Product Information

VESTAKEEP® iC 4800 R

STOCKSHAPES BASED ON POLYETHER ETHER KETONE WITH ENHANCED OSSEOINTEGRATION FOR LONG TERM IMPLANTABLE MEDICAL DEVICES

VESTAKEEP® iC4800 R is a rod stock based on implantable grade polyether ether ketone resin VESTAKEEP® iC4800 G. It contains calcium phosphates to enhance osseointegration. It therefore belongs to the VESTAKEEP® Fusion product family.

Biocompatibility

The base resin VESTAKEEP® iC4800 G is especially designed for long term implantable medical devices. The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

The biocompatibility testing program follows ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

Available biocompatibility reports for VESTAKEEP® iC4800 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	Acute Systemic Toxicity
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-11	Subchronic Systemic Toxicity (28 days)
ISO 10993-6	Test for local effects after Implantation in bone (28, 90, 180 days)
ISO 10993-11	Material-mediated pyrogenes

Delivery

VESTAKEEP® iC4800 R is supplied as stock shapes with a diameter of 10 mm and 20 mm with a length of 3000 mm. Further it is supplied with 40 mm diameter with a length of 2000 mm. Other diameters and lengths are possible.

Key Features

VESTAKEEP®

Industrial Sector
Medical Devices

Processing
Machining

Delivery form
Stock shape (rods and plates)

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	**4700**	MPa	ISO 527
Yield stress	**105**	MPa	ISO 527
Yield strain	**4**	%	ISO 527
Nominal strain at break, tB	**10**	%	ISO 527
Izod Impact notched, 23°C	**4.5**	kJ/m^2	ISO 180/1A
Type of failure	**C**	-	-
Flexural modulus, 23°C	**4700**	MPa	ISO 178
Flexural strength, 23°C	**165**	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	**1460**	kg/m^3	ISO 1183
Density	**1460**	kg/m^3	ASTM D 792

Characteristics

Applications
Medical implants

Special Characteristics
PTFE-free, High impact strength, Semi-crystalline, High viscosity, Self-extinguishing

Features
Low odor, Non-corrosive

Color
Grey

Additives
Inorganic fillers

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