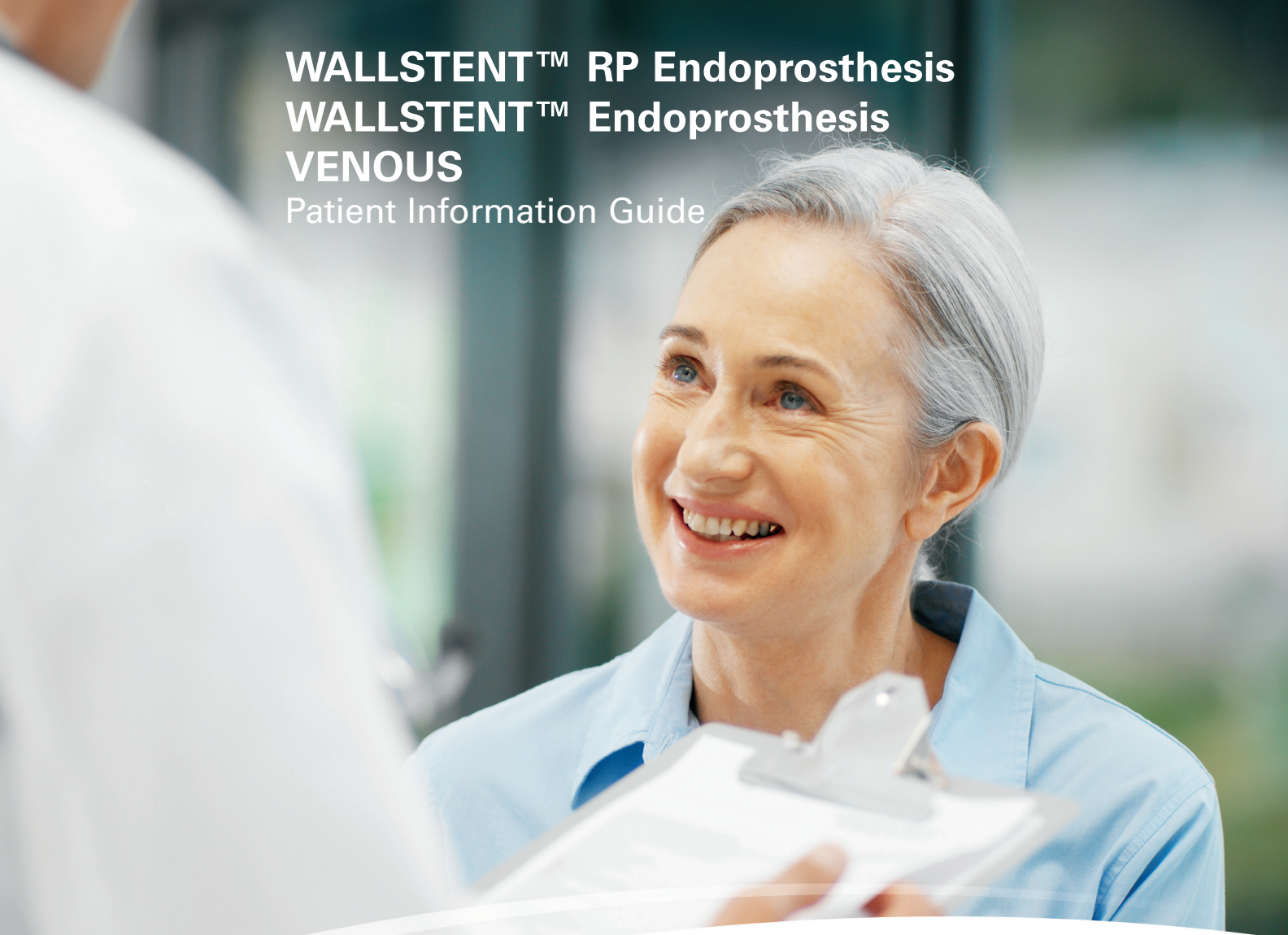
WALLSTENT™ RP Endoprosthesis
WALLSTENT™ Endoprosthesis
VENOUS
Patient Information Guide



Boston Scientific

Introduction to This Guide

You have developed symptoms that are caused by a stenosis or narrowing in a large vein near your heart. To correct this problem, your doctor has prescribed implantation of a Wallstent™ RP Endoprosthesis and Wallstent™ Endprosthesis in that narrowed vein.

