EN-CA English

Cochlear®

Cochlear™ Osia®

Magnetic Resonance Imaging (MRI) Guidelines

FOR PROFESSIONALS

About this guide

This guide applies to the Cochlear™ Osia® implants. It is intended for:

- Specialised health care professionals who prepare and perform MRI scans
- Physicians who refer a Cochlear Osia implant recipient for an MRI scan
- Cochlear Osia implant recipients and/or their carers.

This guide provides information about the safe application of an MRI scan on Cochlear Osia implant recipients.
MRI scans performed under different conditions than those presented in this guide may result in severe patient injury or device malfunction.
Due to the risks associated with using MRI with an implanted medical device, it is important to read, understand, and comply with these instructions to prevent potential harm to the patient and/or device malfunction.
This guide should be read in conjunction with the relevant documents that accompany a Cochlear Osia implant, such as the ***Physician's Guide*** and ***Important information for Osia implant recipients***.
For more information, visit www.cochlear.com/mri or contact your regional Cochlear office. Contact numbers are available on the back cover of these guidelines.

Symbols used in this guide

	Note Important information or advice.
	Caution (no harm) Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.
	Warning (harmful) Potential safety hazards and serious adverse reactions. Could cause harm to person.

Contents

MRI safety information

In order to determine if a patient may receive an MRI scan, you must first identify the patient's implant model.
After you have identified the implant model, locate the MRI safety information for that specific implant model.

All external components of the Cochlear Osia System (e.g. sound processors, and related accessories) are MR unsafe. The patient must remove all external components of their Cochlear Osia System before entering a room where an MRI scanner is located.

Identifying the Cochlear Osia implants

The implant model can be found on the patient's Cochlear patient identification card.
If the patient does not have their patient identification card with them, the implant type and model can be identified without surgical intervention. See ***"X-ray information for identification of Cochlear Osia implants"*** and ***"X-ray guidelines"*** on the following pages.

X-ray information for identification of Cochlear Osia implants

Cochlear Osia implants are made of metal and are implanted under the skin behind the ear. Using an X-ray, the implant can be identified by its shape and the shape of the actuator unit. Use the ***Fig. 1–Fig. 4*** to assist with identifying Cochlear Osia implants when using an X-ray.

X-ray guidelines

Lateral X-ray at 70 kV/ 3 mAs provides sufficient contrast to identify the implant.
A modified Stenver's view is not recommended for implant identification as implants may appear oblique.
Imaging should include an unobstructed view of antenna coils and implant bodies.
Bilateral recipients may have different implant models on either side of the head.
A lateral skull X-ray with a 15 degree cranial tube angle will offset the implants in the image, enabling identifying features to be distinguished.

OSI300 Implants can be distinguished from OSI200 Implants by the three holes adjacent to the magnet. See ***Fig.2*** and ***Fig.4***.

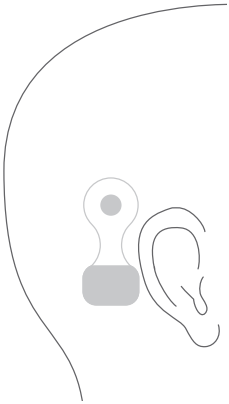


Fig.1: Approximate location of the OSI200 Implant

Fig.2: OSI200 Implant

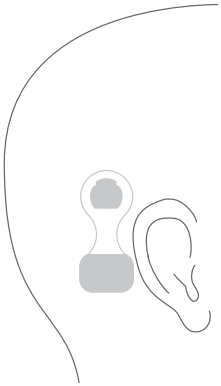


Fig.3: Approximate location of the OSI300 Implant

Fig.4: OSI300 Implant

Performing MRI safely

Non-clinical testing has demonstrated that the Cochlear Osia implants, in combination with the BI300 Implant, are MR Conditional. A patient with a Cochlear Osia implant can be safely scanned under the conditions described in this section. Failure to follow these conditions may result in injury to the patient.

Implant magnet and magnet cassette conditions for MRI

For some implant models and MRI field strengths, bandaging with an MRI kit is required, or the implant magnet or magnet cassette needs to be surgically removed. Refer to the table below for information on each Osia implant model.

Implant type	MRI field strength (T)	Required to remove magnet or magnet cassette Yes/No	MRI Kit required Yes/No
Osia OSI200 Implant	1.5	No	Yes
	3	Yes	No
Osia OSI300 Implant	1.5	No	No
	3	No	No

Table 1: Implant magnet and magnet cassette conditions for MRI.

