Osteopore®

Osteomesh™

for Craniosynostosis Repair

Surgical Technique

SUPPORT
CONFORM
REGENERATE

TABLE OF CONTENTS

INTRODUCTION

SURGICAL TECHNIQUE

PRODUCT INFORMATION

Osteomesh™

Osteomesh™ is a bioresorbable implant with a patented interconnected porous architecture that mimics the natural cancellous bone microstructure. It promotes tissue and vascular ingrowth.

Osteomesh™ is made of Polycaprolactone (PCL), a biodegradable polymer which degrades and resorbs fully in vivo by hydrolysis and is then metabolized by the body. It possesses an optimal resorption rate which maintains mechanical integrity during the healing process – minimizing adverse host-implant and inflammatory reactions.

Depending on the patient's anatomy and metabolism, Osteomesh™ has a gradual resorption profile of approximately 18 – 24 months.

Osteomesh™ is FDA 510(k) cleared. It is fabricated in compliance with current Good Manufacturing Practice (cGMP, EN ISO 13485) and provided sterile (gamma irradiation, EN ISO 11137).

Osteomesh™ Material	Polycaprolactone
Porosity	70%
Sterility	Osteomesh™ is provided sterile by gamma irradiation, in a single layer foil packaging. Do not re-sterilize Osteomesh™. This may cause the implant to not be sterile, and/or not meet the performance specifications and/or alter the material's properties.
Rigidity	Osteomesh™ is a semi-rigid bone filler.
Malleability	You may shape Osteomesh™ using a water bath and only sterile water or saline. Detailed steps are shown on **Page 8**. **Caution:** *Ensure that the temperature does not exceed 45°C. Do not place Osteomesh™ in the water bath for an extended period as it may cause Osteomesh™ to melt.*
Fixation	Fixate Osteomesh™ in place according to the surgeon's professional clinical judgement and current accepted surgical practices. Refer to **Page 8** for detailed implantation instructions.
Shelf Life	2 Years. Do not use Osteomesh™ after the expiry date labelled on the product packaging.

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

Disclaimer

Osteopore® does not provide medical advice, diagnosis or treatment. Information contained in this surgical technique guideline have been provided for general information purposes only. This document is not intended to be a comprehensive document on surgical techniques. The information included cannot and should not replace the independent medical judgment of the treating physician. Decisions on appropriate treatment and surgical technique are the treating physician's responsibility and depend on the physician's training, medical knowledge and the case-specific conditions. Successful implantations are technique sensitive. Sound surgical judgments should be used in the selection of all products. The managing physician should inform the patient regarding the potential benefits, risks and complications associated with the treatment.

Although Osteomesh™ (hereinafter referred to as "product") has been manufactured under carefully controlled conditions, Osteopore® has no control over the conditions under which the product is used. Osteopore®, therefore, disclaims all warranties, both expressed and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose.

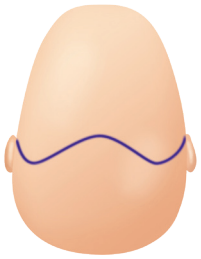
Osteopore® shall not be liable to any person or entity for any medical expenses or any direct, indirect, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Osteopore® to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law.

If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Surgical Exposure of Fused Sutures and Bone Reshaping

1 SURGICAL EXPOSURE

An incision is created to expose the skull and the fused sutures. The type of incision depends on the preferred technique of the surgeon.



NOTE:
Special attention should be placed on meticulous hemostasis.

2 EXPOSURE OF FUSED SUTURES

After craniotomies, cuts in the skull bone are created to excise the fused cranial sutures. Additional cuts in the bone may be made to allow for reshaping of the skull.

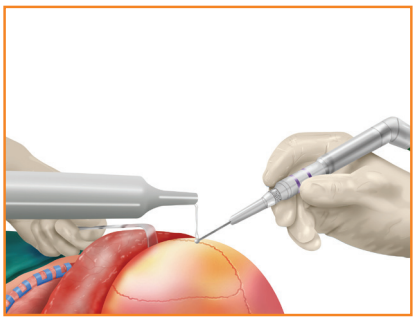
A rongeur and/or high-speed surgical drill may be used.

