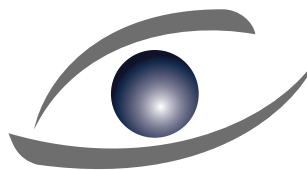


MATRIX
SURGICAL



OMNIPORE[®]
SURGICAL 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 should be customized 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.

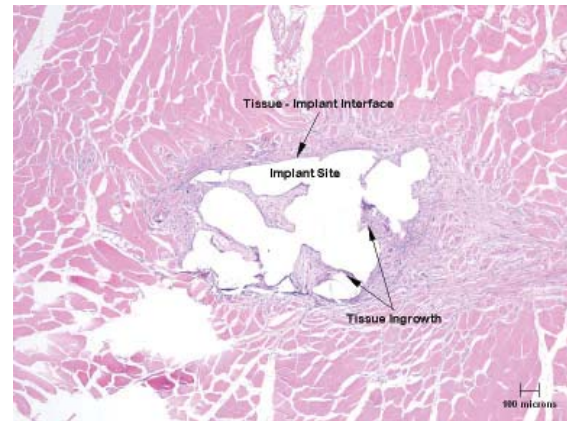


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OMNIPORE® Surgical Implant Handling Techniques

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, Catalogue # OP6359, 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

Micro Thin Sheet

OP843830mm x 50mm x 0.45mm

Ultra Thin Sheets

OP721038mm x 50mm x 0.85mm

OP721250mm x 76mm x 0.85mm

Sheets

OP633038mm x 50mm x 1.5mm

OP633150mm x 76mm x 1.5mm

OP956238mm x 50mm x 3.0mm

Thickness

0.45mm

0.85mm

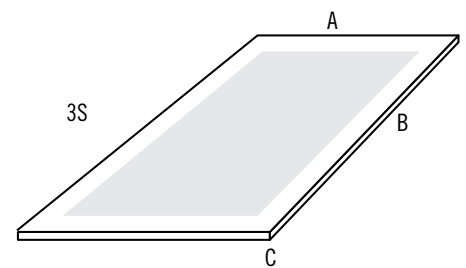
1.5mm

3mm

3S™ Sheets – Smooth Superior Surface

OP8312 Rectangle.....52mm x 76mm x 1.0mm

OP9312 Rectangle.....50mm x 76mm x 1.6mm



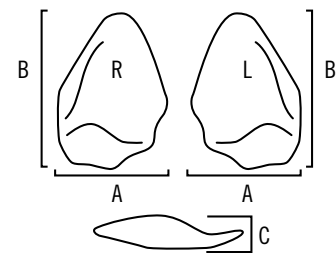
Enophthalmos Wedges

OP9541 Regular – Left.....22mm x 31mm x 7.0mm

OP9542 Regular – Right22mm x 31mm x 7.0mm

OP9543 Large – Left28mm x 40mm x 7.5mm

OP9544 Large– Right.....28mm x 40mm x 7.5mm



Orbital Spheres

Diameter

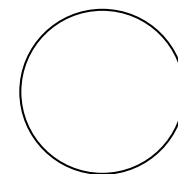
OP6316 Sphere14mm

OP6326 Sphere16mm

OP6327 Sphere18mm

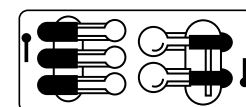
OP6317 Sphere20mm

OP6322 Sphere22mm



Spheres

OP9805 Orbital Volume Sizer Set - Stainless Steel - (Non-sterile)
For 14mm, 16mm, 18mm, 20mm, 22mm spheres



Ocular/Orbital Reconstruction

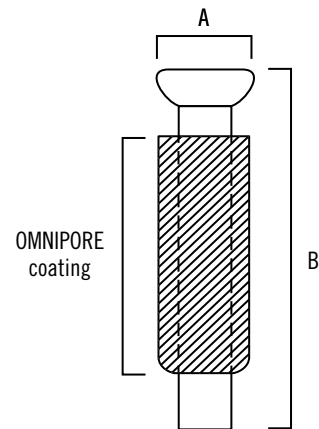
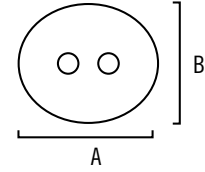
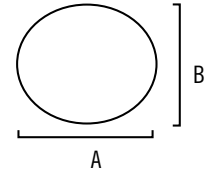
Ocular Conformers

