Vein & Lymphatic University | AVLS | American Venous Forum | SVS Society for Vascular Surgery

Superficial Devices in Clinical Trials Not Approved

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VEITH SYMPOSIUM

Disclosure

Consultant: InVera, MedVasc

Speakers Bureau: Angiodynamics, Boston Sci, BD, InVera

Research: Boston Sci, BD, InVera, Amsel

Royalties: Angiodynamics

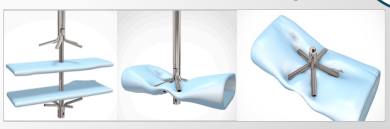
New Venous Devices
Undergoing Trials

Percutaneous Minimally Invasive Clamping Technology

Need for a secure clamp that is self-sealing and through an 18 g needle

THE SOLUTION

SCureClamp® Breakthrough

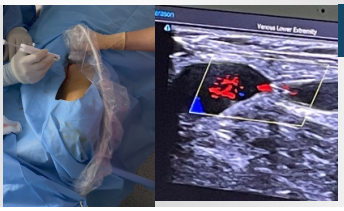


Transfixing *Atraumatic Clamping* *Self Sealing*

Technology paradigm shift in minimally invasive surgery through precise, highly targeted, minimally invasive procedures delivered through a small needle.

FEASIBILITY STUDY

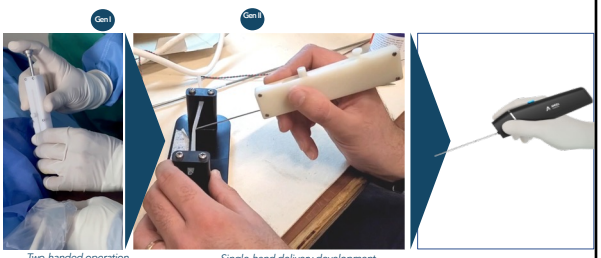
Conducted First in Human Clinical Procedures



Percutaneous Vein Ligation

- ***Average Procedure Time <10 min***
- ***High Safety Profile (12 mo. follow up)***
- ***Significant Improved Patient Quality Of Life Outcomes***

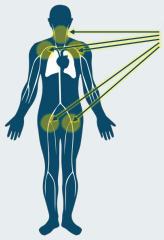
GEN II DEVELOPMENT



Two-handed operation *Single-hand delivery development*

TRAUMA APPLICATION

Military and Civilian Market

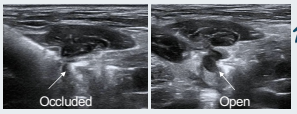


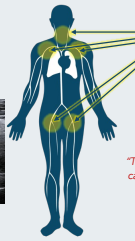
Non-Compressible Junctional Hemorrhage Sites (Neck, Shoulders, Groin)

TRAUMA

Temporary Occluder

Arterial Injury Clamping





Non-Compressible Junctional Hemorrhage Sites (Neck, Shoulders, Groin)

Regions where torniquets cannot be applied

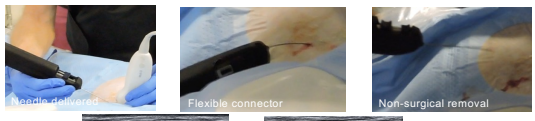
"The most significant preventable cause of death in the prehospital environment is external hemorrhage."

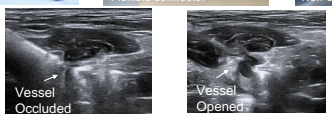
TRAUMA SOLUTION

SCureTO™ (Temporary Occluder)

AMSEL MEDICAL

Saving Limbs Saving Lives



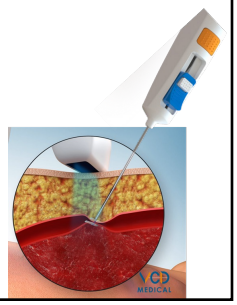


Non-Compressible Junctional Hemorrhage Control

- prolongs the "golden hour" and prevents the reperfusion syndrome

VCD MEDICAL DEVICE

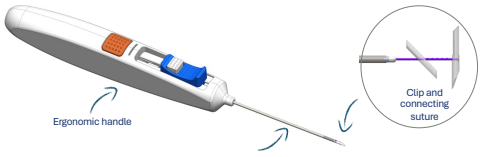
Device Feature	Specification
Clip length	13 mm (0.5'')
Clip material	PLGA
Stainless steel cannula	17 G
PDO suture	2-0 (barbed)
Implant degradation time	6-12 months
Target vein diamter	Up to 11 mm



USE

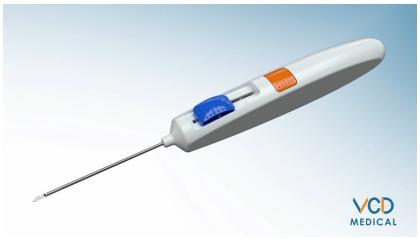
selective closure of superficial veins through US-guided percutaneous access.

transfixes and ligates target vein with an absorbable clip preloaded in a low-profile cannula.



