BIOMET MICROFIXATION
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Instructions for Use (IFU): HTR-PEKK

INDICATIONS

An HTR-PEKK[1] device is intended for the replacement of bony voids in the cranial skeleton. It is a Custom Made Device.

DESCRIPTION OF DEVICE

An HTR-PEKK device is built individually for each patient to correct defects in cranial bone. The HTR-PEKK device is constructed with the use of the patient's CT imaging data and computer aided design to determine the dimensions of each implant. The HTR-PEKK device is built by a LASER sintering machine. The HTR-PEKK device is attached to native bone with commercially available cranioplasty fixation systems. The HTR-PEKK device is a non-load bearing single use device and it is non-sterile.

MATERIAL

Polyetherketoneketone (PEKK)

LABELS

A duplicate of the label has been placed on the last page of the IFU for the patient's record.

CONDITIONS OF USE

Caution: HTR-PEKK devices should only be implanted by Surgeons who are fully experienced in the use of such implants and the required cranial surgical techniques.

CONTRAINDICATIONS

HTR-PEKK devices are contraindicated under any of the following conditions:

1. Infection or sepsis,
2. Degenerative bone disease which would render the device or the treatment unjustifiable,
3. Distant foci of infection which can spread to the implant site,
4. Uncooperative patients or patients with neurologic or psychiatric/psychological dysfunction who are incapable or unwilling to follow postoperative instructions.

WARNINGS

The HTR-PEKK device is not a full or partial load bearing device. Do not use an HTR-PEKK device for replacement of bone within an articulating surface. Patients who engage in contact sports or other activities that risk cranial injury are to be warned that cranial injury may lead to damage of the implant and a subsequent failure of treatment. The patient is to be warned that the device does not replace normal healthy bone and that traumatic injury could necessitate surgical treatment. The patient must be advised of surgical risks and the possible adverse effects.
THE HTR-PEKK DEVICE HAS BEEN DESIGNED TO FIT THE DEFECT EXISTING AT THE TIME OF THE CT SCAN AND IMPLANT FABRICATION. CHANGES IN THE PATIENT'S ANATOMY OCCURRING AFTER THE CT SCAN AS WELL AS THE USE OF THE IMPLANT AFTER SUCH CHANGES MAY RESULT IN A SUB-OPTIMAL FIT WITHIN THE AREA THAT HAS THE DEFECT.

1. Improper selection, placement, positioning, and fixation of the HTR-PEKK device may cause an undesirable result. The Surgeon is to be familiar with the implant and the surgical procedure prior to performing surgery.
2. Appropriate selection of fixation devices for HTR-PEKK devices is left up to the Surgeon's discretion. The Surgeon must follow the manufacturer's instructions for use and specifications for fixation devices.
3. HTR-PEKK devices placed, positioned, and fixated over or near air containing sinuses could result in infection.
4. To prevent dehiscence at the incision site, a firm primary closure of the incision is required.
5. If the Surgeon deems necessary, the re-shaping, sizing, or contouring of the HTR-PEKK device is best accomplished using high-speed rotating instruments. All intraoperative shaping and sizing should be performed away from the surgical site. After implants have been shaped, they must be rinsed in sterile saline to remove any loose particles.
6. Particularly in instances where implants are shaped, intra-operative damage to the implant may occur. It is recommended that HTR-PEKK devices be examined for damage or disfigurement prior to implantation.
7. Pediatric use is not recommended. Rapid remodeling of the pediatric skull may cause dehiscence of the incision, prominence or disfigurement at the implant site, or related complications that could result in the need to remove the implant.

[1] HTR-PEKK is the trade name of Biomet Microfixation for the product that was cleared for distribution in the United States of America (USA) as OsteoFab™ Patient Specific Cranial Device (OPSCD).

8. HTR-PEKK devices are not recommended for patients that have had radiation therapy. Should the Surgeon determine that use of the implant is necessary, the Surgeon should be familiar with all applicable risks.
9. The Surgeon should weigh the risks versus benefits when deciding to remove the HTR-PEKK device. Implant removal should be followed by adequate postoperative management.
10. Do not reuse the HTR-PEKK device. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient. Discard any unused portion of the HTR-PEKK.
11. Test models (provided upon request) are to be utilized for pre-operative planning analyses only, and are not intended to come in contact with the HTR-PEKK device or enter the Operating Room.
12. In-situ screw fixation should be placed in the full thickness of the implant.

POTENTIAL ADVERSE REACTIONS INVOLVING HTR-PEKK DEVICES MAY INCLUDE:

1. Loosening or migration due to loss of fixation or trauma,
2. While rare, sensitivity reactions,
3. Infection leading to failure of the procedure, and/or
4. Peripheral neuropathies. These have been reported in conjunction with surgical procedures involving implantation of various types of devices. Sub-clinical nerve damage occurs more frequently, usually as a result of surgical exposure/trauma.

INTRAOPERATIVE AND EARLY POSTOPERATIVE COMPLICATIONS INVOLVING HTR-PEKK DEVICES MAY INCLUDE:

1. Fracture of the implant,
2. Fracture of bone or soft tissue damage,
3. Extrusion of the implant,
4. Dehiscence of the incision,
5. Prominence or disfigurement at the implant site, and/or
6. Infection.

LATE POSTOPERATIVE COMPLICATIONS INVOLVING HTR-PEKK DEVICES MAY INCLUDE:

1. Fracture of the device due to traumatic injury,
2. Loosening or migration due to loss of fixation or trauma, and/or
3. Prominence or disfigurement over time at or near the implant site.

CLEANING AND HANDLING

An HTR-PEKK device is provided clean and ready to sterilize. The health care facility personnel must handle an HTR-PEKK device with a face mask, hair net, powder free nitrile gloves, booties, and a lab coat to maintain the HTR-PEKK device as clean and ready for sterilization.

STERILIZATION

HTR-PEKK devices are shipped non-sterile and are to be sterilized at the health care facility via steam sterilization. The recommended parameters listed below are based on information from the ANSI/AAMI ST79 – Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Oxford Performance Materials validated the two steam sterilization methods listed below utilizing test specimens that were wrapped with FDA cleared wraps and FDA cleared pouches. The validation protocol utilized FDA cleared steam sterilizers and FDA cleared biological indicators.

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

**For countries outside the USA, exposure time may be increased to 18 minutes to comply with the recommendations from the World Health Organization (WHO).*

Gravity Displacement Steam Sterilization Wrapped:
Temperature: 275°F (135°C)
Time: Ten (10) minutes
Drying Time: Thirty (30) minutes MINIMUM

The health care facility should wrap the HTR-PEKK device with an FDA cleared wrap or an FDA cleared pouch prior to executing either of the two steam sterilization cycles that have been validated by OPM. The health care facility should also utilize steam sterilizers that were cleared by the FDA.

MAGNETIC RESONANCE IMAGING

HTR-PEKK devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating or migration in the MR environment.

CAUTION

Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

Operating Surgeons and all personnel involved with handling an HTR-PEKK device are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of the HTR-PEKK device.

INFORMATION

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SYMBOLS

SYMBOLS


Date of Manufacture


Do Not Reuse


Caution


Manufacturer

Catalogue Number

Batch Code

Authorised Representative in the European

AFFIX COPY OF
DEVICE LABEL
HERE

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