enveno MEDICAL

Setting New Standards for Venous Care

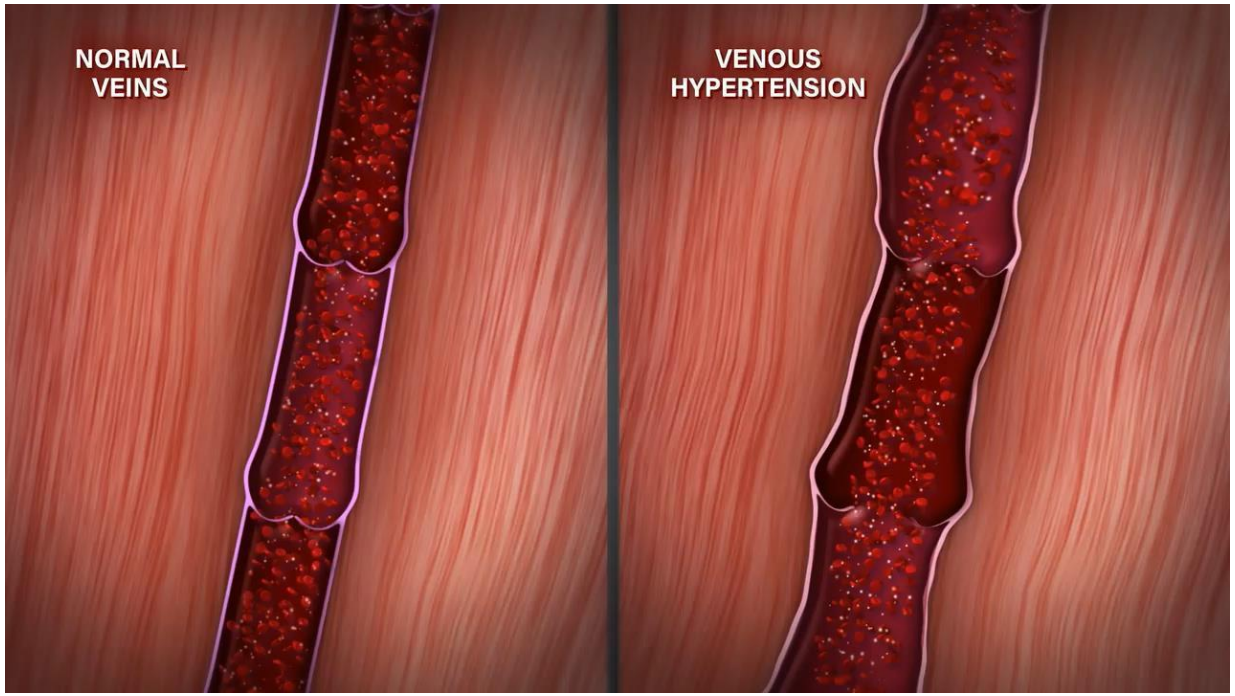
Insertion of Bioprosthetic Femoral Venous Valve Implant

ICD-10 C&M Committee Meeting

March 7, 2023

Chronic Venous Insufficiency (CVI)

Occurs as a result of increased venous pressure (venous hypertension) within the veins of the leg, most often caused by failure of valves within the veins



Leads to:

- Reflux – blood flows in the wrong direction
- Blood pooling in the lower leg
- Venous hypertension
- Pain
- Edema
- Ulceration

There are approximately 2.4M patients in the US affected by CVI[1]

