Do not rely on ECG signal detection for:
- Pacemaker-driven rhythm
- Severe tachycardia

According to clinical judgment and tip placement should be verified by a physician.

Caution: Federal Law (USA) restricts this product to use as a supplemental aid in positioning the catheter tip when cardiac rhythms may change.

The C3 Wave™ System is intended to provide real-time catheter tip positioning when cardiac rhythms may change.


INSTRUCTIONS FOR USE

INDICATIONS FOR USE
- The C3 Wave™ System is indicated for use as a supplemental aid in positioning for Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip positioning information by using the patient's cardiac electrical activity. Confirmation of tip placement should be verified according to clinical judgment and established hospital protocol (e.g., Chest X-Ray, Fluoroscopy).

Note: Limiting, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-Wave:
- Atrial fibrillation
- Atrial flutter
- Severe tachycardia
- Pacer-driven rhythms
- Chronic obstructive pulmonary disorder (COPD)

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

CONTRAINdications
- There are no contraindications associated with the C3 Wave™ System. Consult catheter Instruction for Use (Procedures) for Possible Contraindications.

WARNINGS
- The C3 Wave™ system works with the normal sinus rhythm of the heart. Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-Wave is difficult.

For example, when:
- P-wave is not present
- P-wave is not end-on cm
- P-wave is intermittent

Place ECG adhesive electrodes carefully at locations indicated in these Instructions for Use and/or ECG waveforms that are not described in these Instructions for Use.

All components in the accessory pack are single use items. Do not reuse or reprocess.

Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the trimmed end of the catheter, combined with kinking and excessive forces may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk patient injury.

Attach saline-filled syringe and flush catheter.

Remove the syringe after flushing.

Catheter Insertion
- A. Perform ultrasound and locate vessel.
- B. Follow catheter Instructions for Use regarding Venous Access and Catheter Insertion.
- C. Connect the end of the ECG Clip Cable (provided in the ECG Cable Accessory Pack) through the drape window to the C3 Wave™ patient head.

Note: C3 Wave™ only works with conductive [metal] stylets.

1. Determine the desired indwelling catheter length based on clinician measurement technique and experience, typically the measurement from the zero mark on the catheter to the predetermined catheter external Surface Measurement. See Step 3-D.

2. To ensure adequate catheter length to accommodate P-wave amplitude, it is recommended that the trimmed catheter length is 2cm more than the external/surface measurement.

3. Retract the stylet until it is well behind the targeted catheter cut location. Do not entirely remove the stylet from the catheter.

Note: Catheter depth markings are generally in centimeters—refer to catheter labeling.

4. Follow catheter manufacturer's Instructions for Use for trimming.

Caution: NEVER cut the stylet or thinning wire.

5. Inspect cut surface to ensure there is no loose material.

6. Ensure stylet tip is intact.

Caution: Never use excessive force to advance/remove the stylet as it may damage the device or result in patient injury.

Warning: Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the trimmed end of the catheter, combined with kinking and excessive forces may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk patient injury.

Prepare For Use of C3 Wave™ System.

Prior to use, the clinician must read and understand all labeling and instructions provided with the C3 Wave™ devices (including C3 Wave™ User's Manual).

Follow manufacturer's instructions provided with all accessory devices.

Catheter Insertion Site.
- a. Refer to catheter manufacturer's Instructions for Use.
- b. Mark planned insertion site on patient's arm.

B. Trim catheter to length per the following steps:
- 1. Determine the desired indwelling catheter length based on clinician measurement technique and experience, typically the measurement from the zero mark on the catheter to the predetermined catheter external Surface Measurement. See Step 3-D.

2. To ensure adequate catheter length to accommodate P-wave amplitude, it is recommended that the trimmed catheter length is 2cm more than the external/surface measurement.

3. Retract the stylet until it is well behind the targeted catheter cut location. Do not entirely remove the stylet from the catheter.

Caution: NEVER cut the stylet or thinning wire.

Note: Catheter depth markings are generally in centimeters—refer to catheter labeling.

4. Prepare Sterile Field
- a. Set up sterile field according to catheter Instructions for Use and institutional protocol.
- b. Cover the Remote Control with sterile Cover (provided in the C3 Wave™ ECG Cable Accessory Pack).

5. Prepare Catheter
- a. Follow catheter manufacturer's Instructions for Use and institutional protocol.
- b. Trim catheter to length per the following steps:
- 1. Determine the desired indwelling catheter length based on clinician measurement technique and experience, typically the measurement from the zero mark on the catheter to the predetermined catheter external Surface Measurement. See Step 3-D.

2. To ensure adequate catheter length to accommodate P-wave amplitude, it is recommended that the trimmed catheter length is 2cm more than the external/surface measurement.

3. Retract the stylet until it is well behind the targeted catheter cut location. Do not entirely remove the stylet from the catheter.

Caution: NEVER cut the stylet or thinning wire.

Note: Catheter depth markings are generally in centimeters—refer to catheter labeling.

4. Follow catheter manufacturer's Instructions for Use for trimming.

Caution: NEVER cut the stylet or thinning wire.

5. Inspect cut surface to ensure there is no loose material.

6. Ensure stylet tip is intact.

Caution: Never use excessive force to advance/remove the stylet as it may damage the device or result in patient injury.

Warning: Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the trimmed end of the catheter, combined with kinking and excessive forces may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk patient injury.

Catheter Tip Guidance and Positioning

The following figures show approximate catheter tip positions and representative intravascular ECG waveform of each position:

Figure 1: No evocative P wave change - catheter tip is not in an acceptable position.

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

Figure 3: Downward deflection on the leading edge of the P wave - catheter tip is entering the right atrium.

Figure 4: Biphasic P wave – catheter tip is within the right atrium.
Confirm all Bundle Protocol Parameters have been met.

### Catheter Insertion
- **Catheter advanced to target without resistance?**
- **Stylet removed from catheter without resistance?**

### Catheter Functionality
- **Positive/free flowing blood return (all lumens)?**
- **Flushing without resistance (all lumens)?**

### Objective Assessment
- **Ultrasound assessment of internal jugular vein negative for catheter?**
- **EKG tip location agrees with surface measurement (+/- 2cm)?**

### ECG P Wave Assessment
- **Initial P wave downward deflection noted and documented?**
- **P wave amplification noted & highest waveform documented?**

#### A. As the catheter is advanced toward the SVC/Right atrial junction the P-wave height will increase.

#### B. Advance Catheter until downward deflection is seen on the leading edge of the P-wave. Select the “snapshot icon” using the Remote Control to save the ECG waveforms.

**Note:** P-wave may continue to increase in amplitude when initial downward deflection is observed. In this case, adjust catheter tip position to maximum P-wave amplitude with no downward deflection as shown below.

#### C. Pull catheter back until maximum P-wave is achieved.

#### D. Select the “snapshot” icon using the Remote Control Cable to save the ECG waveforms. Refer to the C3 Wave™ Owners Manual.

#### E. Verify placement (e.g., chest x-ray or Fluoroscopy) prior to releasing catheter for use.

**Warning:** Failure to verify catheter placement may result in serious trauma or fatal complications.

**F.** Using the C3 Wave™ system, central venous catheter tip location can be documented for the patient’s chart. Refer to C3 Wave™ Owner’s Manual.

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**8. Complete PICC Placement Procedure**

**A.** Follow catheter Instructions for Use and institutional protocol.
- remove the stylet
- aspirate and flush catheter
- secure catheter

**B.** Remove drapes and ECG adhesive electrodes and discard according to institutional protocol.

**Caution:** ECG Adhesive Electrode may damage the skin if removed carelessly.

**C.** Disconnect Patient ECG from ECG Clip Cable.

**D.** Dispose of the single use ECG Clip Cable, Remote Cover according to institutional protocol.

**E.** Retain the reusable ECG Snap Leads, ECG Patient Hub, Remote Control and clean per institutional protocol.

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**WARRANTY**

**Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS, PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.**

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**SYMBOL TABLE**

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* This symbol is in accordance with ISO 15223-1.

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