Patient Information Guide

COVERA™ Vascular Covered Stent

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If you or a member of your family has been diagnosed with chronic kidney disease and are being treated with **hemodialysis**, you may have questions about the disease and treatment options, especially if your doctor is proposing to treat you using the COVERA™ Vascular Covered Stent.

This guidebook is designed to help you and your family members understand kidney disease, **hemodialysis** and treatment with a vascular **covered stent**. While this guidebook answers some of the questions patients often ask, it is not meant to replace the medical advice from your doctor. If you have any questions as you read this guidebook, please write them down and discuss them with your doctor or nurse.

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Understanding Kidney Disease

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 20 million people in the United States may have 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.

The two most common treatments for patients like you with chronic kidney disease are 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).

What 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** 3 times per week, and each session lasts 3-4 hours.

What is Arteriovenous Access?

To safely and quickly draw your blood and pass it through the **dialyzer**, your doctor placed either a tube made of special material called an **arteriovenous** (or **AV**) graft under the skin in your arm (see Figure 1) or created an **AV fistula**, which connects an **artery** and a **vein** (see Figure 2).

Your **AV** graft or fistula is used over and over again to draw blood with a needle during **hemodialysis**. During your **hemodialysis** session, two hollow needles are inserted into your **AV** access. 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.

This guidebook is meant to address use of the COVERA™ Vascular Covered Stent as a treatment option after your **AV** graft has been implanted.

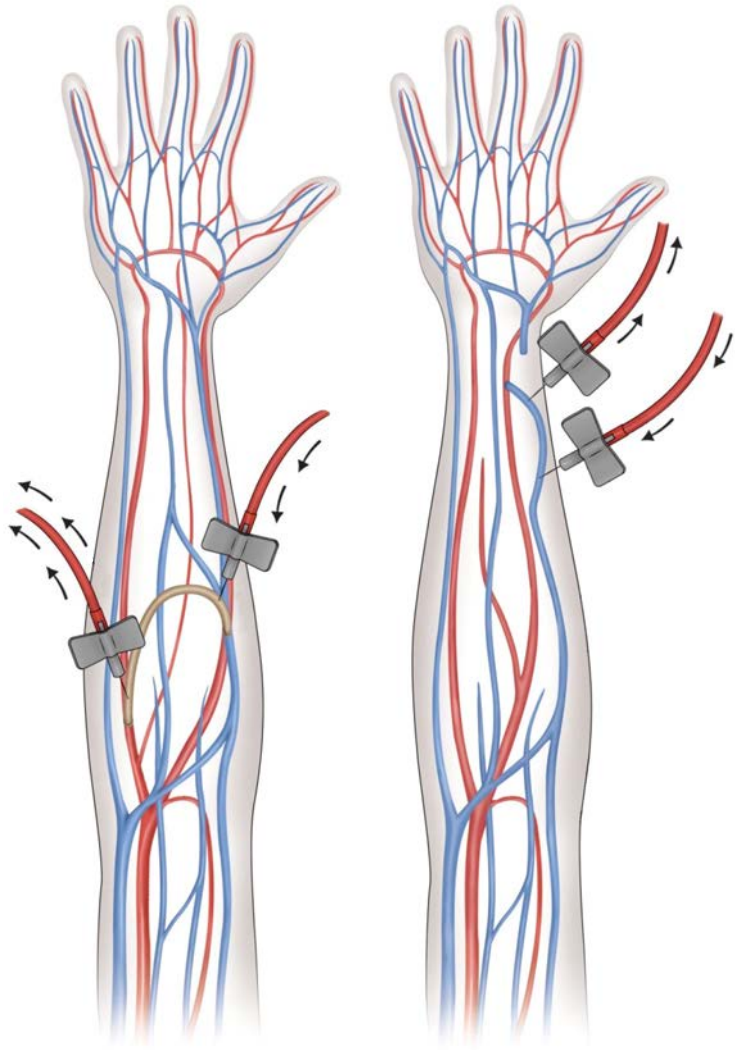


Figure 1 Figure 2

How do I know if My AV Access is Working?

