion of these templates to seat completely in the recess while performing this assessment.

Figure 3-22. The HiRes 90K Surgical Mock-up, CI-4425, can be used as a template when drilling the channel for the fantail and electrode lead.

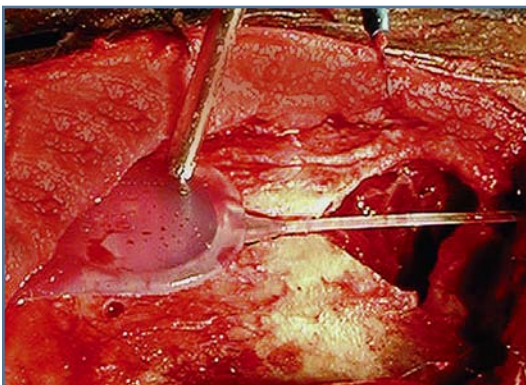
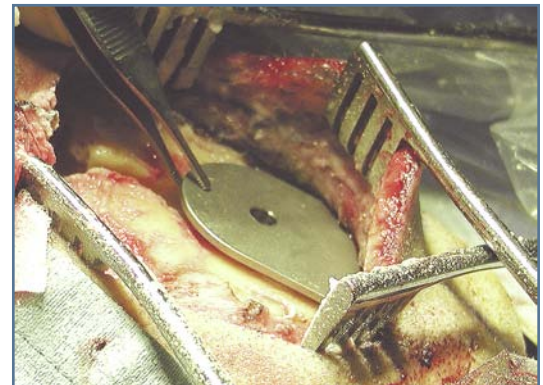


Figure 3-23. Use the Device Coil Gauge, CI-4340 (or HiRes 90K Surgical Mock-up, CI-4425), to size the recessed well/bone bed and ensure sufficient space for the coil.



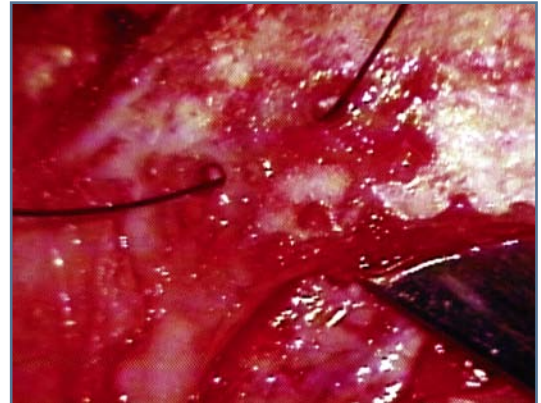
**Step 4:** Drill tie-down holes for the implant.

Suture to bone to secure the implant. After seating the implant in its well, it is essential that the device be secured with non-absorbable sutures-to-bone. Tie-down holes should be drilled so that the non-absorbable sutures can be placed across the titanium case portion of the implant.

Figure 3-24. Suture tie-down holes (arrows) for implant.



Figure 3-25. Pediatric tie-down holes (elevator on dura).



**WARNING:** Failure to follow the recommended surgical procedure for placement and stabilization of the implant device increases the risk of device migration, extrusion, or skin flap erosion. Additional risks include damage due to impact trauma, including breakage of the electrode lead wires. Creating a recessed well or bone bed for the implant and securely stabilizing the device in place with sutures are critical elements of the recommended surgical procedure.

## Minimal Incision Approach

Some minimal incision approaches place the incision half way between the anterior aspect of the well and the external auditory canal (approximately 1 cm posterior to the postauricular crease). Two frequently used *minimal* incision lines are illustrated in Figure 3-26.

One approach using a minimal incision is described as follows:

Using a marker, draw an incision line with sufficient clearance to allow for some change in position if necessary (Figure 3-27).

Figure 3-26. Typical minimal incision lines: shortened conventional incision line (left); Nottingham minimal (right).

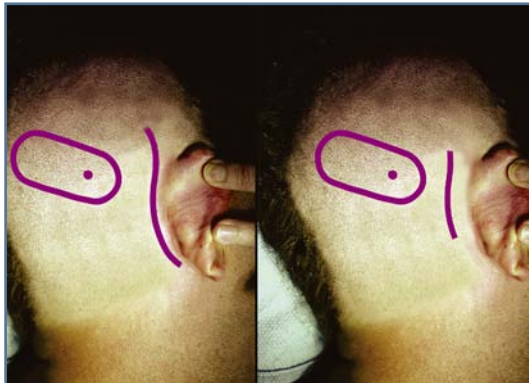


Figure 3-27. The length of the incision line should be 4 or 5 cm.



The incision line should be a minimum of 1.5 cm away from the planned location of the implant (Figure 3-28).

Most surgeons choose to inject local anesthetic along the incision line and at the implant pocket site (Figures 3-29, 3-30).

Figure 3-28. Determine the length of the pocket.



Figure 3-29. Inject along the incision line with a local anesthetic.

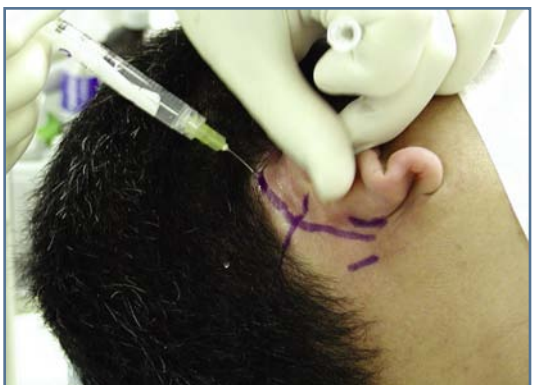
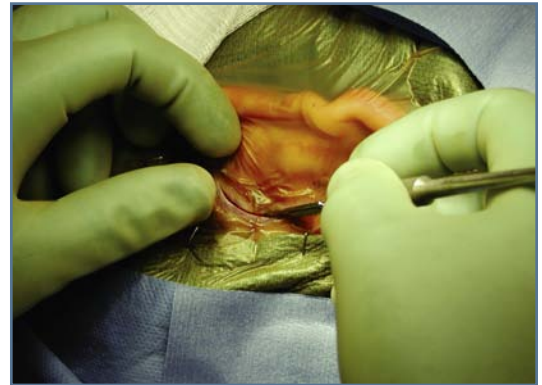


Figure 3-30. Inject the implant pocket site with a local anesthetic.



Figure 3-31. Incision.



When developing the incision keep the following points in mind:

- Maintain hemostasis with skin clips, sutures, and/or electrocautery (Figure 3-32).

**NOTE: Monopolar electrocautery must not be used once the implant is placed in the sterile operative field.**

- Retain some fascia or muscle tissue for later packing of the cochleostomy site.
- When using a minimal incision approach, ensure that the scalp flap over the magnet telemetry coil does not exceed 7 mm.
- A postauricular pocket is created as well as a site for the placement and stabilization of the implant (Figure 3-33).

Figure 3-32. Use electrocautery to control bleeding.

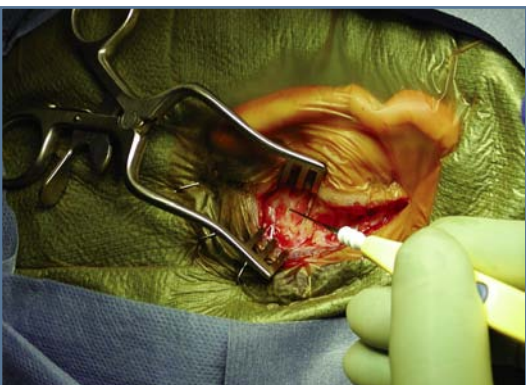
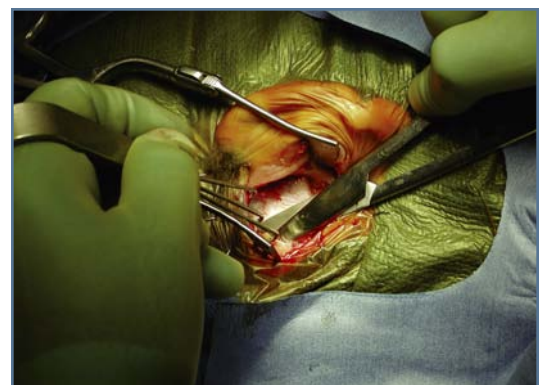


Figure 3-33. Develop the postauricular pocket.



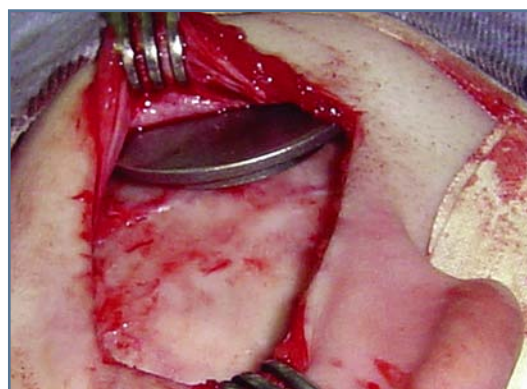
A recessed well for the titanium case, a channel for the electrode fantail and lead, as well as suture tie-down holes should be drilled in order to stabilize and protect the implanted device.

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 (Figures 3-34, 3-35)

*Figure 3-34. Use the Device Coil Gauge, CI-4340, to size the pocket.*



*Figure 3-35. Use the Device Coil Gauge, CI-4340, to size the pocket. In this pediatric patient the temporalis fascia and muscle are elevated in one layer.*



The implant and electrode fantail must not be susceptible to movement along the surface of the skull. Such movement could produce a differential stress on the electrode fantail, leading to damage of the electrode wires. The following four steps are recommended:

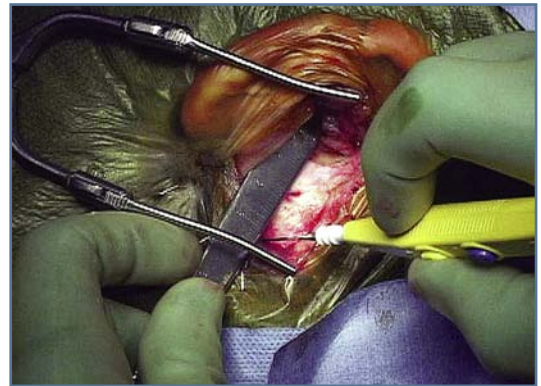
**Step 1:** Locate and drill a recessed well for the titanium case.

Using the Recess Marking Template, CI-4430, place the distal end (or tip) at the posterior canal wall. Orient the template to locate the planned recessed area that will be a minimum of 3.5 cm from the posterior canal wall. Draw or mark the shape of the inside edge of the template and establish the location to be drilled (Figures 3-36, 3-37).

*Figure 3-36. Determine the placement of the recessed well using the Recess Marking Template, CI-4430. The tip of the template is placed at the posterior edge of the ear canal.*



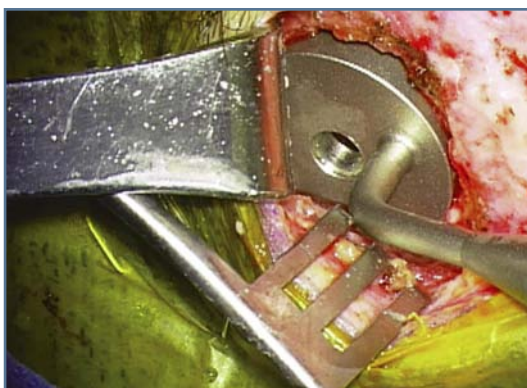
*Figure 3-37. Alternate method to measure the distance from the posterior canal wall and mark the anterior edge of the recessed well.*



The well should have sufficient depth to accommodate the titanium case and is checked by using the Recess Gauge, CI-4330 (Figures 3-38, 3-39).

**NOTE:** The diameter of the Recess Gauge is slightly larger than the titanium case of the implant to ensure that the case will fit. Failure to create a recessed well or bone bed in the mastoid cortex may also cause a high device profile or allow the implant to migrate, potentially leading to extrusion or skin flap erosion.

*Figure 3-38. Use the Recess Gauge, CI-4330, to size the recessed well.*



*Figure 3-39. Drilled recessed well.*



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

Use the metal Device Coil Gauge, CI-4340, and/or the plastic HiRes 90K Surgical Mock-up, CI-4425, 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 the plastic Surgical Mock-up or Device Coil Gauge into position. Allow the titanium case portion of these templates to seat completely in the recess while performing this assessment.

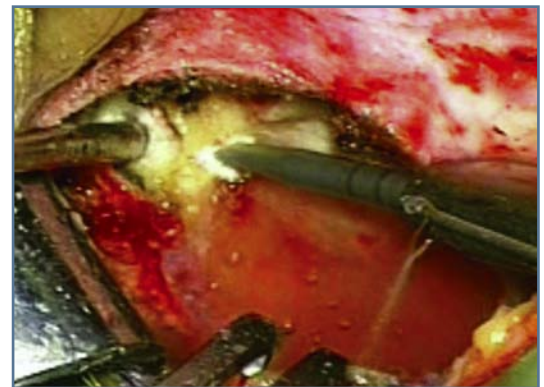
**Step 3:** Drill tie down holes for the implant.

Suture to bone to secure the implant. After seating the implant in its well, it is essential that the device be secured with non-absorbable sutures to bone. Tie-down holes should be drilled so that the non-absorbable sutures can be placed across the titanium case portion of the implant.

*Figure 3-40. Use the Device Coil Gauge, CI-4340 (or HiRes 90K Surgical Mock-up, CI-4425), to size the recessed well/bone bed and coil pocket.*



*Figure 3-41. Prepare tie down holes. Drill a tunnel through the wall of the well and intersecting a hole previously drilled.*



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

To secure and protect the electrode fantail as it exits the implant, a 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 (Figures 3-42, 3-43).

Figure 3-42. The HiRes 90K Surgical Mock-up, CI-4425, can be used as a template when drilling the channel for the fantail and electrode lead.

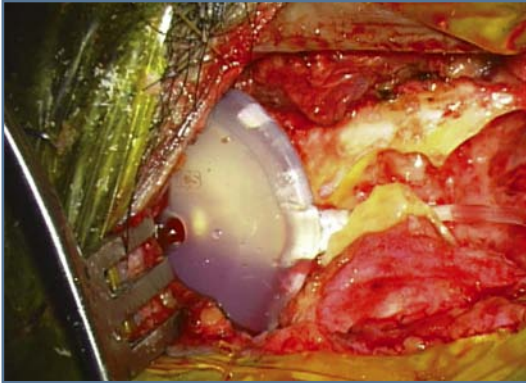
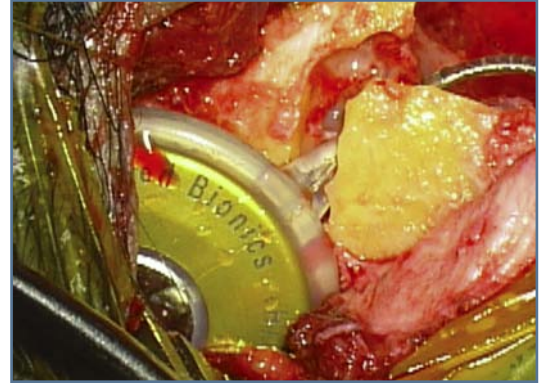


Figure 3-43. HiRes 90K Implant with lead in well to mastoid channel.



**WARNING:** Failure to follow the recommended surgical procedure for placement and stabilization of the implant device increases the risk of device migration, extrusion, or skin flap erosion. Additional risks include damage due to impact trauma, including breakage of the electrode lead wires. Creating a recessed well or bone bed for the implant and securely stabilizing the device in place with sutures are critical elements of the recommended surgical procedure.

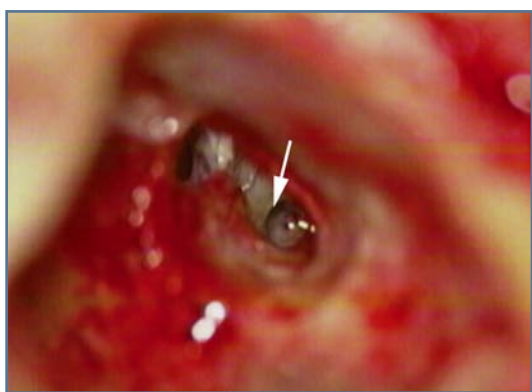
As described in the *Conventional Incision Approach* section, a periosteal flap is raised, a cortical mastoidectomy is performed, and the middle ear and round window are exposed via the facial recess. Keep in mind that the facial recess must be sufficient to accommodate the HiFocus Helix Stylet Assembly and its footpad that will be stabilized on the inferior lip of the cochleostomy or the HiFocus 1j insertion tube.

