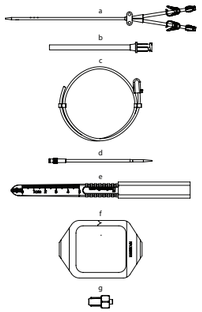
medCOMP®

DUO-FLOW® SIDE X SIDE DOUBLE LUMEN CATHETER INSTRUCTIONS FOR USE

DESCRIPTION:

- The Duo-Flow® Side X Side double lumen catheter is a radiopaque, polyurethane tube with two D-shaped lumina. The lumina can be distinguished by the color-coded luers:
  - Red Adapter = proximal lumen
  - Blue Adapter = distal lumen
- The proximal lumen provides "arterial" outflow from the patient; the distal lumen provides "venous" return.
- The catheter comes in a variety of sizes and is offered with curved or straight extensions.



9F/11F Basic Set Contains: (1) Catheter (a), (1) Introducer Needle (b), (1) Guidewire (c), (1) Dilator (d), (1) Scalpel (e), (1) Adhesive Wound Dressing (f), (2) End Caps (g)
12F Basic Set Contains: (1) Catheter (a), (1) Introducer Needle (b), (1) Guidewire (c), (2) Dilators (d), (1) Scalpel (e), (1) Adhesive Wound Dressing (f), (2) End Caps (g)

INDICATIONS FOR USE:

- The Duo-Flow® Side X Side double lumen catheter is intended for short-term central venous access for hemodialysis, apheresis and infusion.

CONTRAINDICATIONS:

- The catheter is not intended for any purpose other than indicated in these instructions. The Duo-Flow® Side X Side double lumen catheter is intended for short-term (less than 30 days) use. Do not use this catheter in thrombosed vessels or for subclavian puncture when a ventilator is in use.

Do not use this catheter when:

- The patient's body size is insufficient to accommodate the implanted device.
- The superficial or deep tissue will not permit adequate device stabilization and/or access.
- There are known physiological limitations that will not allow placement of the device.
- The patient has known or suspected allergies to any of the materials in the device.
- The patient has received significant radiation at the intended exit site or tunnel.
- The patient has severe chronic obstructive lung disease.

POTENTIAL COMPLICATIONS:

- Air Embolism
- Allergic Reaction
- Arterial Puncture
- Bacteremia
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Carotid Sinus Tract Infection
- Catheter Thrombosis
- Central Venous Thrombosis/Stenosis
- Endocarditis
- Exit Site Infection
- Exsanguination
- Extravasation
- Femoral Artery Bleed
- Femoral Nerve Damage
- Hematoma
- Hemorrhage
- Hemothorax
- Hydrothorax
- Inferior Vena Cava Puncture
- Inflammation, Necrosis, or Scarring of the Skin over the Implant Area
- Laceration of the Vessel
- Lower Limb Ischemia*
- Luminal Thrombosis
- Major Vessel or Right Atrial Damage
- Mediastinal Injury
- Mediastinal Widening
- Nerve Damage (Femoral)*
- Perforation of the Vessel
- Pleural Injury
- Pneumothorax
- Pulmonary Embolism
- Retroperitoneal Bleed
- Right Atrial Puncture
- Sepsis
- Septicemia
- Spontaneous Catheter Tip Malposition
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Trauma to Major Vessel or Right Atrium
- Vascular Thrombosis
- Vein Occlusion*

*Femoral Insertion Potential Complications

WARNINGS AND PRECAUTIONS:

- The catheter should be inserted and removed only by a qualified licensed physician or other health care practitioner authorized by and under the direction of such physician.
- The medical techniques and procedures described in these instructions do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient.
- Any complications arising from non-hemodialysis/ apheresis procedural use of the catheters are the sole responsibility of the person(s) using the catheter.
- Do not use catheter if package has been damaged or previously opened. Do not use catheter if it is crushed, cracked, cut, or otherwise damaged.
- Observe sterile technique at all times when handling the catheter.
- Use the guidewire straightener to insert the "J" end of the guidewire into the introducer needle. Do not insert or withdraw the guidewire forcibly from any component; the wire could break or unravel.
- Immediately after insertion and before using the catheter, use X-ray or fluoroscopy to verify that the catheter tip is positioned correctly; for jugular and subclavian insertions, ensure that the tip is positioned at the junction of the superior vena cava and the right atrium; failure to do so could result in serious trauma or fatal complications.
- To avoid exposure to blood borne pathogens, use universal precautions during catheter insertion and use.
- Single use only. Do not resterilize the catheter and/or components, either before or after use. The manufacturer will not be liable for any damages caused by re-use or resterilization of the catheter or accessories.

