

# FLAIR™

ENDOVASCULAR STENT GRAFT



## Patient Information

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**Y**our doctor has given you this booklet to help you and your family learn more about your disease and also about treatment with the **FLAIR™ Endovascular Stent Graft**.

Be sure to read your booklet. If you have any questions or do not understand something, please ask your doctor or nurse for an explanation.

Be sure to take this “Patient Information” booklet with you at all times. It provides your doctors, nurses, and caregivers with critical information about your **FLAIR™ Endovascular Stent Graft**.

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## What Is Kidney Disease?

In patients like yourself, the kidneys no longer work well and do not efficiently clean your blood. Like you, an estimated 452,000 patients were diagnosed in 2003 with long-term, progressive kidney disease called chronic kidney disease. The two most common causes for this disease are diabetes\* and high blood pressure\*. Chronic kidney disease is rarely curable. Successful treatments, however, such as filtering your blood to clean waste products (peritoneal dialysis\* or hemodialysis\*) or replacing your diseased kidney with a functioning kidney from another person (kidney transplantation\*), can help you carry on with daily life.

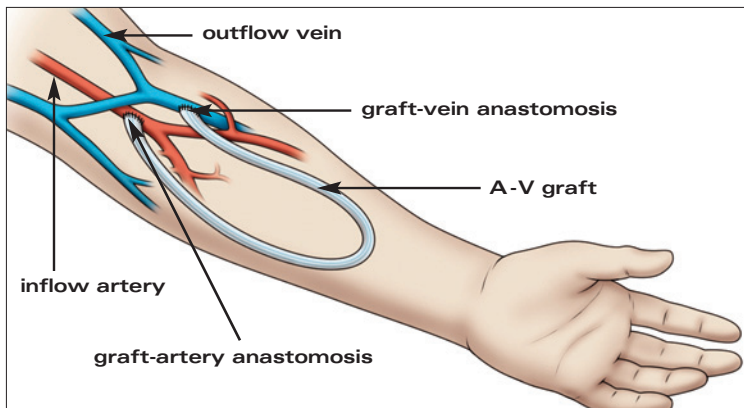
## What Is Hemodialysis?

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Today, the most common treatment for patients like you with chronic kidney disease is hemodialysis. Hemodialysis is a process where your blood is passed through a hemodialysis machine outside your body, called a dialyzer\*. The dialyzer contains special filters and liquids that remove waste products from your blood. Your blood, once “cleaned”, is then returned to your body. Most patients undergo hemodialysis three times per week, and each session lasts 3-4 hours.

To safely and quickly draw your blood and pass it through the dialyzer, your doctor placed a tube made of a special plastic (called an arteriovenous\* or A-V access graft\*) under the skin in your arm. The tube or A-V access graft joins together two different types of blood vessels called an artery\* and a vein\*. A-V access grafts are most commonly made of ePTFE\* (expanded Polytetrafluoroethylene\*), a strong yet flexible plastic material that feels similar to a natural blood vessel. The area where the A-V access graft is connected to your blood vessel is called the A-V anastomosis\*. An example of an A-V access graft is shown in *Figure 1*.

*\*Please see glossary for definition*



**Figure 1:** Forearm loop ePTFE A-V Access Graft

Your A-V access graft becomes an artificial blood vessel that can be used over and over again to draw blood with a needle during hemodialysis. During your hemodialysis session, two hollow needles are inserted into your A-V access graft. One needle is used to draw blood out of your body and bring it to the dialyzer while the second one returns the clean blood to your body.

## How Do I Know My A-V Access Graft Is Working?

Your A-V access graft is your lifeline\*.