## Cochleostomy

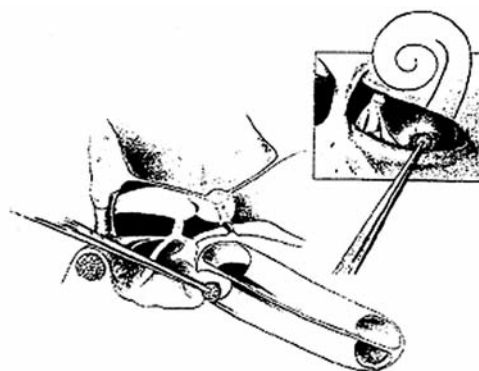
Prior to insertion of the electrode, the bony lip covering the round window niche may be removed in order to expose the round window membrane (Figure 3-44). Care must be taken to avoid damage to the round window membrane until entry into the scala tympani is desired.

Using a rotating micro bur, a fenestra is created into the basal scala tympani just anterior and slightly inferior to the round window, thereby exposing the first turn of the cochlea and avoiding the hook region (Figure 3-45).

*Figure 3-44. Clearly expose the round window (arrow). Right ear.*



*Figure 3-45. 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.

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 damage or an incomplete insertion.

Figure 3-46. Drill the cochleostomy just anterior and inferior to the round window.  
Right ear.

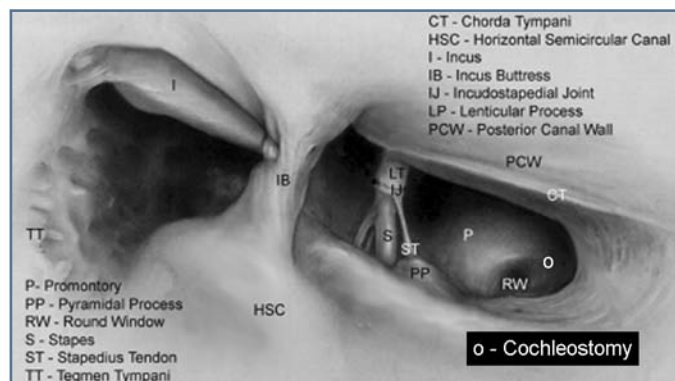
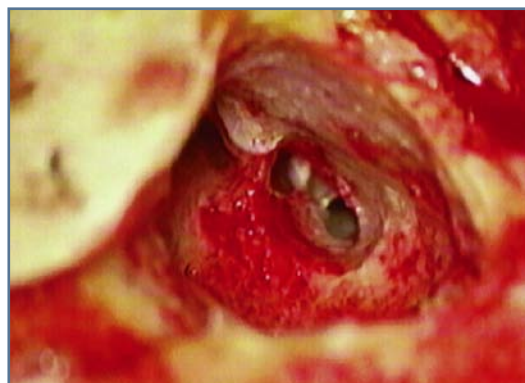


Figure 3-47. Completed cochleostomy.  
Right ear.



## Procedures Before Device Placement

Once the cochleostomy has been prepared, the device should be placed in the patient.

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

See *HiRes 90K Implant Device Package Opening Procedures*, in Section 2, for procedures to open the device package.



# 4. HiRes 90K Fixation

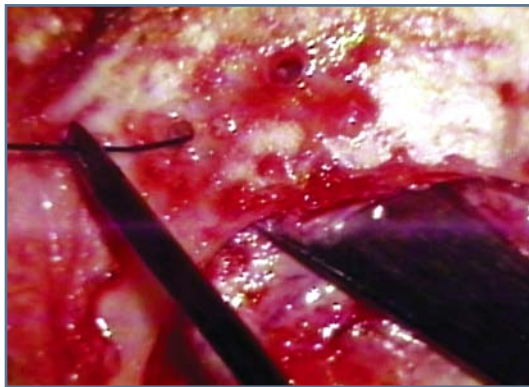
## HiRes 90K Implant Fixation

The implant and electrode fantail must be fit securely within the well and channel previously created. The implant should be stable and sufficiently recessed to avoid a high profile. This is important in order to avoid any 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.

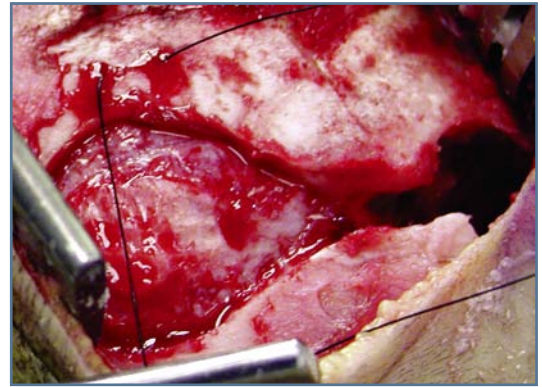
Place sutures into position before placing the implant into the recessed well.

Using the tie-down holes previously drilled, non-absorbable sutures are placed across the titanium case portion of the implant. Suturing through bone is an important final step in securing the device in place. Suturing directly on any portion of the electrode lead or fantail must be avoided.

*Figure 4-1. Placing sutures in a pediatric patient (elevator on dura).*



*Figure 4-2. Sutures in place, pediatric patient.*



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 4-3. Slide the implant under the suture.

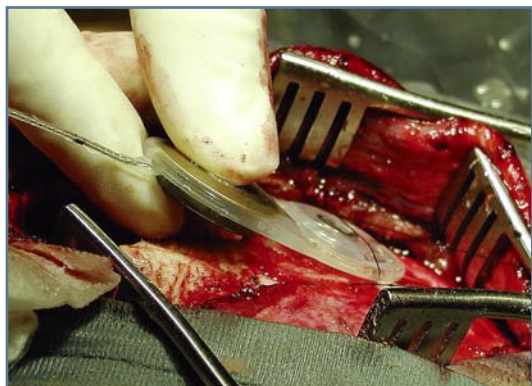
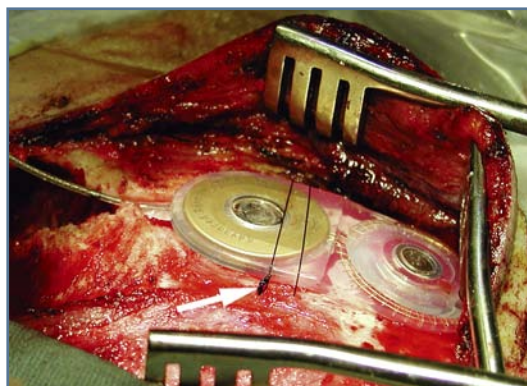


Figure 4-4. HiRes 90K implant sutured in place. Note the suture knots at the side of the implant (arrow).





## HiFocus Helix Electrode Specifications

(Approximate Measurements)

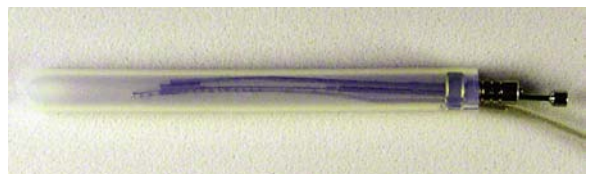
Electrode array tip diameter (distal)	≈ 0.6 mm
Electrode array base diameter (proximal)	≈ 1.1 mm
Spacing between active contacts (distance from midpoint of one contact to another)	≈ 0.85 mm
Total length of active contacts (distance that the electrode contacts are spread over)	≈ 13 mm
Distance between non-stimulating marker pads and contact pad No. 16	≈ 3 mm
Neck/Jog to proximal non-stimulating marker pad	≈ 3 mm
Total length of electrode array (distance from distal electrode tip to proximal electrode jog)	≈ 24.5 mm
Required facial recess minimum width	2 mm
Preferred cochleostomy dimensions (minimum) (an oval with the long axis facing vertically)	1.2 mm x 1.6 mm
Optional cochleostomy size (a circle)	1.6 mm diameter
Electrode lead length from device fantail to proximal electrode jog	≈ 6.5 cm
Distance that electrode array tip extends into cochlea following setup and prior to electrode insertion	4.5 mm
Approximate angular insertion	360° – 420°

The HiFocus Helix electrode array is provided preloaded in the sterile implant tray. The array is loaded on the Stylet Assembly, 6045622-002 (Figure 5-4).

*Figure 5-3. HiRes 90K with HiFocus Helix electrode.*



*Figure 5-4. Preloaded Stylet Assembly, 6045622-002, in its protective tube.*



## HiFocus Helix Electrode Insertion Tool—Stylet Assembly and Handle

The HiFocus Helix Electrode Insertion Tool, which consists of a Stylet Assembly and Handle, CI-4253, is designed to assist the surgeon with the insertion of the HiFocus Helix electrode array into the cochlea. Only the Helix Electrode Insertion Tool should be used for insertion of the HiFocus Helix electrode. The use of other instruments may result in damage to the electrode. The Stylet Assembly and Handle are single-use surgical instruments.

- HiFocus Helix Electrode Insertion Tool, Stylet Assembly (Figure 5-5)

In describing the Stylet Assembly and Handle, the distal and proximal locations are in reference to the surgeon's hand.

The distal portion of the Electrode Insertion Tool is the Stylet Assembly and the distal (curved) end of the Handle. The Stylet Assembly uses a thin wire stylet on which the HiFocus Helix electrode has been preloaded and a mechanism that advances the electrode array off the stylet as the stylet guide-footpad is placed into and pressed against the cochleostomy (Figure 5-6).

Figure 5-5. HiFocus Helix Electrode Insertion Tool, Stylet Assembly, 6045622-002

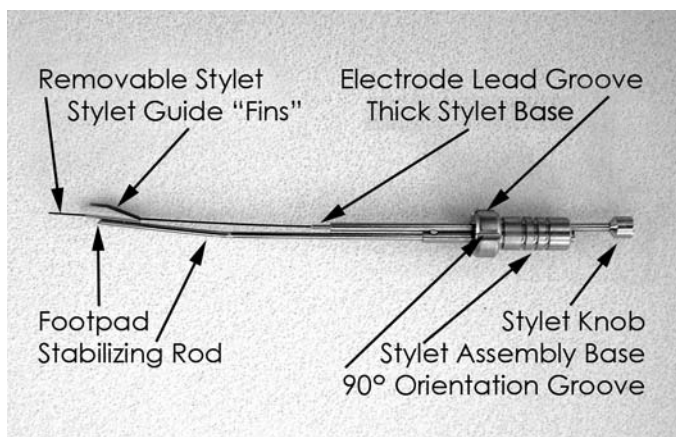
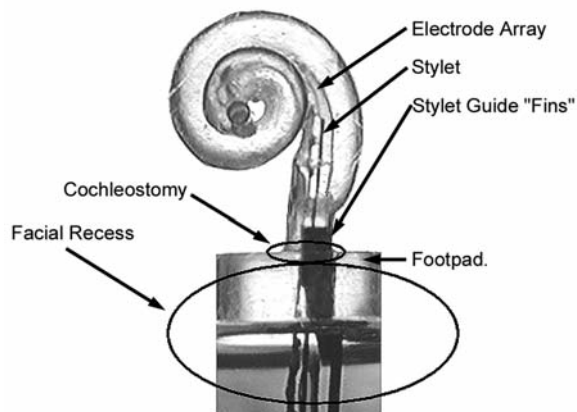


Figure 5-6. Stylet guide-footpad in position against the inferior aspect of the cochleostomy.



- Electrode Insertion Tool, Handle (Figure 5-7).

The *proximal* end of the Electrode Insertion Tool is the straight portion of the Handle (Figure 5-7).

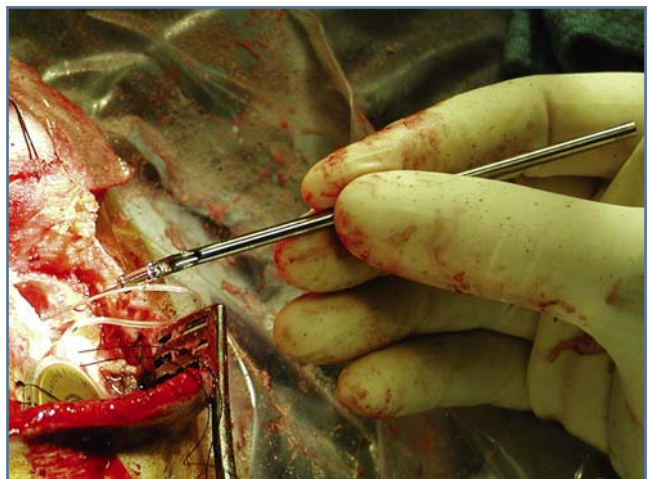
To prepare to insert the HiFocus Helix electrode, attach the Stylet Assembly to the Handle.

For purposes of this procedure, the Electrode Insertion Tool is the *combined* Handle and Stylet Assembly (Figure 5-8).

Figure 5-7. Electrode Insertion Tool, Handle.



Figure 5-8. HiFocus Helix Electrode Insertion Tool—the combined Stylet Assembly and Handle. Right ear.



## How the HiFocus Helix Electrode Insertion Tool Works

The Stylet Assembly consists of two components (Figure 5-9):

- Stabilizer rod and stylet rod
- Pusher

Note that, as the tool handle is pushed forward, (1) the stylet-stabilizer stays in place and (2) the "pusher" moves the electrode forward (Figure 5-10).

Figure 5-9. Stylet Assembly parts.

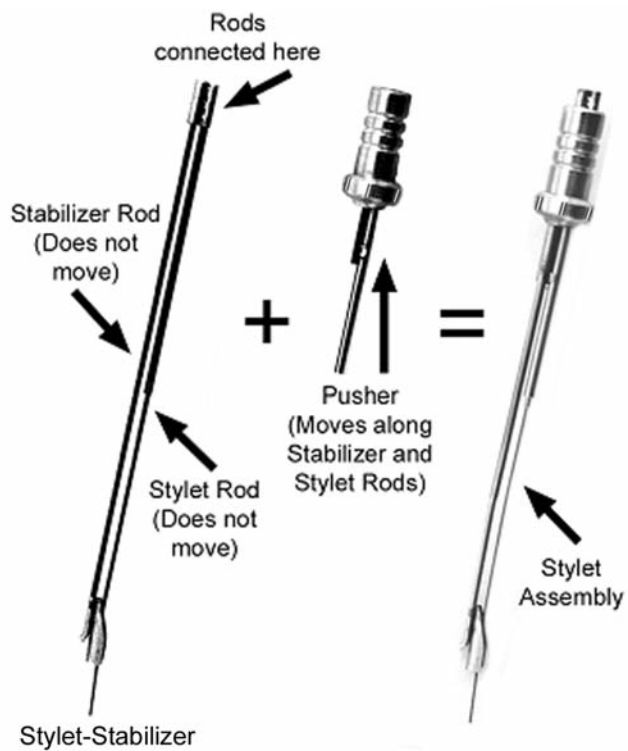
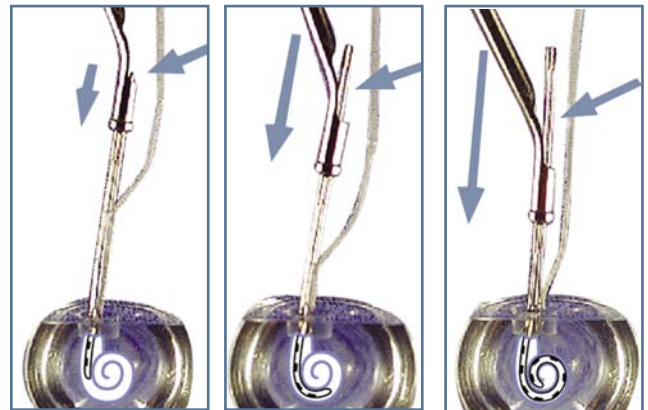


Figure 5-10. HiFocus Helix electrode insertion.

