TidalPort™

An Implanted Drug Delivery Depot

USER'S MANUAL

INSTRUCTIONS FOR USE

INTRODUCTION

The TidalPort™ is a subcutaneously implanted medical device designed for use when repeated access to the vascular system is the therapy of choice. This device provides the user with an easily located needle insertion point for use whenever introducing fluids or medications into the vascular system or for acquiring periodic blood samples.

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

Norfolk Medical™

7350 N. Ridgeway, Skokie , IL 60076 USA

tel. 847-674-7075 • fax. 847-674-7066 • info@norfolkmedical.com

Norfolk Medical Products - TidalPort™
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INTRODUCTION

Description

Norfolk Medical Products, Inc. manufactures a complete line of implantable access ports. Ports are totally implantable devices designed to provide repeated access to the vascular system or a selected body site. The port is intended to facilitate frequent blood sampling or the delivery of medications, nutritions, blood products, and imaging solutions. They are also indicated for the withdrawal of blood samples. Port access is performed by percutaneous needle insertion using a non-coring Huber point needle.

The system consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque silicone or polyurethane catheter. All materials are biocompatible and can be used with virtually all injectable solutions.

Indications for use

The TidalPort™ port line is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for the delivery of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. These subcutaneous devices reduce the trauma associated with multiple punctures or the inconvenience of an externalized catheter.

Contraindications, Warnings, Cautions, and Precautions

Contraindications

The device is contraindicated whenever:

- 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 suspected to be allergic to materials contained in the device.
- Severe chronic obstructive lung disease exists.
- Past irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- Local tissue factors that will prevent proper device stabilization and/or access.

Warnings

- Intended for **single patient use**. **DO NOT REUSE.**
- Norfolk Medical Products, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in

accordance with accepted medical practice and applicable local, state and federal laws and regulations.

- Hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
- Avoid vessel perforation.
- **Pinch-off Prevention:** Catheters placed percutaneously or through a cut-down, into the subclavian vein, should be inserted at the junction of the outer and middle thirds of the clavicle, lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially because such placement can lead to compression of the catheter between the first rib and the clavicle. This can cause damage and even severance of the catheter. A radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and the clavicle.

Note: The TidalPort™ has been tested with 19, 20 and 22 Gauge Huber point needles from Angiodynamics, Smiths Medical, Braun, and Bard Access Systems. Huber point needles from other manufacturers may be suitable but have not been tested. Please refer to the following FDA link for more information regarding non-coring needles:

https://www.fda.gov/Safety/MedWatch/SafetyInformation/

Signs of Pinch-off

Clinical:

- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal.

Radiologic:

Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently.

References:

Aitken DR. et. al. ***"The Pinch-Off Sign: A warning of impending problems with permanent subclavian catheters. "*** Am Surg, 1984: 148:633-6.

Lin CH. et. al. ***"The mechanisms of failure of totally implantable central venous access systems: analysis of 73 cases with fracture of catheter. "*** Eur J Surg Oncol, 2010: 36(5):509-510.

Cautions

- Carefully read and follow all instructions prior to use.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

- Only qualified health care practitioners should insert, manipulate and remove these devices.
- If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.
- Ensure the Blue Boot catheter connector is firmly in place and the catheter shows no signs of kinking.

Precautions

- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions, and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid catheter damage and/or patient injury.

I. Prior to Placement

- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied sterile and is non-pyrogenic. Do not use if package is damaged, opened, or the expiration date has passed. Do not resterilize.
- Inspect kit for presence of all components.
- Prime the device with sterile heparinized saline or normal saline solution to help avoid air embolism.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.

II. During Placement

- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Do not perforate, tear, or fracture the catheter when using a guidewire.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Do not bend the catheter at sharp angles during implantation. This can compromise catheter patency.
- Do not cut or occlude the catheter when using sutures to secure the catheter.
- When using peel-apart introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.

III. After Placement

- Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.

  DO NOT USE A SYRINGE SMALLER THAN 10mL. Small syringes generate greater pressure than do larger syringes. Infusion pressure greater than 25 psi may damage blood vessels and viscus and are not recommended.
- Use only non-coring needles with the port.
- Choose needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Confirm correct positioning of the needle within the port reservoir by aspiration of blood before infusion of any substance. If there is doubt regarding proper needle placement, perform a radiographic dye procedure to confirm placement.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including the following:

Air embolism, bleeding, cardiac arrhythmia, cardiac tamponade, catheter or port erosion through the skin, catheter embolism, catheter or port occlusion, catheter occlusion, damage or breakage due to compression between the clavicle and first rib (catheter pinch-off), catheter or port related sepsis, device rotation or extrusion, endocarditis, extravasation, fibrin sheath formation, hematoma, hemothorax, hydrothorax, intolerance reaction to implanted device, inflammation, necrosis or scarring of skin over implant area, laceration of vessels or viscus, perforation of vessels or viscus, pneumothorax, spontaneous catheter tip malposition or retraction, thoracic duct injury, thromboembolism, vascular thrombosis, vessel erosion, risks normally associated with local and general anesthesia, surgery and post-operative recovery.

These and other complications are well documented in the medical literature and should be carefully considered before placing the port.

References:

Biffi R. et. al. ***"Best choice of central venous insertion site for the prevention of catheter-related complication in adult patients who need cancer therapy: a randomized trial. "*** Ann Oncol, 2009: 20(5):935-40.

Jordan K. et. al. ***"Venous access ports: frequency and management of complications in oncology patients. "*** Onkologie, 2008: 31(7):404-10.

Vescia S. et. al. ***"Management of venous port systems in oncology: a review of the current evidence."*** Ann Oncol, 2008: 19:9-15.

IMPLANTATION INSTRUCTIONS

Read the "Contraindications, Warnings, Cautions, and Precautions" and "Possible Complications" sections of this manual before beginning the procedure.

Implantation Preparation

The following suggestions for surgical implantation are provided as a guide to facilitate safe and prolonged use of the TidalPort™ systems. Since the reservoir body may be placed in a number of areas of the body and the outlet catheter may be placed in a variety of vessels, or other selected sites, use the surgical procedure and the sterile technique that best suits your application and is appropriate for the patient.

Precautions ***Strict attention to aseptic technique is important when implanting this or any other device.***

- Select implantation procedure to be used (cut-down or percutaneous)
- Select the site for the port placement

NOTE The site chosen should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility, does not create pressure points, and does not interfere with clothing. Consider the amount of cutaneous tissue over the port septum as excessive tissue will make access difficult. Conversely, too thin a layer may lead to port erosion. A tissue thickness of 0.5cm to 2cm is appropriate. Pre-operative mapping of the port pocket and catheter insertion site is recommended whenever possible.

- Complete patient implant record including reorder number and lot number.
- Perform adequate anesthesia.
- Create sterile field and open tray.
- Surgically prep and drape the implantation site.
- Prime the system.
- **For Attachable Catheters:** Flush catheter with heparinized saline and clamp the catheter several centimeters from the port/proximal end that will be trimmed.
- **For Preconnected Catheters:** Using a non-coring needle, flush the port and catheter system with heparinized saline to eliminate air from the system. Estimate catheter length required to reach the junction of the superior vena cava and the right atrium by placing the catheter on the chest along the venous path. Mark and cut the catheter on a 90 degree angle at the desired position. Tunnel the catheter from the pocket to the venous entry site.

Cut-Down Procedure

1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site. Use a cut-down incision to expose the entry vein of choice.
2. Perform vessel incision after vessel is isolated and stabilized to prevent bleeding and air aspiration.
3. Insert tapered end of vein pick through the incision and advance it into the vessel.
4. With the vein pick in position, slide the catheter tip into the grooved underside of the pick and advance the catheter tip into the vessel.
5. Withdraw the vein pick.
6. Advance the catheter into the vessel to the desired infusion site.

