DiFUSION Technologies, Inc.

ZFUZE™

Biological Fixation, Bony Ingrowth and Visualization

ZFUZE Osteoconductive PEEK Composite

PEEK polymer has long been a preferred material of choice for load-bearing medical devices, particularlly in scaffolds, specifically in the orthopedic spinal fusion market worldwide. PEEK became the material of choice for most surgeons due to its modulus of elasticity being very close to to that of human bone, its radio transparency which allows for easy visualization and its perceived safety due to its inertness and lack of interacton within the body.

Recent studies have now shown that an inert polymer is less suitable than basic titanium implants since fibrous encapsulation occurs around PEEK implants because of its inertness and its recognition by the body as a foreign substance (Rene Olivares-Navarrete et al.; SPINE 40, 6, 399-404). Surgeons have foregone the visualization and modulus of elasticity benefits of plain PEEK for a "negatively charged" surface of titanium which integrates more naturally into the surrounding tissues even though its high rigidity can result in significant damage to adjacent bone.

ZFUZE is a patented PEEK polymer composite which is made by compounding various forms of "negatively charged Zeolites" — Figure 1 — into the PEEK polymer. This fundamentally changes the surface chemistry from inert as in PEEK to negatively charged as in titanium while preserving the visualization, modulus and strength benefits of PEEK.

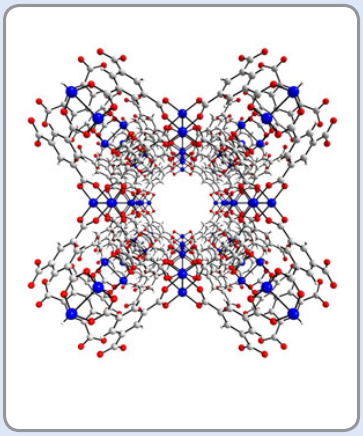


Figure 1.
Aluminum Silicate Zeolite Particle. The negatively charged zeolite matrices act as ideal bonding sites for precursor proteins and osteoblasts cells passing by and give rise to the osteoconductive properties of ZFUZE as shown in Figure 2.

Figure 2.
Negative charging and osteoconductive nature of ZFUZE implant surface.

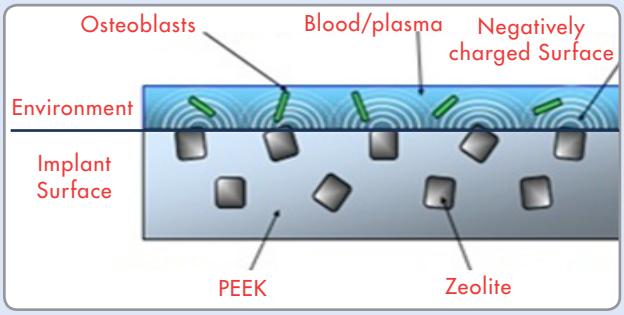
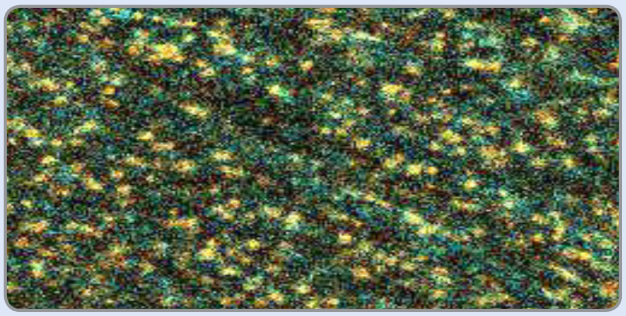


