

# Multi-Lumen Acute Hemodialysis Catheter Product

## Rx only.

### Description:

The Multi-Lumen Acute Hemodialysis Catheter (AHDC) is a central venous catheter (CVC) intended to provide venous access for hemodialysis, apheresis, rapid fluid administration, IV therapy, blood sampling, pressure injection of contrast media, and Central Venous Pressure (CVP) monitoring.

The catheter consists of a polyurethane extrusion with three independent lumens extending throughout the length of the catheter body.

Each lumen exits at the distal end of the catheter through individual ports. A soft tip that is more pliable than the catheter body forms the distal tip of the catheter.

At the proximal end of the juncture hub the lumens are connected to separate extension lines. Each extension line contains either a red or blue clamp to indicate arterial flow (outflow) or venous flow (inflow) respectively. The third lumen contains a brown hub with the pressure rating capabilities of the lumen printed on the hub. Centimeter markings are placed along the length of the indwelling catheter body to facilitate proper positioning.

Multi-Lumen AHDCs have a straight body catheter design and are available in a variety of lengths.

All Multi-Lumen AHDCs are packaged in a variety of kit/set configurations with a variety of components to assist the clinician in catheter insertion and maintaining maximal sterile barrier precautions (where provided).

### Indications for use:

The Multi-Lumen Acute Hemodialysis Catheter (AHDC) is indicated for use in attaining short-term (less than 30 days) vascular access for:

- Hemodialysis
- Apheresis
- Rapid fluid administration
- Intravenous therapy
- Blood sampling
- Pressure injection of contrast media
- Central venous pressure monitoring

The catheter may also be used in a variety of renal replacement therapies, such as hemofiltration and hemoperfusion. The catheter may be inserted into the jugular, subclavian, or femoral veins. The maximum pressure injection flow rate is 6 mL/sec.

### Contraindications:

The Multi-Lumen Acute Hemodialysis Catheter (AHDC) is not designed for long-term ( $\geq 30$  days) hemodialysis or for insertion into thrombosed vessels.

See additional labeling for product specific contraindications.

### **General Warnings and Precautions**

#### Warnings:

1. **Sterile, Single use:** Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.
2. **Read all package insert warnings, precautions and instructions prior to use.** Failure to do so may result in severe patient injury or death.
3. **Practitioners must be aware of complications associated with central venous catheters including, but not limited to:** cardiac tamponade secondary to vessel, atrial or ventricular perforation, pleural (i.e., pneumothorax) and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage, dysrhythmia, fibrin sheath formation, exit site infection, vessel erosion, catheter tip malposition, phlebitis, and SVC syndrome. Potential complications specific to subclavian placement also include, but are not limited to: pulmonary embolism, hemothorax, infection, and clavicle to first rib catheter impingement (“pinch-off”).
4. **Do not place AHDCs/CVCs into or allow them to remain in the right atrium or right ventricle.** X-ray exam or other method in compliance with hospital/institutional protocol must show catheter tip located in lower 1/3 of the Superior Vena Cava (SVC) close to the junction of the SVC and the right atrium. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of guidewire into the heart has also been implicated in causing cardiac perforation and tamponade.
5. **Ensure catheter tip has not entered the heart and lies parallel to vessel wall by performing an x-ray exam or other method in compliance with hospital/institutional protocol.** If catheter position has changed, immediately re-evaluate.

6. Practitioners must be aware of the potential for entrapment of guidewire by any implanted device in circulatory system (i.e., vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding length of guidewire inserted. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire entrapment.
7. Choose appropriate sized catheter for therapeutic needs and size of vessel to be cannulated.
8. Catheter tip must be located in central circulation when administering > 10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with pH less than 5 or greater than 9, and infusates with an osmolality above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
9. Use only securely tightened Luer-Lock connections with any Central Venous Access Device (CVAD) to guard against inadvertent disconnect.
10. Use Luer-Lock connectors to help guard against air embolism and blood loss.

**Precautions:**

1. Do not use if package has been previously opened or damaged.
2. Do not alter the catheter, guidewire, or any other kit/set component during insertion, use, or removal (except as instructed).
3. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
4. Engage safety and/or locking feature of scalpel (where provided) when not in use to reduce risk of sharps injury.
5. Perform hand hygiene:
  - before and immediately after all clinical procedures
  - before donning and after removal of gloves
6. Properly handle and dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for blood borne pathogens and/or hospital/institutional policy.
7. Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to Human Immunodeficiency Virus (HIV) or other blood borne pathogens.

