MED[©]EL

Hearing Loss Solutions Systems and Indications



The Right Solution for Every Candidate

Choosing the optimal solution for a patient with hearing loss is not always easy. Each patient is unique and has individual requirements and expectations. That's why MED-EL is committed to providing the most comprehensive and versatile portfolio of hearing solutions possible. Our portfolio extends from cochlear implants to middle ear implants and bone conduction solutions to auditory brainstem implants.

Our hearing solutions, manufactured in Austria, cover all types of hearing loss and offer the highest quality and reliability. For more than 25 years, we have consistently focused on the development of innovative hearing systems and on bringing groundbreaking technologies to market. We are always looking to the future.

This brochure provides a detailed overview of all MED-EL hearing solutions and their candidacy indications. On the one hand, it serves to explain the functionality and advantages of the systems. On the other hand, it helps audiologists and physicians to find the most suitable solution for a specific patient with hearing loss. Based on the type of hearing loss, hearing specialists can compare the profile of their patients with the indications and audiograms listed above in order to arrive at the appropriate hearing solution.

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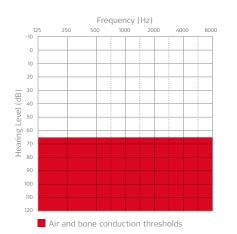
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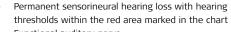
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Sensorineural Hearing Loss





- Functional auditory nerve
- Prior use of optimally fitted hearing aid, if appropriate
- Little or no benefit from acoustic amplification
- Adequate motivation and realistic expectations

Go with the right hearing solution: Page 9 SYNCHRONY

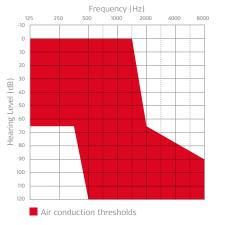
Cochlear Implant System





- Permanent sensorineural hearing loss with stable air conduction thresholds within the red area marked in the chart
- Age 5 years or older
- Normal middle ear functions as shown by audiometric thresholds and impedance measurements
- Speech audiometry curve adequate to the respective PTA with speech understanding
 of at least 50% at MCL with headphones in open-set word test
- Improvement of speech understanding through amplification possible
- Absence of retrocochlear and central auditory disorders
- Adequate motivation and realistic expectations
- Go with the right hearing solution: Page 19 VIBRANT SOUNDBRIDGE Middle Ear Implant System



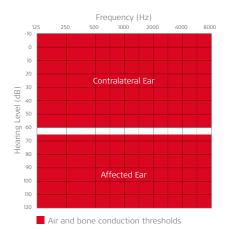


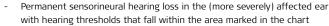
- Partial sensorineural hearing loss with air conduction thresholds within the red area marked in the chart
- Monosyllable score ≤60% at 65dB SPL in best aided condition
- No rapid progressive hearing loss
- No air-bone gap >15dB
- No malformations or obstructions of the cochlea, no otosclerosis or ossification, or external ear contraindications
- Adequate motivation and realistic expectations

Go with the right hearing solution: Page 15 SYNCHRONY EAS Electric-Acoustic Stimulation



Single-Sided Sensorineural Deafness

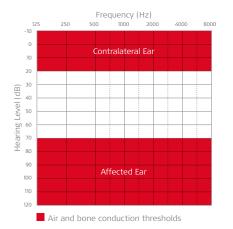




- Indication of normal hearing or mild-to-moderate hearing loss in the contralateral ear with hearing thresholds that fall within the area marked in the chart
- Functional auditory nerve
- Prior use of optimally fitted hearing aid, if appropriate
- Little or no benefit from acoustic amplification
- Adequate motivation and realistic expectations

