

"The case isn't finished until it is "SUTURE-TIGHT"tm"

\$16M Series B preferred equity to fund FDA 510k 100 patient pivotal trial, only 12 mos. follow up

Raised \$12.8M

Post Series A valuation \$17.2M

Joseph Rafferty CEO

J.Rafferty@VESTECK.COM

610-457-7324



The "Suture-Tight" catheter is a platform technology, comes preloaded with 4 nitinol sutures for use in aortic repair, structural heart, peripheral and venous applications.



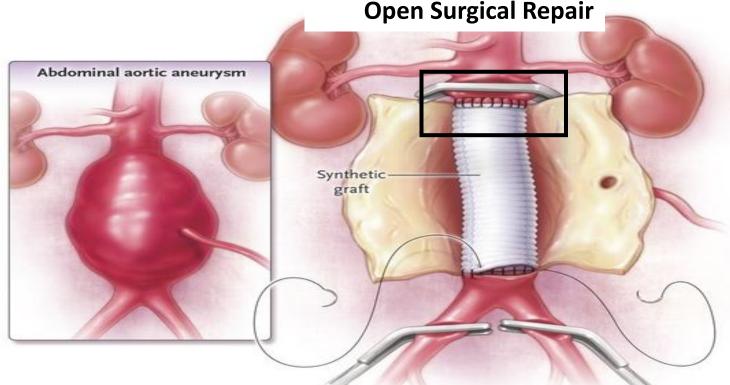




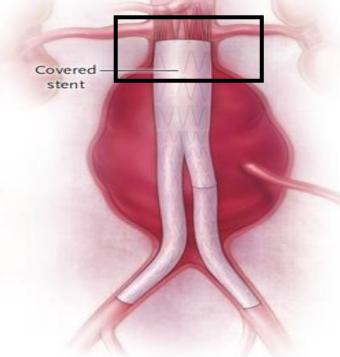
# Why have Medtronic, Boston Sci and Sofinnova made recent investments in the aortic repair market?

- Big profitable aortic repair market
  - Large Baby Boomer population entering peak of aortic disease
  - Well documented global EVAR/TEVAR durability problem
- MDT rejuvenating aortic repair business
  - Funding new 3 studies ~1,000 patients (\$200M?)
- BSX second investment as Nectero validates aortic biology
  - Aortic tissue transitions from elastin to collagen
  - Aorta will dilate regardless of graft implanted
- Sofinnova two investments in aortic repair space

# PROBLEM: EVAR/TEVAR NOT DURABLE AORTIC ANEURYSM PATIENTS HAVE TWO THERAPEUTIC OPTIONS



**Endovascular Repair (EVAR/TEVAR)** 



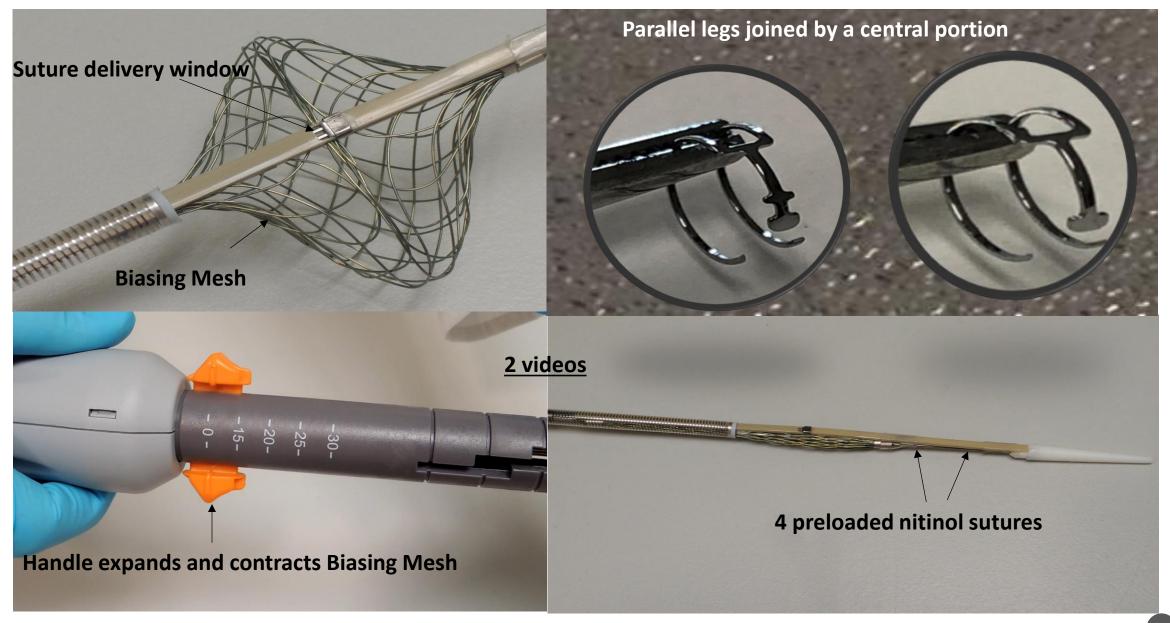
Open Surgical Repair is durable <u>but carries a high</u> mortality rate