- Do not infuse incompatible drugs simultaneously through the same lumen: precipitation could occur.
- Use of the subclavian vein for catheter placement may result in subclavian vein stenosis. Subclavian vein stenosis may impair use of the ipsilateral extremity for future vascular access. Use of the jugular vein may be preferable.
- Avoid air embolism by keeping catheter extension tubing clamped at all times when not in use and by filling the catheter with sterile saline prior to implantation. With each tubing change, purge air from the tubing and aspirate any air in catheter.
- Overtightening catheter connections can crack the adapters.
- Do not clamp the dual lumen portion of the catheter; clamp only the extensions. When clamping, use only clamps supplied with the catheter.
- Clamping the catheter extensions repeatedly in the same spot could weaken the tubing: change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter and hub. Examine tubing after clamping for damage at the end of every treatment.
- Exercise caution when using sharp instruments near the catheter. Catheter tubing can tear when subjected to nicks, excess force, or rough edges.
- Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.
- When infusing anticoagulant lock solution, flush quickly and clamp immediately to ensure anticoagulant lock solution reaches the distal end of the lumen. Do not infuse against a closed clamp or forcibly infuse a blocked catheter: back pressure could force the adapter out of the tubing.
- The Duo-Flow® Side X Side double lumen catheter is intended for short-term (less than 30 days) use.
- End caps are not intended to be punctured with a needle.

Per KDOQI Guidelines:

1. Uncuffed HD catheters should only be used in hospitalized patients and for less than 1 week. Uncuffed femoral catheters should only be used in bed-bound patients.
2. There should be a plan to:
   i) Discontinue, or
   ii) Convert any short-term catheter to a long-term catheter within 1 week.

- Discard catheter after one-time use.
- Do not use acetone or any solution containing acetone on any part of the catheter. Exposure to these agents may cause catheter damage.

Any ONE of the following can be used:

- Bactroban Ointment, 2.% Mupirocin, Polyethylene Glycol Ointment, N.F.
- Silvadene Cream, 1% Silver Sulfadiazine
- 10% Povidone-Iodine Ointment
- Polysporin or Triple Antibiotic Ointment
- 0.1% Gentamycin
- Hydrogen Perioxide 3% Solution
- 10% Iodophor Iodine
- Chloroprep, 2% Chlorhexidine d- Digluconate + 70% Isopropanol (Isopropyl Alcohol)
- Anasept, 0.057% Sodium Hydrochlorite
- 70% Alcohol

- It is recommended that only luer-lock (threaded) connections be used (including syringes, bloodlines, IV tubing, and end caps) with the catheter.
- Federal law (USA) restricts the device to sale by or on the order of a physician. **Rx Only**
- Re-use may lead to infection or illness/injury.
- Contents sterile and non-pyrogenic in unopened or undamaged package.
  STERILIZED BY ETHYLENE OXIDE

STERILE | EO

Discard biohazard according to facility protocol.

- Avoid excessive or repeated suture tightening or knotting at the site of venous insertion.
- Avoid prolonged exposure to ultraviolet light.
- If the placement needle accidentally punctures the pleural space, immediately remove the needle and observe for symptoms of pleural puncture such as shortness of breath, chest pain, and sharp pain on inhalation.
- During removal of the catheter, slowly and gently withdraw the catheter to avoid damage to a vessel.
- Before treatment is started, ensure that all connections to the extracorporeal circuit are checked. During all dialysis procedures, perform inspection of the circuit, with a focus on detecting air and blood leaks.
- Prior to and during use of the catheter, refer to institution catheter patency guidelines to prevent malfunction.
- Femoral catheter insertion and use is associated with increased risks, including infection.
- If the catheter hub or connector separates from the catheter, immediately remove the catheter and observe for blood loss or air entry.
- Prolonged use of the subclavian vein for vascular access may be associated with subclavian vein stenosis.
- Recirculation in femoral catheters has been shown to be significantly greater than in internal jugular or subclavian catheters.
- Keep catheter extension tubing clamped at all times when not in use.
- After use, dispose of the product and its packaging in accordance with administrative and/or local, state and federal laws and regulations.