- easily accomplished, an x-ray should be obtained and further consultation requested.
2. Do not secure, staple, and/or suture directly to outside diameter of catheter body or extension lines to reduce risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
3. Do not use scissors to remove dressing to reduce risk of cutting catheter.
4. Practitioners should be aware that slide clamps may be inadvertently removed and aspirated by confused adults.
5. Do not routinely replace acute hemodialysis catheters solely for the purpose of reducing incidence of infection.
6. Do not use guidewire techniques to replace catheters in patient suspected of having catheter-related infection.
7. Residual catheter track remains an air entry point until completely sealed. Occlusive dressing should remain in place for at least 24 - 72 hours dependent upon amount of time catheter was indwelling.
8. Do not clamp the body of the catheter. Clamp only the extension lines and use only the clamps provided. Never use serrated forceps to clamp the extension lines.
9. Do not use distal lumen for dialysis at any time.

**Precautions:**

1. Ensure catheter patency prior to use. Do not use syringes smaller than 10 mL (a fluid filled 1 mL syringe can exceed 300 psi), to reduce risk of intraluminal leakage or catheter rupture.
2. Continuously monitor indwelling catheter for:
  - desired flow rate
  - security of dressing
  - adherence of stabilization device to skin and connection to catheter
  - correct catheter position; use centimeter markings to identify if catheter position has changed
  - secure Luer-Lock connection(s)
  - signs and symptoms of infection
3. Inject a small amount of radiopaque dye to locate catheter tip if difficulty is encountered in visualizing the catheter tip.
4. Do not use distal lumen for CVP monitoring or infusion while proximal and medial lumens are used for dialysis therapy.

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## ***Catheter Warnings and Precautions***

**Warnings:**

1. Do not apply excessive force in placing or removing catheter. Excessive force can cause catheter breakage. If placement or withdrawal cannot be

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## ***Guidewire/SWG Warnings***

1. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.
2. Passage of guidewire into the right heart can cause dysrhythmias and perforation of vessel, atrial, or

ventricular wall.

3. Do not apply excessive force in removing guidewire or catheter. If withdrawal cannot be easily accomplished, a visual image should be obtained and further consultation requested.

## Tissue Dilator Warning

1. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.

## Pressure Injection Warnings and Precautions

### Warnings:

1. Assess patient for appropriateness of a pressure injection procedure.
2. Pressure injection procedures must be performed by trained personnel well versed in safe technique and potential complications.
3. Discontinue pressure injections at first sign of extravasation or catheter deformation. Follow hospital/institutional protocol for appropriate medical intervention.

### Precautions:

1. Do not exceed maximum pressure of 300 psi on power injector equipment to reduce risk of catheter failure and/or tip displacement.
2. Pressure limit settings on power injector equipment may not prevent over pressurizing an occluded or partially occluded catheter.
3. Use appropriate administration set tubing between catheter and power injector equipment to reduce risk of catheter failure.

## Accessory Component Instructions

Review the list of components that will be utilized before beginning the multi-lumen AHDC insertion procedure. Kits/Sets may not contain all accessory components detailed in these instructions for use. Become familiar with instructions for individual component(s) before beginning the procedure.

## Arrow Advancer:

- Using thumb, straighten the "J" by retracting guidewire into Arrow Advancer (refer to Figures 1 and 2).

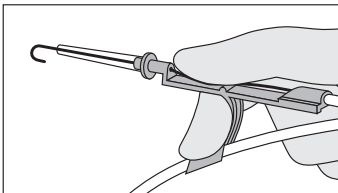


Figure 1

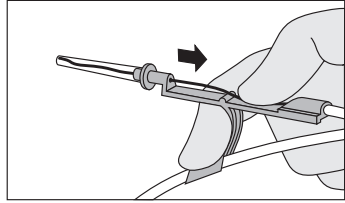


Figure 2

- When tip is straightened, guidewire is ready for insertion. Centimeter marks on guidewire are referenced from "J" Tip: one band indicates 10 cm, two bands 20 cm, and three bands 30 cm.
- Place tip of Arrow Advancer – with "J" retracted – into the hole in rear of Arrow® Raulerson Syringe plunger (refer to Figure 3) or introducer needle.

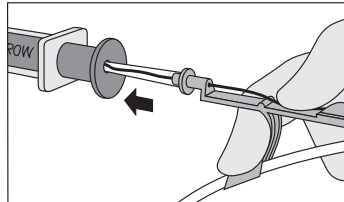


Figure 3

### Alternate Technique:

If a simple straightening tube is preferred, the straightening tube portion of Arrow Advancer can be disconnected from the unit and used separately.

