

MATRIX **SURGICAL USA**

Where Art Meets Science



OMNIPORE[®]
CUSTOMIZED SURGICAL IMPLANTS

OMNIPORE® Customized Surgical Implants

OMNIPORE® Customized Surgical Implants are manufactured from a linear form of high-density polyethylene (HDPE). Polyethylene has a long history of use in surgical implants. The interconnecting open pore structure of OMNIPORE HDPE implants allows for tissue ingrowth. Additionally, the firm nature of the material allows for modification with a surgical instrument without collapsing the pore structure. OMNIPORE Customized Surgical Implants are defect-specific and intended for augmentation and restoration of the cranio-maxillofacial skeleton.

Customized Implant Ordering Process

1. Patient CT scan uploaded to Matrix Surgical USA secure Web Portal. This can be accessed at <http://www.matrixsurgicalusa.com/customized-implants>
2. Matrix Surgical USA *Case Information Form* to be completed by the customer. This form designates the part of the anatomy to be repaired or augmented, the fit of the customized implant and any other instructions on how the implant is to be designed and manufactured.
3. A quote will be issued by Matrix Surgical USA
4. A Purchase Order will need to be received by Matrix Surgical USA prior to Final Design and Manufacturing.
5. Matrix Surgical USA will send a prescription form (“Rx”) with the final design to the customer for review. Once approved, the customer must return the signed Rx to Matrix Surgical USA indicating the design has been approved and manufacturing can proceed.
6. Sterile Implant shipped to customer from Matrix Surgical USA.

CT Scan Upload Instructions

- Step 1** - Go to our website to get started at www.matrixsurgicalusa.com. Once on our website, select “Customized Implants.” On the bottom right of the Customized Implants page, select “Upload CT Scan.” This will take you to the secure site.
- Step 2** - Once in the secure site, click on the “Secure Upload.” Once the upload is completed, customer and Matrix Surgical USA will receive an email notification. If you should need further assistance, please do not hesitate to contact Customer Care at mmartin@matrixsurgicalusa.com.
- Step 3** - From “Available Recipients” select “Matrix Surgical USA.”
- Step 4** - This will take you to the section where your information and details will be required i.e. name, email, etc. In the “Message” section, please enter a subject and a brief description of your requirements and/or questions. Under “Delivery Options,” please check the box so you will be notified when your uploaded files have been received by Matrix Surgical. Then click “Enhanced Upload” at the bottom to begin uploading your files.
- Step 5** - A “Secure Upload” area will appear on the web page. You may drag and drop your files onto the table. *It is very important that we receive the DICOM files.*

Once the upload is completed, you and Matrix Surgical USA will receive an email notification.

Available OMNIPORE Customized Implant Catalogue Numbers:

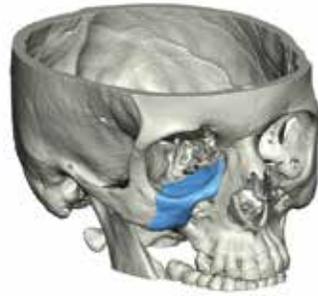
OP89020	OMNIPORE Customized Cranial Implant	OP89024	Facial Implant Template (non-sterile)
OP89021	OMNIPORE Customized Facial Implant	OP89025	Cranial Implant Template (non-sterile)
OP89022	OMNIPORE Contralateral Facial Implant	OP89026	Contralateral Implant Template (non-sterile)
OP89023	Skeletal Model of defect (non-sterile)	OP89027	OmniPore Customized Cutting Guide (sterile)

All OMNIPORE Customized Implants are unique to the patient and therefore are non-cancelable and non-refundable once the order is confirmed by Matrix Surgical USA.

Matrix Surgical USA can design and manufacture patient-specific implants that make it possible to restore the cranial or facial anatomy.



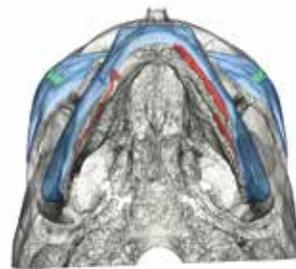
Cranial Defects



Internal Orbit



Mid-face Asymmetries



Mandibular Reconstruction

Note: Images above are produced with 3D imaging software utilized in the design of each customized implant. During the design process, the implant is represented in blue for clarity. Actual implants are composed of white high-density polyethylene.

Single-Stage Surgeries

The design methodology behind OMNIPORE Customized Single-Stage Surgical Implants makes it possible for the surgeon to remove bone and/or soft tissue and restore individual anatomy and aesthetics in a single surgery.



Prior to surgery, the Matrix Surgical engineer and the surgeon engage in a virtual design session over a web platform. The surgeon guides the engineer, defining where bone will be removed, thereby establishing the outer margin of the newly created “virtual” defect. The engineer then designs the implant to reconstruct that defect.

For single-stage cases, a cutting guide is also designed, which allows the surgeon to place the cutting guide over the resection area to guide bone removal.

OMNIPORE® Customized Surgical Implants

CT Scan Protocol

The quality of the CT scan is a critical component for the production of a high-quality customized surgical implant and anatomical model. Please review and follow this protocol and submit your scan using the upload feature on our website, or ship to Matrix Surgical USA, 4025 Welcome All Road, Suite 120, Atlanta, Georgia 30349 U.S.A. If you require further clarification or information, contact customer care at mmartin@matrixsurgicalusa.com.

Requirements

1. Perform a high-resolution 3D helical CT scan according to the following guidelines.
2. Archive the original high-resolution fine-slice data in uncompressed DICOM format.

CT Scanning Guidelines

Provide only the **original sub-millimeter spaced, fine-slice data, NO REFORMATS.**

- Do not use Cone Beam CT (due to insufficient contrast resolution).
- The patient must remain completely still during the scan. If the patient moves during the scan, it must be repeated.
- Where possible, the CT scan should cover from apex to mentum. This is very important for symmetrical restoration.
- The presence of metallic artifacts may obscure the affected anatomy. Minimize this by appropriate positioning of the head.
- The following table outlines appropriate slice thickness and spacing combinations in millimeters:

Anatomy	Slice Thickness	Spacing	Example
Face	0.5 (or nearest to)	0.4	Orbits, Mandible, CTA
Skull	1.0 (or nearest to)	0.8	Cranial Implant
Pitch	1:1	1:1	All

- **Gantry tilt:** Zero (0)
- **Dose:** Use a low mA for bony structures of the head.
- **Field of View (FOV):** To include only the structures of interest to surgeon. For cranial implants, include the entire skull. Ideal - 20-25 cm
- **Archive:** Archive only the sub-millimeter spaced fine slice acquisition data in uncompressed DICOM format.

NOTE: Please include the completed **OMNIPORE** Customized Surgical Implant case information form with CT scan.

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