PSI—Patient Specific Implants.
Derived from CT data for excellent reconstructive results.

Better anatomic fit
Reduced operating time
Satisfying aesthetic results
PSI—Patient Specific Implants

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

Features
– Better anatomic fit versus conventional fixation/reconstruction methods
– Reduced operating time compared to traditional reconstruction methods that require extensive contouring
– Satisfying aesthetic results for surgeon and patient
– Suitable materials for definitive treatment
– Impact- and fracture-resistant for optimal protection of underlying structures
– Autoclavable—withstanding repeated sterilization

Synthes Patient Specific Implants are derived from 1 mm slice DICOM uncompressed CT data, which is obtained from the hospital radiology department.
Medical imaging software is used to visualize the CT data, and to create an anatomically correct skull model and an implant model.

Surgeons have a choice of two biocompatible materials:
- PEEK Optima-LT (polyetheretherketone) or
- Commercially pure (CP) titanium
Synthes will fabricate one nonsterile implant for shipment to the surgeon, after receipt of purchase order and design approval.

Synthes plates and screws are used to attach the Patient Specific Implant to the native bone.
Synthes Patient Specific Implants can be designed to fit voids in the cranial and craniofacial skeleton.

Depending on the size (length, width, and height) of the implant required, Synthes may design a single or multi-piece implant. Multi-piece implants allow the surgeon greater flexibility when treating larger defects.

Multi-piece implants may be joined together using Synthes standard cranial and craniofacial fixation systems.

<table>
<thead>
<tr>
<th>Cranial Applications</th>
<th>Craniofacial Applications</th>
<th>Onlay Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-piece</td>
<td>1-piece</td>
<td>2-piece onlay</td>
</tr>
<tr>
<td>2-piece</td>
<td>3-piece</td>
<td>2-piece onlay</td>
</tr>
<tr>
<td>3-piece</td>
<td></td>
<td>1-piece onlay</td>
</tr>
<tr>
<td>2-piece</td>
<td></td>
<td>1-piece onlay</td>
</tr>
</tbody>
</table>
Choice of Material

PEEK Optima-LT (Polyetheretherketone)

– Engineered for strength, stability and biocompatibility
– Radiolucent (minimal MRI artifact)
– Bone-like strength
– Surgeon can determine plate and screw placement during surgery
– Lightweight
– Autoclavable—withstands repeated sterilization
– Can be used with Synthes cranial and craniofacial fixation systems
– Implant is 3.0 mm thick (nominal)
– If modifications of a PEEK implant are required (e.g. drainage, monitoring devices), they can be performed in the OR with standard instruments

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:
PEEK patient specific implants require minimal (if any) modification. For minor fit modifications, it is suggested that the surgeon modify the patient bone rather than modifying the PEEK patient specific implant. PEEK patient specific implants can be modified with a high speed burr, if needed. 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 (commercially pure, implant grade)

- Ultra-high strength
- Radiopaque
- Excellent biocompatibility
- Autoclavable—withstands repeated sterilization
- Requires the use of Synthes Low Profile Neuro or MatrixNEURO plate and screw fixation systems
- Requires the use of Titanium Low Profile Neuro Machine Screws (488.066) for attachment of the plates to the implant (see Figure 1)
- Titanium implant is 2.5 mm thick (nominal)

Titanium Mechanical Properties

<table>
<thead>
<tr>
<th></th>
<th>Cortical Bone</th>
<th>Titanium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modulus of Elasticity</td>
<td>8–24</td>
<td>103</td>
</tr>
<tr>
<td>(stiffness) (GPa)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yield Strength (MPa)</td>
<td>115</td>
<td>230 (minimum)</td>
</tr>
</tbody>
</table>

Notes regarding the use of Titanium Patient Specific Implants:

Titanium patient specific implants cannot be modified. If there are any minor fit modifications required, the surgeon must modify the patient’s bone.

Titanium patient specific implants require the use of Synthes Low Profile Neuro or MatrixNEURO fixation systems (plates and screws).

The surgeon must preselect the location of Synthes plates and machine screw holes during the implant design review process.

The implant will be provided with threaded screw holes. The Titanium Low Profile Neuro Machine Screws (488.066) are required for attachment of the Low Profile Neuro or MatrixNEURO plates to the titanium implant.
Ordering Process

1
Surgeon sends patient to radiology to be scanned according to Synthes CT Scanning Protocol.

Synthes CT Scanning Protocol can be obtained from a Synthes Sales Consultant or at http://products.synthes.com.

2
The completed Request for Quote (RFQ) form and the CT scan (according to the CT Scanning Protocol) are both sent together to:
Synthes CMF
Attn: Patient Specific Implant Department
1301 Goshen Parkway
West Chester, PA 19380

CT scan and RFQ can be sent overnight via Synthes PSI prepaid mailers.

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 be sent either by mail (express) or fax.
3

Synthes designs the implant and provides a quote to the customer.

The computer images and/or skull model will be sent to the surgeon for review and approval.

**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 RFQ form.

Partially resorbed bone within the defect area (highlighted red), removal of existing implants, unclear defects and resections are some situations which will require consultation with the surgeon to define the implant configuration before the quotation process can begin.
4
Review and approval of the design can be done in one of two ways:
1. A skull model and an implant model are shipped to the surgeon, or
2. Computer images of the defect, the implant and the implant fitted into the defect are sent electronically to the surgeon.

5
Surgeon approves the design.

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.

6
When the purchase order and design approval are received, Synthes starts manufacturing the implant. After manufacturing, one nonsterile implant will be shipped overnight to the surgeon.
Ordering Process Overview

**Start**

1. **Receipt of RFQ, CT Scan* by PSI Department**

   - **Verification of the request**
     - **Yes**
       - **Initial design of the implant**
       - **Quote and implant design to the customer**
     - **No**
       - **Feedback to the customer**

   - **No**
     - **Yes**
       - **+ 2 days**
       - **Re-design of the implant**

2. **Design approved**

   - **Yes**
     - **Receipt of purchase order**
       - **Yes**
         - **Finalize the design for manufacturing**
       - **No**
         - **No order will be placed**

   - **No**
     - **+ 2 days**
     - **Re-design of the implant**

3. **4 Business Days**

   - **Finalize the design for manufacturing**
   - **Manufacturing**
   - **Overnight shipment to customer**

*Following Synthes CT Scanning Protocol*