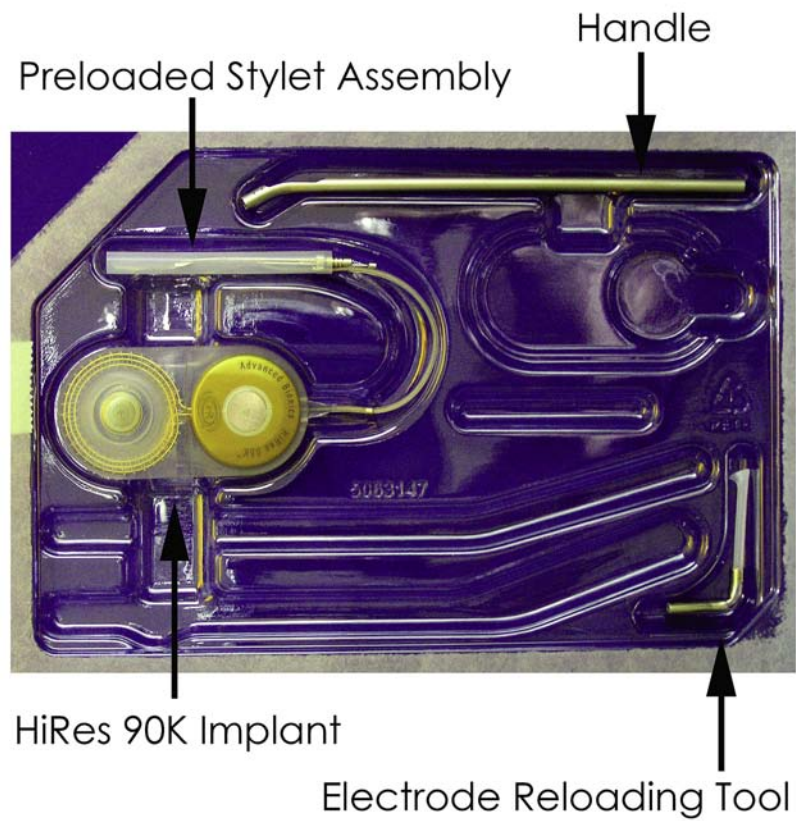


## Single-Use HiFocus Helix Tools

The following single use tools are included in the sterile, inner tray (Figure 5-11):

Tool	Quantity
Helix Electrode Insertion Tool, Stylet Assembly, 6045622-002	1
Helix Electrode Insertion Tool, Handle, 6045622-002	1
Helix Electrode Reloading Tool, 7005593-001	1

Figure 5-11. Sterile inner tray contents.



## HiRes 90K with HiFocus Helix Electrode Equipment Requirements

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

- **Primary and Backup Implants, CI-1400-02H:** The implant with the lower serial number should be used as the primary device. The implant is delivered sterilized, (Figure 5-12).

Figure 5-12. HiRes 90K Implant with HiFocus Helix Electrode, CI-1400-02H.

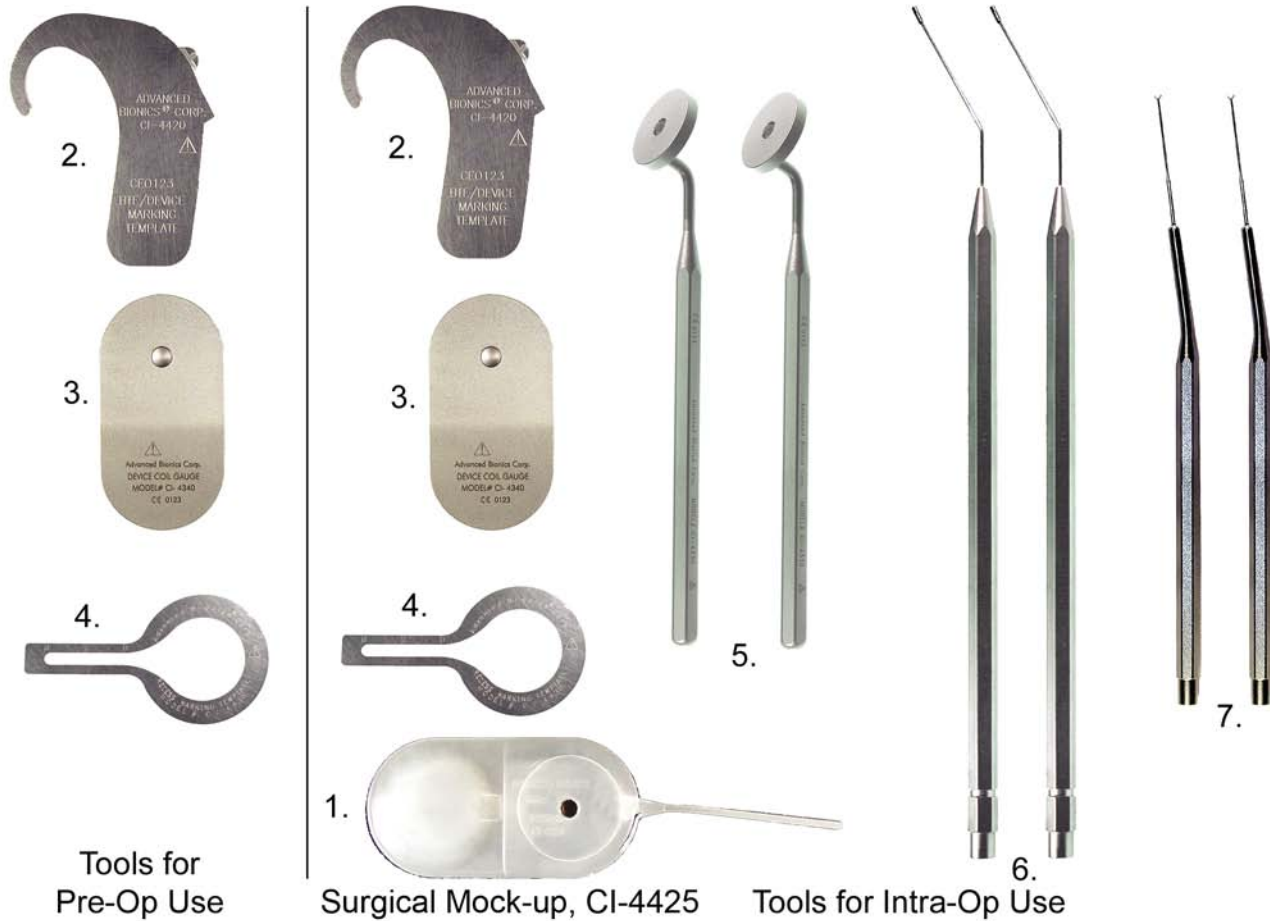


**Following Tools Must Be Sterilized Prior to Surgery (Figure 5-13):**

*Figure 5-13. HiRes 90K Surgical Tool Kit, CI-4500, for preoperative and intraoperative use and HiFocus Helix Electrode Instrument Kit, CI-4501, for electrode implantation. These tools are reusable except for the single-use HiRes 90K plastic Surgical Mock-up, CI-4425, which is provided sterile with the implant package.*

**HiRes 90K Surgical Tool Kit, CI-4500**

**HiFocus Helix Electrode Instrument Kit, CI-4501**



## HiRes 90K Surgical Mock-up, CI-4425

1. **One Single-use HiRes 90K plastic Surgical Mock-up, CI-4425:** This template is provided sterile with the primary HiRes 90K Implant, CI-1400-02H (Figures 5-14, 5-15).

Figure 5-14. HiRes 90K single-use Surgical Mock-up, CI-4425, provided with the implant package.



Figure 5-15. HiRes 90K Surgical Mock-up, CI-4425.



## HiRes 90K Surgical Tool Kit, CI-4500

The HiRes 90K Surgical Tool Kit, CI-4500, includes the following tools and gauges for implantation of the HiRes 90K implant. See Section 1 for a description of the HiRes 90K Surgical Tool Kit, CI-4500.

2. **Two BTE (Behind-the-Ear) Device Marking Templates, CI-4420:** Templates are used for determining device placement (Figure 5-16).

3. **Two Device Coil Gauges, CI-4340:** Mock-ups are provided for determining device placement (Figure 5-17).

Figure 5-16. BTE (Behind-the-Ear) Device Marking Template, CI-4420.



Figure 5-17. Device Coil Gauges, CI-4340.



4. **Two Recess Marking Templates, CI-4430:** Templates are used for determining the site of the recessed well and device placement (Figure 5-18).
5. **Two Recess Gauges, CI-4330:** Recess Gauges are used to verify adequate bone removal for the device titanium case (Figure 5-19).

Figure 5-18. Recess Marking Template, CI-4430.



Figure 5-19. Recess Gauge, CI-4330.



## HiFocus Helix Electrode Instrument Kit, CI-4501

The HiFocus Helix Electrode Instrument Kit, CI-4501, includes the following tools and gauges for insertion of the Helix electrode.

6. **Two Cochleostomy Sizing Gauges, CI-4345, (labeled "Helix"):** The sizing gauge is used to verify adequate cochleostomy size (Figure 5-20).

Figure 5-20. Cochleostomy Sizing Gauge, CI-4345 (labeled "Helix").



7. **Two Electrode Claw Tools, CI-4252:** The Electrode Claw Tool is used to stabilize the electrode following insertion (Figure 5-21).

*Figure 5-21. Electrode Claw Tool, CI-4252, with detail of claw.*



# HiRes 90K with HiFocus Helix Electrode Surgical Equipment Sterilization Guidelines

Surgical Equipment <sup>1</sup>	Product Name	Model No.	Autoclave-Steam	
			136°C/275°F for 5 minutes	Gas EO
122°C/250°F for 30 minutes <sup>2</sup>				
	BTE (Behind-the-Ear) Device Marking Template	CI-4420	OK	NO
	Device Coil Gauge	CI-4340	OK	NO
	3.5 cm Recess Marking Template	CI-4430	OK	NO
	Recess Gauge	CI-4330	OK	NO
	Cochleostomy Sizing Gauge (labeled "Helix")	CI-4345	OK	NO
	Electrode Claw Tool	CI-4252	OK	NO

<sup>1</sup> See the *Decontamination and Resterilization of the Advanced Bionics Surgical Tools* section of this manual for more information.

<sup>2</sup> For other sterilization methods and confirmations, refer to the guidance provided in Association for the Advancement of Medical Instrumentation (AAMI) Technical Information Report (TIR) 12:1994, *Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers or ANSI (American National Standards Institute)/AAMI ST46-1993 Good Hospital Practice: Steam Sterilization and Sterility Assurance*. Users may also refer to the Medical Devices Agency (Medicines and Healthcare products Regulatory Agency [MHRA]) Publication *Sterilization, Disinfection and Cleaning of Medical Equipment, Part 3*. Refer to national standards for minimum temperatures and times.

## HiFocus Helix Electrode—Facial Recess

The facial recess must be sufficiently large (2 mm minimum width) to accommodate the Stylet Assembly guide and footpad that will be stabilized on the inferior lip of the cochleostomy (Figure 5-22). Use a 2 mm bur or an Advanced Bionics "Plastic Tube" Cochleostomy Sizing Gauge, AB-7120, to check for minimum width.

**IMPORTANT:** Develop the facial recess inferior to the cochleostomy to allow for withdrawal of the footpad of the Stylet Assembly following HiFocus Helix electrode insertion.

## HiFocus Helix Electrode—Cochleostomy

The cochleostomy must be sufficiently large to accommodate the stylet guide—the "fins"—of the Stylet Assembly (Figure 5-23).

Figure 5-22. Placement of the preloaded electrode array on its Stylet Assembly with the stylet guide 1 mm within the basal scala.

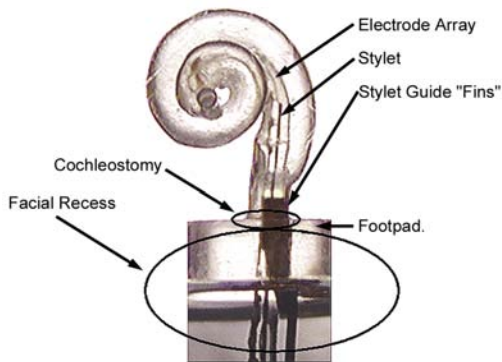
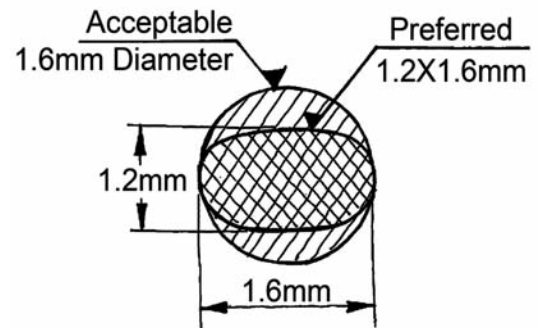


Figure 5-23. Preferred and acceptable cochleostomy dimensions.



The cochleostomy must be large enough (1.2 x 1.6 mm) to place the stylet guide 1 mm within the basal scala. Use the Cochleostomy Sizing Gauge, CI-4345, to establish the correct dimensions of the cochleostomy. The broad (flat) side of the Cochleostomy Sizing Gauge should be oriented vertically and should easily fit 1 mm inside the opening (Figure 5-24). The Cochleostomy Sizing Gauge should fit loosely within the cochleostomy.

Figure 5-24. Use the Cochleostomy Sizing Gauge, CI-4345, to verify the 1.2 x 1.6 mm required cochleostomy dimension.



Figure 5-25. Size the cochleostomy.

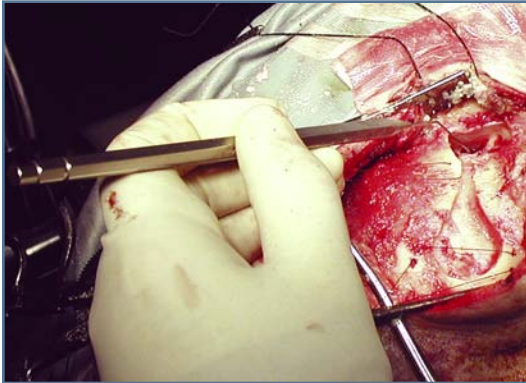
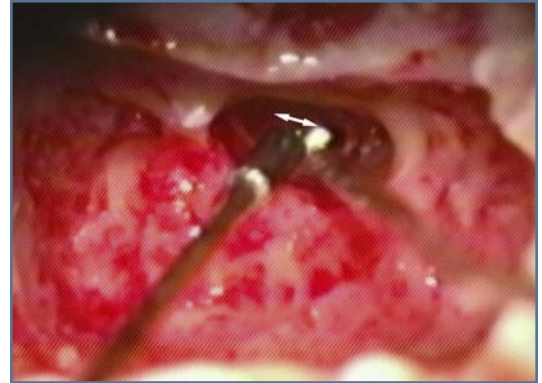


Figure 5-26. The broad (flat) side of the Cochleostomy Sizing Gauge, CI-4345, should be oriented vertically.



**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 damage or an incomplete insertion.

## HiFocus Helix Electrode Insertion

After the HiRes 90K implant has been secured in its well, the HiFocus Helix electrode is inserted into the cochlea through the cochleostomy previously created. The Electrode Insertion Tool is designed to assist in the placement of the HiFocus Helix electrode. The following section outlines the steps that must be performed to ensure successful electrode insertion.

Prepare to assemble the following components (Figure 5-27):

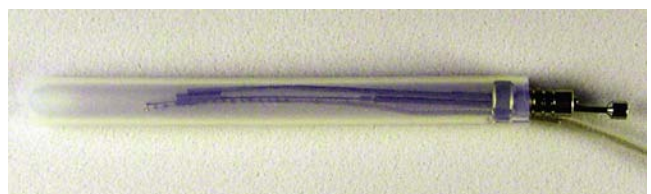
- Electrode Insertion Tool, Stylet Assembly
- Electrode Insertion Tool, Handle

Remove the loaded Stylet Assembly from its protective tube (Figure 5-28). Avoid grasping the Stylet knob.

