

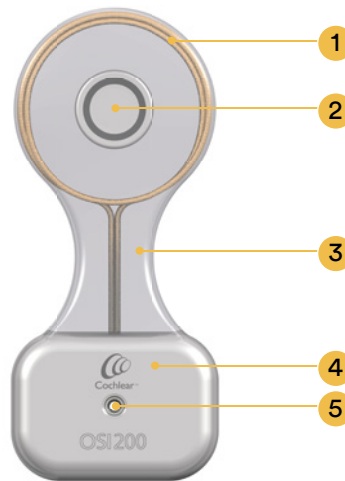


Cochlear[®]
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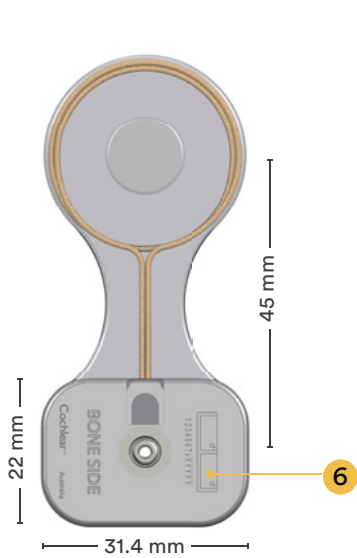
Cochlear™ Osia[®] 2 System Technical Specifications

Cochlear™ Osia[®] OSI200 Implant (P1170466)

- 1 Coil
- 2 Removable magnet
- 3 Waist
- 4 Actuator
- 5 Fixation interface
- 6 Serial number and QR-code
- 7 Fixation screw



Skin side



Bone side



7

OSI200 Implant specifications

Size and weight		
Dimensions	31.4 x 72 x 4.9 mm with silicone	
Weight	20.4 g (including magnet)	
Operating characteristics		
Power and data	Received by 5 MHz inductive link from sound processor coil	
Frequency range as per IEC 60118-7	400Hz-7kHz	
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		
Materials	Quantity (mm ³)	Location
Silicone elastomer	3495	Protective coating and insulation of implant body
Titanium Grade 2 (ASTM standard F-67)	68	Magnet case
Titanium Grade 23 (ASTM standard F136)	1053	Implant body case and fixation screw
Storage		
For long term storage, store at room temperature. Keep dry.		

Cochlear Osia OSI200 Implant template (P1291019)

A single-use sterile marking template to be used during marking of skin and/or bone during surgery to indicate placement of the OSI200 Implant.

Material	Mediprene® 880251
Supply	Sterile
Compatibility	Biocompatible
Size	31.4 x 71.6 x (Ø) 30.6 mm

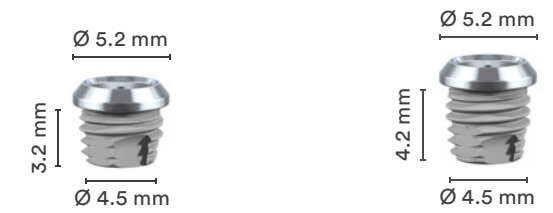


Cochlear BI300 Implant

Cochlear BI300 Implants are made of commercially pure grade 1 to 4 unalloyed titanium (ASTM standard F-67) which has the following chemical composition:

Element	Composition % by weight
Nitrogen (N)	Max 0.03
Carbon (C)	Max 0.08
Hydrogen (H)	Max 0.015
Iron (Fe)	Max 0.20
Oxygen (O)	Max 0.40
Titanium (Ti)	Balance

The conical cover screw is made of titanium alloy, grade 5 (ASTM standard F-136).

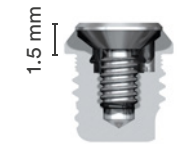


92128
BI300 Implant 3 mm
Weight: 0.19 g

92129
BI300 Implant 4 mm
Weight: 0.26 g



92136
Cover screw conical
Weight: 0.04 g

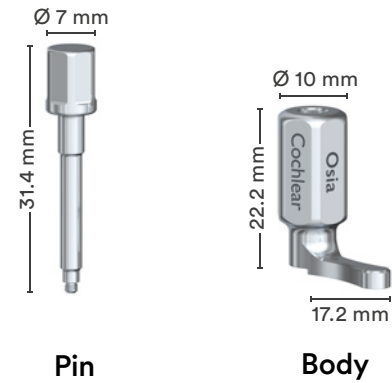


NOTE This figure shows a cross-section of the cover screw conical placed on a BI300 implant. The distance from bone level (under flange) to the top of the cover screw conical is 1.5 mm.