Scan conditions and SAR limits

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners closed bore or wide bore with a circularly polarised (CP) RF field for a maximum active scan time of 60 minutes.

⚠ Warning

MRI scans at 3 T must be performed in quadrature mode or circular polarization mode for the radio frequency (RF) transmit coil. Using a multichannel mode may result in localised heating above safe levels.

A patient with one or two of these implants can be safely scanned in an MR system meeting conditions on the following pages. All scans shall be performed according to the specified SAR limits for the relevant implant.

Consider the following prior to scanning:

- Transmit/receive head coils and whole body coils may be safely used within the recommended SAR limits. Refer to the MRI safety information and recommended SAR limit tables in the following pages.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- It is safe to use local cylindrical RF receive only coils with implants during MRI scanning, provided SAR limits for the transmit coil have not been exceeded.

OSI200 Implant and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR unsafe.
- Use the MRI Kit for MRI scans at 1.5 T with the implant magnet in place. For instructions, see ***"Cochlear Nucleus® Implant Bandage and Splint Kit for MRI (MRI Kit)"*** on ***page 20***.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of 3.2 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg.

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

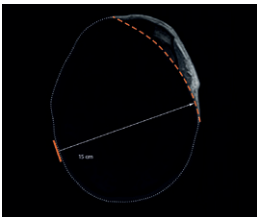
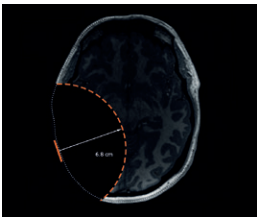
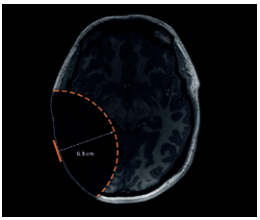
Magnet	Non-Magnetic Plug	No Magnet
		
15 cm (5.9 in)	6.8 cm (2.7 in)	6.3 cm (2.5 in)

Table 2: Maximum image artefact from centre at 1.5 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

Note

The image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

For bilateral OSI200 Implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

OSI200 Implant and 3 T scans

- Surgically remove the implant magnet before MRI scans at 3 T. See OSI200 Implant Physician's Guide for additional information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of 3.2 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg.

Scans must be performed in circular polarization mode.

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

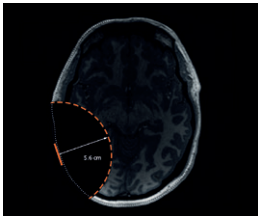
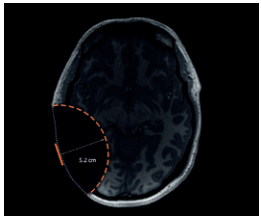
Non-Magnetic Plug	No Magnet
	
5.6 cm (2.2 in)	5.2 cm (2.0 in)

Table 3: Maximum image artefact from centre at 3 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

OSI300 Implant and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of 3.2 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg.

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

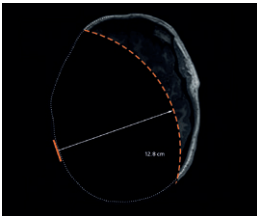
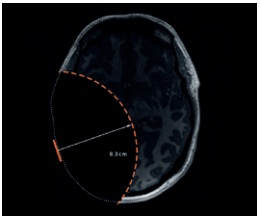
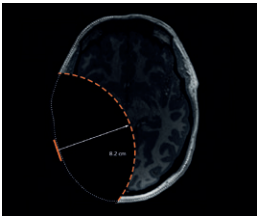
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
12.8 cm (5.0 in)	8.3 cm (3.3 in)	8.2 cm (3.2 in)

Table 4: Maximum image artefact from centre at 1.5 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

Note

The image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

For bilateral OSI300 Implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

OSI300 Implant and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of 3.2 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg.
- Scans must be performed in circular polarization mode.

