

CATHETER MANAGEMENT

HUB ASSEMBLY REPLACEMENT PROCEDURE

THIS PROCEDURE MUST BE PERFORMED BY TRAINED PERSONNEL FAMILIAR WITH ANATOMICAL LANDMARKS, SAFE TECHNIQUES AND POTENTIAL COMPLICATIONS.

This procedure replaces a damaged hub connection assembly that is connected to a fully functional catheter.

BEFORE STARTING

- Remove dressings, and apply appropriate antiseptic agents to the catheter and skin surrounding the hub connection assembly.
- CAUTION:** Do not use acetone on this catheter or catheter degradation may occur.
- Temporarily close catheter by attaching provided clamp, close to the exit site.
- CAUTION:** Catheter must be closed with catheter clamp to prevent blood loss and air embolism.

- Perform fluoroscopy prior to hub connection assembly replacement.
- Follow NKF KDOQI guidelines for proper tip placement to ensure optimal blood flow.
- CAUTION:** Catheter must be inserted with double D cannulas and clamp; insert double D cannulas into the hub connection assembly with sterile normal saline.
- Prime hub replacement connection assembly thoroughly with heparin solution. Do not aspirate, position catheter to compression cap. Do not remove catheter. Advance toward shaft of catheter. Advance toward compression cap. Do not remove catheter. Place with saline solution, so components with saline solution, so components of catheter. Wet compression sleeve and towards hub connection assembly, ensuring connection sleeve is seated inside.

- CAUTION:** To minimise the risk of crushing, orient the catheter so that the red or blue print side is facing up.
- CAUTION:** Orient catheter lumens side connects to blue connector and red to red hub line.
- Ensure that hub connection assembly and that cannula is no longer visible, as separation could occur if compression of catheter onto extension line clamps are closed before attaching catheter.

- Prior to procedure ensure you have the appropriate hub replacement set for the specific length and type of catheter you are repairing.



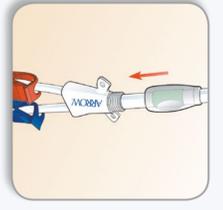
Unscrow threaded hub connection cap from and slide toward clamp.



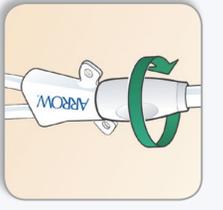
Cut catheter at point where the double D cannula ends, approximately 4 mm from the proximal end of the catheter. Remove and discard threaded compression cap and compression sleeve.



Place new threaded compression cap over compression sleeve and towards hub connection assembly, ensuring connection sleeve is seated inside.



Slide threaded compression cap over compression sleeve and towards hub connection assembly, ensuring connection sleeve is seated inside.



Firmly thread compression cap onto hub connection assembly. The blood should separate from both threads and open clamps. Use syringes to extension position on extension lines, in the event that clamps are not air tight. The priming volume is changed by 0.13 ml/cm of length change.



Flush catheter thoroughly with normal saline to remove residual blood, both post-treatment and before instilling heparin. Inject designated priming volumes as indicated into appropriate cap. Incomplete compression may occur, causing catheter separation.



Remove catheter clamp. Remove hub to skin using suture wing and apply dressing according to hospital protocol.

