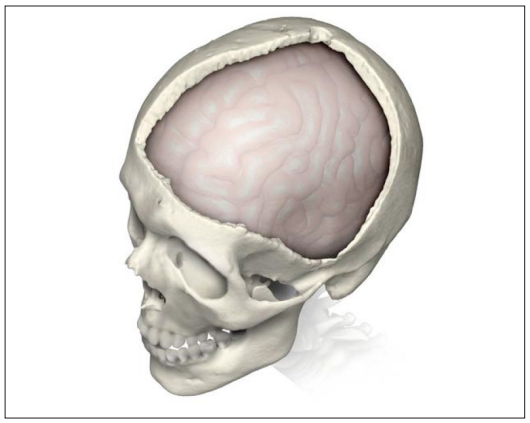
stryker

Cranial iD™ PEEK

Surgical protocol



Step 1: Incision and exposure

- Obtain proper exposure of the region where the defect void exists
- Clear soft tissue from the defect/void area.
- Do not expose the sinuses during surgical site exposure
- Do not puncture the dura during surgical site exposure

The PEEK Customized Cranial Implant kit is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in the cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone); including but not limited to, the correction and prevention of persistent temporal hollowing (PTH) in patients 3.5 years of age and older.*

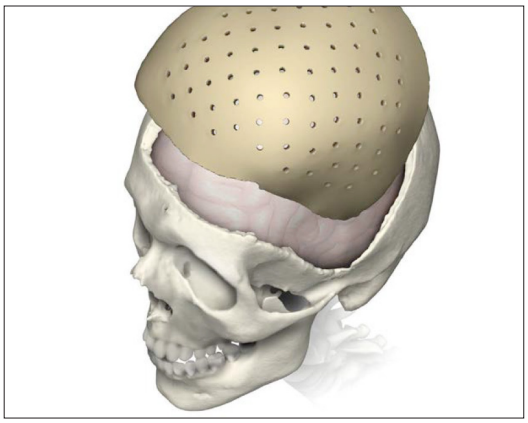
The PEEK Customized Cranial Implant is a customized patient-specific implant based on CT-data and input by the surgeon. The implant is fabricated from polyetheretherketone (PEEK) and is delivered non-sterile. The PEEK Customized Cranial Implant is intended for use in the cranial region.

The PEEK Customized Craniofacial Implant is a customized patient-specific implant based on CT-data and input by the surgeon. The implant is fabricated from polyetheretherketone (PEEK) and is delivered non-sterile. The PEEK Customized Craniofacial Implant is intended for use in the craniofacial region (orbital rim, zygoma, and adjacent bone).

Each PEEK Customized Implant kit consists of one (1) PEEK Customized Cranial Implant or one (1) PEEK Customized Craniofacial Implant, one (1) host bone model (optional), and one (1) design proposal.

The host bone model is provided as a pre-operative guide to demonstrate orientation and fit of the customized implant. The host bone model is delivered non-sterile. For complete cleaning and sterilization instructions for the implant please see the instructions for use (IFU 90-02022).

* Applies to the US market only. Outside the US, PEEK is indicated for patients 12 years of age and older.



Step 2: Placement of implant

Placement of implant

- **Note:** PEEK Customized Implants are delivered non-sterile and clean. You must sterilize the implant before clinical use
- Post-sterilization, place the implant into the defect and ensure proper fit
- Ensure the implant fits freely in the defect/void. **Do not** force the implant into the defect/void
- You may modify the implant by burring. This method has been validated with Stryker Elite Zyphr 2.0 mm, Stryker Elite Zyphr 7.0 mm and Stryker Micro Drill Burr 2.4 mm

Cautions for burring

- Ensure that you burr away from the surgical site.Rinse all burring residue from the implant with sterile saline to ensure surgical site is clean
- **Do not** exceed the maximum burring speed in accordance with the device IFU for burring and nor the 8,000 rpm
- If speed or pressure is too high, melting may occur during modification. Ensure that you monitor hand force, burr wear, and burr speed during burring
- **Do not** remove more implant material than necessary
- **Do not** modify implant thickness at points of fixation. Modification at points of fixation may weaken the implant. Removing too much implant material during modification may result in fracture, cracking, and possible implant failure
- **Do not** modify implants to less than 3mm in thickness
- When removing material along the implant perimeter, ensure at least three points of fixation are distributed evenly across the implant surface as anatomy permits. Modification to less than 3 mm in thickness may weaken the implant and penetration of fixation screws