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

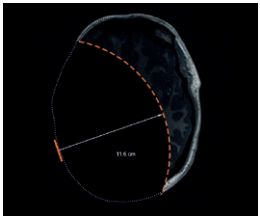
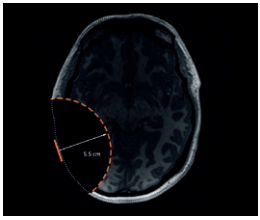
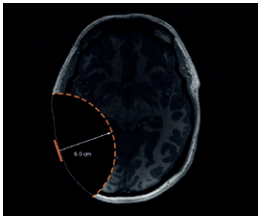
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
11.6 cm (4.6 in)	5.5 cm (2.2 in)	6.0 cm (2.4 in)

Table 5: Maximum image artefact from centre at 3 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

Image interference and artefacts

The Cochlear Osia implants will create shadowing on the MR image near the implant, resulting in a loss of diagnostic information.
If inspecting near the implant, consider removing the implant magnet or magnet cassette as MR image quality may be compromised with it in place.
If the implant magnet or magnet cassette needs to be removed, refer the patient to an appropriate physician to arrange for the magnet or magnet cassette to be removed before the MRI scan.
The further optimisation of scan parameters can be used to minimize the extent of the artefact.
The image artefact extends from the centre of the implant. The Metal Artefact Reduction Sequence (MARS) parameters detailed in the tables below were used to produce the artefact sizes detailed in the following pages.

Parameter	MARS
Scanning sequence	Spin echo
Slice selection	Axial
Slice thickness	5 mm
Repetition time	2375 ms
Echo time	17 ms
Bandwidth	81,664 Hz
Flip angle	90°

Table 6: Scan parameters for scanning in a 1.5 T scanner

Note

The following image artefact results are based on maximum artefact extension from the centre of the implant when scanned at 1.5 T using a Metal Artefact Reduction Sequence (MARS).

For bilateral implant recipients, the image artefacts as shown below are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

OSI300 Implant and 1.5 T scans with MARS sequence

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a MARS sequence scan in the axial plane is:

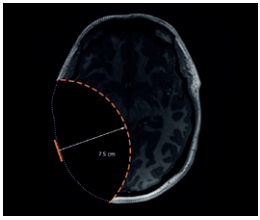
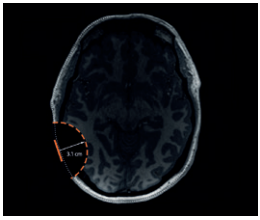
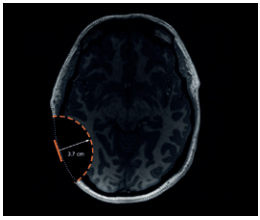
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
7.5 cm (3.0 in)	3.1 cm (1.2 in)	3.7 cm (1.5 in)

Table 7: Maximum image artefact from centre at 1.5 T (MARS sequence).

Parameter	MARS
Scanning sequence	Spin echo
Slice selection	Axial
Slice thickness	5 mm
Repetition time	4000 ms
Echo time	50 ms
Bandwidth	199,936 Hz
Flip angle	90°

Table 8: Scan parameters for scanning in a 3 T scanner

Note

The following image artefact results are based on maximum artefact extension from the centre of the implant when scanned at 3 T using a Metal Artefact Reduction Sequence (MARS).

For bilateral implant recipients, the image artefacts as shown below are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

OSI300 Implant and 3 T scans with MARS sequence

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a MARS sequence scan in the axial plane is:

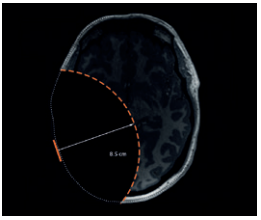
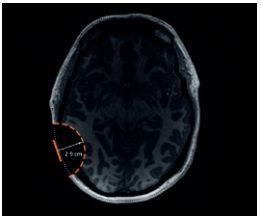
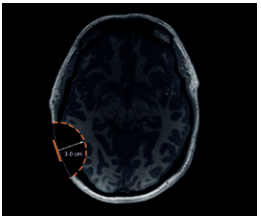
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
8.5 cm (3.3 in)	2.9 cm (1.1 in)	3.0 cm (1.2 in)

Table 9: Maximum image artefact from centre at 3 T (MARS sequence).

Preparation prior to an MRI examination

Cooperation between specialists

Preparing for and conducting an MRI examination for implant recipients requires cooperation between a specialist for the device and/or Osia implant physician, referring physician and radiologist or MR technologist.

Cochlear Osia implant device specialist

Knows the implant type and where to find the correct MR parameters for the implant.

Referring physician

Knows the location of the MR scan and diagnostic information required, and makes a decision on whether the implant magnet or magnet cassette needs to be removed for the MRI examination. Confers with the Osia implant physician regarding the considerations listed in ***"Considerations for referring physicians"*** on ***page 25***.

Cochlear Osia implant physician

If requested by the referring physician, surgically removes the implant magnet or magnet cassette and replaces with a non-magnetic plug or a non-magnetic cassette. After the MRI scan, the implant physician replaces it with a new sterile replacement magnet or magnet cassette.

