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MEDPOR®

customized implant



Operative technique

Device description

The MEDPOR customized implant is a customized patient-specific implant based on CT-data and input by the surgeon. Surgeons supply Stryker with a patient CT scan and the implant is designed to fit the exact patient needs.

Each MEDPOR customized implant Kit contains two (2) identical sterile MEDPOR implants and one (1) sterile host bone model (defect area). The host bone model is provided as a preoperative guide to demonstrate orientation and fit of the customized implant(s). Use the host bone model in the OR to test the orientation and fit of the implant(s) before implantation. Inspect the packaging of the host bone model and the implant to ensure implant sterility and integrity.

Important information

The materials contained in this operative technique have been provided for general information purposes only. The information contained in this booklet cannot and should not replace the independent medical judgment of the treating physician.

As a manufacturer, Stryker does not provide medical advice or services. It is always the responsibility of the treating physician to determine the appropriate treatment and technique, based on the physician's medical knowledge and the individual circumstances of the particular case. It is also the treating physician's sole responsibility to inform the patient about potential risks, complications and benefits of certain products and procedures.

Product material information

The MEDPOR customized implants are manufactured from 100% biocompatible high density porous polyethylene and are designed to maintain the interconnecting open pore structure of the MEDPOR biomaterial to allow for tissue ingrowth.

Compatible Stryker products

Stryker's fixation systems: Universal Neuro, Midface, and Upperface.
For specific fixation instructions, see Section 5: Fixate the implant.



Preoperative overview **for single stage cases**

Single stage MEDPOR customized implants require a pre-determined virtual reconstruction plan from the surgeon to allow for exposure and resection of patient bone and reconstruction with a customized implant within a single procedure. The customized implant provided by Stryker is designed to fit the approved patient specific virtual reconstruction plan.

- Due to the multiple dynamics and variability of patient anatomy, Stryker cannot guarantee a precision fit for this device.
- The customized implant should be modified to fit the exposed defect intraoperatively.
- In case the defect created intraoperatively is outside the boundaries of the approved virtual reconstruction plan, whether due to intentional deviation or altered patient anatomy, the implant provided may not be used to reconstruct patient anatomy.
- Ensure that an alternative reconstruction solution is available and inspected before the operation.

Reference the case-specific design proposal for detailed documentation and images regarding the approved virtual reconstruction plan used for the customized implant design.

Prior to initiating the procedure, inspect the implant packaging to ensure:

- Patient information is correct
- Integrity of the sterile packaging or implant is not compromised

Step 1: Make an incision and expose the site

- Obtain proper exposure of the region where the defect/void exists.
- Clear soft tissue from the defect/void area.
- Clear pre-existing implant(s) and/or bone fragment(s).

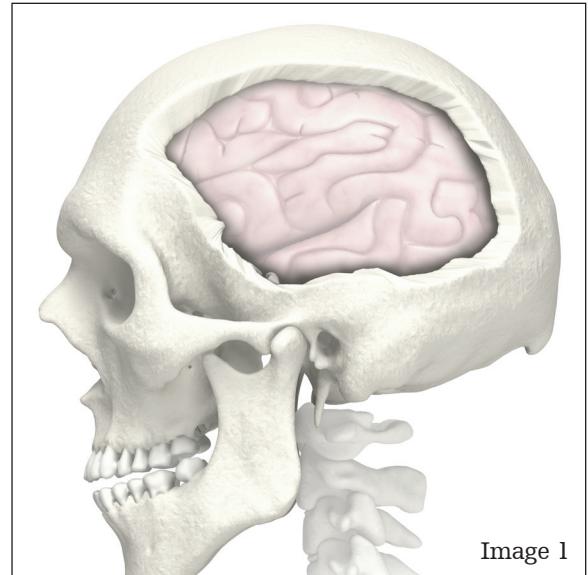


Image 1

Step 2: Create the defect (for single stage only)

- Create defect according to the surgeon's intended resection.

NOTE: Over-resection could potentially result in an ill-fitting or unusable implant.

WARNING

- Do not expose the sinuses during surgical site exposure.
- Do not puncture the dura during surgical site exposure.
- In case the defect created intraoperatively is outside the boundaries of the approved virtual reconstruction plan, whether due to intentional deviation or altered patient anatomy, the implant provided may not be used to reconstruct patient anatomy. Ensure that an alternative reconstruction solution is available and inspected before the operation.



Image 2

Step 3: Prepare the implant

- Remove the implant from its packaging and inspect it to ensure it is free of particulate or contamination.
- Place implant in a sterile basin to prevent contamination.
- Place the implant over the host bone model defect to ensure proper fit and anatomical orientation. (Image 2)
- For placement of augment implants on the host bone model, look for perimeter holes for guidance. (Image 3)

NOTE: You may use the case-specific design proposal and host bone model for reference.

CAUTION

- Use care when removing and inspecting the implant from its protective packaging to ensure sterility and integrity.
- Forcing the implant into the host bone model may compromise implant integrity.

WARNING

- Do not resterilize the MEDPOR customized implants.



Image 3

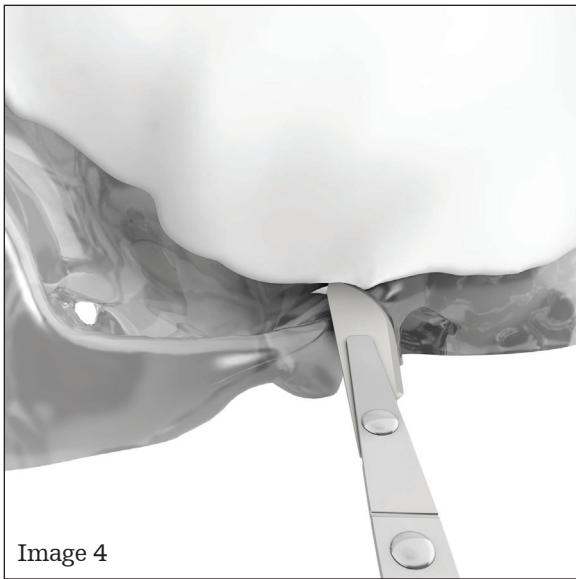


Image 4

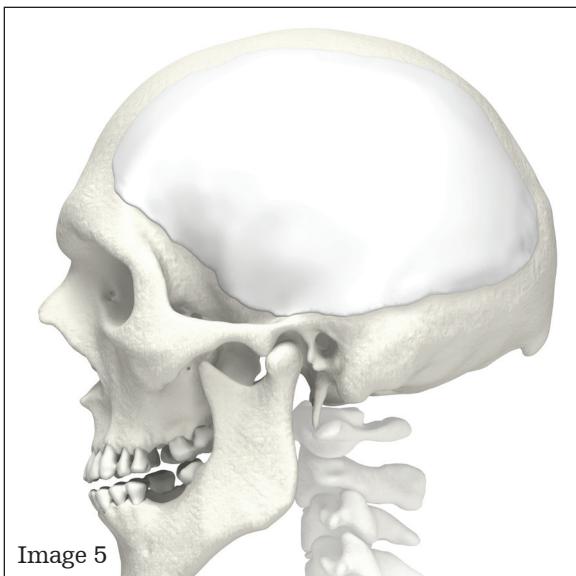


Image 5

Step 4: Modify and place the implant

- Compare the implant to the patient defect to ensure optimal fit and identify areas of the implant requiring modification.
- If necessary, use sharp scalpels or Stryker's burrs/drills to modify the MEDPOR customized implant to the desired shape. (Image 4)
 - In the event that the implant is overmodified, a sterile backup implant is provided.
- Maintain a minimum of 4mm thickness throughout regions of the implant intended to protect the brain and do not over-modify the implant.
- Do not over-modify the flanges in the following areas (if applicable):
 - At the center joint for multi-piece implants, maintain at least a 6mm overlap.
 - At the perimeter, maintain at least 4mm of flange contact to bone.
- Following modification of the implant, thoroughly inspect and remove any loose particles generated by trimming.

CAUTION:

- Modification of the MEDPOR customized implant with a burr may lead to collapsing or closure of pores in the area modified, potentially reducing soft tissue ingrowth over time in this section of the implant.
- If drill speed or hand pressure is too high, implant breakage may occur during modification. To help prevent implant breakage during burring, monitor hand force, burr wear and burr speed.

WARNING:

- Modification of the implant must be performed away from the surgical site. All residue must be removed from the implant to ensure that the surgical site is clean.
- Ensure the implant fits freely over the patient defect. DO NOT force the implant into the defect.
- Handle the implant carefully. Hold the implant in the palm of your hand to prevent scratching or damaging the implant edges while centering the implant over the defect.
- Carefully place the implant to avoid nerve and soft tissue impingement.

Step 5: Fixate the implant

CAUTION

- Use caution not to over-torque the screw as it may result in tearing of the flange and compromise fixation.
- Use caution when fixating the implant and avoid any pre-existing hardware.