NOTE Catheters should be positioned with the catheter tip at the junction of the superior vena cava and right atrium. Verify correct catheter tip position, using fluoroscopy, or appropriate technology. Do not occlude or cut the catheter when using sutures to secure the catheter.

Percutaneous Procedure - Subclavian Vein Approach

1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site.
2. Locate desired vessel using a small gauge needle attached to a syringe.

NOTE The subclavian vein is entered percutaneously at the point that identifies the junction of the outer and middle thirds of the clavicle.

Refer to the "Warnings" section covering catheter Pinch-off.

3. Attach introducer needle to the syringe and insert into vessel alongside the small gauge needle. Remove small gauge needle.
4. Aspirate gently as the insertion is made. If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
5. When the subclavian vein has been entered, remove the syringe leaving the needle in place. Place a finger over the hub of the needle to minimize blood loss and the risk of air aspiration.

   The risk of aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
6. Straighten the "J" tip of the guidewire with the tip straightener and insert tapered end of the tip straightener into the needle.
7. Remove the tip straightener and advance the guidewire into the superior vena cava. Advance the guidewire as far as appropriate for the procedure.

Verify correct positioning, using fluoroscopy, or appropriate technology.

8. Gently withdraw and remove needle.

Caution If the guidewire must be withdrawn while the needle is inserted, remove both the guidewire and needle as a unit to help prevent the needle from damaging or shearing the guidewire.

9. Make a small incision (approx. 1cm wide) parallel to the clavicle with the guidewire at the center of the incision to permit introduction of the vessel dilator and sheath introducer.

Peel-Apart Sheath Introducer Instructions

1. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance it into the vein as a unit, leaving at least 2cm of sheath exposed.

   WARNING: Avoid vessel perforation.

2. Release the locking mechanism and gently withdraw the vessel dilator and "J" tip guidewire, leaving the sheath in place.
   WARNING: Hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
3. Insert catheter into sheath. Advance the catheter through the sheath into the vessel to the desired infusion site. Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium.
4. Verify correct catheter tip placement using fluoroscopy, or appropriate technology.
5. Grasp the two handles of the peel-apart sheath and pull outward and upward at the same time.
6. Peel the sheath away form the catheter completely. Make sure the catheter is not dislodged from the vessel.

Catheter Tunneling Procedure

1. Create a subcutaneous pocket using blunt dissection. Note: Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision.

Attachable Catheters

Create a subcutaneous tunnel from the venous site to the port pocket site using a tunneler or long forceps per the following:

a. Make a small incision at the venous entry site.

b. Insert tip of tunneler into the small incision.

c. Form tunnel by advancing tip of tunneler from the venous entry site to the port pocket site. Caution: Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.

d. Remove Blue Boot connector from the catheter.

e. Attach end of catheter onto the tunneler barb with a twisting motion.

NOTE Barb threads must be completely covered by the catheter to adequately secure the catheter as it is pulled through the tunnel.

5F=1 barb, 7F=2 barbs, 9F=3 barbs

f. Pull the tunneler through to the port pocket site while gently holding the catheter. Remove the catheter from the tunneler.

g. Replace the Blue Boot connector with the wide edge at the port side and the narrow end facing the catheter.

h. Cut the catheter to the proper length at a 90 degree angle, allowing sufficient slack for body movement and port connection.

Preattached Catheters

Create a subcutaneous tunnel from the venous site to the port pocket site per the following:

a. Advance the tip of the tunneler from the port pocket site to the venous entry site.

b. Form tunnel by advancing the tip of the tunneler from the port pocket site to the venous entry site.

Caution Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.

c. Thread the catheter tip on to the end of the tunneler.

d. Pull the tunneler through to the venous entry site while gently holding the catheter. **Do not force the catheter.**

e. Cut off the end of the catheter attached to the tunneler.

f. Estimate the catheter length required for the tip placement at the junction of the superior vena cava and right atrium by placing the catheter on the chest along the venous path to the right atrium. Cut catheter to length at a 90 degree angle.

Connect Catheter to Port

1. Flush all air from the port body using a 10mL syringe with a non-coring needle filled with heparinized saline (100 USP U/mL). Insert the needle through the septum and inject the fluid while pointing the stem/catheter connection upwards.

