



## P.D. Access™ Doppler Guided Arterial Catheterization Set

### Instructions For Use

#### CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician. Do not resterilize and/or reuse.

#### CONTENTS

- One (1)** Vascular Solutions, Inc.  
P.D. Access™ Guided Vascular Access Device  
(REF 78140 / 78145)
- One (1)** Arrow International  
Positive Placement Spring-Wire Guide (REF  
RW-04018)

#### SAFETY AND EFFICACY CONSIDERATIONS

**Warning:** Prior to use, read all package insert warnings, precautions and instructions. Failure to do so may result in severe patient injury or death.

Do not use if package has been previously opened or damaged. Do not alter spring-wire guide during insertion, use or removal. Procedure must be performed by trained personnel well-versed in anatomical landmarks, safe technique and potential complications.

## P.D. Access™ Percutaneous Doppler Vascular Access Device

### Instructions For Use

#### INDICATIONS

Use of the P.D. Access Device is indicated when blood flow must be detected for percutaneous vessel cannulation. The vessel must be of a caliber which would normally be punctured with a needle and/or catheter of this size or larger.

#### CONTRAINDICATIONS

None known.

#### WARNINGS AND PRECAUTIONS

**Warning:** The P.D. Access device is a delicate instrument which must be handled with care. Protect the tip from impact. Prior to use of this device, all equipment to be used for the procedure should be carefully examined. Verify that the luer connections between the needle and probe and between the catheter and needle, if applicable, are snug and that the size is appropriate for the vessel to be accessed.

#### PREPARATIONS FOR USE

1. Attach the cable of the needle to the P.D. Access Monitor by inserting the end with the female connector into the 3-pin connector located on the P.D. Access Monitor. If desired, the P.D. Access Monitor may be placed inside a sterile cover for use in the sterile field. Uncoil the cable completely.
2. Turn the P. D. Access Monitor on using the on/off pushbutton located on the front panel. Adjust the volume to the desired level. (The level of volume is indicated by LED lights located on the front panel of the P.D. Access Monitor).
3. Test the Doppler system by dipping the P.D. Access Device into a sterile container filled with sterile saline and move it back and forth in the solution. An audible Doppler signal should be heard. If this signal is not heard, check the connection.
4. Prepare the access area per normal vessel puncture procedure.
5. Anesthetize per standard procedure as needed with local infiltration of xylocaine or other appropriate anesthetic agent.

6. Use standard procedures to create a small skin incision for vessel puncture, if necessary.
7. Fill a small volume syringe (10cc or smaller) with sterile, normal saline. Expel any air bubbles.
8. Attach the syringe to the luer connector of the needle hub. Express saline through the needle several times to clear any air bubbles existing on the tip of the probe.

#### INSTRUCTIONS FOR USE

To use the P.D. Access Device you will need the following:

- P.D. Access Vascular Access Device
  - P.D. Access Monitor
  - Small volume syringe (10cc or smaller)
  - Sterile, normal saline
  - Sterile bowl or cup
  - Positive Placement Spring-Wire Guide
1. Insert the tip of the needle a short distance into the subcutaneous tissue. (A 45° – 60° angle to the vessel will produce the strongest Doppler signal.)
  2. Express a small amount of saline (1/2cc or smaller) through the tip of the needle to clear any air bubbles existing on the tip of the probe.
  3. Using the tip of the needle as a pivot point, slowly move the needle in a circular slow, sweeping motion, listening for the desired flow signal.
  4. Identify the vessel by location and sound wave form. Arterial flow may be identified as a pulsatile, higher frequency sound. Venous flow may be identified as a windy, lower frequency sound. Venous flow may also exhibit some degree of pulsatility and may be influenced by the respiratory cycle. This phenomenon is especially true for those veins in close proximity to the heart, such as internal jugular and subclavian veins.
- NOTE:** If both arterial and venous signals are heard concurrently, the artery and vein may be superimposed on one another with respect to the ultrasonic beam.
- NOTE:** Palpation of the vein may create enough pressure to cause the venous signal to completely disappear. It is therefore recommended that palpation not be performed when listening for venous signal.
5. If blood flow is not detected, advance the needle further and continue scanning the area, listening for the desired Doppler signal. (If required, more saline (1/2 cc or less) may be injected through the needle to clear any residual air trapped on the tip of the probe.
  6. Once the initial Doppler signal is detected, STOP! Scan the area until the intensity of the signal is maximized. Advance the needle further in that direction (approximately 1-2mm) and STOP again. Scan the area until the signal is maximized.
  7. Once the needle penetrates the vessel, a marked increase in the signal intensity occurs. Due to the compromised needle lumen with the probe in place, backflow will not be as brisk as with traditional punctures.
  8. Once the needle tip is within the vessel, the needle angle may be decreased to facilitate advancement into the vessel. If the audio signal decreased with repositioning, the needle should be advanced or retracted until the audio signal is strong again.
  9. Once needle is sufficiently advanced within vessel, advance catheter into vessel. If necessary or desired, spring-wire guide may be utilized by first removing Doppler probe from needle/catheter assembly by pulling the luer connector from the needle hub. See Positive Placement Spring-Wire Guide Instructions For Use for further information.
  10. Once the catheter has been adequately placed within the vessel, the probe or spring-wire guide is withdrawn by pulling the luer connector from the hub to



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permit passage of a guidewire, catheter or infusate. The catheter may be connected to an intravenous drip or capped and periodically flushed to maintain patency.

