

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 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 COVID-19 Vaccine Ancillary Supply Kit Guidance 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









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Centrally Distributed Vaccines and Ancillary Kits

Vaccines (Centrally Distributed)

Moderna COVID-19 Vaccine (100 Doses/10-Dose Multidose Vials)

This presentation of Moderna COVID-19 Vaccine contains vials authorized for 10-11 doses (maximum 11-dose vial). Associated ancillary kit (page 7) contains supplies to support administration of 10 doses per vial. If a provider draws an 11th dose, they will need to do so using their own supplies.

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 (140 Doses/14-Dose Multidose Vial Presentation)

New Presentation (available May 2021): This presentation of the Moderna COVID-19 Vaccine contains vials authorized for 13-15 doses (maximum 15-dose vial). Associated ancillary kit (page 8) contains supplies to support administration of 14 doses per vial. If a provider draws a 15th dose, they will need to do so using 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 vaccine administration (100 doses)			
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 young populations, pediatric kits will be available for order. Mixed kits may be available for order at a later date.			
Contents: Each kit	Adult Kit	Pediatric Kit	Mixed Kit (Pediatric/Adult)	
contains a label on the	85 needles (22-25G x 1")	105 needles (25G x 1")	95 needles (25G x 1")	
outside of the box with a	20 needles (22-25G x 1.5")	105 syringes (1 mL or 3	10 needles (22-25G x 1.5")	
complete inventory list.	105 syringes (1 mL or 3 mL)	mL)	105 syringes (1 mL or 3 mL)	
	210 alcohol pads	210 alcohol pads	210 alcohol pads	
	 100 vaccination record cards 	 100 vaccination record cards 	100 vaccination record cards	
	 1 needle gauge and length chart 	1 needle gauge and length chart	1 needle gauge and length chart	
	2 face shields	2 face shields	2 face shields	
	4 surgical masks	4 surgical masks	4 surgical masks	
Additional information	Products and brands for kit o vary.	components may		
	 All needles for vaccine admin needles. 	nistration are safety	Ancillary Adult Kit	
	 Kits will include a mixture of and non low dead-volume n 	eedles/syringes.		
	 Due to the limited supply of syringes, specification of pre or syringes is not feasible. 	needles and	able Face Shields 2 ptgsent School	
	Kit and pallet configuration			
	 1 kit = 100 vaccinations (p 	lus overage)		
	 1 pallet = 36 kits (supports plus overage) 	s 3,600 vaccinations,		
	For more information about ar components: <u>COVID-19 Vaccir</u> <u>Kit Guidance</u> .	-		







Ancillary Supply Administration Kit: Standard Syringe (Centrally Distributed)

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 ancillary adult kit)			
Minimum order size and increment	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 young populations, pediatric kits will be available for order. Mixed kits may be available for order at a later date.			
Contents: Each kit contains a label on the outside of the box with a complete inventory list.	• 75 needles (22-25G x 1") • 75 needles (25G x 1") (Pedia • 75 syringes (1 mL or 3 mL, LDV*) • 75 syringes (1 mL or 3 mL, LDV) • Kit court		Mixed Kit (Pediatric/Adult) • Kit contents currently unavailable	
Additional information	 Products and brands for kit components may vary. All needles for vaccine administrations afety needles. Kits will include a mixture of low deat volume and non low dead-volume needles/syringes. Due to the limited supply of needles syringes, specification of preference needles or syringes is not feasible. Kit and pallet configuration 1 kit = 140 vaccinations (plus over 1 pallet = 36 kits (supports 5,040 vaccinations, plus overage) For more information about ancillary k components: COVID-19 Vaccine Ancill Supply Kit Guidance. 	add- ead-	OTY PadeOB Kicerents protect of Chica, 	

*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.









Direct-Ship Vaccine and Ancillary Kit

Pfizer-BioNTech COVID-19 Vaccine (450 doses)

Manufacturer	<u>Pfizer</u>
NDC # in VTrckS	59267-1000-03
Tray dimensions	3 in x 3 in x 1 in
Minimum order size and increment	450 doses
Presentation	6-dose multidose vial/25 MDV per tray
Items automatically added to your VTrckS order when you select this vaccine	Combined administration and mixing kit-450 (includes 0.9% preservative-free normal saline diluent).
Age indications	12 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 1 month (31 days) 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. No dry ice refresher will be sent to follow the Pfizer 450 order size. 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/







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Pfizer-BioNTech COVID-19 Vaccine (1,170 doses)

Manufacturer	Pfizer
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	12 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 1 month (31 days) 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.







Combined Administration and Mixing Kit-450 (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	11111-0013-02 (Adult)* 11111-0013-01 (Pediatric)		
Kit dimensions/weight	Kit box may be one of the following sizes: Adult: 24 in x 15 in x 11 in /17.75 lbs Pediatric: 24 in x 15 in x 11 in / 16.5 lbs		
Minimum order size and increment	Kit to support administration of 450 doses (plu: normal saline diluent	s overage), including 0.9% preservative- free	
Accompanies 0.3mL-dose vaccines	Pfizer-BioNTech		
Order Intention	Kits to support vaccination of adults and childre	en are available to order.	
Contents: Each kit contains a label on the outside of the box with a complete inventory list.	Adult Kit* a 315 needles (22-25G X 1") a 315 syringes (1 mL, LDV) 75 needles (22-25G X 1") 75 syringes (1 mL) 85 needles (22G-25G X 1.5") 85 syringes (1 mL) 80 mixing needles (21-25G X 1.5") 80 mixing syringes (3 mL or 5 mL) 1,200 alcohol pads 450 vaccination record cards 4 needle gauge and length charts 10 face shields 20 surgical masks 75 diluent vials	Pediatric Kit = 315 needles (25G X 1") = 315 syringes (1 mL, LDV) = 160 needles (25G X 1") = 160 syringes (1 mL) = 80 mixing needles (21G-25G X 1.5") = 80 mixing syringes (3 mL or 5 mL) = 1,200 alcohol pads = 450 vaccination record cards = 4 needle gauge and length charts = 10 face shields = 20 surgical masks = 75 diluent vials	

*Some needles from the adult kit may be used for adolescents age 12 through 18 years. Choose the correct needle gauge and needle length using CDC's Vaccine Administration: Needle Gauge and Length job aid (<u>https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf</u>). For adolescents age 12–18 years, use the 22-25 gauge, 1-inch needles from the ancillary kit. For adults age 19 years and older, see the chart referenced previously to determine the correct size based on sex and weight.

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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 = 450 vaccinations (plus overage)
	For more information about ancillary kit components: <u>COVID-19 Vaccine Ancillary Supply</u> <u>Kit Guidance.</u>

ADULT ANCILLARY 450 DOSE MASTER CONVENIENCE KIT ITEM# 1190462				
CONTENTS	QTY	CONTENTS	QTY	
 1mL Syringes (L 22G - 25G, 1 in M 1mL Syringes 22G - 25G, 1.5 in 1mL Syringes 	Needles	3mL or 5mL Syringes Mixing Sterile Alcohol Prep Pads Vaccination Cards Needle Information Card. Disposable Face Shields Surgical Masks 2mL Diluent.	1200 450 4 10 20	Kit contents product of China, India, Singapore, Spain, or US. Assembled b McKesson Medical-Surgica Richmond, VA. US.
LOT XXXXXX EXP YYYY-MM-DD	Component NDC#'s 2mL Diluent 63323-186-0 Alcohol Prep Pads 68599-		(01)1	0612479260471 (17)YYMMDD (10)123456
11111-0013-01 PEDIATRIC ANCILLARY 450 DOSE MASTER CONVENIENCE KIT ITEM# 1190661				
		ITEM# 1190461		
11111-0013-01 P	CON aty	ITEM# 1190461	ΩΤΥ	

(01106124792604 LDT XXXXXXX EXP YYYY-MM-DD 2mc Dilumer 63323-186-02 or 0641-0497-25, (17)YYMM Acadm Pay Pay 46 4999-590-1 (10)1234









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	Only adult kits will be available.	
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	

'Some needles from the adult kit may be used for adolescents age 12 through 18 years. Choose the correct needle gauge and needle length using CDC's Vaccine Administration: Needle Gauge and Length job aid (<u>https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf</u>). For adolescents age 12–18 years, use the 22-25 gauge, 1-inch needles from the ancillary kit. For adults age 19 years and older, see the chart referenced previously to determine the correct size based on sex and weight.