- Separate Arrow Advancer tip or straightening tube from blue Arrow Advancer unit.
- Prepare for insertion by sliding plastic tube over "J" to straighten, if "J" Tip portion of guidewire is used.
- Advance guidewire in routine fashion to desired depth.

## Arrow® Raulerson Syringe:

Arrow Raulerson Syringe is used in conjunction with Arrow Advancer for guidewire insertion.

- Insert introducer needle attached to Arrow Raulerson Syringe into vessel and aspirate.

**NOTE:** A transduction probe is available for pressure wave form transduction.

- Advance guidewire into Arrow Raulerson Syringe approximately 10 cm until it passes through syringe valves (refer to Figure 4) or into introducer needle.

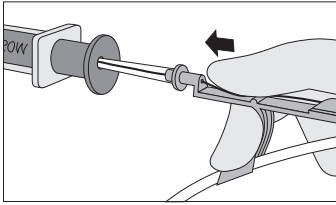


Figure 4

- Raise thumb and pull Arrow Advancer approximately 4 - 8 cm away from Arrow Raulerson Syringe or introducer needle. Lower thumb onto Arrow Advancer and while maintaining a firm grip on SWG, push assembly into syringe barrel to further advance SWG. Continue until SWG reaches desired depth (refer to Figure 5).

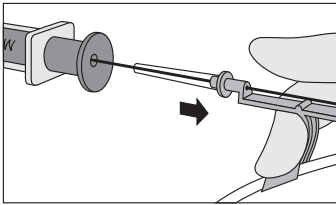


Figure 5

- Hold guidewire in place and remove introducer needle and Arrow Raulerson Syringe.

## Dressing:

A transparent dressing should be used in accordance with manufacturer's instructions for use.

- Prepare site. Allow all preps to dry completely.
- Peel liner from dressing to expose adhesive.
- Place without tension over insertion site. Slowly remove frame while smoothing down dressing edges (refer to Figure 6).

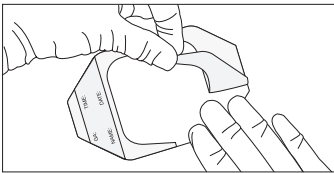


Figure 6

- Label dressing according to hospital/institutional protocol.  
*Refer to individual manufacturer's instructions for more information and specific detailed instructions for dressing removal (not included).*

## Echogenic Needle:

An echogenic needle is used to provide greater needle visibility under ultrasound. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

## Guidewire:

Kits/Sets are available with a variety of guidewires. Guidewires are provided in different diameters, lengths, and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique before beginning the actual insertion procedure.

Image guidance may be used to gain initial venous access.

## Maximal Barrier Drape™:

Drape(s) provide a maximal sterile barrier. Follow the CDC Category 1A Recommendation.

- Unfold the Maximal Barrier Drape™.
- Peel off fenestration backing (refer to Figure 7).



Figure 7

- Position fenestration over intended insertion site (refer to Figure 8).

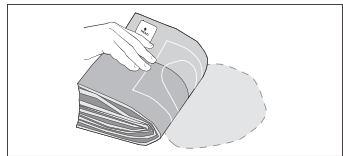


Figure 8

- Unfold width (refer to Figure 9).

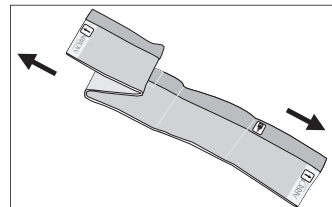


Figure 9

- Unfold towards head (refer to Figure 10).

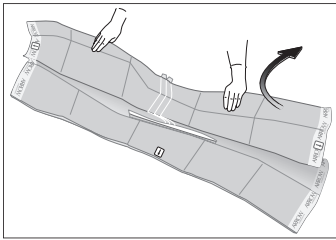


Figure 10

- Unfold towards hand (refer to Figure 11).

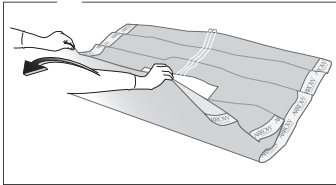


Figure 11

- Perform sterile procedure.
- Tear along seam to remove drape (refer to Figure 12).

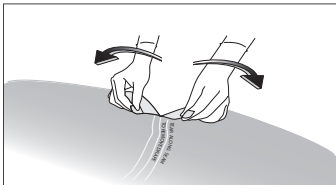


Figure 12

## Protected Needle:

A protected needle should be used in accordance with manufacturer's instructions for use.

⚠ **Warning:** Keep hands behind needle at all times during use and disposal.

⚠ **Precaution:** Use all needles in accordance with OSHA and hospital/institutional safety protocols.

