

Safety Information for Cochlear Implant Recipients and their Carers

Your cochlear implant device is designed to be safe and effective. It consists of both internal and external components. The implant is the internal surgically implanted part and the sound processor is the externally worn equipment. Cochlear implant recipients for the most part can lead a normal life, however for some things it is important to follow the manufacturer's safety instructions.

Manufacturers are responsible for providing safety information for all their products. Device specific safety information is available from each of the manufacturers. You will be provided with a user guide for your particular device. This contains product information and essential safety information. It will inform you of any precautions or warnings or special instructions that you need to follow. It is crucial that you adhere to this advice to prevent harm to you and to avoid damage to your implant / sound processor.

The following information is for devices manufactured by **Oticon Medical**. Information is also available on the website at:

<https://www.oticonmedical.com/cochlear-implants/new-to-cochlear-implants/living-with-a-cochlear-implant>

<https://www.oticonmedical.com/-/media/medical/main/files/ci/products/neuro-one/ifu/en/neuro-one-instructions-for-use---english---m80189.pdf?la=en&hash=4517A08ECE6DB9BDB99F755F780FA5D1FD25671D>

Oticon Medical can be contacted at:

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The British Cochlear Implant Group (BCIG) has compiled a list of frequently asked questions (FAQs) and has asked **Oticon Medical** to provide device specific responses to these questions. BCIG does not accept liability for personal injury resulting from acts or omissions taken on the basis of the information provided.

Cochlear Implant Safety – Frequently Asked Questions

General Questions

Question	Answer
What should I do if I develop an ear infection?	Contact your Implant Centre and follow their advice.
What should I do if I experience pain, swelling, redness or soreness in the region of my implant?	Contact your Implant Centre and follow their advice.
What should I do if I bump my head in the region of the cochlear implant?	Contact your Implant Centre and follow their advice.
Can you provide cremation advice?	The internal device does not need to be removed prior to cremation because it does not contain batteries.

Medical and Dental Diagnostic X-rays and Scans

Before having any type of X-ray or scan, please inform the Radiographer / Radiologist that you have a cochlear implant. You may be required to follow special instructions such as removing your sound processor to allow the scan to be carried out. Oticon Medical has provided the following advice:

Question	Answer
Can I have a diagnostic X-ray of any part of my body?	Yes. There are no contraindications, however the external sound processor should always be removed during the procedure.
Can I have other procedures involving X-rays e.g. dental OPT, mammogram, bone densitometry, CT scan?	Yes. There are no contraindications, however the external sound processor should always be removed during the procedure
Can I have a diagnostic ultrasound scan?	Yes. There are no contraindications, however the external sound processor should always be removed during the procedure
Can I have a Doppler ultrasound scan or echocardiogram?	Yes. There are no contraindications, however the external sound processor should always be removed during the procedure.
Can I have Nuclear Medicine scans involving radionuclides e.g. bone scans, PET, SPECT scans?	Yes. There are no contraindications, however the external sound processor should always be removed during the procedure.
Can I have an MRI Scan?	An MRI exam or the application of an intense magnetic field in the area of the

implant may potentially cause damage to the implant and/or the patient. The answer to this question is different depending upon the type of implant you have:

If you have a DIGISONIC® SP implant, as this contains a permanent (non-removable) magnet an MRI Scan is allowed at a maximum 1.5 Tesla provided below recommendations are followed;

If you have a NEURO Zti implant, which contains a removable magnet, magnet removal is not required for magnetic field strengths at 1.5 Tesla, for a magnetic field strengths greater than 1.5 Tesla magnet removal is required for MRI compatibility, an MRI scan is allowed provided the below recommendations are followed:

Prior to any MRI procedure the radiologist should complete the MRI Exam Form available at

<https://www.oticonmedical.com/-/media/medical/main/files/ci/surgical/mri/en/digisonic%20sp%20mri%20examination%20form%20-%20english%20-%20m80694.pdf?la=en>

Radiology department must fill in this form when dealing with recipients with an Oticon Medical implantable device and fax it to Oticon Medical CI headquarters (+33 (0)4 93 95 38 01) for approval BEFORE performing any MRI exam.

Recommended guidelines for radiologists.

