PSI Patient Specific Implant. Derived from CT data for excellent reconstructive results.
Table of Contents

PSI Patient Specific Implant 2
Choice of Material 4
Quotation Process 6

Warning
This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure “Important Information”. Assembly and disassembly instructions of instruments “Dismantling multipart instruments” can be downloaded from http://www.synthes.com/reprocessing.
**PSI Patient Specific Implant.** Derived from CT data for excellent reconstructive results.

---

**Patient Specific Implant**

Intended for replacement of bony voids in the cranial/craniofacial skeleton.

**Features**

- Better anatomic fit versus conventional fixation/reconstruction methods
- Reduced operating time
- Satisfying aesthetic results for surgeon and patient

---

Synthes Patient Specific Implants are derived from CT data which is obtained from the hospital radiology department.

---

Validated process is used to convert and manipulate the CT data to create an anatomically correct skull model and an implant model.
Surgeons can choose from two methods of reviewing Synthes implant design prior to fabrication of implant:
1. Skull model and implant model are sent to surgeon for review, mark up and/or approval.
2. Computer images of the defect, the implant and the implant fitted into the defect are sent electronically.

Surgeons have a choice of two biocompatible materials:
– PEEK Optima-LT (polyetheretherketone) or
– Commercially pure titanium

When final implant design is determined and a purchase order has been received, Synthes will fabricate one non-sterile implant for shipment to the surgeon.
Choice of Material

PEEK Optima-LT (polyetheretherketone)

Features
- Engineered for strength, stability and biocompatibility
- Radiolucent (minimal MRI artifact)
- Bone-like stiffness and strength
- Surgeon can determine plate and screw placement during surgery
- Light weight
- Autoclavable – withstands repeated sterilization
- Can be used with Synthes standard 1.3 mm to 2.0 mm cranial and craniofacial fixation systems
- Minimum thickness of implant is 3 mm

Titanium (commercially pure, implant grade)

Features
- Ultra high strength
- Radiopaque
- Machine screws (488.066) are needed (See graphics page 5).
- Screw hole position is defined during the design process.
**PEEK Mechanical Properties**

<table>
<thead>
<tr>
<th></th>
<th>Cortical Bone</th>
<th>PEEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modulus of Elasticity (stiffness) (GPa)</td>
<td>8–24</td>
<td>3.6–4.1</td>
</tr>
<tr>
<td>Yield Strength (MPa)</td>
<td>115</td>
<td>113</td>
</tr>
</tbody>
</table>

**Notes regarding the use of PEEK Patient Specific Implants**

For minor fit modifications it is suggested that the surgeon modify the patient bone rather than modifying the PEEK Patient Specific Implant. If needed, PEEK Patient Specific Implants can be modified with a high speed burr. It is suggested that the PEEK implants be modified and rinsed in sterile saline solution away from the implant/surgical site, to ensure that particulate debris does not infiltrate the surgical site after any modifications.

Standard plates and self-tapping or self-drilling screws can be used to attach the PEEK Patient Specific Implant to the patient. *Screw holes, regardless of screw size and type, must be predrilled away from the surgical site.*

---

**Titanium Mechanical Properties**

<table>
<thead>
<tr>
<th></th>
<th>Cortical Bone</th>
<th>Ti-grade 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modulus of Elasticity (stiffness) (GPa)</td>
<td>8–24</td>
<td>103</td>
</tr>
<tr>
<td>Yield Strength (MPa)</td>
<td>115</td>
<td>230 min</td>
</tr>
</tbody>
</table>

![Titanium PSI Implant](image)
1
Surgeon sends patient to radiology to be scanned according to Synthes CT Scanning Protocol.

Notes
- Scans must be less than four months old. Films will not be accepted.
- Patient's CT scan and any additional patient information will be used solely for the production of a Patient Specific Implant. All patient information will be kept confidential.
- The data can either be sent by mail (express) or can be uploaded through an Internet connection. Contact your Synthes representative for details.

2
Surgeon sends to Synthes:
1. The completed Request for Quote form.
2. CT scan according to the CT Scanning Protocol.

CT Scanning Protocol

Preparation of the patient
- Remove any non-fixed metal dentures or jewellery in and near the region to be scanned. Non-metallic dentures may be worn during scan.
- Place the patient supine on the scanner table.
- Instruct the patient not to move.

Aligning the patient
- Scan the patient without gantry tilt (0° angulation).
- If this is not possible, mark the degree of angulation on the scan. Be aware that 3D representation will have an inferior quality due to the tilt.
- Align the patient in a way that prevents as many artefacts as possible.
- Use a head holder to stabilize the position and strap the head securely to prohibit motion.

Scanning instructions
- Set the table height so that the area to be scanned is centred in the scan field.
- All slices must have the same field of view, the same reconstruction centre and the same table height.
- Scan all slices in the same direction.
- Scan with the same slice spacing: slice spacing must be less than or equal to the slice thickness. Slice thickness should preferably not be larger than 1 mm.
- Scan the entire defect as well as 2 cm above and below.
- If high-quality reformatted images from overlapping axial slices are required, it is suggested that additional scans be performed separately.

Reconstruction of the images
- Use the sharpest reconstruction algorithm available, usually described as a bone or high-resolution algorithm.
- Reconstruct the images with a 512/H11503 512 matrix.
- Only the axial images are required.
- Send the images to the surgeon.
- Data or media other than CD will prolong the quoting process, due to added conversion time.
Synthes designs the implant and prepares a quote.

Review and approval of the design can be done in one of two ways:
1. A skull model and an implant model are shipped.
2. Computer images of the defect, the implant and the implant fitted into the defect are sent electronically.

The quote and the computer images will be sent out to the surgeon.

**Note:** If the CT data cannot be reconstructed into a 3-D format, Synthes will request a modified scan. If the defect is not clearly defined, Synthes will contact the surgeon to verify the margins of the defect. In both instances additional time will be needed.

Most defects have borders which are clearly defined on the CT scan, and a quotation can be prepared upon receipt of the scan and the Request for Quote form.

Partially resorbed bone within the defect area (highlighted red) will require consultation with the surgeon to define the implant configuration before the quotation process can begin.
Surgeon accepts the PSI quotation and issues a purchase order to Synthes by signing the form **Order for Custom Made Device.**

Prompt approval of the design is required for the implant to be manufactured in a timely fashion. If changes are required at this stage, the model will be modified, reviewed and approved by the surgeon again. This will delay the start of implant manufacture.

---

When the form **Order for Custom Made Device** is received, Synthes starts manufacturing the implant. One non-sterile implant will be shipped to the surgeon.