**PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology**

**Nursing Polyurethane Catheter**

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**Power Injection Preparation**

- **1.** Place 1st anchor tape over StatLock® stabilization device.
- **2.** Cover site and StatLock® stabilization device with tape with transparent dressing.
- **3.** Place 2nd anchor tape sticky tape on top of transparent dressing.
- **4.** Place 3rd anchor tape sticky wings.

**Power Injection Procedure**

- **1.** Secure catheter with StatLock® stabilization device.
- **2.** Secure catheter with transparent dressing.
- **3.** Disconnect the syringe and attach a sterile end cap to the catheter hub and tighten securely.
- **4.** Remove the injection/needleless cap from the PowerPICC® Catheter with SOLO™2 Valve Technology.
- **5.** Attach the power injection device to the PowerPICC® Catheter with SOLO™2 Valve Technology.
- **6.** Ensure the catheter tip is in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- **7.** Prior to conducting central venous pressure monitoring:
  - **i.** Prior to insertion, ensure that the stylet tip is contained inside and within the catheter placement, tip location, patency and security of dressing.
  - **ii.** The Sherlock™ TLS stylet may be used with patients who have cardiac rhythm devices (e.g. pacemakers and defibrillators) passive magnets that generate a magnetic field. This field can be detected by the Sherlock™ TLS Detector to provide the placer rapid response in the event of migration. The background field of the detector is at a maximum of 1 Gauss which is within the range of operating magnetic fields of most MRI and Catheterization Laboratories.

**Original Placement**

- **1.** Disconnect the power injection device.
- **2.** Flush each lumen of the catheter with a minimum of 10 mL of sterile saline, using a "pulse" or "stop/start" technique. Use of negative pressure to aspirate will decrease the chance of air entering the catheter and cause equipment failure.
- **3.** Examine catheter tip to determine that the entire catheter has been removed. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
- **4.** Caution: Catheters with Sherlock TLS stylet may be partially or completely occluded. Do not flush against catheter. Flush catheter vigorously with sterile saline. Ensure proper positioning of the catheter tip.
- **5.** Caution: Exceeding the maximum power injection flow rate or setting the power injector pressure limit above 300 psi may result in catheter failure.
- **6.** Failure to warm contrast media to body temperature prior to power injection may result in catheter failure. Make sure issue is resolved before power injection.
- **7.** Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
- **8.** Use of alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid alcohol based solutions. These can damage the polyurethane material if used over time.
- **9.** When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid alcohol based solutions. These can damage the polyurethane material if used over time.

**Device Maintenance**

- **1.** Aspirate for adequate blood return and vigorously flush each lumen of the catheter with the full 10 mL of sterile saline. This will ensure the patency of the PowerPICC catheter.
- **2.** Failures to![](image) clear occluded catheters. Refer to institution protocol for clearing occluded catheters.
- **3.** Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against catheter.
- **4.** Caution: Ensure that the stylet tip does not extend beyond the trimmed end markings are in centimeters.
- **5.** The Sherlock™ TLS stylet may be used with patients who have cardiac rhythm devices (e.g. pacemakers and defibrillators) passive magnets that generate a magnetic field. This field can be detected by the Sherlock™ TLS Detector to provide the placer rapid response in the event of migration. The background field of the detector is at a maximum of 1 Gauss which is within the range of operating magnetic fields of most MRI and Catheterization Laboratories.

**Device Storage**

- **1.** Caution: Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.

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**NOTE:**

- **1.** Remove the injection/needleless/end cap on the PowerPICC® Catheter with SOLO™2 Valve Technology.

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**Figure 2**

Incorrect

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**Figure 3**

Correct
A family of peripherally inserted central catheters made from specially-formulated and processed medical grade materials. PowerPICC

Product Description

accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access, as clinically indicated.

General Warnings

• The patient is known or is suspected to be allergic to materials contained in the device.

• Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can adversely affect the catheter and may be necessary based on patient status or use of alternate flushing and locking techniques.

Recommended Flushing/Maintenance Procedure(s)

1. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.

2. Flush each lumen of the catheter with a minimum of 10 mL of preservative-free 0.9% sodium chloride USP (sterile saline), and make sure they do not occlude, puncture, or cut the catheter.

