

Standard 2D Bags for Single Use Bioprocess System

Saint-Gobain is a leading global supplier of 50 mL to 20 L single-use bags for the biopharmaceutical industry. Our single-use bags are constructed of a multilayer film optimized for bioprocess production applications. The film materials are consistent throughout the product range, with LLDPE as the fluid contact material and EVOH as the gas barrier layer. All standard products are free of animal-derived components. Saint-Gobain Bioprocess Systems are manufactured following cGMP that is QSR and ISO 9001: 2015 compliant. Bags are manufactured and assembled at our Plymouth, MN facility that operates a certified ISO Class 7 cleanroom. Our standard designs are ready to fit a range of bioprocess functions, or we can deliver custom products to meet your exacting needs.

Application

- Buffer and Media Storage
- Chromatography Feed
- Intermediate Product Hold
- Bioreactor Feed and Harvest
- Fraction Collection
- Final Product Hold



Technical Data Sheet



Features and Benefits:

SAINT-GOBAIN









International Filter Products

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- Temperature range -80°C to 60°C (-112°F to 140°F).
- Multilayer film structure with LLDPE as the fluid contact material and EVOH as the gas barrier layer.
- Needle-free sampling pot.
- Sealable and weldable tubing on the standard design.
- Sterilized by gamma irradiation.
- ✤ All formulas are Animal-Derived Component Free.
- All-inclusive Validation Guide and the Regulatory Information Overview (RIO) are available for customers upon request.

F	Property	ASTM Method	Formulations Value	Unit
Thickness	50 mL – 1 L Chamber	-	7.0	Millimeter
	2 L – 20 L Chamber	-	12.0	Millimeter
Tensile Strength	ו (MD)	D882A	5300	psi
Tear Resistance)	D1922	>800	grams
Seam Strength		D882	>25	Lbs./in
Dart Impact		D1709	>1600	grams
O ₂ Transmission	n Rate	D412	<0.005	cc/m²/24 hr
CO ₂ Transmissi	on Rate	D395	<1.0	cc/m²/24 hr
Water Vapor Tra	ansmission Rate	D746	2.66 to 2.68	g/m²/24 hr
Operating Temp	erature	-	-80°C to 60°C	°C

Physical Properties:







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Material of Construction

Multilayer Film Structure

Saint-Gobain single-use bags are constructed of multilayer film optimized for bioprocess production applications. Film materials are consistent throughout the product range and are free of materials of animal origin. Offering outstanding biocompatibility, chemical compatibility, barrier, and strength properties, Saint-Gobain films meet the most demanding bioprocess applications.

Fluid Contact Layer - Linear Low-Density Polyethylene (LLDPE)

Provides outstanding biocompatibility with broad chemical compatibility for the safe handling of a wide range of biopharmaceutical liquids.

Gas Barrier Layer- Ethyl Vinyl Alcohol (EVOH)

Provides an excellent barrier to the transmission of oxygen and carbon dioxide.

Strength Layer - Nylon

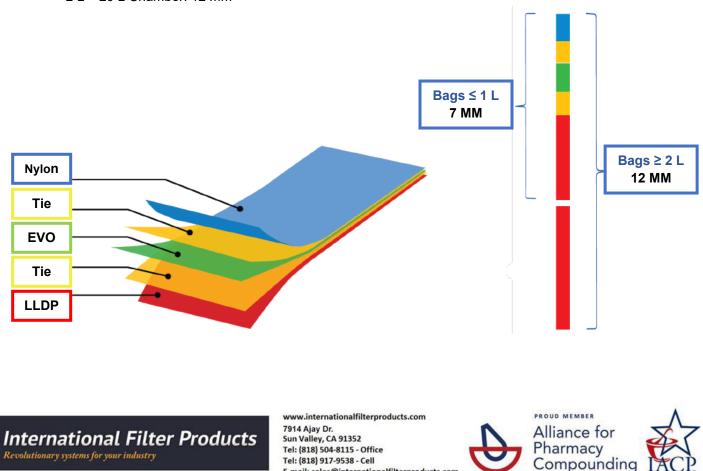
Provides outstanding impact and tear resistance, optimizing the overall toughness of the bag.

