

Patient Guide for the Zilver[®] Vena[™] Venous Self-Expanding Stent



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About this patient guide

You are receiving this patient guide because you or a member of your family has been diagnosed with a narrowed or obstructed vein near your groin (iliac and femoral veins). This patient guide has been provided as a courtesy from Cook Medical. The aim of this guide is to provide you a resource to learn more about iliofemoral venous outflow obstruction and potential treatment options. We hope this information will be helpful to you and your family.

This patient guide answers some questions and provides basic information about the **venous system**, iliofemoral venous outflow obstruction, and treatment of iliofemoral venous outflow obstruction with the Zilver® Vena™ Venous Self-Expanding Stent. For your convenience, a glossary of medical terms is included on pages five and six. Words in bold throughout the text are defined in the glossary.

This guide is not intended to diagnose a medical condition. The treatment of iliofemoral venous outflow obstruction may vary according to an individual's unique needs and doctor assessments. As with any surgery or medical procedure, the best source of information and advice is your doctor. Please discuss your treatment options and any questions you may have with your doctor.

Glossary

Anesthesia – the numbing of pain due to the administration of gases or drugs before surgery.

Anticoagulant – blood thinner or a medicine that reduces your body's ability to form blood clots.

Angioplasty – a way to open narrowed or blocked veins by using a small **balloon catheter**.

Antiplatelet – medicine that helps prevent your blood cells from sticking to each other.

Balloon catheter – a balloon that is attached to, and inflated through, a hollow, flexible tube.

Catheter – a hollow, flexible tube that is used to access parts of the body, such as veins.

Compression therapy – use of special socks or stockings that squeeze the legs to help blood flow more easily through the veins and back to the heart.

Deep vein thrombosis (DVT) – a blood clot that has formed inside a vein deep inside your body. The clot can completely or partially block blood flow.

Duplex ultrasound (DUS) – a way for doctors to see inside the body using soundwaves.

Iliac vein compression – pressure on the outside of the vein, limiting blood flow back to the heart; this can be caused by an artery squeezing the vein, referred to as May-Thurner.

Intravascular ultrasound (IVUS) – a kind of imaging that uses sound waves to see directly inside a vein.

Magnetic resonance imaging (MRI) scan – a way of creating detailed pictures of the body. The MRI scanner uses magnetic fields and radiowaves to create pictures.

Nitinol – a metal that combines nickel and titanium. Nitinol retains its shape, even after being squeezed or bent many times.

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Occlusion – blockage of a vein, allowing no blood flow to return to the heart.

Venography – a way of taking x-rays of veins after a special dye is injected.

Venous system – the collection of all veins, which return blood flow back to the heart.

Iliofemoral venous outflow obstruction

What is iliofemoral venous outflow obstruction?

Blood flows throughout the body in vessels known as arteries and veins; arteries are typically responsible for transporting blood away from the heart, while veins are typically responsible for carrying blood back to the heart.

Iliofemoral venous outflow obstruction occurs when the veins near the groin or pelvis (the iliac and femoral veins) are unable to return blood to the heart normally. When the veins are narrowed (stenosed), less blood can flow through the vessels. This **stenosis** results in a decrease in blood flow through the veins. When the veins are occluded, no blood can flow through the veins.

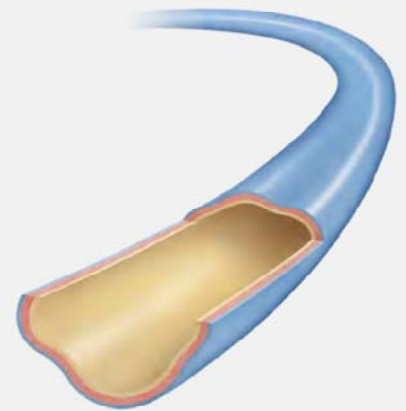
Iliofemoral venous outflow obstruction can be caused by a blood clot inside the vein, called **deep vein thrombosis (DVT)**. A blood clot may form due to a medical condition that makes it easier to form a clot (hypercoagulable) or due to reduced blood flow. A blood clot can reduce or block blood flow through a vessel. Acute **DVT** is new clot. Chronic **DVT** is old or previously diagnosed clot, which can damage the vein and cause it to narrow.

Iliofemoral venous outflow obstruction can also occur from an artery pressing on a vein, often referred to as **iliac vein compression**. Your physician may refer to this as May-Thurner. This condition also results in damage to the vein by causing scar tissue and vein narrowing.

