

VenaSeal™ Closure System



The VenaSeal™ closure system is designed to close varicose veins by in-

jecting a very small amount of proprietary medical adhesive (glue) inside of the vein. The vein is then compressed with ultrasound and remains closed.

With no need for heat, the VenaSeal procedure delivers a comfortable experience and immediate vein closure.

It is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation.

1. How does VenaSeal differ from thermal energy procedures?

Venaseal is the only FDA ap-

proved procedure that uses injection of medical adhesive to close veins. **Because this adhesive works immediately to cause venous closure, compression stockings do not need to be worn after the procedure.**



Thermal procedures such as RFA and EVLA, or chemical irritation of the vein, do not cause immediate closure, so compression stockings need to be worn post procedure. Because thermal energy procedures use heat to close the vein, a large volume of numbing medicine is used.

2. Who is eligible for

VenaSeal?

VenaSeal is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS). VenaSeal system is contraindicated when any of the following conditions exist: previous hypersensitivity reactions to the VenaSeal adhesive or cyanoacrylates, acute superficial thrombophlebitis, thrombophlebitis migrans and acute sepsis.

Although this procedure can be used on many patients with superficial venous reflux, many insurance companies do not cover this procedure. We currently only perform this procedure on patients with eligible insurance coverage. Patients, who wish to pay for this procedure out of pocket, should contact the office for a quote.

3. What can I expect of the VenaSeal procedure?

Before the procedure:

You will have an ultrasound imaging exam of the leg that is to be treated. This exam is important for assessing the diseased superficial vein and planning

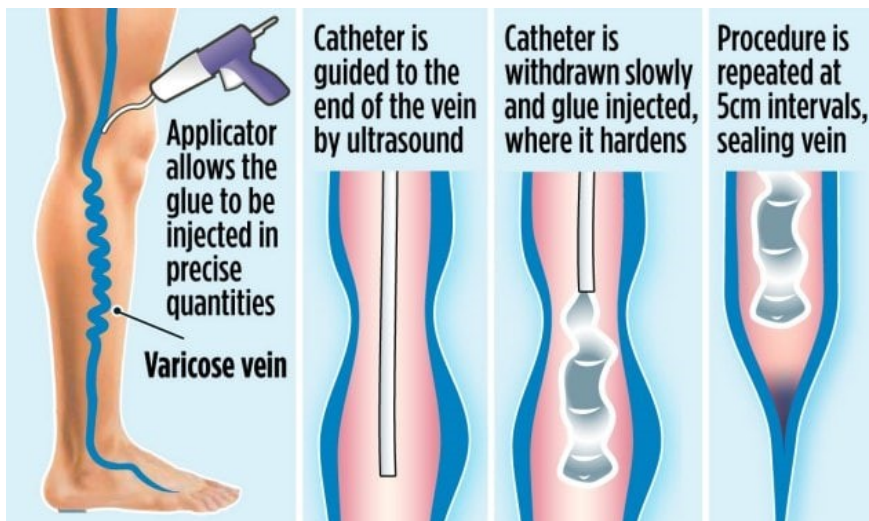
the procedure.

During the procedure:

The provider can discuss the procedure with you. It is performed as an outpatient in the office. The procedure typically takes 1-2 hours and only requires a small amount of local anesthetic (numbing medication). A brief summary of what to expect is below:

**Non-thermal
Non-tumescent
Non-sclerosant**

- You may feel some minor pain or stinging with a needle stick to numb the site where the doctor will access your vein.
- Once the area is numb, your doctor will insert the catheter (i.e., a small hollow tube) into your leg. You may feel some pressure from the placement of the catheter.
- The catheter will be placed in specific areas along the diseased vein to deliver small amounts of the medical adhesive. You may feel some mild sensation of pulling. Ultrasound will be used during the procedure to guide and position the catheter.
- After treatment, the



catheter is removed and a small adhesive bandage placed over the puncture site.

After the procedure:

The provider will recommend follow-up care as needed. Compression stockings do not need to be worn after a Venaseal procedure. There is a follow-up ultrasound in 5-7 days to verify that the vein remained closed. Follow-up office appointments with ultrasound will be performed at 3 months and 1 year to document long term closure of the treated vein.

4. When will my symptoms improve?

Symptoms are caused by the diseased superficial vein. Thus, symptoms may improve as soon as the diseased vein is closed.



5. When can I return to normal activity?

The VenaSeal procedure is designed to reduce recovery time. After the procedure patients should walk for 10-15 minutes. Over the next two weeks, walk daily and

The VenaSeal™ Closure system offers:

- + Rapid return to normal activities after treatment
- + Minimized pain, tenderness and ecchymosis
- + Significant improvement in quality of life

avoid very long periods of inactivity. Depending on the symptoms many patients are able to return to normal activities very shortly following the procedure.

6. Is the VenaSeal procedure painful?

Most patients feel little, if any, pain during the outpatient procedure. Most patients report little-to-no bruising after the VenaSeal procedure.

7. Is Venaseal safe?

Venaseal is FDA approved for the treatment of superficial venous insufficiency/reflux. All medical procedures have some risk.

The adverse events associated with the device are similar to those with traditional endovenous thermal ablation procedures.

In addition, there are several risks unique to the VenaSeal system due to its material and product design as an implant. These potential adverse events include, but are not limited to, allergic reactions to cyanoacrylates, such as hives, asthma, hay

fever and anaphylactic shock, arteriovenous fistula, bleeding from the site of access, deep vein thrombosis (DVT), edema in the treated leg, embolization, including pulmonary embolism (PE), hematoma, hyperpigmentation, infection at the access site, non-specific mild inflammation of the cutaneous and subcutaneous tissue, pain, paresthesia, phlebitis, superficial thrombophlebitis, urticaria or ulceration may occur at the site of injection, vascular rupture and perforation, visible scarring.

Patients who notice an adverse reaction should call the office immediately.

8. What happens to the VenaSeal adhesive?

Only a very small amount of VenaSeal adhesive is used to close the vein. The body will naturally create scar tissue around the adhesive over time to keep the vessel permanently closed. This adhesive is considered a medical device and will be left in the vein.



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