Registration of the implant

Register your patient’s Osia® implant today and allow your patients to stay connected with Cochlear.

Why it’s important to register patients:

• Activates the recipient’s service warranty
• Will allow recipients to receive updates about new Cochlear products, exclusive promotions
• Notice of upcoming events and receive service and repair support
• Gives recipients the opportunity to activate a Cochlear Family membership

Registration card

Please fill out the Registration Card and send it by mail. It is included in the Implant Clinic Docupack, in the box that is sent directly to the OR for surgery.

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.

You can also register your patients online at: https://secure.mycochlear.com. If you don’t have an account you can request access on the link above, click on the access form and fill out the form.

Patient identification card

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

- Osscora Drill Components
- Osscora Handpiece Assembly
- Osscora Drill Quick Guide
- Osscora Drill Errors
ALL OSSCORA SURGICAL SETS ARE DELIVERED WITH THE FOLLOWING COMPONENTS:

- Control unit 115 Volts
- Foot control S-N1
- Motor with 3.5 m cable, includes:
  - Motor protective cover
  - Osscora contra-angle handpiece
- Medical grade power supply
- Irrigation tubing set (6 pcs) and stand

OSSCORA ACCESSORIES

The following Sterilization Cassette can be ordered as an accessory to the Osscora surgical set:

OSSCORA SPARE PARTS

NOTE

The following articles can be ordered as spare parts for the Osscora surgical set:

INSTRUMENT ORGANIZER

OSSCORA ACCESSORIES

Handpiece Assembly

Contra-angle handpiece

- The handpiece consists of 5 pieces. To ensure proper assembly follow the steps below.
- Orient all the pieces so you can read the numbers and align them in a row.

STEP ONE

Insert the Middle gear into Contra-angle head until it engages (“clicks”). Rotate Middle gear to ensure it’s engaged to the head. (Once both pieces are engaged the Chuck head must turn also. Figure A)

STEP TWO

Insert the Knee into the Contra-angle head until it engages. (Four positions are possible, but the image shown below is the preferred connection.)

STEP THREE

Put the Shaft into the Knee.
- Make sure the tiny metal peg on the Shaft fits into the notch of the Knee.

STEP FOUR

Align pins on Knee with slots on Sheath. Press the Sheath firmly against the Knee.

STEP FIVE

Twist clockwise until it engages.

NOTE

For cleaning and sterilization of the Osscora Handpiece and motor with cable, see the Osscora Cleaning and Sterilization Quick Guide.
OSSCORA FOOT CONTROL
- Pump ON/OFF
- Change programs 1-3
- Change motor direction Forward/Reverse rotation (Factory Setting=Variable)
- Start Motor VARIABLE or ON/OFF

OSSCORA SETTINGS

**SPEED**
The speed is adjusted by using the buttons when using program 1 and 2.

**TORQUE**
The torque is adjusted by using the buttons when using the program.

**CAUTION:**
The clinical situation must be taken into consideration when choosing the settings.

OSSCORA SURGICAL SET QUICK GUIDE

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>PROGRAM</th>
<th>DISPLAY</th>
<th>COOLING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drilling*</td>
<td>2</td>
<td>2000 rpm</td>
<td>YES</td>
</tr>
<tr>
<td>Implant Installation</td>
<td></td>
<td>40-50 Ncm</td>
<td>YES, after two turns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20-30 Ncm</td>
<td>YES, after two turns</td>
</tr>
<tr>
<td>Reverse</td>
<td></td>
<td></td>
<td>YES</td>
</tr>
</tbody>
</table>

OSSCORA ERROR MESSAGES

<table>
<thead>
<tr>
<th>ERROR NO.</th>
<th>DESCRIPTION</th>
<th>REMEDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>Electronics overheating-safety shutdown</td>
<td>Switch off the equipment, allow to cool for at least 10 minutes, then restart</td>
</tr>
<tr>
<td>01</td>
<td>Electronics overloaded</td>
<td>Switch off the equipment and restart</td>
</tr>
<tr>
<td>07</td>
<td>Foot control error - initializing</td>
<td>Switch off the equipment, restart, do not actuate foot control when switching on</td>
</tr>
<tr>
<td>09</td>
<td>Foot control error</td>
<td>Switch off the equipment, check connection of the foot control, and then restart</td>
</tr>
<tr>
<td>19</td>
<td>Run limiting control</td>
<td>Switch off the equipment and restart</td>
</tr>
<tr>
<td>99</td>
<td>System failure</td>
<td>Switch off the equipment and restart</td>
</tr>
<tr>
<td>09</td>
<td>Motor temperature too high</td>
<td>Switch off the equipment, allow motor to cool for at least 10 minutes, then restart</td>
</tr>
<tr>
<td>09</td>
<td>Motor connection-safety shutdown</td>
<td>Switch off the equipment, check motor connection, then restart</td>
</tr>
</tbody>
</table>

