EndoForce™ Connector for Endovascular Venous Anastomosis

Patient Guide

Your doctor has given you this Patient Guide to help you learn more about your procedure with the EndoForce™ Connector for Endovascular Venous Anastomosis for connection of a vein to a hemodialysis graft. Please read the entire Patient Guide and discuss any questions that you may have with your doctor.

℞Only

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

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GLOSSARY

Some words in this document might be new or hard to understand. You can use the list of terms to help you while you read. If there are other words you don't know, please ask your doctor to explain them to you.

Term	Definition
Adverse Event	Any unwanted or harmful effect from using a medical product in a patient. The event is serious when the patient outcome is death, life-threatening, requires hospitalization or longer hospitalization, needs medical or surgical treatment to prevent harm, or results in disability or lasting damage.
Anastomosis	A connection between two channels. For example: connection between an artery and a graft (arterial anastomosis) or between a vein and a graft (venous anastomosis).
Angioplasty/ Balloon Angioplasty	A surgery to open a narrowed or clogged blood vessel or graft. A small, thin, plastic tube (called a catheter) with a tiny balloon on the end is placed in the clogged area. The balloon is then blown up to clear the clog and make the vessel or graft wider.
Arteriovenous Graft / AV graft, AVG	A soft tube placed surgically under the skin that connects an artery to a vein. The tube is then used to draw blood using needles for hemodialysis.
Artery	A blood vessel that carries blood away from the heart. Arteries carry blood rich in oxygen to the body.
Catheter	A small, thin, plastic tube that is used to provide access to blood vessels.
Contrast (dye)	A liquid injected into the vessels that helps a doctor to see a patient's blood flow when the patient has an X-ray.
End Stage Renal Disease (ESRD)	A permanent medical condition where the kidneys are damaged and can't clean waste from the blood. Patients with ESRD need hemodialysis to help remove waste from their blood.
ePTFE	Expanded polytetrafluoroethylene is a man-made material that is smooth and doesn't stick. It is used in many medical products, like grafts and the EndoForce™ Connector.
Hemodialysis	A medical process that takes over the job of the kidneys by removing fluid and waste from the blood. To do this, a machine filters the blood and then sends it back to the body.
Intervention/Graft Intervention	A medical procedure done through the skin to help improve the blood flow in grafts. If a graft becomes clogged or too narrow, angioplasty can be used to open it so hemodialysis can be given. A medical procedure may also need to be done to remove the graft if it becomes damaged or infected.

Term	Definition
Introducer/Introducer Sheath	A tube that is placed in an artery or vein so doctors can insert other medical instruments.
Lumen	The inside space of a blood vessel or graft where blood flows.
Magnetic Resonance Imaging (MRI)	A machine that uses magnetic fields and radio waves to see structures inside the body.
Nerve Block	A type of anesthesia where a drug is injected around certain nerves to numb a large area of the body.
Nitinol	A type of metal that is made of nickel and titanium.
Restenosis	Return of a narrowing or clog in a blood vessel or graft.
Stenosis	A narrowing or clog that develops in a blood vessel or graft.
Thrombosis	A blood clot that forms inside a blood vessel or graft, blocking flow.
Ultrasound	A test that uses sound waves and a small device placed on the skin over an AV graft or vessel to check the size of a vessel and how fast the blood is flowing.
Vascular access	A way to reach the blood using needle for hemodialysis. The access lets blood travel to a machine where it is cleaned as it passes through a special filter. This access is usually placed in the arm using surgery.
Vein	A blood vessel that carries blood from the body to the heart.

INTRODUCTION

Vascular Access for Hemodialysis

In patients like you with **end stage renal disease (ESRD)**, the kidneys no longer work well and do not clean your blood like they should. Common ways to treat ESRD are a kidney transplant and **hemodialysis**. A kidney transplant means replacing the diseased kidney with a healthy one from another person. With hemodialysis, which is the more common method, blood is taken out of your body, cleaned by a machine, and then returned to you. The machine removes extra fluid and waste from your blood and helps keep your body's chemicals in balance. This takes about 3 to 4 hours and is usually done 3 times a week.