INSERTING THE CATHETER:

- Caution: Read this procedure carefully before inserting the catheter.
- The operating room is the preferred location for insertion; however, bedside insertion is acceptable if sterile technique is followed.

1. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient and all personnel in attendance wear a mask.
2. Place the patient in a supine position and expose the upper neck, chest or the groin on the side to be accessed.

   For subclavian and jugular insertion: Turn the patient's head slightly to the side to expose the insertion site. The Trendelenburg position may facilitate insertion and prevent air embolism.

   For femoral insertion: Flex the patient's knee on the same side as the insertion site. Abduct the thigh on the same side and place the foot across the opposite leg.
3. Shave the access site (optional) and scrub the area with an appropriate antiseptic solution. Isolate the access site with sterile drapes.
4. Attach an anticoagulant lock solution syringe to each adapter of the catheter. Fill the catheter with appropriate priming volume of anticoagulant lock solution and clamp immediately. Leave the syringes attached to the adaptors.

WARNING: To prevent air embolism, keep the catheter clamped at all times when not attached to a syringe, IV tubing, or bloodlines.

5. Administer local anesthetic to the skin and underlying tissue at the insertion site.
6. Flush an 18G Introducer needle with anticoagulant lock solution. Insert the needle into the vein in the direction of the blood flow. Aspirate a small amount of blood to ensure the needle is correctly positioned in the vein. CAUTION: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that bleeding has stopped and that no hematomas have developed before attempting to cannulate the vein again.
7a. Disconnect the syringe from the needle and promptly insert the flexible "J" end of the guidewire through the introducer needle. Failure to insert promptly may lead to air embolus or blood loss through the needle. Advance the guidewire into the vein.

CAUTION: For subclavian and jugular insertion: The length of wire inserted is determined by the size of the patient. Cardiac arrhythmia can result if the guidewire passes into the right atrium; if symptoms occur, pull back the guidewire until they are eliminated. If the guidewire meets resistance, do not pull it back through the needle. Remove the guidewire and the needle as a unit, and then begin again with a new needle and guidewire.

Do not pull guidewire back forcibly through any components.

7b. Withdraw the introducer needle while holding the guidewire firmly in place. **CAUTION:** Do not let the guidewire move farther into the vein during the following steps.

8. Make a small incision (0.5cm) near the guidewire at the skin entry site to facilitate passage of the dilator and catheter.
9. Thread a dilator over the end of the guidewire and, with a rotating motion, advance the dilator through the skin and soft tissue until it is just inside the vein. If the dilator does not reduce the resistance sufficiently for the catheter to pass over the wire, progress to the next French size dilator. Once the tract is dilated, remove the tissue dilator and discard.

Caution: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

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.

10. Thread the tip of the catheter over the wire. Open the clamp on the distal extension (blue adapter) and remove the syringe to permit the guidewire to exit. Using a rotational motion, advance the catheter through the soft tissue into the vein. Catheter adjustment may be necessary during insertion over the guidewire. CAUTION: Observe the patient carefully for signs and symptoms of cardiac arrhythmia caused by passage of the catheter into the right atrium. If symptoms appear, pull back the tip until they are eliminated. For jugular and subclavian insertions, use x-ray or fluoroscopy to ensure that the tip of the catheter lies at the junction of the superior vena cava and the right atrium. If using the catheter for hemodialysis or apheresis, orient the blue adapter cephalad. This positions the "arterial" inlet away from the wall of the superior vena cava, reducing the potential for one-way inlet obstruction.

11. Holding the catheter firmly in place, gently withdraw the guidewire from the lumen. (If the guidewire meets more than slight resistance, do not pull It through the catheter. Remove the catheter and the guidewire together as a unit and begin again with new catheter and catheter insertion components.)
12. Verify patency by aspirating blood through the blue adapter of the catheter. With patency confirmed, inject sterile normal saline, followed by appropriate anticoagulant lock solution priming volume indicated on catheter extension. Clamp the extension and attach a sterile end cap to the adapter.
13. Release the clamp on the proximal extension (red adapter) and verify patency of the proximal lumen by aspirating blood. Inject sterile normal saline followed by appropriate anticoagulant lock solution priming volume indicated on catheter extension. Clamp the extension and attach a sterile end cap to the adapter.
14. Use x-ray or fluoroscopy to verify correct placement of the catheter tip.

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

15. Suture the catheter to the skin using the rotating suture wing. **Caution:** Do not suture the catheter tubing.
16. Apply dressing to the exit site. Leave the extensions, clamps, adapters, and caps exposed for access by the staff.

CATHETER LOCK:

To maintain patency between dialysis treatments, keep the lumina of the catheter filled with the appropriate concentration and volume of anticoagulant lock solution. Approved anticoagulant lock solution concentrations vary with each institution. Be sure to use those concentrations approved by your facility.

Lock catheter with anticoagulant lock solution after use.

Before initiating treatment, aspirate indwelling anticoagulant lock solution and discard. After treatment, flush well and instill fresh anticoagulant lock solution. If the interdialytic period is less than two days, a lower concentration of anticoagulant lock solution may be desirable.

In all cases, the patient's condition must be considered when choosing an anticoagulant lock solution regime. Use less anticoagulant lock solution in children and in adults with bleeding disorders. **NOTE:** Always defer to the physician's experience and judgement or institution protocol.

Priming Volume Information 9F Duo-Flow® Side x Side Double Lumen Catheter		
Part Description	**Priming Volume (cc)**	
Straight	**Arterial**	**Venous**
9F x 10cm	0.8	1.0
9F x 12cm	0.9	1.0
9F x 15cm	1.0	1.1
9F x 20cm	1.1	1.2
Curved Extensions	**Arterial**	**Venous**
9F x 7.5cm	0.9	1.0
9F x 12cm	1.0	1.1
9F x 15cm	1.1	1.2

Priming Volume Information 11F Duo-Flow® Side x Side Double Lumen Catheter		
Part Description	**Priming Volume (cc)**	
Straight	**Arterial**	**Venous**
11F x 12cm	1.1	1.2
11F x 15cm	1.2	1.4
11F x 20cm	1.4	1.5
11F x 24cm	1.5	1.6
Curved Extensions	**Arterial**	**Venous**
11F x 10cm	1.1	1.2
11F x 12cm	1.2	1.3
11F x 15cm	1.3	1.4
11F x 20cm	1.5	1.6

Priming Volume Information 12F Duo-Flow® Side x Side Double Lumen Catheter		
Part Description	**Priming Volume (cc)**	
Straight	**Arterial**	**Venous**
12F x 15cm	1.2	1.3
12F x 20cm	1.4	1.5
12F x 24cm	1.5	1.6
Curved Extensions	**Arterial**	**Venous**
12F x 13cm	1.1	1.2
12F x 15cm	1.2	1.3
12F x 20cm	1.4	1.5

PREPARATION:

1. Prepare supplies on a clean surface.
2. Wash hands thoroughly with soap and water.
3. Scrub the area surrounding the cap and catheter with an appropriate antiseptic solution. Allow to air dry.
4. Prepare the appropriate anticoagulant lock solution.

PROCEDURE:

1. Aspirate indwelling anticoagulant lock solution from the catheter before infusing fresh anticoagulant lock solution or initiating treatment.
2. Flush each lumen with 10 to 20mL sterile normal saline. Caution: Before flushing, pull the plunger back to verify blood flow and to ensure there are no blood clots. Do not flush clots through the catheter (see "Thrombus Formation").
3. Infuse fresh anticoagulant lock solution, flushing quickly to ensure that anticoagulant lock solution reaches the distal end of the lumen, and clamp immediately. Infusing or clamping too slowly may cause anticoagulant lock solution to exit the catheter from the proximal inlet slots, leaving the distal slot unprotected from thrombus formation. Perform procedure for both lumina. Do not infuse against a closed clamp or forcibly infuse a blocked catheter: back pressure could force the adapter to loosen and potentially come out of the tubing.

Once the lumina have been primed, keep the extensions clamped when not attached to bloodlines or a syringe. If an extension is unclamped, there is high risk of blood loss or air embolism. It also leads to a slightly increased priming volume. As a result of the tube returning to its "normal" unclamped state. This creates a vacuum at the tip, causing blood to be drawn into the distal portion of the catheter, ultimately resulting in a thrombus.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS:

Suspect one-way obstruction when a lumen can be flushed but cannot be aspirated. This is usually caused by tip malposition. Some signs of obstruction:

- There are air bubbles in the tubing set; blood is foamy.
- The venous drip chamber has collapsed or is at a lower level than normal.

