

# Osteoplug®

## Surgical Technique Guide





# TABLE OF CONTENTS

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01

Disclaimer

02

Osteoplug®

03

Osteoplug®  
for Burr Hole  
Reconstruction

04

Osteoplug®  
for Burr Hole  
Reconstruction  
with catheters

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05

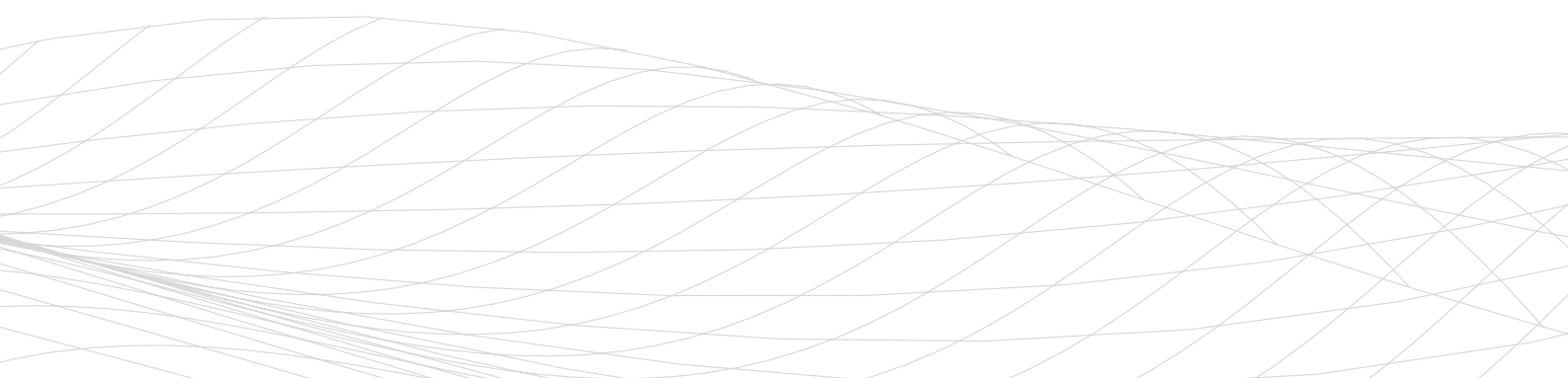
Osteostrip  
for Craniotomy  
Closure

06

Osteostrip for  
Craniotomy Closure  
- Method 1

07

Osteostrip for  
Craniotomy Closure  
- Method 2



# 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 Osteoplug® 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.

# Osteoplug<sup>®</sup> and Osteostrip

Osteoplug<sup>®</sup> and Osteostrip is a bioresorbable implant with a patented interconnected porous architecture that mimics the natural cancellous bone microstructure. This bone scaffold creates an environment for tissue and vascular ingrowth.

Osteoplug<sup>®</sup> and Osteostrip is made of Polycaprolactone (PCL), a biodegradable polymer which degrades and resorbs fully in vivo by hydrolysis. PCL's degradation profile possesses an optimal resorption rate which maintains mechanical integrity during the healing process – minimizing adverse host-implant and inflammatory reactions.

Osteoplug<sup>®</sup> and Osteostrip has a gradual resorption profile of over 24 months.

Osteoplug<sup>®</sup> and Osteostrip 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).

## Intended Use / Indications

Osteoplug<sup>®</sup> and Osteostrip is intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects.

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.

