CLOSUREFAST™ AND VENASEAL™ CLOSURE SYSTEM

INNOVATION IN THE TREATMENT OF CHRONIC VENOUS DISEASE

ClosureFast™
Endovenous Radiofrequency Ablation Catheter

VenaSeal™
Closure System

Medtronic
Further, Together

VALUE SUMMARY

WHAT IS A VALUE SUMMARY?

A Value Summary is an evidence-based review of published data on a particular disease and therapy area presented in a succinct format.

The aim of this Value Summary is to clearly demonstrate the inherent value proposition of Medtronic's endovenous products.

HOW WAS THIS VALUE SUMMARY CONDUCTED?

A comprehensive literature search was conducted in February 2019 using the PubMed, Embase and MEDLINE databases to identify evidence on the clinical need, epidemiology, disease burden and other issues related to Chronic Venous Insufficiency.

HOW DO I USE THIS VALUE SUMMARY?

A Value Summary is intended to be used as a communication and educational tool to internal and external stakeholders important to Medtronic.

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CHRONIC VENOUS INSUFFICIENCY IS A MAJOR PROBLEM, ESPECIALLY IN DEVELOPED COUNTRIES

Chronic Venous Insufficiency represents the most advanced stage of **Chronic Venous Disease**.

The symptoms of Chronic Venous Insufficiency range from pain, swelling, edema, skin discoloration and inflammation to skin ulcers in the most severe cases, resulting in significant burden for patients, health systems and wider society[1,2,3].

PREVALENCE OF CHRONIC VENOUS DISEASE (VEIN CONSULT PROGRAM)[4]

Total prevalence

CVD (C1–C6) **63.69%**
CVI (C3–C6) **25.95%**

Western Europe

CVD (C1–C6) **61.65%**
CVI (C3–C6) **24.88%**

Eastern Europe

CVD (C1–C6) **61.65%**
CVI (C3–C6) **24.88%**

Latin America

CVD (C1–C6) **68.11%**
CVI (C3–C6) **26.62%**

Asia

CVD (C1–C6) **51.93%**
CVI (C3–C6) **19.84%**

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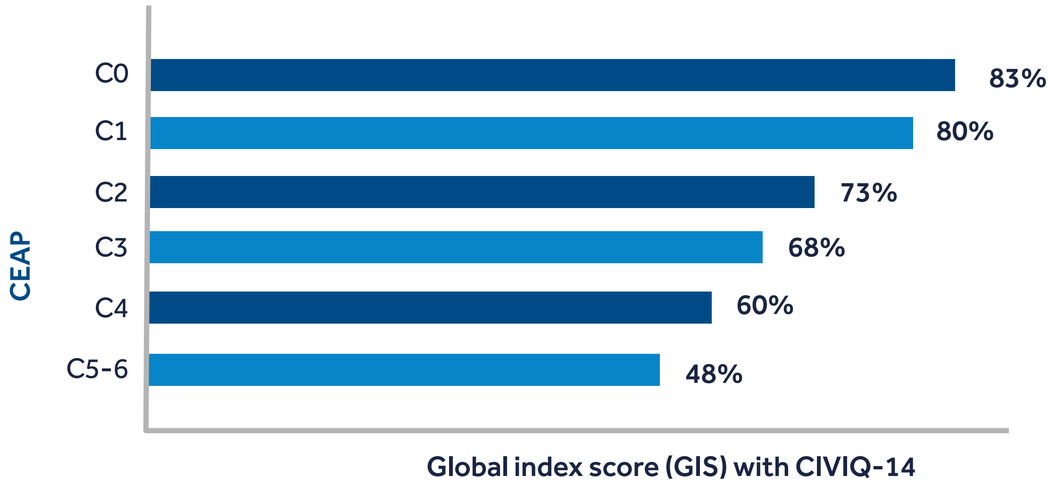
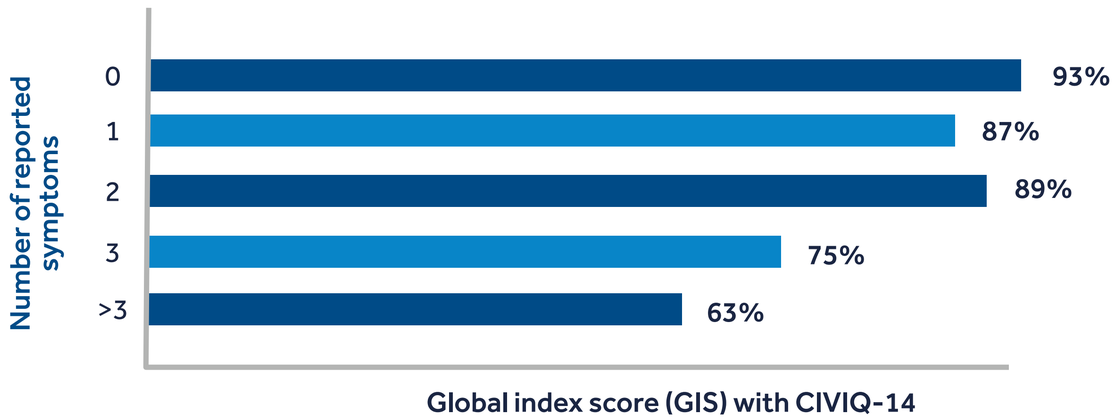
CHRONIC VENOUS INSUFFICIENCY HAS A GREAT IMPACT ON PATIENTS' QUALITY OF LIFE

The high prevalence of Chronic Venous Disease, together with its under-diagnosis and the rapid progression of the disease to more severe stages, negatively affect patients' Quality of Life and increase care burden.