Go with the right hearing solution: Page 9 SYNCHRONY Cochlear Implant System



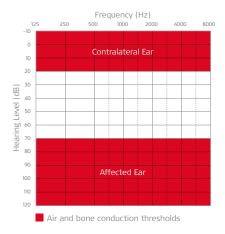


- Permanent sensorineural hearing loss in the affected ear with hearing thresholds that fall within the area marked in the chart
- Indication of normal hearing in the contralateral ear with hearing thresholds that fall within the area marked in the chart
- Age 5 years or older
- Anatomy that allows appropriate placement of the BONEBRIDGE implant
- Absence of retrocochlear and central auditory disorders in the contralateral ear
- Adequate motivation and realistic expectations

Go with the right hearing solution: Page 24 BONEBRIDGE

Bone Conduction Implant System





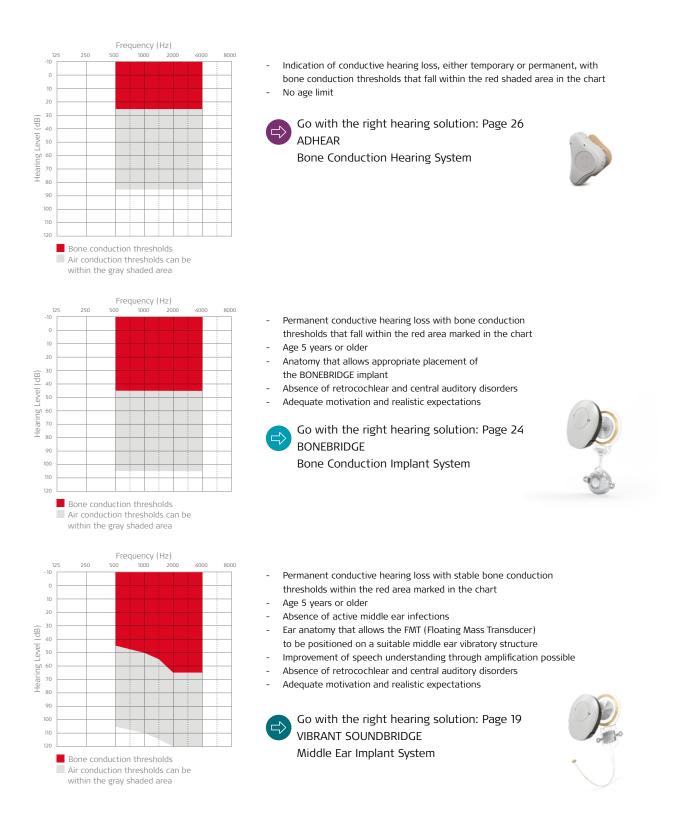
- Temporary or permanent sensorineural hearing loss in the affected ear with hearing thresholds that fall within the area marked in the chart
- Indication of normal hearing in the contralateral ear with hearing thresholds that fall within the area marked in the chart
- No age limit

Go with the right hearing solution: Page 26 ADHEAR

Bone Conduction System

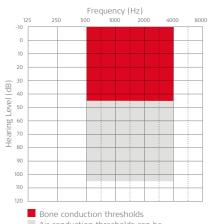


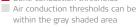
Conductive Hearing Loss

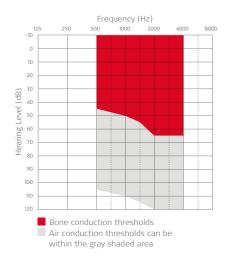




Mixed Hearing Loss







- Permanent hearing loss with bone conduction thresholds that fall within the red area marked in the chart
- Age 5 years or older
- Anatomy that allows appropriate placement of the BONEBRIDGE implant
- Absence of retrocochlear and central auditory disorders
- Adequate motivation and realistic expectations

Go with the right hearing solution: Page 24 BONEBRIDGE

Bone Conduction Implant System



- Permanent hearing loss with bone conduction thresholds that fall within the red area marked in the chart
 - Age 5 years or older
- Absence of active middle ear infections
- Ear anatomy that allows the FMT (Floating Mass Transducer) to be positioned on a suitable middle ear vibratory structure
- Improvement of speech understanding through amplification possible
- Absence of retrocochlear and central auditory disorders
- Adequate motivation and realistic expectations

Go with the right hearing solution: Page 19 VIBRANT SOUNDBRIDGE Middle Ear Implant System





Retrocochlear Hearing Loss

- Minimum age of 15 years if the following is the case: - Bilateral non-functioning auditory nerves
 - Neurofibromatosis type 2 (NF2)
 - Tumors are removed during ABI implantation Minimum age 12 months if the following is the case:
 - No benefit from a CI system
 - Non-functional auditory nerve
 - Aplasia of auditory nerve
 - Hypoplasia of auditory nerve
 - Head trauma
 - Non-NF2 Tumors
 - Severe ossification of the cochlea
- Adequate motivation and realistic expectations





Go with the right hearing solution: Page 28 SYNCHRONY ABI Auditory brainstem implant system





MRI Safety**

Magnet technology designed for MRI

Did you know that 3 out of 4 people will need an MRI in the next 10 years?* All hearing implants listed in this brochure enable fast and secure MRI exams** and are covered against damage during a scan by our life-long and worldwide MRI guarantee.***

^{*} Based on OECD data for Germany, 2014.
** All MED-EL implants listed in this brochure are MR conditional. Recipients with a SYNCHRONY 2 Cochlear Implant may be safely MRI scanned at 0.2, 1.0, 1.5, and 3.0 Tesla following the conditions detailed in the medical procedures manual. Recipients with a SYNCHRONY Brainstem Implant (ABI) may be safely MRI scanned at 0.2, 1.0, 1.5 resla following the conditions detailed in the medical procedures manual. Recipients with BONEBRIDGE may be safely MRI scanned at 1.5 Tesla following the conditions detailed in the instructions for use. Recipients with the SOUNDBRIDGE VORP 503 implant may be safely MRI scanned at 1.5 Tesla following the conditions detailed in the instructions for use.

The terms and conditions of the MRI guarantee can be found at https://go.medel.com/mri-guarantee-terms



SYNCHRONY CI Cochlear Implant System

The new and improved SYNCHRONY Cochlear Implant System provides exceptional hearing performance, outstanding reliability, and MRI safety. It combines several innovative MED-EL technologies to help create the most natural hearing experience possible for our recipients.

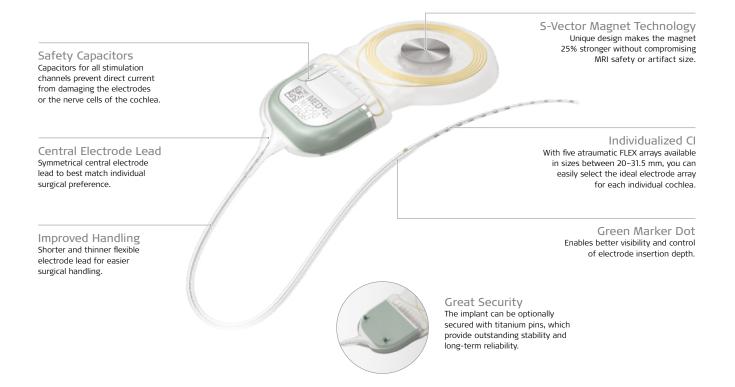
The system consists of an audio processor and the SYNCHRONY 2 Cochlear Implant. The audio processor picks up sounds from the environment, instantly transforms them into electrical signals, and transmits them via a coil to the cochlear implant placed under the skin. From there, the signals travel via an electrode array into the inner ear, where they directly stimulate the cochlea.

The SYNCHRONY Cochlear Implant System is suitable for individuals with severe to profound sensorineural hearing loss on one or both sides in all frequency ranges. For this type of hearing loss, a cochlear implant system is the only way to help restore hearing.



SYNCHRONY 2 Cochlear Implant

MED-EL's latest cochlear implant is robust, compact, enables MRI scans at 3.0 Tesla and is equipped with innovative technical features for the highest sound quality.





