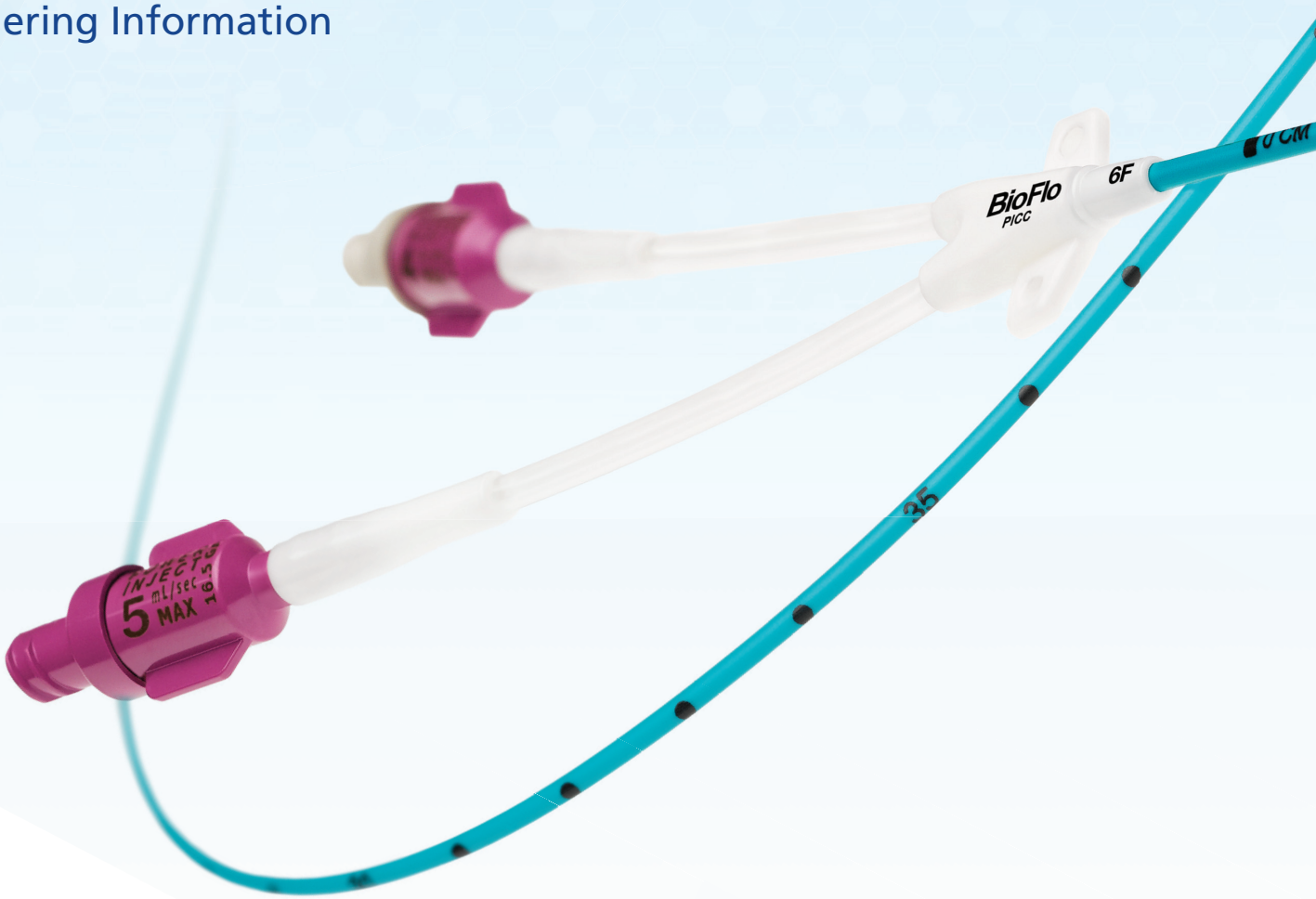
BioFlo PICC

with Endexo and PASV Valve Technology

Ordering Information



BioFlo

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BioFlo* Power Injectable PICC —Non-valved

UPN	Order Number	Lumens	Outer Diameter (F)	Reverse Taper Diameter (F)	Inner Diameter (Ga.)
Nitinol Guidewire					
MST † Kits with 70 cm Wire					
H965458960	45-896	Single	5	6	15.5
H965458950	45-895	Dual	5	7	17.5/17.5

Kit Includes: Catheter, Wire Guide/Flush Assembly, PTFE Coated Stiffening Wire, 21 Ga. x 7 cm (2.75") Safety Introducer Needle with Echogenic Tip, 21 Ga. X 7 cm (2.75") Standard Introducer Needles with Echogenic Tip, 70 cm Hydrophilic-Coated Guidewire, Safety Scalpel, 10 cm Sheath/Dilator, 92 cm Tape Measure, 10 mL Luer Lock Syringe(s), End Cap(s), and Catheter Securement Device.

