SIMPLICITY FOR YOU. DURABILITY FOR THEM.

Abre™
Venous Self-expanding Stent System

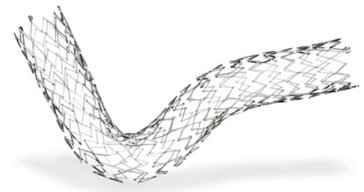
Medtronic

SIMPLICITY FOR YOU.

EASY DEPLOYMENT, TO LET YOU FOCUS ON YOUR PATIENT.[1,2]

The Abre stent minimizes jumping and foreshortening, landing precisely where you need it.[2]

- Triaxial shaft design controls friction and stabilizes stent.[2]
- Rotating thumbwheel offers predictable placement and auditory feedback.[2]

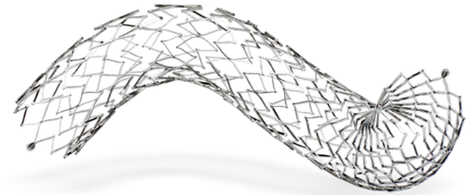


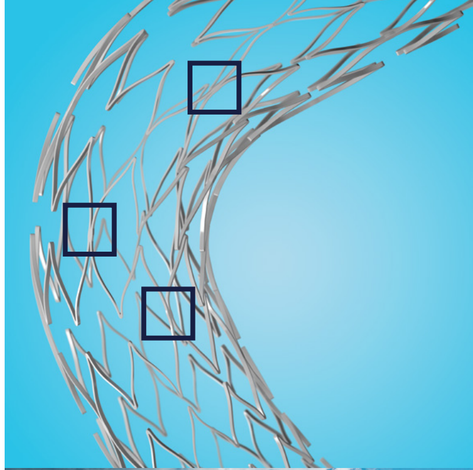
DURABILITY FOR THEM.

DEMONSTRATED ENDURANCE, TO GIVE YOUR PATIENTS FREEDOM OF MOVEMENT.[1,2]

The nitinol Abre stent maintains lumen integrity and flow in diverse patients and anatomies.[1] It ensures radial strength and crush resistance, without compromising flexibility.[2]

- Unique technology:
  - Open-cell design with three offset connection points
  - Struts customized to each size
- Consistent behavior across a broad range of diameters and lengths.[2]





Bench evidence shows
long-term durability.[2]

Clinical evidence shows
real-world dependability,
even in challenging cases.[1]

0%
fracture rate at
50
years
in bench testing[2]

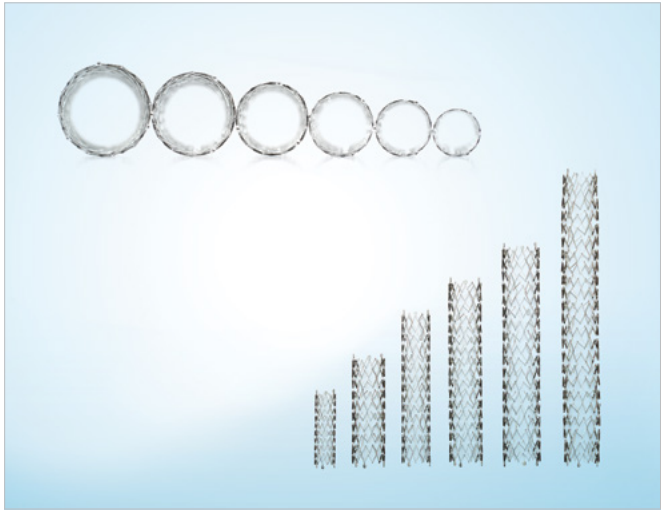
0% fracture rate
in clinical trial with
44%
of stents extending below inguinal ligament into the common femoral vein (CFV)[1]

0%
migration rate
in clinical trial[1]

AB9U10040090

Product Code Diameter Length

Stent Diameters	Stent Lengths and Product Numbers					
	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm
10 mm	AB9U10040090	AB9U10060090	AB9U10080090	AB9U10100090	AB9U10120090	AB9U10150090
12 mm	-	AB9U12060090	AB9U12080090	AB9U12100090	AB9U12120090	AB9U12150090
14 mm	-	AB9U14060090	AB9U14080090	AB9U14100090	AB9U14120090	AB9U14150090
16 mm	-	AB9U16060090	AB9U16080090	AB9U16100090	AB9U16120090	AB9U16150090
18 mm	-	AB9U18060090	AB9U18080090	AB9U18100090	AB9U18120090	AB9U18150090
20 mm	-	AB9U20060090	AB9U20080090	AB9U20100090	AB9U20120090	AB9U20150090



References

[1] ABRE CSR v1.2 30/JUL/2020.

[2] Test data on file at Medtronic. Bench test results may not be indicative of clinical performance.

Brief Statement

Intended Use/Indications: The Abre™ venous self-expanding stent system (Abre™ stent system) is indicated for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

Contraindications: Do not use the Abre™ stent system with patients with known hypersensitivity to nickel titanium (nitinol), with patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system, and with patients in whom anticoagulant or antiplatelet therapy is contraindicated.

Potential Adverse Effects of the Device on Health: The potential adverse effects (e.g., complications) associated with the use of the Abre™ stent system include, but are not limited to, access failure, access site infection, allergic reaction to contrast medium or procedure medications; aneurysm; AV fistula; bleeding; bruising; death; device breakage; device maldeployment; edema; embolization; fever; hematoma; hypertension; hypotension, nausea, or other vasovagal response; infection; myocardial infarction, arrhythmia, or other cardiovascular insufficiency; open surgical repair; pain; pseudoaneurysm; renal insufficiency or renal failure (new or worsening); respiratory distress or pulmonary embolism; sepsis; stent fracture; stent malapposition; stent malposition; stent migration; stroke, paradoxical embolism, transient ischemic attack, or intracerebral hemorrhage; tissue necrosis; venous occlusion, restenosis, or thrombosis, within or outside of stented segment; and vessel damage, including intimal injury, dissection, perforation, or rupture.

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.

medtronic.com/abrestent

Medtronic

ClosureFast™ Radiofrequency Ablation System

DELIVER PATENTED PERFORMANCE WITH CLOSUREFAST™ RFA SYSTEM

The only gap-free thermal ablation system with published long-term clinical data demonstrating safety and efficacy, with a 91.9% closure rate at 5 years.[1,2]

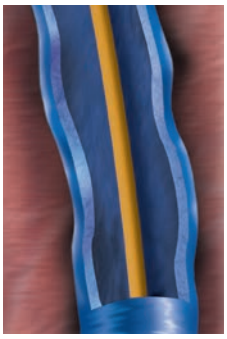
Medtronic

WE'VE GOT YOU COVERED

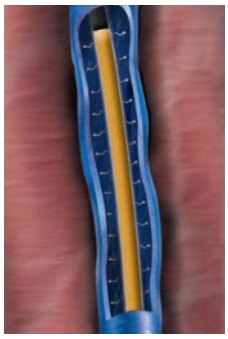
Gap-free thermal ablation

The ClosureFast™ RFA system delivers uniform heat for lasting vein closure.[1]

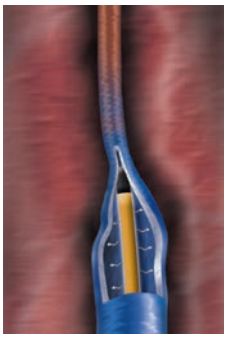
- Patented segmental procedure
- Tumescent anesthesia
- Less pain and bruising than laser energy treatment[3]
- Post-procedure compression stockings required[1]



