

# Patient Information Guide

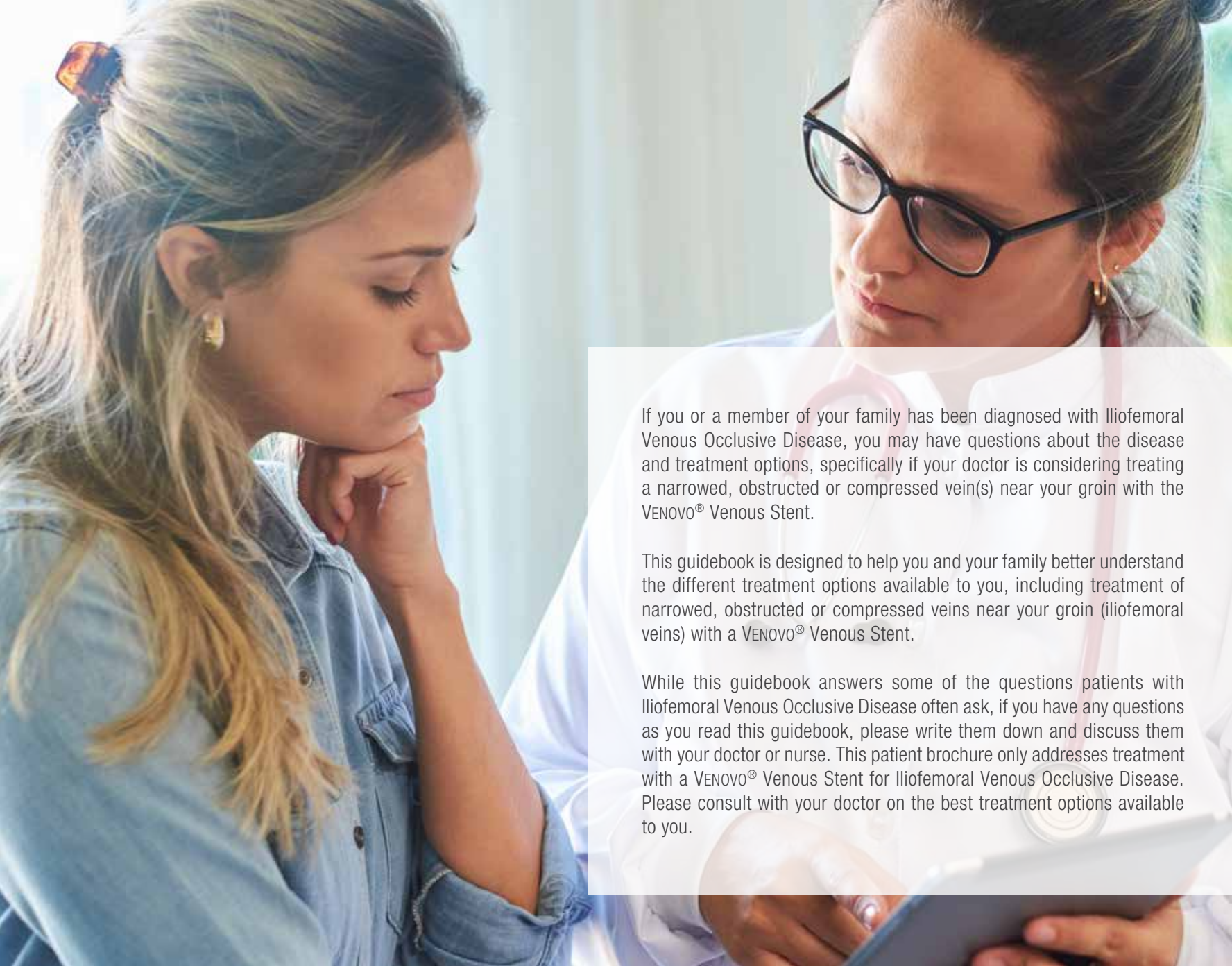


**VENOVO**<sup>®</sup>

Venous Stent System



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has joined BD



If you or a member of your family has been diagnosed with Iliofemoral Venous Occlusive Disease, you may have questions about the disease and treatment options, specifically if your doctor is considering treating a narrowed, obstructed or compressed vein(s) near your groin with the VENOVO® Venous Stent.

This guidebook is designed to help you and your family better understand the different treatment options available to you, including treatment of narrowed, obstructed or compressed veins near your groin (iliofemoral veins) with a VENOVO® Venous Stent.

While this guidebook answers some of the questions patients with Iliofemoral Venous Occlusive Disease often ask, if you have any questions as you read this guidebook, please write them down and discuss them with your doctor or nurse. This patient brochure only addresses treatment with a VENOVO® Venous Stent for Iliofemoral Venous Occlusive Disease. Please consult with your doctor on the best treatment options available to you.

