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 Advanced Bionics.

Safety Information is available on the website at:

www.advancedbionics.com

Advanced Bionics can be contacted at:

Telephone: 01223 847 888

Email: info.uk@advancedbionics.com

BCIG has compiled a list of frequently asked questions (FAQs) and have asked **Advanced Bionics** 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 require to
	be removed 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. Advanced Bionics has provided the following advice:

Question	Answer
Can I have a	Yes
diagnostic x-ray of any	
part of my body?	
Can I have other	Yes
procedures involving x-	
rays e.g. dental OPT,	
mammogram, bone	
densitometry, CT	
scan?	
Can I have a	Diagnostic Ultrasound Energy must not be used in the area
diagnostic ultrasound	of the implant.
scan?	
Can I have a Doppler	Diagnostic Ultrasound Energy must not be used in the area
ultrasound scan or	of the implant.
echocardiogram?	
Can I have Nuclear	No official recommendations. The healthcare provider
Medicine scans	should consult Advanced Bionics with any concerns.
involving radionuclides	
e.g. bone scans, PET,	
SPECT scans?	
Can I have an MRI	Please consult AB's MRI Safety website to confirm
Scan?	regarding your particular AB implant see
	https://advancedbionics.com/gb/en/home/professionals/mri-
	safety-information.html
Are there any other	No
types of scans that	
could be harmful to me	
or my implant or	
require special	
precautions?	

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. Advanced Bionics 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 should remove it from the
	treatment room before each treatment
	session and return it to you immediately
	after each session.
Warnings about Electrosurgical	Diathermy must never be applied.
Instruments and Diathermy	Electrosurgical instruments must not be
	used.
Warnings about Electromagnetic	Electromagnetic Interference (EMI):
Radiation	Radio Frequency (RF) workers may
	be exposed to higher interference. In the presence of high intensity EMI
	you may experience loss of sound. If
	this occurs, move from the area or
	temporarily discontinue use of the
	system by removing the headpiece.
	Electromagnetic Sources: It is
	advised to maintain a minimum

Warnings about Therapeutic Ultrasound, Microwaves and Diathermy Warnings about Neurostimulation	 distance of 30 cm (12in) from electromagnetic emitters such as Radio Frequency Identification (RFID), and metal detectors. It is advised to maintain a minimum distance of 50 cm (20 in) from an electronic article surveillance emitter. The HiRes Ultra implant employs an intermittently keyed back telemetry transmitter that uses a frequency modulated 10.7 MHz signal. This is a near field inductively coupled technology. The digitally-coded, inductive transmission technology used in this device is extremely reliable and experiences virtually no interference from other devices. It should be noted, however, that when operating the device near a computer terminal or other strong electromagnetic fields (e.g., RFID system), it may be necessary to be at least 24" (60 cm) away to ensure proper operation. If the Naida CI Q90 EAS sound processor does not respond to the implant device because of an unusual field disturbance, move away from the disturbing field. Diagnostic Ultrasound Energy must not be used. Neurostimulators may not be used in the vicinity of the implant
Warnings about Electroconvulsive	Must never be used on a cochlear
Therapy	implant patient.
Are there any other medical, surgical or	No official recommendations. Consult
therapeutic treatments that could be harmful to me or my implant or require special precautions?	Advanced Bionics.

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). Advanced Bionics has provided the following advice:

Question	Answer
Are there any sports or activities that are	Physical Activity: When engaging in
not permitted?	physical activities that include the
	possibility of trauma or impact,
	precautions should be taken, such as
	wearing a protective helmet, to reduce
	the risk of damage to the internal device.
Are there any sports or activities where	Physical Activity: When engaging in
head protection is recommended?	physical activities that include the
	possibility of trauma or impact,
	precautions should be taken, such as
	wearing a protective helmet, to reduce
Can you provide advice on what type of	the risk of damage to the internal device. No official recommendations. Consult
head protection is required?	Advanced Bionics.
Can I use electronic equipment for	No official recommendations. Consult
electrolysis, tattoos, pain relief, muscle	Advanced Bionics.
toners, gym equipment etc?	
Can I use hair clippers, electrical razor,	No official recommendations. Consult
hair dryers, curling tongs, hair	Advanced Bionics.
straighteners, head lice comb etc. in the	
region of my implant?	
Can I have procedures carried out that	No official recommendations. Consult
use sources of light (e.g. sun beds) or	Advanced Bionics.
laser for hair removal, tattoo removal	
etc.?	
Warnings about Fairground Rides and	No official recommendations. Consult
Amusement Parks	Advanced Bionics.
Warnings about Extreme Thrill Rides and	No official recommendations. Consult