Disposable catheter inserted into vein



Controlled heat collapses vein

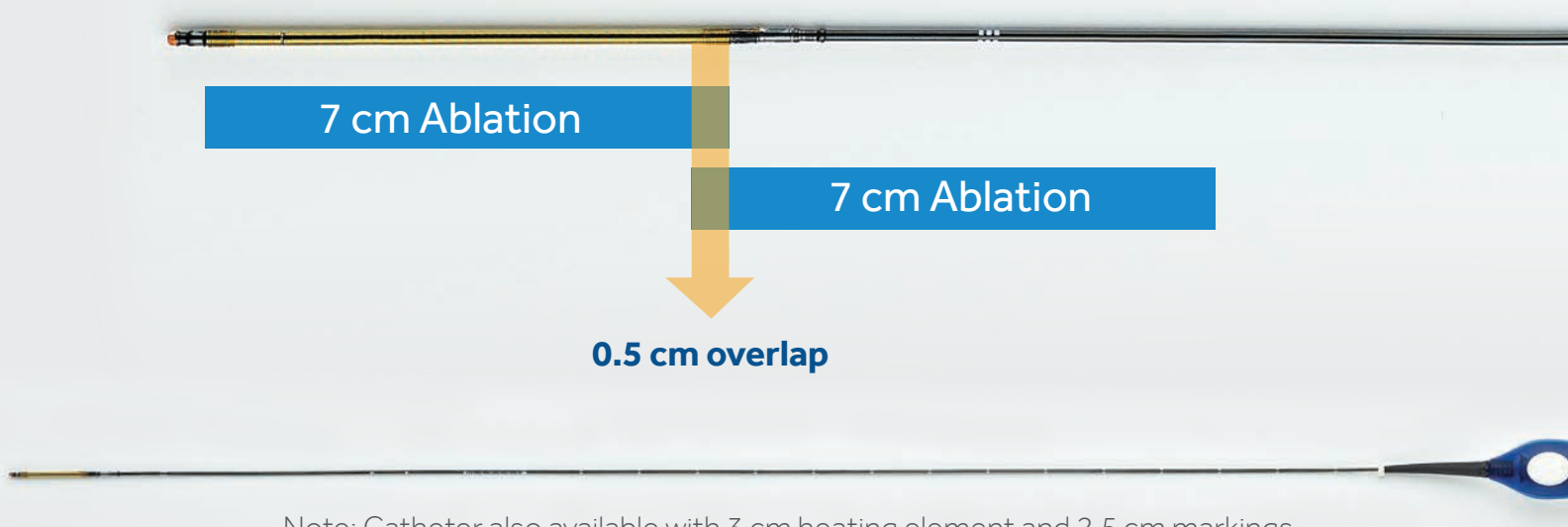


Catheter withdrawn, closing vein

Deliver lasting results with gap-free thermal ablation

The ClosureFast™ procedure features a patented overlap of 0.5 cm at each thermal treatment segment, eliminating gaps between segments — for lasting vein closure.[1,2]

7 cm heating element overlaps the previous segment by 0.5 cm as the device is repositioned.



Note: Catheter also available with 3 cm heating element and 2.5 cm markings.

GO GAP-FREE
FOR PATENTED PERFORMANCE

The ClosureFast™ procedure, with its patented overlap design, is the only RFA procedure for venous reflux with published long-term clinical data demonstrating safety and efficacy, with a 91.9% closure rate at 5 years.[1-4]

PATENTED PERFORMANCE

91.9%
closure rate at 5 years[1]

94.9%
reflux-free rate at 5 years[1]

72%
improvement in VCSS scores at 5 years[4]

UNMATCHED EVIDENCE

250+
published articles and clinical studies[5]

2.5m+
patients treated worldwide[6]

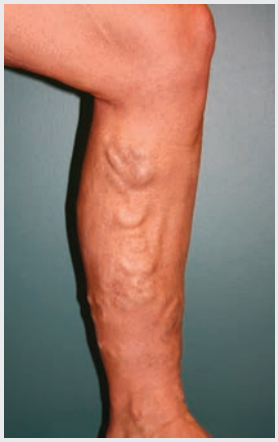
See what the ClosureFast procedure can do for your patients

These pictures show before and after results of ClosureFast procedure treatment only.

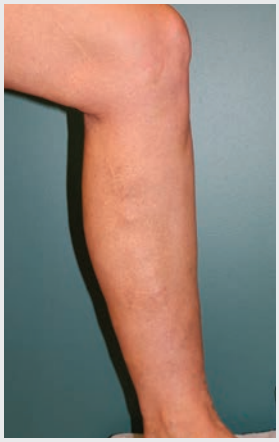
*Individual results may vary.

Photo courtesy of Vein Institute of the North Shore, Beverly, MA.

Before



3 months after*



THE ONLY CLINICALLY PROVEN THERMAL ABLATION SYSTEM.

From the innovation leader in venous disease treatment

Medtronic.com/closurefast

Ordering information for ClosureFast™ RFA System

Order #	Description	Working length	Heating element	Compatible guidewire
CF7-7-60	7 F ClosureFast catheter	60 cm	7 cm	0.025"
CF7-7-100	7 F ClosureFast catheter	100 cm	7 cm	0.025"
CF7-3-60	7 F ClosureFast 3 cm catheter	60 cm	3 cm	0.025"

Order #	Description	Device size	Device length	Compatible guidewire
RFS2-6-12	ClosureRFS stylet	6 F	12 cm	0.035"

Order #	Description	Voltage
RFG3	ClosureRFG Radiofrequency Generator	Universal (100-240 V)

Please review the Instructions for Use for accessories and supplies that you will need to purchase for the ClosureFast procedure.

