Polymershapes

Performance Plastics for the Healthcare Industry

Why Polymershapes?

Polymershapes is the premier distributor of plastic sheet, rod, tube, film, and associated products. Our knowledgeable medical market team understands the critical need for safe and durable products to meet the most stringent medical applications. With an extensive inventory from world-class suppliers, Polymershapes offers a complete portfolio of performance plastics, with available lot and batch traceability, along with expert conversion capabilities including cut-to-size sheet, machining and film conversion. We consistently deliver innovative solutions to delight our customers!

Serving Cutting-Edge Medical Sectors & Applications

Biopharma

Plastics for the production and assembly of pharmaceutical research equipment, and the production of new drugs and therapies. Including the dispensing, packaging and handling of products.

- Filtration & Separation Technologies
- Pharmaceutical Processing & Packaging
- Fill Finish
- Process Equipment
- Fluid Transfer
- ADI-Free Compliant Wetted Materials

Surgical

Plastics are lightweight, resistant to chemicals and easily formable. The materials used in surgical applications meet stringent quality and safety standards.

- Sterilization Trays, Cases & Caddies
- Orthopedic Trial Sizers
- Tools & Instruments
- Aesthetic Dipping Mandrels & Release Films

Medtech

Performance plastic may be used in the production of equipment and tools used for diagnostics, patient care, treatments and improvements of a patient's health.

- Analytical & Diagnostic Equipment
- Anesthetic & Therapy Equipment
- Medical Imaging
- Dental
- Neonatal Intensive Care and Lateral Flow Diagnostics
- Lighting

Fluidics

Plastics may be used in the production of single-use products for fluid management including collecting, transferring, storing, injecting and fluid administration.

- Valves, Pumps & Connectors
- Housings & Manifolds
- Column Hardware
- Sensors
- Manifolds

Application Requirements

Biocompatibility

Suitable materials must be safe when making physical content with the patient. Basic regulations these materials must comply with regulations set by the FDA, ISO 10993 and USP Class VI testing.

Chemical Resistance

It is necessary for medical grade materials to withstand exposure to a number of chemicals including those used in sterilization processes, disinfectants and others they may come into direct contact with.

Sterilization Performance

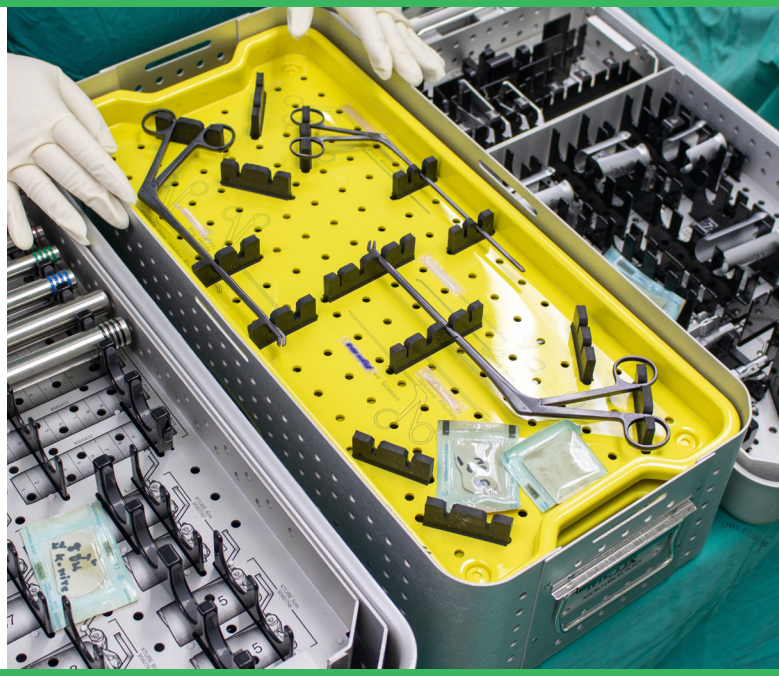
These materials must be easily sterilized under various methods including hot steam, ethylene oxide, plasma and gamma rays. It is important for these materials to have excellent hydrolysis resistance when being sterilized by methods using hot steam.

