

Product Information

**VESTAKEEP® i4 PL**

**IMPLANTABLE GRADE POLYETHER ETHER KETONE PLATES FOR PERMANENT IMPLANTS**



VESTAKEEP® i4 PL are plates based on implantable grade VESTAKEEP® i4 G neat polyether ether ketone resin.

**Proven Biocompatibility of VESTAKEEP® i-Grades**

The extra high purity and extended quality measures make VESTAKEEP® i-Grade materials an excellent choice for permanent implants.

For VESTAKEEP® i4 PL, biocompatibility has been tested according to ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i4 PL complies ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications".

A summary of biocompatibility test results is available upon request.

**Biocompatibility tests available for i4 PL**

STANDARD	DESCRIPTION
ISO 10993-12	GC/MS Fingerprint of extractable organic substances
USP CLASS VI	Acute Systemic Toxicity Intracutaneous Reactivity Muscle Implantation
ISO 10993-5	Cytotoxicity
ISO 10993-10	Irritation: Intracutaneous Reactivity
ISO 10993-10	Sensitization: Maximization test according to Magnusson and Kligman
ISO 10993-11	Subchronic Systemic Toxicity
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Chromosome Aberration test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-6	Test for local effects after Implantation in bone (90 days)

**Delivery of VESTAKEEP® i-Grades**

VESTAKEEP® i4 PL plates have thickness of up to 60 mm, standard width of 500 mm and standard length of 1000 mm.

**Key Features**

**Industrial Sector**

Medical Devices

**Conformity**

Biocompatibility, Medical application

**Delivery form**

Stock shape (rods and plates)

**Additives**

Unfilled

**Resistance to**

Heat (thermal stability), Hydrolysis / hot water, Wear / abrasion, Fatigue resistance, Oil / fuels

**Mechanical properties ISO**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Tensile modulus	<b>580000</b>	psi	ISO 527
Yield stress	<b>15800</b>	psi	ISO 527
Yield strain	<b>4.8</b>	%	ISO 527
Nominal strain at break, tB	<b>&gt;50</b>	%	ISO 527
Izod Impact notched, 23°C	<b>2.62</b>	ftlb/in <sup>2</sup>	ISO 180/1A
Flexural modulus, 23°C	<b>587000</b>	psi	ISO 178

**Thermal properties**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Melting temperature	<b>644</b>	°F	ISO 11357-1/-3
Temp. of deflection under load A, 1.80 MPa	<b>311</b>	°F	ISO 75-1/-2
Temp. of deflection under load B, 0.45 MPa	<b>401</b>	°F	ISO 75-1/-2
Melting Temperature	<b>644</b>	°F	ASTM D 3418

**Physical properties**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Density	<b>1.3</b>	g/cm <sup>3</sup>	ISO 1183
Water absorption	<b>0.4</b>	%	Sim. to ISO 62
Humidity absorption	<b>0.12</b>	%	Sim. to ISO 62
Density	<b>1.3</b>	g/cm <sup>3</sup>	ASTM D 792

**Electrical properties**

	<b>dry</b>	<b>Unit</b>	<b>Test Standard</b>
Relative permittivity, 1MHz	<b>2.8</b>	-	IEC 62631-2-1

**Characteristics**

**Special Characteristics**

Semi-crystalline

**Regulatory**

US Pharmacopeia Class VI conformity

**Color**

Natural color

**Chemical Resistance**

Acid resistance, Alkali resistance, Solvent resistance, Grease resistance, Hydrolytically stable, Oxidation resistance, General chemical resistance