3. Cap catheter.

4. Return to patient positioning, securement, and monitoring.

Caution:

• Brachial Plexus Injury

• Heparin Induced Thrombocytopenia

• Intolerance Reaction to Implanted Materials

• Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to more likely in neonatal patients.

• Exceeding the maximum power injection flow rate or setting the power injector pressure limit above 300 psi may result in catheter embolism.

• Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding.

Alternate Technique:

A safety IV catheter may be used as an alternate to the safety introducer needle.

Perform a nerve block with Bupivicaine or Xylocaine to anesthetize the Integra site.

If using the Sherlock™ TLS stylet, perform this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the arm and is partially advanced into the vessel. The detector identifies the position of the stylet tip. Ensure that the stylet tip remains inside and within 1 cm from the end of the stylet. The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet.

To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the flush solution.

If the catheter or introducer sheath is partially or fully split, the introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.

The fluid level in the catheter will drop if the catheter connector is held above the level of the patient’s heart and opened. This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium.

Note:

Note:

Inspection of the catheter lumen is not necessary, but may be done using the catheter flush tubing in accordance with the manufacturer’s instructions. This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. The fluid level in the catheter will drop if the catheter connector is held above the level of the patient’s heart and opened.
**Product Description**

- **Intended for single use. DO NOT REUSE.** Reuse and/or repackaging may create a risk of patient or user infection, compromise the integrity of the catheter, and lead to catheter failure.
- **Do not use the catheter if there is any evidence of mechanical damage or leaking.** Damage to the catheter may lead to rupture, embolization, or other complications.

**Precautions**

- **The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology indication for power injection of contrast media implies the catheter's design characteristics allow injection of contrast media at high pressures.** Use of inappropriate contrast media injection pressure may lead to catheter failure.
- **Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.** Refer to institution protocol for clearing occluded catheters.
- **This is not a right atrium catheter.** Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in patients with a valvular lesion or other hemodynamic abnormalities. Patients should be monitored for the development of cardiovascular complications after the catheter has been placed in the right atrium.
- **Avoid sharp or acute angles during implantation which could compromise the patency of the catheter lumen.**
- **Never use force to remove the stylet.** Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop advancement and contact your healthcare provider.
- **Do not reinsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.**
- **Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable to kits with Sherlock™ TLS Stylet) after catheter placement.**
- **Do not use scissors to remove dressing to minimize the risk of cutting catheter.**
- **Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or catheter failure.**
- **Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or catheter failure.**
- **Avoid the use of a guidewire designed for peripheral use.** Use a guidewire designed for central use. Refer to institution protocol for use of guidewire in their institution.
- **Avoid the use of a guidewire designed for peripheral use.** Use a guidewire designed for central use. Refer to institution protocol for use of guidewire in their institution.
- **Do not insert stiff end of guidewire into vessel as this may result in vessel damage.**
- **Do not use alcohol to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheter material.**
- **When using alcohol, limit its contact time with polyurethane catheter material to 15 seconds.**
- **Do not pull apart the portion of the sheath that remains in the vessel.**
- **The stylet or stiffening wire needs to be well behind the point the catheter is to be cut.** NEVER cut the catheter in its sheath.
- **Never expose the catheter to the high concentrations of chlorhexidine gluconate.** Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheter material. Use alcohol, when necessary, to limit its contact time with polyurethane catheter material to 15 seconds.
- **Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheter material.**
- **Do not pull apart the portion of the sheath that remains in the vessel.**

**Indications**

- **For central venous access in adult and pediatric patients.**

**Contraindications**

- **Hypersensitivity, anaphylactic or severe reaction to the components of catheters or admixtures is a contraindication.**
- **Hematoma**
- **Extravasation**

**Warnings**

- **The device is contraindicated whenever:***

**Catheter Size Maximum Flow Rate**

<table>
<thead>
<tr>
<th>Size</th>
<th>Maximum Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15 mL/min</td>
</tr>
<tr>
<td>2</td>
<td>30 mL/min</td>
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<tr>
<td>3</td>
<td>60 mL/min</td>
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<tr>
<td>4</td>
<td>90 mL/min</td>
</tr>
<tr>
<td>5</td>
<td>120 mL/min</td>
</tr>
</tbody>
</table>

