PUBLIC RELATIONS TOOLKIT

VenaSeal™ Closure System

Medtronic
Further, Together
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The following suggestions provide a basic overview of how to educate the public about venous reflux disease and the VenaSeal ™ closure system.

Key educational points
This Toolkit provides you with key educational points about venous reflux disease to use in developing a media relations program. It is important that all messages in your campaign are consistent with these key points, and we encourage you to familiarize yourself before you use them in your program.

Identifying media contacts
The first step in launching a media relations program is to identify the appropriate reporters, editors, and news producers in your city or hospital service area:

- Local area print (newspaper), broadcast (television and radio), and online (e-newsletters and blogs) media.
- Identify the top one or two daily and weekly city/community newspapers, appropriate radio and local television news shows, and online outlets that fit your patient demographics.
- Call each outlet and ask for the name of the healthcare and lifestyle reporter(s) and/or editor(s). For television and radio stations, ask for the program director, assignment editor or healthcare correspondent.

Identifying patients
As most news coverage is presented from the patient’s point-of-view, having one or more patients available to speak with reporters/editors may be helpful in securing media interest. Patients who have recently undergone treatment with the VenaSeal ™ closure system (and have compelling stories) are ideal.

- When selecting a patient to be your media spokesperson, consider the following:
  - Was the patient pleased with their treatment and recovery?
  - Has the patient noticed a significant improvement in their quality of life and/or activity level since receiving treatment with the VenaSeal ™ closure system?
  - Does this patient have a unique personal story – e.g., patient can discuss how treatment helped him/her; patient thought it was only a cosmetic issue; patient is approaching a significant milestone where they can demonstrate a change in their quality of life after treatment?
  - Is the patient comfortable speaking in public?
  - Will the patient be available to speak with the media during the day (when most interviews take place), either on the phone, in person, or on camera?
  - Do they understand they will not be compensated for their participation?
  - Is the patient willing to agree in writing to the use and dissemination of name, image, and relevant health information?
Identifying newsworthy topics

Although venous reflux disease is an important health concern, it may not be interesting to local media outlets if they do not believe you have anything new or unique to add to the topic. Finding or creating a timely event, such as an educational program, or offering a unique personal interest story may increase your chances of grabbing the media’s attention. (See “Reasons to Talk to Reporters” for ideas, page 7).

Writing a “pitch” note or press release

Enclosed is a sample pitch note to share with local media to spur interest in the topic/story idea. Once you identify the topic you want to highlight, use this sample as a guide for formatting your own pitch note.

Tips for a successful pitch note:

- The subject line should be as informative as possible in 12 words or less.
- Include the most important and interesting information in the first paragraph.
- Refer to and use your key messages.
- Keep the pitch note brief to maintain reporters’ interest.

Additionally, a sample press release is included, which provides more detail than the pitch note and can be sent out to media contacts for background. The press release can accompany the pitch note in the body of an email (NOTE: some reporters/editors may not like email attachments), or sent as a means of follow up after a phone conversation with a reporter/editor.

Media contact: sending the pitch note / press release

Send the customized pitch note and/or press release to your media contacts by their preferred method (generally via e-mail). Please note that Fridays are not recommended, as spokespeople are often unavailable on weekends and reporters often lose interest over the weekend.

Media contact: follow-up

Here are helpful hints on interacting with the media when following up on a story idea or interview opportunity:

- When speaking with a reporter it is suggested to quickly say hello, identify yourself and inquire whether he/she is on deadline. If they are on deadline, ask when would be an appropriate time to call back. Journalists greatly appreciate it when this type of sensitivity is shown, and they are likely to be receptive when you call back.
- When a reporter is ready to take your call:
  - Say something similar to: “I am calling regarding the information I sent to you about the seriousness of varicose veins, with a local twist...”
  - If the reporter doesn’t remember the correspondence, double check the address and offer to send (e-mail) another copy. Tell them you will follow up in a few days to determine his/her interest.
  - If the reporter does remember it, ask if he/she has any questions or if any additional information is required. Use the pitch note and key messages as guides for your answers. It is also acceptable to ask if the reporter plans to cover the story.
  - Whatever the response, thank the reporter for his/her time even if he/she is curt or abrupt. You never know when you may need to work with them. And an initial “no” does not mean they will never cover the story.
Coordinating interviews

- When arranging interviews and preparing spokespeople, follow the advice outlined in the enclosed document “Interview Tips” (see page 8)

- It is acceptable to ask the reporter for some sample questions to help prepare the person who is being interviewed and make sure they are able to accommodate the reporter’s needs.

