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Reference Guide for Radiologists

MRI INFORMATION CHECKLIST

Australia

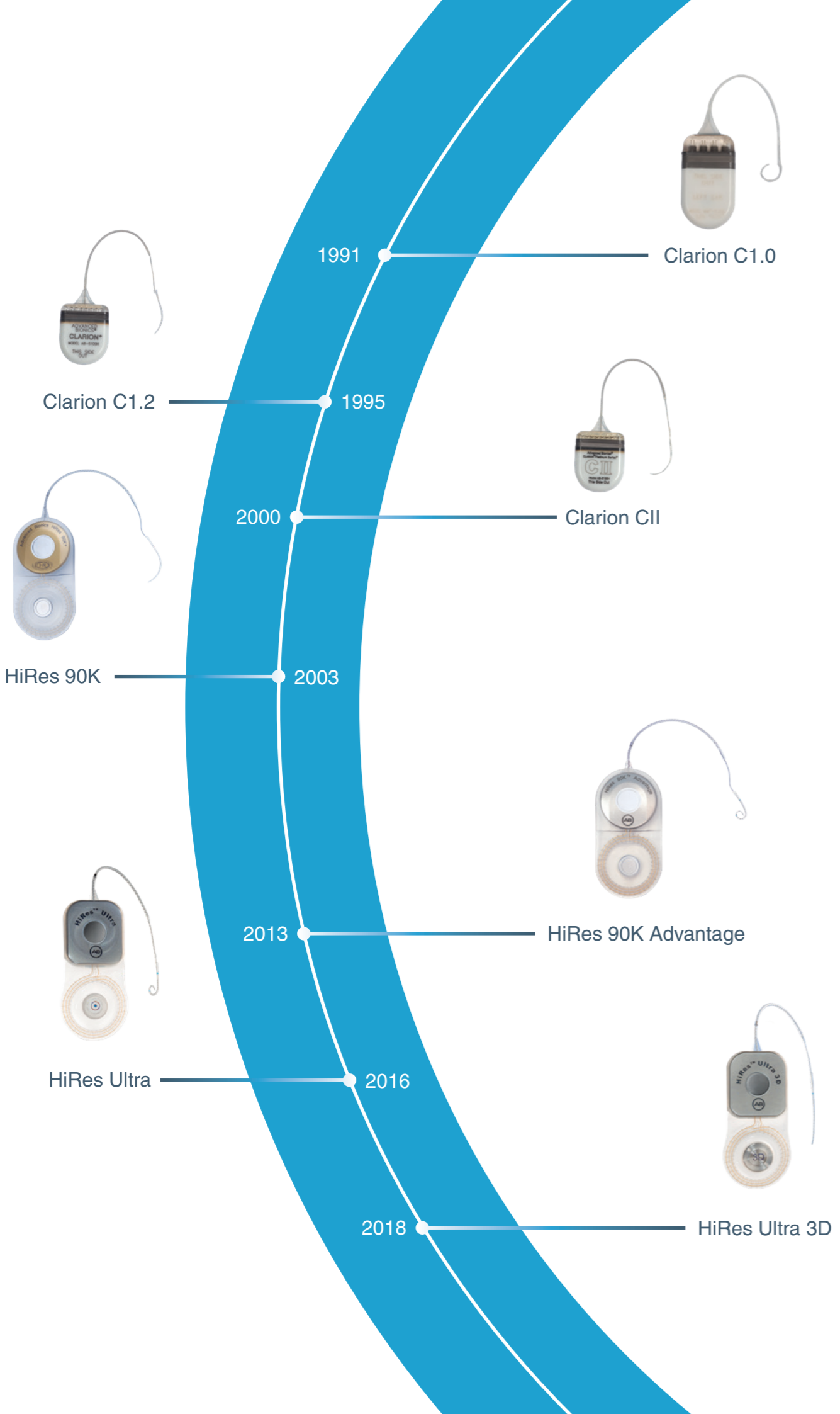


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Reference Guide for Radiologists

MRI INFORMATION CHECKLIST FOR ADVANCED BIONICS COCHLEAR IMPLANTS PATIENTS

Australia



The Instructions in the present document only apply to countries with CE Mark approval.

