

# Why am I the only one using helical limbs?

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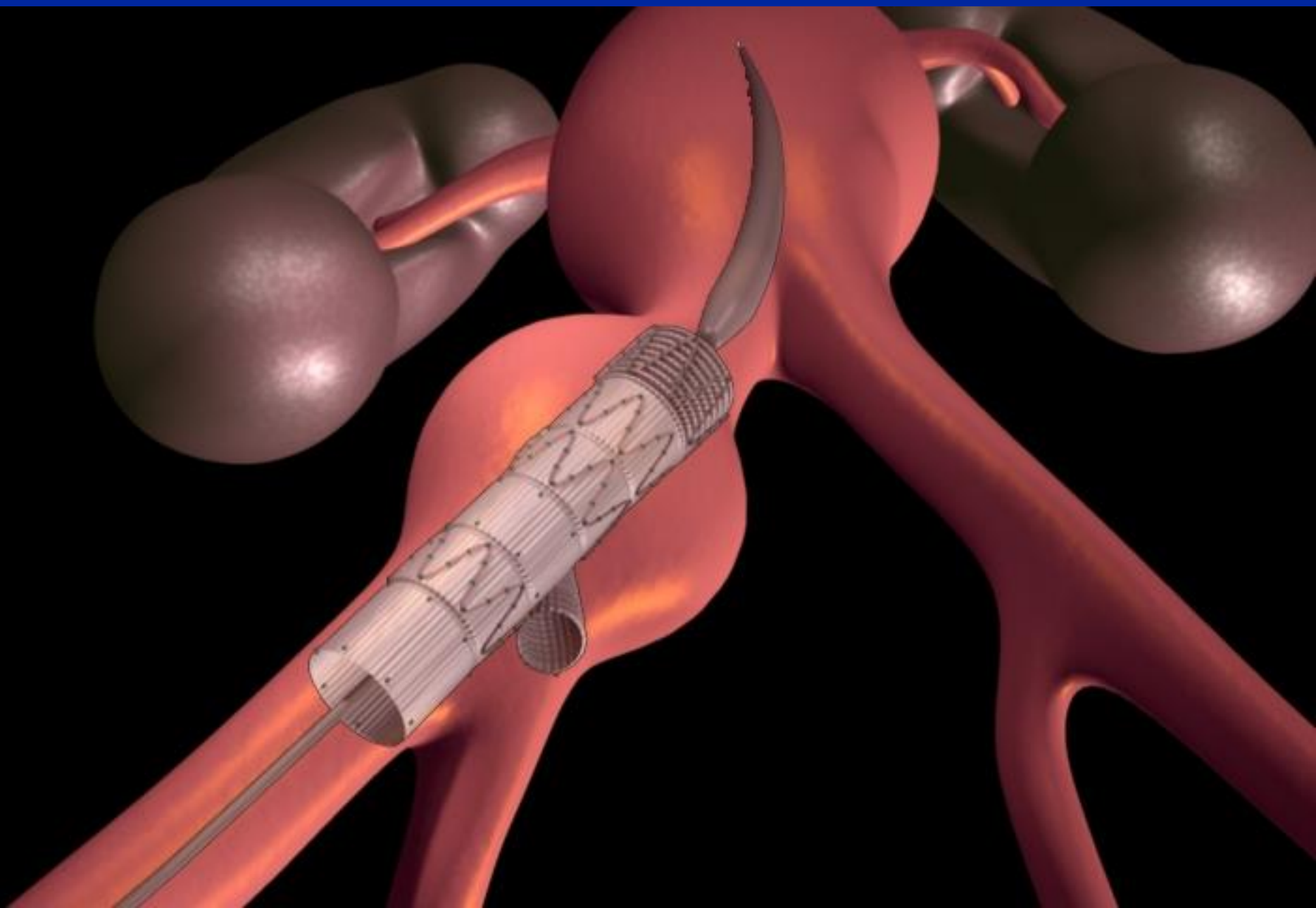
Critical Issues 2016

Lille, France

WTF?

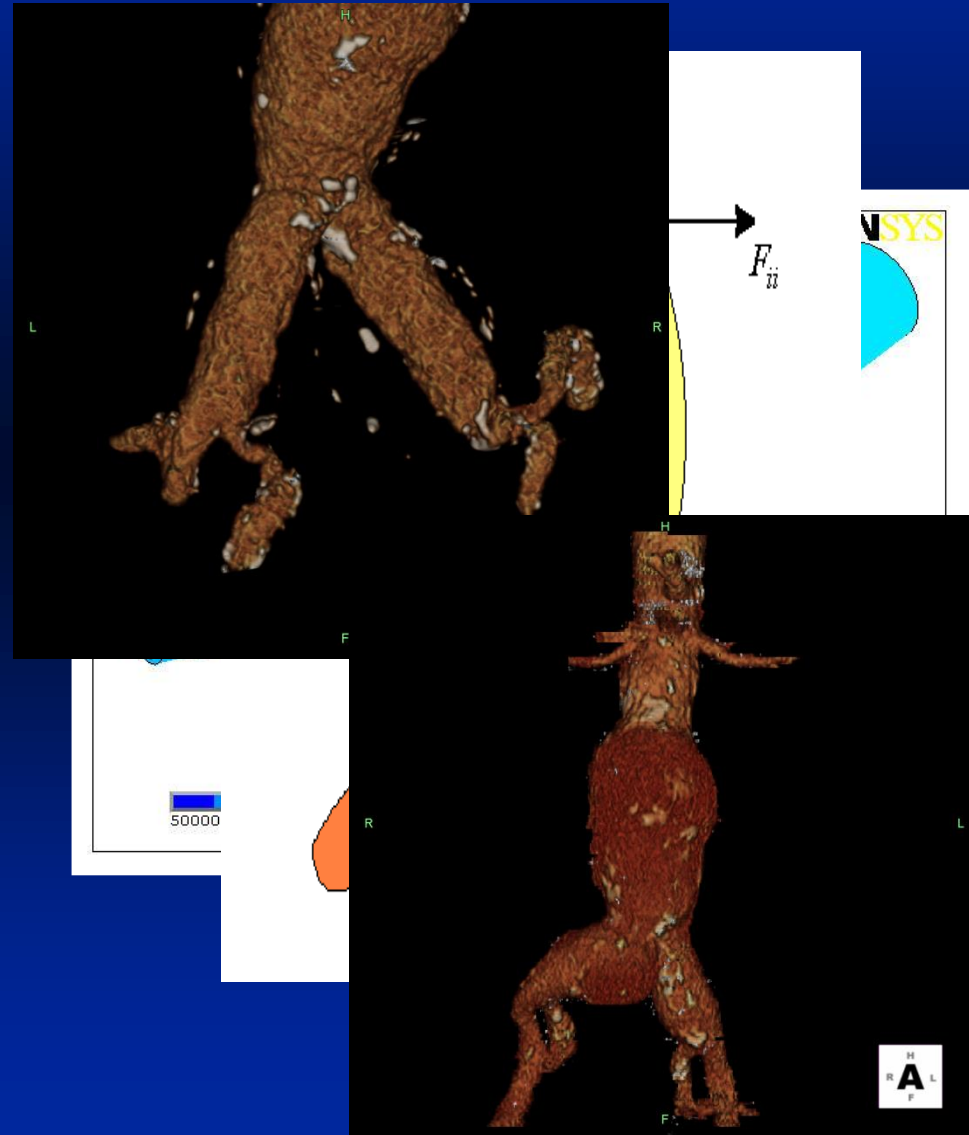
WWRD?



