Mi1000 CONCERTO ABI
Mi1000 CONCERTO PIN ABI
Surgical Guide
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 13485:2016 requirements and complies with US Quality System Regulations and Canadian Medical Device regulations (CAN/CSA ISO 13485-2016). Components of the MED-EL Hearing 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 instructions for use delivered with the implant system.
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Patient selection and evaluation
Intended Use

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.

Selection and Evaluation

If a patient is suffering from retro-cochlear nerve deficiency due to NF2, it is the responsibility of the surgeon to determine for each patient if implantation of the device during tumour removal surgery is appropriate. Most NF2 patients are also suffering from multiple tumour formations in the spine and may therefore be in critical conditions. Thus, it is always recommended to assess the cognitive and behavioural development of a patient for a suitable hearing implant choice and to predict the benefit of ABI implantation.

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 centre 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. Tumour size and/or 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 for NF2 patients. 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 tumour has taken place, the patient’s evaluation should include possible structural 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.

This device is to be used by surgeons who have been trained in the surgical placement of an Auditory Brainstem Implant.
Technical description of the ABI System
The CONCERTO/CONCERTO PIN ABI is the implantable part of the MED-EL Hearing 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 up to 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.
Performance Characteristics

• Output characteristics of a stimulation signal on a 1kOhm resistor:
  Maximum current amplitude:
  Median value = 1250 µA, range = 500 µA
  Maximum pulse width:
  Median value = 203.8 µs, range = 8.2 µs
• The impedance measurement accuracy is typically better than 5%.
• There are no default factory settings of the implant system.
• Proper functioning of the implantable part of the ABI 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 7.6 g (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: 07675 CONCERTO ABI
Order number: 07681 CONCERTO PIN ABI

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 centre of the silicone paddle to allow bipolar stimulation mode during intra-operative measurement. The diameter of the electrode lead increases from ≈ 0.7 mm at the silicone paddle to ≈1.3 mm over a length of ≈10 mm.

Designed Especially for Neurofibromatosis Type II

ABI is a solution for individuals with hearing loss due to non-functional auditory nerve. 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.

Figure 2 The top image displays the channel allocation of ABI Electrode Array (Look from the top of the silicon) - Top View
The below image displays the view from the side of the ABI Electrode Array - Side View

Figure 3 ABI Electrode Array (≈ dimensions in mm, typical values) - Bottom View
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 intra-operative 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 (single-use device)
- ABI Connector Cable (single-use device)
- ABI Stimulator Box with ABI Stimulator Box Test Device

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 Chapter 4 Set-up and recommended measurement for EABR recording).

Figure 4 The top image displays the channel allocation of ABI Placing Electrode (Look from the top of the silicon) - Top View, and the below image displays the view from the side of the image - Side View

Figure 5 ABI Placing Electrode (~ dimensions in mm, typical values)
Technical description of the ABI Placing System

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 ≈2m so that it can lead out of the patient’s environment. The ABI connector cable is sterilized. The connector on the left side of the ABI Connector Cable (see Figure 6) shall be connected to the ABI Placing Electrode (Micro-D Plug). The connector on the right side of the ABI Connector Cable (see Figure 6) shall be connected to the ABI Stimulator Box (see Figure 7).

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 7) allows easy selection of the electrode configuration at the ABI Placing Electrode which is used for bipolar stimulation during EABR measurements.
Pre-use check of the ABI Stimulator Box

Prior to the use of the Auditory Nerve Test System (ANTS) and starting any EABR measurements, a pre-use check shall be performed with the Stimulator Box.

The Stimulator Box must be connected to the Telemetry socket of the MED-EL hardware interface system (Figure 9).

Note: In the MAESTRO software, a “Stimulator Box” patient with a C40+ implant must be created. For the Telemetry measurement, the intra-operative mode and the IFT task shall be selected. Only personnel trained on the use of the MED-EL telemetry system shall perform the pre-use check.

