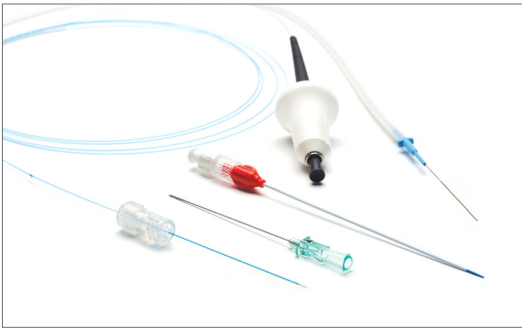




## 400 MICRON PERFORATOR & ACCESSORY VEIN ABLATION KIT

Treat perforator veins with the precision of VenaCure.



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Description	Part #
400 Micron Perforator & Accessory Vein Ablation Kit	H787EVLTPVAKUS5

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.<sup>1</sup>

The VenaCure EVLT System includes a 1470 nm laser, 600 micron or 400 micron 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](http://www.VenaCure-EVLT.com).

1. 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 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 400 micron 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 micron 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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