



CELL THERAPY SOLUTIONS

VueLife® KryoSure® KryoVue®

TABLE OF CONTENTS

- 3 About Saint-Gobain
- 4 Operations Overview
- 5 Custom Solutions Capabilities
- 6 Custom Solutions Manufacturing and Assembly Capabilities
- 8 Custom Molding Capabilities
- 10 Cell Therapy Product Lines
- 11 FEP Film Properties
- 12 VueLife® Cell Culture and Processing Bags
- 16 KryoSure® Cryopreservation Products
- 20 Custom Bag Design
- 21 Fluid Transfer Assemblies
- 22 Accessories



Saint-Gobain designs, manufactures and distributes materials and solutions which are key ingredients in the wellbeing of each of us and the future of all. They can be found everywhere in our living places and our daily life: in buildings, transportation, infrastructure and in so many industrial applications.

ABOUT SAINT-GOBAIN LIFE SCIENCES

Dedicated to improving the quality of life, Saint-Gobain Life Sciences manufactures high performance components used in applications such as biopharmaceutical production, therapeutic cancer treatment and intravenous therapy. Along with material science expertise and collaborative design services, our focus on global quality and regulatory affairs allow us to be the trusted partner to organizations reaching every part of the globe. Combining our technical expertise, global manufacturing capabilities and research and development resources, Saint-Gobain Life Sciences is dedicated to meeting the evolving needs of bioprocess, medical and pharmaceutical customers around the world.

2016 NET SALES **€39.1 BN**

MORE THAN **170,00 EMPLOYEES** AND **100+ NATIONALITIES** REPRESENTED

OVER **4,100 SALES OUTLETS**

ONE OF THE TOP **100 INDUSTRIAL GROUPS** IN THE WORLD WITH AROUND **950 PRODUCTION SITES**

OPERATIONS IN **67 COUNTRIES**

CREATED MORE THAN **350 YEARS** AGO

Saint-Gobain is a global organization ready to serve you.

We operate with 17 facilities serving the Life Science industry, including a 37,000 ft² manufacturing site in Gaithersburg, MD, specifically designed and built for the needs of the Cell Therapy industry.



The Gaithersburg facility offers a wide variety of capabilities focused on the design, development and manufacturing of single-use systems.



FACILITY HIGHLIGHTS:

- > Ultra-clean injection molding and overmolding with capabilities for large size molding
- > ISO 5 space for ultra-clean assembly operations and ISO 7 space for single-use system fabrication
- > Bag manufacturing in an ISO 7 clean room using a proprietary laser welding process
- > Engineering lab for prototyping and development of custom products



QUALITY OVERVIEW

- > FDA Registered Facility
- > Site Quality Management System follow 21 CFR Part 820
- > Cleanroom Certifications per ISO 14644
- > Automated Environmental Controls and Individual Monitoring Capabilities

Saint-Gobain offers custom solutions capabilities for your unique project needs.

Saint-Gobain Life Sciences is proud to take part in providing solutions for a multitude of cell therapy applications while collaborating with customers and industry partners to develop custom disposables, often for integration into automated systems. Through our material science expertise as well as our deep experience in bringing manufacturing technologies to scale, we are uniquely positioned to offer solutions to the numerous challenges faced by cell therapy manufacturers.

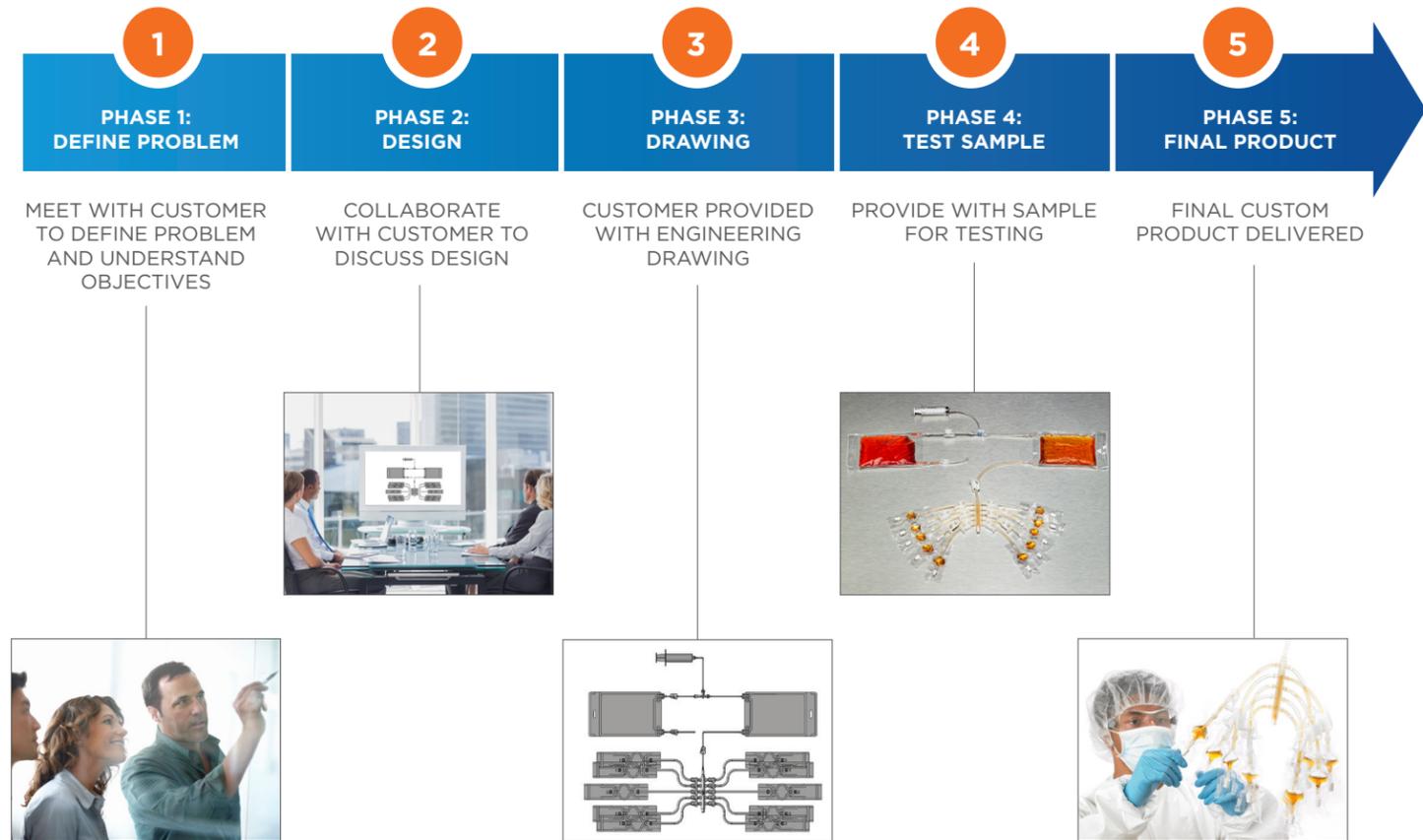
Our proven development methodology ensures that our clients receive a custom solution through a streamlined process.

