

VACCINE PROVIDER PLAYBOOK POINT OF CARE

Indiana Department of Health

May 2021



Introduction

The Indiana Department of Health has developed a process for primary care providers in Indiana to order vaccine directly for in office patient administration. The playbook will guide interested participants through the process of becoming an enrolled provider, ordering vaccine, receiving and storing vaccine, and administering vaccine to their patients. Physicians who have additional questions while reviewing the information in this document are encouraged to reach out to the IDOH point of contact identified in the table below:

Point of Contact Information		
Name Email		
Primary Katie Lamoreaux KLamoreaux@isdh.IN.gov		KLamoreaux@isdh.IN.gov
Secondary Gina Bindley GBindley@isdh.in.gov		GBindley@isdh.in.gov

Vaccine Provider Process

Step 1: Provider Enrollment

Before receiving COVID-19 vaccine, providers must enroll to receive and administer COVID-19 vaccine. Provider enrollment is mandated by the federal government. IDOH has developed an electronic COVID-19 vaccination provider agreement form. This form can be completed at <u>https://eportal.isdh.in.gov/CovidProviderEnrollment/</u>. The linked portal also collects information required by the Centers for Disease Control and Prevention (CDC).

Step 2: Vaccine Scheduling and Reporting

Providers are expected to schedule and report COVID-19 vaccine administration through their own EMR system. If your EMR does not have a bi-directional interface with the Children and Hoosier Immunizations Registry Program (CHIRP) you must contact your primary point of contact at IDOH (identified in the table above) to ensure your data is being correctly recorded. Due to regulations surrounding the COVID-19 vaccine, vaccine administration must be entered in CHIRP regardless of age.

Providers should not order vaccine through the Indiana Immunization Information System (IIS). Ordering will be done through REDCap as explained in the next section of this document.

Step 3: Vaccine Ordering

Vaccine ordering will occur weekly through a REDCap survey that should only be filled out by providers who have enrolled as a provider through the portal. The survey will require providers to input their PIN,



contact information and how much vaccine they would are requesting for the following week. Providers will have until 9 a.m. EDT Wednesday to submit the survey. IDOH will then order the requested vaccine through VOMS. Providers should expect to receive their vaccine no later than noon EDT on the following Wednesday. Ancillary supplies (including diluent in the case of the Pfizer vaccine) will be delivered with the vaccine shipment. See below for a sample cadence of vaccine requests and delivery:

Vaccine Ordering Cadence						
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Vaccine Provider Inv Survey Open	ventory Request	Survey due at 9AM		Vaccine Provider Ir	wentory Request Surv	rey Open
Vaccine Provider Inv Survey Open	ventory Request	Survey due at 9AM				
		Vaccine Shipment Arrival by 12 PM				

Providers will, by default, receive Pfizer vaccine. The minimum order is 60 doses (10 vials=6 doses per vial), and any additional requested doses with be in increments of 60. Concerns about wastage or inability to utilize 6 doses is explained in further sections. Requests for other types of vaccines should be discussed with your primary contact.

The weekly REDcap survey link to order Pfizer vaccine is located below:

https://redcap.isdh.in.gov/surveys/?s=CJCYTKF84Y

This link will not change and <u>must</u> be filled out by 9 a.m. EDT on Wednesday every week in order to receive vaccine by the following Wednesday. If providers do not wish to request additional vaccine, they do not need to fill out the survey.

Step 4: Second Dose Scheduling

Providers must schedule patients for second doses at their facility when administering the first dose of either the Pfizer or Moderna vaccines. The table below describes the CDC recommended dose windows for the COVID-19 vaccines. It is highly recommended that second doses occur within these windows for maximum efficacy.

	Second Dose Windows	
Pfizer	Moderna	Johnson & Johnson (Janssen)
21 – 42 Days	28 – 42 Days	single-dose only



Additional Information

Resources

Ancillary supplies will be included with the vaccine. You will receive a complementary amount that matches amount of vaccine that you are requesting. The ancillary supplies will be shipped directly to you. Provided ancillary supplies will not include gloves, Band-Aids and sharps containers. Please see attached CDC Product Information Guide for COVID-19 Vaccines and Associated Supplies.

Storage and Handling



Indiana Department of Health Immunizations Division COVID-19 Vaccine Storage Temperature Requirements

Temperature Monitoring Guidelines:

- 1. Check and record the min/max temperatures of the storage units each day using a temperature monitoring device.
- 2. If your temperature monitoring device does not automatically record min/max temperatures, record the temperature at the start and end of each workday.

Pfizer-BioNTech COVID-19 Vaccine Storage Temperature Requirements		
 Frozen Storage Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of - 80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at - 25°C to -15°C (-13°F to 5° F) should be tracked and should not exceed 2 weeks. 	 Ultra-Cold Storage Store as frozen liquid at -80°C to - 60°C for up to 6 months. Storage of the vials between -96° C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. 	
 Refrigerator Storage Can be stored at 2°C to 8°C (35°F to 46°F) up to 5 days. Room temperature hold time is no more than 2 hours. Thaw from frozen for 3 hours at 2°C to 8°C (35°F to 46°F) or 30 minutes at room temperature for immediate use. Post dilution in use period is 6 hours. 	Room Temperature Storage • No more than 2 hours	
Thawing	Options	
 Option 1 Transfer frozen vials immediately to refrigerator, and thaw for 3 hours at 2°C to 8°C (35°F to 46°F). Vials may be stored in refrigerator for up to 5 days or 120 hours before dilution. 	 Option 2 Thaw at room temperature for 30 minutes if using immediately. Vials may be held at room temperature for no more than 2 hours prior to dilution. 	
DO NOT REFREEZE THAWED VIALS		



Wastage

It is expected that there will be times when doses from a vial are wasted in order to vaccinate a few individuals. Wastage should be avoided if possible, but please administer to anyone who wants the vaccine. We encourage you to take every opportunity to vaccinate, even if the rest of the vial may not be used. In the case of vaccine wastage, you will need to fill out the <u>vaccine wastage form</u>.

Communications

The Indiana Department of Health has created a <u>provider toolkit</u> to help you communicate with patients regarding COVID-19 vaccination.

The toolkit includes:

- Vaccine posters for waiting areas and exam rooms (English/Spanish)
- After Vaccination Palm Cards with post-vaccination information on all three vaccine types in English/Spanish
- Vaccine hesitancy information: Includes sample communication, tips and other resources
- How to talk to patients
- Youth fact sheet for families with children ages 12-15
- Vaccine effectiveness in Indiana one-sheeter for patients

Adverse Reactions

In the case of an adverse reaction, vaccine recipients and healthcare providers are encouraged to report vaccine reactions to the Vaccine Adverse Event Reporting System (VAERS). VAERS accepts and analyzes

reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.

Providers can also encourage vaccine recipients to sign up for V-safe, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after someone receives a COVID-19 vaccination. Through vsafe, vaccine recipients can quickly tell CDC if they have any side effects after getting the COVID-19 vaccine. Depending on their responses, CDC may follow up with them by phone to get more information. V-safe will also remind them to



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get their second COVID-19 vaccine dose, if needed. CDC is requesting that healthcare providers give patients a V-safe information sheet at the time of vaccination and encourage them to enroll and fill out the surveys when prompted to do so. Vaccinated individuals should register online at <u>https://vsafe.cdc.gov/</u>.

Next Steps

In the future, IDOH plans to move the majority of distribution and ordering vaccines to Langham Logistics. This will ensure that the process is sustainable and as efficient as possible. This process is still under development – IDOH will provide further information as the situation develops.

