**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 **Cochlear**.

Information is available on the website at:

**www.cochlear.com/warnings**

**Cochlear** can be contacted at:

Telephone: **01932 263 600**

or by using the online form:

**http://www.cochlear.com/wps/wcm/connect/uk/contact/contact-us**

BCIG has compiled a list of frequently asked questions (FAQs) and have asked **Cochlear** to provide device specific responses to these questions.

**Cochlear Implant Safety – Frequently Asked Questions**

**General Questions**

| Question | Answer |
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| 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. Cochlear has provided the following advice:

| Question | Answer |
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| Can I have a diagnostic x-ray of any part of my body? | All Nucleus Cochlear Implants are safe to undergo diagnostic x-ray. |
| Can I have other procedures involving x-rays e.g. dental OPT, mammogram, bone densitometry, CT scan? | All Nucleus Cochlear Implants may be subjected to standard dental and diagnostic x-rays, including CT scans. |
| Can I have a diagnostic ultrasound scan? | Diagnostic ultrasound uses low energy sound waves and will not damage your cochlear implant. We do not, however, recommend scanning directly over the implant site. |
| Can I have a Doppler ultrasound scan or echocardiogram? | All Nucleus Cochlear Implants may be subjected to diagnostic ultrasound including Doppler ultrasound or an echocardiogram. We do not, however, |

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| | recommend scanning directly over the implant site. |
| Can I have Nuclear Medicine scans involving radionuclides e.g. bone scans, PET, SPECT scans? | Radio-isotopic scans have specific risks that should be discussed with your healthcare professional. The implant, however, will not be affected by this low dose radiation. |
| Can I have an MRI Scan? | Broadly summarised, when scanning in MRI machines up to 1.5 Tesla, most implants can be safely scanned but a tight pressure bandage may need to be placed over the implant during the procedure (requirements vary as more modern implant types have more flexibility for MRI scanning).<br><br>MRI is also permitted using the stronger 3.0 Tesla MRI machines following Cochlear's guidelines for each implant type.<br><br>If necessary, removal of the internal magnet may be performed as an out-patient procedure, a new magnet being reintroduced after the MRI scan is complete. It is important to contact your implant centre before an MRI takes place.<br><br>See guidelines here: https://www.cochlear.com/bfec2571-3934-4e3a-afc4-517a5f4b2b7e/D1536014_4-02_EN_MRI-GL_NEW+KIT_EMEA_WEB.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPAC |

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| | E-bfec2571-3934-4e3a-afc4-517a5f4b2b7e-npFq351<br><br>For an overview of our implants and MRI, see here: https://www.cochlear.com/uk/en/home/ongoing-care-and-support/device-support/mri-considerations/mri-nucleus |
| Are there any other types of scans that could be harmful to me or my implant or require special precautions? | CAUTION!<br>Any medical scans utilising high magnetic fields or high energy radio waves may pose a risk and should be treated with caution.<br><br>The hospital undertaking the scan should seek guidance from your Implant Centre. |

**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. Cochlear has provided the following advice:

| **Question** | **Answer** |
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| Can I undergo a course of Radiotherapy and are there any special instructions that I need to follow. | Please contact your implant centre before starting any course of radiotherapy. Your implant centre will advise you of any special instructions that you need to follow. Your general |

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| | health takes priority. It is essential that you have access to any treatment that is recommended by your Oncologist. For most patients, there is no risk to the implant but this will depend on the part of the body that is being treated. It is important that you remove your sound processor during treatment. The radiographer will remove it from the treatment room before each treatment session and will return it to you immediately after each session. |
| Warnings about Electrosurgical Instruments and Diathermy | CAUTION!<br>Electrosurgical instruments and diathermy are used in many surgical procedures. These can pose a risk of causing damage to a cochlear implant and specific requirements apply.<br><br>The hospital undertaking procedures requiring electrosurgery or diathermy should seek guidance from your Implant Centre. |
| Warnings about Electromagnetic (EM) Radiation | Cochlear implants comply with applicable CISPR and IEC standards regarding EM/RF immunity. Any equipment working outside values specified in EN45502-2-3 clause 27.3 and 27.4 is unverified.<br><br>In close proximity to equipment that emits high EM/RF fields there may be some perceived interference in the audio signal and normally the sound processor should be removed during clinical testing. |

