

# Boston Scientific

Patient Name \_\_\_\_\_

Implant Date \_\_\_\_\_

Implant Location \_\_\_\_\_

Implanting Physician \_\_\_\_\_

Phone Number \_\_\_\_\_

Hospital Name \_\_\_\_\_

Address \_\_\_\_\_

Primary Physician \_\_\_\_\_



**Magnetic Resonance  
Conditional**

#### MRI Safety Information

Non-clinical testing has demonstrated that the VICI VENOUS STENT® is MR Conditional.

A patient with the VICI VENOUS STENT can be scanned safely, immediately after placement, in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T only.
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m).
- Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2 W/Kg (Normal Operating Mode).

Under the scan conditions defined above, the VICI VENOUS STENT is expected to produce a maximum temperature rise of 6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the VICI VENOUS STENT when imaged with a gradient echo pulse sequence and a 3.0 T MRI system. The lumen of the VICI VENOUS STENT cannot be visualized on the gradient echo or T1-weighted, spin echo pulse sequence.

For more information about indications, contraindications, warnings and instructions for the VICI VENOUS STENT® System, or for copies of the Directions for Use, visit [www.bostonscientific.com](http://www.bostonscientific.com).

You may also call Boston Scientific customer service at **1.888.272.1001** for more information.

Plavix® is a registered trademark of sanofi-aventis.

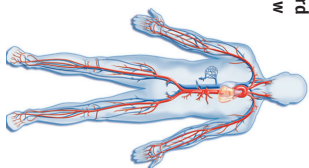
## Boston Scientific

Advancing science for life™

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 Manufacturer**  
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**VICI VENOUS STENT®  
 Patient Information Card**

**INSTRUCTIONS:**  
 Please carry this card  
 at all times and show  
 it to any medical  
 personnel who may  
 treat you.



**Boston Scientific**

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Patient Information Guide

## About Venous Outflow Obstruction

VICI VENOUS STENT® System



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# Glossary

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## **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 to the legs 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.

# Glossary

*(continued)*

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## **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.

## **Venoplasty**

A minimally invasive treatment of the blood vessels that opens blocked veins.

## **Venous Outflow Obstruction (VVO)**

Blockage in a vein that reduces or stops blood flow returning to the heart.

## **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.

# Introduction

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You have developed symptoms that are caused by a stenosis or narrowing in a vein that may restrict blood flow returning to the heart. The stenosis has occurred in a vein, either in your pelvic region or in your lower abdomen, where the Iliofemoral venous vasculature is located. This condition is called Venous Outflow Obstruction (VVO).

To correct this problem, your doctor has prescribed implantation of a VICI VENOUS STENT® in that narrowed vein.

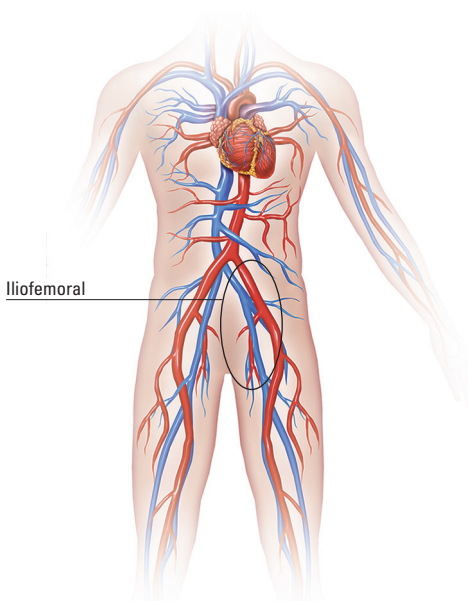
This guide explains the procedure and what you can expect from start to finish. A glossary at the beginning of this guide defines common medical terms about this procedure. You will also learn steps you can take to live a healthier life with VVO.

It also describes the VICI VENOUS STENT 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 VICI VENOUS STENT, please contact Boston Scientific Customer Service at 888-272-1001.

# What is Venous Outflow Obstruction (VVO)?

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. This decreases the amount of blood that can flow through the vessel, producing symptoms such as leg pain and swelling, extensive deep vein thrombosis (DVT), and ulcers which will not heal.

Venous Outflow Obstruction (VVO) is a narrowing that occurs in a vein - a vessel that brings blood back to the heart. VVO is due to either an internal clot formation, as in the case of deep vein thrombosis (DVT), or an external compressional force known as non-thrombotic iliac vein lesions (NIVL).



