



SMART PORT™ CT
With Vortex® Technology

The Intelligent Choice in Injectable Ports

**POWER INJECTABLE
IMPLANTABLE PORT SYSTEMS**

Instructions For Use

ANGIODYNAMICS®

INCORPORATED

INSTRUCTIONS FOR USE

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OVERVIEW

Introduction

AngioDynamics, Incorporated 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. These subcutaneous devices reduce the trauma associated with multiple punctures or the inconvenience of an externalized catheter.

The port is intended to facilitate frequent blood sampling or the delivery of medications, nutritions, blood products and power injection of contrast media for imaging. Access is performed by percutaneous needle insertion using an anti-coring (Huber point) needle.

Important Information Regarding Smart Port™ CT Power Injectable Ports

- Read all instructions prior to utilization of device.
- The LifeGuard™ Safety Infusion Set, 19 or 20 gauge non Y-site needles should be utilized to access the Smart Port™ CT implanted ports for power injection 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 each Smart Port™ CT port. Refer to the Procedure for Power Injection section in this booklet for additional information and instructions. Failure to follow these guidelines can result in over pressurization of the port device. The power injection machine may not prevent over pressurization in the presence of occlusion or resistance.

- Do not exceed 300 p.s.i. Exceeding pressures of 300 p.s.i. could lead to device rupture or catheter malposition.
- Failure to assess the patency of the Smart Port™ CT 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.
- 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 (safety cut-off) settings may not prevent over pressurization of an occluded device.
- 10 mL 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.
- Do not exceed 300 p.s.i. when using the LifeGuard™ Safety Infusion Set.
- Power injection using the Smart Port™ CT implanted ports should be performed by trained clinicians who are knowledgeable about the utilization of the Smart Port™ CT implanted ports.

The LifeGuard™ 19 or 20 gauge non Y-site Safety Infusion Sets should be utilized to perform power injection with Smart Port™ CT power injectable ports

| Model # | Maximum Setting for Flow Rates | Maximum Pressure Setting |
|----------|--------------------------------|--------------------------|
| CT96STSD | 5 mL/sec | 300 p.s.i. |
| CT80STPD | 5 mL/sec | 300 p.s.i. |
| CT75STSD | 5 mL/sec | 300 p.s.i. |
| CT50PTPD | 3 mL/sec | 300 p.s.i. |

Procedure for Power Injection

1. Ensure that the patient has a Smart Port™ CT implanted port. The patient should have a Smart Port™ CT Patient Identification Card, Smart Port™ CT Patient Information Guide, or Smart Port™ CT Key Ring 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 Smart Port™ CT Implanted Ports should be accessed with a 19 or 20 gauge non Y-site LifeGuard™ Safety Infusion Set for injection of contrast media. The tubing on the safety needle should be clamped prior to accessing the port.
3. Remove the injection cap attached to the end of the Power Injectable Safety Infusion Set.
4. Attach a 10 mL or larger syringe to the luer hub end of the Power Injectable Safety 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.

Note: Testing aspiration for simulated blood return is 0.5 mL/sec.

5. Flush the Smart Port™ CT Implantable Port with 10-20 mL 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 Safety Infusion Set tubing.
7. Remove the syringe from the Power Injectable Safety Infusion Set.
8. Attach the power injection tubing per manufacturer's recommendations to the luer hub end of the Power Injectable Safety Infusion Set. Release the clamp.
9. Set the power injection machine per manufacturer's recommendations for a maximum pressure of 300 p.s.i.
10. Perform the study. Do not exceed 300 p.s.i. 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 end of the Power Injectable Safety Infusion Set.
12. Place a new injection cap on the Power Injectable Safety Infusion Set luer hub.
13. Flush the Smart Port™ CT Implantable Port with 10-20 mL 0.9% normal saline.
14. Flush the Smart Port™ CT Implantable Port with 3-5 mL of 10-100 units/mL heparinized saline. Actual amount and strength depends on facility policy.

Indications for Use

The Smart Port™ CT power injectable port line is indicated for any patient requiring repeated access of the vascular system for

delivery of medications, nutritional supplementation, fluids, blood, blood products, sampling of blood and power injection of contrast media for imaging. Smart Port™ CT model CT50PTPD is indicated for peripheral or chest placement.

