



# International Filter Products

*Revolutionary systems for your industry*

## 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



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## Technical Data Sheet

### Features and Benefits:

- ❖ 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.

### Physical Properties:

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 (MD)		D882A	5300	psi
Tear Resistance		D1922	>800	grams
Seam Strength		D882	>25	Lbs./in
Dart Impact		D1709	>1600	grams
O <sub>2</sub> Transmission Rate		D412	<0.005	cc/m <sup>2</sup> /24 hr
CO <sub>2</sub> Transmission Rate		D395	<1.0	cc/m <sup>2</sup> /24 hr
Water Vapor Transmission Rate		D746	2.66 to 2.68	g/m <sup>2</sup> /24 hr
Operating Temperature		-	-80°C to 60°C	°C

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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

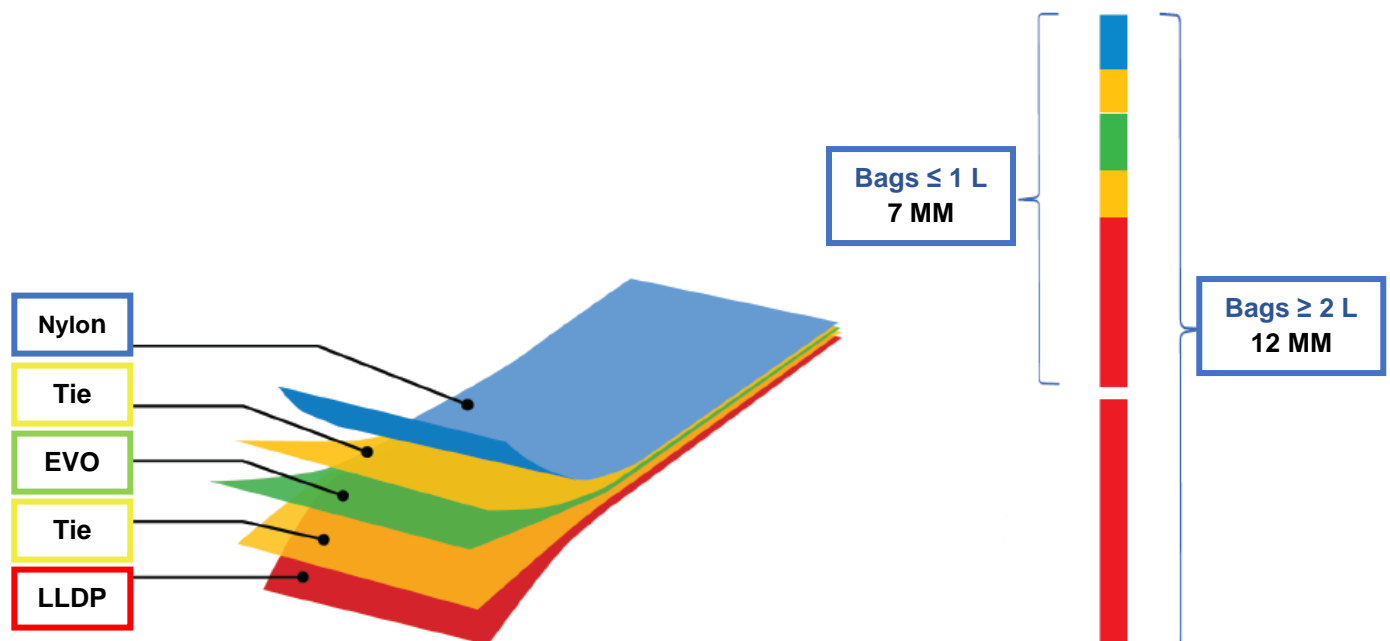
Provides outstanding impact and tear resistance, optimizing the overall toughness of the bag.

### 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



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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:

	Test Protocol	Result
Microbiological Validation of <b>25kGy</b> Radiation Sterilization	ANSI/AAMI/ISO 11137	10 <sup>-6</sup> 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<sup>-6</sup>

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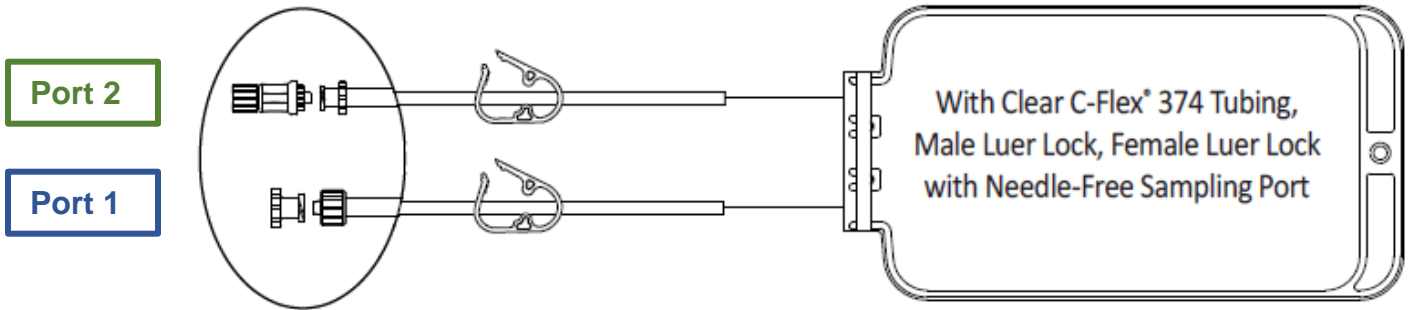
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## Standard 2D Bags, 2 Ports, 50 mL to 500 mL