One of the following adjustments may eliminate the obstruction:

- Have the patient hold his arms above his head and cough.
- Reposition the patient.
- Flush with saline to push the catheter away from the vessel wall.
- Rotate the catheter to position to the arterial inlet away from the wall of the superior vena cava and allow free flow of blood into the arterial lumen.

  Caution: Do not insert the catheter further into the vein.
- Reverse the bloodlines. If the previous methods fail to eliminate the obstruction, connect the arterial bloodline to the venous adapter and the venous bloodline to the arterial adapter. A significant increase in recirculation can be expected. This method is suggested only as an alternative to catheter replacement.
- Administer thrombolytic agent per hospital protocol.

  Note: Always defer to the physician's experience and judgement or institution protocol.

THROMBOSIS FORMATION:

- Never forcibly flush an obstructed lumen.
- If the catheter is blocked, first check to be sure it is not kinked. If thrombus is present, attempt to aspirate the clot gently with a 10 mL syringe. If infusion is still slow, or blood cannot be withdrawn at all, the physician may choose to dissolve the clot with a thrombolytic agent. Streptokinase is not recommended; it is reported to be anaphylactogenic in some patients. The cleared catheter may be used immediately.

NOTE: A catheter that does not clear after a repeated dose of thrombolytic agent may be blocked by a substance other than a blood clot.

EXIT SITE CARE:

Keep exit site dry at all times. Patient 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. To reduce the risk of infection while cleaning and dressing the exit site, wash hands thoroughly and wear sterile gloves. Use aseptic technique when handling the catheter and supplies. Before removing the end cap or any connecting line, clamp the catheter and scrub the area surrounding the cap and catheter with an appropriate antiseptic.

Maintain aseptic technique when handling or using the catheter. Before beginning, don mask, then wash hands thoroughly. Don non-sterile gloves if desired.

1. Remove the wound dressing carefully from the catheter and exit site.
2. Examine the exit site and surrounding area for inflammation, reddening, or discharge. Using a sterile gauze sponge, palpate the area surrounding the exit site for evidence of tenderness. If signs or symptoms of infection are present, notify the physician immediately. Before cleaning an infected site, verify whether the physician would like the exudate cultured. If so, collect the specimen before continuing.
3. Wash hands again, then don sterile gloves.
4. Clean the exit site in a circular motion from the catheter out, using an appropriate antiseptic. Allow to air dry. Apply with either sterile swabs or sterile gauze sponges.

   Do not use acetone or any solution containing acetone on any part of the catheter. Exposure to these agents may cause catheter damage.

   Any ONE of the following can be used:

   - Bactroban Ointment, 2.% Mupirocin, Polyethylene Glycol Ointment, N.F.
   - Silvadene Cream, 1% Silver Sulfadiazine
   - 10% Povidone-Iodine Ointment
   - Polysporin or Triple Antibiotic Ointment
   - 0.1% Gentamycin
   - Hydrogen Perioxide 3% Solution
   - 10% Iodophor Iodine
   - Chloroprep, 2% Chlorhexidine d-Digluconate + 70% Isopropanol (Isopropyl Alcohol)
   - Anasept, 0.057% Sodium Hydrochlorite
   - 70% Alcohol
5. Verify that the sutures are secure in the suture wing. The catheter should not be able to move in and out of the exit site.
6. Apply the transparent occlusive dressing. If desired, sterile gauze sponges can be placed around the catheter at the exit site before the dressing is applied; however, the sponges will impair visual examination of the site. Leave the extensions, clamps, adapters, and end caps exposed for access.

CATHETER REPLACEMENT:

Replace the catheter if infection occurs or if there is a progressive increase in venous resistance or progressive decrease in flow rates during the course of hemodialysis or apheresis treatment.

NOTE: These recommendations are not intended to supersede the physician's experience and judgement in treating specific patients.