Your **AV** access is your lifeline, and you should check every day 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 access by gently pressing the area with your finger. Your access may not be working properly if you notice any of the following signs:

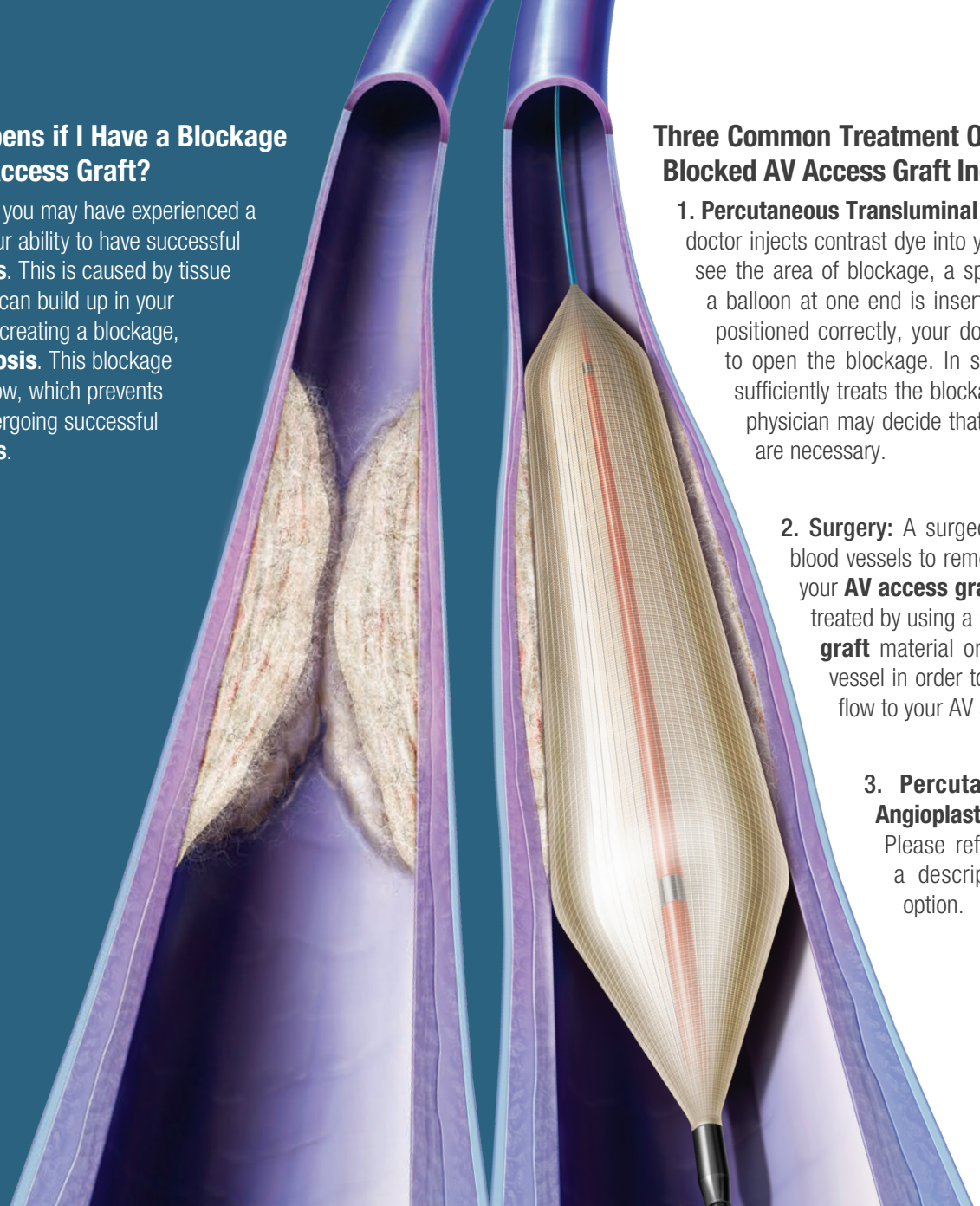
- The feeling of increased pressure in your access during dialysis treatment
- Continued bleeding at the needle sites after dialysis
- No feeling of blood vibrating through your access (i.e. no **thrill**)
- Arm swelling

While checking to ensure your **AV** access is working, it's important to keep your access site clean in order to avoid the risk of infection. If you suspect an infection has occurred, please contact your healthcare provider immediately.

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

What Happens if I Have a Blockage in My AV Access Graft?

At some point you may have experienced a problem in your ability to have successful **hemodialysis**. This is caused by tissue and cells that can build up in your blood vessels creating a blockage, called a **stenosis**. This blockage limits blood flow, which prevents you from undergoing successful **hemodialysis**.



