en

NaviCurve™ Stylet, T-Piece and Accessories

Only for use with VPS Rhythm® systems (VPS Rhythm® Device and VPS Rhythm® DLX Device)

Rx only.

Intended Use:

The Arrow® NaviCurve™ Stylet (Stylet) is intended for use with VPS Rhythm® systems to provide PICC navigation using electromagnetic technology.

Indications for Use for VPS Rhythm Systems:

The VPS Rhythm Device and VPS Rhythm DLX Device are indicated for the positioning of central venous catheters including PICCs. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The VPS Rhythm Device and VPS Rhythm DLX Device are indicated for use as an alternative method to chest X-ray or fluoroscopy for confirmation of central venous catheter tip placement in adult patients.

The TipTracker™ Technology is an optional accessory for use with the VPS Rhythm Device and VPS Rhythm DLX Device, indicated for visual navigation of a peripherally-inserted central catheter (PICC) as it is inserted through the vasculature. The TipTracker technology is used for catheter tip navigation purposes only; it is not used to determine final catheter tip placement.

NOTE: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including:

- ***Atrial fibrillation***
- ***Pacemaker-driven rhythm***
- ***Atrial flutter***
- ***Chronic obstructive pulmonary disease (COPD)***
- ***Severe tachycardia***

Such patients are easily identified prior to central catheter insertion. In these specific cases, use of an additional confirmation method is necessary to confirm catheter tip location.

Additionally for VPS Rhythm DLX Device Only:

For a catheter insertion procedure, ultrasound may optionally be used to assess the blood vessel to aid in selection of catheter size and visualize the blood vessel during initial insertion.

Device Description:

TipTracker Technology facilitates visual navigation of a PICC as it is threaded through the vasculature. The Stylet is placed inside the PICC and an electromagnetic T-piece is placed on the patient's sternum. The system uses electromagnetic technology to track the location of the PICC as it approaches the SVC and displays a blue line on the monitor, illustrating the catheter pathway. The T-piece has a radius of approximately 9" (22 cm) and will identify the Stylet as soon as it appears within that range. As the catheter approaches the heart, electrocardiograph (ECG) waveforms are used to determine final catheter tip location.

For the use of TipTracker Technology, two sterile, single use components are used: a sterile sleeve for the Remote Control and cable and a navigation Stylet, which includes a T-port with side arm. The sterile sleeve provides a means for using the VPS Rhythm Device Remote Control to operate the VPS Rhythm monitor within the sterile field. A non-sterile, single use, T-piece cover is also used.

For use of the VPS Rhythm DLX Device, the same sterile components described above are required. Additionally, the VPS Rhythm DLX Device offers an optional ultrasound-based imaging module for vascular access. A sterile, single use sleeve for the Ultrasound Probe and cable should be used within the sterile field. For the cleared indication for use on ultrasound, refer to the Instructions for Use provided with the Ultrasound Probe.

The Arrow NaviCurve navigation Stylet (0.018" OD x 28-3/4" working length from T-port to tip) is supplied preloaded in specific lumens of 4-6 Fr. Arrow PICCs and incorporates a lubricious PTFE coating along the Stylet body. The Stylet is also available as a replacement component in the event the preloaded Stylet becomes compromised during preparation or use. The Stylet's variable stiffness, and anatomical body and tip curves are designed to aid in PICC insertion.

Contraindications:

There are no contraindications associated with the use of the Stylet. Consult the catheter's Instructions for Use for catheter contraindications.

⚠ *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. **Refer to the VPS Rhythm system Operator's Manual and this IFU for full instructions, indications, contraindication, warnings and precautions. Failure to do so may result in severe patient injury or death.**
4. **Failure to abide by warnings, precautions, and instructions including, but not limited to, flushing or saline column instructions, exposing the Stylet to media other than saline, or excessive wiping, might result in damage to the Stylet coating, which may necessitate intervention or result in serious adverse events.**
5. **The safety and effectiveness of the Stylet has not been established, or is unknown, other than for use within a PICC during placement, per the procedure.**
6. **Do not use excessive force in placing or removing catheter or Stylet. Excessive force can cause component damage or breakage.**
7. **Clinicians must be aware of complications/undesirable side effects associated with stylets including, but not limited to:**
   - additional surgical intervention
   - embolization
   - infection
   - lung irritation
   - thrombosis / thrombus
   - tissue trauma
   - venous spasm
   - vessel perforation
   - vessel trauma

   For complications/undesirable side effects associated with PICCs refer to PICC Instructions for Use.

Precautions:

1. **Do not alter the Stylet or any other kit/set component during insertion, use or removal.**
2. **Do not expose cable plugs or Stylet jack/housing regions to fluids during use. Doing so may result in degraded performance or loss of functionality.**
3. **Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.**
4. **Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.**
5. **If the package is damaged or unintentionally opened before use do not use the device. Dispose of the device.**
6. **Storage conditions for these devices require that they are kept dry and out of direct sunlight.**

Preparation and Use of the Stylet and T-Piece with the VPS Rhythm system:

Follow institutional policy and procedure and manufacturer's guidelines for PICC placement. The Stylet and PICC should be inserted, manipulated, and removed by a qualified health care professional, familiar with the use of the VPS Rhythm system.

Non-Sterile Setup:

1. Turn on the Monitor and follow full instructions in the VPS Rhythm system Operator's Manual for entering the patient ID and entering optional notes.
2. Follow full instructions in the VPS Rhythm system Operator's Manual for connecting the T-piece, Remote Control, and optional Ultrasound Probe connectors to the back of the monitor.
3. Place ECG electrodes.
    a. Attach ECG snap leads to corresponding color of the T-piece ECG hub and attach the electrodes to the snap leads.
    b. Prepare the skin according to institutional policy and procedure to ensure good adherence and electrical contact. Ensure the electrodes are not over any bony prominence.

AHA ECG Cable Connections and Placement

- White to right arm (RA)
- Black to left arm (LA)
- Red to lower left chest or upper left leg (LL)

IEC ECG Cable Connections and Placement

- Red to right arm (R)
- Yellow to left arm (L)
- Green to lower left chest or upper left leg (F)

4. Follow VPS Rhythm system Operator's Manual to obtain an External ECG baseline. Confirm patient is in sinus rhythm.
5. Once baseline external ECG is saved, a window will appear to allow user to enter external measurement and trimmed length. Using landmark technique, obtain external measurement for PICC length; enter into external measurement window. Use Remote Control or touch screen to enter external measurement and trimmed length.
6. Add 2 cm to external measured length and enter as trimmed length. Use this length for trimming, if trimming is required.
7. Place the T-Piece. (Follow the VPS Rhythm system Operator's Manual to safely use the T-piece and set up navigation mode.)

NOTE: Patient should lie in a supine position, if possible.

    a. Insert T-piece inside non-sterile T-piece cover. Close T-piece cover around T-piece base using Velcro strap. Peel tape from T-piece cover.
    b. Apply T-piece to patient's sternum, aligning T-piece notch to the patient's sternal notch. Ensure T-piece is secure and does not move.

Sterile Procedure:

8. Prepare sterile field per institutional policy and procedure and manufacturer's guidelines.
9. Prepare sterile Ultrasound Probe and cable if optional Ultrasound Probe is used with the VPS Rhythm DLX Device.
    a. Remove sterile sleeve and ultrasound accessories from packaging.
    b. Place the sterile ultrasound gel inside the probe cover.
    c. Insert the Ultrasound Probe into the sterile sleeve.
    d. Unroll the sterile sleeve to cover the entire length of the Ultrasound Probe and cable.
    e. Secure the sterile probe sleeve using the sterile bands.
    f. Check for and eliminate bubbles between the face of the Ultrasound Probe and sterile sleeve. If any bubbles are present, the ultrasound image may be affected.
    g. Inspect the sterile probe sleeve to ensure there are no holes or tears.
10. Connect Stylet to Remote Control and cable.
    a. The sterile Remote Control and cable sleeve is similar to an Ultrasound Probe sleeve. Carefully place your hand all the way inside the folded sleeve.
    b. Maintaining sterile technique, firmly grasp the tip of the Remote cable plug through the end of the sterile sleeve and unroll the sterile sleeve to cover the entire length of the Remote Control and cable.
    c. Pull the plastic sleeve tightly over the tip of Remote Control cable plug creating tension against tip of plug.
    d. Connect the Remote Control plug to the Stylet jack, carefully piercing through the sterile sleeve. **Ensure sterile field is maintained**.
11. Prepare PICC per institutional policy and procedure and catheter's Instructions for Use.
    a. Ensure monitor is in Intravascular mode.
    b. Remove any wires or stylets from PICC (if provided). The Stylet will provide some additional support to the catheter to aid in insertion. If additional stiffness is required while threading the PICC, a stiffening wire may be inserted into the opposing lumen that does not contain the Stylet.
    c. If desired, trim PICC per institutional policy and procedure and manufacturer's guidelines.
    d. Pre-flush all catheter lumens.
    e. When using Stylet as a replacement for a Stylet previously preloaded in an Arrow PICC, ensure to place the Stylet in the same lumen as previously loaded.
    f. Adjust Stylet location within PICC:
        - Insert Stylet into PICC until Stylet tip protrudes approximately 1 cm beyond catheter tip.
        - Firmly tighten T-port onto catheter luer.
        - Withdraw Stylet through T-port by 2 cm to ensure Stylet is 1 cm inside catheter lumen (refer to Figure 1).

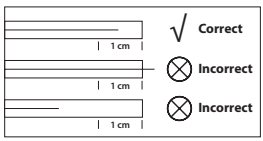

Figure 1

⚠ **Warning: Retract Stylet when trimming. Do not cut Stylet when trimming PICC to reduce risk of damage to Stylet, creation of wire fragment, or embolism. If there is any evidence that Stylet has been cut or damaged, Stylet should not be used.**

⚠ **Warning: Do not attempt to advance Stylet through T-port.**

⚠ **Warning: Ensure Stylet tip does not extend beyond catheter tip to reduce the risk of Stylet or vessel damage.**

⚠ **Warning: Do not kink Stylet to reduce the risk of Stylet damage and difficult removal.**

    g. Flush T-port and clamp T-port extension line. Always maintain a saline column during the procedure.

⚠ **Warning: Do not clamp catheter extension line when Stylet is in PICC to reduce risk of Stylet kinking.**

Complete Procedure & Remove Stylet:

12. Insert PICC and Stylet assembly per institutional policy and procedure and catheter manufacturer's Instructions for Use.

⚠ **Warning: If resistance is observed during insertion/placement, do not apply excessive force or rotate the Stylet housing to reduce risk of possible breakage. If excessive resistance is observed during insertion or damage is suspected, radiographic visualization should be considered along with further clinical consultation.**

13. Complete catheter placement per institutional policy and procedure and catheter manufacturer's Instructions for Use. Refer to the VPS Rhythm system Operator's Manual for instructions on navigation and catheter tip placement and confirmation, using Intravascular ECG.
14. Remove Stylet from catheter.
    a. Disconnect T-Port luer from catheter luer.
    b. Stabilize PICC position by applying light pressure to vein distal to insertion site.
    c. Slowly remove Stylet and T-port as a unit. Do not remove Stylet through T-Port.

⚠ **Warning: Do not apply undue force on Stylet to reduce the risk of possible breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be considered along with further clinical consultation.**

⚠ **Caution: If resistance or catheter bunching is observed, discontinue Stylet withdrawal and allow PICC to return to its normal shape. Flush lumen(s). Repeat until Stylet is easily removed. If great resistance is experienced, withdraw catheter and Stylet together.**

d. Visually inspect Stylet to confirm tip is intact.

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**

en

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

"Rx only" is used 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

Teleflex®

S-20100-201A, Rev. 2 (2022-09)