



# New Venous Devices: Brand-New and Innovative



**Lowell S. Kabnick, MD**

# DISCLOSURE

**Investigational Device not labeled for clinical use**

## Research / Consultant

- Angiodynamics
- Amsel
- Bard
- Boston Scientific
- Venari Medical

## Co-Founder

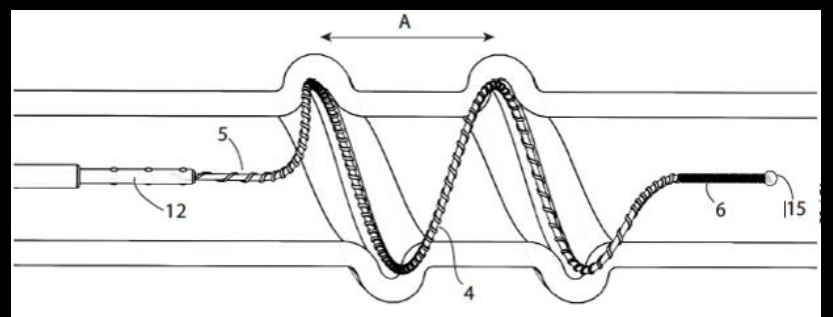
- VSP
- Flebobridge
- Royalties
  - Angiodynamics



# BIOVENA\*

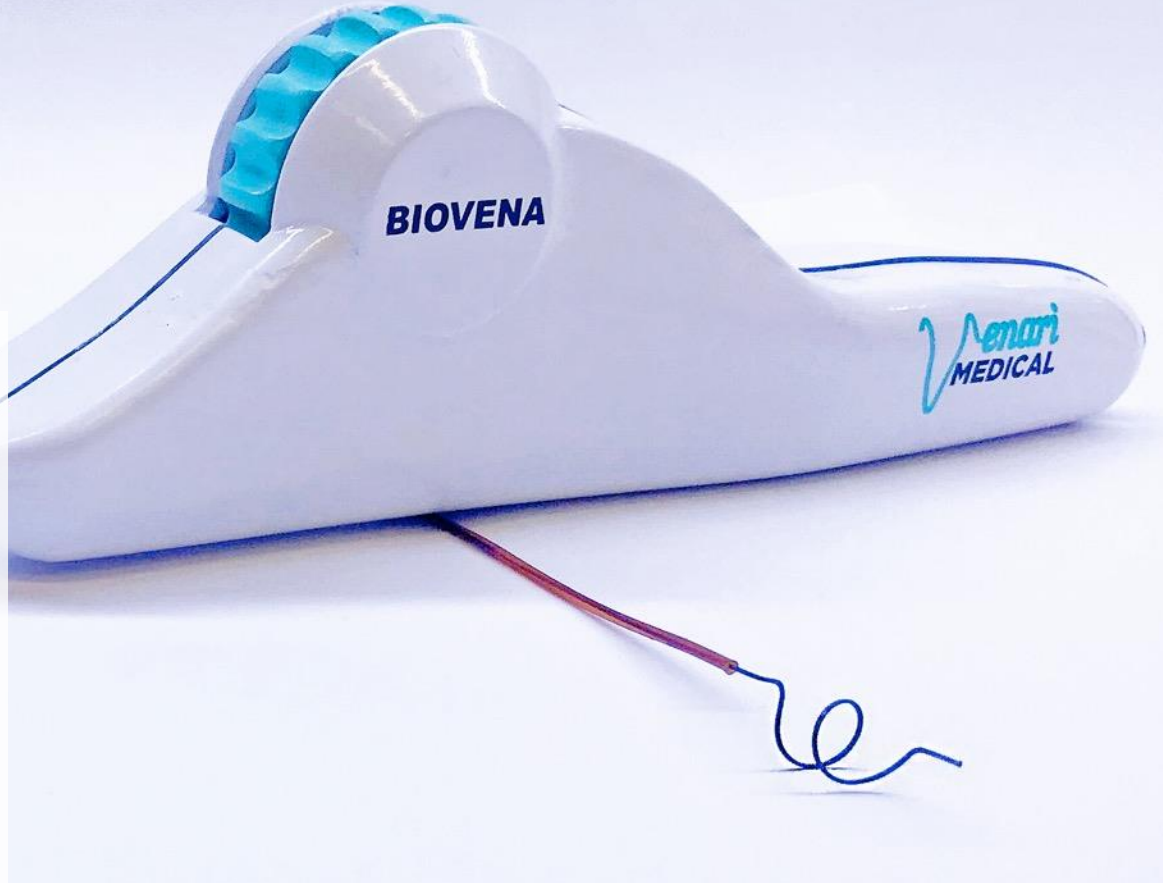
**NON-THERMAL, NON-TUMESCENT,  
NON-CHEMICAL TREATMENT\*  
OF SUPERFICIAL VENOUS DISEASE**

