EN-CA ENGLISH

Cochlear®

Cochlear™ Osia® OSI200 Implant
Surgical Quick Guide

FOR PROFESSIONALS

Surgical checklist

Product Code	Implants	Product image	Availability Yes	No
P1170466	OSI200 Implant		☐	☐
92128	BI300 Implant 3 mm		☐	☐
92129	BI300 Implant 4 mm		☐	☐

Product Code	Single use instruments (sterile)	Product image	Availability Yes	No
OSI200 Implant specific				
P1291019	OSI200 Implant template		☐	☐
BI300 Implant specific				
93363	Conical guide drill 3+4 mm		☐	☐
92140	Widening drill 3 mm with countersink		☐	☐
92141	Widening drill 4 mm with countersink		☐	☐

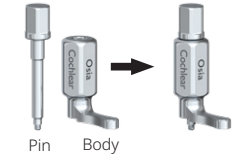
Backup products and additional surgical instruments necessary for Osia OSI200 Implant surgery:

Backup products

- Backup OSI200 Implant (P1170466)
- Backup BI300 Implant 4 mm (92129) or
- Backup BI300 Implant 3 mm (92128)
- Backup Conical guide drill 3+4 mm (93363)
- Backup Widening drill 4 mm with countersink (92141) or
- Backup Widening drill 3 mm with countersink (92140)

Additional instruments

- High speed otologic drill for bone polishing
- Thin, hypodermic needle
- Clamp
- Ruler
- Periosteal elevator

Product Code	Reusable instruments	Product image	Availability Yes	No
OSI200 Implant specific				
P1469690	Bone bed indicator 17 mm		☐	☐
BI300 Implant specific				
90469	Screwdriver unigrip 95 mm		☐	☐
92143 / C9866	Multi wrench with ISO adapter		☐	☐
90381	Machine screwdriver unigrip 25 mm		☐	☐
92142 / P1582230	Implant inserter		☐	☐
91116	Drill indicator		☐	☐
Drilling equipment				
	Drill unit		☐	☐

Product Code	Accessories (sterile)	Product image	Availability Yes	No
P1620873	Sterile Replacement Magnet		☐	☐
P1620901	Sterile Non-Magnetic Plug		☐	☐
92136	Cover screw conical		☐	☐

1. 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.

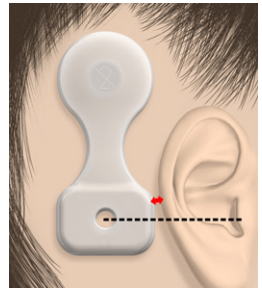


Fig.1: Optimal OSI200 Implant placement

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*).

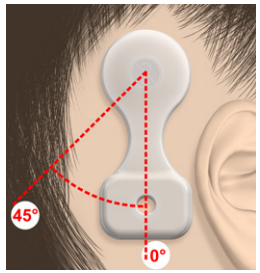


Fig.2: Actuator positioning options

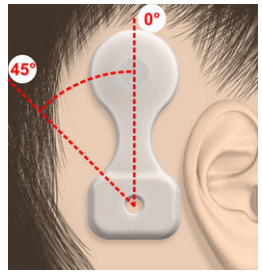


Fig.3: Coil positioning options

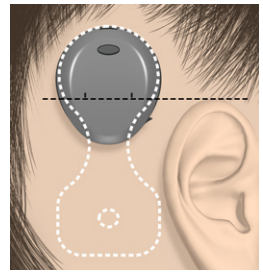


Fig.4: Sound processor placement

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.5*).
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.
4. Before local anaesthesia 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.

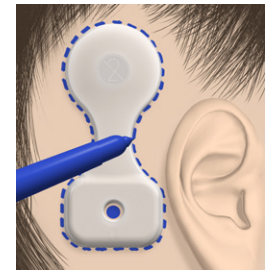


Fig.5: Marking of OSI200 and BI300 Implant

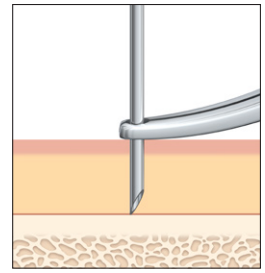


Fig.6: Measuring the skin thickness

Fig.7: Measuring the skin thickness with a ruler

Fig.8: Three measurement points for skin thickness

5. *Fig.9–Fig.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 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.

Example of incision options

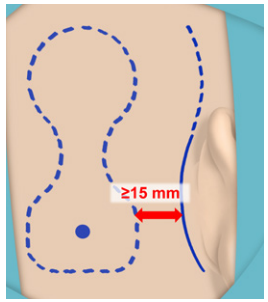


Fig.9: Post-auricular incision with superior extension

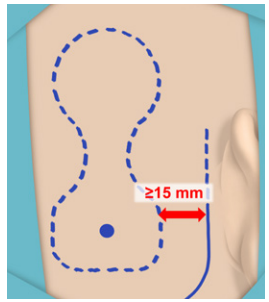


Fig.10: Inferior Post-auricular incision with extension

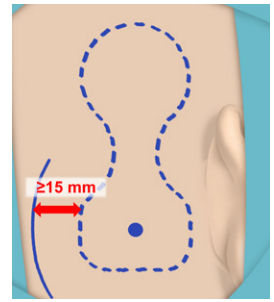


Fig.11: Posterior C-shape incision

2. 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 sub-periosteal 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

1. Before making the incision, the incision line may be infiltrated with local anaesthetic.
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.12*)

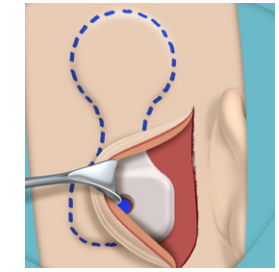


Fig.12: Checking of pocket size with the template

3. BI300 Implant placement

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. 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.13*).

