

MATRIX SURGICAL USA

Where Art Meets Science

OMNIPORE® Customized Surgical Implants



Designing **OMNIPORE** Customized Surgical Implants to meet the unique anatomical needs of each individual patient.

MATRIX SURGICAL USA

Where Art Meets Science

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 Surgical 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 uncompressed) data via a secure, password-protected web portal.
- Provided sterile by Ethylene Oxide.
- Manufactured in the U.S.A.

THE MATRIX SURGICAL USA PROCESS

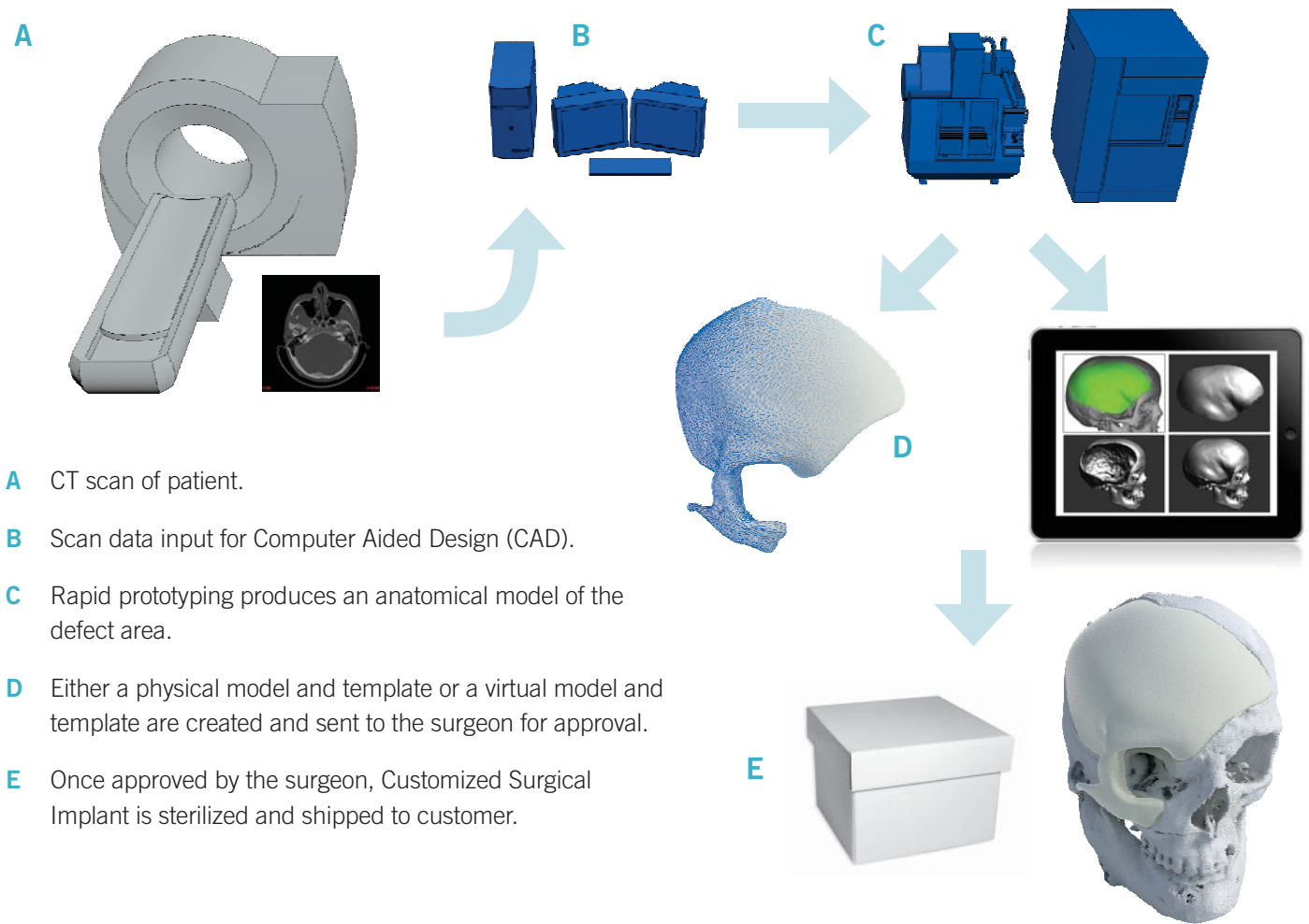
Matrix Surgical USA provides services in medical imaging data optimization and reconstruction as well as 3D data modeling and rapid prototyping for biomedical applications.

A surgical client typically sends a design request through the company website email or through phone contact.

The patient data for the anatomical model is then acquired according to a standardized CT protocol and delivered to Matrix Surgical USA via internet upload or shipping a CD/DVD.

Client consultation is maintained through email and teleconference as the implant design and anatomical model is refined and a 3D dataset is created for visualization. This information is then used to create virtual and physical models.

A physical or virtual model, physical or virtual non-sterile template and prescription form are then sent to the customer for evaluation. Once the design is approved, the surgeon signs the prescription form and returns it to Matrix Surgical USA. The sterile implant is then produced and shipped to the customer.



- A** CT scan of patient.
- B** Scan data input for Computer Aided Design (CAD).
- C** Rapid prototyping produces an anatomical model of the defect area.
- D** Either a physical model and template or a virtual model and template are created and sent to the surgeon for approval.
- E** Once approved by the surgeon, Customized Surgical Implant is sterilized and shipped to customer.

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.

CT SCANNING PROTOCOL OMNIPORE® CUSTOMIZED SURGICAL IMPLANTS & ANATOMICAL MODELS

Thank you for your interest in **OMNIPORE** Customized Surgical Implants. 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 shipping to Matrix Surgical USA, 4025 Welcome All Road, Suite 120, Atlanta, Georgia 30349 U.S.A. Contact customer care at mmartin@matrixsurgicalusa.com if you require further clarification or information.

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

Only provide 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 symmetry restoration cases.
- 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 Order Form with CT Scan.

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