SmartPort+
Implantable Port
with Endexo and Vortex Technology

A Patient's Guide

angiodynamics

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14655333-21A 09/19

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Companion Checklist

A New Standard of Care

Thank you for being a companion to someone who has received an *SmartPort+** Implantable Port with Endexo and *Vortex** Technology. Here are some valuable things to know:

- The device is an implantable port that provides clinicians access for both IV therapy treatments and power-injected Contrast-Enhanced Computed Tomography (CECT) scans.
- Patients receive an identification card, reminder band and key ring card when receiving their port. These help identify them as a patient with an SmartPort+ Implantable Port with Endexo and Vortex Technology.
- Patients with this type of port should carry their patient identification card at all times. They may also wear the reminder band or carry the key ring card as convenient reminders.
- Patients with a port should show their patient identification card to clinicians whenever their port is accessed for a procedure, especially power-injected CECT scans.
- The patient identification card contains important information for the clinician.

Electronic only, does not print

TRAVEL CARDS

Always carry your SmartPort+ Implantable Port patient identification and key ring cards with you.

The patient card has important information about your port that healthcare providers will need to care for you.

Fill out your personal information in the areas provided. Your patient card is conveniently sized to fit in a wallet.

Electronic only, does not print

Information about your SmartPort+ Implantable Port with Endexo and Vortex Technology is available by calling the AngioDynamics Vascular Access Information Line 800.513.6876

SMARTPORT+ IMPLANTABLE PORT

INDICATIONS FOR USE: The ports are indicated for patients who require long-term access to the central venous system for blood specimen withdrawal and administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products, as well as the administration and adequate removal of nuclear medicine.

CONTRAINDICATIONS:

- Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates for pinch-off.[2]
- Presence of infection, bacteremia, or septicemia.
- Past irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- Local tissue factors to prevent proper device stabilization and/or access.
- Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy.
- Presence or suspicion of allergic reaction to materials contained in this device.
- Anatomy is insufficient to accommodate size of the port or the catheter.
- Demonstrated intolerance for an implanted device.

CAUTION: Federal Law (USA) restricts this device for sale by or on the order of a physician.

REFERENCES

1. Stevens, Barbara, et al. "A Randomized, Prospective Trial of Conventional Vascular Ports vs. the Vortex 'Clear-Flow' Reservoir Port in Adult Oncology Patients." Journal of Vascular Access Devices, vol. 5, no. 2, 2000, pp. 37–40.
2. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.' et al. Pinch-off Syndrome: A Complication of Implantable Subclavian Venous Access Devices. Radiology 177: 353-356, 1990.

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SmartPort+
Implantable Port
with Endexo and Vortex Technology

The SmartPort+ Implantable Port with Endexo and Vortex Technology is an implantable port that provides access for both IV therapy and for tests called Contrast-Enhanced Computed Tomography (CECT) scans. You may have heard these tests referred to as "CAT" scans or power injection studies. This is a type of x-ray test that requires a pump to deliver testing fluid fast and at high pressure. This pamphlet provides answers to some of the questions you and your family may have about the SmartPort+ Implantable Port with Endexo and Vortex Technology.

This patient guide is intended to be educational and is not a substitute for the directions for use provided with the device.

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Introduction

Your doctor has prescribed treatment that requires the frequent administration of medications or other fluids directly into your bloodstream and has recommended a SmartPort+ implantable port as the best way for you to receive this treatment. In addition to the administration of fluids and medications, your SmartPort+ device can be used for blood draws and Contrast-Enhanced Computed Tomography (CECT) scans if needed. This patient information guide is designed to answer some of the questions you and your family may have regarding your port. This is only a guide; if you still have questions after reading, please talk with your healthcare provider.

What is a SmartPort+ implantable port?

The device is called an implantable port because it is placed completely under the skin - usually in a convenient and inconspicuous location in your chest or arm.

What are the SmartPort+ implantable ports made of?

The device consists of three parts:

- The port body - a small, hollow chamber made of titanium or plastic with a silicone disk (or septum) at the surface for accessing. The septum is made to be accessed with a special needle (Huber needle) that will allow sealing of the septum upon removal.
- The catheter - a long, soft flexible tube. One end of the catheter is securely connected to the port, and the other end is placed into a large vein in your chest.
- The catheter lock - a component that connects the catheter to the port body.

