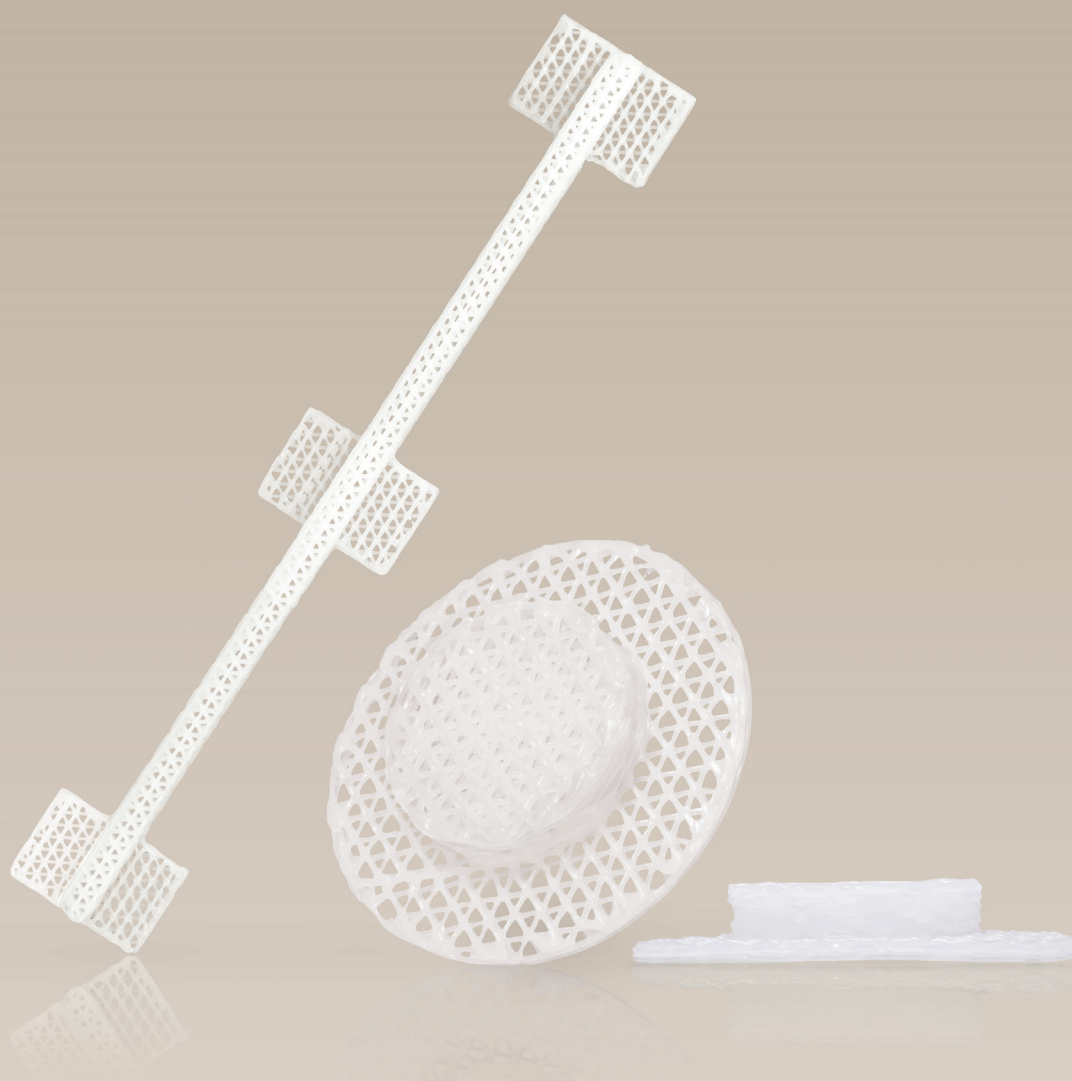


# OSTEOPLUG®



# 1

## BIOMIMETIC

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

# 2

## DESIGN

### 1. RESORBABILITY

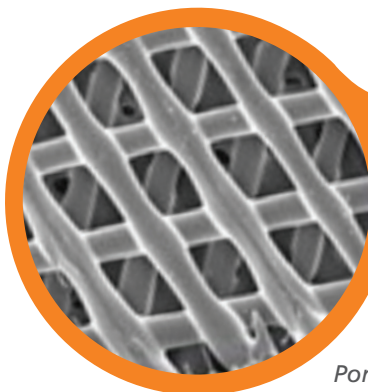
- Polycaprolactone (PCL) is a biodegradable polymer that degrades and resorbs fully in vivo by hydrolysis which is then metabolized by the body.
- **Osteoplug®** has a gradual resorption profile, depending on the patient anatomy and metabolism, of approximately 18-24 months.
- **Osteoplug®** possesses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