Before you can start hemodialysis, doctors need to create a special way to access your blood. This is done through surgery. The site of access lets your blood move through soft tubes to a machine where it is cleaned. There are three ways that this can be done. One way is to place a tube (**catheter**) in your chest that sticks out of the skin and can be used when dialysis is needed right away. A second way is called an arteriovenous fistula or AV fistula. With this method, a doctor connects an **artery** (which carries blood from the heart) to a **vein** (which carries blood back to the heart) in your arm. Once the vein becomes big, it may be used to draw blood. The third method is called an **arteriovenous graft**, or AV graft. An AV graft is a soft, yet strong plastic tube that connects an artery to a vein. The doctor will place the graft under the skin in your arm. One end of the graft will be connected to an artery, and the other end to a vein. These connections are called a graft-artery connection and a graft-vein connection.

Connection of an AV Graft to a Vein and Artery

There are two ways to create an AV graft connection:

1. The doctor may make a cut into the side of an artery or vein and sew the cut ends onto the graft ends using a needle and thread-like material called a suture. This is the traditional method.

2. The doctor may use a device called the EndoForce™ Connector for Endovascular Venous Anastomosis to connect your vein to an AV graft. It is placed in your vein using a thin tube called a **catheter**. One end of the EndoForce™ Connector goes inside the vein and the other end sticks out of the vein and fits in the AV graft. The graft is then sewn to the artery in the traditional way. The doctor will decide if the EndoForce™ Connector can be used for you, based on the size and location of your vein.

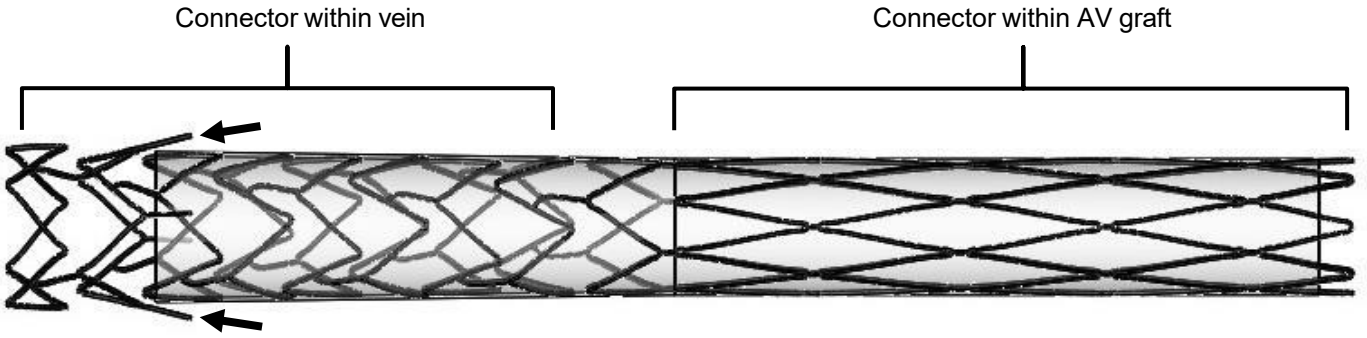
Both treatment options have risks and benefits. Patients should talk with their doctors about which option is best for them.

EndoForce™ Connector for Endovascular Venous Anastomosis

Device Description

The EndoForce™ Connector for Endovascular Venous Anastomosis (also called the EndoForce™ System) includes two parts: the EndoForce™ Connector, which stays in your body permanently, and the EndoForce™ Connector Delivery System, which helps place the connector but is removed from the body at the end of the procedure. The EndoForce™ Connector is a tube made from a metal called **nitinol**, which is a mix of nickel and titanium. It is also coated with a smooth, non-stick material called **ePTFE** (short for expanded polytetrafluoroethylene). The EndoForce™ Connector starts out small inside of a delivery system so the doctor can guide it through the body to the right spot in your vein. The implanted EndoForce™ Connector has three parts: one part that goes inside the vein and has tiny hooks to hold it in place, another part goes inside the AV graft, and a short middle piece between the vein and AV graft (see **Figure 1)**.