Tie Structure

Multiple materials provide bonding between layers and add to the overall performance of the bag.

Film Thickness

- 50 mL 1 L Chamber: 7 mm
- 2 L 20 L Chamber: 12 mm



E-mail: sales@internationalfilterproducts.com

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Regulatory Compliance (Biocompatibility, Physicochemical & Extractable Testing):

Summary of Results: Standard 2D Bags for Single Use Bioprocess System			
Method Description	Reference Standard	Result	
Genotoxicity Test	ISO 10993-3	Meets Criteria	
In Vitro Cytotoxicity	ISO 10993-5	Meets Criteria	
USP Class VI – Biological Reactivity	USP <88>	Meets Criteria	
Bacterial Endotoxin	USP <85>	< 0.03EU/mL	
Subvisible Particulate	USP <788>	Meets Criteria	
Bioburden	ISO 11737-1	< 3 CFU/sample	
Extractables Data	Saint-Gobain Protocol	N/A	

Sterilization:

Microbiological Validation of	Test Protocol	Result
25kGy Radiation Sterilization	ANSI/AAMI/ISO 11137	10 ⁻⁶ SAL 3-Year Expiry

- All part numbers referenced in this document are individually double-pouched within their case and gamma-irradiated at 25-40kGy without sterility assurance.
- Custom bags can be provided with no gamma irradiation, with gamma irradiation, or with gamma irradiation and SAL 10⁻⁶

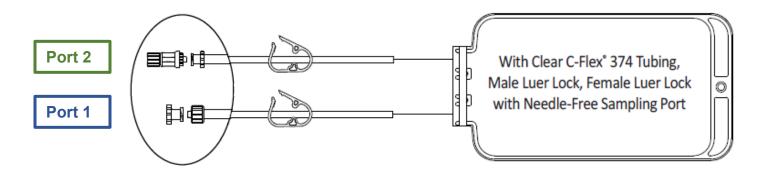








Standard 2D Bags, 2 Ports, 50 mL to 500 mL



Ordering Guide:

Part Number	Description	Dimensions LxW in (cm)	Internal Surface Area in ² (cm ²)	Quantity per Case
BP0050MS	50 mL Bag, STD 2 ports	5.22 in x 3.85 in (13.26 cm x 9.78 cm)	26.00 in ² (167.74 cm ²)	20
BP0150MS	150 mL Bag, STD 2 ports	7.72 in x 3.85 in (19.61 cm x 9.78 cm)	43.50 in ² (280.64 cm ²)	20
BP0250MS	250 mL Bag, STD 2 ports	9.72 in x 3.85 in (24.69 cm x 9.78 cm)	57.00 in ² (367.74 cm ²)	20
BP0500MS	500 mL Bag, STD 2 ports	10.22 in x 5.35 in (25.96 cm x 13.59 cm)	86.21 in ² (556.13 cm ²)	20

Port Information:

Port 1: Male Luer, Luer Cap, Pinch Clamp

Port 2: Female Luer, Needle-Free Site, Luer Thread Cover, Pinch Clamp

Tubing Information (Both Ports):

Material: Clear C-Flex® 374 Length: 12-inch / 304.8 Millimeter OD: 7/16-inch / 6.4 Millimeter ID: 1/4-inch / 3.2 Millimeter Wall Thickness: 1/16-inch / 1.6 Millimeter

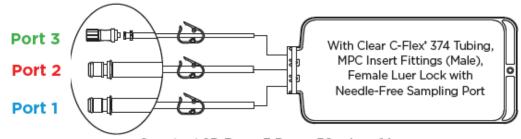








Standard 2D Bags, 3 Ports (6-in Tubing), 50 mL to 1L



Standard 2D Bags, 3 Ports, 50 mL to 1 L

Ordering Guide:

