VENOUS WALLSTENT™
Patient Information Guide
Introduction To This Guide

You have developed symptoms that are caused by a stenosis or narrowing in a vein. The stenosis has occurred in a vein, in either your pelvic region or lower abdomen, where the Iliofemoral venous vasculature is located, or in a vein near your heart.

To correct this problem, your doctor has prescribed implantation of a VENOUS WALLSTENT™ in that narrowed vein.

This guide explains the procedure and what you can expect from start to finish. A glossary at the beginning of this guide defines common medical terms about this procedure.

It also describes the VENOUS WALLSTENT device and answers some questions that patients like you have commonly asked. You should remember that the doctors and nurses who care for you are your best resources for answers to your specific questions. Discuss all your questions with them and follow their recommendations regarding your treatment plan. If you need additional information about the VENOUS WALLSTENT, please contact Boston Scientific Customer Service at 888-272-1001.
Glossary

Angioplasty
A procedure using a special balloon to dilate, or widen, a narrowed blood vessel.

Anticoagulant and Antiplatelet
Medicines that slow down the clotting of blood.

Balloon Catheter
A thin tube with a balloon attached to the tip that can be inflated to open blocked veins.

Blood Vessel
Any of the veins and arteries that carry blood to and from the heart.

Bypass
A surgical procedure used to create an alternate route for blood to flow around narrowed or blocked arteries.

Catheter
A long, flexible tube that can be passed through the blood vessels.

Chronic Venous Insufficiency (CVI)
A condition with the vein that makes it difficult for blood to return to the heart from the legs.

Computer Tomography (CT)
An imaging procedure that uses special x-ray equipment to create detailed pictures, or scans, of areas inside the body.

Contrast Dye
X-ray dye used in diagnostic tests.

Deep Vein Thrombosis (DVT)
A condition where blood clots in a leg vein, causing leg pain or swelling.

Minimally Invasive Procedure
A procedure that uses small instruments or devices to reduce the size of the insertion site and cause a smaller amount of trauma.

MRI (Magnetic Resonance Imaging)
A method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

Non-thrombotic Iliac Vein Lesions (NIVL)
A narrowing in a vein caused by pressure from outside the vein.

Iliofemoral vein
The large veins located in the lower abdomen and upper thigh.

Sedative
A type of medication that makes you relaxed and sleepy. Also called sedation.

Stenosis
A narrowing of the blood vessel.

Stent
A metal tube that supports the blood vessel wall and maintains blood flow through the opened vessel.

Venous Ulcers
Open wounds that appear on or around the ankle.

Varicose Veins
Enlarged blue, red, or flesh colored veins at the skin surface and become painful at times.
About Venous Stenosis

Normally, as the heart pumps, blood flows freely through all the vessels in the body. In some people however, a narrowing or stenosis of a vessel occurs (see Figure 1). This decreases the amount of blood that can flow through the vessel, producing symptoms such as pain or swelling.

Venous stenosis is a narrowing that occurs in a vein - a vessel that brings blood back to the heart. Sometimes venous stenosis can also be called venous outflow obstruction.

When this happens, the vein will not function properly. To restore blood flow, it is necessary to reopen the narrowed area and provide a framework to hold it open. The VENOUS WALLSTENT device is that framework.

Figure 1. Implantation sites of VENOUS WALLSTENT™
About Your VENOUS WALLSTENT™

The VENOUS WALLSTENT (see Figure 2) is a small, flexible, metal tube specifically designed to hold open the narrowed vein that is partially or completely blocked.

The device is collapsed and secured to a long tube called a catheter under a protective sheath or tube.

This catheter is then used to deliver the device to the vein where it will be implanted. When the protective sheath is removed, the device expands outward to the walls of the vein. The VENOUS WALLSTENT is so flexible it will mold itself to the vein as it expands.

Figure 2. VENOUS WALLSTENT
About the Procedure

There are two parts to the implantation procedure. During the first part of the procedure the narrowed part of the vein is dilated with a special balloon. This is called venous angioplasty. During the second part of the procedure the VENOUS WALLSTENT™ is implanted in the dilated vein.

