

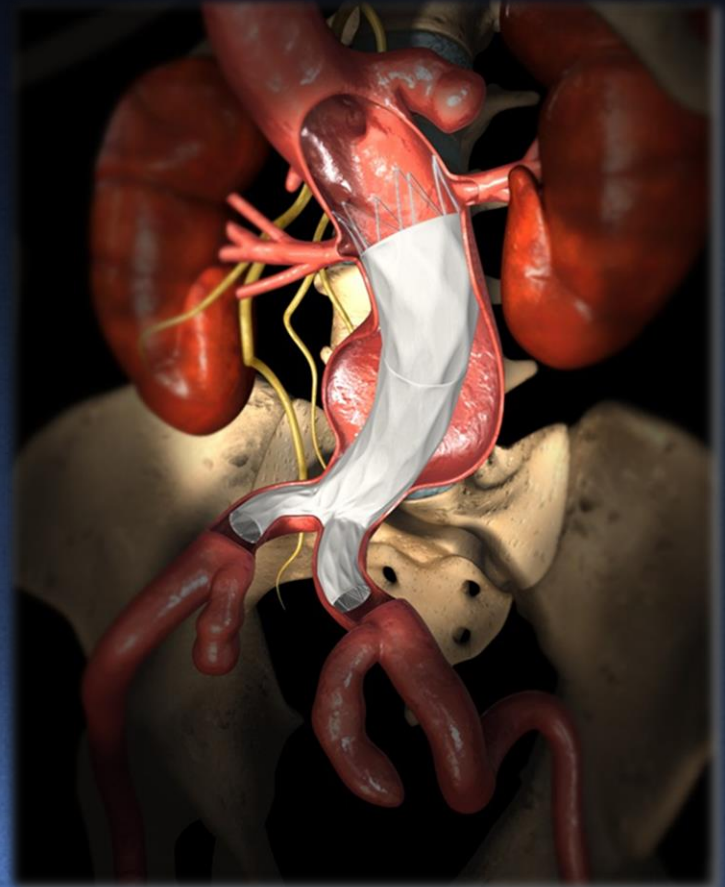


# Large applicability of **Anatomic FiXation**

Jean-Marc Alsac

MD, PhD, Vascular Surgery

Hôpital Européen Georges Pompidou  
Paris, France



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# AAA Activity at



- 120 AAA / year (20 ruptured via SOS Aorte)
- 50 Open Repair
- 70 EVAR



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# Experience Powerlink – Intuitrack - AFX

