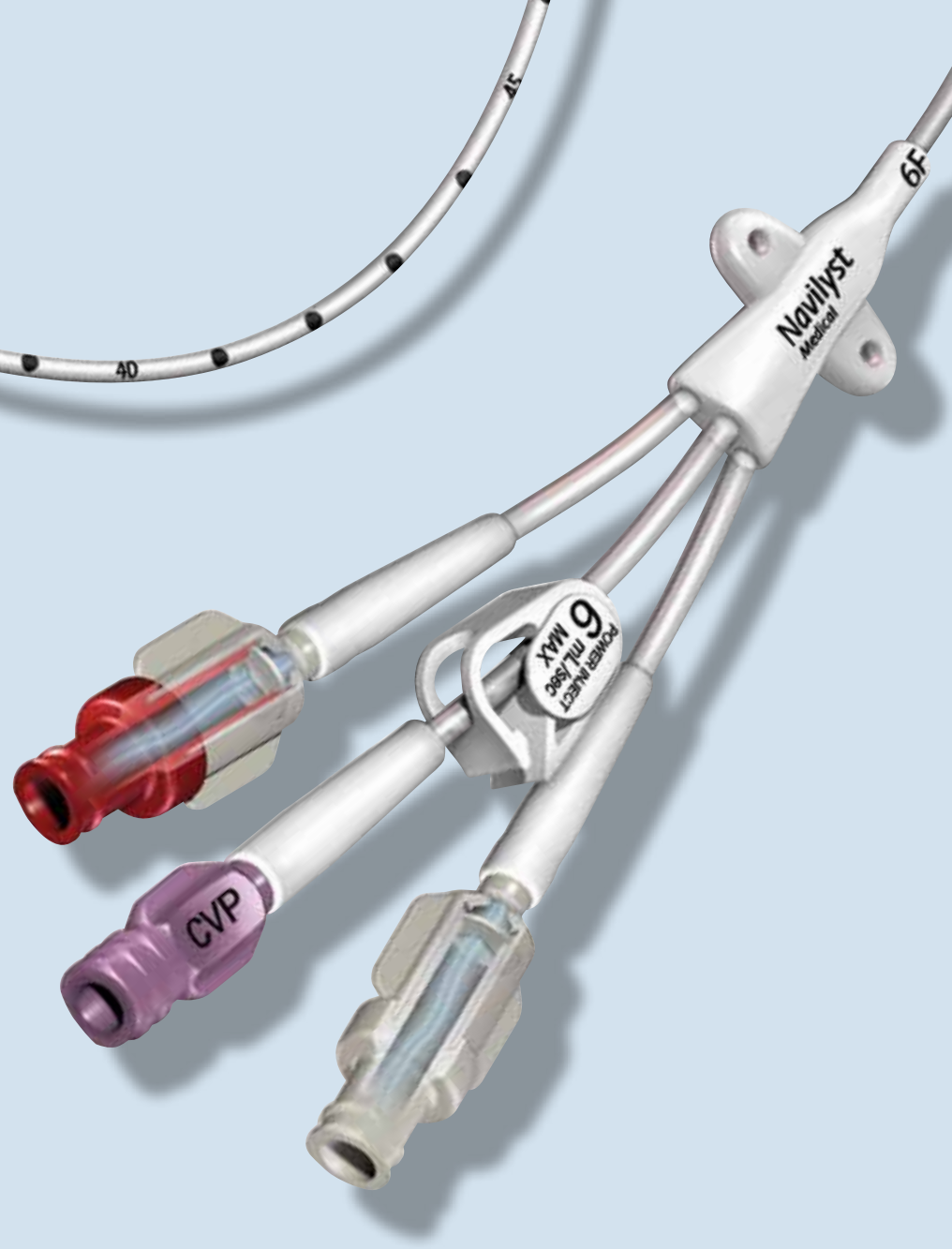
Xcela™ Hybrid PICC
with PASV™ Valve Technology

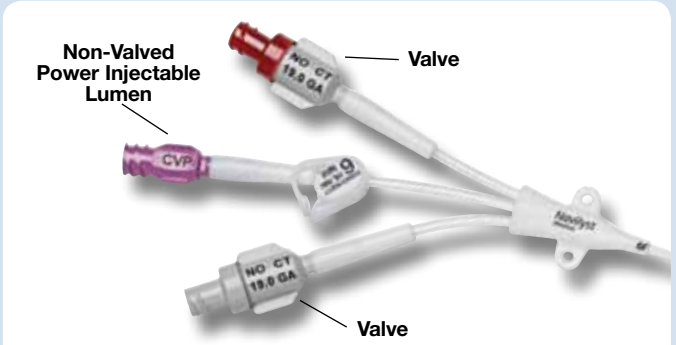


Guidelines for Power Injection

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

1. CONFIRM CATHETER FOR POWER INJECTABILITY

Confirm patient's catheter is an Xcela Hybrid PICC with PASV Valve Technology. The Xcela Hybrid PICC with PASV Valve Technology is identifiable by:



2. PROGRAM POWER INJECTOR

Verify power injector is appropriately programmed and does not exceed catheter maximum flow rate limits.

Warning: The maximum pressure of power injectors used with the Xcela Hybrid PICC with PASV Valve Technology must not exceed 325 psi. Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter. Exceeding maximum flow rate 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. It does not imply that this procedure is appropriate for a particular patient. A trained clinician is responsible for evaluating the status of a patient for a power injection procedure.

Viscosity

	Normal Operating Conditions (6.3 cP*)		Specialized Operating Conditions (11.8 cP**)	
	Length (cm)	Max. Flow Rate (mL/sec)	Length (cm)	Max. Flow Rate (mL/sec)
6FTL	55	6	55	6

Bench testing supports the variation in flow rates between 6.3 and 11.8 cP.
All testing was performed using body temperature medium.
* Maximum flow rate data obtained from 55 cm length catheters. Maximum flow rate on catheter label based on 6.3 cP testing.
** Maximum flow rate on catheter label based upon 11.8 cP testing

3. WARM CONTRAST MEDIA

Warm contrast media to body temperature (37° C).

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

4. INSPECT CATHETER

Inspect catheter for damage. Do not use if damage is found.

5. ASPIRATE BLOOD

Attach syringe, open clamp and aspirate until blood return. Close clamp and remove and discard used syringe.

6. FLUSH LUMEN

Attach syringe filled with 10 mL sterile normal saline, open clamp and vigorously flush lumen. Close clamp, detach syringe and discard.

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, ensure that it will sustain power injection.

7. CONNECT TO POWER INJECTOR

Attach power injector to selected lumen hub per manufacturer's recommendations, and open clamp.

Warning: 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 STUDY AND DISCONNECT POWER INJECTOR

Complete power injection study taking care not to exceed maximum flow rate limit. Disconnect the power injector.

Precaution: It is recommended that institutional protocols be considered for all aspects of catheter use. The Xcela Hybrid PICC with PASV Valve Technology catheter testing included 10 power injection cycles.

9. FLUSH AND FINISH

Flush the Xcela Hybrid PICC with PASV Valve Technology with 20 mL sterile normal saline. Follow with heparin lock per Directions for Use or institutional protocol.

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

XCELA HYBRID PICC WITH PASV VALVE TECHNOLOGY

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: 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 Hybrid 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.

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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