



Product Information Guide for COVID-19 Vaccines and Associated Products

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Version 1–December 4, 2020

Product Information Guide Summary

»Purpose:

This guide provides specifications for COVID-19 vaccine and associated products. This is <u>NOT</u> 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 <u>Vaccine Storage and Handling Toolkit</u> 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 8) provides more specific information on the ancillary supply kits.



At this time, the products in this guide are only available for use in adults (i.e., persons aged 18 years or older). You will receive additional information, and this guide will be updated to reflect any changes COVID-19 age indications.

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

Centrally Distributed Vaccines and Ancillary Kits* Vaccines (Centrally Distributed)

Manufacturer	Moderna	
NDC # in VTrckS	80777-0273-99	
Carton dimensions	53mm x 53mm x 137mm (approximately 2in x 2in x 5 3/8in)	
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	TBD	
On-site vaccine storage	 -25°C to -15°C (-13°F to 5°F) in vaccine storage unit 2° to 8°C (36° to 46°F) in vaccine storage unit for up to 30 days if the vial is not entered. Freezer temperature settings will require adjustment if storing this vaccine and varicella-containing vaccines in the same unit. The temperature range for this vaccine is limited compared to varicella-containing vaccines. 	

*Pfizer's COVID-19 vaccine is **not** centrally distributed; it is distributed directly from the manufacturer. Please refer to the next section for information on Pfizer COVID-19 vaccine.

Ancillary Supply Administration Kit: Standard Syringe (Centrally Distributed)

Kit description	Standard syringe kit for vaccine 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	
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 ordering.	
Contents	Adult KitPediatric KitMixed Kit85 needles (22-25G x 1")105 needles (25G x 1")95 needles (25G x 1")20 needles (22-25G x 1.5")105 syringes (1mL or 3mL)105 syringes (1mL or 3mL)105 syringes (1mL or 3mL)210 alcohol pads100 vaccination record cards100 vaccination record cards1 needle gauge and length chart1 needle gauge and length chart2 face shields4 surgical masks4 surgical masks	
	 Products and brands for kit components may vary. All needles for vaccine administration are safety 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 = 100 vaccinations (plus overage) 1 pallet = 36 kits (supports 3,600 vaccinations, plus overage) 1 pallet = 36 kits (supports 3,600 vaccinations, plus overage) 	
	For more information about ancillary kits components: <u>COVID-19 Vaccine Ancillary Supply Kit</u> Guidance	

Direct-Ship Vaccine and Ancillary Kit Pfizer Vaccine (Direct Ship)

Manufacturer	Pfizer	
NDC # in VTrckS	59267-1000-02	
Tray dimensions	229mm x 229mm x 40mm (approximately 9in x 9in x 1.5in)	
Minimum order size and increment	975 doses	
Presentation	5-dose multidose vial/195 MDV per tray	
Items automatically added to your VTrckS order when you select this vaccine	Combined ancillary supply kit for administration and mixing (includes 0.9% preservative-free normal saline diluent)	
Age indications	TBD	
Vaccination schedule	2-dose series separated by at least 21 days	
On-site vaccine storage	 -80°C to -60°C (-112°F and -76°F) in ultracold storage unit -80°C to -60°C (-112°F and -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. 2°C to 8°C (36°F to 46°F) in a storage unit for up to 5 days (120 hours) 	
Additional information	 Vaccine will be shipped in a container that includes dry ice. Thermal shipping container dimensions are 400mm x 400mm x 560 mm (approximately 15 3/4in x 15 3/4in x 22in). A thermal shipping container holds up to 5 cartons/trays. 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 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	11111-0006-02 (Adult)		
Kit dimensions/weight	24 in x 20 in x 24 in/40 lbs		
Minimum order size and increment	Kit to support administration of 975 doses (plus overage), including 0.9% preservative-free normal saline diluent		
Accompanies 0.3mL- dose vaccines	Pfizer		
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 ordering.		
Contents	Adult Kit*Pediatric Kit*Mixed Kit*829 needles (22-25G X 1.7)1024 needles (25G X 1")926 needles (25G X 1")200 needles (22-25G X 1.5")205 mixing needles (21-25G X1.5")1024 syringes (21-25G X1.5")100 needles (22-25G X1.5")205 mixing needles (21-25G X1.5")1024 syringes (1mL)205 syringes (3mL or 5mL)205 syringes (3mL or 5mL)2458 alcohol pads1000 vaccination record 		
Additional information	 Products and brands for kit components may vary. All needles for vaccine administration are safety needles. Mixing needles are conventional. 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 = 975 vaccinations (plus overage) 1 pallet = 8 kits (supports 7,800 vaccinations, plus overage) To a list (supports 7,800 vaccinations, plus overage) To more information about ancillary kit components: COVID-19 Vaccine Ancillary Supply Kit Guidance 		

*The total number of needles in each adult, pediatric, and mixed combined ancillary supply kit for administration and mixing will vary (adult–1,029; pediatric–1,024; mixed–1,026). The difference in total number is related to increasing the kit build efficiency.