Figure 5-27. Handle, and Stylet Assembly, packaged in the sterile inner tray.



Figure 5-28. Preloaded Stylet Assembly in its protective tube. Note the Stylet knob at the right of the picture. (Figure 5-5).



Hold the Stylet Assembly base and protective tube and remove the Stylet Assembly from its protective tube (Figure 5-29A-B).

Figure 5-29A. Withdraw the Stylet Assembly from the protective tube.

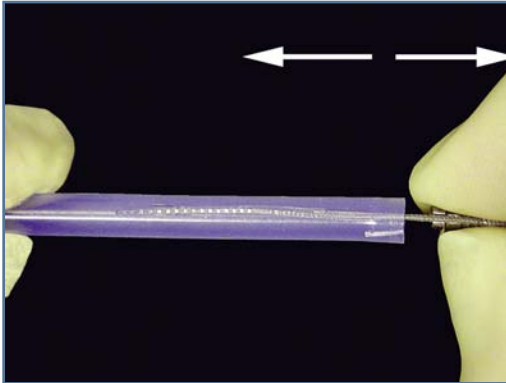
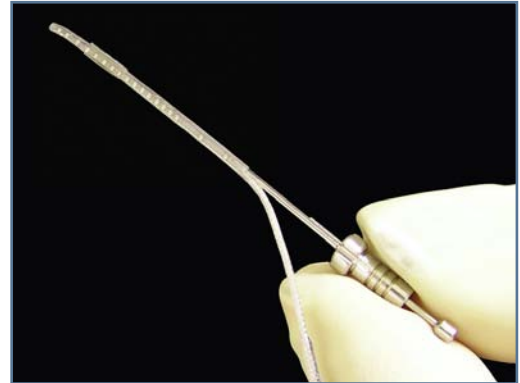


Figure 5-29B. Stylet Assembly following removal from its protective tube.



## Mount the Stylet Assembly into the Handle

In placing the Stylet Assembly into the Handle, the following steps must be performed to ensure successful electrode insertion and subsequent disengagement of the Electrode Insertion Tool:

- Hold the preloaded Stylet Assembly firmly at the proximal end (i.e., the Stylet Assembly base). Do not hold or grasp the electrode anywhere near the array (Figure 5-30A).
- Avoid grasping the Stylet knob.
- Place the Stylet Assembly base into the distal end (nearest the recessed curve) of the Handle.
- The electrode array contact pads on the Stylet Assembly should face in the same direction as the recessed curve of the Handle.
- Both the electrode array contact pads and the opening of the recessed curve in the handle will face superiorly when positioned at the cochleostomy (Figure 5-30B).

Figure 5-30A. Hold the preloaded Stylet Assembly at its proximal end.

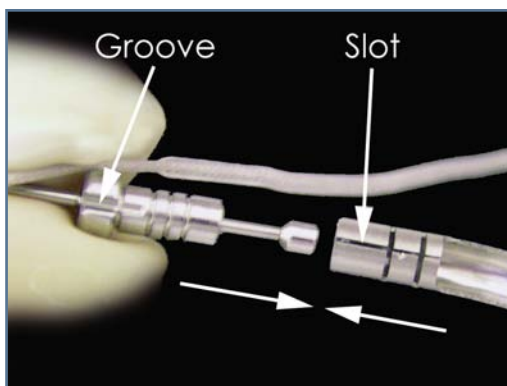
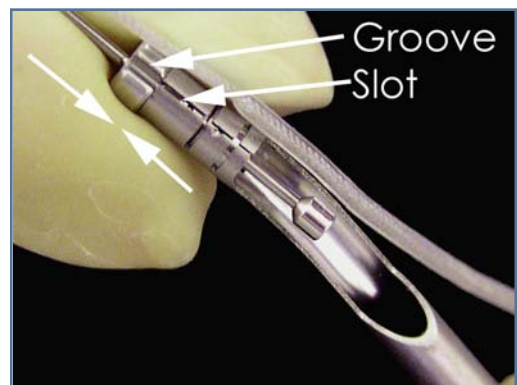


Figure 5-30B. Mount the Stylet Assembly base into the Handle.



- Line up the electrode lead groove of the Stylet Assembly with the Handle slot. Push the Stylet Assembly base into the Handle until it is fully seated (Figure 5-30C).
- Verify that the electrode array is situated between the two fins of the stylet guide (Figure 5-30D).

Figure 5-30C. Line up the electrode lead groove with the Handle slot.

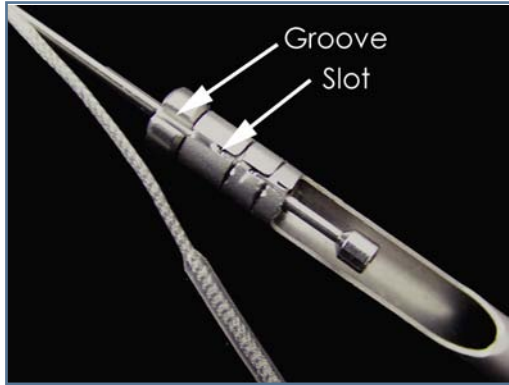
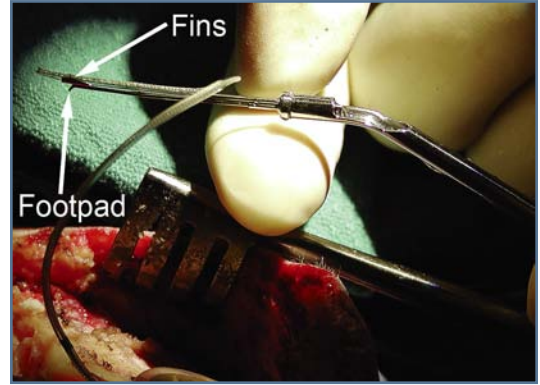
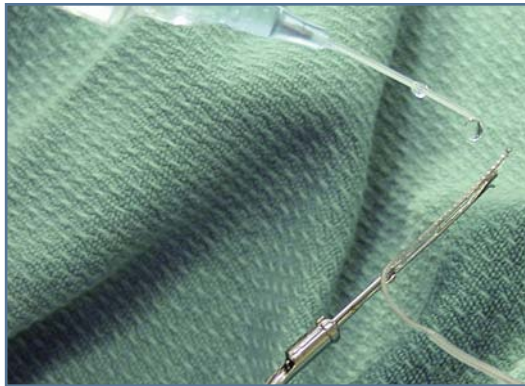


Figure 5-30D. Electrode array placed between the fins of the stylet guide.



- Wet the Helix electrode with saline to facilitate insertion (Figure 5-30E).

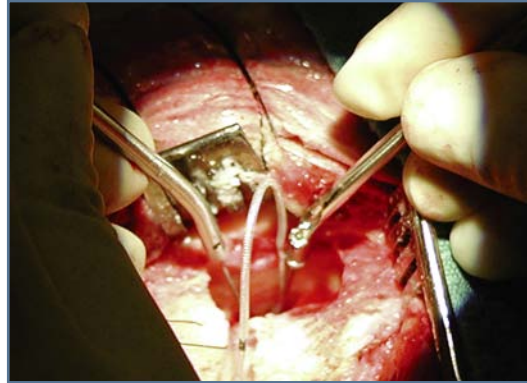
Figure 5-30E. Wet the Helix electrode with saline.



## Prepare for Electrode Insertion—Orient the Insertion Tool

If necessary, reposition retractors to allow for the Electrode Insertion Tool to move forward easily (Figure 5-31).

*Figure 5-31. Check retractor position.*



Orient the Electrode Insertion Tool so that the contact pads of the HiFocus Helix electrode array face superiorly toward the modiolus.

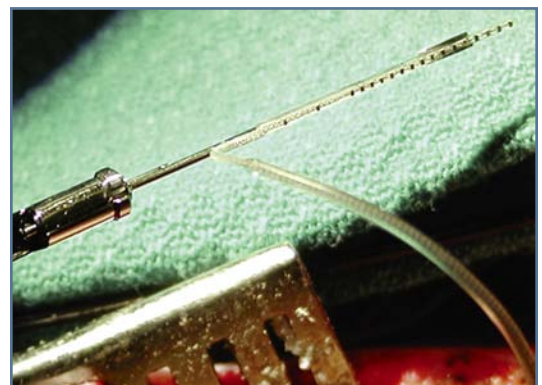
Prior to inserting the HiFocus Helix electrode, it is important to verify that the contact pads of the electrode array face superiorly toward the modiolus. The orientation of the electrode array contact pads indicates the direction that the array will travel when it is expelled off the stylet. It is essential that the HiFocus Helix electrode be released off the stylet so that it curves around the basal turn of the cochlea.

Whether implanting a right or left cochlea, the Stylet Assembly base should be mounted on the Handle so that the contact pads face *superiorly*, toward the modiolus (Figures 5-32A, 5-32B).

*Figure 5-32A. Orient the Stylet Assembly so that contacts are oriented superiorly toward the modiolus. Right cochlea.*



*Figure 5-32B. Orient the Stylet Assembly so that contacts are oriented superiorly toward the modiolus. Left cochlea.*



**IMPORTANT:** It is recommended that, when inserting the HiFocus Helix electrode, the surgeon hold the Electrode Insertion Tool in the same hand as the ear being implanted.

For example, when implanting a *right* ear, hold the Electrode Insertion Tool in the *right* hand. Hold the Electrode Claw Tool, CI-4252, in the *left* hand (Figure 5-33A).

When implanting a *left* ear, hold the Electrode Insertion Tool in the *left* hand. Hold the Electrode Claw Tool, CI-4252, in the *right* hand (Figure 5-33B).

Figure 5-33A. When implanting a right ear, hold the Insertion Tool in the right hand.

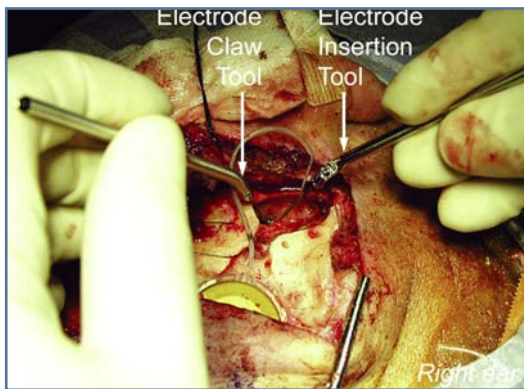
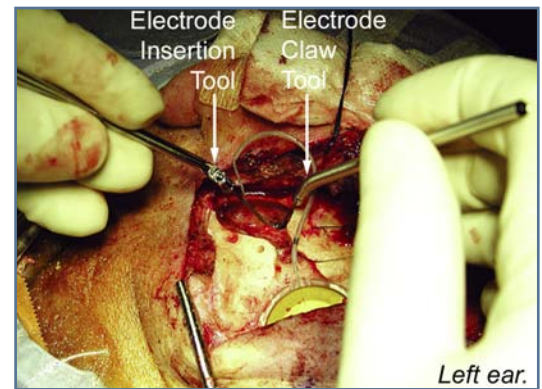


Figure 5-33B. When implanting a left ear, hold the Insertion Tool in the left hand.



## Position the Stylet Guide—Footpad and Insert the HiFocus Helix Electrode Array

Insertion of the HiFocus Helix electrode array with the Electrode Insertion Tool can be described as a two-step process consisting of the placement of the stylet guide-footpad and the release of the electrode array.

Ensure that the electrode array rests between the “fins” of the Stylet Assembly (Figure 5-34).

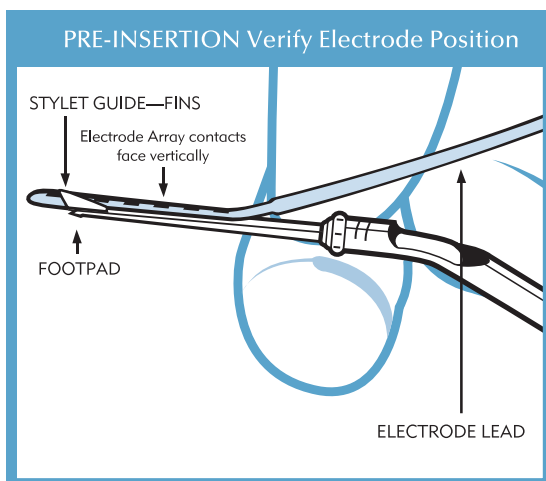


Figure 5-34. Electrode array fully engaged on the stylet. Right ear orientation.

**Step 1:** Position the stylet guide-footpad.

The stylet guide has been carefully designed to accommodate the dimensions of the cochlea. The HiFocus Helix electrode is expelled in such a way that it enters the first cochlear turn and continues around the modiolus.

**NOTE:** Surgeons who typically implant the HiFocus 1j electrode and use the plastic electrode insertion tube should keep in mind that the Stylet Assembly is *not* flexible.

The stylet guide must be positioned just inside the cochleostomy at the beginning of the first turn. The footpad must be positioned on the inferior, bony lip of the cochleostomy. Check to ensure that the facial recess has been adequately developed inferior to the cochleostomy to allow for withdrawal of the footpad. The loaded stylet must be appropriately positioned prior to advancing the Handle.

In order to place the stylet guide 1 mm within the basal scala, the cochleostomy must be sufficiently large (1.2 x 1.6 mm). Use the Cochleostomy Sizing Gauge, CI-4345, to establish the correct dimensions of the cochleostomy. The broad (flat) side of the Cochleostomy Sizing Gauge should be oriented vertically and should easily fit 1 mm inside the opening (Figure 5-35). The Cochleostomy Sizing Gauge should fit *loosely* in the cochleostomy.

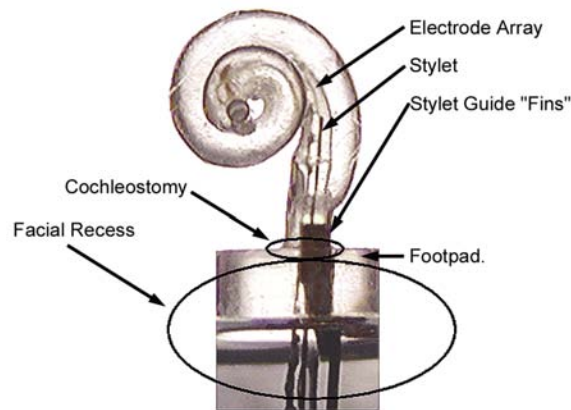
*Figure 5-35. Use the Cochleostomy Sizing Gauge, CI-4345, to verify the 1.2 x 1.6 mm required cochleostomy dimension.*



**CAUTION:** A situation where the dimensions of the cochleostomy are too small (i.e., less than the recommended 1.2 x 1.6 mm) can result in an incomplete insertion of the electrode.

Insert the electrode by placing the distal end of the array into the previously drilled cochleostomy. Stabilize the stylet guide-footpad on the inferior bony lip of the cochleostomy (Figure 5-36).

Figure 5-36. Place the preloaded Stylet Assembly in the cochleostomy. Note that the electrode contact pads face superiorly, toward the modiolus, stapes, and incus bridge.



**Step 2:** Insert the HiFocus Helix electrode array.

After the cochleostomy has been created and the loaded stylet guide-footpad portion of Stylet Assembly is placed on the inferior lip of the cochleostomy, insert the HiFocus Helix electrode by advancing the Handle with a smooth and continuous motion. As the handle is pushed, the HiFocus Helix electrode is expelled off the stylet.

Surgeons may notice some initial resistance as the electrode array moves off the thick portion of the stylet base.

**WARNING:** Excessive insertion force should be avoided in order to prevent damage. Discontinue insertion if resistance is met. Determine the cause of the resistance before continuing. Once the cause has been determined and corrected, reload the array as noted in the section on *Reloading the HiFocus Helix Electrode Array*.

Figure 5-37. HiFocus Helix insertion into cochleostomy. Note how the facial recess has been developed below the level of the cochleostomy. Right ear.

