

Carbon Fibre reinforced PEEK medical Implants

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CFM Technology. The Composite Flow Moulding (CFM) process is a single step processing technology that has set new standards in the use of composites. The net-shape technology enables the manufacturing of fastening elements and other load-bearing components made of continuous fibre reinforced thermoplastics. Pultruded rods with an endless fiber content of approximately 60 % by volume and a thermoplastic matrix are heated above the melting temperature. The products are formed by pushing the material into a cavity, while controlling temperature, pressure and progress. The process allows for shaping complex forms while leaving the continuous fibres intact. This results in components with excellent properties with respect to fatigue resistance, flexural strength, shear and tensile strength. A wide range of different fibres and thermoplastics can be processed using the CFM technology, thus enabling application specific material combinations. The implementation of this CFM technology into the medical field using continuous carbon fibres and PEEK as matrix (CF/PEEK) initiated the development of orthopedic implants with outstanding fatigue properties and optimized visualization in various imaging technologies. icotec ag is the industrial realization of this CFM technology that has been developed since 1992 in cooperation with the Chair of Biocompatible Materials Science and Engineering at the Swiss Federal Institute of Technology (ETH Zürich).

General application. High strength composites of various fibres and matrices have a wide range of applications using combinations of the specific advantages. CFM parts are used in industrial application in areas like fast moving parts, aeronautics, sports, racing and some special applications in research where e.g. metals are totally banned.

Medical application. icotec implants are mostly based on ENDOLIGN™ from Invibio. This medical grade material (CF/PEEK) is used for short- and long-term implantations. This material processed with the icotec CFM technology resulted in a number of innovative CF/PEEK implants like the intervertebral spacers, translaminar facet screws, cervical plates and other implants in orthopedics and traumatology.

Mechanical properties. In general the CF/PEEK as used by icotec is one of the composites with the

highest mechanical properties available. Fatigue properties similar to titanium and static strength as with aluminum make it possible to develop products with true weight bearing functions. In an in vivo handling study (tibia osteotomy in sheep) the icotec Snakeplate and a titanium traumatology plate were compared. The callus formation over time and the mechanical quality of the operated tibiae after 8 weeks were equal, indicating good bone osteotomy healing. These results were repeated in a clinical trial treating humerus shaft fractures.

Material modulus. The modulus of the material can be adapted to the product requirements by adjusting the fibre orientation in the implants. In general the modulus can be expected in a range from 30 to 60 MPa. This is much closer to the modulus of bone than for example titanium (>100). The material modulus combined with the fatigue properties makes it possible to develop dynamic implants. Dynamic implants might promote fracture healing or support physiological functioning of structures.

Biocompatibility. The material CF/PEEK is inert causing a non-specific tissue reaction after implantation. In a comparative in vivo study the soft tissue reaction and reaction to debris did not show significant differences to tissue reactions to Titanium implants. The bio-compatibility of icotec implants is excellent and comparable to PEEK implants. To improve bone-implant contact, if required, a range of coatings are available. In vivo studies showed excellent binding between CF/PEEK, the coatings and newly formed bone.

Optimal visualisation of implants. Composite implants with CF/PEEK are radiolucent and, though visible in CT and MRI, do not cause artifacts as metal implants do. These properties allow for better observation of the region of interest and the use of radio-therapies. icotec has an unique patented procedure to visualize the implants. If required, a controlled visibility can be achieved by adding tantalum fibres. The unique combination of these properties allows icotec to use CF/PEEK for implants in spine surgery, orthopedics and traumatology applications.