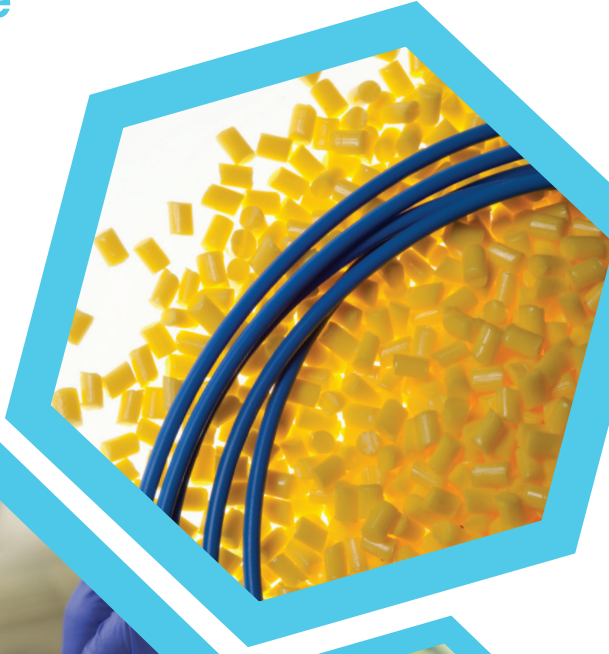




Lubrizol LifeSciences

Medical Device Solutions: Thermoplastic Polyurethane (TPU)



Lubrizol



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About Lubrizol LifeSciences

Lubrizol LifeSciences is a total solutions provider for medical device manufacturers. We specialize in helping customers from idea to execution, and offer innovative materials, drug-eluting device development and best-in-class contract manufacturing services.

When customers partner with Lubrizol LifeSciences, they benefit from working with us at every stage in their development process. Our long history of polymer expertise and continued investment in research and manufacturing, means we offer a smooth and streamlined approach to the development of innovative medical solutions:

- **Polymers** - Our extensive polymer expertise allows us to create comprehensive, customized and application-specific medical grade materials for countless customer innovations.
- **Medical Device Product Development** - We offer a comprehensive suite of services focused on the development and support of advanced drug delivery solutions. We are experts in complex drug-eluting devices.
- **Manufacturing** - Our contract manufacturing capabilities include precision medical extrusion, sub-assembly and braided tubing for minimally invasive medical devices, as well as full-service silicone component and medical device manufacturing including long-term implants.

Medical Grade TPU

Lubrizol LifeSciences' maintains a robust Quality Management System (QMS) for medical grade thermoplastic polyurethanes to ensure patient safety and long-lasting reliability.

Specifically formulated for superior biostability, biocompatibility and processing versatility, LifeSciences' polymer systems are utilized by global leaders throughout the industry. This comprehensive line of medical grade TPUs are ideal for use in cardiology, urology, orthopedics, wound care and many other applications.

LifeSciences' medical grade TPU solutions include:

- Quality consistent with the expectations and needs of the medical device industry
- Products manufactured in ISO 9001:2008–certified facilities (ISO 9001:2015–certification as of September 2018)
- Assistance with regulatory and product compliance requirements
- Biocompatibility test results
- Ethylene Oxide, Gamma and E-beam sterilization compatible
- A wide range of physical properties available
- Custom colors, radiopaque filler and performance additives

Aromatic TPU for Processing and Performance

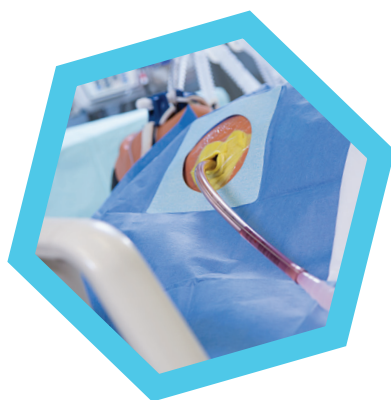
Tecothane™ and Pellethane® medical grade polymers are known for their flexibility and offer a wide range of properties for medical and healthcare products. These aromatic polyether and polyester TPUs are available in natural, radiopaque and custom colors.