REFERENCES

[1] Proebstle TM, Alm BJ, Göckeritz O, et al. Five-year results from the prospective European multicentre cohort study on radiofrequency segmental thermal ablation for incompetent great saphenous veins. *Br J Surg*. February 2015;102(3):212-218.

[2] ClosureFast and ClosureFast RFS Patents. Available at: https://www.medtronic.com/content/dam/medtronic-com/global/Corporate/meaningful-innovation/documents/CVG-Patent-Marking.pdf.pdf. Accessed July 10, 2019.

[3] Almeida JI, Kaufman J, Göckeritz O, et al. Radiofrequency endovenous ClosureFAST versus laser ablation for the treatment of great saphenous reflux: A multicenter, single-blinded, randomized study (RECOVERY Study). *J Vasc Interv Radiol*. June 2009;20(6):752-759.

[4] Morrison N. VeClose 5-year Follow-up Extension Study Results. Presented at Charing Cross 2019; London, UK.

[5] Medtronic ClosureFast Procedure Publications. Medtronic data on file. 2019.

[6] ClosureFast Radiofrequency Ablation (RFA) System patients treated. Medtronic data on file. 2019.

CLOSUREFAST™ 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.

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Medtronic

VenaSeal™ Closure System

Introduce your patients to relief.

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

The VenaSeal closure system offers relief for patients suffering from venous reflux disease by using a medical adhesive to permanently close the vein.

With no need for heat, the VenaSeal procedure delivers a comfortable patient experience[†1,2] and immediate vein closure,[1,2] with the results you have come to expect.

[†]No tumescent, no compression stockings.[‡]

Immediate closure[1,2]

How it works

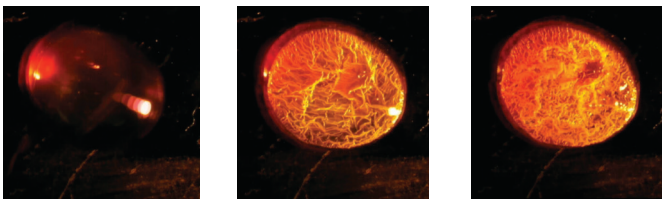
The VenaSeal closure system provides immediate vein closure, delivering consistent and reproducible results for your patients without the need for post-procedure compression stockings.[‡1,2]

Precision

The dispensing gun precisely controls the amount of adhesive, delivering 0.10 cc aliquots with each trigger pull.

Polymerization

Upon contact with blood, the adhesive begins to bond with the intima and compression is applied to close the vein. The adhesive was designed to remain permanently in the diseased vein and is encapsulated by chronic fibrosis.[3]



0 seconds | 24 seconds | 54 seconds

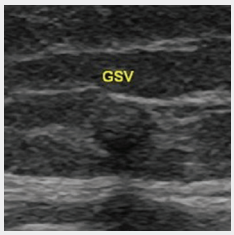
Viscosity

The viscosity of the adhesive is specifically designed to minimize migration and embolization outside the treatment area.

Flexibility

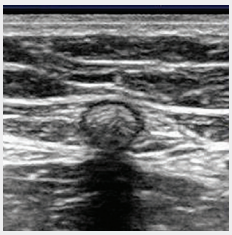
The adhesive is designed to be soft and flexible, and less likely to be felt by the patient.

VenaSeal adhesive over time



30 days
post-procedure

The ultrasound image shows 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.

