

**SCHON™  
LONG-TERM HEMODIALYSIS  
CATHETER**

**INSTRUCTIONS FOR USE**

INDICATIONS FOR USE:

- The SCHON™ Hemodialysis Catheter is indicated for use in attaining Long-Term vascular access for 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 subclavian vein as required.

CONTRAINDICATIONS:

- This catheter is intended for Long-Term vascular access only and should not be used for any purpose other than indicated in these instructions.

- Do not implant catheter in thrombosed vessels.

DESCRIPTION:

- The SCHON™ Hemodialysis Catheter is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent biocompatibility.



POTENTIAL COMPLICATIONS:

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

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

WARNINGS:

- In the rare 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 any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or Vascu-Sheath® introducer and guidewire must be removed together.

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

- This catheter is for Single Use Only.



- Do not re-sterilize the catheter or accessories by any method.

- The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of this catheter or accessories.

- Contents sterile and non-pyrogenic in unopened, undamaged package.  
STERILIZED BY ETHYLENE OXIDE

**STERILE EO**

- Do not use catheter or accessories if package is opened or damaged.

- Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:

- DO NOT use alcohol or acetone based disinfectants on this catheter. Failure of catheter will result. Iodine based solutions are recommended as the antiseptic solution that can be used on this catheter.

- There is a potential for product failure related to the use of ointments on catheters. Do not use ointments of any kind on this catheter.

- Use only ANGIODYNAMICS® Lock Right® Adapters with this catheter.

- Do not use sharp instruments near the extension tubing or catheter lumen.

- Do not use scissors to remove dressing.

- Catheter will be damaged if clamps other than what is provided with this kit are used.

- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the luers and hub of the catheter.

- Examine catheter lumen and extensions before and after each treatment for damage.

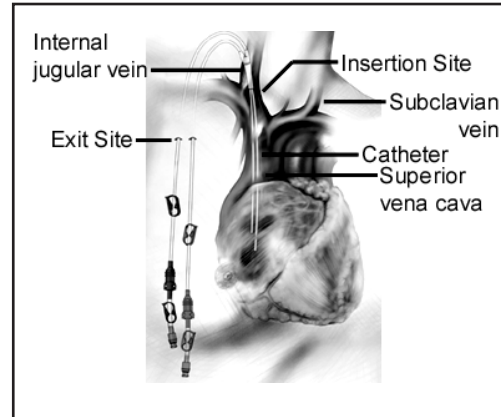
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

- Use only Luer Lock (threaded) Connectors with this catheter.

- Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.

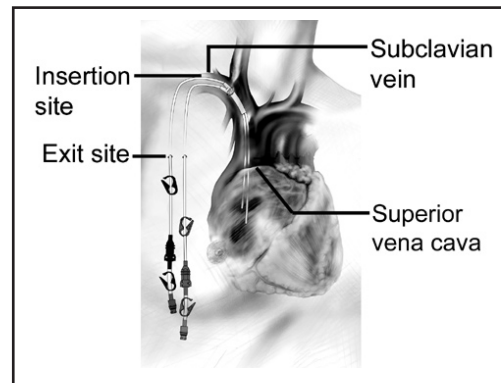
INSERTION SITES:

Internal Jugular Vein



- Have patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

Subclavian Vein



- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

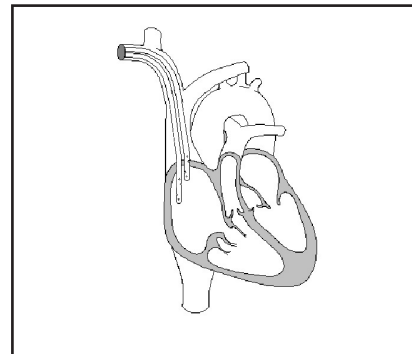
- Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib.)

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.

Tip Placement



- Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to confirm proper tip placement prior to use.

**DIRECTIONS FOR SELDINGER INSERTION**

- Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.

- The 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 the physician's experience and judgement in treating any specific patient.

- Use standard hospital protocols when applicable.

1. Strict aseptic technique must be used during 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 patient wear mask.

2. 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.

