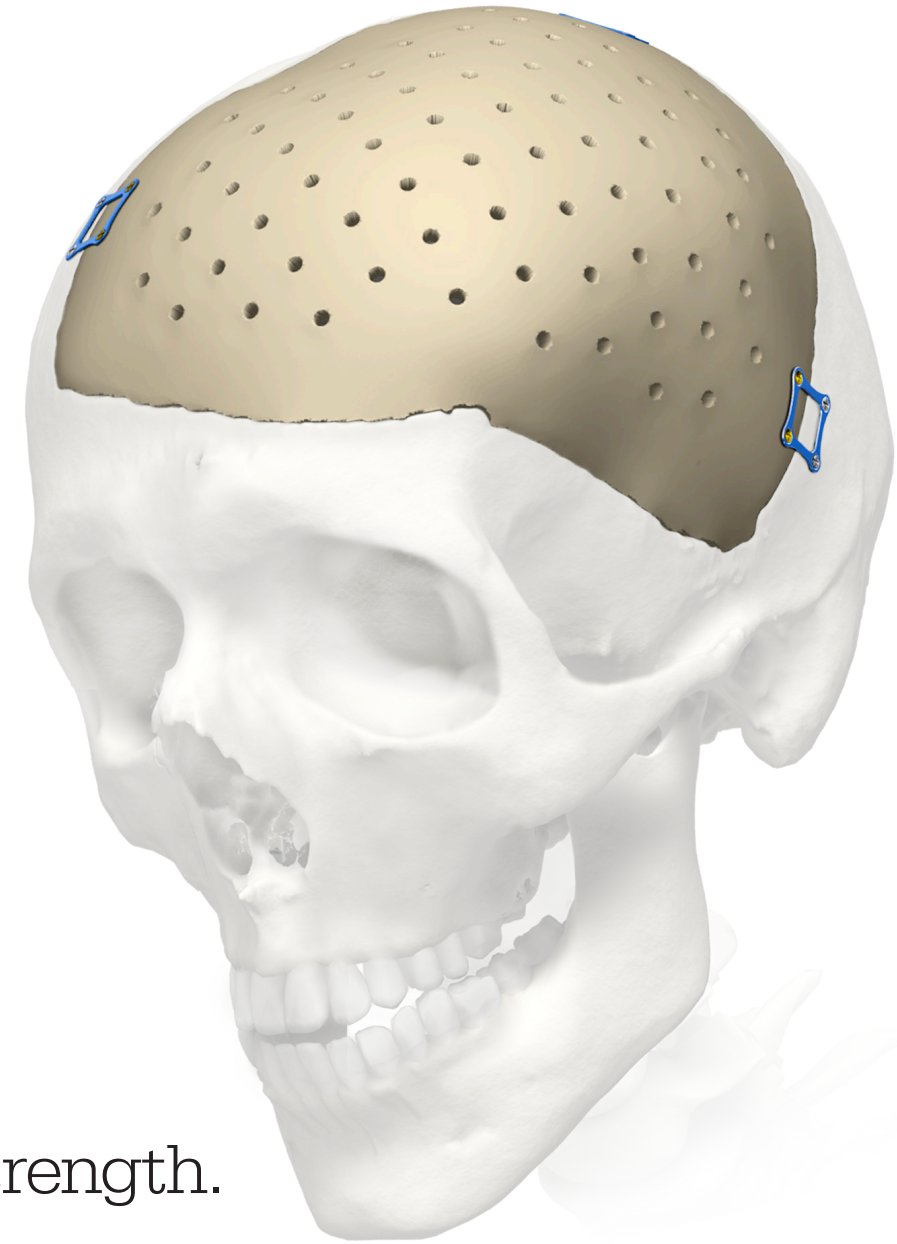
stryker

Cranial iD®

PEEK customized implant



Precise fit.
Excellent strength.

PEEK customized implant

PEEK customized implants by Stryker are designed with exacting parameters to optimize the bone-to-implant interface. Multiple fit options are available to accommodate the needs of both you and your patient. The "best in class" support and expertise of your local Stryker representative combined with the strength and fit of your implant allow you to close and reconstruct with confidence.

We have two distinct offerings based on either your need for **priority** delivery or a more **complex** surgical plan. Our comprehensive, market-leading portfolio of customized products and services allow you to tailor your surgical cases to the unique needs of your patients.

PEEK features and benefits

Precise fit
Designed and manufactured to produce a "drop-in fit"

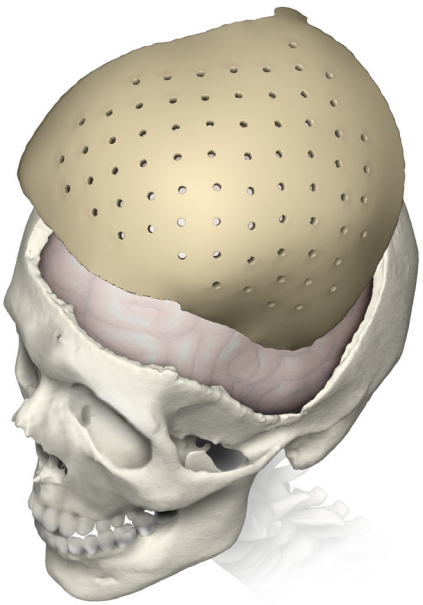
Suture/drainage hole options
Customizable suture/drainage hole design with option for 1-6 pairs or full pattern suture hole implant; hole diameter available in either 2 or 3mm

