MED EL

Mi1250 SYNCHRONY 2

Surgical Guide

AW38204_9.0 (English)

Introduction

The MED-EL Cochlear Implant System serves to restore hearing sensations through electrical stimulation of the auditory nerve. It is the result of many years of research at leading technical institutions throughout the world.

MED-EL cochlear 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). The MED-EL Cochlear Implant System and its components meet the requirements for AIMDD 90/385/EEC, MDD 93/42/EEC or MDR (EU) 2017/745.

This Surgical Guide describes proper techniques for implanting the Mi1250 SYNCHRONY 2 Cochlear Implant (hereafter referred to as the SYNCHRONY 2). It serves as additional information for professionals and should not be used as an instructions for use.

The information in this brochure is believed to be true and correct. However, specifications are subject to change without notice.

Not all products represented on these materials are currently approved or available in all markets. 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

FLEXSOFT / FLEX28 / FLEX26 / FLEX24 / FLEX20 / FORM24 / FORM19 / Standard / Medium / Compressed

The MED-EL Cochlear Implant System is intended to evoke auditory sensations via electrical stimulation of the auditory pathways. It is designed for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The MED-EL Cochlear Implant System is also intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals* with single–sided deafness, which is defined as severe to profound hearing impairment in one ear and normal hearing or mild to moderate hearing impairment in the other ear.

Additionally, the MED-EL Cochlear Implant System, when used in combination with the implant variants SYNCHRONY 2 FLEX24 and SYNCHRONY 2 FLEX20, is intended to evoke auditory sensations via electrical stimulation or via combined electric-acoustic stimulation (EAS) of the auditory pathways for partially deaf individuals, who obtain benefit from acoustic amplification in the lower frequencies only.

FLEX34

The cochlear implant SYNCHRONY 2 is part of the MED-EL Cochlear Implant System. The system consists of implantable and external components. The cochlear implant SYNCHRONY 2 is intended to evoke auditory sensations via electrical stimulation of the auditory pathways for severely to profoundly hearing-impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

The cochlear implant SYNCHRONY 2 is also intended to evoke auditory sensations via electrical stimulation of the auditory pathways for individuals with single-sided deafness (SSD) or asymmetric hearing loss (AHL), where:

- SSD is defined as severe to profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
- AHL is defined as severe to profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear.

* aged 18 years and older (Canada)

Selection and Evaluation

Patients should fulfil the audiological criteria of their respective country for open-set sentence testing and open-set monosyllabic words when tested with hearing aids. MED-EL strongly recommends the use of optimally fitted hearing aids for a minimum of three months before deciding to pursue a cochlear implant. In cases of ossification or deafness due to infectious disease, there may be no need to try a hearing aid, and implantation should generally not be delayed.

A complete cochlear implant evaluation protocol should include an audiologic assessment, a medical/surgical evaluation, counselling sessions and, when possible, a psychological assessment. To obtain the optimal benefit from the implant, candidates should be sufficiently motivated and understand the importance of returning to the implant centre for regular audio processor programming, training, and assessment sessions.

The medical evaluation prior to cochlear implant surgery serves to:

- assess the candidate's health status and ability to undergo surgery
- verify the absence of disease and infection of the outer and middle ear
- screen for cochlear obliteration and other obstacles to electrode insertion
- rule out central auditory lesions and verify a functional auditory nerve

The above evaluations usually involve an otologic/otoscopic examination and a CT scan and/or MRI. If there are concerns about the integrity of the upper auditory pathways and auditory lesions, an MRI is necessary.

It is important to realise that there are a variety of conditions that predispose a person to contracting bacterial meningitis irrespective of cochlear implantation, such as: malformations of the inner ear, history of recurrent meningitis, the presence of CSF leaks, etc. There is no evidence that implantation of a MED-EL device increases the risk for postoperative meningitis. MED-EL encourages all cochlear implant candidates and recipients, especially individuals with cochlear malformations and other risk factors, to discuss with their physician whether vaccination may be appropriate for them. The immunisation status of all cochlear implant candidates should be determined prior to surgery. Vaccination may reduce the risk of infection.

Technical Description of the Implant

The SYNCHRONY 2 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 removable magnet within its centre, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The electrode array can be of different types, thus resulting in different implant variants. This device is intended to be implanted by adequately trained and experienced surgeons only.

The SYNCHRONY 2 has been designed according to the highest safety and reliability standards. All materials used in the construction of the SYNCHRONY 2 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 SYNCHRONY 2 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 safety capacitor to prevent any possible leakage of direct current (DC) to the auditory nerve.

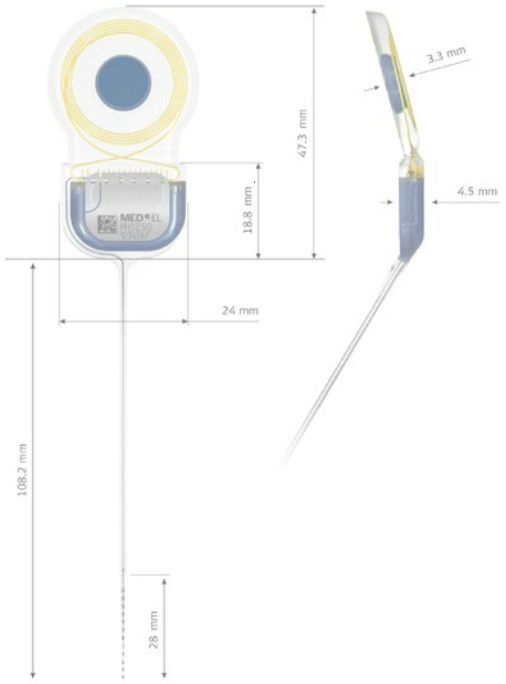


Figure 1 SYNCHRONY 2 Cochlear Implant with FLEX28 electrode array (~dimensions in mm, typical values. Electrode length varies depending on chosen electrode type).

Performance Characteristics

- Output characteristics of a stimulation signal on a 1 kOhm 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 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 7.7 g (typical value).
- The volume of the implant without electrode is 3.8 cm³.
- The electrode is made of medical grade silicone, platinum (electrode contacts) and platinum/iridium (90/10) wires.
- All electrode variants have a straight and flexible design. The electrode does not deliver any pharmaceutical 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 and parylene c.

Implant Variants *

Cochleae may differ significantly in size and shape from one another as can individual cochlear duct lengths. MED-EL offers the largest selection of electrode arrays for each implant variant. Please see Chapter 5, Step 11, “Select Appropriate Electrode Variant” for the circumstances in which each variant should be used.

FLEX34 Electrode Array

Order number: **41550 (SYNCHRONY 2)**
41548 (SYNCHRONY 2 S-Vector)

The FLEX34 electrode array (see Figure 2) is 34 mm long featuring FLEX tip technology for increased mechanical flexibility and enabling CCC (Complete Cochlear Coverage) intended to be used in open cochlea with no obliteration or ossification . The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with 2.6 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The marker ring is located 34 mm from the electrode top and indicates the deepest insertion. Near the marker ring , the electrode lead features a colored silicone marker on the same side of the array as the single apical contacts for improved visibility during surgery

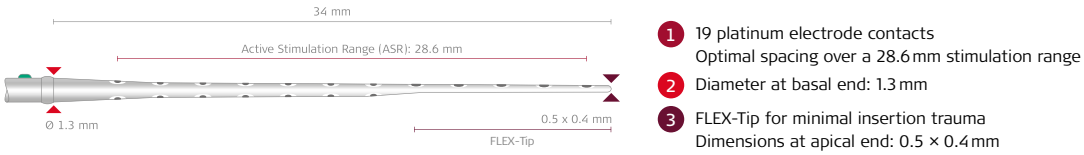


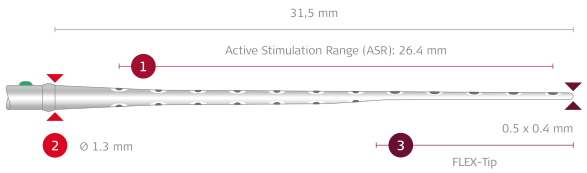
Figure 2 FLEX34 electrode array

* Implant variants availability is subject to regulatory approval

FLEXSOFT™ Electrode Array

Order number: 36707 (SYNCHRONY 2)
39569 (SYNCHRONY 2 S-Vector)

The FLEXSOFT electrode array (see Figure 2) is 31.5 mm long featuring FLEX tip technology for increased mechanical flexibility and enabling CCC (Complete Cochlear Coverage). The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 2.4 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The marker ring is located 31.5 mm from the electrode tip and indicates the deepest insertion. Near the marker ring, the electrode lead features a colored silicone marker on the same side of the array as the single apical contacts for improved visibility during surgery.



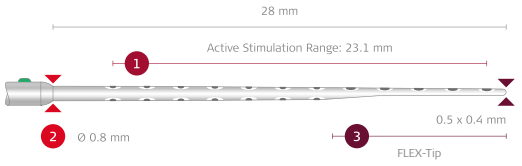
1. 19 platinum electrode contacts
   Optimal spacing over a 26.4 mm stimulation range
2. Diameter at basal end: 1.3 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.4 mm

Figure 3 FLEXSOFT™ electrode array

FLEX28™ Electrode Array

Order number: 36711 (SYNCHRONY 2)
39573 (SYNCHRONY 2 S-Vector)

The FLEX28 electrode array (see Figure 4) is 28 mm long featuring FLEX tip technology suitable for 96 % of all normal cochlear duct lengths. The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 2.1 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The insertion marker is located 28 mm from the electrode tip and indicates the deepest insertion. Near the insertion marker, the electrode lead features a colored silicone marker on the same side of the array as the single apical contacts for improved visibility during surgery.



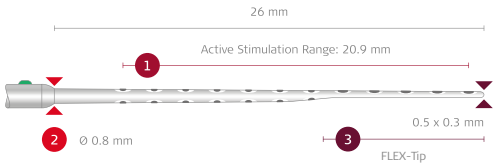
1. 19 platinum electrode contacts
   Optimal spacing over a 23.1 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.4 mm

Figure 4 FLEX28™ electrode array

FLEX26™ Electrode Array

Order number: 36904 (SYNCHRONY 2)
39575 (SYNCHRONY 2 S-Vector)

The FLEX26 electrode array (see Figure 5) is 26 mm long featuring FLEX tip technology and is intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 26mm. The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 1.9 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The insertion marker is located 26 mm from the electrode tip and indicates the deepest insertion. Near the insertion marker, the electrode lead features a colored silicone marker on the same side of the array as the single apical contacts for improved visibility during surgery.



1. 19 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

Figure 5 FLEX26™ electrode array

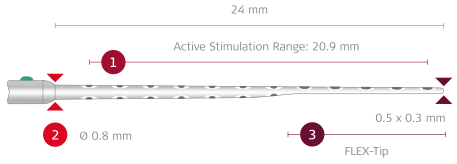
FLEX24™ Electrode Array

EAS

EAS Surgical Training Recommended

Order number: 36709 (SYNCHRONY 2)
39571 (SYNCHRONY 2 S-Vector)

The FLEX24 electrode array (see Figure 6) is 24 mm long featuring FLEX tip technology and designed for combined Electric Acoustic Stimulation (EAS) less than 1.5 turns. The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 1.9 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The insertion marker is located 24 mm from the electrode tip and indicates the deepest insertion. Near the insertion marker, the electrode lead features a colored silicone marker on the same side of the array as the single apical contacts for improved visibility during surgery.



1. 19 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

Figure 6 FLEX24™ electrode array

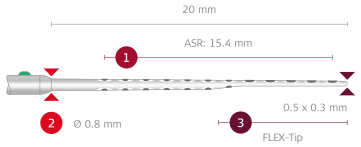
FLEX20™ Electrode Array

EAS

EAS Surgical Training Recommended

Order number: 367181 (SYNCHRONY 2)
39577 (SYNCHRONY 2 S-Vector)

The FLEX20 electrode array (see Figure 7) is 20 mm long featuring FLEX tip technology and designed for combined Electric Acoustic Stimulation (EAS). The contacts for the 12 channels are arranged as 5 single contacts at the apical array end and 7 contact pairs at the base with a 1.4 mm spacing between each channel. The specially designed electrode tip offers increased mechanical flexibility for reduced insertion force. The insertion marker is located 20 mm from the electrode tip and indicates the deepest insertion. Near the insertion marker, the electrode lead features a colored silicone marker on the same side of the array as the single apical contacts for improved visibility during surgery.



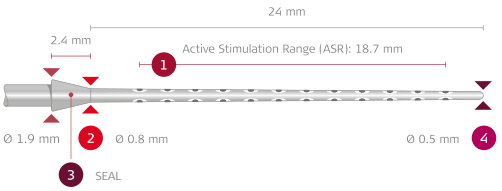
1. 19 platinum electrode contacts
   Optimal spacing over a 15.4 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

Figure 7 FLEX20™ electrode array

FORM 24™ Electrode Array

Order Number: 37185 (SYNCHRONY 2)
39581 (SYNCHRONY 2 S-Vector)

The FORM24 electrode array* (see Figure 8) is 24 mm long designed for open (no obliteration or ossification) or malformed cochleae, especially Type II malformations. It features 12 evenly spaced electrode pairs spaced over 18.7 mm, with 1.7 mm spacing between each contact pair. The FORM24 electrode array features an integrated SEAL function designed to aid closing off the cochlear opening. SEAL is a 2.4 mm conical thickening located at the basal end of the array designed to help control the leakage of cerebrospinal fluid (CSF) during surgery, also known as 'gusher'.



1. 24 platinum electrode contacts
   Optimal spacing over a 18.7 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. SEAL
4. Diameter at apical end: 0.5 mm

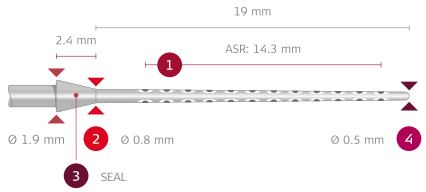
Figure 8 FORM 24™ electrode array

* Electrode development was in close collaboration with Prof. Levent Sennaroglu, Department of Otolaryngology, Hacettepe University Medical Faculty, Turkey

FORM19™ Electrode Array

Order Number: 37183 (SYNCHRONY 2)
39579 (SYNCHRONY 2 S-Vector)

The FORM19 electrode array* (see Figure 9) is 19 mm long designed intended to be used in cochleae with malformation, especially Type I and Type III, obliteration, or ossification. It features 12 evenly spaced electrode pairs spaced over 14.3 mm, with 1.3 mm spacing between each contact pair. The FORM19 electrode array features an integrated SEAL function designed to aid closing off the cochlear opening. SEAL is a 2.4 mm conical thickening located at the basal end of the array designed to help control the leakage of cerebrospinal fluid (CSF) during surgery, also known as 'gusher'.



