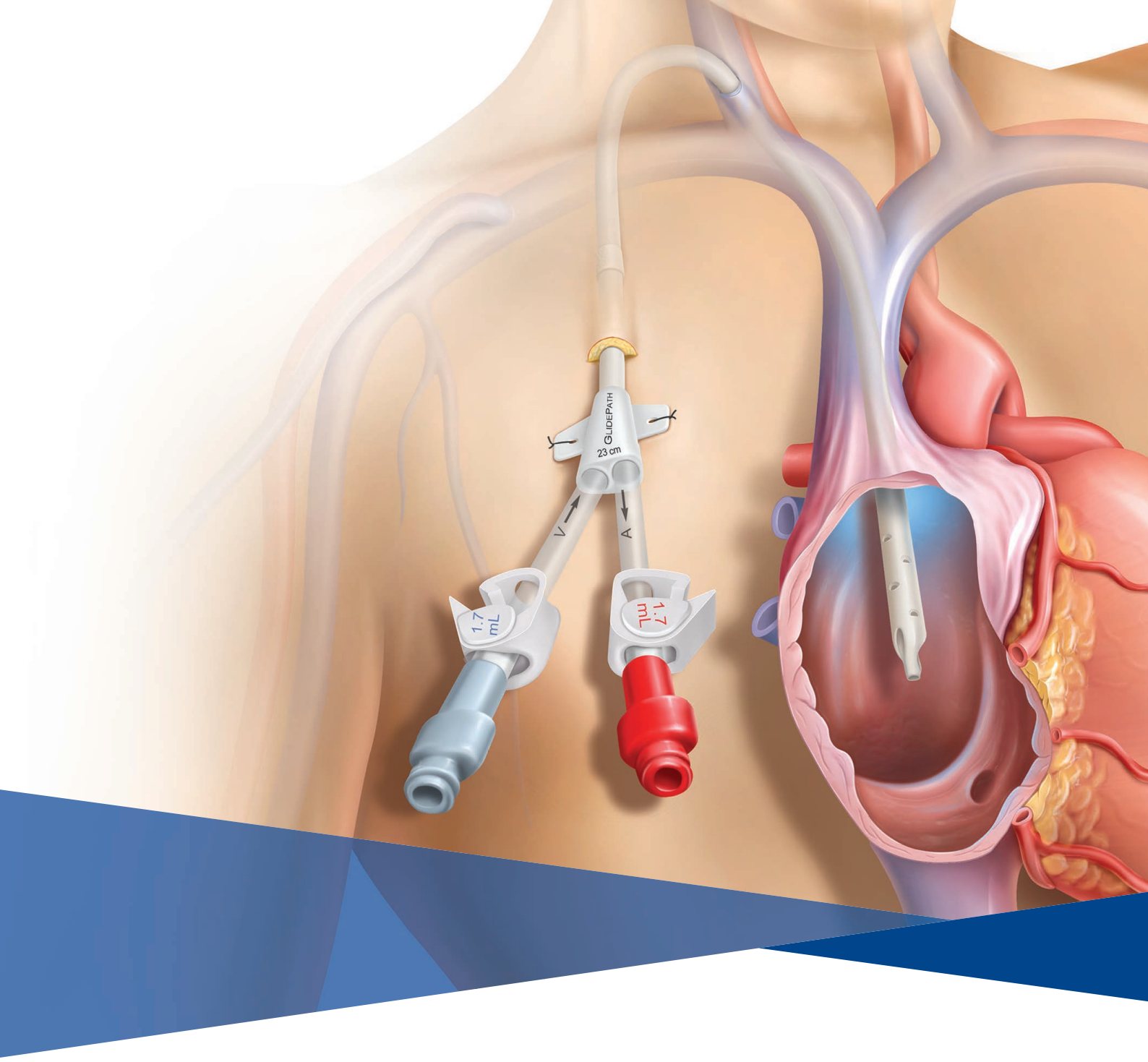


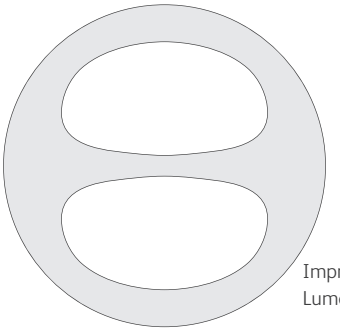
Glidepath™ Long-Term Dialysis Catheter

Exceptional Performance and Ease of Placement

BD

Glidepath™ Catheters Demonstrate

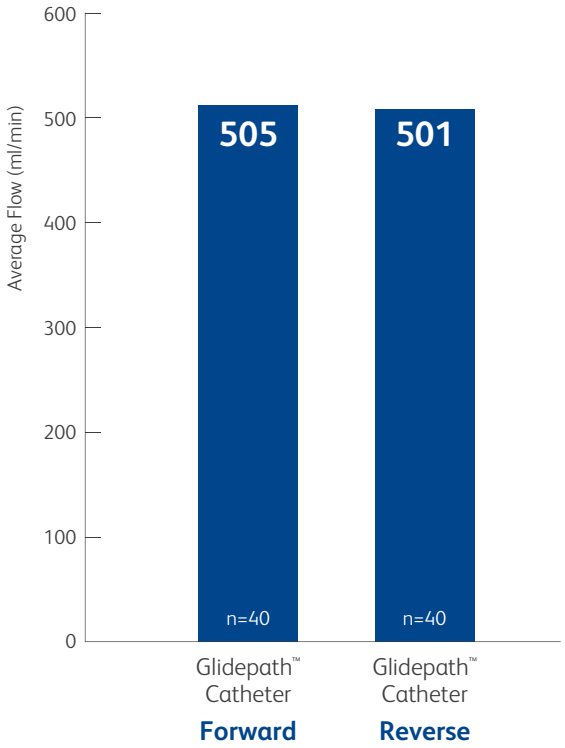
high flow rates & low pressure performance due to its improved inner lumen design



Improved Inner Lumen Design

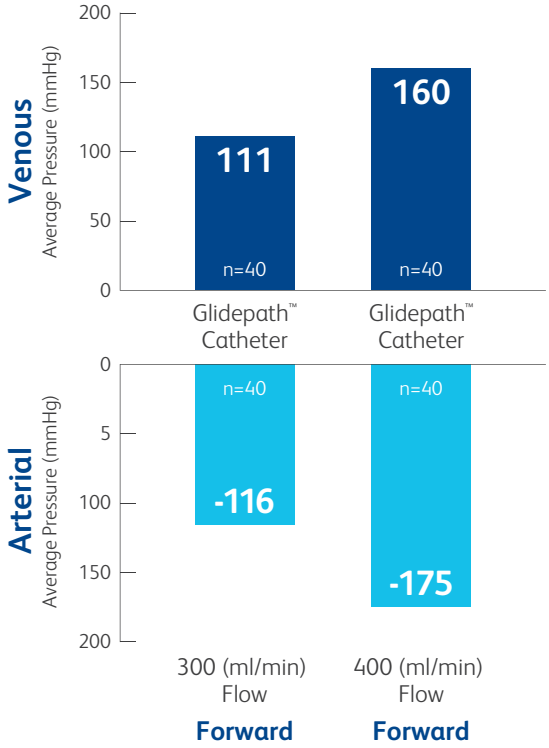