Traceability

Lot and batch traceability is available, please contact your local Polymershapes for more information.

Ultrasonic Testing

Ultrasonic testing for medical grade products ensures purity and durability.



Contact us at info@polymershapes.com

Meeting Regulatory Compliance

With our dedicated medical market team, Polymershapes' portfolio of products and services is designed to meet stringent regulatory standards of the healthcare industry, ensuring your business is equipped with safe and compliant materials.

ISO 10993

ISO 10993 assesses biological health of medical devices. These standards are applicable for active, non-active, implantable and non-implantable devices that may have direct or indirect contact with a patient. These assessments ensure medical devices comprised of plastic materials will not have a negative impact on a patient's health.

FDA Compliant

Many of our high-performing materials meet FDA requirements. With supplier data, we can provide a certification for raw materials that come into direct contact with food. These certifications are derived from the "Code of Federal Regulations" 21CFR, Part 177 set by the FDA.

BPOG

Several performance plastics meet evaluations set forth by The BioPhorum Operations Group (BPOG) for leachables risk from Polymeric Single-Use Systems (SUS) in Biomanufacturing. While not formally recognized by the FDA, these standards and documentation are widely referenced throughout the industry.

USP Class VI

These materials follow USP Class VI guidelines, ensuring that there are no harmful reactions or effects as a result of using these products in medical applications. USP Class VI is a common standard for pharmaceutical tubing, fittings, single-use systems and fabricated parts.

BioPhorum

BioPhorum provides guidance for the industry's emerging technologies and manufacturing processes. As a member, we have the unique opportunity to work alongside industry leaders to define the future for biopharmaceuticals. Polymershapes is able to provide material solutions meeting regulatory standards for these developing technologies.

Performance Plastics for Healthcare

Why Plastics?

Medical applications demand durability, reliability and regulatory compliance. Performance plastics provide a solution to these needs, as they are able to withstand repeated sterilization, are resistant to chemicals, offer enhanced strength and allow for design flexibility.

Selecting the Right Material for Your Application:

- Will this be a bearing & wear (i.e. frictional forces) or structural (static or dynamic) application? What are the thermal requirements of your applications (heat deflection or continuous service temperature)?
- What are the thermal requirements of your application (heat deflection or continuous service temperature)?
- Are there any chemical resistance requirements; either during use or cleaning?
- Determine your machinability requirements
- Do you have other requirements for your material?
  - Toughness / relative impact resistance
  - Dimensional stability
  - Regulatory or agency compliance

Many of the most commonly used Engineering Plastic materials are available in smaller sizes, custom cut to your specific requirements.

Standard & Engineering Materials < 180-230°F

Standard performance plastics materials are best suited for lower operating temperatures (<180°F), offering low moisture absorption and good chemical resistance. Standard materials are often used for orthotic and prosthetic devices, as well as medical cabinetry. Engineering materials are suited for higher operating temperatures (180 - 230°F). Engineering Plastics have good impact and chemical resistance, often being used in applications such as aesthetics molding, neonatal ICU's, or Upstream and Downstream Fluid Management.

Acrylic (PMMA)

Optical Clarity & Durability

Operating Temp: -20 to 190°F

Advantages
- Easy to fabricate
- Transparency
- Design Flexibility

Common Applications
- Prosthetics and Orthotics
- Cement Spacers
- Ocular Use

Common Brands
OPTIX®, PLEXIGLAS®, ACRYLITE®, Polycast®

High-Density Polyethylene (HDPE)

Corrosion & Impact Resistance

Operating Temp: -50 to180°F

Advantages
- Chemical Resistance
- Corrosion Resistance
- Impact Resistance
- Low Moisture Absorption

Common Applications
- Medical Cabinetry
- Bathroom Partitions and Lockers
- Medical Shelving and Storage

Common Brands
Proteus®,TECAFINE®

Polycarbonate (PC)

Clarity & Impact Resistance

Operating Temp: -4 to 265°F

Advantages
- Biocompatibility
- Transparency
- Impact Resistance
- Strength

Common Applications
- Wall Panels
- Sterilization Trays
- Surgical Related Equipment

Common Brands
LEXAN™, TECANAT®, Sustanat®

Polypropylene (PP)

