

Product Information

VESTAKEEP® iC 4520 G

X-RAY OPAQUE POLYETHER ETHER KETONE FOR LONG TERM IMPLANTABLE MEDICAL DEVICES



VESTAKEEP® iC4520 G is an opaque, natural colored, high viscosity polyether ether ketone (PEEK) resin. It contains 20% barium sulphate to render it x-ray opaque.

Proven Biocompatibility

VESTAKEEP® iC4520 G is especially designed for long term implantable medical devices.

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

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

A summary of biocompatibility is available upon request.

Biocompatibility reports available for VESTAKEEP® iC4520 G

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

Processing of VESTAKEEP® i-Grades

VESTAKEEP® iC4520 G can be processed by common melt processing techniques like injection molding and extrusion.

For injection molding, we recommend a melt temperature between 380°C and 400°C during the injection molding process. The mold temperature should be within a temperature range from 160°C to 200°C, preferably 180°C.

Delivery of VESTAKEEP® i-Grades

VESTAKEEP® iC4520 G is supplied as cylindrical pellets in hobbcocks containing 5 kg or 10kg. Polyethylene bags are used as primary packaging.

Key Features

Industrial Sector
Medical Devices

Processing
Injection molding

Delivery form
Pellets, Granules

Resistance to
Heat (thermal stability), UV / light / weathering

Electrical
Insulating

Conformity
Biocompatibility, Medical application

Additives
Mineral fillers

Mechanical properties ISO

	dry	Unit	Test Standard
Tensile modulus	631000	psi	ISO 527
Tensile strength	12300	psi	ISO 527
Yield stress	12300	psi	ISO 527
Yield strain	4.2	%	ISO 527
Nominal strain at break, tB	10	%	ISO 527
Charpy notched impact strength, +23°C	3.33	ftlb/in ²	ISO 179/1eA
Type of failure	C	-	-

Thermal properties

	dry	Unit	Test Standard
Melting temperature	644	°F	ISO 11357-1/-3
Glass transition temperature, 2 nd heating, onset	293	°F	ISO 11357
Glass transition temperature, 2 nd heating, midpoint	311	°F	ISO 11357
Recrystallization temperature, 10 K/min	545^[e]	°F	ISO 11357
Melting Temperature	644	°F	ASTM D 3418

e: 20 K/minute

Physical properties

	dry	Unit	Test Standard
Density	1.5	g/cm ³	ISO 1183

Water absorption	0.4	%	Sim. to ISO 62
Density	1.5	g/cm ³	ASTM D 792

Rheological properties	dry	Unit	Test Standard
Melt volume-flow rate, MVR	10	cm ³ /10min	ISO 1133
Temperature	380	°C	-
Load	5	kg	-

Characteristics

Applications

Medical implants

Special Characteristics

Phosphorus-free, PTFE-free, High impact strength, Semi-crystalline, High viscosity, MRT compatible, Self-extinguishing

Features

Non-corrosive

Color

Natural color

Additives

Inorganic fillers

Chemical Resistance

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