

MATRIX SURGICAL USA

Where Art Meets Science

OMNIPORE[®] SURGICAL IMPLANTS



Porous High-Density Polyethylene
Reconstructive and Aesthetic Implants

OMNIPORE® Surgical Implants

OMNIPORE Surgical Implants are manufactured from a linear high-density polyethylene. Polyethylene has a long history of use in surgical implants. OMNIPORE Surgical Implants allows 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 Porosimetry). 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. 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.

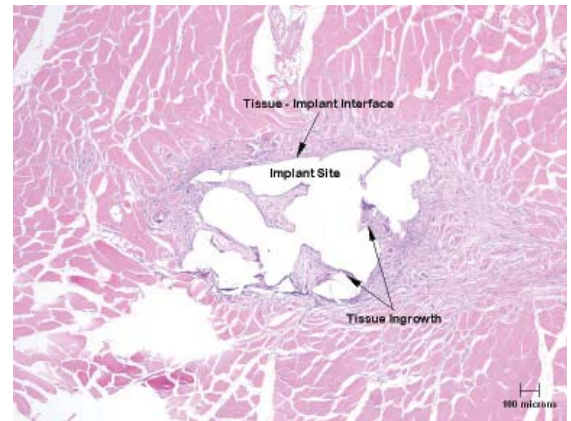


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OMNIPORE® Surgical Implant Handling Techniques

Implant Preparation

OMNIPORE Surgical 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.

Contouring & Shaping

Allow the 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 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.

Ocular/Orbital Reconstruction

OMNIPORE Sheets

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.

Micro Thin Sheet

	A	B	C
OP8438	30mm	50mm	0.45mm

Ultra Thin Sheets

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

Sheets

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

3S™ Sheets – Smooth Superior Surface

OP8312	38mm	50mm	1.0mm
OP9312	38mm	50mm	1.6mm

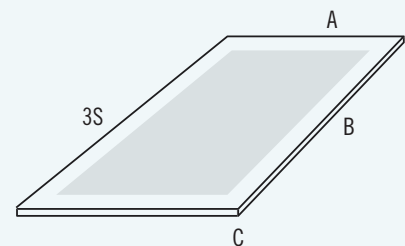
Thickness

0.45mm

0.85mm

1.5mm

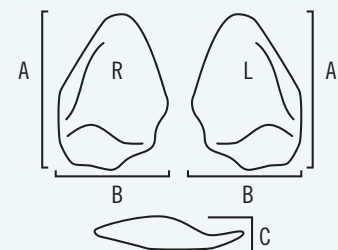
3.0mm



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



Ocular/Orbital Reconstruction

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.

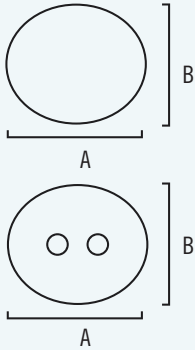
		Diameter
OP6316	Sphere	14mm
OP6326	Sphere	16mm
OP6327	Sphere	18mm
OP6317	Sphere	20mm
OP6322	Sphere	22mm



Ocular Conformers

Ocular Conformers are used after surgery to prevent closure or adhesions during the healing process. The small, convex-shaped acrylic devices have an internal surface that simulates the curvature of the orbit. Vented and non-vented Conformers are available sterile in small, medium and large.

		A	B
OP9547	Non-Vented - Small	22mm	19mm
OP9548	Non-Vented - Medium	24mm	21mm
OP9549	Non-Vented - Large	25mm	22mm
OP9778	Vented - Small	22mm	19mm
OP9779	Vented - Medium	24mm	21mm
OP9780	Vented - Large	25mm	22mm

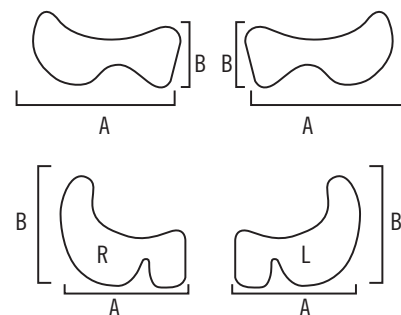


Facial Reconstruction and Cosmetic

Orbital Rims

Matrix Surgical USA offers two styles of orbital rim implants that can be easily trimmed to meet specific patient needs, and are available in left and right orientation. The Inferior Orbital Rim 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. The Extended Orbital Rim is used to augment the inferior rim in trauma or for congenital cases to restore orbital rim anatomy. The implant allows for screw fixation for initial stabilization.