⚠ **Precaution:** Do not attempt to override or defeat the safety locking mechanism of a protected needle.

⚠ **Precaution:** Discard in an approved sharps collector in accordance with applicable regulations and hospital/institutional policy.

### General Guidelines for Protected Needle Use:

- Aspirate medication into syringe using aseptic technique.
- Administer injection following established technique.
- Immediately activate needle protection device upon withdrawal from patient. For greatest safety, use a one-handed technique and activate away from self and others (refer to Figure 13).

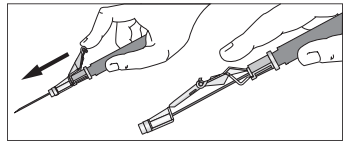


Figure 13

- Visually confirm needle tip is completely covered. If unable to activate, discard immediately into approved sharps collector.
- Activation of protective mechanism may cause minimal splatter of fluid that may remain on needle after injection.
- Discard after single use.

**NOTE:** Use *passive recapping technique to cover needle before transport to point of use.*

## SharpsAway® II Locking Disposal Cup:

The SharpsAway II Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

⚠ **Precaution:** Do not attempt to remove needles that have been placed into SharpsAway II Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 14).

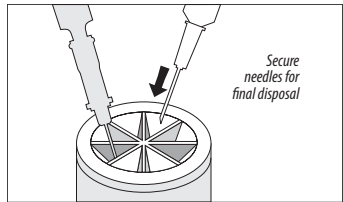


Figure 14

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.
- Discard entire cup, at completion of procedure, into an approved sharps container.
- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

⚠ **Precaution:** Do not re-use needles after they have been placed into the foam SharpsAway system. Particulate matter may adhere to needle tip.

## Pre-AHDC Insertions & Patient Assessment Activities

### A Suggested Procedure:

Clinical assessment of patient must be completed to ensure no contraindications exist.

### ⚠ Procedural Pause:

1. Verify physician order:
  - Confirm correct patient.
  - Confirm correct diagnosis.
  - Confirm correct procedure.

Physician order must include post placement assessment of catheter tip placement (direct visualization technique or other method in compliance with hospital/institutional protocol).

2. Educate patient: Explain procedure to patient. Make sure information is presented with respect to patient's level of understanding, culture, and language.
3. Have informed consent signed, if required.
4. Identify appropriate vein for insertion.
  - Use direct visualization technologies, e.g., ultrasound or fluoroscopy, if available.
  - Assess vein health.
5. Position patient as appropriate for insertion site:
  - Subclavian or Jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce risk of air embolism and enhance venous filling.
  - If femoral approach is used, place patient in supine position.
6. Prepare work area.

### Preparing for Catheter Insertion:

- Clinicians should use sterile technique, maximal sterile barrier precautions throughout the procedure, and dress in protective clothing:
  - mask
  - eye protection
  - sterile gown
  - sterile gloves
  - hair cover

### Prep Puncture Site:

1. Prep puncture site with appropriate antiseptic/agent.
2. Drape puncture site.

See unfolding instructions for Maximal Barrier Drape (where provided) under Accessory Component Instructions section.

3. Perform skin wheal using desired needle and local anesthetic.
4. Dispose of needle.

### Flush Catheter:

1. Flush each lumen with sterile saline solution, to establish patency and prime lumen(s).
2. Clamp or attach Luer-Lock connector(s) to extension line(s) to contain saline within lumen(s).
3. Leave distal extension line uncapped for guidewire passage.

**⚠ Warning:** Do not cut catheter to alter catheter length.

## Catheter Insertion Instructions

### Gain Initial Vessel Access:

**⚠ Warning:** Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Air embolism can occur with these practices.

1. Insert introducer needle or catheter/needle with attached syringe or Arrow Raulerson Syringe (where provided) into vein and aspirate.

See Arrow Raulerson Syringe under Accessory Component Instructions section.

2. Remove locator needle if previously inserted.

**⚠ Precaution:** Do not rely on blood aspirate color to indicate venous access.

**⚠ Precaution:** Do not reinsert needle into introducer catheter to reduce risk of catheter embolism.

### Verify Venous Access:

Utilize one of the following techniques to verify venous access, because of the potential for inadvertent arterial placement:

1. Venous Waveform:
  - Insert fluid primed blunt tip pressure transduction probe into rear of plunger and through valves of the Arrow Raulerson Syringe and observe for central venous pressure waveform.
    - Remove transduction probe if using Arrow Raulerson Syringe.
  - Observe for central venous pressure waveform obtained by a calibrated pressure transducer attached directly to the introducer needle/catheter.
2. Pulsatile Flow (if hemodynamic monitoring equipment is not available):
  - Use transduction probe to open syringe valving system of Arrow Raulerson Syringe and observe for pulsatile flow.
  - Disconnect syringe from needle and observe for pulsatile flow.

