Xcela® Power Injectable PICC

A Patient's Guide

Navilyst Medical

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800.833.9973

NAVPE100 / 5M / 03/11

Persons depicted in this brochure are models and included for illustrative purposes only.

Navilyst Medical

TRAVEL CARD

Support for this product and other Navilyst Medical vascular access products is available by calling the Navilyst Medical Vascular Access Information Line.

800.513.6876

Xcela® Power Injectable PICC

WARNINGS:

- 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 noted on the catheter 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 the 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 300 psi.

Precaution: It is recommended that institutional protocols be considered for all aspects of catheter use. Bench testing has demonstrated that the Xcela Power Injectable PICC is capable of withstanding five power injections which could reasonably occur within a 90-day indwelling period.

Information about your Xcela® Power Injectable PICC is available by calling the Navilyst Medical Vascular Access Information Line 800.513.6876

TRAVEL CARD

Always carry your Xcela® Power Injectable PICC Travel Card with you.

This card has important information about your catheter that healthcare providers will need to care for you.

Fill out your personal information in the areas provided. Your Travel Card is conveniently sized to fit in a wallet.

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26 Forest Street
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Customer Service: 800.833.9973

PATIENT NAME: _____

TELEPHONE: (W) _____ (H) _____

EMERGENCY CONTACT: _____

TELEPHONE: (W) _____ (H) _____

PHYSICIAN NAME: _____

TELEPHONE: _____

INSERTION DATE: _____ 4FSL 5FSL 5FDL 6FDL

TRIMMED LENGTH: _____ LOT NO.: _____

POWER INJECTION:

1. Verify power injector is appropriately programmed and does not exceed catheter flow rate limit.
2. Warm contrast to body temperature (37°C).
3. Inspect catheter for damage.
4. Attach syringe, open clamp and aspirate amount greater than priming volume of catheter, or until blood return. Close clamp, and remove and discard used syringe.
5. Attach syringe filled with 10mL sterile normal saline, open clamp and vigorously flush lumen.
6. Close clamp, and detach syringe and discard.
7. Attach power injector to selected lumen hub per manufacturer's recommendations, and open clamp.
8. Complete power injection study taking care not to exceed maximum flow rate limit, and close clamp.
9. Disconnect the power injector.
10. Vigorously flush catheter with 20mL sterile normal saline and recap.

Xcela® Power Injectable PICC—A Patient's Guide

The Xcela PICC is a special type of PICC that can be used for tests called contrast-enhanced CT scans. You may have even heard these called "CAT" scans. Sometimes, clinicians refer to them as power injection studies. This is a special type of x-ray test that requires a special pump that delivers testing fluid fast and at high pressure. This pamphlet provides some answers to questions that patients and their families may have about the Xcela Power Injectable PICC.

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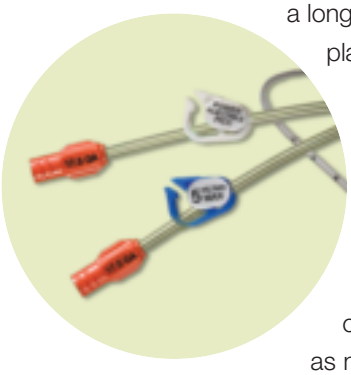
What is a PICC?

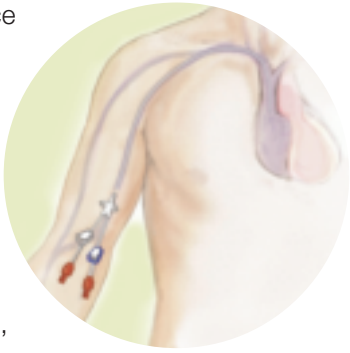
A PICC is a Peripherally Inserted Central Catheter, a long thin tube that is placed into a vein and threaded until the tip is in a very large vein in your chest. The PICC may be used to give medicines and other fluids, such as nutrition and blood products, into the vein. This is called IV or intravenously. Unlike the short IV lines you may have had placed in your hand or arm, a PICC may be in your arm many weeks or months. It may also be possible to take blood samples from your PICC to be used for special tests.



How is the Xcela® PICC placed?

Your Xcela PICC will be placed by a specially trained healthcare provider. This may be done in your room in the hospital, a clinic, the x-ray department or other locations. It is important that you be as comfortable as possible and that you do not move your arm during the PICC placement.