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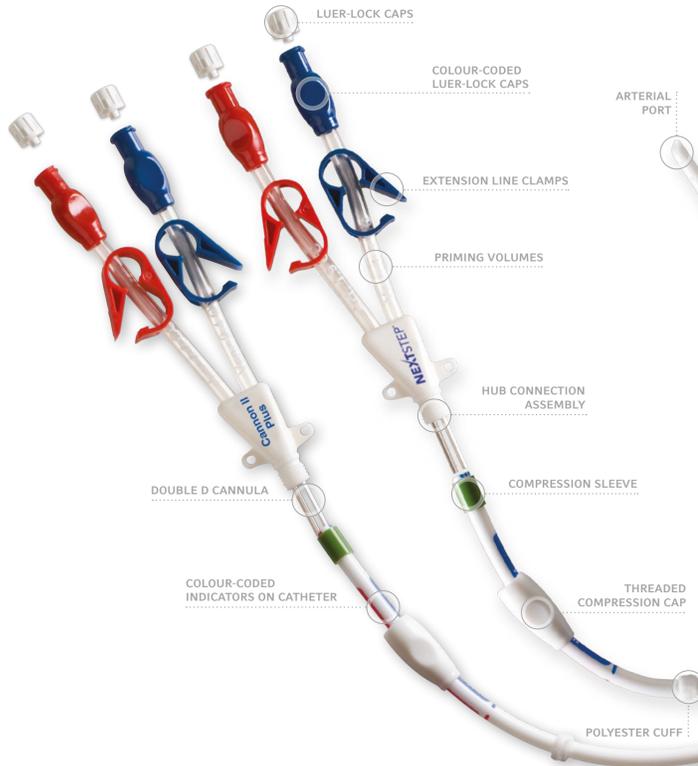
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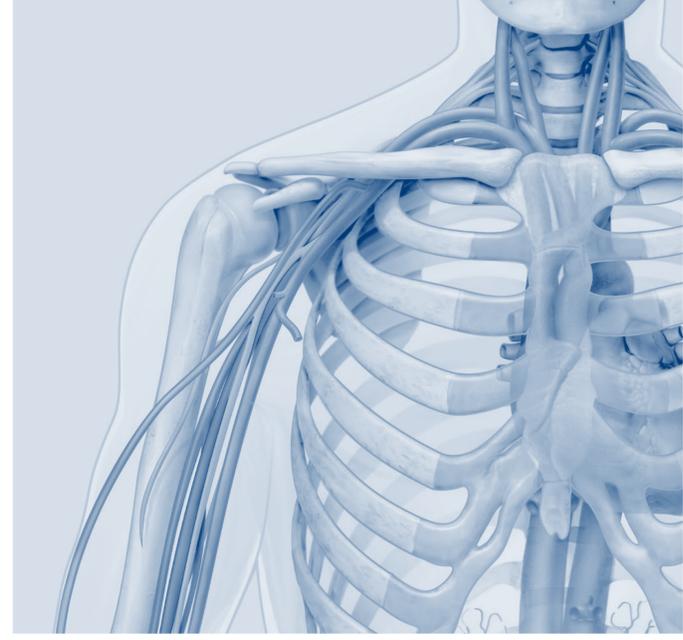
Remove catheter clamp. Remove hub to skin using suture wing and apply dressing according to hospital protocol.

ARROW® RETROGRADE-TUNNELLING CATHETERS



RETROGRADE-TUNNELLING INSERTION POSTER

Arrow® NextStep® and Arrow® Cannon® II Plus Chronic Haemodialysis Catheters



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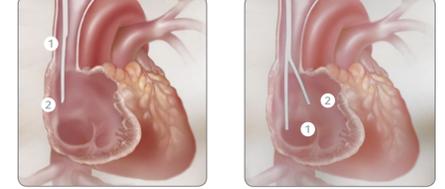
- 1 DaVanzo, W. "Efficacy and Safety of a Retrograde-Tunneled Hemodialysis Catheter—6-Month Clinical Experience With the Cannon Chronic Hemodialysis Catheter." *Journal of Vascular Access*, January–March 2005, Vol. 6, Issue 1, pp. 38–44.
 - 2 Di Lorio, B., Lopez, T., Procidia, M., et al. "Successful Use of Central Venous Catheter as Permanent Hemodialysis Access: 84-Month Follow-Up." *Journal of Vascular Access*, June 2001, Vol. 19, pp. 39–43.
 - 3 NKF-KDOQI Clinical Practice Guide for Vascular Access, New York: National Kidney Foundation, 1997, p. 26.
 - 4 O'Grady, N.P., Alexander, M., Dellinger, E.P., Gerberding, J.L., Heard, S.O., Maki, D.G., Masur, H., McCormick, R.D., Merriam, L.A., Pearson, M.L., Raad, I.I., Randolph, A., Weinstein, R.A. "Guidelines for the Prevention of Intravascular Catheter-Related Infections." *Centers for Disease Control*, August 9, 2002, Vol. 51, No. RR10, pp. 1–26.
- Full bibliography available upon request.

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IMPROVING PLACEMENT ACCURACY

Retrograde tunnelling makes it easier to ideally position the catheter tip, cuff and hub. The Arrow® NextStep® Catheter's unique design is engineered to take advantage of retrograde tunnelling, and to help you achieve the outcomes you want for your patients.



ARROW® NEXTSTEP®

Reversed ports: To help deliver sustained high flow, the Arrow® NextStep® Catheter's ports are reversed and separated to take better advantage of blood flow dynamics. The venous port 1 resides in the SVC, and the arterial port 2 in the right atrium.

ARROW® CANNON® II PLUS

V-tip design: The orientation of the venous 1 and arterial 2 ports on the Arrow® Cannon® II Plus Catheters are designed to provide high flow with less recirculation when placed in the right atrium.