Contraindications

AngioDynamics port systems should not be implanted in the presence of known or suspected infections, bacteremia, septicemia and peritonitis in patients who have exhibited prior intolerance to the materials of construction, or patients whose body size or tissue is insufficient to accommodate the size of the port or catheter.

Warnings

- Do not use smaller than a 10 mL 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 Smart Port™ CT 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 p.s.i. Exceeding pressures of 300 p.s.i. could lead to device rupture or catheter malposition.
- Failure to assess the patency of the Smart Port™ CT 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 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 (safety cut-off) settings may not prevent over pressurization of an occluded device.

How to Identify the Smart Port™ CT Implantable Ports

1. Refer to the patient's chart for implant information (sticker).
2. Each Smart Port™ CT power injectable port is packaged with a Smart Port™ CT Patient Education Packet, which includes a Smart Port™ CT Patient Information Booklet, a Smart Port™ CT Patient Identification Card and a Key Ring Card.
3. Smart Port™ CT implantable ports are identifiable under X-ray or scout scan through visualization of the CT markings located on the bottom of the port (see below images).

Standard Body



Low Profile Body



- At least one of the above means of identifying the power injection capability of Smart Port™ CT should be verified prior to the power injection procedure. If you need additional information, please contact the AngioDynamics Customer Service department at 800-772-6446.

Potential Complications

Use of an AngioDynamics port system involves potential risks normally associated with the insertion or use of any implanted device or indwelling catheter including but not limited to:

| | | |
|------------------------|------------------------|-------------------------|
| Infection | Catheter embolization | Drug extravasation |
| Occlusion | Cardiac arrhythmia | (leakage) |
| Thrombophlebitis | Cardiac puncture | Catheter malposition |
| Pneumothorax | Cardiac tamponade | Air embolism |
| Catheter malposition | Fibrin sheath | Device rotation |
| Migration | Endocarditis | Twiddler Syndrome |
| Inadequate anchoring | Implant rejection | Hemothorax |
| Hemorrhage | Thoracic duct injury | Hydrothorax |
| Vessel trauma | Thromboembolism | Inflammation |
| Puncture of Vessel | Peritonitis | Necrosis or scarring |
| Laceration | Thrombosis | of skin over implant |
| Erosion of vessel | Bleeding | area |
| and skin | Catheter disconnection | Right arterial puncture |
| Catheter Pinch-off | or migration | Peripheral nerve |
| Hematoma | Chylothorax | damage |
| Clot formation | Vein puncture | Surgical complications |
| Catheter fragmentation | | |

These complications are well documented in literature and should be considered when a venous access device is utilized.

Needles

Use of AngioDynamics non-coring (19 or 20 gauge Huber point) needles is recommended for all procedures. These needles have been designed and tested to ensure that septum life is preserved. Use of AngioDynamics LifeGuard™ Safety Infusion Sets (19 or 20 gauge non Y-site) should be utilized for injection of contrast media. Needles are for single use only.

Note: Septum Puncture Life — Under qualified testing procedures, the septum testing was conducted at 10 p.s.i. This pressure exceeds typical levels experienced in clinical practice.

| Needle Gauge | Puncture Life |
|--------------|----------------|
| 19 Gauge | 500 Punctures |
| 20 Gauge | 1000 Punctures |

IMPLANTATION INSTRUCTIONS

General Guidelines

The following suggestions for surgical insertion are provided as an aid to facilitate safe and prolonged use of the AngioDynamics port systems. The Smart Port CT family of ports may be placed in a number of areas of the body and the catheter may be placed in a variety of vessels or other selected sites. Use the surgical procedure and the sterile technique which best suits your application and is appropriate for the patient. AngioDynamics recommends

that the patient, when appropriate, be placed in the Trendelenburg position.

Precautions:

- Strict aseptic technique is of paramount importance when implanting any device.
- Before handling the port, ensure that fingers of surgical gloves are free of talc.
- When suturing around the silicone catheter, avoid excessive suture tightness to prevent occlusion of the catheter. Sutures should not be placed directly on the catheter.
- For peripheral placement, irritation to the vein, resulting in postoperative thrombophlebitis, has been associated with guidewire and introducer insertion.

