Prymax Cathe

Central Venous Catheters

DEVICE DESCRIPTION:

Central venous catheters are single or multiple lumen catheters available in sizes ranging from 4Fr to 8.5Fr/14Ga to 24Ga. Each lumen extends from distal tip to the main junction hub, where it branches into dedicated extension lines. The extension line hubs are labeled to provide identification of the lumen size and location. The catheter body has depth markings to measure in cm from the catheter tips. The extension line marked “distal” is used for device placement using a guide wire and then to infuse fluids. The distal tip is soft to minimize patient trauma during insertion. The device is radiopaque to allow verification of location in the patient.

Available Sizes:

Single lumen catheter

Size	**Length**
14G	130/150/160/200/300mm
16G	50/80/100/130/150/160 /200/300mm
18G	50/70/80/100/130/150/160 /200/300mm
20G	50/70/80/100/130/150/160 /200/300mm
22G	40/50/80/100/130/150/160 /200/300mm
24G	50/80/100/130/150/160 /200/300mm

Double lumen catheter

Size	**Length**
4Fr	50/60/80/100/130/150/160/200/300 mm
5Fr	50/80/100/130/150/160/200/300 mm
7Fr	50/80/100/130/150/160/200/300 mm

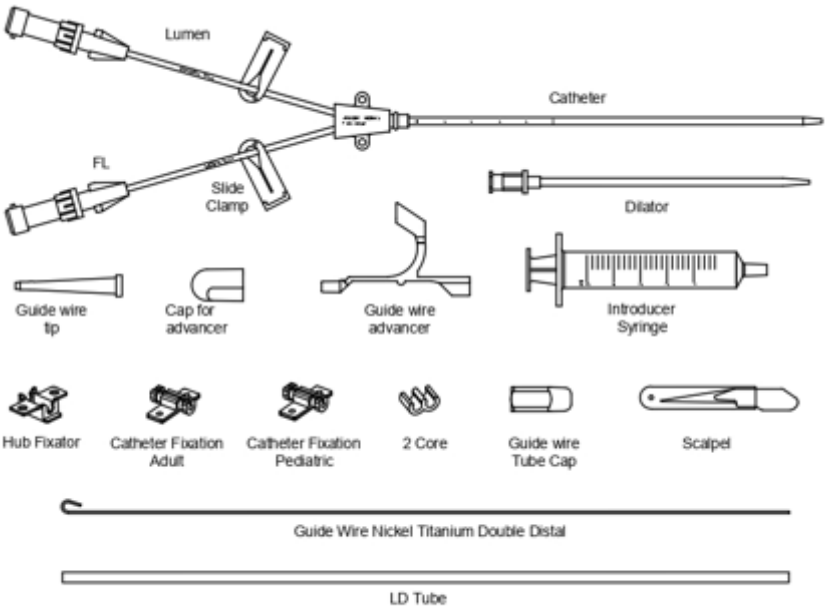
Triple lumen catheter

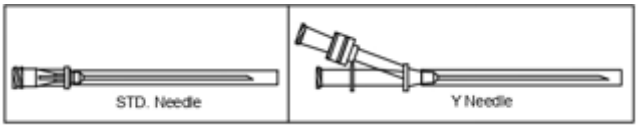
Size	**Length**
4.5Fr	50/60/80/100/130/150/160/200/300 mm
5.5Fr	50/60/80/100/130/150/160/200/300 mm
7Fr	50/80/100/130/150/160/200/300 mm

Four lumen Catheter

Size	**Length**
8.5Fr	50/80/100/130/150/160/200/300 mm

Drawing of product:





CONTENTS:

1. Catheter (Single/Double/Triple/Four lumen)
2. Introducer Needle
3. Syringe (5 ml)
4. Dilator
5. Scalpel
6. Guidewire
7. Catheter fixator
8. Hub fixator

Above mentioned contents are for standard kit. Additional components can be provided with the kit as per the user requirement which includes suture, tegaderm and gauze.

