

# VIVID™

Venous stent for the Iliofemoral Vein Investigational clinical trial using the Vesper DUO Venous Stent System®



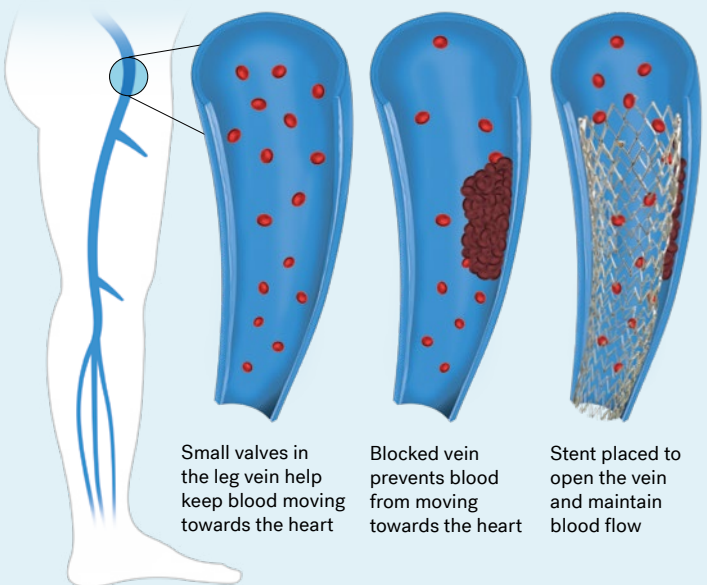
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# UNDERSTANDING VENOUS DISEASE

Chronic venous insufficiency, or CVI, occurs when your leg veins don't allow blood to return back to your heart. Normally, valves inside your deep leg veins keep blood moving against gravity and toward your heart.

When the walls of your vein are weakened and valves are damaged, the blood cannot travel out of the legs. This leads to high pressure in the leg veins and as a result, a person with CVI can experience symptoms like severe swelling, pain, or even skin discoloration and ulcers.

CVI can cause a vein in your leg to narrow or become completely blocked (occluded). To treat blocked veins, a procedure called balloon angioplasty is performed. Angioplasty uses a tiny balloon catheter that is inserted in the blocked vessel to help widen it and improve blood flow. Angioplasty is often combined with the placement of a small wire mesh tube called a stent. The stent helps keep the vein open, decreasing the chance of narrowing again.





IT IS ESTIMATED THAT MORE THAN 30 MILLION ADULTS IN THE UNITED STATES HAVE SOME FORM OF VENOUS DISEASE, WITH CVI BEING A COMMON HEALTH PROBLEM OCCURRING IN UP TO 5% OF THE POPULATION.<sup>1</sup>



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## THE VIVID TRIAL

The VIVID Trial is studying an investigational device called the Vesper DUO Venous Stent System®, which includes both the DUO HYBRID™ and DUO EXTEND™ stents. These new venous stents are designed to endure the unique forces and motion that happen in the deep veins. They are being studied to treat iliac and common femoral vein blockages with or without a history of a blood clot in the legs.

## DO I QUALIFY FOR THE VIVID TRIAL?

Your doctor will discuss the study with you in more detail and decide if you meet the criteria to participate in the VIVID Trial. By participating in this trial, you will receive at least 3 years of medical care following the implant of your venous stent. If you do not qualify, your doctor will discuss other treatment options that are best for you. You will still continue to be followed by your doctor and be treated according to the standard of care at your hospital.



## BENEFITS AND RISKS

There is no guarantee or promise that you will receive any benefits from participating in this trial. If you do receive benefits, the length of time they may last is unknown. Any potential benefits may only be temporary. The use of the Vesper DUO Venous Stent System in treating venous obstructions may result in anticipated potential risks or complications similar to other available endovascular implant devices (such as stents) used in these procedures.

MAKE SURE TO TALK TO YOUR DOCTOR ABOUT ALL THE POTENTIAL BENEFITS AND RISKS ASSOCIATED WITH THE VESPER DUO VENOUS STENT SYSTEM, INCLUDING OTHER OPTIONS FOR THE TREATMENT OF YOUR NARROWED OR BLOCKED VEINS.

For more information visit

<https://clinicaltrials.gov/ct2/show/NCT04580160>

# HOW IT WORKS



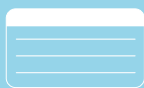
During the procedure, your doctor will place a small tube in your groin and guide it into the blocked vein to perform balloon angioplasty.



A **DUO HYBRID** stent will be placed inside your vein to keep it open so that blood can flow properly. Your doctor will decide if you also need the **DUO EXTEND** stent to open a longer portion of the blocked vein. If so, the second stent will be placed in the same way as the first one.



It is up to you and your doctor whether you will need to stay overnight or for several days for monitoring.



Before being discharged, you will receive a Patient Implant Card that you should carry with you at all times. The Patient Implant Card includes information about your stent, such as the name and identification number of the device, the location of the stent, and the date of your procedure as well as other manufacturing information. This card also contains important Magnetic Resonance Imaging (MRI) information.



An MRI is a medical imaging technique that uses magnetic fields to generate images of the organs of the body. The Patient Implant Card should be presented to your healthcare provider prior to undergoing any procedure, including an MRI.

**Note:** The procedures used to open the narrowed vein in the VIVID Trial are the same procedures used according to your doctor's usual practice, even if you do not wish to participate in the study.

# GLOSSARY

## Balloon Angioplasty

A procedure where a balloon is inserted and inflated in the blocked area of a vein to open it up and improve blood flow.

## Blood Vessel

An artery or vein.

## Catheter

A small, flexible tube that can be passed through blood vessels to administer treatment therapies.

## Chronic Venous Insufficiency (CVI)

A condition that makes it difficult for blood to travel from the legs to the heart.

## Common Femoral Vein

A large vein in the groin that carries blood from the legs toward the heart.

## Iliac Vein

A large vein in the pelvis that carries blood from the legs toward the heart.

## Iliofemoral Vein

The veins that reach from the pelvic region to the groin area.

## Magnetic Resonance Imaging (MRI)

A method of diagnosis that uses magnetic fields and radio waves to obtain detailed images of the inside of your body.

## Stent

An expandable metal tube device that allows for maintained blood flow through an opened vessel.

## Vein

A blood vessel that carries blood from the organs to the heart.



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## REFERENCES

1. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, Lohr JM, McLafferty RB, Meissner MH, Murad MH, Padberg FT, Pappas PJ, Passman MA, Raffetto JD, Vasquez MA, Wakefield TW, Society for Vascular Surgery., American Venous Forum. *J Vasc Surg.* 2011 May; 53(5 Suppl):2S-48S.

**CAUTION:** Investigational device. Limited by Federal (United States) law to investigational use.

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