TidalPort™

An Implanted Drug Delivery Depot

IMPLANTED PORT SYSTEM
NURSING GUIDELINES

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.

The information in this booklet is provided as a reference by the Norfolk Medical education department.

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 vascular access drug delivery systems are implantable devices indicated for patient therapies requiring repeated access to the vascular system.

The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. Specific nursing protocols for the ports will vary with individual patient needs and the setting in which the device is used. We hope you find these guidelines useful in developing the nursing procedures that are appropriate for your institution.

Since the port is totally implanted, it avoids many of the problems associated with external vascular access devices. The skin's natural barrier reduces the risk of infection. Routine daily heparinization and costly dressing changes are not necessary, and because there are no external components, damage to the catheter is unlikely. In addition, the body image is not threatened by the presence of an external catheter. There is no restriction of activity and no constant reminder of the illness.

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 medical literature.

The Implanted Port

The port is inserted during a short surgical procedure. The procedure is relatively simple and the surgeon may elect to place the port in an ambulatory setting.

Pre-operative patient teaching should include a brief description of the device, how it works, an explanation of the procedure for placement, and a discussion of the patient's responsibility in the maintenance of the port. Many patients appreciate the opportunity to see a sample of the port if one is available.

The most common site for the port catheter tip is the superior vena cava via either the subclavian, internal jugular, or cephalic vein. The reservoir is normally placed over a bony prominance, such as a rib, to provide support, and it is secured to the deep fascia. The catheter is placed by venipuncture in the chosen vessel and a pocket is made under the skin for the reservoir/port body.

Once patency is established, the port is secured to the fascia using non-absorbable sutures. The incisions are then closed.

The skin incisions generally require post-operative care for 7-10 days. While some physicians prefer to wait until post-operative edema and discomfort subside before accessing the port, it can be accessed immediately. Ideally, the "Huber" point needle should be inserted in the operating room or no sooner than 48 hours post-operatively. During this period, the site should be monitored for fluid collection or the formation of a hematoma.

USE AND MAINTENANCE INSTRUCTIONS

Inspect and aseptically prepare the injection site prior to accessing the port.

Site Preparation

EQUIPMENT

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

PROCEDURE

1. Explain the procedure to patient. Warn of the 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. Cleanse or scrub the injection site according to the directions from the manufacturer of the cleansing agent. We suggest starting at the port site 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
- Syringe, 10mL or larger
- Extension set with clamp

PROCEDURE

1. 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.

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. Lock the port with 3-5mL of a sterile heparin-saline solution (suggested concentration 100u/mL) after every use and at least once every four weeks.

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

10. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing while still infusing the line. This helps reduce the potential for blood backflow into the catheter tip which could encourage catheter clotting.

Continuous Infusion Procedure

CAUTION: DO NOT USE A SYRINGE SIZE SMALLER THAN 10mL. Prolonged 25 psi infusion pressure may cause damage to vessels and viscus and is therefore not recommended.

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
- 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. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is any doubt regarding the proper needle placement, have a radiograph dye procedure done to confirm placement.
4. Secure needle with transparent dressing to help prevent inadvertent dislodgement.

NOTE For continuous access, change the non-coring needle and transparent dressing every week.

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).

NOTE Always use a luer lock connection on all tubings and connections. Never use a slip tip connection. Pumps must incorporate a functional automatic pressure limiting switch which will shut off the pump before the pressure exceeds 25 psi.

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. Lock the port with 3-5mL of a sterile heparin-saline solution (suggested concentration 100u/mL) after every use and at least once every four weeks.

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

11. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing while still infusing the line. This helps reduce the potential for blood backflow into the catheter tip which could encourage catheter clotting.

Blood Sampling Procedure

EQUIPMENT

- Extension set with clamp
- Non-coring needle
- Syringe filled with sterile normal saline
- Syringe (2) or evacuated blood collection vials
- 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. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.

