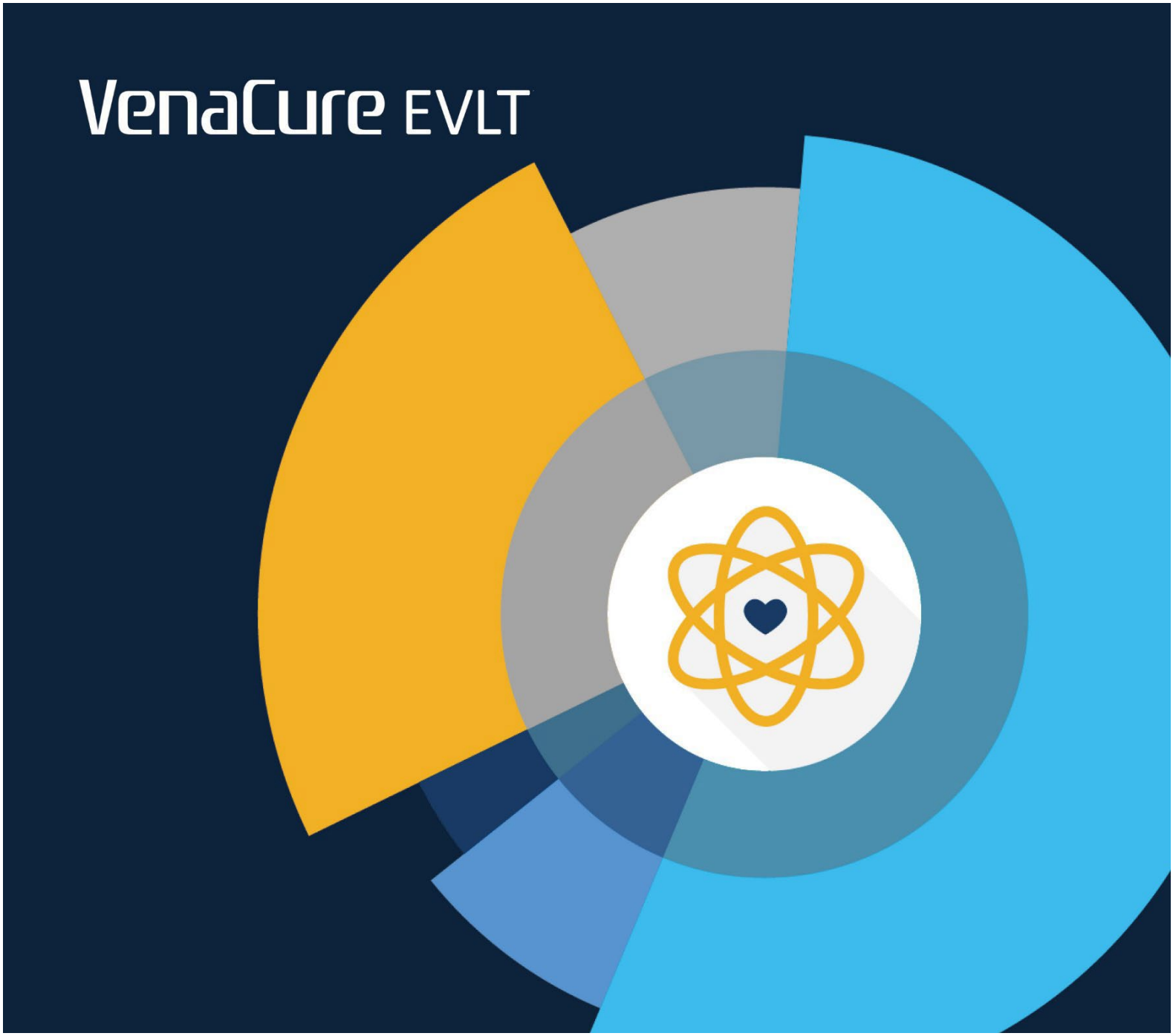


VenaCure EVLT REIMBURSEMENT GUIDE 2024

angiodynamics

VenaCure EVLT Indications for Use

The VenaCure EVLT 1470 Laser and the VenaCure 1470 Pro Laser:

- Are intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb.
- Contraindications for the VenaCure 1470 Pro Laser and the VenaCure EVLT 1470 Laser include but are not limited to the following: Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral arterial disease as determined by an Ankle-Brachial Index < 0.9.

