



400 μ m Fiber Procedure Kit

Treat Superficial Veins with the Precision of the VenaCure EVLT System*

Superficial Veins (SV) associated with Chronic Venous Insufficiency (CVI) are linked to venous hypertension, severe sequelae of CVI, and the development of leg ulcers. Treatment of CVI/SV can lead to reduced recurrence rates for venous ulcers.¹ This represents an opportunity to expand the range of venous disease treated in your practice.

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



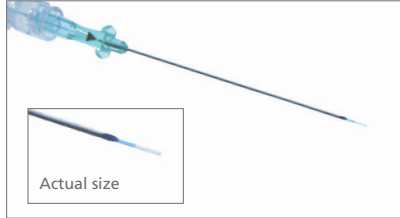
PROCEDURE KIT FEATURES AND BENEFITS

400 µm Optical Fiber

Smaller sized fiber aids in SV access and positioning

21G Venous Access Needle

Ensures easy, atraumatic access



Small profile fits through 21G needle

10 cm x 4F Introducer Sheath

Stiff dilator guides the sheath into the proper subfascial plane

Hub and Compression Clamp

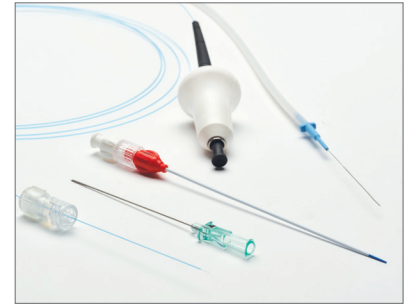
Hub on sheath mates with compression clamp on fiber

.018" Guidewire

Navigates small, tortuous veins with a floppy tip and has a firm anchor to guide sheath and hold it in place

Site Marks on Fiber

Site marks match to sheath to ensure proper positioning



400 µm FIBER PROCEDURE KIT

Description	Part #
400 µm Fiber Procedure Kit	H787EVLTPVAK5

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 µm or 400 µm 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.

- 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
- 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 400 micron VenaCure EVLT Procedure Kit is intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosity. The EVLT Kits are indicated for the treatment of incompetence and reflux of superficial veins of the lower extremity.

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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