Business Unit Vibrant

MED EL

BONEBRIDGE

SAMBA 2 Audio Processor

English

hearLIFE

AW53003_1.0 (English US)

Instructions for use

Table of contents

1. Contents of the package

- SAMBA 2 Audio Processor
- Daily case
- Set of batteries
- Set of interchangeable covers
- Attachment clips for hair and clothes
- Accompanying documents

2. Introduction

These instructions for use cover the use of the SAMBA 2 Audio Processor.

You should read the instructions for use carefully and completely so that you are familiar with the operation and maintenance of your audio processor. Please do not hesitate to contact your audiologist/healthcare professional, clinic or MED-EL representative with any additional questions you may have.

The following symbols will be used throughout this document:

Information indicating a hazardous situation that, if not avoided, could result in death or serious injury.

Information indicating a hazardous situation that, if not avoided, could result in minor injury or inconvenience for the user and/or property damage.

Information particularly relevant for parents, guardians or caregivers of children who use the system.

NOTE:
The SAMBA 2 BB Audio Processor will also be referred to as SAMBA 2 or audio processor in these instructions for use.

CAUTION
The SAMBA 2 Audio Processor is only to be used with a Bonebridge Bone Conduction Implant (BCI 601 or BCI 602).

3. General information

Device description

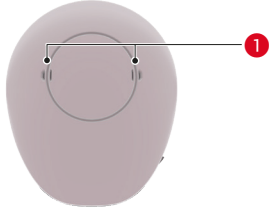
The Bonebridge system consists of two major components: the osseointegrated implant, called Bonebridge Bone Conduction Implant (BCI), and the externally worn audio processor.

The externally worn audio processor is attached to the user's head, behind the ear. A magnet in the audio processor is attracted to an opposing magnet within the implant. The audio processor includes two microphones to pick up sound from the environment, sound processing circuitry to modify the output signal to the user's specific requirements, and a digital compression processor. The device is powered by a single 675 zinc-air battery. The Bonebridge system is activated by simply fitting the audio processor. The audio processor is intended for the home use environment.

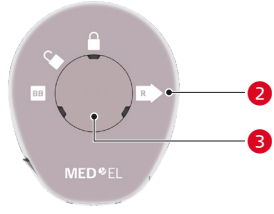
The implanted part of the Bonebridge system consists of the internal coil and the Bone Conduction – Floating Mass Transducer (BC-FMT). A signal from the audio processor is transferred across the skin to the internal coil. The internal coil then relays the signal to the BC-FMT. The BC-FMT converts the signal into vibrations, which are interpreted by the user as sound. The implanted portion of the Bonebridge system is not operated directly and has no specific maintenance requirements. The user does, however, have operation and maintenance responsibilities for the audio processor and its accessories.

SAMBA 2 Audio Processor overview

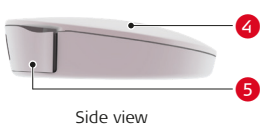
1. Microphone openings
2. Indicator relevant for users with two implants
   (R = right side, L = left side)
3. Magnet
4. Interchangeable cover
5. Battery compartment
6. Air vents
7. Bracket groove (recess for attachment clip fixation)



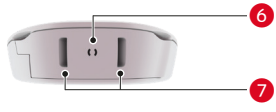
Top view



Bottom view



Side view



Front view

Intended use – Indications – Contraindications

Intended use

The SAMBA 2 Audio Processor is an external part of the Bonebridge system. The Bonebridge is intended to improve hearing for patients with conductive or mixed hearing losses, bilateral fitting or single-sided deafness.

The Bonebridge augments hearing by providing acoustic information to the inner ear via bone conduction. This is achieved by actuating a vibratory transducer, which is implanted in the temporal bone.

Indications and contraindications

Patients implanted with a Bonebridge are indicated to use the SAMBA 2 Audio Processor.

As the SAMBA 2 is a component of the Bonebridge system, all indications and contraindications for the Bonebridge are applicable.

NOTE:
Important information related to indications, contraindications, warnings and risks for your implant are shipped in a separate document to your clinic together with the implant (instructions for use of the implant). If you want to review this information, please contact your clinic or MED-EL.

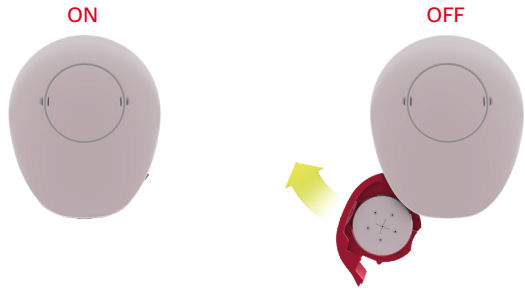
CAUTION
It is recommended that BCI recipients receive age-appropriate vaccinations including a pneumococcal meningitis vaccination prior to implantation.

Intolerances

Persons known to be intolerant of the materials used in the implant or the audio processor should not receive the Bonebridge system. Refer to section **Miscellaneous** for information on the materials used in the SAMBA 2 which are in contact with tissue.

4. User information

Switching SAMBA 2 on/off



Open the battery compartment about 5 mm (3/16 in) to switch the SAMBA 2 off.

Always open the battery compartment whenever the audio processor is not in use to extend the life of your device's battery.

PARENTAL GUIDANCE

If the child/user refuses to wear the audio processor or indicates uncomfortable hearing sensations, remove and turn off the audio processor and have the system checked at the clinic.

Placing SAMBA 2 over the implant

This side up

Implant system activated

The audio processor is kept in position over the implant by magnetic force. Your audiologist/healthcare professional can exchange the magnet of the audio processor to a different strength for your best benefit.

NOTE:
Bilateral users must check the indicator symbols on the bottom of each SAMBA 2 Audio Processor before placing the devices over the implants (R = right side application, L = left side application).

CAUTION
Take care not to drop the audio processor during handling. Keep good hold of the audio processor
- when you place it over the implant.
- when you remove it from the implant.
- during dressing/undressing.

CAUTION
Return to your audiologist/healthcare professional
- if wearing the audio processor causes redness or discomfort to your skin.
- if the audio processor seems to fall off frequently.

Changing program and volume

The audio processor offers up to six programs (one on default). These programs are freely adaptable by the audiologist/healthcare professional.

The audiologist/healthcare professional can adjust the signal processing for different hearing environments (e.g. Program 1 for standard conditions (default), Program 2 for ambient noise, Program 3 optimized for music etc.).

NOTE:
After turning on the audio processor, the first program is always active.

The universal Program 1 automatically adapts to listening situations and has been set and customized by your audiologist/healthcare professional. If you have questions regarding changing the volume and switching between programs, contact your audiologist/healthcare professional.

SAMBA 2 Remote app

The SAMBA 2 Remote app allows you to adjust your SAMBA 2 from your Android or iOS smartphone without the need for any additional hardware. The app is free to download from the Google Play Store or Apple App Store[1].

The SAMBA 2 Remote app generates short control signals which may be audible. While using the app do not hold the loudspeaker of this device to your ears or the ears of others. Do not use the device with headphones, headsets or other audio playback devices.

Installation

1. Install the SAMBA 2 Remote app.
2. Launch the app on your mobile device and follow the instructions given.
3. Setup with QR code: Use this option if you have received a Setup QR code from your audiologist/healthcare professional. Simply scan the QR code.

Manual setup: Use this option, if you don't have a Setup QR code. Follow the prompts on the screen of your device.

Features

- Select hearing programs
- Adjust volume and sound balance
- Adjust of volume of masking signal
- Check battery status of the audio processor
- Mute

1 The SAMBA 2 Remote app may not be available in some countries. Contact your audiologist/healthcare professional or your local MED-EL representative for specific information.

NOTE:
The app only works in one direction and does not receive any information from the audio processor. When switching on, the audio processor automatically starts in the Universal-program (Program 1) and with default volume, whereas the app shows the last chosen program and volume slider position. To switch programs, click on the desired one. To change volume, click on the desired location on the slider bar.

NOTE:
The volume slider is absolute. A particular position of the slider indicates a designated increase or decrease in volume.

NOTE:
If the settings of your audio processor were changed by your healthcare professional, the app needs to be set up again.

Battery status

The audio processor is designed to be very energy-efficient and has a battery lifetime of approximately 8 to 10 days. This is based on an average daily use of 12.6 to 16 hours at an average volume level.

The battery life of the audio processor may vary depending on the selected program, environment and duration of use.

Changing the battery

If the battery is low and you hear a series of beeps, it must be replaced. The loudness and pitch of the beeps can be preset by your audiologist/healthcare professional.

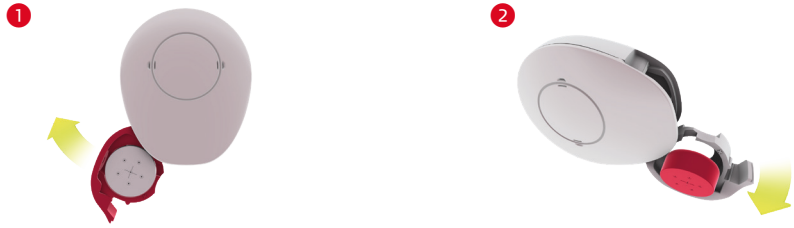
CAUTION
Only use size 675 zinc-air batteries (also called PR44 batteries). Using batteries of other sizes, voltages, or power levels may cause irreparable damage to the audio processor. Never try to recharge 675 zinc-air batteries.

If you notice a change in sound quality, it is recommended that you replace the battery first.

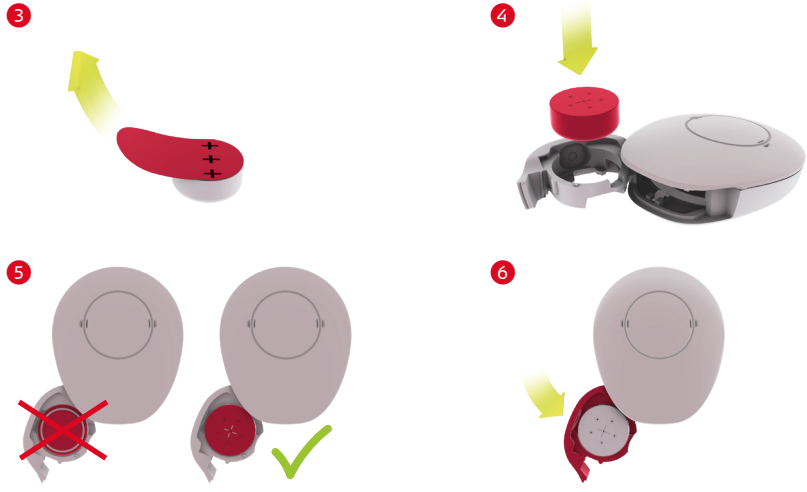
NOTE:
If your device does not work properly, check the section Troubleshooting. If the problem persists, contact your audiologist/healthcare professional.

To change the battery, follow these steps:

Remove used battery



Insert new battery



NOTE:
It is recommended to peel the protective film off the battery one to two minutes before battery insertion. This time is needed for the zinc-air battery to charge up completely.

Spare battery

It is recommended that you always carry a spare battery in its original packaging with you.

Disposal of battery

Always remove the used battery immediately to avoid battery leakage and possible damage to the audio processor. To avoid environmental pollution, do not throw batteries into household trash. Recycle or dispose of used batteries according to local regulations.

PARENTAL GUIDANCE

Parents, guardians or caregivers are advised to regularly change the battery as necessary and, if in doubt, check the status of the battery.

WARNING

To prevent children and those who, for a variety of reasons, lack the ability to appropriately handle and manipulate small parts from swallowing or choking on batteries, always keep new and used batteries out of their reach.
If you suspect your child has swallowed or inserted a button battery, immediately seek for expert advice at your nearest emergency ward.

Changing the cover

Different covers can be used to change and customize the appearance of your SAMBA 2.

NOTE:
If the cover is broken or the membranes underneath the microphone openings are damaged or clogged, the cover must be exchanged.

