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BIOMATERIAL SOLUTIONS

PEEK-OPTIMA™ REINFORCED

CARBON FIBRE REINFORCED COMPOUND

CARBON FIBER-REINFORCED PEEK-OPTIMA® COMPOUND

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Enhanced mechanical strength, bone-like modulus and excellent wear performance for orthopedic implants

Carbon fiber-reinforced PEEK-OPTIMA® compound offers the benefits of unfilled PEEK-OPTIMA with the added advantage of greater mechanical strength and enhanced creep resistance. Additionally, it is a true structural polymer that offers improved wear performance over UHMWPE in articulating joints against various counterfaces.

The compound is composed of short carbon fibers dispersed within a PEEK-OPTIMA polymer matrix. The resulting material has enhanced mechanical and physical properties for more demanding, load-bearing implants and applications requiring blood, bone or tissue contact of more than 30 days.

Carbon fiber-reinforced (CFR) PEEK-OPTIMA compound provides a unique combination of features and benefits, including:

- Excellent wear performance in articulating joints indicates advantage over UHMWPE for joint prostheses and bearing surfaces
- Exceptional fiber-to-matrix bond strength enhances material strength and durability
- Bone-like stiffness can reduce the occurrence of stress shielding
- Proven biocompatibility ensures safe, long term implantation
- Radiolucent on X-rays and CT scans and MRI compatible
- History of use in FDA approved long term implantable devices, in some cases since 1999

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Excellent wear properties in Articulating devices

CFR PEEK-OPTIMA demonstrates excellent wear performance against ceramic, metal and polymeric counterfaces. This wear is significantly lower than that observed for UHMWPE/CoCrMo wear couples under identical conditions.

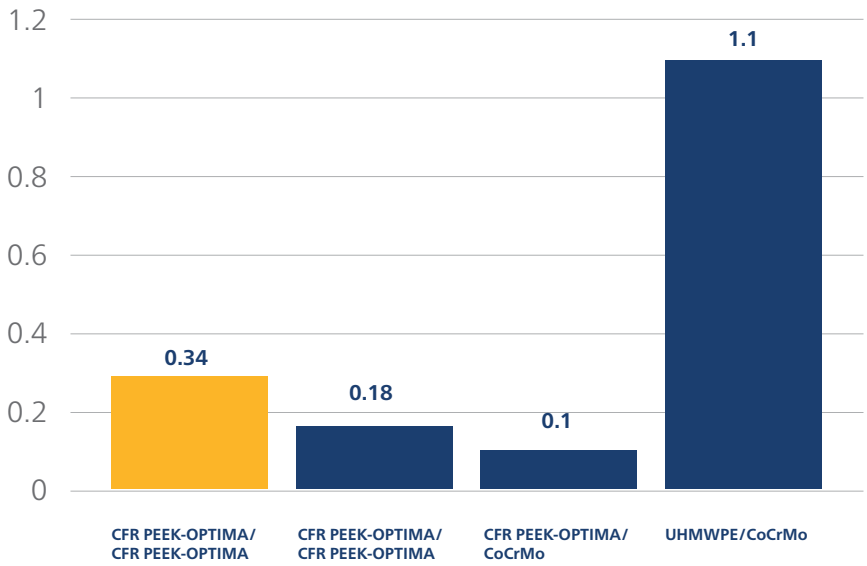
In addition to reduced wear, this material may offer increased implant life span and avoidance of metallic wear debris. Additionally, the improved mechanical properties compared to UHMWPE may allow thinner parts, lower weight prostheses and a greater design flexibility.

Hip simulator testing against ceramic counterfaces confirms that significantly less wear is produced with CFR PEEK-OPTIMA compared to UHMWPE.[1] Furthermore, CFR PEEK-OPTIMA wear debris showed significantly less cytotoxicity compared to metal wear debris in vitro.[2]

Exceptional fiber-matrix bond strength

CFR PEEK-OPTIMA provides an excellent fiber-to-matrix interfacial bond strength. The interfacial strength between carbon and PEEK is at least an order of magnitude stronger than that between carbon fibers and UHMWPE. Additionally, the PEEK-OPTIMA polymer matrix offers superior creep performance compared with UHMWPE.