Dry Ice Kit (Direct Ship)

Kit description	Dry ice kit with starter materials	
NDC # in VTrckS	11111-0007-03	
Kit dimensions/weight	TBD	
Minimum order size and increment	Kit to support initial dry ice recharge of one thermal shipping container	
Accompanies ultracold vaccine	Pfizer	
Contents	 Dry ice (weight and pellet size requested from the Strategic National Stockpile) 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. - 	

Addendum: COVID-19 Vaccine Ancillary Supply Kit Guidance

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 seven different COVID-19 vaccine ancillary kit configurations, 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).

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.

»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?

Refer to page 11 for possible ancillary kits.

Each ancillary kit, **except for the kits designated for use with the Pfizer vaccine**, contains supplies to administer 100 doses of vaccine (with some overage). The **Pfizer vaccination kit** will support 975 doses of vaccine (with some overage). Refer to page 12 for possible variations on kit contents.

How will needles and syringes be packaged?

Needles and syringes for vaccine administration may be packaged as integrated units (i.e. 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 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.

»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. Concerns related to needle/syringe quality and performance or other contents of the vaccine ancillary supply kit should be directed to the state or local health department.

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

Possible Ancillary Kits—COVID-19 Vaccines, Excluding Pfizer

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 (1mL or 3mL)	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 (1mL or 3mL)	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 Ancillary Kits

Product	Quantity
Adult/Pediatric Needle (22–25G x 1")	85
Adult Needle (22–25G x 1.5")	20
Syringe (1mL or 3mL)	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 Mixing Kits

Needle and Syringe Sizes for *Mixing* Kits

Product	Quantity
Needle (19-21G x 1.5")	11
Syringe (5mL or 6mL)	11
Alcohol Pad (sterile, individually sealed)	22







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

Possible Ancillary Kits—COVID-19 Vaccine, Pfizer Only

Needle and Syringe Sizes for Pfizer Mega Adult Ancillary Kits

Needle and Synnge Sizes for Filzer Mega Adult Ancinary Kits		
Product	Quantity	
Needle (22–25G x 1")	829	
Needle (22–25G x 1.5")	200	
Needle, Mixing (21-25G x 1.5")	205	
Syringe (1mL)	1,024	
Syringe, Mixing (3mL or 5mL)	205	
Alcohol Pad (sterile, individually sealed)	2,458	
Vaccination Record Card	1,000	
Needle Gauge and Length Chart	10	
Face Shield	20	
Surgical Mask	40	
Diluent	200	



Needle and Syringe Sizes for Pfizer Mega Pediatric Ancillary Kits

Product	Quantity
Needle (25G x 1")	1,024
Needle, Mixing (21-25G x 1.5")	205
Syringe (1mL)	1,204
Syringe, Mixing (3mL or 5mL)	205
Alcohol Pad (sterile, individually sealed)	2,458
Vaccination Record Card	1,000
Needle Gauge and Length Chart	10
Face Shield	20
Surgical Mask	40
Diluent	200



Needle and Syringe Sizes for Pfizer Mega Mixed Ancillary Kits

Product	Quantity
Needle (25G x 1")	926
Needle (22–25G x 1.5")	100
Needle, Mixing (21–25G x 1.5")	205
Syringe (1mL)	1,024
Syringe, Mixing (3ml or 5ml)	205
Alcohol Pads (sterile, individually sealed)	2,458
Vaccination Record Card	1,000
Needle Gauge and Length Chart	10
Face Shield	20
Surgical Mask	40
Diluent	200



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

General Needle and Syringe Resources



Web Resources

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



PDF Resources

- <u>Vaccine Administration: Needle Gauge and Length–PDF</u>
- 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

• <u>Assemble a Manufacturer-filled Syringe</u>: This training addresses how to assemble a manufacturer-filled syringe, available for a variety of vaccines.