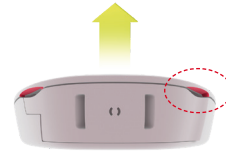
CAUTION
Take care not to stress the battery compartment when changing the cover.

To change the cover, follow these steps:

1

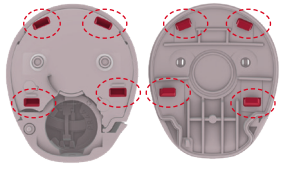
Close the battery compartment.

2



Insert your fingertips into the finger grooves between the cover and the audio processor. Carefully lift and remove the cover.

3



Take a look at your new cover and the snap-on connection (marked). The cover should be affixed in two steps.

4

It is important to snap the cover in place in two steps as shown. First press together on the side far away from the battery compartment, and then on the battery compartment side.

NOTE:
If applied correctly, the cover snaps into place easily. Do not apply undue force.

NOTE:
The battery does not have to be removed to change the cover.

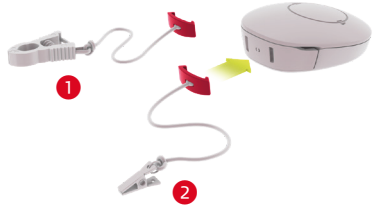
Using the attachment clips

Attachment clips are provided for additional fixation of the audio processor to your hair or clothes. Secured fixation may be desirable for example during sports activities or for children.

PARENTAL GUIDANCE

Especially for children it is recommended to use the attachment clip in situations with a risk of the device falling off.

Additional fixation of the SAMBA 2 with the attachment clip for clothes (1) or the hair (2).



NOTE:
Close the battery compartment and hold the battery compartment closed before you remove the attachment clip from the audio processor.

Maintenance

Your audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time.

Other than replacing the battery there are no serviceable features on the audio processor. If your device does not work properly, check the section **Troubleshooting**. If you cannot solve the problem following the recommended actions in the troubleshooting section, please return to your audiologist/healthcare professional for advice.

Please have your audio processor checked by your audiologist/healthcare professional at least every two years.

Cleaning

It is recommended to clean the audio processor weekly or when necessary. The housing of the audio processor features moisture and dust protection and may be cleaned on the outside with a damp cloth and mild soap or soft baby wipes. Do not clean the audio processor in or under water to prevent water from entering.

CAUTION
The audio processor is not waterproof.

Storage, handling and disposal

Store the audio processor in a dry place and protect it from direct sunlight, e.g. by using the daily case provided. Always remove the battery if you do not use the audio processor for a long period of time to avoid battery leakage and possible damage to the audio processor.

If you live in a humid climate or perspire heavily, it is recommended to use a drying kit for storage (sold separately).

The audio processor must not be disposed of with household waste. You are responsible for disposing the audio processor by returning it to MED-EL or your local MED-EL representative.

Compatibility with optional user accessories

- The SAMBA 2 Remote is an optional mobile application (app) which can assist with switching between simple audio processor settings, as predefined by your audiologist/healthcare professional. The SAMBA 2 Remote app can be downloaded separately.
- SAMBA 2 GO is an optional assistive streaming device which can be used to stream sound from your mobile device or TV. Additionally, it can assist with switching between simple audio processor settings, as predefined by your audiologist/healthcare professional. SAMBA 2 GO is available separately.

5. Troubleshooting

Problem	Possible cause	Recommended action
No sound	No battery inserted	Insert a new battery (see section **Changing the battery**).
	Battery empty	
	Foil covering the battery still in place	Remove the foil covering the battery (see section **Changing the battery**).
	Battery inserted upside down	Check for correct battery position (check polarity, flat side (+) must be on top) (see section **Changing the battery**).
	Microphone openings or membranes clogged	1. Change the cover (see section **Changing the cover**). 2. Contact your audiologist/healthcare professional if the problem persists. Your audiologist/healthcare professional can remove any dirt/obstructions from the microphone openings or membranes.
	Loss of electrical connection due to soiled battery contacts	Remove the cover (see section **Changing the cover**), check visible battery contacts and carefully clean if necessary. Use a cotton swab and a small amount of cleaning alcohol. Gently wipe dry after cleaning.
	No air flow to battery	1. Wait one or two minutes between removing the protective film of the battery and inserting the battery into your audio processor (to make sure the zinc-air battery has been sufficiently subjected to air). 2. Check the battery compartment if the air vents are clogged and remove dirt/obstructions. 3. If you cannot solve the problem yourself, contact your audiologist/healthcare professional.
	Device damaged (e.g. by moisture/shock)	Contact your audiologist/healthcare professional.
	Device turned off unknowingly	Turn on the audio processor (see section **Switching SAMBA 2 on/off**).
Sound weak	Battery low	Insert a new battery (see section **Changing the battery**).
	Microphone openings or membranes clogged	1. Change the cover (see section **Changing the cover**). 2. Contact your audiologist/healthcare professional if the problem persists. Your audiologist/healthcare professional can remove any dirt/obstructions from the microphone openings or membranes.
	Incorrect position of audio processor	Adjust the orientation of the audio processor on your implant (see figures in section **Placing SAMBA 2 over the implant**).
	Volume is turned too low	1. Open and close the battery compartment to reset the audio processor to the default program and volume. 2. The optional SAMBA 2 Remote app or the SAMBA 2 GO streaming device could be used to adjust predefined volume or program settings. 3. If you cannot solve the problem yourself, contact your audiologist/healthcare professional to have the volume settings adapted to your needs.

Problem	Possible cause	Recommended action
Sound too loud	Volume is turned too high	1. Open and close the battery compartment to reset the audio processor to the default program and volume. 2. The optional SAMBA 2 Remote app or the SAMBA 2 GO streaming device could be used to adjust predefined volume or program settings. 3. If you cannot turn down the volume, stop using the audio processor and contact your audiologist/healthcare professional to have the volume settings adapted to your needs.
	Fitting program needs adjustment	Contact your audiologist/healthcare professional to have the volume settings adapted to your needs.
Audio processor cannot be switched on	Battery compartment blocked	1. Check for correct battery position (check polarity, flat side (+) must be on top) (see section **Changing the battery**). 2. Carefully push down the battery when closing the battery compartment (see section **Changing the battery**). 3. If you cannot solve the problem yourself, contact your audiologist/healthcare professional.
Battery insertion not possible	Wrong battery type	Only use 675 zinc-air batteries (PR44 batteries).
	Battery upside down	Check for correct battery position (check polarity, flat side (+) must be on top) (see section **Changing the battery**).
Audio processor falls off frequently	Hair over implant too thick	Thin out your hair over the implant or, in rare cases, shave your hair directly under the audio processor to about 6 mm (¼ in).
	Magnet too weak	Contact your audiologist/healthcare professional.
Skin irritation over implant	Attachment force too high	Contact your audiologist/healthcare professional.
	Allergic reaction	Stop wearing your audio processor and contact your audiologist/healthcare professional. Check for materials of the implant system in tissue contact (see section **Miscellaneous**).
Program selection not possible	Only one program activated	Contact your audiologist/healthcare professional.
	Electrical problems	If all other program selection options listed in this table fail, contact your audiologist/healthcare professional.
SAMBA 2 Remote app not working	SAMBA 2 Remote app does not start	1. Restart your mobile device. 2. Make sure your SAMBA 2 Remote app is up to date. 3. Delete the SAMBA 2 Remote app. 4. Connect to the internet and perform a reinstallation. 5. Contact your audiologist/healthcare professional if the problem persists.
	Distance between audio processor and mobile device exceeds operating distance	1. Bring the mobile device closer to the audio processor. 2. Check broadcast level and select a higher level. 3. Contact your audiologist/healthcare professional if the problem persists.
	SAMBA 2 Remote app not available in some countries	Contact your audiologist/healthcare professional.

Problem	Possible cause	Recommended action
Another remote control affects your audio processor	Interference	Contact your audiologist/healthcare professional.
Unusual sounds, unexpected audible sensations	Signal interference with other equipment (e.g. with hand-held computers, mobile telephones, WLAN routers, theft and metal detection systems)	1. Move away from any possible source of interference. In case you are in an area where theft and metal detection systems are used (e.g. security check-points), temporarily remove the audio processor. 2. Contact your audiologist/healthcare professional if the problem persists.

CAUTION

- Never try to open or repair the audio processor yourself.
- Always contact your audiologist/healthcare professional if the audio processor is damaged or a problem persists after trying the recommended actions described in the section **Troubleshooting**.

6. Audiologist/healthcare professional information

CAUTION

This section is intended for audiologists/healthcare professionals and other professionals like hearing aid programmers.

If your client refuses to wear the audio processor or indicates uncomfortable hearing sensations, immediately remove and turn off the audio processor and check the system.

Do not hesitate to contact your MED-EL representative for any information not provided in these instructions for use.

Supplementary equipment to program and handle the SAMBA 2

The equipment shall consist of:

- SYMFIT 8.0 or higher (programming software provided by MED-EL)
- Magnets of different strengths (provided by MED-EL)
- Magnet exchange tool (provided by MED-EL)
- One of the following compatible interface boxes:
  - HI-PRO box (hearing aid programmer from Otometrics A/S, recommended: HI-PRO 2)
  - NOAHlink device (hearing aid programmer from HIMSA)
  - ConnexxLink device (wireless programmer)

Additional equipment needed for wired programming:

- Programming Cable CS64 and Battery Pill 675 (provided by MED-EL)

Information and recommended training

Audiologists/healthcare professionals should be experienced in the fitting of hearing aids and the application of standard audiological tests and measures. It is recommended that audiologists/healthcare professionals receive specific training regarding the evaluation of candidates and the fitting of the Bonebridge system in adults as well as in children.

Supplementary equipment to be connected to the audio processor for fitting by the audiologist/healthcare professional, the programming cable and the battery pill (both available separately) must be compliant with Type BF of the electrical safety standard IEC 60601-1/ EN 60601-1, indicated by the symbol  . Anyone who connects additional equipment to the audio processor's programming interface configures a medical system, and is, therefore, responsible that the system complies with the requirements of IEC 60601-1 electrical safety standard. If there are any questions, please consult with MED-EL or the regional representative.

Also refer to section **General information** of these instructions for use and the hearing aid programmer's manual (e.g. HI-PRO, NOAHlink or SYMFIT 8.0 or higher).

Programming the SAMBA 2

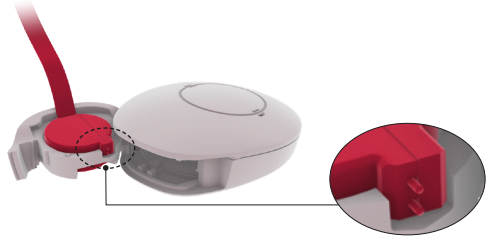
The audio processor can be programmed either wired or wirelessly. The programming software SYMFIT 8.0 or higher is not provided with the audio processor and has to be obtained separately.

CAUTION

Only use the Battery Pill 675 and the Programming Cable CS64 provided by MED-EL for wired programming.
Using other battery pills and programming cables may result in increased electromagnetic emissions or decreased immunity of the audio processor.

Instructions for wired programming

- Open the battery compartment and remove the battery.
- Insert the battery pill into the battery compartment as shown in the figure below.



- Close the battery compartment. Do not force the battery compartment to close, check for the correct position of the battery pill and try again.
- Connect the programming cable to the battery pill.
- Connect the programming cable to the hearing aid programmer.
- Place the audio processor over the implant.
- Program the audio processor. Follow the instructions for use of SYMFIT 8.0 or higher.
- After programming, remove the battery pill from the audio processor.
- Insert a new type 675 zinc-air battery into the audio processor.
- Close the battery compartment.

Instructions for wireless programming

The use of SYMFIT 8.0 or higher is necessary for wireless programming of the audio processor. Follow the instructions for use of SYMFIT 8.0 or higher.

