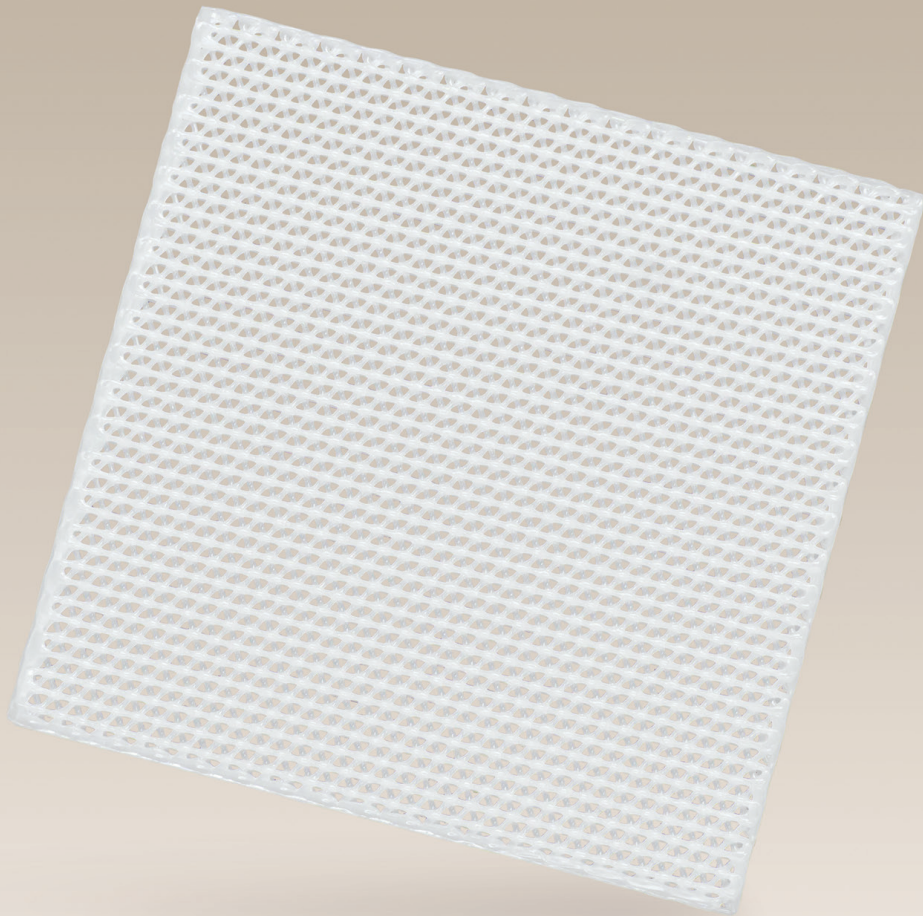


# OSTEOMESH®

In Orbital Floor Reconstruction



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

# 2

## DESIGN

### 1. RESORBABILITY

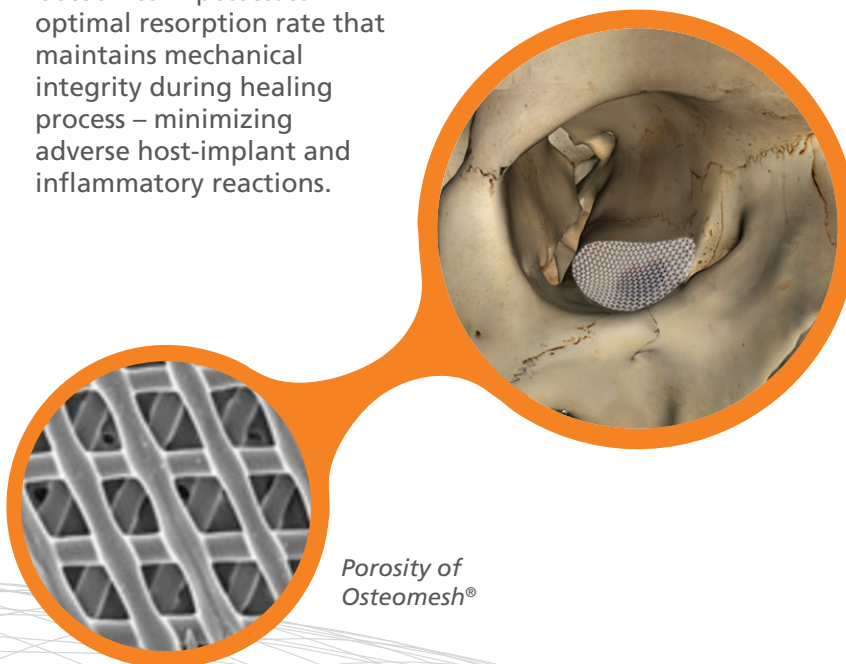
- Polycaprolactone (PCL) is a biodegradable polymer that degrades and resorbs fully in vivo by hydrolysis which is then metabolized by the body.
- **Osteomesh®** has a gradual resorption profile, depending on the patient anatomy and metabolism, of approximately 18-24 months.
- **Osteomesh®** possesses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

### 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 content.



Porosity of  
Osteomesh®



3 views of patient moving eyes  
without restriction

Data on file

### 3

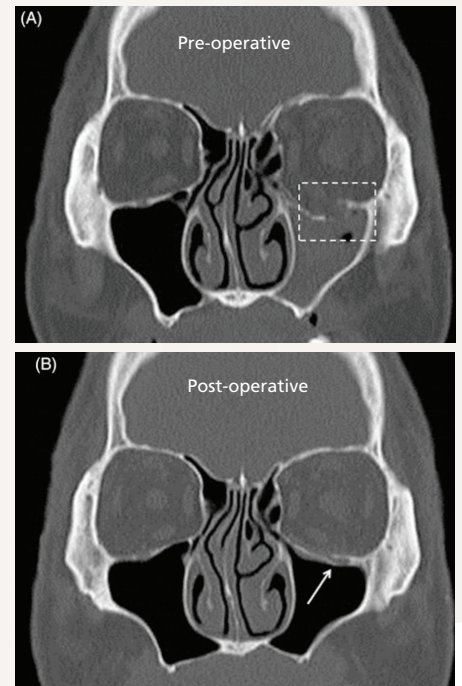
## CLINICAL ADVANTAGE

### 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 fracture with interval between pre and postoperative CT scans - 15 months.

Teo L, Teoh SH, Liu Y, Lim L, Tan B, Schantz JT, et al. A Novel Bioresorbable Implant for Repair of Orbital Floor Fractures. *Orbit*. 2015;34:192-200.

### 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.

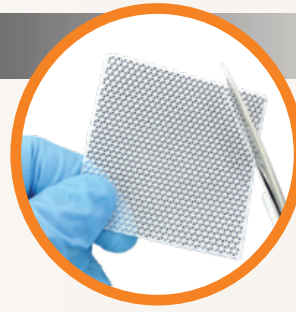
#### 5. CLOSURE

The periosteum and lid tissues are closed in layers.

## 6

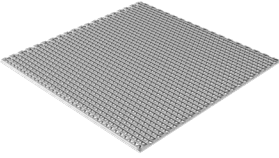


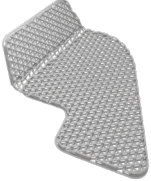

## HANDLING ADVANTAGE

- 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)
<b>PC11</b> 	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		
<b>PC12</b> 	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
<b>PC30</b> 	30	25	1, 1.25, 1.5, 2
<b>PC34</b> 	35	49	1, 1.25, 1.5, 2
<b>PC50</b> 	38	25	1, 1.25
	39	25	1, 1.25, 1.5

For professional use.

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

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