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

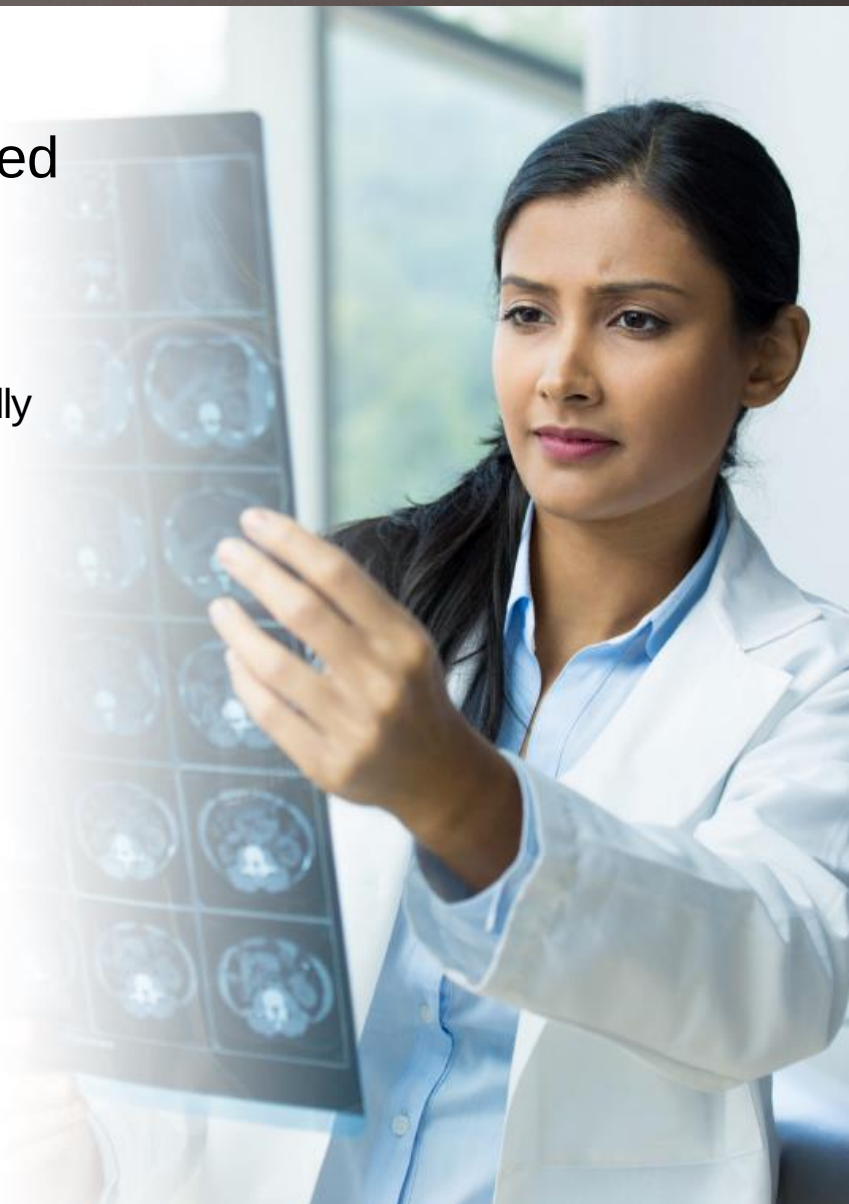
Instructions

Hear now. And always

Cochlear®

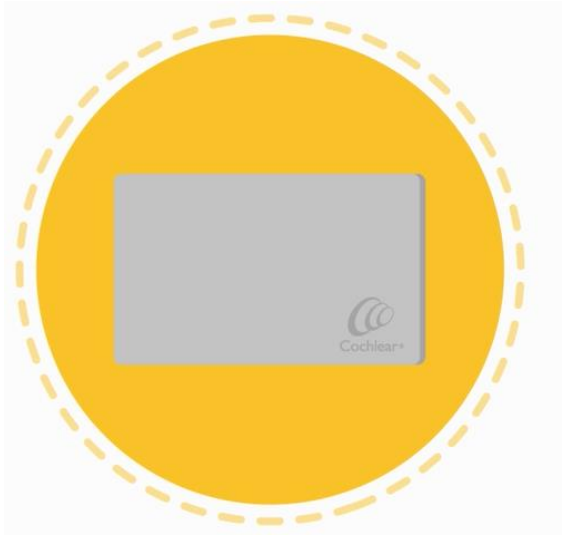
MRI Indications

- Cochlear's Profile™ and CI24RE series cochlear implants are approved for:
  - MRI scans at 3.0T with magnet removed, or
  - MRI scans at 1.5T without having to surgically remove the implant magnet with use of MRI Bandage and Splint Kit for MRI
- The following implants have the above indications:
  - Profile Series: CI512, CI522, CI532
  - CI24RE Series: CI24RE(CA), CI422, CI24(RE)ST, L24 Hybrid