Changing the magnet

The number of dots on the magnet, from one to six, indicates the magnet strength. The magnet strength chosen should be appropriate for the individual user, e.g. weak magnets are indicated for users with thin skin flaps (e.g. children), to reduce the likelihood of skin irritation.

To change the magnet, follow these steps:

1

Turn device upside down.

2

Place magnet exchange tool on magnet.

3

Turn counterclockwise to unlock.

4

Take out magnet.

5

Select new magnet (e.g. one dot = weakest strength).

6

Place new magnet on magnet exchange tool.

7

Insert new magnet.

8

Turn clockwise to lock.

9

Remove magnet exchange tool.

Advanced troubleshooting for the audiologist/healthcare professional

Problem	Possible cause	Recommended action
No sound or sound too weak	Microphone openings or membranes clogged	1. Remove dirt/obstructions if possible and perform a sound check. 2. Change the cover (see section **Changing the cover**) and perform a sound check. 3. Contact your MED-EL representative if the problem persists.
Sound too loud	Fitting program needs adjustment, user-adjustable range of volume settings too wide	Stop client from using the audio processor. 1. Adapt the characteristics of the affected program or adapt the range for volume change by the user (see instructions for use of SYMFIT 8.0 or higher) and perform a sound check. 2. Contact your MED-EL representative if the problem persists.
Audio processor falls off frequently	Magnet too weak	Exchange the magnet for a stronger version (see section **Changing the magnet**).
Skin irritation over implant	Attachment force too high	Exchange the magnet for a weaker version (see section **Changing the magnet**).
Program selection not possible	Only one program activated	Check the program characteristics via SYMFIT 8.0 or higher.
	Electrical problems	Contact your MED-EL representative.
Insertion of battery pill not possible	Battery pill not inserted correctly	Position the two golden contact pins of the battery pill in the recess of the battery compartment before closing the battery compartment (see section **Programming the SAMBA 2**).
	Programming contacts blocked/dirty/corroded	1. Remove dirt/obstructions. 2. Contact your MED-EL representative if the problem persists.
Connection of Programming Cable CS64 to Battery Pill 675 not possible	Contacts dirty/corroded	1. Remove dirt/obstructions in CS64 socket. 2. Clean contacts of the battery pill. 3. Contact your MED-EL representative if the problem persists.
Device failure during/after programming	Intermittence during programming	1. Reprogram the audio processor via SYMFIT 8.0 or higher. 2. Contact your MED-EL representative if the problem persists.
SAMBA 2 Remote app not working	SAMBA 2 Remote app does not start	1. Instruct the user to restart the mobile device. 2. Instruct the user to make sure the SAMBA 2 Remote app is up to date. 3. Instruct the user to bring the device closer to the audio processor. 4. Instruct the user to delete the SAMBA 2 Remote app and to perform a reinstallation. 5. Contact your MED-EL representative if the problem persists.

Problem	Possible cause	Recommended action
SAMBA 2 Remote app not available for mobile device of user's choice	Incompatible operating system	The SAMBA 2 Remote app cannot be used with operating systems other than Android and iOS. The system requirements of the SAMBA 2 Remote app can be found in the app store.
	SAMBA 2 Remote app not available in some countries	Contact your MED-EL representative for specific information or information about other options.
Audio processor is damaged	Various causes	Contact your MED-EL representative if you cannot solve the problem.
A problem persists after trying the recommended actions described in the troubleshooting sections		

7. Warnings and precautions

Carefully read the following section. If you have any questions, consult the surgeon who performed your implant surgery.

Always inform any physician you are visiting for medical treatment that you have a Bonebridge implanted. This knowledge may affect your treatment.

Warnings

The device must not be altered and may only be used as intended!

Electromagnetic compatibility (EMC)

The audio processor is EMC-tested in conformity with the requirements of IEC 60601-1-2:2014 4th edition. Refer to section **Technical data** for detailed compliance information.

The Bonebridge system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these instructions for use.

WARNING

Portable Radio Frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the audio processor, including cables specified by MED-EL. Otherwise, degradation of the performance of the audio processor could result.

Mobile RF communications equipment may affect the performance of the audio processor.

Electromagnetic fields produced by other electrical equipment such as cell phones, metal detectors, microwaves, RFID systems and commercial theft detection systems (also known as electronic article surveillance [EAS]) may interfere with your device. In the event that you perceive unexpected noise or interference in the presence of such electrical equipment, remove the external portion of your device and if the noise or interference persists, move away from the source of electromagnetic field. Please note some of these RF emitters (e.g. RFID) might be concealed and not visible. If you experience repeated interference or have further concerns, contact your hearing healthcare professional.

Precautions

General

The audio processor contains complex electronic parts. These parts are durable but must be treated with care. The audio processor must never be disassembled by anyone other than authorized service personnel. The magnet compartment must be opened only by a trained audiologist/healthcare professional. All sound adjustments shall be made only by a qualified audiologist/healthcare professional. Unauthorized disassembly voids the warranty.

If the child/user refuses to wear the audio processor or indicates uncomfortable hearing sensations, remove and turn off the audio processor and have the system checked at the clinic.

Before turning on the audio processor, check for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the audio processor should not be turned on. Read the section **Troubleshooting** or contact your audiologist/healthcare professional.

Head trauma

A blow to the head may damage the implant and result in its failure. Implant recipients are strongly encouraged to use head protection whenever possible during sports and activities in which head trauma is a risk (e.g. bicycling, motorcycling, skiing) and should never participate in sports in which head trauma is part of the activity (e.g. boxing).

Ingestion of small parts

The audio processor contains small parts that may be hazardous if swallowed. Children should be instructed not to swallow or put any components of the implant system into their mouths and not to play with any components.

Use your own audio processor

The audio processor is specifically adjusted for each individual user. Never exchange your audio processor with another implant system user to avoid distorted or uncomfortably loud sounds.

Water damage

Protect the audio processor from damage through water. Never bathe or shower while wearing the audio processor. The use of a drying kit (not provided with your device) in high humidity or moist conditions is also recommended.

If the audio processor gets wet, turn it off, remove the battery and gently wipe the outside dry, using a soft absorbent cloth. Then allow the audio processor to dry out (preferably overnight). If in doubt, repeat the drying process.

If the humidity problem persists, return the audio processor to your audiologist/healthcare professional for repair or replacement.

Dirt damage

Avoid getting sand or dirt into any part of the audio processor. If the audio processor is not working, try the actions recommended in the section **Troubleshooting**.

If the problem persists, return the audio processor to your audiologist/healthcare professional for repair or replacement.

Range of benefits

The implant system does not restore normal hearing and benefits may vary from one user to another. The correlation between the degree of benefit obtained from an implant and the cause or degree of hearing impairment has not yet been evaluated. There are no definitive tests that can be administered prior to implantation to estimate the degree of benefit a user may receive.

Possible adverse events associated with Bonebridge surgery

The following are known to be possible adverse events associated with major ear surgery: Implant patients are exposed to the usual risks of otologic surgery and general anesthesia, which include, but are not limited to, local skin numbness or pain, infection, transient tinnitus, vertigo or headache, dural erosion/compression, CSF leak, bleeding/hematoma from injury to sigmoid sinus, subdural hematoma, and facial nerve injury. If these occur, they are usually transient and resolve within a few weeks after the surgery. Please consult your clinic for further information.

Other complications that may occur include: post-surgical displacement of the implant; post-surgical translocation of the BC-FMT due to trauma or incorrect position of the implant and extrusion of the implant.

Interference with other equipment

SAMBA 2 Audio Processor

The SAMBA 2 Audio Processor is intended to be used in the home healthcare environment.

- **Mobile phones, cordless telephones:** The implant system has been tested for wireless device compatibility. Any portable phone can be safely used with the SAMBA 2; with certain models audio quality may be compromised.
- **Wireless LAN (WLAN) and other radio frequency transmitters:** To avoid interferences, a distance of 30 cm (12 in) to transmitters shall be observed.
- **Wireless charging pads:** To avoid audible interference, keep a minimum distance of 30 cm (12 in) from wireless charging pads.
- **Other electronic equipment:** The audio processor uses radio frequency only for its internal function. Therefore, its radio frequency emissions are very low and are not likely to cause any interference in nearby electronic equipment. The SAMBA 2 is suitable for use in all establishments.
- **Theft and metal detection systems:** Commercial theft detection systems and metal detectors produce strong electromagnetic fields. Users with an implant should be advised that passing through security metal detectors may activate the detector alarm. For this reason, it is advised that users carry their User Identification Card at all times.
- **RFID:** Certain RFID readers can cause audible interference, resulting in buzzing sound and reduced sound quality. To improve sound quality in such an environment, move away from the RFID reader.
- **Ionizing radiation therapy:** It is recommended not to wear an audio processor during irradiation.
- **Magnetic resonance imaging (MRI) safety information:**

The external components of the MED-EL implant system (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.

Bone Conduction Implant (BCI 601 or BCI 602)

- **Electrosurgery:** Electrosurgical instruments (e.g. monopolar electrocautery) can produce radio frequency voltages that might result in direct coupling between the instrument and the implant. Monopolar electrosurgical instruments must not be used within the vicinity of the implant. The induced currents could cause damage to the implant or the patient's hearing.
- **Therapeutic ultrasound, transcranial magnetic stimulation, electroconvulsive therapy:** May never be applied directly over the implant because these procedures may damage the implant or the patient's hearing.

- **Surgical diathermy:** Diathermy must never be applied over the implant because the high currents induced into the implant could cause damage to the implant or the patient's hearing.
- **Ionizing radiation therapy:** Radiation therapy does not harm the implant. It is recommended not to wear an audio processor during irradiation.
- **X-ray, CT, cobalt treatment, PET scan, diagnostic ultrasound:** There is no restriction within clinically useful exposures. It is recommended not to wear an audio processor during these procedures.
- **Cardioversion:** The energy induced during cardioversion could cause damage to the implant. Defibrillation should not be applied on or near the device.
- **Theft and metal detection systems:** Commercial theft detection systems and metal detectors produce strong electromagnetic fields. Patients with an implant should be advised that passing through security metal detectors may generate harmless audible sensations and may activate the detector alarm. For this reason, it is advised that patients carry their User Identification Card at all times.
- **Magnetic resonance imaging (MRI) safety information:**

	The external components of the MED-EL implant system (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning.	
	The implant components of the MED-EL implant system are MR Conditional.	

Non-clinical testing has demonstrated that the implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T
- Maximum spatial field gradient of 3000 Gauss/cm (30 T/m) or less
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of <4 W/kg (First Level Operating Mode) during body imaging, or Maximum MR system reported, whole-head averaged specific absorption rate (SAR) of <3.2 W/kg (Normal and First Level Operating Mode) during head imaging
- The external components of the Bonebridge system are MR Unsafe and must be removed prior to scanning.

Under the scan conditions defined above, the implant is expected to produce a maximum temperature rise of less than 4 °C (7.2 °F) after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends approximately 15 cm (6 in) from the geometrical center of the implant when imaged with a gradient echo pulse sequence in a 1.5 T MRI system.
The implant has not been tested for safety in combination with other devices.

The audio processor shall not be worn during an MRI examination; however, it is still possible that audible interference can occur. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with a lower SAR and slower gradient slew rates.
The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first.
Scanning under different conditions may result in severe patient injury or device malfunction.

Initial activation

The patient should return for medical clearance and initial activation of the audio processor after the swelling of the skin flap has reduced.

8. Clinical summary

The sections below provide a summary of the clinical studies conducted for the BCI 601 (predicate device): BB001, BB002 and BB003.

NOTE:
The subject audio processor, your SAMBA 2, was not used for these Bonebridge studies. The following clinical data was collected using the predicate audio processor, the Samba.

