BD GlidePath™ 7.5F
Long-Term Dialysis Catheter

BD GlidePath™ 10F
Long-Term Dialysis Catheter

Instructions For Use

Instructions for Use

For GlidePath™ 7.5F and GlidePath™ 10F Straight Configuration Catheters

Information in the IFU should be discussed with the patient, at the discretion of the physician.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Description

The GlidePath™ 7.5F and GlidePath™ 10F catheters are made of radiopaque polyurethane, and allow for adequate dialysis flow rates. The catheter shaft is divided internally into two separate lumens by a septum allowing hemodialysis without the use of a "single needle" system. The catheter comes with a white retention cuff for tissue ingrowth to anchor the catheter.

STERILE EO

Indications for Use

The GlidePath™ 7.5F and GlidePath™ 10F long-term hemodialysis catheters are indicated for use in attaining short-term or long-term vascular access in pediatric, adolescent and adult patients for hemodialysis, hemoperfusion or apheresis as determined by the prescribing physician. Access is attained via the internal jugular vein, subclavian vein, or femoral vein. Catheters longer than 22 cm are intended for femoral vein insertion, depending on patient anatomy and size.

Contraindication

This device is contraindicated for patients exhibiting severe, uncontrolled thrombocytopenia or coagulopathy.

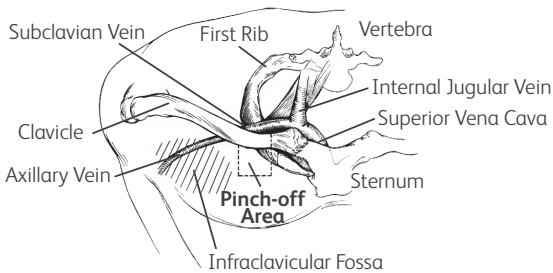
Storage

Keep away from sunlight. Keep dry.

Equipment Required

- Adhesive Dressing
- End Cap
- Scalpel
- Tunneler
- Introducer Needle
- GuideWire
  (10F max size 0.035; 7.5F max size 0.032)
- Appropriate introducer sheath and dilator set
- Contrast medium
- Sterile saline solution
- Heparin solution
- Microintroducer kit

Warnings



WARNING: Percutaneous insertion of the catheter should be made into the axillary-subclavian vein at the junction of the outer and mid-thirds of the clavicle lateral to the thoracic outlet. The catheter should 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.[1] Fluoroscopic or radiographic confirmation of catheter tip placement should be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.[1]

Warnings (cont'd)

- Alcohol or alcohol-containing antiseptics (such as chlorhexidine) may be used to clean the skin exit site. When cleaning the exit site, inadvertent contact with the catheter is acceptable, but repeated catheter contact should be avoided. Apply antiseptic per manufacturer's recommendations. Allow to air dry completely before applying dressing. In all cases skin cleaning/disinfection should follow local facility protocols.
- Alcohol should not be used to lock, soak or declot polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Acetone and Polyethylene Glycol (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.
- Follow Universal Precautions when inserting and maintaining this device.
- Cardiac arrhythmias may result if the guidewire touches the walls of the right atrium. Use cardiac rhythm monitoring to detect arrhythmias.
- Close all clamps only in the center of the extension legs. Extensions may develop cuts or tears if subjected to excessive pulling or contact with rough edges. Repeated clamping near or on the Luer-lock connectors or in the same location on the extension leg may cause tubing fatigue and possible disconnection.
- Catheters should be implanted carefully.
- Any sharp or acute angles that could compromise the opening of the catheter lumens need to be avoided.
- To prevent air embolism and/or blood loss put patient in Trendelenburg position and always place thumb over the exposed orifice of the sheath introducer.
- To avoid damage to vessels and viscus, infusion pressures should 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 should incorporate Luer-lock adapters.
- The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
- Failure to clamp extensions when not in use may lead to air embolism.
- In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis or infusion procedure.
- The risk of infection is increased with femoral vein insertion.
- Do not re-sterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by reuse of the catheter or accessories.
- Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein.[7]
- Intended for Single Use. DO NOT RE-USE. Re-use and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