122

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in ² (cm ²)	Quantity per Case
BP0050M	50 mL Bag, STD 3 ports	5.22 in x 3.85 in (13.26 cm x 9.78 cm)	26.00 in ² (167.74 cm ²)	20
BP0150M	150 mL Bag, STD 3 ports	7.72 in x 3.85 in (19.61 cm x 9.78 cm)	43.50 in ² (280.64 cm ²)	20
BP0250M	250 mL Bag, STD 3 ports	9.72 in x 3.85 in (24.69 cm x 9.78 cm)	57.00 in ² (367.74 cm ²)	20
BP0500M	500 mL Bag, STD 3 ports	10.22 in x 5.35 in (25.96 cm x 13.59 cm)	86.21 in ² (556.13 cm ²)	20
BP0001L	250 mL Bag, STD 3 ports	13.50 in x 6.48 in (34.29 cm x 16.46 cm)	145.42 in ² (935.48 cm ²)	20

Port Information:

- Port 1: MPC Insert, Port Cover, Pinch Clamp
- Port 2: MPC Insert, Port Cover, Pinch Clamp
- Port 3: LL Female + Needle-Free Sampling Port, Luer Cap, Pinch Clamp

Tubing Information:

Port 1	Port 2	Port 3
Material: Clear C-Flex® 374	Material: Clear C-Flex® 374	Material: Clear C-Flex® 374
Length: 6-in / 152.4 mm	Length: 6-in / 152.4 mm	Length: 6-in / 152.4 mm
OD: 7/16-in / 11.2 mm	OD: 7/16-in / 11.2 mm	OD: 1/4-in / 6.4 mm
ID: 1/4-in / 6.4 mm	ID: 1/4-in / 6.4 mm	ID: 1/8-in / 3.2 mm
Wall Thickness: 3/32-in / 2.4mm	Wall Thickness: 3/32-in / 2.4mm	Wall Thickness: 1/16-in / 1.6mm

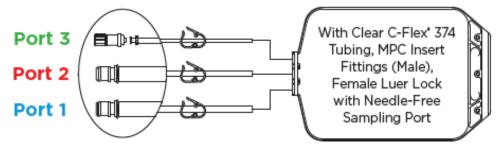








Standard 2D Bags, 3 Ports (6-in Tubing), 2L to 20L



Standard 2D Bags, 3 Ports, 2 L to 20 L

Ordering Guide:

122

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in ² (cm ²)	Quantity per Case
BP0002L	2L Bag, STD 3 ports	15.55 in x 9.35 in (39.37 cm x 23.75 cm)	226.40 in ² (1458.06 cm ²)	20
BP0003L	3L Bag, STD 3 ports	18.05 in x 9.35 in (45.72 cm x 23.75 cm)	271.40 in ² (1748.38 cm ²)	20
BP0005L	5L Bag, STD 3 ports	18.34 in x 12.35 in (46.48 cm x 31.24 cm)	364.52 in ² (2348.38 cm ²)	20
BP0010L	10L Bag, STD 3 ports	27.70 in x 12.35 in (70.36 cm x 31.24 cm)	587.44 in ² (3787.09 cm ²)	10
BP0020L	20L Bag, STD 3 ports	28.12 in x 18.35 in (71.37 cm x 46.48 cm)	887.98 in ² (5722.57 cm ²)	10

Port Information:

- Port 1: MPC Insert, Port Cover, Pinch Clamp
- Port 2: MPC Insert, Port Cover, Pinch Clamp
- Port 3: LL Female + Needle-Free Sampling Port, Luer Cap, Pinch Clamp

Tubing Information:

Port 1	Port 2	Port 3
Material: Clear C-Flex® 374	Material: Clear C-Flex® 374	Material: Clear C-Flex® 374
Length: 6-in / 152.4 mm	Length: 6-in / 152.4 mm	Length: 6-in / 152.4 mm
OD: 5/8-in / 15.9 mm	OD: 5/8-in / 15.9 mm	OD: 1/4-in / 6.4 mm
ID: 3/8-in / 9.6 mm	ID: 3/8-in / 9.6 mm	ID: 1/8-in / 3.2 mm
Wall Thickness: 1/8-in / 3.2mm	Wall Thickness: 1/8-in / 3.2mm	Wall Thickness: 1/16-in / 1.6mm

