

Where Art Meets Science



OMNIPORE® SURGICAL IMPLANT

Porous High-Density Polyethylene Implants For Reconstructive and Aesthetic Surgery

Distributed By:



Implant Preparation

OMNIPORE Surgical Implants and OMNIPORE[®] DUROMAX[®] Orbital Implants are sold sterile and should *never* be re-sterilized. Prior to handling the implants, operating room personnel should put on a clean pair of powder free gloves. Keep the implant in its protective packaging until time of implantation. Upon opening the inner pouch, the implant should be placed in a solution of clean sterile physiologic saline and antibiotics of the surgeon's preference. Strict adherence to the principles of aseptic technique should be followed with these implants. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional.

Cutting

OMNIPORE Surgical Implants are easily cut with a variety of surgical instruments. The unique physical properties of the OMNIPORE Surgical Implants allows for cutting and trimming the implant while maintaining the interconnectivity and the structure of the pores. CAUTION: Do not place or carve the implant on surgical drapes, surgical clothing or any other surface which may contaminate the implant with lint and other particulate matter. A sterile carving block can be used as a work surface for carving OMNIPORE Surgical Implants. When handling, shaping and contouring the OMNIPORE DUROMAX Orbital Implants, sharp edges and exposure of the titanium perimeter should be avoided to minimize trauma to the surrounding tissue, prevent cutting or puncturing sterile gloves or hands.

Contouring & Shaping

Allow the OMNIPORE Surgical Implant to soak several minutes in a hot (above 90°C) saline bath. The hot saline bath will relax the memory of the implant, enabling modification of the shape. Test the implant for flexibility. Soak longer if the implant does not bend easily. Hold the implant in the desired shape and allow it to cool. A cold sterile saline bath can accelerate the cooling process. Repeat these steps if further modification is required.

Implant Stabilization

When fixation of the implant is desired, stabilization may be accomplished with suture, k-wire or rigid fixation screws. In the case of screw fixation, tightening the screw will compress the implant to the bone and will enable the surgeon to sink the screw head flush with the implant surface. One advantage of stabilizing the implant is the ability to delicately shape and feather the edges of the implant in-situ after fixation. Care should be taken to remove all carved debris from the surgical site.

Surgical Revisions

The porous nature of OMNIPORE Surgical Implants allows for soft tissue ingrowth and vascularization of the implant. In patients that may require later surgical revision, the surgeon should be aware of this vascular and soft tissue ingrowth. In the event revision or removal of the implant is required after ingrowth has occurred, the surrounding soft tissue may be raised with a surgical instrument and the implant dissected out with a scalpel or surgical scissors.

OMNIPORE Surgical Implants and OMNIPORE DUROMAX Orbital Implants are provided sterile and should *never* be re-sterilized. Explanted OMNIPORE Surgical Implants should be disposed of in a proper biohazard container. Consult the product information sheet enclosed with each implant for additional information, indications, contraindications and precautions.

OMNIPORE® Surgical Implants

OMNIPORE implants are manufactured from a linear form of high-density polyethylene. Polyethylene has a long history of use in surgical implants. OMNIPORE Surgical Implants allow for tissue ingrowth because of its interconnecting open pore structure. The firm nature of the material allows carving with a sharp instrument without collapsing the pore structure. OMNIPORE Surgical Implants in blocks, sheets and preformed anatomical shapes are intended for augmentation and restoration of the craniomaxillofacial skeleton.

The porosity of OMNIPORE Surgical Implants is maintained large, with average pore sizes greater than 100 microns and pore volume in the 50% range (measured by Mercury Intrusion Porosimitry). Animal data has demonstrated that the OMNIPORE Surgical Implants permit



tissue ingrowth. The clinical significance of tissue ingrowth may vary with the application and implant site. In Vitro and In Vivo biocompatibility studies have shown OMNIPORE Surgical Implants to be free from any observable systemic or cytotoxic effects.

