

Xcela[®] PICC with PASV[®] Valve Technology

Care and Maintenance

Providing power injection capability with the performance of the PASV Valve Technology.

PASV Valve Technology is Designed to Automatically:

1. Close after infusion
2. Open for sampling
3. Remain closed during normal increases in central venous pressure



REFER TO DIRECTIONS FOR USE PROVIDED WITH THE PRODUCT FOR COMPLETE INSTRUCTIONS.

SUGGESTED FLUSHING PROTOCOL

Flush PICC lumens and follow institutional protocol for changing or replacing needleless connectors.

1. Using a 10 mL syringe or larger, flush each lumen with 10 mL sterile normal saline.
2. Flush each lumen using a "pulse" or "stop/start" technique.*
3. Disconnect the syringe.

SUGGESTED VENOUS BLOOD SAMPLING PROTOCOL

1. Flush the selected lumen with 10 mL of sterile normal saline.
2. Using the same syringe, draw 3 to 5 mL of blood by slowly pulling and holding the plunger, allowing the PASV Valve to open.
3. Disconnect and discard the syringe.
4. Attach a second 10 mL syringe or collection set and slowly aspirate the blood sample.
5. Using a 10 mL syringe or larger, flush the selected lumen with a minimum of 20 mL of sterile normal saline using a "pulse" or "stop/start" technique.
6. Disconnect the syringe.

PATIENT EDUCATION

- Complete Travel Card included in Patient Guide and carry at all times.
- Do not use acetone or polyethylene glycol-containing ointments to clean the catheter.
- Protect dressing from exposure to water.
- If dressing becomes wet or loose, have it changed.
- Keep needleless connectors on catheter hub at all times.
- Notify healthcare provider immediately if catheter is damaged.

IMPORTANT CARE GUIDELINES

Always use aseptic technique.

Catheter Care

- The PASV Valve is contained within the PICC hub acting as the clamp. PICCs containing this valve do not require clamps (Figures 1-2).
- Do not use clamps, hemostats or other similar implements to tighten or remove accessories.
- Use a 10 mL syringe or larger.
- When administering care, inspect visible components for damage.
- At each treatment, verify that external catheter length matches measurement recorded upon insertion.

Site Care

- If alcohol-based solutions are used, allow them to completely dry.
- Assess site for potential infection. If redness, swelling or drainage is observed, notify physician.
- Cover site with occlusive dressing applied per institutional protocol. Keep dressing clean, dry and intact at all times (Figure 3).
- Leave extension tubes, hubs and connectors exposed.
- Do not use scissors to remove dressing as this may possibly cut or damage the catheter.



Figure 1



Figure 2



Figure 3

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

*NOTE: This is the recommended flush procedure for this catheter. If using a different procedure, the use of heparin may be necessary. Follow institutional protocol for catheter flushing.

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XCELA PICC WITH PASV VALVE TECHNOLOGY

INTENDED USE/INDICATIONS FOR USE: The Xcela 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.

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. Hypocoagulopathy 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 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 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 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: 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. The Xcela PICC with PASV Valve Technology catheter 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.

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



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For more information, call
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