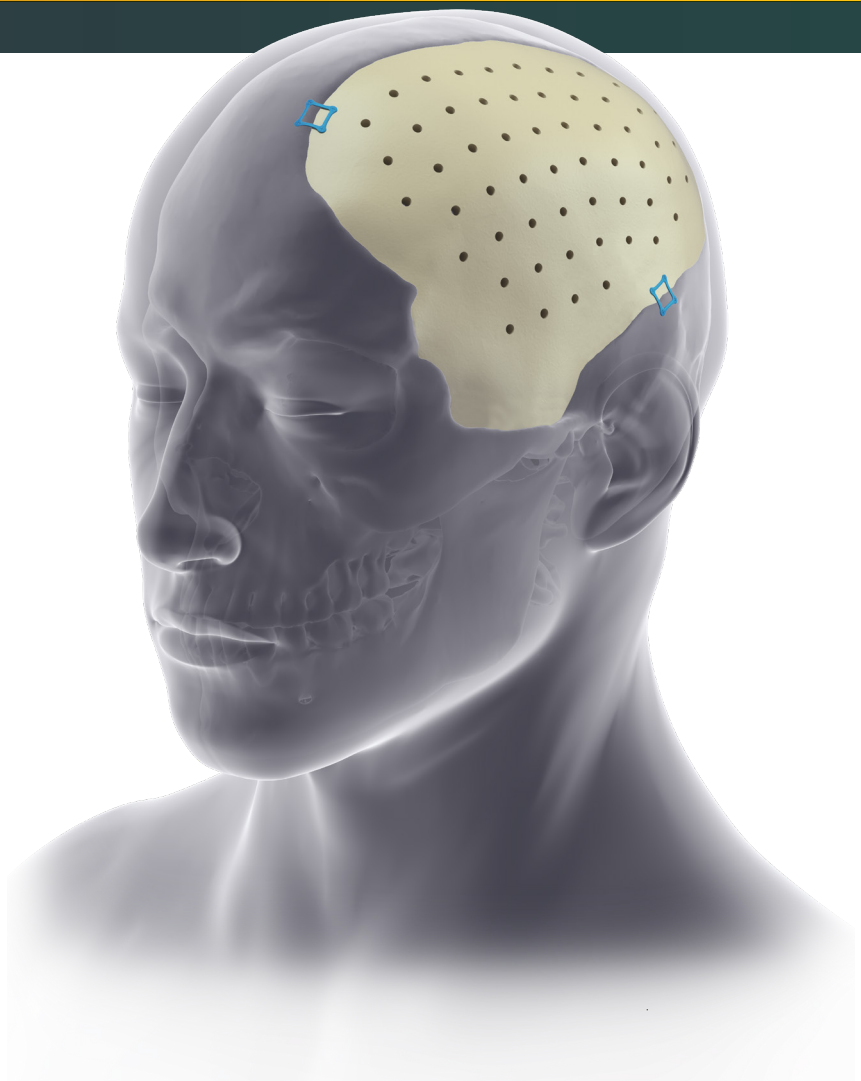
stryker

Cranial iD

Cranial restoration



iD Solutions

Individually designed. Personalised care.

iD Solutions

Individually designed cranial implants for the restoration of cranial defects.

Our iD Solutions, Cranial iD implants allow you to address your patient's desire for complete restoration and aesthetic results. Available in MEDPOR and PEEK, each implant is uniquely designed to fit the bony void and individual anthropometry of your patient. You drive the artistry of each implant through a design session with one of our Design Engineers. The end result is designed for an exceptional fit and contour. Further your ability to address patient needs now and in the future with our Pterional PLUS implant, which is available in PEEK and MEDPOR. Our patient specific implant allows you the opportunity to prevent and correct persistent temporal hollowing (PTH) in your patients. Pterional PLUS can help patients regain confidence helping them to look and feel like themselves again.

