



Thermoplastic Polyurethanes for Medical Applications

热塑性聚氨酯在医疗行业的应用

Clark Yan
2015.Mar

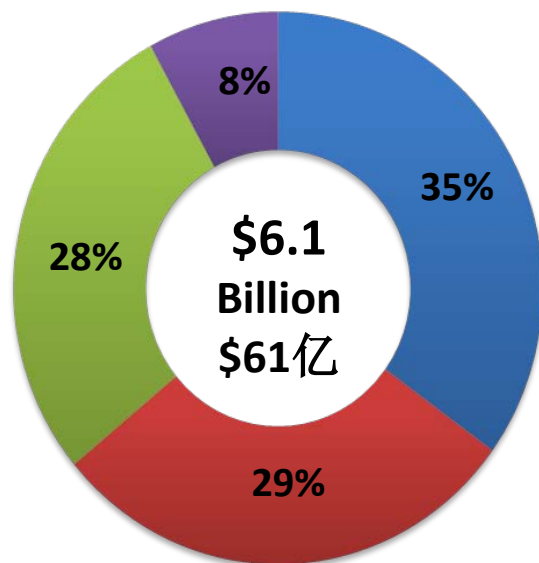




A Balanced International Presence 一家平衡的国际公司

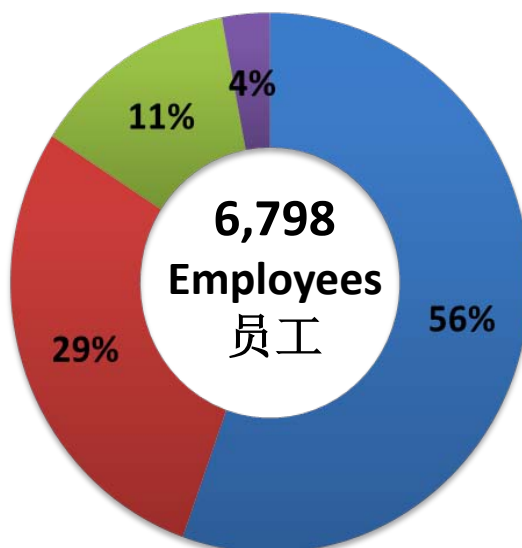
Consolidated Revenues

公司的总收入



Worldwide Employees

全世界员工数



■ North America ■ Europe ■ Asia/ME ■ Latin America

We sell in more than 100 countries~
with more than half of our sales outside of North America

除了北美以外，我们在超过100个国家有着过半的销售额



Revenue and employee information – 2012

数据来源 -2012

- A wholly owned subsidiary of Berkshire Hathaway
- 伯克希尔 - 哈撒韦公司的全资子公司
- 2012: revenues \$162 billion, net income \$15 billion
- 2012总收入\$ 1620亿, 净收入\$ 150亿
- Chairman & CEO: Warren E. Buffett
- 董事长兼首席执行官: 沃伦-巴菲特

TPU was invented by us
我们发明了热塑性聚氨酯

We are the largest TPU Manufacturer
全球最大的热塑性聚氨酯制造商

We have over 50 years of history in TPU
我们在热塑性聚氨酯行业拥有超过**50年**的历史



We have over 30 years of reputation in the medical market
在医疗市场**30多年**的应用历史



We supply into the Military
我们也供应产品给军队



Medical Thermoplastic Polyurethanes

热塑性聚氨酯的微观表现

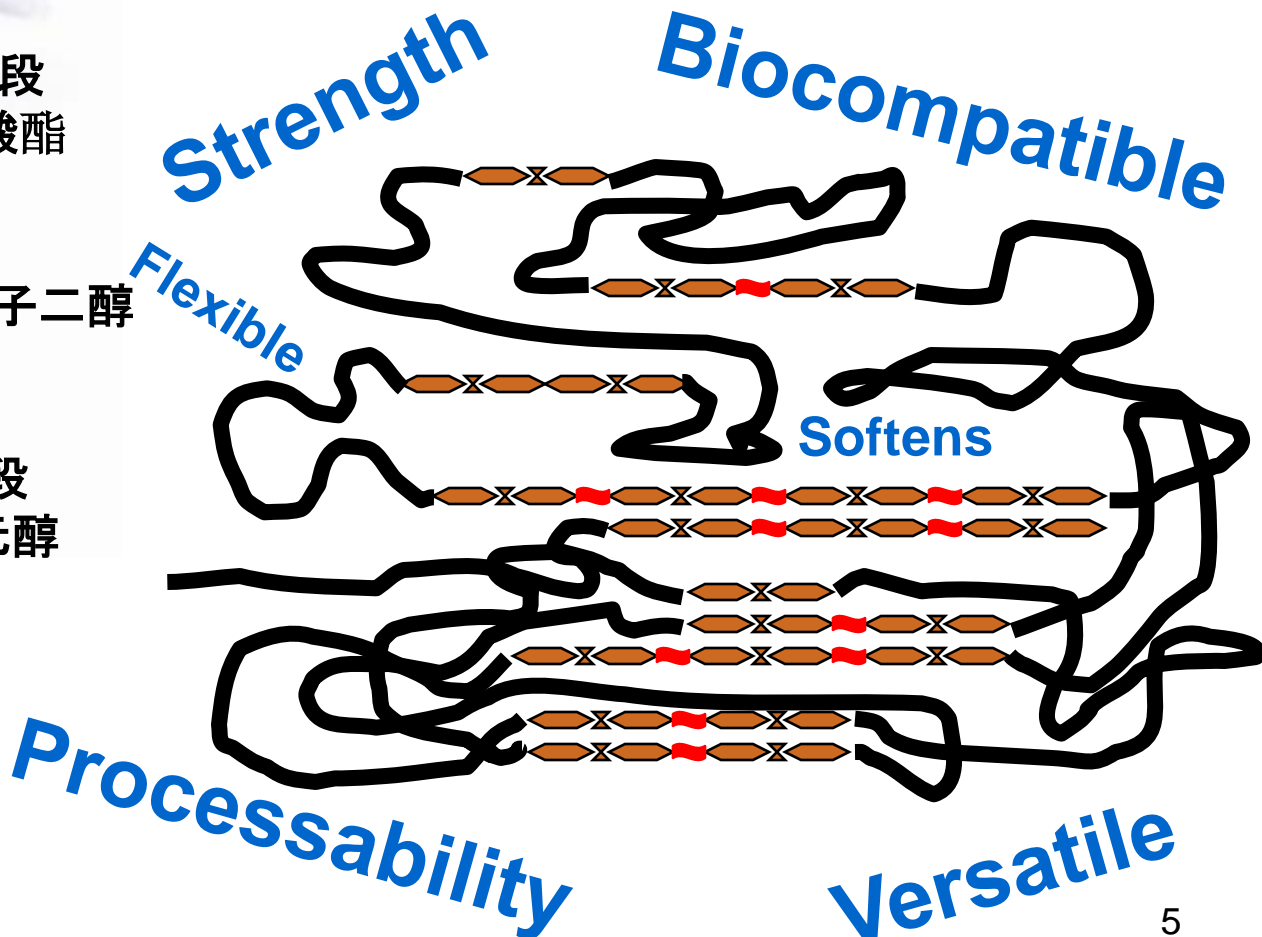
Hard Segment/Domain 硬段
Diisocyanate 二异氰酸酯



