

VESTECK: “Suture-tight” technology

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CRT 2021 Innovative Technologies

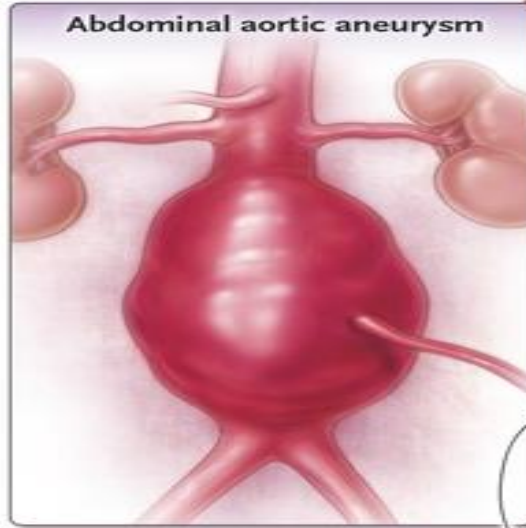
April 17,2021

Disclosures

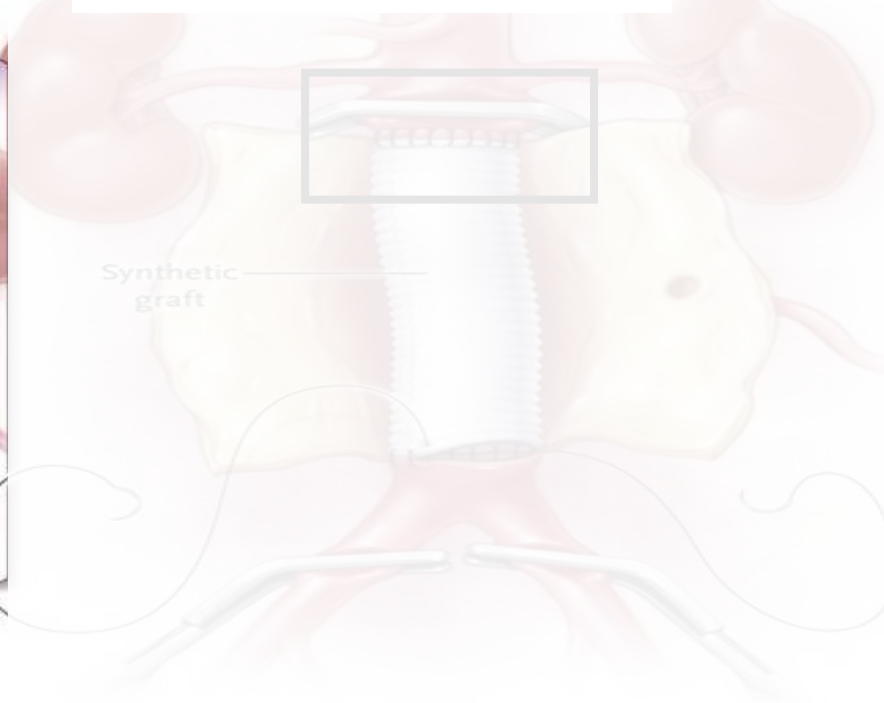
SAB: VESTECK

STATEMENT OF PROBLEM:

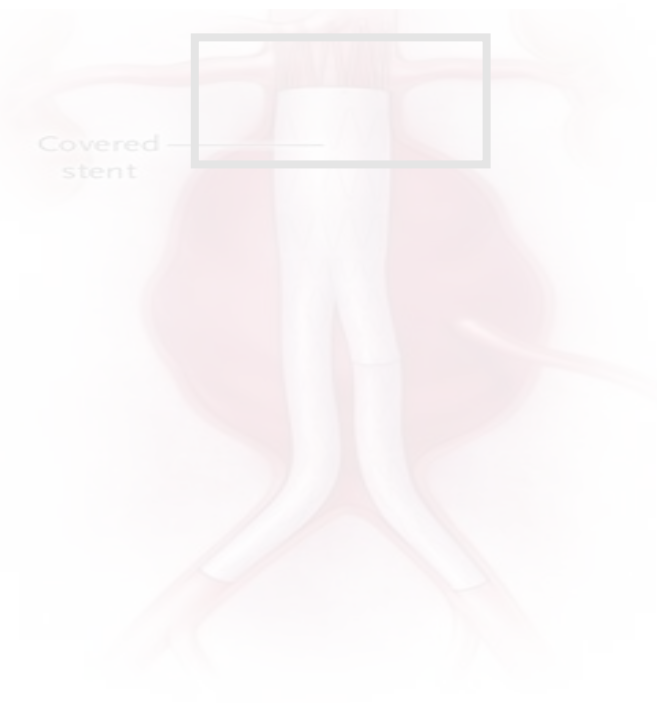
THE TWO THERAPEUTIC OPTIONS FOR AORTIC ANEURYSM PATIENTS



Open Surgical Repair



Endovascular Repair (EVAR)



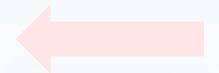
**Open surgical repair: durable
but carries a high mortality rate**

- **4.8%** perioperative mortality
- **19.2%** in high risk patients ^{1,2,3}

**Endovascular approach: selected in
~80% of patients**

But EVAR/TEVAR is not as durable^{1,2}

- **1.2%** perioperative mortality
- **4.7%** in high risk patients ^{1,2,3}



Peer reviewed literature questioning durability of EVAR

- EVAR has significant challenges with endoleaks and graft migration leading to near and long term durability issues ^{1, 2}.
 - 30-40% EVAR grafts currently implanted off label, much of which is centered around angulated and/or short necks. ¹⁷
 - Type IA endoleaks (proximal neck) occur in up to 15-30% of EVAR and 15% of TEVAR in the first 30 days ^{1, 2}
- The intraoperative radiation risks for repeat procedures are not exclusive to the patient but also have implications for the operator and the operative team. ¹¹
- Controversy: UK NICE AAA DRAFT Guidelines directing physicians to perform open vs EVAR procedures in low risk patients, “due to lack of durability and high cost.” ³

Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair



Sarah E. Deery, MD, MPH,^a Emel A. Ergul, MS,^a Marc L. Schermerhorn, MD,^b Jeffrey J. Siracuse, MD,^c Andres Schanzer, MD,^d Philip P. Goodney, MD, MS,^e Richard P. Cambria, MD,^a and Virendra I. Patel, MD, MPH,^a for the Vascular Study Group of New England, *Boston and Worcester, Mass; and Lebanon, NH*

Table V. Cox regression for long-term mortality

Variable	Death hazard ratio	95% CI	P value
Sac expansion	1.5	1.1-2.0	.01
Sac regression	0.6	0.5-0.8	<.001

- 1802 patients
- Status at one year
- Unknown effect of stable versus regression
- Unknown if rate of regression significant

