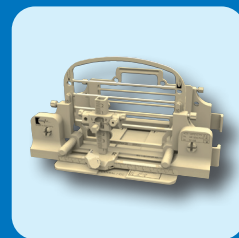




## Engineering and High-Performance Plastics for the Medical Industry



09/2017



Thermoplastics  
Semi-finished products

## ISO 13485 Certified Shaping the Future through Innovation!

Röchling stands for innovation in plastics – we continuously strive to offer new and inventive products that meet the highest standards and changing requirements of the Life Science industry.

We are certified to ISO 13485:2003, the Medical Device Standard that represents the requirements for a comprehensive management system for the design and manufacturing of medical devices. As a stock shape manufacturer of rods and sheets, our quality procedures include key elements such as resin and process validation, product inspection, lot and batch traceability (Device History Record), risk management analysis, corrective and preventive actions and customer feedback.

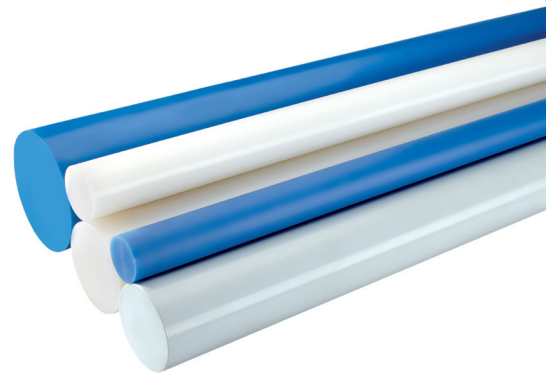
Our customers can be assured that our medical-grade products meet their expectations and comply with regulatory requirements. We offer full lot and batch traceability, detailed certification documents and raw material certificates of compliance.

We manufacture a complete line of engineering and high-performance plastics in rods and sheets

for applications including surgical instruments and devices, orthopedic sizing trials, imaging and monitoring components, surgical trays and caddies, diagnostic and analytical equipment, pharmaceutical manufacturing and biotechnology equipment.

Röchling Engineering Plastics shares your commitment to innovation and quality. Increasingly, the physical properties of high-performance plastics such as impact resistance, dimensional stability and resistance to autoclaving pave the way for new medical device and component designs. For questions relating to material selection and specifications, rely on our expert knowledge.

As a member of The Röchling Group, we are a leading global plastics manufacturer with a workforce of more than 8000 employees with 78 locations in 22 countries. Today, Röchling ranks among the top international leaders in the field of plastics processing.



# Requirements for medical technology



With **medical-grade (MG)** materials, a product range is at your disposal that has been specifically developed with medical technology in mind.

## Biocompatibility

With the raw materials deployed, we utilize plastics and additives that have already been in use in medical-technical applications for many years now. The raw materials are FDA-compliant and free from heavy metals.

## Chemical resistance

**Medical-grade** materials possess good chemical resistance to various conventional disinfectants and cleansers.

## Sterilization performance

A great number of our high-performance materials are very easily sterilizable by means of hot steam, ethylene oxide, plasma and gamma rays.

## Traceability

Röchling offers complete lot and batch traceability for **medical-grade** materials – from semi-finished products right up to the raw materials.

## FDA compatibility

The majority of our high-performance materials meet FDA requirements.

Many colors of our MG products have also been tested in regards to these guidelines.

## Hydrolysis resistance

The excellent hydrolysis resistance of our MG products is indispensable for sterilizability with hot steam.

## Physiological harmlessness

### ISO 10993

Biological evaluation of Medical Devices per ISO 10993

ISO 10993 includes a series of tests for evaluating the biocompatibility of a medical device prior to a clinical trial. Compliance to ISO 10993-5 (tests for in vitro cytotoxicity) is typically the most requested for applications requiring our high-performance plastics.

Many of our products have either been tested and approved by an independent lab to ISO 10993-5 or are produced with raw materials that are certified for approval.

### USP Class VI

Biological tests per USP Class VI

USP tests are used to determine the biological reactivity of plastic materials. Most of our products are USP VI (systemic and intracutaneous toxicity) compliant.

## Food contact guidelines

Compliance with FDA Regulation CFR21

Based on the data from the raw material supplier, we can provide a certification for direct contact with food for a large number of our materials. It is derived from the FDA regulation "Code of Federal Regulations" 21 CFR, Part 177.

## Biocompatibility

Within the scope of selecting the suitable material for a medical-technical application, not only the technical requirements have to be considered, but often it is necessary to ensure the material is compatible with the human organism. The biological assessment of a product is invariably requisite, if there is direct contact of the material or product with the patient.

The extent of such tests depends particularly on the experience already gained for this material in the particular application concerned, and the precise intended use of the medical product (in particular the nature and duration of the physical contact).

