**Prymax Dialysis**

## Hemodialysis Catheter Kit Long Term

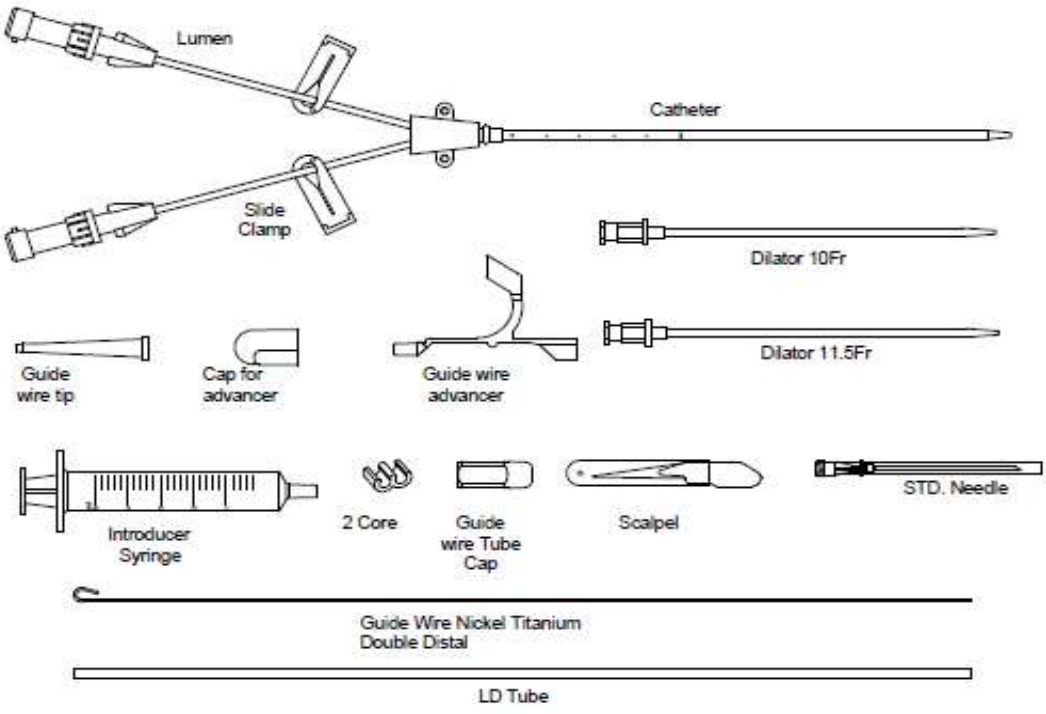
**DEVICE DESCRIPTION:**

hemodialysis catheter is a dual lumen radiopaque catheter with a polyester cuff. The catheter is 15 French, featuring an innovative, dual radiused distal configuration. This distinctively shaped design is intended to leverage the outside of the arc of both the arterial and venous lumens with the intention of eliminating the vein walls as an obstruction.
By convention, the outflow lumen carrying blood from the body is called “arterial” and is marked red and the lumen returning blood is called “venous” and is marked blue.

**AVAILABLE SIZES:**

Double lumen, 15 Fr, straight
Length- 13, 19, 21, 23, 28, 32, 36, 40, 42 cm

**Drawing of product:**




**CONTENTS:**

1. Catheter
2. Introducer Needle
3. Syringe
4. Dilator

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5. Scalpel
6. Guidewire
7. Peelable Introducer
8. Tunneler

# 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:**
Silicone, Polyester, Polycarbonate, Poly propylene, Poly Ethylene, Acrylonitrile-butadiene-styrene, Fluorinated ethylene propylene, Stainless Steel/Nitinol

**INTENDED PURPOSE:**
INTENDED USE: - A dialysis catheter is a catheter used for exchanging blood to and from a hemodialysis machine and a patient. If a patient requires long-term dialysis therapy, a chronic dialysis catheter will be inserted.

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

INTENDED PATIENT POPULATION: Adult patient population of any gender.

**INDICATIONS:**
- Maturation period of internal fistula in need of hemodialysis;
- Transitional period before renal transplant;
- Patients of last stage of uremia;
- Patients unable to receive internal arteriovenous fistula or renal transplant but in need of hemodialysis;
- With severe arterial disease and low blood pressure so that cannot maintain fistula blood flow rate.
- Incapable of receiving venous fistula shunt due to poor cardiac function;
- Fear of repeated vascular access;

**CONTRAINDICATIONS:**
- Infectious or wounded puncture site;
- Any syndrome that can't conduct puncture, such as aerothorax or venosclerosis;
- coagulation disorders;
- Accepting anticoagulant therapy;
- Disorder puncture site: such as severe emphysema or obvious abnormal puncture after operation.
- The Patient is known or is suspected to be allergic to materials contained in the device.

**CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS**

**Clinical Benefits:**

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- Improved quality of life: Taking care of clots early can reduce treatment interruptions and improve quality of life.
- Reduced risk of additional health problems: Hemodialysis can help prevent additional health problems.
- Longer life on dialysis: Hemodialysis can help live longer on dialysis.

**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:**

- Visually inspect the package for any visual defects and open the product in sterile environment.
- Visually inspect the product for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- Before use the product, instruction should be read, and operation should be conducted by well-trained and experienced medical staff.
- Locate puncture site, needle puncturing angle and depth.
- Shaving, sterilizing, draping and local infiltration anesthesia.
- Flush each lumen with normal saline for injection to establish patency and prime lumens.
- Put Seldinger introducer needle into chosen venous; Locate puncture site by observing the back flow of blood.
- Insert guidewire into venous, pull out introducer needle when reach right spot.
- Decide the puncture site as well as distance between puncture site and dacron cuff by tube length.
- Conduct infiltration anesthesia to local subdermal before incise the skin.
- Connect and lock the blunt end of tunneler with the tip of long-term HDC, the sharp of the tunneler conducts the catheter to enter through the incision open and exit from the punctured site by introducer, from which the length is about 2-3cm to the Dacron cuff;

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- Put dilator with valved peelable introducer onto the guidewire, and spin into the skin to dilate.
- Pull out guidewire and dilator, remain peelable sheath, put catheter in the intersection of precava and right atriu, check the location of tube end with X-ray.
- Push the handle of peelable cover down and slowly take it out from vein, then peel away cover from catheter, remain the catheter in vein, prepare heparin saline aside.
- Keep dacron cuff under skin, suture skin incase catheter moves.
- Cover the wound with sterilized adhesive tape.

**WARNINGS & PRECAUTIONS:**

- 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 sheath introducer) and guidewire must be removed together.
- Use of excessive force on the catheter may cause the suture wing to detach from the bifurcation.
- In the event that a clamp breaks, replace the catheter at the earliest opportunity.
- 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.
- Consider all the warnings/precautions given below the steps defined in instruction of 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.
- 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.
- 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.

**ADVERSE EFFECTS:**

Catheter dysfunction (Thrombosis, Fibrin shell formation, Malposition or kinking), Infection (Exit side infection, Tunnel infection, CRBSI), Stenosis & Aneurysm or Pseudoaneurysm

**RE-USE HAZARDS:**

Transmission of infection from one patient to another.

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**PACKAGING:**
The device is packed in tray, 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


Non-pyrogenic

Do not resterilize

Catalogue number



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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.,**
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Haryana, INDIA -121001
www.Prymaxhealthcare.com

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