medCOMP®

14F Split Cath Rg®
LONG-TERM HEMODIALYSIS

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Medcomp® 14F Split Cath Rg® 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.
- Alternate insertion sites include the subclavian vein and femoral vein.

CONTRAINDICATIONS:

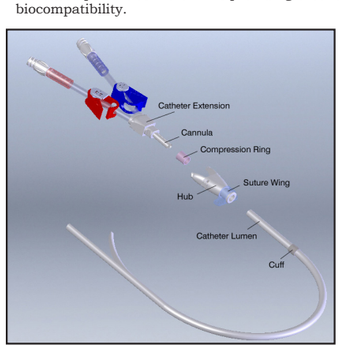
- This catheter is intended for Long-Term vascular access only and should **NOT** be used for any purpose other than indicated in these instructions.

WARNINGS:

- 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 Valved Peelable introducer and guidewire must be removed together.
- Do **NOT** resterilize the catheter or accessories by any method.
- 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.
- Do **NOT** use sharp instruments near the extension tubing or catheter lumen.
- Do **NOT** use scissors to remove dressing.
- End caps are not intended to be punctured with a needle.

DESCRIPTION:

- The versatility of the 14F Split Cath Rg® allows the lumens to be split to form two free floating lumens to help eliminate catheter occlusion by the vessel.
- The 14F Split Cath Rg® is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent biocompatibility.



POTENTIAL COMPLICATIONS:

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

- Before attempting the insertion, ensure that you are familiar with the potential 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.
- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- This catheter is for Single Use Only.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of this catheter or accessories.
- Re-use may lead to infection or illness/injury.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE

STERILE	EO

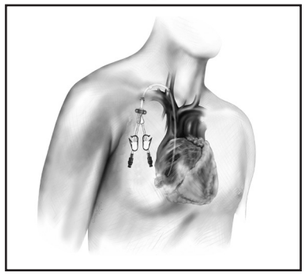
- Catheter will be damaged if clamps other than what is provided with this kit are used.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the luer and adapter of the 14F Split Cath Rg® extension set.
- Examine catheter lumen and extension set before and after each treatment for damage.
- Assure the security of all caps and bloodline connections prior to and between treatments to prevent disconnections resulting in air embolism or blood loss.
- 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.
- When cutting catheter to desired length, assure the lumen is cut square and that the remaining catheter lumen is not damaged.
- Reversing the lines during hemodialysis will increase recirculation.
- Device contains stainless steel components which may respond to magnetic fields created by MRI scanning. Please see the MRI Safety Information portion of these instructions for more details.

INSERTION SITES:

Warning: Physician discretion is strongly advised when inserting this catheter in patients who are unable to take or hold a deep breath.

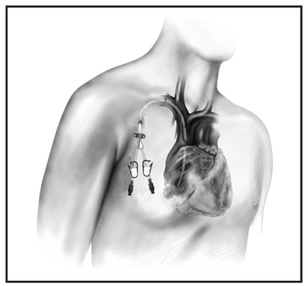
- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

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

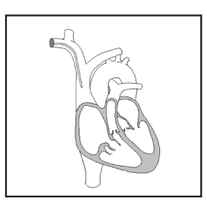


- Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib.)

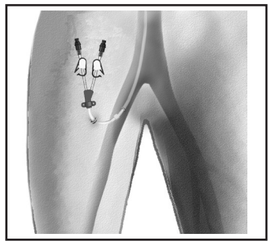
Warning: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.

Warning: Extended use of the subclavian vein may be associated with subclavian vein stenosis.

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 knee on the same 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.

Caution: 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.[1]

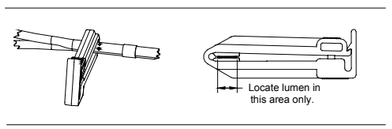
DIRECTIONS FOR SELDINGER INSERTION

- 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 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 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. Split the arterial and venous lumens by grasping the distal ends and gently pull apart the lumens to the point printed "**DO NOT SPLIT BEYOND THIS POINT**".

Warning: Splitting the lumens beyond this point may result in excess tunnel bleeding, infection, or damage to the catheter lumens.

5. Attach syringe to tunneling adaptor and prime lumens. Ensure saline exits both arterial and venous distal tips.
6. Attach temporary lumen clamp between extensions and reference line (dots) as shown in picture.



7. Remove syringe.

INSERTION:

8. Insert the introducer needle with attached syringe, or into the target vein. Aspriate to insure proper placement.
9. 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 signs of 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.

10. Remove needle, leaving guidewire in the target vein. Enlarge puncture site with scalpel.
11. Thread dilator(s) over guidewire into the vessel (a slight twisting motion may be used). Remove dilator(s) when vessel is sufficiently dilated, leaving guidewire in place.

