



HTR-PMMA
PATIENT-MATCHED IMPLANT

BIOMET[®]
MICROFIXATION
One Surgeon. One Patient.



One Surgeon. One Patient.[®]

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a custom, patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

One Surgeon. One Patient.[®]

Neurosurgical Solutions

Biomet Microfixation supports one surgeon providing care to one patient everyday with our innovative line of cranial closure and reconstruction products for neurosurgery. Our commitment to impacting patients' lives starts with thoughtful design and rigorous testing, as well as continuously seeking opportunities to provide best-in-class care that benefits the patient, the surgeon and the hospital.

HTR Patient-Matched Implants

This commitment starts with the most complex cases for cranial reconstruction resulting from tumor, trauma or deformity. Utilizing 3-D imaging, HTR-PMMA provides patient-matched implants that can be designed with four different fit profile options for a truly custom solution.

HTR-PMMA is designed to provide:

- Four fit options
- Implant pre-plating
- Simplified CT data transfer through FTP and PACs
- A porous implant that permits fibrovascular ingrowth and potential for bony attachment¹
- Hydrophilic properties which allow for pre-operative antibiotic solution bath

¹Eppley, Barry L., Matthew Kilgo, and John J. Coleman. Cranial Reconstruction with Computer Generated Hard Tissue Replacement Patient-Matched Implants: Indications, Surgical Technique, and Long Term Follow Up. *Plastic and Reconstructive Surgery* 109.3: 864-71. p. 869



PROVEN MATERIAL

Biomet has many different patient-matched products and we strive to provide personal care to each and every patient. Since 1993, Biomet Microfixation has made nearly 15,000 HTR-PMMA implants.

HTR-PMMA patient-matched implants are made from non-resorbable biocompatible material composed of polymethylmethacrylate (PMMA) spherical macrobeads which are coated and fused together with polyhydroxyethyl-methacrylate (PHEMA). PMMA is well-known, investigated, and has been used clinically for more than 50 years.^{2,3}

2. Provenzano, Matthew J., Kieran, Murphy P. J., Riley III, Lee H. Bone Cements: Review of Their Physicochemical and Biochemical Properties in Percutaneous Vertebroplasty. *AJNR Am J Neuroradiol* August 2004; 25:1286-1290.

3. Nassiri, Naiem, Daniel R. Cleary, and Brett A. Ueek. "Is Cranial Reconstruction with a Hard Tissue Replacement Patient-Matched Implant as Safe as Previously Reported? A 3 Year Experience and Review of the Literature." *Journal of Oral Maxillofacial Surgeons* (2009): 323-27.

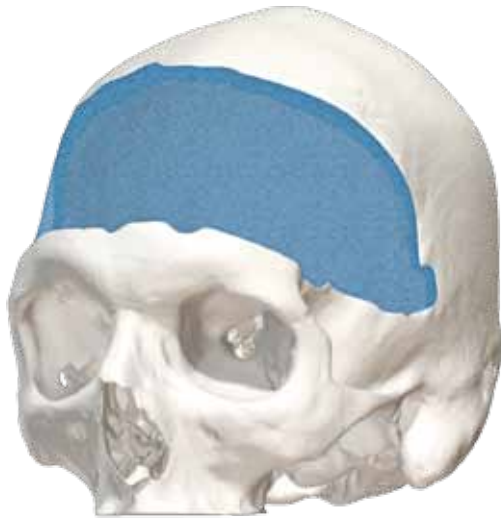
OCCIPITAL DEFECT



MID-ORBITAL DEFECT



FRONTAL DEFECT



LEFT DEFECT



MULTIPLE DEFECT



FRONTAL AND MINI ORBITAL DEFECT



Proven Clinical History

Since 1993, Biomet has provided patient-matched cranial implant solutions.

Indication

HTR-PMMA (Hard Tissue Replacement) polymer implants are intended for reconstruction and augmentation in craniofacial procedures. They are designed to fill voids or defects in bone resulting from disease, traumatic injury or surgical trauma. These devices can be used in aesthetic reconstructive procedures where augmentation or change in bony contours is desired.

Features

Patient Specific Anatomic Fit

HTR-PMMA is designed and manufactured based on uncompressed DICOM CT data.

