Navilyst Medical

Xcela™ Hybrid PICC

with PASV™ Valve Technology

14600125-01 A
2011-10

TABLE OF CONTENTS

Xcela™ Hybrid PICC

with PASV™ Valve Technology

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Navilyst Medical representative. Inspect prior to use to verify that no damage has occurred during shipping.

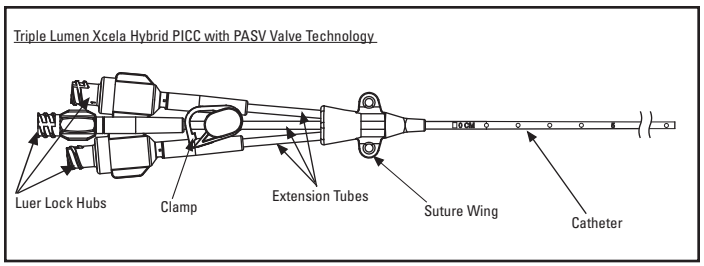
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Xcela Hybrid Peripherally Inserted Central Catheter (PICC) with Pressure Activated Safety Valve (PASV) Technology is a radiopaque, polyurethane catheter with Luer lock hub(s), polyurethane extension tube(s) and suture wing capable of power injection. The lumens are differentiated by colored Luer lock hubs that indicate lumen size. "No CT" for non-power injectable lumens are indicated on the luer lock hubs. For non-valved lumens, maximum power injection flow rates are indicated on the clamp(s.) (Figure 1 and Table 2).

Figure 1. Catheter Configurations



The PASV Valve located within the hub of the valved lumen(s) is a safety feature of the catheter. The valve remains closed when the catheter is not in use and when subjected to normal central venous pressures. When positive pressure (infusion) is applied through the Luer lock hub, the valve opens allowing infusion of fluids through the catheter. When negative pressure (aspiration) is applied, the valve opens allowing for withdrawal of blood into a syringe. The PASV Valve replaces the need for clamps on the extension tube(s) of the catheter used on non-valved lumen(s). As a precaution against contamination, a sterile end cap is placed on the Luer lock hub(s) when the catheter is not in use.

When determining patient selection and catheter diameter, clinicians must consider variations in individual's anatomy and physiology due to size and age (i.e. adult, child or infant). Appropriate guidance, vein assessment and insertion techniques for PICC placement should be employed.

The Xcela Hybrid PICC with PASV Valve Technology is provided in multiple packaging configurations, including:

- Catheter Kit
- Intermediate MST Kit with 45 cm Wire
- Intermediate MST Kit with 45 cm Wire and Lidocaine
- MST Kit with 70 cm Wire
- IR Kit with 145 cm Wire

NOTE: MST=Modified Seldinger Technique; IR= Interventional Radiology

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 pressure monitoring.

Maximum Power Injection Flow Rate*

- 6F Triple Lumen/55 cm - 6 mL/sec

*Refer to table 2

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

Refer to procedural steps for additional warnings. Due to the risk of exposure to bloodborne pathogens, care providers must adhere to guidelines for universal blood and body fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.

Navilyst Medical, Master DFU Template 8in x 8in Global, 146T0808 RevVer. , DFU, XCELA HYBRID PICC w/ PASV VALVE TECHNOLOGY, 14600125-01A

- Do not use if package is opened or damaged.
- If using bacteriostatic saline, do not exceed 30 mL in a 24-hour period.
- Do not fully insert catheter up to suture wing.
- Do not use the catheter with chemicals that are incompatible with any of its accessories, as catheter damage may occur.
- Do not place the catheter into the right atrium or the right ventricle of the heart.
- Do not resheath any needles. Place needles in puncture resistant, leak proof, sharps containers per institutional protocol.
- 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 (Table 2) 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 Power Injectable PICC must not exceed 325 psi (2,240 kPa).
- Prior to loading stylet or guidewire cut catheter to desired length. Do not cut catheter while stylet or guidewire is loaded into catheter as device damage or patient injury may occur.
- Central Venous Pressure (CVP) Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

PRECAUTIONS

Refer to procedural steps for additional precautions.

