DILYS CATH

HEMODIALYSIS CATHETER KIT

INSTRUCTIONS FOR USE

DESCRIPTION

Hemodialysis catheters are made of thermosensitive Bodysoft polyurethane. The catheter is divided into two separate lumens by a septum permitting continuous blood flow with one puncture. The venous lumen extends as a single lumen, approximately three centimeters beyond the dual lumen, to isolate the blood return from the blood intake. The venous extension tip is smaller and more flexible than the body of the catheter allowing easier insertion and greater patient comfort and safety. These products should be stored in a cool, dry place.

INDICATIONS FOR USE

Hemodialysis catheters are indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion and apheresis therapy via the jugular, subclavian, or femoral vein.

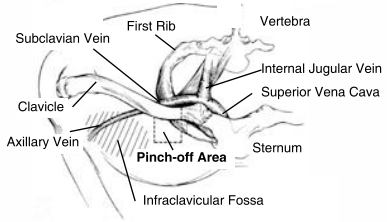
CONTRAINDICATIONS

- The catheter is intended for short-term vascular access only and is not to be used for any purpose other than indicated in these instructions. The catheter must not be left in the femoral vein longer than three days. To maintain peak performance, it is recommended that jugular and subclavian catheters be replaced after four weeks.

WARNINGS:

- **SUBCLAVIAN ONLY.** Pinch-off Prevention: Percutaneous insertion of the catheter must be made into the axillary-subclavian vein at the junction of the outer and mid-third of the clavicle lateral to the thoracic outlet. The catheter must not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to damage or fracture and embolization of the catheter.

  Fluoroscopic or radiographic confirmation of catheter tip placement can be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.



SIGNS OF PINCH-OFF

Clinical:

- Difficulty with blood withdrawal.
- Resistance to infusion of fluids.
- Patient position changes required for infusion of fluids or blood withdrawal.

Radiologic: (see table)

- Grade 1 or 2 distortion on chest X-ray.

Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows: 2,3

Radiologic Signs of Pinch-Off

Grade 0	**No distortion**	**No action.**
Grade 1	**Distortion present without luminal narrowing.**	**Chest x-ray should be taken to monitor progression of pinch-off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.**
Grade 2	**Distortion present with luminal narrowing.**	**Removal of the catheter should be considered.**
Grade 3	**Catheter transection or fracture.**	**Prompt removal of the catheter.**

WARNINGS (cont.):

- Alcohol or alcohol-containing antiseptics (such as chlorhexidine) may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact of the catheter with the solution(s). Solutions should be allowed to completely dry before applying occlusive dressing.
- Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments are the preferred alternative.
- Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by re-use of the catheter or accessories.
- Place all clamps near the center of the polyurethane extension pieces. Polyurethane may develop cuts or tears if subjected to excessive pulling or contact with rough edges. Repeated clamping near or on the Luer-lock connectors may cause tubing fatigue and possible disconnection.

CATHETER REMOVAL

After removing the catheter, apply manual pressure to the puncture site for 10-15 minutes until no signs of bleeding are present. Then apply an occlusive dressing for 8 hours.

DISPOSAL

After use, the catheter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

TROUBLESHOOTING

PATIENT WITH FEVER

Unusual signs or symptoms (e.g. fever, chills) following the procedure may indicate septic thrombosis. If this does result, the catheter can be removed.

INSUFFICIENT FLOW

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by occluded arterial holes resulting from a clot or by side holes contacting the wall of the vein. If manipulation of the catheter through rotation or reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent (e.g. TPA). Physician discretion advised.

CATHETER EXCHANGE

It may become necessary to exchange the indwelling catheter due to infection or a persistent rise in pressures or decrease of flow rates which cannot be rectified through troubleshooting. If this or the recommended 3 day femoral or 4 week subclavian/ jugular indwelling period has elapsed, then a straight “over the guidewire exchange” can be used at the physician’s discretion.