[CLICK HERE FOR ADDITIONAL INFORMATION ON CUSTOM SOLUTIONS](#)

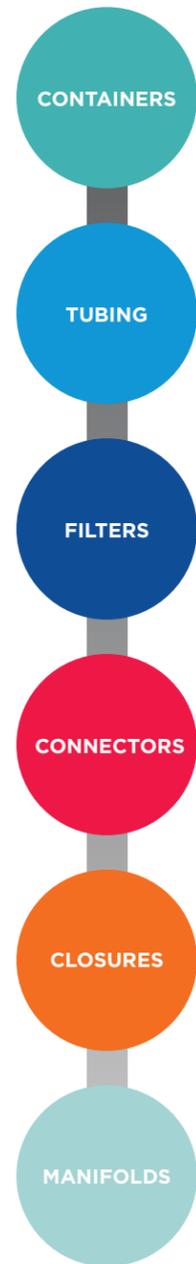
- [CUSTOM SOLUTIONS](#)
- [APPLICATION NOTES](#)
- [VALIDATION GUIDE](#)
- [REQUEST A CUSTOM SOLUTION](#)

BENEFITS OF PARTNERSHIP

- include but are not limited to:*
- > Development Staff of Over 50 Application and Research Engineers
 - > Integration of Components into Single-Use Assemblies
 - > Management of Sterility Validation
 - > "Open Architecture" Philosophy



Saint-Gobain's large product portfolio can be fully integrated into a customizable system that can be configured to meet customers' unique requirements.



CONTAINERS

A variety of bags in fully customizable configurations.

Bag Film Material	Relevant Applications	Bag Size Offerings	Related Saint-Gobain Brands
FEP	Cell Culture, Transfer, Cryopreservation	1 mL - 1 L	VueLife® C and KryoSure®
Surface Treated FEP	Cell Culture, Cell Modification (Transfection/Transduction)	1 mL - 1 L	VueLife® AC
LDPE/EVOH/Nylon	Media and Buffer Preparation and Storage	50 mL - 3000 L	Saint-Gobain Bioprocess Containers

*Custom films also available upon request



Bioprocess Containers



VueLife® and KryoSure®

TUBING

A full range of tubing materials to satisfy all fluid handling requirements.

Tubing Material	Relevant Applications	Related Saint-Gobain Brands
FEP	High Purity Transfer	PharmaFluor®
TPE	Peristaltic Pumping, Welding, Sealing	C-Flex®, PharMed®, PharmaPure®
Platinum Cured Silicone	Peristaltic Pumping	Sani-Tech®
PVC	Welding, Sealing	Tygon®

FEP = Fluorinated Ethylene Propylene
 TPE = Thermoplastic Elastomer
 PVC = Polyvinyl Chloride
 LDPE = Low Density Polyethylene
 EVOH = Ethylene Vinyl Alcohol



TPE Tubing



Silicone Tubing



PVC Tubing

FILTERS

Engineered filtration solutions to meet application-specific requirements.

Filter Membrane	Filter Type	Relevant Applications	Related Saint-Gobain Brands
PES Membrane	Pleated Capsules and Discs	Sterile Filtration	PureFlo® PES Z-Series
PE Membrane	Discs	Venting	PureFlo® PE
Nylon Screen	Pleated Capsules and Discs	Cell Washing	PureFlo® Nylon Screen

PES = Polyethersulfone
 PE = Polyethylene



CONNECTORS

A portfolio of single-use connection and fluid control solutions that focus on leak-free fluid management.

- > Connection Systems
- > Sterile Connector
- > Flow Control



CLOSURES

Overmolded closure systems that assure a sealed pass through of tubing.