**⚠ Warning:** Pulsatile flow is usually an indicator of inadvertent arterial puncture.

### Insert Guidewire:

See Arrow Advancer under Accessory Component Instructions section.

1. Straighten "J" of guidewire by using a straightening tube or Arrow Advancer (where provided).
2. Insert tip of guidewire into plunger of Arrow Raulerson Syringe or into introducer needle.
3. Advance guidewire through Arrow Raulerson Syringe or introducer needle into vein to desired depth.
  - Advancement of "J" Tip through Arrow Raulerson Syringe may require a gentle rotating motion.
  - Advance guidewire until triple band mark reaches rear of Arrow Raulerson Syringe plunger.
4. Use centimeter markings on guidewire as a reference to assist in determining how much guidewire has been inserted.

**NOTE:** If guidewire has three sets of markings, they will be located as follows:

- One band - 10 cm from "J" Tip
- Two bands - 20 cm from "J" Tip
- Three bands - 30 cm from "J" Tip

**NOTE:** When guidewire is used in conjunction with the Arrow Raulerson Syringe (fully aspirated) and a 2-1/2" introducer needle, the following positioning references can be made:

- 20 cm mark entering back of plunger = guidewire tip is at end of needle
- 30 cm mark entering back of plunger = guidewire tip is approximately 10 cm beyond end of needle

**⚠ Precaution:** Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.

**⚠ Warning:** Do not aspirate Arrow Raulerson Syringe while guidewire is in place; air may enter syringe through rear valve.

**⚠ Precaution:** Do not reinfuse blood to reduce risk of blood leakage from rear (cap) of syringe.

**⚠ Warning:** Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.

5. Remove introducer needle and Arrow Raulerson Syringe (or catheter) while holding guidewire in place.

- Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement.
- Enlarge cutaneous puncture site with cutting edge of scalpel, if necessary, positioned away from guidewire.

⚠ **Warning: Do not cut guidewire to alter length.**

⚠ **Warning: Do not cut guidewire with scalpel.**

- Position cutting edge of scalpel away from guidewire.
- Engage safety and/or locking feature of scalpel (where provided) once cutaneous puncture site is enlarged, to reduce risk of cutting the guidewire (refer to Figure 15).

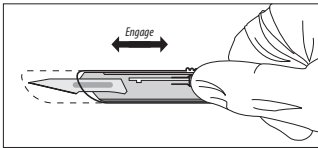


Figure 15

- Use tissue dilator to enlarge puncture site as required.
- ⚠ **Warning: Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.**

#### Advance Catheter:

- Thread tip of catheter over guidewire. Sufficient guidewire length must remain exposed at hub end of catheter to maintain a firm grip on guidewire.
- Grasping near skin, advance catheter into vein with slight twisting motion.
- Use centimeter marks on catheter as positioning reference points.
- Advance catheter to final indwelling position.

**NOTE: Centimeter marking symbology is referenced from catheter tip.**

- numerical: 15, 25
- bands: each band denotes a 10 cm interval, with one band indicating 10 cm, two bands indicating 20 cm, etc.
- dots: each dot denotes a 1 cm interval

**NOTE: When using a subclavian approach, the catheter can be oriented with the outflow (arterial) sideholes toward the center of the vessel to reduce the possibility of contact between the outflow sideholes and the vessel wall.**

- Hold catheter at desired depth and remove guidewire.

**NOTE: Arrow catheters are designed to pass freely over guidewire.**

⚠ **Precaution: If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked about tip of catheter within vessel (refer to Figure 16).**

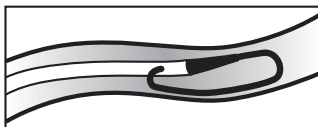


Figure 16

- In this circumstance, pulling back on guidewire may result in undue force being applied resulting in guidewire breakage.
- If resistance is encountered, withdraw catheter relative to guidewire about 2-3 cm and attempt to remove guidewire.

- If resistance is again encountered, remove guidewire and catheter simultaneously.

⚠ **Warning: Do not apply undue force on guidewire to minimize the risk of possible breakage.**

- Verify entire guidewire is intact upon removal.

#### Complete Catheter Insertion:

- Check lumen placement by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.
- Reposition catheter to obtain adequate blood flows, if any extension line exhibits excessive resistance during blood aspiration.
- Flush catheter lumens thoroughly with normal saline to remove residual blood before instilling heparin.
- Inject appropriate amount of heparin solution per hospital/institutional acute dialysis line protocol into dialysis (proximal and medial) lumens to ensure heparin completely fills catheter. Follow hospital/institutional protocol for distal lumen.