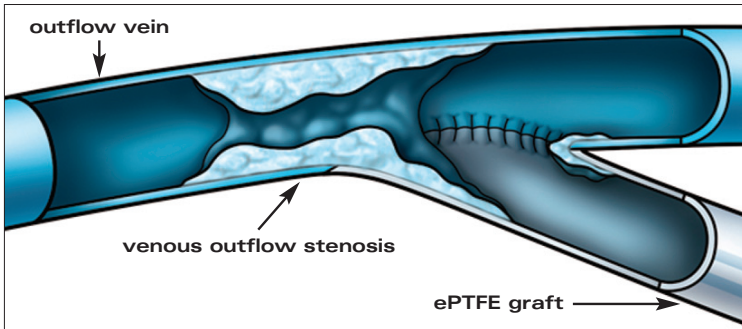
**CAUTION:** Each day you should check your A-V access graft to make sure it is working properly. Make sure you feel a pulse\* or the vibration of blood (called thrill\*) along the entire length of your A-V access graft. Your A-V access graft may not be working properly if you notice any of the following signs:

- The feeling of increased pressure in your A-V access graft during dialysis treatment;
- Continued bleeding at the needle sites after dialysis;
- No feeling of blood vibrating through your access graft (i.e., no thrill); or
- Arm swelling.

*\*Please see glossary for definition*

## Blockage of Your A-V Access Graft

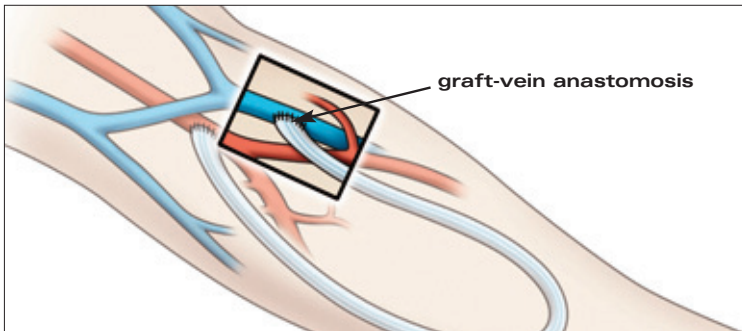
Tissue\* and cells\* can build up at the connection point between your A-V access graft and natural blood vessel (i.e., vein). This causes a narrowing or blockage called a stenosis\* that limits blood flow (See Figure 2).



**Figure 2:** Blockage or stenosis at the connection point between an A-V access graft and blood vessel

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A blockage in your A-V access graft can cause the graft to not work properly and prevent you from undergoing hemodialysis (See Figure 3).



**Figure 3:** The most frequent area of blockage

**CAUTION:** Signs of a blockage or stenosis include:

- Loss of pulse along the length of your A-V access graft;
- Continued bleeding at the needle sites after your dialysis has ended;

*\*Please see glossary for definition*

- No feeling of blood vibrating through your access graft (i.e., no thrill); or
- Arm swelling.

**CAUTION: Your graft will last longer if complete blockage (i.e., thrombosis\*) can be avoided. Therefore, inform your doctor immediately if you notice any of the above warning signs so that he/she can reopen your A-V access graft as soon as possible (Note: additional treatment may be necessary to avoid complete blockage and reopen your A-V access graft).**

## **Treatment Options**

Three options can be used by your doctor to reopen a blocked A-V access graft:

**1 Balloon Inflation (Balloon Angioplasty\*):** First, a small, hollow tube (access sheath\*) is inserted into your A-V access graft. Second, dye is injected through the tube by your doctor so that he/she can see the area of blockage. A second, smaller, spaghetti-sized hollow tube (catheter\*) with a small balloon on one end is then placed through the slightly larger tube that is already in your A-V access graft. Next, the balloon is moved to the area of blockage by your doctor using an x-ray camera (fluoroscopy\*) for guidance. Finally, the balloon is positioned in the narrowed part of your A-V access graft and inflated to open the blockage.

In some cases, balloon inflation opens the narrowed area sufficiently; but in other cases, balloon inflation may not open the area enough to achieve lasting results. Narrowing may return several weeks after balloon inflation, again resulting in a blocked A-V access graft. Also, the narrowed area may open temporarily with inflation of the balloon, but immediately narrow again once the balloon is deflated. In both cases, the above mentioned signs of blockage may return.

