The ARROW® VPS® (Vascular Positioning System®) STYLET Bedside Procedure Kit

INSTRUCTIONS FOR USE

Caution: Federal law restricts this device to sale by or on the order of a physician, or other qualified health care professional

INDICATIONS FOR USE

The VPS® Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The Stylet, when used with the Console, provides real-time catheter tip location information by using the patient’s physiological (cardiac electrical activity and blood flow) information. When the Vascular Positioning System guidance indicator shows a Blue Bullseye, the catheter tip is in the desired location.

The Vascular Positioning System is indicated for use as an alternative method to fluoroscopy or chest X-ray for central venous catheter tip placement confirmation in adult patients, when a steady Blue Bullseye is obtained.

Note: If a steady Blue Bullseye is not obtained, standard hospital practice should be followed to confirm catheter tip location.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the P-wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

DESCRIPTION

The ARROW VPS consists of the ARROW VPS Stylet (Stylet) and either the VasoNovel™ VPS Console (Console) or the ARROW VPS G4™ device.

The Stylet is designed for use with the Console and a compatible central venous access catheter. As supplied, the Stylet is single use, sterile non-pyrogenic and non-toxic. The Stylet is a 6 foot long polymeric tube which contains a Doppler sensor at the distal tip and an intravascular electro-cardiogram (ivECG) signal sensing wire. The Doppler sensor and the ivECG signal sensing wire are used to detect and transmit physiological information to the Console. ARROW VPS Stylets are designed to be used with catheters with a minimum inner lumen diameter of 0.021 inches.

In a study completed to evaluate the performance of the ARROW VPS the following results were obtained from 77 evaluable cases in adult patients. In this study, the probability of correct tip placement when a Blue Bullseye was obtained was 98.4%. In all cases, catheter tip placement was verified using fluoroscopy:

- In 64/77 cases, a Blue Bullseye was obtained.
  - In 64/64 cases where a Blue Bullseye was obtained, the catheter tip was within 1 cm of the lower third of the SVC or at the cavoatrial junction. In 1/64 cases where a Blue Bullseye was obtained, the catheter tip was 1 cm lower than the cavoatrial junction.
- In 13/77 cases, a Blue Bullseye was not obtained.
  - In 2 of these 13 cases where a Blue Bullseye was not obtained, the catheter tip was not in the lower third of the SVC or at the cavoatrial junction and a Blue Bullseye was correctly not obtained.

POSSIBLE COMPLICATIONS ASSOCIATED WITH CENTRAL VENOUS CATHETER INSERTION

Before attempting, ensure that you are familiar with all possible complications and their emergency treatment should any of them occur. Most common complications are:

- Air embolism
- Intolerance reaction to implanted device
- Bleeding
- Perforation of vessels or viscus phlebitis
- Cardiac arrhythmia
- Spontaneous catheter tip malposition or retraction
- Cardiac tamponade
- Pneumothorax
- Catheter embolism
- Vessel erosion
- Hematoma

CONTRAINDICATIONS

All contraindications of central venous catheters apply as specified by the central venous catheter manufacturer. There are no contraindications specific to the ARROW VPS Stylet.

WARNING

The decision to confirm tip position with fluoroscopy or chest X-ray, in addition to a VPS steady Blue Bullseye, should be in accordance with standard hospital practice and the best judgment of the clinician which should take into account the patient’s condition; the experience of the clinician with VPS or similar devices; and the fluid to be infused through the catheter.

WARNINGS, GENERAL

- 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.
- Use aseptic technique during insertion and use.
- If the hub or a connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism.
- Inspect package, kit components and Stylet carefully before use. Do not use if packaging or components are damaged.
- Inspect Stylet connector prior to use. Do not use if connector appears to be damaged.
- Properly handle and dispose of used Stylet in a biohazardous waste container in accordance with U.S. OSHA or other governmental standards for blood borne pathogens and/or hospital/institutional policy.

WARNINGS, PLACEMENT

- Carefully tighten the Touhy Borst. Use care to minimize blood loss and risk of air embolism.
- Place the Stylet in the trimmed catheter, being careful not to kink the Stylet.
- Do not cut Stylet.
- Do not advance the device if unusual resistance is encountered.
- Do not insert or withdraw the Stylet forcibly from the catheter. The device may break.
- If the Stylet and/or catheter are damaged, the catheter and Stylet must be removed together.
- Avoid placement in the right atrium. Monitor catheter placement per institutional policy.

PRECAUTIONS

- Avoid clamping the Stylet.
- Contains DEHP.
**STERILIZATION**
The Stylet is provided sterile using a validated Ethylene Oxide process.

**WARNING:** Do not re-sterilize or damage to the Stylet may occur.

**PREPARATION AND USE**
Read all instructions carefully before using this device. The Stylet and catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional. Follow institutional policy for catheter placement.