The VenaCure EVLT NeverTouch Procedure Kits, VenaCure EVLT NeverTouch Direct Procedure Kits and the VenaCure EVLT Tre-Sheath:

- Are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremities.
- This product should be used only with lasers cleared for use in the treatment of varicose veins, varicosities with superficial reflux of the GSV, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limbs.
- Contraindications for the VenaCure EVLT NeverTouch Procedure Kits, VenaCure EVLT NeverTouch Direct Procedure Kits and the VenaCure EVLT Tre-Sheath include but are not limited to the following: Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral artery disease as determined by an Ankle-Brachial Index <0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment.

The VenaCure EVLT 400 µm Perforator and Accessory Vein Ablation Kit:

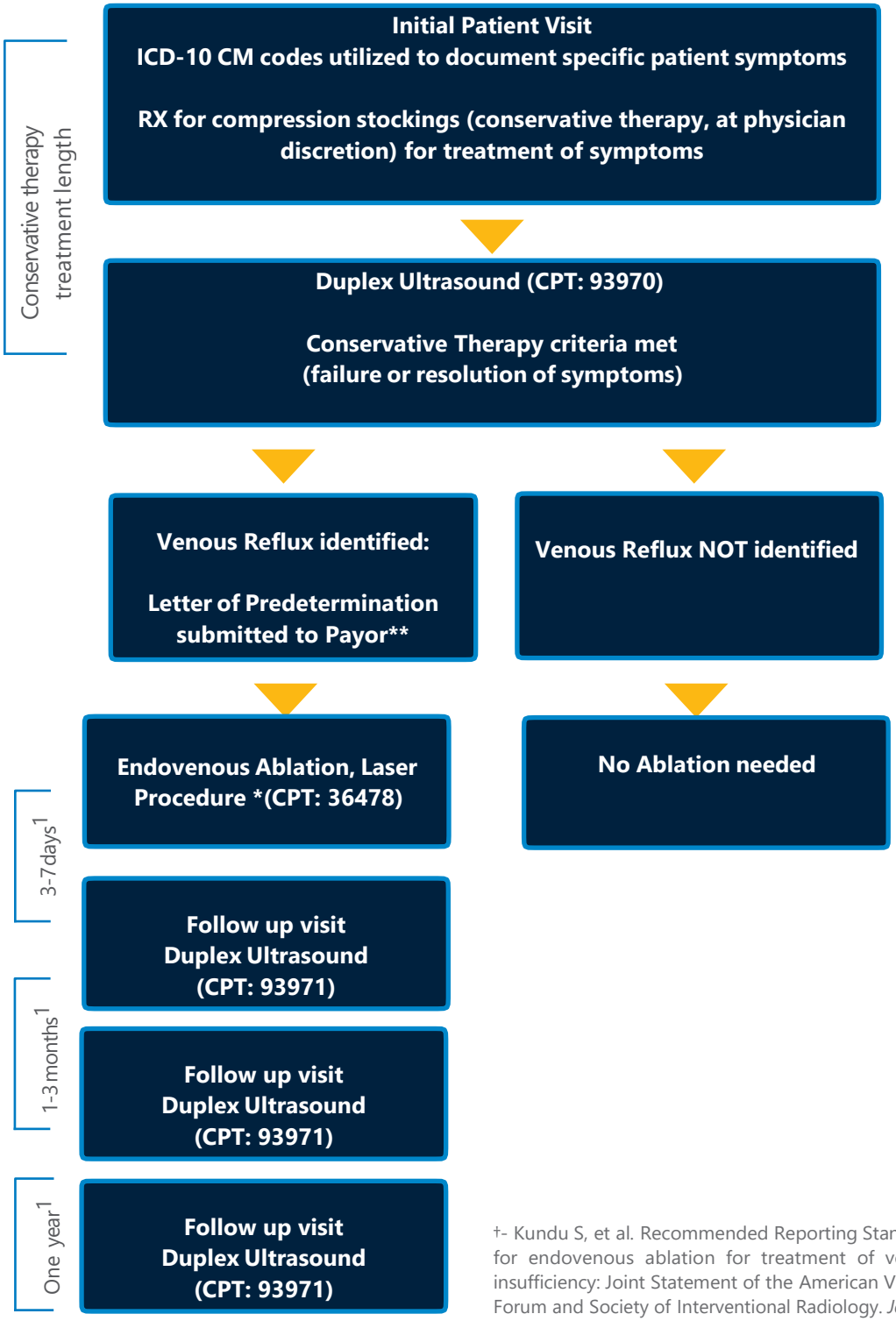
- Is indicated for treatment of incompetence and reflux of superficial veins in the lower extremity. and for treatment of incompetent (i.e., refluxing) perforator veins (IPVs).
- Contraindications for the VenaCure EVLT 400 µm Perforator and Accessory Vein Ablation Kit include but are not limited to the following: Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral arterial disease as determined by an Ankle-Brachial Index < 0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment. Extremely tortuous vein segments may require treatment by alternative techniques (phlebectomy, sclerotherapy).