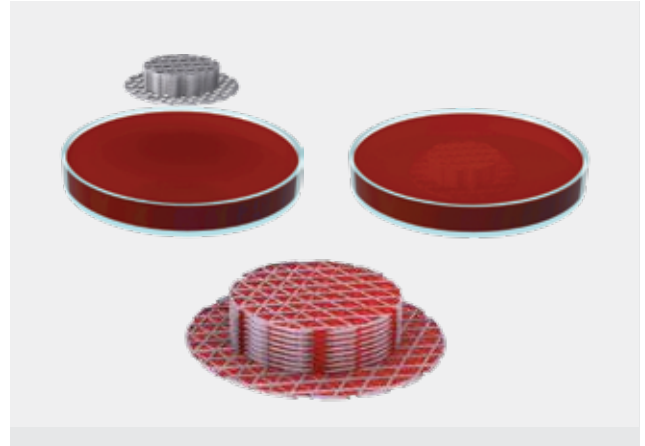
### **CONTRAINDICATIONS**

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.

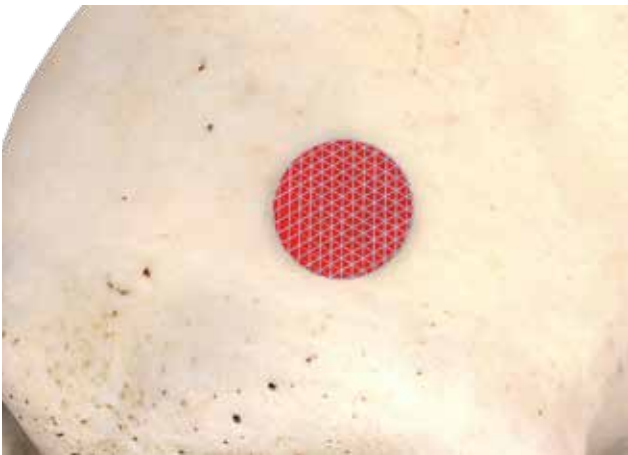
# Osteoplug® for Burr Hole Reconstruction



Burr hole trephination leaves a hole in patient's skull.



Soak Osteoplug® in peripheral blood ensuring that the entire product is coated with coagulated blood. Blood cells act as biologics to the scaffold. The Osteoplug® is ready for use when blood coagulates, and does not drip upon removal from dish.



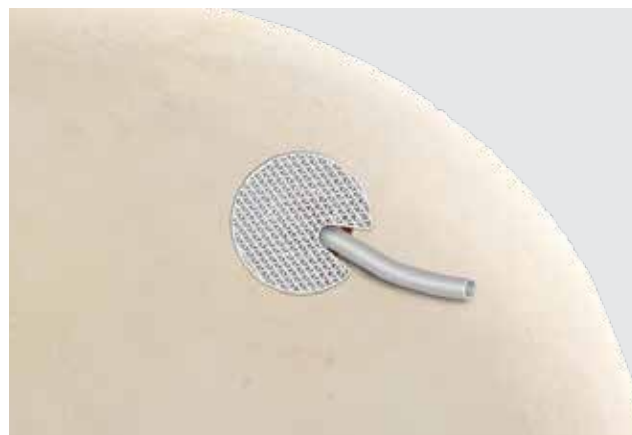
Osteoplug® fits snugly into perforated and hand drill burr holes without requiring fixation.

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

# Osteoplug® for Burr Hole Reconstruction with catheters



Osteoplug®-C comes with a central hole that allows for insertion of a catheter. Insert the catheter\* before inserting the Osteoplug®-C. The device fits snugly into perforated and hand drill burr holes without requiring fixation.



Osteoplug® comes with a U slot that allows for insertion of a catheter\*. Insert the catheter before inserting the Osteoplug®. The device fits snugly into perforated and hand drill burr holes without requiring fixation.



Catheters can be sutured onto the Osteoplug®-C where necessary.

\* Max catheter size: 11 French

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

# Ogestrip for Craniotomy Closure



Craniotomy procedures leave a gap between the patient's bone flap and surrounding native vascularised bone.



Soak both Osteoplug® and Ogestrip in peripheral blood for at least 10 seconds, ensuring that the entire product is coated with coagulated blood. Blood cells act as biologics to the scaffold. The Osteoplug® is ready for use when blood coagulates, and does not drip upon removal from dish. Blood cells act as biologics to the scaffold.