Before the Procedure

Your doctor will instruct you on what you should do – or not do - before you are admitted to the hospital for the angioplasty and implantation. For example, your doctor will discuss with you any medications that you should take as well as any that you should stop taking before the procedure. Before the procedure begins a urinary catheter may be inserted. You are going to be asked to lie fairly still after the procedure; the catheter will help since you will not have to use the bedpan.

You will be moved to a room equipped with x-ray and other equipment. You will lie on a table that allows the doctor to view the procedure using x-rays. You may be given a mild sedative to help you relax but you will probably stay awake. If you have pain, discomfort or nausea, tell your doctor so that medication or other treatment may be provided to you.

During the Venous Angioplasty Procedure

Venous angioplasty is the procedure used to dilate the narrowed area in the vein. For this procedure, a special type of catheter that has a small balloon attached to one end is used.

This procedure begins by cleaning the skin in the area where the catheter will be inserted. You will also be given a local anesthetic to numb the area. Then, a small puncture or incision is made through your skin and a short, smooth, hollow tube called a sheath is placed into your vein. This sheath allows your doctor to insert the other devices that are needed to treat the narrowed vein.

Your doctor will inject a fluid called contrast to help see the narrowed area. A wire is threaded through the veins to that area.

Then the catheter, with the balloon deflated, is threaded over the wire. Once the catheter is in place (see Figure 3), the balloon is inflated and the vein is dilated. This widens your vein and allows blood to flow more freely. Let your doctor know if you experience any pain during this part of the procedure.

Figure 3. Venous Angioplasty
About the Procedure (continued)

**During the VENOUS WALLSTENT™ Implantation Procedure**

After the vein has been widened, the balloon catheter is removed. Then, the special delivery catheter with the VENOUS WALLSTENT mounted on it is inserted. Like the balloon catheter, the delivery catheter is threaded over the wire through the veins to the area where the device will be implanted.

When the device is in the proper place, the protective covering is withdrawn by the physician and the device naturally expands. When it is fully expanded, it fits snugly into the vein and keeps it open (see Figure 4).

The delivery catheter and wire are then removed along with the sheath. Pressure is applied to the area where the sheath was inserted until any bleeding stops.

**After the Procedure**

After the procedure is complete, you will be monitored by specially trained medical staff. They will take your pulse and blood pressure frequently. They will also check to make sure there is no bleeding from your puncture or incision and remind you to remain still. You should make sure to tell them if you are experiencing any pain.

When your doctor decides that you have fully recovered from the procedure, you will return to your hospital room. You may be able to leave the hospital that day or you may stay overnight.

**Caring for Yourself at Home**

Your doctor will explain what you should do when you go home. To speed your recovery, you should carefully follow all instructions about your diet, medications and activity. Make sure to call your doctor immediately if you have any problems or questions. Make sure, too, that you keep all your follow-up appointments.

Before you leave the hospital, you will be given a Patient Implant Card (detach from this Patient Information Guide). Be sure to carry this card with you at all times. In case of an emergency, the card tells medical personnel that you have a VENOUS WALLSTENT in place and this will help them plan your care.
VENOUS WALLSTENT™ Clinical Summary

The VENOUS WALLSTENT has a history of safe and effective use in the treatment of venous stenosis that has been demonstrated within clinical literature. An analysis of 21 studies in the clinical literature (2,268 patients) that included exclusive use of the WALLSTENT was performed. Treatment success after one year was reported as 86.6%.

In combination with additional data sources, this data shows that VENOUS WALLSTENT is safe and effective for the treatment of symptomatic venous outflow obstruction. Your doctor can explain the risks and benefits that are specific to you.
Risks

Your doctor may not consider you to be a good candidate for stenting if you have any of the following conditions:

- You are unable to take medications, such as aspirin or Plavix®, that make it more difficult for your blood to clot.
- You are allergic or sensitive to nickel or any of the metals used to make the VENOUS WALLSTENT™. Discuss the potential for allergy with your doctor if you have ever experienced a skin rash to jewelry, watches, or belt buckles.
- Your doctor has determined that the blocked vein will not allow complete inflation of the balloon catheter or proper placement of the stent.

