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## WARNINGS AND PRECAUTIONS FOR HTR® POLYMER IMPLANTABLE DEVICES

### ATTENTION OPERATING SURGEON

#### DESCRIPTION

HTR® (Hard Tissue Replacement) Polymer Implants are intended for bone replacement or augmentation for treatment of patients whose present conditions, in the surgeon's opinion, cannot be treated satisfactorily using other treatment methods. HTR® Polymer Implants are made of a porous composite material composed of polymethylmethacrylate (PMMA), polyhydroxyethylmethacrylate (PHEMA) and a calcium hydroxide coating. Some designs have a titanium joint. These devices are used for augmenting and contouring bone.

#### INDICATIONS

HTR® (Hard Tissue Replacement) Polymer Implants are intended for reconstruction and augmentation in craniofacial procedures intended 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.

#### CONTRAINDICATIONS

This device is contraindicated under any of the following conditions: 1) infection and 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) patients that have had radiation therapy, and 5) uncooperative patients or patients with neurologic or psychiatric/psychologic dysfunction who are incapable or unwilling to follow postoperative instructions.

#### WARNINGS

These devices are used for augmenting and contouring bone. They are not intended or designed for full or partial load bearing. Do not use these devices for replacement of bone within articulating surfaces. Patients who engage in contact sports or other activities that risk facial injury are to be warned that facial 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. **THIS 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 DEFECT.**

1. Improper selection, placement, positioning, and fixation of the HTR® Polymer Implant can cause a subsequent undesirable result. The surgeon is to be familiar with the implant and the surgical procedure prior to performing surgery.
2. Intraoperative shaping and sizing of the implant can be critical to the cosmetic success of the procedure, as improper shape and size can result in a noticeable undesirable prominence or possible disfigurement at or near the implant site.
3. HTR® Polymer Implants placed, positioned, and fixated over or near air containing sinuses could result in infection.
4. Temporary fixation of the implant prior to the ingrowth of soft or hard tissue may be desirable and critical to the success of the procedure. Temporary fixation can be achieved using screws 2.0 mm in diameter or less.
5. To prevent dehiscence at the incision site, a firm primary closure of the incision is required.
6. Correct methods must be used for shaping and handling the implant. Shaping, sizing, or contouring of HTR® Polymer Implants is best accomplished using sterile rongeurs, nippers or other types of "cutting" instruments. High-speed rotating instruments should be used with caution to avoid overheating the polymer, which may affect the porous surface and inhibit tissue growth. After implants

have been shaped, they must be rinsed in sterile saline to remove any loose particles.

7. Particularly in instances where implants are shaped, intraoperative damage to the molded implant and/or the titanium joint may occur. It is recommended that implants be examined for damage or disfigurement prior to implantation.
8. Rapid remodeling of the pediatric skull may cause the skull to change significantly between the time of the CT scan and the time implants are ready. The custom implant may no longer optimally fit the defect.
9. HTR® Polymer implants are not recommended for patients that have had radiation therapy.
10. Do not reuse HTR® Polymer Implants. While the device may appear clean and undamaged, a used implant may be contaminated as the material is highly absorbent. Discard any unused portion.

#### POSSIBLE ADVERSE REACTIONS

1. While rare, implantation of foreign materials may result in sensitivity reactions.
2. Peripheral neuropathies have been reported in conjunction with surgical procedures involving implantation of various types of devices. Subclinical nerve damage occurs more frequently, usually as a result of surgical exposure/trauma.
3. HTR® Polymer Implants can loosen or migrate due to loss of fixation or trauma.
4. Infection can lead to failure of the procedure.

Intraoperative and early postoperative complications can include: 1) fracture of the implant, 2) fracture of bone or soft tissue damage, 3) extrusion of the implant, 4) dehiscence of the incision, 4) prominence or disfigurement at the implant site, and 5) infection.

Late postoperative complications can include: 1) fracture of the device due to traumatic injury, 2) loosening or migration due to loss of fixation or trauma, and 3) prominence or disfigurement over time at or near the implant site.

#### STERILITY

HTR® Polymer Implants are sterilized using a minimum dose of 25 kGy of gamma radiation. Do not resterilize.

Caution: Federal Law (USA) restricts this device to sale, distribution or use by, or on the order of a physician.

HTR® is a registered trademark of United States Surgical Corporation.

#### DIRECTIONS FOR PREPARATION OF HTR® POLYMER IMPLANTS FOR IMPLANTATION

1. Open the sterile package containing the appropriately sized implant corresponding to the procedure being performed.
2. If the shape of the implant must be adjusted, use sterile "cutting" instruments, such as rongeurs or nippers. Use of high-speed rotating instruments should be used with caution to avoid overheating the polymer. After shaping or sizing, rinse the implant in sterile saline solution.
3. Due to the hydrophilic nature of the implant, it may be soaked in an antibiotic solution to assure adequate removal of air bubbles and then directly implanted.