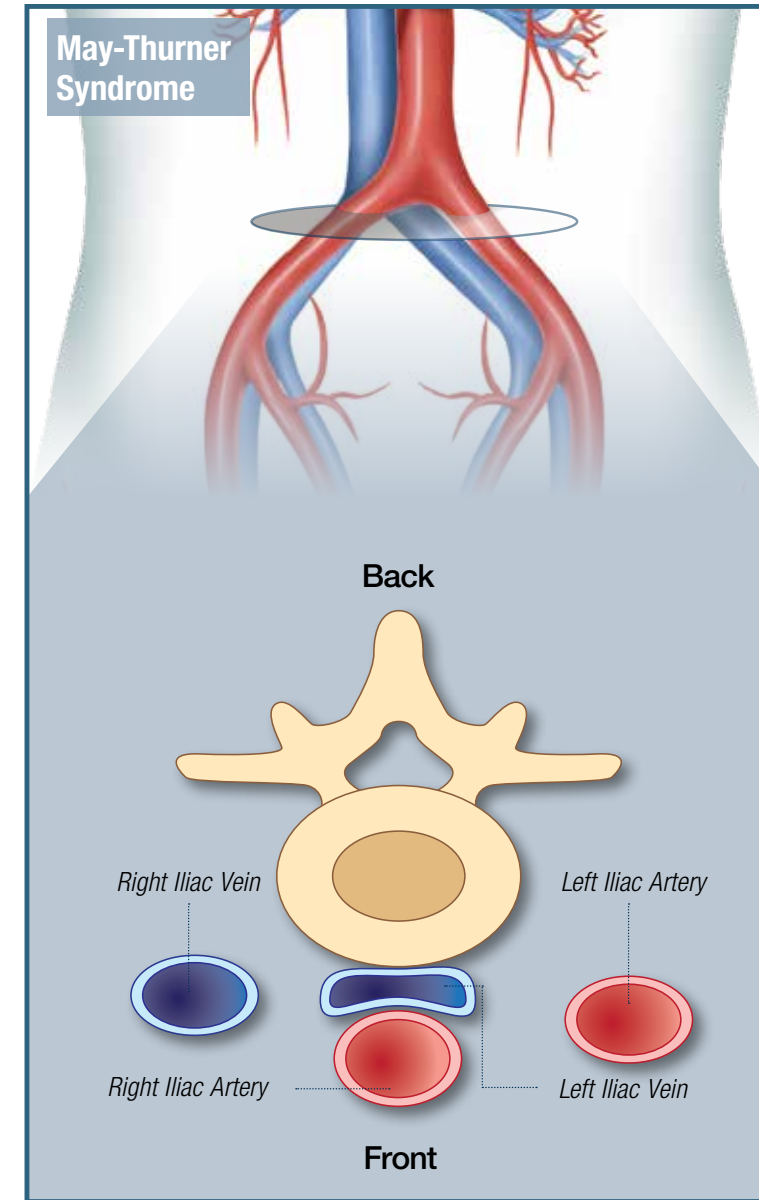
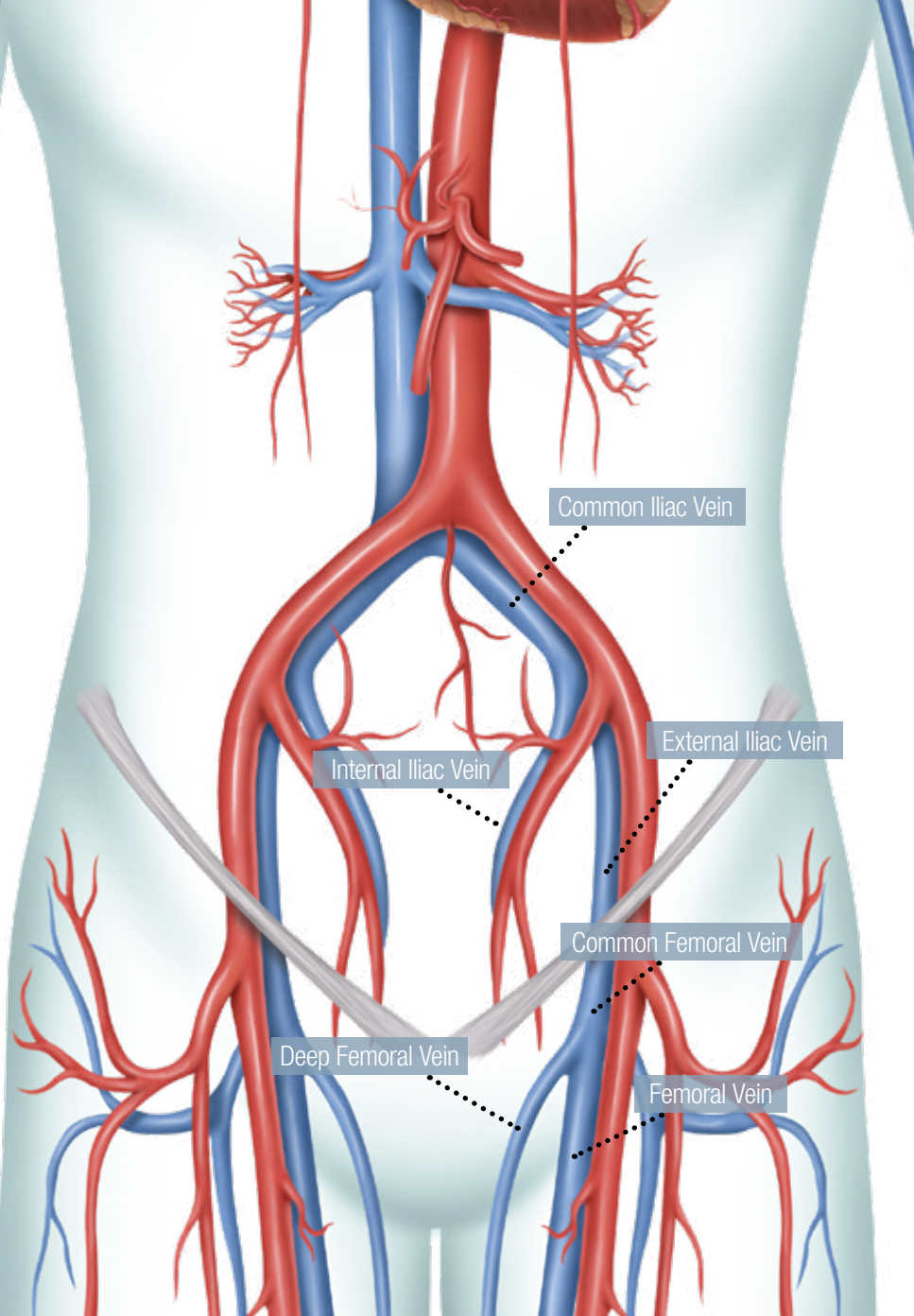
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# Understanding Iliofemoral Venous Occlusive Disease