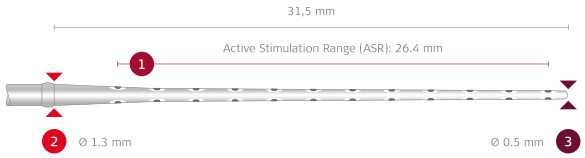
1. 24 platinum electrode contacts
   Optimal spacing over a 14.3 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. SEAL
4. Diameter at apical end: 0.5 mm

Figure 9 FORM19™ electrode array

Standard Electrode Array

Order number: 36701 (SYNCHRONY 2)
39563 (SYNCHRONY 2 S-Vector)

The Standard electrode array (see Figure 10) is 31.5 mm long and designed for long cochlear duct lengths. Contacts are spaced over 26.4 mm with 2.4 mm spacing between each contact pair. The electrode's length allows insertion into the scala tympani and stimulation of the cochlea to the fullest extent possible. The marker ring is located 31.5 mm from the electrode tip and indicates the deepest insertion. The diameter of the array increases to 1.3 mm at the proximal thicker part of the array just before the marker ring.



1. 24 platinum electrode contacts
   Optimal spacing over a 26.4 mm stimulation range
2. Diameter at basal end: 1.3 mm
3. Diameter at apical end: 0.5 mm

Figure 10 Standard electrode array

* Electrode development was in close collaboration with Prof. Levent Sennaroglu, Department of Otolaryngology, Hacettepe University Medical Faculty, Turkey

Medium Electrode Array

Order number: 36703 (SYNCHRONY 2)
39565 (SYNCHRONY 2 S-Vector)

The Medium electrode array (see Figure 11) is 24 mm long and designed for cases where deep insertion is not desired or is not possible due to anatomic restrictions. It features 12 evenly spaced electrode pairs spaced over 20.9 mm, with 1.9 mm spacing between each contact pair. Note that the Medium electrode array is not inserted up to the marker ring.

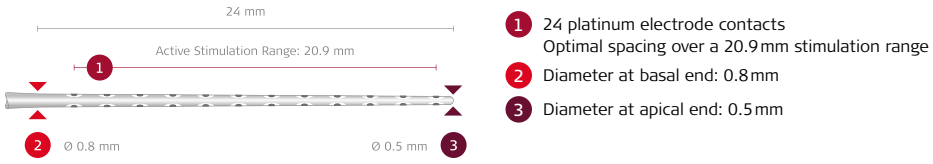


Figure 11 Medium electrode array

Compressed Electrode Array

Order number: 36705 (SYNCHRONY 2)
39567 (SYNCHRONY 2 S-Vector)

The Compressed electrode array (see Figure 11) is 15 mm long and designed for partial ossification or malformation of the cochlea. It features 12 pairs of contacts spaced closer together in the apical end of the array. The contacts are spaced over 12.1 mm, with 1.1 mm between each contact pair. Note that the Compressed electrode array is not inserted to the marker ring.

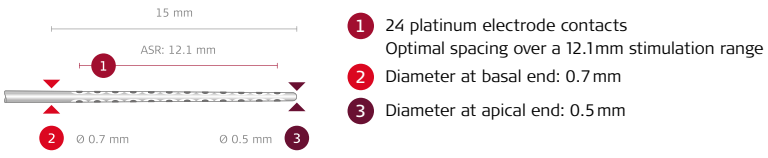


Figure 12 Compressed electrode array

Surgical Tools and Accessories*

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 instructions for use.

Following instruments can support the implantation of the SYNCHRONY 2 Cochlear Implant.

Reusable Surgical Tools

Planning Tools

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.

Figure 13
Processor Template (Ms040213)

Skin Flap Gauge 6 (Ms050212)

Order number: 03543

The 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 necessary for a good magnetic hold and optimal signal transmission. Thick skin flaps should be reduced to 6 mm or less.

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
Skin Flap Gauge 6 (Ms050212)

* Not all products are necessarily approved or available in all countries.
Contact your local MED-EL representative for information on current product availability in your country.

Templates

PIN Drill Guide CL (Ms040216)

Order Number: 36878

The PIN Drill Guide CL is a re-usable surgical instrument which can be used as stimulator template for planning and assessment of the stimulator position of the SYNCHRONY 2 cochlear implant.

It also can be used as a drill guide for determining the distance between the pins of the SYNCHRONY 2 PIN cochlear implant.

This surgical instrument is made for transient use. It consists of a base made of titanium and a clamping handle made of stainless chromate steel. The device is delivered non-sterile.

Figure 15
PIN Drill Guide CL (Ms040216)

Electrode Insertion Tools

SoftGrip Forceps (Ms050207)
SoftGrip Forceps SR (Ms050208)

Order number: **58326 SoftGrip Forceps**
58393 SoftGrip Forceps SR

The SoftGrip Forceps are used to grip and hold the cochlear implant electrode by enclosing it with the longitudinal grooves at the tip of the device and to insert the electrode array into the cochlea.

The SoftGrip Forceps SR (58393) can be used as alternative tool to the SoftGrip Forceps (58326). The device has a self-retaining design to hold the electrodes without any external force.

These tools are re-usable surgical instruments for transient use. They are made from medical grade stainless steel and have a Diamond Like Carbon (DLC) coating. The devices are delivered non-sterile.

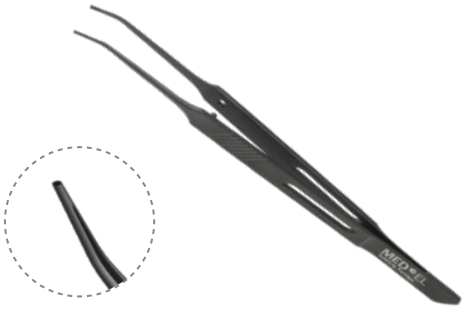


Figure 16
SoftGrip Forceps (Ms050207)

Figure 17
SoftGrip Forceps SR (Ms050208)

Surgical Claw angled (Ms050202)

Order number: 00284

The Surgical Claw angled can help to position and insert the electrode array into the cochlea. The tip of this instrument is slightly bent for better visualisation during electrode insertion.

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

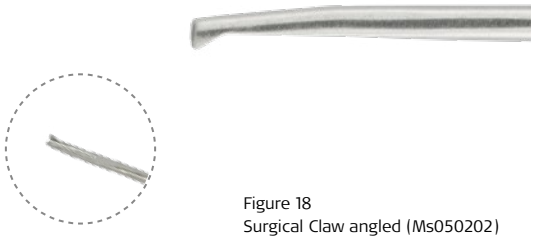


Figure 18
Surgical Claw angled (Ms050202)

Surgical Claw straight (Ms050201)

Order number: 07711

The Surgical Claw straight 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.

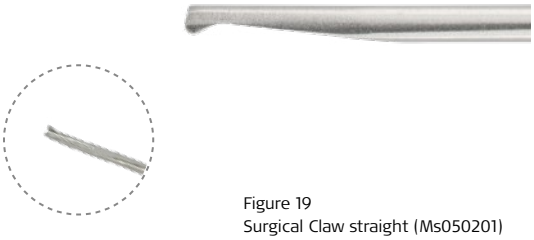


Figure 19
Surgical Claw straight (Ms050201)

Micro Forceps Angled (Ms050204 & Ms050203)

Order number:
05761 Micro Forceps Angled Set (Ms050204) & (Ms050203)
05777 Micro Forceps right angled (Ms050204)
05778 Micro Forceps left angled (Ms050203)

The Micro Forceps left angled and the Micro Forceps right angled are used to grip, hold and insert the electrode into the cochlea without damaging it. It is the surgeon's preference which angled Micro Forceps to use to insert the electrode array in either the left or the right ear. In the closed position, the tips of the forceps are parallel to each other, separated by a distance of 0.25 mm.

These tools are re-usable surgical instruments made from medical grade stainless steel. The devices are delivered non-sterile.

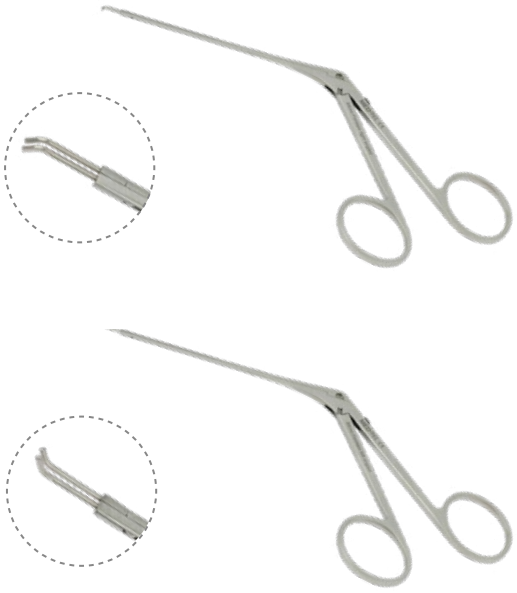


Figure 20
Micro Forceps right angled (Ms050204)
Micro Forceps left angled (Ms050203)

Surgical Instrument Tray

The Surgical Instrument Tray is intended to be used to contain and hold the MED-EL reusable surgical tools for steam sterilization, storage and aseptic presentation in clinical centers. The Surgical Instrument Tray includes a sterilization container consisting of a tray and lockable lid, and a selection of exchangeable tray inlays.

The Surgical Instrument Tray is offered in 4 different configurations with different inlay selections and sizes.
The individual inlays and the sterilization container can also be ordered separately. For recommendations on Surgical Tools to be ordered with the different Surgical Instrument Tray Configurations, please refer to the respective product catalogue for surgical tools and accessories.

Surgical Instrument Tray Configurations

Surgical Instrument Tray – Configuration 1

Order number: 41457

Configuration 1 includes*:
1 x Sterilization Container (Ms990204)
2 x Tray Inlay 3, Small Mat (Ms990207)
1 x Tray Inlay 7, Large Generic (Ms990210)

Figure 21
Surgical Instrument Tray – Configuration 1

Surgical Instrument Tray – Configuration 2

Order number: 41458

Configuration 2 includes*:
1 x Sterilization Container (Ms990204)
1 x Tray Inlay 3, Small Mat (Ms990207)
1 x Tray Inlay 7, Large Generic (Ms990210)
1 x Tray Inlay 8, Small Generic (Ms990211)

Figure 22
Surgical Instrument Tray – Configuration 2

* The surgical tools shown on the pictures are not included in the Surgical Instrument Tray and need to be ordered separately. The pictures illustrate how the surgical tools can be arranged in the Surgical Instrument Tray.

Surgical Instrument Tray – Configuration 3

Order number: 41459

Configuration 3 includes*:
1 x Sterilization Container (Ms990204)
1 x Tray Inlay 6, Large Mat (Ms990209)
2 x Tray Inlay 8, Small Generic (Ms990211)

Figure 23
Surgical Instrument Tray – Configuration 3

Surgical Instrument Tray – Configuration 4

Order number: 41460

Configuration 4 includes*:
1 x Sterilization Container (Ms990204)
1 x Tray Inlay 3, Small Mat (Ms990207)
1 x Tray Inlay 6, Large Mat (Ms990209)
1 x Tray Inlay 8, Small Generic (Ms990211)

Figure 24
Surgical Instrument Tray – Configuration 4

* The surgical tools shown on the pictures are not included in the Surgical Instrument Tray and need to be ordered separately. The pictures illustrate how the surgical tools can be arranged in the Surgical Instrument Tray.

Surgical Tools and Accessories for Magnet Replacement Procedure

The SYNCHRONY 2 Features a Secure Removable Implant Magnet.

The Magnet Replacement Kit, S-Vector Magnet Replacement Kit and Magnet Tool Kit provide all the necessary components for the magnet replacement procedure.

Magnet Replacement Kit

Order number: 09693

Provides the magnet components needed for magnet removal/ insertion and should be used in conjunction with the Magnet Tool Kit. This kit is for single-use only and is delivered sterile.

Includes:
1 Non-Magnetic Spacer (Purple) (Ms010107)*
1 Replacement Magnet (Blue) (Ms010108)*

Figure 25
Non-Magnetic Spacer (Ms010107)

Figure 26
Replacement Magnet (Ms010108)

S-Vector Magnet Replacement Kit

Order number: 38234

Provides the magnet components needed for magnet removal/insertion and should be used in conjunction with the Magnet Tool Kit. This kit is for single-use only and is delivered sterile.

Includes:
1 Non-Magnetic Spacer (Purple) (Ms010107)
1 S-Vector Replacement Magnet (Silver) (Ms010109)

NOTE: The S-Vector Replacement Magnet results in a slightly increased magnetic retention force. Always consider the possibility to adjust the attraction force characteristics by changing the magnet of the external part of the MED-EL Hearing Implant System.

Figure 27
S-Vector Replacement Magnet (Ms010109)

* not sold seperately

Magnet Tool Kit

Order number: 09734

Provides the surgical tools needed for magnet removal/ insertion and should be used in conjunction with the Magnet Replacement Kit or the S-Vector Magnet Replacement Kit. These tools are re-usable instruments for transient use. They are delivered non-sterile.

Includes:
1 Magnet Removal Tool (Ms050206)*
1 Magnet Insertion Tool (Ms050205)*

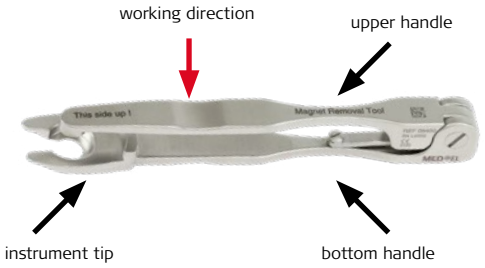


Figure 28
Magnet Removal Tool (Ms050206)

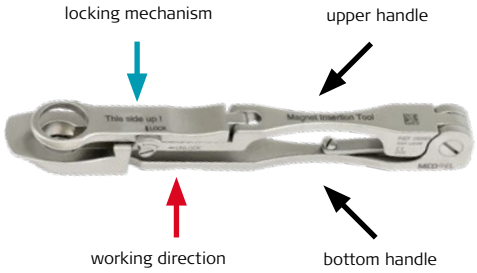


Figure 29
Magnet Insertion Tool (Ms050205)

* not sold seperately

Single-Use Surgical Accessories

Implant Templates

Mi1250 Implant Template (Ms040107)

One template is included in every implant packaging.

Oder number: 36894

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.

Figure 30
Mi1250 Implant Template (Ms040107)

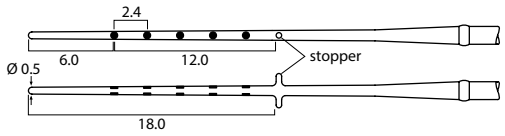
Insertion Test Tools

They are primarily used when ossification or fibrosis is suspected to aid the surgeon in determining which electrode variant to use (e.g. for detailed dimensions please see Chapter 2 Implant Variants).

