

Medical Grade TPU: Chemistry & Customization

Ethicon MGMC Mini-conference

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Jennifer Green, Senior Global Technical Manager, Medical Polymers



Agenda

- Introduction to Lubrizol and LLS Health
- Medical Grade Thermoplastic Polyurethane
 - What is a medical grade?
 - TPU Key Properties & Chemistry
 - Custom Support and Development Capability
- Contract Manufacturing & Design Services

Lubrizol At A Glance



Lubrizol Additives

The global leader in performance additives for transportation and industrial lubrication



Lubrizol Advanced Materials

A leader in polymer-based technology for consumer and industrial applications



The Lubrizol Corporation, a Berkshire Hathaway company, leverages **unmatched chemistry** to unlock **immense possibilities** at the molecular level, driving sustainable and measurable results to help the world **move cleaner, create smarter and live better.**

Lubrizol Pillars & Presence



People

Our foundation for today and the future



Customers

Our growth partners



Enterprise Operations

Our competitive advantage

95+ years

of history and opportunity, founded in 1928

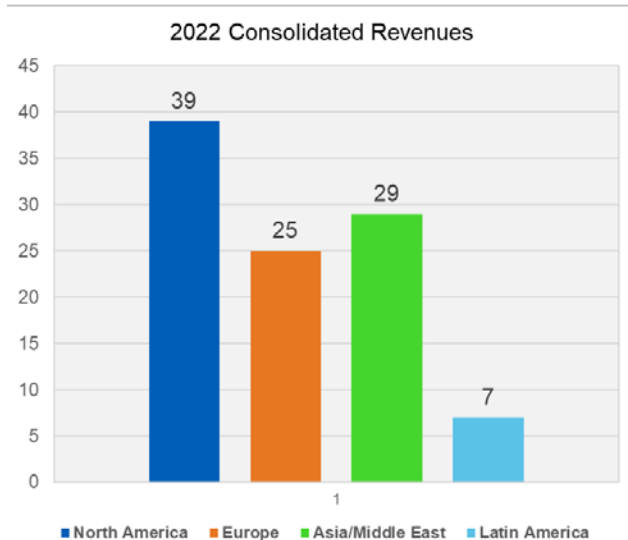
8,000+

Employees over 100 sites

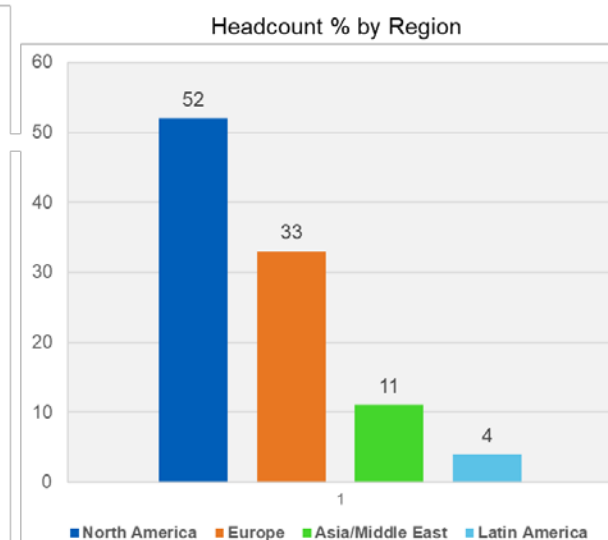
75+

markets

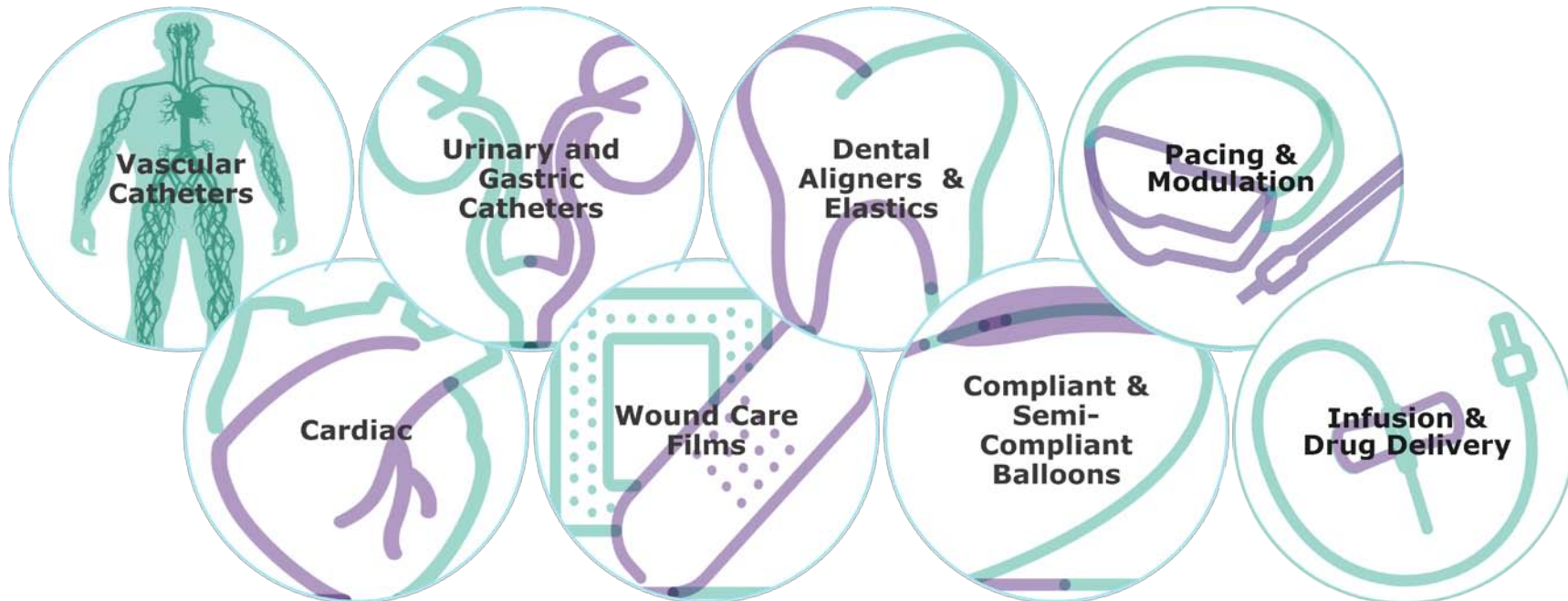
\$6+ Billion Revenues

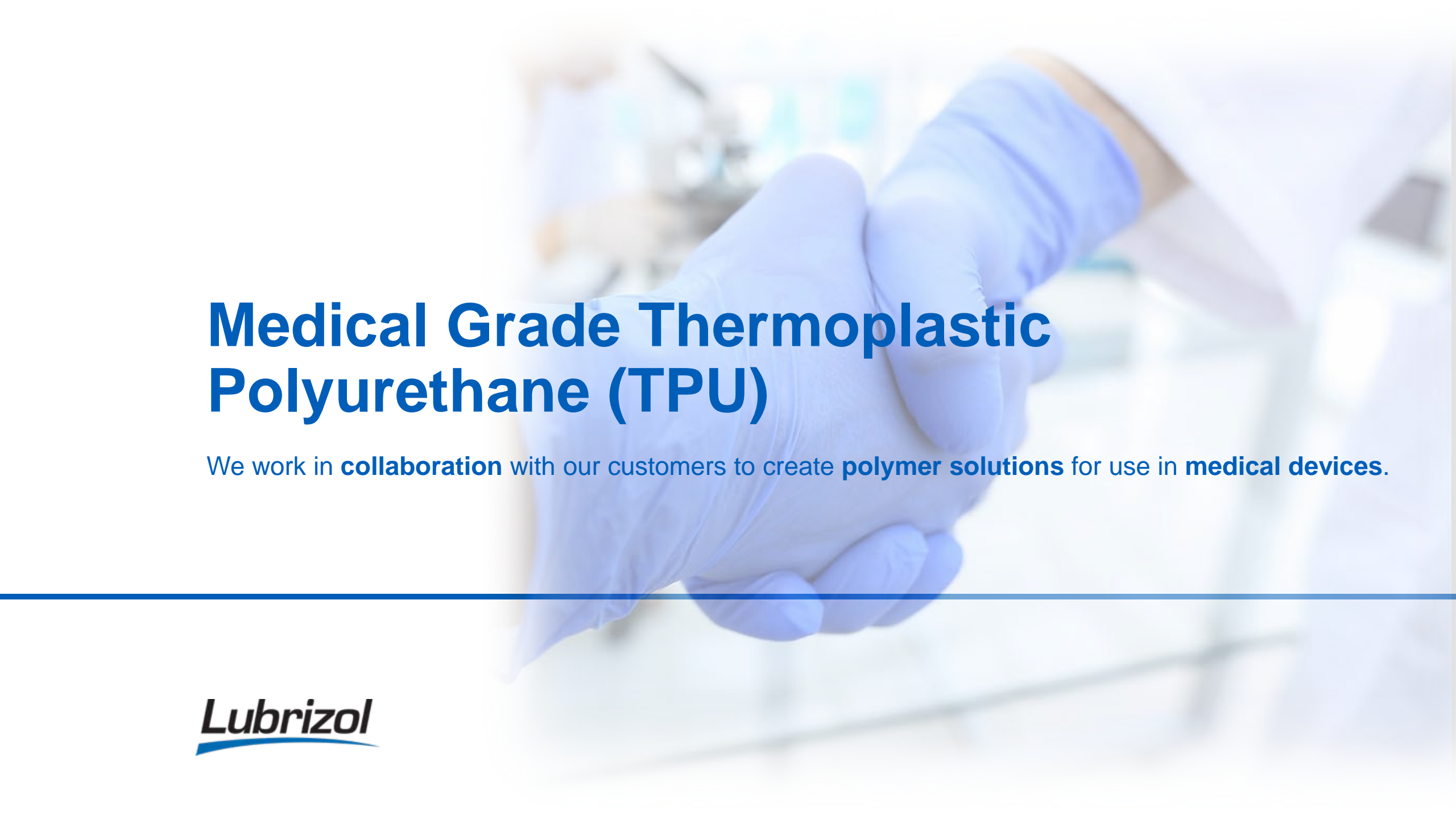


8,000+ Employees



Lubrizol Life Science (LLS) Health Key Markets Served





Medical Grade Thermoplastic Polyurethane (TPU)

We work in **collaboration** with our customers to create **polymer solutions** for use in **medical devices**.

Lubrizol

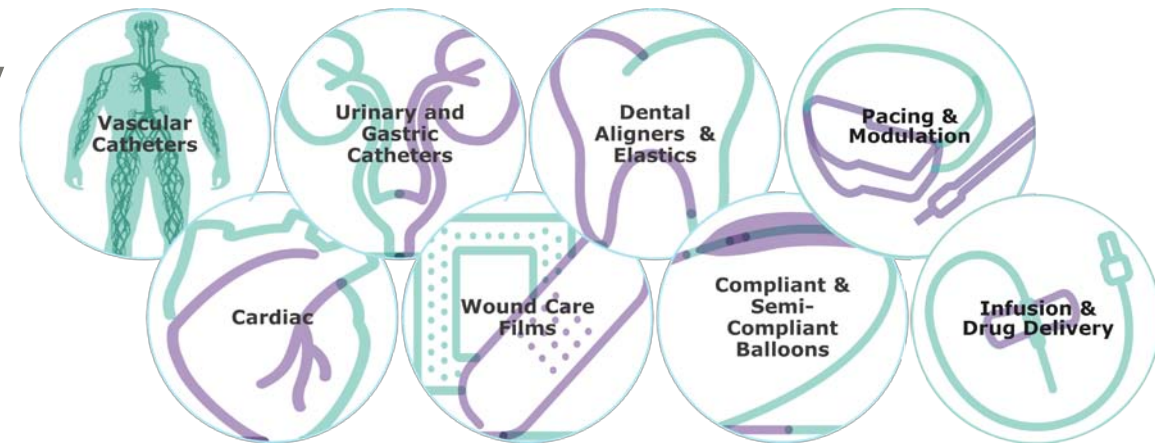
What is a “Medical Grade” TPU?

