Cochlear™ Nucleus® ABI541 auditory brainstem implant

Patient Information
Important: Warnings, Precautions and Electromagnetic Compatibility

United States of America

Hear now. And always

Cochlear®

Contents

Glossary

- Acoustic – Related to sound or hearing.
- Auditory – Related to hearing.
- Bilateral – Both sides of a part of the body.
- Brainstem – Stem-like part at the base of the brain, connected to the spinal cord.
- Cochlear – Relating to the cochlea, which is part of the inner ear.
- Cochlear nucleus – An auditory centre (collection of nerves) in the brainstem that receives input from the cochlear nerve. The cochlear nerve carries auditory information from the inner ear to the brain.
- Cochlear Nucleus ABI541 auditory brainstem implant system – The Cochlear Nucleus ABI541 auditory brainstem implant and sound processor including coil or cable, battery module, and Remote Assistant.
- Dysfunction – When something, such as part of the body, doesn't work properly.
- Neurofibromatosis type 2 (NF2) – Growth of benign tumours on both acoustic nerves, which are the nerves to the ears.
- Nucleus 22 ABI system – Previous Cochlear auditory brainstem implant system, before the Cochlear Nucleus ABI541 auditory brainstem implant system.
- VIIIth nerve – The auditory vestibular nerve, known as the eighth cranial nerve, transmits sound and balance information from the inner ear to the brain.

Why read this document?

Cochlear devices are designed to be safe and effective. However when using the devices it is essential you take care.

This document has important information for people with Cochlear implants, their families and carers. The information is about safe use of Cochlear Nucleus implants, sound processors, remote assistants, and remote controls.

Very important safety information about device use and medical treatments is included. Before starting any medical treatment, tell your physician you have an implant and show them *Medical procedures that can cause harm* on page 12.

This document also covers what the Cochlear implant is, how it works, and how it is implanted.

User guides and other documents are supplied with your device. Please read these documents carefully—they could also contain important safety information.

Symbols used in this document

Note

Important information or advice.

Caution (no harm)

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.

Warning (harmful)

Potential safety hazards and serious adverse reactions.

Could cause harm to person.

What is the Cochlear Nucleus ABI541 auditory brainstem implant?

Cochlear Nucleus ABI541 auditory brainstem implant systems are designed to provide useful hearing to people who have complete or partial dysfunction of the VIIIth nerve bilaterally.

The Cochlear Nucleus ABI541 system has implanted and external components.

External components

External components include a battery-operated sound processor with associated accessories and cables.

The sound processor is worn outside the ear and converts sounds into electrical signals. It is programmed to work with the implant using a Cochlear proprietary programming system.

Implanted component

The auditory brainstem implant is surgically implanted under the skin behind the ear. It includes a receiver/stimulator to receive and decode the electrical signals and an electrode array to deliver these signals to the surface of the cochlear nucleus, which is an auditory centre in the brainstem.

⚠ Caution

Federal law restricts this device to sale by or on the order of a physician.

Why doctors use the Cochlear Nucleus ABI541 auditory brainstem implant – Indications

Doctors use the Cochlear Nucleus ABI541 auditory brainstem implant to restore a level of auditory sensation by electrically stimulating the cochlear nucleus.

The auditory brainstem implant is designed for people 12 years of age or older who have been diagnosed with Neurofibromatosis Type 2 (NF2).

Implantation may occur during first or second side tumour removal, or in patients who have had acoustic tumours removed bilaterally.

Prospective implant recipients and their families should have appropriate expectations regarding the potential benefits of an auditory brainstem implant, and should be highly motivated to participate in the post-operative rehabilitation process.

Deciding whether to get a Cochlear Nucleus ABI541 auditory brainstem implant

Before deciding on implantation, you should discuss the known benefits, risks and alternatives to Cochlear Nucleus ABI541 hearing technology with your surgeon and audiologist.

Benefits

Cochlear Nucleus ABI541 auditory brainstem implant recipients may experience:

- Detection of medium to loud environmental sounds at comfortable listening levels.
- Detection of conversational speech at comfortable listening levels.

Most Cochlear Nucleus ABI541 auditory brainstem implant recipients should also experience:

- Improved perception of the rhythm and volume of speech resulting in limited improvement in speech recognition and communication ability with lip reading.
- Limited improvement in the recognition of environmental sounds.

