

TECAPEEK™

Medical Materials

TECAPEEK™ high performance polymer has successfully replaced glass, stainless steel and titanium in a growing range of medical applications. The material's exceptional combination

of properties allow engineers and designers the ability to create cost-effective, innovative parts that exhibit outstanding wear, heat, electrical and chemical resistance.

The TECAPEEK™ family of materials for medical applications are:

- **TECAPEEK™ MT, unfilled pigmented medical grade PEEK™.**
- **TECAPEEK™ XP98, compression molded 30% carbon fiber filled PEEK™ (isotropic properties).**
- **TECAPEEK™ MT CF30, extruded 30% carbon fiber filled PEEK™.**
- **TECAPEEK™ Classix™, ISO10993 certification by resin and extrusion lot for 30 days contact.**
- **TECAPEEK™ Classix™ XRO-20 radio opaque grade with 20% BaSO₄ added.**

The TECAPEEK™ family of high performance plastics are highly effective in the creation and manufacture of high quality medical instruments. Five separate grades, each with qualities to meet a wide range of requirements for the engineer and product designer.

TYPICAL PROPERTY VALUES

PROPERTIES	ASTM Test Method	Units	TECAPEEK™	TECAPEEK™ MT	TECAPEEK™ MT CF 30	TECAPEEK™ CLASSIX	TECAPEEK™ CLASSIX XRO	TECAPEEK™ XP98	TECAPEEK™ XP98 XRO
PHYSICAL	Density	D792	lbs/in ³	0.0477	0.0477	0.052	0.0499	0.0596	0.0517
	Specific Gravity	D792	gm/cm ³	1.3	1.3	1.41	1.38	1.65	1.43
	Water Absorption, @24 hours, 73°F	D570	%	0.1	0.1	0.06	0.1	-	0.052
	@Saturation, 73°F	D570	%	0.5	0.5	-	0.5	-	-
MECHANICAL	Tensile Strength @ yield, 73°F	D638	psi	14,000	13,775	27,000	13,775	11,600	21,960
	Tensile Modulus 1% Sec 73°F	D638	psi	522,100	435,000	1,885,400	430,000	725,000	1,280,000
	Elongation, Yield 73°F	D638	%	4.9	-	-	-	-	-
	Elongation Break 73°F	D638	%	50	25	1.1	25	2	1.5
	Flexural Strength 73°F	D790	psi	27700	27,000	46,100	27,000	-	32,610
	Flexural Modulus 73°F	D790	psi	530,000	595,000	1,850,000	609,000	580,000	1,500,000
	Compressive Strength 73°F	D695	psi	17,100	16,900	34,800	16,900	-	25,694
	Shear Strength Ultimate 73°F	D3846	psi	7,600	7,500	14,100	7,500	-	13,000
	Izod Impact, Notched 73°F	D256	ft-lbs/in	1.55	1.2	0.9	1.2	-	0.69
	Rockwell Hardness 73°F	D785	-	M99	M99	M107	M99	-	M97
	Limiting PV 2 68°F 1200 in/min	-	psi fpm	170,000	-	385,000	-	-	-
	Coefficient of Friction @ 68°F	-	-	-	-	-	-	-	-
	1200 in/min, 155 lbs load	-	-	0.18	-	0.22	-	-	-
THERMAL	Heat Deflection Temperature @ 264psi	D648	°F	320	320	600	320	-	600
	Maximum Continuous use Temperature	-	°F	500	500	500	500	500	500
	Melting Point	-	°F	644	644	644	644	644	644
	Coefficient of Linear Thermal Expansion	D696	in/in/°F	2.6x10 ⁻⁵	2.6x10 ⁻⁵	0.8x10 ⁻⁵	2.6x10 ⁻⁵	-	0.8x10 ⁻⁵
	Thermal Conductivity	C177	Btu-in/hr-ft ² -F	1.7	-	6.37	-	-	-
	Flammability	UL94	-	V-O	V-O	V-O	-	-	-
ELECTRICAL	Volume Resistivity	D149	ohm-cm	4.9x10 ¹⁶	10 ¹⁶	-	-	-	-
	Surface Resistivity	D257	ohm/square	1x10 ¹⁶	10 ¹⁶	-	-	-	-
	Dielectric Strength	D257	V/mil	190	200	-	-	-	-

This information is only to assist and advise you on current technical knowledge and is given without obligation or liability. All trade and patent rights should be observed. All rights reserved. Data obtained from extruded shapes material. TECAPEEK™ - Ensinger Industries Inc. PEEK™ - Victrex CLASSIX™ - Invibio

MATERIAL AVAILABILITY

Rods: Diameters: 3/16" to 4-3/4" diameter, 10' Length
5" and greater diameter, 5' Length

Plates: 1/4" to 4" thickness inclusive are 2' x 4'



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Medical Materials

TECAPEEK™ grades are characterized by high strength, extreme resistance to hydrolysis and resistance to ionizing radiation. All conventional sterilization methods are compatible. The above medical grades are supported with biocompatibility testing to the ISO10993 matrix to support their use in contact with blood and tissue for 24 hours or less. Additionally, Ensinger is an authorized converter for Invibio's PEEK™ Classix™ resin. PEEK™ Classix™ is tested by resin lot to support contact with the patient for up to 30 days.



