

## Roundtable Discussion: Chronic Venous Disease Treatment Options

With Ramona Gupta, MD, FSIR; Kathleen Ozsvath, MD, FACS;  
and Michael Shao, MD, RPVI

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In the ever-evolving landscape of vascular medicine, addressing the challenges posed by chronic venous disease (CVD) requires a personalized and collaborative approach. In this roundtable discussion, leading experts share their thoughts on navigating current therapeutic options.

#### How do you approach decision-making in selecting a treatment modality for CVD?

**Dr. Gupta:** My first step is to identify the patient's most problematic symptom. Then, I determine whether the imaging findings match the symptomatology. For example, does the patient have bilateral edema but only unilateral superficial venous insufficiency?

Once a patient is deemed an appropriate candidate for treatment, I evaluate their functional status, their compliance with compression, and their overall health status, including any allergies or chronic inflammatory conditions. I use their imaging to determine whether a truncal ablation is necessary, if just branch varicosities require treatment, or if a combination approach is required.

**Dr. Ozsvath:** I start with patient expectations, and then I carefully look at the ultrasound findings and their history. Reviewing history is very important, as it may uncover relevant information, such as a possible hypercoagulable state or deep venous issues. With axial reflux, I discuss the options with the patient, which include ligation and stripping (rarely indicated because the modern options are excellent), thermal ablation, cyanoacrylate, and ultrasound-guided foam sclerotherapy.

Most of my patients undergo thermal ablation, as I have had excellent results over the years and patients are very happy with their outcomes. I also speak to patients about the VenaSeal™ closure system (VenaSeal system; Medtronic) after a discussion about allergies.

**Dr. Shao:** I start with a history and physical exam to understand the patient's goals. I will then select a treatment

modality based on anatomic and clinical factors, taking into account shared decision-making based on patient preferences. Anatomic factors include reflux distribution pattern (above-knee vs below-knee vs diffuse reflux and axial vs tributary reflux), target vein diameter, treatment length, depth, and tortuosity. Clinical factors include presence or absence of venous ulcer(s), ability to tolerate compression, and history of allergic sensitivities.

### **What is important to physicians when choosing a treatment modality?**

**Dr. Gupta:** Experience with the device and patient outcomes are important in my selection of a treatment modality. I want to ensure that the treatment will be durable and effective in resolving the patient's symptoms. I also want to ensure the patient will tolerate the procedure well and be able to manage postprocedure recovery recommendations.

**Dr. Ozsvath:** The techniques available today are excellent and carry very low complication rates.<sup>1</sup> With that said, the anatomy, extent of disease, and history come first and foremost. Next are patient expectations and education in the pros and cons of each intervention, including conservative management.

**Dr. Shao:** Physicians choose a modality based on efficacy and safety. It is well established that catheter-based ablation including radiofrequency ablation (RFA) and cyanoacrylate have excellent efficacy as far as 5-year closure rates.<sup>1</sup> However, radiologic endpoints such as ultrasound closure rate are less important than clinical endpoints such as time to ulcer healing and ulcer recurrence rate. It remains to be seen whether nonthermal ablation modalities may have advantages in these clinical endpoints. Endovenous modalities are generally safe, but considerations such as minimizing risk of thermal nerve injury while maximizing elimination of below-knee reflux come into play, especially in the setting of venous ulcer disease.<sup>2</sup>

### **How do you assess what is important to patients when choosing a treatment modality?**

**Dr. Gupta:** Most patients rely on the physician recommendation when choosing a treatment. If there are multiple options, I walk them through the procedures with clear descriptions so they know exactly what to expect both during and after the procedure. We discuss the pros and cons so they can better compare the alternatives. I assess the patient's overall health status and their treatment goals.

Unfortunately, an assessment of the patient's insurance policy is also necessary to determine which modalities are a treatment option. Aligning the patient's concerns and goals help us reach a decision together.

**Dr. Ozsvath:** I start by asking patients what is most important to them; we go through their history and their family

history, and then we discuss options based on their disease pattern. With experience, I have learned what to ask and what to look for during a physical exam to help me recommend the best treatment option for each individual patient.

**Dr. Shao:** It is important to always ask patients about their goals for treatment. Is the goal to improve physical symptoms, heal an ulcer, prevent recurrent variceal bleeding, and/or improve cosmetic appearance? For example, variceal bleeding typically occurs at the ankle level and may require ablation to the most distal point possible, favoring a nonthermal modality to avoid the risk of thermal nerve injury. The same goes for venous ulcer disease. Most patients will rely on the physician to recommend the best available option. It is still important to discuss the rationale, advantages, and disadvantages of each modality as part of the informed consent process.

### **Could you describe a patient appropriate for the ClosureFast™ RFA system (Medtronic), including the ClosureRFG™ radiofrequency generator and ClosureFast™ endovenous radiofrequency ablation catheter?**

**Dr. Gupta:** Thermal ablation is the conventional choice for many patients because it is reliable and durable, especially in those with large truncal veins ( $>15$  mm)<sup>3</sup> and those with an adhesive allergy, autoimmune condition, or concern for foreign body.

**Dr. Ozsvath:** The ideal ClosureFast system patient is one with a refluxing axial vein that has no scarring from past superficial vein thrombosis (SVT). With that said, past SVT that has left some scarring is not a contraindication, and these patients can be treated successfully.

**Dr. Shao:** A typical patient for whom I would favor treating with the ClosureFast system may have predominant reflux above the knee or a larger-diameter truncal vein, including perhaps a short-segment anterior accessory vein.

