BIOMET® MICROFIXATION

One Surgeon. One Patient.

One Surgeon. One Patient.®

Over one 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.

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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 continuously seeking opportunities to provide best-in-class care that benefits the patient, the surgeon and the hospital.

HTR-PEKK **Patient-Matched Implants**

This commitment starts with the most complex cases for cranial reconstruction due to tumor, trauma and deformity. HTR-PEKK introduces state-of–the-art technology and a novel material for manufacturing implants. Through laser sintering, or 3D printed manufacturing, HTR-PEKK offers complex solutions to match patient needs.

HTR-PEKK **offers:**

- A high strength material with compressive strength of 24.9 Kpsi[1]
- Hydrophilic properties[2]
- Proven biocompatibility[3]
- Four fit options for patient specific aesthetics
- Simplified CT data transfer through FTP and PACS

[1]ASTM F2026-10 material standards on file. [2]Biomet Internal Test Report LT1316, Measurement of Surface Contact Angle of SLS Manufactured PEKK Implants. [3]OPM Internal test report, ISO 10993.

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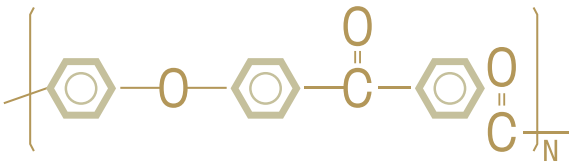
HTR-PEKK Patient-Matched Implant

PEKK Material

PEKK (poly-ether-ketone-ketone) is a biocompatible material from the same polymer family as PEEK. This family of materials has been utilized in orthopedics and trauma since the 1980s.[4] Surgeons can now select a material for medical device implants offering properties such as radiolucency[5] and high mechanical strength.[6]

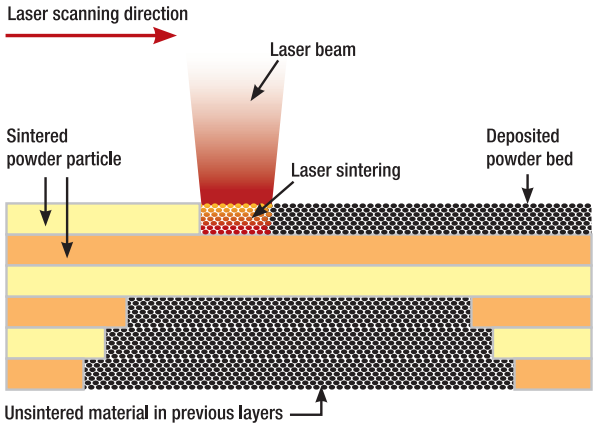


Poly-Ether-Ketone-Ketone

Mechanical Property	Laser Sintered PEKK[7]	Extruded PEEK[8]
Compressive	172 Mpa	131 Mpa
Tensile strength	95.8 (64) Mpa	61 Mpa
Screw pullout[9]	51.1 Lbf	43.5 Lbf

Innovative Manufacturing Technology

HTR-PEKK is the first laser sintered polymer device cleared for sale in the U.S.[10] The laser sintering process fuses material particles together layer by layer to create a lightweight implant with complex designs. Because of the 'printing' technique, laser sintering allows for complex designs beyond what traditional manufacturing methods can build. This method, combined with the unique PEKK material properties, yields an implant with a textured surface.



The laser sintering process fuses together small particles of the PEKK material in layers, which allows for complexities in design compared to milled manufacturing.

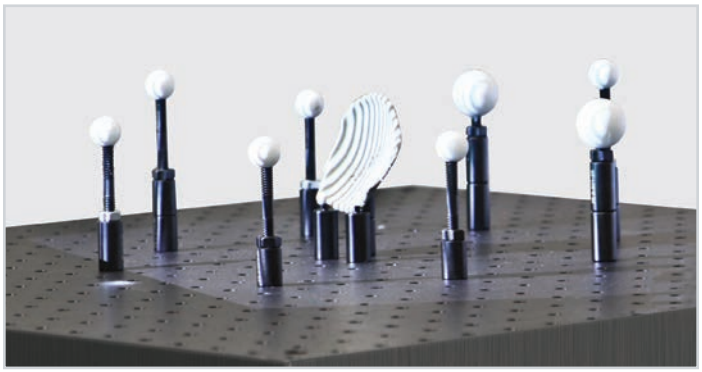
Once removed from the laser sintering machine, each implant is excavated from the PEKK powder bed by hand. The implant is then pressure cleaned to remove unsintered material (pictured above).

[4]Kurtz S. and Devine J., PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials, 2007. 28: p. 4845-4869. [5]Converse, G. et al. Hydroxyapatite whisker-reinforced polyetherketoneketone bone ingrowth scaffolds. Acta Biomaterialia. 2010. (6) pg 856-863. [6]ASTMF2830, F2026. [7]OPM material specs, on file. OsteoFab™ Medical Parts and Implants. [8]OPM material specs, on file. OXPEKK® vs. PEEK Comparison. [9]Biomet Internal Test Report LT1294. [10]510k-K121818

HTR-PEKK is manufactured in partnership with Oxford Performance Materials (OPM) using OsteoFab™ Technology.

Quality Inspection

HTR-PEKK implants are inspected using a white light scanner that measures within 0.002 inches. The scanner compares the final manufactured implant to the surgeon-approved design to ensure accuracy in the manufacturing process.



