PUBLIC RELATIONS TOOLKIT

ClosureFast™ Procedure

Medtronic
Further, Together
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The following suggestions provide a basic overview of how to educate the public about varicose veins, chronic venous insufficiency (CVI), and the ClosureFast™ procedure via local media.

**Key educational points**
This toolkit offers key educational points about varicose veins and CVI for your use as you develop a media relations program. Since it is important that the messages are consistent, we encourage you to familiarize yourself with them before you contact a reporter and utilize them in all of your communications.

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

- Focus on local area print (newspaper), broadcast (television and radio) and online (e-newsletters and blogs) media.
- Make a list of the top one or two daily and weekly city/community newspapers, appropriate radio and local television news shows and online outlets to define your media targets.
- 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 is key to securing media interest and generating high-quality, informative news. Patients who have recently undergone the ClosureFast™ procedure for treatment of their varicose veins or CVI and have compelling stories that would help educate others are ideal.

- When selecting a patient to approach on being a media spokesperson, consider the following:
  - Was the patient pleased with his/her treatment and recovery?
  - Has the patient noticed a significant improvement in his/her quality of life and/or activity level since having the ClosureFast™ procedure?
  - 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 he/she can demonstrate a change in his/her 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 varicose veins and venous disease are important health concerns, it may not be particularly newsworthy if a reporter does not believe there is anything new or unique to add to the topic. Finding or creating a timely event, such as an educational program, or offering a unique story angle will 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 (see page 9 for sample pitch note, page 10 for sample press release)

Enclosed is a sample pitch note to share with reporters to incite interest in the topic/story idea. Once you identify the newsworthy topic you want to highlight, utilize this sample as a guide for formatting your own pitch note. The enclosed sample utilizes new data as a timely news hook.

Be sure to observe the following 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 the key messages provided.
■ Keep the pitch note brief to maintain the reporter’s 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: reporters/editors generally do 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 ClosureFast™ procedure stories.
Primary messages

- More than 190 million people have CVI or varicose veins globally.\(^3\)
- 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 remain undiagnosed and untreated.\(^1,3\)
- If left untreated, varicose veins can progress to CVI\(^5\), which can cause pain, swelling and fatigue of the legs, as well as skin damage and ulcers, in more severe cases.\(^6\)
- It is time for individuals to think differently about varicose veins and their complications and understand that they may not just be a cosmetic issue, but a health concern worthy of medical diagnosis and treatment.
  - Many people misunderstand the causes, risks and treatments for varicose veins.
- With varicose veins and CVI, the valves that push blood from the legs back to the heart no longer function, causing blood to pool in the legs.
  - There are a number of factors that contribute to these conditions, including pregnancy, prolonged sitting or standing, excess weight, lack of exercise, age (50+) and family history.\(^6\)
  - Women are two times more likely than men to develop varicose veins, primarily due to pregnancy.\(^7\)
- Many people are unaware of the ClosureFast™ procedure; the only FDA cleared minimally invasive treatment that uses radiofrequency ablation (uniform heat) for the treatment of CVI to seal off the problem vein, so blood gets re-routed to healthy veins.
  - Covered by most insurance plans (patients should contact their insurance provider prior to receiving treatment to confirm that the ClosureFast™ procedure is covered), the ClosureFast™ procedure allows for a short, comfortable recovery and a quick return to everyday activities while also eliminating varicose veins and improving the appearance of the legs.\(^4,8\)
  - Studies show that the ClosureFast™ procedure is associated with lower rates of pain, bruising and complications when compared to 980 nm laser.\(^4,8\)
  - Data published in the British Journal of Surgery found that CVI patients treated with the ClosureFast™ procedure demonstrated high closure rates and reduction in patient pain scores at five years.\(^14\)
  - The ClosureFast™ procedure allows for a short, comfortable recovery and a quick return to everyday activities.\(^4\)
  - Medtronic ClosureFast™ catheters are backed by five years of clinical data and are sold as a single-use device designed to be used only one time, on one patient.
  - Individual results may vary. As with all medical procedures, there is a chance that complications may occur, including, but not limited to the following: hematoma, vessel perforation, thrombosis, pulmonary embolism, phlebitis, infection, adjacent nerve injury, skin burn or discoloration.
- Visit our practice website, <insert URL> and www.medtronic.com/endovenous to learn more about varicose veins, CVI, and the clinical and lifestyle related benefits associated with the treatment of CVI using the ClosureFast™ procedure. [Include this point or a modification of it to suit your practice].
Here are a few reasons that provide an opportunity to spread venous disease awareness locally:

1. You are a local doctor making a difference by going out of your way to screen your community for varicose veins and chronic venous insufficiency (CVI) as part of a local awareness initiative.