1. Yost, Mary, The Sage Group, Chronic Venous Disease, Epidemiology, Costs, and Consequences, 2016

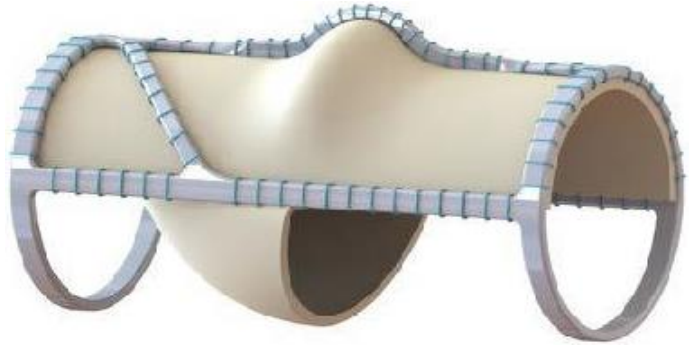
VenoValve

The VenoValve was developed for the treatment of deep venous Chronic Venous Insufficiency (CVI).

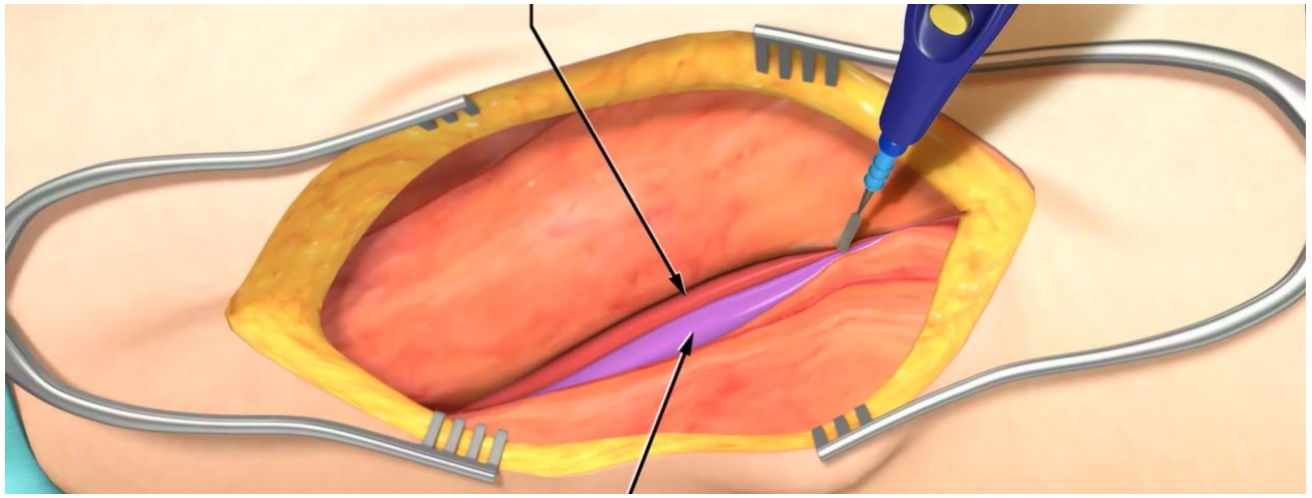
- When implanted into the femoral vein, the VenoValve is designed to act as a one-way valve to help restore proper blood flow up the leg, to return sufficient blood back to the heart
- The VenoValve is made from porcine monocuspid biological component mounted in a rigid supporting metal frame