- Do not advance a guidewire past the level of the axilla without the use of real-time imaging guidance.
- Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into desired position (zero mark).
- If guidewire must be withdrawn, remove the needle and guidewire as a single unit.
- Carefully read all instructions prior to insertion, care or use.
- Do not use sharp objects to open package as damage to the device may occur.
- Catheter insertion should be performed only by a licensed and qualified healthcare practitioner.
- If catheter and accessories show any sign of damage (crimped, crushed, cut, etc.), do not use.
- If using an introducer sheath other than the one provided (as in Modified Seldinger and IR kits), verify that the catheter fits easily through the sheath.
- Do not insert the stiff end of the floppy-tipped guidewire into the vein.
- Exercise care when advancing the catheter or guidewire to avoid trauma to the vessel intima. Do not use clamps, toothed or ribbed forceps. Do not use clamps or other instruments with teeth or sharp edges on the catheter or other instruments to advance or position catheter as catheter damage may occur.
- Avoid sharp or acute angles during insertion which may compromise catheter functionality.
- Acetone and polyethylene glycol-containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
- Catheter replacement may be required if catheter is cut too short.
- Do not use sharp instruments near the extension tubes or catheter shaft.
- Do not suture through any part of the catheter. If using sutures to secure catheter use the suture wings and make sure they do not occlude, puncture, or cut the catheter.
- Following institutional policy, secure catheter externally to prevent catheter movement, migration, damage, kinking or occlusion.
- Ensure that sterile gloves are free of residue.
- 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.
- When discarding used accessories, follow institutional protocol.
- Incompatible drug delivery within the same lumen may cause precipitation. Flush catheter lumen following each infusion.
- It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein.
- Failure to retract the stylet into the catheter prior to catheter insertion may cause vessel damage during insertion procedure.
- 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.
- Catheter tip location needs to be verified. It is recommended to use radiographic visualization. Patient movement may cause catheter tip displacement.

- 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 catheter 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 removal is to be undertaken only by trained, qualified healthcare provider.
- Use of force to remove the catheter may lead to catheter separation. Hold the catheter distal to the suture wing during removal.
- Patients must be educated regarding the care and maintenance of their PICC. The healthcare provider is responsible for this patient instruction.
- 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 or 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.

POTENTIAL COMPLICATIONS/ADVERSE EVENTS

- Air Embolism
- Bleeding
- Brachial Plexus or Other Nerve Injury
- Cardiac Arrhythmia
- Cardiac Puncture
- Cardiac Tamponade
- Catheter Dislodgement
- Catheter Embolism
- Catheter Erosion through Skin/Vessel
- Catheter Fragmentation
- Catheter Malfunction
- Catheter Malposition
- Catheter Migration
- Catheter Occlusion
- Catheter Retraction
- Catheter Rupture
- Death
- Drug or Contrast Medium Precipitate
- Extravasation/Infiltration of Infusate
- Embolism
- Endocarditis
- Hemothorax
- Infection
- Inflammation/Phlebitis
- Intolerance Reaction to Contrast Media
- Intolerance Reaction to Implantation Device
- Malposition
- Myocardial Erosion
- Nerve Damage
- Pain
- Pericardial Effusion
- Pleural Effusion
- Pneumothorax
- Pulmonary Embolism
- Renal Compromise
- Sensitivity or Allergy
- Sepsis
- Subintimal Venous or Myocardial Injection
- Thoracic Duct Injury
- Exit Site Necrosis
- Fibrin Sheath Formation
- Foreign Body Rejection
- Hematoma
- Hemorrhage
- Thromboembolism
- Thrombophlebitis
- Vascular Thrombosis
- Vessel Damage
- Vessel Stenosis

HOW SUPPLIED

Contents supplied STERILE using an ethylene oxide (EO) process. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Please see package label for additional storage conditions.

OPERATIONAL INSTRUCTIONS

The Xcela Hybrid PICC with PASV Valve Technology is to be inserted, manipulated, and removed only by a qualified, licensed healthcare practitioner. The techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for a clinician's experience and judgment in treating any specific patient. Please refer to the appropriate section based upon technique selected.

