GlidePath™

Long-Term Hemodialysis Catheter

GlidePath™ Catheters - Straight			
Tip to Cuff Length	Tip to Hub Length	Standard Kit Product Codes	Exchange Kit Product Codes
15 cm	20 cm	5393150	5397150
19 cm	24 cm	5393190	5397190
23 cm	28 cm	5393230	5397230
27 cm	32 cm	5393270	5397270
31 cm	36 cm	5393310	5397310
35 cm	40 cm	5393350	5397350
42 cm	47 cm	5393420	5397420
50 cm	55 cm	5393500	5397500

GlidePath™ Catheters - Alphacurve™ Catheter		
Tip to Cuff Length	Tip to Hub Length	Standard Kit Product Codes
19 cm	25 cm	5396190
24 cm	29 cm	5396240
28 cm	33 cm	5396280
31 cm	37 cm	5396310

GlidePath™ Catheters - Straight	
Standard Kit Contents	Exchange Kit Contents
· 14.5F Catheter · 15F AirGuard™ Valved Introducer with Peel-Away Sheath/Dilator · 10 - 12F Dualator™ Dilator · Insertion Stylet · Tunneler · 2 End Caps · 8F Dilator · J-Tip Guidewire 0.038" · 18G Introducer Needle · 2 Adhesive Dressings · ID Card · IFU	· 14.5F Catheter · 15F AirGuard™ Valved Introducer with Peel-Away Sheath/Dilator · 10 - 12F Dualator™ Dilator · Insertion Stylet · Tunneler · 2 End Caps · ID Card · IFU

GlidePath™ Catheters - Alphacurve™ Catheter
Standard Kit Contents
The Alphacurve™ Catheter Standard Kit comes with the same contents as the Straight Standard Kit with the exception of the Insertion Stylet.

Product and Packaging Do Not Contain Natural Rubber Latex

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

GlidePath™ Long-Term Hemodialysis Catheter

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.[3] 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 hemodialysis 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 hemodialysis 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 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™ 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 Cuff Erosion Through the Skin, Catheter Embolism, Catheter Occlusion, Damage or Breakage due to Compression Between the Clavicle and First Rib', 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.

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.