Lubrizol Medical Grade TPU

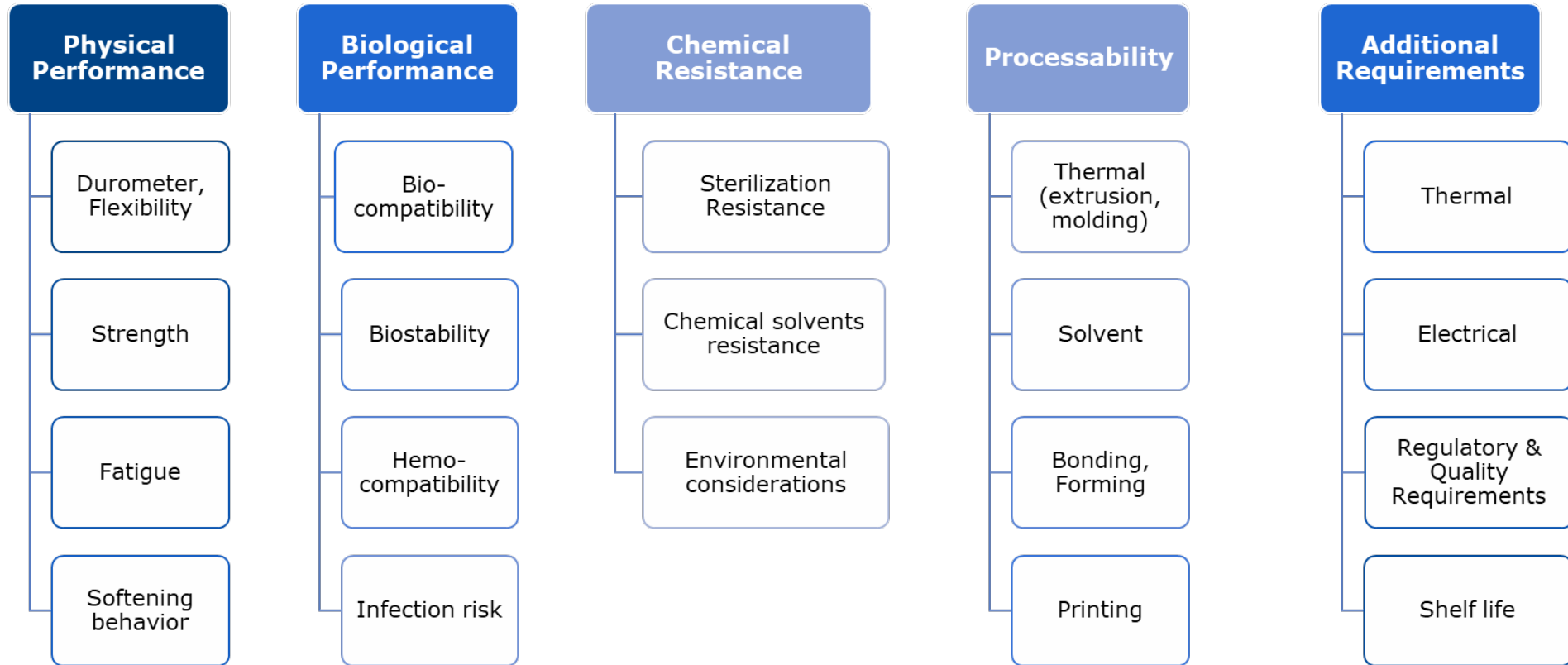
- ✓ Manufactured in ISO 9001 certified facilities
- ✓ Change control & notification policy
- ✓ Manufacturing product-integrity risk assessments
 - ✓ Additional engineering, administrative, product wheel controls
- ✓ Quality audit policy
- ✓ Record & physical sample retention policy
- ✓ Medical device regulatory assistance
 - ✓ US FDA MAF
 - ✓ Regulatory compliance packets
- ✓ Biocompatibility Evaluation
- ✓ Supply continuity considerations

Lubrizol Non-Medical Grade TPU

- ✓ Manufactured in ISO 9001 certified facilities
- Limited change notification
- Limited quality audits
- Medical regulatory assistance not provided
- Biocompatibility not evaluated



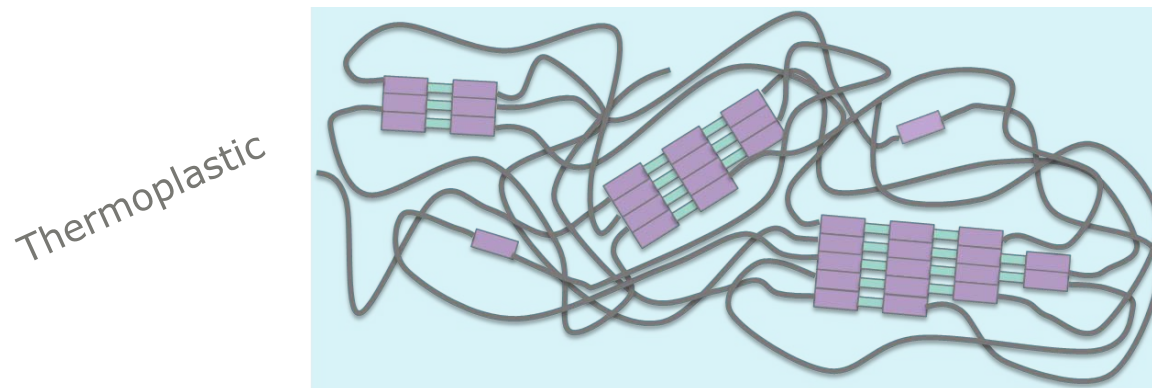
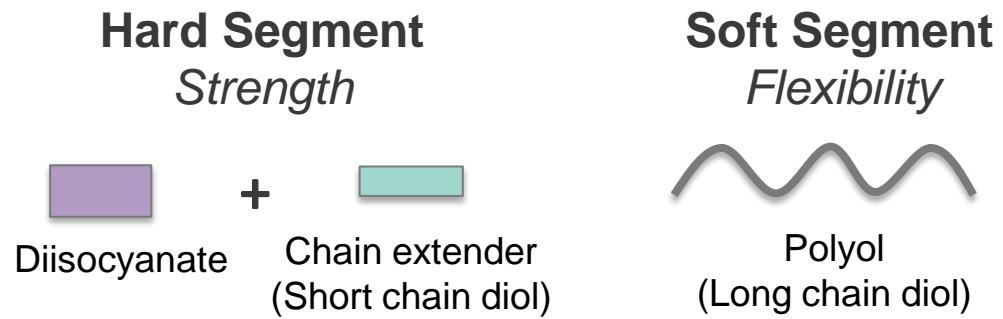
Medical Device & Material Considerations



