

MechanoChemical Endovenous Ablation: Final Results of First Clinical Trial

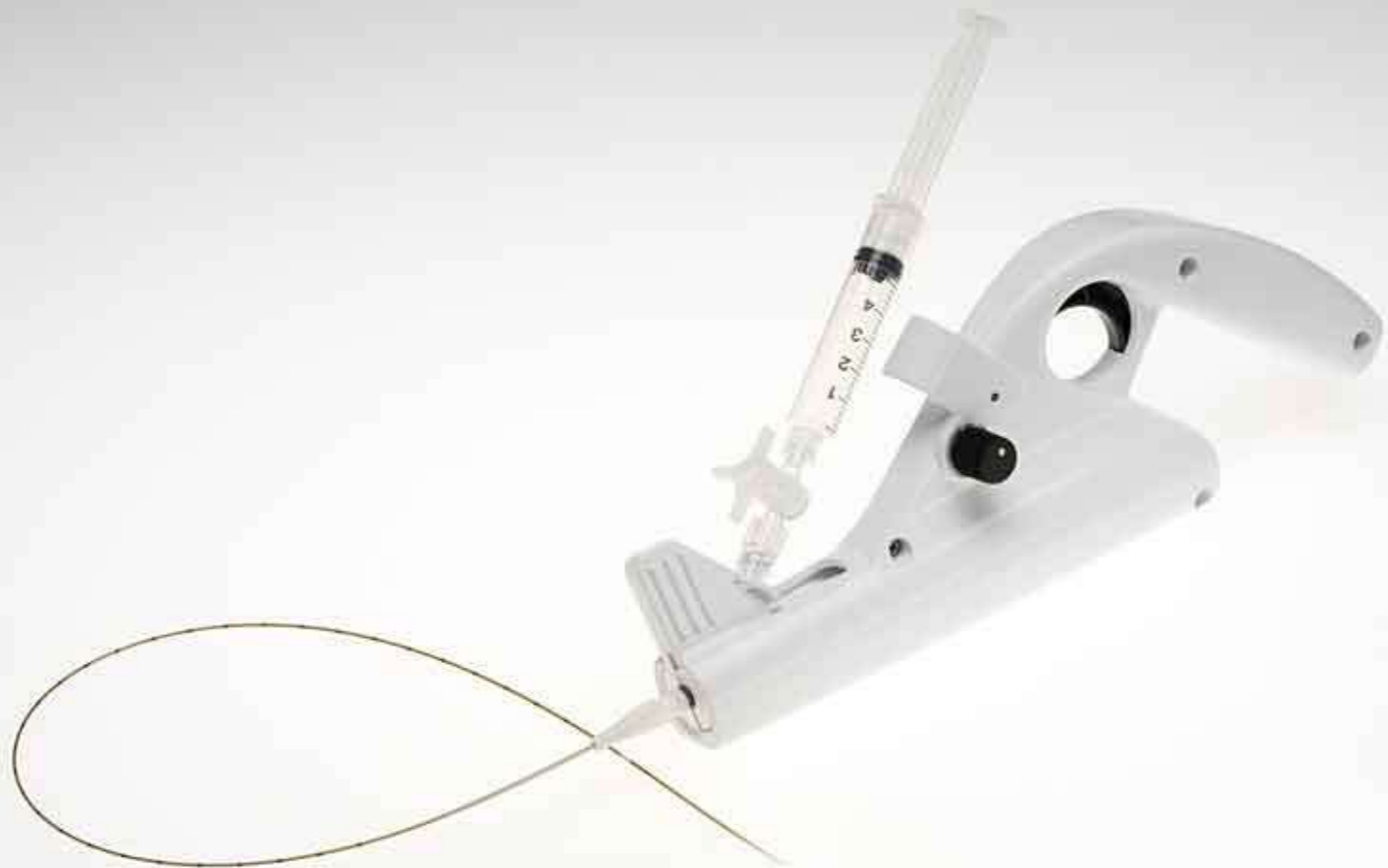
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Words To Live By:

- Respect the elders,
- Embrace the new,
- Encourage the improbable and impractical
- Without bias