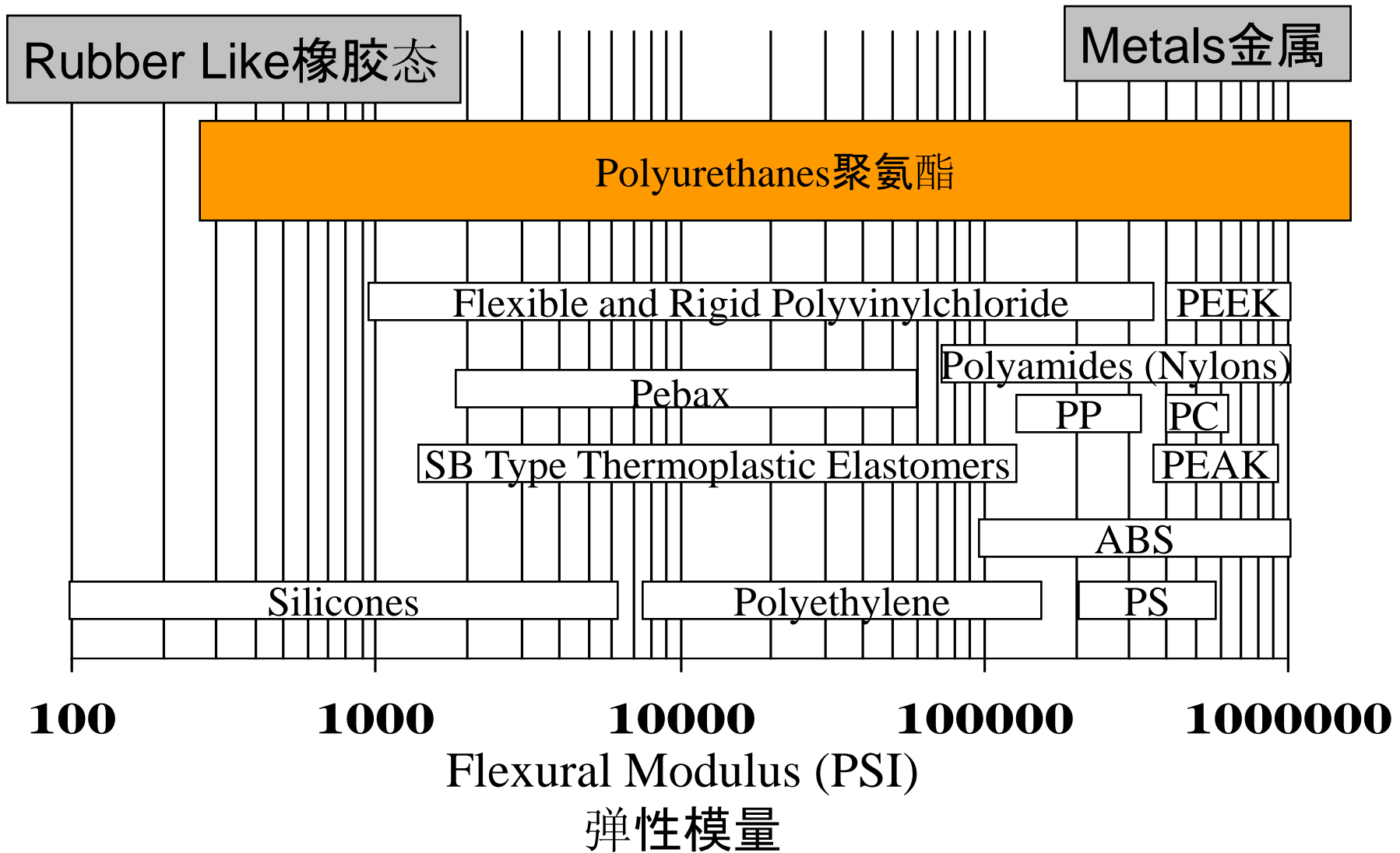
Short chain diol 小分子二醇



Soft Segment/Domain 软段
Macrodiol 大分子多元醇



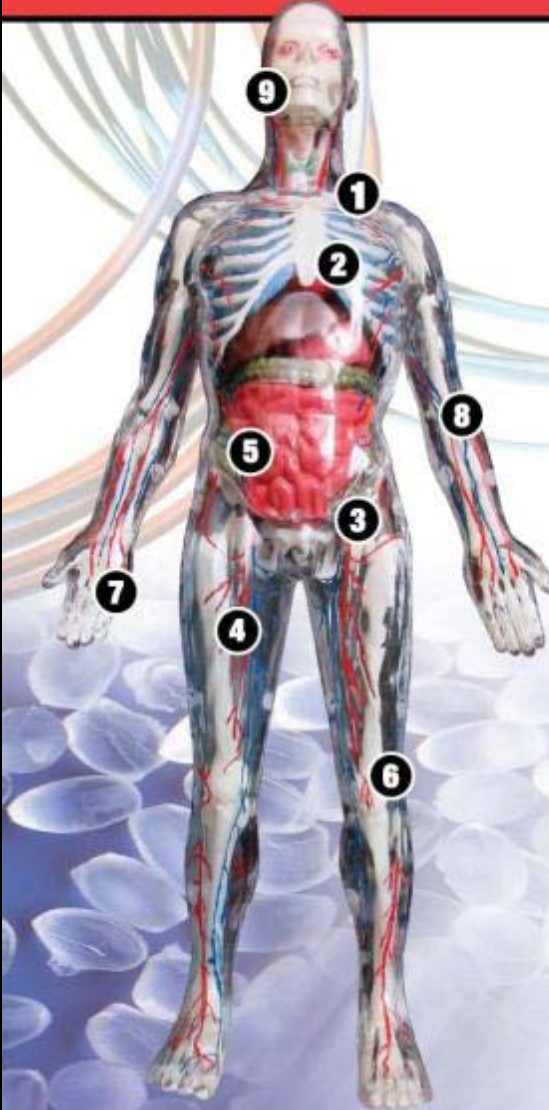
Where Do Polyurethanes Fit? 适合聚氨酯的应用?



Properties of Medical Polyurethanes

- **Strength & Durability**
- **Biocompatibility & Biostability**
- **Unique Softening The Body**
- **Process Versatility / Easy**
- **Adhesive Capability & Weldability**
- **Clarity & Pigments**
- **Radio-opacity & Printability**
By Filler (Barium Sulfate)
Clear Radio-Opaque
- **Kink Properties**
Kink resistance
Kink Recovery
- **Solvent & Chemical & Abrasion Resistant**
- **Flexibility & Elasticity**
- **Rigidity & Dimensional Control**
- **Breathability & Controlled Moisture Absorption**
- **Transportation**
Water / Moisture / Gases / Drugs

