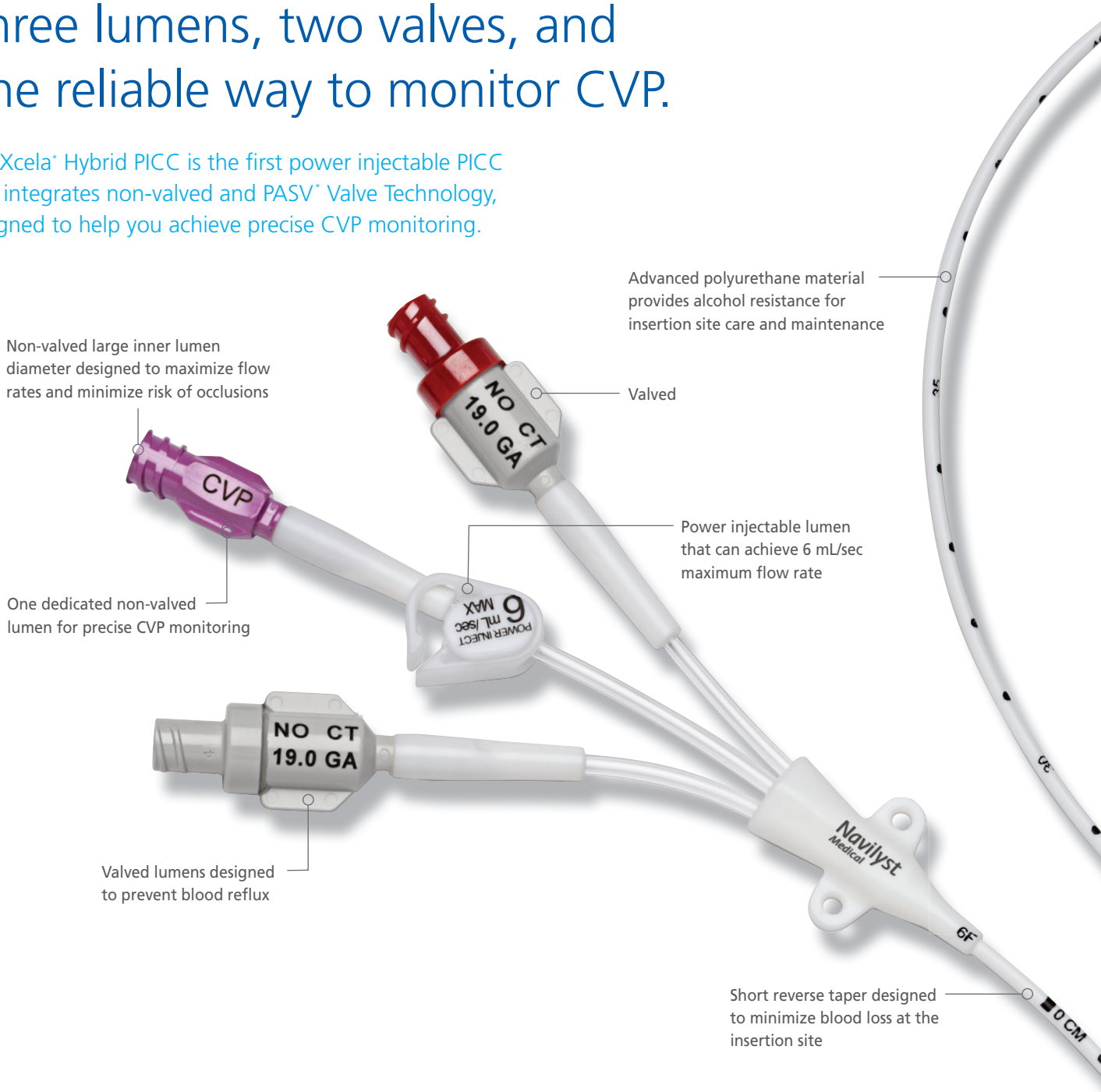
Xcela Hybrid PICC
with PASV Valve Technology

Three lumens, two valves, and one reliable way to monitor CVP.

The Xcela® Hybrid PICC is the first power injectable PICC that integrates non-valved and PASV® Valve Technology, designed to help you achieve precise CVP monitoring.



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Xcela Hybrid PICC

UPN#	Order Number	Description	Lumens	Outer Diameter (F)	Reverse Taper Diameter (F)	Inner Diameter (G)
H965952410	95-241	Catheter Kit	3	6	7	16.5/19/19
KIT INCLUDES: Catheter; 92 cm Tape Measure; Hydrophilic-Coated Stiffening Wire Guide/Flush Assembly; Statlock* Catheter Stabilization Device; and End Cap(s)						
H965952440	95-244	Intermediate MST† Kits with 45 cm Wire	3	6	7	16.5/19/19
KIT INCLUDES: Catheter; Hydrophilic-Coated Stiffening Wire; Stiffening Wire Guide/Flush Assembly; Face Mask; Two Tourniquets; Two 92 cm Tape Measures; Scissors; 24" x 36" Absorbent Poly-Lined Patient Drape; 24" x 38" Absorbent Fenestrated Drape; 3 mL ChloraPrep* Applicator; 3 mL Luer Lock Syringe; 25 Gauge, 5/8" Safety Hypodermic Needle; 21 Gauge, 2.75" Safety Introducer Needle with Echogenic Tip; 45 cm Guidewire with Double Floppy Tip; Safety Scalpel; 7 cm Peelable Sheath/Dilator; Non-Serrated Forceps; Five 2" x 2" Gauze Pads; Five 4" x 4" Gauze Pads; 10 mL Luer Lock Syringe(s); Saline Ampule(s); Safety Ampule Cracker(s); 5 µm Filter Straw(s); Saline Label(s); End Cap(s); Skin Protectant Swabstick; Statlock Catheter Stabilization Device; Tegaderm* Transparent Dressing; and CSR Wrap					
H965952450	95-245	Intermediate MST† Kits with 45 cm Wire and Lidocaine	3	6	7	16.5/19/19
Same kit components as H965952440 / 95-244						
H965952420	95-242	MST† Kits with 70 cm Wire	3	6	7	16.5/19/19
KIT INCLUDES: Catheter; Hydrophilic-Coated Stiffening Wire; Stiffening Wire Guide/Flush Assembly; 92 cm Tape Measure; 10 mL Luer Lock Syringe(s); 21 Gauge, 2.75" Safety Introducer Needle with Echogenic Tip; 21 Gauge, 2.75" Standard Introducer Needle with Echogenic Tip; 70 cm Hydrophilic-Coated Guidewire with Floppy Radiopaque Tip; Safety Scalpel; 10 cm Peelable Sheath/Dilator; Statlock Catheter Securement Device; and End Cap(s)						
H965952460	95-246	MST† Kits with 70 cm Nitinol Wire	3	6	7	16.5/19/19
Same kit components as H965952420 / 95-242						
H965952430	95-243	IR Kits with 145 cm Wire	3	6	7	16.5/19/19
Same kit components as H965952420 / 95-242						
H965952470	95-247	IR Kits with 145 cm Nitinol Wire	3	6	7	16.5/19/19
Same kit components as H965952420 / 95-242						

† Modified Seldinger Technique

Consult your AngioDynamics representative for country specific product availability.

IMPORTANT RISK INFORMATION

INTENDED USE/INDICATIONS FOR USE: The Xcela 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 Xcela 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 Xcela 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 Xcela 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 Xcela 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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