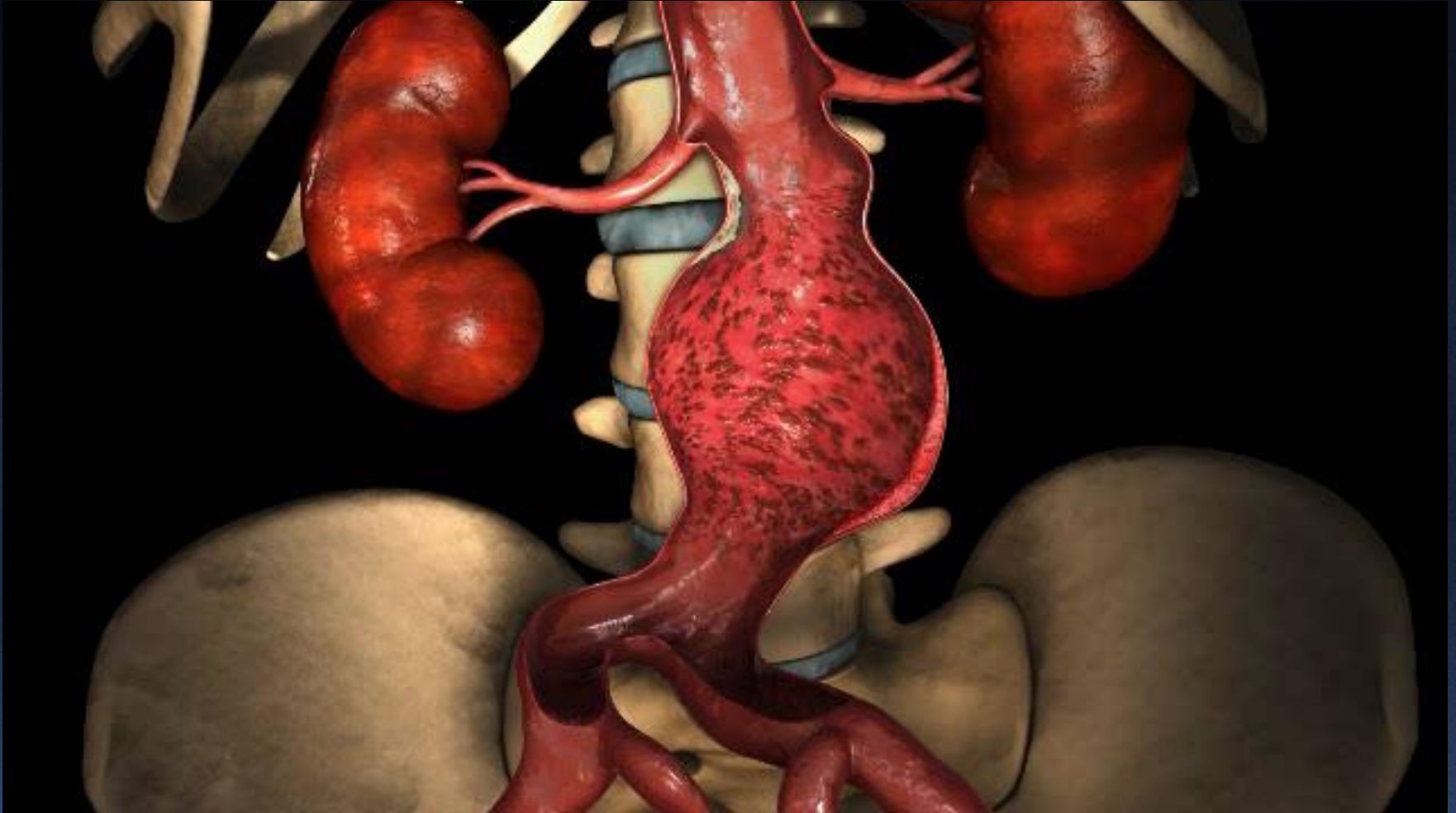
- 70 TEVAR with 10 AUI until 2012
- 2012: 13 Powerlink
- 2013: 20 Intuitrack
- 2014: 32 AFX
- 2015: 45 AFX
- 2016: 63 AFX ...



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

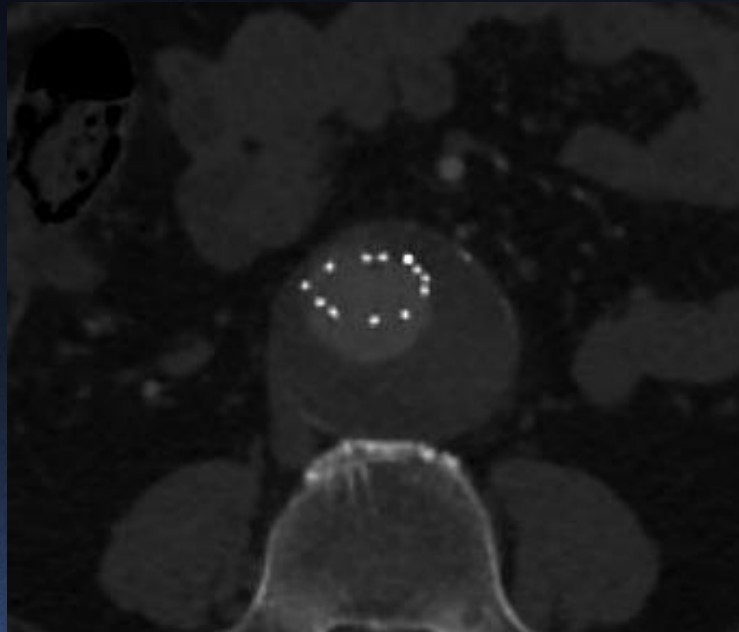
# Anatomic Fixation Design Active Sealing Concept



