

Corning Single-use Technology

Single-use Bags, Tubing, Tank Liners,
and Custom Assemblies

CORNING



Corning Single-use Technology

Single-use systems are designed to be practical and cost-effective alternatives to rigid-walled containers. They are fabricated to match your specific application with a variety of sizes and tubing/connector configurations. These containment and delivery systems preserve the physical, chemical, and functional characteristics of sterile and process fluids. All components can be customized to match your requirements. Visit www.corning.com/lifesciences/bioprocess for additional product and technical information.

Features and Benefits

- ▶ High quality barrier films
- ▶ Sterile
- ▶ Gas and moisture barriers to minimize transmission of oxygen, carbon dioxide, and water vapor
- ▶ Universal connection systems
- ▶ Reduces costs associated with washing, sterilization, and Steam-in-place (SIP)/Clean-in-place (CIP) validations.
- ▶ Reduces the risks associated with cross-contamination
- ▶ Minimal setup time
- ▶ Wide variety of standard configurations
- ▶ Easily integrated in automated systems



Industry Recognized Manufacturing Standards

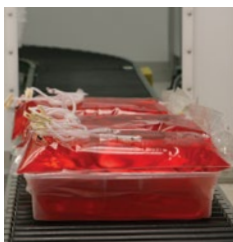
- ▶ cGMP and ISO 13485 manufacturing process
- ▶ Complete documentation and traceability
- ▶ Animal-free materials

Custom Configuration Options

- ▶ 50 mL to 500L sizes
- ▶ 2D and 3D configurations (pillow and gusseted)
- ▶ Hanging designs

Applications

- ▶ Bioreactor and fermentation
- ▶ Media storage and delivery
- ▶ Seed/culture/harvest/recovery
- ▶ Separation
- ▶ Downstream processing
- ▶ Filtration
- ▶ Storage of high purity water
- ▶ Waste containment





Custom Fabrication and Assembly Services

Corning offers extensive custom design services for single-use systems.

Film Materials

- ▶ Ethylene vinyl acetate (EVA)/Ethylene vinyl alcohol (EVOH)
- ▶ Ultra-low density polyethylene (ULDPE)/EVOH
- ▶ ULDPE

Fittings

- ▶ Luer locks
- ▶ CPC connectors
- ▶ Sanitary fitting
- ▶ Hose barbs
- ▶ Spike components
- ▶ Steam-in-place (SIP) connectors



Tubing

- ▶ Chemically resistant, heat sealable flexible tubing
- ▶ Platinum or peroxide cured silicone
- ▶ PVC

Configuration

- ▶ Custom sizes
- ▶ Bottom ports
- ▶ 2D and 3D options
- ▶ Dip tube
- ▶ Recirculation tube

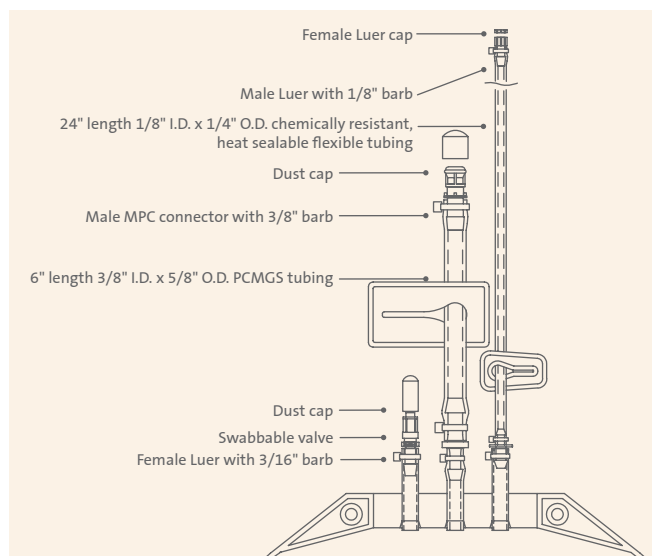


Corning's custom bags generally come with a standard set of claims, which may vary based on the film type and components used in the final, configured design. The claims are generally:

