

Company Insight



RÖCHLING
Engineering Plastics

Why Röchling Should Be Your Supplier For Medical Grade Plastic Materials?

**“Shaping the Future
Through Innovation”**



Röchling Adds Over 1,000,000 # Capacity Due to Growth For Our Medical Grade Plastics Materials

Röchling one of the world's largest manufacturers of Mechanical & High Performance Plastics continues to make investment in new equipment for medical grade plastics in North America.

This new equipment will run medical grade Acetal®, Utem®, PEEK®, Polysulfone, Polycarbonate & Noryl®. This equipment will run rod and board increasing Röchling's US capacity well over the projected demand. A similar expansion is planned for 2012.

“Growing To Service Our Customers Needs”

Black Speck Problems ?

Not with Röchling

I continue to hear about black speck problems in material supplied by manufacturers other than Röchling. Do you have this problem? Please insist on Röchling products in the future to minimize this problem.

Röchling's ISO 13485 procedures have numerous checks to help minimize the chance of black specks in our material. We do comprehensive incoming inspections. We continually inspect product during the manufacturing process and have a detailed outgoing inspection to make sure no contaminated product leaves our manufacturing plant. These procedures and using premixed resin from only the best manufacturers helps us to minimize this problem.

Are we 100% rejection free, no, but our rejection rate for this problem in the last 12 month period was under ½%. If you have had this problem in the past, insist your distributor provides you with Röchling Engineering Plastics materials. If they can't help, please call and we will give you the name of a distributor who will.

Produced By George Southard / G S Sales 317-595-6750

Röchling is the only supplier of
Medical Grade Plastics that is
ISO 13485 Certified !



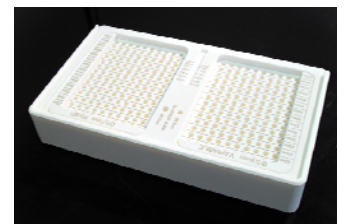
Many of our competitors say that they are ISO 13485 compliant. What does this mean? There is a huge difference between being certified and compliant. With Röchling you can be assured that we are certified and we have to be recertified annually by independent auditing agencies to keep this important certification. Compliance is nothing if you are not audited.

ISO 13485 was published in 2003 and represent the requirements for a comprehensive management system for the design and manufacturing of all medical devices including:

- Controls to ensure product safety
- Risk management activities
- Inspection and traceability'
- Documentation and validation of processes
- Verification of the effectiveness of corrective and preventative actions.

In addition to our new ISO 13485 certification Röchling also offers ISO 10993 compliancy and USP Class VI compliancy or certification.

Compression Molded Medical Grade Polypropylene Sheet, Minimizes Stresses During Machining !



Röchling has the equipment to either extrude or compression mold their Polystone® P Medical Grade Polypropylene sheet. We chose to compression mold and anneal our Polypropylene sheet to give our customers a sheet that would machine great and minimize movement during the machining process. This because it has less stress than an extruded sheet.

If you have not tried the Röchling Polystone® P MG please call and we will send a sample out for your testing. I am sure you will insist on it in the future as many other fabrication facilities are. Call today at 704-922-3520 and ask for Cheri.

E-mail:

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Website:

<http://www.roebling-plastics.us>

Röchling Engineering Plastics

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RÖCHLING's World of Medical Grade Plastics



SustaPEEK MG
SustaPEI MG (ULTEM®)
Sustason PPSU MG (Radel® R)
Sustarin® C MG (Acetal)
Sustason PSU MG (Polysulfone)
Polystone® P MG (Polypropylene)

Innovation is Key

Röchling stands for innovation in plastics – and in order to provide you with state of the art materials which meet the highest standards of the medical industry we continuously invest in new and innovative products and manufacturing technologies. We provide a complete line of Medical Grade plastics for devices, instrumentation and orthopedic trials.

Certificates

- ↻ ASTM
- ↻ USP Class VI
- ↻ ISO 10993-5
- ↻ FDA Compliant
- ↻ Lot & Batch Traceability
- ↻ Ultrasonic Testing



Plastics for the diverse healthcare industry

- ↻ Surgical instruments and devices
- ↻ Orthopedic sizing trials
- ↻ Imaging and monitoring
- ↻ Surgical Trays
- ↻ Diagnostic equipment
- ↻ Dental equipment and devices
- ↻ Pharmaceutical manufacturing
- ↻ Biotechnology

www.roechling-plastics.us

All information contained herein is presented in good faith based upon testing and practical experience. These values are not intended for use in establishing specification values. Röchling Engineering Plastics does not guarantee the accuracy and completeness of this information and it is the customer's sole responsibility to determine the suitability of the products in any given application. Please note that our products are not recommended or intended for use as implants.



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



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:

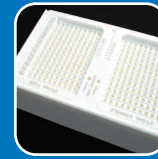
- Excellent thermal stability
- High impact resistance
- Resistance to repeated autoclaving
- Resistance to hydrolysis

Certifications:

- ASTM D6394
- FDA compliant
- USP Class VI compliant

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

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



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



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:

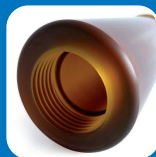
- Continuous use temperature of 480°F
- Outstanding dimensional stability
- High chemical resistance
- Excellent resistance to sterilization

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, Red, Yellow, & Green



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:

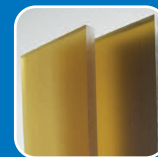
- Strength and modulus at elevated temperatures
- Inherent flame resistance
- Gamma radiation resistance
- Excellent resistance to steam sterilization

Certifications:

- ASTM D5205
- Meets FDA 210 CFR 177.1595
- USP Class VI 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



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 compliant

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

Colors available: Natural (Amber) & White