3. Flush port with sterile normal saline.

4. Withdraw at least 5mL of blood and discard syringe.

5. Aspirate desired blood volume into second syringe or evacuataed blood collection system.

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. Perform heparin lock procedure by flushing the port with 3-5mL heparinized saline after every use and at least once every four weeks.

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

9. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing while still infusing the line. This helps reduce the potential for blood back-flow into the catheter tip which could encourage catheter clotting.

Heparin Lock Procedure

To help prevent clot formation and catheter blockage, implanted ports with catheters should be flushed with 10mL sterile, normal saline using a turbulant push-pause flushing technique after each use followed by 5mL of sterile heparinized saline, the lock. Clamp the tubing while infusing the last 0.5mL of heparinized saline to reduce the potential for blood back-flow into the catheter tip, which could encourage catheter occlusion. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.

Recommended flushing volumes:

PROCEDURE	VOLUME
Port not in use	5cc heparinized saline
After each drug or TPN infusion	10cc sterile normal saline, then 5cc heparinized saline
After blood withdrawal	20cc sterile normal saline, then 5cc heparinized saline

EQUIPMENT

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

NOTE Other concentrations of heparinized saline (10-1000u/mL) have been found to be effective. Determination of the proper concentration and volume should be based on patient's medical condition, laboratory tests, and prior experience. The volumes in this manual serve only as a guide.

NOTE Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade polyurethane catheters exposed to repeated and prolonged exposure.

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 10mL syringe filled with sterile heparinized saline to non-coring needle.
3. Aseptically locate and access the port.
4. Flush and lock the system.

Deaccessing Implanted Ports

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

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 or catheter rupture 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 port.
- The device have no components made of natural latex rubber.

Procedure for Power Injection

1. Ensure the patient has a TidalPort™ implanted port. A commercially available Infusion Set, labeled 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 labelled 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.

TROUBLESHOOTING GUIDE

Aspiration Difficulties

POSSIBLE CAUSES

1. Failure to flush adequately, resulting in lumen obstruction.
2. Catheter tip sucking up to vein wall with aspiration.
3. Blood clot, fibrin sheath or particulate matter obstructing lumen during aspiration.
4. A clot or other obstruction in the catheter lumen can cause a one-way valve effect. During infusion, the catheter wall expands slightly allowing fluid to flow around the obstruction. During aspiration, the catheter wall contracts slightly, tightening around the obstruction and preventing aspiration.
5. Fibrin sheaths usually begin to form within a few days after catheter insertion. They may grow and extend beyond the catheter tip and/or be pulled into and obstruct the catheter during aspiration while resisting infusion.
6. Compression or transection of the catheter between the clavicle and first rib "pinch-off area".
7. Kinked catheter.
8. Malposition or migration of the catheter tip.

POSSIBLE SOLUTIONS

1. If no resistance to infusion is felt, attempt to flush with 10mL normal saline, then pull back gently on syringe plunger 2-3mL and proceed with aspiration.
2. If resistanace to infusion is felt, check for signs of extravasation. If present, notify physician. If not present, proceed to step 4.
3. Attempt to aspirate with a 20mL syringe.
4. Move patient's arm, shoulder, neck, head to see if a change in position will allow aspiration.
5. Obtain physician order for X-Ray to determine catheter position.
6. If the catheter tip is not in the superior vena cava, catheter should be repositioned.
7. If the catheter tip is not in the vein, catheter should be replaced.

8. If the catheter has been placed through the "pinch-off" area and is being compressed, the physician should evaluate the patient for catheter replacement.

Catheter Occlusion

POSSIBLE CAUSES

1. Blood clot obstructing the lumen.
2. Kinked catheter.
3. Catheter tip outside the vein.
4. Catheter transection due to "pinch-off".
5. Obstruction due to protein or lipid depositon.

POSSIBLE SOLUTIONS

1. Ask physician to attempt clot removal.
2. Move patient's arm, shoulder, neck, head to see if a change in position will allow aspiration.
3. Obtain physician order for X-Ray to determine catheter position.
4. If the catheter tip is not in the superior vena cava, catheter should be repositioned.
5. If the catheter tip is not in the vein, catheter should be replaced.
6. If the catheter has been placed through the "pinch-off" area and is being compressed, the physician should evaluate the patient for catheter replacement.