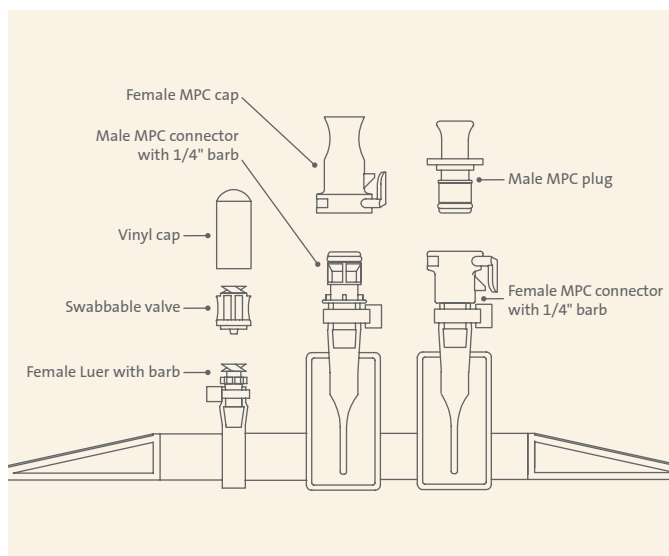
Claim Type	Specification
Irradiation Dose	25.0 - 45.0 kGy
Sterility	Routine sterility testing is performed on representative lot samples following ANSI/AAMI/ISO 11137 guidelines. Periodic validation has determined that an irradiation dose of 25.0 - 45.0 kGy provides a minimum Sterility Assurance Level (SAL) of 10^{-6} for product contact surfaces.
Particulate	Samples of representative lot have been routinely tested in periodic validations and have passed requirements per Particulate Matter in Injections Light Obscuration Particulate Count Test (USP <788>).
Endotoxin	Samples of representative lot are routinely tested in periodic validations for the presence of endotoxin per the USP Bacterial Endotoxin Test (USP <85>). Aqueous extracts contained <0.25 EU/mL as determined by the Limulus Amebocyte Lysate Test (LAL).
Biological Reactivity	Product contact materials have passed USP Class VI testing (USP <88>) and/or ISO 10993.
Cytotoxicity	Product contact films have passed cytotoxicity testing (USP <87> MEM Elution)
Physicochemical	Product contact films have passed USP Physicochemical Tests for Plastics (USP <661>).
EP Testing	Product contact films have passed EP <3.2.2.1> "Plastic Containers for Aqueous Solutions for Parental Infusion".
Inspection	100% visually inspected.

COLLECTION BAGS

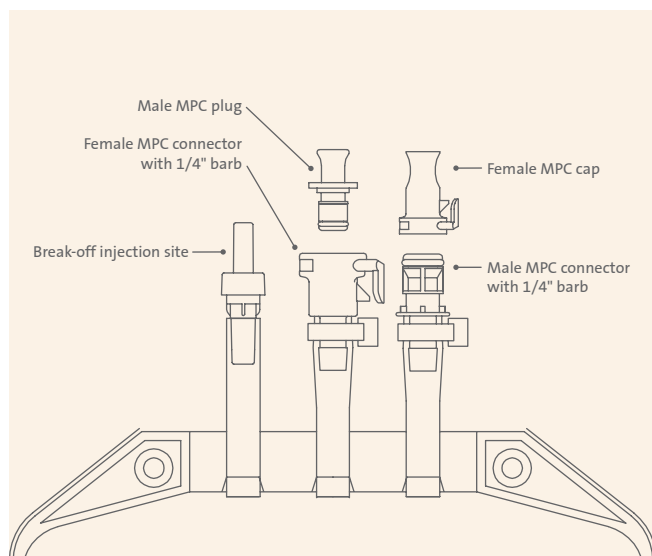
Collection bags are available in 2D hanging configurations with multiple bag volumes and connector configurations.



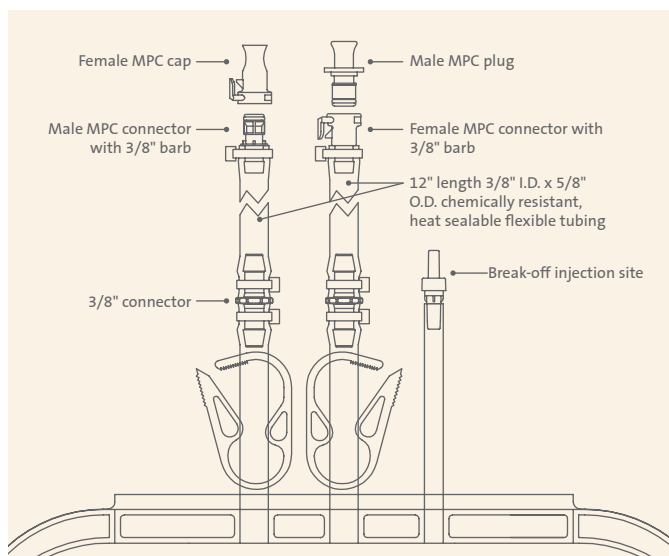
Cat. No.	Film Type	Size	Qty/Pk
91-200-01	EVA	1L	1
91-200-02	EVA	2L	1
91-200-05	EVA	5L	1
91-200-10	EVA	10L	1
91-200-20	EVA	20L	1



Cat. No.	Film Type	Size	Qty/Pk
91-200-36	EVA	10L	1
91-200-39	EVA	20L	1



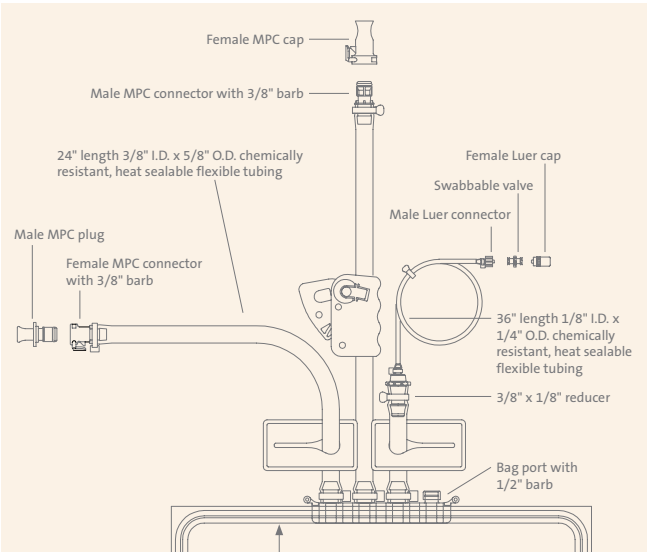
Cat. No.	Film Type	Size	Qty/Pk
91-200-41	EVA	500 mL	1
91-200-42	EVA	1L	1



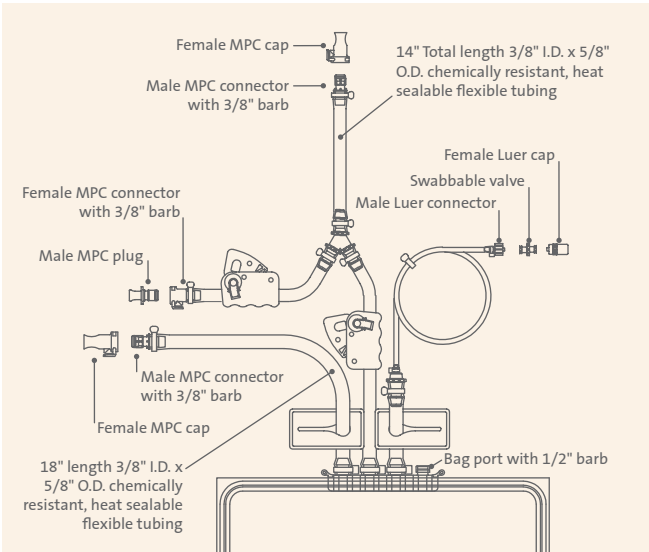
Cat. No.	Film Type	Size	Qty/Pk
91-200-43	EVA	5L	1
91-200-45	EVA	10L	1
91-200-47	EVA	20L	1
91-200-48	EVA	50L	1

