Mission

Trinseo’s mission in the medical devices market is to become a long-term, preferred global supplier for Polycarbonate (PC) and acrylonitrile butadiene styrene (ABS) based products and services. This position will be recognized by our commitment to:

- Supplying high quality global products
- Ensuring a robust management of change policy
- Providing a secured supply chain of custom biocompatible tested products
- Offering valued regulatory support to surpass our customers’ compliancy requirements and expectations
- Bringing innovative products and services to the marketplace in order to provide our customers with a differential advantage

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Introduction

As the need to better manage costs and comply with regulatory requirements continues, manufacturers and molders of medical devices demand resins that not only fulfill traditional performance and regulatory requirements, but are produced under stringent quality guidelines, controlled conditions, and validated processes.

Trinseo understands this and has been supporting the medical devices market with compounded products for single and multiple use devices and equipment housings for over 25 years. As a manufacturer focused on resin quality and product stewardship, we distinguish ourselves by working with our customers strategically, collaboratively and confidentially to solve complex material challenges.

Over the years, we have truly made our mark. We are known for world-class quality and production and industry-leading technology.

This includes the development of our CALIBRE™ MEGARAD™ Polycarbonate Resins with color compensation technology; being one of the suppliers with biocompatible glass filled materials; ABS resins that are produced in a continuous mass production mode for ultra purity; and chemical resistant materials that are effective against today’s most common hospital cleaning agents.

We’ve received acclaim for our clean room production in our Stade, Germany polycarbonate manufacturing plant, taking our quality commitment further downstream. Whereas in the past clean room technology for medical applications was mainly utilized in the fabrication and assembly stages Trinseo has applied this technology in activities where cross contamination can occur.

Trinseo is right scaled. We have extensive global resources across continents but at the same time pride ourselves in being able to offer personalized service and customized products.

We’re uniquely dedicated and committed. We are ideal for customers who want a strategic relationship with a partner that will work with them side by side, helping them develop solutions to reduce costs, differentiate themselves in the marketplace, and increase customer satisfaction.

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**Trinseo is ...**

- Global with manufacturing facilities worldwide to ensure constancy and consistency of supply
- Committed to providing industry-leading quality resins and quality systems to support customers’ compliance with regional and global regulatory standards
- Known for technology leadership, which includes the development of color-stabilized CALIBRE™ MEGARAD™ Polycarbonate Resins
- Dedicated to the medical sector with more than two decades of design, product innovation and technical support history
- Able to provide advanced notification of change with locked formulations as well as lot traceability and extended record retention
Trinseo resins are designed to meet the needs of our customers and their specific medical device applications. Our approach to product development is to utilize our backbone polymers, existing technology building blocks, and new innovations in ways that result in exciting features and benefits for our customers and their applications.

What distinguishes Trinseo is our intense focus on the value of the products and solutions we provide. We work to understand our customers’ goals and then we strive to quantify and express numerically our objectives, arriving at the value our customers need from our materials.

For example, how many cleansers do our materials resist to help fight potential bacteria present in a healthcare environment? How much quicker should the color recovery time be after an appliance is radiation sterilized? These are the metrics, or the numbers, that matter and they let our customers know that the Trinseo material they have chosen makes a difference.

The following pages contain an overview of our products categorized into Polycarbonate Resins, which are used for single and multiple use medical devices, Advanced Resins (polycarbonate blends) which are used for equipment housings and ABS resins, which are used for single use and multiple use medical devices.

Our products are offered under the brand names CALIBRE™ Polycarbonate Resins, CALIBRE™ MEGARAD™ Polycarbonate Resins, EMERGE™ Advanced Resins and MAGNUM™ ABS Resins. Each product shown can be customized to meet specific needs using our technology building blocks and our cross-industry expertise.

Sample plaques of the materials are available from your Trinseo representative or by calling the Customer Information Group.
Polycarbonate Resins

Features of Trinseo CALIBRE™ Polycarbonate:

- Optical Clarity
- Gamma or e-beam radiation; EtO or steam autoclave sterilizable
- Durability/Impact resistance
- Biocompatibility tested grades
- Dimensional stability
- Chemically bondable

Common applications for Polycarbonate Resins for single- and multiple-use medical devices include:

- Renal Care: Blood Filter Housings, Dialyzer Housings
- Fluid and Drug Delivery: Syringes, Stopcocks, Luers
- Diabetes Management: Glucose Meters, Pumps, Insulin Pens
- Monitoring Devices: Housings, Covers
- Surgical Devices: Handles, Housings
- US FDA master access files

CALIBRE™ Polycarbonate Resins

CALIBRE™ 2000 series resins are used for a broad spectrum of medical device applications that require biocompatibility testing according to ISO 10993 and/or USP Class VI standards. Offering high impact strength, transparency, rigidity, dimensional stability and exceptional performance at low and high temperatures, polycarbonate is the preferred material for many applications.

Trinseo offers excellent melt flow consistency, a wide range of melt flows and tints. CALIBRE™ transparent resins are suitable for EtO and Autoclave sterilization. CALIBRE™ opaque resins can also be utilized with gamma and e-beam sterilization.

Glass-Filled Solutions

Trinseo’s CALIBRE™ 5000 series is our portfolio of biocompatibility, glass-filled polycarbonate grades which can be used for a wide range of medical devices (e.g., surgical device handles) and equipment housings that need a high degree of structural support. The materials offer the needed impact resistance and durability for a healthcare environment and are an excellent choice to solve weight reductions issues, potentially replacing traditional metal parts. Offered with both 10 and 20 percent glass fiber added, the glass content improves the basic stiffness of molded parts, creating excellent module support structures. Custom formulations, including the percent of glass fiber content, can be compounded to meet targeted specifications.