REFERENCES

1 Aitken, D.R. and Minton, J.P. “The Pinch-Off Sign: A Warning of Impending Problems with Permanent Subclavian Catheters”, American Journal of Surgery, Vol. 148, Nov. 1984, pp.633-638.

2 Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. Pinch-off syndrome: A complication of implantable subclavian venous access devices. Radiology 177: 353-356, 1990.

3 Ingle, Rebecca,; Nace, Corinne, Venous Access Devices: Catheter Pinch-off and Fracture, 1993, **Bard Access Systems**

Other references available upon request.

An issued or revision date for these instructions is included for the users information. In the event two years have elapsed ’ between this date and product use, the user can contact Bard Access Systems, Inc. to see if additional product information is available.

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A SYSMECH - MAIS JOINT VENTURE

Mais India

The health care specialist

- Repeated over-tightening of bloodlines, syringes and caps will reduce connector life and may lead to connector failure.
- Enzymes in blood and heparin may cause temporary sticking of the extensions when clamped for extended periods of time. To release, open clamp and slide away, gently rotating the tubing between fingers and thumb until the tubing separates.
- To avoid damage to vessels and viscus, infusion pressures must not exceed 25 psi (172 kPa). The use of a 10 ml or larger syringe is recommended because smaller syringes generate more pressure than larger syringes. Note: A three pound (13.3 Newton) force on the plunger of a 3 ml syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10 ml syringe generates less than 15 psi (103 kPa) of pressure.

- Accessories and components used in conjunction with this catheter must incorporate luer-lock adapters in order to avoid inadvertent disconnection.
- Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens.
- Before dialysis begins, all connections to the extra corporeal circuit must be checked carefully. During all dialysis procedures 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 the rare event of a leak, the catheter must be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedure.
- If the dual lumen catheter is not used immediately for treatment, follow the suggested Catheter Patency Guidelines.
- Failure to clamp extensions when not in use may lead to air embolism.
- Verification of the catheter tip location must be confirmed by x-ray to ensure proper placement.
- To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of both lumens immediately prior to using the catheter.
- For jugular and subclavian insertion, the patient must be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guide wire is allowed to pass into the right atrium. The guide wire must be held securely during the procedure.
- The risk of infection is increased with femoral vein insertion.
- Before attempting the insertion of HEMODIALYSIS CATHETER, ensure that you are familiar with the possible complications listed below and their emergency treatment should they occur.

CAUTIONS:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Carefully read and follow all instructions prior to use.
- Strict aseptic technique must be used during the insertion, maintenance and catheter removal procedures.
- Do not pull back guide wire over needle bevel as this may sever the end of the guide wire. The introducer needle must be removed first. Also, if unusual resistance is met during manipulation of the guide wire, discontinue the procedure and determine the cause of resistance before proceeding. Withdraw needle and guide wire if cause of resistance cannot be determined.
- Do not allow the guide wire to inadvertently advance totally into the vessel.
- For jugular and subclavian insertion, the catheter tip must be located above the junction of the superior vena cava and right atrium.
- Sterilized by Ethylene Oxide. Sterile, non-pyrogenic unless package is damaged or opened.
- Single Use Only. Do Not Resterilize.

POSSIBLE COMPLICATIONS

The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications including the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Cuff Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage Due to Compression Between the Clavicle and First Rib[1]
- Catheter-Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis Extravasation
- Fibrin Sheath Formation Hematoma
- Hemothorax Hydrothorax
- Inflammation, Necrosis or Scarring of Skin Over Implant Area
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-operative Recovery

These and other complications are well documented in medical literature and must be carefully considered before placing the catheter. Placement and care of HEMODIALYSIS CATHETER must be performed only by persons knowledgeable of the risks involved and qualified in the procedures.

