Stealth Therapeutics, Inc.

Invisiport™ Instructions for Use

CONFIDENTIAL

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Introduction

Product Description

The Invisiport™ is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle; reference “Procedures for Use” section for recommended needles and infusion sets. The device consists of an injection port made from biocompatible polyurethane with a self-sealing silicone septum. An open ended radiopaque polyurethane catheter is pre-attached to the port. The silicone septum covers a reservoir that can be accessed with a non-coring Huber type needle. Power injection of contrast for imaging examinations can be performed when the port is accessed with a power-injectable Huber needle or infusion set; reference “Power Injection Procedure” section for recommended power injection and infusion sets.

Indications for Use

The *Invisiport*™ is indicated for any patient requiring reliable repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood, or for power injection of contrast when used with a power-injectable Huber needle or infusion set.

For power injection of contrast media the maximum recommended infusion rate is 5 ml/s.

Instructions for Implantation

Contraindications

The *Invisiport*™ is contraindicated*:*

- When the presence of device related infection, bacteremia, or septicemia is known or suspected.
- When the patient's body size is insufficient for the size of the implanted device.
- When the patient is known or suspected to be allergic to materials contained in the device.
- If severe chronic obstructive lung disease exists.
- If the prospective insertion site has been previously irradiated.
- If the prospective placement site has previously suffered episodes of thrombosis or vascular surgical procedures.
- If local tissue factors will prevent proper device stabilization and/or access.

Note: The Invisiport is not made of natural rubber latex.

Warnings

I. During Placement or Removal:

- Intended for Single Patient Use. DO NOT REUSE. The Invisiport is a single use device and should never be re-implanted. Any device that has been contaminated by blood should not be reused or re-sterilized.
- 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 embolization. The risk of air embolization is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
- Avoid vessel perforation.
- Do not power inject through a port system that exhibits signs of pinch-off as it may result in port system failure.

II. During Port Access

- DO NOT USE A SYRINGE SMALLER THAN 10 mL. Prolonged infusion pressure greater than 25 psi may cause damage to a patient's vessels or viscus.
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
- Invisiport™ device indication for power injection of contrast media implies the port's ability to withstand the procedure, but does not imply the appropriateness of the procedure for a particular patient or for a particular infusion set. A suitably trained clinician is responsible

for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.

- Do not exceed a 300 psi pressure limit setting, and a 5 ml/second maximum flow rate setting on the power injection machine if power injecting through the Invisiport™ device.
- 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, which 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 clavicle.
- 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:
  - Distortion present without luminal narrowing,
  - Distortion present with luminal narrowing,
  - Catheter transection or fracture.

Precautions

General:

- Carefully read and follow all instructions prior to use.
- Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only licensed and qualified healthcare practitioners should insert, manipulate and remove these devices.
- When utilizing the Arm Placement via Brachial/Basilic approach, the port should not be placed in the axillary cavity.
- 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.
- 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.

Prior to Placement:

- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed.
- The Invisiport and associated implant components are supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged, opened, or the expiration date has passed.
- Sterilized by ethylene oxide. Do not re-sterilize.
- Inspect kit for presence of all components.
- Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure.

- Fill (prime) the device with sterile heparinized saline or normal saline solution to help avoid air embolism. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port primed with heparinized saline.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.

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 catheter at sharp angles during implantation. This can compromise catheter patency.
- Do not rotate the wing in a counterclockwise direction. This can cause damage to the wing.
- 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.

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! Infusion pressure greater than 25 psi (172 kPa) may damage blood vessels and viscus and is not recommended.
- Use only non-coring needles with the port. See "Procedures for Use" section for recommended needles and infusion sets.
- Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle. The recommend needles should not exceed 1.5 inches in length.
- 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

Use of the *Invisiport*™ involves potential risks normally associated with the insertion or use of any implanted device or indwelling catheter including but not limited to:

Air embolism	Catheter or port related sepsis	Laceration of vessels or viscus
Bleeding	Device rotation or extrusion	Perforation of vessels or viscus
Brachial plexus injury	Endocarditis	Pneumothorax
Cardiac arrhythmia	Drug extravasation	Spontaneous catheter tip
Cardiac tamponade	Fibrin sheath formation	Malposition or retraction