For additional information, including clinical resources, please visit <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html</u>

Information Attached: CDC Product Information Guide for COVID-19 Vaccines and Associated Supplies

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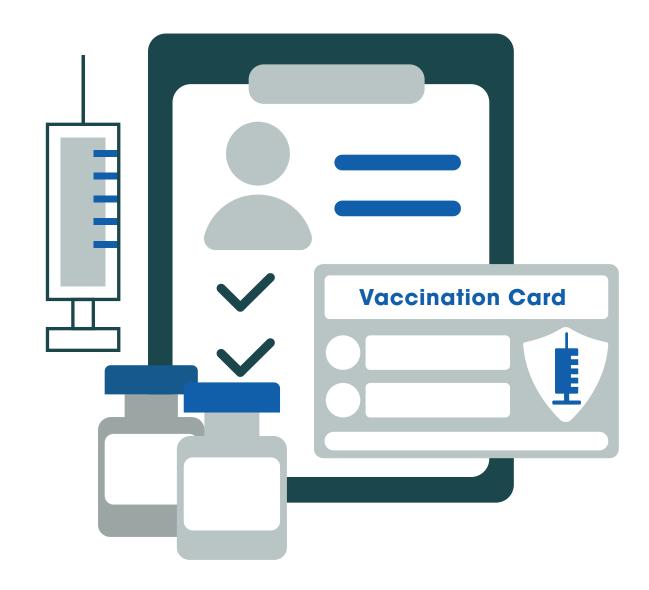












Product Information Guide for COVID-19 Vaccines and Associated Products



COVID-19 Vaccine Product Information Guide









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Pfizer-BioNTech COVID-19 Vaccine and Low Dead-Volume (LDV) Syringes and/or Needles

*Pfizer-BioNTech COVID-19 Vaccine is not centrally distributed; it is distributed directly from the manufacturer. Please refer to the direct-ship section for information on Pfizer-BioNTech COVID-19 Vaccine.

COVID-19 Vaccine Product Information Guide





» Purpose:

This guide provides specifications for COVID-19 vaccine and associated products. **This is NOT a catalog from which you can order products.** It provides key product information including product package dimensions and weight, minimum order quantities, product presentation, distribution method, storage information, and additional information. This guide will be updated as more products become available.

» How to use this guide

Jurisdictional immunization program staff–use this guide to help you:

Learn about available COVID-19 vaccines and associated products.

Provide answers to questions from COVID-19 vaccination providers.

COVID-19 vaccination providers–use this guide to help you:

- Learn about available COVID-19 vaccines and associated products.
- Prepare storage space to ensure ordered quantities can be stored at the proper temperature.
- Prepare staff responsible for receipt and storage of vaccine deliveries.

Refer to CDC's *Vaccine Storage and Handling Toolkit* for recommendations and best practices on related topics such as vaccine inventory management.

» Addendum:

The <u>COVID-19 Vaccine Ancillary Supply Kit Guidance</u> in the addendum (page 15) provides more specific information on the ancillary supply kits.



Additional COVID-19 vaccines may be authorized or licensed in the future. This guide will be updated as more products become available.

VTrckS: https://www.cdc.gov/vaccines/programs/vtrcks/index.html Vaccine Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html







CRETARY FOR AND RESPONSE



Vaccines (Centrally Distributed)

Moderna COVID-19 Vaccine

Manufacturer	<u>Moderna</u>
NDC # in VTrckS	80777-0273-99
Carton dimensions	53 mm x 53 mm x 137 mm (approximately 2 in x 2 in x 5 3/8 in)
Minimum order size and increment	100 doses
Presentation	10-dose multidose vial/10 MDV per carton
Items automatically added to your VTrckS order when you select this product	Ancillary supply administration kit: standard syringe
Vaccination schedule	2-dose series separated by at least 28 days
Age indications	18 years of age and older
On-site vaccine storage	 Unpunctured vials: -50°C to -15°C (-58°F to 5°F) in vaccine storage unit 2°C to 8°C (36°F to 46°F) in vaccine storage unit for up to 30 days 8°C to 25°C (46°F to 77°F) for a total of 24 hours. Punctured vials: 2°C to 25°C (36°F to 77°F) for up to 12 hours after the first puncture The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date: Scan the QR code located on the outer carton, or Go to www.modernatx.com/covid19vaccine-eua/.







» Centrally Distributed Vaccines and Ancillary Kits

Vaccines (Centrally Distributed)

Moderna COVID-19 Vaccine

New Presentation (available May 2021): This ancillary kit supports the Moderna COVID-19 Vaccine vials authorized for 13-15 doses (maximum 15-dose vial). Each kit will contain enough supplies to support 14 doses per vial. If a provider draws a 15th dose, they will need to use their own supplies.

Manufacturer	<u>Moderna</u>
NDC # in VTrckS	80777-0273-98
Carton dimensions	53 mm x 53 mm x 137 mm (approximately 2 in x 2 in x 5 3/8 in)
Minimum order size and increment	140 doses
Presentation	14-dose multidose vial/10 MDV per carton
Items automatically added to your VTrckS order when you select this product	Ancillary supply administration kit: standard syringe
Vaccination schedule	2-dose series separated by at least 28 days
Age indications	18 years of age and older
On-site vaccine storage	 Unpunctured vials: -50°C to -15°C (-58°F to 5°F) in vaccine storage unit 2°C to 8°C (36°F to 46°F) in vaccine storage unit for up to 30 days 8°C to 25°C (46°F to 77°F) for a total of 24 hours. Punctured vials: 2°C to 25°C (36°F to 77°F) for up to 12 hours after the first puncture The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date: Scan the QR code located on the outer carton, or Go to www.modernatx.com/covid19vaccine-eua/.

Moderna: https://www.modernatx.com/covid19vaccine-eua/







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» Centrally Distributed Vaccines and Ancillary Kits

Vaccines (Centrally Distributed)

Janssen COVID-19 Vaccine (Johnson & Johnson)

Manufacturer	Janssen (Johnson & Johnson)
NDC # in VTrckS	59676-0580-15
Carton dimensions	93 mm x 38 mm x 54 mm (approximately 3.66 in x 3.66 in x 2.13 in)
Minimum order size and increment	100 doses
Presentation	5-dose multidose vial/10 MDVs per carton
Items automatically added to your VTrckS order when you select this product	Ancillary supply administration kit: standard syringe
Vaccination schedule	1 dose
Age indications	18 years of age and older
On-site vaccine storage	 Unpunctured vials: 2°C to 8°C (36°F to 46°F) in vaccine storage unit until the expiration date 9°C to 25°C (47°F to 77°F) for up to 12 hours Punctured vials: 2° to 8°C (36° to 46°F) for up to 6 hours At room temperature (maximally 25°C/77°F) for up to 2 hours The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date: Scan the QR code located on the outer carton, or Call 1-800-565-4008, or Go to www.vaxcheck.jnj.