Matching chemistry to performance accelerates device development

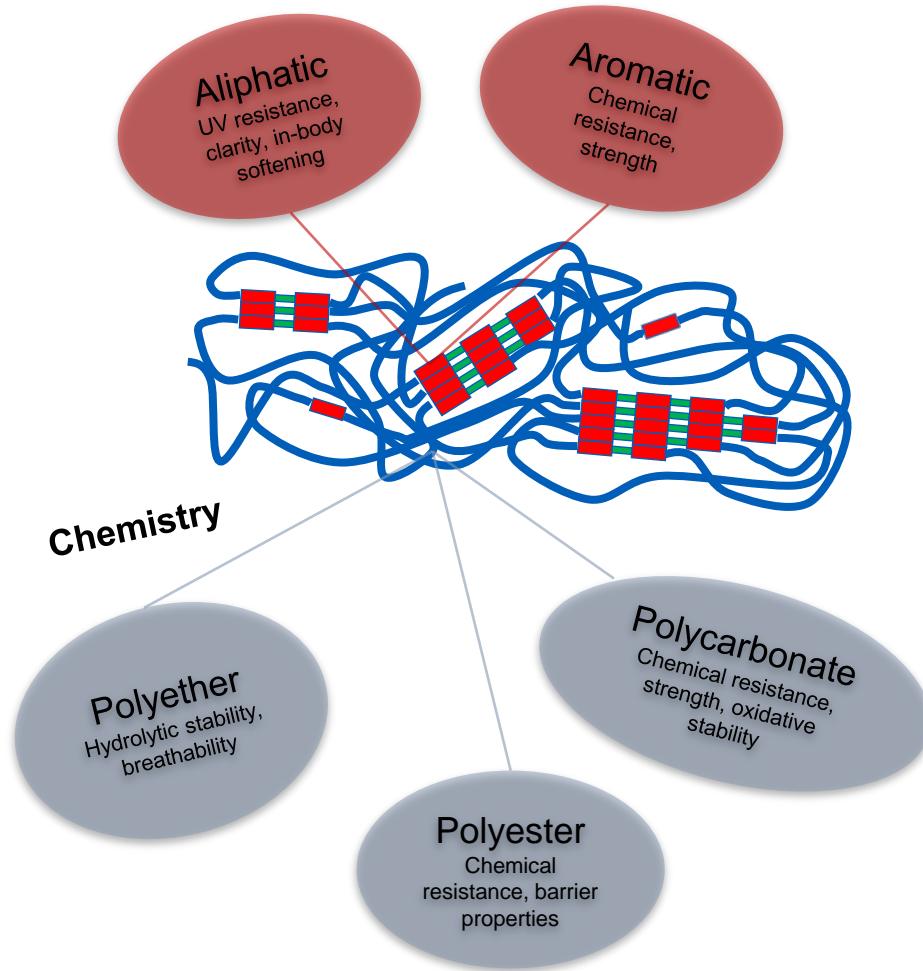
TPU Basics

Urethane = Isocyanate + Alcohol

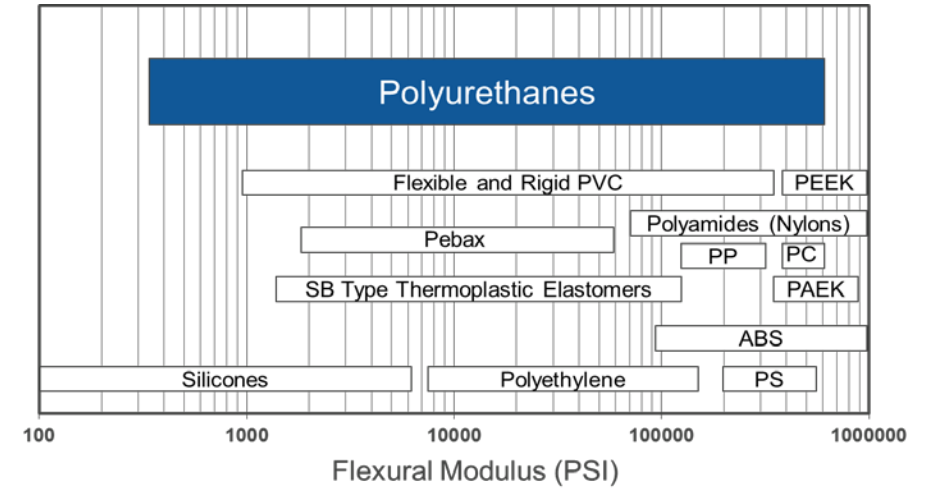


Segmented structure:
Forms reversible crosslinks for strong, elastic properties