Catheter or port erosion through the skin	Hematoma	Thoracic duct injury
Hemothorax	Thromboembolism	Catheter embolism
Hydrothorax	Vascular thrombosis	Catheter occlusion, damage or breakage due to compression between the clavicle and first rib[1]
Intolerance reaction to implanted device	Vessel erosion	Inflammation, necrosis, or scarring of skin over implant area
Catheter fragmentation	Thrombophlebitis	Risks normally associated with local or general anesthesia, surgery and post-operative recovery
Occlusion from clot formation inside the lumen of the catheter	Precipitate formation inside the port from incompatible drugs, or from catheter tip placement against a wall or valve	

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

Note: Septum Puncture Life

Under qualified testing procedures, the septum allows at least 500 punctures using a 22 gauge Huber-type needle, 250 punctures with a 20 gauge Huber-type needle, at an applied pressure of 10 psi; see "Procedures for Use" section.

Implantation Instructions

Please read through complete implantation instructions before implanting the *Invisiport*™, noting "Contraindications, Warnings, and Precautions" and "Possible Complications" sections of this manual before beginning procedure.

Preventing Pinch-Off

The risk of pinch-off syndrome can be avoided by inserting the catheter via the internal jugular (IJ) vein. Subclavian insertion of the catheter medial to the border of the first rib may cause catheter to pinch-off, which in turn results in occlusion, causing port system failure during power injection.

If you choose to insert the catheter into the subclavian vein, it should be inserted lateral to the border of the first rib or at the junction with axillary vein because such insertion will avoid compression of the catheter, which can cause damage and even severance of the catheter. The use of image guidance upon insertion is strongly recommended. A radiographic confirmation of catheter insertion should be made to ensure that the catheter is not being pinched.

General Guidelines

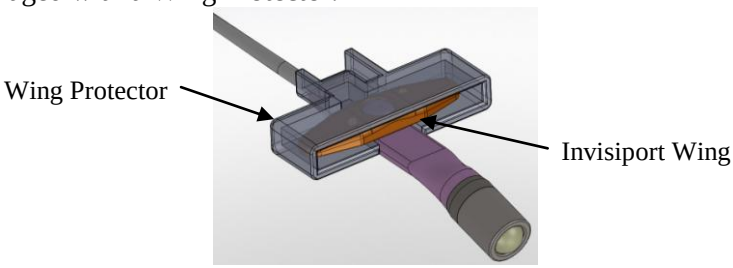
The following suggestions for surgical insertion are provided as an aid to facilitate safe and prolonged use of the *Invisiport™*.

Note: Precautions

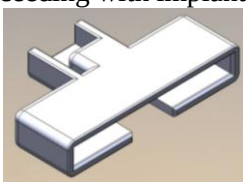
Strict sterile technique is of paramount importance when implanting any device.
Before handling the port, ensure that fingers of surgical gloves are free of talc.
Each access of an *Invisiport™* should be performed using sterile technique.
The anti-coring needle should be advanced through the septum until it contacts the base of the port body. Once positioned in the septum, the needle should not be rocked or tilted. Such movement may cause septum damage.
At no time should the system be left open to air. Tubing clamps should be used to prevent inadvertent air embolism.
When infusing into an *Invisiport™*, do not exceed 300 psi.
Do not use a syringe size smaller than 10 ml. Smaller syringes may create an over pressurized system.

Invisiport™ Preparation

The Invisiport is packaged with a Wing Protector.



Remove this Wing Protector prior to proceeding with implantation processes.



Prior to placement, all air must be removed from the system using 10 ml syringe, or larger, using sterile heparinized saline or normal saline (100 units/ml). Attach the anti-coring needle to the syringe, penetrate the septum of the port, and flush the system.

Wipe or immerse the Invisiport with saline prior to implanting.

Note: Caution

Do not exceed 300 psi pressure when administering fluid into system.
The use of a 10 mL or larger syringe will help prevent this from occurring.

Implantation Procedures

Note: Port Placement Considerations

Placement needs to be supported by underlying bony structure.
Port location should be convenient and comfortable to the patient.
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.

Note: Catheter Placement Considerations

Place catheter tip in area of high blood flow.
Position should be confirmed by appropriate radiographic procedures.