**Precautions for Use**

- **Sterile Field Preparation**
  - **A. Anesthetize with local anesthesia as required.**
  - **B. Disconnect the T-Lock from the stylet funnel.**
  - **A. Insert the safety introducer needle into the desired vein and observe for flashback.**
  - **C. Insert the safety introducer needle into the desired vein and observe for flashback.**
  - **G. Advance the microintroducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel. If resistance is encountered, stop advancement and remove the assembly.**
  - **Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the catheter from moving. If an occlusion is encountered, do not remove the microintroducer assembly.
  - **Alternate Technique:**
    - **A. A safety IV catheter may be used as an alternate to the safety introducer needle.**
    - **B. Disconnect the T-Lock from the stylet funnel.**
    - **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**Alternate Technique:**

- **A. A safety IV catheter may be used as an alternate to the safety introducer needle.**
- **B. Disconnect the T-Lock from the stylet funnel.**
- **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**Complications**

- **Potential complications include the following:**
  - **Malposition or Retraction**
  - **Infection**
  - **Catheter Erosion Through the Skin**
  - **Hematoma**
  - **Extravasation**

**Complications and Prevention**

- **Possible Complications**
  - **Malposition or Retraction**
  - **Infection**
  - **Catheter Erosion Through the Skin**
  - **Hematoma**
  - **Extravasation**

**Preoperative Preparation**

- **A. Anesthetize with local anesthesia as required.**
- **B. Disconnect the T-Lock from the stylet funnel.**
- **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**I. Assure proper alignment of the stylet to the distal end of the trimmed catheter.**

**G. Re-advance the T-lock connector/stylet assembly locking the connector to the stylet funnel. Assure stylet tip is intact.**

**C. Withdraw the entire T-Lock connector/stylet assembly, as one unit.**

**B. Disconnect the T-Lock from the stylet funnel.**

**A. Measure the distance from the insertion site (zero mark) to the desired tip location.**

**C. Insert the safety introducer needle into the desired vein and observe for flashback.**

**G. Advance the microintroducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel. If resistance is encountered, stop advancement and remove the assembly.**

**Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the catheter from moving. If an occlusion is encountered, do not remove the microintroducer assembly.

**Alternate Technique:**

- **A. A safety IV catheter may be used as an alternate to the safety introducer needle.**
- **B. Disconnect the T-Lock from the stylet funnel.**
- **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**IFU using sterile technique.**

**A. Anesthetize with local anesthesia as required.**

**B. Disconnect the T-Lock from the stylet funnel.**

**A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**G. Advance the microintroducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel. If resistance is encountered, stop advancement and remove the assembly.**

**Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the catheter from moving. If an occlusion is encountered, do not remove the microintroducer assembly.

**Alternate Technique:**

- **A. A safety IV catheter may be used as an alternate to the safety introducer needle.**
- **B. Disconnect the T-Lock from the stylet funnel.**
- **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**IFU using sterile technique.**

- **B. Disconnect the T-Lock from the stylet funnel.**
- **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**G. Advance the microintroducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel. If resistance is encountered, stop advancement and remove the assembly.**

**Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the catheter from moving. If an occlusion is encountered, do not remove the microintroducer assembly.

**Alternate Technique:**

- **A. A safety IV catheter may be used as an alternate to the safety introducer needle.**
- **B. Disconnect the T-Lock from the stylet funnel.**
- **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**IFU using sterile technique.**

- **B. Disconnect the T-Lock from the stylet funnel.**
- **A. Insert the safety introducer needle into the desired vein and observe for flashback.**

**G. Advance the microintroducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel. If resistance is encountered, stop advancement and remove the assembly.**

**Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the catheter from moving. If an occlusion is encountered, do not remove the microintroducer assembly.
Product Description

For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Sterilized by ethylene oxide. Do not re-sterilize.

Accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access, as clinically indicated.

Caution:

- Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters.
- When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact with the catheter lumen.
- Past irradiation of prospective insertion site.
- The presence of device-related infection, bacteremia, or septicemia is known or suspected.
- When injecting or infusing medications that are incompatible, always flush the catheter with a minimum of 10 mL of sterile saline.
- The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.
- The PowerPICC Catheter with SOLO™2 Valve Technology is indicated for short or long term peripheral access to the central circulation.