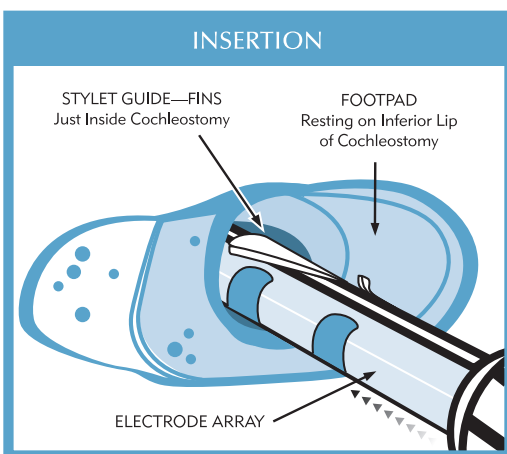
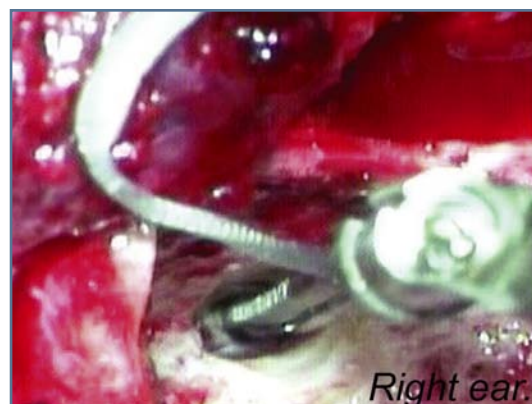


Figure 5-38. HiFocus Helix insertion. Note that the stimulation contact pads of the HiFocus Helix electrode face superiorly toward the modiolus. Right ear.



After fully inserting the HiFocus Helix electrode, use the Claw Tool, CI-4252, to slightly advance the jog/neck of the electrode array into the cochlea and then stabilize the jog/neck *superiorly* on the promontory.

## Withdraw the Electrode Insertion Tool

**CAUTION:** A situation where the inferior aspect of the facial recess has not been developed to accommodate the dimensions of the footpad can result in difficulty removing the Electrode Insertion Tool.

Once the HiFocus Helix electrode has been released, use the Electrode Claw Tool, CI-4252, to stabilize the electrode array while removing the Electrode Insertion Tool (Figure 5-39).

To avoid blocking the removal of the Electrode Insertion Tool's distal stylet guide, move the claw *superiorly* to the stylet guide (Figure 5-40).

Figure 5-39. Stabilize the electrode array at its proximal end when withdrawing the Electrode Insertion Tool. Right ear.

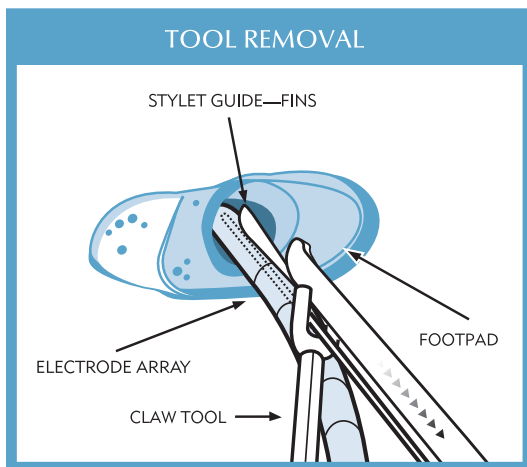
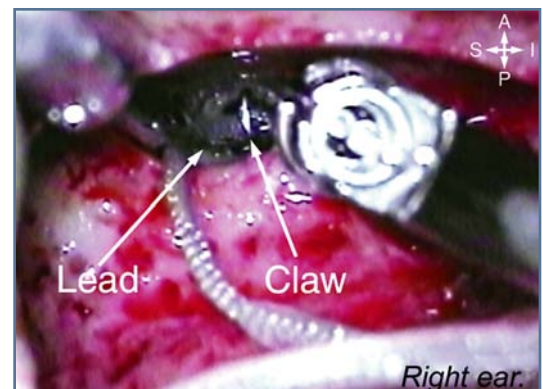


Figure 5-40. Use the Electrode Claw Tool, CI-4252, to stabilize the electrode lead prior to withdrawing the Electrode Insertion Tool. Right ear.



To facilitate the withdrawal of the Stylet Assembly, it is possible to grasp the Stylet Assembly knob and withdraw the proximal end of the stylet rod (Figures 5-41, 5-42).

Figure 5-41. Removable Stylet Assembly.

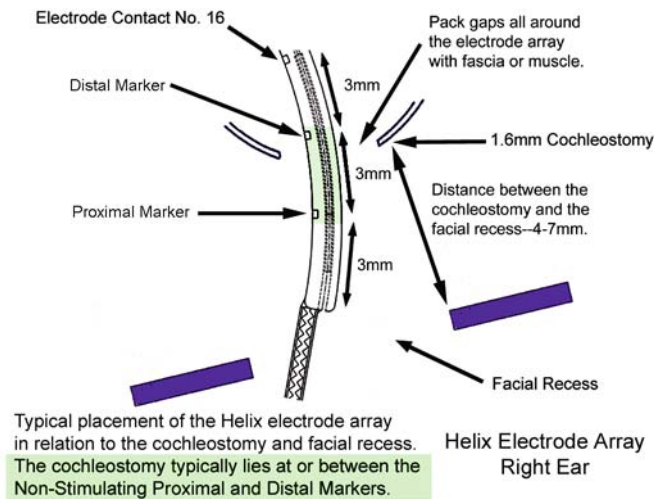


Figure 5-42. Stylet Assembly with stylet knob in place (upper) and partially withdrawn (lower).



Following removal of the Electrode Insertion Tool, inspect the cochleostomy site. The HiFocus Helix electrode array is typically inserted from 18-21 mm. This corresponds to the distal (18.5 mm) and proximal (21.5 mm) nonstimulating pads and their position relative to the cochleostomy. The cochleostomy typically lies at or between the nonstimulating proximal and distal markers (Figure 5-43).

*Figure 5-43. Typical placement of the Helix electrode in relation to the cochleostomy and facial recess. Right ear.*



## Reloading the HiFocus Helix Electrode Array

**Caution:** We recommend the HiFocus Helix electrode be reloaded only one time. If a second reload is necessary, the back-up unit should be used.

Electrode reloading and reinsertion should take place only if:

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

Briefly soak the electrode array and Electrode Reloading Tool in sterile saline. This will provide lubrication.

1. Obtain the Electrode Reloading Tool from the sterile, inner tray (Figure 5-44A).
2. Place the narrow, electrode lead portion of the Helix electrode array into the throat of the Electrode Reloading Tool with the curl of the array facing into the reloading slot (Figure 5-44B).

Figure 5-44A. Electrode Reloading Tool parts.

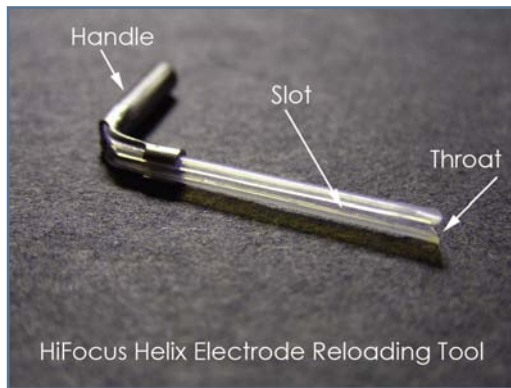
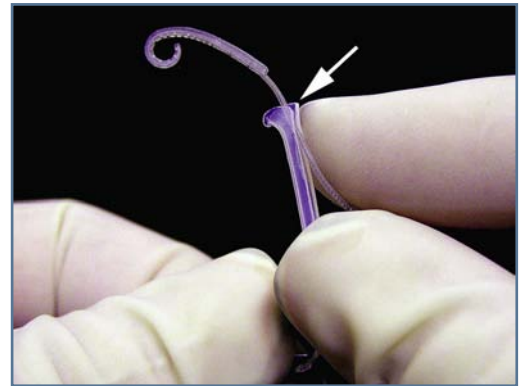


Figure 5-44B. Place the narrow portion of the electrode lead into the throat of the Electrode Reloading Tool.



3. Slide the lead through the slot of the tool. Hold the electrode lead close to the tube (Figure 5-44C).
4. Continue to slide the electrode lead through the reloading slot of the Electrode Reloading Tool until the square end of the electrode and stylet hole are visible at the proximal end of the tool. **Stabilize the thin portion of the electrode lead against the Electrode Reloading Tool handle** (Figure 5-44D).

Figure 5-44C. Slide the electrode lead through the reloading slot of the Electrode Reloading Tool.

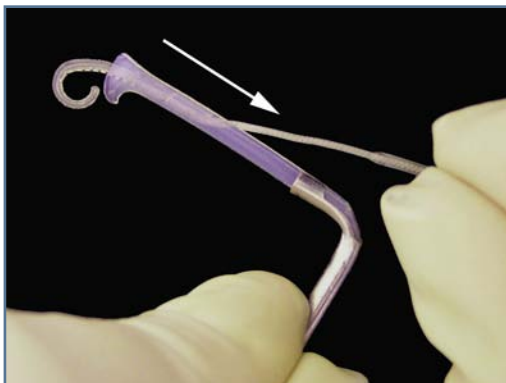
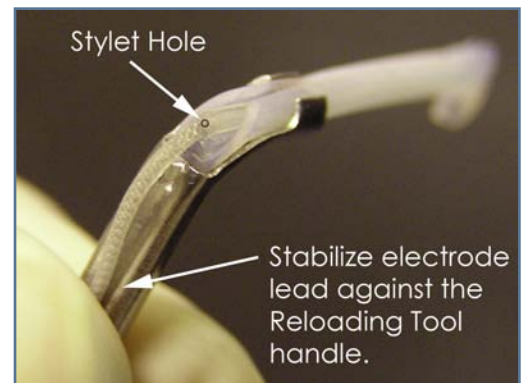


Figure 5-44D. View of the proximal end of the electrode array and the reloading slot of the Electrode Reloading Tool.



- To ensure that the stylet remains fully extended, place your thumb in the recessed curve of the Handle, behind the Stylet Assembly, to ensure that the stylet remains fully extended during reloading (Figure 5-44E).
- While gently holding the electrode lead against the handle of the Electrode Reloading Tool (to stabilize the array in the tool) introduce the stylet into the hole (Figure 5-44F).

**CAUTION:** Damage to the HiFocus Helix electrode array may result if the electrode lead is not stabilized against the handle of the reloading tool with the proximal end of the electrode array at the opening (nearest the handle) of the tool.

Figure 5-44E. Place your thumb in the recessed curve of the Handle to ensure that the stylet-stabilizer assembly remains fully extended during reloading.

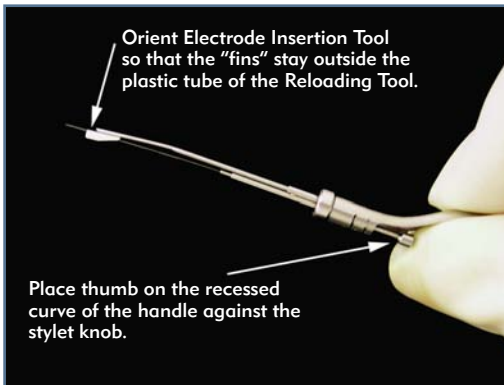
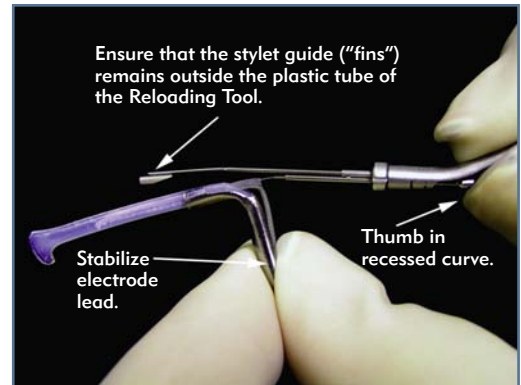


Figure 5-44F. Stabilize the electrode lead against the handle of the Electrode Reloading Tool and introduce the stylet.



- Continue to slide the stylet into the hole of the electrode array until the thick, proximal portion of the stylet base reaches the opening of the hole. Ensure that the proximal, thick stylet base fully engages the array (Figures 5-44G, 5-44H, 5-44I).

Figure 5-44G. Proximal, thick stylet base.

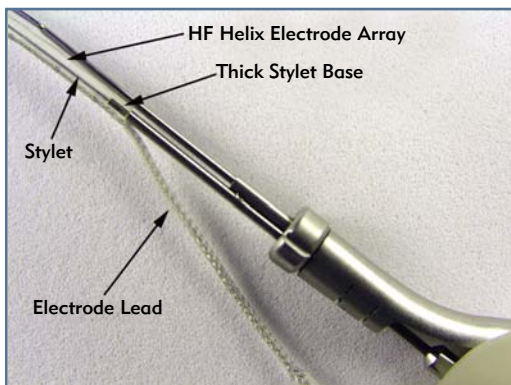


Figure 5-44H. Identify the proximal, thick stylet base.

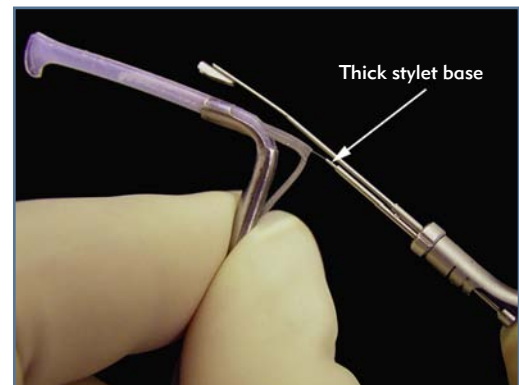


Figure 5-44I. Electrode array loaded over the proximal, thick stylet base.



8. Withdraw the loaded stylet from the Electrode Reloading Tool. Stabilize the electrode lead against the Electrode Insertion Tool handle (Figure 5-44J).
9. Verify that the electrode array is completely loaded and positioned between the fins of the stylet guide (Figure 5-44K).

Figure 5-44J. Withdraw the loaded stylet from the Electrode Reloading Tool.

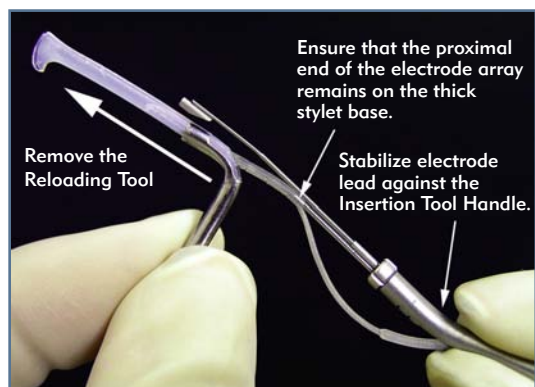


Figure 5-44K. Electrode array fully engaged on the stylet.



10. Follow the previously described two-step procedure to position the stylet guide-footpad portion of the Stylet Assembly and insert the HiFocus Helix electrode array.

**NOTE:** The stylet hole must be sealed if the electrode array has been reloaded. After insertion of the HiFocus Helix electrode array into the cochlea, seal the stylet hole with tissue.

## Determine HiFocus Helix Electrode Insertion Depth

Determine the insertion depth of the HiFocus Helix electrode.

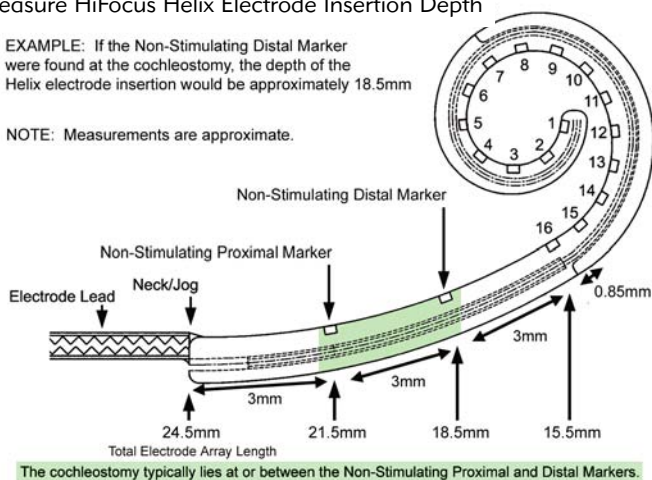
Example: If the non-stimulating proximal marker were found at the cochleostomy, the depth of the HiFocus Helix electrode insertion would be 21.5 mm (Figure 5-45).