Note: Warning

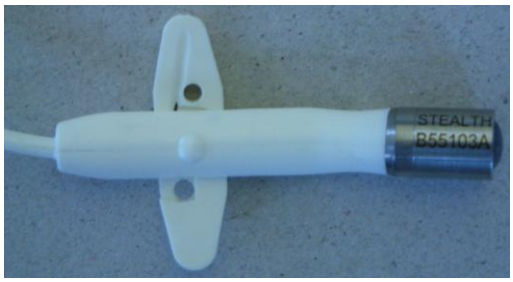
- Avoid medial catheter placement into subclavian vein through Percutaneous Technique. This placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle. Catheter shearing has been reported in the literature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

Percutaneous Procedure

1. Using ultrasound, select an appropriate vein for needle entry.
2. Puncture the skin approximately 5 cm distal to the anticipated vein entry site using the micropuncture needle.
3. Puncture the vein using ultrasound guidance approximately 5 cm proximal to the skin entry site.
4. Place the micro-guidewire through the micropuncture needle.
5. Under fluoroscopic guidance, advance the micro-guidewire to the desired final location of the catheter tip.
6. Remove the micropuncture needle over the micro-guidewire.
7. Measure the distance from the desired catheter tip location to the skin.
8. Trim the distal end of the Invisiport™ to the appropriate length.
9. Make a small incision at the skin entry site and create a small port pocket using blunt dissection.
10. Use the provided Microaccess Tear-Away Introducer Set or a 6 FR introducer of adequate length.
11. Advance the peel-away sheath over the micro-guidewire to the desired final catheter tip position
12. Remove the dilator from the peel-away sheath.
13. Place the Invisiport™ catheter through the peel-away sheath and advance until the port is close to the peel-away sheath
14. Peel away the sheath.

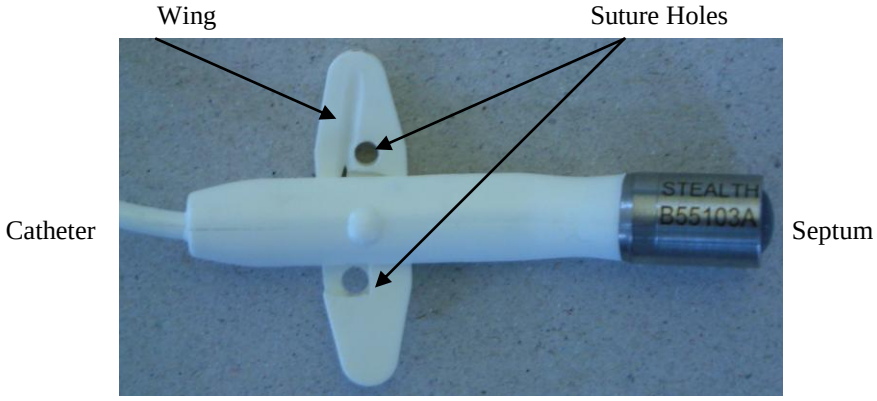
15. Rotate the wing of the Invisiport™ in a clockwise direction until it is parallel with the port body, and insert through the skin incision.

16. When the Invisiport™ is in position, release the wing. Check for complete wing deployment. If the wing is less than fully deployed, manually deploy the wing to the full perpendicular position using forceps or other blunt surgical instrument.



Invisiport with Wing deployed.

17. Consistent with clinical practice, if port fixation is desired place a retention suture through the suture holes in the Invisiport wing.



Invisiport suture holes

18. Prior to wound closure; aspirate well using the provided non-coring needle via septum to confirm ability to withdraw blood.
19. Flush port with 20cc of sterile saline to remove all blood from the system.
20. Follow Heparin Lock procedure.

21. Maintain positive pressure on syringe plunger to avoid reflux of blood into catheter tip.
22. Stabilize port while withdrawing needle.
23. Close incision after wound irrigation by appropriate surgical technique. Dress wound per hospital protocol.