MATERIAL USED:

Polyurethane (PU), Acrylonitrile butadiene styrene (ABS), Polycarbonate (PC), Polyisoprene, PET-G Stainless steel (SS), Nitinol, Polypropylene (PP), Thermoplastic elastomer (TPE), PTFE & LDPE.

INTENDED PURPOSE:

INTENDED USE: Central Venous Catheter is intended to give medicines, fluids, nutrients, or blood products into the central venous system or to withdraw liquids for monitoring purposes from the central venous system.

INTENDED USER: Qualified doctor or surgeon.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender (Adult and Pediatric).

INDICATIONS:
The single and multiple lumen central venous catheters permits venous access of an adult and pediatric patients through veins in the neck (internal jugular vein), chest (subclavian vein or axillary vein) or groin (femoral vein) to administer/withdraw fluids.

CONTRAINDICATIONS:
CVC is contra-indicated in patients with

- Clotting disorders e.g. in therapy with anticoagulants.
- Anatomical anomalities e.g. enlarged stroma, tumors in the neck region, very severe pulmonary emphysema, and postoperative changes at the site of puncture.
- Allergic/hypersensitive to materials used in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS:

Clinical Benefits:
Access to the Central Venous and use the pathway from outside. The clinical outcomes are measured by performance and safety characteristics

Performance Characteristics:

- Catheterisation success rate
- Experience of discomfort and pain

Link for summary of safety and clinical performance of the device:
The link will be provided here after the approval from notified body.

INSTRUCTION FOR USE:
Pre-preparation:

- Open the product in sterile environment.
- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- Position patient as appropriate for insertion site.
- Disinfect the skin and prepare venepuncture site.
- Drape venipuncture site.

Catheter Preparation:

- Flush each lumen with normal saline for injection to establish patency and prime lumens.
- Clamp or attach injection caps to extension line to contain saline with lumen.
  Warning: Air embolism can occur if air allowed to enter a central venous access device or vein. Do not leave open needles or uncapped/unclamped catheters in central venous puncture site. Use only securely injection caps connections with any central venous excess device to guard against inadvertent disconnection.
- Leave distal extension line uncapped for guidewire passage.

Introduction Of Catheter:

- Locate desired vessel using an introducer needle attached to a syringe.

- Position the bevel of the introducer needle in line with the numbers on the syringe. Upon insertion, orient the bevel to open caudally; this facilitates smooth caudal progression of the guide wire down the vein toward the right atrium.
- Insert the introducer needle at the desired landmark while gently withdrawing the plunger of the syringe.
- Advance the needle under and along the inferior border of the clavicle, making sure that the needle is virtually horizontal to the chest wall.
  WARNING: If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
- Change insertion sites after three unsuccessful passes with the introducer needle.
- When venous blood is freely aspirated, disconnect the syringe from the needle, immediately occlude the lumen to prevent air embolism, and reach for the guide wire.
  CAUTION: Gently advance the guidewire through needle into the vessel to the required depth.
  Warning: Never pull back or withdraw the guidewire while the needle is in place. This could damage the wire on the needle bevel. If any resistance is felt to the advancement of the guidewire, do not persist, withdraw both the needle and the guidewire simultaneously.
- Insert the guide wire through the introducer needle using advancer into the vein with the J tip directed caudally to improve successful placement into the vein.
- Use the thumb to advance the guidewire progressively until the 10 cm distance mark is within the needle hub. Gently remove the advancer from the hub. Hold guide wire and remove advancer completely from wire.
- Remove needle.
- Holding the guidewire in place, withdraw the introducer needle and set it aside.
  CAUTION: If the guide wire must be withdrawn while the needle is inserted, remove both the needle and guide wire as a unit to help prevent the needle from damaging or shearing the guide wire.
- Use the tip of the scalpel #11 to make a small incision just against the guide wire to enlarge the catheter entry site.
- Thread the dilator over the guide wire and into the vein with a firm and gentle twisting motion while maintaining constant control of the guide wire. After the dilator is inserted, hold the wire in place and remove the dilator.
  CAUTION: When introducing a catheter or a dilator over the guidewire, make sure that the length of the exposed guidewire is sufficient so that you can maintain a firm grip on the guidewire at all times.
- After removal of dilator, thread the distal tip of the catheter over the guidewire until it exits the distal lumen, and grasp the guide wire as it exits the catheter.
- To aid smooth insertion of catheter, hold catheter close and parallel to the skin and progressively advance catheter to the required depth. The distance markings on the catheter tubing (5 cm onwards at the gap of 1 cm each) facilitate the introduction of the required length of catheter.
- Holding catheter in position at required depth, carefully remove the guidewire. After the wire is removed, occlude the open lumen.
  WARNING: Hold thumb over exposed orifice of the catheter to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the valsalva maneurver.
- Attach a syringe to the main lumen with some saline in it to the hub, and aspirate to check that a free flow of blood confirms correct positioning. Take any needled samples, and then flush the line with saline and recap. Repeat this step with all the lumens.
- Verify proper line placement with chest radiography.

