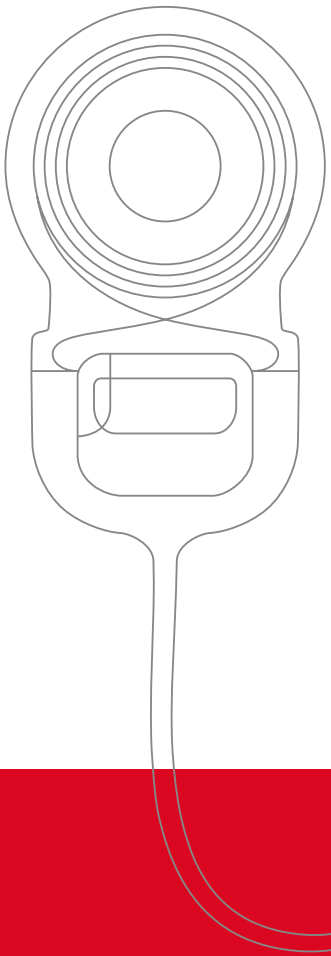
Cochlear Implants

MED EL

Mi1250 SYNCHRONY 2 Cochlear Implant

Standard | Medium | Compressed | FLEX^{SOFT} | FLEX^{28} | FLEX^{26}
FLEX^{24} | FLEX^{20} | FORM^{24} | FORM^{19}

English



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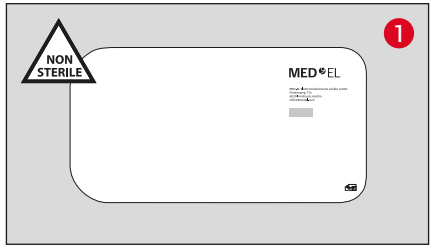
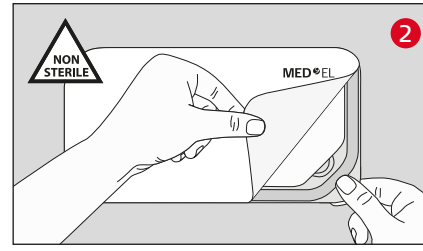
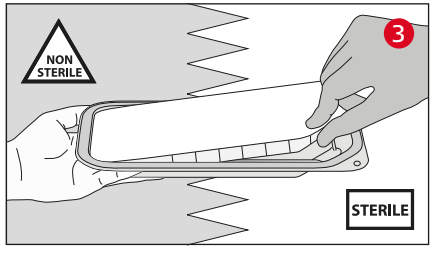
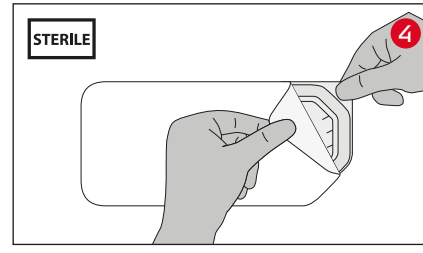
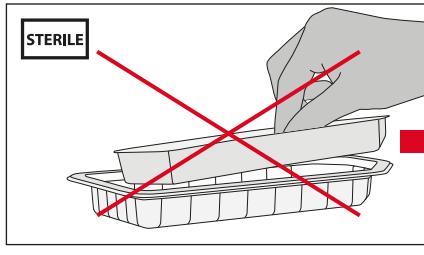
Opening instruction

