

TipTracker™ Stylet, T-Piece and Accessories

Only for use with the VPS Rhythm™ Device

Rx only.

Intended Use:

The TipTracker™ Stylet (Stylet) is intended for use with the VPS Rhythm™ Device to provide PICC navigation using electromagnetic technology.

Indications for Use for the VPS Rhythm Device:

The VPS Rhythm Device is indicated for the positioning of central venous catheters including PICCs. It provides catheter tip location information by using the patient's cardiac electrical activity. The VPS Rhythm Device is 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, 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.

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 VPS Rhythm screen, 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.

The TipTracker Stylet is designed to be used with PICCs with a minimum inner lumen diameter of 0.018 inch, or catheter sizes from 3-6 French. The Stylet should not be used with silicone catheters.

Contraindications:

There are no contraindications associated with the use of the Stylet. Consult the catheter manufacturer's Instructions for Use for possible 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 Device Operator's Manual and this IFU for full instructions, indications, contraindications, warnings and precautions. Failure to do so may result in severe patient injury or death.

4. Do not use excessive force in placing or removing catheter or Stylet. Excessive force can cause component damage or breakage.

Precautions:

1. Do not alter the Stylet or any other kit/set component during insertion, use or removal.
2. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.
3. Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.

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

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, licensed physician or other qualified health care professional, familiar with the use of the VPS Rhythm Device.

Non-Sterile Setup:

1. Turn on the VPS Rhythm Device and follow full instructions in the VPS Rhythm Device Operator's Manual for entering the patient ID and entering optional notes.
2. Connect black T-piece connector to the black socket and the blue Remote Control connector to the blue socket on 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 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 Device 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. Connect TipTracker Stylet to Remote Control and cable.
 - a. The sterile sleeve is similar to an ultrasound probe sleeve and is folded showing an arrow at one end and instructional images at the other. Starting at the instructional end, locate the hand illustration inside the center fold of the sleeve and carefully place your hand all the way inside.
 - b. Maintaining sterile technique, firmly grasp the tip of the Remote cable plug through the end of the sterile sleeve where the arrow is located 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.**
10. Prepare PICC per institutional policy and procedure and catheter manufacturer's Instructions for Use.

Using Valved Catheters

If using a valved PICC special considerations must be made for correct use of the VPS Rhythm Device for PICC tip placement. The ECG signal used for final catheter tip placement is impeded if the PICC's integral valve is closed.

- PICCs with a valve at the distal end: *While advancing catheter towards the SVC, periodically flush the PICC through the T-port sidearm to open the PICC's integral valve.*
- PICCs with a valve integrated into the catheter's luer hub: *The Stylet passes through the valve, keeping it open throughout the procedure.*
NOTE: Always maintain a complete saline column inside the catheter.

NOTE: To maintain a clear waveform, it is recommended to keep the patient as still as possible.

- a. Ensure monitor is in Intravascular mode.
- b. Remove stiffening stylet from PICC (if provided). The TipTracker 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 proximal or medial lumen.
- c. If desired, trim PICC per policy and procedure and manufacturer's guidelines.
- d. Pre-flush all catheter lumens.
- e. If not preloaded, load Stylet into PICC.
- 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).

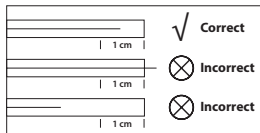


Figure 1

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:



















11. Insert PICC and complete catheter placement per institutional policy and procedure and catheter manufacturer's Instructions for Use. Refer to the VPS Rhythm Device Operator's Manual for instructions on navigation and catheter tip placement and confirmation, using Intravascular ECG.
 12. 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

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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
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Date of manufacture								

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