



# Thoracic and Abdominal Aortic Aneurysm Grafts: Lessons from the Past, Designs for the Future

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## *Disclosure Information*

# Thoracic and Abdominal Aortic Aneurysm Grafts: Lessons from the Past, Designs for the Future

*Robert M. Bersin MD, MPH*

The following relationships exist related to this presentation:

Name of Company: Cook Inc. C, P

Name of Company: Cordis Endovascular AB,C, EI, P, SB

Name of Company: Medtronic Vascular P

Name of Company: W.L. Gore C, P

AB: Advisory Board

C: Consulting Relationship

EI: Equity Interest

GS: Grant Support

P: Proctor or Training Course Sponsorships

SB: Speakers Bureau

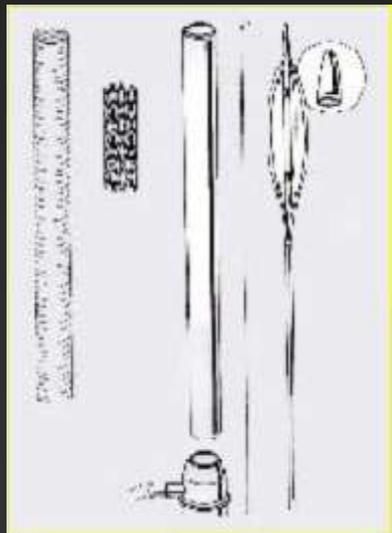
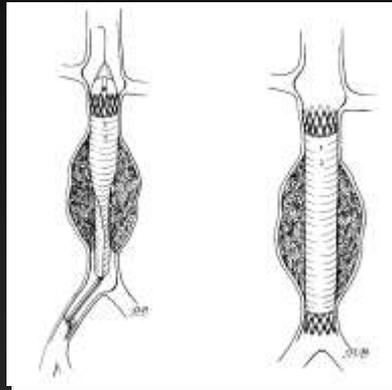
SE: Spouse Employee

SO: Stock Options or Positions

*Off label use of products will be discussed in this presentation: Use of endografts for aortic dissection, ascending, arch and thoracoabdominal aneurysms*



# First AAA Endograft Implant 1990



# EVT ANCURE<sup>®</sup> Endograft

## Features

One-piece

Conformable graft design

Platinum radiopaque markers

ENDO-HOOKS<sup>™</sup> Attachment System

25 Fr inner diameter



# EVAR - Profile and Anatomic Coverage of Current Devices

Medtronic  
AneuRx



Medtronic  
Talent



Gore  
Excluder



Cook  
Zenith



Endologix  
Powerlink



Profile  
(O.D.)

21/22Fr

22/23Fr

20/21Fr

21/24Fr

20/22Fr

Anatomic  
Coverage

≈50%

≈75%

≈60%

≈75%

≈40%





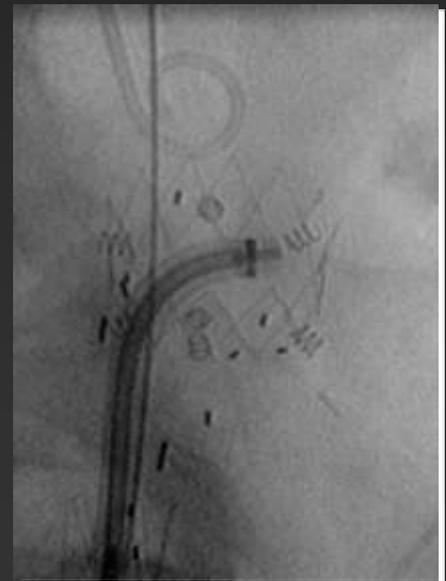
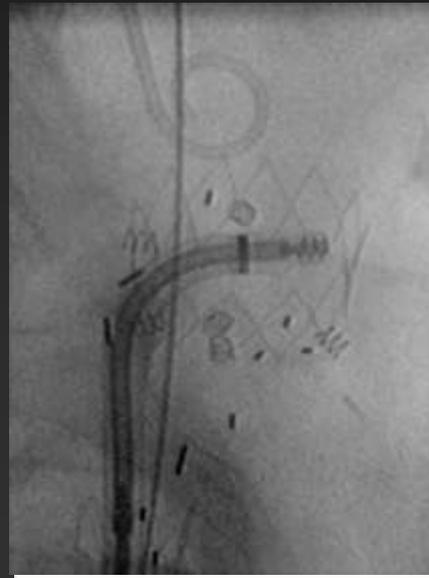
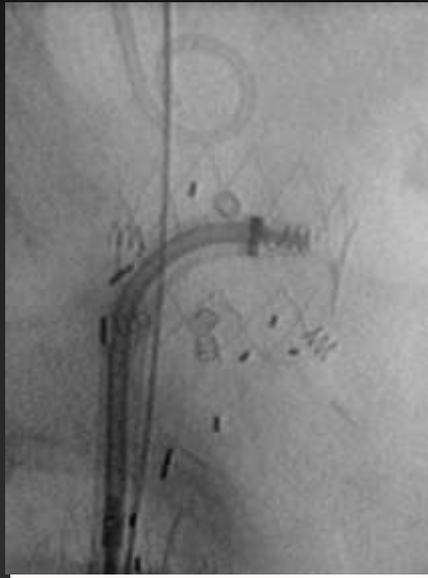
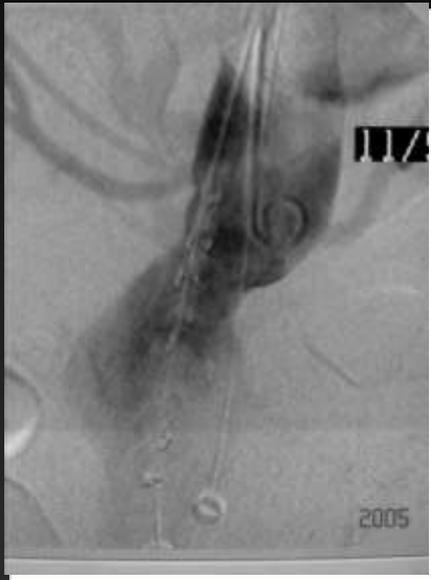
# Aortic Endografts Current Limitations



