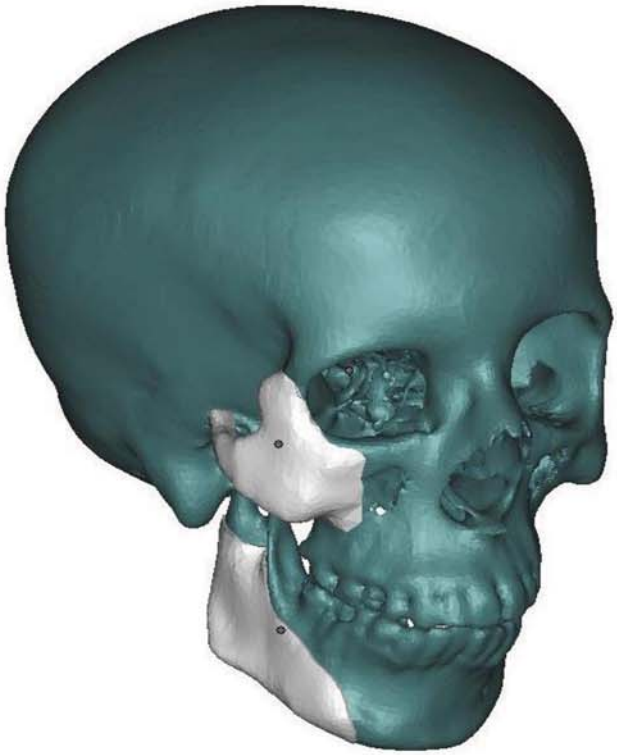
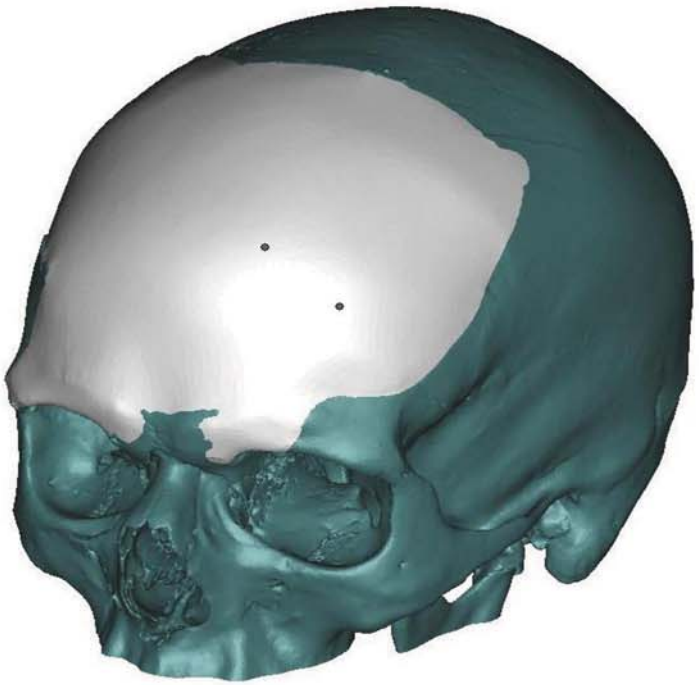
Synergy Medical Corporation

Patient-Specific Surgical Implants
from **PORIFEROUS, LLC.** featuring
SU-POR® Biomaterial





Surgical implants to
meet patient specific
needs

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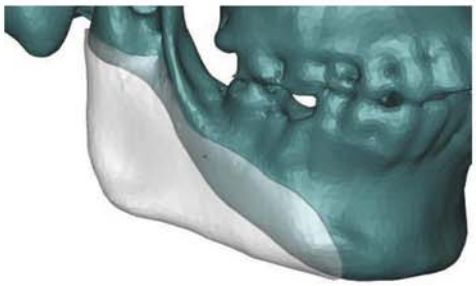
Patient-Specific Surgical Implants from PORIFEROUS, LLC.

SU-POR Patient-Specific Surgical Implants in customized shapes to meet the needs of individual patients are intended for non-weight-bearing applications of craniofacial reconstruction surgery and repair of craniofacial trauma. SU-POR Patient-Specific Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillifacial skeleton.



