OSTEOPORE® REGENERATIVE BONE SCAFFOLD



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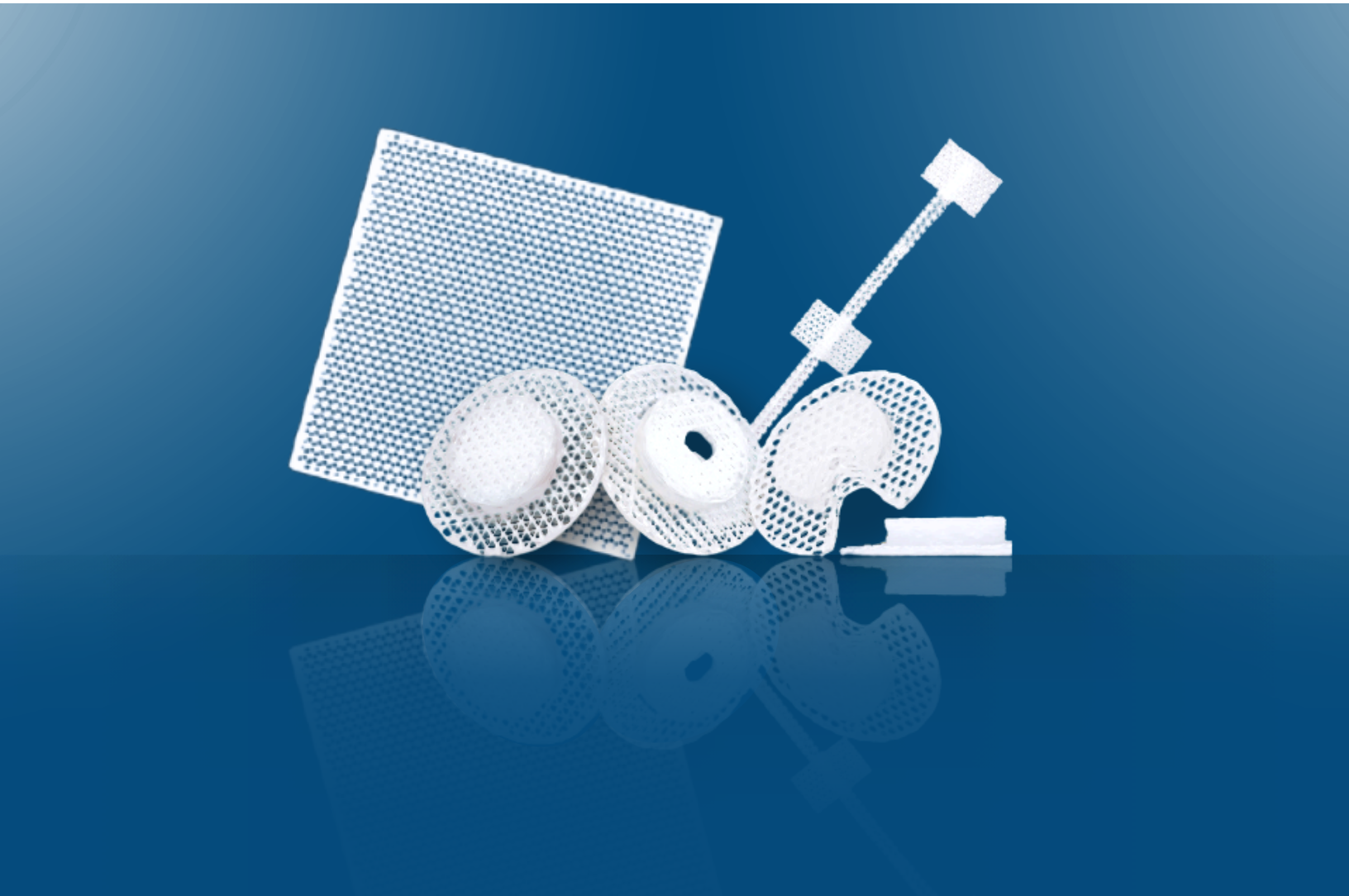
Customized Precision. Expedited.

OSTEOPORE® REGENERATIVE BONE SCAFFOLD

Osteopore® devices are intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects.