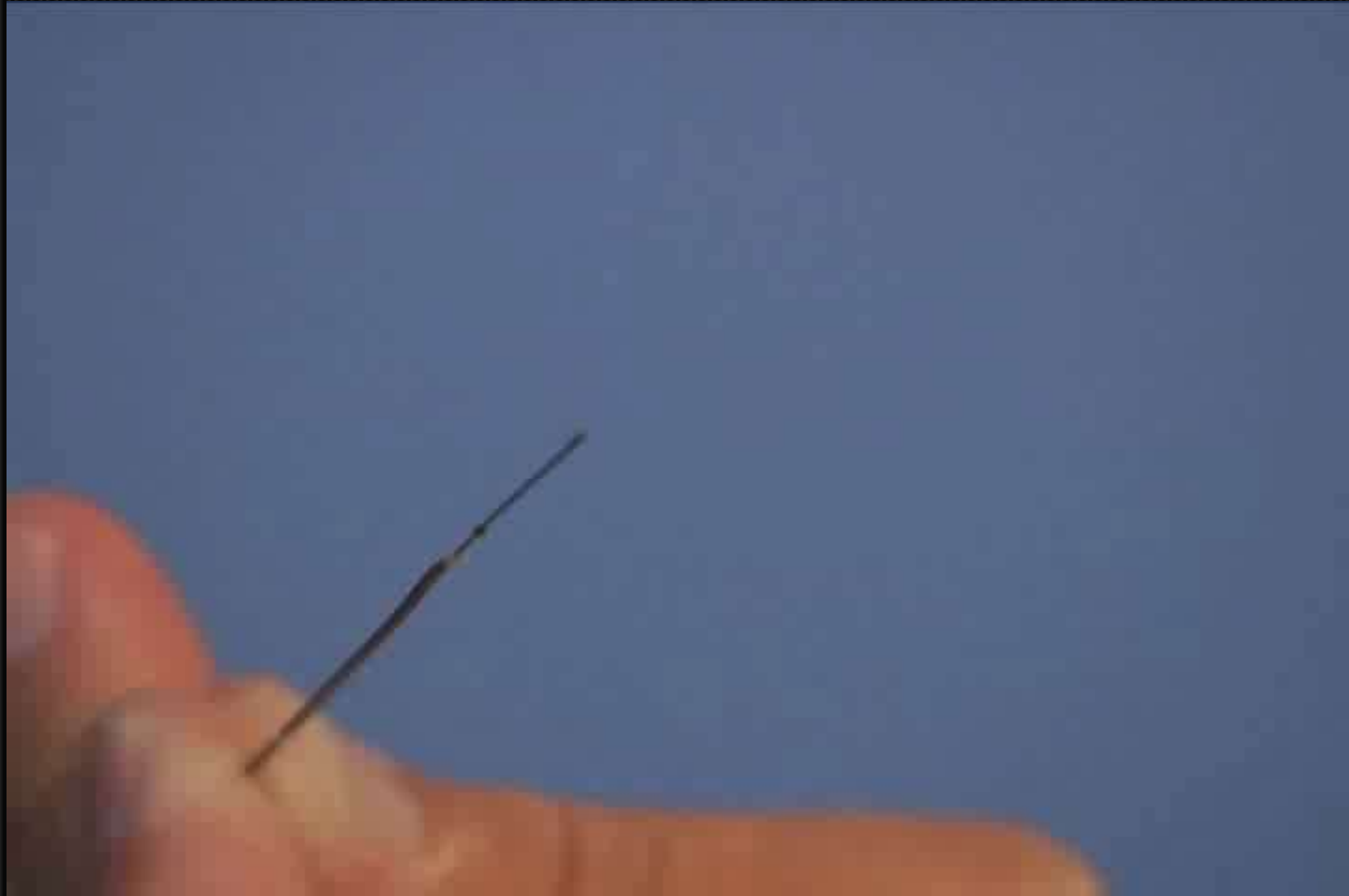
What Is It? ClariVein™



How Does It Work:

- **Combination** – endovenous mechanical and sclerotherapy
- **Endovenous** – wire > rotates > intima damage
- **Sclerosant** – liquid > penetrates > scar
- **End result** – venous occlusion