Recommended Flushing/Maintenance Procedure(s)

1. Identify the Vein and Insertion Site
   - A. Apply a tourniquet above the anticipated insertion site.
   - B. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.

2. Flush each lumen of the catheter with a minimum of 10 mL of preservative-free 0.9% sodium chloride USP (sterile saline), as clinically indicated.

3. If obstruction is noted, reinject 10 mL of sterile saline. Repeat this if a complete flush is not achieved. When using the intermittent flush technique, fluoroscopic guidance is recommended to prevent needle insertion into the right atrium which may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be minimized by using the intermittent flush technique.

4. Sterile Field Preparation
   - A. Apply a tourniquet above the anticipated insertion site.
   - B. Apply underdrape.
   - C. Apply drapes and complete sterile field preparation.

5. Preflush the Catheter
   - A. Identify the Vein and Insertion Site
   - B. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - C. Release tourniquet.

6. Insert Port
   - A. Apply a tourniquet above the anticipated insertion site.
   - B. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - C. Release tourniquet.

7. Insert Catheter
   - A. Insert the catheter introducer sheath through the needle cut-out. Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and avoid excessive force. Ensure the catheter introducer sheath is fully seated by gently rotating the hub of the catheter introducer sheath. The catheter introducer sheath must remain within the lumen of the catheter.
   - B. Apply a sterile dressing to the insertion site.

8. Secure Catheter
   - A. Place the catheter through the sheath and secure the sheath in place using the suture wings that are attached to the device. Avoid placing suture through the sheath for securing the device to the skin. Secure the sheath to the skin with a non-suture method, such as a injection cap and suture or an adhesive strip or dressing. The orientation of the sheath wings must be such that they do not obstruct vascular access or impede catheter withdrawal and must be positioned to allow ready access to the lumen of the catheter.
   - B. The catheter must extend a minimum of 2 cm from the skin. Secure the catheter to the skin using adhesives, a safety introducer needle or catheter, and/or the sheath. The catheter must be secured to the patient's skin to prevent accidental withdrawal of the catheter or sheath. Secure the catheter to prevent movement of the catheter and/or sheath and to minimize the risk of catheter-related infections.

9. Aftercare
   - A. Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and avoid excessive force. Ensure the catheter introducer sheath is fully seated by gently rotating the hub of the catheter introducer sheath. The catheter introducer sheath must remain within the lumen of the catheter.

10. Retract and Remove the Introducer Sheath
   - A. After the catheter is well seated within the vessel, apply sterile dressings to both the catheter and sheath insertion sites. Ensure the catheter bridge is flush with the skin or below the skin.
   - B. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

11. Aspirate and Flush
   - A. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
   - B. Do not remove dressing to reposition catheter.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

12. Aspirate and Flush
   - A. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
   - B. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

13. Aspirate and Flush
   - A. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - B. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

14. Aspirate and Flush
   - A. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
   - B. Do not remove dressing to reposition catheter.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

15. Aspirate and Flush
   - A. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
   - B. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

16. Aspirate and Flush
   - A. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
   - B. Do not remove dressing to reposition catheter.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

17. Aspirate and Flush
   - A. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - B. For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava. The use of a needle to locate the vein is recommended. Failure to do so may cause damage to the vein or the catheter. If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

18. Aspirate and Flush
   - A. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
   - B. Do not remove dressing to reposition catheter.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

19. Aspirate and Flush
   - A. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
   - B. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.

20. Aspirate and Flush
   - A. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
   - B. Do not remove dressing to reposition catheter.
   - C. Slowly remove the T-Lock, stylet funnel, and stylet, as a unit. Do not remove stylet through the introducer sheath.
WARNING: 

See Instructions for Use for full information on catheter use.

Instructions for Use

Before Use

1. Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is contraindicated whenever:

- The device is used in patients who are hypersensitive to components of the device material.
- The device is used in patients who are allergic to polyurethane catheters over time with repeated and prolonged exposure.