Precautions

- Pediatric patients may need multiple types of access over the course of their lives and vessel sizes differ in children from adults. Due to the variety of pediatric catheter lengths available, patient size must be carefully considered relative to the actual length of the catheter being inserted. Physicians should consider the child's age, weight, body surface area and periods of rapid growth when placing a device. Special considerations should be taken in children with congenital anomalies (e.g., congenital heart disease) and/or unique conditions (e.g., hemihypertrophy).
- The selection of the appropriate catheter length and diameter is at the sole discretion of the physician. To achieve proper tip placement and adequate dialysis, proper catheter length selection is important. Routine fluoroscopy or chest x-ray, as per institutional protocol, should always follow the initial insertion of this catheter to confirm proper placement prior to use.

Precautions (cont'd)

*Patient Size (kg)	Tunneled Catheter	†Flow Rate (up to)
< 10 kg	Made on a case by case basis	
10 - 40 kg	GlidePath 7.5F	129 ml/min
20 - 85 kg	GlidePath 10F	256 ml/min

**Catheter selection should be made by physicians on a case by case basis. The weight ranges here are provided for general guidance only and assume a flow rate of 3 ml/kg/min is acceptable in most patients.*

†Flow rates were established via benchtop testing.

- Repeated over tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure. In case of damage, clamp the catheter between the patient and the damaged area with a smooth-edged, atraumatic clamp.
- Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened/damaged or contamination is evident.
- Read the instructions for use carefully before using this device.
- Left sided placement in particular, may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC.[5,8]
- Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result.
- Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse to the catheter.
- Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.
- For optimal product performance, do not insert any portion of the cuff into the vein.
- If the microintroducer guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
- Before attempting the insertion of GlidePath™ 7.5F and GlidePath™ 10F catheters, ensure that you are familiar with the complications listed below and their emergency treatment should any of them occur.
- The complications listed below as well as other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of GlidePath™ 7.5F and GlidePath™ 10F catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

Adverse Reactions

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
- Arterial Puncture
- 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
- Fever
- Fibrin Sheath Formation
- Hematoma
- Hemomediastinum
- Hemothorax
- Hydrothorax
- Infiltration
- Inflammation, Necrosis or scarring of skin over implant area
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Phlebitis
- Pleural injury
- Pneumothorax
- Retroperitoneal bleed
- Right atrial puncture
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery
- Thoracic Duct Injury
- Thromboembolism
- Tunnel infection
- Venous Stenosis
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion

Device Incident Reporting

A notice to the use and/or patient: any serious incident that has occurred in relation to the device should be reported to the manufacturer and appropriate regulatory body (FDA, competent authority, etc.)

Directions For Use

Patient Implant Card

A Patient Implant Card is provided within the product packaging. The patient, implant and hospital information should be recorded on the card as requested. Ensure a peel-away sticker from the product label is placed on the card before it is given to the patient. The sticker contains important information about the implant. The patient should carry the implant card with them and present it to any medical personnel involved in their care.

Insertion Technique (1)

Percutaneous Placement Procedure of the GlidePath™ 7.5F and GlidePath™ 10F Catheters with cuff using the split sheath introducer.

For percutaneous placement, the catheter is inserted in either the subclavian vein or internal jugular vein through a split sheath introducer. It has been reported that right side, internal jugular placement is the preferred initial location of consideration for percutaneous insertion. The patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site. [6,9]

A (Common Steps)

Catheters must be inserted under strict aseptic conditions.