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

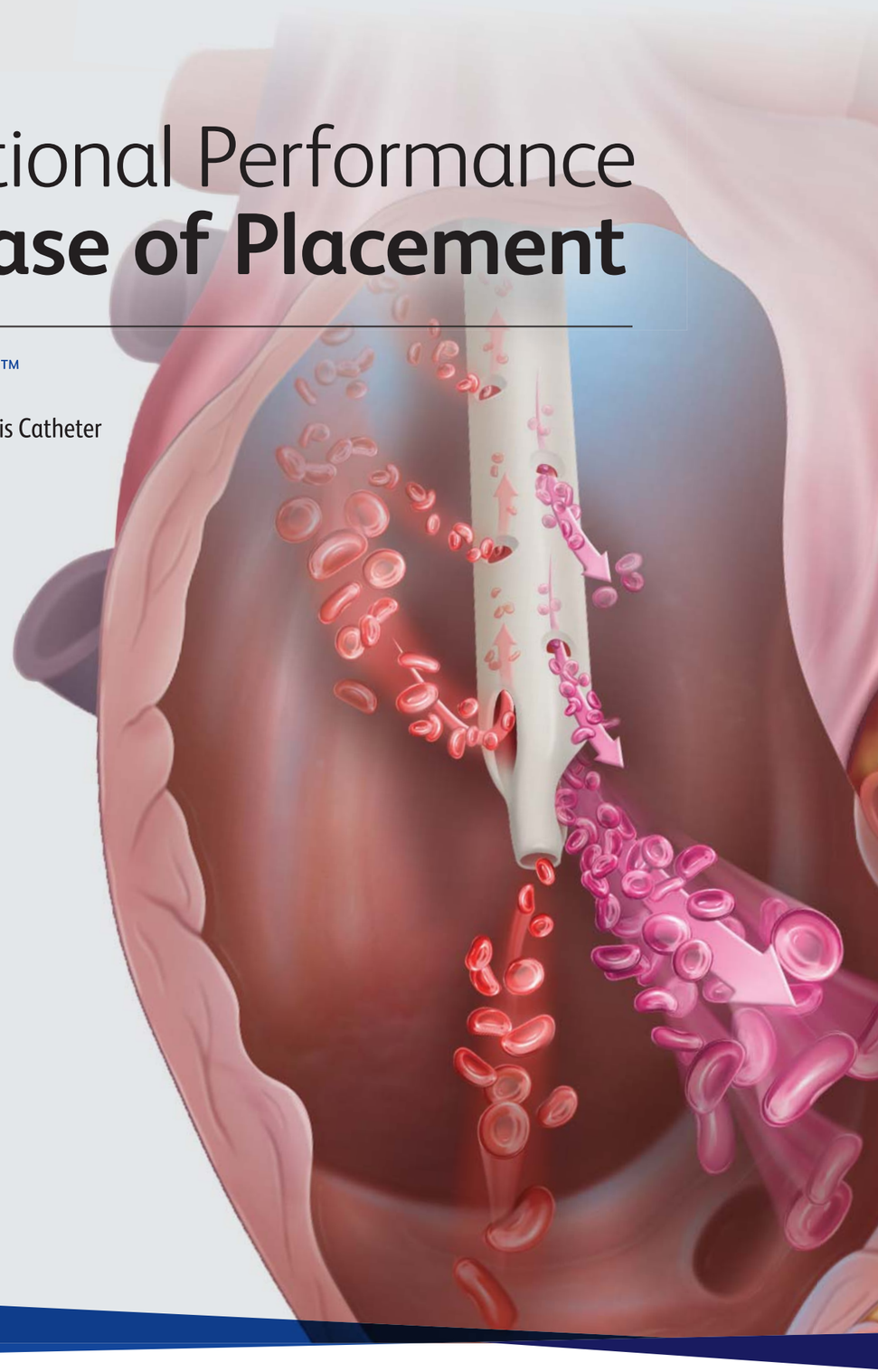
Other references available upon request.

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

Exceptional Performance and **Ease of Placement**

GlidePath™

Long-Term Hemodialysis Catheter

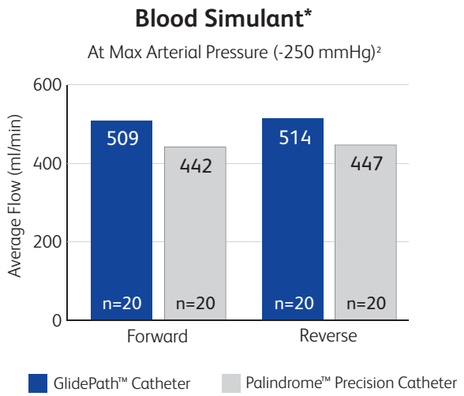


bd.com BD, Tempe, AZ, USA, 1 800 321 4254

Higher Flow Rates

Higher is Better

GlidePath™ Catheters demonstrated on average 15% higher flow rates in forward and reverse flow compared to Palindrome™ Precision catheters[1]



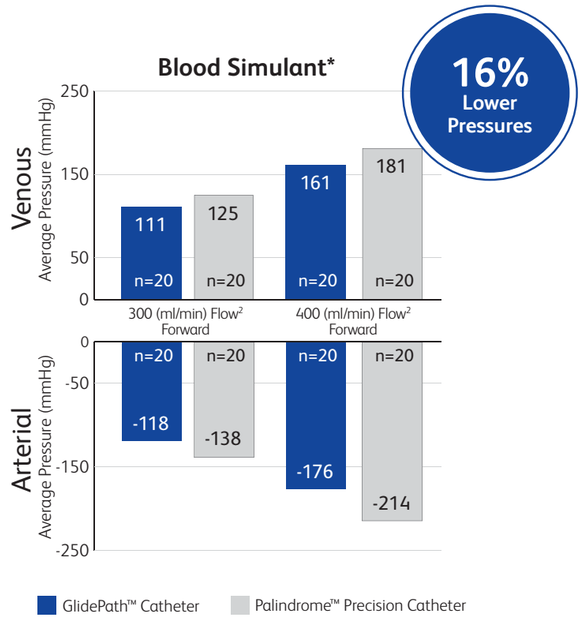
23 cm catheters[3]