V-TIP DESIGN

MR DOES NOT CONTAIN NATURAL RUBBER LATEX

MR Conditional Advisory: Non-clinical testing has demonstrated the device to be MR Conditional. Under specific conditions, a patient with this device can be scanned safely immediately after placement. More detailed information regarding the use of this device in an MR environment is available upon request from Arrow.

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POTENTIAL COMPLICATIONS (BUT NOT LIMITED TO):

| | | | |
|------------------------|----------------------|--------------------------------|-----------------------|
| Septaemia | Leakage of vessel | Thoracic duct laceration | Right atrial puncture |
| Air embolus | Endocarditis | Medasternal injury | Pneumothorax |
| Bacteraemia | thrombosis | Esophageal injury | Haemothorax |
| Brachial plexus injury | Extal site infection | Puncture/perforation of vessel | Cardiac tamponade |
| Tunnel infection | Lumen thrombosis | Functure/perforation of vessel | Cardiac arrhythmia |
| Vascular thrombosis | Arterial injury | Perforal nerve damage | Haemorrhage |
| Vein stenosis | Arterial injury | Perforal nerve damage | Haemorrhage |

CONTRAINDICATIONS

The Arrow® NextStep® and the Arrow® Cannon® II Plus Catheters are intended for long-term haemodialysis vascular access only and should not be used for any purpose other than those indicated herein. Do not use this catheter in patients with thrombosed vessels.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS

One-way obstructions exist when a lumen can be flushed easily, but blood cannot be aspirated. This is usually caused by tip malposition. One of the following adjustments may help:

- reposition catheter
- reposition patient
- have patient cough

RETROGRADE-TUNNELLING INSERTION TECHNIQUE

CATHETER INSERTION PROCEDURE

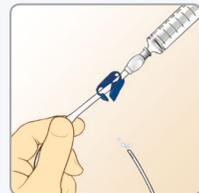
THIS PROCEDURE MUST BE PERFORMED BY TRAINED PERSONNEL WELL VERSED IN ANATOMICAL LANDMARKS, SAFE TECHNIQUES AND POTENTIAL COMPLICATIONS.

Retrograde insertion provides numerous advantages. In particular, this technique:

- Facilitates fast, precise tip placement within the right atrium.
- Helps create a smooth, contoured tunnel tract that:
 - minimises catheter kinking
 - inhibits catheter migration
 - minimises retrograde bleeding
- Exit demarcation permits reproducible cuff positioning and exit site location.



- Securely attach irrigation tube to proximal end of catheter shaft.



- Flush both catheter lumens with saline solution and clamp irrigation tube with catheter pinch clamp. Flush juncture hub assembly with saline solution and clamp extension lines with catheter pinch clamps as well. **NOTE:** Complete this step prior to access.



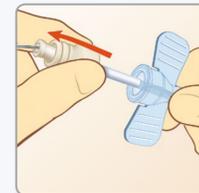
- Access vessel.



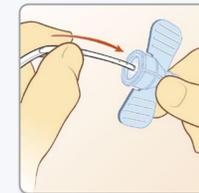
- Dilate tissue.



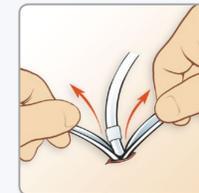
- Position introducer sheath.



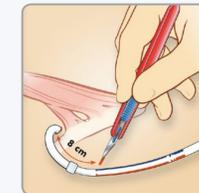
- Remove tissue dilator and guidewire from sheath and occlude.



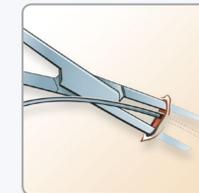
- Place catheter through sheath and into vessel.



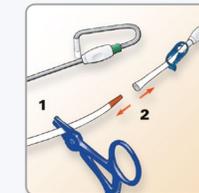
- Remove peel-away sheath. Verify that tips are in the proper position, and remove peel-away sheath.



- Position catheter on the chest with a gentle curve, locate exit site mark on catheter (next to cuff) and make a small incision.



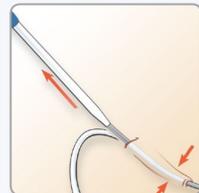
- Create catheter pocket using blunt dissection.



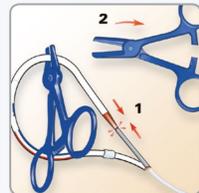
- Precurve tunneler and create tunnel tract.
- **1:** Clamp catheter distal to irrigation tube.
- **2:** Remove irrigation tube.



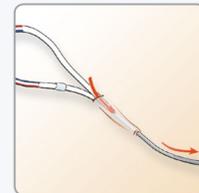
- Dilate tunnel tract with tunnel dilator (optional).
- Do not pass through exit site.



