Exceptional Performance and *Ease of Placement*
**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.

**Lower Pressures**

Lower is Better

GLIDEPATH® catheters demonstrated on average 16% lower pressures in the arterial lumen compared to Palindrome™ Precision catheters.

---

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

<table>
<thead>
<tr>
<th></th>
<th>Average Flow (ml/min)</th>
<th>Average Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLIDEPATH Catheter</td>
<td>509</td>
<td>111</td>
</tr>
<tr>
<td>Palindrome Catheter</td>
<td>442</td>
<td>125</td>
</tr>
<tr>
<td>GLIDEPATH Catheter</td>
<td>514</td>
<td>161</td>
</tr>
<tr>
<td>Palindrome Catheter</td>
<td>447</td>
<td>181</td>
</tr>
</tbody>
</table>

* Tested using 23cm tip to cuff straight catheters for both groups. Flow test performed using blood simulant as flow media for both groups. Bench data on file. May not necessarily correlate to clinical performance.

**Blood Simulant* At Max Venous Pressure**

<table>
<thead>
<tr>
<th></th>
<th>Average Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLIDEPATH Catheter</td>
<td>-118</td>
</tr>
<tr>
<td>Palindrome Catheter</td>
<td>-138</td>
</tr>
<tr>
<td>GLIDEPATH Catheter</td>
<td>-176</td>
</tr>
<tr>
<td>Palindrome Catheter</td>
<td>-214</td>
</tr>
</tbody>
</table>

---

* 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).

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

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* 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.

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

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* Tested using 23cm tip to cuff straight catheters for both groups. Flow test performed using blood simulant as flow media for both groups. May not be representative of actual clinical experience.
Excellent Recirculation Rates

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

Improved Inner Lumen Design

---

*Lumen Design is the Difference
Lumen Designed to Minimize Deflection Under Pressure to Improve Flow Performance

GLIDEPATH®

-8 %

Forward at 400 ml/min

Palindrome™ Precision

-11 %

Arterial Lumen Area Reduction Due to Lumen Deflection†

-11 %

Forward at Max Flow

Pinched Lumen Corners May Impact Flow Performance

-13 %

P*K:

1 Represent 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
† 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‡

Blood Simulant*

<table>
<thead>
<tr>
<th></th>
<th>Average Pressure (mmHg)</th>
<th>n=20</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLIDEPath® Catheter</td>
<td>-130</td>
<td>-130</td>
</tr>
<tr>
<td>Palindrome™ Precision Catheter</td>
<td>-155</td>
<td>-155</td>
</tr>
<tr>
<td>GLIDEPath® Catheter</td>
<td>-128</td>
<td>-128</td>
</tr>
<tr>
<td>Palindrome™ Precision Catheter</td>
<td>-152</td>
<td>-152</td>
</tr>
</tbody>
</table>

23 cm catheters‡‡‡

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

* Bench data on file. May not necessarily correlate to clinical performance.
‡ 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.
‡‡ 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).
‡‡‡ 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** Reduces Risk of Air Embolism

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### Catheter / Introducer Relationship

<table>
<thead>
<tr>
<th>Catheter / Introducer</th>
<th>Catheter Size</th>
<th>Introducer Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLIDEPath® Catheter</td>
<td>14.5 F</td>
<td>15 F</td>
</tr>
<tr>
<td>Palindrome™ Precision</td>
<td>14.5 F</td>
<td>16 F</td>
</tr>
</tbody>
</table>

* Straight codes only
**Front Openings**
Smomer Surface is Better

2x
GlidePath® Average 0.450(μm)
Palindrome™ Precision Average 0.962(μm)

Side Holes
Smother Surface is Better

3x
GlidePath® Median 0.506(μm)
Palindrome™ Precision Median 1.925(μm)

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
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.

<table>
<thead>
<tr>
<th></th>
<th>Average Kink Diameter (in.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GLIDEPATH® Catheter</strong></td>
<td>1.04</td>
</tr>
<tr>
<td><strong>Palindrome™ Precision Catheter</strong></td>
<td>1.12</td>
</tr>
</tbody>
</table>

---

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

**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.*
GLIDEPATH® Catheters - Straight

<table>
<thead>
<tr>
<th>Length (cm)</th>
<th>Tip to Cuff</th>
<th>Tip to Hub</th>
<th>Standard Kit</th>
<th>Exchange Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>20</td>
<td>20</td>
<td>5393150</td>
<td>5397150</td>
</tr>
<tr>
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<tr>
<td>50</td>
<td>55</td>
<td>55</td>
<td>5393500</td>
<td>5397500</td>
</tr>
</tbody>
</table>

GLIDEPATH® Catheters - ALPHACURVE® Catheter

<table>
<thead>
<tr>
<th>Length (cm)</th>
<th>Tip to Cuff</th>
<th>Tip to Hub</th>
<th>Standard Kit</th>
<th>Exchange Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>25</td>
<td>25</td>
<td>5396190</td>
<td></td>
</tr>
<tr>
<td>24</td>
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<td></td>
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<tr>
<td>31</td>
<td>37</td>
<td>37</td>
<td>5396310</td>
<td></td>
</tr>
</tbody>
</table>

GLIDEPATH® Long-Term Dialysis 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 thrombocytopoiesis 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.

- Alcohol or alcohol-containing antiseptics (such as chlorhexidine) should not be used to lock, scale or decrude polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Intended for Single Use. DO NOT REFUSE. Reuse and/or repackaging may cause a risk of patient or user infection and should not be used to lock, scale or decrude polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Contains ingredients that can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or containing ointments can cause failure of this device and should not be used with polyurethane catheters.

Cautions

- Repeated over-tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure.
- Catheter-related Sepsis, Endocarditis, Exit Site Infection, Extensive Necrosis, Extravasation, Fibrotic Sheath Formation, Hematoma, Hemomediatinum, Hemorrhagic, Hydrothorax, Inflammation, Necrosis or scarring of skin over implant area, Intercostal Reaction to Implanted Device, Laceration of Vessels or Viscus, Perforation of Vessels or Viscus, Pneumothorax, Thoracic Duct Injury, Thromboembolism, Venous Stenosis, Venous Thrombosis, Venous Thrombosis, Vessel Erosion, Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery.

References


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 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 Septic, Endocarditis, Ext Site Infection, Extensive Necrosis, Extravasation, Fibrotic Sheath Formation, Hematoma, Hemomediatinum, Hemorrhagic, Hydrothorax, Inflammation, Necrosis or scarring of skin over implant area, Intercostal Reaction to Implanted Device, Laceration of Vessels or Viscus, Perforation of Vessels or Viscus, Pneumothorax, Thoracic Duct Injury, Thromboembolism, Venous Stenosis, Venous Thrombosis, Venous Thrombosis, Vessel Erosion, Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery.

Contact information

The GLIDEPATH® Catheter Standard Kit comes with the same contents as the Straight Standard Kit with the exception of the Insertion Stylet.

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 Septic, Endocarditis, Ext Site Infection, Extensive Necrosis, Extravasation, Fibrotic Sheath Formation, Hematoma, Hemomediatinum, Hemorrhagic, Hydrothorax, Inflammation, Necrosis or scarring of skin over implant area, Intercostal Reaction to Implanted Device, Laceration of Vessels or Viscus, Perforation of Vessels or Viscus, Pneumothorax, Thoracic Duct Injury, Thromboembolism, Venous Stenosis, Venous Thrombosis, Venous Thrombosis, Vessel Erosion, Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery.