

HTR[®]-PMI

Patient Matched Implant



BIOMET[®]
MICROFIXATION
Anticipate. Innovate.™

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

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For more information on HTR®-PMI, please contact us at:

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As the manufacturer of this device, Biomet Microfixation does not practice medicine and does not recommend this product or surgical technique for use on a specific patient. The surgeon who performs any implant procedure must determine the appropriate device and surgical procedure for each individual patient. Information contained in this brochure is intended for surgeon or distributor information only and is not intended for patient distribution. All surgeries carry risks. For additional information, please see package insert or visit our web site at www.biometmicrofixation.com or call 1-800-874-7711.

HTR® is a registered trademark of U.S. Surgical Corp.

Infinite Possibilities



HTR-PMI is indicated for the entire calvarium including the posterior, middle and anterior cranial fossa. Both inlays and onlays may be implanted in the zygomatic and orbital regions. Maxillary and mandibular implants may be fabricated as non-load bearing onlays only.

What Surgeons Are Saying

"I have used the HTR cranioplasty dating back to 1996... The product saves time in the operating room because of its custom fit and leads to an excellent anatomic and cosmetic result."

— Marion L. Walker, M.D.
Salt Lake City, Utah

"After ten years of using this technology, I've not had a single case where a revision was needed due to contour concerns or infection."

— Barry L. Eppley, M.D., D.M.D.
Indianapolis, Indiana

"The HTR-PMI system offers significant advantages in eliminating donor site morbidity, reducing length of surgical procedure and length of hospitalization and provides a custom made porous implant that has allowed me to surgically manage extensive and complex cranial vault deformities in an efficient and safe fashion."

— Christopher R. Forrest, MD., MSc.,
FRCS (C), FACS
Toronto, Canada

Custom HTR Implants In Just 18 Days.*

Anticipation and innovation. These two qualities have made Biomet Microfixation an industry leader. Founded by Walter Lorenz more than thirty years ago, Biomet Microfixation offers instrumentation, plating systems and related products for a wide range of surgical procedures.

Biomet Microfixation is proud to offer HTR-PMI Patient Matched Implants in a remarkably short time—just eighteen days. This is thanks to the unique process of using patient CT-scan data to create highly accurate anatomical models. These models are then used to manufacture HTR implants for a fully patient-matched custom fit.

Handling Features

- Implants are sterile when shipped, saving you time prior to surgery.
- Before implantation, the implants may be soaked in antibiotic solution.
- The implants may be easily contoured intra-operatively with standard craniotomy burrs.
- The implants are specially designed to tolerate drilling and screw fixation during implant placement. Simply drill a pilot hole before inserting screws and refrain from drilling the implant within 4 to 5mm of its perimeter.
- To save time, we offer a complimentary pre-plating service, with costs of plates and screws billed separately.
- For convenience, two sterile implants are provided for each patient.

*Eighteen-day delivery is based on receipt date of CT-scan and includes business days only. Delivery time may vary for complex defects, resection cases or cases requiring design modifications.

More Than 4,500 Cases To Date

Thoroughly Tested. Fully Proven.

HTR-PMI Patient Matched Implants are made from non-resorbable, biocompatible material composed of polymethylmethacrylate (PMMA) spherical macrobeads that are coated and fused together with polyhydroxyethylmethacrylate (PHEMA). Both PMMA and PHEMA have been well known, investigated and clinically used successfully for more than sixty years.

Product Highlights

POROUS Average pore diameter of 250-500 microns supports connective tissue and bone ingrowth.

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

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

HYDROPHILIC Enables antibiotic impregnation pre-operatively and vascular flow post-operatively.

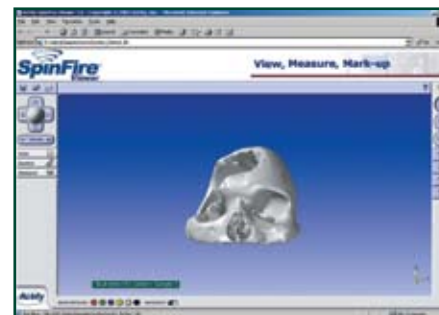
NEGATIVE SURFACE CHARGE May have minor positive effects on bony ingrowth and inhibition of bacterial adhesion.¹

¹Eppley BL, Kilgo M, Coleman JJ. Cranial Reconstruction with Computer Generated Hard-Tissue Replacement Patient-Matched Implants: Indications, Surgical Technique, and Long-Term Follow-Up. *Plastic Reconstructive Surgery*. 109:864, 2002.

View Implants Online

Surgeons may review and approve the skull model and HTR-PMI online to improve turnaround time even further. Specialized software provides the surgeon a variety of options for viewing the 3-D model, defect site and implant.