- Outstanding MRI safety
- Natural hearing experience
- Optimal handling
- Exceptional reliability



Natural Hearing

Structure Preservation The SYNCHRONY 2 Cochlear Implant uses the softest and most flexible electrode arrays available. These can be gently inserted to protect the sensitive structures in the cochlea and help preserve the patient's residual hearing. For cochlear implant users, this not only increases the current benefit of their cochlear implant, but also the opportunity to benefit from future technological developments.

Complete Cochlear Coverage A long electrode can reach the apical region to stimulate the whole cochlea. Only then can the full potential of the cochlea be utilized to provide cochlear implant users with a broad sound spectrum-from the very high to the very low frequencies. In combination with the innovative FineHearing sound coding strategy, electrodes that extend far into the cochlea enable a balanced and as realistic as possible hearing experience, better speech understanding, and more natural musical appreciation.

FineHearing

FineHearing not only covers a broad sound spectrum, but is also capable of providing up to 250 unique spectral bands. Following the functional principle of a natural cochlea, the technology processes sounds differently depending on the frequency. In addition, the fine structure of the signals is also transmitted, which enables a natural hearing sensation.



- Sequential, non-overlapping stimulation on 12 electrode channels
- Simultaneous stimulation on 2 to 12 electrode channels.
- 24 independent current sources
- 250 spectral bands
- Biphasic, symmetric triphasic and triphasic precision pulses

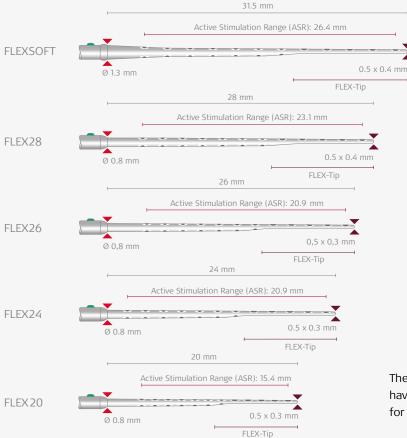
Individualized Cochlear Implants: The Right Electrode for Each Cochlea

Every cochlea is unique. This is why MED-EL has the largest portfolio of electrode-arrays on the market. For each CI candidate, the electrode can be selected that meets the individual requirements and provides the best hearing result for the implantation.

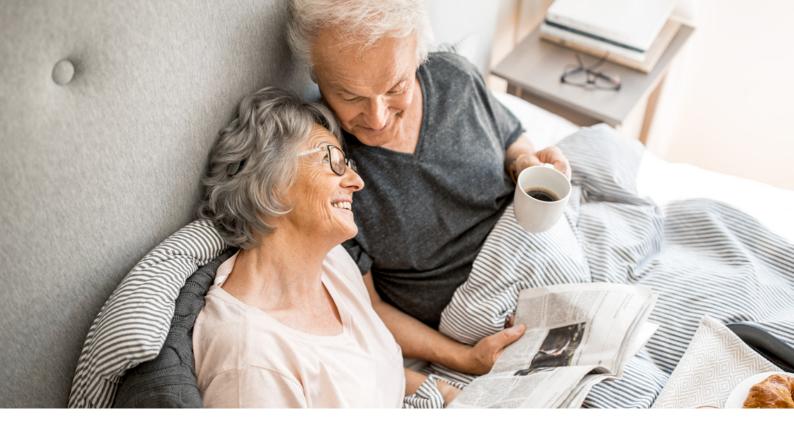
MED-EL also offers the softest and most flexible electrode arrays. The FLEX series has been specially developed to protect the sensitive structures in the cochlea. The electrodes adapt to the inner walls of the cochlea and can be deeply inserted and optimally placed. This allows a broad sound spectrum to be covered and the pitch and stimulation location in the cochlea to match as closely as possible to the natural tonotopic coding.

For CI candidates with malformations of the inner ear, e.g. with malformations of the cochlea-membranes or hypoplasia, MED-EL has developed the FORM series electrode arrays, which help prevent the leakage of cerebrospinal fluid (CSF).





