



Instructions For Use

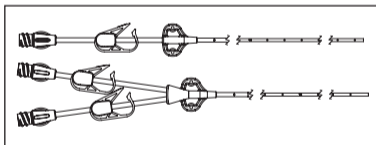
PEGASUS™ CT PICC PERIPHERALLY INSERTED CENTRAL VEIN ACCESS CATHETER

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INSTRUCTIONS FOR USE

DESCRIPTION:

A family of peripherally inserted central catheters made from specially formulated biocompatible medical grade materials. Catheters are packaged in a tray with accessories necessary for a percutaneous microintroducer introduction (Modified Seldinger or Seldinger technique).



INDICATIONS FOR USE:

The Pegasus™ CT PICC catheter is indicated for short term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion, or therapies, use a 4F or larger catheter. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

IMPORTANT INFORMATION PERTAINING TO POWER INJECTION:

- Contrast media should be warmed to body temperature prior to power injection.
- Warning:** Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
- Vigorously flush the PEGASUS CT PICC catheter using a 10mL or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies. This will ensure the patency of the catheter and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion.
- Do not** proceed with power injection study until occlusion has been cleared.
- Warning:** failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.

- Do not** exceed the maximum flow rate printed on the catheter.
- Warning:** Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Warning:** Exceeding the maximum indicated flow rate may result in catheter failure and/or catheter tip displacement.

Warning: PEGASUS™ CT PICC catheter indication of power injection of contrast media implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

CONTRAINDICATIONS:

- The presence of device related infection, bacteremia, or septicemia is known or suspected.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- There has been past irradiation of prospective insertion site.
- There have been previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- There are local tissue factors that may prevent proper device stabilization and/or access.

POSSIBLE COMPLICATIONS:

air embolism	endocarditis	myocardial erosion
bleeding	exit site infection	perforation of vessels viscus phlebitis
brachial plexus injury	exit site necrosis	spontaneous catheter tip malposition or retraction
cardiac arrhythmia	extravasation	thromboembolism
cardiac tamponade	fibrin sheath formation	venous thrombosis
catheter erosion through the skin	hematoma	ventricular thrombosis
catheter embolism	intolerance reaction to implanted device	vessel erosion
catheter occlusion	laceration of vessels or viscus	risks normally associated with local or general anesthesia, surgery, and post-surgery.
catheter related sepsis		

- Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.



www.r4vasular.com
866-943-8090
Maple Grove, MN 55369
Suite 150
7550 Meridian Circle North
r4 Vasular, Inc

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Because of continuing product improvement, prices, specifications, and model availability

TO THE EXTENT PERMITTED UNDER APPLICABLE LAW, THE PRODUCT IS SOLD TO YOU "AS IS" AND THIS LIMITED PRODUCT WARRANTY IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF NON-INFRINGEMENT.

r4 Vasular, Inc. warrants to the purchaser of this product that the product will be free from defects in materials and workmanship for a period of one year from the date of purchase. r4 Vasular's liability under any legal or equitable theory will be exclusively limited to repair or replacement of the defective product, or if in r4 Vasular's opinion repair and replacement would be inadequate, a refund of the purchase price. This limited warranty does not cover (i) wear and tear from use in accordance with the then current specifications, (ii) defects resulting from improper storage or handling, (iii) any use of this product not in accordance with the then current specifications, (iv) attempted re-sterilization or re-use of the catheter, and (v) a catheter that has been altered, modified or repaired by anyone other than r4 Vasular.

WARRANTY



WARNINGS:

- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or sheath/dilator and guidewire must be removed together.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- This catheter is for Single Use Only.



- Do not re-sterilize the catheter or accessories by any method.
- The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE

STERILE EO

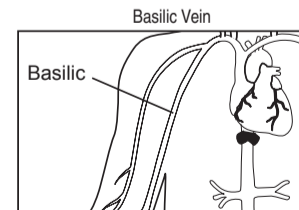
- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:

- Small syringes will generate excessive pressure and may damage the catheter. Ten (10)mL or larger syringes are recommended.
- Do not use sharp instruments near the extension lines or catheter lumen.
- Do not use scissors to remove dressing.
- Catheter will be damaged if clamps other than what is provided with this kit are used.
- Clamping of the tubing repeatedly in the same location will weaken tubing. Avoid clamping near the luer(s) and the hub of the catheter.
- Examine catheter lumen and extension(s) before and after each infusion for damage
- To prevent accidents, assure the security of all caps and connections prior to and between uses.
- Use only Luer Lock (threaded) Connectors with this catheter.
- Confirm catheter tip position by x-ray prior to use. Monitor tip placement routinely per institution policy.

