

THE ART OF PRECISION

Innovative Technology for Varicose Vein Treatment



SMART, GENTLE, EFFICIENT

Radiofrequency ablation (RFA) is an established minimally invasive treatment of varicose veins.

The generator and ProCurve V applicator of the Precision System allow highly accurate and customized varicose vein treatments. Using bipolar radiofrequency technology, the "Pulse RFITT" mode (radiofrequency induced thermotherapy), occludes veins gently and efficiently.

BENEFITS AT A GLANCE

- Applicator with slender 1.8 mm diameter (5 Fr/6 Fr)
- Short electrode tip of 18 mm (enabling treatment of short vein segments e.g. perforators)
- May be positioned up to 1cm inferior of the saphenous junctions
- Tissue heated up to about 100° C
- Protects against thermal damage to the introducer sheath
- Visual and audible feedback of ablation progress
- Auto-Stop feature for increased safety and prevention of overtreatment
- Bipolar and monopolar standard modes with inpatient and outpatient settings for standard electrosurgical instrumentation



PRECISE ABLATION

Self-regulating System

The Precision System includes the following self-regulation features: During the entire ablation procedure, the system delivers only the power actually needed to occlude that particular vein being treated. In addition, the visual and audible feedback informs about the ablation progress. This allows the surgeon to match the rate of applicator withdrawal optimally to the specific characteristics of the target vein, thus achieving customized and precise ablation of the varicose vein.

Impedance Measurement & Auto-Stop Feature

The most notable feature of the system is its continuous intraoperative impedance measurement determining the tissue condition. As tissue impedance rises with progressing ablation, the Precision Generator automatically adjusts its power output. Once the impedance has reached a preset value, the power output is reduced to a minimum. This feature is also known as Auto-Stop.

Once the vein is occluded or the tip is While the RF energy is applied to the adjacent tissue, the power is continuously adapted to within an introducer sheath, the impedance the state of ablation. rises rapidly. POWER **IMPEDANCE IMPEDANCE POWER** The impedance is shown visually and audibly If the impedance rises beyond a preset throughout the whole ablation procedure in value, the power output is reduced to a real-time. minimum (Auto-Stop function).

GENTLE TREATMENT

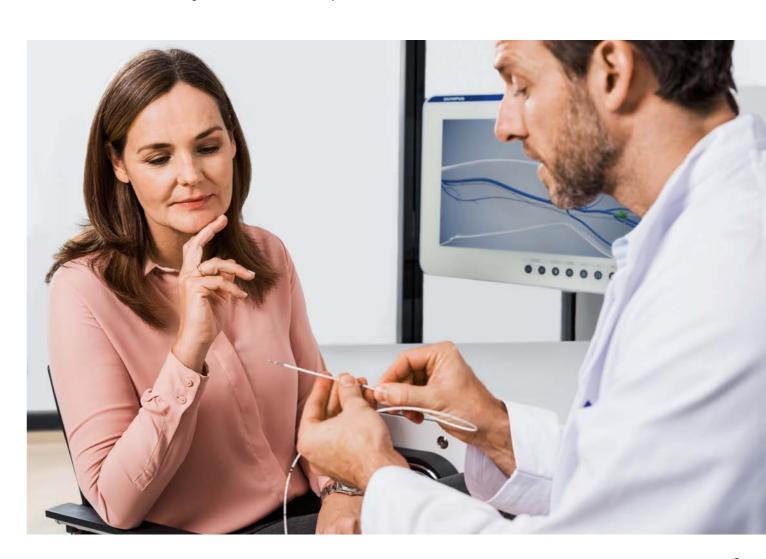
Bipolar Radiofrequency Ablation

In bipolar radiofrequency ablation, the frequency of the current flowing between two electrodes (= bipolar) is in the range of radio waves. The electrode arrangement precisely defines the area to be treated. In this way, the tissue along the tip of the electrode is heated to about 100° C and gently ablated. This precise local application of radiofrequency energy denatures the collagen in the vein wall. The occluded vein remains in the body and is no longer visible.

My first impression of the Precision System is very positive.

[...] Short treatment time and an effective vein occlusion: These are the important quality features for a minimally invasive treatment of varicose veins and for high patient satisfaction.

Stefan Schulte MD, Cologne Vascular Center, Germany



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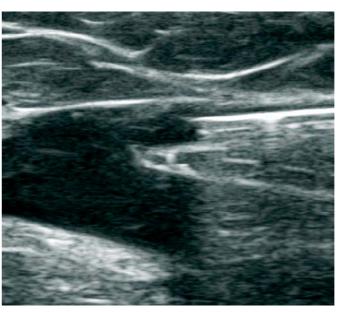
PROCURVE V APPLICATOR

The radiofrequency current does not heat the electrode tip itself, but only the adjacent tissue. Once the generator is deactivated by releasing the foot switch, the treatment stops immediately and there is no risk of thermal injury. Additionally, the Auto-Stop function prevents overtreatment of the vein and damage to the introducer sheath.