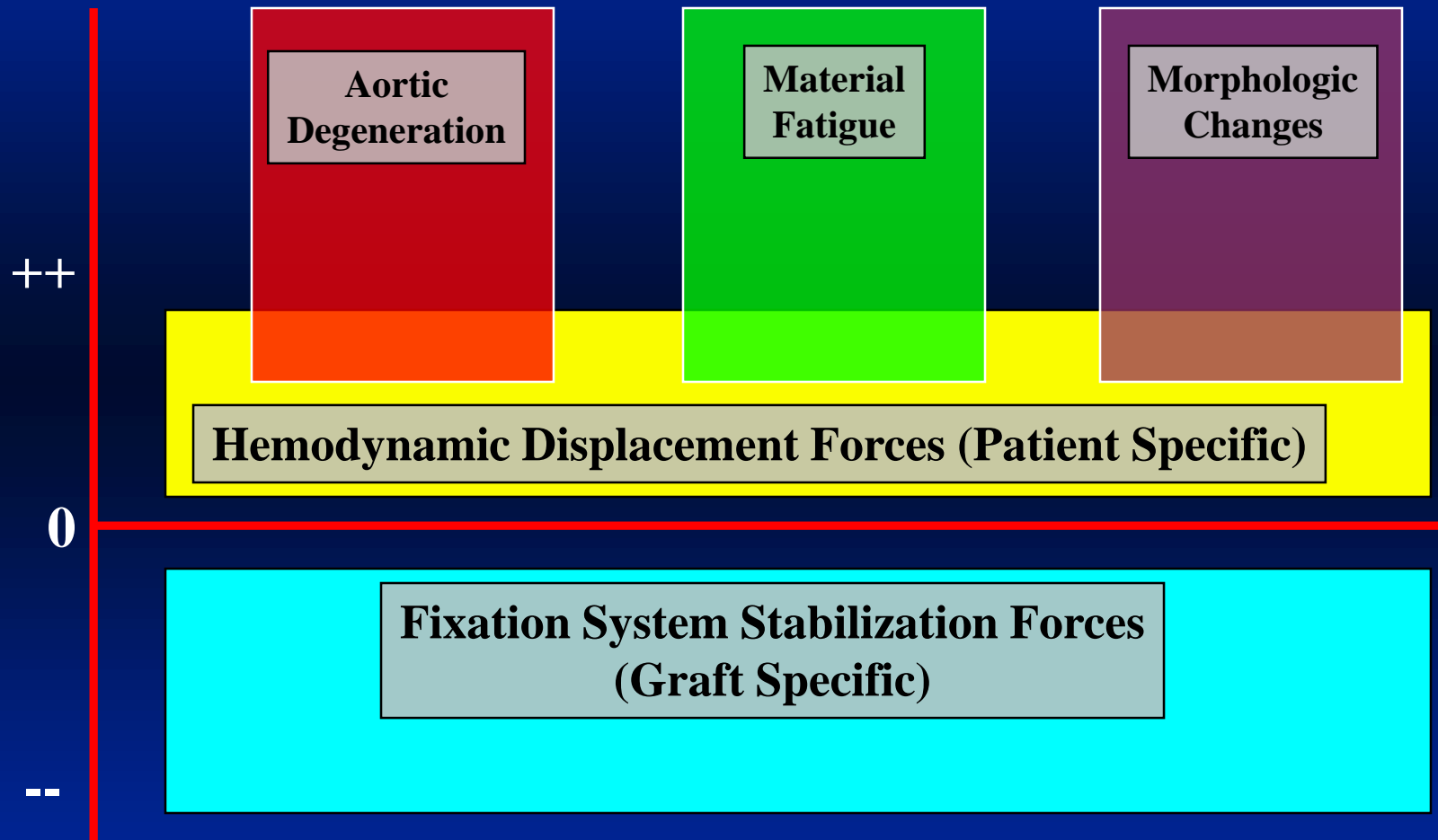


# Implant Objectives

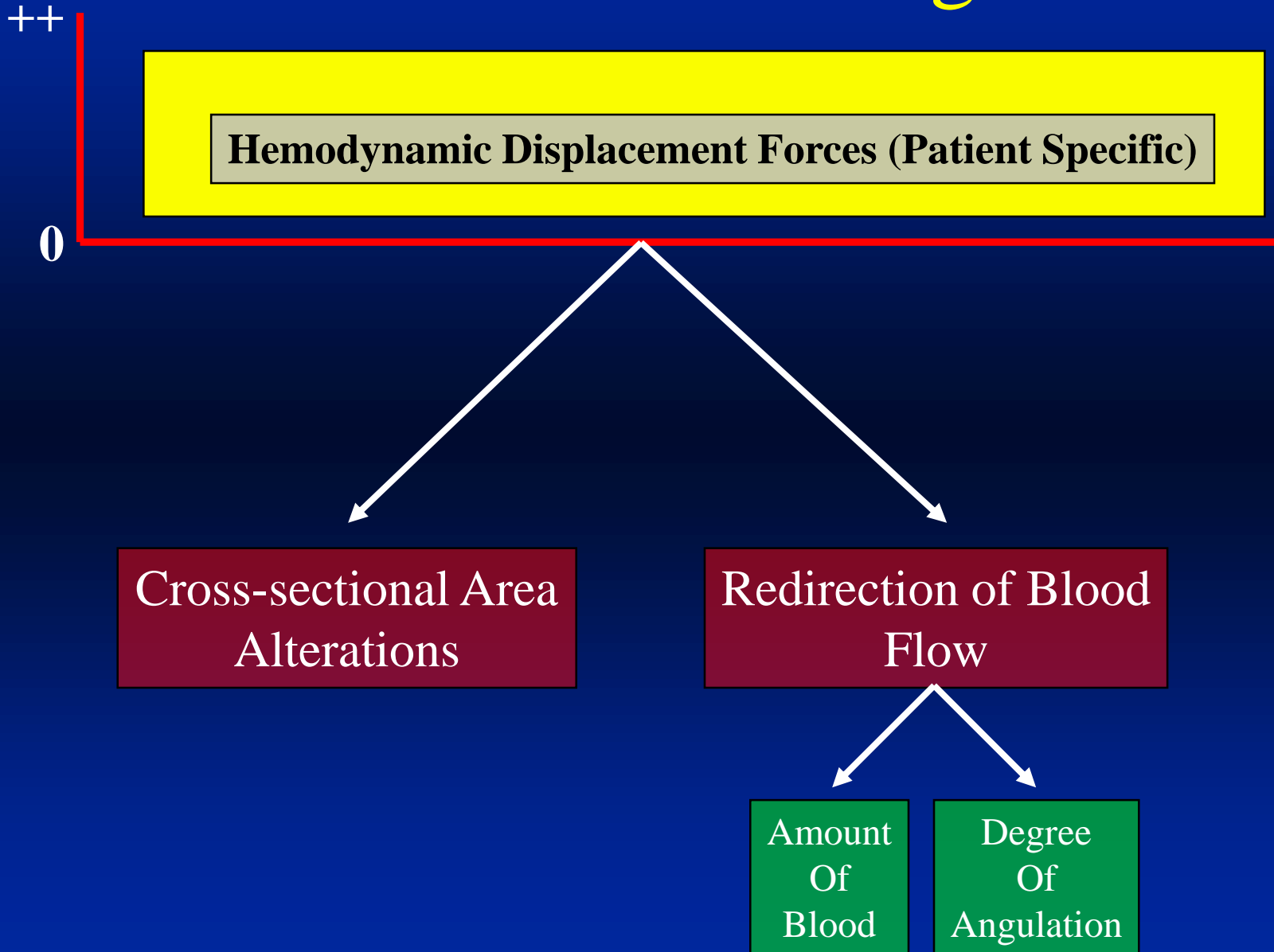
- Treat IAA – preserve hypogastric flow
- Don't disrupt proximal repair
- Able to withstand hemodynamic forces – durable
- Versatile
  - Treat nearly all iliac aneurysms
  - Simple design
  - Simple deployment
  - Mate with a variety of bridging stents