Caution: Do not flush or wipe polyurethane catheters with alcohol at any time prior to implantation or during use.

Port and Catheter Preparation

Prime the port system prior to placement using 10 mL of normal saline or heparinized saline (100 units/mL). Attach the anti-coring (Huber point) needle to the syringe, penetrate the septum of the port, and flush the system.

Caution: Use a 10 mL or larger syringe when administering fluid into system.

Port Placement Considerations

- Placement needs to be supported by underlying bony structure.
- A minimum of three sutures should be used to secure port body.

- Port location should be convenient and comfortable to the patient.
- Avoid placing port system directly under port pocket incision.
- Avoid placing port too deep or too shallow (minimum 0.5 cm - maximum 2 cm under skin surface).
- Pre-operative mapping of location is recommended whenever possible.

Catheter Placement Considerations

Place catheter tip in area of high blood flow.

Warning: Avoid medial catheter placement into subclavian vein through percutaneous technique. This placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle. Catheter shearing has been reported when the catheter is inserted via a more medial route in the subclavian vein.¹

¹. Aiken DR, Minton JP. The "pinch-off " sign: a warning of impending problems with permanent subclavian catheters. Am J Surgery 1994; 148:633-636

The port catheter should be positioned at the selected site of therapy and secured by accepted surgical technique to prevent catheter dislodgement. Position should be confirmed by appropriate radiographic procedures.

Caution: Sufficient slack should be left between the catheter insertion point and the port body to preclude strain on the catheter.

Implantation of Attachable Catheter (Venous/Vascular)

Percutaneous Procedure (attachable catheter)

Prime the port system prior to placement.

- a. Select appropriate French-size sheath introducer.
- b. Puncture skin with introducer needle into the subclavian vein at selected venous site. Gently aspirate while inserting.

Warning: The use of alcohol, acetone, or solutions containing these agents may result in degradation of the plastic introducer needle hub.

- c. Remove syringe, leaving needle in place.

Caution: To prevent air embolism, place thumb over exposed orifice of needle.

- d. Slide the "J" guidewire straightener over the "J" tip of wire. Insert the straightened "J" tip through the percutaneous entry needle and advance the wire 5-10 cm into the vein. Verify guidewire position radiographically.
- e. Withdraw the needle and guidewire straightener, leaving the guidewire in place. Clamp guidewire with hemostat to prevent further advancement into the vascular system.
- f. Create a subcutaneous pocket for the port. An incision is made and pocket formed by either sharp or blunt dissection down to underlying fascia.
- g. Unclamp guidewire and advance dilator/sheath over the exposed "J" wire. Withdraw vessel dilator and "J" wire, leaving sheath in place.

Caution: To prevent air embolism, place thumb over exposed orifice of sheath.

- h. Insert catheter into sheath. Position the distal end of the catheter at the desired location. Peel away sheath while withdrawing it from vessel. Care should be taken not to withdraw catheter as sheath is removed. Catheter position should be confirmed radiographically. Secure catheter in place.
- i. Trim proximal end of catheter and advance through subcutaneous tunnel to the port pocket. Attach catheter to the port body.

Blue Strain Relief Mechanism

Models: CT75STSD, CT80STPD, CT96STSD

Slide the blue strain relief mechanism over the end of the catheter. The tapered end of the blue strain relief mechanism should point away from the proximal end of the catheter. For optimal results the proximal end of the catheter should be dry. Slide the trimmed end of the catheter tip onto the stem until the catheter is flush with the stem flanges. Slide the strain relief mechanism over the catheter and onto the stem until it contacts the port body.

Locking Mechanism Assembly

Model: CT50PTPD

Slide the locking mechanism over the proximal end of the catheter, leaving 1 to 2 cm of catheter protruding. Ensure that the lock is oriented so that the slots on the lock point towards the port and away from the distal end of the catheter. Advance the catheter over the end of the barbed connection until the catheter begins to enter the port body. Slide the lock up to the port body and “snap” into the port.

- j. Secure port body to underlying fascia using non-absorbable sutures and a minimum of three suture sites. Care should be exercised so that incision does not cross septum of port after closure.

