-Withdraw the catheter slightly to reposition the tip. Caution: Do not insert the catheter further into the vein.

-Reverse the bloodlines. If the previous methods fail to resolve a one-way obstruction, the patient may be dialyzed by connecting the arterial bloodline to the venous adaptor and the venous bloodline to the arterial adapter. A significant increase in recirculation may occur.

-Never forcibly flush an obstructed lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider using a thrombolytic agent to dissolve the clot.

INFECTION

Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use **universal blood and body-fluid precautions** in the care of all patients. Sterile technique must be strictly adhered to during the entire procedure.

Clinically recognized infection at the catheter site should be treated with an appropriate antibiotic. If a fever occurs in a patient with a catheter in place, take at least two blood cultures from a site distant from the catheter site. If a blood culture is positive, the catheter should be removed and appropriate antibiotic therapy initiated. Wait 48 hours before inserting another catheter. Insertion should be made only on the side opposite the site which became infected.

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. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
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.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY EFFECT 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.

Captive® J-Straightener is a registered trademark of Lake Region Manufacturing, Inc.

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5.1.1	Manufacturer *	5.6.3	Non-pyrogenic *
5.1.4	Use-by Date *	5.3.2	Keep Away from Sunlight *
5.4.2	Do Not Re-use *	5.2.6	Do Not Resterilize *
5.3.4	Keep Dry *	Rx Only	Prescription Use Only ***
5.1.5 LOT	Batch/Lot Number *	5.1.6 REF	Catalogue Number *
5.2.8	Do Not Use if Package is Damaged *		
5.1.2 EC REP	Authorized Representative in the European Community *		
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *		
5.3.7	Upper and Lower Temperature Limits *		
5.4.3	Consult Instructions for Use *		
5.4.4	Caution, consult Accompanying Documents *		

*** This symbol is in accordance with ISO 15223-1.**
***** FDA guidance Use of Symbols in Labeling.**

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

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medCOMP®

SIDE BY SIDE DOUBLE LUMEN CATHETER

INDICATIONS FOR USE

The Medcomp® Side by Side Double Lumen Catheter is designed for acute hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the jugular vein. Although this catheter may be inserted into the subclavian or femoral, the internal jugular is the preferred site. This catheter is indicated for a duration less than (30) days.

CONTRAINDICATIONS

This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.

POTENTIAL COMPLICATIONS

AIR EMBOLISM
BACTEREMIA
BRACHIAL PLEXUS INJURY
CARDIAC ARRHYTHMIA
CARDIAC TAMPONADE
CENTRAL VENOUS THROMBOSIS
ENDOCARDITIS
EXIT SITE INFECTION
EXSANGUINATION
FEMORAL ARTERY BLEED
FEMORAL NERVE DAMAGE
HEMATOMA
HEMORRHAGE
HEMOTHORAX
INFERIOR VENA CAVA PUNCTURE
LACERATION OF THE VESSEL
LUMINAL 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
VASCULAR THROMBOSIS

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

In the rare event that a hub or connector separates from any component during the insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove catheter immediately.

Do not advance the stainless steel guidewire or catheter if unusual elastic resistance is encountered. Do not insert or withdraw the guidewire forcibly from any component. The wire could break or unravel, in which case both the catheter and guidewire must be removed simultaneously.

WARNINGS

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

Single use only. Do not resterilize the catheter or accessories by any method. The manufacturer will not be liable for any damages caused by re-use or resterilization of the catheter or accessories. SINGLE USE 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

Do not use catheter if package is damaged or has been opened. Do not use if catheter or components show signs of damage (crimped, crushed, cut, etc.)

CATHETER PRECAUTIONS

Do not use sharp instruments near the extension lines or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage catheter. Do not suture through any part of the catheter. Catheter tubing can tear when subjected to excessive force or rough edges.

Use only smooth jawed forceps for clamping when not using the clamp supplied with the catheter. We recommend using only line extension clamps which have been provided for clamping. Clamping the catheter 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 of the catheter. Do not clamp the lumen portion of the catheter. Clamp only the extensions. Examine tubing for damage at the end of each treatment.

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

It is recommended that only luer lock (threaded) connections be used with this catheter (including syringes, bloodlines, IV tubing, and injection caps). Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure. Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.

INSERTION SITES

JUGULAR

Have the 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.

Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.

FEMORAL

The patient should lie completely on his/her back. Both femoral veins 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.

NOTE: For femoral placement, monitor patient closely for thrombosis, infection, and bleeding.

SUBCLAVIAN

The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite that of the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area. Note the position of the subclavian vein which is posterior to the clavicle, superior to the fist rib and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib).

NOTE: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation. Long time use of the subclavian vein may be associated with subclavian vein stenosis.

DIRECTIONS FOR SELDINGER INSERTION:

Read instructions carefully before using this device. The catheter should be inserted, manipulated 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. Use standard hospital protocols.