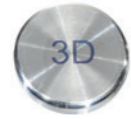
A summary of the MRI Safety Information for all AB Cochlear Implants is provided below. Please proceed to the checklist for the applicable implant for detailed information.

| IMPLANT TYPE | MRI FIELD STRENGTH (T) | SPATIAL GRADIENT FIELD (T/m) | | MAX HEAD SAR (W/kg) | MAX BODY SAR (W/kg) |
|---------------------|------------------------|------------------------------|-------------|---------------------|---------------------|
| HiRes 90K Advantage | 1.5T* | 2.5 T/m | | ≤1.0 W/kg | ≤1.7 W/kg |
| HiRes Ultra | 1.5T | 3.47 T/m | 13.90 T/m** | ≤ 3.2 W/kg | ≤ 2.0 W/kg |
| | 3.0T* | 6.9 T/m | | ≤ 2.6 W/kg | ≤ 2.0 W/kg |
| HiRes Ultra 3D | 1.5T | 20 T/M | | ≤ 3.2 W/kg | ≤ 2.0 W/kg |
| | 3.0T | 20 T/M | | ≤ 2.6 W/kg | ≤ 2.0 W/kg |

* For MRI the magnet has to be removed surgically
** With magnet removed

For additional information regarding the use of an MRI scanner with a HiRes Ultra 3D , please contact Advanced Bionics Technical Support at technicalservices@advancedbionics.com or visit www.advancedbionics.com/mri.

HiRes Ultra 3D



The HiRes™ Ultra 3D cochlear implant has an innovative designed multi-magnet assembly that allows safe MRI scanning with the multi-magnet assembly in place, without angular restrictions of the head, or a bandaging protocol.

MRI Checklist

Step 1: Pre-Scan Patient Screening

Before scheduling an MRI, it's vital to contact the patient's CI clinic or surgeon to answer these questions and fully understand their situation and scanning need¹.

A. Is the user bilaterally implanted (has implants on both left and right ears) with HiRes Ultra 3D?

- YES** Proceed to question B.
- NO** The patient has only one cochlear implant and it is HiRes Ultra 3D. Proceed to question B.
- NO** The patient is bilaterally implanted but has HiRes Ultra 3D on one side and a different CI on the other.
Verify that both implants are conditionally approved for MRI before proceeding with a scan². **NOTE:** The rest of this checklist will not be applicable to the case and it's important to follow the necessary programming, bandaging, surgery and angle protocols for the other CI to ensure patient safety.

B. Is the patient's doctor requesting a reduced image-artifact size around the cochlear implant site (for example, some head, brain or neck scans³)?

- NO** Proceed to Step 2: Prep Patient for Scan.
- YES** **Prior to MRI Scan:**
 - Order a Temporary Non-magnetic Plug (CI-1420) for every HiRes Ultra 3D implant the patient has (2 for bilateral implants, 1 for a single implant).
 - Order a HiRes Ultra 3D Replacement multi-magnet assembly (CI-1419) for every HiRes Ultra 3D implant the patient has (2 for bilateral implants, 1 for a single implant).
 - Schedule surgery with the patient's cochlear implant surgeon to remove the multi-magnet assembly⁴ and possibly replace it with the Temporary Non-Magnetic Plug(s) (CI-1420).
 - After the scan, schedule surgery with the patient's cochlear implant surgeon to replace the Temporary Non-Magnetic Plug (CI-1420)⁴ with the HiRes Ultra 3D Replacement multi-magnet assembly (CI-1419).

Step 2: Patient Preparation on Day of Scanning

Ensure that it has at least been 2-4 weeks since the patient cochlear implant surgery. **NOTE:** This is the recommended minimum duration in order to allow any inflammation from the cochlear implant to subside prior to MRI scan.

Verify the patient does not have any fever.

