



Benefits of Medical-Grade TPU Over Non-Medical Grade Alternatives

In a time of increased scrutiny and product recalls, pursuing innovation while simultaneously ensuring full regulatory compliance is a growing challenge for medical device makers. The Health team of Lubrizol recognizes this challenge and responds to it with a comprehensive line of medical grade thermoplastic polyurethanes (TPUs) ideal for use in multiple applications. In support of its medical grade TPUs, Lubrizol offers the following services listed in this document.

ASSISTANCE WITH REGULATORY AND PRODUCT COMPLIANCE REQUIREMENTS

Lubrizol will assist your efforts to pursue new business opportunities and support your existing business by providing information required by compliance authorities.

Lubrizol will also provide information on polymers necessary to support device filings with the US FDA and other national/regional regulatory bodies.

BIOCOMPATIBILITY TEST RESULTS

Biocompatibility data is available for medical grade TPU products.

HEIGHTENED ATTENTION TO QUALITY CONSISTENT WITH THE EXPECTATIONS AND NEEDS OF THE MEDICAL DEVICE INDUSTRY

Quality systems for medical grade TPUs are comprehensive and include appropriate change and risk management.

There is a strict notification of change policy.

PRODUCT LINES

- Carbothane™ TPU
- Tecoflex™ TPU
- Tecophilic™ TPU
- Isoplast® ETPU
- Pellethane® TPU
- Tecoplast™ TPU
- Tecothane™ TPU

APPLICATION AREAS

- Dental
- Diagnostics
- Electrostimulation
- Endosurgery
- Heart Support & Implants
- Infusion & Drug Delivery
- Urology
- Wound Care



Biocompatibility
data available



Device design



Change notification
management



Compliance
assistance



Manufactured in
ISO-9001 facilities



Sustainability-
focused



DISTINCT ADVANTAGES

When used for healthcare applications, medical grade polymers offer distinct advantages over other non-medical grades of polymers, including biocompatibility data, change notification management, record retention, and regulatory and product compliance support. Above all, our medical grade TPU products offer the reassurance that comes from using the highest grade TPU manufactured under the strictest protocols by the leader in the field of medical grade thermoplastic polyurethane.

- Medical-grade products manufactured in ISO 9001 certified facilities
- Plant audits available upon approval and audit packet availability

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