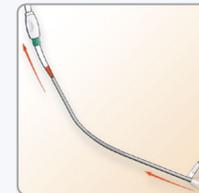
- **1:** Insert distal tip of tunnel dilator to cuff position.
- **2:** Remove tunnel dilator.



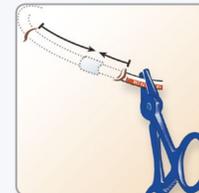
- **1:** Securely attach proximal portion of catheter to tunneler tip.
- **2:** Remove clamp from catheter.



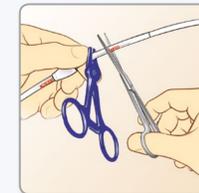
- Gently pull catheter through tunnel tract.



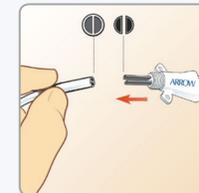
- Advance threaded compression cap and sleeve onto catheter beyond cut line.



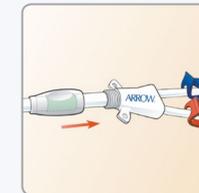
- Clamp catheter close to exit site mark. Use exit site mark on catheter to ensure that cuff is positioned properly.



- Pinch catheter and cut at cut line.



- Align catheter with hub connection assembly (red to red and blue to blue). Insert hub connection assembly double D cannulas into catheter lumens at a 45° angle.



- Slide threaded compression cap forward, with sleeve inside.



- Screw threaded compression cap onto threaded section of hub connection assembly until thread is no longer visible. Do not overtighten.



- Flush and prime catheter lumens per hospital protocol. Inject designated priming volumes. Priming volumes are printed on extension lines. Secure catheter to skin using suture wings. Verify that tips are in the proper position.

CATHETER REMOVAL PROCEDURE

THIS PROCEDURE MUST BE PERFORMED BY TRAINED PERSONNEL FAMILIAR WITH ANATOMICAL LANDMARKS, SAFE TECHNIQUES AND POTENTIAL COMPLICATIONS.

BEFORE REMOVING:

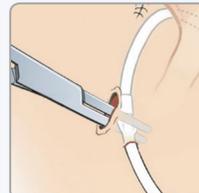
- **WARNING:** Read all package insert warnings, precautions and instructions. Failure to do so may result in severe patient injury or death.
- Place patient in supine position.
- Remove dressing. **WARNING:** To reduce the risk of cutting catheter, do not use scissors to remove dressing.



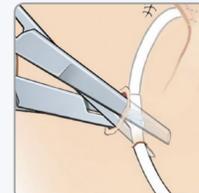
- Palpate along catheter tunnel tract to locate cuff.
- Anaesthetize catheter exit and cuff sites.
- Remove all sutures used to secure catheter, per hospital protocol.
- Make a small incision along length of catheter starting at cuff site.



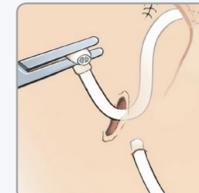
- Using blunt dissection, dissect down cuff at small incision. **CAUTION:** Be careful not to cut catheter.



- When visible, clamp catheter between cuff and exit site.



- Cut catheter between cuff and exit site, and remove internal portion of catheter through cuff incision site.
- Check catheter integrity for tears. Measure catheter when removed; it should be equal to length of catheter when inserted. Confirm presence of entire cuff.



- Remove other catheter section through catheter exit site.
- Follow hospital protocol for wound haemostasis and closure.
- Dress insertion site.
- Document removal procedure.

INFECTION PREVENTION, TREATMENT

- Sterile techniques are mandatory for all pro-catheter procedures.
- Promptly treat clinically recognised infection at a catheter exit site with appropriate antibiotic therapy.
- If a catheterised patient develops a fever, take a minimum of two blood cultures from a site well away from catheter exit site. If blood culture is positive, remove catheter immediately and initiate appropriate antibiotic therapy. Wait 48 hours before replacing catheter. Insertion should be made on opposite side of original catheter exit site, if possible.