other activities with High G Forces	Advanced Bionics.
Warnings about Swimming, Snorkelling,	The Implant is tested to continue
Shallow Diving, Canoeing and Sailing	working at up to a depth of 138ft (HiRes
	Ultra) and 33ft (HiRes 90k) without a
	sound processor nor with a Neptune or
	Naida sound processor in an AquaCase
	protective cover.
Warnings about Scuba Diving	Implant tested to depth of 138ft (HiRes
	Ultra) and 33ft (HiRes 90k)
Are there any other sports, recreational	When engaging in any physical activities
activities or cosmetic procedures that	that include the possibility of trauma or
could be harmful to me or my implant or	impact, precautions should be taken,
require special precautions?	such as wearing a protective helmet, to
	reduce the risk of damage to the internal
	device.

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. Advanced Bionics 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?	It is known that static electricity can potentially damage sensitive electronic components such as the ones used in the cochlear implant system. Care should be taken to avoid situations in which high levels of static electricity are generated. See caution information about Electrostatic Discharge (ESD) in User Guide
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.	Using or being in close vicinity to someone using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone. See warnings about Electromagnetic Radiation
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.	Using or being in close vicinity to someone using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone. See warnings about Electromagnetic Radiation Using or being in close vicinity to someone using some digital cellular
that has potential to interact with my implant , processor or accessories and are any precautions required?	someone using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone.

	See warnings about Electromagnetic Radiation
Warnings about high-voltage equipment,	To avoid interference electrical field
radar, high tension wires, smelting	strengths should be less than 3 V/m in
furnaces etc.	frequency ranges over 150 kHz to 80
	MHz.
	Note: A field strength of 1 v/m represents
	a potential difference of one volt between
	points separated by one meter. Any
	electrically charged object produces an
	electric field. This field has an effect on
	other charged objects in the vicinity. The
	field strength at a particular distance from
	an object is directly proportional to the
	electric charge on that object.
	See warnings about Electromagnetic
	Radiation above.
Warnings about electro-magnetic	See warnings about Electromagnetic
radiation.	Radiation and MRI limitations above.
Are there any other signals or systems	No official recommendations. Consult
that could be harmful to me or my	Advanced Bionics.
implant or require special precautions?	
Can you provide advice for those who	No official recommendations. Consult
are required to wear a Hard Hat in the	Advanced Bionics.
workplace?	

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. Advanced Bionics has provided the following advice:

Answer
See warnings below
See warnings about Electromagnetic
Radiation above.
Ultrasonic Sensors Ultrasonic sensors, sometimes used in lighting sensors and security systems, will not damage your implant system; however, they may be picked up by the headpiece microphone and lead to distorted sound quality when you operate your sound processor in the immediate vicinity of such a sensor. Additionally, if the ultrasonic sound is of a very high intensity, the processor system microphone may become damaged. To avoid hearing any unwanted sound, you should reduce the volume on your sound processor or remove your headpiece when passing near an ultrasonic sensor (e.g. in entrances to libraries). See User Guides
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Can my cochlear implant and	No official recommendations. Consult
accessories interact with any other	Advanced Bionics.
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.	
Can my cochlear implant and	No official recommendations. Consult
accessories interact with medical devices	Advanced Bionics.
in use by others in close proximity e.g.	
can a young CI user feed/sleep on the	
chest of an adult pacemaker user?	
Are there any situations where I should	Metal detectors, x-ray machines, and
switch-off my processor or wireless	security scanners will not damage the
technology e.g. going through airport	implant or sound processor. However, individuals with a cochlear implant should
security, on planes during take-off and	be advised that passing through security
landing, in hospital intensive care units?	metal detectors may activate the detector
	alarm. It is advised that patients carry
	their "Patient Emergency Identification
	Card" with them at all times. Cochlear
	implant users also might hear a distorted
	sound caused by the magnetic field around the security scanner door or
	hand-held scanning wand. Turning the
	sound-processor volume down before
	passing through security screening will
	ensure that those sounds, if they occur,
	are not too loud or uncomfortable.
	X-ray machines will not damage your
	sound processor or implant, but may damage your head piece or
	microphones. Avoid placing any system
	microphones in any checked or carry-on
	baggage that is screened with X-ray.
	During airport security screenings, the
	sound processor and microphone should
	be worn through the metal detector or
	examined by hand. See Cautions in User
	Guide and warnings about Electromagnetic Radiation

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 Advanced Bionics in the first instance.