

Osteopore®

# OSTEOPLUG®-C



CE 0197

# 1

## BIOMIMETIC

- The **Osteoplug®-C** is a bioresorbable implant with a patented interconnected porous architecture that mimics the natural cancellous bone microstructure. It promotes tissue and vascular ingrowth.
- **Osteoplug®-C** is an integrating implant to restore post-trephination burr hole defects by promoting tissue ingrowth, leading to a shift in burr hole reconstructive surgery from purely cosmesis to functional regeneration of damaged tissues.
- **Osteoplug®-C** bears the CE mark of compliance, is FDA 510(k) cleared, fabricated in compliance with current Good Manufacturing Practice (cGMP) and EN ISO 13485 and provided sterile (gamma irradiation, EN ISO 11137).

# 2

## DESIGN

### 1. RESORBABILITY

- Polycaprolactone (PCL) is a biodegradable polymer that degrades and resorbs fully *in vivo* by hydrolysis which is then metabolized by the body.
- **Osteoplug®-C** has a gradual resorption profile, depending on the patient anatomy and metabolism, of approximately 18-24 months.
- **Osteoplug®-C** possesses optimal resorption rate that maintains mechanical integrity during healing process – minimizing adverse host-implant and inflammatory reactions.

### 2. POROSITY

- **Osteoplug®-C** is manufactured with a porous interconnected micro-architecture that demonstrates mechanical properties similar to human cancellous bone.
- Upon implantation, blood and surrounding cells are absorbed into the pores of the scaffold via capillary action – Creating a regenerative niche that is ideal for tissue formation.

### 3. SNAP-FIT DESIGN

- **Osteoplug®-C** is designed to fit perfectly into the post-trephination burr hole defect. This ensures direct interaction between surrounding calvarial bone, allowing repair cells to use the implant as a scaffold, promoting bone tissue regeneration.



*Porosity of Osteoplug®-C*

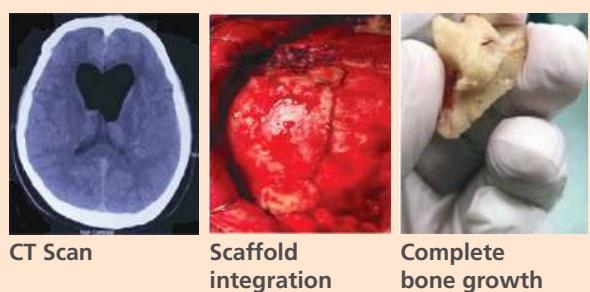
Low SW, Ng YJ, Yeo TT, Chou N.  
Use of Osteoplug polycaprolactone implants as novel burr-hole covers.  
Singapore Med J. 2009;50:777-80.

### 3

## CLINICAL ADVANTAGE

### PATIENT'S PERSPECTIVE

- No patient developing adverse reactions such as pain, scarring, infections or excessive debris production.
- This implant has shown excellent functional and aesthetic outcomes.



(Left) Patient's post-operative CT scan after 2 years, (Middle) Osteointegration seen between the scaffold and the rest of the calvarial bone, (Right) Physical appearance of the regenerated bone (previously Osteoplug®) after 2 years.

Data on file

### CLINICAL PERSPECTIVE

- Implanted since 2004 with no complications when used according to its approved Indications.
- Beyond 2 years of follow up shows host-implant compatibility with no infection and migration of implant.
- Avoided donor site morbidity.
- Designed to perfectly fit into burr holes formed by perforators and other cranial defects, allowing easy handling by surgeons and ensured excellent cosmesis.
- **Osteoplug®-C** were well-integrated into adjacent calvarial bone

### 4

## INDICATIONS FOR USE

**Osteoplug®-C** is indicated for neurosurgical burr holes and allows for the insertion of catheter after cerebral shunt operations.

### 5

## SURGICAL PROTOCOL

### 1. SITE PREPARATION

Prepare the implantation site using standard surgical techniques. Control of active bleeding should be achieved prior to implantation.