VEIN CONSULT PROGRAM: RESULTS OF QUALITY OF LIFE[5]

Clinical Etiology Anatomy Pathophysiology (CEAP)





QUALITY OF LIFE DECREASES AS THE CEAP CLASSIFICATION INCREASES

CEAP 1

CEAP 6

CHRONIC VENOUS INSUFFICIENCY SYMPTOMS WORSEN PATIENTS' QUALITY OF LIFE

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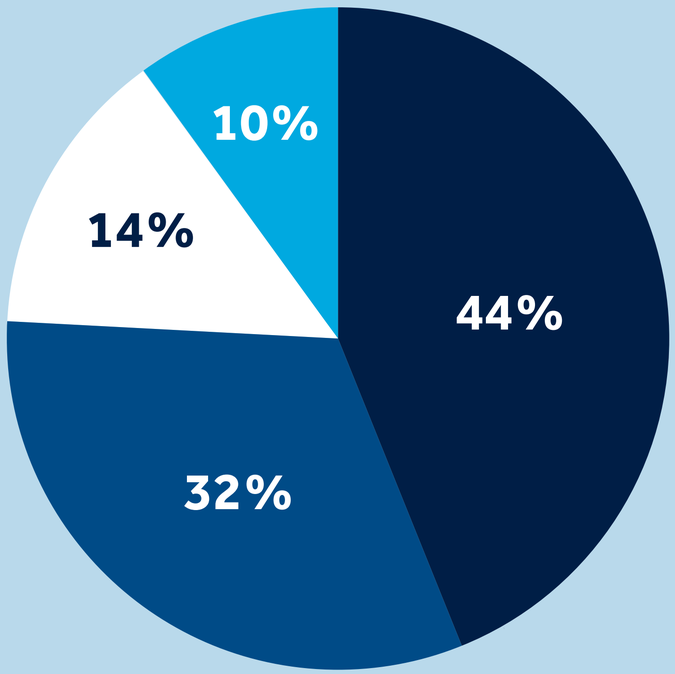
THE TOTAL COST OF THE DISEASE IS EXPECTED **TO INCREASE EVEN MORE IN THE FUTURE**

The high prevalence, diagnosis, treatment and more severe consequences of Chronic Venous Insufficiency have a **high socio-economic impact worldwide**, in terms of direct healthcare costs and loss of productivity.

Annual medical cost of **Chronic Venous Disease** is estimated to be **close to $150K-$1M in USA** and up to **€600M–€900M in Western European countries.**[6,7]

In Western European countries, the average cost of **treating a venous leg ulcer is estimated to be €9K.** 90% of the total cost is associated with direct costs, while the remaining 10% is associated with indirect costs.[7]

NUMBER OF TIMES PATIENTS LOSE WORK DAYS (IN 5 YEARS)[5]



15%
OF THE 25,821 PATIENTS WITH CHRONIC VENOUS INSUFFICIENCY
HAD LOST WORK DAYS[5]

30%
OF THESE PATIENTS
LOST MORE THAN 1 WEEK OF WORK DAYS[5]

12%
LOST MORE THAN 1 MONTH OF WORK DAYS[5]

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CONVENTIONAL SURGERY IS THE MOST WIDELY USED TECHNIQUE

HOWEVER, IT IS NOT FREE OF COMPLICATIONS...

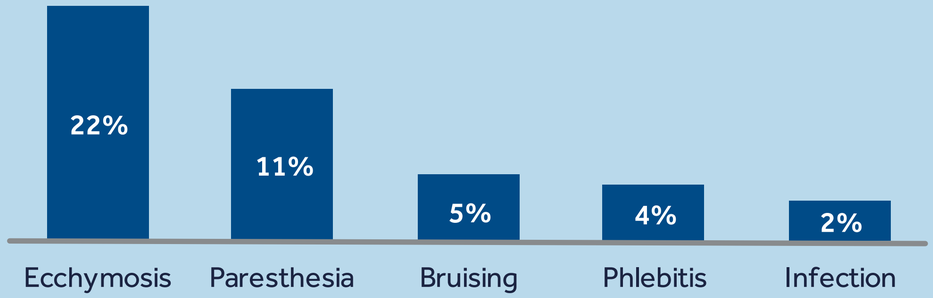
High clinical recurrence rates: Clinical **recurrence rates** for patients undergoing vein stripping was **25–60%** in five years[8,9,10]

High **complications** rates[8]

High **recovery time**[11]

High **postoperative pain**[12]

COMPLICATION RATES RELATED TO STRIPPING OF VARICOSE VEINS[8]