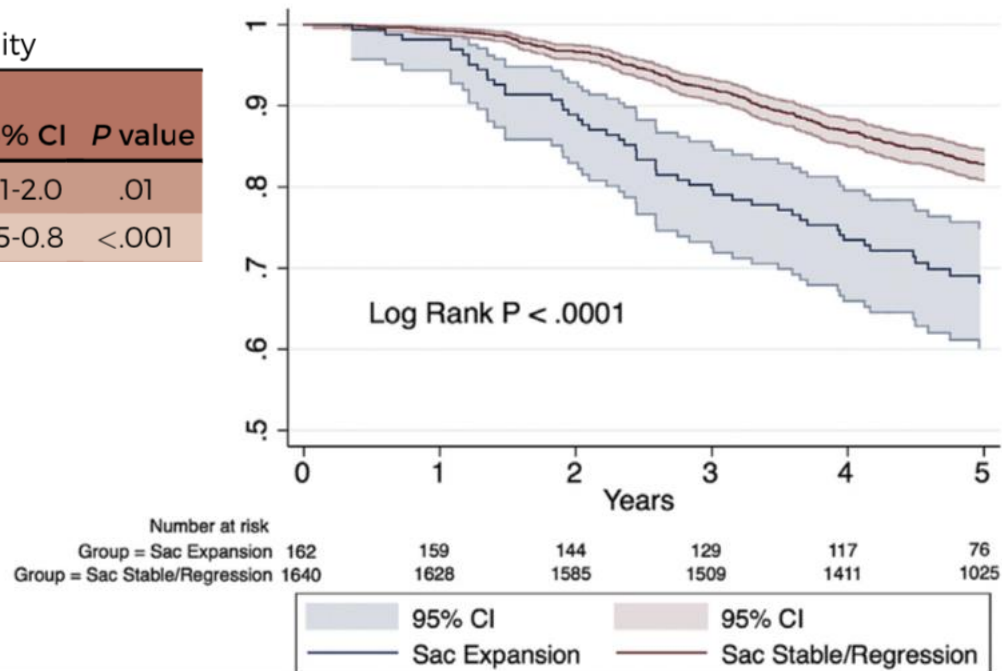


Fig. Kaplan-Meier survival estimates for the full cohort of patients, including those excluded from the remainder of the study because of missing long-term follow-up data. CI, Confidence interval.

From the New England Society for Vascular Surgery

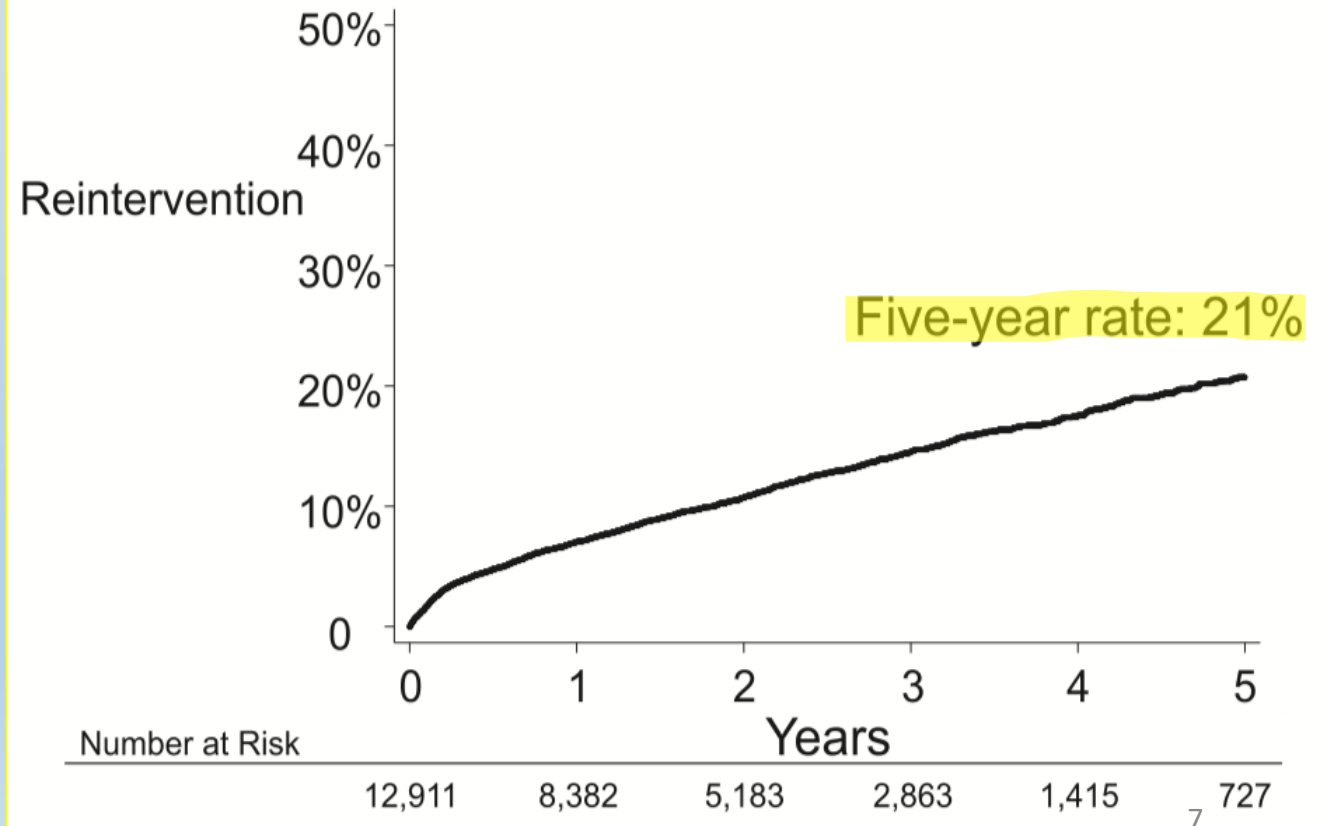
Five-year reintervention after endovascular abdominal aortic aneurysm repair in the Vascular Quality Initiative

Journal of Vascular Surgery
March 2020

Jesse A. Columbo, MD, MS,^{a,b} Niveditta Ramkumar, MPH,^b Pablo Martinez-Camblor, PhD,^b
Ravinder Kang, MD, MS,^b Bjoern D. Suckow, MD, MS,^a A. James O'Malley, PhD,^b Art Sedrakyan, MD, PhD,^c and
Philip P. Goodney, MD, MS,^{a,b} *Lebanon, NH; and New York, NY*

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of the Vascular Quality Initiative-Medicare matched national database
- **Key Findings:** At 5 years, the reintervention rate after 12,911 endovascular abdominal aortic aneurysm repairs was 21%, and late aneurysm rupture rate was 3%. Black patients, those with aneurysms larger than 6 cm, and those who underwent repair urgently or emergently had higher rates of reintervention.
- **Take Home Message:** More than one in five Medicare patients who undergo endovascular abdominal aortic aneurysm repair can expect to undergo reintervention. High-risk subgroups have more adverse outcomes and should be the focus of diligent long-term surveillance.