2. Cleanse all system components with irrigation solution.
3. Connect catheter to port by sliding the catheter over all the barbs on the outlet stem.
4. Advance the Blue Boot over the connection to ensure a secure connection and tight seal.

Position Port and Close Incision Site

Place the port in the subcutaneous pocket to the side of the incision line and secure to the underlying fascia using non-absorbable, monofilament sutures. This will reduce port migration and the possibility of the port flipping over. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.

1. After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.
2. Conduct flow studies on the catheter using a non-coring needle and a 10mL syringe to confirm that flow is not obstructed, that no leaks exist, and that the catheter is correctly positioned.
3. Aspirate to confirm the ability to withdraw blood.
4. Flush and heparin lock the port system as described under heparin lock procedure.
5. Close the incision site, so that the port septum does not lie beneath the incision.
6. Apply dressing according to hospital practice.

USE AND MAINTENANCE INSTRUCTIONS

Site Preparation

EQUIPMENT

- Alcohol wipe
- Antiseptic swabs (3)
- Sterile gloves

PROCEDURE

1. Explain procedure to patient. Warn of needle prick sensation. (Sensation of needle insertion decreases over time. Use of a topical anesthetic may be appropriate.)
2. Wash hands thoroughly.
3. Put on sterile gloves.

4. Paint area with alcohol wipe starting at the port and working outward in a spiral motion over an area 10-13cm in diameter.
5. Repeat step 4 with antiseptic swabs three times.

NOTE Follow established hospital or institutional policy for changing I.V. tubing and accessing cannula.

Accessing the Implanted Port

EQUIPMENT

- Non-coring needle - Huber Point/Deflected Point Needle
- Syringe, 10mL or larger - **DO NOT** use a syringe smaller than 10mL

PROCEDURE

1. Explain procedure to patient and perform aseptic site preparation.
2. Locate port septum by palpation.
3. Locate base of port with non-dominant hand.
   a. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.
   b. Insert needle perpendicular to port septum. Advance needle through the skin and septum until reaching the base of the reservoir.
4. Verify correct needle placement by blood aspiration.
5. Always flush the port following injection.
6. Perform heparin lock procedure (see page 12).

Bolus Injection Procedure

EQUIPMENT

- Non-coring needle
- 10mL syringe filled with sterile normal saline
- Extension set with clamp

PROCEDURE

Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Attach a non-coring needle to the extension set and 10mL syringe filled with sterile normal saline. Expel all air and clamp extension.
3. Aseptically locate and access port.
4. Flush port with 10mL sterile normal saline. Clamp the extension set and remove the syringe.

5. Connect syringe containing the drug to the extension set. Release clamp and begin to administer injection.
6. Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
7. When injection is completed, clamp the extension set.
8. Flush after each injection with 10mL of sterile normal saline to help prevent interaction between incompatible drugs.
9. Perform heparin lock procedure (see page 12).

NOTE The needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.

Continuous Infusion Procedure

EQUIPMENT

- Prescribed I.V. solution
- Extension set with clamp
- 10mL syringe filled with sterile normal saline
- Non-coring needle
- I.V. pole
- I.V. pump (if ordered)
- Transparent dressing
- Antibacterial ointment
- Gauze pads

PROCEDURE

Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Attach non-coring needle to extension set and 10mL syringe filled with sterile normal saline. Expel all air and clamp the extension set.
3. Aseptically locate and access port.
4. Apply antibacterial ointment on the injection site and place a rolled gauze pad under needle hub. Secure needle with transparent dressing to help prevent inadvertent dislodgement.
5. Open clamp and flush port with sterile normal saline. Clamp extension set and remove clamp.
6. Connect fluid delivery system (I.V. set or pump as indicated).
7. Release clamp and initiate infusion. Examine the infusion site for signs of extravasation; if noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.

8. When infusion is complete, clamp extension set and remove the delivery system.
9. Flush after each infusion with 10mL sterile normal saline to help prevent interaction between incompatible drugs.
10. Perform heparin lock procedure.