2. You have a great patient story (e.g. men/women with unique personal/lifestyle story, who can discuss how treatment with the ClosureFast™ procedure helped him/her, or local “celebrity,” e.g., local weather person).

3. You are treating a patient who believed varicose veins were only a cosmetic condition until he/she was diagnosed.

4. One of your patients is approaching a significant milestone where he/she can demonstrate the changes in quality of life after treatment with the ClosureFast™ procedure (e.g., ability to run a marathon, keep up with his/her children or grandchildren etc.).

5. You are involved in a seminar/community talk about varicose veins and CVI or similar event.

6. You are involved in new research, a study, etc. regarding varicose veins or CVI.

7. You know/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 talking 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 ClosureFast™ procedure 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 say “no comment.” It implies that you are hiding something, even if you are not. There is always something you can say in response to a question, no matter how difficult the question.
- Never make “off-the-record” statements. State only what you want to see printed or aired on a broadcast news program. 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: Local <insert city> doctor takes on varicose veins impacting 190M people globally

Dear <insert reporter’s first name>,

Chronic venous insufficiency (CVI) is a serious condition that often manifests as varicose veins. CVI and varicose veins affect more than 190 million people globally1 (more than 30 million Americans).3, <insert local data here>). Despite its prevalence, many times CVI goes undiagnosed or is undertreated. In fact, less than 10 percent of men and women seek treatment.5

Why? Many people with varicose veins believe their condition to be a cosmetic issue. However, if left untreated, varicose veins can progress to CVI,5 a serious disease that can cause leg pain, swelling, restlessness, skin damage and ulcers.6 As a progressive disease, it is important for patients to evaluate treatment options for CVI that demonstrate long-term effectiveness of the procedure, given the chance of reoccurrence.

For patients here in <insert city>, there are treatment options available, including minimally invasive procedures that have clinically demonstrated strong closure rates out to five years. The British Journal of Surgery published the results of a study evaluating the long-term results of patients with CVI being treated with the ClosureFast™ system. The results of the study demonstrated strong closure rates of the diseased vein and minimal treatment side effects at five years.14

The ClosureFast™ system is a minimally invasive treatment that utilizes segmental radiofrequency ablation to seal off and close the problem vein so blood gets re-routed to other veins.

In an effort to educate <insert city> residents about the serious nature of varicose veins, local vein specialist, <insert local physician name, title, institution>, is available to discuss the data, as well as signs and symptoms of the condition.

I can also put you in touch with <insert local patient name>, a XX-year-old local resident who can talk about his/her experience of living with varicose veins and the difference treatment has made in his/her daily life.

(Note that a physician should only include a patient’s name and age after securing written permission to disseminate that information, and has confirmed that the patient was treated for CVI).

Thanks in advance for your consideration.
Best Regards,
<insert communications contact name>
<insert practice/hospital name>
<insert phone number>
<insert email address>
For immediate release

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

<insert practice name/hospital name> USES INNOVATIVE TREATMENT IN <insert city name> FOR PATIENTS WITH CHRONIC VENOUS INSUFFICIENCY (CVI)

The ClosureFast™ radiofrequency ablation system, a clinically proven, minimally invasive treatment, seals problem veins for patients with CVI.

<insert date> <insert city, state> -- <insert practice name/hospital name> today announced the practice is now using innovative technology for the treatment of chronic venous insufficiency, a disease that impacts 190 million people globally (more than 30 million Americans). <insert local data here>.

<insert practice name/hospital name> is using minimally invasive treatment technologies, such as the ClosureFast™ system. The ClosureFast™ system utilizes radiofrequency ablation (uniform heat) to seal off the problem vein so blood gets re-routed to another path. The unique procedure is proven effective in eliminating varicose veins and improving the appearance of the legs, allowing for a short, comfortable recovery and a quick return to everyday activities.

