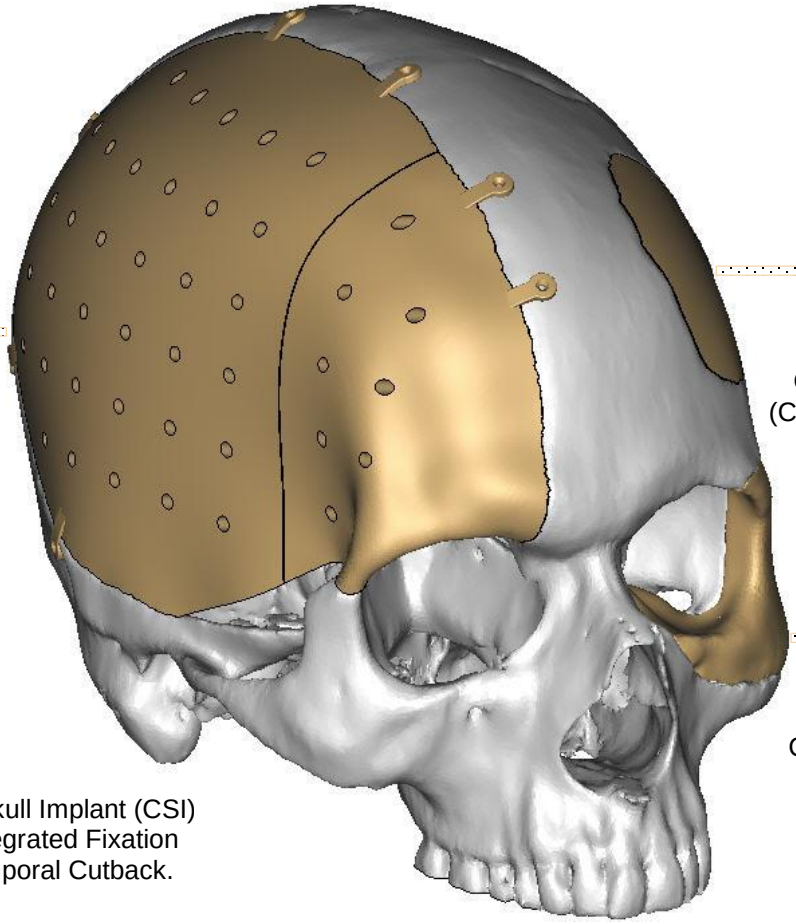
Instructions For Use (IFU)



e.g.
Customized Skull Implant
(CSI) without Perfusion Holes

e.g.
Customized Craniofacial Implant
(CCI) without Perfusion Holes

e.g.
Multi-Part Customized Skull Implant (CSI)
w/ Perfusion Holes, Integrated Fixation
System (IFS), and Temporal Cutback.

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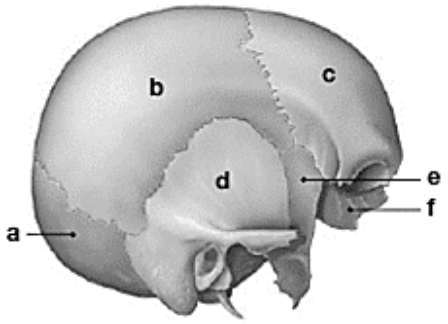
DEFINITIONS:

Skull - A collection of bones and cartilage which encases and protects the brain and chief sense organs; the skeleton of a person's head.

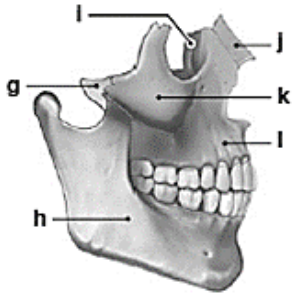
Customized Skull Implant (CSI) - Is a patient-specific implantable medical device that is designed using the patient's CT Scan Data and is intended to fill a bony void or defect area in a patient's specific cranial skeleton.



a. Occipital Bone
b. Parietal Bone
c. Frontal Bone
d. Temporal Bone
e. Sphenoid Bone
f. Ethmoid Bone

Craniofacial - A collection of bones in the facial region of the skull.

Customized Craniofacial Implant (CCI) - Is a patient-specific implantable medical device that is designed using the patient's CT Scan Data and is intended to fill a bony void or defect area in a patient's specific craniofacial skeleton (orbital rim, zygoma, and adjacent bone) excluding the Maxilla (upper jaw area surrounding the teeth only) and Mandible, which are load bearing areas of the facial region.