**NOTE: Priming volumes are printed on extension lines.**

⚠ **Precaution: Ensure designated priming volumes are achieved.**

- Connect infusion port (distal lumen) to appropriate Luer-Lock line as required or it may be "locked" through a connector using standard hospital/institutional central venous line protocol.
  - A slide clamp is provided on distal extension line to occlude flow through the lumen during line and connector change.
- Close pinch extension clamps on proximal and medial extension lines, remove syringes.
- Place a Luer-Lock cap on each hemodialysis (proximal and medial lumens) hub.

**NOTE: Minimize the risk of air embolism by keeping extension lines clamped at all times when not in use and by aspirating and removing indwelling heparin and then flushing catheter with saline prior to each use.**

- Tape Luer-Lock caps and clamps (red and blue) on proximal and medial extension lines between treatments to reduce risk of accidental opening of both, thereby potentially causing blood loss and/or air embolism.

⚠ **Warning: Open distal lumen clamp prior to infusion through the lumen to minimize the risk of damage to extension line from excessive pressure.**

- Secure catheter to patient.
- ⚠ **Precaution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.**
- Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.

⚠ **Precaution: Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of central venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.**

- Assess catheter tip placement in compliance with hospital/institutional protocol.
- If catheter tip is malpositioned, reposition, redress, and re-verify.

## Documentation

Hospitals/institutions must establish a permanent medical record that documents the entire procedure, based upon their policy, procedures, and Best Practices. The actual format can differ from institution to

institution. Report any product defects/failures to organization risk management, manufacturers, and appropriate regulatory agencies.

### Documentation generally includes (but is not limited to) the following information:

1. Device specifics:
  - type, brand, and lot number
  - length and size of Central Venous Access Device (CVAD)
2. Procedure specifics:
  - time out or procedural pause
  - informed consent, as required
  - date, time of insertion, insertion site, number and site attempts, inserter's identification
  - use of visualization and guidance technologies
  - site preparation and technique
3. Patient assessment and response:
  - pertinent diagnosis, assessment, vital signs
  - understanding of procedure, patient's response to procedure
  - complications and barriers to care
4. Therapy specifics:
  - dialysis prescription
5. Visual confirmation:
  - verification of appropriate tip location prior to initial use

Monitor patient for post catheter insertion complications.

## Pressure Injection Instructions

### Use sterile technique.

**⚠ Warning:** Use appropriate method to confirm catheter tip position prior to each pressure injection per hospital/institutional policy.

1. Remove cap or connector from distal (infusion) extension line of catheter.
2. Check for lumen patency of distal extension line of catheter:
  - Remove heparin.
  - Attach 10 mL syringe filled with sterile normal saline.
  - Aspirate catheter for adequate blood return.
  - Vigorously flush catheter.

**⚠ Warning:** Ensure lumen patency prior to pressure injection to reduce risk of catheter failure and/or patient complications.

3. Detach syringe.
4. Attach pressure injection administration set tubing to distal (infusion) extension line of catheter according to manufacturer's recommendations.

**⚠ Precaution:** Do not exceed ten (10) injections or catheter's maximum recommended flow rate located on product labeling and catheter luer hub to reduce risk of catheter failure and/or tip displacement.

**⚠ Warning:** Use only lumen labeled "Pressure Injectable" for power injection to reduce the risk of catheter failure and/or patient complications.

5. Inject contrast media in accordance with hospital/institutional protocol.

**⚠ Precaution:** Warm contrast media to body temperature prior to pressure injection to reduce risk of catheter failure.

**⚠ Precaution:** Follow the contrast media manufacturer's specified instructions for use, contraindications, warnings, and precautions.

6. Disconnect catheter from pressure injector equipment.
7. Flush distal lumen using 10 mL syringe or larger filled with sterile normal saline.
8. Disconnect syringe and replace with sterile cap or connector on catheter extension line.

## Care and Maintenance

### Dressing:

Replace dressing according to hospital/institutional policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised, (i.e., dressing becomes damp, soiled, loosened, or no longer occlusive).

**⚠ Precaution:** Maintain insertion site with regular meticulous redressing using aseptic technique.

- Consult manufacturer's recommendations for dressing specifics.
- Change transparent semipermeable membrane dressing minimally every 7 days.
- Change gauze and tape minimally every 48 hours.
- Label dressing with type, size, and length of catheter; date and time; and initials of the clinician performing dressing change.

