Table of Contents

Introduction 3

What is Peripheral Vascular Disease? 5

What Are Some of the Symptoms of Peripheral Vascular Disease? 7

What Causes Peripheral Vascular Disease? 8

How Do Doctors Treat Peripheral Vascular Disease? 9

What is the GORE VIABAHN® Endoprosthesis? 11

How is the GORE VIABAHN® Endoprosthesis Implanted? 13

What Are the Risks of the GORE VIABAHN® Endoprosthesis? 15

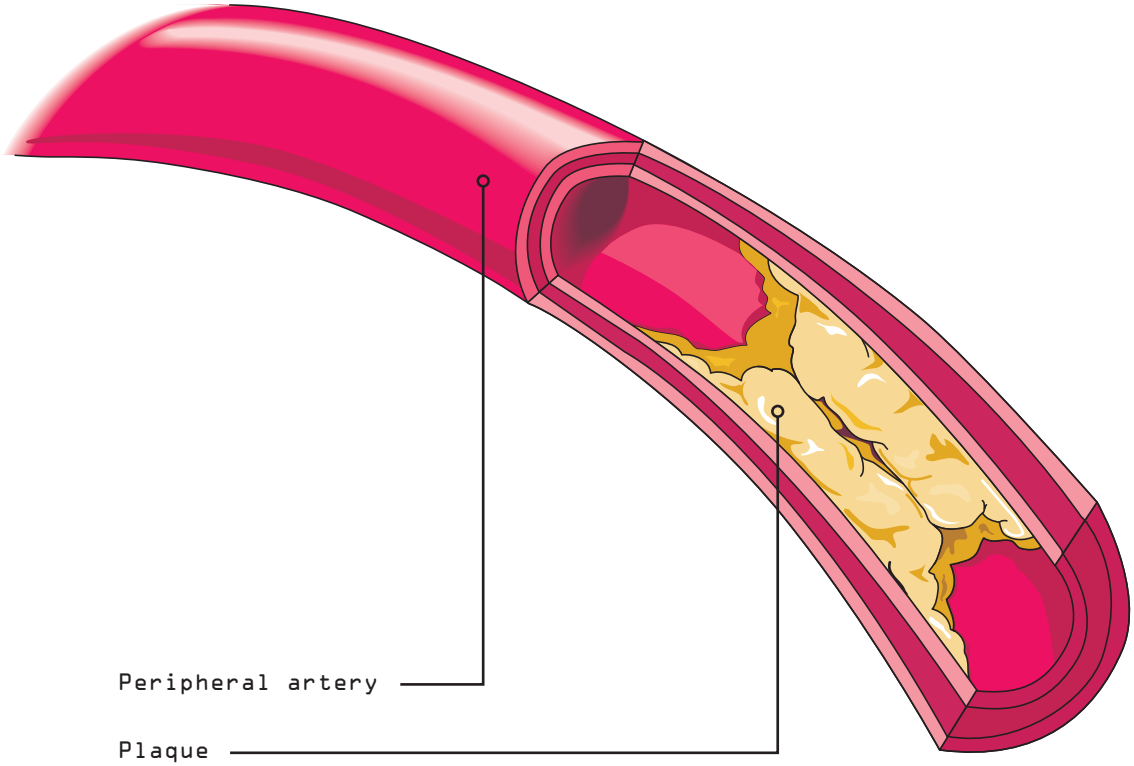
What Follow-Up Examia .....

Introduction

In the U.S. alone, approximately 8-12 million people suffer from some form of peripheral vascular disease (**PVD**). Peripheral vascular disease is caused by the buildup of plaque inside the arteries in the lower limbs, resulting in decreased blood flow. This brochure describes peripheral vascular disease and some of the available treatment options. One new treatment option is **endovascular repair** using an **endovascular graft**.

For your convenience, we have included a **Glossary of Medical Terms** on page 18 and space in this brochure on page 21 to jot down questions to discuss with your doctor. Words that are **bold** throughout the text can be found in the Glossary of Medical Terms.

This brochure is an informational and referral guide only, and is not intended to diagnose a medical condition. As with any surgery or medical procedure, the best resource for information and advice is your doctor. For additional information from Gore & Associates, please call 1-800-528-8763, or visit our website at goremedical.com.



Atherosclerosis — the build-up of plaque and fatty substances in the artery over time.

Figure 1

What is Peripheral Vascular Disease?