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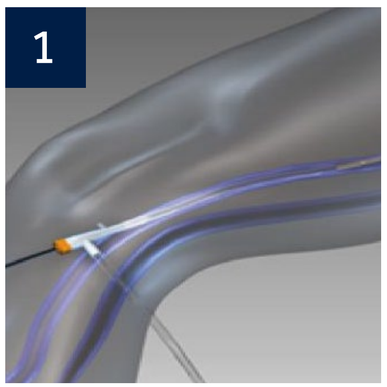
CLOSUREFAST™ APPEARS AS THE ALTERNATIVE OPTION TO CONVENTIONAL SURGERY AND ENDOLASER FOR THE TREATMENT OF CHRONIC VENOUS INSUFFICIENCY

CLOSUREFAST™ PROCEDURE

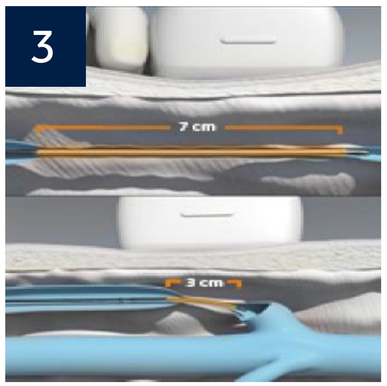


Catheter insertion

Under **ultrasound guidance,** the ClosureFast™ catheter is **inserted into the vein** with final placement of the tip 2cm from the sapheno-femoral junction.

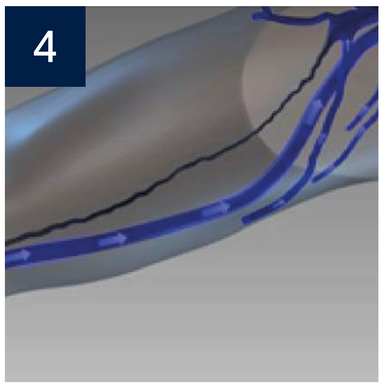
Vessel preparation

Under ultrasound guidance, **perivenous anesthesia** is delivered to the saphenous compartment surrounding the vein.



Segmental ablation

Veins are heated in **3cm or 7cm segment** lengths. When treatment cycle is complete, **shaft markings on ClosureFast™ aid correct repositioning** to the next segment.



Fibrotic occlusion

Heat shrinks and collapses the vein, creating a **fibrotic seal and vein occlusion,** enabling blood flow to be redirected to healthy veins.

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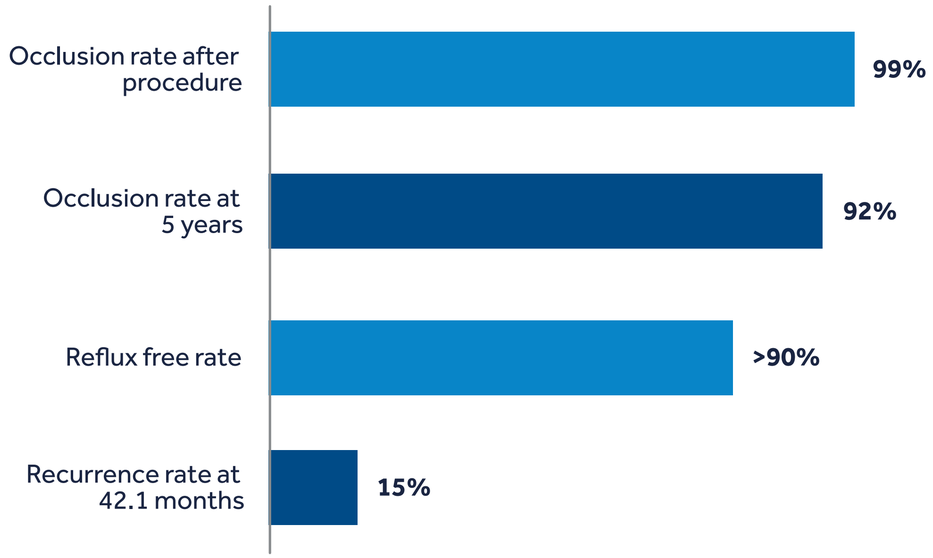
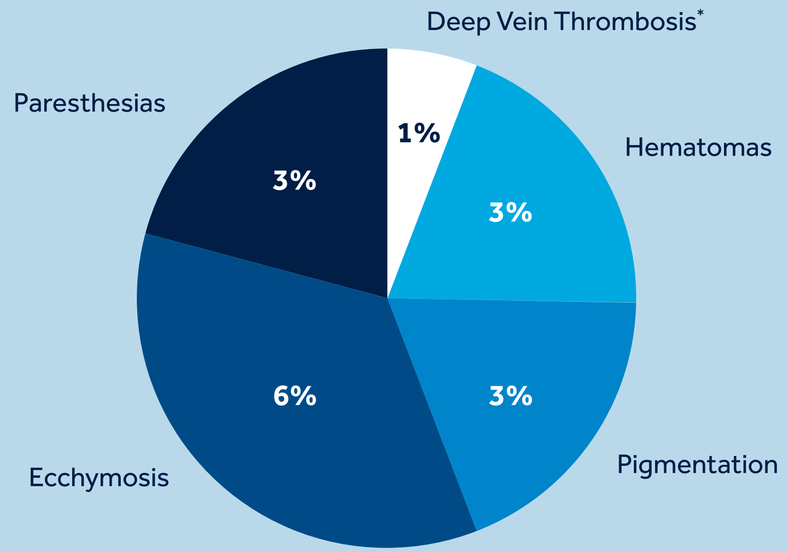
STUDIES ON CLOSUREFAST™ CONFIRM THE HIGH SAFETY AND EFFICACY PROFILE

CLOSUREFAST™[13–17]



CLOSUREFAST™ PROVIDES
HIGH RATES OF VENOUS OCCLUSION AND LOW RECURRENCE RATES

INCIDENCE OF COMPLICATIONS[18]



*The patient who developed Deep Vein Thrombosis (DVT) was later on diagnosed with thrombophilia. DVT was associated to this diagnostic and not with the procedure.

