Indications for Use: Catheter stylets provide internal reinforcement to aid in catheter placement. When used with both the Sherlock TCS* Tip Positioning System (TPS) and the Sherlock 3CG* TPS stylet, they also provide the ability to verify catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.

Warnings:

1. **Precautions:**
   - Prior to initiating the procedure, consult catheter Instructions for Use for possible complications.

2. **Contraindications:**
   - Use of the 3CG* Tip Positioning System (TPS) and the Sapiens* TCS System, include a comprehensive, integrated set of PICC placement tools such as vein location, lumen size, catheter tip location, as indicated by the institutional guidelines and clinical judgment.
   - The Sapiens* TCS system only works for a wide range of heart rhythms.
   - The Sapiens* TCS system may only be used by battery power when in contact with a patient.

3. **Sapiens* TCS system is made of specially formulated materials designed to aid in the placement of peripherally inserted central catheters (PICC). The stylet provides internal reinforcement to aid in catheter placement. To Sherlock 3CG* TPS stylet may be used with the Sherlock TCS* Tip Positioning System (TPS) and Sapiens* TCS System (TCS) to provide catheter tip location information during the procedure.

4. **Note:** The Sherlock 3CG* TPS stylet may be used with patients who have cardiac rhythm devices (e.g., pacemakers and defibrillators) implanted. When a cardiac rhythm device is present, it is recommended that the Sherlock 3CG* TPS stylet be placed on the contralateral side.

5. **Sapiens* TCS system is made of specially formulated materials designed to aid in the placement of peripherally inserted central catheters (PICC). The stylet provides internal reinforcement to aid in catheter placement. When used with the Sapiens* TCS system, include a comprehensive, integrated set of PICC placement tools such as vein location, lumen size, catheter tip location, as indicated by the institutional guidelines and clinical judgment.

6. **Note:** The Sherlock 3CG* TPS stylet may be used with patients who have cardiac rhythm devices (e.g., pacemakers and defibrillators) implanted. When a cardiac rhythm device is present, it is recommended that the Sherlock 3CG* TPS stylet be placed on the contralateral side.

7. **Contraindications:**
   - There are no contraindications associated with the Sherlock 3CG* TPS stylet, Sapiens* TCS system, or Sapiens* TCS system.

8. **Cautions:** Consult catheter Instructions for Use for possible contraindications.

**Warnings:**

- Ensure that the tip does not extend beyond the intended end of the catheter. Extension of the stylet beyond the catheter end, combined with kinking and excess forces, may result in vessel damage, tip damage, difficulty removing stylet tip, separation, potential embolism and risk of patient injury.
- The Sapiens* TCS system only works for a wide range of heart rhythms.
- The Sapiens* TCS system may only be used by battery power when in contact with a patient.

**Instructions for Use:**

1. **Prepare Electronic Systems:**
   - Follow instructions provided with the electronic systems being used.

2. **Position Patient and Perform Ultrasound Pre-Scan:**
   - Position the arm for catheter placement. Optimal position is at a 90-degree angle.
   - Apply couplant above the anticipated insertion site.
   - Perform ultrasound pre-scan.
   - Select a vein based on patient assessment and pre-scan. Recommended veins include saphenous, cephalic, and brachial veins.
   - Note the maximum vessel depth at catheter insertion site as displayed on ultrasound.

   **Maximum vessel depth = cm**

3. **Catheter Placement:**
   - Insert site to allow for easy access.
   - Apply venous pressure for right-side placement.
   - Apply venous pressure for left-side placements.

4. **Remove Sensor:**
   - Attach the assembly to the sensor and place sensor in holder.

5. **Position Sensor on patient chest according to Sapiens* TCS System Instructions for Use.**
   - 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 rolled during measurement procedure.
     - Measurements made directly on patients’ skin. Measuring over clothing, bedding, existing ECG electrodes, wound dressings, or other personal and/or medical equipment may introduce measurement error.

