

# Envirotainer<sup>®</sup>

The Active Cold Chain



## CryoSure<sup>®</sup> systems User Manual

**Dewar Models:**  
**X2, X5, X11**

Doc No. UM-CRYO-3030  
Version 5

[www.envirotainer.com](http://www.envirotainer.com)

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## RECORD OF REVISION

VER. NO.	REVISION
5	<p><b>REVISED:</b></p> <ul style="list-style-type: none"> <li>• <b>1. Introduction:</b> Revised range from 1L to 1,6L.</li> <li>• <b>1.1 Overview:</b> Changed size range of product line from four to three.</li> <li>• <b>1.1.1 Product specification:</b> <ul style="list-style-type: none"> <li>• Row <b>CryoSure system:</b> Removed X1.</li> <li>• Row <b>Autonomous duration:</b> Replaced symbol &gt; (greater than) with ≥ (greater or equal to).</li> </ul> </li> <li>• <b>1.1.2 Payload:</b> Removed X1.</li> <li>• <b>1.2 Technical details:</b> Removed X1.</li> <li>• <b>1.3 Intended use:</b> Added caution admonition regarding to keep CryoSure® systems out of freezer.</li> <li>• <b>1.5 Operating conditions:</b> Removed.</li> <li>• <b>2.3 Symbols on the CryoSure® system:</b> Clarified section.</li> <li>• <b>3.1 Monitoring device options:</b> <ul style="list-style-type: none"> <li>• Renamed chapter.</li> <li>• Removed <b>Fixed probe</b> chapter.</li> <li>• Moved chapter <b>Security seal</b> to <b>3.2 Security seal</b> and added additional information.</li> </ul> </li> <li>• <b>3.3 Preparing a shipment:</b> Rephrased information.</li> <li>• <b>3.4.1 Product loading:</b> <ul style="list-style-type: none"> <li>• Divided main illustration into step-by-step illustrations.</li> <li>• Added instruction concerning envelopes (main shipment and return envelope).</li> <li>• Additional step to check the security seal.</li> <li>• Added instruction to package the product proper to avoid rattle.</li> </ul> </li> <li>• <b>3.4.2 Shipping of loaded product:</b> Updated instruction.</li> <li>• <b>3.4.3 Product unloading:</b> <ul style="list-style-type: none"> <li>• Divided main illustration into step-by-step illustrations.</li> <li>• Removed step 3.</li> <li>• Additional step to check the security seal.</li> <li>• Additional steps to ready the system for return.</li> </ul> </li> <li>• <b>3.4.4 Return the CryoSure® system to Envirotainer®:</b> <ul style="list-style-type: none"> <li>• Renamed chapter.</li> <li>• Updated instruction.</li> </ul> </li> </ul>

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## 1. INTRODUCTION

The CryoSure<sup>®</sup> system is designed for global shipping and storage of pharmaceutical products, clinical trial materials, vaccines, cell & gene therapy, biospecimens and specialty medicines that are required to be kept below -70°C (-94°F).

The CryoSure<sup>®</sup> system uses a unique patented technology combined with dry ice. It is a **reusable** shipping system which offers both mechanical protection of the shipped product and maintains load space temperature below -70°C (-94°F) (average between -74°C and -80°C / -101°F and -112°F).

- Maintains temperature control consistently below -70°C (-94°F)
- Suitable for any destination, domestic or international, and by ground or air, covering the entire shipment duration including delays and customs without the need to re-charge
- Provides mechanical protection during transport by ground or air

The CryoSure<sup>®</sup> system comes in four different sizes, with product space volume from 1,6 L to 11,1 L. The temperature control duration is intended to last throughout the shipment without recharging.

These systems will be pre-charged with dry ice at an Envirotainer<sup>®</sup> facility and be delivered to a second location where temperature-sensitive materials can be loaded into the dewar for transit or storage.

### 1.1 OVERVIEW

The CryoSure<sup>®</sup> product line consist of three different sizes.