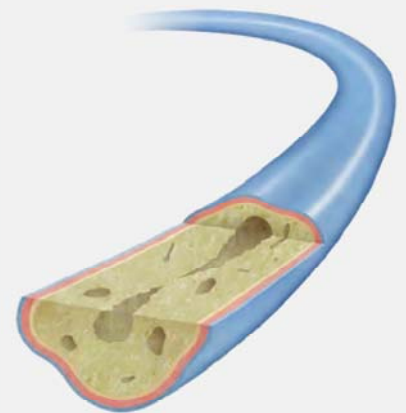


A clot (thrombus) after its removal from a diseased vein.

Reprinted with permission from Anthony J. Comerota, MD, FACS, RVT.



A healthy vein.



A vein that is blocked by a clot (thrombus).

What are the symptoms and risk factors of iliofemoral venous outflow obstruction?

Iliofemoral venous outflow obstruction is typically not a life-threatening condition. Patients may experience the following symptoms:

- Lower back pain
- Leg pain
- Varicose veins
- Swelling of legs
- Skin changes over the legs (red or bluish skin)
- Leg cramps
- Open sores / ulcers

Risk factors may include:

- Family history of venous disease
- Previous history of **DVT**
- Clotting disorder
- Advancing age
- Pregnancy
- Hormone therapy / oral contraceptives
- Obesity
- Trauma
- Immobility

How is iliofemoral venous outflow obstruction diagnosed?

A diagnosis of iliofemoral venous outflow obstruction is based on your medical history, a physical examination, and imaging tests. During the physical exam, your doctor will visually examine and feel your legs. Your doctor may also evaluate your ability to walk. The imaging test may be a **duplex ultrasound (DUS)**, which uses sound waves to allow your doctor to see the veins in your groin. In a **DUS**, your doctor will take the ultrasound probe and hold it against your leg. Depending on the **DUS** results, your doctor will determine what treatment is needed, or if additional imaging is needed, such as **venography** and/or **IVUS (intravascular ultrasound)**.

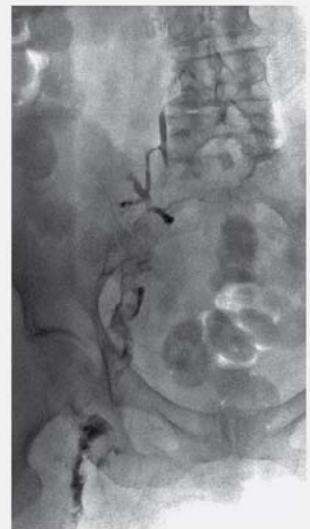
Venography allows a doctor to see the details of your vein, including where the vein is narrowed. **Venography** provide a clearer picture of what is happening to your vein. A dye is injected into the vein, and x-ray images are taken. Depending on what your doctor sees, they may decide on a course of treatment, or may elect to do further imaging, such as **IVUS**, before any treatment is provided.

IVUS also uses sound waves to examine a vein, but creates images from inside the vein. A **catheter** is placed inside the vein and sound waves are used to produce an image of the inside of the vein for your doctor. These images help your doctor determine your individualized treatment plan.

How is iliofemoral venous outflow obstruction treated?

Once diagnosed, iliofemoral venous outflow obstruction may be treated by:

- Medical management (**anticoagulants**, lifestyle changes such as diet, exercise)
- **Compression therapy**
- Venous **angioplasty** and stent placement
- Open surgical repair



This is what **venography** looks like.

Reprinted with permission from Gerard J O'Sullivan, MD.

Some patients will receive **anticoagulants** (blood thinners) to help decrease the body's ability to clot blood. Similarly, most patients will also receive **compression therapy**, in the form of stockings or socks. **Compression therapy** squeezes the legs, which helps to keep blood flowing through your veins and back to the heart.

Anticoagulants, lifestyle changes, and **compression therapy** don't help all patients. Venous **angioplasty** and stent placement or, in some cases, open surgical repair may be necessary to treat iliofemoral venous outflow obstruction. Open surgical repair is not very common, but is a treatment option for patients who can't be treated with **angioplasty** and stent placement won't work. Open surgical repair involves cutting the leg open to expose the affected vein. Once the vein has been exposed, your doctor will cut the vein open and will remove the blockage. Following this, your doctor will stitch and close your vein and leg.



This is a **balloon catheter** breaking up clot inside a blocked vein.



This is a stent placed in the vein where the blood clot originally formed.

