

# OSTEOPLUG™ OSTEOPLUG™ -C

## In Burr Hole Reconstruction



### 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, EN ISO 13485) and provided sterile (gamma irradiation, EN ISO 11137).

### 2 DESIGN

#### 1. RESORBABILITY

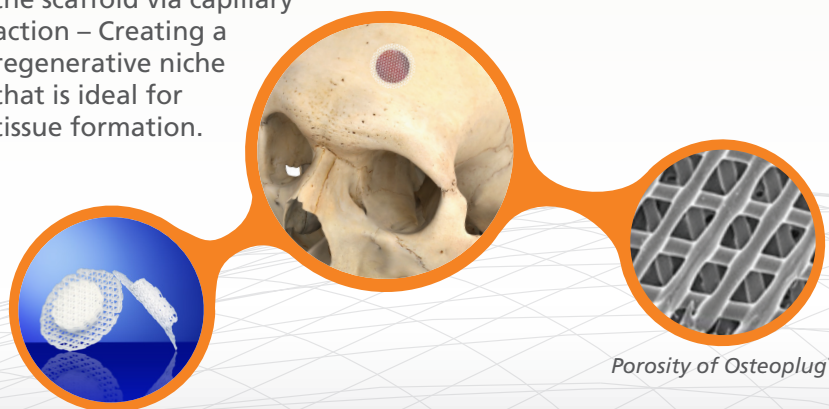
- Polycaprolactone (PCL) is a biodegradable polymer that degrades and resorbs fully in vivo by hydrolysis which is then metabolized by the body.
- Osteoplug™ (-C) has a gradual resorption profile, depending on the patient anatomy and metabolism, of approximately 18-24 months.
- Osteoplug™ (-C) possesses 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.



Osteoplug™

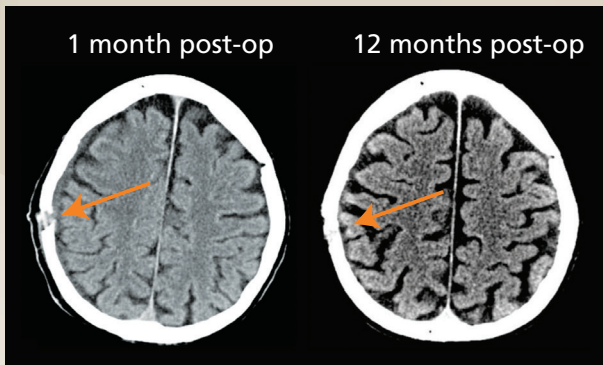
Porosity of Osteoplug™

### 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, 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 intended for use in the repair of neurosurgical burr holes and other cranial defects. It is used to aid closure of post trephination burr hole defects.
- Osteoplug™-C allows the insertion of a 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.

#### 3. IMPLANT PREPARATION

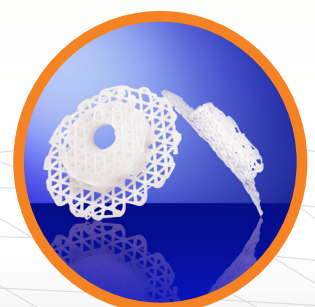
Osteoplug™ (-C) is soaked with patient's blood.

#### 4. INSERTION

Gently lower the Osteoplug™ into the burrhole. The Osteoplug™ would have a snug fit in the defect site. No fixation devices or suturing is required.

#### 5. INSERTION OF CATHETER TUBE (FOR OSTEOPLUG™-C)

After necessary surgical procedure, insert the catheter tube through hole in Osteoplug™-C.



## 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 hole trephined using a perforator, allowing ease of use and streamlining the process of post-trephination cranial reconstruction.
- Osteoplug™ (-C) does not require fixation.

## 7

## OSTEOPLUG™ (-C) SIZE CHART

Recommendation with commercial perforators

BRAND	DRILL SIZE, OUTER DIAMETER (MM)						
	8	9	11	12	13	14	15
Acracut	●		●		●	●	
Adeor (Meridian)		●	●			●	
Aesculap		●		●			●
Bojin	●	●					
Codman		●	●			●	
Aygun		●		●			●
Evonos		●	●		●	●	
Micromar		●	●			●	
Recommended Osteoplug™ (-C)	●	●	●	●	●	●	●