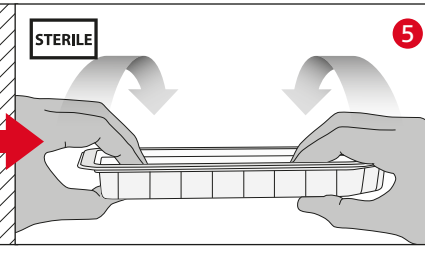


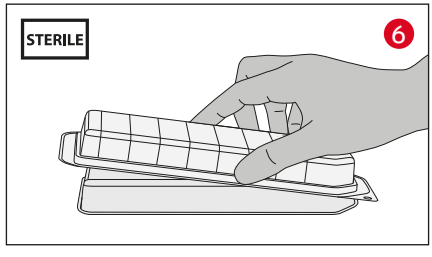


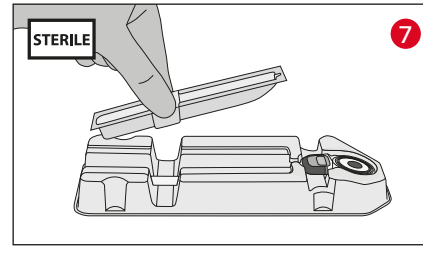


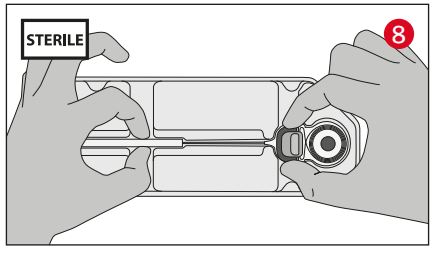


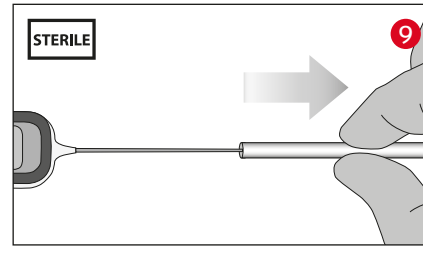




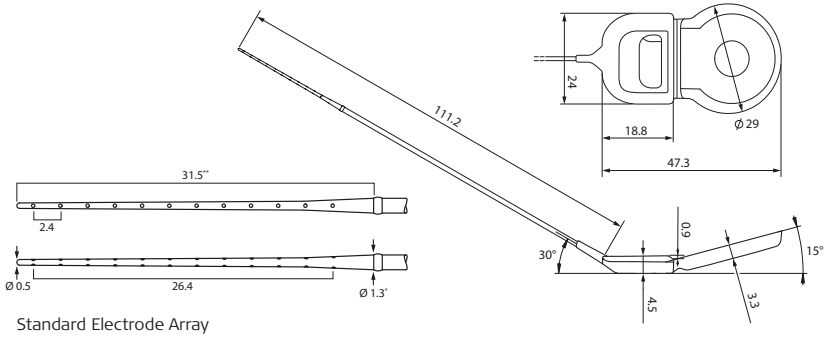






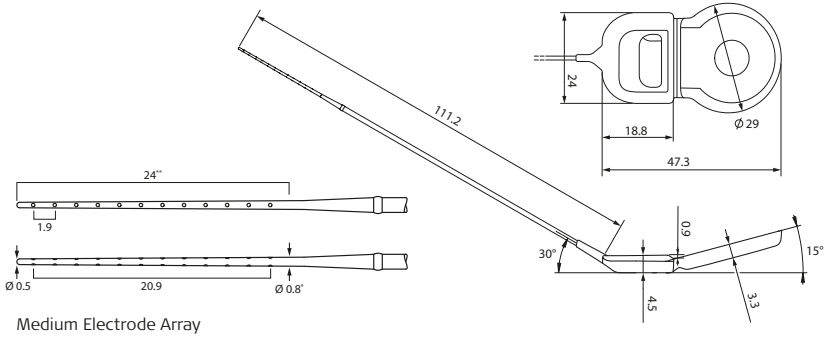


Mi1250 SYNCHRONY 2 Standard