## What are the Iliac and Femoral Veins?

Veins are the part of the circulatory system that returns the “used” blood, which has the oxygen and nutrients removed, back to the heart. Depending upon activity and posture, 60-80% of your resting blood resides within the venous system. The veins contain a series of one-way valves to help keep blood flowing in the right direction back towards the heart. The femoral and iliac veins are deep, large veins that extend from your groin up to your pelvic area, and drain into the largest vein in the abdomen, the vena cava, which goes directly into your heart.



## What is Iliofemoral Venous Occlusive Disease?

Iliofemoral Venous Occlusive Disease occurs when there is impaired blood flow in the iliofemoral vein. This can be caused by acute or chronic Deep Vein Thrombosis (DVT), May-Thurner Syndrome, or a combination of the above. Venous thrombus occurs when a hypercoagulable state and/or impaired blood flow causes the formation of a clot that obstructs the blood flow. If this blockage is caught early, typically within the first two weeks, it is considered an acute DVT. A clot beyond 28 days is considered a chronic DVT, which can result in scar tissue formation, leading to narrowing or blockage of the veins. In other instances, the iliac artery can compress the iliac vein, this is known as May-Thurner Syndrome, which can result in damage and narrowing of the left iliac vein and in some cases cause a DVT. These iliac veins are major exit sites for the blood to get back to the heart. When they are defective or damaged, it prevents the blood flow from getting out of the leg(s) back to the heart.

Some symptoms of Iliofemoral Venous Occlusive Disease include:

- ▶ Swelling of the legs
- ▶ Pain when standing
- ▶ Skin discoloration
- ▶ Ulcers



### What are risk factors for Iliofemoral Venous Occlusive Disease?

Factors that increase the risk of Iliofemoral Venous Occlusive Disease include:

- ▶ Trauma
- ▶ Obesity
- ▶ Pregnancy
- ▶ Surgery
- ▶ Cancer
- ▶ Smoking
- ▶ Anatomy (May-Thurner)
- ▶ Prolonged Immobility / Travel
- ▶ Hospitalization / Nursing Home
- ▶ Genetic Clotting Disorders
- ▶ Oral Contraceptives
- ▶ Hormone Therapy

### How is Iliofemoral Venous Occlusive Disease diagnosed?

Iliofemoral Venous Occlusive Disease is diagnosed based on medical and family history, a physical exam, and diagnostic test results.

