

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

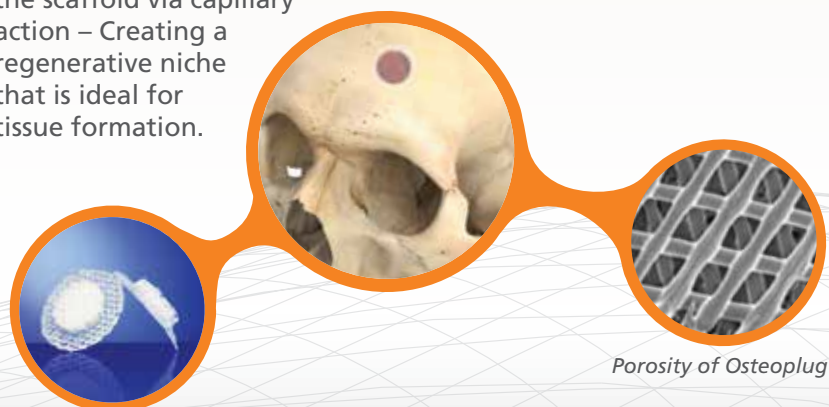
- Polycaprolactone (PCL) is a biodegradable polymer that degrades and resorbs fully in vivo by hydrolysis which is then metabolized by the body.
- Osteoplug™ (-C) has a gradual resorption profile, depending on the patient anatomy and metabolism, of approximately 18-24 months.
- Osteoplug™ (-C) possesses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



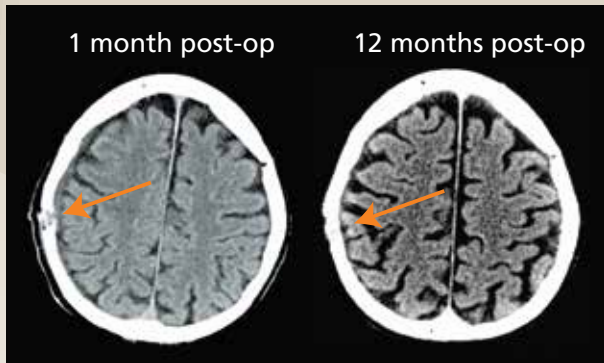
Osteoplug™

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)	●	●	●	●	●	●	●

