VENOUS LEG ULCERS

Medtronic
Further, Together

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- VENOUS LEG ULCER OVERVIEW
- DIAGNOSTIC & TREATMENT PATHWAY
- SOCIETY GUIDELINES
- ENDOVENOUS INTERVENTION OPTIONS
- CASE STUDY-EARLY REFERRALS FOR VASCULAR ASSESSMENT

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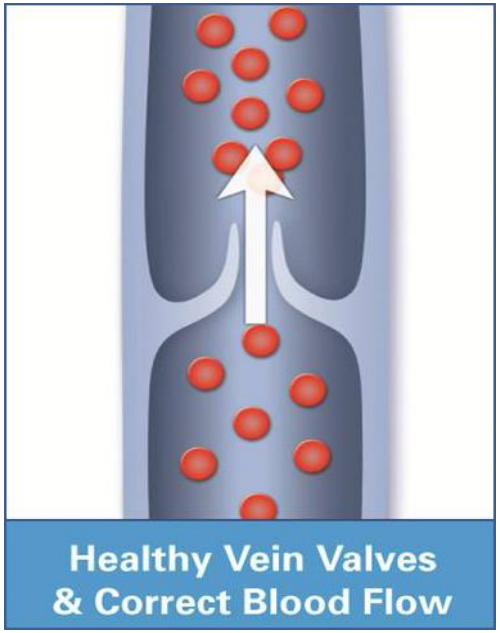
3

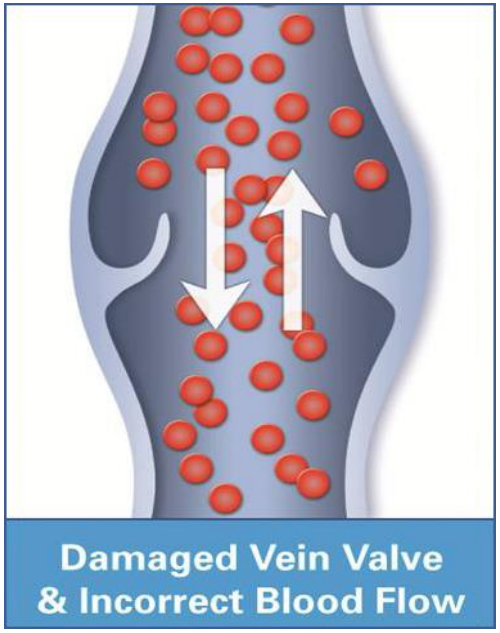
VENOUS ANATOMY

NORMAL VEIN



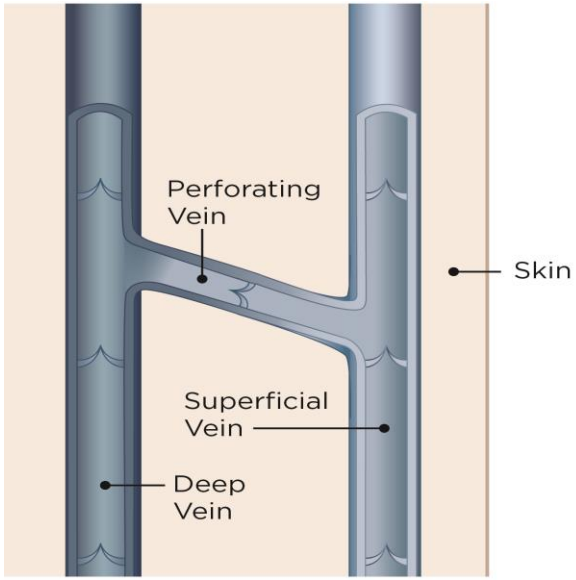
Valves ensure blood flows in one direction