	A	B
OP9429	Inferior Orbital Rim – Left.....	<i>Check website</i>
OP9430	Inferior Orbital Rim – Right	<i>Check website</i>
OP9539	Extended Orbital Rim – Left	<i>Check website</i>
OP9540	Extended Orbital Rim – Right.....	<i>Check website</i>



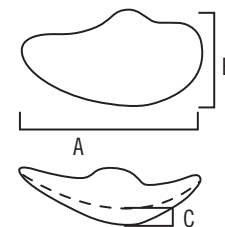
NEW

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.

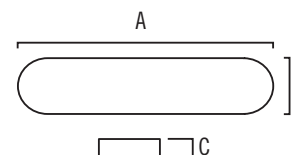
	A	B	C
OP9513	Design Y Malar – Small – Right	52mm x 26mm x 3mm	
OP9514	Design Y Malar – Small – Left	52mm x 26mm x 3mm	
OP9515	Design Y Malar – Medium – Right.....	<i>Check website</i>	
OP9516	Design Y Malar – Medium – Left	<i>Check website</i>	
OP9517	Design Y Malar – Large – Right	<i>Check website</i>	
OP9518	Design Y Malar – Large – Left	<i>Check website</i>	



Nasal Sheet

The Nasal Sheet is used to support tip elevation when nasal tip projection is needed. The Sheet is placed between the media 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.

	A	B	C
OP9536	Nasal Sheet.....	40mm x 9mm x 1.1mm	



*U.S. Patent applications 13/532,283 and 12/342,762

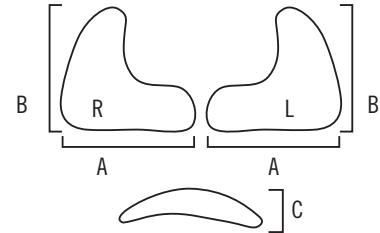
Illustrations are not actual size; please consult dimensional descriptions.

Facial Reconstruction and Cosmetic

Paranasal Shapes

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

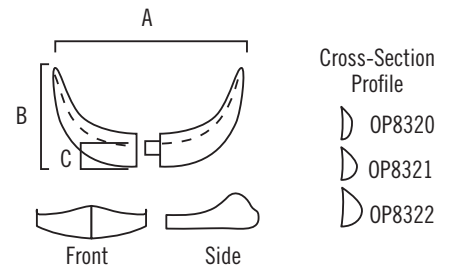
		A	B	C
OP9519	Petite Paranasal – Left	<i>Check website</i>		
OP9520	Petite Paranasal – Right	<i>Check website</i>		
OP9525	Large Paranasal – Left	<i>Check website</i>		
OP9526	Large Paranasal – Right	<i>Check website</i>		



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.

		A	B	C
OP8320	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		



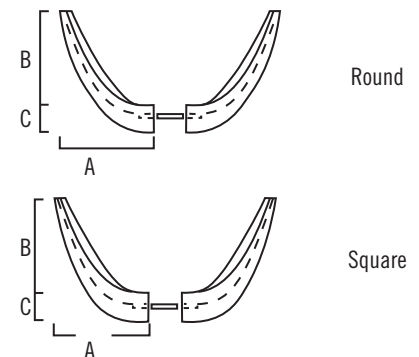
NEW

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.

		A	B	C
OP8313	Design Y Chin – Small Round	<i>Check website</i>		
OP8314	Design Y Chin – Medium Round	<i>Check website</i>		
OP8315	Design Y Chin – Large Round	<i>Check website</i>		
OP8316	Design Y Chin – Small Square	<i>Check website</i>		
OP8317	Design Y Chin – Medium Square	<i>Check website</i>		
OP8318	Design Y Chin – Large Square	<i>Check website</i>		



*U.S. Patent applications 13/532,283 and 12/342,762

Illustrations are not actual size; please consult dimensional descriptions.

Facial Reconstruction and Cosmetic

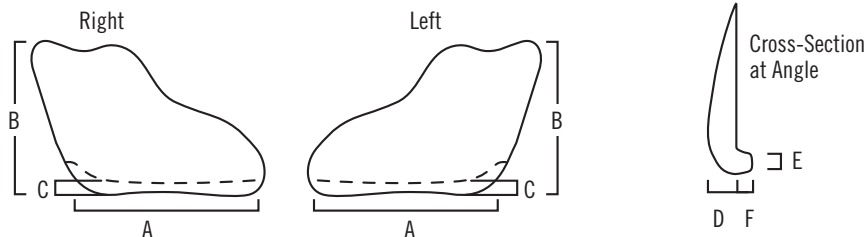
NEW

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. Three sizes with left and right orientation allow the surgeon to meet the requirements of each patient.