- Proximal neck diameters
  - 18-32 mm (Talent—34 mm, Zenith—36 mm)
- Proximal neck lengths (supra and infra renal attachment)
  - 5-15 mm
- Iliac artery size for delivery
  - 6-9 mm
- Iliac artery attachment site diameter
  - 8-20 mm diameter
- Angle of neck to aneurysm  $<60^\circ$



# Aptus Endostapling AAA Device

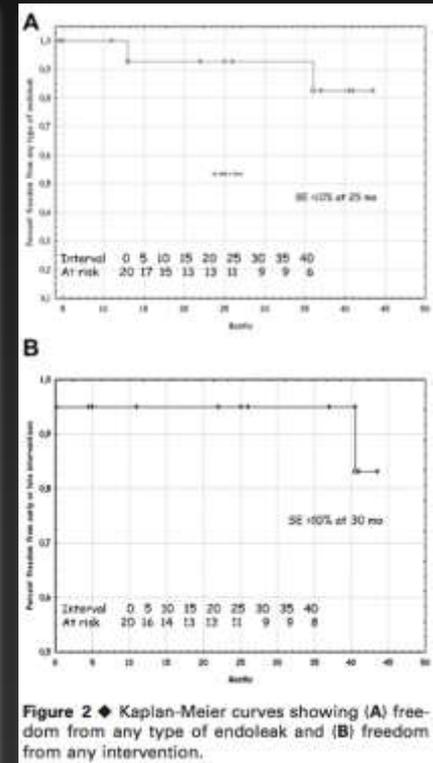


FIM 7-30-05 Venezuela  
STAPLE-2 US IDE Pivotal Trial Completed



# Next Generation Endografts

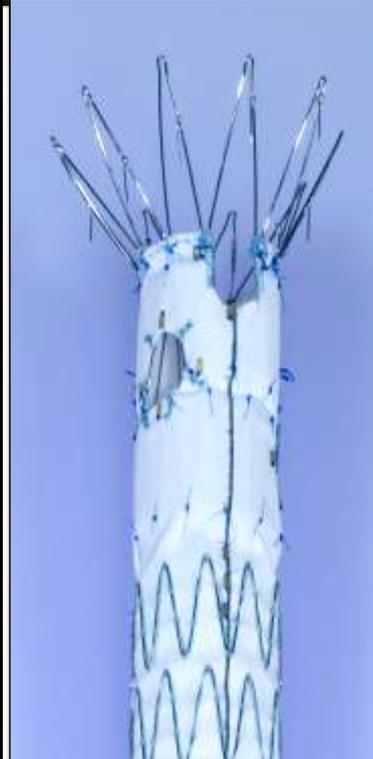
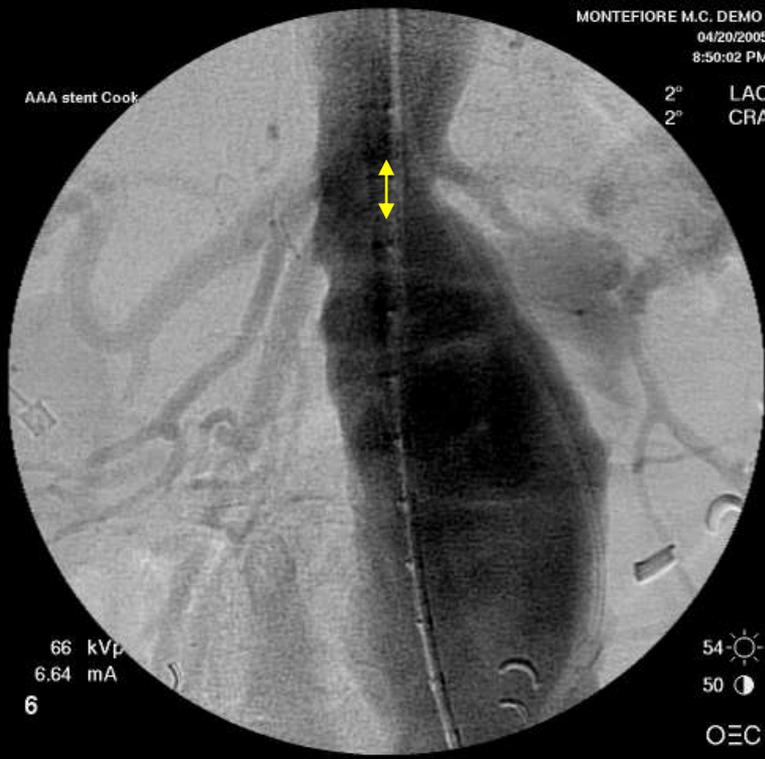
Aorfix Endograft (N=20)



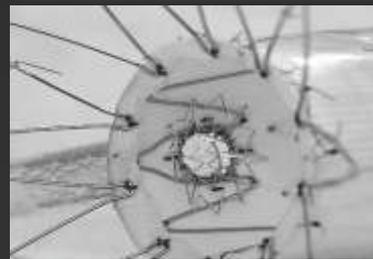
The ARBITER II Trial (N=232)



# Fenestrated Endografts



Proximal Neck 5 mm



# Multi-Branched Endografts



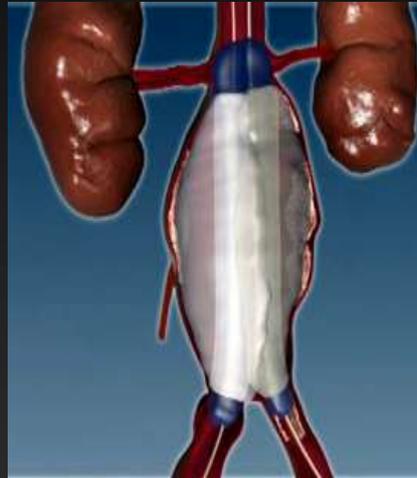
# Nellix AAA Therapy: A No Neck Solution?



