

NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use

Directions for Use

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Indications for Use

The NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use is indicated for use in attaining long term vascular access for chronic hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include the subclavian vein. Catheters greater than 40cm are indicated for femoral vein insertion.

Description

The NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use is a dual lumen, stepped tip radiopaque polyurethane catheter which contains a Dacron biomaterial cuff and two female luer connectors. The DISC (Dermal Ingrowth Support Collar) stabilises the catheter and when aligned with the biomaterial cuff on the catheter shaft facilitates tissue ingrowth, which is considered important in reducing the source of extraluminal infection in patients requiring long term catheterisation. The Catheter, DISC and the following ancillary components required for the procedure (0.038" guidewire, Stainless Steel Tunneler and Sleeve, 16Fr Introducer / Dilator and Luer Caps) are provided in a tray, sealed with a Tyvek lid and placed in a second sterile pouch so that the tray can be delivered to the sterile field

Potential Complications

The following potential complications may arise as a result of placement of the NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use.

Air embolism	Mediastinal Injury
Bacteremia	Perforation of the vessel
Brachial Plexus Injury	Pleural Injury
Cardiac Arrhythmia	Pneumothorax
Cardiac Tamponade	Retroperitoneal bleed
Venous Thrombosis	Right atrial puncture
Endocarditis	Septicemia
Exit Site Infection	Subclavian artery puncture
Exsanguination	Subcutaneous Hematoma
Femoral artery bleed	Superior Vena Cava puncture
Hematoma	Femoral Nerve damage
Hemothorax	Thoracic duct laceration
Inferior Vena Cava puncture	Tunnel infection
Laceration of the vessel	Vascular Thrombosis
Lumen thrombosis	Venous Stenosis

Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

Contraindications

The NexSite™ HD Hemodialysis Stepped Tip Catheter is intended for long term vascular access only and should not be used for any purpose other than those indicated in these Directions for Use.

This device should not be used when:

- The patient has a confirmed or suspected device related infection, bacteraemia or septicaemia.
- The patient's physiology is NOT suitable for placement of the NexSite device; this will include an examination of the anatomy at the proposed catheter exit site.
- The patient is known or suspected to have allergies to the materials used in the construction of the device.
- The patient has previously suffered from venous thrombosis or has had vascular surgery at the proposed placement site.
- The patient has received radiation treatment at the proposed catheter placement site.
- The patient has severe chronic obstructive lung disease.

Warnings

- In the event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from the component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or valved peelable sheath and guidewire must be removed together.
- The device is intended for single use only and should not be reused. Reuse of the device may lead to infection or illness/ injury. The manufacturer shall not be liable for any damages caused by reuse or resterilisation of this catheter or accessories.
- The device is not suitable for resterilisation.
- The contents are sterile and non-pyrogenic in an unopened, undamaged package.

- Do not use the device or device accessories if they are damaged or if the package is opened or damaged. Handle the device in a manner to prevent damage.

Placement

Only a physician familiar with the appropriate techniques should attempt the following procedures.

- If the needle is inadvertently entered in the pleural space, remove the needle immediately and evaluate the patient for symptoms of pneumothorax. Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation which may cause complications. Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- Take care to avoid arterial perforation. If the artery is inadvertently entered during the procedure, withdraw the needle and exert manual pressure immediately.
- The length of wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during the procedure. Cardiac arrhythmia may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during the procedure.
- When creating the tunnel, avoid puncture of the fascia or skin with the tip of the tunneler. When drawing the catheter through the tunnel, ensure that the catheter is secured on the tunneler barbs and that it is covered with the tunneler sleeve before gently drawing the catheter through the tunnel. Do not pull the tunneler out at an angle. Keep tunneler straight to avoid catheter tip damage. When removing the catheter from the tunneler, ensure that the tunneler sleeve is in place.
- Ensure that the catheter and DISC are engaged appropriately by ensuring that the tactile stop is encountered – a gentle tension on the proximal end of the catheter will ensure that the catheter is positioned appropriately. Ensure that the catheter is not kinked in the DISC and that the lumen is patent.
- If using an introducer other than that provided with the NexSite™ HD device, ensure that the introducer is compatible with the catheter.
- The Valved Peelable Introducer Sheath is designed to reduce blood loss and the risk of air intake but is not a hemostasis valve. It is not intended to create a complete two way seal nor is it intended for arterial use. Prevent air aspiration by covering the exposed lumen of the sheath. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva manoeuvre.
- Never leave the sheath in place as an indwelling catheter. Damage to the vein will occur.
- Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimetres at a time.
- Failure to verify catheter placement may result in serious trauma or fatal complications. For catheters placed in the internal jugular or subclavian veins, the distal venous tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure optimal blood flow. Catheters placed in the femoral artery should have the distal tip of the catheter positioned at the junction of the iliac vein and the inferior vena cava
- When the catheter has been placed, fill the catheter with heparinised or normal saline to reduce the risk of air embolism. Ensure that all air has been aspirated from the catheter and extension tubes. Failure to do so may result in an air embolism.

