BUILDING LONG-TERM EVIDENCE WITH HIGH CLINICAL STANDARDS

VeClose
36-month results
IDE Clinical Trial[1]

- One of the largest multi-center, randomized prospective comparisons of superficial venous ablation technologies
- The VenaSeal™ closure system continues to meet the non-inferiority efficacy and safety endpoints
- No DVT, PE, or adhesive-related allergies were reported in the VenaSeal™ closure system cohort

	VenaSeal™ closure system		ClosureFast™ procedure
VeClose 3-year closure rates	94.4%	VS.	91.9% *p-value = 0.745*
AVVQ improvement from baseline	10.71 pts	VS.	9.70 pts *Both improvements are statistically significant from baseline*
VCSS improvement from baseline	3.81 pts	VS.	3.82 pts *Both improvements are statistically significant from baseline*

WHY CHOOSE THE VENASEAL™ CLOSURE SYSTEM

Immediate closure[1,2]
The VenaSeal™ closure system provides immediate vein closure delivering consistent and reproducible results.

A comfortable procedure[1,2]
The VenaSeal™ closure system offers freedom from tumescent anesthesia, thermal nerve injury and post-procedure compression stockings*.

Results you have come to expect
With a 94.4% closure rate at 3 years[3], the VenaSeal™ closure system is a safe and effective treatment option for patients suffering from venous reflux disease.

Medtronic
Further, Together

Trial Overview	Multicenter, prospective, randomized, controlled IDE trial to demonstrate the safety and effectiveness of the VenaSeal™ closure system (N=108) for the treatment of lower extremity truncal reflux compared to ClosureFast™ system (N=114), with a non-inferiority approach. Effectiveness was assessed and compared across groups up to 36 months post-procedure.	
Primary Endpoints	• Complete closure of the target GSV at 3 months after index procedure as judged by the core laboratory. • Complete closure is defined as Doppler ultrasound examination showing closure along entire treated target vein segment with no discrete segments of patency >5cm.	
Secondary Endpoints & Outcomes	**Endpoints**	**Outcomes**
	Intraoperative pain evaluation at Day 3 (self-rated pain experienced during 2 phases of treatment on a 0-10 NRS):	
	Phase 1: Initial local anesthesia injection at the access site to venous access with the micro-access catheter	VenaSeal™ Closure System (1.6), RFA (2.0) (P-value 0.13)
	Phase 2: from introduction of the RFA or VenaSeal™ closure system catheter to completion of vein treatment and device removal	VenaSeal™ Closure System (2.2), RFA (2.4) (P-value 0.11)
	Ecchymosis at Day 3 (investigator assessment of ecchymosis along the treated area using 0-5-point grading scale):	Subjects treated with VenaSeal™ closure system had significantly less ecchymosis at Day 3 compared to RFA (p<0.01)
	0 (none), 1 (<25% of treatment area), 2 (25-50%), 3(50-75%), 4 (75-100%), 5 (extension above or below treatment segment)	
Conclusion	VenaSeal™ closure system is a safe, reliable, non-thermal, non-tumescent, non-scleroscant treatment option for patients, and it demonstrates strong, consistent and durable results through 36 months	

[1] 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.

[2] Almeida JI, Jacier JJ, Mackay EG, Bautista C, Cher DJ and Proebstle TM. Thirty-sixth-month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Journal of Vascular Surgery: Venous and Lymphatic Disorders. 2017. Published Online: 2 June 2017.

[3] 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

* Some patients may benefit from the use of compression stockings post procedure.

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 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.Warning, precautions, and instructions for use can be found in the product labeling. For VenaSeal™ procedure, this labeling can be found at http://manuals.medtronic.com.

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

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

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