ILC DOVER

SENTINEL PROCESS SYSTEMS, INC

BEYOND BOUNDARIES®

# Liquid Single-Use Bags

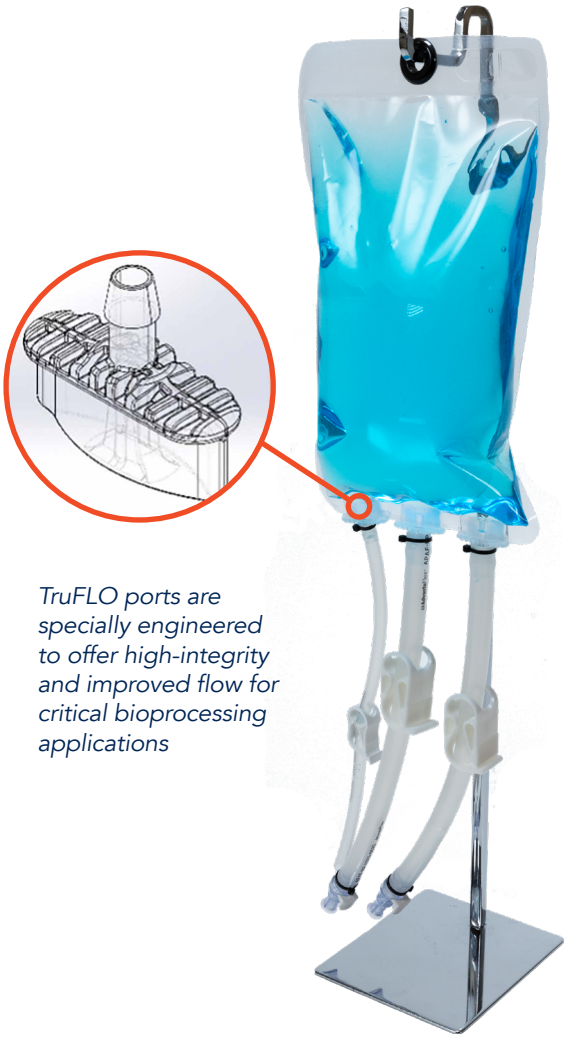
High-performance fluid storage and transfer bags with optimized reliability, throughput, and quality assurance for critical bioprocessing for a variety of upstream and downstream processes

Liquid single-use bags are low-profile containers engineered to bioprocess fluids. Featuring high-integrity and flow-optimized TruFLO ports, liquid single-use bags offer reliable and high-throughput performance. The industry-proven, medical-grade Renolit 9101 multilayer polyethylene film meets the requirements of ISO and USP biocompatibility tests. The film also meets low-permeability and low-temperature requirements while offering high clarity.

Liquid single-use bags are available in standard sizes from 50 mL to 20 L in 2 and 3-port options, and can be customized up to 50 L with up to 4-ports in larger chamber sizes (2 L to 50 L). Custom face-ported 2D bags are also available in 20 L, 50 L, 100 L and 200 L.

## Liquid single-use bags feature a variety of BPOG-compliant standard and custom configurations

| Feature | Configurations |
|---|---|
| Volume | Standard: 50 mL to 20 L<br>Custom: up to 200 L |
| Port | Standard Edge: 2- or 3-port (500 mL to 50 L)<br>Custom Edge: 4-port (2 L to 50 L)<br>Custom Face: 3-port (20 L, 50 L, 100 L, 200 L) |
| Port Size | Edge: 1/8 in, 1/4 in, or 3/8 in<br>Face: 1/4 in, 3/8 in or 1/2 in |
| Tubing | Standard: Thermoplastic Elastomer (TPE)<br>Custom: Platinum-Cured Silicone (PCS) |



*TruFLO ports are specially engineered to offer high-integrity and improved flow for critical bioprocessing applications*

## Benefits

- Unique TruFLO ports design facilitates optimized edge-seal integrity and improved flow rates
- Low-profile design ensures minimal product holdup to maximize product recovery
- Configurable with a wide variety of BPOG-compliant components

## Typical Applications

- Buffer and cell culture media
- Bulk product collections and storage
- Chromatography and filtration buffer
- Fraction collection
- Product sampling and transport