Hydrophilic

Allows for placement of implant into antibiotic solution pre-operatively; enables vascular flow post-operatively.⁴

Porous

Pore diameter ranges from 150 - 350 microns supports possible connective tissue and bone ingrowth.⁵

Rigid and Strong

Implants have a rigidity similar to bone, with a compressive strength of 5,000 psi.⁵

Negative Surface Charge

May have minor positive effects on bony ingrowth and inhibition of bacterial adhesion.⁵

Radiopaque

Implants can be conveniently and accurately monitored post-operatively.⁶

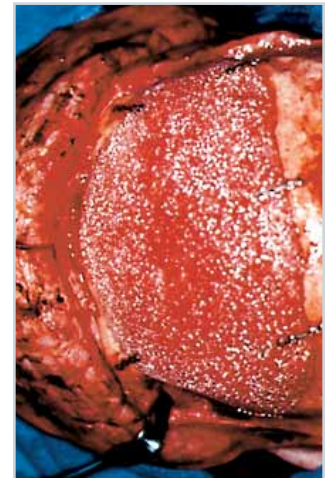


Advantages

- Prior to surgery, the implants can be soaked in antibiotic.
- HTR-PMMA is shipped sterile to save time prior to surgery.
- HTR-PMMA can be contoured intra-operatively with standard craniotomy burrs.
- Screws and plates can be placed during surgery. A pilot hole must be drilled at least 4 to 5mm from the implant perimeter prior to screw insertion.
- Complimentary pre-plating service that saves O.R. time.
- Two sterile implants are provided for each defect.



Pre-Operative



Intra-Operative

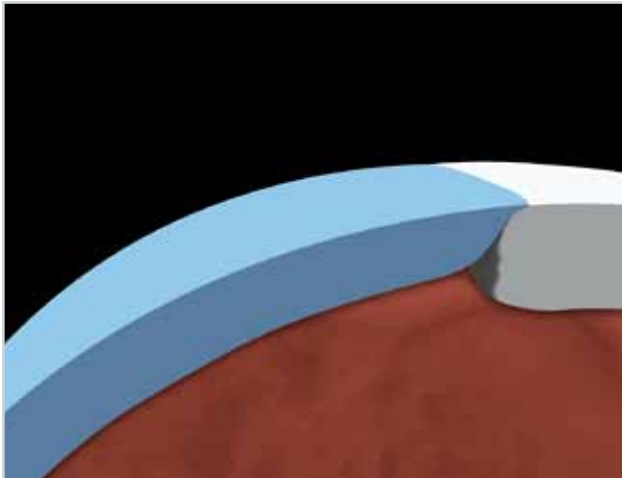


Post-Operative

⁴Eppley, Barry L., Michael Sadove, Hans Holmstrom, and Karl-Erik Kahnberg. HTR Polymer Facial Implants: A Five Year Clinical Experience. *Aesthetic Plastic Surgery* (1995): 445-50. • ⁵Eppley, Barry L., Matthew Kilgo, and John J. Coleman. "Cranial Reconstruction with Computer Generated Hard Tissue Replacement Patient-Matched Implants: Indications, Surgical Technique, and Long Term Follow Up." *Plastic and Reconstructive Surgery* (2001): 109.3: 864-71. • ⁶Kwan, JY, et al. Clinical and Histological Evaluations of Hard tissue Replacement Alloplastic Grafting Material. Case Reports. Abstract 89 46 02; Compendium of Dental Residents' Research Projects and Literature Reviews, USAF School of Aerospace Medicine, 1989.

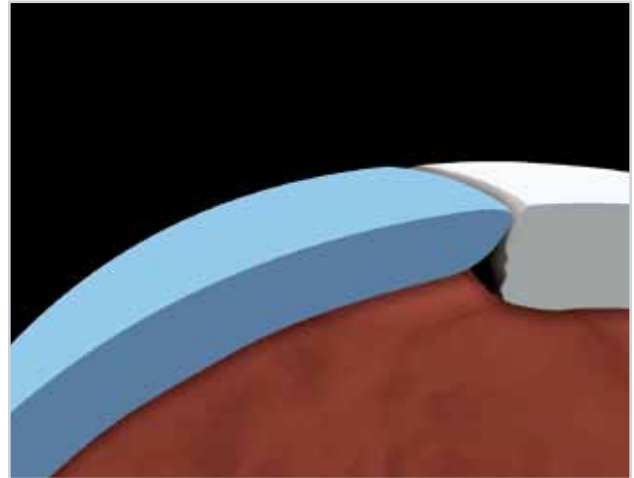
Implant Fit Options

Biomet Microfixation is the only patient-matched cranial implant company that offers four available versions of the HTR-PMMA implant. Our design algorithm technology provides surgeons with flexibility and the confidence that each patient can receive an optimal fit.



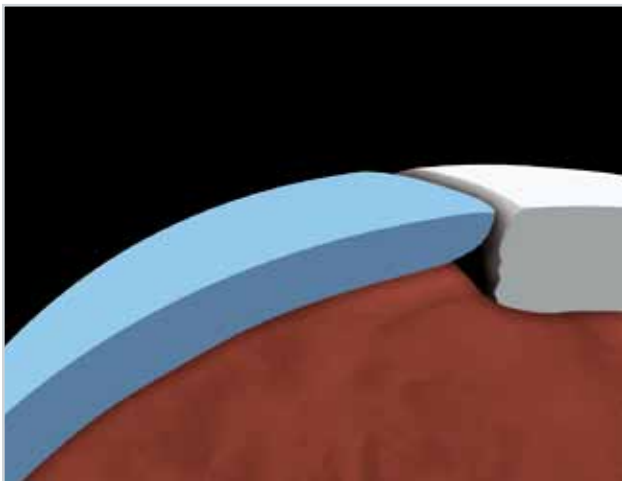
Custom Fit

This design allows for a tight fit (pre-plating recommended). The implant is 4-8mm thick based on the patient's anatomy with a tapered edge to offer a smooth transition to the bone.



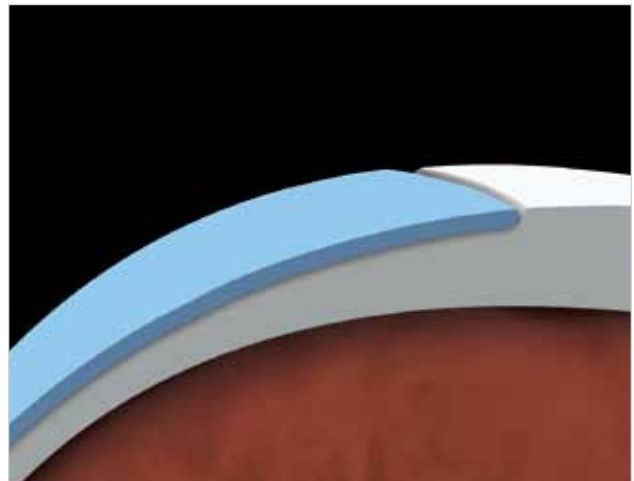
Standard Fit

This design allows for some calcified tissue to remain along the craniectomy walls while still providing a tight custom fit. The implant is 4-8mm thick based on the patient's anatomy with a slightly blunt edge.



Reduced Fit

This design allows for more fit flexibility with the post surgery anatomy. The implant is 5mm thick with a blunt edge and a 0.75mm gap.



Onlay Fit

This design allows the implant to sit directly on the bone surface to improve symmetry of the patient's skull. The implant has a minimum 3mm thickness and can be as thick as 5mm. It is designed with a tapered edge to offer a smooth transition to the bone.