NOTE:
Special attention should be placed on meticulous hemostasis.

3 RESHAPING OF THE AFFECTED BONE

Depending on the type of craniosynostosis and the preferred technique of the surgeon, the affected bone is reshaped and rearranged to best restore the shape of the skull.

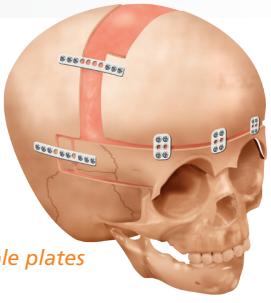
Techniques such as burring of the bone, rotating and reattaching of the remodelled segments, bone bending, separation and barrel stave osteotomies etc. may be used based on the type of craniosynostosis and reconstruction methodology.



NOTE:
Special attention should be placed on meticulous hemostasis.

4 FIXATION OF RESHAPED BONE

The reshaped bone is secured in its new position.
The technique of fixation depends on the surgeon.



In this picture, bioresorbable plates and screws are used.

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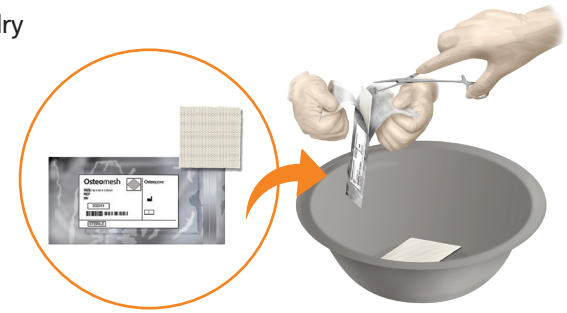
Implantation of Osteomesh™

5 PREPARATION OF OSTEOMESH™

Remove Osteomesh™ from sterile packaging and place into dry sterile bowl.

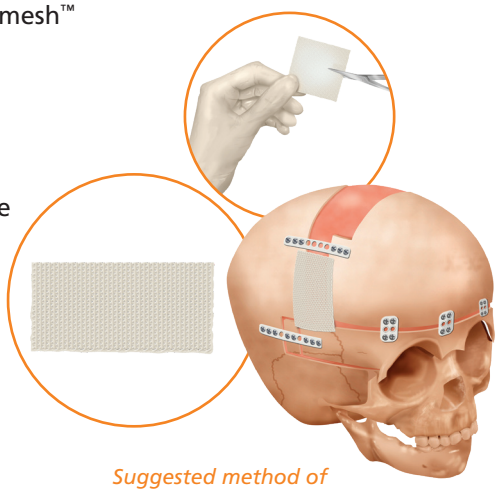
NOTE:
Use aseptic technique.



6 TRIMMING OSTEOMESH™ (if required)

A pair of sterile surgical scissors may be used to cut Osteomesh™ to allow for a more compliant contour to the skull.

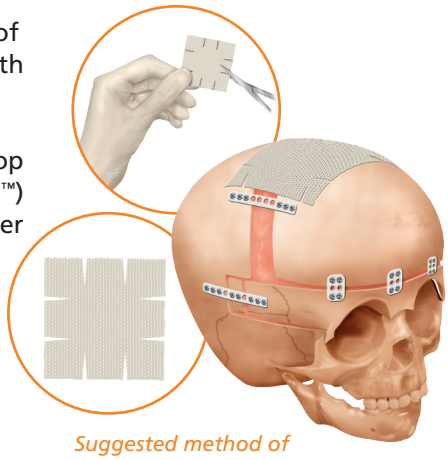
Technique 1: Smaller strips
In an area of the skull with greater curvature (e.g. edges at the top of the skull), Osteomesh™ may be cut into smaller strips and laid across the defect.



Suggested method of deploying Osteomesh®

Technique 2: Small wedge cuts
Small wedge cuts (single or multiple) may be created on the sides of Osteomesh™ to achieve a smoother contour that blends in with the skull.

In an area of the skull with greater curvature (e.g. edges at the top of the skull), a deeper wedge cut (towards the center of Osteomesh™) may be created to allow the mesh surface to achieve a greater contour.



Suggested method of deploying Osteomesh™

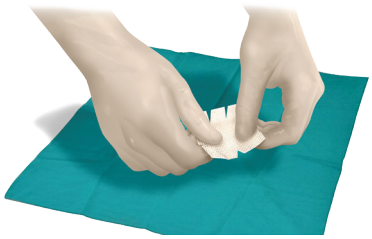
7 MOULDING OSTEOMESH™

1. A warm water bath may be used to shape Osteomesh™ **(~42°C)**.

   CAUTION:
   Ensure that the temperature is not above 45°C.

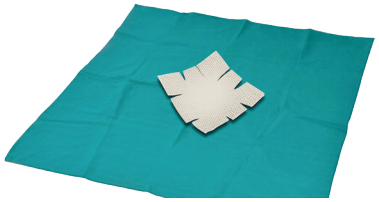
2. Immerse Osteomesh™ for approximately **10 seconds** in the warm saline to make it more malleable.

   CAUTION:
   Do not leave Osteomesh™ unattended in the warm saline for extended periods of time as this may cause it to melt and lose its ability to hold screws.



3. Shape Osteomesh™ while it is in the warm saline and hold it in the desired shape for approximately **5 seconds**.

4. While holding onto the shaped Osteomesh™, remove it from the warm saline. Continue to hold its shape for approximately **10 seconds**. This helps to maintain its new shape.



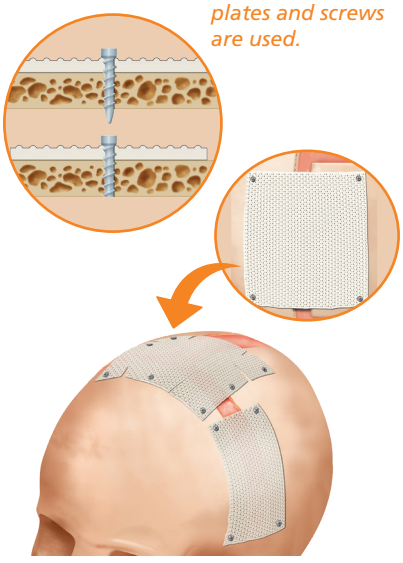
8 FIXATION OF OSTEOMESH™

1. Trim Osteomesh™ to the desired shape and configuration.

2. Osteomesh™ is placed across the skull defects to bridge gaps. Then, secure it in place.

TECHNIQUE TIP:
Gently fix the implant onto the skull when using resorbable screws due to the malleability of the skull in paediatric patients.

In this picture, bioresorbable plates and screws are used.



NOTE:

1. *While using resorbable screws, once the screws are firmly secured onto Osteomesh™, do not continue to advance the screws. This may derange the architecture of the mesh and loosen the fixation of Osteomesh™.*

2. *Permanent titanium screws may be used but the screw head may be palpable when the implant resorbs.*

FIXATION OF OSTEOMESH™ (cont'd)

TECHNIQUE TIP:

When using resorbable screws:

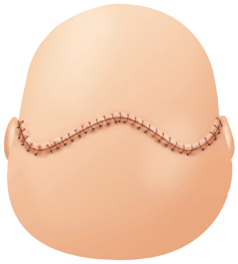
1. Osteomesh™ is positioned in place over the defect.
2. An appropriate siting of the pilot hole is made.
3. A hole is drilled through Osteomesh™ and the skull.

   NOTE:
   Appropriate precautions should be taken to not damage the underlying brain.
4. The drill hole is pre-tapped to ensure smooth passage of the resorbable screws to affix the implant.