The SmartPort+ implantable ports are a differentiated product designed to address catheter complications with the *BioFlo** and Vortex technologies. In special lab testing, the BioFlo catheter material has been shown to reduce thrombus (blood component) accumulation.† The Vortex technology offers efficient flushing action to cleanse the port reservoir, resist sludge build up, and reduce occlusions that may occur as a result of treatment.[1] Keeping your port free of complications is an important part of your treatment.

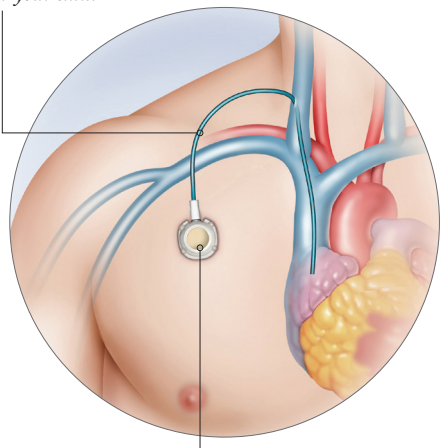
† The in-vitro testing with BioFlo port catheters confirms that the innovative polymer technology is designed to reduce thrombus accumulation by 96% compared to non-coated conventional port catheters (based on platelet count). The reduction in thrombus accumulation was evaluated using in-vitro models. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation. Based on benchtop testing performed up to two hours using bovine bloods which may not be indicative of clinical results. Data on file.

How is your port inserted?

Insertion of the port is a brief procedure done under local or general anesthesia, or sedation. The skin on your chest is first cleaned to remove germs. A small incision is made on your chest to create a space or "pocket" for the port and a "tunnel" for the catheter. The port is inserted under the skin and into the pocket. One end of the catheter is threaded through the tunnel and connected to the port. The other end of the catheter is inserted into a vein in your chest. The tip is positioned near your heart to dilute and distribute your medications. Usually, ultrasound or x-rays are taken during the procedure to make sure the catheter is in the best position. Your incision is stitched closed and covered with a dressing. The healing process may take between one and two weeks. Follow your healthcare providers instructions on the care of your incision and dressings as well as instructions on when the port may be used.

Chest Port Insertion Site

This part of the catheter is in a tunnel under your skin.



This is your chest port site which will be covered with a dressing for a few days until your incision heals.

How is your port used and accessed?

Your healthcare provider can access your port with a non-coring (Huber) needle to give medications or fluids and/or have blood samples withdrawn from your implantable port as part of your IV therapy regimen, eliminating the need to access the veins in your arms with a needle. As a result, treatment may be much more comfortable for you. You may feel a mild pricking when the port is initially accessed. This sensation often gets milder over time.Your SmartPort+ device also provides the ability to perform Contrast-Enhanced Computed Tomography (CECT) scans when accessed with an appropriate power-injectable Huber needle. CECT scans may be ordered by your healthcare team to assist in planning your care.

Identification

How to determine that your port is a SmartPort+ device

There are several ways to determine that you have a SmartPort+ device. Upon receiving your port, your healthcare provider provided you with a packet including a bracelet, identification card, and key ring card. These items let your healthcare provider know that you have a SmartPort+ implantable port. You should always keep your patient identification card with you and present it to your healthcare provider prior to treatment. A trained healthcare provider can also recognize the SmartPort+ device in an X-ray, due to special technology on the port, only visible under X-ray.

What is a Contrast-Enhanced Computed Tomography (CECT) scan?

Contrast-Enhanced Computed Tomography (CECT) scans are safe non-invasive procedures that provide quick and accurate diagnostic information to help your medical team monitor the status of your condition and aid in disease diagnosis. You may have heard of these tests referred to as "CAT" scans or power injection studies. These scans are more sensitive than conventional x-rays. Radiologists can distinguish small differences in your soft tissue that may not be detected with x-rays.

What should you expect during power injection for a CECT scan?

Before performing a CECT scan, the Radiology Team will inject a contrast fluid into your body through your SmartPort+ device to help produce clearer pictures during the CECT scan procedure. Your power injectable port SmartPort+ device, when accessed with an appropriate power injectable Huber needle, has the unique ability to infuse contrast fluid into your blood at a high rate and this procedure is called power-injection. This allows healthcare providers to perform power-injected CECT scans without the need for additional access through veins in your arms or legs.

Commonly asked questions

Q How long will I have my port?