Utilizing advanced modeling systems Poriferous can design patient specific implants for the following types of cases:

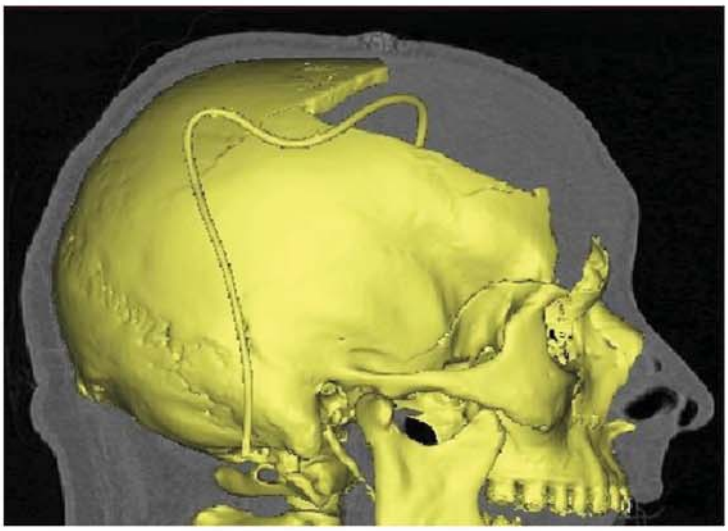
SOFT TISSUE COMPENSATION
Implant is used to restore both a bony surfaces and missing soft tissue anatomy.

CONTRALATERAL RESTORATION
Implant can be designed in cases where the defect crosses the mid-plane.

ASYMMETRY
Often complex implants where our designers work with the surgeon to design implants to provide the desired symmetry.

Features and Benefits

- SU-POR Biomaterial is a brand of porous high density polyethylene that has a long history of use in craniofacial reconstruction and augmentation surgery.
- Provides a customized fit while allowing any needed modifications intra-operatively by bending and by cutting with a scalpel or other surgical cutting instruments.
- Can be stabilized with standard craniofacial fixation systems.
- Radiolucent. The SU-POR Patient-Specific Implants are MR Safe.
- Provided sterile by Ethylene Oxide
- Made in U.S.A



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Patient-Specific Implant THE PROCESS

Poriferous, LLC. designs and manufactures customized implants that meet the specific needs of a individual patient.

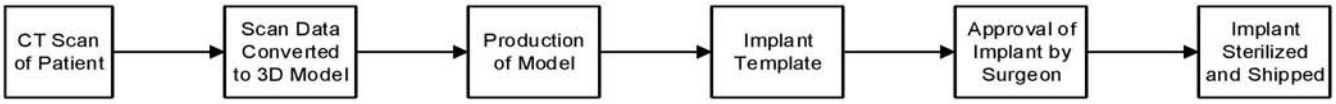
The process begins with a contact from a surgeon inquiring about a Patient-Specific Implant usually via email or telephone.

Surgeon provides the patient-specific data in various forms including CT Scan data, drawings, or physical model. When by CT data, the Scan data is acquired according to a standardized CT protocol and then provided to Poriferous via a secure internet upload or by shipping a CD/DVD. A surgeon also has the option of providing a drawing of the desired implant

The surgeon may elect to personally design the implant using a implant design kit. Surgeon consultation is conducted through email and teleconference as the implant design and anatomical model is produced.

A physical or virtual model, physical or virtual non-sterile template and prescription form are then sent to the surgeon for review and approval. The sterile implant is then produced and shipped to the surgeon. See Page 4 of this document for a detailed process flow chart.

Basic Process Flow



Patient Specific Implant Order Numbers

4350 Patient-Specific Cranial Implant (Includes periorbital patient specific implants) Package includes; online review of skull model, online approval of implant template, one sterile implant plus one back-up implant (Second sterile implant US Only)

4351 Cranial Implant Template add-on (non-implantable)

4353 Patient-Specific Facial Implant includes chin, mandible, malar, and midface. Package includes; one sterile implant, one sterile backup implant (Second sterile implant US ONLY).