Blood Sampling Procedure

EQUIPMENT

- Extension set with clamp
- Non-coring needle
- 10mL syringe filled with sterile normal saline
- 20mL syringe (2)
- Sterile normal saline

PROCEDURE

Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access port.
3. Flush port with sterile normal saline in 10mL syringe.
4. Withdraw at least 5mL of blood and discard syringe.
5. Aspirate desired blood volume into 20mL syringe.
6. Once sample is obtained, perform saline lock procedure by immediately flushing the system with 20mL sterile normal saline.
7. Transfer sample to appropriate blood sample tubes.
8. Perform heparin lock procedure (see below).

Heparin Lock Procedure

To help prevent clot formation and catheter blockage, implanted ports with open ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.

For recommended flushing volumes and procedures refer to Nursing Guidelines Manual

Deaccessing Implanted Ports

NOTE Always remove non-coring needle slowly, while injecting the last 0.5mL of solution, to reduce potential for blood back flow into the catheter tip and possible catheter clotting. Stabilize the port with two fingers during needle withdrawal.

USE OF FIBRINOLYTIC AGENTS FOR CATHETER BLOCKAGE

Use of fibrinolytic agents have successfully cleared clotted catheters when gentle irrigation and aspiration have failed. The procedure may be employed by the order of a physician.

For procedures on the use of fibrinolytic agents refer to Nursing Guidelines Manual & consult the drug manufacturers instructions

IMPORTANT INFORMATION REGARDING TIDALPORT™ POWER INJECTABLE PORTS

- Read all instructions prior to utilization of device.
- Use a Power Infusion Set for power injections of contrast media.
- Contrast dye should be warmed to body temperature prior to utilization for power injection. Failure to have contrast at body temperature may lead to device failure.
- Maximum pressure settings for power injection have been established for the TidalPort™. Failure to follow guidelines can result in over pressurization of the port device. The power injection machine may not prevent over pressurization in the presence of an occlusion or resistance.
- Do not exceed 300 psi. Exceeding pressures of 300 psi could lead to device rupture, catheter rupture, and/or malfunction.
- Failure to assess the patency of the TidalPort™ prior to power injection may lead to device failure or rupture.

Absence of a blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to device use. A blood return should be present prior to use of the device for any therapy or testing.

- If the patient complains of pain, or if there is swelling when the device is flushed or when medication or contrast media is administered, evaluate the device for infiltration, proper needle placement, and potential complications such as occlusion, kinking, breakage, Pinch-Off Syndrome, thrombosis or malposition. Failure to assess these complaints or observations can lead to device failure.
- Power injection machine pressure limiting settings (safety cut-off) may not prevent over pressurization of an occluded device.
- 10mL syringes or larger are recommended for all flushing or injection procedures. Use of smaller syringes may result in system damage.

- The catheter tip should be evaluated for proper location prior to power injection.
- Power injection using the TidalPort™ should be performed by trained clinicians who are knowledgeable about the utilization of the TidalPort™ implanted device.
- The device has no components made of latex rubber.

PROCEDURE FOR POWER INJECTION

1. Ensure the patient has a TidalPort™ implanted port. A commercially available Infusion Set, labelled to perform power injection must be used. The patient should have a TidalPort™ Identification Card.

NOTE **The completed patient identification card should be given to the patient, who should be instructed to carry it at all times.**

2. The TidalPort™ Implanted Ports should be accessed with a 19, 20 or 22 gauge commercially available and labeled Power Infusion Set for injection of contrast media. The tubing on the needle should be clamped prior to accessing the port.
3. Remove the injection cap attached to the end of the Power Injectable Infusion Set.
4. Attach a 10mL or larger syringe to the luer hub end of the Power Injectable Infusion Set tubing, release the clamp and aspirate to confirm blood return.

