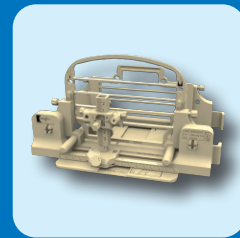




RÖCHLING

Engineering Plastics

Engineering and High-Performance Plastics for the Medical Industry



01/2011



Thermoplastics
Semi-finished products

Shaping the Future through Innovation!

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

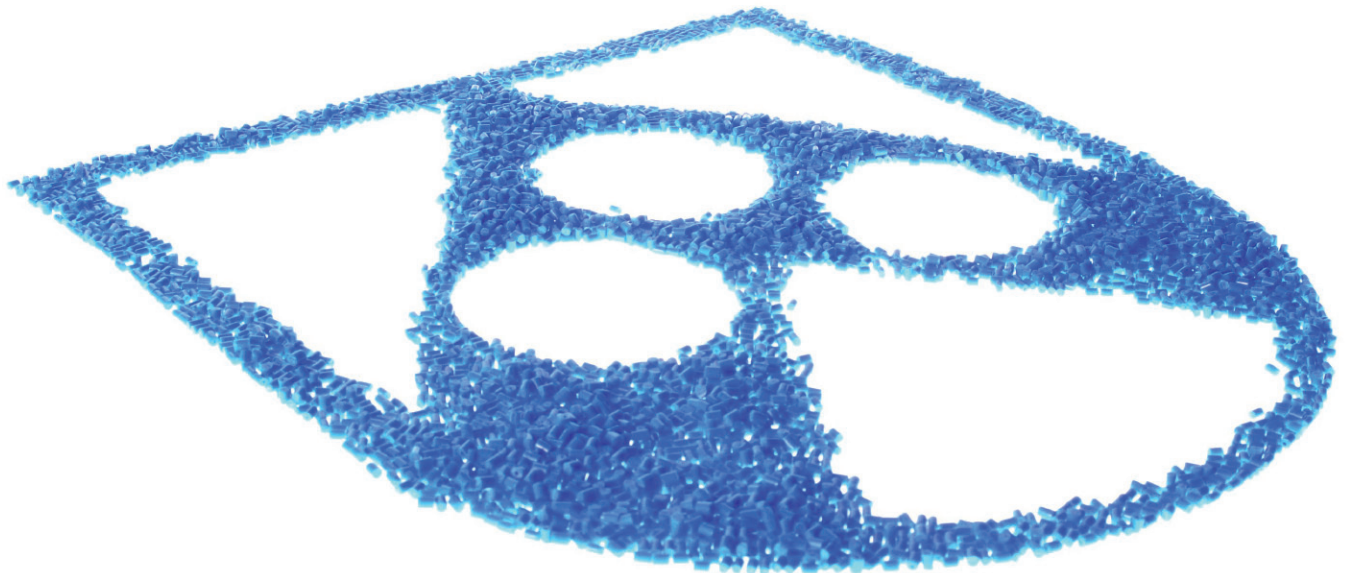
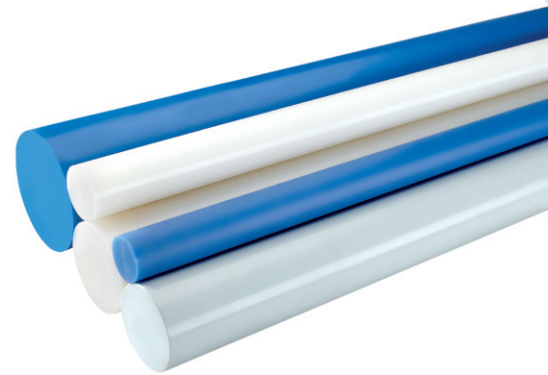
Our **medical-grade** plastics are manufactured with state of the art machinery and technologies to meet the high quality demands of our customers. Our products are subjected to numerous quality tests in all phases of production, including 100% ultrasonic testing – every inch of every rod. We offer full lot and batch traceability, detailed certification documents and raw material certificates of analysis.

In addition to our ISO 9001:2008 Certification, our quality control program includes many of the important ISO 13485 (Medical Device Standard) requirements such as Device History Records, Process Validation and Customer Feedback.

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 provide the way for new designs of medical devices and components. For questions relating to material selection and specifications, rely on us for the expert knowledge.

As a member of The Röchling Group, we are a leading global plastics manufacturer with a workforce of more than 6000 employees with 54 locations in 20 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.

The majority 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 either USP VI (systemic and intracutaneous toxicity) certified or 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 100% ultrasonic testing on all **medical-grade** products to ensure that there are no cracks or voids.



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
- USP Class VI & ISO 10993-5 certified

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

Colors available: Natural, Blue, Red, Yellow, Green, Brown, Black & 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:

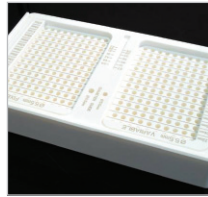
- Continuous use temperature of 250° F
- Easy to machine to close tolerances
- High impact strength
- Good electrical insulation

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:

- USP Class VI certified
- 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



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

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.

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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			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	SUSTAPPO 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 ¹⁶
POM C	SUSTARIN® C MG	Acetal Copolymer	R120	1.2	320	225	180	10 ¹⁶
PEEK	SUSTAPEEK MG	PEEK	R126	1.2	360	320	480	10 ¹⁵
PEI	SUSTAPEI MG	Ultem	R123	0.6	405	395	340	10 ¹⁶
PSU	SUSTASON PSU MG	Polysulfone	R125	1.3	359	345	300	5.0 x 10 ¹⁶
PPO	SUSTAPPO MG	Noryl	R119	3.5	289	260	220	10 ¹⁷
PC	SUSTANAT PC MG	Polycarbonate	R126	10	295	280	250	>10 ¹³
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 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

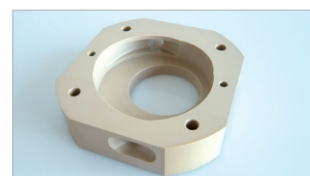
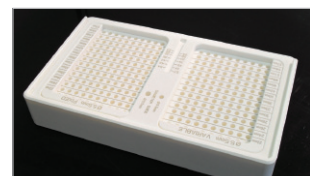
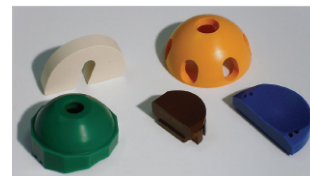
- blocks and housings for dialysis machines
- pistons and valves for anesthetic equipment
- supports and adaptors for respiratory units

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

Nature of the physical contact		Duration of contact	Biological risks													
			Cytotoxicity	Sensitization	Irritation	Acute toxicity	Subchronic toxicity	Genotoxicity	Implantation	Hemocompatibility	Chromical 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 ¹⁾		Sterilization procedure/ ^{°F} ²⁾					
Material	Polymer	Hot steam		Hot air	Ethylene oxide	Plasma	Gamma rays
		250°F	273°F	356°F	140°F	113°F	RT ³⁾
Polystone® P MG	PP-H	↑↑	↑↑	↓	↔	↑	↔
SUSTARIN C MG	POM-C	↑	↔	↓	↑	↑	↓
SUSTAPEEK MG	PEEK	↑↑	↑↑	↑↑	↑↑	↑↑	↑↑
SUSTASON PSU MG	PSU	↑↑	↑	↓	↑	↑	↑
SUSTASON PPSU MG	PPSU	↑↑	↑↑	↔	↑↑	↑↑	↑↑
SUSTAPEI MG	PEI	↑↑	↑↑	↔	↑↑	↑↑	↑↑
SUSTANAT PC MG	PC	↔	↓	↓	↑	↑	↔

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



very good resistance



good resistance



conditional resistance (Number of cycles limited)



no resistance



RÖCHLING

Engineering Plastics

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