Pfizer-BioNTechCOVID-19 Vaccine

SHIPPING AND HANDLING GUIDELINES

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 U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 12 years of age and older. Pfizer-BioNTech COVID-19 Vaccine is authorized for use to provide: a two-dose primary series in individuals 12 years of age and older; a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and a single booster dose in individuals: 65 years of age and older -18 through 64 years of age at high risk of severe COVID-19 - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech that is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a 2-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older. It is also authorized for emergency use to provide: a two-dose primary series in individuals 12 through 15 years; a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and a single booster dose in individuals: 65 years of age and older- 18 through 64 years of age at high risk of severe COVID-19 - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.
Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine.com.

Current as of 22-September -2021. For the most up to date brochure, visit www.cvdvaccine.com.

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CONNECT WITH US

For general questions about the Pfizer-BioNTech COVID-19 Vaccine, visit **www.cvdvaccine.com** or call the telephone number provided below.

www.cvdvaccine.com

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.

GENERAL INFORMATION

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

The nature of this vaccine requires it to be kept at extremely low temperatures **during shipment and storage after it arrives**. 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.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

When you receive the thermal shipping container, inspect to confirm you received the number of vial trays you ordered. **Do not open the vial trays or remove vials until you are ready for thawing or use.** Visit www.cvdvaccine.com for further information. 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 36.5 kg (81 lb). Do not stack or place anything on top of the thermal shipping container.

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 glasses with side shields or safety goggles 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.

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

GENERAL SAFETY GUIDANCE FOR DRY ICE 'CAUTION'

Do not touch - avoid eye contact

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.

Do not eat

Dry ice is harmful if eaten or swallowed. If ingested, seek immediate medical care.

Do not store in confined spaces

Dry ice changes to a gas very rapidly at room temperature, displacing oxygen. Only use dry ice in open or well-ventilated areas.

Do not place in airtight containers

Airtight containers may explode as dry ice rapidly expands to a gas when exposed to temperatures above -109°F (-78°C).

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.

DRY ICE REPLENISHMENT

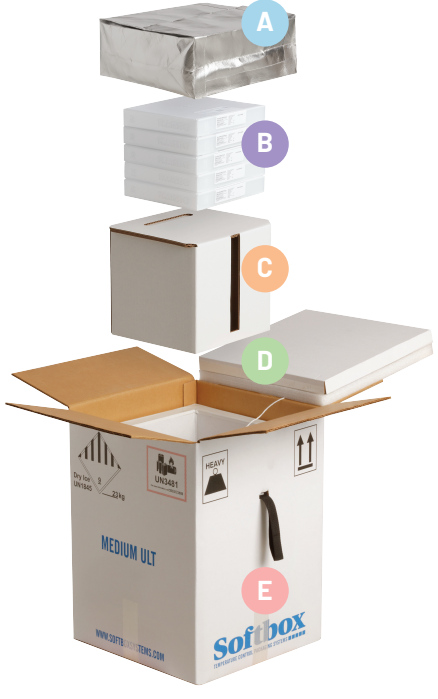
The thermal shipping container can be used as a temporary storage device. For dry ice replenishment requirements, dry ice pellet size, and pack-out instructions for re-icing the thermal shipping container, visit www.cvdvaccine.com. Follow the Guidelines for Safe Storage and Handling of Dry Ice.

The thermal shipping container you received is approximately 36.5 kg (81 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



Item	Description
A DRY ICE POD	*Holds the top layer of dry ice*
B VIAL TRAYS	*Vial trays look like small pizza boxes. Each vial tray contains multiple dose vials. Each thermal shipping container will have up to 5 vial trays inside*
C BOX THAT HOLDS THE VIAL TRAYS	*Box within the thermal shipping container that includes the vial trays. This box has handles and can be fully removed from the thermal shipping container*
D FOAM LID	*Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box*
E THERMAL SHIPPING CONTAINER	*Outer box of the thermal shipping container*

