BioFlo™ PICC
with Endexo™ Technology
Valved and Non-Valved

A Patient's Guide

SPECTRUM VASCULAR™

Spectrum Vascular
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Persons depicted in this brochure are models and included for illustrative purposes only.

SPECTRUM VASCULAR™

BioFlo™ PICC
with Endexo™ Technology

TRAVEL CARD

Support for this product and other Spectrum Vascular vascular access products is available by calling Spectrum Vascular Customer Service.

888.599.2099

WARNINGS:

- 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.
- Exceeding the maximum allowable flow rate noted on the catheter may result in catheter failure and/or catheter tip displacement.
- Catheter indication for power injection of contrast media implies the catheter's ability to withstand this procedure, but does not imply appropriateness of the 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 power injectable 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.
- For the non-valved BioFlo PICC, Central Venous Pressure (CVP) Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

Precaution: It is recommended that institutional protocols be considered for all aspects of catheter use. The BioFlo™ PICC with Endexo™ Technology catheter testing included 10 power injection cycles.

Endexo is a trademark of Evonik Industries AG.

BIOFLO™ PICC WITH ENDEXO™ TECHNOLOGY

INTENDED USE/INDICATIONS FOR USE: The BioFlo PICC with Endexo 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; for central venous pressure monitoring and for power injection of contrast media. 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 vein to be catheterized. Conditions that impede venous return from the extremity such as paralysis or lymphedema after mastectomy Orthopedic or neurological conditions affecting the extremity. Anticipation or presence of dialysis grafts 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 antecubital veins. Anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures. Patients with known allergies to tape or adhesive.

WARNINGS: Due to the risk of exposure to bloodborne pathogens, care providers must adhere to guidelines for universal blood and bodily fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device. Contents are 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. If using bacteriostatic saline, do not exceed 30 mL in a 24-hour period. Do not use the catheter with chemicals that are incompatible with any of its accessories, as catheter damage may occur. 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. Exceeding the maximum allowable flow rate (per the Directions for Use) may result in catheter failure and/or catheter tip displacement. Catheter indication for power injection of 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. For the non-valved BioFlo PICC, Central Venous Pressure (CVP) Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

PRECAUTIONS: Acetone and polyethylene glycol-containing ointments should not be used with polyurethane catheters, as these may cause failure of the device. Following institutional policy, secure catheter externally to prevent catheter movement, migration, damage, kinking or occlusion. It is recommended that only Luer Lock accessories be used with the BioFlo PICC with Endexo and PASV Valve Technology. Repeated over-tightening may reduce hub connector life. Do not use hemostats to secure or remove devices with Luer lock hub connections. If resistance is met while attempting to flush catheter, follow institutional protocol for occluded catheters. Incompatible drug delivery within the same lumen may cause precipitation. Flush catheter lumen following each infusion. Do not use scissors to remove the dressing, as this may possibly cut or damage the catheter. Prior to dressing the catheter and access site, inspect both to assure that they are completely dry of isopropyl alcohol or acetone based cleansing agents. To avoid pooling of an agent, do not fully insert catheter up to suture wing. Apply a sterile end cap on the catheter hub to prevent contamination when not in use. It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. The BioFlo PICC with Endexo and PASV Valve Technology testing included 10 power injection cycles. Do not attempt to repair the catheter. If breaks or leaks are apparent in the catheter, remove the catheter immediately. Catheter use, care or remove is to be undertaken only by a trained, qualified healthcare provider. Avoid blood pressure measurement or the application of a tourniquet to an arm with an implanted device, since occlusion or other damage to the device may occur. Avoid pressure on the inner surface area of axilla of the cannulated arm while using crutches. Use of a needle to access the catheter is not recommended. However, if a needle is used, do not use a needle longer than 1.9 cm as it may cause damage to the valve. Do not reinsert stylet into catheter, as damage to valve, catheter and vein may result. If a needleless connector is attached to catheter hub, first ensure that it will sustain power injection. When inserting a triple lumen catheter, the power injectable lumen must be used for guidewire/stylet placement.

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.

TRAVEL CARD

Always carry your BioFlo™ PICC Travel Card with you.

This card has important information about your catheter that healthcare providers will need to care for you.

Fill out your personal information in the areas provided. Your Travel Card is conveniently sized to fit in a wallet.

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50 Main Street, Suite 1000
White Plains, NY 10606

PATIENT NAME: _____

TELEPHONE: (W) _____ (H) _____

EMERGENCY CONTACT: _____

TELEPHONE: (W) _____ (H) _____

PHYSICIAN NAME: _____

TELEPHONE: _____ INSERTION DATE: _____

NUMBER OF LUMENS: _____ FRENCH SIZE: _____

TRIMMED LENGTH: _____ LOT NO.: _____

POWER INJECTION:

1. Verify power injector is appropriately programmed and does not exceed printed catheter flow rate limit.
2. Warm contrast to body temperature (37°C).
3. Inspect catheter for damage.

VALVED LUMEN STEPS:	NON-VALVED LUMEN STEPS:
4. Attach syringe and aspirate amount greater than priming volume of catheter, or until blood return. Remove and discard used syringe.	4. Attach syringe, open clamp, and aspirate amount greater than priming volume of catheter, or until blood return. Close clamp, and remove and discard used syringe.
5. Attach syringe filled with 10 mL sterile normal saline and vigorously flush lumen.	5. Attach syringe filled with 10 mL sterile normal saline, open clamp, and vigorously flush lumen
6. Detach syringe and discard.	6. Close clamp, and detach syringe and discard.
7. Attach power injector to selected lumen hub per manufacturer's recommendations.	7. Attach power injector to selected lumen hub per manufacturer's recommendations, and open clamp.
8. Complete power injection study taking care not to exceed maximum flow rate limit.	8. Complete power injection study taking care not to exceed maximum flow rate limit, and close clamp.

