

The ClariVein® OC

Proprietary dual action device[^]

ClariVein® OC is a specialty catheter for the infusion of physician-specified agents in the peripheral vasculature including for endovascular occlusion of incompetent veins in patients with superficial venous reflux. The ClariVein® OC is fully disposable, minimally invasive, and can be efficiently used in an office setting. ClariVein® OC offers many patient benefits including minimal post-operative pain and faster recovery¹.

Introduced through a microintroducer set, infusion is through an opening at the distal end of the catheter and fluid is delivered by use of a rotating wire and dispersion tip[^].



Motor Drive Unit:

Drives the wire rotation.

- **Self-Contained & Disposable:** Fully self-contained, single-use device with no need for capital equipment purchase
- **Power System:** The Motor Drive Unit is operated by a low voltage, self-contained power system
- **Variable Rotating Speed:** Multiple speed settings allow for rotating wire and dispersion ball to rotate between approximately 2,000 and 3,500 RPM
- **Single-Handed Operation:** Motor Drive Unit designed to be fully operational with one hand

Catheter Assembly:

The catheter is easily identified under vascular imaging and incorporates a cartridge for secure fastening to the Motor Drive Unit.

- **Ease of Navigation**
- **Small Profile:** < 3 French Infusion Catheter
- **Flexibility:** Multiple catheter lengths available. Navigatable catheter based on patient anatomy and desired tip location
- **Flexible:** coaxial catheter with rotating wire and a dispersion ball at the distal tip
- **Marked:** Conveniently marked catheter shaft allows for accurate pullback and infusion
- **Excellent Visualization:** Rotating wire and dispersion ball easily identified under imaging guidance
- **Cartridge Attachment:** Designed for secure fastening to Motor Drive Unit



Indications For Use: The ClariVein® OC is indicated for infusion of physician-specified agents in the peripheral vasculature including for endovascular occlusion of incompetent veins in patients with superficial venous reflux. **Labeling:** Refer to product labeling provided with each product for Description, Directions for Use, Warnings, Precautions and Potential Complications/Adverse Effects. Please check with your country representative to determine if the ClariVein® OC infusion catheter is available in your country.

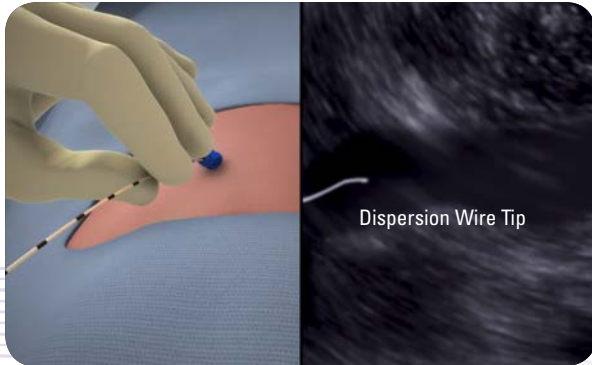
[^] Data on file

1. D. Boersma, et al., Mechanochemical Endovenous Ablation of Small Saphenous Vein Insufficiency Using the ClariVein® Device: One-year Results of a Prospective Series, European Journal of Vascular and Endovascular Surgery, Volume 45 Issue 3 March/2013, p. 299-304.