Figure 1:
EndoForce™ Connector



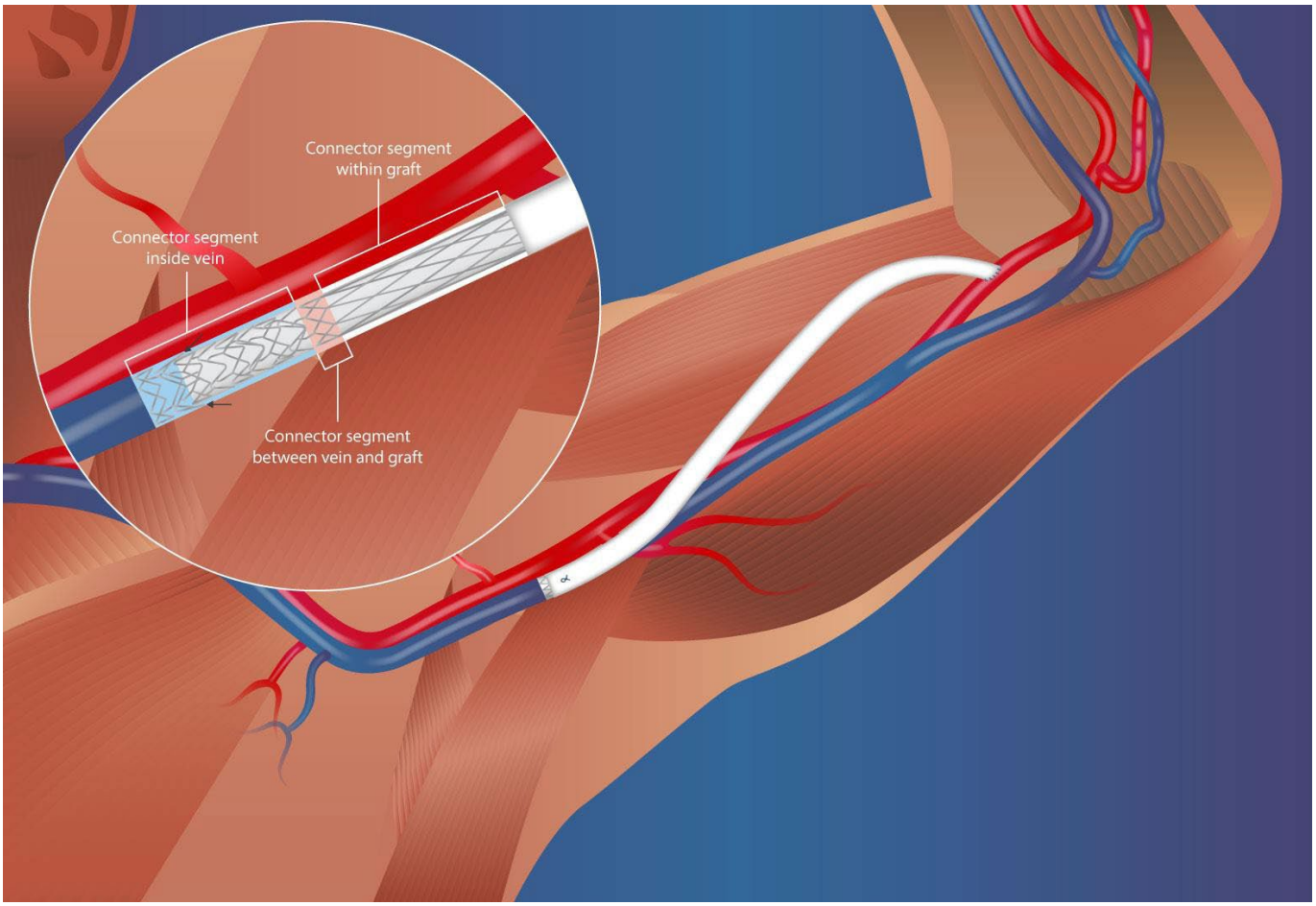
Arrows show tiny hooks that go into the vein wall to hold the implanted Connector in place.

Figure 2 shows an implanted AV graft in the upper arm with a graft-vein connection using the EndoForce™ Connector.

Figure 2:

Implant of an AV Graft in the Upper Arm Using the EndoForce™ Connector

The EndoForce™ Connector connects the vein (blue) to the AV graft (white), creating the graft-vein connection. The graft-artery connection is made by sewing the graft to the artery (red). Figure 2 inset is an "inside view" of the EndoForce™ Connector parts within the vein, between the vein and graft, and within the graft. Arrows show the tiny hooks that go into the vein wall to hold the Connector in place.



When Can the EndoForce™ Connector be used?

The EndoForce™ Connector is a way to attach an AV graft to a vein in the upper arm in patients with ESRD who need hemodialysis. The other end of the AV graft is connected to the artery via traditional suturing. The graft is then used for access during hemodialysis.

The FDA has determined that the EndoForce™ Connector is a safe and effective way to connect a vein to an AV graft placed in the arm.

When Should the EndoForce™ Connector Not be Used?

It is important to tell your doctor about all allergies you know about. The EndoForce™ Connector should not be used in patients who have allergy or sensitivity to the materials used to make the EndoForce™ Connector (ePTFE, titanium or nickel) or to X-ray **contrast** (dye).

What Are the Risks of Using the EndoForce™ Connector?

Possible risks with the EndoForce™ Connector include:

- Placing the device in the wrong place
- Device infection
- Disconnection or movement of the device after it is implanted
- Breakage or other damage of the device after it is implanted, which could cause things like the device being compressed, not opening fully, moving out of place, getting blocked, bending the wrong way, or causing a blood clot.
- Allergic reaction to the materials used in the device (ePTFE, titanium, nickel)

Any of the above events could require surgery.

Possible risks with the procedure used to implant the EndoForce™ Connector include:

- Allergic reaction to the dye used for the X-ray, or the material in the AV graft (ePTFE)
- Bleeding complications
- Bruising
- Bulge in the wall of the artery or pooling of blood around the artery
- Clot in the graft or moving through the blood stream
- Death
- Infection
- Narrowing or blockage of the vein or artery, which could reduce blood flow
- Need to treat or fix problems with the graft
- Putting in a stent or stent graft to fix a problem
- Numbness
- Pain
- Redness, tingling, itchy feeling or peeling skin at the wound site
- Serious injury needing surgery
- Stiffness or swelling of the arm
- Tearing or other damage to the vein or artery

The EndoForce™ Connector is used with a standard ePTFE graft. Possible risks with any graft are explained in the product information provided by the company that made the graft.

What Did the Clinical Study Show?

A total of 158 patients were in a clinical study that was run in the United States. The patients were followed for 6 months after placement of the device. The study results showed that:

- The device was placed correctly in 100% of the patients.
- For at least 6 months after the device was put in, the **vascular access** site created with the EndoForce™ Connector helped with hemodialysis in 92% of patients.
- 35% of patients needed extra procedures within 6 months to keep the vascular access functional.
- 3 patients died during the study in the first 6 months, but their deaths were not linked to the device or procedure.
- 3 patients had a longer hospitalization after the implant procedure for more monitoring. All patients recovered from the event and were discharged.
- 6 patients had infections during the 6 months. None of the infections were linked to the device, but one was linked to the procedure.
- 5 patients had blocked blood flow in the arm where the device was placed. None of the blockages were linked to the device, but all of them were linked to the procedure.

- No patients needed emergency surgery or reported any serious bleeding.

PROCEDURE USING THE EndoForce™ CONNECTOR

Before the Procedure

Your doctor will tell you what you need to do before the procedure.

Your implant surgery will be done in a special operating room that has equipment needed to help put the EndoForce™ Connector into your vein. You will get anesthesia so that you will not feel pain during the procedure. Your doctor will choose the anesthesia that is best for you. This might be general anesthesia which puts you in a deep sleep, or a **nerve block** which keeps you awake but keeps your arm numb so you do not feel pain.

AV Graft Placement Under the Skin

The EndoForce™ Connector is designed to be used with a standard ePTFE AV graft. Your doctor will choose the right AV graft for you and will decide where in your arm the AV graft should be placed.

