Prymax Dialysis

Hemodialysis Catheter Kit

DEVICE DESCRIPTION:

The hemodialysis catheter kit is indicated for use in attaining short term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein. Hemodialysis catheter can be single lumen or multi lumen catheter. Single lumen catheter consists of a tube or lumen ending in a hub that can be capped and used as per requirement. Multiple lumen catheters provide multiple short term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein through a single insertion site, permitting several functions to be performed simultaneously. Catheters are made from the soft polyurethane and have Single, Double, Triple lumens in various lengths.

Available Sizes:

Single lumen catheter

Size (Fr)	**Length** (cm)
6.5	11
7	13
8	16
8.5	16

Double lumen catheter

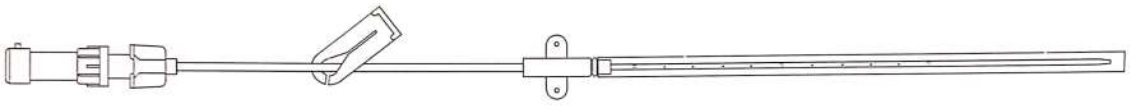
Size (Fr)	**Length** (cm)
6.5	11
8.5	11, 16
11.5	13
12	16, 20

Triple lumen catheter

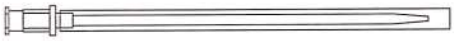
Size (Fr)	**Length** (cm)
12	13, 16, 20

Prepared by:	Approved By:

Drawing of product:



CATHETER 8 FR 16 cm



DILATOR 9 FR 10 cm

CONTENTS:

1. Catheter (Single/Double/Triple lumen)
2. Introducer Needle
3. Syringe
4. Dilator
5. Scalpel
6. Guidewire

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

MATERIAL USED:

Poly urethane, Polycarbonate. Low density Poly Ethylene, Acrylonitrile-butadiene-styrene, Stainless Steel, Poly propylene, Silicon, PC/PBT alloy, Polyoxymethylene

INTENDED PURPOSE:

INTENDED USE: The single and double lumen Haemodialysis catheters are indicated to use for Venous access of the patient & to administer rapid fluid delivery during temporary or acute haemodialysis

INTENDED USER: The device is intended to be used only by a qualified medical professional.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender.

INDICATIONS:

- Hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein
- To supply the temporary blood vessel access in hemodialysis
- Monitor of central venous pressure;
- Continuous or discontinuous venous transfusion

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CONTRAINDICATIONS:

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Infection or cut wound around the puncture area.
- Dysfunction of blood coagulation.
- During the anticoagulant treatment.
- Symptoms of inadaptability to puncture operation, such as Pneumothorax, vein sclerosis.
- Abnormal or unclear anatomical situation at the penetration area, such as sever emphysema, obviously inadaptability from previous operation
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS

Clinical Benefits:

Hemodialysis catheters provide a reliable and immediate way to access the blood for hemodialysis.

Performance Characteristics:

- Catheterisation success rate
- Experience of discomfort and pain

CAUTION/WARNING

- It is strongly recommended that you do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in serve patient injury or death.
- Do not clamp the muti-lumen body the catheter. Clamp only the extension lines an use only the clamps provided. Never use serrated forceps to clamp the extension lines.
- The physician should be aware that certain complications may occur during subclavian insertion such as hem thorax, pneumothorax and hematoma
- Do not cut the catheter to alter length

INSTRUCTION FOR USE:

1. Open the product in sterile environment.

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2. Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
3. Position patient as appropriate for insertion site.
4. Disinfect the skin and prepare venepuncture site.
5. Drape venipuncture site.
6. Prepare and drape puncture with Puncture needle of 18Ga in Case of Adult & 21G in case of Pediatric at site.
7. Prepare the catheter for insertion by flushing each lumen.
8. Clamp extension lines or attach injection caps to the appropriate lumen extension. Leave the distal lumen extension uncapped for guidewire passage.
9. Insert introducer needle supplied with attached syringe into vein and aspirate . Assure a good flow of venous blood is established .
   PRECAUTIONS : The color of the blood aspirated is not always a reliable indicator of venous access. Because of the potential for inadvertent arterial placement.

10. When blood is freely aspirated, disconnect the syringe from the needle, immediately occlude the lumen to prevent air embolism, and reach for the guide wire.
11. Using the guidewire ,advance guidewire spring through guidewire introducer needle into vein . Advance guidewire upto required depth. Advancement of J" tip may require a gentle rotating motion .Warning : Do not cut guidewire to alter length . Do not withdraw guidewire against needle level to avoid possible severing or damaging of guidewire.
12. Straighten the" J" by retracting the guidewire into the dispenser tip straightener .When the tip is straightened, the guidewire is ready for insertion . Centimeter marks are referenced from " J " end. One band indicated 10 cm, two bands 20 cm, and three bands 30 cm.
13. Hold guidewire in place and remove introducer needle for catheter .
    PRECAUTIONS : Maintain firm grip on guidewire at all time. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement .

14. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the guidewire .
    PRECAUTIONS :Do not cut guidewire . Use vessel dilator in place to enlarge site as required .Waning : Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

15. Thread tip of catheter over guidewire . (Sufficient guidewire length must remain exposed at hub end of catheter to maintain firm grip on guidewire) Grasping near skin, advance catheter into vein with slight twisting motion.
    PRECAUTIONS : Suture wing and clamp must not be attached to catheter until guidewire is removed . Using cm marks on catheter as positioning reference

points, advance catheter to final indwelling position. Record indwelling catheter length on patients chart and check position routinely.

16. Hold catheter at desired depth and remove guidewire.
    CAUTION : Although the incidence of guidewire failure is extremely low , practitioner should be aware of the potential for breakage if undue force is applied to the wire. The catheter included in this product has been designed to freely pass over the guidewire If resistance is encountered when attempting to remove the guidewire after catheter placement the guidewire may be kinked about the tip of the catheter within the vessel .In this circumstance, pulling back on the guidewire may results in undue force being applied resulting in guidewire breakage. If resistances encountered, withdraw the catheter relative to the guidewire about 2-3 cm and attempt to remove the guidewire . If resistance is again encountered remove the guidewire and catheter simultaneously.

17. Verify that the entire guidewire is intact upon removal.
18. Check lumen placement by attaching a syringe to each lumen extension and aspirate until free flow of blood is observed. Connect all lumen extension to appropriate attract Lock lines (s) as required . Unused port(s) may be "locked" through injection cap(s) using standard hospital protocol. Slide clamps are provided on lumen extensions to occlude flow through each lumen during line and injection cap change.
    PRECAUTIONS : To avoid damage to lumen extension verify venous access via a wave from obtained by a calibrated pressure transducer . If hemodynamic monitoring equipment is not available to permit.

19. Secure and dress catheter temporarily.
20. Verify catheter tip position by chest x-ray immediately after placement . Precaution: For central venous placement , x-ray exam must show the catheter located in the right side of the mediastnum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized . If catheter tip malpositioned , reposition and reverify.
21. Secure catheter to patient using indwell hub suture holes or movable suture wings and clamp. Precaution: Do not suture directly against the catheter tubing to avoid cutting or damaging the catheter or impeding catheter flow.

Suture wing and suture-wing clamp Instructions:

22. After guidewire has been removed and the necessary lines have bee connected or locked, spread wings of rubber clamp and position on catheter as required to ensure proper tip location. Snap rigid fastener onto catheter clamp. Secure catheter to patient by suturing the suture wing to the skin , using side wings to prevent catheter migration.
23. Dress puncture site as per hospital protocol.

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PRECAUTIONS : Maintain the insertion site with regular meticulous redressing using aseptic technique.

- Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

WARNING & PRECAUTIONS:

1. Hemodialysis catheters should be positioned so that the distal tip of the catheters is in the superior vena cava (SVC) above the junction of the SVC and the right atrium and lies parallel to the vessel wall . Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle.
2. Complications associated with central vein catheters including cardiac tamponade secondary in vessel wall, atria of ventricular perforation, pleural and medinstinal injuries, air embolism, catheter embolism , thoracic , duct separation , bacteremia, septicemia, thrombosis , inadvertent arterial, puncture , nerve damage , hematoma formation , and hemorrhage, and dysrhytmias.
3. Embolism during catheter insertion the patient should be positioned in a slight Trendelenburg position as tolerated.
4. Leaving open needles or catheter in central venous puncture sites or as a consequence of inadvertent disconnects.
5. Guidewire into the right heart can cause arrhythmias, right bundle branch block, and vessel wall , arterial or ventricular perforation.
6. Has immunological response, sensitization or hypersensitivity for foreign materials.
7. 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.
8. Consider all the warnings/precautions given below the steps defined in instruction of use.
9. The product is guaranteed “Sterile” till the package has not been opened or damaged within the expiry date.
10. Do not use if the sterile pack is opened or damaged.
11. Do not reuse, reprocess or re-sterilize. Reuse and re-sterilization of device creates a potential risk of serious injury and/or infection which may lead to death.
12. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation, bleeding, or component damage.

ADVERSE EFFECTS:

Catheter-related bloodstream infections (CRBSIs), exit-site infections, and tunnel infections, Catheter-related thrombus, Central vein stenosis, Air embolism, Bleeding, Cardiac arrhythmias, Dialysis disequilibrium syndrome, Reactions to the HD membrane & Seizures

RE-USE HAZARDS:

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Transmission of infection from one patient to another.

PACKAGING:
The device is packed in Paper Pouch, 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.

DEVICE SHELF LIFE: 3 Year

COUNTRY CODE: 356

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 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

Prepared by:	Approved By:

Non-pyrogenic

Do not resterilize

Catalogue number

Manufacturer

Storage Temperature Range

Conformité Européenne

Do not use if package is damaged

Consult instructions for use

Single Sterile Barrier System

Medical Device

UDI Carrier

Country of Manufacturer

Manufactured By:

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

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