Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
REF	Article number
SN	Serial number (label only)
	Date of manufacture
	Shelf life/ Last day of use (label only)
93°F 40°F	Temperature storage conditions
STERILE	Sterilized using steam or dry heat
	Single patient use
	Do not re-sterilize
	Warnings
	Do not use if package is damaged
	Read the Instruction for Use
	Fragile
MR	MR Conditional
	Unique Device Identifier (UDI)

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OSSDSIGN®

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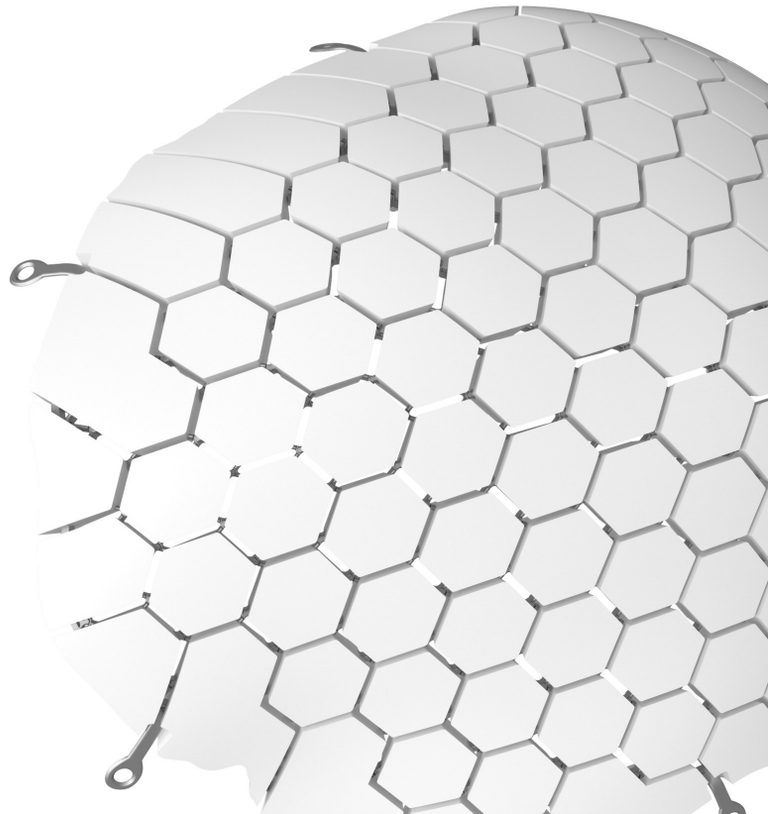
Instruction for Use

OSSDSIGN® Cranial PSI
Patient-specific device

The Instructions For Use must be read and understood prior to clinical use.



Introduction

OSSDSIGN® Cranial PSI (Patient Specific Implant, PSI) is an implanted device that replaces native bone in the cranial skeleton. Each OSSDSIGN® Cranial PSI is a patient-specific device specifically created for a patient's unique anatomical requirements. OSSDSIGN® Cranial PSI consists of a titanium mesh that is largely covered by calcium phosphate ceramic tiles. The titanium mesh provides mechanical stability. The ceramic tiles provide favorable cosmetic outcome by more naturally following the curvature of the skull. OSSDSIGN® Cranial PSI is made from biocompatible material that allows for host tissue integration. The ceramic tiles are designed in a mosaic pattern with space between tiles that allows for circulation of fluids.

Indications for 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.

Warnings

• OSSDSIGN® Cranial PSI is MR Conditional; see important restrictions under MR Safety Information, below.
• Care must be taken to assure that screws do not protrude into the dura. Screws must be shorter than the thickness of the bone into which they are being inserted.