AeroSafe

Item	Description
A DRY ICE POD	*Holds the top layer of dry ice*
B VIAL TRAY	*Vial trays look like small pizza boxes. Each vial tray contains multiple dose vials*
C BOX THAT HOLDS THE VIAL TRAY	*Box within the thermal shipping container that includes the vial tray. This box can be fully removed from the thermal shipping container*
D FOAM LID	*Top foam lid that can be removed from the AeroSafe thermal shipping container. The temperature-monitoring device is located in a foam pocket on the top of the lid*
E THERMAL SHIPPING CONTAINER	*Outer box of the thermal shipping container*

UNPACKING THERMAL SHIPPING CONTAINERS

Step Instructions

Softbox **AeroSafe**

1 For both types of thermal shipping containers, you must first break the seal to open.

2 When you open the thermal shipping container, **you will see a temperature-monitoring device embedded in the foam lid**. In the Softbox thermal shipping container, this lid will be attached to the thermal shipping container.

Take caution when opening the Softbox lid as 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.

When opening the AeroSafe foam lid, gently remove the entire lid (with the temperature-monitoring device still attached) and place to the side.

The Softbox thermal shipping container has an attached foam lid, which is permanently affixed to the lid.

The AeroSafe thermal shipping container has a foam lid that comes completely off.

3 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.**

The temperature-monitoring device you receive will be either a Controlant Real-Time Monitor (pictured above to the left) or a Sensitech Temperature Monitor (pictured above to the right).

Information about temperature monitoring, including devices, can be found at www.cvdvaccine.com.

4 Make sure that you are now wearing waterproof insulated gloves and safety glasses with side shields or safety goggles 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 trays.

If using the thermal shipping container as temporary storage, both of those areas will need to be filled when re-icing.

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

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 tray looks like a small pizza box, and contains multiple dose vials. When diluted, each multiple dose vial contains 6 doses.

5 You will now see a lid for the box that holds the vial trays.

Open the box and you will see the vial trays. There will be up to 5 vial trays inside.

Remove the box that holds the vial trays from the thermal shipping container in order to access and remove the vial trays.

CAUTION: If you feel resistance when trying to remove the box that holds the vial trays, do not pull it out by force. Keep the box inside the thermal shipping container and remove the vial trays separately using the clear plastic straps.

Remember, do not open the vial trays or remove vials until you are ready for thawing or use. Visit www.cvdvaccine.com for further information.

6 Review the Pfizer-BioNTech COVID-19 Vaccine Safety Data Sheet (available by visiting **https://www.pfizer.com/products/safety-data-sheets**).

After removing the vial trays from the thermal shipping container, you must immediately store the vaccine product in the ultra-low-temperature (ULT) freezer.

Masks were worn due to pandemic.

If a ULT freezer is not available, the thermal shipping container may be used as temporary storage. If using the thermal shipping container as temporary storage, it must be opened, inspected, and replenished within 24 hours of receipt.

For information about specific temperature requirements and ranges to monitor, temporary storage information, and re-icing the thermal shipping container, please go to www.cvdvaccine.com.

DISCARDING DRY ICE

After the thermal shipping container is no longer needed to store the vaccine, you can 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.

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RETURNING TEMPERATURE-MONITORING DEVICE AND THERMAL SHIPPING CONTAINER

The thermal shipping container may be used as temporary storage for up to 30 days from delivery.

After use, 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 inner flap of the thermal shipping container. When coordinating the return of the Softbox thermal shipping container, apply the preprinted return shipping label over the existing shipping label. When coordinating the return of the AeroSafe thermal shipping container, follow instructions on the inner flap of the thermal shipping container to ensure the return label is facing outside.
You can contact the carrier identified on the return label to arrange the return.

Discard empty vial trays as medical waste so they cannot be reused.

Elements Required for Return

Softbox:

- Temperature-monitoring device
- Foam Lid (remains attached to box)
- Dry Ice Pod
- Box that holds the vial trays

AeroSafe:

- Temperature-monitoring device
- Foam Lid (can be fully removed from box)
- Dry Ice Pod
- Box that holds the vial trays

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.

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

For assistance on returns, you can contact:

pfizer.logistics@controlant.com

Place the thermal shipping container at the front desk, or 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.

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