Caution: Avoid piercing catheter with suture needle.

- k. Prior to wound closure, aspirate septum to confirm ability to withdraw blood. Flush port with 3-5 mL of 10-100 units/mL of heparinized saline. Maintain positive pressure on syringe plunger to avoid reflux of blood into catheter tip. Stabilize port while withdrawing needle.
- l. Close incision after wound irrigation by appropriate surgical technique. Dress wound per hospital protocol.

Surgical Cutdown (attachable catheter)

Follow general port placement guidelines described under "Port Placement Considerations" and "Percutaneous Procedure".

- a. A small incision is made in deltopectoral groove to expose cephalic vein or a small transverse incision in neck to expose external jugular vein. Isolate vessel.
- b. Introduce catheter through venotomy and advance to desired location. Confirm catheter placement by appropriate radiographic technique. Catheter is passed to pocket site via subcutaneous tunnel.
- c. Anchor catheter at venotomy site. Avoid excessive suture tightness to prevent catheter occlusion.

Caution: Sufficient slack should be left between port and catheter insertion point to preclude strain on the catheter. When using external jugular vein, carefully position the catheter over clavicle to avoid kinking or occlusion.

Implantation of Preattached Catheter (Venous/Vascular)

Prime the port system prior to placement.

1. Select appropriate site for portal placement.
2. Measure appropriate catheter length. Provide slack from port site to allow for body movement, but not enough to allow kinking of catheter.
3. Trim excess catheter by cutting squarely across the distal end. Do not trim catheter at an angle since this could cause the catheter tip to seal off against the side of the vessel.

Percutaneous Procedure (preattached catheter)

- a. Select appropriate French-size sheath introducer.
- b. Puncture skin with introducer needle into the subclavian vein at selected venous site. Gently aspirate while inserting.

Warning: : The use of alcohol, acetone, or solutions containing these agents may result in degradation of the plastic introducer needle hub.

- c. Remove syringe, leaving needle in place.

Caution: To prevent air embolism, place thumb over exposed orifice of needle

- d. Slide the “J” guidewire straightener over the “J” tip of wire. Insert the straightened “J” tip through the percutaneous entry needle and advance the wire 5-10 cm into the vein. Verify guidewire position radiographically.
- e. Withdraw the needle and guidewire straightener, leaving the guidewire in place. Clamp guidewire with hemostat to prevent further advancement into the vascular system.
- f. Create a subcutaneous pocket for the port. An incision is made and pocket formed by either sharp or blunt dissection down to underlying fascia.
- g. Place port in pocket and pass catheter from port pocket to entry site via subcutaneous tunnel.

- h. Unclamp guidewire and advance dilator/sheath over the exposed “J” wire. Withdraw vessel dilator and “J” wire, leaving sheath in place.

Caution: To prevent air embolism, place thumb over exposed orifice of sheath.

- i. Insert catheter into sheath. Position the distal end of the catheter at the desired location. Peel away sheath while withdrawing it from vessel. Care should be taken not to withdraw catheter as sheath is removed. Catheter position should be confirmed radiographically. Secure catheter in place.
- j. Secure port body to underlying fascia using non-absorbable sutures and a minimum of three suture sites. Care should be exercised so that incision does not cross septum of port after closure.

Caution: Avoid piercing catheter with suture needle.

- k. Prior to wound closure, aspirate septum to confirm ability to withdraw blood. Flush port with 3-5 ml of 10-100 units/ml of heparinized saline. Maintain positive pressure on syringe plunger to avoid reflux of blood into catheter tip. Stabilize port while withdrawing needle.
- l. Close incision after wound irrigation by appropriate surgical technique. Dress wound per hospital protocol.

Note: A 90 degree non-coring needle with winged infusion set may be positioned in port septum intraoperatively for patient comfort during initial access.

Surgical Cutdown (preattached catheter)

Follow general port placement guidelines described under “Port Placement Considerations” and “Percutaneous Procedure”.