Warnings for burring

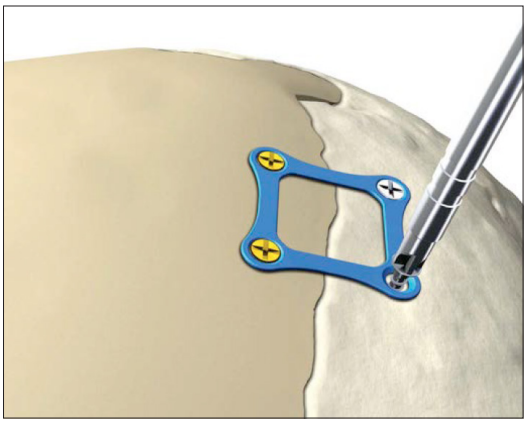
- Ensure there are no jagged edges after implant modification
- Ensure to irrigate while burring. Not irrigating may lead to high temperatures while burring

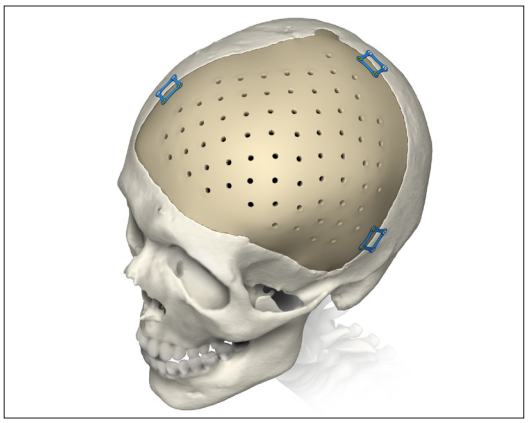
Drainage/dura suture hole recommendations:

- Suspend dura (optional)
- Evaluate if it is necessary to order the implant with dura suture holes. You can order the PEEK Customized Cranial Implant with one to six pairs or a full pattern of dura suture holes

Caution

Do not drill suture holes intraoperatively. Failure to comply may cause the implant to crack and break or may result in short or long term implant failure. Information stated in PEEK CCI IFU.





Step 3: Fixating the implant

Warnings for fixating

- Ensure the tip of the screw does not protrude past the underside of the implant. Protrusion may irritate and/or damage the patient's soft tissue

Cautions for fixating

- Ensure adequate fixation of the implant with at least three devices
- **Do not** use self-drilling screws to fixate the implant.
- Before drilling, ensure that the drill bit is turning clockwise
- Always pre-drill screw holes in the implant away from the surgical site to keep the surgical site clean
- Ensure that you rinse drilling residues from the implant with sterile saline to ensure surgical site is clean. Ensure that you drill a minimum of 4 mm from the edge of the implant

Cautions for drilling

- Maximum drilling speed must be in accordance with Instructions for Use of the drill bit but not more than 8,000 rpm. High drilling speeds may cause the implant to melt
- Ensure that you drill a minimum of 4 mm from the edge of the implant
- Ensure that you irrigate while drilling. Not irrigating may lead to high temperatures while drilling
- If drill speeds are too high or drill bit is rotating counterclockwise, this may cause implant to melt and/or deform, causing cracks. It may also cause screw hole to become too large

Compatible Stryker products

PEEK Customized Cranial/Craniofacial Implants are compatible with the standard Universal Neuro, Universal Midface, and Universal Upperface portfolio of products from Stryker, including plates, screws and drills. Stryker strongly advises against the use of another manufacturer's plates, mesh or screws with the PEEK Customized Cranial/ Craniofacial Implant.

Step 4: Closure

- Close the incision used for the surgical approach in standard fashion

Sterilization warnings

- PEEK Customized Cranial/Craniofacial Implants are supplied non-sterile. Ensure that you sterilize the implant prior to entering the operating room
- Ensure that you comply with the manufacturer's user instructions for sterilizers
- **Do not** sterilize the host bone model. Ensure that the non-sterile host bone model does not come into contact with any sterile products
- All sterilization processes are validated with the sterilizer Systec HX-320 Autoclave
- For initial sterilization and re-sterilization, the parameters have been validated using the methods below:

Parameter limitation for certain markets	Global parameters	Approved parameters outside US	US market only
Cycle type	Prevacuum (3-times prevac)	Prevacuum (3-times prevac)	Immediate use (flash gravity sterilization)
Sterilizer type	Vacuum assisted sterilizer	Vacuum assisted sterilizer	Gravity displacement sterilizer
Wrapping	Double wrapped	Double wrapped	Unwrapped
Sterilization temperature	270° F (132° C)	274° F (134° C)	270° F (132° C)
Minimum exposure time for sterilization	4 minutes	3 minutes	10 minutes
Minimum drying time	15 minutes	15 minutes	N/A

Craniomaxillofacial

This document is intended solely for the use of healthcare professionals. A surgeon 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 surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), 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.

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