ARROW®

Arrow[®]

VPS Rhythm[™] Device with TipTracker[™] Technology Information for Hospital Radiology Department

Technology Overview

The Arrow[®] VPS Rhythm[™] Device with optional TipTracker[™] Technology from Teleflex is designed for Peripherally Inserted Central Catheter (PICC) navigation and tip confirmation.

The VPS Rhythm Device employs ECG technology to guide the clinician in PICC placement to the ideal landing zone, the lower 1/3 of the Superior Vena Cava, near the Cavo-Atrial Junction (SVC-CAJ). PICC navigation is available when the T-piece is placed on the patient's chest, and the PICC contains the TipTracker™ Stylet. A blue TipTracker line appears on the monitor illustrating the pathway of the PICC as it descends towards the SVC. This allows the clinician to make real-time adjustments to the catheter for ease of PICC placement.

As the catheter tip approaches the heart, the VPS Rhythm[™] Device displays the intravascular ECG tracing, in which the P-wave appears to increase in height as it approaches the cavoatrial junction. As the catheter tip passes the SA node, a negative deflection appears on the ECG tracing, indicating the catheter has passed the CAJ.

Withdrawal of the catheter just until this deflection disappears will result in a peaked P-wave, indicating that the catheter is placed at the lower 1/3 of the SVC near the CAJ.

By preventing malposition of the catheter tip, associated complications, such as thrombosis, DVT (Deep Vein Thrombosis) and infection, (which are well documented in clinical literature), can be reduced.



The VPS Rhythm[™] Device is indicated for use as an alternative method to fluoroscopy or chest X-ray for PICC placement confirmation in adult patients, when the intravascular ECG tracing indicates lower 1/3 of SVC placement and all items in the Tip Confirmation Checklist are completed. When this is achieved, the statement "Tip confirmed in lower 1/3 SVC. Line may be released for use," will appear on the JPG report, as valid evidence of correct tip placement.

Note: If all items on the Tip Confirmation Checklist cannot be completed, standard hospital practice should be followed to confirm catheter tip location. See Operator's Manual or TipTracker Stylet Instructions for Use for full Indications for use.

(continued on the other side)



Your Vascular Access/PICC Team is conducting a PICC insertion study using the Arrow[®] VPS Rhythm[™] Device with optional TipTracker Technology for Navigation and Tip Positioning

The VPS Rhythm[™] Device will address two clinical challenges:

- PICC navigation through the vasculature (when TipTracker[™] Technology option is used)
- · Correct placement of the PICC in the lower 1/3 of the SVC-CAJ

Correlation between the VPS Rhythm[™] Device and confirmatory chest X-ray will be checked for_ __cases.

[Teleflex Rep: insert number of cases.]

The following method is recommended for reading the confirmatory X-ray.¹

- Find the Right Atrial Appendage (RAA) and measure 1-2 cm below that point to locate the CAJ. The lower 1/3 of the SVC-CAJ landing zone should be 1 cm above the RAA to 2 cm below the RAA (3 cm landing zone)
- · An alternative method is identifying the carina with the landing zone located 2-5 cm below the carina

Thank you for your time and attention to these details.

Technicians are asked to use the following protocol while taking X-rays.

- Remove any items that interfere with visualization
- Keep head of bed at degrees while shooting film [insert appropriate degrees, per hospital's policy]
- Keep X-ray beam perpendicular to the film
- Shoot X-ray at the End of Expiration, while patient takes a normal breath

References:

- 1 Verhey P, Gosselin M, Primack, Blackburn P, and Kramer A. The right mediastinal border and central venous anatomy on frontal chest radiograph –
- direct CT correlation. J Assoc Vascular Access 2008: 13:32-35.
- Rx Only

See Instructions For Use for detailed information regarding the Indications for Use, contraindications, warnings, and cautions. This material is not intended to replace standard clinical education and training by Teleflex and should be used only as an adjunct to more detailed information that is available about the proper use of the product.

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