

Endovascular Debranching Early IDE Results

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Vascular Innovations

Disclosures

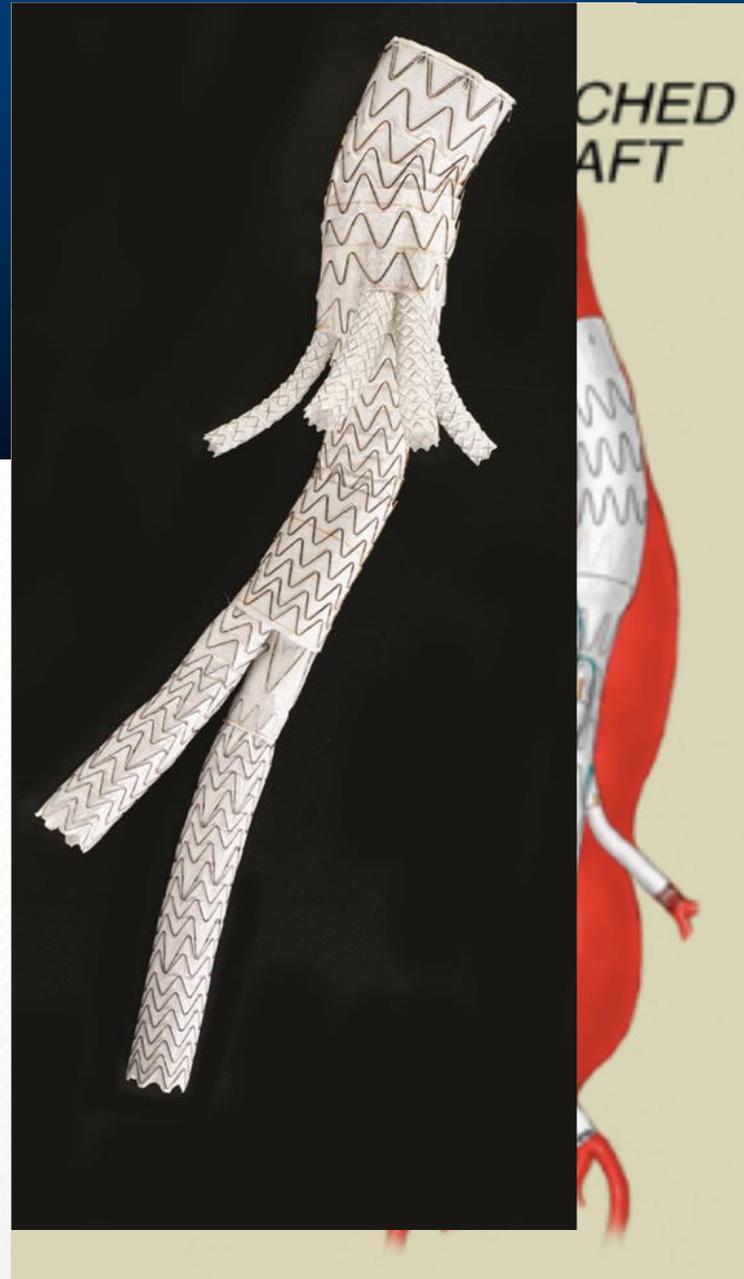
- US Patent and Applications Pending:
 - *U.S. Pat. App. No. 13706036 - Debranching Stent Graft Limb and Methods for Use*
 - *U.S. Pat. App. No. 13706086 - Visceral Double-Barreled Main Body Stent Graft and Methods for Use*
 - *U.S. Pat. App. No. 13706127 - Debranching Visceral Stent Graft and Methods for Use*
 - *U.S. Pat. App. No. 13706144 - Aortic Arch Double-Barreled Main Body Stent Graft and Methods for Use*
 - *U.S. Pat. App. No. 13706158 - Debranching Great Vessel Stent Graft and Methods for Use*
 - *U.S. Pat. App. No. 13706175 - Combination Double-Barreled and Debranching Stent Grafts and Methods for Use*
 - *U.S. Pat. App. No. 61740161 - Stent Deployment Device*
- License Agreement With MDT

Disclaimer

This Presentation discusses the use of an investigational device under PSIDE G140207.

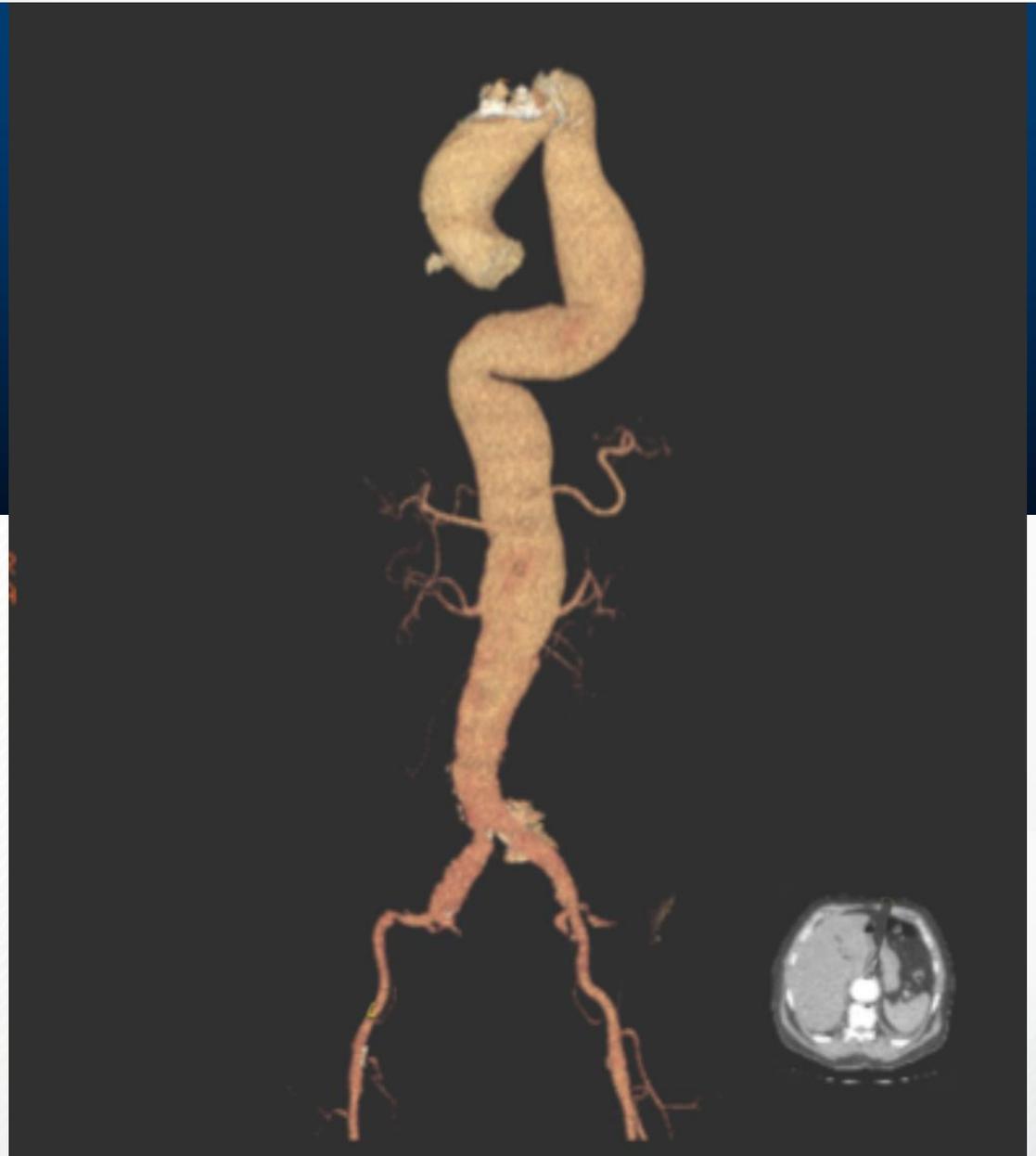
Current Endo Solutions Either Approved or Under Industry Sponsored Study

- **T-Branch**
Approved in Europe and undergoing clinical trial in the U.S.
- **Z-Fem**
4 fenestrations currently undergoing clinical trial in the U.S.
- **Tambe**
Current going through EFS.



