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. 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	Contact your Implant Centre and follow
infection?	their advice.
What should I do if I experience pain,	Contact your Implant Centre and follow
swelling, redness or soreness in the	their advice.
region of my implant?	
What should I do if I bump my head in	Contact your Implant Centre and follow
the region of the cochlear implant?	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
Can I have a diagnostic x-ray of any part	All Nucleus Cochlear Implants are safe to
of my body?	undergo diagnostic x-ray.
Can I have other procedures involving x-	All Nucleus Cochlear Implants may be
rays e.g. dental OPT, mammogram,	subjected to standard dental and
bone densitometry, CT scan?	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	All Nucleus Cochlear Implants may be
echocardiogram?	subjected to diagnostic ultrasound
	including Doppler ultrasound or an
	echocardiogram. We do not, however,
	recommend scanning directly over the
	implant site.
Can I have Nuclear Medicine scans	Radio-isotopic scans have specific risks
involving radionuclides e.g. bone scans,	that should be discussed with your
PET, SPECT scans?	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).

	MRI is also permitted using the stronger
	3.0 Tesla MRI machines following
	Cochlear's guidelines for each implant
	type.
	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.
Are there any other types of scans that	CAUTION!
could be harmful to me or my implant or	Any medical scans utilising high
require special precautions?	magnetic fields or high energy radio
	waves may pose a risk and should be
	treated with caution.
	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
Can I undergo a course of Radiotherapy	Please contact your implant centre
and are there any special instructions	before starting any course of
that I need to follow.	radiotherapy. Your implant centre will
	advise you of any special instructions
	that you need to follow. Your general
	health takes priority. It is essential that
	you have access to any treatment that is
	recommended by your Oncologist. For
	most patients, there is <u>no</u> 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	CAUTION!
Instruments and Diathermy	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.
	The hospital undertaking procedures
	requiring electrosurgery or diathermy
	should seek guidance from your Implant
	Centre.

Warnings about Electromagnetic (EM)	Cochlear implants comply with applicable
Radiation	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.
	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.
Warnings about Therapeutic Ultrasound,	CAUTION!
Microwaves and Diathermy	Therapeutic radiation is designed to have
	a healing effect on damaged body tissue.
	Therapeutic microwave radiation and
	therapeutic diathermy pose a significant
	risk to the implant and should <u>NOT</u> be
	used anywhere on the body.
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	I nerapeutic 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
Wornings shout Neurostimulation	
warnings about neurostimulation	CAUTION!
	Neurosumulators (devices designed to
	stimulate nerves in the body through
	electricity) pose a small risk of damage to
	a coornear implant in the current passes
	Neurostimulators should only be used
	helow the head and neck
Warnings about Electroconvulsive	
Therapy	Electrocopyulsive therapy is
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	contraindicated for all cochlear implant
	users.
Are there any other medical, surgical or	New medical treatments or variations on
therapeutic treatments that could be	existing treatments arise every year. You
harmful to me or my implant or require	should check with Cochlear if you are
special precautions?	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
Are there any sports or activities that are	CAUTION!
not permitted?	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.
	Nucleus Implants are designed to
	withstand knocks and bangs of normal
	life.
Are there any sports or activities where	Head protection should be worn with any
head protection is recommended?	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

	with another person, the ground, an
	object or a ball.
Can you provide advice on what type of	Soft headgear such as a scrum cap is
head protection is required?	recommended for physical sports
	involving some risk of impact.
	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.
	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	Any device that applies current to the
electrolysis, tattoos, pain relief, muscle	surface of the body poses a small risk to
toners, gym equipment etc?	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.
	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

	electrolysis, pose minimal risks provided
	the electrodes are kept more than 1cm
	from the implant.
Can I use hair clippers, electrical razor,	All the listed treatments do not pose a
hair dryers, curling tongs, hair	risk to a cochlear implant provided they
straighteners, head lice comb, etc. in the	are not faulty. The sound processor
region of my implant?	should be removed to avoid potential
	damage.
Can I have procedures carried out that	All listed forms of treatment do not pose
use sources of light (e.g. sun beds) or	a risk to the cochlear implant in normal
laser for hair removal, tattoo removal	use.
etc.?	Sound processors should be removed if
	using sun beds to avoid any possible
	deterioration of the plastics.
	Lasers should not be used directly over
	the implant site.
Warnings about Fairground Rides and	Gentle fairground and amusement park
Amusement Parks	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	CAUTION!
other activities with High G Forces	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

	medical risks for certain middle/inner ear
	conditions and so we would recommend
	contacting your Implant Centre for further
	advice.
Warnings about Swimming, Snorkelling,	Most surface water or shallow water
Shallow Diving, Canoeing and Sailing	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.
	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	If you are unsure about the safety of any
activities or cosmetic procedures that	specific recreational activity or cosmetic
could be harmful to me or my implant or	treatment, please contact Cochlear.
require special precautions?	

