

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. Most cochlear implant recipients can lead a normal life but it is important that you 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 **MED-EL GmbH, Innsbruck, Austria**

Safety Information is available on the website at:

www.medel.com/en-gb/important-safety-information

MED-EL UK Ltd can be contacted at:

Telephone: 0330 123 5601

Email: clinicalsupport@medel.co.uk

BCIG has compiled a list of frequently asked questions (FAQs) and have asked **MED-EL UK Ltd** 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."

Please note: the following material is provided at the request of the BCIG group. It does not constitute an approved / controlled MED-EL document. For definitive guidance, you should refer to the user manual provided with your speech processor, and the online information as per the link provided above. All information is considered correct at the time of writing, but may be superseded as new information becomes available. In the case of any doubt, or need for further information, please contact your implant centre and/or MED-EL UK Ltd.

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?	It is not necessary to remove the internal device prior to cremation.

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. MED-EL UK Ltd has provided the following advice:

Question	Answer
Can I have a diagnostic x-ray of any part of my body?	Yes - these standard clinical imaging techniques do not pose a risk to the implant. Refer to your processor user manual and/or the online guidance for detailed advice.
Can I have other procedures involving x-rays e.g. dental OPT, mammogram, bone densitometry, CT scan?	Yes - these standard clinical imaging techniques do not pose a risk to the implant. Refer to your processor user manual and/or the online guidance for detailed advice.
Can I have a diagnostic ultrasound scan?	Yes - these standard clinical imaging techniques do not pose a risk to the implant. Refer to your processor user manual and/or the online guidance for detailed advice.
Can I have a Doppler ultrasound scan or echocardiogram?	Yes - these standard clinical imaging techniques do not pose a risk to the implant. Refer to your processor user manual and/or the online guidance for detailed advice.
Can I have Nuclear Medicine scans involving radionuclides e.g. bone scans, PET, SPECT scans?	Any therapy / intervention that involves ionising radiation may pose a risk - any necessary ionising radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy. Your / your healthcare provider should contact MED-EL for advice.
Can I have an MRI Scan?	MED-EL implants are MR conditional, which means you may undergo MR scans, but <u>only for specific types, and under specific conditions</u> . You / your healthcare provider should refer to www.medel.com/uk/medical-procedures to learn more and/or contact MED-EL for further advice.
Are there any other types of scans that could be harmful to me or my implant or require special precautions?	Medical imaging covers an extremely broad range of scan types. Some of these may pose a risk. You / your healthcare provider should contact MED-EL for advice.

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. MED-EL UK Ltd has provided the following advice:

Question	Answer
Can I undergo a course of Radiotherapy and are there any special instructions that I need to follow.	Any necessary ionising radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy. MED-EL external components need to be taken off during irradiation. Therapeutic ionising radiation in general may damage electronic components of your MED-EL Implant System and such damage may not be immediately detected. In order to minimise the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radiotherapeutic beam. You / your healthcare provider should contact MED-EL for advice, and you should contact your implant centre before undergoing radiotherapy, or similar treatments.
Warnings about Electrosurgical Instruments and Diathermy	Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode. You / your healthcare provider should contact MED-EL for advice as/if necessary.
Warnings about Electromagnetic Radiation ?	Any necessary ionising radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy. Details regarding the electromagnetic immunity are listed in the technical data section of your audio processor manual. Please contact your CI centre, or MED-EL, for further advice as/if necessary.
Warnings about Therapeutic Ultrasound, Microwaves and Diathermy	<ul style="list-style-type: none"> • Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm. • Therapeutic microwave treatments must not be used in the head and neck area. • Diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue. <p>You / your healthcare provider should contact MED-EL for advice as/if necessary.</p>
Warnings about Neurostimulation	Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue. This applies also to iontophoresis and any other current inducing medical and/or cosmetic treatment. You / your healthcare provider should contact MED-EL for advice as/if necessary.
Warnings about Electroconvulsive Therapy	Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue. You / your healthcare provider should contact MED-EL for advice as/if necessary.

