

Celerity PICC Tip Confirmation System with NAVIGATION

INDICATIONS

Refer to directions for use provided with the product for complete instructions.

Using a patient's electrocardiographic (ECG) waveform for device positioning is not new. Neither are overcomplicated ways of delivering that capability to a clinician. With all of the challenges posed to a vascular access specialist during a procedure, obtaining and interpreting ECG waveforms shouldn't be one.

Achieve catheter placements using the Celerity* PICC Tip Confirmation System with NAVIGATION, indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

INS Standards of Practice 2016: 23.1 "Tip location of CVAD shall be determined radiographically or by other approved technologies prior to initiation of infusion therapy."



P-WAVE CORRELATES TO CATHETER PROXIMITY

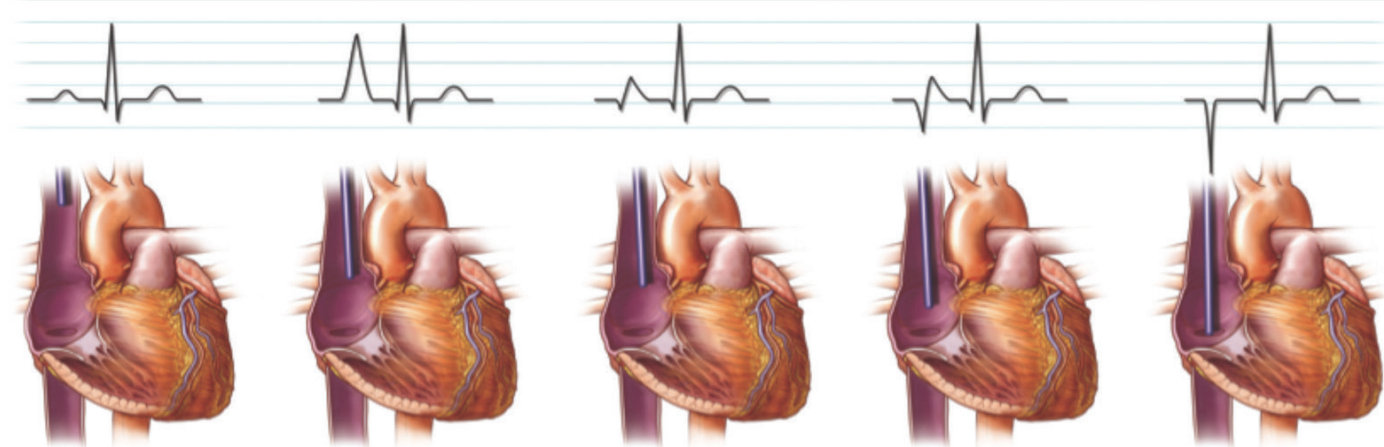


Figure 1
No evident P-wave changes indicates a catheter is not in acceptable position.

Figure 2
A P-wave at its maximum height will indicate the catheter is in the lower 1/3 of superior vena cava/ right atrial junction.

Figure 3
A downward deflection on the leading edge of the P-wave indicates the catheter entering the right atrium.

Figure 4
A biphasic P-wave indicates the catheter is within the right atrium.

Figure 5
An inverted P-wave indicates a catheter is approaching the right ventricle.

GUIDELINES REGARDING CATHETER TIP LOCATION

Organization	Recommendation
Infusion Nurses Society (2016)	The central venous access devices (CVAD) tip location with the greatest safety profile in adults and children is the cavoatrial junction (CAJ).
The Association for Vascular Access (1998)	Lower one-third of the superior vena cava (SVC), close to the junction of the SVC and the right atrium

LIMITATIONS

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
- Atrial flutter
- Severe tachycardia
- Pacemaker-driven rhythm
- Chronic obstructive pulmonary disorder (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

Celerity

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IMPORTANT RISK INFORMATION

CELERITY PICC TIP CONFIRMATION SYSTEM WITH NAVIGATION

INTENDED USE: The Celerity PICC Tip Confirmation System with Navigation is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava as well as magnetic field detection by a navigation stylet.

INDICATIONS FOR USE: The Celerity PICC Tip Confirmation System with Navigation is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity and navigation tracking by use of a magnetic field sensing navigation stylet.

The Celerity PICC Tip Confirmation System with Navigation is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

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
- Atrial flutter
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CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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