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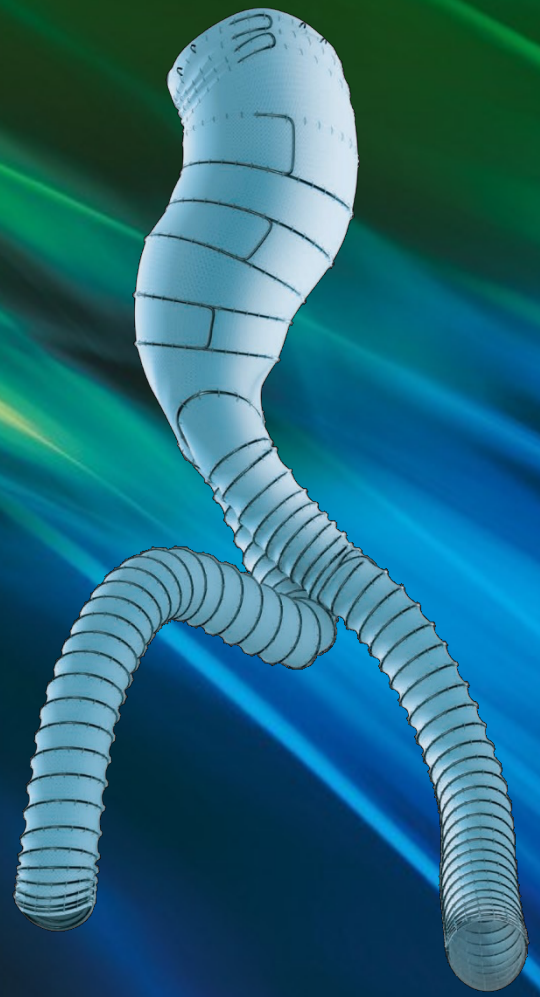
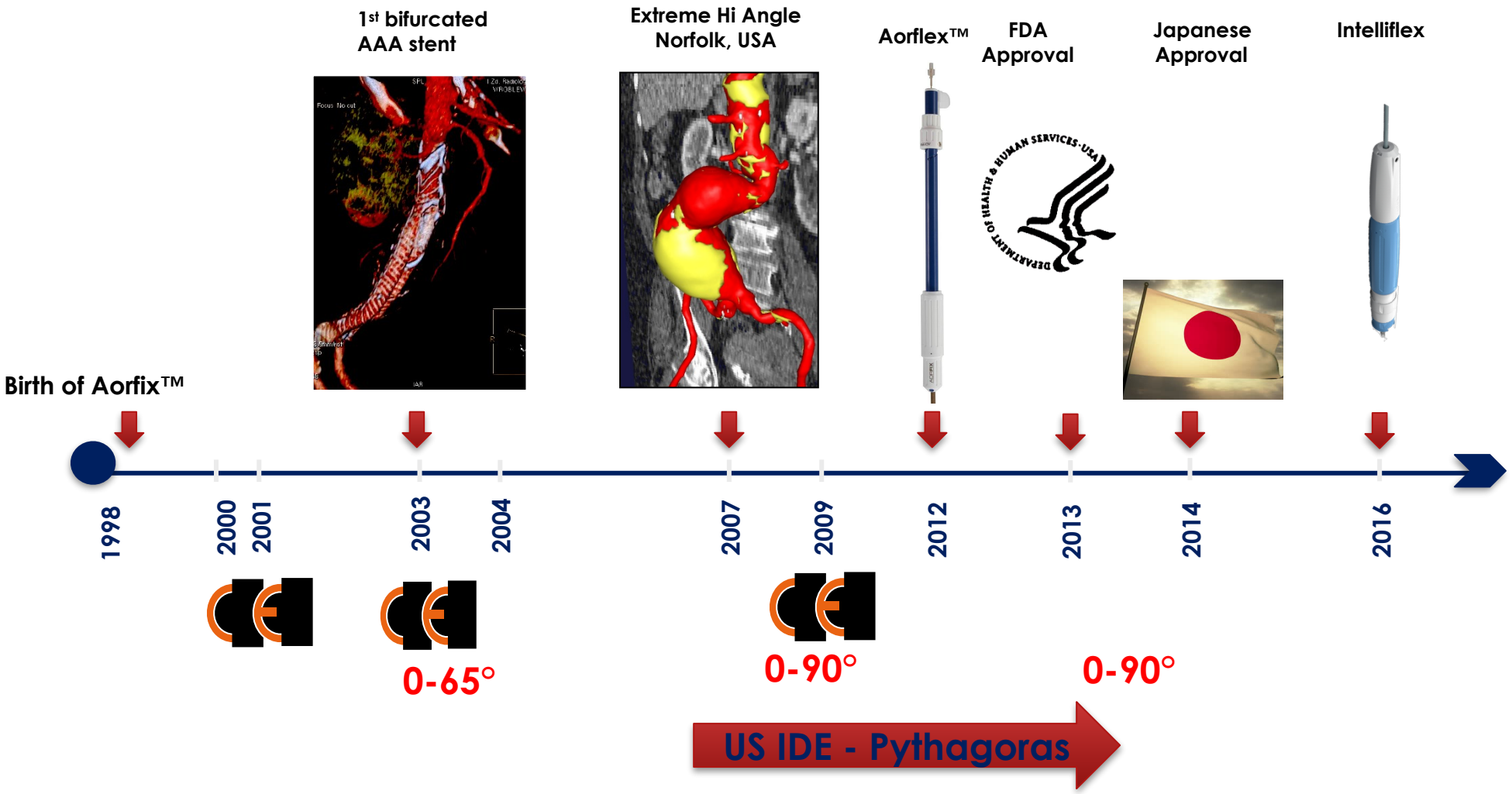
AORFIX™
Endovascular Stent Graft