CLOSUREFAST™ IS ASSOCIATED WITH
LOW COMPLICATION RATES

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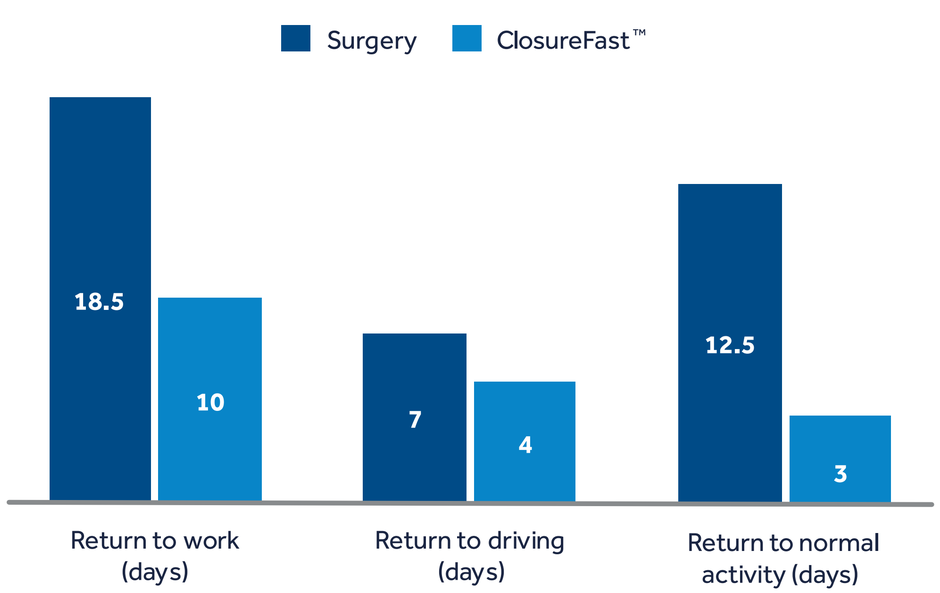
CLOSUREFAST™ HAS SHOWN BETTER RESULTS VS. CONVENTIONAL SURGERY IN THE FOLLOWING THREE ASPECTS:

LESS POSTOPERATIVE PAIN

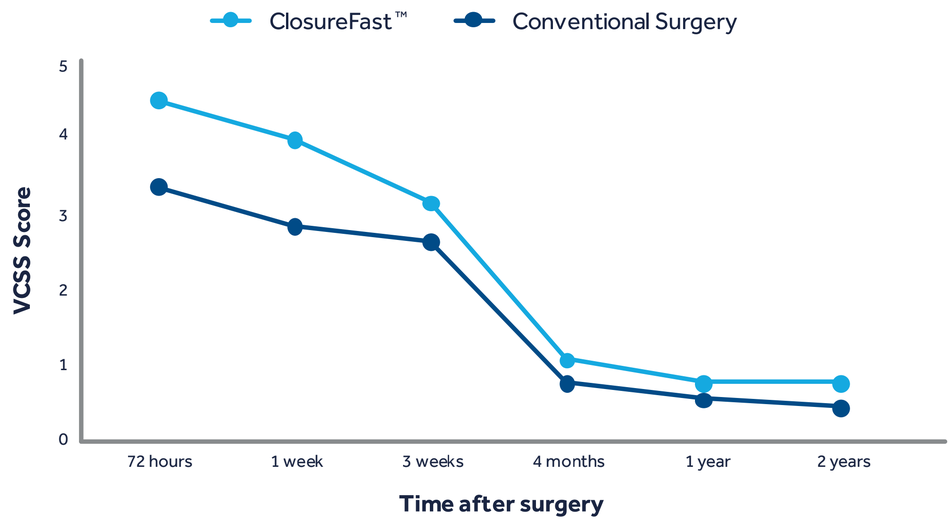
IMPROVED QUALITY OF LIFE

FASTER POSTOPERATIVE RECOVERY

FASTER POSTOPERATIVE RECOVERY[19]



IMPROVED QUALITY OF LIFE[20]



Reduction of up to 55% in postoperative pain compared to conventional surgery.[21]