Advantages of Trinseo’s CALIBRE™ Glass-filled Resins

- High Stiffness/Modulus
- Improved heat distortion
- Biocompatible based on ISO 10993
- Sterilizable by EtO or Autoclave
- UL 94 Rated V-0 at 3 mm and V-2 at 1.5 mm
- US FDA Master access files for selected products
Table 1: Key Properties\(^{(1)}\) of CALIBRE™ Polycarbonate Resins for Medical Applications

<table>
<thead>
<tr>
<th>Grade</th>
<th>CALIBRE™ Polycarbonate Resins: EtO and Steam Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Extrusion Grade, For ethylene oxide and steam sterilization</td>
</tr>
<tr>
<td></td>
<td>Injection Molding, For ethylene oxide and steam sterilization</td>
</tr>
<tr>
<td></td>
<td>Injection Molding, For ethylene oxide and steam sterilization</td>
</tr>
<tr>
<td></td>
<td>High Flow Injection Molding, For ethylene oxide and steam sterilization</td>
</tr>
<tr>
<td></td>
<td>10% Glass-reinforced for improved stiffness and heat distortion</td>
</tr>
<tr>
<td></td>
<td>10% Glass-reinforced for improved stiffness and heat distortion</td>
</tr>
<tr>
<td></td>
<td>20% Glass-reinforced for improved stiffness and heat distortion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Features</th>
<th>Density, g/cm(^3) ISO 1183</th>
<th>Melt Flow Rate, g/10 min ISO 1133 (300°C/1.2 kg)</th>
<th>Tensile Strength at Yield, MPa ISO 527-2(^{(2)})</th>
<th>Tensile Strength at Break, MPa ISO 527-2(^{(2)})</th>
<th>Elongation at Break, % ISO 527-2(^{(2)})</th>
<th>Flexural Modulus, MPa ISO 178(^{(3)})</th>
<th>Notched Izod Impact, 23°C, J/m ASTM D 256</th>
<th>Instrumented Dart Impact, 23°C, J ASTM D 3763(^{(4)})</th>
<th>HDT/A 1,8 MPa, °C, unannealed ISO 75</th>
<th>Vicat Softening Temperature, °C ISO 306(^{(5)})</th>
<th>Light Transmission, % ASTM D 1003(^{(6)})</th>
<th>UL Rating(s)(^{(7, 8)}) UL 94</th>
</tr>
</thead>
<tbody>
<tr>
<td>2060-6</td>
<td>1.2</td>
<td>6</td>
<td>62</td>
<td>72</td>
<td>150</td>
<td>2410</td>
<td>910</td>
<td>90</td>
<td>130</td>
<td>156</td>
<td>89</td>
<td>–</td>
</tr>
<tr>
<td>2061-6</td>
<td>1.2</td>
<td>6</td>
<td>62</td>
<td>68</td>
<td>150</td>
<td>2410</td>
<td>850</td>
<td>89</td>
<td>129</td>
<td>156</td>
<td>89</td>
<td>–</td>
</tr>
<tr>
<td>2061-15</td>
<td>1.2</td>
<td>15</td>
<td>60</td>
<td>68</td>
<td>150</td>
<td>2350</td>
<td>750</td>
<td>81</td>
<td>127</td>
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<td>89</td>
<td>–</td>
</tr>
<tr>
<td>2061-22</td>
<td>1.2</td>
<td>22</td>
<td>62</td>
<td>66</td>
<td>120</td>
<td>2340</td>
<td>750</td>
<td>72</td>
<td>126</td>
<td>147</td>
<td>89</td>
<td>–</td>
</tr>
<tr>
<td>5101-8</td>
<td>1.27</td>
<td>8</td>
<td>62</td>
<td>61</td>
<td>6.0</td>
<td>3170</td>
<td>80</td>
<td>40</td>
<td>134</td>
<td>167</td>
<td>opaque</td>
<td>1.5 mm V-2</td>
</tr>
<tr>
<td>5101-15</td>
<td>1.27</td>
<td>15</td>
<td>62</td>
<td>61</td>
<td>6.0</td>
<td>3170</td>
<td>80</td>
<td>40</td>
<td>134</td>
<td>167</td>
<td>opaque</td>
<td>1.5 mm V-2</td>
</tr>
<tr>
<td>5201-12</td>
<td>1.36</td>
<td>12</td>
<td>83</td>
<td>83</td>
<td>3.0</td>
<td>4830</td>
<td>110</td>
<td>46</td>
<td>138</td>
<td>160</td>
<td>opaque</td>
<td>1.5 mm V-2</td>
</tr>
</tbody>
</table>

\(^{(1)}\) These are typical properties only and are not to be construed as specifications. Users should confirm results by their own tests.

\(^{(2)}\) 50 mm/min

\(^{(3)}\) Method I (3 point load), 2.0 mm/min

\(^{(4)}\) 11.1 ft/sec

\(^{(5)}\) For PC grades: Rate A (50°C/hr), Loading 2 (50N); for PC/AWS, PC/PBT and ABS grades: Rate B (120°C/hr), Loading 1 (10N)

\(^{(6)}\) Light transmission values reported are for untinted resins; please note certain tinted, transparent and opaque colors will have lower light transmission values.