15%
Higher Flow Rates

Lower Pressures

Lower is Better

GlidePath™ Catheters demonstrated on average 16% lower pressures in the arterial lumen compared to Palindrome™ Precision catheters[1]



23 cm catheters[3]

* Bench data on file. May not necessarily correlate to clinical performance.

Flow

[1] Groups found to be statistically different using an Unstacked ANOVA with p-value less than 0.05 at 95% confidence (0.000 for all comparative groups). Calculation of 15% Higher Flow Rate based upon the average of the maximum flow rate values in forward and reverse. Data on file. May not be representative of actual clinical experience.

[2] Flow rates were recorded once the maximum allowable pressure (-250mm Hg) was achieved in the arterial lumen. -250mm Hg is the maximum allowable arterial pressure established for hemodialysis based upon the KDOQI standard (Clinical Practice Guidelines and Clinical Practice Recommendations - 2006 Updates).

[3] Tested using 23cm tip to cuff straight catheters for both groups. Flow test performed using blood simulant as flow media for both groups.

Pressure

[1] Groups found to be statistically different using an Unstacked ANOVA with p-value less than 0.05 at 95% confidence (0.000 for all comparative groups). Calculation of 16% lower pressures based upon the average of the mean arterial pressure values. Data on file. May not be representative of actual clinical experience.

[2] The flow rate through the catheter was maintained at the specified values (300 and 400mL/min respectively) and the corresponding pressures were recorded.

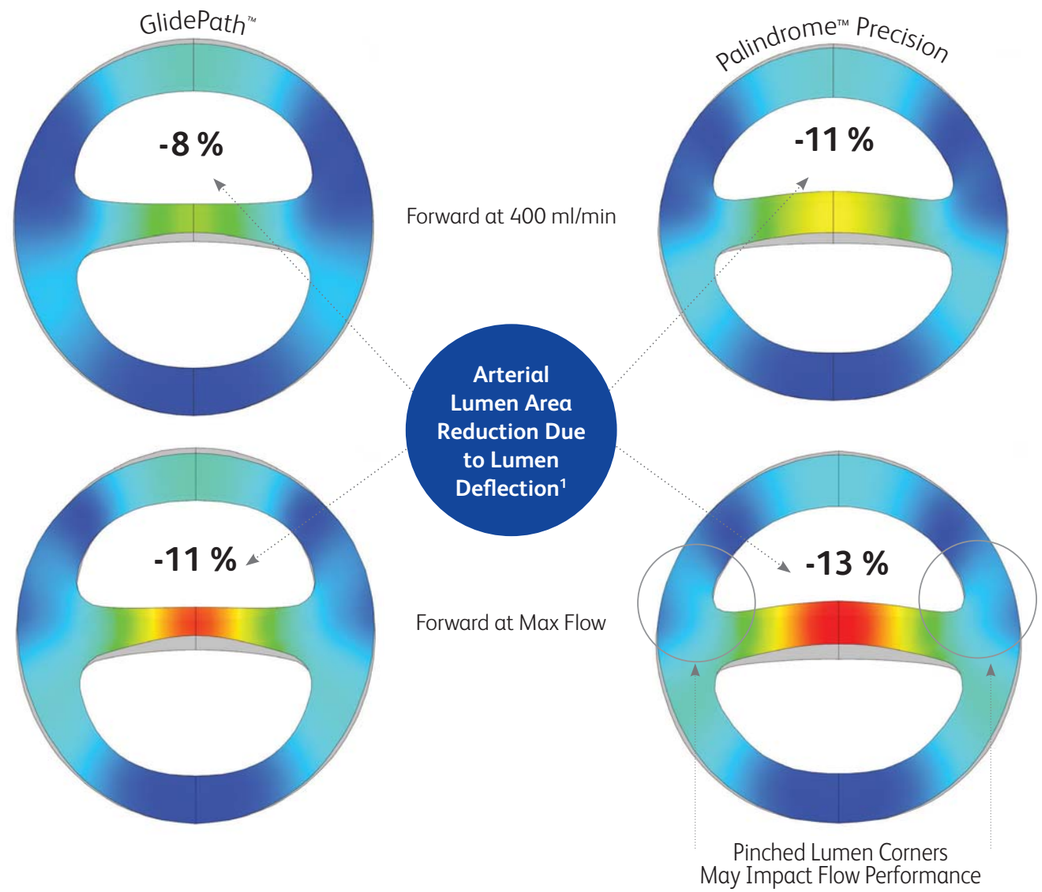
[3] Tested using 23cm tip to cuff straight catheters for both groups. Flow test performed using blood simulant as flow media for both groups.

