ADVANCED TECHNOLOGY SOLUTIONS DESIGNED TO IMPROVE PATIENT OUTCOMES

WITH ENDEXO TECHNOLOGY

ADVANCED TECHNOLOGY

DESIGNED TO IMPROVE OUTCOMES*

COST EFFECTIVE

BioFlo

angiodynamics
EVOLVE TO ADVANCED CATHETER TECHNOLOGY

Reduces the risk of thrombus accumulation on implantable vascular devices from 83% to 96%.*

Reinventing the standard of care by reducing the risk of thrombus accumulation.

Reduction in thrombus accumulation results in a decrease in catheter-related thrombus/occlusions and the associated costs.

* The Endexo catheter is designed to reduce thrombus accumulation. The reduction of thrombus accumulation (based on platelet count) is supported by acute in-vitro testing. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation.

Vascular access procedures are one of the most common procedures performed on patients in hospitals. AngioDynamics is committed to creating strategic partnerships with healthcare institutions to address today’s changing healthcare environment by developing advanced technology that are safe, cost effective and designed to improve patient outcomes.
COMMON VASCULAR ACCESS
DEVICE COMPLICATIONS

PICC-related upper extremity DVT occurs at an average rate of 2.0-7.8%\(^1\) with an average cost of $15,973\(^2\) per incidence.\(^3\)

Estimated 250,000 blood stream infections occur annually in the United States, resulting in significantly higher mortality rates and costs in hospital inpatients.\(^5\)

THROMBOSIS
PICC-related upper extremity DVT occurs at an average rate of 2.0-7.8%\(^1\) with an average cost of $15,973\(^2\) per incidence.

OCCULATION
25% average occlusion rate, most frequent complication of vascular access devices.\(^3\) Single dose of thrombolytic $123.77.\(^4\)

CATHETER-RELATED INFECTIONS
Estimated 250,000 blood stream infections occur annually in the United States, resulting in significantly higher mortality rates and costs in hospital inpatients.\(^5\)

\(*\) Market price for single dose of CathFlo

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We've gravitated towards using this device [PICC] over central venous catheters for good reasons, and it may still be the best choice for some people. However, our findings suggest that patients and physicians should carefully review the risks and benefits when it comes to placing PICCs, especially with respect to blood clots. Our study shows that this risk may be higher than previously recognized and suggests that there is no one-size-fits-all approach when considering use of these devices.

“Selecting a vascular device will always be a nuanced clinical decision. But a little bit of MAGIC almost certainly helps...”
Naomi O’Grady, MD

“This work represents an important achievement – the first time so many specialties were brought together to focus on vascular access...”
Lisa Goral, RN

“For healthcare quality officers and payers, MAGIC is highly relevant because it will facilitate measuring practice and inform quality improvement efforts...”
Scott Woller, MD

MAGIC is a set of recommendations that defines when a particular vascular access device is appropriate for use. Written by 14 of the world’s foremost experts and a patient, MAGIC covers the most commonly used IV devices, indications, patient types, and settings for use. In the world of vascular access, there is nothing else like it.

www.improvepicc.com

Our research is focused on: (a) understanding drivers of PICC use and preventing inappropriate insertion; (b) developing statistical models that predict PICC complications; and (c) designing and implementing interventions to prevent adverse events such as occlusion, thrombembolism, and infection. We work closely with a number of key partners to achieve these goals.

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ADDRESSABLE COMPLICATIONS: PICC-RELATED

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Vineet Chopra, MD

COATED Catheter coatings are present on the catheter surface and known to elude off once they are placed inside the body and begin to lose their platelet adhesion resistance.

IMPREGNATED Impregnated catheters claim to offer thrombus-reducing properties in their pores, leaving the surface vulnerable to platelet adhesion.

ENDEXO Unlike other technologies that are superficial and/or transient, Endexo technology is present for the life of the catheter.

EVOLUTION OF CATHETER TECHNOLOGY

The Endexo polymer mixes with carbothane completely without altering the base properties. Due to the lower surface friction of the Endexo-modified polymer, the material becomes essentially invisible to normal biological defense mechanisms. Thus platelet accretion, clot formation and histochemical reactivity is significantly reduced.

