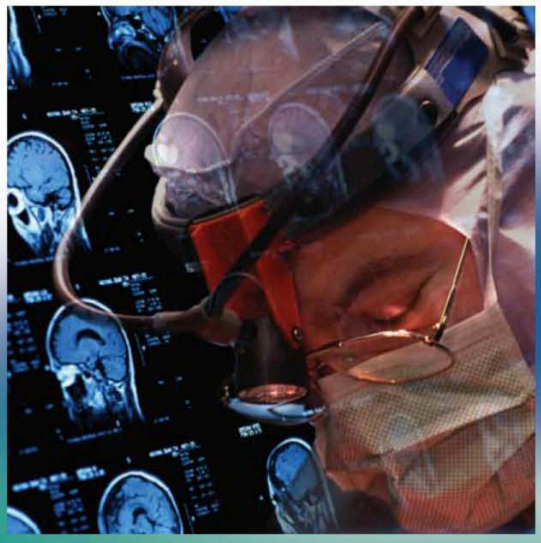
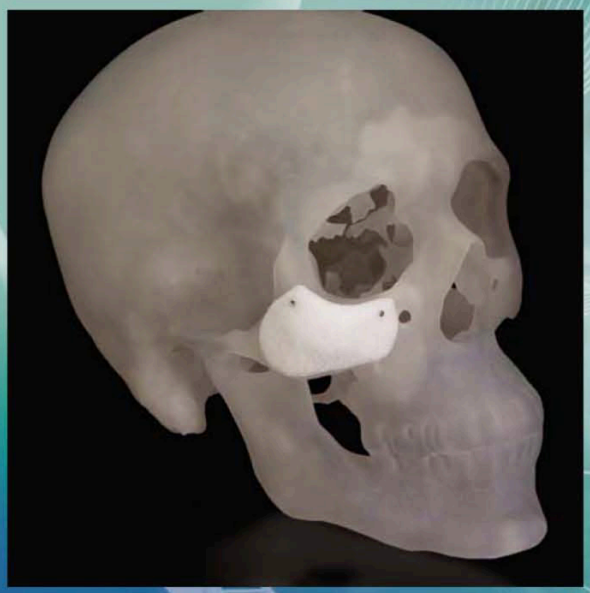
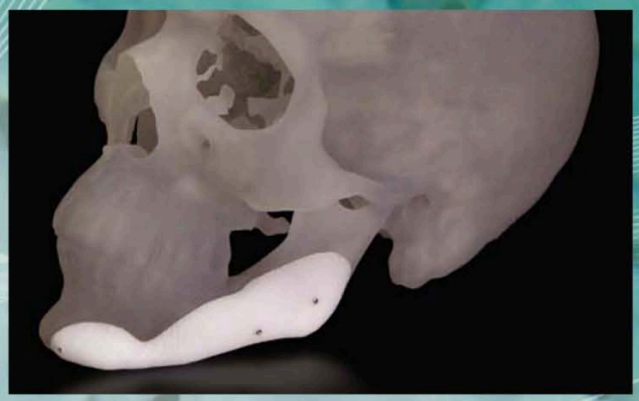
POREX
SURGICAL PRODUCTS GROUP
International



MEDPOR® Biomaterial Customized Implant Services

Innovative Technology in Reconstructive Surgical Implants





Customized Implants Designed for Each Patient's Individual Needs

MEDPOR® Customized Surgical Implants

MEDPOR® Customized Implants from Porex Surgical provide the surgeon with an attractive alternative to complex grafts and other implant materials. MEDPOR Customized Implants are manufactured to the specifications of the surgeon to meet the specific needs of each individual patient. Customized Implants are manufactured to fit a defect or to correct an asymmetry, based on computed tomography (CT) scan data or model provided by the surgeon. Based on the size and complexity of some defects, some customized implants may need to be produced in more than one piece.

- MEDPOR Customized Implants are prescription devices tailored to a patient's individual requirements.
- MEDPOR Customized Surgical Implants are provided sterile and should not be re-sterilized. Implants may require fitting to the defect area at the time of surgery. The implant edges should be delicately shaped and feathered for a smooth transition from the implant to the patient's own bony contour. Fixation of the implant may be accomplished with suture, surgical wire, or craniofacial rigid fixation plates and screws.
- Many complex procedures require prior approval from insurance carriers. Porex Surgical can provide the surgeon with a document package on customized implant procedures.

Steps to Standard Customized Implants Service

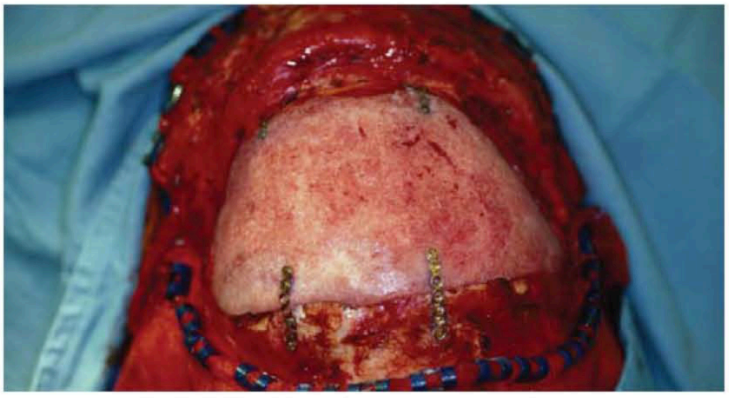
Step 1 - Customized Surgical Model (CSM)
A CSM is developed from the patient's computerized tomography (CT) scan data. CSMs are stereolithography models of bony tissue showing absent bony areas (defect). The CSM is autoclavable and may be utilized for surgical planning.

Step 2 - Customized Implant Template (CIT)
A customized implant shape is created to augment the defect areas evident in the CSM. The non-sterile template, along with a prescription form, is sent to the surgeon for review and approval.

Step 3 - Customized Surgical Implant (CSI)
Upon surgeon approval of the CIT and receipt of a signed prescription, a Customized Surgical Implant (CSI) is produced. The CSI is provided sterile for the surgical procedure.

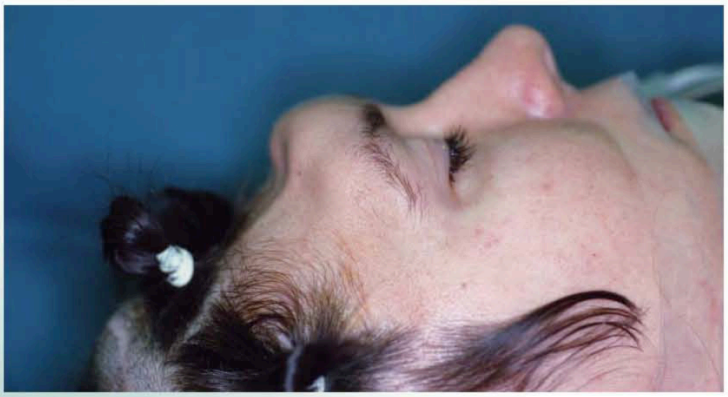
*Note: Standard Implant Services or complex defects requiring a physical skull model and template require additional time and expense to produce. Please call for a quote.

Feathering of the Implant



Fixation of Implant

Photos courtesy of Robert D. Wallace, MD



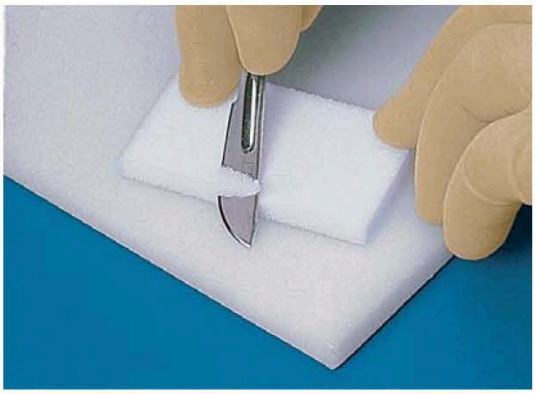
Immediate Pre-Op

Twenty-One Months Post-Op

MEDPOR Biomaterial

MEDPOR Customized Implants are produced from MEDPOR Biomaterial. More than 250,000 procedures have been performed with MEDPOR Biomaterial, with more than 350 published clinical reports in cranial, reconstructive, oculoplastic and aesthetic applications. For more information about MEDPOR Implants or for a complete listing of clinical reports, visit www.porexsurgical.com.

- MEDPOR is a biocompatible, porous polyethylene material. The interconnecting, omni-directional pore structure allows for rapid fibrovascular in-growth and integration of the patient's tissue.



- MEDPOR is easy to work with! The material can be trimmed with a blade, carved and feathered intra-operatively for an excellent final fit.

- No pre-placing of fixation plates! MEDPOR can be easily drilled and fixated, giving the surgeon more flexibility in fixation options and placement.

New and Improved!

e-viewCT™

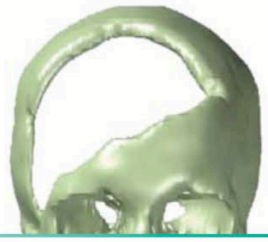
advanced technology for innovative surgeons

Porex Surgical's new and improved interactive Web portal allows for faster and easier transfer of patient data between our highly skilled design staff and the surgeon or radiologist. Customized implant shapes can then be made to fit the defect or to correct an asymmetry. From receipt of CT scan data, to a virtual rotating 3-D skull model and implant template design, to the shipment of the final sterile implant, the redesigned **e-viewCT** Web tool allows the surgeon 24-hour access to the process. The improved tool allows the surgeon to log in with secure access and view the status of a specific case. An individual date stamp is documented as each of the milestones that make up the customized implant process is completed. E-mail notifications of the process can be automatically generated to individuals designated by the surgeon, enabling more efficient planning through faster communication. **e-viewCT** is advanced technology for innovative surgeons.