- Make sure your spokesperson agrees to the use and dissemination of their name, image and health information.

- Provide spokespeople with the following information before the interview to ensure they are prepared:
  - Pitch Note and/or Press Release
  - Topic Information
  - Sample Questions (if available)
  - Key Messages/Talking Points
  - Background information on the publication and reporter
  - Tell your spokesperson that their comments should reflect their honest opinion based on their own experience, regardless of any suggestions in the talking points

Tracking coverage

- Most reporters and news stations will tell you if and when a story will be published/ broadcasted, so your office can look for the stories.

- Save copies of the article or broadcast segment for your files when it appears. Printed articles can be framed and hung in your office so patients can view the coverage and learn about your efforts to educate your community. There are vendors, such as Cision (www.cision.com), that should be able to provide you with a copy of the broadcast segment, as long as you make advance arrangements with them (e.g., call them when you know a television news story is set to air). (Cision.com is not affiliated with Medtronic and its services are not sponsored or endorsed by Medtronic).

- Once you successfully place an article or secure television news coverage, Medtronic would love to see it. Please forward copies of all resulting news coverage to your local Medtronic representative so we can compile a national database of educational VenaSeal™ closure system stories.
More than 190 million people have CVI or varicose veins globally. More than 30 million Americans suffer from varicose veins, or the more serious form of venous disease called chronic venous insufficiency (CVI), yet the majority remains undiagnosed and untreated.\(^1\) \(^2\)

Venous reflux disease, also known as chronic venous insufficiency, develops when the valves that keep blood flowing out of the legs and back to the heart become damaged or diseased.

Superficial venous reflux disease may cause the following signs and symptoms:\(^3\)

- Varicose veins
- Swelling
- Aching
- Cramping
- Itching
- Open skin sores

If venous reflux disease is left untreated, symptoms may worsen over time.

Once the valves in the leg stop working properly, they cannot be repaired. Treatment options available include closing or removing the damaged vein and then redirecting blood flow to healthy veins. Traditionally, surgical stripping or heat-based treatment options are used. However, the VenaSeal™ closure system treats the diseased saphenous veins, without traditional heating or stripping the vein out of the leg.

The VenaSeal™ adhesive used during the procedure is a proprietary cyanoacrylate-based formula specifically designed for the treatment of lower extremity superficial truncal veins, such as the great saphenous vein (GSV).

The VenaSeal™ closure system uses an advanced medical adhesive to safely and effectively close the diseased vein segment. Tumescent anesthesia is not required. Unlike other varicose vein treatments, there is rapid return to normal activities.\(^4\) \(^5\) \(^6\) \(^7\) \(^8\)

The VenaSeal™ closure system delivers a small amount of specially formulated medical adhesive to the diseased vein.\(^4\) \(^5\) \(^6\) The adhesive closes the vein and blood is rerouted through nearby healthy veins.

