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

Directions for Use

Contents

Note to Physicians: Please consult the on-line training video on www.marvaomedical.com for information on the placement procedure for the NexSite HD Symmetric Tip device.

Indications for Use
The NexSite™ HD, Hemodialysis Symmetric 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 which should only be used when no other upper extremity or chest wall options are available. Catheters greater than 40cm are indicated for femoral vein insertion.

DescriptionThe NexSite™ HD, Hemodialysis Symmetric Tip Catheter for long term use (provided in the following tip to cuff lengths19 cm, 23 cm, 27 cm, 31 cm, 35 cm and 55 cm) is a dual lumen, Symmetric tip radiopaque polyurethane catheter which contains a Dacron biomaterial cuff and two female luer connectors. The DISC (**D**ermal **I**ngrowth **S**upport **C**ollar) assists with the direction of the catheter and consists of a biomaterial tissue ingrowth scaffold. The biomaterial scaffolds on the catheter shaft and DISC are aligned and facilitate 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. A stylet is provided to support the catheter in the event of advancement over a guidewire.

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

Air embolism
Bacteremia
Brachial Plexus Injury
Cardiac Arrhythmia
Cardiac Tamponade
Venous Thrombosis
Endocarditis

Exit Site Infection
Exsanguination
Femoral artery bleed
Hematoma
Hemothorax
Inferior Vena Cava puncture
Laceration of the vessel
Lumen thrombosis
Mediastinal Injury
Perforation of the vessel
Pleural Injury
Pneumothorax
Retroperitoneal bleed
Right atrial puncture
Septicemia
Skin Erosion
Subclavian artery puncture
Subcutaneous Hematoma
Superior Vena Cava puncture
Femoral Nerve damage
Thoracic duct laceration
Tunnel infection
Vascular 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 Symmetric Tip Catheter for long term use 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.
- The patient has superior vena cava syndrome.
- The patient has untreated coagulopathy.
- The patient uses a right ventricular assistance device (RVAD)
- The patient already has a device at the intended implantation site.

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.

- The stylet is not to be removed without the guidewire in place. To remove the stylet forcibly in such cases could result in device damage.

- 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.

- 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. The catheter tip is intended to be positioned to the level of the caval atrial junction or beyond to ensure optimum blood flow– avoid placing the catheter tip in a position which may result in cardiac arrhythmia, myocardial erosion or cardiac tamponade.

- 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.

- 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.

- 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.

- In the event of catheter occlusion, refer to the catheter clearing procedure in place at the institution or contact a physician familiar with the appropriate techniques to remove a catheter occlusion.

- 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.

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

- The implanted NexSite HD Catheter and DISC is considered to be MRI safe. It is manufactured from polymer materials which are non-conducting, non- metallic and non- magnetic.

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.

Review catheter summary sheet for details on catheter flow rates, recirculation rates and priming volumes. Note that the mean reverse recirculation rate for the NexSite HD Symmetric Tip Catheter (all lengths) is 2.3%, with reverse recirculation rates ranging from 0.9% to 4.8%.

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 accidents associated with 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 Symmetric Tip Catheter for long term use Placement

Overview:

The NexSite™ HD, Hemodialysis Symmetric Tip Catheter for long term use, is a tunnelled catheter designed to be positioned in a central vein of an adult patient (the internal jugular vein is the preferred vein, however the sub-clavian vein may also be used) 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 internal jugular 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).