Cochlear Bone Bed indicator 17 mm (P1469690)

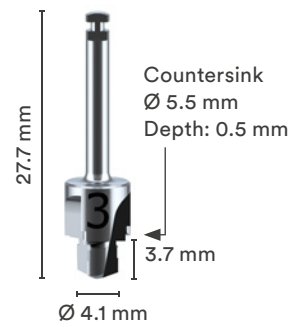
This is a reusable instrument delivered non-sterile for the user to clean and sterilize before use.

Material	Stainless steel
Supply	Clean, not sterile
Compatibility	Biocompatible
Size	Body 22.25 x 17.2 x (Ø) 10 mm Pin 34.15 x (Ø) 7 mm

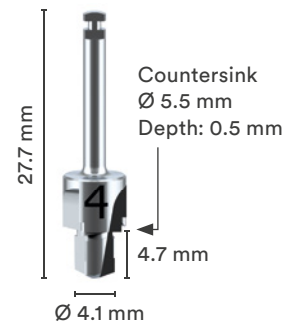


Drills

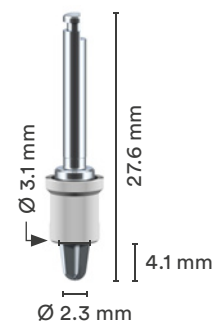
All drills are made of hardened stainless steel (WS 1.4197). The spacer on the Conical guide drill 3+4 mm is made of Celanex 2401 MT.



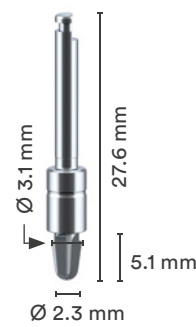
92140
Widening drill 3 mm with countersink
Weight: 1.7 g



92141
Widening drill 4 mm with countersink
Weight: 1.8 g



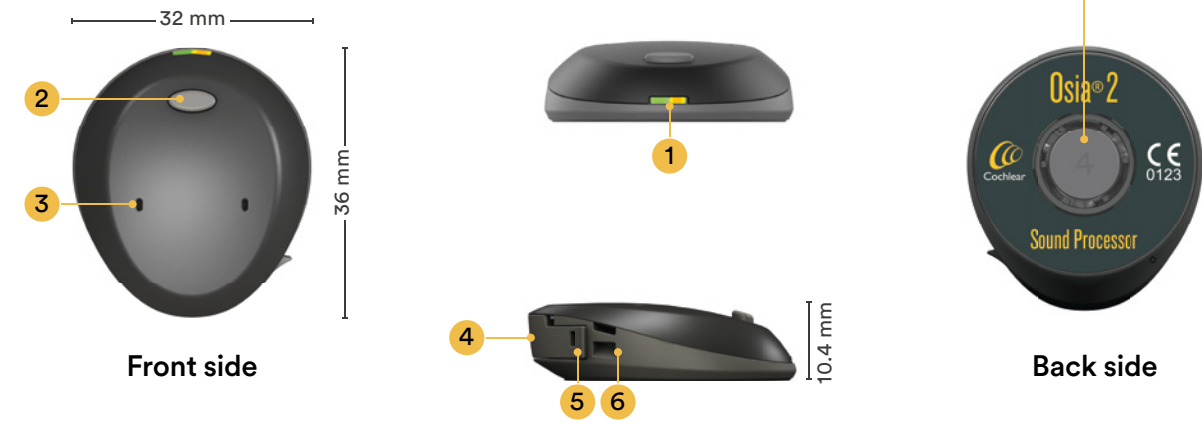
93363
Conical guide drill 3+4 mm
Weight: 1.5 g



NOTE: For the Cochlear BI300 Implant, the conical cover screw and all the drills, the legal manufacturer is:

Cochlear Bone Anchored Solutions AB, Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden Tel: +46 31 792 44 00, Fax: +46 31 792 46 95

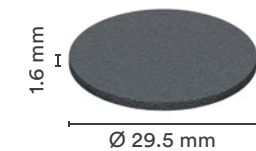
Osia 2 Sound Processor Kit (P1233400)



- 1 LED indicator light
- 2 Control button
- 3 Dual microphone ports
- 4 Battery door
- 5 Tamper proof lock
- 6 Attachment point for safety line
- 7 Transparent window for L/R marking on magnet

Cochlear SoftWear™ pad

The Cochlear SoftWear™ pads are made of a slow recovery foam with a coating of polyurethane medical tape against the skin. The soft pads are latex free.