The VenaSeal™ closure system is a comfortable procedure offering freedom from tumescent anesthesia, multiple needs sticks, thermal nerve injury and post-procedure compression stockings*, enabling patients a rapid return to normal activities following the procedure.\(^4\) \(^5\) \(^6\) \(^7\) \(^8\)

Patients have also reported minimal bruising following the VenaSeal™ closure system procedure.\(^6\)

The VenaSeal™ closure system is designed to minimize patient discomfort and reduce recovery time.\(^5\) \(^6\) \(^9\)

The VenaSeal™ closure system has been shown to be effective in three clinical studies, with demonstrated safety and high closure rates:\(^10\) \(^11\) \(^12\)

- The VeClose pivotal study demonstrates safety and efficacy of the VenaSeal™ closure system with closure rates of 94.4 percent at 36 months.\(^10\)
- Results from the European Saphenous Closure System Observational Prospective (eSCOPE) study as presented in the Journal of Vascular Surgery: Venous and Lymphatic Disorders demonstrate a cumulative closure rate of 88.5 percent and improvement in quality of life scores at 36 months.\(^12\)
- Closure rates in the Feasibility Study were 94.7 percent at 36 months.\(^11\)

During the procedure, a trained clinician fills a syringe with the medical adhesive, which is inserted into a dispensing gun that is attached to a catheter. The catheter is advanced into the diseased vein under ultrasound guidance. The catheter is placed in specific areas along the diseased vein and the clinician conducts a series of trigger pulls to deliver the medical adhesive. Compression is applied to the leg during the procedure.
Here are a few reasons that provide an opportunity to spread venous disease awareness locally:

1. You are one of the first medical centers/practices in the region performing the VenaSeal™ closure system.

2. You have a great patient story (e.g., patient with unique personal/lifestyle story, who can discuss how treatment with the VenaSeal™ closure system helped them).

3. You are treating a patient who is worried about recovery time after the procedure.

4. One of your patients is approaching a significant milestone where s/he can demonstrate the changes in their quality of life after treatment with the VenaSeal™ closure system (e.g., ability to run a marathon, go on vacation, return to work, etc.).

5. You are involved in a seminar/community talk about venous reflux disease or similar event.

6. You are involved in new research, a study, etc. regarding venous reflux disease.

7. You know and can provide local statistics that are significant to this national problem.
When interviewed by a reporter, either in person or over the phone, keep the following points in mind:

- Research the media outlet and reporter/editor who is interviewing you and plan appropriately.
- Always be familiar with your “pitch note” points, and use them in your answers when appropriate.
- Emphasize the most important facts and benefits upfront. Elaborate when necessary, but be concise.
- Be descriptive, “paint a picture” for the reporter, and use appropriate anecdotes to help bring the benefits of screening, diagnosis and treatment with the VenaSeal™ closure system to life for a reporter.
- Be accurate and truthful at all times.
- Correct false premises and incorrect information, but always remain polite and never get defensive.
- Ask for clarification if you do not understand a question.
- Keep your answers conversational.
- If you do not know the answer to a question, it is appropriate to say, “I do not know” and offer to find out. This is much better than improvising facts that cannot be confirmed later.
- If a reporter asks questions that are off track from what you want to address, respond to the query, but then quickly segue to one of your message points.
- Never make “off-the-record” statements. State only what you want to see printed or broadcast. This includes any casual conversations you have with the reporter before or after the “official” interview. When you are speaking with a reporter you are always “on the record.”
- Dress appropriately and professionally for broadcast interviews. Avoid wearing white, as it can create a “glowing” effect, and refrain from wearing too much pattern.
Subject: <institution> one of the first in <city> to use the VenaSeal™ closure system procedure for venous reflux disease

Dear <insert reporter’s first name>,

Local vein specialist <insert local physician name, title, institution> is one of the first in <city> to treat patients with venous reflux disease with the VenaSeal™ closure system, a minimally invasive procedure that uses an advanced medical adhesive to safely and effectively close the diseased vein segment.4,5,6,7

Venous reflux disease affects more than 190 million people globally (30 million Americans <insert local data here>). It occurs when valves in the veins of the lower leg no longer function properly. This allows blood to flow backward, or reflux, resulting in enlarged or varicose veins as well as other symptoms. If venous reflux disease is left untreated, symptoms can worsen over time.

The VenaSeal™ closure system uses medical adhesive to close the vein. It is a comfortable procedure offering freedom from tumescent anesthesia, multiple needle sticks, thermal nerve injury and post-procedure compression stockings*. It enables patients a rapid return to normal activities4,5,6,7,8 with minimal to no bruising.6

For XX-year-old <insert local patient name>, <insert 1-2 line patient story. Example: For 35 year old Trischia, her venous reflux disease was causing her pain while working long shifts as a nurse. After having the VenaSeal™ closure system, she was able to quickly return to normal activities.>

(Note that a physician should only include a patient’s name and age after securing written permission to disseminate that information and the fact that the patient was treated for venous reflux disease).

<Reporter>, would you be interested in speaking with Dr. <insert local physician name> and <insert local patient name> to learn more about venous reflux disease and the VenaSeal™ closure system? I would also be happy to send you additional background about the studies.

Thanks in advance for your consideration.

Best regards,

<insert communications contact name>
<insert institution name>
<insert phone number>
<insert email address>

*Some patients may benefit from the use of compression stocklings post procedure.
For immediate release
<insert date>

Contact:
<insert communication contact>
<insert phone number>
<insert e-mail address>

<Insert practice name/hospital name> ONE OF THE FIRST IN <city> TO TREAT PATIENTS WITH VENOUS REFUX DISEASE USING VENASEAL™ CLOSURE SYSTEM

The VenaSeal™ closure system treats venous reflux disease using an advanced medical adhesive <insert city, state>, <date> -- <insert practice name/hospital name> today announced it is one of the first in <city> to treat patients with venous reflux disease using the VenaSeal™ closure system. The VenaSeal™ closure system is a minimally invasive procedure that uses an advanced medical adhesive to close the diseased vein in patients with symptomatic venous reflux disease.

Venous reflux disease affects more than 190 million people globally (30 million Americans <insert local data here>). It occurs when valves in the veins of the lower leg no longer function properly. This allows blood to flow backward, or reflux, resulting in enlarged, or varicose veins as well as other symptoms.

“Varicose veins may be a sign of a more serious condition known as chronic venous insufficiency, which in severe cases, can result in lifestyle-limiting lower leg pain, swelling, skin damage, and ulcerations,” said <insert physician name, title>. “The VenaSeal™ closure system is an innovative treatment option that improves blood flow by closing the diseased vein. The system has demonstrated effective clinical results and patients can often quickly return to normal activities.”

The VenaSeal™ closure system uses medical adhesive to coapt and close the vein, with high closure rates across three clinical trials.10,11,12 Additionally, patients treated with the VenaSeal™ closure system often have minimal to no bruising,6 and can return quickly to normal activities.6,8

Unlike other heat-based treatments, the VenaSeal™ closure system is a comfortable procedure offering freedom from tumescent anesthesia, multiple needs sticks, thermal nerve injury and post- procedure compression stockings*, and enabling patients a rapid return to normal activities following the procedure.4,5,6,7,8

<sample patient quote – to be substituted with local patient story> “I was starting to feel pain in my legs and thought it was due to the long shifts I work as a nurse,” said <insert patient name, age, details>. “I went to see Dr. <insert name> who diagnosed me with venous reflux disease, the underlying cause of varicose veins. S/He treated me with the VenaSeal™ closure system, and I was able to return to normal activities the next day.”

(Note: that a physician should only include a patient’s name and age after securing written permission to disseminate that information and the fact that the patient was treated for venous reflux disease).

<insert city> -area residents interested in learning more about venous reflux disease and the VenaSeal™ closure system can visit <insert practice website> or medtronic.com/endovenous for more information.

*Some patients may benefit from the use of compression stockings post procedure.
About the VenaSeal™ closure system

The VenaSeal™ closure system is a non-thermal, non-tumescent, non-sclerosant procedure that uses an advanced medical adhesive to close the diseased vein. This unique approach eliminates the risk of nerve injury that is sometimes associated with certain thermal-based procedures. The procedure is administered without the use of tumescent anesthesia, minimizing the need for multiple needle sticks. Patients also report minimal-to-no bruising post procedure.

Visit medtronic.com/endovenous to learn more about venous reflux disease and treatment with the VenaSeal™ closure system.