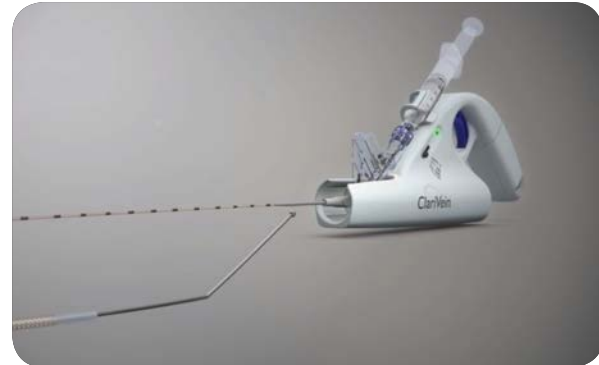
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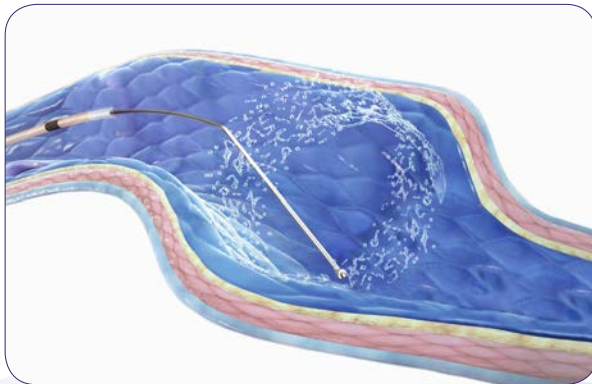
Using The ClariVein® OC



1. ClariVein® OC is introduced percutaneously into the peripheral vasculature under imaging guidance*. The dispersion wire tip is easy to visualize for accurate placement in the treatment zone^.



2. The Catheter Assembly is connected to the Motor Drive Unit (MDU).



3. The MDU rotates the wire and dispersion tip allowing for targeted infusion of the physician-specified agents to the treatment zone.



4. Patients often return to their normal activities immediately post-operative.

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^ Data on file

* Including Ultrasound

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ClariVein®
by VASCULAR INSIGHTS®

The ClariVein® OC Advantage

With more than 60,000 units in the market, the ClariVein® OC device is designed to benefit patients and physicians alike.*

ADVANTAGES:	Physician	Patient
MINIMALLY INVASIVE [^]	✓	✓
FAST PROCEDURE TIME [^]	✓	✓
QUICK RETURN TO NORMAL ACTIVITIES [^]	✓	✓
MINIMIZES PATIENT DISCOMFORT [^]	✓	✓
PERFORMED IN AN OFFICE SETTING [^]	✓	✓
TUMESCENTLESS PROCEDURE DECREASES PROCEDURE TIME [^]	✓	✓
CONTAINS NO PHTHALATE MATERIALS [^]	✓	✓
SELF-CONTAINED DISPOSABLE DEVICE [^]	✓	✓
REDUCED COST: NO USER SERVICEABLE PARTS [^]	✓	✓



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*The ClariVein® family of infusion catheters distributed worldwide.

[^] Data on file

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ClariVein® OC* Versus Radiofrequency

Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins¹

*When using ClariVein® OC for the MOCA procedure and physician-specified agents for the treatment of incompetent veins with superficial venous reflux.

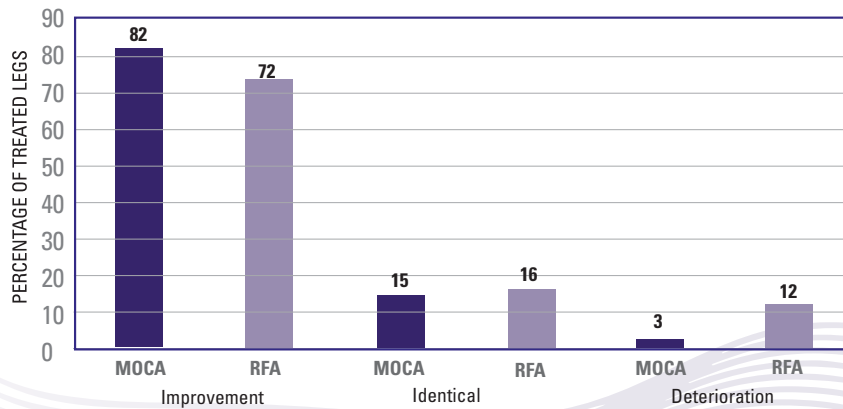


Fig 1. Assessment of the Venous Clinical Severity Score (VCSS) 6 weeks after the treatment with mechanochemical endovenous ablation (MOCA) and radiofrequency ablation (RFA).