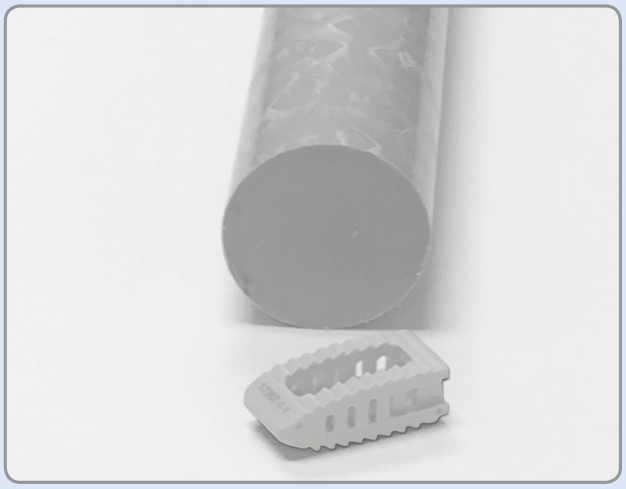
Figure 3 below depicts the dispersion of zeolite (sodium aluminosilicate) on the surface of ZFUZE.

Figure 3.
Al (green) and Si (yellow) EDS maps overlaid onto SEM of ZFUZE (50X).



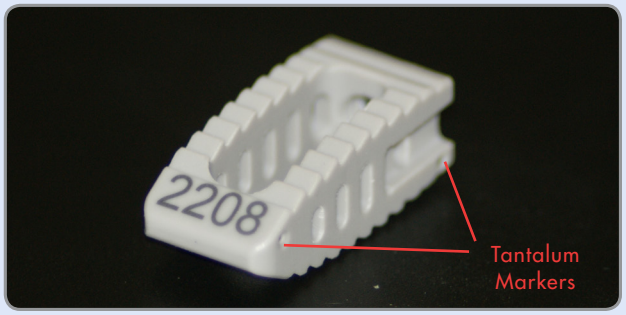
Implants are machined from an extruded rod of the PEEK polymer composite, produced using a patented process.

Figure 4.
ZFUZE in extruded rod form prior to machining of implants.



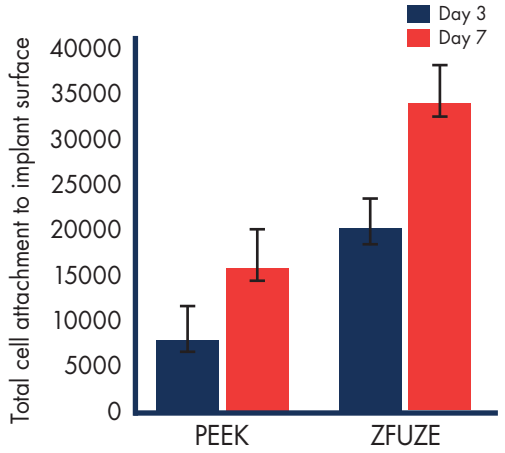
The finished implant is provided with tantalum markers to aid in visualization upon implantation.

Figure 5.
Finished ZFUZE implant with tantalum markers.