The surgeon may rotate, measure, move and section the implant for improved surgical planning. Security and confidentiality are assured with a log-in screen requiring a password and user name unique to each surgeon.

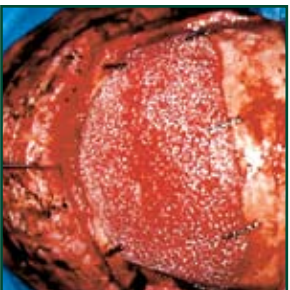


HTR®-PMI CT-Scanning Protocol

Exceptional Results



Pre-Operative



Intra-Operative



Post-Operative

Thank you for your attention to this special scanning protocol for HTR-PMI cases. This protocol should be followed for scans indicated for cranial reconstruction with Biomet Microfixation's HTR-PMI material. Medical Modeling and Biomet Microfixation work together in the design and fabrication of the implant. The CT scan is the most important part of the process and your adherence to the guidelines below is greatly appreciated. Please do not hesitate to contact Medical Modeling toll free at (888)-273-5375 with any questions or prior to using this protocol for the first time.

Please keep in mind the following key points:

- Acquire scans at a high spatial resolution. Series should be acquired with thin, contiguous image slices (<2.0mm, 0.75 – 1.25mm is ideal) and as small a field of view (FOV) as possible while still including the patient's external contour. Patient must remain completely still through the entire scan. If patient motion occurs the scan must be restarted.
- Scan 2cm above and below the area of interest. For cranial defects, please include entire defect plus 2cm above and below the defect. If unsure, please scan from hard palate through the skull vertex.
- Image distortion from patient motion will severely compromise the accuracy of a model. Please ensure that scans are free from motion artifact.
- Do not use a gantry tilt in scanning patients.
- Image artifact caused by metallic implants can obscure anatomy of interest. Please take steps to minimize artifact from the presence of metal. It is useful to position the patient so that the occlusal plane is parallel to the image plane (see figure). This can help to limit artifact from metallic dental implants to the region around the teeth.
- Archive the entire study, preferably in DICOM format, to a removable medium such as Sony/MaxOptix optical disk, Pioneer optical disk, 4 or 8mm DAT, or CD-R. Many of the older proprietary image formats

(for example GE Advantage, Picker, Phillips) can be supported but the most reliable method of image transfer is DICOM format on CD-R. It is also possible to transfer image data via computer network. Please contact our technicians at (888) 273-5375 for details on setting up the means for DICOM Internet transfer.

Example image protocols for cranio-maxillofacial study:

*Acquisition:	Helical
*FOV:	25.0cm
*Gantry tilt:	0 degrees
*Scan spacing:	0.75 – 1.25mm
*Slice thickness:	0.75 – 1.25mm
*Algorithm:	Standard (not bone or detail)
*Pitch:	1:1

Variations on the example are acceptable as long as the above key points are followed. If using a multidetector scanner please be sure to reconstruct images at thin sections (<2.0mm, 0.75 – 1.25mm is ideal).

If using a single slice scanner please do not reconstruct images to slices that are thinner than the original acquisition. This simply interpolates between slices and does not improve the resolution of the exam. If using a single scanner, please scan the patient with the thinnest slice thickness possible (<2.0mm, 0.75 – 1.25mm is ideal).

Medical Modeling can import image data from most mainstream CT scanners and PACS systems and most storage media. Please call us at (888)-273-5375 if you have questions about the inability to read images from your equipment.

DICOM Internet Transfer

Please call to set up an account for pushing DICOM images over the Internet to our server.

How To Order

1. Obtain Patient CT-Scan Data

Request that the patient be scanned according to the **HTR-PMI CT Scanning Protocol**, included in this brochure.

2. Send CT-Scan Data

Send the CT-scan data AND the completed **Surgeon Order Request Forms** (download available from www.htrpmi.com) to:

Medical Modeling LLC
HTR-PMI Department
17301 West Colfax Avenue, Suite 301
Golden, Colorado 80401
Phone: (888) 273-5375 or (303) 277-0430
Fax: 303-273-6463
Email: info@htrpmi.com

3. Review Online

Review the custom implant online or after receipt of the skull model and sample implant. Indicate any necessary adjustments by marking on the skull model. If no adjustments are necessary, complete the **Approval Letter** and the **Pre-Plating Form** provided with the skull model or located online.

4. Send Skull Model & Sample

Send the skull model and sample implant, **Approval Letter** and **Pre-Plating Form** to Medical Modeling at the address provided above.

Manufacturing inquiries should be directed to **Biomet Microfixation** at **800-874-7711, ext. 242** or htrpmi@biomet.com.



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