1. **IDENTIFY THE VEIN AND INSERTION SITE**
2. **POSITION PATIENT and MEASURE FOR CATHETER LENGTH**
3. **POSITION VPS CONSOLE**
   - Place within about 4 feet (1.22 meters) of the insertion site without compromising the intended sterile field.
4. **PLACE ECG ELECTRODES**
   - Prepare the skin according to your hospital procedure to ensure good adherence and electrical contact. Connect all three ECG electrodes to ECG cable. Apply the white lead to the right shoulder, and the red and black leads to the patient’s left side on the hip area. Ensure the electrodes are not over any bony prominence and the electrodes are securely affixed to the skin. Connect the ECG cable to the Console. Check the ECG cable connection is secured. Please refer to the Console Operator’s Manual for details.
5. **STYLET EXTENSION CABLE**
   - If you are using the ARROW VPS G4 device, attach the Stylet Extension Cable to the front of the Base Unit by aligning the red dots on the connectors.
6. **SKIN PREPARATION**
7. **APPLY DRAPEs AND CREATE STERILE FIELD**
8. **SELECT CATHETER/PREPARE CATHETER/STYLET ASSEMBLY**
   a. Trim catheter if desired per manufacturer’s instructions.
   b. **Caution:** Do not cut Stylet. Do not use Stylet if Stylet is cut.
   c. Pre-flush all fluid lumens of catheter.
   d. Remove Stylet/Touhy Borst from tray; remove Stylet sleeve protector.
   e. Visually inspect and ensure the Stylet tip is intact. Keeping the Touhy Borst on the connector end of the Stylet, insert the Stylet through the distal lumen of the catheter until it extends 1 mm from the tip of the catheter.
   f. Firmly tighten the Touhy Borst onto the catheter luer.
   g. Holding the Stylet connector with one hand and the catheter tip with the other hand, form a semi-circle with the Stylet and then extend to verify that the tip of the Stylet remains extended 1 mm beyond the tip of the catheter. If not, loosen the Touhy Borst, adjust the Stylet and repeat until the Stylet is 1 mm beyond the catheter tip.
   h. Tighten Touhy Borst valve securely. Mark the Stylet near the Touhy Borst for reference using the permanent marker end of the utility pen provided in the Bedside Procedure Kit.
   i. Flush Stylet lumen:
      - Attach saline filled syringe to luer of side port adapter and flush adapter and catheter.
      - Clamp side port extension and remove syringe.
   j. Place preloaded catheter onto the sterile field. Clip the catheter/Stylet to the sterile drape to ensure it stays in the sterile field.
   **Note:** Maintain column of saline in contact with the Stylet for the duration of the procedure.
9. **CONNECT THE STYLET CONNECTOR TO THE VPS CONSOLE**
   **Caution:** Ensure that sterile technique is maintained. If needed, discard gloves and change to a new pair of sterile gloves after connecting the Stylet to the Console and completing the setup of the Console per the Console Operator’s Manual.
   **Caution:** Ensure that a tripping hazard is not created when the Stylet is connected to the Console. Tripping over the Stylet may cause malfunction of the Stylet, detachment of the Stylet connectors from the console, or injuries to the user.

If using the VPS G4 device follow Step 9a:

9a. Following sterile technique, CONNECT THE STYLET TO THE STYLET EXTENSION CABLE
   - Use the sterile bag provided, (or a second sterile glove), to connect the non-sterile Stylet Extension Cable to the Stylet. The sterile sheath can be used to cover the Extension Cable
10. **ATTACH STERILE SALINE SYRINGE** to the sidearm of the Touhy Borst and flush catheter while the VPS Console is on. Verify that strong Doppler sound can be heard. Wait 20-30 seconds (2-3 ECG strips) to ensure appropriate ECG signal is observed.
11. **FOLLOW YOUR HOSPITAL PROTOCOL FOR PERFORMING VENIPUNCTURE**
12. **INSERT CATHETER (WITH STYLET) INTO THE VASCULARITY AND ADVANCE SLOWLY**
13. **COMPLETE CATHETER INSERTION**
   a. Follow the instructions of the Console Operator’s Manual for tip location guidance and placement.
   **Note:** PICCs should be positioned with the catheter tip in the lower 1/3 of the SVC-Cavoatrial Junction.
   **WARNING:** Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade.
   **Note:** Confirm and document proper central venous catheter tip placement per institutional policy prior to use of the catheter.
14. **RETRACT AND REMOVE THE INTRODUCER SHEATH**
   a. Follow manufacturer’s instructions or institutional policy.
15. **REMOVE THE STYLET AND TOUHY BORST ASSEMBLY from the catheter**
   b. Disconnect the Touhy Borst and Stylet from the catheter luer connector.
   b. Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.
   c. Slowly remove the Touhy Borst and Stylet, as a unit. Do not remove the Stylet through the Touhy Borst.
   **Caution:** Never use force to remove the Stylet. Resistance can damage the catheter.
   **Caution:** If resistance or bunching of the catheter is observed, discontinue Stylet withdrawal and allow the catheter to return to its normal shape. Flush the lumen. Repeat this procedure until the Stylet is easily removed. If great resistance is experienced, withdraw both the catheter and Stylet together.
16. **ASPIRATE AND FLUSH CATHETER**
   Aspirate and flush according to hospital protocol or manufacturer’s instructions.
17. **SECURING THE CATHETER**
   To minimize the risk of breakage and movement, secure the catheter per institutional policy.
18. **RECORD PERTINENT PATIENT DATA.**

**WARRANTY VASONova, INC. WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.**

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