- > Standard and Custom Sizes
- > Silicone and C-Flex®



MANIFOLDS

Sealed connection systems in a variety of configurations and materials.

- > Available in Silicone and C-Flex®
- > Like Size Connections and Reductions
- > Available for Braided Products as Well



In addition to commercially available standard products for use in bioprocessing, Saint-Gobain offers a variety of custom molding options.

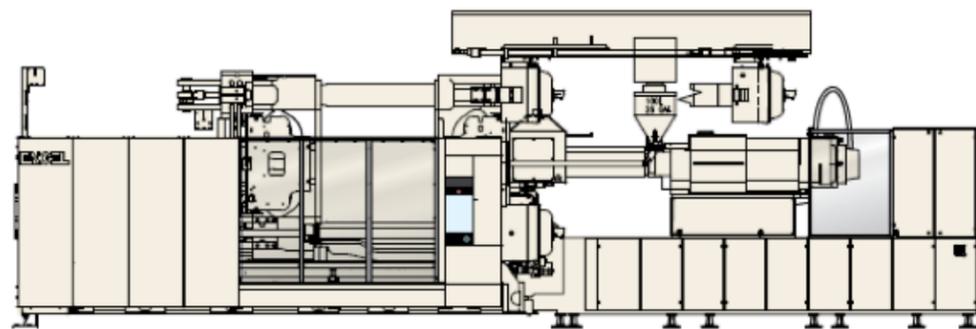
HIGHLIGHTS INCLUDE:

- > Plastic injection molding and over-molding in ISO 8 environment using state-of-the-art molding presses
- > Inspection of molded parts using multi-sensor metrology
- > ISO 5 and ISO 7 assembly spaces
- > Advanced automation with 6-axes robot and ability to develop custom end-of-arm tooling (EAOT) for minimal part handling

Press Size Tonnage	120t	200t	440t
Horizontal (inches)	29	34.6	47
Vertical (inches)	26.7	32.6	43
Platens Minimum Coverage (H x V) (Inches)	13.8 x 13.8	17.9 x 17.9	22.2 x 22.2



> 120 Ton



> 1900 Ton

Sample Work Flow

Raw material fed in via material vacuum system.



1

Parts molded in the ISO 8 cleanroom.



2

Parts transferred to ISO 7 assembly room through a controlled pass through window.



3

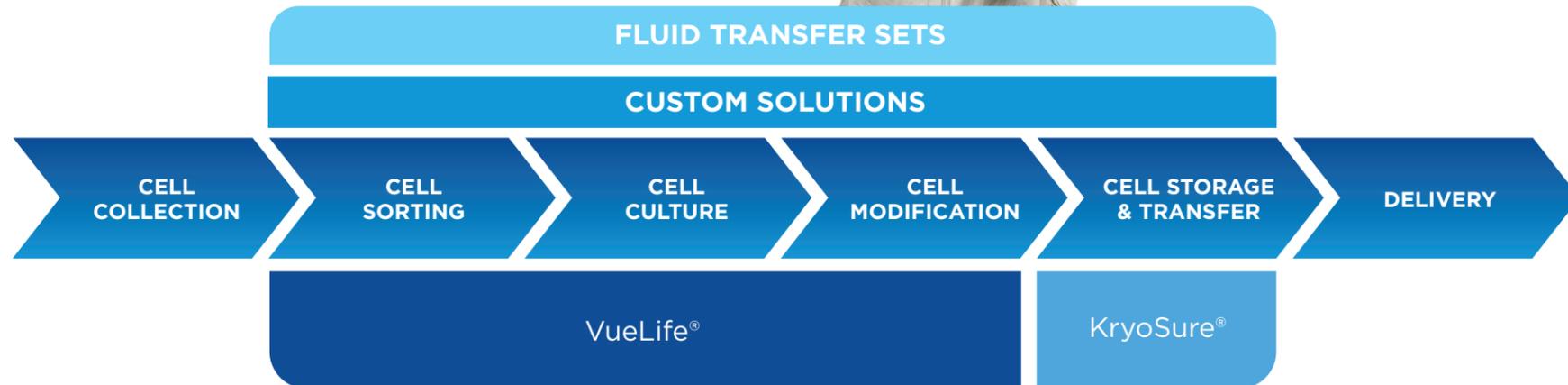
Assembly occurs in ISO 7 cleanroom or in an ISO 5 hood. Assembly could include, but is not limited to: laser welding, gluing, and integrity testing.



4

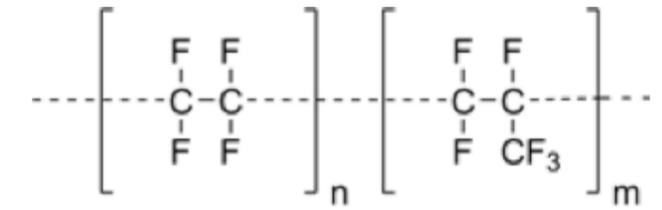
After completion of assembly operations, products are moved to packaging station before awaiting shipment.

Saint-Gobain leverages its own fluorinated ethylene propylene (FEP) film to design and manufacture VueLife® cell culture bags and KryoSure® cryopreservation bags and overwraps utilizing a robotically controlled laser welding process that allows for complete product customization.