SINGLE-USE BAGS FOR CORNING® HYPERSTACK® VESSELS

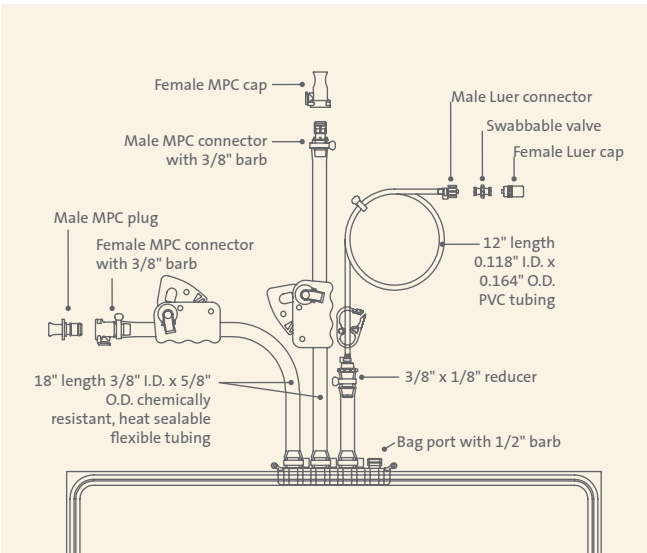
These single-use bags can be connected to tubing by tube welding or by using the pre-assembled multipurpose connectors. They can be used to add media, trypsin, or quenching substrates to culture cells in an entirely closed environment.



Cat. No.	Description	Film Type	Size	Qty/Pk
91-200-75	Trypsin bag	ULDPE	5L	1



Cat. No.	Description	Film Type	Size	Qty/Pk
91-200-76	Quench bag	ULDPE	5L	1



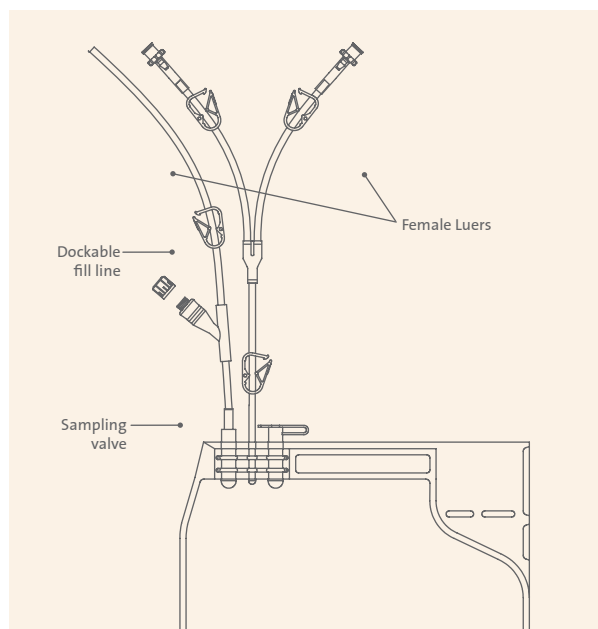
Cat. No.	Description	Film Type	Size	Qty/Pk
91-200-77	Media bag	ULDPE	20L	1

CELL EXPANSION BAGS

Cell expansion bags are intended for the expansion and culture of non-adherent cells. The bags are made from single layer polyolefin, gas permeable film. The integrated tubing allows for functionally closed system filling, feeding, and sampling.