High Flow Rates

Blood Simulant*
At Max Arterial Pressure (-250 mmHg)



Low Pressures

Blood Simulant*



Symmetric Tip Design

Excellent Recirculation Rates -
1% or less on average in both Forward and Reverse*

Tip Designed to **Resist Positional Occlusion**

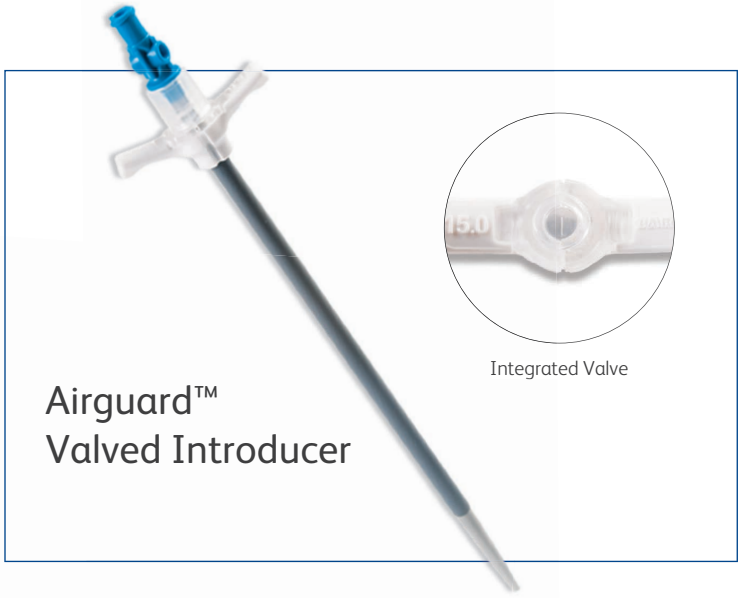
* Bench data on file. May not necessarily correlate to clinical performance. Data using 23 cm catheters.

