

# PFIZER-BIONTECH COVID-19 VACCINE

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## THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS

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](http://www.cvdvaccine.com).



Current as of 22-September 2021. For the most up-to-date brochure, visit [www.cvdvaccine.com](http://www.cvdvaccine.com).

**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 from the thermal shipping container and consult with your Occupational Health Department.

## THERMAL SHIPPING CONTAINER TEMPORARY STORAGE RE-ICING 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 re-icing the thermal shipping container:

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

Also available by visiting [www.cvdvaccine.com](http://www.cvdvaccine.com).

## IMPORTANT INFORMATION

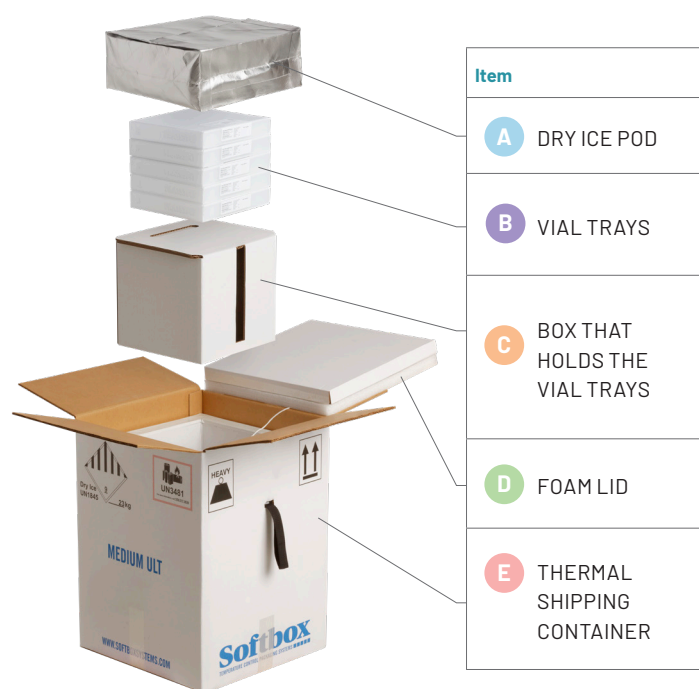
- **24 hours:** The thermal shipping container is qualified with a minimum of 20 kg of dry ice pellets (10 mm–16 mm pellets). If you are using the thermal shipping container as temporary storage, **the container must be opened, inspected, and replenished with dry ice within 24 hours of receipt**
- For 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:** The thermal shipping container should be re-iced **every 5 days**
- If more frequent openings are necessary more frequent dry ice replenishment will be required. Ensure that the thermal shipping container is re-iced at the end of business on days when the vaccination site will be closed the following day, such as weekends or holidays
- **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 from the thermal shipping container and consult with your Occupational Health Department.

## SOFTBOX THERMAL SHIPPING CONTAINER RE-ICING 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 re-icing activities.



**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.



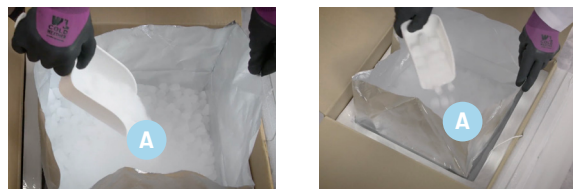
**4** The dry ice pod (**A**) is visible. While wearing waterproof insulated gloves, lift out the dry ice pod (**A**).



**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).



**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 from the thermal shipping container and consult with your Occupational Health Department.

### SOFTBOX THERMAL SHIPPING CONTAINER RE-ICING 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.



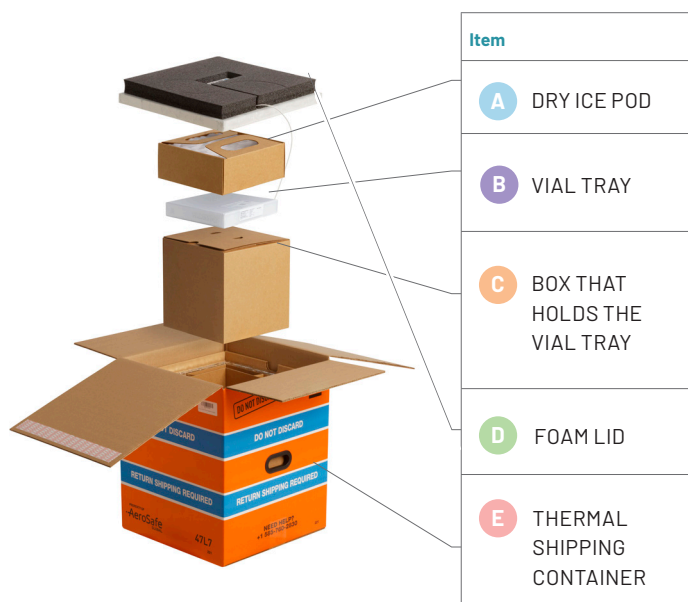
**8** Close the foam lid (**D**) and the thermal shipping container (**E**) and reseal with tape. To maintain required temperature, it is critical that the container lid is flush and properly taped shut. Store in a well-ventilated location.



### AEROSAFE THERMAL SHIPPING CONTAINER RE-ICING 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 re-icing activities.



**3** In a well-ventilated area, open the thermal shipping container (**E**) by cutting the tape on the outside. Lift and remove 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 from the thermal shipping container and consult with your Occupational Health Department.

## AEROSAFE THERMAL SHIPPING CONTAINER RE-ICING INSTRUCTIONS (CONT'D)

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- 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 over fill).



- 7** Add the foam lid (**D**) back on top of the dry ice pod ensuring that it is flush with the top edge of the thermal shipping container (**E**) to maintain the required temperatures.



- 8** Fold the outer flaps and reseal the thermal shipping container (**E**) with tape. To maintain required temperatures, it is critical that the container lid is flush and properly taped shut.



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