

## ViaValve® Safety IV Catheter with Straight Hub and ViaValve® Winged Safety IV Catheter with Winged Hub

### Technical Summary Sheet



ViaValve® Safety IV Catheter with Straight Hub



ViaValve® Winged Safety IV Catheter with Winged Hub

#### Device Description

The ViaValve® Safety IV Catheter and ViaValve® Winged Safety IV Catheter are sterile, non-pyrogenic, single-use, radiopaque intravascular catheter devices used for the administration of medically prescribed fluids. A needle guard is locked over the introducer needle as it is withdrawn from the catheter to reduce the risk of accidental needlesticks. The clear flash chamber provides distinct visibility of blood flashback. The catheter incorporates a valve inside the hub which is designed to reduce blood exposure during initial catheter placement. The end cap promotes intuitive handling and hand positioning. The Luer taper/Luer lock catheter hub is color coded based on catheter gauge size and are available in straight hub and winged hub configurations.

Product does not contain natural made rubber, PVC and DEHP.

#### Indications

A properly placed IV catheter provides access to a vein or artery to sample blood, monitor blood pressure, or administer fluids. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy. 18 through 24 gauge catheters may be used with power injectors up to 300 psi.

#### Precautions

ViaValve® is designed to help reduce the risk of accidental needlesticks. In addition to the instructions for use, it is recommended that the healthcare professional follow the recommendations set forth by the CDC and OSHA standards (USA) or local equivalent for bloodborne pathogens when starting, maintaining, or discarding any IV catheter to avoid the risk of exposure to blood.

Follow current institutional policies and procedures for catheter insertion, maintenance and removal.

## Sterilization Method

Smiths Medical uses a validated sterilization cycle to sterilize this product. Validation and routine operation is performed based upon the guidelines set forth in ISO 11135. The sterilant used is Ethylene Oxide (EO). The products are for single-use only and cannot be resterilized.

## Device Components

Each ViaValve® Safety IV catheter and ViaValve® Winged Safety IV catheter consists of the following key parts: needle bevel, needle, catheter tube, catheter hub with valve and optional wing, ribbed needle housing, flash chamber, sheath, end cap, and the transparent needle guard with push-off tabs.

