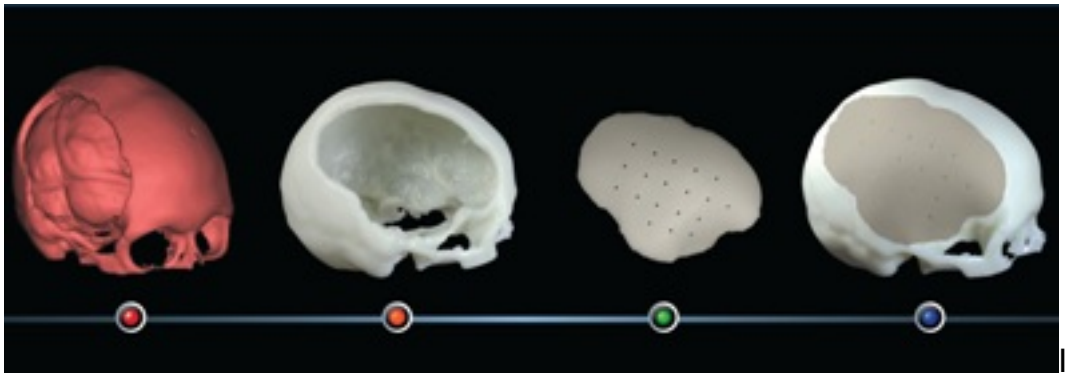
Polymer to be Used in Custom Skull Implants



Invibio Biomaterial Solutions, the market leader in providing PEEK-based biomaterial solutions to medical device manufacturers around the world, announced today that, commencing this summer, Kelyniam Global, Inc. (KLYG) will have commercially available Custom Skull Implants (CSI), manufactured using Invibio's patented PEEK-OPTIMA polymer. Kelyniam, an emerging medical device manufacturer, recently received its FDA 510(k) clearance to market cranial implants.
Designed and manufactured on a patient-by-patient basis, Kelyniam CSI rely on the exceptional strength, bone-like modulus, radiolucency, purity, versatility and guaranteed supply of high quality PEEK-OPTIMA polymer. The Kelyniam CSI is intended to correct or replace bony voids in the cranial skeleton caused by trauma or birth defects while promoting a better anatomic fit versus conventional reconstruction methods and materials.

Invibio's PEEK-OPTIMA polymer features:

- Over a decade of implantation history and use in nearly 3 million implanted devices
- Natural radiolucency and compatibility with medical imaging techniques to allow healing site visualization without artifacts
- Bone-like mechanical properties, exceptional strength and excellent durability

"We chose PEEK-OPTIMA because the product has a long safety record, is compatible with our manufacturing environment and is consistently available on short notice should our customers demand it," said James Ketner, Kelyniam president & CEO.

Streamlined CAD/CAM design and PEEK-OPTIMA processing techniques enables Kelyniam to deliver patient-specific implants in as little as 24 hours from the receipt of CT scans, thus significantly shortening the time between trauma and implantation. Less waiting time means healing can begin more quickly, promoting greater patient satisfaction, shorter hospital stays and minimizing the potential need for subsequent hospital admissions.

A wide range of commercially available fixation systems can be used to attach the Kelyniam CSI to native bone, enabling surgeons to use their preferred fixation device. Because each Kelyniam CSI is created on 3D software and can be surgeon modified before the design is cut, the resulting implant is closely fitted to the defect. Further surgeon modifications are generally not needed and, according to American Journal of Engineering and Applied Sciences operating room time can be reduced by as much as 85% with customized skull implants.

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