INSTRUCTIONS FOR CATHETER INSERTION

The catheter must be inserted only under strict aseptic conditions in which the operator must wear a mask, gown and gloves. For Jugular or Subclavian insertion, the patient must be in a modified Trendelenburg position, with the head turned to the side opposite that of the insertion site. A small rolled towel may be inserted between the shoulder blades. For Femoral insertion, place patient in supine position to expose the side of the groin to be accessed.
The skin above and below the insertion site is prepared by shaving, followed by scrubbing the entire area with a povidone iodine solution, or comparable antiseptic solution.
The area is draped with sterile towels.
The insertion site is identified. A local anesthetic is injected over the site.
A syringe is attached to an introducer needle that will permit passage of the guidewire.
The introducer needle is inserted into the identified vein.
The syringe is removed leaving the introducer needle in place.

WARNING: For jugular and subclavian insertion, the patient must be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire must be held securely during the procedure.

The guidewire can be inserted into the needle hub and passed through the needle. Advance the guidewire to the desired location in the vessel.

CAUTION: Do not pull back guidewire over needle bevel as this may sever the end of the guidewire. The introducer needle must be removed first. Also, if unusual resistance is met during manipulation of the guidewire, discontinue the procedure and determine the cause of resistance before proceeding. Withdraw needle and guidewire if cause of resistance cannot be determined.

Holding the guidewire securely in place, remove the introducer needle.

CAUTION: Do not allow the guidewire to inadvertently advance totally into the vessel.

The introducer needle tract is widened by creating a small surgical incision at the skin exit site followed by the use of a hemostat to dilate the subcutaneous tissues or by using a vessel dilator.

Irrigate the catheter with heparinized-saline filled syringes. The syringes are removed and the arterial extension (identified by the red connector) is clamped.

The catheter is passed over the proximal end of the guidewire by inserting the guidewire tip into the tapered end of the catheter. The venous clamp must be in the open position to allow the catheter to pass completely over the wire and into the vein.

CAUTION: For jugular and subclavian insertion, the catheter tip must be located above the junction of the superior vena cava and right atrium.

The guidewire is removed, and the venous clamp is closed. Irrigate the lumens again with heparinized-saline filled syringes. (It is necessary to open the extension clamps during the irrigation procedure). Close the arterial and the venous clamps and the injection caps are placed over the ends of each luer lock connector on the extension pieces. It is recommended that the venous lumen, as indicated by the BLUE luer lock connector be oriented cephalad.

The suture wing is oriented to the skin surface and attached using either a StatLock* device or suture. A sterile adhesive transparent dressing is used to cover the skin exit site.

WARNING: Verification of the catheter tip location must be confirmed by x-ray to ensure proper placement.

The catheter is now ready for use. The arterial lumen of the catheter is connected to the arterial side of the extra corporeal circuit. The venous lumen of the catheter is connected to the venous side of the extra corporeal circuit.

CATHETER PATENCY GUIDELINES

1. Flush arterial and venous lumens with a minimum of 10 ml of sterile saline.
2. Inject a heparin solution of 5000 units per ml of saline into both the arterial and venous lumens of the catheter. When injecting heparin, inject quickly to insure that the heparin completely fills the lumen of the catheter. The total volume of each heparin solution must be equal to the internal volume of each lumen. Each lumen must be completely filled with a heparin solution. The priming volume is indicated on each lumen.
3. Attach the sterile injection caps to both the arterial and the venous clamping extension pieces.
   WARNING: To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of both lumens immediately prior to using the catheter.
   In most instances, no further heparin injection is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.

Performance Guideline: Flow Rate vs Lumen Pressure		
	Straight Catheter (24 cm)	**Curved Extension Catheter (24 cm)**
	200 ml/min	200 ml/min
Venous	174 mmHg	150 mmHg
Arterial	-133 mmHg	-146 mmHg

CARE AND MAINTENANCE

1. The care and maintenance of the catheter requires well trained, skilled personnel following a detailed protocol. The protocol should include a directive that the catheter is not to be used for any purpose other than the prescribed therapy.
2. The exit site must be checked daily. Sterile technique, including face mask, hand washing and sterile gloves must be used for these procedures.
3. Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.
4. Clean the exit site daily with hydrogen peroxide followed by povidone iodine solution. Clean from the catheter working outward in a circular motion.
5. Cover the exit site per your institution's protocol.

WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments are the preferred alternative.