HTR-PMMA PROCESS FLOW CHART

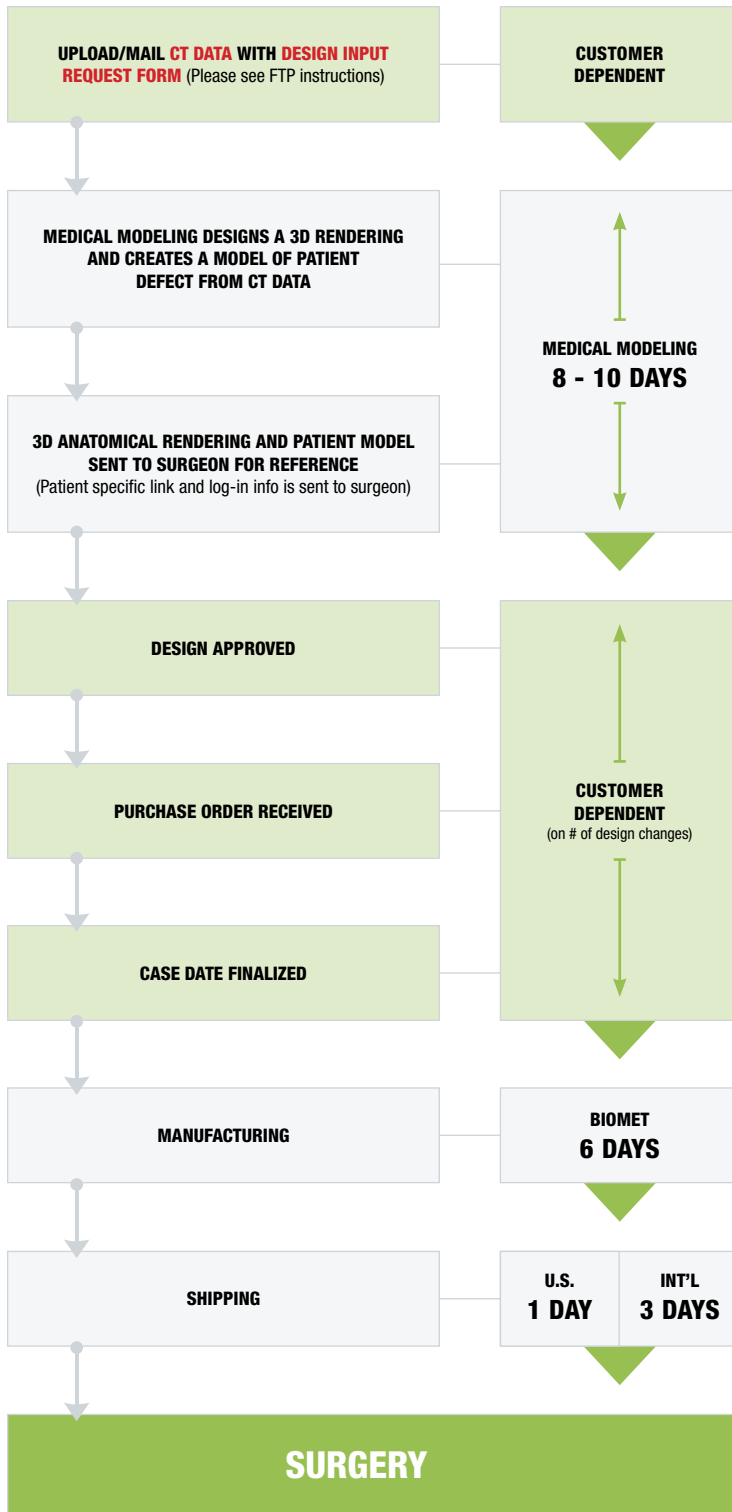
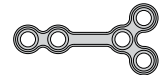


PLATE SELECTION

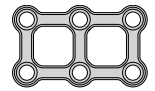
1.5mm Neuro Plates



4-Hole Straight Plate
X-Long, 20mm
01-7048



5-Hole Y Plate
X-Long, 19mm
01-7104



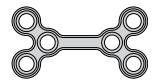
2x3-Hole Rectangle Plate
18mm
01-7136



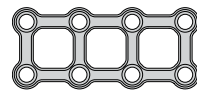
2-Hole Straight Plate
Long, 16mm
01-7347



6-Hole Straight Plate
Long, 27mm
01-7057



6-Hole Double Y Plate
X-Long, 18mm
01-7114

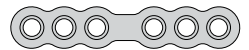


2x4-Hole Rectangle Plate
25mm
01-7137

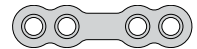


1.5 x 4mm Self-Drilling
X-Drive Screw
91-6104

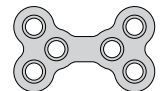
ThinFlap™ Plates



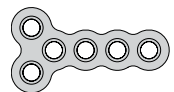
6-Hole Straight Plate
Long, 28mm
19-1040



4-Hole Straight Plate
Long, 22mm
19-1045



Double Y Plate, 18mm
19-1060



Y Plate, 20mm
19-1065



1.5 x 4mm Self-Drilling
X-Drive Screw
91-6704

NOTE: Delivery of implant is dependent on receipt of customer data and surgeon approval time. Biomet is not responsible for delays in shipping that are not under our control.