The VenaCure EVLT OPS Procedure Kits:

- Are intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The EVLT Kits are indicated for treatment of incompetence and reflux of superficial veins in the lower extremity.
- Contraindications: Contraindications include but are not limited to the following, Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral arterial disease as determined by an Ankle-Brachial Index < 0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment.

CAUTION: Federal Law (U.S.) restricts the sale of these devices by or on the order of a physician.

Treatment Map



†- Kundu S, et al. Recommended Reporting Standards for endovenous ablation for treatment of venous insufficiency: Joint Statement of the American Venous Forum and Society of Interventional Radiology. *Journal of Vascular Surgery*. 46(3):582-589

* Please see next page for complete description of CPT 36478.
** Excludes Medicare Plans

Codes for Physician and Outpatient Procedures (JAN 1, 2024 – DEC 31, 2024)

Current Procedural Terminology (CPT®) Codes are used to document the procedures or medical services healthcare professionals provide[1]. Physicians report services using CPT® codes regardless of site of service. Below is a list of commonly reported CPT® codes for endovenous ablation procedures, and Medicare national average payment rates.

To obtain the most accurate reimbursement for a particular procedure, AngioDynamics recommends verifying payor site-of-service requirements and reimbursement specifics prior to scheduling the procedure.

Medicare 2024 National Average Payment (Not Geographically Adjusted)								
Service Provided		Physician Payment[2]				Hospital Outpatient Payment[3]		ASC Payment[4] (Status Indicator)
CPT Code[1]	Description[1]	Non-Facility		Facility		APC Code (Status Indicator)	Payment	
		RVUs	Payment	RVUs	Payment			
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated	28.96	$964.01	8.15	$271.29	5183 (J1)	$3,037.01	$1,548.00 (A2)
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)	8.98	$298.92	3.98	$132.48	Not applicable – No separate payment. Payment is packaged into payment for other services.		
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study (includes technical component and interpretation)	5.61	$186.74	0.97	$32.29	5523 (S)	$233.47	N/A
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study (includes technical component and interpretation)	3.57	$118.84	0.62	$20.64	5522 (S)	$104.75	N/A

HCPCS Codes for Outpatient Procedures

Healthcare Common Procedure Coding System (HCPCS) Level II codes were developed to help categorize, document, and track the use of products, supplies, and services. HCPCS codes should be reported for all device-dependent Ambulatory Payment Classifications (APCs) for procedures conducted in the hospital outpatient setting. While HCPCS codes do not generally result in additional payment, it is important for hospitals to use HCPCS codes as a means of cost reporting which CMS uses to help determine future payment rates. The HCPCS codes listed below may be used for endovenous ablation procedures.