The electrodes of the FLEX series have a flexible, tapered tip (FLEX Tip) for superior atraumaticity.



The Right Audio Processor

SYNCHRONY users can choose between SONNET 2 and RONDO 3.



The audio processors are compatible with all

multichannel cochlear

implants from the past 20+ years.

SONNET 2 Audio Processor

With Automatic Sound Management 3.0 technology (ASM 3.0) and two microphones, the SONNET 2 audio processor enables an effortless listening experience in virtually any listening environment. ASM 3.0 automatically adjusts settings to match the environment and reduces unnecessary background noise.

SONNET 2 offers a robust, splashproof, and lightweight audio processor that is the ideal choice for children and adults with an active lifestyle. It has numerous connectivity options to external audio sources, plus a variety of wearing options and a battery life of up to 60 hours. Audiologists, as well as users, benefit from the integrated datalogging function, which stores information about the use of SONNET 2.



RONDO 3 Audio Processor

RONDO 3 is the ideal choice for cochlear implant users who want simple handling, elegant design, and maximum wearing comfort. It has an integrated battery that always stays in the device and can be charged wirelessly. Placed on its inductive charging station at night, it provides power for an entire day of listening.

Handling RONDO 3 is incredibly simple: No more changing batteries and a single button is all it takes to manage the audio processor. Two microphones, three types of enhanced noise reduction, and Adaptive Intelligence provide for superior hearing performance in any environment. And since it is not worn on the ear and no cable is needed, RONDO 3 is comfortable for everyone—especially those who wear glasses.



SYNCHRONY EAS Electric Acoustic Stimulation

SYNCHRONY EAS (Electric Acoustic Stimulation) combines the electrical stimulation of a cochlear implant with the acoustic amplification of a hearing aid. This combination of two technologies in one system allows people with partial hearing loss to enjoy the full range of the sound spectrum again while benefiting from their natural residual hearing.

Depending on the frequency, the SONNET 2 EAS Audio Processor either converts sound into electrical impulses or amplifies it acoustically. Low-frequency sounds are amplified and pass naturally through the auditory canal into the cochlea. Higher-frequency sounds, which those affected cannot hear due to their partial sensorineural hearing loss, are converted into electrical impulses and transported to the inner ear via the electrode array of the cochlear implant. The settings of both components—the acoustic and the electrical—can be independently adjusted to the needs of the EAS user.



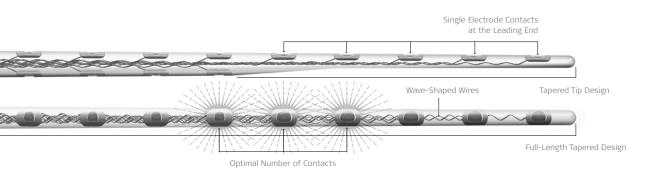
Preserving Residual Hearing

At MED-EL, protecting residual hearing is especially important to us. Protecting functioning inner ear structures supports a more natural overall hearing experience and helps to ensure that those affected can also benefit from future technologies.

In the event of partial hearing loss, it is critical to use electrical stimulation to bridge only the affected areas at the beginning of the cochlea. The areas deeper in the cochlea, on the other hand, are not electrically stimulated and thus retain their function.

For this purpose, MED-EL offers not only very long electrodes but also shorter ones, such as the FLEX20 and FLEX24, which have been specially developed for people with partial hearing loss. They only cover the non-functional cochlear region responsible for the high-frequency range of sounds. Thanks to their unique wave-shaped wires and the FLEXtip technology, these electrodes can be gently inserted, which also protects the sensitive structures in the cochlea.





At a Glance

- Use and preservation of the residual hearing ability
- Both EAS components are separately adjustable
- Automatic Sound Management 3.0
- Compatible with individual earpieces



Two Technologies in One

For people with residual hearing in the low frequency range, there is an audio processor that combines the advantages of acoustic amplification and electrical stimulation.

SONNET 2 EAS Audio Processor

SONNET 2 EAS is essentially a SONNET 2 Cochlear Implant Audio Processor that has an acoustic unit in addition to the technical features listed on page 13. In the low-frequency range, SONNET 2 EAS uses six channel 48 dB acoustic amplification.





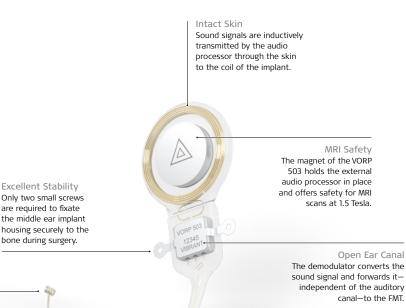
VIBRANT SOUNDBRIDGE

Middle Ear Implant System

VIBRANT SOUNDBRIDGE is an active middle ear implant system that stimulates areas in the middle ear while leaving the skin intact. The implant generates vibrations and causes the middle-ear structure to which it is coupled to vibrate. This technology provides outstanding results in sound quality and speech understanding.

The system consists of the VORP 503 implant and the externally worn SAMBA 2 audio processor. This converts sound into electrical signals and transmits them transcutaneously to the implant. The implant includes a coil, a magnet that holds the audio processor over the implant, a demodulator, and the innovative Floating Mass Transducer (FMT). The FMT converts the sound information into mechanical vibrations and sets in motion the bony structure of the middle ear to which it is attached.





Direct Bone Stimulation The vibrating Floating Mass Transducer (FMT) is attached to a middle ear structure (single point fixation) and causes it to vibrate.

VIBRANT SOUNDBRIDGE offers a treatment option for sensorineural hearing loss or conductive hearing loss, as well as the combination of these two types of hearing loss. In all these cases, SOUNDBRIDGE can be implanted on one or both sides of children and adults. The latest generation of the implant, VORP 503, is MR Conditional at 1.5 Tesla, enabling users to undergo MRI scans if required.

The system is an efficient and comfortable alternative to conventional hearing aids. SOUNDBRIDGE is ideal when it is not possible to wear hearing aids (in the case of ossifications such as diseases of the outer or middle ear or after surgery), or in cases of discomfort (itching, recurrent inflammation of the ear canal), or simply if hearing aids do not achieve satisfactory hearing results.



- Direct stimulation of the middle ear
- No skin irritation
- Comfortable to wear
- Open ear canal
- Ideal for people who experience discomfort with hearing aids _
- The VORP 503 is MR Conditional at 1.5 Tesla.

Versatile Solution

VIBRANT SOUNDBRIDGE uses the remaining functional middle ear structures to transmit acoustic information to the inner ear: Depending on the type of hearing loss, the FMT is connected either to the round window or to a portion of the ossicular chain. In order to place the FMT at the suitable location, so-called "Vibroplasty Couplers" are necessary, which serve as connecting pieces between FMT and the respective structure in the middle ear. There are different couplers from which the appropriate one can be selected according to the anatomical and pathological conditions of the individual. The couplers can be easily slid onto the corresponding middle ear structure during implant placement.



Different Vibroplasty Couplers are available depending on whether the ossicular chain or the round window is to be stimulated: Incus-SP-Coupler, Incus-LP-Coupler, Stapes-SH-Coupler, CliP-Coupler, Round-Window-Soft-Coupler

Due to its revolutionary design, the implant only needs to be attached to a single structure (single point fixation). This makes placement of the FMT independent of skull growth, and therefore making SOUNDBRIDGE a suitable option for both children and adults. The intensity of the vibrations can be adapted to the individual needs of each patient.



SAMBA 2

The SAMBA 2 audio processor can be used with the VIBRANT SOUNDBRIDGE and BONEBRIDGE implant systems.

Optimal Hearing in Every Situation

With SAMBA 2 there is no need to change programs. The Intelligent Sound Adapter 2.0 automatically learns how to give people their best hearing possible in six different listening environments: Quiet, Speech in Quiet, Noise, Speech in Noise, Music, and Car.