DISEASED VEIN

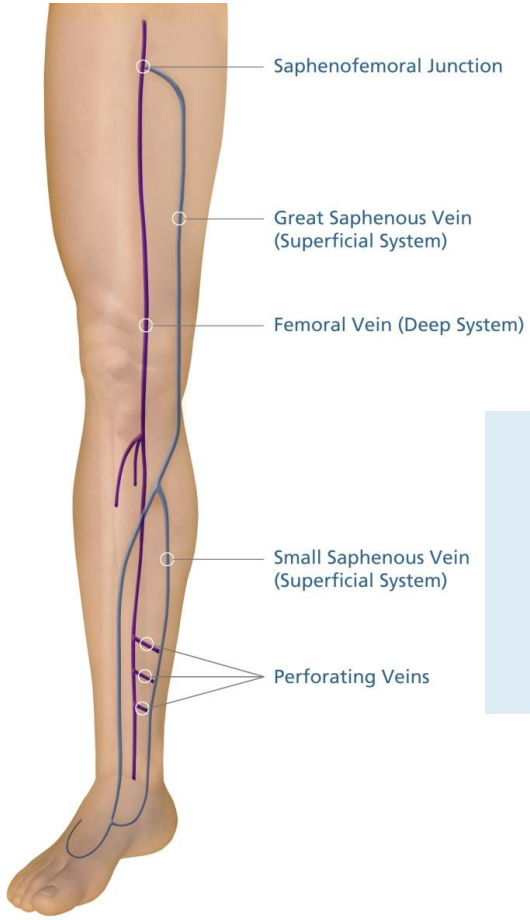


Valves that cannot close allow blood to drain and pool

VENOUS ANATOMY



Perforating veins connect the deep system with the superficial system



Superficial Venous System
- Great Saphenous Vein
- Small Saphenous Vein
- Perforating Veins

Venous leg ulcers can be caused by chronic venous insufficiency (CVI)[1].
This can be caused by reflux in any of the venous systems-whether superficial, perforator, or deep-when the valves of the veins have failed or the vein has become obstructed.[2]

[1]Kanth A, Khan S, Gasparis A, Labropoulos N, et al. The distribution and extent of reflux and ob-struction in patients with active venous ulceration. Phlebology 2015; 30(5): 350-6.
[2]Sufian S, Lakhanpal S, Marquez J, et al. Superficial vein ablation for the treatment of primary chronic venous ulcers. Phlebology 2011; 26: 301-6.

VENOUS DISEASE MAY PROGRESS TO CHRONIC WOUNDS:
VENOUS LEG ULCERS (VLU)

CEAP is a commonly used venous disease classification system
C – Clinical, E – Etiology, A – Anatomy, P - Pathophysiology

Approximately 50% of VLUs may recur within 10 years[1]

[1] Thomas F. O'Donnell Jr et al. Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2014;60:3S-59S.
Images courtesy of Jennifer Heller, M.D. Net Prevalence Patient Population-Internal Estimates

WHY SHOULD WE CARE ABOUT VENOUS LEG ULCER PATIENTS

1 million
people in the U.S. are affected by venous leg ulcers[1]

21% of all wounds seen in wound care clinics are characterized as venous ulcers[2]

70%-90%
of lower extremity ulcers are venous[3,4]

$14.9 billion
is spent annually to treat venous ulcers[3]

Due to pain, mobility limitations and other consequences, venous leg ulcers have been associated with increased rates of depression and substantial decreases in patient quality of life.[5,6,7]

[1]Internal Data,Dymedex Study
[2]The Outpatient Wound Clinic Market 2013 Report and Analytics, Net Health Analytics (2010-2012 claims data
[3]Rice J (2014). Burden of venous leg ulcers in the United States. Journal of Medical Economics. 17(5), 347-356
[4] O'Donnell TF, Passman MA, Marston WA, et al. Management of venous leg ulcers: Clinical Practice Guidelines of the Society for Vascular Surgery® and the American Venous Forum. J Vasc. Surg. 2014: 60; 35-595
5. Valencia IC, Falabella A, Kirsner RS, et al. Chronic venous insufficiency and venous leg ulceration. J Am Acad Dermatol 2001;44:401-21
6. Phillips T, Stanton B, Provan A, et al. A study of the impact of leg ulcers on quality of life: financial, social, and psychologic implications. J Am Acad Dermatol 1994;31:49-53
7. Green J, Jester R. Health-related quality of life and chronic venous leg ulceration: part 1. Wound Care 2009;December:S12-S17

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EVIDENCE BASED TREATMENT ALGORITHM[1]

An Evidence Based Algorithm for Treating Venous Leg Ulcers Utilizing the *Cochrane Database of Systematic Reviews*

Complete medical history and history of ulcer and previous history of ulcers need to be performed.