- 4.8% perioperative mortality
- 19.2% in high risk patients 1,2,3

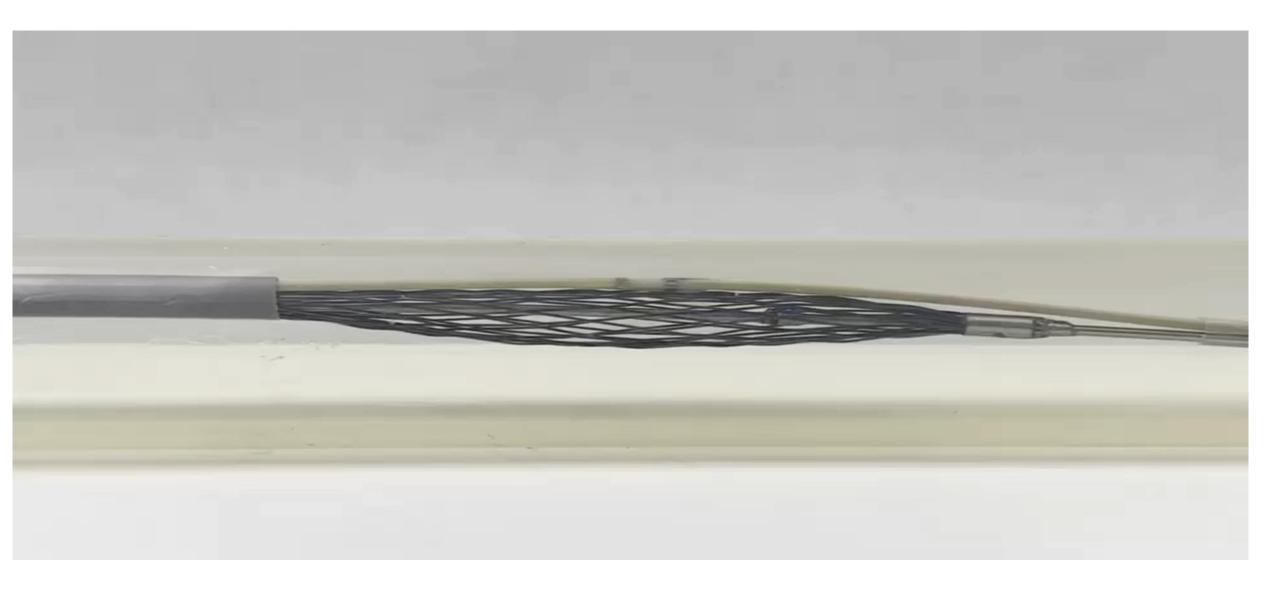
~80% of patients and physicians select an endovascular approach EVAR/TEVAR IS NOT DURABLE 1,2

- 1.2% perioperative mortality
- 4.7% in high risk patients 1,2,3

'Suture-Tight' pre-loaded with 4 pair of nitinol sutures. Speed of EVAR, durability of Open Surgical Repair