The information in this pamphlet will help prepare you for the implantation procedure and let you know what you can do to speed your recovery.

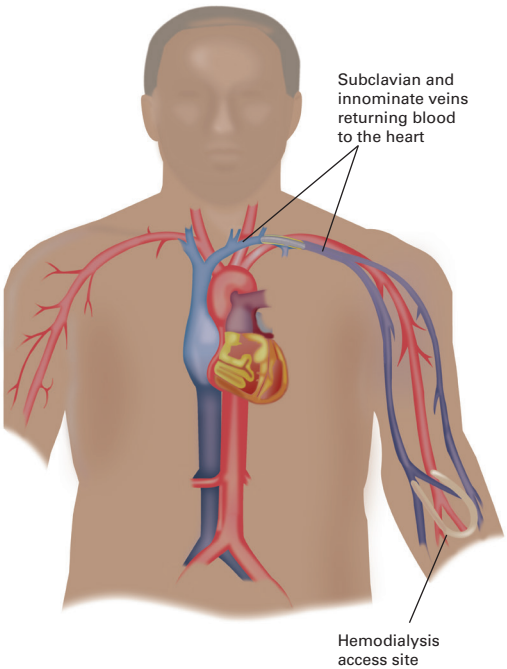
It also describes the Wallstent RP Endoprosthesis and Wallstent Endprosthesis device and answers some questions that patients like you have commonly asked about it. You should remember that the doctors and nurses who care for you are your best resources for answers to your specific questions. Discuss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

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. 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. Although it can occur for a number of reasons, it often develops in people like you who require chronic hemodialysis.

When you have been receiving hemodialysis for a long time, venous stenosis can develop in one of the large veins near your heart. When this happens, the vein side of your hemodialysis access will not function properly. To preserve your access, it is necessary to reopen the narrowed area and provide a framework to hold it open. The Wallstent™ RP Endoprosthesis and Wallstent™ Endprosthesis device is that framework.



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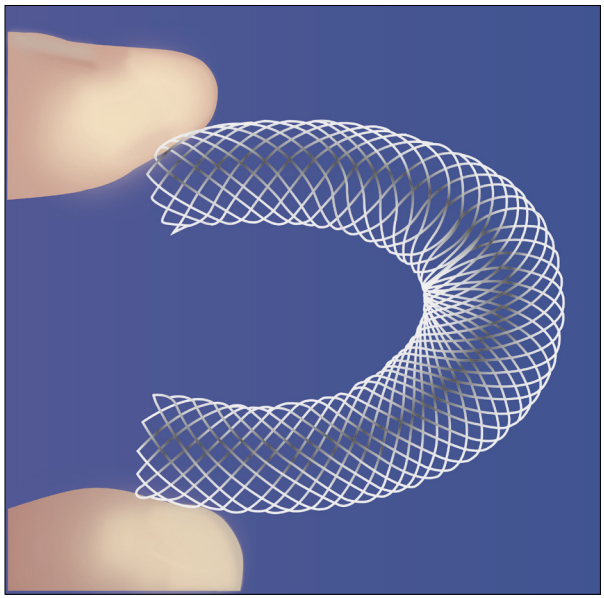
About Your Wallstent™ RP Endoprosthesis and Wallstent™ Endprosthesis

The Wallstent RP Endoprosthesis and Wallstent Endprosthesis 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 covering.

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. Because it is so flexible, it will mold itself to any bends in the vein as it expands.



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 Wallstent™ RP Endoprosthesis and Wallstent™ Endprosthesis 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 discontinue 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, and 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.

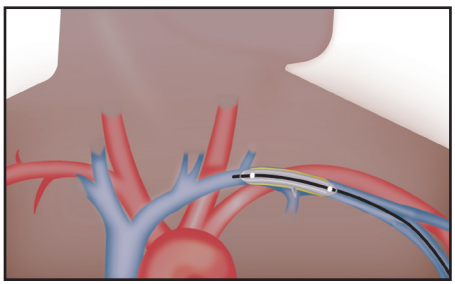
During the Venous Angioplasty Procedure

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. Often, this is the skin on your arm. You will also be given a local anaesthetic 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 a vein in your arm. 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, the balloon is inflated and the vein is dilated. This widens it and allows blood to flow more freely. Let your doctor know if you experience any pain during this part of the procedure.



