Stryker CMF
Customized Implant
PMMA

Surgical Protocol
Step 1
Incision and Exposure:
• Obtain proper exposure of the region where the defect/void exists.
• Be sure to clear soft tissue from the defect/void area.

WARNINGS:
Do not expose the sinuses during surgical site exposure. Do not puncture the dura during surgical site exposure.

Step 2
Placement of Implant:
• Remove implant from sterile packaging and rinse with sterile saline.
• 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.
• Care should be taken when holding the implant. Hold in the palm of the hand to prevent scratching or damaging the implant edges.
• The implant may be modified by burring when necessary. Burring MUST BE performed away from the surgical site and all burring residue should be rinsed from the implant with sterile saline to ensure surgical site is clean.

Burring Recommendations:
All standard neurosurgical burrs.
Limit burr speed as to not damage implant.
Irrigation is recommended during burring.
Implant should not be modified to less than 3 mm in thickness. Implant thickness should not be modified at points of fixation. When removing material along implant perimeter, only remove material that interferes with patient bone.

Drainage/Dura Suture Hole Recommendations:
Distance between drainage/dura suture holes = 10 mm minimum
Drill speed = 1000 rpm
Maximum drill diameter for holes = 2 mm
Drill distance from implant edge = 10 mm minimum
Irrigation is recommended during drilling.

WARNINGS:
If speed or pressure is too high melting may occur during modification. To help prevent melting of implant during burring, monitor hand force, burr wear, and burr speed.
Ensure there are no jagged edges after implant modification. Removing too much implant material during modification may result in fracture, cracking, and possible implant failure.

The Stryker CMF Customized Implant is designed individually for each patient to correct trauma and/or defects in the maxillofacial or craniofacial bone. Surgeons supply Stryker with a patient CT scan and the implant is designed to fit the exact patient needs.

The Stryker CMF Customized Implants are manufactured from Simplex® P Bone Cement, which is a commercially available medical grade polymer. This porous composite material is comprised of methyl methacrylate styrene copolymer, PMMA, and barium sulfate (a radiopacifier). PMMA has been used in Orthopaedics and cranial surgeries for decades.¹

Each Stryker CMF Customized Implant Kit contains two (2) identical sterile PMMA implants and one (1) sterile host bone model (defect area).

The Host Bone model is provided as a pre-operative guide to demonstrate orientation and fit of the customized implant. Use this in the OR to test the orientation and fit of the implant before implantation.

DO NOT RESTERILIZE.
**Step 3**

Fixating the Implant:

DO NOT USE SELF DRILLING SCREWS IN IMPLANT.

- At least three (3) points of fixation are recommended.
- Use Stryker’s self tapping Neuro 2, Midface or Upperface drills and screws with their corresponding titanium plates.
- Screw holes MUST BE pre-drilled in the implant away from the surgical site.
- All drilling residue should be rinsed from the implant with sterile saline to ensure surgical site is clean.
- Before drilling, ensure the drill bit is turning clockwise.
- Ensure the tip of the screw does not protrude past the underside of the implant. This may irritate and/or damage the patient’s soft tissue.

**Drilling Recommendations:**

Drill speed = 1000 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.

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**Step 4**

Closure:

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

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**Compatible Stryker Products:**

The Stryker CMF Customized Implant has only been tested with Stryker fixation systems. It is compatible with the standard Universal Neuro, Universal Midface, and Universal Upperface portfolio of products, including plates, screws, and drills.

**Incompatible Stryker Products:**

Products listed below are incompatible with the drilling and fixation recommendations.

- All self drilling screws
- Neuro-Clip
- 53-05507 – Burr hole plate
- 92-53028 – Rectangle plate
- 92-53215 – Dog Bone plate
- 92-53231 – Box plate
- 55-04231 – 2x2 3D plate
- 55-06231 – 2x2 3D plate
- 55-03731 – 2x2 3D plate
- 55-06731 – 2x2 3D plate

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References

1. Cabanela, Coventry, MacCarty, Miller: The Fate of Patients with Methyl Methacrylate Cranioplasty, 1972

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 the breadth of Stryker product offerings. A surgeon 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.

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