

PATIENTS DESERVE A BETTER IMPLANT SOLUTION

OSSDSIGN® Cranial PSI

Product description

OSSDSIGN® CRANIAL PSI is a biocompatible patient-specific implant, that replaces bony defects in the craniofacial skeleton and enhances the patient's cosmetic appearance.

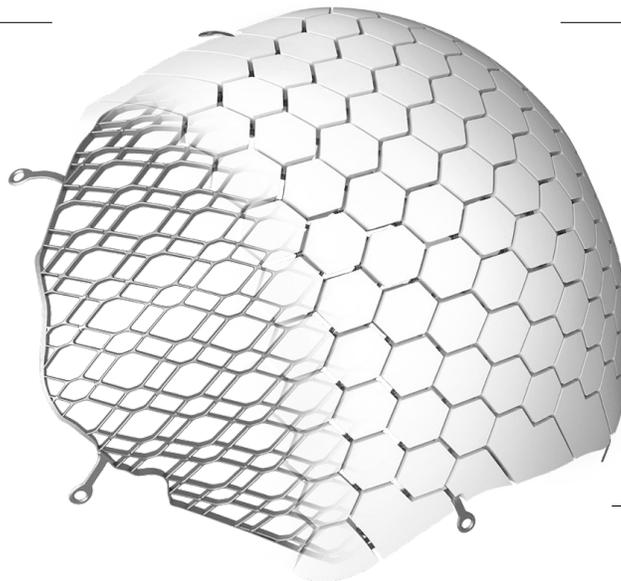
OSSDSIGN Cranial combines a 3D printed titanium mesh with precision molding of the calcium phosphate material. The implants are easy to fixate to the skull with standard neuro micro screws* (1.5 x 3-5 mm) through the customizable low-profile

fixation arms, location decided by the surgeon. The titanium skeleton mesh is embedded in the core of the implant's ceramic tiles which are manufactured, cured and immobilized.

Every implant is tailored to the individual patient's defect, using CAD-technology and 3D printing, resulting in a precise fit for a variety of cranioplasty needs.

* Not provided by OssDsign

Perfect aesthetics regardless of complexity
based on CAD technology and 3D printing.



Mosaic tile design
with inter tile spacing that allows for fluid movement through the device.

Stability and protection
based on the 3D printed titanium skeleton.

Easy handling and fixation
with predesigned, customizable fixation arms.

OSSDSIGN CRANIAL 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.

STERILITY OSSDSIGN Cranial is delivered sterile. Sterilization method is steam sterilization (20 minutes, 250°F (121°C))

MR CONSIDERATIONS OSSDSIGN Cranial 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 electromagnetic simulations demonstrate that OSSDSIGN Cranial is MR Conditional. A patient with this device can be scanned safely in an MR system after implantation under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 2W/Kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system.
- Quadrature transmit coil only

Under the scan conditions defined above, the OSSDSIGN® Cranial PSI is expected to produce a maximum temperature rise of 3.6°F (2°C) after 15 minutes of continued scanning.

STORE the device between 40-93°F (4-34°C).

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



Implant sizes

Size range

OSSDSIGN® Cranial PSI S	1-49 cm ²
OSSDSIGN® Cranial PSI M	50-99 cm ²
OSSDSIGN® Cranial PSI L	100-149 cm ²
OSSDSIGN® Cranial PSI XL	150-200 cm ²

Material phase composition

Monetite (Dicalcium phosphate anhydrous)	CaHPO ₄
β-Tricalcium phosphate	Ca ₃ (PO ₄) ₂
β-Calcium pyrophosphate	Ca ₂ P ₂ O ₇