1. The patient must have been implanted with a cochlear implant at least 6 months prior to the MRI examination.
2. All external parts or cochlear implant system accessories should be removed.
3. The patient must have a compression bandage applied to the head to secure the implant position.
4. For all MRI examinations requiring the

	<p>head of the patient to be placed in the centre of the tunnel, the position of the patient must be conformed to the 'usual position'.</p> <p>Note: When carrying out an MRI exam with a Neuro Zti cochlear implant, do not use the Head Coil Array.</p> <p>5. MRI 3 Tesla can only be performed with a Neuro Zti implant after Magnet removal surgery has taken place.</p> <p>To ensure patient safety during an MRI exam and to prevent damage to the cochlear implant, please refer to the relevant instruction manual or contact Oticon Medical at;</p> <p>cisupportuk@oticonmedical.com</p> <p>Any questions or concerns should be clarified with the manufacturer prior to conducting an MRI exam.</p>
<p>Are there any other types of scans that could be harmful to me or my implant or require special precautions?</p>	<p>If you need to have any other kind of procedure not listed in this document, please contact Oticon Medical and follow their advice.</p>

Medical / Dental Treatments, Therapy and Surgical Procedures

Before having any medical or dental treatment, therapy or surgical procedure, please inform your Doctor, Dentist, Nurse or Therapist that you have a cochlear implant and if you have any other medical devices. Some surgical procedures and treatments that use electrical current, heat, vibration and radiation (especially in the region of the head, neck and shoulders) may be harmful to you and/or your implant. Oticon Medical has provided the following advice:

Question	Answer
<p>Can I undergo a course of Radiotherapy and are there any special instructions that I need to follow.</p>	<p>Please contact your implant centre prior to starting any course of radiotherapy. Your implant centre will advise you of any special instructions that you need to follow as your general health takes priority. For most patients, there is <u>no</u> risk to the implant but</p>

	<p>this will depend on the part of the body that is being treated.</p> <p>We strongly advise against direct irradiation of the implant zone. Direct high exposure of the implant to the rays could lead to partial or total loss of implant function. The damage may not be immediately apparent.</p> <p>It is important that you remove your sound processor during treatment. Please ask the radiographer to remove it from the treatment room before each treatment session and return it to you immediately after each session.</p>
<p>Warnings about Electrosurgical Instruments and Diathermy</p>	<p>Use of diathermy with electromagnetic rays on a patient wearing implanted elements that contain metal is contraindicated. This may cause irreversible damage to the tissues inside the cochlea and to the implant. However, diathermy by ultrasound is allowed on the body below the head or the neck. Avoid the use of monopolar electrosurgical (cautery) instruments. These instruments may produce radiofrequency fields with voltage that might create coupling between the end of the instrument and the electrode array. Currents induced in this way might damage the cochlear tissue or result in permanent damage to the implant.</p>
<p>Warnings about Electromagnetic Radiation</p>	<p>Use of diathermy with electromagnetic rays on a patient wearing implanted elements that contain metal is contraindicated. This may cause irreversible damage to the tissues inside the cochlea and to the implant. However, diathermy by ultrasound is allowed on the body below the head or the neck.</p>
<p>Warnings about Therapeutic Ultrasound, Microwaves and Diathermy</p>	<p>The implant should never be exposed to therapeutic levels of ultrasonic energy. Essentially, the device might create concentration of the ultrasonic field and potentially cause damage.</p> <p>Lithotripsy- no contraindication if the implant area is avoided.</p>
<p>Warnings about Neurostimulation</p>	<p>Neuro-stimulation for the treatment of pain by gate control type currents, endorphin, burst (chronic pain, back pain, neck pain, fibromyalgia, nausea, reflex sympathetic dystrophy, myofascial pain, neuropathic pain, postoperative pain) is contraindicated.</p>
<p>Warnings about Electroconvulsive Therapy</p>	<p>Use of ECT is strongly not recommended.</p> <p>Electrotherapy may send variable strength</p>

	currents to the body. Use of high voltage electrotherapy techniques is contraindicated because of potential damage to the implant system. However, low-voltage electrotherapy may be considered, so long as the electrodes are not placed on the head or neck.
Are there any other medical, surgical or therapeutic treatments that could be harmful to me or my implant or require special precautions?	<p>Magnetophoresis is contraindicated. This process converts magnetic pulses and micro-currents into energy fields. Specifically, the technology is applied via a hand piece and four magnetic heads.</p> <p>We strongly recommend not using radiofrequency treatments. Exposure of the implant via radiofrequency treatment could lead to partial or total loss of implant function. This damage may not be immediately apparent.</p> <p>If you need to have any other kind of exam that is not listed in this document, please contact Oticon Medical and follow their advice.</p>