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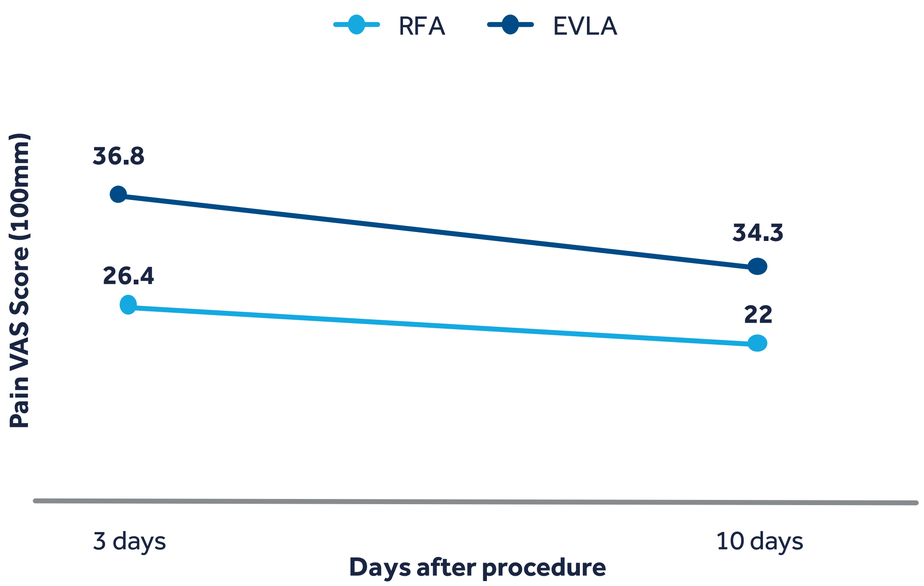
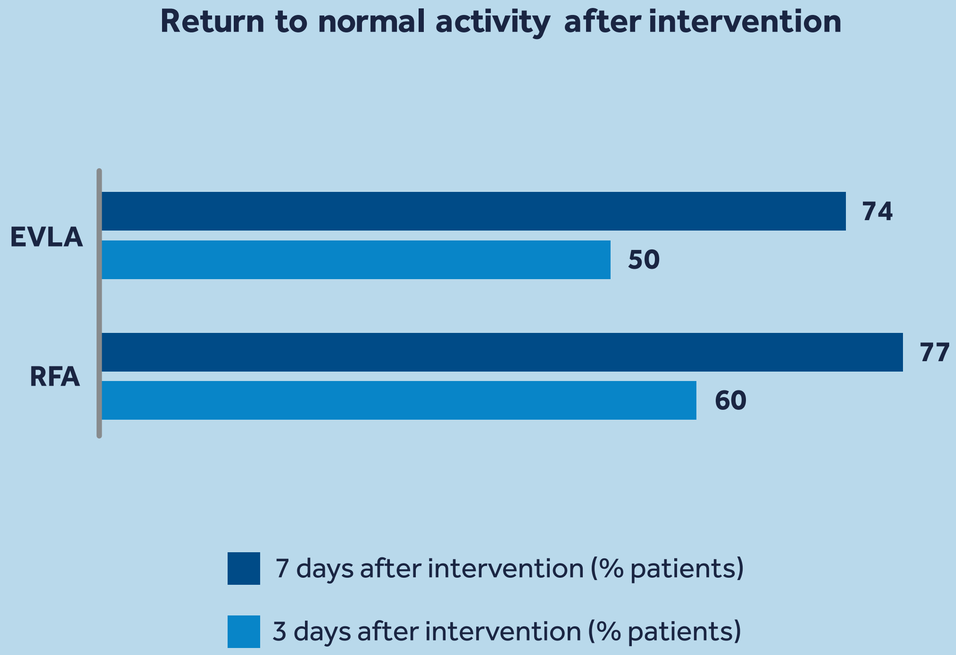
BENEFITS OF CLOSUREFAST™ HAVE BEEN SHOWN **COMPARED TO EVLA TOO**

LESS POSTOPERATIVE PAIN[22]



REDUCED ANALGESICS CONSUMPTION
UP TO 40%[22]

FASTER POSTOPERATIVE RECOVERY[22]



3 OF 5 PATIENTS
RETURN TO NORMAL ACTIVITY AFTER 3 DAYS[22]

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THE CLINICAL BENEFITS OF RADIOFREQUENCY ARE TRANSLATED INTO MONETARY SAVINGS FOR THE HEALTHCARE SYSTEM

BENEFICIAL FOR PATIENTS

- 40% analgesics use (vs. EVLA)[22]
- Return to normal activity after 3 days[19]

REDUCTION IN DIRECT HEALTHCARE COSTS

- 50% length of hospital stay (vs. stripping)[23]
- 50% total number of complications (vs. stripping)[19]
- Procedure time reduction (vs. stripping)[24]
- Freed-up space/ time in OR for other procedures[25,26]

REDUCTION IN INDIRECT COSTS

- 8.5 sick leave days (vs. stripping)[19]
- Improved management of waiting lists[24]
- Cost-saving from moving procedure out of the OR[25]

