EN-US ENGLISH

Cochlear®

Cochlear™ Osia® OSI300 Implant

Physician's Guide

FOR PROFESSIONALS

About this guide

This guide applies to the Cochlear™ Osia® OSI300 Implant (hereafter referred to as OSI300 Implant) and is intended for surgical staff involved in implanting the device.

Surgeons implanting the device should be experienced in cochlear implant and/or bone conduction implant surgery or have received appropriate information and/or training to perform the surgery.

Prior to implantation, ensure all device users are appropriately trained on the surgical procedure, and are thoroughly familiar with the information in this guide and the product labeling. This guide includes important information on MRI, indications, contraindications, potential complications and adverse effects, warnings and precautions.

A surgical procedure for implanting the device is also explained.

This guide does not take into account any particular circumstances or factors relevant to an individual patient or case. Other surgical approaches and variations are practiced and may be more appropriate in certain circumstances. After considering all relevant circumstances, factors and information in each case, the appropriate surgical procedure is determined by the relevant physician exercising independent medical judgment.

Symbols used in this guide

Note
Important information or advice.

Caution (no harm)
Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.

Warning (harmful)
Potential safety hazards and serious adverse reactions.
Could cause harm to person.

Contents

Warnings and cautions for device use

This section does not contain all the important information required to use and implant the device, only critical information to implant the device safely and effectively. Read the full Physician's Guide before implanting the device.

⚠ Warning

Pre-operative

- Prior to implantation, a clinical assessment should be made to ensure that there is adequate bone quality and quantity in the area of implantation to support a successful implantation of both the BI300 Implant and the OSI300 Implant. Conditions affecting bone quality and quantity could for example be patient age, abnormal anatomy, irradiated bone, previous surgeries or other medical conditions as per clinical judgement. If assessed to be required, a pre-operative CT scan could be performed.
- Prior to implantation, make a clinical assessment of the patient's skin condition and skin thickness in the area of the actuator and coil to avoid potential post-surgical skin issues. A skin too thin over the actuator or coil areas may potentially lead to post-surgical skin problems or skin breakdown. A skin too thick over the coil area may lead to retention problems or link communication problems.
- When considering simultaneous implantation of the Osia System with an alloplastic microtia/atresia reconstruction procedure, it is important to consider potential risks, such as increased risk of infection leading to loss of the Osia implant and/or the microtia reconstruction. If a patient is a candidate for ear reconstruction surgery for microtia/atresia, it is strongly recommended that a discussion occur with the patient or carer regarding the increased risks of performing these procedures simultaneously.
- Post-operative wound infection may be prevented by administering a broad spectrum antibiotic before and during surgery.

- The implant is sterilized using Ethylene Oxide (EtO). After the sterilization process, residual EtO is less than 0.4 mg per device. This residual level is suitable for a recipient with a body weight of 7 kg or greater (Calculated with guidance from *EN ISO 10993-7*).
- The OSI300 Implants contain magnets, which should be kept away from neurostimulation devices (for example, deep brain stimulators) and magnetic ventricular shunts, as the magnets may affect the function of these devices. The maximum magnetic field strength at 2.5 cm (1 in) from the edge of the implant, with or without external sound processor magnet coupled to it, in any direction is less than 300 Gauss.

Medical treatments generating induced currents, heat and vibration

- Electrosurgical instruments can induce radio frequency currents that could flow through the implant. When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in) from the implant.
- High currents induced into the device can damage tissue and damage the implant.

Do not use:

- Monopolar electrosurgical instruments on the head or neck of an Osia implant patient.
- Therapeutic or medical diathermy on the head or neck. Therapeutic or medical diathermy may be used below the neck.
- Neurostimulation directly over the implant.
- Ultrasound fields can be inadvertently concentrated at the implant and cause tissue damage or damage the implant.
- Electroconvulsive therapy can cause tissue damage or damage to the implant. Do not use electroconvulsive therapy on an implant patient under any circumstances.

Magnetic Resonance Imaging (MRI)

- The Cochlear Osia OSI300 Implant is MR conditional. See *"MRI safety information"* on *page 39*.

⚠ Caution

- When using sharp instruments near the implant, take care to avoid damaging the OSI300 Implant.
- The implant can be exposed to diagnostic ionising radiation (x-rays, CT-scan). The sound processor must be removed during diagnostic ionising radiation.
- Do not expose the implant to a total dose greater than 70Gy of therapeutic ionising radiation.

Intended use

Intended purpose

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing.

The OSI300 Implant is intended to be used as part of the Cochlear Osia System to convert information from the external Sound Processor into mechanical vibrations.

Osia single-use and reusable surgical instruments are used throughout the surgery to correctly position and attach the Osia implant.

Indications

The Osia System is intended for the following patients and indications:

- Patients 5 years of age or older.
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL.
- Bilateral fitting of the Osia System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies.
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- The Osia System for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
- Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.

Contraindications

- Insufficient bone quality or quantity to support implantation of both the BI300 Implant and the OSI300 Implant
- Chronic or non-revisable vestibular or balance disorders that could prevent benefit from the device, as determined by good clinical judgment
- Abnormally progressive hearing loss
- Evidence that hearing loss is bilateral retrocochlear or bilateral central origin
- Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment
- Skin or scalp conditions that may preclude attachment of the Sound Processor or that may interfere with the use of the Sound Processor.

Potential complications and adverse effects

Prospective implant recipients should be advised of the following risks:

- General risks associated with surgery and general anaesthesia.
- Osseointegration failure – potential causes for failure of osseointegration include lack of adequate bone quantity/quality, trauma, infection, generalized diseases and surgical complications.
- Other medical complications that may require additional medical treatment, such as:
  - Concurrent Cerebrospinal Fluid (CSF) leakage
  - Subdural injury
  - Subcutaneous haematoma
  - Numbness, irritation, inflammation or breakdown of the skin flap
  - Infection
  - In some cases, extrusion of the device caused by a foreign body response to the device
  - Vertigo
- Failure of device component parts (both external and internal) could result in the perception of an uncomfortably loud sound sensation, intermittent sound, or no sound.
- Partial or full failure of the device could require removal or replacement of the implant.

Device description

The system works by converting sound in the environment into vibrations that transmit the sound to the cochlea (inner ear) via bone conduction.

The Osia System contains external and internal (implanted) components.

Implanted components

The Osia OSI300 Implant is surgically implanted under the skin behind the ear. It includes a coil to receive and forward the electrical signal to the actuator where the signal is decoded and transmitted via the BI300 Implant to the cochlea using bone conduction. The actuator connects to the BI300 Implant which osseointegrates with the bone.

External components

The external components include a sound processor, and associated accessories and cables.
The system is programmed by a Cochlear proprietary fitting software.
For more information on the sound processor, refer to the applicable sound processor User Manual.

How the implant is supplied

The OSI300 Implant, OSI200 Implant template, BI300 Implant, drills, non-magnetic cassette and replacement magnet cassette are single-use items supplied separately.

The implant, non-magnetic cassette and replacement magnet cassette are supplied in sterile gas-permeable packaging. Ethylene oxide processing is indicated on the label of each sterile package.

The OSI200 Implant template, the BI300 Implant and the drills are sterilized using irradiation. The sterile processing and the expiration date are indicated on the label of each packaging.

Before opening the sterile package, inspect it carefully. Return the device and packaging to Cochlear if:

- The 'use by' date stamped on the outside package has expired.
- The sterile pack containing the implant is ruptured.
- For items sterilized using ethylene oxide, the EtO dot is green.

Storage

For long term storage, store at room temperature. Keep dry. Handle the package with care. Severe impact may rupture the sterile package inside.

Cochlear™ Osia® OSI300 Implant

OSI300 Implant (P1772248)

1. Coil
2. Implant coil plate with magnet cassette in pocket
3. Waist
4. Actuator
5. Fixation interface
6. Serial number and QR-code
7. Fixation screw

Images not to scale

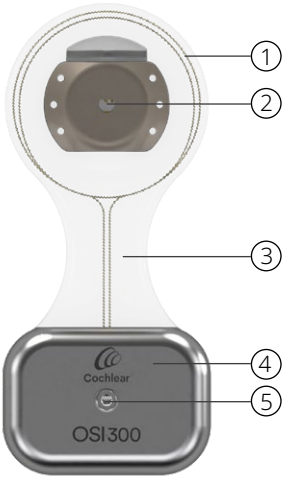


Fig.1: OSI300 Implant (Skin side)

Fig.2: OSI300 Implant (Bone side)

Note

Two fixations screws are available inside the OSI300 Implant sterile package, but only one fixation screw is needed to fix the actuator to the BI300 Implant.

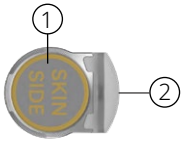
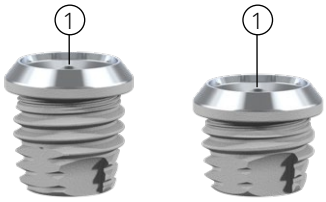


Fig.3: Magnet cassette (skin side)

1. SKIN SIDE engraving denoting correct orientation of magnet cassette in magnet pocket
2. Magnet cassette cover

Cochlear™ BI300 Implant



1. Fixation interface

Available in 3 mm (92128) and 4 mm (92129) lengths

Images not to scale

Surgical instruments and accessories

Warning

Do not use surgical instruments or accessories if they become non-sterile.

Instruments and accessories in this section are appropriate for use with the OSI300 Implant.

Instruments for use during surgery are available to order separately.

The OSI300 Implant and the OSI200 Implant template are packed in separate sterile packaging.

Items used with the OSI300 Implant are referenced in the surgical procedure and MRI safety information sections of this guide.

All used items meant for disposal and/or decontamination must be in accordance to the institution's policy.

Reusable instruments	Product Code
OSI Implant specific	
Bone bed indicator 17 mm	P1469690
BI300 Implant specific	
Screwdriver UniGrip 95 mm	90469
Multi wrench with ISO adapter	92143 / C9866
Machine screwdriver 25 mm UniGrip	90381
Implant inserter	92142 / P1582230
Drill indicator for WS-75 and Osscora	91116
Single-use instruments (sterile)	
OSI Implant specific	
OSI200 Implant template	P1291019
BI300 Implant specific	
Conical guide drill 3+4 mm	93363
Widening drill 3 mm with countersink	92140
Widening drill 4 mm with countersink	92141
Drilling equipment	
Drill unit	
Single-use (sterile)	
Magnet Cassette	P1773917
Non-Magnetic Cassette	P782484
Cover screw conical	92136

Reusable instruments

The Bone bed indicator 17 mm is stainless steel and can be cleaned and resterilized as instructed in the *Cochlear™ Osia® Surgical Instruments Sterilization Reprocessing Guide*.

OSI Implant specific

Pin Body

Bone bed indicator 17 mm (P1469690)

- To ensure adequate clearance above bone level.
- The indicator is delivered in two parts (body and pin) that have to be combined before use.
- Parts do not lock.

Images not to scale

BI300 Implant specific

Screwdriver UniGrip 95 mm (90469)
To tighten and untighten the actuator fixation screw.

Multi wrench with ISO adapter (92143 / C9866)
Torque wrench to tighten and untighten the actuator fixation screw to the BI300 Implant.

Machine screwdriver 25 mm UniGrip (90381)
In conjunction with Multi wrench with ISO adapter to tighten and untighten the actuator fixation screw.

Implant inserter (92142 / P1582230)
To pick up and insert the BI300 Implant.

Drill indicator for WS-75 and Osscora (91116)
To assist in determining the angle of the handpiece while drilling.

Images not to scale

Single-use instruments (sterile)

OSI Implant specific

Warning

- For temporary use only. Not for implantation.
- Supplied sterile. Sterilized using irradiation. Do not resterilize.
- Single-use item. Do not use more than once. Re-use could cause infection.
- Do not use if packaging is damaged.
- Do not use if item becomes non-sterile e.g. dropped or mishandled in theatre after removal from packaging.

OSI200 Implant template (P1291019)
Template of the entire OSI300 Implant to mark the shape of the OSI300 Implant and the BI300 Implant position, check the size of the coil pocket and the appropriate position of the OSI300 Implant and the BI300 Implant.

Note
Two implant templates are needed in each surgery, one for use in the non-sterile field and one for use in the sterile field.

Images not to scale

BI300 Implant specific

Conical guide drill 3+4 mm (93363)
To pre-drill the implant site for the BI300 Implant. When the spacer is removed the depth allows the use of the 4mm implant.

Widening drill 3 mm with countersink (92140)
To widen the pre-drilled implant site for the 3 mm BI300 Implant.

Widening drill 4 mm with countersink (92141)
To widen the pre-drilled implant site for the 4 mm BI300 Implant.

Images not to scale

Single-use (sterile)

These items are supplied sterile for single-use only.

Warning

Do not resterilize. Do not use more than once. Re-use could cause infection.

	**Non-Magnetic Cassette (P782484)** The non-magnetic cassette is intended to be used temporarily in place of the magnet cassette of a hearing implant after the implant magnet cassette is removed.
	**Magnet Cassette (P1773917)** The replacement magnet cassette is intended to be used to replace the magnet of the hearing implant that has been removed to facilitate a medical procedure.
	**Cover screw conical (92136)** To cover the BI300 Implant when placed at the implant site but not used.

Images not to scale

Note

- Non-magnetic cassettes and magnet cassettes are supplied in a silicone carrier, as illustrated below. Remove the cassette from the silicone carrier before use.

- When marking the incision site, the silicone carrier can be used as a template. For details see “Removing and replacing the magnet cassette” on page 40.

Drilling equipment

Low speed and torque controlled drill to place the BI300 Implant. Includes motor with cable, contra-angle handpiece and foot controls.
Has optional integrated irrigation that uses standard irrigation tubing.

Surgical procedure

The surgical procedure described in this guide is only one approach to implanting the OSI300 Implant. The physician may determine that other approaches and variations should be performed.

Where a surgical instrument is mentioned in the procedure, see *"Surgical instruments and accessories"* on *page 14*.

The surgical procedure includes the following:

1. Preparation of implant site (*page 21–24*)

2. Coil pocket creation and incision (*page 25–26*)

3. BI300 Implant placement (*page 27–31*)

4. OSI300 Implant placement (*page 32–35*)

5. Closure (*page 36*)

Note

A backup of the OSI300 Implant, BI300 Implant and the single-use instruments are recommended for each surgery.

1. Preparation of implant site

Relevant products

OSI200 Implant template

Additional:
Hypodermic needle • Clamp • Marking Pen • Ruler

Images not to scale

Position of the OSI300 Implant and sound processor

The OSI300 Implant position is most optimal with the actuator in line with the ear canal or slightly superior **without** touching the pinna (*Fig.4*). Make sure the sound processor will not interfere with the pinna and the placement of glasses. The sound processor should not be overlapped or shadowed by the pinna.

Note

For those patients who may have compromised vascularity due to previous surgeries, consider a placement of the OSI300 Implant that minimizes the skin tension over the actuator. Finding a flat area on the bone surface for the actuator positioning can help to reduce the risk of skin tenting.

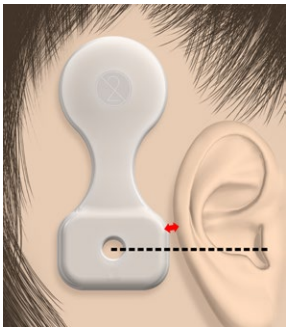


Fig.4: Optimal OSI300 Implant placement

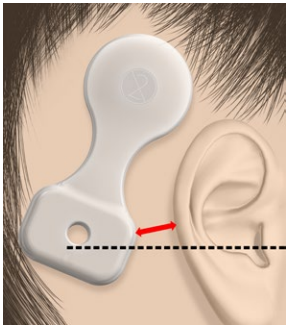


Fig.5: OSI300 Implant placement variation

Variations of the actuator and coil position are possible depending on the anatomy and medical history of the patient.

The ideal placement is around 0° for the coil and the actuator. The maximal deviation should be 45° (*Fig.6, Fig.7*).

The microphones of the sound processor should be placed in line or slightly above the superior part of the pinna to ensure optimal acoustical outcome (*Fig.8*).

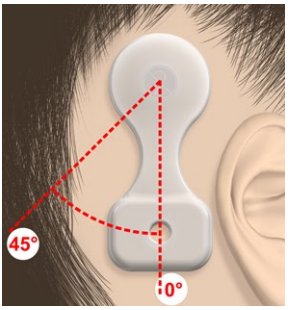


Fig.6: Actuator positioning options

Note

Placing the actuator closer to the ear canal may improve sound transfer to the cochlea.

Depending on the anatomy, the OSI300 Implant position may need to be adjusted, e.g. in mastoidectomy cases, or in cases with reconstruction of the ear.

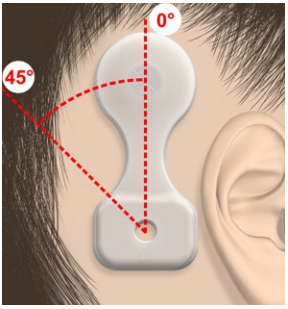


Fig.7: Actuator positioning options

If the recipient has a Cochlear Nucleus Implant on the contra-lateral side, make sure to have a minimal distance of 10 cm between the coils of the implants to avoid interference between the systems.

If the recipient has an OSI200 Implant or OSI300 Implant on the contra-lateral side, keep a minimal distance of 7 cm between the coils of the implants to avoid interference.

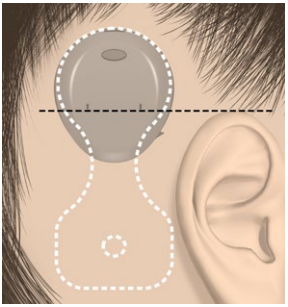


Fig.8: Sound processor placement

Preparation

1. Prepare the patient as for any craniofacial surgical procedure.
2. Use the OSI200 Implant template to plan the correct position and mark it on the skin (*Fig.9*). Make sure the sound processor will not interfere with the pinna and the placement of glasses. The sound processor should not be overlapped or shadowed by the pinna.

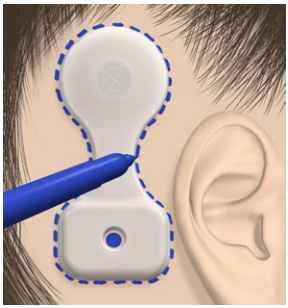


Fig.9: Marking of OSI300 and BI300 Implant

Note

Two implant templates are needed in each surgery, one for use in the non-sterile field and one for use in the sterile field. If a template is used in a non-sterile field make sure to use a new OSI200 Implant template in the sterile field later on.

3. Mark the location of the BI300 Implant using the hole of the actuator area of the OSI200 Implant template and a hypodermic needle inserted down to the bone with marking ink, such as Methylene blue. To avoid deformation of the ear, the actuator should not touch the pinna.

Example of incision options

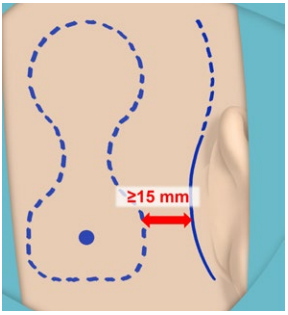


Fig.10: Post-auricularincision with superior extension

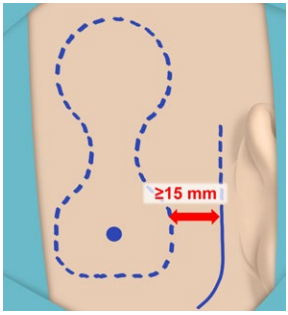


Fig.11: Inferior Post-auricular incision with extension

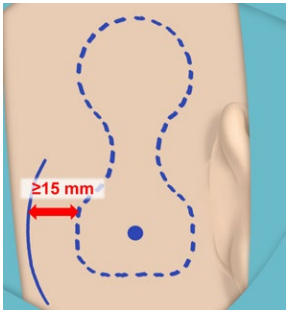


Fig.12: Posterior C-shape incision

Incision type and position

Take the following into consideration when choosing the incision type:

- Ensure visibility and physical access to the implant area to allow for clearance of bone and for placement of the BI300 Implant.
- If tissue thinning is needed, the incision may need to be elongated accordingly.

4. *Fig.10–Fig.12* show possible incision options. **Other variations are possible and depend on the patient's anatomy.** Independent from the incision method, it is important to have a distance of 15 mm or more between the incision and the edge of the implant to avoid tension on the skin and possible post-surgical complications.

Note

A distance of 15 mm or more between the incision and the edge of the implant can help to avoid skin tension and reduce the risk for post-surgical complications.

5. Before local anaesthesia is injected, measure the soft tissue thickness by using a thin hypodermic needle, a clamp (*Fig.13*) and a ruler (*Fig.14*). Measurement points should be distributed over the coil area (*Fig.15*). Do not depress the tissue when measuring.

Skin flap thickness

Caution

- For optimal retention and transmission, the distance between the sound processor and the implant should not exceed 9 mm. A skin too thick over the coil area may lead to retention problems or link communication problems.
- The skin flap thickness, hair type and texture should be incorporated into this measurement. If soft tissue thickness is greater than 9 mm, soft tissue thinning or alternative coil placement is needed.

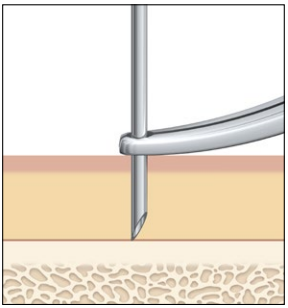


Fig.13: Measuring the skin thickness

Fig.14: Measuring the skin thickness with a ruler

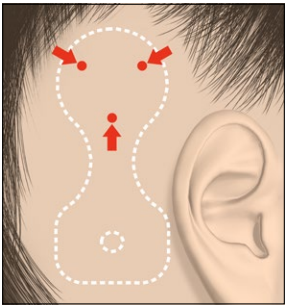


Fig.15: Three measurement points for skin thickness

2. Coil pocket creation and incision

Relevant products

OSI200 Implant template

Additional:
Scalpel • Elevator

Images not to scale

Coil pocket options

A. OSI300 Implant placement in periosteal pocket

Making the incision down and through the periosteum allows for a sub-periosteal coil pocket. This will give the possibility for a tighter fit of the periosteum over the implant.

Note
Consider an off-set of the incisions (skin and periosteum) to reduce the risk for skin breakdown.

B. OSI300 Implant placement lateral to periosteum

Placing the coil lateral to the periosteum and/or muscle layer is an alternative to soft tissue thinning to achieve the desired skin flap thickness. For this approach, make the incision down to but not through the periosteum.

Incision

1. Before making the incision, the incision line may be infiltrated with local anaesthetic and adrenaline, or epinephrine, unless contraindicated.
2. Make the incision as planned with the pocket creation in mind.
3. Create the pocket for the coil using blunt dissection. Keep the pocket tight.
4. Check with the OSI200 Implant template if the pocket size is suitable and if the actuator position is according to plan (*Fig.16*).

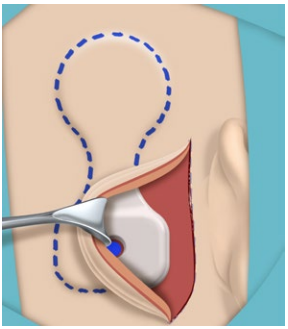


Fig.16: Checking of pocket size with the template

Note

The use of methylene blue is useful to mark the BI300 Implant position. When deciding the final position of the BI300 Implant, it is important to identify the recommended distance between the edge of the OSI300 Implant and the chosen incision line.

3. BI300 Implant placement

Relevant products			
	**Conical guide drill 3+4 mm**		**Implant inserter**
	**Widening drill** with countersinking 3 mm or 4 mm		**BI300 Implant** 3 mm or 4 mm

Images not to scale

Preparation for BI300 Implant placement

1. Clear away the periosteum around the BI300 Implant location using a small cruciate incision. **For uneven bone with sufficient thickness, it is possible to pre-polish the bone before placing the BI300 Implant to reduce the protrusion of the actuator and minimize skin tenting and bulging of the actuator against the skin.** In that case clear away the periosteum to allow for bone polishing.
2. Locate the marking for the BI300 Implant site made previously. When opening up the site it may be necessary to change the implant position due to changed site preference or bone quality. Ensure that no critical considerations are affected, e.g. actuator position in relation to incision.

Drill with the guide drill

3. **Set the drill unit to 2000 rpm with coolant. Use the drill indicator and abundant irrigation during all drilling procedures.** Begin drilling with the conical guide drill with the 3 mm spacer at 2000 rpm (*Fig.17*).
4. Be certain to drill at an angle perpendicular to the bone surface to minimize the need for bone polishing later in the procedure.
5. While drilling, move the drill perpendicular up and down to ensure that irrigation reaches the tip of the drill. Coolant is critical to preserve osteocytes, which are crucial for the osseointegration process.
6. Check the bottom of the site for bone, both visually and with a suitable instrument. Avoid penetrating the wall of the sigmoid sinus or damaging the dura mater.
7. If a 3 mm BI300 Implant is preferred, continue to step 8. If there is adequate bone thickness and a 4 mm BI300 Implant is preferred, remove the white spacer on the guide drill and continue drilling as appropriate to accommodate the 4 mm BI300 Implant. (*Fig.18*).

Fig.17: Guide drill with spacer

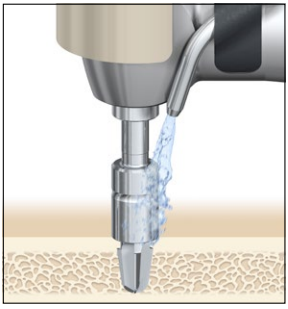


Fig.18: Drilling with Guide drill with spacer removed

Drill with the widening drill

8. Keep the drill unit on 2000 rpm with coolant.
9. Use the corresponding widening drill, depending on the depth reached with the guide drill. Drill perpendicular with an up and down movement to ensure irrigation can sufficiently cool the bone during drilling (*Fig.19*). Minimize the countersink depth to avoid unnecessary bone polishing later in the procedure.

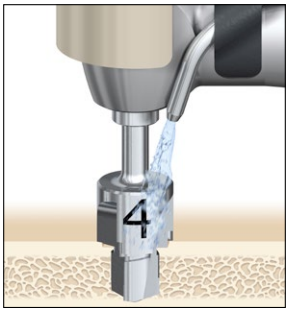


Fig.19: Drilling with widening drill

Warning

Do not widen the implant site larger than the actual drill size. Remove bone chips from the drill flutes.

Ensure the angle of drilling remains constant during this process. Altering the hand or drill angle will overwiden the site.

Note

Ensuring that the BI300 Implant is angled perpendicular to the bone surface is extremely important as the BI300 Implant will dictate the angle of the actuator. A non-perpendicular placement of the actuator may tent the skin and tissue over the implant area or the actuator may touch the bone which can lead to improper connection to the BI300 Implant. Use the Drill indicator during guide drilling, widening, and inserting the BI300 Implant to ensure a perpendicular angle.

BI300 Implant placement

Warning

The BI300 Implant must not come in contact with anything other than the ampoule and Implant inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.

10. Set the drill unit to a torque setting that suits the quality of the bone. If unsure of the bone quality, begin with a lower torque setting and gradually increase.

Bone quality	Suggested torque
Compact bone	40-50 Ncm
Compromised or soft bone	20-30 Ncm

Note

Compromised bone could for example be irradiated bone, bone with thin cortical layer, bone with air cells etc.

11. Use the corresponding BI300 Implant 3 mm or 4 mm based on which widening drill was used. Open the ampoule upright by unscrewing the lid so the bottom section can be placed in a suitable holder on a tray.
12. **Pick up the BI300 Implant using the implant inserter** (*Fig.20-Fig.21*). Using any other instrument could damage the BI300 Implant inner threads.
13. With the drill indicator in place, insert the implant at an angle perpendicular to the bone surface.
14. Place the implant without coolant until the first threads of the implant are well within the bone (two rotations) (*Fig.22*).
15. Once in the bone, continue placement with irrigation. The drill unit stops automatically
    - If the implant is not seated in the bone when the pre-set torque is reached, reverse one thread and increase the torque and reinsert the implant.
    - If the implant enters the site incorrectly, put the drill in reverse and unscrew the implant. Find the correct angle and re-insert the implant. If not successful the second time, a new site should be prepared.
16. Carefully remove the Implant inserter vertically from the implant.

⚠ **Caution**

Using any other instrument could damage the BI300 Implant inner threads.

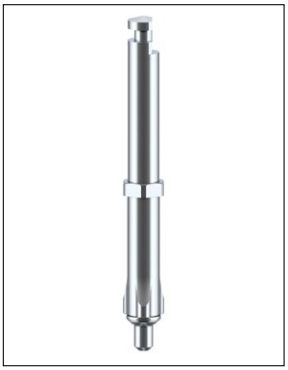


Fig.20: Implant inserter

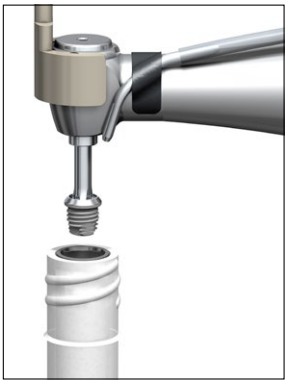


Fig.21: Picking up the BI300 Implant

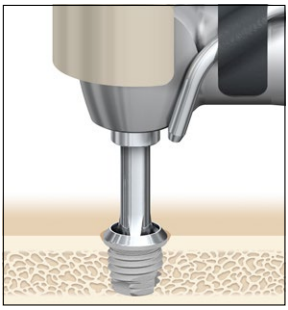


Fig.22: Inserting the BI300 Implant

Note

- When placing the implant in hard bone, slight pressure may need to be applied during the initial insertion. The implant can be tightened manually with the Multi wrench with ISO adapter and the implant inserter. Ensure the correct instruments and torque are used.
- Be very careful not to loosen the implant through leverage, especially if implanting a patient with thin or compromised bone.
- Seal any unused drilled implant sites with bone wax or similar.

4. OSI300 Implant placement

Relevant products			
	Bone bed indicator 17 mm		Screwdriver UniGrip 95 mm
	Multi wrench with ISO adapter		OSI200 Implant template
	Machine screwdriver 25 mm UniGrip		OSI300 Implant

Images not to scale

Checking for clearance

1. Place the Bone bed indicator on the BI300 Implant and gently hand tighten it to the implant threads by turning the top knob. Make sure that it is properly tightened. **Rotate the Bone bed indicator clockwise** to check for interfering bone (*Fig.23*). This will ensure sufficient clearance for a secure connection of the OSI300 Implant on the BI300 Implant.
2. If the Bone bed indicator only touches periosteum, remove the periosteum. If the Bone bed indicator touches bone, remove excess bone using a standard otological high-speed drill. Check repeatedly that sufficient bone has been removed using the Bone bed indicator. **Repeat the above until the bone bed indicator can be rotated 360° clockwise without applying force**.

Fig.23: Checking for interfering bone with Bone bed indicator

Note

If the bone bed indicator is rotated counter-clockwise, this may lead to the loosening of the pin. Ensure the pin is firmly screwed to the BI300 Implant while rotating the bone bed indicator.

Caution

Protect the BI300 Implant threads during bone polishing using the Bone bed indicator.

Note

To ensure a good connection between the actuator and the BI300 Implant, it is important to provide sufficient clearance to the bone. The actuator should not be in contact with the bone, only the BI300 Implant.

Caution

If there isn't sufficient bone clearance and bone polishing is not performed, this could lead to misalignment in the fixation screw between the OSI300 and the BI300 Implant.
Misalignment could damage the internal thread on the BI300 Implant.

3. If soft tissue thinning is required, carefully thin the tissue over the entire coil area. Try to achieve a uniform skin thickness over the coil area for best contact with the sound processor. As an alternative to soft tissue thinning, consider placing the coil on top of the periosteum and/or muscle layer to achieve the desired skin flap thickness.

Note

- If soft tissue thinning is required, only soft tissue should be removed. In case of a periosteal pocket the periosteum is left untouched to ensure a tight pocket.
- Skin that is too thin may increase the risk of skin breakdown which may lead to infection and/or device extrusion.

Caution

If skin thinning is performed over the area of the coil, ensure the skin thickness and vascularity is sufficient to prevent any post-surgical skin issues.

Preparation and insertion of the OSI300 Implant

Warning

- Once the OSI300 Implant is in the surgical field, monopolar electrocautery must not be used.
- Bipolar electrosurgical instruments should be kept more than 1 cm (½ in.) from the implant.

Caution

Care should be taken when handling the implant. Do not drop the actuator on a hard surface.

4. Make a final check with the OSI200 Implant template to ensure the coil fits well in the pocket and can be positioned correctly. Remove the template afterwards.
5. Open up the sterile packaging (*Fig.24*) and gently remove the lid above the implant (marked number 1) as well as the lid above the fixation screws (marked number 2).
   Two fixation screws are available, but only one of them is needed to fix the OSI300 Implant to the BI300 Implant.
6. While the OSI300 Implant is still in the blister pack, use the **screwdriver UniGrip 95 mm to pick up the fixation screw** from the implant blister pack using minimal force. Carefully screw the fixation screw into the actuator until it is fully seated (*Fig.25*).
7. Carefully remove the OSI300 Implant and place it with the coil first into the periosteal pocket. If a different surgical approach was chosen place it accordingly. If instruments are used for placement, be aware to only use blunt instruments to not harm the coil or waist area.

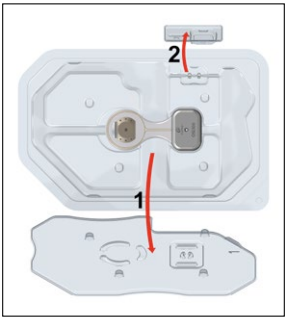


Fig.24: Packaging of the OSI300 Implant

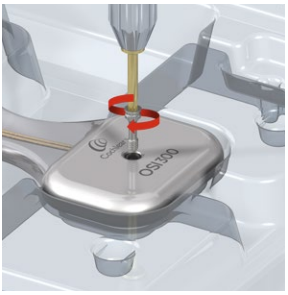


Fig.25: Attaching the fixation screw to the OSI300 Implant

8. Place the center of the actuator on top of the BI300 Implant. The fixation screw will drop significantly when it encounters the BI300 Implant. This will indicate the correct location. Gently hand-tighten the fixation screw with the screwdriver, while holding the actuator with your fingers (*Fig.26*). The actuator should not be in contact with the bone, only the BI300 Implant.
9. Continue to tighten to 25 Ncm with the Machine screwdriver UniGrip and the Multi wrench with the ISO adapter (*Fig.27*), while holding the actuator with your fingers (*Fig.28*). **Keep the implant orientation in mind and check that the implant coil or waist are not kinked before making the final attachment.**

Fig.26: Attaching the actuator to the BI300 Implant.

Note

Keep in mind that the OSI300 Implant contains a magnet and may be attracted to other magnetic devices in the operating room.

Fig.27: Machine screwdriver Unigrip and the Multi wrench with the ISO adapter

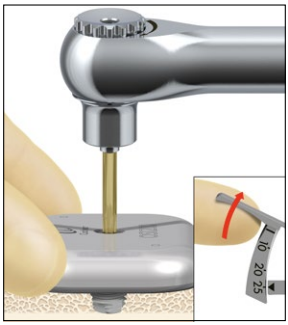


Fig.28: Hand tightening with 25 Ncm

5. Closure

1. Place the skin flap over the implant and suture the skin. If a periosteal flap was created consider suturing the flap off-set to the skin flap. Be careful to not harm the implant while suturing. Consider closing the skin and soft tissue in two separate layers.
2. Apply a pressure dressing for at least 24 hours (*Fig.29*).
3. After removing the pressure dressing, it is possible to use a normal wound dressing during the initial healing period.

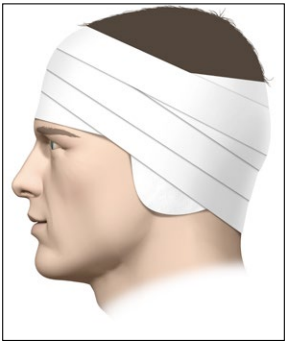


Fig.29: Pressure dressing

Registering the implant

Registration form

The registration form must be completed and returned to your closest Cochlear office or distributor by mail or fax immediately following implantation to validate product warranty.

Patient implant card

Fill out the complete patient implant card with all required details. Give the card to the patient or their carer. The patient or their carer should carry the patient implant card with them.

Post-operative management

Monitor the patient as for all procedures involving general anaesthesia. Keep the pressure dressing on for at least one day, and then monitor and change the dressing as desired.

Fitting the sound processor

Do not fit the sound processor before the wound is sufficiently healed.

The initial fitting procedure for the sound processor should be scheduled approximately four weeks after the operation. In the event that the tissue is still too swollen, consider a later fitting. Fitting should be checked in regular intervals as per clinic protocol.

Identifying the implant

The implant model can be found on the patient's Cochlear patient implant card.

If the patient does not have their patient implant card with them, the implant type and model can be identified without surgical intervention using X-ray (*Fig.30*) or the Cochlear Osia fitting software.

Part 1 of serial number
116003

Part 2 of serial number
XXXXXXY (specific for each implant)

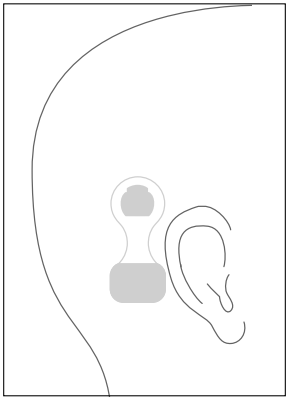


Fig.30: OSI300 Implant position

Explanting the implant

In rare circumstances, it may be necessary to explant an Osia OSI300 Implant. Please follow the steps below.

1. Inform your local Cochlear representative and contact Cochlear to order a Retrieved Device Kit. The kit must be used to transport the explanted device to Cochlear.
2. Read the instructions provided with the kit.
3. Before explanting the device, examine it for any defects. Note these on the form provided with the kit.
4. Try to keep the explanted device intact and undamaged.
5. Disconnect the actuator from the BI300 Implant using the screwdriver UniGrip 95 mm or the Multi Wrench with ISO adapter and Machine screwdriver 25 mm UniGrip.
6. If osseointegrated, the BI300 Implant can remain in place. Only remove it if absolutely necessary. If leaving in place, connect a new Osia OSI300 Implant, or place a cover screw to protect the internal threads of the implant.
7. Return the kit containing the explanted device to the Cochlear address nearest you. The applicable addresses can be found in the Retrieved Device kit.

Reporting problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

MRI safety information

The Cochlear Osia OSI300 Implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

- in the Cochlear™ Osia® Magnetic Resonance Imaging (MRI) Guidelines (supplied with the implant)
- by visiting www.cochlear.com/mri
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.

All external components of the Cochlear Osia System (e.g. sound processors, remote assistants and related accessories) are MR Unsafe. The patient must remove all external components of their Cochlear Osia System before entering a room where an MRI scanner is located.

Removing and replacing the magnet cassette

Cochlear Osia OSI300 Implants are designed to withstand MRI at static magnetic field strengths described in the Cochlear Osia OSI300 Magnetic Resonance Imaging (MRI) Guidelines.

Before an MRI examination, in some instances the magnet cassette must be removed in a sterile surgical environment. If single or multiple MRI examinations on the head are needed with the magnet cassette removed, replace the magnet cassette with a non-magnetic cassette.

Warning

- To prevent infection, do not leave the magnet cassette pocket empty. When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.
- All replacement procedures should take place under sterile conditions.

Caution

When removing or inserting a magnet cassette or non-magnetic cassette:

- Take care to not damage the implant silicone or coil wires. Do not suture directly over the implant silicone or the wires.
- Use a blunt instrument to lift the lip of the silicone elastomer recess.
- Exert minimal force and pressure to the implant during the procedure.

Note

While the magnet cassette is removed, the recipient must wear a Cochlear Disk Retainer to hold the sound processor in place. Disk Retainers are available from Cochlear.

Magnet cassette and non-magnetic cassette

Warning

To avoid implant damage during an MRI examination and potential revision surgery, ensure the correct magnet cassette and non-magnetic cassette are used.
Do not use magnets and non-magnetic plugs for other implants.

Magnet cassettes and non-magnetic cassettes are available from Cochlear.

Fig.31: Cochlear™ Magnet Cassette (P1773917)

Fig.32: Cochlear™ Non-Magnetic Cassette (P782484)

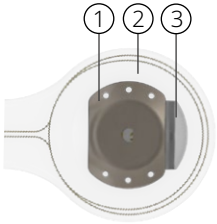
Removing the magnet cassette before implantation

If an MRI examination is scheduled in the near future, it may be appropriate to replace the magnet cassette with a non-magnetic cassette before the device is implanted.

The replacement procedure should take place under sterile conditions.

Replacing the magnet cassette with a non-magnetic cassette before implantation

1. In sterile conditions, remove the Osia OSI300 Implant from its sterile packaging and place it on a flat and stable surface with the bone side (engraved side) facing down.



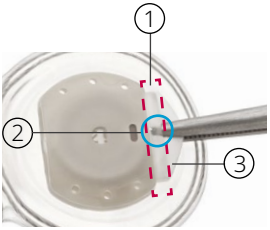
1. Implant coil plate (skin side)
2. Implant coil silicone
3. Magnet cassette cover

Fig.33: OSI300 Implant with magnet cassette

⚠ Warning

To avoid infection, if the sterile package or implant are damaged do not use the implant.

2. At the distal end of the implant coil, carefully position forceps or similar instrument under the silicone lip to hold the center of the magnet cassette cover.



1. Silicone lip
2. Forceps tip under silicone lip
3. Magnet cassette cover

Fig.34: Forceps position on OSI300 magnet cassette cover

⚠ Caution

When holding the magnet cassette cover, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

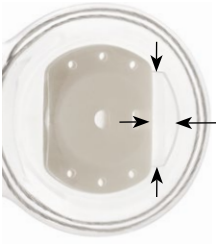


Fig.35: OSI300 Implant with magnet cassette removed

3. Using constant traction, remove the magnet cassette from the magnet pocket. The magnet cassette cover is designed to stretch under the constant traction applied during removal.
   The removal direction is in the same plane as the implant coil, towards the distal end of the implant – see arrow in *Fig.36*.

Caution

To avoid damaging the magnet pocket, do not apply vertical pulling force to the implant coil.

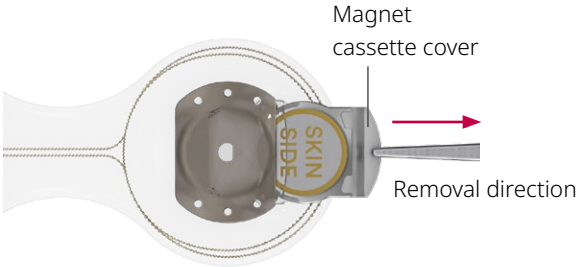


Fig.36: OSI300 Implant with magnet cassette partially removed

Note

If the magnet cassette cover pulls away, use forceps to hold the metal tab and continue removal.

Fig.37: Metal tab on magnet cassette

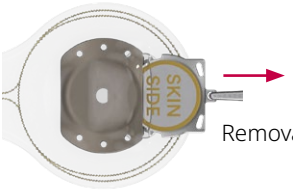


Fig.38: OSI300 Implant, magnet cassette removal using metal tab

4. Dispose of the removed magnet cassette. It is not re-usable.
5. To insert the non-magnetic cassette into the magnet pocket, remove it from the packaging and silicone carrier.
   Ensure the MRI engraving is facing up (skin side).

Warning

To avoid infection, if the sterile package is damaged do not use the non-magnetic cassette.

Insert the non-magnetic cassette into the magnet pocket between the implant coil plates, being careful not to exert undue force or pressure on the implant or implant coil.

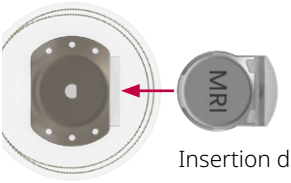


Fig.39: Non-magnetic cassette insertion direction

Ensure the non-magnetic cassette is fully inserted into the magnet pocket and the non-magnetic cassette cover is flush with the surrounding implant silicone.

The implant is now ready for implantation.

When there is no further need for MRI examinations, remove the non-magnetic cassette as instructed in *"Removing and replacing the magnet cassette or non-magnetic cassette after implantation" on page 45*.

Removing and replacing the magnet cassette or non-magnetic cassette after implantation

Warning

Do not use vertical force. Take care not to displace the implant.
Use of excessive or vertical force could lead to implant malfunction and require removal, replacement or revision surgery.

Caution

- Take care not to damage the implant silicone or coil wires.
- When holding the magnet cassette cover or non-magnetic cassette cover, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

Note

The magnet cassette or non-magnetic cassette can be safely removed and replaced with a new magnet cassette or non-magnetic cassette up to eight times without any adverse effect to the implant.

Remove the magnet cassette or non-magnetic cassette in sterile conditions, using either general or local anaesthetic.

1. Make an incision beyond the distal end of the implant coil. (*Fig.40*)

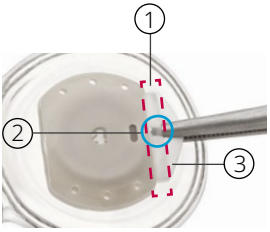
Note

You may use the cassette's silicone carrier to mark the incision:

- outside of the coil area
- with good access to the magnet pocket

2. Cut through any fibrous growth around the implant, exposing the distal end of the implant coil and the cassette cover. Ensure there is good visibility and access to the cassette cover.
3. Stabilise the implant, taking care to minimize force applied to the implant coil.
4. At the distal end of the implant coil, carefully position forceps or similar instrument under the silicone lip to hold the center of the cassette cover.

Fig.40: Marking the incision



1. Silicone lip
2. Forceps tip under silicone lip
3. Magnet cassette cover

Fig.41: Forceps position on OSI300 Implant magnet cassette cover

5. Using constant traction, remove the magnet cassette or non-magnetic cassette from the magnet pocket. The removal direction is in the same plane as the implant coil, towards the distal end of the implant – see arrow in *Fig.42*.

Note

The magnet cassette and non-magnetic cassette have been designed to remain in place and not move during an MRI examination. Therefore additional force may be required to remove the magnet cassette or non-magnetic cassette. In such cases, ensure the implant is sufficiently stabilised during removal.

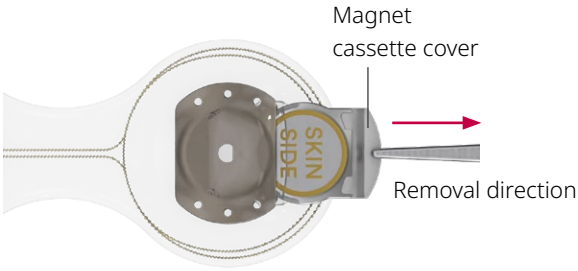


Fig.42: OSI300 Implant with cassette partially removed

Note

If the magnet cassette cover pulls away, use forceps to hold the metal tab and continue removal.

Fig.43: Metal tab on magnet cassette

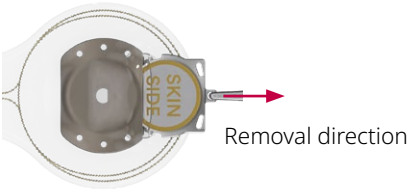


Fig.44: OSI300 Implant, magnet cassette removal using metal tab

6. Dispose of the removed magnet cassette or non-magnetic cassette. They are not re-usable.

7. To insert a magnet cassette or non-magnetic cassette, remove it from the packaging and silicone carrier.

   Ensure that:

- the engraving SKIN SIDE (or MRI) is facing up – see *Fig.45*
- there is good visibility and access to the magnet pocket.

Warning

To avoid infection, if the sterile package is damaged, do not use the replacement magnet cassette or non-magnetic cassette.

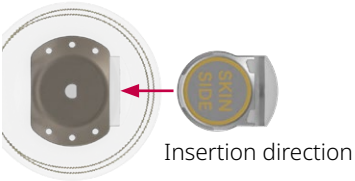


Fig.45: Replacement magnet cassette insertion direction

8. Stabilize the implant, taking care to minimize force applied to the implant coil.
9. Insert the replacement magnet cassette or non-magnetic cassette into the magnet pocket between the implant coil plates, being careful not to exert undue force or pressure on the implant or implant coil.
   Ensure the replacement magnet cassette, or non-magnetic cassette, is fully inserted into the magnet pocket and the cassette cover is flush with the surrounding implant silicone.
10. Closure – close the wound in layers (drainage is not recommended) and apply a large pressure bandage.

OSI300 Implant specifications

Size and weight	
Dimensions	31.4 x 72 x 4.9 mm with silicone Coil: 31 x 3.9 mm thick
Weight	20.53 g (including magnet cassette)
Operating characteristics	
Power and data	Received by 5 MHz inductive link from sound processor coil
Transmitting range	1 to 10 mm
Measurement function	
Implant ID and type check	Enables the sound processor to confirm whether it is coupled to the nominated implant
Materials in contact with body tissues	
Silicone elastomer	Actuator protective coating and insulation Magnet cassette cover Non-magnetic cassette cover
Titanium	Actuator housing, fixation screw and BI300 Implant

General information

Warranty

To the purchaser: the law in some countries requires that the written warranty for this Cochlear Osia OSI300 Implant must be made available for the patient's review before it is sold to them. The Cochlear terms and conditions of warranty should therefore be given to the patient before implantation. The warranty is included in the document pack.

Symbols

The following symbols may appear on your implant packaging:

Specific warnings or precautions associated with the device, which are not otherwise found on the label

Manufacturer

Date of manufacture

Catalogue number

Authorised representative in the European Community

Consult instructions for use

Fragile, handle with care

Do not resterilize

Serial number

Single sterile barrier system with protective packaging inside

Keep dry

Do not re-use

Do not use if package is damaged and consult instructions for use

Rx Only

Caution: US law restricts this device to sale by, or on the order of, a physician

MR Conditional

MR Unsafe

Medical Device

Use by date

Sterilized using ethylene oxide

Sterilized using irradiation

Batch code

Unique device identifier

Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user/recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on www.cochlear.com or request a copy from Cochlear at the address nearest you.

A summary of clinical testing

The following section provides a summary of the clinical testing that has been performed to verify the safety and efficacy of the Osia System. Clinical testing was performed using either a predicate device for which substantial equivalence is claimed (i.e. Cochlear™ Osia™ OSI100 Implant together with the Cochlear™ Osia™ Sound Processor) or the actual device (i.e. Cochlear™ Osia™ OSI200 Implant together with the Cochlear™ Osia™ 2 Sound Processor) in experienced bone conduction hearing implant recipients[1].

Taken together, clinical testing shows that the Osia System is safe and efficacious, significantly improving objective and subjective hearing outcomes and health-related quality of life in subjects with conductive hearing loss, mixed hearing loss, and single-sided sensorineural deafness.

Clinical Performance of a New Implant System for Bone Conduction Hearing

A prospective, multicentre clinical investigation including 51 adults with conductive hearing loss[2] (CHL; n=14), mixed hearing loss (MHL; n=23), or single sided sensorineural deafness (SSD; n=14) was conducted to assess the safety and effectiveness of the Osia System[3]. Subjects were unilaterally (n=49), or bilaterally (n=2) implanted and served as their own controls (i.e. aided hearing with the Osia System vs. preoperative unaided hearing and pre-operative aided with a BP110 Power Sound Processor on a Baha Softband).

With a total follow-up period of 12 months, the primary efficacy and safety evaluations were performed after 3 and 6 months, respectively. The following variables were assessed:

- **Hearing performance:** Thresholds audiometry, free field at individual frequencies [0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0 and 8.0 kHz] and Pure Tone Average [PTA4, Mean of 0.5, 1, 2, and 4 kHz]; Speech in quiet [% correctly perceived words at 50dB, 65dB and 80dB SPL]; Adaptive speech in noise [speech-to-noise ratio, 50% speech understanding].
- **Self-reported assessment:** Speech, Spatial and Qualities of Hearing Scale (SSQ12); Abbreviated Profile of Hearing Aid Benefit (APHAB); Health Utilities Index (HUI®) 23S15Q; Comfort (VAS, 0-100%), Usage.
- **Safety:** Adverse Events, Device deficiencies, Surgical information; Bone conduction (BC) thresholds, preoperative and postoperative etc.

1. *Using a validated Osia System simulation model allowing for a direct and acurate comparison between the systems.*
2. *Bone conduction thresholds with pure tone average (PTA4; mean of 0.5, 1, 2 and 4 kHz) of up to 55 dB SNHL.*
3. *The Cochlear OSI100 Implant and Osia Sound Processor*

Effectiveness results

The results from the clinical investigation demonstrate the following benefits for subjects with CHL / MHL and SSD with regards to hearing benefit and health related quality of life.

Hearing benefit and health related quality of life with the Osia System compared to pre-operative unaided hearing

Audiometric Thresholds

Hearing performance with the Osia System (aided) at 3 months was compared to the pre-operative unaided hearing performance, using free-field thresholds audiometry. Statistically significant improvements in Pure Tone Average (PTA4; mean of 0.5, 1, 2 and 4 kHz) with the Osia System were observed in the total population as well as the two separate sub-groups ($p<0.0001$). Table 1 shows the change in free-field hearing thresholds with the Osia System at 3 months, for both individual frequencies and PTA4 as compared to unaided listening. Improvements in audiometric thresholds were seen for all frequencies in both sub-groups when comparing the Osia System at 3 months with the unaided situation. All improvements were statistically significant except at 0.25 kHz in the SSD group.

Table 1: 3 months aided hearing with the Osia System vs. pre-operative unaided hearing. Table shows the change in free field hearing thresholds (dB HL) for individual frequencies (0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6 and 8 kHz) and as the mean of 0.5, 1, 2 and 4 kHz (PTA4) for the total population as well as the separate sub groups (CHL / MHL and SSD).

Free field thresholds (dB)	Total population (aided vs unaided)	p-value	CHL / MHL (aided vs unaided)	p-value	SSD (aided vs unaided)	p-value
0.25 kHz	**-9.92** (SD 13.04; -48.0 to 20.0; =49)	<.0001	**-12.5** (SD 11.7; -48.0 to 10.0; n=35)	<.0001	**-3.57** (SD 14.5; -35.0 to 20.0; n=14)	0.43
0.5 kHz	**-23.2** (SD 11.4; -52.0 to 0.0; n=49)	<.0001	**-25.1** (SD 10.7; -52.0 to -4.0; n=35)	<.0001	**-18.6** (SD 12.0; -40.0 to 0.0; n=14)	0.0002
0.75 kHz	**-28.0** (SD 12.5; -52.0 to -3.0; n=43)	<.0001	**-28.4** (SD 12.6; -52.0 to -3.0; n=33)	<.0001	**-26.5** (SD 12.5; -50.0 to -10.0; n=10)	0.0013

Free field thresholds (dB)	Total population (aided vs unaided)	p-value	CHL / MHL (aided vs unaided)	p-value	SSD (aided vs unaided)	p-value
1.0 kHz	**-26.7** (SD 11.8; -55.0 to -5.0; n=49)	<.0001	**-26.1** (SD 12.4; -55.0 to -5.0; n=35)	<.0001	**-28.2** (SD 10.3; -50.0 to -10.0; n=14)	<.0001
1.5 kHz	**-24.0** (SD 11.1; -45.0 to 5.0, n=43)	<.0001	**-23.6** (SD 12.2; -45.0 to 5.0; n=33)	<.0001	**-25.5** (SD 6.4; -30.0 to -10.0; n=10)	0.0008
2.0 kHz	**-23.8** (SD 12.1; -50.0 to 10.0; n=49)	<.0001	**-23.4** (SD 13.4; -50.0 to 10.0; n=35)	<.0001	**-24.6** (SD 8.2; -40.0 to -5.0; n=14)	<.0001
3.0 kHz	**-25.5** (SD 10.6; -46.0 to -5.0; n=49)	<.0001	**-25.6** (SD 11.9; -46.0 to -5.0; n=35)	<.0001	**-25.4** (SD 6.3; -40.0 to -20.0; n=14)	<.0001
4.0 kHz	**-26.1** (SD 10.8; -52.0 to -5.0; n=49)	<.0001	**-25.9** (SD 12.0; -52.0 to -5.0; n=35)	<.0001	**-26.8** (SD 7.2; -35.0 to -15.0; n=14)	<.0001
6.0 kHz	**-30.5** (SD 11.8; -60.0 to -5.0; n=47)	<.0001	**-30.6** (SD 13.6; -60.0 to -5.0; n=33)	<.0001	**-30.4** (SD 5.7; -40.0 to -20.0; n=14)	<.0001
8.0 kHz	**-29.7** (SD 13.9; -59.0 to 0.0; n=37)	<.0001	**-28.7** (SD 15.4; -59.0 to 0.0; n=27)	<.0001	**-32.5** (SD 8.9; -45.0 to -15.0; n=10)	0.0008
PTA4; (mean of 0.5, 1, 2 and 4 kHz)	**-24.9** (SD 9.5; -49.5 to -6.3; n=49)	<.0001	**-25.1** (SD 10.5; -49.5 to -6.3; n=35)	<.0001	**-24.6** (SD 6.6; -35.0 to -11.3; n=14)	<.0001

Mean (SD; range Min to Max; n= is presented)
** Negative value= improvement*

Speech in Quiet and Noise

Hearing performance measured as 'adaptive speech recognition in noise' showed statistically significant improvement with the Osia System as compared to the unaided situation for both the total population and the separate sub-groups. Statistically significant improvements were also recorded for all test conditions for speech recognition in quiet for all patient groups. Table 2 presents the change in speech-to-noise ratio and speech in quiet for the total population as well as the separate sub-groups (CHL/MHL and SSD). Table 3 and table 4 present the change in speech understanding with the Osia System as compared to the preoperative unaided situation for each patient. The performance evaluation indicates which patients experienced significantly better (or poorer) hearing performance with the Osia System. Data shows that no patients experienced a poorer performance with the Osia System as compared to the pre-operative unaided situation.

Table 2: 3 months aided hearing with the Osia System vs. pre-operative unaided hearing. Table shows the change in speech-to-noise ratio and speech in quiet for the total population as well as the separate sub groups (CHL / MHL and SSD).

Variable	Total Population (aided vs unaided)	p-value	CHL / MHL (aided vs unaided)	p-value	SSD (aided vs unaided)	p-value
Adaptive speech in noise * SNR 50% performance	**-13.3** (SD 8.1; -47.2 to 0.6; n=48)	<.0001	**-13.4** (SD 8.9; -47.2 to 0.6; n=34)	<.0001	**-13.0** (SD 6.1; -25.9 to 4.5; n=14)	<.0001
Speech in quiet % recognition at 50dB	**37.9** (SD 25.2; -40.0 to 80.0; n=49)	<.0001	**32.8** (SD 25.5; -40.0 to 80.0; n=35)	<.0001	**50.9** (SD 20.0; 5.0 to 74.0; n=14)	<.0001
Speech in quiet % recognition at 65dB	**59.8** (SD 27.1; -5.0 to 100.0; n=49)	<.0001	**61.5** (SD 29.2; -5.0 to 100.0; n=35)	<.0001	**55.6** (SD 21.7; 24.0 to 100.0; n=14)	<.0001
Speech in quiet % recognition at 80dB	**31.7** (SD 32.0; -4.0 to 100.0; n=49)	<.0001	**40.2** (SD 28.0; 0.0 to 100.0; n=35)	<.0001	**10.6** (SD 14.9; -4.0 to 53.0; n=14)	0.0078

Mean (SD; range Min to Max; n= is presented)
** Negative value= improvement*

*Table 3: Pre- vs. post- operative (3 months aided) hearing performance comparisons per patient for the CHL / MHL subgroup. The performance evaluation indicates if the patient experienced a significantly better or poorer hearing performance with the Osia System. Similar mean that the change was not significant. ** means no value available.*

				Adaptive speech in noise (SNR 50%)		Speech in Quiet (% correctly repeated words)					
						50 dB SPL		65 dB SPL		80 dB SPL	
Subject ID	Gender	Age	Type of hearing loss	Change (aided vs unaided)	Performance evaluation	Change (aided vs unaided)	Performance evaluation	Change (aided vs unaided)	Performance evaluation	Change (aided vs unaided)	Performance evaluation
101	M	56	CHL	-	**	23	better	93	better	80	better
102	M	52	CHL	-6,8	better	30	better	28	better	10	similar
103	M	59	CHL	-12	better	40	better	73	better	38	better
104	F	38	CHL	-	**	-	**	-	**	-	**
105	F	47	CHL	-16,4	better	60	better	70	better	90	better
107	M	59	CHL	-3	better	7	similar	80	better	53	better
108	M	63	MHL	-2,9	better	0	similar	6	similar	3	similar
109	M	57	CHL	-8,6	better	8	similar	90	better	27	better
201	F	30	CHL	-17	better	58	better	76	better	20	better
207	M	54	MHL	-13,5	better	64	better	82	better	28	better
208	F	53	MHL	-17,5	better	34	better	76	better	50	better
211	F	49	MHL	-18,3	better	60	better	88	better	18	better
212	F	34	CHL	-6,1	better	72	better	46	better	12	better
213	F	54	CHL	-11,6	better	38	better	12	better	0	similar
301	M	37	MHL	-11	better	15	better	45	better	25	better
302	M	33	MHL	-3,8	better	5	similar	20	better	10	similar
303	M	28	CHL	0,6	similar	-40	poorer	-5	poorer	0	similar
304	F	61	MHL	-9,2	better	0	similar	35	better	40	better
305	M	19	MHL	-23,5	better	40	better	90	better	75	better
306	M	48	MHL	-	**	-	**	-	**	-	**
307	M	52	MHL	-5,1	better	45	better	40	better	20	better
308	F	77	MHL	-13,4	better	0	similar	35	better	55	better
309	F	30	MHL	-47,2	better	20	better	80	better	100	better
310	M	39	MHL	-10,8	better	35	better	80	better	10	similar
401	F	62	MHL	-20,2	better	35	better	100	better	100	better
402	M	66	MHL	-18,5	better	50	better	95	better	100	better
403	F	19	CHL	-5,5	better	40	better	45	better	5	similar
404	M	48	MHL	-14,1	better	20	better	80	better	80	better
405	F	69	MHL	-26,2	better	35	better	100	better	100	better
406	F	45	CHL	-15,7	better	50	better	85	better	50	better
409	F	33	MHL	-13	better	45	better	95	better	65	better
410	M	66	MHL	-2,5	better	0	similar	85	better	50	better
502	M	58	MHL	-18,2	better	34	better	38	better	10	similar
505	F	31	MHL	-9,6	better	80	better	50	better	12	better
506	F	62	MHL	-23,6	better	24	better	48	better	52	better
507	M	42	MHL	-15,9	better	68	better	52	better	8	similar
508	F	21	CHL	-16,7	better	52	better	40	better	10	similar

*Table 4: Pre- vs. post- operative (3 months aided) hearing performance comparisons per patient for the SSD subgroup. The performance evaluation indicates if the patient experienced a significantly better or poorer hearing performance with the Osia System. Similar mean that the change was not significant. ** means no value available.*

				Adaptive speech in noise (SNR 50%)		Speech in Quiet (% correctly repeated words)					
						50 dB SPL		65 dB SPL		80 dB SPL	
Subject ID	Gender	Age	Type of hearing loss	Change (aided vs unaided)	Performance evaluation	Change (aided vs unaided)	Performance evaluation	Change (aided vs unaided)	Performance evaluation	Change (aided vs unaided)	Performance evaluation
106	F	51	SSD	-12	better	5	similar	75	better	53	better
202	M	52	SSD	-7,8	better	56	better	42	better	4	similar
204	M	71	SSD	-4,5	better	60	better	36	better	-4	poorer
205	M	57	SSD	-10,5	better	58	better	68	better	-2	poorer
206	M	48	SSD	-10,7	better	34	better	46	better	-4	poorer
209	M	35	SSD	-12,6	better	72	better	54	better	14	better
210	F	34	SSD	-25,9	better	66	better	84	better	0	similar
407	M	38	SSD	-7,6	bettter	45	better	60	better	15	better
408	M	36	SSD	-6,7	better	50	better	100	better	5	similar
501	M	23	SSD	-17,5	better	44	better	24	better	14	better
503	F	55	SSD	-22,9	better	74	better	66	better	16	better
509	F	64	SSD	-15	better	52	better	56	better	24	better
510	F	57	SSD	-16,1	better	74	better	40	better	12	better
511	F	24	SSD	-11,7	better	22	better	28	better	2	similar

Self-reported assessment of hearing performance

The short form of Speech, Spatial, and Qualities of Hearing questionnaire (SSQ-12) was used in the clinical investigation as it is designed to measure self-reported auditory disability, reflecting the reality of hearing in the everyday world. The study shows statistically significant improvements for all parameters (Total, Speech, Spatial and Quality) for both the total population and for the CHL/MHL sub-group when comparing the Osia System at 3 months with the pre-operative unaided situation. The SSD sub-group experienced a similar pattern with the exception for quality where no statistically significant improvement was recorded.

The Abbreviated Profile of Hearing Aid Benefit (APHAB) comprises of 24 items that are scored in the following four subscales: Ease of communication (EC), Reverberation (RV), Background noise (BN) and Aversiveness (AV). The Global score is the mean of the scores for all items in the EC, RV BN and AV subscales. When comparing the 3 month aided situation with the pre-operative unaided situation, statistically significant improvements were seen for all parameters except for Aversiveness for both total population and the two sub-groups.

Health status, health-related quality of life and utility scores

The generic quality of life scale, Health Utilities Index (HUI), was used to measure health status and health related quality of life. In the total population, statistically significant improvements with the Osia System were reported for the Comprehensive health state and Hearing attribute at 3 months. While the CHL/ MHL sub-group experienced improvements in their health status for the same attributes as the whole population, the small SSD sub-group did not experience any statistically significant difference in health status, as measured by HUI, 3 months after receiving the Osia System.

Table 5 presents the change in self-reported hearing outcomes and health related quality of life for the total populations as well as the different sub-groups after 3 months of aided hearing with the Osia System. Table 6 and 7 present the change in self-reported outcomes per patient. The performance evaluation indicates which patients experienced significantly better, poorer or similar scores with the Osia System as compared to the pre-operative unaided situation.

Table 5: 3 months aided hearing with the Osia System vs. pre-operative unaided hearing. Table shows the change in self-reported outcomes [APHAB, SSQ12 and HUI3] for the total population as well as the separate sub groups (CHL / MHL and SSD).

Variable		Total Population (aided vs unaided)	p-value	CHL / MHL (aided vs unaided)	p-value	SSD (aided vs unaided)	p-value
Abbreviated Profile of Hearing Aid Benefit (APHAB; % benefit)	Ease of communication (EC)	**24.1** (SD 21.7; -33.2 to 72.7; n=46)	<.0001	**28.3** (SD 23.4; -33.2 to 72.7; n=33)	<.0001	**13.5** (SD 11.9; 1.8 to 48.0; n=13)	0.0002
	Background Noise (BN)	**29.4** (SD 20.0; -10.5 to 74.7; n=47)	<.0001	**31.0** (SD 21.0; -10.5 to 74.7; n=33)	<.0001	**25.6** (SD 17.6; 0.0 to 64.3; n=14)	<.0001
	Reverberation (RV)	**25.8** (SD 23.1; -29.3 to 74.5; n=47)	<.0001	**29.1** (SD 24.9; -29.3 to 74.5; n=33)	<.0001	**17.9** (SD 16.3; -8.2 to 45.8; n=14)	0.0018
	Aversiveness (AV)	**-2.22** (SD 22.3; -68.3 to 45.0; n=46)	0.51	**-3.13** (SD 25.9; -68.3 to 45.0; n=33)	0.49	**0.087** (SD 8.3; -14.7 to 12.5 n=13)	0.97
	Global score	**26.1** (SD 18.5; -6.2 to 65.0; n=47)	<.0001	**29.5** (SD 19.6; -6.2 to 65.0; n=33)	<.0001	**18.1** (SD 13.3; 0.0 to 44.6; n=14)	<.0001
Speech, Spatial and Qualities scale (SSQ12)	Speech score	**2.93** (SD 2.21; -1.92 to 6.74; n=46)	<.0001	**3.34** (SD 2.17; -1.92 to 6.74; n=32)	<.0001	**2.00** (SD 2.08; -0.6 to 6.16; n=14)	0.0017
	Spatial score	**2.82** (SD 2.53; -3.00 to 7.93; n=46)	<.0001	**3.11** (SD 2.51; -3.00 to 7.93; n=32)	<.0001	**2.16** (SD 2.52; -0.77 to 7.33; n=14)	0.0029
	Quality score	**1.88** (SD 2.41; -2.58 to 7.50; n=47)	<.0001	**2.38** (SD 2.37; -2.58 to 7.50; n=33)	<.0001	**0.710** (SD 2.14; -2.03 to 5.50; n=14)	0.25
	Total score	**2.57** (SD 2.03; -0.65 to 6.93; n=46)	<.0001	**2.99** (SD 1.93; -0.65 to 6.93; n=32)	<.0001	**1.63** (SD 2.02; -0.63 to 5.70; n=14)	0.0044
Health Utilities Index (HUI)	Hearing attribute	**0.168** (SD 0.326; -0.290 to 1.000; n=43)	0.0014	**0.195** (SD 0.349; -0.290 to 1.000; n=31)	0.0040	**0.101** (SD 0.262; -0.140 to 0.540; n=12)	0.21
	Comprehensive Health State	**0.078** (SD 0.229; -0.472 to 0.795; n=41)	0.035	**0.098** (SD 0.244; -0.472 to 0.795; n=29)	0.039	**0.029** (SD 0.189; -0.275 to 0.287; n=12)	0.6

Mean (SD; range Min to Max; n= is presented)

*Table 6: Pre- vs. post- operative (3 months aided) patient-reported outcomes per patient for the CHL / MHL sub-group. The performance evaluation indicates if the patient experienced a significantly better or poorer score with the Osia System. Similar mean that the change was not significant. - / ** means no value/evaluation available.*

Subject ID	Gender	Age	Type of hearing loss	Global Score (APHAB; % benefit)		Total Score (SSQ12)		Comprehensive Health State (HUI)	
				Change (aided vs. unaided)	Comprehensive Health State (HUI)	Change (aided vs. unaided))	Performance evaluation	Change (aided vs. unaided)	Performance evaluation
101	M	56	CHL	-	**	-0,3	similar	0,31	better
102	M	52	CHL	65	better	3,3	better	0,24	better
103	M	59	CHL	16	similar	2,1	better	-0,02	similar
104	F	38	CHL	26,9	similar	-	**	-	**
105	F	47	CHL	-	**	-	**	-	**
107	M	59	CHL	42,9	better	6,3	better	-	**
108	M	63	MHL	1,1	similar	2	better	-	**
109	M	57	CHL	-	**	-	**	-	**
201	F	30	CHL	51,7	better	3,3	better	0	similar
207	M	54	MHL	-6,2	similar	1,2	better	0,03	similar
208	F	53	MHL	61,3	better	6,9	better	0,55	better
211	F	49	MHL	56,1	better	4,1	better	0,3	better
212	F	34	CHL	41,4	better	4,4	better	0,06	better
213	F	54	CHL	43,3	better	5,8	better	0,03	similar
301	M	37	MHL	36,2	better	4,1	better	-0,05	poorer
302	M	33	MHL	3,3	similar	1,8	better	-0,47	poorer
303	M	28	CHL	4,7	similar	-0,6	similar	-0,3	poorer
304	F	61	MHL	23	similar	3,1	better	0,19	better
305	M	19	MHL	-2,4	similar	-0,3	similar	0,06	better
306	M	48	MHL	-	**	-	**	-	**
307	M	52	MHL	34,2	better	4,1	better	0,1	better
308	F	77	MHL	13,8	similar	3,4	better	-	**
309	F	30	MHL	18,6	similar	-	**	0,03	similar
310	M	39	MHL	32,8	similar	3,3	better	0,15	better
401	F	62	MHL	31,7	similar	1,6	better	0	similar
402	M	66	MHL	29,6	similar	2,7	better	0,07	better
403	F	19	CHL	12,8	similar	1,6	better	-0,12	poorer
404	M	48	MHL	28,1	similar	5,3	better	0,42	better
405	F	69	MHL	51,9	better	2,9	better	0,17	better
406	F	45	CHL	-0,8	similar	5,1	better	-0,02	similar
409	F	33	MHL	46,3	better	3,2	better	0,8	better
410	M	66	MHL	9,1	similar	-0,4	similar	0,04	better
502	M	58	MHL	39,7	better	2,9	better	0,18	better
505	F	31	MHL	48,6	better	4,9	better	-	**
506	F	62	MHL	33,6	better	2,2	better	-0,12	poorer
507	M	42	MHL	47,1	better	4,3	better	0,3	better
508	F	21	CHL	31,2	similar	1,4	better	-0,07	poorer

*Table 7: Pre- vs. post- operative (3 months aided) patient-reported outcomes per patient for the SSD sub-group. The performance evaluation indicates if the patient experienced a significantly better or poorer score with the Osia System. Similar mean that the change was not significant. - / ** means no value/evaluation available.*

Subject ID	Gender	Age	Type of hearing loss	Global score (APHAB; % benefit)		Total score (SSQ12)		Comprehensive Health State (HUI)	
				Change (aided vs. unaided)	Performance evaluation	Change (aided vs. unaided)	Performance evaluation	Change (aided vs. unaided)	Performance evaluation
106	F	51	SSD	30,6	similar	0,4	similar	0,23	better
202	M	52	SSD	10,1	similar	0,3	similar	-0,01	similar
204	M	71	SSD	44,6	better	1,3	better	-0,24	poorer
205	M	57	SSD	0	similar	-0,6	similar	-0,07	poorer
206	M	48	SSD	22,2	similar	1,5	better	-0,07	poorer
209	M	35	SSD	6,8	similar	2,6	better	0,14	better
210	F	34	SSD	14,6	similar	-0,4	similar	-0,01	similar
407	M	38	SSD	14,9	similar	5,5	better	0,17	better
408	M	36	SSD	4,2	similar	1,5	better	-	**
501	M	23	SSD	14,7	similar	1,6	better	-	**
503	F	55	SSD	40,7	better	5,7	better	0,29	better
509	F	64	SSD	17,2	similar	0,5	similar	-0,28	poorer
510	F	57	SSD	25,4	similar	3,2	better	0,27	better
511	F	24	SSD	8,3	similar	-0,3	similar	-0,08	poorer

Hearing performance with the Osia System compared to pre-operative aided hearing assessment using the BP110 Power Sound Processor on Softband

Prior to bone conduction hearing implant surgery, a pre-operative assessment of the anticipated post-operative hearing outcome is routinely performed using a Baha Sound Processor on a Softband. The Softband test allows the patient to pre-operatively experience hearing through the Sound Processor to get an indication of the post-operative hearing outcome. As such, in addition to assessing hearing performance with the Osia System as compared to the pre-operative unaided listening situation, pre-operative aided hearing performance with a BP110 Power Sound Processor on a Baha Softband was also collected. The Baha BP110 Power Sound processor was chosen as it has the same 55 dB fitting range as the Osia System.

Audiometric Thresholds

Table 8 presents the change in free-field hearing thresholds with the Osia System at 3 months, for both individual frequencies and PTA4 (mean of 0.5, 1, 2 and 4 kHz) as compared to pre-operative aided listening with the BP110 Power Sound Processor on Softband. Statistically significant improvements in mean free-field hearing thresholds (PTA4) were observed in the total population and in the CHL/MHL sub-group when comparing the Osia System with pre-operative BP110 on a Baha Softband. While a numerical improvement in PTA4 was observed in the SSD sub-group, this was not statistically significant.

When assessing the audiometric thresholds per frequency, the greatest improvements in free field thresholds were observed at the higher frequencies, i.e. 3 to 4 kHz and above, for both subgroups. This result is expected since passive transcutaneous bone conduction hearing systems (e.g. Baha Attract or Baha sound processors on Softband/ SoundArc) are associated with an attenuation of the signal as it is transmitted through the skin affecting mainly the high frequencies. While being a transcutaneous bone conduction hearing implant system, the vibrating unit (actuator) of the Osia System is placed subcutaneously which allows for direct mechanical stimulation of the skull bone without the loss of signal through the skin.

Table 8: 3 months aided hearing with the Osia System vs. pre-operative aided hearing with BP110 Power on Softband. Table shows the change in free field hearing thresholds (dB HL) for individual frequencies (0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6 and 8 kHz) and as the mean of 0.5, 1, 2 and 4 kHz (PTA4) for the total population as well as the separate sub groups (CHL / MHL and SSD).

Free field thresholds (dB)	Total populaton (Osia vs BP110)	p-value	CHL / MHL (Osia vs BP110)	p-value	SSD (Osia vs BP110)	p-value
0.25 kHz	**4.12** (SD 9.58; -15.0 to 25.0; n=49)	0.025	**1.63** (SD 9.18; -15.0 to 20.0; n=35)	0.31	**10.4** (SD 7.7; 0.0 to 25.0; n=14)	0.0003
0.5 kHz	**-1.98** (SD 8.97; -18.0 to 25.0; n=49)	0.096	**-3.91** (SD 7.98; -18.0 to 15.0; n=35)	0.0073	**2.86** (SD 9.75; -10.00 to 25.00; n=14)	0.37
0.75 kHz	**-2.28** (SD 9.26; -25.00 to 20.00; n=43)	0.015	**-2.67** (SD 9.83; -25.00 to 20.00; n=33)	0.13	**-1.00** (SD 7.4; -10.0 to10.0; n=10)	0.83
1.0 kHz	**0.245** (SD 7.5; -20.0 to 15.0; n=49)	0.67	**0.77** (SD 8.03; -20.0 to 15.0; n=35)	0.59	**-1.07** (SD 5.94; -10.0 to 10.0; n=14)	0.53

Free field thresholds (dB)	Total populaton (Osia vs BP110)	p-value	CHL / MHL (Osia vs BP110)	p-value	SSD (Osia vs BP110)	p-value
1.5 kHz	**-0.140** (SD 8.2; -32.0 to 10.0; n=43)	0.73	**-0.79** (SD 9.16; -32.0 to 10.0; n=33)	0.86**	**2.00** (SD 3.50; 0.0 to 10.0; n=10)	0.25**
2.0 kHz	**-2.24** (SD 9.04; -34.0 to 20.0; n=49)	0.019	**-2.43** (SD 9.91; -34.0 to 20.0; n=35)	0.16	**-1.79** (SD 6.68; -10.00 to 15.00; n=14)	0.45
3.0 kHz	**-3.96** (SD 9.11; -34.00 to 11.00; n=49)	0.0046	**-4.83** (SD 9.65; -34.00 to 11.00; n=35)	0.0051**	**-1.79** (SD 7.50; -15.00 to 10.0; n=14)	0.48**
4.0 kHz	**-8.02** (SD 10.38; -42.0 to 13.0; n=49;	<.0001	**-8.23** (SD 11.4; -42.00 to 13.00; n=35)	<.0001	**-7.50** (SD 7.53; -20.0 to 5.0; n=14)	0.0038
6.0 kHz	**-13.8** (SD 11.1; -41.0 to 20.0; n=48)	<.0001	**-13.8** (SD 12.0; -41.0 to 20.0; n=34)	<.0001	**-13.9** (SD 9.0; -30.0 to 0.0; n=14)	<.0001
8.0 kHz	**-17.0** (SD 18.9; -67.0 to 15.0; n=40)	<.0001	**-16.3** (SD 20.8; -67.0 to 15.0; n=30)	<.0001	**-19.0** (SD 12.4; -40.0 to -5.0; n=10)	0.0035
PTA-4 (mean of 0.5, 1, 2, 4)	**-3.00** (SD 6.37; -23.25 to 15.00; n=49)	<.0001	**-3.45** (SD 7.11; -23.3 to 15.0; n=35)	0.0064	**-1.88** (SD 3.98; -8.8 to 3.8; n=14)	0.10

Mean (SD; range Min to Max; n= is presented)

Speech in Quiet and Noise

Overall, there was a slight improvement in speech recognition in quiet at 65 dB SPL with the Osia System compared to pre-operative aided listening with BP110 on a Softband; however, when assessing the separate sub-groups, patients with a mixed / conductive hearing loss performed better with the Osia System than with BP110 on softband, with statistically significant improvement in word recognition scores at 65 dB and 80 dB SPL, while no significant difference was seen at any SPL for the SSD subgroup. When it comes to the adaptive speech in noise tests, both subgroups experienced a statistically significant improvement with the Osia System as compared to BP110 on softband.

Table 9: 3 months aided hearing with the Osia System vs. pre-operative aided hearing with BP110 Power on Softband. Table shows the change in speech-to-noise ratio and speech in quiet for the total population as well as the separate sub groups (CHL / MHL and SSD).

Variable	Total populaton (Osia vs BP110)	p-value	CHL / MHL (Osia vs BP110)	p-value	SSD (Osia vs BP110)	p-value
Adaptive speech in noise * SNR 50% performance	**-7.22** (SD 6.10; -20.8 to 9.0; n=47)	<.0001	**-6.52** (SD 6.39; -20.8 to 9.0; n=33)	<.0001	**-8.89** (SD 5.17; -18.7 to -1.7; n=14)	<.0001
Speech in quiet % recognition at 50dB	**3.00** (SD 25.6; -65.0 to 60.0; n=48)	0.43	**7.79** (SD 24.8; -65.0; 60.0; n=34)	0.077	**-8.64** (SD 24.7; -58.0 to 24.0; n=14)	0.22
Speech in quiet % recognition at 65dB	**6.69** (SD 21.5; -32.0 to 85.0; n=48)	0.035	**10.0** (SD 24.2; -32.0 to 85.0; n=34)	0.020	**-1.36** (SD 9.3; -25.0 to 12.0; n=14)	0.64
Speech in quiet % recognition at 80dB	**1.73** (SD 8.4; -10.0 to 30.0; n=48)	0.17	**3.26** (SD 9.1; -10.0 to 30.0; n=34)	0.045	**-2.00** (SD 4.6; -10.0 to 6.0; n=14)	0.16

Mean (SD; range Min to Max; n= is presented)
** Negative value= Improvement*

Comfort and usage

Comfort with the use of the Osia System, measured using a visual analogue scale where 0% was defined as no comfort at all and 100% as most comfortable imaginable, showed a total mean comfort of 81% at 3 months and the mean reported daily use was 10.5 hours/day (SD 4.3, range 1.0-18.0 hours/day).

Analysis of the separate subgroups (CHL/MHL and SSD) showed similar trends as for the entire population.

Safety results

Serious Adverse Events (SAEs)

Four (4) Serious Adverse Events (SAEs) were reported within the first six months of the study. Two (2/4) SAEs were unrelated to the study device and/or procedure and the remaining two SAEs were judged as probably related to the procedure.

The procedure-related SAEs occurred in the same patient and stemmed from the same root cause, details are presented below:

SAE: Wound Infection leading to explantation

One study subject suffered a complicated post-operative wound infection which led to removal of the implant.

The subject (a 49-year-old Caucasian male, non-smoker, with mixed hearing loss due to chronic infection, with no surgery relevant medical history or medication) experienced an infection at the implant site, first observed 3 days after surgery.

The surgical procedure involved extensive soft tissue reduction followed by cauterization to stop heavy bleeding. The subject's hospitalization was prolonged due to excessive seroma at the implant site. Revision surgery (debridement and necrectomy) was performed 12 days later and the subject was discharged after an additional 12 days. Sixteen days later the subject was re-hospitalised due to skin necrosis at the implant site; the root cause was bacterial infection, whereby another revision surgery was performed (debridement, rotational skin flap). The subject was treated with antibiotics and could leave the hospital after 5 days. The subject was once again re-hospitalized after twenty days due to skin dehiscence at implant site, whereby surgery was performed to remove the implant.

Assessment of the explanted implant revealed the presence the pathogenic bacterium Klebsiella aerogenes (K. aerogenes) and the biofilm-forming bacterium Propionibacterium acnes (P. acnes).

The SAE was resolved by removing the Osia implant. The BI300 Implant was left in situ and covered with a cover screw in accordance with the recommended surgical procedure.

Other device or procedure related Adverse Events (AEs)

Nineteen (19) Adverse Events (AEs), judged as causally or probably related to the study device and/or procedure, were reported during the first six months of the study. Table 10 presents the details for these AEs:

Table 10: AEs judged as probably or causally related to the study device and/or procedure. Table includes AEs reported at the 6 months primary safety evalution.

Reported AE Term	Related to device	Related to procedure	Event Status (at 6 months)	Adverse Event serious?	Mitigation for the event
BLEEDING FROM MASTOID EMISSARY VEIN STOPPED BY COAGULATION.	Not related	Probable	Resolved	No	Bleeding was stopped by coagulation. Place of implantation had to be moved backwards.
FEELING OF TENSION AT IMPLANT LOCATION	Probable	Not related	Resolved	No	Advised to use softpad when needed
HAEMATOMA HEAD	Not related	Causal relationship	Resolved	No	Additional medical review before switch on of sound processor. Resolved without intervention.
HEADACHE	Probable	Unlikely	Ongoing*	No	Resolved without intervention.
HEAT PRODUCTION AFTER PROCESSOR CHANGE	Causal relationship	Not related	Resolved	No	The reason for "heat production" is not known, but apparently it disappeared after a few hours and did not come back.
HEMATOMA AROUND THE INNER PART OF THE IMPLANT- RIGHT EAR.	Not related	Causal relationship	Resolved	No	Hematoma was removed and future healing proceeded without complications.
IRRITATION/MILD DRAINAGE FROM SURGICAL WOUND	Not related	Probable	Resolved	No	Impacted hairs were removed and impacted area debrided and cauterized.
LIGHT BULGING OF EAR CANAL WALL	Not related	Probable	Resolved with sequelae	No	Patient received middle ear/ear canal surgery. During surgery the ear was completely 'cleaned up' since the patient had often infection in his ear. Bulging of the ear canal can occur after middle ear/ear canal surgery. After the surgery this was completely resolved. In other words, the event was resolved with sequelae on a 'positive note'. Since the patient visited the hospital for routine control visits for this event it was marked as resolved with sequelae.
MEDICAL OCCURRENCE - VAGINAL THRUSH	Not related	Probable	Resolved	No	Resolved with Canesten cream.

Reported AE Term	Related to device	Related to procedure	Event Status (at 6 months)	Adverse Event serious?	Mitigation for the event
NEUROPATHIC PAIN	Not related	Probable	Ongoing*	No	The AE was resolved on 12 month visit due to that the PI documented in eCRF and CRF worksheets the end date for the 12 Month visit, 09Jan2019. The PI judged that the pain was not relevant to the device. Medication prescribed.
NUMBNESS	Probable	Possible	Resolved	No	Resolved without intervention.
PAIN AROUND SURGICAL SITE	Possible	Causal relationship	Resolved	No	GP prescribed medication.
POSITIONAL VERTIGO	Not related	Probable	Resolved	No	Treatment by vestibular pt and home exercises.
POST-OPERATIVE PAIN	Unlikely	Causal relationship	Resolved	No	Resolved without intervention.
POST-OPERATIVE PAIN	Unlikely	Causal relationship	Resolved	No	Resolved without intervention.
POST-OPERATIVE PAIN	Not related	Probable	Resolved	No	Bandage too tight. New bandage.
SWELLING ON ARM	Not related	Probable	Resolved	No	Visited GP and anti-inflammatory medication prescribed.
WARM SKIN WHEN USING DEVICE	Probable	Not related	Ongoing*	No	Patient experienced occasional warmth of the skin when using the device. A telephone call to the patient after the study completion confirmed that the AE is now resolved.
WARMTH/HEATING OF PROCESSOR AFTER REPLACEMENT	Causal relationship	Not related	Resolved	No	The patient received a new processor and the old one was sent to Cochlear, which turned out it worked fine.

** NOTE. AEs reported as ongoing at the 6 months primary safety evaluation – these have been resolved.*

Bone conduction thresholds

Pre- and post-operative bone conduction thresholds were assessed, where shifts in thresholds, relative to the preoperative baseline, were to be reported as an adverse event (AE) when a shift at any frequency exceeds 15 dB HL.

Table 11 presents the unaided post-operative BC thresholds (PTA4, mean of 0.5, 1, 2 and 4 kHz) as compared to the baseline pre-operative BC thresholds for both the total population and for the separate sub-groups. Neither group data nor individual patient data demonstrate any significant thresholds shifts over time, indicating stable inner and middle ear function up to 12 months after implantation. Any individual fluctuations in BC thresholds are most likely due to testing artefact caused by the different placement of the bone oscillator.

Table 11: Bone conduction thresholds (PTA4) per sub-group and visit.

	Pre-op	3 months Post-op	6 months Post-op	12 months Post-op	Change in BC tresholds Post-op vs. Pre-op (3 / 6 / 12 months)
Total population	**20,93** (SD 12,6; 5,0 to 48,8; 20,0; n=43)	**21,71** (SD 12,0; 3,8 to 45,3; 21,3; n=44)	**20,26** (SD 11,2; 5 to 49,8; 18,8; n=46)	**24,21** (SD 12,4; 8,8 to 46,3; 24,2; n=27)	+ 0,8 / - 0,7 / + 3,3
CHL / MHL	**25,78** (SD 11,3; 5,0 to 48,8; 23,8; n=29)	**25,98** (SD 11,1; 3,8 to 45,3; 24,8; n=31)	**23,91** (SD 10,5; 5 to 49,75; 23,75; n=32)	**28,15** (SD 10,5; 8,8 to 46,3; 30,0; n=20)	+ 0,2 / - 1,8 / + 2,3
SSD	**9,55** (SD 6,6; -1,3 to 21,3; 10,0; n=14)	**11,54** (SD 7,0; 1,0 to 22,5; 10,0; n=13)	**10,71** (SD 6,2; 0 to 21,3; 11,9; n=14)	**9,82** (SD 4,2; 2,5 to 15,0; 11,3; n=7)	+ 2,0 / - 1,8 / + 0,3

Subjects' Preference Regarding Hearing Performance and Functionality Using a New Sound Processor

The sound processor used in combination with the OSI200 Implant is the Osia 2 Sound Processor. This sound processor can also be used together with the predicate Osia System implant (i.e. The Cochlear™ Osia™ OSI100 Implant). Eleven (11) subjects (CHL n=2; MHL n=3; SSD n=6) who had completed the above-mentioned clinical investigation were included in this open, single center, prospective, within-subject comparison designed to evaluate the performance and overall preference when using the new Osia 2 Sound Processor. All subjects were active users of the predicate device and fitted with the Osia 2 Sound Processor at the first visit.

The study consisted of 2 to 3 visits over a period of six (6) weeks. Data for the overall objectives was collected before and after 6 weeks of Osia 2 Sound Processor use. Device test order was randomised and each subject was compared to his/her own results.

The following variables were assessed:

- **Hearing performance:** Thresholds audiometry, free field at individual frequencies [0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0 and 8.0 kHz] and Pure Tone Average [PTA4, Mean of 0.5, 1, 2, and 4 kHz]; Speech in quiet [% correctly perceived words at 50dB, 65dB and 80dB SPL]; Adaptive speech in noise [speech-to-noise ratio, 50% speech understanding]
- **Self-reported assessment:** Speech, Spatial and Qualities of Hearing Scale (SSQ12); Abbreviated Profile of Hearing Aid Benefit (APHAB); Quebec User Evaluation of Satisfaction with assistive Technology (QUEST version 2); Comfort (VAS, 0-100%), Usage (magnet choice, battery life, SoftWear Pad use, safety line use, Wireless accessories and iPhone connectivity)
- **Preference:** choice between Osia 2 Sound Processor and predicate device
- **Safety:** Adverse Events, Device deficiencies

Effectiveness results

Audiometric Thresholds

Hearing performance with the Osia 2 Sound Processor was compared to that of the predicate sound procesor (Osia Sound Processor) using free-field thresholds audiometry. A statistically significant improvement in PTA4 was observed with the Osia 2 Sound Processor as compared to the predicate device.

Table 12 shows the change in free-field hearing thresholds with the Osia 2 Sound Processor at 6 weeks, for both individual frequencies and Pure Tone Average (PTA4; mean of 0.5, 1, 2 and 4 kHz) as compared to the predicate device.

Table 12: Aided hearing with the Osia 2 Sound Processor vs. predicate sound processor. Table shows the change in free field hearing thresholds (dB HL) for individual frequencies (0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6 and 8 kHz) and as the mean of 0.5, 1, 2 and 4 kHz (PTA4) for the total study population.

Free field thresholds (dB)	Predicate device (n=11)	Osia 2 Sound Processor (n=11)	Change from predicate device to Osia 2 Sound Processor	p-value
0.25 kHz	**41.4** (SD 7.4; 30.0 to 55.0)	**39.1** (SD 7.4; 30.0 to 55.0)	**-2.27** (SD 4.67; -10.0 to 5.0)	**0.23**
0.5 kHz	**31.4** (SD 5.5; 25.0 to 45.0)	**27.7** (SD 5.6; 15.0 to 35.0)	**-3.64** (SD 5.05; -10.0 to 5.0)	**0.078**
0.75 kHz	**22.7** (SD 5.2; 10.0 to 30.0)	**16.4** (SD 4.5; 10.0 to 25.0)	**-6.36** (SD 3.93; -15.0 to 0.00)	**0.0020**
1.0 kHz	**16.4** (SD 6.7; 5.0 to 25.0)	**12.7** (SD 7.5; 5.0 to 25.0)	**-3.64** (SD 3.93; -10.0 to 0.0)	**0.031**
1.5 kHz	**17.7** (SD 5.6; 5.0 to 25.0)	**14.1** (SD 4.9; 5.0 to 20.0)	**-3.64** (SD 5.95; -10.0 to 5.0)	**0.086**
2.0 kHz	**17.7** (SD 5.6; 5.0 to 25.0)	**15.9** (SD 4.9; 10.0 to 25.0)	**-1.82** (SD 3.37; -5.0 to 5.0)	**0.22**
3.0 kHz	**25.0** (SD 3.9; 20.0 to 30.0)	**20.9** (SD 4.4; 15.0 to 25.0)	**-4.09** (SD 3.75; -10.0 to 0.0)	**0.016**
4.0 kHz	**25.0** (SD 5.0; 20.0 to 35.0)	**24.1** (SD 4.9; 20.0 to 35.0)	**-0.909** (SD 5.39; -10.0 to 10.0)	**0.78**
6.0 kHz	**21.4** (SD 6.4; 15.0 to 35.0)	**16.8** (SD 6.0; 10.0 to 30.0)	**-4.55** (SD 4.16; -10.00 to 0.00)	**0.016**
8.0 kHz	**35.5** (SD 9.3; 20.0 to 50.0)	**33.6** (SD 15.0; 10.0 to 60.0)	**-1.82** (SD 14.71; -30.00 to 15.00)	**0.88**
PTA-4 (mean of 0.5, 1, 2, 4)	**22.6** (SD 3.8; 15.0 to 27.5)	**20.1** (SD 3.4; 15.0 to 25.0)	**-2.50** (SD 2.37; -6.25 to 1.25)	**0.012**

Mean (SD; range Min to Max; n= is presented)

Speech in Quiet and Noise

Both sound processors provided good and comparable hearing benefit with regards to speech recognition in quiet and adaptive speech in noise. No significant differences were seen when comparing the two Osia Sound Processors.

Self-reported assessment of hearing aid outcomes

The short form of 'Speech, Spatial, and Qualities of Hearing questionnaire' (SSQ-12) was used to measure self-reported auditory disability, reflecting the reality of hearing in the everyday world.

For the 'Abbreviated Profile of Hearing Aid Benefit' (APHAB) only the 'aided subscale' was assed (i.e. rating of the non-aided subscale was not assess in this study).

The 'Quebec User Evaluation of Satisfaction with assistive Technology' (QUEST version 2) questionnaire was used to collect information on subjects' preference regarding aesthetics, comfort, usage time and ease of use. Each item was scored using a 5-point scale ranging from 1 to 5, where: 1 (not satisfied at all), 2 (not very satisfied), 3 (more or less satisfied), 4 (quite satisfied), to 5 (very satisfied).

The questionnaires were answered at Visit 1 with respect to "pre-study experience" using the predicate device and at Visit 3 with respect to the past 6 weeks period using the Osia 2 Sound Processor alone without Wireless accessories.

No significant differences in SSQ scores were seen when comparing the two sound processors; however, when looking at the individual and mean values the Speech score was improved with the Osia 2 Sound Processor for all subjects except one (1) who had no change between Visit 3 and Visit 1, the Spatial score was improved for eight (8) subjects and decreased for three (3) subjects, the Quality score was improved for six (6) subjects, decreased for four (4) and remained unchanged for one (1). Finally, the Total score was improved for eight (8) subjects, deceased for one (1) and two (2) had no change.

A numerical improvement in APHAB scores was recorded for all four subscales and for the global score with the Osia 2 Sound Processor indicating an added benefit with the new sound processor over the predicate device.

Overall the subjects were "more or less satisfied" to "very satisfied" with all variables for both sound processors with an overall QUEST score of 4.61 (SD 0.40) for the Osia 2 Sound Processor and 4.38 (SD 0.36) for the predicate device. The two variables that improved the most with the new sound processor were 'Dimensions' and 'Effectiveness' (the degree to which the device meets the subject's needs).

Subjects' Overall Preference

Based on their subjective experience of the overall hearing performance together with the sound quality, aesthetics, comfort, and usability experience of the sound processors, the subjects were asked to state their preferred choice of sound processor. The subject should in relation to this final choice indicate what influenced his/her decision the most (several options possible):

Hearing performance, Sound quality, Aesthetic, Comfort and sound processor ease of use, Possibility to use Wireless accessories, Possibility of iPhone pairing, Other (free text)

All eleven (11) subjects chose the Osia 2 Sound Processor as preferred sound processor.

There was an even distribution between the factors influencing the choice, but the 'Possibility to use wireless accessories' was important for 10 of the 11 subjects and 'Sound quality' was important for the choice for eight (8) of the subjects.

Safety results

No serious adverse event (SAEs) or adverse event of special interest (AESIs) were reported.

One (1) adverse event (AE) was reported as related to the Osia 2 Sound Processor (skin irritation under the sound processor). The AE was resolved after five days of temporary non-use and adding a SoftWear pad to the sound processor.

Evaluation of the hearing performance of a new bone conduction hearing implant system using a simulation model

The substantial equivalence between the Osia 2 System (i.e. The Cochlear™ Osia™ OSI200 Implant and the Osia 2 Sound Processor) and the predicate device (i.e. The Cochlear™ Osia™ OSI100 Implant and Osia Sound Processor) was demonstrated in a single center, single-blinded, randomised, prospective clinical investigation using an Osia System Simulation model. This unique investigational design allows for "in-patient" comparison of the different generation Osia implants and sound processors, which would otherwise not be possible. The aim was to show non-inferiority of the Osia 2 System to the predicate device.

The study included twenty (20) adult Bone conduction hearing implant recipients with conductive hearing loss (CHL; n=10) or mixed hearing loss (MHL; n=10).

The following variables were assessed:

- **Hearing performance:** Thresholds audiometry, free field at individual frequencies [0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0 and 8.0 kHz] and Pure Tone Average [PTA4, Mean of 0.5, 1, 2, and 4 kHz]; Speech in quiet [% correctly perceived words at 50dB, 65dB and 80dB SPL]; Adaptive speech in noise [speech-to-noise ratio, 50% speech understanding].
- **Subjective rating of sound:** e.g. loudness, sound quality, speech understanding, own voice, artefacts and feedback after listening to sound clips.

Effectiveness results

Hearing performance with the Osia 2 System compared to predicate device

Audiometric Thresholds

Hearing performance with the Osia 2 System was compared to that of the predicate device using free-field thresholds audiometry. No differences between the systems were seen in terms of PTA4 (mean of 0.5, 1, 2 and 4 kHz); however, when looking at the individual frequencies the Osia 2 System was significantly better at 0.25 and 0.75 kHz, but worse at 4 and 6 kHz compared to the predicate device.

Table 13: Aided hearing with the Osia 2 System vs. predicate device (OSI200 + Osia 2 SP vs OSI100 + Osia SP). Table shows the change in free field hearing thresholds (dB HL) for individual frequencies (0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6 and 8 kHz) and as the mean of 0.5, 1, 2 and 4 kHz (PTA4) for the total study population.

Free field thresholds (dB)	Predicate device (n=20)	Osia 2 System (n=20)	Change Osia 2 System vs predicate device	p-value
0.25 kHz	**45.8** (SD 9.2; 30.0 to 65.0)	**42.5** (SD 10.5; 20.0 to 60.0)	**-3.25** (SD 4.94; -15.0 to 5.0)	**0.01**
0.5 kHz	**37.0** (SD 9.1; 20.0 to 55.0)	**37.3** (SD 9.5; 10.0 to 55.0)	**0.25** (SD 6.78; -20.0 to 10.0)	**1.00**
0.75 kHz	**28.0** (SD 7.7; 15.0 to 45.0)	**25.5** (SD 7.4; 15.0 to 45.0)	**-2.50** (SD 3.44; -10.0 to 0.0)	**0.008**
1.0 kHz	**25.5** (SD 7.4; 15.0 to 45.0)	**24.8** (SD 9.4; 10.0 to 45.0)	**-0.750** (SD 5.91; -15.0 to 10.0)	**0.60**
1.5 kHz	**27.0** (SD 9.2; 15.0 to 50.0)	**25.5** (SD 11.1; 10.0 to 50.0)	**-1.50** (SD 6.30; -15.0 to 10.0)	**0.32**
2.0 kHz	**30.8** (SD 8.8; 20.0 to 45.0)	**29.0** (SD 9.7; 10.0 to 45.0)	**-1.75** (SD 5.45; -15.0 to 5.0)	**0.18**
3.0 kHz	**31.8** (SD 9.5; 15.0 to 50.0)	**32.5** (SD 11.8; 15.0 to 55.0)	**0.750** (SD 6.54; -20.0 to 15.0)	**0.74**
4.0 kHz	**34.3** (SD 10.5; 20.0 to 50.0)	**41.5** (SD 14.5; 25.0 to 65.0)	**7.25** (SD 6.97; -5.0 to 25.0)	**0.0001**
6.0 kHz	**37.8** (SD 14.9; 10.0 to 60.0)	**41.0** (SD 17.1; 20.0 to 65.0)	**3.25** (SD 6.34; -5.0 to 15.0)	**0.037**
8.0 kHz	**57.5** (SD 19.0; 20.0 to 85.0)	**58.8** (SD 14.4; 35.0 to 75.0)	**1.25** (SD 10.5; -30.0 to 15.0)	**0.69**
PTA-4 (mean of 0.5, 1, 2, 4)	**31.9** (SD 7.5; 21.3 to 47.5)	**33.1** (SD 9.4; 13.8 to 50.0)	**1.25** (SD 4.42; -11.3 to 7.5)	**0.022**

Mean (SD; range Min to Max; n= is presented)

Speech in Quiet and Noise

Both provided good and comparable hearing benefit with regards to speech recognition in quiet and adaptive speech in noise; hence the Osia 2 System fulfills the non-inferiority criteria (Table 14).

Table 14: Aided hearing with the Osia 2 System vs. predicate device Table shows the change in speech-to-noise ratio and speech in quiet for the total population

Variable	Predicate device (n=20)	Osia 2 System (n=20)	Change Osia 2 System vs predicate device	p-value
Adaptive speech in noise * SNR 50% performance	**-3.61** (SD 1.75; -5.8 to 0.4)	**-3.24** (SD 2.25; -5.9 to 1.4)	**0.370** (SD 1.09; -1.7 to 2.9)	**0.15**
Speech in quiet % recognition at 50dB	**46.2** (SD 29.3; 0.0 to 88.0)	**44.0** (SD 32.5; 0.0 to 92.0)	**-2.20** (SD 17.53; -36.0 to 28.0)	**0.59**
Speech in quiet % recognition at 65dB	**86.0** (SD 11.8; 64.0 to 100.0)	**80.9** (SD 17.7, 32.0 to 96.0)	**-5.06** (SD 11.19; -36.0 to 8.0)	**0.052**
Speech in quiet % recognition at 80dB	**92.0** (SD 8.4; 72.0 to 100.0)	**92.2** (SD 8.9; 72.0 to 100.0)	**0.20** (SD 7.28; -12.0 to 16.0)	**0.93**

Mean (SD; range Min to Max; n= is presented)
** negative value = improvement*

Subjective Rating of Sound

For 'Sound Quality'; 'Internal noise'; 'Artefacts'; 'Feedback'; 'Voice clarity' and 'Loudness' there was no significant difference between the Osia 2 System and the predicate device. The only difference was seen for the test 'Quiet conversation' where the Osia 2 System was regarded as being softer than the predicate device (p=0.016).

Safety results

No adverse events or device deficiencies were reported.

Evaluation of the safety and effectiveness of the Cochlear™ Osia® 2 System in a pediatric population

Summary of study methods

A pivotal, prospective, multi-centre, open-label study was conducted to evaluate the safety and effectiveness of the Cochlear Osia 2 System in a group of 50 pediatric participants aged 5 to 11 years who suffer from conductive or mixed hearing loss (up to 55 dB HL), or single-sided deafness (SSD).

Study demographics

Demographic information is summarised below:

- **Age:** All participants were aged between 5 and 11, with an average age of 7.4 years.
- **Gender:** 23 (46%) were females and 27 (54%) were males.
- **Onset of hearing loss:** The average age of onset of reported hearing loss was 0.4 years (test ear) and 0.3 years (contralateral ear) and ranged from 0 to 8 years (test ear) and 0 to 2 years (contralateral ear).
- **Hearing loss type:** 13 (26%) participants reported sensorineural hearing loss, 35 (70%) reported conductive hearing loss, and 2 (4%) reported mixed hearing loss in the test ear.
- **History of hearing loss:** 4 (8%) participants reported congenital hearing loss with progression, 40 (80%) participants reported congenital hearing loss without progression, 4 (8%) participants reported progressive hearing loss, and 2 (4%) participants reported sudden hearing loss in the test ear.
- **Primary cause of hearing loss:** the reported primary cause of hearing loss is listed below for all participants:
  - Atresia: 25 (50%) participants
  - Cholesteatoma: 1 (2%) participant
  - Chronic Otitis Media: 1 (2%) participant
  - Genetic: 2 (4%) participants
  - Microtia: 3 (6%) participants
  - Other: 12 (24%) participants
  - Unknown: 6 (12%) participants.

Reported safety events

The primary endpoint reported adverse events and serious adverse events from surgery through six months postoperatively. The information below summarises the events by type, frequency and severity.

A total of 110 adverse events were reported across 35 participants in this dataset:

- 8 AEs were reported as related to the device;
- 22 AEs were reported as related to the procedure;
  - 2 of the procedure-related adverse events also met criteria and were reported as serious adverse device effects (SADEs).
- 8 AEs met criteria and were reported as serious adverse events (SAEs) unrelated to the device or procedure.

All SAEs and those events related to the device or procedure were resolved at the time of database lock. Three events unrelated to the procedure or device were either unresolved or had an unknown status for this dataset and occurred for participants still participating in the study.

There were no unanticipated adverse device effects (UADEs) reported in the study.

The procedure-related events can be further broken down into categories: related to the Osia procedure (n=12), related to anaesthesia (n=7), and related to a comorbidity (n=3). All procedure-related events occurred within 45 days of the procedure. The two SADEs were as follows:

1. Hematoma: 5-year-old female was brought to urgent care six days post-implantation for swelling over the implant site. Noted fluid collection around the implant with no sign of infection, and the wound was intact. Fluid was drained. The patient was admitted to the hospital for two days. The event resolved 10 days after urgent care visit.
2. Laryngospasm/bronchospasm: 5-year-old male experienced a laryngospasm and bronchospasm upon extubating after the procedure. Anaesthesia was called stat into the room, and the patient received propofol and epinephrine IVs, and placed on 60 mm of positive pressure. With this the patient responded, laryngospasm subsided, and the patient woke up without problems. The patient was discharged home the same day.

Safety of the surgical procedure and use of the Osia 2 System were demonstrated by analysis of the type, frequency and severity of the reported events. The data demonstrates that the reported events related to the device or procedure are consistent with Osia implantation in patients 12 years and older and implantation with the Osia implant deemed safe in children ages 5-11.

Reported safety data from simultaneous ear reconstructions

Of the 50 participants implanted in the study, 7 underwent simultaneous ear reconstruction with Osia implantation. Of those 7 participants, 3 underwent a single-stage approach using a porous polyethylene implant and 4 underwent a two-stage approach using rib cartilage. No complications were reported during any of these procedures.

Following the procedure, 2/3 of the participants who received the single-stage porous polyethylene implant experienced known complications to the porous polyethylene implant device (wound dehiscence and pressure injury) which required an additional procedure to repair. These events were classified as serious adverse events (SAEs) due to the need for further surgical intervention and hospitalisation; however, they were categorised as moderate in severity. The events were resolved without any further complications from the additional procedures.

The third participant who received the porous polyethylene implant experienced severe allergic contact dermatitis that was possibly related to the ointment prescribed for use with the porous polyethylene implant. This participant had a documented medical history of atopical dermatitis. The participant was hospitalised out of an abundance of caution to treat the allergic reaction, which met criteria to be classified as an SAE. This event resolved without any further complications. In all 3 participants, the Osia implant was not affected as a result of these complications.

The 4 participants who received a two-stage approach using rib cartilage did not have any post-operative complications.

Current literature describes the risks and complications associated with ear reconstruction procedures either using a single-stage or two-stage approach. Wang, et al,[1] examined 150 patients ages 6-17 years who received a porous polyethylene implant auricle reconstruction between 2017 and 2019. They found that 16.67% of patients experienced a stent exposure and 2.67% of patients experienced skin collapse.

Reported device deficiencies

19 device deficiencies were reported across 14 participants. There were no device deficiencies reported that led to an adverse event or could have led to a serious adverse device effect. 8 participants experienced a device deficiency with the external Osia 2 Sound Processor that required the device to be replaced. Additionally, 9 participants reported losing their external Osia 2 Sound Processor during the course of the study. The study data shows no adverse effect on performance due to the gap in time of use each participant experienced while waiting to be fit with a replacement processor.

[1] *Wang, M., Xiao, Z., Huang, M., Xie, J., & Liu, G. Clinical effect evaluation and complication analysis of different auricle reconstruction of congenital microtia. Am J Transl Res. 2021;13(12):13877-13885.*

Summary of effectiveness endpoint data

The effectiveness data collected in this study included comparisons of:

- Preoperative SSQ Parental Questionnaire (baseline) compared to postoperative (six months) score using the Osia 2 System
- Preoperative unaided bone conduction thresholds averaged across 0.5, 1, 2 and 3 kHz (PTA4), i.e., baseline compared to postoperative (four weeks) unaided bone conduction thresholds
- Preoperative unaided speech perception in quiet, using CNC words (baseline) compared to postoperative (six months) performance using the Osia 2 System
- Preoperative unaided speech perception in adaptive noise, i.e., BKB-SIN (baseline) compared to postoperative (six months) performance using the Osia 2 System

The results are summarised in the table below. For both the four-week and six-month visit, data was available from 48 participants.

Table 15: Summary of effectiveness data for the Cochlear™ Osia® 2 System in a pediatric population

Effectiveness endpoints	Data	Mean change	Result
Secondary endpoint #1	SSQ Parental Questionnaire	**1.63** (95% CI: 1.18 to 2.07)	Significant clinically meaningful improvement on the questionnaire.
Secondary endpoint #2	Unaided bone conduction PTA	**0.1 dB** (95% CI: -1.3 to 1.6)	The change from baseline to 4-weeks is not clinically meaningful which shows that the surgery does not pose any additional risk to the participants' bone line
Secondary endpoint #3	Speech perception in quiet (CNC)	**63.7%** (95% CI: 56.6 to 70.9)	Significant clinically meaningful improvement of speech perception in quiet (CNC)
Secondary endpoint #4	Speech perception in adaptive noise (BKB-SIN)	**10.1 dB SNR** (95% CI: 7.9 to 12.4)	Significant clinically meaningful improvement of speech perception in adaptive noise (BKB-SIN)

For each endpoint, results were found to be similar for each age group (5-7 and 8-11 years) and for each hearing loss type (conductive/mixed and SSD).

Discussion and conclusion

Results from this study show that the Osia System is a safe and effective treatment for children ages 5-11 years old. Effectiveness was shown through both patient-reported outcomes by the participants' parents and through improved speech intelligibility in both quiet and noise. Safety was demonstrated through the reports of adverse events related to the device and procedure being similar to those experienced by the current indicated population with this device.

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