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| Warnings about Therapeutic Ultrasound, Microwaves and Diathermy | CAUTION!<br>Therapeutic radiation is designed to have a healing effect on damaged body tissue.<br><br>Therapeutic microwave radiation and therapeutic diathermy pose a significant risk to the implant and should NOT be used anywhere on the body.<br><br>Therapeutic ultrasound, such as that used for muscle relief, poses a small risk to the implant and must not be applied directly over the implant site. It is recommended to be used only below the head and neck. |
| Warnings about Neurostimulation | CAUTION!<br>Neurostimulators (devices designed to stimulate nerves in the body through electricity) pose a small risk of damage to a cochlear implant if the current passes close to the implant or electrodes.<br>Neurostimulators should only be used below the head and neck. |
| Warnings about Electroconvulsive Therapy | CAUTION!<br>Electroconvulsive therapy is contraindicated for all cochlear implant users. |
| Are there any other medical, surgical or therapeutic treatments that could be harmful to me or my implant or require special precautions? | New medical treatments or variations on existing treatments arise every year. You should check with Cochlear if you are unsure about any medical, surgical or therapeutic treatments not detailed in this document. |

**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). Cochlear has provided the following advice:

| **Question** | **Answer** |
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| Are there any sports or activities that are not permitted? | CAUTION!<br>Sports are a lifestyle choice however those sports involving a high risk of physical impact with another person, with the ground, or with another object or ball, could result in failure of the external sound processor or the internal implant. Failure of an implant will normally require surgical replacement. Users should be aware of the potential risks of impact and choose sports mindfully. Where contact cannot be avoided, take suitable precautions (e.g. wearing scrum cap/protective headgear, removing the sound processor, etc.) to minimise the risk of damage to the implant or sound processor.<br>Nucleus Implants are designed to withstand knocks and bangs of normal life. |
| Are there any sports or activities where head protection is recommended? | Head protection should be worn with any physical activity that normally recommends head protection (eg cycling or riding). Head protection is recommended for all other sports that pose a significant risk of impact, either |

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| | with another person, the ground, an object or a ball. |
| Can you provide advice on what type of head protection is required? | Soft headgear such as a scrum cap is recommended for physical sports involving some risk of impact.<br><br>Where hard hats would normally be worn (e.g. riding or cycling), you may need to shop around in order to find one that fits comfortably, does not put pressure directly over the implant site and allows the sound processor to be worn if hearing is important. Extra padding around the implant area may improve comfort.<br><br>Whilst a helmet manufacturer's warranty would be voided if a helmet is adapted in any destructive way to fit around an implant and sound processor, sensible judgement should be made in relation to the relative risks if no helmet is worn at all. |
| Can I use electronic equipment for electrolysis, tattoos, pain relief, muscle toners, gym equipment etc? | Any device that applies current to the surface of the body poses a small risk to the implant however that risk is related to the distance between the applied electrodes, the distance to the implant and the amount of current used.<br><br>Muscle relief equipment (e.g. TENS machines, muscle toning belts, etc.) applying currents below the head and neck pose minimal risk. Stimulators applying larger currents but delivered by narrowly spaced electrodes (less than 5mm apart) such as those used for |

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| | electrolysis, pose minimal risks provided the electrodes are kept more than 1cm from the implant. |
| Can I use hair clippers, electrical razor, hair dryers, curling tongs, hair straighteners, head lice comb, etc. in the region of my implant? | All the listed treatments do not pose a risk to a cochlear implant provided they are not faulty. The sound processor should be removed to avoid potential damage. |
| Can I have procedures carried out that use sources of light (e.g. sun beds) or laser for hair removal, tattoo removal etc.? | All listed forms of treatment do not pose a risk to the cochlear implant in normal use.<br>Sound processors should be removed if using sun beds to avoid any possible deterioration of the plastics.<br>Lasers should not be used directly over the implant site. |
| Warnings about Fairground Rides and Amusement Parks | Gentle fairground and amusement park rides which do not subject the user to significant G-forces pose minimal risk to the implant or externals. Nevertheless, it may be necessary to consider retention aids for the sound processor or removing altogether if uncertain. |
| Warnings about Extreme Thrill Rides and other activities with High G Forces | CAUTION!<br>Thrill rides designed to subject the user to significant G-forces could cause external equipment to be dislodged and could cause a recipient's head to impact a hard object which could cause damage to a sound processor, damage to the implant or the electrode array to dislodge. An impact to the implant could cause its failure. Failure of an implant or a dislodged electrode would require surgical revision. Users should be mindful of these risks when choosing rides. Extreme rides may also pose |