A small number of Cochlear Nucleus ABI541 auditory brainstem implant recipients will experience:

- Improved speech recognition without lip reading.

In cases where the Cochlear Nucleus ABI541 auditory brainstem implant is not optimally placed over the cochlear nucleus structure or if the implant moves before initial activation, performance may be less than specified above. In a worst case no auditory sensations will be experienced. In such cases, recipients may choose not to use the device.

Risks

Certain risks are part of all surgery. You should discuss the known risks, benefits and alternatives to Cochlear Nucleus ABI541 hearing technology with your surgeon and audiologist.

Known limitations associated with cochlear implantation, which may also apply to the Cochlear Nucleus ABI541 auditory brainstem implant, are:

- Speech and other sounds will not sound the same as they would for a normal-hearing person, though most recipients accommodate to the sound in a relatively short period of time.
- Some people may not have sufficient auditory nerve fibres to allow successful electrical stimulation.
- Some people may not experience useful understanding of speech.

Any residual hearing in the implanted ear may be lost after receiving an auditory brainstem implant.

Cochlear Nucleus ABI541 auditory brainstem implant recipients may also:

- Experience ringing in the ears, temporary facial nerve twitching, temporary dizziness, or temporary pain caused by the implant.
- Experience sensations or movements not related to sound, such as a tickling sensation in the back of the throat, vision issues, or strange feelings and or movements in a limb.
- Experience uncomfortable loud sounds, intermittent sounds, no sound, or unwanted sensations not related to sound, caused by implant or sound processor component failures.
- Need the implant to be removed or replaced if there are implant component failures.

What happens during the implantation procedure?

Before implantation

To decide if you can get a Cochlear Nucleus ABI541 auditory brainstem implant, your hearing healthcare professional might ask you to get scans of the cochlear nucleus and brainstem.

During implantation

During implant surgery, the surgeon:

- makes an incision behind the ear,
- creates a pocket in the bone for the implant's receiver/stimulator,
- if required, removes a tumour, and,
- places the electrode on the cochlear nucleus.

You should discuss the length of your post-operative hospital stay with your surgeon as it can vary.

After implantation

To stimulate your implant you'll need an external sound processor.

After approximately six weeks of healing, you'll return to your audiologist to have your implant system activated and programmed. The audiologist will also explain how to use and care for your sound processor.

Please read:

- your Sound Processor and Remote Assistant User Guides for instructions on operation, care and maintenance of your external components.
- the rest of this guide for important safety information on how to avoid personal harm and damage to system components.

⚠ Avoiding serious harm – Warnings

This section has important warnings about personal safety. You should also refer to your external product user guides for additional warnings and cautions about those components.

Preoperative

Imaging

Before receiving a Cochlear Nucleus ABI541 auditory brainstem implant, your physician should request scans to check your cochlear nucleus and surrounding structures.

Gamma knife radiation

If you've had gamma knife radiation, your physician should request an MRI of the cochlear nucleus. This is to check the cochlear nucleus and brainstem anatomy for possible injury from the radiotherapy treatment before you receive an auditory brainstem implant.

Bilateral implantation

The effectiveness of bilateral implantation with Cochlear Nucleus ABI541 auditory brainstem implants has not been studied.

Medical procedures that can cause harm

Before any medical or surgical treatment, tell your doctor you have an auditory brainstem implant and show them this information. Some treatments that could injure you or damage your implant are listed below.

Medical treatments generating induced currents, heat and vibration

Before starting any of the treatments below, deactivate the device and remove the sound processor.

Diathermy	Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage or permanent damage to the implant. Medical diathermy using ultrasound may be used below the head and neck.
Electroconvulsive therapy	Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy can cause tissue damage or damage to the implant.
Electrosurgery	Electrosurgical instruments can induce radio frequency currents that could flow through the electrode. Do not use monopolar electrosurgical instruments on the head or neck of an implant patient as induced currents could cause tissue damage or permanent damage to the implant. When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~½ in) from the electrodes.
Ionising radiation therapy	Do not use ionising radiation therapy directly over the implant. It may cause damage to the implant.

