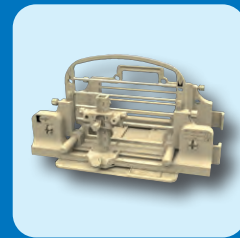




RÖCHLING

Engineering Plastics

Engineering and High-Performance Plastics for the Medical Industry



04/2012



Thermoplastics
Semi-finished products

Product overview

high performance

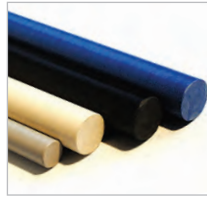
Material selection

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:

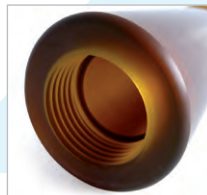
- ☉ Excellent thermal stability
- ☉ High impact resistance
- ☉ Resistance to repeated autoclaving
- ☉ Resistance to hydrolysis

CERTIFICATIONS:

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

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.

PRODUCT FEATURES:

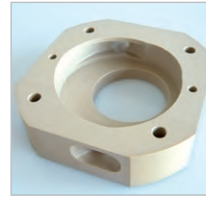
- ☉ Strength and modulus at elevated temperatures
- ☉ Inherent flame resistance
- ☉ Gamma radiation resistance
- ☉ Excellent resistance to steam sterilization

CERTIFICATIONS:

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

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.

PRODUCT FEATURES:

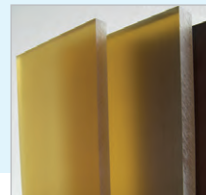
- ☉ Continuous use temperature of 480°F
- ☉ Outstanding dimensional stability
- ☉ High chemical resistance
- ☉ Excellent resistance to sterilization

CERTIFICATIONS:

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

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.

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

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
- USP Class VI & ISO 10993-5 certified

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

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

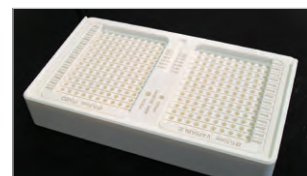
- ☞ blocks and housings for dialysis machines
- ☞ pistons and valves for anesthetic equipment
- ☞ supports and adaptors for respiratory units

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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