The chief basic regulations for biological testing and assessment of materials are ISO 10993 and testing as per United States Pharmacopeia Class VI (USP Class VI for short). Despite the fact that the clearly more comprehensive ISO 10993 was originally meant to supersede testing as per USP Class VI, USP testing is very frequently referred to today to assess plastics.

There are various test results for bio-compatibility according to ISO 10993 and USP Class VI available for the **medical-grade** materials from Röchling.

## Ultrasonic Testing

We perform ultrasonic testing on **medical-grade** products to ensure that there are no cracks or voids.





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.

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.

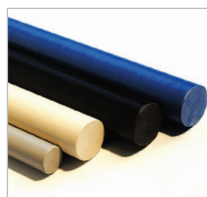
Partially crystalline thermoplastics are a result of the molecular arrangement, usually being opaque. The mechanical properties (strength, toughness and hardness) of this group depend to a great extent on the degree of crystallinity. They feature great resistance to the formation of stress cracks and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

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**Sustason  
PPSU MG  
(Radel®)**

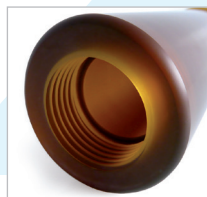
Sustason PPSU MG offers incredible toughness in applications that receive repeated sterilization. With a high heat deflection temperature of 420° F it can absorb tremendous impact without cracking or breaking.

- ➔ Excellent thermal stability
- ➔ High impact resistance
- ➔ Resistance to repeated autoclaving
- ➔ Resistance to hydrolysis

- ➔ ASTM D6394
- ➔ FDA compliant
- ➔ USP Class VI, ISO 10993 compliant

| Products | Sizes                 | Colors   |
|----------|-----------------------|--|
| Sheets   | 3/8" – 2" x 24" x 48" |   |
| Rods     | 1/4" – 6" diameter    |  |

Colors available: Natural (bone), Black, Blue, Grey & Green  
Custom colors available













## SustaPEI MG (Ultem®)

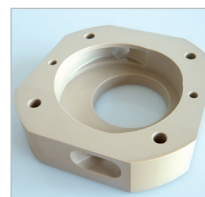
SustaPEI MG (Ultem®) is an amorphous transparent polyetherimide plastic that offers outstanding high heat resistance (up to 356° F), high strength and a broad chemical resistance.

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

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

| Products | Sizes                 | Colors  |
|----------|-----------------------|---|
| Sheets   | 1/4" – 4" x 24" x 48" |      |
| Rods     | 1/4" – 6" diameter    |      |

Colors available: Natural (Amber), Black, Blue, Grey & Green





**SUSTAPEEK  
MG**

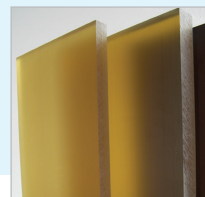
The superior physical properties of SUSTAPEEK MG, including chemical resistance and high temperature stability is the reason that it is increasingly replacing metals and other lower grade plastics in the medical industry.

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

- ➔ ASTM D6262
- ➔ FDA compliant
- ➔ USP Class VI & ISO 10993-5 compliant

| Products | Sizes                 | Colors  |
|----------|-----------------------|---|
| Sheets   | 1/4" – 4" x 24" x 48" |    |
| Rods     | 1/4" – 6" diameter    |  |

Colors available: Natural (tan), Black, Blue, Brown, Yellow & Green





**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.

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

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

| Products | Sizes                 | Colors  |
|----------|-----------------------|---|
| Sheets   | 3/8" – 2" x 24" x 48" |  |
| Rods     | 3/8" – 6" diameter    |  |

Colors available: Natural (Amber) & White

# engineering



**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 compliant

| Products | Sizes                 | Colors          |
|----------|-----------------------|-----------------|
| Sheets   | 3/8" – 4" x 24" x 48" | ● ● ● ● ● ● ● ● |
| Rods     | 3/8" – 8" diameter    | ● ● ● ● ● ● ● ● |

Colors available: Natural, Blue, Red, Orange, Yellow, Green, Brown & Grey  
Custom colors available



**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

| Products | Sizes                 | Colors |
|----------|-----------------------|--------|
| Sheets   | 1/4" – 4" x 24" x 48" | ●      |
| Rods     | 3/8" – 8" diameter    | ●      |

Colors available: Natural



**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:

- ISO 10993 compliant
- FDA compliant

| Products | Sizes                 | Colors |
|----------|-----------------------|--------|
| Sheets   | 1/2" – 3" x 24" x 48" | ● ●    |
| Sheets   | 1/2" – 3" x 40" x 48" | ● ●    |