# Risk of Device Migration

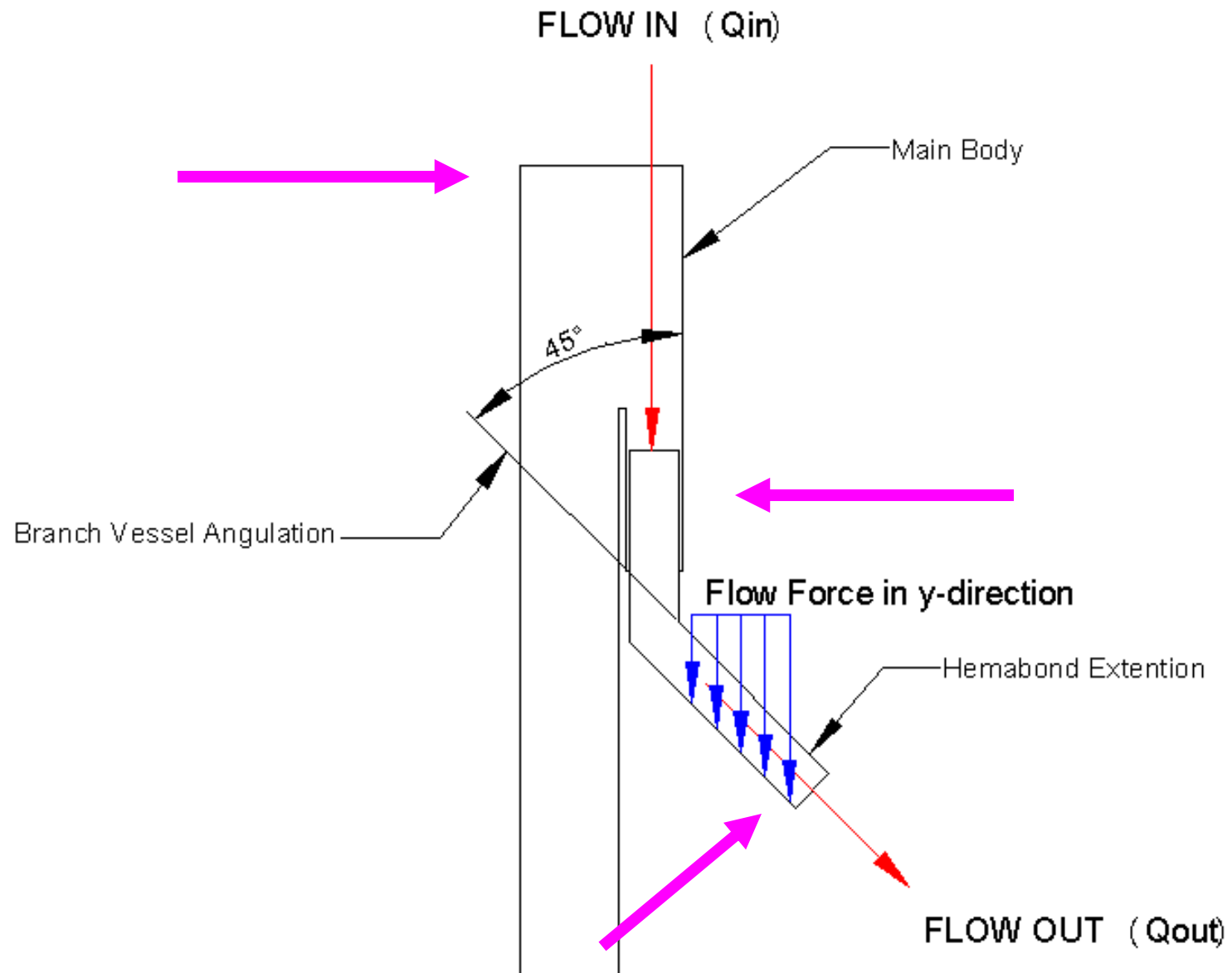


# Risk of Device Migration



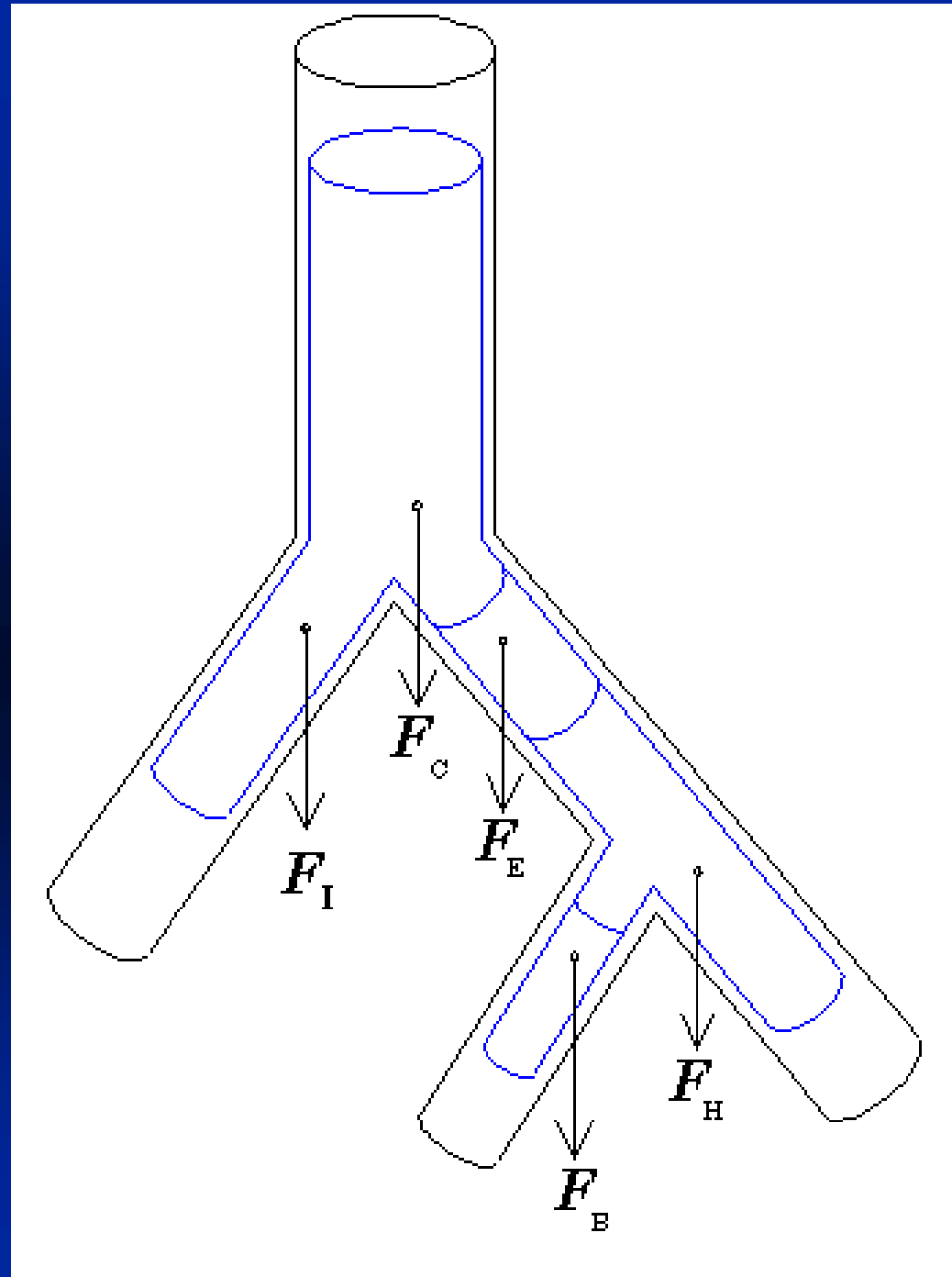


# Resistance to Displacement

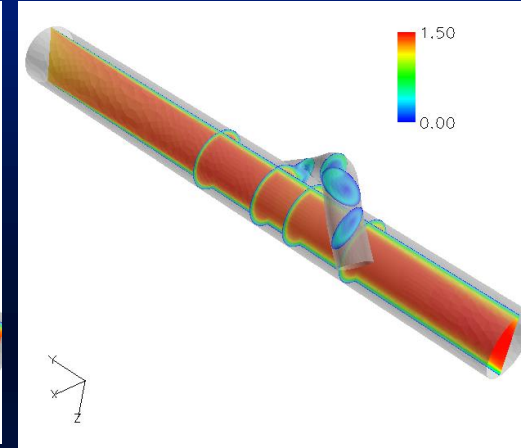
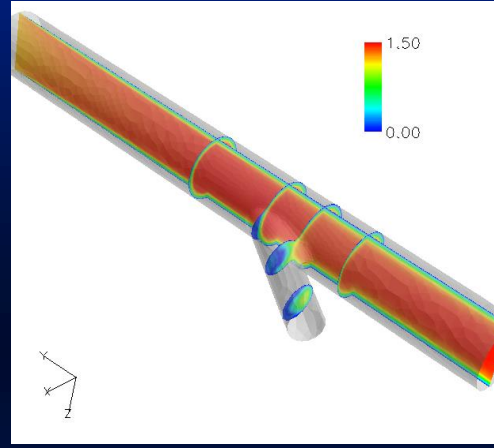
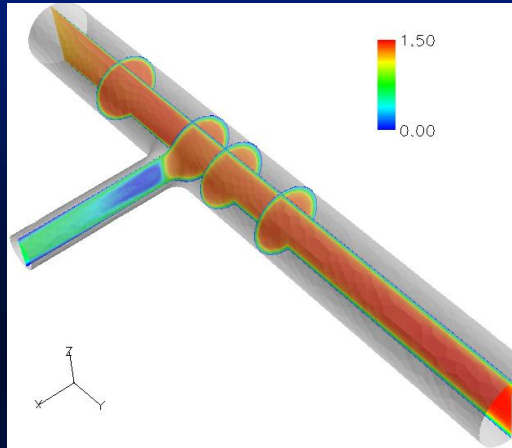


# The Effect of A Double Bifurcation

- The downward force is directed at each bifurcation
- The endograft must endure these forces in an effort to resist failure
  - Migration
  - Component separation
  - Material fatigue



# Mathematical and Computational Fluid Dynamic Assessment of Displacement Forces and Velocities



Max Systolic  
Velocity

**1.1 (m/s)**

**0.9 (m/s)**

**0.6 (m/s)**

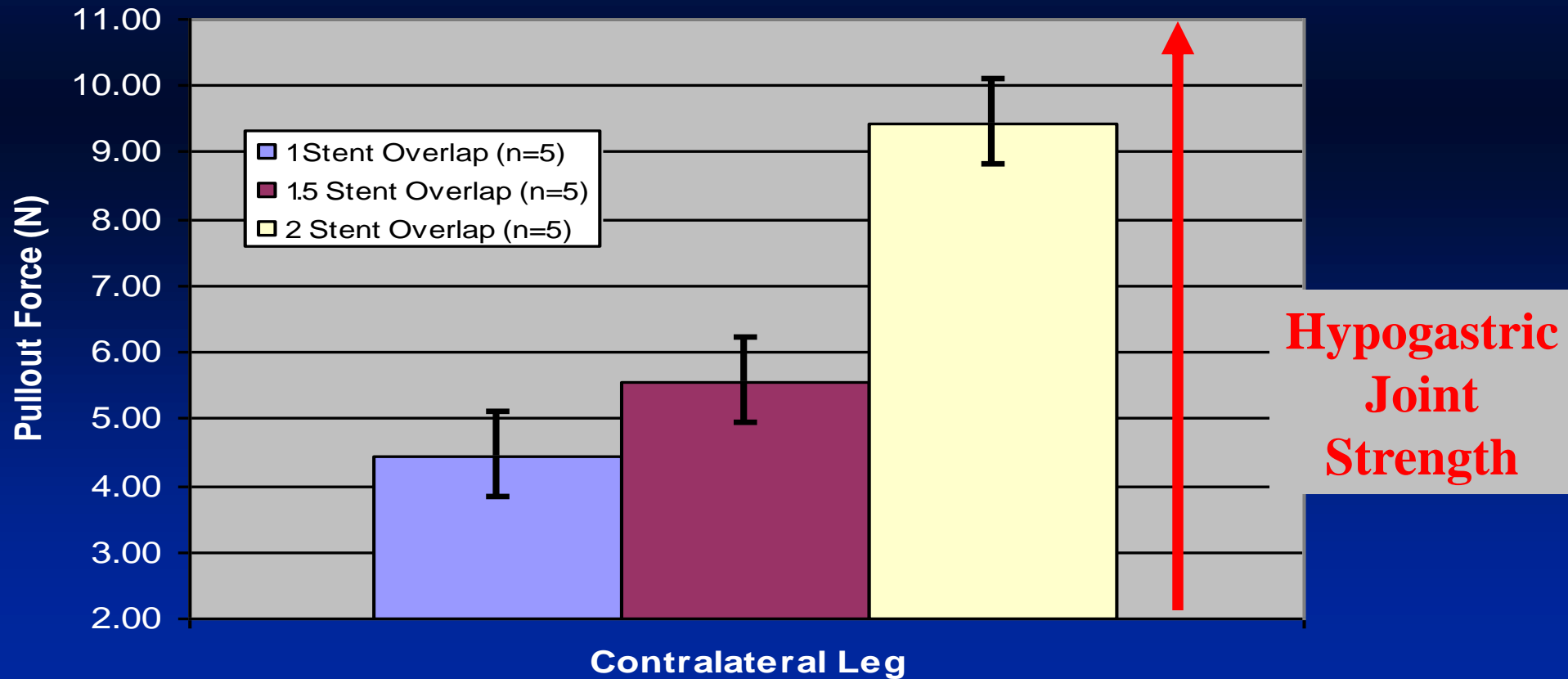
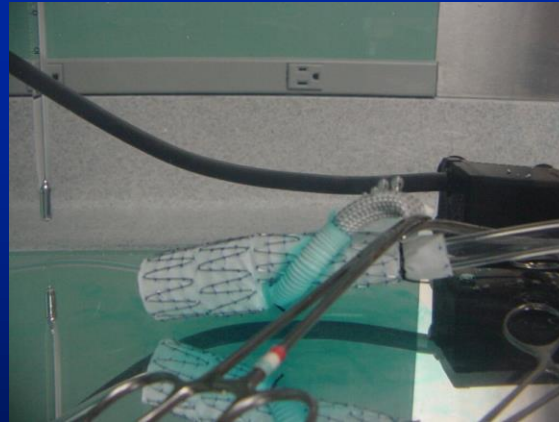
Displacement  
Force

**0.75 N**

**0.25 N**

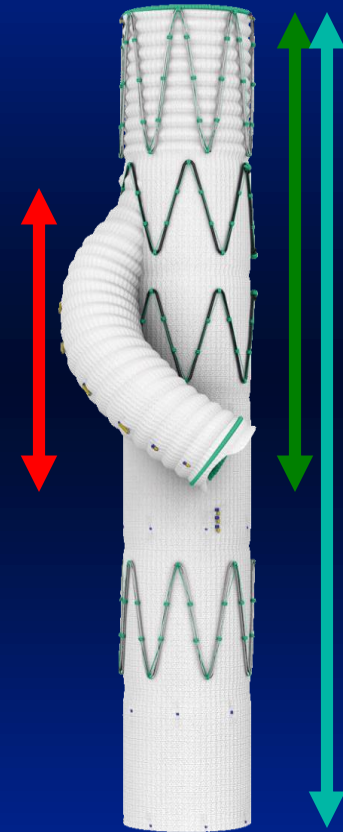
**0.20 N**

# Modular Joint Assessment



# Initial Helical-branch Iliac Device

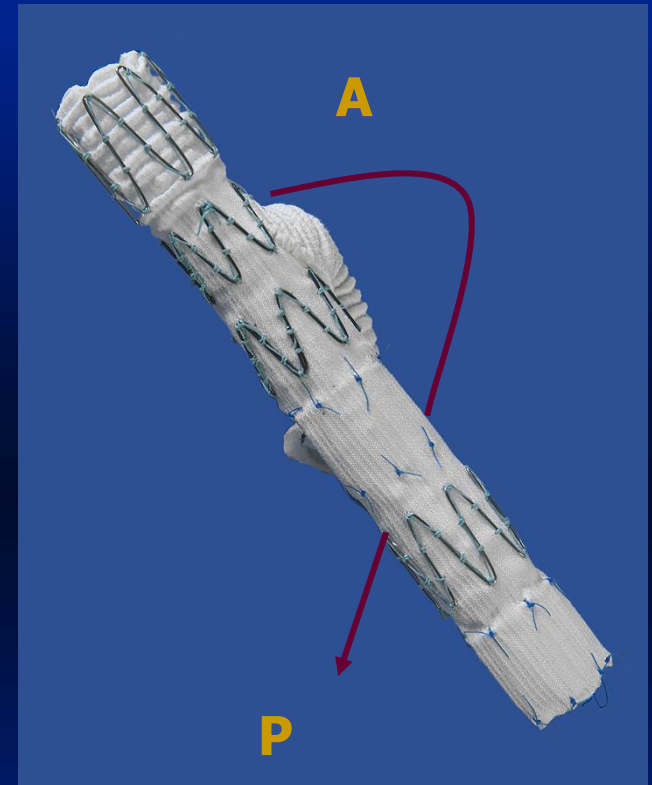
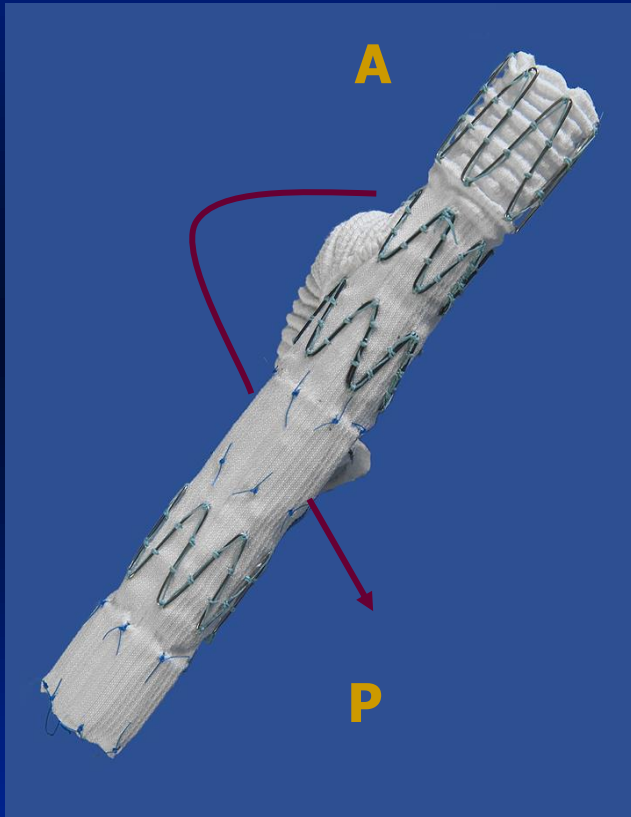
- **Base Graft: 12mm tube graft**
  - Woven polyester graft with stainless steel and nitinol Z-stents
- **Total Device Length – 98 mm**
- **Length to internal iliac branch exit – 52 mm**
- **Vertical branch length 25 mm**



