

# PATIENT INFORMATION GUIDE

Abre™ Venous  
Self-expanding  
Stent System



Medtronic

**YOU HAVE BEEN  
DIAGNOSED WITH  
OBSTRUCTION OF  
THE VEINS IN YOUR  
PELVIC REGION OR  
LOWER ABDOMEN  
(DEEP VENOUS  
OBSTRUCTION)**

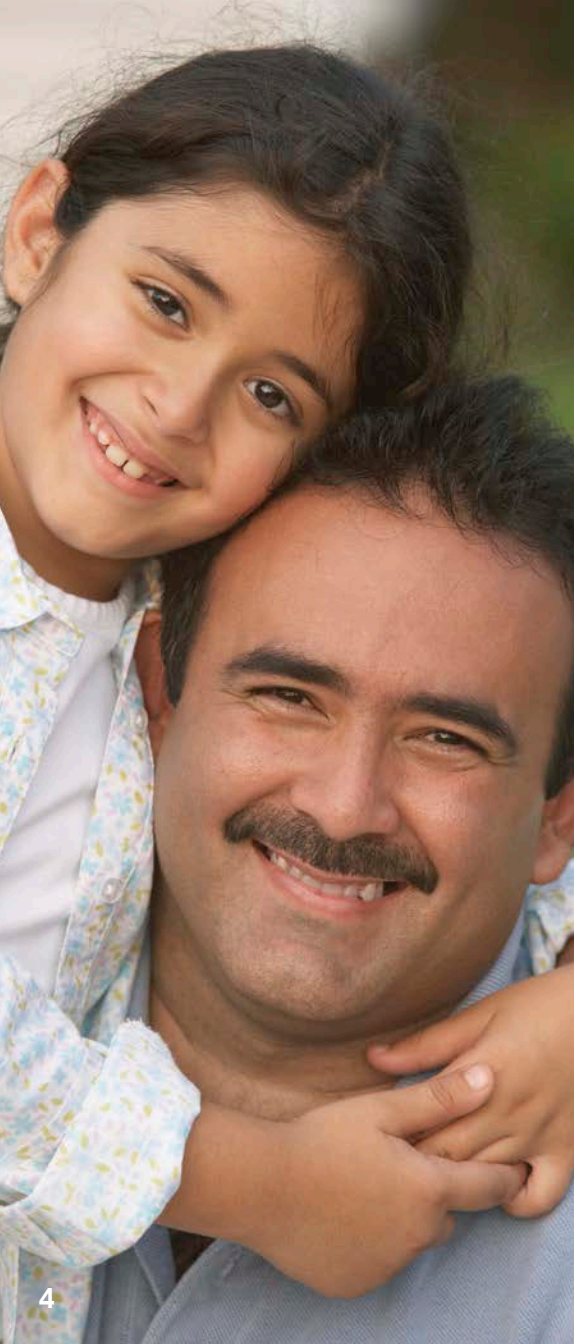
**To correct the issue, your doctor has recommended implantation of the Abre venous self-expanding stent.**

This booklet explains what it means to have deep venous obstruction, the Abre venous self-expanding stent system and its benefits and risks, and what you can expect before, during, and after your procedure. Read this booklet carefully and be sure to write down any questions that come up so you can discuss them with your doctor.



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# GLOSSARY

- **Access site:** Site of incision to start a minimally invasive surgical procedure and insert a delivery system.
- **Anticoagulant or antiplatelet therapy:** Medicines that prevent or treat blood clots.
- **Blood clot:** A mass of blood cells that can block or prevent normal blood flow in arteries or veins.
- **Coagulation:** The process by which blood changes from a liquid to a solid or semisolid state, as a protective mechanism of the body against bleeding.
- **Computed tomography (CT) scan:** Imaging instrument that uses X-rays and a computer to create pictures of your organs, bones, and other tissues.
- **Deep vein:** Vein located deep below the skin, carrying blood back to the heart.
- **Delivery system:** Long, thin, tube-like device with a handle used to insert and deploy a stent into arteries or veins.
- **Deployment (stent deployment):** Releasing of the stent out of the delivery system in the intended treatment area.
- **Iliofemoral veins:** Blood vessels that carry blood out of the leg and toward the heart.