#### 1.1.1 PRODUCT SPECIFICATION

Table 1 Product specification

CryoSure <sup>®</sup> system	X2	X5	X11
<b>Autonomous duration*</b>	≥21 days	≥13 days	≥15 days
<b>Payload opening</b>	Ø 9 cm (Ø 3.5")	Ø 15,2 cm (Ø 6")	Ø 21,3 cm (Ø 8.4")
<b>Dry-ice payload</b>	3,5 kg (7.7 lb.)	3,2 kg (7.2 lb.)	5,5 kg (12 lb.)
<b>Product payload</b>	1,6 L (57.3 oz.)	5 L (177.2 oz.)	11,1 L (391.7 oz.)
<b>Product space (DxH)</b>	8,1x31,9 cm (3.2x12.6")	14,3x31,5 cm (5.6x12.4")	20,7x33,2 cm (8.1x13.1")
<b>Outer dimensions of box (WxLxH)</b>	29,6x29,6x58,9 cm (11.7x11.7x23.2")	33,6x33,6x58,9 cm (13.2x13.2x23.2")	45,6x45,6x64,2 cm (18x18x25.3")
<b>Total weight (excl. product load)</b>	9,8 kg (21.6 lb.)	11,3 kg (24.8 lb.)	19,3 kg (42.4 lb.)
<b>Product holder</b>	0,2 kg (0.5 lb.)	0,5 kg (1.1 lb.)	1,1 kg (2.5 lb.)
<b>Total weight with product holder (excl. product load)</b>	10 kg (22.1 lb.)	11,8 kg (25.9 lb.)	20,4 kg (45 lb.)

\* When exposed to ISTA 7D summer profile

## 1.1.2 PAYLOAD

Table 2 Vials configuration

CryoSure <sup>®</sup> version	# of 2 mL vials	2 mL vials configuration
CryoSure <sup>®</sup> X2	80	Canister holding 16 canes without sleeves; 5 vials/cane
	70	Canister holding 14 canes with sleeves; 5 vials/cane
CryoSure <sup>®</sup> X5	300	Canister holding 60 canes without sleeves; 5 vials/cane
	200	2 boxes oriented vertically; 100 vials/box
CryoSure <sup>®</sup> X11	600	120 canes without sleeves in bags; 5 vials/cane
	500	Rack holding 5 boxes; 100 vials/box

## 1.2 TECHNICAL DETAILS

A complete CryoSure<sup>®</sup> system is comprised of the following components:



Fig. 1 The CryoSure<sup>®</sup> system.

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**Table 3 CryoSure<sup>®</sup> system features**

Pos	Name	Description
A	Dewar	Insulated aluminum container that holds the dry ice pellets and material to be preserved.
B	Product space	To place the product holder in.
C	Security seal	A uniquely numbered seal is attached to the dewars neck before shipment to a lessee. An additional security seal, to be used after loading of the products, is added to the envelope where the shipment documentation can be found.
D	Insulating lid	Cap and insulating cork used to close the dewar opening while allowing carbon dioxide vapor from sublimating dry ice inside the dewar to still vent freely outside the dewar.
E	Foam inserts	Reusable packaging positioned between the dewar and cardboard box that protects the dewar from handling damage: (one (1) bottom, one (1) top, and one (1) main insert for the sides).
F	Cardboard box	External packaging. Shipping, safety, and regulatory stickers are applied to the exterior of the cardboard box as appropriate.
G	Product holder *(standard for X2, and X5)	Cylindrical stainless-steel container with handle for loading materials into, removing materials from, or holding materials within the storage zone of the dewar.
H	Product holder *(standard for X11)	Stainless-steel rack with handle for loading materials into, removing materials from, or holding materials within the storage zone of the dewar.
I	Logger <i>Shipment Report</i>	Temperature logger with a probe that is inserted into the product space to capture the internal temperature.
J	Tracker <i>Live Monitoring</i>	Real-time tracker with a probe that is inserted into the product space to capture the internal temperature. Records the unit's location during the shipment.

**NOTE!**

*\*When booking on the Envirotainer<sup>®</sup> Portal, customers may opt out of using the standard product holder for their shipment depending on the type of product being shipped.*

## 1.3 INTENDED USE

Pre-charged CryoSure<sup>®</sup> systems are delivered with dry ice already loaded inside. In normal operation, users are never required to handle dry ice.