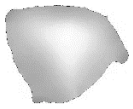
g. Vomer Bone
h. Mandible Bone
i. Lacrimal Bone
j. Nasal Bone
k. Zygomatic Bone
l. Maxilla Bone

INDICATIONS FOR USE

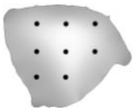
The Customized Craniofacial Implant (CCI) and Customized Skull Implant (CSI) is intended to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton (orbital rim, zygoma, & adjacent bone).

DESCRIPTION OF DEVICE

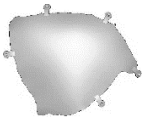
Customized Craniofacial Implants (CCI) and Customized Skull Implants (CSI), known hereafter as Implant, are individually sized and shaped implantable prosthetic plate intended to fill a bony void or defect area in a specific patient's cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone). The size, asymmetrical shape, thickness, contour, and edge profile are design elements of the non-load bearing patient-specific Base Implant that are used to support the base implant in the bony void or defect area while providing for a "Precise Fit". The single patient use base implant (1) is fabricated from a billet block of natural implant grade Polyether ether ketone (PEEK) Thermoplastic Polymer using the patient's CT Scan imaging data, (2) is provided clean but non-sterile for steam sterilization prior to implantation at a hospital or surgical site with neurosurgery capabilities, and (3) are attached to the native bone using commercially available cranioplasty hardware and fasteners. Additional features, as described below, are additional design elements that may be added to the Base Implant, as requested by the Physician.



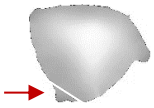
Base Implant - See above.



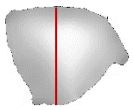
Prefusion Holes are holes in the Base Implant that allow the passage of fluid to an organ or tissue; equally spaced over the contour or curvature of the Base Implant.



Integrated Fixation System Tabs or IFS is a design element used to fixate the Base Implant to the patient's cranial and craniofacial skeleton using commercially available cranioplasty screws; replacing the need to fixate the Base Implant using commercially available cranioplasty hardware.



A Temporal Cutback is a design element, if requested by a Physician, that dictates the shape of the Base Implant in the temporal fossa region of the patient's cranial skeleton to aid in reducing intraoperative tissue trauma or temporalis muscle damage during the cranioplasty surgery.



A Multi-Part Implant is a design element that is used for patients with a bony void or defect area that cannot be filled using a single Base Implant. A Multi-Part Implant is used when (1) the overall implant contour or curvature height exceeds the overall thickness of the billet block of natural implant grade Polyether ether ketone (PEEK) Thermoplastic Polymer, (2) the geometry of the Base Implant causes undercuts, or (3) the Base Implant is non-passive requiring the implants to be installed separately. The Base Implant is manufactured in multiple parts with support lips that run along the top and bottom edges of each implant, allowing the top implant support lip to be supported by the bottom implant support lip. When a Multi-Part Implant is implanted, it functions as a single Base Implant.

CONDITIONS OF USE

CAUTION - The Kelyniam Global Inc. (KGI) Customized Craniofacial Implants (CCI) and Customized Skull Implants (CSI) should only be implanted by surgeons who are fully trained and licensed in the use of such implants and be implanted at a hospital or surgical site with neurosurgery capabilities.

CONTRAINDICATIONS

The Implants are 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.

INTEGRATED FIXATION SYSTEM (IFS) INSTALLATION

The Integrated Fixation System (IFS) is a low-profile tab system that is integrated into the device at strategic locations, used to fixate the device to the patient's cranial and craniofacial skeleton using commercially available cranioplasty fasteners, known hereafter as Screws. Screws are **NOT PROVIDED** with the implant. The countersink and thru hole in the IFS tab are designed to ensure that the profile of the screw is in full contact with the IFS Tab. When the Screw is fully engaged, the head of the Screw must be flush or below the body of the IFS tab. For the best results, the Screw should be inserted perpendicular to the hole in the IFS tab. When fully fastened, the IFS Tab should be sitting flat against the patient's skull.

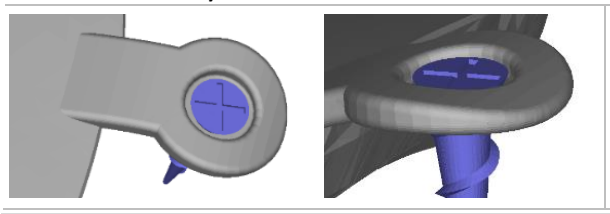


Figure 1 - Section view of an IFS tab with a Screw installed.