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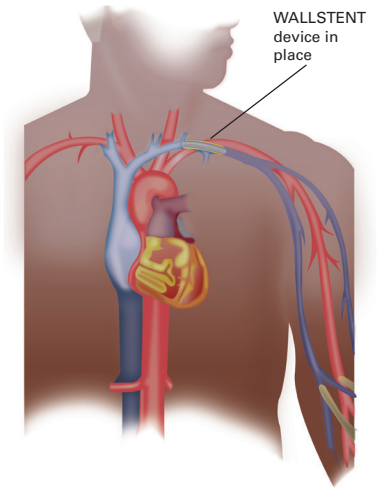
About the Procedure *continued*

During the Wallstent™ RP Endoprosthesis and Wallstent™ Endprosthesis Implantation Procedure

After the vein has been widened, the balloon catheter is removed. Then, the special delivery catheter with the Wallstent RP Endoprosthesis and Wallstent Endprosthesis 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.

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 Identification Card. 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 Wallstent™ RP Endprosthesis and Wallstent™ Endoprosthesis in place and this will help them plan your care.

Commonly Asked Questions

Will I feel the Wallstent™ RP Endoprosthesis and Wallstent™ Endprosthesis?

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

Will the Wallstent RP Endoprosthesis and Wallstent Endprosthesis cause any problems with metal detectors or interfere with future x-ray procedures?

No, the device will not set off a metal detector. The device 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.

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 Wallstent RP Endoprosthesis and Wallstent Endprosthesis sterile?

Yes. The device has been sterilized prior to delivery to your doctor.

Will the Wallstent RP Endoprosthesis and Wallstent Endprosthesis rust?

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

What about after the procedure? Will the Wallstent RP Endoprosthesis and Wallstent Endprosthesis crush, bend or move out of place?

Deformation or migration is possible but rare.

Will the Wallstent RP Endoprosthesis and Wallstent Endprosthesis be removed or need to be replaced?

No, Wallstent is not designed to be removed or replaced.

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Caution: Federal law restricts this device to sale by or on the order of a physician.

Indications
The Wallstent RP Endoprosthesis and Wallstent Endprosthesis device is indicated for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis ≥ 30% for a vein ≤ 10 mm in diameter or ≥ 50% for a vein > 10 mm in diameter, a tear which interrupts the integrity of the intima or lumen, abrupt lesion site occlusion, or refractory spasm. The vessels that can be treated with the WALLSTENT device are the innominate and subclavian veins, ranging from 8.0 mm to 15 mm in diameter.

Contraindications
The Wallstent RP Endoprosthesis and Wallstent Endprosthesis device is contraindicated for use in: patients with bleeding disorders unresponsive to vitamin K or blood product therapy.

Warnings
- Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The long-term outcome following repeat dilation of venous stents is unknown at present.
- When multiple stents are required, stent material should be of similar composition.
- Proper stent sizing is critical to achieving adequate vessel apposition and avoiding possible stent migration.

Precautions
- Do not advance a partially (≤ 50%) deployed stent.
- A stent cannot be repositioned after the deployment threshold has been exceeded.
- Implanting a stent may lead to dissection of the vessel distally, and/or proximally to the stented portion, and may cause acute closure of the vessel requiring additional intervention.

Potential Adverse Effects
- Hemorrhage; Infection; Contract media reactions; Dissection; Distal emboli; Graft rupture; Graft occlusion/restenosis; Graft/vein thrombosis or occlusion; Perforation of the vein; Suture disruption of the anastomosis; Thromboembolism; Transient spasm; Stent misplacement; Stent migration; Vein perforation; Death; Surgical revision; Pseudoaneurysm; Hematoma; Edema; Stent restenosis; Stent thrombosis.

Please ask your physician for a copy of the Patient Information Guide. Additionally the Patient Information Guide for this product is available for the Wallstent RP Endoprosthesis / Wallstent Endoprosthesis Venous 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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