The following diagnostic tests may be performed if Iliofemoral Venous Occlusive Disease is suspected. These tests can be used to diagnose where blockages might be, and how narrow your veins are in the areas of your legs, groin and pelvis.

#### Duplex Ultrasound (DUS)

- ▶ Sound wave imaging of the vein of the leg, pelvis and abdomen (if possible). This study may not be able to image the veins significantly above the level of the groin in some patients.

#### Computerized Tomography (CT) or Magnetic Resonance Imaging (MRI)

- ▶ To see the pelvic and abdomen veins, non-invasive studies such as a CT scan or MRI may be needed to find out where the blood clot is located.

#### Venography and Intravascular Ultrasound (IVUS)

- ▶ Minimally-invasive contrast venography (injecting x-ray dye (contrast) directly into the vein) along with IVUS (a sound wave device placed into the vein to take pictures from the inside) may be needed to accurately determine the length of the blockage and which veins are involved. Intravascular ultrasound may be more reliable for determining the type of disease, its extent and exact location.

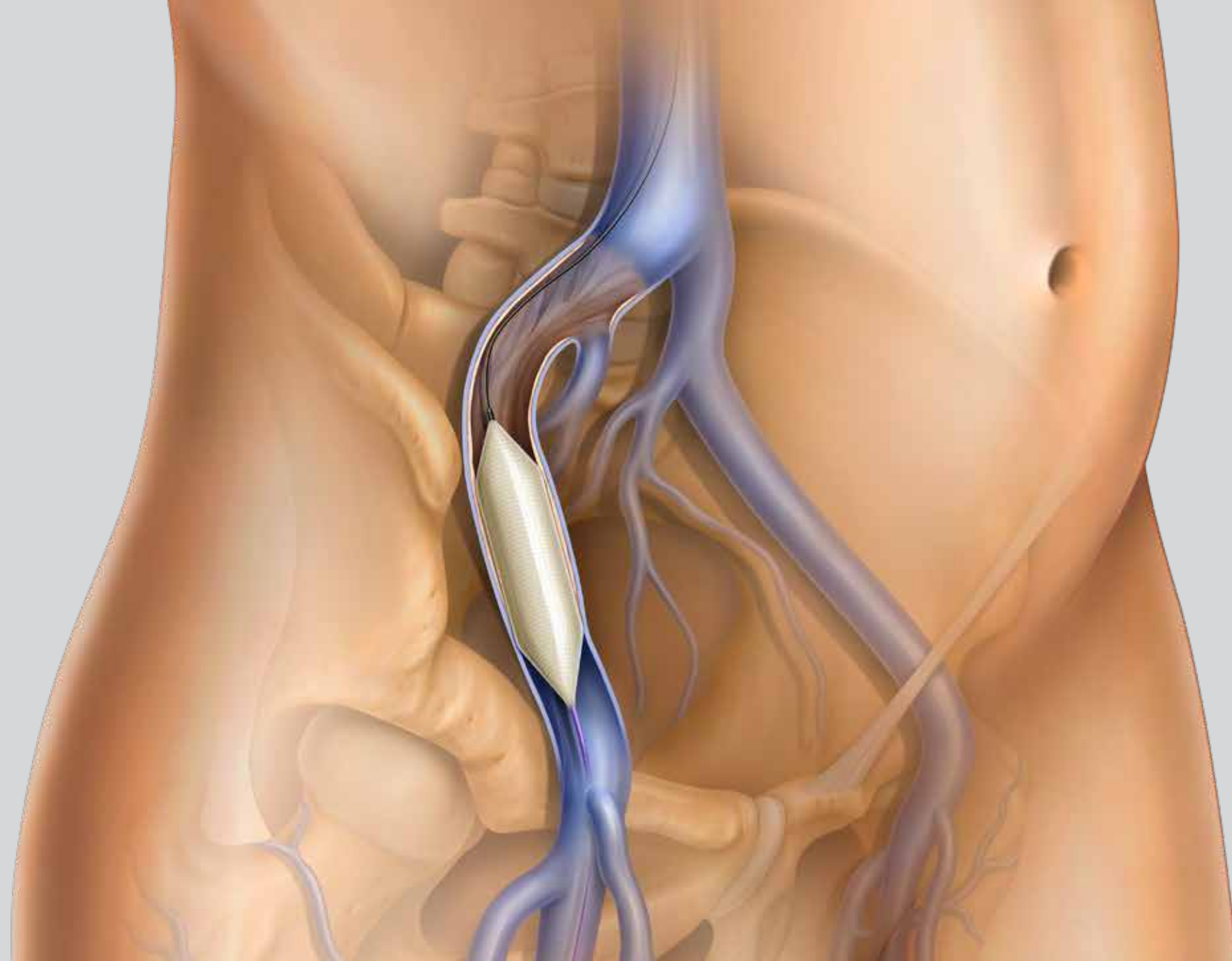
