 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

 Read the Instructions for Use

 Temperature limit

 Patient number

 Hospital name

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® Drawing Guide
Custom-made device

Introduction

OssDsign Drawing Guide is an accessory to the OssDsign Cranial PSI (Patient Specific Implant) device. Each Drawing Guide is a custom-made device specifically created for a patient's unique anatomical requirements. The Drawing Guide consists of a titanium rim that is fixated using fastening points similar to the Cranial PSI device. The titanium rim helps the surgeon to establish a line on the bone surface, which the surgeon cuts along after removing the Drawing Guide. Cutting along this drawn line creates the agreed upon cranial cavity in which the corresponding Cranial PSI device fits.

Intended Use/Indication for Use

OssDsign Drawing Guide is intended to be used as a perioperative medical device accessory for the OssDsign Cranial PSI device by facilitating its accurate placement and fitting.

Warnings

All instructions must be read and understood prior to clinical use.

Contraindications

OssDsign Drawing Guide are not intended for use:

1. With other devices than the corresponding OssDsign Cranial PSI device.
2. In procedures or applications other than those described in the OssDsign Drawing Guide's Instructions For Use.
3. Screws of any length that may contact the dura. To ensure that screws do not protrude into the dura, they must be shorter than the thickness of the bone into which they are inserted.

Precautions

1. Before beginning the procedure: read and understand all Warnings, Contraindications, Precautions, Procedural instructions and Intended use. Assure all necessary components for the procedure are present.
2. This device may only be used by properly trained and experienced medical personnel working in a sterile operating environment.
3. Care should be taken to ensure sufficient soft tissue around the defect is prepared to enable correct placement of the device.
4. OssDsign Drawing Guide is designed to fit a specific defect. If optimal fit is not achieved, do not use force since this may damage the device.
5. To ensure that screws do not protrude into the dura, they must be shorter than the thickness of the bone into which they are inserted.
6. To ensure secure fastening the screws must have a screw head that is larger than the hole in the fastening arm.
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.
8. Do not use the Drawing Guide device during the trimming step.
9. Dispose of any product that has been damaged or mishandled prior to the operation.
10. Do not re-use. Re-use of the device may cause infection due to contamination of the device.
11. 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.

Possible complications

1. Dura rupture from using screws which contacts the dura.
2. Titanium Allergy.

Sterility

OssDsign Drawing Guide is delivered sterile. 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. Do not re-sterilize the device.

Storage information

Store between 4-34°C / 40-93°F

Disposal

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

Procedure

STEP 1

Confirm OssDsign Drawing Guide and 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

Remove the protective silicone plugs from the fastening points of the Drawing Guide device.

STEP 4

Care is taken by the surgeon to properly orient the OssDsign Drawing Guide relative to the anatomical region intended; visual aid is provided within the packaging. The device is fitted into position with fixation arms placed onto the bone **(Figure 1.)**. The Drawing Guide is designed to fit a specific anatomical topography.

STEP 5

OssDsign Drawing Guide is attached to the bone using surgeon-selected, tapered (counter-sunk) titanium screws suitable for cranioplasty, by inserting the screw into the fixation eyelet.

STEP 6

Once attached, the surgeon may use the preferred drawing tool(s) to establish a visual representation of the cranial cavity outline. The line is drawn along the side of the Drawing Guide that does not have fixation points, as seen in **Figure 2.**

STEP 7

Once a clear line has been established, remove the fixation screws and Drawing Guide before removing the excess bone according to standard practice along the drawn line. The marked line includes all bone necessary to be removed for proper placement of the corresponding OssDsign Cranial PSI.

Note: If a cranial perforator is used to establish entrance point(s), ensure that the burr hole is within the drawn line.

STEP 8

When the cranial cavity is established proceed with the usage of the Cranial PSI device.

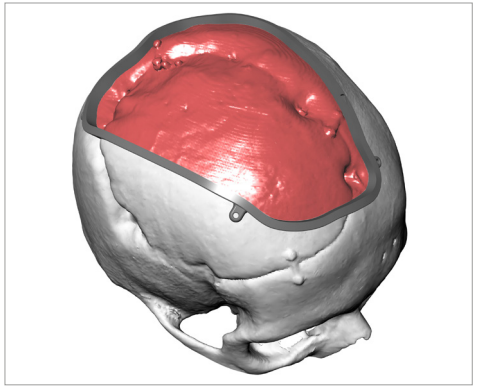

Figure 1. *A visual representation of OssDsign Drawing Guide when positioned in place.*

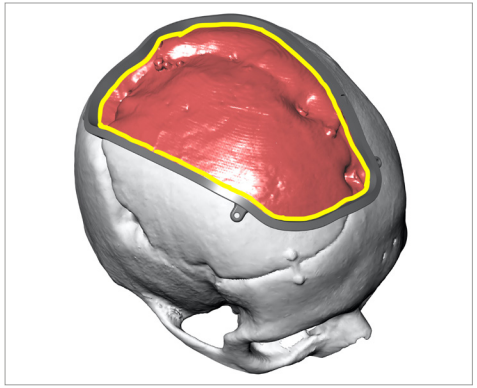

Figure 2. *The yellow line highlights where to draw the line.*