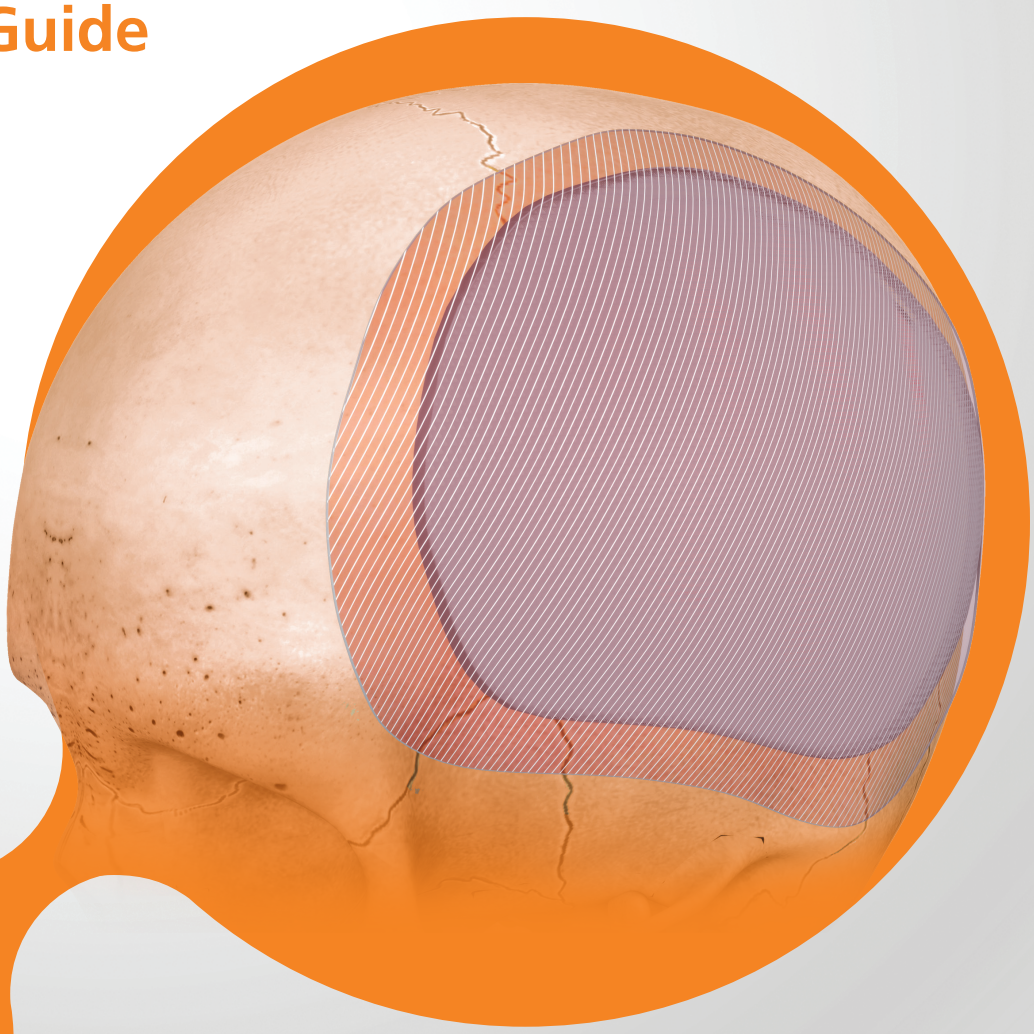
Osteopore®

Osteopore®
Patient Specific Implant

Cranioplasty Surgical Technique Guide



SUPPORT
CONFORM
REGENERATE

Disclaimer

Osteopore® does not provide medical advice, diagnosis or treatment. Information contained in this operative technique guideline have been provided for general information purposes only. The information included cannot and should not replace the independent medical judgment of the treating physician. Decisions on appropriate treatment and surgical technique are treating physician's responsibility and depends on the physician's training, medical knowledge and the case specific conditions. Treating physician should inform the patient regarding the potential benefits, risks and complications associated with the treatment.