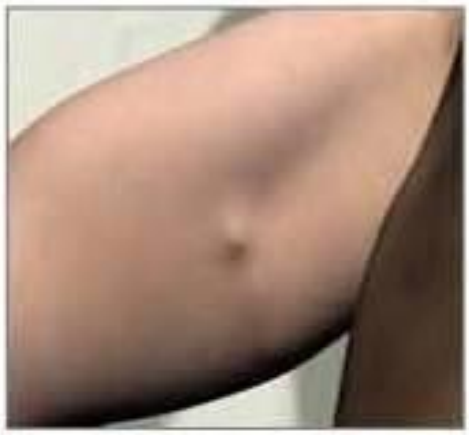
Procedures for Use

Note: The Invisiport has been evaluated for no septum defect when accessed with the following:
Bard Non-Coring Needle – Straight, 20 Gauge x 1.50 inches (250 punctures),,
Bard PowerLoc™ Safety Infusion Set without Y-injection Site, 20 Gauge x 1",
Bard Non-Coring Needle – Straight, 22 Gauge x 1.50 inches (500 punctures),
Bard PowerLoc™ Safety Infusion Set without Y-injection Site, 22 Gauge x 1".
Use of these septum access devices is recommended.

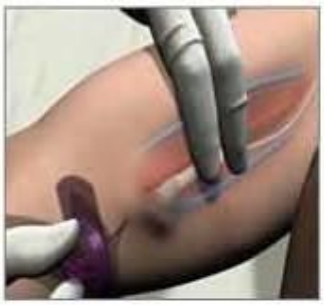
Warning: Needles applied for septum access must be no longer than 1.5 inches.

Bolus Injection/Continuous Infusion

1. Observing sterile technique, prepare injection site.
2. Attach syringe with normal saline to infusion tubing attached to anti-coring needle.
3. Identify the port septum by palpating the center bump on the top of the port.



4. Press down on the catheter side of the port which will cause the septum end to rise up and become visible as a bump under the skin.

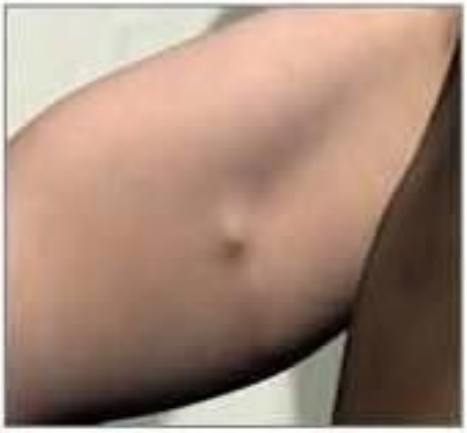


5. Insert the anti-coring needle through the skin, perpendicular to the septum surface, slowly until contact with the base is made, or full length of needle has been inserted.
6. Unclamp infusion tubing and aspirate until a “flash” of blood is seen in the tubing.
7. Inject 3-5 ml of normal saline to flush port catheter.
8. Clamp tubing.

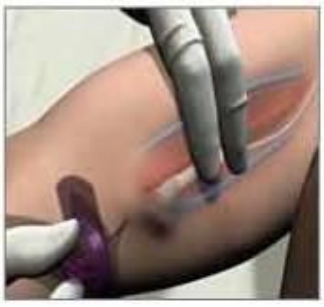
9. Remove syringe from infusion tubing and attach drug syringe.
10. Unclamp tubing and inject drug slowly.
11. At completion of infusion, flush system with 10cc of normal saline to ensure the entire volume of therapeutic solution is washed through the system and into the circulation.
12. For continuous infusion, clamp infusion tubing and carefully disconnect syringe.
13. Connect infusion pump extension tubing to infusion tubing.
14. Tighten all connections.
15. Position and secure height adjustable wings of infusion set.
16. Open tubing clamps.
17. Start infusion pump.
18. At completion of infusion, follow Heparin Lock Procedure.
19. If additional drug infusions are required, flush port with an adequate volume of saline between infusions.

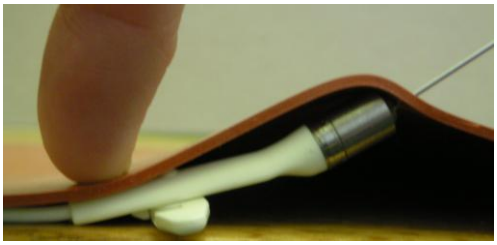
Blood Sampling

1. Blood sampling may be performed as an isolated procedure, at the time of bolus injection, or during the continuous infusion process.
2. Identify the port septum by palpating the center bump on the top of the port.



