Stealth Therapeutics, Inc.

Invisiport™ Patient Information

Manufactured for: Stealth Therapeutics, Inc.
406 Science Drive, Suite 400
Madison, WI 53711

Customer Service: (877) 262-4946
www.stealththerapeutics.com

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Introduction

Your doctor has prescribed and the Invisiport was implanted for your Intravenous (IV) therapy treatments. With your Invisiport, you will be able to receive IV therapy without having to undergo repeated needle sticks.

Please read this Patient Information carefully. It gives you useful information to understand and feel more comfortable with your Invisiport. Your Invisiport is a new device to you and it may not yet be familiar to all clinicians involved in your care. The Invisiport is a low profile port for implantation in the upper arm or chest. This information gives you the ability to inform your doctor(s) about your Invisiport device.

You should also carry your Invisiport Patient Identification Card with you to show to doctor(s) or nurse(s) whenever your port is accessed. It informs these clinicians that you have an Invisiport implanted and provides a summary of important information they should know about the port.

If you need additional information about your Invisiport device, please talk with your doctor or nurse.

Use of Your Invisiport

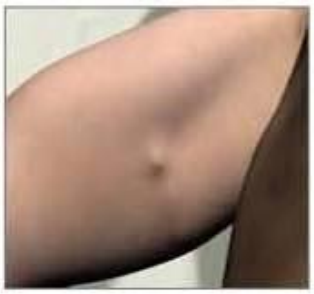
Your Invisiport is an implanted port to allow clinicians to easily deliver medications, deliver fluids, and withdraw blood samples without having to repeatedly stick your peripheral veins with a needle. This makes therapy and treatments more comfortable for you.

Identification of the Invisiport

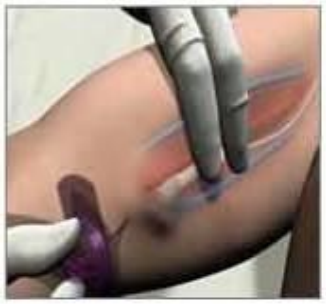
The ways that you and your clinicians can recognize that you have an Invisiport device implanted is to present them with your Invisiport Patient Identification Card. Carry your Invisiport Patient Identification Card with you at all times. Show the card to the clinician(s) whenever your port is accessed for a procedure or treatment.

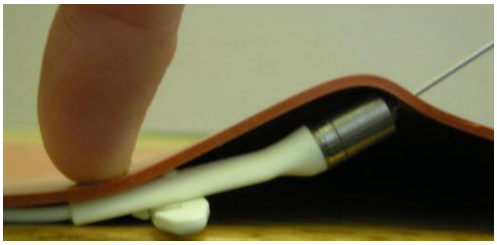
Accessing the Invisiport

Your Invisiport is a small device placed completely beneath the skin, typically in your upper arm. The Invisiport is a cylinder with a hollow space inside that is sealed by a soft top. The Invisiport includes a small, flexible tube called a catheter that is inserted inside one of the large veins that delivers blood to your heart. When a special needle is put into the soft top of the Invisiport, it creates “access” to your bloodstream, allowing medications and fluids to be given and blood samples withdrawn.



Picture 1: Invisiport small bump indicating the location of the Invisiport under the skin





Picture 2: Inserting a non-coring Huber needle into the Invisiport after the distal end rises beneath the skin

If your clinician has any concerns with the Invisiport, have them contact Stealth Therapeutics Customer Service at: (877) 262 - 4946 or review the Invisiport clinician information available at http://www.stealththerapeutics.com/.

Caring for your Invisiport

Your Invisiport requires minimal care between uses because it is completely implanted under the skin. You will receive specific instructions from your clinician. Some general guidelines are described below.

Cleaning the Site

When you do not have a needle in place, the Invisiport will need only minimal care, and you may wash and bathe normally. When a needle is in place, a dressing covers the needle and Invisiport injection site. This secures the needle and keeps the area clean. The dressing should be kept clean and dry. You should inspect the needle injection site and Invisiport area regularly. If the Invisiport seems to have moved, or you notice swelling, bruising, redness, or tenderness, contact your clinician.

Flushing the Invisiport

The Invisiport must be flushed with a heparin solution to prevent blood clots from forming inside the catheter. This creates what is usually referred to as a heparin lock. It is recommended that the Invisiport be flushed after an infusion or injection, and every four weeks when not in use. This will be done by your clinician(s) after a treatment or use of the Invisiport.

Question and Answers

How do I take care of my Invisiport?

During the first few days after receiving the Invisiport, avoid heavy exertion and follow the instructions your doctor or nurse has given you for taking care of the small incision. Once the incision has healed, you do not have to take any special care of the Invisiport and you can resume normal daily activities.

Will the Invisiport affect my daily activities?

Once the incision heals following implantation, you should be able to return to your normal daily activities. Ask your doctor or nurse about specific activities and the appropriate time to resume them.

Can the Invisiport be removed if I no longer need it?

Yes. When no longer needed, the Invisiport can be removed in a simple procedure similar to the one used to implant it.

Is the Invisiport device safe with MRI?

The Invisiport has been evaluated for safe use with Magnetic Resonance Imaging (MRI).
The following MR Conditional compliance information is provided to be shared with your doctor.

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.

What if the clinician has not seen a patient with an Invisiport device before

The Invisiport may not yet be familiar to all clinicians involved in your care. Always show clinicians this Invisiport Patient Information and the Invisiport Patient Identification Card, especially if your Invisiport device will be accessed for power injection of contrast media. This Invisiport Patient and your Invisiport Patient Identification Card contains a summary of important information for the clinician. If clinicians need more information, they may contact Stealth Therapeutics, Inc. Customer Service at (877) 262-4946.

What to Tell Your Clinician

As a patient with an implanted Invisiport, you have the ability to take an active role in your treatment. The best way to be involved is to share information and concerns with your clinician(s). Ask questions about anything that concerns you or if you notice anything that seems unusual.

What to Report to Your Clinician About the Invisiport

Here are some important things to tell your clinician:

- You have an implanted Invisiport.
- If you notice any redness or inflammation at the site of your implant after the incision heals.
- If other clinicians have ever had difficulty withdrawing blood or infusing fluids through your implanted Invisiport.

Precautions for the Invisiport Implanted in the Arm

Do not have blood drawn from or medication infused into any area of the arm that contains your Invisiport, unless it is through the Invisiport. Accidentally puncturing the Invisiport catheter will cause damage.

Do not measure your blood pressure from the arm that contains your Invisiport. It could cause an occlusion (blockage) or other damage to the Invisiport catheter.

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.

References

1. Aiken DR, Minton JP. The “pinch-off” sign: a warning of impending problems with permanent subclavian catheters. Am J Surgery 1984; 148:633-636