Radiologist or MR technologist

Sets up the MRI scan using the correct MR parameters and counsels the implant recipient during the MRI examination. Refer to the process detailed in ***"Considerations for conducting an MRI examination"*** on ***page 18*** and ***"Considerations after an MRI examination"*** on ***page 24***.

Considerations for implant magnet removal

If the implant magnet needs to be removed prior to an MRI examination, close coordination is required between the specialists to perform the implant magnet removal, MRI scan, and subsequent implant magnet replacement.

For details on implant magnet removal, please refer to the ***OSI200 Implant Physician's Guide*** or the ***OSI300 Implant Physician's Guide*** supplied with the system.

See ***"Implant magnet and magnet cassette conditions for MRI"*** on ***page 6***.

OSI300 Implant

For OSI300 Implant recipients, if single or multiple MRI examinations on the head are needed with the magnet cassette removed, the magnet cassette must be replaced (in a sterile surgical environment) with a non-magnetic cassette.

⚠ Warning

To prevent infection, do not leave the magnet pocket empty (for OSI300 Implants). When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.

OSI200 Implant

For recipients (other than OSI300 Implant recipients), if single or multiple MRI examinations on the head are needed with the magnet removed, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the non-magnetic plug prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.

Warning

To prevent infection, do not leave the magnet pocket empty. When removing the magnet, replace the magnet with a non-magnetic plug.

Caution

Non-magnetic cassettes for OSI300 Implants are different to non-magnetic plugs for OSI200 Implants. Ensure the correct non-magnetic cassette or non-magnetic plug is used.

With the non-magnetic cassette or non-magnetic plug in place, MRI scans can be done both at 1.5 T and 3 T without the need for bandaging or use of an MRI Kit.

Note

While the magnet or magnet cassette is removed, the recipient may wear a Cochlear Disk Retainer to hold their sound processor in place. Disk retainers are available from Cochlear.

When there is no further need for MRI examinations, the non-magnetic cassette or non-magnetic plug is removed and replaced by a new sterile replacement magnet or magnet cassette.

The non-magnetic cassette, non-magnetic plug, magnet cassette and sterile replacement magnet are supplied separately in sterile packs. All are single-use items.

Considerations for conducting an MRI examination

These guidelines are specific to Cochlear Osia implants and supplement other MRI examination considerations specified by the MRI machine manufacturer or protocols at the MRI facility.

Prerequisites

The following additional conditions must be met:

- The implant model has been identified. See ***"Identifying the Cochlear Osia implants"*** on ***page 4***.
- If the referring physician has prescribed that the MRI scan be performed without the implant magnet or magnet cassette, confirm that the implant magnet or magnet cassette has been surgically removed.
- If the implant magnet is retained for an MRI scan at 1.5 T, an MRI Kit must be obtained beforehand for use during the MRI scan, except for OSI300 Implants. Contact the nearest Cochlear office or official distributor to order an MRI Kit.

Patient positioning

For safety and comfort, the patient should be in a supine position (lying flat on back, face upward) prior to entering the MRI bore. Align the patient's head with the bore axis of the MRI machine. Advise the patient to lie as still as possible and to not move their head during the MRI scan.

Best practise for minimising risk of discomfort:

- Where possible, the patient should enter the scanner feet-first.
- If a detachable MRI table is available, position the patient on the table outside the MRI room. Make sure the patient is comfortable and immobilized in their scanning position before wheeling into the room.
- If scanning head-first, avoid any head movement (pitching or rolling) near the bore entry and within the bore.
    - Place head pillows or supports as far away from the bore entry as practical.
    - Position the patient and immobilize before moving the table into the bore.

⚠ **Caution**

- When scanning with the implant magnet or magnet cassette in place, ensure that the patient does not move more than 15 degrees (15°) from the centerline (Z-axis) of the bore during the MRI scan.
- Failure to position the patient correctly prior to the MRI scan may result in increased torque on the implant and cause pain, or may cause demagnetisation of the implant magnet.

Patient comfort

For patients where an implant magnet or magnet cassette is in place, explain that they might feel the implant magnet moving slightly and might sense resistance to movement as pressure on the skin.

For devices which require an MRI Kit, the MRI Kit will reduce the likelihood of the implant magnet moving. The sensation will be similar to pressing down firmly on the skin with the thumb.
If the patient experiences pain, consult the patient's physician to determine if the implant magnet or magnet cassette should be removed or if a local anaesthetic may be applied to reduce discomfort.