3. Press down on the catheter side of the port which will cause the septum end to rise up and become visible as a bump under the skin.





4. Insert the anti-coring needle into the prepared site.

5. Withdraw “discard sample” consisting of 5 ml of blood. Discard this sample and syringe. Perform required blood sampling.
6. Immediately flush the catheter with a minimum of 10 ml of saline followed by 5 ml of heparinized saline (100 units/ml) solution to establish the heparin lock.

Heparin Lock Procedure

1. Attach syringe containing 5 ml of heparinized saline (100 units/ml) to infusion tubing.
2. Unclamp.
3. Flush tubing and catheter.
4. Clamp.
5. Maintenance of positive pressure on syringe plunger will prevent blood reflux.
6. Gently withdraw needle from port septum and apply adhesive bandage.

Note: Caution

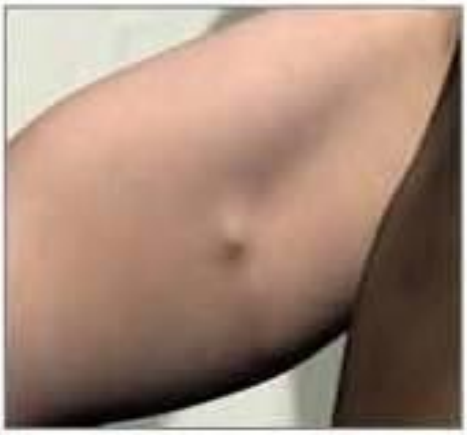
- Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
- Maximum flow rate of 5 ml/min is recommended for heparin lock procedure. This flow will minimize blood reflux into catheter.
- 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.

Note: Clot Formation & Catheter Blockage Considerations

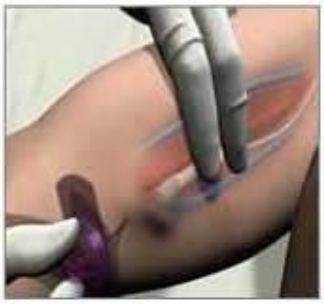
- To help prevent clot formation and catheter blockage, implanted ports with open-ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.

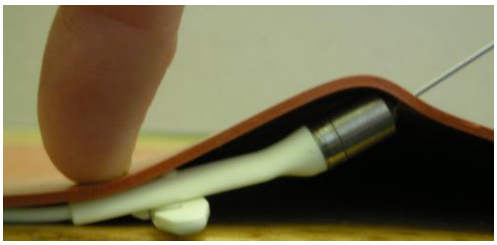
Power Injection Procedure

1. Access the Invisiport™ with the power injection rated Huber needle. Make certain that needle tip is inserted fully within the port.
   Note: The Invisiport has been evaluated for compatibility with the Bard PowerLoc™ Safety Infusion Set without Y-injection Site, 20 Gauge x 1" and Bard PowerLoc™ Safety Infusion Set without Y-injection Site, 22 Gauge x 1" and the 2004 EZ EM single head power injector for CT.
   Note: Follow institutional protocol to verify correct catheter tip position prior to power injection.
   Identify the port septum by palpating the center bump on the top of the port.



   Press down on the catheter side of the port which will cause the septum end to rise up and become visible as a bump under the skin.





2. Attach a syringe filled with sterile normal saline.
3. Instruct the patient to assume the position they will be in during the power injection procedure, before checking for patency.
4. Aspirate for adequate blood return and vigorously flush the port with at least 10 ml of sterile normal saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
5. Detach syringe.
6. Warm contrast media to body temperature.
7. Attach the power injection device to the Huber needle ensuring connection is secured. Check indicated flow rate of safety infusion set and confirm CT settings.
8. Instruct the patient to communicate immediately any pain or change in feeling during the injection.

9. Inject warmed contrast, taking care not to exceed the flow rate limits.
   Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.
   Warning: Exceeding the maximum flow rate may result in Huber needle failure, implanted port failure and/or catheter tip displacement. Do not exceed a 300 psi.
10. Disconnect the power injection device.
11. Flush the Huber needle with 10 ml of sterile normal saline.
12. Perform heparin lock procedure.
    Note: Some patients are hypersensitive to heparin or suffer from heparin induced thrombocytopenia. These patients must not have their port primed with heparinized saline.