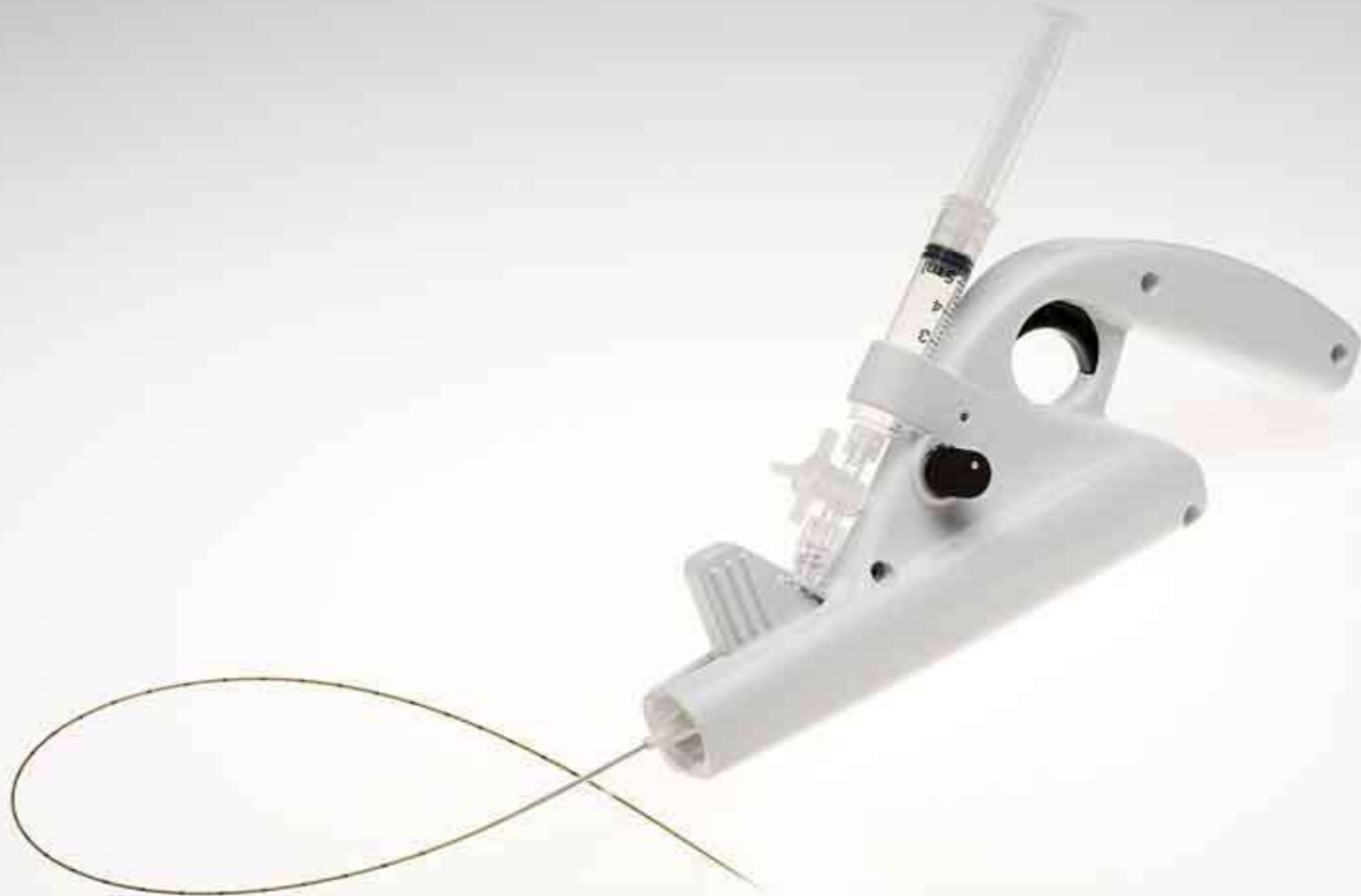
Mechanical Component



Chemical Component



Mechano - Chemical Summary



APET: Steps of EVA

RF/Laser

- A - Access
- P - Position
- E –Exsanguinate
- T –Treat
- APET

ClariVein

- A – Access – **simpler**
- P – Position - **same**
- E - **No Tumescence**
- T – Treat – **faster**
- **APT**