All Cover The Visceral Segment During Placement Of Bridging Stents

What About This



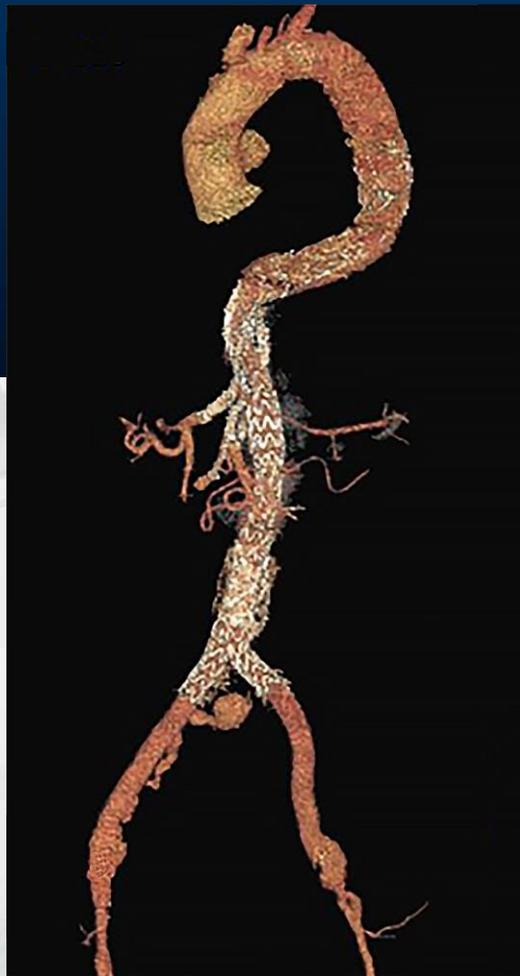
Design Requirements

- Durably exclude the aneurysm with fixation and seal
- Handle virtually any anatomy
- Provide favorable flow characteristics
- Provide unimpeded flow to vital organs throughout the surgery
- Stageable
- Be a fully OFF THE SHELF product

Partnering With Industry

Valiant ThoracoAbdominal Aortic Aneurysm Stent Graft System

VTAAA Stent Graft System



Thoracic Bifurcation
 Prox Ø: 32, 36, 40, 46 mm
 Distal Limb 1 Ø: 20 mm
 Distal Limb 2 Ø: 16 mm
 DS Ø: 22-25 Fr
 DS Type: Valiant Captivia
New Design

Visceral Manifold
 Prox Ø: 24 mm
 Distal Limbs Ø: 8 mm
 DS Ø: 18 Fr
 DS Type: Endurant Limb
New Design

TAAA Debranching Stent Graft System

Key

- 1 Thoracic Bifurcation
- 2 Visceral Manifold
- 3 Bridging Stents 1 - 4
- 4 Descending Extension
- 5 Infrarenal Graft
- 6 Iliac Extension 1 & 2

Visceral Bypass*
 Prox Ø: 16 mm
 Distal Ø: 20 mm
*Identical to Endurant Contralateral Limb Stent Graft and Delivery System
Commercially Available

Bridging Stents
 Atrium iCasts
Commercially Available

Infrarenal Bifurcation
 Prox Ø: 24 mm
 Distal Limb Contra Ø: 14 mm
 Distal Limb Ipsi Ø: 13 mm
Commercially Available

Renal
 Renal

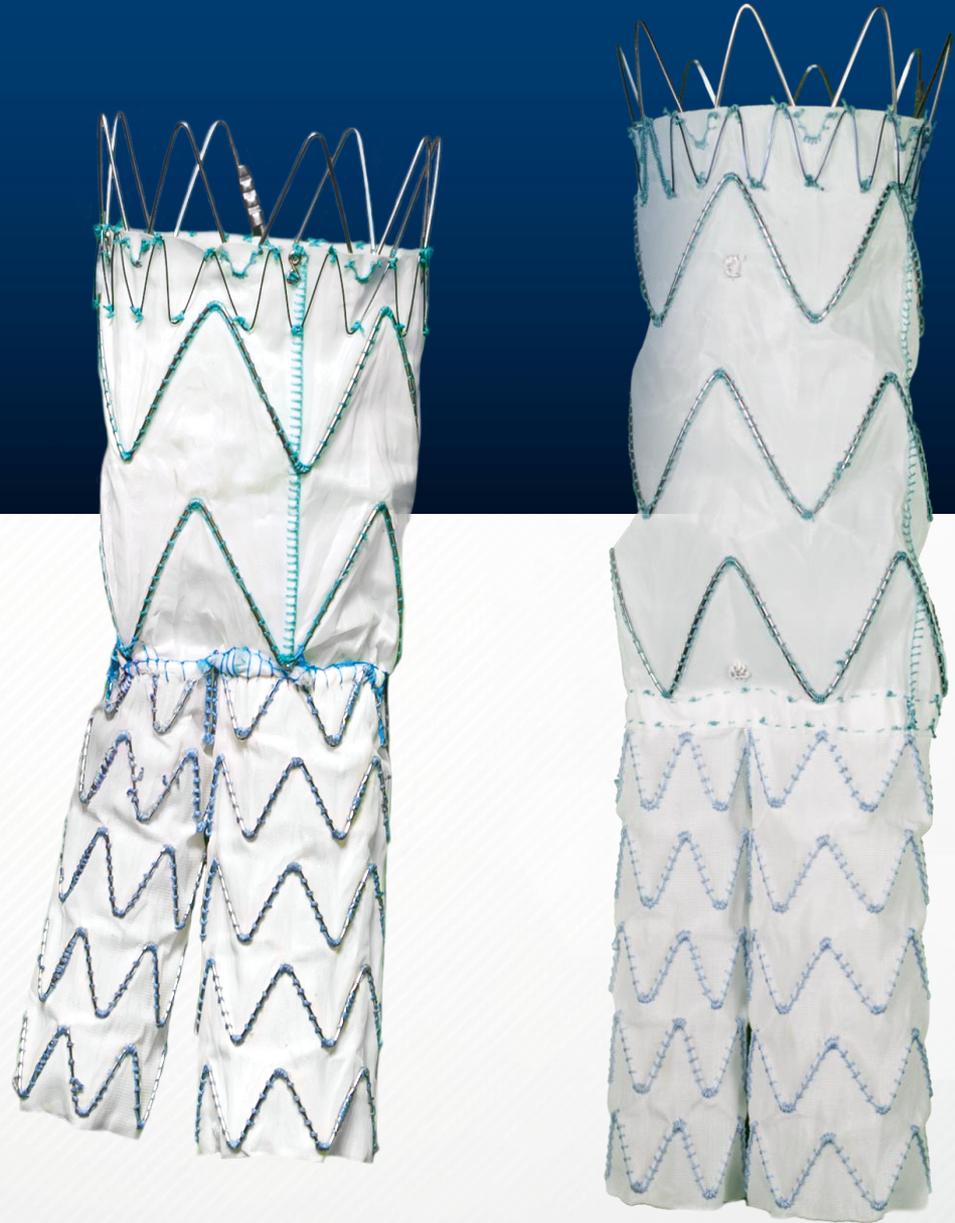
Celiac
 SMA

Iliac

Standard Iliac Limbs
Commercially Available

Iliac

Thoracic Bifurcated Graft (TBG)