Features and Benefits

- ▶ Cell expansion observed with multiple cell models
- ▶ Gas permeable film
- ▶ Reusable sampling valve for in-process testing
- ▶ Tubing for sterile weld connections
- ▶ Scalable, user friendly design
- ▶ Sterility Assurance Level (SAL) of 10^{-6}



Cat. No.	Size	Fill Volume	Qty/Pk
91-200-84	500 mL	190 mL	1
91-200-85	1L	381 mL	1
91-200-86	3L	633 mL	1
91-200-87	5L	1252 mL	1

CRYOPRESERVATION BAGS

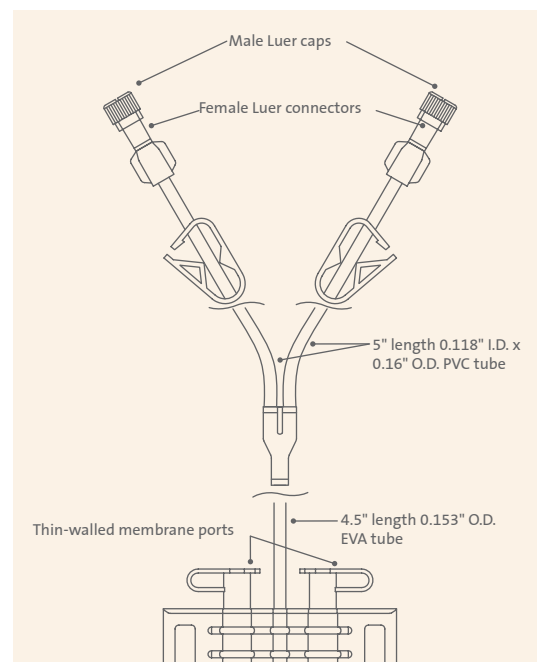
Cryopreservation bags are designed for storage, preservation, and transfer of cells.

Design Offers

- ▶ Unique bag film material remains flexible at low temperatures (-196°C).
- ▶ Proprietary membrane port design offers thinner walls for increased flexibility and attached cap minimizes membrane exposure during freezing.
- ▶ Industry standard label pocket design offers ease-of-use and traceability in labeling.

Features and Benefits

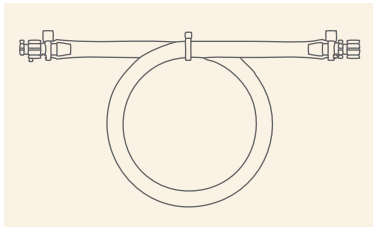
- ▶ Polyolefin film – Proprietary EVA blend specifically selected for its low temperature properties while maintaining flexibility and clarity when filled with liquid.
- ▶ Membrane port – The attached cap snaps into place to protect the contents and minimizes membrane exposure during use.
- ▶ Label pocket – Supports use of computer-generated labels; product information can be viewed quickly by simply opening the freezing cassette.
- ▶ Integral fill tube – The unique manufacturing method used to secure the fill tube to the container body eliminates the need for PVC interfaces with the liquid nitrogen storage section of the container.
- ▶ Interface/Connectors – Compatible with standard tube welding and sealing devices; fits in a variety of freezing cassette systems.



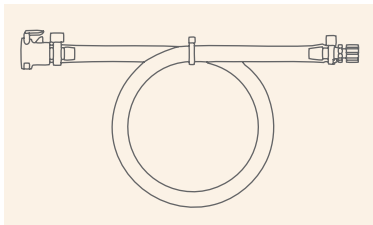
Cat. No.	Size	Fill Volume	Qty/Pk
91-200-88	50 mL	10 - 20 mL	1
91-200-89	250 mL	30 - 70 mL	1
91-200-90	500 mL	55 - 100 mL	1
91-200-91	750 mL	80 - 190 mL	1

TUBING SETS

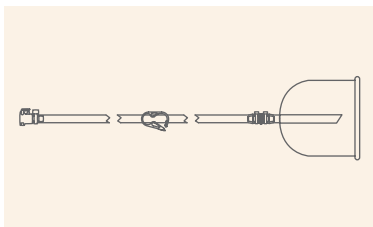
Optional tubing sets are available in combination with all single-use bag options.