Benefits:

- Long history of use in medical applications
- Chemical resistance
- Strength/toughness, abrasion resistance
- Hydrolytic stability
- Available in both molding and extrusion grades

Example applications:

- Catheters and tubing
- Film and sheet
- Wound care
- Long-term implantables
- Balloons



Tecothane™

| Product | Hardness | Flex Modulus* | Elongation** |
|----------------------------|----------|---------------|--------------|
| Aromatic Polyethers | | | |
| TT-1074A | 75A | 1,300 | 550 |
| TT-1085A | 85A | 3,000 | 400 |
| TT-1095A | 94A | 8,000 | 350 |
| TT-1055D | 54D | 18,000 | 300 |
| TT-1065D | 64D | 26,000 | 310 |
| TT-1069D | 69D | 44,000 | 275 |
| TT-1072D | 74D | 73,000 | 150 |

Pellethane®

| Product | Hardness | Flex Modulus* | Elongation** |
|-----------------------------------------------|----------|---------------|--------------|
| Aromatic Polyethers | | | |
| 2363-80A | 81A | - | 550 |
| 2363-80AE† | 85A | - | 650 |
| 5863-82A | 82A | 3,400 | 640 |
| 5863-82AE† | 82A | 3,000 | 650 |
| 5863-85A | 85A | 4,200 | 570 |
| 5863-87A | 87A | 5,600 | 500 |
| 2363-90A | 90A | 11,000 | 500 |
| 2363-90AE† | 90A | 10,000 | 550 |
| 5863-91A | 91A | 5,470 | 525 |
| 2363-55D | 55D | 25,000 | 390 |
| 2363-55DE† | 53D | 22,000 | 450 |
| 2363-65D | 62D | 32,000 | 450 |
| 2363-75D | 76D | 190,000 | 380 |
| Aromatic Polyethers – Breathable Grade | | | |
| 5863-80A | 80A | 3,400 | 700 |
| 5863-90A | 90A | 6,000 | 550 |
| Aromatic Polyesters | | | |
| 5855-92A | 92A | 10,800 | 450 |
| 5855-70D-WF | 70D | 115,000 | 300 |

†Product specially formulated for extrusion processing

Rigid TPU

Isoplast® and Tecoplast™ aromatic polyurethanes are designed for rigid polymer applications such as hubs, fittings or other components that require impact-resistant properties. They are available in impact-modified, clear, pre-colored and glass-filled grades and are formulated to produce durable injection molded components exhibiting high tensile and flexural modulus, as well as superior chemical resistance.

Benefits:

- Chemical resistance
- High tensile modulus and impact resistance
- Clarity and practical toughness

Example applications:

- Catheter hubs and luers
- Dental/orthodontic applications
- Surgical instruments



Isoplast®

| Product | Hardness | Flex Modulus* | Feature |
|---------|----------|---------------|---------------------------------|
| 2510 | 116R | 260,000 | Impact Modified |
| 2530 | 121R | 330,000 | Transparent |
| 2531 | 123R | 340,000 | Transparent |
| 2540 | - | 1,500,000 | 40% Long Glass Fiber Reinforced |

Tecoplast™

| Product | Hardness | Flex Modulus* | Feature |
|---------------|----------|---------------|----------------------|
| TP-470 Clear | 82D | 300,000 | Clear/Transparent |
| OP-770 Opaque | 82D | 250,000 | Opaque/Custom Colors |

Polycarbonate TPU

Carbothane™ offers excellent oxidative stability for long-term blood contact applications. Carbothane™ is available in aromatic and aliphatic versions with a variety of durometer, color and radiopacifier formulations.

Benefits:

- Superior oxidative stability
- Excellent hydrolytic stability
- Outstanding chemical resistance and physical properties

Example applications:

- Long-term catheters
- Other long-term implants
- Balloons



Carbothane™

| Product | Hardness | Flex Modulus* | Elongation** |
|------------------------------------|----------|---------------|--------------|
| Aliphatic Polycarbonate TPU | | | |
| PC-3575A | 73A | 1,300 | 480 |
| PC-3585A | 83A | 1,500 | 380 |
| PC-3595A | 94A | 6,500 | 380 |
| PC-3555D | 55D | 20,000 | 350 |
| PC-3572D | 71D | 130,000 | 320 |
| Aromatic Polycarbonate TPU | | | |
| AC-4075A | 77A | 1,500 | 400 |
| AC-4085A | 85A | 3,500 | 400 |
| AC-4095A | 95A | 10,800 | 370 |
| AC-4055D | 56D | 27,700 | 300 |
| AC-4065D | 70D | 100,000 | 300 |
| AC-4075D | 75D | 220,000 | 250 |

Aliphatic TPU for Processing and Performance

Tecoflex™ TPU offers versatile processing and is resistant to yellowing. This aliphatic polyether TPU is available in a variety of durometer, color and radiopacifier formulations.