2. Carefully read and follow all instructions prior to use.

Provena™ Catheter with SOLO™2 Valve Technology

1. Ensure the catheter is sterile at the time of insertion.
2. Prior to insertion, verify the catheter lumen is functional by aspirating and introducing saline solution. Confirm correct placement by monitoring CVP (central venous pressure) while in situ.
3. Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
4. Use catheter introducers and guidewires with a compatible outer diameter (O.D.) to ensure compatibility with Provena™ catheters.
5. Use the Sherlock™ TLS stylet as a retrieval device to assist with the insertion of PICCs. The Sherlock™ TLS stylet is compatible with the Provena™ catheters.
6. The PowerPICC catheter is for use with a 0.035” guidewire. Insertion of a guidewire into the catheter should be performed by a qualified person.
7. The catheter should be maintained in accordance with standard hospital protocols. Recommended catheter flushing/maintenance schedule includes:
   - Initial flush: Immediately after insertion
   - Daily flush: Every 24 hours
   - Weekly flush: Every 7 days

8. The catheter must be secured in place to minimize risk of catheter breakage and embolization.
9. Do not reinsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.
10. Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
11. To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of flush solution.

Use of Heparin Flush Solution

1. The PowerPICC catheter does not require the use of heparin flush solution to lock the catheter lumens. However, use of heparin flush solution will not prevent thrombus formation.
2. The catheter design allows for central venous pressure (CVP) monitoring and allows for insertion of microintroducer assembly and guidewire up to 16Fr. Catheters are manufactured with a maximum sheath O.D. of 18Fr. The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.
3. To avoid vessel damage, pull back the sheath as far as possible and tear the occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

Post-Procedure

1. The catheter tip location can be visually confirmed with Doppler ultrasonic imaging. The catheter can be scanned in the axilla to confirm positioning. The catheter should be placed in a suitable location for access to the venous system for intravenous therapy, blood sampling, power injection of contrast media, and allows for central venous pressure monitoring.
2. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the PowerPICC catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis.

Precautions

1. Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating device. Use care if placing the Sherlock™ TLS stylet on the same side as the cardiac rhythm device.
2. Use the Sherlock™ TLS stylet as a retrieval device to assist with the insertion of PICCs. The Sherlock™ TLS stylet is compatible with the Provena™ catheters.
3. The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet.
4. When alcohol is used as a skin prep, it must be allowed to completely air dry before proceeding with insertion.
5. Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
6. Do not reinsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.
7. The catheter must be secured in place to minimize risk of catheter breakage and embolization.
8. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
9. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
10. Do not use scissors to remove dressing to minimize the risk of cutting catheter.

Possible Complications

1. Common complications include bleeding, infection, and phlebitis.
2. Venous thromboembolism (VTE) and neurovascular injury are possible complications associated with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some settings.
3. Intolerance reaction to implanted materials.
4. Cardiac tamponade
5. Brachial Plexus Injury
6. Spontaneous Catheter Tip Fragmentation
7. Risks Normally Associated with Local Anesthetic

Troubleshooting

1. If the artery is entered, withdraw the needle or safety IV catheter and apply manual pressure for patient’s heart before removing the injection cap.
2. If the vein is not located after 5-10 minutes, withdraw the guidewire and use a new guidewire. The guidewire should be carefully advanced to the vein to prevent the catheter from exiting the vein.
3. If the catheter is not functioning properly, carefully verify proper catheter and guidewire placement in the vessel.
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Insertion Tools

1. The PowerPICC catheter is designed for use with a 0.035” guidewire. Insertion of a guidewire into the catheter should be performed by a qualified person.
2. The catheter design allows for central venous pressure (CVP) monitoring and allows for insertion of microintroducer assembly and guidewire up to 16Fr. Catheters are manufactured with a maximum sheath O.D. of 18Fr. The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.
3. To avoid vessel damage, pull back the sheath as far as possible and tear the occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

Insertion Techniques

1. The catheter design allows for central venous pressure (CVP) monitoring and allows for insertion of microintroducer assembly and guidewire up to 16Fr. Catheters are manufactured with a maximum sheath O.D. of 18Fr. The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.
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Insertion of the Catheter

1. Insertion of the catheter should be performed by a qualified person.
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The device is contraindicated whenever:

- The PowerPICC® catheter is used for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Caution:

- Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, disconnection, or embolism.
- Local tissue factors will prevent proper device stabilization and/or access.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- Polyurethane catheters over time with repeated and prolonged exposure.