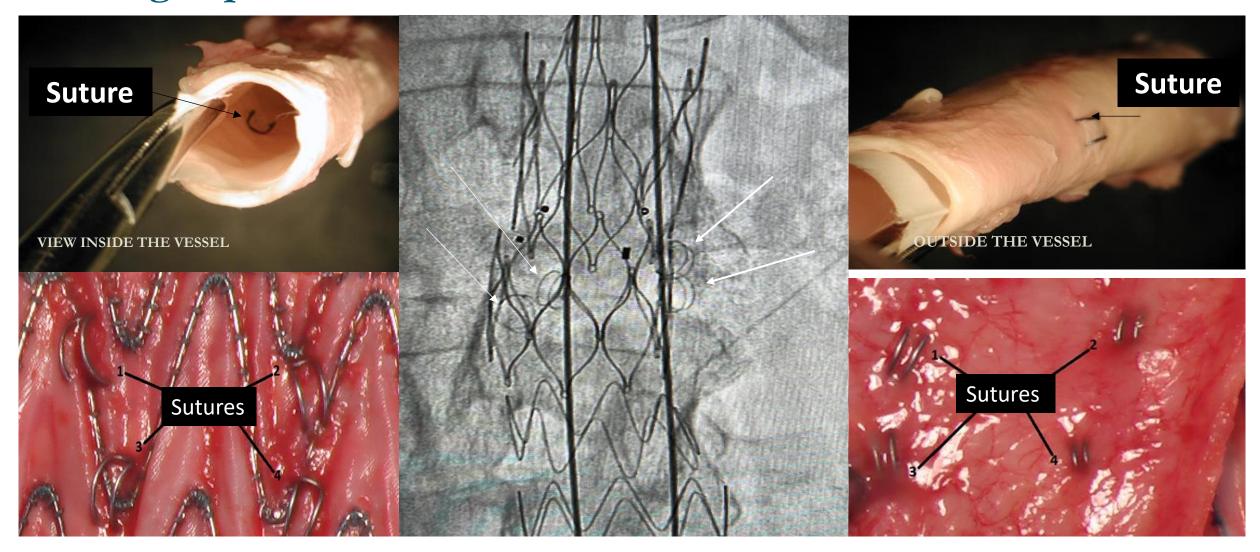


#### "SUTURE-TIGHT" over the wire catheter delivers sutures that can be repositioned, at initial graft implant or during repair procedures



proprietary information

# Vesteck's Suture-Tight catheter secures the graft to the adventitia the strongest part of the aorta

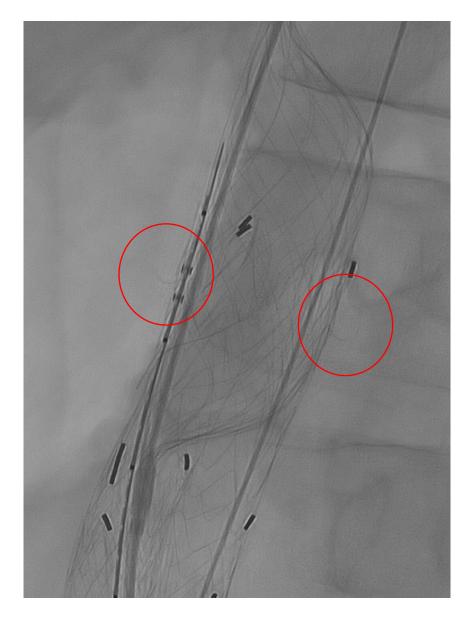


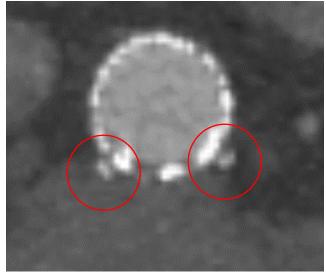
#### Suture-Tight Case Example

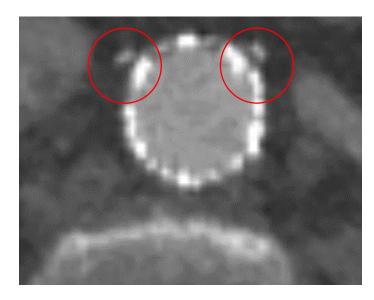
- Case conducted at Prince of Wales in Australia under FIH clinical study (sponsored by Vesteck, Pr. Ramon Varcoe as PI)
- 68 yo male
- AAA: 51mm sac, 17/22 mm neck length/diameter
- Elective EVAR with Gore Excluder
- 4 Suture-Tight Sutures placed in 4 quadrants
- Total time of Suture-Tight procedure was 12 minutes (using both right then left femoral access)
- Same Surgeon previous case, 4 minutes, 4 sutures delivered

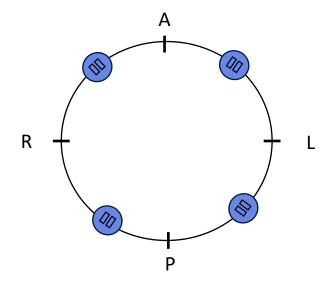


# Suture Deployment





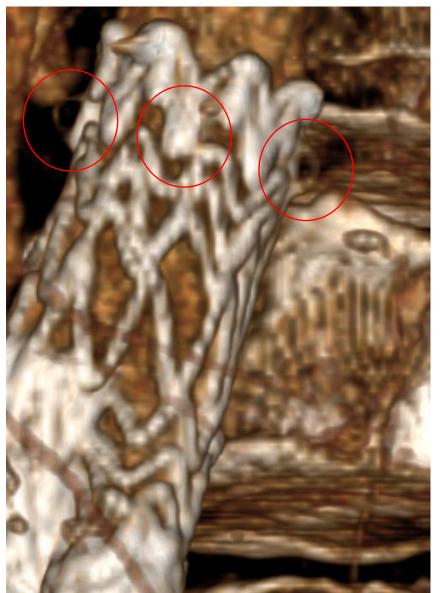




# Follow-up Imaging (L-R: 40°)



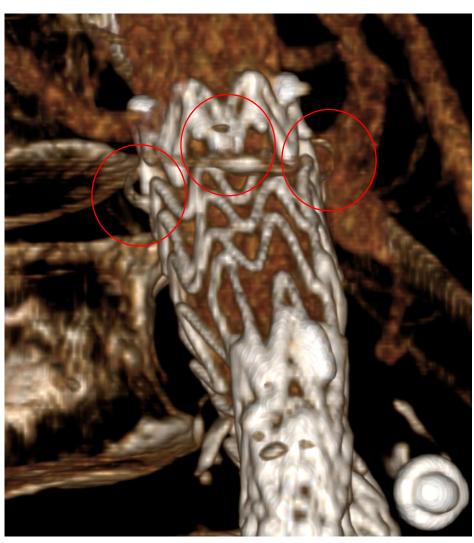
1 Month

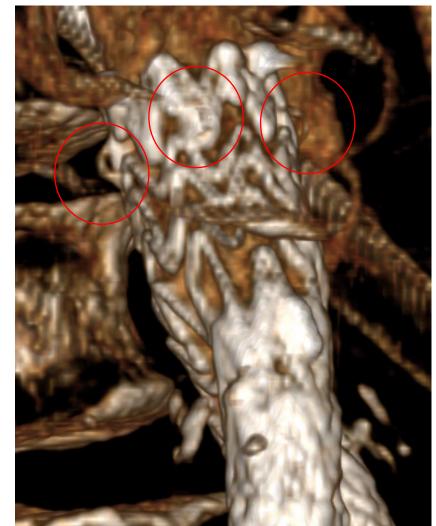


**6 Months** 

# Follow-up Imaging (L-R: -57°)

1 Month





**6 Months** 



#### VESTECK Device works! 14 successful clinical cases completed

8 Different Physician implanters in Canada, Europe, Australia

FIH Case No.	Procedure Date	MD Operator	SAB Member Present	Commercially Available Endograft Placed	Major Adverse Events (MAEs)	Migration	Leaks	Suture fracture or embolization	Case Location
1	23-Feb-2023	Krievins	Yamanouchi	Yes	No	No	No	No	Latvia (CLP-03 FIH Study)
2	23-Feb-2023	Krievins	Yamanouchi	Yes	No	No	No	No	Latvia (CLP-03 FIH Study)
3	8-Mar-2023	Bui	Lyden	Yes	No	No	No	No	Canada (Special Access Program)
4	31-Mar-2023	Bui	Ramaiah	Yes	No	No	No	No	Canada (Special Access Program)
5	31-Mar-2023	Bui	Ramaiah	Yes	No	No	No	No	Canada (Special Access Program)
6	23-May-2023	Krievins	Bui	Yes	No	No	No	No	Latvia (CLP-03 FIH Study)
7	23-May-2023	Krievins	Bui	Yes	No	No	No	No	Latvia (CLP-03 FIH Study)
8	11-Nov-2023	Krievins	-	Yes	No	No	No	No	Latvia (CLP-03 FIH Study)
9	11-Nov-2023	Krievins	-	Yes	No	No	No	No	Latvia (CLP-03 FIH Study)
10	18-Dec-2023	Varcoe	Holden	Yes	No	No	No	No	Australia (CLP-05 FIH Study)
11	19-Dec-2023	Thomas	Varcoe	Yes	No	No	No	No	Australia (CLP-05 FIH Study)
12	19-Dec-2023	Thomas	Varcoe	Yes	No	No	No	No	Australia (CLP-05 FIH Study)
13	23-Feb-2024	Bui	Ramaiah	Yes	No	No	No	No	Canada (Special Access Program)
14	23-Feb-2024	Bui	Ramaiah	Yes	No	No	No	No	Canada (Special Access Program)

#### VESTECK

VESTECK Inc.