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# AFX : Active Sealing Concept



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

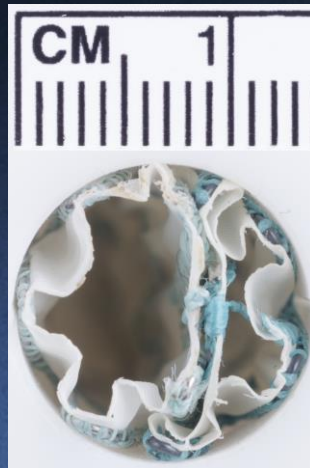


# First Experiences with AFX

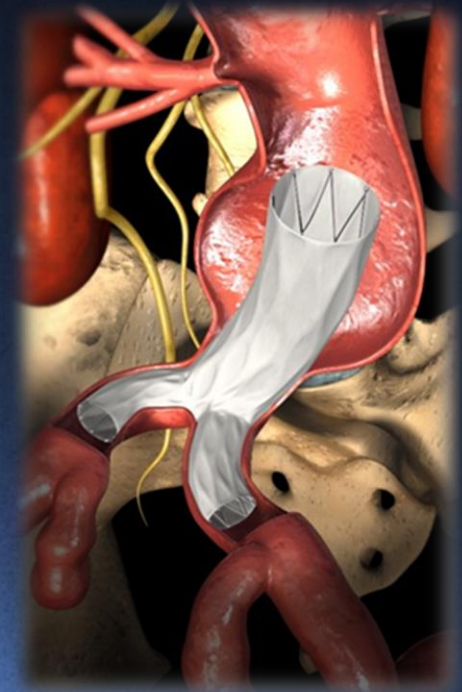
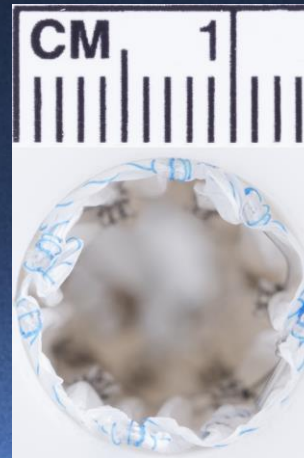
- Narrow distal aortic necks < 18 mm
- Competition between legs in a narrow distal aorta

## Aortic model of 14 mm

Bifurcated Stentgraft  
(Ipsi 13, Contro 16 mm)