NOTE:

When injecting or infusing medications that are incompatible, always flush the catheter with a minimum of 10 mL of sterile saline.
1. Place 1st anchor tape over Dual Lumen Statlock® stabilization device Instructions For Use on the proper use and removal. The StatLock® stabilization device should be monitored for signs of skin irritation or erosion.

2. Cover site and 1st anchor stabilization device with dressing. Tape on top of transparent leg. Wedge tape between hub and wings. Chevron anchor tape on the proper use and removal. The StatLock® stabilization device should be monitored for signs of skin irritation or erosion.

3. Place 2nd anchor tape sticky side of transparent dressing. If CHG allergy is suspected, confirmatory testing is recommended

4. Use of heparin flush solution to lock each lumen of the catheter is optional.

5. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk of patient injury. [See Figure 2]

6. Examine catheter tip to determine that the entire catheter has been removed.

7. Resume removal procedure.

8. If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.

9. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter. Provena™ Catheter with SOLO™2 Valve Technology testing included 10 power injection cycles.

10. The Sherlock™ TLS stylet is made of specially-formulated materials designed to aid in the placement of central venous catheters. The Bard® SCS Catheter with Sherlock™ TLS stylet has been designed to achieve optimal catheter placement and prevent damage to the catheter.

11. Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion. Catheter depth

12. Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion. Catheter depth

13. For additional information, refer to catheter and detector Instructions for Use for the insertion procedure.

14. Before use, ensure that the catheter is in place and the catheter is well suited for the desired point of insertion. Catheter depth

15. Use of a needle longer than 1.6 cm may cause damage to the valve.

16. Suggested Catheter Maintenance

A. Remove the injection/needleless cap from the PowerPICC® Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which can cause catheter failure and/or catheter tip displacement. The detector identifies the position of the stylet tip. Ensure that the stylet tip remains inside and within 1 cm from the end of the catheter. The detector identifies the position of the stylet tip. Ensure that the stylet tip remains inside and within 1 cm from the end of the catheter.

B. Attach a 10 mL or larger syringe filled with sterile saline.

C. Insert the PowerPICC® Catheter with SOLO™2 Valve Technology and prevent damage to the catheter.

D. If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.

E. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter. Provena™ Catheter with SOLO™2 Valve Technology testing included 10 power injection cycles.

F. Examine catheter tip to determine that the entire catheter has been removed.

G. Resume removal procedure.

H. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk of patient injury. [See Figure 2]

I. Use of a needle longer than 1.6 cm may cause damage to the valve.

J. Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion. Catheter depth

K. For additional information, refer to catheter and detector Instructions for Use for the insertion procedure.

L. Use of a needle longer than 1.6 cm may cause damage to the valve.

M. Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion. Catheter depth

N. For additional information, refer to catheter and detector Instructions for Use for the insertion procedure.
The StatLock® stabilization device may be included in PowerPICC

1. Place 1st anchor tape over single lumen.
2. Flush each lumen of the catheter with a minimum of 10 mL of sterile saline, using a "pulse" or "stop/start" technique. Use of heparin flush solution to lock each lumen of the catheter is optional.

3. Remove dressing and StatLock® stabilization device or tape securement strips.
4. Disconnect the T-Lock and stylet funnel from the catheter luer connector.
5. If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
6. Remove slowly. Do not use excessive force. Caution: Do not use scissors to remove dressing to minimize the risk of cutting catheter.

7. Reconnect the T-Lock and stylet funnel to the catheter luer connector.
8. Loosen the T-lock connector/stylet assembly from the stylet funnel.
9. Remove slowly. Do not use excessive force. Caution: Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and advance the catheter into the desired position.

10. The Sherlock™ TLS stylet is made of specially-formulated materials designed to aid in the placement of central venous catheters. It is for use with Provena™ Catheter with SOLO™2 Valve Technology.

11. Caution: Access may be 10.5 French or 9 French hydrophilic introducer-based. Limited access patients requiring smaller access may use smaller access. The stylet or stiffening wire needs to be well behind the point the stylet or stiffening wire is inserted into the vessel. The stylet or stiffening wire length shall not approach the catheter tip to prevent malpositioning and partial or complete occlusion of the catheter lumen. The stylet or stiffening wire shall be removed from the lumen prior to performing venography or any other diagnostic imaging.
1. Place 1st anchor tape over catheter with transparent dressing.