Janssen (Johnson & Johnson): http://www.janssencovid19vaccine.com/



» Ancillary Supply Administration Kit: Standard Syringe (Centrally Distributed)

Kit description	Standard syringe kit for vacci	ine administration	
NDC # in VTrckS	11111-0001-01 (Adult)		
Kit dimensions/weight	14 in x 13 in x 9 in/3.5 lbs (standard ancillary adult kit)		
Minimum order size and increment	Kit to support administration of 100 doses (plus overage)		
Accompanies 0.5mL-dose vaccines	Moderna (10-11 dose vial, supports 10 doses/vial), Janssen		
Order Intention	Initially only adult kits will be available, when authorized for use in younger populations, pediatric and mixed (pediatric and adult) will be available for order.		
Contents: Each kit contains a label on the outside of the box with a complete inventory list.	Adult Kit 85 needles (22-25G x 1") 20 needles (22-25G x 1.5") 105 syringes (1 mL or 3 mL) 210 alcohol pads 100 vaccination record cards 1 needle gauge and length chart 2 face shields 4 surgical masks	 Pediatric Kit 105 needles (25G x 1") 105 syringes (1 mL or 3 mL) 210 alcohol pads 100 vaccination record cards 1 needle gauge and length chart 2 face shields 4 surgical masks 	 Mixed Kit (Pediatric/Adult) 95 needles (25G x 1") 10 needles (22-25G x 1.5") 105 syringes (1 mL or 3 mL) 210 alcohol pads 100 vaccination record cards 1 needle gauge and length chart 2 face shields 4 surgical masks
Additional information	 Products and brands for kirvary. All needles for vaccine adm safety needles. Kits will include a mixture of and non low dead-volume Due to the limited supply of syringes, specification of p needles or syringes is not f Kit and pallet configuration 1 kit = 100 vaccinations of the vaccinations, plus overage For more information about a components: COVID-19 Vaccinations, plus overage 	ninistration are of low dead-volume needles/syringes. of needles and references for reasible. n (plus overage) rts 3,600 ge) ancillary kits	<section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header>





Kit description	Standard syringe kit for vaccine administration (140 doses)			
NDC # in VTrckS	11111-0011-02 (Adult)			
Kit dimensions/weight	14 in x 13 in x 9 in/3.5 lbs (standard an	14 in x 13 in x 9 in/3.5 lbs (standard ancillary adult kit)		
Minimum order size and increment	Kit to support administration of 140 d	Kit to support administration of 140 doses (plus overage)		
Accompanies 0.5mL-dose vaccines	Moderna (13-15 dose vial, supports 14 doses/vial)			
Order Intention	Initially only adult kits will be available, when authorized for use in younger populations, pediatric, and mixed (pediatric and adult) will be available for order.			
Contents: Each kit contains a label on the outside of the box with a complete inventory list.	Adult Kit 75 needles (22-25G x 1") 75 syringes (1 mL or 3 mL, LDV*) 50 needles (22-25G x 1") 50 syringes (1 mL or 3 mL) 25 needles (22-25G x 1.5") 25 syringes (1 mL or 3 mL) 300 alcohol pads 150 vaccination record cards 1 needle gauge and length chart 3 face shields 6 surgical masks	Pediatric Kit • Kit contents currently unavailable	Mixed Kit (Pediatric/Adult) • Kit contents currently unavailable	
Additional information	 Products and brands for kit components may vary. All needles for vaccine administration are safety needles. Kits will include a mixture of low deadvolume needles/syringes. Due to the limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. Kit and pallet configuration 1 kit = 140 vaccinations (plus overage) For more information about ancillary kits components: <u>COVID-19 Vaccine Ancillary Supply Kit Guidance.</u> 			

*LDV = Low dead-volume







» Centrally Distributed Ancillary Supply Kit Volume

Vaccination provider sites will need to prepare space to store vaccine and ancillary kits. Large volume orders of vaccine can be compactly packaged, however, ancillary supply kits to support these orders will require much more storage space. For each 100 doses of vaccine, an ancillary kit measuring 14 in x 13 in x 9 in and weighing 3.5 pounds will be provided. The below picture demonstrates the number and volume of ancillary kits compared to vaccine in a large volume order of 4,000 doses.









CRETARY FOR AND RESPONSE



Pfizer-BioNTech COVID-19 Vaccine (Direct Ship)

Manufacturer	<u>Pfizer</u>
NDC # in VTrckS	59267-1000-02
Tray dimensions	229 mm x 229 mm x 40 mm (approximately 9 in x 9 in x 1.5 in)
Minimum order size and increment	1,170 doses
Presentation	6-dose multidose vial/195 MDV per tray
Items automatically added to your VTrckS order when you select this vaccine	Large combined ancillary supply kit for administration and mixing (includes 0.9% preservative-free normal saline diluent).
Age indications	16 years of age and older
Vaccination schedule	2-dose series separated by at least 21 days
On-site vaccine storage	 Unpunctured Vials: -80°C to -60°C (-112°F to -76°F) in ultracold storage unit until the expiration date -80°C to -60°C (-112°F to -76°F) in the original thermal shipping container with dry ice recharges. Please allow for forthcoming information on the maximum time for storage in these conditions. -25°C and -15°C (-13°F to 5°F) in a freezer for up to 2 weeks (14 days) 2° C to 8°C (36° F to 46°F) in a refrigerated storage unit for up to 5 days (120 hours) Punctured (mixed) vials: 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time the vaccine was mixed with the diluent
Additional information	 Vaccine will be shipped in a container that includes dry ice. Thermal shipping container dimensions are 400 mm x 400 mm x 560 mm (approximately 15 ¾ in x 15 ¾ in x 22 in). A thermal shipping container holds up to 5 cartons/trays. CDC recommends providers consider using the thermal shipping container for temporary storage only. The container requires significant support to store vaccine at proper temperatures, including trained staff, a regular supply of dry ice, and standard operating procedures for regular maintenance. If using the thermal shipping container to store vaccine, add dry ice pellets (9 mm to 16 mm) within 24 hours of delivery and every 5 days or as needed to maintain temperatures. Unless a provider opts out, dry ice will be delivered within 24 hours of vaccine delivery to refill the thermal shipping container for the first re-ice only. Additional dry ice will not be provided. Locate a dry ice source if planning to use the shipping container to store vaccine for more than 5 days. Do not use or store dry ice or liquid nitrogen (LN2) in confined areas, walk-in refrigerators, environmental chambers or rooms without ventilation. A leak in such an area could cause an oxygen-deficient atmosphere. A full shipping container with vaccine and dry ice weighs approximately 80 pounds.

Pfizer: https://www.cvdvaccine.com/







$^{\scriptscriptstyle >}$ Large Combined Ancillary Supply Kit for Administration and Mixing (Direct Ship) *

Kit description	Combined kit with small syringes for vaccine administration, mixing supplies, and diluent
NDC # in VTrckS	11111-0008-02 (Adult)*
Kit dimensions/weight	Kit box may be one of the following sizes: 24 in x 18 in x 20 in/45 – 46 lbs 24 in x 20 in x 18 in / 45 – 46 lbs 24 in x 20 in x 20 in / 45 – 46 lbs 24 in x 20 in x 22 in / 45 – 46 lbs
Minimum order size and increment	Kit to support administration of 1,170 doses (plus overage), including 0.9% preservative- free normal saline diluent
Accompanies 0.3mL-dose vaccines	Pfizer-BioNTech
Order Intention	Initially only adult kits will be available, when authorized for use in younger populations, pediatric and mixed (pediatric and adult) will be available for order.
Contents: Each kit contains a label on the outside of the box with a complete inventory list.	Adult Kit [†] 1,000 needles (22-25G X 1") 240 needles (22-25G X 1.5") 205 mixing needles (21-25G X 1.5") 1,240 syringes (1 mL) 205 syringes (3 mL or 5 mL) 2,900 alcohol pads 1,200 vaccination record cards 10 needle gauge and length charts 25 face shields 50 surgical masks 200 Diluent vials

* For a short period of time, two kits supporting 1,170 doses will be in circulation. The original kit (NDC# 11111-0008-02) will be discontinued in favor of a new kit with a 4:2 ratio of low dead-volume needles/syringes to non-low dead-volume needles/syringes (NDC# 11111-0010-02).