A detailed physical exam with patient supine and standing. Description of ulcer, venous dilation, edema, skin pigmentation, and venus refill time should be documented.

Test for venous disease
1. Venous duplex scan and ultrasound
2. Other test as needed: MRI/CT scan/venous angiogram

Test for arterial disease
1. Pulse exam
2. Ankle/Bracial Index (ABI)
3. Transcutaneous PO^2

Abnormal Arterial Exam
1. Refer for further evaluation and treatment of arterial disease
2. Rule out and/or treat associated etiologies
3. DO NOT USE MULTI-LAYER COMPRESSION/Possible ICP

Classify Venous Disease with CEAP

Ulcer Treatment
1. Debridement of ulcer
2. Exudate management and moisture balance
3. Infection control
4. Address and systemic condition

Assess for negative baseline factors[6]
1. Ulcer >10cm^2
2. Duration X>12
3. PAD
4. X>50% fibrous tissue

Compression *Gold Standard*
- Multi-layer elastic compression dressing should always be used unless there is a concurrent arterial disease
- Use intermittent compression pumps for patients that can not use multi-layer compression[8]

Consider systemic agents

Dressing of choice
- No evidence to show any dressing is more effective
  - Possible use of Cadoxemer Iodine

Failure to get closure of x>40% in 4 weeks

Continue Compression Wound Management

Bi-layered living skin equivalent
(up to 5 applications as required)

- Healed ulcers should be maintained with compressive stockings and appropriate skin care.
- Possible surgical intervention to prevent recurrence.

[1] Howard M. Kimmel et al. An Evidence-Based Algorithm for Treating Venous Leg Ulcers Utilizing the Cochrane Database of Systematic Reviews. WOUNDS 2013;25(9):242-250

BENEFITS OF EVIDENCE & GUIDELINES BASED CARE[1]

- Venous leg ulcer outcomes are optimized when patients receive multidisciplinary care and evidence-based wound management. Dermatology, geriatrics, podiatry, and surgery are just a few specialties that may be utilized to improve outcomes.[1]

- Significant decreases in healing time and costs are associated with guideline adherence. Among veterans with VLUs, those who receive guideline-concordant wound care are 2.5 times more likely to achieve wound healing than are those who receive non-concordant care.[1]

[1] Howard M. Kimmel et al. An Evidence-Based Algorithm for Treating Venous Leg Ulcers Utilizing the Cochrane Database of Systematic Reviews. WOUNDS 2013;25(9):242-250

DIFFERENTIATING VENOUS ULCERS FROM ARTERIAL ULCERS

Arterial Ulcer

Licensed from Custom Medical Stock Photo, 2010

Venous Ulcer

Photo courtesy of J. Zygmunt RVT.RPhs

70-90% of lower extremity ulcers are **venous**[1,2].

Characteristic	Arterial Ulcer[3,4]	Venous Ulcer[3,4]
Location	Toes or foot	Malleolus or metatarsal
Appearance	Irregular margin, cool cyanotic	Typically sloped edges; may have exudate, irregular shape
Foot temperature	Cold	Warm
Pain	Usually severe	Mild
Sensation	Veriable, often decreased	Present variable (pain, temperature)
Arterial Pulses	Absent	Present variable (pain, temperature)
Veins	Collapsed	Dilated, varicosities, edema