Investigational Device not labeled for clinical use



# **IDEAL UNIQUE MECHANICAL APPROACH**

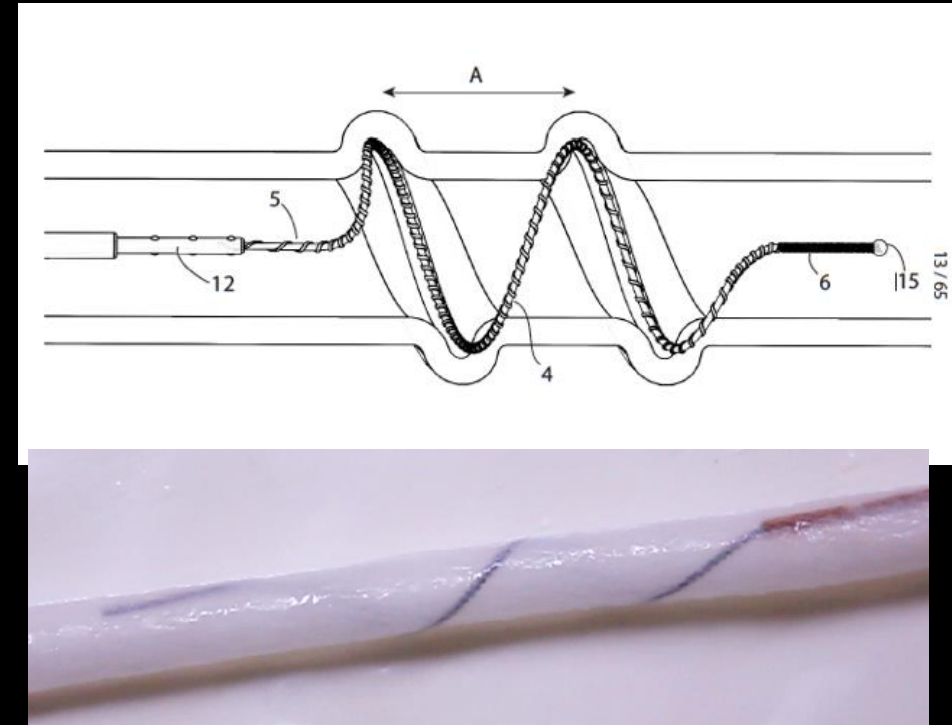
- **LESS INVASIVE**
- **NON-THERMAL, NON-TUMESCENT**
- **NON-CHEMICAL**
- **SINGLE PATIENT USE / MULTIPLE IN SAME PATIENT**



- **4Fr CATHETER**
- **NITINOL HELICAL COIL ABLATION TIP**
- **RECAPTURABLE**

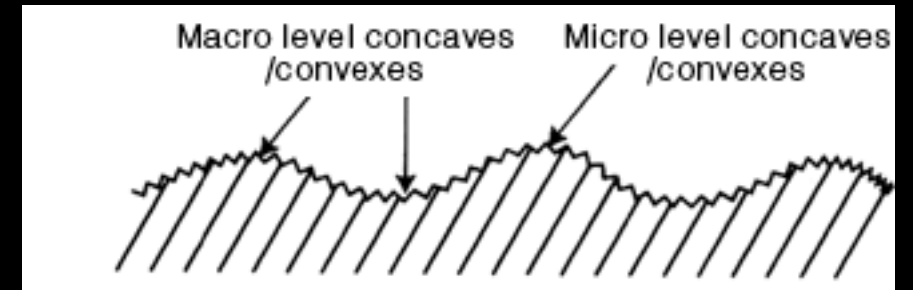
# OPEN HELICAL COIL DESIGN

- **SELF ADJUSTS TO CHANGES IN VEIN DIAMETER AND VALVES**
- **SPECIFIC RADIAL FORCE AND HOOP STRENGTH TO CAUSE MECHANICAL DISRUPTION**



