**DuraMax® CHRONIC HEMODIALYSIS CATHETER INSTRUCTIONS FOR USE**

**INDICATIONS FOR USE:**
- The DuraMax® Hemodialysis Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.

**CONTRAINDICATIONS:**
- The catheter is intended for use in the precutaneous insertion of catheters in the venous system.

**DESCRIPTION:**
- The DuraMax® Hemodialysis Catheter is manufactured from soft radiopaque elastomeric material that provides increased patient comfort while providing excellent biocompatibility.

**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 complete insertion 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 sheath introducer and guidewire must be removed together.
- Use of excessive pull force on the catheter may cause the wave wire to detach from the introducer hub.
- Federal Law (USA) restricts the device to use by or on the order of a physician.

**INSERTIONSites:**
- 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.

**Femoral Vein**

- Have patient sit up straight from the bed to determine the sternum-muscle muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternum-muscle muscle. If open space is encountered, approximately three fingerbreadths above the clavicle. The carotid artery should be palpated medially to the point of catheter insertion.

**Subclavian Vein**

- The patient should lie completely on his/her back. Both femoral arteries should be palpated for site selection and consequence assessment. The line on the side of the insertion site should be flexed and the thigh abducted. Place the foot across the opposite leg. The femoral vein is then posterior/medial to the artery.

**Catheter PRECAUTIONS:**
- Do not re-stereilize the catheter or accessories by any method.
- The manufacturer shall not be liable for any damages caused by reuse or re-stereilization of catheters or accessories.
- Container the device may lead to injury, illness, or death of the patient.
- Reprocessing may compromise the integrity of the device and/or lead to device failure.

**CATHETER PRECAUTIONS:**
- 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.
- In the event a clamp breaks, replace the catheter.
- Clogging of the tip may cause catheter failure.
- Avoid clamping near the luer and hub of the catheter.

**Tip Placement**

1. Select the appropriate catheter length at the site 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 tip placement prior to use.
2. Administer sufficient local anesthetic to anesthetize the insertion site.
3. Make a small incision at the exit site on the chest wall approximately 6–10 cm below the clavicle. Make a second incision above and parallel to the first, at the insertion site. Make the incision at the exit site wide enough to accommodate the catheter, approximately 1 cm.
4. Use blunt dissection to create the subcutaneous tunnel opening. Attach the catheter to the trocar (a slight twisting motion over the guide wire may be helpful). Slide catheter tunneling sleeve over the catheter making certain that the tip covers the distal end of the catheter. Insert the trocar up to the exit site and create a short subcutaneous tunnel. Do not tunnel through muscle. The tunnel should be made with care in order to prevent damage to surrounding vessels.
5. Do not tunnel overexpanded subcutaneous tissue during tunneling. Over-expansion may delay or prevent cuff-in-growth.
6. Lead catheter into the tunnel gently. Do not pull on the catheter tubing. If an unusual resistance is encountered, further blunt dissection may facilitate the insertion. Therefore, do not attempt to advance the trocar with a slight twisting motion to avoid damaging the catheter.
7. Do not pull tunneler out at an angle. Keep tunneler straight to prevent damage to catheter tip.
8. 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.
9. Femoral Catheter tip placement is recommended at the junction of the diastic vein and the inferior vena cava.

**DIRECTIONS FOR SELDINGER INSERTION:**

1. Carefully read instructions 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.

**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.**

**DIRECTIONS FOR SELLINGER INSERTION**

1. Insert the introducer needle with attached syringe into the target vein. Aspirate to ensure proper placement.
2. Insert the introducer needle with attached syringe into the target vein. Aspirate to ensure proper placement.
3. Place the site above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask with forward motion into and past the needle hub into the target vein.
4. Insert the introducer needle with attached syringe into the target vein. Aspirate to ensure proper placement.
5. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Goal linear end of the guidewire into the subclavian vein in its entirety. Insert advancing distal end into the needle hub. Advance guidewire forward into the target vein. **Caution:** The length of the wire inserted is determined by the size of the patient. Meticulous patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. If a cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. This procedure should be held securely during this procedure.
6. Insert needle into the subclavian vein of the patient. Examine catheter lumen and extensions before and after each treatment for damage.
7. Do not use sterile syringes, syringes, or needles. Do not use any specific patient.
8. Use standard hospital protocols when applicable.

**Figure A**

15. Slowly reextract the guidewire and dilator, leaving the sheath in position. The hemodialysis will reduce the loss of blood and the inadvertent aspiration of air through the sheath.
16. Introduce catheter through the hemodialysis-valve and advance in an downward to the patient. The hemodialysis-valve will reduce the loss of blood and the inadvertent aspiration of air through the sheath.
17. Insert the introducer needle with attached syringe into the target vein. Aspirate to ensure proper placement.
18. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Goal linear end of the guidewire into the subclavian vein in its entirety. Insert advancing distal end into the needle hub. Advance guidewire forward into the target vein. **Caution:** The length of the wire inserted is determined by the size of the patient. Meticulous patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. If a cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. This procedure should be held securely during this procedure.
19. Insert needle into the subclavian vein of the patient. Examine catheter lumen and extensions before and after each treatment for damage.
20. Do not use sterile syringes, syringes, or needles. Do not use any specific patient.
21. Use standard hospital protocols when applicable.
28. Catheter must be secured/sutured for entire duration of implantation.

29. 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 or 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 protocol for heparin solutions.

Dress heparin into two syringes, corresponding to the amount designated on the arterial and venous extensions. Assure that the syringes are free of air.

Flow vs. Pressure Data

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Heparin solution: 1000 U/mL

SITE CARE

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

CATHETER REMOVAL

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

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

1. Palpate the catheter exit tunnel to locate the cuff.
2. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
4. Make a 2 cm incision over the cuff, parallel to the catheter.
5. Dissect down to the cuff using blunt and sharp dissection as indicated.
6. When visible, grasp cuff with clamp.
7. Clamp catheter between the cuff and the insertion site.
8. Cut catheter between cuff and exit site. Withdraw internal portion of catheter through the incision in the tunnel.
9. Remove remaining section of catheter (i.e. portion in tunnel) through the exit site.

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

AngioDynamics: DuryMax, and Durathane are registered trademarks of AngioDynamics, Inc.
SafeSheath D-Pro is a registered trademark of Pressure Products Inc.
U.S. Patent pending.

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

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AngioDynamics
103 Quenby Ave.
Queensbury, NY 12426 U.S.A.
Phone: 518-796-1215
Fax: 518-796-1360

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