



VaporShield™

Closed System Transfer Device

INSTRUCTIONS FOR USE



VPS-A01S



Consult instructions for use

For updates to the instructions for use (IFU), go to: www.zephyrusinnovations.com.

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Description

The VaporShield closed system transfer device (CSTD) (the “VaporShield System”) is sterile, for single use, and is intended for direct parenteral injection (subcutaneous / intramuscular) of hazardous or non-hazardous drugs.

A single configuration includes a 1 mL Syringe, 22G [Gauge] cannula, and is pre-assembled with a Drug Vial Holder (DVH). Preassembly of the Syringe and Drug Vial Holder components are interlocked via a flextab snap-fit connection.

During drug draw, the DVH ensures a stable connection between the Drug Vial and the VaporShield Syringe.

The VaporShield Syringe has three (3) settings, two (2) for Needle length, and one (1) for safety: **Lock** for safety device removal, **0.5** inch (13 mm) for shallow injection depth and **0.75** inch (19 mm) for standard injection depth.

In turning the VaporShield Syringe to the “REMOVE” position, the device is automatically locked for safe removal from the DVH.

After medication draw, the DVH is removed from the VaporShield Syringe, and the VaporShield Syringe is used for direct injection of hazardous and non-hazardous medication via subcutaneous or intramuscular administration.

The VaporShield Syringe includes a safety mechanism that is manually activated by full Plunger depression at the end of drug delivery. When activated, the safety mechanism retracts the Needle inside the Plunger Rod for containment, preventing accidental needlestick and disallowing device reuse.

The VaporShield mechanically prevents drug transfer external to the device to minimize individual and environmental drug exposure.

The VaporShield Syringe is intended for parenteral injection (subcutaneous / intramuscular).

Indications for Use

The VaporShield is a sterile, single-use, closed system transfer device (CSTD), incorporating a preassembled Drug Vial holder (DVH) and Syringe (1mL, 22GA). The preassembled device is intended for medication draw from a Drug Vial only. After medication draw, the DVH is removed from the Syringe (note: the DVH remains with the vial), and the Syringe is used for direct injection of hazardous and non-hazardous medication via subcutaneous or intramuscular administration.

The VaporShield Syringe incorporates a safety mechanism which automatically retracts the Needle inside the device for drug containment, and prevention of accidental needlesticks and device reuse. The VaporShield Syringe mechanically prevents drug transfer external to the device to minimize individual and environmental drug exposure.

The VaporShield System is intended for use by medical professionals who prepare/administer injection(s) to adults and adolescents in healthcare facilities. The device is not intended for neonates (< 28 days old), infants (< 2 yrs old), or children (≥ 2 yrs old – 12 yrs old). The VaporShield Device is not intended for Compounding, Reconstitution, Phlebotomy, Intravenous injection, Intraperitoneal injection, or Intrathecal injection.

Contraindications

The VaporShield System is not indicated as a re-usable device.

The VaporShield System is not indicated for use with/on neonates (< 28 days old), infants (< 2 yrs old) or children (≥ 2 – 12 yrs old).

The VaporShield System is not indicated for: compounding, phlebotomy, reconstitution, intravenous injection, intraperitoneal injection, or intrathecal injection.

Warnings

1. Single Use ONLY. Do NOT reuse: Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single-use only.
2. Read the instructions carefully before using this device.
3. Do not expose Needle after medication fill.
4. Do not use the device after the expiration date has passed.
5. Do not use the device if the device is cracked, broken or damaged.
6. Do not use the device if the packaging is punctured or damaged in any way.

7. Do not attempt removal of Drug Vial Holder (DVH) until needle has been retracted into device.
8. If activation fails, hold the Shield steady at the injection site and pull Syringe Barrel back to fully retract Needle.
9. If Needle/cannula is occluded or damaged do not attempt to clear occlusion - Do Not Use device.
10. Mishandling/misuse of device may result in exposure, or a contaminated needlestick, which can cause adverse effects (hazardous drug exposure, infectious disease).
11. Devices that become contaminated with blood are considered hazardous and must be disposed of immediately after use in sharps container, standard biohazard per institutional protocol.
12. If used for injection with hazardous drugs, device and any components are to be treated as hazardous waste; follow institutional & regulatory requirements.