Aorfix
More than Angled necks!



History


1st bifurcated AAA stent
Extreme Hi Angle Norfolk, USA
Aorflex™
FDA Approval
Japanese Approval
Intelliflex
Birth of Aorfix™
1998
2000
2001
2003
2004
2007
2009
2012
2013
2014
2016
0-65°
0-90°
0-90°
US IDE - Pythagoras

Reasons to choose the Aorfix stent graft

- Outstanding long term data
- Flexible and kink resistant legs
- Accommodates disease progression by adapting to changing morphology
- Simplified delivery system with built in exchange sheath
- Proven in 90 degree necks

Outstanding long term data

- Pythagoras trial for U.S. F.D.A. approval
- 230 patients
- 77 patients in the 0-60 degree neck group
- 153 patients >60 degrees
- Five year follow up

- Despite predictors of worse short- and long-term outcomes, pertinent outcomes were better than or similar to those of trials with less severe anatomy.

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Recruited Patient Group

	Aorfix	Aorfix < 60 degrees	Aorfix ≥ 60 degrees
	230	77	153
Variable			
Sac diameter, mm	57 ± 11	54 ± 9	59 ± 12
Proximal neck diameter, mm			
1mm infrarenal	23 ± 3	23 ± 3	22 ± 3
7mm infrarenal	22 ± 3	23 ± 3	22 ± 3
15mm infrarenal	24 ± 5	25 ± 4	24 ± 6
Proximal neck length, mm	23 ± 14	24 ± 15	22 ± 13
Patients with neck length <15mm	71 (31%)	24 (31%)	47 (31%)
Proximal neck angle, degrees	70 ± 23	44 ± 12	83 ± 15
Patients with neck angle > 90 degrees	43 (19%)	0 (0%)	43 (28%)

Endoleaks Identified by: Core lab and intervention

		6m to 1 Year	1 to 2 years	2 to 3 years	3 to 4 years	4 to 5 years
Type I	Total	5 (3.1%)	0 (0.0%)	3 (2.4%)	1 (1.0%)	0 (0.0%)
Type II	Total	40 (25.2%)	28 (20.4%)	17 (13.8%)	12 (12.5%)	10 (11.6%)

