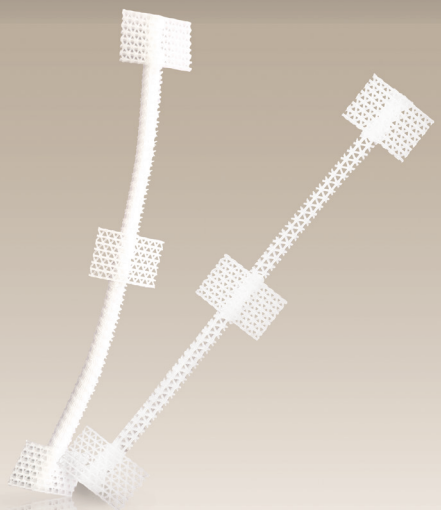
Osteopore™

OSTEOMESH™- OSTEOSTRIP

Repair of Craniotomy Bone Void



1 BIOMIMETIC

- The **Osteomesh™- Osteostrip** is a bioresorbable implant with a patented interconnected porous architecture that mimics the natural cancellous bone microstructure. It promotes tissue and vascular ingrowth.
- **Osteomesh™- Osteostrip** is an integrating implant to restore craniotomy gaps by promoting tissue ingrowth, leading to a shift in craniotomy reconstructive surgery from purely cosmesis to functional regeneration of damaged tissues.
- **Osteomesh™- Osteostrip** 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.
- **Osteomesh™- Osteostrip** has a gradual resorption profile, depending on the patient anatomy and metabolism, of approximately 18-24 months.
- **Osteomesh™- Osteostrip** possesses optimal resorption rate that maintains mechanical integrity during healing process – minimizing adverse host-implant and inflammatory reactions.

2. POROSITY

- **Osteomesh™- Osteostrip** 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. PRESS-FIT DESIGN

- **Osteomesh™- Osteostrip** is a press and fit scaffold which is designed to fill the bone gaps along the craniotomy flap. This ensures direct interaction between surrounding calvarial bone, allowing repair cells to use the implant as a scaffold, promoting bone tissue regeneration.

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.

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.
- **Osteomesh™- Osteostrip** were well-integrated into adjacent calvarial bone.

4 INDICATIONS FOR USE

- **Osteomesh™- Osteostrip** is intended for Craniotomy cuts and other cranial defects.
  It is also for use in the augmentation or restoration of bony contour in craniofacial skeleton.

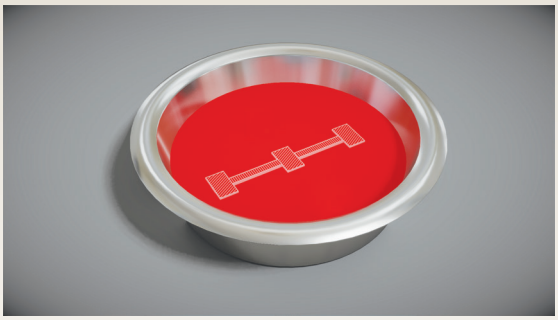
5 PRODUCT CODES AND SIZES

PRODUCT CODE	SIZE (L X B X T)/MM
PTSH-100-002-003-P5 / PC17(100, 2, 4)	100 x 2 x 4
PTSH-100-004-003-P5 / PC17(100, 3.5, 4)	100 x 3.5 x 4
PTSH-060-004-003-P5 / PC18(60, 3.5, 4)	60 x 3.5 x 4
PTSH-060-002-003-P5 / PC18(60, 2, 4)	60 x 2 x 4

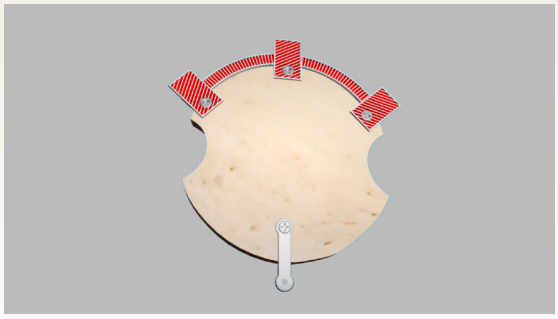
6 SURGICAL PROTOCOL

1. After cranial surgery, bone flap is brought back to its anatomical position.

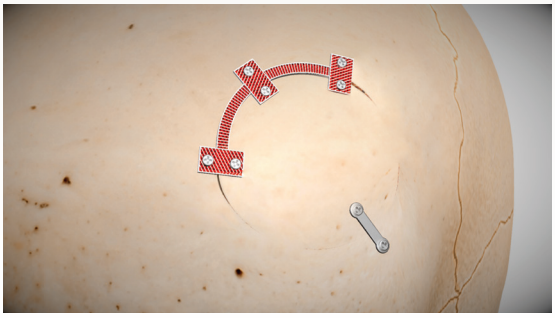
2. Shift the bone flap to the side of the craniotomy to widen the bone gap. Decide the product sizing accordingly based on the perforator and cutter used.



3. Prepare **Osteomesh™- Osteostrip** by soaking into arterial blood



4. Bring the bone flap away from the surgical side, fix the **Osteomesh™- Osteostrip** on the bone flap using plates and screws



5. Following that bone flap is secured to skull.

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

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