Precautions

1. Follow standard infection control procedures as specified in the appropriate published guidelines.
2. This device is to be used by medical professionals only.
3. Verify the Needle extension length (0.5 inch or 13 mm / 0.75 inch or 19 mm) is appropriate for injection and patient needs.
4. Any labels attached to the device by the user should not prevent visual confirmation of Syringe volume(s).
5. Multiple perforations of the drug vial septum during device fill may cause Needle dulling, and may result in patient discomfort during insertion to injection site.
6. The VaporShield System is intended for use with approved drug/biological product indicated for subcutaneous or intramuscular injection/administration. Consult approved drug/biological labelling to ensure administration (recommended: dosage, injection type, areas of the body appropriate for injection) with the VaporShield System comply with prescribed treatment from a licensed physician.

Safety Information

1. Device is not intended to be used for medications not labelled or indicated for Subcutaneous or Intramuscular injection.
2. Medication labelling should be reviewed to confirm dosage volumes are appropriate for this device use.

3. Device is for use in accordance with approved hazardous drug/non-hazardous drug/biological product.

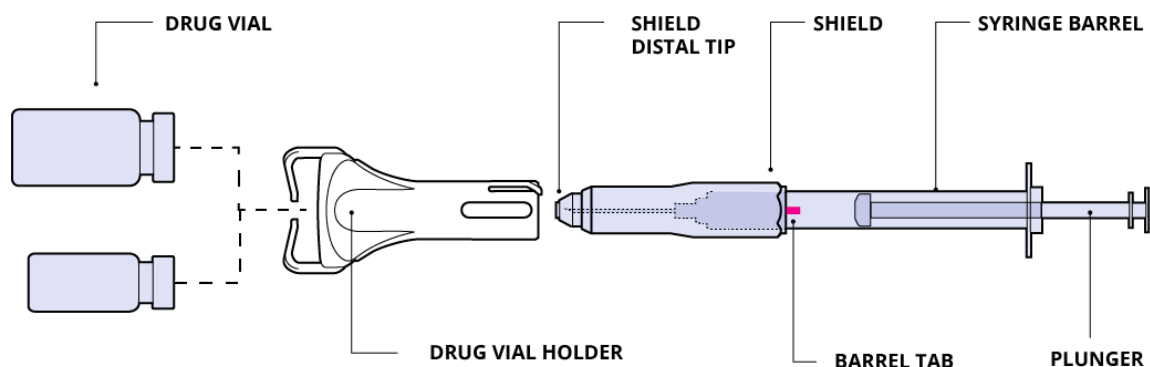
⚠ **Caution:** Federal law restricts this device to sale by or on the order of a physician.

Storage & Handling

1. Store VaporShield components at room temperature in the original packaging.
2. Do not use components if packaging is damaged or past the expiration date.
Single Use ONLY. Do NOT reuse.

VaporShield System Overview

Directions for Use



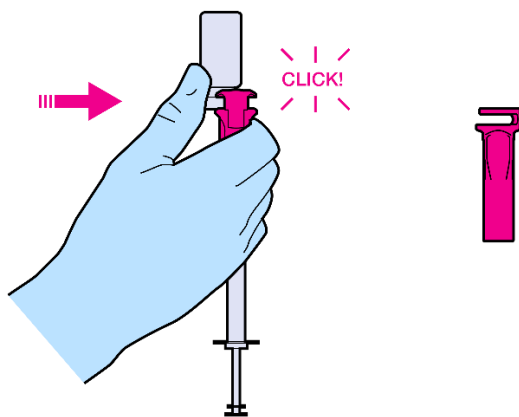
STEP 1 – Checking the Device

1A. Before removing the VaporShield System, inspect the packaging for damage. Do not use if the packaging is punctured/torn, the device is cracked, or the device is broken, do not use.

1B. Remove the VaporShield System from the packaging and check for damage. Do not use if the device is damaged. Verify that the DVH is securely attached to the VaporShield Syringe.

