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Arrow® VPS® Stylet

Rx only

Product Description

The Arrow® VPS® consists of the Arrow VPS Stylet and the Arrow VPS G4™ Device (Console).

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.

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 VPS Stylet, when used with the VPS Console, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a Blue Bullseye, the catheter tip is in the desired location. The VPS 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.

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.

Note:

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.

⚠ *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. **Use aseptic technique during insertion and use.**
4. **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.**
5. **Clinicians must be aware of complications/undesirable side-effects associated with catheter insertion procedures including, but not limited to:**

- air embolism
- bleeding
- brachial plexus injury
- cardiac arrhythmia
- cardiac tamponade
- catheter embolism
- hematoma
- intolerance reaction to implanted device
- myocardial erosion
- perforation of vessels or viscus phlebitis
- spontaneous catheter tip malposition or retraction
- pneumothorax
- vessel erosion

Precautions:

1. **Do not alter any kit/set component during insertion, use or removal (except as instructed).**
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.**

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.

A Suggested Procedure:

Non-Sterile Setup:

1. Place VPS console as necessary to insertion site.
2. 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. Check the ECG cable connection is secured. Please refer to the Console Operator's Manual for details.
3. Attach the Stylet Extension Cable to the front of the Base Unit by aligning the red dots on the connectors.

Sterile Procedure:

1. Prep puncture site.
   a. Prepare clean skin with appropriate antiseptic agent.
   b. Drape puncture site.
   c. Apply sterile probe cover (where provided).
   d. Administer local anesthetic per institutional policies and procedures.
   e. Dispose of needle.
2. **If using VPS Stylet Bedside Procedure Kit,** trim and prepare catheter per manufacturer's instructions.
   a. Pre-flush all lumens of catheter.
   b. Remove VPS Stylet/Tuohy Borst from tray; remove sleeve protector.
   c. Visually inspect and ensure the VPS Stylet tip is intact. Keeping the Tuohy Borst on the Stylet, insert the Stylet through the catheter until it extends 1mm distal to the catheter tip.
   d. Firmly tighten the Tuohy Borst onto the catheter Luer.
3. **If using Arrow PICC kit preloaded with VPS Stylet**, and trimming is required.
   a. Loosen the Tuohy Borst and retract VPS Stylet to facilitate catheter trimming.
   b. If a stiffening stylet is preloaded, disconnect T-Port from Luer and retract stiffening stylet to facilitate trimming.
   c. Trim catheter per instructions for use.
   d. Position VPS Stylet 1mm distal to the catheter tip.
   e. Firmly connect the Tuohy Borst onto the catheter Luer.
   f. If applicable, advance the stiffening stylet and secure the T-Port to the catheter Luer hub. Retract the stiffening stylet through T-Port until it is approximately 1cm inside the catheter.

⚠ **Warning: Use care when tightening the Tuohy Borst to minimize the risk of blood loss and air embolism.**

4. Verify positioning of the VPS Stylet.
   a. 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 1mm beyond the tip of the catheter. If not, loosen the Tuohy Borst, adjust the Stylet and repeat until the Stylet is 1mm distal to the catheter tip.
   b. Tighten Tuohy Borst to secure position on VPS Stylet.

⚠ **Warning: Failure to maintain proper positioning of the VPS Stylet within the catheter may result in primary catheter malposition.**

⚠ **Warning: Do not kink Stylet.**

   c. Create a mark on the VPS Stylet proximal to reference the Tuohy Borst position using the permanent marker provided in the kit.
   d. Flush Stylet lumen(s) through side port(s) and clamp.
      - Attach saline filled syringe to luer of side port adapter and flush adapter and catheter.
      - Clamp side port extension.