***\*Please see glossary for definition***

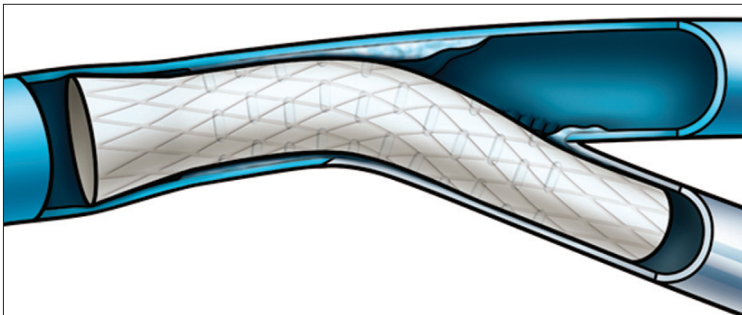
**2 Surgery (Operation):** A doctor (i.e., surgeon\*) can perform an operation to remove the blockage surrounding the connection between your blood vessel and A-V access graft. The blocked area is either replaced or passed around using a new piece of A-V access graft material or a portion of your natural blood vessel (i.e., vein).

**3 Placement of the FLAIR™ Endovascular Stent Graft:**

This is a new method of treating blockages in your A-V access graft. This treatment combines the use of balloon inflation (see Option 1) followed by placement of a metal support tube covered with material similar to your A-V access graft to keep the blocked area open. The metal support tube and material covering the metal are together called a stent graft\*.

As described above, balloon inflation is first performed to open the narrowed segment in your A-V access graft. The **FLAIR™ Endovascular Stent Graft**, mounted on the end of another hollow tube or catheter similar to the balloon, is inserted through the same pathway in your access graft and placed across the narrowed segment that has just been opened with the balloon. The **FLAIR™ Endovascular Stent Graft** is then opened by your doctor in the previously narrowed area. When opened, the device presses against your A-V access graft and blood vessel to keep the area open (See Figure 4).

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**Figure 4:** Previously blocked area after use of the **FLAIR™ Endovascular Stent Graft**

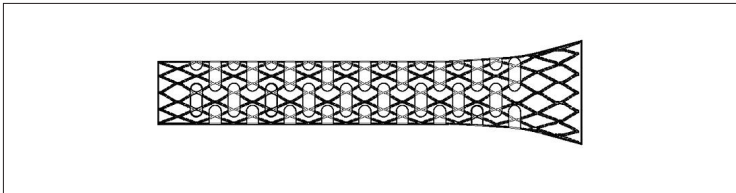
*\*Please see glossary for definition*

The benefit of the **FLAIR™ Endovascular Stent Graft** over balloon inflation alone has been shown in a study in the United States of patient volunteers with A-V access graft blockages like yours. Please ask your doctor for more information about the results of the study.

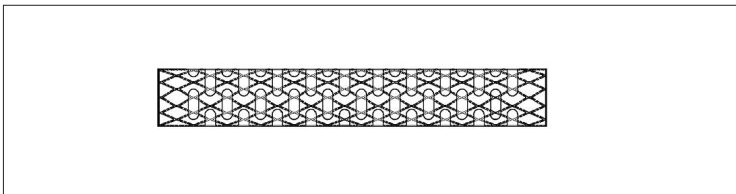
### **What Is the FLAIR™ Endovascular Stent Graft (Device Description)?**

The **FLAIR™ Endovascular Stent Graft** is a flexible support tube made of a special metal called Nitinol\* covered with the same kind of material that makes up your A-V access graft (ePTFE). Nitinol is a metal designed to expand to a predetermined size once it is warmed by the heat of your body.

The **FLAIR™ Endovascular Stent Graft** is available in both flared (*Figure 5*) and cylinder shapes (*Figure 6*).