Posterior View R

# Device Orientation

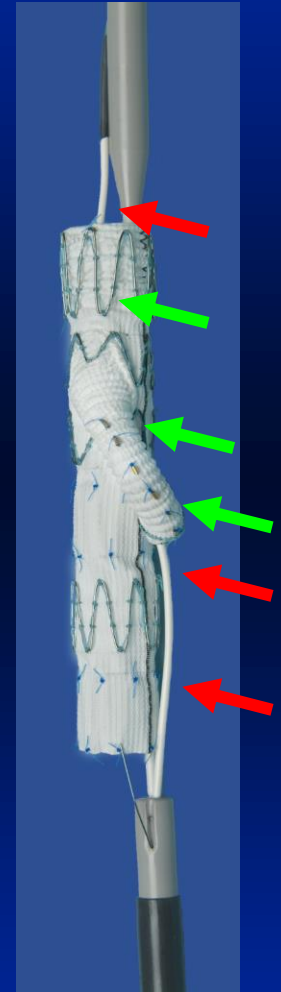
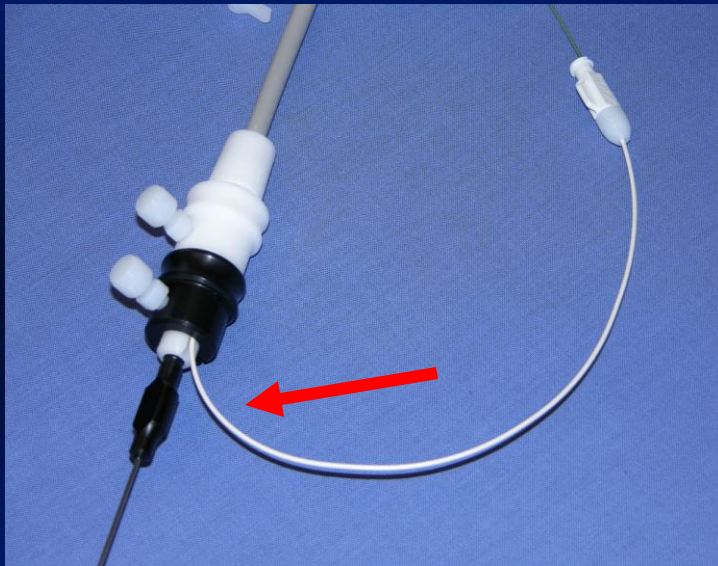
Right Helical Branch



Left Helical Branch

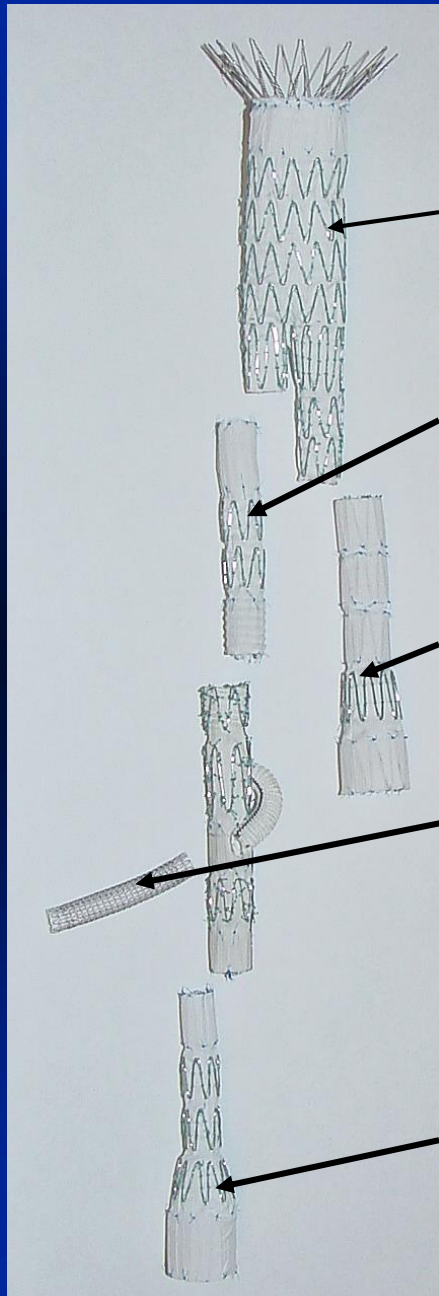
# Preloaded catheter and guide wire

Catheter and guide wire entering device distally



Catheter and guide wire pass along external aspect of distal device, then into the helical branch and proximal graft

# Mating Devices



Zenith Main Body Device

Helical Leg Extension

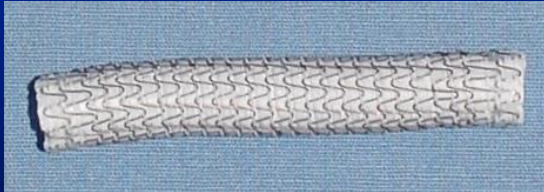
Contralateral Leg Extension

Helical Branch Leg Extension

TFLE



# Mating Devices Tested



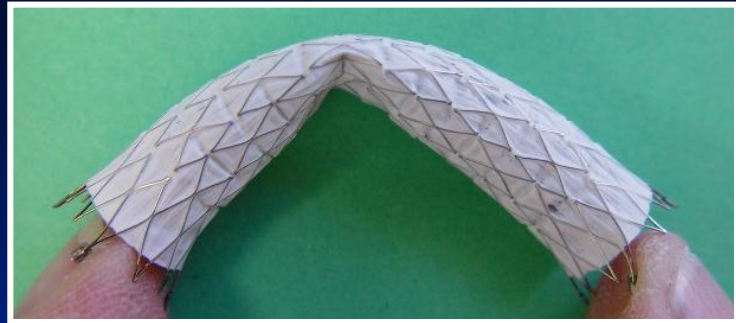
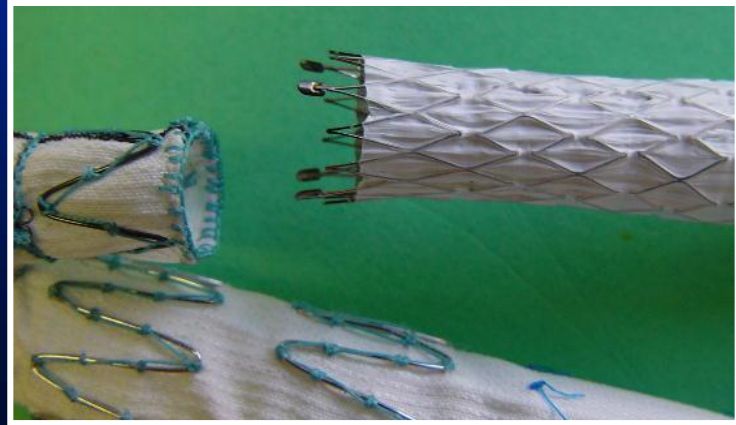
- **Viabahn**
  - 6-8mm diameter for 6mm Helical Branch
  - 8-10 mm diameter for 8mm Helical Branch
- **Jostent Peripheral**
  - 6-8 mm diameter for 6mm Helical Branch
  - 8-10 mm diameter for 8mm Helical Branch
- **Atrium Flyer PV w/cover**
  - 6-8mm diameter for 6mm Helical Branch
  - 8-10 mm diameter for 8mm Helical Branch
- **Bard Fluency**
  - 7-8 mm diameter for 6mm Helical Branch
  - 9-12 mm diameter for 8mm Helical Branch



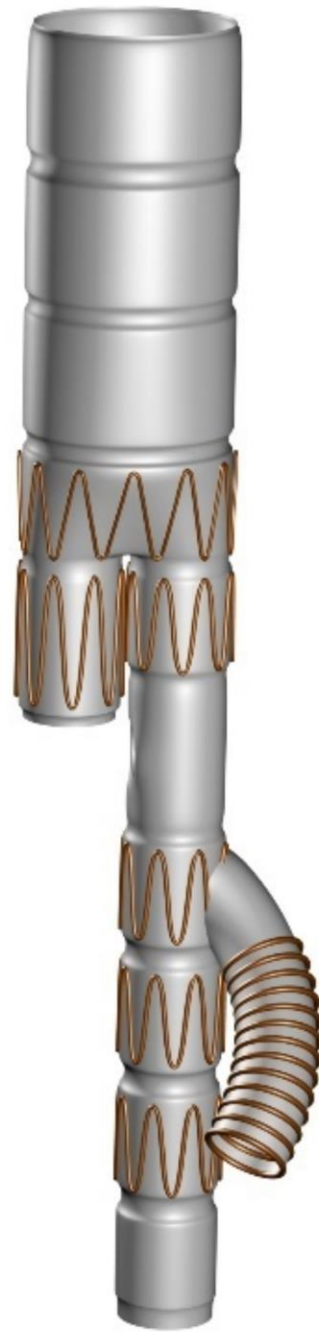
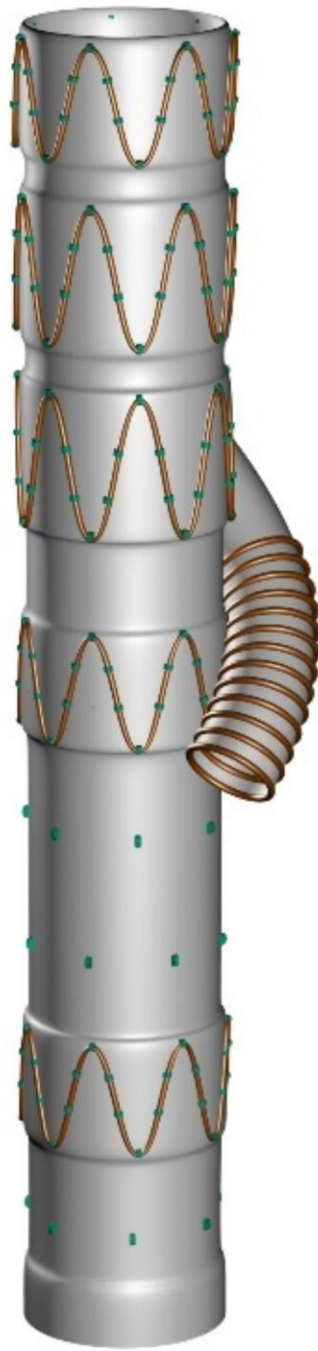
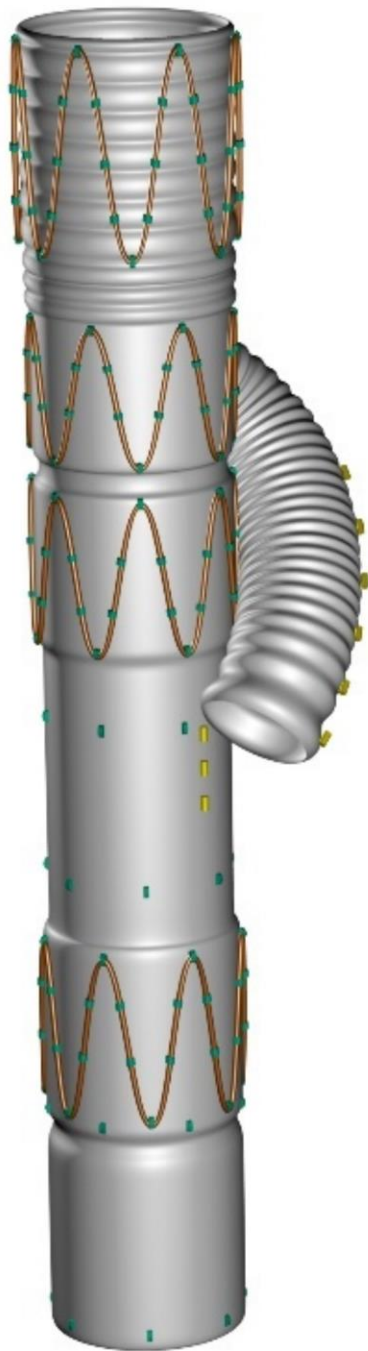
Atrium