## There are 2 methods for filling the bone gap:



### Method 1

Bone flap in contact with native bone.



### Method 2

Bone flap in centre of defect.

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

## Method 1

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Pushing the bone flap to be in contact with 1 side of the native bone

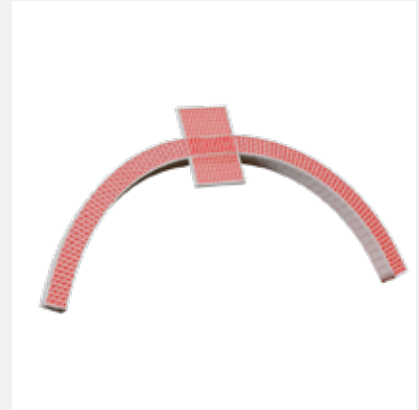


- 1 Use at least 3 sets of plates and screws for fixation.



- 2 Push the bone flap to be in contact with 1 side of the native bone and add fixation.

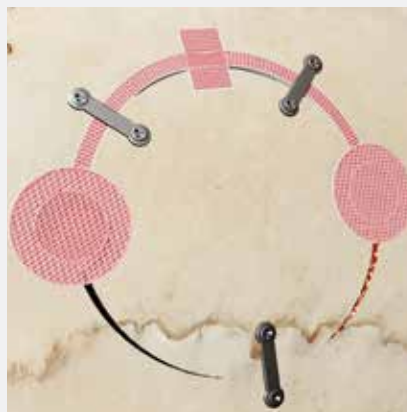
Trim the strip using sharp scissors until the ideal length is achieved. Leave behind at least one flange on the strip for added support.



- 3 Make small kinks on the strip to create the desired curvature to match the curvature of the craniotomy gap to be filled.



- 4 Fit the strip into the craniotomy gap. Fixate the plates on top of the strip to prevent device migration.



- 5 Fit the plugs into the burr holes.

Choose the plug size 2 sizes smaller than the perforator.

## Method 2

Bone flap remains at its original position

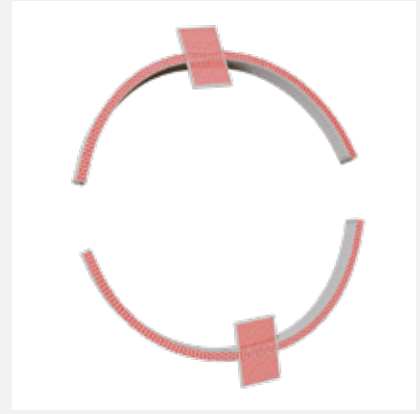


- 1 Use at least 4 sets of plates and screws for fixation.

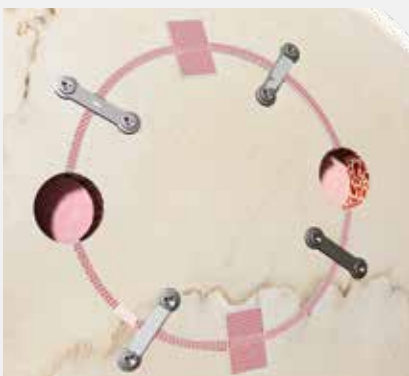


- 2 Place the bone flap in its original position.

Trim the strip using sharp scissors until the ideal length is achieved. Leave behind at least one flange on the strip for added support.



- 3 Make small kinks on the strip to create the desired curvature to match the curvature of the craniotomy gap to be filled.



- 4 Fit the strips into the craniotomy gap. Fixate the plates on top of the strips to prevent device migration.



- 5 Fit the plugs into the burr holes.

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





**For Professional Use.**

CAUTION: See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions. Osteopore®, Osteopore International, the stylized Osteopore® logo, are trademarks of Osteopore International Pte Ltd. © 2023 Osteopore®. All rights reserved.

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Empowering Natural Tissue Regeneration

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MCN 01 079B US Rev 0