Chemical Resistance & Dimensional Stability

Operating Temp: -4 to 212°F

Advantages
- Regulatory Compliance
- Chemical Resistance
- Corrosion Resistance
- Low Moisture Absorption

Common Applications
- Sterilization Trays
- Surgical Caddies
- Surgical Related Equipment
- Prosthetics and Orthotics

Common Brands
Proteus®, Polystone® P

Ultra-High Molecular Weight Polyethylene (UHMW-PE)

Wear resistance & Low Friction

Operating Temp: -436 to 180°F

Advantages
- Advantages
- Impact Strength
- Energy Absorption
- Wear Resistance
- Low Coefficient of Friction

Common Applications
- Surgical Orthotic Implants
- Wear Strips

Common Brands
TIVAR®, Chirulen®, Extrulen®

Acetal (POM)

Wear Resistance

Operating Temp: 208 to 230°F

Advantages
- High Strength & Stiffness
- Wear Resistance
- Low Moisture Absorption
- Steam Resistance

Common Applications
- Star Wheels
- Rub Rails
- Pulleys

Common Brands
Acetron®, TECAFORM®, Sustarin® C

Advanced & Extreme Materials >230°F

For the most demanding applications in the medical industry, advanced and extreme performance plastic materials are often used. These materials provide excellent chemical resistance, high purity and excellent wear properties. Advanced and extreme materials are often used to manufacture biological drugs and therapies equipment, orthopedic implants, and surgical instruments.

Polyetheretherketone (PEEK)

Temperature Resistance & Low Moisture Absorption

Operating Temp: -94 to 480°F

Advantages
- Temperature Resistance
- Chemical Resistance
- Biocompatibility
- Low Moisture Absorption

Common Applications
- Short-term Implants
- Surgical Instruments Handles
- Spinal Fusion Cages
- Wear Rings

Common Brands
Zeniva®, TECAPEEK, SustaPEEK

Polyetherimide (PEI)

Dimensional Stability & Design Flexibility

Operating Temp: -58 to 340°F

Advantages
- High Strength
- Dimensional Stability
- Flame Resistance
- Gamma Radiation Resistance

Common Applications
- Manifolds
- Electrical Component Housings

Common Brands
ULTEM™,Duratron®, TECAPEI, SustaPEI

Fluoropolymers
- PVF (Tedlar®)
- PVDF
- PTFE (Teflon™)
- PCTFE

Polyphenylsulfone (PPSU)

Chemical & Impact Resistance

Operating Temp: -52 to 300°F

Advantages
- Impact Resistance
- Chemical Resistance
- Low Moisture Absorption
- Lot Traceability

Common Applications
- Sterilization Trays & Caddies
- Surgical Instrument Handles
- Implant Trials

Common Brands
RADEL®, Sultron®, Sustason®, TECASON® P

Polysulfone (PSU)

