

Device Description

The DRS Vascular V-Close Suture Retention Appliance is a sterile, single-use, lightweight device made of biocompatible materials that can be easily installed within minutes to assist with venous access hemostasis.

Indications for Use

The V-Close Suture Retention Device is intended to temporarily retain sutures under tension to aid with hemostasis and healing.

Contraindications

Patients with an active local infection.
Patients requiring arterial access hemostasis.

Potential Complications

Potential complications include, but are not limited to, the following:

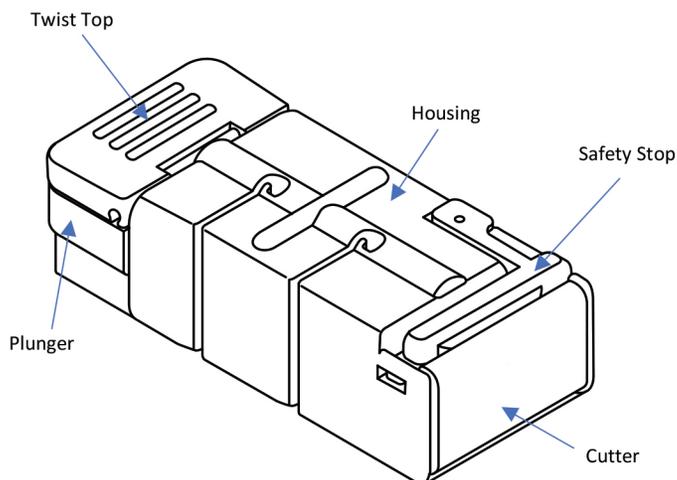
- Access site local infection
- Access site hematoma
- Bleeding
- Epidermal irritation and erythema
- Contact dermatitis

Precautions

- Federal (USA) law restricts this device to sale distribution and use by or on order of a physician. The V-Close should only be used by physicians who have received appropriate training in use of this device.
- Not for arterial access hemostasis.
- For use less than 24 hours.
- Contents are provided STERILE. Do not use if sterile barrier is opened or damaged.
- The device is intended for single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the Device and/or lead to Device failure, which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Device may lead to injury, illness, or death of the patient.
- Inspect packaging and device prior to use. Do not use if any portion of the Device is damaged. Replace with undamaged product.
- Do not use after the USE BY date.
- Store in a cool, dark, dry place.
- Careful review of this document should be performed prior to use of this device.

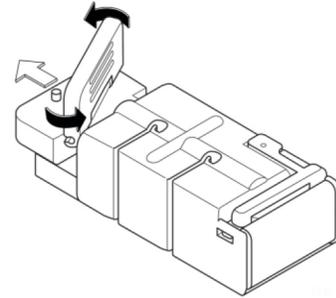
Device Preparation

1. Examine the package and device prior to use. Discard if there is damage.
2. After the procedure, create a figure eight stitch at the access site.

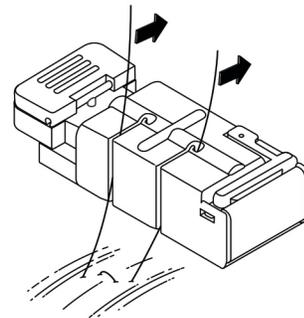


Procedure

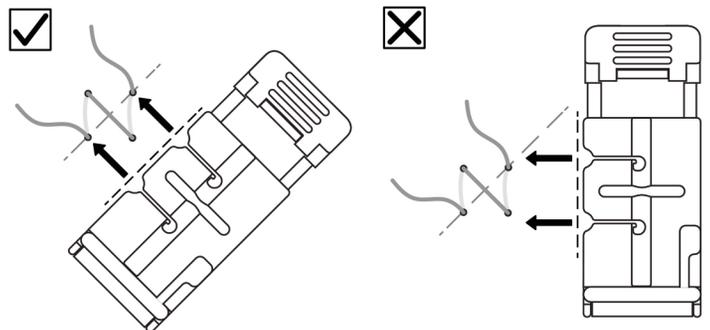
1. Open the V-Close plunger by flipping up the blue twist top and then twisting it until it stops. This should align the slots on the plunger and the main housing. Realign the twist top and snap it back into its original place.