FEP is a fully fluorinated fluoropolymer with unique properties that make it an exceptional material choice for cell therapy applications. Features include:

- > USP Class VI
- > Contains no additives or plasticizers, leading to its extremely low extractables profile
- > Extremely permeable to gases whilst maintaining an excellent barrier to water vapor
- > Broad continuous service temperature of -240°C to +205°C allowing FEP to maintain flexibility even at liquid nitrogen temperatures
- > Can transmit UV, Visible, and IR light
- > Excellent resistance to all common chemicals, including DMSO and DMF



	ASTM Standard	Typical Value
Thickness of FEP	-	5.0 mils
Continuous Service Temperature	-	-240°C to +205°C
Tensile Strength	D882	2500 psi (min)
Elongation at Break	D882	250% (min)
Solar Transmission	E424	96%
Refractive Index	D542	1.341 - 1.347
Oxygen Permeability @ 25°C ¹	-	-2200 cc/m ² -day
Carbon Dioxide Permeability @ 25°C ¹	-	-5200 cc/m ² -day
Water Vapor Permeability @ 37.8°C ¹	F1249	-0.8 g/m ² -day

⁽¹⁾ Transmission rates measured on 5 mil FEP film, the thickness of film used in bag construction



The VueLife® product line offers a permeable solution for cell culture and processing applications. Traditionally featuring a needle-less injection site and at least one PVC tubing length for sterile docking, the unique bag design allows for closed system processing.

The VueLife® “C” bags use an untreated form of FEP film making it an excellent choice for the culturing of suspension cells, such as lymphocytes and monocytes.

VueLife® “AC” bags utilize a treated form of the FEP. This results in the bag interior having a higher surface energy than the VueLife “C” Bag. The modified surface is meant to better promote cell and protein adhesion to the surface of the bag, a feature that can be leveraged for transduction and transfection applications.

VueLife® “HP” is the newly designed cell culture bag for closed system, efficient and scalable cell expansion. By using the novel highly permeable “HP” laminate, VueLife® “HP” allows for increased rates of gas transmission as required by rapidly expanding cell types, such as lymphocytes. By developing this laminate using VueLife® FEP as the fluid contact layer, VueLife® “HP” takes advantage of the key properties inherent to fluoropolymers such as purity and biological and chemical inertness.

Product	Recommended Process Volume	Approx. Maximum Fill Volume	Approx. Interior Surface Area (2 x Bag Face)	Standard Ports & Tubing	Qty/Case
32-C	32 mL	40 mL	87 cm ²	1 FLV port; 7” length of PVC tubing that goes to “Y” with 2 more lengths of 7” tubing, one length sealed off, and one length with female luer port at end	10
72-C	72 mL	175 mL	193 cm ²		10
118-C	118 mL	275 mL	277 cm ²		10
119-C	119 mL	285 mL	286 cm ²		10
197-C	198 mL	500 mL	502 cm ²		10
290-C1	290 mL	900 mL	658 cm ²		10
750-C1	750 mL	2,500 mL	1,643 cm ²	1 FLV port; 1 spike port; 1 length of PVC tubing that goes to “Y” with 2 more lengths of tubing, one length sealed off, and one length with female luer port at end	10

32-AC	32 mL	45 mL	87 cm ²	1 FLV port; 7” length of PVC tubing that goes to “Y” with 2 more lengths of 7” tubing, one length sealed off, and one length with female luer port at end	5
72-AC	72 mL	185 mL	193 cm ²		5
118-AC	118 mL	285 mL	265 cm ²		5
119-AC	119 mL	290 mL	286 cm ²		5
197-AC	198 mL	505 mL	502 cm ²		5
290-AC	290 mL	1,000 mL	671 cm ²		5
750-AC	750 mL	2,500 mL	1,664 cm ²	1 FLV port; 1 spike port; 1 length of PVC tubing that goes to “Y” with 2 more lengths of tubing, one length sealed off, and one length with female luer port at end	5

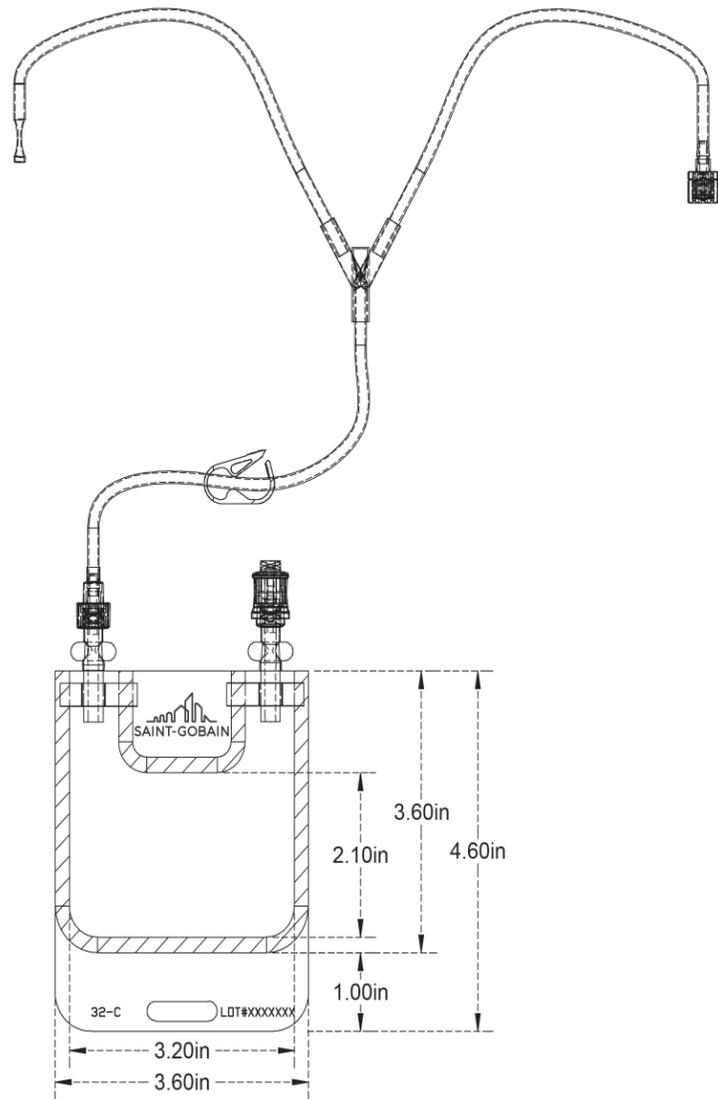
50-HP	50 mL	100 mL	150 cm ²	1 FLV port; 7” length of PVC tubing that goes to “Y” with 2 more lengths of 7” tubing, one length sealed off, and one length with female luer port at end	10
100-HP	100 mL	275 mL	298 cm ²		10
200-HP	200 mL	600 mL	502 cm ²		10
500-HP	500 mL	1,700 mL	1016 cm ²		10
750-HP	750 mL	2,400 mL	1288 cm ²		10
1,000-HP	1,000 mL	4,000 mL	1806 cm ²		10