[1]O'Donnell TF, Passman MA, Marston WA, et al. Management of venous leg ulcers: Clinical Practice Guidelines of the Society for Vascular Surgery® and the
[2]American Venous Forum. *J Vasc. Surg.* 2014: 60; 35-595
[3]Rice JB, Desai U, Cummings AK, et al. Burden of venous leg ulcers in the United States. *J Med Econ*. 2014:17; 347-356.3Spentzouris, G. & Labropoulos, N. (2009). The evaluation of lower- extremity ulcers. Seminars in Interv Radiol, 26(4), 286-295.
[4]Grey, J.E., Enoch, S. & Harding, K.G. (2006). ABC of wound healing: Wound assessment. BMJ (332), 285-288.

VENOUS ULCER HEALING PREDICTOR-THE "4-WEEK" MODEL[1]

Change in wound area at 4 weeks is a strong indicator of healing at 12 weeks or 24 weeks.

The VLU treatment algorithm recommends > **40% wound closure after 4 weeks of conventional therapy** as a surrogate marker for the identification of patients who are likely to achieve complete wound closure with continued conservative treatment.

Week 1 | Week 2 | Week 3 | **Week 4**

A study has shown that patients with **< 40% closure at 4 weeks** are unlikely to achieve complete wound healing and **may benefit from alternative or advanced interventions.**

[1] Howard M. Kimmel et al. An Evidence-Based Algorithm for Treating Venous Leg Ulcers Utilizing the Cochrane Database of Systematic Reviews. WOUNDS 2013;25(9):242-250

ADDITIONAL VENOUS ULCER HEALING PREDICTORS[1]

Ulcer Depth

When comparing partial thickness venous ulcerations and full thickness ulcerations, **full thickness wounds take approximately twice as long to heal.**[1]

Ulcer Duration

According to a study, wounds that were **< 5cm²** and those **ulcerations present for < 6 months** were more **likely to heal by week 24.** The multilayered compressive dressings healed 85% and 88% of these wounds, respectively.[1]

[1] Howard M. Kimmel et al. An Evidence-Based Algorithm for Treating Venous Leg Ulcers Utilizing the Cochrane Database of Systematic Reviews. WOUNDS 2013;25(9):242-250

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AVF/SVS 2014 GUIDELINES FOR VENOUS ULCERS

	Guideline[1]	Grade[1]
Venous Duplex Ultrasound	Guideline 3.9: We recommend comprehensive venous duplex ultrasound examination of the lower extremity in all patients with suspected venous leg ulcer.	1B
Ablation-Prevent Recurrence	Guideline 6.2: In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation* of the incompetent veins in addition to standard compressive therapy to prevent recurrence.	1B
Ablation-Ulcer Healing	Guideline 6.1: In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we suggest ablation* of the incompetent veins in addition to standard compressive therapy to improve ulcer healing.	2C
Ablation-Prevent Ulceration	Guideline 6.4: In a patient with skin changes at risk for venous leg ulcer (C4b) and incompetent superficial veins that have axial reflux directed to the bed of the affected skin, we suggest ablation* of the incompetent superficial veins in addition to standard compressive therapy to prevent ulceration.	2C
Venous angioplasty & Stent recanalization-Prevent Recurrence & Ulcer Healing	Guideline 6.14: In a patient with inferior vena cava or iliac vein chronic total occlusion or severe stenosis, with or without lower extremity deep venous reflux disease, that is associated with skin changes at risk for venous leg ulcer (C4b), healed venous leg ulcer (C5), or active venous leg ulcer (C6), we recommend venous angioplasty and stent recanalization in addition to standard compression therapy to aid in venous ulcer healing and to prevent recurrence.	1C

AVF – American Venous Forum, SVS – Society of Vascular Surgery

*Multiple RCTs show strong and consistent evidence that modern open surgery, radiofrequency, and laser ablation are equivalent in effect and safety

[1] Thomas F. O'Donnell Jr et al. Management of venous leg ulcers: Clinical practical guidelines of the Society for Vascular Surgery and the American Venous Forum. J VascSurg 2014;60:3S-59S.