   **Note:** External measurement can never exactly duplicate the internal vessel anatomy.

6. **Measure path from the planned insertion site:**
   - Follow the step-by-step instructions.
   - Insert site to allow for easy access.
   - Apply venous pressure for right-side placements.
   - Apply venous pressure for left-side placements.

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

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

**Precations:**

- Placement of larger catheters in the antecubital fossa may result in an increased incidence of phlebitis. Placement of PICC above the antecubital fossa is recommended.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.

**Possible Complications:** Consult catheter Instructions for Use for possible complications.

**Warning:** Dangers include:

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

**Precautions:**

- Placement of larger catheters in the antecubital fossa may result in an increased incidence of phlebitis. Placement of PICC above the antecubital fossa is recommended.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.

**Possible Complications:** Consult catheter Instructions for Use for possible complications.

**Instruction for Use:**

1. Prepare Electronic Systems.
   - Follow instructions provided with the electronic systems being used.

2. Position Patient and Perform Ultrasound Pre-Scan.
   - Position the arm for catheter placement. Optimal position is at a 90-degree angle.
   - Apply couplant above the anticipated insertion site.
   - Perform ultrasound pre-scan.
   - Select a vein based on patient assessment and pre-scan. Recommended veins include saphenous, cephalic, and brachial veins.
   - Note the maximum vessel depth at catheter insertion site as displayed on ultrasound.

   **Maximum vessel depth = cm**
Correct the style or offering one needs to be well behind the point the catheter tip is to be. NGU does the style or offering one needs to be behind the point the catheter tip is to be. Inspect cuff surface to ensure there is no loose material – Re-position the T-column connector assembly locking the connector to the catheter hub. Ensure stylet tip is intact – Gently retract the stylet through the locked T-column unit and the stylet tip is contained inside the catheter. – Prior to remove, ensure that the stylet tip is contained inside and the catheter but not more than 1 cm from the external end of the catheter.

**Note:** Catheter depth markings are in centimeters – Using a sterile scalpel or scissors, carefully cut the catheter. – Note: Catheter method for positioning the tip of PICCs: results from two preliminary studies, by Mauro Pittiruti of a Trial to Replace Radiological Confirmation, by Nancy Moureau et al. published in the Journal of the A-...
6. Prepare Catheter
   A. Apply tourniquet above intended insertion site to distend vessel.
   B. Trim catheter to length per the following steps.
      1. Cut catheter to the desired length, as indicated by the institutional guidelines and clinical judgment.
      2. Cease cutting if the catheter is not properly seated.
   C. Secure guidewire.
   D. Perform microintroduction. Follow catheter Instructions for Use regarding microintroduction technique.
   E. Insert catheter until magnet tracking icon appears or catheter is inserted a minimum of 10 cm.
   F. Remove guidewire and dilator from microintroducer. Follow catheter Instructions for Use.
   G. Verify that the P-wave on the intravascular ECG waveform is present, identifiable, and consistent on the main screen of the Sherlock* TCS system.

7. Accession
   A. Attach Catheter Stylet to Fin Assembly.
   B. Uncoil Catheter Stylet Lead.
   C. Perform ultrasound and locate vessel. Follow ultrasound system Instructions for Use.
   D. Select “Freeze” on the main screen of the Sherlock* TCS system.
   E. SLOWLY adjust catheter tip position to maximum P-wave amplitude. Compare the main screen ECG waveform to the waveform obtained pre-interventionally.
   F. Locate and secure remote control.
   G. Verify Placement Prior to Releasing Catheter for Use
      1. Perform ultrasound and locate vessel. Follow ultrasound system Instructions for Use.
      2. Place the stylet connector on or in the immediate vicinity of the Fin Assembly and slide connector forward until fully seated.
      3. Lay catheter on the sterile field.
      4. Confirm magnet tracking icon is present on the screen or in the TCS system.
      5. Insert catheter until the magnetic navigation shows stylet tip crossing consistently downward.
      6. Cease inserting stylet if the catheter tip cannot be visualized.
      7. Continue to SLOWLY advance catheter until catheter tip is contained inside the sterile field, as indicated by the institutional guidelines and clinical judgment.

