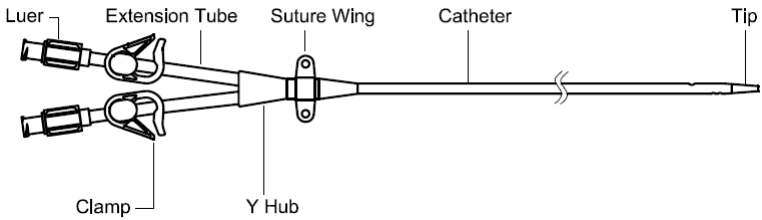
HEMODIALYSIS CATHETER KIT

INSTRUCTIONS FOR USE

ENGLISH



Read the instructions before using this medical device.
THIS MEDICAL DEVICE IS FOR SINGLE USE ONLY
CAUTION: THIS DEVICE IS SUPPLIED STERILE BY ETHYLENE OXIDE GAS AND PYROGEN FREE ONLY IF PACKAGE IS NOT OPENED OR DAMAGED.

< Introduction and Intended Use >

The BIOTEQ Hemodialysis Catheter Kit could be extensive used for blood purification. During the dialysis treatment, patient's blood is withdrawn through one lumen of the catheter and supplied to a hemodialysis device where the blood is purified, the purified blood is then returned through the other lumen of the catheter to the patient's body. This device is percutaneously inserted in femoral veins. The tip of the hemodialysis catheter is positioned and located at the common iliac vein. Femoral venous catheterization is a rapid way to obtain intravenous access in hospitalized or emergency department patients. Intended patient group: adult.

< Contraindications >

Absolute contraindications to femoral central venous access include the following:

1. Venous injury (known or suspected) at the level of the femoral veins or proximally (ie, iliac veins or inferior vena cava)
2. Known or suspected thrombosis of the femoral or iliac veins on the proposed side of venous cannulation
3. Ambulatory patient (because ambulation increases the risk of catheter fracture and migration)
4. The catheter should not be used longer than three to four days maximum per K-DOQI guidelines.

< Instruction for Catheter Insertion >

1. Complete the anesthetic monitoring procedure. Examine the site of insertion and select the most appropriate route.
2. Under the aseptic condition, prepare and check all the equipment for use.
3. Shave the insertion area, sterile the skin and drape the area.
4. Identify the insertion site and exert local anesthetic over the site.
5. Attach an introducer needle to a syringe. Insert the introducer needle into the identified vein. After the needle has penetrated the skin, aspirate gently whilst advancing the needle as directed until the vein is entered. If the vein is not found, slowly withdraw the needle whilst gently aspirating; often the vein has been collapsed and transfixed by the entry of the needle.

6. Remove the syringe and leave the introducer needle in place（If Y shape introducer needle is used, this step can be omitted）.
7. Advance the flexible end of a guide wire through the introducer needle into the vein（If Y shape introducer needle is used, advance the guide wire through the side of Y shape introducer needle）. Holding the guide wire securely in place, and then remove the introducer needle. Use the length markings to check the insertion depth. Do not pull back guide wire over needle bevel as this may damage the end of the guide wire. For jugular and subclavien insertion, do not allow the guide wire to pass into the right atrium, since that may result in cardiac arrhythmia.
8. Use a scalpel to create a small surgical incision at the skin exit site, and advance a dilator over the wire into the vein with a twisting motion to widen up the subcutaneous tissues.
9. Flush the catheter with a saline filled syringe.
10. Hold the guide wire still and advance the catheter over it until the tip of the catheter reach the desired place in the vein.
11. Remove the guide wire.
12. Ensure that blood can runs freely in all lumens of the catheter and flush with saline.
13. Stitch the suture wing to the skin surface to secure the catheter in place.
14. Perform a chest x-ray to ensure the correct position of the catheter tip.
15. After installing the hemodialysis catheter, it can be used with the hemodialysis blood tubing set for hemodialysis.

< Warning >

1. This hemodialysis catheter kit shall be used only by trained nurses and/or doctors who are totally familiar with the procedure.
2. Do not reuse or resterilize the catheter kit.
3. Do not use alcohol or acetone based solutions on the catheter for these solutions may degrade the properties of the catheter.
4. Do not use PEG-containing ointments on polyurethane catheters. Because PEG（polyethylene glycol）can cause failure of the hemodialysis catheter.
5. Do not clamp the catheter body below the Y-hub.
6. To avoid air embolism, clamp the extension tubes when the catheter is not being used.
7. Do not tie the suture too tightly at the venostomy site. Do not pull or tug on catheter.
8. Do not insert the catheter with a sharp or acute angle. This could impose the resistance of the blood flow.

＜Care and Maintenance＞

1. The insertion site must be inspected daily. And clean the insertion site with hydrogen peroxide followed by povidone iodine solution.
2. Heparin must be injected into the catheter lumens regularly to prevent thrombus and obstruction.
3. The volume of heparin solution should be equal to or slightly more than the volume of the lumen that is being “locked”.
4. The priming volumes are printed on the device. Prior to hemodialysis, the indwelling heparin must be aspirated from each lumen.
5. After the heparin has been aspirated the lumens should be flushed with sterile normal saline solution.

< Possible Complications >

Even though the hemodialysis catheters provide an important means of venous access for treatment purposes, the potential complications exist. The potential complications are listed below.

1. Air Embolism
2. Bleeding
3. Brachial Plexus Injury
4. Cardiac Arrhythmia
5. Cardiac Tamponade
6. Catheter Embolism

7. Catheter Occlusion
8. Endocarditis
9. Exit Site necrosis
10. Exit Site Infection
11. Extravasation
12. Fibrin Sheath Formation
13. Hematoma
14. Hemothorax
15. Hydrothorax
16. Inflammation Over Implant Area
17. Injury to Major Vessels or Right Atrium
18. Injury to Surrounding Nerves
19. Injury to Thoracic Duct
20. Laceration of Vessels or Viscus
21. Pneumothorax
22. Sepsis
23. Thrombosis

< Catheter Removal >

Before taking out the catheter from patient, remove dressings and suture material. Ask the patient to hold breath, and then remove the catheter with a gentle pull. After the catheter is removed, apply firm pressure to the puncture site for 10-15 minutes to stop the bleeding. If there is a resistance to prevent the catheter coming out, try rotating it while pulling gently.

The hemodialysis catheter kit is intended for single use. Discard them after use using aseptic techniques for potentially contaminated equipment. Sterility and performance of these devices are guaranteed by the manufacture only if they are intact and prepared as recommended for single use only. The product labeled "for single use only", "disposable" or its equivalent, shall not be reused and should be discarded after their initial use. The reprocessing and reuse of single-use products pose the risk of bacterial growth, contamination, patient injuries and could lead to death. Faulty clean, re-sterilization and tests may allow the transmission of infectious disease between patients; may alter device's mechanical properties and thus risk product failure. It is the end user's responsibility to read and understand the important warnings and to ensure the single use of medical devices. Do not reuse. Hemodialysis catheter kit is intended to be single patient use only and MUST be replaced for each patient.

NOTE：Dispose of safely following local procedures for the disposal of medical waste.

U.S. Federal Law restricts the sale of the device to use under physician's prescription only.

Manufactured by
BIOTEQUE CORPORATION
5F-6,No.23,Sec.1,Chang-An E.Road,Taipei 104,Taiwan
TEL:+886-2-2571-0269 FAX:+886-2-2536-1967

MADE IN TAIWAN

EC REP MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany