To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents from the thermal shipping container and consult with your Occupational Health Department.

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.

TABLE OF CONTENTS

CONNECT WITH US ............................................................................................................. 3
GENERAL INFORMATION .................................................................................................... 4
FACTS ABOUT DRY ICE .................................................................................................... 4
HANDLING .......................................................................................................................... 5
GENERAL SAFETY GUIDANCE FOR DRY ICE ............................................................... 6
VENTILATION .................................................................................................................... 7
BURN TREATMENT ............................................................................................................ 7
DISPOSAL ............................................................................................................................ 7
CONTENTS AND PACKAGING ....................................................................................... 8-9
UNPACKING ...................................................................................................................... 10-12
DISCARDING DRY ICE ..................................................................................................... 13
RETURNING THE THERMAL SHIPPING CONTAINER .............................................. 14-15

Current as of May 19, 2021. For the most up-to-date brochure, visit www.cvdvaccine-us.com.
CONNECT WITH US

For general questions about the Pfizer-BioNTech COVID-19 Vaccine, visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com) or call the telephone number provided below.

[www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)

1-877-VAX-C019
(1-877-829-2619)
GENERAL INFORMATION

This guide details user processes and procedures that must be followed upon receiving the 25-pack cartons of the Pfizer-BioNTech COVID-19 Vaccine.

The nature of this vaccine requires it to be kept at extremely low temperatures during shipment. To achieve this, multiple dose vials of the frozen vaccine are shipped in insulated thermal shipping containers containing dry ice. This allows the vaccine to remain frozen at this low temperature.

For information about specific temperature requirements and ranges to monitor, as well as dry ice safety, storage, and handling, please go to www.cvdvaccine-us.com.

FACTS ABOUT DRY ICE

Dry ice is the frozen form of carbon dioxide. When heated, most frozen solids melt to a liquid form, but dry ice transforms directly into a gas (sublimation). Dry ice sublimes at temperatures at or above -109°F (-78°C).

The main hazards of dry ice include asphyxiation and burns. 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. To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents from the thermal shipping container and consult with your Occupational Health Department.
HANDLING

Use caution when lifting the shipping container, as it may be heavy. Depending on the amount of vaccine ordered, the shipping container can weigh approximately 29 kg to 33 kg (64 lb to 73 lb). Do not place anything on top of the thermal shipping container. Contact Pfizer Customer Service at 1-877-VAX-CO19 (1-877-829-2619) immediately to communicate any issues.

Do not open the vial cartons or remove vials until you are ready for thawing or use. Visit www.cvdvaccine-us.com for further information.

You will need to take precautions when preparing to handle dry ice. 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. Make sure you are wearing safety goggles or safety glasses with side shields and waterproof insulated gloves when handling dry ice.

To ensure all appropriate safeguards are in place, review the Dry Ice Safety Data Sheet, and consult with your Occupational Health Department.

In the event of vial breakage, damage, or leakage, to prevent cuts and exposure to the vaccine, do not handle the vial with bare hands. Wear protective gloves and dispose of the vial pieces in a medical sharps container using forceps, tongs, or other appropriate tools.
<table>
<thead>
<tr>
<th><strong>Do not touch - avoid eye contact</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Use waterproof insulated gloves when removing or adding dry ice to prevent cold burns and frostbite. Avoid contact with face and eyes. Wear safety glasses with side shields or safety goggles.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Do not eat</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry ice is harmful if eaten or swallowed. If ingested, seek immediate medical care.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Do not store in confined spaces</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry ice changes to a gas very rapidly at room temperature, displacing oxygen. Only use dry ice in open or well-ventilated areas.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Do not place in airtight containers</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Airtight containers may explode as dry ice rapidly expands to a gas when exposed to temperatures above -109°F (-78°C).</td>
</tr>
</tbody>
</table>
VENTILATION
At room temperature (including most cold storage temperatures), dry ice becomes carbon dioxide gas, which may cause difficulty breathing or suffocation. If dry ice has been in a closed area, trailer, or container, open doors and allow adequate ventilation before entering. **If you feel short of breath or develop a headache, these may be signs that you have inhaled too much carbon dioxide. Leave the area immediately.** Carbon dioxide is heavier than air and accumulates in low, poorly ventilated spaces.

Operational practices for accessing a closed area where dry ice is present should be reviewed and agreed upon with your Occupational Health and Safety officer.

BURN TREATMENT
Dry ice may cause cold burns to the skin. Use waterproof insulated gloves when handling dry ice. Seek medical care as directed by the Dry Ice Safety Data Sheet.