**Implantation sites of VICI VENOUS STENT®**

## ***The Signs and Symptoms of VVO***

The initial signs and symptoms of VVO are:

- Leg pain and/or swelling (edema)
- Skin color changes in the lower legs
- Leg heaviness and discomfort

All of these symptoms can become disruptive to everyday life, disrupting sleep and social activities, and making physical activities more strenuous.

If not diagnosed and treated properly VVO can lead to chronic venous insufficiency (CVI). CVI is a progressive and cyclical disease. It appears in early stages as spider or varicose veins and in later stages as venous ulcers.

# Treating Venous Outflow Obstruction (VVO)

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VVO can be successfully treated by placing a stent in the narrowed region of the vein. The vein is first opened with a balloon and a stent is used to maintain the opening. This provides an open pathway for return of blood to the heart.

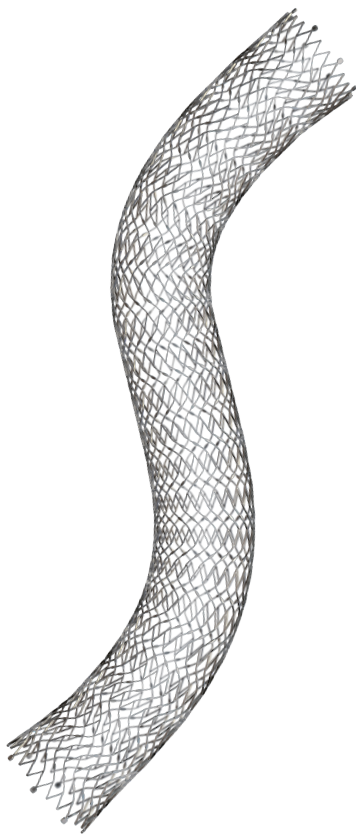
Other treatment options include surgical bypass, venoplasty, medical therapy, and compression stockings.

Your doctor wants you to have a stent placed in one of your iliofemoral veins to treat your VVO. The stent may improve blood flow from your legs to reduce leg and resting pain, and improve quality of life and your ability to walk and move around.

# VICI VENOUS STENT® System

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Using the catheter to navigate to the blockage, the VICI VENOUS STENT, a mixture of nickel and titanium called nitinol, is placed in the vein. Once placed, the stent expands to the vessel wall as a reaction to body heat, to provide a mechanical scaffolding to keep the vein open.



**VICI VENOUS STENT**



# VICI Clinical Summary

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The VICI VENOUS STENT® was evaluated in the VIRTUS Trial. The VIRTUS Trial enrolled 170 patients. After one year, it was determined that the outcome of the procedure was successful in most cases. The results of this study showed that the VICI VENOUS STENT is safe and effective for treating patients with non-cancerous obstructions of the iliofemoral venous segment. 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<sup>®</sup>, that make it more difficult for your blood to clot.**
- **You are allergic or sensitive to nickel, titanium, or tantalum. These are the metals used to make up the VICI VENOUS STENT<sup>®</sup>. 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
- Abscess
- Allergic reactions
- Amputation
- Back pain
- Bleeding
- Bleeding due to antiplatelet medications
- Blockage of blood flow caused by a blood clot
- Blockage of smaller branches of your veins
- Blocking of a blood vessel or organ by a material mass
- Blood clot(s)
- Complications during procedure requiring urgent surgery
- Death
- Difficulty breathing, pneumonia or collapsed lung
- Entanglement of catheter in deployed stent
- Fever
- Heart attack or chest pain
- High blood pressure
- Infection
- Injury, tearing, or damage to your vein
- Kidney failure
- Low blood pressure
- Mild to severe tissue damage
- Nerve or vessel damage
- Organ failure
- Overfilling of the veins with blood
- Pain and tenderness at the entry site
- Pain or swelling caused by a blood clot
- Re-narrowing of the vein around or within the stent

# Risks

## *(continued)*

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- Spasm of the vessel wall
- Stent fracture
- Stent movement, misplacement or jumping
- Stroke
- Total blockage of the stent
- Widening or ballooning of a blood vessel

Your doctor and the medical staff will monitor you during and after the procedure for complications.

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.**

# Before Your Procedure

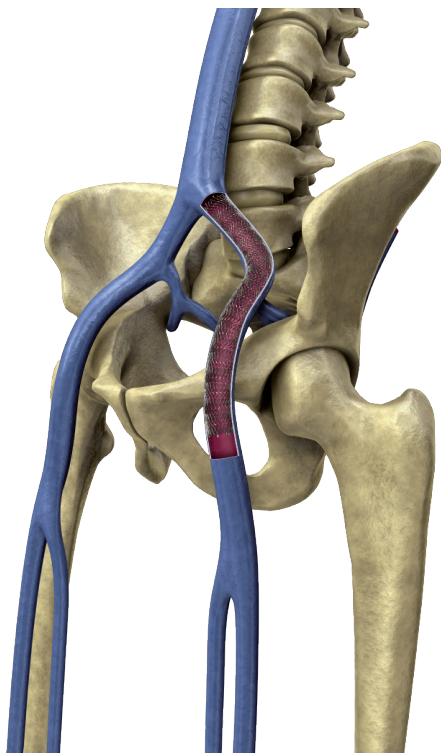
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Below is a typical checklist. Your doctor may ask you to go through this before your procedure.