<p>Are there any other medical, surgical or therapeutic treatments that could be harmful to me or my implant or require special precautions?</p>	<p>This could include any type of existing, or new treatment. Unfortunately, it is not possible to provide a general answer. You / your healthcare provider should contact MED-EL, and your implant centre, for 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). MED-EL UK Ltd. has provided the following advice:

Question	Answer
Are there any sports or activities that are not permitted?	Contact sports, especially those that might result in severe blows to the head or continuous pressure on the implant, pose a risk to the internal device (and the sound processor). This risk may be mitigated by using appropriate protective equipment (e.g. a suitable helmet), but cannot be removed entirely. Refer to your processor user manual and/or the online guidance for detailed advice.
Are there any sports or activities where head protection is recommended?	Use a helmet whenever necessary to protect the implant site from any blows or impacts; and use a helmet for any activities for which wearing one is normally recommended. Refer to your processor user manual and/or the online guidance for detailed advice.
Can you provide advice on what type of head protection is required?	The possible range of applications and head protection types is too broad to provide a general answer - contact your implanting centre, or MED-EL, for further advice
Can I use electronic equipment for electrolysis, tattoos, pain relief, muscle toners, gym equipment etc?	The possible range of applications and equipment types is too broad to provide a general answer - contact your implanting centre, or MED-EL for further advice
Can I use hair clippers, electrical razor, hair dryers, curling tongs, hair straighteners, head lice comb etc. in the region of my implant?	The possible range of applications and equipment types is too broad to provide a general answer - contact your implanting centre, or MED-EL for further advice N.B: Cochlear implant users should <u>not</u> use electric / electronic head lice combs.
Can I have procedures carried out that use sources of light (e.g. sun beds) or laser for hair removal, tattoo removal etc.?	The possible range of applications and equipment types is too broad to provide a general answer - contact your implanting centre, or MED-EL for further advice
Warnings about Fairground Rides and Amusement Parks	Any activity that might result in impact to the head or continuous pressure on the implant, poses a risk to the internal device (and the sound processor). This risk may be mitigated by using appropriate protective /safety equipment, but cannot be removed entirely. Refer to your processor user manual and/or the online guidance for detailed advice.
Warnings about Extreme Thrill Rides and other activities with High G Forces	Any activity that might result in impact to the head or continuous pressure on the implant, poses a risk to the internal device (and the sound processor). This risk may be mitigated by using appropriate protective / safety equipment, but cannot be removed entirely. There is a potential risk that the internal device / electrode array could become dislodged if the user is exposed to high accelerations / 'G forces'

	Refer to your processor user manual and/or the online guidance for detailed advice.
Warnings about Swimming, Snorkelling, Shallow Diving, Canoeing and Sailing	<p>Persons with hearing loss have a greater risk of having balance issues that may compromise orientation if swimming underwater. You should consult an appropriate healthcare professional before participating in water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which may occur during SCUBA diving to depths up to 50 m.</p> <p>Any activity that might result in impact to the head or continuous pressure on the implant, poses a risk to the internal device. This risk may be mitigated by using appropriate protective equipment, but cannot be removed entirely.</p> <p>If using facemasks / goggles, be careful that straps/etc. do not place too much pressure on the implant site.</p> <p>If using the WaterWear accessory for your processor be sure to carefully follow the instructions to ensure a watertight seal.</p> <p>Refer to your processor user manual and/or the online guidance for detailed advice.</p>
Warnings about Scuba Diving	<p>Persons with hearing loss have a greater risk of having balance issues that may compromise orientation if swimming underwater. In any case you should consult an appropriate healthcare professional before participating in water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which may occur during SCUBA diving to depths up to 50 m.</p> <p>Refer to your processor user manual and/or the online guidance for detailed advice.</p>
Are there any other sports, recreational activities or cosmetic procedures that could be harmful to me or my implant or require special precautions?	<p>This represents too broad a range of possibilities to provide specific guidance. You / your healthcare provider should contact MED-EL for advice.</p> <p>Any activity that might result in impact to the head or continuous pressure on the implant, poses a risk to the internal device. This risk may be mitigated by using appropriate protective equipment, but cannot be removed entirely.</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. MED-EL UK Ltd. 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?	Equipment that generates high levels of static charge should be avoided. However it is unlikely that such equipment is found in typical home environments. Electronic devices may be influenced by electrostatic discharge (ESD). Although the MED-EL Cochlear Implant System has several internal safety features designed to reduce ESD, there is a small risk that the external or internal equipment can be damaged if the static discharge flows through the external equipment. Switching off your audio processor will not prevent damage from occurring. In rare cases, the user may experience uncomfortably loud hearing sensations, but the most likely occurrence in case of an ESD event is a short interruption of stimulation or a controlled audio processor shutdown. Refer to your processor user manual and/or the online guidance for detailed advice.
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.	<ul style="list-style-type: none"> • In rare cases, your audio processor may interfere with reception when using certain TV sets (with indoor antennae). Move away from the TV set and/or turn the antenna to reduce interference. • Mobile phones and other portable and mobile RF communications equipment may interfere with the external parts of your MED-EL Cochlear Implant System. As the experience of MED-EL users has shown, the system is compatible with most mobile phones. Results with a certain mobile phone may vary depending on the provider or type of phone. If you are considering purchasing a mobile telephone, you should test it beforehand for possible interference. • Strong magnets - e.g. toys / fridge magnets - if not handled carefully have the potential to become attached to the implant site, and possibly damage the skin over the implant. • Furniture etc. with sharp edges / corners, especially at head height, have the potential to damage the internal device in the event of a fall / impact. • As household equipment can cover an extremely broad range, you/your healthcare provider should contact MED-EL in the case of any doubt. <p>Refer to your processor user manual and/or the online guidance for detailed advice.</p>
Is there any equipment at school, college or university (e.g. in science, technical subjects or home crafts) that has potential to interfere or interact with my implant, processor or accessories and are any precautions required? e.g. Van der Graaf generators.	Equipment generating static charges is dealt with above - CI users should not be involved in applications which involve high-power / charge equipment such as Van der Graaf generators. Ultrasound motion detectors are reported to potentially interfere with the external parts of your MED-EL Cochlear Implant System. Move away from these sensors to avoid muted or reduced volume sensation. As this represents such a broad range of possibilities, you / your healthcare provider should contact MED-EL for further information.
Is there any equipment in the workplace that has potential to interact with my implant , processor or accessories and	Details regarding the electromagnetic immunity are listed in the technical data section of your audio processor manual. Guidance on high energy static electricity is given above. As this represents such a broad range of possibilities, you/your healthcare provide should contact MED-EL for further advice.

