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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

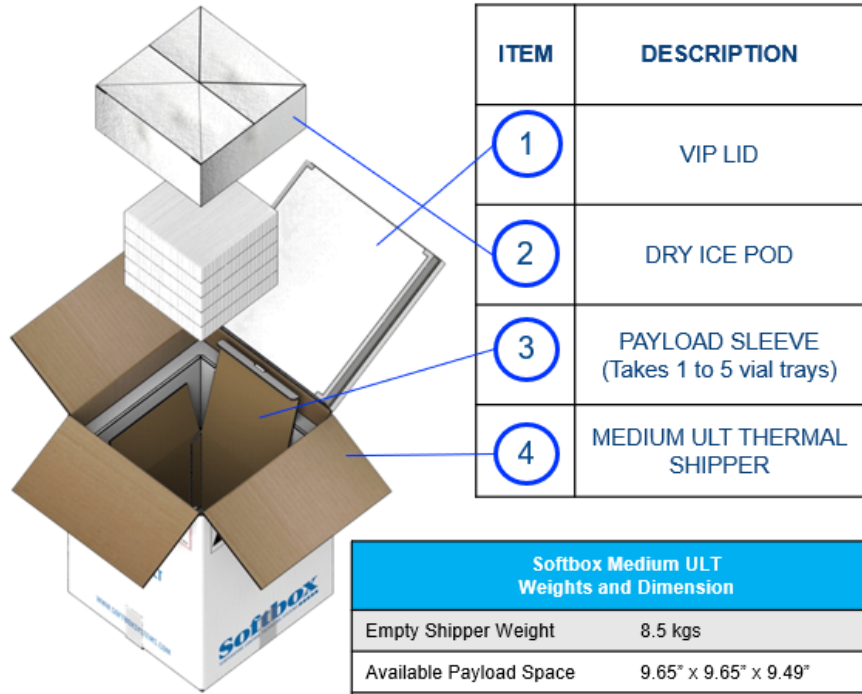
4. Approvals:

Logistics Solutions and Compliance Transport Qualification and Compliance Manager				
Author:	Name	Marci-Ann Ando	Sign/Date	Marci-Ann Ando 20 Oct 2020 20:01:043-0400 REASON: I approve this document as author. 0a1fb5f4-f692-45e0-8d06-8eb5d9529e8f
Logistics Solutions and Compliance Sr. Manager Transport Validation & Innovation				
Approved:	Name	James Jean	Sign/Date	James E Jean 20 Oct 2020 20:16:007-0400 REASON: I approve this document. 524412a2-6820-4b64-8cc4-a43540e06a26

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Appendix A: Instructions
(6 Pages)

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



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

Weight of Vial Tray 1.038 kgs

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




Unpacking Instructions of the Softbox Medium ULT Parcel Shipper

Important Note: Please read the following ancillary documents included with the shipper before performing the unpacking and/or re-icing procedure:

1. Guidelines for Safe, Storage, Use
2. Handling of Dry Ice and Carbon Dioxide, Dry Ice Safety Data Sheet

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).**

Step	Action
1.	<p>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.</p> 
2.	<p>While wearing insulated gloves, take out the Dry Ice Pod.</p> 
3.	<p>Access the payload carton under the thin layer of dry ice and open it.</p> 

4.

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.

*Refer to Recommendations section on the last page for further details on using the thermal shipper as temporary storage.





Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper




Important Note: Please read the following ancillary documents included with the shipper before performing the unpacking and/or re-icing procedure:

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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
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Step	Action
1.	<p>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.</p>
2.	<p>In a well-ventilated area, open the Outer Corrugated Shipper and open the Lid.</p> 
3.	<p>While wearing insulated gloves, take out the Dry Ice Pod.</p> 
4.	<p>Fill the sides of the shipper with dry ice until there is a thin layer of dry ice on top of the Product Carton.</p>

Step	Action
	
5.	<p>Reinsert the Dry Ice Pod and fill with dry ice leaving room between dry ice level and sides of shipper.</p> 
6.	<p>Close the Lid, close the Outer Corrugated Shipper and reseal with tape.</p> 

Recommendations:

- If the specified re-icing requirements are followed after inspecting the shipment within 24 hours of delivery, and the thermal shipping container remains unopened, the thermal shipping container can be kept for 10 days if 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 shipper 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.

- Local dry ice suppliers should be used for re-icing the thermal shipper
- Temperature monitoring is to be used if thermal shipping system is used as temporary storage. Sites are responsible for obtaining their own temperature monitoring devices to monitor temperatures when using the thermal shipping system as temporary storage. Temperature monitors capable of being in a dry ice environment to be used and placed in the location of the vial tray within the thermal shipping system.
- The thermal shipper 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.