Thermedics™ Polymer Products Applications

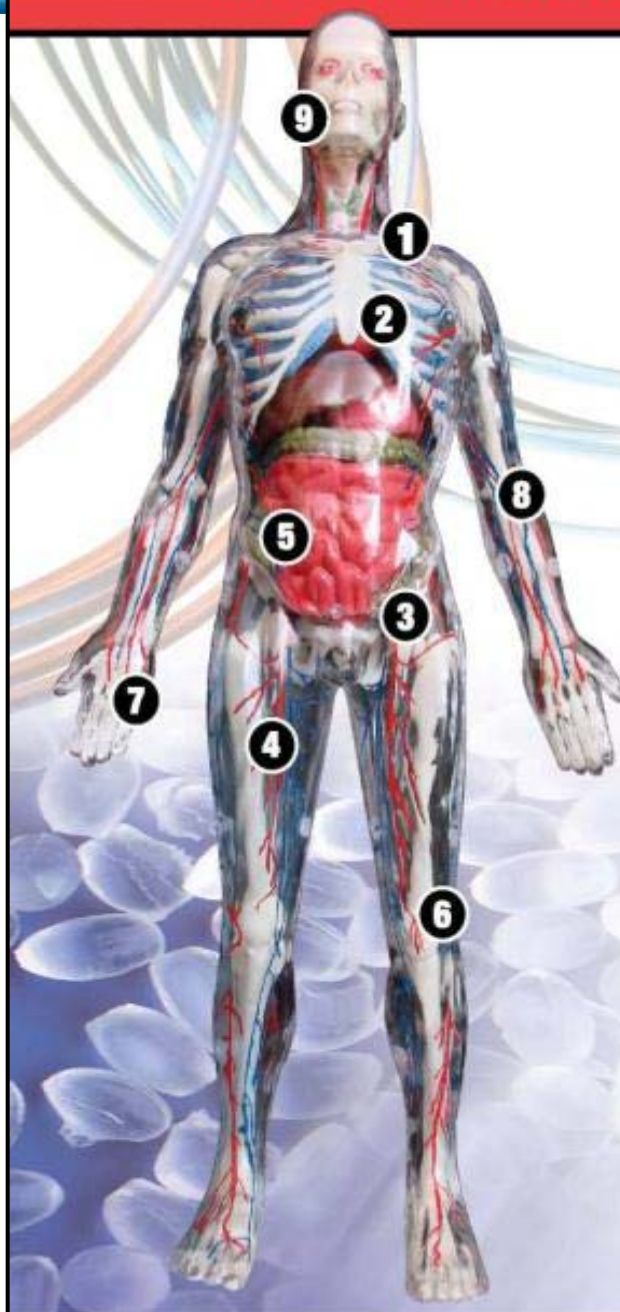


- ONCOLOGY**
 - Ports
 - PICC Catheters
- CARDIOVASCULAR**
 - Pacemaker Leads
 - Central Venous Catheters
 - Dilator / Sheath Sets
 - High Pressure Contrast Media Tubing
 - Pacemaker Headers
 - Intra-aortic balloon catheters
- UROLOGY**
 - Dialysis Catheters
 - BPH Ablation Catheters
 - Ureteral Stents
- NEUROVASCULAR**
 - Pain Management Devices
- GASTROENTEROLOGY**
 - Percutaneous Endoscopic Gastrostomy (PEG) Tubes
 - Nasogastric Feeding Tubes
- ORTHOPEDICS**
 - Specialty Applications
- WOUND CARE**
 - Dressings
 - Drug Delivery Systems
- IV THERAPY**
 - IV Catheters
- ORTHODONTICS**
 - Alignment Devices and Accessories
 - Ligature Retainers
- MISCELLANEOUS**
 - Condoms
 - Gowns
 - Gloves
 - Surgical Bags
 - Endoscopes
 - Guidewire Jackets/Castings
 - Various Inflation Balloons
 - Insulin Pump Tubing
 - Equipment Housings

路博润医疗级TPU性能

- 高强度 & 耐久性
- 生物相容性和生物稳定性
- 独特的体感软化
- 加工多样性 / 易加工
- 黏附能力和可焊性
- 透明 & 可着色
- 射线不透性 & 可印刷
 - 填料(硫酸钡)/透明的射线不透
- 扭结性能 (扭结抵抗 / 回复)
- 耐 溶剂 / 化学腐蚀 / 磨损
- 柔顺性 & 弹性
- 刚度 & 尺寸稳定性
- 透气 & 吸湿
- 传递性 (水, 湿气, 气体, 药物)

Thermedics™ Polymer Products Applications



1 血管通路

- 端口
- 中心静脉导管
- 扩张鞘设备
- 透析导管

2 心脏辅助装置

- 起搏器导线
- 搏器导入管

3 泌尿学

- 良性前列腺增生消融导管
- 输尿管支架

4 神经血管

- 疼痛管理装置

5 胃肠病学

- 经皮内镜下胃造瘘 (PEG) 置管

6 整形外科

- 特殊用途

7 伤口护理

- 敷料
- 药物输送系统

8 静脉治疗

- 静脉导管
- PICC导管

9 口腔正畸学

- 准直器械及附件
- 结扎线固位体

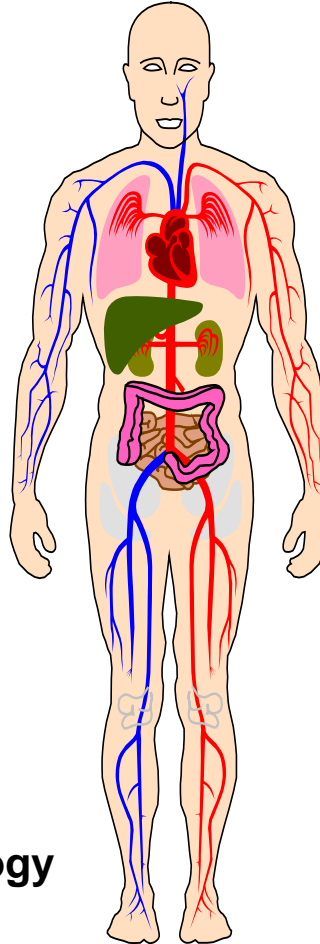
10 其他

- 避孕套
- 手术服
- 手套
- 手术袋
- 内窥镜
- 导线套及涂层
- 各种充气气囊
- 胰岛素泵输注导管
- 设备外壳
- 高压造影剂管
- 主动脉内球囊导管s
- 喂食用鼻胃管

Medical Grade Material Requirements

医疗级材料的要求

- **Acceptable Surface Chemistry**
- 可接受的表面化学性能
- **Non-Toxic** 无毒
- **Non-Hemolytic** 非溶血性
- **Non-Sensitizer** 无致敏物质
- **Low Extractables**
- 低可萃取物
- **Biostability** 生物稳定性
 - **Hydrolytic Stability**
 - 水解稳定性
 - **Oxidative Stability**
 - 氧化稳定性
- **Implantation** 植入
 - **ISO 10993-6 (Pass)**
 - **30-day and 90-day Subcutaneous Implants**
 - **30天 和 90天 皮下植入测试**
 - **Passed with Histopathology**
 - 病理组织学测试 通过
 - **Maintained Physical Properties** 保持物理性能



- **Cytotoxicity** 细胞毒性
 - **ISO 10993-5**
- **Hemolysis** 溶血测试
 - **Direct/ Indirect** 直接/间接
 - **ISO 10993-4**
- **USP Class VI Testing**
- **USP Class VI** 测试
 - **Acute Systemic** 急性系统测试
 - **ISO 10993-11**
 - **Acute Intracutaneous** 急性皮内测试
 - **ISO 10993-10**
 - **Implant** 植入测试
 - **ISO 10993-6**
- **Ames Mutagenicity**
- **Ames** 诱变性测试 (检查致癌物质)
- **Pyrogen Test** 热原测试
 - **ISO 10993-12**
- **OTHERS**

Sterilization Methods 灭菌方法

- ETO (Ethylene Oxide) ETO (环氧乙烷)
- Gamma/E-Beam 伽玛射线 Gamma / 电子束 E-Beam
- Peroxides 过氧化物
- ~~Autoclave 高压蒸气灭菌~~

TPU	Type	EtO	Peroxide	E-Beam	Gamma 25 kGy	Gamma 50 kGy	Dry Heat	Autoclave
Tecoflex™	Aliphatic	√	√	√	√	√	X	X
Tecothane™	Aromatic	√	√	○	○	○	○	X
Carbothane™	Aliphatic	√	√	√	√	√	X	X
Tecophilic™	Aliphatic	√	√	√	√	√	X	X
Isoplast®	Aromatic	√	√	○	○	○	○	X
Pellethane®	Aromatic	√	√	○	○	○	○	X
Tecoplast®	Aromatic	√	√	○	○	○	○	X

Key: √ Recommend | ○ May Cause Discoloration† | X Do Not Recommend

Samples tested using only a single cycle.
Users should confirm results with their own tests.
†Performance is not affected by discoloration.