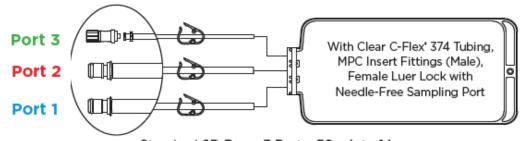








Standard 2D Bags, 3 Ports (20-in Tubing), 50 mL to 1L



Standard 2D Bags, 3 Ports, 50 mL to 1 L

Ordering Guide:

122

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in ² (cm ²)	Quantity per Case
BP0050M	50 mL Bag, STD 3 ports	5.22 in x 3.85 in (13.26 cm x 9.78 cm)	26.00 in ² (167.74 cm ²)	20
BP0150M	150 mL Bag, STD 3 ports	7.72 in x 3.85 in (19.61 cm x 9.78 cm)	43.50 in ² (280.64 cm ²)	20
BP0250M	250 mL Bag, STD 3 ports	9.72 in x 3.85 in (24.69 cm x 9.78 cm)	57.00 in ² (367.74 cm ²)	20
BP0500M	500 mL Bag, STD 3 ports	10.22 in x 5.35 in (25.96 cm x 13.59 cm)	86.21 in ² (556.13 cm ²)	20
BP0001L	250 mL Bag, STD 3 ports	13.50 in x 6.48 in (34.29 cm x 16.46 cm)	145.42 in ² (935.48 cm ²)	20

Port Information:

- Port 1: MPC Insert, Port Cover, Pinch Clamp
- Port 2: MPC Insert, Port Cover, Pinch Clamp
- Port 3: LL Female + Needle-Free Sampling Port, Luer Cap, Pinch Clamp

Tubing Information:

Port 1	Port 2	Port 3
Material: Clear C-Flex® 374	Material: Clear C-Flex® 374	Material: Clear C-Flex® 374
Length: 20-in / 508 mm	Length: 20-in / 508 mm	Length: 20-in / 508 mm
OD: 7/16-in / 11.2 mm	OD: 7/16-in / 11.2 mm	OD: 1/4-in / 6.4 mm
ID: 1/4-in / 6.4 mm	ID: 1/4-in / 6.4 mm	ID: 1/8-in / 3.2 mm
Wall Thickness: 3/32-in / 2.4mm	Wall Thickness: 3/32-in / 2.4mm	Wall Thickness: 1/16-in / 1.6mm

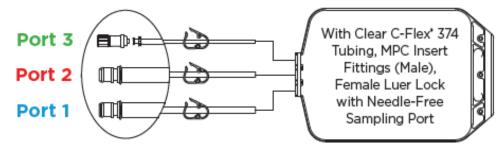








Standard 2D Bags, 3 Ports (20-in Tubing), 2L to 20L



Standard 2D Bags, 3 Ports, 2 L to 20 L

Ordering Guide:

122

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in ² (cm ²)	Quantity per Case
BP0002L	2L Bag, STD 3 ports	15.55 in x 9.35 in (39.37 cm x 23.75 cm)	226.40 in ² (1458.06 cm ²)	20
BP0003L	3L Bag, STD 3 ports	18.05 in x 9.35 in (45.72 cm x 23.75 cm)	271.40 in ² (1748.38 cm ²)	20
BP0005L	5L Bag, STD 3 ports	18.34 in x 12.35 in (46.48 cm x 31.24 cm)	364.52 in ² (2348.38 cm ²)	20
BP0010L	10L Bag, STD 3 ports	27.70 in x 12.35 in (70.36 cm x 31.24 cm)	587.44 in ² (3787.09 cm ²)	10
BP0020L	20L Bag, STD 3 ports	28.12 in x 18.35 in (71.37 cm x 46.48 cm)	887.98 in ² (5722.57 cm ²)	10

Port Information:

- Port 1: MPC Insert, Port Cover, Pinch Clamp
- Port 2: MPC Insert, Port Cover, Pinch Clamp
- Port 3: LL Female + Needle-Free Sampling Port, Luer Cap, Pinch Clamp

Tubing Information:

1
.6mm