Figure 5-45. Determine electrode array insertion depth.

### Method To Measure HiFocus Helix Electrode Insertion Depth

EXAMPLE: If the Non-Stimulating Distal Marker were found at the cochleostomy, the depth of the Helix electrode insertion would be approximately 18.5mm

NOTE: Measurements are approximate.



The insertion depth of the HiFocus Helix electrode may also be determined by estimating the distance between the neck/jog and cochleostomy with a stapedectomy measuring stick.

Since the non-stimulating proximal and distal markers are 3 mm away from each other, the surgeon can arrive at a reasonable estimate of HiFocus Helix electrode insertion relative to the two markers.

## Pack the Cochleostomy

To secure the HiFocus Helix electrode in place, fascia or muscle should be well packed all around the cochleostomy site.

NOTE: Pack circumferentially all around the electrode array (Figure 5-47).

Figure 5-46. Electrode array in place. Right ear.

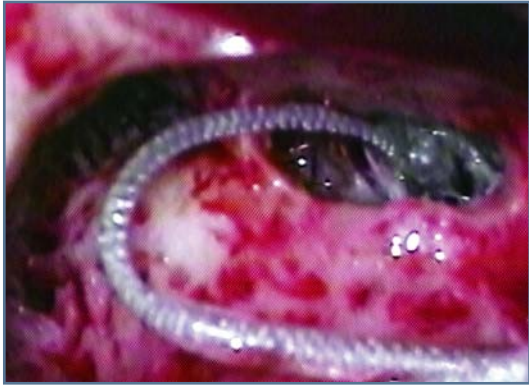
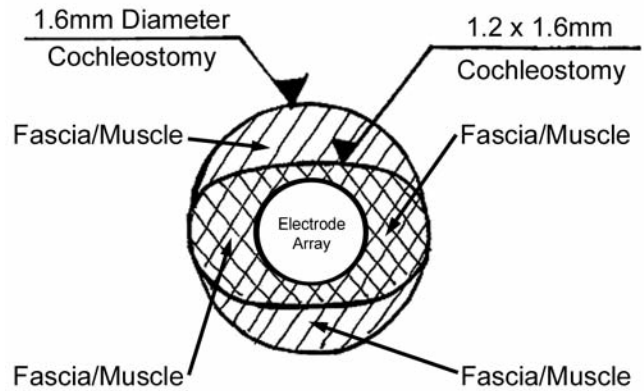


Figure 5-47. Pack fascia or muscle circumferentially all around the electrode array.



Also, the stilet hole can be completely covered with fascia or muscle. This should be performed particularly if it was necessary to reload the HiFocus Helix electrode. In addition, the walls of the cochleostomy should be retained to as great an extent as possible, particularly the inferior wall of the basal turn, to assist in the prevention of electrode movement (Figure 5-48).

## Coil the Electrode Lead

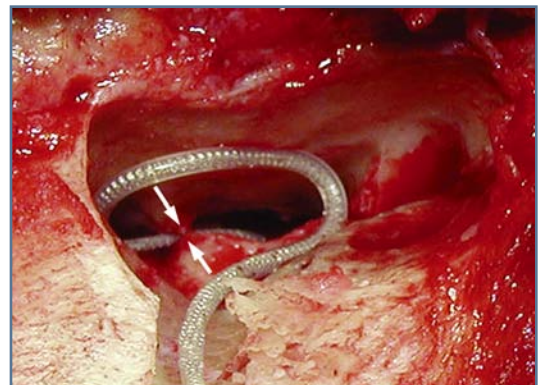
Once the HiFocus Helix electrode array has been secured at the cochleostomy site, the proximal lead of the implant is placed in the recessed well to mastoid groove or channel. The more distal portion of the electrode lead is coiled inside the mastoid cavity, using the mastoid cavity bony overhangs to retain the coiled lead in position.

A split incus bridge technique may be used to secure the HiFocus Helix electrode array if the surgeon wishes (Figure 5-49).

Figure 5-48. Pack the cochleostomy.



Figure 5-49. Split incus bridge used to secure the HiFocus Helix electrode array. Right ear.



In children, while performing the cortical mastoidectomy it is important to enlarge the cavity *inferiorly* to adequately accommodate the electrode lead.

## Imaging

Intraoperative x-rays are strongly recommended to verify electrode placement (Figure 5-50).

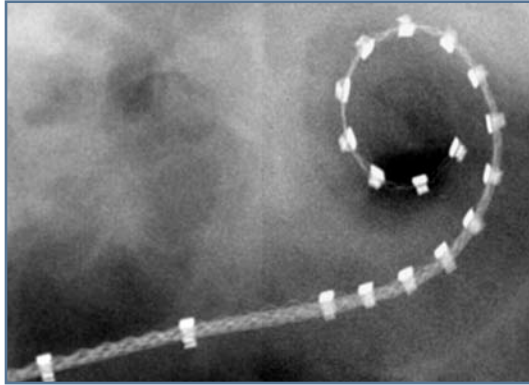
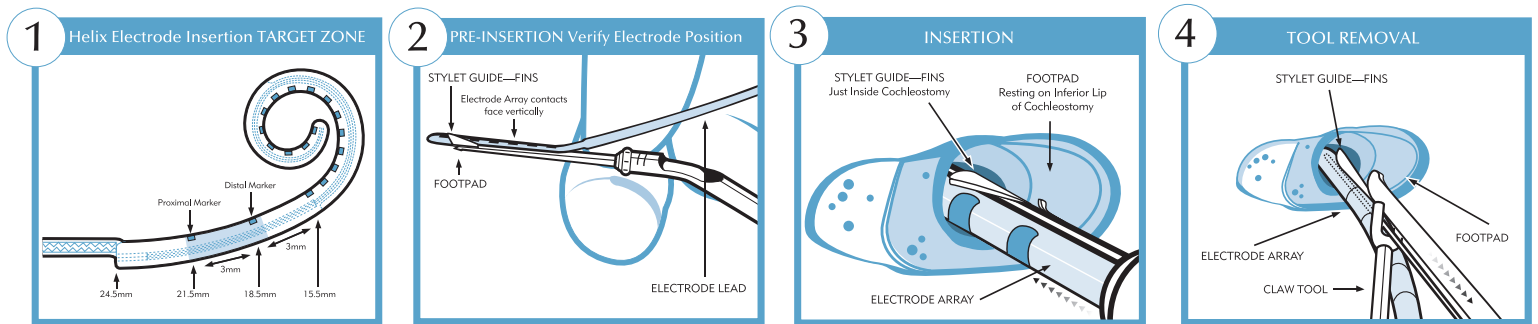
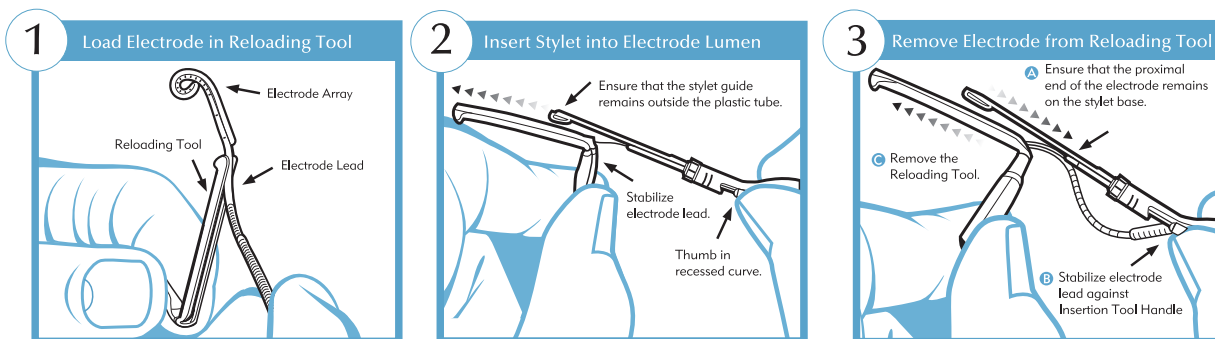


Figure 5-50. HiFocus Helix electrode intraoperative x-ray.

## HiFocus Helix Insertion Sequence



## HiFocus Helix Reloading Sequence



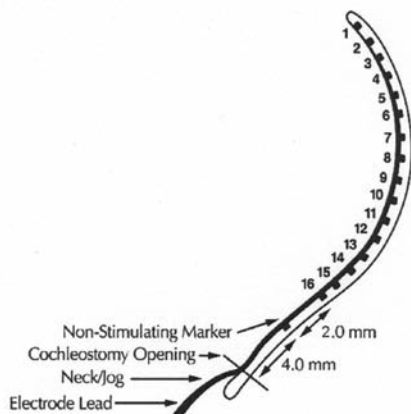
# 6. HiFocus 1j Electrode

## HiFocus 1j Electrode Description

The HiFocus 1j electrode consists of a fantail, electrode lead, and HiFocus 1j electrode array. The electrodes, composed of platinum-iridium alloy, are housed in a silicone carrier and extend from the titanium case. The HiFocus 1j intracochlear electrode array is designed to be inserted approximately 25 mm into a normally patent cochlea. It consists of 16 planer 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.

The neck refers to the jog at the proximal end of the array that transitions the array to the lead. The fantail is directly connected to the electronic implant. The lead, which extends from the fantail, refers to the silicone carrier in which the electrode wires are enclosed (Figure 6-1).

Figure 6-1. HiFocus 1j electrode array.



## HiFocus 1j Electrode Specifications

(Approximate Measurements)

Electrode array tip diameter (distal)	≈0.4 mm
Electrode array base diameter (proximal)	≈0.8 mm
Spacing between active contacts (distance from midpoint of one contact to another)	≈1.1 mm
Total length of active contacts (distance that the electrode contacts are spread over)	≈17 mm
Distance between non-stimulating marker pad and contact pad No. 16	≈2 mm
Neck/Jog to proximal non stimulating marker pad.	≈ 4 mm
Total length of electrode array (distance from distal electrode tip to proximal electrode jog)	≈25 mm
Preferred cochleostomy dimensions (minimum) (using Plastic Insertion Tube)	2 mm diameter
Optional cochleostomy size (using a Metal Insertion Tube, AB-6135)	1.5 mm diameter
Electrode lead length from device fantail to proximal electrode jog	≈8.5 cm
Approximate angular insertion	400° – 500°

The HiRes 90K implant is packaged with its HiFocus 1j electrode array preloaded in a plastic insertion tube (Figure 6-2). The preloaded plastic insertion tube is mated with the Electrode Insertion Tool, MMT-6111. The insertion tube has a slot into which the electrode array is loaded. An additional single use Metal Insertion Tube, AB-6135, is packaged with the implant.

Figure 6-2. Plastic Insertion Tube with preloaded HiFocus 1j electrode.

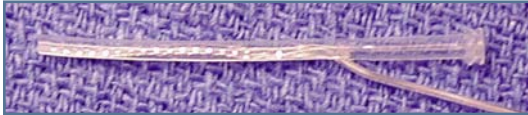
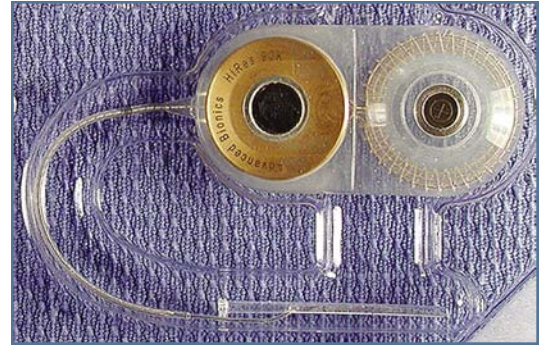


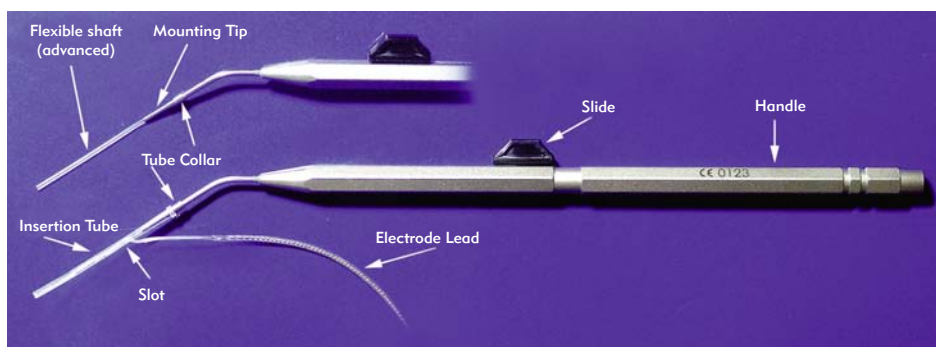
Figure 6-3. HiRes 90K implant with HiFocus 1j electrode.



## HiFocus 1j Electrode Insertion Tool and Tube

The Electrode Insertion Tool, MMT-6111, is designed to assist the surgeon with the insertion of the HiFocus 1j electrode array into the cochlea (Figure 6-4). Only the HiFocus 1j electrode Insertion Tool should be used for insertion of the HiFocus 1j electrode. The use of other instruments may result in damage to the electrode. The Electrode Insertion Tool is a reusable, surgical instrument. Instructions regarding its decontamination and resterilization can be found in the *Special Handling* section of this manual.

Figure 6-4. HiFocus 1j Electrode Insertion Tool, MMT-6111, and tube.



In describing the HiFocus 1j Electrode Insertion Tool, the distal and proximal locations are in reference to the surgeon's hand. The main body of the surgical stainless steel Insertion Tool is called the *handle*. The handle has a *slide* that can be advanced or retracted by pushing it through the *track* seen on the distal half of the handle. The most distal portion of the tool is referred to as the *mounting tip*. When the slide is advanced, a *flexible shaft* is expelled through the end of the mounting tip. When the slide is moved in the proximal direction, the *flexible shaft* is retracted into the mounting tip. The flexible shaft releases the electrode, pushing it out of the Insertion Tube as the slide is advanced. Toward the end

of the mounting tip is a raised ring, referred to as the *tip collar*. The raised rings, found at the proximal end of the Insertion Tube, are called the *tube collar*. Although the Electrode Insertion Tool is constructed of a very durable stainless steel with a special alloy flexible shaft, it is a delicate surgical instrument. It must never be dropped onto a hard surface. If this occurs, the Insertion Tool must be decontaminated, resterilized, and carefully tested for proper, smooth operation before reuse.

