


Update on the VESTECK Endosuturing Technology:


How does it work
How is it different from Endoanchors
Early clinical results



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Disclosure

Lombard Medical Ltd., Nectero Ltd., Vesteck Ltd.

X I have the following potential conflicts of interest to report:

- Receipt of grants/research support
- Receipt of honoraria and travel support
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Member of the VESTECK Ltd. SAB

Durability of EVAR

Endoleaks
Migration
Endoleaks

A systematic review and meta-analysis of long-term reinstitution after endovascular abdominal aortic aneurysm repair

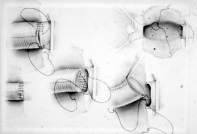
Journal of Vascular Surgery

Open repair remains the gold standard for AAA treatment durability

A systematic review and meta-analysis of the long-term outcomes of endovascular versus open repair of abdominal aortic aneurysm

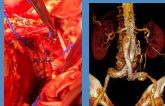
J Vasc Surg. 2019 Sep;70(3):954-969.e30. doi: 10.1016/j.jvs.2019.01.076. Epub 2019 May 27.

Ben Li¹, Shajin Khan¹, Konrad Salata¹, Mohamed A Hussein¹, Charles de Mestral¹, Eliza Greco¹, Badr A Aljabir², Thomas L Forbes², Subodh Verma⁴, Mohammed Al-Omran⁵

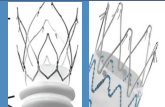


Competent suture lines

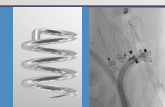
Prophylactic and Tx of Endoleaks/Migration



Hybrid technique



Bare stents and hooks, anchors



APTUS endoanchors

There is need for a new endovascular fixation models

Suture-Tight™ Suture Delivery System





16 Fr delivery system
Nitinol double-sutures
4 sutures per device loaded

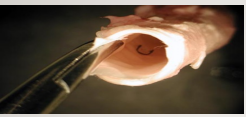





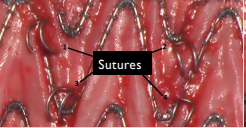
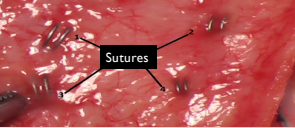


Not commercially available in US/OU

Suture-Tight™ Suture Delivery System

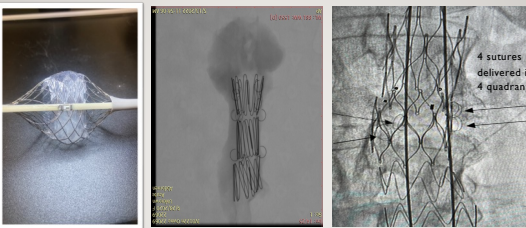



Sutures secures the graft to the adventitia the strongest part of the aorta

David H. Deaton Veith, 2022

Suture-Tight™ Suture Delivery System



4 sutures delivered in 4 quadrants

Distal Delivery System Improvements


- **Central Mesh Membrane** – protects implanted Sutures, stabilizes biasing mesh
- **Improved Housing Deflection** – enables placement of sutures in more difficult spots
- **Proximal and distal catheter flexibility** – improves deflection of mesh while maintaining rapid, precise suture delivery

Not commercially available in US/OUS

Suture-Tight™ FIH

Prospective, multicenter, single-arm trial to evaluate the VESTECK endosuture Procedure for AAA treatment after EVAR

Successfully completed: 9 FIH cases – 6 in Latvia, 3 in AU
5 in Canada through *Special Access Program*



VESTECK FIH Study Design

Primary Endpoints	Safety: MAE at 30 days Efficacy: Endosutures after EVAR
Key Inclusion Criteria	Successful EVAR procedure Proximal neck at least 20 mm; no thrombus
Clinical Follow Up	30 days, 3 months and 6 months
Independent Review	Core Lab (CTA and Angio) SAB review

FIH Results VESTECK procedure

Baseline Lesion Characteristics

N = 9 patients	
Procedural Technical Success, N	9/9 (100%)
Number of endo-sutures (mean)	3-4
Time of endo-suture procedure (min)	14 (+5)
Contrast used for the procedure (ml)	0
Safety outcomes	No device related AE's

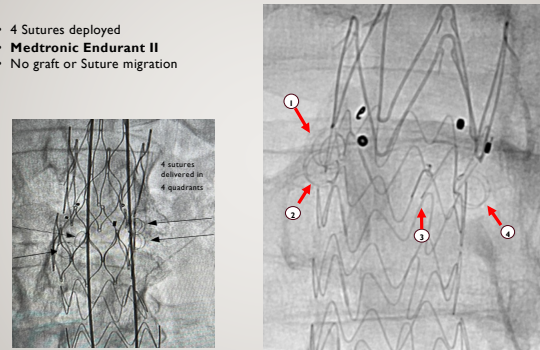
1st FIH case LATVIA

23 February 2023



1st FIM case LATVIA

- 4 Sutures deployed
- **Medtronic Endurant II**
- No graft or Suture migration



1st FIH case LATVIA

6 moth follow-up

- No graft or Suture migration
- Strong suture incorporation

The image block contains several medical images: two axial CT scans of the spine showing suture placement, a 3D reconstruction of the aorta with sutures, and a circular diagram with a green arrow pointing to a specific location.

6st FIH case AUSTRALIA

- GEN 2 device
- Medtronic Endurant II
- 4 Sutures successfully deployed
- Precise deployment
- No graft or Suture migration

The image block contains a 3D reconstruction of the aorta, a long fluoroscopic image showing the deployment of sutures along the length of the aorta, and a small inset image showing a close-up of the suture placement.

Courtesy of Prof. Ramon Varcoe

6st FIH case AUSTRALIA

- GEN 2 device
- Gore Excluder
- 4 Sutures successfully deployed
- Procedure time 12 minutes
- No graft or Suture migration

The image block contains a 3D reconstruction of the aorta, a long fluoroscopic image with red circles highlighting specific areas, two circular diagrams with red circles, and a circular diagram with letters A, L, P, R.

Courtesy of Prof. Ramon Varcoe

Conclusions

- "Suture-Tight™ Suture Delivery System: 9 patients successfully completed in FIM study
- Impressions: fast, safe, flexible, accurate suture placement
- Potentially can:
 - Secure proximal and distal anastomosis and seal
 - Diminish need for long-term F/u of proximal neck
 - Useful for repair procedures
- More clinical studies are needed
 - VESTECK is starting FDA 510K clinical trial in the near future

THANK YOU

The image block features a scenic view of a city with a large cathedral and a river, the text "THANK YOU" in red, and a photograph of surgeons in an operating room.