EN-CA ENGLISH

Cochlear®

Cochlear™ Osia® OSI300 Implant
Surgical Quick Guide

FOR PROFESSIONALS

Surgical checklist

Product Code	Implants	Product image	Availability Yes	Availability No
P1772248	OSI300 Implant		☐	☐
92128	BI300 Implant 3 mm		☐	☐
92129	BI300 Implant 4 mm		☐	☐

Product Code	Single-use instruments (sterile)	Product image	Availability Yes	Availability No
P1291019	OSI200 Implant template *Two implant templates are needed in each surgery.*		☐	☐
BI300 Implant specific				
93363	Conical guide drill 3+4 mm		☐	☐
92140	Widening drill 3 mm with countersink		☐	☐
92141	Widening drill 4 mm with countersink		☐	☐

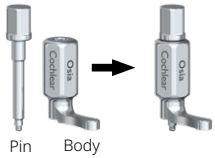
Backup products and additional surgical instruments necessary for Osia OSI300 Implant surgery:

Backup products

- Backup OSI300 Implant (P1772248)
- 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
P1469690	Bone bed indicator 17 mm		☐	☐
BI300 Implant specific				
90469	Screwdriver unigrip 95 mm		☐	☐
92143 / C9866	Multi wrench with ISO adapter		☐	☐
90381	Machine screwdriver 25 mm UniGrip		☐	☐
92142 / P1582230	Implant inserter		☐	☐
91116	Drill indicator for WS-75 and Osscora		☐	☐
Drilling equipment				
	Drill unit	 	☐	☐

Product Code	Single-use (sterile)	Product image	Availability	
			Yes	No
P1773917	Magnet Cassette		☐	☐
P782484	Non-Magnetic Cassette		☐	☐
92136	Cover screw conical		☐	☐

This Quick Guide does not contain all the important information required to use and implant the device. Consult the *OSI300 Implant Physician's Guide* for Warnings and Cautions for device use.

1. Preparation of implant site

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.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.

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.

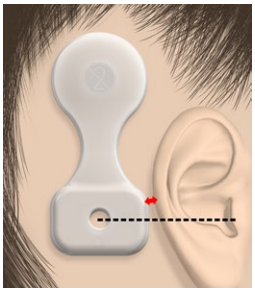


Fig.1: Optimal OSI300 Implant placement

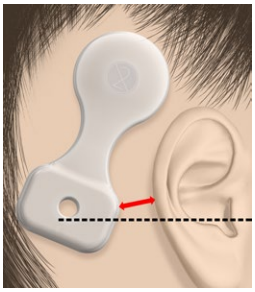


Fig.2: OSI300 Implant placement variation

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.3*, *Fig.4*).

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.5*).
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.

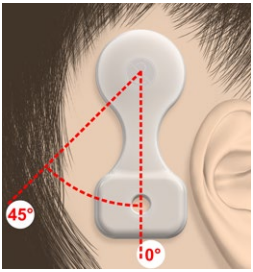


Fig.3: Actuator positioning options

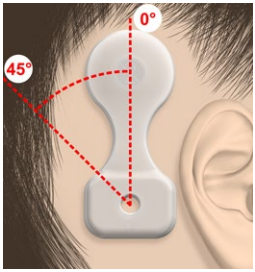


Fig.4: Coil positioning options

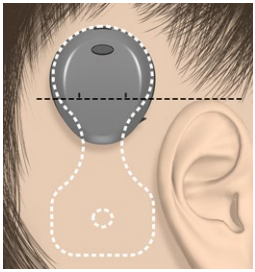


Fig.5: Sound processor placement

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.6*).
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. *Fig.7–Fig.9* 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.

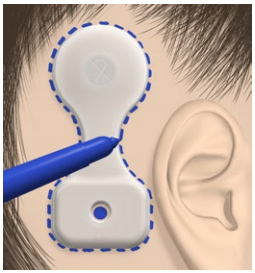


Fig.6: Marking of OSI300 and BI300 Implant

Example of incision options

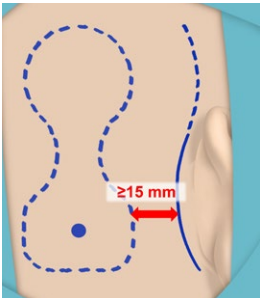


Fig.7: Post-auricular incision with superior extension

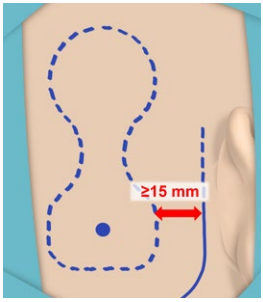


Fig.8: Inferior Post-auricular incision with extension

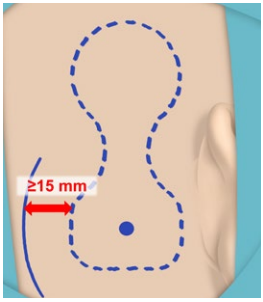


Fig.9: Posterior C-shape incision

5. Before local anaesthesia is injected, measure the soft tissue thickness by using a thin hypodermic needle, a clamp (*Fig.10*) and a ruler (*Fig.11*).
   Measurement points should be distributed over the coil area (*Fig.12*). Do not depress the tissue when measuring.

Skin flap thickness

- 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.