Cat. No.	Description	Qty/Pk
91-700-00	36" length 1/4" I.D. clear, chemically resistant, heat sealable flexible tubing Male Luer and female Luer cap Female Luer and male Luer cap	1



Cat. No.	Description	Qty/Pk
91-700-04	36" length 1/4" I.D. clear, chemically resistant, heat sealable flexible tubing Female MPC connector Female Luer and male Luer cap	1



Cat. No.	Description	Qty/Pk
91-700-12	24" length 1/4" I.D. clear, chemically resistant, heat sealable flexible tubing Female MPC connector with 1/4" barb Pinch clamp Filling bell	1

TANK LINERS

Corning's portfolio of sterile tank liners are designed to fit cylindrical tanks. Tank liners are manufactured with ultra-low density polyethylene (ULDPE) and are available in a range of sizes.



Features and Benefits

- ▶ Irradiated, individually packaged
- ▶ Animal-free components
- ▶ Reduce costs associated with the cleaning and validation of tanks
- ▶ Reduce labor costs and increase turnaround time
- ▶ Reduce the risks associated with cross-contamination
- ▶ Help extend the life of reusable tanks, resulting in lower capital expenditures
- ▶ Wide variety of sizes

Gusseted Tank Liners (3D)

Cat. No.	Max. Volume	Diameter	Approx. Depth	Qty/Pk
91-300-15	50L	13"	27"	1
91-300-25	100L	18"	30"	1
91-300-35	200L	22"	36"	1

Non-gusseted Tank Liners (2D)

Cat. No.	Max. Volume	Diameter	Approx. Depth	Qty/Pk
91-300-20	130L	18"	30"	1
91-300-30	200L	22.5"	36"	1

FILM TYPES

Corning® single-use containers are available in multiple formats with different types of film. Each film type is selected to provide a high quality, cost effective, flexible container. Depending on the application, Corning can customize the bag’s components (e.g., film type, configuration, and connectors) to preserve the physical, chemical, and functional characteristics of the sterile fluids.

As the pharmaceutical industry attempts to replace steel, glass, and hard plastic containers, single-use containers reduce the risk of cross-contamination while reducing cleaning and cleaning validation. The purpose of this report is to demonstrate the suitability of Corning single-use containers for research and product development in biopharmaceutical applications.

We will describe the biocompatibility and other tests used to rigorously assess Corning film types and show detailed physical specifications for each film. Film types and film layering (containing tie layers, fluid contact layers, as well as outer layers to support use requirements) are classified by their fluid contact layer.

Films

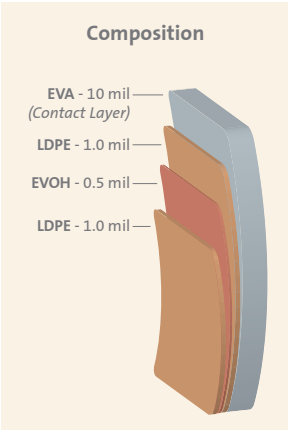
EVA/EVOH, ULDPE/EVOH, Polyolefin, ULDPE

Biocompatibility

Our film for single-use products undergoes a range of biocompatibility tests to ensure they are safe for use in manufacturing. USP <88> Class VI tests for in vivo reaction to the material, while <87> tests for in vitro reactions (toxicity). USP <661> tests for harmful extractables that may affect a process solution. USP <85> tests for the presence of bacterial endotoxins.

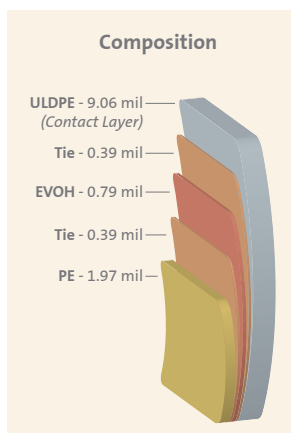
EVA/EVOH Film

12.5 mil co-extrusion film — Collection bags.