Post placement

- Care must be taken when using sharp objects or needles in close proximity to catheter. Contact from sharp objects may cause catheter failure.
- Only clamp the catheter with in line clamps provided. In event of an issue occurring with the catheter, necessary remedial action must be taken prior to the continuation of the dialysis treatment.
- In the event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove catheter.
- Extension clamps should only be open for aspiration, flushing and dialysis treatment. In most instances, no further heparin is necessary for 48 – 72 hours, provided the lumens have not been aspirated or flushed.
- When opening the catheter end caps ensure that the catheter is positioned below the level of the patient's heart.
- Do not use antimicrobial ointment following catheter placement.

- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.
- Do not use the catheter if there are signs of mechanical damage or leaking. Always review hospital or unit protocol, potential complications and their treatment, warnings and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems.
- Catheter integrity has been demonstrated following exposure to the following chemical disinfectants: Aqueous – iodophor, Aqueous –Chlorhexidine gluconate, Alcohol iodophor, and Alcohol – Chlorhexidine gluconate.

Catheter removal

Only a physician familiar with the appropriate techniques should attempt the following procedures.

- If blunt dissecting the catheter at the exit site, take care to ensure that it is dissected around the catheter cuff and take extreme care not to cut / damage the catheter.
- When removing the catheter, DO NOT cut the catheter prior to removal from the vein to prevent the occurrence of an air embolism.
- There should be no resistance as the catheter is being withdrawn from the vein. In the event of resistance on removing the catheter do not continue pulling against the resistance – reposition the patient to potentially free the resistance.
- All used devices or components thereof are potentially biohazard and should be handled and disposed of accordingly.

Catheter Precautions

- Use Universal Precautions for catheter insertion while inserting the device. Read all directions for use and instructions prior to commencing the procedure. Ensure that the product is within its expiry date.
- Check that all device components are present in the pack and that none of the components are physically damaged.
- Ensure that all cutting / sharp implements, such as scalpels, scissors etc are removed from the vicinity of the catheter to prevent catheter damage.
- Do not use scissors to remove dressing.
- The mean reverse recirculation rate for the 24cm, 28cm, 32cm 36cm and 40cm NexSite HD Stepped Tip Catheter is 28%. The mean reverse recirculation rate for the 55cm NexSite HD Stepped Tip catheter is 20%.
- Catheter may be damaged if clamps other than what is provided with the catheter are used.
- Repeated clamping of the tubing in the same location may weaken catheter tubing. Avoid clamping near the luers and hub of the catheter.
- Examine the catheter lumens and extensions before and after each treatment for damage.
- To prevent accidental opening of the catheter caps, ensure the security of all caps and bloodline connections prior to and between treatments.
- Only use luer lock (threaded) connectors with this catheter.
- Repeated overtightening of bloodlines, syringes and caps will reduce connector life and could lead to potential connector failure.

NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use Placement

Overview:

The NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use, is a tunneled catheter designed to be positioned in a central vein of an adult patient with the distal end of the catheter positioned in the superior vena cava, above the right atrium. The catheter is tunneled from the catheter exit site to the venotomy where it enters the central vein. The DISC (Dermal Ingrowth Support Collar) is positioned sub-cutaneously at the catheter exit site. The catheter is aligned within the DISC and the biomaterial scaffolds interface to facilitate tissue ingrowth (See Figure 1). Catheters greater than 40cm are indicated for femoral vein insertion with the catheter tip placed at the junction of the iliac vein and the inferior vena cava. (See Figures 1 and 2).