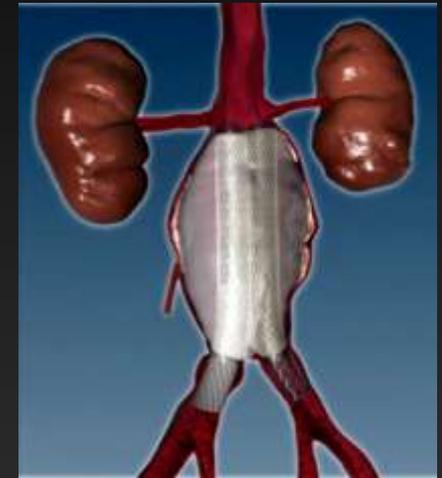
1. Two Delivery Catheters access the Aneurysm



2. Sheaths are retracted to expose Endografts and Endoframes mounted on Balloons



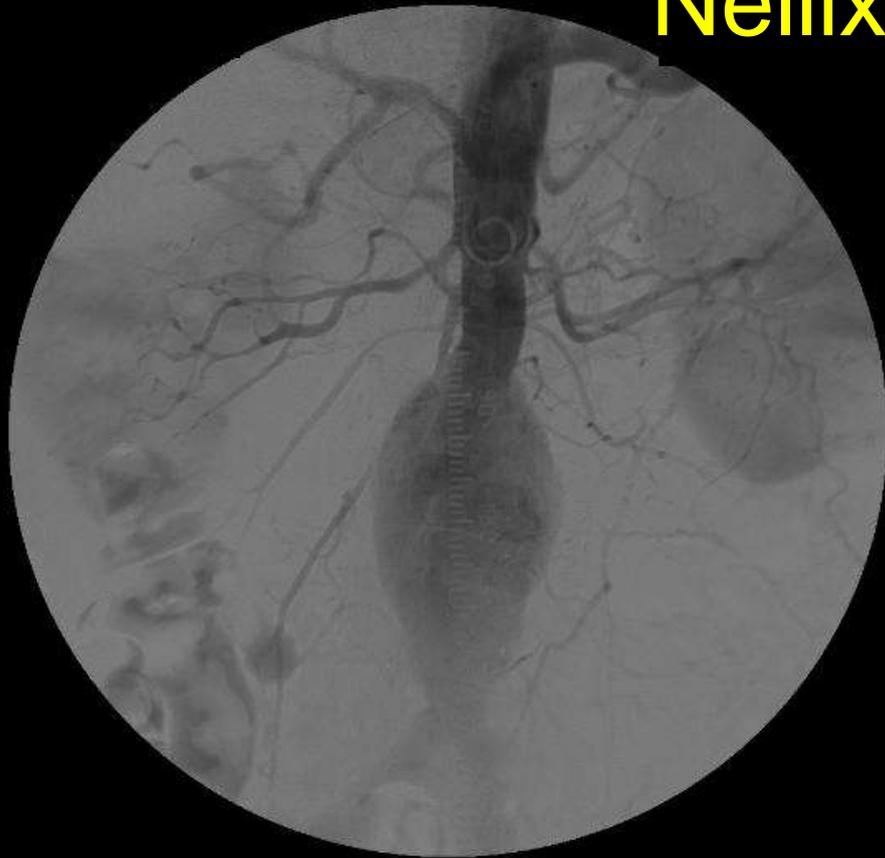
3. Balloons are inflated to expand Endografts. Endografts are then filled with Polymer



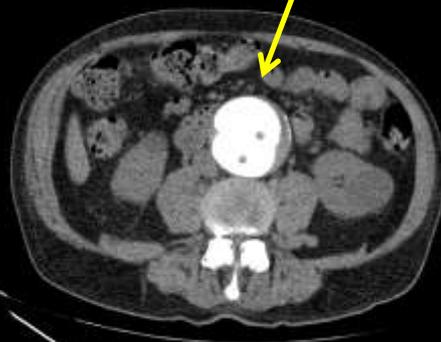
4. Balloons are removed and Endoprosthesis is delivered. Extension cuffs are used per patient's anatomical needs.



