

SN-PEEK COMPOSITE MATERIAL



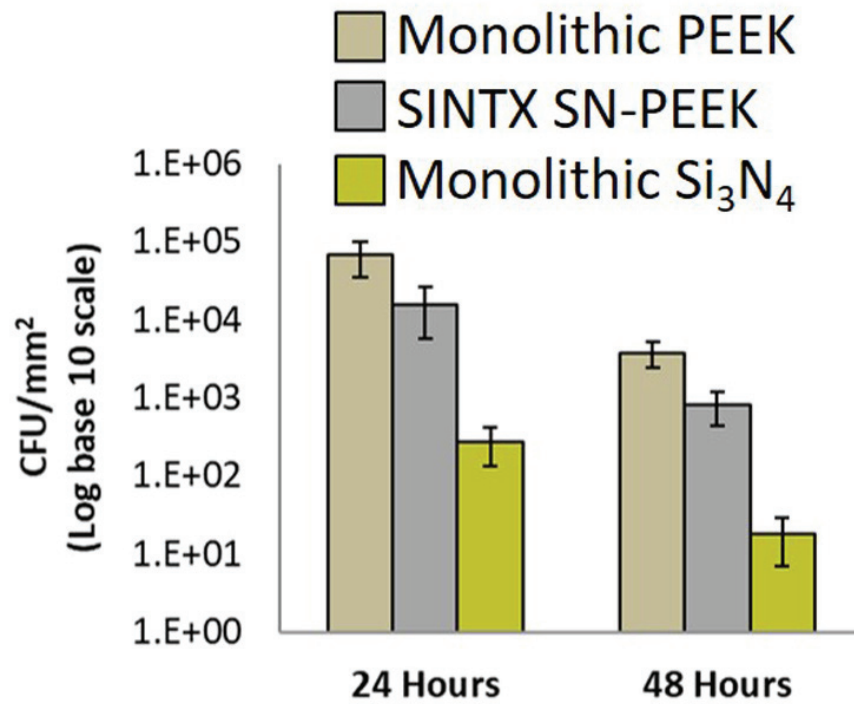
SINTX SN (Silicon Nitride)-PEEK composite combines the unique and beneficial bioactivity of silicon nitride with the familiar fit, feel, and processing properties of conventional polyetheretherketone (PEEK) polymer.^{1,2} This material is produced by compounding an extremely fine particulate form of SINTX AP² Si₃N₄ bioceramic into an implant grade PEEK matrix. Coating delamination concerns are avoided since the bioceramic is uniformly dispersed throughout the polymer volume instead of adhered to the surface. Subsequent forming operations produce new surfaces with the same enhanced properties as the original stock composite, giving device manufacturers design and process flexibility when working with this material. In addition to exhibiting comparable mechanical properties to monolithic PEEK, SN-PEEK has demonstrated improved imaging properties along with resistance to biofilm formation and up regulation of bone cell activity during testing *in vitro*³.

MATERIAL PROPERTIES				
Property	SINTX SN-PEEK	Implant Grade PEEK	Units	Test Method
Specific Gravity	1.614	1.291 ¹ 1.3 ²	- -	ASTM D792 ISO 1183
Tensile Modulus	4306 6036	3600 ¹	MPa MPa	ASTM D638 ISO 527-1,2:2012(E)
Tensile Strength (Yield)	89.7	95 ¹ 100-115 ²	MPa MPa	ASTM D638 ISO 527-1,2:2012(E)
Tensile Elongation (Yield)	3.40%	5.2% ¹	% %	ASTM D638 ISO 527-1,2:2012(E)
Tensile Elongation (Break)	5%	35% ¹ 20-40% ²	% %	ASTM D638 ISO 527-1,2:2012(E)
Flexural Modulus	4340 5985	4000 ¹ 4000-4200 ²	MPa MPa	ASTM D790 ISO 178:210/Amd.1:2013(E)
Flexural Strength (Yield)		150 ¹	MPa	ASTM D790
Flexural Stress at 3.5% strain	144		MPa	ISO 178:210/Amd.1:2013(E)
Flexural Strength (Break)	154	165-170 ²	MPa	ISO 178:210/Amd.1:2013(E)
Flexural Strain (break)	4.30%		%	ISO 178:210/Amd.1:2013(E)
Maximum Compressive Strength	479	135 ²	MPa	ISO 604:2002(E)
Deformation at Max. Comp. Str.	66%		%	ISO 604:2002(E)
Poisson's Ratio	0.4	0.36 ²	-	ASTM D638-14
Notched Izod Impact Strength	4.3	4.5-7.5 ²	kJ/mm ²	ISO 180:2000/Amd.1:2006(E)
Cytotoxicity	In process	Pass ¹		ISO 10993:5
Chemical Characterization	in process	Pass ¹		ISO 10993:18

