

Real World Evidence Study of a New ECG-Guided Tip Positioning Device for Central Venous Catheter Placement

Amy Bardin, EdD, EMBA, RRT, FAARC, VA-BC; Thomas Philbeck, PhD, MBA

Nick Potochick, MS; John McDonald, PhD
Teleflex Incorporated Clinical & Medical Affairs

Background and Objectives

The Arrow VPS Rhythm DLX with Tip Tracker Technology is indicated for the positioning of central venous access devices as, including peripherally-inserted central catheters (PICCs) an alternative to chest X-ray/fluoroscopy for confirmation of catheter tip placement in adults. Introduced in 2022, a retrospective study was performed to collect real-world evidence to substantiate performance and safety of the device.

Methods and Materials

- Primary endpoint was the success rate for catheter tip location (proportion of cases in which the catheter was successfully placed using the patient's ECG p-wave).
- Secondary endpoint was the rate of device related adverse events.
- Study protocol was reviewed by a central IRB and determined to be exempt from consent/continued review.
- The study was conducted in US by clinicians who had used the device.



Results

- Investigators at two sites collected data for 85 cases
- In most cases (56.5%), the patients were male and 87.1% were >55 years old.
- In 65 (76.4%) and 20 (23.5%) cases, the NaviCurve and the VPS TipTracker stylets were used, respectively

Results

- All PICCs placed and ready to use between 5 and 30 minutes after initiation of placement procedure
- In 100% of qualifying cases, catheter tip navigation and placement confirmation were successful
- No malpositioned catheters; no adverse events.

Conclusions

- In first study describing Arrow VPS Rhythm DLX, the device showed positive outcomes regarding performance and safety.
- Device performed as intended with a high level of success and no adverse events
- For all patients who qualified for ECG guided insertion, the device consistently facilitated successful placement of a PICC, determined by the ECG P-wave deflection
- Demonstrated ability to safely place PICCs at the bedside and immediate use of the catheter other advantages
- Avoided X-ray exposure and the associated time and costs
- Study confirmed general safety and performance of the device

Disclosure: All authors were, or are, employees of Teleflex Incorporated, the parent company of the manufacturer of the Arrow VPS Rhythm DLX device used in the study described herein.