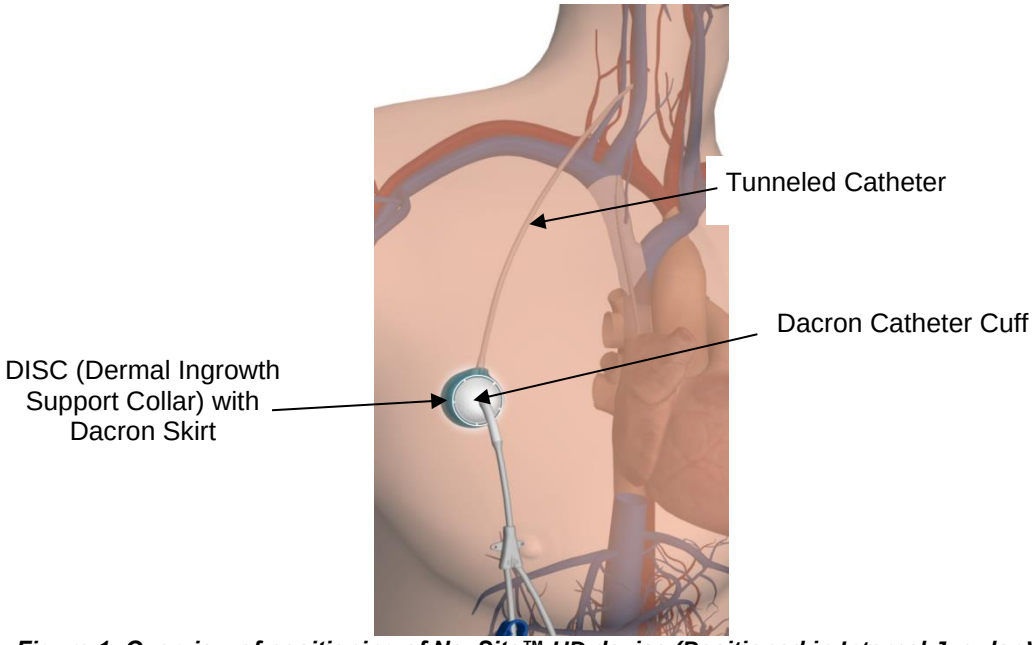


Figure 1: Overview of positioning of NexSite™ HD device (Positioned in Internal Jugular Vein)

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 insertion 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 nor 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.

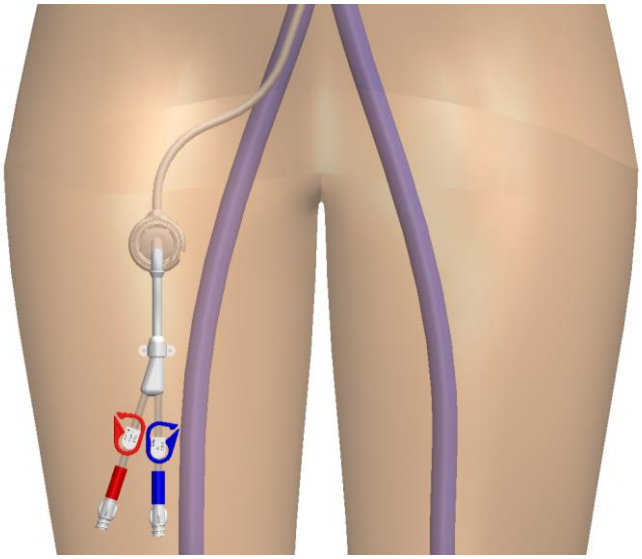


Figure 2: Overview of positioning of 55cm NexSite™ HD device (Positioned in Femoral Vein)

DISC (Dermal Ingrowth Support Collar) Placement

13. Create a slightly curved incision (1 – 2cm in length) (suitable for the shape of the DISC (**D**ermal **I**ngrowth **S**upport **C**ollar) at the marked catheter exit site.

14. Form a deep 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. If not required, remove the catheter stylet over the guidewire. 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)

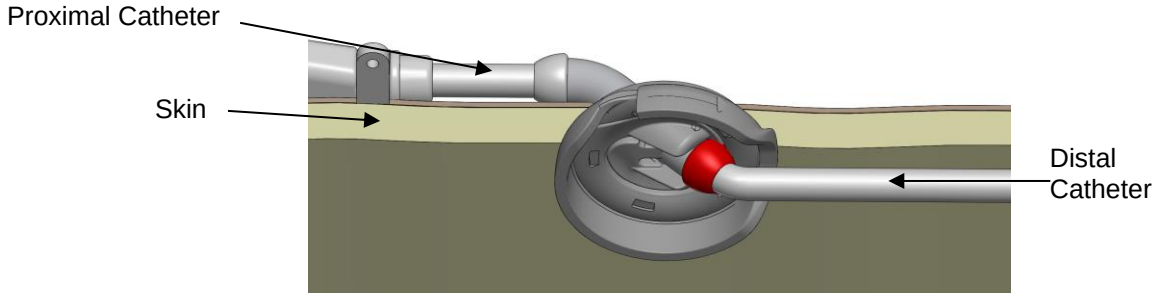


Figure 3: Representative Image of alignment of Catheter with DISC (Dermal Ingrowth Support Collar) (Note – distal cuff end is in red for illustration purposes only).

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 Catheter lumen to two of the tunneler barbs.

20. Retract the tunneler sleeve over the Tunneler barb and attached catheter.. 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.

<u>Warning</u>: 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, 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. Withdraw the catheter gently until a tactile stop is encountered.

<u>Warning:</u> 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.

<u>Warning:</u> 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 to verify patency. If there is difficulty aspirating blood reposition the catheter and repeat blood withdrawal through both lumens. When correct catheter positioning has been achieved, Flush the catheter with sterile saline to remove any blood.