The CryoSure<sup>®</sup> system is designed for global shipping and storage of pharmaceutical products, clinical trial materials, vaccines, cell & gene therapy, biospecimens, and specialty medicines that are required to be kept below -70°C (-94°F).

The CryoSure<sup>®</sup> system offers both mechanical protection of the shipped product and maintains load space temperature below -70°C (-94°F) throughout the shipping duration.

Refer to **2. Safety**.



### CAUTION!

Biological materials used with the CryoSure<sup>®</sup> systems are limited to Biological Substance Category B materials specified under UN 3373 and exceptions defined in IATA 3.6.2.2.3.

**No pathogenic Category A materials (UN 2814, UN 2900) or medical or clinical wastes (UN 3291) shall be used with the CryoSure<sup>®</sup> systems.**



### CAUTION!

Do not put the CryoSure<sup>®</sup> systems in a freezer.

## 1.4 CONTACT

For contact information to our operations centers, refer to [www.envirotainer.com](http://www.envirotainer.com).

For questions regarding this manual or the CryoSure<sup>®</sup> systems, send an e-mail to [support@envirotainer.com](mailto:support@envirotainer.com).

## 2. SAFETY

- Read the manual before handling and operating the CryoSure® system.
- Read the Safety Data Sheet for dry ice (**UN1845**).
- Pay attention to warning stickers and texts attached to the CryoSure® system.

### 2.1 SYMBOLS

#### 2.1.1 SYMBOLS IN THE MANUAL

The following symbols are used in the manual:

	<b>WARNING!</b> Indicates a possible danger that <b>can</b> lead to death or serious injury if necessary measures are not taken.
	<b>CAUTION!</b> Indicates a possible hazard that <b>can</b> lead to injury or material / equipment damage if necessary measures are not taken.
	<b>NOTE!</b> Practical information or tips on how to perform a procedure.

### 2.2 SHIPPING REGULATIONS

The United States Department of Transportation (**DOT**) and related international government agencies regulate shipments containing dry ice and biological materials. In addition, the International Air Transport Association (**IATA**) maintains standards that guide airline polices regarding dry ice and biological material shipments. Users of a pre-charged CryoSure® system should review and follow all appropriate government and carrier requirements for labeling and packaging shipments containing dry ice or biological materials.

### 2.3 SYMBOLS ON THE CRYOSURE® SYSTEM

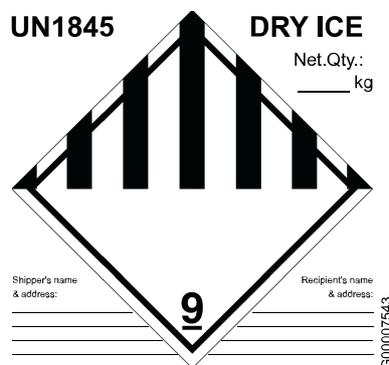


Fig. 2



 **WARNING!**

**UN1845** (Dry ice) is solidified carbon dioxide. At normal atmospheric pressure, dry ice sublimates to carbon dioxide vapor at approximately  $-78.5^{\circ}\text{C}$  ( $-109.3^{\circ}\text{F}$ ). Dry ice is very cold, and contact with dry ice or areas cooled by dry ice can cause frostbite. The CryoSure<sup>®</sup> pre-charged system is delivered with dry ice already loaded inside. In normal operation, it should not be necessary for users of a pre-charged CryoSure<sup>®</sup> system to handle dry ice. The interior spaces and surfaces of a pre-charged dewar are very cold, and users are advised to wear appropriate gloves when interacting with the interior of the dewar or items recently removed from the interior. The carbon dioxide gas generated by sublimation of dry ice can create potentially hazardous carbon dioxide-enriched and/or oxygen-deficient atmospheres. Users of dry ice or dry ice-containing systems are recommended to evaluate the potential for atmospheric hazards in their working environment and take appropriate steps to address such hazards (for example, by using air monitoring devices and adequate ventilation).