The success of any implant is dependent upon careful handling and good surgical technique. Porous materials are particularly susceptible to contamination either by micro-organisms or foreign material. In order to reduce the chance of contamination by preoperative handling, OMNIPORE Surgical Implants are provided sterile in a variety of shapes and sizes. OMNIPORE Surgical Implants should remain in the protective pouch until the implant site has been prepared.

Select from an array of anatomical shapes, sheets/blocks and spheres including:

- Preformed shapes for chin, malar, rim, midface and mandibular augmentation
- Reconstructive shapes for traumatic defects and Microtic ears
- Sheets, wedges and blocks for orbital floor and wall repair
- Spheres for enucleation and evisceration procedures

A reference list of articles/presentations and publications on high-density polyethylene craniofacial implants and porous polyethylene is available upon request from Matrix Surgical USA.

Complete product labeling is included in the package insert provided with each OMNIPORE Surgical Implant and OMNIPORE DUROMAX Orbital Implant. The surgeon should adequately review this information before using the product.

The intent of this brochure is to provide the surgeon with illustrations and dimensions of the many shapes of OMNIPORE Surgical Implants and ancillary surgical products. Implants can be tailored to accommodate the individual need of the patient.

Surgeons should utilize proper surgical techniques for which they were trained and their clinical experience to determine appropriate surgical procedures. Successful implantations are technique sensitive. Sound surgical judgment should be used in the selection/shaping and implantation of OMNIPORE Surgical Implants and OMNIPORE DUROMAX Orbital Implants.

Design Y[™] Mandible Onlays*

Designed in conjunction with Michael J. Yaremchuk, M.D.

Design Y Mandible Onlays benefit patients who have skeleton mandibular deficiencies or surgically altered anatomy. Implant design provides the opportunity for augmentation of ramus height and ramus width. It also provides the opportunity to alter the inclination of the mandibular plane and restore continuity of the mandibular border. The registration tab allows for ideal and symmetric placement. Three sizes with left and right orientation allow the surgeon to meet the requirements of each patient.



Design Y[™] Chins*

Designed in conjunction with Michael J. Yaremchuk, M.D.

Design Y Chin implants come as a three-part assembly – right and left halves joined by a connecting tab – which allows for easier insertion. Two styles (round and square) are offered in a range of sizes to address patient needs. The Design Y Chin implants are uniquely designed with registration tabs which act as a flange to allow the implant to "hug" the inferior border of the mandible. Together with the connecting tab, the registration tabs allow for precise, symmetric augmentation of the chin complex. Implants can be easily trimmed and contoured to meet size requirements.

Design Y[™] Chins

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OP8313	Design Y [™] Chin – Small Round	.35mm :	x 32mm x	4.0mm
OP8314	Design Y [™] Chin – Medium Round	.37mm :	x 32mm x	6.0mm
OP8315	Design Y [™] Chin – Large Round	.40mm :	x 32mm x	9.0mm
OP8316	Design Y [™] Chin – Small Square	.35mm :	x 32mm x	4.0mm
OP8317	Design Y [™] Chin – Medium Square	.37mm :	x 32mm x	6.0mm
OP8318	Design Y [™] Chin – Large Square	.40mm :	x 32mm x	9.0mm





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Design Y[™] Malars*

Designed in conjunction with Michael J. Yaremchuk, M.D.

Design Y Malars are used to reproduce normal contours of the facial skeleton. The Design Y Malar implants are uniquely designed with registration tabs which allow ideal and symmetric placement. Implants augment the projection of the malar prominence and extend from the infraorbital foramen, medially, to the zygomatico-temporal suture, laterally. They can be easily trimmed and contoured with a scalpel to meet specific patient requirements. Malars are available in a variety of sizes to minimize the need for alteration.