Counsel the patient regarding the possibility of auditory sensations during the scan.

Remove patient's sound processor and headpiece before entering a room containing an MRI scanner. **NOTE:** The external sound processor and headpiece are MR unsafe.

Proceed with MRI scan in adherence with the following important scanning guidelines:

MRI Scan Safety Guidelines

Testing has demonstrated that the HiRes Ultra 3D cochlear implant is MR Conditional. Unilateral and bilateral recipients with this device with multi-magnet assembly in place can be safely scanned in a horizontal closed-bore quadrature coil MR system meeting the following conditions:

| MRI FIELD STRENGTH | 1.5 T | 3.0 T |
|---------------------------------|-----------|-----------|
| Maximum Spatial Field Gradient | 20 T/m | 20 T/m |
| RMS Gradient Field | 34.4 T/s | 34.4 T/s |
| Peak Slew Rate | 200 T/m/s | 200 T/m/s |
| Maximum whole body averaged SAR | 2.0 W/kg | 2.0 W/kg |
| Maximum head averaged SAR | 3.2 W/kg | 2.6 W/kg |

When tested under the scan conditions defined above the HiRes Ultra 3D cochlear implant produced a maximum temperature rise of <3°C after 15 minutes of continuous scanning.

NOTE: During the scan, patients might perceive auditory sensations. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of the auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.

The largest artifact at 3.0T is >15cm when imaged under spin echo and gradient echo sequences. Smaller artifacts are possible using different scanning parameters only.

Step 3: Post-Scan Patient Management

Was the multi-magnet assembly removed prior to MRI scan?

- YES** Confirm multi-magnet assembly replacement surgery schedule with the cochlear implant surgeon and patient.
- NO** The cochlear implant user may reattach and start using the external components (sound processor and headpiece) upon exiting the MRI field zone.

For additional information regarding the use of an MRI scanner with a HiRes Ultra 3D cochlear implant, please contact Advanced Bionics Technical Support at technicalservices@advancedbionics.com or visit www.advancedbionics.com/mri.

HiRes Ultra



The HiRes™ Ultra cochlear implant is indicated for 3.0 Tesla MRI with magnet removal and 1.5 Tesla MRI scanning with the magnet in and head bandaging protocol.

MRI Checklist

Step 1: Pre-Scan Patient Screening

Before scheduling an MRI, it's vital to contact the patient's CI clinic or surgeon to answer these questions and fully understand their situation and scanning need.

A. Is the user bilaterally implanted with HiRes Ultra?

- YES** Proceed to question B^{1,2}.
- NO** The patient has only one cochlear implant and it is HiRes Ultra. Proceed to question B^{1,2}.
- NO** The patient is bilaterally implanted and has HiRes Ultra only on one side.
Verify that both implants are conditionally approved for MRI before proceeding with a scan¹. **NOTE:** The rest of this checklist will not be applicable to the case and it's important to follow the necessary programming, bandaging, surgery and angle protocols for the other non-HiRes Ultra CI to ensure patient safety.

B. Is the patient's doctor requesting a 1.5 Tesla MRI?

- YES** Proceed to head bandaging protocol on pages 10 and 11.

C. Is the patient's doctor requesting a reduced image artifact size around the cochlear implant site (for example, head and neck scans³)?

- NO** Proceed to head bandaging protocol on pages 10 and 11.

D. Is the patient's doctor requesting a 3.0 Tesla MRI or a reduced image artifact size around the cochlear implant site (for example, head and neck scans³)?

- YES** **STOP**, magnet removal is needed. Please observe the following steps.

Prior to MRI Scan:

Order a Temporary Non-magnetic Plug (CI-1411) for every HiRes Ultra implant the patient has (2 for bilateral implants, 1 for a single implant).

Order a HiRes Ultra Replacement magnet (CI-1413) for every HiRes Ultra implant the patient has (2 for bilateral implants, 1 for a single implant).