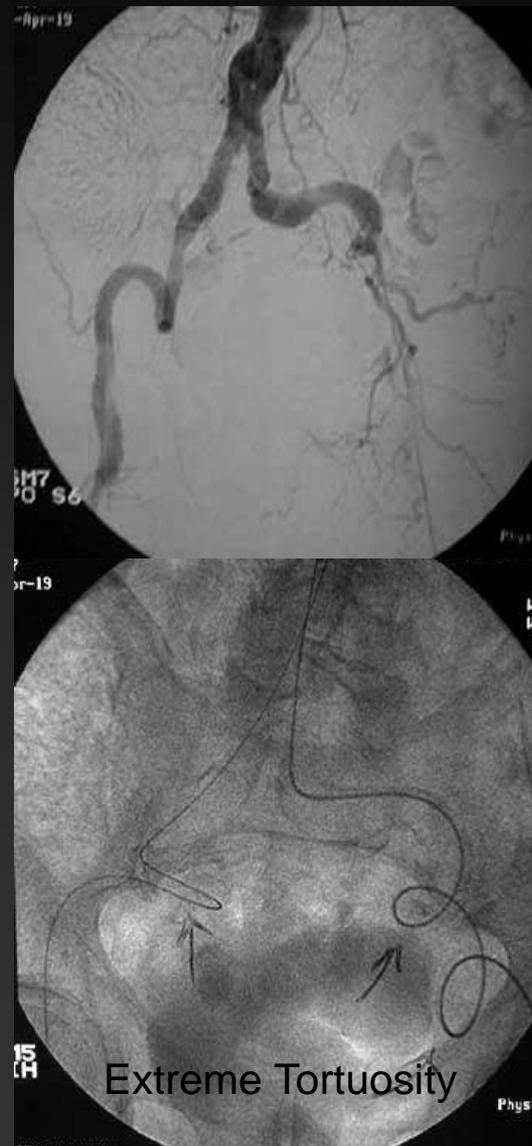
# Nellix Device



Polymer Fill



# The Unmet Need for Percutaneous Access





# Endurant Endograft

## Design Characteristics

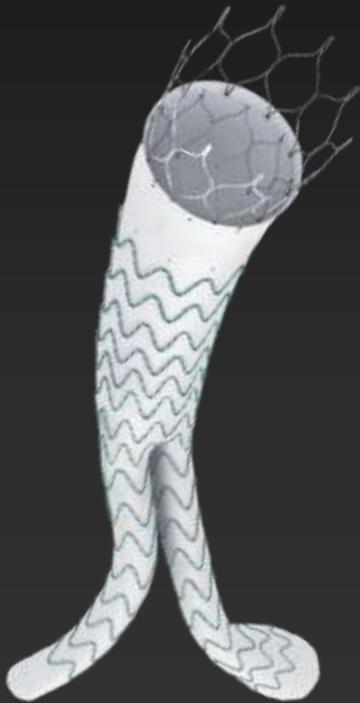
- Three-piece modular
- Suprarenal stent with hook fixation
- More flexible main body and limbs
- Lower-profile delivery: 18- and 20-F OD
- Treats shorter and more angulated necks



# Next Generation LP EVAR Devices

## Common Design Characteristics

- Three-piece modular
- Suprarenal stent with hook fixation
- Lower-profile delivery: 12-16F OD