Proposed TBG Devices

Valiant Main Component

Diameter Size Match

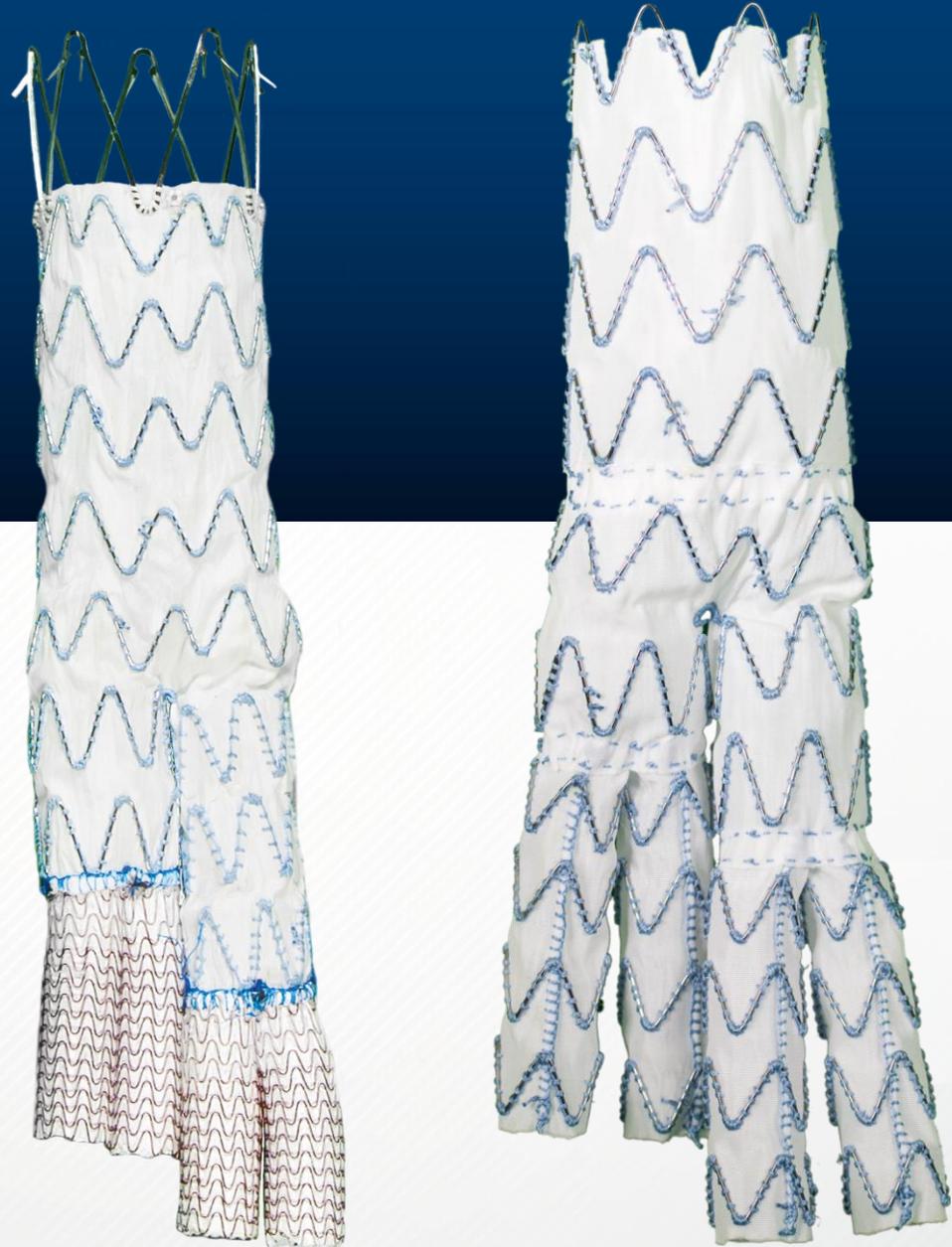
Endurant Extension

20mm Limb

16mm Limb



Visceral Manifold (VM)



Visceral Manifold (VM)

