 Manufacturer

SN Serial number

REF Catalogue number

STERILE Sterilized using steam

Do not resterilize

Single use

 Use-by date

 Caution

 Do not use if package is damaged

 Consult Instructions for Use

 Fragile, handle with care

 MR Conditional

 Temperature limit

 Patient number

 Hospital

MD Medical Device

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Complaint/Incident Reporting:

Any serious incident that has occurred in relation to the device shall be reported to OssDsign: **clinical@ossdsign.com** and the competent authority of the country in which the user and/or patient is established.

OSSDSIGN®

Instructions for Use

OssDsign® Cranial PSI
Custom-made device

Read the Instructions for Use including warnings and precautions prior to clinical application. The Instructions for Use must be understood and followed.

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 follow 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.

The osteoconductive ceramic component of OssDsign Cranial PSI resorbs and is replaced with bone during the healing process.

Indications for use/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.

⚠ Warnings

- OssDsign Cranial PSI is MR Conditional; see important restrictions under MRI Safety Information.
- 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.

MR Safety information

Non-clinical testing and electromagnetic simulations demonstrated that 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 transmit and receive is permitted
- Head coil receive only; do not use with head transmit coil
- Quadrature transmit coils only.

Under the scan conditions defined above, OssDsign Cranial PSI is expected to produce a maximum temperature rise of 2˚ C after 15-minutes of continuous scanning.

Artefact information

In non-clinical testing, the image artefact caused by OssDsign Cranial PSI extends approximately 7 mm from this device 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. Patients with active local infection.
3. Procedures or applications other than those described in OssDsign Cranial PSI Instructions for Use.
4. Patients with foreign body sensitivity or metal allergies.
5. Patients who are potentially non-compliant with post-operative 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 procedure described in 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, Procedures and the Intended Use. Before beginning the procedure, assure all necessary components for the procedure are present.
2. OssDsign Cranial PSI is delivered pre-formed 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. Up to 1 mm of ceramic may be removed at the edge of the device with a scalpel to improve fit. Cutting or reshaping of the titanium mesh is not permitted.
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 to account for the presence of the device.
6. Excessive screw tightening may cause loose titanium or bone fragments. Any such fragment must be removed.
7. 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.
8. To ensure secure fixation the screws must have a screw head that is larger than the hole in the fixation arm.
9. 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.
10. Dispose of, and do not implant any product that has been explanted or damaged prior to the operation.
11. Do not re-use the device. Re-use of the device may cause infection due to contamination of the device.
12. In case of cerebral edema/brain swelling ensure appropriate measures are taken in order to enable the appropriate placement of the device.

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, irrigate area 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.
5. Infection.
6. Wound dehiscence.

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).

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 selected by the surgeon.

STEP 3

Care is taken to properly orient OssDsign Cranial PSI relative to the defect and the device is fitted into position with fixation arms overlapping healthy skull bone. View visual aid for orientation marker.
If required, the outer edges of the device can be trimmed slightly to optimize the fit between the device and the bone surface. In such cases, a scalpel is used to carefully remove a maximum of 1 mm from the periphery of the device. Make sure that no debris from trimming falls into the surgical site.
Fixation 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 fixation arms.

STEP 5

Close wound according to the procedure selected by the surgeon.

Disposal

- A non-contaminated device may be disposed of as general waste.
- A contaminated device should be disposed of as biohazard waste.

Patient Information

Information to be conveyed to the patient:
OssDsign Cranial PSI is MR conditional. If the patient is to be subjected to magnetic resonance imaging, the patient shall inform its healthcare provider of the implant. OssDsign Cranial PSI may affect radiotherapy. If the patient is to be subjected to radiotherapy, the patient shall inform its healthcare provider of the implant.