⚠ **Precaution: Do not clamp catheter lumen containing VPS Stylet.**

⚠ **Warning: Do not advance the device if unusual resistance is encountered.**

⚠ **Warning: Do not insert or withdraw the Stylet forcibly from the catheter. The device may break.**

⚠ **Warning: To minimize breakage, do not forcibly insert or withdraw stylet(s) from catheter. If stylet or catheter are damaged, the stylet and catheter must be removed together.**

⚠ **Warning: Use care when tightening the Tuohy Borst to minimize the risk of blood loss and air embolism.**

NOTE: Maintain column of saline in contact with the VPS Stylet for the duration of the procedure.

⚠ **Precaution: Ensure that sterile technique is maintained.**

⚠ **Precaution: Ensure that a tripping hazard is not created when the VPS 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.**

5. Connect to VPS Console.
   a. Connect the VPS Stylet to the Stylet extension cable using sterile technique.
   b. Perform flush test by flushing through side port of Tuohy Borst adapter while the VPS console is on verify Doppler sound. Wait 20-30 seconds to ensure appropriate ECG signal is observed.
6. Advance catheter, with stylet(s) slowly through peel-away sheath to final indwelling position. If resistance is met retract and/or gently flush while advancing catheter.
   a. If unable to advance the single lumen catheter/VPS stylet assembly, a stiffening stylet component may be used as a mitigation technique, if provided.
      i. Disconnect the VPS Stylet/Tuohy-Borst assembly from the catheter Luer hub and remove as a unit.
      ii. To ensure the stiffening stylet will not extend beyond the distal tip of the catheter when inserted, the T-port should be positioned on the body of the stylet such that the length from the distal tip to the T-port is 10cm greater than the final trimmed length of the catheter. (This accounts for the length of the juncture hub, extension line, and luer hub.) Reference the length markings on the stiffening stylet, or use the sterile tape measure included in the kit to confirm.

Note: Stiffening stylet length markings are provided in 5 cm increments starting 20cm from the distal tip of the stylet.

      iii. Insert the stiffening stylet /T-Port assembly into the PICC and secure to the Luer hub.
      iv. Advance catheter/stiffening stylet assembly a few centimeters from the intended target location.
      v. Disconnect and remove stiffening stylet/T-Port.
      vi. Reload the VPS Stylet and secure Tuohy-Borst to Luer hub. Flush through Tuohy-Borst side port.
      vii. Confirm the Touhy-Borst remains tightened at the original reference mark location on the VPS Stylet (see step 4c) and complete catheter insertion.
7. Verify catheter tip position per Console Operator's Manual.

NOTE: Catheters should be positioned with the 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.

8. Remove the peel-away sheath per manufacturer's instructions.
9. Remove the stylet(s) from the catheter.
   a. Disconnect the Tuohy Borst and/or T-Port from the catheter luer connector(s).
   b. Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.
   c. If present, slowly remove the T-port and stiffening stylet, as a unit. Do not remove the stylet through the T-Port.
   d. Slowly remove the Tuohy Borst and VPS Stylet, as a unit. Do not remove the Stylet through the Tuohy Borst.

⚠ **Precaution: Do not use force to remove stylet(s) to minimize risk of damage to catheter.**

⚠ **Precaution: If resistance is felt, discontinue Stylet withdrawal. Flush the lumen and reattempt stylet withdrawal. If stylet is unable to be removed, the stylet and catheter must be removed together.**

⚠ **Warning: To minimize breakage, do not forcibly insert or withdraw stylet from catheter. If stylet or catheter are damaged, the stylet and catheter must be removed together.**

10. Aspirate and flush the catheter according to hospital protocol or manufacturer's instructions.
11. Secure the catheter per institutional policy and procedure to minimize the risk of breakage and movement.
12. Record Pertinent Patient Data.

See Console Operator's Manual for details.

Warranty: Teleflex, 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.

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	Electronic instructions for use	Unique device identifier						

"Rx only" is use within this labeling to communicate the following statement as presented in the FDA CFR: Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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
VPS Technical Support: +1.877.236.6869

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