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.
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.

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.

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

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

CUSTOM SOLUTIONS CAPABILITIES

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

operations overview

Custom Solutions Capabilities

1. Phase 1: Define Problem
   - Meet with customer to define problem and understand objectives

2. Phase 2: Design
   - Collaborate with customer to discuss design

3. Phase 3: Drawing
   - Customer provided with engineering drawing

4. Phase 4: Test Sample
   - Provide with sample for testing

5. Phase 5: Final Product
   - Final custom product delivered
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.

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

*Custom films also available upon request

**TUBING**

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

<table>
<thead>
<tr>
<th>Tubing Material</th>
<th>Relevant Applications</th>
<th>Related Saint-Gobain Brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEP</td>
<td>High Purity Transfer</td>
<td>PharmaFluor®</td>
</tr>
<tr>
<td>TPE</td>
<td>Peristaltic Pumping, Welding, Sealing</td>
<td>C-Flex®, PharMed®, PharmaPure®</td>
</tr>
<tr>
<td>Platinum Cured Silicone</td>
<td>Peristaltic Pumping</td>
<td>Sani-Tech®</td>
</tr>
<tr>
<td>PVC</td>
<td>Welding, Sealing</td>
<td>Tygon®</td>
</tr>
</tbody>
</table>

**FILTERS**

Engineered filtration solutions to meet application-specific requirements.

<table>
<thead>
<tr>
<th>Filter Membrane</th>
<th>Filter Type</th>
<th>Relevant Applications</th>
<th>Related Saint-Gobain Brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>PES Membrane</td>
<td>Pleated Capsules and Discs</td>
<td>Sterile Filtration</td>
<td>PureFlo® PES Z-Series</td>
</tr>
<tr>
<td>PE Membrane</td>
<td>Discs</td>
<td>Venting</td>
<td>PureFlo® PE</td>
</tr>
<tr>
<td>Nylon Screen</td>
<td>Pleated Capsules and Discs</td>
<td>Cell Washing</td>
<td>PureFlo® Nylon Screen</td>
</tr>
</tbody>
</table>

**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

---

**Custom Solutions Manufacturing and Assembly Capabilities**

**CONTAINERS**

**TUBING**

**FILTERS**

**CONNECTORS**

**CLOSURES**

**MANIFOLDS**
Custom Molding Capabilities

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
- Advanced automation with 6-axes robot and ability to develop custom end-of-arm tooling (EAOT) for minimal part handling
- Inspection of molded parts using multi-sensor metrology
- ISO 5 and ISO 7 assembly spaces

<table>
<thead>
<tr>
<th>Press Size Tonnage</th>
<th>120t</th>
<th>200t</th>
<th>440t</th>
<th>1900t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal (inches)</td>
<td>29</td>
<td>34.6</td>
<td>47</td>
<td>95</td>
</tr>
<tr>
<td>Vertical (inches)</td>
<td>26.7</td>
<td>32.6</td>
<td>43</td>
<td>85</td>
</tr>
<tr>
<td>Platen Minimum Coverage (H x V) (Inches)</td>
<td>13.8 x 13.8</td>
<td>17.9 x 17.9</td>
<td>22.2 x 22.2</td>
<td>59.0 x 53.4</td>
</tr>
</tbody>
</table>

**Sample Work Flow**

1. Raw material fed in via material vacuum system.
2. Parts molded in the ISO 8 cleanroom.
3. Parts transferred to ISO 7 assembly room through a controlled pass through window.
4. 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.

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

FEP Film Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>ASTM Standard</th>
<th>Typical Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness of FEP</td>
<td></td>
<td>5.0 mils</td>
</tr>
<tr>
<td>Continuous Service Temperature</td>
<td></td>
<td>-240°C to +205°C</td>
</tr>
<tr>
<td>Tensile Strength</td>
<td>E882</td>
<td>2500 psi (min)</td>
</tr>
<tr>
<td>Elongation at Break</td>
<td>D882</td>
<td>250% (min)</td>
</tr>
<tr>
<td>Solar Transmission</td>
<td>E424</td>
<td>96%</td>
</tr>
<tr>
<td>Refractive Index</td>
<td>D542</td>
<td>1.341 - 1.347</td>
</tr>
<tr>
<td>Oxygen Permeability @ 25°C</td>
<td></td>
<td>~2200 cc/m²-day</td>
</tr>
<tr>
<td>Carbon Dioxide Permeability @ 25°C</td>
<td></td>
<td>~5200 cc/m²-day</td>
</tr>
<tr>
<td>Water Vapor Permeability @ 37.8°C</td>
<td>F1249</td>
<td>~0.8 g/m²·day</td>
</tr>
</tbody>
</table>

(1) Transmission rates measured on 5 mil FEP film, the thickness of film used in bag construction.
The VueLife® product line offers a highly 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.