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 are organized by:



Web resources

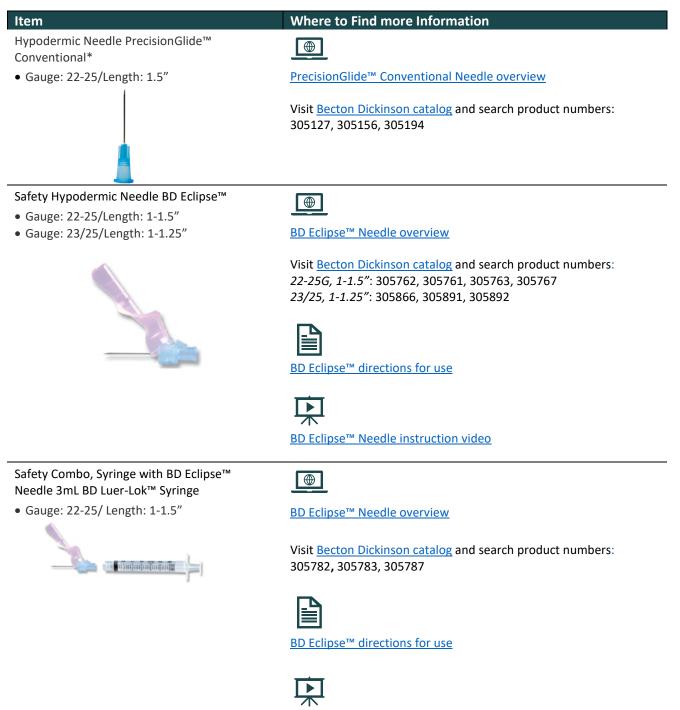


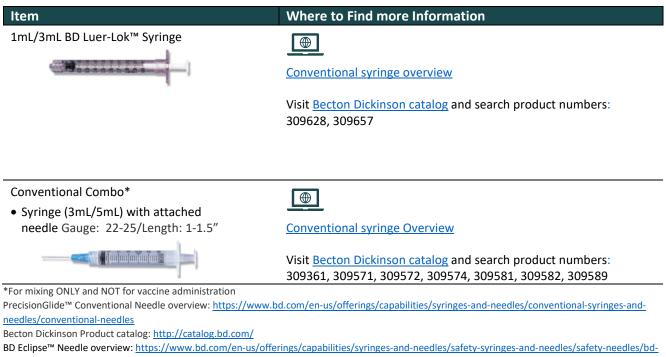
Pdf resources



Video resources

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



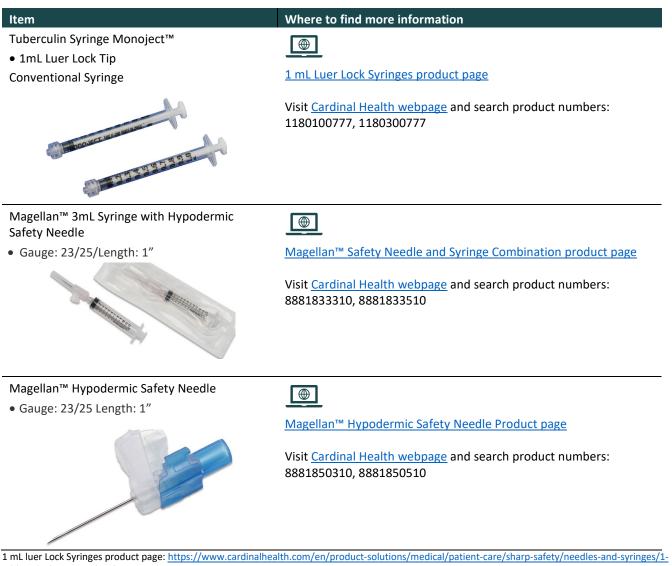


eclipse-needle

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/conventional-syringes-and-needles/conventional-syringes

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



ml-luer-lock-syringes.html

Cardinal Health webpage: https://www.cardinalhealth.com/en.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: <u>https://www.cardinalhealth.com/en/product-solutions/medical/patient-care/sharp-safety/needles-and-syringes/safety-needles-html</u>

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

Item	Where to find more information
Safety Combo, 1mL Syringe with Safety Needle*	Website and product information currently unavailable.
• Gauge: 23- 25/Length: 1-1.5"	
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.

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Goldbelt (Contact information currently unavailable)

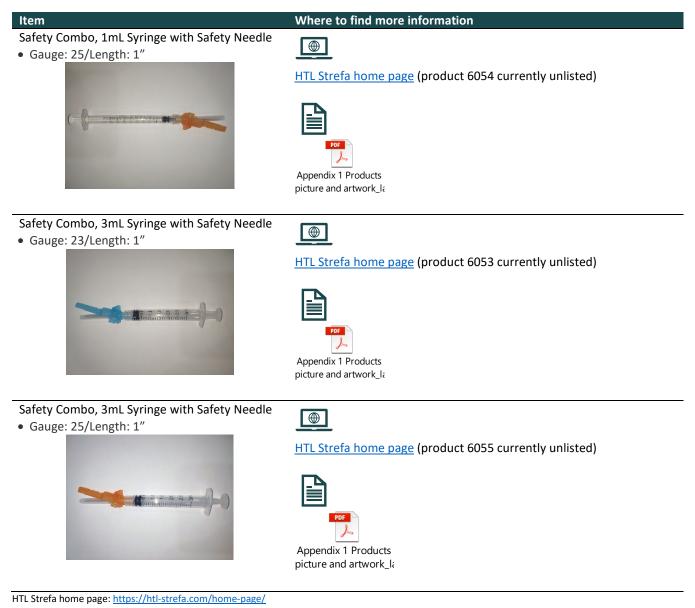
Item	Where to find more information
Safety Needle*	Website and product information currently unavailable.
 Gauge: 23-25/Length: 1-1.5" 	
Conventional Syringe 1mL*	Website and product information currently unavailable.
Conventional Syringe 3mL*	Website and product information currently unavailable.
aduntuntuntunt	
Conventional Syringe 5mL*	Website and product information currently unavailable.
CI O P SS	

