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.

## DEVICE DESCRIPTION

Intravascular Catheter is designed to reduce blood injectors having a maximum pressure setting of 300 psi IV Catheter is suitable for use with low pressure power being infused, and duration of therapy. The AccuCath® of vascular anatomy, appropriateness of the solution may be used with consideration given to adequacy patient’s vascular system to sample blood, monitor blood needle to enhance flashback visualization, and a safety over a guidewire with an atraumatic tip design; a notched insertion.

### 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 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 warm contrast media to body temperature prior to power injection may result in catheter failure.

### 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.

### INDICATIONS FOR USE

The AccuCath® 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® IV Catheter is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/second.

### 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 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 warm contrast media to body temperature prior to power injection may result in catheter failure.

### 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

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 guidewire tip is not present, contact Bard Access Systems, Inc.
4. Advance guidewire from current position by moving the slider (E) toward catheter tip until fully deployed and 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.
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 must be retracted, remove the entire device to prevent the needle from damaging or shearing the guidewire.
7. 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.
8. 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.
9. 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.
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.

### DISPOSAL

Do not use if package is damaged. Do not reuse Manufacturer: Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, Utah 84116 USA Lot number 801-522-5000 www.bardaccess.com

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Not made with natural rubber latex

Non pyrogenic

Sterilized using ethylene oxide

Streelma (EC) number

Consult instructions for use

Do not resterilize

Manufacturer: Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, Utah 84116 USA 801-522-5000 www.bardaccess.com 0741179 1601R

Do not use if package is damaged

Do not reuse

Manufacturer

Sterilized using ethylene oxide

Streelma (EC) number

Lot number

Use by
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 INSERT NEEDLE IN VEIN
6 DEPLOY GUIDEWIRE
7 ADVANCE CATHETER
8 DEPRESS SAFETY ACTIVATION BUTTON
9 CONNECT ACCESSORY DEVICE
10 SECURE AND DRESS SITE