ENGLEWOOD HEALTH

HIFU:
HIGH INTENSITY FOCUSED ULTRASOUND

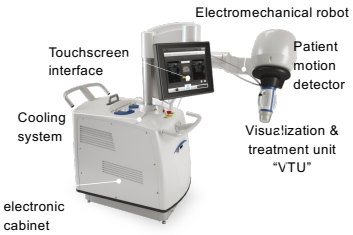
DOES IT WORK? WHO CARES?

STEVE ELIAS

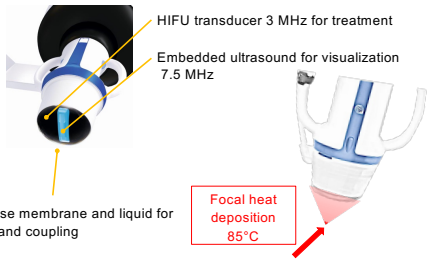
DISCLOSURES

BD	Consultant
Boston Scientific	Advisory Board
Cook	Advisory Board
Crossfire Medical	Consultant
Elastimed	Consultant
EnVeno	Stock options
Medtronic Inc.	Advisory Board
Philips	Advisory Board
Sun Scientific	Advisory Board
Tactile Medical	Advisory Board
Theraclion	Consultant
USA Therm	Advisory Board/Stock
VVT Medical	Advisory Board/Stock
VB Devices	Advisory Board/Stock

HIFU (SONOVEIN®) Device



Visualization & Treatment Unit (VTU)



PRECISE FOCAL HEATING

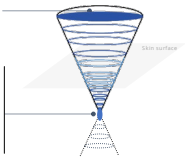
THERACLION

The ultrasound signal is emitted by a spherical transducer and concentrated on a focal point

The deposition of high energy creates a quick temperature rise at the focal point

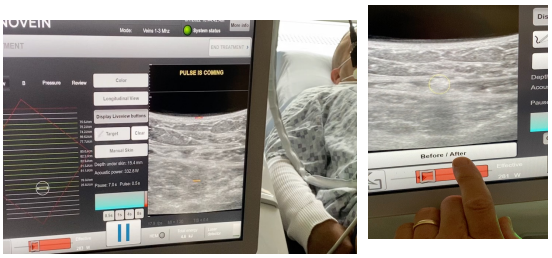
Tissue temperature reaches coagulation levels and induces further tissular effect at the target site

Thermal deposition is restricted to a very precise volume, slightly taller than wide

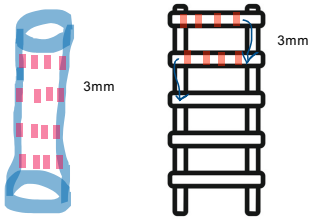


PATIENT POSITIONING

TREATMENT



TECHNIQUE: CONCEPT



TREATMENT PROCEDURE

2023: Initial Investigator Initiated Trial for FDA Single Center - Englewood

- 18 patients, 20 GSVs
- CEAP: **80% C2** (16), C3 (1), C4 (2), C6 (1)
- Diameter pre-Tx : **7mm** (3.8-15.7mm)

Results: 3 Months

Primary Endpoint

- 100% technical feasibility (principal study objective)
  - No anesthesia – not even local
  - No post procedure compression

Results: 3 months post

Secondary Endpoint

- **Ablation of venous reflux – 95%** (19/20)
- Patient-rated pain of the HIFU treatment – 20 out of 100 (0-80)
- No complications
  - No nerve, skin injury, DVT/SVT
- VCSS – 6.9 Pre → 1.1 post @ 3months

VEINRESET: FDA Approved Trial 4 sites

- Steve Elias – Englewood Health NJ USA
- Tony Gasparis – Northwell Health NY USA
- Alfred Obermayer – Melk Austria FIH
- Jaroslav Strejcek – Prague Czech Republic

- 70 pts total – enrollment complete June 2024

VEINRESET: US DATA 35 Patients

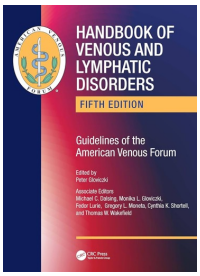
- 31/35 closed at 1 week) -89%
- 24/26 closed at 3 months – 92.3%
- 9/9 closed 6 months – 100%
- No SAEs globally
- Very similar to initial Englewood data

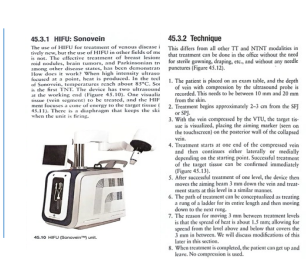
WORLDWIDE LOCATIONS

THERACLION

Handbook of Venous and Lymphatic Disorders

Fifth Edition (2024) / Edited by Peter Gloviczki / author S Elias MD





45.3.1 HIFU: Sonovein

45.3.2 Technique

THOUGHTS AND LESSONS LEARNED

- HIFU works for veins and many other clinical scenarios
- Depth – 12 to 22mm from skin when compressed
- Size – 10mm or smaller
- Length treated – 15cm (45-60 mins)
- Local anesthesia – between vein and muscle posteriorly
- No compression, immediate ambulation
- Faster -AI, double distance between vein segments (3mm)
- ASV short, Perforators, Transcutaneous CHIVA, GSV

FREE

venousedge.com

FREE