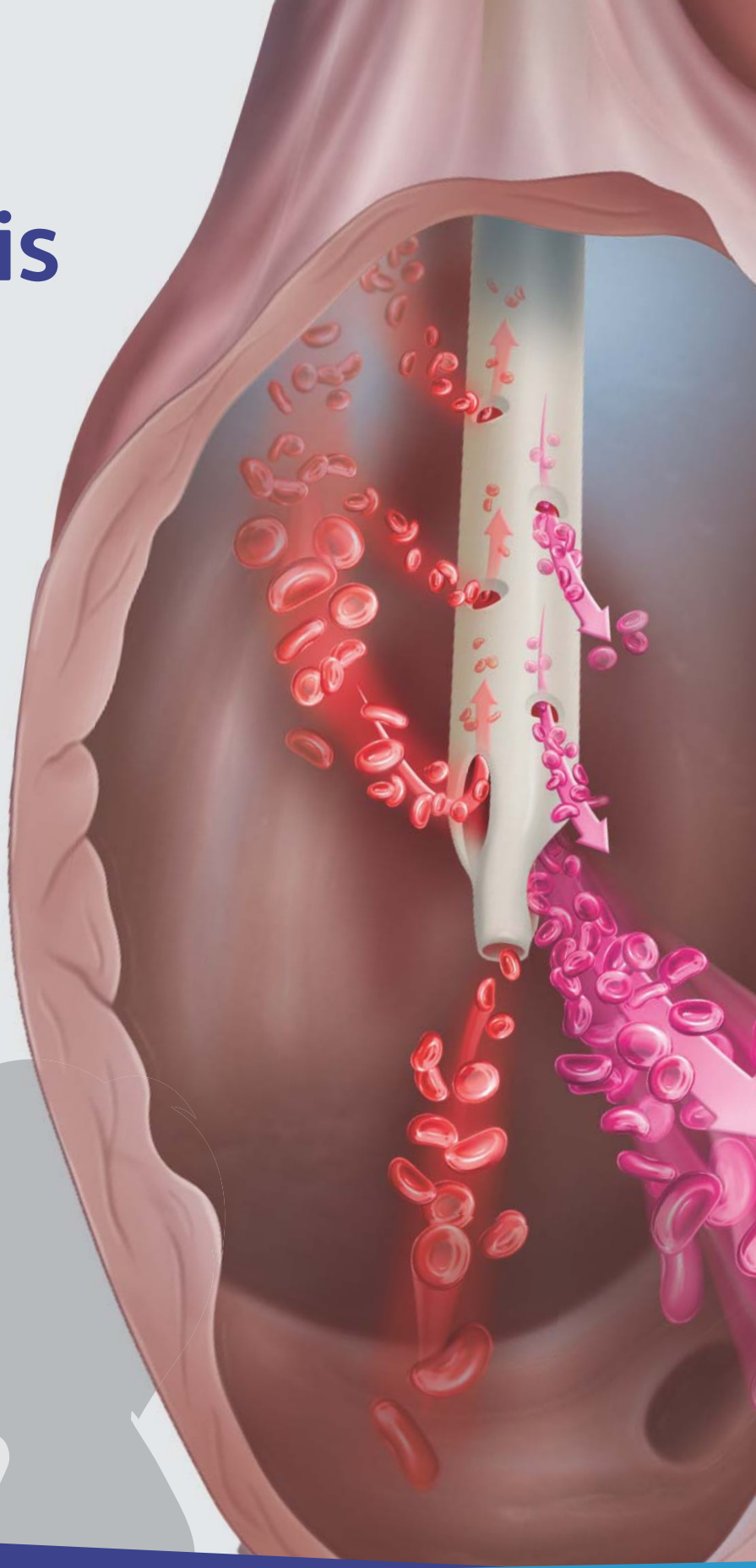
Pediatric Hemodialysis Access

Symmetric tip catheter with a **smaller French size** and **shorter lengths** to more adequately address the needs of pediatric patients.

GlidePath™ 10F

Long-Term Dialysis Catheter



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GlidePath™ 10F

Long-Term Dialysis Catheter

GlidePath™ 10F Codes - Standard Kits		
Tip to Cuff Length	Tip to Hub Length	Product codes
10 cm	13 cm	5303100
12 cm	15 cm	5303120
15 cm	18 cm	5304150
19 cm	22 cm	5303190
23 cm	26 cm	5303230

10F Kit Components

- 10F Catheter
- 10F AirGuard™ Valved Introducer with Peel Away Sheath/Dilator
- 10-12 F Dualator™ Dilator
- Tunneler
- 2 End Caps
- 8 Fr Dilator
- J-Tip Guidewire 0.035"
- 18 Gauge Introducer Needle
- 2 Adhesive Dressing
- ID Card

I authorize the purchase of these products.

PHYSICIAN NAME

PHYSICIAN SIGNATURE

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

GlidePath™ 10F Long-Term Dialysis Catheter

Indications for Use: The 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.

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] • 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 with the solution(s). Solutions should be allowed to completely dry 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. • 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. • 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. • 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™ 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™ 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 Rib1 • Catheter-related Sepsis • Endocarditis • Exit Site Infection • Exit Site Necrosis • Extravasation • Fibrin Sheath Formation • Hematoma • Hemomediastinum • 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 • 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

References: 1. Aitken D, Minton J. The "pinch-off sign": A warning of impending problems with permanent subclavian catheters. The American Journal of Surgery. 1984;148:633-638.

For full IFU please visit http://www.bardpv.com/glidepath-ifu.php

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and directions for use.

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