COVID-19 Vaccine

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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 deadvolume 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> <u>Supply Kit Guidance.</u>













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 for the 1,170-dose presentation only.	
	A dry ice kit will NOT be supplied as the initial dry ice recharge for the Pfizer 450-dose presentation.	
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 KI1 ITEM# 1189856	ZML	
CONTENTS	QTY	CONTENTS	QTY	
 1mL Syringes (L) 22G - 25G, 1 in N 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 	Kit contents product of China, India, Singapore, Spain, or USA. Assembled by McKesson Medical-Surgica Richmond, VA. USA
LOT XXXXXX EXP YYYY-DD-MM	Component NDC#'s 2mL Diluent 63323-11 Alcohol Prep Pads 68:	86-02 or 0641-0497-25,	(01)10	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

COVID-19 Vaccine

Product Information Guide







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)
- 450 doses of vaccine (Pfizer-BioNTech)
- 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
- COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations PDF

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")	95
Adult Needle (22–25G x 1.5")	10
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

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





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 **Pediatric** Ancillary Kits

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

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

Kit contents not yet available

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

COVID-19 Vaccine

Product Information Guide





Possible Ancillary Kits—COVID-19 Vaccine Supporting 450 Doses (Pfizer-BioNTech)

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

PRODUCT	QUANTITY
Needle (22–25G x 1")	315
Syringe (1 mL, LDV)	315
Needle (22-25G x 1")	75
Syringe (1 mL)	75
Needle (22–25G x 1.5")	85
Syringe (1 mL)	85
Needle, Mixing (21-25G x 1.5")	80
Syringe, Mixing (3 mL or 5 mL)	80
Alcohol Pad (sterile, individually sealed)	1,200
Vaccination Record Card	450
Needle Gauge and Length Chart	4
Face Shield	10
Surgical Mask	20
Diluent	75

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

PRODUCT	QUANTITY
Needle (25G x 1")	315
Syringe (1 mL, LDV)	315
Needle (25G x 1")	160
Syringe (1 mL)	160
Needle, Mixing (21–25G x 1.5")	80
Syringe, Mixing (3 mL or 5 mL)	80
Alcohol Pad (sterile, individually sealed)	1,200
Vaccination Record Card	450
Needle Gauge and Length Chart	4
Face Shield	10
Surgical Mask	20
Diluent	75







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

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

* Some needles from the adult kit may be used for adolescents age 12 through 18 years. Choose the correct needle gauge and needle length using CDC's Vaccine Administration: Needle Gauge and Length job aid (<u>https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf</u>). For adolescents age 12–18 years, use the 22-25 gauge, 1-inch needles from the ancillary kit. For adults age 19 years and older, see the chart referenced previously to determine the correct size based on sex and weight.

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*	PrecisionGlide [™] Conventional Needle overview			
Gauge: 22-25/Length: 1.5"	Visit Becton Dickinson catalog 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 Becton Dickinson catalog 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	BD Eclipse™ Needle overview			
Luer-Lok™ Syringe ■ Gauge: 22-25/ Length: 1-1.5″	Visit Becton Dickinson catalog 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 Becton Dickinson catalog 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 Becton Dickinson catalog 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/

PrecisionGlide™ Conventional Needle overview: https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/conventional-syringes-and-needles/conventional-needles/

BD Eclipse[™] Needle overview: https://www.bd.com/en-us/offerings/capabilities/syringes-and-needles/safety-syringes-and-needles/safety-needles/bd-eclipse-needle

BD Eclipse™ directions for use: https://www.bd.com/documents/guides/directions-for-use/MPS_HY_Eclipse-needle-usage-guidelines_DF_EN.pdf

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

COVID-19 Vaccine

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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/safety-needles-and-syringe-combination.html</u>

Magellan™ Hypodermic Safety Needle product page: https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safety-

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

ІТЕМ	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)*

ІТЕМ	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle Gauge: 23/Length: 1"	Product Number: Carepoint 35-8204 See page 31 of this guide for additional information.
Safety Combo, 1mL Syringe with Safety Needle Gauge: 25/ Length: 1"	Product Number: Carepoint 35-8203 <u>See page 31 of this guide for additional information.</u>
Safety Combo, FlipLock 3mL Syringe with Safety Needle Gauge: 23/Length: 1"	Product Number: 822331 See page 32–34 of this guide for additional information.
Safety Combo, FlipLock 3mL Syringe with Safety Needle Gauge: 25/ Length: 1"	Product Number: 825231 See page 32–34 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 32–34 of this guide for additional information.