Cook Zenith LP 16F



Trivascular 14F



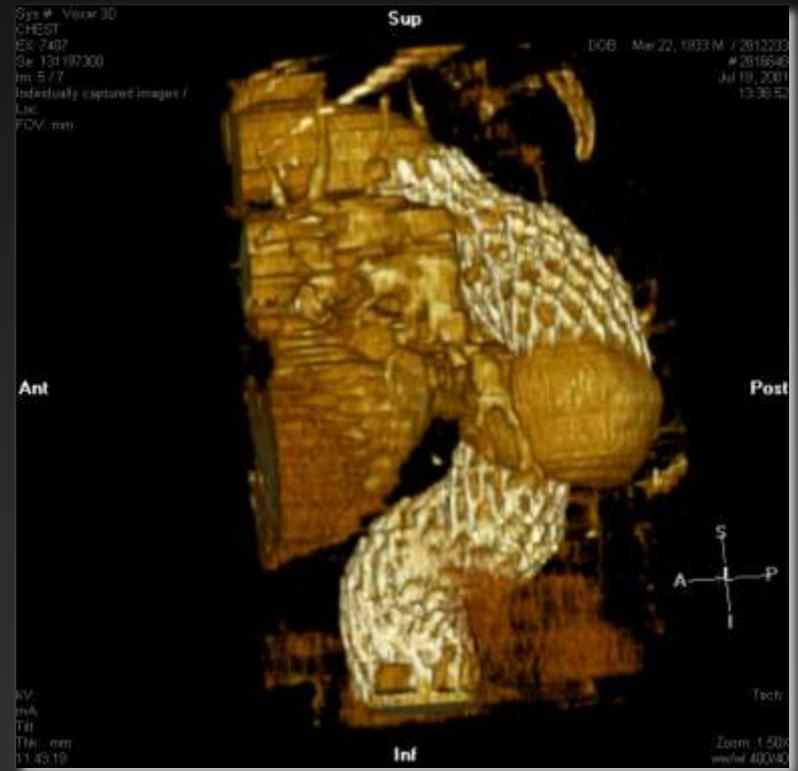
Cordis Ambition 12F



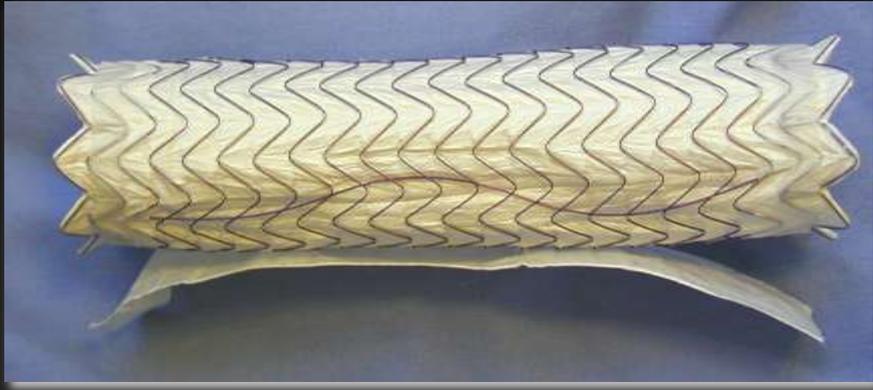
# AneuRx Thoracic Stent-Graft System



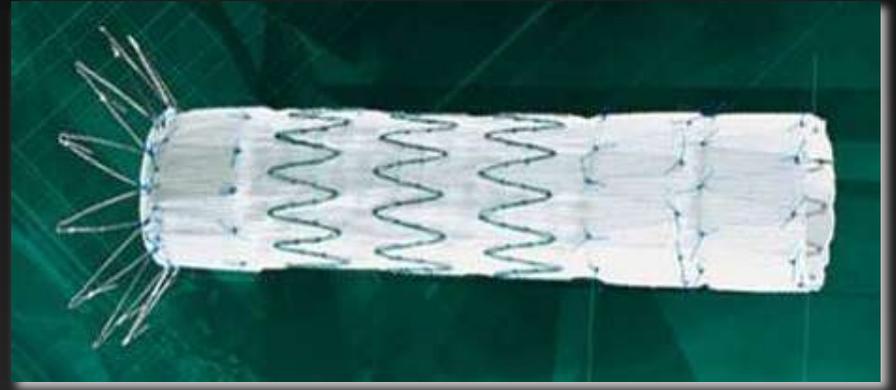
# AneuRx Thoracic Stent-Graft System



# Thoracic Endografts



WL Gore TAG thoracic device



Cook TX2 thoracic device



Medtronic TALENT thoracic device



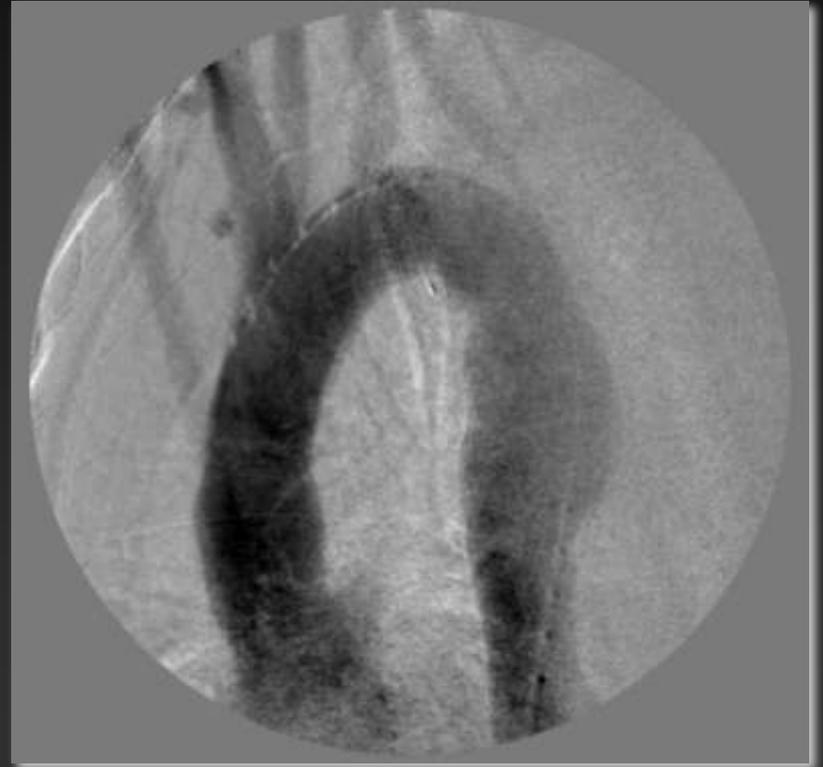
# Descending Thoracic Aneurysm with Acute Dissection



