



TRINSEO™

Fast Facts



Glass-Filled Polycarbonate Resins for Medical Applications

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Trinseo's CALIBRE™ 5000 Series is our portfolio of glass-filled polycarbonate medical resins for the medical devices industry. This series of medical resins offers valued design freedom by providing a balance of flexural strength and stiffness, dimensional stability, and practical toughness for the most demanding applications. The Trinseo difference is comprehensive ISO10993 biocompatible test support data, robust lot traceability and a strict management of change process that supports our customer's compliance to ISO13485 requirements throughout their product life cycle.

Advantages and Benefits

Customized Structural Strength

- Trinseo's glass-filled resins can be custom formulated to meet specific needs of an application with varying glass content up to 40 percent to achieve desired results (See chart on the following page.) The custom specified resins offer the desired balance of strength and stiffness for components of devices such as hand held instruments that must provide a reliable and consistent force to fire of the mechanical mechanism. They are also ideal for endo-mechanical housings and components, such as triggers and housings.

Biocompatibility Tested

- Physical, chemical and toxicological testing has been done on the resin as well as colorants according to ISO 10993 standards to determine biocompatibility. A summary of the test results is available upon request. Our standard grades are also listed with FDA Master Access Files in order to assist with regulatory compliance.

Ignition Resistance

- CALIBRE™ 5101 and 5201 Glass-Filled Polycarbonate Resins have UL94 ratings indicating these grades are suitable for certain powered device applications, such as battery powered surgical devices and low powered units. The UL94 flammability ratings include V-2 at 1.5mm and V-0 at 3.0mm. See the Yellow

Cards associated with these products for specific details.

Sterilizable

- CALIBRE™ 5101 and 5201 Glass-Filled Polycarbonate Resins can be sterilized using the common methods shown below. Physical properties and part appearance are typically maintained with exposure. With irradiation treatment, certain colors may exhibit slight color changes that often return to the original color within a period of time.

Ethylene Oxide	Up to 5 Cycles
Gamma Radiation	Up to 10 Mrad (100kGy)
e-beam Radiation	Up to 10 Mrad (100kGy)

Regulatory Support

- Global regulations around glass-filled resins are increasingly stringent and complex. In order to be compliant with regulations, Trinseo has regional product stewards who provide customers with detailed information regarding its materials. Our Regulatory Data Sheets (RDS) include comprehensive, global regulatory data on the glass-filled plastics allowing OEMs to determine the suitability of the materials for their intended end use.

Sampling Available

The following grades are available for immediate sampling through Trinseo's Sample Stock Program:

- CALIBRE™ 5101-15 FC770001 Polycarbonate Resins, BLACK, 10% GLASS
- CALIBRE™ 5201-12 FC850122 Polycarbonate Resins, WHITE, 20% GLASS

Key mechanical and thermal properties for these Sample Stock grades can be seen in Chart 2, which represents Flexural Stress vs. Strain (ASTM D790), and Chart 3, which represent Deflection Temperature Under Load @ 264psi (ASTM D648). Trinseo will consider custom formulations with specific glass content and color to meet desired specification.

Focused on Meeting your Needs. The CALIBRE™ 5000 Series Polycarbonate Resins was designed for applications requiring enhanced strength and stiffness, dimensional stability and an alternate material resulting in lighter weight devices. In addition to these materials, Trinseo offers a full portfolio of CALIBRE™ Polycarbonate Resins, EMERGE™ Advanced Resins and MAGNUM™ ABS Resins for single and multiple use devices and equipment housings in a variety of medical application areas. For more information, contact us at 1-855-TRINSEO (+1-855-874-6736) or visit us online at <http://www.trinseo.com>.

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CALIBRE™ 5000 Series: from 0 – 40 % Glass Filled

The chart at the right indicates the tendency of the material to bend under an established load with glass filled resins from 0 to 40 percent content. With an increased content of glass filler, greater stiffness is achieved which makes CALIBRE™ 5000 Series Polycarbonate Resins ideal for devices ranging from hand held instruments to equipment housings as an alternative to metal or non-filled plastics.

The charts that follow reflect the most common percentage of glass filler at 10 and 20 percent.

Flexural Modulus, ASTM D790

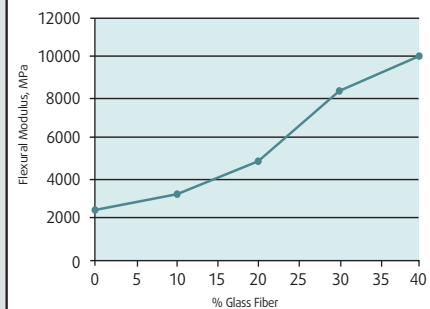


Chart 1: Flexural Modulus, ASTM

Resins 10% and 20% Glass Filled

The tests of Flexural Stress and Deflection Temperature were done to indicate the point at which the material would bend with glass content of 10 and 20 percent under an established load. Both charts indicate that when compared with polycarbonate with 0 percent glass filler, not only will a higher percentage of filler make the material more resistant to bending, materials with higher glass content are more resistant to deflection even under extreme heat. In addition to structural integrity, the higher percentage of glass filler allows manufacturers to achieve a much faster molding process due to the ability to remove a part from a mold quicker without deformation.

Trinseo will work with customers to formulate a resin with an ideal percentage of glass filler to achieve specific results.

Flexural Stress, ASTM D790

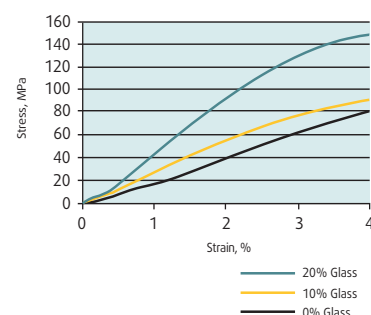


Chart 2: Flexural Stress, ASTM

Deflection Temperature Under Load, 264psi, °C

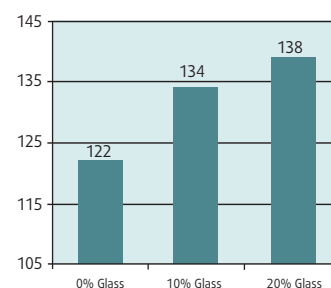


Chart 3: Deflection Temperature

Because **CALIBRE™ 5000 Series Polycarbonate Resins** are medical grade polymers, they are designed to provide the biocompatibility, sterilization options, and molding characteristics required by the medical industry. Biocompatibility testing has been conducted for these polymers.



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