Three Common Treatment Options to Reopen a Blocked AV Access Graft Include:

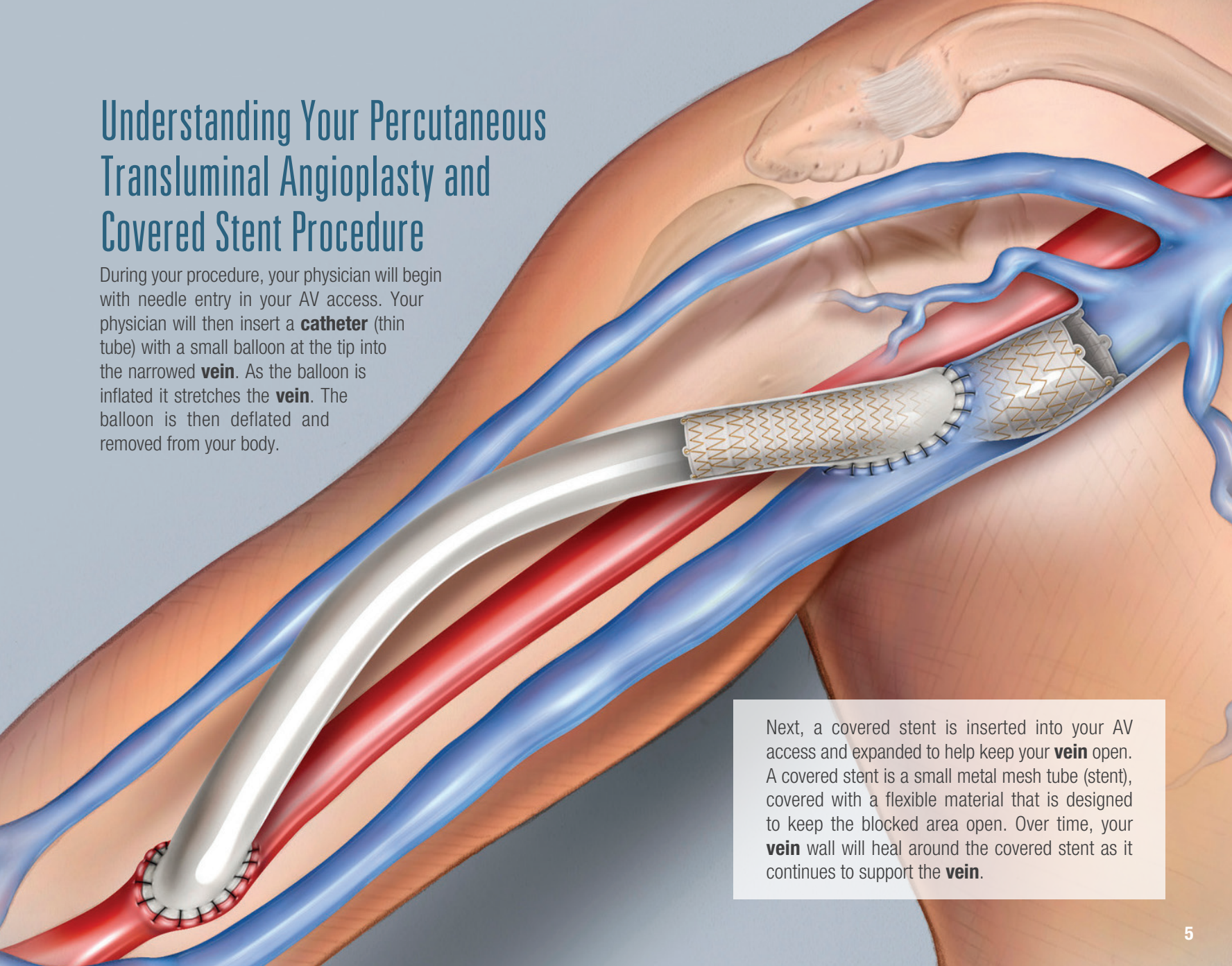
1. **Percutaneous Transluminal Angioplasty:** After your doctor injects contrast dye into your **AV access graft** to see the area of blockage, a specialized **catheter** with a balloon at one end is inserted. Once the balloon is positioned correctly, your doctor inflates the balloon to open the blockage. In some cases, the balloon sufficiently treats the blockage. In other cases, your physician may decide that other treatment options are necessary.

2. **Surgery:** A surgeon can operate on your blood vessels to remove the blockage around your **AV access graft**. The blockage can be treated by using a new piece of **AV access graft** material or with your native blood vessel in order to restore adequate blood flow to your AV access.

3. **Percutaneous Transluminal Angioplasty and Covered Stenting**: Please refer to the next page for a description of this treatment option.

Understanding Your Percutaneous Transluminal Angioplasty and Covered Stent Procedure

During your procedure, your physician will begin with needle entry in your AV access. Your physician will then insert a **catheter** (thin tube) with a small balloon at the tip into the narrowed **vein**. As the balloon is inflated it stretches the **vein**. The balloon is then deflated and removed from your body.