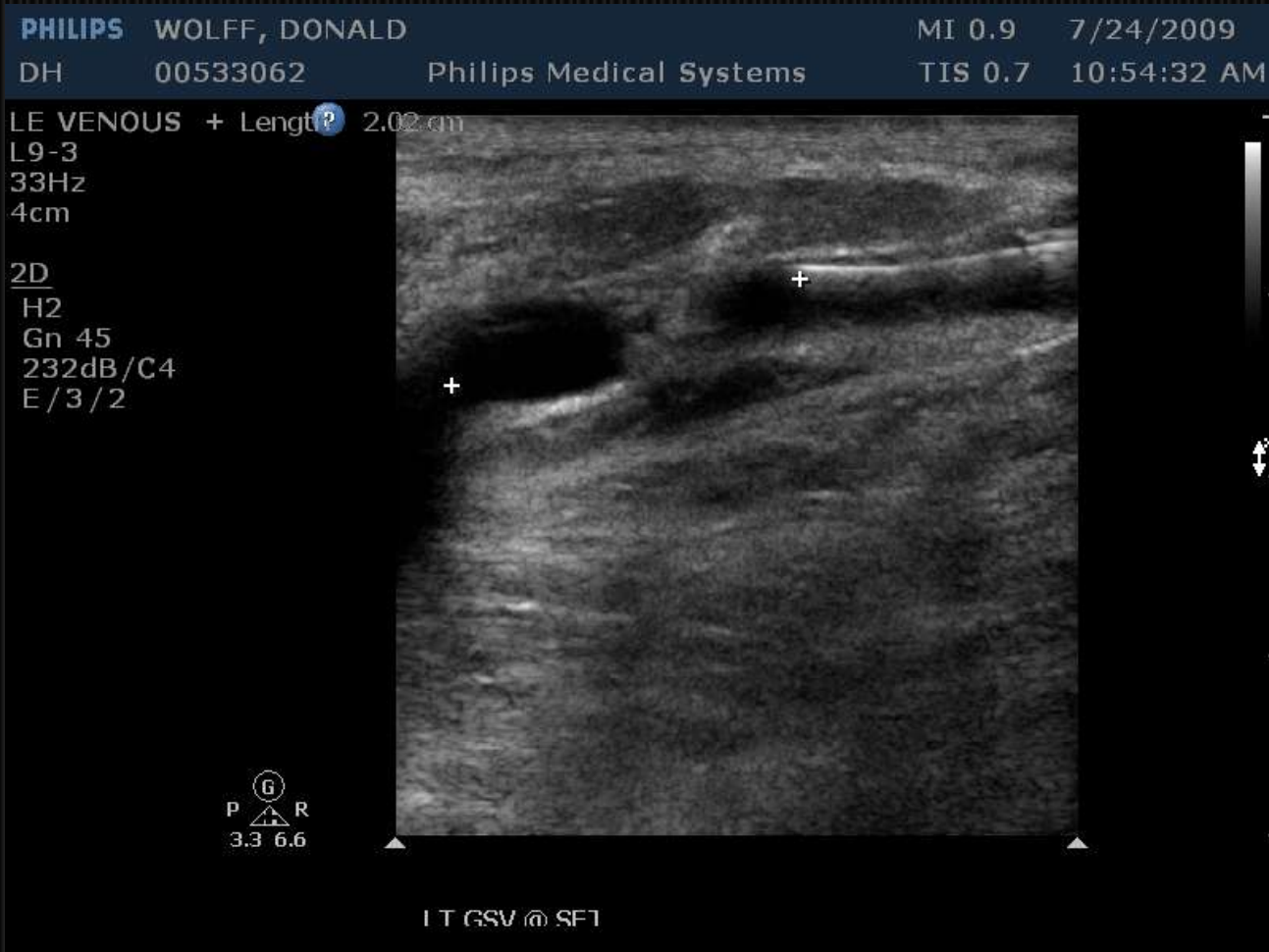
Access: ClariVein

- Percutaneous ultrasound guided
- 4 fr. micropuncture sheath
- 18 gauge IV access
- No further wires or larger sheath exchange

Position: Wire exposed



Position: Wire 2 cm SFJ



Treat: ClariVein

- Pullback 1.0 – 1.5 mm. per second
- Inject during pullback
- Sodium tetradecyl sulfate 1.5%
(or equivalent sclerosant)
- Injection rate limited by catheter lumen size
(12cc of 1.5% STD)