2. Cover site and StatLock® dressing.

3. Place 3rd anchor tape sticky side up, under one extension of transparent dressing.

4. Place 2nd anchor tape over catheter with transparent dressing.

5. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with catheter placement, tip location, patency and security of dressing.


7. Use only lumens marked "Power Injectable" for power injection of contrast media.

8. Detach syringe.

9. Aspirate for adequate blood return and vigorously flush each lumen of the catheter with the full 10 mL of sterile saline. This will allow monitoring of catheter patency.

10. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum power injection flow rate.

11. Power Injection Procedure

   A. Remove the injection/needleless cap from the PowerPICC® or Power High-Line® Power Injection Hub.

   B. Grasp catheter near insertion site.

   C. Occluded or Partially Occluded Catheter

      1. Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against catheter but not more than 1 cm from the trimmed end of the catheter. [See Figure 2]

      2. It is recommended that a continuous infusion of sterile saline (3 mL/hr) is maintained through the catheter while measuring CVP to determine if the catheter is patent.


      7. Note: The Author's Demonstration of the Sherlock™ TLS Device in the video for illustration purposes may not necessarily represent the actual use of the device. When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid damage to the polyurethane material if used over time. Caution: Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients should be monitored closely for signs of bleeding.

   D. Power PICC® or Power High-Line® catheters are designed for fluid and power injection in association with insertion, rapid flushing, or manipulation of the catheter. Power injections may be performed under sterile technique with 3 mL or 10 mL syringes. See Cautions section for instructions before flushing catheter with saline.

   E. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter side up, under one extension of PICC® or Power High-Line® catheter and wings. Chevron anchor tape on top of transparent dressing between hub and wings.

   F. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter side up, under one extension of PICC® or Power High-Line® catheter and wings. Chevron anchor tape on top of transparent dressing between hub and wings.

   G. Re-advance the T-lock connector/stylet assembly locking the connector to the catheter hub. If resistance is met when flushing, discontinuation of flushing and removal of connectors may be necessary.

   H. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum power injection flow rate.

   I. Disconnect the T-Lock and stylet funnel from the catheter luer connector.

   J. Resume removal procedure.

   K. Complete T-Lock Stylet Connection

      1. Aspirate for adequate blood return and vigorously flush each lumen of the catheter with the full 10 mL of sterile saline. This will allow monitoring of catheter patency.

      2. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter side up, under one extension of PICC® or Power High-Line® catheter and wings. Chevron anchor tape on top of transparent dressing between hub and wings.

      3. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with catheter placement, tip location, patency and security of dressing.

     4. Connect the T-Lock and stylet funnel to the catheter luer connector. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with catheter placement, tip location, patency and security of dressing.

   L. Occluded or Partially Occluded Catheter

      1. Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against catheter but not more than 1 cm from the trimmed end of the catheter. [See Figure 2]

      2. It is recommended that a continuous infusion of sterile saline (3 mL/hr) is maintained through the catheter while measuring CVP to determine if the catheter is patent.


      7. Note: The Author's Demonstration of the Sherlock™ TLS Device in the video for illustration purposes may not necessarily represent the actual use of the device. When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid damage to the polyurethane material if used over time. Caution: Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients should be monitored closely for signs of bleeding.

   M. Power PICC® or Power High-Line® catheters are designed for fluid and power injection in association with insertion, rapid flushing, or manipulation of the catheter. Power injections may be performed under sterile technique with 3 mL or 10 mL syringes. See Cautions section for instructions before flushing catheter with saline.

   N. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter side up, under one extension of PICC® or Power High-Line® catheter and wings. Chevron anchor tape on top of transparent dressing between hub and wings.

   O. Re-advance the T-lock connector/stylet assembly locking the connector to the catheter hub. If resistance is met when flushing, discontinuation of flushing and removal of connectors may be necessary.

   P. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum power injection flow rate.