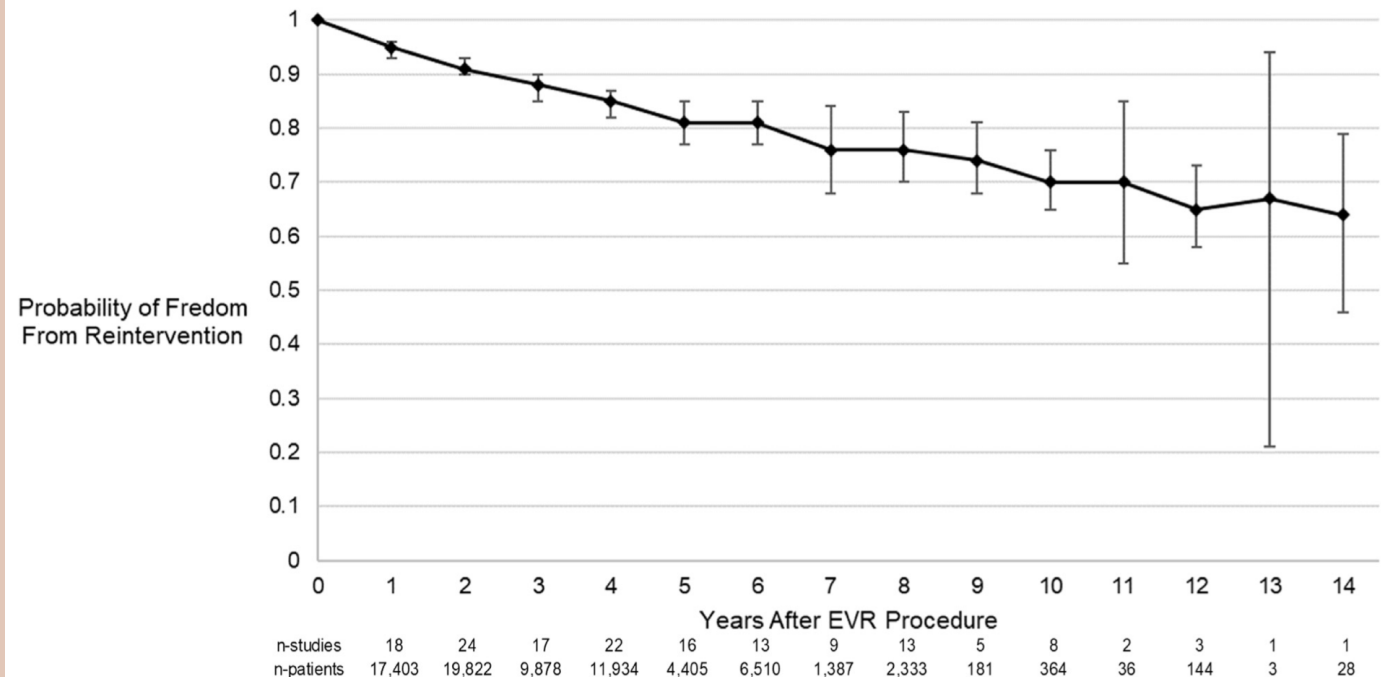


A systematic review and meta-analysis of long-term reintervention after endovascular abdominal aortic aneurysm repair

Zachary J. Wanken, MD, MS,^{a,b} J. Aaron Barnes, MD,^a Spencer W. Trooboff, MD, MBA,^b Jesse A. Columbo, MD, MS,^a Tarun K. Jella, MPH,^b Daniel J. Kim, MPH,^b Arian Khoshgowari, MPH,^b Natalie B. V. Riblet, MD, MPH,^b and Philip P. Goodney, MD, MS,^{a,b} *Lebanon and Hanover, NH*

ARTICLE HIGHLIGHTS

- **Type of Research:** Systematic review and meta-analysis of published rates of reintervention procedures after endovascular aneurysm repair (EVAR)
- **Key Findings:** Up to 19% of EVAR patients will require a reintervention at 5 years, 30% at 10 years, and 35% at 14 years. However, reintervention rates have improved over time. Through 7 years of follow-up, the proportion of patients who do not require reintervention has improved from 50% in 1998 to 86% in 2008.
- **Take Home Message:** EVAR patients remain at risk for reintervention indefinitely. However, reintervention rates have improved over time, with newer devices exhibiting lower rates.

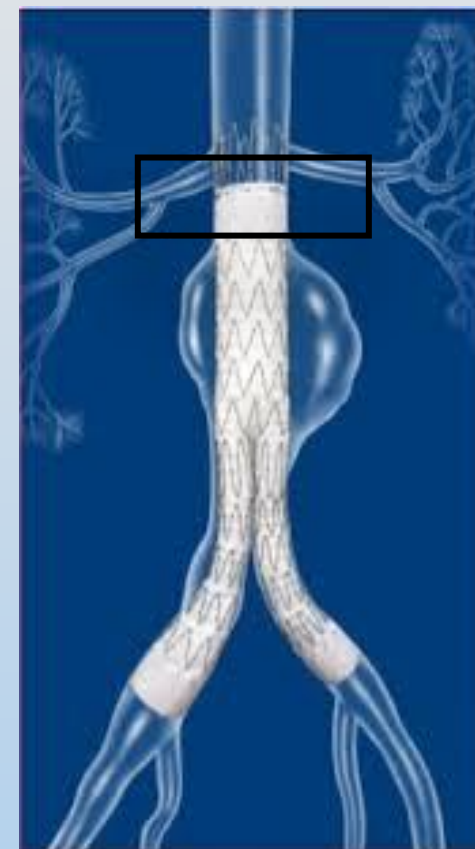


Why “Suture-Tight” Now?

- Endovascular repair remains the *de facto* standard of care for aortic aneurysm repair in the US
- However, the broad peer reviewed literature demonstrates that *EVAR/TEVAR lacks long term freedom from reintervention requirements* ^{1,2}
 - Reintervention rate 21% at 5 years, 30% at 10 years, 35% at 14 years
- Payors shifting from “Fee for Service” to “Quality Initiatives”, read: global cost of care (which is obviously affected by durability and effectiveness)
 - EVAR Repair procedures create an incremental cost to the health care system of >\$9B over the next 10 years
- **ANSWER: Endoanchors** work! Medtronic is doing the research!
 - Reliable proximal cuff seal reduces leaks and migration leading to aneurysm sac shrinkage...and better patient outcomes

Medtronic's post-market Anchor Registry proves Endoanchors work

- >1,800 patients studied
- Proximal sealing = Aneurysm sac shrinkage
- Aneurysm sac shrinkage = increased long-term survival
- Aneurysm sac shrinkage = fewer cardiac events (!)

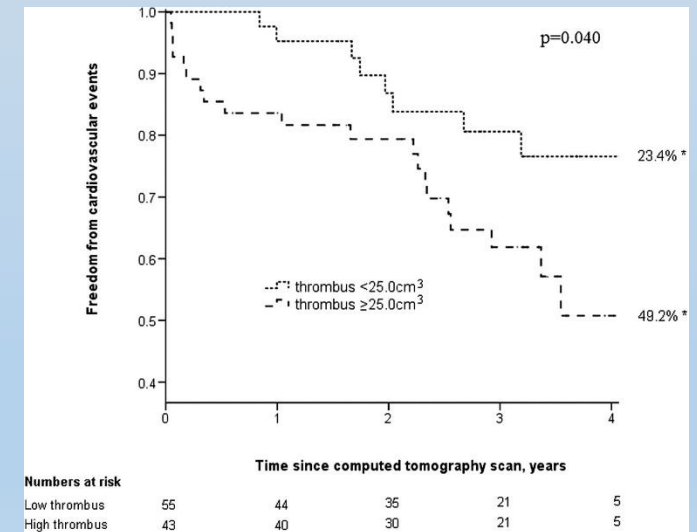
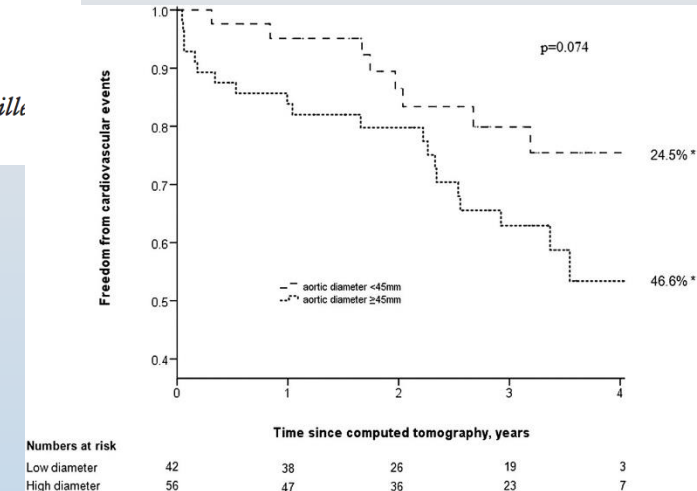


“Suture-Tight” is next generation technology, improved ease of use

Thrombus volume is associated with cardiovascular events and aneurysm growth in patients who have abdominal aortic aneurysms

Adam Parr, MBBS (Hons), Moira McCann, PhD, Barbara Bradshaw, RGN,
Anwar Shahzad, MBBS, MRCP UK, Petra Buttner, PhD, and Jonathan Golledge, MChir, *Townsville
Queensland, Australia*

- 98 patients / 3 years f/u
- Cardiovascular events
 - 23.4% for small thrombus
 - 49.2% for large thrombus
- RR of 2.4 for large thrombus
 - Independent of other risk factors
- Aneurysm growth in large thrombus significantly more and independent of initial size
 - RR of 15



VESTECK Inc.