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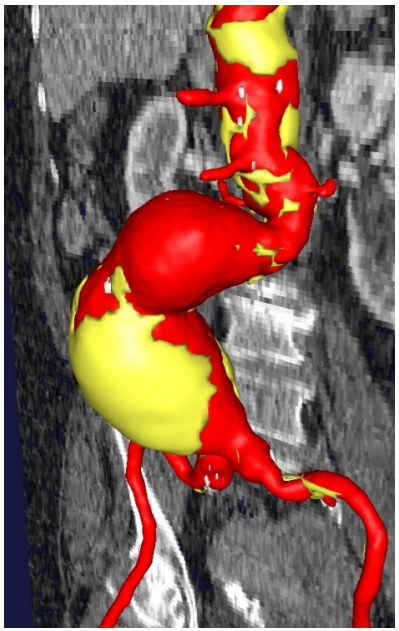
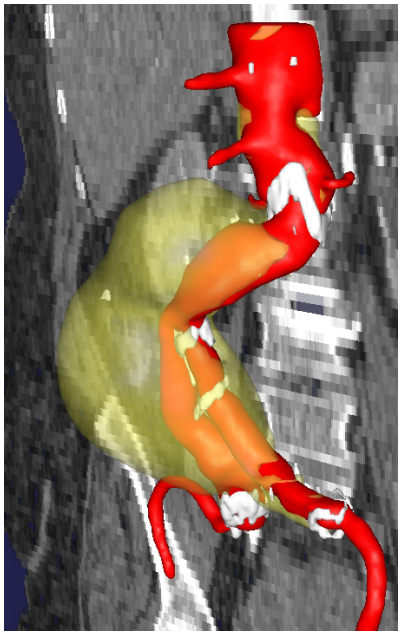
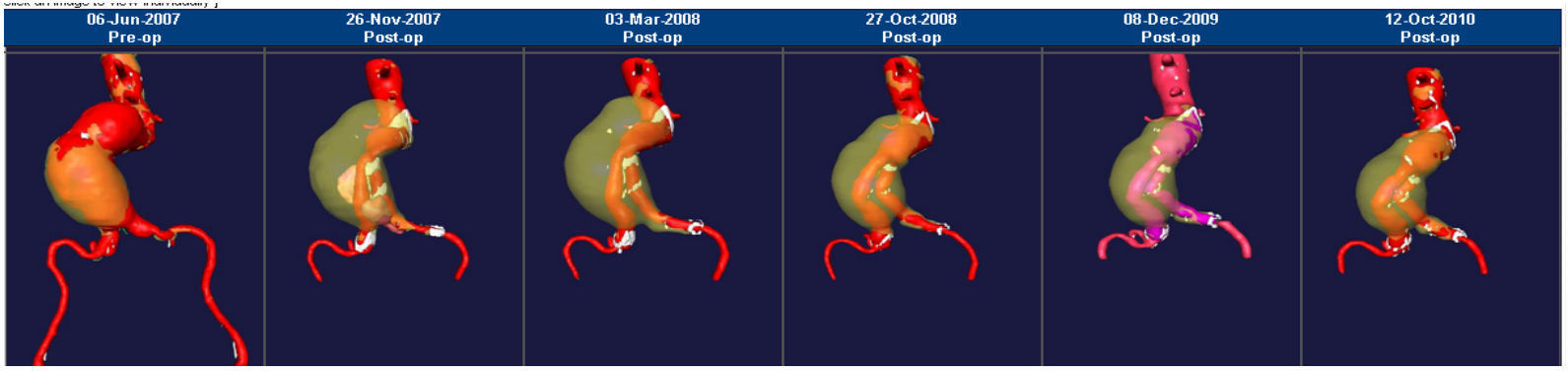
Ability to Treat Highly Angulated Necks







Sac Changes

	Year 1 N=185	Year 2 N=164	Year 3 N=146	Year 4 N=118	Year 5 N=108
New Enlargement	1	10	8	4	9
Continued Enlargement	1	1	3	8	7
Total Enlarging sacs	2 (1%)	11 (7%)	11 (8%)	12 (10%)	16 (15%)
Newly Stable	104	8	5	8	4
Continued Stability	-	54	46	36	25
Total Stable Sacs	104 (56%)	62 (38%)	51 (35%)	44 (37%)	29 (27%)
New Shrinkage	79	29	6	1	6
Continued Shrinkage	-	62	78	61	57
Total Shrinking Sacs	79 (43%)	91 (55%)	84 (58%)	62 (53%)	63 (58%)

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Schanzer's study of 10,228 patients demonstrated concerning high rates of sac expansion at 5 years

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background—The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection for endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance with anatomic guidelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR AAA sac enlargement.

