What is Maven?
What is the data?

Jeffrey G. Carr, MD, FACC, FSCAI, FOEIS

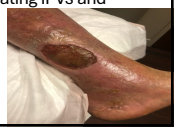
Christus Health- Cardiac and Vascular Institute
Medical Director- Vein Center of East Texas
Tyler, Texas

Disclosures

- Becton Dickinson- Consultant, faculty
- Former Chief Medical Officer- Venclose, Inc.

Why Treat Incompetent Perforator Veins (IPVs)? Unmet Needs

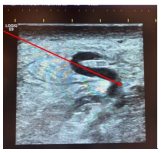
- High rates of vein leg ulcers (VLUs) in US- 6M est.
- VLUs have high recurrence rates– 50-70% in 6 mos.
- IPVs associated with nonhealing VLUs and recurrence[1]
- IPVs associated with recurrent varicose veins [2]
- Ulcer healing and recurrence rates improved by treating IPVs and truncal veins vs. truncal veins alone[3]
- Available IPV treatment options and devices cumbersome and sub optimally effective



[1]O'Donnell JVS 2014 , [2]Bush 2014, [3]Lawrence JVS V&L Dz 2014 and 2020

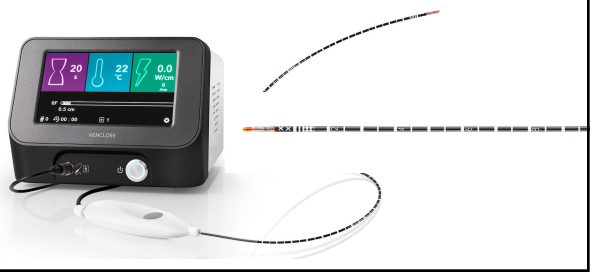
Desired Qualities of Devices to Treat IPVs:

Design-



- Ease of intraluminal access
- Flexible – negotiate variant and tortuous anatomies
- Consistent and uniform endoluminal injury
- Maximize surface area and length of IPV treated
- Precision on treatment locations
- Quick and efficient
- Safe- avoidance of DVT, nerve, skin or arteriole injury

Venclose Maven™ Perforator Catheter



Indications for Use and Contraindications

Indications for Use in the United States

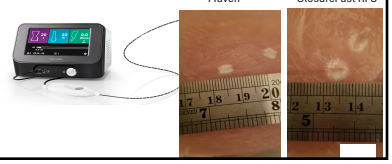
- The Venclose Maven™ Catheter is intended for endovascular coagulation of blood vessels in patients with perforator and tributary vein reflux

Contraindications

- The Venclose Maven™ Catheter is contraindicated in patients with thrombus in the vein segment to be treated.

Design

- 6F, handle, cable
  - Flexible shaft, slide marker
  - Up to 0.025" guidewire
- 0.5 cm coil length
- 40 cm catheter shaft
- 130ºC treatment temperature
- 20 seconds treatment cycle
- Generator



Positioning the Venclose Maven™ Perforator Catheter

Pre-map treatment zones (for # of treatment zones)
The orange tip of the catheter is inactive
0.5 cm – active treatment element 0.5 cm treatment zone

Target-Deep Fascial plane

Ensure that the distal tip of the catheter is greater than **0.5 cm** from the deep venous system.

Do not treat within the deep venous system.

Ensure that the proximal end of the heating element is at least **0.5 cm** from the skin.

Venclose Maven™ Instructions for Use.

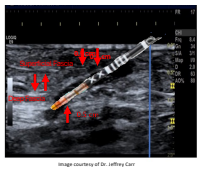
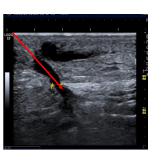
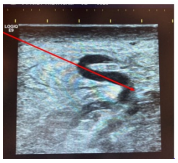


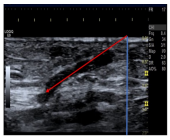
Image courtesy of Dr. Jeffrey Carr

Technique and Approach

- Identify landmarks with DUS
- TARGET: Ablate just below or at the deep fascial plane (bottleneck) and longest surface area able
- Stay > 5mm away from deep veins, arterioles, skin, bone
- If large feeding tributaries for inflow, consider concomitant UGS of tributaries

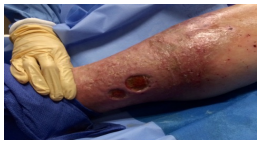


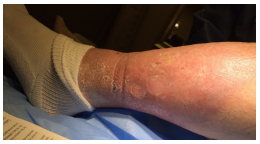




Efficacy Rates for IPV Treatment

- How do we define success?
  - Permanent closure?
  - Patency, but reflux-free (< 500ms)?
  - Ulcer or wound healing?





IPV Closure Rates by Various Devices

- Ultrasound-Guided Sclerotherapy: 75% at 20 mos.[1]
- Cyanoacrylate: 86% at approx. 2 mos.[2]
- Laser: SECURE Trial 76%, at 1 mo.; 62% at 6 mos. CEAP4B-6 [3]
- Radiofrequency ablation: RFS Stylet 60-80% [4]
- Radiofrequency ablation: Maven FDA IDE Safety Study – 30d no adverse events [5] (Post-market efficacy study in process)

- 60-80% Closure rates
- Only 2 RCTs for IPVs ulcer healing outcomes[6]

[1]Thibault, J.Derm.Surg. Onc 1992, [2]Mordhorst, Phlebology 2021, [3]Gibson, JVS-VL 2020, [4]Aurshina, JVS-VL 2018, [5]FDA Submission- Unpublished 2021, [6]Gohel, NEJM 2018, Abdelgawad Vascular 2022

MAVEN IDE STUDY FOR IPVs — Safety Trial

N=30 patients- CEAP 4b-6 Prospective, Single center
Primary endpoints:
- No adverse events- No DVT, PE, nerve injury, phlebitis, etc.
- 100% technical success (i.e., delivery of intended energy to targeted vein using 12g angiocath for access)

Secondary endpoints:
- Occlusion and reflux rates

	3-day Follow-up	15-day Follow-up	30-day Follow-up
Primary: AE Rate	0% (None)	0% (None)	0% (None)
Primary: Technical Success	100%	100%	100%
Secondary: Occlusion Rate	76.7% 23 of 30	73.3% 22 of 30	80.0% 24 of 30
Secondary: Reflux Free Rate	86.7% 26 of 30	83.3% 25 of 30	93.3% 28 of 30

Takeaways
- Occlusion 77% at 3d. and 80% at 30d.
- Reflux free 93% at 30d.

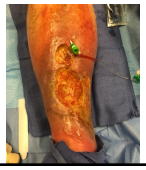
- Symptomatic and ulcer improvement was not studied (safety trial)
- Over the wire and standard sheath access not performed- (true lumen access may be enhanced)

- Correct identification of treated vein at DUS follow-up is critical for correct occlusion and reflux assessment

Maven Post Market Study

A Post-Market, Multi-Center, Prospective, Interventional Study using the Venclose ™ System and Venclose MAVEN™ System for Treatment of Chronic Venous Insufficiency of the Great and Small Saphenous Veins and Incompetent Perforator Veins

- 174 patients to be treated with Maven at 30 sites
- Safety and efficacy endpoints to 24 months
- Ulcer healing rates to 3 months



Conclusions

- IPVs are associated with poor healing VLUs and recurrences
- Maven designed to meet multiple challenges in treating IPVs
- Maven is safe in a small single center study
- Post-market Maven study will help guide treatment algorithms and inform efficacy for IPV treatments