24mm Main Body

14mm Proximal Limbs

8mm Individual Limbs



Assembled System



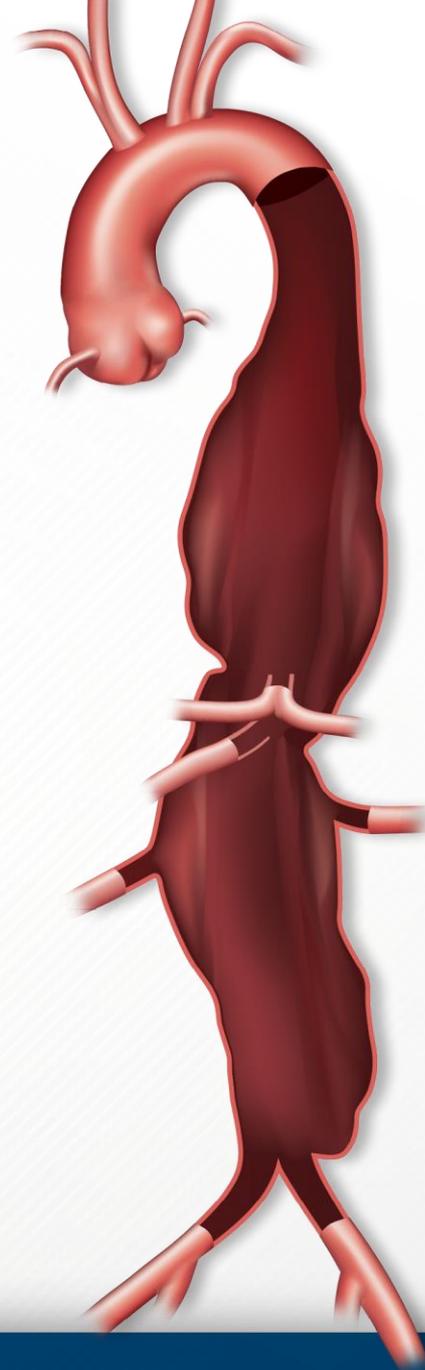
Paradigm Shift

- Proximal Deployment
- Endo-Bypass
- Delayed Primary Seal

Who Said It Has To Look Like The Native Vessel

Thoracoabdominal Aortic Aneurysm Repair

Proximal Deployment
Endo-Bypasses
Delayed Distal Seal



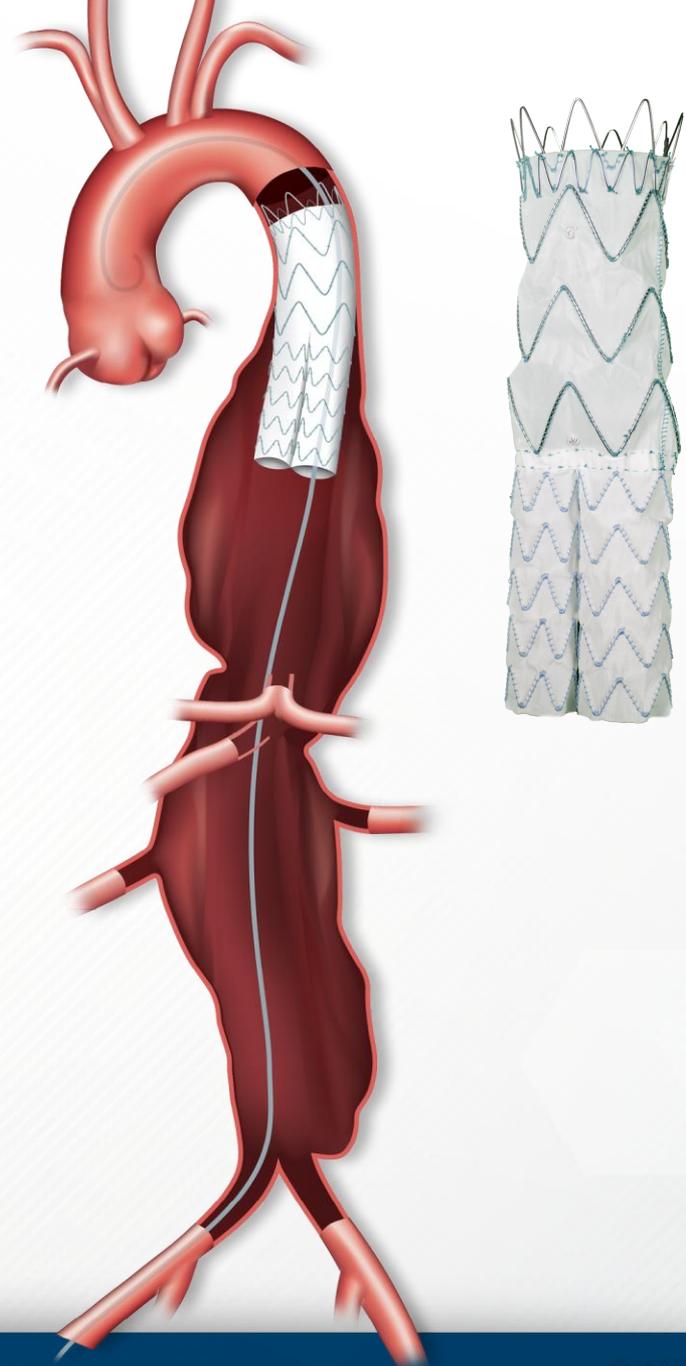
Proximal Deployment

Place the Thoracic Bifurcated Graft and Visceral Manifold above the “branch vessels.”

This allows for continued perfusion throughout the procedure.

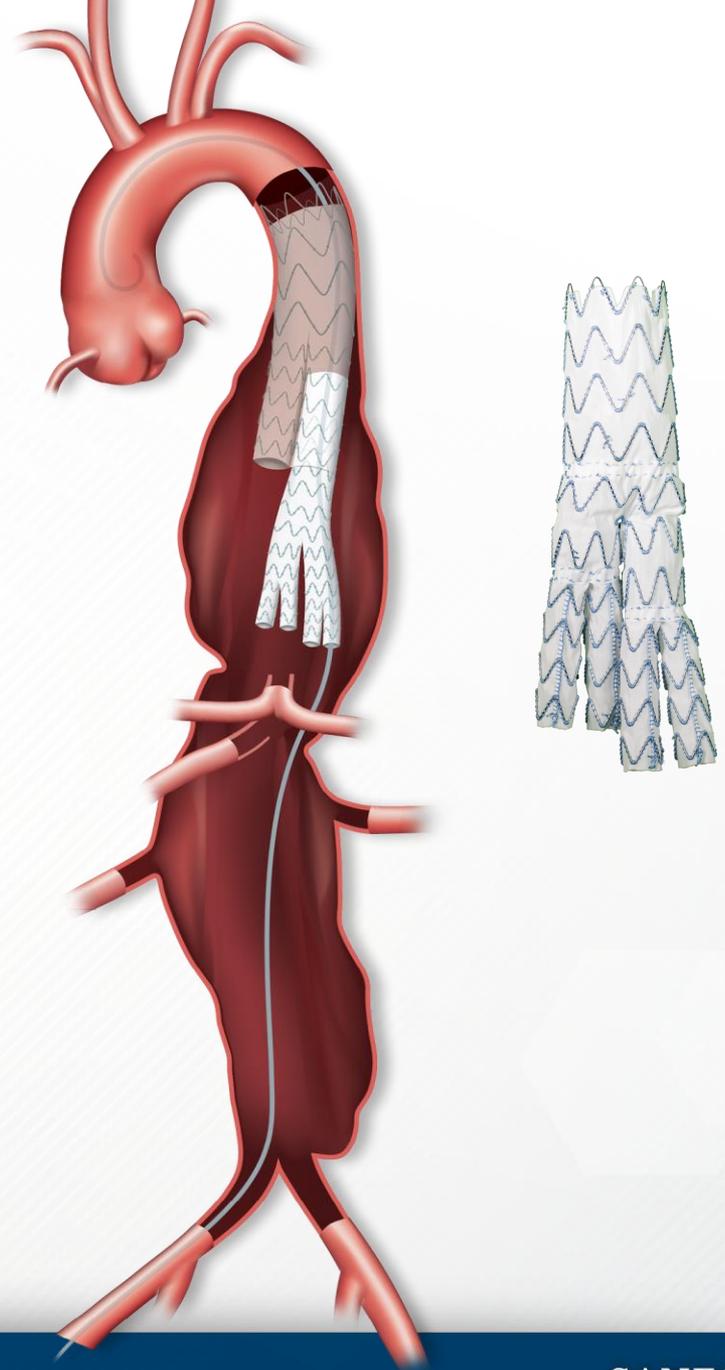
ThoracoAbdominal Aortic Aneurysm

Proximal Deployment Of Thoracic Bifurcated Graft



ThoracoAbdominal Aortic Aneurysm

Proximal Deployment Of Visceral Manifold



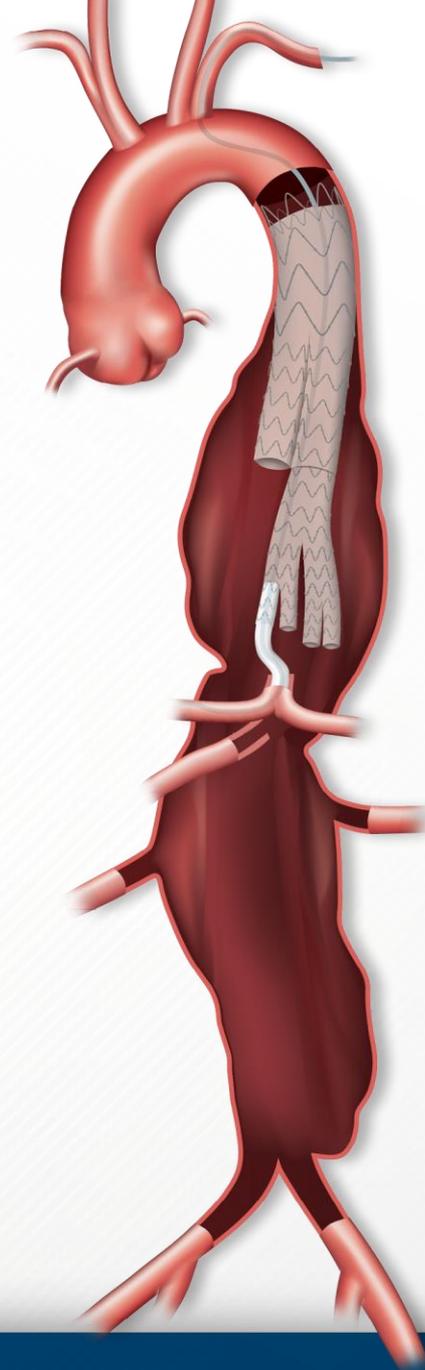
Endo-Bypass

Each of the branch vessels are stented individually from a position more proximally.

These bridging stents are slightly longer, but the favorable flow characteristics and conformability to anatomic variations mirror many of the lessons we've learned from open bypass.