Osteoplug®, Osteoplug®-C, Osteostrip, and Osteomesh® are bioresorbable implants with a patented interconnected porous architecture that mimics the natural cancellous bone microstructure. This bone scaffold creates an environment for tissue and vascular ingrowth.

Osteopore® devices are made of Polycaprolactone (PCL), a biodegradable polymer that degrades and resorbs fully over a period of 18-24 months. 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®

BURR HOLE COVERS

- MUSHROOM BUTTON DESIGN
- TIGHT FIT MECHANISM
- BIOCOMPATIBLE
- OSTEOCONDUCTIVE
- RESTORE BONE
- BIOMIMETIC POROUS ARCHITECTURE
- BIORESORBABLE PCL
- SIZED TO THE PERFORATOR
- NO ADDITIONAL FIXATION REQUIRED

Osteoplug® is designed and intended for the repair of neurosurgical burr holes. It is manufactured from polycaprolactone (PCL), a biodegradable polymer that degrades and resorbs fully in vivo by hydrolysis and is then fully metabolized without any toxic by-product. Its porous, interconnected microarchitecture demonstrates mechanical properties similar to human cancellous bone and provides a regenerative niche suitable for bone formation. The plug is sized to correspond to the perforator and does not require additional fixation.

OSTEOPLUG® BURR HOLE COVER PC 22



CATALOG NO.	A, LENGTH (MM)	B, BREADTH (MM)	C, THICKNESS (MM)	O, OVERALL Ø (MM)
PC22 (11, 11, 4)	11	11	4	19
PC22 (13, 13, 4)	13	13	4	22
PC22 (14, 14, 4)	14	14	4	24
PC22 (15, 15, 4)	15	15	4	25

Overall Ø is the outer (flange) diameter of the cover; A is the plug diameter. Additional sizes are available. Please contact Kelyniam for more information.

SURGICAL PROCEDURE

- Burr Hole Reconstruction

OSTEOPLUG® & OSTEOPLUG®-C

DRAINS & SHUNTS

- U-SLOT (PC 23) FOR DRAIN INSERTION
- ROUND HOLE (PC 24) FOR SHUNT INSERTION
- DRAINS EASILY REMOVED AFTER RECOVERY

OSTEOPLUG® BURR HOLE COVER PC 23

U-slot for drain insertion



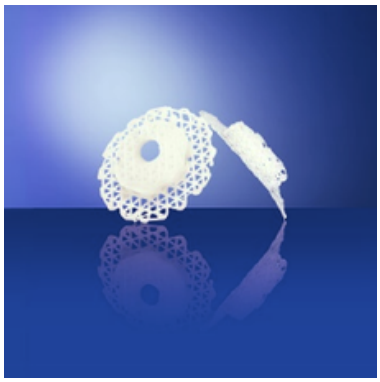
CATALOG NO.	A, LENGTH (MM)	B, BREADTH (MM)	C, THICKNESS (MM)	O, OVERALL Ø (MM)	U, U-SLOT WIDTH (MM)	M, MAX. CATHETER (FR)
PC23 (11, 11, 4)	11	11	4	19	3.7	8
PC23 (13, 13, 4)	13	13	4	22	4.3	9
PC23 (14, 14, 4)	14	14	4	24	4.7	9
PC23 (15, 15, 4)	15	15	4	25	5	9

SURGICAL PROCEDURE

- SDH Drainage

OSTEOPLUG®-C BURR HOLE COVER PC 24

Round hole for shunt insertion



CATALOG NO.	A, LENGTH (MM)	B, BREADTH (MM)	C, THICKNESS (MM)	O, OVERALL Ø (MM)	M, MAX. CATHETER (FR)
PC24 (11, 11, 4)	11	11	4	19	11
PC24 (13, 13, 4)	13	13	4	22	11
PC24 (14, 14, 4)	14	14	4	24	11
PC24 (15, 15, 4)	15	15	4	25	11

