

K E L Y N I A M

Customized Precision. Expedited.





Custom Crafted Cranial and Craniofacial Implants

- The only PEEK implant manufacturer with an FDA-cleared & USPTO approved patent for temporal cutback and the Integrated Fixation System (IFS).
- Integrated Fixation System - (IFS Tabs) provide surgeons with an efficient option to secure the implant with commercially available cranial fixation screws, providing a decrease in OR time and cost savings by reducing the amount of fixation hardware needed.

Implant Development in 24-Hours

- The efficient 24-hour TAT (Turnaround-Time), may facilitate reduced hospital length of stay.
- Implant is available within 24-hours of CT scan receipt for emergency cases.
- Rehabilitative care may be provided sooner with expedited delivery.

Innovative Technology - Implants made of PEEK

- Biocompatible.
- Sonolucent, radiolucent and non-magnetic (no MRI or CT artifact).
- Compatible with MRI and CT Scans.
- Proven implant material, provides strength and stability.
- Implants can be easily sterilized per IFU and hospital internal steam sterilization procedures, and are modifiable in the Operating Room.

Kelyniam Engineering

- Industry leaders with proven experience: 10 years in the cranial and craniofacial market with over 2750 successful implants.
- The only implant with FDA-cleared temporal cutback design and IFS tabs.
- Every implant is custom designed for the surgeon for a precise fit based on each patient's anatomy.

Patent Approved Integrated Fixation System (IFS) Tabs

- Pre-drilling and fixated standard plating is no longer required.
- Cost and time savings – Eliminates the need for plates and numerous screws.
- Cosmetically elegant appearance with counter-sunk screw technology.



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Core Features & Benefits

Integrated Fixation System - (IFS Tabs) provide surgeons with an efficient option to secure the implant with appropriate sized, commercially available craniofacial fixation screws. This feature provides a decrease in OR time and cost savings by markedly reducing the amount of fixation hardware needed.

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

Base Implant - 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 a "Precise Fit" and restoration of the unique individual skull and facial contours.

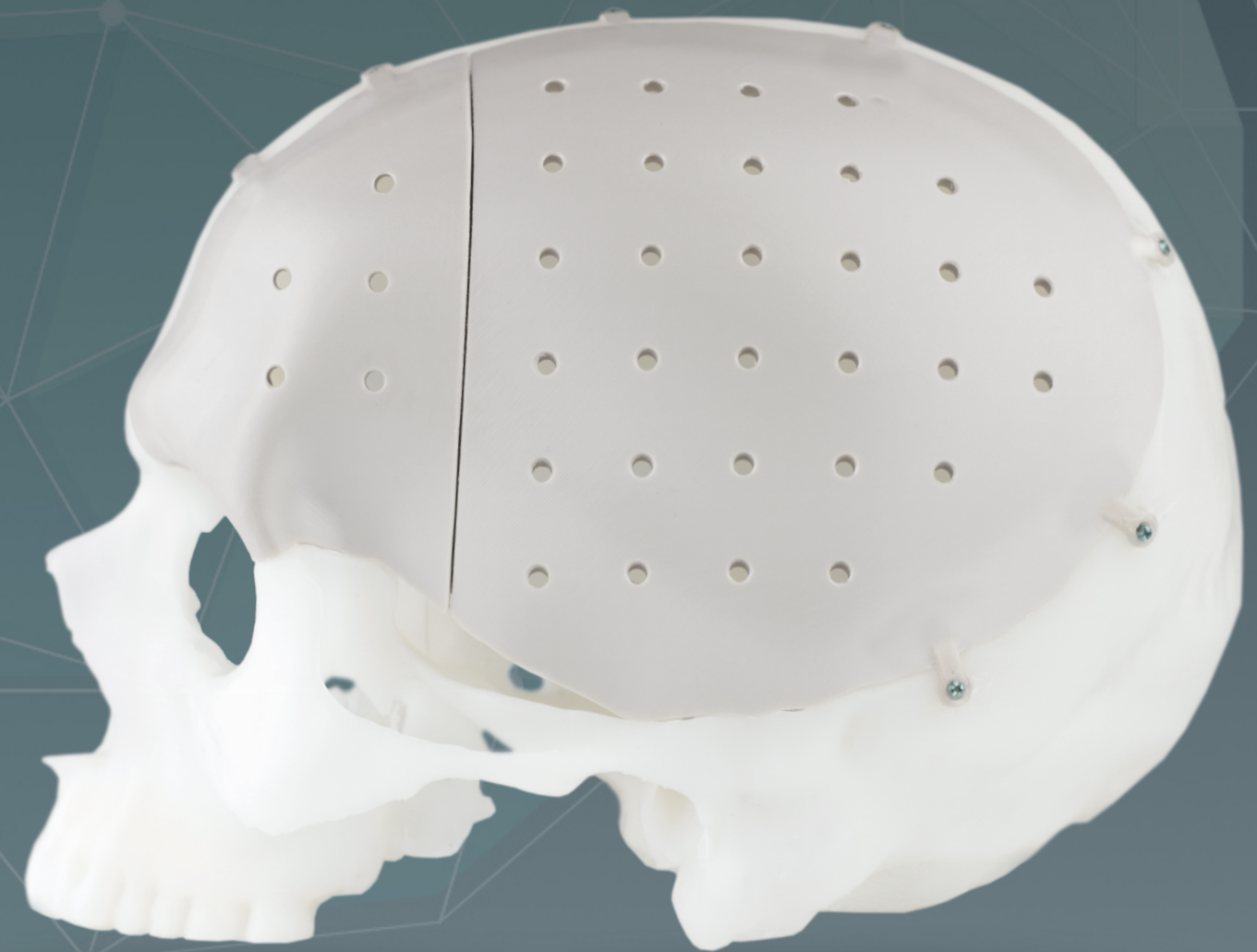
Temporal Cutback - Aides in reducing intraoperative tissue trauma or temporalis muscle damage in the temporal fossa region during the exposure.