Polyurethane Uses in Medical

Cardiovascular

- Cardiac assist pump bladders, tubing, housing, coatings
- Heart pacemaker connectors, coatings, lead insulators
- Heart valves
- Vascular grafts, patches
- Blood bags
- Blood oxygenating tubing, conduits

Orthopedics

- Orthopedic splints
- Bone adhesives
- Percutaneous shunts



Polyurethane

Wound Care

- Reconstructive surgery materials
- Skin dressings and tapes
- Suture material
- Surgical drapes
- Transdermal drug delivery patches
- Wound dressings

Miscellaneous

- Catheters
- Closures
- Fittings
- Connectors

Gastroenterology & Urology

- Endotracheal tubes
- Synthetic bile ducts
- Hemodialysis tubing, membranes, connectors

热塑性聚氨酯在医疗的应用

心血管类

- 心脏辅助泵, 袋, 管等,
- 心脏起搏器及植入型心律转复除颤器 (ICD) 的导线和导入管
- 心脏瓣膜
- 中心静脉导管/ 透析导管
- 血袋
- VAD (心室辅助装置) 导管

整形外科

- 骨科夹板
- 骨粘合剂
- 经皮分流器

热塑性聚氨酯

胃肠病学和泌尿学

- 经皮肝穿刺导管
- 导尿管
- 良性前列腺增生消融导管
- 自导管

伤口护理

- 再造手术材料
- 皮肤敷料和胶带
- 缝合材料
- 外科消毒帷帘
- 透皮给药补丁
- 伤口敷料

其他

- 避孕套
- 手术服
- 内窥镜
- 医用包装

医用级聚氨酯的应用

- ◉ 外周穿刺置入中心静脉导管
- ◉ 中央静脉导管
- ◉ 硬膜外导管
- ◉ 输尿管支架导管
- ◉ 新型胃鼻喂食管
- ◉ 主动脉气球导管泵
- ◉ PEG管
- ◉ 热稀释导管
- ◉ 血管导管和气囊
- ◉ 起搏器导线和头
- ◉ 扩张器、导引器、鞘
- ◉ 与针头相连的导管
- ◉ 浸入尿液的设施
- ◉ 避孕套
- ◉ 创伤敷料用薄膜
- ◉ 正畸带
- ◉ 医用服
- ◉ 呼吸气管
- ◉ 医用袋



Applications of Medical-Grade Polyurethane

- ◉ Peripherally Inserted Central Catheters (PCC)
- ◉ Central Venous Catheter
- ◉ Epidural Catheters
- ◉ Urological Stents
- ◉ Neo-gastric Nasal Feeding Tubes
- ◉ Intra-aortic Balloon Pumps
- ◉ PEG Tubes
- ◉ Thermal Dilution Catheters
- ◉ Angioplasty Catheters and Balloons
- ◉ Pacemakers Leads and Headers
- ◉ Over-the-Needle Catheters
- ◉ Dilators, Introducers, Sheaths
- ◉ Interurinary Devices
- ◉ Condoms
- ◉ Films for Wound Dressings
- ◉ Orthodontic Bands
- ◉ Medical Gowns
- ◉ Tracheal Tubes
- ◉ Medical Bags



Polyurethane for Cardiology

Lubrizol LifeScience Polymers develops high-performance polymers as part of its [Aromatic Carbothane™](#), [Isoplast®](#), [Pellethane®](#), and [Tecothane™](#) TPU lines intended for use in cardiology-related products for use inside and outside the body.

Polymers for Cardiology Applications In the Body

Lubrizol LifeScience Polymers medical products have been used safely within the body for more than 30 years. Engineered Isoplast polymers, in particular, do not promote tissue ingrowth and possess the biocompatibility, hydrolytic stability, chemical resistance, sealability and non-softening properties to perform particularly well in applications such as pacemaker headers.



Product Lines

[Aromatic Carbothane™ TPUs](#)

[Isoplast® ETPUs](#)

[Pellethane® TPUs](#)

[Tecothane™ TPUs](#)

Polymers for Cardiology Applications Outside the Body

Our engineered polymers are also ideal for other cardiology-related applications, such as automated external defibrillators (AEDs). Lubrizol polymers can provide the hardness required for AED casing as well as soft AED grips and bumper guards. Lubrizol polymers also excel in other external applications such as EKG leads and cable jacketing due to their durability, flexibility, sealability, flame retardancy, resistance to disinfectant solution, abrasion resistance, non-tackiness properties, excellent colorability and printability.

针对心血管应用的热塑性聚氨酯

路博润生命科学聚合物开发高性能聚合物，作为其 [芳香族Carbothane™](#), [Isoplast®](#), [Pellethane®](#)以及 [Tecothane™](#) 针对体内和体外心血管相关产品的热塑性聚氨酯系列的一部分。

针对体内心血管应用的聚合物

逾30年来，路博润生命科学聚合物体内医疗产品一直安全地发挥效用。特种Isoplast聚合物尤为如此，它不会引起组织内生，且具备生物相容性、水解稳定性、耐化学性、密封性和非软化性，尤其可在起搏器导入管等应用中发挥良好的效用。



针对体外心血管应用的聚合物

我们的特种聚合物还是其他心血管相关应用的理想选择，如自动体外除颤器等（AED）。路博润聚合物可达到AED套管以及AED夹具和缓冲保护器的硬度要求。由于具备耐用性、柔韧性、密封性、阻燃性、消毒溶液耐性、耐磨损性、非粘附性、卓越的可着色性和可印刷性，路博润聚合物在其他体外应用中也表现出色，例如心电图线和电缆护套等。

产品系列

[芳香族Carbothane™热塑性聚氨酯](#)

[Isoplast® ETPUs](#)

[Pellethane® TPUs](#)

[Tecothane™ TPUs](#)

TPU Medical Supplies

Lubrizol LifeScience Polymers produces a wide variety of polymers stemming from its [Carbothane™](#), [Pellethane®](#), [Tecothane™](#), [Tecoflex™](#), [Isoplast®](#) and [Tecophilic™](#) TPU lines for use in plastic-based medical supplies. With the exception of tubes and catheters, Lubrizol does not produce end-use medical products, but has the capabilities to thoroughly test medical polymer performance.