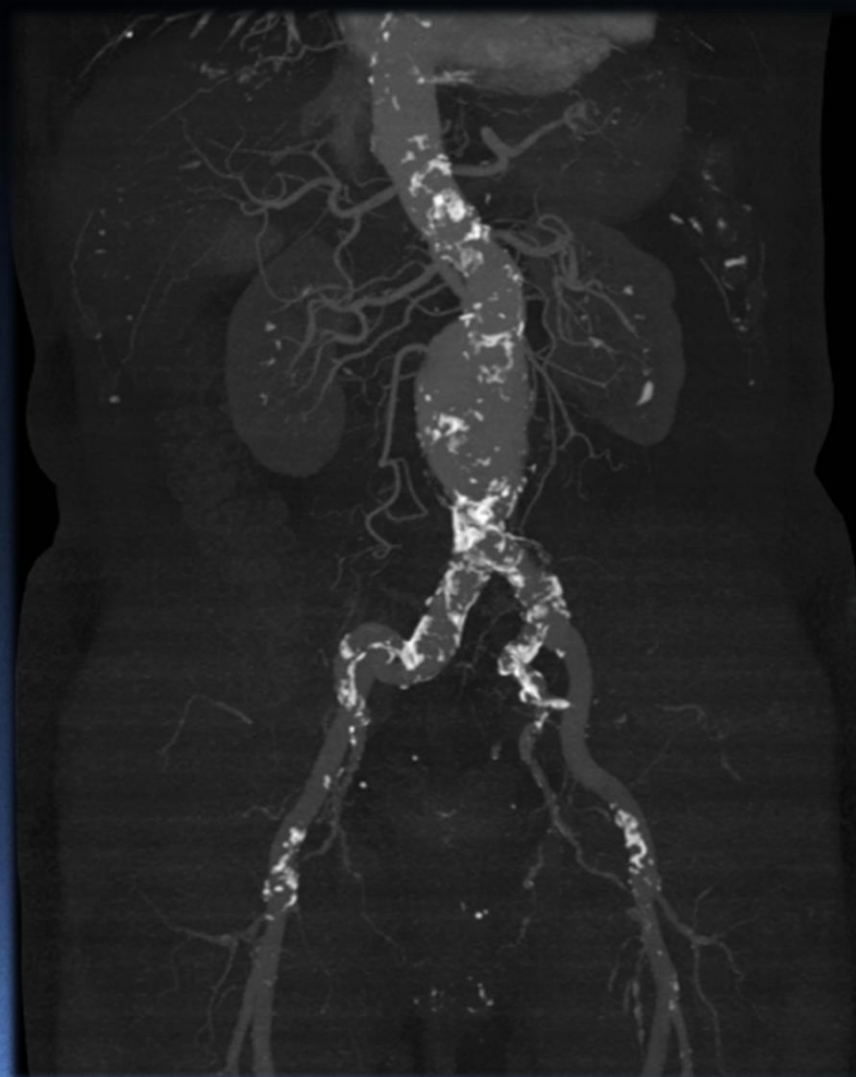
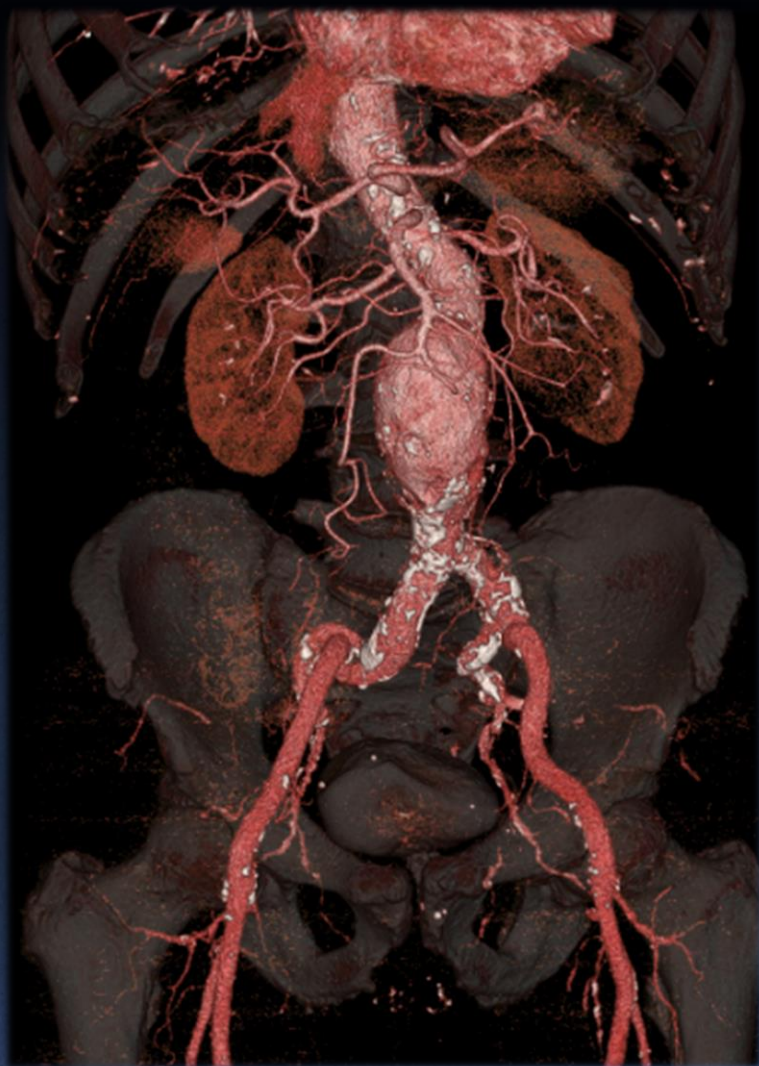