# Stanford Type B Dissection



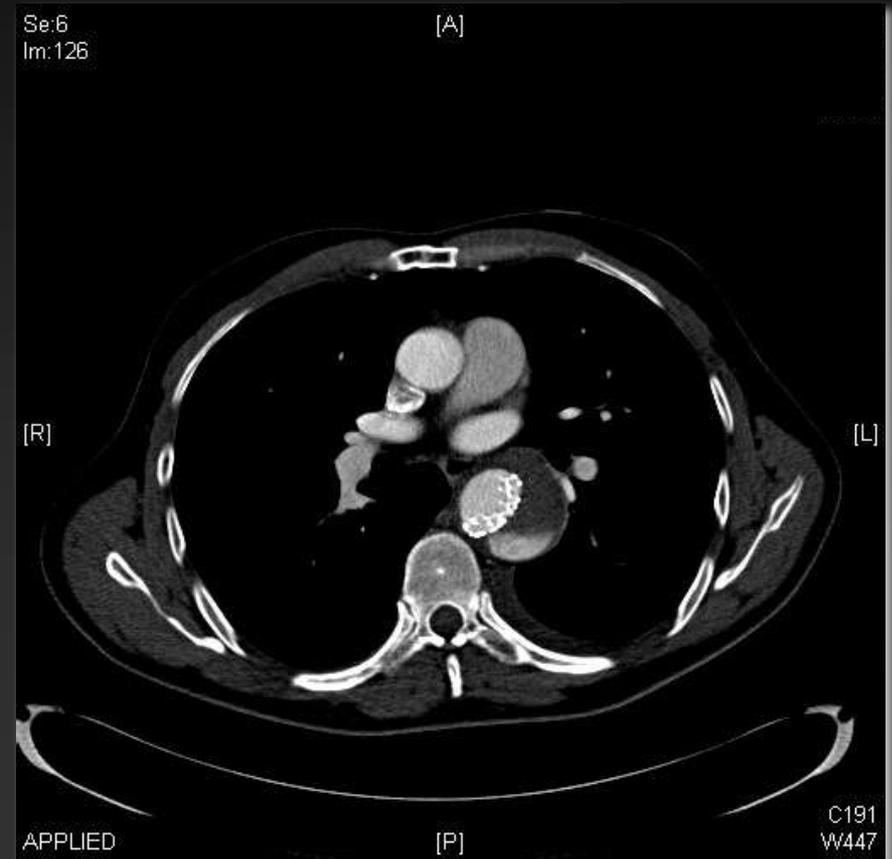
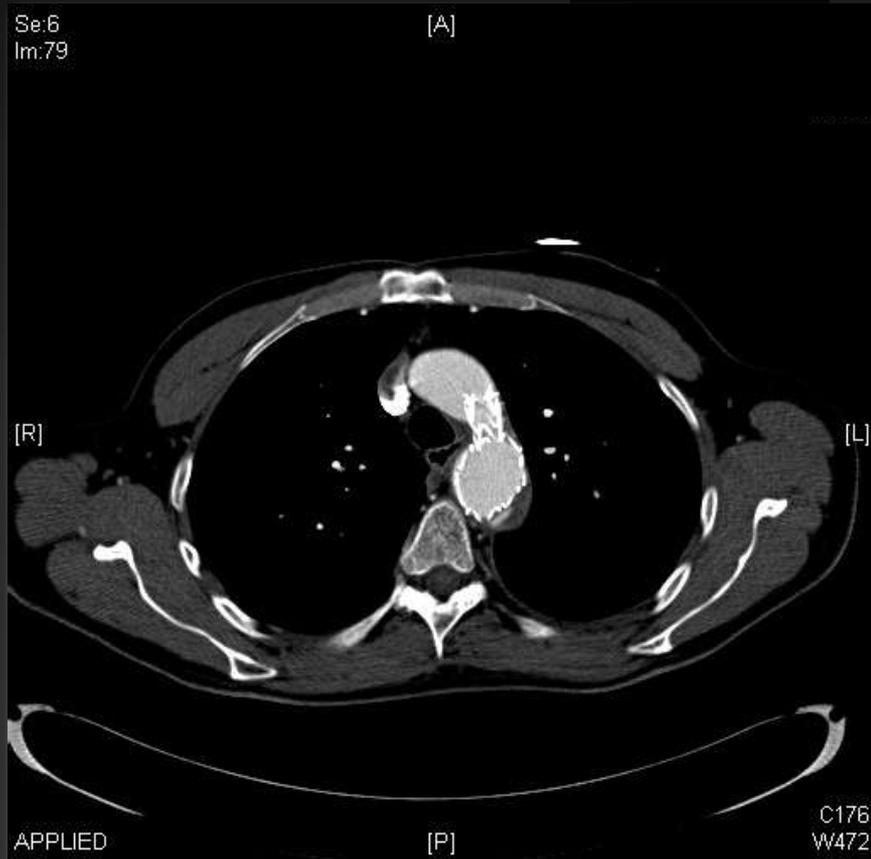
26 mm proximal neck diameter by CTA  
30 mm proximal neck diameter by IVUS  
33 mm distal neck diameter at 20 cm



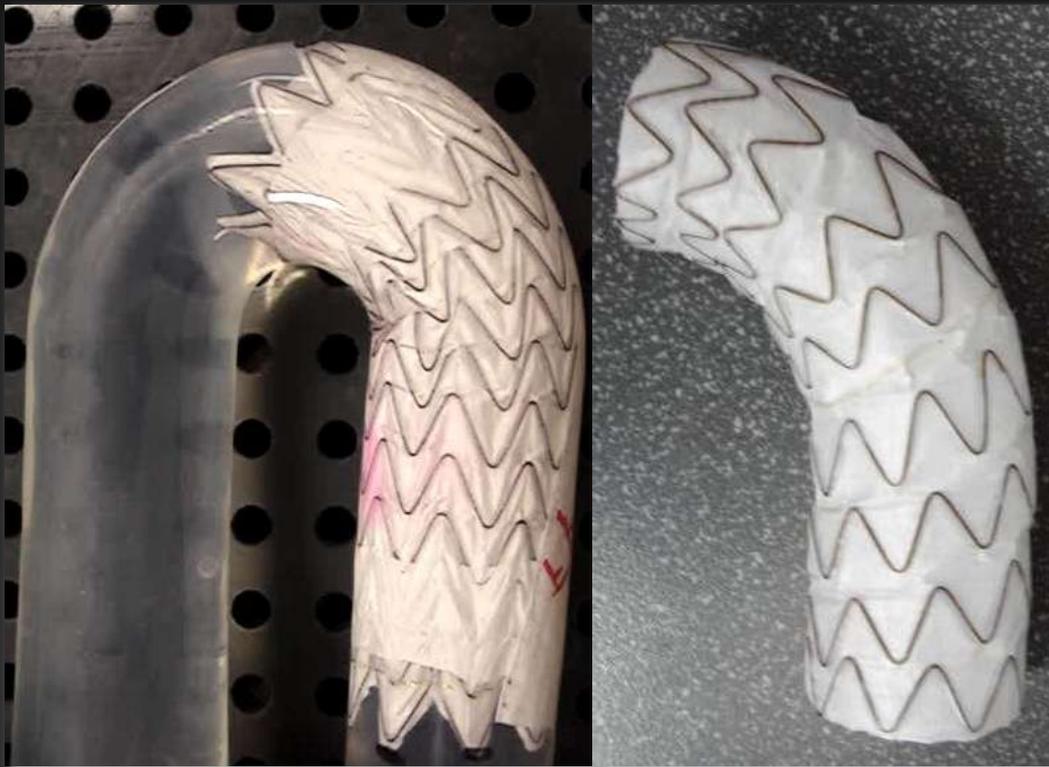
34 mm x 20 cm Gore TAG device



# Acute Proximal Endograft Collapse



# Curved TAG Endograft



Current TAG Device

Pre-Curved Device

## Clinical Trials

- 08-01 Acute Type B Dissection
- 08-02 Traumatic Transection
- 08-03 Aneurysm of the DTA