The white light laser scanner uses a series of reference patterns to construct a 3D model of the implant.

A deviation map is generated from the white light data and compares the STL design file to the final manufactured implant.

HTR-PEKK Application

HTR-PEKK is intended for the replacement of bony voids in the cranial skeleton. The HTR-PEKK implant comes non-sterile and should be sterilized through autoclave standards.[11] This implant may be fixated using the range of Biomet Microfixation's neurosurgical solutions products including the 1.5mm Neuro Lorenz® Plating System and the ThinFlap™ Plating System.

- Intraoperative fixation of the HTR-PEKK cranial implant can utilize the 1.5mm Neuro Lorenz Plating System or ThinFlap Plating System. Pre-drilling of screw holes is recommended.
- If necessary, the reshaping, resizing or contouring of the implant is best accomplished using high speed rotating instruments. All intraoperative shaping should be made away from the surgical site and the implant should be rinsed with saline to remove any loose particles before implantation.[11]

Sterilization Standards[11]

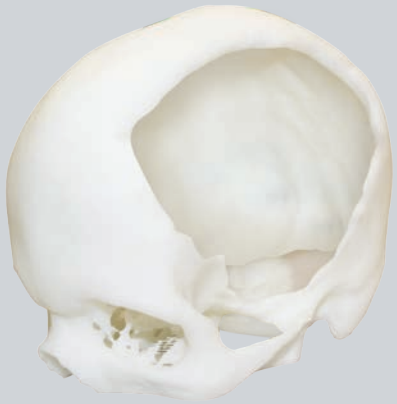
PRE-VACUUMED STEAM STERILIZATION (HI-VAC) WRAPPED	
Temperature	270° F - 279° F (132° C - 137° C)
Time	Four (4) Minutes*
Drying Time	Thirty (30) Minutes MINIMUM
GRAVITY DISPLACEMENT STEAM STERILIZATION WRAPPED	
Temperature	275° F (135° C)
Time	Ten (10) Minutes
Drying Time	Thirty (30) Minutes MINIMUM

[11]HTR-PEKK IFU #QMSD-6001. *For countries outside of USA, exposure time maybe increased to 18 minutes to comply with the recommendations from the World Health Organization (WHO)

HTR-PEKK Patient-Matched Implant

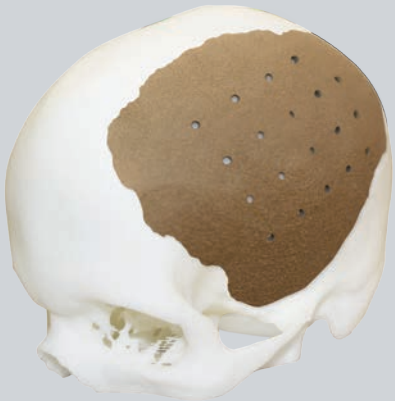
HTR-PMI PROCESS FLOW CHART

UPLOAD/MAIL CT DATA WITH DESIGN INPUT REQUEST FORM (Please see FTP/PACS instructions)	**CUSTOMER DEPENDENT**
MEDICAL MODELING DESIGNS A 3D RENDERING OF PATIENT DEFECT FROM CT DATA	**MEDICAL MODELING 2 DAYS***
3D ANATOMICAL RENDERING SENT TO SURGEON FOR REFERENCE (Patient specific link and log in info is sent to surgeon)	
DESIGN APPROVED	**CUSTOMER DEPENDENT** (on # of design changes)
PURCHASE ORDER RECEIVED	
CASE DATE FINALIZED	
MANUFACTURING	**OPM** (Oxford Performance Materials) **5 DAYS**
SHIPPING	**US 1 DAY** / **INT'L 3 DAYS**
SURGERY	



SKULL DEFECT

PATIENT-MATCHED PEKK IMPLANT



MODEL OF SKULL WITH PATIENT-MATCHED IMPLANT

*This step takes up to 5 days if approval by skull model is requested by the surgeon. 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-PMI 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

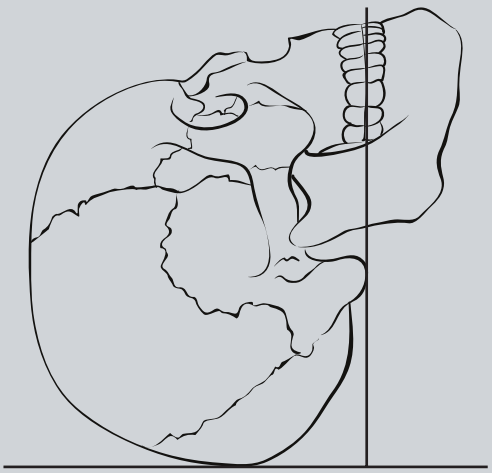
- Use a 3D scanning routine that provides high resolution images as comparable to image guided surgery, stereotactic planning, or other 3D applications.
- Acquire scans at a high spatial resolution. Series should be acquired with thin, contiguous image slices (equivalent thickness and spacing of 1.25mm 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 PARAMETER*

Scan Spacing:	Less than 1.25 mm (equal to slice thickness)
Slice Thickness:	Less than 1.25 mm (equal to scan spacing)
Field of View:	25.0 cm
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.

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-PEKK, please call our HTR hotline at 904.741.9242 or contact us at:

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