**Figure 5:** Flared configuration



**Figure 6:** Cylindrical configuration

*\*Please see glossary for definition*

### ***When can the device be used (Indication for Use\*)?***

The **FLAIR™ Endovascular Stent Graft** is indicated for use in the treatment of stenoses at the venous anastomosis of ePTFE or other synthetic arteriovenous (A-V) access grafts. **In other words, the device can be used to support or hold open a blocked area at the connection of your A-V access graft and natural blood vessel (i.e., vein).**

### ***When should the device not be used***

***(Contraindications\*)?*** There are no known reasons not to use the **FLAIR™ Endovascular Stent Graft** for the treatment of blockages at the connection of your A-V access graft and blood vessel.

## **Important Questions to Ask Your Doctor Before the Procedure**

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### **Q What additional tests can I expect if my doctor suspects a blockage of my A-V access graft?**

Your doctor might evaluate your A-V access graft with a sound-wave test called ultrasound\*. Using an instrument placed on top of your skin, your doctor can measure the size of your blood vessels and the flow of your blood from outside your body.

You may also be referred for an x-ray test called a venogram\*. Dye is injected into your blood vessels through a small tube placed in your arm. The dye is visible with x-ray, and allows your doctor to see the narrowing in your A-V access graft.

*\*Please see glossary for definition*

## **Q** How do I know whether the **FLAIR™ Endovascular Stent Graft** is right for me?

You are considered a candidate for treatment with the **FLAIR™ Endovascular Stent Graft** unless you have any of the following conditions:

- Blood-clotting\* disorders;
- Blood poisoning (called septicemia\*);
- Allergy or sensitivity to nickel-titanium\*, the metals that make up the special nitinol support tube;
- Allergy or sensitivity to x-ray dye that can not be treated with drugs given to you by your doctor prior to the procedure;
- Infected A-V access graft; or
- New A-V access graft (the graft has been in your arm for less than 30 days).

Please talk to your doctor to determine whether the **FLAIR™ Endovascular Stent Graft** is right for you. Your doctor should consult the **FLAIR™ Endovascular Stent Graft** "Instructions for Use" (available on [www.bardpv.com](http://www.bardpv.com) or call 1-800-562-0027) for a complete list of warnings and precautions.

Below is a partial list that might help you decide whether the **FLAIR™ Endovascular Stent Graft** is right for you:

**WARNINGS:** The **FLAIR™ Endovascular Stent Graft** is designed to stay in your body permanently. It can only be removed by a doctor through an operation (i.e., surgical removal).

**PRECAUTIONS:** The safety and effectiveness of the device if placed across an angle that is greater than 90° (a full L-shaped bend) have not been established.

The safety and effectiveness of the device placed across the elbow (resulting in repeated bending of the device) have not been established.

## **Q** What risks can I face as a result of the procedure with the *FLAIR™ Endovascular Stent Graft*?

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Your doctor should discuss the procedure in detail with you and explain the possible risks and potential benefits of the device. Please make sure that your doctor answers all of your questions.

The procedure may cause some pain and discomfort. You may feel pressure in your arm when the balloon is inflated and possibly pressure and a burning sensation when x-ray dye is injected into your access graft.

**WARNING:** Although rare, dye injection may produce an allergic reaction causing low blood pressure and breathing difficulties. It is important that you tell your doctor about any allergies you might have before the procedure.

**CAUTION: The procedure used to place the *FLAIR™ Endovascular Stent Graft* may involve certain risks. These risks include but are not limited to:**

- Complete blockage of your A-V access graft (i.e., thrombosis\*);
- Re-narrowing of your A-V access graft (i.e., restenosis\*) requiring another procedure;
- A bulge or enlargement of your blood vessel (i.e., pseudoaneurysm\*);
- A tear or break in your blood vessel;
- A hole in your blood vessel;
- Pain;
- Infection;
- Excessive bleeding;
- Arm or hand swelling;
- A lack of blood flow to the area around your A-V access graft and blood vessel that can prevent enough blood from flowing to other parts of your body (i.e., steal syndrome\*);
- Heart failure caused by loss of pumping power by the heart, resulting in fluids collecting in the body (i.e., congestive heart failure\*);
- Bleeding or blockage of blood flow in the brain sometimes leading to loss of consciousness, feeling, and motion (i.e., stroke\*); or
- Death.

