BioFlo Port
with Endexo Technology

A Patient's Guide

angiodynamics

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BioFlo Port
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Companion Checklist

A New Standard of Care

Thank you for being a companion to someone who has received an BioFlo Port with Endexo 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 BioFlo Port with Endexo 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.

TRAVEL CARDS

Always carry your BioFlo 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.

Information about your BioFlo Port with Endexo Technology is available by calling the AngioDynamics Vascular Access Information Line 800.513.6876

BioFlo Port
with Endexo Technology

The BioFlo* Port with Endexo* 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 BioFlo Port with Endexo 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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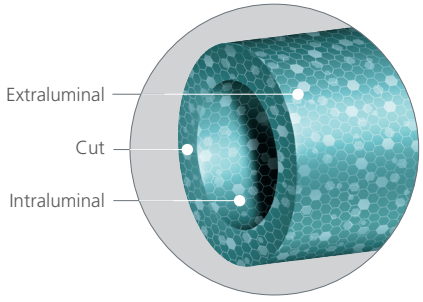
What is Endexo Techology?

The BioFlo Port is the first implantable port with Endexo Technology, providing a catheter material more resistant to the in-vitro accumulation of blood components compared to non-coated conventional port catheters (based on platelet count).†

Endexo Technology

Make protection part of the mix.

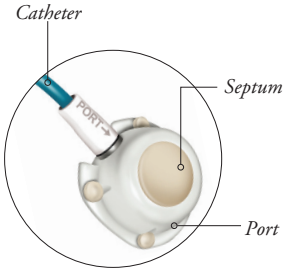
Endexo Technology is a permanent and non-eluting polymer that is "blended" into the polyurethane from which the catheter is made. It is present throughout the extraluminal and intraluminal catheter material, and remains present for the life of the catheter.



† The reduction in thrombus accumulation (based on platelet count) is supported by acute in-vitro testing. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation.

Why do I need a power injectable port?

Your doctor has determined that as part of your treatment, you will need a port to receive your medications by intravenous (IV) injection. This method of drug delivery involves infusion of your medication into a large vein, a blood vessel that directs blood back to your heart. A power injectable port also provides the ability to perform Contrast-Enhanced Computed Tomography (CECT) scans which produce superior images of your body to help your medical team better manage your treatment. With your power injectable port, you will be able to receive both IV therapy and CECT scans.



A power injectable port consists of a small, hollow chamber (the port) and a catheter. The center area of the port is called the septum. The catheter is a long, soft hollow tube. One end of the catheter is securely connected to the port, and the other end is placed into a large vein that delivers blood to your heart. There are a variety of power injectable port systems available. Your port is a non-valved power injectable port.

When a non-coring needle is put into the septum of the port, it creates "access" to your bloodstream, meaning that medicines and fluids can be given and blood samples withdrawn.

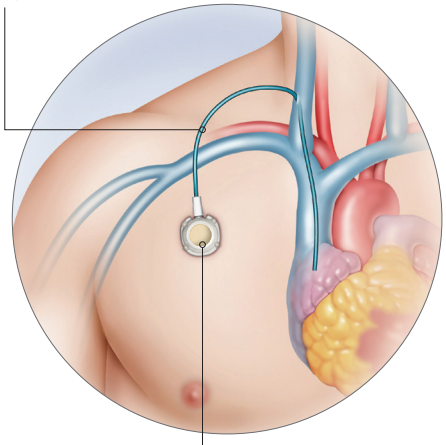
For CECT scans, the power injectable port is used with a power injectable non-coring needle. This enables fluids called contrast agents to be power-injected (delivered at a high rate) into your bloodstream. As a result, vessels in your body show up more clearly, making it easier for your doctor to monitor the status of your condition. Power-injected CECT scans are procedures that provide important information for disease diagnosis and management.

How is a power injectable port inserted?

Insertion of the port is a brief procedure done under local or general anesthesia. 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 help dilute and distribute your medications. Usually, 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 until it heals, a process that takes a few days.

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 do I know I have a BioFlo Port with Endexo Technology?

There are several ways to determine that you have this type of port.

Upon receiving your port, you will also receive a patient identification/key ring card and reminder band identifying you as a patient with an BioFlo Port with Endexo Technology.

Be sure to carry your patient card with you at all times. Show your healthcare provider your patient card before your port is accessed for a procedure. You may also wear the reminder band or carry the key ring card as convenient reminders to tell your healthcare provider you have an BioFlo Port with Endexo Technology.

Your port has the letters "CT" on the port body, which can be detected via an appropriate imaging technology, distinguishing it from traditional ports. Trained healthcare providers can recognize the CT marking under your skin by reading the image.

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

Contrast-Enhanced Computed Tomography (CECT) scans are procedures that provide quick and accurate diagnostic information to help your medical team manage your care. These scans are more sensitive than conventional x-rays. Radiologists can distinguish small differences in your vessels that may not be detected with x-rays.

