Indications for Use: Catheter styles provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG* Tip Confirmation System (TCS), the Sherlock 3CG* TPS stylet also allows the provider real-time feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.

To Sherlock 3CG* Tip Confirmation System (TCS) is a next generation, fully integrated magnetic tracking and ECG-based peripherally inserted central catheter (PICC) tip confirmation technology, which represents the next evolution of the Sherlock 11T tip location system and the previously marketed Sherlock Tip Confirmation System. The patented Fat-Map® (FMI) technology was a prospective, single-arm, single-center study designed to assess the efficacy of the ECG method for correctly positioning the tip of catheters placed via the peripherally inserted central catheter (PICC) method. The study showed that the Sherlock 3CG* TPS stylet was able to achieve 99.1% (482/485) accuracy of the Fat-Map® technology with regard to correct positioning of the catheter tip. Cannulation sites were typically located at or below the antecubital fossa, with 38.6% of cannulation sites being within 1 cm of the cardiac rhythm device.

Contraindications: The Sherlock 3CG* TPS stylet is contraindicated in patients who have cardiac rhythm devices (e.g., pacemakers and defibrillators) implanted. When a cardiac rhythm device is present, it is recommended to place skin 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 of phlebitis. Placement of PICC above the antecubital fossa is recommended.

Precautions: These conditions may be a result of heart rhythm abnormalities, atrial fibrillation, atrial flutter, severe tachycardia or presence of cardiac rhythm devices. These include, but are not limited to:
- Tachycardia or bradycardia
- Failure to verify catheter tip location through using your institution’s guidelines.

Possible Complications: Consult catheter instructions for use for possible complications.

Warning: Do not rely on ECG signal detection for catheter tip positioning when interpretation of the intracardiac ECG waveform is difficult. For example, when:
- P-wave is not identifiable
- P-wave is not present intravascular ECG P-wave is difficult. For example, when:

Electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms of phlebitis. Placement of PICC above the antecubital fossa is recommended.

Placement of larger catheters at or below the antecubital fossa may result in an increased incidence of phlebitis. Placement of PICC above the antecubital fossa is recommended.

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

- Right-Sided Placement
- Left-Sided Placement

B. Position Sensor on patient’s chest according to instructions provided with the electronic system being used.

A. Attach ECG electrodes to right clavicular head. Measure to right-sided clavicular head for left- or right-sided placements.

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

D. In cases where target external depth is significant, maximum venous depth may be added to measured path to determine final external measurement:

Maximum vessel depth = cm

E. Accurately mark planned insertion site on patient’s arm.

2. Determine External Measurement

A. For central placement, the recommended target location is the lower 1/3 of the Superior Vena Cava (SVC), close to the junction of the SVC and the right atrium.

B. 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 PICC, venous access devices, or other personal and/or medical equipment may introduce measurement error.

Note: External measurement can be exactly duplicated the internal venous anatomy.

3. Determine External Measurement

A. Insertion sites to aid catheter insertion

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

- Right-sided placements.

1. Insertion site to aid catheter insertion

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

- Right-sided placements.

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

D. In cases where target external depth is significant, maximum venous depth may be added to measured path to determine final external measurement:

Maximum vessel depth = cm

E. Accurately mark planned insertion site on patient’s arm.

F. Right-Sided Placement

2. Determine External Measurement

3. Determine External Measurement

4. Position Patient and Perform Ultrasonic Pre-Scan

5. PICC Placement Instructions for Use

B. Position Patient and Perform Ultrasonic Pre-Scan

D. Select a site based on patient assessment and pre-scan. Recommended sites are basilic, cephalic, and basilical veins.

F. Note the maximum vessel depth at catheter insertion site as displayed on ultrasonic.
Place remote control in remote control holder. Cover the probe and cable.

Note:

Manufacturer: Bard Access Systems, Inc.
salt Lake City, Utah 84116 U.S.A.
605 North 5600 West
Bard Access Systems, Inc.

References:
6. Prepare Catheter

A. Pre-flush all lumens of the catheter with sterile normal saline to wet hydrophilic stylet. Follow catheter instructions for use.

B. Aspirate and Flush. Follow catheter Instructions for Use.

C. Calibrate magnetic tracking system immediately prior to catheter insertion. Follow Sherlock 3CG* TCS Instructions for Use.

D. At this point, the catheter may need to be flushed to stabilize the waveform. If necessary, attach saline-filled syringe. Flush catheter with saline and wait for intravascular ECG waveform to stabilize.

7. Catheter Tip Guidance and Positioning

A. Place skin electrodes carefully at locations indicated in these Instructions for Use. In each case, rely on magnetic navigation and external measurement for confirmation and never insert the stylet beyond the recommended locations.

B. Aspirate and flush. Follow catheter instructions for use.

C. Select “Freeze” on the Sherlock 3CG* TCS screen intravascular ECG waveform to the reference screen intravascular ECG waveform while observing the reference waveform. The reference waveform is the intravascular ECG waveform that is most similar to the intravascular ECG waveform observed. In this case, adjust catheter tip position to maximum P-wave amplitude with no negative deflection as shown in Figure 6.

These conditions may be a result of heart rhythm abnormalities, atrial flutter, atrial tachycardia or presence of complex rhythm devices. In these cases, rely on magnetic navigation and external measurement for tip positioning and use real-time or fluoroless to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.

Note: Patients may experience discomfort during attempted ECG guided catheterization.

8. Catheter Tip Guidance and Positioning

A. Pre-flush the system to remove air from the system.

B. Place sterile gloves on patient’s hands.

C. Prepare insertion site and sterile field according to catheter instructions for use and institutional protocol.

D. Check the security of the Fin Assembly to Sensor connection, as well as the placement and security of the electrodes.

E. Remove drapes, external electrodes and sensor.


Note: If applicable, ensure the remote control is not disconnected.

References

1) 14 subjects evaluated. 113 confirmed. Data on file. Bard Access Systems, Salt Lake City, Utah


ACCESS SYSTEMS

Manufacturer: Baird Access Systems, Inc.
6646 South Delaware Road
Salt Lake City, Utah 84119 USA
1-800-522-5308
Customer Service: 800-140-8860
Clinical Information: 800-443-3385
www.bardaccess.com