SAMBA 2's advanced noise reduction technology not only reduces everyday noises but also filters out background speech noise. Speech Tracking adapts the microphones toward speech no matter what direction voices come from, making conversations easier to follow, even in the car.

Managing settings is simple thanks to the optional SAMBA 2 Remote. This app helps switch between simple, predefined audio processor settings directly from a smartphone. And for easy connectivity, there is SAMBA 2 GO. This optional assistive listening device can be used to stream sound from phones, TVs, tablets, and many other devices.





Stylish Design

SAMBA 2 has been designed with simple elegance and all-day comfort in mind. The lightweight, externally worn audio processor is sleek enough to hide under hair. The covers are easy to change and are available in a variety of different colors and designs. Users have the option of wearing their SAMBA 2 as an eye-catching accessory with a colorful pattern or discreetly matching it to their hair color.

Hearing Made Simple

With quick-change batteries, design covers and attachment clips, using SAMBA 2 is easy and intuitive. And SAMBA 2's self-learning system not only makes everyday handling simple for recipients but also saves time for audiologists and acousticians, as fewer adjustment appointments are required.



At a Glance

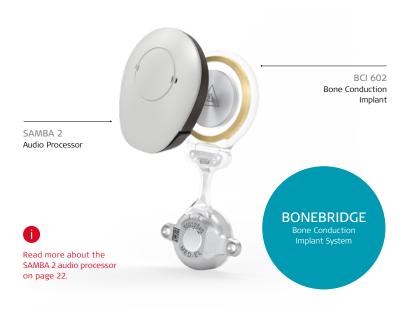
- Sleek design
- 6 environments
- Intelligent Sound Adapter 2.0
- Optional SAMBA 2 Remote app
- Intuitive fitting

BONEBRIDGE Bone Conduction Implant System

BONEBRIDGE is the only active bone conduction implant system that's already in its second generation. And just like the first generation BONEBRIDGE, the implant is placed fully under the skin. "Active" means that the implant itself generates vibrations and delivers them directly to the bone.

The system consists of the externally worn SAMBA 2 audio processor and the BCI 602 bone conduction implant placed under the skin. The implant has a signal converter that creates vibrations in the cranial bone using the sound information detected by the audio processor. Through bone conduction, the vibrations finally reach the inner ear, where they are processed in a natural way.

BONEBRIDGE offers a treatment option for unilateral or bilateral conductive and mixed hearing loss. In addition, the system is used for unilateral severe to profound sensorineural hearing loss. If there is unilateral hearing loss, BONEBRIDGE directs sound information from the affected side via the cranial bone to the contralateral, healthy ear.



Intact Skin The recorded sound signal is inductively transmitted by the audio processor through the intact skin to the coil of the implant.

> MRI Safety The magnet not only ensures that the externally worn audio processor remains in place, but also allows MRIs at 1.5 Tesla.

Active Bone Conduction The transducer from the implant generates the vibrations. It is implanted into the bone and causes it to vibrate directly.

Precise Signal Processing In the demodulator, the sounds captured by the microphone of the audio processor are prepared for the transducer.

Active Bone Conduction

The ergonomically-designed transducer on the implant itself produces vibrations and transmits them to the bone through direct contact. The vibrations are not dampened by skin or other tissue. Combined with state-of-the-art signal processing, this technology enables improved speech understanding and excellent sound quality over a wide frequency range. Additionally, as there is no physical connection between the microphone and the implant, feedback noise is minimized.

Intact Skin

The audio processor transmits sound information in the form of electrical signals. These are received by the implant with the vibrating transducer BC-FMT (Bone Conduction Floating Mass Transducer), which is safely embedded under the intact skin. Thanks to this unique concept, continuous skin or wound care is not necessary.

Open Ear Canal

The position of the implant offers another advantage: Blockages in the outer or middle ear (e.g. due to atresia, otosclerosis and ossification, or after middle ear surgery) are avoided. Since the transducer sits directly in the mastoid bone, the external auditory canal remains completely untouched by BONEBRIDGE. Specifically for children and adults with malformations and chronic inflammations of the outer or middle ear, the system is the ideal solution.