Before performing a CECT scan, the Radiology Team will inject a contrast agent, which is a fluid that acts like a dye, into your body to help produce clearer pictures during the CECT scan procedure. Your power injectable port, when used with a power injectable non-coring needle, has the unique ability to allow healthcare providers to perform CECT scans.

Commonly asked questions

Q How long will I have my power injectable port?

A Your doctor will determine how long you will need your power injectable 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 of my power injectable port?

A After receiving your power injectable port, avoid heavy exertion for a few days and follow the instructions your doctor or nurse has given you.

Q Will my power injectable port affect my daily activities?

A Once the small 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.

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

A A bandage will be required until your incision heals. After your incision has healed, a bandage is not required. If you are receiving 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 power injectable port is placed. Ask your doctor or nurse.

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

A Yes, it will need to be flushed every 4 weeks.

Q Will my power injectable port activate security alarms?

A Security systems most likely will not detect the small amount of metal in the device. If it does occur, simply show your patient identification card.

Q Is my power injectable port safe with CTs and MRIs?

A Yes. The materials used in the BioFlo Port with Endexo Technology are safe with CT and MRI procedures and injectable fluids used with these procedures. Please ask your doctor or nurse if you have any questions.

Q What if my healthcare provider has not seen a patient with an BioFlo Port with Endexo Technology before?

A The BioFlo Port with Endexo Technology may not be familiar to all clinicians involved in your care. Always show your clinicians your patient identification card as it contains a summary of important information they need to know.

Important information your healthcare provider should know:

- You have an BioFlo Port with Endexo Technology.
- 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 heparin-induced thrombocytopenia (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 any tissue diseases or suffered from tissue erosion.
- If other healthcare providers have ever had difficulty withdrawing blood or infusing fluids through your power injectable port, including the need for you to change position to allow blood or fluid to flow.

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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_____

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Notes:

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BIOFLO PORT WITH ENDEXO TECHNOLOGY

INDICATIONS FOR USE: The BioFlo Port with Endexo Technology is indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal. When used with a power injectable needle, the BioFlo Port with Endexo Technology is indicated for power injection of contrast media. The maximum recommended infusion rate is 5 mL/sec with a 19 G or 20 G noncoring power injectable needle or 2 mL/sec with a 22 G non-coring power injectable needle.

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. Presence of infection, bacteremia, septicemia or peritonitis. 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. Body size is insufficient to accommodate size of the port or the catheter. Demonstrated intolerance for an implanted device.

WARNINGS: Do not suture catheter to port, port stem, or surrounding tissue. Any damage or constriction of catheter may compromise power injection performance and catheter integrity. Do not use syringes smaller than 10 mL when accessing the port as system damage can occur. Flushing occluded catheters with small syringes can create excessive pressures within the port system. Failure to use a power injectable needle with the BioFlo Port with Endexo Technology for a power injection procedure may result in port system failure and patient injury may occur. Failure to ensure patency of the catheter prior to power injection studies may result in port system failure and patient injury may occur. Do not power inject through a port system that exhibits signs of clavicle-first-rib compression or pinch-off as it may result in port system failure and patient injury may occur. Failure to warm contrast media to body temperature may result in port system failure and patient injury may occur. Do not exceed 300 psi pressure limit setting or the maximum recommended flow rate setting. Exceeding these limits may result in port system failure and/or catheter tip displacement. If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately as patient injury may occur.

PRECAUTIONS: To avert device damage and/or patient injury during catheter placement: Avoid accidental device contact with sharp instrument and mechanical damage to the catheter material; Use only smooth-edged atraumatic clamps or forceps; Do not use the catheter if there is any evidence of mechanical damage or leaking; Avoid sharp or acute angles during implantation which could compromise the patency of the catheter lumen(s); Carefully follow the connection technique given in these instructions to insure proper catheter connection and to avoid catheter damage. Assure tight connection between port chamber and catheter. Prior to any treatment palpate correct position of the port body and assure no signs or symptoms of port site irritation or infection exist. Only use non-coring needles to access the port membrane. The non-coring needle tip is intended to prevent damage of the membrane. Palpate the port and port septum then access the septum with the non-coring needle at a 90 degree angle. Puncture skin directly over septum and gently advance needle through septum until it contacts bottom of portal chamber. Do not apply excessive force once the needle contacts the port floor. After implantation and after any treatment via the port, the system should be flushed with normal saline for injection per institutional protocol. For precise drug administration please refer to the individual pharmaceutical instructions. Prior to injection or infusion, aspirate to ensure a brisk blood return. If more than one drug is to be administered, between the individual drug applications, flush the system with 5 to 10 mL normal saline for injection to prevent drug interactions. After any infusion, injection or bolus application, the system should be flushed with normal saline for injection or locked with a heparin solution per institutional protocol to prevent thrombotic occlusion of the catheter. Do not use alcohol to soak or declot polyurethane catheters because alcohol is known to degrade the polyurethane material over time with repeated and prolonged exposure.

Refer to Directions for Use provided with the product for complete instructions, warnings and precautions.

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