

Pediatric Two-Lumen Hemodialysis Catheter Product

Rx only.

Indications for Use:

The pediatric two-lumen hemodialysis catheter permits venous access to the central circulation system for rapid fluid administration, temporary or acute hemodialysis and apheresis. It may be inserted into the jugular, subclavian, or femoral veins of children, adolescents and small adults.

Contraindications:

The pediatric two-lumen hemodialysis catheter is not designed for long-term (≥ 30 days) hemodialysis or for use in patients with thrombosed vessels.

Clinical Benefits to be Expected:

Permits venous access for short term hemodialysis and apheresis.

Permits venous access by way of the jugular, subclavian or femoral veins.

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. Do not place/advance catheter into or allow it to remain in the right atrium or right ventricle. The catheter tip should be advanced into the lower 1/3 of the Superior Vena Cava.
For femoral vein approach, catheter should be advanced into vessel so catheter tip lies parallel to vessel wall and does not enter right atrium.
Catheter tip location should be confirmed according to institutional policy and procedure.
Patient size must be carefully considered relative to actual length of catheter introduced.
4. Clinicians must be aware of potential entrapment of the guidewire if any implanted device in circulatory system. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire entrapment.
5. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation, bleeding, or component damage.
6. Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel, atrial or ventricular wall.
7. Do not apply excessive force in placing or removing catheter or guidewire. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.
8. Using catheters not indicated for pressure injection for such applications can result in inter-lumen crossover or rupture with potential for injury.

9. 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.
10. Air embolism can occur if air is allowed to enter a vascular access device or vein. Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Use only securely tightened Luer-Lock connections with any vascular access device to guard against inadvertent disconnection.
11. Use of subclavian vein insertion site may be associated with subclavian stenosis.
12. Clinicians must be aware of complications/undesirable side-effects 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/injury
- hematoma
- hemorrhage
- fibrin sheath formation
- exit site infection
- vessel erosion
- catheter tip malposition
- dysrhythmias
- extravasation
- brachial plexus injury
- cardiac arrhythmia
- exsanguination

Precautions:

1. Do not alter the catheter, guidewire or any other kit/set component during insertion, use or removal.
2. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.
3. Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.
4. Some disinfectants used at catheter insertion site contain solvents which can weaken the catheter material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.
 - Do not use acetone on catheter surface.
 - Do not use alcohol to soak catheter surface or allow alcohol to dwell in a catheter lumen to restore catheter patency or as an infection prevention measure.
 - Do not use polyethylene glycol containing ointments at insertion site.
 - Take care when infusing drugs with a high concentration of alcohol.

- Allow insertion site to dry completely prior to applying dressing.
5. Ensure catheter patency prior to use. Do not use syringes smaller than 10 mL to reduce risk of intraluminal leakage or catheter rupture.
 6. Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.
 7. 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.
 8. Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position, and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.
 9. Only x-ray examination of the catheter placement can ensure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position has changed, immediately perform chest x-ray examination to confirm catheter tip position.
 10. For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.

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.

A Suggested Procedure: Use sterile technique.

Prep Puncture Site:

1. 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.
 - Femoral approach: Place patient in supine position.
2. Measure the patient's external anatomy to estimate the length of catheter required to place the distal tip in the SVC.
3. Prepare clean skin with an appropriate antiseptic agent.
4. Drape puncture site.
5. Administer local anesthetic per institutional policies and procedures.
6. Dispose of needle.

SharpsAway® II Locking Disposal Cup (where provided):

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

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 1).

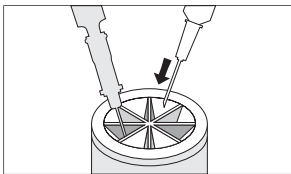


Figure 1

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.

⚠️ 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.

- 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.

Prepare Catheter:

7. Flush each lumen with sterile normal saline for injection to establish patency and prime lumen(s).
8. Clamp or attach Luer-Lock connector(s) to extension line(s) to contain saline within lumen(s).
9. Leave distal extension line uncapped for guidewire passage.

⚠️ Warning: Do not cut catheter to alter length.

Gain Initial Venous Access:

Echogenic Needle (where provided):

An echogenic needle is used to allow access to the vascular system for the introduction of a guidewire to facilitate catheter placement. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Protected Needle/Safety Needle (where provided):

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

Arrow® Raulerson Syringe (where provided):

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

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

NOTE: The preferred insertion site for central venous catheters is the right internal jugular vein. Other options include the right external jugular vein, left internal and external jugular vein. Subclavian access should be used only when no other upper-extremity or chest-wall options are available.

⚠️ Warning: Do not leave open needles or uncapped, undamped catheters in central venous puncture site. Air embolism can occur if air is allowed to enter a central venous access device or vein.

⚠️ Precaution: Do not reinsert needle into introducer catheter (where provided) to reduce risk of catheter embolus.

Verify Venous Access:

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

- Central Venous Waveform:
 - Insert fluid primed blunt tip pressure transduction probe into rear of plunger and through valves of Arrow Raulerson Syringe and observe for central venous pressure waveform.
 - Remove transduction probe if using Arrow Raulerson Syringe.
- 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.

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

Insert Guidewire:

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.

Arrow Advancer (where provided):

Arrow Advancer is used to straighten "J" tip of guidewire for introduction of the guidewire into Arrow Raulerson Syringe or a needle.

- Using thumb, retract "J" (refer to Figure 2).

