

INSTRUCTIONS FOR USE

To use the SmartNeedle Device you will need the following:

- SmartNeedle Vascular Access Device
- SmartNeedle Monitor
- Small volume syringe (10cc or smaller)
- Sterile, normal saline
- Sterile bowl or cup

Instructions For Use

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician. This device is intended for single use only. Do not resterilize and/or reuse.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE OF THIS PRODUCT, OBSERVE ALL WARNINGS AND PRECAUTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS

DESCRIPTION

The SmartNeedle™ Vascular Access Device consists of a detachable probe situated inside the lumen of a standard introducer needle. The needle and probe are attached by means of a luer adapter. The SmartNeedle Device is used for detecting and precisely locating blood flow within the anatomy. Flow is detected by an audio output from the SmartNeedle™ Monitor (sold separately).

INDICATIONS

Use of the SmartNeedle 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

The SmartNeedle 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 SmartNeedle Monitor by inserting the end with the male 3-pin connector into the female jack located on the SmartNeedle Monitor. If desired, the SmartNeedle Monitor may be placed inside a sterile cover for use in the sterile field.
2. Turn the SmartNeedle 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 SmartNeedle Monitor).
3. Test the Doppler system by dipping the SmartNeedle 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.

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's angle may be decreased, if desired, to facilitate passage of a guidewire. If the audio signal decreases with repositioning, the needle should be advanced or retracted until the audio signal is strong again.
WARNING: Before withdrawing the probe assembly from the needle in a central venous puncture, the patient should suspend respiration to prevent the introduction of air into the venous system.
9. Stabilize the needle with one hand; unscrew the luer connector on the hub, and remove the probe assembly from the needle.
NOTE: Arterial cannulation should produce a brisk pulsatile flow with the probe assembly removed from the needle. If this is not observed, wipe down and reinsert the 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 when the probe assembly is removed. 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.
10. Once satisfactory position is assured, advance the guide wire into the vessel per standard technique.
11. Withdraw the needle, and insert the catheter or sheath over the guidewire using standard technique.



Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Tel: +1 763-656-4300
Fax: +1 763-656-4250
www.vascularesolutions.com

HOW SUPPLIED

The SmartNeedle Vascular Access Device is supplied ethylene oxide sterilized. A sterile cover is available for enclosing a non-sterile SmartNeedle Monitor in a sterile field. The needle and/or probe, catheter and the cover are intended for single use only. Do not resterilize or reuse.

STORAGE

Store in a cool, dry place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that the 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 SmartNeedle 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 SmartNeedle. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

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