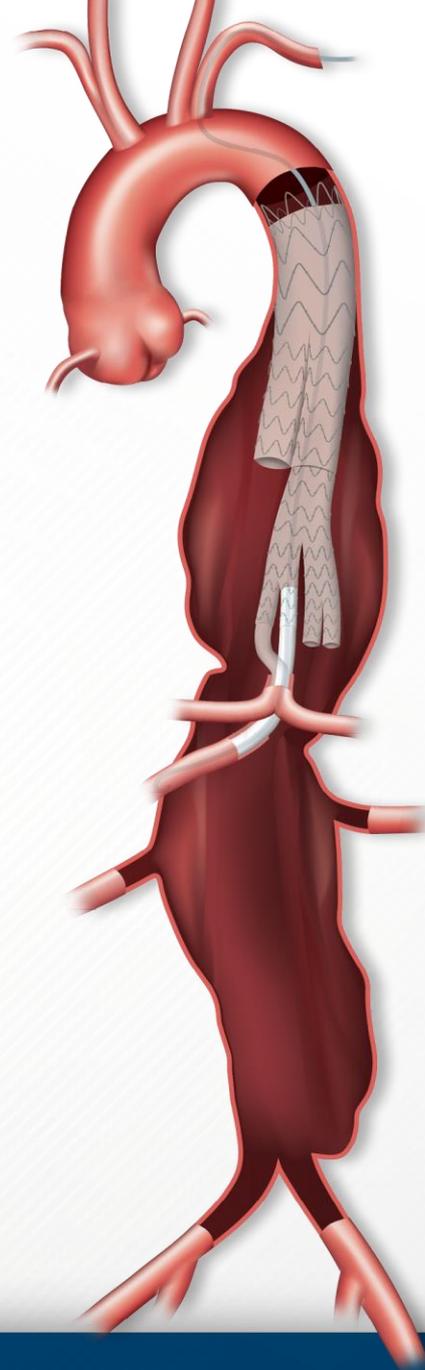
ThoracoAbdominal Aortic Aneurysm

Endo-Bypass



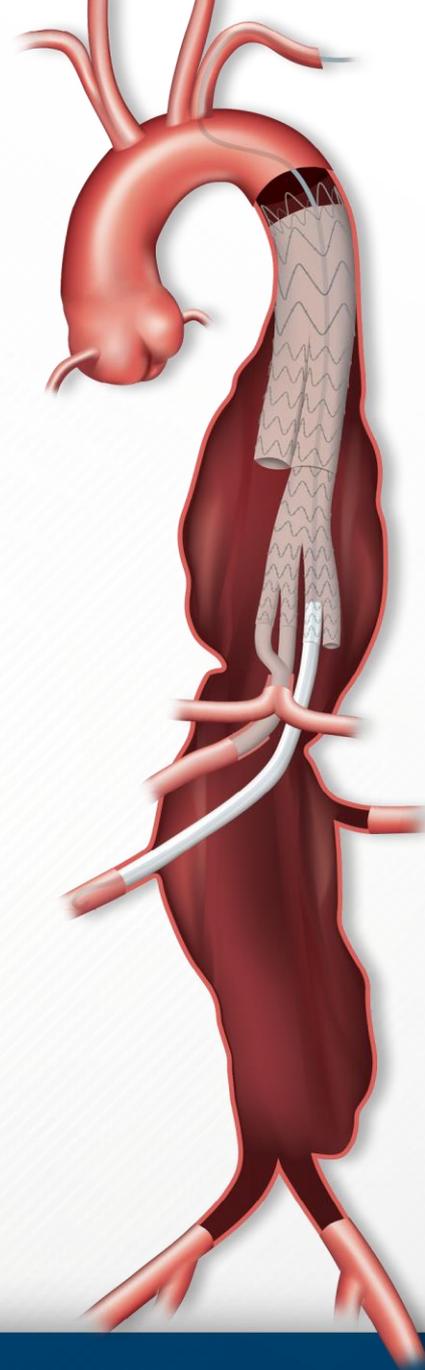
ThoracoAbdominal Aortic Aneurysm

Endo-Bypass



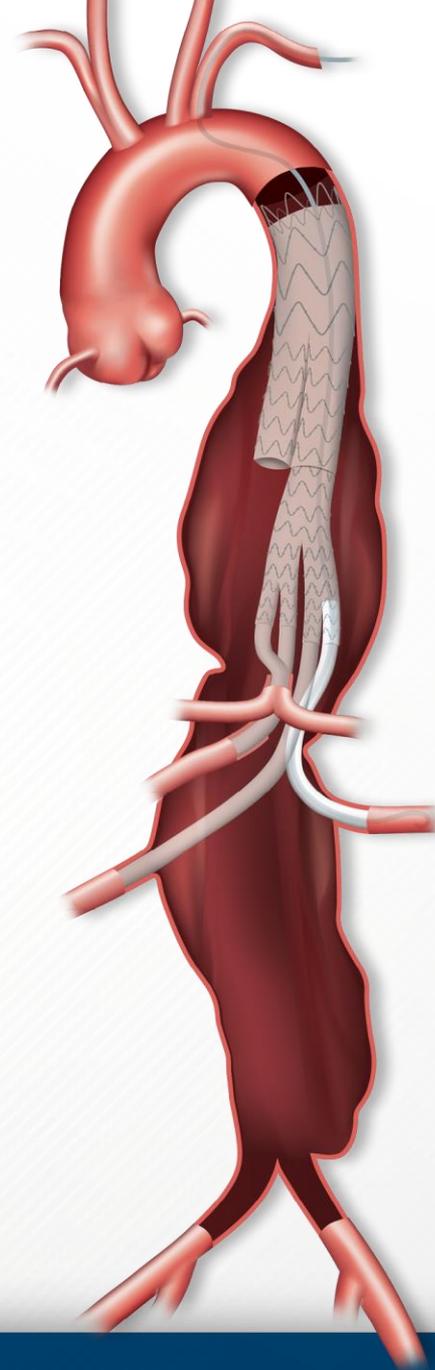
ThoracoAbdominal Aortic Aneurysm

Endo-Bypass



ThoracoAbdominal Aortic Aneurysm

Endo-Bypass

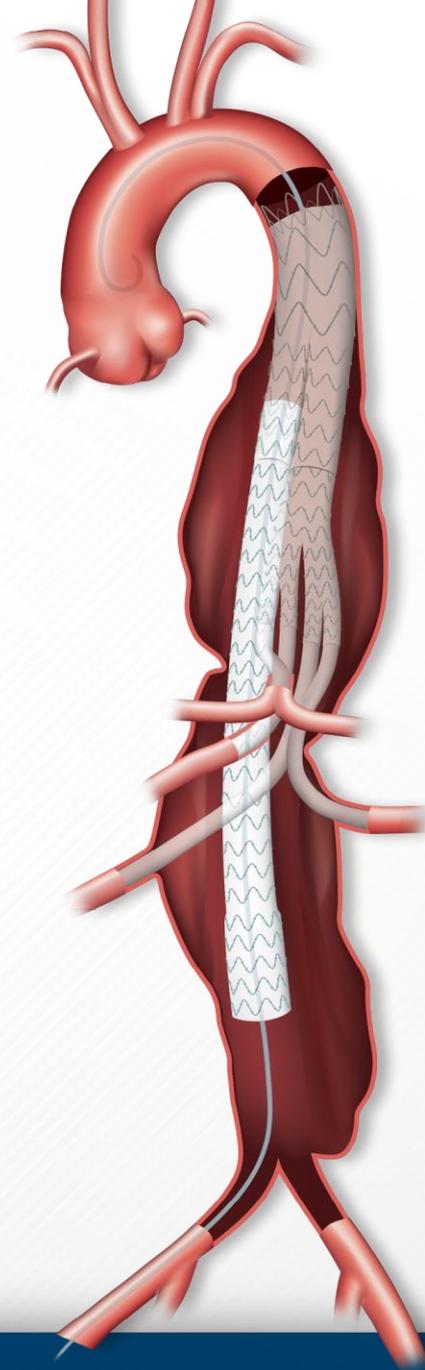


Delayed Distal Seal

Once flow has been secured to each of the involved branches, then the open limb of the proximal compartmentalizing graft can be extended distally excluding the diseased segment of vessel.