DISPOSAL
Once dry ice is no longer needed, open the container and leave it at room temperature in a well-ventilated area. It will readily sublime from a solid to a gas. DO NOT leave dry ice in an unsecured area. DO NOT place in drain or flush in toilet. DO NOT dispose in trash. DO NOT place in a closed area such as an airtight container or walk-in cooler.
The thermal shipping container you received is approximately 29 kg to 33 kg (64 lb to 73 lb) and should be opened on the floor, as it may be heavy.

**CONTENTS AND PACKAGING**

There are two types of thermal shipping containers: a Softbox thermal shipping container and an AeroSafe thermal shipping container. Their outer appearance is different, but their components are very similar. **Do not discard the original thermal shipping container or any of its components.**

### Softbox

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A DRY ICE POD</td>
<td>Holds the top layer of dry ice</td>
</tr>
<tr>
<td>B X-DIVIDER</td>
<td>Cardboard X-divider placed on top of the bagged vial cartons to ensure the bagged vial cartons stay in place</td>
</tr>
<tr>
<td>C VIAL CARTONS* IN BAG</td>
<td>Each carton contains 25 multiple dose vials</td>
</tr>
<tr>
<td>D FOAM LID</td>
<td>Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box</td>
</tr>
<tr>
<td>E BOX THAT HOLDS THE VIAL CARTONS</td>
<td>Box within the thermal shipping container that includes the vial cartons. This box should not be removed. The 25-pack cartons are placed into a bag before being placed into the box</td>
</tr>
<tr>
<td>F THERMAL SHIPPING CONTAINER</td>
<td>Outer box of the thermal shipping container</td>
</tr>
</tbody>
</table>

*There are scenarios where you could receive more than the depicted amount.
## AeroSafe

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. DRY ICE POD</td>
<td>Holds the top layer of dry ice</td>
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<td>Cardboard X-divider placed on top of the bagged vial cartons to ensure the bagged vial cartons stay in place</td>
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<tr>
<td>C. VIAL CARTONS* IN BAG</td>
<td>Each carton contains 25 multiple dose vials</td>
</tr>
<tr>
<td>D. FOAM LID</td>
<td>Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box</td>
</tr>
<tr>
<td>E. ALUMINUM INNER LINING</td>
<td>Structure that holds the vial cartons in place, is integrated into the thermal shipping container. The 25-pack cartons are placed into a bag before being placed into the aluminum inner lining</td>
</tr>
<tr>
<td>F. THERMAL SHIPPING CONTAINER</td>
<td>Outer box of the thermal shipping container</td>
</tr>
</tbody>
</table>

*There are scenarios where you could receive more than the depicted amount.
# UNPACKING THERMAL SHIPPING CONTAINERS

<table>
<thead>
<tr>
<th>Step Instructions</th>
<th>Softbox</th>
<th>AeroSafe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong></td>
<td>For both types of thermal shipping containers, you must first break the seal to open.</td>
<td><img src="image1.png" alt="Softbox lid" /></td>
</tr>
</tbody>
</table>

| **2** | When you open the thermal shipping container, **you will see a temperature-monitoring device embedded in the foam lid.**  
Take caution when opening the thermal shipping containers. On the Softbox lid, you’ll notice one flap of the thermal shipping container is permanently affixed to the lid. Do not pull this flap. When opening the lid, use the three finger holes in the foam lid, which will then allow the lid to swing open.  
Gently open the AeroSafe lid using the cutout in the foam lid. | ![Softbox lid](image1.png) | ![AeroSafe lid](image2.png) |
| | ![The lids of both the Softbox and AeroSafe thermal shipping containers will remain attached to the outer box of the thermal shipping container.](image3.png) | }
The temperature-monitoring device continuously tracks the temperature during shipment to ensure the frozen vaccine product has been maintained at the required temperature during transport to vaccination centers. **Upon receipt, press and hold the stop button for 5 seconds. Sites are responsible for continuing to monitor the product storage temperature.**

Information about temperature monitoring can be found at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

**3**

Make sure that you are now wearing waterproof insulated gloves and safety goggles or safety glasses with side shields as you prepare to handle layers of the container that have dry ice.

Beneath the foam lid is the dry ice pod, which holds a layer of dry ice to help maintain the temperature of the multiple dose vials.

There will also be dry ice in compartments in the container that surround the box that holds the vial cartons.

Using your waterproof insulated gloves, remove the dry ice pod.

**4**

The Softbox thermal shipping container has compartments that allow dry ice to be distributed on all sides of the box. They are only accessible after removing the dry ice pod.