		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

OMNIPORE Coated Tear Drains

OP81118	OMNIPORE Coated Tear Drain.....	3.5mm	18mm
OP81119	OMNIPORE Coated Tear Drain.....	3.5mm	19mm
OP81120	OMNIPORE Coated Tear Drain.....	3.5mm	20mm
OP81121	OMNIPORE Coated Tear Drain.....	3.5mm	21mm
OP81122	OMNIPORE Coated Tear Drain.....	3.5mm	22mm

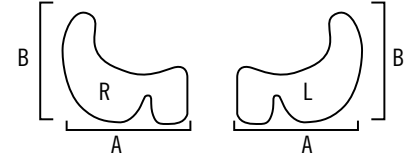
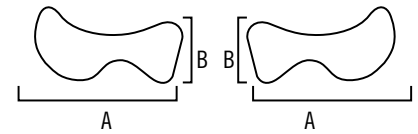
Other sizes available by special order.



Facial Reconstruction and Cosmetic

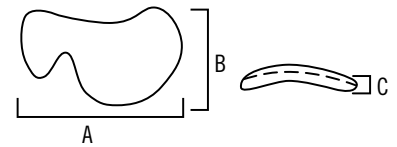
Orbital Rims

		A	B
OP9429	Inferior Orbital Rim – Left.....	43mm	18mm
OP9430	Inferior Orbital Rim – Right.....	43mm	18mm
OP9539	Extended Orbital Rim – Left.....	47mm	40mm
OP9540	Extended Orbital Rim – Right.....	47mm	40mm



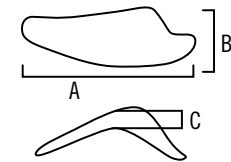
Midface Implants

		A	B	C
OP83003	Midface Rim – Left.....	47mm	28mm	3.0mm
OP83004	Midface Rim – Right.....	47mm	28mm	3.0mm



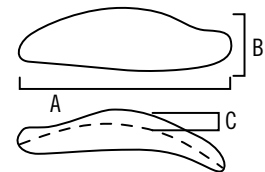
Malar Shapes

OP9501	Super Petite – Left.....	50mm	19mm	3.0mm
OP9502	Super Petite – Right.....	50mm	19mm	3.0mm
OP9503	Petite – Left.....	50mm	19mm	5.0mm
OP9504	Petite – Right.....	50mm	19mm	5.0mm



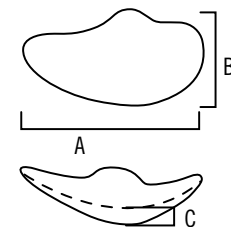
Additional Malar Shapes

OP9507	Small – Left.....	64mm	19mm	3.0mm
OP9508	Small – Right.....	64mm	19mm	3.0mm
OP9509	Medium – Left.....	64mm	19mm	4.5mm
OP9510	Medium – Right.....	64mm	19mm	4.5mm
OP9511	Large – Left.....	64mm	19mm	7.0mm
OP9512	Large – Right.....	64mm	19mm	7.0mm



Additional Malar Shapes

OP9513	Small Extended Contoured – Left.....	45mm	24mm	3.0mm
OP9514	Small Extended Contoured – Right.....	45mm	24mm	3.0mm
OP9515	Medium Extended Contoured – Left.....	50mm	26mm	4.0mm
OP9516	Medium Extended Contoured – Right.....	50mm	26mm	4.0mm
OP9517	Large Extended Contoured – Left.....	55mm	27mm	5.0mm
OP9518	Large Extended Contoured – Right.....	55mm	27mm	5.0mm



Facial Reconstruction and Cosmetic

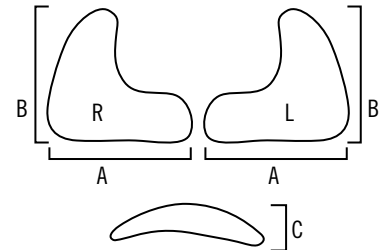
Nasal Sheet (Strut)

