



Target Medical

Disposable Hemodialysis Catheter Kit Instruction For Use



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Beijing Target Medical Technologies, Inc.

[Product Name]

Disposable Hemodialysis Catheter Kit

[Description]

Disposable Hemodialysis Catheter kit contains hemodialysis catheter, scalpel, introducer needle (18G) and blue introducer syringe (5mL)/Y-introducer needle (18G), guide wire (0.038”), dilator (10-12.5F), syringe (5 mL), syringe needle, and heparin cap . Straight and curved hemodialysis catheter of double lumen and triple lumen are provided. Both the distal venous (blue) and the proximal arterial (red) lumens may be used for hemodialysis, hemoperfusion, and apheresis treatments. For the triple-lumen catheter, the medial third (transparent) lumen is completely independent from the two dialysis lumens and may be used for intravenous therapy and central venous pressure monitoring. The catheter contains no additives or coatings.

Type		Flow rate	Lumen		
Length			Distal	Proximal	Middle
13cm	double-lumen 11.5 F		305ml/min	305ml/min	-
	double-lumen 12 F		310ml/min	310ml/min	-
	triple-lumen 12 F		80ml/min	245ml/min	245ml/min
16cm	double-lumen 11.5 F		285ml/min	285ml/min	-
	double-lumen 12 F		295ml/min	295ml/min	-
	triple-lumen 12 F		72ml/min	227ml/min	227ml/min
20cm	double-lumen 11.5 F		265ml/min	265ml/min	-
	double-lumen 12 F		285ml/min	285ml/min	-
	triple-lumen 12 F		65ml/min	210ml/min	210ml/min

[Product Structure]

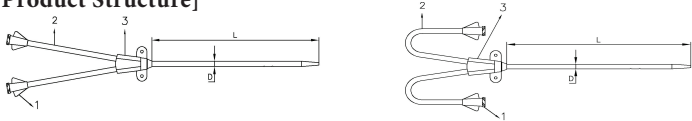


Figure 1 Double-Lumen Catheter

- D: Outer Diameter of the catheter
- L: Effective length of the catheter
- 1: Hub
- 2:Extension tube
- 3: Delta

Remark: The distance between markers is 1cm, and the distance between number markers is 5cm.

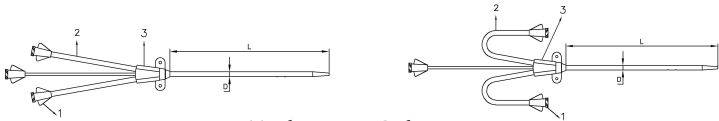


Figure 2 Triple-Lumen Catheter

- D: Outer Diameter of the catheter
- L: Effective length of the catheter
- 1: Hub
- 2: Extension tube
- 3: Delta

[Indications For Use]

Disposable hemodialysis catheter kit is intended for intervention in the blood vessels (through femoral vein, internal jugular vein or subclavian vein as required) by percutaneous punctuations to attain short-term (less than 30 day) access for hemodialysis, hemoperfusion and apheresis treatments. The triple-lumen is with a third internal lumen for intravenous therapy and central venous pressure monitoring.

[Operation Procedures]

Preparation before operation

- ※ Select catheter specifications based on patient characteristics.
- ※ Pre-use inspection: the packing should be undamaged and the product should be in good condition.
- ※ Assess the patient’s venous condition and select the best puncture vessel.

Disposable Hemodialysis Catheter insert operation

- (1)Establish a sterile area, open the catheter package, wear gloves, apply sterile techniques, prepare a heparin cap, aspirate saline, and heparinized saline.
- (2)Degrease,sterilize(Iodophor) and local anesthesia the puncture site, and roll out the sterile hole towel.
- (3)Flush the catheter lumen, clamp extension tube or install heparin cap to extension tube, but the distal lumen of extension tube should be kept open for introducing the guide wire.
- (4)The Blue Introducer Syringe is attached to introducer needle that will permit passage of the guidewire, (If a Y needle is used, A Syringe is attached to Y Introducer needle that will permit passage of the guidewire) , The introducer needle is inserted into the identified vein, then pump back to ensure a good venous reflux (Tip: the color of the pumped back blood is not always a reliable sign of the vein).
- (5)Insert the guide wire (Diameter:0.038",Length:60cm) to the expected position, adjust the guide wire insertion depth according to the guide wire’s mark, and the marks start with "J", each bar represents 10cm. The guide wire may be slightly rotated during operation, and do not forcibly insert guide wire when it comes to resistance.
- (6)After fixing the guide wire, withdraw the introducer needle and the Blue Introducer Syringe (or Y-introducer needle and the Syringe).

