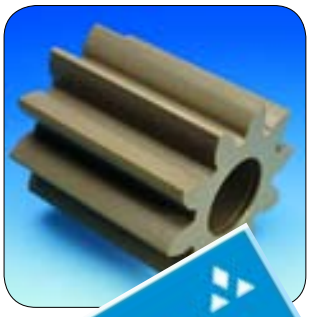
High Purity Plastics



°C
260

KETRON PEEK 1000

Properties:

- unfilled, high crystalline plastic
- high mechanical properties
- resistant up to 260 °C in air, short term up to 300 °C
- very stable
- excellent chemical and hydrolysis resistance up to +200°C
- extremely good radiaton resistance (gamma-Röntgen)
- FDA conformity

KETRON PEEK-TX

Properties:

- PTFE filled
- lower coefficient of friction
- good electrical isolating properties
- FDA conformity

KETRON PEEK 1000 LSG black

Properties:

- black
- FDA conformity
- biocompatibility acc. to ISO 10993
- other colours possible, not acc. to ISO 10993
- resistant to sterilisation, up to 134 °C
- resistant to detergents and desinfection solvents

KETRON PEEK-CLASSIX LSG

Properties:

- biocompatibility acc. to USP class VI
- FDA 21 CFR 177.2415 conformity
- delivered with certificate
- extremely resistant to hydrolysis
- can be sterilised with steam, gamma radiation and ethyleneoxyde
- standard colour is white
- very high mechanical values
- suitable for many medical-technical applications:
  Examples are catheters, medication dosing systems, devices in contact with blood (dialysis), endoscopes, surgical instruments, analytical instruments, measurement probes in the pharmaceutical area and short-term implants.
  Further examples of use are for functional parts in production, filling and packaging plants for pharmaceuticals.

Applications KETRON PEEK 1000:

- back-up rings in seals
- scrapers in the food industry
- medical devices
- bearings in pumps for high pressure
- FDA conformity
- low smoke emission (V-0)

This page gives an overview of standard available high purity semi-finished products. Our machine shop realises your finished product.

Biocompatibility for Life Science Products:
The biocompatibility describes the compatibility of a material to the tissue or the physiological system of the patient. The assessment is performed using various tests acc. to USP (US Pharmacopoeia) Claas VI or acc. to ISO 10993.
Resistance to different sterilisation procedures and chemicals: multi-ple-use equipment in medical technology has to have good resistance towards preparatory procedures such as sterilisation and disinfection. The requirements are best met with high-performance plastics.

The table below gives a summary of the FDA CFR 21, ISO10993 and USP Class VI materials.

Applications in food/pharma technologies

Material	*DIN description*	*FDA conformity*	*USP class VI conform*	*ISO 10993*	*Sterilisation*	
					Steam 134 °C	*Gamma radiation*
KETRON PEEK-1000 LSG BLACK	PEEK	X		X	+	+
ERIFLON PTFE	PTFE	X			+	-
RX® PES-1000	PES-1000	X			0	+
RADEL PPSU-1000	PPSU-1000	X	X		+	+
PSU-1000	PSU	X	X		0	+
PVDF	PVDF	X			+	+
PC-1000	PC-1000	X			-	+
ERTALON 66SA	PA 66	X			-	0
ERTALYTE	PETP	X			-	+
ACETRON LSG	POM-C	X			0	-
MULTILENE	HMPE	X			-	0
RX® MULTILENE PP-FG (food grade)	PP (stab)	X			0	-
KETRON PEEK-1000	PEEK	X	-	X	-	
KETRON PEEK-CLASSIX LSG	PEEK	X	X	X	+	+

X FDA conformity and biocompatibility / + resistant / 0 medium resistant / - not resistant

We produce your product in our modern production plant.

KETRON PEEK-CLASSIX LSG

for medical-technical applications

KETRON PEEK-CLASSIX LSG is an ultra-high performance biocompatible thermoplastic, the mechanical properties of which are comparable with those of KETRON PEEK-1000 and KETRON PEEK-1000 LSG BLACK.

Polyaryletherketone belongs to the group of polymers which have the best chemical resistance and biocompatibility. It shows a particularly good combination of strength, rigidity, thoughness and hardness, which proves ideal for medical-technical applications.

The polymer can be processed and shaped using customary processes, such as injection moulding, extrusion, machining and compression moulding. This gives manufacturers of medical products and applications wide-ranging flexibiity in design and manufacture.

Main characteristics

- extremely good chemical resistance
- mechanical strength
- dimensional stability
- excellent abrasion and impact strength
- can be frequently and repeatedly sterilised with conventional methods (hot steam, gamma radiation, plasma and ethylene oxide) without interfering with the mechanical properties
- extreme resistance to hydrolisis, even at high temperatures
- can be produced as thin as wall tubes
- standard colour is currently creamy-white, further colours and modifications upon request

Applications

KETRON PEEK-CLASSIX LSG is suitable for many medical-technical applications. Examples are catheters, medication dosing systems, devices in contact with blood (dialysis), endoscopes, surgical instruments, analytical instruments, measurement probes in the pharmaceutical area and short-term implants. Further examples of use are for functional parts in production, filling and packaging plants for pharmaceuticals.

Specifications

The basic prerequisites for the medical-technical area have been demonstrated and are, of course, satisfied by KETRON PEEK-CLASSIX LSG with regard to FDA conformity and biocompatibility testing according to USP. In addition, each raw material batch undergoes cytotoxicity testing. Semi-finished goods are also tested for cytotoxicity according to ISO 10993 after the raw material stressing processes of extrusion and tempering for each production batch. In this way, the medical device industry has a highly qualified product at its disposal, which includes development safety and reliability.

KETRON PEEK-CLASSIX LSG is suitable for medical-technical applications with less than 30 days blood contact. It is unsuitable, however, for applications in permanent implants, which are in contact with blood or tissue for longer than 30 days.

RX® MULTILENE PP-FG

dimensionally stable and light weight.

Resistant to chemicals with stable colour.

Sterilisation containers, eg. for surgical instruments have to provide high dimensional stability, especially throughout repeated sterilisation cycles.
Due to a special stabilisation process, RX® MULTILENE PP-FG shows a better resistance to higher temperatures than standard polypropylene. Compared to other materials, eg. stainless steel and PTFE, RX® MULTILENE PP-FG possesses a much lower density which results in a reduced weight of the component parts. Standard colour is white, however, other colours can be produced according to customer preferences.

Preferred fields
Medical technology and food processing

Applications
Surgical trays, surgical related equipment, implant trials

Properties
- good resistance to cleaning agents and disinfectants
- can be repeatedly sterilised with hot steam
- high dimensional stability
- good machinability
- laser marking possible
- FDA conformity of raw material and colour pigments

Very stable after exposure to chemicals
Exposure in two different chemical systems for cleaning and hot steam autoclaving:
- Ecolab chemistry
- Boxer chemistry
- 300 cycles of exposure

The comparison between RX® MULTILENE PP-FG and RX® MULTILENE PP shows good resistance to chemical agents. Minimal property variation of RX® MULTILENE PP-FG in the Ecolab and Borer tests.

- no optical changes
- no serious changes in mechanical properties

RX® PP layerpads

innovation for your sterilisation process!

Advantages:

- Longer lifetime thanks to higher HDT
- Increased rigidity with higher temperatures
- CNC-made holes: no burrs or permanent distortion with die-cutting
- Possibility to obtain with 1 structured side, preventing sticking together of the sheets when loaded automatically
- FDA-compliant: suitable for direct contact with foodstuffs
- Thickness: 1 - 5 mm
- Max. width: 1500 mm

In order to offer our customers a solution for the restricted resistance to sterilisation cycles, ERIKS has developed 2 special types of materials:

- RX® PPH-0: special granulated polypropylene with improved mechanical properties
- RX® PPH-2: polypropylene with 30% talcum for 130°C

Properties	*Test Methode*	*RX® PPH-2*	*RX® PPH-0*	*RX® PPH*	*Unit*
Density	ISO 1183	1,09	0,91	0,91	g/cm^3
Flexural Modulus (23°C)	ISO 178	2800	2200	1150	MPa
Tensile Strength	ISO 527	40	40	32	MPa
Impact Strength	ISO 179-1	1,85	2,6	7	KJ/m^2
Hardness	ISO 868	80	80	70	Shore D
Vicat Softening Temp.	ISO 306/A	160	160	90	°C
HDT at 0,45 MPa	ISO 75/B	140	130	86	°C
HDT at 1,8 MPa	ISO 75/A	110	81	53	°C
FDA		Yes	Yes	Yes	compliancy