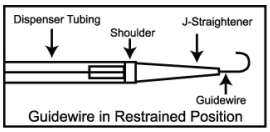
1. Strict aseptic technique must be used during the insertion, maintenance and catheter removal procedures. Provide a sterile operative field. The operating room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient wear a mask.

2. The selection of the appropriate cannula length is at the sole discretion of the physician. To concurrently achieve proper tip positioning, 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.

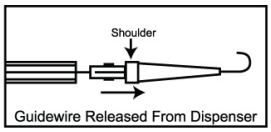
3. Administer sufficient local anesthetic to completely anesthetize the insertion site.

4. Insert the introducer needle with attached syringe into the selected site. Aspirate to insure proper placement.

5. Remove guidewire from Captive J-Straightener by grasping the shoulder of the straightener and gently pulling it from the dispenser tubing. DO NOT pull the guidewire prior to releasing the Captive J-Straightener as this may damage the guidewire.



Guidewire in Restrained Position



Guidewire Released From Dispenser

6. Remove the syringe, placing thumb over the end to prevent blood loss or air embolism. Insert the flexible end of the guidewire through the needle and into the vein.

Caution: The length of 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 the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

Caution: When introducer needle is used, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

7. Remove needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site with scalpel.

8. Thread dilator over guidewire into the vessel (a slight twisting motion may be used). Remove dilator when vessel is sufficiently dilated, leaving guidewire in place.

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.

9. The catheter is irrigated with saline-filled syringes. The syringes are removed and the arterial extension is clamped. With the venous extension unclamped, thread the distal tip of the catheter over the guidewire. The catheter may be rotated gently during insertion until the tip is correctly positioned. The guidewire is removed, and the venous clamp is closed.

10. Attach syringes on both extensions and open clamps. Blood should aspirate easily from both venous and arterial sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to sustain adequate blood flow. Once adequate blood flow has been established, both lumens are irrigated again with saline-filled syringes. It is necessary to open the extension clamps during the irrigation procedure. Clamp the extensions, remove the syringes and place an injection cap on each luer lock connector.Avoid air embolism by keeping catheter 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.

11. Do not clamp the dual lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamp(s) provided.

12. Immediately after insertion, confirm proper placement of the tip of the catheter with x-ray. The catheter tip should lie at the junction of the superior vena cava and the right atrium. 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. Femoral tip placement to be determined by physician.

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

13. Suture the catheter to the skin using the rotating wing. Do not suture the catheter tubing.Cover the exit site with occlusive dressing.

Record indwelling catheter length and lot number on patient's chart and check position routinely.

Before dialysis begins, all connections to the extracorporeal circuit should be checked carefully. During all dialysis procedures, frequent visual inspection should be conducted to detect leaks and prevent blood loss or entry of air into the the extracorporeal circuit. In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedure. Excess blood leakage may lead to patient shock.

HEPARINIZATION

If the catheter is not 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.
- **INJECT A HEPARIN SOLUTION INTO EACH LUMEN OF THE CATHETER. WHEN INJECTING THE HEPARIN, INJECT QUICKLY TO ENSURE THAT THE HEPARIN COMPLETELY FILLS THE LUMEN OF THE CATHETER. THE TOTAL VOLUME OF EACH HEPARIN SOLUTION SHOULD BE EQUAL TO THE INTERNAL VOLUME OF EACH LUMEN. EACH LUMEN MUST BE COMPLETELY FILLED WITH A HEPARIN SOLUTION.**
- Clamp the arterial and venous extension pieces, remove syringe, and attach a sterile injection cap to each luer lock connector. Once the lumina have been heparinized, keep both extensions clamped when not attached to bloodlines or a syringe. If either clamp is opened, blood may enter the distal portion of the catheters, ultimately causing a thrombus.
- In most instances, no further heparin is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.
- 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.

To maintain catheter patency, ensure that a sufficient heparin concentration is used. Since this concentration may vary from institution to institution, please consult your hospital protocol.

Before infusing fresh heparin, aspirate indwelling heparin and flush each lumen with sterile normal saline.

Never forcibly flush a clotted lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may attempt using a thrombolytic agent.

SITE CARE

Clean the skin around the catheter. Cover exit site with an occlusive dressing. Leave the extensions, clamps, adapters and caps exposed for access by the staff.

Wound dressings must be kept dry. 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.

INSUFFICIENT FLOWS

Excessive force should not be used to flush an obstructed lumen. Insufficient blood flow may be caused by occluded arterial holes resulting from a clot or by side holes contacting the wall of the vein. If manipulation of the catheter through rotation (except single lumen catheters) or reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent. Physician discretion is advised.

MANAGEMENT OF ONE-WAY OBSTRUCTION

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 the patient.

-Have the 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.

WARNING:
ONLY A PHYSICIAN SHOULD ATTEMPT THE FOLLOWING PROCEDURES

-Rotate the catheter to reorient the tip position with respect to vascular anatomy. In subclavian and jugular insertion, tip malposition usually can be avoided if the venous adapter is oriented toward the midline on insertion. This positions the arterial inlet away form the wall of the superior vena cava, allowing free blood flow into the arterial lumen.