The Stimulator Box Test Device (Figure 10) is plugged into the Stimulator Box. The measured impedance (Z) must change by more than 0.4 kΩ for each step of the Stimulator Box switch turning from 1–2 to 3–4 as illustrated in the Figure below.

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

All measured values shall lie between 1.5 and 9 kΩ. Only the impedance value measured at channel 1 shall be used for this check. All other values show “HI” (High Impedance) as measured values. If the measured values do not fulfill the above-mentioned criteria, please return the Stimulator Box to MED-EL for maintenance.
Set-up and recommended measurement for EABR recording
Recording Electrode placement

Before surgery, recording electrodes are placed on the contralateral mastoid (negative), on the vertex (positive) and on the lower forehead (ground). For bilateral recordings a recording may be placed on the ipsilateral tragus. These electrodes are connected to the EABR recording system. Try to avoid placing any two electrodes too closely together.

Impedance of recording electrodes

The impedance of any recording electrode should be less than 5 kΩ. There should be no greater difference between the individual electrode impedance than 2 kΩ.

Recommended general set-up of the EABR measurement system

<table>
<thead>
<tr>
<th>Stimuli:</th>
<th>Single pulse</th>
</tr>
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<tbody>
<tr>
<td>Number of pulses:</td>
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</tr>
<tr>
<td>Phase duration:</td>
<td>Starting from 60μs</td>
</tr>
<tr>
<td>Repetition rate (Utility frequency 50Hz):</td>
<td>34</td>
</tr>
<tr>
<td>Alternating polarity:</td>
<td>yes</td>
</tr>
<tr>
<td>Window:</td>
<td>10 ms</td>
</tr>
<tr>
<td>Gain:</td>
<td>100,000 or 50–100 μV amplifier range or auto-gain</td>
</tr>
<tr>
<td>Hi filter:</td>
<td>3000 Hz</td>
</tr>
<tr>
<td>Lo filter:</td>
<td>30–50 Hz</td>
</tr>
<tr>
<td>Sweep:</td>
<td>1000–2000</td>
</tr>
<tr>
<td>Trigger:</td>
<td>external (MED-EL hardware interface system triggers the EABR measurement system)</td>
</tr>
</tbody>
</table>

Figure 11 Positions of the recording electrodes for EABR measurements
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 12 for correct connection).

Figure 13 shows the block diagram of the eABR recording setup. 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 brainstem tissue, 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 each selector switch position. It shall be repeated after the ABI Placing Electrode has been manipulated by the surgeon. Make sure that the ABI Placing Electrode is inserted into the lateral recess.

Figure 12 Correct connection of the ABI Placing Electrode with the ABI Connector Cable

Figure 13 Setup for EABR recording with ABI Placing System
Using the MED-EL application software

**EABR Task**

**Channel selection for ABI Placing System**
Select channel 1 for stimulation during intra-operative 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.

*Note:* The following limits shall not be exceeded:
- 1000 cu
- 150 µs

**Extended setup**
For EABR recording, single stimulus pulses are used. Alternating pulses can be used to reduce the stimulus artefact. 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 artefact during EABR recording. Waves IV and V become visible at a latency of 1 to 2 ms.

*Note:* Figure 14 shows a theoretical recording. During intra-operative EABR measurements only one wave (IV or V) is visible (at the recording monitor).

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Please refer to the MED-EL Evoked Potential Guide for further information and troubleshooting.
**Recommendations for stimulation with the Placing system**

For the first position an EABR recording with a pulse duration of 60 μs and an amplitude of 100 cu shall be performed. Typically, an electrode configuration of 1-4 is selected with the Stimulator Box. The stimulation levels shall be increased until a clear EABR response is visible or the stimulation levels reach a level of 500 cu. For the following stimulation positions the same level should be used for stimulation. In case of no response, the stimulation level shall be increased up to 1000 cu. When a response is present the optimal position of the Placing Electrode shall be found by selecting different electrode configurations on the Stimulator Box. According with the eABR results, the surgeon may adjust the position of the Placing electrode. When a repositioning is necessary, eABR measurements shall be repeated after the new placement.

