



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 VasoNova™ 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	Myocardial erosion
Brachial plexus injury	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.