		A	D	L L
OP9513	Design $Y^{\text{\tiny M}}$ Malar – Small – Right	52mm	x 26mm	x 3.0mm
OP9514	Design Y [™] Malar – Small – Left	52mm	x 26mm	x 3.0mm
OP9515	Design Y [™] Malar – Medium – Right	52mm	x 27mm	x 4.0mm
OP9516	Design Y [™] Malar – Medium – Left	52mm	x 27mm	x 4.0mm
OP9517	Design Y [™] Malar – Large – Right	52mm	x 28mm	x 5.0mm
OP9518	Design Y [™] Malar – Large – Left	52mm	x 28mm	x 5.0mm





Design Y[™] Inferior Orbital Rims

The Inferior Orbital Rim Implant can provide anterior projection and may be trimmed to the specific needs of the patient. A small flange assists with positioning of the implant on the most anterior aspect of the orbital floor. Screw fixation to the underlying skeleton is possible.

		N	D
OP9429	Inferior Orbital Rim – Left	48mm x	25mm
0P9430	Inferior Orbital Rim – Right	48mm x	25mm





Extended Orbital Rims

The Extended Orbital Rim Implant can be used to augment the inferior and lateral orbital rim in trauma or for congenital cases. The implant allows for screw fixation for initial stabilization.

OP9539	Extended Orbital Rim – Left	53mm x 31mm	
OP9540	Extended Orbital Rim – Right	53mm x 31mm	





Facial Reconstruction and Cosmetic Implants

Two-Piece Chin Designs

The Two-Piece Chin implant comes in two pieces: a right half and a left half. Segmentation facilitates easy placement of the implant. Designed for the reconstruction of the retrusive or hypoplastic chin, the two-piece design also provides flexibility and proper anatomical positioning of the implant. Implants are available in several anterior projections.

		Α	B	C
0P8320	Two-Piece Chin – Small	62mm >	x 27mm x	5.0mm
OP8321	Two-Piece Chin – Medium	64mm >	x 32mm x	7.0mm
OP8322	Two-Piece Chin – Large	64mm >	x 36mm x	9.0mm





Osteotomy Gap Implant

The Osteotomy Gap Implant is designed to correct the inferior border contour irregularities of the mandible which inevitably occur after sagittal split osteotomy or sliding genioplasty. Each sterile package contains two implants.

OP7550	Osteotomy Gap Implant	34mm x 19mm





Nasal Reconstruction

Nasal Sheet

The Nasal Sheet is used to support tip elevation when nasal tip projection is needed. The Sheet is placed between the Medial Crura of the alar cartilage. Meticulous surgical technique should be used to prevent the implant from extending above the alar cartilage into the tip area.



Paranasal Shapes Crescent-shaped Paranasal Implants are designed to augment both the lateral and the inferior aspects of the pirform aperture. Implants can be carved to allow selective augmentation. The implants are available with right and left orientation and are available in two sizes.

		A	D	6
OP9519	Petite Paranasal – Left	29mm x	19mm >	(6.0mm
0P9520	Petite Paranasal – Right	29mm x	19mm >	(6.0mm
OP9525	Large Paranasal – Left	35mm x	26mm >	« 9.0mm
0P9526	Large Paranasal – Right	35mm x	26mm >	(9.0mm







Microtia Reconstruction

Ear Implants

The OMNIPORE Base and Helical Rim Implants offer maximum flexibility to the surgeon in shaping the height and projection of the helix. The surgeon should always cover the entire implant with a vascular flap (i.e., temporal parietal fascia flap) followed by a skin graft to prevent late exposure of the implant. OMNIPORE Ear Implants are suitable for primary or secondary repair in both congenital and traumatic indications.

Ear Base Shapes

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0P8330	Ear Base Extended – Right	.35mm	x 53mm
OP8331	Ear Base Extended – Left	.35mm	x 53mm

Helical Rims

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0P8328	Helical Rim – Right	.50mm	x 61mm
OP8329	Helical Rim – Left	.50mm	x 61mm





NEW

JR[™] Ear Base*

Designed in conjunction with John Reinisch, M.D.

