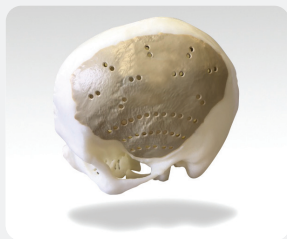


TECHNOLOGY OVERVIEW

PEEK-OPTIMA Natural polymer paving the way for custom CMF implants

- ▶ Can be used in large complex reconstruction cases following trauma, cancer or infection
- ▶ Better patient outcomes with comparable¹ overall costs versus other materials
- ▶ Shorter operating room time, surgical ward and ICU stay^{2,3}



▶ Custom cranial plate made from PEEK-OPTIMA Natural. This product is not available for distribution and implantation, worldwide.

Unique attributes for custom cranioplasty

- ▶ Light-weight, non-metallic alternative to titanium
- ▶ Modulus similar to bone
- ▶ Reduced stress shielding
- ▶ Strong, especially beneficial in the frontal bone region, prone to impact
- ▶ Compatible with CAD/CAM milling processes, for a more precise implant fixation, while still allowing intra-operative fine-tuning of contours
- ▶ Can withstand multiple steam sterilization cycles
- ▶ Radiolucent and artifact-free imaging on CT and MRI, facilitating post-operative monitoring
- ▶ Permeable to ultrasound, allowing visualization of intracranial parenchymal and vascular structures⁴

MATERIAL BENEFITS

Benefits of custom PEEK-OPTIMA Natural implants

- ▶ High aesthetic outcomes and patient satisfaction⁵⁻⁹
- ▶ Good outcomes in large or complex defects¹⁰
- ▶ Radiotherapy can be used in oncology cases⁷
- ▶ Significantly lower complication rates compared to autologous bone²

Challenges with other material options

Autologous bone

- ▶ Non-customizable using patient's own bone
- ▶ Store in abdominal cavity or freeze prior to second surgery
- ▶ Potential for bone resorption resulting in less than ideal aesthetics often leading to a second surgery¹¹

Poly-methyl-methacrylate (PMMA)

- ▶ Exothermic curing process raising potential for thermal necrosis¹²

Titanium (mesh or plate)

- ▶ Challenges with implant exposure^{13,14} temperature sensitivity¹⁵ and artifact generation on MRI¹⁶
- ▶ Association between some forms of metal hypersensitivity and higher rates of titanium plate exposure¹⁷

Lower post-operative complications and implant failures with PEEK implants¹⁸

	PEEK vs. Autologous Bone		PEEK vs. Titanium	
	PEEK	Autologous Bone	PEEK	Titanium
Complication rates	0%	37.0%	16.7%	30.1%
	7.69-fold*		7.87-fold*	
Implant failure rates	0%	10.9%	8.3%	26.5%
	1.74-fold*		5.88-fold*	

*Increased odds ratio over PEEK cranioplasty group

CLINICAL EVIDENCE

Beneficial patient outcomes compared to metal

- ▶ Lower complication rates^{13,19}
- ▶ Lower implant failure rates¹⁹
- ▶ Brain function improvement¹⁴
- ▶ Cosmetic satisfaction¹⁴

Complication and cranioplasty implant failure rates¹⁹

	PEEK-OPTIMA Natural	Titanium	Titanium + Acrylic
Complication rates	0%	80%	43%
Implant Failure rates	0%	60%	43%

Brain function improvement, cosmetic satisfaction and overall lower complication rates¹⁴

	PEEK-OPTIMA Natural	Titanium
Brain function improvement	25.3%	10.9%*
Cosmetic satisfaction	94.7%	80.9%*
Complications		
Overall complication rate	17.3%	31.8%*
Post-operative new epilepsy episodes	4.0%	18.2%*
Post-operative implant exposure	1.3%	9.1%*
Surgical site infections	2.7%	6.4%
Post-operative hematoma	4.0%	7.3%
Subgaleal effusion	8.0%	10.9%
Re-operation rates	1.3%	10.0%*

*p<0.05

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