Sports, Beauty and Leisure

Your cochlear implant (the inside part) is vulnerable to damage from significant bumps or falls and pressure. The implant can break or become dislodged from its original position. Surgery may be required to (re-)move the implant and replacement may or may not be possible. Cochlear implant recipients should not participate in activities where there is a high risk of head injury or sustained pressure to the implant site. For some activities head protection may be recommended and for others it may be advisable to remove the external equipment (sound processor and/or accessories). Oticon Medical has provided the following advice:

Question	Answer
Are there any sports or activities that are not permitted?	<p>You can participate in most sport activities with your cochlear implant. However, depending on the sport, certain precautions are advisable to further protect your implant and sound processor against damage.</p> <p>Recommendations include use of a protective helmet, a retention system for holding or keeping the sound processor securely in place, or removal of the sound processor altogether during selected activities.</p>

	<p>Strong impact may damage your cochlear implant system, and you may lose your sound processor if it is not held securely in place.</p> <p>Participation in high impact contact sports (e.g. boxing, fight sports, etc.) is not advisable. Deep-sea (Scuba) diving below a depth of 20 m is also not recommended for patients with a cochlear implant.</p>
Are there any sports or activities where head protection is recommended?	Depending on the sport, both the use of head protection and removal of the sound processor may be necessary where the risk of direct impact to the implant area is increased (e.g. cycling, riding, contact/fight sports).
Can you provide advice on what type of head protection is required?	Information on the most popular and effective head protection options has been shared on many cochlear implant user forums, such as http://soundingboard.earfoundation.org.uk/forum/
Can I use electronic equipment for electrolysis, tattoos, pain relief, muscle toners, gym equipment etc.?	<p>The use of transcutaneous electrical nerve stimulators for examination or treatment is strictly prohibited.</p> <p>Other equipment involving the use of skin surface stimulation, such as electrolysis, tattoos, pain relief, muscle toners and gym equipment can be used as long as they avoid the head and neck area.</p>
Can I use hair clippers, electrical razor, hair dryers, curling tongs, hair straighteners, head lice comb etc. in the region of my implant?	Yes, after removal of the sound processor.
Can I have procedures carried out that use sources of light (e.g. sun beds) or laser for hair removal, tattoo removal etc.?	Laser therapy is possible if not directly applied to the implant area. Removal of the external sound processor is recommended.
Warnings about Fairground Rides and Amusement Parks	Use of the safety cable, especially during sporting activities and avoids undue loss of the processor. Use of any other compatible retention device is advisable.
Warnings about Extreme Thrill Rides and other activities with High G Forces	At the very least, patients should consider using a device for holding the sound processor securely in place during these activities, or removal of the sound processor to minimize the risk of damage and/or loss.
Warnings about Swimming, Snorkelling, Shallow Diving, Canoeing and Sailing	The external sound processors (Saphyr Neo and Neuro One) are water resistant

	<p>but not waterproof. It is recommended that care be taken to protect sound processors from water, and removed during water sport activity if necessary.</p> <p>More information can be found on practical and effective options for use during water sports on cochlear implant user forums such as http://soundingboard.earfoundation.org.uk/forum/</p>
Warnings about Scuba Diving	Scuba diving below a depth of 20 m is not advised for anyone with a cochlear implant. The external sound processor should be removed during any diving activity.
Are there any other sports, recreational activities or cosmetic procedures that could be harmful to me or my implant or require special precautions?	<p>Radiofrequency treatment (such as the Derma Wand system) is contraindicated for patients with cochlear implants. The use of radio frequency could cause irreversible damage to the implant.</p> <p>Neuromuscular electrical stimulation (such as the Revitive system) is contraindicated for patients with cochlear implants.</p>

At Home, Education and in the Workplace

You are very unlikely to come across any equipment in your home that has the potential to interact or cause damage to your implant. However, warnings are in place for those working with high powered electrical equipment and electromagnetic radiation in the workplace or in places of education. Oticon Medical has provided the following advice:

