INSTRUCTIONS FOR USE

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

2. Use only Luer Lock (threaded) connectors with this catheter.

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

4. Use standard hospital protocols.

5. The heparin solution must be removed immediately.

6. Do not advance the stainless steel guidewire or catheter if ultrasound resistance is excessive.

7. Do not insert or withdraw the guidewire forcibly from any component. The wire could break or unravel. If the guidewire became damaged, the catheter and guidewire must be removed together.

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

9. This catheter is for Single Use Only.

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

11. Re-use may lead to infection or illness/injury.

12. The manufacturer shall not be liable for any damages caused by re-use or reserialization of this catheter or accessories.

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

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

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

CATHETER PRECAUTIONS:

1. Do not use sharp instruments near the insertion area. A small rolled towel may be placed under the insertion area to facilitate the extension of the catheter.

2. The position of the subclavian vein, which is posterior to the clavicle, is easily damaged.

3. Clamping the catheter repeatedly in the same location will weaken the tubing. Avoid clamping near the lumen and hub of the catheter.

4. Do not clamp over guidewire or stylet - tubing may become damaged.

5. Examine catheter lumens and extensions before and after each treatment for damage.

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

7. 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.)

8. The patient should lie completely on his/her back. Both femoral veins should be palpated for venous selection and confirmation assessment. The knee 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.

9. If a leak is found, the catheter should be removed and precautions to prevent blood loss or air embolism are taken.

10. Monitor patient for arrhythmia throughout this procedure. Cardiac arrhythmia may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

11. If a leak is found, the catheter should be removed and precautions to prevent blood loss or air embolism are taken.

12. Attach syringes to both extensions and open clamps. Blood should aspirate easily from both arterial and venous sites. If either side exhibits abnormal resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flow.

13. If a leak is found, the catheter should be removed and precautions to prevent blood loss or air embolism are taken.

14. Clamp the extensions, remove the syringes, and place an injectant on each hanger lock connector. Avoid air embolism by keeping 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.

15. Cover the insertion site with an occlusive dressing.

16. The length of the wire inserted is determined by the size of the patient. Monitor the wire as it enters the venous system and note the location of the wire. Do not allow the wire to pass into the right atrium. The guidewire should be held securely during this procedure.

17. Thread the dilator over the proximal end of the guidewire. Dilate subcutaneous tissue and vein wall to allow easy passage into target vein.

18. Catheter must be secured/sutured for continued use in serious trauma or fatal complications.

CATHETER SECUREMENT AND WOUND DRESSING:

19. Catheter must be secured/sutured for continued use in serious trauma or fatal complications.

HEMODIALYSIS TREATMENT:

20. The heparin solution must be removed from the subclavian vein prior to treatment. Prevent systemic heparinization of the patient. Heparin use should be based on dialysis unit protocol.

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

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

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


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

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

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.

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.

SITE CARE

Warning: DO NOT use iodine or iodine based products on this catheter. Failure of catheter will occur. Alcohol based solutions are recommended as the antiseptic solution that can be used on this catheter.

- Clean the skin around catheter. Cover the exit site with occlusive dressing. Leave the extensions, clamps, adapters and caps exposed for access by staff.
- Wound dressings must be kept dry. Patients 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.

Heparination

- 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 concentration.

Obstructions due to clotting or fibrin sheath may result in either complete or partial occlusion of the arterial side holes. These obstructions may be managed using appropriate mechanical or chemical intervention. Routine heparinization is recommended as the antiseptic solution that can be used on this catheter.

- Apply dressing in a manner to promote optimal healing.

Difficulties frequently arise in maintaining patency between treatments. If the catheter is not to be used immediately for treatment, follow the suggested patency guidelines. To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.

- Follow hospital protocol for heparin concentration.

- 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.
- 2. Remove injection caps from the extensions.
- 3. Attach a syringe containing heparin solution to the female luer of each extension.
- 4. Open extension clamps.
- 5. Aspirate to insure that no air will be forced into the patient.
- 6. Inject heparin into each lumen using quick bolus technique.
- 7. Close extension clamps.
- 8. Remove syringes.
- 9. Attach a sterile injection cap onto the female luer of each extension.

Warning: Do not use iodine or iodine based products on this catheter. Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp reserves the right to modify its products or contents without notice.

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