

Surgical Guideline

Mi1000 CONCERTO ABI

Mi1000 CONCERTO PIN ABI



hearLIFE

Introduction

The MED-EL CONCERTO/CONCERTO PIN Auditory Brainstem Implant System serves to restore some sense of hearing by electrical stimulation of the cochlear nucleus (CN). It is the result of many years of research and is intended for use in patients with non-functional cochlear nerves.

This Surgical Guideline describes proper techniques for implanting the Mi1000 CONCERTO/CONCERTO PIN Auditory Brainstem Implant (ABI) (hereafter referred to as the CONCERTO/CONCERTO PIN ABI). It serves as additional information for professionals and should not be used as an "Instructions for Use".

MED-EL implants are manufactured to the highest quality standards in order to ensure long term reliability. All materials used in the implant have been rigorously tested for biocompatibility, durability and reliability. MED-EL applies a quality management system that meets all EN ISO 13485:2003 requirements and complies with US Quality System Regulations and Canadian Medical Device regulations (CAN/CSA ISO 13485-2003). Components of the MED-EL Cochlear Implant System meet the requirements for AIMD 90/385/EEC and MDD 93/42/EEC.

The information in this Surgical Guideline is believed to be true and correct, however, some specifications may be subject to change without notice.

For country specific information please see the applicable "Instruction for Use" delivered with the implant system.

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I. Patient selection and evaluation

Indication

The CONCERTO/CONCERTO PIN ABI is used for electrical stimulation of the cochlear nucleus (CN) via an implanted stimulator and a specially designed electrode array to evoke auditory sensations in patients with non-functional cochlear nerves. Likely cause of damage may include trauma, inflammation or in most cases the degeneration of the cochlear nerve, e.g. related to a bilateral acoustic neurinoma (Neurofibromatosis 2 - NF2).

deformation caused by such irradiation. Large structural deformation may prevent proper ABI placement and should be evaluated by the surgeon. Before surgery, the patient must be informed about the function of the implant, the risks of surgery and implantation, realistic expectations and rehabilitation plans after surgery. A personal conversation between patient and surgeon should help the patient to gain a general idea about the device and to estimate risks and benefits of the Implant CONCERTO/CONCERTO PIN ABI.

Selection and Evaluation

If patients suffering from NF2, it is the responsibility of the surgeon to determine for each patient if implantation of the device during tumor removal surgery is appropriate. Most NF2 patients also suffer from multiple tumor formations in the spine. The personal situation of these patients may therefore be very difficult and critical.

This device is to be used by surgeons who have been trained in the surgical placement of an Auditory Brainstem Implant.

Patients who are selected for an ABI implantation should have a stable psychological status and be willing to learn to use the ABI system. To obtain the optimal benefit from the implant, candidates must be sufficiently motivated and must understand the importance of returning to the implant center for regular audio processor programming, training, and assessment sessions. Preoperative psychological tests shall be performed. In addition to the mental condition of the patient, the physical condition shall also be assessed for an implantation. Tumor size and cochlear nerve condition should be assessed preoperatively either by performing MRI and/or CT scanning and electrophysiological measurements (ABR, EABR, eCochG). Also a preoperative spinal MRI is essential. Experienced Neuro- and ENT-surgeons shall decide in accordance with the test results and their own personal experience if a patient is a suitable candidate for an ABI implantation.

If previous irradiation of the tumor has taken place, the patient's evaluation should include possible structural

II. Technical description of the ABI System

The CONCERTO/CONCERTO PIN ABI is the implantable part of the MED-EL Cochlear Implant System and can only be used together with compatible MED-EL external components.

The device consists of a stimulator, a coil with a magnet within its centre, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. This device is intended to be implanted by adequately trained and experienced surgeons only.

The CONCERTO/CONCERTO PIN ABI has been designed according to the highest safety and reliability standards. All materials used in the construction of the CONCERTO/CONCERTO PIN ABI have been extensively tested for biological compatibility and durability. The power required by the implant is transmitted from the external audio processor through the intact skin via an inductive link. The implant therefore contains no batteries or other components that require replacement.

The implant offers a stimulation mode and a telemetry mode. Stimulation sequences of biphasic and triphasic pulses can be delivered sequentially or simultaneously on two or more channels. In telemetry mode the device allows a functional check about the technical status of the implant including communication over the transcutaneous link as well as the assessment of the electrode impedances and recording of the electrically evoked compound action potential of the hearing nerve.

The electronics of the CONCERTO/CONCERTO PIN ABI contain a powerful custom-made circuit that is capable of processing large amounts of information at a very rapid rate. It can stimulate at 50,704 pulses per second. This capability makes the implant compatible with a wide range of pulsatile processing strategies and future developments in speech processing. A telemetry feature enables the clinic to verify the functional status of the implant within a matter of seconds. For added safety, each output has a capacitor to prevent any possible leakage of DC current to the auditory nerve.

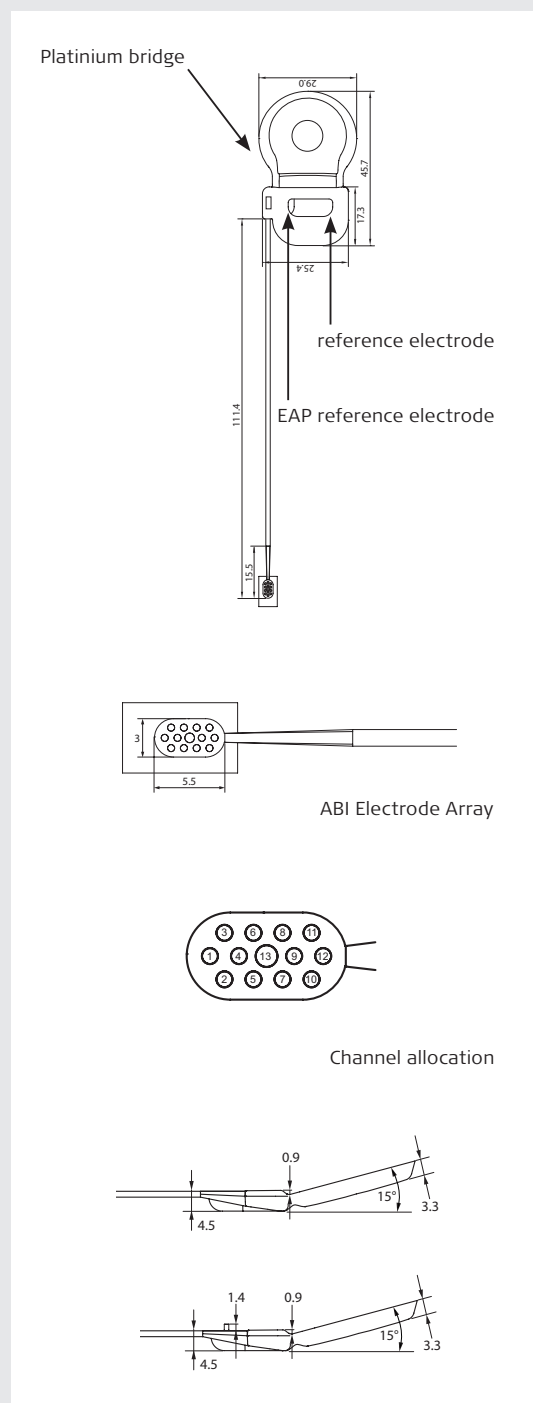


Figure 1 Implant CONCERTO/CONCERTO PIN ABI
(~ dimensions in mm, typical values)

Performance Characteristics

- Output characteristics of a stimulation signal on a 1 kOhm resistor:
Maximum current amplitude:
Median value = 1250 μ A, range = 500 μ A
Maximum pulse width:
Median value = 203.8 μ s, range = 8.2 μ s
- The impedance measurement accuracy is typically better than 5%.
- When keeping to the safety guidelines the implant is conditionally MRI safe for MR scanner field strengths of 0.2 Tesla, 1.0 Tesla and 1.5 Tesla.
- There are no default factory settings of the implant system.
- Proper functioning of the implantable part of the CI system can be checked by performing telemetry (refer to MED-EL application software user manual).
- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The implant has a mass of 7.6g (typical value).
- The volume of the implant without electrode is 3.7 cm³.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires and nitinol.
- All electrode variants have a straight and flexible design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm².
- Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium.

ABI Active Electrode

Order number CONCERTO ABI 07675

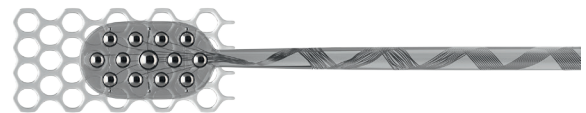
Order number CONCERTO PIN ABI 07681

The ABI Active Electrode has an oval shaped flat silicone paddle (electrode array) with 12 active contacts and 1 reference contact. A polyester mesh embedded in silicone exceeds the size of the silicone paddle. This paddle is slightly pre-shaped to fit onto the curved brain surface.

An additional contact is placed in the center of the silicone paddle to allow bipolar stimulation mode during intraoperative measurement. The diameter of the electrode lead increases from \approx 0.7 mm at the silicone paddle to \approx 1.3 mm over a length of \approx 10 mm.

Designed Especially for Neurofibromatosis Type II

ABI is a solution for individuals with hearing loss due to a non-functioning auditory nerve (Neurofibromatosis Type II). Bypassing both the inner ear and the auditory nerve, the MED-EL ABI stimulates the cochlear nucleus (CN) and provides users with a variety of hearing sensations to assist with sound awareness and communication.



ABI Electrode Array

Featuring 12 contacts arranged on a soft, pre-shaped silicone paddle.

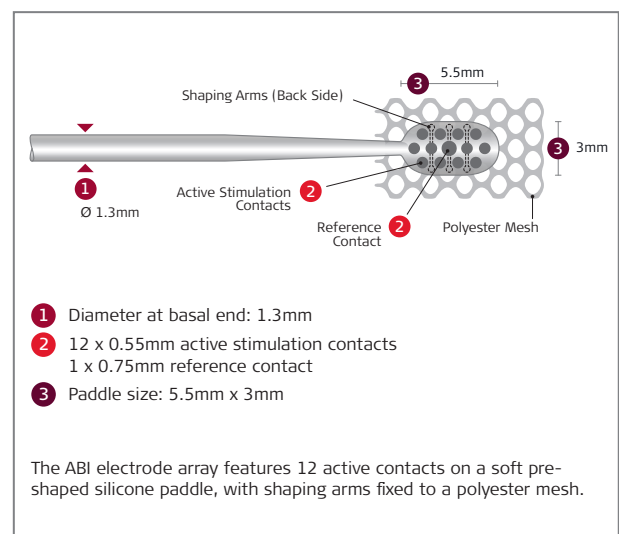


Figure 2 ABI Electrode Array (~ dimensions in mm, typical values)

ABI Placing System

CAUTION

For detailed information on the ABI Placing System, MED-EL hardware interface system and MED-EL application software please refer to the applicable instruction for use and user manual.

The ABI Placing System for the Implant CONCERTO/ CONCERTO PIN ABI is designed exclusively for transient intraoperative stimulation of the cochlear nucleus. During stimulation of the cochlear nucleus, Electrical Evoked Auditory Brainstem Responses (EABR) shall be recorded, to estimate the best position for the ABI electrode array.

The ABI Placing System consists of:

- ABI Placing Electrode
- ABI Connector Cable
- ABI Stimulator Box

ABI Placing Electrode

The electrode array and the lead of the ABI Placing Electrode have the same dimensions as the CONCERTO/ CONCERTO PIN ABI electrode array. The paddle has only 4 electrode contacts instead of 12 + 1 and there is no polyester mesh. The Micro-D Plug is the connective part of the ABI Placing Electrode and shall be connected to the ABI Connector Cable (see section IV Set-up and recommended measurement for EABR recording).

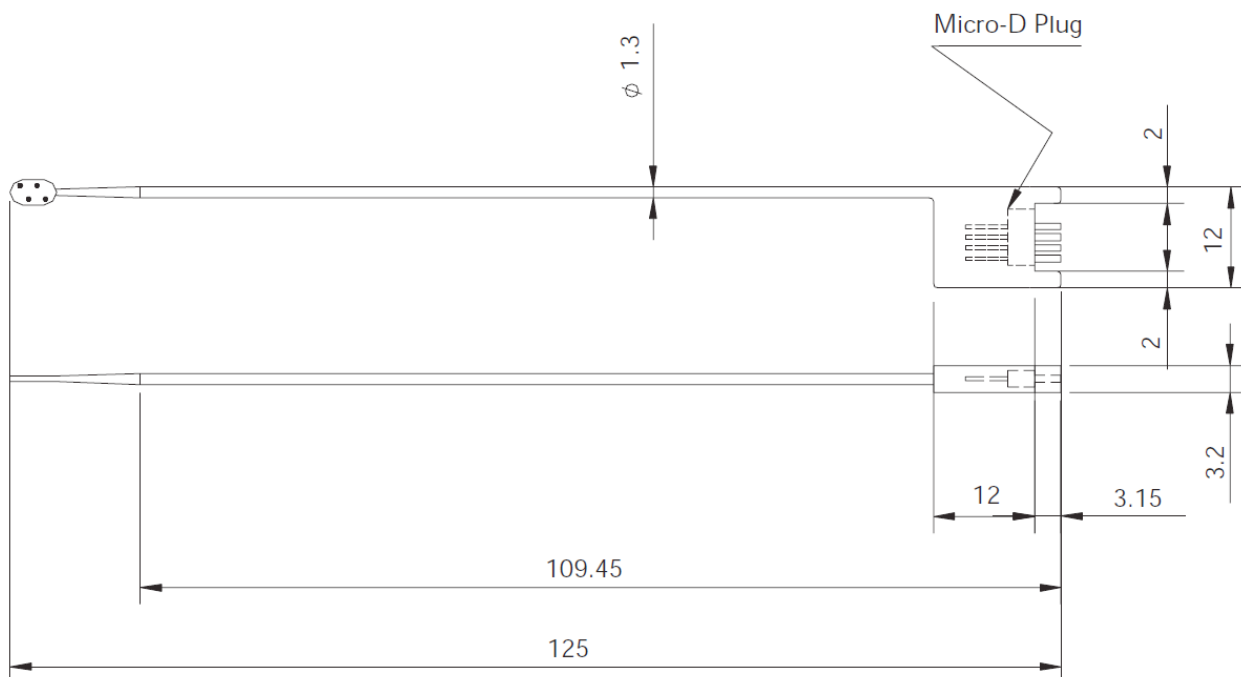


Figure 3 ABI Placing Electrode (~ dimensions in mm, typical values)

ABI Connector Cable

The ABI Connector Cable is designed to transfer stimulation pulses from the ABI Stimulator Box to the ABI Placing Electrode. The length of the cable is ≈ 2 m so that it can lead out of the patient's environment. The connector on the left side of the ABI Connector Cable (see Figure 4) shall be connected to the ABI Placing Electrode (Micro-D Plug). The connector on the right side of the ABI Connector Cable (see Figure 4) shall be connected to the ABI Stimulator Box (see Figure 5).

ABI Stimulator Box

Pre-use check of the ABI Stimulator Box

CAUTION

Do not use an ABI Stimulator Box for intra-operative stimulation if the ABI Stimulator Box is not functioning correctly.

The ABI Stimulator Box generates biphasic stimulation pulses controlled by the MED-EL hardware interface system via the coil placed on the ABI Stimulator Box. The selector switch (see Figure 5) allows easy selection of the electrode configuration at the ABI Placing Electrode which is used for bipolar stimulation during EABR measurements.

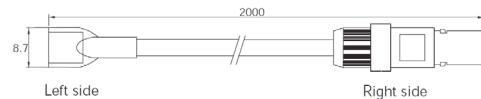


Figure 4 ABI Connector Cable

(~ dimensions in mm, typical values)

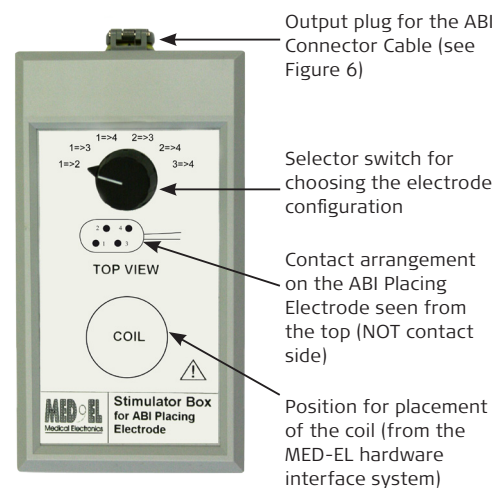


Figure 5 ABI Stimulator Box



Figure 6 ABI Stimulator Box

Prior to the use of the ABI Placing System, a pre-use check shall be performed with the ABI Stimulator Box.

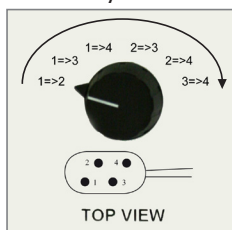
Note: Only personnel trained on the use of the MED-EL telemetry system shall perform the pre-use check.

The following steps shall be followed when performing the pre-use check:

Setup of measurement

Connect the ABI Stimulator Box Test Device to the ABI Stimulator Box.

Telemetry



Start the telemetry measurements at the selector switch configuration 1=>2 and proceed clockwise.

Note: The impedance measured at switch position 1=>2 shall be lower than the impedance measured at switch position 1=>3. All subsequently measured impedance values shall be lower than the values measured at the switch position before.

Acceptance criteria

The difference of the measured impedance values between each step shall be greater than 0.4 k Ω . All measured values shall lie between 1.5 k Ω and 9 k Ω . If the measured values fulfill the acceptance criteria the ABI Stimulator Box can be used for intra-operative stimulation together with ABI Placing Electrode and the ABI Connector Cable.

Note: Only the impedance value measured at Channel 1 shall be used as information for the pre use check. All other channels show HI (High impedance) as measured values.

If the measured values do not fulfill the requirements please return the ABI Stimulator Box to MED-EL for maintenance.

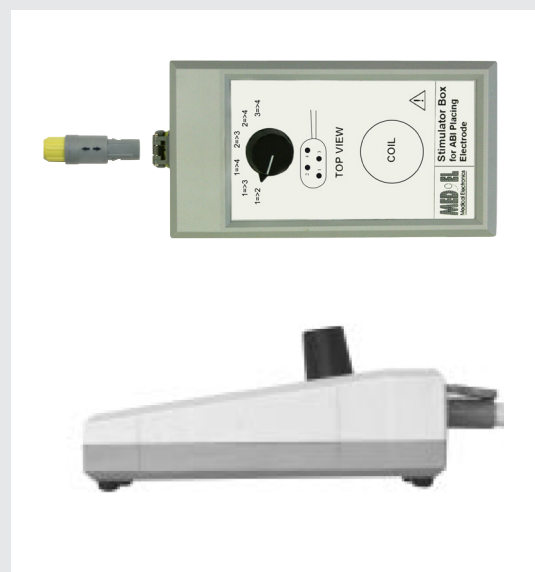


Figure 7 Correct connection of the ABI Stimulator Box Test Device to the ABI Stimulator Box

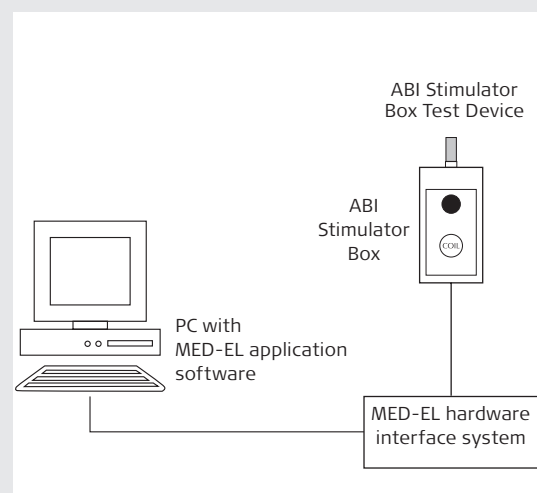


Figure 8 Set up of Telemetry System

III. Set-up and recommended measurement for EABR recording

Set-up for ABI Placing System

Before starting the measurement, the ABI Placing Electrode shall be connected to the ABI Connector Cable via the Micro-D Plug (see Figure 9 for correct connection).

