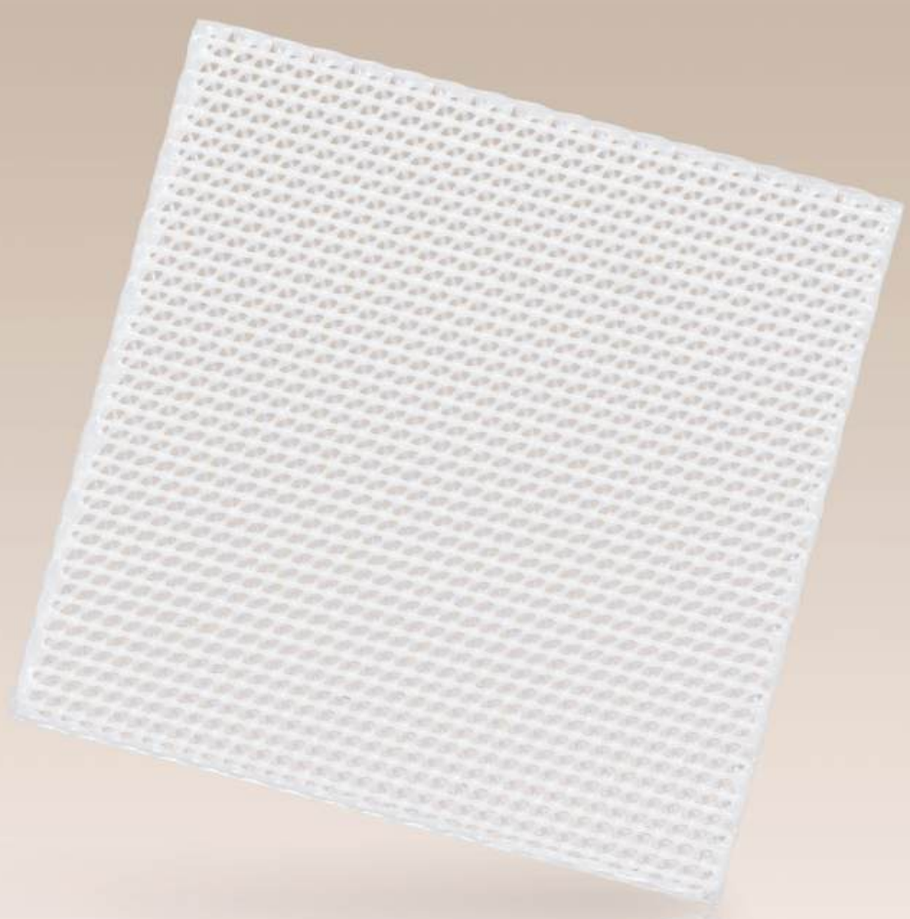
Osteopore®

OSTEOMESH®

In Orbital Floor Reconstruction



CE 0197

1 BIOMIMETIC

- The **Osteomesh**® is a bioresorbable implant with a patented interconnected porous architecture that mimics the natural cancellous bone microstructure. It promotes tissue and vascular ingrowth.
- **Osteomesh**® is an integrating implant for the repair of orbital fractures, leading to a shift in orbital reconstructive surgery from purely repairing bony defects to functional regeneration of damaged tissues.
- **Osteomesh**® 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).

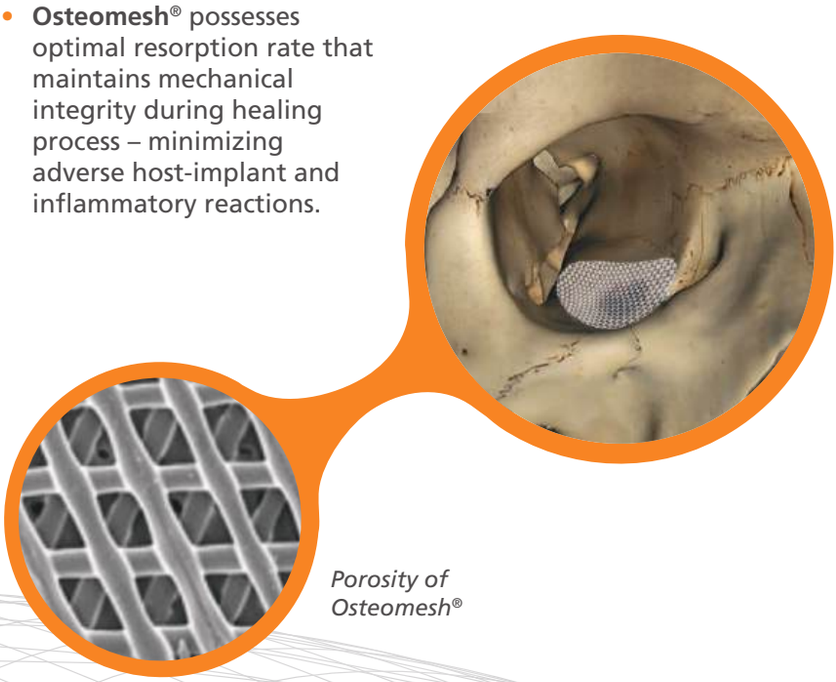
2 DESIGN

1. RESORBABILITY

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

2. POROSITY

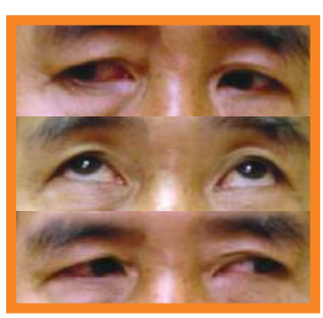
- **Osteomesh**® is manufactured with a porous interconnected micro-architecture that demonstrates mechanical properties similar to human cancellous bone.
- Upon implantation, blood and surrounding cells are absorbed into the pores of the scaffold via capillary action – Creating a regenerative niche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