RESET FACTORY SETTINGS:

- Factory setting
- Always starts with program 1 (P1)
- Switch off the control unit. Keep P1 pressed and simultaneously switch on the control unit. Keep P1 pressed as long as “DE FAU” appears on the display.

If one of the error messages described above cannot be rectified by switching off the Osscora surgical set and then switching it on again, the equipment must be checked by a service agent. For contact details, please contact your local Cochlear office or your local Cochlear representative.

If a total failure of the equipment occurs caused by external circumstances, the equipment must be switched off and then on again.
Osia Surgical Procedure

The surgical procedure described in this guide is only one approach to implanting the Osia OSI200 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 Components on page 12.
Surgical Instruments and Components

**REUSABLE ITEMS**

FZU1099 - Osia® Instrument Set
The set includes instruments to the right. The instruments can also be ordered individually.

- 91116 Drill Indicator for WS-75 and Osicoe
- 92142 Implant Inserter
- P146090 Bone Bed Indicator 17mm
- 90381 Mainscrew Screwdriver Ungo 25mm
- 90469 Suction Tip 35mm
- 92143 Multi Wrench & ISO Adapter
- 90944 Raspatorium
- 90943 Drill Indicator

**DISPOSABLE ITEMS - ONE TIME USE ONLY**

- 93363 Conical Guide Drill 3 x 4mm
- 92140 Widening Drill 3mm with Countersink
- 92141 Widening Drill 4mm with Countersink

**Drills**

**NOTE**
The conical guide drill has a removable spacer for drilling to different depths.

**OSI200 - Implant Template**

**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.

- P1291019 OSI200 Implant Template

**Images are not to scale**

*ISO Adapter can be ordered separately, the part number is 92347.

**OSIA Surgery Guide**

**ADDITIONAL ITEMS NEEDED**

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/haematost and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution / patient preparation solution
- Saline (for irrigation)
- Sterile drapes in various sizes
- Basic ear instrument set
- Scalpel blades

- Suction tubing and tip
- Gauze swabs
- Suture material
- Antimicrobial ointment for dressing
- Self-retaining retractor
- High speed otologic drill for bone polishing
- Thin, hypodermic needle
- Clamp
- Ruler
- Periosteal elevator

Possible Mayo Stand set-up with Baha surgical instruments and additional instruments.
STEP ONE

PREPARATION OF IMPLANT SITE

Position of the OSI200 Implant and sound processor

The OSI200 Implant position is most optimal with the actuator close to and in horizontal line with the ear canal or slightly superior without touching the pinna (Fig. 1). 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.

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. 2, Fig. 3).

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.

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. 4).

STEP ONE – CONT.

PREPARATION OF IMPLANT SITE

Preparation

- Prepare the patient as for any craniofacial surgical procedure.
- Use the OSI200 Implant template to plan the correct position and mark it on the skin (Fig. 5).
- 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.
- Before local anesthesia is injected, measure the soft tissue thickness by using a thin hypodermic needle, a clamp (Fig. 6) and a ruler (Fig. 7).

Measurement points should be distributed over the coil area (Fig. 8). Do not depress the tissue when measuring.

The transmitting range of the OSI200 Implant is 1 mm to 10 mm. However, a maximum skin flap thickness of 9 mm over the coil area is required for good magnet retention.

Take patient hair and potential use of optional Cochlear SoftWear™ Pad into consideration when determining if soft tissue thinning is needed.
STEP ONE – CONT.
PREPARATION OF IMPLANT SITE

EXAMPLE OF INCISION OPTIONS

- Figures 9-11 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 10-15 mm distance between the incision and the edge of the implant to avoid tension on the skin and possible complications later on.

STEPS TWO
COIL POCKET CREATION AND INCISION

Coil pocket options

A. OSI200 Implant placement in periosteal pocket
   - Making the incision down and through the periosteum allows for a subperiosteal coil pocket. This will give the possibility for a tighter fit of the periosteum over the implant.

B. OSI200 Implant placement lateral to periosteum
   - Making the incision down to but not through the periosteum allows for a coil placement lateral to the periosteum.
   - In the event that the skin flap is outside of surgical recommendations, this will allow easier thinning of the skin flap.

Incision

- Before making the incision, the incision line may be infiltrated with local anesthetic.
- Make the incision as planned with the pocket creation in mind.
- Create the pocket for the coil using blunt dissection. Keep the pocket tight.
- Check with the OSI200 Implant template if the pocket size is suitable and if the actuator position is according to plan (Fig. 12).
**Preparation for BI300 Implant placement**

- 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. In that case, clear away the periosteum to allow for bone polishing.
- 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**

- Insert the guide drill on the handpiece to start drilling with the guide drill and 3 mm spacer (already on the drill bit).
- 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. 13).
- Be certain to drill at an angle perpendicular to the bone surface to minimize the need for bone polishing later in the procedure.
- While drilling, move the drill perpendicular up and down to ensure that irrigation reaches the tip of the drill.
- Check the bottom of the site repeatedly for bone, both visually and with a suitable instrument. Avoid penetrating the wall of the sigmoid sinus or damaging the dura mater.
- If there is adequate bone thickness, remove the white spacer on the guide drill and continue drilling to a depth of 4 mm. (Fig. 14).

**Drill with the widening drill**

- Change the guide drill for the widening drill on the handpiece. (Press the button at the top of the head of the handpiece to remove the guide drill.)
- Widen the site with the relevant widening drill 3 mm or 4 mm at 2000 rpm.
- Drill perpendicular with an up and down movement to ensure irrigation can sufficiently cool the bone during drilling (Fig. 15).
- Minimize the countersink depth to avoid unnecessary bone polishing later in the procedure.

**BI300 Implant placement**

Inside of the sterile product box of the implant, there is a peel-open pack with a plastic ampule. (This is only a container for the sterile product.) Inside the plastic ampule, a titanium casing holds the product (Fig. 16). The product should not be touched but rather picked up with the relevant instrument.

- Open the ampule upright by unscrewing the lid so the bottom section can be placed in a suitable holder on a tray.
- The implant must not come in contact with anything other than the ampule and abutment inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.
- Change the widening drill on the handpiece to the implant inserter.
- Set the drill unit to a torque setting that suits the quality of the bone (program implant installation for the Osscora surgical set). If unsure of the bone quality, begin with a lower torque setting and gradually increase.

<table>
<thead>
<tr>
<th>Bone quality</th>
<th>Suggested torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compact bone</td>
<td>40-50 Ncm</td>
</tr>
<tr>
<td>Compromised or soft bone</td>
<td>20-30 Ncm</td>
</tr>
</tbody>
</table>
STEP THREE – CONT. BI300 IMPLANT PLACEMENT

• Pick up the BI300 Implant using the implant inserter (Fig. 17). Using any other instrument could damage the BI300 Implant inner threads.

• With the drill indicator in place, insert the implant at an angle perpendicular to the bone surface.

• Place the implant without coolant until the first threads of the implant are well within the bone (two rotations). Once in the bone, continue placement with irrigation (Fig. 18).

• Carefully remove the Implant inserter vertically from the implant.

OSIA SURGERY GUIDE

STEP FOUR OSI200 IMPLANT PLACEMENT

Checking for clearance

• 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. 19). This will allow sufficient clearance for the correct mounting of the OSI200 Implant.

• 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 until the bone bed indicator can be rotated 360° clockwise without applying force.

• 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.
STEP FOUR – CONT. OSI200 IMPLANT PLACEMENT

Preparation and insertion of the OSI200 Implant

- 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.

- Open up the sterile packaging (Fig. 20).

- Use the screwdriver unigrip 95 mm to pick up the fixation screw from the implant blister pack using minimal force. While still in the blister pack, carefully screw the fixation screw into the actuator until it is fully seated (Fig. 21).

- Carefully remove the OSI200 Implant from the blister pack 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.

