

Product Information

VESTAKEEP® i4 R

IMPLANTABLE GRADE POLYETHER ETHER KETONE ROD STOCK FOR PERMANENT IMPLANTS



VESTAKEEP® i4 R is a rod stock based on implantable grade neat polyether ether ketone resin VESTAKEEP® i4 G.

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.

The biocompatibility of VESTAKEEP® i4 R has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

VESTAKEEP® i4 R complies to 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 R

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 R rods are available in different diameters and lengths.

Dimensions of VESTAKEEP® i4 R

Diameter	Standard length*
6 to 20 mm	3000 mm
25 to 60 mm	2000 mm
70 to 100 mm	1000 mm

* Custom lengths are also available

Key Features

Industrial Sector

Medical Devices

Conformity

Biocompatibility, Medical application

Resistance to

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

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	6	kJ/m ²	ISO 180/1A
Flexural modulus, 23°C	4050	MPa	ISO 178
Flexural strength, 23°C	160	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

Relative permittivity, 1MHz

dry

2.8

Unit

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Test Standard

IEC 62631-2-1

Characteristics

Applications

Medical implants

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, Oil resistance, Oxidation resistance, General chemical resistance