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

12. Thread Valved Peelable introducer over the proximal end of the guidewire. Once the Valved Peelable introducer is in target vein, remove the guidewire leaving the sheath and dilator in position.

Warning: 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, regrasp 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.

Warning: Never leave sheaths in place as indwelling catheters. Damage to the vein will occur.

13. Install end cap over dilator openings to prevent blood loss or air embolism.
14. Remove dilator and end cap from sheath.
15. Insert catheter tip into and through the sheath until tip is correctly positioned in the target vein.
16. Remove the Valved Peelable introducer slowly pulling the sheath out of the vessel while splitting the sheath by grasping the tabs and pulling them apart.

Warning: 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.

17. Make any adjustments to catheter position under 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.

Note: Femoral catheter tip placement is recommended at the junction of the iliac vein and the inferior vena cava.[1]

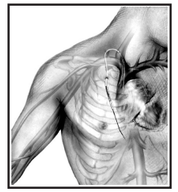
TUNNELIZATION & CUFF PLACEMENT:

18. Position catheter over anticipated tunnel path.
19. Note the desired location at which the cuff will be positioned.
20. Administer sufficient anesthetic to the entire length of tunnel path and exit site.
21. Remove stylet and clamp lumen prior to tunnelization.
22. Perform retrograde tunnel two possible ways.

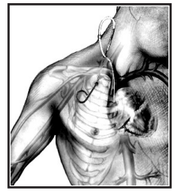
    22a. Using straight blunt tunneler (remove tunneling sleeve). Attach tunneler to tunneler adaptor at priming end of lumen. Tunnel down chest wall.

    22b. Using ring handled tunneler. Insert ring handled tunneler through exit site up to the catheter through tunnel. Attach catheter to the tunneler and pull lumen back through to the exit site.

22a.



22b.



23. Remove and retain temporary lumen clamp for subsequent instructions.
24. Make an incision at the tunnel exit site. Make the incision at the exit site wide enough to accommodate the cuff, approximately 1cm.
25. Use blunt dissection to create the subcutaneous tunnel opening. Insert the tunneler into the insertion site and create a short subcutaneous tunnel. Tunnel in the direction of the tunnel exit site incision. Do not tunnel through muscle. The tunnel should be made with care in order to prevent damage to surrounding vessels.

    25a. For Femoral Vein Insertion: Create subcutaneous tunnel with the catheter exit site in the pelvic region.

Warning: Do **NOT** over-expand subcutaneous tissue during tunneling. Over-expansion may delay/prevent cuff in-growth.

26. Lead catheter into the tunnel gently. Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion.

Warning: Do **NOT** pull tunneler out at an angle. Keep tunneler straight to prevent damage to catheter tip.

Note: A tunnel with a wide gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the extension set of the catheter from entering the exit site, yet long enough to keep the cuff 2cm (minimum) from the skin opening.

27. Reattach temporary lumen clamp in same location as previously noted in #6.

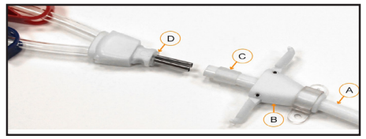
ASSEMBLY OF THE 14F Split Cath Rg®:

28. Clamp using catheter clamp provided to prevent blood loss or air embolism.

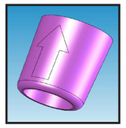
29. Remove tunneling adaptor by cutting catheter lumen squarely at the designated line and in such a manner that produces a clean, smooth surface. Cut only at designated line.

Caution: Use only the Medcomp® 14F Split Cath Rg® extension with this catheter.

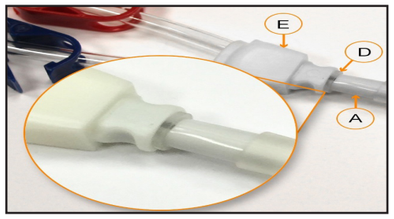
Warning: Do **NOT** soak catheter end, hub, compression ring or extensions in any antiseptic (i.e. alcohol, PVP, etc.) before or during assembly.



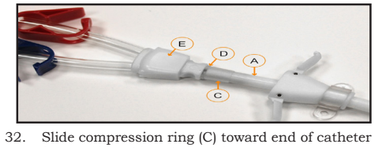
30. Slide the catheter lumen (A) into the hub (B). If the compression ring (C) dislodges from the hub, slide it over catheter lumen (A). The arrow indicator on the compression ring must be pointed upward, toward gasket (D) on the catheter extension.



Note: A replacement compression ring is included in the kit.

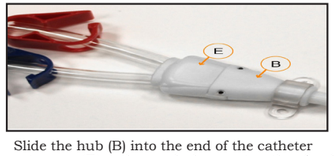


31. Align the arterial (Red) and venous (Blue) lumen printing with like color clamps of the extension assembly and insert the metal cannula of the catheter extension (E) into the catheter lumen (A). The catheter lumen must be **FULLY** seated against the gasket (D) on the catheter extension (until no metal is visible).