Biocompatibility Tests	Test Protocol	Result
Biological Reactivity Tests, In Vivo, Plastics Class VI	USP <88>	Met USP requirements
Biological Reactivity Test, In Vitro	USP <87>	Met USP requirements
Bacterial Endotoxin Test, LAL Kinetic Chromogenic	USP <85>	Met USP requirements
Physical Tests	USP <661>	Met USP requirements
Hemolysis	ISO <10993-4>	Met ISO requirements
Cytotoxicity	ISO <10993-5>	Met ISO requirements
Plastic Containers for Aqueous Solutions for Parenteral Infusion	EP <3.2.2.1>	Met EP requirements
Extractables Testing	BPOG Extractables Protocol-2014 Published Version	For characterization

Physical Properties	Test Standard	Doses (kGy)	Attribute	Result
Overall Thickness	ASTM D6988	0	Overall Thickness (in.)	Met incoming requirements
Film Tensile Properties (Non-Aged Aged)	ASTM D882	25-45	Maximum Tensile Stress (psi)	2922 2804
			Elongation at Break (in.)	19.5 17.35
			2% Secant Modulus (psi)	15593 16319
			Yield Stress (psi)	2854 2786
Puncture Resistance (Non-Aged Aged)	ASTM F1306	25-45	Maximum Load (lbf)	16.16 15.94
			Elongation at Maximum Load (in.)	1.32 1.20
Glass Transition Temperature by DMA	ASM E1640	25-45	Glass Transition Temperature (°C)	-134.43 (°C)
Oxygen Permeability (Non-Aged Aged)	ASTM F1927	25-45	Oxygen Transmission Rate (cc/m²/day)	1.61 1.54
Carbon Dioxide Permeability (Non-Aged Aged)	ASTM F2476	25-45	Carbon Dioxide Transmission Rate (cc/m²/day)	6 5
Water Vapor Permeability (Non-Aged Aged)	ASTM F1249	25-45	Water Vapor Transmission Rate (g/m²/day)	1.785 1.615



ULDPE/EVOH Film

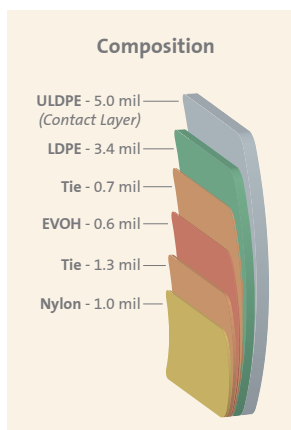
Multilayer structure with ULDPE fluid contact layer and PE outer layer. Film is animal-free. Suitable for rocking bioreactor bags.

Physical Properties*	Result	Test Protocol
Haze (%)	7	ASTM D1003
Clarity (%)	97	ASTM D1003
Transmittance (%)	93	ASTM D1003
Tensile strength at break (MPa)	13	ASTM D882
Elongation at break	350%	ASTM D882
Elastic modulus (MPa)	270	ASTM D882
Break at cold temperature	below -45°C	ISO 8570
Density (g/cm ³)	0.9	ASTM D792
H ₂ O transmission rate (g/m ² /24 hrs)**	0.32	ASTM F1249 (100% RH, 23°C)
O ₂ permeability (cm ³ /m ² /24 hrs)**	<0.05	ASTM D3985 (0% RH, 23°C)
CO ₂ permeability (cm ³ /m ² /24 hrs)**	<0.2	ASTM F2476 (0% RH, 23°C)

*Post-gamma irradiation 25 kGy except ** which is 50 kGy

ULDPE/EVOH Film

Multilayer structure with ULDPE fluid contact layer and nylon outer layer. Bags for Corning® HYPERStack® vessels, collection bags.



Biocompatibility Tests*	Result	Test Protocol
USP Class VI	Pass	USP <88>
Cytotoxicity	Pass	USP <87>
Bacterial endotoxin	≤0.5 EU/mL	USP <85>
Heavy metals	<1 ppm	USP <661>
Buffering capacity	0.10 mL	USP <661>
Non-volatile residue	1.6 mg	USP <661>
Residue on ignition	<5 mg	USP <661>

