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	Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper	CONFIDENTIAL

1. Purpose

Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper with version control.

2. Appendices

Appendix ID	Title
Appendix A	Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper

3. Change History

Issue Number	Description of Change(s)	Reason for Change(s)
1.0	Initial Release	Initial Release
2.0	Updated formatting and pictures for clarity.	Updated formatting and pictures for clarity.

4. Approvals:

Logistics Solutions and Compliance Transport Qualification and Compliance Manager					
Author:	Name	5.1.2e	Sign/Date	5.1.2e	21 Oct 2020 18:47:044-0400
Logistics Solutions and Compliance Sr. Manager Transport Validation & Innovation					
Approved:	Name	5.1.2e	Sign/Date	5.1.2e	21 Oct 2020 19:11:006-0400
REASON: I approve this document as author. 0a1fb514-1692-45e0-8d06-8eb5d9529e8f 524412a2-6820-4b64-8cc4-a43540e06a26					

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Appendix A: Instructions (12 Pages)

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Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper

1. Purpose

The purpose of this controlled document is to provide unpackaging and re-icing requirements on the Softbox Medium ULT Parcel Shipper with Dry Ice.

CAUTION: Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen resulting in asphyxiation. Exposed skin should be protected from contact with dry ice. Eye protection is recommended (for example, safety glasses).

Appropriate training to be been conducted for personnel handling dry ice and documented within their relevant training system as required.

2. Scope

This controlled document is applicable to unpackaging and re-icing requirements using the Softbox Medium ULT Parcel Shipper with Dry Ice.

Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper

3. Reference Documents

Document Number	Description
N/A	Safe Handling Guidelines for Dry Ice
N/A	Safety Data Sheet Dry Ice

4. General Requirements**4.1. Materials**

Specification Number	Description
CD-88557	SPEC – Softbox Medium ULT Parcel Shipper
N/A	Insulated (Thermal) Gloves
N/A	Safety Glasses
N/A	Carton Sealing Tape
N/A	Dry Ice Pellets (10 to 16 mm)

4.2. Recommendations**Recommendations (Using Thermal Shipping Container as Temporary Storage)**

- The thermal shipping container is a passive (non-compressor) device that contains dry ice as the energy source to maintain the required temperatures when maintained properly as defined by Pfizer instructions. The dry ice in the thermal shipper will deplete over a number of days (duration will vary depending on use and care), which will impact how long the shipper holds the temperatures. This differs from an ultra-low-temperature freezer, an active (electronically powered, compressor-driven) device, which when plugged in, is designed to maintain ultra-low temperatures indefinitely. The longer the thermal shipping container remains closed, the longer it will take for the dry ice to deplete.
- The thermal shipping container should be stored at 15° to 25° Celsius, which is 59° to 77° Fahrenheit.
- The thermal shipping container is qualified with a minimum of 23 kgs of dry ice pellets (10 mm – 16 mm pellets). Upon receipt and after opening, the box should be replenished/inspected with dry ice within 24 hours by adding dry ice to the maximum within the payload insert areas and dry ice pod.
- The thermal shipping container should be re-iced every 5 days.
 - This can help maintain the level of dry ice and the temperature of the vaccine product. It is recommended that the thermal shipping container not be opened more than 2 times a day, and shouldn't be opened for more than 1 minute at a time. If that is followed, the thermal shipping container should then be re-iced every 5 days.

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Recommendations (Using Thermal Shipping Container as Temporary Storage)	
• Local dry ice suppliers should be used for re-icing the thermal shipping container. • Temperature monitoring devices to be used if thermal shipping container is used as temporary storage. Sites are responsible for obtaining their own temperature monitoring devices to monitor temperatures when using the thermal shipping container as temporary storage. Temperature monitoring devices (probe or probeless) capable of being in a dry ice environment to be used and placed in the location of the vial tray payload area within the thermal shipping container. • The thermal shipping container should be returned within 20 business days of delivery, including temperature data logger. • If you receive a Controlant Real-Time Temperature Monitor, it must be returned with the thermal shipping container. • If you receive a Sensitech Temperature Monitor, it does not need to be returned.	