## Component Composition

**Catheter Tube:** Polyurethane (PUR)

**Eyelet:** Stainless steel

**Catheter Hub:** Polypropylene

**Seal:** Silicone rubber

**Sheath:** Polypropylene

**End Cap:** Polycarbonate

**Needle Guard:** Polycarbonate

**Needle:** Stainless steel

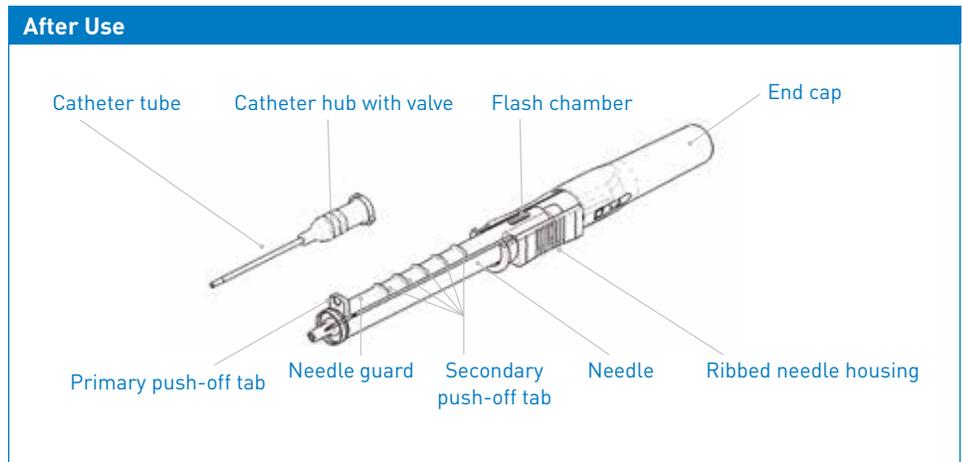
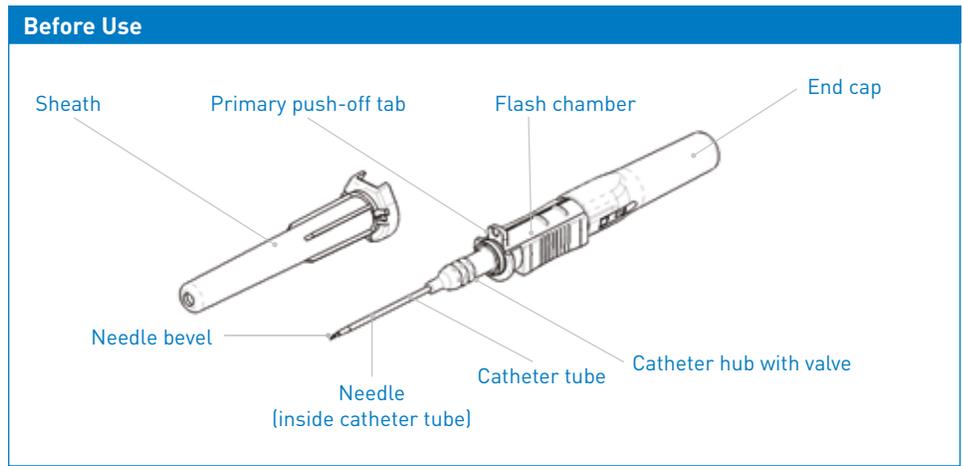
**Ribbed Needle Housing:** Polycarbonate

**Porous Barrier:** Polyethylene

**Lubricants:** Silicone



ViaValve® Straight Hub Catheter



## Labeling and Packaging

One (1) catheter unit is packaged per each flexible, peel-open blister. The blister label is color-coded based on catheter gauge size and is printed with product specific information. Product is sterile, non-toxic and non-pyrogenic unless package is open, wet, or damaged.

Discard if open, wet, or damaged. Fifty (50) units are packed per shelf pack, and four (4) shelf packs are packed per shipper. The lot number and expiration date are located on the individual package, shelf and case pack labels.

## Labeling and Packaging

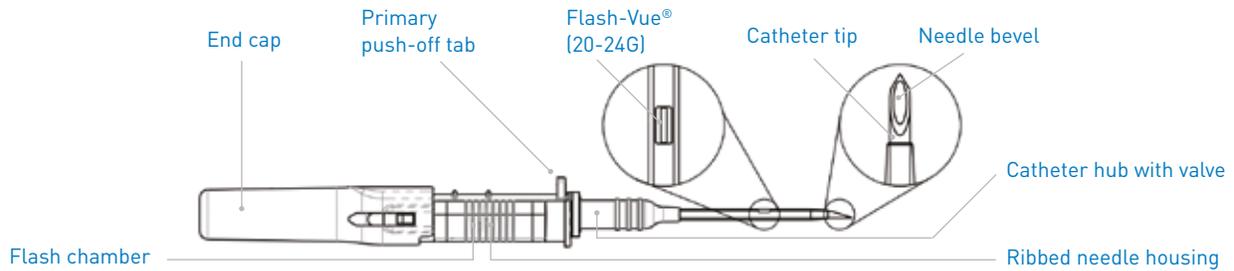
Container Type	Length	Width	Height	Weight
ST Box (50 units)	174.6 mm	88.9 mm	161.9 mm	0.45 kg
Shipper (200 units)	330.2 mm	184.2 mm	177.8 mm	2.00 kg