Next, a covered stent is inserted into your AV access and expanded to help keep your **vein** open. A covered stent is a small metal mesh tube (stent), covered with a flexible material that is designed to keep the blocked area open. Over time, your **vein** wall will heal around the covered stent as it continues to support the **vein**.

What is the COVERA™ Vascular Covered Stent?

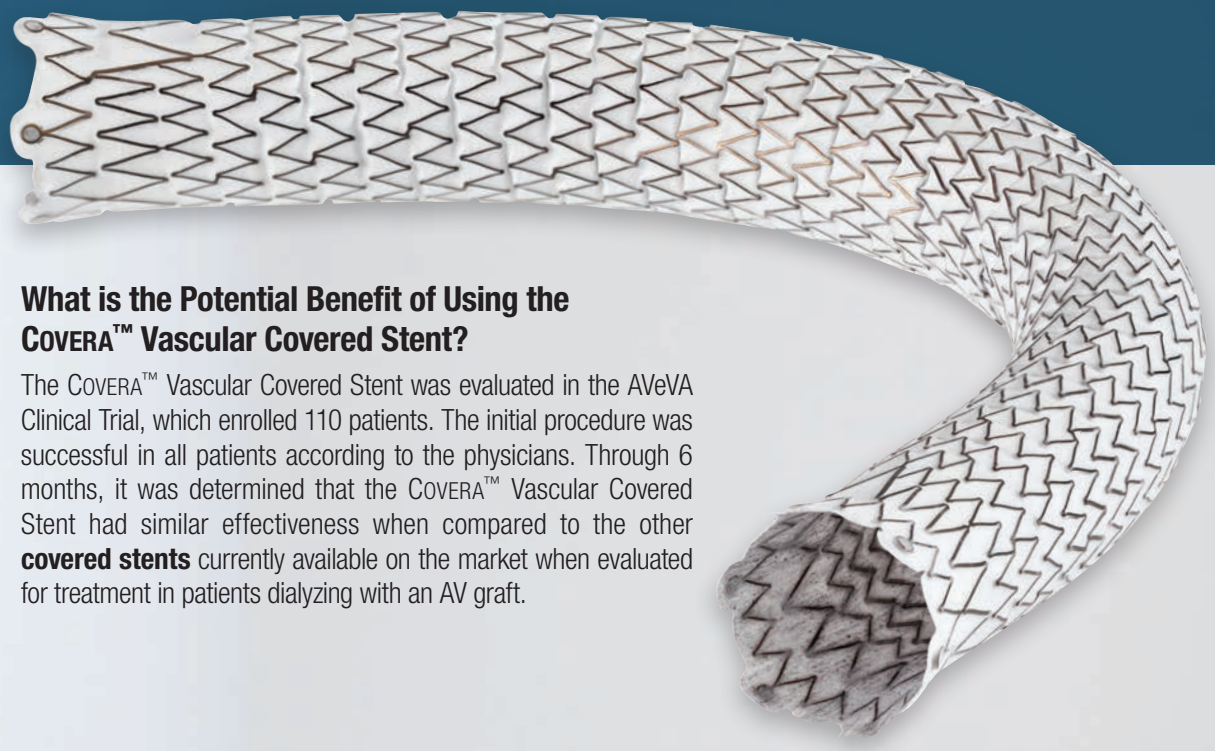
The COVERA™ Vascular Covered Stent is a flexible mesh tube made from **nitinol**, which is a nickel titanium alloy that has shape memory and is designed to expand to a specified size when warmed to body temperature. The **nitinol** tube is covered with a flexible material called expanded polytetrafluoroethylene, or **ePTFE** for short. The **covered stent** comes inside a delivery system **catheter** which allows the doctor to advance it through your body to the specific narrowing in the **vein**.

When Can the Device Be Used (Indications for Use)?

The COVERA™ Vascular Covered Stent is intended to treat narrowing (**stenosis**) in upper arm **veins** of patients who are dialyzing with an **arteriovenous** (AV) graft. The COVERA™ Vascular Covered Stent is only intended to treat the narrowing at the location where your **AV access graft** is sutured to your **vein**.

When Should the Device Not Be Used (Contraindications)?

There are no known specific situations in which the COVERA™ Vascular Covered Stent should not be used because it may be harmful to you.



What is the Potential Benefit of Using the COVERA™ Vascular Covered Stent?

The COVERA™ Vascular Covered Stent was evaluated in the AVeVA Clinical Trial, which enrolled 110 patients. The initial procedure was successful in all patients according to the physicians. Through 6 months, it was determined that the COVERA™ Vascular Covered Stent had similar effectiveness when compared to the other **covered stents** currently available on the market when evaluated for treatment in patients dialyzing with an AV graft.