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 and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advancer so that only the end of the guidewire is visible. Insert advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

**Caution:** The length of the 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 this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

6. Remove needle, leaving guidewire in the vessel. Note the depth markings on guidewire. Select appropriate length of catheter, using fluoroscopy to determine the distance to the base of the right atrium. Enlarge cutaneous puncture site with scalpel.

7. Dilate the tract by passing just the dilator over the wire and into the vein. When fully dilated, remove from vessel and reassemble sheath/dilator. Thread sheath/dilator over the guidewire into the vessel. Remove guidewire, leaving dilator and sheath in place. Place a finger over the end of the dilator to prevent blood loss or air embolism.

**Caution:** DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrab the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.

**Note:** For alternate sheath method, see Micro Puncture Insertion Method Section.

**Caution:** Never leave sheath/dilator in place as an indwelling catheter. Damage to the vein will occur.

**Caution:** To reduce blood loss, pull back the distal lumen of the catheter so that it is even with the proximal lumen 4-5cm back with thumb and forefinger and insert so that both lumens are in line. Once the catheters are inserted, you may allow the distal lumen to extend and continue advancing the catheters to the hub.

8. Irrigate catheter with heparinized saline-filled syringes, then clamp catheter extensions to assure that heparinized saline is not inadvertently drained from lumens. Use clamps provided.

9. Remove dilator from sheath.

10. Insert distal ends of the catheter into and through the sheath until catheter tip is correctly positioned in the target vein.

11. Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

**Caution:** 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 centimeters at a time. Continue in this manner until the sheath is completely removed from the vessel, and then completely tear apart the sheath and discard.

12. Make any adjustments to catheter under fluoroscopy. The venous distal tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure optimal blood flow.

13. Make a 1cm incision vertically above the insertion site. Using blunt dissection, create a subcutaneous pocket for the hub of the catheter.

14. Pre-curve the tunnelers by bending them into the shape of a "C". Attach a threaded trocar to the proximal end of one of the catheters. Trocar is inserted using a clockwise motion. Remove the clamp from that extension. Insert the trocar into the subcutaneous pocket and create a short subcutaneous tunnel. The tunnel track should be a gentle curve in the shape of a "C".

**Notes:**

- Do not tunnel through the muscle.

- The tunnel should be made with care in order to prevent damaging surrounding vessels and/or adjacent catheter.

- Lead catheter into the tunnel gently.

- Catheter hub should lie at the top of the tunnel, under the subcutaneous pocket.

- Do not pull or tug the catheter tubing.

- If resistance is encountered, further dissection may facilitate insertion.

**Note:** For ease in dressing the exit site and for patient comfort, locate the subcutaneous tunnel below the vessel entry site. A tunnel with a wide gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the hub of the catheter 8-10cm from the skin exit site. Remove the catheter from the trocars.

15. Repeat for second catheter and place extensions onto catheters (see instructions).

16. Seat the hub of the catheter within the 1cm incision (pocket) and make any adjustments to the extensions to insure a gentle curve in the tunnel. Confirm the tip placement with fluoroscopy or x-ray and confirm that there are no kinks in the catheter in the neck or chest, especially at the junction of the exit tubing and the hub. Make sure the tunnelers go through separate subcutaneous tracks to insure the self retaining features of the SCHON™ system.

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

17. 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 flows.

18. Once adequate aspiration has been achieved, both lumens should be irrigated with saline-filled syringes using quick bolus technique. Assure that extension clamps are open during irrigation procedure.

19. 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.

**Caution:** Do not clamp the dual lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamps provided.

- To maintain patency, a thrombolytic agent lock must be created in both lumens. This mixture is then left to dwell for a minimum of 4 hours or up to 48 hours. If dialysis is initiated before 4 hours, the catheters should be repacked with the thrombolytic agent solution after treatment and allowed to dwell over night. Refer to hospital guidelines concerning thrombolytic agents.

**Note:** Use of thrombolytic agent may cause systemic fibrinolysis if infused into the circulation. Refer to manufacturer's instructions, indications for use, and contraindications before using any thrombolytic agent.

**Caution:** Assure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism.

- Once the catheter is locked with a thrombolytic agent solution, close the clamps and install injection caps onto the extensions' female luer.
- Confirm proper tip placement with fluoroscopy. 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.