The JR[™] Ear Base implants offer maximum flexibility and provide the surgeon with an attractive alternative from the variable results obtained with cartilage grafts traditionally used in ear reconstruction. The two-piece design of the JR Ear Base combined with the Helical Rim allows for tailoring the height and projection of the helix. The surgeon should always cover the entire implant with a vascular flap (i.e., temporal parietal fascia flap) followed by a skin graft to prevent late exposure of the implant. JR Ear Base implants are suitable for primary or secondary repair in both congenital and traumatic indications.



JR[™] Ear Base Shapes

0P8332	JR Ear Base – Right	63mm x 31mm x 17mm
0P8333	JR Ear Base – Left	63mm x 31mm x 17mm







Temporal Hollowing

Pterional Implant

The Pterional Implant is used to correct temporal hollowing defects in patients who have had temporalis muscle atrophy due to surgical interventions through a pterional approach to the brain. The implant is placed deep to the temporalis when closing and can be secured with screw fixation to the surrounding temporal bone. Available in one size and left and right orientation, the Pterional Implant is smaller than the BENDBLOCK TF2 Implant, although similar in design.

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OP9864	Right	45mm	x 44mm	x 7.0mm	x 3.0mm
OP9865	Left	45mm	x 44mm	x 7.0mm	x 3.0mm





BENDBLOCK[™] TF2 Implant

The BENDBLOCK TF2 Implant is designed to augment deficient soft tissue in the temporal region after trauma or when the temporalis muscle has been mobilized to a secondary site for reconstruction. Available in left and right orientation, the BENDBLOCK TF2 includes pedicles for volume enhancement that can be easily trimmed away with a scalpel depending on the specific needs of the patient.

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0P9857	TF2 Small – Left	.76mm	х	61mm x 19mm
0P9858	TF2 Small – Right	.76mm	Х	61mm x 19mm
OP9859	TF2 Medium – Left	.90mm	Х	73mm x 19mm
OP9860	TF2 Medium – Right	.90mm	Х	73mm x 19mm
OP9861	TF2 Large – Left	.101mm	Х	85mm x 19mm
OP9862	TF2 Large – Right	.101mm	Х	85mm x 19mm

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Craniotomy Gap Wedge

Craniotomy Gap Wedge are implants designed to fit into the gap along a bone flap that is often left following a craniotomy. The top of the implant is shaped to extend over both sides of the gap and also allows for curvature. Each sterile package contains two implants.

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OP82011	Craniotomy Gap	Wedge	102mm x	10mm x	4.7mm x	0.6mm	





NEW

Burr Hole Covers

Designed to fill and cover holes made by a cranial perforator, our low-profile Burr Hole Covers are available in two styles. The stems of the cover allow for easy size modifications. The superior flange covers gaps between the cranial hole and the bone flap. Design OP7511 includes a port in the flange (14.28mm long and 4.3mm wide) to accommodate the insertion of a drain.

		A	D	6
OP7511 Quantity – 1	Burr Hole Cover with Drain Port	24mm x	13mm x	6.5mm
OP7512 Quantity – 1	Burr Hole Cover	24mm x	13mm x	6.5mm









Blocks

OMNIPORE Blocks provide surgeons with ultimate flexibility in craniofacial augmentation and reconstruction. While in the sterile operating room, the surgeon can carve the blocks to meet individualized implant contours without worries of collapsing the pore structure. Soaking the implant in a hot, sterile saline bath for several minutes allows modification of the shape.