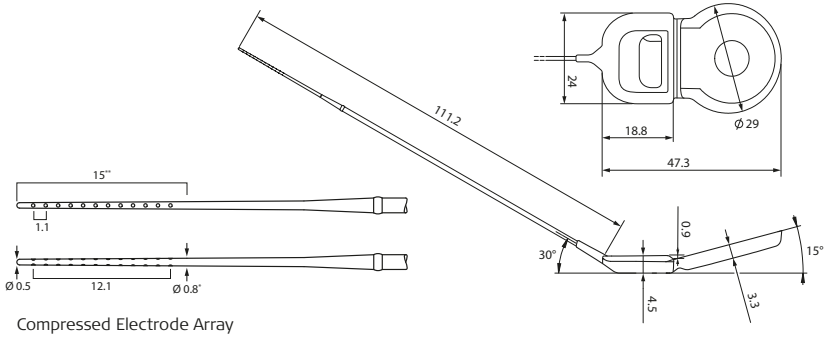
Standard Electrode Array

Mi1250 SYNCHRONY 2 Medium



Medium Electrode Array

Mi1250 SYNCHRONY 2 Compressed



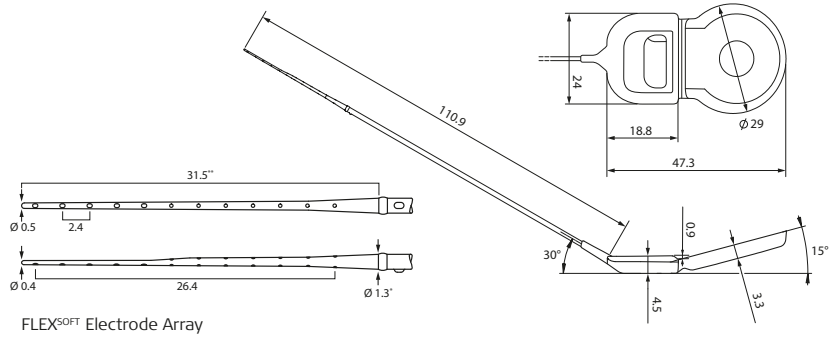
Compressed Electrode Array

Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

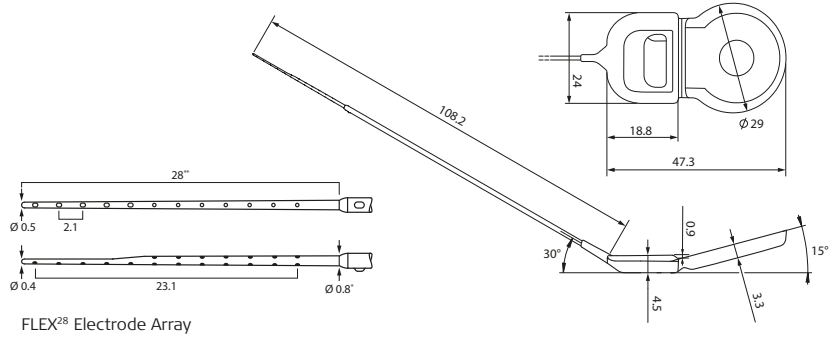
** Recommended insertion depth of electrode array

Mi1250 SYNCHRONY 2 FLEX^{SOFT}



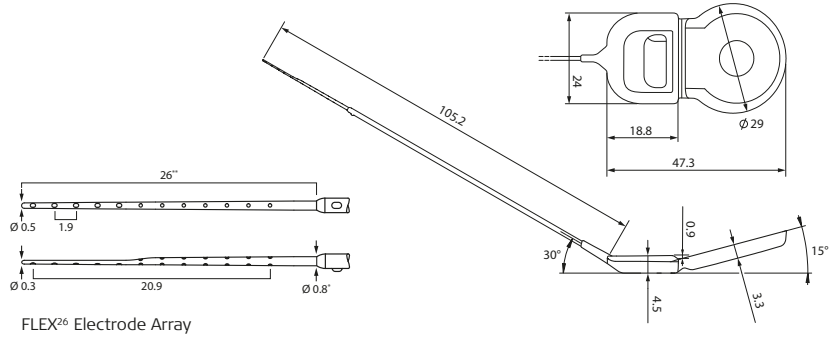
FLEX^{SOFT} Electrode Array

Mi1250 SYNCHRONY 2 FLEX^{28}



FLEX^{28} Electrode Array

Mi1250 SYNCHRONY 2 FLEX^{26}



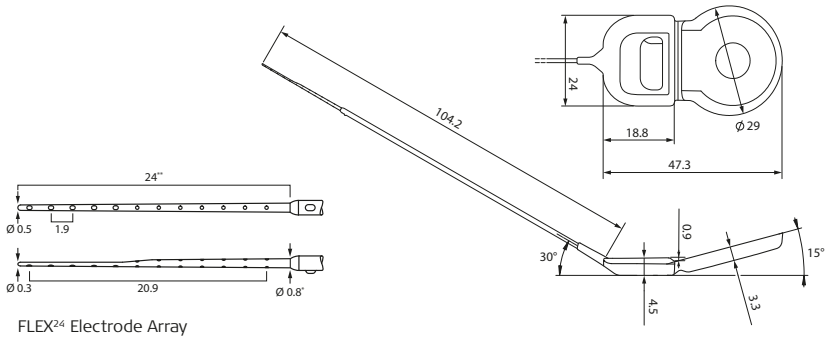
FLEX^{26} Electrode Array

Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

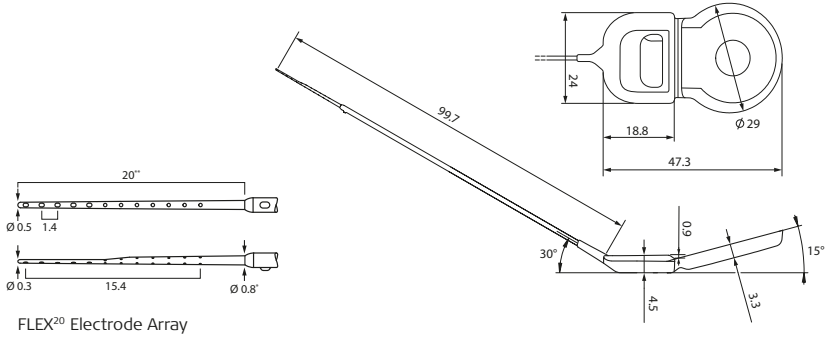
** Recommended insertion depth of electrode array

Mi1250 SYNCHRONY 2 FLEX^{24}



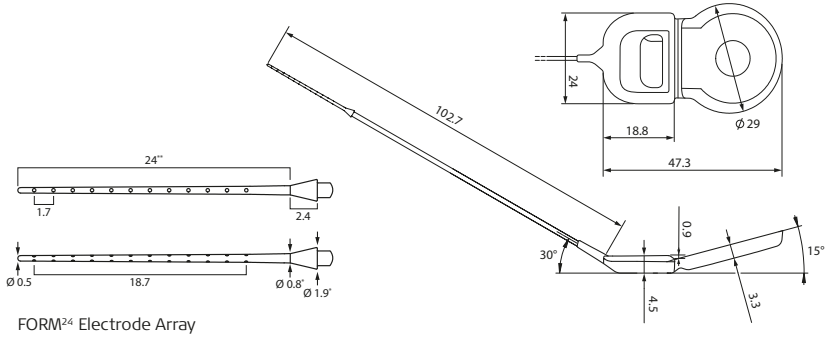
FLEX^{24} Electrode Array

Mi1250 SYNCHRONY 2 FLEX^{20}



FLEX^{20} Electrode Array

Mi1250 SYNCHRONY 2 FORM^{24}



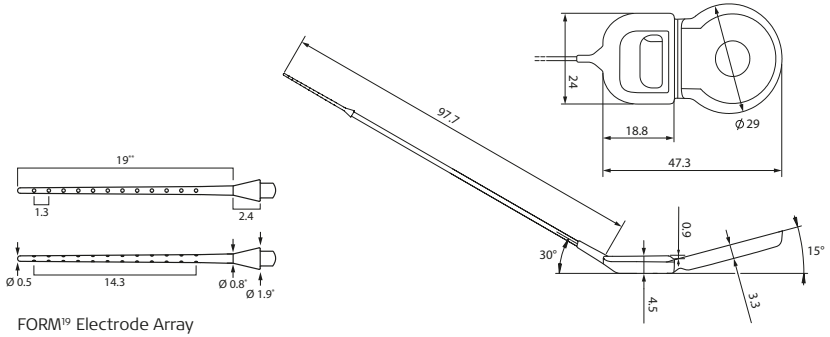
FORM^{24} Electrode Array

Typical dimensions in mm

* Recommended diameter of cochleostomy & RW opening

** Recommended insertion depth of electrode array

Mi1250 SYNCHRONY 2 FORM[19]



FORM[19] Electrode Array

Typical dimensions in mm
* Recommended diameter of cochleostomy & RW opening
** Recommended insertion depth of electrode array

Instructions for use

Mi1250 SYNCHRONY 2 cochlear implant

Device description

The Mi1250 SYNCHRONY 2 cochlear implant (hereafter referred to as 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 center, a reference electrode, an EAP reference electrode and an active electrode permanently attached to the stimulator. The active electrode can be of different types, thus resulting in different implant variants (implant family SYNCHRONY 2). This device is intended to be implanted by adequately trained and experienced surgeons only.