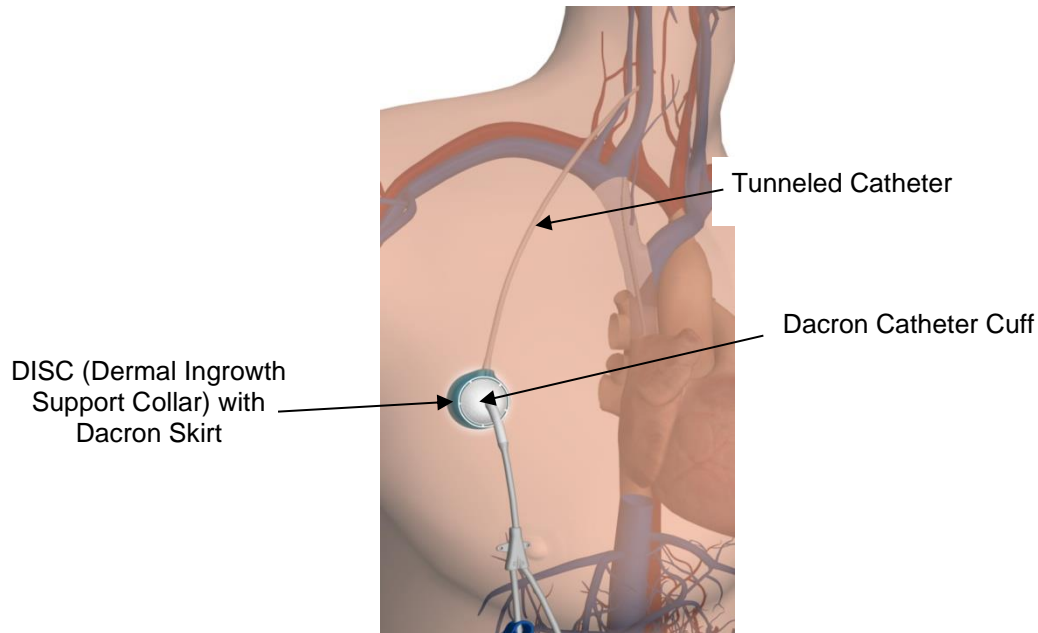


Figure 1: Overview of positioning of NexSite™ HD device (Positioned in Internal Jugular Vein)

The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine X ray should always follow the initial placement of this catheter to confirm proper placement prior to use.

Procedural Preparation

1. Use maximal barrier precautions at all times during the catheter insertion procedure by ensuring:
 - Strict compliance with hand hygiene by all the staff assisting with the procedure.
 - Covering the patient with sterile drapes from head to toe with an appropriate opening for the catheter insertion site.
 - All staff assisting with the procedure should wear a cap (covering all the hair), a face mask (covering the nose and mouth), protective eyewear, a sterile gown and sterile gloves, covering the cuff of the gown.
2. Create a sterile field and open the device tray and contents.
3. Prepare the venipuncture and catheter exit site areas using a single patient use application of 2% chlorhexidine gluconate in 70% IPA solution and allow the skin to dry. If the skin is visibly dirty, it should be washed with soap and water prior to skin asepsis using a single patient use application of 2% chlorhexidine gluconate in 70% IPA solution.
4. Position the patient in the Trendelenburg position with their head turned from the venipuncture site.
5. Measure the catheter against the chest wall of the patient to determine the location of DISC insertion / Catheter exit site, tunnel and venotomy sites. Mark the locations.
6. Administer local anaesthetic in the venipuncture area and along the proposed tunnel channel and catheter exit site areas.

Venotomy

7. Identify the required vessel, preferably the right internal jugular, for the venotomy. If using the subclavian vein, note the correct position of the subclavian vein which is superior to the first rib and anterior to the subclavian artery (at a point just lateral to the angle made by the clavicle and the first rib).
Warning: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation which may cause complications. Extended use of the subclavian vein may be associated with subclavian vein stenosis.
8. Using ultrasound guidance and a micropuncture set establish venous access with the 0.038" guidewire provided with the NexSite™ HD device.
9. Confirm that the guidewire is located in the required location using fluoroscopy.
10. Remove the micropuncture dilator leaving the guidewire in place. Using the guidewire markings as reference, determine the distance from the venotomy to SVC/ right atrial junction. If required, thread additional dilators over the guidewire in the target vein to ensure that the vessel is sufficiently dilated, leaving the guidewire in place.
Warning: The length of wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during the procedure. Cardiac arrhythmia may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during the procedure.
11. Remove the dilator from the valved peelable introducer sheath and slide the valve over the sheath opening. Insert the dilator through the valve and lock in place using the rotating collar.
Warning: The Valved Peelable Introducer Sheath is designed to reduce blood loss and the risk of air intake but is not a hemostasis valve. It is not intended to create a complete two way seal not is it intended for arterial use.
12. Taking the guidewire extending from the venotomy, advance, using rotational motion, the valved peelable introducer sheath vessel dilator and sheath over the guidewire into the vein, leaving at least 2cm of the sheath exposed.