Neurostimulation	Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage or permanent damage to the implant.
Therapeutic ultrasound	Do not use therapeutic levels of ultrasound energy directly over the implant. It may inadvertently concentrate the ultrasound field and cause tissue damage or damage to the implant.

MRI safety information

The Cochlear Nucleus ABI541 auditory brainstem implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe injury or device malfunction.

Full MRI safety information is available:

- in the *Cochlear Nucleus Implants MRI Guidelines*
- by visiting www.cochlear.us/mri
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.

Refer to the *Cochlear Nucleus Implants MRI Guidelines* for a complete list of Warnings and Cautions.

All external components of the Cochlear implant system (e.g. sound processors, remote assistants and related accessories) are MR Unsafe. The recipient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

If you have an, you can safely receive an MRI scan only under certain conditions.

What is an MRI?

Radiologists and MR technologists are medical specialists experienced in diagnosing disease and injuries using a range of imaging techniques. One of these imaging techniques is magnetic resonance imaging (MRI).

MRI is a diagnostic tool to obtain images of organs and tissues using a very powerful magnetic field measured in tesla (T). MRI scans can range in strength from 0.2 T to 7 T, with 1.5 T being the most common.

Safety concerns for medical device implants and MRI

Due to the powerful magnetic and radio-frequency fields, medical device implants with metallic or ferromagnetic components such as pacemakers, defibrillators, catheters, pumps and cochlear implants can create problems for MRI scans. The risks include the potential for device repositioning, localised heating, unusual sounds or sensations, pain or injury and distortion of the MR image.

Cochlear Nucleus implants and MRI compatibility

A Cochlear Nucleus implant is a medical treatment for moderate to profound hearing loss. Inside each Cochlear Nucleus implant is a magnet.

To ensure MRI compatibility, Cochlear Nucleus implants feature a removable magnet. The magnet is easy to remove and replace if needed. In the rare case that a recipient needs serial MRI scans, a non-magnetic plug is available to prevent fibrous tissue growing in the implant magnet recess.

Cochlear Nucleus implants are approved for MRI scans under specific conditions at 1.5 T with the magnet in place and at 3 T with the magnet removed.

Meningitis

Before implantation, ask your primary-care physician and implanting surgeon about your vaccination status against micro-organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and you should be appropriately counselled of this risk.

Other pre-operative conditions may increase the risk of meningitis, with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture or defect with CSF communication.

Head trauma

A blow to the head in the area of the implant may damage the implant and result in its failure. For recommendations on how to minimise the chance of experiencing head trauma see https://www.cdc.gov/traumaticbraininjury/prevention.html

Electrical stimulation – long term effects

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown. There is no long-term data available on the effects of electrical stimulation on hearing sensitivity.

Sound processor

Sound processors not programmed for the implant

Only use the sound processor programmed for your ABI541 auditory brainstem implant. Using a sound processor programmed for another recipient, or a sound processor programmed for any implant type used on a different ear, could cause undesirable effects, such as disturbing your heart rhythm.

Small parts

Caregivers should be counselled that the external sound processor contains small parts that may be hazardous if swallowed or may cause choking if ingested or inhaled.

Batteries and battery chargers

Battery use and ingestion

When using disposable batteries with the sound processor, only use battery types recommended by your clinician or Cochlear. Other types may not have enough energy to allow your processor to operate for a long time.

Cochlear does not recommend the use of silver oxide or alkaline batteries.

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If batteries are swallowed, seek prompt medical attention at the nearest emergency centre.

Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician.

Caregivers should touch the recipient's processor to check for heat if the recipient is showing signs of discomfort.

Rechargeable batteries should NEVER be worn beneath clothing, including scarves and headwear covering the ears.

The rechargeable battery should not be used by patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

Overheating

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Caregivers should touch the processor to check for heat if the recipient is showing signs of discomfort.

The manufacturer recommends only the use of Cochlear rechargeable battery modules and zinc air disposable batteries.

Silver oxide batteries should **not** be used with your processor. In some circumstances, use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device.

Also, use of silver oxide batteries may damage your processor.

Sleeping

Do not wear your processor while sleeping, as you may not become aware of it becoming unusually warm or hot.

Pressure

Do not apply continued pressure to the coil when in contact with the skin as this may result in pressure sores. For example, sleeping or lying on the coil, or wearing tight fitting headwear.

If the coil magnet is too strong or is in contact with the skin, pressure sores may develop at the coil site. If this happens or if you experience any discomfort in this area, contact your clinician.

Uncomfortable sound levels

If the sound becomes uncomfortable, remove your external equipment immediately (processor, coil, monitor earphones, acoustic component) and contact your clinician.

If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, could cause extreme discomfort.

Adverse environments

Operation of your auditory brainstem implant system could be adversely affected in environments of high magnetic field strength and high electric field strengths, e.g. close to high power commercial radio transmitters.

Seek medical advice before entering any environment that may adversely affect the operation of your auditory brainstem implant, including areas with a warning notice preventing entry by patients fitted with a pacemaker.

⚠ Avoiding other harm – Cautions

This section includes information about safe and effective use of your auditory brainstem implant system, and how to avoid damaging components.

General use

- Use your auditory brainstem implant system only with approved devices and accessories listed in the Sound Processor User Guide.
- If you experience a significant change in performance, turn off your processor and contact your implant centre.
- Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- No modification of external equipment is allowed. If your processor is modified or opened by anyone other than Cochlear's qualified service personnel, the warranty is invalid.

Sound processor

- Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another person. Using the wrong processor could result in loud or distorted sounds that may cause extreme discomfort.
- Do not operate your processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).
- Do not store your processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).
- Your processor's sound quality may be intermittently distorted when you are approximately 1.6 km or 1 mile from a radio or television transmission tower.

  Additional sources of interference include, but are not limited to:

  – Security systems
  – Industrial machinery and power systems
  – Mobile communications equipment, including cellular telephones and certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

  To reduce or stop interference, move away from the source. If your processor stops working, turn the power switch off and then back on. The effect is temporary and will not damage your processor.

Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some implant recipients may experience distorted sound sensation when passing through or near these devices. To avoid distortion, turn off your processor when near one of these devices.

If you are passing through or near a metal detector or a theft detection system, you should keep sound processors at least 20 cm (0.66 ft) away from the detection devices of these systems.

The materials used in the implant may activate metal detection systems. For this reason, always carry your Cochlear Implant Patient Identification Card with you.

Mobile telephones

Some types of digital mobile telephones may interfere with the operation of external equipment, such as Global System for Mobile communications (GSM) as used in some countries. You may perceive a distorted sound sensation when within 1–4 m (~3–12 ft) of a digital mobile telephone in use.

Scuba diving

Implant Type	Maximum depth
ABI541 implant	40 m (~131 ft)

Table 1: Maximum diving depths when wearing implants

The sound processor must be removed before diving. You should seek medical advice for conditions that might contraindicate diving, such as middle ear infection. When wearing a mask, avoid pressure over the implant site.

Air travel

Transmitting devices such as mobile or cell phones sometimes need to be switched off on aircraft. If you have a remote control (Remote Assistant) for your processor, check with the airline if you can use it. Your remote transmits high frequency radio waves so it might need to be switched off. You can wear your sound processor.

Retention aids

When using retention aids such as the Snugfit™ or LiteWear, it may take longer to remove the processor if it becomes unusually warm or hot.

Do not attach the LiteWear beneath layers of clothing.

Electrostatic discharge (ESD)

Remove the processor before engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides. In rare cases, a discharge of static electricity can damage the electrical components of the auditory brainstem implant system or corrupt the program in the processor.

If static electricity is present (for example when removing or putting on clothes over your head, or getting out of a vehicle), before the auditory brainstem implant system contacts any object or person you should touch something conductive, such as a metal door handle.

Electromagnetic interference with medical devices

Cochlear Nucleus Remote Assistants meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the Remote Assistant radiates electromagnetic energy it could interfere with other medical devices, such as cardiac pacemakers and implantable defibrillators, when used nearby.

The Remote Assistant should be kept at least 6 in (~15.2 cm) away from devices that could receive electromagnetic interference. For added assurance, please also check the recommendations of the device manufacturer.

Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration

The Cochlear Nucleus Series Sound Processor and Remote Assistant are intended for use in the electromagnetic environments specified in this document.

They have been tested and found to be in compliance as shown. You should take care to use your processor as described.

Electromagnetic emissions

<table>
<tr><th>Emission test</th><th>Compliance</th><th>Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>RF energy is only used for its internal function. The RF emissions are very low and not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td rowspan="2">Not applicable</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td></tr>
</table>

Table 2: Electromagnetic emissions

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	See ***Electrostatic discharge (ESD)*** on page 23.
Electrical fast transient/burst IEC 61000-4-4	Not applicable		
Surge IEC 61000-4-5			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	Not applicable 3 V/m 80 MHz to 2.5 GHz	3 V/m	See the ***Warnings*** and ***Cautions*** sections, and ***Guidance*** on page 26.

Table 3: Electromagnetic immunity

Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance (d):

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

Note

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Explanatory notes:

a. Field strengths from fixed transmitters, such as base stations for radio (cellular or cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the processor is used exceeds the applicable RF compliance level above, the processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the processor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

Your processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled.

To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23

Table 4: Recommended separation distances

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

How we studied auditory brainstem implants

The clinical study results below reflect clinical trials conducted with the Nucleus 22 ABI system.

Clinical results

The effectiveness of the auditory brainstem device, programmed to implement the SPEAK speech processing strategy, was assessed in 60 recipients of the Nucleus 22 ABI system following three to six months of device use. Effectiveness was measured using a standard battery of recorded audiological tests, including measures of environmental sound identification, closed and open set speech perception, and lipreading enhancement.

The environmental sounds and speech perception tests were administered to subjects in quiet, at 70 dB SPL. For each of these sound-alone tests, individual subject results were compared to chance performance levels using a binomial statistical model.

Lipreading enhancement was assessed using medially placed vowels, consonants and CUNY sentence materials.

Using the binomial statistic, each subject's performance in the vision alone condition was compared to his or her performance when lipreading was supplemented with sound from the Nucleus 22 ABI.

As a final measure of effectiveness, 44 of the 60 subjects (73%) completed and returned postoperative questionnaires regarding device-related benefits.

Effective auditory stimulation

- Eighty-two percent of the implanted subjects were able to perceive sound and use the device postoperatively.

Identification of environmental sounds

- Eighty-two percent of the subjects scored significantly above chance on a recorded, closed set test of environmental sound identification.
- Using the device, subjects recognised 53.9% of common environmental sounds, on average, and 65% of the sample recognised 50% or more of the sounds.

Lipreading enhancement

- Eighty-five percent of the subjects demonstrated statistically significant improvements in open set sentence understanding, when using the device in conjunction with lipreading.
- The average sentence recognition score improved from 31.2% for lipreading alone, to 53.5% when subjects combined auditory information from the device with lipreading.

Open set sentence recognition

- Using sound alone, 12% of study participants scored greater than 10% on a difficult open set test of sentence understanding.

Questionnaire results

- Sixty-one percent of the subjects who received the device following removal of their second-side tumour reported using the device on a daily basis for ten or more hours.
- Eighty percent of the respondents reported receiving benefit from the auditory brainstem implant and 84% indicated that the decision to get the device was the right one.
- Seventy-three percent of the respondents would recommend a Nucleus 22 ABI system to others.

Individualisation of treatment

Patient selection criteria

1. Diagnosis of Neurofibromatosis Type 2 (NF2).
2. First-side or second-side acoustic tumour removal required (or previous bilateral tumour removal).
3. Twelve (12) years of age or older.
4. Psychologically and motivationally suitable.

Clinical considerations

In order to place the electrode array on the surface of the cochlear nucleus, the surgeon must be able to visualise specific anatomical landmarks. Because many NF2 patients have large tumours that compress the brainstem and distort the underlying anatomy, it may be difficult or impossible for the surgeon to correctly place the array. For this reason, patients with large, long-standing tumours may not benefit from the device after surgery. In this series of patients, 16 of the 90 recipients (17.8%) were unable to use the system due to misplacement or migration of the electrode array.

Patients who receive the device when their first tumour is removed and who have usable hearing in the other ear are unlikely to use the device on a regular basis. Most often, these recipients start full-time use of the device after the surgical removal of their second-side tumour.

Where you can find more information

For additional information concerning Cochlear Americas and the Cochlear Nucleus ABI541 auditory brainstem implant, visit Cochlear's website at www.cochlear.com or call 1 800 523 5798.

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