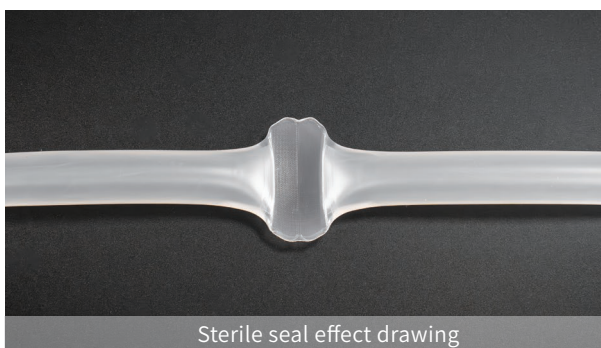


Le-Flex® TPE Tubing

Fluid management is crucial in the production of biologics. From upstream cell culture and downstream purification to final preparation filling, it plays an essential role, with the tube set being key to successfully implementing the single-use manufacturing process.

LePure Biotech Le-Flex® thermoplastic tubes are designed to meet the high standards of biologics applications. With superior sealing and aseptic welding capabilities, they ensure system integrity and sterility. Additionally, Le-Flex® tubes are available in various specifications to meet the diverse needs of customers in different application scenarios.



Typical applications

Widely used in the fluid treatment process for producing antibodies, vaccines, cell and gene therapies, and other biologics.

- Sterile seal break
- Aseptic welding connection to achieve aseptic transfer of liquid
- Preparation of medium and buffer
- Cell culture and fermentation

Advantage

- With excellent thermal sealing and aseptic welding capabilities, it can be aseptic thermal welding with mainstream TPE pipelines on the market
- Low levels of extractable and particulate matter content to comply with regulatory requirements
- Withstand dual sterilization methods (gamma irradiation and high-pressure steam)
- Low temperature embrittlement point -65°C, can achieve cryogenic liquid storage and transfer

Quality specification

- The production site has been certified by SGS and is compliant with ISO 9001 quality management system standards.
- Manufactured from pharmaceutical grade thermoplastic raw materials and verified to a variety of specifications, validation tests include:

- | | | | |
|--|--|---|--|
| ☒ Blasting test | ☒ Air tightness test | ☒ Bacterial challenge test | ☒ Elastomer testing |
| ☒ Physical and chemical test | ☒ Extractable test | ☒ Nitrosamine impurity test | ☒ Test for insoluble particles |

Technical specification

Regulatory compliance

Test standard	Test item	Test result
USP<788>	Particles test	$\geq 10 \mu\text{m} : \leq 10 \uparrow / \text{mL}$ $\geq 25 \mu\text{m} : \leq 1 \uparrow / \text{mL}$
USP<85>	Endotoxin test	$< 0.125 \text{EU/mL}$
USP<87>	Biological reactivity Tests, in vitro	Pass
USP<88>ClassVI	Biological reactivity Tests, in vivo, class VI	Pass
USP <381>	Rubber closures for containers test	Pass
USP<661>	Physiochemical test	Pass
USP <665>	Extractable test	Pass
USP <1469>	Nitrosamine content test	Pass
USP790	Visible impurity inspection	Pass
Internal standard	Burst pressure test	Pass
Internal standard	Leaking test	Pass
Internal standard	Bacterial challenge test	Pass
Internal standard	Chemical resistance test	Pass

Physical parameters

Test standard	Test item	Test result	
		Pre-gamma radiation	Post-gamma radiation
ASTM D2440	Hardness	59-61 Shore A	57-59 Shore A
ASTM D412	Tensile strength	14.5 Mpa	12.6 Mpa
ASTM D412	Elongation at Break	758%	753%
ASTM D412	100% constant elongation stress	1.9 Mpa	1.6 Mpa
ASTM D412	300% constant elongation stress	3.5 Mpa	3.3 Mpa
ASTM D412	300% tensile permanent deformation	12%	16%
ASTM D624	Tear strength	30 KN/m	29.8 KN/m
ASTM D395	Compression set "B" (22hrs, 70°C)	61%	63%
ASTM D746	Brittleness temperature Test	-70°C	-65°C

Sterilization method and validity period

Sterilization Methods	Gamma irradiation sterilization: 25-40 kGy High temperature steam sterilization: 121°C,30min (Repeated autoclaving is not recommended)
Temperature tolerance	-65~135°C
Self-life	5 years

Ordering information

Item No.	ID(mm)	OD(mm)	Packing specification
LF-0125-0250	1/8" (3.2 mm)	1/4" (6.4 mm)	15m/ roll; Double packing
LF-0188-0313	3/16" (4.8 mm)	5/16" (8.0 mm)	15m/ roll; Double packing
LF-0250-0375	1/4" (6.4 mm)	3/8" (9.6 mm)	15m/ roll; Double packing
LF-0250-0437	1/4" (6.4 mm)	7/16" (11.1 mm)	15m/ roll; Double packing
LF-0250-0500	1/4" (6.4 mm)	1/2" (12.7 mm)	15m/ roll; Double packing
LF-0313-0500	5/16"(8.0mm)	1/2"(12.7mm)	15m/ roll; Double packing
LF-0375-0500	3/8"(9.6mm)	1/2"(12.7mm)	15m/ roll; Double packing
LF-0375-0563	3/8"(9.6mm)	9/16"(14.4mm)	15m/ roll; Double packing
LF-0375-0625	3/8" (9.6 mm)	5/8" (15.9 mm)	15m/ roll; Double packing
LF-0500-0875	5/8"(15.9mm)	7/8"(22.2mm)	15m/ roll; Double packing
LF-0500-0750	1/2" (12.7 mm)	3/4" (19.1 mm)	15m/ roll; Double packing
LF-0750-1000	3/4" (19.1 mm)	1" (25.4 mm)	4.5m/ roll; Double packing

Note:

1. The table lists standard in-stock product codes. For special requirements (e.g., length, dimensions, or irradiation sterilization), please contact your local sales representative immediately.
2. The products listed in the table are sold in a non-sterile form. Sterile versions are available, with sterilization performed via gamma irradiation at a dose of 25–45 kGy . The product code naming convention for irradiated sterilization is as follows:

Non-sterile: LF-0125-0250

Sterile: LF-0125-0250-G