Note: For Femoral Vein insertion the patient should lie completely on his/ her back and both femoral arteries should be palpated for site selection. The knee on the side of the selected insertion site should be flexed and the thigh abducted and the foot across the opposite leg. The femoral vein is then posterior/ medial to the artery. Catheters placed in the femoral vein should be tunneled to a pelvic area rather than an inguinal area to minimise the risk of infections.

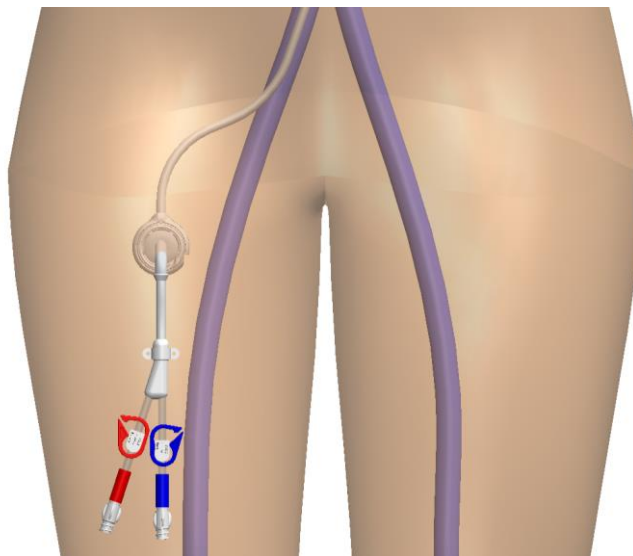


Figure 2: Overview of positioning of 55cm NexSite™ HD device (Positioned in Femoral Vein)

DISC (Dermal Ingrowth Support Collar) Placement

13. Create an incision (1 – 2cm in length) (suitable for the shape of the DISC (Dermal Ingrowth Support Collar) at the marked catheter exit site.
14. Form a pocket for the DISC by subcutaneous blunt dissection using a scissors or forceps.
15. Using a sterile scalpel, create an opening through the skin above the pocket to form the transcutaneous catheter exit site.
16. Thread the Catheter through the catheter exit site into the sub-cutaneous pocket and allow the catheter to exit the pocket. Wipe the catheter to remove any blood from the catheter.
17. Place the DISC over the distal end of the catheter and thread it over the catheter and position loosely in the formed pocket. The catheter must enter the “Skirt” side of the DISC and exit along its tab (See Figure 3).

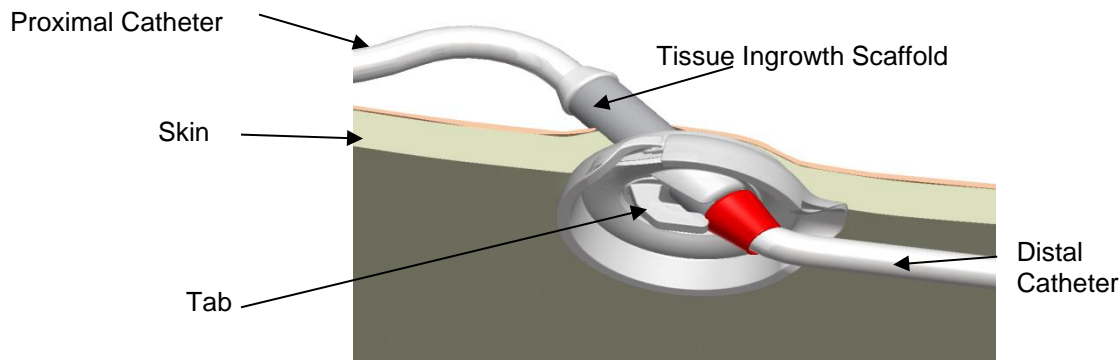


Figure 3: Representative Image of alignment of Catheter with DISC (Dermal Ingrowth Support Collar) (Note – distal cuff end is in red for illustration purposes only).