WARNING: Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein.[7]

CAUTION: As reported in literature, left sided catheter placement may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC.[5,8]

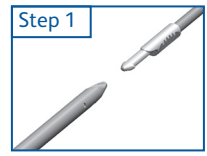
1. Provide a sterile field throughout the procedure. The operator should wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient.
2. Prepare the access site using standard surgical technique and drape the prepped area with sterile towels. If hair removal is necessary, use clippers or depilatories. Next, scrub the entire area preferably with chlorhexidine gluconate unless contraindicated in which case povidone-iodine solution may be used. Use a back-and-forth friction scrub for at least 30 seconds[10]. Do not wipe or blot. Allow antiseptic solution to air dry completely before puncturing the site.
3. (If applicable) Administer local anesthesia to the insertion site and the path for subcutaneous tunnel.
4. Flush each lumen with heparin solution prior to insertion and clamp the extension legs.
5. Insert the introducer needle with an attached syringe to the desired location. Aspirate gently as the insertion is made.
6. When the vein has been entered, remove the syringe leaving the needle in place.
7. If using a micropuncture set, insert the flexible end of the microintroducer guidewire into the needle. Advance the microintroducer guidewire as far as appropriate. Verify correct positioning, using fluoroscopy or ultrasound.
    - Gently withdraw and remove the needle, while holding the guidewire in position. **CAUTION:** If the micro-introducer guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
    - Advance the small sheath and dilator together as a unit over the micro-introducer guidewire, using a slight rotational motion. Advance the unit into the vein as far as appropriate.
    - Withdraw the dilator and micro-introducer guidewire, leaving the small sheath in place. **WARNING:** Place a thumb over the orifice of the sheath to minimize blood loss and risk of air aspiration.

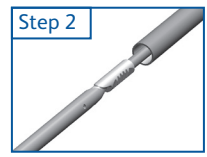
A (Common Steps) *(cont'd)*

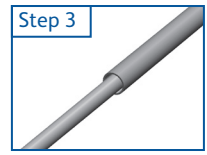
8. The standard guidewire can be inserted into the needle hub and passed through the needle. Advance the standard guidewire to the desired location in the vessel.
9. If using a microintroducer, gently withdraw and remove the small sheath, while holding the standard guidewire in position.
10. Remove the needle while holding the guidewire in place. Wipe the guidewire clean and secure it in place.
    CAUTION: Do not pull back standard guidewire over needle bevel as this could sever the end of the guidewire. The introducer needle must be removed first.
11. Make a small incision at the insertion site. Make a second incision at the desired exit site of the catheter.
12. Go to B (Common Steps).

B (Common Steps)

1. With a tunneler, create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site. If using the tunneler in the kit *(see Steps 1 to 3 on the right)*, introduce the tip of the tunneler into the opening on the arterial lumen until the stepped section of the tunneler touches the distal tip of the catheter. Do not apply pressure causing the distal tip of the catheter to fold over the stepped section of the tunneler *(see Step 2 image)*. This allows the catheter to be threaded through the tissue as the tunnel is created. Slide the sheath found on the tunneler over the catheter tip/tunneler connection until it stops. In addition, ensure the open end of sheath is covering the catheter tip. This will reduce the drag on the catheter tip in the skin tunnel and secure the catheter to the tunneler. (After positioning cuff, tunneler can be removed by sliding sheath away from the catheter and pulling tunneler from catheter tip.) The catheter should not be forced through the tunnel.







2. Position the white retention cuff approximately midway between the skin exit site and the venous entry site, 3 cm minimum, from the venous entry site. Detach tunneler from catheter.

C (Insertion Techniques: Percutaneous Placement)

Insertion Technique (1)

1. Fill the catheter lumens with heparinized saline solution.
2. Advance the dilator sheath introducer assembly over the exposed guidewire into the vessel.
   CAUTION: Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result. As reported in literature, left sided catheter placement may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC.[5,8]
   WARNING: Cardiac arrhythmias may result if the guidewire is allowed to touch the walls of the right atrium.
3. Withdraw the vessel dilator and guidewire, leaving the introducer sheath in place.
   CAUTION: Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse to the catheter.
   WARNING: To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer.
4. Remove thumb and feed distal section of catheter into the sheath introducer. Advance the catheter tip. Catheter tip placement, tip orientation and proper length selection is left to the discretion of the physician. However, routine x-ray should always follow the initial insertion to confirm proper placement of the catheter tips prior to use. The recommended tip location is at the junction of the superior vena cava/right atrium (SVC/RA) or in the mid right atrium.[6] All tip placements should be confirmed by fluoroscopy.
5. With the catheter advanced, peel away the sheath by gripping the "T" handle and breaking it apart with a downward and outward motion to initiate separation and withdrawal of the sheath.
   CAUTION: Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.
   CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.
6. Go to D (Common Steps).