SURGICAL PROCEDURE

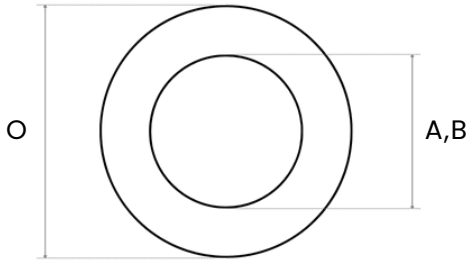
- CSF Shunting

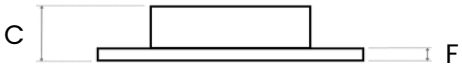
OSTEOPLUG®

TECHNICAL SPECIFICATIONS

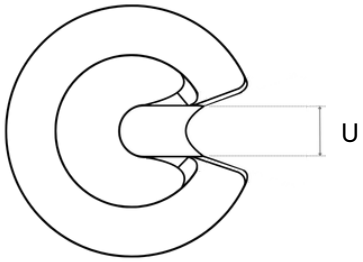
- 3D-PRINTED POLYCAPROLACTONE (PCL)
- INTERCONNECTED POROSITY, APPROX. 70%
- FULLY RESORBS OVER A PERIOD OF 18-24 MONTHS
- 4 MM OVERALL THICKNESS

PC 22

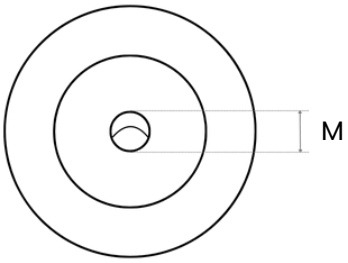




PC 23



PC 24



DIMENSION KEY

DIMENSION	DESCRIPTION
A,B	Length & Breadth: Plug diameter; corresponds to the perforator size
C	Thickness, total: 4 mm
F	Flange thickness: 1 mm
O	Overall Ø: diameter of cover including the flange
U	Width of the U-slot that accepts a drain
M	Max catheter: Largest catheter size (French) accepted by the opening

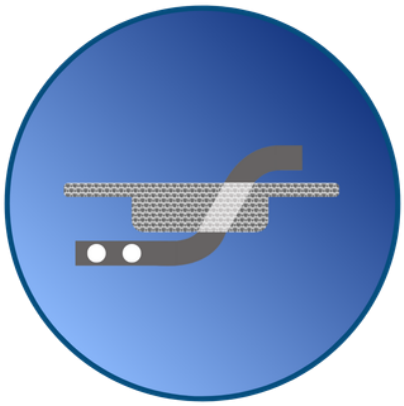
OSTEOPLUG®
SURGICAL TECHNIQUE

1 SITE PREPARATION

Prepare the implantation site using standard surgical techniques. Ensure that hemostasis is achieved prior to implantation. Do not use bone wax for hemostasis.

2 IMPLANT SELECTION

Select the plug diameter that best suits the perforator drill bit size. Select the plug shape that best suits the catheter of choice.



PC 23
U-slot for drain insertion

3 IMPLANT PREPARATION

Osteoplug® is soaked with the patient's blood.

4 INSERTION

Gently lower Osteoplug® into the surgically created defect. Insert the catheter tube through the hole, or pass it over the slanted side of the notch, and make sure the drain is not compressed. Osteoplug® has a snug fit in the defect site. No fixation devices or suturing are required.



PC 24
Round hole for shunt insertion

5 SCALP CLOSURE

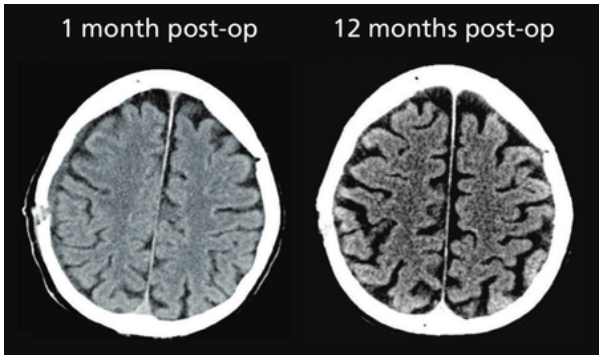
Close the scalp using standard surgical techniques.

IMPORTANT

The regenerative capacity of the scaffold depends on cells and biological factors from the surrounding bone and blood. Bone wax is a non-regenerating material and appears to attenuate bone regeneration.[3] Refer to the Instructions for Use supplied with the device for full indications, contraindications, warnings and precautions.

OSTEOPLUG®

CLINICAL EVIDENCE



Axial CT at 1 month post-op showing the burr hole, and at 12 months post-op showing the burr hole covered with native bone.[1]

Osteoplug® has been implanted since 2004 and has shown excellent functional and aesthetic outcomes. No major complications or adverse reactions have been reported.

