Product Information VESTAKEEP[®] iC 4520 R

STOCK SHAPES BASED ON X-RAY OPAQUE POLYETHER ETHER KETONE FOR LONG TERM IMPLANTABLE MEDICAL DEVICES

VESTAKEEP* iC4520 R is a rod stock based on implantable grade polyether ether ketone resin VESTAKEEP* iC4520 G. It contains 20% barium sulphate to render it X-ray opaque.

Proven Biocompatibility VESTAKEEP* iC4520 R is especially designed for long term implantable medical devices.

The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

Biocompatibility of has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

A summary of biocompatibility test results is available upon request.

Biocompatibility reports available for VESTAKEEP* iC4520 R

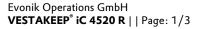
STANDARD	DESCRIPTION
ISO 10993-12	GC/MS Fingerprint of extractable organic substances
USP CLASS VI	Acute Systemic Toxicity Intracutaneous Reactivity Muscle Implantation
ISO 10993-5	Cytotoxicity
ISO 10993-10	Irritation: Intracutaneous Reactivity
ISO 10993-10	Sensitization: Maximization test according 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 (180 days)
ISO 10993-11	Material-mediated pyrogenes

Delivery of VESTAKEEP® i-Grades VESTAKEEP® iC4520 R is supplied as stock shapes with 10 mm and 20 mm diameter and a length of 30000 mm. Other diameters and lengths are possible.

The results shown have been generated from a low number of production lots. Therefore, they are preliminary and not yet the result of a statistical evaluation. Therefore they must not be used to establish specifications.

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



VESTAKEEP®



VESTAKEEP®

Key Features

Industrial Sector Medical Devices

Processing Machining

Delivery form Stock shape (rods and plates)

Optics Opaque Resistance to

Heat (thermal stability), Hydrolysis / hot water, UV / light / weathering

Electrical Insulating

Conformity Biocompatibility, Medical application

Additives Mineral fillers

Mechanical properties ISO	dry	Unit	Test Standard
Tensile modulus	4800	MPa	ISO 527
Yield stress	110	MPa	ISO 527
Yield strain	4.2	%	ISO 527
Strain at break, B	10	%	ISO 527
Izod Impact notched, 23°C	5.2	kJ/m²	ISO 180/1A
Type of failure	С	-	-
Flexural modulus, 23°C	4700	MPa	ISO 178
Flexural strength, 23°C	170	MPa	ISO 178
Thermal properties	dry	Unit	Test Standard
Melting temperature	340	°C	ISO 11357-1/-3
Glass transition temperature, 2 nd heating, onset	145	°C	ISO 11357
Glass transition temperature, 2 nd heating, midpoint	155	°C	ISO 11357
Recrystallization temperature, 10 K/min	285 ^[e]	°C	ISO 11357
Melting Temperature	340	°C	ASTM D 3418
20 K/minute			
Discriminal accounting	dav	11-24	Test Steederd
Physical properties	dry	Unit	Test Standard
Density	1500	kg/m³	ISO 1183



VESTAKEEP[®]

Water absorption	0.4	%	Sim. to ISO 62
Density	1500	kg/m³	ASTM D 792

Characteristics

Applications Medical implants

Special Characteristics

Phosphorus-free, PTFE-free, High impact strength, Semicrystalline, High viscosity, Self-extinguishing

Features

Low odor, Non-corrosive

Color Natural color

Additives Inorganic fillers

Chemical Resistance

Acid resistance, Solvent resistance, Oxidation resistance, Radiation resistance, General chemical resistance

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