Jet Medical® SA

CVC CATHETERS

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Jet Medical® CVC Catheter is designed for Long Term central venous access in adults and children. It can be used for total parenteral nutrition (T.P.N.), infusion of I.V. liquids, blood products, and drugs. It can also be used for repeated withdrawal of blood samples.
- It is inserted percutaneously and is primarily placed in the subclavian vein with tip ending in mid to lower SVC.
- Alternate insertion sites include internal jugular vein as required.

CONTRAINDICATIONS:

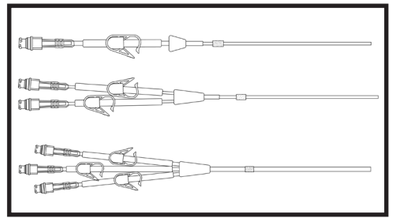
- The presence of device related infection, bacteremia, or septicemia is known or suspected.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- There has been past irradiation of prospective insertion site.
- There have been previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- There are local tissue factors that may prevent proper device stabilization and/or access.

WARNINGS:

- This catheter is **NOT** intended for any use other than that which is indicated. It is **NOT** recommended for use in hemodialysis or in hemoperfusion procedures, nor in patients with severe chronic obstructive lung disease.
- 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 Vascu-Sheath® introducer and the 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 iodine or iodine based disinfectants on this catheter. Failure of catheter will occur. Alcohol based solutions are recommended as the antiseptic solution that can be used on this catheter.
- Do **NOT** use sharp instruments near the extension lines or catheter lumen.
- Do **NOT** use scissors to remove dressing.

DESCRIPTION:

- The Jet Medical® CVC Catheter is manufactured from soft radiopaque silicone material.



POTENTIAL COMPLICATIONS:

- Air Embolism
- Bacteremia
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Chylothorax
- Endocarditis
- Exit Site Infection
- Exsanguination
- Hematoma
- Hemorrhage
- Hemothorax
- Hydrothorax
- Laceration of the Vessel
- 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

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

CAUTIONS:

- 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 those provided with this kit are used.
- Clamping of the tubing repeatedly in the same location may weaken tubing.
- Clamp **only** on clamping sleeve of catheter.
- Avoid clamping near luer and hub of the catheter.
- Examine catheter lumen and extension tubing for damage before and after each treatment.
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
- Use only luer lock (threaded) connections with this catheter (including syringes, IV tubing, and injection caps).
- Repeated overtightening of syringes and caps will reduce connector life and could lead to potential connector failure.
- A 10cc syringe or larger should be used. The smaller the volume of the syringe, the higher the pressure that can be generated. Catheter rupture with possible embolization may occur.
- Avoid bolus infusion of viscous solutions.
- Appropriate methods must be used to avoid air embolism. The catheter must be filled with saline and clamped when the catheter is inserted into the venous system.
- Watch for infection at the exit site or systemic infection in which either are considered indications for intensive treatment and possible removal of the catheter. Appropriate cultures and intensive workups for infection should be instituted.
- The catheter allows for blood draws, intravenous therapy, and infusion of medications into the central venous system. Refer to standards of practice and institutional policies for compatible infusion agents for central venous access.
- Follow all contraindications, warnings, precautions, and instructions for all infusates as specified by their manufacture.

INSERTION SITES:

When placing catheters through percutaneous introducers, caution should be exercised to avoid inadvertent penetration of vital structures in the thorax. Catheters placed percutaneously or through a cut-down should be inserted into the subclavian vein at the angle of the outer third of the clavicle lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to severing or damaging of the catheter. A fluoroscopic or radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

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

- 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.

WARNING:

- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- Avoid medial catheter placement into subclavian vein through percutaneous technique. This placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle. Catheter shearing has been reported when the catheter is inserted via a more medial route in the subclavian vein.[1]

[1] Aiken DR, Minton JP. The "pinch-off" sign: a warning of impending problems with permanent subclavian catheters. Am J Surgery 1994; 148: 633-636.

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.