- Place the center of the actuator on top of the BI300 Implant and gently hand-tighten the fixation screw with the screwdriver, while holding the actuator in place with your fingers (Fig. 22).

- Continue to tighten to 25 Ncm with the Machine screwdriver Unigrip and the Multi wrench with the ISO adapter, while holding the actuator in place or stable with your fingers (Fig. 23).

STEP FIVE CLOSURE

- 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.

- Apply a pressure dressing for at least 24 hours (Fig. 24).

NOTE
Remember to complete the registration form and allow your patient’s to stay connected with Cochlear.
Post-operative Management

- Post-operative management
- Removing or replacing the magnet
- Removing the magnet before implantation
- Removing the magnet after implantation
- Inserting a replacement magnet
Explanting the implant

In rare circumstances, it may be necessary to explant an Osia OSI200 Implant. Please follow the steps below.

- Inform your local Cochlear representative and contact Cochlear to order a Cochlear Nucleus® Retrieved Medical Device kit. The kit must be used to transport the explanted device to Cochlear.
- Read the instructions provided with the kit.
- Before explanting the device, examine it for any defects. Note these on the form provided with the kit.
- Try to keep the explanted device intact and undamaged.
- Disconnect the actuator unit from the BI300 Implant using the screwdriver UniGrip 95 mm or the Multi Wrench with ISO adapter and Machine screwdriver UniGrip 25 mm.
- If osseointegrated, the BI300 Implant can remain in place. Only remove it if absolutely necessary. If leaving in place, connect a new Osia OSI200 Implant, or place a cover screw to protect the internal threads of the implant.
- Return the kit containing the explanted device to the Cochlear address nearest you. The applicable addresses can be found in the Retrieved Medical 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 immediately.
REMOWING OR REPLACING THE MAGNET

For Osia OSI200 Implant recipients requiring a single MRI examination or multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug.

In the magnet’s absence, the plug prevents fibrous tissue growing into the recess. Such growth would make magnet replacement difficult. When there is no further need for MRI examinations, the non-magnetic plug is removed, and a replacement magnet is inserted.

The non-magnetic plug and replacement magnet are supplied separately in sterile packs (Fig. 26, Fig. 27). Both are single-use items.

WARNING
Do not leave the magnet pocket empty. When removing the implant magnet, replace the magnet with a sterile non-magnetic plug.

All replacement procedures should take place under sterile conditions.

CAUTION
When removing or inserting a magnet or non-magnetic plug:
• Take care not to 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 is removed, the recipient must wear a retainer disc to hold the sound processor in place. Retainer discs are available from Cochlear.

MRI safety information

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.

WARNING
Do not leave the magnet pocket empty. When removing the implant magnet, replace the magnet with a sterile non-magnetic plug.

All replacement procedures should take place under sterile conditions.

CAUTION
When removing or inserting a magnet or non-magnetic plug:
• Take care not to 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 is removed, the recipient must wear a retainer disc to hold the sound processor in place. Retainer discs are available from Cochlear.
REMOVING THE MAGNET AFTER IMPLANTATION

For recipients requiring a single or multiple MRI examinations after implantation, remove the magnet and insert a non-magnetic plug. Perform the procedure in sterile conditions, using either general or local anesthetic.

• Make a small incision (Fig. 28) outside of the coil area with good access to the magnet pocket.
• Cut through any fibrous growth around the implant and expose the magnet.
• Using an elevator or similar instrument, carefully lift the lip of the silicone elastomer recess across the magnet, move the suture out of the way.
• Remove the sterile non-magnetic plug from its packaging. Lift the lip of the recess using an elevator and press the non-magnetic plug (Fig. 26) into position. Be careful not to exert undue pressure on the implant.
• The Osia OSI200 Implant is now ready for implantation. Follow the surgical steps described earlier in this guide.

When there is no further need for MRI examinations, remove the non-magnetic plug and insert a replacement magnet following the steps in Inserting a replacement magnet on page 32.

REMOVING THE MAGNET BEFORE IMPLANTATION

For recipients requiring repeated MRI examinations in the foreseeable future, it may be appropriate to replace the magnet with a non-magnetic plug (available from Cochlear) before implantation of the OSI200 Implant.