SITE CARE

- Alcohol, alcohol-based solutions (e.g., Hibiclens®, ChlorPrep®), iodine-based solutions (povidone-iodine), PEG-based ointments (e.g., Bactroban®), hydrogen peroxide or ExSept Plus® are accepted for use with these catheters. Solution must be completely dry before applying an occlusive dressing.
- **WARNING: Avoid excessive or prolonged use of alcohol-based solutions and ointments to clean catheter or for site care.**
- Clean skin around catheter using approved antiseptic solutions. Cover exit site with sterile occlusive dressing for the duration of implantation. If catheter swelling is observed, discontinue use and replace catheter.
- Wound dressings must be kept clean and dry. **CAUTION:** Do not submerge the catheter in water. Showering should only be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter.⁴
- If excessive perspiration or accidental wetting compromises dressing adhesion, medical or nursing staff must change dressing under sterile conditions.
- Heparinisation: To maintain patency of catheter between treatments, a heparin lock should be created in each catheter lumen. Follow hospital protocol for concentration of heparin used.
- If catheter is not in use catheter should be flushed and re-packed with heparin every 48–72 hours.
- The manufacturer shall not be liable for any damages caused by re-sterilisation or re-use of this catheter or accessories.

CATHETER PRECAUTIONS

- Do not use acetone, as catheter degradation may result (refer to Site Care information for specific catheter body antiseptic requirements).
- Do not use sharp instruments near extension lines or catheter lumen.
- To minimise the risk of cutting catheter, do not use scissors to remove dressing.
- Do not use clamps other than those that are provided. Using other clamps will damage the catheter.
- Repeatedly clamping tubing in same location will weaken tubing.
- Avoid clamping near Luer-lock fittings.
- Examine catheter and extension lines for any signs of damage before and after each treatment.
- Tape Luer-lock caps and clamps between treatments to reduce risk of accidental opening of either, as this may cause blood loss and/or air embolism.
- Repeatedly overtightening of bloodlines, syringes and caps will reduce connector life and might lead to potential connector failure.
- Catheter must be closed with catheter clamp to prevent blood loss and air embolism.
- Orient the catheter so the scissor symbol is facing up. This will permit accurate clamping/cutting of catheter.
- Ensure 6 cm of exposed catheter remains at exit site. Remaining recommended catheter length facilitates catheter repair should extension line damage occur over time.
- Orient catheter lumen prior to connection; blue printed side of catheter is connected to blue connector hub line and red printed side to red hub line.
- Ensure that hub connection assembly cannula is fully seated in catheter and that cannula is not visible. Failure to do so could compromise compression of catheter onto connector and catheter separation could occur.
- Ensure extension line clamps are closed prior to catheter attachment.
- Ensure designated priming volumes are achieved.
- Ensure that compression sleeve is securely positioned inside threaded compression cap. Do not try to place compression sleeve onto hub connection assembly cannula and then apply threaded compression cap. Incomplete compression may occur causing catheter separation. Remove catheter clamp.

WARNINGS

- Placement or removal of the catheter only when prescribed by a physician.
- Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death. Catheter should be inserted, manipulated and removed by a qualified, licensed physician or another qualified health care professional under direction of a physician.
- Medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for a physician's experience and judgment when treating a specific patient.
- Sterile, single use: Do not reuse, reprocess or sterilise. Reusing a device creates a potential risk of serious injury and/or infection which may lead to death.
- Immediately take appropriate actions to prevent blood loss or air from entering the catheter (air embolism) if a Luer connector should become detached from a catheter at any time.
- Do not use chronic dialysis catheters for extended use unless no other haemodialysis access options exist. Chronic dialysis catheters should be used only as bridge devices.
- Do not leave open needles or uncapped, unclamped catheters in central venous puncture sites. Air embolism may otherwise occur.
- Use only securely tightened Luer-lock connections with any Venous Access Device (VAD) to guard against inadvertent disconnection and to help guard against air embolism and blood loss.
- Tape connections of bloodlines during treatment to reduce risk of accidental disconnection.
- Pulsatile flow is usually an indicator of inadvertent arterial puncture.
- Do not alter the catheter/sheath or any other kit/set component during insertion, use or removal.
- All chronic dialysis catheters should be used as bridge devices and are not intended for extended use unless no other haemodialysis access options exist.
- The green compression sleeve **MUST** be present when threading compression cap onto hub connection assembly. Failure to do so may result in air embolism, blood loss, or catheter separation.
- Avoid excessive or prolonged use of alcohol-based solutions and ointments to clean catheter or site care.
- Do not apply excessive force when 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.
- Physician caution is strongly advised when inserting this catheter into patients who are unable to take and hold a deep breath.
- Patients requiring ventilator support are at an increased risk of pneumothorax during subclavian vein cannulation.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- To ensure proper right atrial placement, the appropriate catheter length is required.
- Confirm final position of catheter with a chest X-ray. Routine X-rays should always follow initial insertion or repositioning of this catheter to confirm proper tip placement prior to use.