Computational Fluid Dynamic Model

Flow Performance And Lumen Design

Lumen Design is the Difference

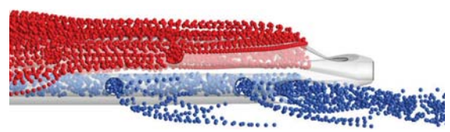
Lumen Designed to Minimize Deflection Under Pressure to Improve Flow Performance



Excellent Recirculation Rates

1% or Less on Average in Both Forward and Reverse*

Improved Inner Lumen Design



Computational Model of Arterial and Venous flow streams at 300ml/min -Forward Flow[2]

[1] Represents catheter lumen wall and septum deflection when flowing at 400ml/min and at max. allowable arterial pressure (when -250mm Hg is reached per KDOQI Standard). Fluid Structure Interaction Model was run using both catheter tubes as used in the straight catheter configuration. Data on file. May not be representative of actual clinical experience.

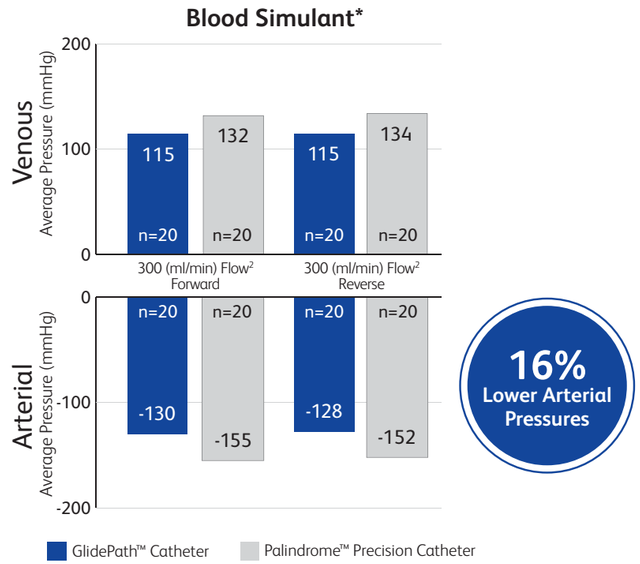
Recirculation

[2] Computational Fluid Dynamics Model was created for analyzing blood simulant recirculation at the catheter tip. Data on file. May not be representative of actual clinical experience.

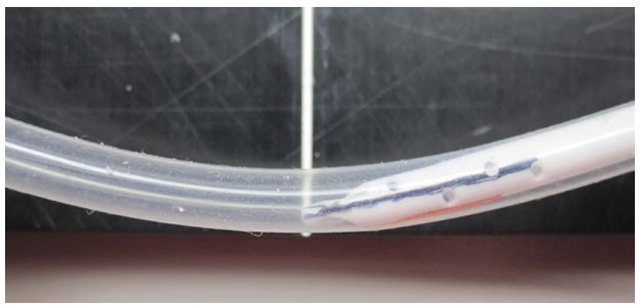
Flow-Pressure Under Partial Occlusion

Lower Pressure is Better

GlidePath™ Catheters demonstrated on average **16% lower arterial pressures** compared to Palindrome™ Precision catheters[1]



23 cm catheters[3]



Arterial Side of the Catheter Tip Forced Against the Tube Wall During Flow

* Bench data on file. May not necessarily correlate to clinical performance.