\(^{(7)}\) Resins containing ignition-resistant additives do not readily support ignition. However, they will burn under the right conditions of heat and oxygen supply. The resins should not be exposed to direct flame or extreme heat. Results of small-scale flammability tests on these or any other materials are not to be considered indicative of the behavior of these materials under actual fire conditions.

\(^{(8)}\) UL Listings vary by color. For specific information, see UL File E54680.
**CALIBRE™ MEGARAD™ Polycarbonate Resins**

CALIBRE™ MEGARAD™ 2081 is recommend for polycarbonate applications utilizing gamma or e-beam irradiation sterilization methods. During these irradiation processes polycarbonate experiences a slight color change in the final product. Trinseo offers a range of CALIBRE™ MEGARAD™ tints that are designed to provide the appropriate amount of color compensation for a select number of irradiation sterilization cycles to meet final desired color specification.

New grade, CALIBRE™ MEGARAD™ 2091, is designed for use in oxygen-free irradiation processes. This resins offers improved color recovery and stabilization for these unique situations.

This technology has been the enable for success with CALIBRE™ MEGARAD™ polycarbonate resins for over 25 years.

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**Table 2: Key Properties**(9) of CALIBRE™ MEGARAD™ PC Resins for Medical Applications

<table>
<thead>
<tr>
<th>Grade</th>
<th>CALIBRE™ MEGARAD™ Polycarbonate Resins: Gamma and Electron Beam Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2080 Series</td>
</tr>
<tr>
<td></td>
<td>2081-6LR</td>
</tr>
<tr>
<td><strong>Features</strong></td>
<td></td>
</tr>
<tr>
<td>Lipid-resistant(7), Improved resistance to lipids</td>
<td>Injection Molding, Designed to reduce color shift after high-energy sterilization</td>
</tr>
<tr>
<td>Density, g/cm³</td>
<td>ISO 1183</td>
</tr>
<tr>
<td>Melt Flow Rate, g/10 min</td>
<td>ISO 1133 (300°C/1.2 kg)</td>
</tr>
<tr>
<td>Tensile Strength at Yield, MPa</td>
<td>ISO 527-2(2)</td>
</tr>
<tr>
<td>Tensile Strength at Break, MPa</td>
<td>ISO 527-2(2)</td>
</tr>
<tr>
<td>Elongation at Break, %</td>
<td>ISO 527-2(2)</td>
</tr>
<tr>
<td>Flexural Modulus, MPa</td>
<td>ISO 178(3)</td>
</tr>
<tr>
<td>Notched Izod Impact, 23°C, J/m</td>
<td>ASTM D 256</td>
</tr>
<tr>
<td>Instrumented Dart Impact, 23°C, J</td>
<td>ASTM D 3763(4)</td>
</tr>
<tr>
<td>HDT/A, 1.8 MPa, °C</td>
<td>ISO 75</td>
</tr>
<tr>
<td>Vicat Softening Temperature, °C</td>
<td>ISO 306(6)</td>
</tr>
<tr>
<td>Light Transmission, %</td>
<td>ASTM D 1003(5)</td>
</tr>
</tbody>
</table>

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1. These are typical properties only and are not to be construed as specifications. Users should confirm results by their own tests.
2. 50 mm/min
3. Method 3 (point load), 2.0 mm/min
4. 11.1 ft/sec
5. For PC grades: Rate A (50°C/hr, Loading 2 (50N)), for PC/ABS, PC/PET and ABS grades: Rate E (120°C/hr, Loading 1 (10N))
6. Light transmission values reported are for untinted resin; please note certain tinted, transparent and opaque colors will have lower light transmission values.
7. When exposed to a 25% intralipid emulsion solution under strained conditions, CALIBRE™ MEGARAD™ 2081-6LR exhibits significant property retention compared to standard polycarbonate.
8. When exposed to a standard single pass of 2.5 Mrad gamma radiation, new CALIBRE™ MEGARAD™ 2091 Polycarbonate Resins typically return to the desired color specification 25 percent faster than other loading radiation-stabilized products.
Advanced Resins

Features of Trinseo EMERGE™ Advanced Resins:

- Biocompatibility tested grades
- Chemical resistance to Hospital cleaners and disinfectants
- Low temperature ductility
- Higher stiffness performance
- Durability/Impact Resistance
- Lightweight
- Ignition resistance/UL94 certification
- Customized color services
- Aesthetic appeal

Common applications for compounded Advanced Resins:

- Patient monitoring equipment housings
- Medical imaging and diagnostic equipment
- Cabinet components and enclosures
- Home healthcare housings and monitoring
- Pumps and oxygenators
- Dental equipment housings

Trinseo has developed a number of advanced resins based on our polymer resin feedstocks, to serve the medical market. Offering special performance attributes such as chemical and ignition resistance, superior aesthetics and outstanding haptics, Trinseo’s EMERGE™ materials are specialized engineering materials that balance a variety of attributes to meet the needs of specific applications. Trinseo’s EMERGE™ Advanced Resins with their superior performance have provided solutions to challenges in the medical industry for decades.
Chemical Resistant PC/PET Solutions

Trinseo’s EMERGE™ 9000 CR series is our portfolio of chemical resistant polycarbonate (PC) polyethylene terephthalate (PET) blends designed to address the concern in the medical industry over hospital acquired infections and the need for today’s medical housings to endure exposure to powerful disinfectants and cleaners.

Resistant to the most common chemical antagonists in a healthcare environment (Chart 1), Trinseo’s innovative materials provide excellent resistance to chemicals that can attack plastic surfaces, and can lead to crazing, cracking and eventual product failure.

