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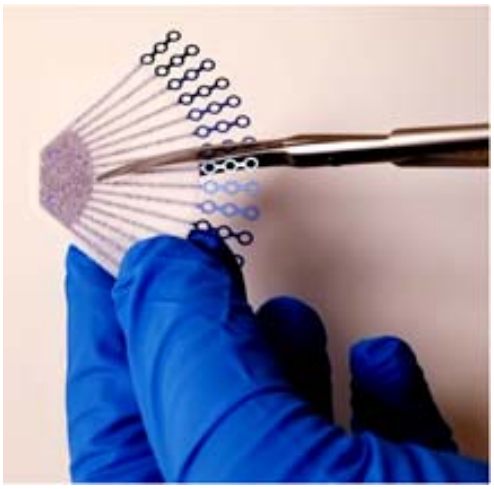
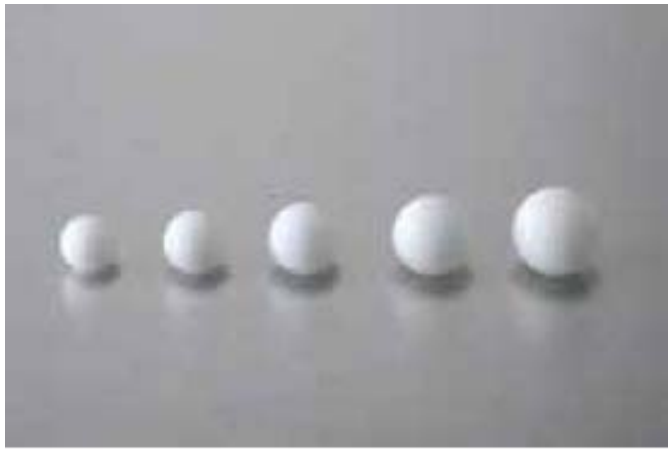
OMNIPORE® SURGICAL ORBITAL IMPLANTS
DUROMAX® Orbital Implants

SURGICAL IMPLANT GUIDE





Orbital-Maxillofacial Reconstruction

Orbital Maxillofacial Solutions by
Matrix Surgical USA

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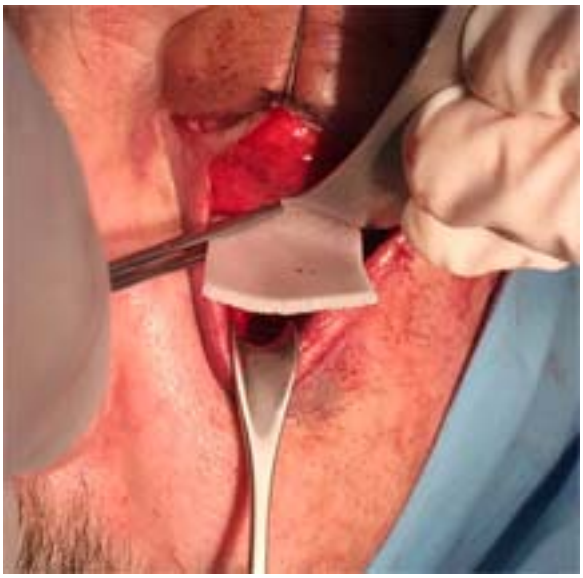
OMNIPORE® POROUS POLYETHYLENE IMPLANTS



OMNIPORE® Surgical Implants are manufactured from an inert nonabsorbable polymer formulated to contain a network of open and interconnecting pores. These interconnected pores allow fibrovascular tissue ingrowth and relative host incorporation, rather than the host encapsulation observed with smooth-surface implants.[1]

OMNIPORE Surgical Implants are well-suited for maxillofacial reconstruction and augmentation. The implant's porous structure promotes tissue ingrowth and results in rapid integration and stabilization.

