Endovenous Delivery Of New Valve Prosthesis In Humans: The New Trend

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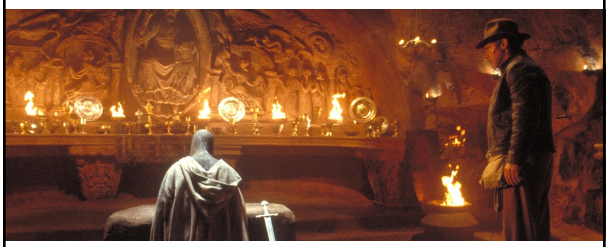
Deep Venous Reflux



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Deep Vein Valve Te

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InnoVein	...ted OUS, ...boptimal ...lts **Closed**
	Company ceased operations/funding

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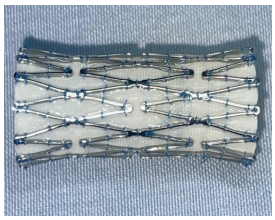
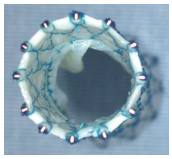
EnVVe system: 3 layers, Nitinol, PET Skirt, Porcine Pericardium with Valve





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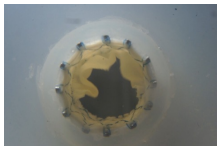
Valve Function

- The enVVe Valve function and the physiological conditions it experiences in vivo are significantly different from what a cardiac valve may experience.
- The higher flow rate conditions (e.g., 2 LPM) are still low compared to aortic valve conditions and are not associated with shear induced blood damage. Therefore, the "worst case" is still the low flow condition.
- Potential for turbulence is low due to low flow rates.
- PV leakage is a relatively small percentage of total leakage, particularly on a venous valve. PV leakage might create high velocity jets that can damage blood; however, the velocity is not at a meaningfully high level for a venous valve



High-speed Video of Opening/Closing of 12mm size enVVe Valve at 100 Million Cycles of Durability Testing

Valve Type	Condition	Simulated Cardiac Output (mLPM)	Opening/Closing Rate Per Minute	Mean Pressure (mmHg)	Systolic Duration (%)
Venous Valve	Supine Rest	350	35	12	73
	Standing Rest	200	20	55	65
	Walking	800	40	30	65
	Worst Case	2000	80	75	65
Aortic Valve	Normotensive	5000	70	100	35

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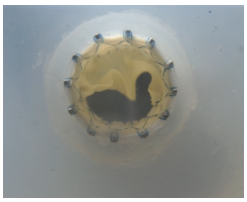
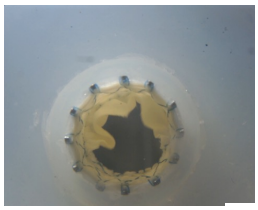
Evaluation of Durability of Leaflets

Baseline



100 Million Cycles



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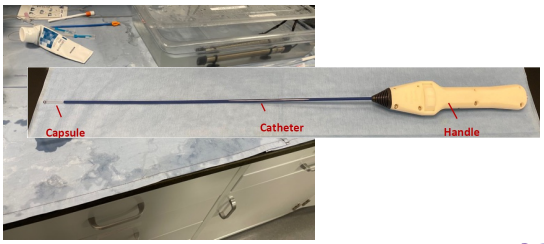
Delivery System, 13Fr



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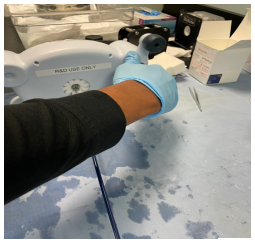

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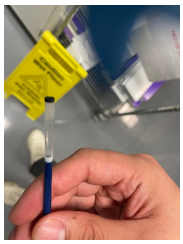
Marker Cath and Crimping of the Device



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Sizing

3 sizes available

Device Size	Vein Size
9mm	7.5 - 8.5 mm Vein
10 mm	8.5 - 9.5 mm Vein
12 mm	9.5 - 11.5 mm Vein

Measurements for sizing includes: Largest size

Duplex imaging of Femoral Vein in standing position

Venography sizing with marker wire

IVUS measurements at rest and with fluid expansion

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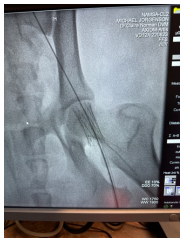
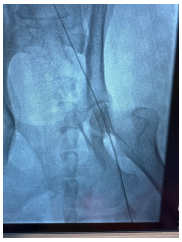
Implanted Devices in Canine Model





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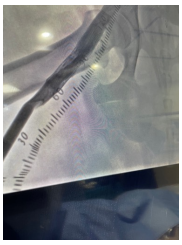
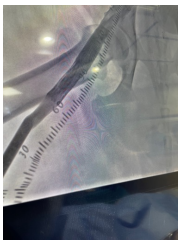
Deployment and Migration

With this sizing method

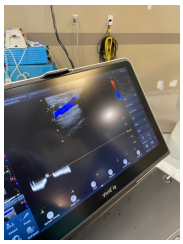
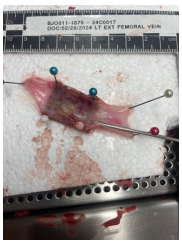
Precise deployment
No migration
No embolization
No acute stent or valve issues
No valve thrombosis

Venogram at 3 months

3 month stents in Iliac System. No Intimal Hyperplasia

Duplex Imaging, Device at 30 Days

Conclusion

Early animal studies show promise for a percutaneous device for deep venous reflux

Pivotal trial will start in Q3 – Q4 of 2025

Thank You