 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

 Fragile

 Non-sterile

 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® Cranial PSI Accessories
Custom-made device

Introduction

OssDsign Cranial PSI Accessories are available to OssDsign Cranial PSI (Patient Specific Implant) device. Each available accessory is a custom-made device specifically created after the patient's unique anatomy. OssDsign Cranial PSI Accessories are intended to aid the surgeon in achieving the best fit possible of OssDsign Cranial PSI. The available accessories are Original and Modified Anatomical Models, Cranial Implant Trial and Plastic Drawing Guide. Please read the intended use for each different accessory device below.

Intended Use / Indication for Use

Anatomical Model Original

Intended as visual and tactile guidance and orientation of the patient's anatomy.

Anatomical Model Modified

Intended as visual and tactile guidance and orientation of the patient's anatomy after removal of specific region of interest.

Cranial Implant Trial

Intended to be used as a perioperative surgical guide by facilitating accurate visualization, placement and fitting of corresponding OssDsign Cranial PSI.

Plastic Drawing Guide

Intended to be used during surgery as a perioperative surgical guide to facilitate accurate placement and fitting.

⚠ Warnings

- All instructions must be read and understood prior to clinical use.
- Do not implant. OssDsign Cranial PSI Accessories are not intended to be implanted.
- Anatomical Model Original & Anatomical Model Modified are for non-sterile use only.

Contraindications

OssDsign Cranial PSI Accessories are not intended for use with:

- Other devices than the corresponding OssDsign Cranial PSI device.
- Procedures or applications other than those described in the OssDsign Cranial PSI Accessories Instructions For Use.
- 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.

Cranial Implant Trial (delivered sterile)

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

2. If Plastic Drawing Guide is part of the kit, apply the device as described in the previous section, prior to breaking the sterile barrier of Cranial Implant Trial.

3. Place Cranial Implant Trial into the cranial cavity according to **Fig. 10a**, to determine if the corresponding OssDsign Cranial PSI is compatible with the cranial cavity. The Orientation Marker **(Fig. 10b)** points towards the anterior part of the patient's skull. Do not open the OssDsign Cranial PSI device until Cranial Implant Trial fit is confirmed.

4. If the Cranial Implant Trial does not fit into the cranial cavity, define which regions are prohibiting the optimal fit and amend these as deemed necessary.

5. Once the Cranial Implant Trial fits into the cranial cavity, note the Fixation Markers on the device, which highlight the location of the corresponding OssDsign Cranial PSI's Fixation arms. Further dissection of tissue may be needed to accommodate proper fixation of OssDsign Cranial PSI (approximately 10mm outwards from the edge of Cranial Implant Trial, **Fig. 11**).

Fig. 10a

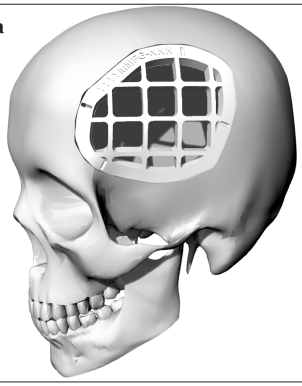
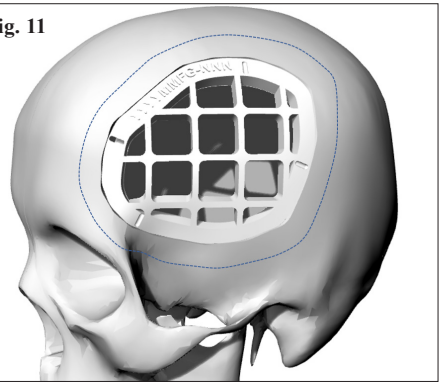


Fig. 10b

Fig. 11



Procedure

Confirm OssDsign Cranial PSI Accessories and OssDsign Cranial PSI product labels, patient ID, expiration date, quantity on hand and ensure all components are for the same patient.

For OssDsign Cranial PSI, Cranial Implant Trial and Plastic Drawing Guide ensure intact sterility barrier before starting surgery.

For each device of OssDsign Cranial PSI Accessories, see the following device specific procedure steps.

Anatomical Model Original (non-sterile)

The device can be used during pre-operative planning to help the end user to orientate the patient's current bone anatomy, considering other structures in relation to the existing bone **(Figs. 1-3)**. Anatomical Model Original is not intended to be in contact with sterile devices, as it is non-sterile.

Fig. 1

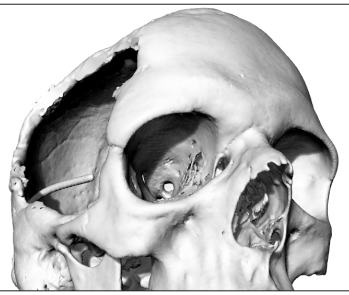


Fig. 2

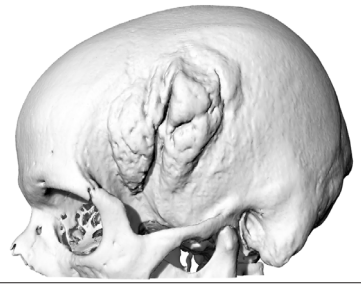
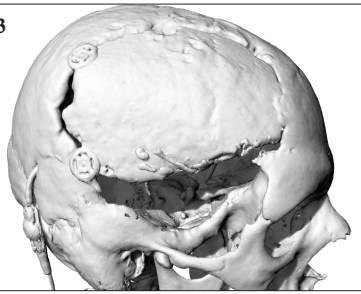


Fig. 3



Anatomical Model Modified (non-sterile)

The device can be used during pre-operative planning to help the end user to orientate the patient's bone anatomy after pre-planned modifications, considering other structures in relation to the existing bone **(Figs. 4-6)**.