Application showing the use of TECAPEEK™ in an endoscopic surgical device.

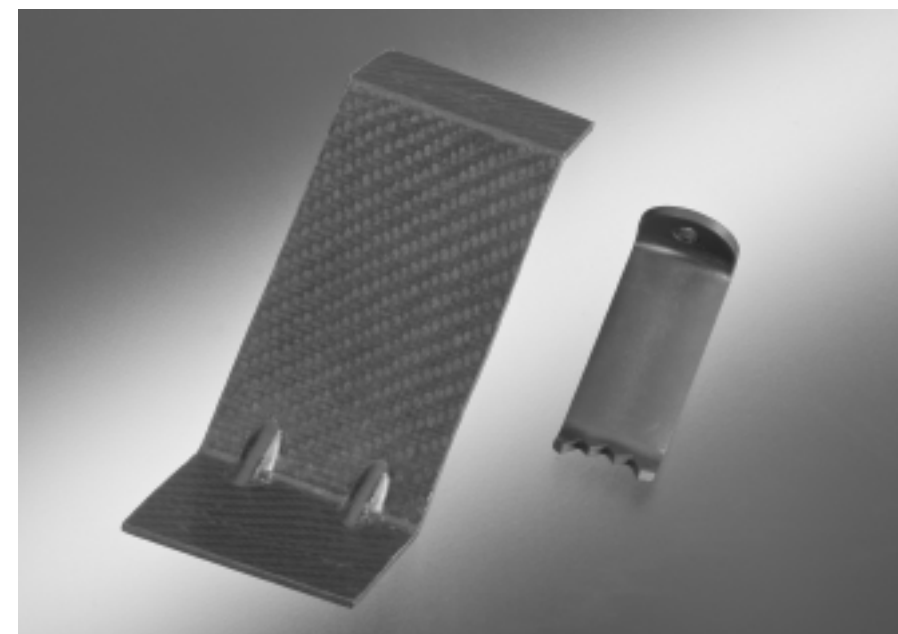
TECAPEEK™ MT

Offered in colors and in natural for the purposes of instrument identification, or for use in setting up the equipment in preparation for machining Invibio PEEK™ Optima™ implants. The machining properties are the same, but the colored rod will eliminate the possibility of mixing the set-up parts with the actual implant parts.



TECAPEEK™ XP98 and MT CF30

Both grades are reinforced with 30% carbon fiber and differentiated by their processing methods. Plastics as well as carbon fiber are radiolucent which make these materials ideal for the higher modulus requirement of target devices for internal fixation bone trauma nails and plates. Both materials are offered in standard shapes with TECAPEEK™ XP98 also available as a neat net shape and TECAPEEK™ MT CF30 as an injection molded part by Ensinger Putnam Precision Molding.



TECAPEEK™ grades are available in standard, custom near net shapes and finished molded parts. One material for many processes provides more flexibility for scale up without a formal material change.

TECAPEEK™ Classix™ and Classix™ XRO™-20 Radio Opaque

These materials are offered for extended time contact with the patient and are tested by resin lot with an additional cytotoxicity test by extrusion lot. A typical extended contact application would be temporary dental implants. Since plastics are typically transparent to X-rays, the XRO formulation allows oral surgeons to see the orientation of the temporary abutment by reflecting the X-rays, thus making the part visible.



TECAPEEK™ Classix™ XRO™ Radio Opaque materials are clearly visible on X-rays.

MRI Imaging and Artifact Concerns

Ensinger has tested various filled TECAPEEK™ grades to determine issue of image artifacts when used as components within and just outside MRI coils. A data base of image testing results are available for discussion for these grades as well as other Ensinger TECA-grades.

Processing

Ensinger Inc. is unique in offering extrusion, compression molding and injection molding processes for our proprietary line of TECAPEEK™ and other medical grade materials. TECAPEEK™ shapes are extruded at our facilities in Nufringen, Germany as well as Washington, Pennsylvania. Ensinger Special Polymers compression molds basic and custom near net shapes in Houston, Texas. Ensinger Putnam Precision Molding offers molding services for high end thermoplastic resins, and has been an end point for process conversion of higher volume application requirements that evolved from lower volume machined clinical trials and initial product launches.