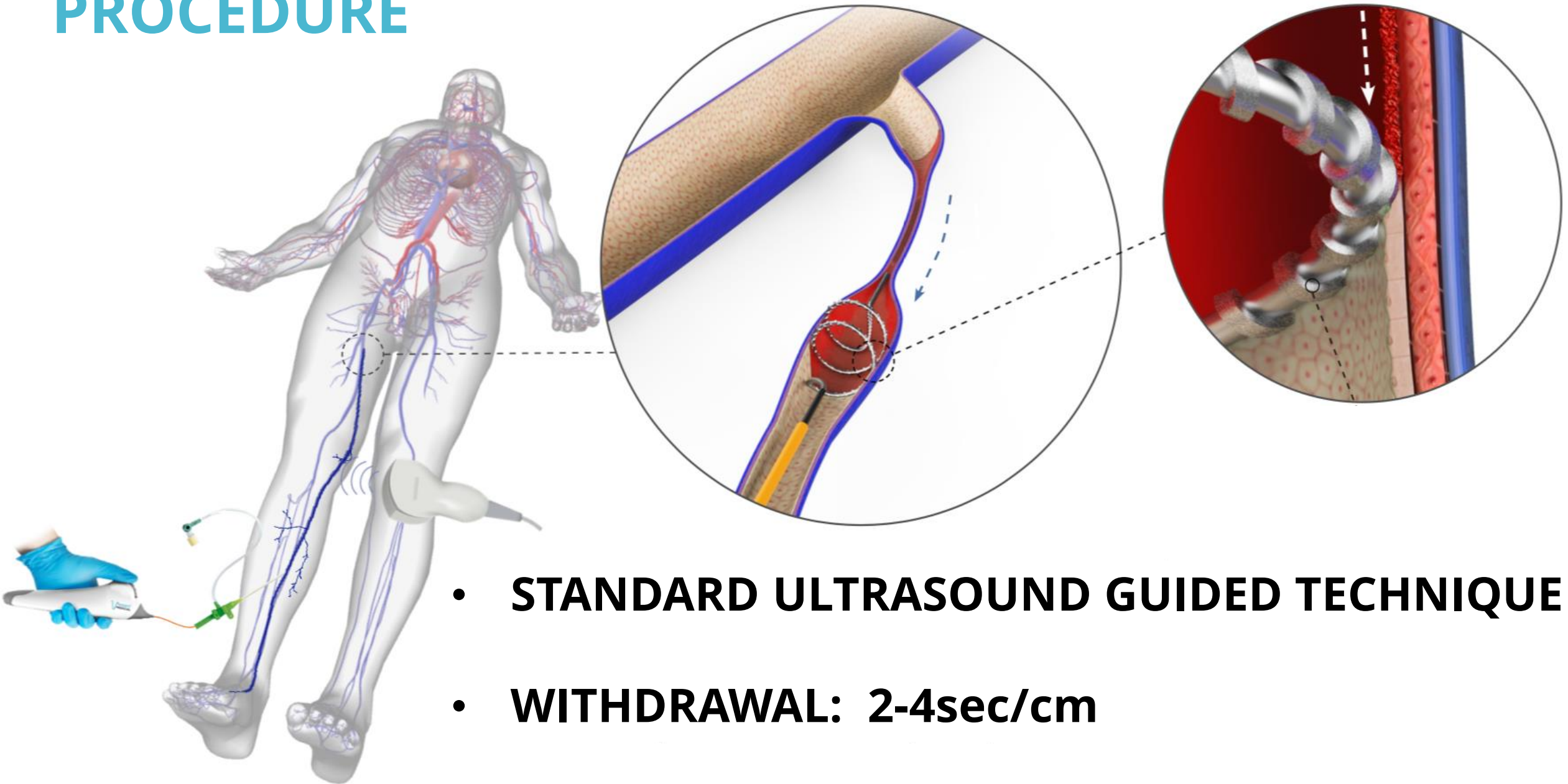
# SURFACE ROUGHNESS

- **HAS MACRO AND MICRO ABRASIVE SURFACES**
- **NOT RELIANT ON ORIENTATION OF OUTER SURFACE TO VEIN WALL**
- **NO HOOKS OR PROTRUSIONS - AVOIDING RISK OF SNAGGING**