#### "TECHNOLOGY SIGNIFICANLTLY DERISKED"

- 14 clinical cases successfully completed, 6 and 12 months out
- KOL's in alignment. "will become the standard of care for all EVAR/TEVAR."
  - speaking at global meetings VIVA, VEITH, CHARRING CROSS, ISET, TED, GREENBERG STENT
- Clear FDA 510K regulatory pathway, only 100 patients, 1 year follow up
  - 5 Pre-sub meetings, IDE reviewed
- Existing DRG/CPT reimbursements for initial implant and repair procedures
- "SUTURE-TIGHT System" 3 new issued patents, 2 more filed, 2 existing
  - US, Canada, AU, NZ, EU, UK, China, Japan, On the way in India.
- Australia LLC formed
  - leverage currency exchange and 43.7% R&D investment rebate, will conduct 50% of clinical trial in A
     Not available for sale in USA/OUS

# \$4.8 B Global Aortic Repair Market by 2028 14, 15

# Initially targeting very 2 large markets

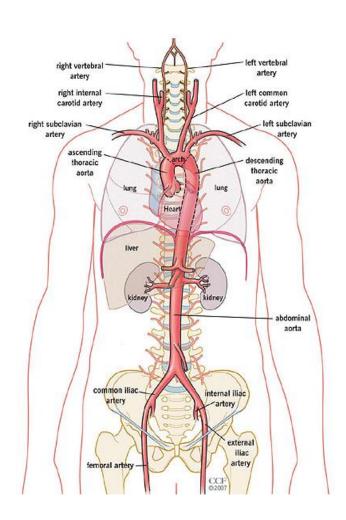
#### Initial implant EVAR/TEVAR

- >3M global patients with abdominal and thoracic aneurysms
- >400,000 global patients diagnosed and monitored
- >125,000 globally AAA/TAA procedures performed

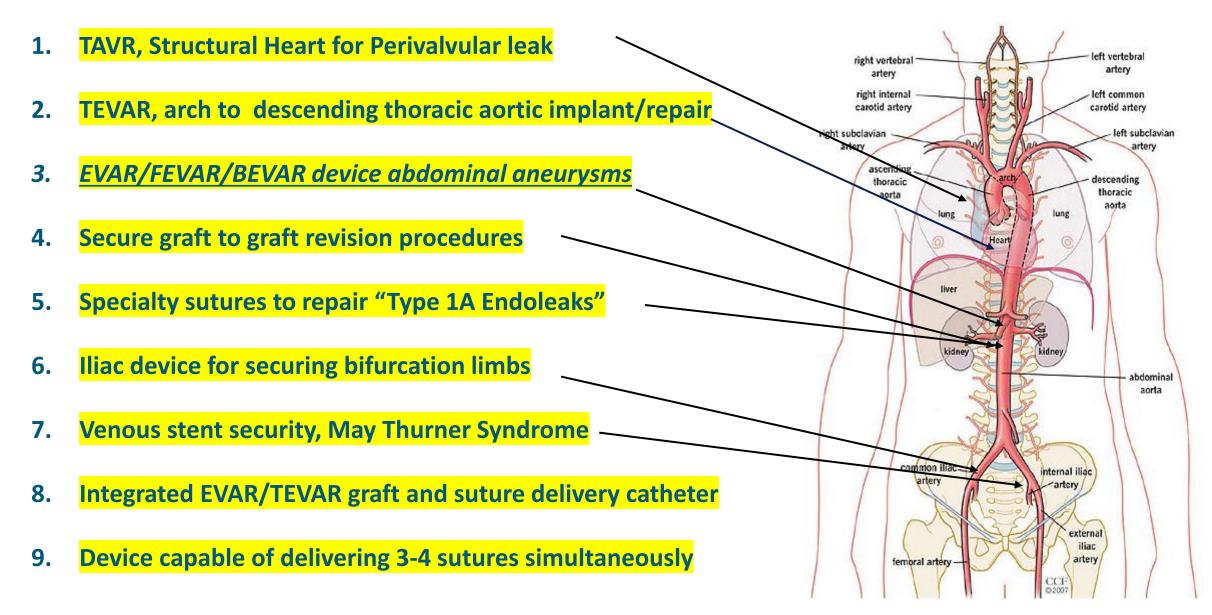
#### Repair procedures ~1 M patients with failing implants

• 5-year EVAR re-intervention rate 21% (TEVAR is higher.)

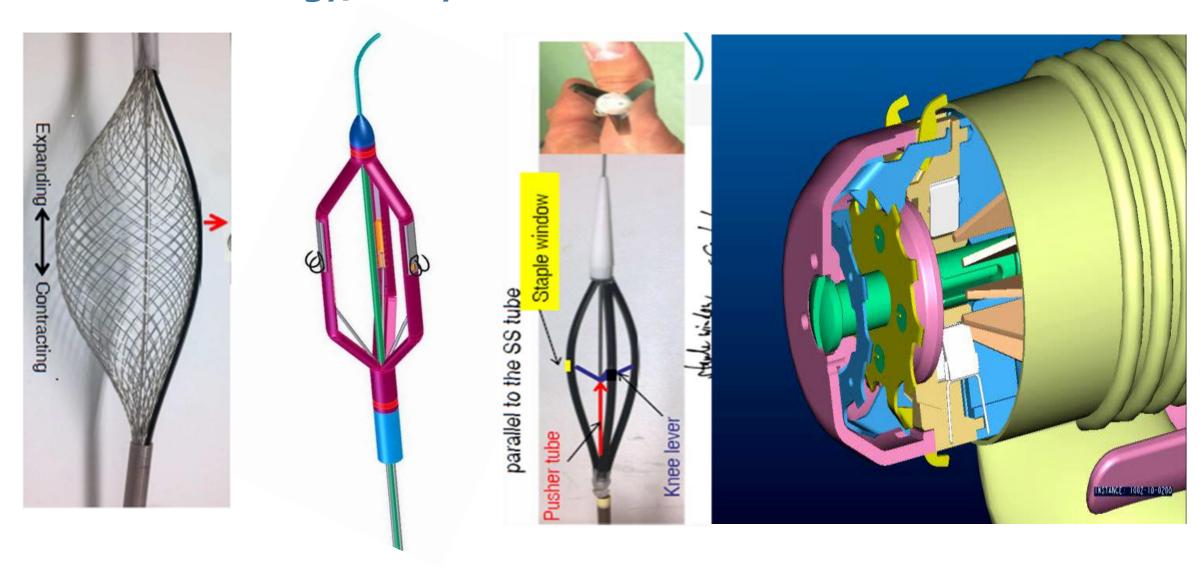
#### Will bring an incremental \$700 M at 50% Global TAM



#### VESTECK platform device, aortic, structural heart, peripheral, venous, Gl



## Platform technology, today and the future



### Market Modeling as a "tuck in" for an existing sales team

	Market Share	<u>2027</u>	<u>2028</u>	<u>2029</u>	<u>2030</u>	<u>2031</u>
US AAA TAM		127,642	132,573	137,746	143,173	148,865
DeNovo and Repair	20%	\$ 127,642,249	\$ 132,573,499	\$ 137,746,380	\$ 143,172,732	\$ 148,864,975
	30%	\$ 191,463,373	\$ \$ <mark>198,860,248</mark>	\$ 206,619,569	\$ 214,759,097	\$ 223,297,462
	40%	\$ 255,284,498	\$ \$ 265,146,997	\$ <mark>275,492,759</mark>	\$ 286,345,463	\$ 297,729,950
	<mark>50%</mark>	\$ 319,105,622	\$ 331,433,747	\$ 344,365,949	\$ 357,931,829	\$ 372,162,437