⚠ **Caution**

If administering local anaesthetic, take care not to perforate the implant silicone.

In addition, explain to the patient that they may perceive sounds during the MRI scan.

Perform the MRI scan

The MRI scan must be performed using the MRI safety information identified for the patient's implant model.

Performing an MRI Scan on other body locations

When an implant recipient requires an MRI on a location of their body away from the implant site, you must still follow the MRI safety information for the recipient's implant model. See ***"Identifying the Cochlear Osia implants"*** and related ***"MRI safety information"*** on ***page 4***.

Cochlear Nucleus® Implant Bandage and Splint Kit for MRI (MRI Kit)

Intended use

The MRI Kit is intended to be used on Cochlear Osia implant recipients to prevent implant magnet dislodgement during MRI scans at 1.5 T.
The MRI Kit is intended for use with Cochlear Osia implants and the following Cochlear Nucleus implants:

- CI500 Series – CI512, CI522, CI532 and ABI541
- CI24RE Series – CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST)

Contraindications

There are no contraindications for the MRI Kit.

Obtaining an MRI Kit

Contact the nearest Cochlear office or official distributor to order an MRI Kit.
The MRI Kit contains:

Item	Description
Flat-plastic splints	To be placed against the skin over the implant magnet site.
Elasticised compression bandage	For securing the splint against the implant magnet site.
Surgical tape	For securing the bandage and splint in place.

Fig.5: Content of MRI Kit

Using the MRI Kit

Follow this procedure to use the MRI Kit. When used as instructed, the supplied splint and bandage should reduce the likelihood of magnet movement when in or near the MRI scanner.

1. Preparation

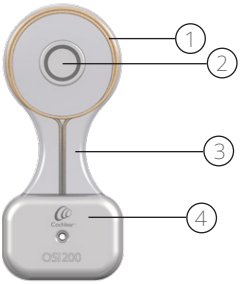
1. Prior to entering the MRI room and before removing the sound processor, mark on the patient's head an outline of the sound processor. Once the sound processor has been removed from the head, mark on the patient's head the centre position of the sound processor magnet. If necessary, shave the patient's head at the sound processor magnet location so this marking is more visible and easier to locate during the splinting process. This marking is essential to ensure that the splint is placed in the correct location.
2. In the event that the location of the implant has not been marked, it can be located by:
   - Using ferromagnetic material, such as a paper clip – the material will be attracted to the implant magnet.

Warning

The ferromagnetic material must be removed before entering the MRI room.

- Touch – gently feel around the implant site to locate the position of the implant coil. The implant is comprised of the round implant coil, the waist and the actuator ***"Fig.6: OSI200 Implant (P1170466)"***.

The implant magnet will be at the centre of the implant coil. For further explanation of the prevailing implant see "***X-ray information for Cochlear Osia implants"*** section.



1 Coil
2 Removable magnet
3 Waist
4 Actuator

Skin side

Fig.6: OSI200 Implant (P1170466)

Note

The intent of the splint is to provide pressure over the implant magnet – not the actuator.

2. Bandaging

1. Use a splint from the MRI Kit and centre it over the implant magnet site (as marked) against the skin. Ensure the splint is held in place over the implant magnet. You may need the assistance of another person to hold the splint in place while you bandage. Otherwise, use the supplied tape to maintain the splint position prior to bandaging.
2. Use the elasticised compression bandage from the MRI Kit and ensure the centre line of the bandage is over the implant magnet site and the splint is fully covered. See Figure 5.

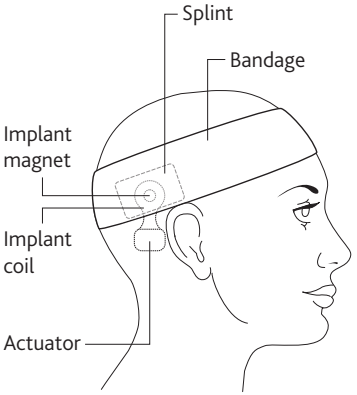
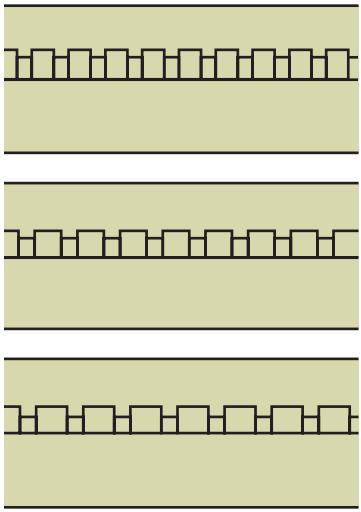


Fig.7: Fitting the MRI Kit splint and compression bandage. Position the splint over the implant magnet site and then apply the bandage over the centre of the splint and the centre of the implant magnet site.