Tunneling Procedure (Note: The Tunnel is created from the pocket to the venotomy)

18. Using the provided Tunneler, place the distal rounded end of the Tunneler under the skin at the pocket.
19. Attach the venous Catheter lumen to two of the tunneler barbs.
20. Retract the tunneler sleeve over the Tunneler to catheter interface (ensuring that the entire staggered tip of the catheter is covered with the catheter sleeve). Carefully, advance the tunneler sub-cutaneously from the pocket to the venotomy, avoiding inadvertent puncture of the skin or fascia with the tip of the tunneler.
Warning: Do not over-expand the sub-cutaneous tissue during tunnelling.
21. Disconnect the tunneler from the catheter with a slight twisting motion and discard the tunneler.
Warning: Do not pull the tunneler out at an angle. Keep tunneler straight to avoid catheter tip damage.

Catheter Positioning

22. Irrigate the catheter with saline and then clamp the catheter extensions to ensure that the saline is not inadvertently drained from the lumens. Use the clamps provided.
23. Position the DISC in the pocket and locate the catheter at the catheter exit site to ensure that the catheter cuff is positioned transcutaneously and that the cuff is aligned with the DISC sub-cutaneously by withdrawing the catheter gently until a tactile stop is encountered as illustrated in Figure 3.
Warning: Ensure that the catheter and DISC are engaged appropriately by ensuring that the tactile stop is encountered – a gentle tension on the proximal end of the catheter will ensure that the catheter is positioned appropriately.
24. Remove the vessel dilator and guidewire leaving the sheath in place.
Warning: Never leave the sheath in place as an indwelling catheter. Damage to the vein will occur.
25. Advance the distal tip of the catheter through the valve of the introducer sheath. To prevent kinking the catheter it may be necessary to advance in small steps by grasping the catheter close to the sheath.
26. Advance the catheter into the vein. Confirm that the catheter is positioned appropriately radiographically.
27. Unclamp the catheter and withdraw blood through both catheter lumens. If the catheter is not positioned appropriately reposition the catheter and repeat blood withdrawal through both lumens. Flush the catheter with sterile saline to remove any blood when correct catheter positioning has been obtained.
28. When the catheter is positioned appropriately, crack the sheath handle in half. Peel the non valved side of the handle away from the catheter. Near the valve hold the catheter firmly in place and pull the valve off the catheter. Remove the sheath from the patient. It is normal to experience some resistance while pulling the catheter through the slit on the valve.
Warning: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimetres at a time.
29. Make any final adjustments to the catheter under fluoroscopy. For catheters placed in the internal jugular or subclavian veins, the distal venous tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure optimal blood flow. Catheters placed in the femoral artery should have the distal tip of the catheter positioned at the junction of the iliac vein and the inferior vena cava. Confirm that the position of the catheter at the exit site is appropriate.
Warning: Failure to verify catheter placement may result in serious trauma or fatal complications.
30. Attach syringes to both extensions and open clamps. Blood should aspirate easily from both arterial and venous sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flow.
31. Once adequate aspiration has been achieved, both lumens should be irrigated with saline filled syringes using quick bolus technique. Ensure that extension tubes clamps are open during the irrigation procedure. The catheter priming volumes are indicated on the catheter clamps and are also provided below:

Priming Volumes

Size of Catheter (cm)	Arterial Lumen (mL)	Venous Lumen(mL)
24	1.9	2.0
28	2.1	2.2
32	2.3	2.3
36	2.5	2.6
40	2.6	2.7
55	3.4	3.4

32. Close the extension clamps. Remove the syringes and place an injection cap on each luer lock connector. Avoid air embolism by keeping extension tubing clamped at all times when not in use, and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
Warning: Ensure that all air has been aspirated from the catheter and extension tubes. Failure to do so may result in an air embolism.
33. To maintain patency, a lock as per relevant hospital protocol must be created in both lumens. Once the catheter is locked with heparin, close the clamps and place injection caps on the extension tubes luers.

34. Suture the pocket incision and close the venotomy site with a suture or using an appropriate adhesive.
35. Secure the proximal portion of the catheter with a Statlock device.
Warning: Care must be taken when using sharp objects or needles in close proximity to catheter. Contact from sharp objects may cause catheter failure.
36. Cover the catheter exit site with a sterile, transparent, semi-permeable, self-adhesive polyurethane dressing.
37. Record the catheter model, length and lot number on the patient chart.