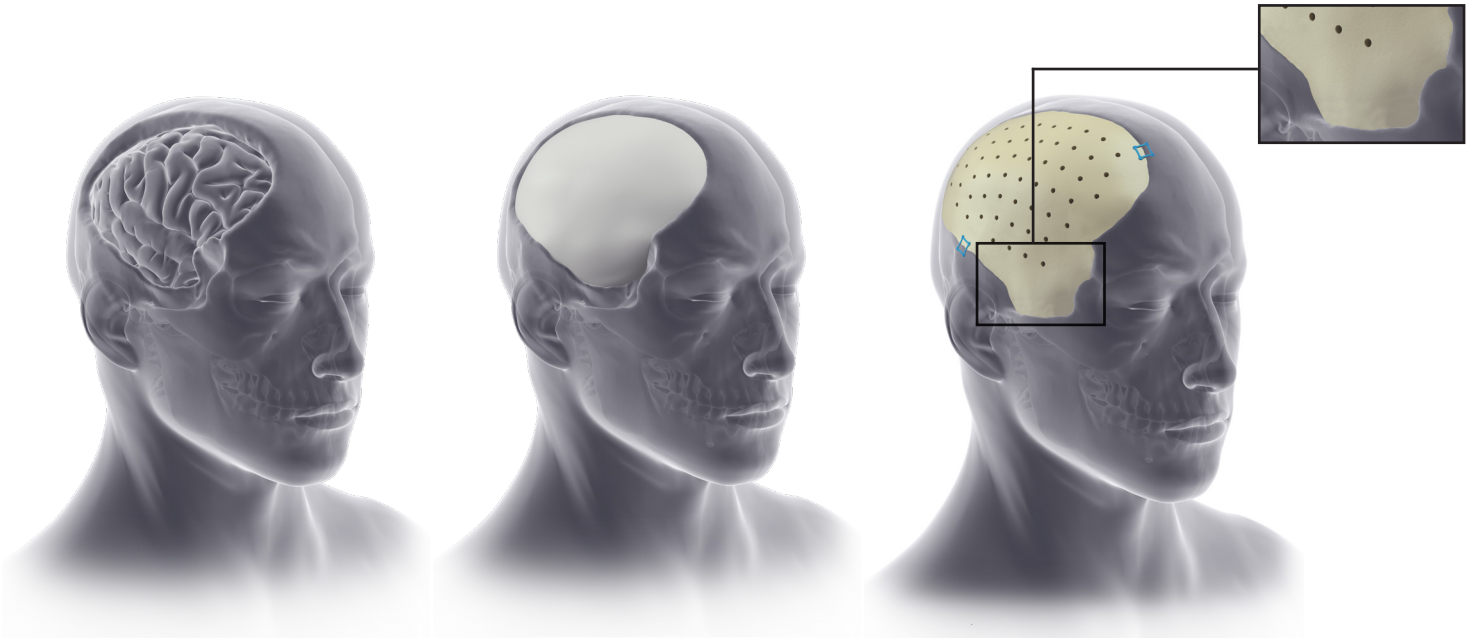
Pterional PLUS

Individually designed. **Personalised** care.

Pterional PLUS is our exclusive patient specific implant intended for the correction and prevention of persistent temporal hollowing (PTH). This patient specific cranial implant is designed using the patient's own CT-data and anatomy, incorporating your surgical expertise, in order to estimate a patient's soft tissue atrophy and create an implant that accommodates for the atrophy. MEDPOR Pterional PLUS is delivered with two sterile implants and a sterile host-bone model.

Pterional PLUS was born out of our passion and commitment to working with our customers. Pterional PLUS is designed to serve as both a safe and effective solution for temporal hollowing, along with restoring the patient's original appearance.

*Pterional PLUS available in both PEEK and MEDPOR material.



PEEK

Precise fit. Excellent **strength**.

PEEK patient specific implants are designed with exacting parameters to optimise the bone-to-implant interface. Multiple fit options are available to accommodate the needs of both you and your patient.

PEEK implants have a longstanding history with an excellent safety profile fully supported by documented clinical evidence[1, 2, 3]. The support of our sales representative combined with the strength and fit of our 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 portfolio of patient specific 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 surgical fit and definition.

Suture/drainage hole options
Customisable 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[4]
PEEK implant: 115 MPa Yield Strength[5]

Sterilisation
PEEK implants are delivered non-sterile and must be sterilised before implantation. See IFU for sterilisation requirements and re-sterilise the implant if it should ever become contaminated.

Modification
If needed, the PEEK implant may be modified by burring with a burr speed of 8,000 rpms or lower.

PEEK single stage features and benefits

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.

PEEK Priority features, benefits and requirements

Priority turnaround
Implants are intended to arrive to your facility within 5 business days, in general. Excludes out-of-spec CT scans.

Same day approval
In order to achieve a Priority timeline for all PEEK Priority implants, design approval is required within the same day a design proposal is delivered. Proposal review and approval may be executed via email, scanned documentation or the online application.

Single piece cranial implant
In order to achieve the Priority timeline, only single-piece implant cases will qualify.

Note: Removal of bone fragments, calcifications or small implants may qualify as Priority.

Ordering information

Reference number	PEEK implant description	Delivery time (standard business days)	Host	Request for redesign allowed
78-50010	PEEK - Priority - S	5 days	no	no
78-50020	PEEK - Priority - M			
78-50030	PEEK - Priority - L			
78-50040	PEEK - Priority - XL			
78-10010	PEEK - Complex - S	Minimum 12 days	yes	yes
78-10020	PEEK - Complex - M			
78-10030	PEEK - Complex - L			
78-10040	PEEK - Complex - XL			
78-10100	PEEK craniofacial implant kit			

▯ PEEK Priority ▯ PEEK Complex

To order, contact your Stryker representative or visit **stryker.com**

MEDPOR

Proven.[6] Adaptable. Comprehensive.

MEDPOR porous polyethylene implants provide surgeons with an expanding range of options for reconstruction and augmentation. MEDPOR is a biocompatible, high density, porous polyethylene material. The interconnecting, omni-directional pore structure may allow for fibrovascular in-growth and integration of the patient's tissue.[6]

More than 400,000 procedures have been performed with MEDPOR biomaterial, with more than 350 published clinical reports in cranial, reconstructive, oculoplastic and cosmetic applications.