# Standard Configurations

## Liquid single-use bags with TruFLO ports

### 2-Port Configurations

| Size | Port Sizes | Dimensions (W x L) | Internal Surface Area | Connections | Smart Part # |
|---|---|---|---|---|---|
| 50 mL | 1/4 in | 5.37 x 4.25 in | 20 $in^2$ | Luer (Body & Insert) | EP050M2PTL-G |
| 100 mL | 1/4 in | 5.37 x 4.75 in | 25 $in^2$ | Luer (Body & Insert) | EP100M2PTL-G |
| 250 mL | 1/4 in | 5.37 x 6.50 in | 41 $in^2$ | Luer (Body & Insert) | EP250M2PTL-G |
| 500 mL | 1/4 in | 7.07 x 7.75 in | 65 $in^2$ | Luer (Body & Insert) | EP500M2PTL-G |
| 1 L | 1/4 in | 7.07 x 10.31 in | 104 $in^2$ | Luer (Body & Insert) | EP001L2PTL-G |
| 500 mL | 3/8 in | 7.07 x 7.75 in | 65 $in^2$ | MPCs (F&M) | EP500M2PTM-G |
| 1 L | 3/8 in | 7.07 x 10.31 in | 104 $in^2$ | MPCs (F&M) | EP001L2PTM-G |
| 2 L | 3/8 in | 7.07 x 15.75 in | 173 $in^2$ | MPCs (F&M) | EP002L2PTM-G |
| 5 L | 3/8 in | 14.25 x 14.91 in | 280 $in^2$ | MPCs (F&M) | EP005L2PTM-G |
| 10 L | 3/8 in | 16.75 x 18.88 in | 440 $in^2$ | MPCs (F&M) | EP010L2PTM-G |
| 20 L | 3/8 in | 17.50 x 28.38 in | 772 $in^2$ | MPCs (F&M) | EP020L2PTM-G |

### 3-Port Configurations

| Size | Port Sizes | Dimensions (W x L) | Internal Surface Area | Connections* | Smart Part # |
|---|---|---|---|---|---|
| 500 mL | 3/8 in (2) & 1/4 in | 7.0x x 7.75 in | 65 $in^2$ | MPCs (F&M), Injection Cap | EP500M3PTM-G |
| 1 L | 3/8 in (2) & 1/4 in | 7.07 x 10.31 in | 104 $in^2$ | MPCs (F&M), Injection Cap | EP001L3PTM-G |
| 2 L | 3/8 in (2) & 1/4 in | 7.07 x 15.75 in | 173 $in^2$ | MPCs (F&M), Injection Cap | EP002L3PTM-G |
| 5 L | 3/8 in (2) & 1/4 in | 14.25 x 14.91 in | 280 $in^2$ | MPCs (F&M), Injection Cap | EP005L3PTM-G |
| 10 L | 3/8 in (2) & 1/4 in | 16.75 x 18.88 in | 440 $in^2$ | MPCs (F&M), Injection Cap | EP010L3PTM-G |
| 20 L | 3/8 in (2) & 1/4 in | 17.50 x 28.38 in | 772 $in^2$ | MPCs (F&M), Injection Cap | EP020L3PTM-G |

** via 12-inch TPE tubing*

# Medical-Grade Renolit 9101 PE Film

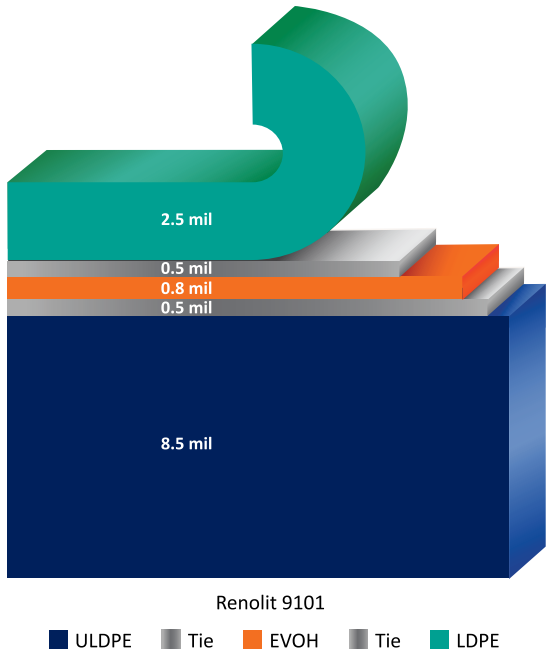
All liquid single-use bags are manufactured with industry-proven, medical-grade Renolit 9101 film, a multilayer film composed of a high-purity biocompatible polyethylene (PE) contact layer with internal ethylene vinyl alcohol (EVOH) oxygen-barrier.

## Physical Properties

| Property | Typical Value* |
|---|---|
| Film Thickness | 0.325 mm |
| Clarity | 97% (ASTM D-1003) |
| Tensile Strength at Break | 13MPa (ASTM D-882) |
| Elongation at Break | 350% (ASTM D-882) |
| Break at Cold Temperature | < -45°C (ISO 8570) |
| Water Vapor Transmission† | 0.32 g/m²/day (ASTM F-1249) |
| $O_2$ Permeability‡ | <0.05 cm³/m²/day/bar (ASTM D-3985) |
| $CO_2$ Permeability‡ | <0.2 cm³/m²/day/bar (ASTM F-2476) |

* *Transmission values for film gamma-irradiated with 50 KGy. Other are for film gamma-irradiated with 25 KGy.*
† *@ 23 °C, 100% RH.*
‡ *@ 23 °C, 0% RH.*