(7) Use the scalpel to make a small surgical incision at the exit of the skin site followed by the use of a tissue dilator to dilate the subcutaneous tissues or by using a vessel dilator. Remove the Tissue dilator.

(8) Deliver the tip of the hemodialysis catheter along the guide wire to the expected position.

(9) Hold the catheter tightly, and slowly pull out the guide wire and check if it is intact.

(10) The venous stanch clip is closed. Irrigate the lumens with heparinized-saline filled syringes. (It is necessary to open the extension clamps during the irrigation close the arterial and the venous clamps and the Heparin caps are placed over the ends of each Hub connector on the extension pieces. The blue Hub is the vena cava.

(11) Use a suture or a StatLock device needle to fix the catheter clamp.

(12) Cover the aseptic dressing to protect the puncture site.

(13) The catheter is now ready for use. For hemodialysis, hemoperfusion, or apheresis the arterial (pink) lumen of the catheter is connected to the arterial side of the extracorporeal circuit. The venous (blue) lumen of the catheter is connected to the venous side of the extracorporeal circuit.

Connection of the hemodialysis catheter

(1) Prepare the iodophor disinfectant swabs and medical waste bags;

(2) Open the external dressing of the venous catheter.

(3) The patient's head biased to the contralateral, and put the sterile treatment towel under the venous catheter.

(4) Remove the inner dressing of venous catheter and place the catheter under the sterile treatment towel.

(5) Disinfect the catheter and catheter clip respectively, and place them under the sterile treatment towel.

(6) Check whether the clip is in the closed state and then remove the catheter heparin cap, and disinfect the catheter connector respectively.

(7) Use a syringe to withdraw the heparin in the catheter, push to the gauze to check whether there is a clot, and the amount was about 2ml for each arterial and vein blood vessel. If the catheter is obstructed for pumping back the blood, check the reason carefully, it is strictly forbidden to use the syringe forced injection to catheter lumen.

(8) Inject the first dose of heparin (using a low-molecular heparin as an anticoagulant) from the venous end of the catheter according to the doctor's advice and connect the cardiopulmonary bypass to the catheter base.

(9) Place the medical waste in the medical waste containers.

Central venous pressure monitoring (CVP)

For the triple-lumen catheter, the third (brown) lumen can be used for central venous pressure monitoring.

- Prior to conducting central venous pressure monitoring.
- Ensure proper positioning of the catheter tip.
- Flush catheter vigorously with sterile normal saline.
- Ensure the pressure transducer is at the level of the right atrium.

- It is recommended that a continuous infusion of saline (3 mL/hr) is maintained through the catheter while measuring CVP to improve accuracy of CVP results.
- CVP Monitoring is intended to be performed through the distal (purple) lumen.
- Use your institution's protocols for central venous pressure monitoring procedures.

WARNING: CVP Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

WARNING: CVP Monitoring should not be performed during hemodialysis, hemoperfusion, or apheresis.

The end of the treatment

(1) Assess the patient's condition and measure vital signs. Assess whether treatment time and amount of dewatering meet the requirements.

(2) Turn off the blood pump, separate the pipeline of arterial end, connect with 500ml saline, and then turn on the blood pump, return the blood, and the blood flow rate is 50-100ml / min;

(3) Do not squeeze the pipeline of vein end by hands during the blood transfusion. When the saline return to the vein pot, stop continuing to return the blood, close the vein catheter clip and catheter vein end clip;

(4) Flush the lumen with 10ml normal saline, and seal the tube with heparin saline. Lock the heparin cap. Cover the gauze and wrap the catheter with gauze and secure.

(5) Measure patient's vital signs again, assess patient weight and dewatering condition. Accurate registration of all nursing records.

※ Remove the hemodialysis catheter

After use, remove all fixing devices and slowly withdraw the hemodialysis catheter followed by 15-20 minutes local press.