- **BB001:** multi-center, non-randomized, non-blinded, repeated-measures clinical study of 12 adults and 12 children to demonstrate long-term safety and effectiveness of the MED-EL Bonebridge system in conductive and mixed hearing losses (CHL, MHL).
- **BB002:** multi-center, non-randomized, non-blinded, repeated-measures clinical study of 45 adults and 8 children to demonstrate long-term safety and effectiveness of the MED-EL Bonebridge system in conductive and mixed hearing losses (CHL, MHL).
- **BB003:** multi-center, non-randomized, non-blinded, repeated-measures clinical study of 13 adults to demonstrate the clinical benefit of the Bonebridge in single-sided deafness (SSD) on the long-term scale up to at least 13 months after surgery.

Prospective clinical study: Bonebridge in CHL & MHL (BB001)

The purpose of this multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the long-term safety and effectiveness of the MED-EL Bonebridge system in conductive and mixed hearing losses (CHL, MHL).

Six tests were evaluated in order to determine safety and effectiveness of the MED-EL Bonebridge system pre-operatively and one and three months post-operatively:

Word recognition score	(WRS; Freiburger Monosyllables)
Speech reception threshold	(SRT; OLSA)
Warble tones	(WT)
Bone conduction	(BC)
Air conduction	(AC)
Hearing device satisfaction scale	(HDSS)

In total, 24 subjects (12 adult and 12 pediatric subjects) were enrolled in the study. The data presented here covers all 24 subjects who had reached the final three-month post-operative evaluation at the time of data analysis. Subjects were fitted approximately one month post-operatively with the audio processor.

Primary study endpoint

The primary effectiveness endpoint was the improvement in speech perception in the post-activation aided condition compared to the pre-operatively unaided condition. A change of at least 15 % in the word recognition scores (Freiburger monosyllables) was considered clinically significant.

Secondary study endpoints

The first secondary effectiveness endpoint was an improvement in the speech reception threshold (Oldenburger sentence test: OLSA). For this analysis, an improvement of 15 dB SPL in OLSA was considered clinically significant.

The second secondary effectiveness endpoint was the improvement in sound perception (WT) in the post-activation aided condition compared to the pre-operative unaided condition for audiometric test frequencies 0.5 to 8 kHz. A more than 10 dB improvement (functional gain) at one or more test frequencies was considered significant.

The secondary safety endpoints were stable hearing thresholds for bone conduction characterized by no difference between pre- and post-operative bone conduction thresholds for audiometric test frequencies from 0.5 to 4 kHz. A decrease of 5 dB or less at a particular frequency is within test-retest reliability and was not considered clinically significant.

Safety was further evaluated by tabulations of all adverse events (AEs) and serious adverse events (SAEs). Safety data was collected on all implanted subjects.

Subjective device satisfaction and benefit was determined by the HDSS questionnaire.

The HDSS (German language version) consists of 21 categories and is scored using the Likert[1]- scale. Items are presented in a phrase related to an aspect of hearing implant use. The rate of satisfaction for each question category is calculated and summarized using descriptive statistics.

1 Likert (1932-1933). "A technique for the measurement of attitudes." Archives of Psychology Vol 22 (No. 140): 5-55.

Inclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

General inclusion criteria:

a. Geographically and physically able to return to the investigational center for scheduled evaluations and follow-up appointments
b. Fluency in the language used in the investigational center and used for evaluation
c. No prior or current use of an active middle ear hearing implant or bone anchored hearing aid in either ear
d. Persons who, after being informed that a different acoustic hearing aid than the one they currently have may provide improved hearing, still request an implant
e. The AC thresholds in the non-implanted ear should not be severely-to-profoundly impaired (for masking reasons)
f. Absence of non-revisable, chronic tinnitus, episodic tinnitus may be considered in some cases but must be discussed with the sponsor prior to enrollment
g. Stable inner ear function and absence of episodic hearing fluctuation(s)

Adult: Persons aged 18 years or over:

h. Persons who are psychologically and emotionally stable with realistic expectations of the benefits and limitations of the Bonebridge
i. The physician must fully assess the potential risks and benefits for the patient prior to the decision to implant the Bonebridge. The physician must exercise medical judgment and consider the patient's complete medical history.

Pediatric: Persons aged five to seventeen years:

j. Persons who are psychologically and emotionally stable with realistic expectations of the benefits and limitations of the Bonebridge
k. Attempts shall have been made to be appropriately fit with a hearing aid within 36 months prior to enrollment or shall not be able to wear a hearing aid for medical reasons
l. All audiometric evaluations should be indicative of a conductive or mixed hearing loss
m. Stable inner ear function and absence of episodic hearing fluctuation(s)

Audiological/medical inclusion criteria:

n. Presence of a conductive or mixed hearing loss as indicated by audiometric testing. That is, presence of an air-bone gap of at least 10 dB at three or more of the frequencies 0.5, 1, 2, 3 and 4 kHz.
o. Pure-tone bone conduction threshold levels at or within the levels stated in Table 1.

Frequency (kHz)	0.5	1.0	2.0	3.0	4.0
BC upper limit (dB HL)	45	45	45	45	45

Table 1: Indication range upper limits (dB HL) of bone conduction thresholds as a function of frequency for persons with conductive or mixed hearing loss

Exclusion criteria

Subjects were excluded from the study for any of the following reasons:

a. Chronic or non-revisable vestibular or balance disorders
b. Abnormally progressive hearing loss
c. Chronic pain in or about the head
d. Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment

The following exclusion criteria apply for all subjects:

e. Evidence that hearing loss is of retrocochlear or central origin
f. Non-responsive ear infection that could impair success with a bone conduction device
g. Skin or scalp conditions that may preclude attachment of the audio processor or that may interfere with the use of the audio processor
h. Skull size or abnormality that would preclude appropriate placement of the Bonebridge implant as determined by CT scan
i. Persons not able to undergo general or local anesthesia

Description of tests

Speech perception testing

The following tests were conducted in a sound field with the speaker at 0° azimuth and 1m away from and at level with the subject's head in a sound-attenuated room.

1. **Word recognition score**
   Open-set, monosyllabic words were tested using the Freiburger monosyllables word recognition test. Testing was completed in quiet at 65 dB SPL in the sound field and results were reported in percent correctly understood words.

2. **Speech reception threshold**
   Open-set sentences were tested using the OLSA. The OLSA was administered and the speech level in dB SPL for 50 % correct recognition was determined. This test was performed in quiet.

Audiometric tests (sound field)

The following test was conducted in a sound field with the speaker at 0° azimuth and 1m away from and at level with the subject's head in a sound-attenuated room.

Warble Tones (WT)
WT were applied in the sound field and thresholds were measured using a standard bracketing procedure at 0.5, 1, 2, 3, 4, 6 and 8 kHz.

Audiometric tests (basic test battery)

The following tests were conducted on each ear individually:

Bone conduction (BC)

BC was tested by pure tones applied via a bone conduction vibrator at the mastoid and thresholds were measured using a standard bracketing procedure at 0.5, 1, 2, 3 and 4 kHz.

Air conduction (AC)

AC was tested by pure tones applied using insert earphones or traditional headphones and thresholds were measured using a standard bracketing procedure at 0.5, 1, 2, 3, 4, 6 and 8 kHz.

Device satisfaction & benefit

Hearing device satisfaction scale

Subjective device satisfaction was tested by means of the hearing device satisfaction scale (HDSS)/hearing device satisfaction scale – parent (HDSS-P, for parents of implantees), a self-assessment questionnaire. HDSS measures parameters such as comfort, handling, and changes in quality of life. The HDSS consists of 21 questions/categories regarding the subjective device satisfaction with response options transformed into a percentage ranging from very satisfied (100 %), satisfied (75 %), sometimes satisfied/dissatisfied (50 %), dissatisfied (25 %), to very dissatisfied (0 %) based on the answers given.

Clinical trial results

The table below provides details on the number of subjects for each interval completed.

# of subjects	Total
Pre-operative	12 adult and 12 pediatric
1 month post-operative (initial activation)	12 adult and 12 pediatric
3 months post-operative	12 adult and 12 pediatric

Demographics

The table below provides information on subject demographics, including gender, age at implantation, average of previous ear surgeries and number of subjects with previous ear surgeries.

Parameter/category or statistic	Total (N = 24)	Adult (N = 12)	Pediatric (N = 12)
Gender			
Male %	29.17% (N = 7)	25% (N = 3)	33.3% (N = 4)
Female %	70.83% (N = 17)	75% (N = 9)	66.7% (N = 8)
Age (years) mean (min – max)	28 (5 - 69)	44 (19 - 69)	11 (5 - 17)
Implant side			
Left %	29.2% (N = 7)	25% (N = 3)	33.3% (N = 4)
Right %	70.8% (N = 17)	75% (N = 9)	66.7% (N = 8)
Previous ear surgeries			
Average surgeries per subject	1.3	2.1	One pediatric subject was previously operated with 5 previous ear surgeries.
Previously operated subjects	50% (N = 12)	91.7% (N = 11)	

Parameter/category or statistic	Total (N = 24)		Adult (N = 12)		Pediatric (N = 12)	
Disease etiology	%	N	%	N	%	N
Cholesteatoma	16.67	4	33.33	4	0.00	0
Atresia auris	41.67	10	25.00	3	58.33	7
COM	12.5	3	16.67	2	8.33	1
Chron. mastoiditis	4.17	1	8.33	1	0.00	0
Otosclerosis	4.17	1	8.33	1	0.00	0
Microtia	8.33	2	0.00	0	16.67	2
Ear canal stenosis	4.17	1	0.00	0	8.33	1
Anotia	4.17	1	0.00	0	8.33	1
Glomus tumor	4.17	1	8.33	1	0.00	0

Speech perception result (primary endpoint effectiveness)

For the primary endpoint of improvement on Freiburger monosyllabic words in quiet the average unaided pre-operative word recognition score correct was 14.55 % (±21.62 %) for pediatric and 14.17 % (±18.07 %) for adult subjects. Three months post-operative, in the Bonebridge-aided condition, subjects' mean word recognition score correct was 82.08 % (±12.5 %) for pediatrics and 92.92 % (±6.89 %) for adults. Statistical analysis revealed a significant improvement in WRS in the Bonebridge-aided condition for pediatric and adult subjects, as compared to the pre-operatively unaided condition. At the three-month appointment 100 % of all adult and pediatric subjects showed an improvement in word recognition score.

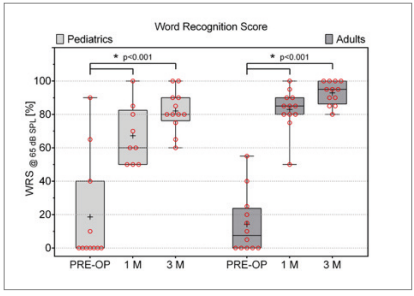


Figure 1: Word recognition scores for pediatrics and adults. Box plots: median = horizontal lines; + = mean; ANOVA alpha level: 0.05; * = significance; red circles depict distribution of individual values. Pre-op = pre-operative, 1M = one month post-operative, 3M = three months post-operative.

Freiburger	Pediatric (N = 12)			Adult (N = 12)		
word recognition score	Score [%]	Std.	N	Score [%]	Std.	N
pre-operative	14.55	21.62	11	14.17	18.07	12
1 month post-operative	67.22	17.87	9	82.92	12.52	12
3 months post-operative	82.08	12.15	12	92.92	6.89	12

WRS in % of subjects BETTER, EQUAL or WORSE pediatric Pre-operative vs.:	BETTER	EQUAL	WORSE
1 month post-operative	100.00 %	0.00 %	0.00 %
3 months post-operative	100.00 %	0.00 %	0.00 %

WRS in % of subjects BETTER, EQUAL or WORSE adult Pre-operative vs.:	BETTER	EQUAL	WORSE
1 month post-operative	100.00 %	0.00 %	0.00 %
3 months post-operative	100.00 %	0.00 %	0.00 %

Speech perception result (secondary endpoint effectiveness)

Additionally, improvement in speech understanding in quiet was assessed with OLSA speech reception threshold sentences in quiet. Pediatric subjects improved from mean 72.70 dB SPL (±5.94 dB SPL) pre-operatively unaided to mean 45.18 dB SPL (±6.95 dB SPL) three months post-operatively aided with the Bonebridge. Adult subjects improved from mean 61.97 dB SPL (±8.61 dB SPL) pre-operatively unaided to mean 36.58 dB SPL (±8.77 dB SPL) three months post-operatively aided with the Bonebridge.