- **Intravascular ultrasound (IVUS):** Imaging instrument that uses sound waves to see arteries and veins from within the blood vessel.
- **Magnetic resonance (MR) venography:** A scanner that uses magnetic waves to produce an image of your body's soft tissue and bones.
- **Minimally invasive surgical procedure:** Procedure that minimizes the size of the surgical site with the use of small instruments or devices.
- **Nitinol:** A metal alloy made primarily of nickel and titanium that is frequently used in implanted medical devices.
- **Self-expanding stent:** Stent that expands to a specified size and shape.
- **Stent:** A metal mesh tube that is implanted to open blocked blood vessels and restore blood flow.
- **Venogram:** X-ray procedure in which contrast dye is injected into the blood vessels. It facilitates imaging of the procedure to diagnose and/or treat a narrowing or blockage.
- **X-ray procedure:** Image of the internal composition of the body produced by X-rays passing through the body and being absorbed to different degrees by different materials in the body.



Abre venous stent

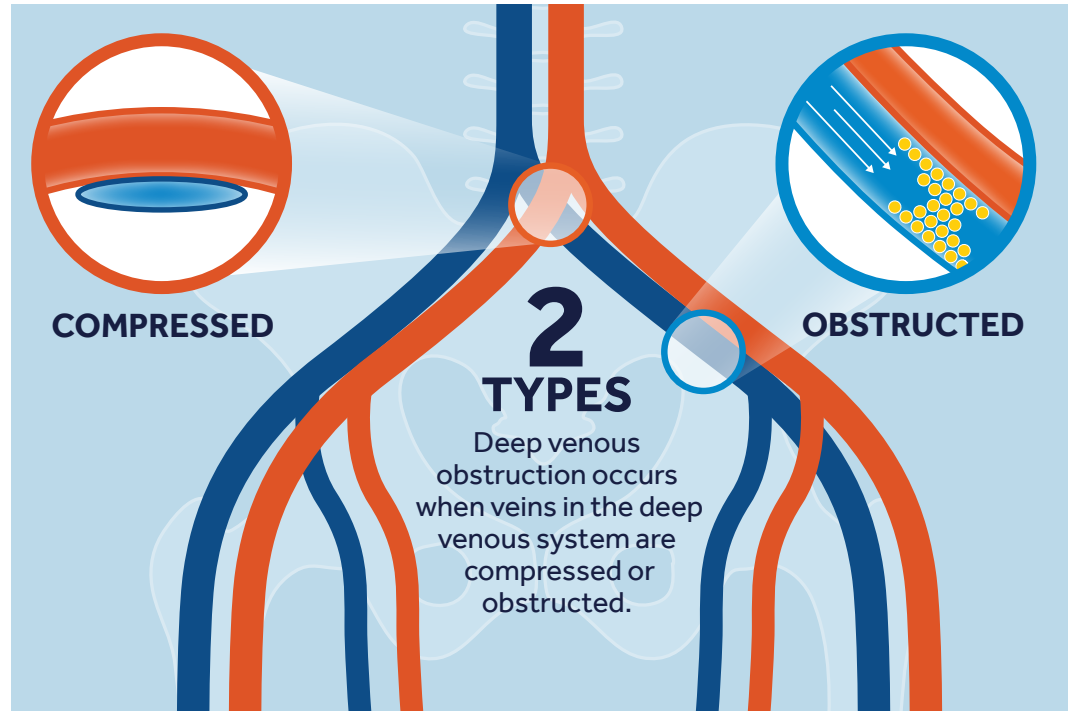
# WHAT IS DEEP VENOUS OBSTRUCTION?

## Deep venous obstruction

occurs when the blood flow in the veins located in your pelvic area — called the iliofemoral veins — is decreased or blocked.

While arteries bring oxygen-rich blood from your heart to the rest of your body, your veins return blood to the heart to be reoxygenated through the lungs.

When your leg veins cannot carry enough blood back to your heart, this is called deep venous disease or obstruction. It may cause changes including leg swelling, skin changes, leg ulcers, and/or pain.