MRI Bandage and Splint Kit (MRI Kit)

- To help prevent discomfort or dislodgement of the implant magnet during an MRI scan, we have made available the MRI Bandage and Splint Kit.
- Use of the MRI Kit is mandatory in the USA for MRI at 1.5 Tesla with the magnet in place.
- A video of these instructions is also available here. The Guidelines document can also be downloaded from the same webpage.
- ***Please refer to the Guidelines document for complete wrapping and MRI instructions***
- Guidelines booklet is also shipped with each MRI Kit.
- The MRI Kit (P773147) contains:

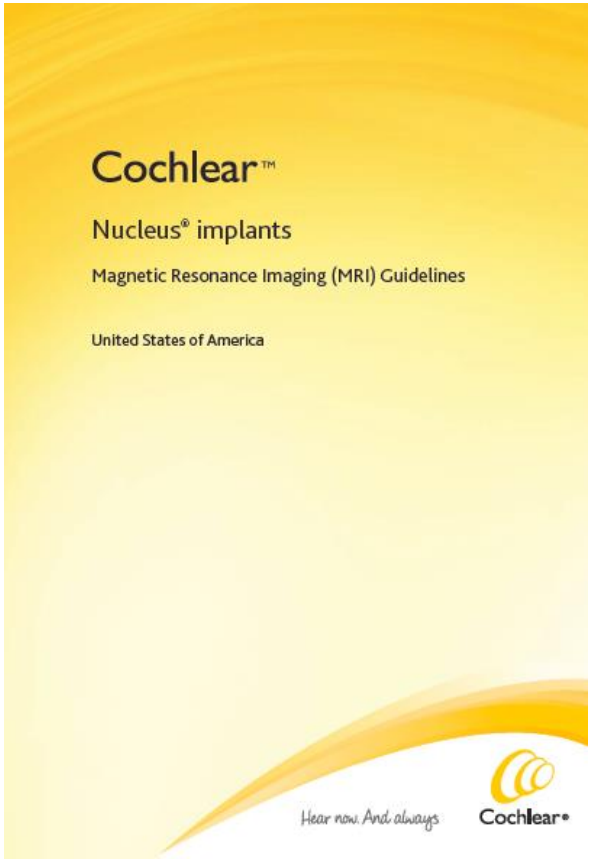


2 x Splints

Compression Bandage

Surgical Tape

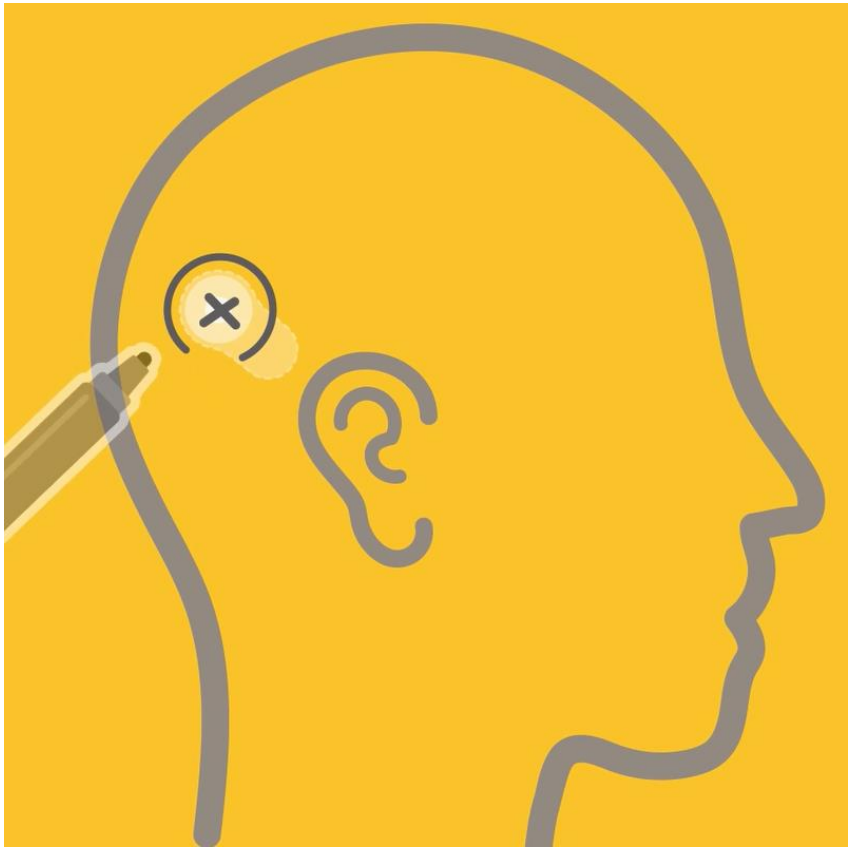
Step 1 – Identify Implant Type on Patient's head



