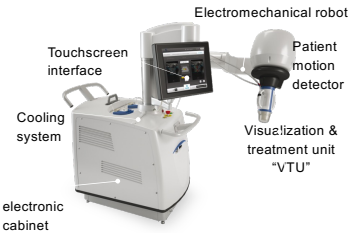
  
**ENGLEWOOD HEALTH**  
**HIFU:**  
**HIGH INTENSITY FOCUSED ULTRASOUND**  
**DOES IT WORK? WHO CARES?**  
  
**STEVE ELIAS**

### 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



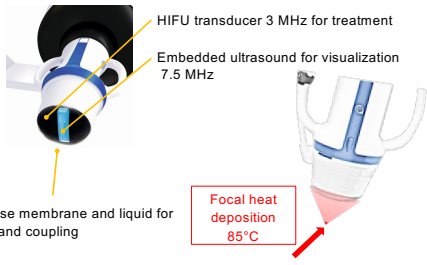
### HIFU (SONOVEIN®) Device




Electromechanical robot  
 Touchscreen interface  
 Patient motion detector  
 Cooling system  
 Visualization & treatment unit "VTU"  
 electronic cabinet




### Visualization & Treatment Unit (VTU)

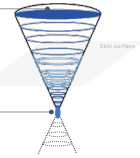


HIFU transducer 3 MHz for treatment  
 Embedded ultrasound for visualization 7.5 MHz  
 Single use membrane and liquid for cooling and coupling  
 Focal heat deposition 85°C




### PRECISE FOCAL HEATING







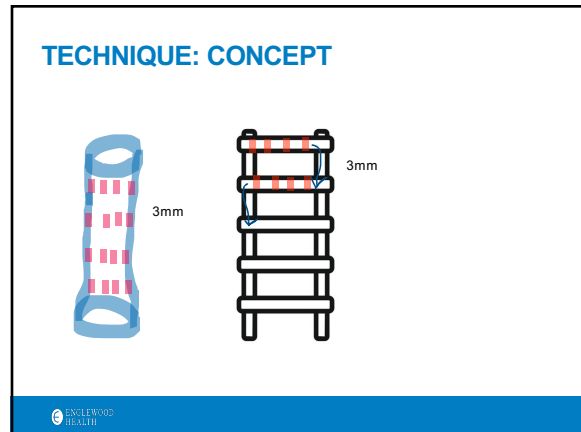
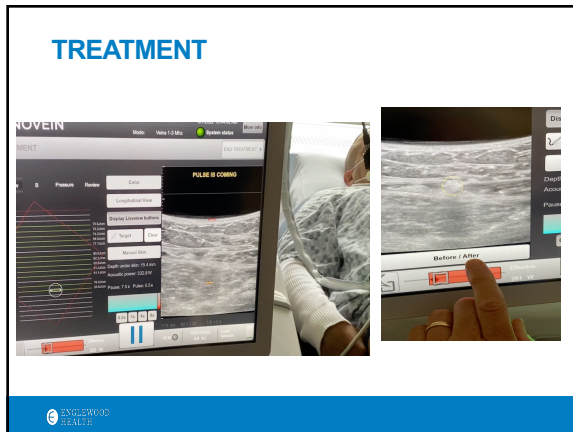
The ultrasound signal is emitted by a spherical transducer and concentrated on a focal point  
 The deposition of high energy creates a quick temperature rise at the focal point  
 Tissue temperature reaches coagulation levels and induces further tissular effect at the target site  
 Thermal deposition is restricted to a very precise volume, slightly taller than wide



### PATIENT POSITIONING







### 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

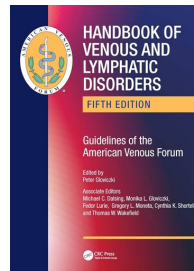
- 31/35 closed at 1 week) -89%
- 24/26 closed at 3 months – 92.3%
- 9/9 closed 6 months – 100%
- No SAEs globally
- Very similar to initial Englewood data



### WORLDWIDE LOCATIONS



### Handbook of Venous and Lymphatic Disorders Fifth Edition (2024) / Edited by Peter Glociczki / author S Elias MD



#### 45.3.1 HIFU: Sono vein

The use of HIFU for treatment of venous disease is similar to the use of HIFU for the treatment of solid tumors. The specific treatment of venous disease includes: breast cancer, and Perforators in chronic venous disease. The HIFU device is used to treat the vein. The HIFU device is positioned in the vein and the HIFU energy is applied to the vein. The HIFU energy is applied to the vein and the HIFU energy is applied to the vein. The HIFU energy is applied to the vein and the HIFU energy is applied to the vein.

#### 45.3.2 Technique

1. The patient is placed on an exam table, and the depth of vein with compression by the ultrasound probe is recorded. This needs to be between 10 mm and 20 mm from the skin.
2. Standard High approximately 2-3 cm from the vein.
3. With the vein compressed by the US, the target vein is visualized, showing the entire length of the vein on the backboard on the posterior wall of the ultrasound probe.
4. Treatment starts at one end of the compressed vein and then continues caudad, typically in 10mm increments on the starting point. Successful treatment of the target vein can be confirmed immediately.
5. After successful treatment of one vein, the device then moves the starting point 1 cm down the vein and treatment starts at this level in a similar manner.
6. The patient is placed on the backboard and the starting point of the vein is marked with a skin marker.
7. The probe is moved to the next vein and treatment starts at this level in a similar manner.
8. The probe is moved to the next vein and treatment starts at this level in a similar manner.
9. The probe is moved to the next vein and treatment starts at this level in a similar manner.
10. The probe is moved to the next vein and treatment starts at this level in a similar manner.



### 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



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