- Tell your doctor about any medications you are taking, and bring the medications to your appointments.
- Let your doctor know about any allergies you have. It is important he or she knows about allergies to contrast dye, iodine, nickel, titanium, or tantalum.
- Tell your doctor if you cannot take aspirin or blood thinning medicines. These medications are usually prescribed before and after your procedure.
- Do not eat or drink anything after midnight on the night before your procedure.
- Follow the instructions you receive from your doctor and nurses.
- Make sure you understand the possible risks and benefits of your stent procedure.
- You could be given a sedative to relax you before starting

# During a Typical Stenting Procedure

Venous stenting is usually a same-day, minimally invasive procedure. The actual procedure is generally under 2 hours. The procedure involves a small incision in the leg or neck (the entry site), ultrasound and venography to guide the procedure, and is performed under general or local anesthesia. A balloon catheter may be used to prepare the injured vein to accept a stent. One or more stents may be placed depending on the length of the treated area.



**VICI VENOUS STENT® in place**

# After a Typical Stenting Procedure

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Bruising or discoloration around the entry site is common. While anticoagulation therapy and compression stockings are used after the procedure, specific requirements may vary from physician to physician. You should follow any post care instructions provided by your physician.

- You may feel sleepy from the sedative given to you. This will wear off over the next few hours.
- You will be taken to a unit where nurses and doctors can monitor you.
- Your heart rate, blood pressure, and the entry site in your groin will be checked frequently.
- You will be asked to drink a lot of liquids to flush the contrast dye out of your system.
- You will have to stay in bed for several hours.
- You will be asked to keep your leg straight so the entry site in your groin can heal well.
- You may need a short hospital stay.
- You should alert your doctor or nurse if you experience any of these symptoms:
  - Leg or foot pain
  - Unusual coldness and/or skin discoloration in the leg or foot
  - Numbness in the leg or foot
  - Reappearance of the symptoms you had before treatment
  - Pain, bleeding or infection at the entry site
- You should avoid straining yourself or lifting “heavy” items until your doctor lets you know that it is okay to do so.
- You should keep all follow-up appointments requested by your doctor and bring your medications with you.

# Commonly Asked Questions

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## ■ Will I feel the VICI VENOUS STENT®?

No, you should not feel the VICI VENOUS STENT after placement. If you feel anything abnormal, please tell your doctor.

## ■ Will the VICI VENOUS STENT cause any problems with metal detectors or interfere with future x-ray procedures?

No, the VICI VENOUS STENT will not set off a metal detector. The VICI VENOUS STENT 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 VICI VENOUS STENT sterile?

Yes, the VICI VENOUS STENT has been sterilized prior to delivery to your doctor.

## ■ Will the VICI VENOUS STENT rust?

No, the VICI VENOUS STENT is made from a special medical-grade metal alloy that will not rust.

## ■ What about after the procedure? Will the VICI VENOUS STENT crush, bend or move out of place?

Damage to the stent or migration is possible but rare.

## ■ Will the VICI VENOUS STENT be removed or need to be replaced?

No, the VICI VENOUS STENT is not designed to be removed or replaced.

# Living with VOO

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Treatment for VOO includes controlling things that can cause the re-occurrence of symptoms. You cannot control some risk factors, such as your age, gender, ethnic background or family history. However, you can change many of the risk factors for this disease.

**Your doctor may suggest the following healthy lifestyle changes:**

- Lose excess weight
- Quit smoking
- Exercise regularly
- Control stress
- Decrease fat in your diet
- Limit alcohol consumption

Reducing your risk factors can also have a positive impact on the long-term success of VOO treatment. Talk to your health care providers today about how to increase your chances for a healthier outcome and a more rewarding life.





Patient Name	Emergency Contact Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant

**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 VICI VENOUS STENT® products on the Boston Scientific website. To view, download or print the Patient Information Guide, go to [www.bostonscientific.com](http://www.bostonscientific.com). You may also request a hard copy of the Patient Information Guide by calling **888-272-1001**.

***Stent Identification Information***

Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

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