NOTE: Strict aseptic technique must be used during insertion, routine maintenance and removal procedures.

Prior to use, carefully examine the product to verify that it has not expired and the sterile package has not been damaged in shipment.

PRECAUTION: Do not use sharp objects to open package.

Table 1. Catheter Specifications

French Size (mm) (Outer Diameter)	Lumens / Configuration	Lumen Gauge[1]	Catheter Length (cm)	Minimum Gravity Flow Rate (Water)	Lumen Size (mm)	Priming Volume
6F (2.20)	3 / Hybrid	16.5 [2] 19.0 [3]	55	892 mL/hr [2] 30 mL/hr [3]	1.1/0.6/0.6	<0.7 mL [2] <0.6 mL [3]

1 Maximum guidewire compatibility is 0.018 in. (0.46 mm).
2 Large Power Injectable Lumen (non-valved purple lumen)
3 Small Non-Power Injectable Lumens (valved lumens)

INSTRUCTIONS FOR USE

CATHETER INSERTION DIRECTIONS

Patient Preparation

1. If placing catheter at patient bedside, apply tourniquet to upper arm. Common veins used for insertion include the Basilic, Brachials and Cephalic. Release tourniquet.
2. Prepare sterile field and supplies.
3. Prepare the insertion site and surrounding area with an acceptable topical antimicrobial cleansing agent according to institutional policies and procedures.

Venous Access

Access vein using the following appropriate method.

Using Guidewire

a. Insert introducer needle, bevel up, into selected vein, and confirm vessel entry.

b. Insert soft or guiding tip of the guidewire through the needle and into the vein to the desired position based on clinical practice guidelines and standards or institutional policy and procedure.

NOTE: If using 145 cm or 70 cm hydrophilic guidewire, fill the wire holder (hoop) or bathe the guidewire with sterile normal saline for injection to ensure activation of the hydrophilic coating prior to the procedure. This may need to be repeated during the procedure by gently flushing the catheter with sterile normal saline solution for injection through the supplied flush assembly with the guidewire in place.

c. If IR-145cm or MST-70 cm Kit is used, use fluoroscopic visualization to advance tip of guidewire to desired catheter termination location. Recommended tip location is at junction of superior vena cava and right atrium.

PRECAUTION: If guidewire must be withdrawn, remove the needle and guidewire as a single unit.

d. Gently withdraw needle from guidewire while holding guidewire in place.

Safety Needle Use

e. To activate safety mechanism, hold safety handle in one hand and rotate flashback chamber counterclockwise.

f. Pull back on flashback chamber until needle tip disappears into safety handle and locks securely into needle handle (indicated by audible click and feel).

g. Verify needle tip is securely locked inside safety handle by pushing flashback chamber forward while holding safety handle. Repeat prior step, if necessary. Discard per institutional protocol.

Access without using guidewire

a. Select peelable sheath safety introducer needle.

b. Insert peelable sheath safety introducer needle per manufacturer's instructions for use.

NOTE: Ensure sheath lies within vessel.

c. Release tourniquet.

d. Retract needle halfway out of peelable sheath, maintaining sheath position.

e. Hold peelable sheath in place, and remove safety needle per manufacturer's instructions for use. Discard according to institutional protocol.

NOTE: Do not reinsert introducer needle into peelable sheath, as this may cause damage to sheath.

Catheter Preparation

NOTE: Catheter preparation may occur prior to venous access, if catheter is being placed at patient bedside.

4. Determine catheter length.

NOTE: Recommended tip location is at junction of superior vena cava and right atrium.

a. **Bedside Placement:** Position patient with arm extended outward from body at a 90-degree angle, or as tolerated. Measure distance along vein track between selected insertion site and the desired catheter tip location.

b. **Placement via Imaging:** Measure length of guidewire protruding from skin, or to 60 cm marking on guidewire (IR-145cm Kit only). Use disposable tape measure to assess fractional lengths. Subtract measured length from 60 cm to determine cut length of catheter.