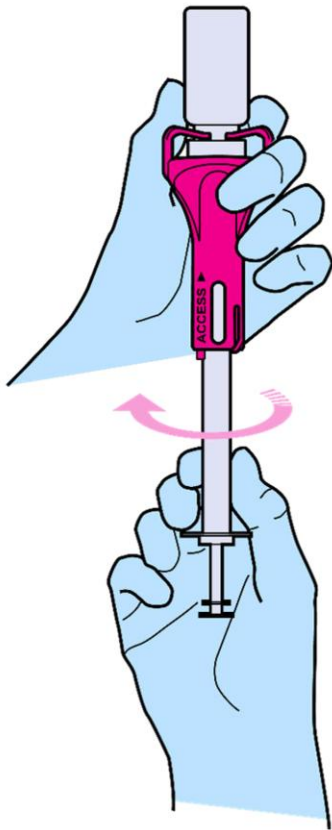
STEP 2 – Attach Drug Vial

2. Slide the Flange [Head/Top] of the Drug Vial onto the DVH until there is an audible and tactile click. The Drug Vial should feel secure when attached correctly (i.e. not loose). Please note: when attached correctly the Drug Vial should feel secure, but may be able to spin in the DVH.



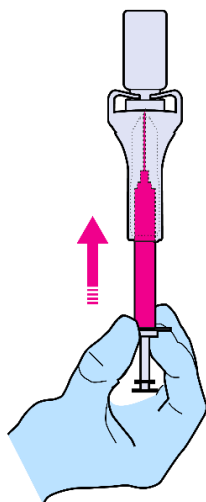
STEP 3 – Access the Medication

3A. Hold the DVH securely in one hand. Grip the Syringe Barrel in your other hand [as shown], twist it left to align the Barrel Tab with **ACCESS ►**



3B. Continuing to hold the device by the Syringe Barrel and the DVH, push the Syringe Barrel into the DVH to insert the Needle into Drug Vial. Please note: do not press the Plunger.

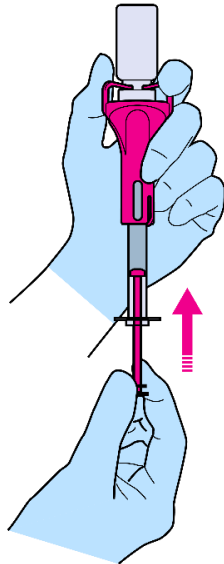
Note: the Magenta/Pink Settings Tab should not be visible.



STEP 4 – Draw Medication

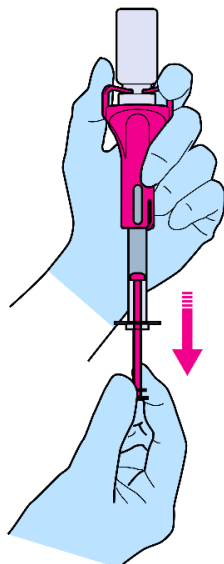
4A. Hold DVH securely and gently press the Plunger to purge air from the VaporShield System into the Drug Vial.

Note: Applying too much pressure during depression can prematurely activate device. If device is activated prematurely, remove drug vial and use new VaporShield system.



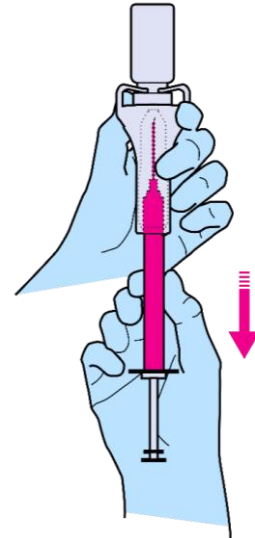
4B. Retract (Pull back) Plunger to draw the desired amount of medication.

Please note: If necessary to extract the maximum amount from the Drug Vial, users can pull back the Syringe Barrel, pulling the Needle back towards the Septum of the Drug Vial.



STEP 5 – Remove Drug Vial Holder

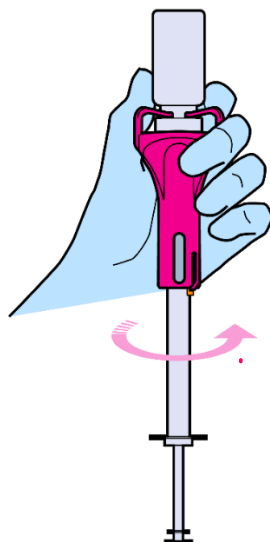
5A. Continue to hold the device securely by the Drug Vial Holder. Use your opposing hand to pull the Syringe Barrel back fully [until the Barrel Tab is visible] to remove the