Question	Answer
Should I be concerned about static electricity at home, in the car, in the office, children's play equipment (ball pools etc.) and are any precautions required?	No. Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.
Is there any standard household equipment that has potential to interact with my implant, processor or accessories and are any precautions required? e.g. induction hobs.	Wave transmission radios, cell phones, Wi-Fi, Bluetooth, and other networks do not seem to generate interference problems. For induction plates, it is advisable to maintain a distance of approximately 1 m away from the implanted ear.
Is there any equipment at school, college or university (e.g. in science, technical subjects or home crafts) that has potential to interfere	Use of the Van der Graaf generator or similar equipment is strictly prohibited. It is advisable to maintain a minimal safe distance of approximately 3 m away from the

or interact with my implant, processor or accessories and are any precautions required? e.g. Van der Graaf generators.	generator during active use. At this distance, removal of the sound processor is not necessary. Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.
Is there any equipment in the workplace that has potential to interact with my implant, processor or accessories and are any precautions required?	Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.
Warnings about high-voltage equipment, radar, high tension wires, smelting furnaces etc.	Jobs or activities involving high-voltage equipment, radar and/or high tension wires are strongly not recommended.
Warnings about electro-magnetic radiation.	Jobs or activities involving electro-magnetic radiation are strongly not recommended.
Are there any other signals or systems that could be harmful to me or my implant or require special precautions?	Wave transmission radios, cell phones, Wi-Fi, Bluetooth, and other networks do not seem to generate interference problems. Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.
Can you provide advice for those who are required to wear a Hard Hat in the work place?	For people who need to wear a hard hat, we recommend the use of an accessory to protect the sound processor against sweat or humidity, such as the clip cover. The clip cover is also equipped with a special clip to ensure that the sound processor is securely held in place.

Interactions and Interference

In everyday life it is very rare for other equipment to interact or interfere with your sound processor or wireless technology. If this happens you may experience intermittent or distorted sound. It will not damage your processor and the effect is only temporary. It will go away when you move away from the source of interference. Do not remain close to the source of interference for any longer than necessary (or switch-off your processor in advance). It is equally unlikely that your cochlear implant, sound processor or wireless technology will affect the functionality of nearby electrical equipment. If this happens, move away from the affected electronic device. You may be asked to switch-off your processor or wireless technology in restricted areas where radio frequency transmission is prohibited. Oticon Medical has provided the following advice:

Question	Answer
<p>Are there any known sources of interference that may interact with my cochlear implant and accessories and are there any precautions that I should follow?</p>	<p>Wave transmission radios, cell phones, Wi-Fi, Bluetooth, and other networks do not seem to generate interference problems. Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.</p>
<p>Do my cochlear implant or accessories have the potential to interact or cause interference in other electrical equipment nearby and are there any precautions that I should follow?</p>	<p>It is unlikely that your cochlear implant, sound processor or wireless technology will affect the functionality of nearby electrical equipment. If this happens, move away from the affected electronic device. You may be asked to switch-off your processor or wireless technology in restricted areas where radio frequency transmission is prohibited.</p> <p>Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.</p>
<p>Can my cochlear implant and accessories interact with any other medical devices that I have? e.g. cardiac pacemaker or any electro-medical equipment that I rely upon e.g. insulin pumps, dialysis equipment etc.</p>	<p>It is highly unlikely that your cochlear implant, sound processor or wireless technology will affect the functionality of nearby medical devices. If you are unsure, please contact Oticon Medical for advice.</p> <p>Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.</p>
<p>Can my cochlear implant and accessories interact with medical devices in use by others in close proximity e.g. can a young CI user feed/sleep on the chest of an adult pacemaker user?</p>	<p>It is highly unlikely that your cochlear implant, sound processor or wireless technology will affect the functionality of nearby medical devices. If you are unsure, please contact Oticon Medical for advice.</p> <p>Your processor is designed to provide effective protection against electrostatic discharge (compliance with NF EN 60601-1-2: 2007) to prevent any damage to the device or alteration to the listening program.</p>
<p>Are there any situations where I should switch-off my processor or wireless technology e.g. going through airport</p>	<p>Wave transmission radios, cell phones, Wi-Fi, Bluetooth, and other networks do not seem to generate interference problems.</p> <p>Security gates (at airports, shopping centres,</p>

security, on planes during take-off and landing, in hospital intensive care units?

etc.) produce powerful electromagnetic fields. Passing through or close to these gates may trigger the detector alarm or disrupt the sound received by the person wearing the implant. It is recommended that you switch off your sound processor and inform the security officers by showing your implant ID or patient card.

Travelling by plane, as with all electrical equipment, passengers with a cochlear implant should comply with safety instructions and switch off your sound processor during take-off and landing.

This document was prepared in November 2017 and is due for review in November 2019. If you have any further questions regarding safety, please do not contact BCIG. Always contact your cochlear implant centre and/or Oticon Medical in the first instance.