Benefits:

- Clarity
- Non-yellowing
- Excellent in-body softening
- Wide processing window for extrusion
- Molding and solvent processing grades available

Example applications:

- Balloons
- Catheters
- Coatings
- Electrospinning

Tecoflex™

| Product | Hardness | Flex Modulus* | Elongation** |
|--------------------------------|----------|---------------|--------------|
| Extrusion Grade | | | |
| EG-80A | 72A | 1,000 | 660 |
| EG-85A | 77A | 2,300 | 550 |
| EG-93A | 87A | 3,200 | 390 |
| EG-100A | 94A | 10,000 | 370 |
| EG-60D | 51D | 13,000 | 360 |
| EG-65D | 60D | 37,000 | 360 |
| EG-68D | 63D | 46,000 | 350 |
| EG-72D | 67D | 92,000 | 310 |
| Injection Molding Grade | | | |
| MG-8020 | 79D | 165,000 | 60 |
| MG-8812 | 83D | 230,000 | 6 |
| Solution Grade | | | |
| SG-80A | 72A | 1,000 | 660 |
| SG-85A | 77A | 2,300 | 550 |
| SG-93A | 87A | 3,200 | 390 |
| SG-60D | 51D | 13,000 | 360 |

Highly Resilient/Non-softening TPU

Tecobax™ TPU is a patented, novel non-softening, low tack, highly resilient TPU with distinct mechanical properties. This aliphatic polyether TPU is available in a variety of durometer, color and radiopacifier formulations.

Benefits:

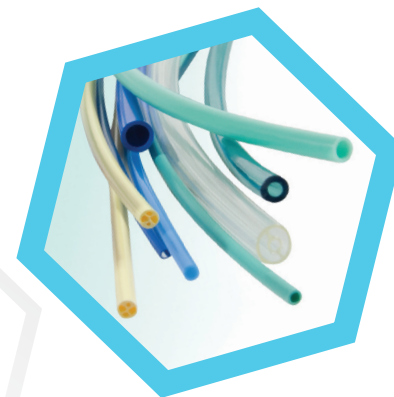
- Kink resistance
- Tensile strength
- Torque transfer

Example applications:

- Urology
- Pain management
- Short-term catheters
- Balloons

Tecobax™

| Product | Hardness | Flex Modulus* | Elongation** |
|---------|----------|---------------|--------------|
| TB-25D | 24D | 4,000 | 800 |
| TB-40D | 40D | 11,900 | 700 |
| TB-45D | 47D | 17,900 | 650 |



Hydrophilic TPU

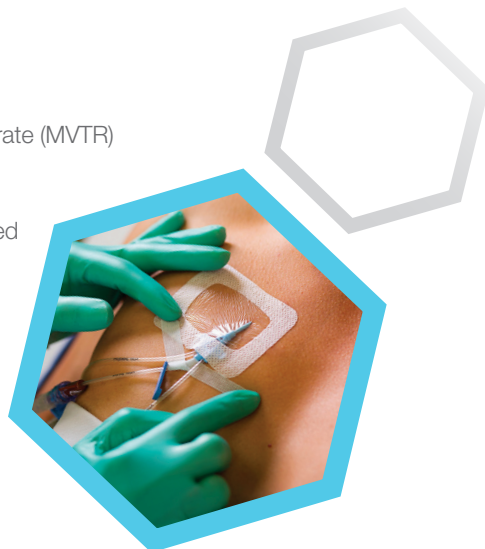
Tecophilic™ aliphatic polyether TPU is formulated to absorb 20 to 900% water (by weight) of the dry resin while maintaining physical properties. Solution, hydrogel and extrusion grades available.

Benefits:

- Hydrophilic
- High moisture vapor transmission rate (MVTR)
- Water swell-able
- Processing flexibility
- High surface lubricity when hydrated

Example applications:

- Catheters
- Wound care
- Semi permeable membranes
- Hydrophilic coatings
- Balloons



Tecophilic™

| Product | Hardness | Flex Modulus* | Elongation Dry/Wet** | H ₂ O Absorption*** |
|------------------------|-----------------|---------------|----------------------|--------------------------------|
| Extrusion Grade | | | | |
| HP-93A-100 | 83A | 2,900 | 1,040/620 | 100% |
| HP-60D-20 | 43D | 4,300 | 430/390 | 20% |
| HP-60D-35 | 42D | 4,000 | 450/390 | 35% |
| HP-60D-60 | 41D | 4,000 | 500/300 | 60% |
| Solution Grade | | | | |
| SP-80A-150 | 70A | - | 1,000/600 | 150% |
| SP-93A-100 | 83A | - | 1,040/620 | 100% |
| SP-60D-60 | 41D | - | 500/300 | 60% |
| Hydrogel Grade | | | | |
| TG-500 | 60D DRY/80A wet | - | 100/200 | 500% |
| TG-2000 | 60D DRY | - | 100/WEAK GEL | 900% |