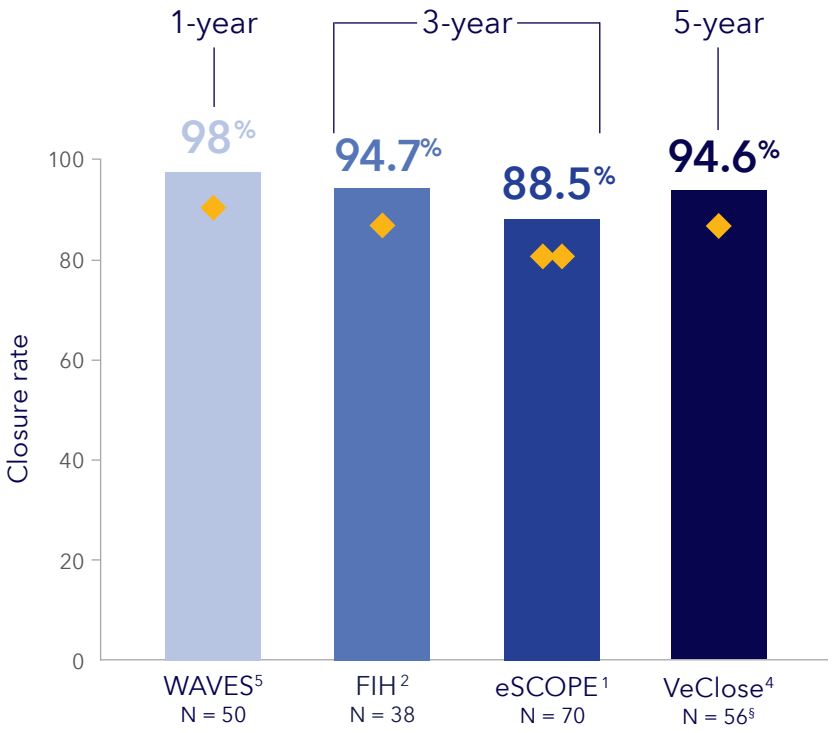
The results you have come to expect

VeClose 5-year Extension Study (IDE clinical trial)[4]

- One of the largest multicenter, randomized prospective comparisons of superficial venous ablation technologies
- **No DVT, PE, or adhesive-related allergies** were reported in the VenaSeal closure system study arm

94.6%
closure at
5 years[4]

VenaSeal system clinical study overview



[§]VenaSeal closure system includes nine roll-in patients.

Definition of occlusion

> 10 — No discrete segment of patency > 10 cm in the treated vein segment

> 5 — No discrete segment of patency > 5 cm in the treated vein segment

Study design

WAVES: Prospective, single-center, multi-investigator, post-market study

FIH: Prospective, single-center study

eSCOPE: Prospective, multicenter, post-market study

VeClose: Prospective, multicenter, randomized controlled trial

VenaSeal closure system

A comfortable patient experience

The VenaSeal closure system offers:

- Rapid return to normal activities after treatment[6,7]
- Minimized pain, tenderness and ecchymosis[7]
- Significant improvements in quality of life[8]

The VenaSeal closure system eliminates:[1,2]

- Tumescent anesthesia
- Thermal nerve injury
- Post-procedure compression stockings‡

Adverse events can include allergic reaction, inflammation, phlebitis, deep vein thrombosis and/or pulmonary embolism.

VenaSeal closure system is now reimbursed where covered under codes 36482 and 36483.Ω

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

ΩCPT codes for cyanoacrylate (VenaSeal system) do not guarantee payer coverage. Medtronic is actively pursuing coverage for VenaSeal system with Medicare, Medicaid, Commercial, and VA payers.

References

[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, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM. Thirty-sixth-month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *J Vasc Surg Venous Lymphat Disord.* September 2017;5(5):658-666.

[3]Lui DM, et al. Cyanoacrylate Embolization for the Treatment of Saphenous Vein Reflux: Ultrasound Appearance and Correlative Findings of Comparative Model Histology. ACP 2014.

[4]Morrison N, Gibson K, Vasquez M, Weiss R, Jones A. Five-year extension study of patients from a randomized clinical trial (VeClose) comparing cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. *J Vasc Surg Venous Lymphat Disord.* November 2020;8(6):978-989.

[5]Gibson K. Cyanoacrylate Closure of Incompetent Great, Small and Accessory Saphenous Veins without the use of Post-Procedure Compression: A Post-Market Evaluation of the VenaSeal System (WAVES trial): 12 Month Data. Presented at Charing Cross 2016; London, UK.

[6]Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). *Vascular.* April 2017;25(2):149-156.

[7]Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *J Vasc Surg.* April 2015;61(4):985-994.

[8]Morrison N, Gibson K, Vasquez M, et al. VeClose trial 12-month outcomes of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins. *J Vasc Surg Venous Lymphat Disord.* May 2017;5(3):321-330.

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.

Learn more at
medtronic.com/VenaSeal

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