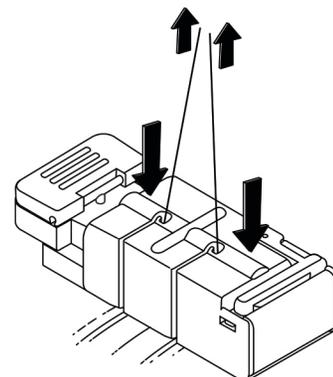
2. Insert each end of the suture through the two slots and slide the suture all the way to the back of the slot.



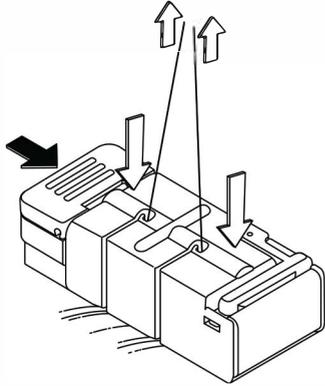
NOTE: To properly engage both free ends of the suture, orient the V-Close device parallel to the line joining the free ends of the suture. It is likely the ends of the suture will not be fully captured when the device is at an angle to the suture. See Figure below.



3. Apply tension to the sutures while pressing the V-Close against the skin. At this time remove any therapeutic devices or sheaths from the access site. Ensure the access site is clear and reapply tension to the suture and press the V-Close against the skin to ensure good contact.



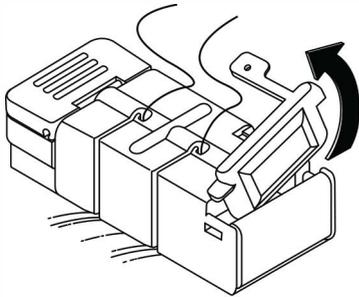
- Push the plunger inside the housing until the plunger neck is flush with the housing. The captured sutures should be visible through the housing.



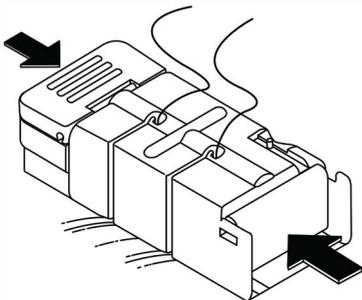
- Apply a slight tug to the device to ensure sufficient pressure, secure sutures and hemostasis at the access site. To check for hemostasis, flip the twist top and twist the same way as in Step 1.

Device Removal

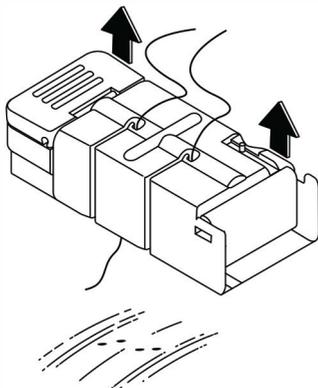
- To cut the sutures, remove the red safety tab from the device.



- Hold both ends of the device and push in the Cutter holder. This should cut one of the suture lines close to the skin.

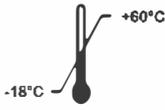


- Gently pull on the device and the suture can be slowly pulled out.



- Discard of the device per hospital policy.

Symbols Glossary

	Lot Number		Attention
	Catalog Number		Sterilized using ethylene oxide
	Manufacturer		Prescription use only
	Do not re-use		Keep Dry
	Do not re-sterilize		Consult Instructions for Use
	Do not use if package is damaged		Latex free
	Use By Date		Store between -18°C and +60°C
	Keep away from heat		

V-Close Suture Retention Device is covered by US Pat US 12,185,929 B2 and other pending patents.



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