

400 MICRON PERFORATOR & ACCESSORY VEIN ABLATION KIT

Treat perforator veins with the precision of VenaCure.



400 MICRON PERFORATOR & ACCESSORY VEIN ABLATION KIT (PVAK)

Incompetent Perforator Veins (IPV) associated with Chronic Venous Insufficiency (CVI) are linked to venous hypertension, severe sequelae of CVI, and the development of leg ulcers. Treatment of IPV and CVI can lead to reduced rates of recurrences for venous ulcers.¹

With 20% of limbs with CVI also displaying IPV (a full 66% when skin changes are also present)¹, this represents a significant opportunity to expand the range of venous disease treatment for your patients and practice.

The 400 micron low-profile fiber allows for simple access and accurate positioning. Additionally, the office-based procedure uses only local anesthesia, so patients can easily resume most normal activities following the procedure.

PROCEDURE KIT FEATURES AND BENEFITS

- **400 micron Optical Fiber**
Smaller sized fiber aids in SV access and positioning
- **21G Venous Access Needle**
Ensures easy, atraumatic access
- **.018" Guidewire**
Navigates small, tortuous veins with a floppy tip; hub has firm anchor to guide sheath and hold fiber in place



The fiber's small profile fits through 21G needle

CEAP CLASSIFICATION CHART



C1-Telangiectasia or reticular veins (i.e., spider veins)



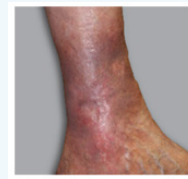
C2-Varicose veins, larger than 3 mm



C3-Edema (fluid in the skin)



C4-Skin changes (i.e., pigmentation, eczema, lipodermatosclerosis)



C5-Healed venous ulcer



C6-Active venous ulcer



Scan the code to learn more about the SeCure Study for the treatment of Incompetent Perforator Veins with the VenaCure EVLT 400 um Laser Fiber

PROCEDURE STEPS

The information below represents an abbreviation of the steps to treat a vein with the VenaCure 400 micron Perforator & Accessory Vein Ablation Kit (PVAK). All the steps necessary to successfully treat a varicose vein have not been included. Please refer to the IFU/DFU and Operator's Manual for detailed steps necessary to use the kit and laser to treat veins. Refer to Operator's Manual and/or IFU for full indications for use, contraindications, warnings and precautions.

WITH SHEATH

Using the black Site Mark as the insertion stop point, secure fiber to sheath. At this point, fiber tip is 1.5cm from tip of sheath. Setback from deep system 2cm. Energy delivery via continuous using 30-50J/cm parameter.

NOTE: When fiber is locked into sheath, treatment length is 10cm.

1

Access using
micro-access kit

2

Remove
guidewire/
dilator

3

Insert fiber to
site mark;
place 2cm from
saphenofemoral
junction

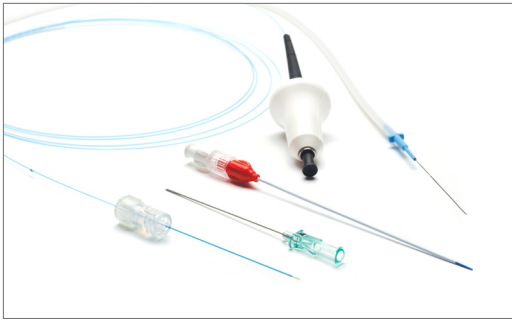
4

Infuse local
anesthetic

5

Activate laser to
treat vein





400 MICRON PERFORATOR & ACCESSORY VEIN ABLATION KIT

Description	Part #
400 Micron Perforator & Accessory Vein Ablation Kit	H787EVLTPVAKU5

AngioDynamics' VenaCure EVLT endovenous laser vein treatment offers patients a minimally-invasive choice for treating the source of their varicose veins and provides them with a potentially quicker recovery and return to normal daily routines, as compared to surgical stripping.² The VenaCure EVLT System includes a 1470 nm laser, 600 um or 400 um laser fiber procedure kits including accessories, marketing materials, support and more. For more information on these products, including our proprietary NeverTouch* fiber technology, please visit www.VenaCure-EVLT.com.

1. Barwell, J. R., et al. (2004, June 5). Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): Randomised controlled trial. *The Lancet*, 363, 1854-1859
2. Brittenden, J., et al. (2015, April). Clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: Results from the Comparison of Laser, Surgery and foam Sclerotherapy (CLASS) randomised controlled trial. *Health Technology Assessment*, 19(27).

IMPORTANT RISK INFORMATION

INDICATION FOR USE: The 400nm 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 400nm Perforator and Accessory Vein Ablation Kit is indicated for treatment of incompetence and reflux of superficial veins in the lower extremity, and for the treatment of incompetent (i.e. refluxing) perforator veins (IPVs).

CONTRAINDICATIONS: Patients should not have their varicosities ablated who have the following conditions: thrombus in the vein segment to be treated; aneurysmal section in the vein segment to be treated; peripheral artery disease as determined by Ankle Brachial Pressure Index with a value of <0.9; an inability to ambulate; deep vein thrombosis; pregnant or breast-feeding; or patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment.

WARNINGS AND PRECAUTIONS: Read the Instructions For Use and the Laser Operator's manual thoroughly prior to using the VenaCure EVLT Procedure Kits with the 400 µm Fiber. Observe all warnings, precautions and cautions noted. Failure to do so may result in patient complications. Laser protective eyewear must be worn by everyone in the treatment room, including the patient.

CAUTION: Intended for use only by fully trained physicians. Federal (USA) law restricts these devices to sale by or on the order of a physician. The VenaCure EVLT Procedure Kit is intended for single patient use only. Inspect the sealed packages before opening. If seals are broken or the packages are damaged, treat as non-sterile and discard. Ensure expiration dates are still valid. Treatment of a vein located close to the skin surface may result in a skin burn. Tissue not targeted for treatment must be protected from injury by direct and reflected laser energy.

POTENTIAL COMPLICATIONS: Adverse reactions may include, but are not limited to: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia due to thermal damage of adjacent sensory nerves, skin burns, and thrombophlebitis.

Indications, contraindications, warnings and instructions for use can be found in the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.



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