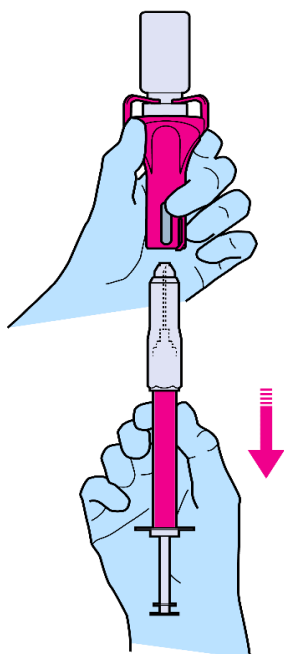
Needle from the Drug Vial. **Note:** Do not press the Plunger.

5B. Twist the Syringe Barrel (right) to align the Barrel Tab with **REMOVE ►**

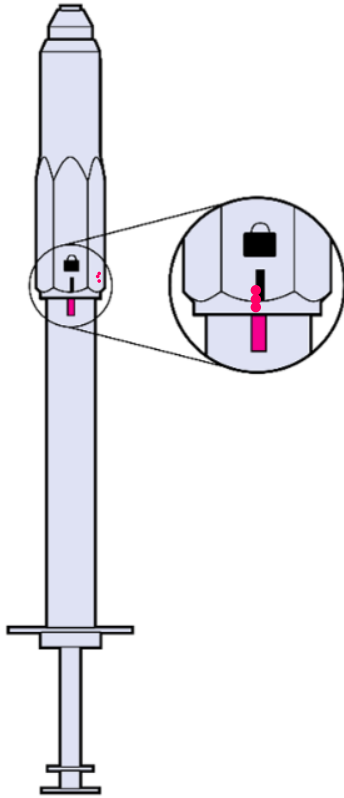
This will now allow you to remove the device.



5C. Pull the Syringe Barrel away from the DVH until the device is removed.



5D. The Barrel Tab is now in the **Lock** Position for safe transport.



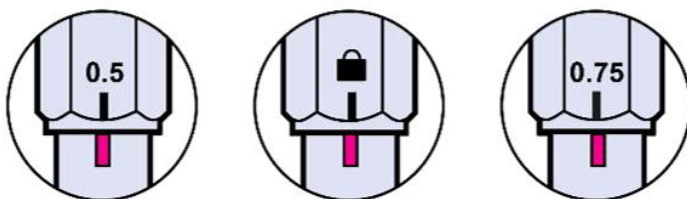
STEP 6 – Transfer

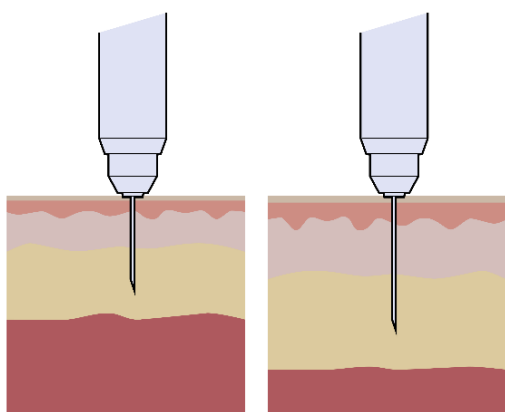
6. Transport the prepared VaporShield Syringe to the patient bedside in accordance with institutional hazardous drug handling procedures.

STEP 7 – Adjust Injection Depth

7. Holding the Shield, twist the Syringe Barrel until the **Magenta/Pink** Barrel Tab aligns with the desired length, 0.5 inch (13 mm) or 0.75 inch (19 mm), marked on the Shield.

Note: do not attempt to adjust the injection depth after insertion of the Needle into the patient.