WARNING

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

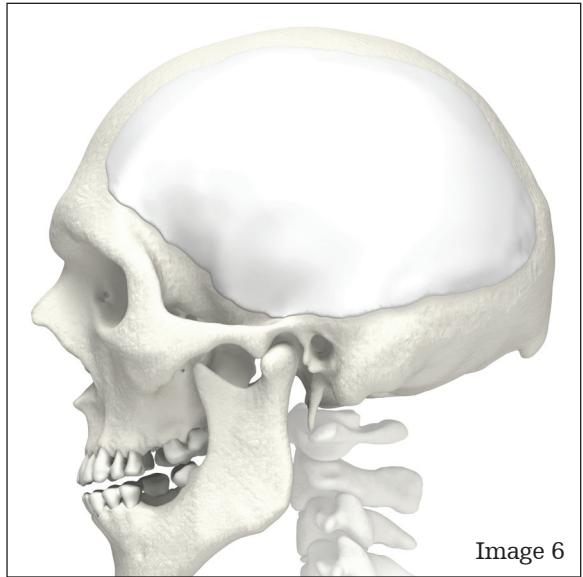


Image 6

Option 1: Fixate a flanged cranial implant

- Center the implant before fixation. (Image 6)
- Use at least three (3) points of fixation, positioned in such a way that each screw is centered in the flange, maintaining at least 4mm of material overlap to the patient bone. (Image 7)
- To fixate the flange, use Stryker's Universal Neuro, Universal Midface or Universal Upperface self-drilling screws 4mm or longer.

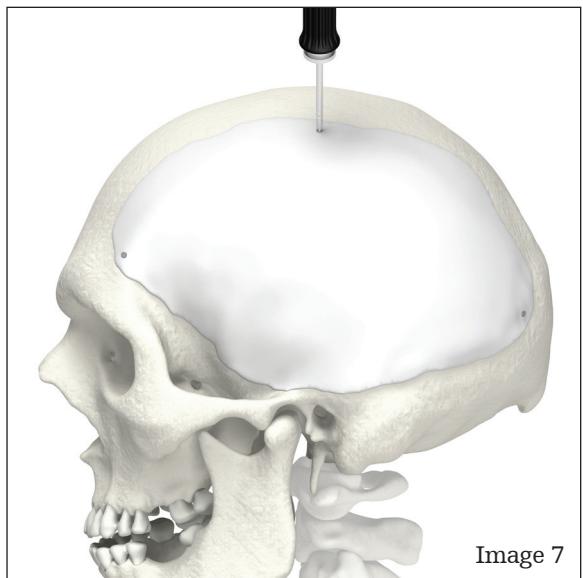


Image 7

Option 2: Fixate an inlay cranial implant

- Pre-plate the implant away from the surgical site:
 - Use at least four (4) points of fixation distributed evenly across the implant perimeter as anatomy permits.
 - To fixate the implant, use Stryker's Universal Neuro, Universal Midface or Universal Upperface self-drilling screws 4mm or longer and corresponding titanium plates.
 - Plates should be selected so that the screws are able to achieve anchoring into both the patient bone and implant.
- Insert the implant into patient defect. The implant may be biased towards aesthetic areas (non-hair-bearing anatomy) prior to fixation in order to ensure optimal aesthetic result.
- Fixate the implant to healthy bone at four (4) points of fixation. (Image 8)

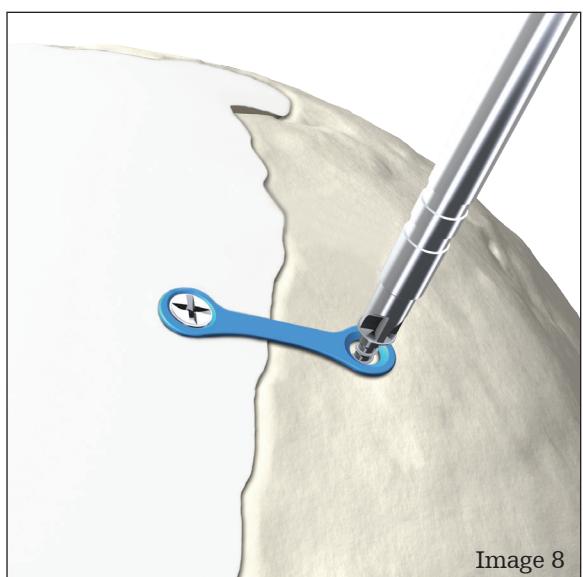


Image 8

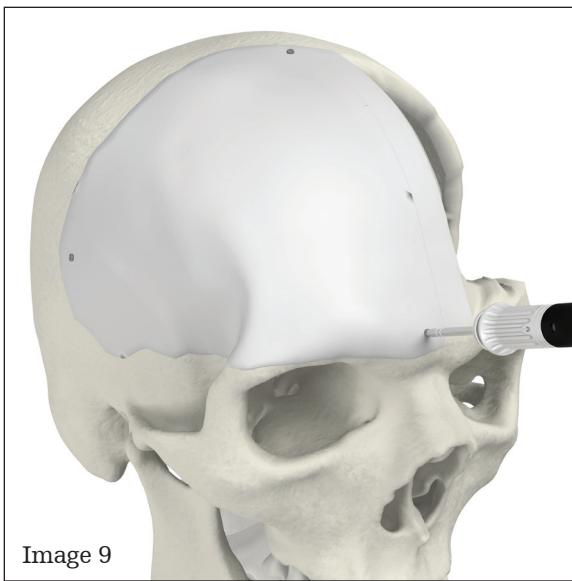


Image 9

Option 3: Fixate a multi-piece cranial implant

- Insert the “bottom” implant first and fixate to patient bone. (Image 9)
- Insert the “top” implant, centering for joint overlap and fixate to patient bone. (Image 10)

NOTE: When placing a multi-piece cranial implant, fixate according to inlay/flanged guidelines detailed in options 1 and 2. Screws may be placed along the overlapping portion of the joint between two implants as deemed necessary.

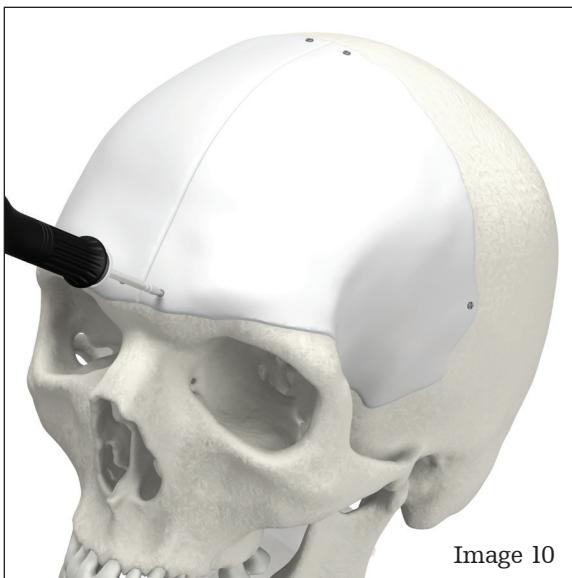


Image 10

Option 4: Fixate an augment implant

- Use Stryker’s Universal Neuro, Universal Midface or Universal Upperface self-drilling screws of a sufficient length relative to the thickness of the implant to ensure anchoring into the bone.
- Use at least two points of fixation to achieve implant stabilization for each implant. (Image 11)

NOTE: The surgeon must use his/her best clinical judgment to ensure that both tissue health and adequate tissue coverage can be achieved prior to implantation. Surgeon should use care not to penetrate the sinus(es) while fixating the implant.

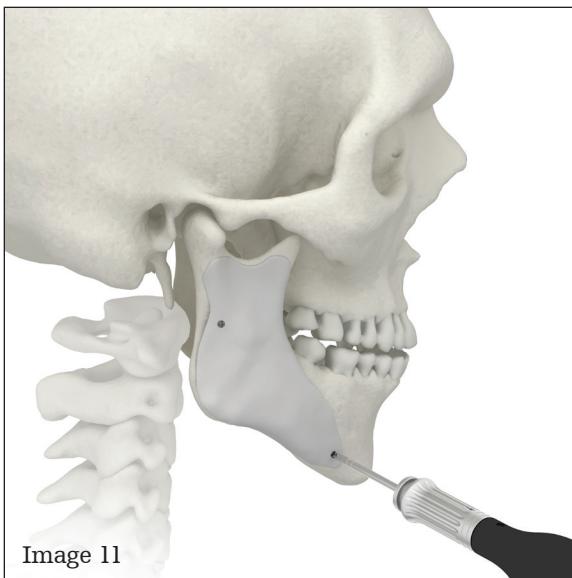


Image 11

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Craniomaxillofacial

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. Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: Leibinger, MEDPOR, Stryker, Universal Midface, Universal Neuro, Universal Upperface. All other trademarks are trademarks of their respective owners or holders.

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