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 implant has a mass of 7.7 g (typical weight).
For principal dimensions of the implant refer to the drawings on the previous pages.
The volume of the implant without electrode is 3.9 cm^3.
Following materials are in direct contact with human tissue: medical grade silicone, platinum, iridium and parylene c.

Purpose of the device

Perception of environmental sound and potential for improvement of communicational abilities.

Performance characteristics

- Output characteristics of a stimulation signal on a 1kOhm resistor:
  Maximum current amplitude: Median value = 1250 µA, range = 500 µA
  Maximum pulse width: Median value = 203.8 µs, range = 8.2 µs
- The impedance measurement accuracy is typically better than 5 %.
- The implant is MR Conditional for scanner field strengths of 0.2 T, 1.0 T, 1.5 T and 3 T.
  For more information please refer to the Medical Procedures Manual.
- 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 the MED-EL application software user manual).

Specification and characteristics for each lead and electrode array

- The implant has 24 independent current sources stimulating 12 independent electrode channels in monopolar mode.
- The electrode is made of medical grade silicone, platinum (electrode contacts), platinum/iridium (90/10) wires and PEEK.
- All electrode variants have a straight design. The electrode does not deliver any medicinal substances.
- Geometric surface area of the stimulation reference electrode = 50 mm².
- Physical dimensions of the electrodes[1]:

Electrode type	Length of the electrode lead *	Cross-sectional dimensions of the electrode array		Geometric surface area per channel		Distance	
		at proximal end of array *	at distal end of array *	of smallest stimulating electrode contact **	of largest stimulating electrode contact **	between contacts *	between most proximal and most distal contact *
Standard	111.2	1.3 × 1.3	0.5 × 0.5	0.14	0.14	2.4	26.4
Medium	111.2	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.9	20.9
Compressed	111.2	0.7 × 0.7	0.5 × 0.5	0.14	0.14	1.1	12.1
FLEX^{SOFT}	110.9	1.3 × 1.3	0.5 × 0.4	0.13	0.14	2.4	26.4
FLEX^{28}	108.2	0.8 × 0.8	0.5 × 0.4	0.13	0.14	2.1	23.1
FLEX^{26}	105.2	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9
FLEX^{24}	104.2	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.9	20.9
FLEX^{20}	99.7	0.8 × 0.8	0.5 × 0.3	0.13	0.14	1.4	15.4
FORM^{24}	102.7	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.7	18.7
FORM^{19}	97.7	0.8 × 0.8	0.5 × 0.5	0.14	0.14	1.3	14.3

* typical value, mm | ** typical value, mm²

The implant does not have any connector.

Intended use

The MED-EL Cochlear Implant System 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.

Additionally, the MED-EL Cochlear Implant System used in combination with the implant variant SYNCHRONY 2 FLEX^{24} 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.

1 Some implant electrode types mentioned may not be released for distribution in all markets. Please contact your local MED-EL representative for information on current product availability in your country.

Additionally, the MED-EL Cochlear Implant System used in combination with the implant variant SYNCHRONY 2 FLEX[20] 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.

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.

Indications

- The cochlear implant evokes acoustic perception via electrical stimulation of the auditory nerve. A functional auditory nerve is thus a prerequisite for successful cochlear implantation.
- MED-EL strongly recommends using optimally fitted hearing aids for a minimum of three months before deciding that a cochlear implant is the preferential option. However, if an individual was deafened by an infectious disease, which can lead to ossification and if there are signs of cochlear ossification there may be no need to try a hearing aid. In these cases, implantation should not usually be delayed.
- To obtain the optimal benefit from the implant, the prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant and shall understand the importance of returning to the implant center for regular audio processor programming, assessment sessions and training.
- A preoperative assessment according to the local professional standards must be conducted.
- Cochlear implants SYNCHRONY 2 Standard are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31mm.
- Cochlear implants SYNCHRONY 2 Medium are intended to be used in open cochleae (no obliteration or ossification) with mild malformation for an electrode insertion depth of about 24mm as per request of the surgeon.
- Cochlear implants SYNCHRONY 2 Compressed are intended to be used in cochleae with moderate obliteration, ossification, or malformation for an electrode insertion depth of about 15mm as per request of the surgeon.
- Cochlear implants SYNCHRONY 2 FLEX^{SOFT} are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 31mm.
- Cochlear implants SYNCHRONY 2 FLEX[28] are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 28mm.
- Cochlear implants SYNCHRONY 2 FLEX[26] are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 26mm.