Trinseo’s PC/PET resins balance the important properties needed by manufacturers and molders in their ongoing efforts to extend the functionality, reliability and lifecycle of their products. In addition the materials maintain the aesthetically-pleasing appearance expected for medical device housings.

To accommodate powered equipment, grades are available with UL 94 ratings of V-1 @ 1.5 mm, V-0 @ 2.0 mm and 5VA @ 2.5 mm.

Advantages of Trinseo’s EMERGE™ PC/PET Solutions

- Biocompatibility tested
- Exceptional Chemical Resistance
- High Impact Resistance
- Excellent Heat Resistance
- Toughness Across Temperature Ranges
- UV Stability
- Ignition Resistance
- Low Shrinkage

Chart 1: Resistance to Selected Cleaners/Disinfectants(1,2)

<table>
<thead>
<tr>
<th>Cleaner/Disinfectant</th>
<th>Retention of Ultimate Tensile Elongation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EMERGE™ PC/PET 9500CR</td>
</tr>
<tr>
<td>Wex-Cide 128</td>
<td>●●●</td>
</tr>
<tr>
<td>Virex® II 256</td>
<td>●●●</td>
</tr>
<tr>
<td>Cavicide®</td>
<td>●●●</td>
</tr>
<tr>
<td>CIDEX PLUS®</td>
<td>●●●</td>
</tr>
<tr>
<td>50% Bleach</td>
<td>●●●</td>
</tr>
<tr>
<td>70% IPA</td>
<td>●●●</td>
</tr>
<tr>
<td>Sani-Cloth® Plus</td>
<td>●●●</td>
</tr>
<tr>
<td>Sani-Cloth® AF</td>
<td>●●●</td>
</tr>
<tr>
<td>Clorox Healthcare® Bleach Germicidal Wipe</td>
<td>●●●</td>
</tr>
<tr>
<td>Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipe</td>
<td>●</td>
</tr>
<tr>
<td>Virex® TB</td>
<td>●●●</td>
</tr>
</tbody>
</table>

(1) Trinseo testing. Complete protocols and results available upon request.
(2) Tested after 1 day exposure to chemicals under 1% strain.
(3) Trademark of Diversey, Inc.
(4) Trademark of Metrex Research Corporation.
(5) Trademark of Johnson & Johnson.
(6) Trademark of Professional Disposables International, Inc.
(7) Trademark of The Clorox Company.
When selecting materials for equipment housings, manufacturers and molders need to consider a number of properties including durability, appearance and processing. A balance of these properties is critical and results in equipment that maintains its integrity and aesthetics over time.

Trinseo’s EMERGE™ PC/ABS 7000 Series combines the physical properties of polycarbonate with the processability, toughness and flow of ABS, resulting in a superior blend. It is ideal for a broad range of applications, with various degrees of economy, where a number of important properties, including a flammability rating and biocompatibility, are needed.

### Advantages of Trinseo’s EMERGE™ PC/ABS Solutions
- Durability and Toughness
- Non-halogenated Ignition Resistance
- Processability
- Pleasing Aesthetics
- Biocompatibility Tested (Part 5 & 10)

### Table 3: Key Properties of EMERGE™ Advanced Resins for Medical Applications

<table>
<thead>
<tr>
<th>Grade</th>
<th>PC/ABS 7100</th>
<th>PC/ABS EU 7700</th>
<th>XZ 92718.00</th>
<th>PC/PET 9100CR</th>
<th>PC/PET 9500CR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Features</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Purpose</td>
<td>Ignition-resistant&lt;sup&gt;(6)&lt;/sup&gt;, Non-halogenated additives, UV Stabilized</td>
<td>Experimental Ignition-resistant&lt;sup&gt;(6)&lt;/sup&gt;, PC/ABS for extrusion containing, Non-halogenated additives</td>
<td>Exceptional chemical resistance</td>
<td>Ignition-resistant&lt;sup&gt;(6)&lt;/sup&gt;, Exceptional chemical resistance</td>
<td></td>
</tr>
<tr>
<td>Density, g/cm&lt;sup&gt;3&lt;/sup&gt;</td>
<td>ISO 1183</td>
<td>1.11</td>
<td>1.17</td>
<td>1.18</td>
<td>1.23</td>
</tr>
<tr>
<td>Melt Flow Rate, g/10 min</td>
<td>ISO 1133</td>
<td>25 (260°C/5.0 kg)</td>
<td>11 (230°C/3.8 kg)</td>
<td>25 (230°C/3.8 kg)</td>
<td>8.5 (260°C/5.0 kg)</td>
</tr>
<tr>
<td>Tensile Strength at Yield, MPa</td>
<td>ISO 527-2&lt;sup&gt;(2)&lt;/sup&gt;</td>
<td>50</td>
<td>55</td>
<td>63</td>
<td>50</td>
</tr>
<tr>
<td>Tensile Strength at Break, MPa</td>
<td>ISO 527-2&lt;sup&gt;(2)&lt;/sup&gt;</td>
<td>-</td>
<td>43</td>
<td>58</td>
<td>56</td>
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<tr>
<td>Elongation at Break, %</td>
<td>ISO 527-2&lt;sup&gt;(2)&lt;/sup&gt;</td>
<td>50</td>
<td>43</td>
<td>135</td>
<td>150</td>
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<tr>
<td>Flexural Modulus, MPa</td>
<td>ISO 178&lt;sup&gt;(3)&lt;/sup&gt;</td>
<td>2340</td>
<td>2690</td>
<td>2585</td>
<td>2100&lt;sup&gt;(8)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Notched Izod Impact, 23°C, J/m</td>
<td>ASTM D 256</td>
<td>480</td>
<td>480</td>
<td>-</td>
<td>910</td>
</tr>
<tr>
<td>Instrumented Dart Impact, 23°C, J</td>
<td>ASTM D 3763&lt;sup&gt;(6)&lt;/sup&gt;</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>63</td>
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<tr>
<td>HDT/A, 1.8 MPa, °C</td>
<td>ISO 75</td>
<td>95</td>
<td>80</td>
<td>90</td>
<td>87</td>
</tr>
<tr>
<td>Vicat Softening Temperature, °C</td>
<td>ISO 306&lt;sup&gt;(1)&lt;/sup&gt;</td>
<td>133</td>
<td>104</td>
<td>115</td>
<td>144</td>
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<tr>
<td>UL Rating(s)&lt;sup&gt;(6,7)&lt;/sup&gt;</td>
<td>UL 94</td>
<td>1.0 mm HB</td>
<td>1.5 mm V-0 2.0 mm V-0 2.5 mm V-0 2.5 mm V-0 1.5 mm V-0 1.5 mm V-0 2.0 mm V-0 2.5 mm V-0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>(1)</sup> These are typical properties only and are not to be construed as specifications. Users should confirm results by their own tests.  
<sup>(2)</sup> 50 mm/min.  
<sup>(3)</sup> Method I (3 point load), 2.0 mm/min.  
<sup>(4)</sup> 11.1 ft/sec.  
<sup>(5)</sup> For PC grades: Rate A (50°C/hr), Loading 2 (50N); for PC/ABS, PC/PET and ABS grades: Rate B (120°C/hr), Loading 1 (10N).  
<sup>(6)</sup> Resins containing ignition-resistant additives do not readily support ignition. However, they will burn under the right conditions of heat and oxygen supply. Results of small-scale flammability tests on these or any other materials are not to be considered indicative of the behavior of these materials under actual fire conditions.  
<sup>(7)</sup> UL 94 Listings vary by color. For specific information, see UL File E54680.  
<sup>(8)</sup> 1.3 mm/min.
Advantages of Trinseo MAGNUM™ ABS Resins

