AngioDynamics, Smart Port Patient Education Guide, 8" x 6" Booklet, 14656995-01A - English

SMART PORT®

Patient Education

A guide to your Smart Port® power-injectable port

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Dear Patient,

Your doctor has recommended that you receive the Smart Port® power-injectable implantable port. To introduce you to the Smart Port® power-injectable port, we have prepared this brief booklet. As with any medical treatment, there are risks associated with the use of an implantable port. This booklet can provide you with general information about the device. We urge you to discuss any questions you may have about the device, or your treatment, with your doctor or nurse. You should follow your doctor's advice and instructions concerning your implantable port and medical treatment.

We have also provided a Smart Port® power-injectable port identification card with a snap-off key ring card that we recommend you carry with you at all times. *Present this card to any clinician who is going to access your port for any procedure, especially if that procedure is a power-injected Computed Tomography (CT) scan. The Smart Port® power-injectable port identification card provides the clinician with information about the device and special instructions for using the port. It also provides the clinician with contact information if he or she has any questions or needs additional information.*

Sincerely,

The Team at AngioDynamics®

Patient Education Packet

It is very important for patients receiving the Smart Port® power-injectable port to carry the Smart Port® power-injectable port identification card and identification key ring card at all times. Patients should provide the identification card to any clinician who is going to access their port for any procedure, especially if that procedure is a power injected CT scan. This is also important in the event of an emergency, so that the medical personnel will be aware that you have a Smart Port® CT power-injectable port. We have included such a card and key ring attachment for your convenience. This card can be found in the patient education packet.

Prior to leaving the hospital, please have the physician who inserted your Smart Port® power-injectable port, or one of the nursing staff, help you fill in the required information. Remember to have this card with you when you visit your doctor, hospital, clinic or dentist so that the information on your port will be immediately available.

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Will my insurance company pay for the Smart Port® Power-Injectable Port?

This varies from insurance company to insurance company. In general, most companies provide coverage for the placement and care of a port.

Will my Smart Port® Power-Injectable Port be affected by x-rays, MRI, or other diagnostic tests my doctor may order?

There are no components in the Smart Port® power-injectable port that could be affected by various methods of imaging. Your physician or nurse may call our Customer Service Department if any questions arise.

How long can the Smart Port® Power-Injectable Port remain implanted, and can it be removed once it is no longer needed?

The Smart Port® power-injectable port may remain in place for extensive periods, as long as your physician feels your medical treatment requires it. Once your physician has determined that your port is no longer needed, it can be removed during a brief surgical procedure.

Will my Smart Port® Power-Injectable Port be visible?

The port is implanted completely under the skin. During the immediate period following implantation, there may be some redness and swelling. This irritation should disappear in a few weeks. There will be a small raised area over the port, which can be felt and may be visible. There will also be a small scar located near the port, which should also diminish in visibility over time.

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The Smart Port® Power-Injectable Port Advantage

AngioDynamics manufactures implantable access devices designed to help people continue their normal activities while receiving medical treatments.

The distinctive feature of an implantable port is that it is placed completely under the skin. This placement allows almost complete freedom of movement for the patient.

The Smart Port™ power-injectable port is a new type of port that offers the ability for a clinician to access a vein for intravenous (I.V.) injection therapy of medication or fluids and for administering power-injected contrast to perform a Computed Tomography (CT) scan. Power-injected CT scans provide the physicians with clearer images of your body to help determine the best medical treatment options for you. The ability to access your port for power-injected contrast CT scans prevents the need for additional needle sticks in your arm and wrist veins.

In addition, once the Smart Port® power-injectable port is in place, repeated access to the bloodstream or a specific body site to administer therapy, or withdraw blood, can be accomplished with greater ease and less discomfort. Lastly, the Smart Port™ power-injectable port requires minimal care.

Description of the Smart Port® Power Injectable Port

The Smart Port® power-injectable port is a small metal disc about 2 cm in diameter (the size of a nickel) with a slightly raised rubber injection site called the port septum. Since the septum is raised, it is easily identified from the surface of your skin, making injections quick and easy. The septum is made of a silicone material, which reseals itself after each use. The silicone material allows the septum to be punctured many hundreds of times with a special needle, and yet retain its integrity.

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Questions Regarding your Smart Port® power-Injectable port

Why do I need a Smart Port® Power-Injectable Port?

Your doctor has recommended the Smart Port® power-injectable port for you because it is a reliable means for the administration of therapy for your specific medical needs and allows for power injecting contrast in the system to perform a CT scan. The port allows easy repeated access to the bloodstream, or a specific body site, which in turn causes less vessel or site damage.

Will I have to be stuck with a needle and will it be painful?

You will need to have a needle inserted into the port septum to administer therapy, withdraw blood or have contrast power injected through the Smart Port® port system, but the access site will be easy to locate.

You will notice some swelling and tenderness at the implantation site immediately following the port insertion. This may cause some pain and discomfort when your nurse or doctor inserts a needle into the port. However, over time, the initial tenderness will subside and needle insertions should become less painful.

Will my normal activities be affected by Smart Port® Power-Injectable Port?

