**OSSDSIGN® CRANIAL PSI**

**INTRODUCTION**

OSSDSIGN Cranial PSI is a biocompatible custom-made implant that replaces bony defects in the craniofacial skeleton and enhances the patient’s cosmetic appearance. Every implant is tailored to the individual patient’s defect and anatomical requirements using CAD-technology and 3D printing, resulting in a precise fit for a variety of cranioplasty needs.

OSSDSIGN Cranial is uniquely designed with a titanium skeleton that is largely covered by OssDsign’s proprietary calcium phosphate material. The titanium skeleton is produced with the latest technology in 3D printing and is embedded in the core of the implant’s calcium phosphate tiles, which are manufactured, cured and immobilized. The customized low-profile fixation arms allow for easy fixation to the skull with standard neuro micro screws* (1.5 x 3-5 mm). Every implant is delivered sterile and ready to use.

**INTERNATIONAL SIZES**

<table>
<thead>
<tr>
<th>OSSDSIGN® Cranial PSI S</th>
<th>SIZE RANGE</th>
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</thead>
<tbody>
<tr>
<td>OSSDSIGN® Cranial PSI M</td>
<td>51-100 cm³</td>
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<tr>
<td>OSSDSIGN® Cranial PSI L</td>
<td>101-150 cm³</td>
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<tr>
<td>OSSDSIGN® Cranial PSI XL</td>
<td>151-250 cm³</td>
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**GERMAN SIZES**

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<thead>
<tr>
<th>OSSDSIGN® Cranial PSI S</th>
<th>SIZE RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSSDSIGN® Cranial PSI L</td>
<td>1-80 cm³</td>
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</tbody>
</table>

**MATERIAL PHASE COMPOSITION**

- Monetite (Dicalcium phosphate anhydrous) $\text{CaHPO}_4$
- $\beta$-Tricalcium phosphate $\text{Ca}_3(\text{PO}_4)_2$
- $\beta$-Calcium pyrophosphate $\text{Ca}_2\text{P}_2\text{O}_7$

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*Not provided by OssDsign
INTENDED USE

OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

STORAGE

Store between 4-34 °C (40-93 °F).

STERILITY

OSSDSIGN Cranial PSI is delivered sterile and is confirmed to remain sterile for one year from date of manufacture. Sterilization method used by the manufacturer is steam sterilization (20 minutes, 121 °C). The device may not be re-sterilized due to risk of contamination.

MR CONDITIONAL

OSSDSIGN Cranial PSI is partially made from titanium, a material that is non-magnetic but may heat when subject to a strong magnetic field. Non-clinical testing and in-vivo electromagnetic simulations demonstrate that OSSDSIGN Cranial is MR Conditional. A patient with this device can be scanned safely in a MR system after implantation under the conditions described in ‘MR Considerations’ or in the Instructions for Use.

Always read the Instructions for Use which accompany the product for indications, contraindications, warnings and precautions.

OSSDSIGN CRANIOPLASTY ACCESSORIES

OSSDSIGN® Cranioplasty Accessories are a collection of devices aimed to facilitate an optimal placement and fitting of OSSDSIGN Cranial PSI. Each available accessory is a custom-made device specifically designed for the patient’s unique anatomy by using patient specific CT data and 3D printing. All devices are manufactured using PA 2200 and are delivered sterile.


PRODUCT DESCRIPTION

Anatomical Model Original (AMO)
The AMO is a 3D-printed replica of the patient’s skull anatomy, allowing the surgeon to orientate the patient’s current bone anatomy to evaluate specific features.

Anatomical Model Modified (AMM)
Similar to the AMO, the device is based on the patient’s CT data and 3D-printing, but it also includes computerized changes to specific anatomical regions.

Plastic Drawing Guide (PDG)
The PDG is a perioperative tool designed to fit a specific topography, and is often recommended for cases where there is a need to create a cranial cavity optimal for the corresponding Cranial PSI. The device is also available in titanium, allowing for more design options in complex areas.

Cranial Implant Trial (CIT)
The CIT represents OSSDSIGN Cranial PSI in terms of shape and may be placed into the cranial cavity during surgery to determine if the corresponding Cranial PSI has an optimal fit, without having to break the implant’s sterile barrier. The device is supplied with every OSSDSIGN Cranial PSI shipment.