[1] Groups found to be statistically different using an Unstacked ANOVA with p-value less than 0.05 at 95% confidence (0.000 for all comparative groups). Calculation of 16% lower pressures based upon the average of the mean arterial pressure values. Data on file. May not be representative of actual clinical experience.

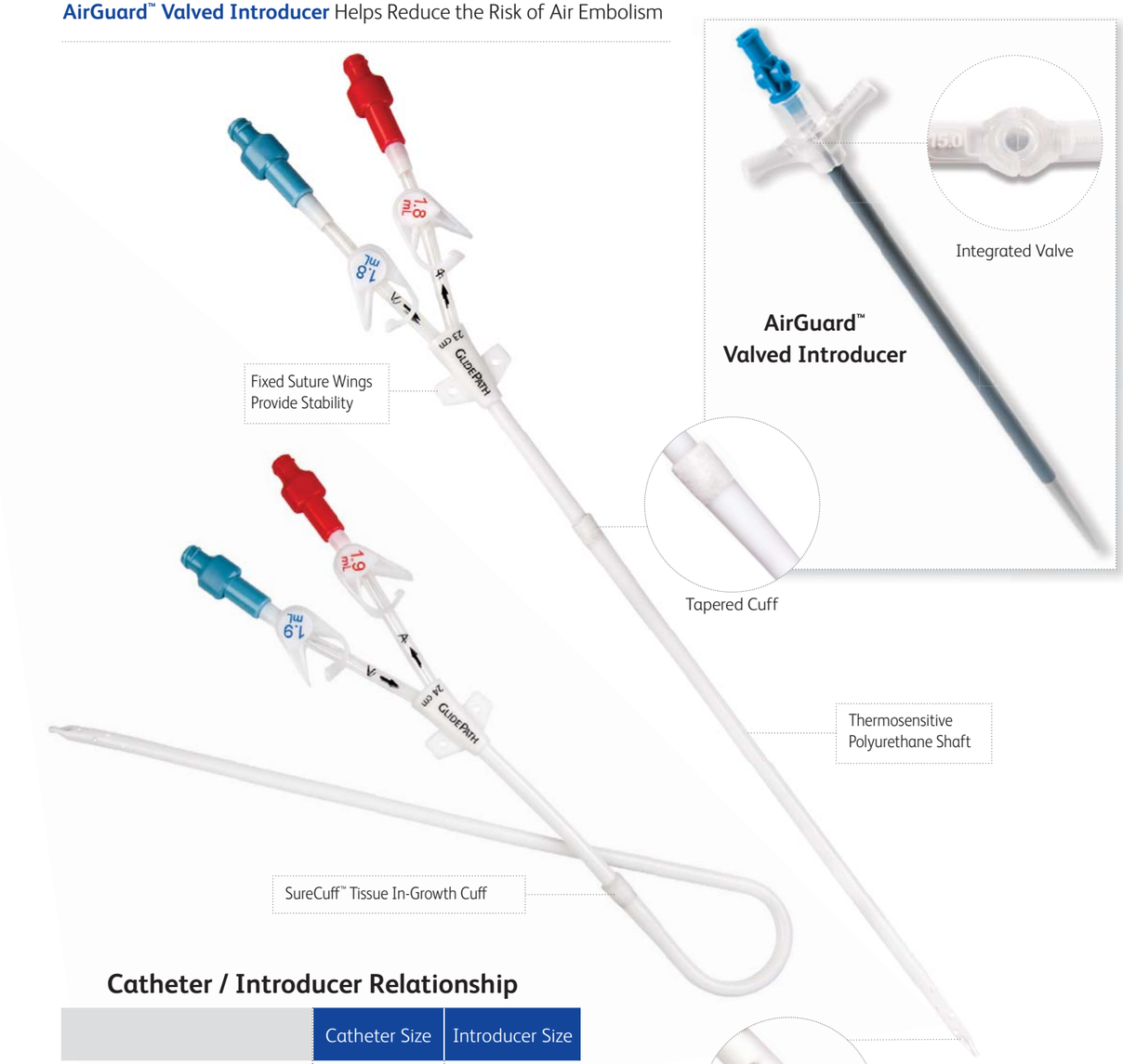
[2] 300 mL/min flow was kept consistent during this test. This is the minimum flow rate established for hemodialysis by the National Kidney Foundation (Clinical Practice Guidelines and Clinical Practice Recommendations - 2006 updates).