Your doctor will use regular surgical methods to place the AV graft under your skin. Small cuts will be made in your skin to place the AV graft and EndoForce™ Connector.

Connecting the AV Graft to a Vein and Artery

Your doctor will use a needle to access the vein and will insert a small tube, called an **introducer**. The EndoForce™ delivery system with the EndoForce™ Connector is moved through the small tube and placed in the vein. After the EndoForce™ Connector is placed in the vein, the delivery system is taken out of the body and the graft-end of the EndoForce™ Connector is placed in the AV graft.

Next, the artery is connected to the graft using standard suturing (sewing). A special dye is injected so your doctor can use an X-ray to see the AV graft. This makes sure that there is enough blood flowing through the completed AV graft and that there are no bends.

AFTER YOUR PROCEDURE USING THE EndoForce™ CONNECTOR

After the Procedure

After the procedure, you will be moved to another room where you will be watched closely while you recover. Many patients who have this type of procedure can go home within 24 hours.

Things to Consider with Hemodialysis Access

It is important that you tell your caregivers that your AV graft was put in using the EndoForce™ Connector. Your caregivers will need to avoid placing a hemodialysis needle directly into the EndoForce™ Connector. They will also need to avoid placing constant pressure directly over the area where it is attached to your vein. The doctor who does your AV graft surgery will give you instructions on where the hemodialysis needles can go in your arm. If you or caregivers have any questions about where to place the needles, you should contact the doctor who did your AV graft surgery.

Medicines

You do not need any special medicines because you have the EndoForce™ Connector. Your doctor will let you know if you need to start or keep taking medicines for your regular treatment.

Care after the Procedure

After the procedure, care of the EndoForce™ Connector is the same as the care for any AV graft. You should avoid wearing tight clothes or jewelry on the arm with the graft. You should also avoid carrying heavy things or sleeping on that arm. Also, avoid having anyone take blood or measure blood pressure on this arm.

Your doctor will continue to check the hemodialysis vascular access to make sure the blood flow is fast enough and to check for possible blockages that might be starting. This is usually done using **ultrasound** (sound waves).

Implant Card

Your doctor will give you a card to show that you have an EndoForce™ Connector implant. Keep this card with you at all times and show it to doctors or other healthcare workers when you get medical care. This card will let them know that you have an EndoForce™ Connector in your arm.

Safety During Magnetic Resonance Imaging (MRI)

MRI is a special test that uses magnets to take pictures of the inside of your body. Safety tests were done to show that the EndoForce™ Connector is "MR-Conditional." This means that that a patient with an EndoForce™ Connector implant may safely have an MRI if certain rules are followed. Before you get an MRI, tell the doctor or the MRI technician that you have an EndoForce™ Connector. Also show them your implant card so that they can decide how to do your MRI safely.

Patients with an implanted EndoForce™ Connector should register these MR conditions with the MedicAlert Foundation (*www.medicalert.org).*

FREQUENTLY ASKED QUESTIONS

Can I walk through metal detectors?

Yes, it is safe for you to walk through metal detectors. Walking through a metal detector will not affect or damage the EndoForce™ Connector and the metal detector will not alarm.

Will I be able to feel the EndoForce™ Connector?

There are no nerve endings in the walls of your veins and arteries, so you will not be able to feel the EndoForce™ Connector.

Can the EndoForce™ Connector be removed?

The EndoForce™ Connector is meant to stay in your body, but if your AV graft becomes infected, your doctor may decide to remove the graft and the EndoForce™ Connector.

When can my AV graft connected with the EndoForce™ Connector be used for hemodialysis?

Using the AV graft for hemodialysis depends on the type of AV graft that you have, and not on the EndoForce™ Connector. Most AV grafts can be used for hemodialysis after about 2-6 weeks. Some types of AV grafts are made in a way that allows them to be used right away or within 1-2 days after the graft implant. Your doctor will decide when you can start using your AV graft for hemodialysis.

What should I know about the AV graft?

Your doctor will give you information about your implanted AV graft and answer any questions you may have.