

Magnetic Resonance Imaging (MRI)

MRI is contraindicated except under the circumstances described below. Do not allow a patient with an implant to be in a room where an MRI scanner is located except under the following special circumstances. The patient must take off the processor before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the implant. With the magnet removed, image shadowing may extend as far as 6 cm (~2.5 in.) from the implant. With the magnet in place, image shadowing may extend as far as 11 cm (~4.3 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

Indications for MRI safety depend on the model of the implant. If uncertain, to verify the model, the physician should use an X-ray to check the radiopaque lettering on the implant. There are platinum characters printed on each implant. The middle character indicates the model. Unlike other Nucleus implants, the CI512, CI513, CI522, CI551 and ABI541 implants do not have radiopaque lettering.

Cochlear™ Nucleus® CI422, CI512, CI513, CI522, Freedom™ and Hybrid™ implants

Non-clinical testing according to the international standard ASTM F2182 has demonstrated that the above implants can be scanned safely in 1.5 tesla and 3.0 tesla static magnetic fields at a maximum head averaged Specific Absorption Rate (SAR) of 2 W/kg for 15 minutes of scanning. In non-clinical testing, the above implants produced a temperature rise of less than 2 °C (3.6 °F) at a maximum local SAR of 2 W/kg under specific test conditions stated above.

Cochlear Nucleus ABI541 implants

Non-clinical testing according to the international standard ASTM F2182 has demonstrated that the ABI541 implant can be scanned safely in 1.5 and 3.0 tesla static magnetic fields at a maximum head averaged SAR of 0.7 W/kg and 0.5 W/kg respectively for 15 minutes of scanning.

Cochlear Nucleus CI551 implants

Non-clinical testing according to the international standard ASTM F2182 has demonstrated that the CI551 implant can be scanned safely in 1.5 tesla and 3.0 tesla static magnetic fields at a maximum head averaged SAR of 1.0 W/kg and 0.6 W/kg respectively for 15 minutes of scanning.

MRI machines provide SAR level monitoring for the head or for whole body levels according to specific landmarks. The table below gives guidance on respective levels permissible with the above implants.

Implant type	MRI field strength	Maximum Head SAR	Average Whole Body SAR		
			Landmark location above shoulder	Landmark location chest	Landmark location below chest
CI422 CI512 CI513 CI522 Freedom Hybrid	1.5 T and 3.0T	2.0 W/kg	0.5 W/kg	1.0 W/kg	2.0 W/kg
ABI541	1.5 T	0.7 W/kg	0.7 W/kg	1.0 W/kg	1.5 W/kg
	3.0 T	0.5 W/kg	0.5 W/kg	0.7 W/kg	1.0 W/kg
CI551	1.5 T	1.0 W/kg	1.0 W/kg	1.5 W/kg	2.0 W/kg
	3.0 T	0.6 W/kg	0.7 W/kg	1.0 W/kg	1.5 W/kg

Table 1: SAR levels during MRI (non-clinical testing)

MRI machine manufacturers may claim that the scanning of patients with implanted devices is generally contra-indicated. This is a general precautionary claim, as MRI machine manufacturers are unable to ensure safety for all types of implantable devices. Cochlear has performed specific testing for the above implants and established the necessary SAR safety limits as outlined. Recently available MRI machines are able to monitor SAR levels. The MRI machine manufacturer should be able to provide advice on how to maintain SAR levels with their machine.

CI512, CI513, CI522, CI551 and ABI541 Implants (no radiopaque characters)	
CI422, Freedom, Hybrid and Nucleus 24 Implants (middle radiopaque character: C, G, H, P, T, 2, 4, 5, 6, 7 or 13)	
More than 1.5 tesla (T), up to and including 3.0 T	Surgically remove the magnet for MRI. Tissue damage may occur if the magnet is in place during MRI.
More than 0.2 T, up to and including 1.5 T	Leave the magnet in place for MRI. Bandaging required.
0.2 T or less	Leave the magnet in place for MRI. No bandaging required.
Nucleus 22 with removable magnet (middle radiopaque character: L or J)	
Up to and including 1.5 T	Surgically remove the magnet for MRI. Tissue damage may occur if the magnet is in place during MRI.
Nucleus 22 without removable magnet	
All levels of tesla	MRI is contraindicated.

Table 2: MRI in Europe and all other countries in the European region

For more information about magnet removal, refer to the Surgeon's Guide or contact Cochlear.

Performing an MRI scan with the magnet in place

The magnet can only be left in place for some implants at certain field strengths. See Table 2 to determine if the magnet can be left in place.

1. Inform the patient that they may feel a slight pulling sensation during the scan. See Patient comfort below.

2. Remove the patient's external equipment (processor and coil) before they enter the MRI room.

The patient cannot hear without the external equipment.

3. If the scan is at 0.2 T or less, bandaging is not required but acceptable to do so. Proceed to step

4. If the scan is at more than 0.2 T, up to and including 1.5 T (the magnet must be removed at over 1.5 T), bandage around the head as follows:

- Use an elasticised compression bandage with a maximum width of 10 cm or 4 in. Generic bandages are suitable. No special bandage is required.
- Ensure the centreline of the bandage is over the implant magnet site.
- Use a minimum of two layers at or near full stretch to apply firm pressure to the implant site. 'Full stretch' = no elasticity remaining in bandage.
- If the patient experiences pain with the bandage in place, check that it is not too tight, and if necessary, consider performing an MRI scan at 0.2 T (no bandaging required). Alternatively, consult the patient's physician to determine if the magnet should be removed or if a local anaesthetic may be applied to reduce discomfort. See Patient comfort below.



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

Conduct the MRI scan. There is no need to position the patient in a particular way because of the implant.

Patient comfort

Explain to the patient that the compression bandage (for MRI above 0.2 T) will prevent the implant magnet from moving. However, the patient may still sense the resistance to movement as pressure on the skin. The sensation will be similar to pressing down firmly on the skin with the thumb and will not damage the implant or hurt the patient.

Source:

Cochlear™. Nucleus® cochlear implants, Hybrid™ implants and Nucleus® auditory brainstem implants
Important Information