- MAGNUM™ 8391 MED is ISO 10993 biocompatibility tested
- Continuous mass polymerization process
- Excellent Processability – wide processing window
- Lot-to-Lot Consistency – in processing and performance
- Superior Natural Resin Whiteness – less pigment needed
- Compatible with Secondary Finishing Techniques – ease of solvent and sonic welding
- MAGNUM™ 8391 MED is available precolored in standards medical colors

Common applications for ABS resins include:

- Disposable IV connectors and valves
- Drug delivery device housings
- Instrument handles

As the demand for attractive medical equipment grows, manufacturers and molders are looking for materials that provide pleasing aesthetics and advanced performance. They also need to meet the necessary requirements of the medical industry: biocompatibility, regulatory compliance, and sterilization options.

Trinseo’s MAGNUM™ ABS Resins have been relied on for decades satisfying the most critical needs of medical device designers and fabricators looking to differentiate their products and provide end-user satisfaction. They have several advantages:

**Mass Production Process:** MAGNUM™ ABS resins are manufactured with continuous mass polymerization technology. This ensures superior lot-to-lot consistency of properties including color, rheology and physical structure. Mass polymerization also results in a purer polymer compared to competitive emulsion ABS resins.

**Processing Characteristics:** MAGNUM™ ABS resins are thermally stable and offer a wide processing window to ensure excellent processability. The superior natural whiteness of the resins resulting from the mass production process allows for ease of in-house coloring and less pigment needed.

**Sterilization Options:** Medical devices made of MAGNUM™ ABS resins can be sterilized by gamma radiation, ethylene oxide (ETO) gas, and electron beam radiation and will maintain their essential properties following exposure. Steam autoclave is not recommended.
### Table 4: Key Properties of MAGNUM™ ABS Resins for Medical Applications

<table>
<thead>
<tr>
<th>Grade</th>
<th>Features</th>
<th>Density, g/cm²</th>
<th>Melt Flow Rate, g/10 min</th>
<th>Tensile Strength at Yield, MPa</th>
<th>Tensile Strength at Break, MPa</th>
<th>Elongation at Break, %</th>
<th>Flexural Modulus, MPa</th>
<th>Notched Izod Impact, 23°C, J/m</th>
<th>HD1/A, 1,8 MPa, °C</th>
<th>Vicat Softening Temperature, °C</th>
<th>Light Transmission, %</th>
<th>UL Rating(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8391 MED</td>
<td>High Flow for injection moulding, Glossy finish</td>
<td>1.05</td>
<td>28</td>
<td>47</td>
<td>35</td>
<td>8.7</td>
<td>2400</td>
<td>230</td>
<td>74</td>
<td>99</td>
<td>opaque</td>
<td>1.5 mm HB</td>
</tr>
<tr>
<td>3904</td>
<td>Extrusion grade, Matt finish</td>
<td>1.05</td>
<td>4.5</td>
<td>39</td>
<td>-</td>
<td>45</td>
<td>1900</td>
<td>-</td>
<td>-</td>
<td>97</td>
<td>opaque</td>
<td>1.5 mm HB</td>
</tr>
</tbody>
</table>

*(1) These are typical properties only and are not to be construed as specifications. Users should confirm results by their own tests.