WARNING: Avoid positioning the catheter tip in the right atrium.

- The preferred location of the catheter tip is at the junction of the superior vena cava and the right atrium.
- Connect main lumen, and any other lumens required at this point, via the included three-way stopcocks to appropriate and prepared equipment.
- Suture the catheter in place using wing/clamp. It can also be sutured directly at the puncture site with the movable wing /clamp.
- Dress the incision site and catheter according to the hospital or departmental protocol.
- Check catheter and dressing regularly for evidence of catheter movement, interrupted flow rates, leakage, security of all connection and signs of infection.

Removal Procedure:

Special attention requires for removal of a subclavian or jugular catheter from the exit site. Following removal direct firm pressure is needed for at least 10 minutes over the vessel, to prevent the formation of a haematoma. The site should then be observed closely, and further pressure applied if needed.

WARNINGS & PRECAUTIONS:

- Read all the information mentioned in instruction for use. Failure to do so may result in severe patient injury or death. The product should be used according to the instructions for use.
- The product is guaranteed, Sterile till the package has not been opened or damaged within the expiry date.
- Do not use if the sterile pack is opened or damaged.
- Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.
- Clinicians must be aware of potential entrapment of the guidewire by any implanted device in circulatory system. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire entrapment.
- Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation, bleeding, or component damage.
- Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block and a perforation of vessel, atrial or ventricular wall.
- Do not apply excessive force in placing or removing catheter or guidewire. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained, and further consultation requested.
- Do not secure, staple and/or suture directly to outside diameter of catheter body or extension lines to reduce risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
- The slide clamp on the extension line can be used to close the catheter briefly when infusion and transfusions are changed. Clinicians should be aware that the slide clamps may be inadvertently removed.
- Change contaminated dressings per hospital policy.

ADVERSE EFFECTS:

Possible complications associated with percutaneous catheter placement include vessel wall perforation, arterial puncture, arterial catheterization, haemorrhage, air embolism, catheter

embolism, haemotoma at the site of puncture, pneumothorax, haemothorax, blood stream infections.

Other effects are pain, discomfort, bleeding, nerve injury, allergic reaction from hypersensitivity to materials used in the device, local insertion site infection etc.

RE-USE HAZARDS:
Transmission of infection from one patient to another.

PACKAGING:
The device is packed in blister pack sealed with Tyvek paper, which is further packed in inner carton & master carton.

STERILIZATION:
Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:
Temperature Limit: 15^{o}C to 40^{o}C.

DISPOSAL
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:
In case of any serious adverse event please report the same to (Add Company's e mail Id and EU rep mail id.) info@prymaxhealthcare.com & gloizou@compliancems.com.au.

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY
Refer to the company's return good policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number


Do not re-use

Sterilized by Ethylene Oxide


Manufacturing date


Use-by date


Caution


Non-pyrogenic

Do not resterilize

Catalogue number

Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged and consult Instructions for Use

Consult instructions for use

Single Sterile Barrier System

Medical Device

UDI Carrier

Manufacturer:

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53/17,Industrial Area NIT, Faridabad,
Haryana, INDIA -121001
www.Prymaxhealthcare.com

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