

-Never forcibly flush an obstructed lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider chemical intervention using a thrombolytic agent.

INFECTION

Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use **universal blood and body-fluid precautions** in the care of all patients. Sterile technique must be strictly adhered to during the entire procedure

Clinically recognized infection at the catheter site should be treated with an appropriate antibiotic. If a fever occurs in a patient with a catheter in place, take at least two blood cultures from a site distant from the catheter site. If a blood culture is positive, the catheter should be removed and appropriate antibiotic therapy initiated. Wait 48 hours before inserting another catheter. Insertion should be made only on the side opposite the site which became infected.

CATHETER REMOVAL

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

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.
















1. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
2. Withdraw catheter through the exit site.
3. Apply pressure to exit site for approximately 10-15 minutes or until bleeding stops.
4. Apply dressing in a manner to promote optimal healing.

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* This symbol is in accordance with ISO 15223-1.

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SUBCLAVIAN CATHETER

INDICATIONS FOR USE

The Subclavian Catheter is designed for acute hemodialysis and apheresis. It may be inserted percutaneously and the preferred site is the subclavian vein. This catheter is indicated for a duration less than (30) days.

CONTRAINDICATIONS

This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.

POTENTIAL COMPLICATIONS

- Air Embolism
- Bacteremia
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Central Venous Thrombosis
- Endocarditis
- Exit Site Infection
- Exsanguination
- Hematoma
- Hemorrhage
- Hemothorax
- Laceration of the vessel
- Luminal Thrombosis
- Mediastinal Injury
- Perforation of the vessel
- Pleural Injury
- Pneumothorax
- Retroperitoneal Bleed
- Right Atrial Puncture
- Septicemia
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Vascular Thrombosis

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

In the rare event that a hub or connector separates from any component during the insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove catheter immediately.

Do not advance the stainless steel guidewire or catheter if unusual elastic resistance is encountered. Do not insert or withdraw the guidewire forcibly from any component. The wire could break or unravel, in which case both the catheter and guidewire must be removed simultaneously.

WARNINGS

Federal law (USA) restricts the device to sale by or on the order of a physician.

Single use only. Do not resterilize the catheter or accessories by any method. The manufacturer will not be liable for any damages caused by re-use or reesterilization of the catheter or accessories. Re-use may lead to infection or illness/injury.



Contents sterile and non-pyrogenic in unopened or undamaged package.

Sterilized by Ethylene Oxide.



Do not use catheter if package is damaged or has been opened. Do not use if catheter or components show signs of damage (crimped, crushed, cut, etc.)

CATHETER PRECAUTIONS

Do not use sharp instruments near the extension lines or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage catheter. Do not suture through any part of the catheter. Catheter tubing can tear when subjected to excessive force or rough edges.

Use only smooth jawed forceps for clamping when not using the clamp supplied with the catheter. We recommend using only line extension clamps which have been provided for clamping. Clamping the catheter repeatedly in the same spot could weaken the tubing. Change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter and hub of the catheter. Do not clamp the lumen portion of the catheter. Clamp only the extensions. Examine tubing for damage at the end of each treatment.

To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

It is recommended that only luer lock (threaded) connections be used with this catheter (including syringes, bloodlines, IV tubing, and injection caps). Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure. Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.

INSERTION SITES

SUBCLAVIAN

The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite that of the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area. Note the position of the subclavian vein which is posterior to the clavicle, 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).

NOTE: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation. Long time use of the subclavian vein may be associated with subclavian vein stenosis.

DIRECTIONS FOR SELDINGER INSERTION

Read instructions carefully before using this device. The catheter should be inserted, manipulated and removed only by a qualified, licensed physician or other health care practitioner, authorized by and under the direction of such physician. The medical techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient. Use standard hospital protocols.

1. Strict aseptic technique must be used during the insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The operating room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient wear a mask.
2. The selection of the appropriate catheter length is at the sole discretion of the physician. To concurrently achieve proper tip positioning, 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.
3. Administer sufficient local anesthetic to completely anesthetize the insertion site.
4. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement.
5. Remove the syringe, placing thumb over the end of the needle to prevent blood loss or air embolism. Insert the flexible end of the guidewire through the needle and into the vein. Insert distal end of guidewire advancer into needle end. Advance guidewire with thumb in a forward movement through the needle and into the vein.