HCPCS Code[5]	HCPCS Description[5]	VenaCure EVLT System Product
C1888	Catheter, ablation, non-cardiac, endovascular (implantable)	VenaCure EVLT NeverTouch Kits
C2629	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser	
C1769	Guide wire	

ICD-10-CM Diagnosis Codes (October 2023 to September 2024)

Diagnosis codes are used by healthcare providers to document all patient conditions associated with the procedures performed. Secondary diagnosis codes corresponding to additional conditions at the time of admission, or developed subsequently, and which had an effect on the treatment received or the length of stay, should be reported. The ICD-10-CM codes below are examples of diagnosis codes that may apply for endovenous ablation procedures. Coding of additional diagnoses codes, just as for principal diagnosis coding, is dependent on the documentation in the patient's medical records. Final coding decisions are at the discretion of the provider.

ICD-10-CM Code	Code Description
I83.001	Varicose veins of unspecified lower extremity w/ ulcer of thigh
I83.002	Varicose veins of unspecified lower extremity w/ ulcer of calf
I83.003	Varicose veins of unspecified lower extremity w/ ulcer of ankle
I83.004	Varicose veins of unspecified lower extremity w/ ulcer of heel and midfoot
I83.005	Varicose veins of unspecified lower extremity w/ ulcer other part of foot
I83.008	Varicose veins of unspecified lower extremity w/ ulcer other part of lower leg
I83.009	Varicose veins of unspecified lower extremity w/ ulcer of unspecified site
I83.011	Varicose veins of right lower extremity w/ ulcer of thigh
I83.012	Varicose veins of right lower extremity w/ ulcer of calf
I83.013	Varicose veins of right lower extremity w/ ulcer of ankle
I83.014	Varicose veins of right lower extremity w/ ulcer of heel and midfoot
I83.015	Varicose veins of right lower extremity w/ ulcer other part of foot
I83.018	Varicose veins of right lower extremity w/ ulcer other part of lower leg
I83.019	Varicose veins of right lower extremity w/ ulcer of unspecified site
I83.021	Varicose veins of left lower extremity w/ ulcer of thigh
I83.022	Varicose veins of left lower extremity w/ ulcer of calf
I83.023	Varicose veins of left lower extremity w/ ulcer of ankle
I83.024	Varicose veins of left lower extremity w/ ulcer of heel and midfoot

ICD-10-CM Code	Code Description
I83.025	Varicose veins of left lower extremity w/ ulcer other part of foot
I83.028	Varicose veins of left lower extremity w/ ulcer other part of lower leg
I83.029	Varicose veins of left lower extremity w/ ulcer of unspecified site
I83.10	Varicose veins of unspecified lower extremity w/ inflammation
I83.11	Varicose veins of right lower extremity w/ inflammation
I83.12	Varicose veins of left lower extremity w/ inflammation
I83.201	Varicose veins of unspecified lower extremity w/ both ulcer of thigh & inflammation
I83.202	Varicose veins of unspecified lower extremity w/ both ulcer of calf & inflammation
I83.203	Varicose veins of unspecified lower extremity w/ both ulcer of ankle & inflammation
I83.204	Varicose veins of unspecified lower extremity w/ both ulcer of heel & midfoot & inflammation
I83.205	Varicose veins of unspecified lower extremity w/ both ulcer other part of foot & inflammation
I83.208	Varicose veins of unspecified lower extremity w/ both ulcer of other part of lower extremity & inflammation
I83.209	Varicose veins of unspecified lower extremity w/ both ulcer of unspecified site & inflammation
I83.211	Varicose veins of right lower extremity w/ both ulcer of thigh & inflammation
I83.212	Varicose veins of right lower extremity w/ both ulcer of calf & inflammation
I83.213	Varicose veins of right lower extremity w/ both ulcer of ankle & inflammation
I83.214	Varicose veins of right lower extremity w/ both ulcer of heel & midfoot & inflammation
I83.215	Varicose veins of right lower extremity w/ both ulcer other part of foot & inflammation
I83.218	Varicose veins of right lower extremity w/ both ulcer of other part of lower extremity & inflammation
I83.219	Varicose veins of right lower extremity w/ both ulcer of unspecified site & inflammation
I83.221	Varicose veins of left lower extremity w/ both ulcer of thigh & inflammation
I83.222	Varicose veins of left lower extremity w/ both ulcer of calf & inflammation
I83.223	Varicose veins of left lower extremity w/ both ulcer of ankle & inflammation
I83.224	Varicose veins of left lower extremity w/ both ulcer of heel & midfoot and inflammation
I83.225	Varicose veins of left lower extremity w/ both ulcer other part of foot & inflammation
I83.228	Varicose veins of left lower extremity w/ both ulcer of other part of lower extremity & inflammation
I83.229	Varicose veins of left lower extremity w/ both ulcer of unspecified site & inflammation