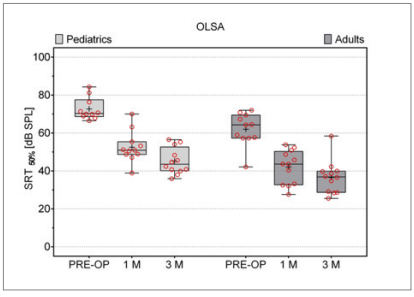


Figure 2: Speech reception thresholds for pediatric and adult subjects. Box plots: median = horizontal lines; + = mean; red circles depict distribution of individual values. Pre-op = pre-operative, 1M = one month post-operative, 3M = three months post-operative

OLSA	Pediatric (N = 12)			Adult (N = 12)		
Speech Reception Threshold	dB SPL	Std.	N	dB SPL	Std.	N
pre-operative	72.70	5.94	10	61.97	8.61	11
1 month post-operative	52.55	8.24	11	42.05	8.87	12
3 months post-operative	45.18	6.95	12	36.58	8.77	12

100 % of all pediatric and 90.91 % of all adult subjects showed a speech improvement three months post-operatively.

SRT in % of subjects BETTER, EQUAL or WORSE pediatric Pre-operative vs.:	BETTER	EQUAL	WORSE
1 month post-operative	90.00 %	10.00 %	0.00 %
3 months post-operative	100.00 %	0.00 %	0.00 %

SRT in % of subjects BETTER, EQUAL or WORSE adult Pre-operative vs.:	BETTER	EQUAL	WORSE
1 month post-operative	100.00 %	0.00 %	0.00 %
3 months post-operative	90.91%	0.00 %	9.09 %

Audiometric results sound field (secondary endpoint effectiveness)

Pediatric subjects improved from mean 55.95 dB SPL (±3.04 dB SPL) pre-operatively unaided to mean 28.99 dB SPL (±3.97 dB SPL) three months post-operatively aided with the Bonebridge. Adult subjects improved from mean 57.98 dB SPL (±3.07 dB SPL) pre-operatively unaided to mean 33.33 dB SPL (±3.97 dB SPL) three months post-operatively aided with the Bonebridge. All subjects (100 %) showed mean improved functional gains three months post-operatively.

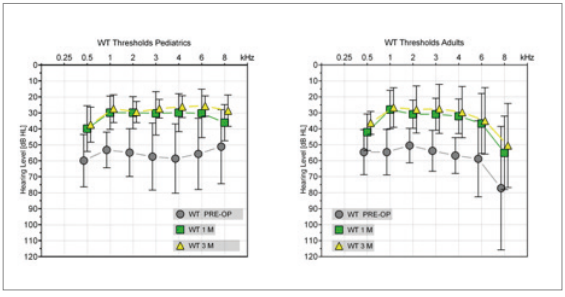


Figure 3: Mean residual warble tone thresholds with standard deviations: pre-operative (dark grey), one (green) and three (yellow) months post-operatively for all pediatric and adult subjects.

WT thresholds	PRE-OP			1 M			3 M		
pediatrics	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
MEAN	55.95	3.07	12	32.44	4.04	12	28.99	3.97	12
0.5 kHz	60.00	16.38	12	40.00	14.30	12	37.50	10.98	12
1 kHz	53.33	11.15	12	30.00	10.45	12	27.50	8.66	12
2 kHz	55.00	14.92	12	30.00	10.00	12	29.58	6.56	12
3 kHz	57.50	20.94	12	30.42	13.56	12	27.50	5.84	12
4 kHz	58.75	21.65	12	30.00	11.87	12	26.25	6.78	12
6 kHz	55.83	22.24	12	30.42	15.15	12	25.83	6.34	12
8 kHz	51.25	23.17	12	36.25	11.31	12	28.75	9.80	12

WT thresholds	PRE-OP			1 M			3 M		
adults	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
MEAN	57.98	3.07	12	36.49	4.04	12	33.33	3.97	12
0.5 kHz	54.58	14.05	12	42.08	11.37	12	36.25	7.11	12
1 kHz	54.58	14.22	12	27.92	11.96	12	26.67	12.31	12
2 kHz	50.42	10.76	12	30.83	8.75	12	27.92	14.69	12
3 kHz	53.75	12.81	12	30.83	9.96	12	27.50	15.30	12
4 kHz	56.67	11.15	12	32.08	10.76	12	29.58	16.02	12
6 kHz	58.75	23.75	12	36.67	18.75	12	35.00	20.78	12
8 kHz	77.08	38.58	12	55.00	22.96	12	50.42	26.24	12

Audiometric results basic test battery (secondary endpoint safety)

The secondary endpoint of unchanged residual hearing was measured by unaided audiologic thresholds from pre-operatively unaided to the three-month post-operative endpoint. The results of descriptive analyses of BC and AC thresholds presented below show that Bonebridge treatment had no effect on residual hearing.

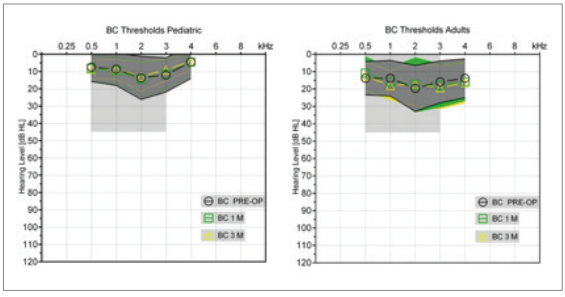


Figure 4: Mean residual bone conduction thresholds and area of standard deviation: pre-operative (dark grey), one (green) and three (yellow) months post-operatively for all pediatric and adult subjects. The rectangular area (light grey) depicts the indication range of 45 dB HL pre-operatively.

Bone conduction thresholds	PRE-OP			1 M			3 M		
pediatrics	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
0.5 kHz	7.50	8.39	12	8.33	7.79	12	8.75	5.28	12
1 kHz	8.75	9.32	12	9.58	7.22	12	8.75	5.69	12
2 kHz	13.75	12.45	12	14.58	9.88	12	12.92	8.38	12
3 kHz	12.08	9.88	12	11.67	8.07	12	9.17	6.34	12
4 kHz	4.58	9.64	12	4.58	7.82	12	4.17	4.69	12

Bone conduction thresholds	PRE-OP			1 M			3 M		
adults	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
0.5 kHz	13.75	9.56	12	10.83	9.49	12	12.50	7.83	12
1 kHz	13.75	10.25	12	15.83	8.21	12	17.92	8.38	12
2 kHz	19.58	13.22	12	17.50	15.59	12	17.08	12.52	12
3 kHz	15.83	12.03	12	17.92	12.52	12	19.17	12.22	12
4 kHz	13.75	11.10	12	15.83	10.84	12	16.25	11.70	12

Air conduction thresholds	PRE-OP			1 M			3 M		
pediatrics	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
0.5 kHz	64.58	16.71	12	65.45	16.50	11	65.00	17.71	12
1 kHz	56.25	17.21	12	57.27	16.79	11	61.25	12.99	12
2 kHz	56.25	17.73	12	54.09	15.14	11	56.67	12.67	12
3 kHz	57.08	22.20	12	53.18	13.09	11	58.33	11.35	12
4 kHz	55.00	22.76	12	54.55	12.14	11	56.25	15.09	12
6 kHz	63.33	22.90	12	59.09	17.15	11	58.75	14.94	12
8 kHz	61.25	22.58	12	57.73	15.39	11	62.50	14.06	12

Air conduction thresholds	PRE-OP			1 M			3 M		
adults	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
0.5 kHz	63.75	20.24	12	62.50	20.73	12	61.25	19.08	12
1 kHz	60.83	19.17	12	57.50	19.60	12	59.58	22.10	12
2 kHz	51.25	19.55	12	48.75	18.60	12	50.42	17.77	12
3 kHz	55.83	15.50	12	56.25	15.09	12	52.08	21.37	12
4 kHz	58.75	14.79	12	59.58	9.64	12	54.58	19.48	12
6 kHz	66.82	16.32	11	68.33	18.26	12	66.67	27.33	12
8 kHz	65.00	21.21	9	60.00	14.36	9	56.25	20.83	8

Twelve months post-operatively 8 % of the pediatric and 25 % of the adult subjects experienced decreases at one or more bone conduction frequencies greater than 10 dB HL and 25 % of the subjects experienced decreases at one or more air conduction frequencies greater than 10 dB HL.

Percentage of pediatric subjects with post-operative decreases at one or more frequencies greater than 10 dB HL

	BC		AC	
1 month post-operative	25 %	3/12 N	18 %	2/11 N
3 months post-operative	8 %	1/12 N	25 %	7/12 N

Percentage of adult subjects with post-operative decreases at one or more frequencies greater than 10 dB HL

	BC		AC	
1 month post-operative	8 %	1/12 N	33 %	4/12 N
3 months post-operative	25 %	3/12 N	25 %	3/12 N

Subjective device satisfaction (secondary endpoints)

On average, pediatric and adult subjects were satisfied to very satisfied three months after the Bonebridge treatment. Only one adult subject was sometimes satisfied/dissatisfied with the device at the three-month evaluation time point.

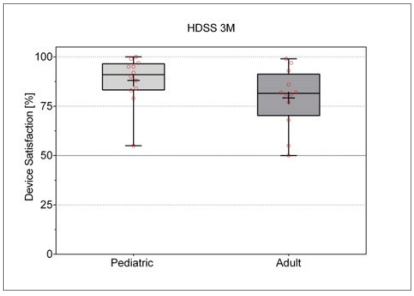


Figure 5: HDSS mean overall satisfaction three months post-operatively for pediatric and adult subjects. Box plots: median = horizontal lines; + = mean: 100 % = very satisfied, 75 % = satisfied, 50 % = sometimes satisfied/ dissatisfied, 25 % = dissatisfied, 0 % = very dissatisfied

HDSS	Pediatric (N = 12)			Adult (N = 12)		
Overall device satisfaction	Score [%]	Std.	N	Score [%]	Std.	N
3 months post-operative	88	12.38	12	79	15.45	12

HDSS in % of subjects BETTER, EQUAL or WORSE Pre-operative vs.:	BETTER	EQUAL	WORSE
Pediatric	100 %	0.00 %	0.00 %
Adult	91.67 %	8.33 %	0.00 %

Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as non-serious/serious, device/procedure-related or unrelated. A total of 5 adverse events occurring in 5 subjects were reported as related to either the device or the procedure.

No serious adverse event related to the procedure or the device was reported during the course of the BB001 study.

Details on the type and number of device- and procedure-related adverse events can be found in the table below:

Events reported as device- or procedure-related for 24 subjects during BB001 study	No. of events	Pediatric adult	% of subjects	% resolved
Itching at the implant side	1	Pediatric	4.2 %	100 %
Skin infection at the implant side	1	Adult	4.2 %	100 %
Post-operative subcutaneous seroma	1	Adult	4.2 %	100 %
Vertigo	1	Adult	4.2 %	100 %
Tinnitus	1	Adult	4.2 %	100 %

Prospective post-market clinical study: Bonebridge in CHL & MHL (BB002)

The purpose of this multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the long-term safety and effectiveness of the MED-EL Bonebridge system in conductive and mixed hearing losses (CHL, MHL).