* OTHER TYPES OF PORTS, TUBING, AND CONNECTIONS AVAILABLE UPON REQUEST

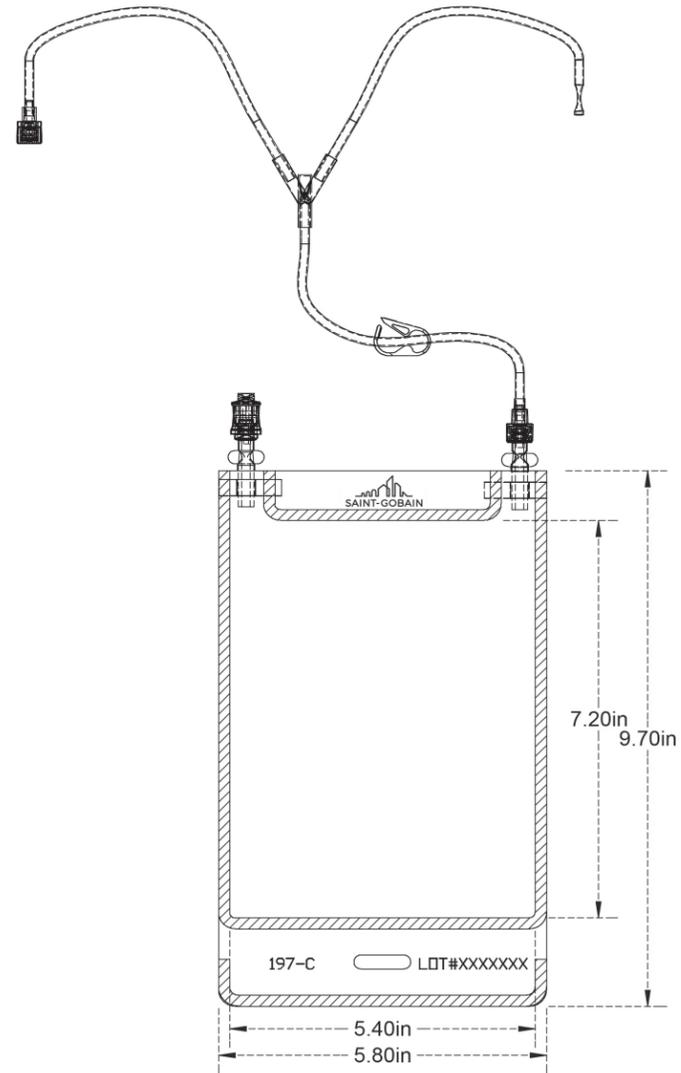
FOR ADDITIONAL INFORMATION ON CELL CULTURE

- ▼
- [VUELIFE®](#)
- [REFERENCES](#)
- [VALIDATION GUIDE](#)
- [REQUEST A SAMPLE](#)