- Cochlear implants SYNCHRONY 2 FLEX[24] for non-EAS indication are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 24 mm as per request of the surgeon.
- Cochlear implants SYNCHRONY 2 FLEX[24] used for EAS are indicated for partially deaf individuals with mild to moderate sensorineural hearing loss in the low frequencies, sloping to a profound sensorineural hearing loss in the high frequencies.
- Cochlear implants SYNCHRONY 2 FLEX[20] for non-EAS indication are intended to be used in open cochleae (no obliteration or ossification) for an electrode insertion depth of about 20 mm as per request of the surgeon.
- Cochlear implants SYNCHRONY 2 FLEX[20] used for EAS are indicated for partially deaf individuals with mild to moderate sensorineural hearing loss in the low frequencies, sloping to a profound sensorineural hearing loss in the high frequencies.
- Cochlear implants SYNCHRONY 2 FORM[24] are intended to be used in open cochleae (no obliteration or ossification) or in cochleae with malformation for an electrode insertion depth of about 24 mm and/or when cerebrospinal fluid (CSF) leakage is expected.
- Cochlear implants SYNCHRONY 2 FORM[19] are intended to be used in cochleae with malformation, obliteration or ossification for an electrode insertion depth of about 19 mm and/or when cerebrospinal fluid (CSF) leakage is expected.

Contraindications

An individual must not be implanted,
- if the individual is known to be intolerant of the materials used in the implant (including medical grade silicone, platinum, iridium and parylene c);
- if there is an absence of cochlear development;
- if the cause of deafness is non-functionality of the auditory nerve and/or the upper auditory pathway;
- if external or middle ear infections are present or if the tympanic membrane is perforated in the ear to be implanted;
- if there are medical contraindications to surgery of the middle and inner ear and anesthesia as required;
- if anatomic abnormalities are present that would prevent appropriate placement of the stimulator housing in the bone of the skull or prevent placement of the chosen electrode array into the cochlea, using the implant shall be carefully considered prior to surgery;
- if the psychological status of the individual is unstable or
- if the individual has unrealistic expectations.

Implantation of cochlear implants SYNCHRONY 2 FLEX[24] used for EAS is contraindicated for partially deaf individuals with strong progressive hearing loss who are unable to use amplification devices and/or have cochlear malformations.

Implantation of cochlear implants SYNCHRONY 2 FLEX[20] used for EAS is contraindicated for partially deaf individuals with strong progressive hearing loss who are unable to use amplification devices and/or have cochlear malformations.

Undesirable side effects – Risks related to the implant

Possible postoperative side effects include the following: loss of residual hearing, dizziness, increased vertigo, delay of healing of the scar, impairment of the sense of taste, potential for swallowing difficulties, numbness, increased tinnitus, stimulation of the facial nerve, temporary pain and uncomfortable sounds during stimulation.

Sterility

The implant has been subjected to a validated ethylene oxide sterilization process and is supplied in sterile packaging. Once the sterile packaging has been opened, the implant cannot be resterilized. Do not use if sterile packaging is damaged. The implant is for single use only. Do not remove from sterile packaging until required.

Storage, shipment and disposal

The sterilized implant may only be shipped[2] between –29 °C and +60 °C and stored inside the implant box at room temperature. Each device must be implanted before the use-by date specified on the package. Packaging[3] should be disposed of in accordance with local legislation.