Features

- Porous structure supports tissue ingrowth
- 3S™ implants have a smooth superior surface reducing the ability for tissue ingrowth (bottom surface macroporous)
- Nonabsorbable and biocompatible material
- Semi-rigid material is strong, yet flexible
- Modifiable and easily contoured with surgical instrument
- Implants may be fixated with screws, wire or sutures

Clinical applications

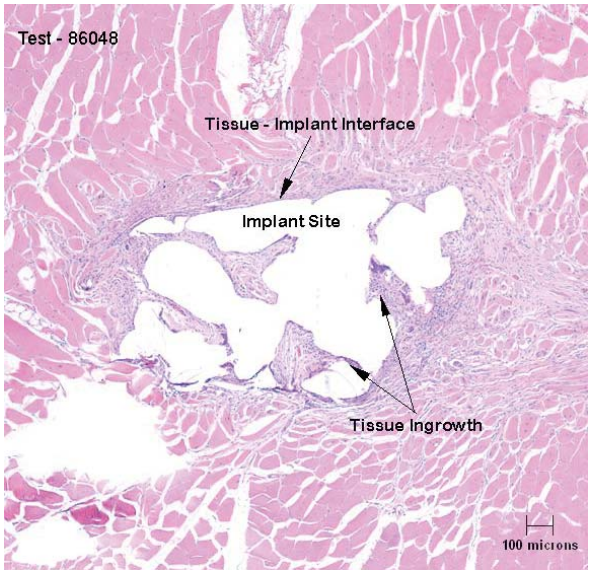
Orbital augmentation and reconstruction

- Orbital floor/wall
- Anophthalmos
- Enophthalmos

Reference

1 Yaremchuk MJ. Facial Skeletal Reconstruction Using Porous Polyethylene Implants. Pla5!ic *Reconstr Surg.* 2003; 111(6):1818-27.

HDPE Material



Tissue Ingrowth

Material

OMNIPORE Surgical Implants are manufactured from high-density polyethylene (HDPE) into a porous form which allows for tissue ingrowth. HDPE has a long history of use as a surgical implant material and meets ASTM standards.[2]. In addition, OMNIPORE Surgical Implants have passed ISO standard tests for biocompatibility.[3] The OMNIPORE® DUROMAX® Orbital Surgical Implant designs incorporate titanium plates constructed from commercially pure titanium (ASTMF67).

Indications

OMNIPORE Surgical Implants in block, sheet and anatomic shapes are intended for non-weight-bearing applications of craniofacial reconstruction/ cosmetic surgery and repair of craniofacial trauma. OMNIPORE Surgical Implants are also intended for the augmentation or restoration of contour in the cranio-maxillofacial skeleton.

OMNIPORE DUROMAX Orbital Surgical Implants are intended for non-weight-bearing applications of maxillofacial and orbital reconstruction/cosmetic surgery and repair of maxillofacial and orbital trauma.

Contraindications

- Active or latent infection
- Inadequate coverage of healthy, vascularized tissue
- Full load-bearing applications
- Systemic disorders that cause poor wound healing or may lead to soft tissue deterioration over the implant

References
2 ASTM F755, Standard Specification for Selection of Porous Polyethylene for Use in Surgical Implants.
3 ISO 10993, Biological Evaluation of Medical Devices.

OMNIPORE® SURGICAL IMPLANT SHEETS

OMNIPORE Micro Thin Sheet

OMNIPORE 3S Sheet

OMNIPORE Ultra Thin Sheet

OMNIPORE Enophthalmos Wedge

OMNIPORE Surgical Implant Sheets and E-Wedge

OMNIPORE Surgical Implant Sheets and E-Wedge are designed to maintain an omnidirectional porous structure throughout the implant to support tissue ingrowth.

OMNIPORE 3S™ Sheets

Implants are engineered to have a smooth superior surface to minimize tissue adhesion and an open porous structure on the inferior surface to support tissue ingrowth.

- Radiolucency reduces interference with diagnostic imaging
- Anatomic shapes, proven through many years of clinical history, allow quick implantation and minimize trimming
- Shapes for customized shaping available in multiple sizes and thicknesses to meet clinical needs

Tip: For smooth superior surface implants, orient the implant so the smooth side of the implant faces toward the soft tissue to minimize adhesion and ensure motility of the globe.

OMNIPORE® DUROMAX® ORBITAL FLOOR IMPLANTS

OMNIPORE DUROMAX Orbital Floor Implants come in four configurations and contain embedded, commercially pure titanium. US design patent pending.