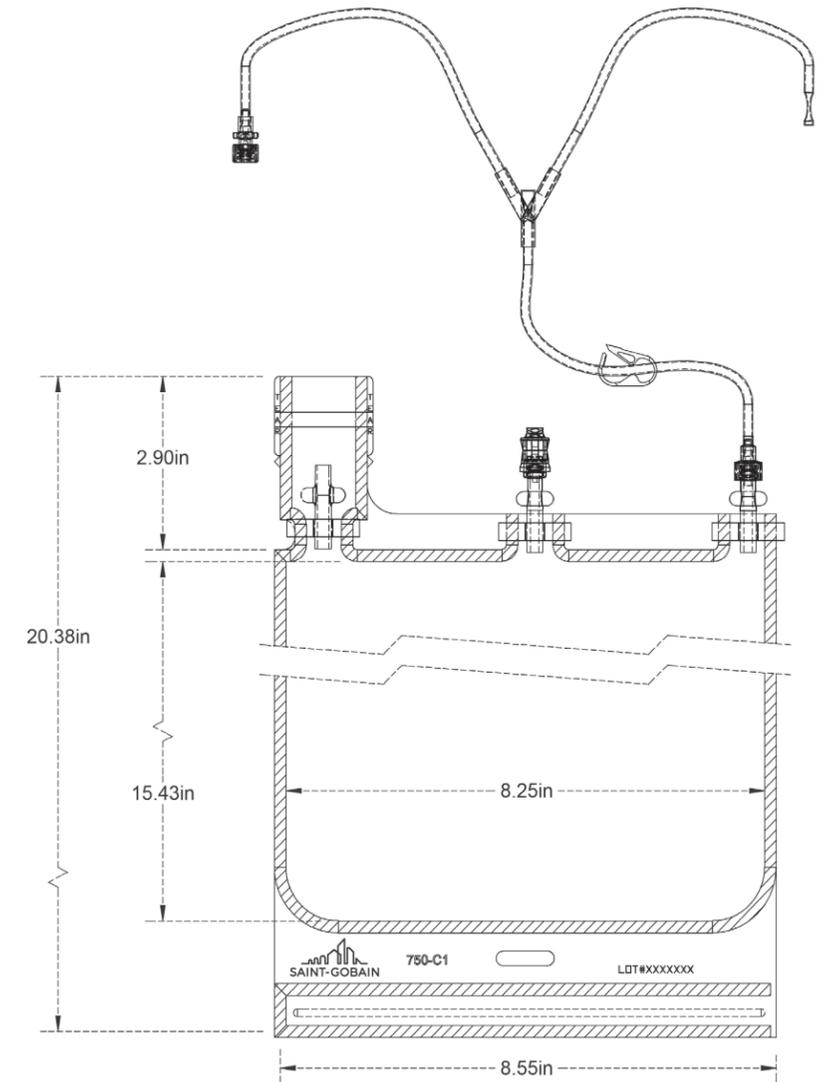
32-C



197-C



750-C1





The KryoSure® product line allows for durable, transparent, and flexible storage down to liquid nitrogen temperatures. Traditionally featuring at least one PVC tubing length for sterile docking, the unique bag design allows for closed system processing.

The KryoSure® “F” bags use an untreated form of FEP film, include label pockets for identification, and offer FEP port covers for additional protection during cryopreservation. The bags are also designed with rounded inside corners to reduce the risk of ice points that may cause damage.

In addition, Saint-Gobain offers KryoSure® FEP overwraps and sterility covers that can be used in addition to the cryopreservation bags.

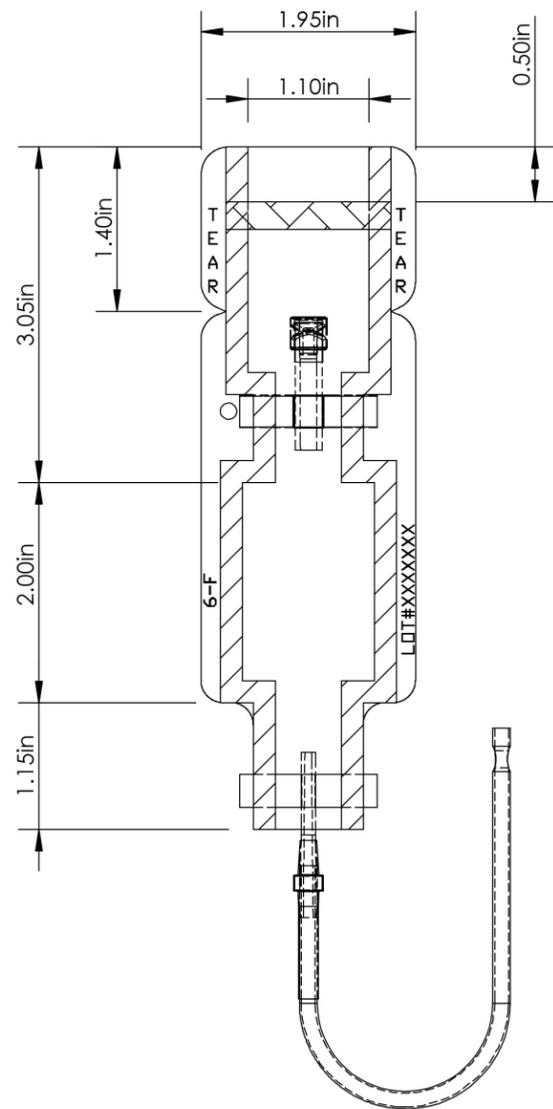
Product	Recommended Process Volume	Approx. Maximum Fill Volume	Approx. Interior Surface Area (2 x Bag Face)	Standard Ports & Tubing	Qty/Case
6-F	6 mL	7 mL	28 cm ²	1 isoprene injection port; 1 length of PVC tubing tube; 1 spike port	10
20-F	20 mL	55 mL	144 cm ²	1 spike port; 1 length of PVC tubing that goes to “Y” with 2 more lengths of tubing, one length sealed off, and one length with female luer port at end	10
62-F	62 mL	250 mL	235 cm ²	2 spike ports; 1 length of PVC tubing with female luer at the end	10
120-F	120 mL	480 mL	362 cm ²	2 spike ports; 1 length PVC tubing, with segment numbers, with female luer at the end	10
180-F	180 mL	625 mL	451 cm ²		10