## Renolit 9101 PE Film Layers




## Quality, Regulatory, and Biocompatibility Properties

| Category | Property/Test* |
|---|---|
| Composition | • High-purity polyethylene (PE) and ethylene vinyl alcohol (EVOH)<br>• Animal-Derived Ingredient (ADI) Free |
| Biocompatibility | • ISO 10993-4, Hemolysis<br>• ISO 10993-5, Cytotoxicity<br>• ISO 10993-6, Implantation<br>• ISO 10993-10, Irritation and Sensitization<br>• ISO 10993-11, Acute System Toxicity<br>• USP <85>, Bacterial Endotoxins – LAL test<br>• USP <87>, Biological Reactivity in vitro<br>• USP <88>, Biological Reactivity in vivo, Class VI |
| Extractables/Leachables | • USP <661.1>, Polyethylene Physiochemical Tests, Extractable Metals, Plastic Additives<br>• Ph. Eur. 3.1.5, Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations |
| Recommended Sterilization Method | Gamma |

* *Pharmacopoeia and Biocompatibility compliance test reports available upon request*

## Questions or Inquiries?

More information is available at **www.ilcdover.com**, or by contacting us at **customer_service@ilcdover.com** or simply by reaching out to your dedicated ILC Dover sales representative.

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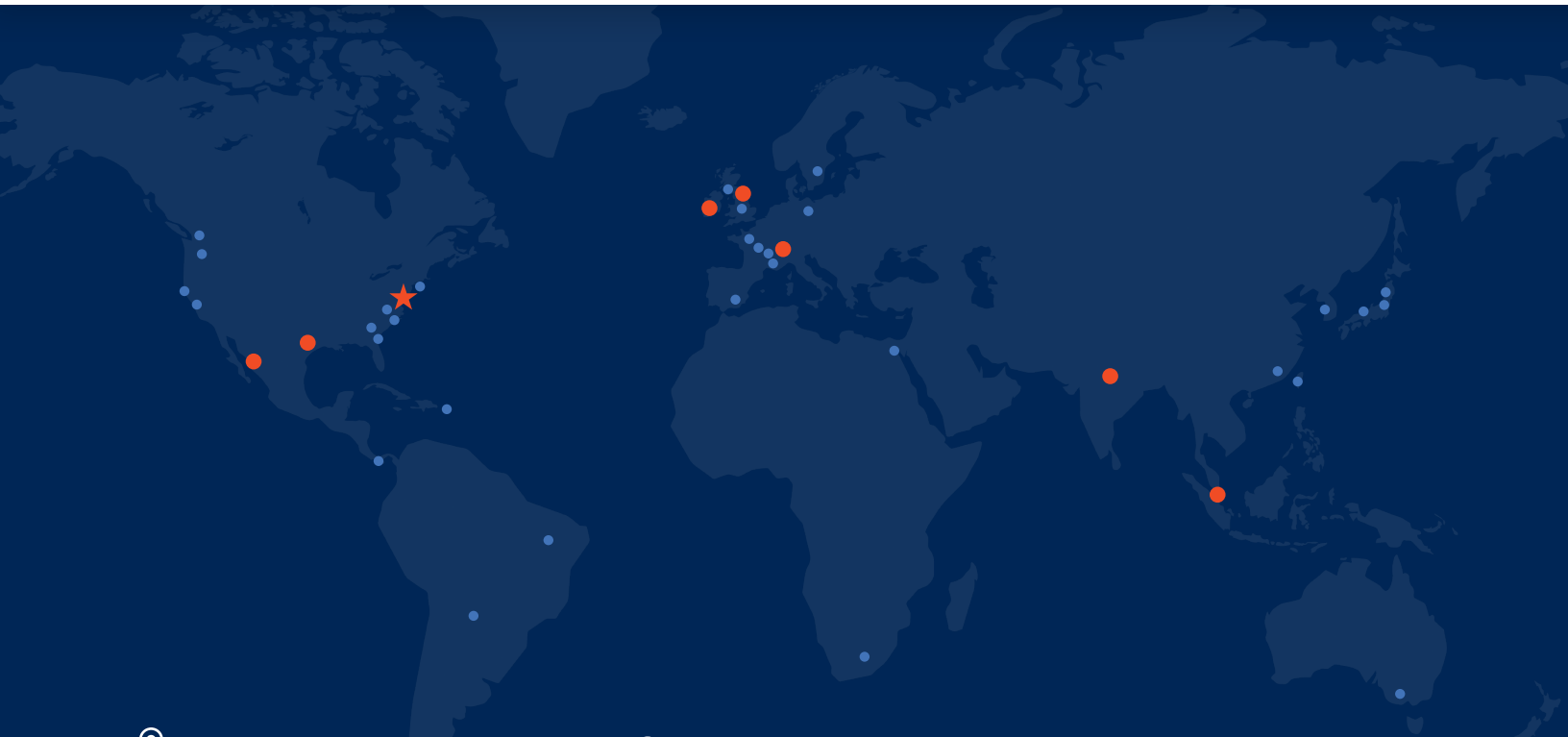
# BEYOND BOUNDARIES®

ILC Dover is a world-leader in the innovative design and production of engineered flexible protective solutions for pharmaceutical and biopharmaceutical, flood protection, personal protection, bulk packaging, and aerospace industries. Our customers will attest to our relentless dedication to high value products, advanced technology, and responsive service, as our visionary flexible protective solutions have improved efficiency while safeguarding people, product, and infrastructure in hazardous conditions since 1947.

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MKT-0336 Certified System ISO 9001



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