**CAUTION: Specific risks associated with stent grafts like the *FLAIR™ Endovascular Stent Graft* include:**

- Placement of the device in the wrong spot;
- Movement of the device once it is placed in your body;
- Breakage of the metal support tube (i.e., fracture\*);
- Bending or kinking of the device;
- The device not opening enough in your body; or
- Movement of the device causing blockage of blood flow.

The above device-related events might result in additional procedures and/or the placement of a second **FLAIR™ Endovascular Stent Graft**.

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**Q**

**What is the potential benefit of using the *FLAIR™ Endovascular Stent Graft*?**

The benefit of the **FLAIR™ Endovascular Stent Graft** over balloon inflation alone has been demonstrated in a study in the United States of patient volunteers with A-V access graft blockages like yours. For more details about the study and the benefits of the **FLAIR™ Endovascular Stent Graft**, please talk to your doctor.

*\*Please see glossary for definition*

## **Treatment After Placement of Your FLAIR™ Endovascular Stent Graft**

**WARNINGS:** It is important that you explain to your caregivers and nurses that you have a **FLAIR™ Endovascular Stent Graft**. When performing dialysis, they need to avoid:

- Placing a dialysis needle directly into the **FLAIR™ Endovascular Stent Graft**, or
- Applying constant pressure directly over the area where the **FLAIR™ Endovascular Stent Graft** has been placed.

If you have questions or concerns about the care of your **FLAIR™ Endovascular Stent Graft** after placement, please contact your doctor.

## **Safety During Magnetic Resonance Imaging (MRI\*)**

After placement of your **FLAIR™ Endovascular Stent Graft**, your doctor may request a special test that uses electric waves from a magnet to obtain images of the inside of your body, called an MRI. Your **FLAIR™ Endovascular Stent Graft** is classified as MR-Conditional. This means that an MRI can be done safely if specific testing conditions are followed.

For further details on how an MRI can be performed safely following placement of your device, your doctor can refer to the “Instructions for Use” for the **FLAIR™ Endovascular Stent Graft** available on [www.bardpv.com](http://www.bardpv.com) or call 1-800-562-0027.

## Glossary

Arteriovenous (A-V)	A term that refers to two different kinds of blood vessels — an artery and a vein.
Access Sheath	A hollow tube used to enter the body.
A-V Access Graft	A tube made of a special plastic that joins together an artery and a vein. Your doctor placed an A-V access graft under the skin in your arm so that blood can be drawn safely and quickly with a needle to be filtered and cleaned.
A-V Anastomosis	The connection between an A-V access graft and blood vessel.
Artery	A blood vessel that carries blood from the heart and lungs through the body. Blood in arteries is full of oxygen.
Balloon Angioplasty	A procedure where a small hollow tube with a balloon on one end is inflated inside of a blood vessel to open a blocked or narrowed area.
Blood Clot	A clump of blood cells that blocks or prevents normal blood flow.
Blood Vessel	A series of natural tubes in the body that carry blood from (artery) or to (vein) the heart.
Catheter	A thin, hollow tube that is generally used to carry fluids into or out of the body. It can also be used to place something in the body, like a balloon or stent graft.
Cell	The smallest basic unit of all living organisms. Sometimes called the “building block of life.”
Congestive Heart Failure	Heart disease caused by loss of pumping power of the heart. A condition where a diseased heart can not pump out all of the blood. As a result, fluid builds up in the blood vessels and body tissues.
Contraindications	A condition that makes a specific treatment or procedure improper or undesirable.
Diabetes	A disease where the body does not properly control the amount of sugar in the blood. As a result, the level of sugar in the blood is too high. Diabetes can lead to kidney problems like yours.