<table>
<thead>
<tr>
<th>Product</th>
<th>Recommended Process Volume</th>
<th>Approx. Maximum Fill Volume</th>
<th>Approx. Interior Surface Area (2 x Bag Face)</th>
<th>Standard Ports &amp; Tubing</th>
<th>Qty/Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>32-C</td>
<td>32 mL</td>
<td>40 mL</td>
<td>87 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>72-C</td>
<td>72 mL</td>
<td>175 mL</td>
<td>193 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>118-C</td>
<td>118 mL</td>
<td>275 mL</td>
<td>277 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>119-C</td>
<td>119 mL</td>
<td>285 mL</td>
<td>286 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>197-C</td>
<td>198 mL</td>
<td>500 mL</td>
<td>502 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>290-C</td>
<td>290 mL</td>
<td>900 mL</td>
<td>658 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>750-C1</td>
<td>750 mL</td>
<td>2,500 mL</td>
<td>1,643 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>32-AC</td>
<td>32 mL</td>
<td>45 mL</td>
<td>87 cm²</td>
<td>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</td>
<td>5</td>
</tr>
<tr>
<td>72-AC</td>
<td>72 mL</td>
<td>185 mL</td>
<td>193 cm²</td>
<td>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</td>
<td>5</td>
</tr>
<tr>
<td>118-AC</td>
<td>118 mL</td>
<td>285 mL</td>
<td>265 cm²</td>
<td>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</td>
<td>5</td>
</tr>
<tr>
<td>119-AC</td>
<td>119 mL</td>
<td>290 mL</td>
<td>286 cm²</td>
<td>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</td>
<td>5</td>
</tr>
<tr>
<td>197-AC</td>
<td>198 mL</td>
<td>505 mL</td>
<td>502 cm²</td>
<td>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</td>
<td>5</td>
</tr>
<tr>
<td>290-AC</td>
<td>290 mL</td>
<td>1,000 mL</td>
<td>671 cm²</td>
<td>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</td>
<td>5</td>
</tr>
<tr>
<td>750-AC</td>
<td>750 mL</td>
<td>2,500 mL</td>
<td>1,664 cm²</td>
<td>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</td>
<td>5</td>
</tr>
</tbody>
</table>

* OTHER TYPES OF PORTS, TUBING, AND CONNECTIONS AVAILABLE UPON REQUEST
VueLife® Cell Culture and Processing Bags

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.

---

### KryoSure® Cryopreservation Bags

<table>
<thead>
<tr>
<th>Product</th>
<th>Recommended Process Volume</th>
<th>Approx. Maximum Fill Volume</th>
<th>Approx. Interior Surface Area (2 x Bag Face)</th>
<th>Standard Ports &amp; Tubing</th>
<th>Qty/Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-F</td>
<td>6 mL</td>
<td>7 mL</td>
<td>28 cm²</td>
<td>1 isoprene injection port; 1 length of PVC tubing tube; 1 spike port</td>
<td>10</td>
</tr>
<tr>
<td>20-F</td>
<td>20 mL</td>
<td>55 mL</td>
<td>144 cm²</td>
<td>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</td>
<td>10</td>
</tr>
<tr>
<td>62-F</td>
<td>62 mL</td>
<td>250 mL</td>
<td>235 cm²</td>
<td>2 spike ports; 1 length of PVC tubing with female luer at the end</td>
<td>10</td>
</tr>
<tr>
<td>120-F</td>
<td>120 mL</td>
<td>480 mL</td>
<td>362 cm²</td>
<td>2 spike ports; 1 length PVC tubing, with segment numbers, with female luer at the end</td>
<td>10</td>
</tr>
<tr>
<td>180-F</td>
<td>180 mL</td>
<td>625 mL</td>
<td>451 cm²</td>
<td>2 spike ports; 1 length PVC tubing, with segment numbers, with female luer at the end</td>
<td>10</td>
</tr>
</tbody>
</table>

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

---

**CLICK HERE FOR ADDITIONAL INFORMATION ON CRYOPRESERVATION**

**KRYOSURE REFERENCES**

**VALIDATION GUIDE**

**REQUEST A SAMPLE**
KryoSure® Cryopreservation Bags

6-F

20-F

62-F

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.
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.

**CULTURE RACK:**
The culture rack is meant to support cell culture containers during incubation and is highly recommended. The rack allows for VueLife® bags to be lifted off the incubator shelf to allow for gas flow through both the bottom and top of the bag, maximizing oxygen permeability into the bag.

**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.