The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields. To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

THERMAL SHIPPING CONTAINER TEMPORARY STORAGE DRY ICE REPLACEMENT INSTRUCTIONS

Follow the instructions and requirements outlined in this booklet when using the thermal shipping container for temporary storage of the Pfizer-BioNTech COVID-19 Vaccine. The thermal shipping container may be used as temporary storage for up to 30 days from delivery.

Note: Please read the following ancillary documents included with the thermal shipping container before unpacking and/or replenishing dry ice in the thermal shipping container:

1. Dry Ice Safety Data Sheet
2. Shipping and Handling Guidelines

Also available by visiting www.cvdvaccine-us.com.

IMPORTANT INFORMATION

- **24 hours:** The thermal shipping container is qualified with a minimum of 20 kg of dry ice pellets (10 mm–16 mm pellets). If you are using the thermal shipping container as temporary storage, the container must be opened, inspected, and replenished with dry ice within 24 hours of receipt.

- For the thermal shipping container to maintain the ultra-low temperatures required, it is recommended that the thermal shipping container itself be stored at 15° to 25° Celsius (59° to 77° Fahrenheit).

- To help maintain the level of dry ice and the temperature of the vaccine product:
  - **2x/Day:** It is recommended that the thermal shipping container not be opened more than 2 times a day.
  - **3 Minutes:** The thermal shipping container should not be opened more than 3 minutes at a time.
  - **5 Days:** Replenish dry ice in the thermal shipping container every 5 days.

- If more frequent openings are necessary more frequent dry ice replenishment will be required. Be sure to replenish dry ice in the thermal shipping container at the end of business on days when the vaccination site will be closed the following day, such as weekends or holidays.

- For information on handling the vial trays and vials, please visit www.cvdvaccine-us.com.

- After use, the thermal shipping container and the temperature-monitoring device must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources.
**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, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields. To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

**SOFTBOX THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS**

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, causing asphyxiation.

2. Below is an overview of the components within the thermal shipping container for dry ice replenishment.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A DRY ICE POD</td>
<td></td>
</tr>
<tr>
<td>B VIAL TRAYS</td>
<td></td>
</tr>
<tr>
<td>C BOX THAT HOLDS THE VIAL TRAYS</td>
<td></td>
</tr>
<tr>
<td>D FOAM LID</td>
<td></td>
</tr>
<tr>
<td>E THERMAL SHIPPING CONTAINER</td>
<td></td>
</tr>
</tbody>
</table>

3. In a well-ventilated area, open the thermal shipping container (E) by cutting the tape on the outside of the box. Lift the foam lid (D) using the three finger holes.

4. The dry ice pod (A) is visible. While wearing waterproof insulated gloves, lift out the dry ice pod (A).

5. Fill any low areas in the side compartments of the thermal shipping container (E) with dry ice pellets until completely filled, so that it is equal with but does not exceed the top edges of the box that holds the vial trays (C).

6. Reinsert the dry ice pod (A) on top of the box that holds the vial tray. Then fill the dry ice pod (A) to the top with dry ice (do not overfill).
Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields. To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

SOFTBOX THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS (CONT’D)

7. Close the dry ice pod (A), ensuring that it is flush with the top edge of the thermal shipping container (E) to maintain the required temperatures.

8. Close the foam lid (D) and the thermal shipping container (E) and reseal with tape. To maintain required temperature, it is critical that the container lid is flush and properly taped shut. Store in a well-ventilated location.

AEROSAFE THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS

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, causing asphyxiation.

2. Below is an overview of the components within the thermal shipping container for dry ice replenishment.

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<th>Item</th>
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<tbody>
<tr>
<td>A</td>
<td>DRY ICE POD</td>
</tr>
<tr>
<td>B</td>
<td>VIAL TRAYS</td>
</tr>
<tr>
<td>C</td>
<td>ALUMINUM INNER LINING</td>
</tr>
<tr>
<td>D</td>
<td>FOAM LID</td>
</tr>
<tr>
<td>E</td>
<td>THERMAL SHIPPING CONTAINER</td>
</tr>
</tbody>
</table>

3. In a well-ventilated area, open the thermal shipping container (E) by cutting the tape on the outside. Gently open the AeroSafe lid using the cutout in the foam lid (D).

4. The dry ice pod (A) is visible. While wearing waterproof insulated gloves, lift out the dry ice pod (A).

5. Fill any low areas in the side compartments of the thermal shipping container (E) with dry ice pellets until completely filled, so that it is equal with but does not exceed the top edges of the side compartments.
**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, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields. To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

**AEROSAFE THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS (CONT’D)**

**6** Reinsert the dry ice pod (A) into the aluminum lining cavity, which holds the vial trays. The dry ice pod has a ledge that rests on the aluminum lining. Then fill the dry ice pod (A) to the top with dry ice (do not overfill).

**7** Close the foam lid (D) and the thermal shipping container (E) and reseal with tape. To maintain required temperatures, it is critical that the container lid is flush and properly taped shut.

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Emergency Use Authorization Holder

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.

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