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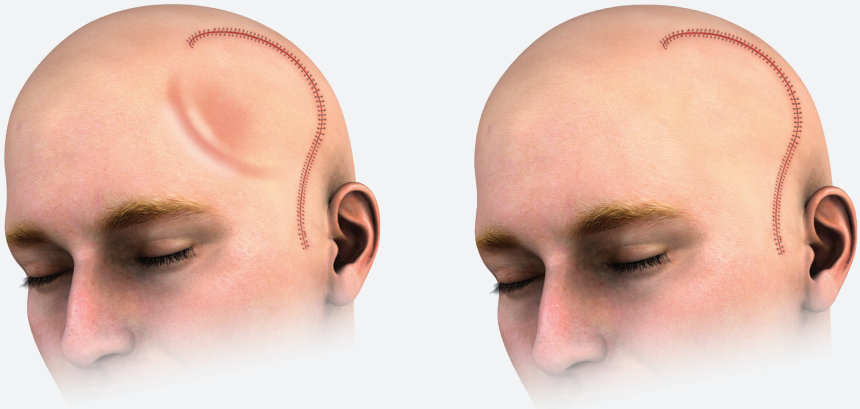
Introduction

Osteopore® Patient Specific Implant (PSI) is a customizable, 3D printed implant used for the reconstruction of cranial defects during cranioplasty. The device provides protection to the brain and aesthetic reconstruction of the patient's skull (Figure 1).



Before Osteopore® Device | After Osteopore® Device

Figure 1: Good aesthetic results can be achieved using the Osteopore® Device

The device is manufactured from Polycaprolactone and Tricalcium Phosphate (80:20) and provides a biomimetic scaffold that facilitates bone regeneration and slowly resorbs over a period of 18 - 24 months. It has a compressive strength similar to cancellous bone.[1] The device is used in combination with bone marrow aspirate (BMA) to achieve optimal bone healing.

Intended Use

Osteopore® PSI is intended to use for reconstruction of cranial defects and each implant is designed specifically to fit the needs of the patient. For details on indications, contraindications and other relevant information please refer to instructions for use.

WARNING:
Before starting the procedure inspect the implant packaging to confirm the patient information is correct and integrity of the sterile package is not damaged or compromised.

PREPARATION:
Read the label on the device box. Ensure that the patient's initials indicated on the label is correct. The device and Cutting Guide are provided in a sterile manner in a single layer packaging. Open the box carefully and check for the following contents:

1. Implant (Sterile Packed)
2. Cutting Guide (Sterile Packed)
3. Patient labels (Non-sterile)
4. Instruction for Use (Non-sterile)

Surgical Approach

1 Positioning

Position the patient in the appropriate surgical position according to the defect region, bone marrow aspiration location and prepare for procedure to minimize intraoperative re-positioning.

Note:
If the patient is in a supine position, BMA can be harvested from the Anterior Superior Iliac Spine (ASIS). Whereas, if the patient is in a left/right lateral position, BMA can be harvested from the Posterior Superior Iliac Spine (PSIS).

2 Surgical Exposure

1. Obtain proper exposure of the surgical site by clearing excess soft tissue using a surgical blade and/or electrocautery (Figure 2).

2. Ensure that the patient's dura is either intact or has been repaired, and is covering the brain. Do not puncture the dura during exposure.

3. Visually examine the defect site for any infection and/or alterations in the patient anatomy.

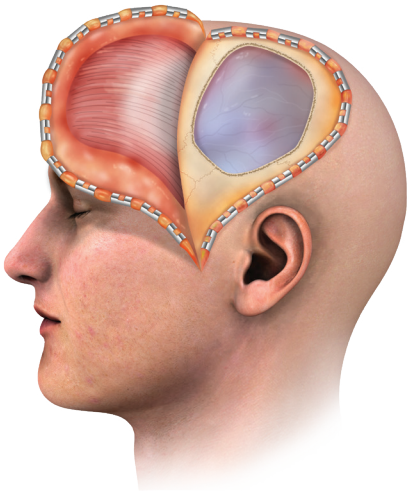


Figure 2: Surgical exposure

Defect Site Preparation

3 Cutting Guide Preparation

Open Cutting Guide packaging under aseptic conditions without contaminating the Cutting Guide. Gently remove the Cutting Guide from the packaging (Figure 3). Place the sterile Cutting Guide on a flat, sterile tray.

Figure 3: Cutting Guide

4 Cutting Guide Placement

Place the Cutting Guide over the cranial defect and ensure that the Cutting Guide matches the anatomical orientation and proper defect shape (Figure 4).

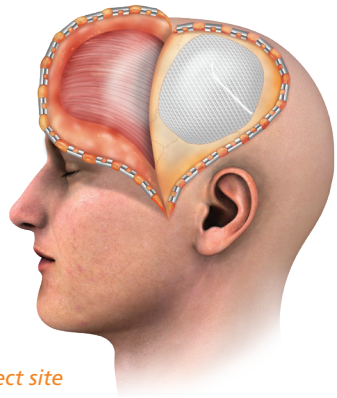


Figure 4: Cutting Guide placement over the defect site

5 Defect Site Preparation

1. Check for excess bone using the Cutting Guide.
2. If excess bone interferes with the fitting, carefully remove the excess bone using a rongeur or a surgical drill while checking the defect borders with the Cutting Guide.
3. Cutting Guide should fit the defect properly after removal of excess bone.