HTR-PMMA CT SCANNING PROTOCOL

The quality of the CT scan is the most important aspect of creating case-specific anatomical models and prostheses. Biomet Microfixation and Medical Modeling understand concerns about keeping the radiation doses to patients as low as possible; therefore, please use these guidelines as appropriate for your patients. **Please contact our HTR hotline at 904.741.9242 with any questions.**

KEY GUIDELINES

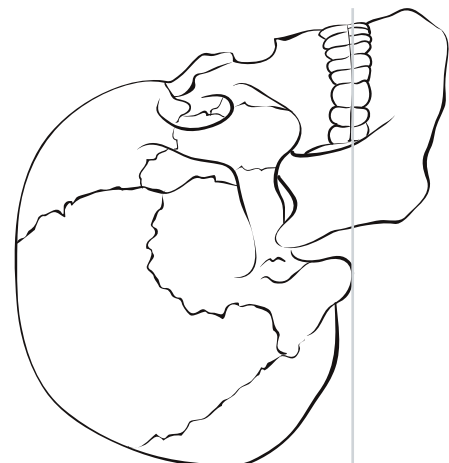
- ▶ Use a 3D scanning routine that provides high resolution images as comparable to image guided surgery, stereotactic planning, or other 3D applications.
- ▶ Acquire scans at a high spatial resolution. Series should be acquired with thin, contiguous image slices (equivalent thickness and spacing of 1.25mm or less) and as small a field of view (FOV) as possible while still including the patient’s external contour.
- ▶ Scan 2cm above and below the area of interest. For cranial defects, please include the entire defect plus 2cm above and below the defect. If unsure, please scan from hard palate through the skull vertex.
- ▶ Provide images in the original scanning plane. If software post-processing is performed to reorient or reformat the scan volume, then a series of thin slice images in the original acquisition plane **MUST** be included.
- ▶ Do **NOT** use a gantry tilt during image acquisition. Images acquired with gantry tilt and then post-processed to reorient images (i.e. “take out” tilt) are not acceptable.
- ▶ **Please ensure that scans are free from motion artifact.** Patient must remain completely still through the entire scan. If patient motion occurs, the scan must be restarted. Image distortion from patient motion can severely compromise the accuracy of a model.

PREFERRED SCANNING PARAMETERS*

Scan Spacing:	Less than 1.25mm (equal to slice thickness)
Slice Thickness:	Less than 1.250mm (equal to scan spacing)
Field of View:	25.0cm
Algorithm: (examples)	GE: Standard (not bone or detail) Siemens: H30s Toshiba: FC20 Philips: B
Gantry Tilt:	0°
Archive Media:	CD or DVD
File Type:	DICOM (uncompressed)
Series:	Original/Primary/Axial (No recon, reformat or post process data)

PATIENT POSITIONING

Occlusal plane should be parallel to the gantry



NOTE: Please save protocol as Biomet Microfixation HTR, and in the Study Description field, put BIOMETMF. Scans must be less than 6 months old.

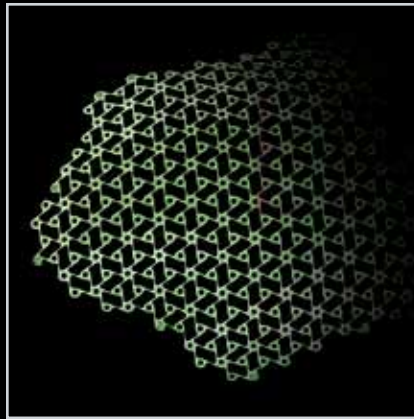
* If scanner cannot meet above parameters, please contact Medical Modeling for further instructions.

Biomet Neurosurgical Solutions

To learn more about Biomet Neurosurgical solutions, please visit our website, www.biometmicrofixation.com



HTR-PEKK



CranioCurve™



iQ™ Intelligent System



1.5 Neuro System



ThinFlap™



Mimix®



RapidFlap™ Spin Down



RapidFlap™ LS



SterileTrac™

Combining the Art and Science of Care

Founded by eight visionaries driven to improve the lives of patients, our philosophy has always been to approach every innovation as if it's meant for a family member.

More than 30 years later, we still operate the same way, putting the patient-surgeon connection first while advancing surgical techniques and devices.

At Biomet, the tremendous advancements we've made in the past are the motivation for our future. We'll continue to strengthen the patient surgeon connection with solutions that combine clinical mastery and the human element.

One Surgeon. One Patient.®

What fascinates you about the body is also what drives us. That's why we're always pushing the boundaries of engineering to make products that help you keep the human form as glorious as it was intended. To learn more about our breadth of products, call 800.874.7711 or visit us online at www.biometmicrofixation.com.

We'd love to join you in a conversation about the future.



For more information on HTR-PMMA, please call our HTR hotline at 904.741.9242 or contact us at:

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