Ease of **Placement**

One Pre-Loaded Stylet to Simplify Over-the-Wire Placement†

Smooth Tapered Tip and Tapered Cuff for Easy Insertion

Airguard™ Valved Introducer Reduces Risk of Air Embolism



Catheter / Introducer Relationship

	Catheter Size	Introducer Size
Glidepath™ Catheter	14.5 F	15 F

† Straight codes only.

Glidepath™ Long-Term Dialysis Catheter - Ordering Information

Glidepath™ Catheters - Straight		
Tip to Cuff Length	Tip to Hub Length	Standard Kit Product Codes
15 cm	20 cm	6393150
19 cm	24 cm	6393190
23 cm	28 cm	6393230
27 cm	32 cm	6393270

Glidepath™ Catheters - Alphacurve™ Catheter		
Tip to Cuff Length	Tip to Hub Length	Standard Kit Product Codes
19 cm	25cm	6396190
24 cm	29 cm	6396240

Glidepath™ Catheters - Straight , Alphacurve™ Catheter

Standard Kit Contents

- 14.5 Fr Catheter
- 15 Fr Airguard™ Valved Introducer with Peel-Away Sheath/Dilator
- 10 - 12 Fr Dualator™ Dilator
- Insertion Stylet
- Tunneler
- 2 End Caps
- 8 Fr Dilator
- J-Tip Guidewire 0.038"
- 18 Gauge Introducer Needle
- 2 Adhesive Dressings
- ID Card
- IFU

References

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

[5] Mickley, V., "Central venous catheters: many questions: few answers", Nephrol Dial Transplant , (2002) 17:1368-1373.

[7] Sulek, CA., Blas, ML., Lobato, EB, "A randomized study of left versus right internal jugular vein cannulation in adults." J Clin Anesth . 2000 Mar;12(2):142-5

[8] Tan, P.L., Gibson, M., "Central Venous Catheters: the role of radiology", Clin Rad . 2006, 61:13-22

Other references available upon request.

Please consult package inserts for more detailed safety information and instructions for use.

Indications for Use The Glidepath™ long-term hemodialysis catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein. Catheters longer than 40 cm are intended for femoral vein insertion. **Contraindications** This device is contraindicated for patients exhibiting severe, uncontrolled thrombocytopenia or coagulopathy. **Warnings** Percutaneous insertion of the catheter should 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 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. • 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 (e.g., Polysporin® ointment) are the preferred alternative. • Follow Universal Precautions when inserting and maintaining this device. • Cardiac arrhythmias may result if the guidewire and/or stylet 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 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 resterilize 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] • 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. • Intended for Single Use. DO NOT REUSE. Reuse 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. **Cautions** • 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. • Sterile and non-pyrogenic only if packaging is not opened, damaged or broken. • Read the instructions for use carefully before using this device. • CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. • 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. • Stylet is intended for use over a guidewire to aid in placement. Inserting the stylet into the venotomy without tracking over a guidewire could result in vessel damage including perforation. • Failure to retract the stylet when inserting the tunneler into the catheter tip can result in damage to the stylet. • Ensure that the catheter does not move out of the vein while removing the insertion stylet. • Care should be taken not to advance the split sheath too far into the 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 cu 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™ 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™ catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures. **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, Arterial Puncture, Bleeding, Brachial Plexus Injury, Cardiac Arrhythmia, Cardiac Tamponade, Catheter or Cu Erosion Through the Skin, Catheter Embolism, 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, Pneumothorax, Thoracic Duct Injury, Thromboembolism, Venous Stenosis, Venous Thrombosis, Ventricular Thrombosis, Vessel Erosion, Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery.

바드코리아(주) 06236 서울시 강남구 테헤란로 142, 15층
T. 02-2188-2900 F. 02-539-3081

bd.com/ko-kr