Porosity of Osteomesh®

3. INTERCONNECTED MICRO-ARCHITECTURE

- Interconnected microarchitecture of the **Osteomesh**® is designed to accommodate tissue ingrowth, in order to provide sufficient support to withstand in vivo loading forces of the orbital ontent.



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3 views of patient moving eyes without restriction

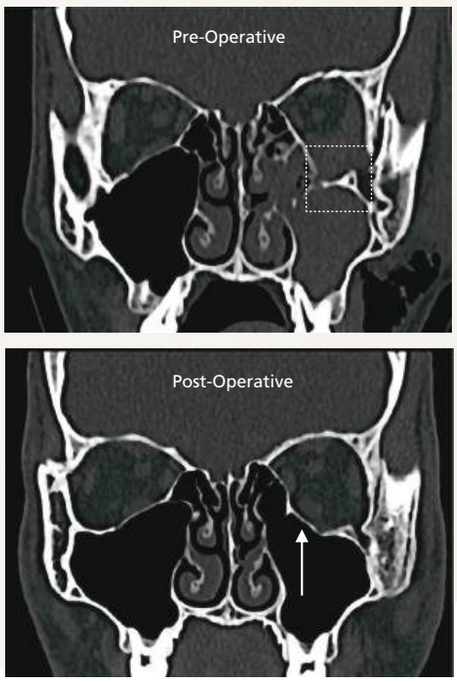
3 CLINICAL ADVANTAGE

PATIENT'S PERSPECTIVE

- No known adverse reactions such as pain, scarring.
- No long-term foreign body reaction.
- Good functional and aesthetic outcomes.
- Demonstrable improvements in ocular motility and binocular single vision.

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.
- Restore the structural integrity of the orbital floor by bridging the defect and preventing orbital contents from herniating into the adjacent periorbital sinuses.
- Prevent extra-ocular motility limitations, is malleable and easy for surgeon handling.



Preoperative and postoperative CT scan of orbital fracture (12 months Post-Op)

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4 INDICATIONS FOR USE

Osteomesh® is indicated for the repair of orbital floor fractures.

5 SURGICAL PROTOCOL

1. SITE PREPARATION

Prepare the implantation site using standard surgical techniques. (e.g. transconjunctival, subciliary, and orbital rim approach). Control of active bleeding should be achieved prior to implantation of the material.

2. IMPLANT SELECTION

Select the mesh size that best suit the the fracture type and extent

3. IMPLANT PREPARATION (SIZE/CUT IF REQUIRED)

Use a surgical scissors to trim the **Osteomesh®** to fit the defect. Trim the device away from surgical site to prevent particles from depositing at the site.

4. INSERTION

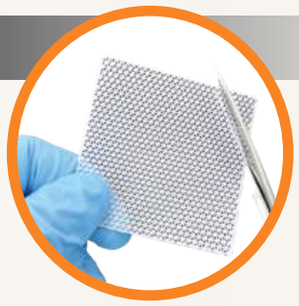
Retract the orbital tissue to expose the floor defect and place the **Osteomesh®** onto the orbital floor to reconstruct the defect.

5. CLOSURE

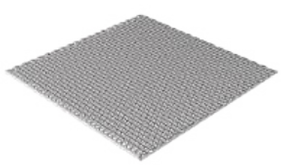
The periosteum and lid tissues are closed in layers.

6 HANDLING ADVANTAGE

- **Osteomesh®** does not need to be contoured.
- **Osteomesh®** does not require fixation.
- **Osteomesh®** can be easily cut with scissors.



7 APPROVED LIST OF SIZES

	LENGTH (mm)	BREADTH (mm)	THICKNESS (mm)
PC11 	20	20	1, 1.25, 1.5, 2, 2.5, 3, 4, 5
	40	40	
	25	10	1, 1.25, 1.5
	25	25	1, 1.25, 1.5, 2, 2.5, 3
	30	30	1
	80	60	
	50	50	1, 1.25, 1.5, 2, 3, 4, 5
	100	100	
	60	15, 20, 25, 30, 35	5
	100		
PC12 	39	10	1, 1.25, 1.5
	50	50	1, 1.25, 2, 3, 4, 5
	100	100	1, 1.25, 1.5, 2, 3, 4, 5
PC30 	30	25	1, 1.25, 1.5, 2
PC34 	35	49	1, 1.25, 1.5, 2
PC50 	38	25	1, 1.25
	39	25	1, 1.25, 1.5

Osteopore®
Empowering Natural Tissue Regeneration

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