Engineering and High-Performance Plastics for the Medical Industry

Thermoplastics
Semi-finished products
Product overview

Material selection

High Performance plastics are generally defined by their ability to maintain their physical properties under thermal, chemical or electrical stress, while operating at elevated temperatures above 300° F. These materials typically feature high strength and stiffness as well as outstanding chemical resistance and electrical properties.

Engineering plastics are among the most common and useful thermoplastics and typically exhibit good mechanical properties. These materials generally have one or two main attributes that best fit the needs of the application and should be taken into consideration when deciding on a specific plastic.

Amorphous thermoplastics are mostly transparent or translucent due to their polymer structure. Their mechanical properties remain almost unchanged over a wide temperature range, frequently right up to their continuous operating temperature. They are susceptible to stress cracking and this should be taken into account when machining them. Amorphous plastics include PPSU, PEI, PSU, PC and PPO.

Partially crystalline thermoplastics are a result of the molecular arrangement, usually being opaque. The mechanical properties (strength, toughness and hardness) of this group depend to a great extent on the degree of crystallinity. They feature great resistance to the formation of stress cracks and very good chemical resistance. Partially crystalline plastics include Acetal, PP and PEEK.

Sustason PPSU MG (Radel®)

Sustason PPSU MG offers incredible toughness in applications that receive repeated sterilization. With a high heat deflection temperature of 420° F it can absorb tremendous impact without cracking or breaking.

PRODUCT FEATURES:
- Excellent thermal stability
- High impact resistance
- Resistance to repeated autoclaving
- Resistance to hydrolysis

CERTIFICATIONS:
- ASTM D6394
- FDA compliant
- USP Class VI, ISO 10993 compliant

SustaPEEK MG

The superior physical properties of SustaPEEK MG, including chemical resistance and high temperature stability is the reason that it is increasingly replacing metals and other lower grade plastics in the medical industry.

PRODUCT FEATURES:
- Continuous use temperature of 480°F
- Outstanding dimensional stability
- High chemical resistance
- Excellent resistance to sterilization

CERTIFICATIONS:
- ASTM D6262
- FDA compliant
- USP Class VI & ISO 10993-5 certified

SustaPEI MG (Ultem®)

SustaPEI MG (Ultem®) is an amorphous transparent polyetherimide plastic that offers outstanding high heat resistance (up to 356° F), high strength and a broad chemical resistance.

PRODUCT FEATURES:
- Strength and modulus at elevated temperatures
- Inherent flame resistance
- Gamma radiation resistance
- Excellent resistance to steam sterilization

CERTIFICATIONS:
- ASTM D5205
- Meets FDA 210 CFR 177.1595
- USP Class VI, ISO 10993 compliant

Sustason PSU MG (Polysulfone)

Sustason PSU MG is a semi-transparent amorphous thermoplastic with an amber tint. Due to its inherent resistance to hot water and steam, it is regularly used in medical applications where repeated sterilization is required.

PRODUCT FEATURES:
- Continuous use temperature of 300°F
- Long-term resistance to steam sterilization
- Resistant to hydrolysis
- Strength and dimensional stability

CERTIFICATIONS:
- ASTM D6394
- FDA compliant
- USP Class VI, ISO 10993 compliant

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- USP Class VI, ISO 10993 compliant
**Sustarin® C MG**

Acetal (Celcon®)

Sustarin® C MG is easy to machine to close tolerances and is very dimensionally stable. The material has excellent wear properties and low coefficient of friction.

**PRODUCT FEATURES:**
- Excellent dimensional stability
- Easy to machine to close tolerances
- Porosity free
- Available in multiple colors

**CERTIFICATIONS:**
- ASTM D6100
- FDA21 CFR 177.2470
- USP Class VI & ISO 10993-5 certified

**Polystone® P MG**

(Polypropylene)

Polystone® P MG is a compression molded polypropylene that is manufactured by a unique heat stabilization process. This product is easily machined and is specifically designed for surgical trays and caddies.

**PRODUCT FEATURES:**
- Excellent dimensional stability
- Resistant to steam autoclaving
- Laser markable
- Low moisture absorption

**CERTIFICATIONS:**
- USP Class VI certified
- FDA compliant

**Sustanat PC MG**

(Polycarbonate)

Sustanat PC is ideally suited for applications that demand high impact strength. It is an amorphous, transparent product that exhibits good electrical and mechanical properties along with excellent dimensional stability.