[3] Tested using 23cm tip to cuff straight catheters for both groups. Flow test performed using blood simulant as flow media for both groups.

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

Smooth Tapered Tip and Tapered Cuff for Easy Insertion

AirGuard™ Valved Introducer Helps Reduce the Risk of Air Embolism

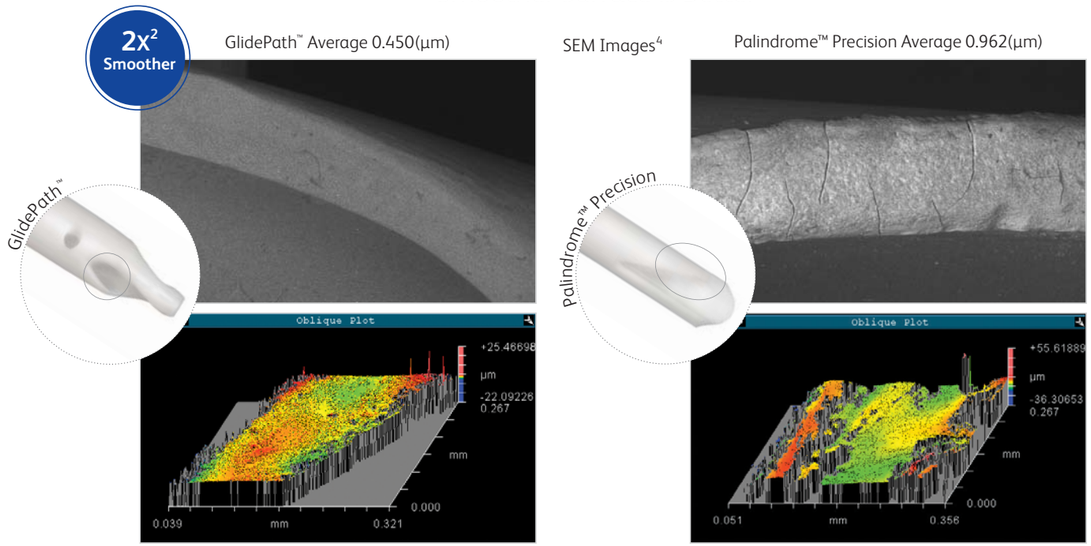


Catheter / Introducer Relationship

	Catheter Size	Introducer Size
GlidePath™ Catheter	14.5 F	15 F
Palindrome™ Precision Catheter	14.5 F	16 F