What are the Risks of the COVERA™ Vascular Covered Stent Implantation Procedure?

As with any procedure, there is a chance that complications may occur. The following are some of the risks that may be associated with your **covered stent** implantation procedure. Be sure to discuss any questions you may have with your doctor.

- Formation of **blood clots**
- Recurrence of the narrowing/blockage (**restenosis**)
- A bulge or enlargement of the blood vessel (**pseudoaneurysm** or false **aneurysm**)
- A tear or break in the blood vessel
- A hole in the blood vessel (extravasation)
- Bleeding at access site
- Pain
- Sepsis/Infection
- Bruising/swelling at procedure site (hematoma)
- Arm or hand swelling (edema)
- A sudden contraction of the blood vessel (vasospasm)
- Perforation
- Dissection
- Numbness
- Lack of blood flow to the area around the AV access and blood vessels (**steal syndrome**)
- **Congestive heart failure**
- **Stroke** (cerebrovascular accident)
- Allergic reaction
- Rash
- Reaction to contrast
- Fever
- Prolonged bleeding
- Heart rhythm disturbance (ventricular fibrillation)
- Face or neck swelling (edema)
- Coughing up blood (hemoptysis)

Important Questions

Q: What additional tests can I expect if my doctor suspects a blockage of my AV access graft?

Your doctor might evaluate your **AV 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 **AV access graft**.

Q: How do I know whether the COVERA™ Vascular Covered Stent is right for me?

Please talk to your doctor to determine whether the COVERA™ Vascular Covered Stent is right for you. Your doctor should consult the COVERA™ Vascular Covered Stent "Instructions for Use" (available on www.bardpv.com or call 1-800-562-0027) for a complete list of warnings and precautions.

You are considered a candidate for treatment with the COVERA™ Vascular Covered Stent unless you have any of the following conditions:

- Blood-clotting disorders;
- Blood poisoning (called septicemia);
- Allergy or sensitivity to nickel-titanium or tantalum, the metals that make up the stent;
- Allergy or sensitivity to x-ray dye that cannot be treated with drugs given to you by your doctor prior to the procedure;
- Infected **AV access graft**; or
- New **AV access graft** (the graft has been in your arm for less than 30 days).