- Radiographic visibility
- Increased contour retention
- Anatomical shape
- Polyethylene sheets reduce exposure of sharp titanium edges after cutting
- Fixation hole positions allow optimal screw placement
- Compatible with 1.5 mm titanium screws

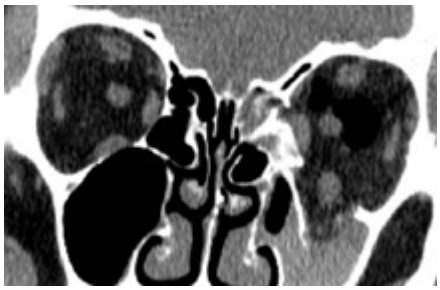
Technique tip: For rigid fixation to the orbital skeleton, cantilever one or more titanium plates over the orbital rim. With a screw driver, advance a self-drilling titanium screw (a 1.5mm diameter screw head is optimal) through one of the holes in the titanium plates, making sure to get good purchase of bone and the screw head is compressed flush with the screw hole on the titanium plate.

Small 1.0mm thick - OP9550

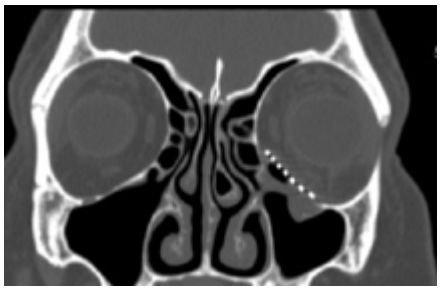
Large 1.0mm thick – OP9560

Small 1.5mm thick – OP9551

Large 1.5mm thick – OP9561



Pre-op



Post-op with DUROMAX OP9550

Pre- and post-op photos provided by Paul Langer, MD

HANDLING

OMNIPORE Porous Polyethylene Implants are provided sterile and pyrogen-free, for single-patient use. Do not resterilize.

Do not remove OMNIPORE Implants from their packaging until time of implantation.

Handle implants with clean, powder-free gloves to prevent contamination.

Caution

- Do not place implants on surgical drapes, surgical clothing, or any other material that may contaminate the implants with lint or other particulate matter. Implants may be placed in sterile saline to prevent contamination.
- Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged packages.
- DO NOT USE if there is loss of sterility of the device.
- The implants are intended for SINGLE use only.
- DO NOT re-sterilize.

SIZING

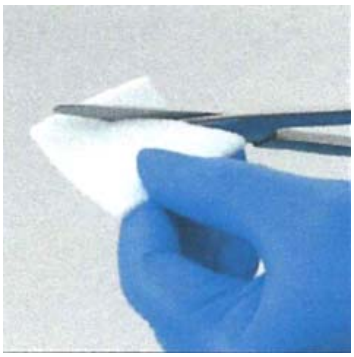
OMNIPORE Surgical Implants can be easily cut and sculpted with scissors, high-speed burr, or a scalpel.

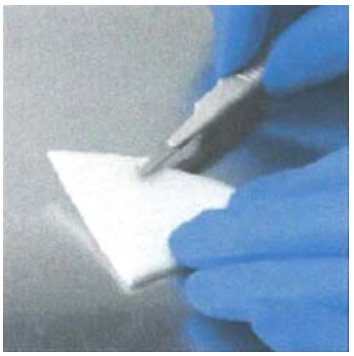
Thicker implants may be adapted to the surgical site using bone cutters or cutting burrs to achieve the desired shape. If the implant is burred, reestablish the open pore structure by shaving the outer surface with a scalpel.

Multiple pieces can be stacked and sutured together when thicker or larger implants are required.

After sizing the implant, rinse it in sterile saline solution to remove loose particles.

Once fixated to the skeleton, if in-place contouring is needed, use suction to remove any loose particles from the surgical site.





Caution

- Do not place or carve the implant on cloth or any other surface that may contaminate the implant with lint and other particulate matter.
- The implants are NOT to be modified by any electrosurgery device.

CONTOURING

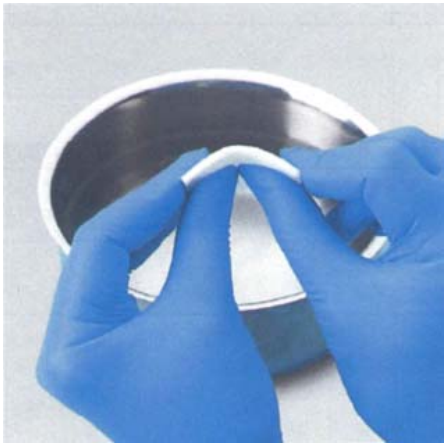
OMNIPORE Surgical Implants can be contoured by submerging in hot, sterile saline (over 70°C/160°F) for several minutes until the implant softens. Higher temperatures will improve the ability to contour the implant.