Anatomical Model Modified is not intended to be in contact with sterile devices, as it is non-sterile.

The Anatomical Model Modified may contain Fixation Markers that indicate the placement of corresponding OssDsign Cranial PSI's fixation arms **(Fig. 5)**.

The Anatomical Model Modified may be divided in X/Y/Z sections per surgeon request for easier visual access **(Fig. 6)**.

Fig. 4a

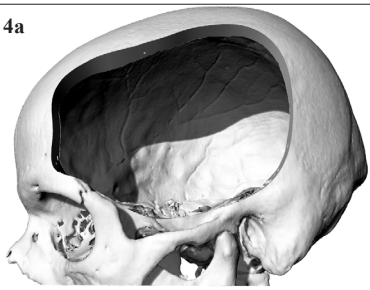


Fig. 4b

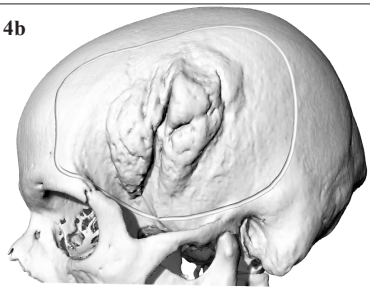


Fig. 5

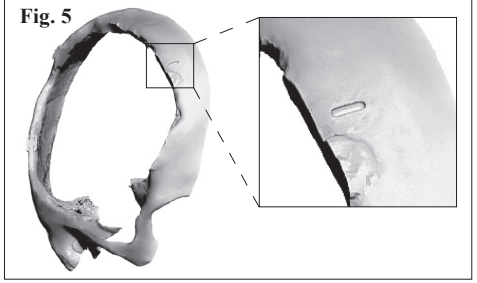
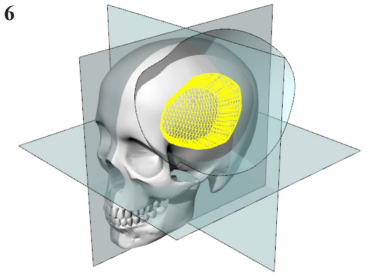


Fig. 6



Plastic Drawing Guide (delivered sterile)

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

2. Care is taken by the surgeon to properly orient Plastic Drawing Guide relative to the anatomical region intended; a visual aid is provided within the packaging. The device is fitted into position with fixation arms placed onto the bone **(Fig. 7)**. Plastic Drawing Guide is designed to fit a specific anatomical topography.

3. Plastic 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 eyelets **(Fig. 8)**.

4. 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 inner perimeter of the device **(Fig. 9)**.

5. Once a clear line has been established, remove the fixation screws and Plastic 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.

Fig. 7

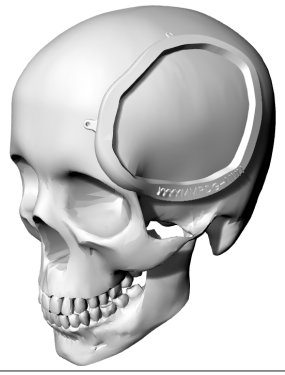


Fig. 8

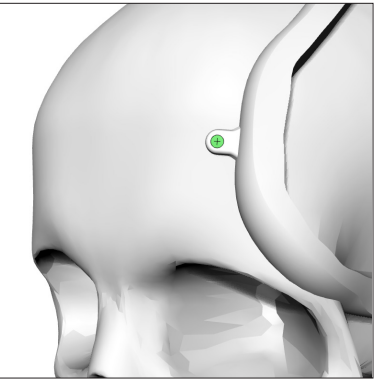
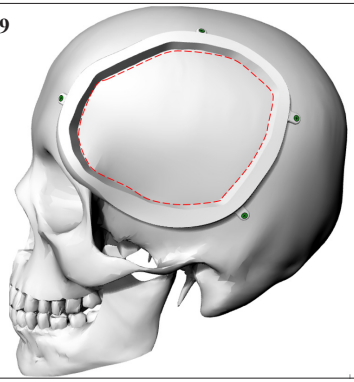


Fig. 9



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. Cranial Implant Trial and Plastic Drawing Guide may only be used in the sterile operating environment.

3. Cranial PSI Accessories may only be used by trained and experienced medical personnel.

4. Care should be taken to ensure sufficient soft tissue around the defect is prepared to enable correct placement of the device.

5. The devices are designed for specific defect. If optimal fit is not achieved, do not use force since this may damage the device.

6. 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.

7. To ensure secure fixation, the screws must have a screw head that is larger than the hole in the fixation arm.

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.

9. Do not use the Plastic Drawing Guide device during the trimming step.

10. Dispose of any product that has been damaged or mishandled prior to the operation.

11. Do not re-use. Re-use of the device may cause infection due to contamination of the device.

12. The surgeon is responsible for selecting appropriate patients and procedures.

Possible complications

- Dura rupture from using screws which contacts the dura.
- Polyamide Allergy.

Sterility

Plastic Drawing Guide and Cranial Implant Trial are provided sterile. Do not resterilize.

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 if the product is mishandled.

Anatomical Model Original and Anatomical Model Modified are for non-sterile use only.

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.