Hemodialysis Treatment

1. The heparin solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be in accordance with established protocols at the dialysis unit.
2. Before dialysis begins all connections to the catheter and extracorporeal circuits should be carefully examined.
3. Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.
4. If a leak is found, the catheter should be immediately clamped distal to the leak.
Warning: Only clamp the catheter with in line clamps provided. In event of an issue occurring with the catheter, necessary remedial action must be taken prior to the continuation of the dialysis treatment.

Notes: A summary of the recirculation rates is provided below:

Catheter Length	Maximum Recommended Flow Rate	Mean forward recirculation rate	Mean reverse recirculation rate
24cm, 28cm, 32cm 36cm, 40cm	400ml/min	0%	28%
55cm	300ml/min	0%	20%

Excessive blood loss may lead to patient shock. Hemodialysis should be performed under physician's instructions.

Anti-coagulant Catheter Lock

If the catheter is not to be used for immediate treatment, a heparin lock (concentration as per hospital protocol) must be created in each catheter lumen to maintain catheter patency. The heparin lock is administered as follows:

1. Draw heparin into two syringes, corresponding to the amount designated on the arterial and venous extensions. Ensure that the syringes are free of air.
2. Remove injection caps from the extension tube luers.
3. Attach a syringe containing heparin solution to the female luer of each extension tube and open extension clamps.
4. Aspirate to ensure that no air will be forced into the patient.
5. Inject heparin into each lumen using quick bolus technique. Ensure that each lumen is completely filled with heparin to ensure effectiveness.
6. Close extension clamps.
7. Remove syringes and attach sterile injection caps to the extension luers.

Warning: Extension clamps should only be open for aspiration, flushing and dialysis treatment. In most instances, no further heparin is necessary for 48 – 72 hours, provided the lumens have not been aspirated or flushed.

Site Care

The following supplies will be required for dressing and maintaining catheter patency.

- Sterile dressing pack and drapes
- Sterile cleansing swabs
- Transparent dressing
- Sterile Gloves
- 10ml sodium chloride 0.9%, preferably prefilled syringes
- Hypoallergenic Tape
- Injection Caps
- Swabs

The following is the procedure to be used each time the catheter is to be dressed / flushed.

- Use sterile gloves if deemed appropriate by hospital procedure.
- Wash your hands carefully with soap and hot water for at least one minute. Rinse completely and allow to air dry.
- If appropriate, decontaminate the injection cap with a recommended cleansing agent for 15 seconds and allow to dry for a minimum of 30 seconds.
- Unwrap the supplies required for the procedure – take care not to touch the supplies and keep them sterile.
- Draw up saline into the syringe if pre-filled syringes are not available.
- Remove the dressing at the exit site – start removing the dressing at the top of the bandage and remove bandage in a downwards motion.
- Wash your hands carefully with soap and hot water for at least one minute. Rinse completely and allow to air dry.
- Observe the catheter exit site, to check if there are any signs of infection, redness or discharge.
- Put on new sterile gloves if required.
- Clean the exit site with sterile cleansing swabs in circular motions from the exit site to approx 8cm from the exit site. Cleanse in a downward motion from the exit site. Allow to dry and repeat this procedure three times.
- Wipe the outside of the catheter with a sterile wipe- wiping from the exit site to the luer caps. Take care not to pull the catheter at this point.
- Place a sterile semi-permeable, self adhesive polyurethane dressing over the catheter exit site.
- Apply a cover dressing over the dressing.
- Wound dressings must be kept clean and dry.

Warnings: If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.

Catheter integrity has been demonstrated following exposure to the following chemical disinfectants: Aqueous – iodophor, Aqueous –Chlorhexidine gluconate, Alcohol iodophor, and Alcohol – Chlorhexidine gluconate.

Precaution: Patients must not swim, shower or soak the dressing while bathing.

Catheter Performance

Flow Rates:

The pressures (mmHg) at a range of flow rates for the NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use are as outlined in Table 1. The recommended flow rate for the NexSite™ HD, Hemodialysis Stepped Tip Catheter for long term use is from 200ml/min to 400ml/minute for 24cm to 40cm catheters and from 200ml/min to 300ml/min for 55cm catheters. The recommended flow rates for the catheter is dependent on catheter length with lower flow rates being recommended for longer catheters due to higher pressures.