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THERMAL ABLATION ACCOUNTS FOR 97% OF ALL CVI PROCEDURES IN US*

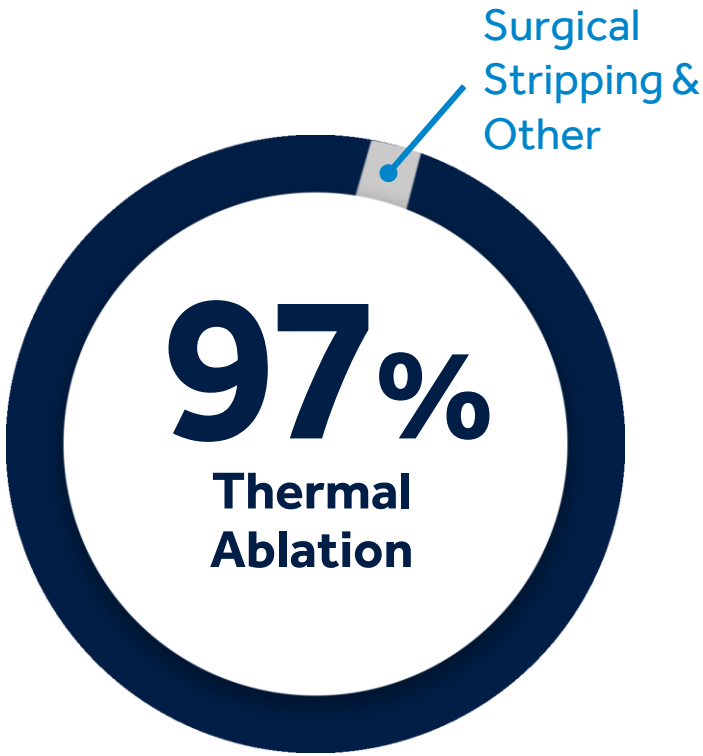
Thermal Ablation
- Radiofrequency ablation (RFA)
- Laser ablation

Surgical Stripping

Other

Non-thermal, Non-tumescent
- Mechanochemical
- Sclerotherapy

Non-thermal, Non-tumescent, Non-sclerosant
- Medical adhesive



*Internal Data on File,

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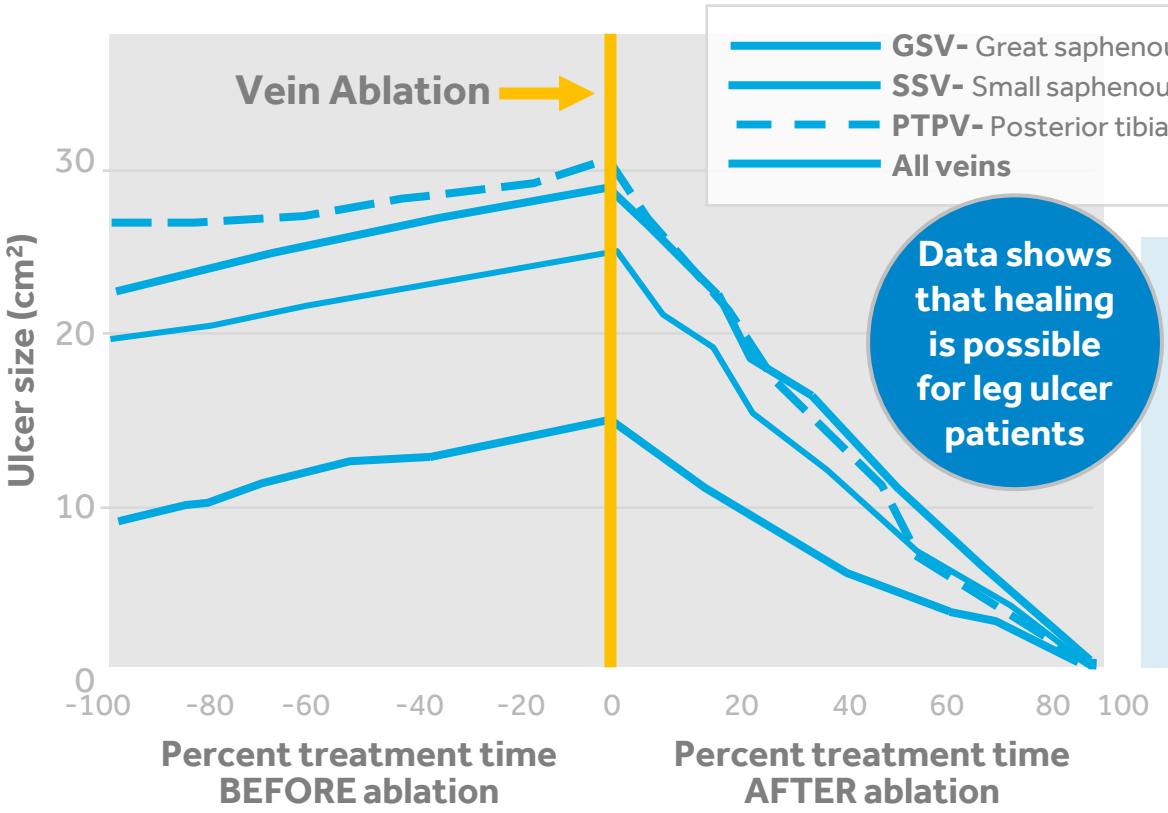
ABLATION: A PROVEN SOLUTION FOR PATIENTS WITH LOWER EXTREMITY ULCERS[1]