Vascular disease involves the buildup of plaque and fatty substances on the inner lining of arteries, a process called **atherosclerosis** (see Figure 1). This process commonly occurs in arteries throughout the body over time. The presence of **atherosclerosis** in **peripheral arteries** is usually referred to as peripheral vascular disease. The term **stenosis** describes a **lesion** in the artery in which blood flow is partially blocked; a lesion in which the artery is completely blocked is called an **occlusion**.

The most common locations of **PVD** (peripheral vascular disease) are in the legs, arms, neck, and kidneys. During early stages of **PVD**, symptoms are usually rare; however, as the buildup of plaque progresses, it blocks the flow of blood through the artery to tissues and organs. The symptoms resulting from **PVD** depend on the location and extent of the disease. Over time, symptoms may stabilize or may become worse, requiring intervention to open the blockage.

The information in this brochure will focus on the treatment of **PVD** in the **superficial femoral arteries (SFA)**, blood vessels that deliver blood to the legs.

What Are Some of the Symptoms of Peripheral Vascular Disease?

Many people do not experience any symptoms of peripheral vascular disease **(PVD)**. In many of these cases, treatment is unnecessary. However, as symptoms increase in severity, action may be required. Depending on the location of the disease, one or more of the following symptoms may be present:

- Claudication (dull pain in the buttocks, thighs, calves, or feet following exercise or walking)
- Numbness or tingling in the leg, foot, or toes
- Changes in skin color (i.e., paleness or a bluish color) in the leg, foot, or toes
- Absence of a pulse
- Ulcers (sores) on the foot or toes that will not heal
- Gangrene
- Hypertension (uncontrolled high blood pressure)
- Kidney failure

PVD is usually identified as a result of the development of one or more of the symptoms mentioned above. If your physician suspects the presence of **PVD**, a medical test such as an **angiogram** or **ultrasound** is usually conducted to confirm it or rule it out.

What Causes Peripheral Vascular Disease?

Over time, the accumulation of fatty substances on the vessel wall, combined with inflammation of the vessel wall, limits blood flow. When the blood flow becomes severely limited, the muscles surrounding the artery do not receive enough oxygen, and you feel pain. The cause of this process is not completely understood, but many factors have been identified that increase the likelihood of **PVD**.

Risk factors for developing **PVD** include:

- heredity (family history)
- smoking
- diabetes
- heart disease
- obesity
- high blood pressure
- high cholesterol

Most doctors will advise simple preventative measures such as keeping your blood pressure under control, stopping smoking, exercising regularly, and reducing cholesterol in your diet. These lifestyle changes could also aid in preventing further problems in the future.

How Do Doctors Treat Peripheral Vascular Disease?

The amount and location of the peripheral vascular disease, and your general health, will determine how you should be treated. When the symptoms are mild, your doctor may only recommend periodic check-ups. However, more serious symptoms may require treatment. Several options are available if your doctor feels treatment is necessary:

- Risk Factor Modification: Before performing a procedure, your doctor may recommend changes in your lifestyle to treat your **PVD**, including decreasing the amount of fat and cholesterol in your diet, stopping smoking, and exercising regularly.

- Medical Management: Your physician may also prescribe medicine to improve the blood flow in your arteries or to lower the cholesterol present in your blood.

- Bypass Surgery: If lifestyle modification and medical management fail to remove the symptoms, direct treatment may be necessary. Your physician may choose to surgically bypass the diseased artery with either a man-made graft or one of your own veins. Bypass surgery has been performed for many years with well-established, long-term results.

- Interventional Treatment: Many of the potential complications that could occur with traditional **open surgery** may be avoided by a more recently available technique called interventional treatment. Interventional treatment does not require open surgery. By using small wires and X-rays, doctors can work inside the blocked artery. This procedure is performed through a small hole in an artery in the groin, and may include **angioplasty** (opening the blockage by inflating a small balloon in the diseased area), or **stenting** (placement of a small, metallic device in the diseased area to hold the artery open).

Artist's rendition of the
GORE VIABAHN® Endoprosthesis
in the superficial femoral artery

Figure 2

Plaque

ePTFE graft

Nitinol stent

Figure 3

Photograph of several sizes of the
GORE VIABAHN® Endoprosthesis

What is the GORE VIABAHN® Endoprosthesis?

The GORE VIABAHN® Endoprosthesis is a very thin vascular graft that is supported by a metallic support structure known as a stent. The graft is made from fluoropolymer (expanded polytetrafluoroethylene or "**ePTFE**" and fluorinated ethylene propylene or "FEP") materials, which have been used safely in vascular grafts for 30 years. The stent is made of a flexible, high-strength metal called **Nitinol** (see Figures 2 and 3).