Warning: Use of the catheter at rates in excess of the recommended flow rates may result in pressures in excess of 250mmHg which could result in red blood cell hemolysis.

Size	Flow ml/min	Rate	100ml/min	200ml/min	300ml/min	400ml/min
15.5Fr X 24cm		Venous	17	44	80	112
		Arterial	22	47	84	128
15.5Fr X 28cm		Venous	21	50	88	124
		Arterial	26	52	91	130
15.5Fr X 32cm		Venous	21	50	82	118
		Arterial	22	48	82	124
15.5Fr X 36cm		Venous	21	51	85	122
		Arterial	24	56	96	146
15.5Fr X 40cm		Venous	27	62	101	143
		Arterial	25	57	97	146
15.5Fr X 55cm		Venous	36	79	128	
		Arterial	34	74	124	

Note: Flow rates provided are from In Vitro data using a blood simulate approximating the viscosity of whole blood

Warning: Always review hospital or unit protocol, potential complications and their treatment, warnings and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems.

Only a physician familiar with the appropriate techniques should attempt the following procedures.

Insufficient Flow

The following may cause insufficient blood flows:

- Occluded arterial holes due to clotting or fibrin sheath.
- Occlusion of the arterial side holes due to contact with vein wall.

Solutions include chemical intervention utilizing a thrombolytic agent.

Management of One Way Obstruction

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 resolve the obstruction:

- Reposition Catheter
- Reposition Patient
- Have patient cough
- Provided there is no resistance, flush the catheter vigorously with sterile saline to try to move the tip away from the vessel wall.

Infection

Use Universal Blood and Body fluid Precautions for all catheter manipulations.

Adhere to a strict aseptic technique.

Clinically recognised infection at a catheter exit site should be treated promptly with antibiotic therapy.

If fever occurs in a patient with a catheter in place, take a minimum of two blood cultures from a distant site to the catheter exit site. If blood culture is positive the catheter should be removed and appropriate antibiotic therapy initiated. Wait 48 hours before catheter replacement. Insertion should be made on the opposite side of the original catheter exit site if possible.

Warning: The incidence of infection may be increased with femoral vein insertion.

Catheter Removal

The NexSite™ HD device is designed to facilitate skin healing at the catheter exit site. The device may be removed by the “Pull and Peel” technique or surgically depending on the physician’s preference. Surgical removal is recommended when the device is infected or has been implanted for less than 2 weeks. When the catheter is being removed from the vein the physician should feel very little resistance.

1. Administer local anaesthetic at the catheter exit site.
2. Blunt dissect around the catheter cuff to free the catheter.
3. Gently pull the catheter to remove the catheter from the patient with a number of gentle tugs – when the catheter cuff is free from the surrounding tissue, the physician should feel a “freeing” of the catheter.



Figure 4: Overview of Catheter Removal.

4. If it is not possible to remove the catheter following blunt dissection, make a small incision distal to the exit site and clamp the catheter before cutting the catheter proximal to the clamp. Remove the distal portion of the catheter from the venotomy and discard. Dissect around the catheter and under the DISC, and gently remove the proximal end of the catheter.
5. When the catheter is removed, insert a Clamp into the catheter exit site incision and grab the tab located under the sub-cutaneous DISC – this tab should be easily located at the catheter exit site once the catheter has been removed.

6. When the tab is secured in the Clamp pull the tab through the Catheter exit site – this will initiate the DISC unravelling. Continue to withdraw the DISC through the exit site until the entire DISC has been removed.
7. Remove the DISC’s Dacron skirt with a forceps if it is visible at the catheter exit site. If the DISC’s skirt remains in place following removal, leave it in place.
8. Apply pressure at the catheter exit site to minimise bleeding as required and close the exit site.
9. In the event that the catheter and / or DISC cannot be removed by the minimally invasive method, the DISC is infected, or the catheter and DISC has only been implanted for 14 days or less, remove the catheter and / or DISC surgically.

The following steps are important for creating an incision and surgically removing the DISC.

- Use Aseptic Technique.
- Make an incision lateral to the DISC and clamp the catheter.
- Grip the catheter that is extending through the tunnel with a blunt forceps.
- Applying traction, gently remove the catheter from the venotomy.
- Free the catheter cuff from the tissue prior to removal.
- Remove the catheter.
- Remove the DISC by gripping the DISC with a forceps and remove through the incision.