Note: Make sure that the connection is as shown in Figure 10.

The ABI Connector Cable shall lead out of the immediate patient environment and shall be connected to the ABI Stimulator Box (used for ABI Placing Electrode only). The ABI Stimulator Box is driven via an inductive link by the MED-EL hardware interface system, which triggers the EABR measurement system. It is also possible that the EABR measurement system triggers the MED-EL hardware interface system.

Note: The integrity of the electrical pathway between the ABI Placing Electrode, ABI Connector Cable and the ABI Stimulator Box (and the functioning of the ABI Stimulator Box) shall be checked before starting the EABR measurement with a telemetry measurement of channel one. This measurement shall be done with the selector switch position 1-2 and 3-4. Make sure that the ABI Placing Electrode is inserted into the lateral recess.

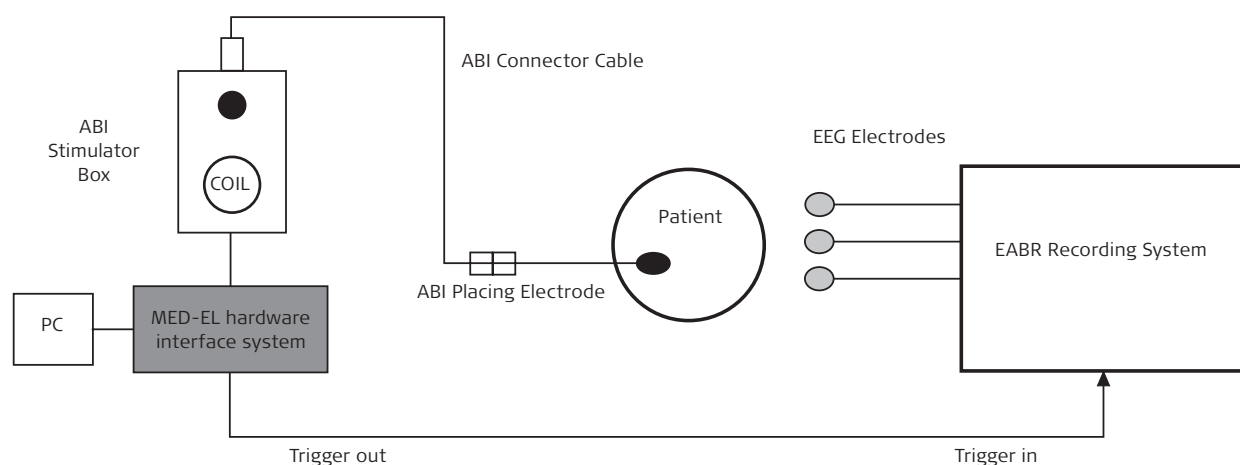
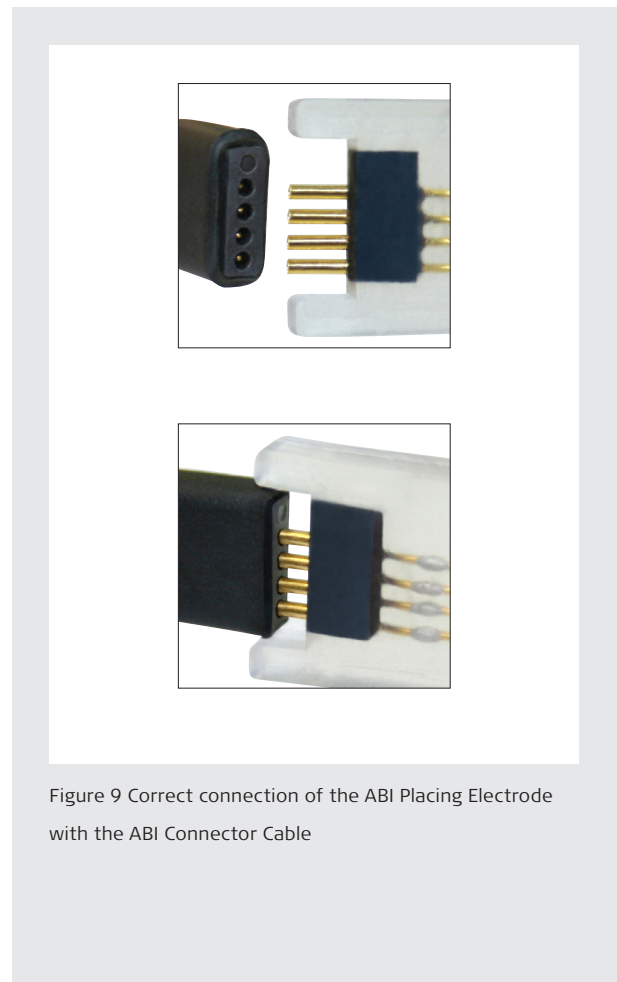


Figure 10 Setup for EABR recording with ABI Placing System

Set-up for CONCERTO/CONCERTO PIN ABI System

CAUTION

Prior the EABR measurement impedance telemetry should be performed.

For the EABR set-up using CONCERTO/CONCERTO PIN ABI system, the coil from the MED-EL hardware interface system is directly placed on the CONCERTO/CONCERTO PIN ABI implant (Figure 11). Before starting the measurement, the ABI Electrode shall be placed on the brainstem.

Recommended measurement for EABR recording

EEG – Electrode Placement

Before surgery, EEG-Electrodes are placed on the contralateral mastoid (negative), on the vertex (positive) and on the lower forehead (ground). These electrodes are connected during surgery to the EABR recording system. Try to avoid placing any two electrodes too close together.

Impedance of EEG-Electrodes

The impedance of any recording electrode should be less than 2 k Ω . There should be no greater difference between the individual electrode impedance less than 2 k Ω .

General set-up of the EABR measurement system

Window:	10 ms
Points:	256
Gain:	20,000 - 50,000
Hi filter:	3000 Hz
Lo filter:	30 – 100 Hz
Sweep:	200 – 1500
Trigger:	external (MED-EL hardware interface system triggers the EABR measurement system)

Note: It is also possible that the EABR measurement system triggers the MED-EL hardware interface systems (internal).

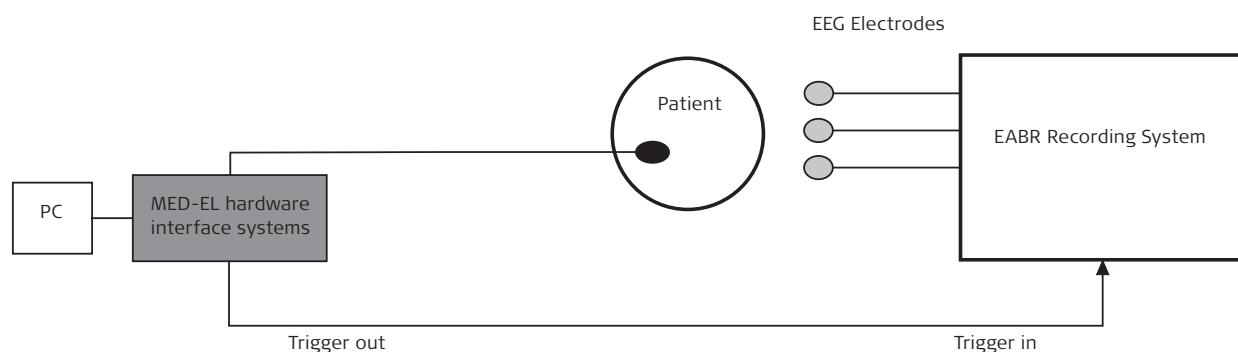


Figure 11 Setup for EABR recording with CONCERTO/CONCERTO PIN ABI implant.

Using the MED-EL application software EABR Task

Channel selection for ABI Placing System

Select channel 1 for stimulation during intraoperative measurement.

Note: The selection of the active contact pair at the ABI Placing Electrode is made with the selector switch of the ABI Stimulator Box. The selected stimulation configuration (1-2, 1-3, 1-4, 2-3, 2-4, 3-4) can be chosen via the selector switch. The selected stimulation configuration shall not be changed during stimulation in order not to influence the measured EABR curves.

Stimulation parameters

The stimulation parameters are set via the MED-EL application software.

Note: This setting shall be done by trained personnel only. The measurement typically starts with an electrode configuration of 1-4 selected with the ABI Stimulator Box. The stimulation parameters are set to pulse duration of 30 μ s/phase and a stimulation current of 300 cu (current units).

Note: The following limits shall not be exceeded:

- 1000 cu
- 150 μ s

Extended setup

For EABR recording, single stimulus pulses are used. Alternating pulses can be used to reduce the stimulus artifact. Leave the HF signal turned on. Stimulation rate: between 10 Hz and 35 Hz

EABR curve

Wave III generated at the cochlear nucleus is normally overlapped by the stimulus artifact during EABR recording. Waves IV and V become visible at a latency of 1 to 2 ms.

Note: Figure 12 shows a theoretical recording. During intraoperative EABR measurements only one wave (IV or V) is visible (at the recording monitor).