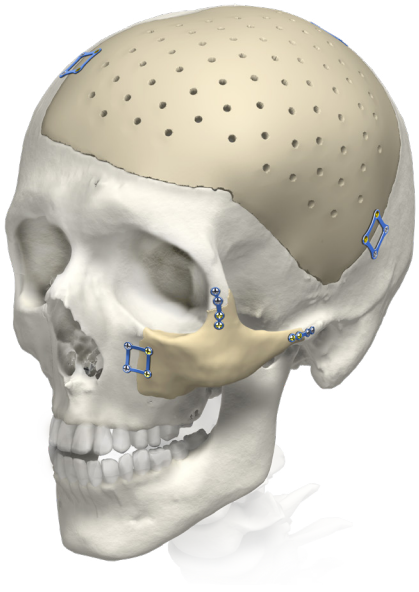
Thickness options
Implant wall thickness provided in either 3.3, 4, 5, or 6mm to cater to patient-specific needs; tapered toward thin bone option also available

Strength
Cranial bone: 100 MPa Yield Strength[1]
PEEK implant: 115 MPa Yield Strength[2]

Sterilization
PEEK implants are delivered non-sterile and **must** be sterilized before implantation. See IFU for sterilization requirements and re-sterilize the implant if it should ever become contaminated

Modification
If needed, the PEEK implant may be modified by burring





PEEK Priority

Priority timeline
Implants are intended to be designed, manufactured and shipped to your facility within **5 standard business days**

PEEK Complex

Standard timeline
Implants are intended to be designed, manufactured and delivered to your facility within **12 standard business days**

Host bone model
Provided in every Complex implant kit, the host bone model acts as a preoperative guide to demonstrate orientation and fit of the PEEK Complex implant

Single stage with guides
The PEEK single stage kit comes with one non-sterile implant and one non-sterile host bone. Single stage is compatible with 3D Systems guides, along with navigation

PEEK Single stage

PEEK Single stage allows the surgeon to address their patients' needs in one surgery

3D Systems' VSP® solutions

3D Systems offers surgical marking guides in cap or ring style, along with anatomical models

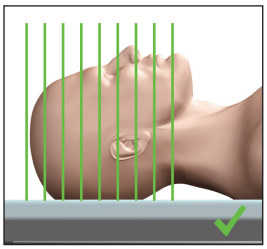
Navigation

Navigation can be integrated to transfer the planned resection outline to the patient's bony anatomy

CMF customized implants (CI)

CT scan protocol

Phone: 855 479 5224
Email: CMFcustomizedimplants@stryker.com

Patient positioning		
Head alignment	Remain straight in neutral position.	 No oblique angle of locator/survey lines.
Gantry tilt	0° gantry tilt.	No gantry tilt (CT).

Scan length/Field of view (FOV)	
Scan length	For **cranial** defects, encompass the **entire skull**, including at least 2 slices superior to the skull.
FOV	For **mandibular** defects, encompass the entire mandible. Select FOV to include all surrounding anatomy.

Scanning process	
Patient movement	Avoid patient motion. If the scan shows motion artifacts, the scan cannot be used.

Acquisition	
Slice thickness	Maximum = 1.5 mm (1 mm preferred)
Beam collimation	Width and detector configuration necessary to achieve actual slice thickness.
Table increment	Constant table increment, no gaps. Smaller than or equal to slice thickness.
Sequential scanners	No overlap and no gap.
Single-slice helical scanners	Beam pitch = 1
Multi-slice helical scanners	Beam pitch < 1 (GE: High Quality; Toshiba: Detail)
Slice orientation	Axial slice orientation.
Algorithm (Kernel)	Bone algorithm.
	Warning: DO NOT post process to alter slice orientation or thickness.

Data		
Series ID	All images of a scan should be stored in one series.	
File format	DICOM format. Cone beam (CBCT) scans accepted Contrast not required.	**No** raw data. **Do not compress.** Inclusion of CT Viewer not recommended.
No raw data	Archive **only the relevant examination** in uncompressed DICOM (CD-R preferred).	
Data storage	**Recommendation: Save raw data for at least 14 days after scan.**	

Guidance for pediatric scanning

Exposure to ionizing radiation is of particular concern in pediatric patients. Check if existing scans meets the requirements for Stryker implant design. To avoid rescanning of patients, follow the parameters given in the Stryker Scan Protocol and use reduced dose and child - sized protocols where appropriate. Stryker recommends consulting the instructions for use provided by your imaging device manufacturer, and limiting radiation dosage to the amount clinically necessary. Statutory national Diagnostic Reference Levels (DRLs) for pediatric as well as for adult CT examinations must be complied with. Limit the dose by reducing Tube Voltage (kV) and the Tube-Current-Time product (mAs), consider patient size and activate Tube Current Modulation and/or Automatic Exposure Control if applicable and indicated for pediatric patients.

Craniomaxillofacial

References
1. J Motherway, P Verschueren, G Perre, J Sloten, M Gilchrist. "The Mechanical Properties of Cranial Bone: The Effect of Loading Rate and Cranial Sampling Position".
2. InVibio Limited. PEEK-Optima Polymer Typical Material Properties Brochure.
3. Liu JK, Gotfried ON, Cole CD, Dougherty,WR, CouldwellWT, "MEDPOR Porous Polyethylene implant for Cranioplasty and Skull Base Reconstruction"Neurosurgery. April 2004.

Stryker Craniomaxillofacial
Kalamazoo, MI 49002 USA
t: 269 389 5346,
f: 877 648 7114
toll free: 800 962 6558

stryker.com/cmf

CCI-BR-7_Rev.None_29598

Printed in USA