# PROCEDURE



- **STANDARD ULTRASOUND GUIDED TECHNIQUE**
- **WITHDRAWAL: 2-4sec/cm**



# WITHDRAWAL PROCESS

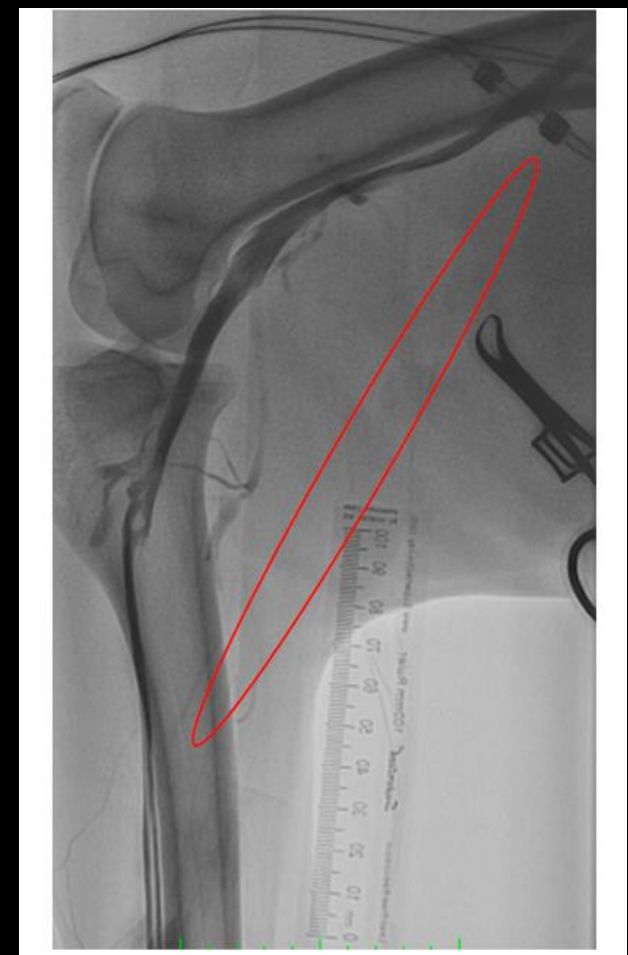
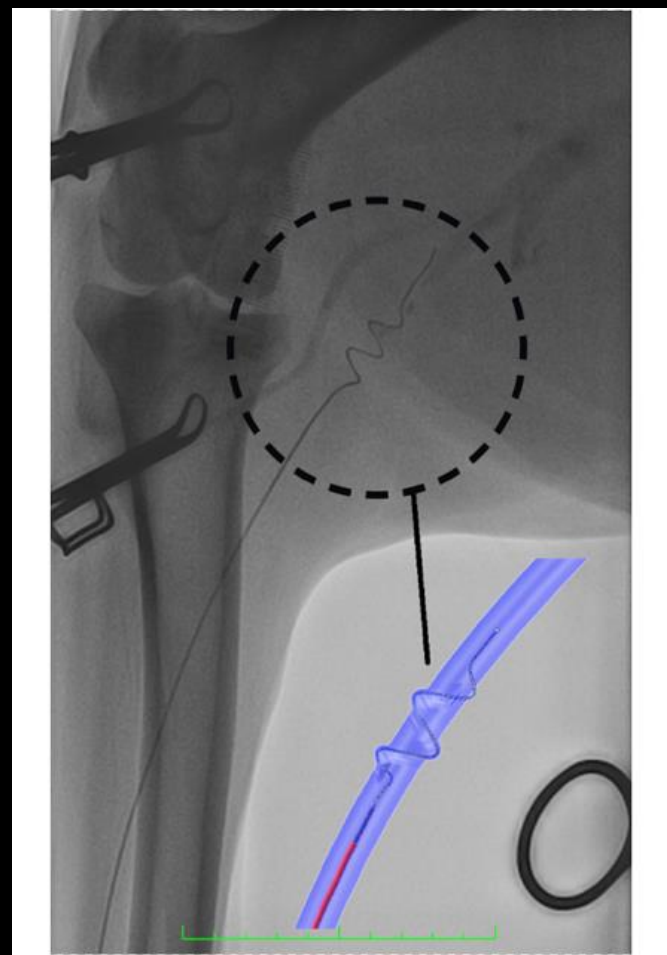
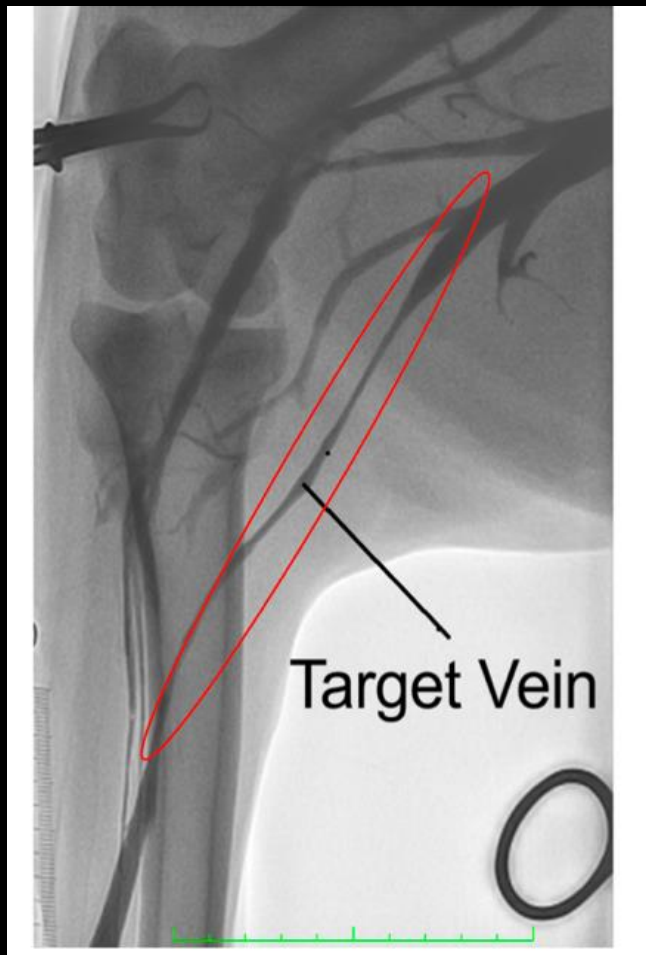
1907090852041