Methods and Results—Patients with pre-EVAR and at least 1 post-EVAR computed tomography scan were identified from the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore, morphological measurements were compared with the most liberal and the most conservative published anatomic guidelines as stated in each manufacturer's instructions for use. The primary study outcome was post-EVAR AAA sac enlargement (>5-mm diameter increase). In 10 228 patients undergoing EVAR, 59% had a maximum AAA diameter below the 55-mm threshold at which intervention is recommended over surveillance. Only 42% of patients had anatomy that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age ≥80 years, aortic neck diameter ≥28 mm, aortic neck angle >60°, and common iliac artery diameter >20 mm.

Conclusion—In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture. **(*Circulation*. 2011;123:00-00.)**

The 5-year post-EVAR rate of AAA sac enlargement was 41%.

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Jikei University Kashiwa Hospital

	N	Shrinkage	No change	Expansion
Excluder	16	2(12.5%)	10(62.5%)	4(25.0%)
Endurant	22	8(36.4%)	8(36.4%)	6(27.2%)
AFX	18	9(50.0%)	6(33.3%)	3((16.7%)
AORFIX	**38**	**21(55.3%)**	**15(39.5%)**	**2((5.3%)**

Time period : March 2015-Dec 2017
Follow up : ≧6month
Case number : 94
Exclusion : CIAA、embolization of branchs (IMA, Lumbar A etc)

2019 Feb JCSVS

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Flexible and kink resistant legs

- Limbs have a continuous spiral stent
- Provides superb flexibility and kink / occlusion resistance
- Pythagoras study only had one late (post 30 day) limb occlusion

Helical design of the stents keeps the vessel patent even with the tortuous anatomy

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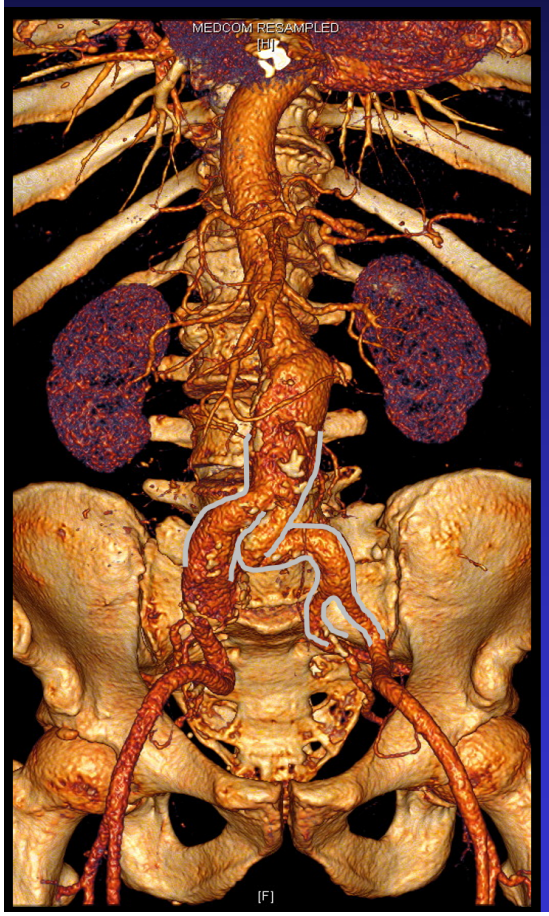
Flexible and kink resistant legs