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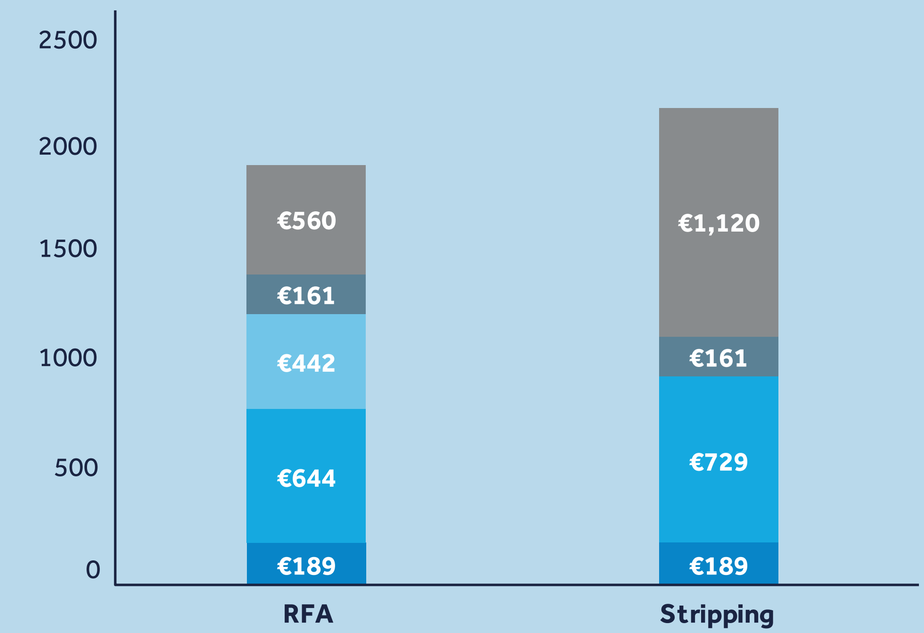
RADIOFREQUENCY ABLATION HAS DEMONSTRATED TO BE THE THERAPY OF CHOICE **IN THE TREATMENT OF CHRONIC VENOUS INSUFFICIENCY IN SEVERAL STUDIES**

ClosureFast™ **resulted in cost savings** compared to conventional surgery from a society perspective

Cost difference per patient[27]



Radiofrequency Ablation has shown to be an **efficient alternative** to **EVLA** in various studies

STUDY	ICER (RFA VS EVLA)
Epstein[28]	**RFA** dominant
Gohel[27]	17,350 £/**QALY**

The higher cost of **Radiofrequency Ablation** catheters is offset by **lower consumption of healthcare resources and lower loss of labour productivity.**

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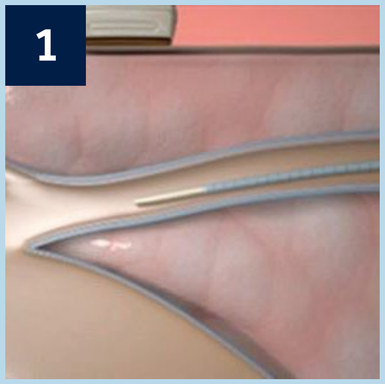
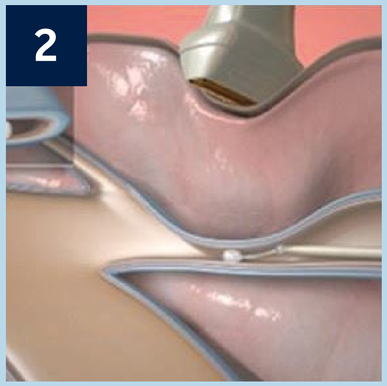
VENASEAL™ SHOULD BE THE NON-TUMESCENT TREATMENT OF CHOICE FOR CHRONIC VENOUS INSUFFICIENCY **DUE TO ITS EASE-OF-USE, RELIABILITY AND CONSISTENT OUTCOMES**

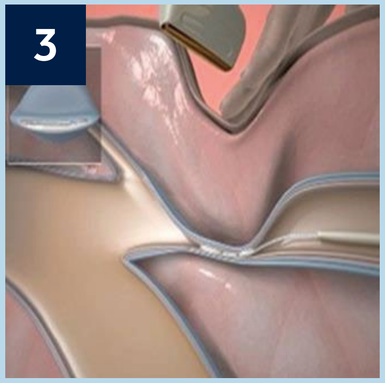
VENASEAL™ CLOSURE SYSTEM



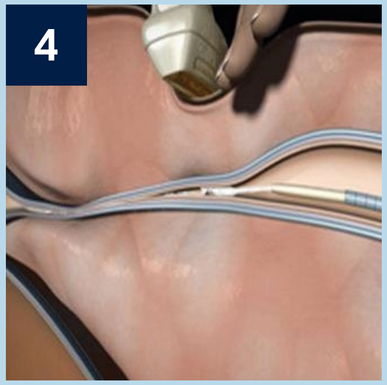
Catheter insertion
Under ultrasound guidance, the VenaSeal™ catheter is inserted into the vein through a small access site in the leg.



Adhesive Injection
Medical adhesive is carefully injected into the vein.



Compression
The catheter is withdrawn, leaving a bead of adhesive. Mild compression to the exterior leg during treatment allows the adhesive to seal the vein.



Occlusion
The adhesive closes the diseased vein, diverting blood flow to healthy veins. Over time, the occluded vein will be absorbed by the body.

