



# V•Stick™ Vascular Access Set



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STERILE EO     LOT REF

   RxOnly 

 <https://www.argonmedical.com/products/>

The symbols glossary is located electronically at [www.argonmedical.com/symbols](http://www.argonmedical.com/symbols)

### Device Description

The V•Stick™ Vascular Access Set consists of a 4F or 5F coaxial introducer set (with a 3F standard or 3F stiff dilator), a 21ga entry needle (with an echogenic or non-echogenic tip), and a nitinol core with stainless steel coil 0.018" x 40cm vascular access mandrel guidewire with an articulatable tip.

### Intended Purpose/ Intended Use

V•Stick™ Vascular Access Sets facilitate fine needle venous or arterial puncture and tissue dilation for subsequent positioning of a 0.035" or 0.038" guidewire.

### Intended Patient Population

The V•Stick™ Vascular Access Set is intended for use in adults, as deemed appropriate by the qualified physician.

### Indication for Use

The V•Stick™ Vascular Access Sets is intended for use in the introduction and placement of guidewires and/or catheters.

### Intended Users

The V•Stick™ Vascular Access Set should be used by qualified medical professionals trained in vascular access procedures.

### Device Lifetime

V•Stick™ Vascular Access Set is intended for continuous use for less than 60 minutes.

### Clinical Benefits

V•Stick™ Vascular Access Set provides an indirect clinical benefit to the patient by enabling peripheral venous or arterial guidewire placement.

### Risks and side effects

The following complications are generally associated with access procedures and may occur when using the V•Stick™ Vascular Access Set:

- Thrombosis
- Bleeding
- Hematoma
- Occlusion
- Infection
- Phlebitis
- Vasospasm
- Vessel trauma, dissection

### Contraindications

This device is contraindicated for use on patients who cannot receive antiplatelet and/or anticoagulant therapy. Physician judgment should be used in determining when percutaneous interventional procedures are contraindicated.

### Warnings

- Contents are supplied sterile and are intended for single use only. Do not re-sterilize
- Reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection or other injury.
- Do not use if package is open or damaged and if the expiry date has been exceeded.
- Do not continue to use if any of the components are damaged during the procedure.
- The device is not intended for use in the coronary arteries or the neurovasculature.
- When introducing the guidewire, appropriate systemic anticoagulation should be used to prevent thrombus formation on the guidewire. Preclinical studies indicate that thrombus formation occurred on the guidewire when anticoagulation was not used.
- Do not withdraw the guidewire back through the metal cannula of the puncture needle after it has been inserted as it may damage the guidewire. If the guidewire tip must be withdrawn while the needle is inserted, remove both the needle and the guidewire as a unit.

### Precautions

- Do not use if any components are damaged, bent, or kinked as vessel damage and/or inability to advance/withdraw guidewire may occur.

- Never advance or withdraw the guidewire against resistance until the cause of resistance is determined by fluoroscopy. Excessive force against resistance may result in damage to the guidewire and catheter or vessel perforation.
- If the guidewire kinks, or a vascular spasm is suspected, cease manipulation of the guidewire and carefully withdraw it from the vessel.

### Pre-Procedure Preparation

1. Prior to use, carefully inspect the packaging and assembly for damage.
2. Utilizing sterile technique, remove the components from their packaging and transfer to the sterile field.
3. Thoroughly flush the introducer set and guidewire with heparinized saline.

### Directions for Use

1. Perform a skin incision under local anesthesia.
2. Do a fine needle puncture of the vessel using the 21ga needle.
3. Introduce the guidewire, making sure to loosen the straightener together with the guidewire on the circular dispenser.

**WARNING – Do not withdraw the guidewire back through the metal cannula of the puncture needle after it has been inserted as it may damage the guidewire. If the guidewire tip must be withdrawn while the needle is inserted, remove both the needle and the guidewire as a unit.**

4. Remove the needle, place the fully assembled coaxial introducer system over the guidewire, and advance it to dilate the vessel.
5. Loosen the inner dilator, making sure that the tip of the sheath introducer has been properly placed inside the vessel.
6. Remove the inner dilator and the 0.018" guidewire (included in the set).
7. Introduce a 0.035" guidewire or a 0.038" guidewire (not included in the set) through the sheath introducer.
8. Remove the sheath introducer.
9. Advance the required catheter over the guidewire.

### Storage and Handling Conditions

Store in a cool, dry area.

### Disposal

After use, handle and dispose in accordance with hospitals policies and procedures concerning biohazard materials and waste.

**Note:** In the event a serious incident related to this device occurs, the event should be reported to Argon Medical at [quality.regulatory@argonmedical.com](mailto:quality.regulatory@argonmedical.com) as well as to the competent health authority where the user/patient resides.