Six tests were evaluated in order to determine safety and effectiveness of the MED-EL Bonebridge system pre-operatively and one, three and twelve months post-operatively:

Word recognition score	(WRS; Freiburger Monosyllables)
Speech reception threshold	(SRT; OLSA)
Warble tones	(WT)
Bone conduction	(BC)
Air conduction	(AC)
Hearing device satisfaction scale	(HDSS)

In total, 57 subjects were enrolled in the study. The data presented here covers all 53 subjects who had reached the twelve-month post-operative evaluation at the time of data analysis. Subjects were fitted approximately one month post-operatively with the audio processor.

Primary study endpoint

The primary effectiveness endpoint was the improvement in speech perception in the post-activation aided condition compared to the pre-operatively unaided condition. A change of at least 15 % in the word recognition scores (Freiburger monosyllables) was considered clinically significant.

Secondary study endpoints

The first secondary effectiveness endpoint was an improvement in the speech reception threshold (OLSA). For this analysis, an improvement of 15 dB SPL in OLSA was considered clinically significant.

The second secondary effectiveness endpoint was the improvement in sound perception (WT) in the post-activation aided condition compared to the pre-operatively unaided condition for audiometric test frequencies from 0.5 to 8 kHz. A more than 10 dB improvement (functional gain) at one or more test frequencies was considered significant.

The secondary safety endpoints were stable hearing thresholds for bone conduction characterized by no difference between pre- and post-operative bone conduction thresholds for audiometric test frequencies from 0.5 to 4 kHz. A decrease of 5 dB or less at a particular frequency is within test-retest reliability and was not considered clinically significant. A decrease of more than 10 dB in subject individual PTA4 (0.5, 1, 2 and 4 kHz) at the twelve-month interval was reported as an adverse event.

Safety was further evaluated by tabulations of all adverse events (AEs) and serious adverse events (SAEs). Safety data was collected on all implanted subjects.

The third secondary endpoint was the subjective hearing device benefit and device satisfaction measured using the HDSS questionnaire.

Inclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

General inclusion criteria:

a. Geographically and physically able to return to the investigational center for scheduled evaluations and follow-up appointments
b. Reasonable travel distance to the study center (arrival, study appointment and departure should be accomplishable within one day)
c. Fluency in the language used in the investigational center and used for evaluation
d. Age 5 or older
e. Psychological and emotional stability with realistic expectations of the benefits and limitations of the Bonebridge
f. Emotional and psychological ability to understand and perform on required study procedures
g. The patient should have tried any means of hearing amplification before (medical and/or audiological feasibility preconditioned)

Audiological/medical inclusion criteria:

h. Feasibility of the reliable testing of target parameters (e.g. proper masking of the contralateral side) as listed in the protocol (WRS, SRT etc.)
i. Presence of a conductive or mixed hearing loss as indicated by audiometric testing. That is, presence of an air-bone gap of at least 10 dB at three or more of the frequencies 0.5, 1, 2 and 3 kHz. All audiometric evaluations should be indicative of a conductive or mixed hearing loss.
j. Pure-tone bone conduction threshold levels at or within the levels stated in Table 2.

Frequency (kHz)	0.5	1.0	2.0	3.0
BC upper limit (dB HL)	45	45	45	45

Table 2: Indication range upper limits (dB HL) of bone conduction thresholds as a function of frequency for persons with conductive or mixed hearing loss

Exclusion criteria

Subjects were excluded from the study for any of the following reasons:

a. Chronic or non-revisable vestibular or balance disorders
b. Abnormally progressive hearing loss
c. Evidence that hearing loss is of retrocochlear or central origin
d. Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment
e. Chronic headache or pain in the head region
f. Non-responsive ear infection that could impair success with a bone conduction device
g. Skin or scalp conditions that may preclude attachment of the audio processor or that may interfere with the use of the audio processor
h. Abnormal skull size or any other abnormality that would preclude appropriate placement of the BCI as determined by CT scan
i. Impossibility to undergo general or local anesthesia
j. Single-sided sensorineural deafness, that is severe to profound sensorineural deafness in one ear while the other ear has normal hearing
k. Pathological conditions causative for inner ear hearing instability (threshold fluctuation) or progressive inner ear hearing loss
l. Allergy or intolerance to one or more of the materials of the device that are in contact with the body
m. In patients bilaterally implanted with the Bonebridge, only one ear needs to be chosen to be tested in the study

Description of tests

Speech perception testing

The following tests were conducted in a sound field with the speaker at 0° azimuth and 1m away from and at level with the subject's head in a sound-attenuated room.

1. **Word recognition score**
   Open-set, monosyllabic words were tested using the Freiburger monosyllables word recognition test. Testing was completed in quiet at 65 dB SPL in the sound field and results were reported as percent correctly understood words.

2. **Speech reception threshold**
   Open-set sentences were tested using the OLSA. The OLSA was administered and the speech level in dB SPL for 50 % correct recognition was determined. This test was performed in quiet.

Audiometric tests (sound field)

The following test was conducted in a sound field with the speaker at 0° azimuth and 1m away from and at level with the subject's head in a sound-attenuated room.

Warble tones (WT)

WT were applied in the sound field and thresholds were measured using a standard bracketing procedure at 0.5, 1, 2, 3, 4, 6 and 8 kHz.

Audiometric tests (basic test battery)

The following tests were conducted on each ear individually.

Bone conduction (BC)

BC was tested by pure tones using a bone conduction vibrator at the mastoid and thresholds were measured using a standard bracketing procedure at 0.5, 1, 2, 3 and 4 kHz.

Air conduction (AC)

AC was tested by pure tones using insert earphones or traditional headphones and thresholds were measured using a standard bracketing procedure at 0.5, 1, 2, 3, 4, 6 and 8 kHz.

Device satisfaction & benefit

Hearing device satisfaction scale

Subjective device satisfaction was tested by means of the hearing device satisfaction scale (HDSS)/hearing device satisfaction scale – parent (HDSS-P, for parents of implantees), a self-assessment questionnaire. HDSS measures parameters such as comfort, handling, and changes in quality of life. The HDSS consists of 21 questions/categories regarding the subjective device satisfaction with response options transformed into a percentage ranging from very satisfied (100 %), satisfied (75 %), sometimes satisfied/dissatisfied (50 %), dissatisfied (25 %), to very dissatisfied (0 %) based on the answers given.

Clinical trial results

Of the 57 total subjects implanted, 53 had reached the twelve-month post-operative time point on the date of analysis. One subject withdrew from the study after implantation; therefore, safety results for 52 subjects and audiometric results for 52 subjects were analyzed. The table below provides details on the number of subjects for each interval completed.

# of subjects	Total
Pre-operative	53
1 month post-operative (initial activation)	52
3 months post-operative	52
12 months post-operative	50

Demographics

The table below provides information on subject demographics, including gender, age at implantation, average of previous ear surgeries and number of subjects with previous ear surgeries.

Parameter/category or statistic	Total (N = 53)	Adult (N = 45)	Pediatric (N = 8)
Gender			
Male %	58.5% (N = 22)	37.7% (N = 17)	62.5% (N = 5)
Female %	41.5% (N = 31)	62.3% (N = 28)	37.5% (N = 3)
Age (years) mean (min – max)	41 (5 – 76) (N = 53)	47 (18 – 76) (N = 45)	11 (5 – 17) (N = 8)
Implant side			
Left %	41.5% (N = 22)	42.2% (N = 19)	37.5% (N = 3)
Right %	58.5% (N = 31)	57.8% (N = 26)	62.5% (N = 5)
Previous ear surgeries			
Average surgeries per subject	3.66	3.61	Only one pediatric subject was previously operated with 5 previous ear surgeries.
Previously operated subjects	60.38% (N = 32)	68.89% (N = 31)	

Parameter/category or statistic	Total (N = 53)		Adult (N = 45)		Pediatric (N =8)	
Disease etiology	%	N	%	N	%	N
Chronic otitis media	30.19	16	28.30	15	1.89	1
Atresia	22.64	12	16.98	9	5.66	3
Cholesteatoma	20.75	11	20.75	11	-	-
Ear dysplasia	7.55	4	5.66	3	1.89	1
Malformation	1.89	1	-	-	1.89	1
Ear dysplasia/Franceschetti syndrome	1.89	1	1.89	1	-	-
Chronic mastoiditis	1.89	1	1.89	1	-	-
Stenosis	1.89	1	1.89	1	-	-
Anomalius bar	1.89	1	1.89	1	-	-
Congenital syndromic malformation	1.89	1	-	-	1.89	1
Otosclerosis	1.89	1	1.89	1	-	-
Glomus tumor	1.89	1	1.89	1	-	-
Osteogenesis imperfecta otosclerosis	1.89	1	1.89	1	-	-
Microtia	1.89	1	-	-	1.89	1

Speech perception result (primary endpoint effectiveness)

For the primary endpoint of improvement on Freiburger monosyllabic words in quiet, the average unaided pre-operative score was 19.57 % (±21.7 %) correct. Twelve months post-operatively, in the Bonebridge-aided condition, subjects' mean score was 82.9 % (±18.1 %) correct. This represents a mean improvement with the Bonebridge of 63.3 %. Statistical analysis revealed a significant improvement in WRS in the Bonebridge-aided condition, as compared to the pre-operatively unaided condition. At the twelve-month appointment 97.78 % showed an improvement in WRS. One subject showed a change in WRS from pre-operative 65 % over 80 % at three months to 60 % at twelve months which recovered at a later appointment to 95 %.

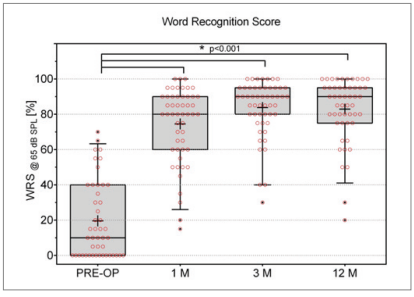


Figure 6: Word recognition scores for all subjects. Box plots: median = horizontal lines; + = mean; ANOVA alpha level: 0.05; * = significance; red circles depict distribution of individual values. Pre-op = pre-operative, 1M = one month post-operative, 3M = three months post-operative, 12M = twelve months post-operative

Freiburger word recognition score	Total (N = 52)			Adult (N = 44)			Pediatric (N = 8)		
	Score [%]	Std.	N	Score [%]	Std.	N	Score [%]	Std.	N
pre-operative	19.57	21.70	46	20.00	21.64	39	17.14	23.60	7
1 month post-operative	74.51	21.01	51	75.00	21.73	44	71.43	16.76	7
3 months post-operative	83.75	15.84	52	84.66	15.72	44	78.75	16.64	8
12 months post-operative	82.90	18.10	50	82.91	18.68	43	82.86	15.24	7

WRS in % of subjects BETTER, EQUAL or WORSE Pre-operative vs.:	BETTER	EQUAL	WORSE
1 month post-operative	100.00 %	0.00 %	0.00 %
3 months post-operative	100.00 %	0.00 %	0.00 %
12 months post-operative	97.78 %	0.00 %	2.22 %

Speech perception result (secondary endpoint effectiveness)

Additionally, improvement in speech understanding in quiet was assessed with OLSA speech reception threshold sentences in quiet. Subjects improved from mean 63.69 dB SPL (±11.81 dB SPL) pre-operatively unaided to mean 39.71 dB SPL (±8.84 dB SPL) twelve months post-operatively aided with the Bonebridge. Twelve months post-operatively mean improvement in speech perception was 24 dB SPL. 100 % of all subjects showed a speech improvement twelve months post-operatively.