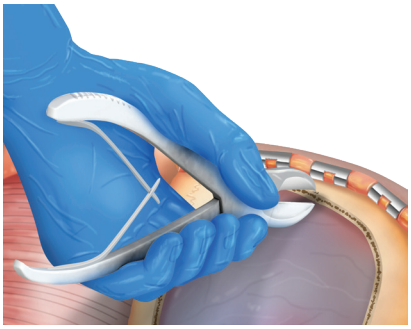


Figure 5: Defect Site Preparation

Warning: This description is not sufficient for immediate application of the instrument. Instruction by a surgeon experienced in handling the instrumentation is highly recommended.

The Device Preparation

6 Device Removal From Package

1. Open the device packaging under aseptic conditions and without contaminating the device. Remove the device from the packaging gently (Figure 6). Place the sterile the device on a flat, sterile tray.

2. Visually inspect the device and confirm that it is free from any particulates or contamination. No cracks or damages should be present on the device surface.

Figure 6: Device removal from package

7 Device Preparation

1. Place the device over the cranial defect and check for proper fit. Identify if any implant modification is required.

   CAUTION:
   Do not force the implant into the defect.

Figure 7: Device Preparation

2. If implant is not fitting, bone modification should be done first before any subsequent modification of the device. Refer to Step 5 for bone modification. Remove the device from surgical site and retain in a sterile tray while performing the bone modification.

Bone Marrow Aspiration & Incorporation

8 Bone Marrow Aspiration

1. As cranioplasty is a critical size defect, the use of bone marrow aspirate is compulsory. The volume of bone marrow aspirate is provided in the Design Appendix provided at design confirmation of the device with Osteopore®.

   CAUTION:
   Do not aspirate the bone marrow before the implant is ready for use.

2. DO NOT use Heparin or EDTA anticoagulants.

3. Follow manufacturer's instructions for bone marrow aspiration kit.

POSITION:
If the patient is in a lateral recumbent or prone position, the aspiration may be done posteriorly from the Posterior Superior Iliac Spine (PSIS). If the patient is in a supine position, the aspiration may be done anteriorly from the Anterior Superior Iliac Spine (ASIS) (Figure 8).

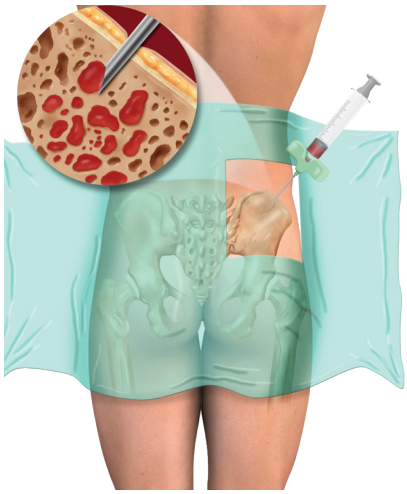


Figure 8: Bone marrow aspiration from Anterior Superior Iliac Spine.

9 BMA Incorporation into the Device

1. Place the device into a kidney dish with the interior side facing up.

2. Incorporate the bone marrow aspirate over the device using a sterile syringe. Begin from the outer edges of the implant and gradually move towards the inner centre. Make sure whole device is covered with the BMA (Figure 9). Leave the device to soak for 10 - 15 minutes to allow coagulation. This improves retention of the bone marrow by the device.

Figure 9: BMA is incorporated into the device

Device Placement

10 Bone Preparation

Prepare the native bone for implant placement while the device is left soaking in BMA. Refresh the bone edges with electrocautery to stimulate minute amounts of bleeding. This aids in the subsequent vascularization process.

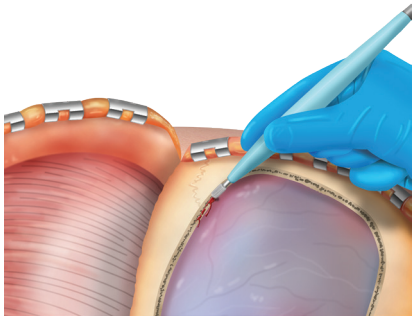


Figure 10: Bone edges are refreshed before the device is placed

11 Device Placement

Carefully place the device over the cranial defect. The device should be well fitted to the defect site. (Figure 11)

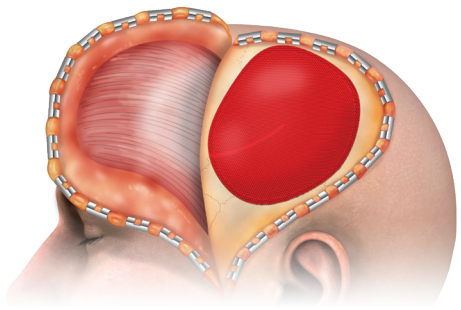


Figure 11: Device Placement

Fixation of Device

12 Fixation

Secure the device to the surrounding calvarial bone using either plates and screws (Figure 12A), or sutures (Figure 12B) to fixate the flange of the device to the adjacent bone. Ensure that the device is secured evenly round the entire circumference and firmly affixed to ensure contours of implant maintain alignment with native cranium.

WARNING:
Screws passing through the patient's bone and the flange might touch and irritate the dura which may cause complications. Ensure properly sized screws are used to avoid such problems.

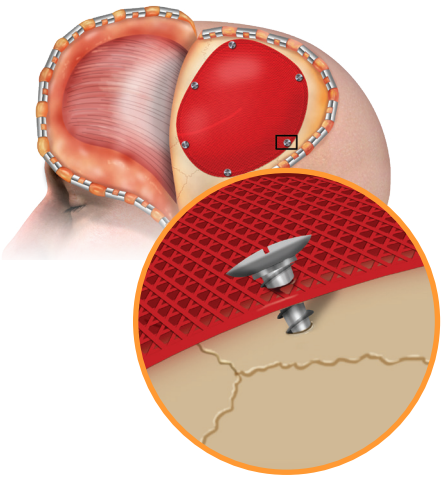


Figure 12A: Device fixation using screws

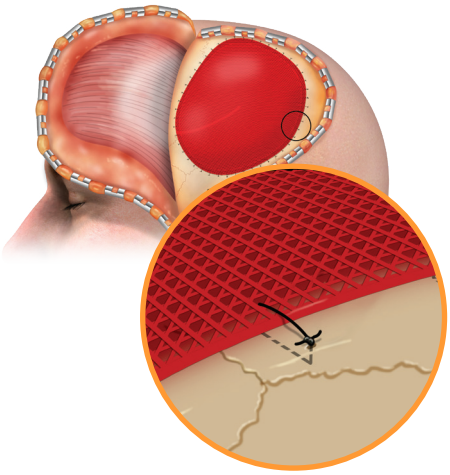


Figure 12B: Device fixation using sutures

CAUTION:
When using screws, ensure each screw is firmly seated onto the flange surface only. (Do not continue to advance the screw into the flange. Continued screw tightening will split the flanges and compromise fixation.)

13 Closure

Cover the device with any available pericranial flap.

WARNING:
Do not irrigate the wound after the device is implanted.

Closure of Surgical Site

14 Bone Preparation

1. Close skin in layers and finish surgery. (Figure 14)

2. The closure technique, method and products used should follow the current standard of care. Careful attention to skin closure will help prevent excessive tension or disruption of connective tissue. If required advanced wound closure techniques such as skin grafts can be used.

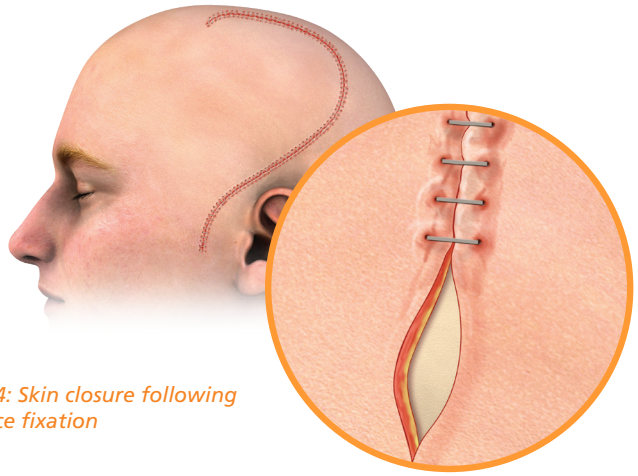


Figure 14: Skin closure following the device fixation

References:
1-Test Report No.7191152139-EEC16-WBH_CR1, 05.12.2016, PSB Singapore

For Professional Use.

CAUTION: See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Osteopore®

Empowering Natural Tissue Regeneration

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MCN 01 063B XE Rev 0