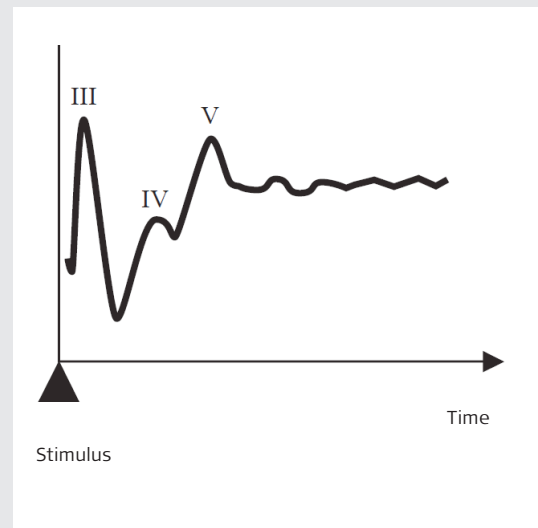


Figure 12 Theoretical EABR recording (stimulation of the cochlear nucleus – Waring 1993)

IV. Surgical tools

Note that the surgical tools supplied by MED-EL should not be modified in any way. Modification of any of the tools is done at the surgeon’s own risk.

Detailed instruction of the reprocessing process and the individual preparation before cleaning the tools can be found in the appropriate Instruction for Use.

This is a collection of tools for implantation of the CONCERTO/CONCERTO PIN ABI Implant.

	Order number:
Mi1000 Implant Template, PIN	Shipped with the implant
PIN Drill Guide SI	09906
Processor Template	01557
Skin Flap Gauge 6	03543
Surgical Claw Angled	00284
Micro Forceps Angled	05761, 05777, 05778

Mi1000 Implant Template

Mi1000 Implant Template, PIN

Shipped with the implant

This template is used to assess the size and the position of the implant on the skull.

This tool is delivered in a sterile packaging and is a single-use device only.



Figure 13 Mi1000 Implant Template
Mi1000 Implant Template, PIN

PIN Drill Guide SI

Order Number: 09906

The PIN Drill Guide SI is a re-usable surgical instrument for creation of defined holes on the skull for the fixation pins of the CONCERTO PIN Cochlear Implant. It consists of a PIN Drilling Template made of titanium and a Clamping Handle made of stainless chomate steel. The device is especially recommended for surgeons using a small incision.

This tool is a re-usable surgical instrument for transient use. The device is delivered non-sterile.

Processor Template

Order number: 01557

The Processor Template (TEMPO+/OPUS template) shows the minimum spacing which must remain free behind the ear so that the external coil and the BTE Audio Processor do not interfere with each other when worn by the patient post-operatively.

This tool is a re-usable surgical instrument for transient use made from medical grade stainless steel. The device is delivered non-sterile.

Skin Flap Gauge 6

Order number: 03543

Skin Flap Gauge 6 is used to evaluate the thickness of the skin flap in the area covering the cochlear implant. A skin flap thickness of 6 mm or less is recommended for a good magnetic hold and optimal signal transmission. Skin flaps thicker than 6 mm should be thinned out.

This tool is a re-usable surgical instrument for transient use made from medical grade stainless steel. The device is delivered non-sterile.



Figure 14 PIN Drill Guide SI



Figure 15 Processor Template (TEMPO+/OPUS template)



Figure 16 Skin Flap Gauge 6

Micro Forceps Angled

Order number: 05761 right- & left-angled
05777 right-angled
05778 left-angled

The Micro Forceps left angled and the Micro Forceps right angled are used to grip, hold and insert the electrode without damaging it. Which kind of angled Micro Forceps is used to insert the electrode depends on the preference of the surgeon. In the closed position, the tips of the forceps are parallel to each other, separated by a distance of 0.25 mm.

This tool is a re-usable surgical instrument for transient use made from medical grade stainless steel. The device is delivered non-sterile.

Surgical Claw Angled

Order number: 00284

The claw can help to position and manoeuvre the electrode.

This tool is a re-usable surgical instrument for transient use made from medical grade stainless steel. The device is delivered non-sterile.



Figure 17 Micro Forceps right angled,
Micro Forceps left angled



Figure 18 Surgical Claw

The following tools are additions to the surgical kit and may be ordered separately:

Surgical Claw Straight

Order number: 07711

The Surgical Claw can help to position and insert the electrode array into the cochlea. The tip of this instrument is straight.

This tool is a re-usable surgical instrument made from medical grade stainless steel. The device is delivered non-sterile.



Figure 19 Surgical Claw Straight

Mi1000 PIN Drill Guide

Order number: 07613

Consisting of:

Mi1000 PIN Stimulator Template: 07748

The Mi1000 PIN Drill Guide is a re-usable surgical instrument for creation of defined holes in the skull for the pins of MED-EL hearing implant housing variants with pins. It consists of a Mi1000 PIN Stimulator Template made of titanium and a Clamping Handle made of stainless chromate steel. The device is delivered non-sterile.



Figure 20 Mi1000 PIN Drill Guide

FENTEXmedical Forceps

FENTEXmedical GmbH is specialized in the development, manufacturing and marketing of surgical instruments and visualization systems for ENT, Head & Neck and Facial Surgery.

Basic description of the device:

CI Electrode Insertion Forceps L=155 mm, with longitudinal groove, for electrodes with a basal diameter in the range 0.8 – 1.3 mm

FENTEXmedical forceps have been successfully tested at headquarters with all MED-EL electrode arrays. This surgical tool is no MED-EL product and may therefore be ordered directly at your local FENTEXmedical distributor.

<http://www.fentexmedical.com/>



Figure 21 FENTEXmedical Forceps

AESCULAP Micro Forceps, bayonet-shaped

It is recommended to use a micro forceps (bayonet-shaped, 200 mm long and with rounded edges at the tip with a width of 0.6 mm) during placement of the ABI electrode array and the ABI Placing Electrode to protect the leads of the electrodes against damage. This is a standard surgical tool for brain surgery.

This tool is a re-usable surgical instrument made from medical grade stainless steel. The device is delivered non-sterile.

Supplier:

AESCULAP AG & CO. KG
Am AESCULAP-Platz
D-78532 Tuttlingen
Germany

Technical Data:

Micro forceps, bayonet-shaped
Yasargil profile handles
200 mm long
Width at the tip 0.6 mm (rounded edges)



Figure 22 AESCULAP Micro Forceps, bayonet-shaped

V. General remarks about the surgery

The implant is fixed in a bed drilled in the mastoid, and the ABI electrode array is inserted into the lateral recess [LR] of the IV. ventricle. The implant position should maximize the available electrode lead.

Surgical notes

- (a) Sterility of the Implant CONCERTO/CONCERTO PIN ABI, the ABI Placing Electrode and the ABI Connector Cable must be ensured at all times.
- (b) Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated. The surgeon should prescribe adequate dosing for each patient's condition.
- (c) The CONCERTO/CONCERTO PIN ABI electrode array shall be inserted into the lateral recess without compressing the electrode lead or touching the electrode contacts.
- (d) Only MED-EL approved and recommended surgical instruments should be used during the insertion process, other instruments (probes, hooks, forceps, tweezers, etc.) can damage the electrode or the other parts of the device. The implant contains a strong magnet. Never use magnetic surgical tools.
- (e) The stimulator shall be securely anchored in a bed drilled in the mastoid bone and the electrode lead protected in a bony channel without sharp edges in such a way that there will be no postoperative movement. Movement results in fatigue and possible subsequent failure of electrical connections.
- (f) Uni- or monopolar diathermy may not be used after the implant is introduced into the surgical field as it may cause damage to the implant.
- (g) The implant must never be dropped onto a hard surface; damage to the stimulator or electrodes during the operation will invalidate the warranty.
- (h) The serial number of the implant must be visible on the implant before fixing it in place.
- (i) Other risks after surgery may be avoided by following the instructions in the applicable MED-EL CONCERTO/CONCERTO PIN ABI instruction for use.
- (j) In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6mm.
- (k) Do not place the sutures directly over the electrode lead.

VI. Surgical procedure

General information

In general, an ABI implantation is performed as a procedure for restoration of sound perception of NF2 patients immediately after resection of an acoustic neuroma. Patients with other lesions involving the cochlear nerve and causing massive hearing impairment up to deafness may also be candidates.

For the resection of an acoustic neuroma, which is the main indication for receiving an ABI, it is recommended to use the semi-sitting position of the patient as a result of clinical experience. The head is fixed in a Mayfield clamp and rotated approximately 30° to the affected side. This rotation is necessary for a direct approach to the dorsal side of the petrous bone, and, in addition, the opening of the lateral recess rotates towards the surgeon, so that access is facilitated.

The reported advantage of this semi-sitting position is an intraoperatively well-balanced blood circulation in the body of the patient. Therefore, the blood pressure in the venous vessels of the head decreases which is advantageous to the surgical procedure. It is also possible to perform this surgery with the patient in a horizontal position, but it is not recommended here.

Intensive intraoperative monitoring is necessary during acoustic neuroma surgery and implantation of the ABI to control and protect nerve structures in and around the brainstem. Cochlea-vestibular (VIII.), facial (VII.) and caudal cranial (IX., X.) nerve structures should be monitored during surgery. Electrodes for measuring the nerve potentials are fixed on the patient before starting the surgery. The anesthetist shall be familiar with the monitoring, detection and management of air embolism and should also be familiar with anaesthetics connected with electrophysiological measurements.

The use of electrosurgery in ABI patients due to further tumor removal surgeries is likely. If an electroscalpel is used in close proximity of the CONCERTO/CONCERTO PIN ABI electrode, the electrode could be damaged by the electrical current and cause a system failure. The surgeon shall not use an electroscalpel while operating close to the CONCERTO/CONCERTO PIN ABI electrode. Electroscalpel use during operations not close the electrode poses no risk for the implant.

STEP 1: Placement of the EABR Recording Electrodes

After the patient is in a semi-sitting position, as recommended above, the EEG electrodes are placed on the contralateral mastoid (negative), on the vertex (positive) and on the lower forehead (ground). These electrodes shall be connected during surgery to the EABR recording system. (Also refer to the section 5 Set-Up and Recommended Measurement for EABR Recording)

STEP 2: Mark Implant Position

Place the Processor Template behind the ear and position the Mi1000 Implant Template. There are various orientation options. A suggested orientation for each ear is shown in Figure 23 and Figure 24, but the orientation depends on various factors, like e.g. the curvature of the skull.