*(2) 50 mm/min

*(3) Method I (3 point load), 2.0 mm/min

*(4) For PC grades: Rate A (50°C/hr), Loading 2 (5G/m²); for PC/ABS, PC/PET and ABS grades: Rate B (120°C/hr), Loading 1 (10N)

*(5) Light transmission values reported are for untinted resins; please note certain tinted, transparent and opaque colors will have lower light transmission values.

*(6) Resins containing ignition-resistant additives do not readily support ignition. However, they will burn under the right conditions of heat and oxygen supply. The resins should not be exposed to direct flame or extreme heat. Results of small-scale flammability tests on these or any other materials are not to be considered indicative of the behavior of these materials under actual fire conditions.

*(7) UL Listings vary by color. For specific information, see UL File E54680.

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### Chart 2: Advantages of Trinseo’s MAGNUM™ ABS Resins

**Three proven reasons to choose MAGNUM™ ABS resins**

1. **Consistency**. MAGNUM™ ABS resins have more consistent color, lot-to-lot and run after run.

2. **Thermal Stability**. MAGNUM™ ABS resins provide among the best thermal characteristics in the industry, resulting in higher color stability.

3. **Base Color**. MAGNUM™ ABS resins have exceptionally low base color, allowing lower pigment levels for your desired sheet color.

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All data based on Trinseo testing. Complete protocols and results available upon request.
Critical Product Properties

To perform favorably in a healthcare environment and provide for optimal patient safety, Medical Device applications require added robustness in their materials. The following pages outline the following requirements:

- Biocompatibility
- Sterilizable
- Chemical Resistance

Biocompatibility

Physical, chemical and toxicological testing is done according to ISO 10993 and/or USP Class VI standards to determine biocompatibility of various resin grades and color combinations. Trinseo CALIBRE™ Polycarbonate Resins and CALIBRE™ MEGARAD™ Polycarbonate Resins for medical applications have been tested according to ISO 10993 and/or USP Class VI standards.

Following are the typical tests considered:

<table>
<thead>
<tr>
<th>Biocompatibility Testing for CALIBRE™ Polycarbonate Resins</th>
</tr>
</thead>
<tbody>
<tr>
<td>USP and ISO Cytotoxicity (Current USP and ISO 10993 Part 5)</td>
</tr>
<tr>
<td>USP and ISO Intracutaneous (Current USP and ISO 10993 Part 10)</td>
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<tr>
<td>USP and ISO Systemic Toxicity (Current USP and ISO 10993 Part 11)</td>
</tr>
<tr>
<td>In Vitro Hemolysis – Extraction and Direct Contact (ISO 10993 Part 4)</td>
</tr>
<tr>
<td>ISO Sensitization (ISO 10993 Part 10)</td>
</tr>
<tr>
<td>USP and ISO Implantation (Current USP and ISO 10993 Part 6)</td>
</tr>
<tr>
<td>Physicochemical Study (Current USP)</td>
</tr>
</tbody>
</table>

Biocompatible Vs Food Contact Grade

Trinseo offers materials for medical devices that adhere to the most stringent regulatory requirements, addressing not only compliancy issues but production needs. “Biocompatible” means the materials have been approved to come in contact with human tissue and fluid at varying lengths of exposure.

“Food Contact Grade” means the materials are approved to come in contact with the food we consume a part of harvesting, processing or packaging. Trinseo is pleased to offer both classifications based on chemical composition of the materials and will recommend the optimum material for a specific application.
Despite the excellent properties of polycarbonate, when sterilized by irradiation, the material can exhibit a significant discoloration and a resulting reduction in light transmittance. The physical properties of the polycarbonate can be impacted as well. These effects present a challenge to manufacturers and health care professionals who are concerned about the aesthetics and long-term functionality of their medical devices.

Trinseo has responded by developing radiation-stabilized CALIBRE™ and CALIBRE™ MEGARAD™ Polycarbonate Resins that can withstand the highest sterilization methods and at the same time quickly equilibrate to an acceptable threshold color following exposure. Depending on the application and the specific color recovery time needed, Trinseo can provide an optimal solution.

The most common methods used for sterilizing medical devices are detailed below. Each method differs in its aggressiveness, radiation dosage, recommended cycles of radiation, and environmental conditions:

**Steam Autoclaving:** CALIBRE™ 2061 and CALIBRE™ MEGARAD™ Polycarbonate Resins typically withstand one to five autoclave cycles (depending on cycle parameters). Polycarbonate begins to exhibit molecular weight loss, impact reduction and haze after two hours of cumulative autoclave exposure.¹

**Ethylene Oxide:** CALIBRE™ 2061 and CALIBRE™ MEGARAD™ Polycarbonate Resins can be sterilized using an ethylene oxide method up to five cycles at normal conditions. Physical properties and color are maintained but multiple exposures can reduce the tensile elongation properties of the polymer.²

**Gamma or Electron Beam Radiation:** CALIBRE™ MEGARAD™ 2081 Polycarbonate Resins are designed to reduce post-irradiation color shift associated with these methods. Grades are available for three common irradiation intensities. The product has been designed to maintain mechanical properties up to 10 Mrad (100kGy) of radiation exposure.³

Today’s plastics need to withstand the conditions in healthcare settings. They need to have chemical resistant properties as well as other properties needed by manufacturers such as ignition resistance, durability and aesthetic appeal. The challenge — and where innovation really occurs — is to manage these properties to ensure that one property isn’t compromised in favor of another.

These chemicals pose a challenge to the equipment because they have a tendency to attack the surface materials. In the case of plastic, constant cleaning can cause cracking, crazing, embrittlement, and eventually shorten equipment life.