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» Large Combined Ancillary Supply Kit for Administration and Mixing (Direct Ship)

Additional information	 Products and brands for kit components may vary. All needles for vaccine administration are safety needles.
	 Kits will include a mixture of low dead- volume and non low dead-volume needles/syringes.
	 Needles for mixing diluent with vaccine are conventional needles.
	 Due to the limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible.
	Kit and pallet configuration
	 1 kit = 1,170 vaccinations (plus overage)
	 1 pallet = 8 kits (supports 9,360 vaccinations, plus overage)
	For more information about ancillary kit components: <u>COVID-19 Vaccine Ancillary</u> Supply Kit Guidance.

11111-0008-02		ncillary 117 nvenience ITEM# 1183217		er
CONTENTS	QTY	CONTENTS	ΟΤΥ	
 22G - 25G, 1 in Ne 22G - 25G, 1.5 in N 1mL Syringes 21G - 25G, 1.5 in N 3mL or 5mL Syrin 	leedles	 Surgical Masks 		Kit contents product of China, Singapore, Spain, or USA. Assembled by McKesson Medical-Surgical Richmond, VA. USA
Sterile Alcohol Pri LOT XXXXXX EXP YYYY-MM-DD	ep Pads2900 Alcol	iol Prep Pads NDC# 68599- Diluent NDC# 63323-186-0	(01 5804-1	1)10612479259932 (17)YYMMDD (10)123456







Product Information Guide





$^{\scriptscriptstyle >}$ Large Combined Ancillary Supply Kit for Administration and Mixing (Direct Ship) *

Kit description	Combined kit with small syringes for vaccine administration (with a 4:2 ratio of low dead-volume needles/syringes to non-low dead-volume needles/syringes), mixing supplies, and diluent.		
NDC # in VTrckS	11111-0010-02 (Adult)*		
Kit dimensions/weight	Kit box may be one of the following sizes: 24 in x 18 in x 20 in/45 – 46 lbs 24 in x 20 in x 18 in / 45 – 46 lbs 24 in x 20 in x 20 in / 45 – 46 lbs 24 in x 20 in x 22 in / 45 – 46 lbs 		
Minimum order size and increment	Kit to support administration of 1,170 doses (plus overage), including 0.9% preservative- free normal saline diluent		
Accompanies 0.3mL-dose vaccines	Pfizer-BioNTech		
Order Intention	Initially only adult kits will be available, when authorized for use in younger populations, pediatric and mixed (pediatric and adult) will be available for order.		
Contents: Each kit contains a label on the outside of the box with a complete inventory list.	Adult Kit 830 needles (22-25G X 1") 830 syringes (1 mL, LDV) 185 needles (22-25G X 1") 185 syringes (1 mL) 225 needles (22G-25G X 1.5") 225 syringes (1 mL) 205 mixing needles (22-25G X 1.5") 205 mixing needles (22-25G X 1.5") 205 mixing syringes (3 mL or 5 mL) 2,900 alcohol pads 1,200 vaccination record cards 10 needle gauge and length charts 25 face shields 50 surgical masks 200 Diluent vials [‡]	Pediatric Kit • Kit contents currently unavailable	Mixed Kit (Pediatric/Adult) • Kit contents currently unavailable

* For a short period of time, two kits supporting 1,170 doses will be in circulation. The original kit (NDC# 11111-0008-02) will be discontinued in favor of a new kit with a 4:2 ratio of low dead-volume needles/syringes to non-low dead-volume needles/syringes (NDC# 11111-0010-02).

COVID-19 Vaccine

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» Large Combined Ancillary Supply Kit for Administration and Mixing (Direct Ship)

Products and brands for kit components may vary.	11111-6016-92 ADULT ANCILLARY 1170 4:2 MASTER
 All needles for vaccine administration 	CONVENIENCE KIT 2ML Internet 1189856 CONTENTS GTY • 220 - 250, 1 in Needles 830 • 1mL Sympas Liuby 830 • 1mL Sympas Liuby 830
 Kits will include a mixture of low dead- volume and non low dead-volume 	
 Needles for mixing diluent with vaccine are conventional needles. 	DDP YYYY DD-MM Alcohol Pege Pads 68599 5804-1 (10)123456
 Due to the limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. 	
Kit and pallet configuration	
 1 kit = 1,170 vaccinations (plus overage) 	
 1 pallet = 8 kits (supports 9,360 vaccinations, plus overage) 	
For more information about ancillary kit components: <u>COVID-19 Vaccine Ancillary</u> Supply Kit Guidance.	
	 components may vary. All needles for vaccine administration are safety needles. Kits will include a mixture of low dead-volume and non low dead-volume needles/syringes. Needles for mixing diluent with vaccine are conventional needles. Due to the limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. Kit and pallet configuration 1 kit = 1,170 vaccinations (plus overage) 1 pallet = 8 kits (supports 9,360 vaccinations, plus overage) For more information about ancillary kit







» Dry Ice Kit (Direct Ship)

Kit description	Dry ice kit with starter materials
NDC # in VTrckS	11111-0007-03
Kit dimensions/weight	18 in x 14 in x 14 in/39 lbs
Minimum order size and increment	Kit to support initial dry ice recharge of one thermal shipping container
Accompanies ultracold vaccine	Pfizer-BioNTech
Contents	 Dry ice (~35 pounds) Gloves for working with dry ice (1 pair) Face shield (1) Ice scoop (1) OSHA dry ice safety card (1)
Additional information	Products and brands for kit components may vary.







MCKESSON

Contents and Quantities for Mega Kits to Support Pfizer-BioNTech Vaccine

December 11, 2020

This is a clarification about the needle and syringes included in the COVID-19 ancillary supply kits for administering Pfizer's ultra-frozen vaccine. Based on questions coming into our call centers supporting the distribution of the ancillary supply kits, there is some confusion about the quantities of needles and syringes included in the kits. Each kit is clearly labeled with a complete inventory list. (See example below.)

	CUN	/ENIENCE KIT ITEM# 1189856	ZML	
CONTENTS	QTY	CONTENTS	QTY	
 1mL Syringes (LE 22G - 25G, 1 in Ne 1mL Syringes 22G - 25G, 1.5 in 1mL Syringes 	eedles	 3mL or 5mL Syring Sterile Alcohol Prep Vaccination Cards Needle Information Disposable Face Sh Surgical Masks 2mL Diluent 	o Pads2900 1200 Card10 .ields25 50	Kit contents product of China India, Singapore, Spain, or USA. Assembled b McKesson Medical-Surgica Richmond, VA. US/
LOT XXXXXX EXP YYYY-DD-MM	Component NDC#'s 2mL Diluent 63323-1 Alcohol Prep Pads 68	36-02 or 0641-0497-25, 599-5804-1	(01)106	512479260440 (17)YYMMDD (10)123456

Procuring the sheer number of needles and syringes needed to support an operation of this size involves complex logistics, which is why vaccine administrators may see variance in how the supplies are packaged. The listed products may be received as a combo, defined as a single packaged needle and syringe, or as individual components. The quantities listed on the label represent the minimum number of total combinations in each kit.

For example, if the kit above was shipped with (830) 1mL-25Gx1" syringe/needle combos, (185) 25Gx1" needles, and (225) 25Gx1.5" needles for administration, the kit would only contain (410) 1mL syringes to accompany the (185) 25Gx1" needles and (225) 25Gx1.5" needles. This would yield a total of (1,240) needles with accompanying syringes (some packaged together, some individually).

Please note there will be multiple configurations used as products continue to be procured to support the assembly of these and other ancillary supply kits. Regardless of configuration, the kit contents will meet the minimum quantities listed on the kit content labels and will support the same total number of doses.

We hope this communication helps your teams as they review the content in the kits to ensure their readiness for administration when you receive the vaccine doses.