D (Common Steps)

1. Confirm catheter patency by releasing clamp and aspirating blood through each lumen.
2. Flush each lumen with 10 mL sterile saline using a 10 mL or larger syringe.
   WARNING: To avoid damage to vessels and viscus, infusion pressures should 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
3. Inject heparin solution into each lumen in amounts equal to the priming volumes as printed on the catheter clamps. Be sure to clamp each lumen immediately.
   WARNING: Failure to clamp extensions when not in use may lead to air embolism.
4. For additional security, suture the entire entry site, or use a Statlock® Catheter Stabilization device to anchor the catheter.
5. Follow your hospital protocol for dressing change and exit site care. Allow alcohol-containing agents (e.g., ChloraPrep™ solution) to air dry completely before dressing catheter.
   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.
6. Verify the catheter tip location with x-ray or fluoroscopy.

Insertion Technique (2) Sheathless Procedure[2]:

For sheathless placement, the catheter is preferably inserted into the internal jugular vein. For the sheathless procedure, the patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.

1. Go to A (Common Steps).
2. Go to B (Common Steps).
3. Skip C (Insertion Technique (1) Percutaneous Placement).
4. Sequentially dilate (guiding dilators over the guidewire) the venous puncture site to accommodate the catheter (dilate vessel to at least the same French size as the catheter, and preferably to 1.5 F larger).
5. After removing the dilator, keep the guidewire in the venous system while applying digital compression at the puncture site to maintain hemostasis.
6. The proximal end of the guidewire must be inserted into the end hole of the catheter tip and threaded into the arterial lumen. The guidewire must be threaded through the arterial lumen until it extends out the arterial Luer-lock connector (red).
7. To minimize the risk of air embolism, clamp the venous extension leg (indicated by the blue Luer-lock connector).
8. Advance the catheter over the wire, until the tip reaches the desired location. Note that some resistance may be experienced when passing the catheter through the soft tissues, but this should subside once the catheter tip is intravascular.
   CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.
   WARNING: Cardiac arrhythmias may result if the guidewire is allowed to touch the walls of the right atrium.
9. Remove the guidewire while applying forward pressure on the catheter so it does not withdraw.
   CAUTION: Ensure that the catheter does not move out of the vein while removing the insertion.
10. Go to D (Common Steps).

Insertion Technique (3) Femoral Vein Placement Procedure:

For femoral placement, the patient should be positioned supine, and the catheter tip should be inserted to the junction of the iliac vein and inferior vena cava[3].

WARNING: The risk of infection is increased with femoral vein insertion.

NOTE: Catheters longer than 22 cm are intended for femoral vein insertion, depending on patient anatomy and size.

Insertion Technique (3) Femoral Vein Placement Procedure (cont'd)

1. Assess the right and left femoral areas for suitability for catheter placement. Ultrasound may be helpful.
2. On the same side as the insertion site, the patient's knee should be flexed, and the thigh abducted with the foot placed across the opposing leg.
3. Locate the femoral vein, posterior/medial to the femoral artery.
4. Go to A (Common Steps).
5. Go to B (Common Steps), directing tunnel laterally to decrease the risk of infection.[4]
6. Go to C (Insertion Technique (1) Percutaneous Placement).

GlidePath™ 7.5F and GlidePath™ 10F Catheter Flow Rates, Venous and Arterial Pressures

Please refer to the insert for complete Flow Rate Information and Charts.

Recommended Dressing Technique

Apply dressing per facility protocol and change if bloody, non-adherent or wet. Dress per hospital protocol.