Polycarbonate is frequently used in medical applications where contact with chemicals such as disinfectants, detergents, food, cosmetic substances, oil and grease is intended or cannot be avoided. The extent to which polymers’ properties are compromised, e.g., experience stress cracks, partially dissolve, plasticize, react chemically, or absorb chemicals, is determined by a number of factors related to both the chemical and the polymer itself.

These include:

- Polymers are more susceptible to solvent of chemical attack when under stress and/or strain
- The nature and strength of the chemical will affect the amount of damage
- The extent of chemical attack on a certain polymer is mainly dependent on the chemical structure of the polymer
- The effects of chemical exposure are increased at higher temperatures and with longer periods of time
- Is dependent on the part design and is application specific

Trinseo has many resins with excellent chemical resistance properties. Standardized tests have been conducted on our materials to determine the chemical resistance to many potential antagonists. Additional information on chemical resistance of specific products is available through Trinseo.
Trinseo has the global technical resources to meet the current and future needs of our customers. Our Research & Development (R&D) and testing laboratories for our plastics business are strategically located across North America, Europe and Asia Pacific, and we have 10 manufacturing plants to support plastics production throughout the world.

All of our facilities adhere to disciplined quality processes, controlled conditions and validated processes to provide material consistently, predictably and reliably, according to specification. In addition, we continuously work with our customers to understand ongoing requirements and ensure continuous improvement and innovation throughout our relationships. Trinseo’s management system integrates the key elements of several external standards into its best practices, including ISO-9001.

Our emphasis is on ensuring its highest quality resin feedstocks for producing its compounds and blends for specialty market applications. Resins used in regional compounding come from two outstanding sources of polycarbonate resins, which include our two replicate production facility in Stade, Germany, our joint venture, Sumika Trinseo Polycarbonate Ltd., in Ehime and Japan. By using our best sources for resins, managed under tight controlled conditions, we are able to deliver product consistently, predictably and with medical equivalency across the globe.

Device manufacturers demand the highest-quality products free of defects and contaminants, with many applications requiring a tolerance level of “0” for defects in material composition. Trinseo utilizes clean room technology at its polycarbonate manufacturing facility in Stade, Germany where the technology is applied in three areas: Extruder (resin processing), Laboratory (resin compounding) and Packaging (pellet transfer and final packaging.)

Using clean room technology, Trinseo is able to significantly minimize the risk of foreign contamination in its polycarbonate resins and provides customers with a superior product and an industry-recognized level of cleanliness.

The resin, offered under the CALIBRE™ Polycarbonate Resins brand, is used primarily for single-and multiple-use surgical instruments, devices, and equipment. CALIBRE™ Polycarbonate Resins can be produced in standard form or with color compensation technology to ensure color stability following gamma and electron-beam radiation.

Because our customers’ medical device applications are highly regulated, Trinseo has established processes to provide documentation of quality assurance throughout the life cycle of their products. We adhere to a Management of Change process that includes:

- Lot Traceability
- Formulation Lock
- Notification of Change
- Extended Record and Sample Retention

Our goal is to provide end-to-end support to our customers. Contact your Trinseo representative to discuss your quality assurance needs and how Trinseo can support your specific application needs.
Trinseo understands the importance to our customers of manufacturing products that are compliant with increasingly complex global standards and governmental regulations and that can be used safely in their intended applications. This includes sensitive end uses such as food contact and medical applications. Trinseo is available to assist its customers in those endeavors.

To meet this need, Trinseo has dedicated Product Stewards supporting each of our sales regions (North America, South America, Europe, Middle East, Africa, and Asia Pacific). We are committed to providing global comprehensive regulatory data on all Trinseo products. Our goal is to provide information as requested by our customers, allowing them to determine the suitability of our products for their intended end use.

**Categories of Support:**

- Responsive to EH&S Regulatory Inquiries and time sensitive requests
- Product Compositional Disclosure
- Safety Data Sheets and Hazard Communications
- Raw Material Supplier Regulatory Management
- Product Regulatory Management/Global Regulatory Awareness
- Regulatory Information (Regulatory Datasheets)/on-line access (24/7) for Medical products
- Summaries on Biocompatibility Studies
- FDA Master Access Files
- Toxicological Focus on Critical Raw Materials (such as BPA)
- Medical Applications Policy
- Notification of Change Policy
Regulatory Data

Trinseo makes available to our customer Regulatory Data Sheets (RDS), which are a compilation of applicable requirements for our products and additional information. The RDS is a service to our customers and provides information not required to be included in Safety Data Sheets.

The following is a sampling of the regulatory information available in Regulatory Data Sheets (RDS) which are available on the Trinseo website for our medical grade products.

- Biocompatibility (Medical Grade) Status
- Global Chemical Inventory Compliance
- US Food & Drug Administration (FDA)/EU Food Contact Status
- Animal Derived Components/Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE)
- Allergens (such as wheat, tree nuts and soy)
- Genetically Modified Organisms (GMOs)
- EU REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)
- EU Directive Restriction of Hazardous Substances (RoHS)
- EU Directive on Waste Electrical and Electronic Equipment (WEEE)
- Compositional Information/Substances of Concern

When other regulatory information is required, Trinseo will provide individual support to accommodate these needs.