Venous **angioplasty** and stent placement is a treatment to help restore blood flow through your blocked iliac and femoral veins. Before the procedure, your doctor may give you medicine to help you relax (sedation). To access the veins, a small needle is inserted to the veins through a small incision in the leg. Your doctor may insert a special **catheter** into your veins that has a balloon (**balloon catheter**) attached to it. Your doctor can inflate this balloon inside your blocked vein. The balloon may push soft blood clots and scar tissue against the vein wall. You might feel some pressure or pain when the **balloon catheter** is inflated. After the vein has been pushed open by the balloon, your doctor deflates and pulls it out.

If the vein is too narrow after **angioplasty**, or your doctor thinks that **angioplasty** alone won't keep your vein open, a stent may be

placed in the blocked vein. A stent is a small, metal tube that lines the inside of the vein and helps keep the vein open and blood flowing easily. Like balloons, stents are delivered into the vein in a **catheter** (delivery system). After the stent is expanded at the area of narrowing, your doctor will remove the **catheter** from your body. Another **balloon catheter** may be used to further expand the size of the stent within the vein. Once placed, a stent remains in your body forever. The stent will help maintain blood flow to the heart.

After your procedure, you will go to a recovery area and be monitored. Your doctor will decide when you can go home. Your doctor will talk to you about what activities you can do and what medication you will take. Your doctor may prescribe you **anticoagulants** (blood thinners), to help prevent the future occurrence of a blocked vein by reducing the body's ability to clot blood. Your doctor might also ask you to wear **compression therapy** socks or stockings, to help prevent the future occurrence of a blocked vein by squeezing your legs to help blood flow more easily through the veins.

About the Zilver[®] Vena[™] Venous Self-Expanding Stent



The Zilver[®] Vena[™] Venous Self-Expanding Stent is a small, flexible stent. The stent is used to treat patients with iliofemoral venous outflow obstruction.

The stent is made of **nitinol**. **Nitinol** is a mixture of two metals: nickel and titanium. Things that are made of **nitinol** return to their original shape after they are squeezed or bent. **Nitinol** makes the Zilver[®] Vena[™] Venous Self-Expanding Stent open by itself (or self-expand) when your doctor puts it in your vein. Stents like the Zilver[®] Vena[™] Venous Self-Expanding Stent that open by themselves are called self-expanding stents.

Different sizes of the Zilver[®] Vena[™] Venous Self-Expanding Stent are available. Your doctor will measure your vein to decide what size is right for you.

What are the benefits of the Zilver[®] Vena[™] Venous Self-Expanding Stent?

The Zilver[®] Vena[™] Venous Self-Expanding Stent holds open the iliac and femoral veins, which helps blood flow normally back to the heart. This may help reduce symptoms associated with iliofemoral venous outflow obstruction, such as leg pain and swelling.

The Zilver[®] Vena[™] Venous Self-Expanding Stent was evaluated in the VIVO Clinical Study,¹ which included 243 patients. Procedure and three-year follow-up results indicate that the Zilver[®] Vena[™] Venous Self-Expanding Stent is safe and effective for treatment of symptomatic iliofemoral venous outflow obstruction.

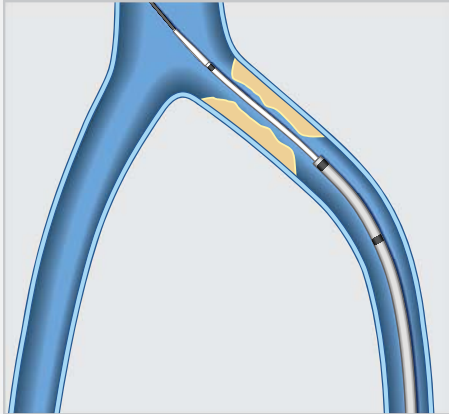
¹ VIVO clinical study. ClinicalTrials.gov Web site. <https://clinicaltrials.gov/ct2/show/NCT01970007>. Published October 25, 2013. Updated January 22, 2020. Accessed February 27, 2020.

Who should not receive a Zilver® Vena™ Venous Self-Expanding Stent?

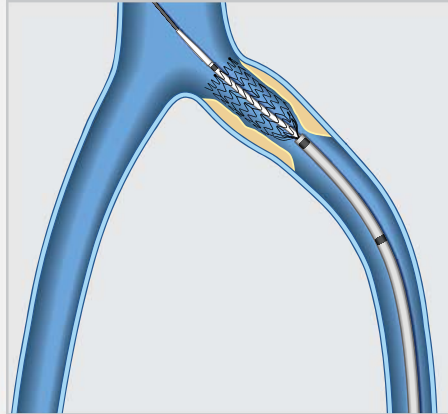
Prior to stent placement, your doctor will determine if you are a candidate for the Zilver® Vena™ Venous Self-Expanding Stent.

