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

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/m^2	ISO 180/1A
Type of failure	**C**	-	-
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

e: 20 K/minute

Physical properties	dry	Unit	Test Standard
Density	**1500**	kg/m^3	ISO 1183

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, Semi-crystalline, 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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