- a. A small incision is made in deltopectoral groove to expose cephalic vein or a small transverse incision in neck to expose external jugular vein. Isolate vessel.
 - b. Introduce catheter through venotomy and advance to desired location. Confirm catheter placement by appropriate radiographic technique.
 - c. Anchor catheter at venotomy site. Avoid excessive suture tightness to prevent catheter occlusion.
-

Caution: Sufficient slack should be left between port and catheter insertion point to preclude strain on the catheter. When using external jugular vein, carefully position the catheter over clavicle to avoid kinking or occlusion.

Note: A 90 degree anti-coring needle with winged infusion set may be positioned in the port septum intraoperatively for patient comfort during initial access.

Peripheral Procedure, Upper Arm

Model: CT50PTPD

- a. Under ultrasound or fluoroscopic guidance, locate desired vessel in the mid-arm above the antecubital space, and well below the subaxillary area using an introducer needle attached to a syringe. Gently aspirate while inserting.
- b. Remove the syringe, leaving the needle in place.
- c. Insert the guidewire into the needle. Under fluoroscopic guidance, advance the wire into the area of the Superior Vena Cava (SVC). Verify guidewire position radiographically.
- d. Withdraw the needle, leaving the guidewire in place. Clamp guidewire with hemostat to prevent further advancement into the vascular system.
- e. Unclamp guidewire and advance the dilator and sheath assembly into the vein over the guidewire with a twisting motion. Withdraw the dilator, leaving the sheath and guidewire in place.

CAUTION: Bending or inserting the dilator and sheath assembly with excessive force may damage the dilator or sheath.

CAUTION: Using excessive force on the guidewire may damage the guidewire.

- f. Make a skin incision at the puncture site, approximately 2.5 cm in length. Create a subcutaneous pocket for the port by either sharp or blunt dissection down to underlying fascia.
 - g. Advance the catheter over the guidewire and through the sheath. It is recommended that the catheter tip be placed in the lower portion of the SVC.
 - h. Remove the guidewire and sheath gradually. Care should be taken not to withdraw catheter as sheath is removed. Confirm the location of the catheter tip under fluoroscopy.
-

NOTE: Clinicians should exercise judgment in catheter tip placement. Movement of the arm in which the system is implanted may be associated with movement of the catheter tip.

- i. Trim proximal end of the catheter to the desired length with a perpendicular cut. A perpendicular cut aids the sealing of the catheter to the port fitting.
 - j. Slide the catheter over the port body fitting up to the fitting flange.
 - k. Ensure that the lock is oriented so that the slots on the lock point towards the port and away from the distal end of the catheter. Slide the connector over the catheter until the connector snaps and the connection is visually confirmed.
-

NOTE: Improper assembly may result in catheter damage, leakage, or possible disconnection.

- l. Suture port to underlying fascia using at least one 2-0 silk suture placed through each suture hole. Care should be exercised so that the incision does not cross the septum access area.
- m. Before closing the incision, aspirate to confirm ability to draw blood. Flush port with 5-10 ml of normal saline followed by 3-5ml of 10-100 units/ml of heparinized saline. Maintain positive pressure. Confirm the position of the catheter again using fluoroscopy or X-ray.
- n. Close incision by appropriate surgical technique. Dress wound per hospital protocol.

Cut-Down Procedure, Cephalic Vein

- a. Perform vessel incision to expose chosen vein. Isolate vein and stabilize to prevent bleeding and air aspiration.
- b. Insert the tapered end of the vein pick through the incision and advance into the vessel.
- c. Position the vein. Slide the catheter tip into the grooved underside of pick and advance the catheter tip into the vessel.
- d. Withdraw the vein pick.
- e. Advance the catheter into the vessel to the desired infusion site.
- f. Confirm catheter placement by radiographic technique.
- g. Anchor catheter at venotomy site. Avoid excessive suture tightness to prevent catheter occlusion.
- h. Make a skin incision at the puncture site, approximately 2.5 cm in length. Create a subcutaneous pocket for the port by either sharp or blunt dissection down to underlying fascia.
- i. Suture port to underlying fascia using at least one 2-0 silk suture placed through each suture hole. Care should be exercised so that the incision does not cross the septum access area.
- j. Before closing the incision, aspirate to confirm ability to draw blood. Flush port with 5-10 ml of normal saline

followed by 3-5ml of 10-100 units/ml of heparinized saline. Maintain positive pressure. Confirm the position of the catheter again using fluoroscopy or X-ray.