The “Suture-Tight” catheter delivers nitinol sutures, securing endovascular aortic repair grafts to the aorta at the time of initial implant or repair procedure

“We don’t sell the endovascular grafts, we sell the suturing catheter that makes the grafts last longer.”



SUTURE-TIGHT catheter

16F OTW 0.035" prototypes demonstrated proof of concept pre-clinical cases

- Design and validation driven by physician input
- Supplied preloaded with 4 sets of sutures, so fits smoothly into existing procedural workflow
- Rapid, precise, safe, secure, sutures the graft to the aortic adventitia
 - No embolization, full-circumference graft access, can seal >2 mm endoleak gap
- Endovascular platform of 7 catheters, EVAR first device target, possibly Structural Heart and GI.



VESTECK "Suture-Tight" Nitinol Suture System

Suture delivery window

Biasing Mesh

Parallel legs joined by a central portion

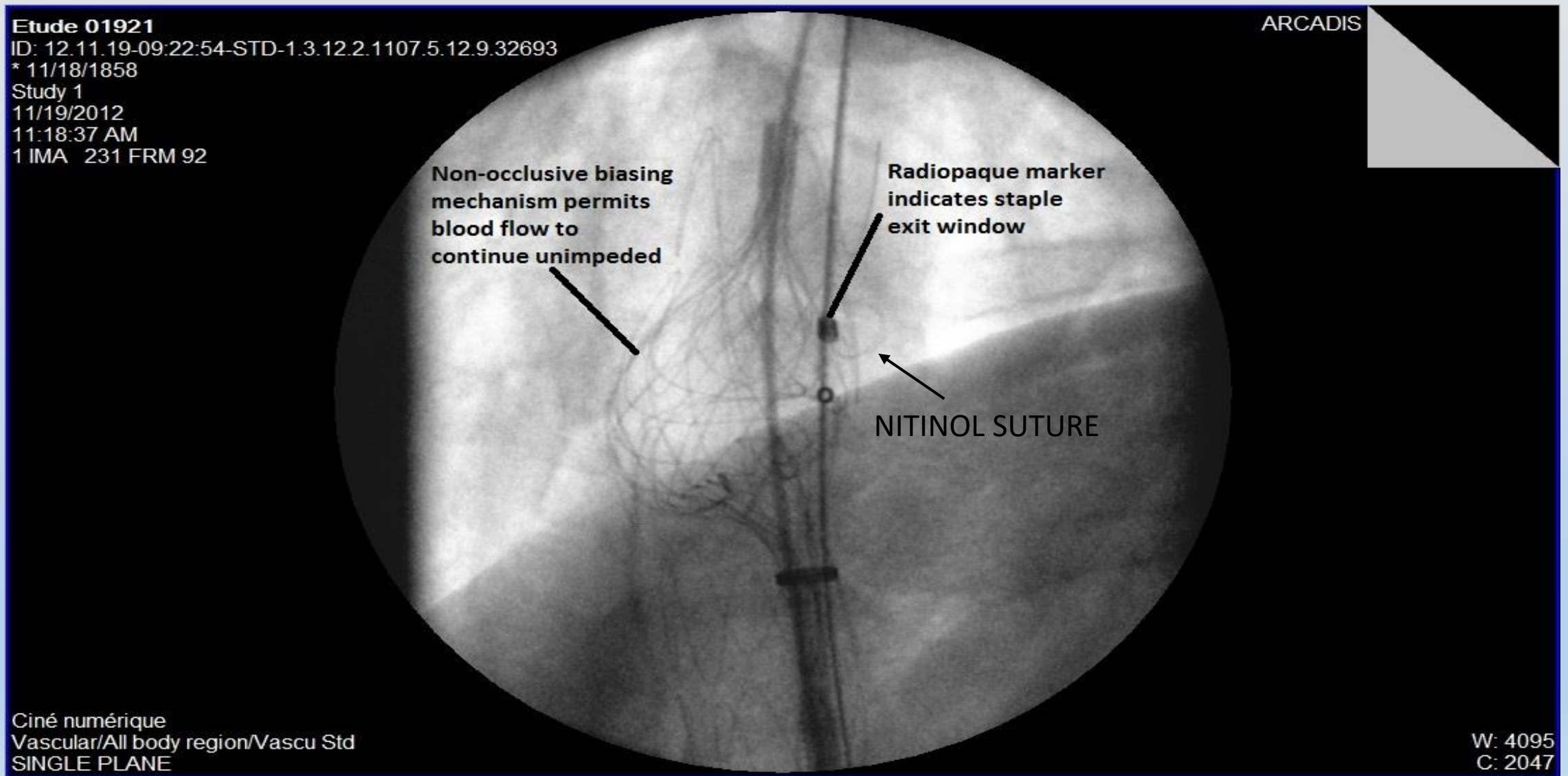
Slide expands and contracts Biasing Mesh

Sutures preloaded and stored

Nitinol sutures can be accurately placed, retracted and repositioned up until the final release.

