

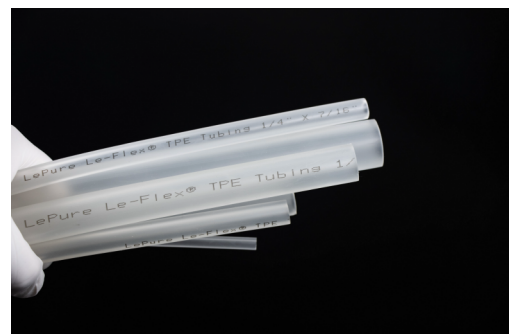
# Le-Flex<sup>®</sup>

TPE Tubing: safe, reliable

Developed and produced through proprietary technology by LePure Biotech, Le-Flex<sup>®</sup> tubing meets product safety requirements and has excellent physicochemical properties. It meets the heat-seal and welding demands for fluid management in bioprocess applications, and ensures the system integrity and sterility. Le-Flex<sup>®</sup> tubing is produced in Class 7 cleanroom with high quality standard.

## Typical applications

- Sterile disconnection and connection
- Pre-assembly for single-use system
- Preparation of culture medium and buffer solution
- Cells culture and fermentation



## Properties and advantages

- Sterile thermal welding with mainstream products on the market
- Excellent anti-gamma yellowing performance
- Low extractables and particulate release
- Pre-assembled custom designs
- Robust supply chain to keep up with strong market growth
- Complete validation documents
- Operating temperature range: -60 to 135°C
- ADCF: animal-derived component free

## Technical parameters

### 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% of stress at definite elongation	1.9 MPa	1.6 MPa
ASTM D412	300% of stress at definite elongation	3.5 MPa	3.3 MPa
ASTM D624	Tear strength	30 KN/m	29.8 KN/m
ASTM D412	300% of tensile set	12%	16%
ASTM D395	Compression set "B" (22hrs, 70°C)	61%	63%
ASTM D746	Brittleness temperature Test	-70°C	-66°C

### Pharmacopoeia compliance

Test standard	Test item	Test result
USP <661>	Physico-Chemical Tests	Passed
USP <788>	Insoluble particles Tests	≥10 µm: ≤10 pcs/mL ≥25 µm: ≤1pcs/mL

### Biocompatibility

Test standard	Test item	Test result
ISO 10993-4	Hemolysis	Pass
ISO 10993-5	Cytotoxicity	Pass
ISO 10993-6	Implantation Tests	Pass
ISO 10993-10	Irritation and Sensitization Tests	Pass
ISO 10993-11	Acute Systemic Toxicity Tests	Pass
USP <85>	Bacterial endotoxin Tests	Pass
USP <87>	Biological reactivity Tests, in vitro	Pass
USP <88>	Biological reactivity Tests, in vivo, class VI	Pass

## Sterilization method

High-pressure steam sterilization	121°C/30min
Gamma irradiation sterilization	25-40 kGy

## Performance test

Test standard	Test item	Test result
ASTM F1980-2016	Validity	Three years
Enterprise standard method	Heat-seal/welding burst pressure Test	Pass
Enterprise standard method	Heat-seal/welding air tightness Test	Pass
Enterprise standard method	Welding strength Test	Pass

## Specification parameters

Item No.	ID xOD (mm)	ID xOD (inch)	Packaging specification
LF-0125-0250	3.2×6.4	1/8×1/4	15 m/volume, double packing
LF-0188-0313	4.8×8.0	3/16×5/16	15 m/volume, double packing
LF-0250-0375	6.4×9.6	1/4×3/8	15 m/volume, double packing
LF-0250-0437	6.4×11.1	1/4×7/16	15 m/volume, double packing
LF-0250-0500	6.4×12.7	1/4×1/2	15 m/volume, double packing
LF-0375-0625	9.6×15.9	3/8×5/8	15 m/volume, double packing
LF-0500-0750	12.7×19.1	1/2×3/4	15 m/volume, double packing
LF-0750-1000	19.1×25.4	3/4×1	4.5 m/volume, double packing



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