Multi-Part Implant - Used when the defect is too large to be filled with a single implant or to simplify the surgery. All Multi-Part implants are manufactured with a lap joint to strengthen the assembly and allow for a precise fit and safe implantation. This feature is available upon request on any implant.

Cranial Implant Utilization & Preparation

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, and adjacent bone).

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



CT Scan Protocol

The Kelyniam specialized CT Scan Protocol ensures that the Customized Craniofacial or Skull Implant will have a “Precise Fit.”

Scanning Parameters

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



Ordering Process

CT Scan of the Patient - The patient must be scanned with Kelyniam's CT Scan Protocol for optimal results. Any scan deviating from this protocol is not recommended.

Upload Patient Data

Option 1
(800) 280-8192

Option 2
Send a request for an upload link and instructions to Info@kelyniam.com

Option 3
If the CT scan cannot be uploaded, please send to the address provided below:

Kelyniam Global
Attn: CAD
97 River Rd
Suite A
Canton, CT 06019



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Ordering Process Continued

CT Data Review

Patient CT data will be reviewed and the defect will be identified by our design team. If the defect cannot be clearly identified, images will be sent to the surgeon or sales representative for additional input. Images can be marked or modified by the surgeon to indicate bone removal, defect location, etc. and sent directly to info@kelyniam.com.

The Kelyniam design team will review the modifications and proceed with the design proposal. In addition, upon request, a WebEx can be scheduled with our design team for surgical planning.

Design Proposal

A design proposal will be sent to the surgeon for electronic signature and should be carefully reviewed. For urgent cases, the design proposal will be sent within 1-2 hours of receiving the patient data to allow for next day delivery. For non-urgent cases, a design proposal and a model of the implant (if requested) can be provided for review before proceeding to production to ensure the surgeon is content with the final product. Our design team is dedicated to creating a true customized prosthetic to provide the best outcome for surgeons and patients.

Final Production

Once the design is finalized and approved by the surgeon, the cranial implant will be shipped either the same or following business day. Our 24-Hour Turnaround service is available for urgent cases across the USA, as well as same day delivery, if needed. Of note, approval of the design must be finalized by 11AM EST for the 24-Hour Turnaround service.

General Contact Information

Customer Service - (800) 280-8192

Fax - (501) 641-2000

"Kelyniam's custom PEEK cranioplasty implant fits like a cork in a bottle. The addition of surgeon-determined cranial fixation tabs shortens operative time and decreases the future potential for hardware failure such as plate loosening or screw back-out. The simplicity of the design allows for a rapid 24 hour production time that results in fast and seamless patient care."

~ Walter A. Hall, M.D., MBA

Professor of Neurosurgery
SUNY Upstate Medical University
Syracuse, New York





Patent Approved
IFS Tabs



ISO
13485:2016
Registered



Cleared as a medical device

K103582
K121755
K182711

97 River Road | Suite A | Canton, CT 06019

800-280-8192 | kelyniam.com | info@kelyniam.com

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.

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