



## **Stealth Therapeutics, Inc.**

### **Infusion Nurse Training Manual For the Invisiport® Product Line**

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## Introduction

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### **Purpose of this Manual**

This manual is provided as a reference for infusion nurses who will be accessing the Invisiport on regular basis. It does not describe the implantation process or the power injection procedure, which are both described in the Invisiport's instructions for use.

### **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

Warning: The Instructions for Use for the Invisiport variation, 4.4 Fr or 6 Fr, provide safe power injection guidance. Reference the appropriate Invisiport instructions for use "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.

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

## Instructions for Invisiport Access

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### Precautions 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 “Instructions for Invisiport Access” 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.

## Instructions for Invisiport Access

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### **Notes on Access Needles and Septum Puncture Life**

The Invisiport has been evaluated for no septum defect when accessed with the following:

Progressive Medical Needle – Straight, 20 Gauge x 1.50 inches (250 punctures)  
Bard Non-Coring Needle – Straight, 20 Gauge x 1.50 inches (250 punctures)  
Bard PowerLoc™ Safety Infusion Set, no Y-injection Site, 20 Gauge x 1" (250 punctures)  
Bard Non-Coring Needle – Straight, 22 Gauge x 1.50 inches (750 punctures),  
Bard PowerLoc™ Safety Infusion Set without Y-injection Site, 22 Gauge x 1" (750 punctures)

**Needles applied for septum access must be non-coring Huber needles which are no longer than 1.5 inches.**

### **Septum Puncture Life**

Under qualified testing procedures, the septum allows at least 750 punctures using a 22 gauge Huber-type needle, 250 punctures with a 20 gauge Huber-type needle, at an applied pressure of 10 psi.

## Instructions for Invisiport Access

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### Use of the Practice Dummy

An Invisiport practice dummy is provided to infusion nursing teams who are new to the Invisiport. It is used to help identify the Invisiport under the skin and provide practice with accessing the port by pressing down on the catheter end of the port causing the septum end to rise and become a visible, accessible bump under the skin.

The Invisiport practice dummy includes an adjustable tissue tray and tissue module from Simulab. The Invisiport is implanted in the tissue model. Infusion nurses are encouraged to practice with the model according to their clinic's protocols before accessing their first Invisiport patient.



**Invisiport Practice Dummy**

## Instructions for Invisiport Access

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### **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.

## Instructions for Invisiport Access

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### **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.

# Instructions for Invisiport Access

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## 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 of Caution

1. 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.
2. Maximum flow rate of 5 ml/min is recommended for heparin lock procedure. This flow will minimize blood reflux into catheter.
3. 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.**



## Invisiport Care Guidelines

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### **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*<sup>™</sup> patent, the system must be flushed with heparinized saline at regular intervals.

### **Heparin Concentration**

100 units/ml of heparinized saline with a 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.

## Images Demonstrating Invisiport Access Process

1. Identify the port septum by palpating the center bump on the top of the port.



2. Press down on the catheter side of the port, causing the septum end to rise up becoming visible as a bump under the skin.



3. 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.