A Your doctor will determine how long you will need your port. When your port is no longer needed, it can be removed in a procedure similar to the one used to implant it.

Q How do I take care for my port?

A After receiving your port, avoid heavy exertion for a few days and follow the instructions your healthcare provider has provided you.

Q Will my port affect my daily activities?

A Once the small incision heals, you should be able to return to your normal daily activities. Ask your healthcare provider about specific activities and the appropriate time to resume them.

Q Will I need to wear a bandage over my port?

A A bandage may be required until your incision heals. After your incision has healed, a bandage is not required. If you are receiving a continuous infusion of fluids, a bandage may be applied to stabilize and protect the needle while it is in place.

Q Do I have to stop wearing certain types of clothing?

A It will depend on where your port is placed. Ask your healthcare provider for further guidance.

Q Will my port need to be accessed when not in use?

A Yes, it will need to be flushed every 4 weeks or according to the practices at the institution where you receive care.

Q Will my port activate security alarms?

A Security systems will most likely not detect the small amount of metal in the device. If it does occur, simply show your patient identification card. You may declare your implant prior to entering security screening in order to be screened in the most appropriate way.

Q Is my port safe with CECTs and MRIs?

A The materials used in the SmartPort+ devices are safe with CECT procedures up to 300 psi. MRI is compatible up to 7 T. Please ask your healthcare provider if you have any questions.

Q What if my healthcare provider has not seen a patient with a SmartPort+ device before?

A Always show healthcare providers your patient identification card as it contains a summary of important information about your port. If they have more questions, they can call the AngioDynamics Clinical Information number at 800-772-6446 option 5.

Q What do I do if I have a question or suspect a problem?

A After the procedure you will see some redness or tenderness in the area. This should go away in 24 to 48 hours. If you notice unusual changes in the skin such as increased swelling, redness or soreness, pain, fever, chills, shortness of breath, or dizziness, then you should contact your health care provider right away.

Talk to your healthcare providers

As a patient with a new medical port device, the best way to be involved is to be informed and to share information and concerns with your healthcare provider.

What information you should share with your healthcare provider

- You have a SmartPort+ implantable port.
- If you notice any redness or inflammation at the site of your implantable port after your incision heals.
- If you have a fever.
- If you have allergies to any medications or materials.
- If you have an allergy to heparin.
- If you are taking blood-thinning medications such as heparin or warfarin.
- If you have previously been treated with radiation.
- If you have ever been diagnosed with, or treated for, venous thrombosis.
- If you have ever been diagnosed with lung disease.
- If you have ever been diagnosed with any tissue diseases or suffered from tissue erosion.
- If other healthcare providers have ever had difficulty withdrawing blood or infusing fluids through your port, including the need for you to change position to allow blood or fluid to flow properly.

Patient check list

- [ ] The SmartPort+ implantable port provides access for IV treatments and power-injected Contrast-Enhanced Computed Tomography (CECT) scans.

- [ ] Your healthcare provider should provide you with a SmartPort+ patient packet including an identification card, bracelet, and key ring card. These help you and your healthcare provider know you have a SmartPort+ device.

- [ ] You should keep your identification care with you and present it to your nurse prior to treatment. If the healthcare provider needs additional information, they may call the AngioDynamics Clinical Information number at 800-772-6446.

- [ ] Speak up and share your concerns with your healthcare provider.

- [ ] Additional patient information and educational tools may be accessed by visiting www.angiodynamics.com.

Commonly used terms

Implantable Port
A fluid and/or medication delivery device with a hollow chamber—called the port—that is connected to a hollow, soft catheter.

Power Injectable Port
A type of implantable port that provides access for both IV therapy and for tests called Contrast-Enhanced Computed Tomography (CECT) scans.

Contrast-Enhanced Computed Tomography (CECT)
A type of x-ray test that requires a pump to deliver testing fluid fast and at a high pressure. These tests are designed to produce superior images of your body to help your medical team better manage your treatment.

Septum
The septum is the center of the port. A non-coring needle is inserted through the septum to deliver your fluid and/or medications.

Catheter
Hollow tube connected to the port body that is inserted into a blood vessel.

Infusion
The delivery of fluid and medication into a blood vessel.

Recommended Flushing Protocols

(to be completed by your healthcare provider)

Maintenance _____

After medication/TPN _____

After blood sampling _____

Additional Instructions

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Notes: