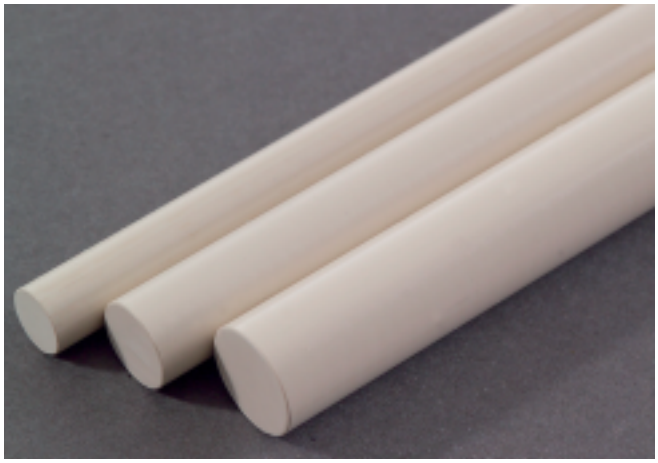
TECAPEEK Classix for medical-technical applications



TECAPEEK Classix is an ultra-high performance biocompatible thermoplastic, the mechanical properties of which are comparable with those of TECAPEEK and TECAPEEK MT.
Polyaryletherketone belongs to the group of polymers which have the best chemical resistance. It shows a particularly good combination of strength, rigidity, toughness and hardness, which proves ideal for medicinal-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 flexibility 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 hydrolysis, even at high temperatures
- Can be used to manufacture thin wall thicknesses
- Standard colour is currently creamy-white, further colours and modifications upon request.

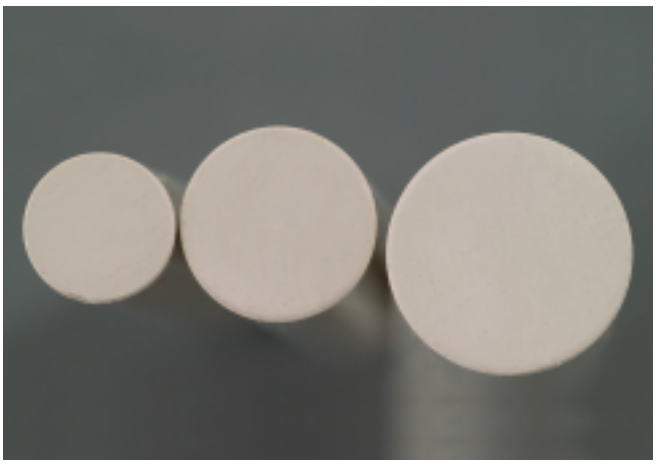
Application examples

TECAPEEK Classix is suitable for many medical-technical applications. Examples are catheters, tubes (MIC), medication dosing systems, devices in contact with blood (dialysis), laparoscopes, 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 TECAPEEK Classix with regard to FDA conformity and biocompatibility testing according to USP. In addition, each raw material batch undergoes cytotoxicity testing. Furthermore, the semi-finished goods are also tested for cytotoxicity according to ISO 10993 after the 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.

TECAPEEK Classix 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. For requirements which go beyond this, PEEK Optima™ is available from Invibio® Ltd.



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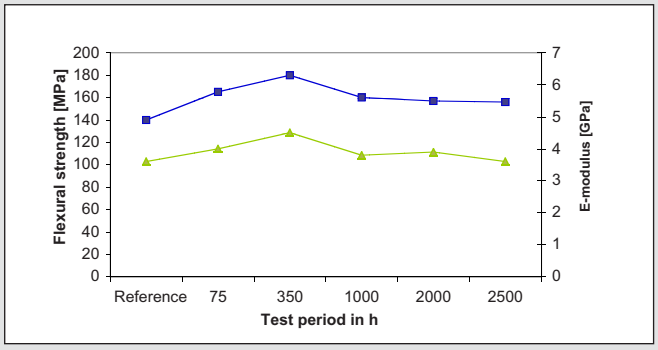
Technical Properties