Chemical and Hydrolysis resistance

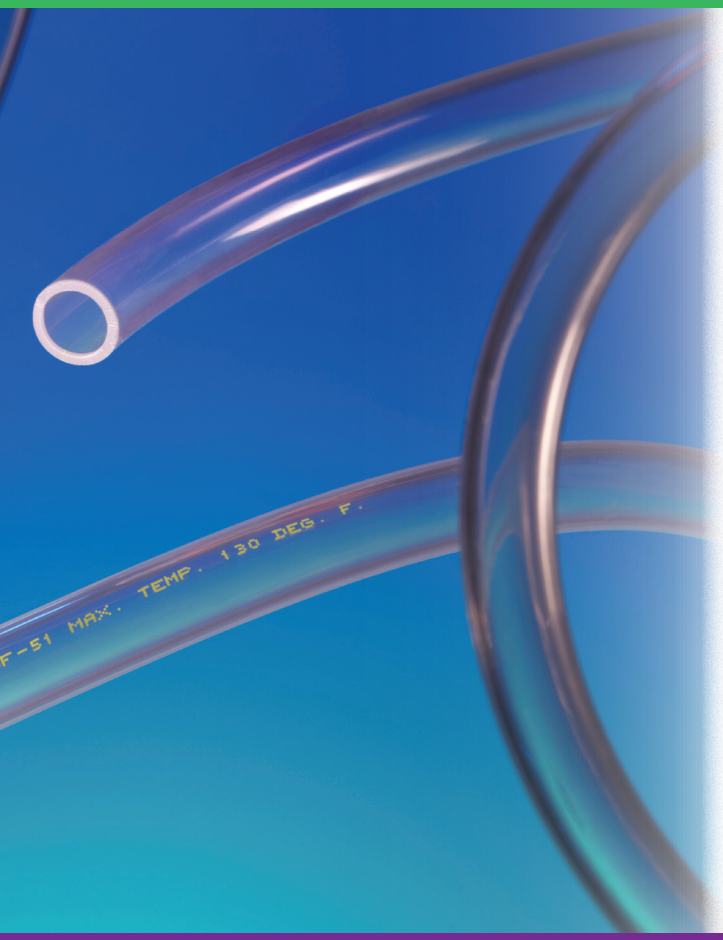
Operating Temp: -150 to 340°F

Advantages
- Semi-transparent
- Chemical Resistance
- Hydrolysis Resistance
- Heat Resistance

Common Applications
- Endoscopic Housings & Eye Pieces
- Medical Device Components
- Sterilization Trays
- Surgical Instrument Handles

Common Brands
Sultron®, TECASON® S, Sustason®

Tubing



Ethylene Tetrafluoroethylene (ETFE)

Flexibility & Chemical Resistance

Operating Temp: -454 to 500°F

Advantages

- Durability
- Flexibility
- Abrasion Resistance
- Chemical Resistance

Common Applications

- Diagnostics & Lab Testing
- Cell Harvest Systems
- Product Filtration & Fermentation
- Vaccine Manufacturing

Common Brands

VERSILON™

Platinum Cured Silicone

Flexibility & Low Extratables

FDA COMPLIANT USP CLASS VI

Operating Temp: -112 to 419°F

Advantages

- Contains no Peroxide by-products, Chlorophenyls or PCBs
- No Organic Plasticizers, Phthalates or Latex Additives
- Easily Sterilized
- Wide Temperature Range

Common Applications

- Ultrapure fluid transfer
- Filling machines
- Steam or gas transfer
- Cleanroom

Film

Through our specialty PolymerFilms division, Polymershapes is proud to offer a complete portfolio of thin-gauge performance plastics for medical applications.

Blown & Extruded Films

- Polycarbonate (LEXAN™)
- Polypropylene
- Polyethylene
- Polyimides
- Polyester
- ECTFE
- PTFE
- Fluoropolymers
  - PVF (Tedlar®)
  - ETFE (Tefzel™)
  - PFA (Teflon™)
  - FEP (Teflon™)

Cutting-Edge Applications

- TFF Cassettes
- Filtration Media
- Point of Care – Self Diagnostic Strips
- Device Packaging
- Face Shields
- Sterilization Packaging
- Fluidics Diaphragms
- Equipment Overlays
- Equipment Protection Masking
- Hydrophilic and Specialty Coated Films

PolymerFilms
A DIVISION OF POLYMERSHAPES

Biocompatibility & Sterilization

Nature of the Physical Contact		Duration of Contact	Biological Risks: Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Subacute / Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronical toxicity	Cancerogenity	Reproductive / Developmental Toxicity	Degradation
Medical products with contact to body surfaces	Skin	A	◆	◆	◆									
		B	◆	◆	◆									
	Mucous Membrane	C	◆	◆	◆	●	◆	◆	●		●			
		A	◆	◆	◆									
	Injured Surface	B	◆	◆	◆	●	●		●					
		C	◆	◆	◆	◆	◆	◆	●		●	●		
Medical products, coming into contact with the interior of the body from outside	Blood System Indirectly	A	◆	◆	◆	◆					◆			
		B	◆	◆	◆	◆	●				◆			
	Tissue / Bone / Dentin	C	◆	◆	◆	◆	◆	◆	◆		◆			
		A	◆	◆	◆	●								
	Circulating Blood	B	◆	◆	◆	◆	◆	◆	◆	◆				
		C	◆	◆	◆	◆	◆	◆	◆	◆	●	●		
Implantable medical products	Tissue / Bone	A	◆	◆	◆	●								
		B	◆	◆	◆	◆	◆	◆	◆					
	Blood	A	◆	◆	◆	◆	◆	◆	◆	◆	●	●		
		B	◆	◆	◆	◆		●	◆	◆				