As with any stent procedure, there is a chance that complications may occur, including but not limited to those listed below. Ask your doctor to discuss the risk of these complications, as some are extremely rare.

- Abnormal communication between an artery and a vein
- Allergic reaction
- Bleeding
- Blockage of blood flow caused by a blood clot
- Blockage of your blood vessels or stent
- Blocking of a blood vessel or organ by a material mass, air bubble(s), tissue, or clots
- Blood clot(s)
- Bruising at your groin area
- Chest pain
- Complications requiring urgent medical procedure or surgery
- Death
- Difficulty breathing caused by blood clot(s) in the lungs
- Fever
- Heart attack
- Infection
- Injury, tearing, or damage to your blood vessel
- Kidney damage or failure
- Mild to severe tissue damage
- Overfilling of the veins with blood causing swelling and pain
- Pain
- Re-narrowing of the vein around or within the stent.
- Spasm of the vessel wall
- Stent fracture
- Stent movement or misplacement
- Stroke or mini-stroke
- Temporary change in blood pressure during the procedure

Your doctor and the medical staff will monitor you during and after the procedure. If a complication does occur, your doctor will decide if you require treatment. In the event of complications, surgical removal of the stent may be required.

Note: It is very common for your doctor to prescribe specific medications before, during and after your stent placement. These medications are intended to help decrease the risk of forming a blood clot in your vein. Please check with your doctor to find the right medication for you.

For more information discuss with your physician or contact Boston Scientific Customer Service at 888-272-1001.
Commonly Asked Questions

■ Will I feel the VENOUS WALLSTENT™?
No, you should not feel the VENOUS WALLSTENT after placement. If you feel anything abnormal, please tell your doctor.

■ Will the VENOUS WALLSTENT cause any problems with metal detectors or interfere with future x-ray procedures?
No, the VENOUS WALLSTENT will not set off a metal detector. The VENOUS WALLSTENT is visible on x-ray, but will not preclude the use of future medical imaging procedures. However, you should always notify your doctors that you have a device in place, especially before you have x-rays, CT scans or MRI scans.

Specific information in regard to MRI is provided in the Patient Implant Card attached to this Patient Information Guide.

■ How often should I see my doctor?
Your doctor will tell you how often you need to be seen and explain any special symptoms you should look for.

■ Is the VENOUS WALLSTENT sterile?
Yes, the VENOUS WALLSTENT has been sterilized prior to delivery to your doctor.

■ Will the VENOUS WALLSTENT rust?
No, the VENOUS WALLSTENT is made from a special medical-grade metal alloy that will not rust.

■ What about after the procedure? Will the VENOUS WALLSTENT crush, bend or move out of place?
Damage to the stent or migration is possible but rare.

■ Will the VENOUS WALLSTENT be removed or need to be replaced?
No, the VENOUS WALLSTENT is not designed to be removed or replaced.
Magnetic Resonance Conditional

Non-clinical testing has demonstrated the VENOUS WALLSTENT system is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla.
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤1 W/kg for patient landmarks above the umbilicus (patient navel) and ≤2 W/kg (Normal Operating Mode) for patient landmarks below the umbilicus.

MRI at 1.5 T or 3 T may be performed immediately following the implantation of the VENOUS WALLSTENT. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

It is recommended that patients register the conditions under which the implant can be scanned safely with the Medic Alert Foundation (www.medicalert.org) or an equivalent organization.
PLEASE CARRY YOUR CARD AT ALL TIMES.

Please ask your physician for a copy of the Patient Information Guide. Additionally, the Patient Information Guide for this product is available for the VENOUS WALLSTENT™ products on the Boston Scientific website. To view, download, or print the Patient Information Guide, go to www.bostonscientific.com. You may also request a hard copy of the Patient Information Guide by calling 888-272-1001.

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**Stent Identification Information**

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