Prior to implantation, the endoprosthesis is compressed on the end of a long, thin, tube-like device called a **delivery catheter** (see Figure 4). This allows the device to be inserted into your bloodstream through a small hole and guided to the diseased area of the blood vessel without open surgery. The diseased artery is then opened up by releasing the endoprosthesis from the **delivery catheter** inside the blood vessel, making a new path for the blood to flow.

Figure 4

GORE VIABAHN® Endoprosthesis compressed on a delivery catheter

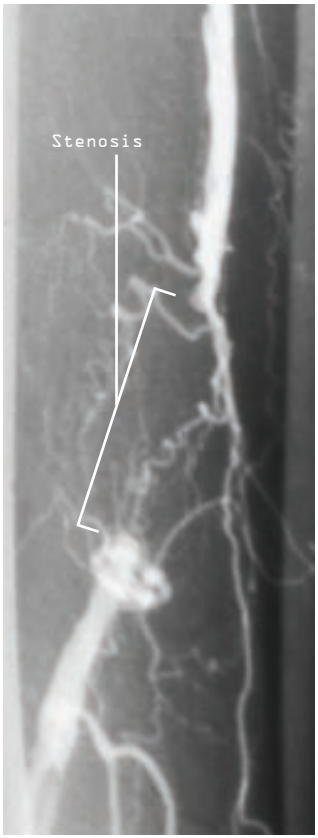


Figure 5a
Pre-procedure

An angiogram showing a section of the superficial femoral artery blocked with plaque.

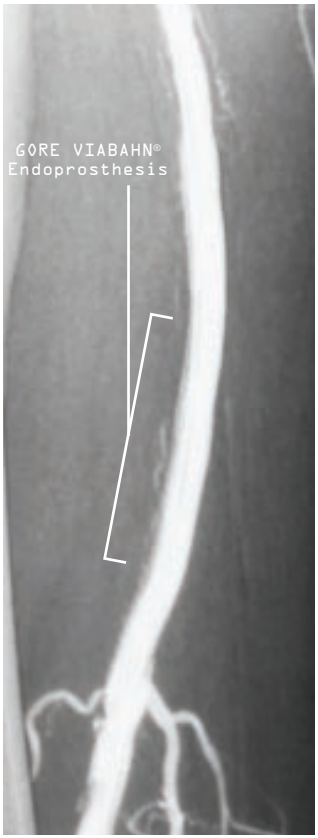


Figure 5b
Post-procedure

An angiogram with blood flowing through a GORE VIABAHN® Endoprosthesis in the superficial femoral artery.

How is the GORE VIABAHN® Endoprosthesis Implanted?

To treat your vascular disease, the GORE VIABAHN® Endoprosthesis is placed inside the blood vessel to create a new, disease-free channel for blood flow. The **endovascular graft** is implanted using **fluoroscopy** (real-time X-ray images) viewed on a TV monitor in these simple steps:

1. A **delivery catheter** is inserted into the **femoral artery** and carefully guided through the leg artery to the site of the blockage.

2. Once the **delivery catheter** reaches the diseased area, the **endovascular graft** is released from the **delivery catheter**.

3. The device self-expands to the diameter of the blood vessel that is being treated.
   The **endovascular graft** is designed to keep blood flow away from the diseased portion of the artery wall; at the same time it provides a new surface lining along the diseased portion of the artery wall.

4. The **delivery catheter** is withdrawn from the body.

At the end of the procedure, your doctor will check the position of the implanted device and also check the blood flow on a TV monitor using a technique called X-ray **angiography** (see Figures 5a and 5b).

What Are the Risks of the GORE VIABAHN® Endoprosthesis?

Implantation of a GORE VIABAHN® Endoprosthesis may cause complications at the insertion site artery, or in the leg artery it is intended to treat. Complications that are related to the device may include but are not limited to:

- **Hematoma** (bruise)
- **Stenosis** (narrowing of the device)
- Thrombosis (blood clot in the artery or device)
- **Occlusion** (complete blockage of the blood flowing in the artery or device)
- **Distal embolism** (blood clot in the artery that has traveled down to the arteries in the lower leg or foot)
- Vessel wall trauma and/or rupture
- Infection
- Inflammation
- Fever and/or pain in the absence of infection
- Device failure
- Allergic reaction to the x-ray dye or other procedural components (including metals in the device)
- Radiation injury
- X-Ray induced renal failure

Be sure to discuss these risks and any other concerns you have with your physician.

What Follow-Up Examinations Should I Have?