*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"	EasyTouch-FlipLock_ CP EasyTouch-Safety_Sy Syringe_Instructions.r;Safety_Flyer_ProductSringe_Needle_Brochu
	Product Number: Carepoint 35-8204
Safety Combo, 1mL Syringe with Safety Needle • Gauge: 25/ Length: 1"	EasyTouch-FlipLock_ CP EasyTouch-Safety_Sy Syringe_Instructions.pSafety_Flyer_ProductSringe_Needle_Brochui
	Product Number: Carepoint 35-8203
Safety Combo, FlipLock 3mL Syringe with Safety Needle	PDF PDF
• Gauge: 23/Length: 1"	EasyTouch-FlipLock_CP EasyTouch-Safety_Sy Syringe_Instructions.pSafety_Flyer_ProductSringe_Needle_Brochu
	Product Number: 822331
Safety Combo, FlipLock	
3mL Syringe with Safety Needle	
• Gauge: 25/ Length: 1"	EasyTouch-FlipLock_CP EasyTouch-Safety_Sy Syringe_Instructions.pSafety_Flyer_ProductSringe_Needle_Brochu
	·, <u> </u>
	Product Number: 825231
Safety Needle	PDF PDF 0
• Gauge: 25/ Length: 1"	EasyTouch-FlipLock_ CP EasyTouch-Safety_Sy Syringe_Instructions.pSafety_Flyer_ProductSringe_Needle_Brochui
	Product Numbers:
-	25G x 1": EasyTouch 802501
• Gauge: 23/ Length: 1"	23G x 1": EasyTouch 812301

HTL Strefa (Phone: 877-660-1900)

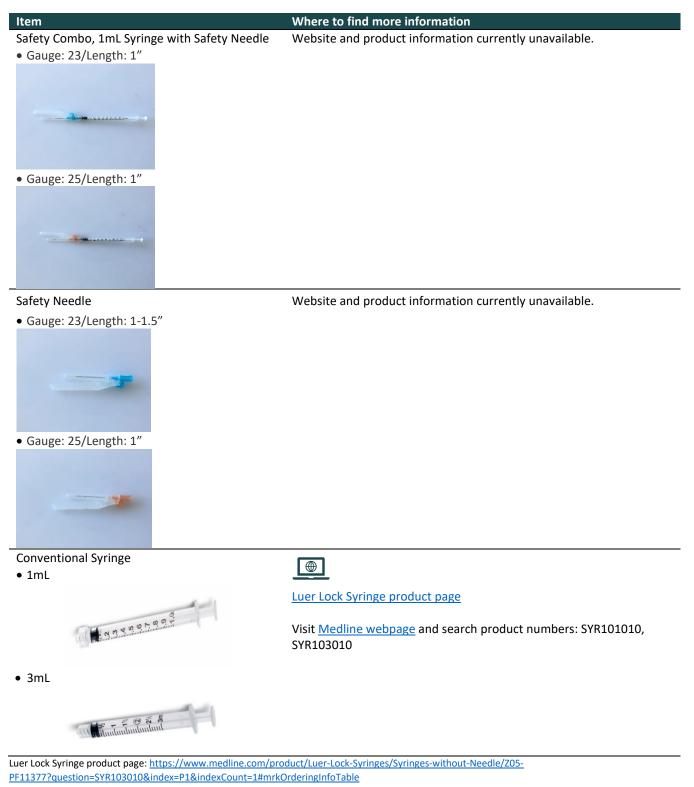


Marathon/Smiths Medical (Phone: 941-704-7864)

Item	Where to find more information
Safety Combo, 3mL Syringe with Safety Needle*	Website and product information currently unavailable.
• Gauge: 22-25/Length: 1-1.5"	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)



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*	Website and product information currently unavailable.
• Gauge: 23-25/Size: 1"	

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 • Gauge: 23/25/Length: 1"	Visit <u>Retractable Technologies Inc. webpage</u> and search product numbers: 10161, 10311, 10391
	VanishPoint [®] Syringes brochure VanishPoint [®] Syringes product usage information VanishPoint [®] Syringes video

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: <u>https://youtu.be/wC-uXq3uUdQ</u>