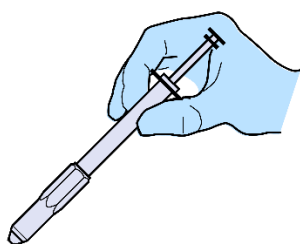




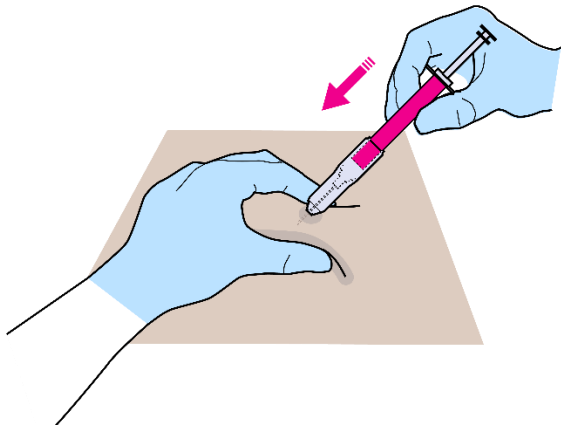
STEP 8 – Insert Needle

Note: Follow standard guidelines for preparing the injection site and Needle insertion.

8A. Holding the Syringe Barrel at the back (proximal end), place the tip of the device onto the injection site.



8B. Press the Syringe Barrel forward to the injection site to insert the Needle. **Note:** Users can confirm the Needle is being inserted by feeling / observing the Syringe Barrel slide into the Shield.



Confirmation of full Needle insertion is when there is no further travel or the Shield stops at the following markings on the Syringe Barrel:

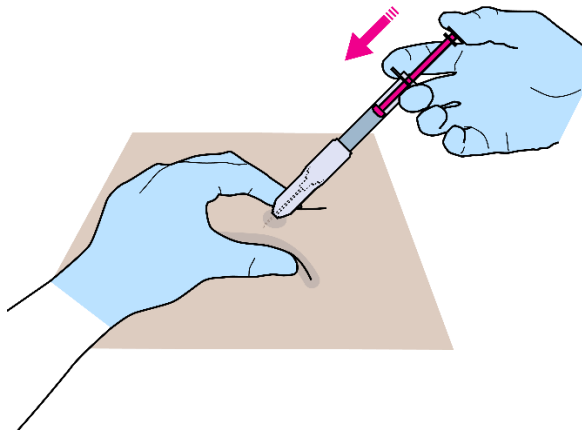
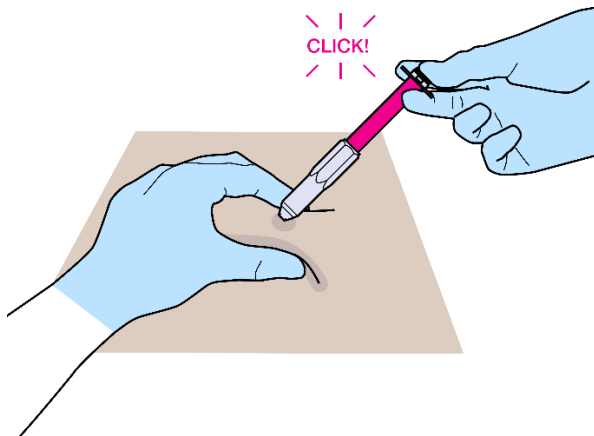
- 0.5 inch (13 mm) length – Shield edge stops at 0.25 mL
- 0.75 inch (19 mm) length – Shield edge stops at 0.40 mL

STEP 9 – Administer Medication

Note: Follow standard guidelines to control the rate of administration.

9. Fully depress the Plunger until you hear / feel a “click.”

Note: This activates the automatic retraction of the Needle into the Plunger. The Shield is propelled forward as the device is removed.



⚠ Warning: If activation fails, hold the Shield steady at the injection site and pull Syringe Barrel back to fully retract Needle.

STEP 10 – Device Disposal

10. Verify the Needle is inside the device then discard the device into Sharps Container per institutional protocol.

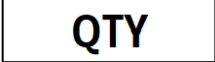


Symbols

The following symbols may appear in the instructions for use or on the packaging and labelling:

SYMBOL	MEANING (please check correct text)
Rx ONLY	CAUTION: U. S. federal law restricts this device to sale by or on the order of a physician.
	Manufacturer
	Date of manufacture
	Keep away from sunlight
	Catalog number
	Batch code

	Use-by date
	Storage temperature
	Single-Use only. Do not re-use
	Device is non-toxic
	Consult instructions for use
	Caution
	Non-pyrogenic

	Do not use if package is broken
	Sterilized using ethylene oxide with single sterile barrier system
	Do not resterilize
	Medical Device
	Unique Device Identifier
	Indicates number of pieces contained within package

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