Venous

R: 46 G: 46 B: 46



# BIOVENA™ CLINICAL APPLICATION

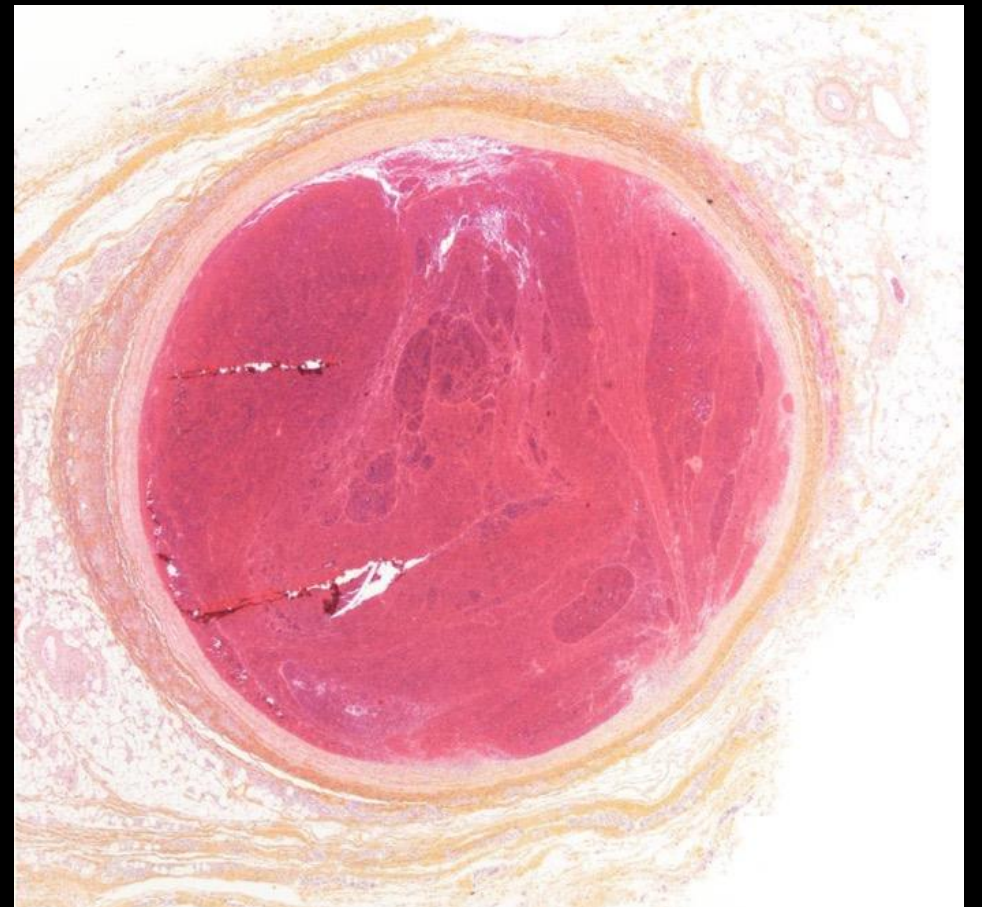


# PRE-CLINICAL STUDIES

Location	Date	Study Title	Number veins treated (animal model)
<b>Semmelweis University, Budapest</b>	May 2018	Acute/Chronic Study	12 (5 goats, 1 sheep)
<b>IMMR Paris</b>	Sept 2018	Acute Study	3 (1 sheep)
<b>Semmelweis University, Budapest</b>	July 2019	Comparative study	14 (5 sheep)
<b>Semmelweis University, Budapest</b>	August 2019	Simulated Use	3 (1 sheep)

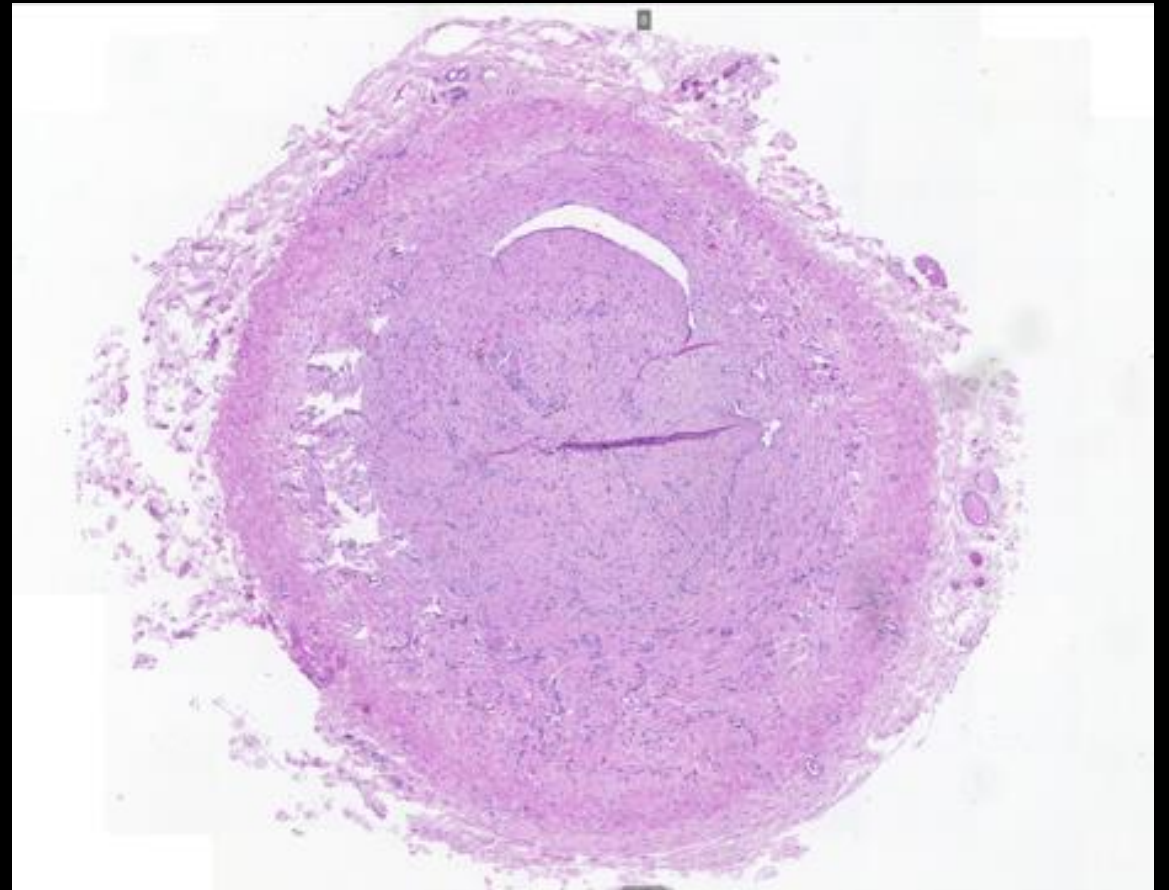
# DAY 7 HISTOLOGY

- **COMPLETE ENDOTHELIAL DISRUPTION**
- **COMPLETE THROMBOTIC OCCLUSION**
- **EARLY FIBROTIC TRANSFORMATION**



# DAY 84

- **MATURE FIBROTIC TRANSFORMATION**



# CONCLUSION

- POTENTIAL FOR A **PURELY MECHANICAL DEVICE**
- NEXT STEPS: VALIDATION IN CLINICAL SETTING



**Internal Compression Therapy - A Novel Method In  
The Treatment Of Deep Venous Insufficiency -  
1.5 Years Clinical Results**

**Lowell S. Kabnick, MD  
Erdinc Eroglu, MD**

# Disclosures

- No conflicts



Treatment modalities are limited in the treatment of deep venous insufficiency and the success rate is low.

- internal valvuloplasty
- external valvuloplasty
- external band
- femoral transposition
- vein transplantation
- neovalve reconstruction (?)
- valve inplant (?)

# Deep Venous Insufficiency (ICT)



**Increased Vein Diameter is the Real Problem!**  
Superficial venous insufficiency (SVI) can be treated with multiple methods. But all treatment methods for SVI are essentially the problematic vein walls by heat ablation, sclerotherapy or surgically removed. These treatment options are not applicable for deep venous insufficiency (DVI). DVI is generally an isolated syndrome that affects health of the chronically in the long run. However, it is believed that there is a best treatment option, success rate is absolutely low.

**Repair & Restore the Function of the Valves**  
ICT works as an end-station for the dilated vein and helps vein to restore original diameter. With the help of end-station, distance between vein valves get closer and valves start functioning right.

**How it Works!**  
ICT works as an end-station for vein valves. Procedure is fast, safe and easy. It can be done in outpatient conditions in minutes. Procedure steps are as follows:

- Mapping and detecting problematic vein valves to be treated with Duplex Ultrasound (DUS).
- Placing a RF introduce sheath between vein and muscle fascia a few cm before the target valve.
- Sending the specially treated RF application catheter to the treatment zone between vein and muscle fascia through the introduce sheath.
- Injection of necessary amount of biopolymer around the vein valve.

**ICT THE NEW VEIN RESTORING MODALITY**  
Internal Compression THERAPY

**Advantages**

- ICT is the first real treatment option for SVI.
- ICT fixes the problematic vein by preserving it.
- It is the only solution for deep venous insufficiency so far.
- It is fast, safe and effective.
- Can be performed under outpatient conditions.
- Patient can return their daily activities immediately.

**INDICATIONS**

- Deep venous insufficiency
- Superficial venous insufficiency accompanying deep venous insufficiency
- Chronic venous insufficiency



???

Hyaluronic acid  
Polidocanol  
Cyanoacrylate

# Materials and Methods

- **30 patients** with venous insufficiency October 2017 - February 2018 and diagnosed as isolated deep venous insufficiency were included in the study.
- Preop Common Femoral vein diameters, reflux duration, VCSS values and
  - procedure duration was recorded post operatively.
- Follow-up visit: 1, 6 and 18 months

# Demographics/Procedure Duration

- Age (year) :  $40.9 \pm 7.6$  (29-56)
- Sex (M/F) : M 40% (12); F 60% (18)
- Duration (min) :  $22.7 \pm 2.9$  (20-30)



# Results

	<b>Preop</b>	<b>Post op</b>	<b>1 month</b>	<b>6. months</b>	<b>18. months</b>	<b>p</b>
Vein Diameter (mm)	12.7 ± 0.9	9.9 ± 0.7	10.0 ± 0.7	9.9 ± 0.7	9.9 ± 0.7	<0.001
Reflux Duration (sec)	3 (2-6)	0 (0-0)	0 (0-0)	0 (0-1)	0 (0-1)	<0.001
VCSS	11 (10-13)		8 (6-10)	7 (4-9)	6 (4-9)	<0.01

# Conclusions

- feasibility study presents 18-month results of ICT application in patients with deep venous insufficiency revealed high clinical success and patient satisfaction

Additional trials will be needed with longer follow up

# Thank you

- [lsk@lowellkabnickmd.com](mailto:lsk@lowellkabnickmd.com)

