

# 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% BaSO<sub>4</sub> 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   |
|-------------------|---|-------|------------------------------|----------------------|----------------------|----------------------|-----------------------|----------------|----------------------|
| <b>PHYSICAL</b>   | Density                                 | D792  | lbs/in <sup>3</sup>          | 0.0477               | 0.0477               | 0.052                | 0.0499                | 0.0596         | 0.0517               |
|                   | Specific Gravity                        | D792  | gm/cm <sup>3</sup>           | 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                   | -              | -                    |
| <b>MECHANICAL</b> | 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                 | -                     | -              | -                    |
| <b>THERMAL</b>    | Heat Deflection Temperature @ 264psi    | D648  | -                            | 320                  | 320                  | 600                  | 320                   | -              | 600                  |
|                   | Maximum Continuous use Temperature      | -     | °F                           | 482                  | 482                  | 482                  | 482                   | 482            | 482                  |
|                   | Melting Point                           | -     | °F                           | 644                  | 644                  | 644                  | 644                   | 644            | 644                  |
|                   | Coefficient of Linear Thermal Expansion | D696  | in/in/°F                     | 2.6x10 <sup>-5</sup> | 2.6x10 <sup>-5</sup> | 0.8x10 <sup>-5</sup> | 2.6x10 <sup>-5</sup>  | -              | 0.8x10 <sup>-5</sup> |
|                   | Thermal Conductivity                    | C177  | Btu-in/hr-ft <sup>2</sup> -F | 1.7                  | -                    | 6.37                 | -                     | -              | -                    |
|                   | Flammability                            | UL94  | -                            | V-O                  | V-O                  | V-O                  | -                     | -              | -                    |
| <b>ELECTRICAL</b> | Volume Resistivity                      | D149  | ohm-cm                       | 4.9x10 <sup>16</sup> | 10 <sup>16</sup>     | -                    | -                     | -              | -                    |
|                   | Surface Resistivity                     | D257  | ohm/square                   | 1x10 <sup>16</sup>   | 10 <sup>16</sup>     | -                    | -                     | -              | -                    |
|                   | Dielectric Strength                     | D257  | V/mil                        | 190                  | 200                  | -                    | -                     | -              | -                    |

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### 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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# TECAPEEK™

## 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.

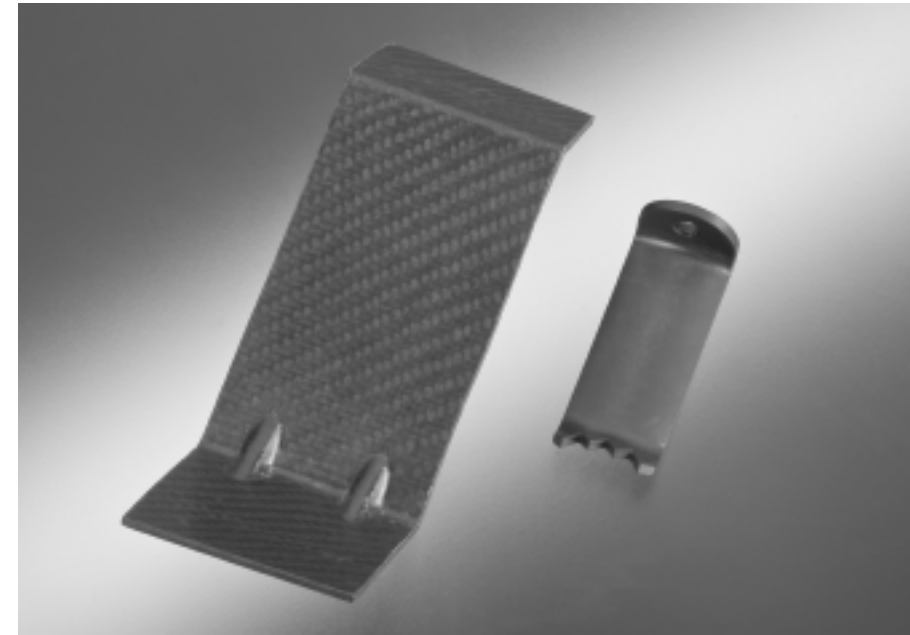
### TECAPEEK™ MT

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.