**PRODUCT FEATURES:**
- Continuous use temperature of 250° F
- Easy to machine to close tolerances
- High impact strength
- Good electrical insulation

**CERTIFICATIONS:**
- ASTM D6098 PC 0111
- ASTM D3935 PC 0111
- Natural meets FDA 21 CFR 177.1582
- USP Class VI compliant

**Susta PPO MG**

(Noryl®)

SustaPPO is excellent for medical device applications due to its machineability, excellent impact properties and resistance to repeated autoclaving cycles.

**PRODUCT FEATURES:**
- Resistant to acids and bases
- Thermal and electrical resistance
- Excellent hydrolytic stability
- Balance of strength, stiffness & dimension stability

**CERTIFICATIONS:**
- ASTM D4349
- FDA compliant
- ISO 10993 compliant

**Colors available:** Natural meets FDA 21 CFR 177.1582

**General notes**

All the information contained in this product range has been researched to the best of our knowledge. Nonetheless, errors cannot be completely precluded. For this reason, the information contained in the present product range does not involve any kind of obligation or warranty. Accordingly, we therefore do not undertake any responsibility nor any resultant or any other liability, arising in any manner from utilisation of this information. No responsibility is undertaken either for the completeness of the products, processes, properties, etc. covered. Data concerning weights are purely computed values, ensuing from the density and the mean value of the tolerance dimensions.

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**Application of materials of Röchling not intended for implants**

The materials described in this product range are not suitable for application as medical implants. Furthermore, they should not be put to use in medical technical fields, necessitating direct, long-term contact of the material with the patient.

**Sterilization and multiple use of medical products**

For classification of the sterilization resistance of our materials, various criteria were referred to, such as change to the mechanical properties, change in weight or loss in transparency (amorphous materials). For these reasons, this assessment only represents recommendations and not definite commitment for the suitability of a material for a specific reprocessing procedure. Should the medical product be re-used, it is incumbent upon the manufacturer of the product to determine the suitability and the number of possible reprocessing cycles for a process.
Material properties and applications

### Material properties

<table>
<thead>
<tr>
<th>Material</th>
<th>Specific Gravity</th>
<th>Tensile Strength</th>
<th>Tensile Modulus</th>
<th>Tensile Elongation</th>
<th>Flexural Strength</th>
<th>Flexural Modulus</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPSU</td>
<td>1.29</td>
<td>11,000</td>
<td>390,000</td>
<td>30</td>
<td>15,500</td>
<td>350,000</td>
</tr>
<tr>
<td>POM C</td>
<td>1.41</td>
<td>9,500</td>
<td>400,000</td>
<td>40</td>
<td>12,000</td>
<td>400,000</td>
</tr>
<tr>
<td>PEEK</td>
<td>1.32</td>
<td>16,000</td>
<td>500,000</td>
<td>20</td>
<td>25,000</td>
<td>600,000</td>
</tr>
<tr>
<td>PEI</td>
<td>1.27</td>
<td>16,700</td>
<td>480,000</td>
<td>80</td>
<td>20,000</td>
<td>500,000</td>
</tr>
<tr>
<td>PSU</td>
<td>1.24</td>
<td>10,200</td>
<td>360,000</td>
<td>30</td>
<td>15,400</td>
<td>390,000</td>
</tr>
<tr>
<td>PPO</td>
<td>1.08</td>
<td>9.400</td>
<td>350,000</td>
<td>30</td>
<td>13,400</td>
<td>360,000</td>
</tr>
<tr>
<td>PC</td>
<td>1.20</td>
<td>10,000</td>
<td>320,000</td>
<td>75</td>
<td>13,000</td>
<td>340,000</td>
</tr>
<tr>
<td>PP</td>
<td>0.91</td>
<td>4,700</td>
<td>232,000</td>
<td>—</td>
<td>—</td>
<td>180,000</td>
</tr>
</tbody>
</table>

### Applications for medical technology

Today, finished products machined from our plastics are used in a host of medical devices and instruments. For applications requiring proven biocompatibility we offer a variety of medical-grade materials as well a comprehensive offering of standard plastics for applications that do not come into direct contact with patients.