• In sterile conditions, remove the Osia OSI200 Implant from its sterile packaging and place it on a flat and stable surface, with the grey ring (denoting polarity) facing up (Fig. 27).
• Using an elevator or similar instrument, lift the lip of the silicone elastomer recess around the magnet and remove the magnet from the implant. When removing the magnet, minimize the pressure applied to the implant coil.
• Remove the sterile non-magnetic plug from its packaging. Lift the lip of the recess using an elevator and press the non-magnetic plug (Fig. 26) into position. Be careful not to exert undue pressure on the implant.
• The Osia OSI200 Implant is now ready for implantation. Follow the surgical steps described earlier in this guide.

When there is no further need for MRI examinations, remove the non-magnetic plug and insert a replacement magnet following the steps in Inserting a replacement magnet on page 32.

FIG. 28  Suggested incision area
When MRI is no longer a regular necessity, remove the non-magnetic plug and insert a replacement magnet. Perform the procedure in sterile conditions, using either general or local anesthetic.

- Make a small incision (Fig. 29) outside of the coil area with good access to the magnet pocket.
- Cut through any fibrous growth around the implant and expose the non-magnetic plug.
- Using an elevator or similar instrument, carefully lift the lip of the silicone elastomer recess and remove the non-magnetic plug. If a retaining suture runs across the plug, move the suture out of the way.
- Remove the sterile replacement magnet from its packaging. Use the elevator to lift the lip of the recess and press the replacement magnet with the grey ring (denoting polarity) facing up (Fig. 26) into position, keeping in mind that the silicone lip retains the replacement magnet. Be careful not to exert undue pressure on the implant. Non-magnetic instruments may be useful.
- Close the wound in layers.

For additional information about magnet removal, contact Cochlear.
Awareness

• BI300 Implant Compatibility Guide
• How to attach the fixation screw to the OSI200 Implant
• How to use the Multi Wrench
OSIA

BI300 IMPLANT COMPATIBILITY GUIDE

OSI200 IS ONLY COMPATIBLE WITH THE BI300 SERIES IMPLANT.

TRI-LOBE SHAPE CONNECTION FROM OSI200 FIXATION SCREW TO IMPLANT

HEXAGONAL SHAPE CONNECTION FROM ABUTMENT TO IMPLANT

IMAGE OF THE TOP OF THE OSI200 IMPLANT

IMAGE OF THE TOP OF THE 200 SERIES IMPLANT

HOW TO ATTACH THE FIXATION SCREW TO THE OSI200 IMPLANT

• Open up the sterile packaging (Fig. 30) 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 OSI200 Implant to the BI300 Implant.

• Use the screwdriver UniGrip 95 mm to pick up the fixation screw from the implant blister pack using minimal force.

• While still in the blister pack, carefully screw the fixation screw into the actuator until it is fully seated (Fig. 31).

FIG. 30 Packaging of the OSI200 Implant

FIG. 31 Attaching the fixation screw to the OSI200 Implant

ATTACHING THE FIXATION SCREW TO THE OSI200 IMPLANT

AWARENESS
HOW TO USE THE MULTI WRENCH

• Tightening of abutment screw to 25 Ncm using the Multi Wrench (“IN” facing upwards) and the machine screwdriver Unigrip 25 mm.

• Insert the ISO adapter in the multi wrench and then insert the machine Unigrip screwdriver in the ISO adapter.

• The multi wrench torque limit is 25 Ncm.

• Manual insertion of implant during surgery with implant inserter. Rotate the whole Multi Wrench shaft clockwise (“IN” facing upwards).
As your patient’s partner in hearing for life, Cochlear believes it is important to convey not only the benefits, but also the potential risks associated with a procedure. Not everyone with hearing loss is a candidate for a System. The Osia System is contraindicated for patients with:

- Insufficient bone quality or quantity to support implantation of both the BI300 Implant and the OSI200 Implant
- Chronic or non-reversible 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

All surgical procedures include an element of risk, and it is impossible to guarantee success. The device may fail to osseointegrate for a number of reasons, including physiological and surgical issues as well as traumatic impact to the implant site. For complete information regarding the risks and benefits of a procedure, please refer to the Instructions For Use.

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As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 600,000 implantable devices, helping people of all ages to hear and connect with life’s opportunities.

We aim to give people the best lifelong hearing experience and access to innovative future technologies. We collaborate with leading clinical, research and support networks.

That’s why more people choose Cochlear than any other hearing implant company.