### Ordering Guide:

Part Number	Description	Dimensions LxW in (cm)	Internal Surface Area in <sup>2</sup> (cm <sup>2</sup> )	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 <sup>2</sup> (167.74 cm <sup>2</sup> )	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 <sup>2</sup> (280.64 cm <sup>2</sup> )	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 <sup>2</sup> (367.74 cm <sup>2</sup> )	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 <sup>2</sup> (556.13 cm <sup>2</sup> )	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

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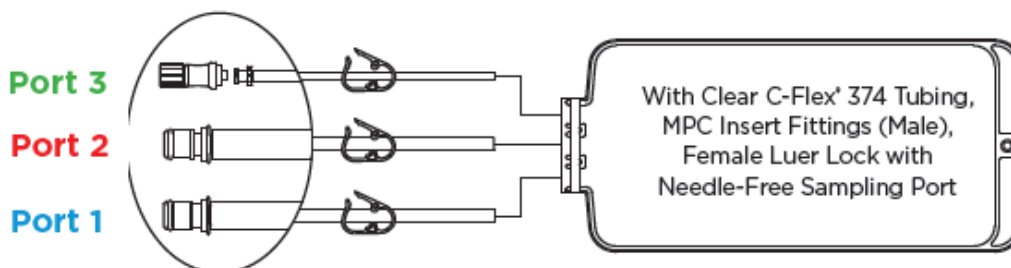




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## Standard 2D Bags, 3 Ports (6-in Tubing), 50 mL to 1L



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

### Ordering Guide:

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in <sup>2</sup> (cm <sup>2</sup> )	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 <sup>2</sup> (167.74 cm <sup>2</sup> )	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 <sup>2</sup> (280.64 cm <sup>2</sup> )	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 <sup>2</sup> (367.74 cm <sup>2</sup> )	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 <sup>2</sup> (556.13 cm <sup>2</sup> )	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 <sup>2</sup> (935.48 cm <sup>2</sup> )	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
<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374
<b>Length:</b> 6-in / 152.4 mm	<b>Length:</b> 6-in / 152.4 mm	<b>Length:</b> 6-in / 152.4 mm
<b>OD:</b> 7/16-in / 11.2 mm	<b>OD:</b> 7/16-in / 11.2 mm	<b>OD:</b> 1/4-in / 6.4 mm
<b>ID:</b> 1/4-in / 6.4 mm	<b>ID:</b> 1/4-in / 6.4 mm	<b>ID:</b> 1/8-in / 3.2 mm
<b>Wall Thickness:</b> 3/32-in / 2.4mm	<b>Wall Thickness:</b> 3/32-in / 2.4mm	<b>Wall Thickness:</b> 1/16-in / 1.6mm

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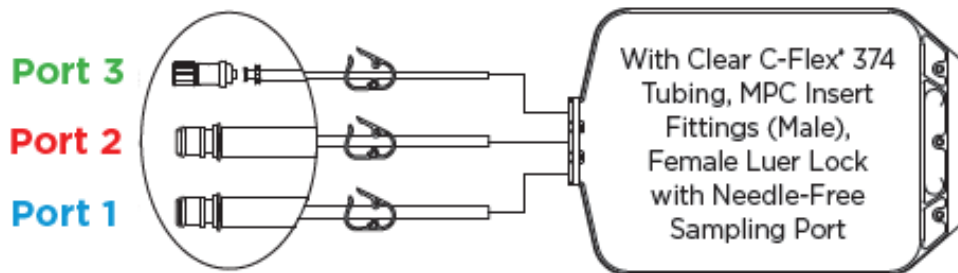




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## Standard 2D Bags, 3 Ports (6-in Tubing), 2L to 20L