Remove the implant from the hot saline and contour to the desired shape. If there is too much resistance, return the implant to hot saline.

Use a second pair of gloves if the implant remains too hot to touch.

Allow the implant to cool completely to maintain the achieved shape. Cold, sterile saline can accelerate the cooling process.

The process can be repeated until the final form desired is achieved.



STABILIZING

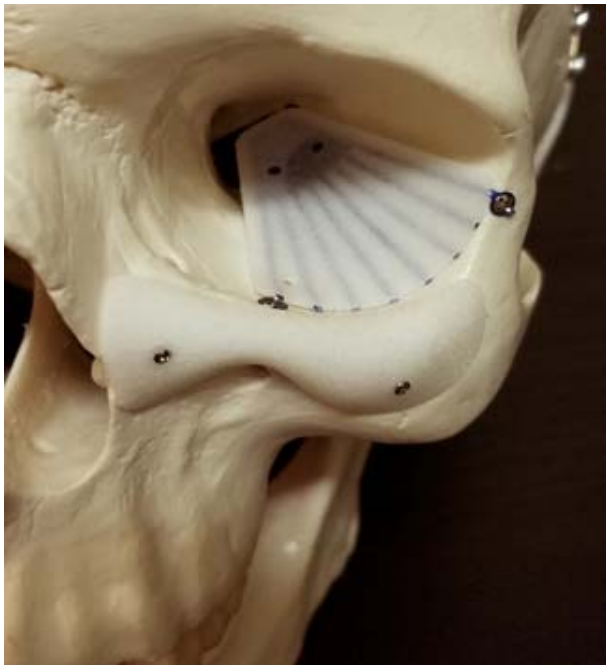
If desired, implants may be stabilized with screws, wire, or suture.

OMNIPORE Surgical Implants and DUROMAX Orbital Floor Implants are compatible with 1.5 mm titanium bone screws.

When using screws, tighten them sufficiently to compress the implant to the bone and minimize the screw profile.

Make any final modifications in situ. Feather the edges of the implant to create a smooth transition and minimize palpability.

Important: Take care to remove all carved debris from the surgical site.



Catalog Numbers, Product Description and Dimensional Information

Micro Thin Sheet

OP8438	30mm x 50mm x .045mm

Ultra Thin Sheet

OP7210	38mm x 50mm x 0.85mm
OP7212	50mm x 76mm x 0.85mm

Channel Sheet

OP9530	50mm x 50mm x 2.0mm

Sheets

OP6330	38mm x 50mm x 1.5mm
OP6331	50mm x 76mm x 1.5mm
OP9562	38mm x 50mm x 3.0mm

3S™ Sheet - Smooth Superior Surface

OP8312	38mm x 50mm x 1.0mm
OP9312	38mm x 50mm x 1.7mm

DUROMAX® Orbital Floor Implants

OP9550	49.25mm x 35mm x 1.0mm
OP9551	49.25mm x 35mm x 1.5mm
OP9560	49.50mm x 60mm x 1.0mm
OP9561	49.50mm x 60mm x 1.5mm

Enophthalmos Wedge

OP9541	31mm x 22mm x 6.5mm – Regular - Left
OP9542	31mm x 22mm x 6.5mm – Regular – Right
OP9543	39mm x 28mm x 7.5mm – Large –Left
OP9544	39mm x 28mm x 7.5mm – Large -Right

Orbital Implants

OP6316	Sphere – 14mm
OP6326	Sphere – 16mm
OP6327	Sphere – 18mm
OP6317	Sphere – 20mm
OP6322	Sphere – 22mm

OMNIPORE CUSTOMIZED IMPLANTS AVAILABLE UPON REQUEST

Warnings and Precautions

OMNIPORE Surgical Implants are not intended for load-bearing applications. The device can break or bend as a result of stress or activity, which could cause failure of the device or the treatment.

The surgeon is to be thoroughly familiar with the devices, the method of application, the instruments, and the surgical procedure. The surgeon must select a type or types of internal fixation appropriate for the treatment.

Improper selection, placement, positioning, and fixation of the devices can cause subsequent undesirable results.

Porous polyethylene implants should not be used in areas exposed to the outside environment.

The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the implant construct, which could require additional surgery and device removal.

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