Technical Properties	Units	TECAPEEK Classix
DIN designation		PEEK
Density (ASTM D 792, DIN 53 479)	ρ g/cm³	1,38
Tensile strength at break (ASTM D 638, DIN EN ISO 527)	σ_S MPa	95
Elongation at yield (ASTM D 638, DIN EN ISO 527, ASTM D 1708 (a))	ε_R %	>25
Flexural strength (ASTM D 730, DIN EN ISO 178)	σ_3 MPa	160
Modulus of elasticity after flexural test (ASTM D 790, DIN EN ISO 178)	E_B MPa	4200
Hardness (Ball-pressure: ISO 2039/1, Shore D: ASTM D 2240, DIN 53 505 (d), Rockwell: ASTM D 785 , ISO 2039/2 (r), Other: ASTM D 785 (a), DIN 43 456 (s))	H_K MPa	
Impact strength (DIN EN ISO 179, Izod: ASTM D 256, DIN EN ISO 180 (i), Charpy: DIN EN ISO 179 21, Notched impact: DIN 53 456 (k))	a_n kJ/m²	
Glass transition temperature (DIN 53 736)	Tg °C	343
Heat distortion temperature (DIN 53 461) acc. to ISO R 75 process A	HDT/A °C	143
Service temperature short-term permanent	°C °C	
Thermal conductivity (23 °C)	λ W/(K.m)	
Coefficient of linear expansion (23 °C, ASTM D 696, DIN 53 752, ASTM E 831)	α 10^{-5} 1/K	
Specific volume resistance (ASTM D 257, EC 93, DIN IEC 60093)	ρ_D Ω · cm	
Moisture absorption in standard climate 23 °C / 50% rel. humidity (DIN EN ISO 62)	W(H_2O) %	
Flammability acc. to UL standard 94		

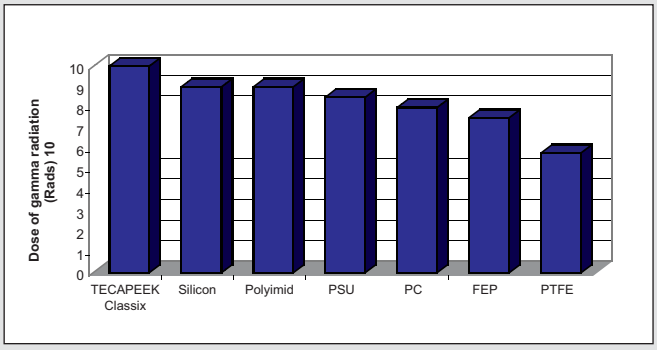
** expected values

Comparison of the areas of application and specifications of TECAPEEK Classix, TECAPEEK MT, and TECAPEEK:

	Medical-technical areas of application	Conformity Delimitation
TECAPEEK Classix	Delivery systems such as e.g. stent balloons, catheters, tubes. Applications in contact with medicines and blood (dialysis). Short-term implants in dental applications (max. 30 days in contact with tissue). Applications in neurology, urology/gynaecology and pharmacy	| FDA 21 CFR 177.2415 | FDA 21 CFR 177.3297 (pigments) Biocompatibility tests: | USP class VI: intracutaneous reactivity, short-term implantation (repetition on raw material), cytotoxicity (each raw material batch) | ISO 10993: General toxicology, sensitisation, cytotoxicity (each production batch of semi-finished goods)
	–> intrinsic medical-technical applications; max. 30 days tissue contact	
TECAPEEK MT	Laparoscopes Instrument handles Surgical tools Endoscopes	| FDA 21 CFR 177.2415 | FDA 21 CFR 178.3297 (pigments) Biocompatibility tests: | ISO 1099 Test on semi-finished goods): Cytotoxicity, intracutaneous reactivity, haemocompatibility, irritation and sensitisation
	–> paramedical applications; limited tissue contact up to max. 24 hours	
TECAPEEK	Equipment, analysis: Sterilisation equipment Chromatography components Casings, pumps, valves Tube connections Dialysis accessories	| FDA 21 CFR 177.2415
	–> extra-medical applications; no direct tissue contact	



The material excels by its extreme resistance to hydrolysis. The graph shows the mechanical properties of TECAPEEK Classix over stress periods of differing length (hot steam at 200 °C and 14 bar pressure).



TECAPEEK Classix has increased resistance to gamma radiation compared to other plastics.

Information concerning the exclusion of liability and Terms and Conditions of Delivery can be found in our Semi-finished products catalogue or under www.ensinger-online.com.

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