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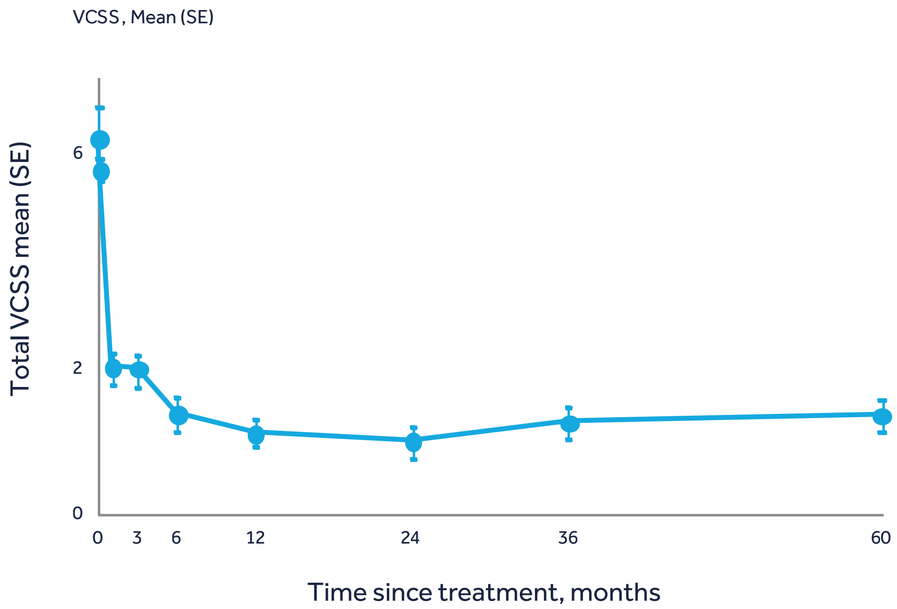
VENASEAL™ CLOSURE SYSTEM IS AN INNOVATIVE AND EFFECTIVE TREATMENT OPTION TO CONVENTIONAL TREATMENT AND PROVIDES **MINIMAL INCONVENIENCE TO PATIENTS**

VECLOSE EXTENSION STUDY 5-YEAR SNAPSHOT[29]

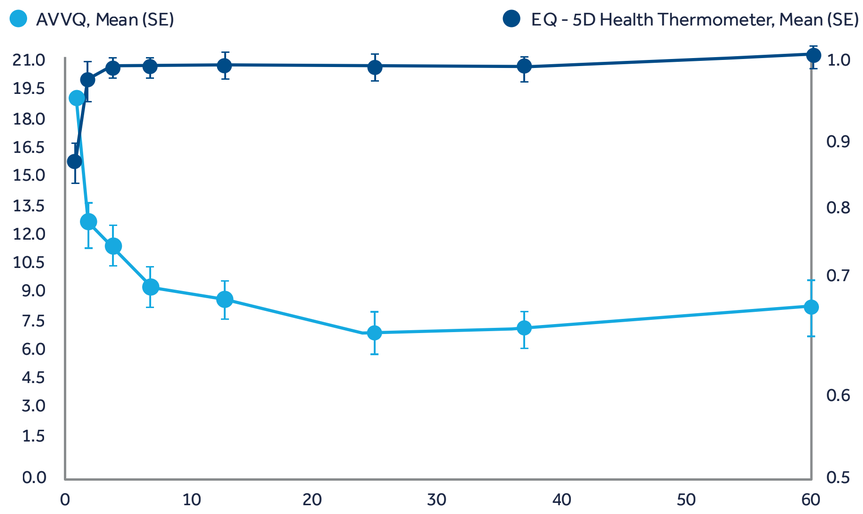
	VenaSeal™ closure system
5-year closure rates (> 5cm Segment)	94.6% (53/56)

When asked at 5 years,
9 out of 10
VenaSeal™ closure system treated patients would choose the VenaSeal™ procedure again.[29]

VENOUS CLINICAL SEVERITY SCORE (VCSS) AFTER VENASEAL™ CLOSURE SYSTEM[30]



QUALITY OF LIFE OF PATIENTS TREATED WITH VENASEAL™ CLOSURE SYSTEM[29]



VENASEAL™ CLOSURE SYSTEM PROVIDES
HIGH RATES OF VENOUS OCCLUSION,
AN IMPROVEMENT IN QUALITY OF LIFE
AND IN PATIENTS' SYMPTOMS

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THE CLINICAL EVIDENCE SUPPORTS THE SAFETY OF VENASEAL™ CLOSURE SYSTEM, PROVIDING A CLINICAL IMPROVEMENT COMPARED TO RADIOFREQUENCY ABLATION

KAPLAN-MEIER ESTIMATES FOR FREEDOM FROM RECANALIZATION†

Non-inferiority demonstrated.*

KAPLAN-MEIER ESTIMATES	VENASEAL™	RFA
Month 1	100%	94.6%
Month 3	99.0%	94.6%
Month 6	99.0%	91.7%
Month 12	97.0%	90.7%
Month 24	94.6%	89.5%
Month 36	91.4%	85.2%
Month 60	91.4%	85.2%

- Higher occlusion rates at 60 months[29]
- Improvement in Quality of Life, similar to that provided by ClosureFast™
- Relatively low rate of complications

FASTER POSTOPERATIVE RECOVERY††

VenaSeal™: **75%**
RFA: **72%**
Improvement from baseline

VenaSeal™: Signs/symptoms associated with venous reflux disease improved over time and was maintained through 60 months.

VenaSeal™: **55%**
RFA: **67%**
Improvement from baseline

AVVQ: Subjects experienced improvement decreasing total AVVQ score over time through 60 months.

VenaSeal™: **22%**
RFA: **15%**
Improvement from baseline

EQ-5D VAS: Subjects reported slight improvement in their current health state over time through 60 months.