32. Slide compression ring (C) toward end of catheter lumen (A) until seated as shown.

Caution: Compression ring **MUST** be fully seated.



33. Slide the hub (B) into the end of the catheter extension (E) and press hub arms together firmly around the extension base. A gentle tug will assure proper assembly.

Caution: Hub arms **MUST** be fully engaged.

34. Attach syringes to the 14F Split Cath Rg® extension and open clamps. Remove the temporary lumen clamp from the catheter. Blood should aspirate easily from the catheter. If the catheter exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to sustain adequate blood flow.

35. Once adequate aspiration has been achieved, the extension should be irrigated with heparin filled syringes using quick bolus technique. Assure that extension clamps are open for irrigation procedure.

Caution: Assure that all air has been aspirated from catheter and the 14F Split Cath Rg® extension. Failure to do so may result in air embolism.

36. Once the catheter is locked with heparin, close the extension clamps and remove the syringes, and install the end caps onto the extension's female luers.

37. 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 (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.[1]

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

CATHETER SECUREMENT AND WOUND DRESSING:

38. Suture insertion site closed. Suture the catheter to the skin using the suture wing hub. Do not suture the catheter tubing. Suture wing hub(s) should be flush against patient's skin.

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.

39. Cover the insertion and exit site with an occlusive dressings.

40. Catheter must be secured/sutured for entire duration of implantation.

41. Record catheter length and catheter lot number on patient's chart.

HEMODIALYSIS TREATMENT

- Scrub catheter hubs with an appropiate antiseptic after cap is removed and before accessing. Perform every time catheter is accessed or disconnected.
- 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.

Caution: Excessive blood loss may lead to patient shock.

- Hemodialysis should be performed under physician's instructions.
- Reversing the lines during hemodialysis will increase recirculation.

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 concentration.

1. Draw heparin into two syringes, corresponding to the amount indicated on catheter lumen. Assure that the syringes are free of air.

Note: Priming volume values printed on lumen include extension set.

2. Remove end 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.

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

7. Close extension clamps.

Caution: Clamps should only be open for aspiration, flushing, and dialysis treatment.

8. Remove syringes.
9. Attach a sterile end 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

- Clean skin around catheter. Chlorhexidine gluconate solutions are recommended; however, iodine-based solutions can be used. 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.
- Apply antibiotic ointment or povidone-iodine ointment to catheter exit sites during dressing change.

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.

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.

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.
3. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
4. Make a 2cm 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.

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

10. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.
11. Suture incision and apply dressing in a manner to promote optimal healing.
12. Check catheter for integrity when removed.

Flow vs. Pressure:

Size	Blood Flow Rate	
	300 ml/min	400 ml/min
14F x 24cm	**mmHg**	**mmHg**
Venous	64	100
Arterial	-71	-112
14F x 40cm	**mmHg**	**mmHg**
Venous	90	140
Arterial	-90	-143

Note: Table demonstrates average pressure of arterial and venous lumens during a simulated dialysis treatment at the respective flow rates indicated on the table. Fluid used was 55% Saline and 45% Glycerine with a viscosity similar to blood (3 to 4 centipose).

Priming Volume:

14F Split Cath Rg® Length	Venous	Arterial
24cm (1st cut)	1.9cc	1.8cc
24cm (2nd cut)	1.8cc	1.7cc
40cm (1st cut)	2.5cc	2.4cc
40cm (2nd cut)	2.4cc	2.3cc

MRI LABELING BASED ON THE TEST RESULTS

MRI Safety Information

MR

Non-clinical testing has demonstrated that the 14F Split Cath Rg® catheter/Extension Assembly is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) 4 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the 14F Split Cath Rg® catheter/Extension Assembly is expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the 14F Split Cath Rg® catheter/Extension Assembly when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

SYMBOL TABLE

5.1.1	Manufacturer *
5.3.4	Keep Dry *
5.4.2	Do Not Re-use *
5.6.3	Non-pyrogenic *
5.3.2	Keep Away from Sunlight *
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *
5.1.4	Use-by Date *
5.2.6 NON STERILE	Do Not Resterilize *
5.1.5 LOT	Batch/Lot Number *
5.1.6 REF	Catalogue Number *
5.4.4	Caution, consult Accompanying Documents *
MR	MR Conditional - 3 Tesla ****
5.2.8	Do Not Use if Package is Damaged *

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

***** FDA guidance Use of Symbols in Labeling.**

******This Symbol is in accordance with ASTM F 2503-13**

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

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 in accordance with all relevant regulatory requirements.

References:

1. Zaleski GX, Funaki B, Lorenz JM, Garofalo RS, Moscatel MA, Rosenblum JD, Leef JA. Experience with tunneled femoral hemodialysis catheters. *Am J Roentgenol.* 1999 Feb;172(2):493-6.

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