Caution: The length of wire inserted is determined by the size of the patient. Monitor patient for signs of arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

Caution: When introducer needle is used, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

6. Remove needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site with scalpel.
7. Thread dilator over guidewire into the vessel (a slight twisting motion may be used). Remove dilator when vessel is sufficiently dilated, leaving guidewire in place.

Caution: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

Caution: Insufficient tissue dilation can cause compression of the catheter lumen against the guidewire causing difficulty in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire.

8. The catheter is irrigated with saline-filled syringes. The syringes are removed and the arterial extension is clamped. With the venous extension unclamped, thread the distal tip of the catheter over the guidewire. The catheter may be rotated gently during insertion until the tip is correctly positioned. The guidewire and integral stylet are removed, and the venous clamp is closed.
9. Attach syringes on both extensions and open clamps. Blood should aspirate easily from both venous and arterial sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to sustain adequate blood flow. Once adequate blood flow has been established, both lumens are irrigated again with saline-filled syringes. It is necessary to open the extension clamps during the irrigation procedure. Clamp the extensions, remove the syringes and place an injection cap on each luer lock connector. Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by filling the catheter with saline prior to use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
10. Do not clamp the dual lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamp(s) provided.
11. Immediately after insertion, confirm proper placement of the tip of the catheter with x-ray. The catheter tip should lie at the junction of the superior vena cava and the right atrium. Observe the patient carefully for signs and symptoms of cardiac arrhythmia caused by passage of the catheter into the right atrium. If symptoms appear, pull back the tip until they are eliminated.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

12. Suture the catheter to the skin using the rotating wing. Do not suture the catheter tubing. Cover the exit site with an occlusive dressing.
13. Catheter must be secured/sutured for entire duration of implantation.
14. Record indwelling catheter length and lot number on patient's chart and check position routinely.

Before dialysis begins, all connections to the extracorporeal circuit should be checked carefully. During all dialysis procedures, frequent visual inspection should be conducted to detect leaks and prevent blood loss or entry of air into the the extracorporeal circuit. In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedure. Excess blood leakage may lead to patient shock.

HEPARINIZATION

If the catheter is not used immediately for treatment, follow the suggested catheter patency guidelines:

- To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.
- Follow facility protocol for heparin concentration.
- Clamp the arterial and venous extension pieces, remove syringe, and attach a sterile injection cap to each luer lock connector. Once the lumina have been heparinized, keep both extensions clamped when not attached to bloodlines or a syringe. If either clamp is opened, blood may enter the distal portion of the catheters, ultimately causing a thrombus.
- In most instances, no further heparin is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.
- The heparin solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol.

Before infusing fresh heparin, aspirate indwelling heparin and flush each lumen with sterile normal saline.

Never forcibly flush a clotted lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may attempt chemical intervention utilizing a thrombolytic agent.

SITE CARE

Warning: DO NOT use ointments of any kind with this catheter.

Clean the skin around the catheter. Cover exit site with an occlusive dressing and leave the extensions, clamps, adapters and caps exposed for access by the staff.

Wound dressings must be kept dry. Patient must not swim, shower, or soak dressing while bathing. If adhesion of dressing is compromised by profuse perspiration or accidental wetting, the dressing must be changed by the medical or nursing staff under sterile conditions.

INSUFFICIENT FLOWS

Excessive force should not be used to flush an obstructed lumen. Insufficient blood flow may be caused by occluded arterial holes resulting from a clot or by side holes contacting the wall of the vein. If manipulation of the catheter through rotation (except single lumen catheters) or reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent. Physician discretion is advised.

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 the patient.

-Have the patient cough.

-Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.

**WARNING:
ONLY A PHYSICIAN SHOULD ATTEMPT THE FOLLOWING PROCEDURES**

-Rotate the catheter to reorient the tip position with respect to vascular anatomy. In subclavian and jugular insertion, tip malposition usually can be avoided if the venous adapter is oriented toward the midline on insertion. This positions the arterial inlet away from the wall of the superior vena cava, allowing free blood flow into the arterial lumen.

-Withdraw the catheter slightly to reposition the tip. Caution: Do not insert the catheter further into the vein.

-Reverse the bloodlines. If the previous methods fail to resolve a one-way obstruction, the patient may be dialyzed by connecting the arterial bloodline to the venous adaptor and the venous bloodline to the arterial adapter. A significant increase in recirculation may occur.