Refer MRI Guidelines document on how to identify type of implant(s) the patient has and appropriate MRI indications for that type of implant(s). NOTE: Not all implants have the same MRI indications.

Step 2 - Locate the Implant Magnet

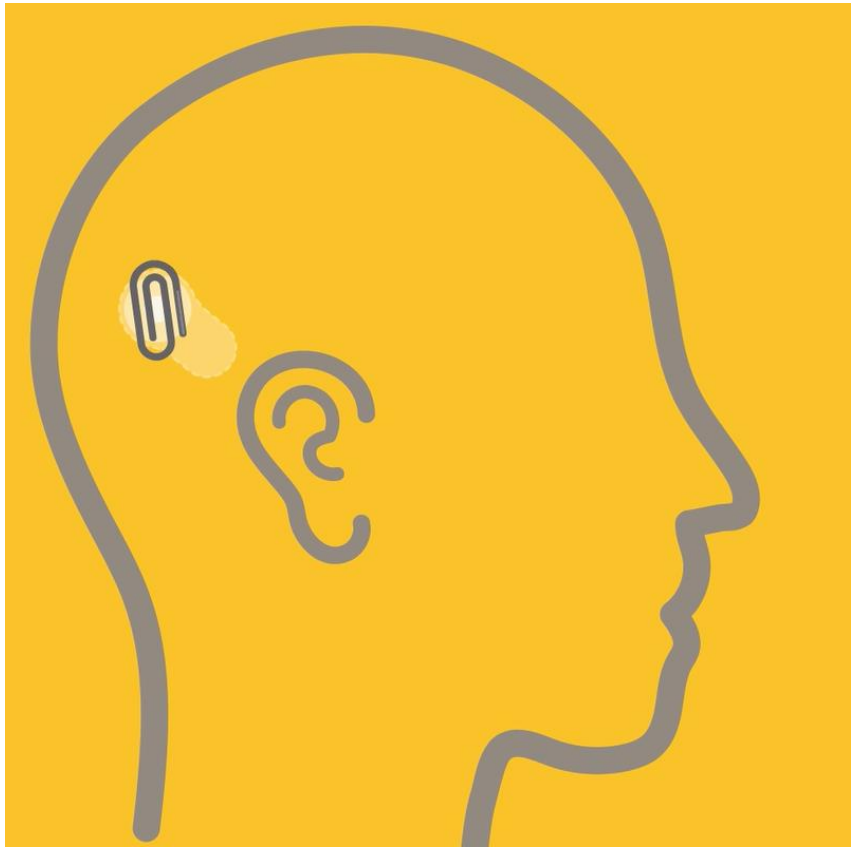
Before entering the MRI room, and before removing the sound processor, mark an outline of the sound processor coil on the head.



Once the coil has been removed, mark the center position of the coil magnet.

NOTE: If necessary, shave the patient's head at the coil 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.

