KryoSure® and KryoVue®
Cryopreservation Products

Non-reactive fluorinated ethylene propylene (FEP) bags providing safe use, storage and transport for immunologic and biologic applications
Safe Storage and Transport of Valuable Biologics

Saint-Gobain offers a complete line of FEP cryopreservation bags and overwraps designed to safely freeze and protect your biologics at temperatures as low as -200°C.
KryoSure® Cryopreservation Bags are made of fluorinated ethylene propylene (FEP). Tough, transparent and flexible at extreme temperatures (working range of -200°C to +200°C), FEP is the only Class VI material known to remain flexible in liquid nitrogen, making it ideal for cryopreservation applications. KryoSure bags provide a non-reactive closed system with no materials that can adversely affect cell cultures. KryoSure bags are designed with rounded inside corners to reduce the risk of sharp ice points that can damage the bag.

**General Bag Features**
- Non-reactive with virtually all chemicals and biologicals, including DMSO and DMF
- Remains flexible in liquid nitrogen
- Hydrophobic nature offers enhanced retrieval of contents
- Rounded corners provide for cold strength durability during and maximal product retrieval after cryopreservation
- Large label pocket allows easy readability of content information
- ISO-compliant spike port with septum protected by an integral tear-open, tamper-evident cover
- Each bag is individually tested and inspected
- Steam sterilized: Sterility Assurance Level (SAL) $10^{-6}$
- FDA 510(k) cleared; inquire regarding Device Master File
- Custom sizes and port configurations available

**FEP Bag Material**
- 5 mil (.005") fluorinated ethylene propylene (FEP) film
- USP Class VI compliant
- Hydrophobic nature of FEP offers enhanced retrieval of contents
- Film and ports are animal-derived component free (ADCF)
- Optically clear; transmits UV, visible and IR light
- Non-immunogenic; FEP material has no extractables, compliant with USP <661>
KryoSure® Blood Component Freezing Bags

KryoSure® Blood Component Freezing Bags are made from the highest quality USP Class VI materials. The design and materials permit the bag to remain flexible in liquid nitrogen, greatly enhancing reliability during short- or long-term cryopreservation.

Features

> Unique number engraved into the label pocket and etched into the fill tube in three places provides unalterable segments for cross-identification
> Each segment contains approximately 0.15 ml
> Segments may be stored in the large, integrally attached label pocket
> Two sterile covered spike ports and a PVC fill tube for sterile docking
> ISBT 128 compliant label pocket and bag remain transparent while frozen

Applications

> Designed for normal to extreme cryopreservation temperatures
> Contains and protects liquids and suspensions in mechanical freezers, vapor phase freezers and liquid nitrogen environments
> Fits in most standard metal freezer cassettes
> May be used for cell culture or centrifugation with proper handling

Inlet Line

Standard system consists of 4 mm PVC (standard I.V.) tubing with a clamp. Custom systems readily available with C-Flex® or other tubing combinations upon request. Sterile docking to the inlet line permits sterile filling of the bag. Another option is to fill through the female Luer connector. The inlet line and fittings can be removed prior to cryopreservation.

Exit Port

Manufactured from FEP, the exit spike port is ISO compliant and features a septum protected from external contamination by an integral tear-open, tamper-evident cover.
KryoSure® Blood Component Freezing Bag Properties

<table>
<thead>
<tr>
<th>Capacity</th>
<th>6 ml</th>
<th>50 ml</th>
<th>200 ml</th>
<th>480 ml</th>
<th>625 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalog Number</td>
<td>6-F</td>
<td>20-F</td>
<td>60-F</td>
<td>120-F</td>
<td>180-F</td>
</tr>
<tr>
<td>Volume Range</td>
<td>0.1-6 ml</td>
<td>5-20 ml</td>
<td>40–60 ml</td>
<td>50–120 ml</td>
<td>100–180 ml</td>
</tr>
<tr>
<td>Freeze Volume (at 1 cm thick)</td>
<td>6 ml</td>
<td>20 ml</td>
<td>60 ml</td>
<td>120 ml</td>
<td>180 ml</td>
</tr>
<tr>
<td>Inside Surface Area (2 sides)</td>
<td>40 cm²</td>
<td>144 cm²</td>
<td>255 cm²</td>
<td>362 cm²</td>
<td>445 cm²</td>
</tr>
<tr>
<td>Outside Dimensions</td>
<td>16 cm x 5.1 cm</td>
<td>33 cm x 7.6 cm</td>
<td>36.2 cm x 12.7 cm</td>
<td>40.6 cm x 12.7 cm</td>
<td>43.7 cm x 12.7 cm</td>
</tr>
<tr>
<td>Length with Label Folded</td>
<td>NA</td>
<td>21.4 cm</td>
<td>24.3 cm</td>
<td>28.7 cm</td>
<td>31.8 cm</td>
</tr>
<tr>
<td>Label Pocket Size</td>
<td>NA</td>
<td>11.9 cm x 7.6 cm</td>
<td>11.4 cm x 12.7 cm</td>
<td>11.4 cm x 12.7 cm</td>
<td>11.4 cm x 12.7 cm</td>
</tr>
</tbody>
</table>