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
Should I be concerned about static	Cochlear implants and sound processors
electricity at home, in the car, in the	are designed to offer immunity to normal
office, children's play equipment (ball	levels of static electricity. Higher levels
pools etc.) and are any precautions	of static electricity such as that generated
required?	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	Very few household items present any
equipment that has potential to interact	risk to a cochlear implant.
with my implant, processor or	The use of induction hobs in the kitchen,
accessories and are any precautions	whilst not posing any significant risk, can
required? e.g. induction hobs	cause interference if the implant system
	is closer than 50cm from the cooker
	surface.
	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.
	Strip lights, dimmer switches and
	equipment with electrical motors
	sometimes emit electromagnetic energy
	that can be perceived by an implant user
	as interference at very close range. Such
	interference will not damage the implant
	system.
	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	CAUTION!
or university (e.g. in science, technical	Some schools will demonstrate Van der
subjects or home crafts) that has	Graaf generators in science classes to
potential to interfere or interact with my	illustrate the properties of static
implant, processor or accessories and	electricity. High voltages discharging
are any precautions required? e.g. Van	through the equipment of a cochlear
der Graaf generators	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).
	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.
	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.
Is there any equipment in the workplace	The workplace is a varied environment
that has potential to interact with my	and risks depend heavily on the work
implant , processor or accessories and	undertaken. If there is a risk of coming
are any precautions required?	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,	CAUTION!
radar, high tension wires, smelting	High voltage equipment poses a risk to a
furnaces etc.	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.
	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	Cochlear implants comply with applicable
radiation.	standards regarding EM/RF immunity.
	Any equipment working outside values
	specified in EN45502-2-3 clause 27.3
	and 27.4 is unverified.

	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 the
	sound processor but might be disturbing.
Are there any other signals or systems	Any equipment that emits a radio signal,
that could be harmful to me or my	especially those that are switched on and
implant or require special precautions?	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	Hard hats are recommended in
are required to wear a Hard Hat in the	environments where there is a tangible
work place?	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 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
Are there any known sources of	Cochlear implants comply with relevant
interference that may interact with my	standards regarding EM/RF immunity
cochlear implant and accessories and	and should not be harmed by RF
are there any precautions that I should	transmission at distances considered
follow?	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	Your cochlear implant equipment
have the potential to interact or cause	consists of a transmitting device using
interference in other electrical equipment	the 2.5MHz or 5.0MHz radio frequency
nearby and are there any precautions	band, and a strong transmitter coil
that I should follow?	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.
	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	CAUTION!
accessories interact with any other	Some medical equipment such as
medical devices that I have? e.g. cardiac	cardiac pacemakers, intracardiac
pacemaker or any electro-medical	defibrillators (ICDs) and programmable
equipment that I rely upon e.g. insulin	valve shunt systems, have parameters
pumps, dialysis equipment etc.	that can sometimes be adjusted using
	nearby magnets. Never place a
	transmitter coil magnet directly over a
	pacemaker, ICD or programmable valve
	shunt system.
	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	CAUTION!
accessories interact with medical devices	Some medical equipment used by other
in use by others in close proximity e.g.	people, such as cardiac pacemakers,
can a young CI user feed/sleep on the	ICDs and programmable valve shunt
chest of an adult pacemaker user?	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.
Are there any situations where I should	Security scanners are ubiquitous at
switch-off my processor or wireless	airports and increasingly common at
technology e.g. going through airport	transport hubs, public buildings and even
security, on planes during take-off and	some hotels. It is normally required for
landing, in hospital intensive care units?	personally-worn electrical equipment to
	be removed and scanned, in order to
	pass security checks.
	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.
Since your CI equipment comprises a
transmitter, some airlines might request
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.