#### Surgical instruments and supplies

- handles and grips for instrumentation
- sizing trials for knee and hip replacement
- fixation devices
- endoscopic housings and eyepieces
- sterilization trays and caddies

#### Diagnostic

- parts for X-ray and MRI devices
- components for supports and biopsy units

#### Therapeutic systems

- blocks and housings for dialysis machines
- pistons and valves for anesthetic equipment
- supports and adaptors for respiratory units

#### Dental

- grips and handles for dental instruments
- components for treatment and therapy units

#### Pharmaceutical and biotechnology

- components for sample changers
- valve housings and nozzles for fluid distribution
- spectrometer parts for chromatography systems
- wear parts for pill and tablet production
**Biocompatibility**

Biocompatible implies that a medical device is safe for human use. The ISO 10993 standard plays an important role in the assessment of the biocompatibility of a medical device through a series of tests depending on the intended use and the time that it is exposed to the human body. Most importantly, the ISO 10993-5 test method assesses the in vitro cytotoxicity of medical devices and is designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

**Sterilization and disinfection**

An essential aspect of selecting a suitable plastic for a medical technology application is also the requirement for repeated sterilization and disinfection of the product. The cleaning process typically occurs in autoclaving devices at elevated temperatures (greater than 250°F) with steam or suitable disinfectants. The resistance of the polymer should be checked in each case.

### Selection of the tests as per ISO 10993-1

<table>
<thead>
<tr>
<th>Nature of the physical contact</th>
<th>Duration of contact</th>
<th>Biological risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>A</td>
<td>×</td>
</tr>
<tr>
<td>Mucous membrane</td>
<td>B</td>
<td>×</td>
</tr>
<tr>
<td>Injured surface</td>
<td>C</td>
<td>× × ×</td>
</tr>
<tr>
<td>Blood system directly</td>
<td>A</td>
<td>×</td>
</tr>
<tr>
<td>Tissue / bone / dentin</td>
<td>B</td>
<td>× × ×</td>
</tr>
<tr>
<td>Circulating blood</td>
<td>C</td>
<td>× × ×</td>
</tr>
<tr>
<td>Tissue / bone</td>
<td>A</td>
<td>× × ×</td>
</tr>
<tr>
<td>Blood</td>
<td>C</td>
<td>× × ×</td>
</tr>
</tbody>
</table>

- ×: Test to be included in ISO 10993-1
- +: additional tests, which may be applicable

### Sterilization resistance

<table>
<thead>
<tr>
<th>Material</th>
<th>Polymer</th>
<th>Sterilization procedure/°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUSTARIN® C MG</td>
<td>POM-C</td>
<td>++, ++, ++, ++, ++, ++, ++</td>
</tr>
<tr>
<td>SUSTAPEEK MG</td>
<td>PEEK</td>
<td>++, ++, ++, ++, ++, ++, ++</td>
</tr>
<tr>
<td>SUSTASON PSU MG</td>
<td>PSU</td>
<td>++, ++, ++, ++, ++, ++, ++</td>
</tr>
<tr>
<td>SUSTASON PPSU MG</td>
<td>PPSU</td>
<td>++, ++, ++, ++, ++, ++, ++</td>
</tr>
<tr>
<td>SUSTAPEI MG</td>
<td>PEI</td>
<td>++, ++, ++, ++, ++, ++, ++</td>
</tr>
<tr>
<td>SUSTANAT PC MG</td>
<td>PC</td>
<td>++, ++, ++, ++, ++, ++, ++</td>
</tr>
</tbody>
</table>

- ++: very good resistance
- +: good resistance
- -: conditional resistance (Number of cycles limited)
- -: no resistance

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1) with the changes to the mechanical properties being taken into due account
2) Guide values
3) RT = room temperature

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Biodegradation, Cancerogenicity, Reproduction toxicity, Hemocompatibility, Presence of particulate matter, Microbiological contamination, Sensitization, Irritation, Cytotoxicity, Genotoxicity, Acute toxicity, Subchronic toxicity, Chronic toxicity, Implantation, Duration of contact, Nature of the physical contact, Medical products, with contact to body surfaces, Medical products, coming into contact with the interior of the body from outside, Implantable medical products, Skin, Mucous membrane, Injured surface, Blood system, Tissue / bone / dentin, Circulating blood, Tissue / bone, Blood, Skin, Mucous membrane, Injured surface, Blood.