If Envirotainer<sup>®</sup> *Live monitoring* service is used, include the following declaration to the AWB: **“Not restricted, as per Special Provision A199”**

## 2.4 CLEANLINESS OF PRODUCT

The CryoSure<sup>®</sup> system is cleaned using VIRKON<sup>™</sup> solution and Isopropyl alcohol according to Envirotainer<sup>®</sup> instruction **SOP-ENV-0229** and **SOP-ENV-0234**.

### 3. USING THE CRYOSURE<sup>®</sup> SYSTEM

#### 3.1 MONITORING DEVICE OPTIONS

The following devices/services may be added and booked on the Envirotainer<sup>®</sup> Portal.

 **CAUTION!**  
Keep the devices in their original position.

##### 3.1.1 LOGGER DEVICE

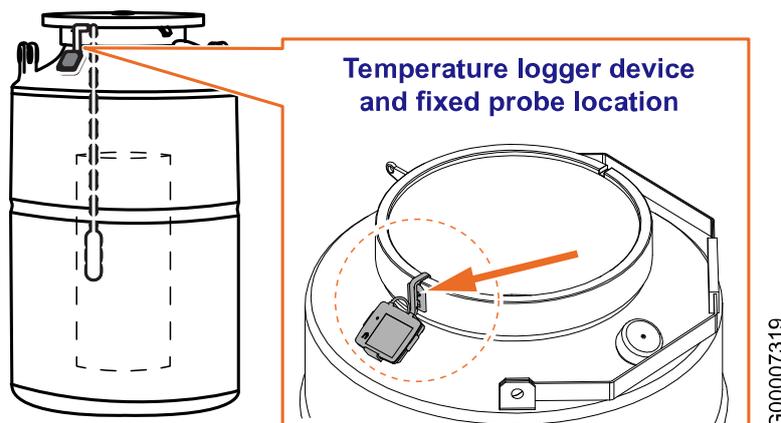


Fig. 3

The temperature logger device will be mounted on the neck of the dewar as part of the *Shipment report* services.

##### 3.1.2 TRACKING DEVICE

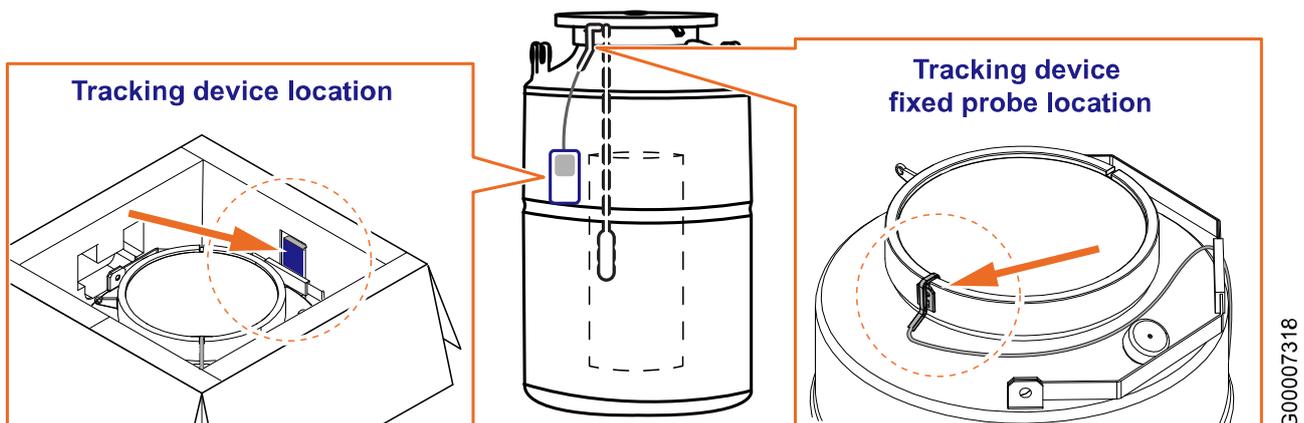


Fig. 4

The tracking device will be secured in a special compartment within the protective foam packaging on the inside of the box as part of the *Live monitoring* services.