IR Kits with 145 cm Wire					
H965458850	45-885	Single	4	6	17
H965458860	45-886	Single	5	6	15.5
H965458870	45-887	Dual	5	7	17.5/17.5
H965458880	45-888	Dual	6	7	16.5/16.5

Kit Includes: Catheter, Wire Guide/Flush Assembly, PTFE Coated Stiffening Wire, 21 Ga. x 7 cm (2.75") Safety Introducer Needle with Echogenic Tip, 21 Ga. X 7 cm (2.75") Standard Introducer Needles with Echogenic Tip, 145 cm Hydrophilic-Coated Guidewire with Floppy Platinum Tip, Safety Scalpel, 10 cm Sheath/Dilator, 92 cm Tape Measure, 10 mL Luer Lock Syringe(s), End Cap(s), and Catheter Securement Device.

†Modified Seldinger Technique.

BioFlo Power Injectable PICC—w/ PASV Valve Technology

UPN	Order Number	Lumens	Outer Diameter (F)	Reverse Taper Diameter (F)	Inner Diameter (Ga.)
Nitinol Guidewire					
MST † Kits with 70 cm Wire					
H965458940	45-894	Single	3	4	20
H965458910	45-891	Single	4	6	17
H965458920	45-892	Single	5	6	15.5
H965458890	45-889	Dual	5	7	17.5/17.5
H965458900	45-890	Dual	6	7	16.5/16.5
H965458930	45-893	Triple	6	7	16.5/19/19
H965458970	45-897	Triple Hybrid	6	7	16.5/19/19

Kit Includes: Catheter; PTFE Coated Stiffening Wire; Stiffening Wire Guide/Flush Assembly; 92 cm Tape Measure; 10 mL Luer Lock Syringe(s); 21 Ga. x 7 cm (2.75") Safety Introducer Needle with Echogenic Tip; 21 Ga. x 7 cm (2.75") Standard Introducer Needle with Echogenic Tip; 70 cm Hydrophilic-Coated Guidewire; Safety Scalpel; 10 cm Peelable Sheath/Dilator; StatLock Catheter Securement Device; and End Cap(s).

IR Kits with 145 cm Wire					
H965458810	45-881	Single	4	6	17
H965458820	45-882	Single	5	6	15.5
H965458830	45-883	Dual	5	7	17.5/17.5
H965458840	45-884	Triple	6	7	16.5/19/19
H965458980	45-898	Triple Hybrid	6	7	16.5/19/19

Kit Includes: Catheter; PTFE Coated Stiffening Wire; Stiffening Wire Guide/Flush Assembly; 92 cm Tape Measure; 10 mL Luer Lock Syringe(s); 21 Ga. x 7 cm (2.75") Safety Introducer Needle with Echogenic Tip; 21 Ga. x 7 cm (2.75") Standard Introducer Needle with Echogenic Tip; 145 cm Hydrophilic-Coated Guidewire; Safety Scalpel; 10 cm Peelable Sheath/Dilator; StatLock Catheter Securement Device; and End Cap(s).

†Modified Seldinger Technique.

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IMPORTANT RISK INFORMATION

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.

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.

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

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 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.

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

IMPORTANT RISK INFORMATION

INTENDED USE/INDICATIONS FOR USE: The BioFlo Hybrid PICC with 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. Non-valved lumens are indicated for central venous pressuring monitoring. The maximum power injection flow rate for the BioFlo Hybrid PICC with PASV Valve Technology is 6 mL/sec.

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.

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. 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. 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 Hybrid PICC with PASV Valve Technology must not exceed 325 psi. Exceeding maximum allowable flow rate may result in catheter failure and/or catheter tip displacement. For triple lumen catheters only the purple (non-valved) 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. 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 Hybrid PICC with 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 Hybrid PICC with 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.

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