CVI, which can sometimes present as varicose veins, is a serious health issue for <insert city> area residents. In fact, less than 10 percent of people seek treatment for varicose veins. Many people with varicose veins believe their condition to be a cosmetic issue. However, if left untreated, varicose veins can progress to CVI, a serious disease that can cause leg pain, swelling, restlessness, skin damage and ulcers.

“As a progressive disease, it is important for patients to evaluate treatment options that demonstrate long-term effectiveness of the procedure given the chance of reoccurrence,” said <insert physician name, title>. “Data published in the British Journal of Surgery found that CVI patients treated with the ClosureFast™ procedure had strong closure rates and minimal treatment side effects at five years.”

With CVI and varicose veins, the valves in the leg veins that direct blood from the legs back toward the heart no longer function properly, causing blood to pool in the legs. Although this can occur at any time, increased age is a risk factor. Varicose veins and CVI also tend to be more prevalent in women who have been pregnant, in people who have a family history of CVI or those whose jobs require them to spend a great deal of time standing.

Studies show that the ClosureFast™ procedure is associated with lower rates of pain, bruising and complications, and a faster improvement in patients’ quality of life when compared to 980 nm laser ablation.

The procedure is generally conducted in a physician’s office or outpatient setting, and is covered by most health insurance. The average patient typically resumes normal activities within a few days following treatment, and most patients report a noticeable improvement in their symptoms within one to two weeks after the procedure.

For more information about treatment for CVI, visit: <<practice website>>.

About Practice
<<insert boilerplate>>
Product Images and Procedure Animation
Contact your Medtronic sales representative to request a copy of our product images and procedure animation.
Many vein specialists like to market the ClosureFast™ procedure 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 the 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 ClosureFast™ procedure only.
- No sclerotherapy
- No phlebectomy
- No laser
- 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
- Take within 3 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”
Frequently Asked Questions

The frequently asked questions can be utilized on print or digital content to provide clarity to patients on venous disease and the ClosureFast™ procedure.

What is the ClosureFast™ procedure?
The ClosureFast™ procedure is a minimally invasive treatment that uses radiofrequency (RF) energy to effectively treat patients with varicose veins or chronic venous insufficiency (CVI). Because the valves in the legs cannot be repaired, the only alternative is to re-route the blood flow from the diseased veins to the healthy veins.

To do this, a vein specialist inserts a catheter into the diseased vein through a tiny incision below the knee. Guided by ultrasound imaging, a vein specialist will treat the vein in 7 cm segments for 20 seconds each. The catheter delivers consistent and uniform heat to contract the collagen in the vein walls, causing them to collapse and close. After the vein is sealed shut, blood is then naturally redirected to healthy veins. The treated vein then becomes fibrous tissue and will gradually be absorbed into surrounding tissue.

How effective is the ClosureFast™ procedure?
The ClosureFast™ procedure has been shown in a large multicenter study to be 94.9% reflux-free at 5 years.6 Treating with the ClosureFast™ catheter resulted in high closure rates with improvements in CEAP Class grading and VCSS out to 5 years post treatment. The ClosureFast™ procedure has been shown in a large multicenter study to be 94.9% reflux-free at 5 years.14 The RECOVERY Study showed that patients experience less bruising and pain, and fewer complications with the ClosureFast™ procedure, using the Medtronic ClosureFast™ endovenous radiofrequency ablation (RFA) catheter in comparison to 980 nm laser ablation.4

The ClosureFast™ procedure is performed as a medical necessity as diagnosed by a trained vein specialist. It is not designed to address spider veins or cosmetic issues. As with any medical procedure, you should consult a vein specialist and review all safety information associated with the procedure.

How is the ClosureFast™ procedure different from vein ligation and stripping?
Vein stripping is a surgical procedure. The surgeon makes an incision in your groin and ties off the vein, after which a "stripper" tool is threaded through the leg vein in order to pull it out through a second incision just above the calf. Bruising and swelling often occur post-procedure and nerve tissues surrounding the treated vein can be damaged, causing numbness or burning around the site.

The ClosureFast™ procedure is minimally invasive. In contrast to vein stripping, the vein remains in place and is closed using a special catheter inserted through a small incision below the knee.

Vein stripping is usually performed in an operating room under a general anesthetic, while the ClosureFast™ procedure is often performed in an outpatient setting, typically using local or regional anesthesia.
How is the ClosureFast™ procedure different from laser ablation?