### Exit Site Care:

Alcohol, chlorhexidine-based solutions (e.g., Chloraprep®, Hibiclen®), iodine-based solutions (Povidone-Iodine), hydrogen peroxide, or ExSept Plus® are accepted for use with this catheter at the exit site (including the juncture hub and catheter body).

**⚠ Precaution:** Avoid excessive or prolonged use of alcohol-based solutions and ointments to clean catheter or site care. Excessive or prolonged use of alcohol-based solutions and ointments can weaken the structure of polyurethane materials.

**⚠ Precaution:** Do not use acetone on catheter surface. Acetone can weaken the structure of polyurethane materials.

- Clean skin around catheter using acceptable skin antiseptics.
- Cover exit site with sterile occlusive dressing.

### Catheter Patency:

Maintain catheter patency according to hospital/institutional policies, procedures, and practice guidelines. All personnel who care for patients with acute hemodialysis catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

- Solution and frequency of flushing a venous access catheter should be established in hospital/institutional policy.
- Establish and maintain catheter patency.

**⚠ Warning:** Prior to hemodialysis, the indwelling heparin must be aspirated from each dialysis (proximal and medial) lumen. After the heparin has been aspirated, the lumens should be flushed with sterile normal saline solution.



- Volume of lock solution for dialysis lumens (proximal and medial) should be equal to the priming volume of the catheter.
- Volume of lock solution for the infusion lumen (distal lumen) should be equal to or slightly more than the priming volume of the lumen that is being “locked”.

**NOTE:** Priming volumes are printed on extension lines.

**NOTE:** Neutral as well as positive displacement valve systems have also been shown to help prevent occlusion.

### Heparinization:

- To maintain patency of catheter between treatments, a lock must be created in each lumen of the catheter. Concentration of heparin used should be determined by hospital/institutional protocol.
- If catheter is not going to be used, it is recommended that catheter be flushed and relocked with heparin every 48-72 hours.

**⚠️ Precaution:** Assess patient for heparin sensitivity. Heparin-Induced Thrombocytopenia (HIT) has been reported with use of heparin flush solutions.

### Infusion (Distal) Lumen:

Follow established hospital/institutional protocols for central lines.

1. Properly cleanse connector with an appropriate antiseptic before being accessed.

**NOTE:** Alcohol, chlorhexidine-based solutions (e.g., Chloraprep, Hibiclens), iodine-based solutions (Povidone-Iodine), hydrogen peroxide, or ExSept Plus are accepted for use with the distal luer hub and extension line.

2. Properly flush using a positive-pressure flushing technique to help prevent occlusion.

**⚠️ Warning:** Open distal lumen clamp prior to infusion through lumen to reduce risk of damage to extension line from excessive pressure.

- The SASH or SAS method of flushing will help eliminate occlusions in the distal lumen due to incompatible solutions:
  - Saline
  - Administer drug
  - Saline
  - Heparin (if used)
- 3. Cover luer hub with new sterile cap after each access.

### Dialysis (Proximal and Medial) Lumens:

Follow established hospital/institutional protocols for initiating dialysis treatment.

1. Properly cleanse all connectors with an appropriate antiseptic before connecting extension lines to dialysis machine.

**NOTE:** Alcohol, chlorhexidine-based solutions (e.g., Hibiclens) and iodine-based solutions (Povidone-Iodine) are accepted for use with the dialysis luer hubs and extension lines.

2. Properly flush using a positive-pressure flushing technique to help prevent occlusion.

**⚠️ Warning:** Open dialysis lumen clamp prior to infusion through lumen to reduce risk of damage to extension line from excessive pressure.

- The SASH or SAS method of flushing will help eliminate occlusions in the dialysis lumen due to incompatible solutions:
  - Saline
  - Administer drug
  - Saline
  - Heparin (if used)
- 3. Cover luer hub with new sterile cap after each dialysis treatment.

### Proper Blood Flow:

1. If there is difficulty maintaining adequate blood flow during the hemodialysis treatment, the following measures can be tried:
  - lower patient’s head
  - change patient’s position
  - apply external pressure to catheter exit site over sterile dressing
  - check for catheter kinks
  - rotate catheter if moveable within rotating suture wings
  - loosen tight dressing
  - reverse blood flow only if other attempts fail
2. If the above measures fail and the flow problems are felt to be due to a clotted catheter, fibrinolytic agents can be used as prescribed.

## Blood Sampling Instructions

Perform Blood Sampling using Hub-To-Hub Technique or through a needleless injection cap system.