Schedule surgery with the patient's cochlear implant surgeon to remove the magnet(s) and possibly replace it with the Temporary Non-Magnetic Plug(s) (CI-1411).

After the scan, schedule surgery with the patient's cochlear implant surgeon to replace the Temporary Non-Magnetic Plug(s) with the HiRes Ultra Replacement magnet (CI-1413).

The measured range of MRI device image artifact radius extending from the HiRes Ultra cochlear implant for spin and gradient echo sequences and all imaging planes are provided in tables A and B.

Table A: Artifact at 3.0T MRI Field Strength
(magnet removed - Spin echo sequence)

| IMPLANTED | MAGNET | ARTIFACT RANGE |
|--------------|---------|----------------|
| Unilaterally | Removed | 4.7 cm |
| Bilaterally | Removed | 4.7 cm |

Table B: Artifact at 1.5T MRI Field Strength
(Gradient echo sequence)

| IMPLANTED | MAGNET | ARTIFACT RANGE |
|--------------|----------|----------------|
| Unilaterally | In place | ~ 7.9 cm |
| | Removed | ~ 3.1 cm |
| Bilaterally | In place | > 9.5 cm |
| | Removed | ~ 4.2 cm |

Step 2: Patient Preparation on Day of Scanning

Ensure that it has at least been 2-4 weeks since the patient cochlear implant surgery. **NOTE:** This is the recommended minimum duration in order to allow any inflammation from the cochlear implant to subside prior to MRI scan.

Verify the patient does not have any fever.

Counsel the patient regarding the possibility of auditory sensations during the scan.

Remove patient's sound processor and headpiece before entering a room containing an MRI scanner. **NOTE:** The external sound processor and headpiece are MR unsafe.

Important MRI Scan Safety Guidelines

Testing has demonstrated that the HiRes Ultra cochlear implant is MR Conditional. Unilateral and bilateral recipients with this device can be safely scanned in a horizontal closed-bore quadrature coil MR system meeting the following conditions:

| MRI FIELD STRENGTH | 1.5 T | 3.0 T |
|---------------------------------|---|----------------------------------|
| Maximum Spatial Field Gradient | 3.47 T/m (13.90 T/m with magnet removed) | 6.9 T/m (with magnet removed) |
| RMS Gradient Field | 34.4 T/s | 34.4 T/s |
| Peak Slew Rate | 200 T/m/s | 200 T/m/s |
| Maximum whole body averaged SAR | 2.0 W/kg | 2.0 W/kg |
| Maximum head averaged SAR | 3.2 W/kg | 2.6 W/kg |

When tested under the scan conditions defined above the HiRes Ultra cochlear implant produced a maximum temperature rise of <3°C after 15 minutes of continuous scanning and continuous 3.0T scanning.

NOTE: During the scan, patients might perceive auditory sensations. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of the auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.

Step 3: Post-Scan Patient Management

Was the magnet removed prior to MRI scan?

- YES** Confirm magnet replacement surgery schedule with the cochlear implant surgeon and patient.
- NO** The cochlear implant user may reattach and start using the external components (sound processor and headpiece) upon exiting the MRI field zone.

HiRes 90K Family



The HiRes 90K™ family devices are indicated for 1.5 Tesla MRI scanning with magnet removed.

MRI Checklist

Step 1: Pre-Scan Patient Screening

Before scheduling an MRI, it's vital to contact the patient's CI clinic or surgeon to answer these questions and fully understand their situation and scanning need.

A. Is the user bilaterally implanted with cochlear implants of the HiRes 90K family?

- YES** Proceed to magnet removal.
- NO** The patient has only one cochlear implant and it is one of the HiRes 90K family. Proceed to magnet removal.
- NO** The patient is bilaterally implanted and has one of the HiRes 90K family devices on one side.

Verify that both implants are conditionally approved for MRI before proceeding with a scan¹. **NOTE:** The rest of this checklist will not be applicable to the case and it's important to follow the necessary programming, bandaging, surgery and angle protocols for the other non-HiRes 90K CI to ensure patient safety.

