

RELIABLE OCCLUSIONS

FEWER COMPLICATIONS

LESS PAIN

LONG TERM **CLINICAL DATA**



PROVEN TECHNOLOGY CLOSUREFASTTM CATHETER

CLINICAL DATA COMPARISON RFA VERSUS EVLA



2+ MILLION PATIENTS TREATED IN OVER 100 COUNTRIES¹

A PROVEN THERAPY WITH 5-YEAR CLINICAL RESULTS²

10+ YEARS OF PATIENT CARE



ClosureFast[™] Endovenous Radiofrequency Ablation







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CLOSUREFAST[™]

No need to worry about the fiber pullback speed!

The ClosureFast[™] Endovenous Radiofrequency Ablation (RFA) Catheter uses segmental ablation technology to deliver precise, uniform, radiofrequency energy to the catheter's heating element.¹

- Segmental ablation eliminates the inconsistency related to variable pullback speeds
- Thermal energy is only delivered during each segmental ablation interval lasting 20 seconds, giving consistency throughout the procedure
- The device is only moved following each segmental ablation period giving accurate, reliable energy delivery
- RF delivery can be repeated at a given segment up to 3 treatments
- Saphenous veins exceeding 12mm in diameter are successfully closed using the ClosureFast[™] catheter³

ClosureFast[™] Endovenous Radiofrequency Ablation

LASER

Even for well-trained physicians there can be inconsistencies in treatment delivery.⁴

These variations (too low pullback speed and consequently too high LEED) could easily explain why the complication rate or recurrence rate are sometimes reported in clinical studies.⁴

Laser is not a single procedure but rather an approach composed of several variables under the control of the operator.⁵







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RFA has a lower risk of complications than EVLA.^{6,7}

From 12 articles published (10 RCT's and 2 Cohort studies) comparing the vein ablated length, pain scores (at 3 days and 10 days), quality of life and occlusion, overall complications (thrombophlebitis, haematoma and recanalization) between the EVLA and RFA group.⁶

Several randomized controlled trials (RCTs) have compared different interventions for chronic venous insufficiency (CVI) management.

Odds of occurrence of adverse events was

- 3.3 times in the sclerotherapy arm,
- 2.7 times in the EVLA arm,
- **1.6** times with surgery and
- 1.1 times with RFA vs VenaSeal system arm.⁸

(20 RCTs and 4570 patients)

ClosureFast[™] Endovenous Radiofrequency Ablation

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While the gold-tip NeverTouch[™] fiber resulted in fewer complications, it also resulted in a lower efficacy rate than the bare-tip fiber laser.⁹

Efficacy rate at 5 months:



Fig. 1 Impact of laser fiber design on outcome of endovenous ablation









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The sequence of pain scores below demonstrates that **ClosureFast[™] patients have significantly less post-operative** pain than those in the EVLA and stripping groups.¹⁰



Time after treatment (days)

Fig. 2 Mean (s.d.) pain scores on a visual analogue scale from 0 to 10 for the first 10 days after treatment.

ClosureFast[™] Endovenous Radiofrequency Ablation

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There was no relationship between postoperative pain scores and laser WL. Additionally, laser WL did not affect the technical success or occurrence of complications.¹¹

	Group 1 (N=54, 980- nm Laser)	Group 2 (N=36, 1470- nm Laser)			
Age (years)	42.03 <u>+</u> 11.81	44.21 <u>+</u> 12.44			
Pain	3.25 <u>+</u> 2.42	3.45 <u>+</u> 2.30			
* Student test for equality of variances. Data are given as mean + standard deviation.					

Fig. 3 Comparison of age and pain scores in groups 1 and 2.









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5-YEAR FOLLOW-UP OF A RANDOMIZED CLINICAL TRIAL

Five hundred patients with Great Saphenous Vein (GSV) reflux and varicose veins were randomized to one of 4 treatments modality.

The data below represents the legs that developed recurrent varicose veins.¹²

Treatment	No. of legs treated	Legs with recurrence	Clinical recurrence
RFA	147	19	13%
EVLA	144 ª	42	29%
UGFS	144	28	19%
HL/S	142	38	27%

a. 127 legs were treated with 1470-nm laser 17 legs were treated with 980-nm laser

HL/S: high ligation and stripping



RFA: radiofrequency ablation; EVLA: endovenous laser ablation; UGFS: ultrasound-guided foam sclerotherapy;









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5-YEAR RESULTS FROM THE PROSPECTIVE EUROPEAN **MULTICENTRE COHORT STUDY**

295 limbs (225 patients) were treated with the **ClosureFast**[™] catheter at **8 sites** across Europe. Patients were evaluated at **3**, **6**, **12**, **24**, **36** and **60** months post-procedure.²

> 295 Limbs (225 Patients)

> > 3 Months

6 Months

1 Year

2 Years

3 Years

5 Years



ClosureFast[™] Endovenous Radiofrequency Ablation



Vein Occlusion	No Reflux
99.7%	99.7%
98.6%	99.3%
96.3%	99.0%
94.5%	97.2%
92.6%	95.7%
91.9%	94.9%









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- 1. Medtronic data on file
- data presented is conducted with the ClosureFast 7 cm
- http://ves.sagepub.com/cgi/content/abstract/43/6/567
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- Turkey). 19. 10.5152/dir.2013.023
- International Angiology, June 2017, 36(3):281-8

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events.

For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu

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3. David Calcagno, John A. Rossi and Chi Ha. Effect of Saphenous Vein Diameter on Closure Rate With ClosureFAST Radiofrequency Catheter

4. Endovenous laser treatment of the great saphenous vein: Measurement of the pullback speed of the fiber by magnetic trackin. June 2013 https://www.researchgate.net/publication/257736373_Endovenous_laser_treatment_of_the_great_saphenous_vein_Measurement_of_

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10. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation,

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