VenaSeal™
Closure System

IMPROVED COMFORT RAPID RECOVERY[1,4]

- Rapid return to normal activities[3]
- Non-tumescent treatment — no multiple needle sticks
- Minimal-to-no bruising[1,4]
- No post-procedure compression stockings[2,3*]

Non-thermal. Non-tumescent. Non-sclerosant.

The VenaSeal™ procedure is the only non-thermal, non-tumescent, non-sclerosant procedure that uses a specially formulated medical adhesive delivered endovenously to close the vein. This unique approach eliminates the risk of thermal nerve injury when treating the small saphenous vein, which is a risk sometimes associated with certain thermal-based procedures. Clinical studies have demonstrated that the procedure is safe and effective.[1-4] The procedure is administered without the use of tumescent anesthesia, avoiding patient discomfort associated with multiple needle sticks.

Sealed By EVIDENCE

	Feasibility Study[2,5]	eSCOPE Trial[3]	VeClose Study[1,4] (U.S. Pivotal Trial)	
Study Design	Prospective, single-center study	Prospective, multi-center, post-market study	Prospective, multi-center, randomized controlled trial	
Patients Enrolled (n)	38	70	242*	
Closure Rate	1-year: 92% (n=36) 2-year: 92% (n=24)	1-year: 92.9% (n=66)	VenaSeal 1-year: 97.2% (n=104)	RF 1-year: 97.1% (n=108)
Definition of Closure	No discrete segment of patency >5 cm in the treated vein segment	No discrete segment of patency >10 cm in the treated vein segment	No discrete segment of patency >5 cm in the treated vein segment	
Serious Adverse Events Related to Study Device or Procedure	0	0	0	

*20 were roll-in patients treated by the VenaSeal closure system.

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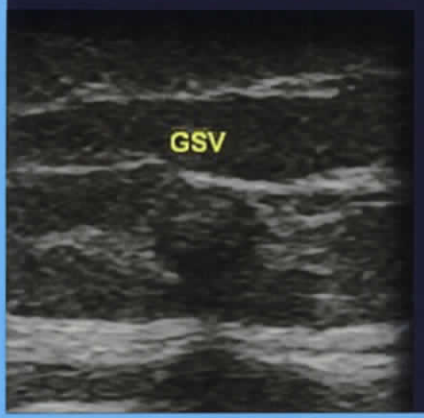
Further, Together

METHOD OF ACTION

The VenaSeal™ proprietary cyanoacrylate-based adhesive safely and effectively closes the diseased vein segment.[1-4]

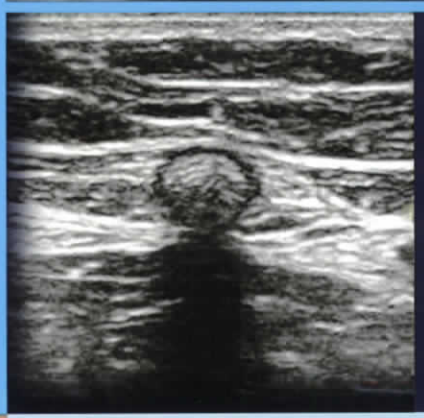
- The procedure can be completed in an office or hospital setting and requires no additional capital equipment
- The proprietary catheter is highly visible under ultrasound, allowing precise delivery of the adhesive
- VenaSeal adhesive is delivered in 0.10 cc allotments along the length of the vein segment

VEINS TREATED WITH THE VENASEAL CLOSURE SYSTEM



30 days post-procedure

The ultrasound image shows a chronic foreign body reaction leading to fibrous occlusion in treated veins



12 months post-procedure

The VenaSeal adhesive is sonographically dense, as demonstrated by the shadowing in this ultrasound image

References: 1. Morrison, N. Use of Cyanoacrylate adhesive for Treatment of Incompetent Great Saphenous Veins: 12-month Results of the VeClose Trial. European Venous Forum, 2015. **2.** Almeida JI, Javier JJ, Mackay EG et al. Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Phlebology/Venous Forum of the Royal Society of Medicine, 2014. **3.** Proebstle TM, Alm J, Dimitri S et al. The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. J Vasc Surg Venous and Lymphat Disord. **4.** Morrison N, Gibson K, McEnroe S et al. Randomized trial comparing cyanoacrylate embolization and radio frequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg. **5.** Almeida JI, Javier JJ, Mackay EG, Bautista C, Proebstle TM. First human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. J Vasc Surg Venous and Lymphat Disord. 2013;1(2):174-80.

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

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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.