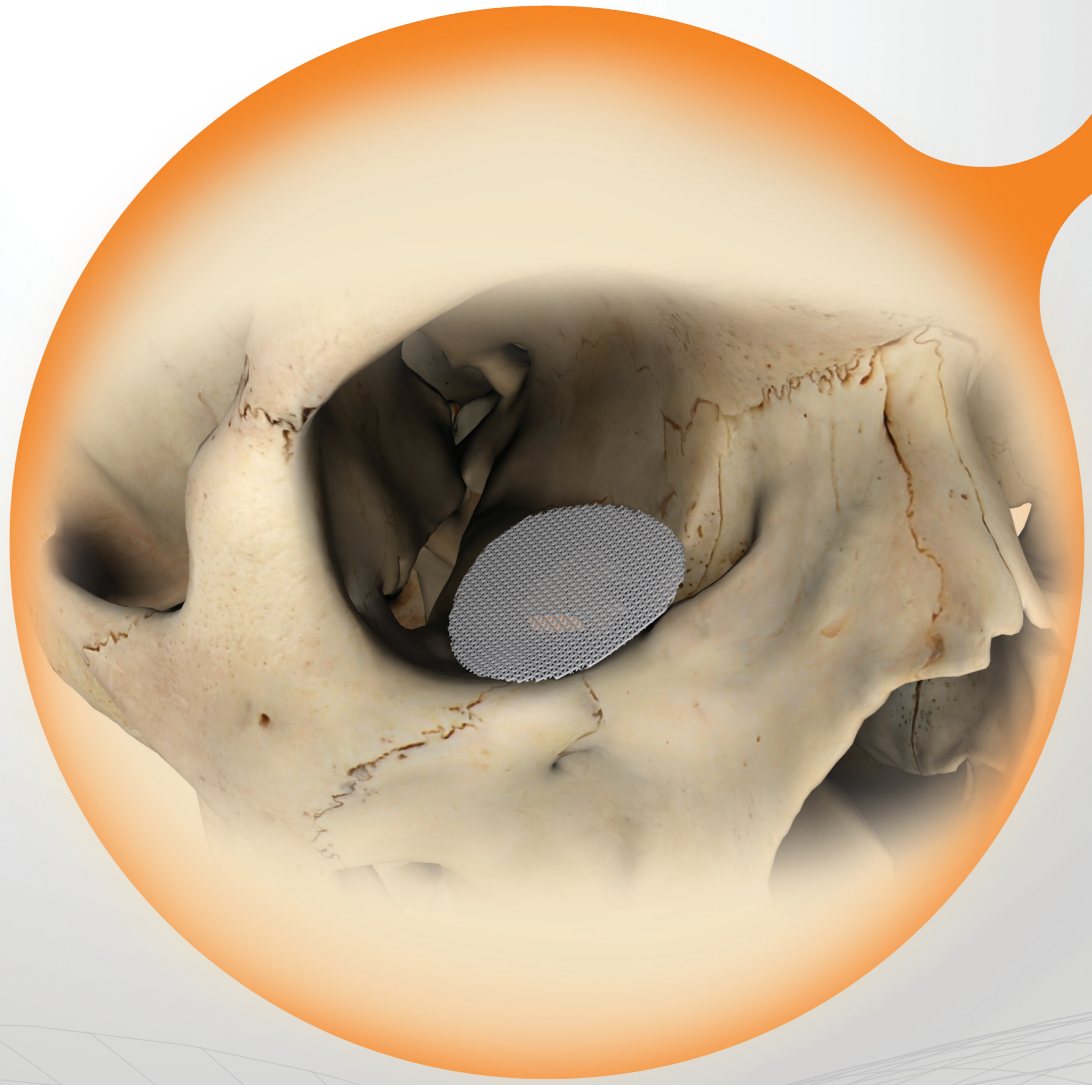
Osteopore®

Osteomesh™

Repair of Orbital Floor Fractures Surgical Technique



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Warning: This description is not sufficient for immediate application of the implant. Instruction by a surgeon experienced in handling the implant is highly recommended.