INSERTION SITES:

- The basilic, median antecubital, or cephalic vein may be catheterized. The basilic vein above the antecubital fossa is the preferred site.



DIRECTIONS FOR MODIFIED SELDINGER INSERTION

- Read instruction carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
- The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.
- Use standard hospital protocols when applicable.

PRIOR TO PLACEMENT

Identify insertion site and vein, taking into account the following variables:

- Patient diagnosis
- Unusual anatomical variables
- Anticipated dwell time of catheter
- Age and size of patient
- Type and purpose of IV therapy

- Apply tourniquet to arm above anticipated insertion site
- Select vein based on assessment
- Release tourniquet



PREPARE CATHETER AND GUIDEWIRE

1. Preflush catheter, sideport adapter, and positive pressure access port(s)
 - Attach saline filled syringe to luer of sideport adapter and flush adapter and catheter. Clamp sideport extension and remove syringe. If using double lumen catheter, attach positive pressure access port to remaining extension. Attach saline filled syringe to the positive pressure access port and completely flush catheter lumen. Remove syringe from access port prior to clamping extension.

Caution: Never close clamp on catheter stylet; stylet and catheter damage may result.

Caution: The positive pressure access port should not be used with needles, blunt cannula, or other non-luer connectors, or luer connectors with visible defects. If needle access is attempted, the positive pressure access port must be replaced immediately. Do not exceed 100 actuations.

2. Soak the guidewire for a minute or more with sterile normal saline to activate the wire's coating.

Note: If the surface of the wire becomes dry, soak for another minute to rehydrate coating.

INSERTION

3. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves and mask.

4. Apply tourniquet to arm above anticipated insertion site to distend the vein.

5. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement. Release tourniquet.

6. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Draw the flexible end of the marked .018" guidewire back into the advancer so that only the end of the guidewire is visible. Insert the advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

Note: For alternate insertion method, see Directions for Seldinger Insertion Section

7. Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over proximal end of the guidewire into the target vein. Advance the guidewire until it reaches the caval atrial junction. Once the guidewire is in place, measure the depth of the guidewire by reading the markings on the wire. Remove the guidewire leaving the sheath and dilator in the vein.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until the sheath/dilator is fully inserted.

Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

8. Loosen locking collar of the sideport and withdraw stylet back beyond the point where the catheter is to be trimmed by at least ¼ inch (1cm). Cut catheter to length determined by marked guidewire.

Caution: never attempt to cut stylet.

Caution: Always withdraw stylet back beyond the tip off the catheter prior to insertion.

9. Once proper catheter length and stylet position has been achieved, tighten locking collar to keep stylet in place.

10. Remove dilator from sheath.

11. Insert distal tip of catheter into and through the sheath until the catheter tip is correctly positioned in the target vein.

12. Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

13. Make any adjustments to the catheter under fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction.

Caution: Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use the serrated forceps, use only the in-line clamps(s) provided.

14. Remove the stylet by applying gentle pressure with one hand above the insertion site while grasping the stylet with the other hand and slowly pulling back with a constant motion. Remove sideport adapter and replace with a positive pressure access port. Attach saline filled syringe to positive pressure access port, aspirate lumen and then irrigate with saline. Remove syringe prior to clamping extension.

Caution: If difficulty and/or bunching of the catheter lumen are experienced while removing the stylet, additional flushing of the catheter may be helpful. The catheter may need to be repositioned to allow for removal of the stylet.

Caution: Do not attempt to reinsert stylet once it has been withdrawn.

Caution: Never leave stylet in place after catheter insertion; injury may occur. Remove both stylet and sideport adapter after insertion.

15. Attach syringe(s) to extension(s) and open clamp(s). Blood should aspirate easily. If excessive resistance to blood aspiration is experienced, the catheter may need to be repositioned to obtain adequate flow.

16. Once adequate aspiration has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.

Caution: Small syringes will generate excessive pressure and may damage the catheter. Ten (10)mL or larger syringes are recommended.

17. Remove the syringe(s) and close extension clamp(s). Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

18. Confirm and document proper tip placement with fluoroscopy prior to use. The distal tip should be positioned at the level of the caval atrial junction.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

Note: If there is no blood return, verify catheter position before use.

CATHETER SECUREMENT AND WOUND DRESSING:

- The insertion site and external portion of the catheter should always be covered with a protective dressing.