## HiRes 90K with HiFocus 1j Electrode Equipment Requirements

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

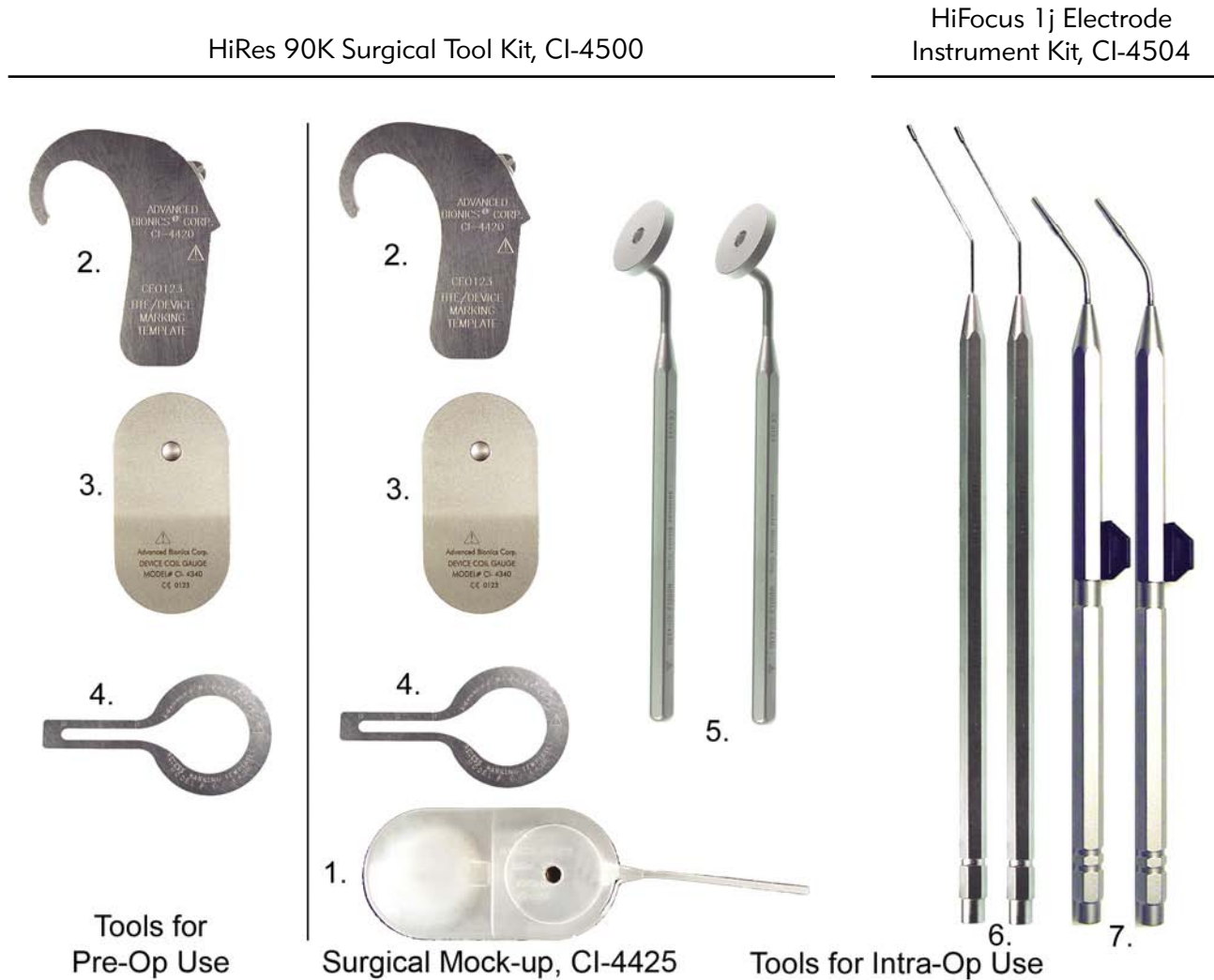
- **Primary and Backup Implants, CI-1400-01:** The implant with the lower serial number should be used as the primary device. The implant is delivered sterilized (Figure 6-5).

Figure 6-5. HiRes 90K Implant with HiFocus 1j Electrode, CI-1400-01.



**The Following Tools Must Be Sterilized Prior to Surgery (Figure 6-6):**

*Figure 6-6. HiRes 90K Surgical Tool Kit, CI-4500, for preoperative and intraoperative use and HiFocus 1j Electrode Instrument Kit, CI-4504, for electrode implantation. These tools are reusable except for the single-use HiRes 90K plastic Surgical Mock-up, CI-4425, which is provided sterile with the implant package.*



**HiRes 90K Surgical Mock-up, CI-4425**

1. One HiRes 90K single-use Surgical Mock-up, CI-4425: This template is provided sterile with the primary HiRes 90K Implant, CI-1400-01 (Figures 6-7, 6-8).

Figure 6-7. HiRes 90K single-use Surgical Mock-up, CI-4425, provided with the implant package.



Figure 6-8. HiRes 90K Surgical Mock-up, CI-4425.



## HiRes 90K Surgical Tool Kit, CI-4500

The HiRes 90K Surgical Tool Kit, CI-4500, includes the following tools and gauges for implantation of the HiRes 90K implant. See Section 1 for a description of the HiRes 90K Surgical Tool Kit, CI-4500.

2. **Two BTE (Behind-the-Ear) Device Marking Templates, CI-4420:** Templates are used for determining device placement (Figure 6-9).
3. **Two Device Coil Gauges, CI-4340:** Mock-ups are provided for determining device placement (Figure 6-10).

Figure 6-9. BTE Device Marking Template, CI-4420.



Figure 6-10. Device Coil Gauge, CI-4340, top, bottom.



4. Two Recess Marking Templates, CI-4430: Templates are used for determining the site of the recessed well and device placement (Figure 6-11).
5. Two Recess Gauges, CI-4330: Recess Gauges are used to verify adequate bone removal for the device titanium case (Figure 6-12).

Figure 6-11. Recess Marking Template, CI-4430.



Figure 6-12. Recess Gauge, CI-4330.



## HiFocus 1j Electrode Instrument Kit, CI-4504

The HiFocus 1j Electrode Instrument Kit, CI-4504, includes the following tools and gauges for insertion of the HiFocus 1j electrode.

6. Two Cochleostomy Sizing Gauges, AB-7120, (labeled "Plastic Tube Gauge"): The sizing gauge is used to verify adequate cochleostomy size (Figure 6-13).

Figure 6-13. Cochleostomy Sizing Gauge, AB-7120 (Labeled "Plastic Tube Gauge").



7. Two Electrode Insertion Tools, MMT-6111. The Insertion Tool is used to expel the HiFocus 1j electrode array from its insertion tube. (Figure 6-14).

Figure 6-14. Electrode Insertion Tool, MMT-6111.



8. The HiFocus 1j electrode is loaded in a plastic insertion tube, MMT-6135. An additional metal insertion tube, AB-6135, is provided along with the implant in the sterile plastic tray (Figure 6-15).
9. Metal Electrode Insertion Tube, AB-6135, (optional): Additional stainless steel electrode insertion tubes are available upon request and must be autoclaved sterilized prior to use. Metal insertion tubes are a single-use disposable product (Figure 6-16).

Figure 6-15. Plastic Insertion Tube, MMT-6135.



Figure 6-16. Metal Insertion Tube, AB-6135 (a backup Metal Insertion Tube, AB-6135, is included in the implant package).



## Using the Metal Insertion Tube, AB-6135

Keep the following points in mind:

- Metal insertion tubes are a single-use item.
- Use plenty of saline—irrigation—when using the metal tube.
- Avoid moving the metal tube unnecessarily when it has been placed in the cochlea. This will help to avoid any possible damage to the basilar membrane and/or other cochlear structures.
- If the electrode array moves out of the cochlea following insertion avoid using the metal tip to stabilize the array. In this case it is possible to pinch the electrode between the metal tube tip and the nearby bone.

# HiRes 90K with HiFocus 1j Electrode Surgical Equipment Sterilization Guidelines

Surgical Equipment <sup>1</sup>	Product Name	Model No.	Autoclave-Steam	
			136°C/275°F for 5 minutes	Gas EO
			122°C/250°F for 30 minutes <sup>2</sup>	
	BTE (Behind-the-Ear) Device Marking Template	CI-4420	OK	NO
	Device Coil Gauge	CI-4340	OK	NO
	3.5 cm Recess Marking Template	CI-4430	OK	NO
	Recess Gauge	CI-4330	OK	NO
	Cochleostomy Sizing Gauge (labeled "Plastic Tube Gauge")	AB-7120	OK	NO
	Electrode Insertion Tool	MMT-6111	OK	NO
	Metal Insertion Tube (optional)	AB-6135	OK	NO
	Plastic Insertion Tube (if provided separately)	MMT-6135	NO	OK

<sup>1</sup> See the *Decontamination and Resterilization of the Advanced Bionics Surgical Tools* section of this manual for more information.

<sup>2</sup> For other sterilization methods and confirmations, refer to the guidance provided in Association for the Advancement of Medical Instrumentation (AAMI) Technical Information Report (TIR) 12:1994, *Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers or ANSI (American National Standards Institute)/AAMI ST46 1993 Good Hospital Practice: Steam Sterilization and Sterility Assurance*. Users may also refer to the (Medicines and Healthcare products Regulatory Agency [MHRA]) Publication *Sterilization, Disinfection and Cleaning of Medical Equipment, Part 3*. Refer to national standards for minimum temperatures and times.

## HiFocus 1j Electrode Insertion

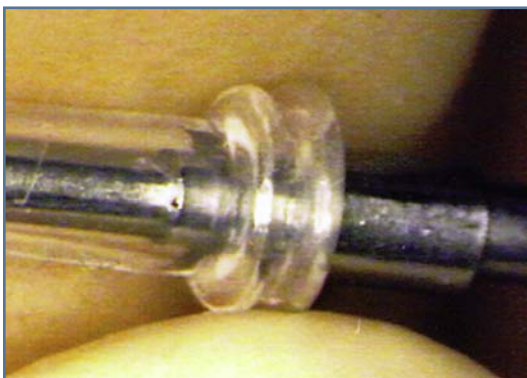
After the HiRes 90K implant has been secured in its well, the HiFocus 1j electrode is inserted into the cochlea through the cochleostomy previously created. The Electrode Insertion Tool is designed to assist in the placement of the HiFocus1j electrode. The following section outlines the steps that must be performed to ensure successful electrode insertion.

### Mate the Insertion Tube to the Electrode Insertion Tool

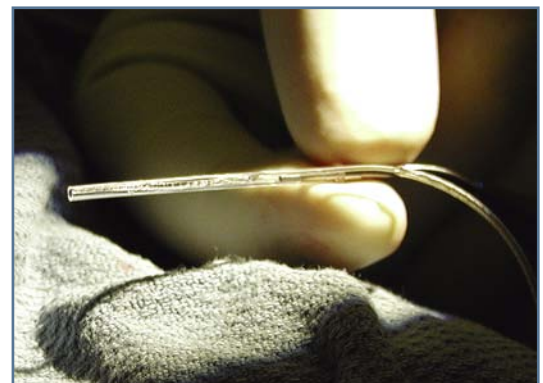
In placing the Insertion Tube (loaded with the HiFocus1j electrode) onto the Electrode Insertion Tool, MMT-6111, the following steps must be performed to ensure successful electrode insertion and subsequent disengagement of the Insertion Tool:

- Verify that the flexible shaft is fully retracted into the mounting tip by moving the tool slide to its most proximal position.
- Hold the Insertion Tube firmly at the proximal end (i.e., the tube collar) of the tube. Do not hold or grasp the tube anywhere on its slotted portion.
- Place the Insertion Tube on the end of the Electrode Insertion Tool.
- Push the Insertion Tube onto the Electrode Insertion Tool until the tube collar fully contacts the tip collar, located at the distal end of the Insertion Tool mounting tip (Figures 6-17, 6-18). Some resistance may be felt until the tip collar is reached.

*Figure 6-17. Mount the insertion tube onto the Insertion Tool, MMT-6111.*



*Figure 6-18. Insertion Tube to Insertion Tool, MMT-6111, mating.*



**CAUTION:** Failure to place the Insertion Tube so that it is in full contact with the Insertion Tool tip collar may result in an electrode that is not fully expelled during insertion or that is extracted from the cochlea when removal of the tube is attempted. If the electrode is partially extruded from the cochlea, the electrode must be removed completely, reloaded into the tube, and reinserted.

### Rotate the Insertion Tube Slot Toward the Modiolus

Prior to inserting the electrode, it is important to *verify that the slot of the Insertion Tube is directed towards the modiolus*. The orientation of the slot indicates the direction that the electrode array will exit the tube. It is essential that the HiFocus 1j Electrode exit the Insertion Tube so that it curves around the basal turn of the cochlea.

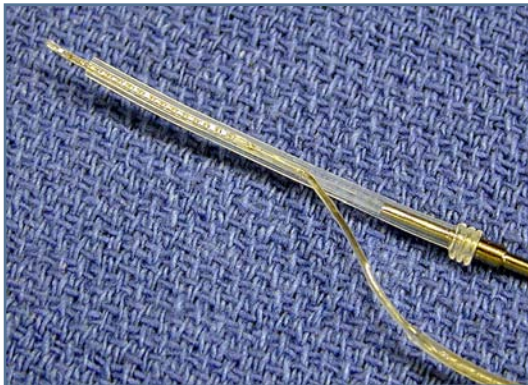
Whether a right or left cochlea, the Insertion Tube should be rotated on the Electrode Insertion Tool so that the slot faces *superiorly*, toward the modiolus. This allows the Electrode Insertion Tool to be held with the same hand regardless of whether the electrode is being implanted in a right or left cochlea.

## Verify the Orientation of the HiFocus 1j Electrode Array

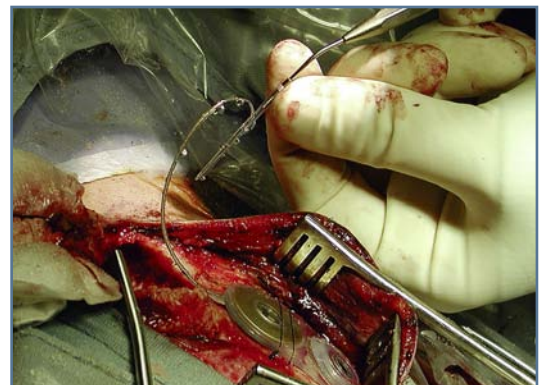
Before electrode insertion, ensure that the HiFocus 1j electrode array exits and curves in the proper direction (i.e., the slot of the Insertion Tube is oriented superiorly *toward* the modiolus) as the electrode is released from the tube. This involves partially expelling the electrode array from the tube to determine its orientation and then safely guiding the electrode array back into the tube. To do this properly, without subjecting the electrode array to any stress, follow these steps:

- Advance the Electrode Insertion Tool slide with a smooth and continuous motion until approximately three electrode contact pads have exited the tube.
- Verify that the HiFocus 1j electrode array faces toward Insertion Tube slot (Figure 6-19).
- Adjust the orientation of the tube slot as necessary so that the electrode array curves in the direction of the modiolus.
- Fully retract the flexible shaft of the Electrode Insertion Tool by pulling back the slide.
- Gently pull on the neck region while guiding the electrode array back into the tube.
- Take particular care with the distal end of the electrode array, to ensure that it does not get caught in the tube opening. It may be necessary to straighten the electrode tip while gently pulling on the neck region to guide the tip into the tube.
- Continue to slide the electrode array into the tube until the most distal end is completely inside the Insertion Tube.

*Figure 6-19. Advance the HiFocus 1j electrode out of its insertion tube to verify proper electrode orientation and that the electrode array will follow the lumen of the osseous spiral lamina.*



*Figure 6-20. Prepare to insert the HiFocus 1j electrode. Right ear.*



## Position the Insertion Tube and Insert the HiFocus 1j Electrode Array

Insertion of the HiFocus 1j electrode with the Electrode Insertion Tool can be described as a two-step process consisting of placement of the Insertion Tube and release of the electrode array.

**Step 1:** Position the Insertion Tube.

The Insertion Tube has been carefully designed to accommodate the dimensions of the cochlea. The HiFocus 1j electrode is expelled in such a way that it enters the first cochlear turn and continues around the modiolus. The distal end of the Insertion Tube should be positioned 2-3 mm inside the cochleostomy at the beginning of the first turn (Figure 6-21). The Insertion Tube must be appropriately positioned prior to advancing the slide.

**CAUTION:** If the Insertion Tube is not positioned at a sufficient depth, the electrode could meet the hook region and could then fold over upon itself.

In order to place the Insertion Tube deeply within the basal cochlea, the cochleostomy must be appropriately sized. Use the Cochleostomy Sizing Gauge labeled Plastic Tube Gauge, AB-7120, to establish the correct dimensions of the cochleostomy. The tip of the cochleostomy sizing gauge must fit easily 2-3 mm inside the opening.

**CAUTION:** If the diameter of the cochleostomy is too small, the slot of the Insertion Tube is forced against the electrode, causing pressure to be exerted on the electrode itself. This pressure can result in electrode damage or an incomplete insertion.

**Step 2:** Insert the HiFocus 1j electrode array.

After the cochleostomy has been created and the loaded Insertion Tube placed at the appropriate location and depth, the HiFocus 1j electrode is inserted by advancing the insertion tool slide with a smooth and continuous motion.

**WARNING:** Excessive insertion force should be avoided in order to prevent damage. Discontinue insertion if resistance is met. Determine the cause of the resistance before continuing.

**IMPORTANT:** If the jog or neck of the electrode array is expelled through the slot of the insertion tube, this may be an indication that the electrode is meeting resistance.