You should avoid strenuous activities in the immediate period following the Smart Port® power-injectable port placement procedure. Your normal activities can be resumed once your incisions heal. With your doctor's approval, you may bathe, swim and exercise while your port is not accessed with a needle.

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- Catheter migration can occur spontaneously and result in the catheter being positioned outside of the intended vessel
- Catheter disconnection is the separation of the catheter from the port
- Skin erosion can occur over the port site
- Complications associated with surgery
- Rejection of the device by the patient's body

Care of the Smart Port® Power-Injectable Port

Because the Smart Port® power-injectable port is implanted completely beneath the skin, it requires minimal care. If permitted by your doctor, and subject to his or her instructions, you may bathe, swim and exercise as you always have, without worry about damaging the port. Once the skin has healed after surgery, there is no need to cover your port site with a dressing when the port is not accessed with a needle. In between treatments, you may not even remember that you have an implantable port, since it will be visible only as a small bump on your skin.

Periodically, your Smart Port® power-injectable port will need to be "flushed" to ensure that it remains in working order. Your doctor or nurse will let you know how often this needs to be done and who will perform this flushing procedure. In addition, you should examine your port site regularly. Once the initial expected tenderness and swelling during the post-operative period has subsided, you should notify your doctor or nurse if you notice any additional swelling, discoloration (bruising), redness, tenderness, pain, or drainage at the incision sites, the needle insertion site, or the port pocket, or if you begin to run a fever or experience any unusual symptoms.

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Attached to the base of the Smart Port® power-injectable port is a narrow, flexible tube called a catheter. The catheter is usually inserted into a large blood vessel and delivers your therapy from the port body into your bloodstream.

Placement of the Smart Port® Power-Injectable Port

Although each person's situation is unique, the Smart Port™ power-injectable port is usually inserted during a brief surgical procedure performed under local anesthesia. You may even have your port inserted in a day surgery or ambulatory surgery unit and go home shortly afterwards.

During the procedure, your surgeon will make two small incisions. The catheter is placed into the selected blood vessel or body site through one incision and then tunneled under the skin to the other incision site. Here, a "pocket" is formed under the skin to hold the port. The catheter is attached to the port and the port is then sutured in place securely within the pocket. An x-ray will be performed to verify that the catheter is in the proper position in the blood vessel. A few stitches are required to close the pocket once the port is in place.

Bandages may be taped over the incisions for the first few post-operative days. The skin overlying the port will be swollen and tender, but this irritation should go away as the incisions heal.

The port may be used immediately, if necessary, or your doctor may wait until the swelling has decreased. During these first few days after surgery, it is important that you avoid any heavy exertion or strenuous activities.

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Use of the Smart Port® CT Power-Injectable Port

The most frequent use of a port is for venous access. "Venous" refers to certain blood vessels in the body. "Access", in this context, means a way of entering these vessels.

Using a special anti-coring needle, your doctor or nurse can go through the skin overlying the port and into the center of the septum with one quick needle stick. These needles can then be used for a variety of purposes, such as administration of intravenous fluids, blood products and medications, as well as withdrawal of blood samples for laboratory tests.

With your Smart Port® power-injectable port and the LifeGuard™ Safety Infusion Needle Set, the clinicians can power-inject contrast to perform a Computed Tomography (CT) scan. This makes it easier for the physician to plan and/or monitor your medical treatment. A CT scan is a safe, non-invasive procedure that provides valuable information to your doctor.

Injections of medications can be done over a very short period of time (called a "bolus") or over a prolonged period of time (called a "continuous infusion"). Continuous infusions may last anywhere from one hour to several days or longer, and may require the use of a portable infusion pump to control the rate of the infusion. If your medication is to be given over a long period of time, the needle will stay in place, covered with a sterile dressing, and be changed at intervals as decided by your doctor. Once the needle is removed, the dressing is no longer needed.

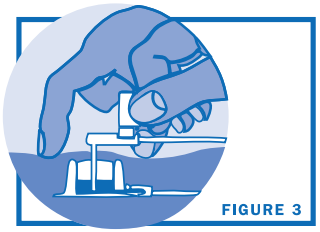

FIGURE 3

Potential Problems with the Smart Port® Power-Injectable Port

The use and maintenance of long-term vascular access devices may cause possible problems or complications. Listed below are the signals associated with the more common complications. If any of these symptoms appear, or any other unusual symptoms, it is important to contact your doctor or nurse immediately.

What you are experiencing?	Possible Reason
Inability to withdraw blood, or inability to flush the port and catheter using normal pressure.	Catheter occlusion or blockage
Aching discomfort, swelling or pain in the shoulder, neck or arm.	Vein thrombosis
Pain or redness over or around the port site, fever, or any unusual drainage from the incision site.	Infection of the port pocket or at the needle insertion site.
Burning sensation upon infusion of medication.	Extravasation/ infiltration–the leakage of drug into the tissue surrounding the port

Other complications include, but are not limited to:

- Catheter pinch-off- the catheter being "pinched" between the clavicle and first rib-can lead to catheter shear, which results in breakage of the catheter
- Device rotation or dislodgement can occur if the port is not well sutured in place or with excessive manipulation of the port

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