MULTI-PART INSTALLATION

A Multi-Part Implant is for patients with bony voids or defects with (1) an overall implant contour height that exceed the dimensions (i.e. thickness) of the PEEK raw material used for manufacturing or (2) geometry causing undercuts or non-passive fitting implants that must be installed separately. The device is manufactured in multiple parts with a support lip that runs along the edge of the first device, allowing support for the second device. When a Multi-Part Implant is implanted, it functions as a single implant.

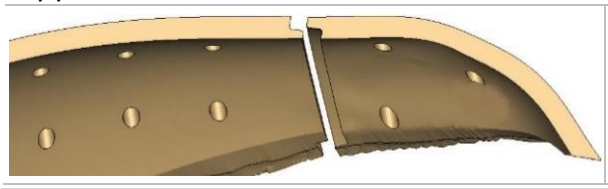


Figure 2 - Section view of a Multi-Part Implant showing the support lips, allowing the Multi-Part Implant to be connected.

CORRECT/INCORRECT INSATLLATION OF IMPLANTS WITH IFS OR MULTI-PART IMPLANTS WITH IFS

Correct Use

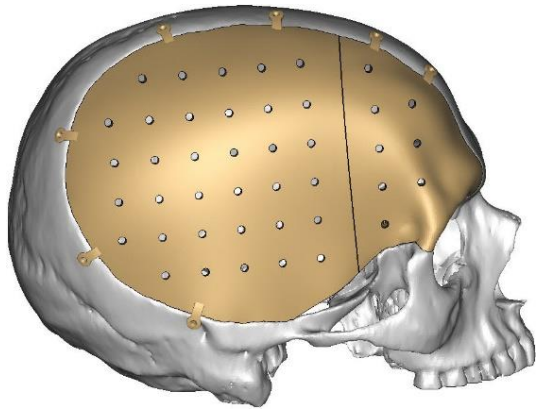


Figure 3 - The contoured edge of the Implant is fully sitting on the existing defects edge of the patient's cranial and craniofacial skeleton. The Multi-Part support lips are fully seated, and the IFS tabs are sitting flat against the patient's skull. No visible gaps all around.

Incorrect Use

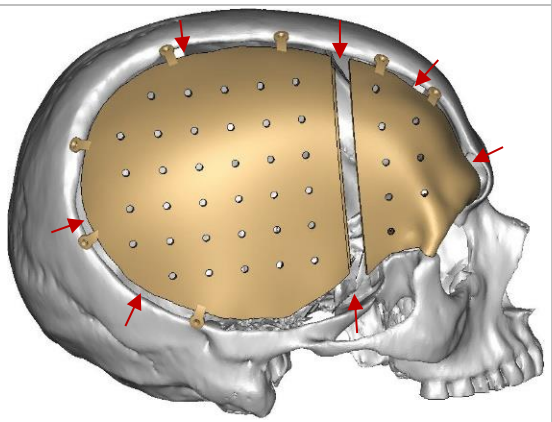


Figure 4 - DO NOT use the Implant with IFS or a Multi-Part Implant with IFS to fixate to the patient's skull if the contoured edge of the Implant is **NOT** sitting on the patient's existing defects edge. Gaps are clearly visible all around (see red arrows depicting the gaps) and the IFS tabs are **NOT** fully seated on the patient's skull. Without the proper edge support, the chance of failure increases. In cases where there is not proper edge support, the IFS should be removed and commercially available, cranioplasty fixation hardware and screws can be used to fixate the Implant to the patient's skull.

WARNINGS AND ADDITIONAL INFORMATION

The Implants are used to fill a bony void or defect area in a patient's specific cranial and craniofacial skeleton. They are not intended for load bearing applications such as the Maxilla (upper jaw area surrounding the teeth only) and Mandible. Do not use these devices for replacement of bone within articulating surfaces. Patients who engage in contact sports or other activities that risk cranial and/or facial injury are to be warned that cranial and/or 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 - Do not reuse the Implant. Discard any unused portions.

CAUTION - The Implant has been designed and manufactured to fit the bony void or defect area existing at the time of the CT Scan. Using an Implant after the recommended 6 months use by date may result in a sub-optimal fit within the bony void or defect area.