About Practice
<<Insert boilerplate>>
The VenaSeal™ closure system is a non-thermal, non-tumescent, non-sclerosant procedure that uses an advanced medical adhesive to close the diseased vein. The system has been shown to be effective in three clinical studies, with demonstrated safety and high closure rates.\textsuperscript{10,11,12}

**VenaSeal Sapheon Closure System vs. Radiofrequency Ablation for Incompetent Greater Saphenous Veins (VeClose Pivotal Study)**

VeClose pivotal study is a prospective, randomized study comparing the VenaSeal™ closure system to radiofrequency ablation. The study enrolled 242 patients at 10 sites across the U.S. The VeClose pivotal study continues to demonstrate safety and efficacy of the VenaSeal™ closure system with closure rates of 94.4 percent at 36 months.\textsuperscript{10}

**European Sapheon Closure System Observational Prospective (eSCOPE)**

European Sapheon Closure System Observational Prospective (eSCOPE) was a prospective, multicenter, single-arm study that enrolled 70 patients at seven sites in Europe. Results from the study as presented in the *Journal of Vascular Surgery: Venous and Lymphatic Disorders* demonstrate that the VenaSeal™ closure system had a cumulative closure rate of 88.5 percent and improvement in quality of life scores at 36 months.\textsuperscript{12}

**VenaSeal™ Closure System – Feasibility Study**

The feasibility study for the VenaSeal™ closure system was a prospective, single-center study to demonstrate the feasibility, safety and efficacy. The study enrolled 38 patients. Results of the trial demonstrated the safety and efficacy of the procedure, with closure rates at 94.7 percent at 36 months.\textsuperscript{11}

<table>
<thead>
<tr>
<th>Study design</th>
<th>VeClose Study\textsuperscript{10} (U.S. Pivotal Trial)</th>
<th>eSCOPE Trial\textsuperscript{12}</th>
<th>Feasibility Study\textsuperscript{11}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Prospective, multi-center, randomized controlled trial</td>
<td>Prospective, multicenter, post-market study</td>
<td>Prospective, single-center study</td>
</tr>
<tr>
<td>Patients enrolled</td>
<td>242**</td>
<td>70</td>
<td>38</td>
</tr>
<tr>
<td>Closure rate</td>
<td>VenaSeal™ 3-year: 94.4%</td>
<td>RF 3-year: 91.9%</td>
<td>3-year: 94.7%</td>
</tr>
<tr>
<td>Definition of closure</td>
<td>No discrete segment of patency &gt; 5 cm in the treated vein segment</td>
<td>No discrete segment of patency &gt; 10 cm in the treated vein segment</td>
<td>No discrete segment of patency &gt; 5 cm in the treated vein segment</td>
</tr>
<tr>
<td>Serious adverse events related to study device or procedure</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>

*20 were roll-in patients treated by the VenaSeal™ closure system.*
The VenaSeal™ closure system is a non-thermal, non-tumescent, non-sclerosant procedure that uses an advanced medical adhesive to close the diseased vein. This unique approach eliminates the risk of thermal nerve injury that is sometimes associated with certain thermal-based procedures. The procedure is administered without the use of tumescent anesthesia, minimizing the need for multiple needle sticks. Patients also report minimal-to-no bruising post procedure.

Prepare the VenaSeal™ closure system
A trained clinician fills a syringe with the medical adhesive, which is inserted into the VenaSeal™ closure system’s dispensing gun that is attached to a catheter.

Deliver adhesive and compression sequences
The catheter is advanced into the diseased vein under ultrasound guidance.

The catheter is placed in specific areas along the diseased vein and the clinician conducts a series of trigger pulls to deliver the medical adhesive. Compression is applied to the leg during the procedure.