- MEDPOR implants are easy to bring into final fit according to the patient-specific needs within the OR.
- No pre-placing of fixation plates. MEDPOR can be easily drilled and fixated and is designed to accept screws and plates without cracking, giving the surgeon more flexibility in fixation options and placement.
- MEDPOR surgical implants can be cut with a variety of surgical instruments. Implants may require fitting to the defect area at the time of surgery. The implant edges can be delicately shaped and feathered for a smooth transitionfrom the implant to the patient's own bony contour.
- MEDPOR's two surgical implants are provided sterile and must not be resterilised.
- Do not place or carve the implant on surgical drapes, surgical clothing or any other surface that may contaminate the implant with lint and other particulate matter.

MEDPOR

Proven.[6] Adaptable. Comprehensive.

MEDPOR single stage

MEDPOR single stage allows the surgeon to address their patients' needs in one surgery. Through pre-surgical planning a predictive craniotomy is made, leading to the design of a patient specific implant delivered to the hospital prior to surgery.

Surgeon collaboration will be required at design phase to best identify the important inputs needed for design which include the following:

- Define resection plan (tumor boundary, etc.)
- Define maximum reconstruction/implant coverage area
- Anatomical landmarks and CT reference points

The MEDPOR single stage kit comes with 2 sterile MEDPOR implants, 1 sterile host bone and the design proposal with imbedded 3D PDF viewer. The 3D implant design file (STL format) is available upon request by the surgeon. The aim of the solution is to deliver efficient and effective patient outcomes and to drive efficiency in the OR.

Ordering information

Reference number	MEDPOR implant description	Delivery time (business days)	Host bone model	Request for redesign allowed	Note
5444-0-110	MEDPOR CUSTOM.CRANIAL IMPLANT KIT, S	17 days	yes	yes	Same part numbers for Single Stage
5444-0-210	MEDPOR CUSTOM.CRANIAL IMPLANT KIT, M	17 days	yes	yes	Same part numbers for Single Stage
5444-0-310	MEDPOR CUSTOM.CRANIAL IMPLANT KIT, L	17 days	yes	yes	Same part numbers for Single Stage
5444-0-410	MEDPOR CUSTOM.CRANIAL IMPLANT KIT, XL	17 days	yes	yes	Same part numbers for Single Stage
5444-1-110	MEDPOR CUSTOM.CRANIAL IMPL. KIT-PLUS, S	17 days	yes	yes	Same part numbers for Single Stage
5444-1-210	MEDPOR CUSTOM.CRANIAL IMPL. KIT-PLUS, M	17 days	yes	yes	Same part numbers for Single Stage
5444-1-310	MEDPOR CUSTOM.CRANIAL IMPL. KIT-PLUS, L	17 days	yes	yes	Same part numbers for Single Stage
5444-1-410	MEDPOR CUSTOM.CRANIAL IMPL. KIT-PLUS, XL	17 days	yes	yes	Same part numbers for Single Stage

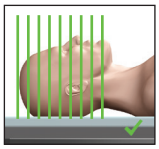
CMF patient specific implants (CI)

CT scan protocol

Email: CMFcustomizedimplants@stryker.com

Protocol for medical CT scanners

Patient positioning	
Head alignment	Remain straight in neutral position.
Gantry tilt	0° gantry tilt.
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. **No** raw data. **No** cone beam scans. **Do not compress.** Contrast not required. 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.**



No oblique angle of locator/survey lines.

No gantry tilt (CT).

Craniomaxillofacial

This document is intended solely for the use of healthcare professionals.

A healthcare professional must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that healthcare professionals be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A healthcare professional must always refer to the package insert, product label and/or instructions for use before using any Stryker product.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The products depicted are CE marked in accordance with applicable EU Regulations and Directives.

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References
1. P. D. Nguyen, D. Y. Khechoyan, J. H. Phillips, C. R. Forrest, “Custom CAD/CAM implants for complex craniofacial reconstruction in children: Our experience based on 136 cases”, Journal of Plastic, Reconstructive & Aesthetic Surgery, July 2018
2. B. Lethaus, M. Bloebaum, B. Essers, M. P Laak, T Steiner, P. Kessler, “Patient-Specific Implants Compared With Stored Bone Grafts for Patients With Interval Cranioplasty”, Journal of Craniofacial Surgery, January 2014
3. G. Gerbino, E. Zavattero, F. Zenga, F. A. Bianchi, P. Garzino-Demo, S. Berrone, “Primary and secondary reconstruction of complex craniofacial defects using polyetheretherketone custom-made implants”, October 2015
4. 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".
5. InVibio Limited. PEEK-Optima Polymer Typical Material Properties Brochure.
6. Liu JK, Gotfried ON, Cole CD, Dougherty,WR, CouldwellWT, “MEDPOR Porous Polyethylene implant for Cranioplasty and Skull Base Reconstruction”Neurosurgery. April 2004.