B. Magnet Removal

Magnet removal is needed. Please observe the following steps.

Prior to MRI Scan:

Order a Temporary Non-magnetic Plug (CI-1410) for every HiRes 90K family device the patient has (2 for bilateral implants, 1 for a single implant).

Order a HiRes 90K Replacement magnet (CI-1412) for every HiRes 90K family device the patient has (2 for bilateral implants, 1 for a single implant).

Schedule surgery with the patient's cochlear implant surgeon to remove the magnet(s) and possibly replace it with the Temporary Non-Magnetic Plug(s) (CI-1410).

After the scan, schedule surgery with the patient's cochlear implant surgeon to replace the Temporary Non-Magnetic Plug(s) with the HiRes 90K Replacement magnet (CI-1412).

The measured range of MRI device image artifact radius extending from the HiRes 90K Advantage cochlear implant for a gradient echo sequence and all imaging planes are provided in table C.

Table C: Artifact at 1.5T MRI Field Strength

| IMPLANTED | MAGNET | ARTIFACT RANGE |
|--------------|----------|----------------|
| Unilaterally | Removed* | ~ 6 cm |

* With temporary non-magnetic plug

These artifacts may result in a loss of diagnostic information in the implant vicinity.

Step 2: Patient Preparation on Day of Scanning

Ensure that it has at least been 2-4 weeks since the patient cochlear implant surgery. **NOTE:** This is the recommended minimum duration in order to allow any inflammation from the cochlear implant to subside prior to MRI scan.

Verify the patient does not have any fever.

Counsel the patient regarding the possibility of auditory sensations, pain, pressure or discomfort during the scan.

Remove patient's sound processor and headpiece before entering a room containing an MRI scanner. **NOTE:** The external sound processor and headpiece are MR unsafe.

Important MRI Scan Safety Guidelines

Testing has demonstrated that the devices of the HiRes 90K family are MR Conditional. Unilateral and bilateral recipients with these devices can be safely scanned in a horizontal closed-bore quadrature coil MR system meeting the following conditions:

| MRI FIELD STRENGTH | 1.5 T | 3.0 T |
|---------------------------------|------------|-------|
| Maximum Spatial Field Gradient | 4.1 T/m* | none |
| RMS Gradient Field | 30 T/s | none |
| Peak Slew Rate | 150 T/m/s | none |
| Maximum whole body averaged SAR | ≤ 1.7 W/kg | none |
| Maximum head averaged SAR | ≤ 1.0 W/kg | none |

* With temporary non-magnetic plug

When tested under scan conditions defined above with the patient's head in the center of the MR scanner, the HiRes 90K Advantage implant produced a maximum temperature rise of <2.4°C after 15 minutes of continuous scanning when using a body coil and whole body averaged SAR of 2 W/kg. **NOTE:** During the scan, patients might perceive auditory sensations. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of the auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.

Step 3: Post-Scan Patient Management

Confirm magnet replacement surgery schedule with the cochlear implant surgeon and patient.

Head Bandaging Protocol

Required Material

- Hurt-Free Wrap – Hospital Grade, Latex Free, 5 cm width, Johnson & Johnson (or equivalent)
- Flexible tape, Latex Free, 2 – 2.5 cm width, 3M – Nexcare (or equivalent)
- Patient Headpiece
- MRI Antenna Coil Cover (CI-7521) Advanced Bionics
- Marking Pen

The MRI Antenna Coil Cover is intended to be used along with a bandaging protocol to allow the patient to undergo an MRI procedure with the magnet left in place. Instructions for use must be followed, including the recommended bandaging protocol.

Compression Dressing prior to MRI Procedure with HiRes 90K Users

This document will provide general guidance for applying appropriate compression dressing over the site of the implanted device (and magnet) in order to perform an MRI procedure.

1. Place patient in sitting position to allow access to the implant site. **NOTE:** If the patient is bilaterally implanted, prepare to locate both implant devices using the following steps. Both implant locations must have compression dressing placed over their magnets.