COVID-19 Vaccine Product Information Guide





HTL Strefa (Phone: 877-660-1900)

ІТЕМ	WHERE TO FIND MORE INFORMATION
Safety Combo, 1mL Syringe with Safety Needle Gauge: 25/Length: 1"	<u>HTL Strefa home page</u> (product 6054 currently unlisted) See page 35 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 35 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) See page 35 of this guide for instructions for use.

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

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

ITEM	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 NeedleGauge: 23/Length: 1-1.5"Gauge: 25/Length: 1"	Website and product information currently unavailable.	
Conventional Syringe 1mL 3mL 	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/product/Luer-Lock-Syringes/Syringes-without-Needle/Z05-PF11377?question=SYR103010&index=P1&indexCount=1#mrkOrderingInfoTable







Quality Impact (Contact information currently unavailable)

ІТЕМ		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)

ITEM	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://retractable.com/Products</u>

VanishPoint[®] Syringes brochure: <u>https://d2ghdaxqb194v2.cloudfront.net/577/166728.pdf</u>

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 Box Item Product 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



CAREPOINT

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

FOR SINGLE U

• 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.











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

Silan Aller	ITEM#	GAUGE	LENGTH	BOX QTY	CASE QTY	NDC# 08496-
FLIPLOCK NEEDLES 23	812301	23G	25mm, 1″	50/box	5/case	0201-01
150	812307	23G	40mm, 1.5″	50/box	5/case	0202-01
WHENENER	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



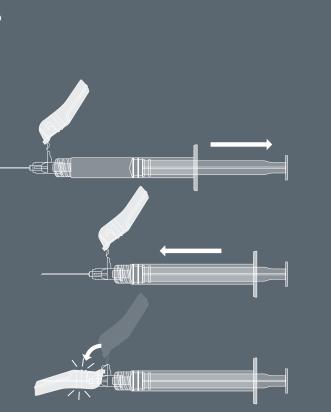
INJECT

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:

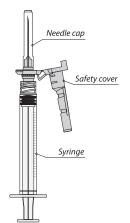
HTL-STREFA, Inc. 3005 Chastain Meadows Pkwy, Suite 300 Marietta, GA 30066, USA T:+1 770 528 0410; F: +1 770 528 0411 www.htl-strefa.com; E: info@htl-strefa.com The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose.

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.

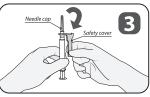
INSTRUCTIONS FOR USE

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.



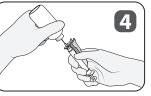
Administer injection according to established protocol.



6



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.







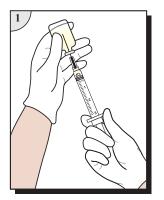
CE

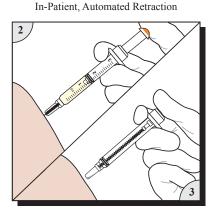




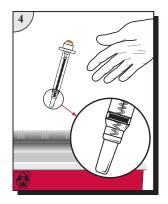
Syringe

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.



511 Lobo Lane Little Elm, Texas 75068-5295 Tel: (972) 294-1400 Toll Free 1-888-703-1010 M01 REV. 11 EX.JUL 2019 0 2003, 2019 Retractable Technologies, Inc. All rights reserved.









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

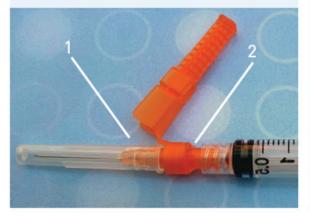


Two points of connection

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

Ensure the 2 connections are secure by:

- 1. Twisting to tighten the needle into the Needle-Pro® orange safety device AND
- 2. 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

Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442, USA

Phone: 1-214-618-0218 Toll-Free USA 1-800-258-5361

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

Smiths Medical is part of the global technology business Smiths Group plc. Please see the instructions for Use/Operator's Manual for a complete listing of the Indications, contraindikations, warnings and precautions. Jelco, NeedlePro, and the Smiths Medical design mark are trademarks of Smiths Medical. The symbol Φ 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 of 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.

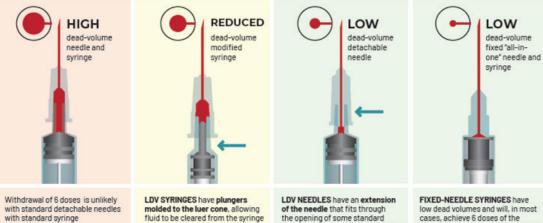
After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial.

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.



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tip during injection