1 Data obtained from Solvay Zeniva® ZA-500 data sheet (dated July 14, 2015).

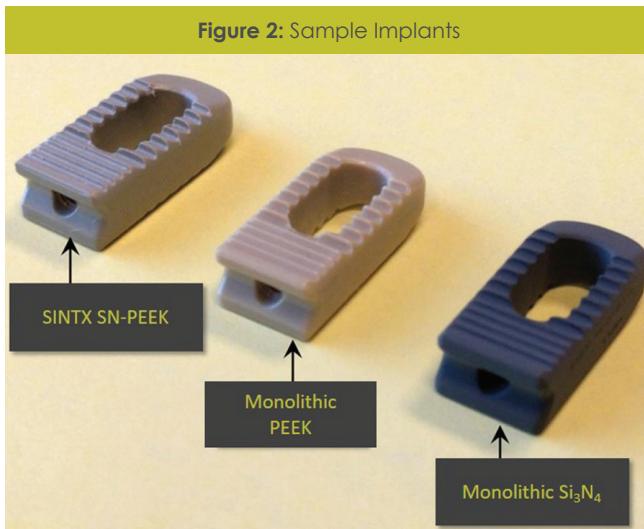
2 Data obtained from Invibio® PEEK-OPTIMA® Natural data sheet (INV-TS-PN-E-0087-A October 2013).

Figure 1: Bacterial Biofilm Formation on Biomaterials



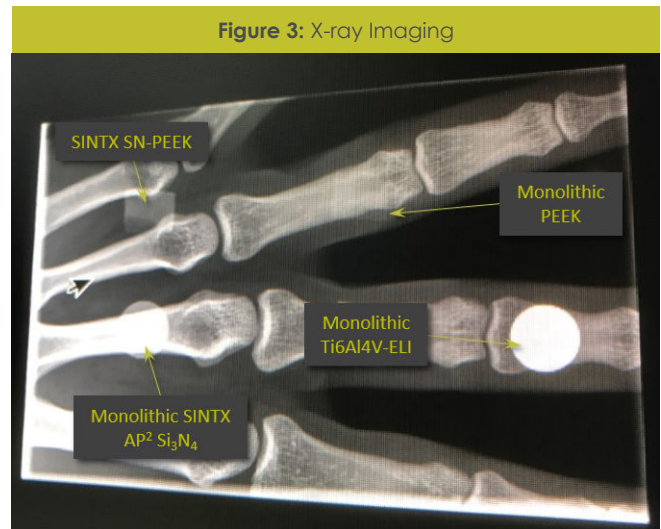
Comparison of *in vitro* *S. epidermidis* biofilm formation on monolithic PEEK, SINTX SN-PEEK composite, and monolithic SINTX AP² Si₃N₄ using the protocol of Bock et al.⁴

Figure 2: Sample Implants



SINTX SN-PEEK composite, PEEK, and monolithic SINTX AP² Si₃N₄ formed into a representative implant geometry.

Figure 3: X-ray Imaging



X-ray radiograph showing various biomaterials beneath a human hand as a demonstration of radiotransparency (adapted from Pezzotti et al.³).

REFERENCES:

1. Pezzotti, G. et al., "Human Osteoblasts Grow Transitional Si/N Apatite in Quickly Osteointegrated Si₃N₄ Cervical Insert," *Acta Biomater.*, 64, 411-420, (2017).
2. Pezzotti, G. et al., "Bioactive Silicon Nitride: A New Therapeutic Material for Osteoarthropathy," *Sci. Rep.*, 7 44848 (2017).
3. Pezzotti et al., *Macromol. Biosci.* 2018, 1800033.
4. Bock et al., *J. Biomed. Mater. Res. A.* 2017, 105(5):1521-1534.