- k. Close incision by appropriate surgical technique. Dress wound per hospital protocol.

After Implantation and During System Use

- 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.

Post-Operative Care

The incision site should be monitored for signs of infection, inflammation, hematoma, device rotation or erosion. Routine wound care should be given to these sites. The Smart Port™ CT may be used immediately after verification of catheter placement. Instruct patient to avoid any heavy exertion or strenuous activity during the first few days after surgery.

Confirm correct positioning of the needle within the port reservoir by aspiration of blood before any infusion.

Contact physician if inability to obtain blood return. Following each infusion, the system should be flushed immediately with 5-10 ml of normal saline followed by 3-5 ml of 10-100 units/ml of heparinized saline. Determination of the appropriate heparin concentrations, volume and flushing frequency should be based on patient's medical condition and prior clinical experience.

PROCEDURES FOR USE

Accessing the Smart Port™ CT Power Injectable Ports

General Guidelines

- Each access of an AngioDynamics Smart Port™ CT should be performed using aseptic technique.
- Identify the port septum by palpating outer perimeter of the Smart Port™ CT power injectable port.
- Attach syringe with 10-20 mL 0.9% normal saline to tubing and anti-coring (huber point) needle. Locate the port silicone septum and place the LifeGuard™ Safety Infusion Set perpendicular into the septum until the bevel of the needle stops against the bottom of port. Once positioned in the septum, the needle should not be rocked or tilted. Such movement may cause septum damage.
- Unclamp tubing and inject 3-5 mL of normal saline to flush port catheter. Close clamp of tubing.
- Attach at least a 10 mL syringe with 10 mL 0.9% normal saline flush and aspirate blood to confirm placement and aspiration.
- Flush port with 3-5 mL of 10-100 units/mL of heparinized saline. Maintain positive pressure on syringe plunger to avoid reflux of blood into catheter tip.

Note: Determination of the appropriate amounts of sterile normal saline and heparinized saline concentration, volume, and flushing frequency should be based on patient's condition and facility protocol.

Bolus Injection/Continuous Infusion

1. Identify the Smart Port™ CT power injectable port septum by palpating outer perimeter of the port.
 2. Observing aseptic technique, prepare injection site.
 3. Attach syringe with normal saline to tubing and anti-coring (huber point) needle.
 4. Insert the anti-coring (huber point) needle through the skin perpendicular to the port and advance slowly until contact with the base is made.
 5. Unclamp tubing and inject 3-5 mL of normal saline to flush port catheter. Clamp tubing.
-

Note: If vascular access, needle placement should be confirmed by aspiration.

6. Remove syringe from tubing and attach drug syringe. Unclamp tubing and inject drug slowly.
 7. For continuous infusion, connect infusion pump to extension tubing. Tighten all connections. Position and secure height adjustable wings of infusion set. Start infusion pump. Open tubing clamp.
-

Caution: Examine injection site closely. If patient feels an abnormal sensation or pain at injection site, it may indicate the drug has extravasated. Discontinue infusion immediately and proceed with accepted extravasation protocol. Notify physician immediately.

8. Clamp tubing and carefully disconnect syringe.
9. Reattach syringe filled with normal saline. Unclamp tubing and flush catheter.
10. If additional drug infusions are required, flush port with an adequate volume of saline between infusions and repeat steps 6 through 10.
11. Heparin Lock Procedure

- a. Attach syringe containing 3-5 mL of heparinized saline (100 units/mL) to tubing.
- b. Flush catheter.

Caution: Maximum flow rate of 5 mL/min is recommended for heparin lock procedure. This flow will minimize blood reflux into catheter.

- c. Maintenance of positive pressure on syringe plunger will prevent blood reflux.
12. Gently withdraw needle from port septum and apply adhesive bandage.

Caution: It is extremely important to adequately flush the port after blood withdrawal. Occlusion of the catheter can occur if blood is left in the catheter for an extended period of time.

Blood Sampling

Blood sampling may be performed as an isolated procedure at the time of bolus injection, or during the continuous infusion process.

1. Insert the anti-coring needle into the prepared site and flush with 5-10 mL of normal saline solution.
2. Withdraw "discard sample" consisting of 5 mL of blood. Discard this sample and syringe. Perform required blood sampling.
3. Immediately flush the catheter with a minimum of 10 mL of saline followed by 3-5 mL of 10-100 units/ml heparinized saline solution to establish the heparin lock.

System Maintenance

- INS guidelines suggest every 24-48 hour dressing changes with

a gauze-tape type dressing. If utilizing transparent dressings, the dressing change frequency for the catheter should be every 3-7 days, or as needed.

- ALWAYS maintain Universal Precautions and utilize sterile technique throughout insertion and care and maintenance procedures.
- Change the dressing immediately if the dressing is wet or is not occlusive, using sterile technique. An occlusive dressing should be placed over insertion site at all times.

Troubleshooting the Smart Port™ CT Implantable Ports

Catheter Obstruction

- Power injection should not be performed if blood aspiration is not present or the port is difficult to flush. If the implanted port is utilized, it may result in device failure or patient injury.

One-Way Obstruction (able to infuse through the port system but unable to aspirate blood):

Causes

- Failure to adequately flush the implanted port.
- The catheter may be abutting the vessel wall. Aspiration may cause the vessel wall to be drawn into the catheter, thus blocking withdrawal. An infusion forces the catheter tip away from the wall and restores patency.
- Repositioning of the patient may restore the ability to aspirate blood from the port system. The following maneuvers may be helpful:
- Have the patient turn head in the opposite direction from the port body.
 - Have patient perform Valsalva maneuver.
 - Have patient cough.

- Have patient extend arm over head.
- Have patient lie in the decubitus position.
- Positional access problems with port may be found to be self-correcting during a subsequent access of the port system.
- Improper needle placement.
- A fibrin tail, clot or sheath may be on or within the catheter.
- A Thrombolytic agent may be used on the order of a physician to restore patency. The procedure should be outlined by the drug manufacturer's labeling. Use facility protocol to determine which Thrombolytic agent to use.
- The use of Streptokinase has been known to cause allergic and anaphylactogenic reactions.
- A contrast study performed through the port may confirm fibrin sheath presence, kinking, malposition, or Pinch-Off Syndrome.
- Malposition of the catheter from the lower portion of superior vena cava (SVC).

Caution: Do not use a syringe smaller than 10 mL.

Two-Way Obstruction (unable to infuse through the port system and unable to aspirate blood):

Causes

- A fibrin tail, clot or sheath may be on or within the catheter.
- The anti-coring (huber point) needle may not be patent or properly positioned within the port septum.
- Confirm that the needle is of sufficient length and, when positioned in the septum, the needle opening is not occluded by the septum.
- The clamp on the anti-coring (huber point) needle should be open.
- A drug precipitate caused by incompatible drugs infused through the port may be obstructing the system. To prevent,

use adequate amounts of sterile normal saline between incompatible solutions.

- A Thrombolytic agent may be used on the order of a physician to restore patency. The procedure should be outlined by the drug manufacturer's labeling. Use facility protocol to determine which Thrombolytic agent to use.
- The use of Streptokinase has been known to cause allergic and anaphylactogenic reactions.
- A contrast study performed through the port may confirm fibrin sheath presence, kinking, malposition, or Pinch-Off Syndrome.

Caution: Do not force solutions through the port system to clear an obstruction. A high pressure situation may cause irreversible catheter damage, leading to port system explant.

Pinch-Off Syndrome

Pinch-Off Syndrome signs may include difficulty in aspirating blood, resistance to flushing or infusion of medications or fluids that improves with position changes, infraclavicular pain and/or swelling with catheter flushing or infusion palpitations, sudden onset chest pain, cardiac arrhythmias, extra heart sound, chest wall swelling at the port pocket, vein insertion site, pain in shoulder or port area not associated with swelling, cough, paresthesia of arm on side of catheter withdrawal occlusion or swishing sound with catheter flushing.

Warning: Avoid medial catheter placement into Subclavian vein through percutaneous technique. This placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle. Catheter shearing has been reported when the catheter is inserted via a more medial route in the Subclavian vein.¹

¹. Aiken DR, Minton JP. The "pinch-off" sign: a warning of impending problems with permanent subclavian catheters. Am J Surgery 1994; 148:633-636

Note: If infusion or aspiration is successful upon lifting arm above the head and turning the head, consider Pinch-Off Syndrome as a possible cause. The line should be radiologically evaluated if Pinch-Off Syndrome is suspected.

A chest x-ray can help diagnose the grade of pinch-off or catheter fracture radiologically at the costoclavicular area. Below is a chart that will help define grade, catheter distortion, significance and recommendation:

| Grade | Catheter Distortion | Significance | Recommended Intervention |
|-------|--|-------------------------------|--------------------------|
| 0 | No distortion | NONE | NONE |
| 1 | Some degree of distortion with luminal narrowing | Not certain | Close follow-up |
| 2 | Distortion with luminal narrowing | Fracture likely | Remove catheter |
| 3 | Fracture | Risk of catheter embolization | Remove catheter promptly |

Warning: If Pinch-Off Syndrome is suspected, the port should be evaluated prior to power injection.

Use of a Thrombolytic Agent for Catheter Clearance

There are no Thrombolytic agents that are contraindicated for use with ports manufactured by AngioDynamics, Inc. Thrombolytic agents have been successfully utilized to restore patency of both One-Way and Two-Way Obstructions. The type and amount of the Thrombolytic agent used for catheter clearance should be based on facility policy.

Note: Thrombolytic agents will not successfully clear occlusions caused by administration of incompatible medications. Adequate amounts of 0.9% normal saline between incompatible medications should be utilized to help prevent occlusions.

Explantation of a Smart Port™ CT Power Injectable Port

Ports and catheters which are explanted due to suspected malfunction should be returned to AngioDynamics for analysis. The AngioDynamics customer service department must be contacted to obtain a return authorization number and instructions. AngioDynamics will provide an explant kit for use in storage and shipment of the explanted device. Hospitals must advise AngioDynamics of any infectious disease that the patient is known to have.

No returned product will be accepted without an RGA number and properly packaged in a AngioDynamics explant kit or equivalent.

Discontinuing System Use

AngioDynamics recommends that the clinician consider explantation of the system once it is determined that it is no longer required for therapy. If the clinician decides to leave the system in place, AngioDynamics recommends that periodic X-rays be taken with the patient in an upright, arms at side position. This procedure will verify catheter placement and detect problems with the system such as pinching of the catheter between the clavicle and first rib.

Smart Port™ CT System Care Guidelines

Site Preparation: Always access the system using aseptic technique.

Syringes: 10 mL syringes or larger are recommended for all flushing or injection procedures. Use of smaller syringes may result in system damage.

Needles: Use AngioDynamics anti-coring (huber point) needles only. Use only AngioDynamics LifeGuard™ Safety Infusion sets (19 or 20 gauge non y-site) for injection of contrast media.

Saline Flushes: Prior to drug administration, flush the system with saline solution to remove heparin. If more than one drug is administered, flush the system with saline solution between drugs. After patient treatment is completed, always flush the system to cleanse the catheter and port chamber.

Heparin Flush Schedule: To keep the Smart Port™ CT system patent, the system must be flushed with heparinized saline at regular intervals.

Heparin Concentration: (10-100 units/mL) of heparinized saline. Typical volume of 3-5 mL.

Venous Systems: "Heparin lock" once every 4 weeks.

Note: Follow institutional guidelines for infusion set use. Center for Disease Control (CDC) recommends that I.V. tubing be changed every 48 hours.



REFER TO ENCLOSED INSTRUCTIONS FOR
PROPER USE OF THIS DEVICE



SINGLE USE ONLY. DO NOT REUSE.
DO NOT RESTERILIZE.

STERILE EO

STERILIZED WITH ETHYLENE OXIDE
NON-PYROGENIC. DO NOT RESTERILIZE.
STERILE IF PACKAGE IS NOT OPENED OR DAMAGED.

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

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of AngioDynamics, Incorporated
Vortex® and AngioDynamics® are registered trademarks
of AngioDynamics, Incorporated

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AngioDynamics®, Incorporated

One Horizon Way, Manchester, GA 31816 USA
518-798-1215 • 800-772-6446
www.AngioDynamics.com

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