TPU for Drug-Eluting Devices

Pathway™ Polymer Excipients

Pathway™ Polymer excipients are a customizable, reliable choice for developing a drug-eluting medical device. Pathway™ has been used to develop everything from drug-eluting device coatings to intravaginal rings, and comes in both hydrophobic and hydrophilic grades; Drug Master Files and regulatory support are available for both.

Benefits:

- Customizable to meet drug delivery needs (drug substance and release rate)
- Exceptional durability, even when soft
- Good chemical resistance
- Superior clarity

Example applications:

- Drug-eluting devices

For more information about drug-eluting device capabilities, please contact your LifeSciences' representative.



Specialty Materials

Tecothane™ Soft resin delivers distinct surface characteristics, unique physical properties and superior softness. This aromatic polyester hydrocarbon-based TPU is currently available down to a natural 62A shore hardness.

Benefits:

- Softness
- Hydrophobic, low moisture vapor transmission rate (MVTR)
- Chemical resistant
- Up to 75% bio-sourced

Example applications:

- Soft-tip tubing
- Silicone alternative
- Balloons

Tecothane™ Soft

| Product | Hardness | Flex Modulus* | Elongation** |
|---------|----------|---------------|--------------|
| AR-62A | 62A | 750 | 900 |
| AR-75A | 79A | 2,500 | 530 |
| AR-85A | 89A | 6,700 | 400 |
| AR-95A | 97A | 21,000 | 370 |

Tecoflex™ 1-MP Adhesive Grade

Tecoflex™ 1-MP is a one-part adhesive based on a fast-crystallizing polyurethane resin.

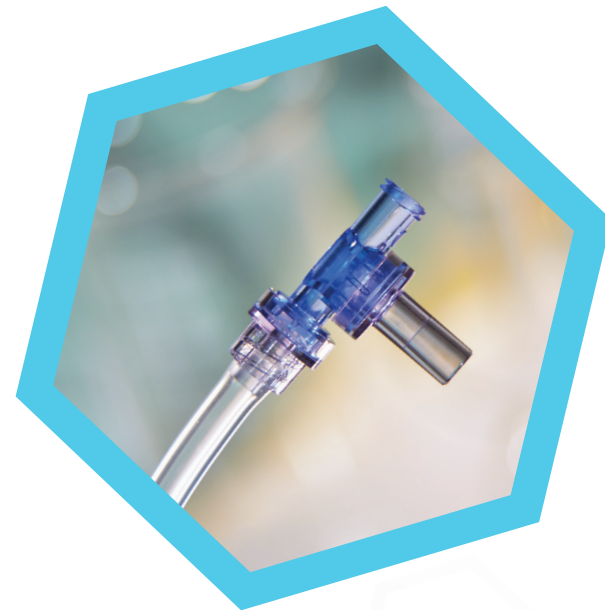
Benefits:

- Excellent results with the following substrates:
 - Polyurethanes
 - Plasticized vinyls
 - Polycarbonates
 - Acrylics
 - Chlorinated SBR rubbers
 - Primed metals

Example applications:

- Medical device assembly

| Product | Solids (%) | Brookfield Viscosity (cps) | Color |
|---------------|------------|----------------------------|-------------------------|
| 1-MP Adhesive | 8 | 200-300 | Light Gray, Translucent |



*Flexural Modulus (psi): ASTM D790, **Elongation (%): ASTM D412, ***H2O Absorption: Lubrizol Method
 Note: 20% and 40% barium-sulfate filled are available for most products.

Lubrizol LifeSciences

Lubrizol LifeSciences is the preferred Contract Development and Manufacturing Organization (CDMO) partner for complex pharmaceuticals and high-end medical devices providing differentiated polymers and excipients, along with state-of-the-art design, development and manufacturing services to the healthcare industry.



Lubrizol LifeSciences

For more information, visit Lubrizol.com/LifeSciences or email us at LifeSciences@Lubrizol.com



Global Headquarters | 9911 Brecksville Road | Cleveland, OH 44141-3201 USA

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