PEEK Customized Skull & Craniofacial Implants

Precise Fit in 24 Hours or Less
**Integrated Fixation System (IFS Tabs)**

The optional integrated tabs provide a fast and easy way to secure the implant with appropriate size, commercially available craniofacial fixation screws. This feature provides significant OR time and cost savings by markedly reducing the fixation hardware needed.

**Perfusion Holes**

Perfusion Holes can be equally spaced over the contour of the implant to allow for the passage of fluid.

**Base Implant**

A Base Implant is an 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 while providing for a “Precise Fit” and restoration of the unique individual skull and facial contours.
A Multi-Part Implant is used when the defect is too large to be filled with a single implant or when a Multi-Part implant will simplify the surgery. All Multi-part implants are manufactured with a lap joint to strengthen the assembly and allow for a price fit and safe implantation. This feature is available upon request on any implant.

Additional features are FDA cleared with Craniofacial and Skull Implants.

The only PEEK Implant manufacturer with FDA cleared Integrated Tabs.

Implants are designed to have “Precise Fit” in the bony void or defect area.

Industry leading 24 hours or less turn-around time available, if requested.

Exceptional customer service.

**Temporal Cutback**
Temporal Cutback aids in reducing intraoperative tissue trauma or temporalis muscle damage in the temporal fossa region during the exposure.

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Intended 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).

CT Scan Protocol

KELYNIAM CT Scan protocol ensures that the Customized Craniofacial or Skull Implant will have a “Precise Fit”.

Surgical Model Kits

Provides Surgical Model Kits intended to assist the physician with a physical 3D model to determine fitment prior to ordering a Customized Craniofacial or Skull Implant. Available upon request.

Steam Sterilization

Kelyniam implants are provided clean but non-sterile, and require steam sterilization prior to implantation. Sterilization is required according to the IFU or hospital internal steam sterilization procedures.

Acquisition: Axial/Helical
Field of View (FOV): 20-25cm
Gantry Tilt: 0~
Occlusal Plane: Correct position of the patient
Spacing: ≤ 1.25mm
Slice Thickness: ≤ 1.25mm
Algorithm: Standard (not bone or detail)
MA: 170/>280
Time: 1 second

Surgical use of an implantable device carries the potential risk of infection.
Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.