**Recommendations for stimulation with the active ABI electrode**

For the first position electrode 6 shall be selected and an EABR recording with a pulse duration of 60 μs and an amplitude of 100 cu shall be performed.

The stimulation levels shall be increased until a clear eABR response is visible or the stimulation levels reach a level of 500 cu. For the following stimulation positions the same level should be used for stimulation. In case of no response, the stimulation level shall be increased up to 1000 cu. The suggested protocol for stimulation is as follows.

- Electrode 6
- Electrode 5
- Electrode 9
- Electrode 1
- Electrode 12

If an auditory response is found on all positions, the position is final.
Set-up and recommended measurement for eABR recording

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 15). Before starting the measurement, the ABI Electrode shall be placed on the brainstem.

Figure 15 Setup for EABR recording with CONCERTO/CONCERTO PIN ABI implant.
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.

**CI Surgical Instrument Tray**

Order number: 33117

The CI Surgical Instrument Tray is a collection of reusable tools for implantation of all current titanium MED-EL cochlear and ABI implants. The tools should be sterilized before use.

CI Instrument Tray includes:

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<th>Order number</th>
</tr>
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<td>05064</td>
</tr>
<tr>
<td>1 SONATA Stimulator Template</td>
<td>04715</td>
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<tr>
<td>1 PIN Drill Guide SI</td>
<td>09906</td>
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<tr>
<td>1 Processor Template</td>
<td>07537</td>
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<tr>
<td>1 Skin Flap Gauge 6</td>
<td>03543</td>
</tr>
<tr>
<td>1 Surgical Claw Angled</td>
<td>00284</td>
</tr>
<tr>
<td>1 Micro Forceps Right-Angled</td>
<td>05777</td>
</tr>
<tr>
<td>1 Micro Forceps Left-Angled</td>
<td>05778</td>
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**PIN Drill Guide SI (Ms040211)**

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 SYNCHRONY PIN Implant. It consists of a PIN Drilling Template made of titanium and a Clamping Handle made of stainless chromate 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 (Ms040213)

Order number: 01557

The Processor 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. The section of the Processor Template closest to the pinna (auricle) depicts the outline of MED-EL’s BTE processors. The section furthest from the pinna represents the safety distance between pinna and stimulator of the implant.

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 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.
Additional Implant Tools

These additional tools can be used for implanting CONCERTO but are not included in the CI Surgical Instrument Tray.

**Mi1000 Implant Template**

Mi1000 Implant Template, PIN

One template is included in every implant packaging.

Order number:

06292 Mi1000 Implant Template
06283 Mi1000 Implant Template PIN

This silastic template is intended to be transiently used as a surgical tool which can aid surgeons in evaluating the position of the implant on the skull and to estimate the fit of the implant in the implant bed or sub-periosteal pocket. The template is delivered sterile and is intended for single use only.

**PIN Check Template (Ms040214)**

Order number: 37956

The PIN Check Template is a re-usable surgical template which replicates the distance and size of the pins of the MED-EL hearing implants with PINs. It can aid surgeons in checking the distance between the holes created for the implant pins. This surgical instrument is made for transient use. It consists of a base and a clamping handle made of stainless chromate steel. The device is delivered non-sterile.

**FENTEXmedical Forceps**

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

Basic description of the device:
Electrode Insertion Forceps L=155mm, with longitudinal groove, for electrodes with a basal diameter in the range 0.8 – 1.3mm

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/
General remarks about the surgery
Surgical notes

