en

Guidewire (Spring-Wire Guide) Product

Rx only.

Indications for Use:

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

Contraindications:

None known.

Clinical Benefits to be Expected:

The ability to guide and control the advancing movement of the catheter body through the vessel, to gain access to the vascular system through a single puncture site access.

⚠ *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. **Clinicians must be aware of potential entrapment of the guidewire by any implanted device in circulatory system. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire entrapment.**
4. **Do not use excessive force when introducing guidewire as this can lead to vessel perforation, bleeding, or component damage.**
5. **Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel, atrial or ventricular wall.**
6. **Do not apply excessive force in placing or removing guidewire. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.**
7. **Clinicians must be aware of complications/undesirable side-effects associated with central venous catheters including, but not limited to:**
   - knotting/kinking
   - separation of the coil and core wires
   - vessel perforation
   - malposition
   - guidewire retention/ intravascular loss
   - guidewire entrapment
   - arterial puncture
   - posterior wall puncture
   - bleeding
   - mediastinal hematoma
   - pleural effusion

Precautions:

1. **Do not alter the guidewire or any other kit/set component during insertion, use or removal.**
2. **Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.**
3. **Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.**
4. **Prior to attempting catheter exchange procedure remove catheter clamp and fastener (if applicable).**

A Suggested Procedure: Use sterile technique.

Prep Puncture Site:

1. Prepare patient per institutional policies and procedure and follow manufacturer's instructions for desired insertion procedure.
2. Insert desired tip of guidewire through the introducer needle or catheter into insertion site.

⚠ **Warning: Do not insert the solid proximal end (without coil) of guidewire, where provided, as it may lead to vessel damage.**

- If a "J" tip guidewire with a straightening tube is used, prepare for insertion by sliding the plastic tube over the "J" to straighten.
- If a "J" tip guidewire with an Arrow Advancer is used follow instructions below.

Arrow Advancer (where applicable):

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).

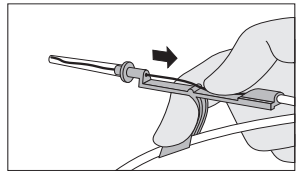

Figure 1

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

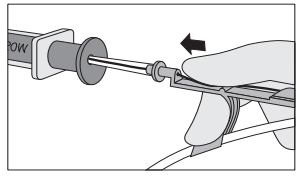

Figure 2

- If using Arrow Raulerson Syringe, 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.
- 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 2). Continue until guidewire reaches desired depth.

3. 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 withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.**

4. Remove introducer needle and Arrow Raulerson Syringe (or catheter) while holding guidewire in place.
5. Use centimeter markings on guidewire to adjust indwelling length according to desired depth.
6. If necessary, enlarge cutaneous puncture site with cutting edge of scalpel, positioned away from guidewire.

⚠ **Warning: Do not cut guidewire to alter length.**

⚠ **Warning: Do not cut guidewire with scalpel.**

- **Position cutting edge of scalpel away from guidewire.**
- **Engage safety and/or locking feature of scalpel (where provided) when not in use to reduce the risk of sharps injury.**

7. Continue procedure per manufacturer's instructions.

⚠ **Precaution: If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked around tip of catheter within vessel (refer to Figure 3).**

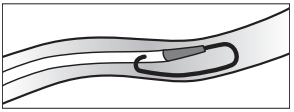

Figure 3

- In this circumstance, pulling back on guidewire may result in undue force being applied resulting in guidewire breakage.
- If resistance is encountered, withdraw catheter relative to guidewire about 2-3 cm and attempt to remove guidewire.
- If resistance is again encountered, remove guidewire and catheter simultaneously.

⚠ **Warning: Do not apply excessive force in removing guidewire. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.**

8. Always verify entire guidewire is intact upon removal.
9. Document procedure per institutional policies and procedures.

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**

en

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	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

Arrow International LLC
Subsidiary of Teleflex Incorporated
3015 Carrington Mill Blvd., Morrisville, NC 27560 USA
USA: 1 866 246 6990 | International: +1 919 544 8000

K-15703-110C (2021-01)

Teleflex®