JoMed



Fluency



# Outcomes

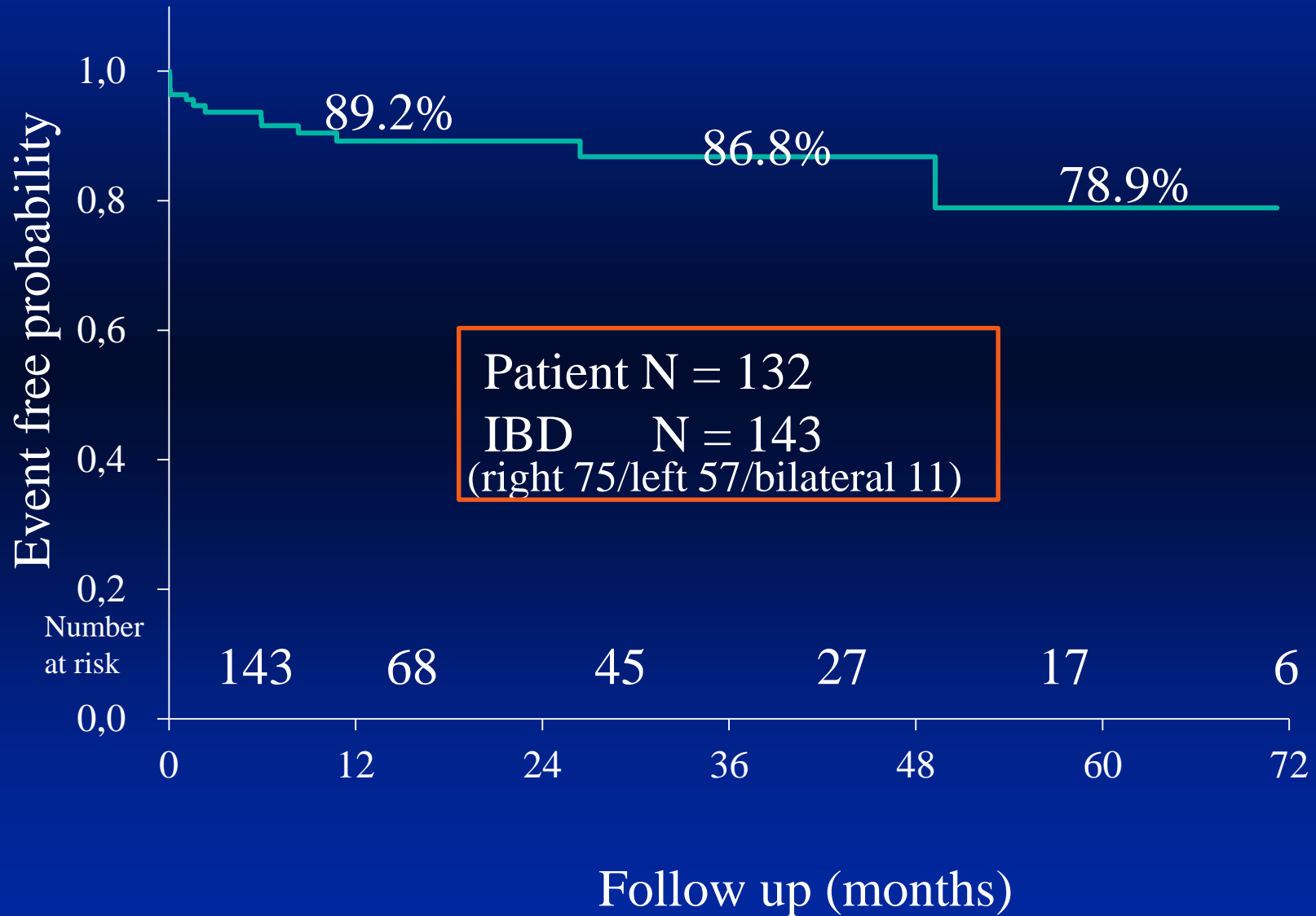
- October 2003-February 2012: N=138 branches, 130 patients
  - 98 standard
  - 40 bifurcated-bifurcated
- Mean F/U: 16.2 months (1-72 mos)
- Proximal component
  - FEVAR: 70 (51%)
  - Zenith Trifab EVAR: 63 (45%)
  - Pre-existing EVAR: 5 (4%)

# Outcomes

- Mortality/Survival
  - 1 perioperative death (MI)
  - 5 year survival = 62%
    - 65% for TAAA
    - 60% for AAA
- Technical Success = 95% (9 failures)
  - 7 inability to cannulate IIA
  - 2 dislodgement of system with placement of other components

# Hypogastric Branch Patency

## 44 Bifurcated-Bifurcated Devices



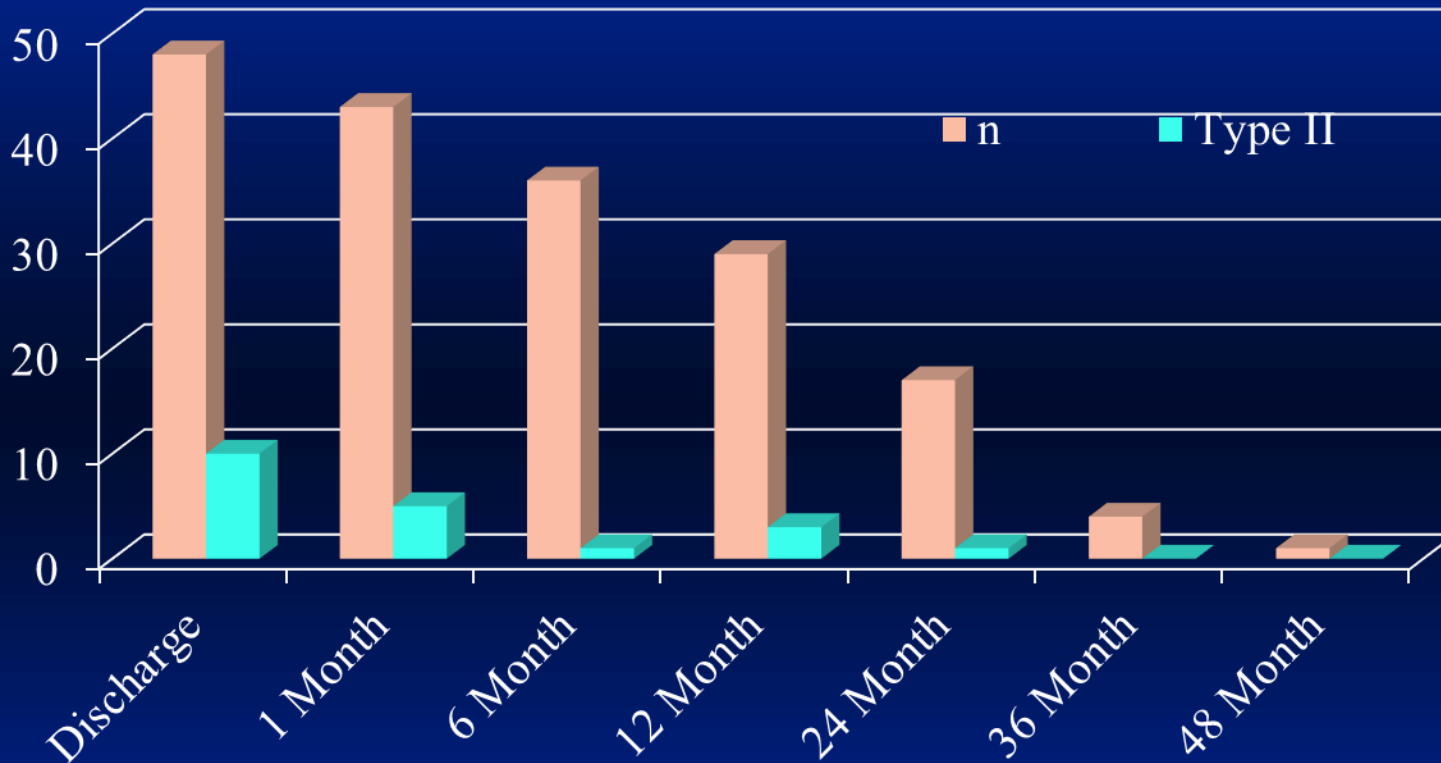
# Aneurysm Shrinkage >5mm

n= number with CT at time frame

	6 mo.	12 mo.	24 mo.	36 mo.	48 mo.
AAA	55%	66%	78%	80%	100%
	21/38	19/29	14/18	4/5	1/1
	n = 38	n = 29	n = 18	n = 5	n = 1
CIA	26% 10/39	43% 13/30	56% 10/18	80% 4/5	100% 1/1
	n = 39	n = 30	n = 18	n = 5	n = 1



# Endoleaks

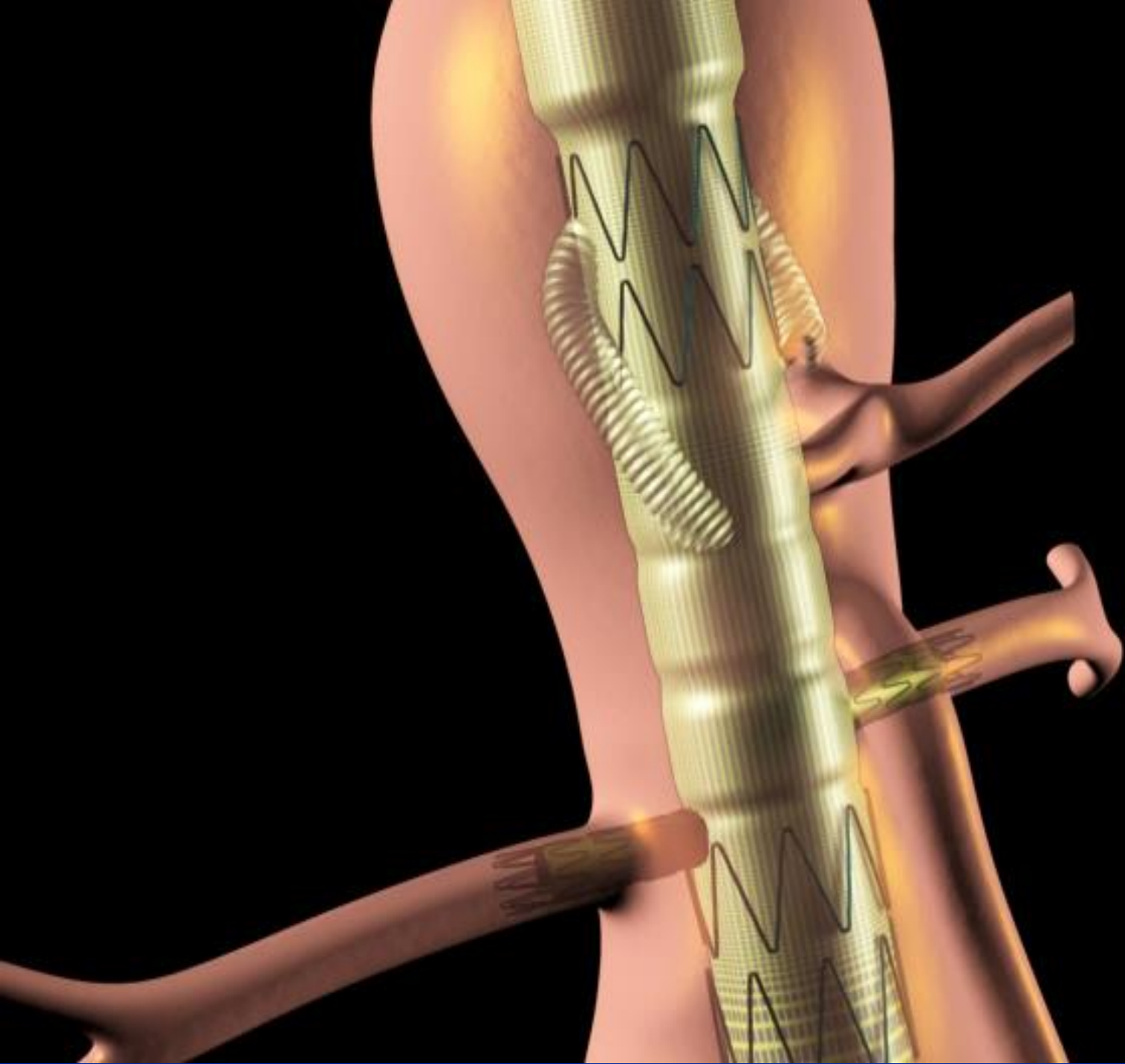


There were no Type I or Type III endoleaks.