Exit Site Cleaning

- Clean the exit site at each dialysis treatment with chlorhexidine gluconate unless contraindicated. Apply antiseptic per manufacturer's recommendations. Allow to air dry completely.
- Cover the exit site with sterile, transparent, semipermeable dressing or per hospital protocol. Recommended Cleaning Solutions Exit Site:
 - Chlorhexidine gluconate 2% solution (preferred)
 - Povidone iodine
 - Chlorhexidine patches

[Contraindications]

This catheter is intended for short-term vascular access only and is not to be used for any other purpose other than indicated in these instructions.

This catheter is also contraindicated:

- When the patient's body size is insufficient to accommodate the size of the implanted catheter.
- When the patient is known or is suspected to be allergic to the material contained in the catheter.
- If the prospective insertion site has been previously irradiated.

- If the prospective placement site has previously suffered episodes of venous thrombus or vascular surgical procedures.
- For patients with severe cardio-cerebro vascular complications.
- For patients with severe bleeding (blood coagulation) disorder or anemia.
- For patients with severe hypotension or shock.
- If the patient have had major surgery recently.
- For patients in the end stage of uremia along with irreversible complications.
- For patients with uncontrolled diabetes.
- If infection at the puncture site is manifested.
- For patients with malignant diseases like cancer.
- For high-risk elderly patients, psychopaths and infants who could not cooperate.
- For patients with poor or impaired vascular access in superior and inferior vena cava, subclavian vein, jugular vein, femoral vein.

[Possible Complications]

Common complications include:

Infection, CR-BSI (Catheter-related blood stream infection), Catheter-related sepsis, Catheter occlusion, Hematoma, Bleeding, Hemothorax/Pneumothorax, Leakage, Catheter dislocation, Component damage, Stenosis/Thrombosis, Venous air embolism, Endocarditis, Arterial puncture, Myocardial perforation/cardiac tamponade, Nerve damage.

[Warnings]

- The thickest guide wire diameter applicable is 0.038 "
- Effective length is expressed in whole millimeters
- Do not overexert when remove the guide wire or catheter. X-ray examination should be taken if there is problem.
- Connection joint must be connected with the Luer joint to avoid air embolism.
- Medical staff should take comprehensive prevention measures to avoid blood pathogens.

[Precautions]




- This device is suitable for any adult patients with indication except of whom with contraindications. The device is not suitable for pregnancy or breast-feeding women.
- Intended users are the competent physicians and nurses who have the training of hemodialysis catheter management.
- Intended for single use only.
- This product is sterilized by ethylene oxide sterilization. Do not use it if any damage should be found on the package.
- This product must be used within the 2-year validity of sterilization.
- The catheter should be inserted slowly to prevent the opening of the catheter lumen from being damaged by any sharp or acute angles.
- All connections to the extra-corporeal circuit must be examined carefully before dialysis. During all procedures of dialysis frequent visual inspection must be conducted to detect leaks and prevent blood loss or entry of air into the extra-corporeal circuit. Excess blood leakage may lead to patient shock.
- In rare event of leakage, the catheter must be clamped immediately and necessary remedial measures must be taken before resuming dialysis procedure.

- Verification of the catheter tip location must be confirmed by x-ray to ensure proper placement.
- Repeated clamping around or on the Luer-lock connectors may cause catheter fatigue or possible disconnection.
- This product should be stored in a cool, dry, clean and well ventilated room with relative humidity below 80%RH and room temperature range of 1°C~ 40°C, without corrosive gas.
- The catheter must not be left in the femoral vein longer than three days. It is recommended that jugular and subclavian catheters should be replaced after 20 days.

[Disposal]

Used products should be handled and disposed of in accordance with applicable local laws and regulations to avoid potential environmental pollution.

[Explanation of Symbol]

			
Manufacturer	Date of manufacture	Batch code	Sterilized using ethylene oxide
			
Catalogue number	Do not resterilize	Caution	Consult instructions for use
			
Serial number	Temperature limit	Do not re-use	Keep away from sunlight
			
Non-pyrogenic	This Way Up	Keep dry	Authorised Representative In The European Community
			
Use-by date	Fragile, handle with care	Do not use if package is damaged	CE Mark And Identification Number Of Notified Body