- Sterility of the Implant CONCERTO/CONCERTO PIN ABI, the ABI Placing Electrode and the ABI Connector Cable must always be ensured.
- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated. The surgeon should prescribe adequate dosing for each patient’s condition.
- The CONCERTO/CONCERTO PIN ABI electrode array shall be inserted into the lateral recess without compressing the electrode lead or touching the electrode contacts.
- 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.
- 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 electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against post-operative movement and excessive mechanical impact.
- Do not place sutures over the active electrode lead. Good physical and thus stable electrical contact between stimulation reference electrode and surrounding tissue is essential for electrical stimulation. Therefore, do not place any fixation sutures directly over the reference electrode and do not recess the stimulator too deeply to avoid any air gap over the reference electrode.
- Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- The implant must never be dropped onto a hard surface; damage to the stimulator or electrodes during the operation will invalidate the warranty.
- The serial number of the implant must be visible on the implant before fixing it in place.
- 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 6 mm.
- Other risks after surgery may be avoided by following the instructions in the applicable CONCERTO/CONCERTO PIN ABI instruction for use.
Surgical procedure
General information

In general, an ABI implantation is performed as a procedure for restoration of sound perception of patients with the cochlear nerve deficiency who cannot benefit from cochlear implants and causing massive hearing impairment up to deafness may also be candidates such as NF2 patients immediately after resection of an acoustic neuroma.

For the resection of an acoustic neuroma, 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 intra-operative monitoring is necessary throughout the surgery to control and protect nerve structures in and around the brainstem. Vestibulocochlear (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 anaesthetist 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 electrosurgical instruments in ABI patients due to further tumour removal surgeries is likely. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
STEP 1: Mark Implant Position

After the EABR electrode placement (see Chapter 4), place the Processor Template behind the ear and position the Mi1000 Implant Template. The section of the Processor Template closest to the pinna (auricle) depicts the outline of MED-EL’s BTE processors. The section furthest from the pinna represents the safety distance between pinna and stimulator of the implant. 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 clockwise 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 30° 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 with the placement of the implants. The second side should be placed specifically to match the location of the first to give a symmetric appearance of the external part. The skull curvature and pinna position need to be taken into consideration when placing the second implant similar to the contralateral side.
STEP 2: Plan Incision

Choose the line of incision so that a well vascularised skin flap result. For the left ear a “regular question mark shape” incision shall be used (Figure 25). For the right ear a “mirrored question mark shape” incision shall be used (Figure 26). To ensure that the scar will not be directly over the implant body, the straight part of the incision should be positioned about two fingers-breadth behind the ear. In addition, make sure that the incision ends below the mastoid tip. Incise the tissue with a scalpel and use bipolar electrocoagulation for homeostasis.
STEP 3-A: Open Skin Flap

The incision is made, and the wound is held open by retractor(s) or suture(s). 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 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 and Figure 28)
In order to achieve a well vascularizing double skin flap, an ‘L shape’ incision line is created in the peristeum along the posterior portion of the mastoid and the superior portion of the suboccipital muscles. The subperiosteum of the suboccipital muscles are retracted medially and inferiorly to expose the groove beneath the digastric muscle. Bleeding from the retraction of the skin flap must be controlled before drilling.
STEP 3-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 6 mm.

Evaluate the portion of the flap over the magnet and receiving coil with the Skin Flap Gauge 6, as shown in Figure 29 and Figure 30. 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.

Alternatively, a hockey-stick incision normally used for vestibular schwannoma surgery can be performed. The coil and the housing of the auditory brainstem implant can then be inserted into a subcutaneous pocket. In this case, using a PIN implant variant is recommended.
STEP 4: Craniotomy

The craniotomy is based on the asterion, the posterior aspect of the sigmoid sinus and the inferior aspect of the transverse sinus (Figure 31). A rectangular craniotomy is performed, with dimensions of approximately 3 cm along the sigmoid sinus and 2.5 cm along the transverse.

In paediatric patients, care must be taken for planning the craniotomy as the sigmoid sinus can be diverted from its usual position.
CAUTION
Retractors may distort the actual position of the implant in relation to the pinna as the ear is retracted.

The Mi1000 Implant Template should be placed on the skull vertically to ensure enough length of the electrode lead and in order to visually check its proper position. Mark the Implant Stimulator Housing and Electrode Lead Channel on the skull (see Figure 33).