MRI Safety Information

MR Conditional

Non-clinical testing and electromagnetic simulations demonstrated that the OSSDSIGN® Cranial PSI 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 field gradient of 3000 Gauss/cm (30 T/m)
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) and head average SAR of <3.2 W/kg (Normal Operating Mode)
• Body coil only, do not use head transmit/receive coil
• Quadrature transmit coils only
Under the scan conditions defined above, the OSSDSIGN® Cranial PSI is expected to produce a maximum temperature rise of 2˚ C after 15-minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the Cranial PSI extends approximately 7 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Contraindications

OSSDSIGN® Cranial PSI is not intended for use with:

1. Patients with incomplete cranial growth
2. Infected areas
3. Procedures or applications other than those described in the OSSDSIGN® Cranial PSI Instructions For Use
4. Patients with foreign body sensitivity or metal allergies
5. Patients who are potentially non-compliant with after-procedure instructions common to all implants, such as observing standard wound healing instructions and to use care with the anatomical location such as avoiding blows to the head
6. Screws of any length that may contact the dura

Precautions

1. Before implanting OSSDSIGN® Cranial PSI the surgeon should position the device according to the Directions for Use described in the OSSDSIGN® Cranial PSI Instructions For Use. Incorrectly placed devices will affect the functional and aesthetical outcome of the procedure. Before implantation: read and understand all Contraindications, Warnings, Precautions, Directions and the Intended Use. Before beginning the procedure, assure all necessary components for the procedure are present.

2. OSSDSIGN® Cranial PSI is delivered preformed to fit the defect of the specific patient for whom it was designed. The procedure can proceed even if an individual tile has been damaged or has detached from the device during operation. This will not reduce the stability of the device.

3. This device may only be used by properly trained and experienced medical personnel working in a sterile operating environment.

4. The surgeon is responsible for proper selection of appropriate patients and procedures, the adequacy of medical personnel training and experience, and all decisions to remove other implants.

5. Radiotherapy after implantation may require alternate dosing and planning to account for the presence of the device.

6. OSSDSIGN® Cranial PSI is carefully designed to fit a specific patient's defect. If the surgeon desires to modify the fit, bone must be removed from the patient defect using standard surgical procedures. Do not remove material from the OSSDSIGN® Cranial PSI. No cutting or reshaping of the device is permitted. For best results, implant within six months from date of manufacture.

7. Excessive screw tightening may cause loose titanium or bone fragments. Any such fragments must be removed.

8. Excessive screw tightening may cause screws to strip out of the bone intended for attachment. If a screw hole strips out, emergency or self-tapping screws may be used, following the Instructions For Use of the screw manufacturer. Do not use screws of a length that may contact the dura.

9. To reduce the risk of pulling out a screw, wiggle the screwdriver to loosen the screwdriver-screw connection prior to disengaging the screwdriver from the screw.

10. Screws must be removed prior to explantation. The device is integrated into neighboring bone and soft tissue over time, which may affect the surgical procedure if explantation is required.

11. Fastening arms may be gently adjusted to improve the fit.

12. Dispose of, and do not implant any product that has been explanted, damaged or mishandled prior to the operation.

13. USA federal law restricts the use of this device to sale by or on the order of a physician.

Possible complications

1. Unintended durotomy from using screws which contact the dura
2. Titanium allergy
3. Tile or tile chips loosening during operation. Remove tile or tile chip and proceed with implantation.
4. Device does not fit due to changes in the patient's defect size due to either bone growth or bone resorption occurring since the CT scan was performed

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 manufacturer cannot guarantee device sterility if the inner package seal is broken or if the package is improperly opened or the product mishandled. The device may not be re-sterilized.

Storage information

Store between 4-34°C (40-93°F)

Date of last revision

This Instructions For Use was last revised April 2017.

Directions for Use/Procedure

Step 1.

Confirm OSSDSIGN® Cranial PSI product labeling, patient ID, expiration date, quantity on hand and intact sterility barrier before starting surgery.

Step 2.

The defect is surgically exposed according to the procedure elected by the surgeon.

Step 3.

Care is taken by the surgeon to properly orient the OSSDSIGN® Cranial PSI relative to the defect and the device is fitted into position with fastening arms overlapping healthy skull bone.

• OSSDSIGN® Cranial PSI is carefully designed to fit a specific patient's defect. If the surgeon desires to modify the fit, bone must be removed from the patient defect using standard surgical procedures. Do not remove material from the OSSDSIGN® Cranial PSI. No cutting or reshaping of the device is permitted.

• Fastening arms may be gently adjusted to improve the fit.

Step 4.

OSSDSIGN® Cranial PSI is attached to surrounding bone using tapered (counter-sunk) titanium screws suitable for application in the skull, inserted into the fastening arms.

Step 5.

Close wound according to the procedure selected by the surgeon.