The PASV (Pressure Activated Safety Valve) Valve is a direction-specific valve located in the proximal end of the BioFlo PICC so that it does not interfere with blood flow or catheter trimming.

**BioFlo PICC**

**Value-Added Programs and Services**

**Convenience Kit Program**

Improve clinician efficiency, productivity and cost savings with our Conveniences Kit Program. Our comprehensive Program provides clinicians with solutions to streamline PICC placement procedures, eliminate inventories of unnecessary supplies and meet department budget guidelines. In addition, clinicians are able to choose from our broad portfolio of PICCs for a variety of placement settings, insertion techniques and clinical applications.

**Clinical Education**

AngioDynamics retains a highly credentialed team of clinical specialists committed to providing educational support and training.

In addition, a wide range of continuing education programs and support materials are available to you, including wall charts and patient education materials, all designed to reinforce best practices for catheter insertion, care and maintenance.

**Technical Support**

For this product and other AngioDynamics Vascular Access products, you can access 24 hours a day by calling:

**Vascular Access Product Reference Line**

800.513.6876

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In Canada

For more information, call

800.268.0184

800.833.9973

www.angiodynamics.com

Marlborough, MA 01752

26 Forest Street

Navilyst Medical, Inc.

Manufacturer:

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247 East Street

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Tel: 800.833.9972 in Canada

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Due to the risk of exposure to bloodborne pathogens, care providers must adhere to guidelines for universal blood and bodily fluid precautions in the

material difference.

with Endexo® and PASV Valve Technology

BioFlo PICC

with Endexo® and PASV Valve Technology

The Power of PASV®

PASV Valve Technology

The PASV (Pressure Activated Safety Valve) Valve is a direction-specific valve located in the proximal end of the BioFlo PICC so that it does not interfere with blood flow or catheter trimming.

Infusion

Operates with minimal pressure and automatically closes off flow

Aspiration

Opens for sampling and aspiration and automatically closes to prevent reflux in the catheter tip

Closed

Resists blood flow or catheter trimming.

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Endexo Technology is a permanent and non-eluting polymer that is "blended" into the polyurethane from which the BioFlo PICC is made, truly making protection against thrombus accumulation an integral part of the catheter material. It is not a coating, it is not impregnated into the catheter and it does not contain heparin or antibiotics.

• The only PICC manufactured with Endexo Technology, a permanent and non-eluting integral polymer.
• In-vitro blood loop model test results show that on average the BioFlo PICC with Endexo Technology has 87% less thrombus accumulation on its surface compared to commonly used PICCs (based on platelet count). †
• Endexo Technology has been shown to be effective in reducing thrombus accumulation. The reduction in thrombus accumulation was evaluated using in-vitro and in-vivo models. Pre-clinical in-vitro and in-vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation.

• Available with PASV Valve Technology, making it the first catheter that combines all of these properties with our patented valve designed to automatically resist backflow and reduce blood reflux on the inside of the catheter. The BioFlo PICC is also available in non-valved configurations.

† Based on benchtop test results which may not be indicative of clinical results. Data on file.

Biocompatible and flexible tubing is shown at 1500X magnification. SEM (Scanning Electron Microscopy) Images

The BioFlo PICC at 15X magnification

Catheter with significant thrombus accumulation.

Competitor B at 1500X magnification

Catheter with fibrin sheath and distinct fibrin strands in the process of forming.

Competitor B at 1000X magnification

Catheter shows a thin sheath where fibrin is forming.
The PASV (Pressure Activated Safety Valve) Valve is a direction-specific valve located in the proximal end of the BioFlo PICC so that it does not interfere with blood flow or catheter trimming.

**BioFlo PICC**

with Endexo and PASV Valve Technology

**Value-Added Programs and Services**

**Convenience Kit Program**

- Improve clinical efficiency, productivity and cost savings with our Conveniences Kit Program. Our comprehensive program provides clinician with solutions to streamline PICC placement procedures, eliminate hassles ofunnecessary supplies and meet department guidelines. In addition, clinicians are able to choose from our broad portfolio of PICCs for a variety of placement settings, insertion techniques and clinical applications.

**Clinical Education**

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**Technical Support**

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**Manufacturer:**

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Navilyst Medical, Inc.

24 East Street

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The PASV (Pressure Activated Safety Valve) Valve is a direction-specific valve located in the proximal end of the catheter. It is designed to reduce blood reflux that could lead to catheter-related complications.

**Value Added Programs and Services**

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**Technical Support**

For more information, contact us at 800.513.6876. 24 hours a day, 7 days a week. Technical Support is available at AngioDynamics.com. Professional reference materials are available 24 hours a day by calling: 800.513.6876.

**Indications**

- Venous pressure to prevent reflux in the catheter tip
- For normal increases in central venous pressure
- To prevent aspiration
- To reduce thrombotic occlusions
- For catheter trimming

**Contraindications**

- Venous thrombosis in any portion of the vein to be catheterized
- Conditions that impede venous return from the extremity such as venous reflux
- Orthopedic or neurological conditions affecting the extremity
- Anticipation or presence of dialysis grafts or other intraluminal devices
- Hypercoagulopathy unless careful consideration is 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 antecubital veins

**Warnings**

- Content is supplied sterile by EO for single patient use only. Do not use if sterile barrier is damaged. Do not use if product has been damaged. Do not reuse, reprocess, or resterilize. To do so may compromise device integrity and/or lead to device failure which in turn may result in patient injury, illness or death; and may also create a risk of contamination, patient infection or cross infection which may lead to injury, illness or death of the patient.
- Do not place the catheter into the right atrium or the right ventricle of the heart.
- Do not attempt to trim the catheter with the guidewire or stylet loaded as catheter, stylet, or guidewire may become damaged resulting in patient injury.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter.
- Power injection indication for contrast media implies the catheter's ability to withstand this procedure, but does not imply appropriateness of this procedure for a particular patient.
- A trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- The maximum pressure of power injectors used with the BioFlo PICC must not exceed 325 psi.
- For triple lumen catheters, only the purple lumen is for power injection.
- Do not use lumen marked "No CT" for power injection of contrast media as it may result in catheter damage or patient injury.

**Precautions**

- Following institutional policy, secure catheter externally to prevent catheter movement.
- Do not store with polyurethane catheters, as these may cause failure of the device.
- Refer to Directions for Use provided with the product for complete instructions, warnings and precautions.

**CAUTION:**

- Under no circumstances should any device be used for direct contact with blood, blood products, or fluids for parenteral or intravascular use unless the device has been approved by the regulatory agency for such use.
- All devices require proper handling, including flushing of occluded catheters and power injection. The BioFlo PICC catheter testing included 10 power injection cycles. Use it will sustain power injection. When inserting a triple lumen catheter, the power injectable lumen must be used for guidewire/stylet placement.

**Making a material difference.**