9. Disconnect the power injector.
10. Vigorously flush catheter with 20 mL sterile normal saline and recap.
11. For non-valved PICCs, flush with heparin per institutional protocol.
12. Do not use lumen marked "No CT" for power injection.

BioFlo™ PICC — A Patient's Guide

The BioFlo PICC with Endexo™ Technology can be used for tests called contrast-enhanced CT scans. You may have even heard these called "CAT" scans. Sometimes, clinicians refer to them as power injection studies. This test requires a pump that delivers testing fluid fast and at high pressure. This pamphlet provides some answers to questions that patients and their families may have about the BioFlo PICC.

This Patient Guide is intended to be educational and is not a substitute for the Directions for Use provided with the product.

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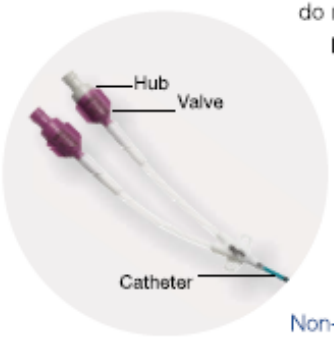
What is a PICC?

A PICC is a Peripherally Inserted Central Catheter, a long thin tube that is placed into a vein and threaded until the tip is in a very large vein in your chest. The PICC may be used to deliver medicines and other fluids, such as nutrition and blood products, into the vein. This is called IV or intravenous delivery. Unlike the short IV lines you may have had placed in your hand or arm, a PICC may remain in your arm many weeks or months. It may also be possible to take blood samples from your PICC to be used for special tests.

There are a variety of PICCs available. Some have a valve located in an area at the end of the catheter called the hub, while others do not. Valved catheters generally do not have clamps like non-valved catheters. Your physician will determine which type of PICC is best for you.

Valved PICC



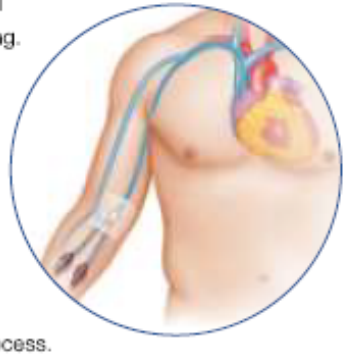
Non-Valved PICC

How is the BioFlo™ PICC placed?

Your BioFlo PICC will be placed by a trained healthcare provider. This may be done in your room in the hospital, a clinic, the x-ray department or other locations. You should be as comfortable as possible and should try not to move your arm during the PICC placement.

Your arm will be cleaned, and you will be covered with special cloths to keep the area as clean as possible – this is called sterile technique. The person placing your PICC will wear a mask, gown, gloves and hat. This is to protect you and keep the area clean during the procedure.

A numbing medicine may be given at the place where the catheter will enter your arm. This is done through a very small needle and may sting. In some cases, an ultrasound machine, or x-ray machine, may be used to look at your veins. The PICC is threaded into the vein during this visualization process.



After the PICC is in place, a sterile dressing will be put over the insertion site (the place on your arm where the PICC enters the vein). An x-ray image may be taken to make sure the PICC tip is in the right position in a vein in your chest.

How do I care for my BioFlo™ PICC?

Your PICC will need to be cared for and kept clean. Care will include changing the dressing any time it becomes loose, soiled or wet and at least one time every week. This may be done by a healthcare provider, or at the suggestion of the healthcare provider, by you, a family member or friend that has been taught how the dressing is changed.

A sterile end cap will be placed on the end of the catheter that is called the hub. This keeps the catheter closed when not being used. Certain end caps allow access to the catheter without removing it from the hub. Some PICCs have one opening (lumen) and others may have multiple lumens. Notify your healthcare provider if your end cap(s) becomes loose, comes off or is leaking. The end caps should be changed at least one time per week, or as often as your healthcare provider otherwise suggests.

Before any medicine or fluid is given, or blood is drawn, the end cap and/or hub should be cleaned with a special cleaning solution. This is done to prevent germs from getting into your catheter. Your healthcare provider will teach you how to clean the end cap.

Should I limit my activities while I have the BioFlo™ PICC?

Generally, bending your arm, reaching and doing everyday activities will not harm your PICC. You should not lift heavy objects, or carry objects held in the bend of your arm that may put strain on the PICC or the dressing.

If your healthcare provider approves, you may take a shower or bath with the PICC in place as long as you cover the PICC and dressing with plastic wrap, a plastic bag or material that will keep it from getting wet. You should NOT do other activities, like swimming, that may get the catheter or dressing wet. A wet dressing or catheter may put you at risk for infection.

Notify your healthcare provider or seek medical attention if you have:

- Redness, soreness or swelling at the PICC insertion site or on your arm
- Fever, chills or vomiting
- Any problems with your catheter while caring for it
- Difficulty giving medications, or being able to draw blood
- A catheter that becomes damaged in any way, leaks, is torn or broken

Recommended Flushing Protocols

(to be completed by your healthcare provider)

Solution _____

Volume/Lumen _____

Schedule _____

Additional Instructions

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