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Vascular Access Guidewire (Spring-Wire Guide)

Rx only.

Indications for Use:

To facilitate the placement of devices for diagnostic and interventional procedures.

Contraindications:

None known.

⚠ *General Warnings and Precautions*

Warnings:

1. **Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.**
2. **Read all package insert warnings, precautions and instructions prior to use. Failure to do so may result in severe patient injury or death.**
3. **Do NOT cut guidewire to alter length.**
4. **To prevent possible tissue damage, care should be taken when manipulating a catheter over a guidewire during catheter placement. If resistance is met during catheter placement, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, remove the guidewire and catheter as a unit to prevent possible damage and/or complications.**
5. **A guidewire is a delicate instrument and must not be advanced, withdrawn, or torqued if resistance is met. Excessive force against resistance may result in core protrusion, material fatigue, and separation of the guidewire tip, damage to the catheter/device or vessel damage. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.**
6. **Vascular access guidewires incorporate various performance characteristics from tip shape to body stiffness. Extreme care must be taken in choosing the correct guidewire to minimize the risk of vessel perforation or vasculature damage. Prior to use, confirm compatibility of guidewire outer diameter with the inner diameter of the device being used with the guidewire.**
7. **Clinicians must be aware of complications/undesirable side-effects associated with central venous catheters including, but not limited to:**
   - hematoma
   - pseudoaneurysm
   - embolism
   - bloodstream infection
   - site infection
   - cellulitis
   - death
   - additional surgical intervention
   - AV fistula formation
   - knotting
   - separation of the coil and core wires
   - vessel perforation
   - vessel spasm
   - malposition
   - displacement of vena cava filters
   - cardiac tamponade
   - cardiac dysrhythmias

Precautions:

1. **Exercise care in handling of the guidewire prior to and during a procedure to reduce the possibility of accidental breakage, bending, kinking, coil separation or contamination. Do not use a guidewire that has been damaged. Do not attempt to straighten a wire that has been kinked or bent. Do not re-introduce a guidewire if damage is present or suspected.**
2. **Refer to the instructions supplied with any interventional device to be used in conjunction with the vascular access guidewire for their intended uses, contraindications, and potential complications.**
3. **Some guidewires may contain nickel, which may cause allergic reactions in patients who have nickel sensitivities.**

Kits/Sets may not contain all accessory components detailed in these instructions for use. Become familiar with instructions for individual component(s) before beginning the procedure.

A Suggested Procedure: Use sterile technique.

1. Follow manufacturer's instructions for patient preparation and venous access.

NOTE: Centimeter marks on guidewire are referenced from "J" end. One band indicates 10 cm, two bands 20 cm, and three bands 32 cm.

2. Insert desired tip of guidewire through the introducer needle or catheter into vein.

   Straightening Tube (where provided): If the "J" tip portion of the guidewire is used, prepare for insertion by sliding the plastic tube over the "J" to straighten.

Arrow® GlideWheel™ Wire Advancer or Standard Arrow® Advancer (where provided):

Arrow Advancer is used to straighten "J" Tip of guidewire for introduction of the guidewire into Arrow® Raulerson Syringe or a needle.

- Using thumb, retract "J" (refer to Figure 1 GlideWheel or 1A Standard Advancer depending on which Arrow Advancer is provided).

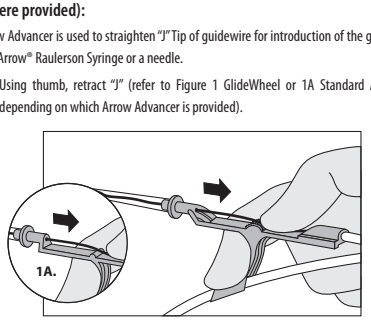

Figure 1

- Place tip of Arrow Advancer – with "J" retracted – into the hole in rear of Arrow Raulerson Syringe plunger or introducer needle.

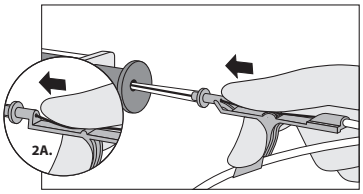

Figure 2

3. Advance guidewire into Arrow Raulerson Syringe approximately 10 cm until it passes through syringe valves or into introducer needle.
   - Advancement of guidewire through Arrow Raulerson Syringe may require a gentle twisting motion.
4. If using Arrow GlideWheel Advancer, advance guidewire through the Arrow Raulerson Syringe or through the introducer needle by pushing advancer wheel and guidewire forward (refer to Figure 2). Continue until guidewire reaches desired depth.

4A. If using standard Arrow Advancer, raise thumb and pull Arrow Advancer approximately 4 - 8 cm away from Arrow Raulerson Syringe or introducer needle. Lower thumb onto Arrow Advancer and while maintaining a firm grip on guidewire, push assembly into syringe barrel to further advance guidewire (refer to Figure 2A). Continue until guidewire reaches desired depth.

5. Use centimeter markings (where provided) on guidewire as a reference to assist in determining how much guidewire has been inserted.

NOTE: When guidewire is used in conjunction with Arrow Raulerson Syringe (fully aspirated) and a 2-1/2" (6.35 cm) introducer needle, the following positioning references can be made:

- ***20 cm mark (two bands) entering back of plunger = guidewire tip at end of needle***
- ***32 cm mark (three bands) entering back of plunger = guidewire tip approximately 10 cm beyond end of needle***

⚠ **Precaution: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed for handling purposes. A non-controlled guidewire can lead to wire embolus.**

⚠ **Warning: Do not aspirate Arrow Raulerson Syringe while guidewire is in place; air may enter syringe through rear valve.**

⚠ **Precaution: Do not reinfuse blood to reduce risk of blood leakage from rear (cap) of syringe.**

⚠ **Warning: Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.**

6. Remove introducer needle and Arrow Raulerson Syringe (or catheter) while holding guidewire in place.
7. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement.
8. Continue procedure per manufacturer's instructions.
9. Verify that entire guidewire is intact upon removal.

For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks, medical literature, and Arrow International LLC website: www.teleflex.com

A pdf copy of this IFU is located at **www.teleflex.com/IFU**

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Symbol Glossary: Symbols are in compliance with ISO 15223-1.
Some symbols may not apply to this product. Refer to product labeling for symbols that apply specifically to this product.

Caution	Medical device	Consult instructions for use	Contains a medicinal substance	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	Single sterile barrier system with protective packaging inside	
Single sterile barrier system	Keep away from sunlight	Keep dry	Do not use if package is damaged	Not made with natural rubber latex	Catalogue number	Lot number	Use by	Manufacturer
Date of manufacture								

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