NOTE **Absence of a blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to catheter usage. A blood return should be present prior to usage of device.**

5. Flush the TidalPort™ Implantable Port with 10-20mL of 0.9% normal saline. The device should flush without resistance.

Warning: **Not assessing patency may result in device failure.**

6. Close the clamp on the Power Injectable Infusion Set tubing.
7. Remove the syringe from the Power Injectable Infusion Set.
8. Attach the power injection tubing per manufacturer's recommendations to the luer hub end of the Power Injectable Infusion Set. Release the clamp.
9. **Set the power injection machine per manufacturer's recommendations for a maximum pressure of 300 psi. Flow rate as indicated.**

19 or 20 gauge / 5ml/sec • 22 gauge / 2ml/sec.

10. Perform the study. Do not exceed 300 psi during injection of contrast dye. Refer to the Procedure for Power Injection section in this booklet for

additional information and instructions.

11. Close the clamp. Disengage the power injection tubing from the luer hub of the Power Injectable Infusion Set.
12. Place a new injection cap on the Power injectable Infusion Set luer hub.
13. Flush the TidalPort™ Implantable Port with 10-20mL 0.9% normal saline.
14. Flush the TidalPort™ Implantable Port with 3-5mL of 10-100 units/mL heparinized saline. Actual amount and strength depends on facility policy.

Warnings

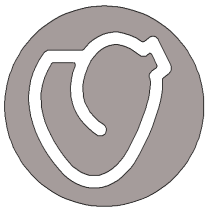
- Do not use smaller than a 10mL syringe. These syringes are recommended for all flushing or injection procedures. Use of smaller syringes may result in system damage.
- Contrast dye should be warmed to body temperature prior to utilization for power injection. Failure to have contrast at body temperature may lead to device failure.
- Do not exceed the maximum pressure settings that have been established for the TidalPort™ power injectable ports. Failure can result in over pressurization of the port device. Power injection machine may not prevent over pressurization in the presence of occlusion or resistance. Refer to the Procedure for Power injection section in this booklet for additional information and instructions.
- **Do not exceed 300 psi. Exceeding pressures of 300 psi could lead to device rupture or catheter malposition.**
- **Failure to assess the patency of the TidalPort™ Implanted Port prior to power injection may lead to device rupture or failure.**
- Absence of a blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to device usage. A blood return should be present prior to usage of device for any therapy or testing.
- Do not attempt to measure the patient's blood pressure on the arm in which a peripheral system is located, since catheter occlusion or other damage to the catheter could occur.
- If the patient complains of pain, or there is swelling when the device is flushed or when mediation or contrast media is administered, evaluate the device for infiltration, proper needle placment, and potential complications such as occlusion, kinking, breakage, Pinch-Off Syndrome, thrombosis or malposition. Failure to assess these complaints or observations can lead to device failure.
- Power injection machine pressure limiting (safety cut-off) settings may not prevent over pressurization of an occluded device.

- Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.
- Reprocessing may compromise the integrity of the device and/or lead to device failure.

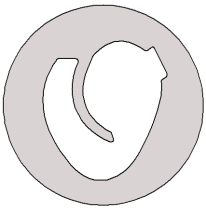
How to Identify the TidalPort™ Implantable Port

- Refer to the patients chart for implant information.
- Each TidalPort™ is packaged with a Patient Identification Card.
- All TidalPort™ implantable ports are identifiable by the Norfolk Medical logo as seen on the base in an X-Ray.

X-Ray View of Undersurface of the TidalPort™



This view of the heart logo will be seen on an X-Ray of the Titanium TidalPort™



This view of the heart logo will be seen on an X-Ray of the Polysulfone TidalPort™

- All Norfolk Medical TidalPort™ Devices are power injectable up to 5mL/sec and a maximum pressure setting of 300 PSI. If you need additional information, please contact Norfolk Medical Products Customer Service at 847-674-7075.

Notes:

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Important Information

Patient Name:

Surgeon:

Hospital:

Surgery Date:

Oncologist:

Norfolk Medical™

7350 N. Ridgeway, Skokie, IL 60076 USA

tel. 847-674-7075 • fax. 847-674-7066 • info@norfolkmedical.com

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