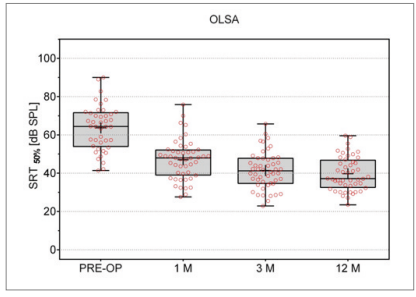


Figure 7: Speech reception thresholds for all subjects. Box plots: median = horizontal lines; + = mean; red circles depict distribution of individual values. Pre-op = pre-operative, 1M = one month post-operative, 3M = three months post-operative, 12M = twelve months post-operative

OLSA	Total (N = 52)			Adult (N = 44)			Pediatric (N = 8)		
speech reception threshold	dB SPL	Std.	N	dB SPL	Std.	N	dB SPL	Std.	N
pre-operative	63.69	11.81	42	62.21	11.69	36	72.60	8.70	6
1 month post-operative	47.01	10.41	48	45.99	10.51	41	53.01	7.97	7
3 months post-operative	41.42	9.51	50	40.63	9.81	42	45.53	6.83	8
12 months post-operative	39.71	8.84	48	39.19	9.09	41	42.80	7.01	7

SRT in % of subjects BETTER, EQUAL or WORSE Pre-operative vs.:	BETTER	EQUAL	WORSE
1 month post-operative	97.56 %	2.44 %	0.00 %
3 months post-operative	95.12 %	0.00 %	4.88 %
12 months post-operative	100.00 %	0.00 %	0.00 %

Audiometric results sound field (secondary endpoint effectiveness)

For the secondary endpoint of improvement on warble tones, the average unaided pre-operative threshold improved from 56.94 dB SPL (±12.57 dB SPL) to 29.33 dB SPL (±8.83 dB SPL) twelve months post-operatively in the aided condition. The mean functional gain was 28.89 dB SPL in the Bonebridge-aided condition twelve months post-operatively. All subjects (100 %) showed improved functional gain twelve months post-operatively.

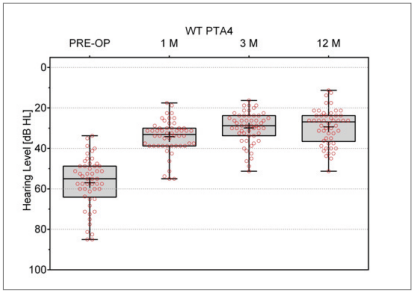


Figure 8: Warble tone thresholds using the pure-tone average of 0.5, 1, 2 and 4 kHz: Box plots: median = horizontal lines; + = mean; red circles depict distribution of individual values. Pre-op = pre-operative, 1M = one month post-operative, 3M = three months post-operative, 12M = twelve months post-operative

WT	Total (N = 52)			Adult (N = 44)			Pediatric (N = 8)		
warble tones	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
pre-operative	56.94	12.57	50	57.64	12.89	42	53.28	10.75	8
1 month post-operative	34.16	8.18	52	34.26	8.00	44	33.59	9.69	8
3 months post-operative	29.88	7.99	52	30.06	8.29	44	28.91	6.49	8
12 months post-operative	29.33	8.89	50	29.71	9.11	43	26.96	7.56	7

WT PTA_4 in % of subjects BETTER, EQUAL or WORSE Pre-operative vs.:	BETTER	EQUAL	WORSE
1 month post-operative	96.00 %	4.00 %	0.00 %
3 months post-operative	100.00 %	0.00 %	0.00 %
12 months post-operative	100.00 %	0.00 %	0.00 %

Audiometric results basic test battery (secondary endpoint safety)

The secondary endpoint of unchanged residual hearing was measured by unaided audiologic PTA4 (0.5, 1, 2 and 4 kHz) thresholds from pre-operatively unaided to the twelve-month post-operative endpoint. The results of descriptive analyses of BC and AC thresholds presented below show that Bonebridge treatment had no effect on residual hearing.

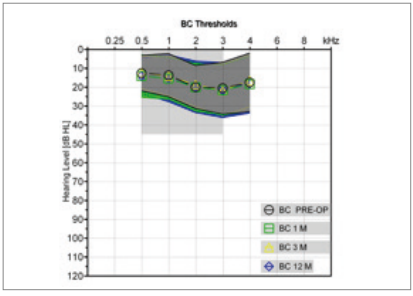


Figure 9: Mean residual bone conduction thresholds and area of standard deviation: pre-operative (dark grey), at one (green), three (yellow) and twelve (blue) months post-operatively for all subjects. The rectangular area (light grey) depicts the indication range of 45 dB HL pre-operatively.

BC	Total (N = 52)			Adult (N = 44)			Pediatric (N = 8)		
Bone conduction thresholds	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
pre-operative	16.03	9.70	52	17.41	9.57	44	8.44	6.71	8
1 month post-operative	17.17	10.39	52	18.59	10.27	44	9.38	7.53	8
3 months post-operative	15.66	8.63	52	16.88	8.63	44	8.91	4.88	8
12 months post-operative	17.03	10.24	50	18.11	10.25	43	10.36	7.83	7

AC	Total (N = 52)			Adult (N = 44)			Pediatric (N = 8)		
Air conduction thresholds	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
pre-operative	59.12	14.76	51	59.68	15.08	43	56.09	13.34	8
1 month post-operative	58.52	15.08	50	58.89	15.36	43	56.25	14.03	7
3 months post-operative	58.48	15.26	52	58.43	15.59	44	58.75	14.25	8
12 months post-operative	58.21	16.45	49	58.32	16.84	42	57.50	15.02	7

Twelve months post-operatively 21.15 % of the subjects experienced decreases at one or more bone conduction frequencies greater than 10 dB HL and 38.78 % of the subjects experienced decreases at one or more air conduction frequencies greater than 10 dB HL.

Percentage of subjects with post-operative decreases at one or more frequencies greater than 10 dB HL				
	BC		AC	
1 month post-operative	17.31 %	9/52 N	26.00 %	13/50 N
3 months post-operative	23.08 %	12/52 N	27.45 %	14/51 N
12 months post-operative	21.15 %	11/49 N	38.78 %	19/50 N

Subjective device satisfaction (secondary endpoints)

On average, subjects were satisfied or very satisfied three months after the Bonebridge treatment (80.8 %) and this result remained stable at the twelve-month (80.2 %) post-operative appointment.

Only two adult subjects were just under 50 % satisfied at the three months evaluation time point (48.68 % and 48.75 %, respectively) with both being more satisfied at the twelve months appointment (50 % and 67.11 %). At the twelve-month appointment 97.44 % were satisfied with the device and just one subject or 2.56 % were sometimes satisfied/dissatisfied with the device.

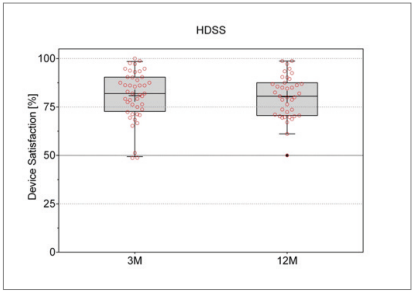


Figure 10: HDSS mean overall satisfaction three and twelve months post-operatively for all subjects. Box Plots: median = horizontal lines; + = mean

HDSS	Total (N = 52)			Adult (N = 44)			Pediatric (N = 8)		
overall device satisfaction	%	Std.	N	%	Std.	N	%	Std.	N
3 months post-operative	80.80	12.61	44	79.40	12.30	37	88.50	12.29	7
12 months post-operative	80.20	10.93	39	79.60	10.52	36	87.90	15.43	3

HDSS in % of subjects BETTER, EQUAL or WORSE			
Pre-operative vs.:	BETTER	EQUAL	WORSE
3 months post-operative	95.45 %	0.00 %	4.55 %
12 months post-operative	97.44 %	2.56 %	0.00 %

Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as non-serious/serious, device-/procedure-related or unrelated. A total of 31 adverse events, one temporary loss of residual hearing and one serious adverse event unrelated to the procedure or the device were reported up to twelve months after implantation.

The temporary loss of residual hearing was just 2.5 dB above the limit and was solved without treatment as the residual hearing threshold recovered at a later time point. One serious adverse event unrelated to the device reports on ear canal inflammation with subsequent cholesteatoma removal surgery and antibiotic treatment.

18 adverse events occurring in 15 subjects were reported as related to either the device or the procedure, with two reported as device-related serious adverse events (SADE), 4 reported as device-related adverse events and 12 reported as procedure-related adverse events. One subject who experienced a SADE on skin infection and subsequent explantation was excluded from the study analysis as the inclusion criteria were not met from the beginning (the patient's skin was too thin already pre-operatively).

Details on the type and number of device- and procedure-related adverse events can be found below:

Events reported as device- or procedure-related for 52 subjects	No. of events	No. of subjects	% of subjects	% resolved
Itching at the implant side	1	1	1.92 %	100 %
Skin irritation at the implant side	3	3	5.77 %	100 %
Skin infection at the implant side	2	2	3.85 %	100 %
Headaches	1	1	1.92 %	100 %
Headaches and skin irritation	1	1	1.92 %	100 %
Pain at the implant side	2	2	3.85 %	100 %
Pain at the implant side and skin infection	1	1	1.92 %	100 %
Pain due to post-operative scar formation	1	1	1.92 %	100 %
Occasional pain due to skin nerve cut	1	1	1.92 %	0 %
Post-operative subcutaneous seroma	1	1	1.92 %	100 %
Revision surgery to thin out the subcutaneous fascia	1	1	1.92 %	100 %
Vertigo	1	1	1.92 %	100 %
Tinnitus	1	1	1.92 %	100 %

* Some subjects experienced more than one adverse event. Some adverse events in this table were already reported in the BB001 study.

Prospective post-market clinical study: Bonebridge in SSD (BB003)

The purpose of this multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the clinical benefit of the Bonebridge in single-sided deafness (SSD) on the long-term scale up to at least thirteen months after surgery.

Three tests were evaluated in order to determine benefit of the MED-EL Bonebridge system at baseline (at initial fitting one-month post-operatively) and six and twelve months post-operatively:

Speech reception threshold in noise	(signal to noise ratio SNR; OLSA)
Speech spatial qualities-benefit questionnaire	(SSQ-B)
Bern benefit in single-sided deafness questionnaire	(BBSS)

In total, 16 subjects have been enrolled in the 2012 BB003 study as of August 2016. This interim analysis covers all 13 SSD subjects that had attended the twelve-month after baseline testing appointment at the time point of analysis in August 2016.

Primary study endpoint

It is expected that speech understanding in noise will improve in individual subjects as a result of the experimental treatment. This will be evaluated by comparing speech recognition testing in noise with Bonebridge-aided and Bonebridge-unaided conditions. For speech testing in noise monosyllabic words shall be recognized in a sentence. A difference of >1dB SNR between aided and unaided condition is considered clinically significant when noise (N) is presented from the front and speech (S) from the side of the deaf ear.

Secondary study endpoints

It is expected that subjective hearing device benefit and device satisfaction may improve for most individual subjects as a result of the experimental treatment. This will be evaluated by the SSQ-B (the speech, spatial and qualities of hearing scale - "benefit" version) and by the BBSS (Bern benefit in single-sided deafness questionnaire) for each individual subject.

Inclusion criteria

a. Bonebridge users aged 18 years or older
b. Single-sided sensorineural deafness, that is severe-to-profound sensorineural deafness in one ear while the other ear has normal hearing (air conduction should be equal to or better than 20 dB HL measured at 0.5, 1, 2 and 3 kHz)

Frequency (kHz)	0.5	1.0	2.0	3.0
AC upper limit (dB HL)	20	20	20	20

Table 3: Indication range upper limits (dB HL) of air conduction thresholds as a function of frequency for the normal hearing ear in persons with single-sided sensorineural deafness

c. Implantation of the device should not date back more than three months prior to study initiation
d. Geographically and physically able to return to the investigational center for scheduled evaluations and follow-up appointments
e. Fluency in the language used in the investigational center and used for evaluation
f. Signed and dated informed consent before the start of any study-specific procedure
g. Subjects should be emotionally and psychologically able to understand and perform on required study procedures

Exclusion criteria

h. Lack of compliance with any inclusion criteria
i. Lack of compliance in regularly using the device (4 to 6 hours per day)

Description of tests

Speech perception testing in noise

Speech understanding in noise (SNR, signal to noise ratio) was evaluated by the at 65 dB SPL noise for 50 % correct understanding of sentences. Noise is abbreviated as "N". The signal – which is a sentence from a given test list of the OLSA – is abbreviated as "S". The sentence levels were tested adaptively while the noise level was kept constant at 65 dB SPL until the subject recognized 50 % correct. Then the signal-to-noise ratio (dB SNR) was calculated. Noise was administered from the front (N0° azimuth) and the sentences were applied to the deaf Bonebridge-implanted ear (S90°).

Device satisfaction & benefit

In this study, the SSQ-B questionnaire was administered which uses a visual analogue scale similarly to the SSQ questionnaire. The SSQ-B intends to measure the benefit for first-time users implanted with a Bonebridge by asking how the respondent's ability or experience is now, compared to before Bonebridge implantation. The scale of the SSQ-B ranges from

−5 to +5, where −5 indicates 'much worse' with the Bonebridge than without, while +5 indicates 'much better'. The midpoint of the scale (0) indicates that the ability or experience is 'unchanged'. A positive rating always indicates an improvement with the Bonebridge, while a negative rating always indicates worse ability or experience.

The BBSS is a questionnaire comprising 10 questions rating from −5 to +5, where −5 indicates 'much easier/better' without the Bonebridge, while +5 indicates 'much easier/better' with the Bonebridge. The midpoint of the scale (0) indicates that the ability or experience is 'unchanged'. A positive rating always indicates a perceived benefit with the Bonebridge, while a negative rating always indicates worse perceived benefit.

The BBSS originally assesses the subjective benefit of unilaterally deaf patients when using a CROS device (contralateral routing of signals). The questionnaire allows an efficient estimation of whether the user will decide against such a device. If scores are equal to or lower than 10 points, patients highly likely would decide against the device. Scores above 15 suggest that patients would ultimately decide for a Bonebridge.

Clinical trial results

Of the 16 subjects enrolled, 13 had reached the 12-month after baseline testing appointment on the date of analysis.

Demographics

The table below provides information on subject demographics, including gender, age at implantation, and implanted side.

Parameter/category or statistic	Total (N = 13)
Gender	
Male %	53.85 % (N = 7)
Female %	46.15 % (N = 6)
Age (years) mean (min – max)	39 (18-59) (N = 13)
Implant side	
Left %	46.15 % (N = 6)
Right %	53.85 % (N = 7)

Speech perception results (primary endpoint)

Statistical analysis revealed a significant improvement between the aided and the unaided test condition at baseline testing (p = 0.002), and at long-term twelve-month testing (p = 0.007). A trend to significance was reached at six-month testing (p = 0.021), which would be significant without correction for multiplicity by Bonferroni correction with p <0.05. The mean improvement against baseline (–1.51 dB SNR improvement), six months (–2.3 dB SNR improvement) and twelve months (–1.56 dB SNR improvement) is highest at six months. Pairwise improvements are –1.6 dB SNR at baseline, –2.26 dB SNR at six months and –1.62 dB SNR at twelve months. At twelve months 88.89 % of all subjects showed improved SNRs.

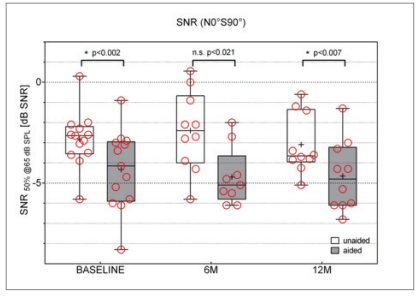


Figure 11: SNR (S90° N0°): unaided compared to the aided condition at baseline (initial activation), six and twelve months after baseline for all subjects. Box Plots: median = horizontal lines; + = mean; Wilcoxon signed-rank test Bonferroni corrected alpha level: p <0.017; * = significance; n.s.= no-significance

Signal to noise ratio	unaided			aided		
(SNR | S_{90} N_0)	dB SNR	Std.	N	dB SNR	Std.	N
Baseline	–2.82	1.37	13	–4.33	1.94	13
6 months post-operative	–2.41	1.96	10	–4.70	1.44	9
12 months post-operative	–3.09	1.48	10	–4.65	1.73	10

SNR in % of subjects BETTER, EQUAL or WORSE Pre-operative vs.:	BETTER	EQUAL	WORSE
Baseline	91.67 %	0.00 %	8.33 %
6 months post-operative	87.50 %	0.00 %	12.50 %
12 months post-operative	88.89 %	0.00 %	11.11 %

Subjective device satisfaction (secondary endpoints)

SSQ-B

Overall the outcome of the SSQ-B shows that subjects with SSD benefited from the Bonebridge treatment as an overall mean improvement was reached for all subscales. For the SSQ-B, only one subject (9.99 %) reported a worse experience with the Bonebridge at twelve months. All other study participants (90.91%) reported a better experience.

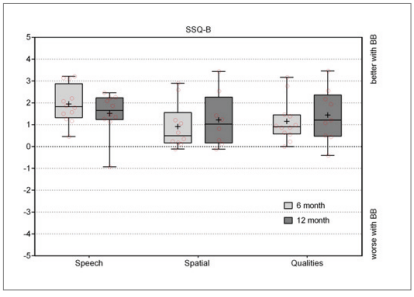


Figure 12: SSQ-B speech spatial qualities overall total score; six and twelve months after baseline for all subjects. Box plots: median = horizontal lines; + = mean;

SSQ-B subscales	Speech			Spatial			Qualities		
	Mean	Std.	N	Mean	Std.	N	Mean	Std.	N
6 months post-operative	+1.94	0.86	12	+0.92	1.05	10	+1.16	0.95	12
12 months post-operative	+1.52	0.98	10	+1.22	1.24	8	+1.44	1.2	9

SSQ-B in % of subjects BETTER, EQUAL or WORSE Pre-operative vs.:	BETTER	EQUAL	WORSE
6 months post-operative	100 %	0.00 %	0.00 %
12 months post-operative	90.91%	0.00 %	9.09 %

BBSS

Overall the outcome of the BBSS shows that subjects with SSD benefited from the Bonebridge treatment as an overall mean improvement in summed scores was reached. All subjects reported benefit with Bonebridge according to the BBSS.

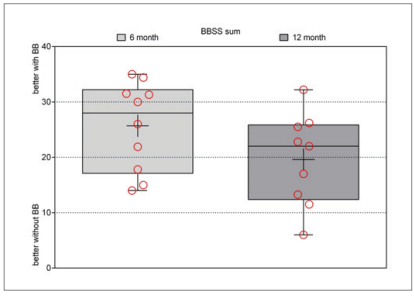


Figure 13: BBSS overall total score; six and twelve months after baseline for all subjects. Box plots: median = horizontal lines; + = mean;

BBSS	Mean	Std.	N
6 months post-operative	25.69	7.99	10
12 months post-operative	19.61	8.30	9

BBSS in % of subjects BETTER, EQUAL or WORSE Pre-operative vs.:	BETTER	EQUAL	WORSE
6 months post-operative	100 %	0.00 %	0.00 %
12 months post-operative	100 %	0.00 %	0.00 %

Safety

A total of 2 procedure-related adverse events were reported up to twelve months following baseline testing.

Events reported as device- or procedure-related for 13 subjects	No. of events	No. of subjects	% of subjects	% resolved
Wound healing problems	1	1	7.69 %	100 %
Occasionally local swelling at the implant site in the evening resolving in the morning	1	1	7.69 %	reoccurring

9. Miscellaneous

Technical data

Dimensions	Primarily circular shape Length: 36.4 mm (1 7/16 in) (battery compartment closed) Width: 30.4 mm (1 3/16 in) Height: 10.2 mm (13/32 in) (tallest point) Weight including battery and magnet (strength 1): 9.3 g (0.33 oz)
Material in tissue contact	Eastman Tritan Copolyester MX731
Power supply	One non-rechargeable 675 zinc-air button cell with a nominal 1.4 V supply (IEC identifier: PR44)
Audio frequency range	250 Hz to 8 kHz
Signal processing	18-band digital equalizer 18 (each dual or syllabic) compression channels Noise reduction control Feedback cancellation
Control	Turn off the system by opening the battery compartment about 5 mm (¼ in).
Degrees of protection provided by enclosures	IP54
Operating conditions	Temperature: +5 °C (+41 °F) to +40 °C (104 °F) Relative humidity: 15 % to 90 % Atmospheric pressure: 70 to 106 kPa
Conditions of transport and storage between uses	Temperature: −25 °C (−13 °F) to +60 °C (+140 °F) Relative humidity: 10 % to 90 % max. Atmospheric pressure: 70 to 106 kPa
Removable parts	Cover including microphone protection membranes Battery (not inserted on delivery) Attachment clips Magnet (only to be operated by professionals)
Expected service life	The expected service life of the SAMBA 2 (incl. all accessories) as defined in IEC 60601-1 is 5 years.
Wireless technology	• Connection between audio processor and implant Type: NFMI (near-field magnetic induction) Frequency: 120 kHz Modulation type: Voice AM Wireless range: 10 mm (3/8 in) • Connection between audio processor and SAMBA 2 GO (streaming device) Type: NFMI (near-field magnetic induction) Frequency: 3.28 MHz Modulation type: DPM (digital phase modulation) Wireless range: 0.3 m (12 in)

EMC compliance information

Emissions test

RF emissions **CISPR 11**	Group 1, Class B	

Immunity

Electrostatic discharge (ESD) IEC 61000-4-2	+/–8 kV contact, +/–15 kV air	
Radiated RF IEC 61000-4-3	80 MHz to 6 GHz	10 V/m
	380 MHz to 390 MHz	27 V/m
	430 MHz to 470 MHz	28 V/m
	704 MHz to 787 MHz	9 V/m
	800 MHz to 960 MHz	28 V/m
	1700 MHz to 1990 MHz	28 V/m
	2400 MHz to 2570 MHz	28 V/m
	5100 MHz to 5800 MHz	9 V/m
Radiated magnet fields	1 kHz, 2 kHz	84 A/m, 42 A/m
	0.003 MHz to 30 MHz*	28 A/m descending linearly above 0.15 MHz
	134 kHz*	65 A/m
	13.56 MHz	7.5 A/m
Conducted RF on programming cable only IEC 61000-4-6	0.15 MHz to 80 MHz	3 Vrms
	ISM/amateur bands	10 Vrms
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	

* Audio quality may be compromised

Quality of service

Once switched on, the SAMBA 2 will automatically begin to transmit sound. When the SAMBA 2 is magnetically attached to the implant, the link is established.

The Bonebridge system has been tested for wireless device compatibility.

Security

The Bonebridge system wireless technology is secure because:

- No user-specific information is stored inside the Bonebridge implant.
- The wireless link of the Bonebridge system is merely 10 mm (3/8 in) so any intruder to the Bonebridge system is required to be in very close range.

Warranty statement

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

Symbols

CE marking, first applied in 2020


Caution


Refer to instructions for use


Manufacturer

Serial number

Catalog number


Fragile, handle with care


Temperature limit


Humidity limitation


Type BF applied part (IEC 60601-1/EN 60601-1): The bottom surface of the SAMBA 2, which is in contact with the patient, is a Type BF applied part.


Non-ionizing electromagnetic radiation

IP54 Dust-protected. Protected against splashing water.

Prescription only (USA)

Indicator for left side application

Indicator for right side application


Information indicating a hazardous situation that, if not avoided, could result in minor injury or inconvenience for the user and/or property damage.

Information indicating a hazardous situation that, if not avoided, could result in death or serious injury.

Information particularly relevant for parents, guardians or caregivers of children who use the system.

Radio frequency/Telecommunication information

Radio equipment registration number: FCC ID: VNP-WL607

NOTICE: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTICE: Changes or modifications made to this equipment not expressly approved by MED-EL may void the FCC authorization to operate this equipment.

Please help us to improve the quality of these instructions for use by making any suggestions. For further information regarding the use of this MED-EL product, or to report any problems, please contact:

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Please refer to the accompanying Contact Sheet for your local office.

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