### **Could you describe a patient appropriate for the VenaSeal closure system?**

**Dr. Gupta:** The VenaSeal system is ideal in many clinical situations. I rely heavily on it for patients who are unable to wear compression during their recovery. It is also ideal in patients with venous ulcers in whom I'd like to achieve truncal ablation more distal into the calf or ankle without risking nerve injury. Similarly, these patients often have advanced lipodermatosclerosis, which can make achieving adequate tumescent anesthesia difficult. It is also ideal in the young, active patient who wants no downtime or for a patient with concerns about intraprocedural pain, as it requires only a single needle stick.

**Dr. Ozsvath:** The VenaSeal system is a good option in patients who understand that it is an implant and who have

no allergies to the product. It is also preferred in those who have a fear of needles.

**Dr. Shao:** A typical patient for whom I would favor treating with the VenaSeal system may be one who has diffuse reflux from saphenofemoral junction to the ankle or significant reflux below the knee, particularly patients with venous ulcer disease. Prolonged healing of venous ulcers and high recurrence rate may be due to persistent untreated reflux below the knee.

### Will data from the VenaSeal Spectrum Program (NCT03820947) change the way you approach CVD patients?

**Dr. Gupta:** My main hope for the VenaSeal Spectrum Program is that it provides data demonstrating efficacy and durability that will help obtain approval by additional insurance carriers so that I am able to offer this procedure to more patients. My secondary hope is that it proves superior in closing chronic venous ulcers and gives patients a more efficacious method of treatment.

**Dr. Ozsvath:** Research is paramount to understanding and identifying the best treatments for individual patients. We know that both the VenaSeal and the ClosureFast systems are excellent modalities overall. The results will be helpful and insightful.

**Dr. Shao:** The results will inform whether the VenaSeal system may have advantages over thermal modalities and surgical stripping in periprocedural and postprocedural patient satisfaction and, perhaps, more complete elimination of target vein reflux. Of particular interest to me is the program's

venous leg ulcer study that will assess ulcer healing and ulcer recurrence rates with the VenaSeal system.

### Are there other considerations for treating patients with CVD?

**Dr. Gupta:** When treating CVD, clinicians must be aware of the complex interconnections between the superficial, deep, and pelvic venous systems. Knowledge of these networks, their relationships, and their clinical presentation is necessary to achieve successful outcomes.

**Dr. Ozsvath:** I think it is important to consider, discuss, and study the deep system in patients with CEAP (clinical, etiological, anatomic, pathophysiological) 4 to 6 disease.

**Dr. Shao:** In the United States, insurance coverage impacts treatment modality selection, unfortunately. Clinical trials such as the VenaSeal Spectrum Program will add to the body of evidence that has established the safety and long-term efficacy of newer nonthermal modalities and delineate which patients may benefit the most from these treatments. Hopefully, this will spur expansion of insurance coverage for the newer nonthermal modalities. ■

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2. Gliviczki P, Lawrence PF, Wasan SM, et al. The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II: endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine. *J Vasc Surg Venous Lymphat Disord.* 2024;12:101670. doi: 10.1016/j.jvsv.2023.08.011
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## Medtronic

### ClosureFast™ endovenous radiofrequency ablation (RFA) Catheter

#### Reference Statement

**Indications for Use:** The ClosureFast™ endovenous radiofrequency ablation (RFA) catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

**Contraindications:** The ClosureFast catheter is contraindicated for use in patients with thrombus in the target vein segment.

**Potential Adverse Effects of the Device on Health:** The potential complications include, but are not limited to, the following: adjacent nerve injury, hematoma, pulmonary embolism, thrombosis, infection, phlebitis, skin burn or discoloration, and vessel perforation.

**Important:** Please reference the Instructions For Use (IFU) for a complete listing of indications, contraindications, warnings and precautions, adverse effects, and suggested procedure.

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

### ClosureRFG™ Radiofrequency Generator

#### Reference Statement

**Indications for Use:** The ClosureRFG generator is used with radiofrequency catheters intended for vessel and tissue coagulation.

**Contraindications:** Refer to the applicable radiofrequency catheter instructions for use for a list of contraindications related to a ClosureFast system procedure.

**Potential Adverse Effects of the Device on Health:** Refer to the applicable radiofrequency catheter instructions for use for a list of potential complications related to a ClosureFast system procedure.

**Important:** Please reference the Operation Manual for a complete listing of indications, warnings, precautions safety notices, and operational information.

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

### VenaSeal™ closure system Brief Statement

**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 as a system. The use of the 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, acute sepsis.

**Potential Adverse Effects of the Device on Health:** The potential adverse effects (e.g., complications) associated with the use of the VenaSeal system include, but are not limited to, adverse reactions to a foreign body (including, but not limited to, nonspecific mild inflammation of the cutaneous and subcutaneous tissue), arteriovenous fistula, bleeding from the access site, deep vein thrombosis (DVT), edema in the treated leg, embolization, including pulmonary embolism (PE), hematoma, hyperpigmentation, hypersensitivity or allergic reactions to cyanoacrylates, such as urticaria, shortness of breath, and anaphylactic shock, infection at the access site, pain, paresthesia, phlebitis, superficial thrombophlebitis, urticaria, erythema, or ulceration may occur at the injection site, vascular rupture and perforation, visible scarring.

Warnings, precautions, and instructions for use can be found in the product labeling at <http://manuals.medtronic.com>.

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

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