# Understanding Your Stent Procedure

Blockage or narrowing of the deep veins in your pelvis and groin, including the iliac and femoral veins, prevent blood flow from getting out of the leg(s) and back to the heart. The VENOVO® Venous Stent is one of many devices that can be used to treat problems affecting the deep veins in your body. Please consult your doctor to learn more about the best treatment option for you.

## What is Venous Angioplasty and Stenting

In preparation for your procedure, you may receive sedative medication or general anesthesia. During your venous angioplasty and stenting procedure, your physician may numb the skin and begin with needle entry in your vein(s). Your physician will then insert a catheter (thin tube) with a small balloon at the tip of the catheter into the affected vein. As the balloon is inflated it pushes the scar tissue or clot outward against the wall of the vein. This helps to reopen the blocked vein and restore blood flow back to the heart. The balloon is then deflated and removed from your body.

Then, a stent, which is a small metal wire mesh tube, is expanded inside of the vein to help keep the vein open. By doing so, this will help maintain adequate blood flow back to the heart, which can help alleviate your leg symptoms (i.e., pain and swelling).



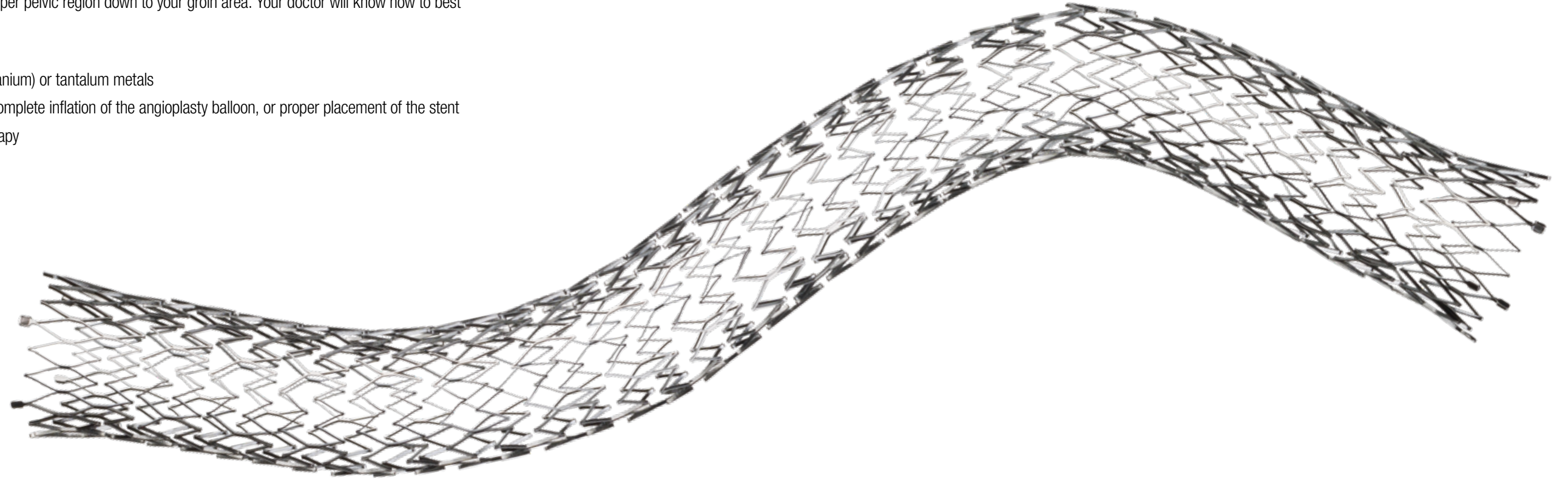
## What is the VENOVO® Venous Stent?

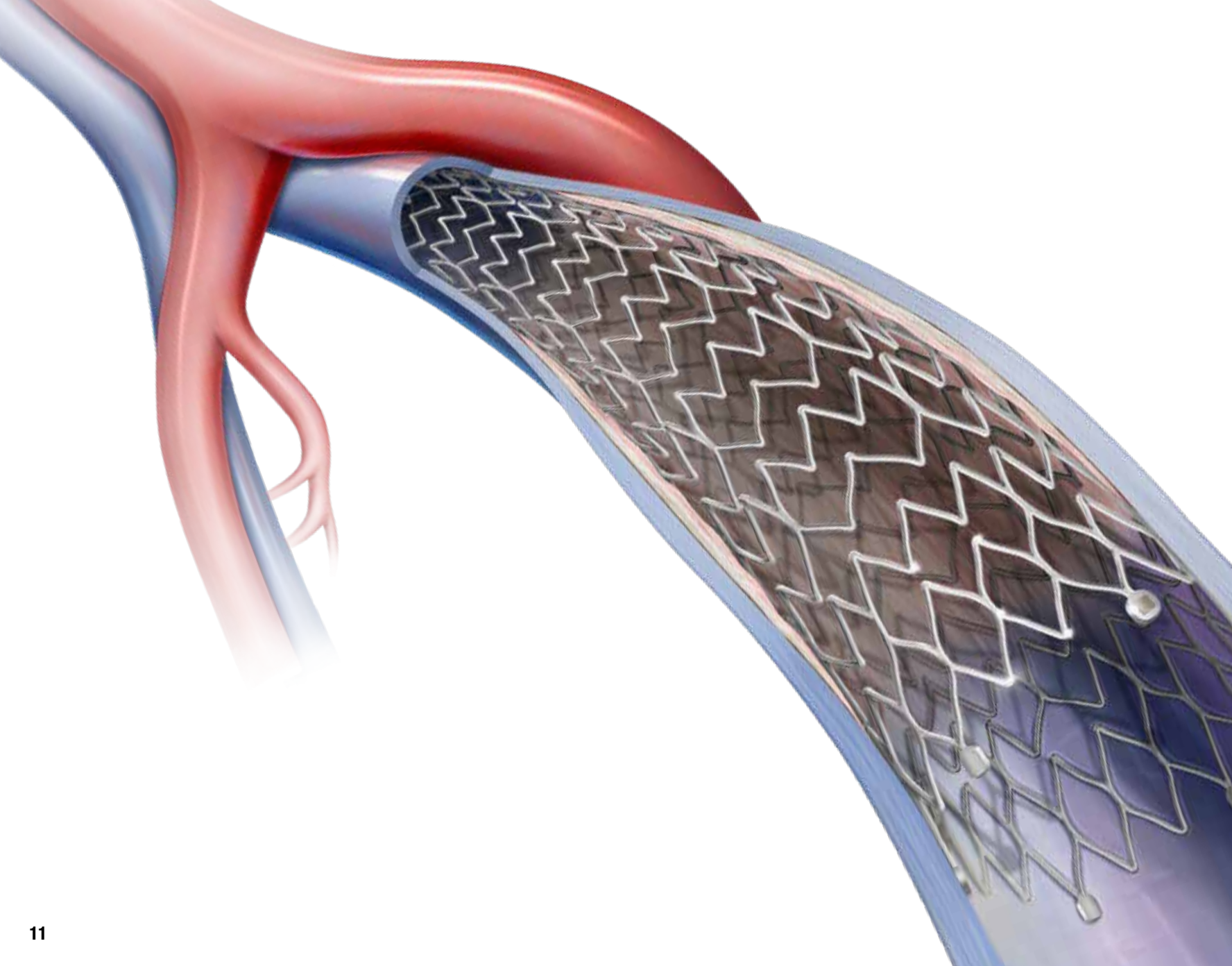
The VENOVO® Venous Stent is a flexible mesh tube made from nitinol. Nitinol is a nickel titanium alloy that has shape memory and is designed to expand to a specified size when warmed to body temperature. The stent comes inside a delivery system catheter which allows the doctor to advance it through your body to the specific narrowing in the vein.

- ▶ When can the device be used? (Indications for Use)

The VENOVO® Venous Stent is used to treat a narrowed vein found in the upper pelvic region down to your groin area. Your doctor will know how to best choose the correct stent size.

- ▶ When should the device not be used? (Contraindications)
  - ▶ If you have a known hypersensitivity or allergy to nitinol (nickel-titanium) or tantalum metals
  - ▶ If the doctor has determined that the blocked vein will not allow complete inflation of the angioplasty balloon, or proper placement of the stent
  - ▶ Patients who cannot receive intraprocedural anti-coagulation therapy





### What are the risks of the VENOVO® Venous Stent implantation procedure?

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. Be sure to discuss any questions you may have with your doctor.