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.
    Note: 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 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 vein 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 on the catheter summary sheet of the DFU.

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 heparin lock (concentration as per the relevant hospital protocol) must be created in both lumens. Once the catheter is locked with heparin, close the clamps and install injection caps on the extension tubes luers.

34. Suture the pocket incision making sure to avoid unnecessary tension on the sutures. Close the venotomy site with a suture or using an appropriate adhesive.

35. Secure the proximal portion of the catheter with a Statlock device or suture the catheter hub wings to the skin to prevent catheter migration. The catheter must be secured or sutured for the entire duration of implantation. Avoid unnecessary manipulation of the catheter when it is in situ.

Warning: Take Care not to pull the catheter when it is in place.

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:* necessary remedial action must be taken prior to the continuation of the dialysis treatment. 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 catheter lumen priming volume tags. 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

Warning: Take Care not to pull the catheter during site care procedures.

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.

<u>Warning:</u> 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 glucontate, Alcohol iodophor, and Alcohol – Chlorhexidine glucontate.

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

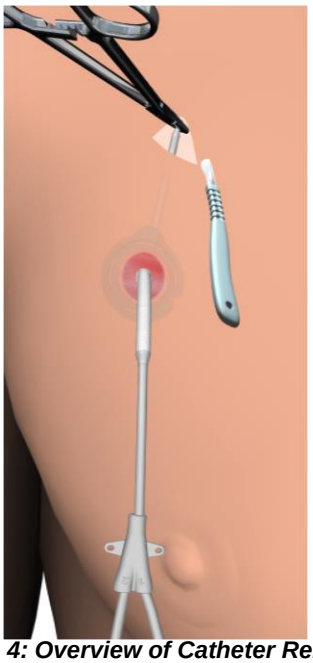
Catheter Removal

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. To avoid damage to the catheter, a sharp instrument should not be used.

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.



4. If it is not possible to remove the catheter following blunt dissection, make a small incision distal to the exit site **as per Figure 4**. Clamp the catheter and cut 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.

Figure 4: Overview of Catheter Removal when catheter cannot be removed by blunt dissection.

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 Dacron Skirt has tissue ingrowth and remains in place following DISC removal, seal the exit site.

8. Apply pressure at the catheter exit site to minimise bleeding as required.

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.

Catheter Summary for NexSite HD, Hemodialysis Symmetric Tip Catheter for long term use							
Catalogue Number		**NEXHDSY1551901**	**NEXHDSY1552301**	**NEXHDSY1552701**	**NEXHDSY1553101**	**NEXHDSY31553501**	**NEXHDSY1555501**
Catheter Dimensions							
Effective Length (Bifurcation joint to Catheter tip.		25cm	29cm	33cm	37cm	41cm	61cm
Tip to catheter cuff length		19cm	23cm	27cm	31cm	35cm	55cm
Priming Volumes							
Arterial & Venous(ml)		2.0ml	2.2ml	2.4ml	2.6ml	2.8ml	3.8ml
Catheter pressure at range of Flow Rates (mmHg)*							
100ml/min	Venous	16.6	18.8	20.6	22.0	24.9	36.3
	Arterial	18.6	22.1	24.4	28.2	28.6	41.3
200ml.min	Venous	37.8	42.9	47.5	49.5	56.4	79.3
	Arterial	40.4	47.4	52.1	61.3	62.8	88.8
300ml/min	Venous	62.1	70.0	78.0	80.2	91.3	126.5
	Arterial	68.5	78.4	86.8	102.3	103.6	145.4
400ml/min	Venous	88.8	100.4	111.7	114.8	129.5	178.3
	Arterial	101.6	115.9	129.3	148.8	155.4	212.4
Maximum Recommended Flow Rate		400ml/min	400ml/min	400ml/min	400ml/min	400ml/min	400ml/min
Mean % Recirculation at maximum recommended flow rate							
Forward (range)		2.3% (1.7 -3.2%)	2.0%(1.7-2.3%)	1.9%(1.8 -2.1%)	2.2% (1.6-3.0%)	2.5% (2.1-2.9%)	2.1% (0.4-4.8%)
Reverse (range)		2.1%(1.8 - 2.7%)	1.8% (1.1-2.3%)	2.0% (1.1-3.0%)	2.0% (0.9-2.9%)	3.5% (2.6-4.1%)	2.6% (1.1-4.8%)

**Flow rates provided are from in Vitro data using a blood simulate approximating the viscosity of blood.*