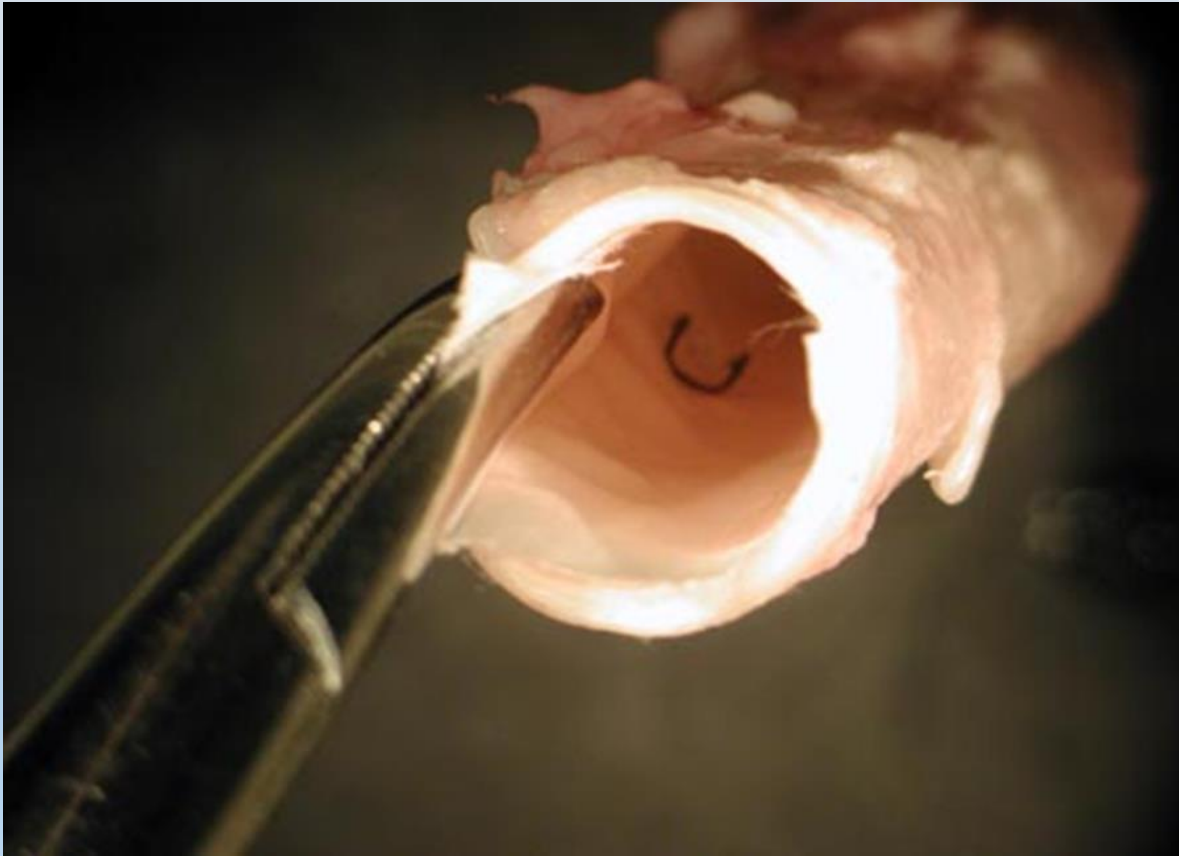


Radiopaque markers, placement of nitinol sutures, sheep model

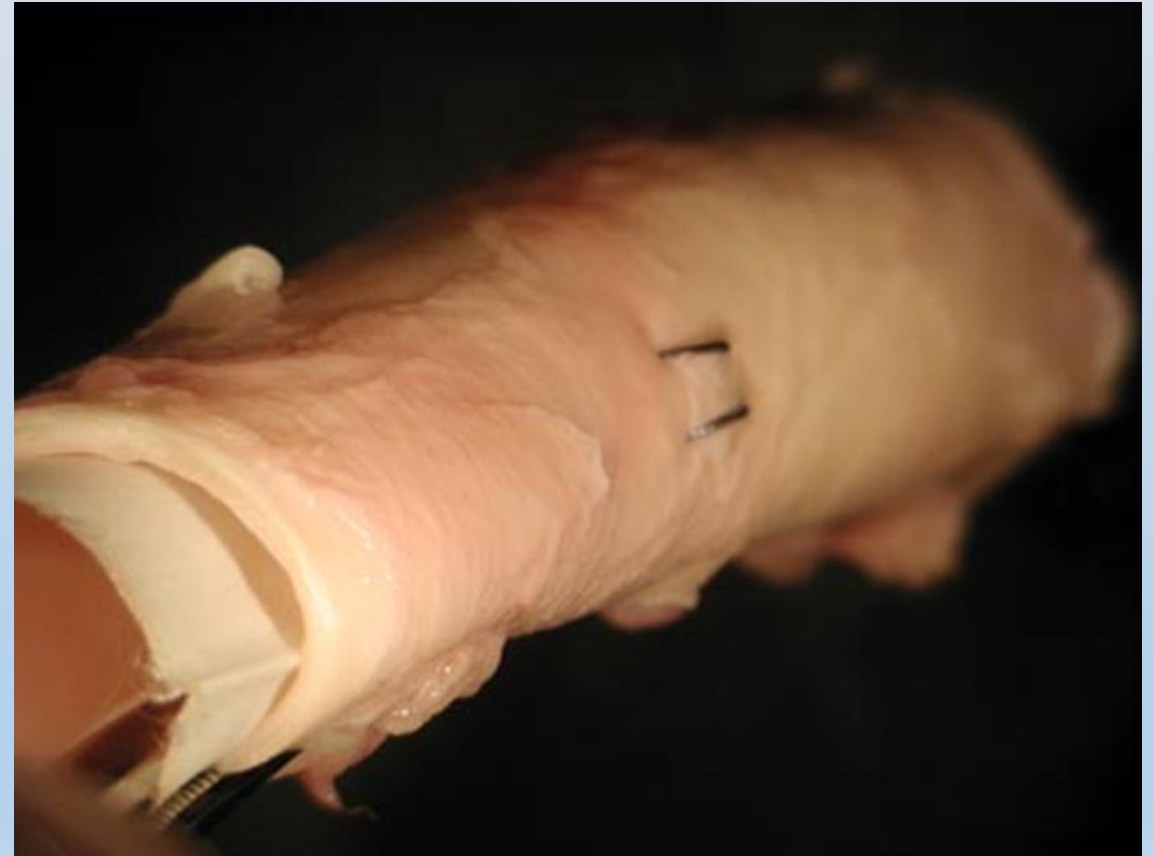


Nitinol suture configuration bench top porcine aorta attached to graft

DACRON GRAFT LUMEN THE VESSEL

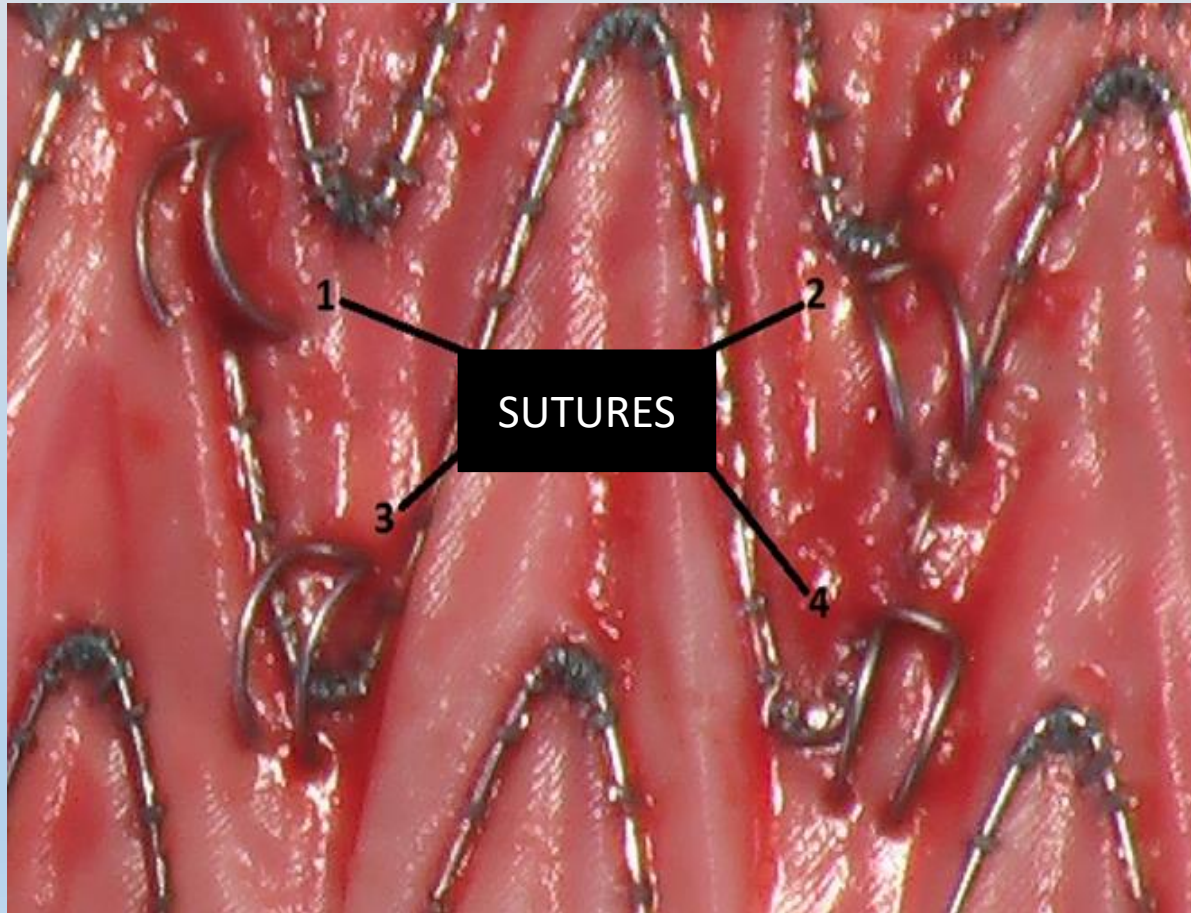


SECURING THE ADVENTITIA

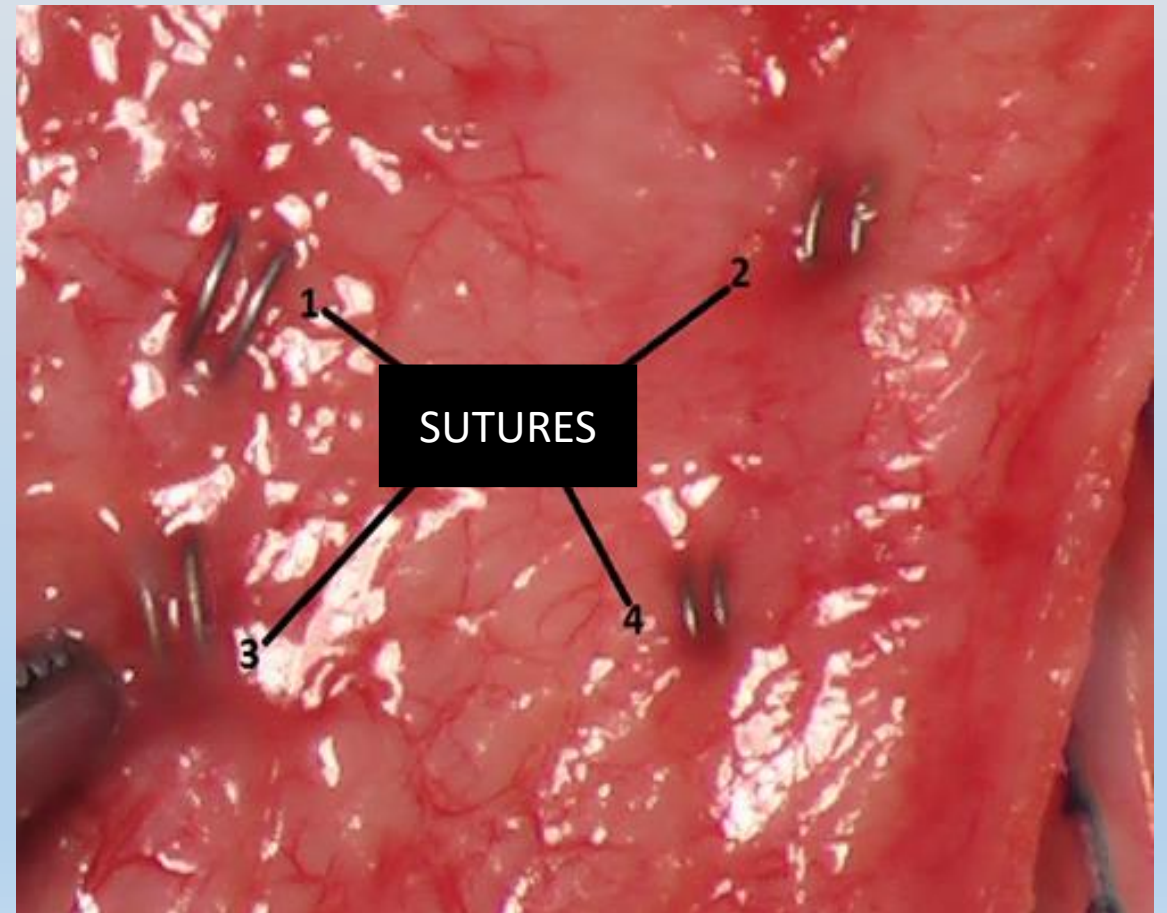


Nitinol suture configuration human cadaveric aorta attached to graft

APPEARANCE INSIDE THE GRAFT

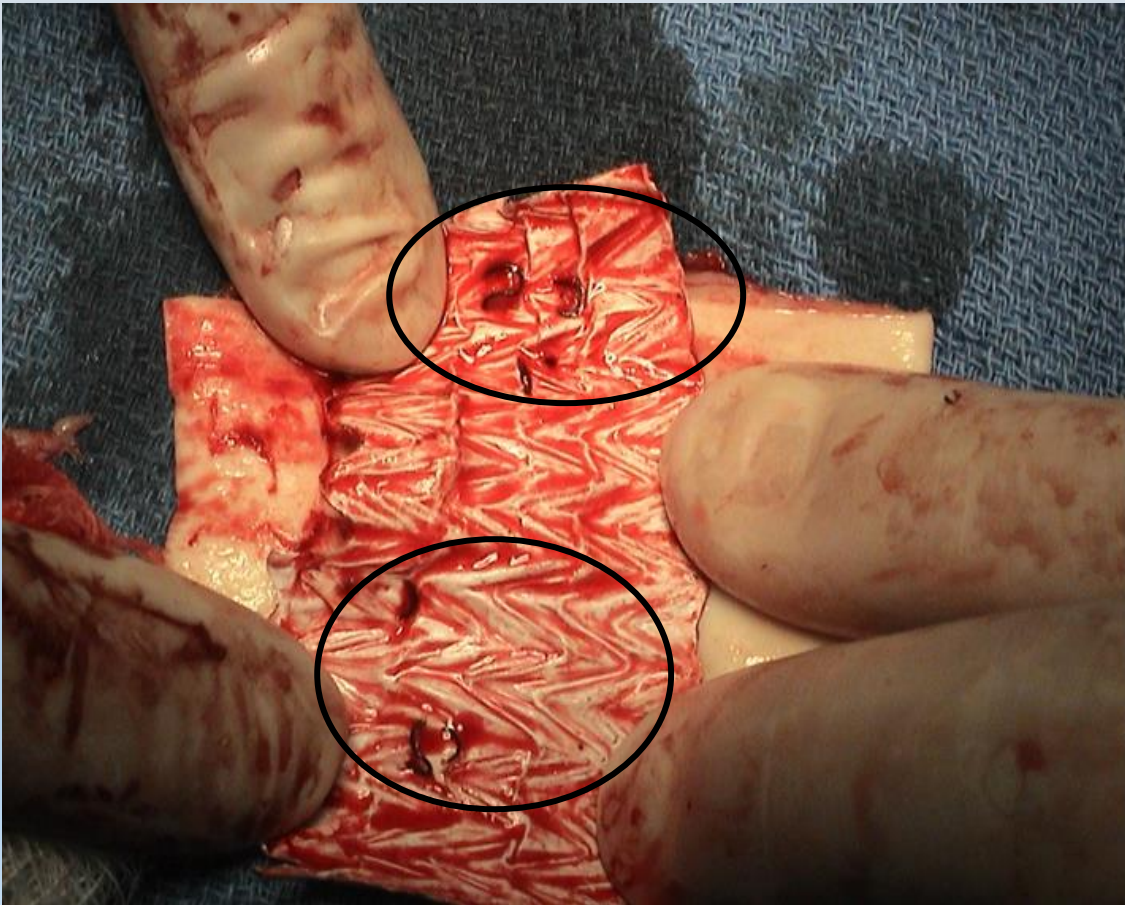


APPEARANCE OUTSIDE THE AORTA

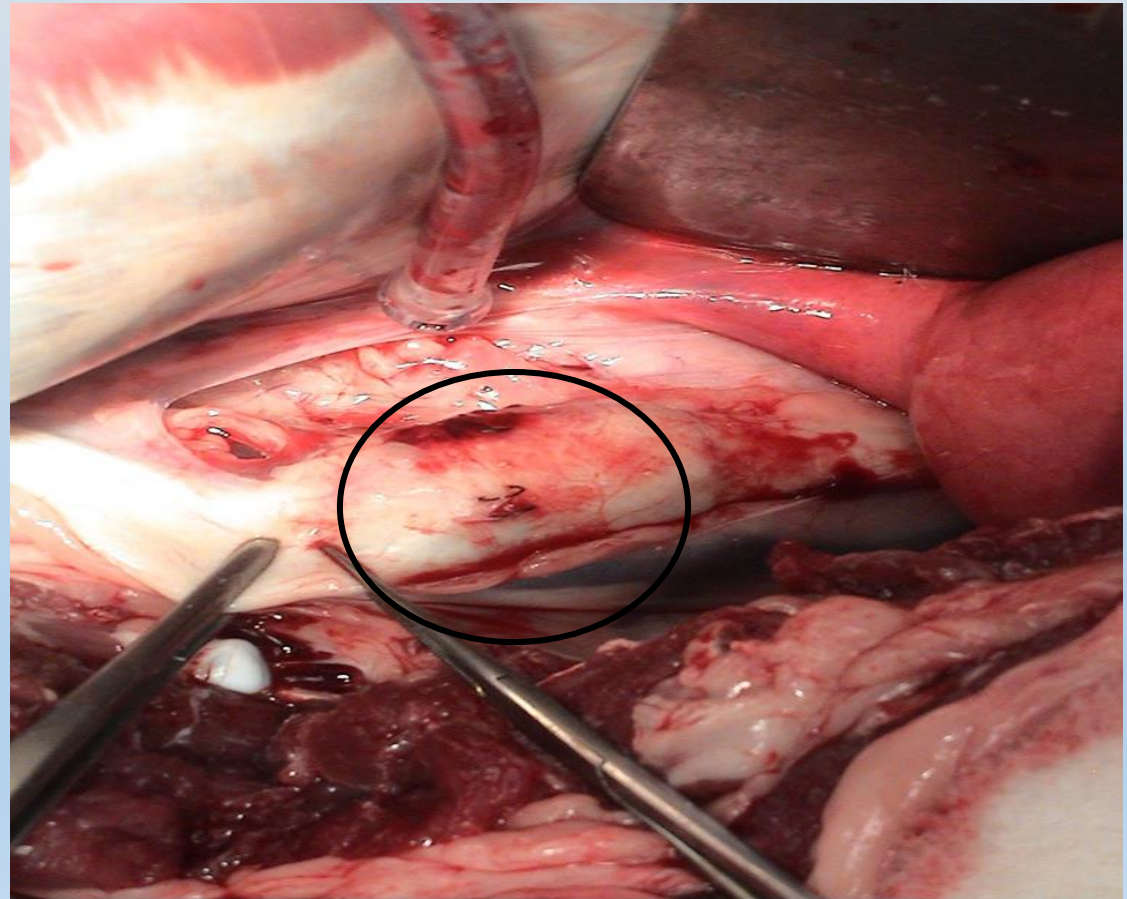