5. Cut catheter to length using previous measurements.

NOTE: Cut catheter tip squarely. Inspect cut surfaces to ensure there is no loose material or rough edges.

6. Attach flush assembly to catheter hub. Ensure locking collar is in open position (Figure 2).

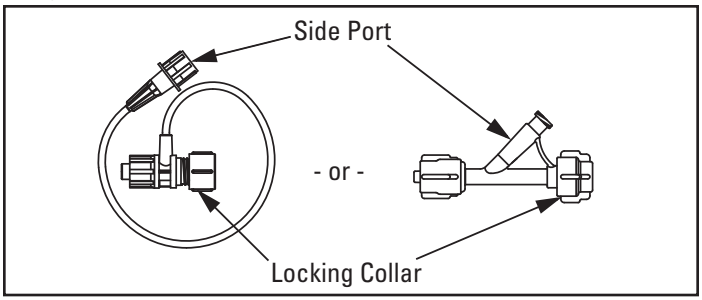


Figure 2. Flush Assemblies

NOTE: For multi lumen catheters, be sure to prime each lumen prior to insertion.

7. Draw 10 mL sterile normal saline into syringe, remove cap on side port of flush assembly, and attach syringe.

8. While covering locking collar opening with finger to prevent fluid loss, prime flush assembly and catheter.

PRECAUTION: When inserting a **triple lumen catheter**, the purple (non-valved) power injectable lumen must be used for stylet placement.

9. If stylet is used (recommended for all techniques except for Seldinger technique), advance stylet slowly through flush assembly locking collar into catheter until tip of stylet extends beyond end of catheter. Continue to inject sterile normal saline, as needed, to assist in advancement.
10. Retract stylet back to a position at least one cm within the catheter (Figure 3).

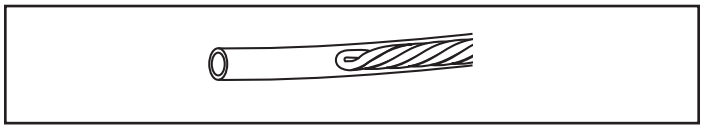


Figure 3. Stylet Position within Catheter

PRECAUTION: Failure to retract stylet into catheter prior to catheter insertion may cause vessel damage during insertion procedure.

11. Turn flush assembly locking collar clockwise to secure stylet in place.

WARNING: Do not cut stylet or guidewire.

PRECAUTION: Do not reinsert stylet into catheter, as damage to valve, catheter and vein may result.

PRECAUTION: Do not apply any type of clamp on catheter or extension tube while stylet is inside catheter. Stylet may become kinked and damage catheter, resulting in leakage or fracture of catheter.

12. Remove syringe from flush assembly and place cap on side port.

Catheter Placement

Using Guidewire

a. Alongside guidewire, nick insertion site with safety scalpel. To use safety scalpel, depress top button on protective shield, and retract to rear locked position. Once nick is made, depress top button again and advance to forward locked position at lock indicator line.

b. Advance peelable sheath/dilator assembly over guidewire. Advance assembly into the vein.

c. **Seldinger technique:** Withdraw the dilator, leaving the sheath and guidewire in place. **Modified technique:** Withdraw dilator and guidewire, leaving peelable sheath in place. Cover opening to prevent blood loss and/or air embolism.

PRECAUTION: Seldinger technique: When inserting a **triple lumen catheter**, the purple (non-valved) power injectable lumen must be used for guidewire placement.

13. If placing catheter at patient bedside, turn patient's head toward insertion side with chin to shoulder.
14. Slowly and incrementally, insert catheter through the peelable sheath to desired tip position.

NOTE: If practicing Seldinger technique, wet the exposed segment of the 145 cm guidewire with saline and thread catheter over guidewire first.