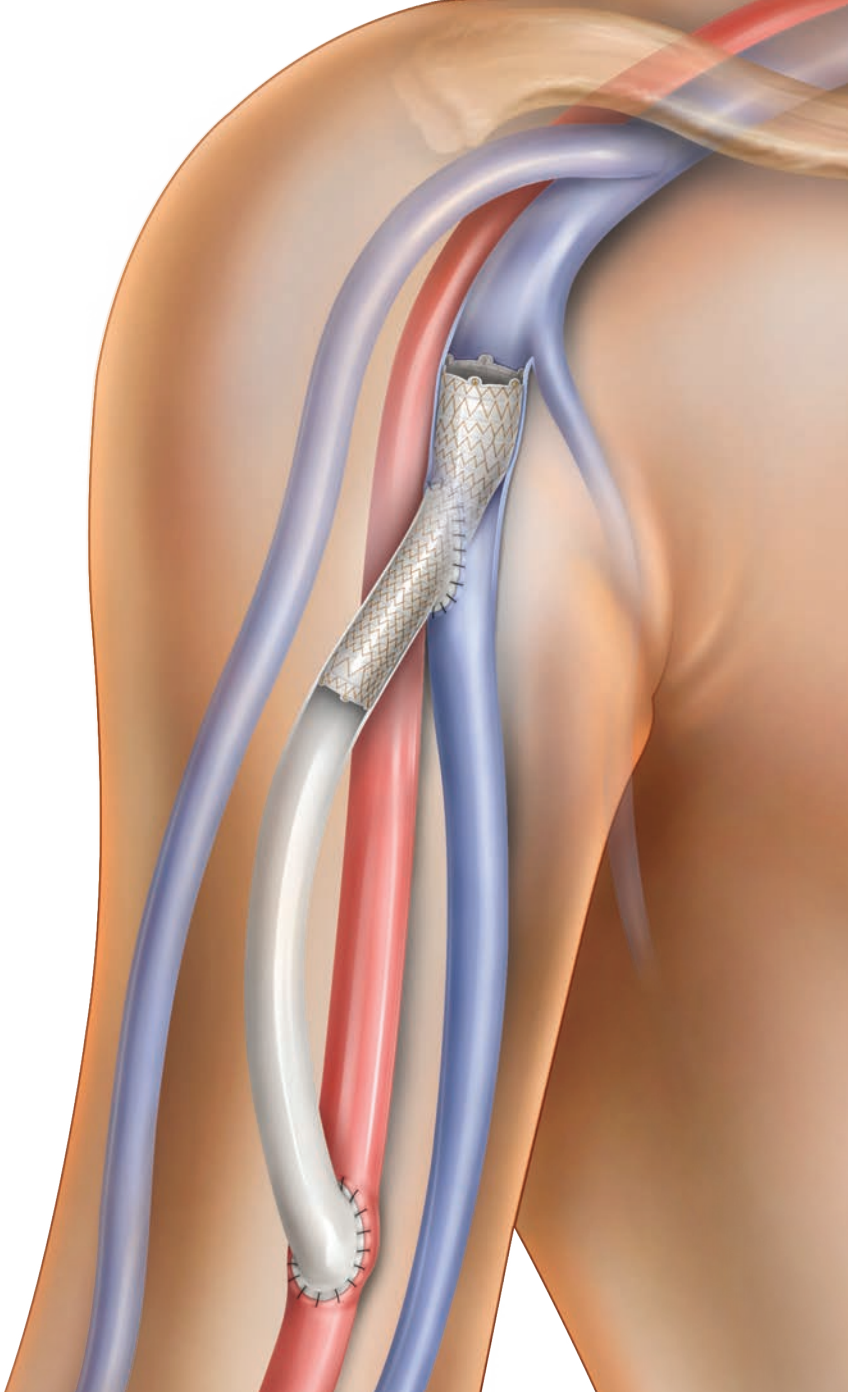
Important Questions

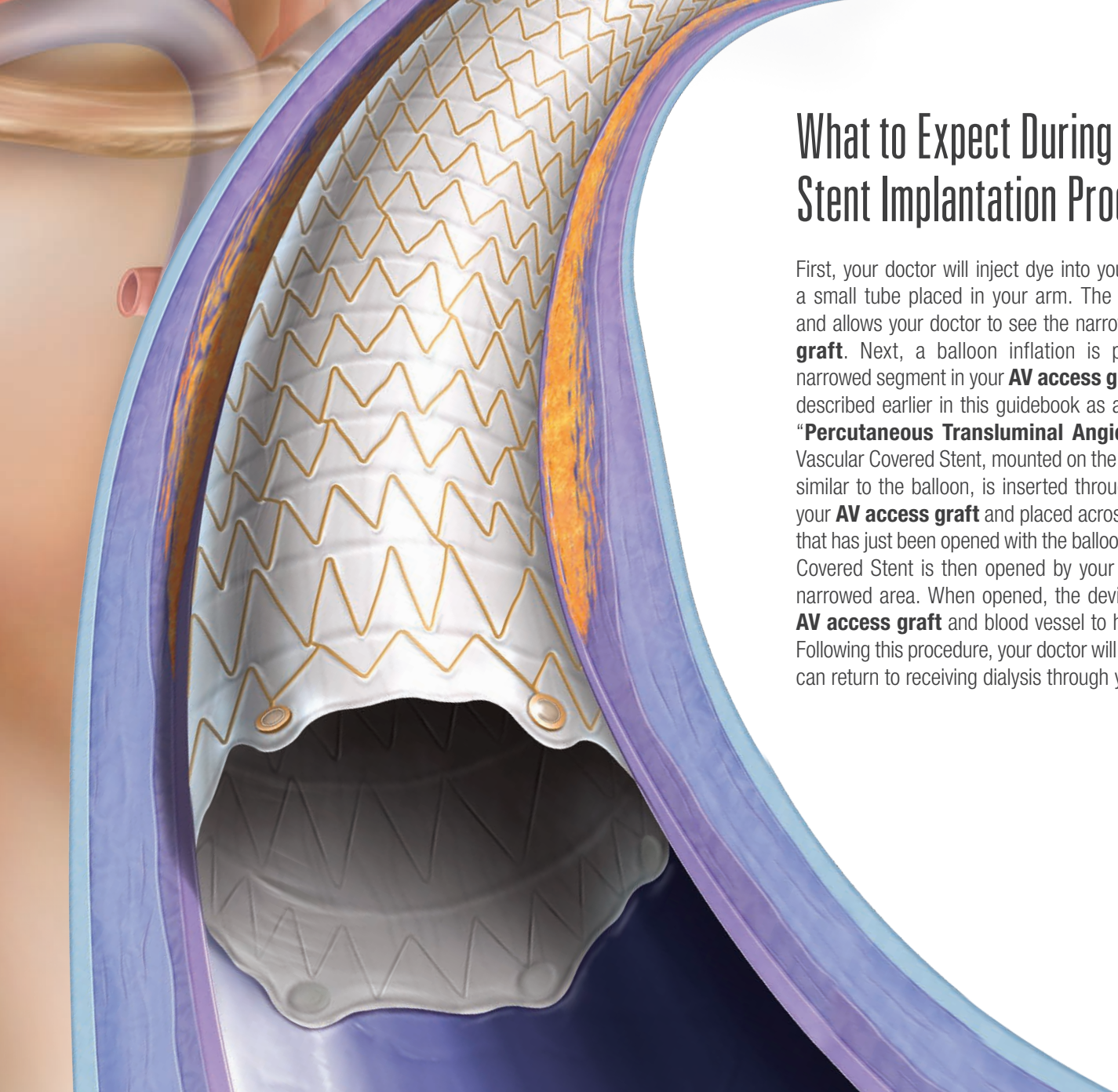
Q: What are the specific risks associated with a covered stent like the COVERA™ Vascular Covered Stent?