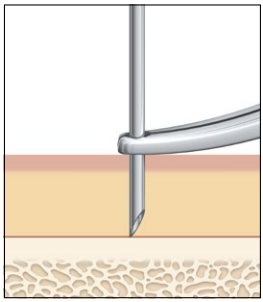


Fig.10: Measuring the skin thickness

Fig.11: Measuring the skin thickness with a ruler

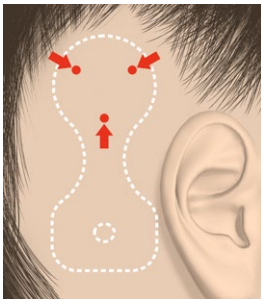


Fig.12: Three measurement points for skin thickness

2. Coil pocket creation and incision

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.

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.13*)

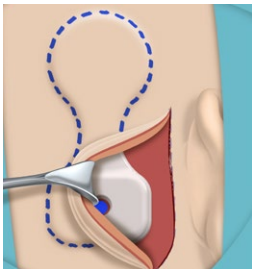


Fig.13: Checking of pocket size with the template

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 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.14*).

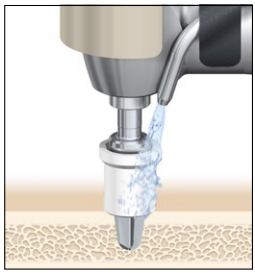


Fig.14: Guide drill with spacer

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.
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.15*).

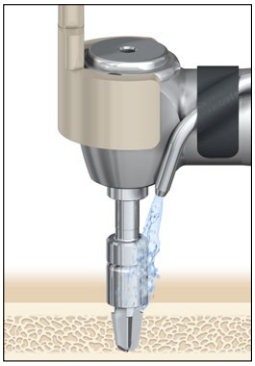


Fig.15: Drilling with Guide drill with spacer removed

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.16*). Minimise the countersink depth to avoid unnecessary bone polishing later in the procedure.

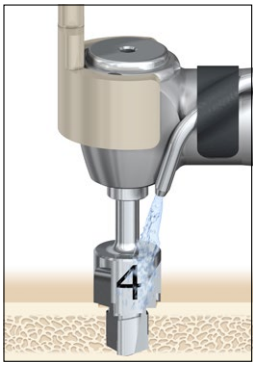


Fig.16: Drilling with widening drill

BI300 Implant placement

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

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.17–Fig.18*). 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) (*Fig.19*).
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.

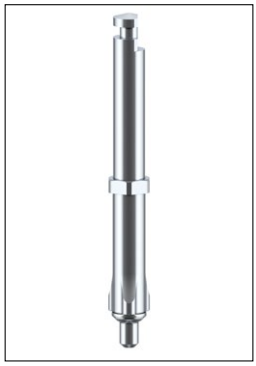


Fig.17: Implant inserter

Fig.18: Picking up the BI300 Implant

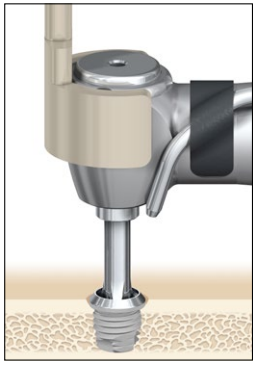


Fig.19: Inserting the BI300 Implant

4. OSI300 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.20*). 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 he Bone bed indicator. **Repeat the above until the bone bed indicator can be rotated 360° clockwise without applying force**.

Fig.20: Checking for interfering bone with Bone bed indicator

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.

Preparation and insertion of the OSI300 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.21*) 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.22*).

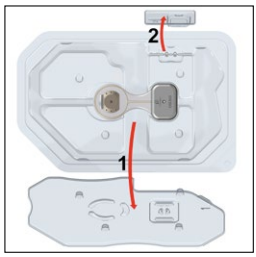


Fig.21: Packaging of the OSI300 Implant

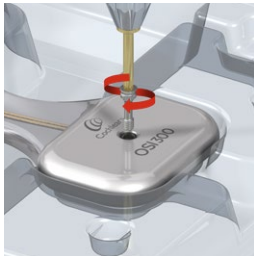


Fig.22: Attaching the fixation screw to the OSI300 Implant

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.
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.23*).
9. Continue to tighten to 25 Ncm with the Machine screwdriver Unigrip and the Multi wrench with the ISO adapter (*Fig.24*), while holding the actuator with your fingers (*Fig.25*). **Keep the implant orientation in mind and check that the implant coil or waist are not kinked before making the final attachment.**

Fig.23: Attaching the actuator to the BI300 Implant.

Fig.24: Machine screwdriver Unigrip and the Multi wrench with the ISO adapter

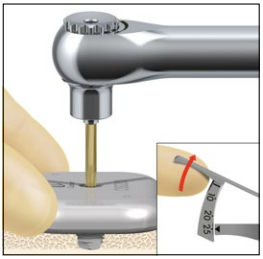


Fig.25: Hand tightening with 25 Ncm

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.26*).
3. After removing the pressure dressing, it is possible to use a normal wound dressing during the initial healing period.

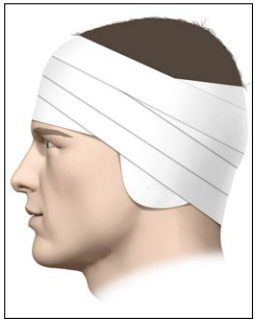


Fig.26: Pressure dressing

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