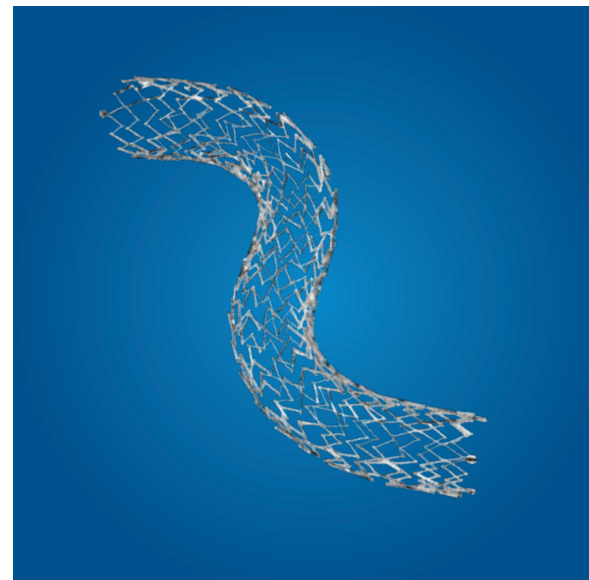
Deep venous obstruction illustration

# WHAT IS THE ABRE VENOUS SELF-EXPANDING STENT SYSTEM?

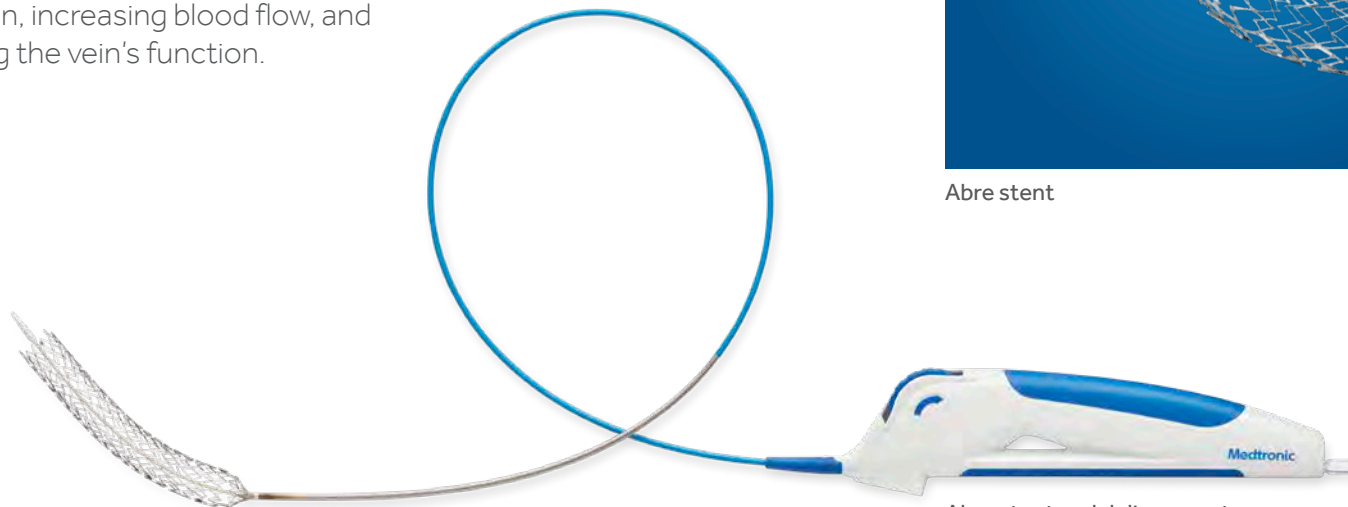
## The Abre system includes both the stent and the delivery system.

The stent is a flexible, self-expandable mesh tube made of nitinol (an alloy of nickel and titanium). The delivery system is a long, thin, tube-like device with a handle, which is used to insert and deploy the stent in the diseased segment of the vein.

The Abre stent is designed to be implanted in narrow or blocked iliofemoral veins. The stent is placed in the vein during a minimally invasive surgical procedure, and it opens and supports the vein wall, allowing blood to flow toward the heart. After the procedure, the stent remains in the iliofemoral vein, keeping the vein open, increasing blood flow, and restoring the vein's function.