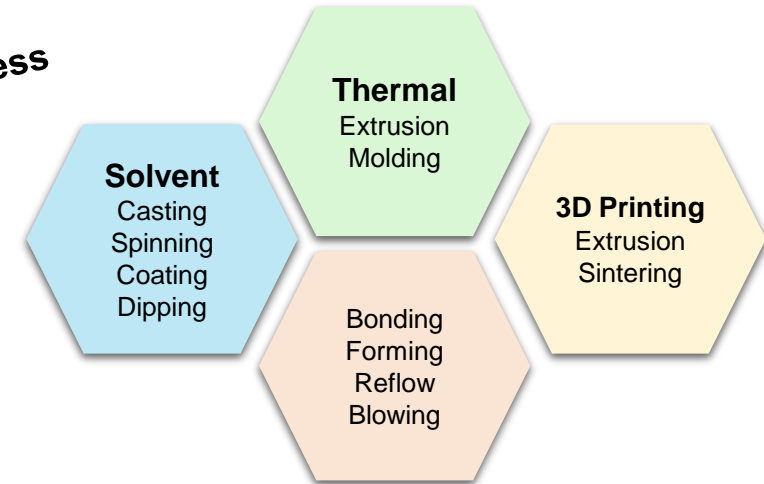
TPU Versatility



Properties

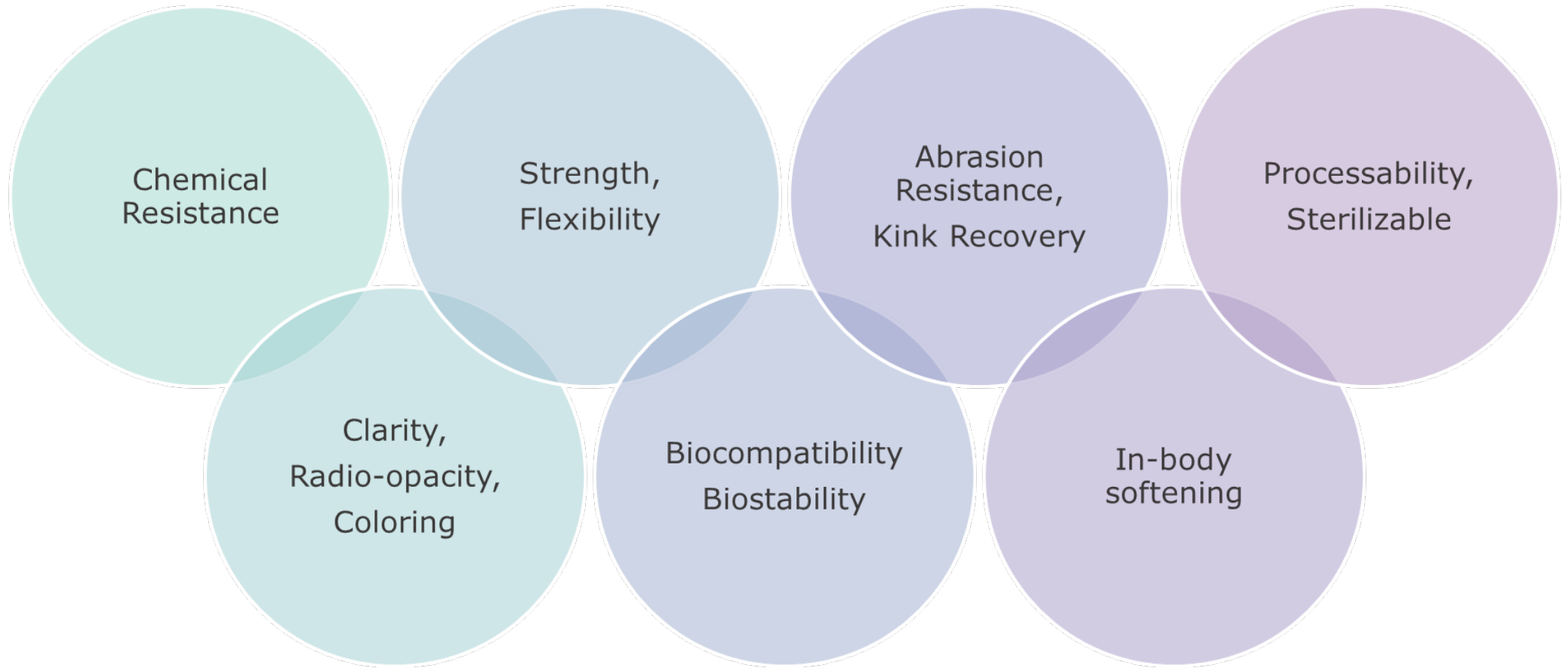


Process

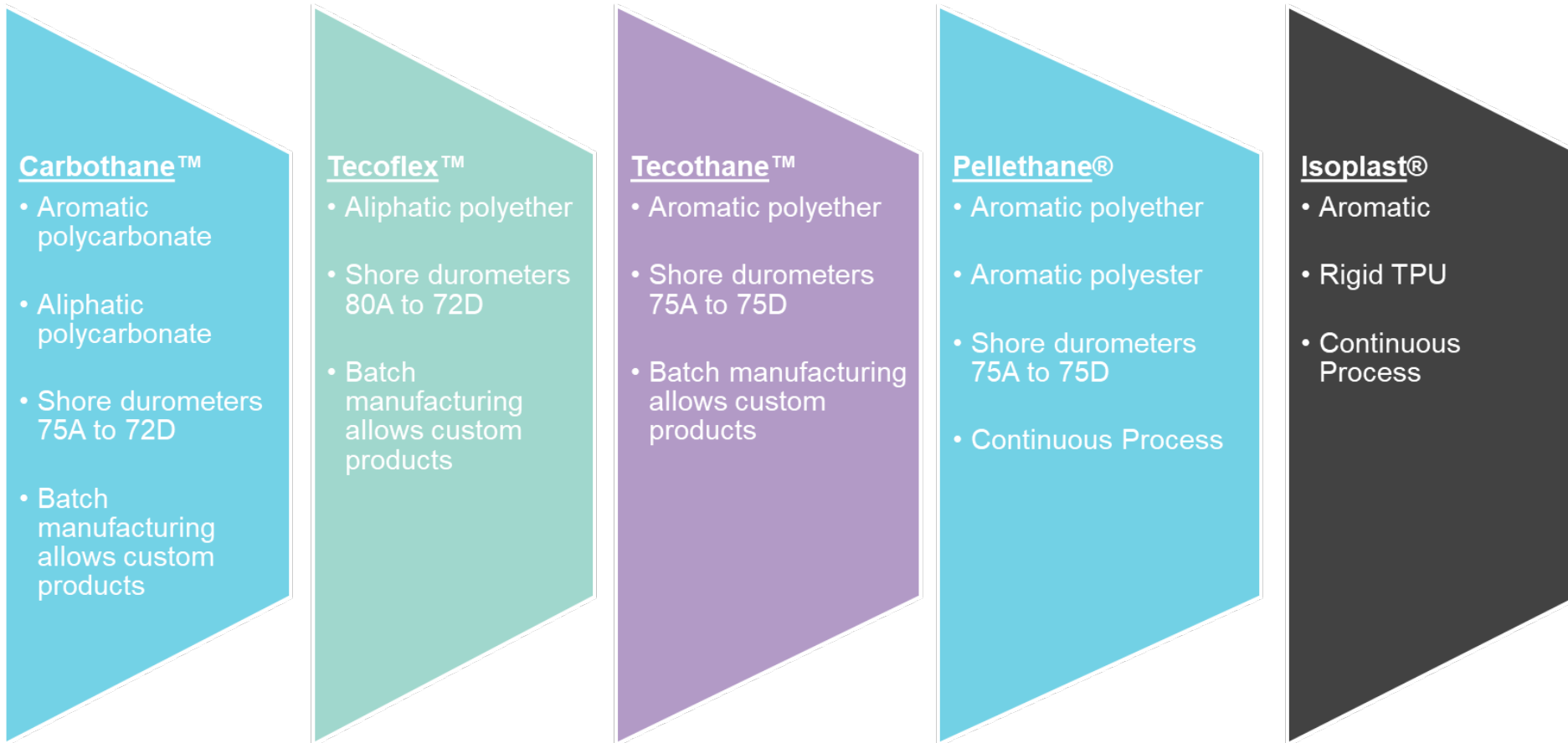


TPU chemistry provides options for performance versatility

TPU Key Properties in Medical Device Applications



Major LLS Health TPU Product Families



Other grades:

- *Tecophilic™ – Aliphatic polyether (hydrophilic grade)*
- *Tecothane™ Soft – Aromatic hydrocarbon-ester*
- *Tecoplast™ – Rigid Aromatic made by batch process*