## Remove the Electrode Insertion Tool

Once the HiFocus 1j electrode has been released, continue to advance the Electrode Insertion Tool slide while simultaneously withdrawing the tool. This allows complete removal of the Electrode Insertion Tool while maintaining the electrode array in the appropriate position. Thus, the smooth disengagement of the Electrode Insertion Tool involves coordinating two concurrent actions: advancing the slide forward and withdrawing the Tool backward or out of the cochleostomy (Figure 6-22). Use a gimmick to gently hold the electrode array in place while the Insertion Tool and Tube are withdrawn. Continue to maintain the position of the electrode array while beginning to pack the cochleostomy. This will minimize any movement of the array.

Figure 6-21. Placement of the HiFocus 1j electrode loaded in a Metal Insertion Tube, AB-6135.

Note that the tube slot faces superiorly, toward the modiolus, stapes, and incus bridge. Right ear.

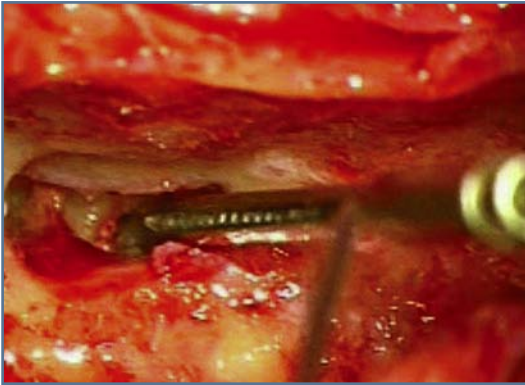
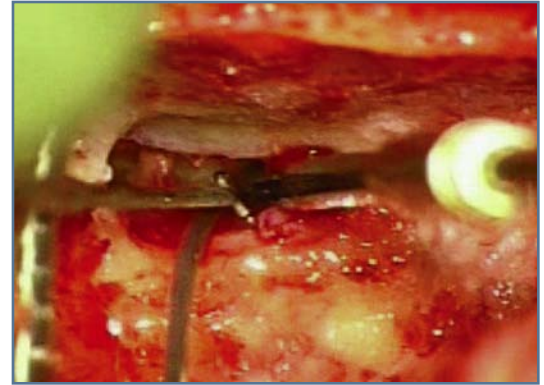


Figure 6-22. Release of the electrode array followed by withdrawal of the Electrode Insertion Tool and tube. Use a gimmick or the Electrode Claw Tool, CI-4252, to stabilize the electrode while the Insertion Tool and tube are withdrawn. Right ear.



## If It Becomes Necessary to Reload the HiFocus 1j Electrode Array into the Insertion Tool

If the HiFocus 1j electrode array is pulled out of the cochlea during removal of the Insertion Tool, or if the stainless steel Insertion Tube is to be used, the electrode must be gently expelled from the tube, reloaded into the tube, and inserted again. To reload the electrode into the tube, follow these steps:

- Verify that the flexible shaft of the Insertion Tool is fully retracted by pulling the slide toward you.
- Briefly soak the electrode array and Insertion Tube in sterile saline. This provides lubrication.
- Verify that the Insertion Tube is fully seated on the Insertion Tool (i.e., flush against the tool tip collar). The electrode array can also be placed in the tube with the tube held free in the surgeon's hand.
- Line up and place the most proximal end of the electrode array into the opening of the slotted Insertion Tube. That is, the neck region is placed into the slot of the tube, as shown in Figure 6-19.
- Gently pull the neck region while guiding the HiFocus 1j electrode into the distal opening of the tube. Maintain the orientation of the curl parallel to the opening in the tube, so that when the electrode is expelled it curves toward the modiolus.
- Take particular care with the distal end of the electrode array to ensure that it does not get caught in the tube opening. It may be necessary to gently straighten out the electrode tip while pulling on the neck region to guide the tip into the tube.
- Continue to slide the electrode into the tube until the most distal end is completely inside the insertion tube (Figure 6-23).
- If not done previously, seat the insertion tube fully on the Electrode Insertion Tool, flush against the tool tip collar.

Figure 6-23. Reload the HiFocus 1j electrode array into plastic insertion tube.



## Following Removal of the Electrode Insertion Tool

Typical placement of the HiFocus 1j electrode is shown in Figures 6-24 and 6-25.

Figure 6-24. Typical placement of the HiFocus 1j electrode array. Right ear.

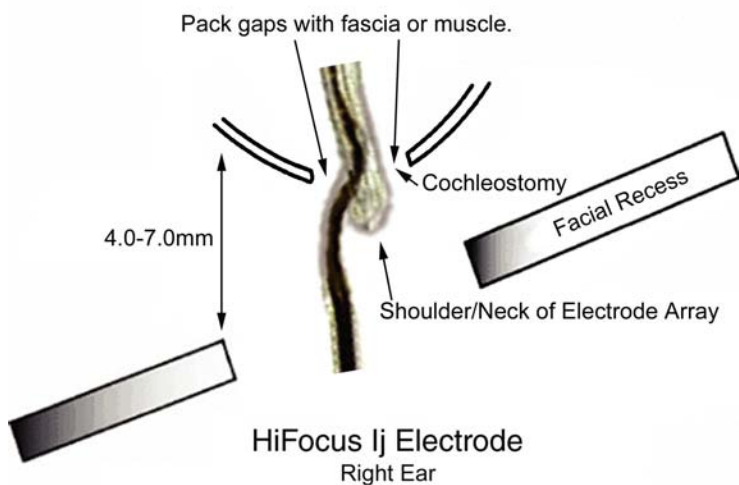


Figure 6-25. Inserted HiFocus 1j electrode. Right ear.



## Pack the Cochleostomy

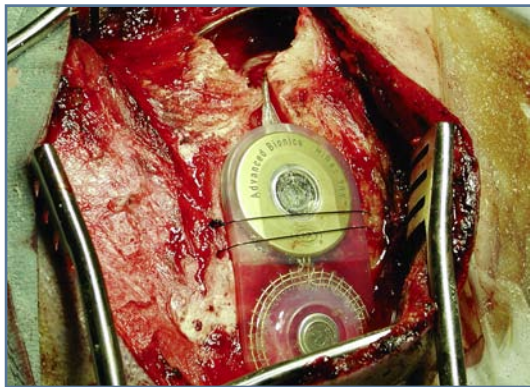
To secure the HiFocus 1j electrode in place, fascia or muscle should be well packed all around the cochleostomy site. In addition, the walls of the cochleostomy should be retained to as great an extent as possible, particularly the *inferior* wall of the basal turn, to assist in the prevention of electrode movement.

## Coil the Electrode Lead

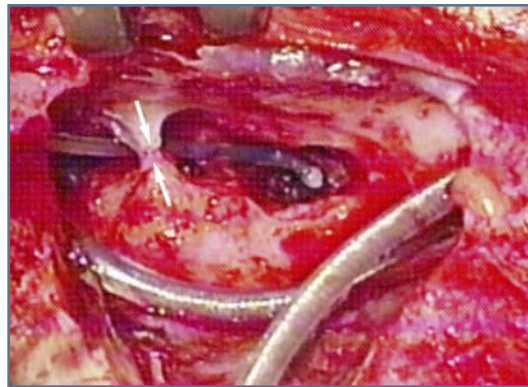
Once the HiFocus 1j electrode array has been secured at the cochleostomy site, the proximal lead of the implant is placed in the groove or channel and under the bony overhang previously created. The more distal electrode lead is coiled inside the mastoid cavity, utilizing the bony overhangs to retain the coiled lead in position (Figure 6-26).

A split incus bridge technique may be used to secure the HiFocus 1j electrode array if the surgeon wishes (Figure 6-27).

*Figure 6-26. Implant sutured in recessed well with HiFocus 1j electrode lead coiled into position.*



*Figure 6-27. Split incus bridge used to secure the HiFocus 1j electrode array. Right ear.*

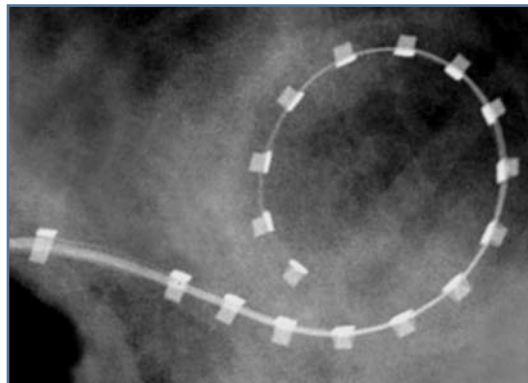


In children, while performing the cortical mastoidectomy it is important to enlarge the cavity *inferiorly* to adequately accommodate the electrode lead.

## Imaging

Intraoperative x-rays are strongly recommended to verify electrode placement (Figure 6-28).

*Figure 6-28. HiFocus 1j electrode, intraoperative x-ray.*



# 7. Closing Procedures

## Testing

Intraoperative testing of the HiRes 90K 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 light, 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.

## 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 strongly recommended to verify electrode placement.



# 8 Special Handling

## Ordering the HiRes 90K with *HiFocus Helix* or *HiFocus 1j* Electrode

The following two charts list part number information for ordering the HiRes 90K with HiFocus Helix or HiRes 90K with HiFocus 1j electrode.

Description	Part No.
HiRes 90K with HiFocus Helix electrode	CI-1400-02H
HiRes 90K with HiFocus 1j electrode	CI-1400-01

## Surgeon's Tools – Ordering Information

The following two charts identify the surgeon's tools needed for HiRes 90K with HiFocus Helix or HiFocus 1j surgeries. While the surgeon's tools for implanting the HiRes 90K implant receiver package remain the same, the tools required for the HiFocus Helix electrode are different from those of the HiFocus 1j electrode.

### Surgeon's Tools Needed When Implanting the HiRes 90K with *HiFocus Helix* Electrode, CI-1400-02H

NOTE: A single-use, non-sterile silicone plastic Surgical Mock-up, CI-4425, is included with the HiRes 90K implant, CI-1400-02H.

#### HiRes 90K Surgical Kit, CI-8160

Description	Part No.	Qty
Surgeon's Manual	9055112-002	1
Surgeon's Video	CI-8167	1
HiRes 90K Surgeon's Tool Kit (see below for Tool Kit contents)	CI-4500	1
Device Marking Template	CI-4420	2
Recess Marking Template	CI-4430	2
Recess Gauge	CI-4330	2
Device Coil Gauge	CI-4340	2

#### *HiFocus Helix* Electrode Instrument Kit, CI-4501

Description	Part No.	Qty
Cochleostomy Sizing Gauge ("Helix")	CI-4345	2
Electrode Claw Tool	CI-4252	2

## Surgeon's Tools Needed When Implanting the HiRes 90K with *HiFocus 1j* Electrode, CI-1400-01

NOTE: A single-use, non-sterile silicone plastic Surgical Mock-up, CI-4425, is included with the HiRes 90K implant, CI-1400-01.

### HiRes 90K Surgical Kit, CI-8160

Description	Part No.	Qty
Surgeon's Manual	9055112-002	1
Surgeon's Video	CI-8167	1
HiRes 90K Surgeon's Tool Kit (see below for Tool Kit contents)	CI-4500	1
Device Marking Template	CI-4420	2
Recess Marking Template	CI-4430	2
Recess Gauge	CI-4330	2
Device Coil Gauge	CI-4340	2

### *HiFocus 1j* Electrode Instrument Kit, CI-4504

Description	Part No.	Qty
Cochleostomy Sizing Gauge ("Plastic Tube Gauge")	AB-7120	2
Electrode Insertion Tool	MMT-6111	2
Metal Insertion Tube, optional. (All <i>HiFocus 1j</i> electrodes are preloaded in a plastic Insertion Tube, MMT-6135. An extra Metal Insertion Tube, AB-6135, is provided in the sterile tray with the implant.)	AB-6135	2

## Handling

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

Neither the implant nor the Electrode Insertion Tool is intended to tolerate a drop onto a hard surface. If the implant falls onto a hard surface, it must be returned to the factory 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 stamped on the packaging and is two years from the date of the original sterilization.

## Sterilization

The HiRes 90K implant and HiFocus electrode device is 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.

## Decontamination and Resterilization of the Advanced Bionics Surgical Tools

The following Advanced Bionics tools are reusable surgical instruments.

- BTE (Behind the Ear) Device Marking Template, CI-4420
- Device Coil Gauge, CI-4340
- Recess Marking Template, CI-4430
- Recess Gauge, CI-4330
- HiFocus Helix Cochleostomy Sizing Gauge, CI-4345
- Electrode Claw Tool, CI-4252
- Cochleostomy Sizing Gauge ("Plastic Tube Gauge"), AB-7120

The procedures outlined below must be followed prior to reuse.

1. Place templates/gauges in an enzyme or detergent based pre-soaking solution for a minimum of 15 minutes.
2. Manually clean the templates/gauges with a fine brush. Pay particular attention to the edges of the templates/gages. Clean to remove any visible biological material.
3. Place the templates/gauges in an ultrasonic cleaner for 20 minutes in a solution of warm (80°F to 110°F/27°C to 43°C) water and a low-sudsing, free rinsing detergent with a pH of 6-9 (recommended detergent: Terg-A-Zyme).
4. Remove templates/gauges. Rinse with distilled or deionized water and place the tool in an ultrasonic cleaner with distilled or deionized water for 10 minutes. Place on a clean towel or absorbent pad and carefully inspect the cloth surfaces for traces of biological residue. If biological residue is noted, repeat step 3 until no residue is present.
5. For gravity-displacement, sterilize the templates/gauges by autoclaving at 136°C/275°F for 5 minutes or 122°C/250°F for 30 minutes.

**NOTE:** Different facilities may vary their decontamination and sterilization procedures based on new or modified guidelines. Thus each facility must determine if the above procedures are acceptable or need to be modified to accommodate their approved internal guidelines.

## Decontamination and Resterilization of the HiFocus 1j Electrode Insertion Tool

The Electrode Insertion Tool, MMT-6111, is a reusable surgical instrument. The procedures outlined below must be followed prior to reuse.

1. Fully extend the Electrode Insertion Tool plunger spring by gently pushing the slide on the handle forward.
2. Place the Electrode Insertion Tool with the fully extended flexible shaft in an enzyme or detergent based presoaking solution (1% detergent) for a minimum of 15 minutes.
3. Manually clean the insertion instrument with a fine brush. Pay particular attention to the flexible shaft and slide slot. Care should be taken to avoid bending or pulling the flexible shaft. Fully retract and extend the flexible shaft several times and clean to remove any visible biological material.
4. With the flexible shaft fully extended, rinse the Electrode Insertion Tool in fresh enzyme or detergent solution.
5. Place the Electrode Insertion Tool with the flexible shaft fully extended in an ultrasonic cleaner for 20 minutes in a solution of warm (80°F-110°F/27°C-43°C) water and low sudsing, free rinsing detergent with a pH of 6-9 (recommended detergent: Terg-A-Zyme). A pH of 6-11 is required in some European countries.
6. Remove the Electrode Insertion Tool. Rinse with distilled or deionized water and place the tool in an ultrasonic cleaner with distilled or deionized water for 10 minutes. Actuate the flexible shaft several times during the rinsing.

Place on a clean white towel or absorbent pad and carefully inspect the cloth surface for traces of biological residue. If biological residue is noted, repeat the previous step until no residue is present.

7. Retract the flexible shaft and sterilize the Electrode Insertion Tool by autoclaving at 136°C/275°F for 5 minutes or 122°C/250°F for 30 minutes.

**NOTE:** Different facilities may vary their decontamination and sterilization procedures based on new or modified guidelines. Thus each facility must determine if the above procedures are acceptable or need to be modified to accommodate their approved internal guidelines.

## Storage

HiRes 90K implants should be stored where temperatures do not exceed 122°F/50°C, nor fall below 32°F/0°C.

## Explant of the HiRes 90K

All explanted devices should be returned to Advanced Bionics. All contaminated parts must be returned in the Cochlear Implant—Explant Return Kit, 5093145-001, in accordance with International Air Transport Association (IATA) rules. Please contact the company for further information.