Insertion Test Device (ITD) (Ms010117)

Order number: 02081

The ITD is similar to the Standard electrode array in dimension and shape. It has a stopper at 18.0 mm and 5 pairs of markers to help determine insertion depth up to a maximum of 18.0 mm. The Insertion Test Device is delivered in sterile packaging and is a single-use device only.



Typical dimensions in mm

Contact spacing:	2.4 mm
Markers:	2×5
Max. insertion depth:	18.0 mm

Figure 31 Insertion Test Device (Ms010117)

Insertion Electrode (IE)

With the Insertion Electrode (IE) the surgeon can establish whether the cochlear lumen is obstructed or if it is freely accessible up to different insertion depths depending upon the considered electrode variant planned for the implantation.

The Insertion Electrodes are delivered in sterile packaging and are single-use devices only.

Order Number	Insertion Electrode Array
41621	IE FLEX34 (Ms010120)
08255	IE FLEXSOFT (Ms010115)
08348	IE FLEX28 (Ms010114)
36633	IE FLEX26 (Ms010116)
08257	IE FLEX24 (Ms010113)
08254	IE Standard (Ms010110)
08256	IE Medium (Ms010111)
08258	IE Compressed (Ms010112)

Additional Accessories

Insertion Probe (Ms010118)

Order number: 33563

The stiff side (blue) of the Insertion Probe is intended to dilate the cochlear lumen up to a length of 20 mm in cases where fibrotic tissue is present. The other side (transparent) can be used to confirm access up to 31.5 mm. The Insertion Probe shall not be used, if residual hearing preservation is required.

Figure 32
Insertion Probe (Ms010118)

Insertion Probe Long (Ms010119)

Order number: 40555

The Insertion Probe L is intended to dilate the cochlear lumen up to a length of 31.5 mm in cases where fibrotic tissue is present. The Insertion Probe shall not be used, if residual hearing preservation is required.

Figure 33
Insertion Probe Long (Ms010119)

Fixation Clip (Ms010103)

Order number: 09917

The Fixation Clip is a single-use long-term passive implantable device to be implanted during MED-EL Cochlear Implant surgery. The Fixation Clip is intended to stabilize the electrode lead inside the middle ear cavity and should be used after the implant is immobilised and the electrode was inserted into the cochlea.

The Fixation Clip is intended for single use only.

Figure 34
Fixation Clip (Ms010103)

General Remarks About the Surgery

- Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated.
- Facial nerve monitoring is recommended. When carried out, neuromuscular blockage should be avoided.
- Evaluation of possible electrode insertion length for the individual patient is recommended prior to surgery. This can be performed by acquiring a CT scan. Furthermore, OTOPLAN can support healthcare professionals in preoperative planning and postoperative quality checks of otological procedures*.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface; the implantable antenna coil with the magnet must not be bent or flexed; damage to the implant or electrodes during handling and surgery will void the warranty.
- Before opening the implant box a telemetry should be done to check the integrity of the implant inside the box.
- In cases where the patient has a thick skin flap, the flap should be thinned to no more than 6 mm. Use the Skin Flap Gauge 6 to accurately determine skin flap thickness.
- Make sure the implant is immobilised so that there will be no postoperative movement. For a more detailed description, please refer to Step 12 "Immobilise the Implant".
- 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.
- Do not place sutures over the 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.
- Only surgical instruments approved by MED-EL should be used during the insertion process, other instruments (probes, hooks, forceps, tweezers, etc.) can damage the electrode array.
- The electrode array should be inserted as far as possible or planned, according to the individual electrode insertion length, into the cochlea without compressing the array, or using excessive force.
- After the electrode array has been inserted into the cochlea, small pieces of fascia should be placed around the electrode array at the entrance to the cochlea to secure the electrode array and to seal the cochlea opening.
- The excess electrode lead must be placed forcefree and secured with caution under the cortical overhang in the mastoid cavity, so that the electrode array will not migrate out of the cochlea or be subject to external pressure that could cause movement and subsequent damage to the electrical connections.
- 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 electrode array.
- A paper on pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis may be useful additional reading. (Arnold et al, ORL 2002;64:382-389).
- Middle ear infection or a temporary loss of lymphatic fluid in cochlea can lead to temporarily elevated electrode impedances or impedance fluctuations. Such impedance fluctuations can cause variation in loudness which may in some cases resolve on its own over the course of a few weeks, other cases may require surgical intervention.

* Implant variants availability and OTOPLAN are subject to regulatory approval. OTOPLAN is a software offered by CASCINATION AG, Bern, Switzerland. Please contact your local MED-EL representative if you are interested in surgical planning possibilities.

Surgical Procedure

The SYNCHRONY 2 Cochlear Implant can be implanted using a small incision, however, for a better visualisation only, the following illustrations include an enlarged incision area. Additionally, some of the medical illustrations are schematic and can differ from a patient's anatomical situation.

Every CI surgery should be performed as atraumatically as possible so that critical structures and existing residual hearing can be preserved. Additional important surgical steps for EAS patients can be found in the dedicated EAS infoboxes. Summarised EAS information can be found in the appendix.

STEP 1: Prepare Patient

As a prophylactic measure, intravenous antibiotics should be given 1/2 to 1 hour before the incision is made.

After the patient has been anaesthetised, the incision area should be shaved. Usually an area including the incision line and the area between the incision and the pinna is shaved. Some surgeons choose to shave only the area over the predetermined line of the incision, and they recommend a margin of at least 2 cm around the incision. Meticulous care should be taken to ensure that the site is well cleansed. After cleansing and draping the site, inject local anaesthetics containing vasoconstrictors, e.g. adrenaline 1:200,000 up to 20 mls.

EAS

- Please ensure that corticosteroids (crystalline triamcinolone solution or dexamethasone), intravenous corticosteroids, and hyaluronic acid are all available for the surgery.
- Administer intravenous antibiotics from the Cephalosporin group approximately half an hour before the skin incision.

STEP 2: Mark Implant Position

Place the Processor Template behind the ear and position the Mi1250 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 is shown in Figure 35, but the orientation depends on various factors, like e.g. the curvature of the skull.

Position the implant template in such a way that the SYNCHRONY 2 Cochlear Implant 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° according to surgeons preference and individual circumstances.

Once the ideal placement has been found, surgical ink is used to outline the implant position on the skin. This position can be later on translated onto the patients skull (see STEP 5).

When implanting a patient bilaterally, care should be taken with the placement of the implants. In particular the second side should be placed specifically to match the location of the first to give a symmetric appearance of the external system components like Coils or Single Unit Audio Processors. The skull curvature and pinna position need to be taken into consideration when placing the second implant similar to the contralateral side.

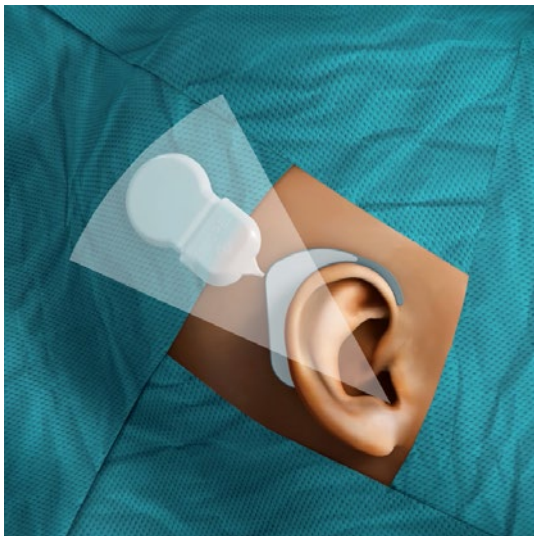


Figure 35
Suggested orientation of the templates.
This applies in equal measure for the left, and the right side.

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 haemostasis.

An example of a commonly used postaural incision is shown in Figure 36 and Figure 37. 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.

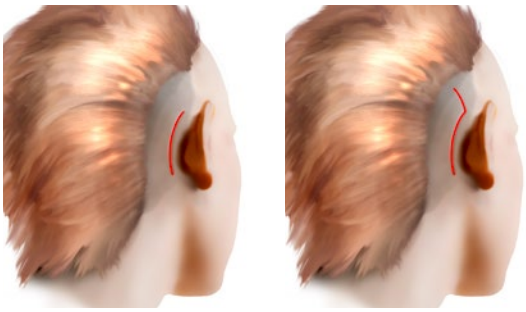


Figure 36
Minimal incision (left picture) and lazy "S" incision (right picture) – right ear

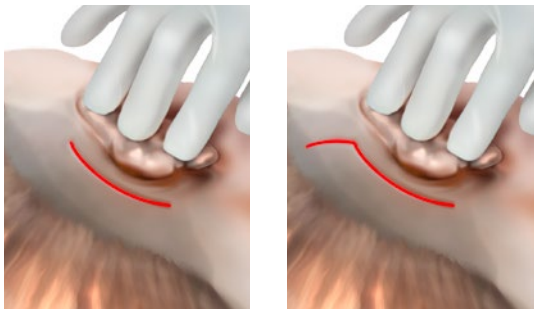


Figure 37
Minimal incision (left picture) and lazy "S" incision (right picture) – right ear – close up

STEP 4: 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 38)

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.

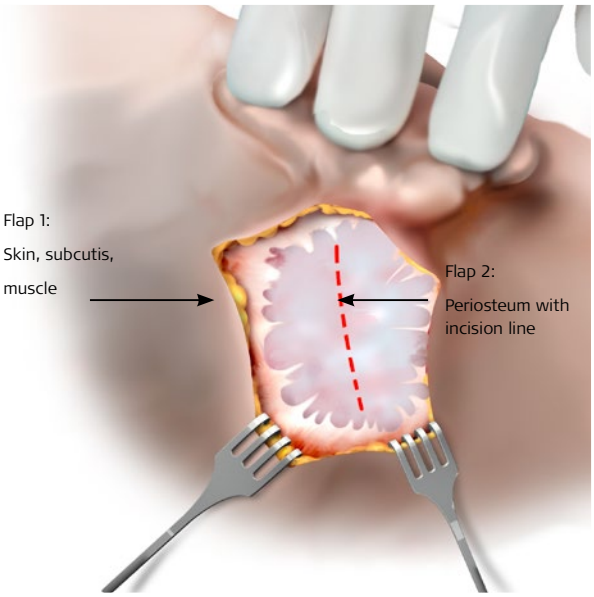


Figure 38
Double layer skin flap – right ear

STEP 5: Prepare Sub-Periosteal Pocket

Prepare the sub-periosteal pocket e.g. with a raspatory in order to make space for the implant body. Make sure that the size of the sub-periosteal pocket is comparable to the implant size and not larger than necessary for additional implant stabilisation and minimal invasiveness. The implant markings on the head of the patient, carried out in STEP 2, can assist you in defining the right size.

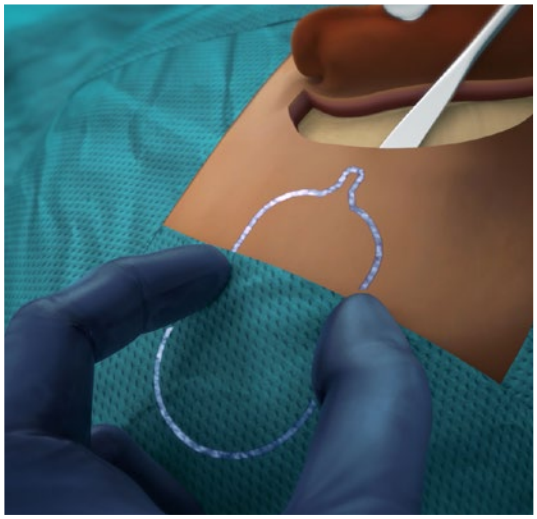


Figure 39
Preparing sub-periosteal pocket - right ear

STEP 6: 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 implant magnet and receiving coil with the Skin Flap Gauge 6, as shown in Figure 40. 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.

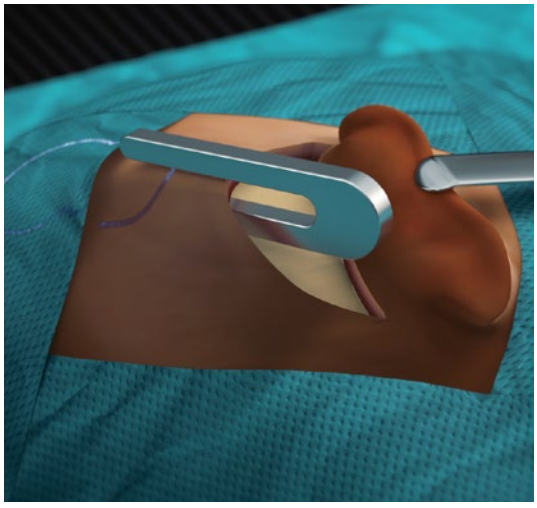


Figure 40
Using the Skin Flap Gauge 6 – right ear

STEP 7: Transfer Implant Position on Patients Skull

CAUTION

Retractors may distort the actual position of the implant in relation to the pinna as the ear is retracted.

In consideration of the previously defined implant and coil position in Step 2, it might be necessary to transfer this position onto the patients skull bone to ensure a consistent placement. Therefore the Mi1250 Implant Template should be placed in the subperiosteal pocket in accordance with the outside marking and a re-marking with a surgical pen is performed on the bone (see Figure 41). For this step, also the PIN Drill Guide CL can be used (see Chapter 3 Surgical Tools and Accessories). It is the surgeons decision to either perform this step before or after creating the middle ear access.

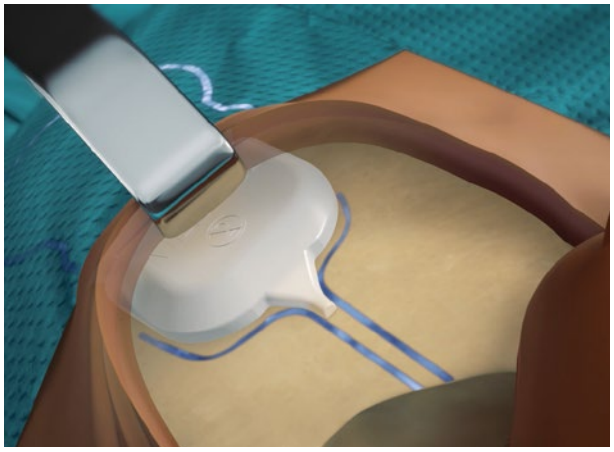


Figure 41
Marking the implant position with the Implant Template – right ear

STEP 8: Drill Mastoidectomy and Posterior Tympanotomy

CAUTION

Clear identification of the anatomical landmarks is required. When drilling, care should be taken to avoid exposing the dura inadvertently. If the dura is exposed as a landmark, exposure shall be kept to an absolute minimum. Inadequate large exposure or injury to the dura may reduce the barrier to future infection and may increase the potential risk for future meningitis. For example, neuro-radiological follow-up in cases of fractures of the anterior skull base have shown that acute progressing meningitis may occur, even years later. Similar mechanisms may also exist in respect of ear and mastoid surgery.

