

# 2D Bioprocess Bags

Featuring Medical Grade Renolit 9101 PE Film

## Key Benefits

- Bag chambers are manufactured using industry-proven Renolit 9101
- Strong physical design for the safe storage of product and process fluids
- TruFlo ports engineered for improved flow and minimum hold-up
- Flexible customization utilizing tubing, components, and vendor of choice
- Assembled in ISO Class 7 clean room

## Standard Configurations

- Volumes of 50 mL to 20L

## Port configurations:

- 2-ports for all (50 mL to 20 L)
- 3-port (500 mL to 20 L)
- 4-port custom (2L to 20L)

## Port size

- 1/8 in, 1/4 in, or 3/8 in

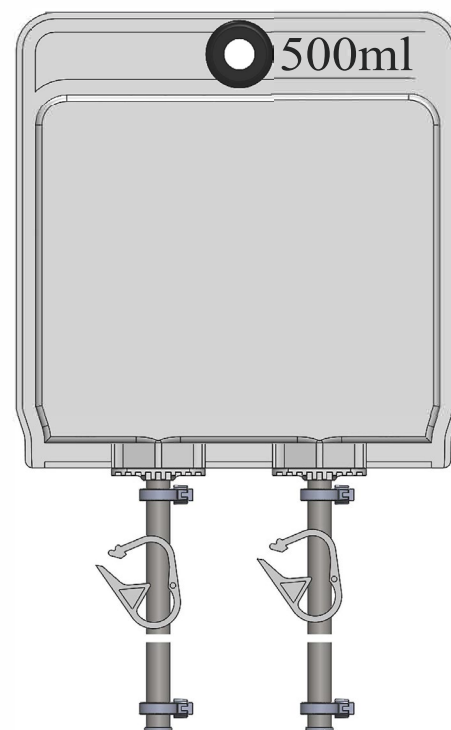
## Applications

- Media and buffer storage
- Aseptic sampling
- Product collection and storage
- Customized filling manifolds



**Stocked Bags - Other sizes and configurations available. Contact us.**

Description	Capacity	Ports Sizes & Qty.			Internal Surface Area (in <sup>2</sup> )
		1/8in	1/4in	3/8in	
<b>Two-Port Bags</b>  (Choose bags with 1/8-, 1/4- or 3/8-inch ports in a given capacity.)	50mL	2	2	—	20
	100mL	2	2	—	25
	250mL	2	2	—	41
	500mL	2	2	2	65
	1L	2	2	2	104
	2L	—	—	2	173
	5L	—	—	2	280
	10L	—	—	2	440
	20L	—	—	2	772
<b>Three-Port Bags</b>  (All bags have a single 1/8-inch port and two 3/8-inch ports)	500mL	1	—	2	65
	1L	1	—	2	104
	2L	1	—	2	173
	5L	1	—	2	280
	10L	1	—	2	440
	20L	1	—	2	772

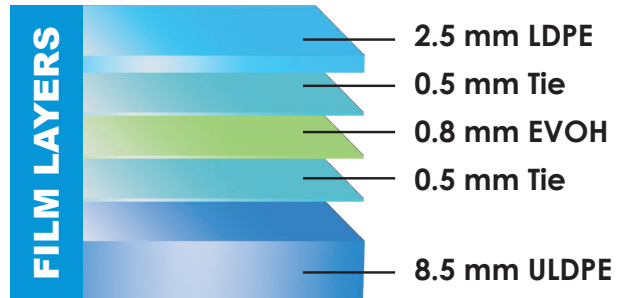


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# Medical Grade Renolit 9101 PE Film

## Renolit 9101 Polyethylene Film

All liquid single-use chambers 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.

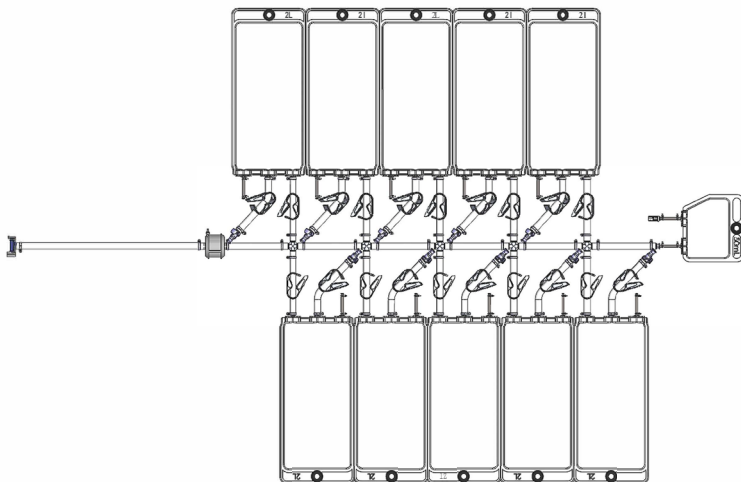


### Physical Properties

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/m <sup>2</sup> /day (ASTM F-1249)
O <sub>2</sub> Permeability‡	<0.05 cm <sup>3</sup> /m <sup>2</sup> /day/bar (ASTM D-3985)
CO <sub>2</sub> Permeability‡	<0.2 cm <sup>3</sup> /m <sup>2</sup> /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.



### Quality, Regulatory and Biocompatibility Properties

Category	Property / Test*
Composition	<ul style="list-style-type: none"> <li>High-purity polyethylene (PE) and ethylene vinyl alcohol (EVOH)</li> <li>Animal-Derived Ingredient (ADI) Free</li> </ul>
Biocompatibility	<ul style="list-style-type: none"> <li>ISO 10993-4, Hemolysis</li> <li>ISO 10993-5, Cytotoxicity</li> <li>ISO 10993-6, Implantation</li> <li>ISO 10993-10, Irritation and Sensitization</li> <li>ISO 10993-11, Acute System Toxicity</li> <li>USP &lt;85&gt;, Bacterial Endotoxins – LAL test</li> <li>USP &lt;87&gt;, Biological Reactivity in vitro</li> <li>USP &lt;88&gt;, Biological Reactivity in vivo, Class VI</li> </ul>
Extractables / Leachables	<ul style="list-style-type: none"> <li>USP &lt;661.1&gt;, Polyethylene Physicochemical Tests, Extractable Metals, Plastic Additives</li> <li>Ph. Eur. 3.1.5, Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations</li> </ul>
Recommended Sterilization Method	<ul style="list-style-type: none"> <li>Gamma</li> </ul>

\* Pharmacopoeia and Biocompatibility compliance test reports available upon request



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