I. **PREPARATION:**

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 cannula french size 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 intial insertion of this catheter to confirm proper placement prior to use.

II. **TUNNELING:**

1. Administer sufficient local anesthetic to completely anesthetize the insertion and exit site.

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

2. Make a small incision at the exit site. Make a second incision at the insertion site. Make the incision at the exit site wide enough to accommodate the cuff, approximately 1cm.
3. Use blunt dissection to create the subcutaneous tunnel opening. Do **NOT** tunnel through muscle. The tunnel should be made with care in order to prevent damage to surrounding vessels.

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

4. Slide distal end of the catheter over the barb of the tunneler.
5. The barb must be completely covered by the catheter tip to adequately secure the catheter as it is pulled through the tunnel.
6. Advance the tunneler through the subcutaneous layer from the exit site to the insertion site.
7. Lead catheter into the tunnel gently. Do **NOT** pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion.

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

8. After reaching the insertion site, remove catheter from the tunneler.
9. Cut the catheter at a 45° angle to the appropriate length to allow it to lie in the junction of the superior vena cava and right atrium. Cut smaller lumen shorter than the larger lumen.

III. **VEIN ACCESS AND INSERTION OF CATHETER:**

1. Prime the catheter with locking solution. The extensions are clamped and the syringes are removed.
2. Attach the introducer needle to the syringe. Firmly seat the needle onto the syringe.

   Warning: Failure to seat the needle properly will result in air entering the syringe through the luer.

3. Insert the introducer needle with attached syringe, or into the target vein. Aspirate to insure proper placement.
4. 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.
5. Remove needle, leaving guidewire in the target 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. DO **NOT** withdraw guidewire against needle bevel to avoid possible severing of guidewire.

6. Thread Vascu-Sheath® introducer over guidewire. Remove guidewire. You may need to enlarge puncture site with the scalpel before passing the introducer over the guidewire.

   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 sheath in place as an indwelling catheter. Damage to the vessel will occur.

7. Remove introducer dilator leaving sheath.
8. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vessel.

   Warning: Do **NOT** pull catheter back through the sheath once it has been inserted.

9. Remove the tearaway sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

   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.

10. Attach syringe(s) on extension(s) and open clamp(s). Blood should aspirate easily from extension(s). If catheter exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to sustain

adequate blood flow. Radiological confirmation of position is required.

11. To determine priming volume and lock catheter, see "Catheter Locking" section.

12. Avoid air embolism by keeping extension tubing clamped at all times when not 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.

    Caution: Do **NOT** clamp the lumen portion of the catheter. Clamp **only** on the clamping sleeve of the extension(s). Do **NOT** use serated forceps, use only the in-line clamp(s) provided.

13. 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.

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

    Warning: Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

14. Cover the exit site with an occlusive dressing.

15. Catheter must be secured for entire duration of implantation.

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

INFUSION TREATMENT

- The locking solution must be removed from each lumen prior to treatment. Aspiration should be based on hospital/facility protocol.
- Before infusion begins, all connections 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 on clamping sleeve with in-line clamps provided.

- In the rare event of a leak, the catheter should be clamped immediately.
- Necessary remedial action must be taken prior to the continuation of the infusion treatment.

Caution: Excessive blood loss may lead to patient shock.

- Infusion treatment should be performed under physician's instructions.

CATHETER LOCKING

- If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.
- To maintain patency between treatments, a lock must be created in each lumen of the catheter.
- Follow hospital protocol for locking.
- Determine catheter priming volume.

1. Connect saline filled syringe to catheter extension.
2. Flush catheter with saline. Note the volume of saline in syringe after flushing.
3. Aspirate the catheter until first sign of blood flashback.
4. Note the new volume of saline in syringe.
5. Priming volume equals the final volume in syringe minus the initial volume.
6. Record priming volume on patient's chart.
7. Repeat for each extension.
8. Draw locking solution into syringe(s), corresponding to the amount previously determined. Assure that the syringe(s) is free of air.
9. Remove injection cap(s) from the extension(s).
10. Open extension clamp(s).
11. Aspirate to insure that no air will be forced into the patient.
12. Inject locking solution into lumen(s) using quick bolus technique.

