INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Medcomp® Titan HD™ 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 includes the 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.

DESCRIPTION:

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

POTENTIAL COMPLICATIONS:

- The incidence of infection may be decreased by using sterile technique.

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

WARNINGS:

- In the rare event that a hub or connector separate 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 from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or Valved Peelable 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.
- Re-Use may lead to infection or illness.
- 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.
- STERILE BY ETHYLENE OXIDE
- Do not use catheter or accessories if package is open or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

INSERTION SITES:

- Have patient lie flat on 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 where the carotid arch should be palpated medial to the point of catheter insertion.

Subclavian Vein

- Do not use sharp instruments near the extension tubing or catheter lumen.
- Do not use scissors to remove dressing. catheter.
- Catheter will be damaged if clamps other than what is provided with this kit are used.
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- Examine catheter lumen and extensions before and after each treatment for damage.
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Tip Placement

- Femoral Vein

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

Internal Jugular Vein

- Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.
- The selection of the appropriate catheter length is at the sole discretion of the physician. A proper tip placement, proper catheter length, selection is important. Routinely x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.
- Administer sufficient local anesthetic to completely anesthetize the insertion site.
- Make a small incision at the exit site on the chest wall approximately 8-10cm 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 cuff, approximately 1-2cm.
- Use blunt dissection to create the subcutaneous tunnel opening. Unthread stylet cap from venous femoral lumen and slide to the venous lumen until the tip is no longer visible. Attach vacuum lumen to syringe. Slide tunneling sleeve over the catheter making certain that the sleeve covers the arterial tip of the catheter. Insert the trocar into the exit site and create a short subcutaneous tunnel which provides tunneling through the muscle. The tunnel should be made with care in order to prevent damage to surrounding vessels.
- For Femoral Vein Insertion: Create subcutaneous tunnel with the catheter exit site in the pubic region.

Cautions: The incidence of infection may be increased with femoral vein insertion.

- 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.
- Femoral catheter tip placement is recommended at the junction of the iliac vein and the inferior vena cava.

DIRECTIONS FOR SELLINGER 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 are not to represent all medically acceptable protocols, use are they intended to substitute for the physician’s experience and judgment 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 operating 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.

7. Push stylet back into catheter and tighten stylet cap onto venous catheter luer.

8. Irrigate catheter with saline, then clamp catheter extensions at syringe. Recap syringe. Irrigate catheter with saline is not inadvertently drained from lumen. Use clamps provided.

9. Insert the introducer needle with attached syringe into the tunneling area. Aspire to ensure proper placement.

10. Remove the syringe and place thumb over end of the needle to prevent blood loss or air embolism. Draw flexible end of guide wire back into advanced state so that only the end of the guide wire is visible. Insert advance guide wire with forward motion into and past the needle hub into the target vein.

Caution: The length of the wire is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The physician 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 secured during this procedure.

11. Remove needle, leaving guidewire in the target vein. Enlarge cutaneous puncture site with scalpel.

12. Thread dilator(s) over guide wire into the vessel (or slight twisting motion may be used). Remove dilator(s) when vessel is sufficiently dilated, leaving guidewire in place.

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

The Valved Pleurable Introducer Shhath is designed to reduce blood loss and risk of air embolism but it is not a hemostasis valve.

It is not intended to create a complete two-way seal nor is it intended for arterial use.

The valve will substantially reduce air intake. At 12-mm Hg suction pressure of the Valved Pleurable Introducer Shhath may allow up to 4cc/sec of air to pass through the valve.

The valve will substantially reduce the rate of blood loss but some blood loss through the valve may occur.

13. Remove the dilator from the sheath and slide the catheter over the sheath opening. Insert the dilator through the valve and lock in place using the rotating collar.
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 the catheter and extracorporeal circuits should be examined carefully.
• Ensure that extension clamps are open during dialysis treatment.
• After dialysis begins all connections to the catheter and extracorporeal circuits should be examined carefully.
• If a leak is found, the catheter should be clamped immediately.
• Catheter is compatible with on-table 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.

HEMORRHAGE
• If hemorrhage is not to be used immediately for treatment, follow the suggested catheter patency guidelines.
• Hemorrhage should be performed under physician’s instructions.

HEPAPTINIZATION
• To maintain patency, a heparin lock must be created in both lumens. Refer to hospital heparinization guidelines.

CAUTION:
• Ensure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism.

22. 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 flow.

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

24. Close the extension clamps, remove the syringes, and place the catheter on each hair lockavoider. Avoid air embolism by keeping extension tubing clamped at all times. Remove it 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.

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

26. Once the catheter is locked with heparin, close the clamps and install injection caps onto the extensions’ female luer.

27. Confirm proper tip placement with fluoroscopy. The distal seive tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure optimal blood flow (as recommended in current NKF DOQI Guidelines).

Note: Femoral catheter tip placement is recommended at the junction of the iliac vein and the inferior vena cava.

CAUTION:
• Failure to verify catheter tip placement may result in serious trauma or fatal complications.

CATHETER SECUREMENT AND WOUND DRESSING:
• Suture insertion site closed. Suture the catheter to the skin using the suture material corresponding to the amount designated by the physician’s instructions. 

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.

29. Cover the insertion and exit site with an occlusive dressing.

30. Catheter must be secured/flushed for entire duration of implantation.

31. Record catheter length and catheter lot number on patient’s chart.

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• 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.

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

INSUFFICIENT FLOWS:
• The following may cause insufficient blood flow:
  - Occluded arterial holes due to clotting or embolism.
  - Occlusion of the arterial side holes due to clotting, or embolism.
  - Occlusion of the arterial side holes due to contact with vein wall.
  - Occlusion of the venous side holes due to contact with extension caps.
  - Chemical intervention utilizing a thromolytic agent.

MANAGEMENT OF ONE-WAY MALPOSITION:
• One-way obstructions exist when a lumen fails to aspirate while another, corresponding to the amount designated by the physician’s instructions. 

CAUTION:
• 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.

CATHETER REMOVAL
• 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 at one 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 #1.3.

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

WARNING:
• 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.


References:

PN 40247
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