Information about use – General precautions and warnings

- The device must not be altered and must only be used as intended.
- Expected performance with the cochlear implant cannot be accurately predicted. The prospective implant users and their families shall be highly motivated and have realistic expectations about the expected benefit of the implant.
- Long-term damage to neural tissue following continuous chronic electrical stimulation has not been observed with cochlear implants.
- Sterility of the implant must be ensured at all times.
- The implant must never be dropped onto a hard surface or be held only by the electrode; damage to the implant or electrodes during implantation will invalidate the warranty.
- Device failure may occur due to mechanical damage of the implanted parts, e.g. resulting from a blow to the head, or due to electronic or other technical failure of the implant. Replacement of the device is required in these cases.

2 For shipping, the Implant Box shall be packed into a protective padded cardboard box (or similar).
3 The cardboard and plastic implant packaging (PETG and Tyvek) are manufactured from recyclable materials.

- For important information regarding everyday use of the MED-EL Cochlear Implant System and the applicable audio processor please consult the audio processor user manual.
- Particular attention should be paid to pediatric patients with developmental challenges (e.g. Cornelia-de-Lange syndrome), as they may present an increased risk of suffocation and/or laryngeal injury from attempting to swallow the coil and/or other external parts.
- 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.
- Most water sports should not cause any problem if the external parts of the implant system are removed. If headgear or face mask are worn, care must be taken to ensure that the strap is not too tight over the site of the implant. In case the MED-EL implant user wants to dive, the user should consult an experienced physician about the possibilities and personal restrictions when performing water sports, especially in the case of SCUBA diving. The implant is robust against pressure changes which occur during SCUBA diving to depths up to 50 m.

Surgical precautions and warnings – Risks related to surgery

- Cochlear implant surgery is comparable to middle ear surgery with additional access to the inner ear. The normal risks of surgery and general anesthesia are applicable. Primary surgical risks include the following: infection, inflammation, swelling, necrosis, hematoma, leakage of CSF, damage to the facial nerve, pain, scarring of the wound, skin irritation, swallowing difficulties and complications related to general anesthesia. Additionally, meningitis[4] can be a rare postoperative complication, but has the potential to be serious. The risk of meningitis may be reduced, for example by vaccination, antibiotic coverage and surgical technique.
- If available, facial nerve monitoring is recommended and if carried out, neural muscular blockade should be avoided.
- Prophylactic use of antibiotics is recommended for all implant recipients unless medically contraindicated.
- 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.

4 A paper reporting on the pathomechanisms, clinical symptoms, conservative and surgical treatments in cases of meningitis, published by Arnold et al (ORL 2002;64:382-389), may be useful additional reading.

- All sharp edges of bone must be removed and drilling should be completed before the cochlea is opened to prevent any bone dust from entering.
- In order to achieve good magnetic holding power and optimal coupling the distance between the lateral side of the implant and the surface of the skin (with hair) shall not exceed 6 mm.
- The serial number of the implant must be visible on the implant before fixing it in place.
- The implant must be immobilized in a flat stimulator bed drilled in the temporal bone. The electrode lead should be placed in a ramp-like bony channel without sharp edges to protect it against postoperative movement and excessive mechanical impact. The anterior stimulator edge should not be recessed to a depth more than 2 mm.
- Additional immobilization of the implant needs to be done (e.g. with sutures). It should be done 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.
- The electrode can be inserted in the cochlea either through the round window (RW) or via a cochleostomy. When performing a cochleostomy, in order to minimize the risk of postoperative infection, care should be taken that the round window and its membrane remain intact during drilling.

  Recommended diameter of the cochleostomy & RW opening:

Electrode type	
Standard	1.3 mm
Medium	0.8 mm
Compressed	0.8 mm
FLEX^{SOFT}	1.3 mm
FLEX^{28}	0.8 mm

Electrode type	
FLEX^{26}	0.8 mm
FLEX^{24}	0.8 mm
FLEX^{20}	0.8 mm
FORM^{24}	1.0 mm
FORM^{19}	1.0 mm

- The small marker on the electrode lead indicates the contact orientation of the five single-sided contacts at the leading apical electrode end. For the FLEX electrode variants, the marker is colored.
- Insertion of the electrode array into the cochlea will probably destroy any remaining hearing that may have been present in that ear pre-surgically.
- Only MED-EL approved surgical instruments must be used during the electrode array insertion process.
- The implant contains a strong magnet. Never use magnetic surgical tools.
- The electrode array should be inserted into the cochlea up to the recommended depth without squeezing the electrode array or the electrode lead and without touching the electrode contacts. To minimize the risk of postoperative infection rinsed fascia or similar tissue (muscle is not recommended) should be used. Create a seal around the electrode array at the entrance into the cochlea to secure the electrode array and to seal the cochlea opening.