Data shows that healing is possible for leg ulcer patients

Six-month patient follow-up demonstrates a significant change in ulcer size and healing rate from pre-to post-ablation. Early intervention and treatment with compression and ablation can significantly improve quality of life for patients with this condition.

Ablation method used was radiofrequency ablation (Medtronic ClosureFast™ procedure).

In addition to standard compression therapy, 2014 SVS/AVF venous leg ulcer guidelines detail ablation of the incompetent veins to prevent recurrence and improve ulcer healing.

[1] Howard M. Kimmel et al. An Evidence-Based Algorithm for Treating Venous Leg Ulcers Utilizing the Cochrane Database of Systematic Reviews. WOUNDS 2013;25(9):242-250

MEDTRONIC TECHNOLOGY OFFERINGS

RFA Technology- ClosureFast™ System

- >15 years of market experience
- 3 components:
  - Closure RFG™ Generator
  - ClosureFast™ Catheter
  - ClosureRFS™ Stylet

**ClosureFast™ Catheter & ClosureRFS™ Stylet are sterile, single use only*

Adhesive Technology- VenaSeal™ Closure System

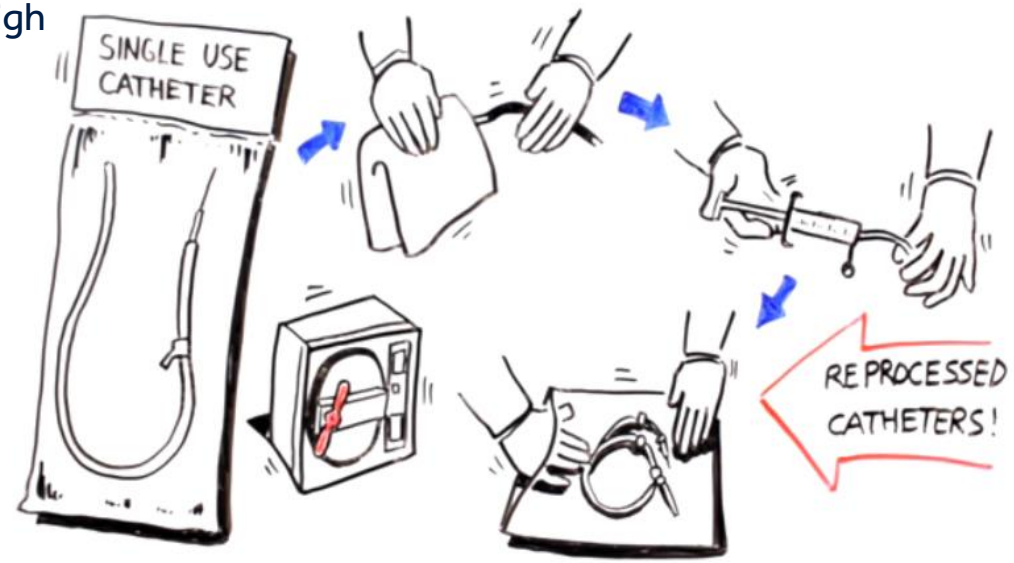
- Eliminates need for tumescent anesthesia.
- No risk of thermal injury.
- No post treatment compression stockings needed.[1,2*]
- Rapid return to normal activities.[2]
- Indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV)

