

ARROW® VPS G4™ VASCULAR POSITIONING SYSTEM®

Pre-Trial Information

The ARROW® VPS G4™ Vascular Positioning System® consists of the ARROW® VPS® Stylet (Stylet) and VPS G4 Base Unit and Interface (VPS G4 Device).

Consensus from all relevant departments in your facility will help us provide the most successful experience for you during this trial period. The following guidelines are provided to ensure your best possible VPS G4 Device trial experience.

DEFINITION & PURPOSE:

Indications for Use and Replacement of Chest X-ray

The VPS Stylet and VPS G4 Device are indicated for guidance and tip positioning for central venous catheters. The VPS G4 Device 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 symbol is obtained.

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

Refer to VPS G4 Device Operator's Manual and VPS Stylet Bedside Procedure Kit Instructions for Use for complete Indications for Use statements.

TRIAL OBJECTIVES:

Our primary objective is to demonstrate how easily and safely the ARROW® VPS G4™ Device can replace post insertion central line catheter tip placement chest X-rays (CXRs), per the Indications for Use mentioned above.

TRIAL SUCCESS:

A successful trial is defined as one where the viability of the ARROW® VPS G4™ Device has been established as a way to replace, or greatly reduce, the need for confirmatory CXRs for PICC or CVC placement. This will be achieved by reaching 90% or greater optimal catheter tip positioning, as confirmed by data on file. For the purpose of this trial, optimal catheter tip position is considered the lower 1/3 of the SVC or the Cavo-Atrial Junction (per INS, AVA and ONS standards and positioning statements).

LEARNING CURVE:

As with any new technology, each clinician using the ARROW® VPS G4™ Device can expect to experience a learning curve. Each identified clinician at your facility will have an experienced preceptor during this trial, who will guide them and help increase their confidence and skill level with this technology.

ARROW®
NEVER SETTLE™

TRIAL PARAMETERS:

- Identify 2–3 key individuals to participate in this trial. They should be free from other duties during this time.
- Because of the simplicity of the ARROW® VPS G4™ Device, trial periods are relatively short. Distractions should be avoided and time allowed for patient care. At the request of the facility, the timeframe of a trial can be adjusted to meet extenuating circumstances.
- Our trial and training process will occur during this timeframe: _____.
- Please inform Hospitalists, Radiology and Certified Nursing Specialists that the trial is taking place on these days. (This will increase the likelihood of securing patients for this process.)

POTENTIAL SCENARIOS: (Can be customized for your facility)

Day 1: Didactic training and simulated training, usually 2–3 hours needed. Continued didactic training at the bedside during live insertions.

Day 2: All day bedside insertions.

Day 3: All day bedside insertions.

NEEDS: FOR DIDACTIC TRAINING (Circle all required)

- A dedicated room large enough to accommodate 2 trainers and 2–3 of your staff, required only for 3 hours of the first day.
- AV equipment, if practical.
- A bed or table large enough to simulate the practice area.
- A Peter PICC Line™ if available.
- Ultrasound with stand to accommodate the Console (or alternative).
- Other bedside table if needed (for field set-up).
- ECG electrodes (as necessary).
- Non-sterile saline flushes.

ARROW RESPONSIBILITIES:

ARROW will provide training and education, clinical, sales and product support during the trial.

ARROW will:

- Support clinicians during the bedside procedure.
- Provide 1 ARROW® VPS G4™ Device (including accessories), and 8 ARROW® VPS® Stylets (1 box) during the trial process. Additional Stylets can be purchased.

We look forward to conducting a successful trial with you and your team. You will discover how safe and simple it can be to effectively replace chest X-ray, in adult patients, in the presence of a steady Blue Bullseye symbol, during central line placement.

Peter PICC Line is a trademark of VATA, Inc.

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