19. Cover the exit site with an occlusive dressing according to the facility policy.

20. Record catheter length, catheter lot number, and tip position on the patient's chart.

DIRECTIONS FOR SELDINGER INSERTION

1. Follow directions for Modified Seldinger Insertion, up to step #6
 2. Remove needle, leaving guidewire in the targeted vein. Advance the guidewire until it reaches the caval atrial junction. Once the guidewire is in place, measure the depth of the guidewire by reading the markings on the wire.
 3. Cut catheter to length determined by marked guidewire.
 4. Insert proximal end of wire into distal tip of catheter lumen. Feed catheter lumen into the vessel following the guidewire. Advance catheter lumen along the guidewire until the distal tip is correctly positioned in the target vein. The distal tip should be positioned at the level of the caval atrial junction.
- Caution:** A skin nick may be required to feed the catheter smoothly into the vessel.
5. Make any adjustments to catheter under fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction.
- Caution:** Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use serrated forceps; use only in-line clamps provided.
6. Remove the wire from the catheter. Remove by applying gentle pressure with one hand above the insertion site while grasping the 130cm wire with the other hand and pulling slowly back with a constant motion.
 7. Follow directions for Modified Seldinger insertion, from step #15 on.

POWER INJECTION PROCEDURE

1. Remove the injection/needleless cap from the PEGASUS™ CT PICC catheter.
 2. Using a 10mL or larger syringe(s), aspirate catheter lumen(s) to assure patency and remove heparin. Discard syringe(s).
 3. Attach a 10mL or larger syringe filled with sterile normal saline and vigorously flush the catheter with the full 10mL of sterile normal saline.
Warning: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
 4. Detach syringe.
 5. Attach the power injection device to the PEGASUS™ CT PICC catheter per manufacturer's recommendations.
- Warning:** Always use connector tubing between power injector syringe and catheter. Do not attempt to connect power injector syringe directly to the catheter. Damage may result.
6. Complete power injection study taking care not to exceed the flow rate limits.
Warning: Exceeding the maximum indicated flow rate may result in catheter failure and/or catheter tip displacement.
 7. Disconnect the power injection device.
 8. Flush the PEGASUS™ CT PICC catheter with 10mL of sterile normal saline, using a 10mL or larger syringe. If double lumen catheter, flush both lumens.
 9. Replace the injection/needleless cap on the PEGASUS™ CT PICC catheter.

INFUSION

- Before infusion begins all connections should be examined carefully.
- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.
- If leak is found, the catheter should be clamped immediately and replaced.
- Necessary remedial action must be taken prior to the continuation of the treatment.

Note: Excessive blood loss may lead to patient shock.

CATHETER MAINTENANCE

- **Dressing Changes** – A dressing should cover the insertion site at all times. The dressing should be changed per institutional policy or any time the dressing becomes soiled, wet, or non-occlusive.

Note: During all dressing changes the external length of the catheter should be measured to determine if catheter migration has occurred. Periodically confirm catheter placement and tip location by imaging method.

- **Flushing and Heparinization** – Follow institutional policy for flushing frequency and heparin concentration.
- The catheter should be flushed with normal saline prior to drug administration to remove heparin solution.
- After drug administration each lumen should be flushed again with normal saline and then locked with heparin to maintain patency.

Injection Caps – Injection cap(s) or positive pressure access port(s) should be changed per institutional policy. If using the supplied positive access port(s), do not exceed 100 actuations.

CATHETER PERFORMANCE

- **Occluded/Partially Occluded Catheter**–If resistance is encountered to aspirating or flushing, the lumen may be partially or completely occluded.

Warning: Do not flush against resistance.

If the lumen will neither aspirate nor flush, and it has been determined that the catheter is occluded with blood, follow institutional de clotting procedure.

Infection

Caution: Due to risk of exposure to HIV or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

- Sterile technique should always be strictly adhered to.
- Clinically recognized infection should be treated promptly per institutional policy.

CATHETER REMOVAL

Warning: Only a clinician familiar with the appropriate techniques should attempt the following procedures.

Caution: Always review facility protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Wash hands, gather equipment
2. Remove old dressing and inspect insertion site for redness, tenderness, and drainage.
3. Grasp catheter near insertion site and using a slow steady motion, remove catheter from vein.
4. If resistance is felt – STOP. Retape the catheter and apply a warm compress to the extremity for 20-30 minutes.
5. Resume removal procedure. If further difficulty is encountered, follow institutional policy for further intervention.
6. Apply pressure, if necessary, until bleeding stops and dress site following institutional policy.

Note: Inspect catheter and measure length. It must be equal to the baseline measurement taken when the catheter was inserted.