Medical supply applications benefiting from Lubrizol polymers include:

- **Latex-free condoms** and other products requiring thinner, monolithic, continuous film layers that provides barrier properties. The performance levels provided by thermoplastic polyurethane (TPU) allow for thinner constructions than alternative materials.
- **Surgical garments** and products that require breathability, high moisture vapor transmission rate (MVTR), chemical resistance and broad compatibility with many substrates.
- **Medical bags** that require transparency, high impact strength, tear strength, multilayer construction, a lack of plasticizers and ultrasound weldability—something that cannot be achieved with other materials. TPU provides these properties, and does so very efficiently.
- **Gloves** that must be latex free, sticky on the outside, soft inside, thin, and possessing barrier properties. Numerous properties can be included in these gloves via a multilayer construction.
- **Tubing** for external use, including peristaltic pump tubing. TPU can serve as an alternative to silicone, and Lubrizol -constructed tubing can exhibit a wide range of properties thanks to multilayer construction.
- **Flame retardant plastics**, which includes both tubing for external use and wire.



热塑性聚氨酯医疗用品

路博润生命科学聚合物提供大量聚合物，包括 [Carbothane™](#), [Pellethane®](#), [Tecothane™](#), [Tecoflex™](#), [Isoplast®](#) 并 [Tecophilic™](#) 热塑性聚氨酯产品，适用于塑料类医疗用品。除管材和导管之外，路博润不生产医疗成品，但是有能力对医疗聚合物性能进行全面测试。

使用路博润聚合物的医疗用品应用包括：

- **不含乳胶避孕套**以及需要更薄、单层连续薄膜层提供阻隔性能的其他产品。热塑性聚氨酯（TPU）的性能级别确保可以实现比其它替代性材质更轻薄的特性。
- **外科服**与需要透气性、高湿蒸汽透射率（MVTR）、耐化学性并大量兼容多种基材的其他产品。
- **医用袋**，需要透明度、高冲击强度、撕扯强度、多层结构、不含塑化剂以及超声焊接性（其它材质无法实现这一点）。热塑性聚氨酯能够非常高效地提供这些性能。
- **手套**：必须不含乳胶、外部有摩擦力、内部柔软，轻薄并具有屏障特性。可通过多层结构实现手套的各种特性。
- **管材**：外用，包括蠕动泵输注导管。热塑性聚氨酯可作为硅胶的替代物，路博润推出的管材具备多层结构，因而拥有广泛特性。
- **阻燃塑料制品**：包括外用管材和缆线。



Polyurethane for Orthopedics

Lubrizol's thermoplastic polyurethane resins (TPUs) in the Carbothane® and Isoplast® product lines possess a number of properties useful to arthroplasty specialists designing orthopedic products such as fixtures (including screws, pins and spinal fixations), and synthetic replacements for joints, bone and spines. These resins can be customized to suit individual patient requirements, and can adhere to metal, resist abrasion, reduce stress shielding, and allow for micro-movements and shock absorption. They also possess the biocompatibility, flex fatigue and mechanical strength and radiopacity properties to make them ideal for use within the body.

用于整形外科的热塑性聚氨酯

路博润 Carbothane® 和 Isoplast® 产品系列的热塑性聚氨酯树脂 (TPU) 具有一系列对于设计整形外科产品如相关零件 (包括螺丝、销钉和脊柱固定件) 以及关节、骨骼和脊柱置换件的关节成形术专家们来说具备很实用的特性。此类树脂可以进行定制以适应每位患者的需要, 它可附着于金属、耐磨损、减少应力遮挡效应、允许微小运动并可吸收震动。它们还具有生物相容性、耐弯曲疲劳、具高机械强度并且射线不能穿透, 这使它们成为应用于人体内部的理想材料。



Polymers for Urological Applications

Lubrizol LifeScience Polymers' engineered polymers are well suited for use in a variety of urological applications because of their biocompatibility, chemical (acidic) resistance, hydrophilic (water absorption) properties, indwelling softening characteristics and lubricity. For this reason, usage of Lubrizol polymers can play a significant role in minimizing patient discomfort that can result from catheter usage for a variety of reasons.

Potential urological applications for Lubrizol polymers include:

- BPH ablation catheters
- Ureteral stents
- Intermittent catheters
- Urethral catheters
- Self catheters

All Lubrizol polymers used for catheter applications, including those from the [Carbothane™](#), [Pellethane®](#) and [Tecothane™](#) TPU lines, are also plasticizer free, making them safer to use than alternative materials. Lubrizol offers complete catheter systems - not only tubes, but all the connectors that go with them.

泌尿科应用聚合物

路博润生命科学聚合物推出的特种聚合物因其生物兼容性、耐化学性（酸性）、亲水（吸水）性、留置软化特性和润滑性等特点，非常适合用于各种泌尿科应用。出于这个原因，对于因使用导管导致的各种患者不适性，使用路博润聚合物即可最大程度地予以降低。

路博润聚合物的潜在泌尿科应用包括：

- 良性前列腺增生消融导管
- 输尿管支架
- 间歇性导尿管
- 导尿管
- 自导管

用于导管应用的所有路博润聚合物，包括 [Carbothane™](#), [Pellethane®](#) 并 [Tecothane™](#) 热塑性聚氨酯产品，均不含塑化剂，从而比其它材质更为安全。路博润提供全套导管系统——不仅包括导管，还包括导管连接器。

Product Lines

[Carbothane™ TPUs](#)

[Pellethane® TPUs](#)

[Tecothane™ TPUs](#)

产品系列

[Carbothane™ TPUs](#)

[Pellethane® TPUs](#)

[Tecothane™ TPUs](#)

Polymers for Vascular Applications

Vascular therapies represent an alternative to traditional invasive surgical techniques for the treatment of disease such as coronary artery disease. These procedures improve patient comfort by reducing pain and risk as well as yielding quicker recovery at lower cost.

Engineered polymer resins from Lubrizol LifeScience Polymers are well suited for use in endovascular medical devices (used in the treatment of cardiovascular, peripheral vascular and neurovascular diseases) because of their long history of proven biocompatibility and indwelling softening characteristics. Lubrizol polymers have been used in vascular applications for more than 30 years.

Potential vascular applications conducive to Lubrizol polymer usage include:

- Central venous catheters (CVC)
- Peripherally inserted central catheters (PICC)
- Dialysis catheters

Polymers included in the [Tecoflex™](#), [Carbothane™](#), [Pellethane®](#), and [Tecothane™](#) TPU lines are ideal for vascular applications, and can be easily customized.



Product Lines

[Carbothane™ TPUs](#)

[Pellethane® TPUs](#)

[Tecoflex™ TPUs](#)

[Tecothane™ TPUs](#)

适用于血管应用的聚合物

在治疗冠状动脉疾病等疾病方面，血管疗法可以取代传统的侵入性手术治疗。这些方法可以较低的成本减少患者痛苦和治疗风险，并使患者较快恢复，从而改善了患者舒适度。

路博润生命科学聚合物推出的特种聚合物树脂经长期证明具有行之有效的生物相容性和留置软化特性，非常适合用于血管内医疗器械（用于治疗心血管、外周血管及脑血管疾病）。路博润聚合物已经应用于血管应用达30多年。

适合使用路博润聚合物的潜在血管应用包括：

- 中心静脉导管（CVC）
- 外周置入中心静脉导管（PICC）
- 透析导管

在 [Tecoflex™](#), [Carbothane™](#), [Pellethane®](#) 以及 [Tecothane™](#) 热塑性聚氨酯管道中使用的聚合物适用于血管应用，并可轻松定制。



产品系列

[Carbothane™ TPUs](#)

[Pellethane® TPUs](#)

[Tecoflex™ TPUs](#)

[Tecothane™ TPUs](#)

Wound Care

As a technology leader and one of the largest providers of engineered polymers, Lubrizol is your custom solution development partner. At Lubrizol LifeScience Polymers, we apply our technical expertise and portfolio of specialty thermoplastic polyurethane (TPU) products to develop innovative treatments for burns, lacerations, infection, ulcers and general tissue damage. Our polymers, including the [Pellethane®](#) and [Tecothane™](#) TPU product lines, are frequently tailored for use in applications such as films, tapes, backings, and synthetic dressings.