An ellipsoid coagulation volume is generated around the tip of the bipolar electrode. This ensures that only little heat is delivered beyond the spherical electrode tip. The applicator may be placed closely distal to the saphenous junctions.

Benefits at a Glance

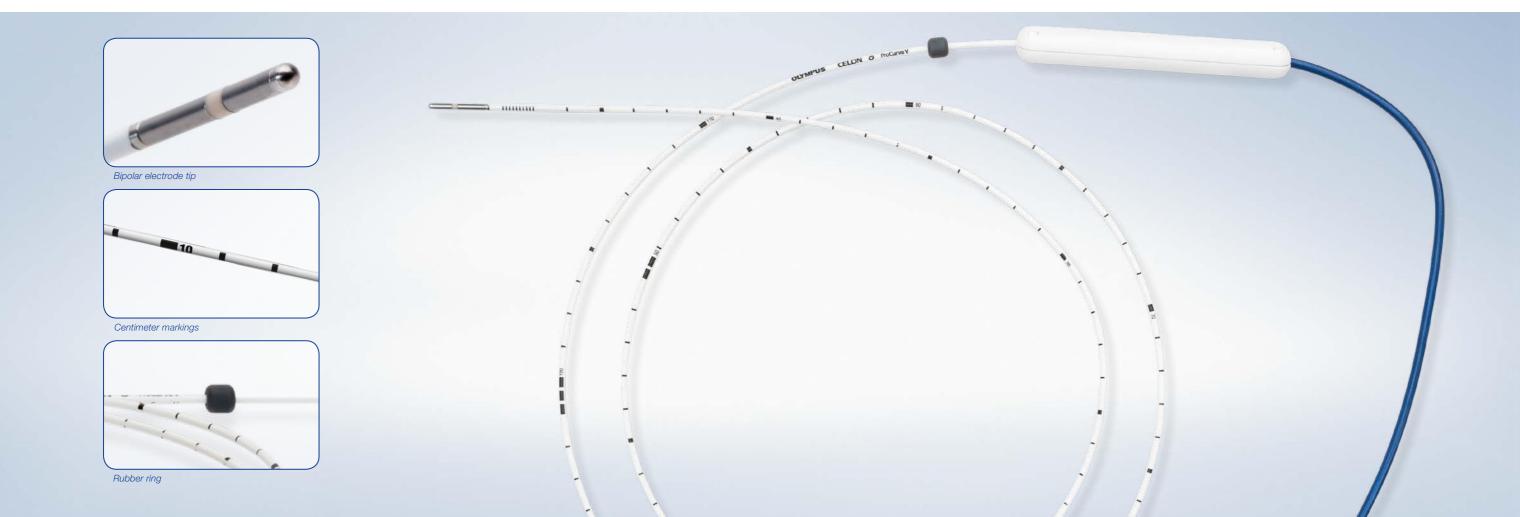
- · Slender diameter of 1.8 mm (5 Fr/6 Fr)
- · Flexible shaft for easy insertion
- · Centimeter markings for precise placement (Rubber ring-positioning guide)
- · Clear tip visualization on ultrasound for easy positioning
- Short electrode tip of 18 mm (enabling treatment of short vein segments e.g. perforators)
- May be positioned up to 1 cm inferior of the saphenous junctions
- · Tissue heated up to about 100° C
- · Protects against thermal damage to the introducer sheath
- · Continuous withdrawal with inbuilt auto-feedback control



ultrasound and positioned 1 cm below saphenous junctions. During ablation, the continuous pull back speed is determined by the characteristics of the vein being treated.

The bipolar applicator tip can be easily seen on

By courtesy of Stefan Schulte MD, Cologne Vascular Center, Germany



PRECISION GENERATOR

All-in-One: A Single Generator for Varicose Veins and Standard Electrosurgical Procedures

The Precision Generator is a radiofrequency-based platform comprising a variety of functions in one unit. In addition to the "Pulse RFITT" mode for the treatment of varicose veins, the generator may also be employed in standard inpatient and outpatient surgical procedures: The bipolar "SoftCoag" mode has an optional Auto-Start feature which activates the power output whenever the bipolar forceps touches the tissue to be coagulated. This does not require activation with the foot switch. During monopolar cutting, the "Fast Spark Monitor" ensures constant spark intensity to produce a good, even, cutting quality.