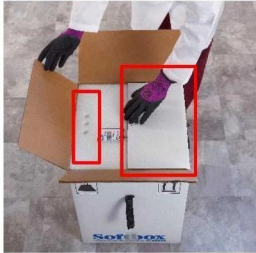
5. Procedure

5.1. Unpackaging

Responsible Role	Action Step
Operator	1. Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation.
	2. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.

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Responsible Role	Action Step
	
	3. Open the lid. Note: One side of the thermal shipping container is permanently affixed so it is recommended to use the three finger hole die-cut on the foam.  Once the lid is opened the dry ice pod will be seen as illustrated below. 
	4. While wearing insulated (thermal) gloves, take out the Dry Ice Pod.

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Responsible Role	Action Step
	
	5. Access the payload sleeve, which is on top of a thin layer of dry ice and open it.  Note: The payload sleeve does not have a bottom, so do not pull it out of the thermal shipping container.
	6. Take out the product for inspection and immediately (within one minute of opening) store in an ultra-low temperature freezer or prepare for use. If shipper will be used as temporary storage for remaining vial trays, immediately re-insert the trays within one minute of opening and follow the re-icing instructions.

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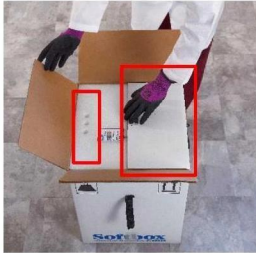
Responsible Role	Action Step
	 *Refer to Recommendations section of this procedure for further details on using the thermal shipping container as temporary storage.
	7. If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return. Dry ice must be discarded in a well ventilated area before considering returning the thermal shipping container.

5.2. Re-Icing

Responsible Role	Action Step
Operator	1. Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation.
	2. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.

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Responsible Role	Action Step
	
	3. Open the lid. Note: One side of the thermal shipping container is permanently affixed so it is recommended to use the three finger hole die-cut on the foam.  Once the lid is opened the dry ice pod will be seen as illustrated below. 
	4. While wearing insulated (thermal) gloves, take out the Dry Ice Pod.

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Responsible Role	Action Step
	 5. Fill the sides of the payload sleeve with dry ice until it's equal with the corrugated structure. 

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Responsible Role	Action Step
	
	6. Reinsert the Dry Ice Pod and fill with dry ice leaving room between dry ice level and sides of shipper. 
	7. Close the Dry Ice Pod. 
	8. Close the Lid, the Outer Corrugated Shipper and reseal with tape.

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Responsible Role	Action Step
	

6. History of changes

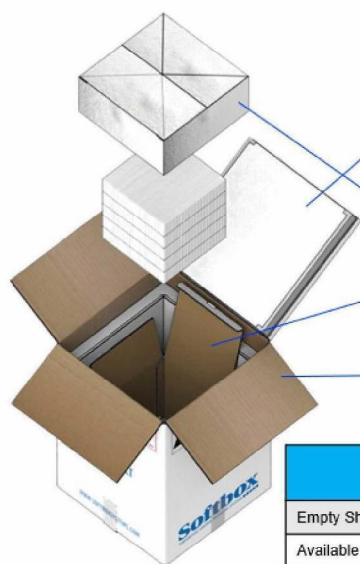
Version	History of Changes
01	Initial version
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7. Appendix

7.1 Appendix 1: Softbox Medium ULT Parcel Shipper

Note: Approximate weights are based on maximum configuration of dry ice.


ITEM	DESCRIPTION
1	VIP LID
2	DRY ICE POD
3	PAYLOAD SLEEVE (Takes 1 to 5 vial trays)
4	MEDIUM ULT THERMAL SHIPPER

Softbox Medium ULT Weights and Dimension	
Empty Shipper Weight	8.5 kgs
Available Payload Space	9.65" x 9.65" x 9.49"
External Dimension	15.75" x 15.75" x 22.04"
Amount of Dry Ice	23 kgs
Tare Weight w/ Dry Ice	31.5 kgs
Total Weight w/ 1 Vial Tray	32.6 kgs
Total Weight w/ 5 Vial Trays	36.7 kgs

Weight of Vial Tray 1.038 kgs