# Medtronic Thoracic Device Portfolio



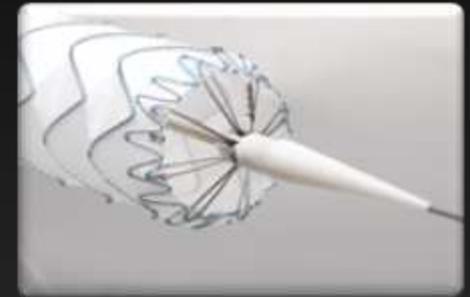
Talent Thoracic Xcelerant

- Approved U.S. '08
- 5-peak proximal bare spring with radial force
- Diameters (22-46mm)
- Lengths (110 – 116mm)
- 22F, 24F, 25F
- Pros: accuracy, ease of use, >20K implants WW



Talent Thoracic Captivia

- IDE trial completed
- 5-peak bare spring, proximal tip capture delivery, hydrophilic coating
- Lengths to 200mm
- Pros: Tip capture, improved accuracy, easier iliac access, longer lengths

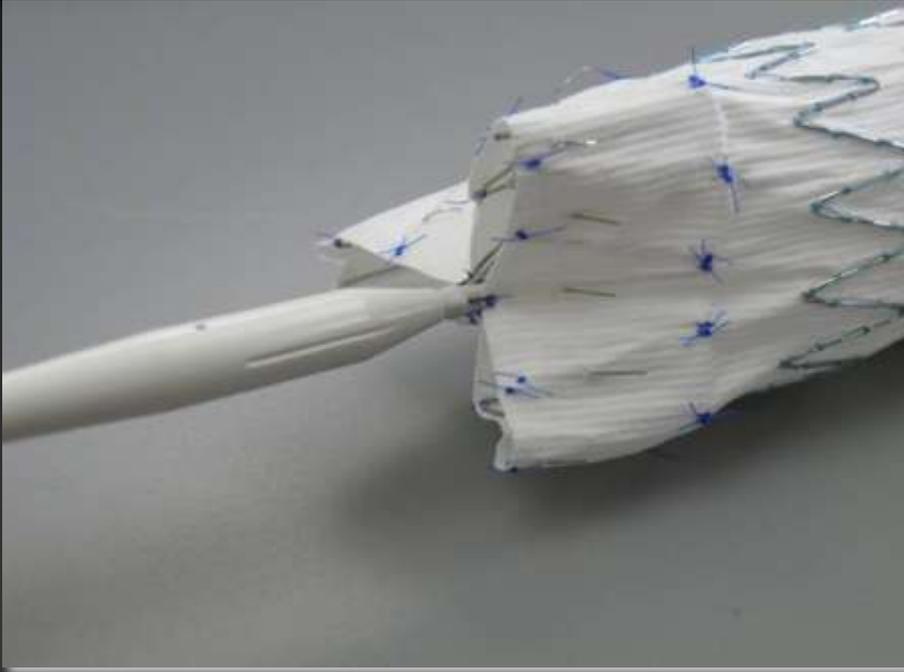


Valiant on Captivia

- CE Mark October '09
- 8-peak proximal bare spring, no connecting bar, tip capture delivery, hydrophilic coating
- Pros: Tip capture, accuracy, increased patient applicability in more challenging cases, high conformability, # 1 TEVAR device OUS