   Q. Disconnect the T-Lock and stylet funnel from the catheter luer connector.

   R. Resume removal procedure.

   S. Occluded or Partially Occluded Catheter

      1. Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against catheter but not more than 1 cm from the trimmed end of the catheter. [See Figure 2]

      2. It is recommended that a continuous infusion of sterile saline (3 mL/hr) is maintained through the catheter while measuring CVP to determine if the catheter is patent.


      7. Note: The Author's Demonstration of the Sherlock™ TLS Device in the video for illustration purposes may not necessarily represent the actual use of the device. When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid damage to the polyurethane material if used over time. Caution: Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients should be monitored closely for signs of bleeding.

   T. Power PICC® or Power High-Line® catheters are designed for fluid and power injection in association with insertion, rapid flushing, or manipulation of the catheter. Power injections may be performed under sterile technique with 3 mL or 10 mL syringes. See Cautions section for instructions before flushing catheter with saline.

   U. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter side up, under one extension of PICC® or Power High-Line® catheter and wings. Chevron anchor tape on top of transparent dressing between hub and wings.

   V. Re-advance the T-lock connector/stylet assembly locking the connector to the catheter hub. If resistance is met when flushing, discontinuation of flushing and removal of connectors may be necessary.

   W. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum power injection flow rate.

   X. Disconnect the T-Lock and stylet funnel from the catheter luer connector.

   Y. Resume removal procedure.
The StatLock® stabilization device may be included in PowerPICC® wings.

Single Lumen Tape Strip Stabilization Procedure

2. Cover site and StatLock® stabilization device with transparent dressing.
3. Place 2nd anchor tape sticky side up under remaining hub.
4. Chevron anchor tape on top of transparent dressing.

WARNING: A. PICCs should be positioned with the catheter tip in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or stabilization device Instructions For Use on the proper use and removal. The StatLock® stabilization device should be monitored for signs of bowing or dislodgement.

I. Disconnect the power injection device.
J. Open catheter lumen with the sterile T-lock connector/stylet assembly.
K. Flush the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology kits. Please refer to manufacturer’s catheter and detector Instructions For Use for the insertion procedure.
L. Connect the catheter lumen to the Power injector machine. The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology may not require a preservative for stabilization while the catheter and detector are being connected.

Caution: If CHG allergy is suspected, confirmatory testing is recommended. As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients.

2. Prior to blood sampling when infusing TPN, follow routine maintenance procedure except use 20 mL of sterile saline and flush to clear TPN from the catheter.

3. Place 4 F Dual Lumen 5 mL/sec flush solution in each catheter lumen.

A./V. Access

4. Prior to blood sampling when infusing TPN, follow routine maintenance procedure except use 20 mL of sterile saline and flush to clear TPN from the catheter.

5. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk of patient injury. [See Figure 2]

C. Withdraw the entire T-lock connector/stylet assembly as one unit.

Caution: The stylet or stiffening wire needs to be well behind the point the catheter but not more than 1 cm from the trimmed end of the catheter. [See Figure 2]

D. For additional information, refer to catheter and detector Instructions for Use for the insertion procedure.

E. Insertion of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together.

Caution: The insertion of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together.

F. Contrast media should be warmed to body temperature prior to power injection.

G. The patient should be monitored for adverse reactions and/or signs of anaphylaxis. The patient, or a responsible family member/representative, should be educated about recognizing and reporting adverse reactions and/or signs of anaphylaxis during and after power injection. The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology may not prevent preservatives for stabilization while the catheter and detector are being connected.

Caution: The patient should be monitored for adverse reactions and/or signs of anaphylaxis. The patient, or a responsible family member/representative, should be educated about recognizing and reporting adverse reactions and/or signs of anaphylaxis during and after power injection. The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology may not prevent preservatives for stabilization while the catheter and detector are being connected.

H. The detector identifies the position of the stylet tip. Ensure that the stylet tip remains inside and within 1 cm from the 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 of patient injury. [See Figure 2]

I. Ensure the pressure transducer is at the level of the right atrium.

J. Flush catheter vigorously with sterile saline.

K. Aspirate for adequate blood return and vigorously flush each lumen of the catheter with the full 10 mL of sterile saline. This will ensure blood return and minimize risk of occlusion.

L. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion is resolved. Use of heparin flush solution to lock each lumen of the catheter is optional.

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