### 2. IMPLANT SELECTION

Select the plug diameter that best suit perforator drill bit size.

Select the plug shape that best suit catheter of choice.

### 3. IMPLANT PREPARATION

**Osteoplug®-C** is soaked with patient's blood.

### 4. INSERTION

Gently lower the **Osteoplug®-C** into the surgically created defect. Insert catheter tube through the hole or pass over the slanted side of the notch and make sure drain is not compressed. The **Osteoplug®-C** would have a snug fit in the defect site. No fixation devices or suturing is required.



*Osteoplug®-C*



*Osteoplug®-C*

### 5. SCALP CLOSURE

Close the scalp using standard surgical techniques.

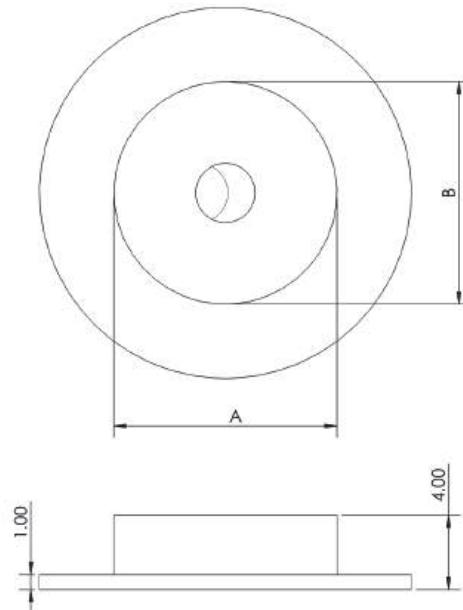
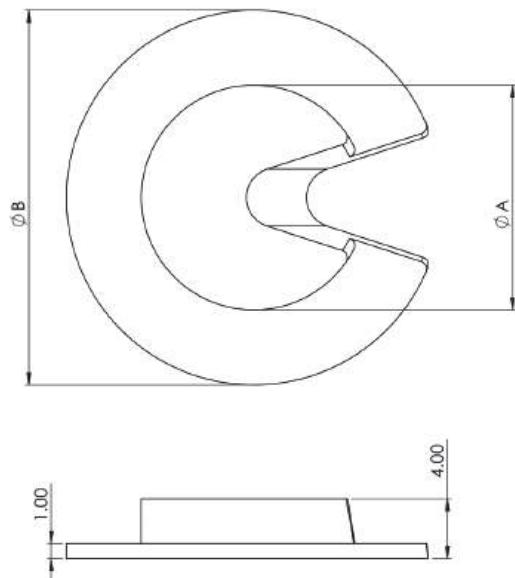
## 6

## HANDLING ADVANTAGE

- Osteoplug®-C conforms to the defect, thus maximizing direct contact with viable host bone.
- Osteoplug®-C is designed to perfectly fit into burr holes formed by perforators and other cranial defects, allowing easy handling by surgeons and ensured excellent cosmesis
- Osteoplug®-C does not require fixation.

## 7

## OSTEOPLUG™-C SIZE CHART



Product Code	A (mm)	B (mm)	Maximum Catheter Size (Fr)
PC23(8, 8, 4)	8	14	7
PC23(9, 9, 4)	9	15	7
PC23(10, 10, 4)	10	17	8
PC23(11, 11, 4)	11	19	8
PC23(12, 12, 4)	12	20	8
PC23(13, 13, 4)	13	22	9
PC23(14, 14, 4)	14	24	9
PC23(15, 15, 4)	15	25	9

Product Code	A (mm)	B (mm)	Maximum Catheter Size (Fr)
PC24(10, 10, 4)	10	17	11
PC24(11, 11, 4)	11	19	11
PC24(12, 12, 4)	12	20	11
PC24(13, 13, 4)	13	22	11
PC24(14, 14, 4)	14	24	11
PC24(15, 15, 4)	15	25	11

For professional use.

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

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