VenaSeal™ Closure System Marketing Assets
Contact your Medtronic sales representative to request access to our Asset Library – a singular, online resource to equip you with a variety of market development, patient and physician education materials.
Many vein specialists like to market the VenaSeal™ closure system by sharing “before and after” photos on their practice websites, via social media channels, in local media interviews and on patient-facing materials (brochures, e-newsletters, etc.). This is an effective marketing tactic; however, it is important to obtain written consent from the patient prior to using their name or photos and ensure that you obtain high-resolution images. Following are guidelines on how to effectively capture “before and after” photos:

**Ensure subjects were treated with the VenaSeal™ closure system only**

- No sclerotherapy
- No phlebectomy
- No thermal ablation
- No adjunctive procedures

**Before**

- Set digital camera to its highest resolution setting to ensure best quality
- Use good room lighting (take a photo with and without a flash to ensure good quality photos)
- Have the patient standing up
- Take photo from the leg angle (do not shoot from above and then crop out the rest of the body)
- Include the entire lower leg from over the knee, down to the foot
- No pen markings

**Note:** Be sure to have [patients][models][actors] sign a release that gives your practice the right to use their images, story, voice and video in a variety of media. It is best to work with your attorney to develop a release that satisfies your specific needs, but forms can also be found on the internet.

**After**

- Use same body position/proximity to the camera/angle/standing location/background/lighting
- Set digital camera to its highest resolution setting to ensure best quality
- Taken within three months time (preferable, but not necessary)
- Indicate on your photos how much time has elapsed between shots
- Be sure to use images that represent the typical before and after condition of your patients
- Be sure to include a footnote indicating that “individual results may vary”
The frequently asked questions can be utilized on print or digital content to provide clarity to patients on venous disease and the VenaSeal™ closure system.

**What is venous reflux disease?**
Healthy leg veins have valves that keep blood flowing to the heart. Venous reflux disease, also known as chronic venous disease, develops when the valves stop working properly and allow blood to flow backward (i.e., reflux) and pool in the lower leg veins. If venous reflux disease is left untreated, symptoms can worsen over time. As a result, vein valves will not close properly, leading to signs and symptoms such as:

- Varicose veins
- Aching
- Swelling
- Cramping
- Heaviness or tiredness
- Itching
- Restlessness
- Open skin sores

**How prevalent is venous reflux disease?**

- More than 190 million people have CVI or varicose veins globally. In the U.S., more than 30 million Americans suffer from varicose veins, or the more serious form of venous disease called chronic venous insufficiency (CVI), yet the majority remains undiagnosed and untreated.\(^1\,^2\)
- Varicose veins, a common symptom of venous reflux disease, can affect up to 40 percent of adults.\(^3\)
- Varicose veins are more common in those who are overweight, and in women who have had more than two pregnancies.\(^4\)
- Women usually have multiple risk factors for the development of varicose veins. In fact, varicose veins are most common in women (75 percent of those diagnosed) than in men (25 percent of those diagnosed).\(^5\)
- Up to 55 percent of American women may be affected by varicose veins in their lifetime.\(^6\)
- It is common for varicose veins to become more prominent during pregnancy and worsen with successive pregnancies.\(^7\)
How is venous reflux disease treated?
Venous reflux disease treatment aims to reduce or stop the backward flow of blood. Treating the diseased vein improves overall blood flow and relieves symptoms. For some patients, compression stockings alone may improve blood flow. For other patients, closing or removing the diseased vein may be necessary to improve blood flow. Closing or removing the diseased vein directs blood to nearby healthy veins.

What is the VenaSeal™ closure system?
The VenaSeal™ closure system is a non-thermal, non-tumescent, non-sclerosant procedure that uses an advanced medical adhesive to close the diseased vein.

What does it treat?
The VenaSeal™ closure system treats symptomatic venous reflux disease in the lower extremity superficial truncal veins, often the underlying cause of painful varicose veins.

How does it work?
During the procedure, a trained clinician fills a syringe with the medical adhesive, which is inserted into the VenaSeal™ closure system’s dispensing gun that is attached to a catheter. The catheter is advanced into the diseased vein under ultrasound guidance. The catheter is placed in specific areas along the diseased vein and the clinician conducts a series of trigger pulls to deliver the medical adhesive. Compression is applied to the leg during the procedure.

