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| | Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper | CONFIDENTIAL |

1. Purpose

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper with version control.

2. Appendices


| Appendix ID | Title |
|-------------|---|
| Appendix A | Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 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 18:48:024-0400 REASON: I approve this document as author. 0a1fb5f4-f692-45e0-8d06-8eb5d9529e8f |
| Logistics Solutions and Compliance Sr. Manager Transport Validation & Innovation | | | | |
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Appendix A: Instructions
(11 Pages)

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper

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Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper

1. Purpose

The purpose of this controlled document is to provide unpackaging and re-icing requirements on the AeroSafe 47L7 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 AeroSafe 47L7 ULT Parcel Shipper with Dry Ice.

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 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-86218 | SPEC – AeroSafe 47L7 Small 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 22 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.

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper



| Recommendations (Using Thermal Shipping Container as Temporary Storage) |
|--|
| <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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. |

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper

| Responsible Role | Action Step |
|------------------|---|
| |  |
| | <p data-bbox="612 1111 1181 1193">3. Remove the VIP Lid carefully as the temperature monitor probe is connected to the Payload Box. Care should be taken to not disconnect the probe from the Payload Box.</p>  |
| | <p data-bbox="612 1503 1181 1556">4. While wearing insulated (thermal) gloves, take out the Dry Ice Tray.</p> |

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper

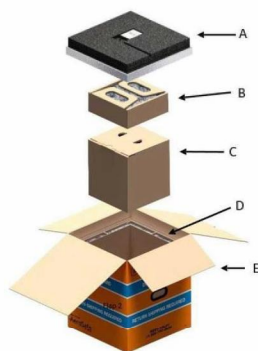
| Responsible Role | Action Step |
|------------------|--|
| |  |
| | <p>5. Remove the Payload Box from the thermal shipper by carefully pulling directly upwards. Care should be taken to not disconnect the probe from the Payload Box.</p>  |
| | <p>6. Open the Payload Box and remove the vial tray.</p> |
| | <p>7. 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 vials within tray, immediately re-insert the tray with vials within one minute of opening and follow the re-icing instructions.</p> <p>*Refer to Recommendations section of this procedure for further details on using the thermal shipping container as temporary storage.</p> |
| | <p>8. If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return.</p> |

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper

| Responsible Role | Action Step |
|------------------|--|
| | Dry ice must be discarded in a well ventilated area before considering returning the thermal shipping container. |

5.2. Re-Icing

| | Description |
|---|-------------------------|
| A | VIP Lid |
| B | Dry Ice Tray |
| C | Payload Box |
| D | Corner Dry Ice Scaffold |
| E | 47L7 Shipper |






| Responsible Role | Action Step |
|------------------|---|
| Operator | <ol style="list-style-type: none"> 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. |

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper

| Responsible Role | Action Step |
|------------------|--|
| |  |
| | <p>3. Remove the VIP lid, Item A.</p>  |
| | <p>4. While wearing insulated (thermal) gloves, take out the Dry Ice Tray, Item B as required to get better access to the Scaffolding to begin re-icing.</p> |
| | <p>5. Fill the Scaffolding, Item D of the shipper with dry ice to the top of the scaffolding.</p> |

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| Responsible Role | Action Step |
|------------------|--|
| | <p>6. Reinsert the Dry Ice Tray, Item B on top of the Payload Box, Item C. Fill the Dry Ice Tray, Item B with dry ice to the top.</p>  |
| | <p>7. Add the VIP Shipper Lid, Item A back on top.</p>  |
| | <p>8. Fold the outer corrugated flaps and reseal shipper with tape.</p>  |

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6. History of changes

| Version | History of Changes |
|---------|--|
| 01 | Initial version |
| 02 | Updated formatting and pictures for clarity. |

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7. Appendix

7.1 Appendix 1: AeroSafe 47L7 ULT Parcel Shipper

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

| ITEM | DESCRIPTION |
|------|------------------------------------|
| 1 | VIP LID |
| 2 | DRY ICE TRAY |
| 3 | PAYLOAD BOX (Takes 1 vial tray) |
| 4 | 47L7 THERMAL SHIPPER |

| Aerosafe 47L7 Weights and Dimension | |
|--|-----------------------|
| Empty Shipper Weight | 9.4 kgs |
| Available Payload Space | 9.75" x 9.75" x 9.75" |
| External Dimension | 17.5" x 17.5" x 21.5" |
| Amount of Dry Ice | 22 kgs |
| Tare Weight w/ Dry Ice | 31.4 kgs |
| Total weight w/ 1 vial tray | 32.5 kgs |

| | |
|---------------------|-----------|
| Weight of Vial Tray | 1.038 kgs |
|---------------------|-----------|