	A	B	C
OP6332	 13mm x	38mm >	< 3.0mm
0P6333	 13mm x	38mm >	(6.0mm
0P6335	 25mm x	50mm >	(3.0mm
0P6336	 25mm x	50mm >	(6.0mm
0P6338	 38mm x	63mm >	(3.0mm
OP6339	 38mm x	63mm >	(6.0mm



Cranial Reconstruction

BENDBLOCK[™] Implant

The BENDBLOCK Implant is designed for use in small or medium split-thickness cranial defects and contour deformities. The superior surface of the BENDBLOCK is smooth, while a pattern of pedicles on the inferior surface offer volume and flexibility. The implant can be modified with a scalpel to create a flange for fixation to the surrounding bone.

		A	B	C
OP6314	BENDBLOCK Implant	.95mm >	x 58mm :	x 4.5mm















BENDBLOCK[™] Cranial Grid Implant

The BENDBLOCK Cranial Grid Implant is designed to fill full thickness cranial defects. The inferior surface's waffle-pattern design provides strength and flexibility, while allowing the implant to be easily cut and shaped as needed. The implant's shape mimics the contour of the cranium, with further tailoring available by soaking the implant in a hot, sterile saline bath for several minutes to relax the memory, and upon removal from the bath, bending it to assume a revised shape while it cools.

OP9524 Cranial Grid 110mm x 97.5mm x 5.25mm

Cranial Hemisphere

The OMNIPORE Cranial Hemisphere is designed to be used for large cranial defects, providing surgeons with an off-the-shelf alternative to customized implants as well as complex grafts or other implant materials. The Cranial Hemisphere approximates the contour of a half cranium and can be trimmed with a blade to fit the defect. The edges can be delicately shaped and feathered using surgical scissors or a blade for a smooth transition between the implant and the patient's cranium. To fixate the implant, use sutures, surgical wire or craniofacial rigid fixation plates and screws.

		A	B	C
OP82000	Cranial Hemisphere – Right	174mm x	133mm	x 5.0mm
OP82001	Cranial Hemisphere – Left	174mm x	133mm	x 5.0mm

Sellar Buttress Implant (SBI[™])

Used in repairing the floor of the sella turcica, the Sellar Buttress Implant (SBI) is available in two sizes and configurations. The small SBI comes with a single, protruding tab to facilitate handling and placement while the large SBI has three tabs to allow the surgeon more than one opportunity to size and modify the implant for the patient's needs.

		A	Б	G	U
OP82007	Sellar Buttress Implant	20mm x	20mm x	2.45mm	x 0.45mm
0P82008	Sellar Buttress Implant – Large	40mm :	(40mm)	« 2.7mm	x 0.70mm





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Occipital Implant

The Occipital Implant is designed for reconstruction of the posterior cranium or correction of contour deformities. It provides an option to other repair materials for cranium reconstruction. The superior surface of the Occipital Implant is smooth, while a pattern of pedicles on the inferior surface offers volume enhancement that can be easily trimmed away with a scalpel, depending on the specific needs of the patient.

		A	В	U
OP82030	Occipital Implant – Small	.56.5mm	ı x 46.5mm	x1.1mm
OP82031	Occipital Implant – Large	.80.5mm	x 61.5mm	x2.0mm











Orbital Volume Replacement and Enophthalmus Correction

Orbital Spheres

OMINPORE Spheres can be used for enucleation or evisceration procedures. OmniPore ocular implants are engineered to be macroporous to facilitate fibrovascular ingrowth, yet smoother on the exterior surface to reduce friction on the overlying soft tissue. Rectus muscles can be sutured directly to the surface of the implant obviating the need for a tissue wrap.

		Diameter
OP6316	Sphere	 14mm
0P6326	Sphere	 16mm
OP6327	Sphere	 18mm
OP6317	Sphere	 20mm
OP6322	Sphere	 22mm





Enophthalmos Wedges

Enophthalmos Wedges help elevate and anteriorize the globe and provide volume to restore the orbit to its normal size and shape. Two sizes are available in left and right orientation.