Facial nerve monitoring is recommended; when carried out, neuromuscular blockade should be avoided.

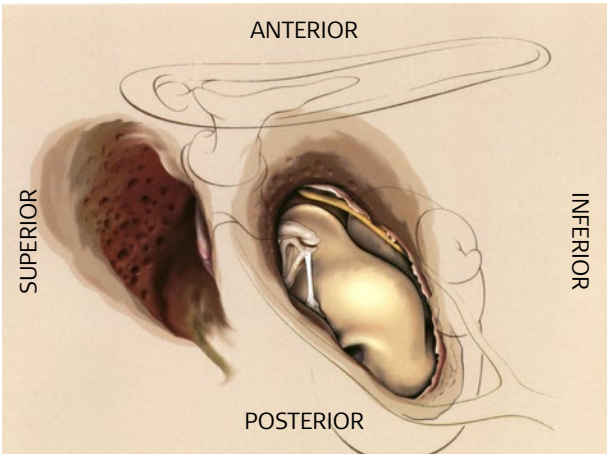


Figure 42
Posterior epitympanotomy and posterior tympanotomy – right ear

A standard cortical mastoidectomy is performed with a cutting burr, while ensuring good irrigation. A cortical overhang should be left, both superiorly and posteriorly; it can later serve as a natural support for the electrode lead as it is placed in the mastoid cavity.

The fossa incudis should be located, and the tip of the short process of the incus is identified to ensure the proper orientation of the posterior tympanotomy. This important part of the operation should be practiced many times on human cadaver temporal bones before live surgery is performed. A triangular opening is made between the mastoid and the facial nerve, which is referred to as the facial recess. The posterior limit is the vertical portion of the facial nerve, the anterior limits are the annulus and chorda tympani, and the upper aspect is a posterior buttress at the level of the fossa incudis. Start drilling immediately below the fossa incudis, using a 3 mm diamond burr centred on the tip of the short process. Use high magnification and copious irrigation. Extreme care should be taken in drilling the posterior tympanotomy and the surgeon should be aware of any possible anatomical variants of the facial nerve.

The following should be visible after the posterior tympanotomy: the long process of the incus, the incudostapedial joint, the stapes pyramid and stapedius tendon, the promontory and the round window niche (see Figure 43 and Figure 44).

When the Fixation Clip will be used to stabilise the electrode lead inside the middle ear cavity care should be taken that the posterior buttress (see Figure 44) is created accordingly to the dimensions of the Fixation Clip. The recommended size of the posterior buttress is 2 mm.

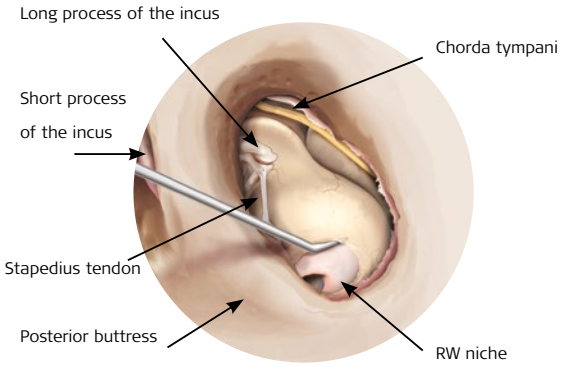


Figure 43
Posterior tympanotomy microscopic view – right ear

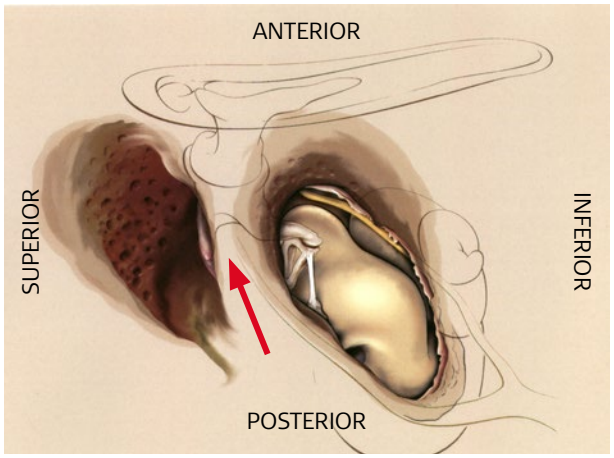


Figure 44
Posterior buttress prepared for the Fixation Clip – right ear

EAS

- It is recommended to create a larger posterior tympanotomy (as compared to that of a standard cochlear implantation) beside the posterior epitympanotomy in order to provide a better view as well as more space to manoeuvre the electrode array.
- Elevate a mucosal flap to avoid mucosal bleeding when opening the cochlea.

STEP 9: Preparation for Implant Fixation and Drilling Electrode Lead Channel

CAUTION

- The implant fantail and the proximal part of the electrode lead should be secured within a ramp-like bony channel without sharp edges. Otherwise these parts may be exposed on the patients skull and vulnerable to possible postoperative movement and external 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. Drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- Protect the middle ear cavity from bone dust contamination by closing it with e.g. medical gauze.

As described in STEP 7, use the implant position markings on the skull for drilling the implant bed and electrode lead channel. Use the Mi1250 Implant Template or the PIN Drill Guide CL for checking the proper size, depth, and flatness of the implant bed.

If the implant is fixed with sutures, a diamond burr should be used to drill the suture holes so that the implant can be immobilised at a later stage. The holes should be drilled such that the sutures do not cross the central electrode lead exit (see Figure 45).

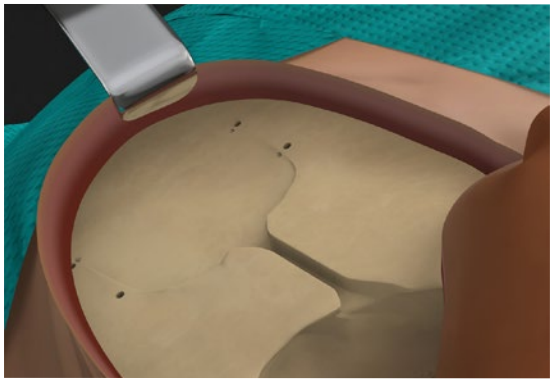


Figure 45
Implant bed, suture holes, and electrode lead channel – right ear

For protection and secure placement of the fantail and electrode lead, a smooth, ramp-like channel has to be drilled in the bone leading to the posterior edge of the cortical mastoidectomy (Figure 38). It is recommended to fully recess the electrode lead within this channel, otherwise these parts may be exposed on the patients skull to possible postoperative movement and external impact. The electrode lead of the SYNCHRONY 2 is 1.3 mm in diameter. Therefore, a 1.5 mm deep bony channel is sufficient (Figure 46).

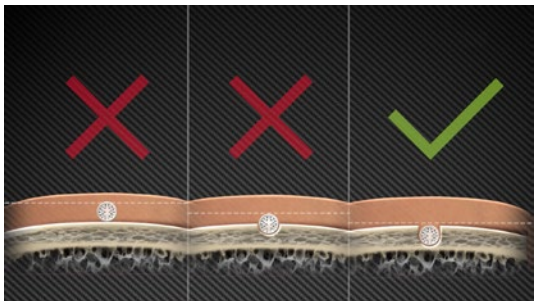


Figure 46
Full recessment of the electrode lead

The electrode lead should be fixed in the electrode lead channel. For example, drilling an open bony bridge (Figure 47A) or a tight channel with small overhang (Figure 47B). If it is not possible to drill a 2 mm deep implant bed and to not fully recess the electrode lead, you can add bone paté over the channel and the proximal side of the implant housing for increased protection (Figure 47C).

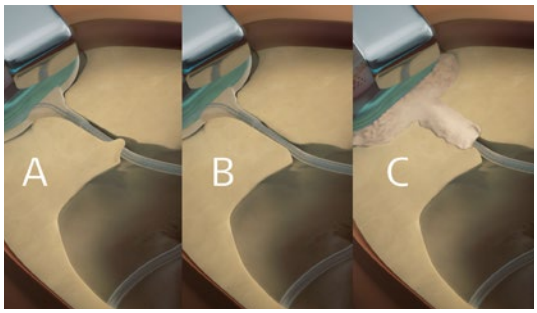


Figure 47
Different types of electrode lead channels

STEP 10 – VARIANT 1: Preparation for a Round Window Opening

CAUTION

- Always use a slow turning diamond drill to avoid acoustic trauma when drilling the round window (RW) niche (approx. 1000rpm).
- Try to keep the RW membrane intact until the insertion of the electrode.

A clear view of the RW membrane is fundamental for the successful performance of a round window opening. Therefore, the drilled area of the posterior tympanotomy is usually slightly larger than that of a standard posterior tympanotomy to get a clear view of the RW niche.

Before starting the preparation of the RW niche, a mucosal fold should be removed from the promontory. This prevents mucosal bleeding and provides better feedback from the tip of the drill (see Figure 48).

Figure 48
Elevating a mucosal flap – right ear

To facilitate the electrode insertion a portion of the anterior-inferior bony RW margin as well as the superior overhang of the RW niche needs to be drilled away. This increases the accessibility of the RW and prevents the electrode from being directed towards the modiolus. One potential risk associated with drilling the RW margin relates to its close proximity to the opening of the cochlear aqueduct. Care should be taken to avoid this inner ear structure.

Advantages of a RW opening:

- The amount of drilling is significantly reduced compared to a cochleostomy and no endosteal preparations in the direct vicinity of the basilar membrane are needed.
- The round window always leads into the correct scala for an electrode insertion – the scala tympani.

To enter the middle portion of the scala tympani and to get visualisation of the RW membrane, the posterior-superior lip of the round window niche and the inferior margin of the round window should be drilled away. By doing this, the round window will be exposed for best insertion of the electrode array (see Figure 49).

The RW niche is drilled and exposure should be extensive enough to comfortably fit the electrode. An appropriate RW opening in relation to size, is dependent upon the type of electrode array chosen. Please refer to STEP 11, "Select Appropriate Electrode Variant".

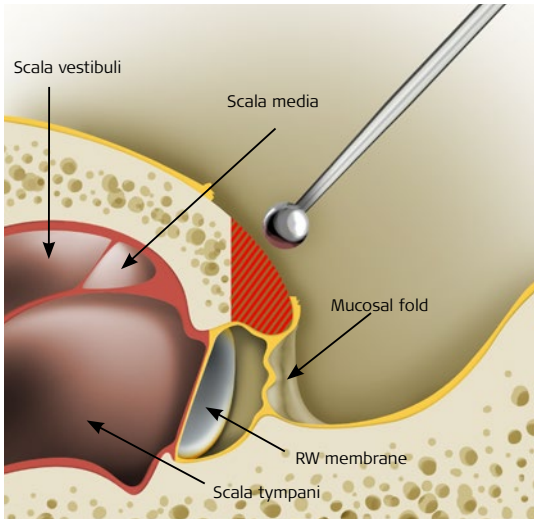


Figure 49
RW niche anatomy

EAS

- Begin drilling near the cochlea use a slow turning diamond drill to avoid acoustic trauma.
- To enter the middle portion of the scala tympani and to get visualisation of the round window membrane, the posterior-superior lip of the round window niche and the inferior margin of the round window should be drilled away to expose the round window membrane at least 0.8 mm.
- Fill the electrode insertion site with corticosteroid.
- Protect the middle ear cavity from bone dust contamination by closing it with medical gauze.

STEP 10 – VARIANT 2: Preparation for a Cochleostomy

CAUTION

- For drilling the cochleostomy, always use a slowly turning diamond drill to avoid acoustic trauma (approx. 1000rpm).
- Try to keep the endosteum intact until the insertion of the electrode.

Before preparing to drill the cochleostomy, the mucosal fold should be removed over the promontory. This prevents mucosal bleeding and provides better feedback from the tip of the drill (see Figure 50).

The round window niche is identified and the cochleostomy is made inferior and slightly anterior to it. Many surgeons have a preferred technique to locate the best promontory point to begin drilling the cochleostomy. One recommendation is to use the width of the stapes as a measuring tool. The cochleostomy is made inferior to the stapedial tendon at a distance twice the width of the stapes and inferior and slightly anterior to the round window.

Figure 50
Removal of a mucosal fold & marking of cochleostomy – right ear

Figure 51
Drilling the cochleostomy inferior and slightly anterior to the round window – right ear

The cochleostomy is drilled and the exposure of the endosteum should be big enough to comfortable fit the electrode. An appropriate cochleostomy size is dependent upon the type of electrode array chosen. Please refer to STEP 11, "Select Appropriate Electrode Variant".

The bony lip of the cochleostomy is slightly smoothed with a small diamond drill bit.

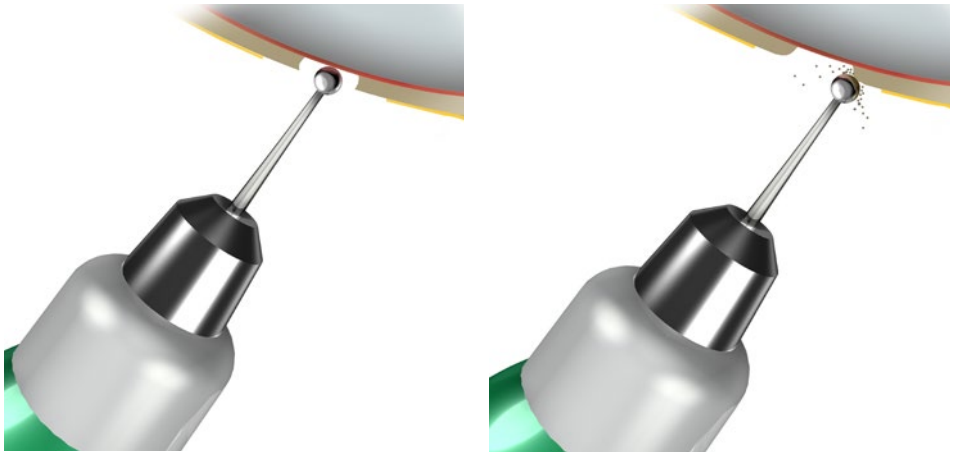


Figure 52 Drilling the cochleostomy and leaving the endosteum intact when drilling (upper picture), smoothing the edges of the cochleostomy (lower picture)

EAS

- Begin drilling near the cochlea use a slowly turning diamond drill to avoid acoustic trauma.
- The cochleostomy should be drilled inferior and slightly anterior to the round window annulus to achieve a scala tympani insertion and to avoid damage to the osseous spiral lamina. The endosteum should be exposed to at least 0.8 mm.
- Fill the electrode insertion site with corticosteroid solution.
- Protect the middle ear cavity from bone dust contamination by closing it e.g. with medical gauze.

STEP 11: Select Appropriate Electrode Variant*

Complete Cochlear Coverage (CCC) means stimulating the cochlea from the base to the apical region in order to stimulate a maximum number of nerve fibres. Stimulation of the entire frequency range with a deeply inserted, long array provides the implant user with the best possible outcomes in speech performance measures and in sound quality.