1. Endexo alters the surface chemistry of the device.
2. The surface reduces the rate of bioaccretion.
3. Endexo mixes into the parent polymer seamlessly.

The “non-stick” characteristics of the Endexo material and resultant catheter construction reduce the adherence of blood components, such as platelets and thrombus. Not containing heparin, the Endexo technology may help to minimize complications associated with heparin. Additionally, the Endexo technology does not contain antibiotics or antimicrobial agents, aiding to reduce potential complications associated with bacterial resistance. The Endexo material is throughout the catheter (i.e., inside, outside and cut surfaces) and remains for the life of the device. In fact, the exposure of the BioFlo PICC to simulated implant flow conditions (i.e., temperature, flow, pH and time) demonstrated that the Endexo polymer concentration within the BioFlo PICC did not degrade or change over extended durations.

PERFORMANCE IN IN-VITRO EVALUATIONS

High-magnification images of blood loop samples show that the BioFlo PICC has a marked reduction in thrombus when compared to control.

BioFlo PICC 5 F DL Catheter has no visible thrombus, fibrin sheath, or clot.

S F DL Competitive PICC Catheter with significant thrombus accumulation.

BLOOD LOOP (IN VITRO): RESULTS

Data on file.

PERFORMANCE IN CLINICAL EVALUATIONS

<table>
<thead>
<tr>
<th>FACILITY NAME</th>
<th># OF PICCS PLACED</th>
<th>DVT REDUCTION</th>
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<tbody>
<tr>
<td>Academic Medical Center</td>
<td>1,251</td>
<td>85%</td>
</tr>
<tr>
<td>Community Hospital</td>
<td>535</td>
<td>25%</td>
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<td>Community Hospital</td>
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<tr>
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<tr>
<td>International Hospital</td>
<td>60</td>
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<td>Health System</td>
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<tr>
<td>Academic Medical Center</td>
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<td>55%</td>
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<tr>
<td></td>
<td><strong>7,241</strong></td>
<td><strong>51%</strong></td>
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<table>
<thead>
<tr>
<th>FACILITY NAME</th>
<th># OF PICCS PLACED</th>
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</thead>
<tbody>
<tr>
<td>Children’s Hospital</td>
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<td>62%</td>
</tr>
<tr>
<td>Community Hospital</td>
<td>533</td>
<td>75%</td>
</tr>
<tr>
<td>Community Hospital</td>
<td>1,212</td>
<td>62%</td>
</tr>
<tr>
<td>Hospital Group</td>
<td>252</td>
<td>73%</td>
</tr>
<tr>
<td></td>
<td><strong>2,474</strong></td>
<td><strong>68%</strong></td>
</tr>
</tbody>
</table>

Data on file. Data was obtained during hospital product evaluations, several of these sites are working toward publications. Based on data collected at individual institutions, results may not be indicative of clinical experiences at other institutions.


The complication rates were tracked and calculated for the following metrics:

- **Occlusions**: Standard polyurethane PICC 10.2%, anti-thrombogenic PICC 2.8% (73% reduction).
- **UEDVTs**: Standard polyurethane PICC 1.4%, anti-thrombogenic PICC 0.3% (80% reduction).
- **Average Monthly Cathflo Expense**: Standard polyurethane PICC $1,638.89, anti-thrombogenic PICC $583.33 (64% reduction).

**RISK REDUCTION: SINGLE CENTER PROSPECTIVE HOSPITAL STUDY**

- **Occlusions**: Standard Polyurethane PICC 12.2%, Anti-Thrombogenic PICC 4.0% (69% reduction).
- **UEDVTs**: Standard Polyurethane PICC 2.1%, Anti-Thrombogenic PICC 0.3% (80% reduction).
- **Average Monthly Cathflo Expense**: Standard Polyurethane PICC $1,638.89, Anti-Thrombogenic PICC $583.33 (64% reduction).