- ▶ Abnormal blood pressure (hypotension/hypertension)
- ▶ Abnormal connection between an artery and vein
- ▶ Additional surgical procedures
- ▶ Allergic reactions
- ▶ Bleeding at procedure site
- ▶ Breakage/fracture of the stent
- ▶ Bruising/swelling at procedure site
- ▶ Chest pain or discomfort
- ▶ Damage to the vein
- ▶ Death
- ▶ Excessive bleeding requiring transfusion
- ▶ Fever
- ▶ Formation of blood clots in arteries or veins
- ▶ Incorrect placement of the stent
- ▶ Infection
- ▶ Kidney failure
- ▶ Limb loss (amputation)
- ▶ Movement of the stent after implantation
- ▶ Pain
- ▶ Pieces of the clot, pieces of the device, or fragments of blood clots that can block the vein
- ▶ Pieces of the clot or pieces of the device that can break loose and travel up in the blood stream
- ▶ Recurrence of the narrowing/blockage (restenosis)
- ▶ Reduction of blood flow or damage to tissue/organs
- ▶ Respiratory arrest
- ▶ Spasm of vein
- ▶ Weakening of the vein wall (aneurysm)

### What is the potential benefit of using the VENOVO® Venous Stent?

The VENOVO® Venous Stent was evaluated in the VERNACULAR clinical study, which included 170 patients. The initial procedure was successful in all patients according to the physicians and one year follow-up results indicate that the VENOVO® Venous Stent is safe and effective for treatment of symptomatic iliofemoral venous outflow obstruction. For more information on the VENOVO® Venous Stent please visit [www.bardpv.com/portfolio/venovo](http://www.bardpv.com/portfolio/venovo).

# After Your VENOVO® Venous Stent Implantation Procedure

## What to expect during your recovery

Before you leave the hospital, your doctor will speak to you about what kind of activities you can do, what you should eat, and what medicine you will need to take. You will be told when you can start to return to normal activities and return to work. Your physician may prescribe medications for you to take to prevent blood clots from forming in your newly-opened blood vessel. It is important to follow your doctor's instructions and to keep all follow-up appointments. During these follow-up appointments, your doctor will monitor your progress and evaluate your medications and the status of your disease.



## Living with Iliofemoral Venous Occlusive Disease

Living a healthy, active lifestyle can greatly improve your quality of life and reduce the risk of developing new blockages and narrowing in your veins.

You should talk to your doctor about lifestyle changes and how to increase your chances for a healthier outcome and a more rewarding life.



## Keep your stent implant card handy

Your stent implant card contains important information about the stent you had implanted. Be sure to show your implant card to any health care providers that treat you in the future.

It is recommended to register the stent implant under MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or an equivalent organization.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant and direct them to follow the instructions written on the implant card or included in this booklet.

## Safety during Magnetic Resonance Imaging (MRI)

After placement of your VENOVO® Venous Stent, your doctor may request a special test that uses electrical waves from a magnet to obtain images of the inside of your body, called an MRI. Your VENOVO® Venous Stent has been classified as MR Conditional. This means that an MRI can be done safely if specific testing conditions are followed. These conditions are outlined on the implant card that was provided to you as part of your procedure. Please provide this information to anyone assisting you with an MRI. A copy of the information located on the card is also provided below.

Non-clinical testing has demonstrated that the VENOVO® Venous Stent is MR Conditional for single and overlapping placement in the iliac and femoral veins for all clinically relevant lengths. Based upon preclinical testing, patients with the VENOVO® Venous Stent can be scanned safely, immediately after placement of this implant, under the following conditions:

- ▶ Static magnetic field of 1.5 or 3.0 Tesla only.
- ▶ Spatial gradient field of 3000 Gauss/cm or less.
- ▶ Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning for landmark above umbilicus and 1 W/kg for landmark below umbilicus.

### 3.0 Tesla Temperature Rise

In an analysis based on non-clinical testing according to ASTM F2182-11a and computer modeling of a patient, the 10 x 80 mm VENOVO® Venous Stent was determined to produce a potential worst-case temperature rise of 5.2°C at the whole body SAR limits stated above for 15 minutes of MR scanning in a 3.0 Tesla whole body MR system. Cooling due to blood flow inside the stent and perfusion in the vascular bed surrounding the stent was included in the assessment of in-vivo temperature rise.

### 1.5 Tesla Temperature Rise


In an analysis based on non-clinical testing according to ASTM F2182-11a and computer modeling of a patient, the 10 x 160 mm VENOVO® Venous Stent was determined to produce a potential worst-case temperature rise of 3.4°C at the whole body SAR limits stated above for 15 minutes of MR scanning in a 1.5 Tesla whole body MR system. Cooling due to blood flow inside the stent and perfusion in the vascular bed surrounding the stent was included in the assessment of in-vivo temperature rise.


### Image Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. Artifact tests were performed according to ASTM F2119-07. Maximum artifact extended 22 mm beyond the stent for the spin echo sequence and 5 mm for the gradient echo sequence. The lumen was obscured.

### Additional Information

The VENOVO® Venous Stent has not been evaluated in MRI systems with field strengths other than 1.5 or 3.0 Tesla. The heating effect in the MRI environment for fractured stents is not known. The presence of other implants or the health state of the patient may require reduction of the MRI limits listed above.

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Please visit <a href="http://www.bardpv.com/portfolio/venovo">www.bardpv.com/portfolio/venovo</a> for more information on the VENOVO® Venous Stent.		
Call 1-800-562-0027 to request a hard copy version of the Patient Information Guide.		
Apply removable Sticker from Product Label here		

<b>VENOVO® Venous Stent System</b>	
Non-clinical testing has demonstrated that the VENOVO® Venous Stent is MR Conditional for single and overlapping placement in the iliac and femoral veins for all clinically relevant lengths. Based upon the preclinical testing, patients with the VENOVO® Venous Stent can be scanned safely, immediately after placement of this implant, under the following conditions:	
<ul style="list-style-type: none"><li>• Static magnetic field of 1.5 or 3.0 Tesla only.</li><li>• Spatial gradient field of 3000 Gauss/cm or less.</li><li>• Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning for landmark above umbilicus and 1W/kg for landmark below umbilicus.</li></ul>	
The VENOVO® Venous Stent has not been evaluated in MRI systems other than 1.5 or 3.0 Tesla.	
Patient's Name: _____	
Date of Implant(s): _____ Site of Implant(s): _____	
Implanting Physician: _____	
Hospital: _____	
Address: _____	
Telephone: _____	
<b>Remember to carry this card with you</b>	

# Glossary

## **Anticoagulant**

Medications that prevent blood clots from forming.

## **Antiplatelet**

Medications that prevent blood clots from forming.

## **Artery**

A blood vessel that carries blood from the heart and lungs through the body. Blood in arteries is full of oxygen.

## **Balloon Angioplasty**

A procedure where a small tube containing a balloon at the tip is passed through to the blocked area of a vein. The balloon is inflated and opens the blocked area in the vein. Also called Percutaneous Transluminal Angioplasty (PTA).

## **Blood Clot**

A clump of blood cells that can block or prevent normal blood flow.

## **Blood Vessel**

An artery or vein.

## **Catheter**

A small, hollow tube used for gaining access to a blood vessel and delivering treatment therapies.

## **Computed Tomography (CT) Scan**

Special X-ray tests that produces cross-sectional pictures of the organs, bones and other tissues using X-rays and a computer.

## **Contraindications**

A condition that makes a specific treatment or procedure improper or undesirable.

## **Doppler Ultrasound**

A non-invasive test to detect venous disease that evaluates blood flow in the major veins of the leg.

## **Fluoroscopy**

An X-ray procedure in which contrast dye is injected into the veins to find narrowing or blockage of the vein.

## **Hypercoagulable**

Factors in your blood that increase your chance of developing blood clots.

## **Hypertension**

A condition where the pressure inside the blood vessels is too high. Also known as high blood pressure.

## **Hypotension**

A condition where the pressure inside the blood vessels is too low. Also known as low blood pressure.

## **Iliofemoral Veins**

The veins that extend from your pelvic region down to the groin area.

## **Iliofemoral Venous Occlusive Disease**

Vascular disease when the veins in the extremities become narrowed or obstructed limiting blood flow back to the heart.

## **Indication for Use**

When/where a device or procedure can be used.

## **Intravascular Ultrasound (IVUS)**

Medical imaging diagnostic test that uses sound waves to see inside blood vessels.

# Glossary

## **Lesion**

A narrowing or blockage of a vein. Also known as a stenosis.

## **Lumen**

The inner channel of a vein or artery.

## **MRI (Magnetic Resonance Imaging)**

A diagnostic test that uses magnetic waves to obtain images of the inside of your body.

## **Nitinol**

A special metal made of nickel and titanium that remembers its shape. Nitinol can be compressed when cold and expands back to its original shape and size when heated.

## **Percutaneous**

Performed through a small opening in the skin.

## **Stenosis**

A narrowing or blockage of a blood vessel. Also known as a lesion.

## **Stent**

An expandable, metallic, tubular shaped device that provides structural support for a vessel.

## **Venography**

An X-ray procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the vein.

## **Vein**

A blood vessel that carries blood from the organs of the body back to the heart. Blood in the veins is deoxygenated.



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