9 CLOSURE OF SURGICAL SITE

Close the skin in layers. The technique, method and products used to achieve closure of surgical site should follow the current standard of care.

NOTE:
Paying careful attention to skin closure will help to prevent excessive tension or disruption of the connective tissue.



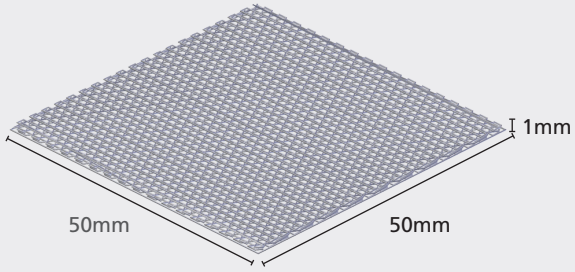
Post-Operative Care

10 POST-OPERATIVE CARE

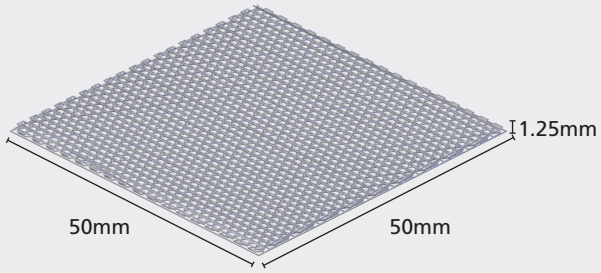
Post-operative care should be conducted according to the surgeon's protocol and current standard of care.

This is the experience in cases from Professor Lim Thiam Chye (Head and Senior Consultant, Division of Plastic, Reconstructive and Aesthetics Surgery, Department of Surgery, National University Hospital).

Implant Sizes



Product Code	Length/mm	Breadth/mm	Thickness/mm
PC11(50,50,1) / PTSH-050-050-001-P	50	50	1.00



Product Code	Length/mm	Breadth/mm	Thickness/mm
PC11(50,50,1.25) / PTSH-050-050-001-P2	50	50	1.25

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

Intended Use / Indications

The Osteopore® PCL Scaffold Bone Filler is a Bone Void Filler.

It is intended for use in the following:

- Repair of neurosurgical burr holes
- Repair of craniotomy cuts and other cranial defects
- Augmentation or restoration of bony contour in the craniofacial skeleton

Please refer to the Instructions for Use which is provided together with the product for more details on indications, contraindications and other relevant information.

NOTE:
The Intended Use / Indications may differ between countries.
Please check with your local sales representative for more information.

Contraindications

1. Do not use in patients with conditions including latent or active infections, systemic disorders which will hinder wound healing, or with insufficient quantity or quality of bone stock.
2. Do not use in contaminated surgical areas.
3. Do not use in patients with septic reactions.
4. Not indicated for load bearing anatomical sites.
5. Do not use in areas exposed to outside environment.

Warnings

1. Do not expose the scaffold to heat over 45°C.
2. Do not use if a package has been opened or damaged.
3. For single use only. Additional sterilization may alter device characteristics, e.g. advanced resorption.
4. Do not use if there is a loss of sterility.
5. Do not resterilize.
6. Do not expose to direct sunlight.
7. Excessive bending (>90°) of the device will cause scaffold rods to break down, thus rendering it unsuitable for implantation.
8. Disposal of devices that have been implanted but then removed from the patient are deemed contaminated and shall be disposed.

Precautions

1. Patient must be warned that excessive stress or load on surgical site post-implantation will cause it to loosen or fracture.
2. Patient must be educated of the surgical risk and possible postoperative effects if due care and instructions are not followed.
3. External exposure should be avoided. (Osteomesh™ only)
4. The safety and effectiveness of adding any substances to the device is not known. These may change the setting time, strength, and reaction rate.
5. The safety and effectiveness of the material when used adjacent to non-viable bone is not known. If there is a need to re-operate in the area of the implant, the device should be removed.

For Professional Use.

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

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