## 3.2 SECURITY SEAL

All CryoSure<sup>®</sup> systems are released from Envirotainer<sup>®</sup> with an Envirotainer-marked seal and an extra Envirotainer-marked seal is provided to be used for the customer's shipment.

Always use a security seal to secure the lid in the correct position.

Upon receiving a shipment without, or with a tampered Envirotainer<sup>®</sup>-marked seal, report according to internal procedures.

## 3.3 PREPARING A SHIPMENT

Pre-condition the product to -70°C (-94°F) or below, to guarantee the full autonomy of the CryoSure<sup>®</sup> system.

## 3.4 OPERATING INSTRUCTIONS

1. Product loading, **3.4.1 Product loading**.
2. Shipping CryoSure<sup>®</sup> system, **3.4.2 Shipping of loaded product**.
  - Remove old labels and documents.
  - Prepare new labels and documents for cardboard box.
3. Receiving CryoSure<sup>®</sup> system and removing products, **3.4.3 Product unloading**.
4. Returning CryoSure<sup>®</sup> system to Envirotainer<sup>®</sup>, **3.4.4 Return the CryoSure<sup>®</sup> system to Envirotainer<sup>®</sup>**.
  - Remove or cover old labels and documents.
  - Prepare new labels and documents for cardboard box.

### 3.4.1 PRODUCT LOADING

1. Inspect the outer packaging. If the cardboard box is too worn for use, contact Envirotainer<sup>®</sup> for support. Refer to **1.4 Contact**

2. Open the box:

2a. Set aside the top foam and envelopes.

 **CAUTION!**  
Keep the top foam and envelopes.

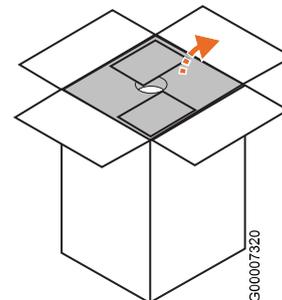


Fig. 5

2b. Check that there is no missing or tampered seal. Refer to **3.2 Security seal**.

2c. Cut and dispose of the security seal.

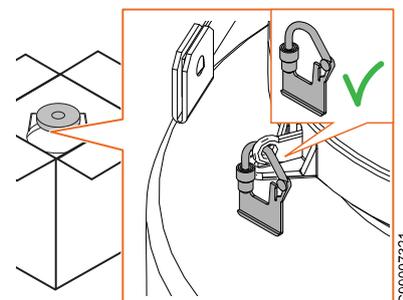


Fig. 6

2d. Wear safety gloves and remove lid. Place the lid to one side.

 **CAUTION!**  
Keep the lid

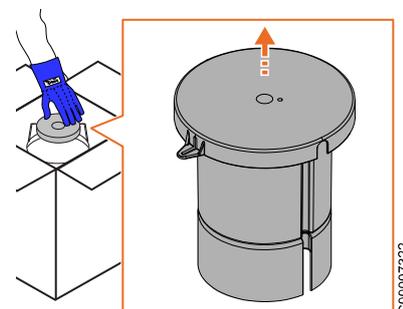


Fig. 7

3. Load the product:

3a. Lift the product holder by its handle and remove it from the dewar.

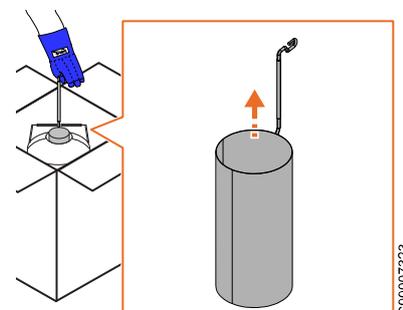
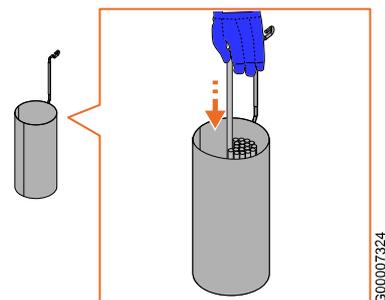


Fig. 8



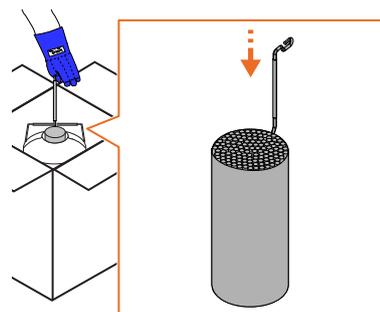
- 3b. Load and package the product proper to avoid rattle, into the product holder. Follow all applicable government and carrier requirements for packaging the product.