Note: Lumen(s) should be completely filled with locking solution to ensure effectiveness.

13. Close extension clamp(s).

Caution: Extension clamp(s) should only be open for aspiration, flushing, and infusion treatment.

14. Remove syringe(s).
15. Attach a sterile injection cap onto the female luer(s) of the extension(s).

- In most instances, no further locking solution is necessary for 48-72 hours, provided the catheters have not been aspirated or flushed.

SITE CARE

Warning: DO **NOT** use iodine or iodine based products on this catheter. Failure of catheter will result. Alcohol based solutions are recommended as the antiseptic solution that can be used on this catheter.

- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extension(s), clamp(s), and cap(s) 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.

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.

MANAGEMENT OF OBSTRUCTIONS:

Excessive force should not be used to flush an obstructed lumen. Central venous access catheters may become occluded due to clotting.

Aspiration has proven useful in declotting the catheter. Wire stylets must not be inserted into the catheter.

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.

No resistance should be felt when withdrawing catheter from vein. If resistance is encountered, do not continue pulling against resistance since this may cause catheter breakage and air embolism. Free up resistance before proceeding.

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. Make a 2cm incision over the cuff, parallel to the catheter.
4. Dissect down to the cuff using blunt and sharp dissection as indicated.
5. When visible, grasp cuff with clamp.
6. Clamp catheter between the cuff and the insertion site.
7. Cut catheter between cuff and exit site. Withdraw internal portion of catheter through the incision in the tunnel.
8. Remove the 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.

9. Apply pressure to proximal tunnel approximately 10-15 minutes or until bleeding stops.
10. Suture incision and apply dressing in a manner to promote optimal healing.
11. Check catheter for integrity and measure catheter when removed. It must be equal to the length of catheter when it was inserted.

Catheter	Lumen 1	Lumen 2	Lumen 3
6F Sgl Lmn	0.9		
7F Sgl Lmn	1.1		
9.5F Sgl Lmn	2.9		
7F Dbl Lmn	0.8	0.8	
9.5F Dbl Lmn	1.4	1.4	
11F Dbl Lmn	1.5	1.4	
14F Dbl Lmn	2.4	2	
12.5F Trip Lmn	1	1	1.9

Priming Volume (mL)	Lumen Ga	Lumen Length (cm)														
		20	25	30	35	40	45	50	55	60	65	70	75	80	85	90
6F Single	22	0.4	0.5	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.8	0.8	0.8	0.9
7F Single	20	0.5	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9	1.0	1.0	1.0	1.1	1.1
9.5F Single	14	0.9	1.1	1.2	1.3	1.5	1.6	1.8	1.9	2.0	2.2	2.3	2.5	2.6	2.7	2.9
7F Double	22	0.5	0.5	0.5	0.5	0.6	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.8	0.8	0.8
	22	0.5	0.5	0.5	0.5	0.6	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.8	0.8	0.8
9.5F Double	17	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3	1.4
	17	0.6	0.6	0.7	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3	1.4
11F Double	17	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3	1.4	1.5
	17	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.3	1.3	1.4	1.5
14F Double	16	0.8	0.9	1.0	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4
	17	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
12.5F Triple	17	0.7	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.7	1.8	1.9
	20	0.5	0.6	0.6	0.6	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.9	0.9	0.9	1.0
	20	0.5	0.6	0.6	0.6	0.7	0.7	0.7	0.8	0.8	0.8	0.9	0.9	0.9	1.0	1.0

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.

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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 NON STERILE	Do Not Resterilize *
5.1.5 LOT	Batch/Lot Number *
5.1.6 REF	Catalogue Number *
Rx Only	Prescription Use Only ***
5.1.2 EC REP	Authorized Representative in the European Community*
5.4.4	Caution, consult Accompanying Documents *

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

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

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EC REP

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