Our products for advanced wound care applications exhibit biocompatibility, absorbency, high strength, processing versatility and a unique balance of barrier and moisture vapor transmission rate (MVTR) properties. Lubrizol's medical polymer products— are precisely tuned to ensure the necessary amount of protection for healing tissues while also maintaining breathability and patient comfort.

We also provide [Carbopol® carbomers](#) and [Tecophilic™ polymers](#) which can absorb high levels of wound exudate and aid in blood clotting in acute, severe wounds. Carbopol polymers may also provide a buffering effect on the wound, which can assist in pH optimization at the wound site.

伤口护理

作为技术领先企业和特种聚合物最大规模供应商之一的路博润，是您的定制解决方案开发合作伙伴。对于路博润生命科学聚合物，我们应用自己的技术专长和特种热塑性聚氨酯产品，针对烫伤、割伤、感染、溃疡以及一般组织损伤开发创新疗法。我们的聚合物，包括 [Pellethane®](#) 并 [Tecothane™](#) 热塑性聚氨酯系列产品，常定制用于薄膜、胶带、衬垫以及合成敷料等应用。

我们针对高级伤口护理应用推出的产品具备生物相容性、吸水性、高强度、加工多样性，以及独特的阻隔与湿蒸汽透射率平衡特性。路博润的医疗聚合物产品经过精心配制，确保能为愈合组织提供足够保护，同时还能保持透气性和患者舒适性。



我们还提供 [Carbopol® carbomers](#) 并 [Tecophilic™](#) 聚合物，它们可吸收大量创面渗液，并可帮助严重的急性伤口血液凝固。[Carbopol](#) 聚合物还可为伤口提供缓冲效果，有助于在创伤处实现pH值优化。

Key Market Trends

- **PVC has been banned in Europe due to the issue of plasticizer. Similar trend in North America, which has seen a large decrease in PVC consumption.**

<http://www.lubrizol.com/Medical/Literature/TPU-vs-PVC-Chinese.pdf>

— 热塑性聚氨酯：在医疗器械和伤口护理产品制造中比聚氯乙烯更安全的优质替代品

在选择用于制造塑料医疗器械（如医疗袋和导管）的聚合物时，请务必牢记不仅要考虑聚合材料是否能满足功能要求，还必须考虑最终应用的安全要求。几十年来，聚氯乙烯（PVC）由于成本低廉且软化后功能优异，一直是医疗器械制造中广泛采用的材料。但是，世界各地的生产商出于各种原因逐渐开始摆脱对 PVC 的依赖，其中最主要原因是含有 PVC 的医疗器械在常规使用和废弃处理时会释放出有害的化学物质。

热塑性聚氨酯（TPU）是一种可靠优质的 PVC 替代品。对于许多生产商来说，它不但可以满足医疗器械应用的需求，而且更加安全，是取代 PVC 的理想材料。本文将探讨改变 PVC 和 TPU 在医疗器械市场中使用情况的部分促进因素，并深入分析在医疗产品市场越来越排斥含 PVC 产品的情况下，何种优势使 TPU 成为 PVC 的最佳替代品。

医疗市场的主要趋势

- 由于塑化剂的风险，**PVC**已经被禁止，北美也开始出现类似的趋势，这已经导致**PVC**需求的显著下降

<http://www.lubrizol.com/Medical/Literature/TPU-vs-PVC-Chinese.pdf>

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非PVC的解决方案

Non-PVC solution

更多创新

More Innovative

针对健康护理的超前的聚合物科学

Pioneering polymer science for healthcare

我们的医疗级热塑性聚氨酯 (TPU)，可以单独使用或组合，创造安全和生物稳定性的产品，以满足无PVC的需求并提供广泛的加工选择。

Our medical-grade TPUs, used alone or in combination, create safe and biostable products that meets the requirement of non-PVC needs & offers wide options of process.

更多适应

More Adaptable

服务于不断变化需求的患者

Serving the ever-changing needs of patients

- 不含邻苯二甲酸酯类塑化剂
- 洁净，透明，可配色
- 生物相容性
- 法规遵从
- 扭结阻力和扭结恢复
- 高强度，易加工和焊接
- No phthalate plasticizers
- Clean, clear and colorable
- Biocompatible
- Regulatory compliance
- Kink resistance & kink recovery
- Strength, processing ease & welding

领先的技术

For the leading technology

- 输液管
- 医疗用袋
- 血液用袋
- 医疗服装及手术单
- IV tubes
- Medical bags
- Blood bags
- Medical garments & drapes



Key Market Trends

- **Recent law suites, such as with CR Bard or American Medical Systems (\$54 million), using non-medical grades, have highlighting the potential liability associated by using non-regulated materials.**
- **Agencies such as the FDA, have sharply increased their audits to the manufacturing facilities of medical devices in 2014. They favor medical grade offerings that provide change notification, biocompatibility testing (ISO10993), and manufactured in ISO compliant facilities.**
- **For cost effectiveness and waste reduction, the trend is towards medical devices that can be used multiple times versus just once. This requires two things: A durable construction/material and the ability to resist sterilization many times over and over.**
- **In terms of sterilization, hydrogen peroxide systems are gaining major acceptance and market share by medical care facilities. TPU's are not only suitable for such process, but can be exposed many times to this process without the loss of performance.**

医疗市场的主要趋势

- 比如最近诸如 **CR Bard**或者**AMS**的一些法律纠纷显示了使用不受监控的材料存在的风险.
- 从**2013**年，美国药检局等机构已经大幅度提高了他们对于医疗制造商的监督。他们支持使用医疗级的原料，这些医疗剂原料制造商能够提供变更通知，生物一致性测试（**ISO10993**）以及用于生产控制的**ISO**文件
- 为了节约成本和减少废弃物，开始更倾向于多次使用而不是即抛型 这里有两个要求耐用的结构或者材料，另外就是能够多次消毒灭菌
- 关于灭菌，双氧水法正在获得过多关注以及取得了不错的市场份额。 **TPU**不但能够适合双氧水灭菌而且还能够多次灭菌后还保持良好的性能

Key Market Trends 医疗市场的主要趋势

- **Based on the above trends, the replacement of traditional materials such as rubber, PVC, silicones, and even metals are being accelerated due to some of their shortcomings. The very broad TPU range that Lubrizol has to offer, from very soft to hard, allows us to provide the right material to a broad range of applications such as catheters, garments, bags, tubing, wire & cable, surgical tools, or housings for electronic equipment.**

基于上述趋势，由于橡胶，硅胶，PVC甚至金属的缺陷，对于他们的取代过程正在加速。路博润提供种类繁多的TPU产品，从超软的到坚硬的，让我们能够给提供合适的原料给各种不同的应用，比如医疗导管，防护服，袋子，线缆，外科工具以及用于电器产品的防护套等等。

- **Acceleration of healthcare and well-being in growth geographies.**

健康产业在不同地区的加速发展。

- **Focus on Healthcare Acquired Infections (HAI): Insurances are not willing to pay for these occurrences any longer.**