Product Stewardship

Trinseo and its subsidiaries have a fundamental concern for all who make, distribute, and use its products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health and environmental information on our products to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products – from the initial concept and research, to manufacture, use, sales, disposal, and recycle of each product.
Sustainability

Trinseo is a preferred partner for sustainable solutions. We look at evolving global trends, emerging issues, and local interests and are committed to managing our business in a safe and responsible way so as to meet the current needs of our customers and communities, without jeopardizing the ability of future generations to accomplish their own objectives.

We make business decisions and align processes keeping our actions and their consequences in mind. We help our customers achieve their sustainability objectives by delivering the materials needed for sustainable applications.

The people of Trinseo are committed to:

- Continually innovating and developing new and improved products and processes that improve Trinseo’s and our customers’ sustainability
- Promoting the responsible use of our materials through product stewardship
- Operating responsibly with respect to the environment, health and safety, using resources more efficiently, adhering to the principles of Responsible Care®, and being a good neighbor in the communities where we operate

Read about how our engineering polymers enable life saving medical devices and our complete sustainability efforts at www.trinseo.com/sustainability.

Global Support

With global resources, Trinseo can meet current and future customer needs. The company has Research & Development and testing laboratories located across Europe, North America, and Asia Pacific as well as 10 manufacturing plants worldwide to support plastics production.

Trinseo works seamlessly with its customers, acting as an extension of their new product development efforts. The company has a network of Medical Account Specialists, Application Development Engineers (ADEs) and Technical Service & Development Specialists (TS&D) with depth of experience and cross-industry knowledge.

For global customers, the company can provide a local connection for production, for optimal timeliness and efficiency and serve as area guide with insights into the marketplace and regional regulations.

Trinseo’s go-to-market service model includes select distribution partners and agents worldwide to advise customers on resin choices and provide supply chain management guidance and complex inventory support.

This document provides a brief overview of Trinseo products and technologies offered to the Medical market. Additional information about the suitability of our products for potential applications or any of the topics covered in this document is available by contacting Trinseo at www.trinseo.com or as indicated on the back cover.
NOTICE REGARDING MEDICAL APPLICATION
RESTRICTIONS

Trinseo Medical Application Policy which is set forth below:

Trinseo produces medical grade resins under stringent quality guidelines and controlled conditions. We strive to understand our customers’ needs and expectations regarding patient safety, reliability, and compliance with regulatory requirements, and to provide biocompatible resins according to ISO 10993 standards. Additionally, Trinseo medical grade resins are subject to management of change and “formula lock” that involve notifying customers of an upcoming change followed by locking that formula for an extended period of time.

Based on Trinseo’s interest in collaborating with its customers, Trinseo has developed an internal process for reviewing customer requests for use of ISO 10993-certified materials in certain medical applications. Through this review process, we determine whether or not Trinseo will support the use of Trinseo materials in the proposed medical application based on 1) Device Category, 2) Type of Body Contact, and 3) Duration of Body Contact utilizing the ISO 10933-1:2009 guidelines, Biological Evaluation of Medical Devices Part 1: Evaluation & Testing.

As part of the Trinseo review process, Trinseo will consider the proposed medical applications based on the following guidelines:

Category A (Limited Exposure): Trinseo may support the use of Trinseo materials in medical applications involving transient or limited contact with internal human body fluids or tissues, where “transient” means less than 24 hours.

Category B (Prolonged Exposure): Trinseo may support the use of Trinseo materials in medical applications involving contact with internal human body fluids or tissues for up to 29 days.

Category C (“Permanent” Contact): Trinseo may support the use of Trinseo materials in medical applications involving contact with internal human body fluids or tissues for greater than 29 days.

However, in no event will Trinseo support the use of Trinseo materials in medical applications classified as implant devices or birth control devices, defined as applications designed specifically to promote or interfere with human reproduction.

If customers, distributors or resellers fail to comply with this Policy, and Trinseo becomes aware of said situation, then Trinseo business units shall take steps required to immediately preclude further sales to that end use.

In all of the categories above, Trinseo will exercise its business judgment and conduct appropriate assessments when forming supplier/customer relationships and supplying materials. Trinseo has not designed or tested its products with respect to all possible uses in medical applications. While Trinseo will commit to meet product specifications and quality standards agreed with the customer, it is the responsibility of the medical device or pharmaceutical manufacturer to determine the suitability of the parts and raw materials, including Trinseo products, used in final products to ensure safe, suitable, lawful and technical compliance for the intended end use.
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Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

No freedom from infringement of any patent owned by Trinseo or others is to be inferred. Because use conditions and applicable laws may differ from one location to another and may change with time, the customer is responsible for determining whether products and the information in this document are appropriate for the customer’s use and for ensuring that the customer’s workplace and disposal practices are in compliance with applicable legal requirements. Although the information herein is provided in good faith and was believed to be accurate when prepared, Trinseo assumes no obligation or liability for the information in this document.

NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS

Trinseo requests that customers refer to Trinseo’s Medical Application Policy http://www.trinseo.com/medical.htm before considering the use of Trinseo products in medical applications. The restrictions and disclaimers set forth in that policy are incorporated by reference.

Refer to the full medical application policy on the inside back cover.

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For more information on products, innovations, expertise, and other services available from Trinseo, visit www.trinseo.com, or contact us as indicated below.

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www.trinseo.com

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If products are described as “experimental” or “developmental”: (1) product specifications may not be fully determined; (2) analysis of hazards and caution in handling and use are required; (3) there is greater potential for Trinseo to change specifications and/or discontinue production, and (4) although Trinseo may from time to time provide samples of such products, Trinseo is not obligated to supply or otherwise commercialize such products for any use or application whatsoever.

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