



INSTRUCTIONS FOR USE

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

- C3 Wave™ System Instructions for Use: These instructions are for use in conjunction with the C3 Wave™ System Owner's Manual.

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 location 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
- 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.

INTENDED USE

- C3 Wave™ System 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.

CONTRAINDICATIONS

- There are no contraindications associated with the C3 Wave™ system. Consult catheter Instructions for Use for Possible Catheter 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 identifiable
- P-wave is intermittent

- Place ECG adhesive electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms 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.

- Monitor catheter tip placement during insertion procedure and verify catheter tip location placement using your institutions' guidelines.

- Failure to verify catheter placement may result in serious trauma or fatal complications.

- Inspect package and product prior to use to verify that no damage has occurred during shipping.

- Reuse or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

- Reuse or reprocessing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

- Contamination of the device may lead to injury, illness or death of the patient.

- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

PRECAUTIONS

- NEVER cut the stylet or stiffening wire.

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

PROCEDURAL INSTRUCTIONS

1. 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™ Owner's Manual).
- Follow manufacturer's instructions provided with all accessory devices.

2. Identify Catheter Insertion Site.

- Refer to catheter manufacturer's Instructions for Use.
- Mark planned insertion site on patient's arm.

3. Determine External Surface Measurement.

- For central venous placement, the recommended target tip location is the lower 1/3 of the Superior Vena Cava (SVC)/right atrial junction.
- Use the following guidelines during patient positioning and measurement.

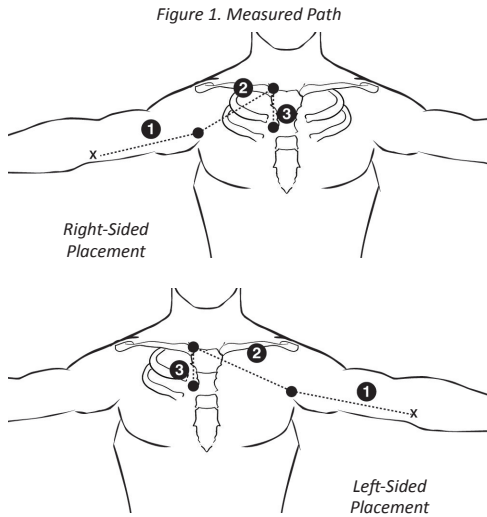
- When possible, ensure patient has both shoulders in contact with the bed. Patient should not be rotated during measurement procedure.

- When possible, measure directly on patient's skin. Measuring over clothing, bedding, existing ECG adhesive electrodes, wound dressings, or other personal and/or medical equipment may introduce measurement error.

Note: External surface measurement can never exactly duplicate the internal venous anatomy.

- Measure path from the planned insertion site using the following external landmarks:

- Insertion site to axillary crease.



- Axillary crease to right clavicular head. Measure to the right clavicular head for both left and right-sided placements.

- Right clavicular head to the right sternal border at the third intercostal space.

Note: The first intercostals space may be difficult to palpate due to its proximity to the clavicle.

- Record External Surface Measurement_____cm

PREPARE ELECTRODES

- Attach ECG Patient Hub to the three ECG snap leads.

- Prepare and attach ECG adhesive electrodes per the following steps.

Caution: ECG adhesive electrodes should be applied only to intact, clean skin (e.g. not over open wounds, lesions, infected or inflamed areas). For best results use the supplied ECG adhesive electrodes.

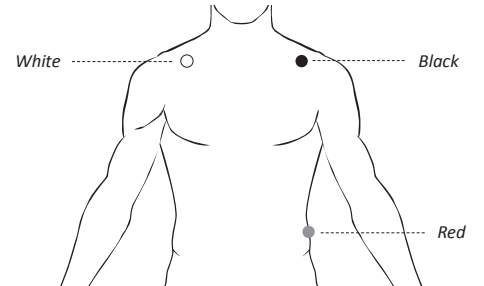
- Attach ECG adhesive electrodes to all three ECG snap leads.
- Remove backing and press ECG adhesive electrodes firmly onto skin at the specified locations

Warning: Place ECG adhesive electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms that are not described in these Instructions for Use.

- Black ECG snap lead/adhesive electrode on the patient's left upper chest.