MED-EL Cochlear Implants are available with several different electrode options. For hearing preservation with especially atraumatic electrode arrays, or for even the most difficult cases of cochlear ossification, obstructions or malformations (see Figure 53).

Reduced Cochlear Duct Length or Malformations

Depending on the cochlear duct length or the malformation of the cochlea, a FORM24, FORM19, FLEX24, FLEX20, Medium or Compressed electrode array may be appropriate for optimal cochlear coverage and stimulation.

Cochlear Ossification

The surgeon must be prepared for unexpected findings during surgery. Depending on the degree of ossification, different surgical approaches and electrode arrays can be used.

Partial Ossification

If only the inferior section of the basal coil is ossified, drilling along the basal turn can often reveal an open lumen in the further course of the scala tympani. In such cases, a FLEX34, FLEXSOFT, FLEX28 or Standard electrode array can be inserted.

If the ossification is also in the ascending section of the basal turn, and a drill-through cannot be achieved, there are various options:

- The cochleostomy can be widened in a superior direction to reach the scala vestibuli. If this scala is patent, a FLEX34, FLEXSOFT, FLEX28 or Standard electrode array can be inserted.
- The Compressed electrode array can be inserted into the tunnel which has been drilled into the lower basal coil.

* Implant variants availability and OTOPLAN are subject to regulatory approval. OTOPLAN is a software offered by CASCINATION AG, Bern, Switzerland. Please contact your local MED-EL representative if you are interested in surgical planning possibilities.

Fibrosis

In cases where fibrotic tissue is present in the cochlear lumen, the Insertion Probe or the Insertion Probe L can be used to dilate the cochlear lumen up to a length of 20mm or 31.5 mm respectively. The Insertion Probe and the Insertion Probe L shall not be used if residual hearing preservation is required.

If fibrotic tissue is present, the tip of the Insertion Probe or the Insertion Probe L is placed in the cochlear opening and the array is carefully inserted as deeply as necessary to dilate the cochlea lumen. To prevent early kinking of the device it is helpful to hold it with an insertion tool as close as possible to the cochlear opening. The marker dot on the device that is still visible outside of the cochlea after insertion provides information about the approximate insertion depth.

After insertion, the device is carefully retracted from the cochlea. If loose fibrotic particles are present in the lumen, they should be cautiously removed.

Insertion Test Tools

Evaluation of possible electrode insertion length for the individual patient should be done prior to the surgery. This can be performed by acquiring a CT scan. Furthermore, OTOPLAN can support healthcare professionals in preoperative planning and postoperative quality checks of otological procedures*.

With the help of the Insertion Test Device (ITD) or the Insertion Electrode (IE), the surgeon can establish whether the cochlear lumen is obstructed or if it is freely accessible up to different insertion depths depending upon the considered electrode variant planned for the implantation.

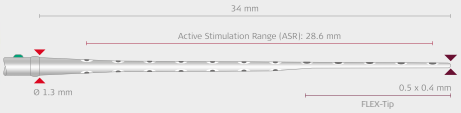
The Insertion Test Device and the Insertion Electrode variants shall not be used in patients where residual hearing shall be preserved.

* Implant variants availability and OTOPLAN are subject to regulatory approval. OTOPLAN is a software offered by CASCINATION AG, Bern, Switzerland. Please contact your local MED-EL representative if you are interested in surgical planning possibilities.

FLEX34

A 34 mm electrode array featuring FLEX tip technology for increased mechanical flexibility and enabling CCC

41550 (SYNCHRONY 2)
41548 (SYNCHRONY 2 S-Vector)

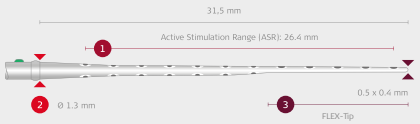


1. 19 platinum electrode contacts
   Optimal spacing over a 28.6 mm stimulation range
2. Diameter at basal end: 1.3 m
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.4 mm

FLEXSOFT™

A 31.5 mm electrode array featuring FLEX tip technology for increased mechanical flexibility and enabling CCC.

36707 (SYNCHRONY 2)
39569 (SYNCHRONY 2 S-Vector)

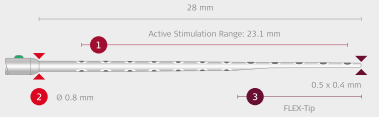


1. 19 platinum electrode contacts
   Optimal spacing over a 26.4 mm stimulation range
2. Diameter at basal end: 1.3 m
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.4 mm

FLEX28™

A 28 mm electrode array suitable for 96 % of all normal cochlear duct lengths featuring FLEX tip technology. Optimised for insertion into the apical region (CCC).

36711 (SYNCHRONY 2)
39573 (SYNCHRONY 2 S-Vector)

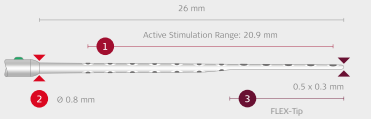


1. 19 platinum electrode contacts
   Optimal spacing over a 23.1 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.4 mm

FLEX26™

A 26 mm electrode array featuring FLEX tip technology and designed to increased mechanical flexibility for reduced insertion force.

36904 (SYNCHRONY 2)
39575 (SYNCHRONY 2 S-Vector)

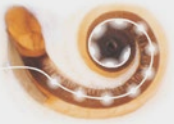


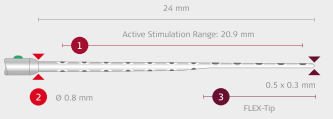
1. 19 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

FLEX24™

A 24 mm electrode array featuring FLEX tip technology and designed for combined Electric Acoustic Stimulation (EAS) with insertion less than 1.5 turns.

36709 (SYNCHRONY 2)
39571 (SYNCHRONY 2 S-Vector)



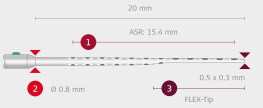


1. 19 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

FLEX20™

A 20 mm electrode array featuring FLEX-Tip technology and designed to be used in cases of partial deafness or for other specific needs or surgical preferences.

367181 (SYNCHRONY 2)
39577 (SYNCHRONY 2 S-Vector)



1. 19 platinum electrode contacts
   Optimal spacing over a 15.4 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

Figure 53 MED-EL electrodes

FORM24™

A 24 mm electrode array featuring CSF SEAL designed for open (no obliteration or ossification) or malformed cochleae, especially Type II malformations. Also for cases where CSF leakage is expected.

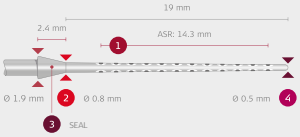
37185 (SYNCHRONY 2)
39581 (SYNCHRONY 2 S-Vector)

1. 24 platinum electrode contacts Optimal spacing over a 18.7 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. SEAL
4. Diameter at apical end: 0.5 mm

FORM19™

A 19 mm electrode array featuring CSF SEAL designed to be used in cochleae with malformation, especially Type I and Type III, obliteration, or ossification. Also for cases where CSF leakage is expected.

37183 (SYNCHRONY 2)
39579 (SYNCHRONY 2 S-Vector)

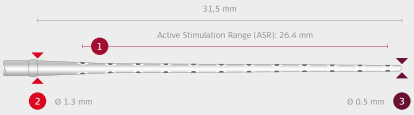


1. 24 platinum electrode contacts Optimal spacing over a 14.3 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. SEAL
4. Diameter at apical end: 0.5 mm

Standard

A 31.5 mm electrode array designed for long cochlear duct lengths.

36701 (SYNCHRONY 2)
39563 (SYNCHRONY 2 S-Vector)



1. 24 platinum electrode contacts Optimal spacing over a 26.4 mm stimulation range
2. Diameter at basal end: 1.3 mm
3. Diameter at apical end: 0.5 mm

Medium

A 24 mm electrode array designed for cases where deep insertion is not desired or is not possible due to anatomic restrictions.

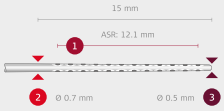
36703 (SYNCHRONY 2)
39565 (SYNCHRONY 2 S-Vector)

1. 24 platinum electrode contacts Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. Diameter at apical end: 0.5 mm

Compressed

A 15 mm electrode array designed for partial ossification or malformation of the cochlea.

36705 (SYNCHRONY 2)
39567 (SYNCHRONY 2 S-Vector)



1. 24 platinum electrode contacts Optimal spacing over a 12.1 mm stimulation range
2. Diameter at basal end: 0.7 mm
3. Diameter at apical end: 0.5 mm

Figure 53 MED-EL electrodes

STEP 12: Immobilise the Implant

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 electrode array.
- 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 9 should be used to secure the implant in its bed and the electrode lead should be placed into the drilled channel leading into the mastoid. Make sure the electrode channel is deep enough to prevent the lead to be exposed directly on the skull (see Figure 54). Please refer back to STEP 9 for a more detailed description on different ways for preparing the electrode lead channel.

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.

Try to manage the excess electrode lead in the mastoid cavity in such a way, that no additional pressure is placed by the lead laterally on the outer skin layers when closing the surgical wound.

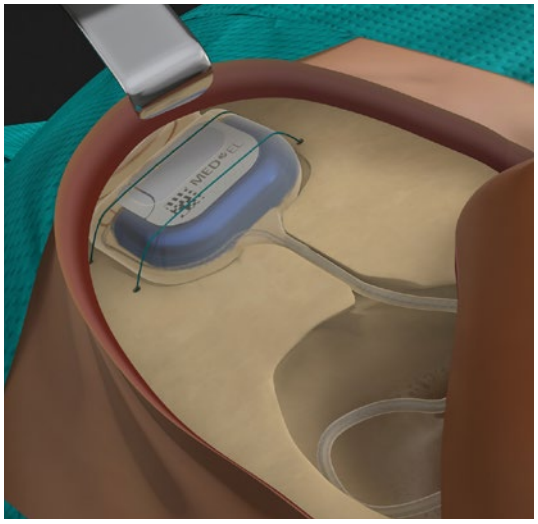


Figure 54
Implant immobilised in implant bed with two sutures not crossing over the reference electrodes – right ear

STEP 13: Opening the Cochlea

Before inserting the electrode array into the cochlea, either the RW membrane for a RW insertion or the endosteum for a cochleostomy insertion, needs to be incised.

Either a micro-lancette or a micro-hook can be used to open the cochlea (see Figure 55, Figure 56 and Figure 57).

Figure 55 RW membrane incision with a 45° micro-hook

Figure 56 Endosteum incision with a 45° micro-hook

Figure 57 Endosteum incision with a micro-lancette

EAS

- Prior to opening the cochlea, clean the surgical field, change gloves, remove the gauze used to keep bone dust out of the middle ear cavity and administer a single dose of intravenous corticosteroids to protect the inner ear.
- Place a drop of corticosteroid on the round window membrane or endosteum to reduce fibrotic reaction and cover it with a drop of hyaluronic acid. This will keep the corticosteroid in place and protect it from bone dust.
- Using a micro-lancette or micro-hook, carefully incise the round window membrane in its inferior-anterior quadrant to at least 0.8 mm.
- Using a micro-lancette or micro-hook, carefully incise the endosteum to at least 0.8 mm.
- Avoid suctioning in the open region of the cochlea.

STEP 14: Insert the Electrode Array

CAUTION

- Only surgical tools approved by MED-EL should be used to insert the electrode array into the cochlea.
- Under no circumstances should any excessive force be used during electrode insertion.
- Insertion of an electrode array into the cochlea may result in the loss of residual hearing which was present in that ear prior to surgery.

Begin to insert the electrode array in a way that the electrode lead is not coiled up or in the line of sight before finishing the insertion (see Figure 58).

Perform the excess lead management after completing electrode insertion.

It is important for the electrode array to approach the anterior portion of the basal turn at an angle so that it slides along the lateral wall of the scala tympani. Therefore, the recommended direction for insertion of the electrode array is coming from the posterior buttress at the incus and progressing towards the round window opening. This procedure, known as tangential insertion, facilitates deep electrode insertion (see Figure 59).

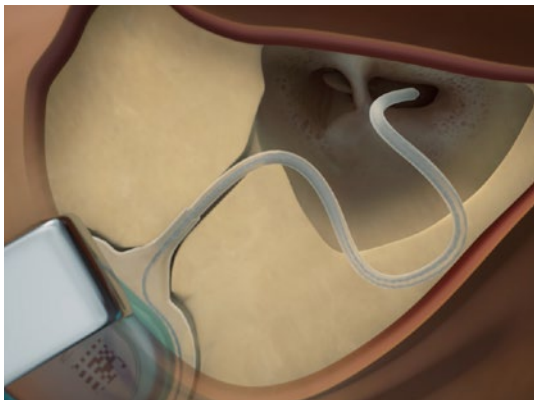


Figure 58
Direction of electrode insertion – right ear

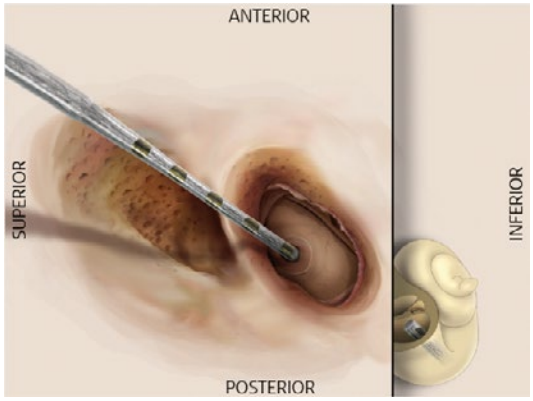


Figure 59
Direction of electrode insertion – right ear

The individual insertion direction for each case should be considered in order to reach a tangential electrode insertion (see Figure 60). Non-tangential insertion should be avoided.

Surgical tools approved by MED-EL should be used to insert the electrode array into the cochlea (please see Chapter 3 Surgical Tools and Accessories). Use of lubrication or anti-inflammatory compounds during electrode insertion is up to the surgeon.

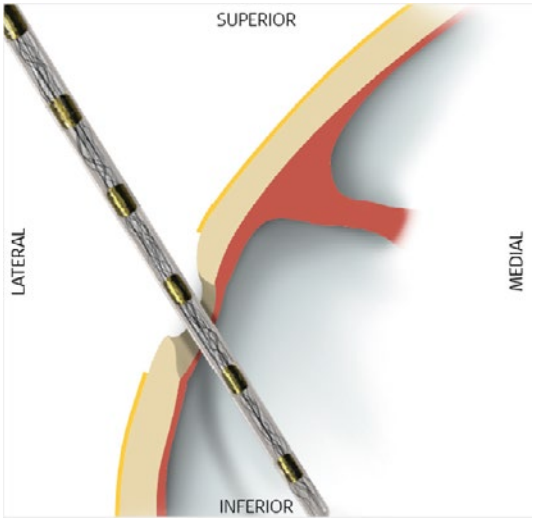


Figure 60
Recommended insertion direction to reach a tangential electrode insertion

The electrode lead is held very carefully at the proximal thicker part, just above the marker ring or insertion marker (depending on the electrode array used). The tip of the electrode array is guided toward the cochlea opening. After the tip is gently manoeuvred further into the cochlea, the electrode array can be gripped between the contacts (see Figure 61). During insertion it is essential that the electrode contacts are not mechanically damaged and that no excessive force is used.