Other terms to describe VenoValve

- bioprosthetic valve
- venous valve
- venous valve implant



Implantation Procedure

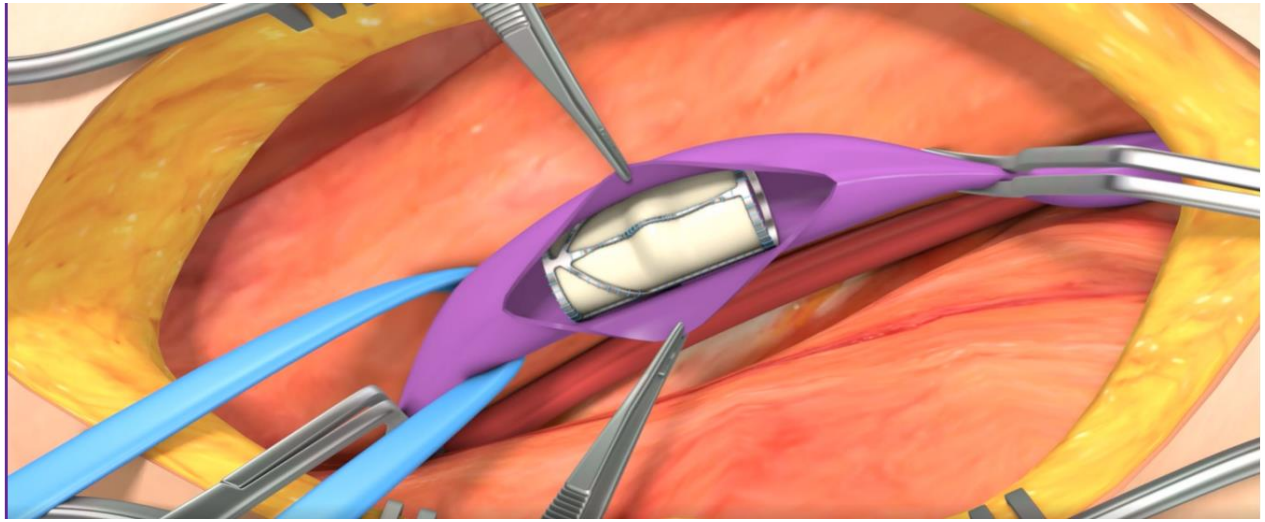


1

A “lazy-S” incision is made in the mid to upper thigh. The femoral vein is identified and isolated.

2

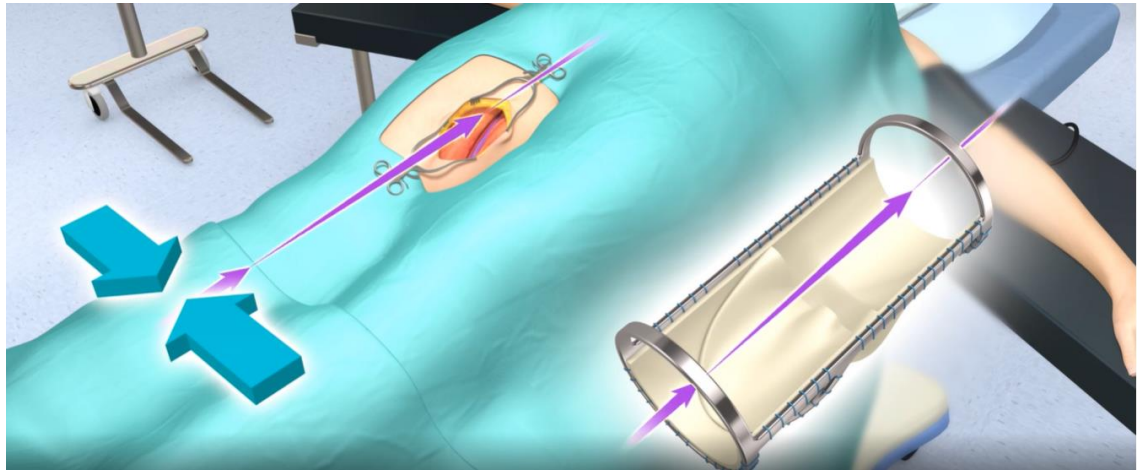
A longitudinal venotomy is performed. The VenoValve is inserted through the venotomy and tacked in place within the vein. The venotomy is then closed.