References

1. CPT© 2023 Professional. American Medical Association (AMA). All rights reserved. CPT® is a registered trademark of the AMA. No fee schedules, basic units, relative values, or related listings are included in CPT® including for Category 3 codes. Inclusion of a CPT® code does not represent AMA endorsement or imply any coverage or reimbursement policy. Reimbursement information here is from the Centers for Medicare and Medicaid Services (CMS), see sources below. Applicable FARS/DFARS restrictions apply to Government Use.
2. CMS, CMS 1784-F: Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2024. Conversion factor $32.7375. https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f. Published November 16, 2023. Effective January 1, 2024. Accessed November 27, 2023.
3. CMS, CMS-1786-FC: Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment Period (NFRM). https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc Published November 16, 2023. Effective January 1, 2024. Accessed November 27, 2023.
4. CMS, CMS-1786-FC: Ambulatory Surgical Center Payment- Notice of Final Rulemaking with Comment Period (NFRM) https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1786-fc. Published November 16, 2023. Effective January 1, 2024. Accessed November 27, 2023.
5. AAPC. 2022 HCPCS Level II Expert: Service Supply Codes for Caregivers and Suppliers. American Academy of Professional Coders; 2022.

Important Risk Information

Indications for Use: The VenaCure EVLT 400µm Perforator and Accessory Vein Ablation Kit is intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The VenaCure EVLT 400µm Perforator and Accessory Vein Ablation Kit is indicated for treatment of incompetence and reflux of superficial veins in the lower extremity, and for treatment of incompetent (i.e. refluxing) perforator veins (IPVs) Contraindications: Contraindications include but are not limited to the following, Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral arterial disease as determined by an Ankle- Brachial Index < 0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment. Extremely tortuous vein segments may require treatment by alternative techniques (phlebectomy, sclerotherapy). Warnings: Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Treatment of a vein located close to the skin surface may result in a skin burn. Paresthesia may occur from thermal damage to adjacent sensory nerves. Tissue not targeted for treatment must be protected from injury by direct and reflected laser energy with appropriate eye and protective wear for any person present in the operating room. Prior to and during use, avoid damaging the fiber by striking, stressing or excessive bending. Do not coil the fiber tighter than a radius of 60 mm. The positions of the Site Marks on the EVLT fiber have been matched to the introducer sheath provided in the VenaCure EVLT 400µm Perforator and Accessory Vein Ablation Kit. Alternative sheaths must not be substituted. Do not tighten the compression clamp on sheath until fiber is in position. Laser protective eye wear must be worn by everyone in the treatment room including the patient. Adverse Events: Potential complications include, but are not limited to the following: DEHP Exposure, Deep Venous Thrombus, Hematoma, Hemorrhage, Infection, Necrosis, Neovascularization,
Non-Target Irradiation, Paresthesia, Phlebitis, Pulmonary Embolism, Skin Burns and Pain, Infection, Skin Pigmentation Alteration, Thrombophlebitis, Thrombosis, and Vessel Perforation. Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use: The VenaCure EVLT NeverTouch Procedure Kits, VenaCure EVLT NeverTouch Direct Procedure Kits and the VenaCure EVLT Tre' Sheath are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremities. This product should be used only with lasers cleared for use in the treatment of varicose veins, varicosities with superficial reflux of the GSV, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limbs. Contraindications: Contraindications include but are not limited to the following, Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral artery disease as determined by an Ankle-Brachial Index <0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment. Warnings: Treatment of a vein located close to the skin surface may result in skin burn. Paresthesia may occur from thermal damage to adjacent sensory nerves. Tissue not targeted for treatment must be protected from injury by direct and reflected laser energy. Use appropriate eye and protective wear for both patient and operating personnel. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping. Storage instructions: Keep away from sunlight; Keep dry; Upper limit of temperature: 27 degrees Celsius. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness, or death of the patient. Reprocessing may compromise the integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness or death. VenaCure EVLT NeverTouch Procedure Kit is to be treated as contaminated biomedical waste subsequent to use. Additionally, the needle provided within the kit is a sharp device. The used or unused devices, as well as the sharps, should be disposed of in accordance with hospital, administrative and/or local government policy for such items. Uncontaminated device packaging should be recycled if applicable or disposed of as common waste in accordance with hospital, administrative and/or local government policy for such items. The fiber, guidewire and needle contain cobalt. Cobalt is classified as CMR 1B and is present in a concentration above 0.1% weight by weight. Potential Complications: The potential complications include but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, skin pigmentation alteration, neovascularization, paresthesia due to thermal damage of adjacent sensory nerves, anesthetic tumescence, non-target irradiation, hemorrhage, necrosis, air embolism, scarring, skin burns and pain. Refer to Instructions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Potential Complications and Contraindications prior to use of the product. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use: The VenaCure EVLT OPS Procedure Kits are intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The EVLT Kits are indicated for treatment of incompetence and reflux of superficial veins in the lower extremity. Contraindications: Contraindications include but are not limited to the following, Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral arterial disease as determined by an Ankle-Brachial Index
< 0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment. Warnings: Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Treatment of a vein located close to the skin surface may result in a skin burn. Paresthesia may occur from thermal damage to adjacent sensory nerves. Tissue not targeted for treatment must be protected from injury by direct and reflected laser energy with appropriate eye and protective wear for any person present in the operating room. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the device and / or lead to device failure. Laser protective eyewear must be worn by everyone in the treatment room.