are any precautions required?	
Warnings about high-voltage equipment, radar, high tension wires, smelting furnaces etc.	Details regarding the electromagnetic immunity are listed in the technical data section of your audio processor manual. Please contact your CI centre or MED-EL if you have questions about any specific application which involves high voltages / energies.
Warnings about electro-magnetic radiation.	Details regarding the electromagnetic immunity are listed in the technical data section of your audio processor manual. Please contact your CI centre or MED-EL if you have questions about any specific application which involves high voltages / energies.
Are there any other signals or systems that could be harmful to me or my implant or require special precautions?	Details regarding the electromagnetic immunity are listed in the technical data section of your audio processor manual. As this represents such a broad range of possibilities, you/your healthcare provide should contact MED-EL for further advice.
Can you provide advice for those who are required to wear a Hard Hat in the workplace?	CI users should follow applicable workplace guidance on the use of personal protective equipment. Any activity that might result in impact to the head or continuous pressure on the implant, poses a risk to the internal device. This risk may be mitigated by using appropriate protective equipment, but cannot be removed entirely. If headgear or face masks are worn, care must be taken to ensure that the strap is not too tight over the implant site. Refer to your processor user manual and/or the online guidance for detailed advice.

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. MED-EL UK Ltd has provided the following advice:

Question	Answer
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?	Details regarding electromagnetic immunity are listed in the technical data of your audio processor manual. Please contact your CI centre or MED-EL if you have questions about any specific application which involves high voltages / energies.
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?	MED-EL audio processors use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Refer to your processor user manual and/or the online guidance for detailed advice.
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.	As this represents a broad range of possibilities, it is not possible to provide specific guidance. You / your healthcare provider should contact MED-EL for further advice, and also contact the provider/manufacture of the medical device for guidance. N.B. some medical devices are magnet-adjustable - close proximity of the internal / external magnet could lead to inadvertent changes in such devices' operation.
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?	As this represents a broad range of possibilities, it is not possible to provide specific guidance. You / your healthcare provider should contact MED-EL for further advice, and also contact the provider/manufacture of the medical device for guidance. N.B. some medical devices are magnet-adjustable - close proximity of the internal / external magnet could lead to inadvertent changes in such devices operation.

Are there any situations where I should switch-off my processor or wireless technology e.g. going through airport security, on planes during take-off and landing, in hospital intensive care units?

Metal detectors, some anti-theft devices and other RF transmitters may produce sounds only heard by the implant user, if they are near to these devices. To avoid this, switch off your audio processor when walking through metal detectors or when in the vicinity of an RF transmitter.

The implant itself may trigger a metal detector, so make sure that you carry your MED-EL ID card with you at all times to identify yourself as a cochlear implant user, as needed.

EASA (European Aviation Safety Agency) and FAA (Federal Aviation Administration) aviation safety guidelines recommend airlines to allow the use of cochlear implants during all phases of flight, i.e. the audio processor may also remain switched on during taxi, takeoff and landing. However, we recommend to check with your airline about possible specific regulations.

For more specific guidance, you/your healthcare provider should contact MED-EL for further advice.

This document was prepared in March 2020 and is due for review in March 2022. If you have any further questions regarding safety, please do not contact BCIG. Always contact your cochlear implant centre and/or MED-EL UK Ltd in the first instance.