◆ Test to be included to ISO 10993-5

● 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]					
Polymer	Hot Steam		Hot Air	Ethylene Oxide	Plasma	Gamma Rays
	250°F	273°F	356°F	140°F	113°F	RT[3]
PP-H	^^	^^	v	–	^	–
POM-C	^	–	v	^	^	v
PEEK	^^	^^	^^	^^	^^	^^
PSU	^^	^	v	^	^	^
PPSU	^^	^^	^^	^^	^^	^^
PEI	^^	^^	^^	^^	^^	^^
PC	–	v	v	^	^	–

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) v No resistance

Plastics Services

Fabrication Services

Polymershapes supports your growth and success with industry-leading fabrication services. Our facilities, equipment, and expertise provide a wide variety of solutions for your plastic fabrication and conversion needs.

CNC Services

- Turning
- Milling
- Standard 6” depth of cut
- Quick turnaround + improved part optimization
- Sawing of multiple sheets/ stacks for high volume production
- Radius and straight cuts
- Generate maximum yield, reduce waste and minimize cost
- Excellent repeatability
- Camera-guided precision cutting and routing
- Wide range of part sizes
- Custom job support and turnkey service

Other Services

- Thermoforming
- Injection Molding
- 3D Printing
- Die Cutting
- Laminating
- Slitting
- Edge finishing
- Heat welding
- Heat and cold stamping
- Strip heater bending
- Barcoding

Recycling

Solid Shape Recycling

Polymershapes makes recycling support convenient and easy through our nationwide facility network. Polymershapes supplies gaylord containers for depositing scrap. Notify us when your containers are full, we will deliver fresh containers. We also haul away any containers that are full. The scrap is then processed, and turned into new material.

From the Gaylord **To the Recycler** **Re-Pelletization** **To a New Material**

Custom Recycling Services for End-of-Life Products

With our network of material distribution, fabrication and recycling services, Polymershapes can facilitate the entire lifecycle of products. When a product reaches end-of-life status, a number of our locations can take the product back for disassembly and recycling, turning the materials into second stream production, all with documentation.

Sustainability Partners

BioPhorum

As a member of BioPhorum, Polymershapes works with trusted leaders to deliver a tangible and measurable impact on the biopharmaceutical industry’s sustainabie developmental goals and agenda. BioPhorum Sustainability is working to support the industry’s transition to a low carbon, circular future.

Statera™

Polymershapes offers Statera™ products from Mitsubishi Chemical Group, This growing high-performance engineering plastics product line is made using recycled content. Current product availability includes:

- TIVAR® Sterra™ UHMW-PE
- Acetron® C Sterra™ POM-C
- Ertalyte® Sterra™ PET
- Ketron® Sterra™ PEEK

ECO USA

Polymershapes is proud to partner with ECO USA to offer silicone recycling – closing the loop for excess cured silicone solids.

We Work With World Class Suppliers

MITSUBISHI CHEMICAL GROUP | Advanced Materials

LEXAN™ Tough Virtually Unbreakable
Polycarbonate Film & Sheet

PLASKOLITE

SIMONA AMERICA GROUP

RÖCHLING Engineering Plastics

Ensinger

Westlake plastics LIFE IN POLYMERS

SAINT-GOBAIN

POLYMER INDUSTRIES GEARED TOWARDS EXCELLENCE

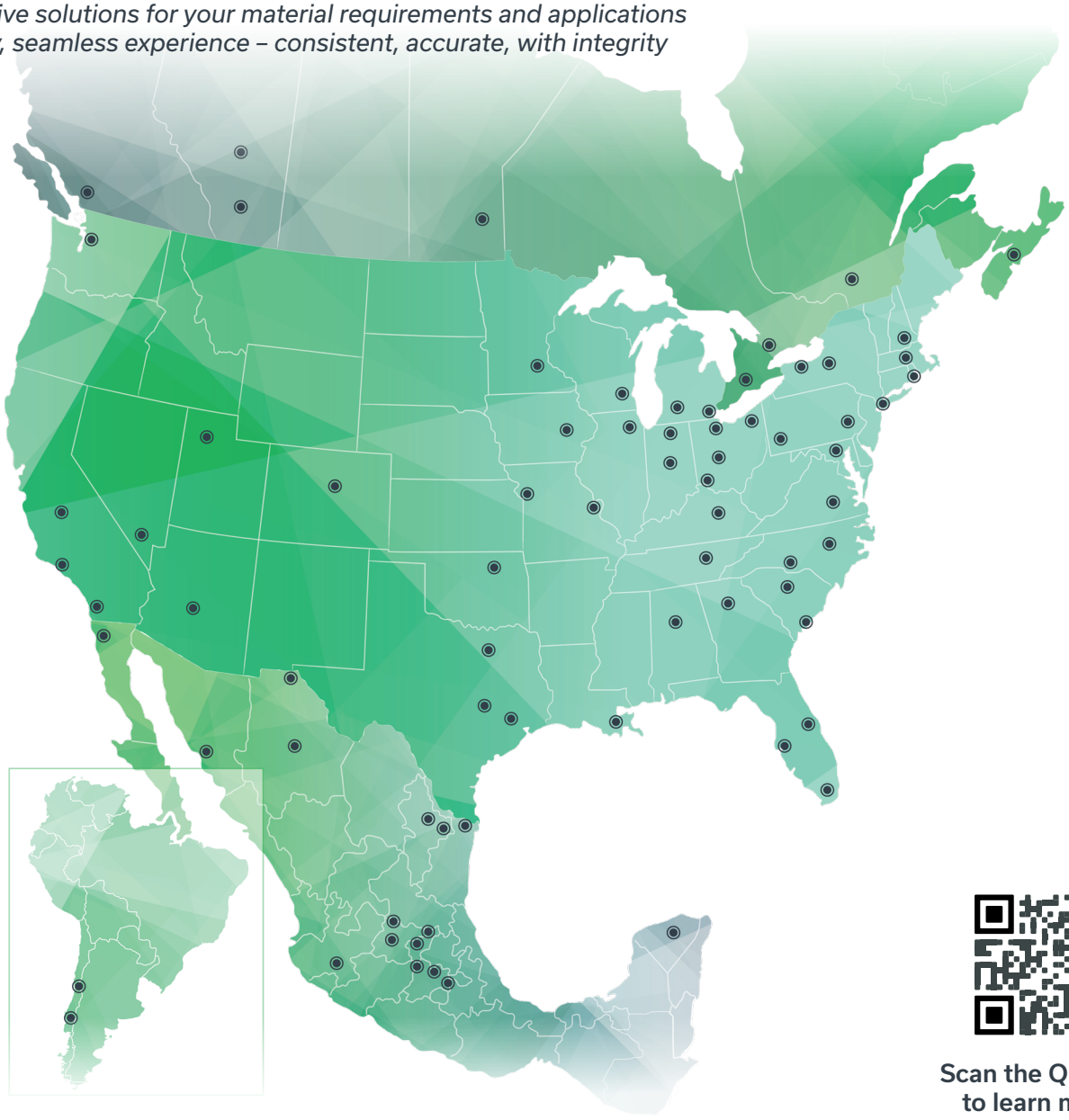
GENESIS MEDICAL PLASTICS ISO 13485:2016

Chemours™

SPARTECH

Polymershapes is the premier distributor of plastic sheet, rod, tube, film, and associated products, with over 75 years of industry-leading heritage. We have the industry's most knowledgeable and highly trained sales and customer service team. Our network of 80+ stocking facilities, located throughout the United States, Canada, Mexico and Chile, enables our customers access to extensive local inventory from world-class supplier partners, and we can provide same-day delivery in many locations.

- *Expert conversion capabilities including cut-to-size sheets, film conversion and CNC routing and machining*
- *Innovative solutions for your material requirements and applications*
- *An easy, seamless experience – consistent, accurate, with integrity*



Scan the QR code to learn more!

Contact us for quotes & availability:
info@polymershapes.com | polymershapes.com