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Fig. 9

- 3c. Lift the product holder into the dewar.

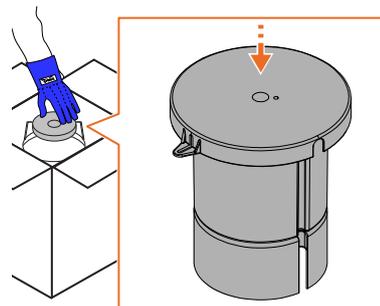


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Fig. 10

- 4. Place the following items back in place:

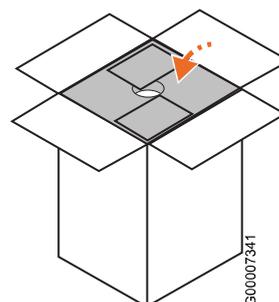
- 4a. Lid (wear safety gloves).



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Fig. 11

- 4b. Top foam and envelopes.



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Fig. 12

## 3.4.2 SHIPPING OF LOADED PRODUCT

### ⚠ CAUTION!

After the dewar has been loaded with product and properly packaged with all required components, labels need to be applied to the exterior of the cardboard box in accordance with government (e.g., US DOT, EU ADR) regulations and carrier (e.g., IATA) requirements.

Please ensure that all needed documents according to the correspondent regulations are on hand (for example shippers declaration, pro forma invoices and packing lists).

1. Locate the envelope marked “Main shipment” and open it.

Items inside envelope:

- Safety seal
- Quick sheet
- Dangerous goods label (**UN1845**)
- Delivery note
- Additional documents

2. Remove or cover the parcel carrier label.

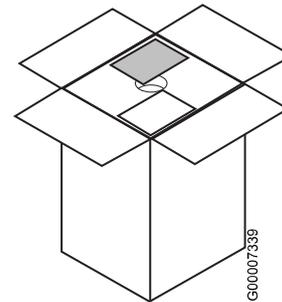


Fig. 13

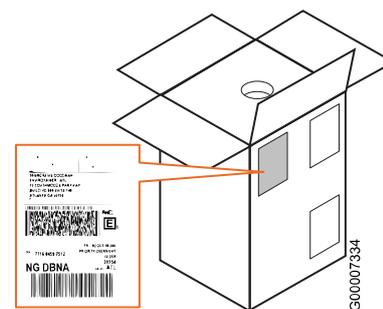


Fig. 14

3. Remove or cover the dangerous goods label (**UN1845**) where you are notified as **consignee**.

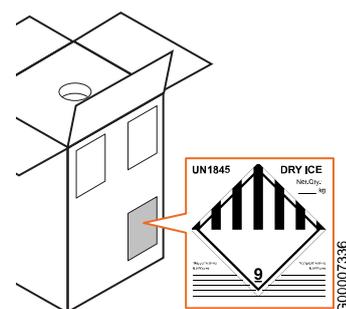


Fig. 15



4. Apply the labels to the exterior of the box in accordance with government regulations and carrier requirements.

 **CAUTION!**  
Ensure necessary documents are in the document pouch.

5. Close and seal the cardboard box with clear packing tape.

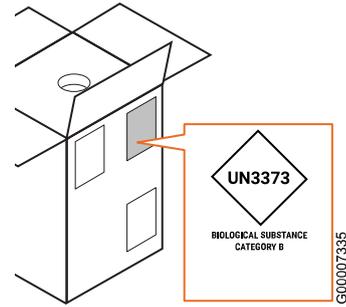


Fig. 16

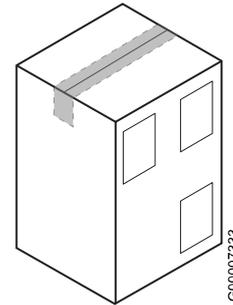


Fig. 17

### 3.4.3 PRODUCT UNLOADING

1. Unpack:

- 1a. Open the box and set aside the top foam and “Return” envelope.