8. Catheter Tip Guidance and Positioning
   The following figures show approximate catheter tip positions and representative intravascular ECG waveforms:

   - Leave catheter on the sterile field.
   - Ensure catheter tip is contained inside the sterile field.
   - Sapiens* TCS system can be used as reference. Refer to Figure 7 for the TCS system.

   These conditions may be a result of heart rhythm abnormalities, atrial fibrillation, atrial flutter, severe heart rate changes, or other factors that may prevent accurate measurement and external verification for tip positioning and use of ECG fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.

9. Catheter Tip Guidance and Positioning
   The following figures show approximate catheter tip positions and representative intravascular ECG waveforms:

   - P-wave is not present
   - P-wave is not identifiable
   - P-wave in incorrect location
   - P-wave is not present
   - P-wave is not identifiable
   - P-wave in incorrect location

These conditions may be a result of heart rhythm abnormalities, atrial fibrillation, atrial flutter, severe heart rate changes, or other factors that may prevent accurate measurement and external verification for tip positioning and use of ECG fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.

10. Complete Removal of Procedure
   A. Remove the Stylet / Lock Assembly.
   B. When using the Sherlock* TCS system with the ECG waveform display, the external ECG waveform should be visible and consistent at this time.
   C. Continue to SLOWLY advance catheter until catheter tip is contained inside the sterile field, as indicated by the institutional guidelines and clinical judgment.
   D. Confirm catheter tip is contained inside the sterile field, as indicated by the institutional guidelines and clinical judgment.
   E. Advance or retreat catheter from maximum P-wave to place tip in desired location per institutional protocol. Note catheter side-in-positioning.
   F. Record ECG waveforms and catheter tip positioning. Refer to Sapiens* TCS Instructions for Use.
   G. Verify Placement Prior to Releasing Catheter for Use
      1. Insert catheter until the magnet tracking icon is present on the screen or in the TCS system.
      2. Lay catheter on the sterile field.
      3. Sapiens* TCS system can be used as reference. Refer to Figure 7 for the TCS system.
      4. Ensure that the P-wave on the intravascular ECG waveform is present, identifiable, and consistent on the main screen of the Sapiens* TCS system.

   These conditions may be a result of heart rhythm abnormalities, atrial fibrillation, atrial flutter, severe heart rate changes, or other factors that may prevent accurate measurement and external verification for tip positioning and use of ECG fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.

References
Precautions:

1. Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patient problems or patient discomfort.
2. 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.

Indications for Use: Catheter styles provide internal reinforcement to aid in catheter placement. When used both with the Sherlock CGP Tip Positioning System (TPS), the Sherlock CGP Tip Stylet also provides the required stiffening wire needed to position the stylet through the use of magnetic navigation and cardiology signal detection.

When used with the Sapiens Tip Confirmation Systems (TCS), the Sherlock CGP Stylet also provides the required stiffening wire needed to position the stylet through the use of cardiology signal detection.

Description: The Sherlock CGP Tip Stylet is made of specially formulated materials designed to aid in the placement of peripherally inserted central catheters (PICC). The Stylet material provides internal reinforcement to aid in catheter placement. The Sherlock CGP Tip Stylet may be used with the Sherlock CGP Tip Positioning System (TPS) and the Sapiens Tip Confirmation System (TCS) to provide catheter tip placement information during the procedure.

The Sherlock CGP Tip Stylet, Sapiens TCS System, Sapiens TCS System, and the Site-Rite Ultrasonic System, include a comprehensive, integrated set of PICC placement tools such as vein location, lumen size identification, needle guidance areas, catheter tip orientation, catheter tip depth, catheter tip placement confirmation, and cardiac electrical signal detection.