Treat SFJ: Rotate and Inject



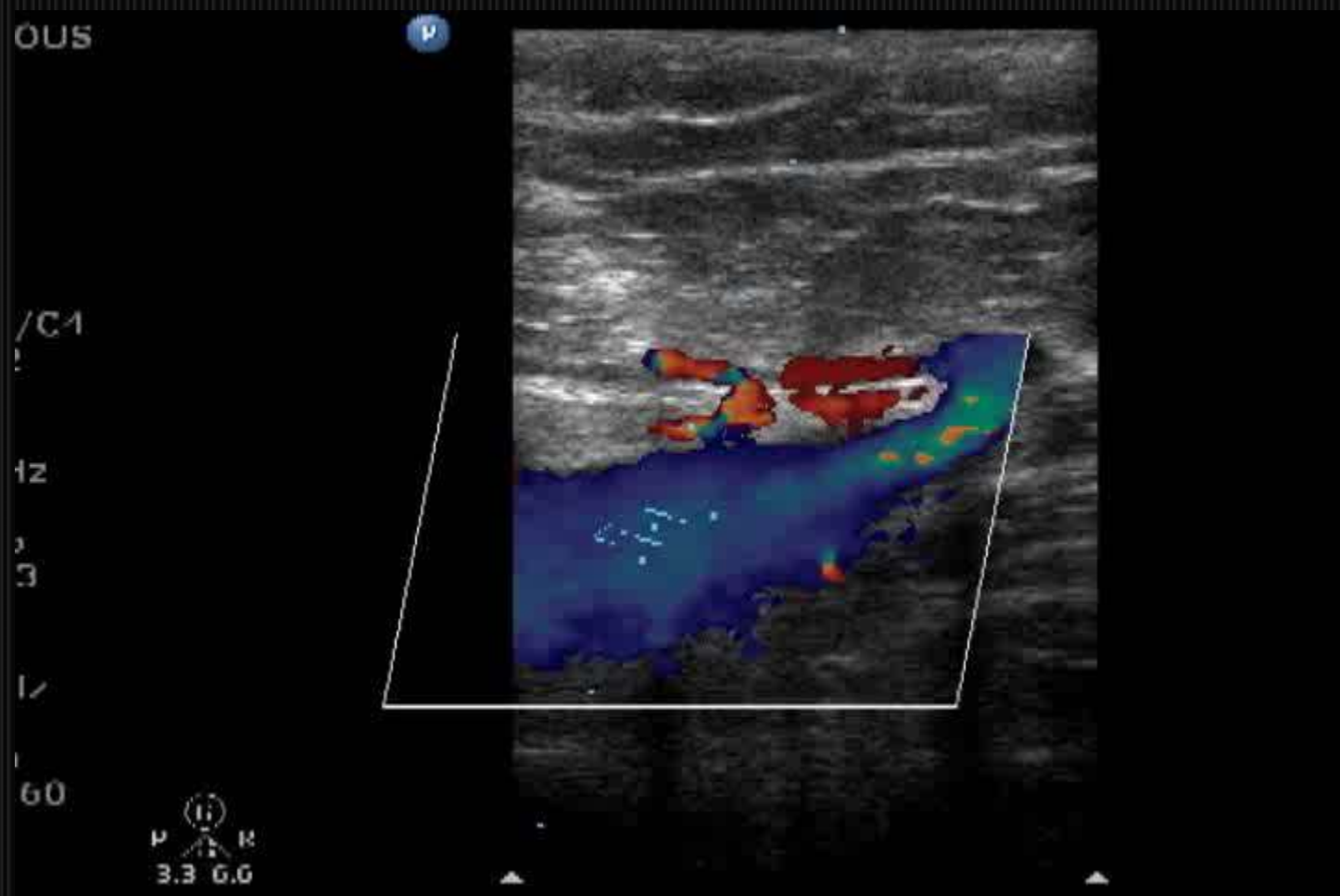
Treat Mid GSV: Wire/Sclerosant Mix



Treat: Injection & Pullback



Post Treatment: SFJ



Post Treatment:

- Compression X 48hrs
- Compression 2 weeks
- Full activity (exercise, lifting etc.)

Clinical Trial: ClariVein

- 30 limbs
- GSV only
- C₂ – 24 C₃ – 2 C₄ – 4
- Avg. 55 years
- Treat GSV only (no treatment VV or IPV)
- 6 month follow up to complete trial
- **No tumescence or sedation**

Procedure Statistics: ClariVein

- GSV size – 8.1 mm.
- GSV length treated – 36 cm.
- GSV treatment time – 5 min.
- Overall treatment time - 14 min

Completed Trial - 6 Month F/U

- All GSV closed except 1st patient – competent
- 1 month – 30
- 3 month – 29/30
- 6 month – 29/30
- 12 month – 22/22

Complications

- Subcutaneous ecchymoses – 3 pts.
- Side branch tear?
- **No** DVT
- **No** nerve injury
- **No** skin injury

Advantages: Real/Theoretical

- Minimal risk – nerve, skin, DVT, discomfort
- Fast and simple – less steps
- Treat lower (ankle, calf, SSV) or residual GSV
- Some branch VV/ IPV treated at same time
- No tumescence or sedation
- No thermal injury risk
- No energy source - generator

Limitations:

- 30 patients –safety and efficacy
 - (55 since trial) (Europe 3 month)
- Follow up 6 months (22 to 1 year)
- Recanalized post thrombotic GSV/SSV
- Large veins > 12 mm. – not in trial (19mm)
- SSV – not done in trial – 9 post trial occluded

Perspective September 2009:

- Another good option
- Simpler
- Faster
- Capital cost less
- **Tumescentless** – already there
 - everyone else is trying
 - RF/ Laser/Varisolve
- “Foam rescue” – small segments recanalize
- Most GSV or SSV

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