15. Holding catheter steady, slowly withdraw peelable sheath from insertion site.
16. Grasp wings of sheath firmly, and pull apart applying equal pressure to both wings – peel the sheath away from the catheter using a forward motion. Discard according to institutional protocol.
17. Slowly advance remaining catheter into vein until "0" mark on catheter is at insertion site. Do not fully insert catheter to suture wing.
18. Loosen flush assembly from catheter hub and withdraw, with stylet or guidewire, while holding suture wing in place. Discard according to institutional protocol.
19. Once catheter is inserted, aspirate gently with 10 mL syringe attached to catheter hub and observe for blood return. Detach and discard according to institutional protocol.

PRECAUTION: Do not reinsert stylet into catheter, as damage to valve, catheter or vein may occur.

20. See ***FLUSHING (Valved Lumens) FLUSHING AND HEPARINIZATION (Non-Valved Lumens)*** and ***CATHETER STABILIZATION*** sections for next steps.
21. Verify catheter tip location using radiographic visualization per institutional protocol.

FLUSHING (VALVED LUMENS)

Recommended Procedure

1. Flush the catheter after every use, or at least every seven days when not in use, to maintain patency. Use a 10 mL syringe or larger.
2. Flush the catheter with a minimum of 10 mL of sterile normal saline, using a "pulse" or "stop/start" technique.

WARNING: If using bacteriostatic saline, do not exceed 30 mL in a 24-hour period.

3. Disconnect the syringe and attach a sterile end cap to each Luer lock hub.

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

PRECAUTION: Incompatible drug delivery within the same lumen may cause precipitation. Ensure that the catheter lumen is flushed following each infusion.

PRECAUTION: If resistance is met when flushing, it is recommended that no further attempts be made. Further flushing may result in catheter rupture. Refer to institutional protocol for clearing occluded catheters.

PRECAUTION: Place a cap on the hub after use to reduce the risk of contamination.

FLUSHING AND HEPARINIZATION (NON-VALVED LUMENS)

1. Attach syringe to hub, open clamp and aspirate blood.
2. Close clamp, detach syringe and discard.

3. Attach syringe filled with 10 mL sterile normal saline, open clamp, and flush lumen, using a "pulse" or "stop/start" technique.

NOTE: If flushing after a power injection, use 20 mL sterile normal saline.

4. Close clamp, detach syringe and discard.
5. Draw heparinized saline into syringe and attach to hub.
6. Open clamp, and inject amount equal to or greater than priming volume into lumen (see Table 1).
7. Maintaining positive pressure on syringe, close clamp, detach syringe and discard.
8. Repeat for second lumen, if necessary.

NOTE: Never leave catheter uncapped.

NOTE: Flush catheter after every use. When not in use, flush at least every 12 hours, or according to institutional protocol to maintain patency.

CATHETER STABILIZATION

1. Prepare stabilization site with alcohol and remove betadine, if present.
2. Apply skin prep solution for enhanced adherence and skin protection. Allow skin prep solution to completely dry (10-15 seconds).
3. Slide device under suture wing. Slide one suture hole over a post, then slide that post and suture wing toward opposite side until second suture hole easily fits over second post.
4. Close lids over posts to secure catheter.
5. Peel away paper backing and place on skin.
6. Apply adhesive strip at or near insertion site.

CONTRAINDICATION: Patients with known tape or adhesive allergies.

PRECAUTION: Do not use where loss of adherence could occur, such as with a confused patient, unattended access device, diaphoretic or non-adherent skin.

PRECAUTION: Minimize catheter manipulation during application and removal.

NOTE: Monitor stabilization device daily. Replace at least every seven days.

POWER INJECTION

Table 2. Power Injection Specifications

French Size (mm) (Outer Diameter)	Lumens / Configurations	Catheter Length (cm)	Maximum Flow Rate for 11.8 cP CT Contrast (ml/sec)[1]	Maximum Flow Rate for 6.3 cP CT Contrast (ml/sec)[4]	Maximum Catheter Pressure at Maximum (psi[1,2](kPa))	Maximum Static Burst Pressure Post Injection (psi[3](kPa))
6F (2.20)[5]	3 / Hybrid	55	6	6	281 (1,937)	207 (1,427)

1 Testing was conducted using contrast with viscosity of 11.8 centipoise (cP), measured at body temperature (37°C) with injector set at 325 psi (2,240 kPa). Data represent approximate flow capabilities of power injection of contrast media.
2 Internal catheter pressure data point observed during power injection testing.
3 Burst pressure is the static burst pressure failure point of the catheter after completion of 10 power injection cycles.
4 Testing was conducted using contrast with viscosity of 6.3 centipoise (cP), measured at body temperature (37°C) with injector set at 325 psi (2,240 kPa). Data represent approximate flow capabilities of power injection of contrast media.
5 Only the large, power injectable lumen (non-valved purple luer) is to be used for power injection.

WARNING: During power injection testing catheter pressures did not exceed those outlined in Table 2.

WARNING: During static burst pressure testing, catheter failure was recorded as detailed in Table 2.

WARNING: Exceeding maximum allowable flow rate (Table 2) may result in catheter failure and/or catheter tip displacement.

1. Verify power injector is appropriately programmed and does not exceed catheter flow rate limit (see Table 2).
2. Warm contrast to body temperature (37°C).

WARNING: Failure to warm contrast media to body temperature prior to power injection study may result in catheter failure.

3. Inspect catheter for damage.
4. Attach syringe and aspirate amount greater than priming volume of catheter, or until blood return (Table 1). Remove and discard used syringe according to institutional protocol.
5. Attach syringe filled with 10 mL sterile normal saline and vigorously flush lumen.
6. Detach syringe and discard according to institutional protocol.

WARNING: Failure to ensure catheter patency prior to power injection studies may result in catheter failure.

PRECAUTION: If a needleless connector is attached to catheter hub, first ensure that it will sustain power injection.

7. Attach power injector to selected lumen hub per manufacturer's recommendations.

WARNING: For **triple lumen catheters** only the purple (non-valved) lumen is for power injection. Do not use lumens marked "No CT" for power injection of contrast media as it may result in device damage or patient injury.

8. Complete power injection study taking care not to exceed maximum flow rate limit (Table 2).

PRECAUTION: 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.

9. Disconnect the power injector.
10. Refer to ***FLUSHING*** section.

CATHETER MAINTENANCE

It is recommended that institutional protocols be followed for all aspects of catheter care, use and maintenance. The following care, use and maintenance information is not intended as a substitute for institutional protocol, but rather, to describe guidelines and recommendations that can be used successfully with the Xcela Hybrid PICC with PASV Valve Technology.

GENERAL CATHETER CARE AND USE

- Use aseptic technique during catheter care and use.
- Use Standard and Universal Precautions during catheter care procedures.
- Never leave catheter uncapped.
- Do not use clamps, or instruments with teeth or sharp edges on the catheter, as catheter damage may occur.

CARE OF INSERTION SITE AND DRESSING

- Examine insertion site, including catheter stabilization device, routinely and with each dressing change, for complications.
- Follow institutional protocol for dressing change. It is recommended that dressings be changed weekly and as necessary.
- To maintain unobstructed flow, make sure there are no kinks in catheter or IV tubing.

WARNING: Prior to dressing catheter and access site, inspect both to assure they are completely dry of isopropyl alcohol-based cleansing agents.

- A sterile, occlusive dressing covering the entire insertion site, suture wing and at least 2.5 cm of the extension tube is recommended.
- All efforts are to be made to keep insertion site and dressing clean, dry and intact.

DRESSING REMOVAL

- Stabilize catheter and Luer lock hub during dressing removal to prevent accidental dislodgment.
- Separate dressing away from Luer lock hub and toward insertion site. As you separate, keep any tape and dressing close to patient's arm to avoid dislodging catheter or sutures.

ASSESSING CATHETER INTEGRITY

Assess catheter integrity before any injection/infusion by completing the following steps:

- Examine and palpate catheter tract and insertion site for complications.
- Using a 10 mL syringe, aspirate slowly for blood return. Difficulty in withdrawing blood may indicate catheter compression, malposition, and/or obstruction. Discard syringe according to institutional protocol.
- Using a second 10 mL syringe, flush catheter with 10 mL of sterile normal saline to clear catheter.

