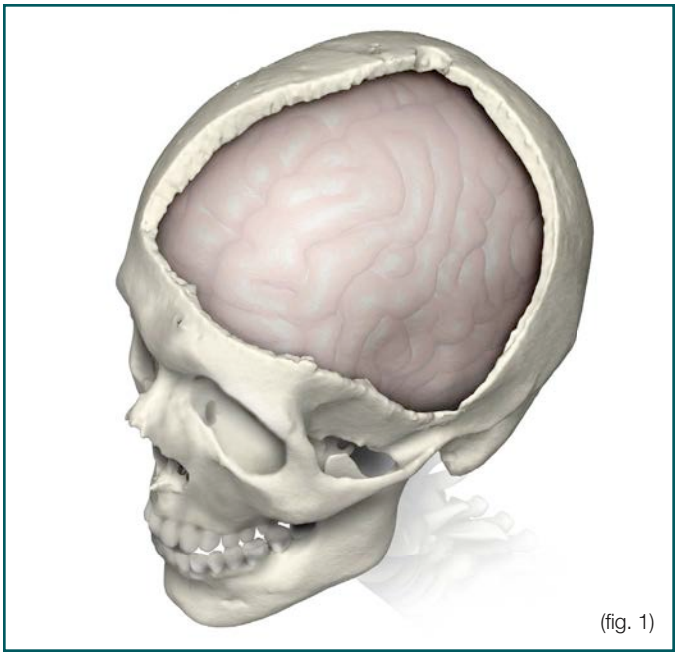
stryker®

Craniomaxillofacial

Stryker CMF
Customized Implant
PEEK

Surgical Protocol



(fig. 1)

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 filling bony voids in the cranial and craniofacial skeleton in patients 12 years of age and older.

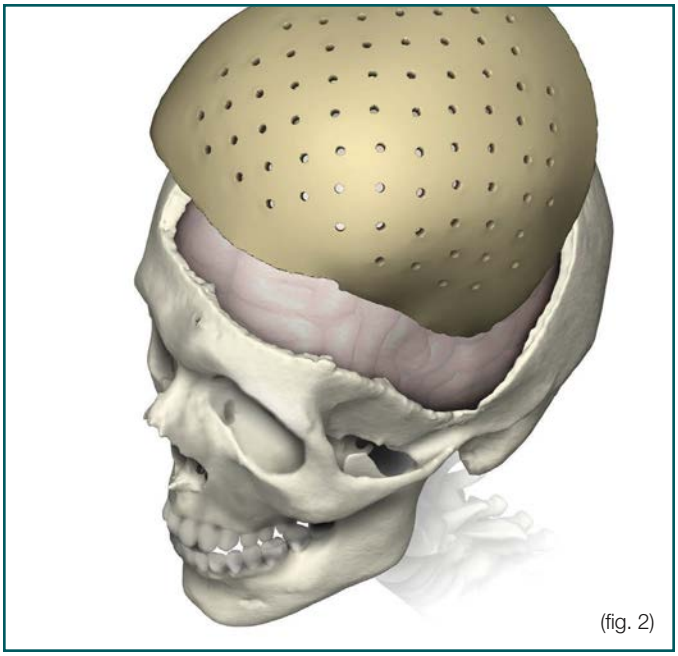
Each PEEK Customized Implant Kit consists of one (1) PEEK Customized Cranial Implant or one (1) PEEK Customized Craniofacial Implant, one (1) Host Bone Model, and one (1) Design Proposal.

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 intended to be used to fill bony voids in the cranial skeleton. It is delivered non-sterile.

The PEEK Customized Craniofacial Implant is a customized patient-specific implant based on CT-data. The implant is fabricated from polyetheretherketone (PEEK) and is intended to be used to fill bony voids in the craniofacial region (orbital rim, zygoma, and adjacent bone). The implant matches the shape and dimensions of the missing bone fragments. It is delivered non-sterile.

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).