**WARNING:** Before withdrawing the needle and/or probe assembly in a central venous puncture, the patient should suspend respiration to prevent the introduction of air into the venous system.

**NOTE:** Arterial cannulation should produce a brisk pulsatile flow with the needle and probe assembly removed from the catheter. If this is not observed, wipe down and reinsert the needle and probe assembly. Expel any air bubble with saline, readjust needle position using the audio signal, and repuncture the vessel.

**NOTE:** Venous cannulation may or may not clearly demonstrate backflow, depending on venous pressure upon removal of the probe assembly. If backflow is not clearly demonstrated, adequate position in the vein may be shown by connecting a second syringe to the needle and aspirating blood.

the guidewire approaches the tip of the needle. As a reference; with the actuating lever located at the reference mark, the tip of the guidewire will be approximately ¼" (6.35mm) beyond the end of the needle.

**Precaution:** If resistance is encountered while advancing spring-wire guide, do not force feed. Withdraw entire unit and attempt new puncture.

**Warning:** Do not retract spring-wire guide against edge of needle while in vessel to minimize the risk of spring-wire guide damage.

4. Firmly hold introducer needle hub in position and advance catheter forward with a slight rotating motion over spring-wire guide into vessel (refer to Figure 3).



5. Hold catheter in place and remove needle and spring-wire guide assembly. Pulsatile blood flow indicates positive arterial placement. **Precaution:** Do not reinsert needle into catheter to minimize risk of catheter damage.
6. Verify entire spring-wire guide is in tact upon removal.

#### HOW SUPPLIED

The P.D. Access Vascular Access Device and Positive Placement Spring-Wire Guide are supplied ethylene oxide sterilized. A sterile cover is separately available for enclosing a non-sterile P.D. Access™ Monitor within a sterile field. **The entirety of this product is intended for single use only. Do not resterilize or reuse.** This product contains no natural rubber latex.

#### STORAGE

Store in a cool, dry place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that devices are used prior to the sterilization expiration date on the package label.

#### DISPOSAL

After use, all parts of this disposable device should be treated as potentially biohazardous, and disposed of properly.

#### LIMITED WARRANTY

**Vascular Solutions, Inc. warrants that the P.D. Access Device is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special or consequential damages arising from the use of the P.D. Access Device. Damage to the product through misuse alteration, improper storage or improper handling shall void this limited warranty.**

No employee, agent or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

**THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.**

#### REFERENCES

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3. Cucchiara RF, Muzzi DA. Guide-wire retention after arterial catheter insertion. *Anesth Analg*. 1992;74:303-304.
4. Hickman JA, McCririck A. Failure of a spring wire guide. *Anesthesia and Intens Care*. 1990;18:587. Letter.
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9. Reynen K. 14-year follow-up of central embolization by guide wire. *N Engl J Med*. 1993;329:970-971. Letter.
10. Trujillo MH, Arai K. Hydrothorax after inadvertent placement of a central venous catheter in left pericardiophrenic vein. *J Intensive Care Med*. 1994;9:257-260.

It is recommended that the user be acquainted with the reference literature.

#### MANUFACTURER INFORMATION:

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**Positive Placement Spring-Wire Guide**  
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## Positive Placement Spring-Wire Guide

### Instructions For Use

#### INDICATIONS

The Spring-Wire Guide is indicated for use with arterial/venous (AV) catheter introduction.

#### WARNINGS AND PRECAUTIONS\*

**Warning:** Practitioners must be aware of complications with spring-wire guide use including knotting<sup>5,6</sup> separation of the coil and core wires<sup>1,2,3,4,8,9</sup> vessel perforations and malposition.<sup>10</sup>

**Warning:** Do not apply excessive force in removing guidewire. If withdrawal cannot be easily accomplished, a radiograph should be obtained and further consultation requested.

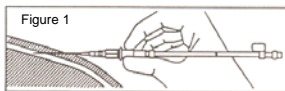
**Warning:** Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of patients.

Carefully read all warnings and precautions throughout procedure instructions.

\*If you have any questions or would like additional reference information, please contact Arrow International, Inc.

#### AV CATHETER INTRODUCTION

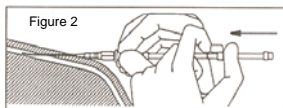
1. Prior to use, ensure proper placement of the needle is accomplished using the P.D. Access Doppler Guided Vascular Access Device. **Precaution:** If both vessel walls are punctured, subsequent advancement of spring-wire guide could result in inadvertent sub-vascular placement.
2. Remove the Doppler probe from needle/catheter assembly by pulling the luer connector from the needle hub. Attach spring-wire tube to hub of needle (refer to Figure 1).



3. Stabilize position of introducer needle and carefully advance spring-wire guide as far as required into vessel using actuating lever (refer to Figure 2).

**Precaution:** Do not advance guide wire unless there is free blood flashback.

**Precaution:** Do not advance guidewire unless there is free blood flashback.



As the guidewire actuating lever approaches the reference mark on the guidewire feed tube, the tip of