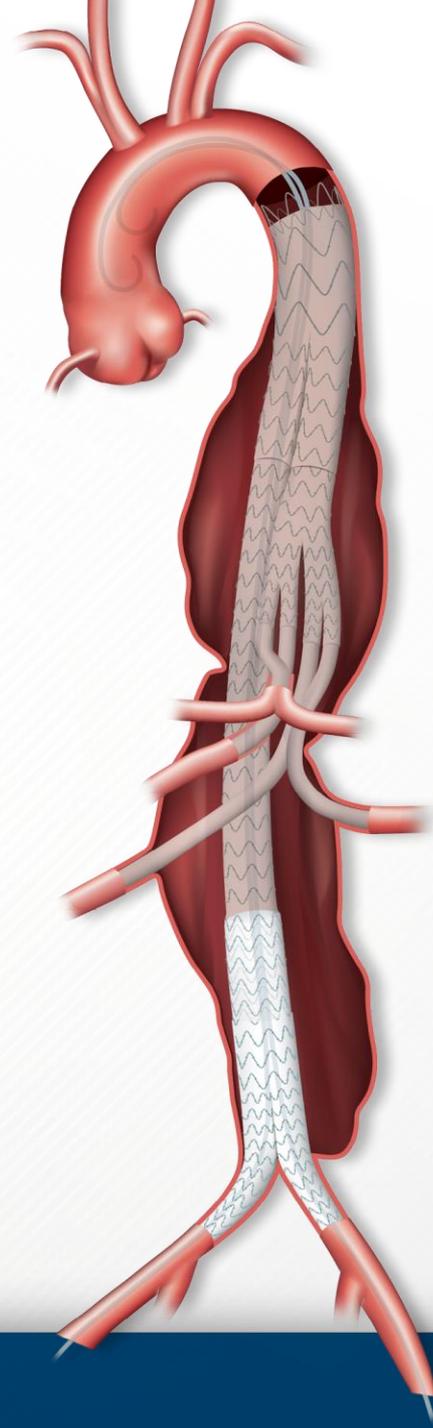
ThoracoAbdominal Aortic Aneurysm

Delayed Distal Seal



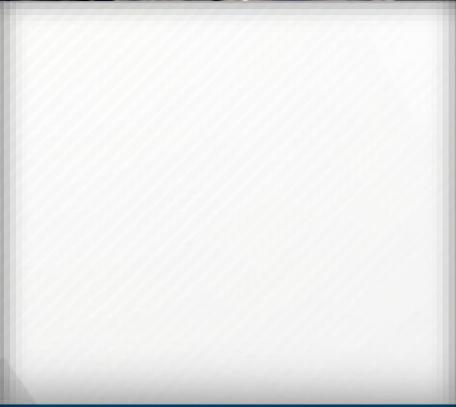
ThoracoAbdominal Aortic Aneurysm

Delayed Distal Seal

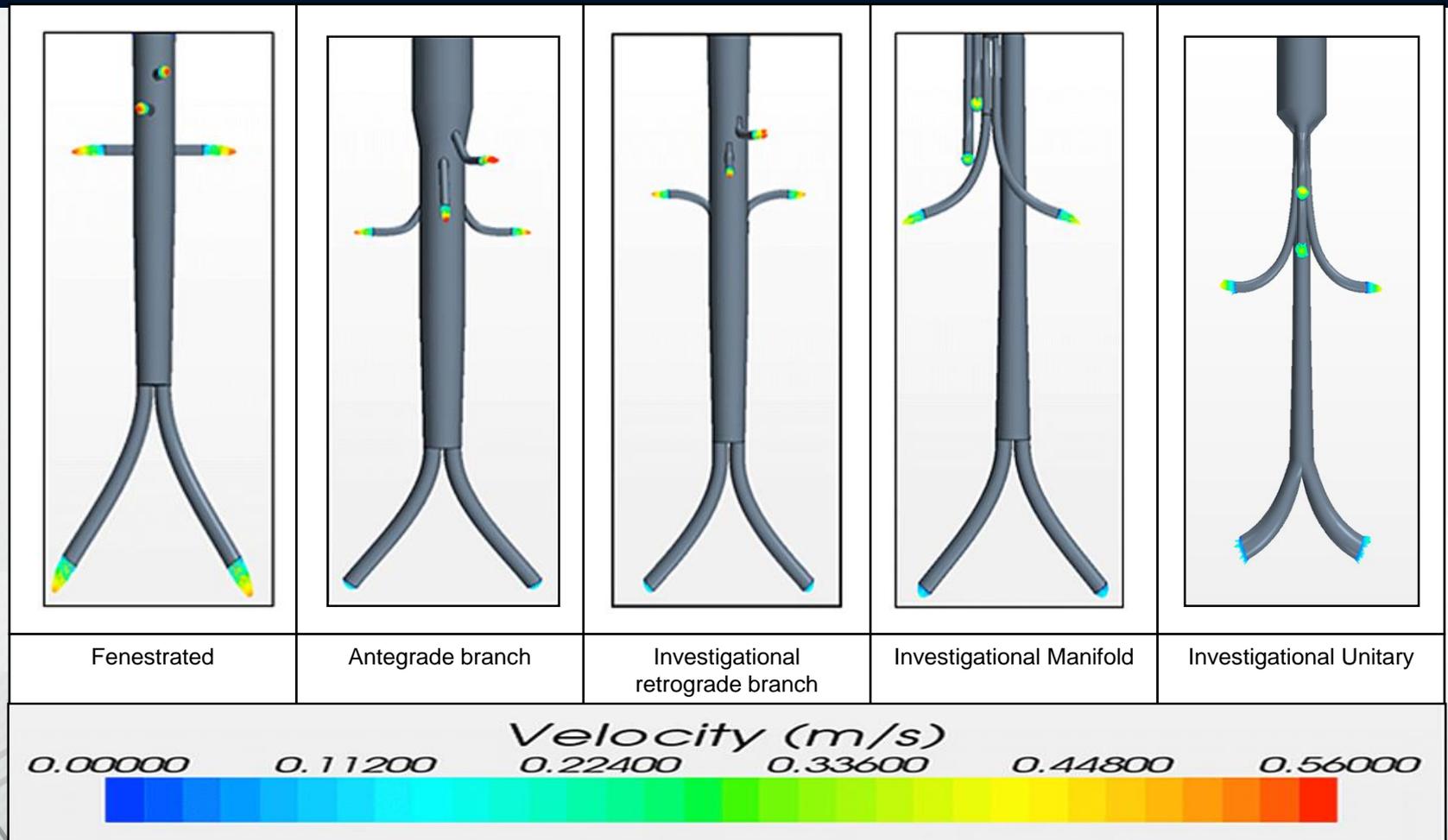


ThoracoAbdominal Aortic Aneurysm

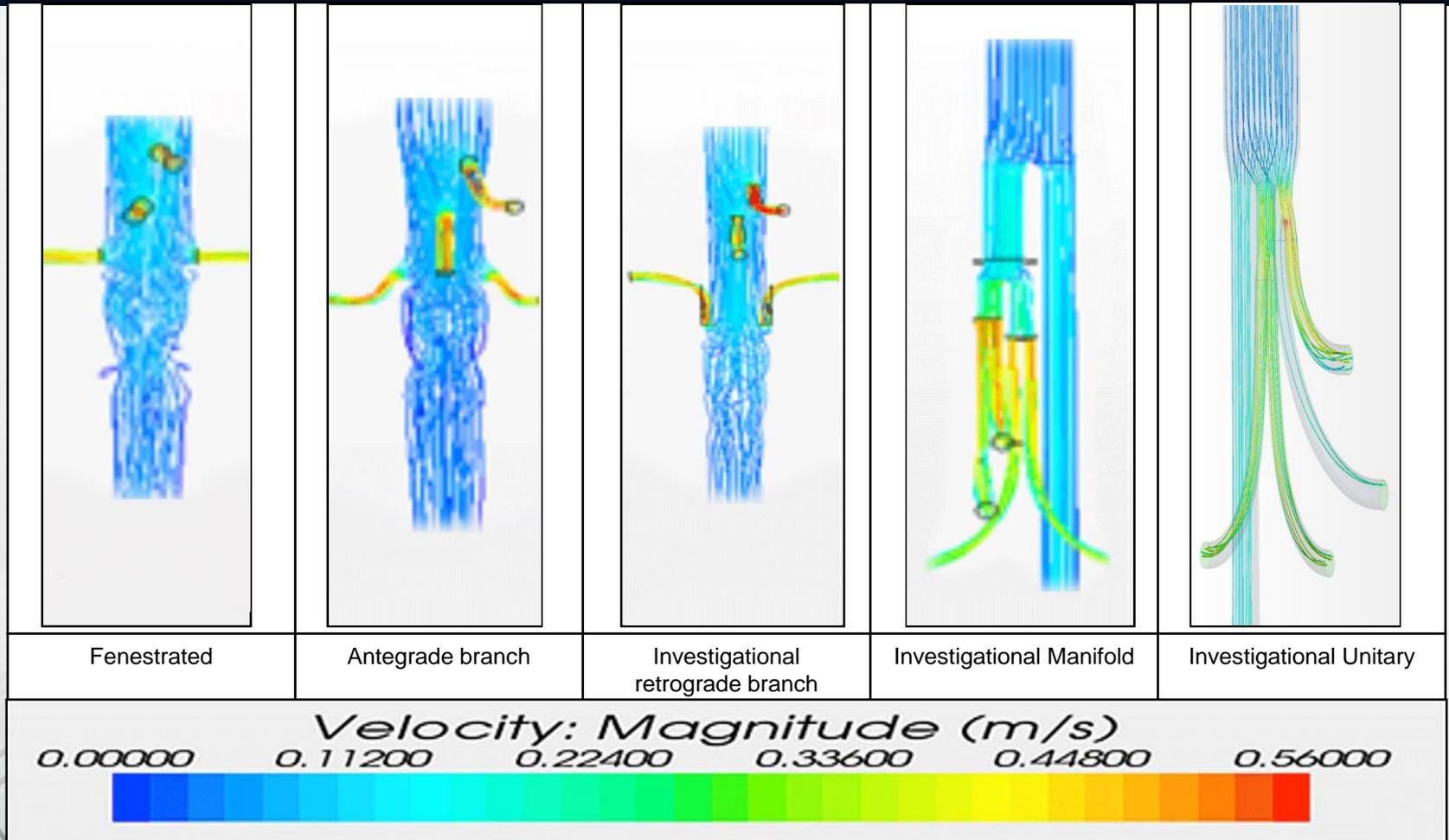




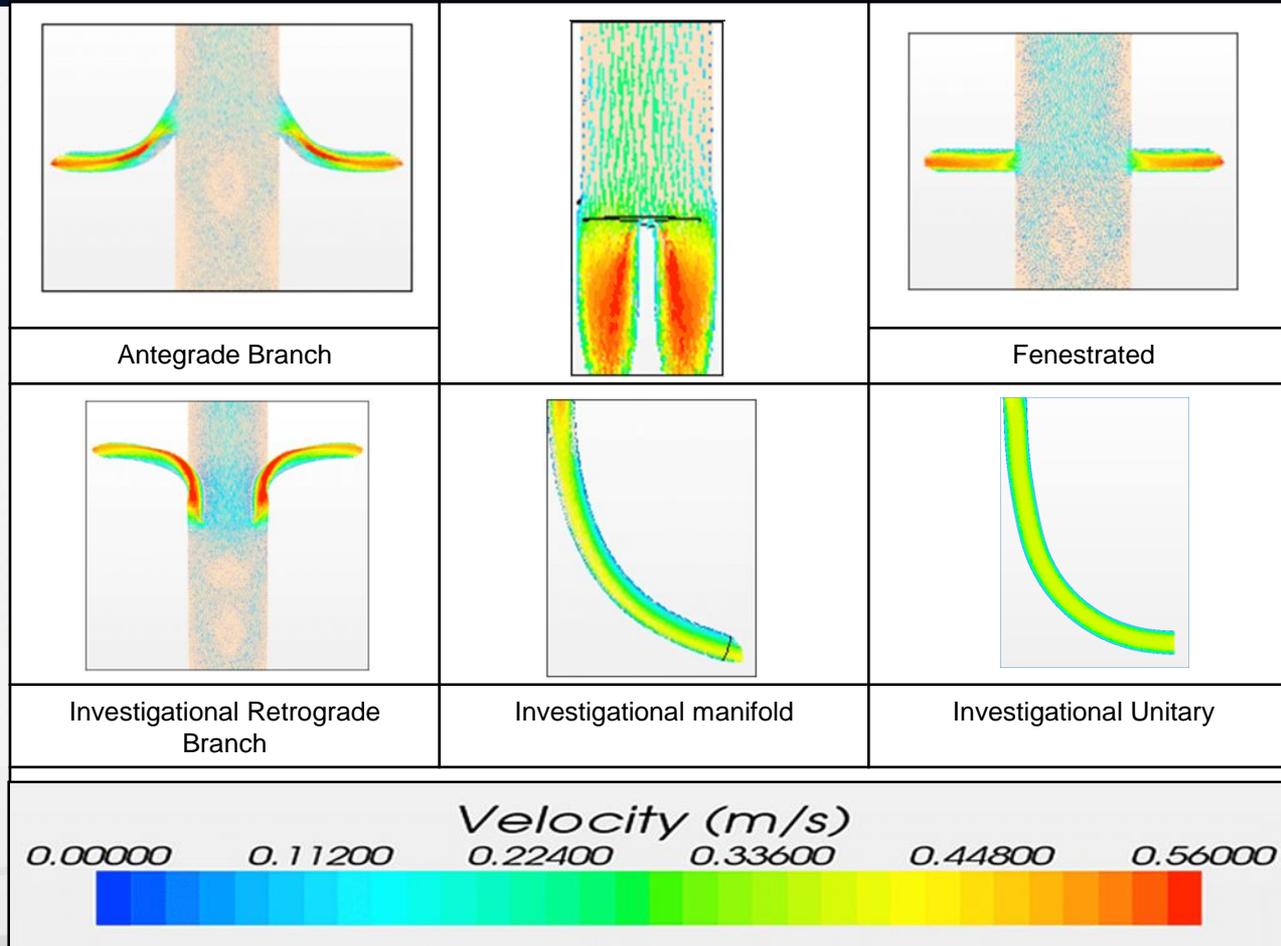
Outflow Conditions of Each Configuration Under Steady State



Velocity Streamlines (steady-state condition)



Velocity Vector Profile (steady-state condition)



34 Total Patients Treated With Graft Modifications

Gender:

20 males

14 females

Mean Age:

72 (58-89)

Previous Aortic Surgery

14/34

34 Patients Treated

- 30 TAAA
 - 25 NonEmergent
 - 23 TBG/VM
 - 2 VM systems
 - 5 TAAA after TBD
 - 5 TBG/VM
- 1 Outlier Configuration
- 3 Emergent Leaking
 - 1 TBG/VM
 - 2 Modified Configurations

Intra-Op

All 34 Patients

- ASA Score 4 or greater 14/34
- Length of Surgery 366min (198-499)
- Fluoro Time 108.3min (52-239)
- Total Contrast Used 177.3ml (87-357)
- Target Vessels Debranched 125/128*