Invisiport Power Injection Parameter Summary		
Maximum Power Injection Flow Rate (Note 1)	Average Pressure in Portal Reservoir (Note 2)	Average Invisiport Static Burst Pressure (Note 3)
5 ml/sec	57 psi	188 psi

NOTES:

1. Maximum Power Injection Flow Rate is the indicated port/catheter system capability for the power injection of contrast media.
2. Internal port pressure measured at the maximum indicated power injection flow rate for power injection (5 ml/sec) using simulated contrast media with an 11.8 centipoise (cp) viscosity and a Bard PowerLoc™ Safety Infusion Set without Y-injection Site, 20 Gauge needle
3. Average Invisiport Static Burst Pressure is the burst pressure of the Invisiport when fully occluded.

System Maintenance

Venous Systems

After use, the port should be flushed with at least 20 ml of normal saline. This should be followed by a "heparin lock". If the port is not being used, a "heparin lock" should be administered every 4 weeks.

Patient Identification Card

A Patient Identification Card is included with the Patient's Manual, which accompanies each Invisiport. The completed card should be given to the patient who should be instructed to carry it at all times.

Explantation of the *Invisiport*™

Suspected Malfunctions
Ports and catheters which are explanted due to suspected malfunction should be returned to Stealth Therapeutics for analysis. Stealth Therapeutics must be contacted to obtain a return authorization number and instructions.

Explant Kits
Stealth Therapeutics will provide an explant kit for use in storage and shipment of the explanted device. Hospitals must advise Stealth Therapeutics of any infectious disease that the patient is known to have.

Return Packaging
No returned product will be accepted without an RMA number and properly packaged in a Stealth Therapeutics explant kit. Contact Stealth Therapeutics for return.

Stealth Therapeutics Customer Service contact phone number (877) 262 - 4946.

Discontinuing *Invisiport*™ Use

Removing the *Invisiport*™
Stealth Therapeutics recommends that the clinician explant the system once it is determined that it is no longer required for therapy.

Leaving the *Invisiport*™ in Place
If the clinician decides to leave the system in place, Stealth Therapeutics recommends that periodic X-rays be taken with the patient in 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.

Invisiport™ Care Guidelines

Site Preparation
Always access the system using sterile 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 anti-coring (Huber point) needles only.

Saline Flushes
Prior to drug administration, aspirate 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 with 10 cc of sterile injectable saline to cleanse the catheter and port chamber. Follow Heparin Lock Procedure.

Heparin Flush Schedule
To keep the *Invisiport*™ patent, the system must be flushed with heparinized saline at regular intervals.

Heparin Concentration
100 units/ml of heparinized saline. Typical volume of 5 ml.

Venous Systems
Perform a "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.
Never inject fluid or materials which are not labeled sterile or are not approved for human infusion. Do not use this system if there are any questions or uncertainty regarding these instructions.

Questions regarding use of Stealth Therapeutics products may be directed to the company Monday through Friday between 8 A.M. and 5 P.M CST, Stealth Therapeutics Customer Service contact phone number (877) 262-4946.

References

1. Aiken DR, Minton JP. The "pinch-off" sign: a warning of impending problems with permanent subclavian catheters. Am J Surgery 1984; 148:633-6

Invisiport™ MRI Compatibility

The Invisiport has been evaluated for use in MRI. The following MR Conditional compliance information is provided.

MRI Information

MR Conditional

The Stealth Invisiport was determined to be MR-Conditional.

Non-clinical testing demonstrated that the Stealth Invisiport is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
-Static magnetic field of 3-Tesla or less,
-Maximum spatial gradient magnetic field of 720-Gauss/cm or less.

MRI-Related Heating
In non-clinical testing, the Stealth Invisiport produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: *Highest temperature change* +1.7°C.

Therefore, the MRI-related heating experiments for the Stealth Invisiport at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Stealth Invisiport. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	844-mm^2	435-mm^2	1,581-mm^2	1,480-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

The image artifact extends approximately 10-mm from the device, when scanned in non-clinical testing using the gradient echo pulse sequence in a 3-Tesla MR system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) with a transmit/receive RF body coil.