At a Glance

- Excellent hearing results
- No skin irritation
- Open ear canal
- MR Conditional at 1.5 Tesla



ADHEAR is the only non-surgical bone conduction device that transports sound without exerting pressure on the skin.

The ADHEAR system consists of an adhesive adapter and an audio processor. The adhesive adapter is placed on the skin behind the ear and the audio processor is attached to the adapter with a simple click. The processor picks up sound waves, converts them into vibrations, and transfers them to the bone via the adhesive adapter. Through bone conduction, the sound information reaches the inner ear, where it is processed. ADHEAR can help people with conductive hearing loss or unilateral deafness to hear better in an easy and effective way. ADHEAR is the ideal solution for children who are too young for a bone conduction implant and adults who cannot or do not want to undergo surgery. Since it leaves all outer and inner parts of the ear completely free, the gentle system is also suitable for candidates with malformations or chronic diseases of the ears.

ADHEAR is very well suited for the treatment of temporary hearing loss, but can also serve as a long-term solution for permanent conductive hearing loss or unilateral deafness. A great advantage of the system lies in its discrete appearance and easyto-use design. Since ADHEAR does not require any surgical intervention and can be attached and used in a few simple steps, it can be tried out by suitable candidates at any time.







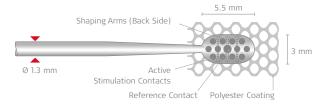
- Non-surgical solution
- Suitable for all age groups
- High wearing comfort without pressure on the skin
- All-day wearing comfort

SYNCHRONY ABI Auditory Brainstem Implant

The SYNCHRONY ABI system is designed for individuals with a non-functional auditory nerve. Causes for a missing or damaged auditory nerve can be congenital aplasia or hypoplasia, severe head injuries, serious ossifications in the cochlea and tumor diseases such as NF2 (neurofibromatosis type 2). If NF2 tumors are present, they are surgically removed during ABI implantation.







MED-EL's special electrode array features twelve independent electrodes, arranged on a soft, preformed silicone matrix.

The ABI system consists of an audio processor (SONNET 2 or RONDO 3, see page 13) and the SYNCHRONY Auditory Brainstem Implant. The audio processor detects sounds and converts them into electrical signals. The signals are transmitted to the cochlear nucleus via an electrode array that bypasses the auditory nerve. This electrical stimulation allows ABI users to perceive a spectrum of different auditory impressions and actively supports sound recognition and communication. There are two cochlear nuclei in the brain stem, so an ABI system can potentially be implanted on both sides.

Candidate Selection Tool

For All MED-EL Hearing Solutions

You can also obtain in-depth information on the selection of a suitable hearing solution for your patients online. Click your way step-by-step through our Candidate Selection Tool and answer a few questions based on the patient data and audiometric measurements you have. The web application will suggest a hearing system for your respective patient. The app includes all MED-EL systems and therefore all types of hearing loss. It is free, easy to use, and runs on your computer as well as on your tablet or smartphone.

Try it now: partner.medel.pro/candidacy

Or you can scan the QR code with your smartphone to go directly to the application.





At a Glance

- Individual system recommendation in just a few steps
- Comprehensive information on all MED-EL hearing solutions
- Optimized for PC, Tablet, and Smartphone
- No login or download required
- Intuitive controls
- Free of charge



MED-EL Professional Blog

Discover our MED-EL Professional Blog for ENT surgeons, audiologists, and rehabilitation specialists. Subscribe to the blog to receive interesting articles, clinical case studies, information on new hearing solutions, rehabilitation materials, and much more directly to your inbox, week by week.

blog.medel.pro

Scan the QR code with your smartphone, to go directly to the blog.





Get in Touch

Are you a hearing professional? Would you like more information about one of our hearing solutions? Get in touch—we look forward to hearing from you.

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