Note: All dimensions and volumes are +/− 8% except as noted
The unique design of the KryoSure® Vaccine Freezing Bag allows for closed system sterile transfer and aseptic recovery of sterile contents such as cellular vaccines, donor lymphocyte infusions (DLI) and other small volume, clinical and industrial applications and other small volume, clinical, biotech and biopharm applications.

Features

- Bag is emptied by needle access through a conventional septum after removing the tamper-evident, liquid nitrogen-proof cover
- Heat-sealable bag neck isolates and encapsulates contents in fully closed and sealed bag
- High-temperature bar sealer required for sealing and removing the inlet port; two options available
- Label attachment hole for tying label to bag
- A wide range of ports, port protection and label packets available
- Other custom sizes available

Applications

- Freeze, thaw and dispense individual doses created from a common reservoir, sterile transferred by use of TS 917 sterile transfer set (sold separately)
- Contains and protects liquids and suspensions in mechanical freezers, vapor phase or liquid nitrogen environments
- Multiple bags will fit in most standard metal freezer cassettes
- May be used for cell culture or centrifugation with proper handling

Inlet Line

The inlet line consists of 4 mm PVC tubing for sterile connection. The fill tube and the tube connector can be completely removed by sealing and severing the neck of the bag.

Exit Port

Manufactured from USP Class VI latex-free polyisoprene, the needle access septum is protected from external contamination by an integral tear-open, tamper-evident cover.

KryoSure® Vaccine Freezing Bag Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity</td>
<td>6 ml</td>
</tr>
<tr>
<td>Catalog Number</td>
<td>6-F</td>
</tr>
<tr>
<td>Usage Range</td>
<td>0.1–6 ml</td>
</tr>
<tr>
<td>Freeze Volume (at 1 cm thick)</td>
<td>6 ml</td>
</tr>
<tr>
<td>Inside Surface Area (2 sides)</td>
<td>40 cm²</td>
</tr>
<tr>
<td>Outside Dimensions (fill port removed, ready to freeze)</td>
<td>16.0 cm x 5.1 cm</td>
</tr>
<tr>
<td>Label Attachment Hole</td>
<td>0.25 cm</td>
</tr>
</tbody>
</table>

Note: All dimensions and volumes are +/- 8% except as noted.
The KryoVue® Peel Pouch is a cryopreservation overwrap designed to protect valuable samples that are stored in liquid nitrogen. Simply peel open the package to retrieve contents.

**Features**

- > 2 mil thick Kapton® film with FEP inside and polyimide outside
- > Outside dimension: 12.6 cm x 30.4 cm
  Inside dimension: 11.6 cm x 26.3 cm
- > Transparent, with a light amber tint
- > Provides a barrier to liquid nitrogen and contaminants
- > Remains flexible in liquid nitrogen
- > Working useful temperature range from -200°C to +200°C
- > Optional port for vacuum sealing
- > Non-immunogenic; FEP material has no extractables, compliant with USP <661>
- > Manufactured without adhesives
- > Can be pre-printed with your company information and written on for documentation

Kapton® is a registered trademark of E.I. du Pont de Nemours & Co.
IMPORTANT: It is the user’s responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Performance Plastics assumes no responsibility for any product failures that occur due to misuse of the materials it provides arising out of the design, fabrication, or application of the products into which the materials are incorporated.

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WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain Performance Plastics warrants this product to be free from defects in materials and workmanship.

WARNING: The content of Saint-Gobain Performance Plastics’ tubing materials is not certified by the FDA for implant devices and is neither designed nor intended to be used in medical applications involving permanent implantation in the human body or permanent contact with body fluids or tissues. Failure to comply with this warning may lead to serious bodily injury or death.

Contact us for customized solutions, further information and to place an order

BIOPHARMACEUTICAL PRODUCTS MANUFACTURING FACILITY

Saint-Gobain Performance Plastics
431-A East Diamond Avenue
Gaithersburg, MD 20877
Phone: 301-990-1407
Phone: 800-360-1050

WWW.BIOPHARM.SAINT-GOBAIN.COM
WWW.TOAFC.COM

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