**DEVICE DESCRIPTION**

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

**POSSIBLE COMPLICATIONS**

The potential exists for serious complications including the following:

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

**INSERTION 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.
   
   **Note:** Verify the guidewire coil (A) is present and not damaged (bent, kinked, etc.). If the 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 into the needle by moving the slider away (B) from the catheter tip.

5. Break catheter tip adhesion before inserting by slightly rotating the catheter hub before returning it to its final position with the catheter tip facing up.

6. Insert the needle into the vein and observe for blood return in the catheter and flashback indicator.

7. Slowly deploy guidewire into vessel by gently moving slider (E) toward catheter tip until fully deployed and it stops.

8. Advance catheter into vessel using two fingers at catheter hub and opposite hand to stabilize the device. Avoid simultaneous pulling the needle out as the catheter is pushed in.

**POWER INJECTION PROCEDURE**

1. Remove the injection / needleless cap from the AccuCath Ace™ IV 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. Ensure proper needle retraction.

   **Warning:** Do not force or retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

3. Do not bend the needle before or during use as this may affect proper needle retraction.

   **Caution:** Do not force or retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

**INDICATIONS FOR USE**

The AccuCath Ace™ Intravascular Catheter is inserted into a patient’s vascular system to sample blood, monitor blood pressure, or administer fluids intravasately. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath Ace™ IV Catheter is suitable for use with power injectors.

**CONTRAINDICATIONS**

This device is not designed, sold or intended for use except as indicated.

**WARNINGS**

- 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 force or retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

- Do not bend the needle before or during use as this may affect proper needle retraction.

**PRECAUTIONS**

- Only qualified health care practitioners should insert, manipulate and remove these devices.

- Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

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

- Follow Universal Precautions when inserting and maintaining the catheter.

- Measures should be taken to avoid kinking or obstructing the catheter during power injection to avoid device failure.

- Avoid unnecessary manipulation of the catheter or device. Needle and guidewire and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

- Report needle stick injuries immediately and follow established institutional protocol.

- Leaving the needle tip positioned within the catheter hub (C) for a prolonged period may result in blood leakage.

- Disconnection of any luer device from the hub (C) requires venous compression to prevent potential blood leakage.

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

- Be sure to move the slider all the way back until it stops. Then fully retract the guidewire back into 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 coiled 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 venous access.

- Break catheter tip adhesion before inserting by slightly rotating the catheter hub before returning it to its position with the catheter tip facing up.

- Insert the needle into the vein and observe for blood return in the catheter and flashback indicator.

- Note: If inserting at a steeper angle, lower catheter and stabilise before deploying the guidewire.

- 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 must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

- Note: If blood return is visualized and the guidewire will advance, but the catheter will not, consider rotating the device 180 degrees (bevel down) before re-advancing the needle and catheter.

- Advancement of the catheter tip may result in catheter failure. Proceed with the catheter tip at the catheter hub. Be sure to move the slider all the way back until it stops.

- Note: If blood return is visualized and the guidewire will advance, but the catheter will not, consider rotating the device 180 degrees (bevel down) before re-advancing the needle and catheter.

- Slowly advance catheter into vessel using two fingers at catheter hub and opposite hand to stabilize the device. Avoid simultaneous pulling the needle out as the catheter is pushed in.

- When 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.

- 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.

- **Warning:** Do not retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

- **Note:** If blood return is visualized and the guidewire will advance, but the catheter will not, consider rotating the device 180 degrees (bevel down) before re-advancing the needle and catheter.

- **Warning:** Do not bend the needle before or during use as this may affect proper needle retraction.

- **Caution:** Do not retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

- **Note:** If blood return is visualized and the guidewire will advance, but the catheter will not, consider rotating the device 180 degrees (bevel down) before re-advancing the needle and catheter.

- **Warning:** Do not retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

- **Note:** If blood return is visualized and the guidewire will advance, but the catheter will not, consider rotating the device 180 degrees (bevel down) before re-advancing the needle and catheter.

- **Warning:** Do not retract the guidewire. Retracting the guidewire may increase the risk of guidewire damage. If the guidewire must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.

- **Note:** If blood return is visualized and the guidewire will advance, but the catheter will not, consider rotating the device 180 degrees (bevel down) before re-advancing the needle and catheter.
1. Identify vein and insertion site
2. Clean and prepare insertion site per institutional policy
3. Remove needle cover
4. Fully advance and fully retract guidewire
5. Break catheter tip adhesion
6. Insert needle in vein and observe flashback
7. Deploy guidewire
8. Advance catheter
9. Depress safety activation button
10. Connect accessory device
11. Secure and dress site