* OTHER TYPES OF PORTS, TUBING, AND CONNECTIONS AVAILABLE UPON REQUEST

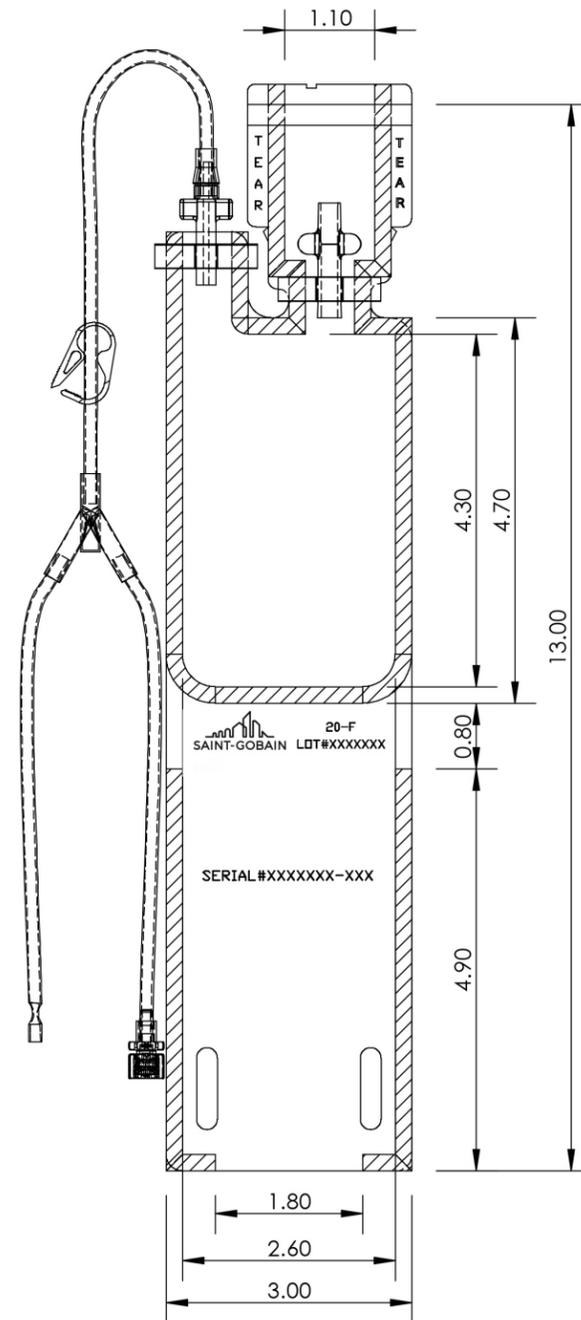
FOR ADDITIONAL INFORMATION ON CRYOPRESERVATION

- ▼
- [KRYOSURE® VALIDATION GUIDE](#)
- [REQUEST A SAMPLE](#)