Secure MRI Antenna Coil Cover over implant magnet site

2. Place the patient headpiece, with cable removed, over the implant site (Fig. A). The magnets will hold the headpiece in place.
3. Cut a piece of the Coach bandage that is long enough to wrap around the head once.
4. Wrap tight this piece around the head, so that the bandage covers the patient headpiece. (Fig. B)
5. Outline the position of the headpiece on the bandage using a marker or pen. (Fig. C)
6. Slip out the patient headpiece, but keep the bandage in place. (Fig. D)
7. Slide the MRI Antenna Coil Cover under the bandage (Fig. E), lining it up with the outline of the headpiece. (Fig. F)



A. Patient headpiece magnetically attached



B. Patient headpiece under bandage



C. Marked bandage showing outline of headpiece



D. Removing headpiece with bandage in place



E. Inserting MRI Antenna Coil Cover



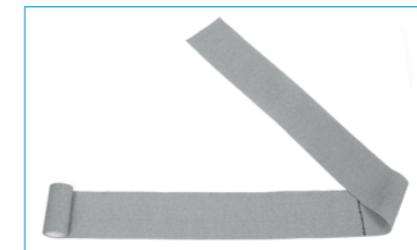
F. MRI Antenna Coil Cover under marked outline

Measure head size and bandage length needed for compression wrapping

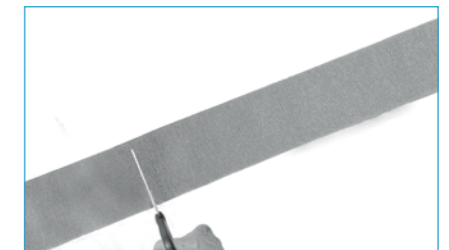
8. Take the remaining Coach bandage roll and wrap the bandage around the head once, without stretching.
9. Mark the location on the bandage that is one full wrap around the head. This is the head circumference. (Fig. G)
10. Unwrap the piece of bandage with the marked head circumference, and place it on a flat surface.
11. Unroll the remaining bandage roll.
12. Fold over the bandage start and crease at the marked head circumference. (Fig. H)
13. Cut or tear the remaining bandage where it overlaps with the bandage start. (Fig. I) The resulting bandage piece length is twice the head circumference.



G. Remaining Coach bandage roll wrapped once around head



H. Marked head circumference, Fold and crease bandage



I. Remaining bandage cut where it overlaps with the bandage start

Apply compression bandaging

14. Wrap this cut piece, this time very tightly, by stretching the marked line an additional half turn around the head. (Fig. J) This ensures 150% extension of the bandage. **NOTE:** After 1.5 turns, the marked line should be on the opposite side of the head from where you started the wrap.
15. Continue wrapping the bandage at 150% extension for an additional 1.5 turns, resulting in 3 full turns total. (Fig. K) **NOTE:** After 3 turns, the bandage should end where you started the wrap (further is acceptable also).



J. Tight wrapping, stretching the marked line an additional half turn



K. At least 3 full turns to be completed

After the MRI

Once the MRI procedure has been completed, gently remove the coach wrap, tape, and the MRI antenna coil cover. Discard all components including the MRI antenna coil cover.

Please go back to step 2.

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AdvancedBionics.com/contact

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Please contact your local AB representative for regulatory approval and availability in your region.

1. Failure to do so can lead to device movement, device damage, multi-magnet assembly movement, patient discomfort, or trauma and pain to the patient.
2. If cochlear implant models on either side are different, the MRI safety criteria that is most restrictive of the two implant models must be applied at the discretion of a qualified MRI professional. MRI procedures are contraindicated for CLARION (C1 and CII) cochlear implant recipients. For more information please contact Advanced Bionics Technical Support at technicalservices@advancedbionics.com or visit www.advancedbionics.com/mri.
3. Reduced-image artifact scans may require that the implanted multi-magnet assembly be removed prior to scanning.
4. Instructions for removal and replacement are provided with CI-1419 and CI-1420.