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 may increase the risk of guidewire damage. If the guidewire must be retracted, 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. Intended for single use only. Do not reuse. 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 warn contrast media to body temperature prior to power injection may result in catheter failure. The fluid level in 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. Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure. Attach the power injection device to the AccuCath® Intravascular Catheter. Attach a 10 mL or larger syringe filled with sterile saline. Never use if package number is damaged, leak proof shars container.

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
- Exit Site Necrosis
- Extravasation/Infiltration
- Fibrous 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

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POWER INJECTION PROCEDURE

1. Remove the injection / needleless cap from the AccuCath® Intravascular Catheter.
2. Attach a 10 mL or larger syringe filled with sterile saline.
3. Flush catheter vigorously to ensure patency.
4. Caution: To ensure patency of the catheter prior to power injection studies may result in catheter failure.
5. Attach the power injection device to the AccuCath® Intravascular Catheter per manufacturer’s recommendations.
6. To achieve maximum flow rate, contrast media should be warmed to body temperature prior to power injection.
7. Warning: Failure to warn contrast media to body temperature prior to power injection may result in catheter failure.
8. Complete power injection study taking care not to exceed the flow rate limits.
9. Warning: Power injector machine pressure limiting feature may not prevent overpressurization of an occluded catheter, which may lead to catheter failure.
10. Disconnect the power injection device.
12. 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>Warmed (37°C)</td>
<td>11.8 cP</td>
<td>6</td>
<td>300 max</td>
</tr>
<tr>
<td>20 Ga</td>
<td>7 Visipaque 320</td>
<td>9.0 cP</td>
<td>8</td>
<td>300 max</td>
</tr>
<tr>
<td>22 Ga</td>
<td>Warmed (37°C)</td>
<td>11.8 cP</td>
<td>6</td>
<td>300 max</td>
</tr>
</tbody>
</table>

Caution: When using room temperature (20°C) contrast with a 2.6 cP viscosity, maximum flow rate may not be achieved.

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Not made with natural rubber latex
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