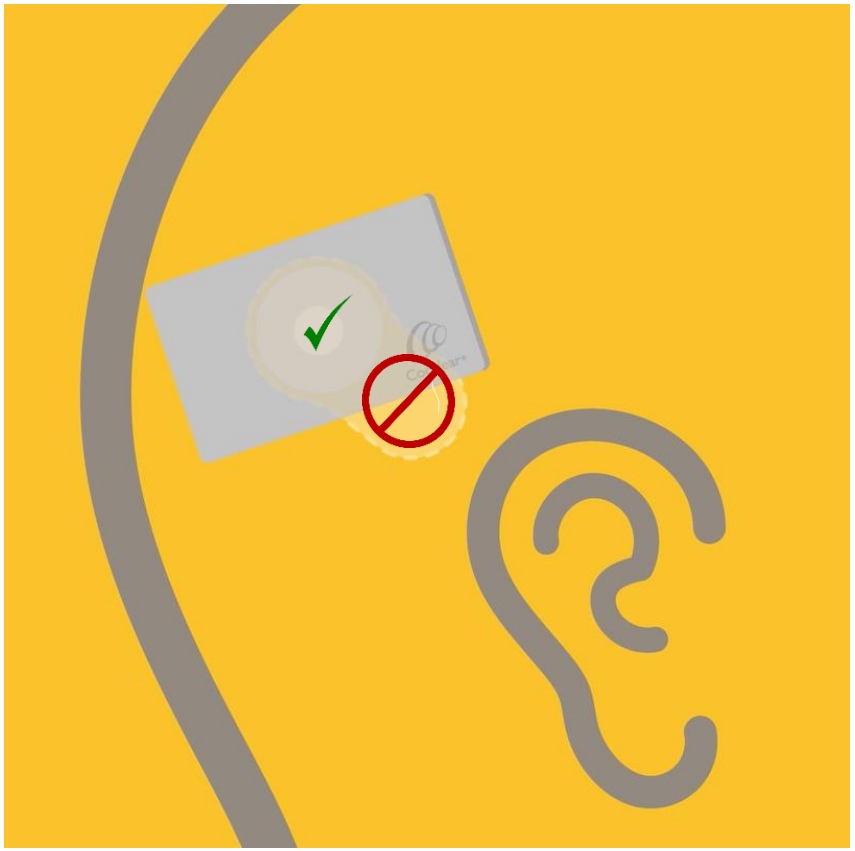
Step 2 - Locate the Implant Magnet



If the location of the implant magnet has not been marked, it may be located by using a ferromagnetic object such as a paperclip, as the object will be attracted to the implant magnet.

Step 3 – Position the Splint on the Head

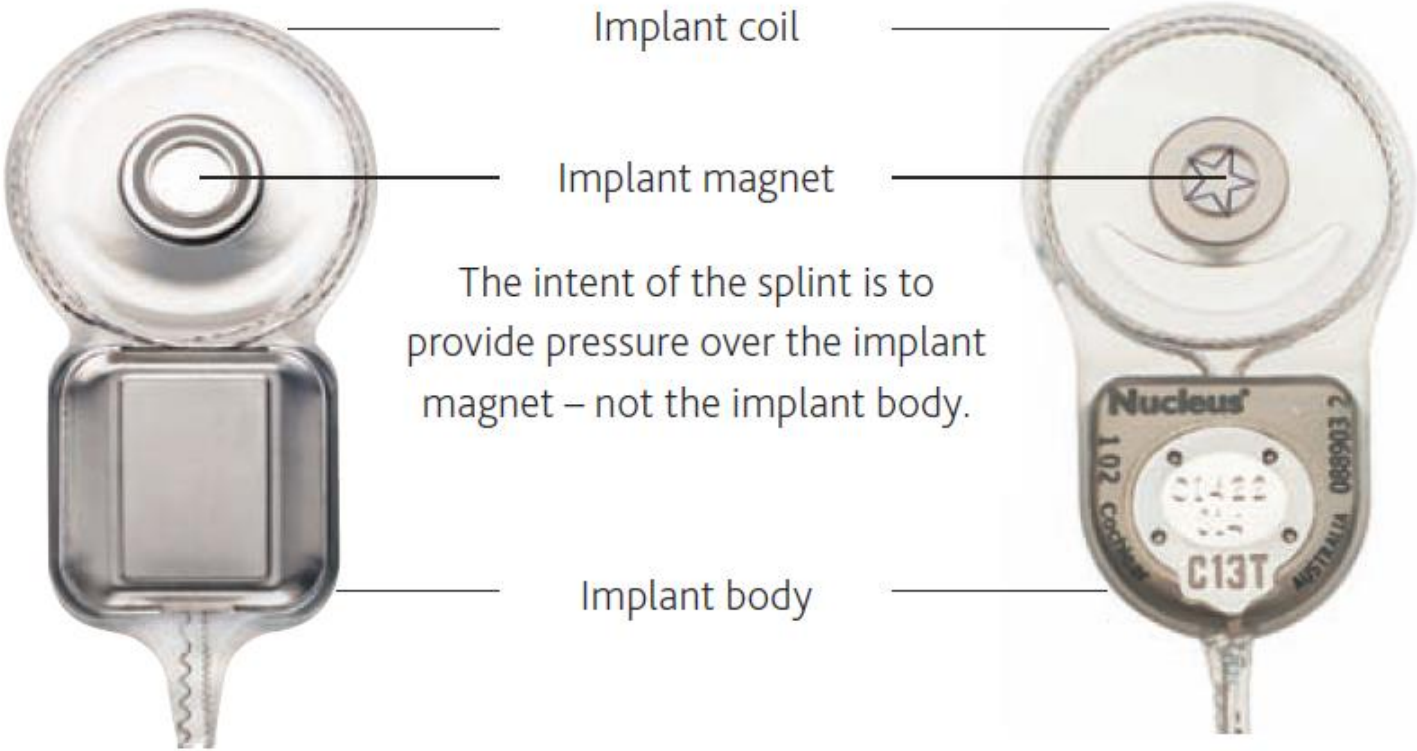
Remember that ferromagnetic material must be removed before entering the MRI room.