Please direct any issues regarding the ancillary kits to support the Pfizer COVID-19 vaccine to McKesson Customer Service at:

McKesson Customer Service Phone #: 833-272-6634 Email: <u>SNSSupport@McKesson.com</u>











» Addendum: COVID-19 Vaccine Ancillary Supply Kit Guidance









Purpose:

This guidance provides an overview of the COVID-19 vaccine ancillary supply kits the U.S. Department of Health and Human Services (HHS) is providing to enrolled COVID-19 vaccination providers as part of the federal COVID-19 Vaccination Program. It includes a general description of different COVID-19 vaccine ancillary kit configurations for administration, as well as a list of select corresponding products, product descriptions, and product quantities. For reference and to access additional product-specific information and training resources, this document also includes website hyperlinks and contact information for select product manufacturers.

Background:

HHS is providing ancillary supply kits for the administration of COVID-19 vaccine. The Strategic National Stockpile (SNS), managed by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), is partnering with McKesson Corporation to produce, store, and distribute these vaccine ancillary supply kits on behalf of the SNS.

How to use this guide:

Jurisdictional immunization program staff–use this guide to help you:

• Learn about products that will arrive in ancillary kit(s).

Ancillary kit basics:

How does a provider order ancillary kits?

You do not need to order ancillary kits. When you order COVID-19 vaccine in VTrckS, ancillary supplies will automatically be ordered in amounts to match the vaccine orders.

Note: To receive COVID-19 vaccine, vaccination provider facilities and organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program.

How much do ancillary kits cost?

Ancillary kits will be provided at no cost to enrolled COVID-19 vaccination providers.

What products are in ancillary kits?

Ancillary kits contain supplies (with some overage) to administer:

- 100 doses of vaccine (Moderna and Janssen)
- 140 doses of vaccine (Moderna)
- 1,170 doses of vaccine (Pfizer-BioNTech)

Refer to page 18 for possible variations on kits contents.

COVID-19 vaccination providers-use this guide to help you:

- Learn about products that will arrive in ancillary kit(s).
- Prepare storage space for the ancillary kit products you will receive.

How will needles and syringes be packaged?

Needles and syringes for vaccine administration may be packaged as integrated units (i.e., combo needles and syringes for which NO assembly required) or as separate items in a kit (i.e., assembly required).

Can I order specific brand(s) of needles and/or syringes?

Due to a limited supply of needles and syringes, specification of preferences for needles or syringes is not feasible. Products included in the kits may vary over time. In order to meet the demand for supplies, the federal government has purchased single-use, sterile needles and syringes from multiple manufacturers (to include foreign sources) to ensure adequate supplies. These products are approved by the U.S. Food and Drug Administration, safety-engineered and compliant with standards established by the Occupational Safety and Health Administration.

What is considered "pediatric" and "adult"?

For the purpose of immunizations pediatric is birth through 18 years and adult is 19 years and older. Refer to each product's EUA for age indications.







» COVID-19 Vaccine Ancillary Supply Kit Guidance (continued)

Related guidance and resources:

- Preliminary Strategy for Distributing a COVID-19 Vaccine PDF
- <u>COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations PDF</u>

Contact for questions:

Vaccination providers should contact the manufacturer with questions related to proper product use.

Becton Dickinson (BD) Worldwide	https://www.bd.com/en-us/	844-823-5433
Cardinal Health	https://www.cardinalhealth.com/en.html	1-800-964-5227
HTL Strefa	https://htl-strefa.com/home-page/	877-660-1900
Duopross Meditech Corp	https://www.duopross.com/	1-800-844-1350
Retractable Technologies Inc. (RTI)	https://retractable.com/	888-703-1010
Marathon/Smiths Medical	N/A	941-704-7864

For any issues with equipment (e.g., faulty equipment), contact McKesson Customer Service Team at 833-272-6634 or <u>SNSSupport@McKesson.com</u>.







» Possible Ancillary Kits—COVID-19 Vaccines Supporting 100 Doses (Moderna and Janssen)

The following tables list the contents of each possible ancillary kit by product and quantity. All kits are configured for 100 doses with 5% surplus.

Needle and Syringe	Sizes for Adult Ancillary Kits
--------------------	---------------------------------------

PRODUCT	QUANTITY
Needle (22–25G x 1")	85
Needle (22–25G x 1.5")	20
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Needle and Syringe Sizes for **Mixed (Pediatric/Adult)** Ancillary Kits

PRODUCT	QUANTITY
Adult/Pediatric Needle (22–25G x 1")	85
Adult Needle (22–25G x 1.5")	20
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Needle and Syringe Sizes for **Pediatric** Ancillary Kits

PRODUCT	QUANTITY
Needle (25G x 1")	105
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Needle Gauge and Length Chart: www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf



» Possible Ancillary Kits—COVID-19 Vaccines Supporting 140 Doses (Moderna)

The following tables list the contents of each possible ancillary kit by product and quantity. All kits are configured for 140 doses with 5% surplus.

Needle and Syringe Sizes for **Adult** Ancillary Kits

PRODUCT	QUANTITY	
Needle (22–25G x 1")	75	
Syringe (1 mL or 3mL, LDV)	75	
Needle (22–25G x 1")	50	
Syringe (1 mL or 3mL)	50	
Needle (22–25G x 1.5")	25	
Syringe (1 mL or 3 mL)	25	
Alcohol Pad (sterile, individually sealed)	300	
Vaccination Record Card	150	
Needle Gauge and Length Chart	1	
Face Shield	3	
Surgical Mask	6	

Needle and Syringe Sizes for **Mixed (Pediatric/Adult)** Ancillary Kits

Kit contents not yet available

Needle and Syringe Sizes for **Pediatric** Ancillary Kits

Kit contents not yet available

Note: Kit contents for pediatric and mixed (pediatric/adult) kits currently unavailable.







» Possible Ancillary Kits—COVID-19 Vaccine Supporting 1,170 Doses (Pfizer-BioNTech)*

Needle and Syringe Sizes for Large Combined **Adult** Ancillary Kits

PRODUCT	QUANTITY
Needle (22–25G x 1")	1,000
Needle (22–25G x 1.5")	240
Needle, Mixing (21-25G x 1.5")	205
Syringe (1 mL)	1,240
Syringe, Mixing (3 mL or 5 mL)	205
Alcohol Pad (sterile, individually sealed)	2,900
Vaccination Record Card	1,200
Needle Gauge and Length Chart	10
Face Shield	25
Surgical Mask	50
Diluent	200

 $\label{eq:linear} \textbf{Needle Gauge and Length Chart: } www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf \\$

* For a short period of time, two kits supporting 1,170 doses will be in circulation. The original kit (NDC# 11111-0008-02) will be discontinued in favor of a new kit with a 4:2 ratio of low dead-volume needles/syringes to non-low dead-volume needles/syringes (NDC# 11111-0010-02).





» Possible Ancillary Kits—COVID-19 Vaccine Supporting 1,170 Doses (Pfizer-BioNTech)*

Needle and Syringe Sizes for Large Combined **Adult** Ancillary Kits

PRODUCT	QUANTITY
Needle (22–25G x 1")	830
Syringe (1 mL, LDV)	830
Needle (22-25G x 1")	185
Syringe (1 mL)	185
Needle (22–25G x 1.5")	225
Syringe (1 mL)	225
Needle, Mixing (21-25G x 1.5")	205
Syringe, Mixing (3 mL or 5 mL)	205
Alcohol Pad (sterile, individually sealed)	2,900
Vaccination Record Card	1,200
Needle Gauge and Length Chart	10
Face Shield	25
Surgical Mask	50
Diluent	200

Needle and Syringe Sizes for Large Combined **Mixed (Pediatric/Adult)** Ancillary Kits

Kit contents not yet available

Needle and Syringe Sizes for Large Combined **Pediatric** Ancillary Kits

Kit contents not yet available

Needle Gauge and Length Chart: www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

* For a short period of time, two kits supporting 1,170 doses will be in circulation. The original kit (NDC# 11111-0008-02) will be discontinued in favor of a new kit with a 4:2 ratio of low dead-volume needles/syringes to non-low dead-volume needles/syringes (NDC# 11111-0010-02).