Instruct the patient to avoid hot baths and vigorous activity for 7 days following VenaCure EVLT. Adverse Events: Potential complications include, but are not limited to the following: Hematoma, Infection, Paresthesia, Phlebitis, Pulmonary Embolism, Skin Burns, Thrombophlebitis, Thrombosis, and Vessel Perforation. Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use: The VenaCure 1470 Pro laser is intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb. Contraindications: Contraindications include but are not limited to the following, Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral arterial disease as determined by an Ankle-Brachial Index < 0.9. Warnings: This device is not intended to be used in MR environment. Restrict Access to the working area. All the personnel present in the laser working area must wear all the protective devices. Openings inside installation area that are transparent to laser radiation must be properly darkened. All operators should become familiar with all the requirements for safe use of the medical laser systems as described in CAN/CSA- Z386-14 (Safe use of lasers in health care). Mobile phones and similar electrical devices must be switched off when the laser device is working. To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth. The Device shall be installed and used in compliance with the national or local requirements in place in your country. Do not wrap the footswitch with any plastic (or other material) film or cover bag, unless authorized by the manufacturer. The unauthorized use of wrapping bags/films may block the pedal in pressed position and cause unwanted laser emission. If optical fiber is hardly bent or improperly secured, it can lead to damage the fiber and/or harm to the patient or user! For proper use, refer to the Instruction for Use for VenaCure EVLT procedure kits. When selecting a pre-set program, it is a Physician responsibility to check and verify the eligibility of the laser output parameters to the treatment of interest and, in case, to adjust them before proceeding. As with any conventional surgical operations, adverse reactions may occur following treatment. Use cautiously with patients who have had difficulty with previous laser procedures. This operation shall be performed with the device switched off and disconnected from the mains. Use of controls, adjustments, or demonstration of procedures other than those specified herein may result in hazardous radiation exposure. Adverse Events: Potential complications include but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, skin pigmentation alteration, neovascularization, paresthesia due to thermal damage of adjacent sensory nerves, anesthetic tumescence, non-target irradiation, hemorrhage, necrosis, DEHP exposure, skin burns and pain. Refer to Instructions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Potential Adverse Effects and Contraindications prior to use of the product. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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