Center an MRI Kit splint over the implant magnet site and press against the skin.

The splint should put pressure over the implant magnet, not the implant body.

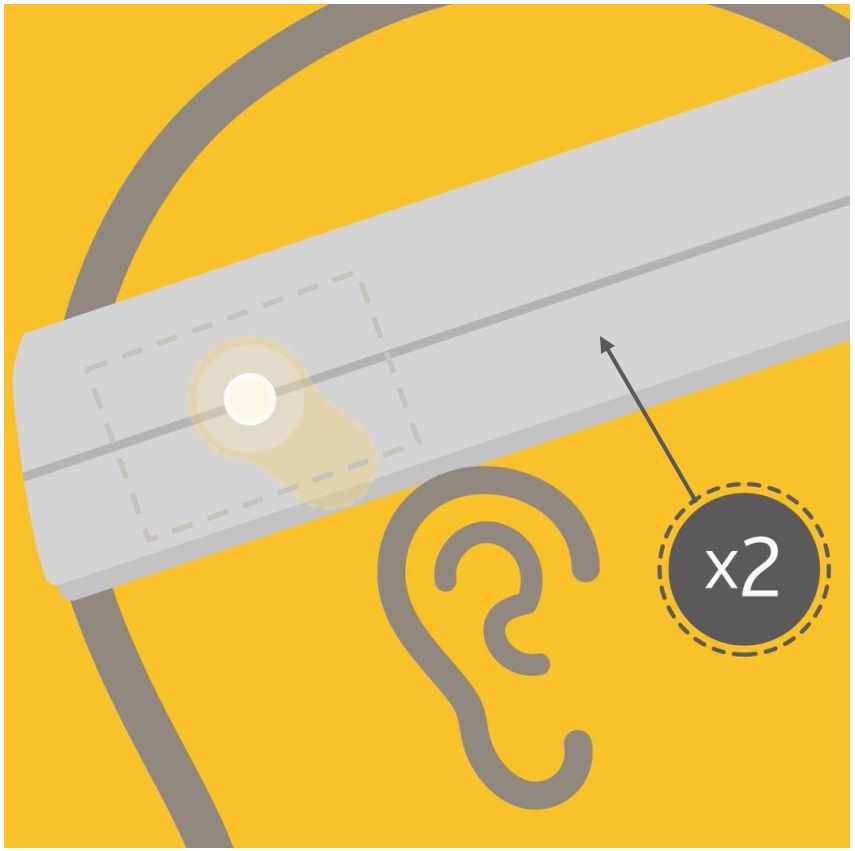
Location of Implant Magnet



Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants

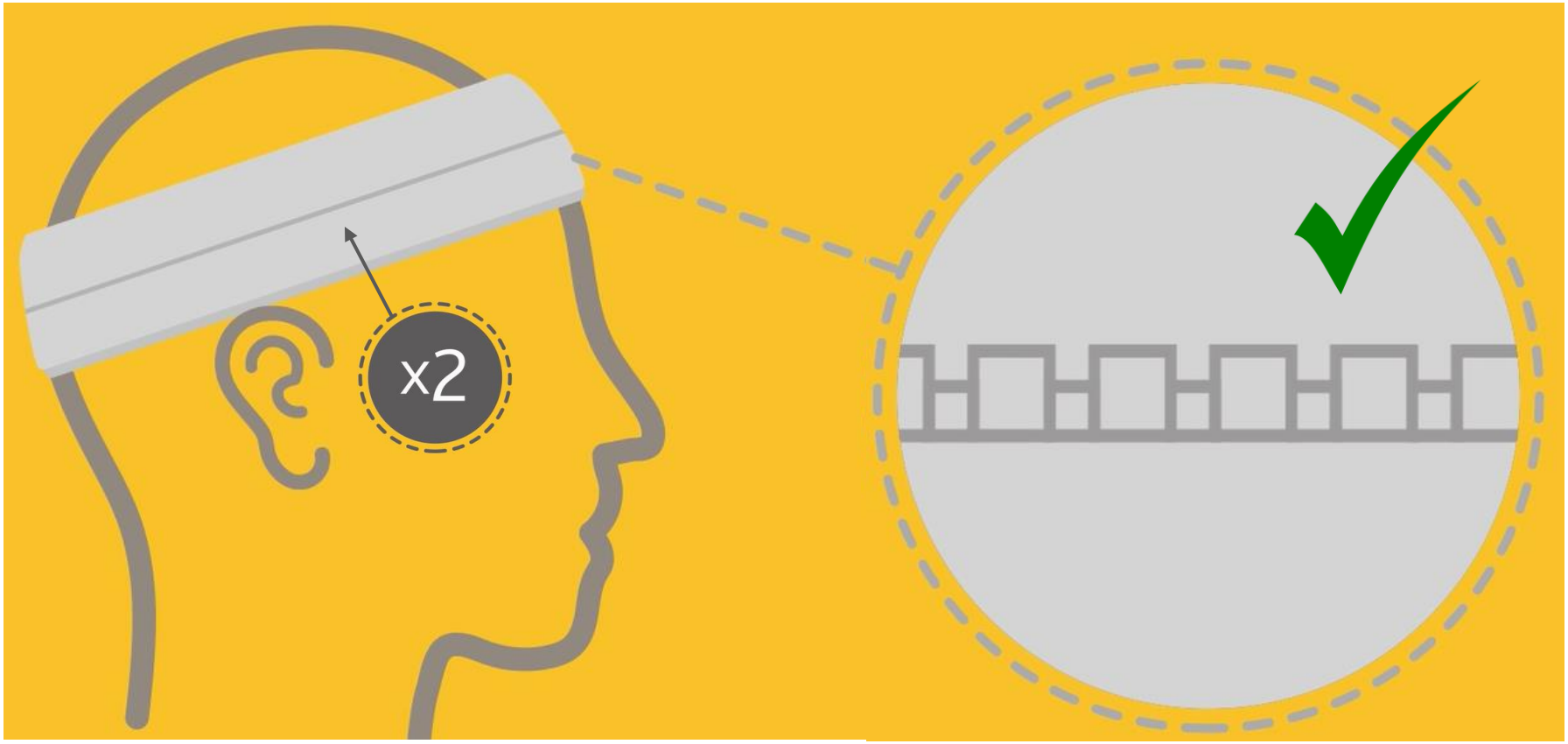
Step 4 – Wrap the Bandage

Ensure that the splint is held in place; it may help to use the supplied surgical tape to keep it in position. You may need the assistance of another person to hold the splint in place while you bandage.



Then, wrap the elasticized compression bandage around the head twice, ensuring the center line of the bandage is fully over the implant magnet. The bandage should completely cover the splint.

Step 4 – Wrap the Bandage



To ensure that the bandage is tight enough, a minimum of two bandage layers are required.

When the bandage is at the required tightness, the small rectangular tension markers will stretch to become square in shape.

Step 5 – Tape the Bandage

Finally, wrap two layers of the surgical tape around the bandage center line to secure it in place, ensuring that the tape ends overlap.

Step 6 – Instructions for Radiologist

For 1.5T with magnet in place with use of MRI Splint Kit:

- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.
- ****Please refer to the Guidelines document for complete set of instructions for specific implant/electrode****

Step 6 – Instructions for Radiologist

For 3T with magnet 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 <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.
- ****Please refer to the Guidelines document for complete set of instructions for specific implant/electrode****

Step 7 – Perform MRI

Once this process is complete you are ready for your MRI.

Customers, hospitals and clinics looking to order the Bandage and Splint Kit should contact Cochlear Clinic Customer Service at: 1-877-883-3101 or camclinicservices@cochlear.com. Hospital and clinics with questions on the Nucleus® Implant Bandage and Splint Kit for MRI or on magnet removal should refer to the Guidelines document or contact Cochlear Surgical Support at: 1-877-279-5411.

Hear now. And always