

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.

FOR FURTHER INFORMATION PLEASE CONTACT US AT EVONIK-HP@EVONIK.COM
OR VISIT OUR PRODUCT AT WWW.EVONIK.COM/MEDICAL-TECHNOLOGY

Key Features

Industrial Sector

Medical Devices

Delivery form

Stock shape (rods and plates)

Resistance to

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

Conformity

Biocompatibility, Medical application

Additives

Unfilled

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

This information and all technical and other advice are based on Evonik's present knowledge and experience. However, Evonik assumes no liability for such information or advice, including the extent to which such information or advice may relate to third party intellectual property rights. Evonik reserves the right to make any changes to information or advice at any time, without prior or subsequent notice. Evonik disclaims all representations and warranties, whether express or implied, and shall have no liability for, merchantability of the product or its fitness for a particular purpose (even if Evonik is aware of such purpose), or otherwise. EVONIK SHALL NOT BE RESPONSIBLE FOR CONSEQUENTIAL, INDIRECT OR INCIDENTAL DAMAGES (INCLUDING LOSS OF PROFITS) OF ANY KIND. It is the customer's sole responsibility to arrange for inspection and testing of all products by qualified experts. Reference to trade names used by other companies is neither a recommendation nor an endorsement of the corresponding product, and does not imply that similar products could not be used.

* is a registered trademark of Evonik Industries AG or one of its subsidiaries

Evonik Operations GmbH
Smart Materials
High Performance Polymers
 45772 Marl / Germany
 Tel: +49 2365 49-9878
evonik-hp@evonik.com
www.plastics-database.com