1 Almeida, J 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.
2 Morrison, N. Use of Cyanoacrylate adhesive for Treatment of Incompetent Great Saphenous Veins: 12-month Results of the VeClose Trial, European Venous Forum, 2015.
*Some patients may benefit from compression stockings post procedure.

REPROCESSING – WHAT YOU & YOUR PATIENTS NEED TO KNOW

What is reprocessing in the medical device space?

"Resterilized" or "reprocessed" medical devices are used in the medical field with surgical tools and instruments that are autoclaved/sterilized at high heat and pressure after each patient use.



What does it mean when catheters are reprocessed?

Companies such as Vascular Solutions are collecting used ClosureFast catheters, re-sterilizing them, and then selling them back to doctors to be used in other patients.[1]

To learn more, view the video: *http://medtronicendovenous.com/patients/6-0-find-a-doctor/*

REFERENCES
[1] Northeast Scientific, INC Reprocessed Varicose Vein RF Catheter Aug 2009. K090661.
https://www.accessdata.fda.gov/cdrh_docs/pdf9/K090661.pdf

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THE COMPARISON: SINGLE USE VS. REPROCESSED

What should you consider when referring patients?

- ClosureFast™ Catheters are backed by 5 years of clinical data and are sold as a single-use device designed to be used only one time, on one patient.
- In fact, one research study[2] found that reprocessed ClosureFast™ catheters performed equivalent to new ClosureFast™ catheters.
- However, a different research study[3] tested reprocessed catheters and found that even after resterilization, reprocessed catheters were not 100% clean – some tested positive for particulates, while others tested positive for unidentified liquids.

[2] J.H. Isobe, K.C. Sentell, L.A. Nichols, C.S. Simms. Twelve-Month Experience Using Reprocessed ClosureFast Radiofrequency Catheters. J Vasc Surg. Venous and Lymphatic Disorders. Jan 2014; 2: 115–116
[3] Ximedica. Covidien Reprocessed CLF Catheter Evaluation Report. REP-2003. funded by Covidien, an affiliated of Medtronic

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LEVERAGING GUIDELINES FOR EARLIER PATIENT REFERRALS[1]

Background

UK NICE Clinical Guidelines CG 168 published in July 2013 recommended that venous leg ulcers be referred for specialist vascular assessment. The aim was to determine the impact of NICE CG 168 on referrals to leg ulcer clinic.

NICE National Institute for Health and Care Excellence

Method

A comparison of prospectively gathered data on patients referred to clinic before (January 2011 to June 2012) and after (January 2014 to June 2015) NICE guidelines

Results

- There was a twofold increase in referrals (181 patients, 220 legs vs. 385 patients, 453 legs)
- Significant increase in endothermal ablation (2 vs. 32 legs)
- No change in patients undergoing compression (62.8% vs. 63% legs)

[1] A. H. Davies et al. Impact of National Institute of Health and Care Excellent (NICE) Clinical Guidelines (CG 168) on the Referral and Management of Leg Ulcers. J Vasc Surg 2016; 4(1):144

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 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, this labeling can be found at http://useifu.venaseal.com.

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

THANK YOU