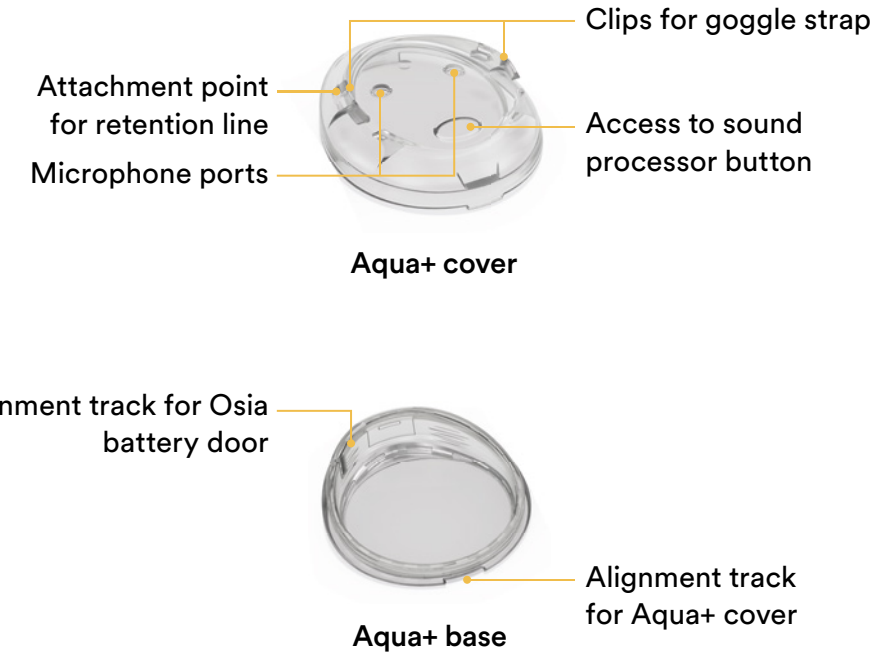


P793406
20 pads

Osia 2 Sound Processor specifications

Size and weight		
Dimensions	Length - 36 mm Width - 32 mm Depth - 10.4 mm	
Weight	6.2 g (no batteries or magnet) 7.8 g (including Magnet 1) 9.4 g (including Magnet 1 and a zinc air battery)	
Operating characteristics		
Sound output frequency range (as per IEC 60118-7)	400 Hz to 7 kHz	
Operating voltage	1.05 V to 1.45 V	
Wireless technology	Proprietary low power bi-directional wireless link (wireless accessories) Published commercial wireless protocol (Bluetooth® Low Energy)	
Operating frequency RF (radio frequency) communication to implant	5 MHz	
Operating frequency RF (radio frequency) transmission	2.4 GHz	
Power consumption	10 mW to 25 mW	
Battery	One PR44 (zinc air) button cell battery, 1.4V (nominal) High power 675 (PR44) zinc air disposable battery designed for hearing implant use	
Materials	Sound processor enclosure: PA12 (Polyamide 12) Magnet housing: PA12 (Polyamide 12) Magnets: Gold coated	
Ingress Protection Rating		
IP52	Protected against failure from dust penetration and falling drops of water.	
IP57 (with battery cavity excluded)	Protected against failure from dust penetration and from water ingress at 1 meter depth for 30 minutes.	
Environmental conditions	Minimum	Maximum
Storage & transport temperature	-10°C (14°F)	+55°C (131°F)
Storage & transport humidity	0% RH	90% RH
Operating temperature	+5°C (41°F)	+40°C (104°F)
Operating relative humidity	0% RH	90% RH
Operating pressure	700 hPa	1060 hPa

Cochlear Osia 2 Aqua+ (P1302699)



Osia 2 Aqua+ technical specifications

Size and weight		
Dimensions	Length - 42 mm Width - 38 mm Depth - 13.9 mm	
Weight	4.5 g - Osia 2 Aqua+ unit 13.9 g Osia 2 Aqua+ unit including a sound processor with magnet (strength 1) and battery	
Other information		
Batteries when using the Osia 2 Sound Processor with the Osia 2 Aqua+	Alkaline (LR44) Nickel metal hydride (P675) Silver oxide (SR44) - Silver oxide batteries are contraindicated by the FDA	
Materials	Plastic: Grilamid TR90 PA12 Silicone: SHINETSU LSR, KE-2090 40A	
Ingress Protection Rating		
IP68	Protected from dust penetration and is waterproof down to 3 meters for a maximum of 2 hours	
Environmental conditions	Minimum	Maximum
Storage & transport temperature	-10°C (14°F)	+55°C (131°F)
Storage & transport humidity	0% RH	90% RH
Operating temperature	+5°C (41°F)	+40°C (104°F)

* The Cochlear Osia 2 Sound Processor is protected against water to level IP52 of the International Standard IEC60529 and IP57 with the battery compartment removed. The Cochlear Osia 2 Sound Processor with Aqua+ is dust and water resistant to the level of IP68 of the International Standard IEC60529 when used with LR44 alkaline or nickel metal hydride disposable batteries. This water protection rating means that the sound processor with the Aqua+ can be continuously submerged under water to a depth of up to 3 meters (9 feet and 9 inches) for up to 2 hours. Refer to the relevant User Guide for more information.

Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 650,000 devices and helped 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 next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

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

This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

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