Pushing the Boundaries: TPU Innovation

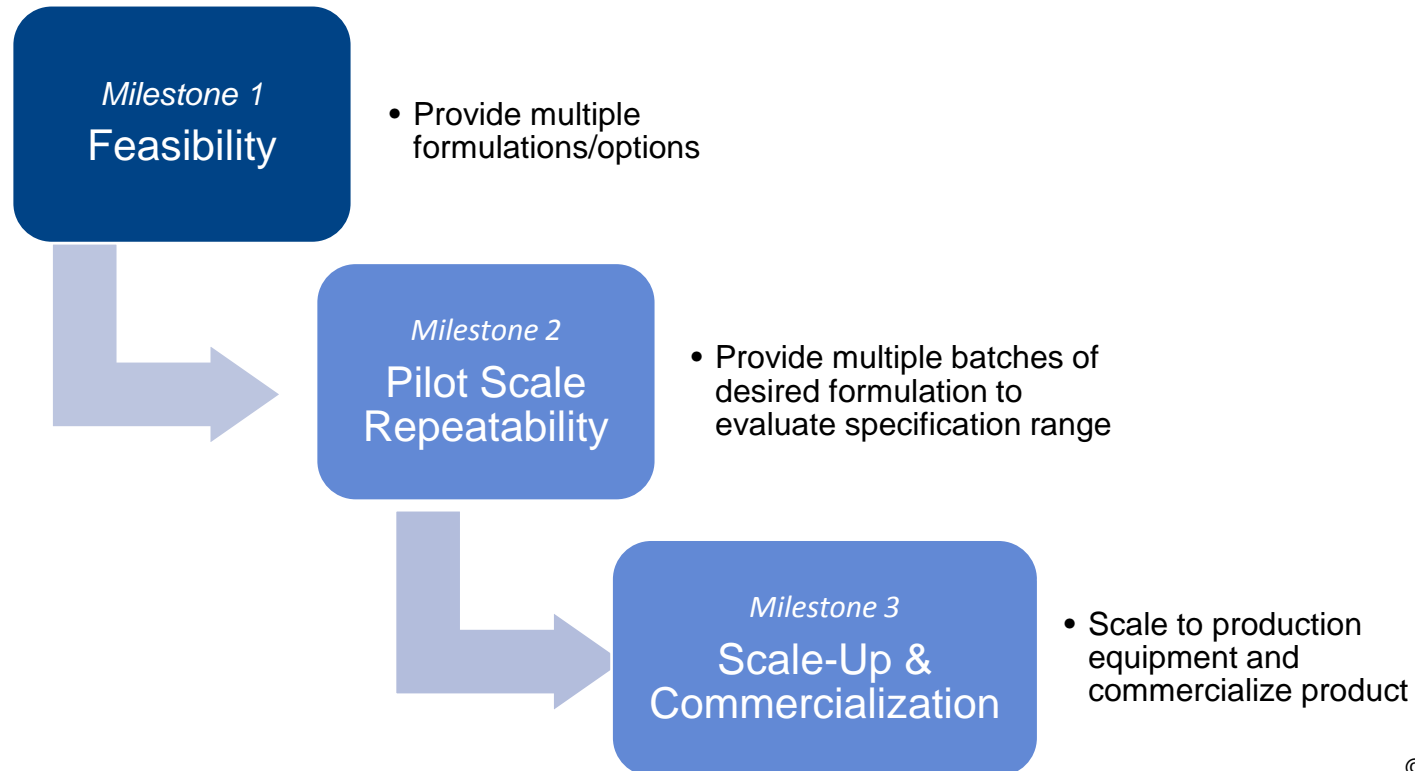
- Softer (yet strong)
- Rigid and non-softening
- Enhanced biostability
- Sustainably sourced raw materials
- Functional surface properties



Custom Support & Development Services



Example Development Project Milestones:





Contract Manufacturing & Design Services

Comprehensive suite of capabilities in device manufacturing from design to final assembly delivers value and efficiency to the marketplace

Lubrizol

Contract Manufacturing Capabilities in Primary Markets Served

Strategic Focus/Primary Target Markets



Coronary, Peripheral, Neuro Delivery Systems & PTA/PTCA Balloon Catheters



Structural Heart Catheters & Delivery System



Electrophysiology / Ablation



AAA Stent Delivery Systems



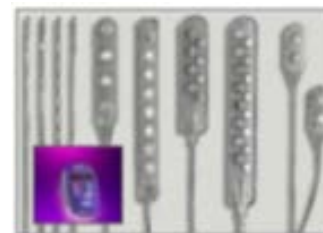
Venogram Occlusion Balloons

PTCA/PTA Balloon Catheters, Precision Extrusion and 2nd Ops of PEBAX, Nylons, TPU and Silicone

Electrostimulation/LTI



ICD and Pacing Leads



Neuromodulation Leads



Insulin Delivery Tubing

Precision Extrusion and 2nd Ops of TPU and Silicone

Aesthetic, Neurosurgery, IV Therapy & Bariatric Implants/LTI, Ophthalmology



Breast Implants & Tissue Expanders



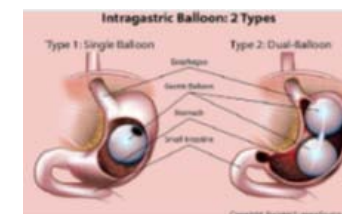
Ophthalmology: Phaco -Sleeve



Hydrocephalus Drains & Shunts



Oncology



Bariatric

Precision Extrusion, Molding, Dip Casting, Sheeting, and 2nd Ops of TPU and Silicone

Thank you!

www.lubrizol.com/Health/Medical