# TX2 with Pro-Form



Original TX2

-Trigger-wires constrain the PROXIMAL end of the sealing stent



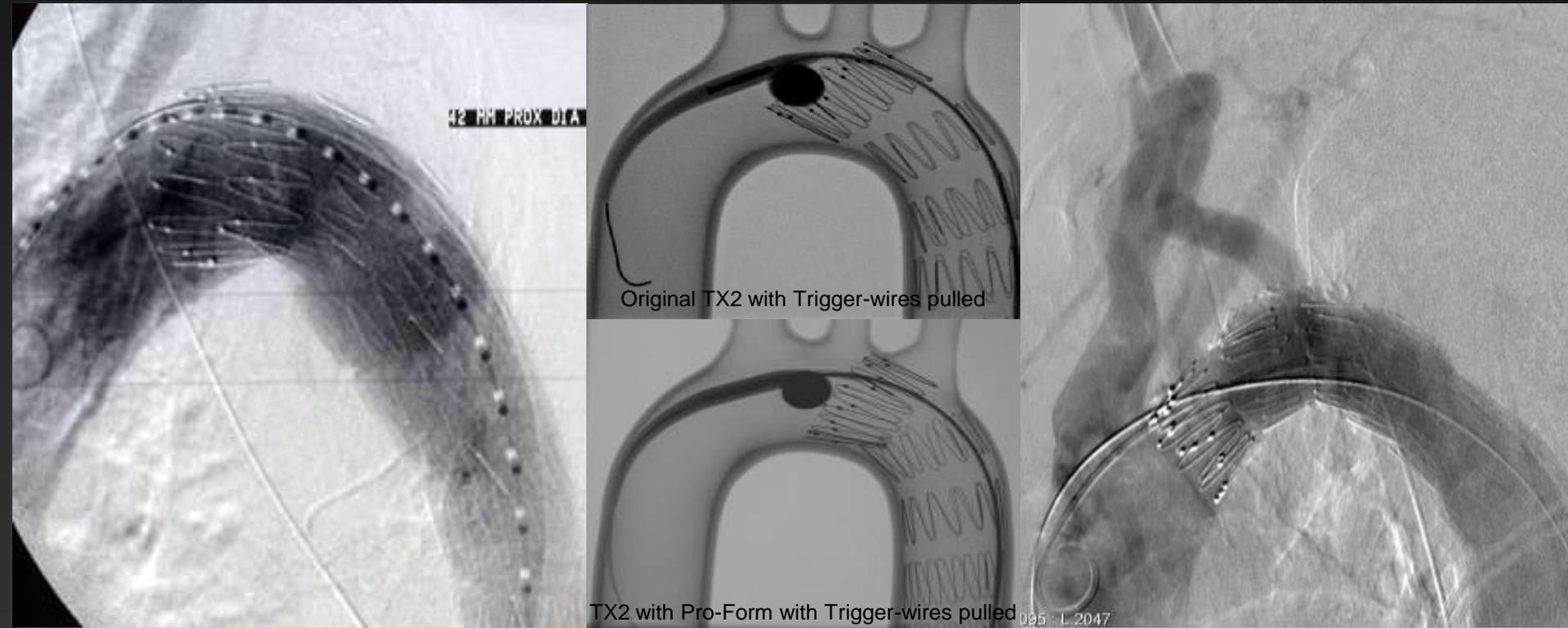
TX2 with Pro-Form

- Trigger-wires constrain PROXIMAL and DISTAL end of the sealing stent



# Zenith TX2 with Pro-Form

Addresses the “Bird’s Beak” effect



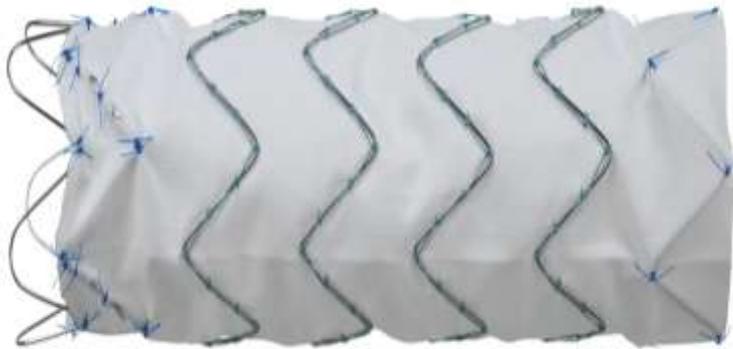
Original TX2

TX2 with Pro-Form



# Next Generation TX2

## TX2-Low Profile



Proximal Component



Distal Component

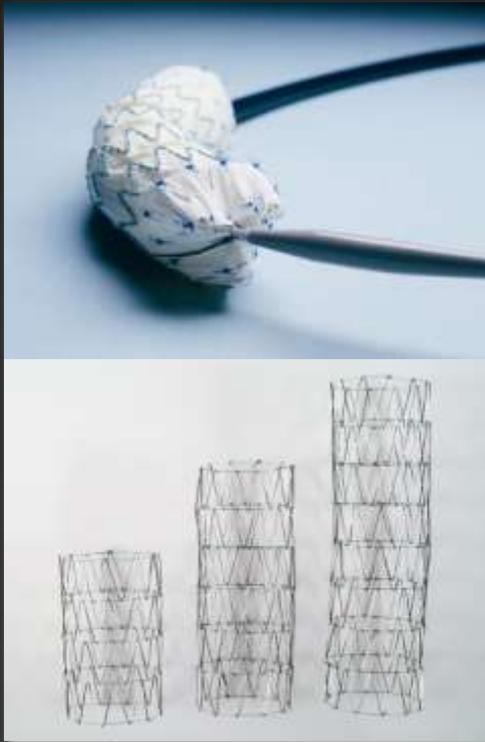
### Graft Diameters Introducer ID

18 – 30	mm	16 Fr
32 – 40	mm	18 Fr
42 – 46	mm	20 Fr

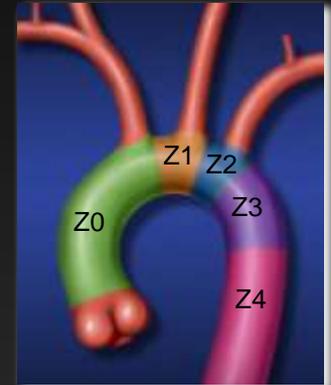


# TX2 Dissection Device

- Bare Z's - Stainless steel stacked stent bodies connected with 5.0 Prolene
- 46 mm diameter X 3 lengths: 82, 123, 164 mm
  - very low radial force; expand over time
  - STABLE Trial is adding 36 mm bare stent and TX2 with Pro-Form



# Chuter Arch Branched Device

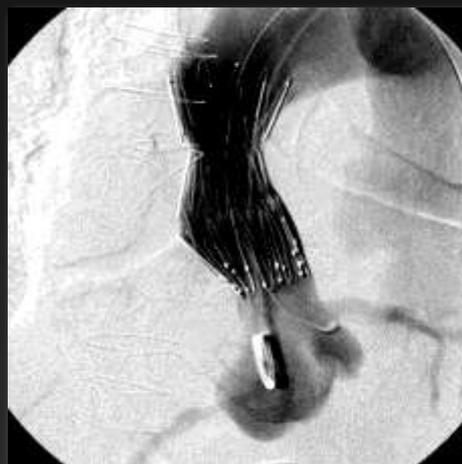


# Ascending Aortic Devices

TX2-LP Devices (28 - 46 mm)



Ascending Graft



Arch Bare Stent