	Market share	<u>2027</u>	<u>2028</u>	<u>2029</u>	<u>2030</u>	<u>2031</u>
<u>Global TEVAR</u>	20%	\$ 8,418,068	\$ 8,830,553	\$ 9,263,250	\$ 9,717,149	\$ 10,193,290
<u>DeNovo</u>	30%	\$ 12,627,101	\$ 13,245,829	\$ 13,894,875	\$ 14,575,724	\$ 15,289,934
-	40%	\$ 16,836,135	\$ 17,661,106	\$ 18,526,500	\$ 19,434,299	\$ 20,386,579
<u>-</u>	50%	\$ 21,045,169	\$ 22,076,382	\$ 23,158,125	\$ 24,292,873	\$ 25,483,224
-						
<u>Global</u>	Market share	<u>2027</u>	<u>2028</u>	<u>2029</u>	<u>2030</u>	<u>2031</u>
DeNovo and Redo	20%	\$ 255,284,498	\$ 265,146,997	\$ 275,492,759	\$ 286,345,463	\$ 297,729,950
<u>EVAR</u>	30%	\$ 382,926,747	\$ 397,720,496	\$ 413,239,139	\$ 429,518,195	\$ 446,594,925
<u>-</u>	40%	\$ 510,568,996	\$ 530,293,994	\$ 550,985,518	\$ 572,690,927	\$ 595,459,900
_	<mark>50%</mark>	\$ 638,211,245	\$ 662,867,493	\$ 688,731,898	\$ 715,863,658	\$ 744,324,875
_						
Global EVAR/TEVAR	Market share	<u>2027</u>	<u>2028</u>	<u>2029</u>	<u>2030</u>	<u>2031</u>
_	20%	\$ 263,702,565	\$ 273,977,550	\$ 284,756,009	\$ 296,062,613	\$ 307,923,240
	30%	\$ 395,553,848	\$ 410,966,325	\$ 427,134,014	\$ 444,093,919	\$ 461,884,859
	40%	\$ 527,405,131	\$ 547,955,100	\$ 569,512,018	\$ 592,125,225	\$ 615,846,479
	<mark>50%</mark>	\$ 659,256,414	\$ 684,943,875	\$ 711,890,023	\$ 740,156,531	\$ 769,808,099

#### Competition:

# Medtronic Heli-FX Repurposed hernia mesh tac

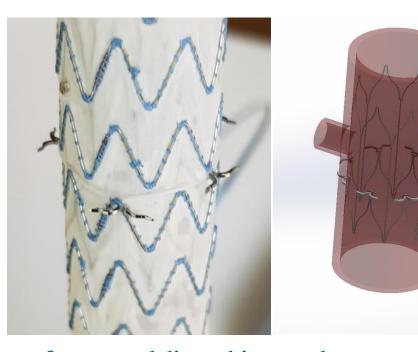
Commercially available, very challenging to use System list price ~\$8,200, ASP ~\$6,000 10 sutures



"<u>~30% Heli-FX are maldeployed and...not useful"</u> 19



Not commercially available
A Sofinnova Portfolio Company



8 sutures delivered in one shot
-challenge with calcium, thrombus, hostile neck, angles

VESTECK Inc.

Not available for sale in USA/OUS



# "SUTURE-TIGHT" has More clinical applications.

Designed by physicians to fit smoothly into existing procedural workflow.



- ✓ Very easy to use- single insertion
- ✓ Safety- sutures preloaded virtually eliminate embolization
- ✓ Speed- faster suture delivery
- ✓ Accuracy-precise placement
- ✓ Durability- Nitinol shape memory

\$3,500 list price, \$2,500 ASP catheter preloaded with 4 sutures. \$5,000 – gross revenue per patient. 15% cost of parts/labor

## Endovascular/Peripheral M&A Recent Acquisitions

- > \$415M Inari acquires LimbFlow (recent FDA, \$0 revenue)
- > \$360M Endologix acquires PQ bypass (pre FDA, \$0 revenue)
- ➤ \$890M Abbott acquires CSI (\$36.9M loss)
- > \$370M Boston Scientific acquires Devoro, clot removal(pre FDA \$0 revenue)
- > \$360M Phillips acquires InTact, spot stent (\$125M invested < \$50M revenue)
- > \$340M Edwards acquires Valtech's repair of tricuspid +mitral valves
- > \$280M Terumo acquires Sequent Web's Embolization System
- > \$270M Boston Scientific acquires Claret Medical (<\$20M revenue)
- > \$230M SpectraNetics acquires Angioscore
- > \$110M Medtronic acquires Aptus Medical 2015
- > \$225M CryoLife acquires Jotec GmbH

VESTECK Inc.