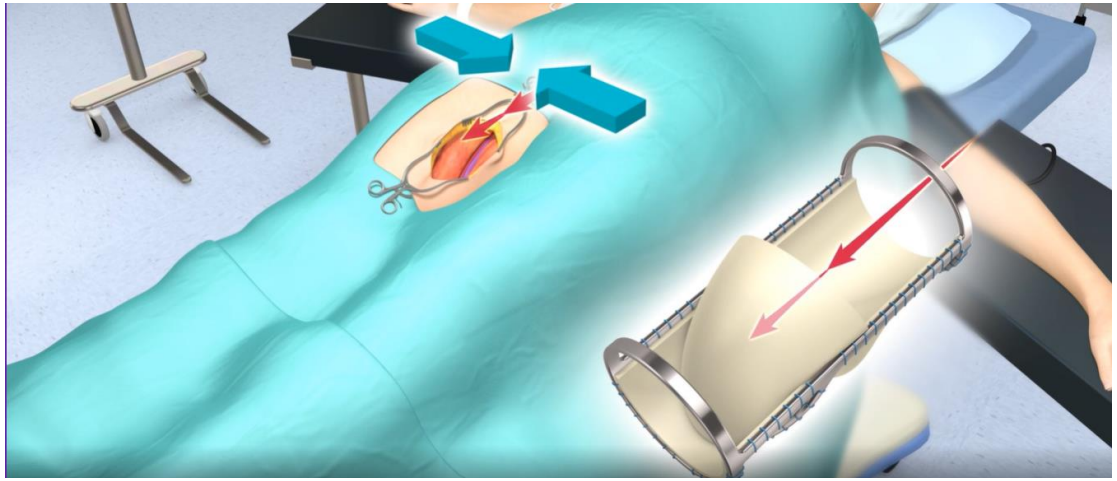
Implantation Procedure

3

After blood flow is restored, the calf muscle is compressed to ensure the venotomy does not leak and that blood flows correctly through the VenoValve. Once proper functioning is confirmed, the incision is closed.



When the calf is compressed, pressure in the femoral vein increases and blood flows up the leg through the VenoValve



When pressure in the femoral vein decreases, the VenoValve leaflet deploys, preventing backwards flow of blood

Procedure Details

The VenoValve is permanently implanted in the femoral vein only and details of the procedure would be documented in the operating room report

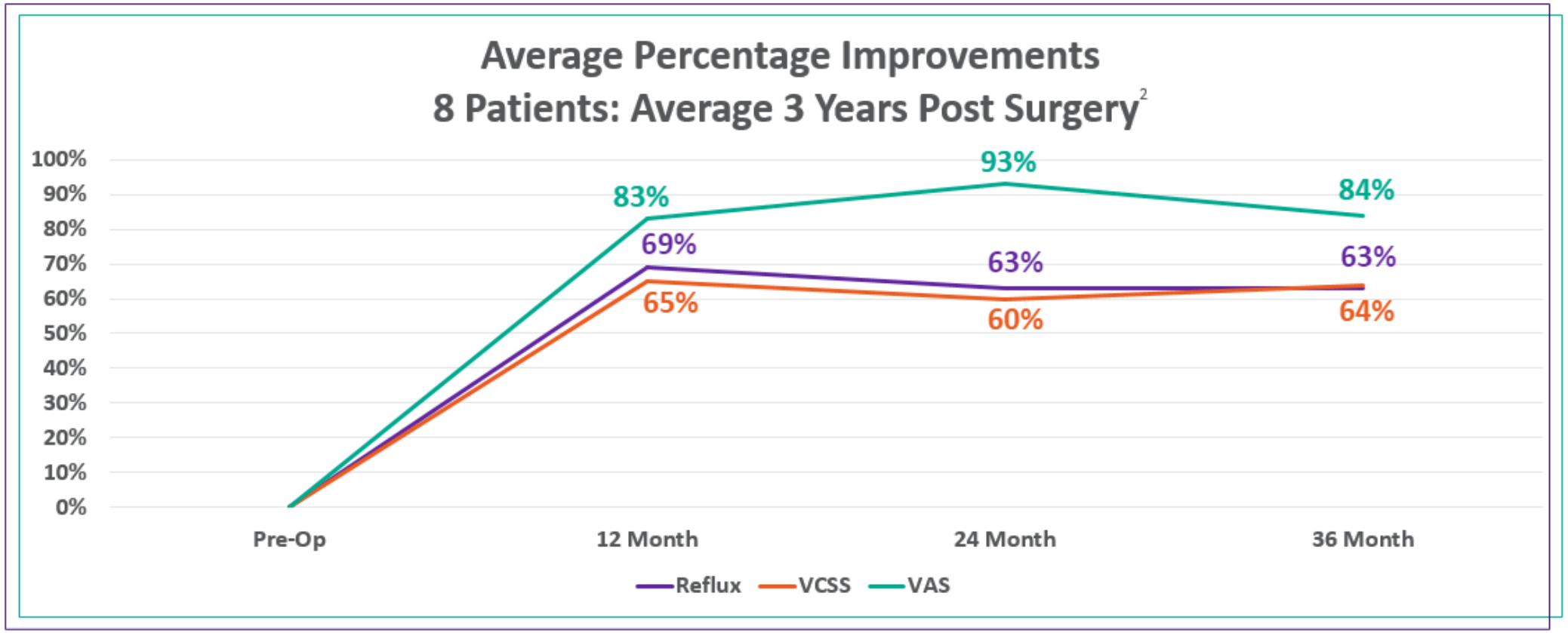
- Only one VenoValve is implanted in each leg. It is not expected that bilateral procedures would be performed at the same time
- If the patient also has stenosis in his or her femoral vein or a deep vein thrombosis clot, they may need a stent placed or a thrombectomy, however this is not expected to be routine and would likely be performed separately