3. Use a minimum of two bandage layers at full stretch (no elasticity remaining in the bandage). When the bandage is at its maximum tightness, the small rectangular tension markers will stretch to become square in shape. See ***"Fig.8: Comparison of compression bandage tightness" on page 23***.
4. Use the surgical tape from the MRI Kit to secure the bandage by wrapping two surgical tape layers around the head, over the bandage center line. Ensure the tape ends overlap.
5. Conduct the MRI scan.

6. Once the MRI scan is complete, follow the instructions in ***"Considerations after an MRI examination"*** on ***page 24***.



Pattern on compression bandage before stretching

Pattern on compression bandage with inadequate stretch

Pattern on compression bandage with the correct (full) stretch

Fig.8: Comparison of compression bandage tightness

Considerations after an MRI examination

With the implant magnet in place

After the patient leaves the MRI room, remove the MRI Kit contents from the patient's head, as required. Ask the patient to place the sound processor on their head and turn it on.

Confirm:

- Placement of the sound processor is correct
- There is no discomfort
- Sound is perceived as normal

If there is discomfort or a change in sound perception, or problems with the placement of the sound processor, ask the patient to seek assistance from their implant clinician as soon as possible.

With the implant magnet removed

See ***"Considerations for implant magnet removal"*** on ***page 16***.

Considerations for referring physicians

If you are a physician referring a Cochlear Osia implant recipient for an MRI scan, it is essential that you consider the following:

- Understand and inform the patient of the risks associated with MRI.
  See ***"Risks associated with MRI and Cochlear Osia implants"*** on ***page 27***.
- Understand the conditions for an MRI scan and ensure that there is a clear indication for the MRI examination.
- Identify if the patient has any other medical device implants, active or abandoned. If another implant is present, verify MRI compatibility before conducting an MRI examination. If MRI safety information for the implanted devices are not followed potential risks include:

  - movement or damage to the device
  - weakening of the implant magnet or magnet cassette
  - uncomfortable sensation for the patient
  - skin or tissue trauma for the patient

- The Cochlear Osia implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant artefact dimension tables in the ***"Image interference and artefacts"*** section.

Consider the following:

- If the required diagnostic information is in the area of the implant, the implant magnet or magnet cassette may need to be removed.
- Timing of the implant surgery and MRI exposure.
- Age and general health of the implant recipient and time to recover from the implant magnet or magnet cassette surgery or potential trauma.
- Existing or potential for tissue scarring in the location of the implant magnet or magnet cassette.
- If the implant magnet or magnet cassette needs to be removed, refer the patient to an appropriate physician to arrange for the magnet or magnet cassette to be removed before the MRI scan.
- If the implant magnet is retained for an MRI scan at 1.5 T, a Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) must be obtained beforehand for use during the MRI scan, except for the OSI300 Implant. Contact the nearest Cochlear office or official distributor to order an MRI Kit.
  See ***"Cochlear Nucleus® Implant Bandage and Splint Kit for MRI (MRI Kit)"*** on ***page 20***.
- Head bandaging is not required for OSI300 Implants, even with a magnet cassette in place, at 1.5 T or 3 T.
  Unnecessary use of a head bandage or splint with OSI300 Implants will apply undue pressure and may increase patient discomfort.

Risks associated with MRI and Cochlear Osia implants

The potential risks of performing MRI examinations on patients with Cochlear Osia implants include:

Device movement

Scanning outside of the parameters contained in these guidelines may lead to the implant magnet or device moving out of position during an MRI examination causing skin or tissue trauma.

Damage to the device

MRI exposure beyond the values contained in these guidelines may cause damage to the device.

Weakening of implant magnet

Scanning at static magnetic field strengths at values other than those contained in these guidelines may lead to a weakening of the implant magnet.
Incorrect patient positioning prior to the MRI scan or head movement during the scan may result in implant demagnetisation.

Uncomfortable sensation

MRI exposure beyond the values contained in these guidelines may result in the patient perceiving sound or noise and/or pain.

Implant heating

Use the recommended SAR values contained in these guidelines to ensure the implant does not heat beyond safe levels.

Image artefact

The Cochlear Osia implants will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information.
If inspecting near the implant, removal of the implant magnet should be considered as MR image quality may be compromised with it in place.

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