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INDICATIONS

Patient Specific Implants are intended for the replacement of bony voids in the cranial/craniofacial skeleton.

DESCRIPTION OF DEVICE

The Kelyniam Global Inc. customized cranial/craniofacial implants are a non-load bearing, single use device and are:

- Manufactured using Polyether ether ketone (PEEK) implantable grade materials (i.e. PEEK-OPTIMA® or Vestakeep i4®).
- Designed individually for each patient to correct defects in cranial/facial bone.
- Individually sized and shaped implantable prosthetic cranioplasty plates intended to fill defects in a specific patient's cranial skeleton.
- Fabricated using the patient's CT imaging data.
- Provided non-sterile for sterilization prior to implantation.
- Attached to the native bone using commercially available, non-biodegradable fixation screws or any commercially available cranioplasty fixation system.

CONDITIONS OF USE

CAUTION - The Kelyniam Global Inc. customized cranial/craniofacial implants should only be implanted by surgeons who are fully trained and licensed in the use of such implants and the required specialized cranial surgical techniques.

CONTRAINDICATIONS

This device is contraindicated under any of the following conditions:

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

KELYNIAM GLOBAL INC. CUSTOMIZED CRANIAL/CRANIOFACIAL IMPLANT

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.

CAUTION - 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 defected area.

- Improper selection, placement, positioning, and fixation of the Kelyniam Global Inc. Customized Cranial/Craniofacial Implant can cause a subsequent undesirable result. The surgeon is to be familiar with the implant and the surgical procedure prior to performing the surgery.
- If a commercially available, non-biodegradable fixation system are to be used, a minimum of 3 fixation points is recommended. The screw holes must be pre-drilled (away from the surgical site) and should be at least 4mm from the edge of the implant. The screws should not protrude past the underside of the implant to avoid tissue damage.
- Due to the customized nature of the implant, the appropriate selection of FDA approved fixation devices are left to the surgeon's discretion.
- All instructions for fixation (drilling, tapping of holes, and insertion of screws) should be followed by FDA approved commercially available, non-biodegradable manufacturer's instructions and specifications.
- Optional pre-surgical models may have been provided to allow for detailed orientation and inspection of form, fit, & function (proper alignment and orientation of the device).
- Intra-operative shaping and sizing of the implant can be critical to the cosmetic success of the procedure. Improper shape and size can result in a noticeable undesirable prominence or possible disfigurement at or near the implant site. All intra-operative shaping and sizing should be performed away from the surgical site.
- Kelyniam Customized Cranial/Craniofacial Implants placed, positioned and fixated over or near air containing sinuses could result in infection.
- Kelyniam Global Inc. Customized Cranial/Craniofacial Implants are not recommended for patients that have had radiation therapy. Should the surgeon determine that use of this implant is necessary and appropriate for a patient that has had previous radiation therapy; the surgeon should be familiar with all applicable surgical techniques.
- To prevent dehiscence at the incision site, a firm primary closure of the incision is required.
- If the surgeon deems necessary, the re-shaping, sizing, or contouring of the Kelyniam Global Inc. Customized Cranial/Craniofacial Implant, it is best accomplished using high-speed rotating instruments. After the implant has been shaped, they must be rinsed in sterile saline to remove any loose particles. Particularly in instances where implants are shaped, intra-operative damage to the

molded implant may occur. It is recommended that the implant be examined for damage or disfigurement prior to implantation.

- 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.
- The surgeon should weigh the risks versus benefits when deciding to remove the implant. Implant removal should be followed by adequate postoperative management.
- Do not reuse Kelyniam Global Inc. Customized Cranial/Craniofacial Implants. Discard any unused portion.
- The device must be sterilized prior to use per ANSI/AAMI ST79.
- Surgical models, if provided, are to be used for pre-operative planning analysis only and are not intended to come in contact with the Kelyniam Customized Cranial/Craniofacial Implants or enter the Operating Room.

POTENTIAL ADVERSE REACTIONS

- While rare, implantation of foreign materials may result in sensitivity reactions.
- Peripheral neuropathies 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.
- Kelyniam Global Inc. Customized Cranial/Craniofacial Implants can loosen/migrate due to loss of fixation or trauma.
- Infection can lead to failure of the procedure.

INTRAOPERATIVE AND EARLY POSTOPERATIVE COMPLICATIONS CAN INCLUDE:

- Fracture of the implant;
- Fracture of bone or soft tissue damage;
- Dehiscence of the incision;
- Prominence or disfigurement at the implant site; and
- Infection.

LATE POSTOPERATIVE COMPLICATIONS CAN INCLUDE:

- Fracture of the device due to traumatic injury;
- Loosening or migration due to loss of fixation or trauma; and
- Prominence or disfigurement over time at or near the implant site.

INSPECTION

All implantable devices are shipped **NON-STERILE** from Kelyniam Global Inc. in a sealed polyethylene bag to be repackaged at the hospital prior to steam sterilization. The seals along with the entire pouch should be inspected to ensure they have not been tampered with or damaged during shipping. All devices must be checked to include a twelve (12) digit alpha-numeric case number which matches the case number on the product label.

CLEANING

This implant was produced in a non-sterile cleanroom environment and has been manually cleaned using a 70% alcohol solution. **The implant MUST BE sterilized before use.**

STERILIZATION

The Kelyniam Customized Cranial/Craniofacial Implants are supplied clean but non-sterile and should be repackaged before steam sterilization. Prior to sterilization, the Kelyniam Customized Implant together with an FDA approved biological Indicator should be double pouched in FDA approved steam sterilization pouches. All materials used should be applicable to the method of sterilization to be performed. The recommended parameters listed below are based on Laboratory testing conducted to establish sterility. These are in accordance with ANSI/AAMI ST79 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities

RECOMMENDATIONS FOR STEAM STERILIZATION

Method	Cycle	Minimum Exposure Time	Minimum Exposure Temperature	Drying
Steam	Gravity Displacement	10 minutes	132°C (270°F)	30 minutes
Steam	Pre-vacuum	4 minutes	132°C (270°F)	30 minutes

Figure 7 - Sterilization Recommendations

STORAGE

Kelyniam Customized Cranial/Craniofacial Implants should be stored in a controlled environment at approximately 24°C (75°F) in accordance with AAMI ST79.

DO NOT USE IF THE PACKAGE IS OPEN OR DAMAGED

Following sterilization, the package should again be inspected to ensure the integrity of the packaging was maintained. Product not scheduled for immediate use should be stored in a cool dry place.

MAGNETIC RESONANCE IMAGING

The Kelyniam Customized Cranial/Craniofacial Implants described in this Instruction For Use (IFU) have not been evaluated for safety and compatibility in the MR environment by Kelyniam Global, Inc. These implants have not been tested for heating or migration in the MR environment by Kelyniam Global, Inc.

****Kelyniam Global, Inc. shall not be liable for any data supplied by any third party.****

CAUTION

Federal (USA) law restrictions require these devices be sold by or on the order of a licensed physician.

INFORMATION

For further information, please contact Customer Service at:

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