## Product Range and Flow Rates

ViaValve® Safety IV Catheter (Polyurethane)	ViaValve® Winged Catheter (Polyurethane)	Gauge Size/Length	Flow Rate mL/min	Units Per Case
3268		14g x 1 1/4 in.	360	200
3262	3282	16g x 1 1/4 in.	220	200
3265	3285	18g x 1 1/4 in.	110	200
3267*	3287*	20g x 1 in.	65	200
3266*	3286*	20g x 1 1/4 in.	63	200
3260*	3280*	22g x 1 in.	38	200
3263*	3283	24g x 5/8 in.	24	200

\* Features a FLASH-VUE® notched needle for early flash detection

**Figure 1.**

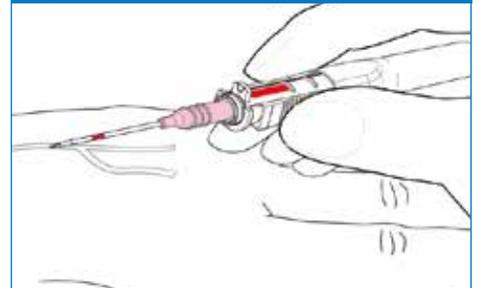


**Instructions for use**

Due to the risk of bloodborne pathogen exposure, follow Standard Precautions during placement, use and removal of an IV catheter.

1. Select and prepare site per institutional policy. Apply tourniquet.
2. Remove sheath in straight outward motion and inspect device. Ensure catheter hub and primary push-off tab are fully seated to the ribbed needle housing assembly.
3. Hold the device by the ribbed needle housing with thumb and fingers on opposite sides. Verify that the primary push-off tab and needle bevel are in the “up” position.
4. Anchor the vein with gentle skin traction.
5. Insert the needle into the skin and vein at an appropriate angle. Blood flashback into the flash chamber confirms vein entry. (Fig. 2) Gauges 20, 22, and 24 provide an early indication of flashback via the FLASH-VUE® window. (Fig. 1)
6. Decrease angle and insert device slightly to assure catheter entry into the vein.
7. Holding the ribbed needle housing stable, place your finger on the primary push-off tab and thread the desired length of the catheter off the needle and into the vein. As you thread the catheter, the needle guard begins to cover the needle. (Fig. 3)
8. Keep your finger on the primary push-off tab to stabilize the device, and then retract the ribbed needle housing until it securely locks into place. An audible click indicates that the safety mechanism has been activated. (Fig. 4)
9. Remove tourniquet.
10. Before disconnecting the ribbed needle housing from the hub, apply digital pressure as needed to the vein, distal to the catheter tip.
11. Anchor the catheter hub and disconnect the needle housing by pulling backward with a slight upward motion. (Fig. 5)
12. Attach IV connector, stabilize device and apply dressing per institutional policy.
13. The valve will allow flow once the Luer connector is attached and will remain open after initial activation. Therefore, digital pressure will be required prior to disconnecting the Luer connector from the hub, in order to prevent blood leakage.
14. Immediately discard unit into a puncture resistant, leak-proof, disposable sharps container.

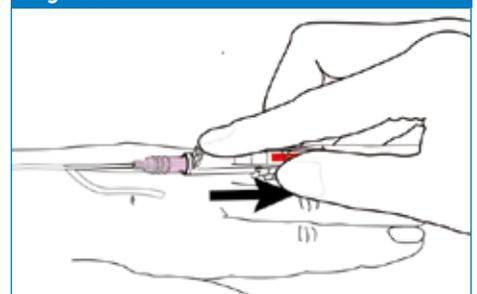
**Figure 2.**



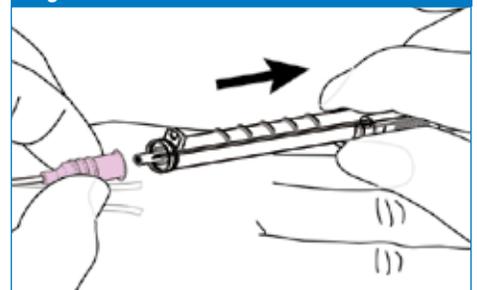
**Figure 3.**



**Figure 4.**



**Figure 5.**



PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN ALL GEOGRAPHIES

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