



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

Easy handling and fixation
With predesigned, customizable fixation arms

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

Stability and protection
Based on the 3D printed titanium skeleton

PATIENTS DESERVE A BETTER IMPLANT SOLUTION

OSSDSIGN® CRANIAL PSI

OssDsign Cranial PSI is a biocompatible patient-specific implant that replaces bony defects in the cranial skeleton and enhances the patient’s cosmetic appearance. Every implant is tailored to the individual patient’s defect and anatomical requirements. Computer aided design technology allows OssDsign Cranial PSI to deliver 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 implants are

delivered sterile and ready to use. The customized low-profile fixation arms allow for easy fixation to the skull with standard neuro micro screws* (1.5 x 3-5 mm).

IMPLANT SIZES	SIZE RANGE
OssDsign Cranial PSI S	1-50 cm ²
OssDsign Cranial PSI M	51-100 cm ²
OssDsign Cranial PSI L	101-150 cm ²
OssDsign Cranial PSI XL	151-200 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

*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

OssDsign Cranial can be stored between 40-93 °F (4-34 °C).

STERILITY

The device is delivered sterile and is confirmed to remain sterile for one year from the date of manufacture. Sterilization method used by the manufacturer is steam sterilization (20 minutes, 250°F (121°C)). The device may not be re-sterilized.

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 an MR system after implantation under the conditions described in 'MR Considerations' or in the Instruction for Use.

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

THE COMPLETE CRANIOPLASTY SOLUTION

OssDsign Cranial PSI offers an unique approach to cranioplasty by combining biocompatible calcium phosphate with a 3D printed titanium reinforcement. From the curvature of the implant to the number of the fixation points, our customers maintain complete control throughout the design process. Our CAD-engineer team takes great pride in their ability to tailor solutions for all cranioplasty needs, regardless of complexity.

Representation of OssDsign Cranial PSI fixated to the skull. The fixation is performed via low-profile fixation arms integrated into the titanium reinforcement. The location of the fixation arms can be adjusted during the design process.

