

# 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

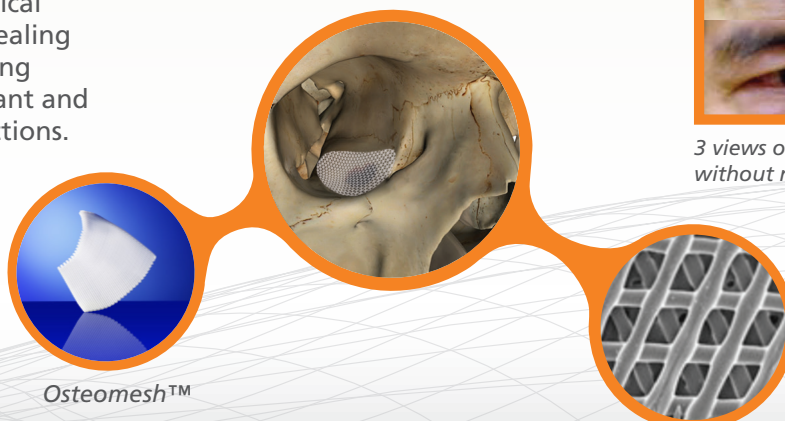
- **Osteomesh™** is manufactured with a porous interconnected micro-architecture that demonstrates mechanical properties similar to human cancellous bone.
- Upon implantation, blood and surrounding cells are absorbed into the pores of the scaffold via capillary action – Creating a regenerative niche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

#### 3. INTERCONNECTED MICRO-ARCHITECTURE

- Interconnected micro-architecture 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.



3 views of patient moving eyes without restriction



Osteomesh™

Porosity of Osteomesh™

### 3

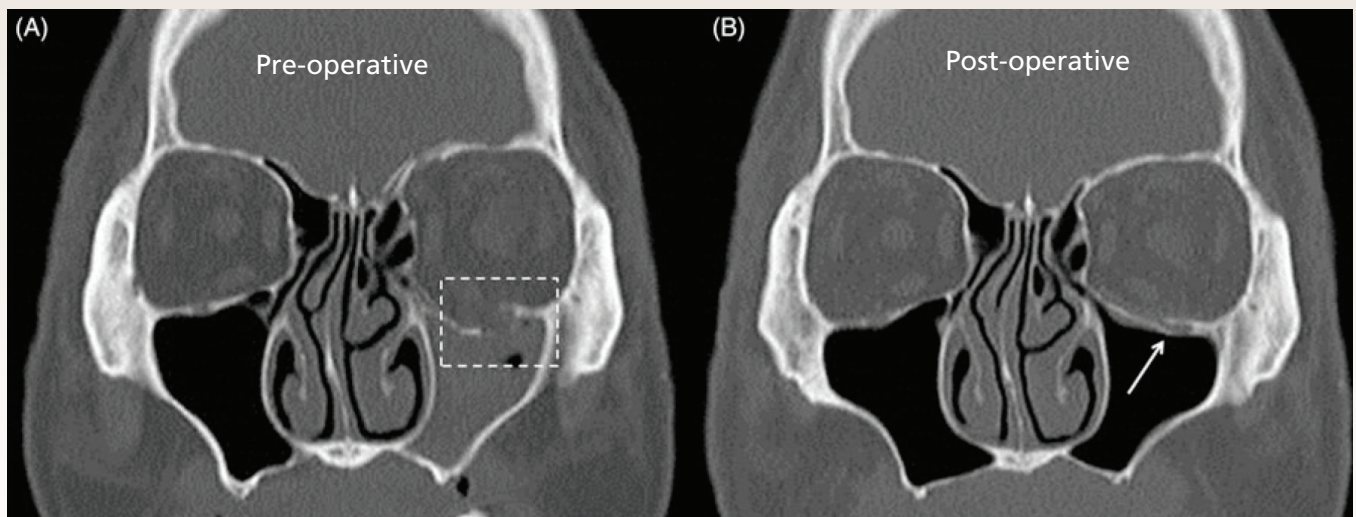
## CLINICAL ADVANTAGE

### 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 intended for use in the repair of orbital floor fractures.

## 5

## SURGICAL PROTOCOL

### 1. PREPARE THE SITE/SURGICAL APPROACH/INCISION

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. SELECT IMPLANT

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

### 3. SIZE/CUT (IF REQUIRED)

Use a surgical scissors to trim the **Osteomesh™** to fit the defect.

### 4. INSERT

Retract the orbital tissue to expose the floor defect and place the **Osteomesh™** onto the orbital floor to reconstruct the defect. The smooth surface should be placed against the orbit.

## 6

## HANDLING ADVANTAGE

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