Is there clinical data to support the use of the VenaSeal™ closure system?
The VenaSeal™ closure system has been shown to be effective in three clinical studies, with demonstrated safety and high closure rates.\(^{10,11,12}\)

- The VeClose pivotal study demonstrates safety and efficacy of the VenaSeal™ closure system with closure rates of 94.4 percent at 36 months.\(^{10}\)
- Results from the European Sapheon Closure System Observational ProspectivE (eSCOPE) study as presented in the *Journal of Vascular Surgery* demonstrate a cumulative closure rate of 88.5 percent and improvement in quality of life scores at 36 months.\(^{12}\)
- Closure rates in the Feasibility Study were 94.7 percent at 36 months.\(^{11}\)

How does the VenaSeal™ closure system differ from thermal energy procedures?
The VenaSeal™ closure system uses an adhesive to close the vein. Thermal energy uses heat to close the vein. The intense heat requires a large volume of dilute numbing medicine, which is injected through multiple needle sticks. The injections may cause pain and bruising after the procedure.
How quickly can patients return to normal activities post procedure?
The VenaSeal™ closure system procedure is designed to minimize patient discomfort and reduce recovery time.5,6,9 After the procedure, a small bandage will be placed at the access site. Patients are able to rapidly return to normal activities.6,8 Additionally, patients have reported minimal bruising following the VenaSeal™ closure system procedure.6

How can patients learn more about venous reflux disease and the VenaSeal™ closure system?
Visit our practice website, <insert URL> and <insert VenaSeal™ website>, to learn more about venous reflux disease, and the clinical and lifestyle related benefits associated with the VenaSeal™ closure system.

Is treatment with the VenaSeal™ closure system suitable for everyone?
The VenaSeal™ closure system should not be used in patients who have a known hypersensitivity to the VenaSeal™ closure system’s adhesive, acute inflammation of the veins due to blood clots, or acute whole-body infection. Adverse events observed in the VenaSeal™ closure system trials—and generally associated with treatments of this condition—including vein inflammation (phlebitis) and burning or tingling (paresthesia) in the treatment zone. A vein specialist can tell you if the VenaSeal™ closure system is the right option for your situation.3

What happens to the treated vein left behind in the leg? Don’t I need it?
Faulty valves interfere with the normal return of blood through the venous system. Closing these diseased veins helps to re-route the blood through nearby veins, improving circulation and relieving most symptoms. Only a very small amount of VenaSeal™ adhesive is used to close the vein. Your body will naturally create scar tissue around the adhesive over time to keep the vessel permanently closed.

Is the VenaSeal™ closure system procedure covered by insurance?
As with any procedure, insurance coverage may vary. Those interested in the VenaSeal™ closure system should contact their insurance provider for more information.
*Some patients may benefit from the use of compression stockings post procedure.


10 Morrison, N. VenaSeal Closure System vs. Radiofrequency Ablation for Incompetent Great Saphenous Veins (VeClose). 36 Month Results presented at: IVC: April 20,2017; Miami, FL.


12 Proebstle TM. The European Multicenter Study on Cyanoacrylate Embolization of Refluxing Great Saphenous Veins without Tumescent Anesthesia and without Compression Therapy. Results presented at: Charing Cross; 2016; London, UK.


**Intended Use/Indications:** The VenaSeal™ closure system (VenaSeal™ system) 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. The VenaSeal™ system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS).

**Contraindications:** Separate use of the individual components of the VenaSeal™ Closure System is contraindicated. These components must be used in combination as a system. The use of the VenaSeal™ system is contraindicated when any of the following conditions exist: previous hypersensitivity reactions to the VenaSeal™ system adhesive or cyanoacrylates, acute superficial thrombophlebitis, thrombophlebitis migrans, acute sepsis exists.

**Potential Adverse Effects of the Device on Health:** Below is a list of the potential adverse effects (e.g., complications) associated with the use of the VenaSeal™ system. 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.

Warnings, precautions, and instructions for use can be found in the product labeling at [http://manuals.medtronic.com](http://manuals.medtronic.com). 

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.