In monopolar procedures, the contact of the neutral electrode to the patients skin is continously monitored, improving safety and control. As soon as the neutral electrode is slightly loose, this feature triggers an alarm, thereby protecting the skin against thermal injury. Operation of the user-friendly touchscreen is intuitive. Saving custom procedure settings simplifies the daily routine of healthcare professionals.

OLYMPUS B BIPOLAR Pulse RFITT CELON O Precision & MONOPOL **OLYMPUS**

Benefits at a Glance

Smart

- Display of power, energy output, and duration of ablation
- Visual and audible feedback of ablation progress
- Saving of custom procedure settings

Gentle

- RFITT modes for less postoperative pain and hematoma due to lower temperatures (~100° C)
- Auto-Stop feature for more safety and prevention of overtreatment

· Monitoring of the tissue change

through impedance feedback

Efficient

- · Bipolar and monopolar standard modes
- · Automatic applicator detection
- · Simple touchscreen operation
- Auto-Start feature (with bipolar forceps)
 "Fast Spark Monitor" for constant cutting quality in different tissues
- Continuous monitoring of neutral electrode contact for safer monopolar application

Pulse RFITT for Treatment of Varicose Veins



Bipolar and Monopolar Modes for Standard Electrosurgical Procedures



SoftCoag: Little carbonization and adhesion, Auto-Start selectable



FineCut: Low spark intensity for small thermal effects

PureCut:

Medium spark intensity for medium thermal effects

StrongCut:

High spark intensity for large thermal effects



A Return

Effective coagulation with less carbonization and adhesion

ForceCoag:

Rapid and effective coagulation

8

CLINICAL RESULTS

Burns are less likely for RFITT due to its automatic, impedance-feedback cut-off when the treatment sheath is entered. No instances of skin burns occurred [...]

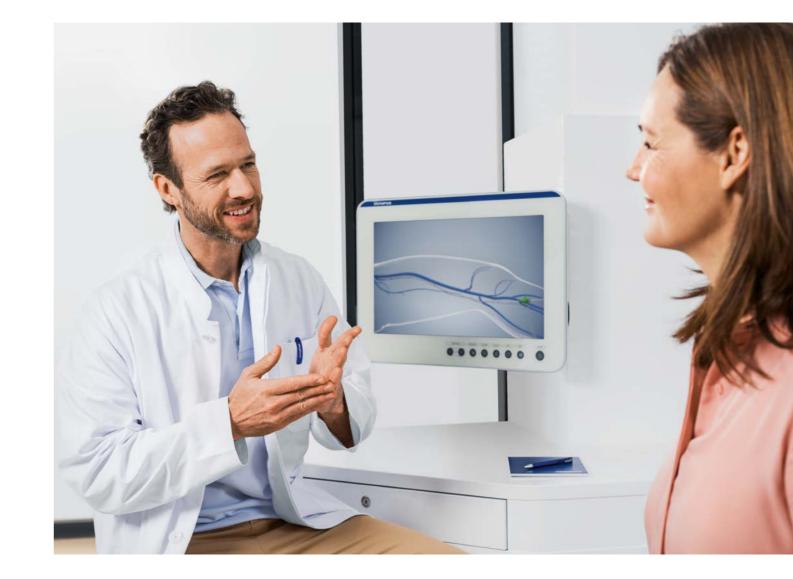
Goodyear SJ, Nyamekye IK. Radiofrequency ablation of varicose veins: Best practice techniques and evidence. [Phlebology 2015 Nov;30(2 Suppl):9-17.]

Complete occlusion rates of 98.4 % were achieved [...]

Braithwaite B et al.. Radiofrequency-induced thermal therapy: results of a European multicentre study of resistive ablation of incompetent truncal varicose veins. [Phlebology. 2013 Feb;28(1):38-46.]

RFA was less painful for patients than EVLA and produced less bruising in the postoperative period with comparable success rates [...]

Goode SD et al.. Laser and radiofrequency ablation study (LARA study): a randomised study comparing radiofrequency ablation and endovenous laser ablation (810 nm). [Eur J Vasc Endovasc Surg. 2010 Aug;40(2):246-53.]





10

PRODUCT OVERVIEW OF THE OLYMPUS PRECISION SYSTEM





Product Information	
Part Number	
WB990207	Bipolar RF applicator "CELON ProCurve V" (5 units/box)
WA90008A	Electrosurgical generator "CELON Precision" (Erbe Standard/Type E), incl. foot switch
WA90009A	Electrosurgical generator "CELON Precision" (Bovi Standard/Type B), incl. foot switch
WA95621A	Power cord EU, type E/F
WA95622A	Power cord US, type B
WA95623A	Power cord UK, type G