#### "VESTECK will become the standard of care for every EVAR/TEVAR patient."

David H Deaton MD, Vascular Surgeon, Former Chief. Vascular Surgery Georgetown, former APTUS CMO



#### Global Key Opinion Leaders are in alignment

When asked about the patient benefits of the VESTECK, "SUTURE-TIGHT" catheter technology
SAB member Professor Michel Reijnen said,



"After >25 years of performing EVAR procedures we are still encountering the same problems as in the past...leaks and migration.

We therefore <u>we need novel solutions</u>, adding different technologies to EVAR, in order to make the treatment more effective and durable."

#### KOL'S "SUTURE-TIGHT "for initial implant and repair"



"We are in need of additional tools like this to help our EVAR/TEVAR patients."

Sean Lyden MD, Vascular Surgeon, Chairman Department of Vascular Surgery Cleveland Clinic, OH



"I'll use VESTECK even in patients who are within the IFU and have increased risk of proximal failure." Daniel Clair MD, Chairman Dept. Vascular Surgery Vanderbilt University Medical Center, TN



"VESTECK, SUTURE-TIGHT is a tool that interventionalists need now."
Peter Schneider MD, Vascular Surgeon, University San Francisco



"I will allow MLH physicians to use "SUTURE-TIGHT" we can't predict which patient's aortas will dilate. So, with an easy to use, safe, fast, inexpensive system like this....

William Gray MD, Interventional Cardiologist, Cardiovascular System Chief Main Line Health, Phila. PA



"Fits easily into my EVAR/TEVAR procedural workflow right away." Venkatesh Ramaiah MD, Chief/Network Director Complex Vascular Services Honor Health Phoenix AZ

#### Global Scientific Advisory Board



Dr. Sean Lyden

<u>VESTECK CMO</u>

Chair of the Department of Vascular
Surgery Cleveland Clinic



Dr. Venkatesh Ramaiah

Honor Health Chief

Network Director, Complex Vascular

Services



**Prof. Ramon Varcoe**Director of Surgery Sydney AU



**Dr. Daniel Clair** Chair Dept of Vascular Surgery Vanderbilt University



**Dr. Dai Yamanouchi**Chair. Department of Vascular Surgery Fujita
University Hospitals Japan



System Chief Division of Cardiovascular
Disease at Main Line Health, PA



**Dr. Sukgu Han**Chief Div. Vascular
Surgery/Endovascular Therapy
USC



Prof. Andrew Holden
Director Northern Region
Interventional Radiology Service
New Zealand



**Dr. David Deaton**Inroad Medical
Former Chief Medical Officer
of APTUS



**Prof. Michel Reijnen**Endovascular Imaging and Innovation
University of Twente, Netherlands



**Dr. Bao Bui**Endovascular Intervention
University Sherbrooke, Quebec CA



**Prof. Dainis Krievins**Professor, Director: Institute of
Research of P. Stradins University
Hospital Latvia

### Our M&A options have physician relationships and sales bags to tuck in

**EVAR/TEVAR Graft companies** 











Medtronic













VESTECK Inc.

Peripheral companies w/relationships



































Joseph W. Rafferty CEO

Dr. John Edoga Founder

Dr. Thierry Richard Founder

Terrie Heidemann

Director Quality

Elisa Harvey DVM, PhD Regulatory Consultant

## Leadership: with deep endovascular market knowledge, execute and exit



Laura Lund, PhD

Director Clinical Strategy Consultant



COO, VP R&D



Dennis McGrath
Chief Financial Consultant
Treasurer



Ted Wulfman
Chief Technology Officer



Dorothy Abel
Regulatory Consultant

#### \$16M Series B will be used to fund 100 PT FDA 510K clearance

Q2 '27

**FDA** 

**Submission** 

#### **Culture of Milestone achievement**

15 Successful pre-clinical labs

5 Pre-Sub meetings w/FDA

October '21 Carlsbad CA R&D office rapid prototype clean room mfg. devices Australian, LLC. wholly owned subsidiary formed

Q1 '24

<u>Successfully</u>

<u>completed</u>

14 Clinical Cases

Q2 '23 "Remote Surgical Suture" patent Published by USPTO

Q2 '25
begin
100 Patient
clinical trial,
W 12 month
follow up

Q3 '27 FDA Clearance

M&A Inflection

or

Commercialization

Filed 3 new

comprehensive

patent applications



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