**RISK REDUCTION: SINGLE-CENTER RETROSPECTIVE STUDY (24 Months)**

30% Reduction in UEDVTs as Compared to Standard Polyurethane


These results are based on individual site experiences and may not be indicative of clinical evidence at other institutes.
INCREASING NEED FOR CLINICAL AND HEALTHCARE QUALITY DATA

Changes in Reimbursement
Bundled Payment Models
Quality Measures
More Transparency

TRENDS IN HEALTH CARE ECONOMICS

REGULATORY
PAYORS
HOSPITALS
PHYSICIANS
PATIENTS

INCREASING NEED FOR CLINICAL AND HEALTHCARE QUALITY DATA

Angiodynamics is the only provider of Enadox technology for vascular access devices.

Enadox provides a safe, cost-effective, advanced technology designed to improve patient outcomes.
IMPORTANT RISK INFORMATION

**BIOFLO PICC WITH ENDEXO AND PASV VALVE TECHNOLOGY**

**INTENDED USE/INDICATIONS FOR USE:** The BioFlo PICC with Endexo and PASV Valve Technology is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

**CONTRAINDICATIONS:** Venous thrombosis in any portion of the vessels to be cannulated. Conditions that impede venous return from the extremity such as paralysis or lymphedema. Orthopedic or neurologic conditions affecting the extremity such as paralysis or other intraluminal devices. Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy. Pre-existing skin surface or subsurface infection at or near the proposed catheter insertion site. Anatomical distortion of the veins from surgery, injury or trauma. Inadequate skin flaps. Anatomical irregularities (structural or vascular) which may compromise catheter insertion and/or care procedures. Refer to Directions for Use provided with the product for complete instructions, warnings and precautions.

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

**BIOFLO PORTS WITH ENDEXO TECHNOLOGY**

**INTENDED USE/INDICATIONS FOR USE:** The BioFlo Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, IV fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples. When used with a power injectable needle, the BioFlo Port is intended for use with power injectable needles for power injection of contrast media. The maximum recommended infusion rate is 5 mL/sec with a 19 G or 20 G non-coring power injectable needle or 2 mL/sec with a 22 G non-coring power injectable needle.

**CONTRAINDICATIONS:** Inadequate body size to support device, bacteraemia, sepsis, known or suspected allergic response to materials, infection, peritonitis, past irradiation of prospective insertion site, previous episodes of venous thrombosis or vascular surgical procedures at the postoperative placement site, local tissue factors will prevent proper device stabilization and/or access. Refer to the package insert provided with the product for complete instructions, warnings and precautions.

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

**BIOFLO DURAMAX DIALYSIS CATHETER WITH ENDEXO TECHNOLOGY**

**INDICATIONS FOR USE:** The BioFlo Duramax Dialysis Catheter with Endexo Technology is indicated for use in attaining long-term vascular access for hemodialysis and apheresis in adults. Catheters greater than 40 cm are intended for femoral vein insertion.

**CONTRAINDICATIONS:** The catheter is intended for long-term vascular access only and should not be used for any purpose other than indicated in the instructions for use.

**WARNINGS AND PRECAUTIONS:** Please see package insert for complete list of warnings and precautions.

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

**BIOFLO MIDLINE CATHETER WITH ENDEXO TECHNOLOGY**

**INTENDED USE/INDICATIONS FOR USE:** The BioFlo Midline catheter with ENDEXO technology is indicated for short-term access (< 30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products. Catheters greater than 40 cm are intended for femoral vein insertion.

**CONTRAINDICATIONS:** Venous thrombosis in any portion of the vessels to be cannulated. Conditions that impede venous return from the extremity such as paralysis or lymphedema after mastectomy. Orthopedic or neurologic conditions affecting the extremity such as paralysis or other intraluminal devices. Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy. Pre-existing skin surface or subsurface infection at or near the proposed catheter insertion site. Anatomical distortion of the veins from surgery, injury or trauma. Inadequate skin flaps. Anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures. Refer to the Directions for Use provided with the product for complete instructions, warnings and precautions.

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