Make sure that the length of the electrode lead allows placement of the electrode paddle without compressing or extending the lead. The available length of the electrode lead is depending on the position of the implant bed. Rotating the implant clock or counterclockwise might increase the available length.

Position the implant template in such a way that the CONCERTO/CONCERTO PIN ABI will be in the hair bearing area. The lower part of the stimulator should be under or close to the temporal line, with an angle between 35° and 60°. The electrode exits on the lateral side of the implant. Therefore the electrode lead comes out superiorly for the left ear and inferiorly for the right ear.

Once the implant template is in place, surgical ink may be used to mark its position on the surface of the skin. Surgeons may choose to transpose the position of the implant template onto the surface of the bone by using a hypodermic needle inserted perpendicularly to the skin at points along the side of the implant template.

When implanting a patient bilaterally care should be taken of the placement of the implants. In particular the second side should be placed specifically to match the location of the first to give symmetric appearance of the external part. The skull curvature and pinna position needs to be taken into consideration when placing the second implant in a similar location as the contralateral side.



Figure 23 (left ear): Suggested orientation of the templates

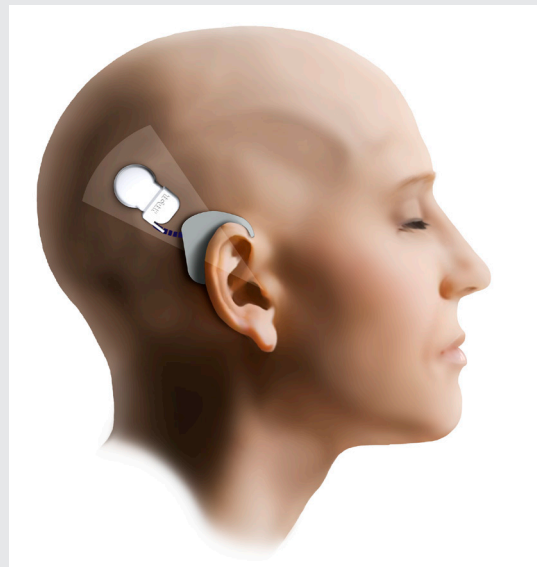


Figure 24 (right ear): Suggested orientation of the templates

STEP 3: Plan Incision

Choose the line of incision so that a well vascularised skin flap results. Make the incision 1–2 cm from the implant to ensure that the scar will not lie directly over the body of the implant. Incise the tissue with a scalpel and use bipolar electrocoagulation for hemostasis.

An example of a commonly used postaural incision is shown in Figure 25 and Figure 26. Postaural incisions start in the sulcus behind the pinna and extend posteriorly.

For greater mastoid bone exposure, each of these incisions can be extended posteriorly in the shape of an arc.

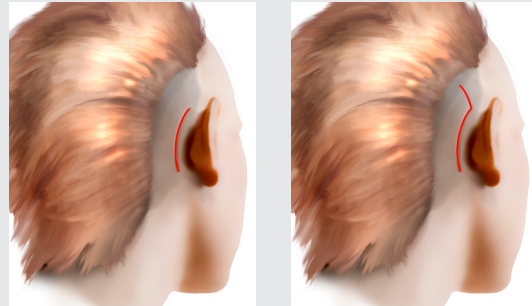


Figure 25 Minimal incision (left picture) and lazy "S" incision (right picture) – right ear

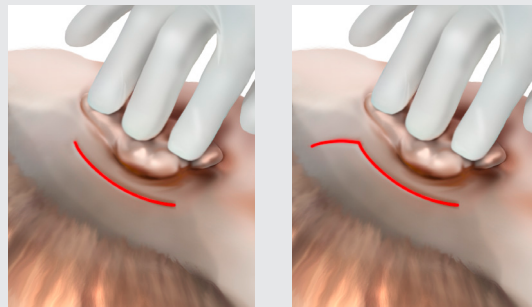


Figure 26 Minimal incision (left picture) and lazy "S" incision (right picture) – right ear – close up

STEP 4-A: Open Skin Flap

The incision is made and the wound is held open by retractors. At all times care should be taken to ensure that the flap is kept moist with damp surgical gauze.

Either a single layer skin flap – all four layers, skin, subcutis, muscle and periosteum are incised in a single cut, or a double layer skin flap can be performed.

A double layer skin flap may:

- reduce the chance of infection because the incisions are at different locations and layers, and
- allow better healing so it is often used for re-implantations and when encountering postauricular scar formation.

Double layer skin flap (see Figure 27)

The four different tissue layers skin, subcutis, muscle, and periosteum are incised with two different incisions. First, the skin, subcutis and muscle are raised and retracted. Second, the periosteum is incised, the periosteum is freed from the surface of the bone and then retracted in another location.

Various methods may be used when incising the periosteum. Care should be taken to avoid incision over the implant later on.

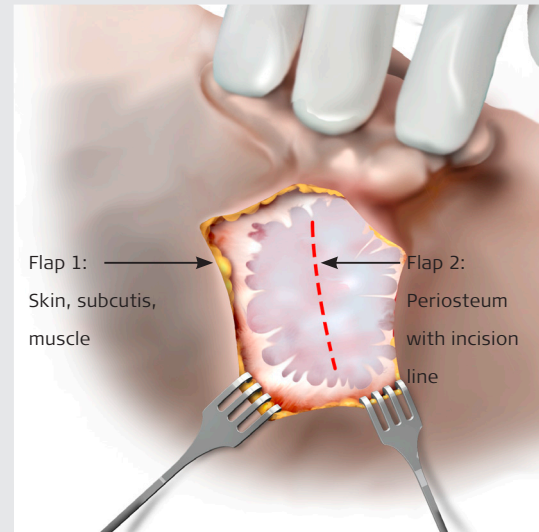


Figure 27 Double layer skin flap – right ear

STEP 4-B: Skin Flap Thickness

In order to achieve good magnetic hold and optimal signal transmission, the skin flap or the muscle may need to be thinned out so it does not exceed 6mm.

Evaluate the portion of the flap over the magnet and receiving coil with the Skin Flap Gauge 6, as shown in Figure 28. If the flap does not fit in the gauge loosely, carefully thin the flap until it does. It is important to avoid over-thinning of the flap, which may result in wound complications. Care must be taken to avoid exposing hair follicles.

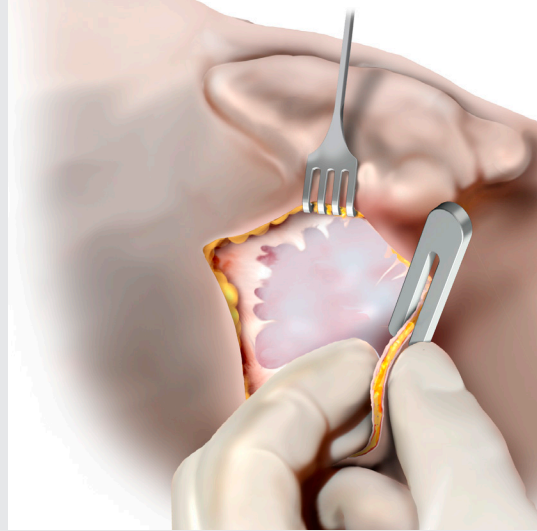


Figure 28 Using the Skin Flap Gauge 6 – right ear

STEP 5: Tumor Removal Surgery

If necessary, the acoustic neuroma is removed in a standard tumor removal surgery. Either a suboccipital or a translabyrinthine approach can be used for this surgery. A suboccipital approach makes the preservation of the cochlear nerve during tumor removal possible due to a lateral perspective. By stimulating the tissue in the area of the cochlear nerve and measuring EABR potentials intraoperatively with special ball electrodes, the boundary between tumor and nerve tissue can be determined electrophysiologically. If the cochlear nerve is not yet destroyed by the tumor, it can be uncovered from tumor tissue and functionally preserved with this method. A suboccipital approach is recommended by the expert surgeons who shared their experience for these guidelines.

The opening in the skull normally has a diameter of 25 – 35 mm. The brain is retracted from the skull with a dissector for obtaining access to the region of the cochlear nerve. For ABI implantation via a suboccipital approach, a retrosigmoidal trepanation is used. If the opening is not located correctly (too high or too far back), the lead of the Auditory Brainstem Implant may be too short and the CONCERTO/CONCERTO PIN ABI electrode array not placeable in the lateral recess. A correct location of the trepanation is therefore of high importance.

STEP 6: Preparation of the Lateral Recess

After complete tumor resection, the exits of the nerves VII., VIII. and the caudal groups IX. and X. from the brainstem shall be identified. Then, the flocculus of the cerebellum is identified and smoothly retracted in a small amount. In most cases, the choroid plexus of the IV. ventricle is then exposed.

The arachnoid membrane covering these structures is then gently dissected. The preparation should be directed towards the space between plexus and brainstem.

All vessels supplying the brainstem must be preserved. Thereafter, a 45° inclined dissector can be inserted into the lateral recess. This can be facilitated by additional retraction of the cerebellar hemisphere. Care must be taken that there are no vessels inside the recess, running in cranio-caudal direction. Such vessels may be injured or impede implantation by narrowing or occluding the entrance to the IV ventricle.

STEP 7: EABR Recording

Prior to implantation of the Implant CONCERTO/CONCERTO PIN ABI, EABR measurements should be performed. Connect the ABI Connector Cable and the ABI Placing Electrode via the Micro-D Plug (also refer to III Set-up and recommended measurement for EABR recording). The transition of the ABI Connector Cable to the ABI Placing Electrode shall not be brought into contact with the surgery wound. Connect the ABI Connector Cable, located outside the patient environment, to the plug of the ABI Stimulator Box (used for ABI Placing Electrode only).

Prior to placement of the ABI Placing Electrode, the anatomical facts need to be established. The positioning of the ABI Placing Electrode shall be done in accordance with anatomical landmarks. The lateral recess is opened 4 mm and the ABI Placing Electrode is inserted with the recommended tools. The ABI Placing Electrode has the same shape and dimensions as the CONCERTO/CONCERTO PIN ABI electrode with a reduced number of contacts and no polyester mesh. Care shall be taken regarding the electrode orientation, the contacts shall face the brainstem surface.

By stimulating the brainstem with bipolar, biphasic current pulses, EABR potentials shall be assessed. If EABRs become identifiable, an ABI can be used. If no EABRs are measurable, a repositioning of the ABI Placing Electrode may be necessary. Again, EABRs shall be assessed. Placement of the CONCERTO/CONCERTO PIN ABI electrode in the absence of clear EABRs may only be done if the surgeon considers the anatomical landmarks to be sufficient and reliable.

STEP 8: Drilling the Implant Bed

CAUTION

The implant must be immobilised in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.

Care shall be taken that the platinum bridge and electrode leads are not compressed by sutures or other structures, i.e. bony rims.

STEP 8-A: CONCERTO

The implant must be immobilised in a flat stimulator bed drilled in the temporal bone. In adults, it may not be necessary to expose the dura, but in small children with a thin skull, drilling to the dura may sometimes be required in order to ensure that the stimulator is well recessed in its bed. If drilling down to the dura is necessary a bony island should remain. Ideally, the stimulator is recessed approximately 2 mm.

Once again the Mi1000 Implant Template can be used to mark the flatness on the skull and the correct position for the implant bed (see Figure 29).

If, for example, the implant is fixed with sutures, a diamond burr should be used to drill the holes so that the implant can be immobilised later. The suture holes should be drilled such that the sutures do not cross the electrode, but rather only cross the silicone over-mold (see Figure 30).

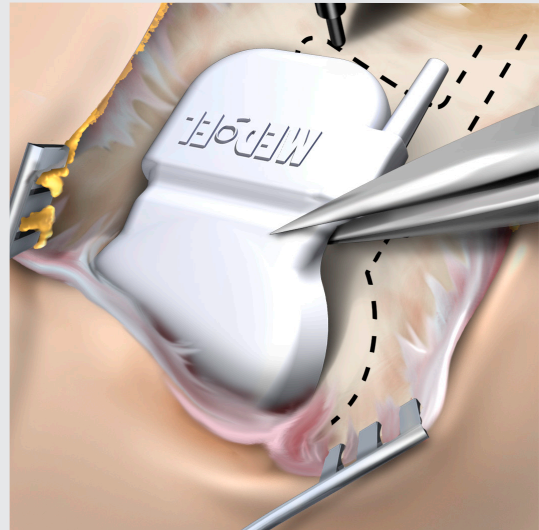


Figure 29 Marking the implant position with the Implant Template – right ear

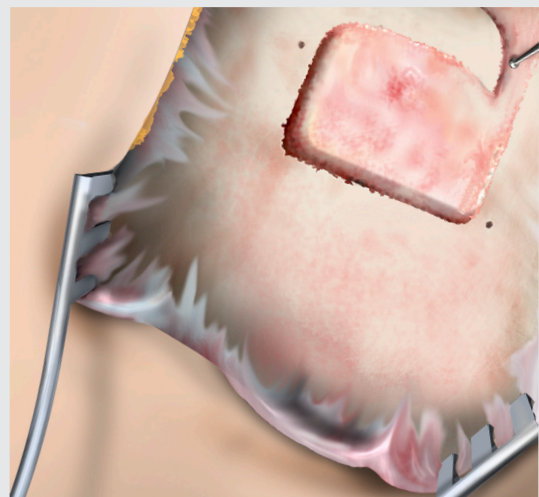


Figure 30 Flat stimulator bed, electrode channel and suture holes for single stitch – right ear

STEP 8-B: CONCERTO PIN

The Mi1000 Implant Template, PIN can be used to mark the correct position of the stimulator and the electrode channel (see Figure 31).

The temporal bone area, in which the stimulator is placed, must be flattened to ensure sufficient stimulator immobilisation. The flattening also ensures a flat stimulator position without a later rocking of the implant and enables a good positioning of the pins in the drilled holes (see Figure 32). The immobilisation of the CONCERTO PIN ABI with the two pins and an additional suture over the stimulator stabilizes the stimulator against translational and rotational motion.

Furthermore, the electrode lead should be protected in a ramp-like bony channel without sharp edges which is drilled into the skull. It is important to ensure that the channel is deep and wide enough to comfortably accommodate the electrode. This protect the electrode lead against postoperative movement and excessive mechanical impact.

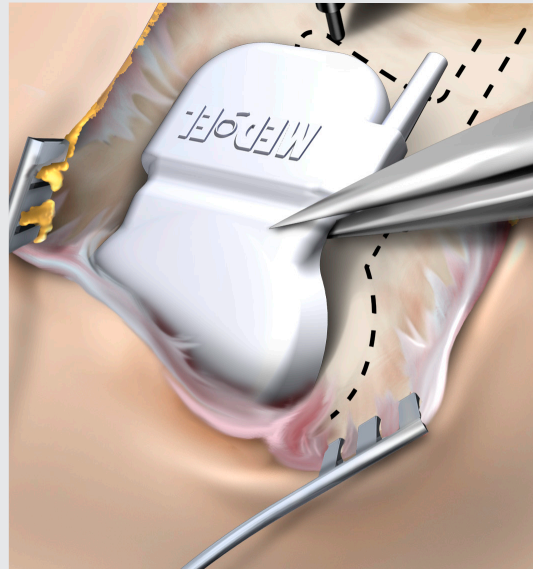


Figure 31 Marking the implant position with the Implant Template – right ear

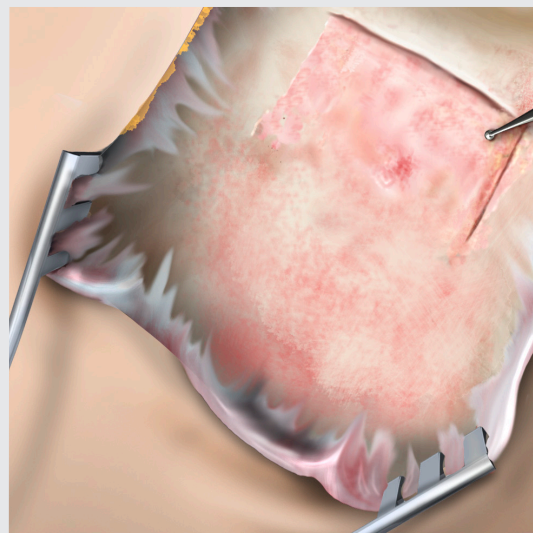


Figure 32 Flattening of the stimulator area – right ear

The two pins of the CONCERTO PIN ABI should be recessed into the skull with PIN Drill Guide SI or the Mi1000 PIN Drill Guide to a depth of 1.5 mm (see Figure 33).

The PIN Drill Guide SI or Mi1000 PIN Drill Guide is used to support the drilling of the holes of the fixation pins into the skull in a defined distance and depth.

For drilling the holes into the flat area, the following methods can be used:

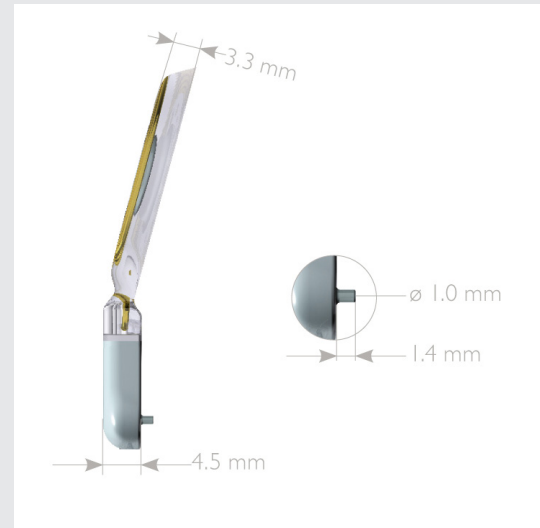


Figure 33 CONCERTO PIN ABI – Dimensions of the pins

PIN Drill Guide SI and a diamond burr of 1.0 mm

CAUTION

- Ensure that the dura is not inadvertently damaged when drilling the holes.
- Always use a slow turning drill, e.g. 2000 rpm.
- Stop drilling when a depth of 1.5 mm is achieved.

Use the diamond burr of 1.0 mm to mark both hole positions and drill through the PIN Drill Guide SI. Avoid recessing the pins deeper than 1.5 mm (see Figure 34).

PIN Drill Guide SI and a surgical pen (surgical ink)

CAUTION

- Ensure that the dura is not inadvertently damaged when drilling the holes.
- Use a diamond burr of 1.0 mm for drilling the holes.
- Always use a slow turning drill, e.g. 2000 rpm.
- Stop drilling when a depth of 1.5 mm is achieved.

When using a surgical pen or surgical ink for marking the position of the holes through the PIN Drill Guide SI, be aware that the irrigation of the drill can wash your markings away. Drying the bone with a sterile tissue helps to better mark the holes with the surgical pen or ink. Use the diamond burr of 1.0 mm to mark both hole positions. Then, drill the full depth of the pin hole. Avoid recessing the pins deeper than 1.5 mm.

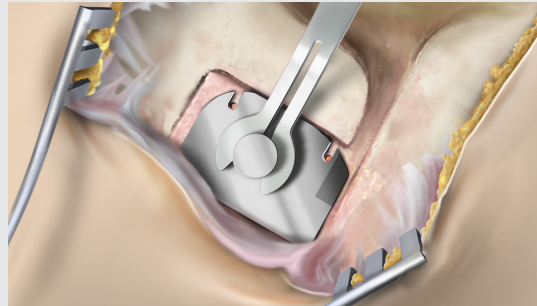


Figure 34 Using the PIN Drill Guide SI

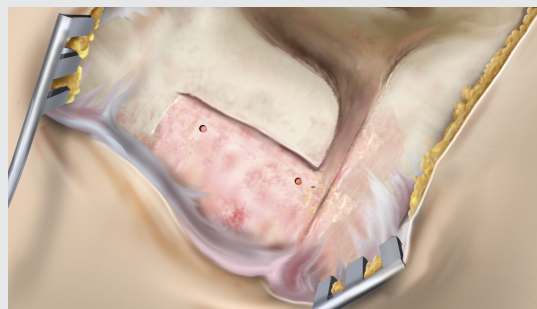


Figure 35 Flat stimulator area with pin holes, electrode channel – right ear

STEP 9: Immobilise the Implant

STEP 9-A: CONCERTO

CAUTION

- If monopolar diathermy has been used, it must now be disconnected. High current levels may cause damage to the implant. If bipolar cautery must be used, the tips of the cautery should be kept at least 3 cm away from the implant.
- Additional immobilisation of the implant needs to be performed.
- If sutures are chosen for immobilisation of the implant do not place the sutures directly over the electrode lead.

Additional immobilisation of the implant needs to be performed (e.g. with sutures). It should be conducted in such a way that there will be no postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.

When the implant is immobilised with sutures, the holes drilled in STEP 8 should be used to secure the implant in its bed and the electrode should be placed into the drilled channel leading into the mastoid. Make sure the electrode channel is deep enough to prevent the tie-down from exerting pressure and damaging the electrode. MED-EL recommends the use of the following techniques (details in Figure 36, Figure 37).

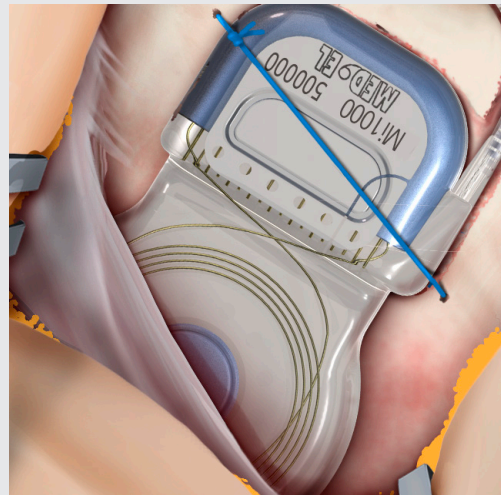


Figure 36 Implant immobilised with a single stitch – right ear

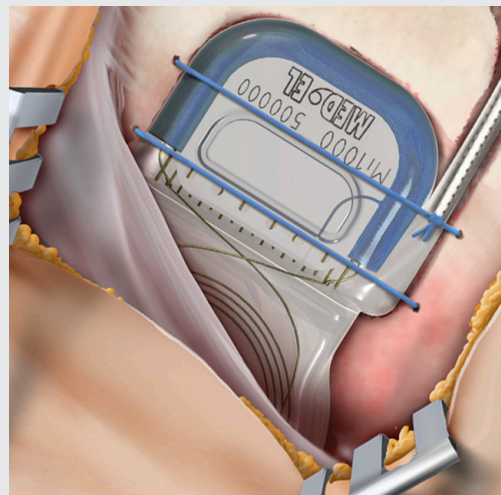


Figure 37 Implant immobilised with double stitches – right ear

STEP 9-B: CONCERTO PIN

CAUTION

- If monopolar diathermy has been used, it must now be disconnected. High current levels may cause damage to the implant. If bipolar cautery must be used, the tips of the cautery should be kept at least 3 cm away from the implant.
- Recessing the pins and efficient immobilisation of the stimulator is important to prevent postoperative movement.
- Do not place the sutures directly over the electrode lead.

The area of the temporal bone on which the stimulator will be placed, shall be flattened in order to ensure that the implant is sufficiently immobilised. The two pins of the CONCERTO PIN Cochlear Implant should be recessed into the skull with the PIN Drill Guide SI to a depth of 1.5mm. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact.

The two pins give additional stability against translational and rotational motion. Recessing the pins and efficient immobilisation of the stimulator (e.g. with sutures) is important to prevent postoperative movement. Continuous movement may result in mechanical fatigue and subsequent premature failure of electrical connections.

When the implant is immobilised with sutures, holes drilled into the bone should be used to secure the implant in its flat area and the electrode should be placed into the drilled channel leading into the mastoid. Ensure that the electrode channel is deep enough to prevent the tie-down from exerting pressure and damaging the electrode. MED-EL recommends the use of different immobilisation techniques (details on Figure 38, Figure 39).

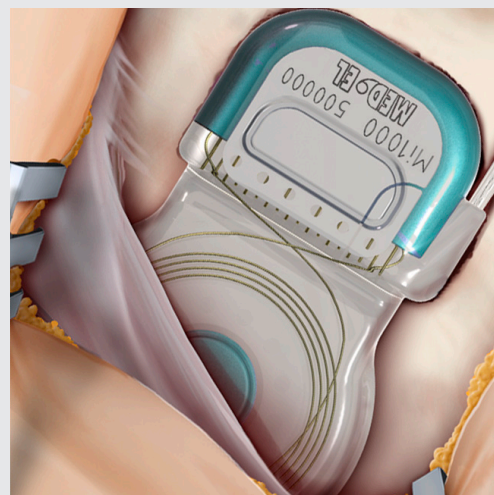


Figure 38 Implant immobilised with a tight periosteum pocket – right ear

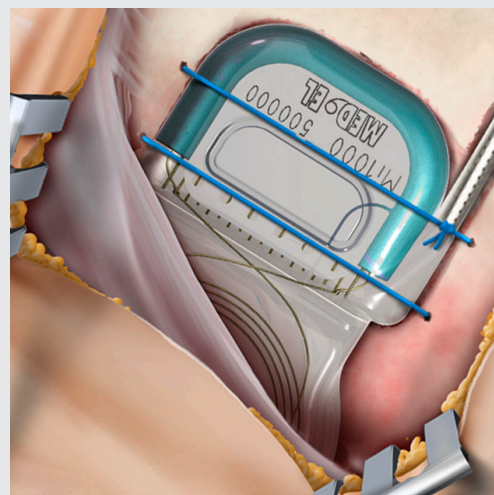


Figure 39 Implant immobilised with stitches – right ear

STEP 10 Intra-operative Recordings

At this stage intra-operative recordings like Impedance Field Telemetry (IFT) and Electrically Evoked Brainstem Response (EABR) can be performed.

Intra-operative measurements are performed with the appropriate MED-EL application software and the MED-EL hardware interface system. For details please refer to the applicable User Manual. It is not possible to sterilise any component of the MED-EL clinical interface system. When used in a sterile environment, the coil and cable should be covered with sterile material (i.e. "sterile sleeve").

Since the coil should not be placed directly on the implant, either sterile gauze drenched in saline solution or the skin flap should be placed between the coil and the implant. Moistening the underside of the skin flap with sterile saline or pooling saline over the ground electrode of the implant prior to performing intra-operative recordings may improve readings.

IFT (Impedance Field Telemetry)

After the implant is in place, a telemetry check allows:

- individual electrode impedance measurements
- verification of the absence of short and open circuits between electrodes
- determination of voltage distribution across the cochlear nucleus

As with any telemetry system, intra-operative impedance testing may not provide an accurate representation of later electrode function. "High" values observed intra-operatively may be caused by air bubbles on the electrode contact surface. These generally dissipate within a few hours or days after surgery.

EABR (Electrically Evoked Brainstem Response)

For details regarding EABR please refer to the section III Set-up and recommended measurement for EABR recording.

STEP 11: Implantation Procedure with EABRs

After fixation of the stimulator, the ABI Active Electrode shall be placed. The polyester mesh which is embedded in the silicone of the ABI electrode array is cut to fit in the lateral recess, and the ABI electrode array is placed into the estimated correct location. Go on with the procedure in STEP 12: EABR Measurements during Stimulation via the Implant CONCERTO/CONCERTO PIN ABI.

STEP 12: Implantation Procedure in Case of Absence of EABRs

To determine the best stimulation area, the ABI Placing Electrode is placed into the lateral recess again. EABRs are recorded by stimulating the CN in any bipolar configuration mode possible with the four contacts. EABR measurements are repeated until the stimulation area has been found where all electrode combinations elicit EABRs. If no EABRs can be recorded, the surgeon has to decide if the anatomical landmarks are sufficiently reliable to proceed with the implantation.

The ABI Placing Electrode is then retracted and substituted by the ABI Active Electrode. The polyester mesh which is embedded in the array is cut to fit into the lateral recess, and the CONCERTO/CONCERTO PIN ABI electrode array is placed in the location where the ABI Placing Electrode evoked EABRs. Therefore, the insertion depth into the lateral recess shall be the same for both electrodes.

STEP 13: EABR Measurements during stimulation via the CONCERTO/CONCERTO PIN ABI

Before fixation of the ABI Active Electrode, a final EABR check via the implant is performed. The appropriate coil of the MED-EL hardware interface system is put into a sterile sleeve and placed on the implant. For correct recording of potentials, the MED-EL hardware interface system shall trigger the measuring device (see III Set-Up and Recommended Measurement for EABR Recording).

This measurement via the implant should be used as a final check. The results from the ABI Placing Electrode are primarily used for the determination of the stimulation site.

STEP 14: Fixation of the Electrode

CAUTION

Improper fixation or placement of the ABI electrode array may result in dislocation. This is true especially when a large lateral recess is present.

The ABI Active Electrode can be prefixed onto the brainstem surface with a piece of hemostyptic material and fibrine glue to prevent postsurgical displacement. The main fixation is achieved by gluing the electrode lead to the rostral surface of the cerebellum. Useful for this procedure is a collagen foam covered with instant glue (TachoComp™).