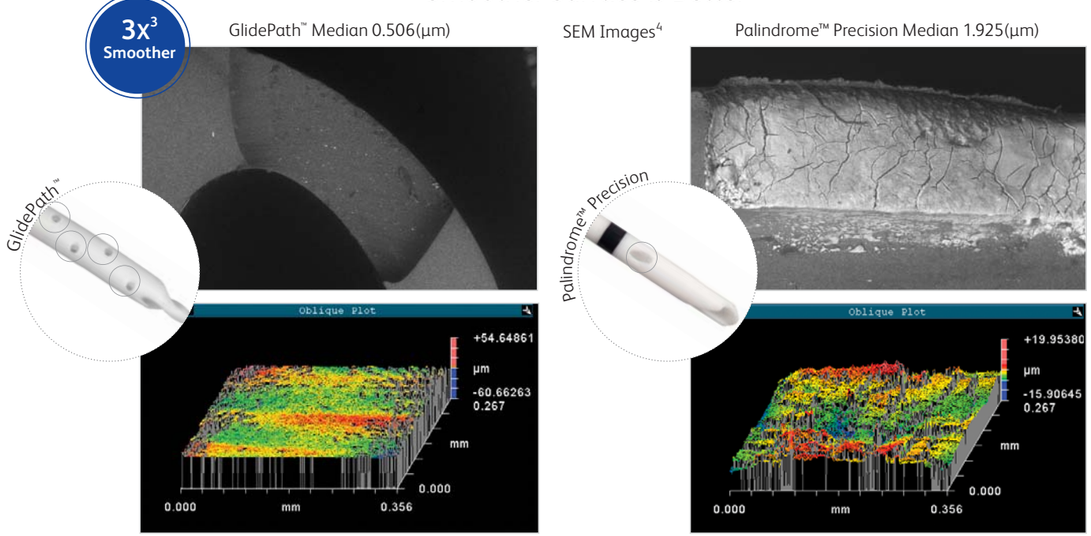
Front Openings[1]

Smoother Surface is Better



Side Holes[1]

Smoother Surface is Better



Representative Images

[1] Optical Profilometry tested using Zygo Optical System on the edges of the distal tip features, N=20 per group, GlidePath™ and Palindrome™ Precision.

[2] Groups found to be statistically different using an unstacked ANOVA with p-value less than 0.05 at 95% confidence (0.000 for all comparative groups). Calculation of at least 2X smoother based upon the ratios of mean surface roughness values.

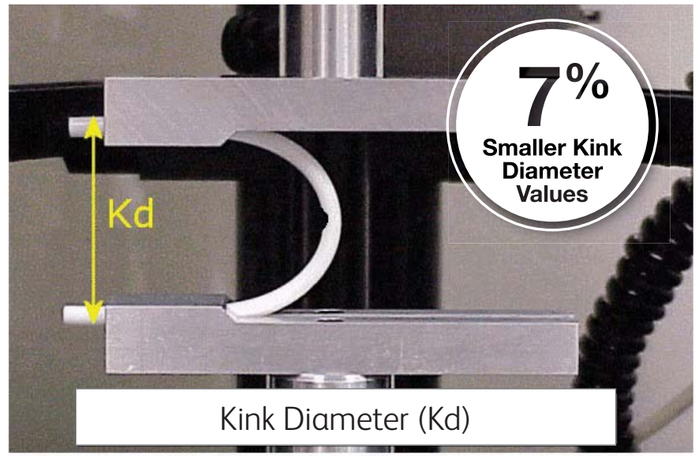
[3] Groups found to be statistically different using a Kruskal-Wallis analysis, which resulted in a p-value of 0.000. Calculation of at least 3X smoother based upon the ratios of median surface roughness values.

[4] SEM images reflect surface roughness on each feature. Images were captured using the same SEM imaging mode and magnification for side by side comparison purposes.

Kink Diameter[1]

Smaller Kink Diameter is Better

The GlidePath™ Catheter shaft demonstrated on average up to **7% smaller kink diameter values** when compared to the Palindrome™ Precision catheters[2]



Kink Diameter= Furthest Distance Achieved Before Kink Occurs

Kink Diameter

Smaller is Better

	Average Kink Diameter (in.)
GlidePath™ Catheter	1.04
Palindrome™ Precision Catheter	1.12

[1] Tested using catheter shafts from 23cm tip to cuff straight catheters (GlidePath n=20, Palindrome Precision n=20)

[2] Groups found to be statistically different using an Unstacked ANOVA with p-value less than 0.05 at 95% confidence (0.000 for all comparative groups). Calculation based upon the ratios of average kink diameter values. Data on file. May not be representative of actual clinical experience.