Challenging iliac anatomy



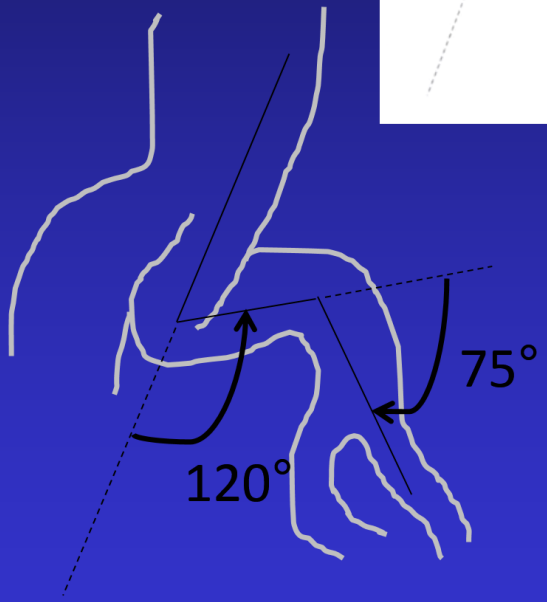
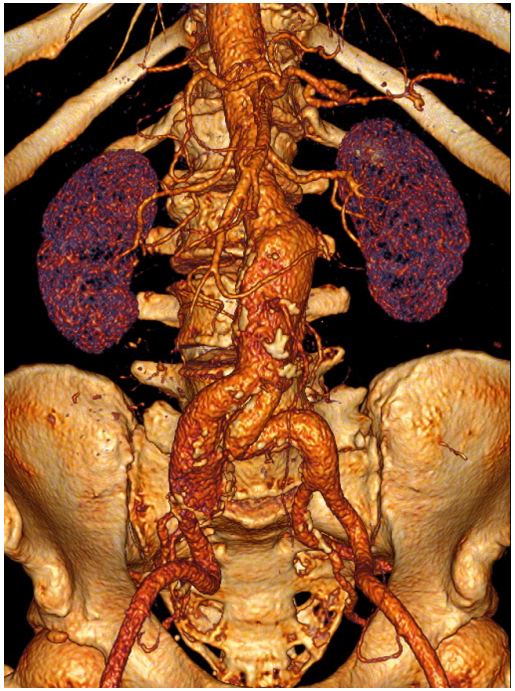
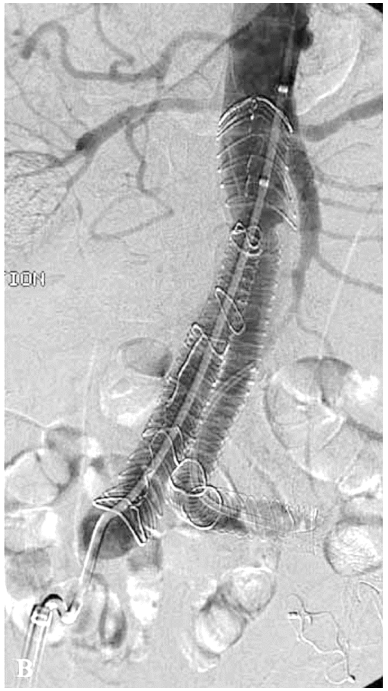
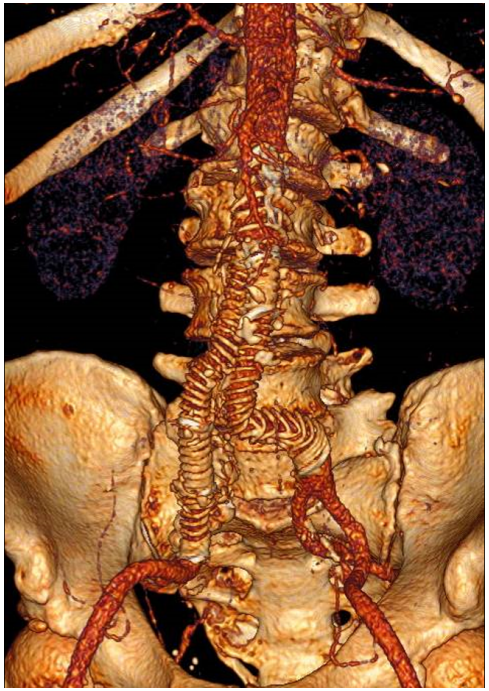


Illustration: AR Weale

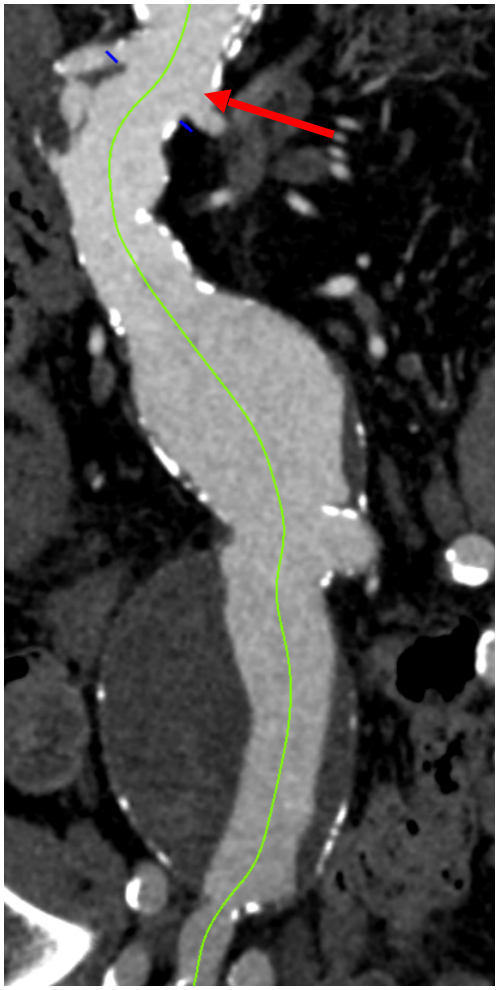
Flexible and kink resistant legs

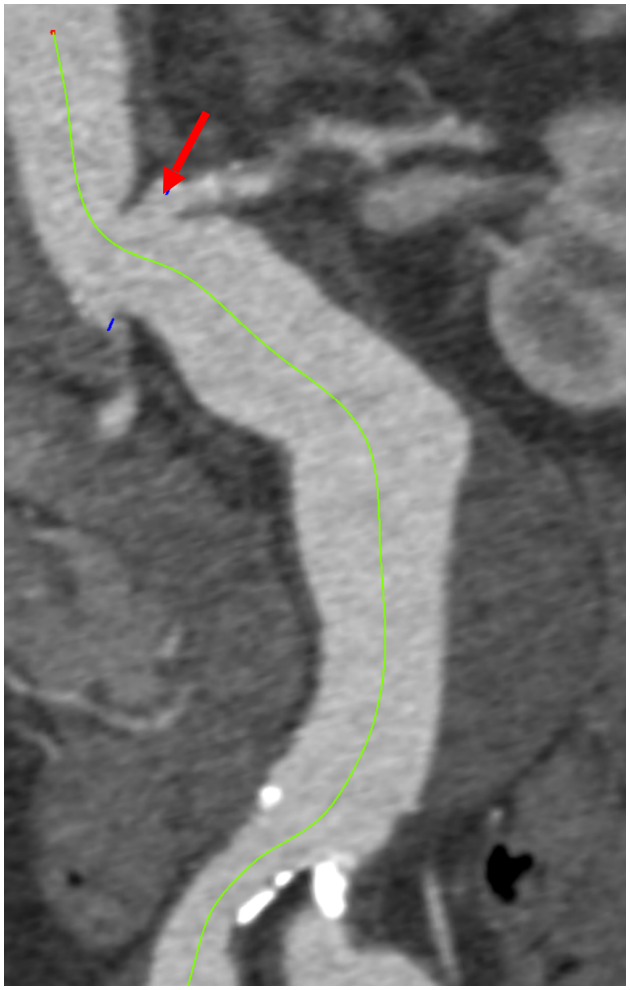






At the the renal arteries, the aorta is resistant to disease-induced changes in diameter