SUTURE CONFIGURATION LIVE SHEEP THORACIC AORTA

LUMEN OF THE TEVAR GRAFT



SUTURES THROUGH THE ADVENTITIA



Penetrates moderately calcified cadaveric aorta



VESTECK 3rd Generation



VS



Heli-FX MDT 1st Generation

Faster, significant improvement in ease of use	YES	NO	
Safer, No dropped sutures	YES	NO	
Preloaded with 4 nitinol sutures	YES	NO	
More precise suture placement	Yes	NO	
Improved proximal seal	YES	NO	
Succeeds independent of anatomy	YES	NO	
Better visualization for accurate placement	YES	NO	
Can actively fix bifurcated graft limbs	YES	NO	
Can attach two grafts together	YES	NO	
Reposition suture until final release	YES	NO	
Improved productivity, cost/radiation reduction	YES	NO	

Stacking new and existing Intellectual Property

**Issued US Patents
assigned to
Vesteck by
Dr. Edoga and Dr.
Richard**



US 8,157,146 B2

Issued on April 17, 2012



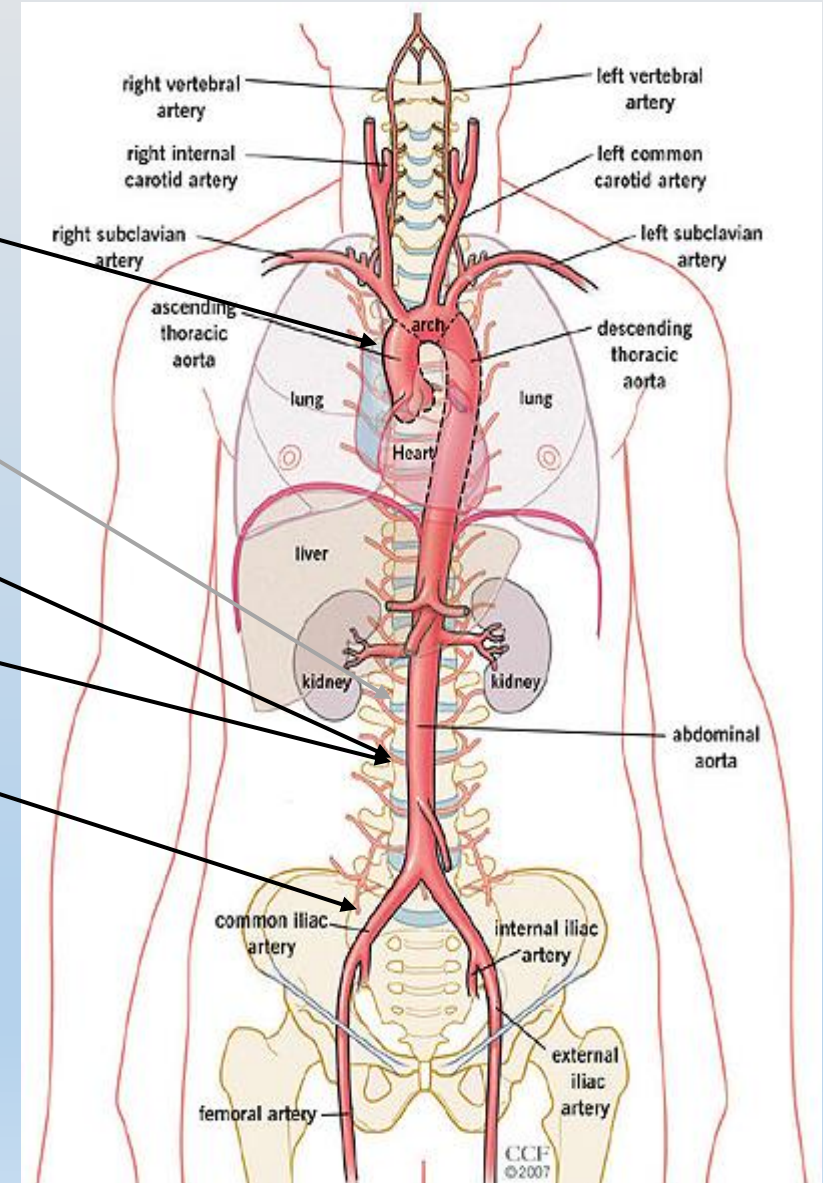
US 8,627,992 B2

Issued on January 14, 2014

Aggressively expanding patent portfolio, recently filed first new patent

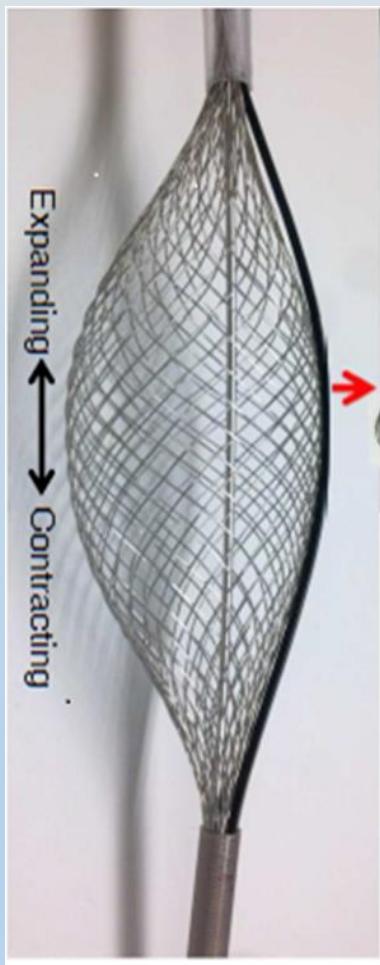
7 devices to repair the aorta from top to bottom