保险公司不再愿意为不安全材料的使用所产生的事故买单

<http://www.lubrizol.com/Medical/>

Medical grade Thermoplastic PolyUrethanes:

医疗规格的热塑性聚氨酯

- Our Medical grade materials are produced under the strictest manufacturing specifications in accordance with cGMP standards. 我们的医疗规格是根据CGMP标准在最严格的生产规范下生产的。
- Our manufacturing facilities are ISO 9001:2008 certified. 我们的生产流程经过了ISO9001: 2008认证
- Lubrizol offers a wide variety of TPU's that are designated as medical grade biomaterials having passed either USP Class, VI, MEM Elution or other relevant tests in order to establish their biocompatibility and biostability. 路博润提供多种专为医疗应用设计的聚氨酯产品，并且为了保证这些生物材料的生物相容性和生物稳定性，这些产品都已经通过了USP Class VI，MEM Elution以及相关的测试。
- Increased level of quality assurance testing and evaluations. 高等级的质量测试以及评估
- Record retention policy 记录保留的规定
- Raw material selection 原料筛选
- Notification of change policy 变更通知
- Compliance Department which provides documentation and information for regulatory submissions. 法律部门为客户注册提供相关的文件和信息

The Benefits of Medical-Grade TPU Over Industrial Alternatives

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 drug and device filings with the US FDA and other national/regional regulatory bodies

Biocompatibility test results

- Baseline biocompatibility data is available for many of our medical grade TPU products

Heightened attention to quality that is consistent with the expectations and needs of the medical device industry

- Quality systems for medical grade TPUs are comprehensive and include appropriate change management
- There is a strict notification of change policy
- Records are retained for a minimum of seven years

Medical-grade products manufactured in ISO 9001:2008–certified facilities

Plant audits available upon approval and audit packet availability

Opportunities to assess and address risk identified

Strict adherence to policies and procedures

When used for healthcare applications, medical grade polymers offer distinct advantages over other industrial 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 engineered polymers.



医疗级TPU 相对于工业替代物的好处

协助满足监管和产品合规要求

- Lubrizol 将协助您的工作，以寻求新的业务机会以及通过提供合规机构要求的信息支持您现有的业务
- Lubrizol 还将提供关于聚合物的信息，这些信息是向美国 FDA 和其他国家 / 地区监管机构提交药物和设备申请时所必需的

生物相容性测试结果

- 基线生物相容性数据适用于我们的许多医疗级 TPU 产品

对质量的高度关注符合医疗设备行业的预期和需求

- 医疗级 TPU 的质量系统是全面的，并且包括适当的变化管理
- 存在严格的变化政策通知
- 记录至少被保留七年

医疗级产品在 ISO 9001:2008 认证设施生产

根据批准和审计包可用性提供工厂审计

评估和解决已发现的风险的机会

严格遵守政策和程序

当被用于医疗保健应用时，相对于其他工业级聚合物而言，医疗级聚合物提供独特的好处，包括生物相容性数据、变化通知管理、记录保留以及监管和产品合规支持。最重要的是，我们的医疗级 TPU 产品能够提供保证，这种保证来自于使用工程聚合物领域的领导者根据最严格的协议生产的最高级的 TPU。



Processes 加工

Blow Molding



Calendering



Extrusion



Fabric Coating



Film & Sheet



Injection Molding



Overmolding



Solution Process



Versatility
多样性

“High Modulus” ETPU Resins“

高模量ETPU树脂 Isoplast®

Amorphous Resins 无定形树脂

(e.g. PC, PSU 聚砜)

- **Clarity,**
- **Toughness**
- **Dimensional Stability**
- 透明
- 坚韧
- 尺寸稳定性



Crystalline Resins 结晶性树脂

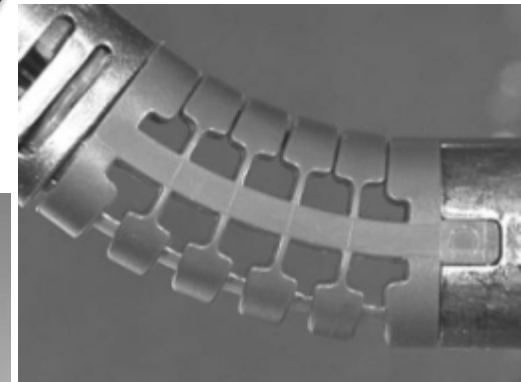
(e.g. PA, PEEK)

- **Fatigue**
- **Excellent Chemical**
- **Creep Resistance**
- 抗疲劳
- 卓越的耐化学性
- 抗蠕变力



ETPU

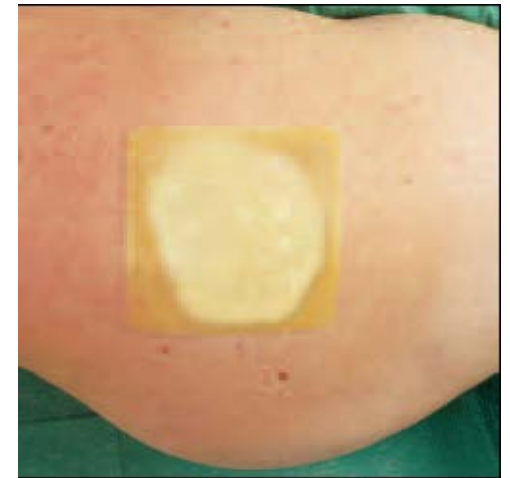
- ✓ **Clarity**
- ✓ **Toughness**
- ✓ **Dimensional Stability**
- ✓ **Fatigue**
- ✓ **Excellent Chemical**
- ✓ **Creep Resistance**
- ✓ 透明
- ✓ 坚韧
- ✓ 尺寸稳定性
- ✓ 抗疲劳
- ✓ 卓越的耐化学性
- ✓ 抗蠕变力



TPU Is Primary Polymer for Synthetic Dressings In.....

TPU是合成敷料材料的首选

- **Films & Adhesive Continuous Layers**
 - Biocompatible with human tissue
 - Provides balance of MVTR
 - Possess level of infection resistance
- **薄膜 & 胶黏剂连续层**
 - 与人体组织的生物相容性
 - 水汽透湿率的完美平衡
 - 抗感染



领先的伤口护理技术

Advanced Wound Care

更多创新

More Innovative

针对健康护理的超前的聚合物科学

Pioneering polymer science for healthcare

我们运用我们的技术专长和独特的产品化学特性，设计并提供功能性聚合物的伤口护理应用系统。

We apply our technical expertise and specialty chemicals portfolio to design and deliver functional polymer systems for wound care applications.