Please be aware that sealing of the cochlear opening with the marker ring should not be achieved with the Medium and Compressed electrode arrays.

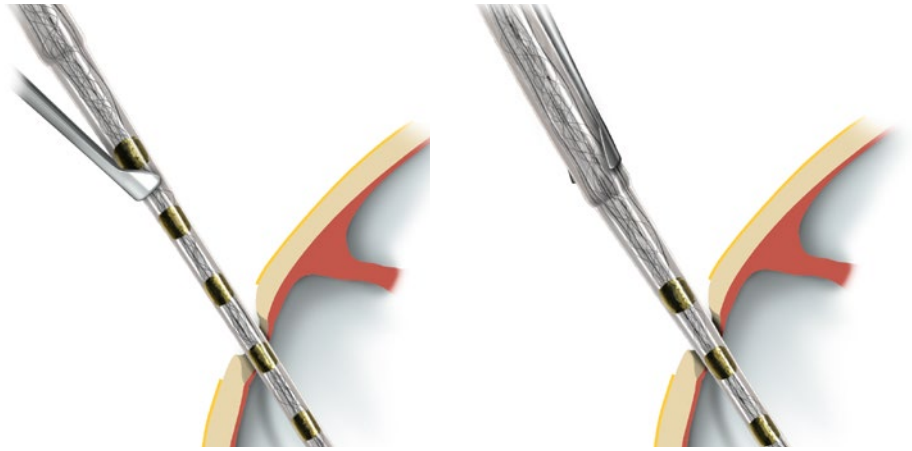


Figure 61 Detail of electrode insertion – manoeuvre the electrode array between the contacts & after the marker ring or insertion marker

EAS

- Since EAS candidates show good residual hearing in the low frequencies, a tangential insertion -i.e. ideal electrode insertion direction to reach the lateral wall of the cochlear at the beginning of the basal turn in the hook region- is strongly recommended for straight electrode designs. This ensures that our highly flexible electrodes glide along the lateral wall when inserted further into the cochlear, minimising possible damage to the delicate structures and at the same time allow a full insertion in conjunction with the choice of EAS approved electrode arrays (as desired by the surgeon).

If resistance is encountered before reaching the marker ring or insertion marker, the electrode array may buckle. In such cases, electrode insertion should be stopped. Excessive force should not be used, as it may result in intra-cochlear damage.

The following measures may be helpful in such situations:

- **Carefully rotate the electrode**
  Due to the unique oval design of the electrode array, the electrode can be slightly rotated to allow it to slide deeper into the cochlea.
- **Small movements close to the insertion site**
  Hold the electrode no more than 2 mm from the cochleostomy or round window opening. Gently insert the electrode with one stroke, release it and grasp it again 2 mm from the insertion side. Repeat this procedure until complete insertion is achieved.
- **Slow the rate of insertion**
  Slow the speed that the electrode is introduced into the opening. Frequent pauses during insertion can allow the electrode to gently slide along the cochlear duct.
- **Use of lubricant**
  As known from soft surgical techniques, the use of a lubricant can help smoothing the electrode insertion.

Figure 62 shows the use of MED-EL SoftGrip Forceps as an example. For a complete overview of all insertion tools please refer back to Chapter 3 Surgical Tools and Accessories.

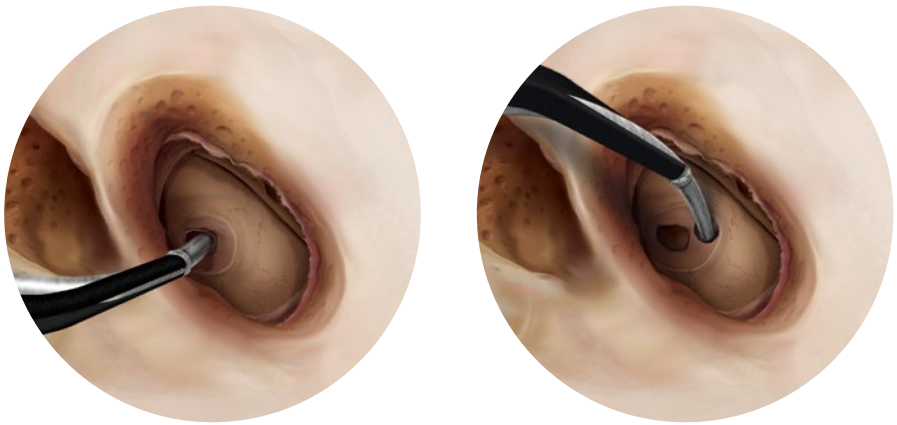


Figure 62 Full insertion of the electrode array – SoftGrip Forceps positioned behind the marker ring or insertion marker – right ear

EAS

- Immediately start the electrode insertion through the drop of corticosteroid and hyaluronic acid.
- The recommended direction for insertion of the electrode array is coming from the posterior buttress at the incus and progressing towards the round window opening.

STEP 15: Seal Cochlear Opening

CAUTION

- To minimise the risk of postoperative infection additional sealing of the cochlear opening should be done for all MED-EL electrode arrays.
- Once the electrode array has been inserted into the cochlea, the electrode lead should be fixed so that no postoperative movement will occur.
- Please be aware that sealing of the cochlear opening with the marker ring should not be achieved with the Medium and Compressed electrode arrays.

When the electrode array is fully inserted, the marker ring or insertion marker will support sealing the cochlear opening during surgery and provide an additional point of fixation (see Figure 63). This sealing will only take place with the FORM24, FORM19, FLEX34, FLEXSOFT, FLEX28, FLEX26, FLEX24, FLEX20 and Standard electrode array fully inserted.

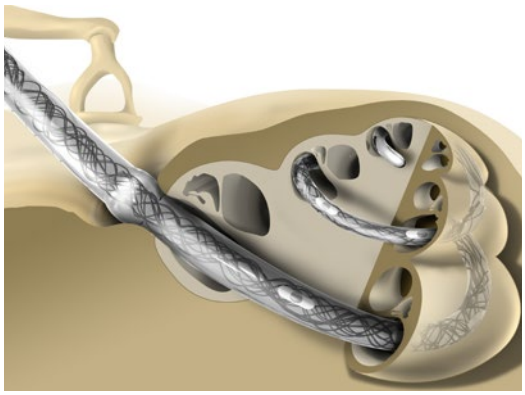


Figure 63
The marker ring or insertion marker can seal the cochlear opening, aiding in its fixation – right ear (Standard electrode array shown)

Please be aware that sealing of the cochlear opening with the marker ring should not be achieved with the Medium and Compressed electrode arrays since their intended insertion depths are 24 mm and 15 mm, respectively, and the marker ring is located at a distance of 31.5 mm from the tip of the electrode array.

For all MED-EL electrode arrays, use a small fascial graft around the electrode array at the entrance to the cochlea to secure the electrode array and to seal the opening (see Figure 64). Before application, rinse the small pieces with saline solution to prevent contamination of the electrode and to increase flexibility of the graft.

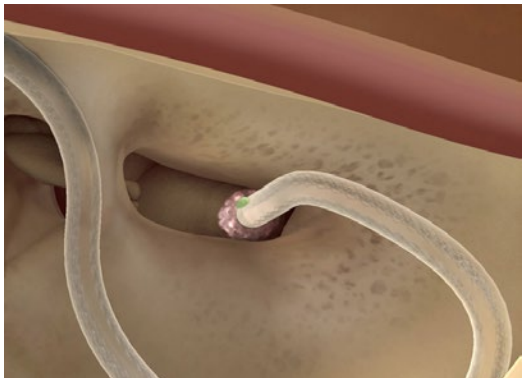


Figure 64
Sealing the Round Window opening with fascia

STEP 16: Secure Electrode Lead

The excess electrode lead should be placed force free inside the mastoid cavity in such a way that additional pressure is not placed on the periosteum closing the mastoid cavity. A force free excess lead management also minimizes the probability of post operative electrode migration. It is advantageous to form a S-shape with the excess lead (see Figure 65). Drilling a mastoidectomy with overhang further helps to stabilise the excess lead inside the mastoid cavity. According to surgeons preference, the excess lead in the mastoid cavity can be additionally immobilised with e.g. bone paté or fibrin glue.

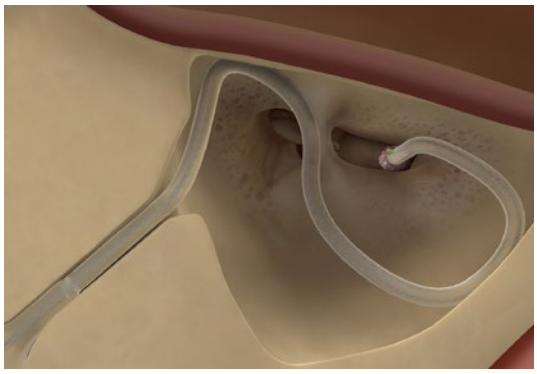


Figure 65
The electrode lead should be placed under the cortical overhang of the mastoid cavity – right ear

Securing the electrode lead with the Fixation Clip*

Order number: 09917

MED-EL offers a Fixation Clip to effectively secure the electrode lead to the posterior buttress (incus bridge).

CAUTION

- The Fixation Clip shall not be used in the case that the posterior buttress is not suitable for placing the Fixation Clip.
- The recommended diameter of the posterior buttress is 2 mm.
- Accidental bending of the Fixation Clip during removal from its packaging must be avoided in order to prevent functional damage.
- Care should be taken that during the fixation of the bone fixation clip, the incudostapedial joint, and the posterior incudal ligament are not harmed and the movements of the ossicles are not inhibited.
- Care should be taken not to squeeze or damage the electrode.

The Fixation Clip shall be used exclusively with MED-EL electrodes that have a diameter of 1.3 mm at the distal part of the electrode lead (see Figure 67).

Figure 66 Fixation Clip Ms010103

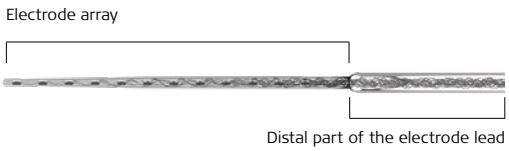


Figure 67 Distal part of the electrode lead

The openings are not of the same size. The larger opening of the Fixation Clip is the bone fixation clip and the smaller opening of the Fixation Clip is the electrode fixation clip (see Figure 68).

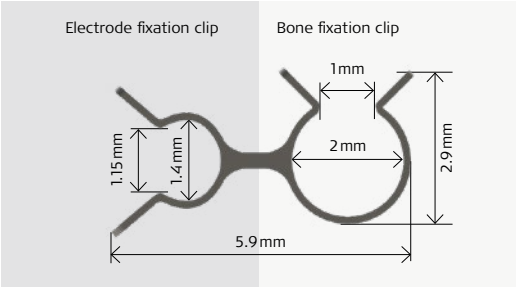


Figure 68
Dimensions of the Fixation Clip

* Fixation Clip development was in close collaboration with Prof. Joachim Müller, Klinik und Poliklinik für Hals-, Nasen- und Ohrenheilkunde München Großhadern, Germany

First the larger clip (bone fixation clip) shall be placed on the posterior buttress (see Figure 69).

Next, the bone fixation clip shall be properly crimped to the posterior buttress (see Figure 70). For crimping the Fixation Clip a micro forceps should be used (e.g. Hartmann Alligator Forceps, 8 mm).

After fixing the bone fixation clip, the electrode fixation clip shall be closed over the electrode lead so that both ends of the electrode fixation clip come together and the clip is completely closed (see Figure 71).

The electrode lead is longer than required in order to accommodate anatomical variants and to compensate for skull growth in children.

The electrode lead is placed in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place to avoid postoperative movements due to contractions of the temporalis muscle (see Figure 72).

Additional immobilisation of the electrode lead inside the electrode channel could be done, e.g. with bone paté or bone wax.

Figure 69
Placement of the Fixation Clip on the posterior buttress

Figure 70
Bone fixation clip crimped on the posterior buttress

Figure 71
Electrode fixation clip closed over the electrode

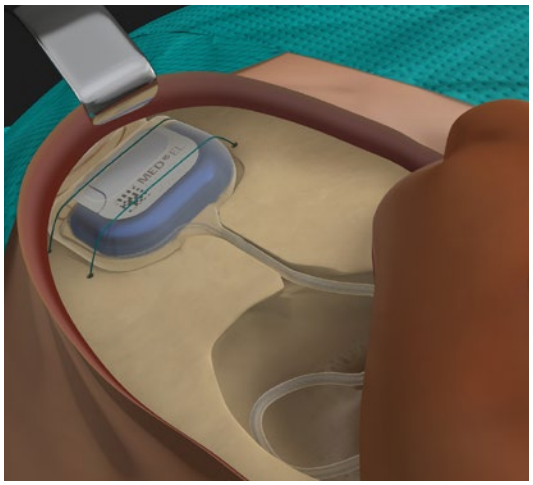


Figure 72
The electrode lead should be placed under the cortical overhang of the mastoid cavity – right ear

STEP 17: Intra-Operative Recordings

At this stage intra-operative recordings like Impedance Field Telemetry (IFT), Electrically Evoked Stapedius Reflex Threshold (ESRT), Electrically Evoked Brainstem Response (EABR) or Auditory Nerve Response Telemetry (ART) 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 Software user manual. It is not possible to sterilise any component of the MED-EL hardware interface system. When used in a sterile environment, the coil and cable should be covered with sterile material (i.e. "sterile sleeve"). The appropriate coil should be used during intra-operative recordings.

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 intra-cochlear voltage distribution

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.

ESRT (Electrical Stapedius Reflex Threshold)

If ESRT thresholds are measured, care should be taken that no muscle relaxant is used during the last half hour before performing the measurements.

Note that observation of the reflex is not possible in some implanted patients due to various physiological and anatomical reasons. In addition, observation of the reflex may not be possible due to anaesthesia. Therefore, absence of a reflex should not be taken as an indication of implant malfunction or lack of auditory response without other more direct evidence.

Intra-operatively, the presence of the reflex can be monitored either by direct observation of the ipsilateral tendon, through the microscope, or by impedance probe measurements in the contralateral ear. Direct observation is employed in most cases, as this is normally straightforward and does not require additional equipment. Probe measurements are usually restricted to research studies.

