

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.

Custom lengths are also available

The values presented are typical or average values, they do not constitute a specification.

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

	dry	Unit	Test Standard
Tensile modulus	4000	MPa	ISO 527
Yield stress	109	MPa	ISO 527
Yield strain	4.8	%	ISO 527
Nominal strain at break, tB	>50	%	ISO 527
Izod Impact notched, 23°C	5.5	kJ/m ²	ISO 180/1A
Flexural modulus, 23°C	4050	MPa	ISO 178

Thermal properties

	dry	Unit	Test Standard
Melting temperature	340	°C	ISO 11357-1/-3
Temp. of deflection under load A, 1.80 MPa	155	°C	ISO 75-1/-2
Temp. of deflection under load B, 0.45 MPa	205	°C	ISO 75-1/-2
Melting Temperature	340	°C	ASTM D 3418

Physical properties

	dry	Unit	Test Standard
Density	1300	kg/m ³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62
Humidity absorption	0.12	%	Sim. to ISO 62
Density	1300	kg/m ³	ASTM D 792

Electrical properties

	dry	Unit	Test Standard
Relative permittivity, 1MHz	2.8	-	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