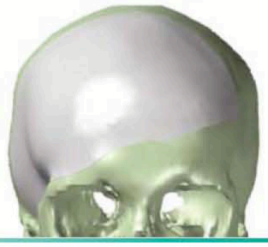
MEDPOR® Customized Implant Scanning Protocol

Information and guidelines follow for providing CT data to Porex Surgical to create a MEDPOR Customized Implant. Obtaining a recent scan with adherence to the guidelines and parameters listed below is critical to the fit of the final MEDPOR Customized Implant, as well as reducing the turn-around time. If a proprietary viewer software is used to store and manage the original data files, please contact Porex Surgical in the U.S. at 1-800-521-7321/ 1-678-479-1610 or in Germany at +49 (89) 232415-12 for additional instructions.

Scanning Guidelines



- The scan should include 2cm beyond the defect area or area of interest.
- Please provide the original DICOM slice data on MOD/CD/DVD (MOD will be returned).
- Do not reformat or include viewer software with data.
- Data can be transferred via the secure **e-viewCT** Web utility (contact USA or Germany office for details).
- Important position or details should be noted, as well as an asymmetrical element of the patient to indicate left and/or right.
- If a surgical model is ordered which incorporates the mandible, the mandible portion of the model will be fused to the skull unless a bite jib is used during the scanning process.
- No contrast required.

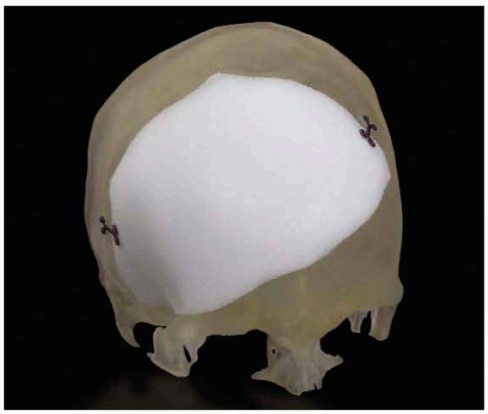


Scanning Parameters: Cranial Defects

Acquisition: Axial/Helical
F.O.V.: Include all areas of interest
Gantry Tilt: 0
Spacing: Overlapping
Slice Thickness: 1-1.25mm (preferred)
(3mm Max)
Algorithm: Standard
MA: 170ma/280kvp or lower
Time: 2 seconds or less

Scanning Parameters: Facial Defects

Acquisition: Axial/Helical
F.O.V.: Include all areas of interest
Gantry Tilt: 0
Spacing: Overlapping
Slice Thickness: 1-1.25mm (preferred)
(1.5mm Max)
Algorithm: Standard
MA: 120—180ma/120kvp or lower
Time: 2 seconds or less



MEDPOR® Fixation System

The new MEDPOR® Fixation System was designed specifically for fixation of porous high-density polyethylene implants, providing a complete closure system with MEDPOR Customized Implants or off-the-shelf Cranial Implants.

Cat. #80080 MEDPOR Fixation System – Cranial

The MEDPOR® Cranial Fixation System is color-coded to ensure correct orientation and is packaged in a sterile kit for one-time use. Kits include the following:

- *(8) Bone screws, blue, 1.5mm diameter x 4mm length*
- *(8) MEDPOR screws, magenta, 2.0mm diameter x 4mm length*
- *(4) Bone plate, double-Y configuration, .60mm thick*
- *Driver handle – accepts driver and pilot hole drill*
- *Forceps*
- *Pilot hole drill (option for bone, not necessary for MEDPOR)*
- *(1) Rescue screw, green, 1.8mm diameter x 4mm length*
- *(1) Rescue screw, gold, 2.3mm diameter x 4mm length*

MEDPOR (Magenta) Screw

Bone (Blue) Screw

The MEDPOR screw (magenta) is optimized for fixating porous high-density polyethylene:

- Threads have greater projection than conventional bone screws
- MEDPOR (magenta) screws have greater resistance to pull-out than conventional bone screws

(Reference: ASTM F543-07 Standard Specification and Test Methods for Metallic Medical Bone Screws)

Double "Y" Plate

- Plate thickness, .60mm
- Low plate and screw profile designed for decreased palpability
- Plates are color-coded for ease of identification: MEDPOR side = magenta, bone side = blue)

POREX
SURGICAL PRODUCTS GROUP

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