DEVICE DESCRIPTION

The AccuCath® Intravascular Catheter system consists of a radiopaque catheter with a valve mechanism delivered over a guidewire with an atrumatic tip design; a notched needle to enhance flashback visualization, and a safety container that prevents sharp injuries. The AccuCath® Intravascular Catheter is designed to reduce blood exposure during insertion.

POSSIBLE COMPLICATIONS

The potential exists for serious complications including the following:

- Air Embolism
- Bleeding
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Exit Site Infection
- Extravasation/Infarction
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration or Perforation of Vessels or Viscus
- Phlebitis
- Thromboembolism
- Venous Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

INSTRUCTION INSTRUCTIONS

1. Identify the vein and insertion site.
2. Clean and prep insertion site per your institution’s policy.
3. Remove needle cover and inspect the catheter unit. Break catheter tip adhesion before inserting a syringe with the guidewire hub before returning to its final position with catheter tab facing up.
   - Note: Verify the guidewire coil (A) is present and not damaged (before Kermed). If guidewire tip is not present, contact Bard Access Systems, Inc.
4. Advance guidewire from current position by moving the slider (E) toward the catheter tip until it stops. Then fully retract the guidewire back to the needle by moving the slider away from the catheter tip.
   - Note: Be sure to move the slider all the way back until it stops and the coil tip is not visible. If there is excessive force or the guidewire is unable to freely advance, contact Bard Access Systems, Inc. Guidewire must be fully retracted prior to vascular access.
5. Insert the needle into the vein and observe for blood return in the catheter.
   - Note: If inserting at a steeper angle, lower catheter and stabilize before deploying the guidewire.
6. Slowly deploy guidewire into vessel by gently moving slider (E) toward catheter tip until fully deployed and it stops.
   - Warning: Do not force or retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire is unable to freely advance, contact Bard Access Systems, Inc. Guidewire must be fully retracted prior to vascular access.
   - Warning: Do not force or retract the guidewire. If needle retraction does not occur, depress white button (D) again. If the needle does not retract on the second attempt, contact Bard Access Systems, Inc.
7. Verify the guidewire coil (A) is present and not damaged (before Kermed). If guidewire tip is not present, contact Bard Access Systems, Inc.
8. Advance catheter into vessel using two fingers at catheter hub and opposite hand to stabilize the device. Avoid simultaneously pulling the needle out as the catheter is being inserted.
   - Warning: Once the catheter has been advanced, do not re-insert the needle back into the catheter or pull the catheter back onto the needle. If the catheter needs to be repositioned, either do so without the aid of the needle, or remove both the catheter and the needle as a unit to prevent the needle from damaging or shearing the catheter.
   - Do not bend the needle before or during use as this may affect proper needle retraction.
   - Avoid accidental contact with sharp instruments and mechanical damage to the catheter material. Use only smooth-edged atrumatic clamps or forceps.
   - If needle retraction does not occur, depress white button (D) again. If the needle does not retract on the second attempt, carefully withdraw the needle and guidewire and contact Bard Access Systems, Inc.
9. Intended for single use only. Do not re-use. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
   - Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
   - 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 and potential air embolism while changing injection caps, hold the connector below the level of the patient’s heart before removing the injection cap.
10. Caution: Disconnect of any luer device from the hub (C) requires venous compression to prevent potential blood leakage.
   - Note: Blood flow from the catheter hub (C) will be restricted immediately after needle retraction until a secure luer connection is made.
   - Note: Care should be taken to not leave the catheter hub (C) open without connecting to an accessory device. Blood leakage from the hub may occur unless a complete luer connection is made within 10 seconds.
   - Note: The flow path is permanently opened once a secure luer connection is made.
   - Secure catheter and apply sterile transparent dressing over insertion site per your institution’s policy.
   - Immediately discard the safety chamber into a puncture resistant, leak proof sharps container.

POWDER INJECTION PROCEDURE

1. Remove the injection / needleless cap from the AccuCath® Intravascular Catheter.
   - Warning: 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 and potential air embolism while changing injection caps, hold the connector below the level of the patient’s heart before removing the injection cap.
2. Attach a 10 mL or larger syringe filled with sterile saline.
3. Flush catheter vigorously to ensure patency.
   - Warning: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
4. Detach syringe.
   - Attach the power injection device to the AccuCath® Intravascular Catheter per manufacturer’s recommendations.
5. To achieve maximum flow rate, contrast media should be warmed to body temperature prior to power injection.
   - Warning: Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
6. Complete power injection study taking care not to exceed the flow rate limits.
   - Warning: Power injector machine pressure limiting feature may not prevent overpressurization of an occluded catheter, which may lead to catheter failure.
   - Warning: Exceeding the maximum flow rate or the maximum pressure of power injectors of 300 psi (2068 kPa) may result in catheter failure and/or catheter tip displacement.
7. Disconnect the power injection device.
9. Flush the AccuCath® Intravascular Catheter with 10 mL of sterile saline, or per facility protocol.

<table>
<thead>
<tr>
<th>Gauge Size</th>
<th>Contrast Media Temperature</th>
<th>Contrast Media Viscosity</th>
<th>Max Flow (mL/sec)</th>
<th>Injector Safety Cut-off (PSI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Ga</td>
<td>Warned (37°C)</td>
<td>11.8 cP</td>
<td>6</td>
<td>300 max</td>
</tr>
<tr>
<td>20 Ga</td>
<td>Warned (37°C)</td>
<td>11.8 cP</td>
<td>6</td>
<td>300 max</td>
</tr>
<tr>
<td>22 Ga</td>
<td>Warned (37°C)</td>
<td>11.8 cP</td>
<td>6</td>
<td>300 max</td>
</tr>
</tbody>
</table>

Visipaque 320

Caution: When using room temperature (20°C) contrast with a 26.6 cP viscosity, maximum flow rate may not be achieved.

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Note: The flow path is permanently opened once a secure luer connection is made.

10. Secure catheter and apply sterile transparent dressing over insertion site per your institution’s policy.

11. Immediately discard the safety chamber into a puncture resistant, leak proof sharps container.

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11. Immediately discard the safety chamber into a puncture resistant, leak proof sharps container.
1. Identify vein and insertion site
2. Clean and prepare insertion site per institutional policy
3. Remove needle cover and break tip adhesion
4. Fully advance and fully retract guidewire
5. Insert needle in vein
6. Deploy guidewire
7. Advance catheter
8. Depress safety activation button
9. Connect accessory device
10. Secure and dress site