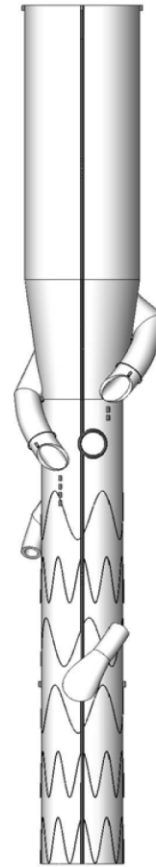
One patient was treated at 12 months for an endoleak. Other Type II Endoleaks resolved on their own.

Wong S, et al. J Vasc Surg 2013; 58: 861-9



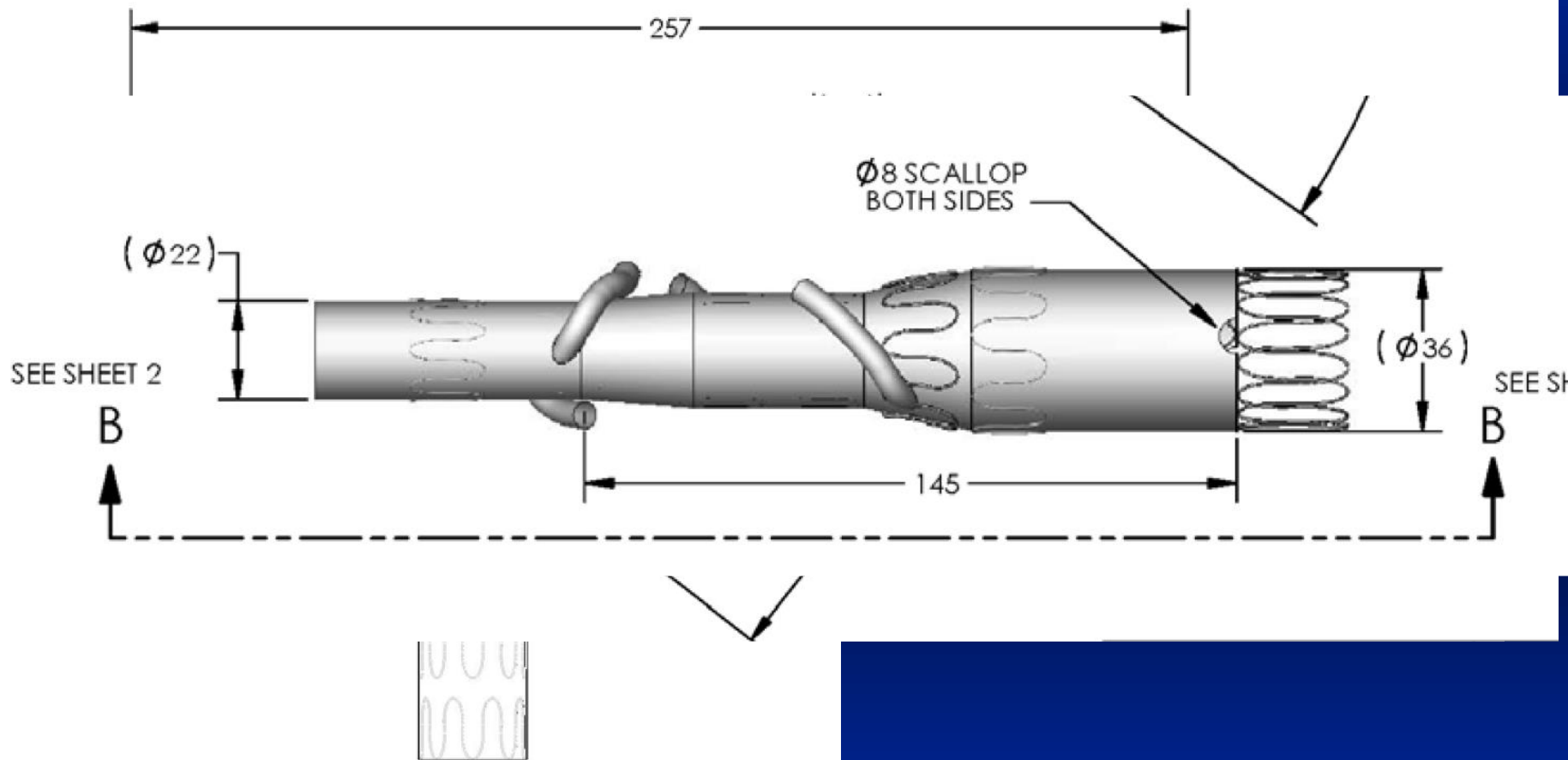
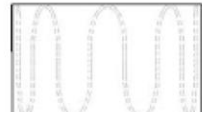


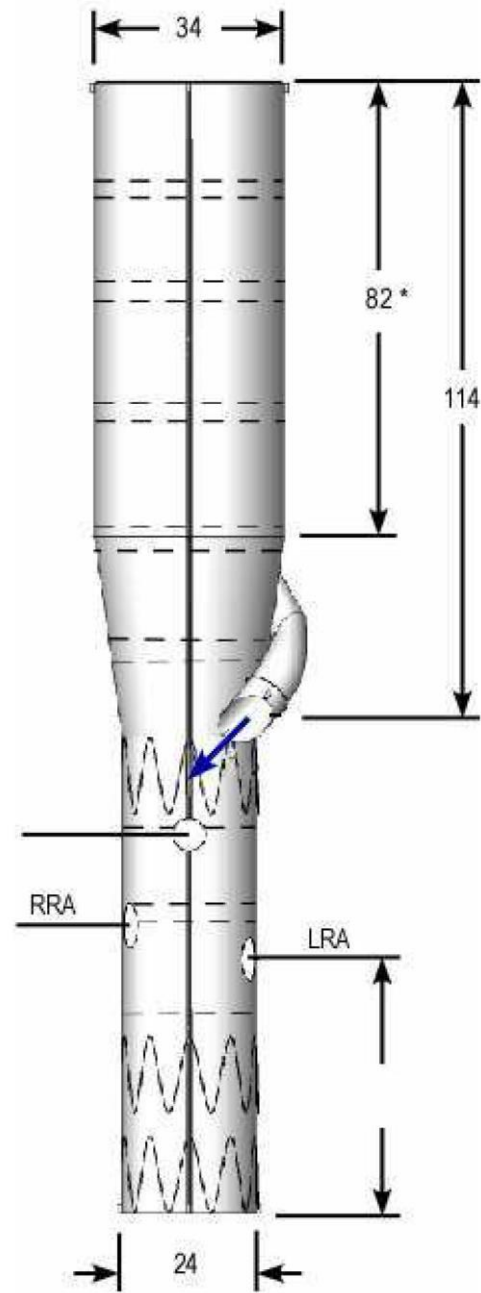
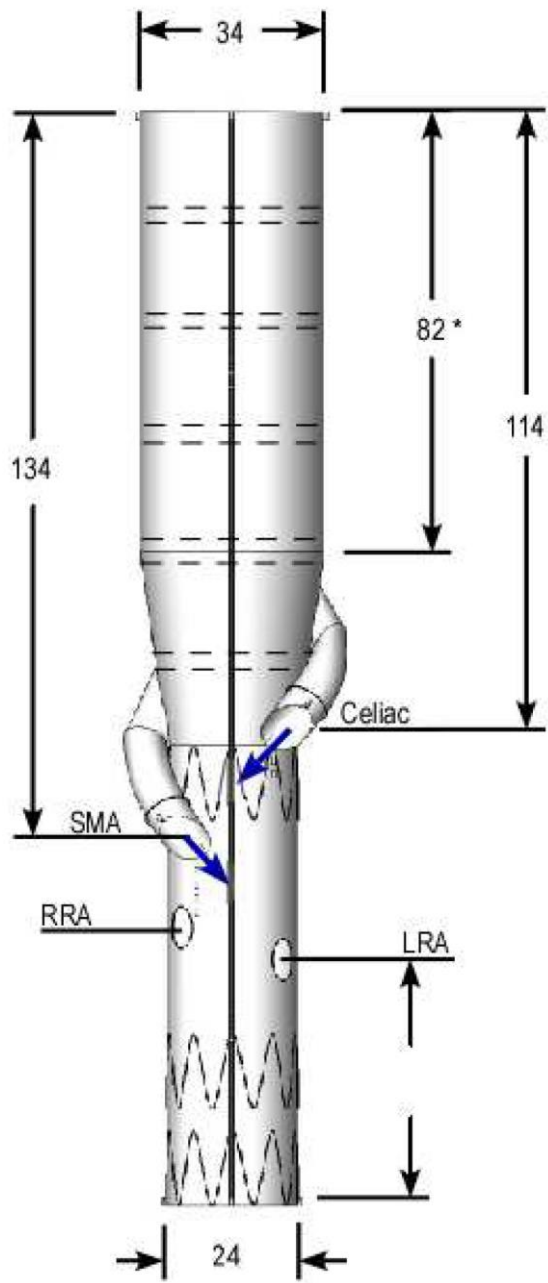
# Visceral Helical Device 2002 - 2010



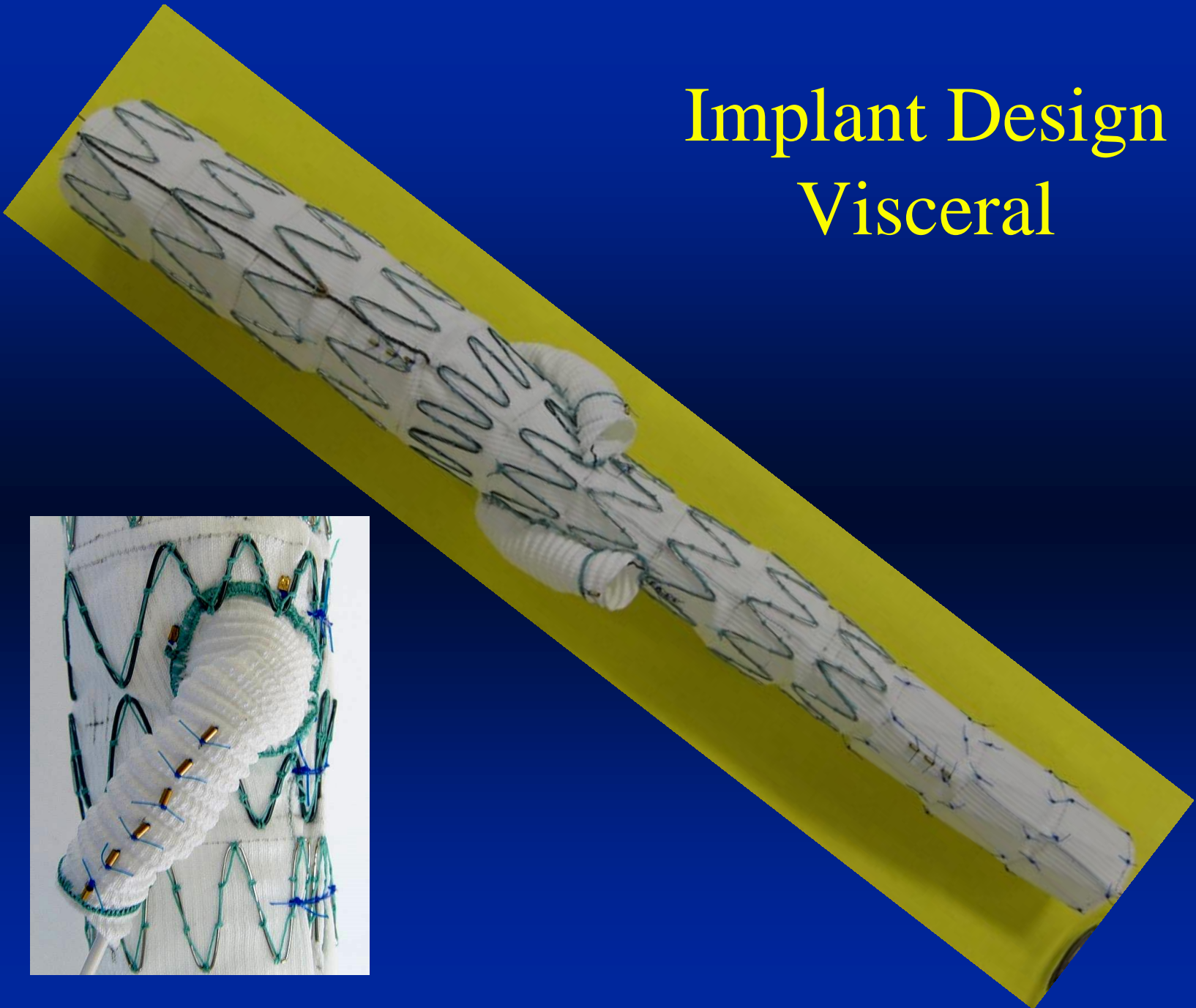
Aortic Replacement Lab  
Dr. Roy Greenberg