#### **CATHETER SECUREMENT AND WOUND DRESSING:**

- Suture insertion site closed. These catheters are self-seating and do not need to be sutured at the exit sites or hub. Do not suture catheter tubing.

**Caution:** Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

- Cover the insertion and exit site with an occlusive dressing.
- Record catheter length and catheter lot number on patient's chart.

#### **HEMODIALYSIS TREATMENT**

- 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 dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully.

- Frequent visual inspection should be conducted to detect leaks to prevent blood loss and air embolism.

- If a leak is found, the catheter should be clamped immediately.

**Caution:** Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

**Note:** Excessive blood loss may lead to patient shock.

- Hemodialysis should be performed under physician's instructions.

#### **HEPARINIZATION**

- If the catheter is not to be 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 hospital/facility protocol for heparin concentration.

- Draw heparin into two syringes, corresponding to the amount designated on the arterial and venous extensions. Assure that the syringes are free of air.
- Remove injection caps from the extensions.
- Attach a syringe containing heparin solution to the female luer of each extension.
- Open extension clamps.
- Aspirate to insure that no air will be forced into the patient.
- Inject heparin into each lumen using quick bolus technique.

**Note:** Each lumen should be completely filled with heparin to ensure effectiveness.

- Close extension clamps.

**Caution:** Extension clamps should only be open for aspiration, flushing, and dialysis treatment.

- Remove syringes.
- Attach a sterile injection cap onto the female luers of the extensions.

- In most instances, no further heparin is necessary for 48-72 hours, provided the lumens have not been aspirated or flushed.

#### **SITE CARE**

**Warning:** DO NOT use alcohol or acetone based disinfectants on this catheter. Failure of catheter will result. Iodine based solutions are recommended as the antiseptic solution that can be used on this catheter.

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

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

- Wound dressings must be kept clean and dry.

**Caution:** Patients must not swim, shower, or soak dressing while bathing.

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

#### **CATHETER PERFORMANCE**

**Caution:** 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.

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

#### **INSUFFICIENT FLOWS:**

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 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 resolve the obstruction:

- Reposition catheter.

- Reposition patient.

- Have 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.

#### **INFECTION:**

**Caution:** Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

- Sterile technique should always be strictly adhered to.

- Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.

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

#### **MICRO PUNCTURE INSERTION METHOD**

- Once an .018" guidewire has been introduced into the target vein, the 4F sheath dilator should be threaded over the proximal end of the wire and inserted into the target vein.

- When the 4F sheath dilator is located in the target vein, remove the guidewire and dilator one at a time.

- Insert an .038" guidewire into and through the sheath until it is located in the target vein.

- Remove the sheath and continue following directions starting at #7 of "Directions for Seldinger Insertion".

#### **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.

- Palpate the catheter exit tunnel to locate the hub of the catheter.

- Administer sufficient local anesthetic to hub site to completely anesthetize the area.

- Make a 2cm incision over the hub, parallel to the catheter. In most cases, opening the original incision for insertion will provide adequate exposure to extract the hub safely.

- Dissect down to the hub using blunt and sharp dissection as indicated.

- When visible, remove the hub and extension legs through the wound.

- Clamp both extension tubes.

- Cut the catheters between the clamp and the exit site. Withdraw the external portion of the catheter through the exit site.

- Remove the catheter from the venotomy site.

**Caution:** Do not pull distal end of catheter through incision as contamination of wound may occur.

- Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.

- Suture incision and apply dressing in a manner to promote optimal healing.

- Check catheter integrity for tears and measure catheter when removed. It must be equal to the length of catheter when it was inserted.

#### **FLOW RATE vs. VENOUS PRESSURE**

300 ml/MIN	350 ml/MIN	400 ml/MIN
80 mmHg	110 mmHg	120 mmHg

FLOW RATE TESTING REPRESENTS OPTIMUM LABORATORY CONDITIONS.

Manufactured for:

# ANGIODYNAMICS®

603 Queensbury Ave., Queensbury, NY 12804 U.S.A.  
PHONE: 518-798-1215  
FAX: 518-798-3625

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•STORE IN A COOL DRY PLACE • PROTECT FROM UV LIGHT•



Kit contents will include (1) Hemodialysis Catheter and accessories. For exact kit contents refer to the product label.