Note: The Sherlock CGP Tip Stylet may be used with patients who have cardiac rhythm devices (e.g. pacemakers and defibrillators) implanted. When a cardiac rhythm device is present, it is recommended that the Sherlock CGP Tip Stylet be placed on the contralateral side.

Contraindications: There are no contraindications associated with the Sherlock CGP Tip Stylet, Sapiens TCS System, or Sapiens TCS System. Consult catheter instructions for use for possible catheter contraindications.

Warnings:

- Ensure that the stylet tip does not extend beyond the intended 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, exit site damage, thoracic vessel injury, embolism, needle injury, and patient injury.
- Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intracardiac ECG P-wave is difficult. For example, when:
  - P waves are not present
  - P waves are not interpretable
  - P waves are isometric
  - These conditions may be a result of heart rhythm abnormalities, atrial fibrillation, atrial flutter, severe chest pain, or presence of cardiac rhythm devices. In these cases, rely on magnetic navigation and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.
- Do not rely on ECG signal detection for catheter tip positioning when there are no observable changes in the P-wave. In these cases, rely on magnetic navigation and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.
- Place the electrodes carefully adjacent to the veins, as indicated in these instructions for use, and ensure good skin-electrode contact. Failure to do so may cause unreliable ECG waveforms and/or ECG waveforms that are not described in these instructions for use. In such a case, rely on magnetic navigation and external measurement for tip positioning and use chest X-ray or fluoroscopy to confirm catheter tip location, as indicated by the institutional guidelines and clinical judgment.
- Monitor catheter tip placement during insertion procedure and verify catheter tip location using your institution's guidelines.
- Failure to verify catheter tip placement may result in serious trauma or fatal complications.

Precautions:

1. 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.
2. Avoid placement or securement of the catheter when kinking may occur, to minimize stress on the catheter, patient problems or patient discomfort.
3. This stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.
4. Caution: Federal law restricts this device to sale by or on the order of a physician.
5. The magnetic detector identifies the relative position of the stylet tip. Ensure that the stylet tip remains inside and within 1 cm from the end of the catheter tip. Failure to do so could result in degraded magnetic navigation.
6. Never use excessive force to remove the stylet tip as it may damage the device.
7. Ensure the Sapiens TCS remote control is not discarded.

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

Indication for Use:

1. Prepare Electronic Systems
   - Follow instructions provided with the electronic systems being used.
2. Position Patient and Perform Ultrasound Pre-Scan
   A. Position the arm for catheter placement. Optimal position is at a 45-degree angle.
   B. Apply contact ray above the anticipated insertion site.
   C. Perform ultrasound pre-scan.
   D. Select a vein based on patient assessment and pre-scan. Recommended veins: basilic, cephalic, and brachial veins.
   E. Note the maximum vessel depth at catheter insertion site as displayed on ultrasound.
   F. Accurately mark planned insertion site on patients arm.
   G. Place red electrode on patient’s left shoulder or shoulder girdle. Place black electrode on patient’s right shoulder or shoulder girdle.

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

Instructions for Use

1. Prepare Electronic Systems
   - Follow instructions provided with the electronic systems being used.
2. Position Patient and Perform Ultrasound Pre-Scan
   A. Position the arm for catheter placement. Optimal position is at a 45-degree angle.
   B. Apply contact ray above the anticipated insertion site.
   C. Perform ultrasound pre-scan.
   D. Select a vein based on patient assessment and pre-scan. Recommended veins: basilic, cephalic, and brachial veins.
   E. Note the maximum vessel depth at catheter insertion site as displayed on ultrasound.
   F. Accurately mark planned insertion site on patients arm.

Caution: 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.

Caution: Avoid placement or reinsertion of the catheter where kinking may occur to minimize stress on the catheter, patient problems or patient discomfort.

G. Release tourniquet.