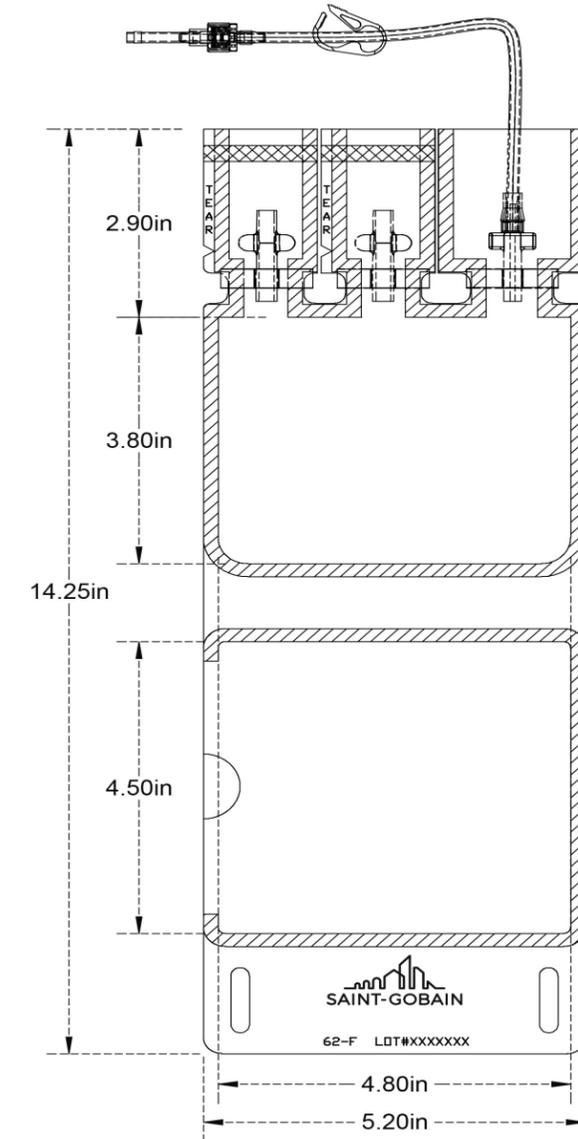
6-F

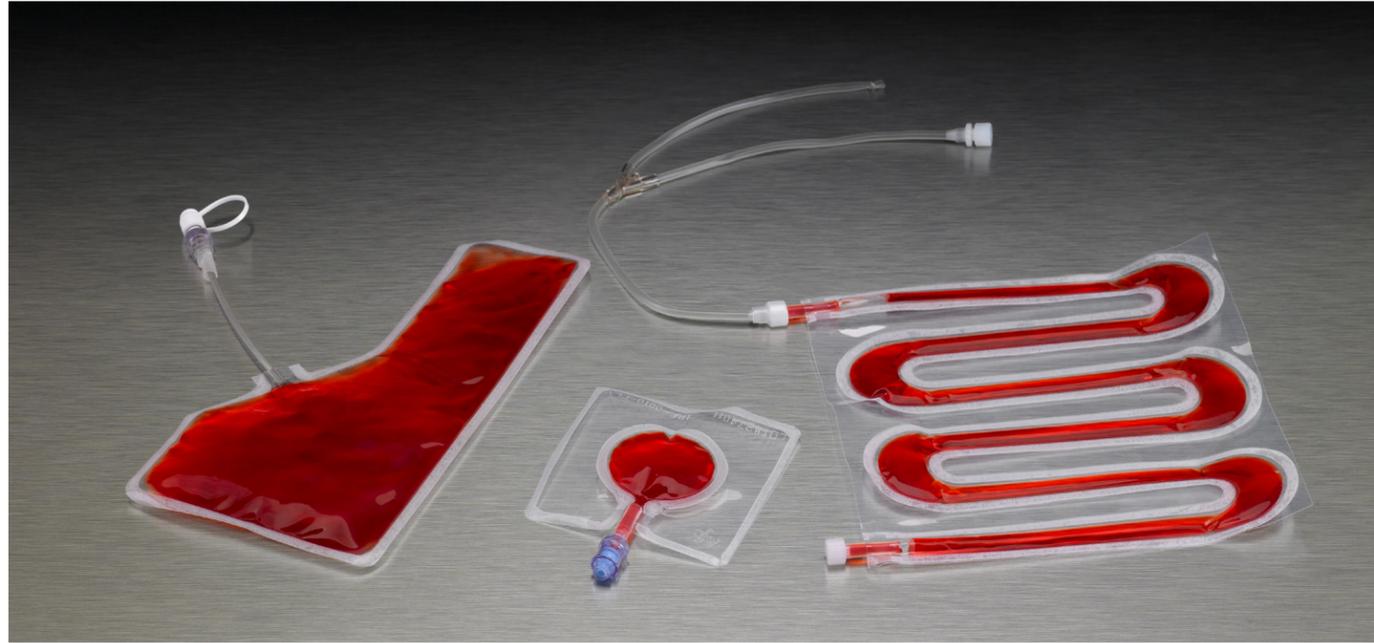


20-F



62-F





Saint-Gobain's proprietary laser welding technology allows for the creation of custom bags of virtually any shape with sizes ranging from 1mL to 50L.

Unlike traditional bag manufacturing methods, no investment in tooling/molds is required to create a custom product and therefore time lines and commitments can be greatly reduced. This unique manufacturing process, coupled with our application expertise, allows us to be able to quickly address custom solution requests, even at order quantities as low as 10 items.

In addition to size and shape, bags can also be customized by substituting tubing, ports, or connections types.



Saint-Gobain offers a wide range of fluid transfer assemblies to meet specific customer applications. These assemblies include a broad choice of products, including, but not limited to: C-Flex® tubing, Tygon® tubing, syringes, clamps, and luer adapters to address all fluid transfer needs.

All fluid transfer assemblies are manufactured to exceed expectations for quality and performance. The assemblies are designed for use not only with VueLife® culture bags and KryoSure® cryopreservation bags, but also with other systems. They can be used as standalone systems as well.

FOR ADDITIONAL
INFORMATION ON
FLUID TRANSFER



FLUID TRANSFER
ASSEMBLIES

APPLICATION NOTES

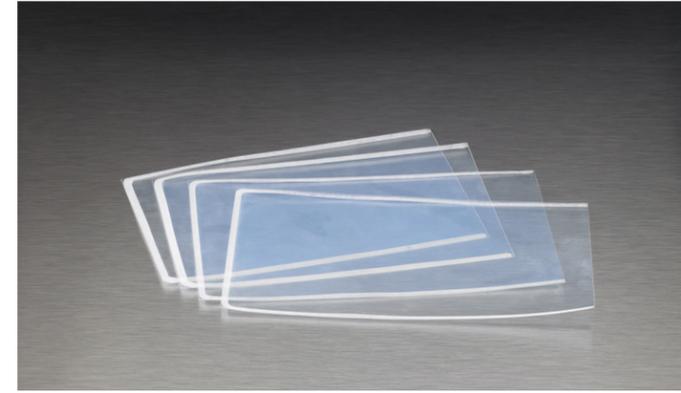
VALIDATION GUIDE

Saint-Gobain provides a wide variety of accessory items engineered to complement our VueLife® culture bags, KryoSure® cryopreservation bags and overwraps, and fluid transfer assemblies.



CLAMPS:

Clamps are used to restrict the area within a VueLife® culture bag as needed for seeding and expanding cultures. As cells proliferate, the clamp is moved to accommodate additional media. Clamps come in a range of sizes.



KRYOSURE® OVERWRAPS:

Bags with one open end that are made from the same USP Class VI, fluorinated ethylene propylene (FEP) used for KryoSure® freezing bags. Overwraps are meant to be used for an added layer of protection during cryopreservation. Most overwraps are available as both sterile and non-sterile products.

FOR ADDITIONAL
INFORMATION ON
ACCESSORIES



APPLICATION NOTES

VALIDATION GUIDE



Saint-Gobain Life Sciences

**50 West Watkins Mill Road
Gaithersburg, MD 20878**

1-800-360-1050

celltherapy.saint-gobain.com

FLS-5289G-1122-BPS

©2022 Saint-Gobain Life Sciences