Dialyzer	A machine that filters blood. Used for patients like you with chronic kidney disease. Blood containing waste products is run through filters outside of your body and then returned once it is cleaned.
ePTFE	Expanded Polytetrafluoroethylene. A strong, flexible plastic that is used to make artificial blood vessels. More than likely your A-V access graft is made of ePTFE. It is the most popular material to make A-V access grafts, and is used as the covering for the <b>FLAIR™ Endovascular Stent Graft</b> .
Fluoroscopy	A medical procedure that involves a moving x-ray image of the body. By injecting dye and using a moving x-ray machine, your doctor can see a movie of the inside of your blood vessels rather than just a still photo.
Fracture	A break or crack. In this case, a break or crack in the metal support tube of a stent graft.
Hemodialysis	A procedure that uses a machine outside of your body to filter or clean your blood because your kidneys are not working properly.
High Blood Pressure	Called hypertension. A condition where there is too much pressure inside of your blood vessels. Blood is pushed too hard by the heart against the blood vessel walls. High blood pressure can lead to kidney problems like yours.
Indications for Use	When a device or procedure can be used.
Kidney Transplantation	A procedure that replaces a diseased kidney from one person with a healthy kidney from another person.
Lifeline	A term that refers to a support that enables people to live. In this case, it is used to indicate the importance of your A-V access graft.
MRI	MRI stands for Magnetic Resonance Imaging. A test that uses electric waves from a moving magnet to obtain images of the inside of your body.

Nickel-Titanium	Two metals that when combined make nitinol (defined below). Some people are allergic to nickel-titanium, so it is important that you tell your doctor about any allergies that you may have before your procedure.
Nitinol	A special metal made of nickel and titanium that remembers its shape. Nitinol can be compressed when cold and expands back to its original shape and size when heated. Nitinol is used as the support tube in many stent grafts, including the <b>FLAIR™ Endovascular Stent Graft</b> . The special properties of a tube made of nitinol allow it to expand to fit your blood vessel once it is heated by the temperature of your body.
Peritoneal Dialysis	A method used to filter your blood when the kidneys are not working properly. First, a soft plastic tube called a catheter (see definition above) is surgically inserted into your abdomen (belly). The tube is used to fill the abdomen with a special fluid called dialysis solution. Your blood is then filtered through this solution that pulls wastes from your blood. The special fluid and waste can then be drained from your body.
Pseudoaneurysm	Also known as a false aneurysm. A bulging or enlargement of a blood vessel or A-V access graft caused by some kind of damage. For example, a false aneurysm can be created in an A-V access graft by repeated needle sticks in the same spot.
Pulse	A rhythm or beat felt when touching the skin over your blood vessels. Your pulse is created by the beating of your heart.
Septicemia	Blood poisoning.
Steal Syndrome	A lack of blood flow to the area around your A-V access graft. This condition can prevent enough blood from flowing to other parts of your body such as your hands and fingers. The lack of blood flow can cause the hands and fingers to be painful, discolored, or cold.

Stenosis or Restenosis	The narrowing or blockage of an A-V access graft or blood vessel caused by the buildup of tissue and cells. Restenosis refers to a return of the narrowing or blockage after the area has already been opened.
Stent Graft	A metal support tube that is covered by a material similar to the material that makes up your A-V access graft. A stent graft provides support for a blood vessel that has been narrowed or blocked.
Stroke	Temporary or permanent loss of blood supply to the brain. This condition can lead to a loss of feeling, motion, speech, or death.
Surgery	The treatment of diseases or other medical conditions by operating on a patient to remove or repair parts of the body.
Surgeon	A medical doctor that specializes in doing surgery or operations.
Thrill	The vibration or tremble of blood that you can feel flowing through your A-V access graft.
Thrombosis	A complete blockage inside your A-V access graft.
Tissue	A group of cells (“building blocks”) that work together to perform a specific function. Your A-V access graft can become blocked by the buildup of cells and tissue.
Ultrasound	A sound wave test. Using an instrument placed over your blood vessel on top of your skin, your doctor can measure the size of your blood vessels and the flow of your blood without entering your body.
Vein	A blood vessel that carries blood from the organs of the body back to your heart.
Venogram	An x-ray test where dye is first injected into your blood vessels through a catheter. The dye is visible with x-ray, and allows your doctor to see a narrowing or blockage in your blood vessel or A-V access graft.

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