Safety issues in first year included 1 seroma (which was aspirated), 3 minor wound infections, 1 over anticoagulation and 1 occlusion due to patient non-compliance.

- Year 2 there were no reported adverse events; one reported case of contralateral ulcer development.
- Year 3 had 1 report of occlusion due to patient non-compliance

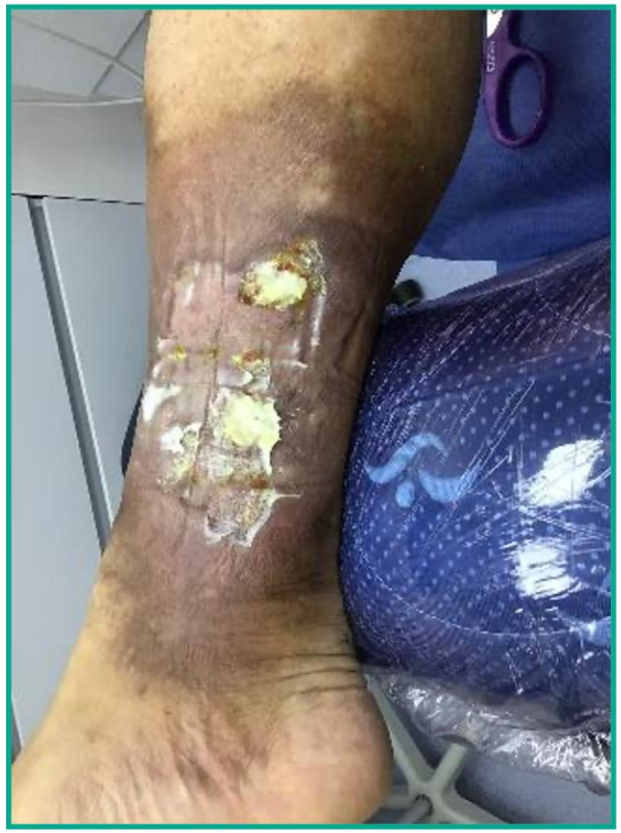
Results from First-In-Human Trial

Improvement is Maintained for 3 Years for all Endpoints



2. 36 month results for 8 patients compared to Pre-VenoValve® implantation

Venous Ulcer Healing After VenoValve Implant



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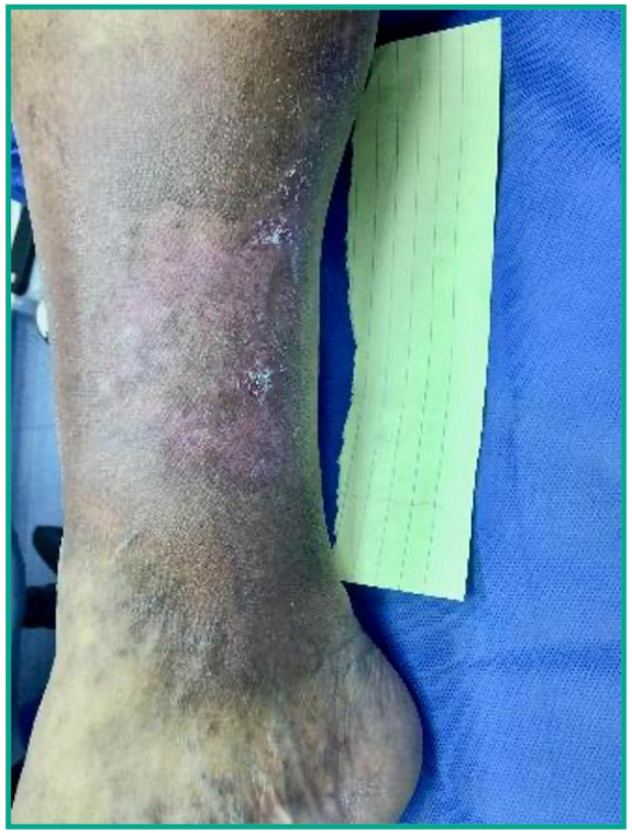