	A	B	C
OP9536 Nasal Sheet (Strut)	40mm	9mm	1.1mm



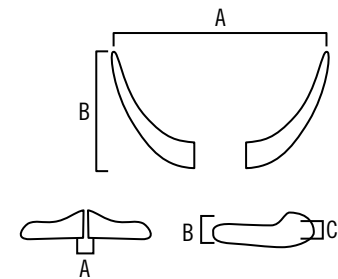
Paranasal Shapes

OP9519	Petite Paranasal – Left	28mm	x 26mm	x 4.5mm
OP9520	Petite Paranasal – Right.....	28mm	x 26mm	x 4.5mm
OP9525	Large Paranasal – Left	30mm	x 28mm	x 7.0mm
OP9526	Large Paranasal – Right.....	30mm	x 28mm	x 7.0mm



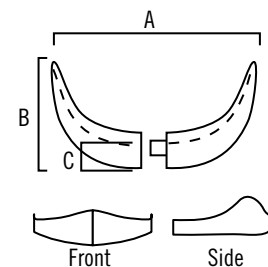
Contoured Two-Piece Chins

OP86000	Contoured Two-Piece Chins – 3mm	72mm	x 42mm	x 3.0mm
OP86001	Contoured Two-Piece Chins – 5mm	74mm	x 42mm	x 5.0mm
OP86002	Contoured Two-Piece Chins – 7mm	78mm	x 50mm	x 7.0mm
OP86003	Contoured Two-Piece Chins – 9mm	80mm	x 55mm	x 9.0mm



Two-Piece Chin Designs

OP8320	Two-Piece – Small	56mm	x 33mm	x 5.0mm
OP8321	Two-Piece – Medium	56mm	x 36mm	x 7.0mm
OP8322	Two-Piece – Large	57mm	x 38mm	x 9.0mm

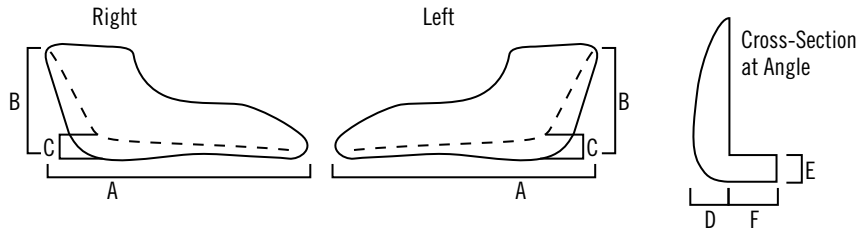


Cross-Section Profile
 OP8320
 OP8321
 OP8322

Facial Reconstruction and Cosmetic

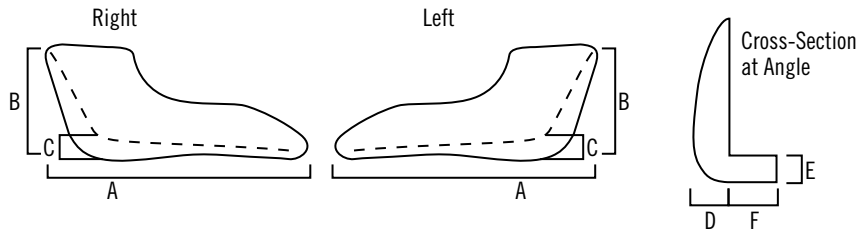
Mandibular Angle Reconstructive Onlay Shapes

	A	B	C	D	E	F	
OP7537	Ramus w/Inferior Ridge E5 – Left	79mm	32mm	5.0mm	7.0mm	5.0mm	10mm
OP7538	Ramus w/Inferior Ridge E5 – Right	79mm	32mm	5.0mm	7.0mm	5.0mm	10mm
OP7539	Ramus w/Inferior Ridge E10 – Left	79mm	32mm	10mm	7.0mm	10mm	10mm
OP7540	Ramus w/Inferior Ridge E10 – Right	79mm	32mm	10mm	7.0mm	10mm	10mm



