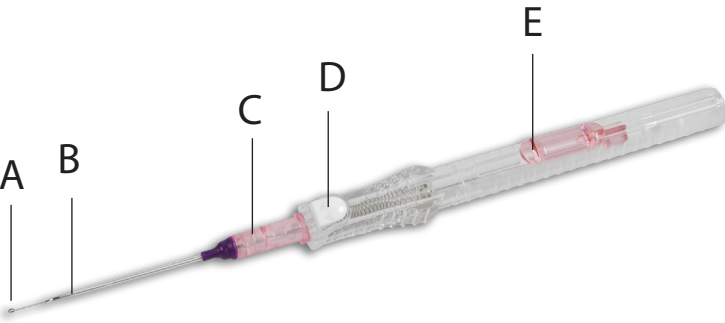


AccuCath Ace™

intravascular catheter

DEVICE DESCRIPTION

The AccuCath Ace™ Intravascular Catheter system consists of a radiopaque catheter with a valve mechanism delivered over a guidewire with an atraumatic 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.



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 intravenously. 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.
- Avoid accidental device contact with sharp instruments and mechanical damage to the catheter material. Use only smooth-edged atraumatic 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 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.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Power injector machine pressure limiting feature may not prevent overpressurization of an occluded catheter, which may lead to catheter failure.
- 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.
- If the artery is unintentionally entered, withdraw the needle and apply manual pressure for several minutes. Failure to do so may lead to patient blood loss.

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.
- After use, this product may be a potential biohazard. Handle 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.

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
- 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

INSERTION INSTRUCTIONS

- Identify the vein and insertion site.
- Clean and prep insertion site per your institution’s policy.
- Remove needle cover and inspect the catheter unit.
Note: Verify the guidewire coil (A) is present and not damaged (bent, kinked, etc.). If guidewire tip is not present, contact Bard Access Systems, Inc.
- 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 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 vascular access.
- Break catheter tip adhesion before inserting by slightly rotating the catheter hub before returning it to its final position with the catheter tab 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 stabilize 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.
- 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 pushed in.
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.
Caution: Leaving the needle tip positioned within the catheter hub (C) for a prolonged period may result in blood leakage.
Note: Catheter hub needs to be advanced at least 0.5cm for safety mechanism to activate.
- Depress the safety activation button (D) while stabilizing the catheter with opposite hand. This will retract the needle (B) and proximal portion of the guidewire in to safety chamber. Coiled tip (A) should remain visible for inspection.
Warning: 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.
Warning: Do not bend the needle before or during use as this may affect proper needle retraction.
Caution: Report needle stick injuries immediately and follow established institutional protocol.
Note: Ensure the guidewire is fully deployed prior to safety activation.
- Securely connect any accessory device to the catheter hub (C) and flush prior to infusion.
Caution: Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.

- Caution:** Disconnection 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.

POWER INJECTION PROCEDURE

- 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.
- Attach a 10 mL or larger syringe filled with sterile saline.
- Flush catheter vigorously to ensure patency.
Warning: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Detach syringe.
- Attach the power injection device to the AccuCath Ace™ IV Catheter per manufacturer’s recommendations.
- 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.
- 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.
- Disconnect the power injection device.
- Attach a new sterile injection / needleless cap on the AccuCath Ace™ IV Catheter.
- Flush the AccuCath Ace™ IV Catheter with 10 mL of sterile saline, or per facility protocol.

Gauge Size	Contrast Media¹ Temperature	Contrast Media¹ Viscosity	Max Flow (mL / sec)	Injector Safety Cut-off (PSI)
18 Ga	Warmed (37° C)	11.8 cP	6	300 max
20 Ga				
22 Ga				

¹ 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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Revised date: February 2018

Do not use if package is damaged

Do not reuse

Manufacturer

Product catalog number

Lot number

Non pyrogenic

Consult instructions for use

Do not resterilize

Sterilized using ethylene oxide

Use by

Quantity

Not made with natural rubber latex

Rx Only

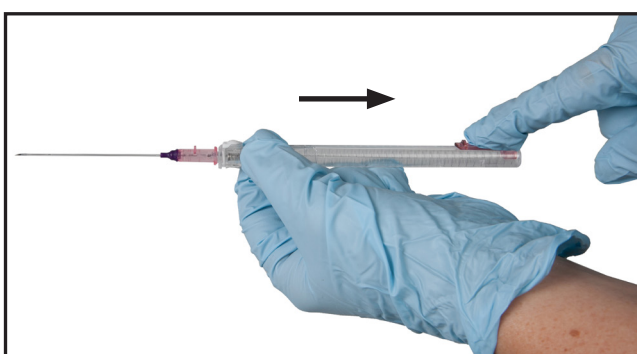
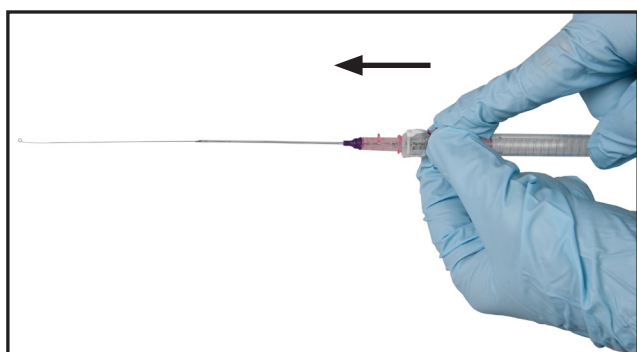
1 IDENTIFY VEIN AND INSERTION SITE

2 CLEAN AND PREPARE INSERTION SITE PER INSTITUTIONAL POLICY

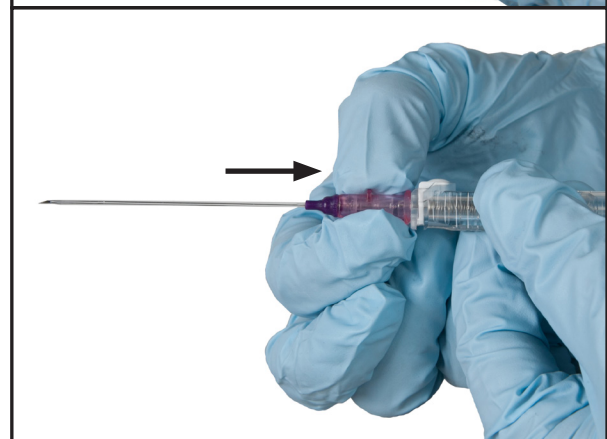
3 REMOVE NEEDLE COVER



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