- After insertion, the electrode lead shall be fixed so that no postoperative movement will occur. The excess electrode lead must be looped in the mastoid cavity well below the surface of the bone, using the cortical overhang to hold it in place, so that the electrode array will not move out of the cochlea or be subject to external pressure that could cause movement and subsequent damage of electrical connections.
- Do not place the sutures directly over the electrode lead.
- Inaccurate placement of the electrode array may impair acoustic perception with the device and may necessitate additional surgery. Improper fixation or placement of the electrode lead may also result in premature failure of the implant.
- 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.
- Other risks after surgery may be avoided by following the instructions in the applicable MED-EL audio processor user manual and the MED-EL application software user manual.
- Cochlear implantation in partially deaf individuals with low frequency hearing carries the risk of partial or total hearing loss which should be clearly explained to the individual by the surgeon prior to implantation. However, studies have shown benefits using electrical stimulation solely in this group of recipients even if residual hearing is lost. Etiology, duration of partial deafness and hearing aid benefit should be taken into consideration and hearing preservation surgical technique should be applied.
- In case of a magnet exchange surgery MED-EL recommends the use of the following tools: The Magnet Removal Tool (Ms050206) or the Magnet Insertion Tool (Ms050205) can be used in combination with the Non-Magnetic Spacer (Ms010107), the Replacement Magnet (Ms010108) as well as the S-Vector Replacement Magnet (Ms010109)[5].
- After removal of the Non-Magnetic Spacer, make sure that a fresh Replacement Magnet or S-Vector Replacement Magnet is inserted to re-establish full functionality of the implant.
- The implant is compatible with both replacement implant magnet variants, either the Replacement Magnet or the S-Vector Replacement Magnet. 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 Cochlear Implant System.
- Please refer to the applicable Instructions for Use of these devices for further surgical precautions and warnings.

5 Some accessories mentioned may not be released for distribution in all markets. Please contact your local MED-EL representative for information on current product availability in your country.

Interference with other equipment, robustness of the device in special medical or diagnostic environments

For safety recommendations and guidelines related to medical procedures, including MRI scanning, please refer to the Medical Procedures Manual.

Explantation

The implant may become non-functional, either by accident or due to medical or technical reasons. In this case it is strongly recommended to explant the device.
If for any reason the device is not used anymore, it is strongly recommended to explant the device. If an explantation is not performed, functional checks of the implant on a regular basis are strongly recommended.
If possible, the device should be removed without damaging or cutting it.

MED-EL recommends assessment of the device status based on functionality check results (telemetry measurement) as well as on x-ray imaging of the device prior to its explantation, showing electrode contact positions within the cochlea as they are in the implanted condition.
Furthermore, a digital photo of the revealed device taken prior to removal from the body would be desirable.
Further details regarding the device condition as found during explantation surgery are requested within MED-EL's "Device Explant Report Form" (AW8352), which is contained in MED-EL's "Explant Kit" (PN04175).

Please make sure that the "Device Explant Report Form" is completed and provided along with the functionality check results, x-ray images, photos and the explanted device itself.

Returning explanted devices

- After the device has been surgically removed, follow the cleaning and disinfection procedures established at the explantation site, avoiding damage to the implant if possible. Always follow locally established procedures for potentially bio-hazardous material.
- The device is to be returned to MED-EL in the Returned Implant Kit. Follow the enclosed packaging instruction.
- The device is returned to:
  MED-EL Elektromedizinische Geräte GmbH
  Worldwide Headquarters
  Safety adviser for the transport of dangerous goods
  Fürstenweg 77a
  6020 Innsbruck
  Austria

Warranty

Please refer to the accompanying Warranty Statement for information on our warranty provisions.

Symbols

CE marking, first applied in 2019


Caution


Do not reuse

MR Conditional


Manufacturer


Date of manufacture


Use-by date

Catalog number

Serial number

Sterilized using ethylene oxide

Help and contact

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.
Please visit us at www.medel.com

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