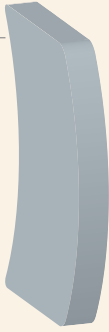
*Post-gamma irradiation >45 kGy

Physical Properties*	Result	Test Protocol
Haze	60%	ASTM D1003 (outside dry/inside dry)
Tensile strength (MPa)	20.8	ASTM D882
Elongation	486%	ASTM D882
Yield strength (MPa)	13.6	ASTM D882
2% Secant modulus (MPa)	395	ASTM D882
Tensile toughness	3.0 kN-cm	ASTM D1004
Puncture resistance	49 N	ASTM F1306
Seam strength	49.1 N/cm	ASTM F88
O ₂ transmission rate (cc/m ² /day)	0.64	ASTM D3985 (0% RH outside, 90% RH inside, 23°C)
CO ₂ transmission rate (cc/m ² /day)	1.71	Mocon method (0% RH outside, 100% RH inside, 23°C)
Water vapor transmission rate (g/m ² /day)	0.34	ASTM F1249 (0% RH outside, 100% RH inside, 23°C)
Glass transition temperature	-27°C	ASTM E1640

*Post-gamma irradiation 25-40 kGy

Composition

PO - 12 mil
(Contact Layer)



Polyolefin (PO) Film

Single-web, 12 mil polyolefin monolayer designed for extremely low temperatures—Cell expansion and cryopreservation bags.

Biocompatibility Tests*	Result	Test Protocol
USP Class VI	Pass	USP <88>
Cytotoxicity	Pass	ISO 10993-5; USP <87>
Hemolysis	Pass	ISO 10993-4
Heavy metals	Pass	USP <661>
Buffering capacity	Pass	USP <661>
Non-volatile residue	Pass	USP <661>
Residue on ignition	Pass	USP <661>
Sensitization and intracutaneous reactivity	Pass	ISO 10993-10
Systemic toxicity	Pass	ISO 10993-11
Bacterial endotoxin	<20 EU/device	USP <85>

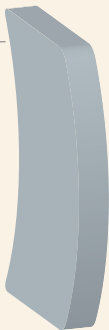
* Post-gamma irradiation

Physical Properties*	Result	Test Protocol
Elongation at break, MD/TD	650/700%	ASTM D882
Modulus at 100% elongation, MD/TD (psi)	550/500	ASTM D882
Tear resistance, MD/TD (Lbf/in.)	200/250	ASTM D1004
Low temp. brittleness	Below -100°C	ASTM D1790
Tensile strength at break, MD/TD (psi)	3200/2900	ASTM D882
O ₂ transmission (cm ³ /m ² /24 hrs)	2200	ASTM D3985 (0% RH; 0°C)
CO ₂ transmission (cm ³ /m ² /24 hrs)	9000	ASTM F2476 (0% RH; 0°C)
Moisture vapor transmission (g/m ² /24 hrs)	3.9	ASTM F1249

*Pre-gamma irradiation

Composition

ULDPE - 5.0 mil
(Contact Layer)



Tank Liner Film

Biocompatibility Tests*	Result	Test Protocol
USP intracutaneous reactivity	Pass	USP <88>
USP acute systemic injection	Pass	USP <88>
USP intramuscular implantation	Pass	USP <88>
Toxicity	Pass	USP <87>
Physiochemical test for plastics	Pass	USP <661>

*Post-gamma irradiation > 45 kGy

Physical Properties*	Result	Test Protocol
Tensile strength	25.0 MPa	ASTM D882
Elongation	833%	ASTM D882
Yield strength	8.3 MPa	ASTM D882
2% Secant modulus	138 MPa	ASTM D882
Tensile toughness	1.8 kN-cm	ASTM D1004
Puncture resistance	29 N	ASTM F1306
Seam strength	17.5 N/cm	ASTM F88
Glass transition temperature	-29.5°C	ASTM 1640
H ₂ O transmission (g/100 in ² /24 hrs)	0.073	ASTM F1249 (0% RH outside, 100% RH inside, 23°C)
CO ₂ transmission (cm ³ /100 in ² /24 hrs)	621	Mocon method (0% RH outside, 100% RH inside, 23°C)
O ₂ transmission (cm ³ /100 in ² /24 hrs)	129	ASTM D3985 (50% RH outside, 90% RH inside, 23°C)

*Post-gamma irradiation 25-40 kGy

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