EABR (Electrically Evoked Brainstem Response)

With the addition of the EABR task, it is possible to measure and record the response of the entire auditory pathway to stimulation from the implant. EABR recordings can be used to determine the best placement of an Auditory Brainstem Implant during surgery, and they can also provide interesting information on the function of the whole auditory pathway. The MED-EL application software EABR parameters can be adjusted to facilitate recording of early, middle and late electrical potentials. To obtain measurements with the EABR task, it is necessary to also use a separate neurodiagnostic computer with a trigger input, along with scalp recording electrodes.

ART™ (Auditory Nerve Response Telemetry)

MED-EL offers implants that are capable of recording compound action potentials – small voltage changes that are created by the auditory nerve when it transmits a signal to the brainstem. The measurement is done a few microseconds after the end of a stimulation pulse. The recorded signal is called the Evoked Compound Action Potential (ECAP or EAP) of the auditory nerve. It has an amplitude of about 0.01 to 2 mV and takes place within roughly one millisecond after the stimulation pulse. Due to these very short, small response levels, special artifact reduction methods are used to enhance viewing of the nerve response.

STEP 18: Close Wound

For additional immobilisation of the implant and the electrode lead, the periosteum should be separately sutured over the implant region and the mastoid cavity. Care should be taken not to damage the implant or the electrode.

The rest of the wound should be closed in layers with staples or absorbable subcutaneous sutures.

The area of the wound is covered with a compress and sterile gauze applying an even pressure distribution.

EAS

- A course of steroids and antibiotics should be given postoperatively.

Appendix

Magnet Replacement Procedure

The magnet replacement procedure can be performed with all MED-EL cochlear implants featuring a removable implant magnet.

Surgical Procedure

STEP 1: Opening the skin flap

When opening the skin flap, keep an adequate distance between the incision and the coil. This will prevent damage to the implant under the skin. For marking the incision either the patient's audio processor coil or the MAX Coil S can be used. When used in a sterile environment, the Coil should be covered with sterile material (i.e. "sterile sleeve").

MED-EL recommends a distance of 5 to 15 mm from the coil and an opening angle between 160° and 200°. Carefully dissect the fibrous tissue to locate the coil part of the implant and expose the magnet. The wound should be opened in layers.

NOTE: MED-EL recommends replacing an implant magnet always with a magnet of the original type. Nevertheless, in case of a medical reason, selecting an alternative replacement magnet may be necessary (please refer to the Chapter 3 Surgical Tools and Accessories - Magnet Tool Kits).

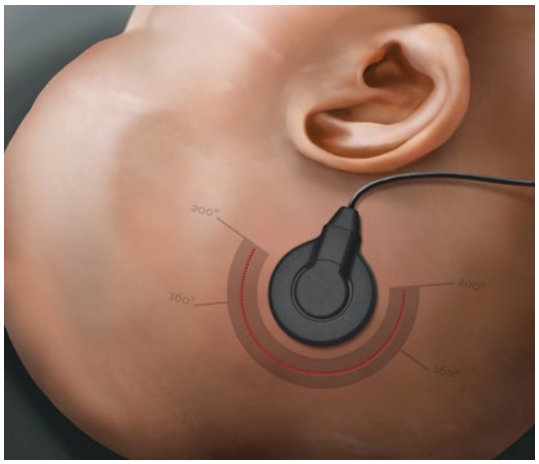


Figure 73 Showing recommended incision line with MAX Coil S in non-sterile environment

Figure 74 Implant coil with inserted magnet after opening the skin flap

STEP 2: Removing the Implant Magnet or Non-Magnetic Spacer

CAUTION

To avoid movement of the implant it is recommended to fix the stimulator by pressing it against the bone with one hand.

1. Place the Magnet Removal Tool in front of the implant coil.
2. Lift the coil part of the implant by sliding the tip of the Magnet Removal Tool under the implant coil.
3. Centre the implant coil in the tip part of the Magnet Removal Tool.
4. Push the Implant Magnet or Non- Magnetic Spacer out of the implant coil by pressing together the two handles of the Magnet Removal Tool.
5. MED-EL recommends checking that the two handles of the Magnet Removal Tool are completely re-opened before pulling out the instrument.
6. Remove the Magnet Removal Tool by slowly pulling out the instrument from the implant coil.
7. After pulling out the instrument, the Implant Magnet or Non-Magnetic Spacer can be removed from the tip of the Magnet Removal Tool by lifting the upper handle. The removed Implant Magnet or Non-Magnetic Spacer can be disposed of.

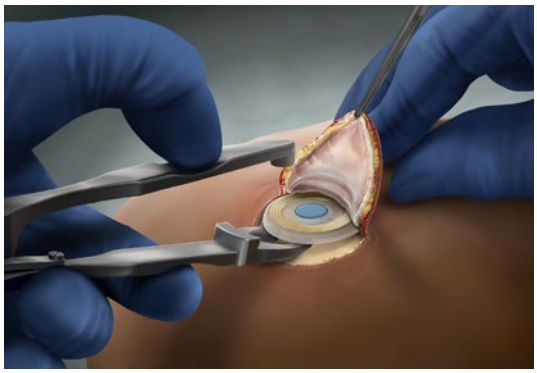


Figure 75 Lifting the implant coil with the Magnet Removal Tool

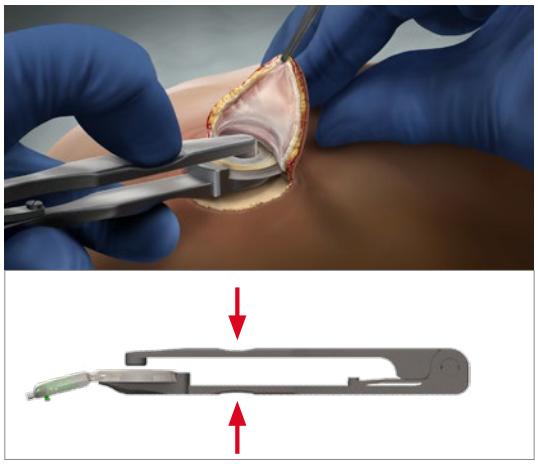


Figure 76 Centring the implant coil and pressing the two handles together for removing the magnet

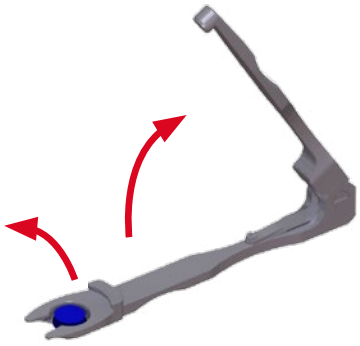


Figure 77 Opening the instrument and removing the magnet from the instrument tip

STEP 3: Inserting the Non-Magnetic Spacer or Replacement Magnet

CAUTION

To avoid movement of the implant it is recommended to fix the stimulator by pressing it against the bone with one hand.

1. Open the upper handle of the Magnet Insertion Tool by unlocking the small locking mechanism and lifting the counter blade.
2. Place the Non-Magnetic Spacer or Replacement Magnet in the front part of the Magnet Insertion Tool. The Non- Magnetic Spacer or Replacement Magnet is correctly placed into the tip when the serial number labelling is not readable from the top.
3. Close the counter blade and lock the locking mechanism.
4. Place the Magnet Insertion Tool in front of the implant coil.
5. Lift the coil part of the implant by sliding the tip of the Magnet Insertion Tool under the implant coil.

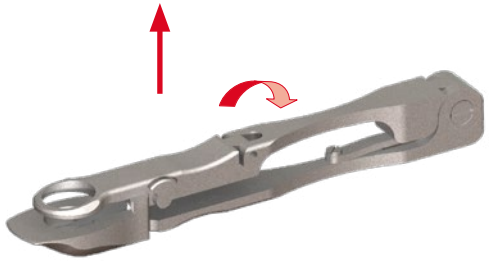


Figure 78 Unlocking the locking mechanism and lifting the upper handle

Figure 79 Placing the Non-Magnetic Spacer or the Replacement Magnet in the tip of the Magnet Insertion Tool

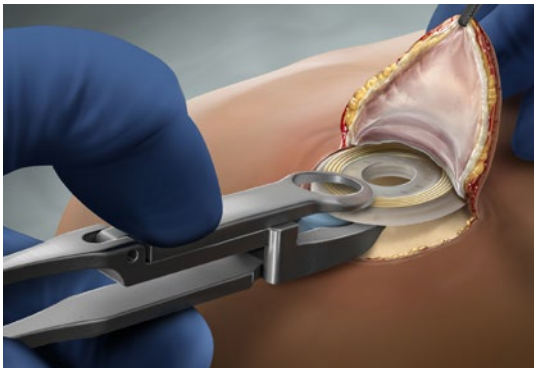


Figure 80 Lifting the implant coil with the Magnet Insertion Tool

6. Centre the implant coil in the tip part of the Magnet Insertion Tool so the Non-Magnetic Spacer or Replacement Magnet is completely visible through the hole in the implant coil.
7. For complete insertion of the Non- Magnetic Spacer or Replacement Magnet into the implant coil, insert the Non- Magnetic Spacer or Replacement Magnet into the implant coil by pressing the two handles of the instrument together until the two handles are touching.
8. Re-open the two handles of the Magnet Insertion Tool.
9. MED-EL recommends checking that the two blades of the Magnet Insertion Tool are completely re-opened before pulling out the instrument.
10. Remove the Magnet Insertion Tool by slowly pulling out the instrument from the implant coil.
11. Check the correct magnet position.

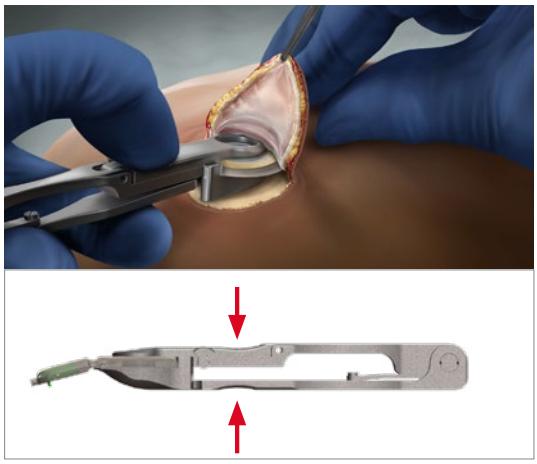


Figure 81 Centring the implant coil and pressing the two handles together for inserting the magnet

STEP 4: Close wound

Before closing the wound visually confirm that either the:

- blue Replacement Magnet (Ms010108)
- silver S-Vector Replacement Magnet (Ms010109)
- purple Non-Magnetic Spacer (Ms010107)

was inserted as appropriate. When closing the wound, care should be taken not to damage the implant. The wound should be cleaned and closed in layers with staples or absorbable subcutaneous sutures. The area of the wound should then be covered with a compress and sterile gauze, and even pressure should be applied.

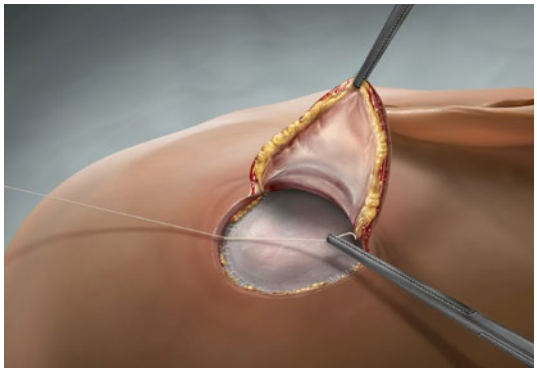


Figure 82 Suturing the wound

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 cochlear 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 mastoid cavity and facial 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 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 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.

EAS

Recommended EAS Surgical Technique

A special marked paragraph can be found in each Surgical Step showing details which are important for Hearing Preservation for an EAS surgery. A summary on the additional EAS related surgical steps can be found in Figure 83.

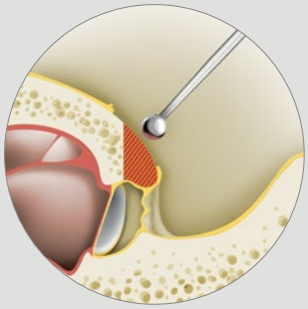
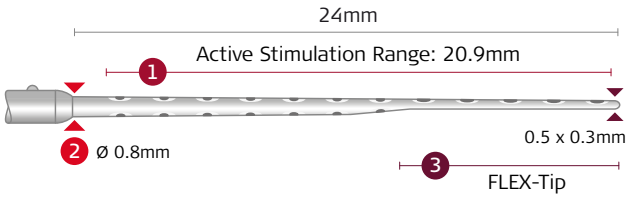
Round Window Insertion	Cochleostomy Insertion
Please ensure that corticosteroids (crystalline triamcinolone solution or dexamethasone), intravenous corticosteroids, and hyaluronic acid are all available for the surgery.	
Administer intravenous antibiotics from the Cephalosporin group and intravenous corticosteroids at least half an hour before the skin incision.	
It is recommended to create a larger posterior tympanotomy (as compared to that of a standard cochlear implantation) beside the posterior epitympanotomy in order to provide a better view as well as more space to manoeuvre the electrode array.	
Elevate a mucosal flap to avoid mucosal bleeding when opening the cochlea.	
Begin drilling near the cochlea use a slowly turning diamond drill to avoid acoustic trauma.	
To enter the middle portion of the scala tympani and to get visualisation of the round window membrane, the posterior-superior lip of the round window niche and the inferior margin of the round window should be drilled away to expose the round window membrane to at least 0.8 mm.	The cochleostomy should be drilled inferior and slightly anterior to the round window annulus to achieve a scala tympani insertion and to avoid damage to the osseous spiral lamina. The endosteum should be exposed to at least 0.8 mm.
	
Fill the electrode insertion site with corticosteroids.	
Protect the middle ear cavity from bone dust contamination by closing it with medical gauze.	
Drill the implant bed and immobilise the implant.	
Prior to opening the cochlea, clean the surgical field, change gloves, remove the gauze used to keep bone dust out of the middle ear cavity.	
Place a drop of corticosteroid on the round window membrane or endosteum to reduce fibrotic reaction and cover it with a drop of hyaluronic acid. This will keep the corticosteroid in place and protect it from bone dust.	

Figure 83 Recommended EAS Surgical Technique (Part 1)

EAS

Round Window Insertion	Cochleostomy Insertion
Using a micro-lancette or micro-hook, carefully incise the round window membrane in its inferior-anterior quadrant to at least 0.8 mm.	With a micro-lancette or micro-hook, carefully incise the endosteum to at least 0.8 mm.
Avoid suctioning in the open region of the cochlea.	
Immediately start the electrode insertion through the drop of corticosteroid and hyaluronic acid.	
General insertion direction is from superior-posterior to anterior-inferior.	

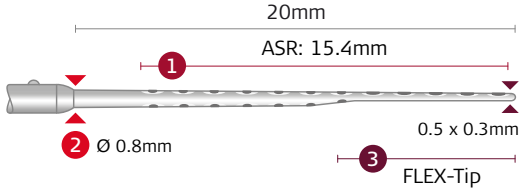
FLEX24 Electrode Array



1. 19 platinum electrode contacts
   Optimal spacing over a 15.4 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

Insert the FLEX24 electrode so that it covers less than 1.5 turns of the cochlea (22-24mm, e.g. determined by pre-operative CT scan).

