Xcela™ PICC with PASV™ Valve Technology

Redefining the PICC

Navilyst Medical

Navilyst Medical

Combining The Power of PASV™ and Power Injection

You have the power to redefine patient care with a power injectable PICC that incorporates PASV™ Valve Technology. The Xcela™ PICC with PASV Valve Technology is designed to provide a high degree of safety, ease and confidence in patient care.

Power Injectable

Advanced features such as large lumen diameters allow the Xcela PICC with PASV Valve Technology to deliver the power injection flow rates required for contrast-enhanced CTs compatible with up to 325 psi CT injectors.

Integrated Design

The innovative design of PASV Valve Technology along with the advanced material of the Xcela Power Injectable PICC offers a solution to vascular access needs.

Confidence in Results

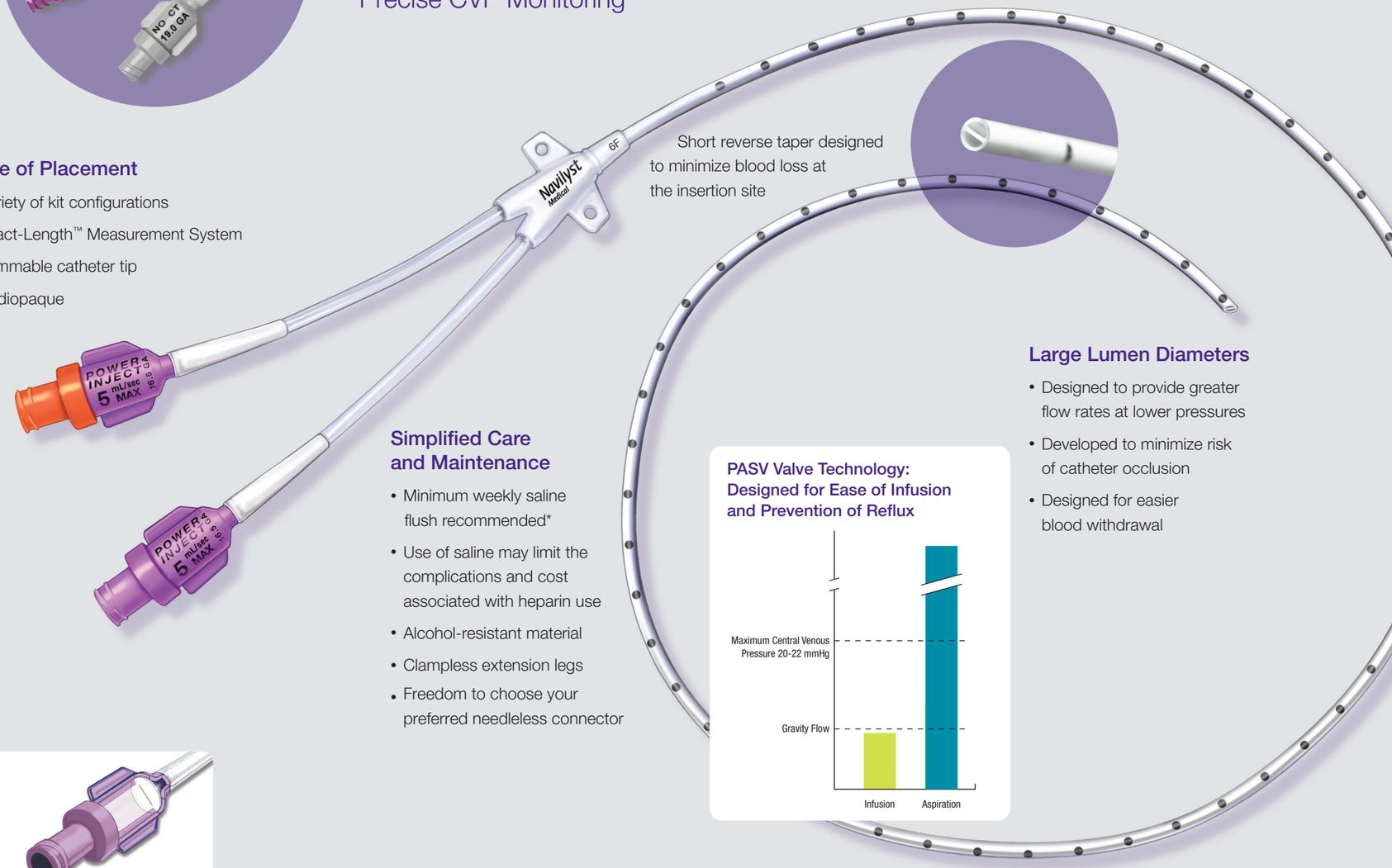
The PASV Valve Technology design automatically resists backflow, reducing blood reflux that could lead to catheter-related complications.