Up to 10 years of follow-up data shows excellent tissue compatibility without abnormal inflammatory reactions. As a bioresorbable implant, Osteoplug® is designed to avoid complications associated with permanent materials, such as implant extrusion and migration.[1,2]

10-YEAR RETROSPECTIVE STUDY [3]

Yang M, Ng HJH, Nga VDW, Chou N, Yeo TT. J 3D Print Med 2020;4:9–16. Osteoplug® and Osteoplug®-C, Singapore, 2006–2015.

MEASURE	FINDING
Population	174 consecutive patients, 275 burr holes closed. Mean age 64.6 years. Follow-up up to 9.5 years.
Indications	Chronic subdural hematoma 41%; acute-on-chronic and subacute SDH 30%; intracerebral hematoma 14%; brain tumor biopsy 8.5%; hydrocephalus shunt 4.5%.
Wound infection	1 of 275 implants (0.36%); 1 of 174 patients (0.57%). Not increased compared with published literature.
CSDH re-operation	10 of 72 CSDH cases (9 for recurrence, 1 for wound infection). Recurrence reported as comparable to published series without a burr hole cover.
Shunts and biopsy	No new complications with Osteoplug®-C in VP shunt surgery; no added risk in stereotactic brain biopsy.
Tissue response	Explant at 3.5 months: extensive tissue ingrowth, with blood vessel infiltration throughout. Serial CT in two patients (up to 8 years): tissue ingrowth, no scalp depressions.

CONCLUSIONS

- No increase in infection or complication rates was observed with Osteoplug® across the burr hole indications studied.[3]
- Histological and radiological findings suggest tissue regeneration. No cortical bone-like findings were seen on the two long-term CT cases, and no scalp depressions or cosmetic complaints were reported in the observed period.[3]
- Limitations: retrospective design, no control group, no randomization, and no quantitative measure of cosmetic benefit.[3]

OSTEOSTRIP

FILLING IN CRANIOTOMY GAPS CAN RESULT IN IMPROVED COSMESIS, REDUCED PAIN, AND INCREASED PATIENT SATISFACTION. THE OSTEOPORE IMPLANT FULLY RESORBS OVER A PERIOD OF 18-24 MONTHS. [1, 2, 3]

OSTEOSTRIP PC 17



CATALOG NO.	A, LENGTH (MM)	B, BREADTH (MM)	C, THICKNESS (MM)
PC17 (100, 2, 4)	100	2	4
PC17 (100, 3.5, 4)	100	3.5	4

SURGICAL PROCEDURE

- Craniotomy

OSTEOMESH®

- MAXIMIZED BONE CONTACT
- OSTEOCONDUCTIVE
- SEMI-FLEXIBLE
- CAN BE TRIMMED

OSTEOMESH® PC 11



CATALOG NO.	A, LENGTH (MM)	B, BREADTH (MM)	C, THICKNESS (MM)
PC11 (50, 50, 1)	50	50	1
PC11 (50, 50, 1.25)	50	50	1.25
PC11 (50, 50, 2)	50	50	2

SURGICAL PROCEDURE

- Cranial vault remodeling
- Orbital Floor Repair Surgery
- Endonasal Transsphenoidal Surgery

Intended Use / Indications

Osteoplug®, Osteoplug®-C, Osteostrip, and Osteomesh® are 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.

Caution: US law restricts this device to sale by or on the order of a physician.

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®, Osteoplug®-C, Osteostrip, and Osteomesh® have been manufactured under carefully controlled conditions, Osteopore® has no control over the conditions under which the product is used. Osteopore®, therefore, disclaims all conditions, warranties, guarantees, 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.

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Important information:
Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings, and precautions.

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[1] Low SW et al. Use of Osteoplug polycaprolactone implants as novel burr-hole covers. Singapore Med J 2009; 50(8): 777-780.

[2] Schantz JT et al. Cranioplasty after trephination using a novel biodegradable burr hole cover: technical case report. Neurosurgery 58[ONS Suppl 1]:ONS-176, 2006.

[3] Yang M et al. Cranial reconstruction using a polycaprolactone implant after burr hole trephination. Journal of 3D Printing Medicine 2020; 4:9-16.

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