

Material Data Sheet

for: **Pekkton[®] ivory**

1. Composition

Polyetherketoneketone (PEKK)
Titanium Dioxide

2. Physical properties

Glass temperature	T _g = 157 °C	ASTM-D3418
Melting temperature	T _m =363 °C	ASTM-D3418
Color	whitish	

3. Mechanical properties

Young's modulus	5.1 GPa	ASTM-D638
Tensile strength@break	115 MPa	ASTM-D638
Flexural modulus	5.0 GPa	ASTM-D790
Flexural strength@5% strain	200 MPa	ASTM-D790
Hardness	252 MPa	ISO 2039-1

Values for mechanical properties are based on standard geometries.

The values may vary depending on shape, design and processing parameters.

4. Biological testing

Pekkton[®] ivory as base material is tested and found to comply with **USP Class VI** biocompatibility standards. It has met or exceed the requirements of the United States Pharmacopeia for biological tests according to:

Cytotoxicity Elution Test according to USP32:2009 <87> and ISO 10993-5:2009
(Study No.: 110042, BSL Bioservices, DE-82152 Planegg)

Intracutaneous Reactivity according to USP 32<88>
(Study No.: 110043, BSL Bioservices, DE-82152 Planegg)

Accute Systemic Toxicity – System Injection Test according to USP 32<88>
(Study No.: 110043, BSL Bioservices, DE-82152 Planegg)

Muscle Implantation according to USP 32<88>
(Study No.: 110043, BSL Bioservices, DE-82152 Planegg)

5. Sterilization

Due to its high glass transition temperature (157°C) above normal steam sterilization temperatures of 121°C to 134°C and thanks to its natural hydrolysis resistance, Pekkton[®] ivory is particularly suited to steam sterilization without any noticeable changes in mechanical or physical properties.

6. Monitoring

Manufacture, packing and delivery are constantly monitored by the quality management system standards according to ISO 9001 and ISO 13485.

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