Abre stent



Abre stent and delivery system



# WHAT ARE THE BENEFITS OF THE ABRE VENOUS STENT?

## THE PRIMARY BENEFIT OF THE ABRE STENT

is to open the compressed or obstructed iliofemoral vein and restore blood flow and vein function. This procedure has the potential to improve signs and symptoms of venous disease, including limb pain, swelling, and skin changes, and to enhance quality of life.

## A CLINICAL TRIAL CALLED THE ABRE STUDY

was conducted in the United States and Europe and was used to assess the clinical outcomes, performance, and safety of the Abre stent system. A total of 200 subjects at 24 different locations were treated in the trial. Outcomes from the trial through one year post-treatment showed that the stent is safe to use and is effective in treating deep venous obstruction.



# WHAT ARE THE RISKS AND CONTRAINDICATIONS?

**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 stent implantation procedure. Discuss any questions you may have with your doctor.

Risks include:

- Abnormal connection between artery and vein
- Additional surgical procedures
- Allergic reactions
- Bleeding or bruising
- Blockage of vein within or outside of stented segment
- Death
- Difficulty breathing or blockage of artery in lung
- Fever
- Formation of blood-filled cavity due to weakening of vessel wall
- Heart attack or alteration in heartbeat
- High blood pressure (hypertension)
- Infection
- Localized death of tissue due to lack of blood supply
- Nausea, low blood pressure (hypotension), or other vasovagal response
- New or worsening kidney failure
- Pain
- Stent misplacement, movement, or poor fit against vein wall
- Stent or delivery system breakage
- Stroke, bleeding in brain, or arterial blockage in brain
- Swelling caused by accumulation of fluid or blood in tissues
- Unintended movement of blood clot, device, or part of device, which might block a blood vessel
- Vessel damage, including tear or rupture

Abre stent is not indicated for patients that:

- Are not able to have anticoagulant or antiplatelet therapy (therapy that retards or inhibits the coagulation of blood)
- Are allergic to nitinol
- Have a blockage in their vein that prevents complete inflation of a small balloon, or proper placement of the stent or stent delivery system



# WHAT CAN YOU EXPECT FROM THE PROCEDURE?

## BEFORE THE PROCEDURE

Your doctor will review your information and ask questions about your past medical history, injuries, interventions, and medications that are relevant to your current state of health. They may use a variety of imaging techniques to visualize your veins and/or determine the degree of your venous disease. These techniques may include IVUS, X-ray, venogram, CT scan, or MR venography.

## DURING THE PROCEDURE

As the implant procedure begins, you will receive an anesthetic (pain medication) to help avoid discomfort.

Your doctor will insert a needle in your leg (or neck or arm) to access the obstructed vein and might insert and inflate a small balloon to help open it.

Your doctor will then remove the balloon and position the Abre delivery system to release the Abre stent where the diseased segment of the vein is located. During deployment, the Abre stent self-expands to the vessel wall to keep the vein open. Your doctor will then remove the delivery system, leaving the stent within the vein. Depending on the extent of the diseased area, additional Abre stent(s) may be placed.

Your doctor may decide to temporarily inflate a balloon in the Abre stent(s) to ensure that it is fully open and fits tightly in place.

Venogram and IVUS may be used during the procedure to ensure the stent is correctly placed and working.

Once this is confirmed, your doctor will end the procedure and place a bandage over the insertion site.

You may have some discomfort at this site, and if so, you may receive some medication to help reduce the pain.

## **AFTER THE PROCEDURE**

You may be discharged from the hospital on the same day or within the next few days after your Abre stent placement procedure. Prior to leaving the hospital, your physician may examine your limbs for signs of venous disease or complications, perform an ultrasound to visualize the treated vein(s), and discuss medications and follow-up appointments.

It's important to note that remaining active and living a healthy lifestyle can reduce your risk of developing additional venous disease. As always, discuss any lifestyle changes with your doctor.

REMAIN  
ACTIVE  
& LIVE A  
HEALTHY  
LIFESTYLE



Please refer to your doctor in case of doubts or questions.

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