Cochlear®

Cochlear™ Osia®
OSI200 Implant template

INSTRUCTIONS FOR USE

EN

FOR PROFESSIONALS

Contents

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OSI200 Implant template

Intended purpose

The OSI200 Implant template is intended to be used throughout the surgery to correctly position and attach the OSI200 Implant or OSI300 Implant.

Medical Indications

The OSI200 Implant template has no medical indication in itself. It will support the medical indications of compatible OSI Implant (OSI200 Implant and OSI300 Implant).

Contraindications

The OSI200 Implant template is contraindicated for use with Implants other that the OSI200 Implant or the OSI300 Implant.

Intended patient population

Refer to the OSI200 Implant Physician's Guide or the OSI300 Implant Physician's Guide.

Clinical benefits

The OSI200 Implant template functions as part of the Cochlear Osia System. Most recipients of a bone conduction hearing solution will experience an improved hearing performance and quality of life compared to unaided listening.

Intended users

The intended users of the OSI200 Implant template in a surgical environment are surgeons and qualified medical professionals (e.g. registered nurses).

Serious incidents

Serious incidents are rare, any serious incident in relation to your device should be reported to your Cochlear representative and to the medical device authority in your country, if available.

Using the template

The sterile single use OSI200 Implant template can be used:

- Before making the incision to mark the implant shape
- After making the incision, to check the implant position
- During the coil pocket creation to check for its size

Note: When using the OSI200 Implant template in a non-sterile area, make sure to use a new sterile implant template in the sterile field.
For details on the above procedures refer to the OSI200 Implant Physician's Guide or OSI300 Implant Physician's Guide.

Storage

For long term storage, store at room temperature. Keep dry. For details on storage conditions or technical specifications, refer to the OSI200 Implant Physician's Guide or OSI300 Implant Physician's Guide.

Disposal

OSI200 Implant templates that have been in patient contact should be placed into the correct clinical waste container for disposal. Follow the legal provisions for your country and the hygiene instructions of your hospital or clinic.

Summary of safety and clinical performance

https://ec.europa.eu/tools/eudamed

Labelling symbols

By prescription			Rx Only
Date of manufacture		Manufacturer	
Authorised representative in the European Community		Use by date	
Warning. Potential safety hazards and serious adverse reactions. Could cause harm to person.			
UK Conformity mark with approved body number		Keep dry	
CE registration mark with notified body number		Medical device	

⚠ Warnings

For temporary use only. Not for implantation.

Supplied sterile. Sterilized using irradiation. STERILE R

Sterile barrier		Single sterile barrier system with protective packaging outside	
Do not reuse. Do not resterilise.		Do not use if package is damaged and consult instructions for use	

Do not use if template becomes non-sterile e.g. if dropped or mishandled in theatre after removal from packaging.

Compatible with OSI200 Implant and OSI300 Implant.
Not all products are approved in all markets.

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