Confidence in Choice

With the Xcela Power Injectable PICC with PASV Valve Technology, clinicians have the ability to choose the right PICC for the right patient.

Xcela™ PICC with PASV™ Valve Technology

Available in a 6 F Triple Lumen Hybrid Configuration for Precise CVP Monitoring



Short reverse taper designed to minimize blood loss at the insertion site

Ease of Placement

- Variety of kit configurations
- Exact-Length™ Measurement System
- Trimmable catheter tip
- Radiopaque

Simplified Care and Maintenance

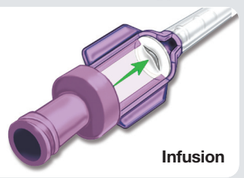
- Minimum weekly saline flush recommended*
- Use of saline may limit the complications and cost associated with heparin use
- Alcohol-resistant material
- Clampless extension legs
- Freedom to choose your preferred needleless connector

Large Lumen Diameters

- Designed to provide greater flow rates at lower pressures
- Developed to minimize risk of catheter occlusion
- Designed for easier blood withdrawal

PASV Valve Technology: Designed for Ease of Infusion and Prevention of Reflux

PASV Valve Technology is Designed to Automatically:



Open with minimal pressure and automatically close after infusion

Open for sampling and resist pressure fluctuations that may cause blood reflux

Remain closed during normal increases in central venous pressure to prevent blood reflux in the catheter tip

*Follow institutional policies and procedures for catheter flushing.

The Power of PASV™ Putting the Patient First

Xcela™ PICC with PASV™ Valve Technology

Value-Added Programs and Services

Convenience Kit Program

Improve clinician efficiency, productivity and cost savings with Navilyst Medical's Convenience Kit Program. Our comprehensive Program provides clinicians with solutions to streamline PICC placement procedures, eliminate the cost 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

Navilyst Medical 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 material, all designed to reinforce best practices for catheter insertion, care and maintenance.

Technical Support

for this product and other Navilyst Medical Vascular Access Products is available 24 hours a day by calling:

Vascular Access Products Reference Line
800.513.6876

Contact Navilyst Medical to learn more about our products, programs and services.

XCELA PICC WITH PASV VALVE TECHNOLOGY

XCELA HYBRID PICC WITH PASV VALVE TECHNOLOGY

INTENDED USE/INDICATIONS FOR USE: The Xcela PICC with PASV Valve Technology and Xcela Hybrid PICC with PASV Valve Technology are 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. Only the Xcela Hybrid PICC with PASV Valve Technology device has a lumen 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. 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. 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 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 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: The Xcela PICC with PASV Valve Technology and the Xcela Hybrid PICC with PASV Valve Technology: Do not insert the stiff end of the floppy-tipped guidewire into the vein. 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 institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein including flushing of occluded catheters and power injection. Testing included 10 power injection cycles. 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. Do not attempt to repair the catheter. If breaks or leaks are apparent in the catheter, remove the catheter immediately. Catheter use, care or removal is to be undertaken only by a trained, qualified healthcare provider. 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. It is recommended that only Luer Lock accessories be used. 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. 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. Xcela Hybrid PICC with PASV Valve Technology: Central Venous Pressure (CVP) Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function. 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.

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.

Navilyst Medical

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800.833.9973 in the United States
800.268.0184 in Canada

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