Figure 33 The silastic template and marking dot (without drilling) - right ear
STEP 6: Drill Stimulator Bed and Electrode Channel

STEP 6-A: CONCERTO

**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.
- The anterior stimulator edge should not be recessed to a depth more than 2 mm.
- All sharp edges of bone must be removed in order to avoid possible damage to the electrode lead.
- Protect the dura from bone dust contamination by closing it with medical gauze.

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 34).

For protection and placement of the electrode lead, a smooth channel must be drilled in the bone leading to the mastoid. Make sure that the channel is deep and wide enough to comfortably accommodate the electrode lead.

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 35).
STEP 6-B: CONCERTO PIN

CAUTION

- 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 Auditory Brainstem Implant should be recessed into the skull to a depth of 1.5 mm.
- The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against post-operative movement and excessive mechanical impact.
- All sharp edges of bone must be removed to avoid possible damage to the electrode lead. Drilling should be completed before the dura is opened to prevent any bone dust from entering.

The Mi1000 Implant Template, PIN can be used to mark the correct position of the stimulator and the electrode channel (see Figure 36).

The temporal bone area, in which the stimulator is placed, must be flattened to ensure enough stimulator immobilisation (see Figure 37). 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. The immobilisation of the CONCERTO PIN with the two pins stabilises 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 protects the electrode lead against postoperative movement and excessive mechanical impact.

For implant fixation, due to the flat bony surface prepared for CONCERTO PIN implant, it can be challenging to drill suture holes between the receiving coil and the stimulator housing, hence the titanium plates can be used instead of creating suture holes for the suture (see Figure 38).
The two pins of the CONCERTO PIN Auditory Brainstem Implant should be recessed into the skull with the PIN Drill Guide SI to a depth of 1.5 mm (see Figure 39).

The PIN Drill Guide SI is used to support the drilling of holes in the flattened area on the temporal bone at a defined distance and depth. These holes will be used for later placement of the fixation pins found on the underside of the implant housing.

For drilling the holes into the flat area, the following methods can be used:
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 /1.5mm to mark both hole positions and drill through the PIN Drill Guide SI. Avoid recessing the pins deeper than 1.5 mm by using a slow drilling speed (around 2,000 rpm) and removing the PIN Drill Guide SI before trying to achieve the depth of max. 1.5mm (see Figure 40).

After finishing the PIN holes you can use the PIN Check Template to verify the distance between the holes created for the implant pins (see page 20, figure 21)

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 1.4 mm to mark both hole positions. Then, drill the full depth of the pin hole. Avoid recessing the pins deeper than 1.5 mm.
STEP 7: Preparation of the Lateral Recess

**CAUTION**

- Ensure that all vessels supplying the brainstem are preserved.

Once the craniotomy is achieved, the dura is opened with a U-shaped incision. Before retracting the cerebellum, the cerebrospinal fluid (CSF) should flow out through the incision so that the brain can relax.

Identify the exits of the nerves VII and VIII and the caudal groups IX and X. After, find the flocculus of the cerebellum and smoothly retract it. In most cases, the choroid plexus of the IV ventricle is then exposed.

Gently dissect the arachnoid membrane covering these structures towards the space between plexus and brainstem.

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 Fourth ventricle.
STEP 8: Tumour Removal (in case of NF2)

If necessary, the acoustic neuroma is removed in a standard tumour 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 tumour 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 tumour and nerve tissue can be determined electrophysiologically. If the cochlear nerve is not yet destroyed by the tumour, it can be uncovered from tumour 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 9: EABR Recording with Placing Electrode

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 Chapter 4 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 enough and reliable.
STEP 10: Immobilise the Implant

STEP 10-A: CONCERTO

CAUTION

• Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
• 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 post-operative 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 6-A should be used to secure the implant in its bed and the electrode should be placed into the drilled channel leading into the brain or the titanium plates can be used for fixing the suture as shown in Figure 44. Make sure the electrode channel is deep enough to prevent the tie-down from exerting pressure and damaging the electrode.

