UNPACKING AND REPACKING INSTRUCTIONS

Unpacking Instructions

L7093.002 (06/2015)



The shipment will be packaged as shown here and delivered via approved courier, FedEx[®], or UPS[®].

Step 1: Take notice of the date/time stamp which is located on the upper left corner of the envelope taped to the top of the box. It represents the expiration date/time (Eastern Time) for the shipment. Please ensure that the allograft(s) will be thawed for implantation, placed in a low temperature storage freezer (at or below -135°C), or returned to CryoLife[®] before the expiration date/time.



Step 2: Open the envelope which is taped on top of the box and retrieve the following contents:

- Implant Stickers (Courtesy Labels)
- Unpacking and Repacking Instructions
- Certificate of Assurance
- Instructions for Use
- Thaw and Rinse Instructions
- Prepaid FedEx or UPS Return Label
- Packing List

Read the following completely before proceeding with Unpacking Instructions



Step 3: Remove the Packing List from the sleeve attached to the outside of the box. This List contains the allograft type, size, quantity, and purchase order number.



Step 4: Cut the tape and open the flaps of the box. Do not remove the shipping container from the box.



Step 5: Remove the white foam cross pads. NOTE: Do not discard white or blue foam pads because they are needed during the Repacking Instructions.

Do not proceed unless one of the following applies:

• Allograft(s) will be used for a case

• Allograft(s) will be placed in a low temperature storage freezer, at or below -135°C

NOTE: The impact of completing Step 6 and cutting the CryoLife cable tie is in the Returns Policy at www.cryolife.com/returnpolicy



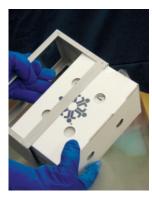
Step 6: Refer to the instructions on the lid before opening the shipping container. Cut the CryoLife cable tie to open the lid of the container.



Step 7: Pull the lid off the container. The fog and vapor are normal and should be expected. The contents of the container can be as cold as -196°C.



Step 8: Using insulated gloves (or towels) and protective eyewear, remove the metal rack from inside the shipping container by lifting the handle.



Step 9: Slide the cardboard protective sleeve out of the metal rack through the opening on the side and carefully open it. NOTE: This sleeve can store up to four allografts housed in small cardboard boxes. If less than four allografts are shipped, empty cardboard boxes are inserted for added protection during transport.



Step 10: Remove all small cardboard boxes that are labeled (these contain allografts). Immediately place into a low temperature storage freezer (at or below -135°C) or begin Thaw and Rinse Instructions. (WARNING: Exposure to room air temperature for more than 3 minutes may cause transient warming of the tissue). Carefully replace metal rack back into the shipping container and replace the lid.

If an allograft is to be stored in a low temperature storage freezer (at or below -135°C), locate an empty slot in the racking system that is not exposed to liquid nitrogen and carefully place the allograft into the empty slot. The allograft should remain in the cardboard box throughout the duration of the allograft's storage at the facility. This will allow for the opportunity of the end-user to scan the Unique Device Identifier (UDI) if they wish to do so during the time the allograft is being stored. Note: Currently, only SynerGraft[®] tissue is labeled with the UDI. Return the racking system to the storage freezer and close the lid. Allow the allograft to equilibrate with the liquid nitrogen vapor for a minimum of two (2) hours. After the equilibration period, the allograft may be submerged in liquid nitrogen for long-term storage.





UNPACKING AND REPACKING INSTRUCTIONS

Repacking Instructions – Read completely before beginning repacking procedure.

The shipper is reusable and MUST be returned to CryoLife using the applicable option below:

Option 1

Returning an Empty Shipping Container

The empty shipping container must be returned to CryoLife. Failure to do so will cause CryoLife to charge your facility for such container. NOTE: You do not need to replace the empty cardboard boxes into the cardboard protective sleeve because no allografts are being returned.



Step 1: Using insulated gloves (or towels) and protective eyewear, replace the cardboard protective sleeve into the metal rack and insert into the shipping container.



Step 2: Replace the lid on the container to ensure the vent holes in the side of the lid line up with the vent holes in the neck of the shipping container.



Step 3: Replace all blue foam corner pads and white foam cross pads. Include any unused paperwork. Close the flaps of the box and tape the box closed.



Step 4: Place the prepaid return label (provided in the envelope from Step 2 of the Unpacking Instructions) on top of the original FedEx® or UPS® label. If the tissue was delivered via courier, place the return label in a visible location on top of the box. The shipping container is ready to be returned. Send box to shipping so it can be promptly returned to CryoLife.

Option 2

Returning Allografts in a Shipping Container

Please note that CryoLife may not accept allografts for return. You must receive authorization before allografts can be returned. Please refer to the Returns Policy at www.cryolife.com/returnpolicy for details regarding returns.

Step 1: Call CryoLife Customer Service Department at 1-888-427-9654 to receive authorization and to arrange for courier transport. NOTE: If the CryoLife cable tie was cut, and the allograft(s), which remained in the shipping container, needs to be returned, the following procedure must be followed to assure the safe transport of the allograft(s) back to CryoLife. If the CryoLife cable tie was NOT cut, the allograft(s) may be returned to CryoLife by simply following Step 5, below.



Step 2: Upon authorization, use insulated gloves (or towels) and protective eyewear to replace all empty cardboard boxes into the cardboard protective sleeve along with the unused allograft(s).



Step 3: Replace the cardboard protective sleeve into the metal rack and insert into the shipping container.



Step 4: Replace the lid on the container ensuring the vent holes in the side of the lid line up with the vent holes in the neck of the shipping container.



Step 5: Replace all blue foam corner pads and white foam cross pads. Include any unused paperwork. Close the flaps of the box and tape

the box closed. The shipping container is ready to be returned. Follow additional instructions provided by CryoLife Customer Service during Step 1.

If your facility does not have regularly scheduled small package pick-up service, then call your local CryoLife Technical Representative, Cardiac Specialist, or the CryoLife Shipping Department at 1-800-438-8285 or 1-770-419-3355 to arrange for pick-up.



Life Restoring Technologies

CryoLife, Inc. • 1655 Roberts Boulevard, NW • Kennesaw, Georgia 30144 • USA 1-800-438-8285 or 1-770-419-3355 (phone) • 1-770-590-3753 (fax) • www.cryolife.com (website)

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