	A	B	C	D	E	F
OP7541	Design Y Mandible Onlay – Left <i>Check website</i>					
OP7542	Design Y Mandible Onlay – Right <i>Check website</i>					
OP7543	Design Y Mandible Onlay – Left <i>Check website</i>					
OP7544	Design Y Mandible Onlay – Right <i>Check website</i>					
OP7545	Design Y Mandible Onlay – Left <i>Check website</i>					
OP7546	Design Y Mandible Onlay – Right <i>Check website</i>					

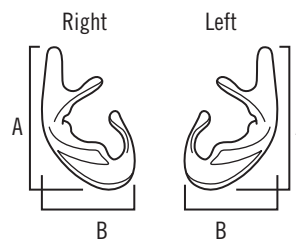


Ear Implants

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.

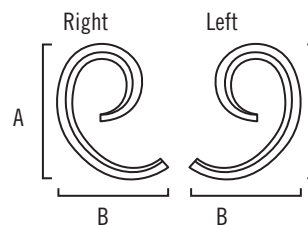
Ear Base Shapes

	A	B
OP8330	Ear Base Extended – Right53mm x 35mm	
OP8331	Ear Base Extended – Left53mm x 35mm	



Helical Rims

OP8328	Helical Rim – Right61mm x 50mm	
OP8329	Helical Rim – Left61mm x 50mm	



*U.S. Patent applications 13/532,283 and 12/342,762

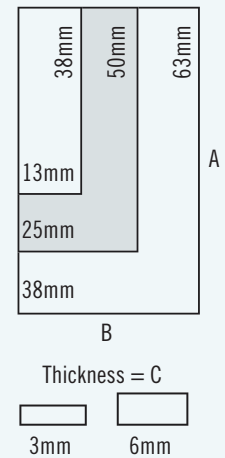
Illustrations are not actual size; please consult dimensional descriptions.

Cranial Reconstruction

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	38mm	13mm	3.0mm
OP6333	38mm	13mm	6.0mm
OP6335	50mm	25mm	3.0mm
OP6336	50mm	25mm	6.0mm
OP6338	63mm	38mm	3.0mm
OP6339	63mm	38mm	6.0mm

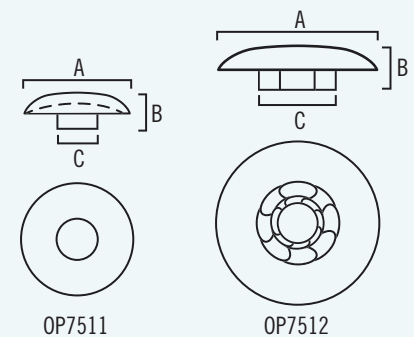


NEW

Burr Hole Covers

Designed to fill and cover holes made by a cranial perforator, Burr Hole Covers are available in two sizes. The stem of the large cover allows for easy size modifications. The superior flange covers gaps between the cranial hole and the bone flap.

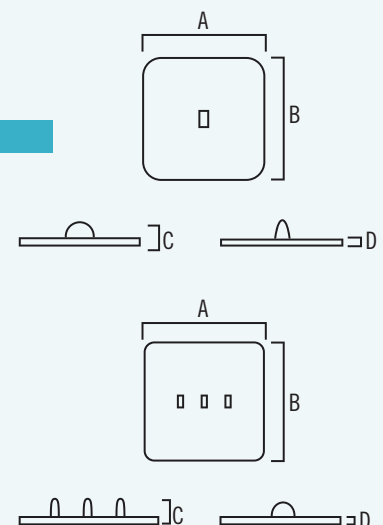
OP7511	Burr Hole Cover	Check website
Quantity – 1			
OP7512	Burr Hole Cover	Check website
Quantity – 1			



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 give the surgeon the flexibility to modify the implant without sacrificing any handling characteristics.

	A	B	C	D
OP82007	Sellar Buttress Implant.....Check website			
OP82008	Sellar Buttress Implant 3S™ – Large.....Check website			



Cranial Reconstruction

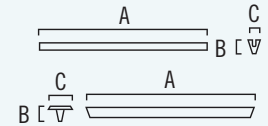
NEW

Craniotomy Gap Wedge

Craniotomy Gap Wedges are triangle-shaped implants designed to fit into the gap along a bone flap that is often left following a craniotomy. The V shape is a wedge-shaped strip with a channel down the middle. The T shape has a thin, flat top surface extending over a thinner wedge. Each sterile package contains one of each style.