1. TEVAR device for thoracic aortic implant/repair
2. EVAR device for abdominal aortic aneurysms
3. Secure graft to graft revision procedures
4. Device with sutures to repair “Endoleaks”
5. Iliac device for securing bifurcation limbs
6. Integrated EVAR/TEVAR graft and suture delivery catheter
7. Simultaneous Multiple suture delivery

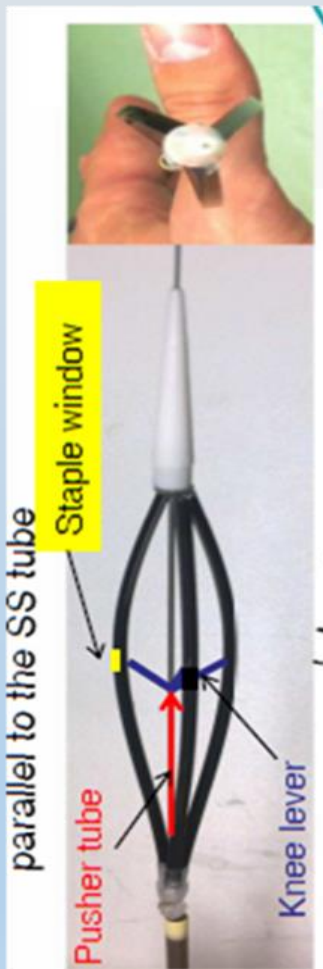


New Product Pipeline

EVAR, TEVAR and Integrated delivery graft and suture together



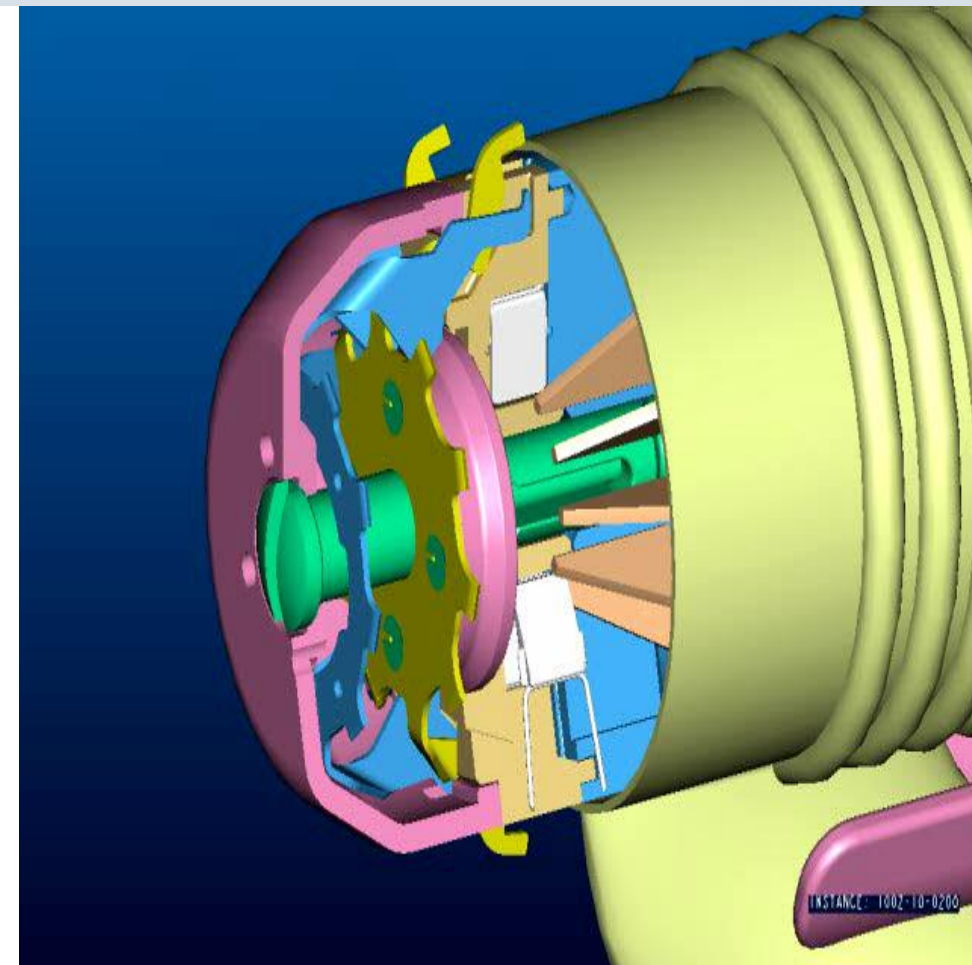
TODAY



**CONCEPT
PROTOTYPE**



**CONCEPT OF
TOMORROW**



**VESTECK GRAFT RETENTION
MECHANISM**

Vesteck, Inc.



*The annual listing of 10 companies that are at the forefront of providing
Cardio Vascular Devices solutions and impacting the industry*

Summary

- Although a preferred technology by patients and physicians, aortic endografting carries a meaningful re-intervention and failure rate with important clinical sequela
- Existing technology has demonstrated clinical benefit to proximal neck attachment
- VESTECK Suture-Tight technology offers advantages over current offerings:
 - Multiple sutures (4) per catheter
 - Spans large gaps
 - Accesses full circumference of graft easily
 - Assures apposition and placement accuracy

Questions and Discussion

Footnotes

1. [https://www.jvascsurg.org/article/S0741-5214\(17\)32369-8/pdf](https://www.jvascsurg.org/article/S0741-5214(17)32369-8/pdf)
2. <http://cdt.amegroups.com/article/viewFile/16911/17207>
3. <https://www.nice.org.uk/guidance/gid-cgwave0769/documents/short-version-of-draft-guideline>
4. <https://www.ncbi.nlm.nih.gov/pubmed/?term=Primary+EndoAnchoring+in+the+Endovascular+Repair+of+Abdominal+Aortic+Aneurysms+With+an+Unfavorable+Neck>
5. Society of Vascular Surgery https://m.youtube.com/watch?time_continue=32&v=v8hJFeKWs4A
6. <https://gore.rccsclients.com/wp-content/uploads/national-pdfs/2019%20IPPS%20Endovascular%20Repair%20of%20AAA%20EVAR%20Reimbursement%20Info.pdfaneurysm-necks/>
7. <https://www.ncbi.nlm.nih.gov/pubmed/29290495>
8. <https://www.uptodate.com/contents/endovascular-repair-of-abdominal-aortic-aneurysm/abstract/96>
9. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5970963/figure/F2/>
10. [https://www.jvascsurg.org/article/S0741-5214\(08\)01807-7/fulltext](https://www.jvascsurg.org/article/S0741-5214(08)01807-7/fulltext)
11. <https://www.ncbi.nlm.nih.gov/pubmed?term=28160528>
12. <https://www.uptodate.com/contents/endoleak-following-endovascular-aortic-repair>
13. <https://www.globaldata.com/aortic-stent-graft-global-market-reach-4-5bn-2028/>
14. <https://www.medtechdive.com/news/aortic-stent-graft-market-on-path-to-solid-growth/544730/>
15. <https://www.ncbi.nlm.nih.gov/pubmed?term=28160528>
16. [https://www.jvascsurg.org/article/S0741-5214\(16\)30903-X/fulltext](https://www.jvascsurg.org/article/S0741-5214(16)30903-X/fulltext)
17. <https://www.vumedi.com/video/current-status-of-evar-for-infra-renal-aneurysm-and-the-need-for-re-intervention/>