1. Place the patient in a supine position and expose the exit site.
2. Maintain sterile technique. Remove the dressing and examine the exit site and surrounding area for signs or symptoms of infection. If present, the physician must determine whether to postpone catheter replacement until the infection has been successfully treated, or to access the patient in another site.
3. Gown; don sterile gloves, scrub the external portions of the catheter and surrounding area with an appropriate antiseptic, then isolate the site with sterile drapes.
4. Flush both lumina of the new catheter with 3 to 4 mL anticoagulant lock solution and clamp immediately.
5. Cut and remove the old sutures carefully from the skin.
6. Ensure that the clamp on the distal extension (blue adapter) of the indwelling catheter is closed. Simultaneously remove the end cap from the blue adapter while placing the "J" end of the correct guidewire into the lumen of the adapter. Open the clamp and pass the guidewire through the catheter to the appropriate position. Caution for subclavian and jugular insertion: Observe the patient for cardiac arrhythmia which may result if the guidewire passes into the right atrium.
7. Hold the guidewire steady to keep it from exiting the vein. Carefully remove the catheter by slicing it over the wire. Discard the old catheter.
8. Pass the new catheter over the guidewire following Steps 10 through 15 in INSERTING THE CATHETER.

12F Duo-Flow Side x Side Double Lumen Catheter
Average Pressure - mmHg

Flow Rate (ml/min)			100	200	300	400	500
Straight	15cm	Venous	10	30	53	88	128
		Arterial	-11	-29	-51	-79	-111
	20cm	Venous	12	32	62	101	150
		Arterial	-11	-30	-55	-89	-122
	24cm	Venous	20	40	70	114	166
		Arterial	-19	-37	-62	-99	-137
Curved Extensions	13cm	Venous	18	39	62	100	140
		Arterial	-10	-20	-42	-70	-99
	15cm	Venous	20	40	68	101	141
		Arterial	-10	-22	-43	-70	-101
	20cm	Venous	14	40	69	107	153
		Arterial	-11	-31	-59	-90	-126

11F Duo-Flow Side x Side Double Lumen Catheter
Average Pressure - mmHg

Flow Rate (ml/min)			100	200	300	400	500
Straight	12cm	Venous	10	31	59	91	129
		Arterial	-14	-30	-50	-80	-110
	15cm	Venous	9	31	60	94	134
		Arterial	-14	-32	-57	-86	-121
	20cm	Venous	11	35	64	100	141
		Arterial	-15	-36	-62	-94	-131
	24cm	Venous	20	39	71	116	167
		Arterial	-19	-40	-63	-101	-141
Curved Extensions	10cm	Venous	20	39	61	92	125
		Arterial	-9	-20	-37	-59	-82
	12cm	Venous	10	30	54	85	120
		Arterial	-10	-21	-42	-69	-95
	15cm	Venous	20	41	68	101	112
		Arterial	-10	-20	-42	-70	-101
	20cm	Venous	25	50	79	116	159
		Arterial	-10	-30	-52	-86	-121

9F Duo-Flow Side x Side Double Lumen Catheter
Average Pressure - mmHg

Flow Rate (ml/min)			100	200	300	400	500
Straight	10cm	Venous	12	40	92	109	147
		Arterial	-10	-34	-63	-99	-139
	12cm	Venous	20	47	83	124	166
		Arterial	-20	-41	-72	-110	-148
	15cm	Venous	20	52	88	131	173
		Arterial	-21	-48	-80	-119	-160
	20cm	Venous	24	60	104	154	200
		Arterial	-29	-59	-96	-141	-186
Curved Extensions	7.5cm	Venous	19	46	75	113	154
		Arterial	-10	-33	-53	-86	-123
	12cm	Venous	20	49	89	131	171
		Arterial	-20	-52	-87	-134	-180
	15cm	Venous	29	61	103	158	199
		Arterial	-16	-43	-81	-129	-176

Flow Rate vs. Pressure Data was obtained in vitro using a glycerin/saline analog with a viscosity of 3.5cP.

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 without notice.

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 *
5.2.8	Do Not Use if Package is Damaged *
5.1.4	Use-by Date *
5.2.6 STERILIZE	Do Not Resterilize *
5.1.5 LOT	Batch/Lot Number *
5.1.6 REF	Catalogue Number *
5.3.6	Upper Limit of Temperature *
5.4.4	Caution, consult Accompanying Documents *
Rx Only	Prescription Use Only ***
MR	MR Safe ****

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

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

******This Symbol is in accordance with ASTM F 2503-20**

Note: Temperature symbols : "This symbol only applies to kits with drugs".

MR

Medical Components, Inc.
1499 Delp Drive
Harleysville, PA 19438 U.S.A.
Tel:215-256-4201
Fax:215-256-1787
www.medcompnet.com

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