		A	В	C
OP9541	Regular – Left	31mm	x 22mm	x 6.5mm
0P9542	Regular – Right	31mm	x 22mm	x 6.5mm
0P9543	Large – Left	39mm	x 28mm	x 7.5mm
0P9544	Large– Right		x 28mm	x 7.5mm





Orbital Floor Repair

OMNIPORE Sheets

Micro Thin Sheet

Ultra Thin Sheets

0P8438

OP7210

OP7212

Sheets 0P6330

OP6331

0P9562

OMNIPORE Sheets are used for craniofacial reconstruction and augmentation and are available in a variety of sizes and thicknesses. All Sheets come sterile and individually packaged and can be modified intraoperatively to conform to the skeleton. The 3S[™] Sheets have a smooth superior surface which may prevent tissue attachment to the superior surface of the implant.





3S[™] Sheets – Smooth Superior Surface

OP8312	
OP9312	



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30mm x 50mm x 0.45mm



Channel Sheet

The OMNIPORE Channel Sheet is designed to repair significant orbital floor and wall trauma. The channels allow for placement with many sizes of rigid fixation plates and have been designed on angles so that the implant can be contoured and bent to the desired shape and still have fixation on strategic landmarks such as the inferior orbital rim, medial orbital wall and posterior ledge. The implant also comes with a smooth superior surface. *Channel Implant does not come with plates.*





Orbital Floor Repair

OMNIPORE® DUROMAX® Orbital Implants

OMNIPORE[®] DUROMAX[®] Orbital Implants are intended for non-weight bearing applications of maxillofacial reconstruction surgery and repair of the orbital skeletal framework, including orbital walls, floors, rims and roof. OMNIPORE DUROMAX Orbital Implants come in four configurations that contain medical-grade titanium. US design patent pending.

Characteristics of OMNIPORE DUROMAX Orbital Implants include:

- Provide radiographic visibility
- Increased contour retention
- Anatomical shape
- Fixation hole positions allow screw placement
- Two thicknesses: 1.0 mm and 1.5 mm
- Compatibility with 1.5 mm titanium screws



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0P9550	DUROMAX – Small –	· 1.0mm	49.25mm	x 35mm :	x 1.0mm
OP9551	DUROMAX - Small -	1.5mm	49.25mm	x 35mm :	x 1.5mm
0P9560	DUROMAX - Large -	1.0mm	49.5mm x	60mm x	1.0mm
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Terms and Conditions

To Order:

- All implants are shipped three-day business delivery within the U.S.
- Delivery times may vary according to freight delivery schedules.
- Delivery by any other service or carrier specified by the customer will be at the customer's expense.
- Current Price List pricing shall apply on invoiced product sales unless contractual pricing is established by written agreement.

Return Merchandise Authorization (RMA):

- Prior authorization and a Return Merchandise Authorization (RMA) must be obtained from OsteoMed.
- Call OsteoMed Customer Service at 800-456-7779 to request an RMA#.
- Freight charges for merchandise returned are the responsibility of the customer.
- Back-up" implant products for surgery may be purchased at the current list price, unless contractual pricing is established.
- Returned product must be adequately packaged to prevent damage during the return shipment.
- A 10% restocking charge will be applied to returned items and must be returned within 30 days of date of invoice.

Credit and/or Refund May NOT be Issued for the Following Returns:

- Merchandise returned by other than original purchaser.
- Merchandise sold on a non-returnable basis, i.e. customized implants, shelf-pack quantities and non-implantable devices.
- Merchandise that has been opened, water damaged, crushed or otherwise damaged.
- Merchandise not returned in sellable condition.

No returns are allowed after 30 days from date of invoice.

Any merchandise returned other than in accordance with the above policies shall become the property of OsteoMed and will be dispositioned in an appropriate manner. The decision of OsteoMed with respect to the condition of the returned merchandise shall be final.



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Refer to the provided Instructions for Use for the complete Indications, Contraindications, Warnings, and Instructions for Use.

