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

**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.

**DESCRIPTION:**
- The Medcomp® Tunnelled Dialysis Catheter is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent biocompatibility.

**POSSIBLE COMPLICATIONS:**
- 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 trocar to the sheath may break or unravel. If the guidewire becomes damaged or clogged, do not attempt to repair it. Preferable Introducer and guidewire must be removed together.
- Federal Law (U.S.A) restricts the device to sale by or on the order of a physician.
- This catheter is for Single Use Only.
- Do not resterilize the catheter or accessories.
- Contents sterile and non-sterile in unopened, undamaged packaging.
- Potentially oxidized by Ethylene Oxide.
- Do not use catheter or accessories package if opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

**CATHER PREREQUISITES:**
- 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 those provided with this kit are used.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the lumen and hub of the catheter.
- Examiner 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:**
- **EQUIPMENT:**
- A sterile operative field. The Operating Room is the preferred insertion area. The nurse should remain in the sterile field.
- Use clamps provided.
- Advancer’s stylet cap onto venous catheter luer.
- Never leave sheath in place as an indwelling intravenous catheter.
- TROCAR:
- A sterile disposable 22-gauge needle with a length of 1.5 inches and a stylet.
- INSTRUMENTS:
- HAVE PATIENT WEAR A MASK.
- **WARNING:**
- **CATHETERIZATION:**
- The patient should lie completely on his/her back. Both femoral arteries should be palpated for site selection and consequence assessment.
- The knee on the same side of the insertion site should be flexed and the thigh abducted. Place the opposite leg. The femoral vein is then accessible to the artery.
- **Cautions:** The incidence of infection may be increased with femoral vein insertion.
- **DIRECTIONS FOR SELDINGER INSERTION:**
- **Note:** A tunnel with a gentle arc accesses the risk of kinking. The tunnel should be short enough to keep the V-port of the catheter from entering the exit site, yet long enough to keep the cuff 2cm (minimum) from the skin opening.
- **1.** Push stylet back into catheter and tighten stylet cap onto venous catheter lumen.
- **2.** Irrigate catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drawn from lumen. Use clamps provided.
- **3.** Insert the introducer needle with attached syringe into the target vein. Aspirate to confirm correct placement prior to use.
- **4.** Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Once flow of guidewire back into advance as that only the end of the guidewire is visible. Insert advancement's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.
- **5.** **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 arrhythmia may result if guidance wire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.
- **6.** **Caution:** If alternate sheath is used, follow manufacturer’s instructions.
- **7.** After the catheter has been positioned, crack the sheath handle in half.
- **8.** Pull the non-valved side of the handle partially away from the catheter.

**POTENTIAL COMPLICATIONS:**
- **Subclavian Artery Puncture**
- **Retroperitoneal Bleed**
- **Do not use sharp instruments near the Subclavian Artery Puncture**
- **Use only Luer Lock (threaded) Connectors**
- **Laceration of the Vessel**
- **Lumen Thrombosis**
- **Do not insert or withdraw the guidewire**
- It may be inserted percutaneously and is recommended at the junction of the iliac veins. The patient should lie completely on his/her back. Both femoral arteries should be palpated for site selection and consequence assessment.
- The knee on the same side of the insertion site should be flexed and the thigh abducted. Place the opposite leg. The femoral vein is then accessible to the artery.
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- **8.** Pull the non-valved side of the handle partially away from the catheter.
Clinically recognized infection at a catheter

If a leak is found, the catheter should be removed. End caps should be flushed using saline before removal. If the catheter is inadvertently removed, it should not be replaced. Notify the Medical Component Service Center immediately.

Cover the exit site with occlusive dressing

Follow hospital protocol for heparinization guidelines. The 4F introducer, in response to catheter performance problems, should always use Universal Blood and Body Fluid Precautions in the care of all patients.

Catheter is compatible with ointments

Hemodialysis should be performed under sterile technique. Prior to each use, with each change in catheter, and extracorporeal circuits should be flushed with saline to try to move the tip away from the vessel wall.

INFECCTION:

Catheter: 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 entry. If wound cultures are 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.

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 fileter sheath.

- Occlusion of the arterial side holes due to contact with vein wall.

Solutions include:

- Chemical intervention utilizing a local anesthetic agent.

MANAGEMENT OF ONE-WAY OBSTRACTIONS:

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.

Caution: Do not pull distal end of catheter through incision as contamination of the vessel 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 the catheter when it was inserted.

HOMEOIATHYIS 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 begin 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 extension clamps.

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

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

If profuse periparation or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile technique.

SITE CARE

Catheter is compatible with ointments.

Close skin around catheter.

Chlorhexidine gluconate solutions are recommended.

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: Do not suture the catheter tubing.

Fluid Precautions in the care of all patients.

CATHETER REMOVAL

Caution: Remove syringes.

Close the extension clamps, remove the syringes.

For aspiration, flushing, and dialysis treatment, clamp immediately.

Shoot catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.

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

**Rx Only**

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