USE OF FIBRINOLYTIC AGENTS FOR CATHETER BLOCKAGE

Use of fibrinolytic agents have successfully cleared clotted catheters when gentle irrigation and aspiration have failed. The following procedure may be employed on the order of a physician. Additional instructions provided by the drug manufacturer should be followed.

EQUIPMENT

- Non-coring needle
- 10mL syringe containing port priming volume of a fibrinolytic agent
- 20mL syringe filled with sterile, normal saline

PROCEDURE

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

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access the port with a non-coring needle attached to a 10mL syringe void of air and filled with port priming volume of a fibrinolytic agent.
3. Gently instill fibrinolytic solution. Use a gentle pull-push action on the syringe plunger to maximize solution mixing within port and catheter.

   WARNING: ***Occluded catheters may not accept all of the solution. If strong resistance is felt, do not attempt to force solution into catheter. Leave solution in place for 15 minutes.***
4. Attempt to aspirate solution and the clot(s).
5. If unsuccessful, repeat the procedure.
6. Once blockage has been cleared, flush catheter with at least 20mL sterile, normal saline.
7. Perform heparin lock procedure.

DECISION TREE

Management of an Occluded Catheter

MANAGEMENT OF OCCLUDED CENTRAL VENOUS ACCESS DEVICES*

* **BJ Holcombe, S. Forloines, LW Garmhause.** "Restoring Patency of Long-Term Central Venous Access Devices" Jour. of I.V. Nursing, Vol. 15, No. 1, Jan/Feb 1992

Tips when Accessing the TidalPort™

An aseptic technique is essential

1. Scrub the injection site with an appropriate surgical scrub using aseptic technique
2. Using sterile gloves, palpate the implant site to locate both the port and its septum (fig. 1).

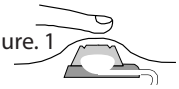
Figure. 1

3. To access the TidalPort™, isolate the top surface. Then, while stabilizing the port with the forefinger and thumb, puncture the skin and septum with the "Huber" point needle or needle set. Needle entry and contact with the needle stop are discerned by the "feel" of the needle as it passes through the septum to the base. Direct the needle perpendicular to the palpated surface. This will guide you to the center of the port (fig. 2).

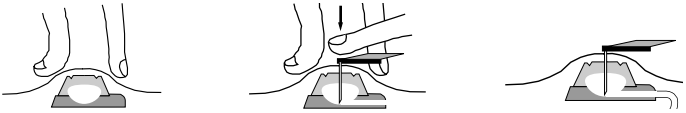
Figure 2

Caution **The needle must be held securely against the base below the septum during these procedures to avoid injecting the drug into the subcutaneous tissue. Do not impart angular motion or twist the needle and syringe once in the septum.**

4. Prior to injecting any drug, flush the TidalPort™ with 20mL of normal saline to check needle placement.
5. Inject the drug applying consistent, firm pressure or connect the extension set to an appropriate infusion pump
6. After each drug injection, flush the port with 10mL of normal saline solution.

Caution **Do not aspirate or allow fluids to proceed retrograde without flushing the TidalPort™. Standing blood in the catheter is likely to result in catheter occlusion. Flushing is vital to continued use of the port.**

7. After injecting saline, detach the syringe from the needle leaving the needle in place within the septum.
8. Attach a different syringe filled with 100u/mL heparinized saline. Inject 5mL of this solution into the port. This constitutes a "heparin lock" and will help deter catheter tip occlusion by the invasion of blood into the catheter.
9. Withdraw the needle and syringe while maintaining positive pressure on the plunger of the syringe. Discard used components.
10. Examine the injection site closely. Palpate the area to ensure that the drug was delivered to the specific site and that the "heparin lock" was completed properly.

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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