The Zilver® Vena™ Venous Self-Expanding Stent should not be used in patients:

- Who have a lesion that prevents crossing or complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.
- Who cannot receive specific blood thinning medications, such as aspirin or coumadin, among others.



This is what the Zilver® Vena™ stent looks like as it is inserted into the vein. The Zilver® Vena™ stent is completely contained inside thin, flexible tubing, called a **catheter**.



This is what the Zilver® Vena™ stent looks like as it is being expanded inside the vein. After the Zilver® Vena™ stent is outside of the **catheter**, the **catheter** is removed.

Risks associated with the use of the Zilver® Vena™ Venous Self-Expanding Stent*

Placement of the Zilver® Vena™ Venous Self-Expanding Stent has some risks, including, but not limited to:

- Abdominal or back pain
- Abrupt stent closure
- Allergic reaction to **anticoagulant** and/or antithrombotic therapy or contrast medium
- Allergic reaction to **nitinol** (nickel-titanium)
- Amputation
- Aneurysm
- Arrhythmia (abnormal heartbeat)
- Arteriovenous fistula (AVF; an abnormal connection between a vein and artery)
- Bleeding associated with anticoagulation
- Death
- Embolism (a clot that has migrated and blocks blood flow in a vessel)
- Fever
- Hematoma (a collection of blood trapped in a tissue layer) / hemorrhage (excessive loss of blood) at access site
- Hypersensitivity reactions
- Hypertension (a blood pressure that is higher than normal)
- Hypotension (a blood pressure that is lower than normal), nausea, or symptoms of a vasovagal response (a nervous system reaction causing slow heartbeat, low blood pressure, and potentially fainting)

- Infection / abscess (a collection of pus in a tissue) formation at the access site
- Intimal (inner lining of a vessel) injury / dissection (a separation of vessel layers)
- Myocardial infarction (MI) (heart attack)
- Pseudoaneurysm (large opening or dilation of an artery, giving the appearance of a rupture) formation
- Pulmonary embolism (a clot that has migrated and blocks blood flow in an artery of the lung)
- Renal (kidney) failure
- Restenosis (recurrence of a narrowed vessel or stent), **occlusion**, or thrombosis of the stented vein
- Septicemia (a blood infection) / bacteremia (bacteria in the blood)
- Stent malapposition (separation of a stent from the inner lining of the vessel wall)
- Stent migration or embolization
- Stent strut fracture
- Stroke (blockage of blood flow in the brain resulting in damage to brain tissue)
- Tissue necrosis (tissue death)
- Vasospasm
- Vessel perforation / rupture (the bursting of a blood vessel)
- Worsened pain

Before and after your Zilver® Vena™ Self-Expanding Stent placement

What to expect before your procedure:

Your doctor will tell you how to prepare for your stent placement. You may have to take drugs such as aspirin (**antiplatelet**) for a few days before the procedure to prevent blood clots. You may also have to stop eating and / or drinking before your procedure.

What to expect after your procedure:

When your procedure is finished, you will go to a recovery area. You may feel some pain and may be given pain-relief drugs. Nurses will closely monitor your blood pressure and heart rate. Your doctor will decide when you can go home, and when it is okay for you to resume normal activity.

Your doctor may prescribe blood thinners after you receive your stent. These drugs prevent blood clots from forming.

Patients in the Zilver® Vena™ VIVO Clinical Study,¹ were prescribed an **anticoagulant** (blood thinner) for at least six months in addition to an aspirin (**antiplatelet**) for the duration of the study. Ask your doctor what drugs are being prescribed, and don't stop taking these drugs without your doctor's approval. Please remember, as with any surgery or medical procedure, the best source of information and advice is your doctor. It is important to follow your doctor's instructions and to come back to be evaluated by your doctor.

¹ VIVO clinical study. ClinicalTrials.gov Web site. <https://clinicaltrials.gov/ct2/show/NCT01970007>. Published October 25, 2013. Updated January 22, 2020. Accessed February 27, 2020.

Important contact information

Emergency medical care:

My doctor's contact information:

Your patient card

After your procedure, your doctor will give you a patient card. You should keep your patient card and be ready to provide it when receiving medical care in the future. Your patient card lets medical professionals know that you have a Zilver® Vena™ Venous Self-Expanding Stent placed permanently in your body. Other healthcare providers will want to know that you have a metal stent inside your body before they ask you to undergo a **magnetic resonance imaging (MRI) scan**. MRI scanners use electromagnetic fields to create detailed images of your body. Your patient card helps medical staff know what **MRI** scanner settings are safe for you.

Cook recommends that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