COVID-19 Vaccine

Product Information Guide









Web Resources:

 <u>Vaccine Administration Resource Library</u>: Includes resources for preparing, administering, and documenting vaccines



PDF Resources:

- Vaccine Administration: Needle Gauge and Length–PDF
- Vaccine Administration: Intramuscular (IM) Injection Children 7 through 18 years of age-PDF
- Vaccine Administration: Intramuscular (IM) Injection Adults 19 years of age and older–PDF



Video Resources:

- Intramuscular (IM) Injection: Supplies (Adults 19 Years of Age and Older): This training addresses how to select the equipment needed to prepare an intramuscular (IM) injection for adults 19 years of age and older.
- Intramuscular (IM) Injection: Supplies (Children Birth through 18 Years of Age): This training addresses how to select the equipment needed to prepare an intramuscular (IM) injection for children from birth through 18 years of age.
- Intramuscular (IM) Injection Sites: This training helps providers identify intramuscular (IM) injection sites. A needle is used to inject the vaccine into the muscle.



Training Resources:

 <u>Vaccine Administration e-Learn</u>: A self-paced vaccine administration course that provides comprehensive training using videos, job aids, and other resources







» Specific Ancillary Kit Products and Product Information

The following tables, organized by manufacturer or broker, list possible ancillary kit products with an example image (colors may vary) and links to more information. Resources for additional information include:

- Web resources
- PDF resources
- Video resources

Becton Dickinson Products (Phone: 844-823-5433)

ІТЕМ	WHERE TO FIND MORE INFORMATION
Hypodermic Needle PrecisionGlide™ Conventional* ■ Gauge: 22-25/Length: 1.5″	PrecisionGlide [™] Conventional Needle overview
	Visit <u>Becton Dickinson catalog</u> and search product numbers: 305127, 305156, 305194
Safety Hypodermic Needle BD Eclipse™	BD Eclipse [™] Needle overview
 Gauge: 22-25/Length: 1-1.5" Gauge: 23/25/Length: 1-1.25" 	Visit <u>Becton Dickinson catalog</u> and search product numbers: 22-25G, 1-1.5": 305762, 305761, 305763, 305767 23/25, 1-1.25": 305866, 305891, 305892
	BD Eclipse [™] directions for use
	BD Eclipse [™] Needle instruction video
Safety Combo, Syringe with BD Eclipse™ Needle 3mL BD Luer-Lok™ Syringe	<u>BD Eclipse[™] Needle overview</u>
 Gauge: 22-25/ Length: 1-1.5" 	Visit <u>Becton Dickinson catalog</u> and search product numbers: 305782, 305783, 305787
	BD Eclipse [™] directions for use
	BD Eclipse [™] Needle Instruction video
1mL/3mL BD Luer-Lok™ Syringe	Conventional syringe overview
	Visit <u>Becton Dickinson catalog</u> and search product numbers: 309628, 309657
Conventional Combo*	Conventional syringe overview
 Syringe (3mL/5mL) with attached needle Gauge: 22-25/Length: 1-1.5" 	Visit <u>Becton Dickinson catalog</u> and search product numbers: 309361, 309571, 309572, 309574, 309581, 309582, 309589

*For mixing ONLY and NOT for vaccine administration

Becton Dickinson Product catalog: http://catalog.bd.com/

BD Eclipse[™] directions for use: <u>https://www.bd.com/documents/guides/directions-for-use/MPS_HY_Eclipse-needle-usage-guidelines_DF_EN.pdf</u> BD Eclipse[™] Needle instruction video: <u>https://www.bd.com/en-us/company/video-gallery?video=6186777712001</u>

Conventional Syringe overview: https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/conventional-syringes-and-needles/convention

PrecisionGlide[™] Conventional Needle overview: <u>https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/conventional-syringes-and-needles/conventional-needles/ BD Eclipse[™] Needle overview: <u>https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/safety-syringes-and-needles/safety-needles/bd-eclipse-needle</u> BD Eclipse[™] directions for use https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/safety-syringes-and-needles/safety-needles/bd-eclipse-needle</u>

COVID-19 Vaccine

Product Information Guide





Cardinal Health (Phone: 1-800-964-5227)

ІТЕМ	WHERE TO FIND MORE INFORMATION
Tuberculin Syringe Monoject™ 1mL Luer Lock Tip Conventional Syringe 	<u>1 mL Luer Lock Syringes product page</u> Visit <u>Cardinal Health webpage</u> and search product numbers: 1180100777, 1180300777
Magellan [™] 3mL Syringe with Hypodermic Safety Needle ■ Gauge: 23/25/Length: 1"	Magellan [™] Safety Needle and Syringe Combination product page Visit <u>Cardinal Health webpage</u> and search product numbers: 8881833310, 8881833510
Magellan [™] Hypodermic Safety Needle ■ Gauge: 23/25 Length: 1"	Magellan [™] Hypodermic Safety Needle Product page Visit <u>Cardinal Health webpage</u> and search product numbers: 8881850310, 8881850510

Cardinal Health webpage: https://www.cardinalhealth.com/en.html

1 mL luer Lock Syringes product page: https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/1-ml-luer-lock-syringes.html Magellan[™] Safety Needle and Syringe Combination product page: <u>https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safe-</u> ty-needles-and-syringes/magellan-safety-needle-and-syringes/combination.html Magellan™ Hypodermic Safety Needle product page: https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safety-needles-and-sy-

ringes/magellan-safety-needles.html

Duopross Meditech Corp (Phone: 1-800-844-1350)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle* Gauge: 23- 25/Length: 1-1.5"	 Website and product information currently unavailable.
Safety Combo, 3mL Syringe with Safety Needle* Gauge: 23-25/Length: 1-1.5"	 Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not currently available.







Goldbelt (Contact information currently unavailable)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Needle* Gauge: 23-25/Length: 1-1.5"	Website and product information currently unavailable.
Conventional Syringe 1mL*	Website and product information currently unavailable.
Conventional Syringe 3mL*	Website and product information currently unavailable.
Conventional Syringe 5mL*	Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not available currently.

Gold Coast (contact information not currently available)*

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle Gauge: 23/Length: 1"	Product Number: Carepoint 35-8204 See page 27 of this guide for additional information.
Safety Combo, 1mL Syringe with Safety Needle Gauge: 25/ Length: 1"	Product Number: Carepoint 35-8203 See page 27 of this guide for additional information.
Safety Combo, FlipLock 3mL Syringe with Safety Needle Gauge: 23/Length: 1"	Product Number: 822331 See page 28–30 of this guide for additional information.
Safety Combo, FlipLock 3mL Syringe with Safety Needle Gauge: 25/ Length: 1"	Product Number: 825231 See page 28–30 of this guide for additional information.
Safety Needle Gauge: 25/ Length: 1" Gauge: 23/ Length: 1"	Product Numbers: 25G x 1": EasyTouch 802501 23G x 1": EasyTouch 812301 See page 28–30 of this guide for additional information.