STEP 15: Removal of the Platinum Bridge on the Implant Housing

The platinum bridge (Figure 40) on the implant housing shall be removed with forceps. The platinum bridge is fixed with silicone only on its edges. This allows the lifting of the platinum bridge (Figure 41) from the surface of the implant. Pull out the whole platinum bridge (Figure 42 and Figure 43). Make sure that there is no residual platinum foil on the implant housing (Figure 43).

STEP 16: Closing the wound

After implantation, the dura shall be closed in a watertight fashion. The entry of the electrode lead into the dura is sealed with fibrin glue or TachoComp™. The housing is covered in a double layer technique by the periosteum and the galea flap, which has in contrast to the normal skin incision in acoustic neurinoma surgery a mirrored question mark shape on the left and a regular question mark shape on the right side. The wound should be closed in layers. No drainage is used. The area of the wound is covered with a compress and sterile gauze applying even pressure.

Remark for initial fitting

CAUTION

The initial fitting of the audio processor is done typically six to eight weeks after surgery. The fitting shall be performed in the intensive care unit of the hospital or in the presence of an intensive care crash cart.



Figure 40 Platinum bridge



Figure 41 Lifting of the platinum bridge



Figure 42 Pull out left side



Figure 43 Platinum bridge removed

Appendix

MRI Caution

MRI is possible in patients with cochlear or auditory brainstem implants only with specified models of MRI machines.

Evidence has been provided for these implants to pose no known hazard in magnetic field strengths of 0.2T, 1.0T and 1.5T (without surgical removal of the internal magnet) when the following safety recommendations and guidelines are adhered to. The physician/MRI operator should always be informed that a patient is a cochlear implant or an auditory brainstem implant user and that special safety recommendations and guidelines have to be followed:

Safety recommendations and guidelines for MRI scanning:

- MRI scanner with static magnetic field strength of 0.2T, 1.0T or 1.5T only. No other field strengths are allowed. (When using other field strengths, injury to the patient and/or damage to the implant are possible.)
- MRI scan not earlier than 6 months post implantation. (Performing an MRI at an earlier stage may result in implant displacement and/or damage to the implant)
- A minimum thickness of the bone underneath the implant magnet of 0.4mm is required in order to withstand forces of 5 N (equals a gravitational force of about 0.5 kg) or up to 9N for the C40 cochlear implant. (In an MRI scanner torque forces act on the implant magnet, exerting rotational pressure: the device will try to turn to line up with force lines. The resulting forces on the edges of the implant are counterbalanced by the cranial bone and the skin flap. Bone underneath the implant magnet should be thick enough to withstand these exerting forces.)
- Patients with mechanically damaged implants must not undergo MRI. (Ignoring this guideline could result in injury to the patient.)

Safety Guidelines:

- Before patients enter any MRI room all external components of the implant system (audio processor and accessories) must be removed. For field strengths

of 1.0T or 1.5T a supportive head bandage must be placed over the implant. A supportive head bandage may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 44). The bandage shall fit tightly but should not cause pain.

- Head orientation: In case of 1.0T and 1.5T systems, the longitudinal axis of the head must be parallel to the main magnetic field of the scanner. For example this is the case when the patient is in a supine position with the head kept straight. (The patient should not turn or bend his/her head to the side; otherwise partial demagnetization of the implant magnet is possible.) In case of 0.2 T scanners, no specific head orientation is required.
- Sequences in Normal Operating Mode shall be used only! During the scan patients might perceive auditory sensations such as clicking or beeping. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.

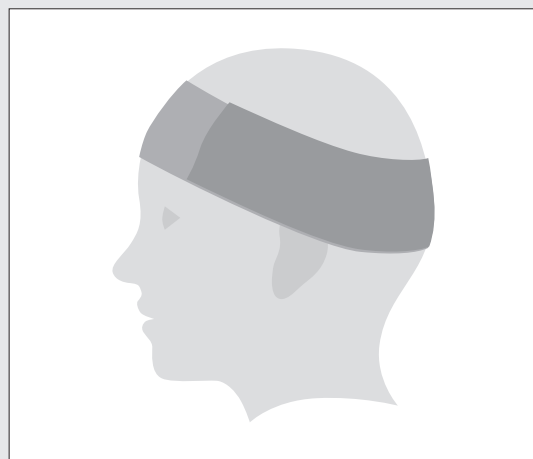


Figure 44 Head bandage to support fixation of the implant.

- Image artifacts are to be expected (refer to Figure 45).
 - The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first to minimize any risk of weakening the implant magnet.
 - The above instructions also apply for patients with bilateral cochlear implants or bilateral auditory brainstem implants.
- If the conditions for MR safety and the Safety Guidelines are not followed, injury to the patient and/or damage to the implant may result!

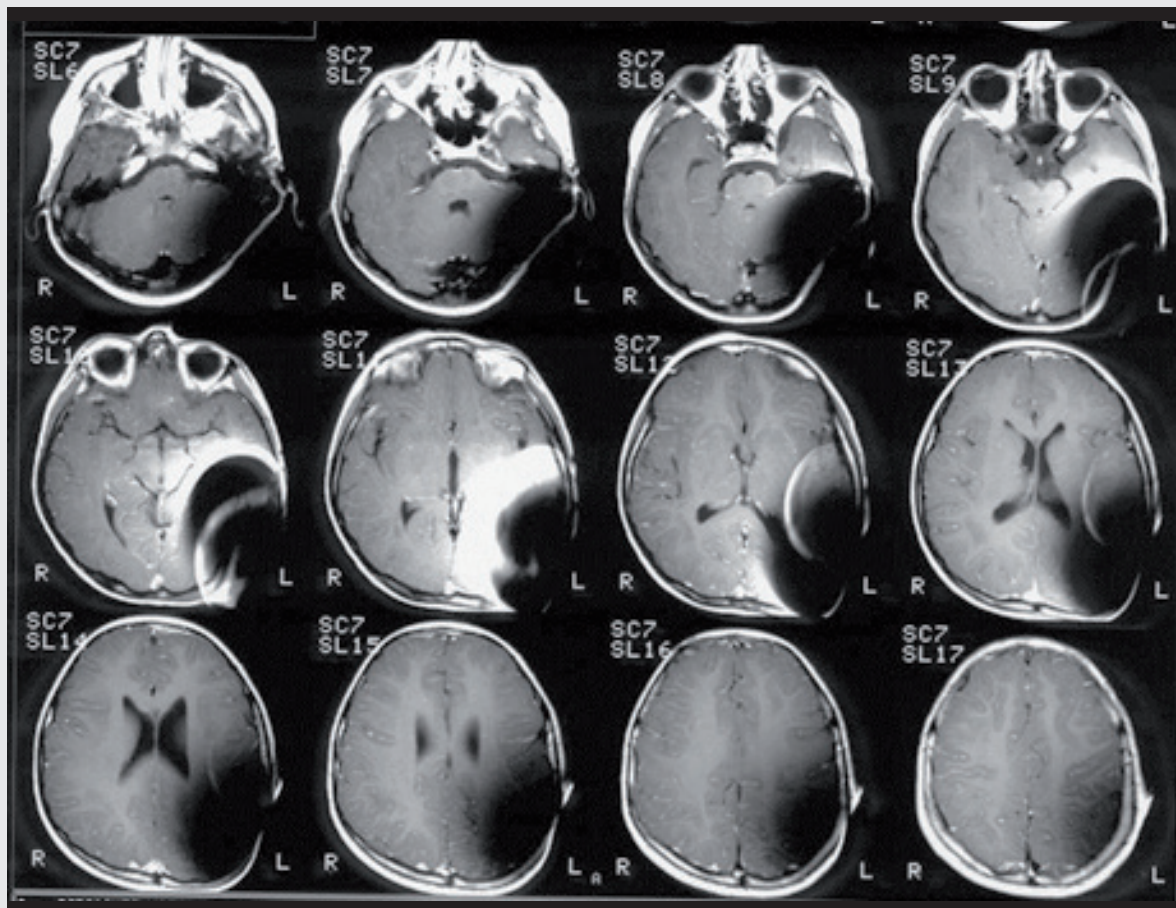


Figure 45 MR images obtained with a 1.5T scanner (8 year old child)"

X-rays

The CONCERTO/CONCERTO PIN ABI can be identified by x-ray post surgery. Right is an example for the devices.

Explanting the Device

- The implant may become non-functional, either by accident or due to medical or technical reasons. In this case, it is strongly recommended to replace the device.
- If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed, functional checks of the implant on a regular basis are strongly recommended.
- If possible, the device should be removed without damaging or cutting it. Damage to the device during or after explantation may prevent or reduce the manufacturer's ability to determine the root cause of failure.
- Staff should follow common universal precautions and handle the explanted device as potentially contaminated biohazardous material.
- After explantation, the implant should be appropriately cleaned and disinfected. During cleaning, extraneous tissue should be removed, but only to such an extent that damage to the implant is not risked.
- An explanted device should be placed in a leak-proof, disinfected (or sterile) container filled with saline and returned to MED-EL Headquarters. The device should be accompanied by written information including the reason for explantation.



Figure 46 X-ray of CONCERTO CI bilateral, Courtesy of University Clinic of Halle (Saale), ENT and Radiology

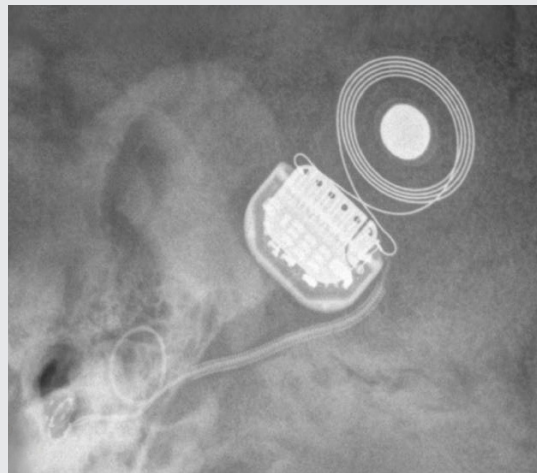


Figure 47 X-ray of CONCERTO PIN CI, Courtesy of University of Innsbruck

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