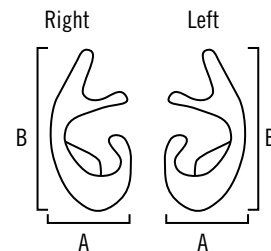
Mandibular Angle Aesthetic Onlay Shapes

OP7541	Ramus w/Inferior Ridge E5 – Left	79mm	32mm	5.0mm	5.0mm	5.0mm	4.0mm
OP7542	Ramus w/Inferior Ridge E5 – Right	79mm	32mm	5.0mm	5.0mm	5.0mm	4.0mm
OP7543	Ramus w/Inferior Ridge E10 – Left	79mm	32mm	10mm	5.0mm	10mm	4.0mm
OP7544	Ramus w/Inferior Ridge E10 – Right	79mm	32mm	10mm	5.0mm	10mm	4.0mm
OP88051	Ramus w/Inferior Ridge Large – Left	79mm	37mm	5.0mm	10mm	5.0mm	4.0mm
OP88052	Ramus w/Inferior Ridge Large – Right	79mm	37mm	5.0mm	10mm	5.0mm	4.0mm



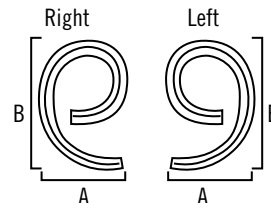
Ear Base Shapes

	A	B
OP8330	Ear Base Extended – Right	30mm x 59mm
OP8331	Ear Base Extended – Left	30mm x 59mm



Helical Rims

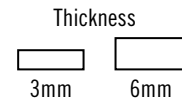
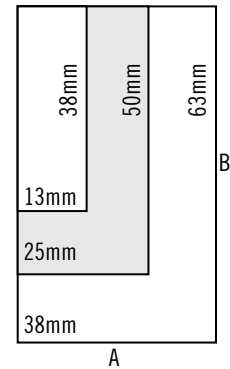
OP8328	Helical Rim – Right	37mm x 62mm
OP8329	Helical Rim – Left	37mm x 62mm



Cranial Reconstruction

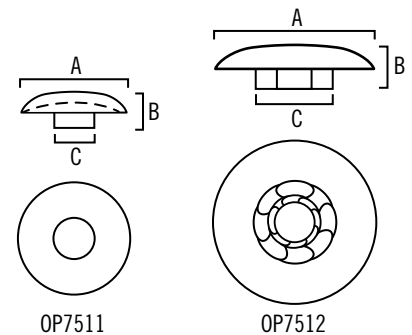
Blocks

	A	B	C
OP6332	13mm	38mm	3.0mm
OP6333	13mm	38mm	6.0mm
OP6335	25mm	50mm	3.0mm
OP6336	25mm	50mm	6.0mm
OP6338	38mm	63mm	3.0mm
OP6339	38mm	63mm	6.0mm



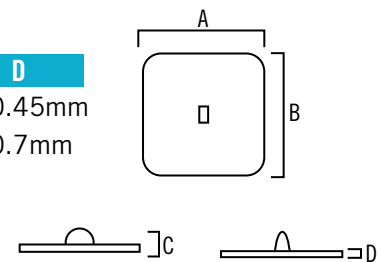
Burr Hole Covers

OP7511	Burr Hole Cover	15mm x 3.0mm x 5.0mm
(Package of 3)		
OP7512	Burr Hole Cover	29mm x 7.0mm x 14mm
(Package of 3)		



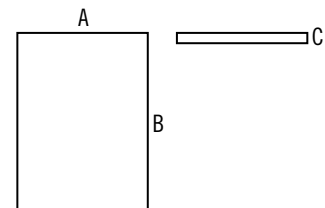
Sellar Buttress Implant (SBI™)

	A	B	C	D
OP82007	20mm	20mm	2.5mm	0.45mm
OP82008	40mm	40mm	2.5mm	0.7mm



Carving Block

	A	B	C
OP6359	152mm	203mm	12mm



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, surgical scissors or power instrument.
- 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-implantable
OP89025	Cranial Implant Template non-implantable
OP89026*	Contralateral Implant Template non-implantable

*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.



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 please contact your local OMNIPORE Surgical Implants distributor.

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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CE Certificate Number US12/82636 ISO Certificate Number US12/82605 CMDCAS ISO13485:
2003 Number US12/82606

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