 **CAUTION!**  
Keep the top foam and envelope.

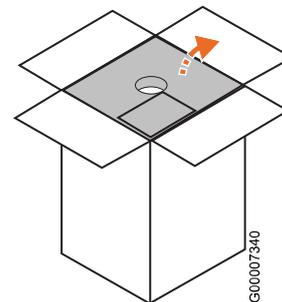


Fig. 18

- 1b. Check that there is no missing or tampered seal. Refer to **3.2 Security seal**.

- 1c. Cut and dispose of the security seal.

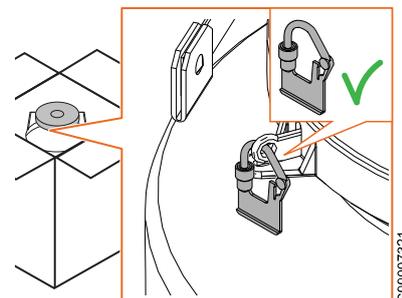


Fig. 19

- 1d. Wear safety gloves and remove lid. Place the lid to one side.

 **CAUTION!**  
Keep the lid

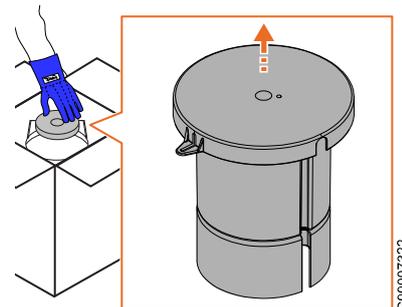


Fig. 20

2. Unload product:

- 2a. Lift the product holder by its handle and remove it from the dewar.

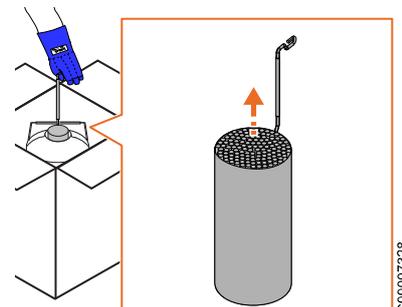


Fig. 21



2b. Remove the product from the product holder.

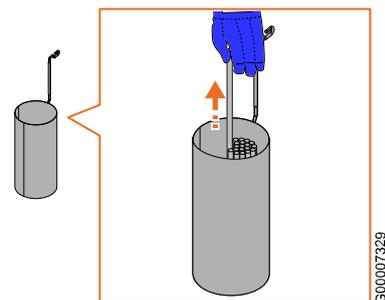


Fig. 22

2c. Lift the empty product holder into the dewar.

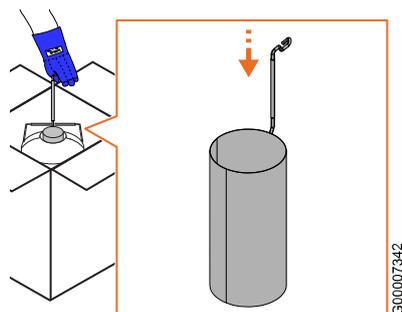


Fig. 23

3. Place the following items back in place:

3a. Lid (wear safety gloves).

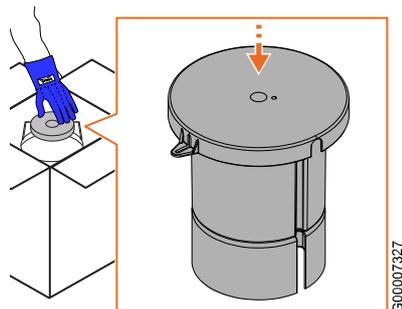


Fig. 24

3b. Top foam and "Return" envelope.