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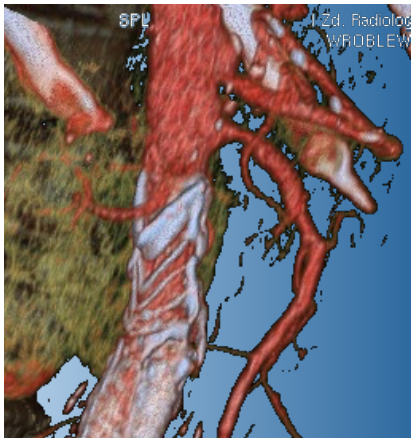
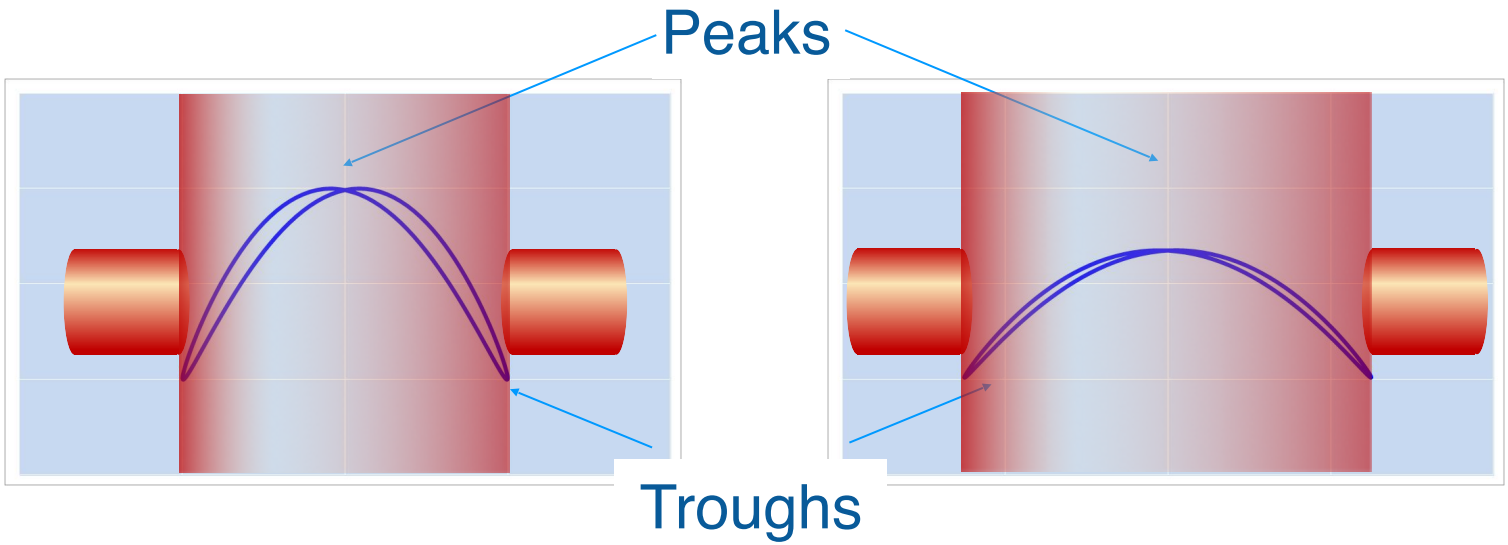
The Aorfix fishmouth is placed in the aorta where it is most resistant to diameter change





The fish-mouth follows the peri-renal region which is established as the most stable part of the aorta

As the neck expands, the peaks flatten, the troughs are stable and remain fixed.
No late renal occlusion

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Simplified Delivery System

- 18 f integrated sheath allows placement of extensions or ballooning without removing the main device
- Hydrophilic coating
- Intuitive deployment
- ‘Y’ mechanism allows controlled top end deployment and has been used to permit repositionability

Proven in 90 degree necks

- The only device with FDA approval for highly angled necks
- Well established and proven in this anatomy with multiple publications showing consistently good results.

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