**PEEK-OPTIMA™ Natural Polymer**

For patient-specific cranio-maxillofacial (CMF) implants

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**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 comparable overall costs versus other materials
- Shorter operating room time, surgical ward and ICU stay

*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 structures

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**MATERIAL BENEFITS**

Benefits of custom PEEK-OPTIMA Natural implants

- High aesthetic outcomes and patient satisfaction
- Good outcomes in large or complex defects
- Radiotherapy can be used in oncology cases
- Significantly lower complication rates compared to autologous bone

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 surgery

**Poly-methyl-methacrylate (PMMA)**

- Exothermic curing process raising potential for thermal necrosis

**Titanium (mesh or plate)**

- Challenges with implant exposure temperature sensitivity and artifact generation on MRI
- Association between some forms of metal hypersensitivity and higher rates of titanium plate exposure

Lower post-operative complications and implant failures with PEEK implants

<table>
<thead>
<tr>
<th>Complication</th>
<th>PEEK vs. Autologous Bone</th>
<th>PEEK vs. Titanium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication rates</td>
<td>0%</td>
<td>7.69-fold*</td>
</tr>
<tr>
<td>Implant failure rates</td>
<td>0%</td>
<td>1.74-fold*</td>
</tr>
</tbody>
</table>

*Increased odds ratio over PEEK cranioplasty group

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**CLINICAL EVIDENCE**

Beneficial patient outcomes compared to metal

- Lower complication rates
- Lower implant failure rates
- Brain function improvement
- Cosmetic satisfaction

Complication and cranioplasty implant failure rates

<table>
<thead>
<tr>
<th>Complication</th>
<th>PEEK-OPTIMA Natural</th>
<th>Titanium</th>
<th>Titanium + Acrylic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication rates</td>
<td>0%</td>
<td>80%</td>
<td>43%</td>
</tr>
<tr>
<td>Implant Failure rates</td>
<td>0%</td>
<td>60%</td>
<td>43%</td>
</tr>
</tbody>
</table>

Brain function improvement, cosmetic satisfaction and overall lower complication rates

<table>
<thead>
<tr>
<th>Complication</th>
<th>PEEK-OPTIMA Natural</th>
<th>Titanium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain function improvement</td>
<td>25.3%</td>
<td>10.9%*</td>
</tr>
<tr>
<td>Cosmetic satisfaction</td>
<td>94.7%</td>
<td>80.9%*</td>
</tr>
</tbody>
</table>

Overall complications

<table>
<thead>
<tr>
<th>Overall complication</th>
<th>PEEK-OPTIMA Natural</th>
<th>Titanium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall complication rate</td>
<td>17.3%</td>
<td>31.8%*</td>
</tr>
<tr>
<td>Post-operative new epilepsy episodes</td>
<td>4.0%</td>
<td>18.2%*</td>
</tr>
<tr>
<td>Post-operative implant exposure</td>
<td>1.3%</td>
<td>9.1%*</td>
</tr>
<tr>
<td>Surgical site infections</td>
<td>2.7%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Subgaleal effusion</td>
<td>8.0%</td>
<td>10.9%</td>
</tr>
<tr>
<td>Re-operation rates</td>
<td>1.3%</td>
<td>10.0%*</td>
</tr>
</tbody>
</table>

*p<0.05
For further information call us toll free at 866-INVIBIO or +44 (0)1253 898000 or please visit our website at:

Invibio.com

REFERENCES


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