**3 vessels were unsuccessfully debranched secondary to previously placed suprarenal fixated stent grafts*

In Hospital Post-Op Results

All 34 Patients

- Mortality rate 1/34
- MI 1/34
- Renal Failure 5/34
- CVA 0/34
- Paraplegia 3/34
- LOS 8.4 days (3-26)
- Discharged to Home 21/34 w/ LOS 5.3 days

Mid-term Follow-up

All 34 Patients

30 Day Mortality 2/34 Both rupture patients

1yr All Cause Mortality 12/34

Device Related Death 1 at 19 months

Renal Failure 0 new cases

Paraplegia 0 new cases

EndoLeaks 7 Total 5-Type 2 & 2- Type 3

Both T-3 Resolved – One Required Coil Intervention

No Evidence of Graft Migration

Branch Graft Patency

122/125 97%+ > 1yr

Clinical Results Summarized

All 34 Patients

- In Hospital Mortality 1/34
- 30 Day Mortality 2/34
- Aneurysm Related Mortality 2/34
- 1yr All Cause Mortality 12/34
- Late Device Related Mortality 1/34 at 19mo
- Renal Failure 5/34
- Paraplegia 3/34
- Patency Rates 122/125
- Secondary Interventions 1/122 EndoBypasses



I & II

10/34
5.1-7.2 cm



III

10/34
5.2-9.6 cm



IV

13/34
5.0-12.1 cm



V

1/34
5.3 cm



I & II

10/34
5.1-7.2 cm



III

10/34
5.2-9.6 cm



IV

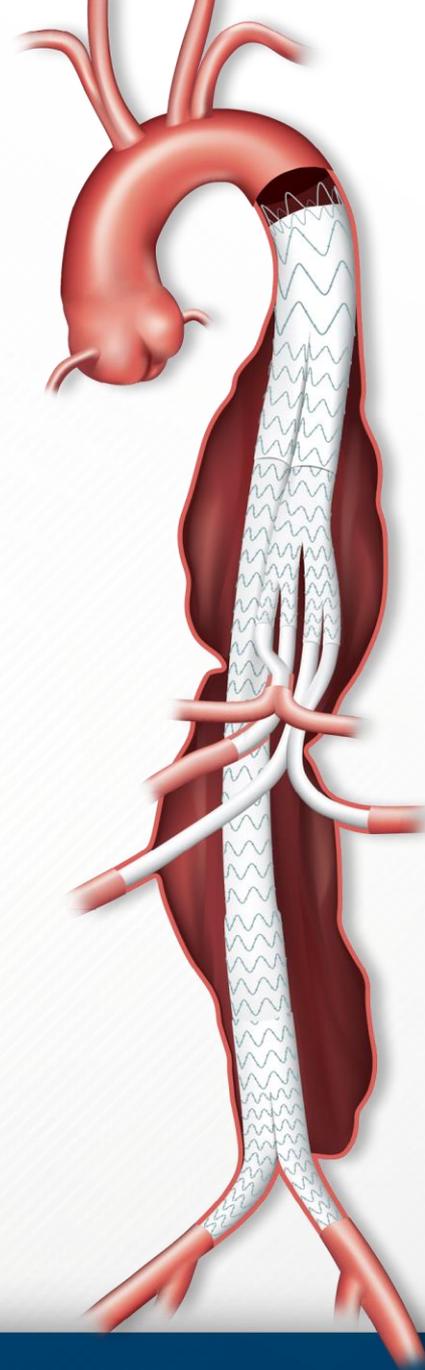
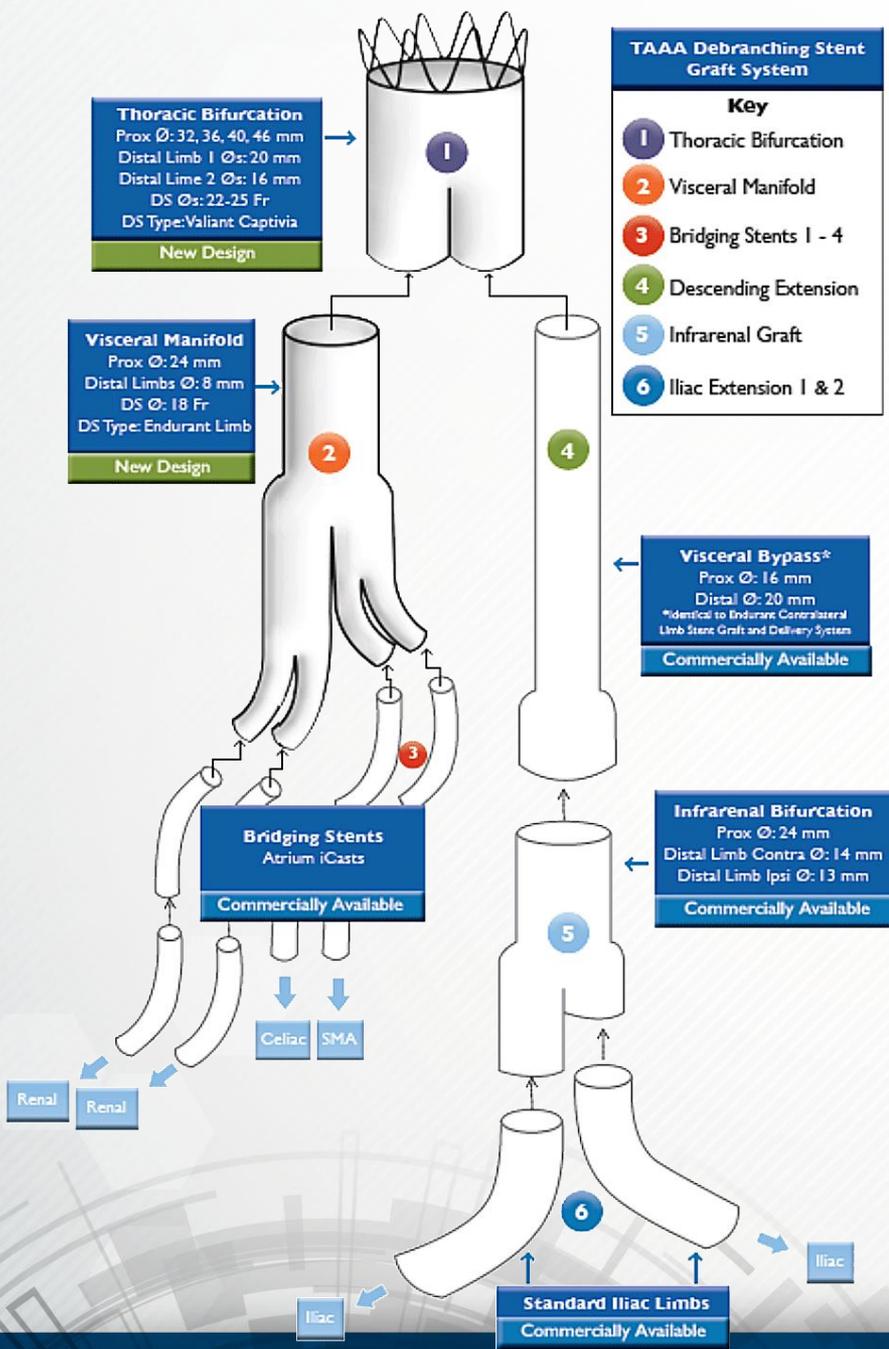
13/34
5.1-12.1 cm



V

1/34
5.3cm

Conclusions



By approaching this problem from
a non-anatomical standpoint

of

Proximal Deployment

Endo-Bypass

Delayed Distal Seal

We've been able to perform
in-situ customized
aneurysm repairs

Handling virtually any anatomy

With very reasonable results
treating one of vascular
surgeries most challenging
disease processes



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Vascular Innovations