1. Follow all institutional protocols for accessing central lines.
2. Clamp distal extension line and cleanse extension line hub or needleless injection cap according to institutional protocol.
3. Attach 10-mL syringe and unclamp the distal extension line.
4. Slowly withdraw the syringe plunger to aspirate a total of 5 mL of blood.
5. Clamp extension line and, according to institutional protocol, immediately discard the syringe containing the waste blood.
6. Cleanse distal extension line hub or needleless injection cap according to institutional protocol.
7. Insert vacuum blood collection sleeve or connect a new 10 mL syringe to the distal extension line.
8. Unclamp distal extension line and collect desired amount of blood into 10 mL syringe. If using syringe, take care to slowly aspirate in order to minimize mechanical hemolysis of blood sample.

**NOTE:** Based on in vitro hemolysis testing, the minimum time for drawing 5 mL of blood is 20 seconds.

9. After blood sampling, flush catheter through distal extension line using normal saline according to institutional protocol.
10. Attach a new sterile injection cap according to institutional protocol.

## Catheter Removal Instructions

1. Perform catheter removal:
  - following order of authorized prescriber
  - in accordance with hospital/institutional policies, procedures, and practice guidelines
2. Remove catheter immediately upon patient assessment for:
  - suspected contamination (i.e., when catheters are inserted during a medical emergency or if adherence to aseptic technique cannot be ensured)
  - unresolved complication(s)
  - discontinuation of therapy
  - source of infection

**⚠ Warning: Do not use guidewire techniques to replace catheters in patient suspected of having catheter-related infection.**

3. Place patient in supine position, as clinically indicated to reduce risk of potential air embolism.
4. Remove dressing.

**⚠ Warning: Do not use scissors to remove dressing to reduce risk of cutting catheter.**

5. Place sterile gauze pad over insertion site and catheter.
6. Remove catheter by slowly pulling it parallel to skin. If resistance is met while removing, catheter should not be forcibly removed and physician should be notified.

**⚠ Warning: Do not apply excessive force in placing or removing catheter. Excessive force can cause catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.**

7. Apply direct pressure to site until hemostasis is achieved.
8. Upon removal of catheter:
  - inspect for intact Blue FlexTip®
  - ensure entire catheter length has been removed
9. Apply antiseptic ointment to insertion site. Dress insertion site. Assess site every 24 hours until site is epithelialized.

**⚠ Warning: Residual catheter track remains an air entry point until**

**completely sealed. Occlusive dressing should remain in place for at least 24 - 72 hours dependent upon amount of time catheter was indwelling.**

10. Document catheter removal procedure on patient's chart per hospital/institutional protocol.

### Include:

- catheter condition
- length of catheter removed/presence of intact catheter tip
- patient's tolerance of the procedure
- any interventions needed for removal

## Catheter Performance

- Based on pressure versus flow rate testing with the Arrow International, LLC Multi-Lumen Acute Hemodialysis Catheter, use of the device with blood flow rates above 300 mL/min may result in high venous and/or arterial pressures and increased risk for catheter malfunction and potential clinical complications, including hemolysis and decreased delivery of blood to the dialyzer.
- The forward and reverse recirculation rates for the Arrow Multi-Lumen Acute Hemodialysis Catheter are 1.2% and 8.5%, respectively.
- Based on recirculation testing with the Arrow International, LLC Multi-Lumen Acute Hemodialysis Catheter, reversal of flow will increase recirculation rates.

For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks, medical literature, and Arrow International LLC website: [www.teleflex.com](http://www.teleflex.com)




















A pdf copy of this IFU is located at [www.teleflex.com/IFU](http://www.teleflex.com/IFU)



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Symbol Glossary: Symbols are in compliance with ISO 15223-1.

Some symbols may not apply to this product. Refer to product labeling for symbols that apply specifically to this product.

								
Caution	Medical device	Consult instructions for use	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	Single sterile barrier system with protective packaging inside	Single sterile barrier system	
								
Keep away from sunlight	Keep dry	Do not use if package is damaged	Not made with natural rubber latex	Temperature limitation	MR safe*	Catalogue number	Lot number	Use by
		<p><i>* The Multi-Lumen Acute Hemodialysis Catheter for High Volume Infusions is MR Safe, an item that poses no known hazards in all MR environments.</i></p> <p><i>Arrow, the Arrow logo, Maximal Barrier Drape, SharpsAway, Teleflex and the Teleflex logo are trademarks or registered trademarks of Teleflex Incorporated or its affiliates, in the U.S. and/or other countries. © 2021 Teleflex Incorporated. All rights reserved.</i></p>						
Manufacturer	Date of manufacture							

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