RESPONSE

HTL Strefa (Phone: 877-660-1900)

ІТЕМ	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle Gauge: 25/Length: 1"	HTL Strefa home page (product 6054 currently unlisted) See page 31 of this guide for instructions for use.
Safety Combo, 3mL Syringe with Safety Needle Gauge: 23/Length: 1"	HTL Strefa home page (product 6053 currently unlisted) See page 31 of this guide for instructions for use.
Safety Combo, 3mL Syringe with Safety Needle Gauge: 25/Length: 1"	<u>HTL Strefa home page</u> (product 6055 currently unlisted) <u>See page 31 of this guide for instructions for use.</u>

HTL Strefa home page: https://htl-strefa.com/home-page/

Marathon/Smiths Medical (Phone: 941-704-7864)

ІТЕМ	WHERE TO FIND MORE INFORMATION
Safety Combo, 3mL Syringe with Safety Needle* Gauge: 22-25/Length: 1-1.5"	Website and product information currently unavailable. See page 33 for Identification and Connection Guide and QR code for a short video describing the connections. Product numbers: 4234, 4236, 423510

*Image for product is a placeholder stock image only. Product image is not available currently.

Medline (Contact information currently unavailable)

ITEM		WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle	-	Website and product information currently unavailable.
Gauge: 23/Length: 1"Gauge: 25/Length: 1"		
Safety Needle Gauge: 23/Length: 1-1.5" Gauge: 25/Length: 1"		Website and product information currently unavailable.
Conventional Syringe 1mL 3mL	Antropological and	Luer Lock Syringe product page Visit <u>Medline webpage</u> and search product numbers: SYR101010, SYR103010

Luer Lock Syringe product page: https://www.medline.com/product/Luer-Lock-Syringes/Syringes-without-Needle/Z05-PF11377?question=SYR103010&index=P1&indexCount=1#mrkOrderingInfoTable Medline webpage: https://www.medline.com







Quality Impact (Contact information currently unavailable)

ITEM	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle* Gauge: 23-25/Size: 1"	 Website and product information currently unavailable.
Safety Combo, 3mL Syringe with Safety Needle* Gauge: 23-25/Size: 1"	Website and product information currently unavailable.

*Image for product is a placeholder stock image only. Product image is not available currently.

Retractable Technologies Inc. (Phone: 888-703-1010)

ІТЕМ	WHERE TO FIND MORE INFORMATION
Safety Combo Unit, 1mL/3ml, with attached needle	Visit <u>Retractable Technologies Inc. webpage</u> and search product numbers: 10161, 10311, 10391
Gauge: 23/25/Length: 1"	VanishPoint [®] Syringes brochure
	VanishPoint [®] Syringes product usage information
	VanishPoint [®] Syringes video

Retractable Technologies Inc. webpage: <u>https://vanishpoint.com/</u>

VanishPoint® Syringes brochure: https://d2ghdaxqb194v2.cloudfront.net/577/166728.pdf

VanishPoint® Syringes product usage information: https://d2ghdaxqb194v2.cloudfront.net/577/166715.pdf

VanishPoint® Syringes video: https://youtu.be/wC-uXq3uUdQ







» Gold Coast CarePoint Safety Needles and Syringes



SAFETY NEEDLES 25/23 Gauges (Variety of Lengths) • Boxes of 50, sterile needles are sealed in individual • Easy, three-way safety wing activation: packages for assurance and convenience forefinger, thumb or hard surface · Compatible with all major brands of luer lock syringes • Needles are UV bonded to ensure stability • Lubricated needle provides smooth injection • Easy to read tri-lingual packaging Item Product Box Case UPC Number Description Quantity Quantity 16/bxs 32-8700 25G x 5/8" (.625) 786227081005 50 ct. 32-8701 25G x 1″ 786227081015 50 ct. 16/bxs 32-8702 25G x 1 1/2" (1.5) 786227081025 50 ct. 16/bxs 32-8703 23G x 1" 16/bxs 786227081035 50 ct. 32-8704 23G x 1 1/2" (1.5) 786227081045 50 ct. 16/bxs

3cc Syringes

LUER LOCK SYRINGES WITH SAFETY NEEDLES



- Boxes of 50, sterile needles are sealed in individual packages for assurance and convenience
- Compatible with all major brands of luer lock syringes
- Lubricated needle provides smooth injection



- Easy, three-way safety wing activation: forefinger, thumb or hard surface
- Needles are UV bonded to ensure stability
- Easy to read tri-lingual packaging

ltem Number	Product Description	UPC	Box Quantity	Case Quantity
35-8200	25G x 5/8" 3cc	786227082005	50 ct.	8/bxs
35-8201	25G x 1″ 3cc	786227082015	50 ct.	8/bxs
35-8202	23G x 1″ 3cc	786227082025	50 ct.	8/bxs



For questions regarding the CarePoint Safety Line, contact Allison Medical Customer Service at: 1-800-886-1618







» Gold Coast Easy Touch FlipLock Safety Syringes Brochure

FlipLock[™] Safety Syringes

SIMPLE & SMART

EasyTouch FlipLock Safety Syringes offer an easy and simple solution in caregiver protection. After injection, just flip the protective shield over the needle until it clicks and locks in place. Hands and fingers stay away from the exposed needle. Simple, smart and cost-effective.



✓ Easy to Use ✓ Protective Cover Shields Needle After Use ✓ Protective Cover Shields Needle After Use ✓ Familiar Technology Requires Limited Training ✓ Multi-lock Safety System ✓ Contains No Natural Rubber Latex ✓ Safety Engineered

05/06/2021 CS321629-V







» Gold Coast Easy Touch FlipLock Safety Syringes Brochure

FlipLock[™] Safety Syringes

FlipLock[™] Safety Syringe w/ Exchangeable Needle



ITEM#	ML/CC	GAUGE	LENGTH	BOX QTY	CASE QTY	NDC# 08496-
822331	3mL	23G	25mm, 1″	100/box	6/case	0263-01
822337	3mL	23G	40mm, 1.5″	100/box	6/case	0293-01
825231	3mL	25G	25mm, 1″	100/box	6/case	7012-01
825211	1mL	25G	25mm, 1″	100/box	6/case	0248-01

FlipLock[™] Needles

Aller Aller	ITEM#	GAUGE	LENGTH	BOX QTY	CASE QTY	NDC# 08496-
FLIPLOCK NEEDLES 23 *	812301	23G	25mm, 1″	50/box	5/case	0201-01
50 mm	812307	23G	40mm, 1.5″	50/box	5/case	0202-01
manage	812501	25G	25mm, 1″	50/box	5/case	0204-01

Luer Lock Barrels

	ITEM#	ML/CC	DESCRIPTION	BOX QTY	CASE QTY	NDC# 08496-
casy Touch	802015	1mL	Luer Lock Barrel (INS)	100/box	6/case	0164-01
	802030	3mL	Luer Lock Barrel (TB)	100/box	6/case	0159-01







» Gold Coast Easy Touch Fluringe Fliplock Safety Syringes

Easy•Touch[®] FLURINGE[®] FLIPLOCK[™] SAFETY SYRINGES



LOAD SYRINGE Pull the plunger back to load the syringe



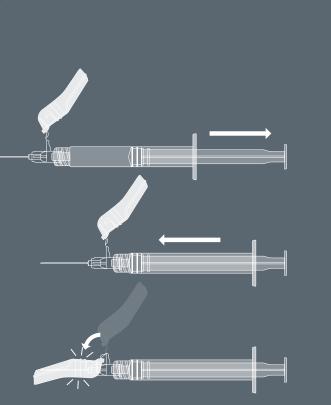
INJECT

Push the plunger in one smooth motion to administer medication



FLIP

Flip the protective shield over the used needle until it clicks into place. Discard according to local regulations









» HTL Strefa DropSafe Syringe with Safety Needle Instructions for Use



Manufactured for: HTL-STREFA S.A. ul. Adamówek 7, 95-035 Ozorków, Poland T: +48 42 270 00 10; F: +48 42 270 00 20 www.htl-strefa.com, E: info@htl-strefa.pl

Distributed by:

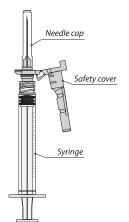
HTL-STREFA, Inc. 3005 Chastain Meadows Pkwy, Suite 300 Marietta, GA 30066, USA T: +1 770 528 0410; F: +1 770 528 0411 www.htl-strefa.com; E: info@htl-strefa.com The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose.