NOTE: If catheter integrity is questioned as a result of any of the above steps, do not use catheter without further inquiry and resolution of the problem.

BLOOD SAMPLING

Recommended Procedure

1. Stop administration of infusates.
2. Using aseptic technique, swab catheter hub and allow to air dry.
3. Flush the selected lumen with 10 mL of sterile normal saline.
4. Using the same syringe, aspirate a small amount of blood and fluid (3-5 mL minimum). To verify patency for valved lumens, aspiration to be performed by pulling slowly and holding the plunger, allowing the PASV™ Valve to open. Discard syringe according to institutional protocol.
5. Using a second 10 mL syringe or collection set, slowly withdraw specimen.
6. Refer to ***FLUSHING (Valved Lumen) and FLUSHING AND HEPARINIZATION (Non-valved lumen)*** section.
7. Attach a sterile end cap to the Luer lock hub.
8. Transfer specimens per institutional protocol.

CENTRAL VENOUS PRESSURE MONITORING (NON-VALVED LUMENS ONLY)

1. Ensure proper catheter tip positioning prior to conducting central venous pressure (CVP) monitoring.
2. Refer to ***FLUSHING AND HEPARINIZATION (Non-Valved Lumens)*** section for next step.
3. Flush catheter vigorously with 10mL normal saline.
4. Ensure the pressure transducer is at the level of the right atrium.
5. It is recommended that a continuous infusion of normal saline (3mL/hr) is maintained.
6. Use your institution's protocol for CVP monitoring procedures.

WARNING: CVP monitoring should always be used in conjunction with other patient Assessment metrics when evaluating cardiac function.

Navilyst Medical, Master DFU Template 8in x 8in Global, 146T0808 RevVer. , DFU, XCELA HYBRID PICC w/ PASV VALVE TECHNOLOGY, 14600125-01A

MANAGEMENT OF LUMEN OCCLUSION

The lumens of PICCs may infrequently become obstructed. Lumen obstruction is usually evident by failure to aspirate or infuse through the lumen or inadequate flow and/or high resistance pressures during aspiration and/or infusion. The causes may include but not limited to catheter tip malposition, catheter kink, or clot. One of the following may resolve the obstruction:

- Verify there is no kinked tubing in the catheter section external to the body.
- Reposition the patient.
- Have the patient cough.
- Provided there is no resistance with aspiration, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall. Use a 10 mL or larger syringe.

PRECAUTION: Never forcibly flush an obstructed lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, consult institutional protocol for management of thrombosis.

CATHETER REPAIR

In the event that the catheter is accidentally torn or broken, it is recommended that the catheter be replaced.

CATHETER REMOVAL

Catheter removal is per the discretion of the physician in regards to the patient's therapy regimen.

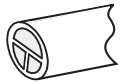
1. Position patient upright with arm at 45-degree angle outward from body. Maintain insertion site below level of heart.
2. See ***DRESSING REMOVAL*** section.
3. Open catheter stabilization device retainer lids and remove catheter from retainer.

NOTE: It is preferred to use aseptic technique for the following steps.

4. To remove catheter, grasp catheter between suture wing and insertion site and remove slowly, in small increments, keeping catheter parallel to skin surface. Do not grasp Luer lock hub to remove catheter, as catheter damage may occur.
5. If resistance is still met, follow institutional protocol for the management of difficult-to-remove catheters.
6. To verify that entire catheter has been removed, measure and compare catheter length with initial length recorded at time of insertion.
7. Apply generous amount of alcohol to loosen edges of catheter stabilization device. While lifting adhesive pad, gently stroke undersurface of pad with alcohol to dissolve adhesive.
8. Following removal of catheter, cover insertion site with occlusive dressing for at least 24 hours.

WARRANTY

Navilyst Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Navilyst Medical's control directly affect the instrument and the results obtained from its use. Navilyst Medical's obligation under this warranty is limited to the repair or replacement of this instrument and Navilyst Medical shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Navilyst Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Navilyst Medical assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.



Triple Lumen

Legal Manufacturer

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

Recyclable Package