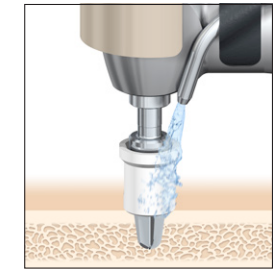


Fig.13: Guide drill with spacer

4. Be certain to drill at an angle perpendicular to the bone surface to minimise 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.
6. 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.
7. 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*).

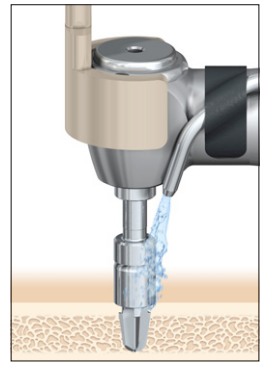


Fig.14: Drilling with Guide drill with spacer removed

Drill with the widening drill

8. Widen the site with the relevant widening drill 3 mm or 4 mm at 2000 rpm.
9. Drill perpendicular with an up and down movement to ensure irrigation can sufficiently cool the bone during drilling (*Fig.15*). Minimise the countersink depth to avoid unnecessary bone polishing later in the procedure.

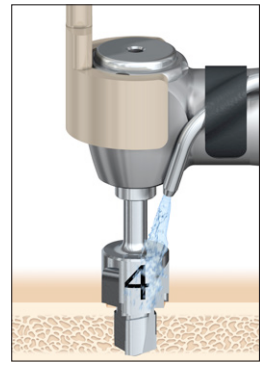


Fig.15: Drilling with widening drill

BI300 Implant placement

10. Set the drill unit to a torque setting that suits the quality of the bone (program implant installation for the drill unit). 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

11. 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.16*). Using any other tool 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). Once in the bone, continue placement with irrigation (*Fig.17*).
15. Carefully remove the Implant inserter vertically from the implant.

Fig.16: Picking up the BI300 Implant

Fig.17: Inserting the BI300 Implant

4. OSI200 Implant placement

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.18*). This will allow sufficient clearance for the correct mounting of the OSI200 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 until the bone bed indicator can be rotated 360° clockwise without applying force.
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.

Fig.18: Checking for interfering bone with Bone bed indicator

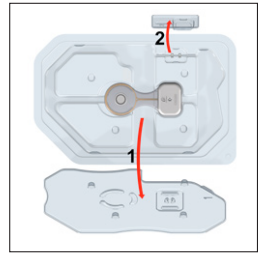


Fig.19: Packaging of the OSI200 Implant

Preparation and insertion of the OSI200 Implant

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.19*).
6. 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.20*).
7. Carefully remove the OSI200 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 ones to not harm the coil or waist area.
8. Place the centre of the actuator on top of the BI300 Implant and gently hand-tighten the fixation screw with the screwdriver, while holding the actuator with your fingers (*Fig.21*).
9. Continue to tighten to 25 Ncm with the Machine screwdriver Unigrip and the Multi wrench with the ISO adapter, while holding the actuator with your fingers (*Fig.22*).

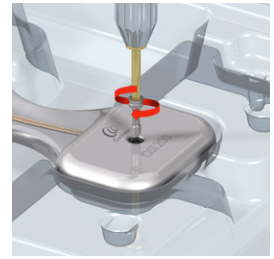


Fig.20: Attaching the fixation screw to the OSI200 Implant

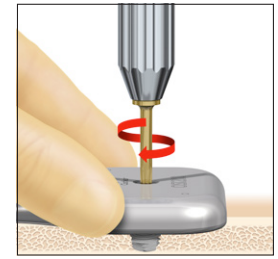


Fig.21: Attaching the actuator to the BI300 Implant.

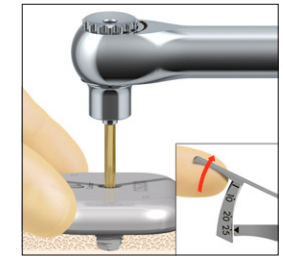


Fig.22: Hand tightening with 25 Ncm

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.23*).

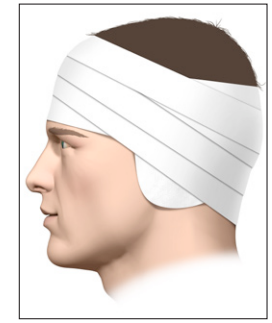


Fig.23: Pressure dressing

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