Ask your healthcare professional for assistance in choosing the needle length, injection site and technique appropriate for you.

The needle fits any standard luer lock or luer slip syringe and it is equipped with a safety cover, that prevents needle stick self-injury after use.

INSTRUCTIONS FOR USE

Follow your recommended clinical procedures for drug injections. See the patient information leaflet of the drug.





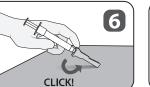
Peel blister pack of the DropSafe Syringe with Safety Needle. Use aseptic technique.



Pull back the safety cover to enable a clear view of the injection site then remove the needle cap.



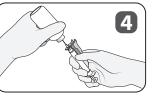
Administer injection according to established protocol.



Do not recap needle with needle cap. Immediately after injection, activate the safety cover by pressing down on a flat surface until you feel or hear an audible click, indicating the cover is securely locked over the needle.



Ensure needle is firmly attached to the luer lock or luer slip syringe.



Draw up the medication according to its reference information. Prime the needle, if required.



Once the cover is securely locked over the needle, dispose of syringe and needle in an approved sharps container.







()

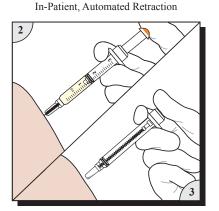




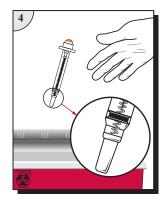
Syringe

Standard Draw Procedure





Non-Reusable



Product Usage Information:

- 1. Prepare and give injection using aseptic technique according to institutional policy.
- 2. For injection into patients, continue depressing plunger to activate automatic needle retraction *while needle is still in patient.* For injection into IV ports, continue depressing plunger to activate automatic needle retraction and *immediately remove needle from port. Full dose is administered only when needle retraction is activated.*
- 3. Needle will automatically retract into syringe, preventing exposure to contaminated needle and rendering syringe non-reusable. In the event that needle retraction mechanism does not activate, discard syringe in an appropriate sharps container per protocol of institution. Do not recap contaminated needles.
- 4. Dispose of VanishPoint[®] syringe in an appropriate sharps container per protocol of institution.

Precautions:

- Single use only. Reuse of this device may result in exposure to bloodborne pathogens, including Hepatitis B virus (HBV), Hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
- · Contents are sterile, non-toxic, and non-pyrogenic. Do not use if product or package is damaged.
- Not made with natural rubber latex.
- Use only with attached needle. Needle cannot be changed.
- Automated needle retraction occurs only when barrel is emptied and plunger is fully depressed.
- For applications where full dose is not administered, expel remaining contents according to institutional policy and activate needle retraction.
- U.S. Federal Law restricts this device to sale by or on the order of a physician.



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» Smiths Medical Needle-Pro® and Needle-Pro® Edge™ Safety Devices

Needle-Pro[®] and Needle-Pro[®] Edge[™] Safety Devices

Identification and Connection Guide

Smiths Medical offers the Needle-Pro[®] and Needle-Pro[®] Edge[™] hypodermic safety devices. It is important to identify which device you are using and review the Instructions for Use prior to using. The information below is to assist you in identifying which device you are using and to help ensure the connections are tightened and secure prior to use.

Needle-Pro® Hypodermic Safety Device

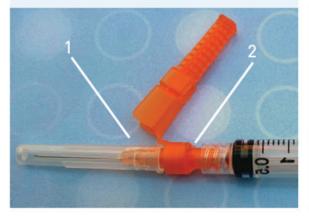


Two points of connection

- Needle to Needle-Pro[®] orange safety device (1)
- Needle-Pro[®] orange safety device to syringe (2)

Ensure the 2 connections are secure by:

- Twisting to tighten the needle into the Needle-Pro[®] orange safety device AND
- Twisting to tighten the Needle-Pro[®] orange safety device into the syringe



Needle-Pro® EDGE[®] Hypodermic Safety Device



One connection

Needle-Pro[®] Edge[™] safety device to syringe (1)

Ensure the connection is secure by:

 Twisting to tighten the connection between the Needle-Pro[®] Edge[™] and syringe prior to use



Scan the QR Code for a short video describing the connections.



Contact customer services at 1-800-258-5361 or at www.smiths-medical.custhelp.com

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

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Find your local contact information at: www.smiths-medical.com/customer-support

Smiths Medical is part of the global technology business Smiths Group pic. Please see the instructions for Use/Operator's Manual for a complete listing of the indications, contraind kations, warnings and precautions. Jelco, NeedlePro, and the Smiths Medical design mark are trademarks of Smiths Medical. The symbol © indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries. All other names and marks mentioned are the trademarks or service marks of their respective owners. ©2021 Smiths Medical. All rights reserved. VA0241.ENAM.Rev.A.0121





Product Information Guide





» Pfizer-BioNTech COVID-19 Vaccine and Low Dead-Volume (LDV) Syringes and/or Needles

Pfizer-BioNTech COVID-19 Vaccine and LOW DEAD-VOLUME (LDV) SYRINGES AND/OR NEEDLES

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 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.

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com.

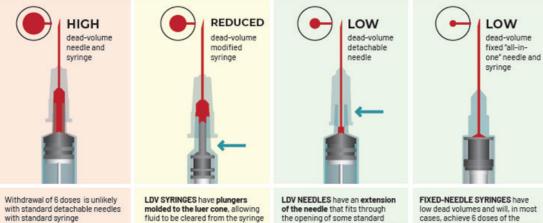
After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial.

Use of low dead-volume (LDV) syringes and/or needles may maximize the potential number of vaccine doses and minimize vaccine wastage¹



Low dead-volume (also called low dead-space) is the amount of fluid remaining within the syringe and needle after an injection is completed²

Characteristics of LDV syringes and needles



cases, achieve 6 doses of the Pfizer-BioNTech COVID-19 Vaccine

Compatible LDV syringe and/or needle pairings may successfully withdraw 6 doses of Pfizer-BioNTech COVID-19 Vaccine, but not all combinations have been assessed or have a low dead volume that is small enough to allow extraction of a sixth dose

The Centers for Disease Control and Prevention (CDC) is partnering with McKesson to provide ancillary kits containing needles and syringes for use with all COVID-19 vaccines. Please reach out to your state, local, or tribal health department and/or the CDC for more information. Pfizer makes no guarantee of the type or quality of the needles and syringes within the ancillary kits or the capability to withdraw 6 doses. For further information, please contact the manufacturer directly.

Find out more about the Pfizer-BioNTech COVID-19 Vaccine at

www.cvdvaccine-us.com



syringes, allowing for a reduction in

dead space

References: 1 Jarrahian C, Rein-Weston A, Saxon G, et al. Vial usage, device dead space, vaccine wastage, and dose accuracy of intradermal delivery devices for inactivated poliovirus vaccine (IPV). Voccine. 2017;35: 1789-1796. 2. Kesten JM, Ayres R, Neale J, et al. Acceptability of low dead space syringes and implications for their introduction: a qualitative study in the West of England. Int J Drug Policy. 2017;39:99-108.



New York, NY 10017

Pfizer Inc.

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tip during injection