Repair of Orbital Floor Fractures using OSTEOMESH™

1 Anaesthesia

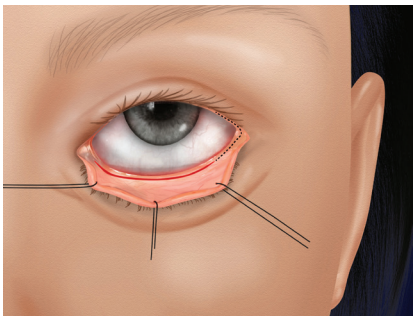
After patient is placed under general anaesthesia, inject preferred local anaesthesia subconjunctivally in the inferior fornix.

2 Forced Duction Test

Assess any motility restrictions due to entrapment of orbital tissue by forced duction test.

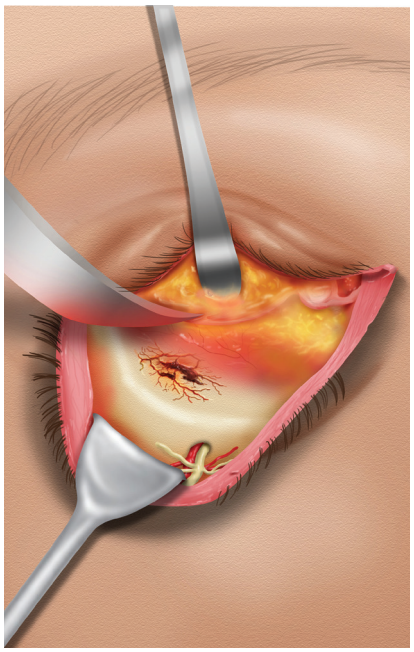
3 Incision

A transconjunctival incision is made between the lower border of the tarsus and the inferior fornix. Continue dissection down to the infraorbital rim in the pre-septal plane to expose the periosteum along the inferior orbital rim, avoiding the orbicularis muscle anteriorly and orbital fat posteriorly.



4 Orbital Floor Exposure

Using a Freer or Cottle elevator gently elevate the periosteum posteriorly along the floor of the orbit until the anterior aspect of the fracture is seen.



In order to improve visualization and protect the globe, a malleable reactor may be used to elevate the orbital tissues. Carefully elevate orbital soft tissues from the fracture site in a hand-over-hand technique. Care must be taken to avoid damage to the infraorbital neovascular bundle. Locate the orbital floor fracture which is often found in the inferomedial orbit. Ensure that the medial, lateral and especially posterior edges of the fracture site are well visualised and exposed.

After completely exposing the orbital fracture, herniated orbital tissue can be elevated and retracted from the fracture site using a malleable retractor.

Any bone fragment can be extracted using a muscle hook or forceps.

Large fractures may require release of tissues at the inferior orbital fissure to gain access to the lateral floor and lateral wall of the orbit.

Care should be taken to avoid compression of the orbital apex structures by the malleable retractor or the periosteal elevator by ensuring not too far posteriorly. The pupil should be monitored throughout the surgery.

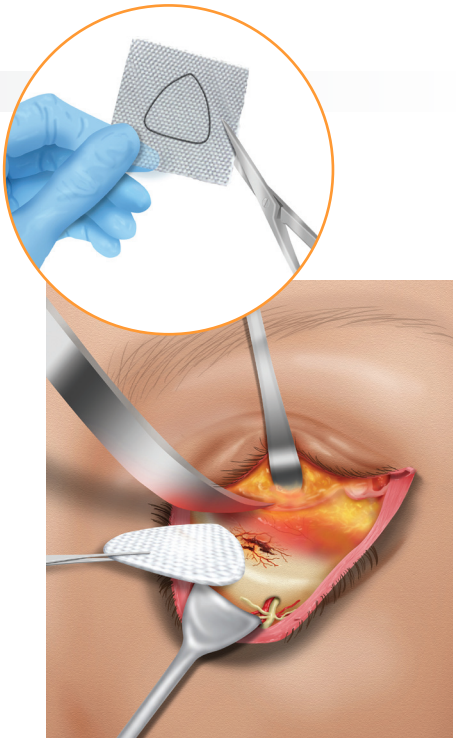
5 Placement of Osteomesh™

Cut the implant to fit the floor of the orbit with enough overlap over the fracture edges.

Trim the edges using sharp scissors until ideal fit is achieved.