FLEX20 Electrode Array



1. 19 platinum electrode contacts
   Optimal spacing over a 20.9 mm stimulation range
2. Diameter at basal end: 0.8 mm
3. FLEX-Tip for minimal insertion trauma
   Dimensions at apical end: 0.5 × 0.3 mm

To seal the cochlea, use a small fascial graft.
To prevent contamination of the electrode and to increase flexibility, rinse the fascial graft with saline solution.

A course of steroids and antibiotics should be given postoperatively.

Figure 83 Recommended EAS Surgical Technique (Part 2)

Literature

The following is a list of references on general CI surgery:

The Mi1000 CONCERTO PIN cochlear implant: An evaluation of its safety and stability in adults and children.
Kuzovkov V, Sugarova S, Yanov Y. Acta Otolaryngol. 2016 Mar;136(3):236-40.

Evaluation of a minimally invasive surgical fixation technique for young children with the Concerto Pin cochlear implant system.
Schnabl J; Wolf-Magele A; Pok SM; Url C; Zorowka P; Sprinzl G Eur Arch Otorhinolaryngol, 2014 Mar 23.

The Effects of Insertion Speed on Inner Ear Function during Cochlear Implantation: A Comparison Study
Rajan GP; Kontorinis G; Kuthubutheen J; Audiol Neurootol, 18(1), 2012 Sep 22, p. 17–22.

Synchrony Pin: A Novel Concept of Cochlear Implant Fixation.
Schnabl J; Markl A; Hormann R; Wolf-Magele A; Schartinger V; Sprinzl G; Otol Neurotol, 2012.

Depth of Electrode Insertion and Postoperative Performance in Humans with Cochlear Implants: A Histopathologic Study.
Lee J; Nadol JB; Eddington DK; Audiol Neurootol, 15(5), 2010, 323-331.

Cochlear implantation in inner ear malformations
Sennaroglu L; Cochlear Implants Int, 2009.

Scala tympani cochleostomy I: results of a survey.
Adunka OF; Buchman CA; Laryngoscope 2007; 117(12):2187-2194.

Cochlear implant electrode insertion: The round window revisited.
Roland P; Wright C; Isaacson B; Laryngoscope 2007; 117(8):1397-402.

Scala tympani cochleostomy II: Topography and histology.
Adunka O; Radeloff A; Gstoettner W; Pillsbury H; Buchman C; Laryngoscope 2007; XX:1-6.

Preservation of basal inner ear structures in cochlear implantation.
Adunka O; Gstoettner W; Hambek M; Unkelbach MH; Radeloff A; Kiefer J; ORL J Otorhinolaryngol Relat Spec. 2004; 66(6):306-12.

Cochlear implantation via the round window membrane minimizes trauma to cochlear structures: A histologically controlled insertion study.
Adunka O; Unkelbach MH; Mack M; Hambek M; Gstöttner W and Kiefer J; Acta Otolaryngol 2004; 124: 807-812.

J. Müller, F. Schön, J. Helms: Safe fixation of mounts for cochlear implant electrodes initial experience with a new titanium clip.
Laryngo-Rhino-Otol 1998;77:238-240.

The length of the organ of Corti in man.
Hardy M; American Journal of Anatomy, 62(2), 1938, 179-311.

The following is a list of references on bilateral CI surgery:

Assessment of electrode placement and audiological outcomes in bilateral cochlear implantation.
Wanna GB, Noble JH, McRackan TR, Dawant BM, Dietrich MS, Watkins LD, Rivas A, Schuman TA, Labadie RF; Otol Neurotol. 2011 Apr.

Binaural cochlear implantation after bilateral temporal bone fractures.
Zanetti D, Campovecchi CB, Pasini S.; Int J Audiol. 2010 Jul 8.

Bilateral cochlear implantation in a patient with bilateral temporal bone fractures.
Chung JH, Shin MC, Min HJ, Park CW, Lee SH.; Am J Otolaryngol. 2010 May 3.

Bilateral cochlear implantation in children with anomalous cochleovestibular anatomy
Chadha NK; James AL; Gordon KA; Blaser S; Papsin BC.; Arch Otolaryngol Head Neck Surg, 135(9), 2009 Sep.

Bilateral, simultaneous cochlear implantation in children: surgical considerations.
Migirov, L. & Kronenberg, J.; J Laryngol Otol. 2009 Mar 3:1-3.

Otopathological Findings in a Patients with Bilateral Cochlear Implants.
House, W., Johnsson, L. & Linthicum, F.; USPHS Research, 74, 2006.

Cochlear implantation in a patient with bilateral temporal bone fractures.
Simons, J., Whitaker, M. & Hirsch, B.; Otolaryngol Head Neck Surg, 132, 809-811; 2005.

Bilateral cochlear implantation.
Lustig, L. & Wackym, P.; Operative Techniques in Otolaryngology, 16, 2005.

Insertion depth differences in bilateral cochlear implantees
Fielden C; Long C; Cooper H; Proops D; Donaldson I; Craddock L.; Cochlear Implants Int, 6 Suppl 1, 2005 Sep.

The following is a list of references on HP and EAS:

Hearing preservation after cochlear reimplantation
Helbig S; Rajan GP; Stover T; Lockley M; Kuthubutheen J; Green KM; Otol Neurotol, 34(1), 2013 Jan, p. 61–65.

The Round Window: Is it the "Cochleostomy" of Choice? Experience in 130 Consecutive Cochlear Implants.
Gudis DA, Montes M, Bigelow DC, Ruckenstein MJ.; Otol Neurotol. 2012 Sep 11.

Evaluation of round window accessibility to cochlear implant insertion.
Leong AC, Jiang D, Agger A, Fitzgerald-O'Connor A.; Eur Arch Otorhinolaryngol. 2012 Jul 18.

Hearing preservation after cochlear implantation using deeply inserted flex atraumatic electrode arrays.
Tamir S, Ferrary E, Borel S, Sterkers O, Bozorg Grayeli A.; Audiol Neurootol. 2012;17(5):331-7.

Hearing preservation and hearing improvement after reimplantation of pediatric and adult patients with partial deafness: a retrospective case series review.
Jayawardena J, Kuthubutheen J, Rajan G.; Otol Neurotol. 2012 Jul;33(5):740-4.

Scalar localization by computed tomography of cochlear implant electrode carriers designed for deep insertion.
Helbig S, Mack M, Schell B, Bratzke H, Stöver T, Helbig M.; Otol Neurotol. 2012 Jul;33(5):745-50.

A case series of paediatric hearing preservation cochlear implantation: a new treatment modality for children with drug-induced or congenital partial deafness.
Kuthubutheen J, Hedne CN, Krishnaswamy J, Rajan GP.; Audiol Neurootol. 2012;17(5):321-30.

Cochlear implantation and hearing preservation: Results in 21 consecutively operated patients using the round window approach.
Erixon E, Köbler S, Rask-Andersen H.; Acta Otolaryngol. 2012.

Achievement of hearing preservation in the presence of an electrode covering the residual hearing region.
Usami SI; Moteki H; Suzuki N; Fukuoka H; Miyagawa M; Nishio SY; Takumi Y; Iwasaki S; Jolly C; Acta Otolaryngol, 2011.

Combined electric acoustic stimulation with the PULSARCI(100) implant system using the FLEX(EAS) electrode array.
Helbig S; Van de Heyning P; Kiefer J; Baumann U; Kleine-Punte A; Brockmeier H; Anderson I; Gstoettner W; Acta Otolaryngol, 2011.

Atraumatic round window deep insertion of cochlear electrodes.
Skarzynski H; Lorens A; Zgoda M; Piotrowska A; Skarzynski PH; Szkielkowska A.; Acta Otolaryngol, 2011.

Hearing Preservation After Complete Cochlear Coverage in Cochlear Implantation With the Free-Fitting FLEXSOFT Electrode Carrier
Helbig S; Baumann U; Hey C; Helbig M; Otol Neurotol, 2011 Jul 1.

Is Electric Acoustic Stimulation Better Than Conventional Cochlear Implantation for Speech Perception in Quiet?
Adunka OF; Pillsbury HC; Adunka MC; Buchman CA; Otol Neurotol, 2010.

Electric Acoustic Stimulation in Patients with Postlingual Severe High-Frequency Hearing Loss: Clinical Experience.
Arnoldner C; Helbig S; Wagenblast J; Baumgartner WD; Hamzavi JS; Riss D; Gstoettner W; Adv Otorhinolaryngol, 67, 2010.

Partial deafness cochlear implantation at the university of kansas: techniques and outcomes.
Prentiss S; Sykes K; Staecker HJ; Am Acad Audiol, 21(3), 2010.

Preliminary Results of Electric and Acoustic Stimulation Using the MED-EL Sonata Flex EAS Electrode Array.
Walker A; Mawman D; Brough J; O'Driscoll M; Ramsden R; Green K; Freeman S; Cochlear Implants Int, 11 (Suppl. 2), 2010.

Electric Acoustic Stimulation (EAS) of the Auditory System: Experience and Results of Ten Patients Using MED-EL's M and FlexEAS Electrodes.
Lee A; Jiang D; McLaren S; Nunn T; Demler J; Tysome J; Connor S; Fitzgerald O'Connor A; Clinical Otolaryngology, 2010.

Results of partial deafness cochlear implantation using various electrode designs.
Skarzynski H; Lorens A; Piotrowska A; Podskarbi-Fayette R; Audiol Neurootol, 14 Suppl 1, 2009.

Preservation of low frequency hearing in partial deafness cochlear implantation (PDCI) using the round window surgical approach.
Skarzynski H; Lorens A; Piotrowska A; Anderson I; Acta Otolaryngol 2007; 127(1): 41-8.

Outcomes in adults implanted with the FLEXsoft electrode.
Baumgartner W; Jappel A; Morera Perez C; Gstöttner W; Müller J; Kiefer J; Van De Heyning P; Anderson I; Bryde Nielsen S.; Acta Otolaryngol, 127(579), 2007.

Method for hearing preservation in cochlear implant surgery.
Roland P; Gstoettner W; Adunka O.; Otolaryngol 2005; 16: 93-100.

Conservation of low-frequency hearing in cochlear implantation.
Kiefer J et al.; Acta Otolaryngol 2004; 124: 272-280.

The following is a list of references on young children:

Functional outcome of sequential bilateral cochlear implantation in young children: 36 months postoperative results
Scherf FW; Van DL; van WA; Wouters J; Desloovere C; Dhooge I; Offeciers E; Deggouj N; De RL; De BM; Van de Heyning PH; Int J Pediatr Otorhinolaryngol, 2009 Feb 26.

Ear Surgery in Infants Under One Year of Age: Its Risks and Implications for Cochlear Implant Surgery
Johr M; Ho A; Wagner CS; Linder T; Otol Neurotol, 29(3), 2008 Apr, p. 310–313.

Surgical Factors in Pediatric Cochlear Implantation and Their Early Effects on Electrode Activation and Functional Outcomes
Francis HW; Buchman CA; Visaya JM; Wang NY; Zwolan TA; Fink NE; Niparko JK; Otol Neurotol, 2008 Apr 4.

Hearing benefits of second-side cochlear implantation in two groups of children
Scherf F.; van Deun L.; van Wieringen A.; Wouters J.; Desloovere C.; Dhooge I.; Offeciers E.; Deggouj N.; De Raeve L.; De Bodt M.; Van De Heyning P.; Int J Pediatr Otorhinolaryngol, 71(12), 2007 Dec, p. 1855–1863.

Simultaneous versus sequential bilateral implantation in young children: Effects on central auditory system development and plasticity
Sharma A.; Gilley P.; Martin K.; Roland P.; Bauer P; Dorman M.; Audiological Medicine, 5(4), 2007, p. 218–223.

Complications in children with long-term cochlear implants
Lin Y.; Lee F.; Peng S.; ORL J Otorhinolaryngol Relat Spec, 68(4), 2006, p. 237–242.

Cochlear implantation in children younger than 12 months of age
Wackym P.; Firszt J.; Runge-Samuelson C; Operative Techniques in Otolaryngology, 16, 2005, p. 101–106.

Cochlear implantation in deaf infants
Miyamoto R.; Houston D; Bergeson T; Laryngoscope, 115, 2005, p. 1376–1380.

Cochlear implantation at under 12 months: Report on 10 patients
Colletti V; Carner M; Miorelli V; Guida M; Colletti L; Fiorino F; Laryngoscope, 115, 2005, p. 445–449.

The following is a list of references on alternative approaches:

VERIA TECHNIQUE

Veria operation: Updated.
Kiratzidis T, Arnold W, Iliades T.; ORL 64:406-412, 2002.

Veria operation.
Kiratzidis T, Iliades T, Arnold W.; ORL 64:413-416, 2002.

Veria operation: Cochlear implantation without a mastoidectomy and a posterior tympanotomy.
Kiratzidis T.; Adv Otorhinolaryngol 57:127-130, 2000.

SUPRAMEATAL APPROACH

How we do it? The suprameatal approach – An alternative surgical technique for cochlear implantation.
Kronenberg J; Migirov L.; Cochlear Implants International 7:142-147, 2006.

The Suprameatal Approach: An alternative surgical approach to cochlear implantation.
Kronenberg J; Baumgartner W; Migirov L; Dagan T; Hildesheimer M.; Otol Neurotol 25:41-45, 2004.

The role of Mastoidectomy in cochlear implant surgery.
Kronenberg J; Migirov L.; Acta Otolaryngol 123:219-222, 2003.

The suprameatal approach in cochlear implant surgery: Our experience with 80 patients.
Kronenberg J; Migirov L; Baumgartner W.; ORL 64:403-405, 2002.

Suprameatal approach. New surgical approach for cochlear implantation.
Kronenberg J; Migirov L; Dagan T; J.Laryngol Otol 115:283-285, 2001.

PERI CANAL TECHNIQUE

Cochlear implantation without mastoidectomy: The pericanal electrode insertion technique.
Häusler R; Acta Oto-Laryngologica 122:715-719, 2002.

ATTICOTOMY APPROACH

Transepitympanic Approach in Cochlear Implantation.
Nahler A; Böheim K; 5th European Congress of Oto-Rhino-Laryngology Head and Neck Surgery, Rodos-Kos Hellas 2004. (Poster)

Kombinierter Epitympanaler – Transmeataler Zugang bei Cochleaimplantation.
Nahler A; Böheim K; 47. Österreichischer HNO-Kongreß 2003. (in German)

Transatical Approach Modifications.
Cózar; Fragola; Calderón; Revilla; González de Ubiéta; Poster presentation Las Palmas 2002. (Poster),
Arauz: http://www.implantescocleares.com/ (in Spanish, with video).

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