(fig. 2)

Step 2

Placement of Implant:

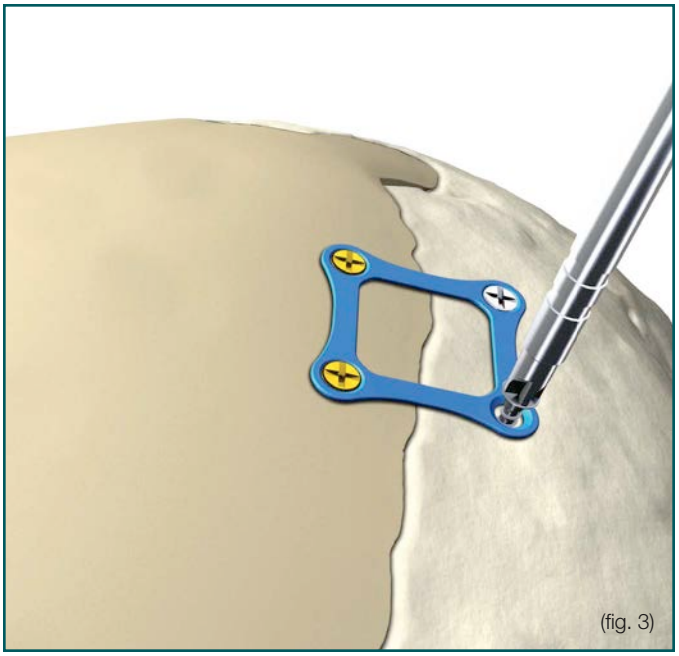
- NOTE: PEEK Customized Cranial/Craniofacial Implants are delivered non-sterile and clean. You must sterilize the implant before clinical use.
- Post-sterilization, place the implant into the defect and ensure proper fit.
- Ensure the implant fits freely in the defect/void. DO NOT force the implant into 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.

Burring Recommendations:

- 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.
- Maximum burring speed in accordance with the IFU of the burr but not more than 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.
- Do not modify implants to less than 3mm in thickness.
- When removing material along implant perimeter, the length of the trimmed rim portion must not exceed 20% of the implant's perimeter. The distance between bone defect surface and the trimmed implant rim must not be larger than 10mm.
- Ensure there are no jagged edges after implant modification.

Drainage/Dura Suture Hole Recommendations:

- 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.



(fig. 3)

Step 3

Fixating the Implant:

- Ensure adequate fixation of the implant with at least three points of fixation.
- 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.
- 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.

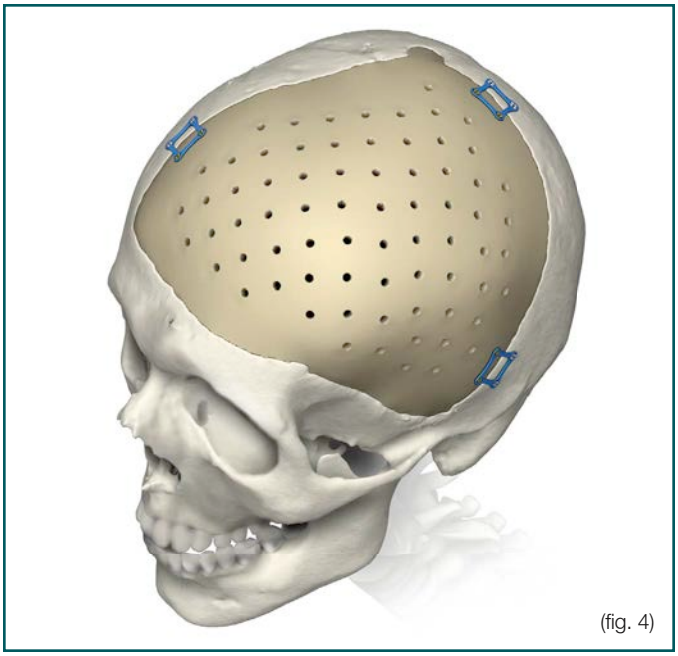
Drilling Recommendations:

- Drill speed = Maximum burring speed in accordance with the IFU of the burr but not more than 8,000 rpm.
- Drill distance from implant edge = 4mm minimum
- Irrigation is recommended during drilling

WARNINGS:
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.



(fig. 4)

Step 4

Closure:

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

Sterilization Recommendations:

- 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.
- For initial sterilization and re-sterilization, the parameters have been validated using the methods below:

Parameter Limitation for Certain Markets	No Market Limitation	Not for the US Market	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

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Literature Number: 9410-400-354 Rev. A
DDM/PS 1k 1/13

Printed in USA

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