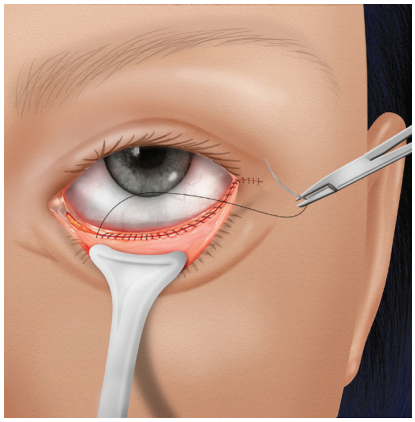
The posterior aspect of the implant should rest on the orbital floor posterior to the most posterior aspect of the fracture site (i.e. the posterior ledge).

Repeat the forced duction test to ensure there is entrapment of tissue by the implant.



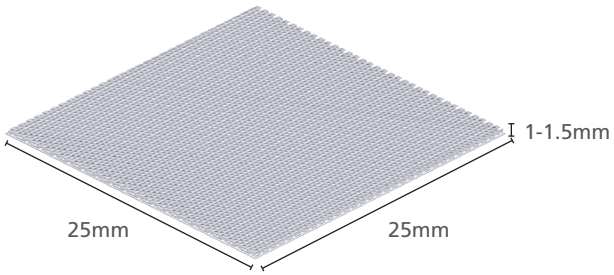
6 Closure

Close in layers - the periosteum followed by conjunctiva with an absorbable suture such as Vicryl.

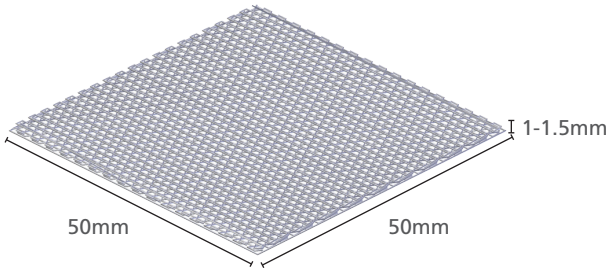


This is the experience in cases from Dr. Stephanie Young (MBBS, M.Med (Ophth) FRCOphth (London) FAMS), Visiting Consultant at the Ophthalmology Department in National University Hospital (NUH), Senior Consultant Ophthalmologist and Director of Ophthalmic Plastic & Reconstructive Surgery at Eagle Eye Center Singapore

Implant Sizes



Length/mm	Breadth/mm	Thickness/mm
25	25	1 - 1.5



Length/mm	Breadth/mm	Thickness/mm
50	50	1 - 1.5

Please refer to the Instructions for Use which is provided together with the product for more details on indications, contraindications and other relevant information.

NOTE:
The Intended Use / Indications may differ between countries.
Please check with your local sales representative for more information.

Osteomesh™

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 made of Polycaprolactone (PCL), a biodegradable polymer which degrades and resorbs fully in vivo by hydrolysis and is then metabolized by the body. It possesses an optimal resorption rate which maintains mechanical integrity during the healing process – minimizing adverse host-implant and inflammatory reactions.

Depending on the patient's anatomy and metabolism, Osteomesh™ has a gradual resorption profile of approximately 18 – 24 months.

Osteomesh™ is FDA 510(k) cleared. It is fabricated in compliance with current Good Manufacturing Practice (cGMP, EN ISO 13485) and provided sterile (gamma irradiation, EN ISO 11137).

Osteomesh™ Material	Polycaprolactone
Porosity	70%
Sterility	Osteomesh™ is provided sterile by gamma irradiation, in a single layer foil packaging. Do not re-sterilize Osteomesh™. This may cause the implant to not be sterile, and/or not meet the performance specifications and/or alter the material's properties.
Rigidity	Osteomesh™ is a semi-rigid bone filler.
Malleability	You may shape Osteomesh™ using only sterile warm saline. **Caution:** *Ensure that the temperature does not exceed 45°C. Do not place Osteomesh™ in the warm saline for an extended period as it may cause Osteomesh™ to melt.*
Shelf Life	3 Years. Do not use Osteomesh™ after the expiry date labelled on the product packaging.

Intended Use / Indications

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

Please refer to the Instructions for Use which is provided together with the product for more details on indications, contraindications and other relevant information.

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Contraindications

1. Do not use in patients with conditions including latent or active infections, systemic disorders which will hinder wound healing, or with insufficient quantity or quality of bone stock.
2. Do not use in contaminated surgical areas.
3. Do not use in patients with septic reactions.
4. Not indicated for load bearing anatomical sites.
5. Do not use in areas exposed to outside environment.

For Professional Use.

CAUTION: See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions. Osteopore devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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