New Superficial Venous Devices: Pre-FDA Approval

HOW IT WORKS



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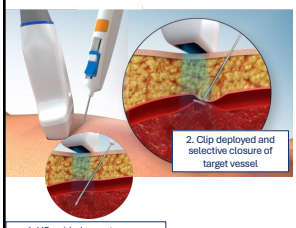
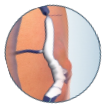


USE IN CLINICAL PRACTICE



Clip the **GSV** and **combine with non-thermal** technologies to **maximize effectiveness** and **minimize thromboembolic risk**.

Rx tortuous collaterals, CHIVA, SSV ligation + foam, etc

New Superficial Venous Devices: Pre-FDA Approval

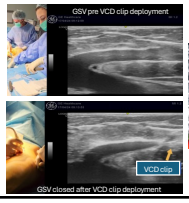
VCD MEDICAL

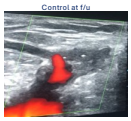
CLINICAL EXPERIENCE: FIH TRIAL

24 patients successfully treated in First In Human trial using VCD combined with PCF.

- Treatment with VCD proven to be **safe** and **feasible** in all the patients.
- **Vein diameters treated up to 16 mm**
- **All GSV occluded** at control[1].
- **No major Adverse Events**[1] after 4.6 months average f/u.

VCD use for **GSV** treatment (FIH)

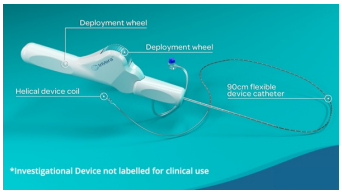




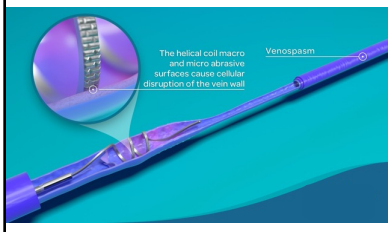
Promising results after use of VCD in the treatment of **collaterals** and **perforators** (FIH).

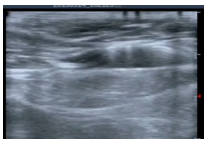
InVera

1. MECHANICAL ONLY
2. MECHANICAL CHEMICAL

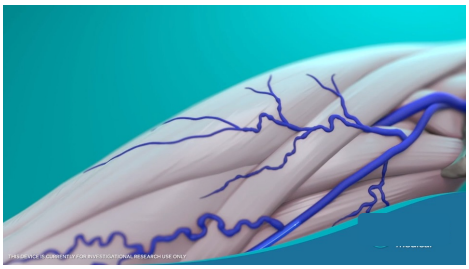


Mechanical Only Mechanism of Action





InVera Procedure Video

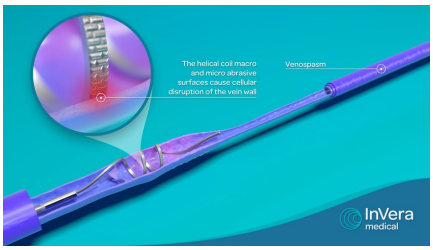


Pilot Clinical Trial : Mechanical-Only

- N=13 patients EU study *(PI Dr Attila Szabó, Hungary)*
- Significant improvement in Quality of Life (HASTI) at 6 months
- 53% (7/13) Ultrasound Responder rate at 6 months = substantial diameter reduction, 1 patient complete closure
- Proven Safety profile, no device related adverse events
- Well tolerated with single injection Local Anesthetic
- Summary : Safe and Effective inducing Vein wall fibrosis, High recanalisation rate

Co-funded by the European Union

InVera Mechanical Chemical Ablation



Mechanical Chemical Pilot Clinical Trial : Interim Results

N=3 patients (C2 to C4) enrolled EU study *(PIs, Dr Imre Bihari, Dr Attila Szabó Hungary)*

No Adverse Events

Ultrasound Closure and elimination of truncal reflux in all patients at 3 month follow up

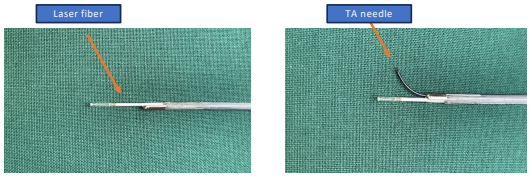
- Improved clinical (rVCSS) and Quality of Life (HASTI) scores
- Recruitment ongoing

Co-funded by the European Union

Solutio™ by MedVasc

A new catheter, for tumescent anesthesia delivery when treating varicose veins

Solutio™



MED Vasc

WITH SOLUTIO

Solutio™ First-in-man clinical study

9 consecutive patients

- 8 (89%) women and 1 (11%) man
- 57 years mean age (min 35y max 76y)

Insufficiency of GSV from SFJ to proximal ⅓ of lower leg,

- 34.1cms mean length treated (min 20cm, max 46cm)

Pain score during deployment of tumescent

- 0.8 mean value (min 0, max 2,4, median 0,5) VAS max 10.