Your physician will schedule regular follow-up visits to check on the implanted device, such as at 1, 6, or 12 months following implantation, and then once a year thereafter. It is important that you go to all follow-up visits recommended by your doctor. During these visits, if the physician feels that there is a problem with the **endovascuar graft** or that the disease has spread to other locations in your arteries, additional tests may be conducted.

When Should I Call My Doctor?

The long-term safety and effectiveness of **endovascular repair** have not been established. **WARNING:** If your original symptoms return, or if you experience sudden pain in the treated leg, call your physician immediately. A return of symptoms can indicate either a failure of the endoprosthesis or a progression of the disease to other areas in the artery. In such cases, your doctor may recommend outpatient procedures and/or surgery. It is important to discuss with your doctor other potential symptoms or warning signs that indicate that the device is not working properly.

As with any surgery or medical procedure, there are potential complications with the treatment of **PVD**. Discuss the risks and benefits with your doctor, and refer to this brochure for basic information.

Glossary of Medical Terms

Angiography/Angiogram
A method whereby dye is injected into the bloodstream to view blood flow through the blood vessels under X-ray. Utilizes contrast (dye) and small radiation exposure. The resulting image is an angiogram.

Angioplasty
Opening a blockage in a vessel by inflating a small balloon in the diseased area.

Atherosclerosis
The build-up of plaque and fatty acids in the artery over time.

Contrast (dye)
A drug injected into the vascular system to show blood flow through the blood vessels on the X-ray image.

CT Scan (Computed Tomography Scan)
An imaging technique that creates very precise, thin, cross-sectional views of your abdomen and legs or concerned blood vessels. This technique often utilizes contrast (dye) and small radiation exposure.
Also known as a CAT scan.

Delivery Catheter
A long, thin, tube-like tool that assists in the positioning and delivering of an endovascular graft through the vascular system.

Distal Embolism
Blood clot in the artery that has traveled down to the arteries in the lower leg or foot.

Endovascular Graft
A synthetic graft implanted within a diseased vessel intended to support weakened vessel walls without the use of open surgery techniques. Endovascular grafts are delivered to the diseased blood vessel at a small size and then deployed or expanded to the size of the vessel in which it is placed.

ePTFE
Expanded polytetrafluoroethylene, an inert and biocompatible polymer which can be used for medical devices.

Endovascular Repair
Considered to be less invasive than open surgery, it involves the use of an endovascular graft to make a new path for blood to flow.

Endovascular Treatment
The use of real time X-rays and guidewires to treat unhealthy arteries with small incisions in the femoral arteries.

Femoral Arteries
Arteries located in each leg near the groin which carry blood to the femur or thigh region of each leg and the rest of the leg and foot.

Fluoroscopy
A real time X-ray image that is viewed on a TV monitor and used with a C-arm during endovascular repair.

Guidewire
Long, flexible wire that is placed in an artery to track a delivery catheter and other endovascular accessories to implant an endovascular graft.

Hematoma (bruise)
Small blood vessels that tear or rupture under the skin leaving blood to leak and cause a black-and-blue color.

IVUS (Intravascular Ultrasound)
An ultrasound probe on a delivery catheter placed inside your arteries to see the vessel walls and measure diameters and lengths of your arteries.

Lesion
A diseased section of a blood vessel.

MRI (Magnetic Resonance Imaging)
A procedure using magnetic fields and radio waves to form an image of structures inside the body.

Nitinol
An inert, high-strength metal which is a mixture of nickel and titanium.

Occlusion
The blocking of an artery, causing normal blood flow to stop.

Open Surgery
An operation where an incision is made into the body to get access to a particular organ, for example, bypass surgery.

Peripheral Arteries
Arteries outside of the heart (coronary arteries) and aorta. For example, arteries in your arms or legs.

PVD
Peripheral vascular disease.

Radiation
A form of energy that allows your doctor to see blood vessel structures and other anatomy inside your body.

Stenosis
Narrowing or partial blockage of the artery or the inside of the endovascular graft.

Stenting
An endovascular repair with the placement of a small, metallic device in the diseased artery in an attempt to hold the artery open.

Superficial Femoral Artery (SFA)
Portion of the femoral artery in the thigh.

Synthetic Graft
A man-made material in tube form intended to replace diseased human vessels.

Ultrasound
An image created through the use of high-frequency sound waves.

Where Can I Get More Information?

Society of Interventional Radiology
www.sirweb.org

US National Library of Medicine
www.medlineplus.gov

US Department of Health and Human Services
Food and Drug Administration
www.fda.gov

W. L. Gore & Associates, Inc.
www.goremedical.com

Photograph of several sizes of the GORE VIABAHN® Endoprosthesis

Questions for My Doctor —