更多适应

More Adaptable

服务于需求不断变化的患者

Serving the ever-changing needs of patients

- 透气性
- 吸收性
- 生物相容性
- Breathable barrier properties
- Absorbency
- Biocompatibility

领先的技术

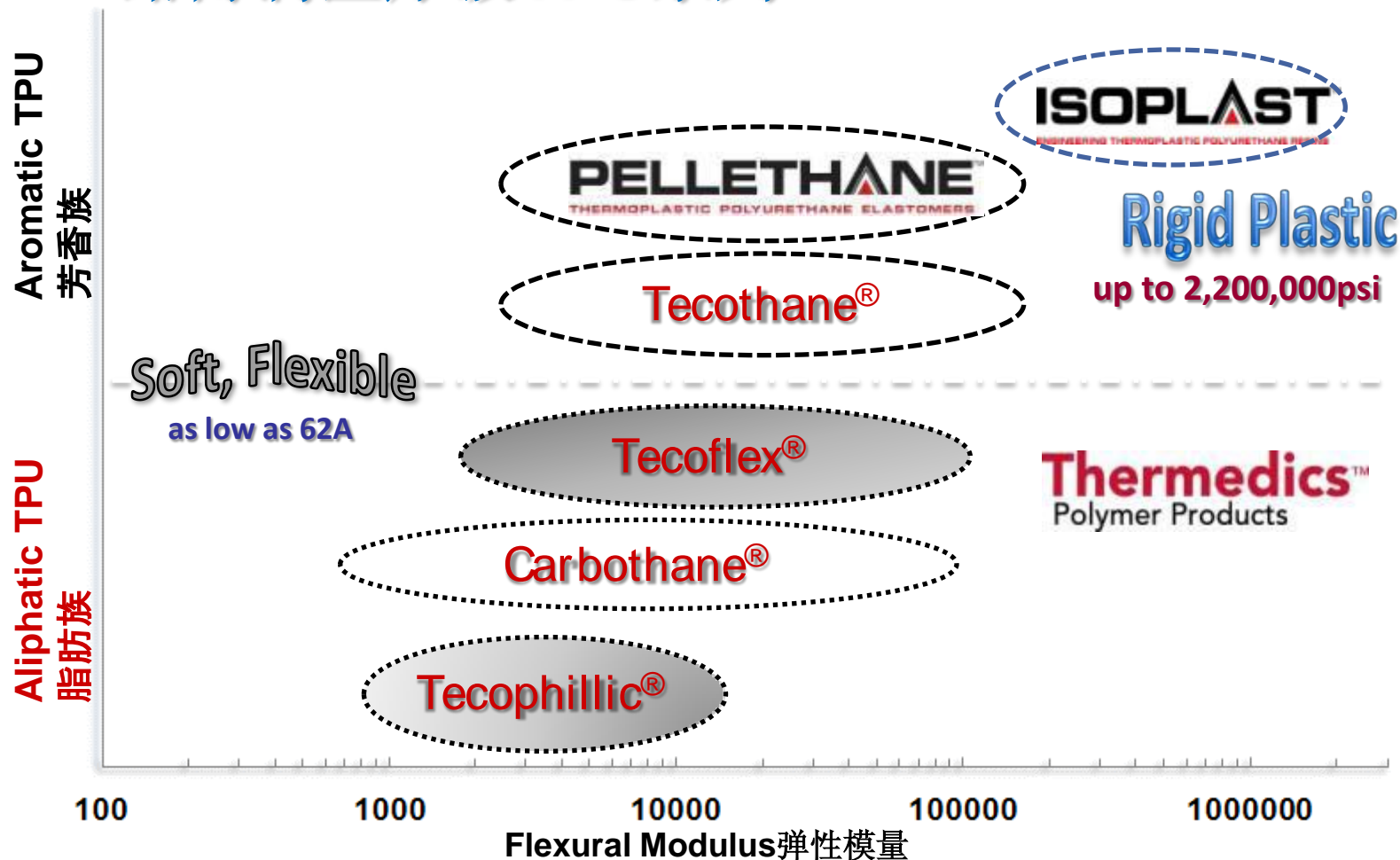
For the leading technology

- 胶带
- 薄膜
- 敷料
- Tapes
- Film
- Dressings



Lubrizol's Medical Grade Polymers

路博润医疗级TPU系列



Lubrizol offers the largest TPU product portfolio

路博润提供广范围的医疗级产品系列

Products Summary

	<u>Carbothane® TPU</u>	<u>Tecoflex® TPU</u>	<u>Tecophilic® TPU</u>	<u>Isoplast® ETPU</u>	<u>Pellethane® TPU</u>	<u>Tecoplast® TPU</u>	<u>Tecothane® TPU</u>
Aromatic or Aliphatic	Aliphatic Aromatic	Aliphatic	Aliphatic	Aromatic	Aromatic	Aromatic	Aromatic
Base	Polycarbonate-based	Polyether-based	Polyether-based	Transparent, Impact-Modified or Glass-Reinforced	Polyether & Polyester-based	Polyether-based	Polyether & Polyester-based
Durometer Range	70A - 71D	72A - 83D	70A - 60D	85D - 125R	81A - 76D	82D - 84D	62A - 84D
Radiopacifiers (available with)	Barium Sulfate Tungsten	Barium Sulfate Bismuth Salt Tungsten	Barium Sulfate Bismuth Salt Tungsten	N/A	N/A	Barium Sulfate	Barium Sulfate Tungsten
Custom Colors (available with)	Yes	Yes	Limited	Limited	No	Yes	Yes
Solution Grades	No*	Yes	Yes	No*	No	No*	No*
Hydrogel Grade	No	No	Yes	No	No	No	No
Extrusion and/or Molding Grades	Both	Both	Both	Primarily Injection Molding	Both	Primarily Injection Molding	Both
Biostability (< 30 days)	Good	Good	Good	Good	Good	Good	Good
Biostability (≥ 30 days)	Best	Shore D - Good Shore A - Application Dependent	Not Determined	Good	Shore D - Good Shore A - Application Dependent	Good	Shore D - Good Shore A - Application Dependent
Strength	Good	Good	Dry - Good Wet - Fair	Good	Best	Good	Best
Flexibility	Good	Best	Good	Poor	Good	Poor	Good
Solvent Resistance	Good	Good	Good	Best	Best	Good	Best

* Extrusion and injection molding grade can be dissolved in specific organic solvents.

产品概述

	<u>Carbothane® TPU</u>	<u>Tecoflex® TPU</u>	<u>Tecophilic® 热塑性聚氨酯</u>	<u>Isoplast® ETPU</u>	<u>Pellethane® 热塑性聚氨酯</u>	<u>Tecoplast® TPU</u>	<u>Tecothane® TPU</u>
芳香族或脂肪族	脂肪族芳香族	脂肪族	脂肪族	芳香族	芳香族	芳香族	芳香族
基底	聚碳酸酯基	聚酯基	聚酯基	透明、抗冲改性或玻璃增强型	聚酯基和聚酯基	聚酯基	聚酯基和聚酯基
硬度范围	70A - 71D	72A - 83D	70A - 60D	85D - 125R	81A - 76D	82D - 84D	62A - 84D
不透射线物质 (可提供)	硫酸钡 钨	硫酸钡 钨	硫酸钡 钨	无	无	硫酸钡	硫酸钡 钨
定制颜色 (可提供)	是	是	有限	有限	否	是	是
溶解等级	否*	是	是	否*	否	否*	否*
水凝胶等级	否	否	是	否	否	否	否
挤塑和模塑等级	兼有	兼有	兼有	主要为注塑	兼有	主要为注塑	兼有
生物稳定性 (< 30 天)	良好	良好	良好	良好	良好	良好	良好
生物稳定性 (≥ 30 天)	最佳	Shore D - 良好 Shore A - 视应用而定	未确定	良好	Shore D - 良好 Shore A - 视应用而定	良好	Shore D - 良好 Shore A - 视应用而定
强度	良好	良好	干性 - 良好 湿性 - 一般	良好	最佳	良好	最佳
灵活性	良好	最佳	良好	不良	良好	不良	良好
耐溶剂性	良好	良好	良好	最佳	最佳	良好	最佳

* 挤塑和注塑级可在特定有机溶剂中溶解。