### 2. POROSITY

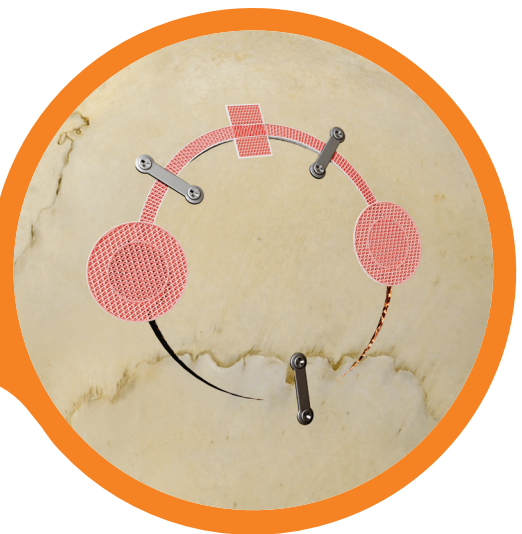
- **Osteoplug®** is manufactured with a porous interconnected micro-architecture that demonstrates mechanical properties similar to human cancellous bone.
- Upon implantation, blood and surrounding cells are absorbed into the pores of the scaffold via capillary action – Creating a regenerative niche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

### 3. SNAP-FIT DESIGN

- **Osteoplug®** is designed to fit perfectly into the burr hole defect and fresh craniotomy cuts. 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®*

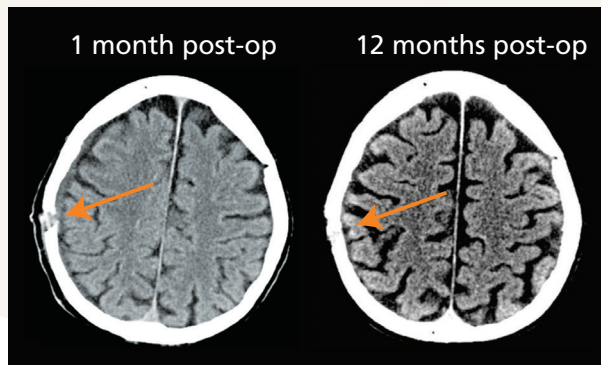


### 3

## 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.



1 month post-op axial CT showing burr hole clearly.  
12 month post-op axial CT showing that the burr hole has been covered with native bone.

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.

### 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®** were well-integrated into adjacent calvarial bone

### 4

## INDICATIONS FOR USE

**Osteoplug®** is indicated for the repair of neurosurgical burr holes and fresh craniotomy cuts.

### 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 appropriate plug size that best suits burr hole defect.

#### 3. IMPLANT PREPARATION

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

#### 4. INSERTION

Gently lower the **Osteoplug®** into the surgically created defect. The **Osteoplug®** would have a snug fit in the defect site. No fixation devices or suturing is required.

#### 5. SCALP CLOSURE

Close the scalp using standard surgical techniques.

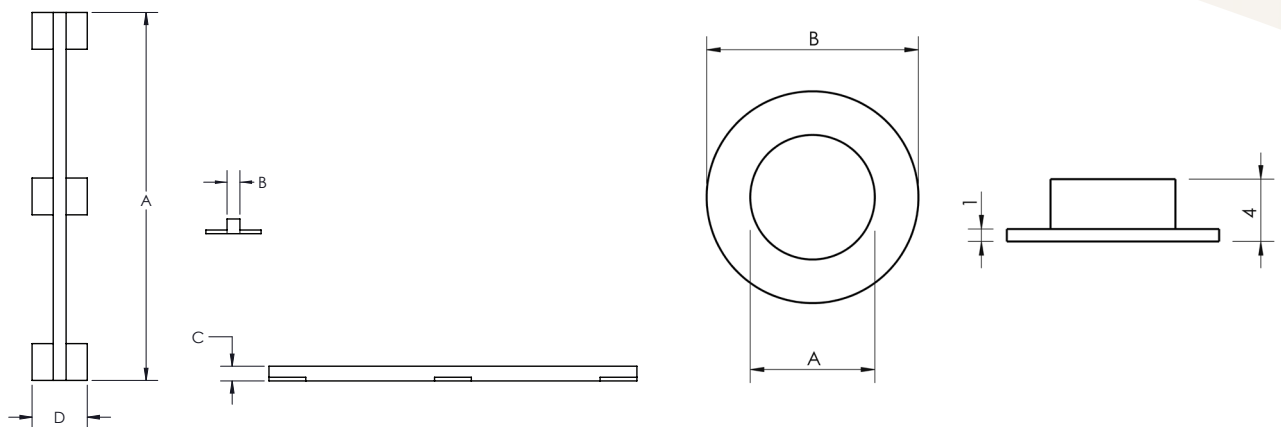
## 6

## HANDLING ADVANTAGE

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

## 7

## OSTEOPLUG® SIZE CHART



| PRODUCT CODE       | A   | B   | C | D  |
|--------------------|-----|-----|---|----|
| PC17 (100, 2, 4)   | 100 | 2   | 4 | 15 |
| PC17 (100, 3.5, 4) | 100 | 3.5 | 4 | 15 |

| Product Code    | A (mm) | B (mm) |
|-----------------|--------|--------|
| PC22(8, 8, 4)   | 8      | 14     |
| PC22(9, 9, 4)   | 9      | 15     |
| PC22(10, 10, 4) | 10     | 17     |
| PC22(11, 11, 4) | 11     | 19     |
| PC22(12, 12, 4) | 12     | 20     |
| PC22(13, 13, 4) | 13     | 22     |
| PC22(14, 14, 4) | 14     | 24     |
| PC22(15, 15, 4) | 15     | 25     |