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

### Ordering Guide:

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in <sup>2</sup> (cm <sup>2</sup> )	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 <sup>2</sup> (1458.06 cm <sup>2</sup> )	20
BP0003L	3L Bag, STD 3 ports	18.05 in x 9.35 in (45.72 cm x 23.75 cm)	271.40 in <sup>2</sup> (1748.38 cm <sup>2</sup> )	20
BP0005L	5L Bag, STD 3 ports	18.34 in x 12.35 in (46.48 cm x 31.24 cm)	364.52 in <sup>2</sup> (2348.38 cm <sup>2</sup> )	20
BP0010L	10L Bag, STD 3 ports	27.70 in x 12.35 in (70.36 cm x 31.24 cm)	587.44 in <sup>2</sup> (3787.09 cm <sup>2</sup> )	10
BP0020L	20L Bag, STD 3 ports	28.12 in x 18.35 in (71.37 cm x 46.48 cm)	887.98 in <sup>2</sup> (5722.57 cm <sup>2</sup> )	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
<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374
<b>Length:</b> 6-in / 152.4 mm	<b>Length:</b> 6-in / 152.4 mm	<b>Length:</b> 6-in / 152.4 mm
<b>OD:</b> 5/8-in / 15.9 mm	<b>OD:</b> 5/8-in / 15.9 mm	<b>OD:</b> 1/4-in / 6.4 mm
<b>ID:</b> 3/8-in / 9.6 mm	<b>ID:</b> 3/8-in / 9.6 mm	<b>ID:</b> 1/8-in / 3.2 mm
<b>Wall Thickness:</b> 1/8-in / 3.2mm	<b>Wall Thickness:</b> 1/8-in / 3.2mm	<b>Wall Thickness:</b> 1/16-in / 1.6mm

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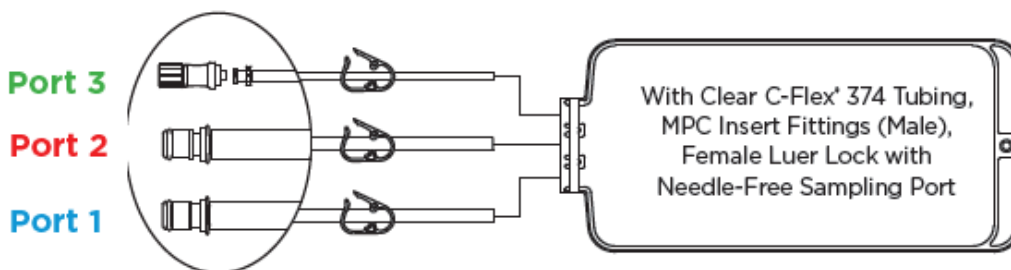




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## Standard 2D Bags, 3 Ports (20-in Tubing), 50 mL to 1L



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

### Ordering Guide:

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in <sup>2</sup> (cm <sup>2</sup> )	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 <sup>2</sup> (167.74 cm <sup>2</sup> )	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 <sup>2</sup> (280.64 cm <sup>2</sup> )	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 <sup>2</sup> (367.74 cm <sup>2</sup> )	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 <sup>2</sup> (556.13 cm <sup>2</sup> )	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 <sup>2</sup> (935.48 cm <sup>2</sup> )	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
<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374
<b>Length:</b> 20-in / 508 mm	<b>Length:</b> 20-in / 508 mm	<b>Length:</b> 20-in / 508 mm
<b>OD:</b> 7/16-in / 11.2 mm	<b>OD:</b> 7/16-in / 11.2 mm	<b>OD:</b> 1/4-in / 6.4 mm
<b>ID:</b> 1/4-in / 6.4 mm	<b>ID:</b> 1/4-in / 6.4 mm	<b>ID:</b> 1/8-in / 3.2 mm
<b>Wall Thickness:</b> 3/32-in / 2.4mm	<b>Wall Thickness:</b> 3/32-in / 2.4mm	<b>Wall Thickness:</b> 1/16-in / 1.6mm

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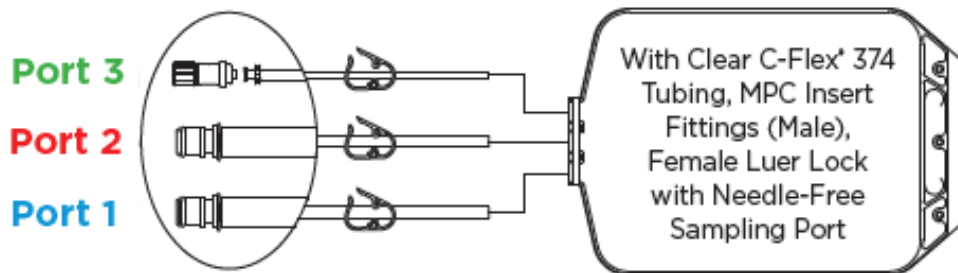




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## Standard 2D Bags, 3 Ports (20-in Tubing), 2L to 20L



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

### Ordering Guide:

Part Number	Description	Dimension LxW in (cm)	Internal Surface Area in <sup>2</sup> (cm <sup>2</sup> )	Quantity per Case
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**Port 2:** MPC Insert, Port Cover, Pinch Clamp

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### Tubing Information:

Port 1	Port 2	Port 3
<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374	<b>Material:</b> Clear C-Flex® 374
<b>Length:</b> 20-in / 508 mm	<b>Length:</b> 20-in / 508 mm	<b>Length:</b> 20-in / 508 mm
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