Care and Maintenance

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.

Accessing Catheter, Cap Changes, Dressing Changes[6]

- Experienced personnel
- Use aseptic technique
- Proper hand hygiene
- Clean gloves to access catheter and remove dressing and sterile gloves for dressing changes
- Surgical mask (1 for the patient and 1 for the healthcare professional)
- Catheter exit site should be examined for signs of infection and dressings should be changed at each dialysis treatment.
- Catheter Luer-lock connectors with end caps attached should be soaked for 3 to 5 minutes in povidone iodine and then allowed to dry before separation.
- Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.

Exit Site Cleaning[11]

- Use aseptic technique (as outlined above).
- 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

Catheter Luer-lock Connectors/End Caps:

- Povidone iodine (allow connectors/end caps to soak for 3 to 5 minutes)
  WARNING: Alcohol should not be used to lock, soak or declot polyurethane dialysis catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure. Hand cleaner solutions are not intended to be used for disinfecting BD dialysis catheter Luer-lock connectors.

Exit Site:

- Chlorhexidine gluconate 2% solution (preferred)[6, 10, 11, 12, 13]
- Chlorhexidine gluconate 4% solution
- Dilute aqueous sodium hypochlorite
- 0.55% sodium hypochlorite solution
- Povidone iodine
- Hydrogen peroxide
- Chlorhexidine patches
- Bacitracin zinc ointments in petrolatum bases

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.

Post Dialysis

Use aseptic technique (as outlined above).

1. Flush arterial and venous lumens with a minimum of 10 mL of sterile saline.
   WARNING: 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.
2. Inject heparin solution into both the arterial and venous lumens of the catheter. The appropriate heparin solution concentration and flushing frequency should be based on hospital protocol. Heparin solution of 1,000 to 5,000 units/mL has been found to be effective for maintaining the patency of hemodialysis and apheresis catheters.[14] When injecting heparin solution, inject quickly and clamp extension while under positive pressure. Heparin solution volume to lock each lumen must be equal to the priming volume of each lumen. Priming volumes are marked on each lumen.
3. Clean catheter Luer-lock connectors per hospital protocol. Attach sterile end 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 solution injection is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.
4. This catheter may contain a Heparin solution - aspirate based on the priming volume or as appropriate for each specific catheter.

Catheter Removal

Evaluate the catheter routinely and promptly remove any nonessential catheter[11] per physician's orders. The white retention cuff facilitates tissue in-growth. The catheter must be surgically removed. Free the cuff from the tissue and pull the catheter gently and smoothly. After removing the catheter, apply manual pressure to the puncture site for 10-15 minutes until no signs of bleeding are present. Then apply sterile, transparent, semipermeable dressing or dressing per hospital protocol for a minimum of 8 hours. Follow hospital protocol regarding bed rest after catheter removal.

Disposal

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

Troubleshooting

Patient With Fever

Patient with fever and chills following the procedure may be indicative of catheter related bacteremia. If bacteremia is present, removal of the catheter may be indicated.

Insufficient Flow

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

Catheter Exchange

Do not routinely replace dialysis catheters to prevent catheter-related infections.[13] It may become necessary to exchange the indwelling catheter due to a persistent rise in pressures or decrease of flow rates which cannot be rectified through troubleshooting.

Catheter exchanges should be performed under strict aseptic conditions in which the physician should wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient.

Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

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An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

Revision Date: November 2020

Assembled in Mexico.


Biohazard


Consult Instructions For Use


Date Of Manufacture

Do Not Resterilize


Do Not Re-use


Do Not Use If Package Is Damaged

French Size


Keep Away From Sunlight


Keep Dry


Length

Lot Number

Medical Device

MR Safe


Non-Pyrogenic

Not Made With Natural Rubber Latex


Quantity

Reorder Number

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.


Sterile Barrier

Sterilized Using Ethylene Oxide

Straight

Tip To Cuff Length

Tip To Hub Length


Use By Date

Manufacturer:
Bard Peripheral Vascular, Inc.
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