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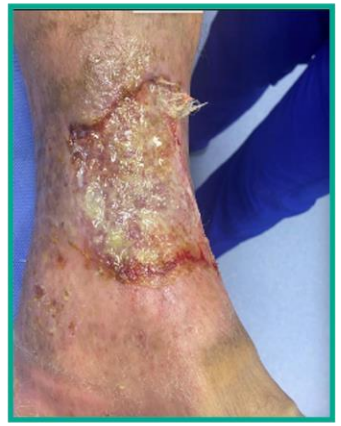

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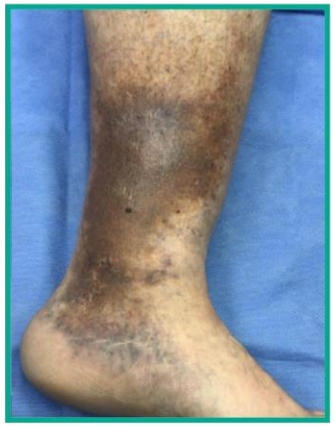

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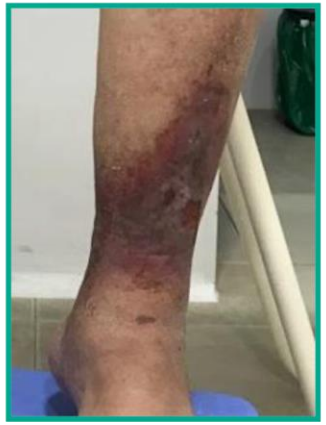

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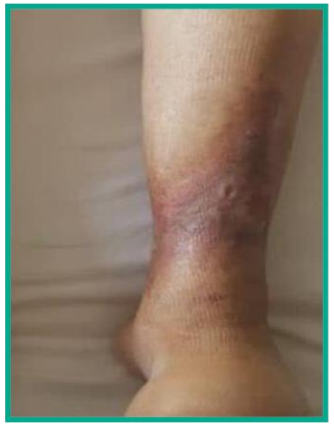

AFTER

Results from first in human trial

Summary

- The VenoValve is currently being studied in a pivotal trial and expected to be FDA approved in Q1 2025

- No existing ICD-10-PCS code currently describes the implantation of a bioprosthetic valve into the femoral vein

Thank you