

PURITY ONE™

# 3D BAG SOLUTIONS

Customized & Assembled for You

## 3D Single-Use Bags for Bioprocessing

Purity One™ 3D Bags are engineered for aseptic fluid storage and handling applications. Manufactured in an ISO Class 7 cleanroom, Purity One™'s 3D Bags are constructed from USP Class VI, film and components. The film utilizes a five-layer construction with a LDPE outer layer, EVOH barrier layer, and a ULDPE fluid contact layer.

Available in standard volumes ranging from 50L – 2500L with 1, 2, 3, 4 and 5 port configurations, the 3D bags can also be custom made with specific dimensions to retrofit your existing totes. Purity One™ 3D Bags are the leading solution for your filling, transfer and storage applications.



### Specifications:

- ISO 7 Cleanroom
- USP <88> Class VI Materials
- Animal Derivative Free
- Validation Guide
- Extractables (BPOG) Report

\*Port Sizes: 1/8", 3/16", 1/4", 3/8", 1/2", 5/8", 3/4", 1"

3D BAGS	PORTS	PORT SIZE
50L	Up to 5	1/8" - 1"
100L	Up to 5	1/8" - 1"
200L	Up to 5	1/8" - 1"
500L	Up to 5	1/8" - 1"
1000L	Up to 5	1/8" - 1"
2500L	Up to 5	1/8" - 1"

# 3D BAG SOLUTIONS

Customized & Assembled for You

## Physical Properties

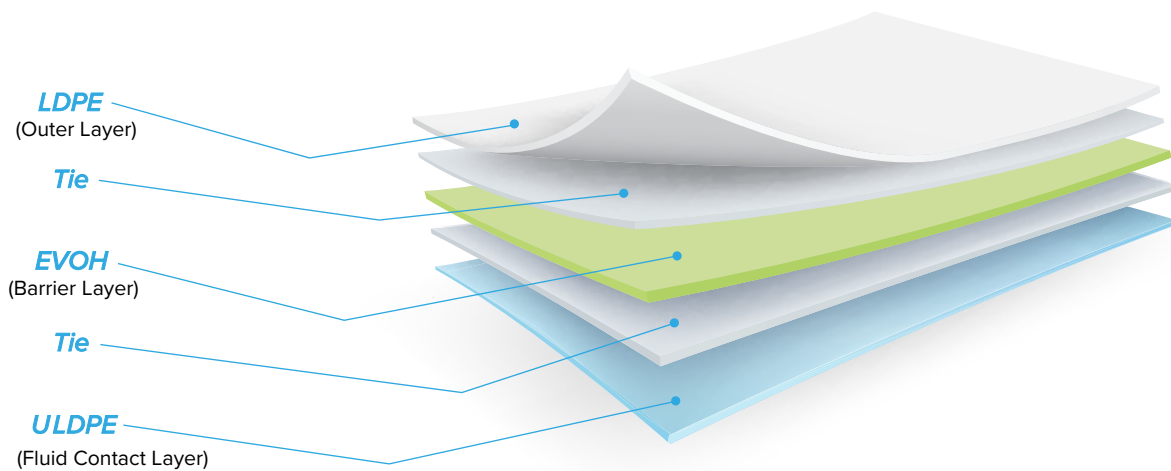
Property	Typical Value Pre   Post Gamma	Method
Haze	7   7 %	ASTM D-1003
Clarity	97   97 %	ASTM D-1003
Transmittance	93   93 %	ASTM D-1003
Elongation at Break	370   350 %	ASTM D-882
Tensile Strength at Break	14   13 MPa	ASTM D-882
Elastic Modulus	250   270 MPa	ASTM D-882
Break at Cold Temperature	<-45   <-45 °C	ISO 8570
Density	0.9   0.9 g/cm <sup>3</sup>	ASTM D-792
Water Vapor Transmission Rate (23°C, 100% RH)	0.35   0.32 g/m <sup>2</sup> / day	ASTM F-1249
O <sub>2</sub> Permeability (23°C, 0% RH)	<0.05   <0.05 cm <sup>3</sup> / m <sup>2</sup> /day/bar	ASTM D-3985
CO <sub>2</sub> Permeability (23°C, 0% RH)	<0.2   <0.2 cm <sup>3</sup> / m <sup>2</sup> /day/bar	ASTM F-2476

## Biocompatibility

Method	Description
ISO 10993-4	Hemolysis
ISO 10993-5	Cytotoxicity
ISO 10993-6	Implantation
ISO 10993-10	Irritation and Sensitization
ISO 10993-11	Acute Systemic Toxicity
USP <85>	Bacterial Endotoxins - LAL
USP <87>	Biological Reactivity, in vitro
USP <88>	Biological Reactivity, in vivo, Class VI
USP <661.1>	Polyethylene Physicochemical Tests, Extractable Metals, Plastic Additives
EP 3.1.5	<0.05   <0.05 cm <sup>3</sup> / m <sup>2</sup> /day/bar

### Multilayer Film Structure:

Purity One single-use bags are constructed of a 12.8 mil multilayer film optimized for bioprocess production applications. Film materials are consistent throughout the product range, and are free of materials of animal origin.



*Purity One™ manufactures single-use and custom hose solutions that are critical to improving quality of life and overall wellness for people all around the world. With our combined technical expertise and cleanroom assembly capabilities, we focus on providing a level of service and quality-assurance that is unparalleled in the global life sciences, biopharmaceutical and pharmaceuticals industries.*

195 Industrial Drive  
Northampton MA 01060

(413)320-4650

[sales@purityone.com](mailto:sales@purityone.com)

[purityone.com](http://purityone.com)



IMPORTANT: Users are accountable for verifying that Purity One™ products are appropriate and safe for their intended purposes, and that the materials used conform to all relevant medical regulatory standards. Purity One™ disclaims any liability for product failures resulting from the improper use of materials supplied, whether in the design, construction, or application of the products in which these materials are utilized.