4354 Contralateral charge for Patient-Specific Facial Implant

4355 Skeletal model of defect area

4356 Facial Implant Template add-on (non-implantable)

4357 Bilateral Implant add-on (non-implantable)

Note: When requesting implants involving complex defects the process may require additional cost and time.

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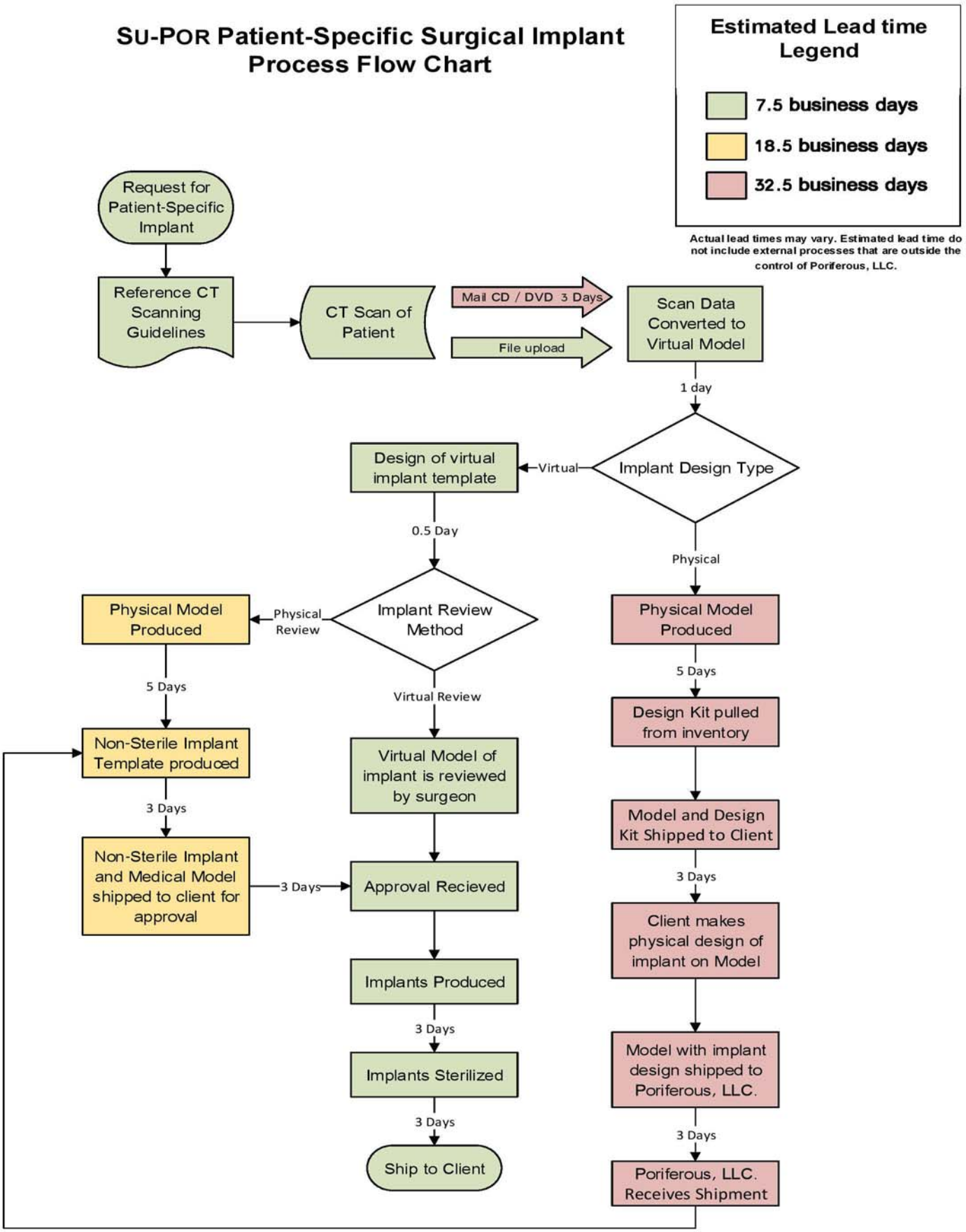
SU-POR Patient-Specific Surgical Implant Process Flow Chart