A B C

- OP82011 Craniotomy Gap Wedge V*Check website*
- Craniotomy Gap Wedge T*Check website*



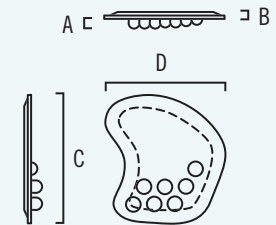
NEW

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.

A B C D

- OP9864 Right*Check website*
- OP9865 Left*Check website*



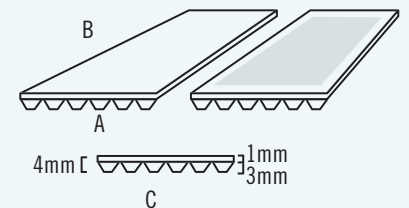
NEW

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*Check website*
- OP6315 BENDBLOCK Implant 3S™*Check website*



Cranial Reconstruction

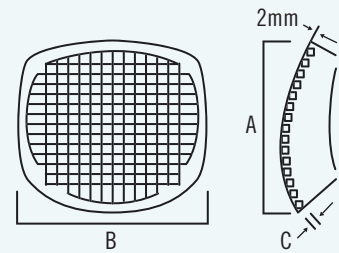
NEW

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.

A B C

OP9524 Cranial Grid *Check website*



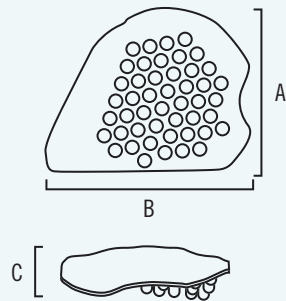
NEW

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.

A B C

OP9857 TF2 Small – Left *Check website*
 OP9858 TF2 Small – Right *Check website*
 OP9859 TF2 Medium – Left *Check website*
 OP9860 TF2 Medium – Right *Check website*
 OP9861 TF2 Large – Left *Check website*
 OP9862 TF2 Large – Right *Check website*



OMNIPORE® Customized Surgical Implants

Utilizing the latest and most innovative computer imaging and modeling technologies, Matrix Surgical USA can design precisely fitted patient-specific implants which:

- **Restore normal craniofacial anatomy**
- **Obliterate bony defects in the skull or orbits**
- **Augment facial skeletal or soft tissue defects**

Matrix Surgical USA specializes in the advanced modeling of **OMNIPORE** Customized Implants including the following case types:

COMPLEX ASYMMETRY

Asymmetry cases in which bilateral symmetry cannot be represented by a simple mid plane, where there is a significant amount of hardware already in place or when the bone surface has a very irregular surface.



CONTRALATERAL IMPLANT

The desired implant crosses the mid plane and requires model estimation of missing anatomy.



SOFT TISSUE COMPENSATION

A hard implant is used to restore both a bony surface and missing soft tissue anatomy.

Key Features and Benefits

- Made from Porous High-Density Polyethylene, a biomaterial with a long history of use in craniofacial reconstruction and augmentation surgery.
- More precise fit compared to off-the-shelf options. Further refinements intra-operatively are possible with a scalpel or surgical scissors.
- Reduced surgery time.
- Can be stabilized with standard craniofacial fixation systems.
- Radiolucent. Minimal artifact on MRI scan.
- Patients do not experience sensitivity to extreme temperature changes as with titanium implants.
- Ability to accept CT Scan (DICOM) data via a secure, password-protected web portal.
- Provided sterile by Ethylene Oxide.
- Manufactured in the U.S.A.

OP89020	OMNIPORE Customized Cranial Implant
OP89021	OMNIPORE Customized Facial Implant
OP89022	Contralateral Charge for customized Facial Implant
OP89023	Skeletal Model of defect area
OP89024	Facial Implant Template non-sterile
OP89025	Cranial Implant Template non-sterile
OP89026*	Contralateral Implant Template non-sterile

*Complex contralateral defects, or defects involving the orbital structures or facial structures may require additional expense, time and/or a physical skull model and template.

CALL CUSTOMER CARE FOR FURTHER INFORMATION.

MATRIX SURGICAL USA

Where Art Meets Science

OMNIPORE® Surgical Implants and Ocular Conformers are provided sterile by Matrix Surgical USA. DO NOT USE any implant or conformer if the package is open, damaged or wet. All STERILE items are considered single use and cannot be re-sterilized.

Surgeons should consult the package insert for instructions on the proper use and precautions for any OMNIPORE Surgical Implants or Ocular Conformers prior to use. For additional information worldwide, please contact your local OMNIPORE Surgical Implants Distributor; in the U.S., please contact Matrix Surgical USA directly using the information below.

Distributors should consult their distributor agreements for any claims.

All products manufactured and distributed by Matrix Surgical USA are latex free.

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