- Placement of the device in the wrong location
- Movement of the device, causing blockage of blood flow (embolism)
- Breakage/fracture of the metal
- Bending or kinking of the device
- Failure of the device to open to its pre-determined size
- The need for additional medical procedures such as **percutaneous transluminal angioplasty**, **covered stenting**, or surgery

The COVERA™ Vascular Covered Stent can only be removed through a surgical procedure.

As a reminder, blood flow may not be fully restored after placement of the COVERA™ Vascular Covered Stent and you should regularly check your **AV access graft** to ensure it is working properly. If you suspect there is a problem with your AV access or notice any of the warning signs mentioned previously in this guidebook, you should inform your doctor or nurse immediately.





What to Expect During Your Covered Stent Implantation Procedure

First, your doctor will inject dye 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 **AV access graft**. Next, a balloon inflation is performed to open the narrowed segment in your **AV access graft**. This procedure was described earlier in this guidebook as a treatment option called "**Percutaneous Transluminal Angioplasty**." The COVERA™ Vascular Covered Stent, mounted on the end of another **catheter** similar to the balloon, is inserted through the same pathway in your **AV access graft** and placed across the narrowed segment that has just been opened with the balloon. The COVERA™ Vascular Covered Stent is then opened by your doctor in the previously narrowed area. When opened, the device presses against your **AV access graft** and blood vessel to help keep the area open. Following this procedure, your doctor will inform you how soon you can return to receiving dialysis through your **AV access graft**.

What to Expect After the Implantation Procedure

Before you leave the hospital, your doctor will speak to you about what kind of activity you can do, what you should eat, and what medicine you will need to take. You will be told when you can start to return to normal activities and return to work. Your physician may prescribe medications for you to take to prevent **blood clots** from forming in your newly opened **AV access graft**. It is important to follow your doctor's instructions and to keep all follow-up appointments. During these follow-up appointments, your doctor will monitor your progress and evaluate your medications and the status of your disease.

Treatment After Placement of Your COVERA™ Vascular Covered Stent

It is important that you explain to your caregivers and nurses that you have a COVERA™ Vascular Covered Stent. When performing dialysis, they need to avoid:

- Placing a dialysis needle directly into the COVERA™ Vascular Covered Stent
- Applying constant pressure directly over the area where the COVERA™ Vascular Covered Stent has been placed

Keep Your COVERA™ Vascular Covered Stent Card Handy

Your implant card contains important information about the device you had implanted. Be sure to show your implant card to any health care providers that treat you in the future. It is recommended to register the implant under MedicAlert Foundation (www.medicalert.org) or an equivalent organization. If you require a **magnetic resonance imaging (MRI)** scan, tell your doctor or **MRI** technician that you have a **stent** implant and direct them to follow the instructions written on the implant card or included in this booklet.

Safety during Magnetic Resonance Imaging (MRI)

After placement of your COVERA™ Vascular Covered Stent, your doctor may request a special test that uses electrical waves from a magnet to obtain images of the inside of your body, called an **MRI**. Your COVERA™ Vascular Covered Stent has been classified as MR Conditional. This means that an **MRI** can be done safely if specific testing conditions are followed. These conditions are outlined on the implant card that was provided to you as part of your procedure. Please provide this information to anyone assisting you with an **MRI**. A copy of the information located on the card is also provided below.

Non-clinical testing has demonstrated that the COVERA™ Vascular Covered Stent is MR Conditional. The COVERA™ Vascular Covered Stent can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of 3000 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning

3.0 Tesla Temperature Rise

In an analysis based on non-clinical testing according to ASTM F2182-11a and computer modeling of a patient, the 6 x 100 mm Covera™ Vascular Covered Stent was determined to produce a potential worst-case temperature rise of 2.9 °C at a whole body SAR of 1 W/kg for 15 minutes of MR scanning in a 3.0 Tesla whole body MR system. Cooling due to blood flow inside the covered stent and perfusion in the vascular bed surrounding the covered stent was included in the assessment of in-vivo temperature rise.

1.5 Tesla Temperature Rise

In an analysis based on non-clinical testing according to ASTM F2182-11a and computer modeling of a patient, the 6 x 100 mm Covera™ Vascular Covered Stent was determined to produce a potential worst-case temperature rise of 2.7 °C at the a whole body SAR of 1 W/kg for 15 minutes of MR scanning in a 1.5 Tesla whole body MR system. Cooling due to blood flow inside the covered stent and perfusion in the vascular bed surrounding the covered stent was included in the assessment of in-vivo temperature rise

Image Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the covered stent. Artifact tests were performed according to ASTM F2119-07. Maximum artifact extended 5.5 mm beyond the covered stent for the spin echo sequence and 5.5 mm for the gradient echo sequence. The lumen was obscured.

Additional Information

Good clinical MR practice should be followed, including placement of padding between the bore wall and the patient and avoiding contact between the hands and the body. The Covera™ Vascular Covered Stent has not been evaluated in **MRI** systems with field strengths other than 1.5 or 3.0 Tesla. The heating effect in the **MRI** environment for fractured covered stents is not known. The presence of other implants or the health state of the patient may require reduction of the **MRI** limits listed above.

Notes

Glossary

Aneurysm

An excessive localized enlargement of a blood vessel caused by a weakening of the blood vessel wall.

Arteriovenous (AV)

A term that refers to two different kinds of blood vessels–an artery and a vein.

Artery

A blood vessel that carries blood from the heart and lungs through the body. Blood in arteries is full of oxygen.

AV Access Graft

A tube made of a special plastic that joins together an artery and a vein. Your doctor placed an AV 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.

AV Fistula

The connection between an artery and a vein in order to receive hemodialysis.

Blood Clot

A clump of blood cells that can block or prevent normal blood flow.

Catheter

A small, hollow tube used for gaining access to a blood vessel and delivering treatment therapies.

Congestive Heart Failure

Heart disease caused by loss of pumping power of the heart. A condition where a diseased heart cannot pump out all of the blood. As a result, fluid builds up in the blood vessels and body tissues.

Contraindications

Describes situations in which the device should not be used.

Covered Stent

A metal support tube that is covered by a material similar to the material used to create AV grafts (see ePTFE). A covered stent (stent graft) provides support for a blood vessel that has been narrowed or blocked.

Diabetes

A disease affecting one's metabolism of glucose (sugar) which can cause changes in the blood vessels. These changes may result in the development of peripheral arterial disease.

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 AV access graft is made of ePTFE. It is the most popular material to make AV access grafts, and is used as the covering for the COVERA™ Vascular Covered Stent.

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

A condition where the force of blood against the artery wall is too high. Also known as hypertension.

Glossary

Indication for Use

When/where a device or procedure can be used.

MRI (Magnetic Resonance Imaging)

A diagnostic test that uses magnetic waves to obtain images of the inside of your body.

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.

Percutaneous Transluminal Angioplasty (PTA)

A procedure where a small tube containing a balloon at the tip is passed through to the blocked area of a blood vessel. The balloon is inflated and opens the blocked area in the blood vessel. Also called Balloon Angioplasty.

Peritoneal Dialysis

A way to remove waste products from your blood when your kidneys can no longer do the job adequately. A cleansing fluid flows through a tube (catheter) into part of your abdomen and filters waste products from your blood.

Pseudoaneurysm

Also known as a false aneurysm. A bulging or enlargement of a blood vessel or AV access graft caused by some kind of damage. For example, a false aneurysm can be created in an AV access graft or fistula 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.

Steal Syndrome

A lack of blood flow to the area around your AV access. 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

A narrowing or blockage of a blood vessel. Also known as a lesion.

Stent

An expandable, metallic, tubular shaped device that provides structural support for a vessel.

Stroke

Temporary or permanent loss of blood supply to the brain. This condition can lead to a loss of feeling, motion, speech, or death.

Thrill

The vibration or tremble of blood that you can feel flowing through your AV access.

Thrombosis

A blood clot/blockage.

Vein

A blood vessel that carries blood from the organs of the body back to your heart.

Please visit www.bardpv.com/covera-ifu.php for more detailed safety information and instructions for use.

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