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| | medical risks for certain middle/inner ear conditions and so we would recommend contacting your Implant Centre for further advice. |
| Warnings about Swimming, Snorkelling, Shallow Diving, Canoeing and Sailing | Most surface water or shallow water sports present negligible risks to the implant. Consider the use of head protection if sailing in case of accidental impact by the boom. The Aqua Accessory or Aqua Plus should be used if the sound processor might be exposed to sustained, full water immersion. |
| Warnings about Scuba Diving | Recreational diving normally poses no significant risk to the implant up to depths of 25m for all implants except the Nucleus 5 (CI500-series) which can be immersed to 40m.<br>Any headwear (e.g. goggles) should be adjusted to avoid pressure being applied directly over the implant site as far as possible. |
| Are there any other sports, recreational activities or cosmetic procedures that could be harmful to me or my implant or require special precautions? | If you are unsure about the safety of any specific recreational activity or cosmetic treatment, please contact Cochlear. |

**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. Cochlear has provided the following advice:

| **Question** | **Answer** |
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| Should I be concerned about static electricity at home, in the car, in the | Cochlear implants and sound processors are designed to offer |

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| office, children's play equipment (ball pools etc.) and are any precautions required? | immunity to normal levels of static electricity. Higher levels of static electricity such as that generated by some children's play slides can pose a risk of damage to external equipment or even, in rare circumstances, the implant itself. Any equipment that is known to generate high levels of static charge or any technical equipment specifically designed to generate static charge should be avoided. If avoidance is not practicable then removal of the sound processor is advised. You should also avoid touching the sound processor if you or a recipient is aware that you have become charged (e.g. hair standing on end). In this case you should touch a metal surface first before touching the sound processor. |
| 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 | Very few household items present any risk to a cochlear implant.<br>The use of induction hobs in the kitchen, whilst not posing any significant risk, can cause interference if the implant system is closer than 50cm from the cooker surface.<br>The use of child toys utilising extremely strong neodymium magnets (e.g. zoids) could weaken the implant magnet's pocket increasing the risk of magnet dislocation. Children should not place magnets other than those in the headset coil, onto their implant.<br>Strip lights, dimmer switches and equipment with electrical motors sometimes emit electromagnetic energy that can be perceived by an implant |

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| | user as interference at very close range. Such interference will not damage the implant system.<br>Parents/carers should also be aware of the potential risks of kitchen table edges which are often at head height to an implanted child. Impact to a table edge could risk damage to the sound processor or internal implant. |
| 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 | CAUTION!<br>Some schools will demonstrate Van der Graaf generators in science classes to illustrate the properties of static electricity. High voltages discharging through the equipment of a cochlear implant user can pose a risk of damage to the externals or even to the implant. It is recommended that implant users do not get involved directly in experiments with static and should stand at a sensible distance from a charged Van de Graaf generator (we suggest a minimum of 2 arm-spans away, to avoid accidental or deliberate discharge pranks).<br>The use of extremely strong neodymium magnets in science classes could weaken the implant magnet's pocket risking magnet dislocation. Children should not place such magnets onto their implant.<br>Chemistry experiments use a wide range of chemicals, some of which may be corrosive. It is advised not to allow the sound processor to come into contact with any chemicals used in experiments. |

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| Is there any equipment in the workplace that has potential to interact with my implant , processor or accessories and are any precautions required? | The workplace is a varied environment and risks depend heavily on the work undertaken. If there is a risk of coming into close proximity to equipment using high level magnetism (e.g. metal separation plants), strong EM fields (e.g. power generators, MIG welding), or strong RF fields (e.g. telecommunications masts) seek further advice from Cochlear. |
| Warnings about high-voltage equipment, radar, high tension wires, smelting furnaces etc. | CAUTION!<br>High voltage equipment poses a risk to a cochlear implant system and may also pose a risk to health. Cochlear implant users should avoid contact with such equipment including electric fences and high tension (HT) circuits in automobiles.<br>In close proximity to high voltage equipment, radars or telecommunications equipment there may be some perceived interference in the audio signal. This itself is not harmful but should be treated as a warning that a potential hazard is nearby. |
| Warnings about electro-magnetic radiation. | Cochlear implants comply with applicable standards regarding EM/RF immunity. Any equipment working outside values specified in EN45502-2-3 clause 27.3 and 27.4 is unverified.<br><br>In close proximity to equipment that emits high EM fields there may be some perceived interference in the audio signal which would not cause harm to |

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| | the sound processor but might be disturbing. |
| Are there any other signals or systems that could be harmful to me or my implant or require special precautions? | Any equipment that emits a radio signal, especially those that are switched on and off could cause audio disturbance to a sound processor. This would not cause harm to the sound processor but might be disturbing. |
| Can you provide advice for those who are required to wear a Hard Hat in the work place? | Hard hats are recommended in environments where there is a tangible risk of falling debris or a tangible risk of impact from another person or object. Cochlear implant users in these environments must follow health and safety guidance or otherwise avoid the restricted area. Hard hats can be uncomfortable if the supporting straps pass over the implant site or otherwise put pressure on the implant. Additional foam padding should be considered around any potential contact point. When putting on or taking off a hard hat, take care not to rub a tight strap over the implant area as this could cause the internal magnet or the implant to be dislodged requiring surgical intervention. |

**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. Cochlear has provided the following advice:

| Question | Answer |
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| 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? | Cochlear implants comply with relevant standards regarding EM/RF immunity and should not be harmed by RF transmission at distances considered safe to the public. Certain equipment that generates pulsatile RF fields including mobile phones, mobile transmitter masts, wireless routers and other Bluetooth devices can, in some rare circumstances, be perceived by the implant user at close range. This interference does not pose a risk of causing damage to the cochlear implant system but could be disturbing. If interference is experienced it may be necessary to move further away from the equipment generating this transmission. |
| 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? | Your cochlear implant equipment consists of a transmitting device using the 2.5MHz or 5.0MHz radio frequency band, and a strong transmitter coil magnet used for retention. Other equipment with susceptibility to magnetism or susceptible to transmissions at the listed frequencies could be affected, but would only likely occur at very close range (e.g. within a few centimetres from the transmitter coil). Under these circumstances it is extremely unusual for a cochlear implant user to need to switch off their external equipment but in cases of doubt, please contact Cochlear. |

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| | Private pilots or passengers in light aircraft should be aware of the potential disturbance that the implant and transmitter coil magnets could cause to sensitive navigational equipment relying on magnetism. |
| 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. | CAUTION!<br>Some medical equipment such as cardiac pacemakers, intracardiac defibrillators (ICDs) and programmable valve shunt systems, have parameters that can sometimes be adjusted using nearby magnets. Never place a transmitter coil magnet directly over a pacemaker, ICD or programmable valve shunt system.<br>Although no specific interaction is known, it is nevertheless recommended not to allow the transmitter coil to come into direct contact with any other medical equipment. |
| 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? | CAUTION!<br>Some medical equipment used by other people, such as cardiac pacemakers, ICDs and programmable valve shunt systems, have parameters that can be adjusted using nearby magnets. Since the implant and the headset both contain a magnet, in remote situations an unwanted interaction might be possible. We advise users and responsible carers to be alert to these risks and to avoid allowing the implant or headset magnet to come into very close proximity (less than 5cm) of other medical devices. |

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| 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? | Security scanners are ubiquitous at airports and increasingly common at transport hubs, public buildings and even some hotels. It is normally required for personally-worn electrical equipment to be removed and scanned, in order to pass security checks.<br><br>A cochlear implant and the externally worn sound processor may cause the scanner to sound an alarm. When approaching such a scanner we advise that you proactively inform the security staff that you have a medical device called a cochlear implant that is necessary in order to be able to hear. Presenting your user ID card will assist security staff in evaluating your equipment. They may allow you to pass through the scanner or they may insist that the sound processor is removed and scanned by the x-ray machine. Neither passing through the metal detector, undergoing a body scan nor allowing your sound processor to pass through an x-ray machine will risk damage to your equipment, however some scanners may interfere with your sound processor microphone such that you hear noises whilst passing through the machine. You might prefer to remove your sound processor to avoid this risk. We advise that you cooperate fully with all security requests.<br><br>Since your CI equipment comprises a transmitter, some airlines might request |

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| | that your sound processor is switched off during take-off and landing or even for the duration of the flight. We recommend you present your ID card and alert the air crew to the fact that you need to be able to hear instructions for your own safety and security. Increasingly airlines are sympathetic to cochlear implant users and normally allow their use throughout all phases of the flight. The final decision whether your sound processor can be used on board an aircraft rests with the airline and/or the captain on board your plane. |

**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. Please contact your cochlear implant centre in the first instance.**