Figure 44 Implant immobilised with Suture – right ear
STEP 10-B: CONCERTO PIN

CAUTION

- Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Recessing the pins and efficient immobilisation of the stimulator is important to prevent post-operative movement.
- Do not place the sutures directly over the electrode lead.

When the implant is immobilised with sutures, the titanium plates could be used to secure the implant in its flat area, the PINs should immobilise the implant against translational and rotating motion, 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 45).
STEP 11: 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 Chapter 4 Set-up and recommended measurement for EABR recording.
STEP 11-A: Implantation Procedure with EABRs

After fixation of the stimulator, the ABI Active Electrode shall be placed to approximately the same position as the removed placing electrode. The polyester mesh which is embedded in the silicone of the ABI electrode array can be cut to fit in the lateral recess. Go on with the procedure in STEP 12: EABR Measurements during Stimulation via the Implant CONCERTO/CONCERTO PIN ABI.

STEP 11-B: 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 were all electrode combinations elicit EABRs. If no EABRs can be recorded, the surgeon must 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 12: 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 Chapter 4 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 13: 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 14: Removal of the Platinum Bridge on the Implant Housing

The platinum bridge (Figure 46) on the implant housing shall be removed with forceps or micro hook. The platinum bridge is fixed with silicone only on its edges. This allows the lifting of the platinum bridge (Figure 47) from the surface of the implant. Pull out the whole platinum bridge (Figure 48 and Figure 49). Make sure that there is no residual platinum foil on the implant housing (Figure 49).
STEP 15: 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.
Appendix
Interference with other equipment, robustness of the device in special environments

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to Medical Procedures Manual shipped together with the implant or visit www.medel.com/isi.

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 possible.
- 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.
- In some countries, explanting hearing implants postmortem is mandatory because of environmental concerns; please check the local regulations.
- Prior to explantation in a revision case, please provide a device status assessment via telemetry measurement and preferably a high-resolution CT-Scan or X-Ray imaging. Please also take a picture of the device to be explanted, where it is still situated on the patient’s skull before removing it. Furthermore, please take another picture of the lateral recess prior to removal of the implant and electrode lead from the body.
- 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 ability of the manufacturer 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 for analysis and disposal. The device should be accompanied by written information including the reason for explantation. For such purpose, MED-EL can provide an Explant Kit (order number 04175). Please contact your local MED-EL representative in case of a scheduled device explantation.
- MED-EL implantable devices are intended for single use only. Do not resterilise and reimplant explanted devices.
Appendix

Literature on ABI

The Ml1000 CONCERTO PIN cochlear implant: An evaluation of its safety and stability in adults and children.

Auditory brainstem implants for neurofibromatosis type 2.

Auditory brainstem implantation.

Early surgical results of auditory brainstem implantation in nontumor patients

Complications in auditory brainstem implant surgery in adults and children.

Preliminary results of auditory brainstem implantation in prelingually deaf children with inner ear malformations including severe stenosis of the cochlear aperture and aplasia of the cochlear nerve.

Outcomes in nontumor adults fitted with the auditory brainstem implant: 10 years' experience.

Bilateral electric stimulation from auditory brainstem implants in a patient with neurofibromatosis type 2.

The High Rate CIS Auditory Brainstem Implant for Restoration of Hearing in NF-2 Patients.

The first successful case of hearing produced by electrical stimulation of the human midbrain.

Three-year experience in the rehabilitation of brainstem implant patients.

An auditory brainstem implant system.

First auditory brainstem implantation in Poland: auditory perception results over 12 months

Intraoperative Electrophysiologic Monitoring to assist Placement of Auditory Brain Stem Implant.

Lateral Skull Base Surgery the House Clinic Atlas: The retrosigmoid approach.
Appendix

MED-EL Surgical Videos

Please contact your local MED-EL office or distributor for the latest MED-EL Surgical Videos or visit the MED-EL Professional Webpage (www.medel.com/professionals).

MED-EL Contacts

For MED-EL Contacts please visit the MED-EL Webpage (www.medel.com/contact-offices).