Colors available: Black & White



**SustaPPO 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

| Products | Sizes                 | Colors      |
|----------|-----------------------|-------------|
| Sheets   | 3/8" – 2" x 24" x 48" | ● ● ● ● ● ● |
| Rods     | 3/8" – 6" diameter    | ● ● ● ● ● ● |

Colors available: Grey, Blue, Brown, Yellow & Green

## 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.

Our Medical Grade semi-finished products are not intended for the manufacture of implants, critical components of medical devices, permanent oral or dental contact of more than twenty-four (24) hours with body fluids and/or tissue/bones. The processors and marketers of medical devices are advised that any intended application must be carefully examined. In the EU, medical products may only be placed on the market if they have been CE-marked in the procedure provided for them and also fulfill all the requirements of the respective relevant legislation. The sole responsibility for the evaluation of the end product for the intended use and compliance with the applicable requirements lies solely with the manufacturer/marketer of the respective product/end product.

## 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   |                  |                  | Specific Gravity | Tensile Strength | Tensile Modulus | Tensile Elongation | Flexural Strength | Flexural Modulus |
|------------|------------------|------------------|------------------|------------------|-----------------|--------------------|-------------------|------------------|
| Trade Name | Common Name      |                  | D792             | D638 PSI         | D638 PSI        | D638 %             | D790 PSI          | D790 PSI         |
| PPSU       | SUSTASON PPSU MG | Radel R          | 1.29             | 11,000           | 390,000         | 30                 | 15,500            | 350,000          |
| POM C      | SUSTARIN® C MG   | Acetal Copolymer | 1.41             | 9,500            | 400,000         | 40                 | 12,000            | 400,000          |
| PEEK       | SUSTAPEEK MG     | PEEK             | 1.32             | 16,000           | 500,000         | 20                 | 25,000            | 600,000          |
| PEI        | SUSTAPEI MG      | Ultem            | 1.27             | 16,700           | 480,000         | 80                 | 20,000            | 500,000          |
| PSU        | SUSTASON PSU MG  | Polysulfone      | 1.24             | 10,200           | 360,000         | 30                 | 15,400            | 390,000          |
| PPO        | SUSTA PPO MG     | Noryl            | 1.08             | 9,400            | 350,000         | 30                 | 13,400            | 360,000          |
| PC         | SUSTANAT PC MG   | Polycarbonate    | 1.20             | 10,000           | 320,000         | 75                 | 13,000            | 340,000          |
| PP         | Polystone® P MG  | Polypropylene    | 0.91             | 4,700            | 232,000         | —                  | —                 | 180,000          |

| Material   |                  |                  | Rockwell Hardness | Izod Impact Notched | Heat Deflection Temp. @ 66 psi | Heat Deflection Temp. @ 264 psi | Continuous Use | Volume Resistivity     |
|------------|------------------|------------------|-------------------|---------------------|--------------------------------|---------------------------------|----------------|------------------------|
| Trade Name | Common Name      |                  | D785 R            | D256 ft. lb/in      | D648 °F                        | D648 °F                         | °F             | D257 ohm-cm            |
| PPSU       | SUSTASON PPSU MG | Radel R          | R120              | 13                  | 417                            | 420                             | 320            | 10 <sup>16</sup>       |
| POM C      | SUSTARIN® C MG   | Acetal Copolymer | R120              | 1.2                 | 320                            | 225                             | 180            | 10 <sup>16</sup>       |
| PEEK       | SUSTAPEEK MG     | PEEK             | R126              | 1.2                 | 360                            | 320                             | 480            | 10 <sup>15</sup>       |
| PEI        | SUSTAPEI MG      | Ultem            | R123              | 0.6                 | 405                            | 395                             | 340            | 10 <sup>16</sup>       |
| PSU        | SUSTASON PSU MG  | Polysulfone      | R125              | 1.3                 | 359                            | 345                             | 300            | 5.0 x 10 <sup>16</sup> |
| PPO        | SUSTA PPO MG     | Noryl            | R119              | 3.5                 | 289                            | 260                             | 220            | 10 <sup>17</sup>       |
| PC         | SUSTANAT PC MG   | Polycarbonate    | R126              | 10                  | 295                            | 280                             | 250            | >10 <sup>13</sup>      |
| PP         | Polystone® P MG  | Polypropylene    | —                 | 1.9                 | 221                            | 149                             | 180            | —                      |

## 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 as 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

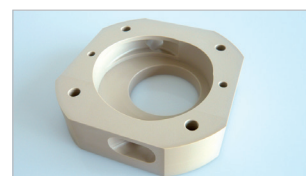
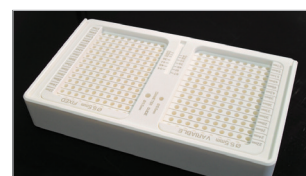
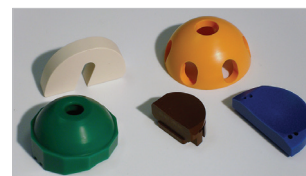
- blocks and housings for dialysis machines
- pistons and valves for anesthetic equipment
- supports and adaptors for respiratory units