Your arm will be cleaned, and you will be covered with special cloths to keep the area as clean as possible—this is called sterile technique. The person placing your PICC will wear a mask, gown, gloves and hat. This is to protect you and keep the area clean during the procedure.



A numbing medicine may be given at the place where the catheter will enter your arm. This is done through a very small needle and may sting. In some cases, an ultrasound machine, or special x-ray machine, may be used to look at your veins. The PICC is threaded into the vein. After the PICC is in place, a sterile dressing will be put over the insertion site (the place on your arm where the PICC enters the vein). An x-ray will be taken to make sure the PICC tip is in the right position in a vein in your chest.

How do I care for my Xcela® PICC?

Your PICC will need to be cared for and kept clean. Care will include changing the dressing any time it becomes loose, soiled or wet and at least one time every week. This may be done by a healthcare provider, or at the suggestion of the healthcare provider, by you, a family member or friend that has been taught how the dressing is changed.

A sterile end cap will be placed on the end of the catheter that is called the hub. This keeps the catheter closed when not being used. Certain end caps allow access to the catheter without removing it from the hub. Some PICCs have one opening (lumen) and others may have two lumens. Notify your healthcare provider if your end cap(s) becomes loose, comes off or is leaking. The end caps should be changed at least one time per week, or as often as your healthcare provider suggests.

Before any medicine or fluid is given, or blood is drawn, the end cap and/or hub must be cleaned with a special cleaning solution. This is done to prevent germs from getting into your catheter. Your healthcare provider will teach you how to clean the end cap.

Should I limit my activities while I have the Xcela® PICC?

Generally, bending your arm, reaching and doing everyday activities will not harm your PICC. You should not lift heavy objects, or carry objects held in the bend of your arm that may put strain on the PICC or the dressing.

If your healthcare provider approves, you may take a shower or bath with the PICC in place as long as you cover the PICC and dressing with plastic wrap, a plastic bag or material that will keep it from getting wet. You should NOT do other activities, like swimming, that may get the catheter or dressing wet. A wet dressing or catheter may put you at risk for infection.

Notify your healthcare provider or seek medical attention if you have:

- Redness, soreness or swelling at the PICC insertion site or on your arm
- Fever, chills or vomiting
- Any problems with your catheter while caring for it
- Difficulty giving medications, or being able to draw blood
- A catheter that becomes damaged in any way, leaks, is torn or broken

It is important that your healthcare provider is aware of the following information regarding contrast-enhanced CTs:

- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Exceeding the maximum allowable flow rate indicated on the catheter may result in catheter failure and/or catheter tip displacement.
- Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of an occluded catheter.
- The maximum pressure of power injectors used with the Xcela® Power Injectable PICC must not exceed 300 psi.
- 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.
- It is recommended that institutional protocols be considered for all aspects of catheter use. Bench testing has demonstrated that the Xcela Power Injectable PICC is capable of withstanding five power injections which could reasonably occur within a 90-day indwelling period.

Recommended Flushing Protocols

(to be completed by your healthcare provider)

Solution _____

Volume/Lumen _____

Schedule _____

Additional Instructions

_____

_____

_____

_____

_____

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_____

_____

_____

_____

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XCELA® POWER INJECTABLE PICC

INDICATIONS: The Xcela® Power Injectable PICC 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; 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; anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures.

WARNINGS: Do not use the catheter with chemicals that are incompatible with any of its accessories, as catheter damage may occur; 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 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 300 psi.

ADVERSE EVENTS: Potential complications include, but are not limited to catheter dislodgement, embolism, fragmentation, migration, or rupture; air embolism; drug or contrast medium extravasation, or precipitate; intolerance reaction to contrast media.

PRECAUTIONS: Acetone and polyethylene glycol-containing ointments should not be used with polyurethane catheters, as these may cause failure of the device; if resistance is met while attempting to flush catheter, follow institutional protocol for occluded catheters; it is recommended that institutional protocols be considered for all aspects of catheter use. Bench testing has demonstrated that the Xcela Power Injectable PICC is capable of withstanding five power injections, which could reasonably occur during a 90-day catheter indwelling period; refer to Directions for Use for complete instructions.

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