BVD60110031 REV A  
AP VIEW

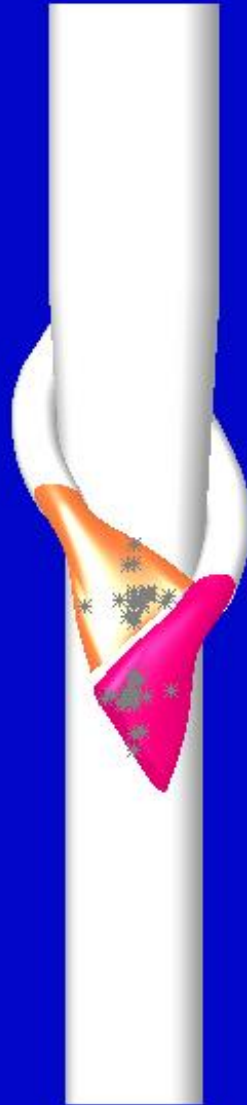




# Implant Design Visceral



# Standard Visceral Design

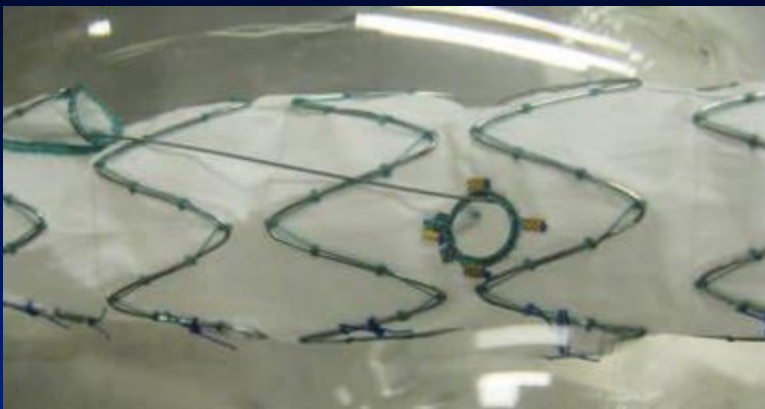
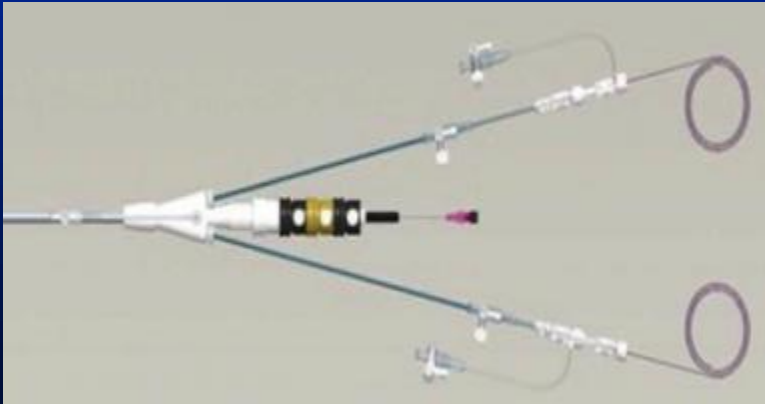


Projection “limits”





# Preloaded Catheter and Wire Systems



# Repair Types

942 F/B-EVAR  
(2004-2013)

Excluded  
588 JR and type  
IV TAAA

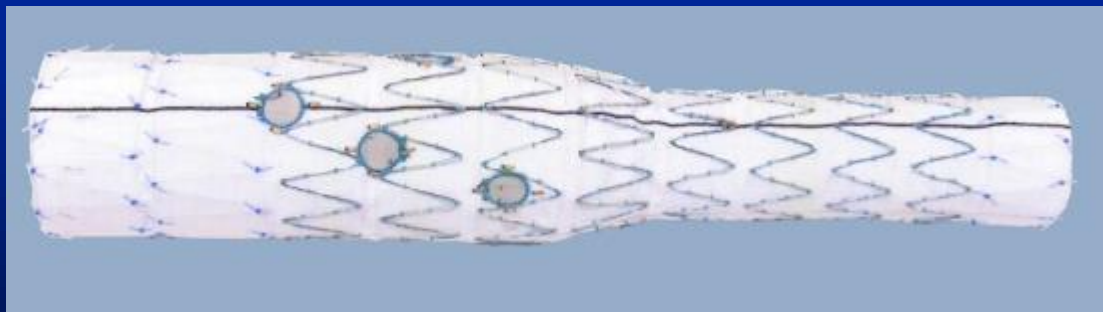
354 Extensive  
TAAA

128 Type II  
TAAA

226 Type III  
TAAA



# Device Configuration: 1320 Target Vessels



274 Patients  
(77.4%)

Fenestrations Only



45 Patients  
(12.7%)

Single Helical Branch with Fenestrations



35 Patients  
(9.9%)

Double Helical Branches with Fenestrations

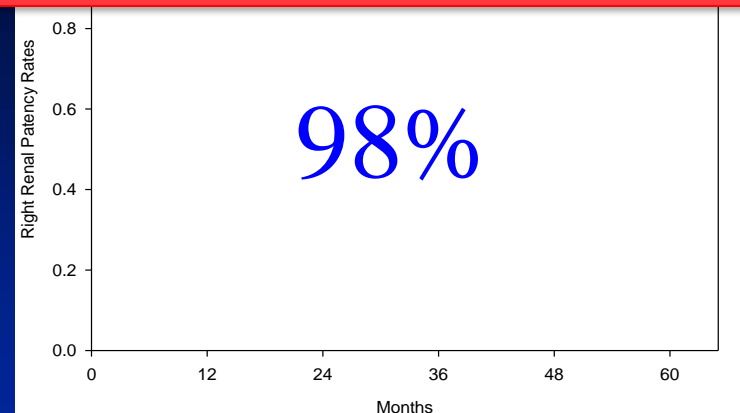
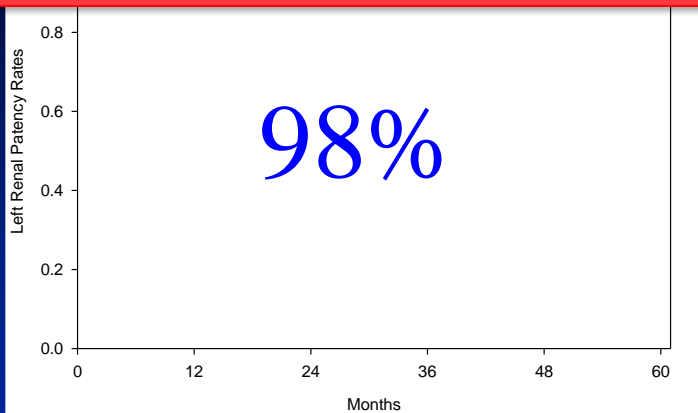
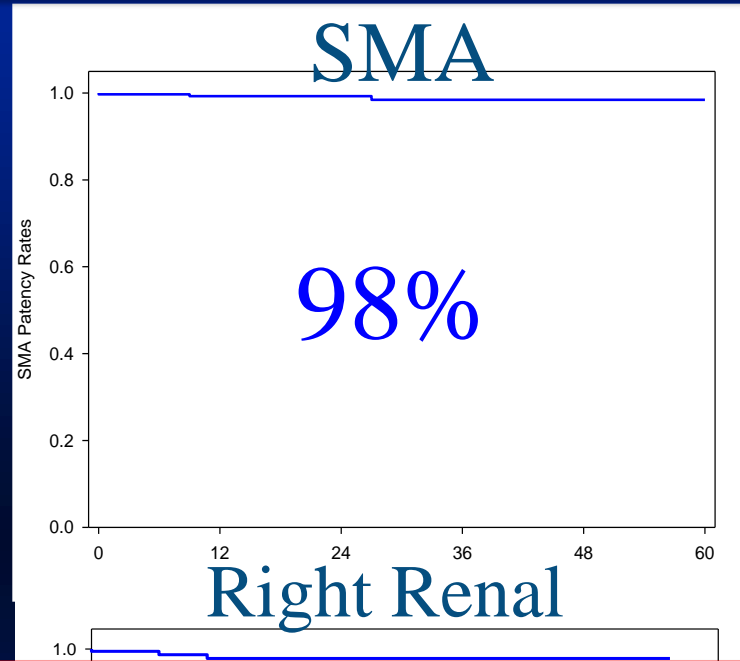
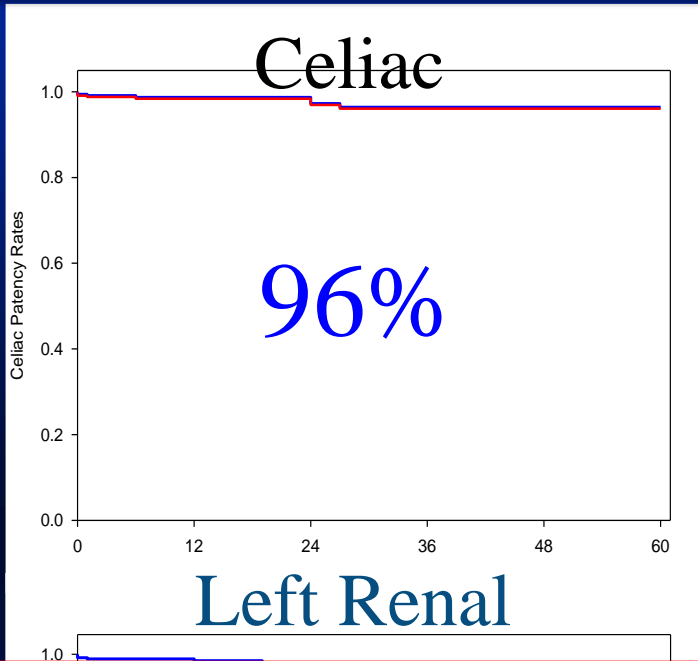
# Technical Success Rates

Statistical analysis:

No negative effect of helical limb design with a trend towards improved outcomes with helical branch use

- 21 patients (6%) had unstented planned target vessels
- 10 patients (2.8%) had persistent endoleak