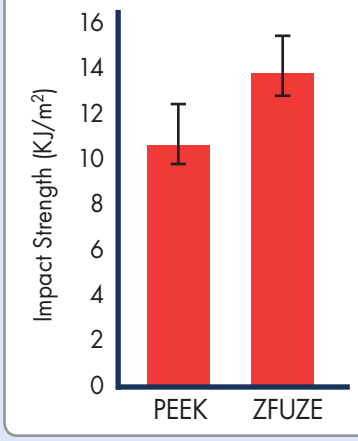


Cellular and Biomechanical ASTM Testing Results

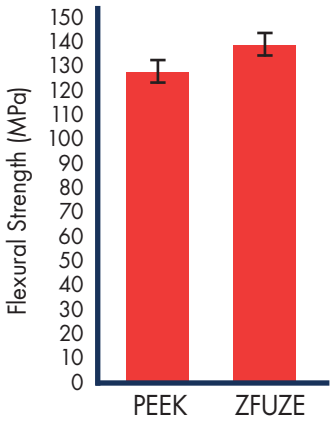
Cell Culture Data - PEEK vs. ZFUZE



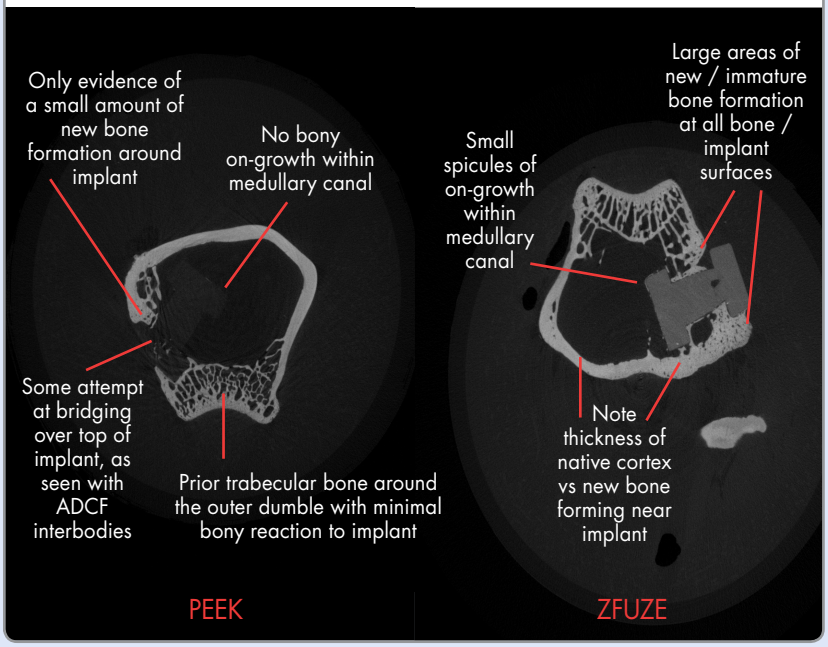
Samples for Izod Testing (ASTM D256)



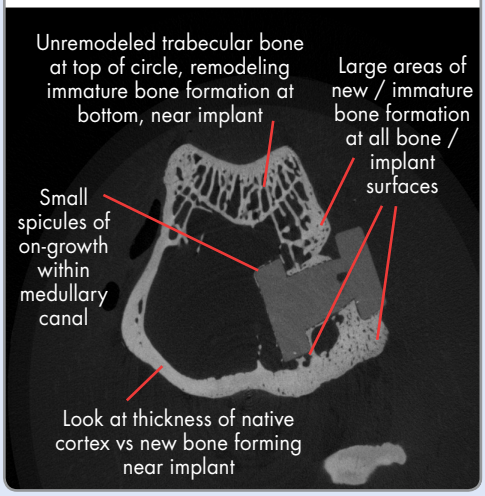
Samples for Flexural Anlaysis (ASTM D790)



Micro-CT Imaging - PEEK vs. ZFUZE



Magnified ZFUZE Micro-CT Image



New bone formation at all bone implant surfaces, currently immature / woven bone given 12-week time period. Clearly shows that body is reacting to implant by trying to incorporate it into bone, rather than fibrous layer or no reaction, as typically seen with plain PEEK.

Biological Fixation, Bony Ingrowth and Visualization

ZFUZE offers the surgeon and patient all the properties and benefits which made PEEK the leading biomaterial in the orthopedic market:

- Ability to verify fusion on radiographs and CT scans
- Easy to remove during revision surgery
- Same modulus as cortical bone — less subsidence in disc space

Our patented process of compounding Zeolite ceramics into PEEK allows for cellular attachment to the negatively charged surface chemistry of ZFUZE, thereby providing a higher degree osteoconduction than outdated titanium implants:

- Bony ingrowth into the Zeolite scaffolds on the surface
- Zeolite attracts and binds precursor cells and proteins to the surface, providing biological fixation of the implant within the graft site
- TITANIUM implants in the interbody spinal space are extremely difficult to remove, unlike ZFUZE and even PEEK

ZFUZE™

For further information call us at 512.863.7777 or please visit our website at:

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