- Improper selection, placement, positioning, and fixation of the Implant can cause a subsequent undesirable result. It is the responsibility of the surgeon to be familiar with the location and positioning of the implant based on the Design Proposal/RX established during the design process.
- If commercially available fixation is used, the minimum recommendations are three (3) fixation points and 4mm away from the Implants edge. Pre-drill the screw holes in the Implant, away from the surgical site but in a sterile environment (i.e. Operating Room) using sterile, , high-speed rotating instruments. The screws should not protrude past the underside of the implant to avoid damaging the dura.
- Due to the customized nature of the Implant, the appropriate selection of FDA cleared 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 cleared commercially available fixation systems manufacturer's instructions and specifications.
- Intra-operative re-shaping and re-sizing of the implant should be performed away from the surgical site utilizing high-speed, rotary instruments. It is important that any loose particulate should be removed with sterile saline rinse.
- Implants placed, positioned, or fixated over or near air cavities (e.g. sinuses), could result in infection.
- To prevent dehiscence at the incision site, a firm primary closure of the incision is required.
- Modification (e.g. re-shaping, sizing, contouring) of the Implant must be done by a Surgeon in a sterile environment (i.e. Operating Room) using a sterile, high-speed rotating instruments. After the implant has been modified, verify that the Implant is clean, and/or free of cracks, burrs, and chips. Rinse the Implant in sterile saline to remove any loose particles. Intra-operative damage may occur to the Implant after it has been modified. Examine for damage or disfigurement prior to implantation.
- Instruments used to modify the Implant shall be sterilized using the hospital or surgical site's internal procedures for sterilizing instrument for use in a sterile environment (i.e. Operating Room).
- Pediatric use is not recommended. Rapid remodeling of the pediatric cranial/craniofacial skeleton 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.
- The device must be steam sterilized prior to use per ANSI/AAMI ST79.
- Surgical Model Kit, if provided, are to be used for pre-operative planning analysis only (e.g. form, fit, function, alignment, orientation). Surgical Model Kit is not a medical device, is clearly labeled as "do not sterilize/do not implant" and is not intended to come in contact with the Implant 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.
- Implants can loosen/migrate due to loss of fixation or trauma.
- Infection can lead to failure of the procedure.

INTRAOPERATIVE/EARLY POSTOPERATIVE COMPLICATIONS CAN INCLUDE, BUT NOT LIMITED TO:

- 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, BUT NOT LIMITED TOO:

- 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

Implants are shipped clean but **NON-STERILE** from Kelyniam Global Inc. (KGI) in a tamper proof sealed FDA and USDA cleared, clear plastic bag. Inspect the Implants packaging to ensure they have not been tampered with or damaged during shipping and that the Implant includes a twelve (12) digit alpha-numeric case number which matches the case number on the product identification label. The Implants are to be repackaged as stated below, at the hospital or surgical site with neurosurgery capabilities prior to steam sterilization.

CLEANING

This implant was produced in a non-sterile, clean environment. The Implant was manually cleaned using 70% isopropyl alcohol before being placed in a tamper proof sealed FDA and USDA cleared, clear plastic bag.

CAUTION - The device must be steam sterilized before use.

STERILIZATION

The Implants are supplied clean but **NON-STERILE** and should be repackaged before steam sterilization. Prior to steam sterilization, wrap the Implant with an FDA cleared biological Indicator in 2 layers of 1-ply FDA cleared polypropylene sterilization wrap using sequential envelope folding techniques. Sterilize the Implant using the hospital or surgical site with neurosurgery capabilities internal procedures for the method of steam sterilization to be performed. The recommended parameters listed below are based on 3rd party Laboratory testing conducted by Kelyniam Global Inc. (KGI) to establish sterility. These are in accordance with ANSI/AAMI ST79 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.

CAUTION - Kelyniam Global, Inc. (KGI) is not liable for any data supplied by any 3rd party testing facility.

RECOMMENDATIONS FOR STEAM STERILIZATION

Sterilization Method	Wrapping Method	Sterilizer Type	Preconditioning Pulses	Minimum Temperature Exposure	Full Cycle Time	Dry Time
Steam	Wrap the device in two layers of FDA cleared polypropylene sterilization wrap (i.e. Halyard Health H600 Sterilization Wrap) using sequential envelope folding techniques.	Pre-vacuum	4	132°C (270°F)	4 minutes	30 minutes

Figure 5 Steam Sterilization Recommendations

STORAGE

It is recommended that Implants 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 steam 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 Global Inc. (KGI) implants are electrically nonconductive and nonmagnetic and poses no known hazards in all MR environments. The KGI Implants are MR Safe.

RX STATEMENT

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

SYMBOLS CONTAINED IN DEVICE LABELING

 Part Number	 Expiry Date	 Non-sterile
 Lot Number	 Single Patient Use	 Manufactured By
 Serial Number	 Prescription	 Instructions For Use

Figure 6 - Symbols referenced on device labeling.

NOTES

INFORMATION

For further information, please contact Customer Service at:

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Fax: (501) 641-2000
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URL: http:\\www.kelyniam.com

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