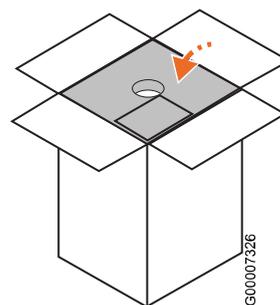


Fig. 25

## 3.4.4 RETURN THE CRYOSURE<sup>®</sup> SYSTEM TO ENVIROTAINER<sup>®</sup>

### NOTE!

**When will the empty CryoSure<sup>®</sup> be picked up for return?** You will receive an e-mail reminder 2 days before the scheduled pickup. Modify the pickup date through the link provided in the e-mail or contact your Logistics Service provider. If you haven't received the reminder, contact Envirotainer<sup>®</sup> customer service. Refer to [1.4 Contact](#).

1. Locate the envelope marked “Return” and open it.

Items inside envelope:

- Cover stickers
- Quick sheet
- Dangerous goods label (**UN1845**)
- Document pouch containing:
  - Return shipment label where Envirotainer<sup>®</sup> is notified as the consignee
  - Invoices

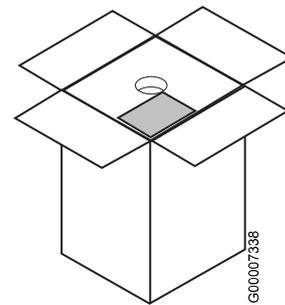


Fig. 26

2. Cover all the labels on the cardboard box with the cover stickers.

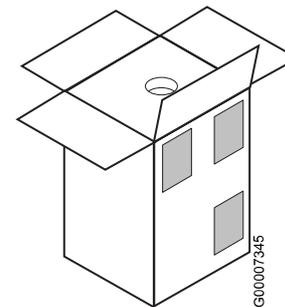


Fig. 27

3. Attach the dangerous goods label (**UN1845**).

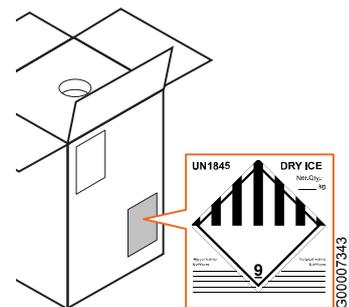


Fig. 28



4. Attach the return shipment label.

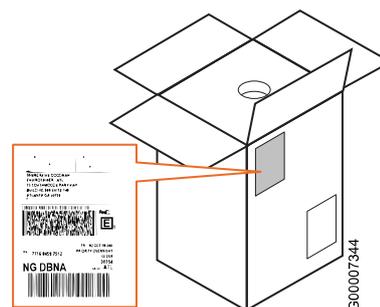


Fig. 29

5. Close the cardboard box, and seal with clear packing tape.

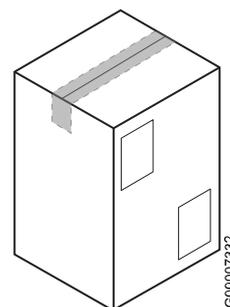


Fig. 30

### 3.5 MONITOR THE AUTONOMY DURATION LEFT ON YOUR CRYOSURE<sup>®</sup> SYSTEM

Every time a CryoSure<sup>®</sup> system is released, a unique QR code sticker is printed and placed on the outside of the cardboard box. By scanning the QR code with your smartphone, you will get access to the DuraWatch<sup>®</sup> service which provide information about this unique shipment, including how many days and hours of cooling capacity is remaining.

In addition to cooling capacity remaining, DuraWatch<sup>®</sup> also provides:

- Contact details to schedule pickup of the CryoSure<sup>®</sup> system
- Shipping route information
- Product details (dewar dimension and other measurements)
- User Manual

The QR code can be scanned by anyone handling the CryoSure<sup>®</sup> system and not only the customer placing the CryoSure<sup>®</sup> orders. However, information in DuraWatch<sup>®</sup> is non-sensitive. For any detailed information around a CryoSure<sup>®</sup> order you still need to login to the Envirotainer<sup>®</sup> Portal.

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# Envirotainer Engineering AB

[www.envirotainer.com](http://www.envirotainer.com)

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