- This study has demonstrated that postoperative pain is significantly lower after MOCA compared with RFA, corresponding to a 74% reduction in pain for the first 14 postoperative days¹.
- The time to return to normal activities was 1.0 day (IQR, 0-1.0) in the MOCA group and 1.0 day (IQR, 1.0-3.0) in the RFA group, which was significantly longer (P=.01)¹.
- The median time to work resumption for employees was significantly shorter in the MOCA group than in the RFA group (P=.02), respectively, 1.0 days (IQR, 1.0-3.75) vs 2.0 days (IQR, 2.0-7.0)¹.

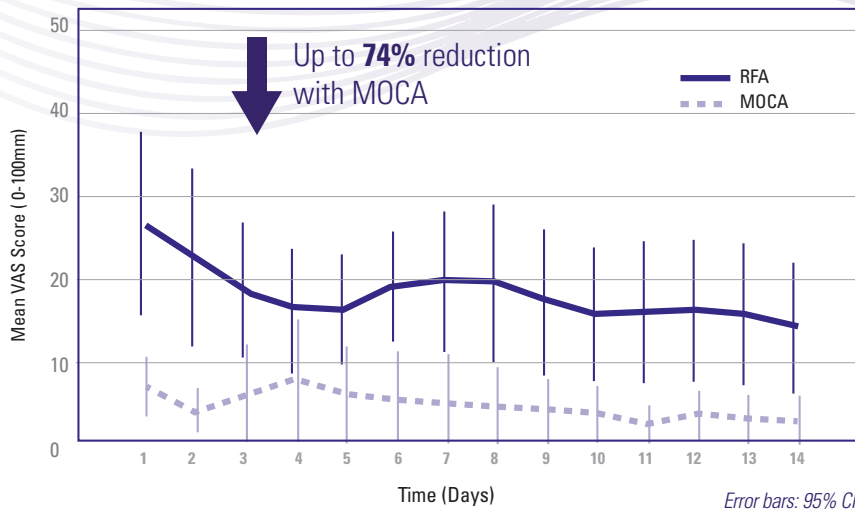


Fig 2. Mean postoperative pain scores on a 0 to 100 mm visual analogue scale for 14 days after mechanochemical endovenous ablation (MOCA) and radiofrequency ablation (RFA). CI, Confidence interval; VAS, visual analog scale.



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1. R. van Eekeren, et al., Postoperative Pain and Early Quality of Life After Radiofrequency Ablation and Mechanochemical Endovenous Ablation of Incompetent Great Saphenous Veins, Journal of Vascular Surgery, Volume 57, Number 2, February 2013, p. 445-450.

*Results of one clinical study may not be indicative of all clinical experiences.

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ClariVein® OC* Comparison to Thermal Ablation for Treatment of Incompetent Veins due to Superficial Venous Reflux

Thermal Ablation

YES
NO
YES
6 FR OR LARGER
YES
YES
YES
YES
GSV & SSV - May not be suited for smaller vessels due to thermal damage risk ¹
Risk from thermal energy ²
YES
RF: Park and Wait LASER: 1.5mm/SECOND

Requires Tumescant Anesthesia
Requires Sclerosing Agent*
Risk of Thermal Damage Nerves Skin Paresthesia
Percutaneous Access
Capital Equipment Investment
Lease Agreement
Contract Purchasing
Equipment Maintenance Contract
Treatment Suitability
Patient Pain & Bruising
Image Visualization
Pullback Timing & Method

ClariVein® OC

NO
YES
NO
4 FR OR LARGER [^]
NO
NO
NO
NO
GSV & SSV - Plus small vessels all the way to ankle. Some studies show success in the venous ulcer beds ²
74% less post-operative pain ¹ less bruising
YES
1-3mm/SECOND

*When using ClariVein® OC for the delivery of sclerosant. Refer to sclerosant labeling for important information.

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2. Hayley M Moore, Tristan RA Lane, Ian J Franklin and Alun H Davies Retrograde Mechanochemical Ablation of the Small Saphenous Vein for the Treatment of a Venous Ulcer 1708538113516320 first published December 17, 2013