No serious adverse events on follow up.

2 mild device deficiencies (corrected Gen 2)

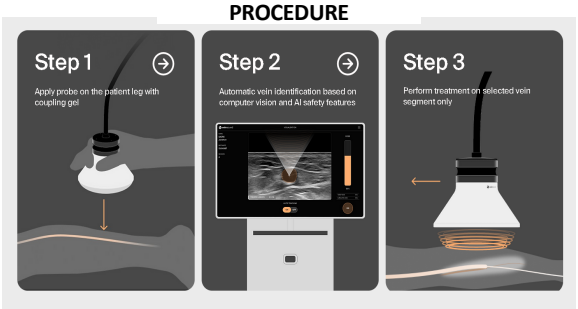
The catheter was reported safe and easy to use.

VEINSOUND

Veinsound uses High-Intensity Focused Ultrasound (HIFU) to obliterate varicose veins by non-thermal cavitation.

It works by exciting the small air bubbles naturally present in the veins. These bubbles oscillate until they collapse, effectively scouring and treating the inner walls of the vein.

PROCEDURE



WHAT IS CAVITATION

HIFU can induce cavitation, which involves the formation and collapse of microbubbles within the vessel. This process can lead to vessel occlusion through several mechanisms:

1.Mechanical Damage: The rapid collapse of these microbubbles generates shock waves and high shear forces, causing mechanical damage to the vessel walls.

2. Radiation Force: The ultrasound waves exert a force on the vessel walls, which can contribute to the mechanical disruption and eventual closure of the vessel[3].

Cavitation Effect: When ultrasound waves are directed at the targeted vein, they create rapid oscillations in the tissues and blood, producing microscopic bubbles. These bubbles form and collapse quickly (known as cavitation), generating high mechanical stress and heat at the targeted location.

When using High-Intensity Focused Ultrasound (HIFU) for vein treatment with a focus on cavitation rather than thermal effects, the mechanism relies on the creation of tiny bubbles within the liquid environment of the blood vessel. Here's how cavitation works in this context:

1.Focused Ultrasound Waves: The HIFU device sends high-frequency sound waves that are focused onto a small, specific area within the blood vessel. Unlike thermal-based treatments, this approach uses the mechanical effects of ultrasound rather than heat.

2.Formation of Microbubbles: The high-frequency ultrasound waves cause rapid oscillations in the liquid environment (blood) at the target area. This results in the formation of microbubbles due to fluctuations in pressure. These bubbles can grow and contract as the ultrasound waves continue to pass through the liquid.

3.Collapse of Bubbles (Inertial Cavitation): Once the microbubbles reach a certain size, they collapse or implode, a process known as inertial cavitation. This implosion generates strong mechanical forces, shock waves, and shear forces in the surrounding liquid and vessel wall.

4.Mechanical Damage to Vessel Walls: The intense mechanical energy produced by cavitation damages the endothelial cells lining the vein walls. This mechanical disruption can cause the vein to lose its structural integrity, leading to vessel closure.

5.Inflammatory and Fibrotic Response: As the vein wall is damaged by the mechanical forces, the body responds with an inflammatory reaction, eventually leading to fibrosis (scar tissue formation) within the vein. This fibrosis helps to seal off the vein, preventing blood from flowing through it.

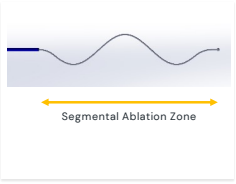
6.Minimizing Thermal Effects: By adjusting the parameters of the ultrasound (frequency, pulse duration, and intensity), HIFU can be tuned to maximize cavitation while minimizing heat production. This allows for vein closure through mechanical forces alone rather than thermal coagulation, making it a safer option in certain cases where thermal damage might be risky.

In summary, cavitation via HIFU relies on generating and collapsing bubbles to apply mechanical stress to the vein walls, causing structural damage that leads to vein closure without relying on thermal effects. This non-thermal approach has potential applications in vein treatment, though more research is needed to refine its efficacy and safety.

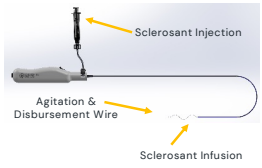
SONOVEIN FDA TRIAL (Thermal) (in progress)

WAVELLA: Segmental MOCA

Similar Treatment Length as Medtronic RF Catheter



Straightforward Drug Infusion Over Mechanical Dispersion Wire



To be presented by S. Elias