- Red ECG snap lead/adhesive electrode on patient's lower left side, inferior to the umbilicus and laterally along the mid-axillary line.

Caution: Placement of red electrode outside of this region may result in reduced ECG performance.



- White ECG snap lead/ECG adhesive electrode on patient's right upper chest.

Caution: If skin irritation occurs, discontinue ECG adhesive electrode use immediately.

- Evaluate baseline ECG waveform.

- With the C3 Wave™ system running in Surface Mode, the external ECG waveform should be visible and stable at this time.

- Verify that the P-wave is present, identifiable and consistent on the main screen of the C3 Wave™ system.

- Obtain snapshot of baseline ECG.

- Enter surface external measurement. (See Step 3-D).

4. Prepare Sterile Field

- Set up sterile field according to catheter Instructions for Use and institutional protocol.

- Cover the Remote Control with sterile Cover (provided in the C3 Wave™ ECG Cable Accessory Pack).

5. Prepare Catheter

- Follow catheter manufacturer's Instructions for Use and institutional protocol.

- Trim catheter to length per the following steps.

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

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

- 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.

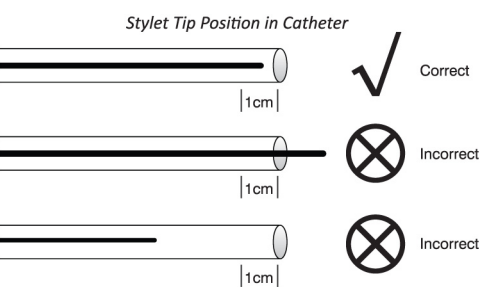
- Follow catheter manufacturer's Instructions for Use for trimming.

Caution: NEVER cut the stylet or stiffening wire.

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

- 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.



- Prior to catheter insertion, ensure that the stylet tip is contained within the catheter, but not more than 1 cm from the trimmed end of the catheter, secure stylet within the catheter manufacturer's Instructions.

Warning: Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end 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.

6. Catheter Insertion

- Perform ultrasound and locate vessel. Follow ultrasound system Instructions for Use.

- Follow catheter Instructions for Use regarding Venous Access and Catheter Insertion.

- Connect the end of the ECG Clip Cable (provided in the ECG Cable Accessory Pack) through the drape window to the ECG patient hub.

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

- Secure the ECG Clip Cable (alligator clamp) to the proximal end of the stylet.

- Place C3 Wave™ System monitor in 'PICC Mode' and insert catheter per manufacturer's Instructions for Use.

- Flush catheter with saline and wait for intravascular ECG waveform to stabilize on monitor screen.

- Verify that the P-wave on the intravascular ECG waveform is present, identifiable, and consistent on monitor screen.

Warning: Do not rely on ECG signal detection for Catheter tip positioning when interpretation of the P-wave is difficult. For example, when:

- P-wave is not present
- P-wave is not identifiable
- P-wave is intermittent

7. Catheter Tip Guidance and Positioning

The following figures show approximate catheter tip positions and representative intravascular ECG waveforms.

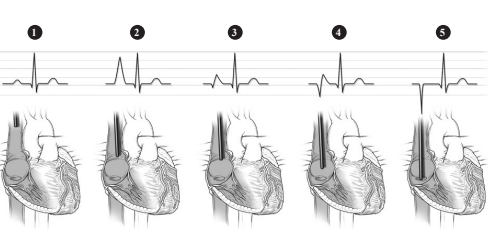
Figure 1: No evident P wave change - catheter tip is not in an acceptable position.

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.

Figure 5: Inverted P wave - catheter tip is approaching the right ventricle.



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
US 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.

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 Hub 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.











WARRANTY

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SYMBOL TABLE	
5.1.1	 Manufacturer *
5.3.4	 Keep Dry *
5.6.3	 Non-pyrogenic *
5.3.2	 Keep Away from Sunlight *
5.2.3	 Sterilized Using Ethylene Oxide *
5.2.8	 Do Not Use if Package is Damaged *
5.1.4	 Use By Date *
5.2.6	 Do Not Resterilize *
5.1.5	 Batch/Lot Number *
5.1.6	 Catalogue Number *

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



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