The ClosureFast™ procedure utilizes radiofrequency energy to provide consistent and controlled heat to contract the collagen in the vein walls, causing them to collapse and seal. Once a leg vein is closed, blood flow is redirected to healthy veins.

Laser ablation uses laser heat to collapse and seal the affected vein. The laser targets blood in the vein, causing it to heat. This heat creates a steam bubble inside the vein, causing damage to the vein so that it collapses. Unlike the ClosureFast™ procedure, laser temperatures can reach over 1334 °C, which can lead to increased bruising and post-procedural pain for the patient.16 Animal studies have shown that laser can potentially lead to perforation and destruction of the vein walls13, causing significantly more bruising and post-procedure pain for patients (see next page for potential risks and/or complications associated with the ClosureFast™ procedure).

The RECOVERY Study compared the experience of patients treated with the ClosureFast™ procedure and those treated with 980 nm laser ablation.4 The findings clearly demonstrated that the ClosureFast procedure resulted in less pain, less bruising, and fewer complications.4

In the RECOVERY Study, the author concluded, “RF thermal ablation (ClosureFast™ procedure) was significantly superior to laser ablation as measured by a comprehensive array of postprocedural recovery and quality of life parameters in a randomized prospective comparison between these two thermal ablation modalities for closure of the Great Saphenous Vein.”4

How long does the ClosureFast™ procedure take?

The ClosureFast™ procedure takes approximately 45-60 minutes. Most patients typically spend two to three hours at the medical facility due to normal pre- and post-treatment procedures.

Does the ClosureFast™ procedure require anesthesia?

The ClosureFast™ procedure can be performed under local, regional or general anesthesia. It is generally performed using local anesthesia in a vein specialist’s office or an outpatient surgical facility.

After the ClosureFast™ procedure, how quickly can I return to normal activities?

Many patients experience a quick return to normal activities, typically within a few days.4 For a few weeks following the treatment, a vein specialist may recommend a regular walking regimen and suggest you refrain from very strenuous activities (i.e., heavy lifting) or prolonged periods of standing.
How soon will my symptoms improve after the ClosureFast™ procedure?
Most patients report a noticeable improvement in their symptoms within one to two weeks following the procedure. For any cosmetic symptoms that are not completely resolved following the procedure, you may consider adjunctive treatment including sclerotherapy (small chemical injections) or micro phlebectomy (removal of varicose veins through small skin punctures under local anesthesia).

What potential risks and complications are associated with the ClosureFast™ procedure? Can I expect any pain, bruising or tenderness after the ClosureFast™ procedure?
As with any medical intervention, potential risks and complications exist with the ClosureFast™ procedure. A vein specialist will have a consultation with you to determine if your conditions present any special risks. They will also review with you potential complications associated with the ClosureFast™ procedure, which can include but not limited to the following: adjacent nerve injury, hematoma, pulmonary embolism, thrombosis, infection, phlebitis, skin burn or discoloration, or vessel perforation.

Patients report minimal to no scarring, bruising or swelling following the ClosureFast™ procedure.

Is the ClosureFast™ procedure suitable for everyone?
A vein specialist can tell you if the ClosureFast™ procedure is the right option for your vein problem. Experience has shown that many patients with chronic venous insufficiency can be treated with the ClosureFast™ procedure.

Is age an important consideration for the ClosureFast™ procedure?
The most important step in determining whether or not the ClosureFast™ procedure is appropriate for you is a complete ultrasound examination by a vein specialist. Age alone is not a factor in determining whether or not the ClosureFast™ procedure is appropriate for you. The ClosureFast™ procedure has been used to treat both women and men across a wide range of ages.

What happens to the treated vein left behind in the leg? Don't I need it?
After treatment, the affected vein simply becomes fibrous tissue. Over time, the vein will be completely absorbed into surrounding tissue. Faulty valves interfere with the normal return of blood through the venous system. Closing these diseased veins helps to re-route the blood, improving circulation and relieving most symptoms.

Is the ClosureFast™ procedure covered by insurance?
Many insurance companies pay for the ClosureFast™ procedure in part or in full. The ClosureFast™ procedure has coverage policies with major health insurers. A vein specialist can discuss your insurance coverage further at the time of consultation.
REFERENCES


CLOSEFAST™ PROCEDURE REFERENCE STATEMENT

IMPORTANT: Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.