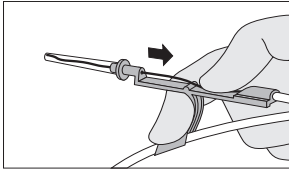


Figure 2

- Place tip of Arrow Advancer – with “J” retracted – into the hole in rear of Arrow Raulerson Syringe plunger or introducer needle.

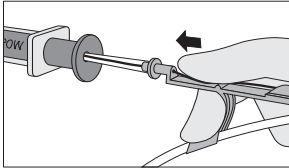


Figure 3

- Advance guidewire into Arrow Raulerson Syringe approximately 10 cm until it passes through syringe valves or into introducer needle.
 - Advancement of guidewire through Arrow Raulerson Syringe may require a gentle twisting motion.
 - 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 guidewire, push assembly into syringe barrel to further advance guidewire (refer to Figure 3). Continue until guidewire reaches desired depth.

Alternate Technique:

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

Separate the Advancer tip or straightening tube from the blue Advancer unit. If the “J” tip portion of the guidewire is used, prepare for insertion by sliding the plastic tube over the “J” to straighten. The guidewire should then be advanced in the routine fashion to the desired depth.

- Use centimeter markings (where provided) on guidewire as a reference to assist in determining how much guidewire has been inserted.

NOTE: When guidewire is used in conjunction with Arrow Raulerson Syringe (fully aspirated) and a 2-1/2” (6.35 cm) introducer needle, the following positioning references can be made:

- 20 cm mark (two bands) entering back of plunger = guidewire tip at end of needle
- 32 cm mark (three bands) entering back of plunger = guidewire tip approximately 10 cm beyond end of needle

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

⚠️ 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.

- 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, 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) when not in use to reduce the risk of sharps injury.

- Use tissue dilator to enlarge tissue tract to the vein as required. Follow the angle of the guidewire slowly through the skin.

⚠️ 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.

- Using centimeter marks on catheter as positioning reference points, advance catheter to final indwelling position.

NOTE: Centimeter marking symbology is referenced from catheter tip.

- numerical: 5, 15, 25, etc.
- 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

- Hold catheter at desired depth and remove guidewire.

⚠️ Precaution: If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked around tip of catheter within vessel (refer to Figure 4).

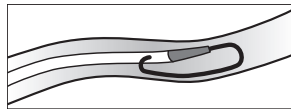


Figure 4

- 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 reduce risk of possible breakage.

- Always verify entire guidewire is intact upon removal.

Complete Catheter Insertion:

- Check lumen patency by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.

- Flush lumen(s) to completely clear blood from catheter.

- Connect all extension line(s) to appropriate Luer-Lock connector(s) as required. Unused port(s) may be “locked” through Luer-Lock connector(s) using standard institutional policies and procedures.

- Pinch clamp(s) are provided on extension lines to occlude flow through each lumen during line and Luer-Lock connector changes.

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

- Secure and dress catheter temporarily.

- Verify catheter tip position by chest x-ray immediately after placement.

⚠️ Precaution: X-ray exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized. If catheter tip is malpositioned, reposition and re-verify.

Secure Catheter:

27. Use triangular juncture hub as primary securement site.

⚠️ **Precaution:** 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.

Catheter Stabilization Device (where provided):

A catheter stabilization device should be used in accordance with manufacturer's instructions for use.

28. Ensure insertion site is dry before applying dressing per manufacturer's instructions.
29. Assess catheter tip placement in compliance with institutional policies and procedures.
30. If catheter tip is malpositioned, assess and replace or reposition according to institutional policies and procedures.
31. Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

Care and Maintenance:

Dressing:

Dress according to institutional policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened or no longer occlusive.

Catheter Patency:

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

Catheter Exchange Procedure: Use sterile technique.

1. Proceed per hospital protocol. Cutting the catheter is not recommended due to the potential for catheter embolism.

Catheter Removal Instructions:

1. Position patient as clinically indicated to reduce risk of potential air embolism.
 2. Remove dressing.
- ⚠️** **Precaution:** To reduce the risk of cutting catheter do not use scissors to remove dressing.
3. Remove from catheter securement device(s).
 4. Ask patient to take a breath and hold it if removing jugular or subclavian catheter.

5. Remove catheter by slowly pulling it parallel to skin. If resistance is met while removing catheter **STOP**

⚠️ **Precaution:** Catheter should not be forcibly removed, doing so may result in catheter breakage and embolization. Follow institutional policies and procedures for difficult to remove catheter.

6. Apply direct pressure to site until hemostasis is achieved followed by an ointment-based occlusive dressing.

⚠️ **Warning:** Residual catheter track remains an air entry point until site is epithelialized. Occlusive dressing should remain in place for at least 24 hours or until site appears epithelialized.

7. Document catheter removal procedure including confirmation that entire catheter length and tip has been removed per institutional policies and procedures.

Heparinization (Hemodialysis):

1. A variety of "locking" solution concentrations are utilized to maintain the patency of the catheter. The amount of heparin used depends on physician preference, hospital protocol, and patient condition.
2. The volume of heparin solution should be equal to or slightly more than the volume of the lumen that is being "locked".
3. Prior to hemodialysis, aspirate the indwelling heparin from each lumen. After the heparin has been aspirated the lumens should be flushed with sterile normal saline solution.

Poor 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 able 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 clogged catheter, fibrinolytic agents can be used as prescribed.



















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

A pdf copy of this IFU is located at 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	Contains a medicinal substance	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	Catalogue number	Lot number	Use by	Manufacturer
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Date of manufacture								

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