The AeroSafe thermal shipping container has dry ice compartments on the sides that can be accessed with the dry ice pod still in the container.
Each vial carton contains 25 multiple dose vials.

Remove the X-divider (as applicable) from the thermal shipping container to get to the bag that contains the vial cartons. Carefully open the bag to remove the vial cartons. Please note that the bag is not a storage option and does not provide cold-chain protection.

You must immediately store the vaccine product, preferably in an ultra-low-temperature (ULT) freezer. The thermal shipping container included with your supply of 25-pack cartons is meant to be returned within 10 days of delivery and should not be used as temporary storage.

Storage options for the 25-pack cartons include a ULT freezer (preferred) at -80°C to -60°C (-112°F to -76°F) until expiry date printed on label, a freezer for 2 weeks at -25°C to -15°C (-13°F to 5°F), or a refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. For important additional details about transferring between storage environments, please see www.cvdvaccine-us.com/product-storage-and-dry-ice.

Important Note: Do not open the vial cartons or remove vials until you are ready for thawing or use. Visit www.cvdvaccine-us.com for further information.

Review the Pfizer-BioNTech COVID-19 Vaccine Safety Data Sheet (available by visiting https://safetydatasheets.pfizer.com/).
DISCARDING DRY ICE

The thermal shipping container included with your supply of 25-pack cartons is meant to be returned within 10 days of delivery and should not be used as temporary storage. Prior to returning the thermal shipping container, please discard the dry ice. Take necessary precautions by reviewing the Dry Ice Safety Data Sheet, and consult with your Occupational Health Department.

To discard, open the thermal shipping container and leave it at room temperature in a well-ventilated area. It will sublime from a solid to a gas. DO NOT leave dry ice in an unsecured area. DO NOT place in drain or flush in toilet. DO NOT dispose in trash. DO NOT place in a closed area such as an airtight container or walk-in cooler.

Masks were worn due to pandemic; refer to SDS for dry ice protection.

For information about specific temperature requirements and ranges to monitor and temporary storage information, please go to www.cvdvaccine-us.com.

In the US, issues with the shipment should be immediately communicated to Pfizer Customer Service at 1-800-666-7248. For countries outside of the US, visit www.pfizer.com/products/product-contact-information to see the list of Pfizer’s Global Medical Information Numbers.
RETURNING TEMPERATURE-MONITORING DEVICE AND THERMAL SHIPPING CONTAINER

Within 10 days of receipt, the thermal shipping container, including the temperature-monitoring device, must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources.

When the thermal shipping container is ready to be returned, and all the components are inside, seal it with tape. A preprinted return shipping label will be included inside the thermal shipping container or already adhered to the flap of the thermal shipping container.

**Contact the carrier identified on the return label to arrange the return.**

When coordinating the return of the Softbox thermal shipping container, apply the preprinted return shipping label over the existing shipping label.

The AeroSafe thermal shipping container has a peel-away tape backing under the flaps to seal the container closed. When coordinating the return of the AeroSafe thermal shipping container, follow instructions on the flap of the thermal shipping container to ensure the return label is facing outside.

**Ensure Authenticity—Help Prevent Counterfeiting:** Ensure the safety of the vaccine vials by limiting access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, discard vaccine vials in sharps containers and empty vial cartons as medical waste or deface or safely crush all materials so they cannot be reused. Remember, Pfizer-BioNTech COVID-19 Vaccines are only available through government-authorized vaccination centers – such as hospitals, outpatient clinics, pharmacies, and community vaccination locations. The Pfizer-BioNTech COVID-19 Vaccine can only be administered by licensed healthcare professionals, or other individuals that are approved vaccinators, at government-authorized vaccination sites. Individual doses are not for sale.

**Elements Required for Return**

- Thermal shipping container and inner components
- Temperature-monitoring device
- Dry ice pod
Note: Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipping container are covered by placing a blank label over them in preparation for the return, as the container no longer contains dry ice.

For Softbox, blank sticker labels to place over the UN1845 markings can be found on the back page of the Shipping and Handling Guidelines.

For AeroSafe, a label can be found on the inside flap of the thermal shipping container. This label is to cover both the UN1845 markings and the original shipping label.

For assistance on returns, you can contact:
US number: +1 701-540-4039
EU/UK number: +44 161-519-6199
pfizer.logistics@controlant.com

Additional contacts for AeroSafe returns:
US number: +1 855-551-4919
returns@aerosafeglobal.com

Place the thermal shipping container at a designated pickup location.
Use peel-off stickers to cover UN1845 markings.
Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipping container are covered by placing blank labels over them, in preparation for the return, as the container no longer contains dry ice.