# 36 Month Branch Vessel Patency



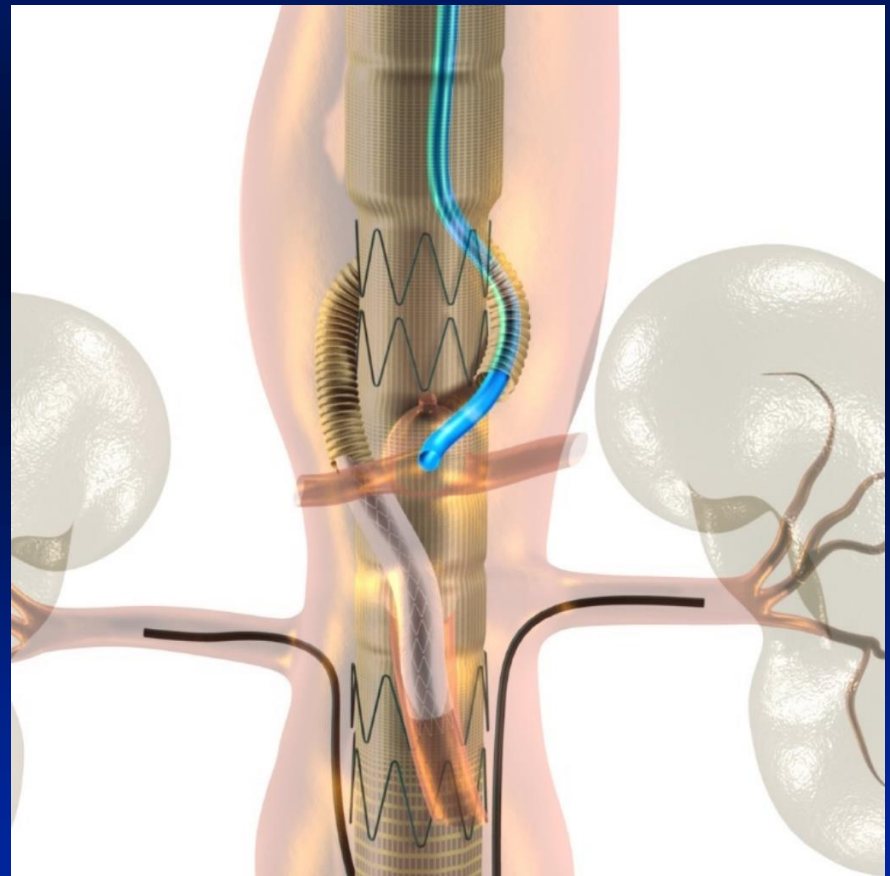
Primary Patency  
Secondary Patency

# Endoleak

- No bridging stent – helical limb associated endoleak

# Downside of Helical Limb

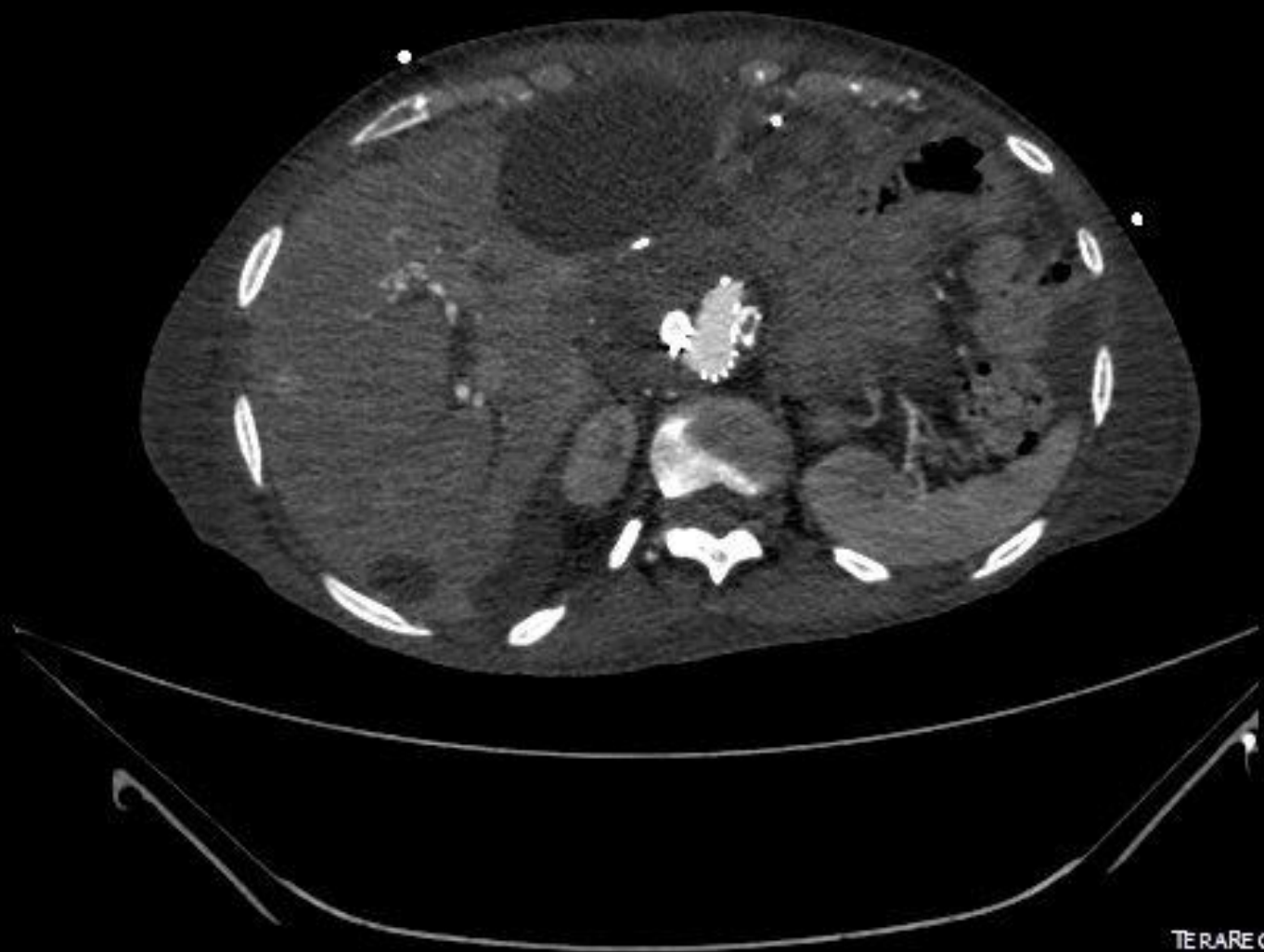
- Can be difficult to access – easier with preloaded system



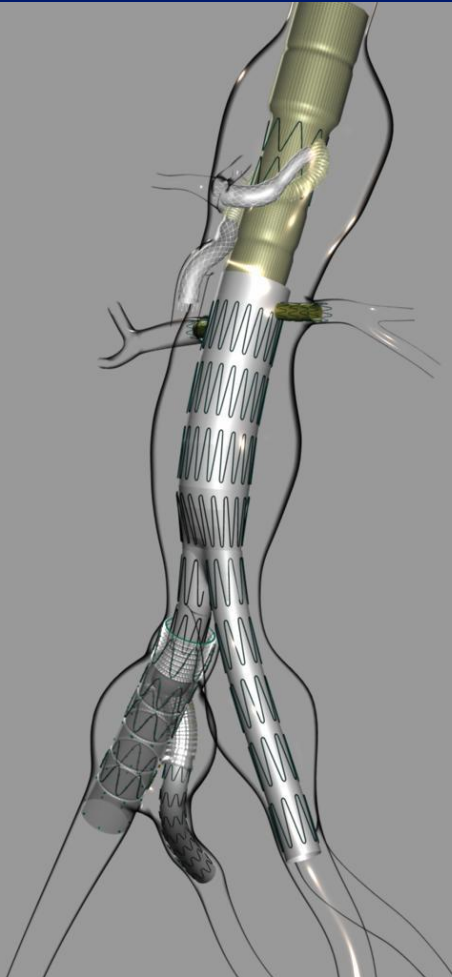


# Downside of Helical Limb

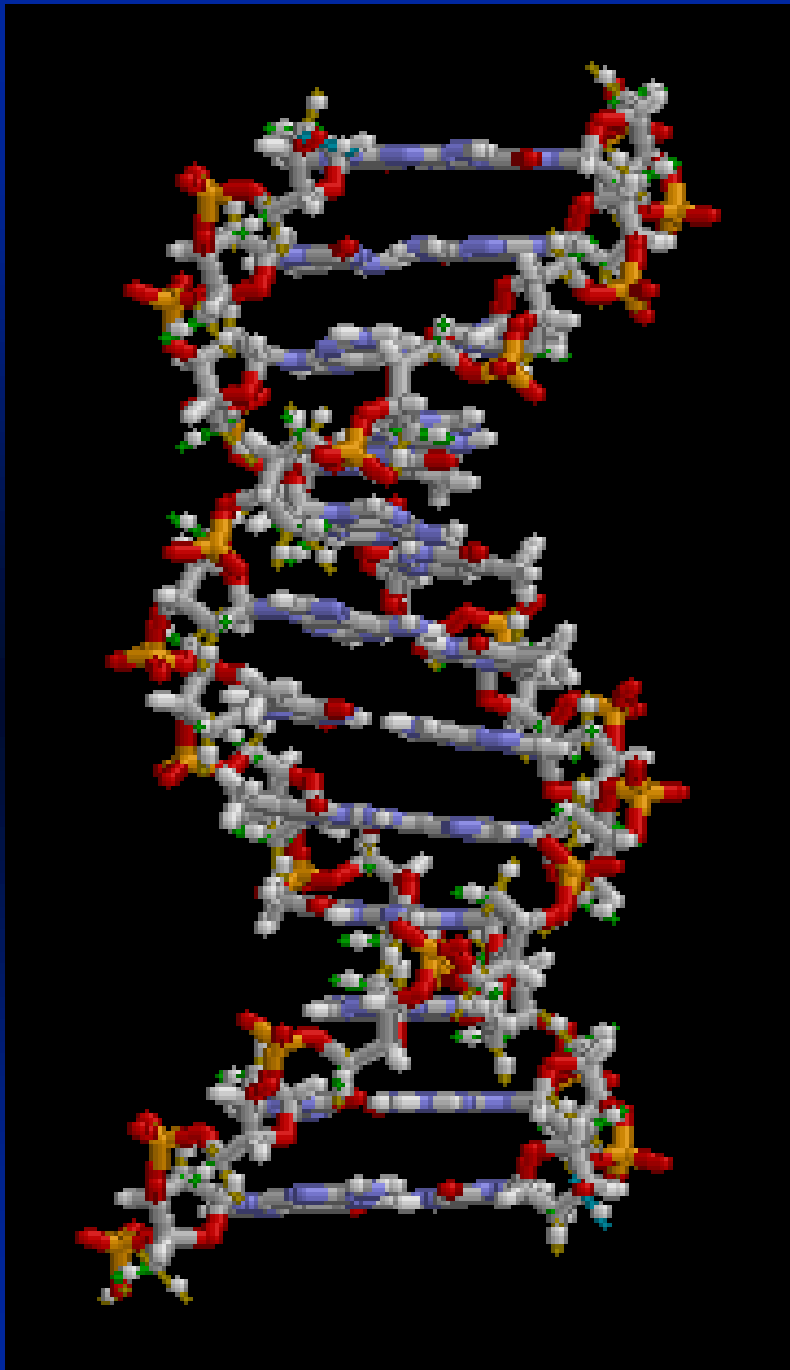
- Packing density – increased
- Can have some limitations depending on the location of the helical limb to the aortic morphology



# We will continue to develop this technology



- Improved ease of use
- Decreased delivery profile
- Increased application to aneurysmal disease



After all...

the helix  
is the basis of life