Total Wear Factor for Carbon Fiber-Reinforced PEEK-OPTIMA Compound Against Various Counterfaces



Scholes, S.C. and Unsworth, A. investigating the potential of implantable grade PEEK as a bearing material against various counterfaces. Presented at: European Society for Biomaterials conference; September 2006; Nantes, France.

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Tailored mechanical properties

The compounding of PEEK-OPTIMA polymer with short carbon fibers significantly increases the strength of the natural unfilled polymer to address the needs of applications requiring a higher stress tolerance.

Especially important for orthopedic applications, the flexural stiffness of CFR PEEK OPTIMA is similar to cortical bone, thus reducing complications associated with stress shielding.

Proven biocompatibility

Extensive testing of CFR PEEK-OPTIMA compound to ISO 10993 standards demonstrated no evidence of cytotoxicity, systemic toxicity, irritation or any macroscopic reaction response. Results have been lodged with the US FDA and can reduce the time and expense of the approval process.

Processing and design flexibility

CFR PEEK-OPTIMA compound is available in granular form for injection molding and extrusion. Established techniques can be used for improving fixation via hydroxyapatite and titanium coatings.

Quality and integrity assured

In compliance with ISO 9000 and ISO 13485 standards, Invibio embraces all the principles of Good Manufacturing Practice (GMP) in relation to the manufacture of CFR PEEK-OPTIMA compound.

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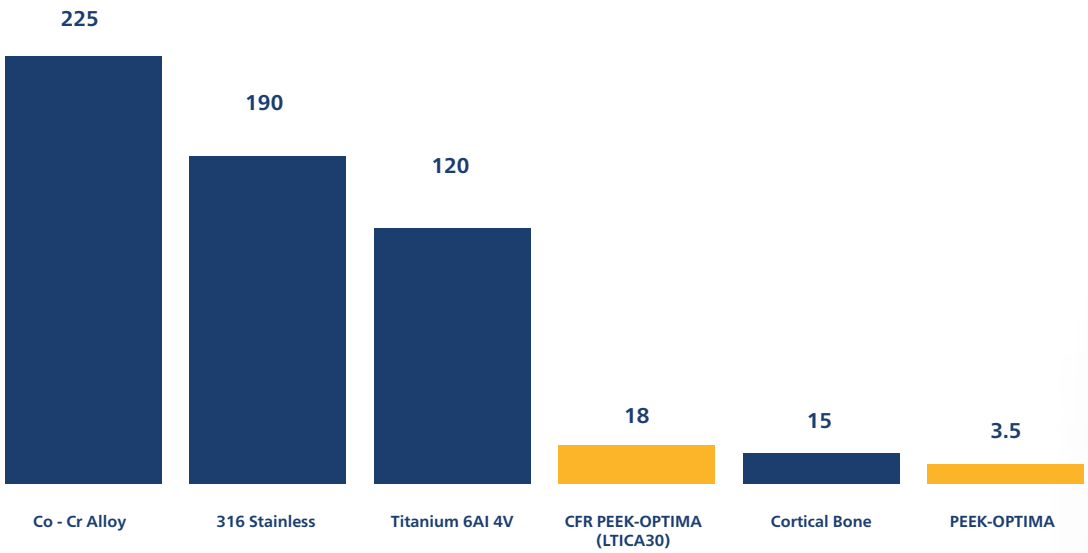
Relative Elastic Modulus of PEEK-OPTIMA and Implantable Metals



Source for metals data: Ratner et al, eds. An Introduct ion to Materials in Medicine. Elsevier Academic Press. Co Cr modulus is an average and approximation.

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