### 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 and sterilization performance

## 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

|  |                        |                     | Biological risks |               |            |                |                     |              |              |                   |                  |                 |                       |                |
|--|------------------------|---------------------|------------------|---------------|------------|----------------|---------------------|--------------|--------------|-------------------|------------------|-----------------|-----------------------|----------------|
| Nature of the physical contact   |                        | Duration of contact | Cytotoxicity     | Sensitization | Irritation | Acute toxicity | Subchronic toxicity | Genotoxicity | Implantation | Hemocompatibility | Chronic toxicity | Carcinogenicity | Reproduction toxicity | Biodegradation |
| Medical products with contact to body surfaces                                   | Skin                   | A                   | x                | x             | x          |                |                     |              |              |                   |                  |                 |                       |                |
|  |                        | B                   | x                | x             | x          |                |                     |              |              |                   |                  |                 |                       |                |
|  | Mucous membrane        | C                   | x                | x             | x          |                |                     |              |              |                   |                  |                 |                       |                |
|  |                        | A                   | x                | x             | x          |                |                     |              |              |                   |                  |                 |                       |                |
|  | Injured surface        | B                   | x                | x             | x          | •              | •                   | •            | •            |                   |                  |                 |                       |                |
|  |                        | C                   | x                | x             | x          | •              | x                   | x            | •            |                   | •                |                 |                       |                |
| Medical products, coming into contact with the interior of the body from outside | Blood system directly  | A                   | x                | x             | x          | •              |                     |              |              |                   |                  |                 |                       |                |
|  |                        | B                   | x                | x             | x          | •              | •                   |              | •            |                   |                  |                 |                       |                |
|  | Tissue / bone / dentin | C                   | x                | x             | x          | •              | x                   | x            | •            |                   | •                |                 |                       |                |
|  |                        | A                   | x                | x             | x          | x              |                     |              |              | x                 |                  |                 |                       |                |
|  | Circulating blood      | B                   | x                | x             | x          | x              | •                   |              |              | x                 |                  |                 |                       |                |
|  |                        | C                   | x                | x             | •          | x              | x                   | x            | •            | x                 | x                | x               |                       |                |
| Implantable medical products   | Tissue / bone          | A                   | x                | x             | x          | •              |                     |              |              |                   |                  |                 |                       |                |
|  |                        | B                   | x                | x             | x          | •              | •                   | x            | x            |                   |                  |                 |                       |                |
|  | Blood                  | C                   | x                | x             | x          | •              | •                   | x            | x            |                   | •                | x               |                       |                |
|  |                        | A                   | x                | x             | x          | x              |                     | •            |              | x                 |                  |                 |                       |                |

x Test to be included to ISO 10993-1

• additional tests, which may be applicable

A = short-term (= 24 h)

B = protracted (> 24 h to 30 d)

C = continuous (> 30 d)

| Sterilization resistance <sup>1)</sup> |         | Sterilization procedure/°F <sup>2)</sup> |       |         |                |        |                  |
|--|---------|--|-------|---------|----------------|--------|------------------|
| Material                               | Polymer | Hot steam                                |       | Hot air | Ethylene oxide | Plasma | Gamma rays       |
|  |         | 250°F                                    | 273°F | 356°F   | 140°F          | 113°F  | RT <sup>3)</sup> |
| <b>Polystone® P MG</b>                 | PP-H    | ↑↑                                       | ↑↑    | ↓       | ↔              | ↑      | ↔                |
| <b>SUSTARIN® C MG</b>                  | POM-C   | ↑  | ↔     | ↓       | ↑              | ↑      | ↓                |
| <b>SUSTAPEEK MG</b>                    | PEEK    | ↑↑                                       | ↑↑    | ↑↑      | ↑↑             | ↑↑     | ↑↑               |
| <b>SUSTASON PSU MG</b>                 | PSU     | ↑↑                                       | ↑     | ↓       | ↑              | ↑      | ↑                |
| <b>SUSTASON PPSU MG</b>                | PPSU    | ↑↑                                       | ↑↑    | ↔       | ↑↑             | ↑↑     | ↑↑               |
| <b>SUSTAPEI MG</b>                     | PEI     | ↑↑                                       | ↑↑    | ↔       | ↑↑             | ↑↑     | ↑↑               |
| <b>SUSTANAT PC MG</b>                  | PC      | ↔  | ↓     | ↓       | ↑              | ↑      | ↔                |

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



very good resistance



good resistance



conditional resistance (Number of cycles limited)



no resistance



# RÖCHLING

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