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PORIFEROUS Scanning Protocol for SU-POR Patient-Specific Surgical Implants

The quality of the CT data is essential to the design and manufacture of SU-POR Patient-Specific Surgical Implants. Provided below is the protocol to follow:

CT Scanning Guidelines

- The patient must to stabilized and remain completely still throughout the entire scan. If patient movement occurs the scan must be restarted to achieve the best implant fit.
- The scan should include 2cm beyond the defect area or area of interest.
- Please provide the original DICOM slice data.
- Do not reformat or include viewer software with data.
- Important position or details should be noted as well as any asymmetrical element of the patient to indicate left and/or right.
- The use of a bite jib during the scanning process for the mandible or the maxilla is recommendation otherwise they will be fused in the model.

SCANNING PARAMETERS:

Cranial Defects

- Acquisition: Axial/Helical
- F.O.V.: Include all areas of interest. 20-25 cm is preferred
- 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

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

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What makes SU-POR® Biomaterial By PORIFEROUS, LLC. SU-POR-IOR?

Surgical – Suturable – Su-Por-Ior

SU-POR Biomaterial is a brand of alloplastic porous high density polyethylene (HDPE) that is readily modified and shaped to suit the functional and anatomical requirements of the patient. The interconnecting pores of the porous HDPE permits fibrovascular ingrowth into the implant. SU-POR Implants are provided in block, sheet, and anatomical shapes intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

SU-POR Implants are single use, non-pyrogenic, packaged in double peel Tyvek/Mylar pouches, and provided sterile by ethylene oxide (EO) terminal sterilization.

SU-POR Surgical Implants were tested to the biocompatibility standards to demonstrate that they are substantially equivalent materials as the predicate devices, Porex Surgical Inc. MEDPOR®, in regards to Cytotoxicity, ISO Systemic Toxicity, ISO Intracutaneous Study, USP Pyrogen Study, and ISO Muscle Implantation Study. SU-POR Surgical Implants completed sterilization validation to demonstrate that they are sterile devices for implantation as equivalent to the predicate devices. SU-POR Surgical Implants completed material-to-material mechanical testing specific to impact resistance, flexural properties, tensile strength, material purity per USP, and porosity.

SU-POR Surgical Implants have the same intended use and indications for use, and technological characteristics and principles of operation as the predicate devices. SU-POR Surgical Implants are substantially equivalent based on the testing, (discussed above), that demonstrates that the device is as safe, as effective, and performs as well as, or better, than the predicate device.

Additionally SU-POR Surgical Implants are:

- MR Safe, having established safety and compatibility of passive implants in the Magnetic Resonance (MR) environment.
- Easy to cut with a scalpel, can be bent into shape, and have superior suturability made possible by proprietary manufacturing knowledge that make the material easy for the surgeon to use.

Poriferous holds the following quality certifications including: ISO 13485:2003, EN ISO 13485:2012, Directive 93/42/EEC, and CMDCAS for Health Canada.

Poriferous, LLC. is operated by professionals who were a part of the original team that introduced porous HDPE as a alloplastic material in 1985. We know porous polyethylene and can deliver the results our surgeons demand.

Poriferous distinguishes itself in extensive ownership of technology and in-house services. We perform all processes associated with manufacturing of our products in-house. This strategic advantage allows us to truly focus on our customers' needs and to continually advance the technology of SU-POR Surgical Implants.

It is our goal to provide all surgeons with the best products that help them produce the optimum results for their patients. Poriferous is a true innovator of technology in pursuit for the highest quality, pioneering surgical implants . Aaron Noble, Founder and CEO is the inventor of the titanium embedded porous polyethylene product, (Craniofacial Implant -United States 8298292 -Europe DE 602007012046 D1), and of the custom implant process (Porous Laser Sintered Articles -United States 8142886), Our product offerings include many patent-pending technologies that we believe will soon change the way the world looks at porous plastic implants.