† Projected rates over the life of follow-up, retaining the memory of subjects until they have reached failure or last point of follow-up.
* Non-inferiority based on one-sided 97.5% confidence interval with lower limit = -3.5%, and maring of -10%.
†† VenaSeal closure system randomized data only, roll-in data excluded.

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THE HIGHER INITIAL INVESTMENT IS OFFSET BY THE BENEFITS PROVIDED

BENEFICIAL FOR PATIENTS

- No bandages, no compression therapy[31]
- Return to normal activity after 2.4 days[32]

REDUCTION IN DIRECT HEALTHCARE COSTS

- No hospitalization or prolonged postoperative[31]
- Lower number of complementary procedures and medical visits[31]
- Procedure time reduction (vs. EVLA)[33]

REDUCTION IN INDIRECT COSTS

- 23.5 sick leave days (vs. stripping)[34]
- Improved management of waiting lists[33]

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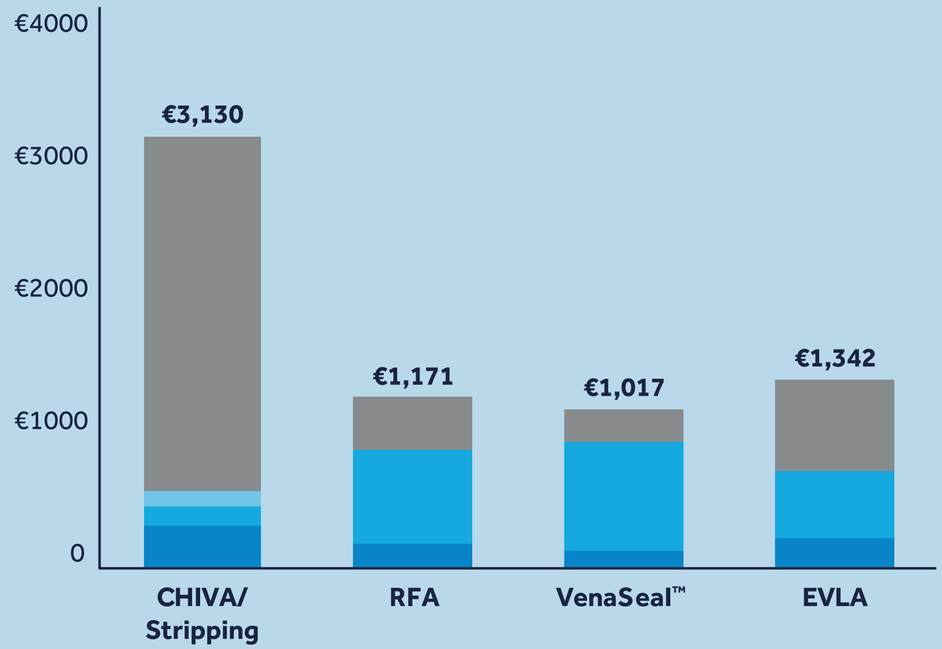
VENASEAL™ CLOSURE SYSTEM HAS SHOWN **TO BE AN EFFICIENT AND THE LEAST EXPENSIVE TREATMENT COMPARED TO OTHER MODALITIES**

VenaSeal™ Closure System provides **monetary savings** compared to other treatments

Cost difference per patient[34]



MEAN SICK LEAVE DAYS[32]	
Stripping	25.5
RFA	5
VenaSeal™	2
EVLA	6

The results of the cost analysis carried out in the **University Hospital San Cecilio of Granada** showed that **medical adhesive was the least expensive alternative** because of reduction in resource consumption and patients´ faster return to work.

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CONCLUSIONS

- It is estimated that **70% of the global population** has some stage of Chronic Venous Disease
- Due to the ageing of the population, it is estimated that **incidence of the disease will increase** dramatically in the coming decades
- This will lead to an **increase in the direct healthcare costs and loss of productivity** associated with Chronic Venous Insufficiency
- Therefore, **new therapies** meeting the necessary characteristics for the adequate treatment of Chronic Venous Insufficiency **are required**
- **ClosureFast™ and VenaSeal™ Closure System** are alternative therapies to conventional treatment, effective and provide minimal inconvenience to patients suffering from this disease
- ClosureFast™ has shown **less postoperative pain, higher Quality of Life, and faster patient's recovery** compared to conventional surgery
- VenaSeal™ Closure System represents a new generation of techniques for the management of Chronic Venous Insufficiency, which is performed **without tumescent anaesthesia, and does not require postoperative analgesia or compression therapy**

ClosureFast™
Endovenous Radiofrequency Ablation Catheter

VenaSeal™
Closure System

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ABBREVIATIONS

AVVQ	Aberdeen Varicose Vein Questionnaire
CEAP	Clinical Etiology Anatomy Pathophysiology
CIVIQ-14	Chronic Venous Insufficiency Questionnaire-14
CVD	Chronic Venous Disease
CVI	Chronic Venous Insufficiency
DVT	Deep Vein Thrombosis
EQ-5D	EuroQol-5D
EVLA	EndoVenous Laser Ablation
GIS	Global Index Score
ICER	Incremental Cost-Effectiveness Ratio
QALY	Quality-Adjusted Life Year
RFA	Radio Frequency Ablation
VAS	Visual Analogue Scale
VCSS	Venous Clinical Severity Score

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