AFX 28 mm



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

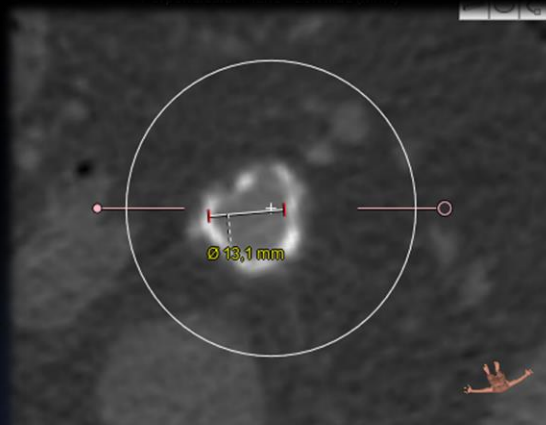
*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



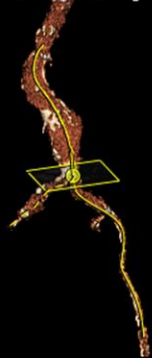
*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

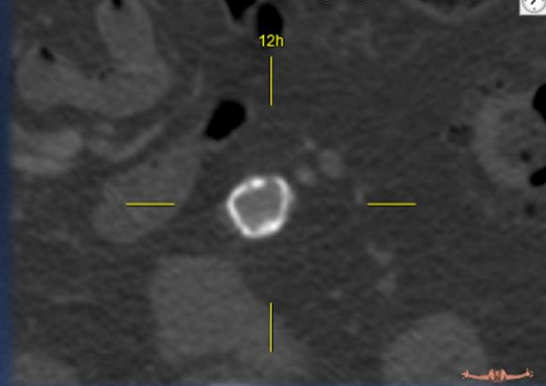




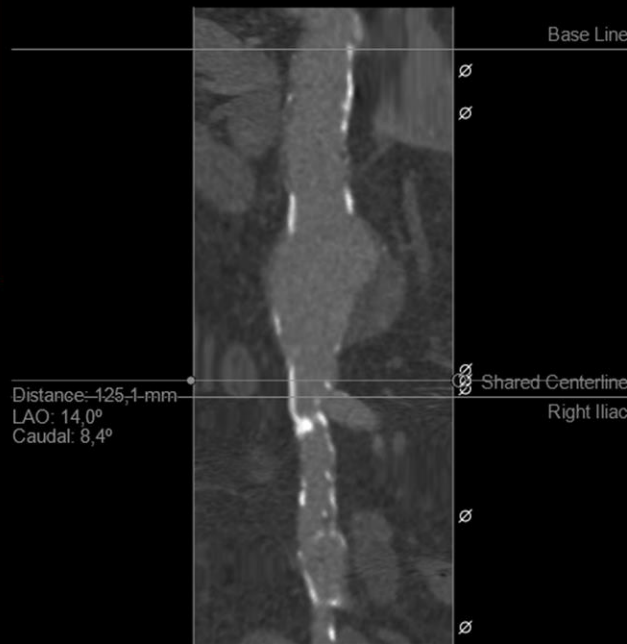
Volume Rendering



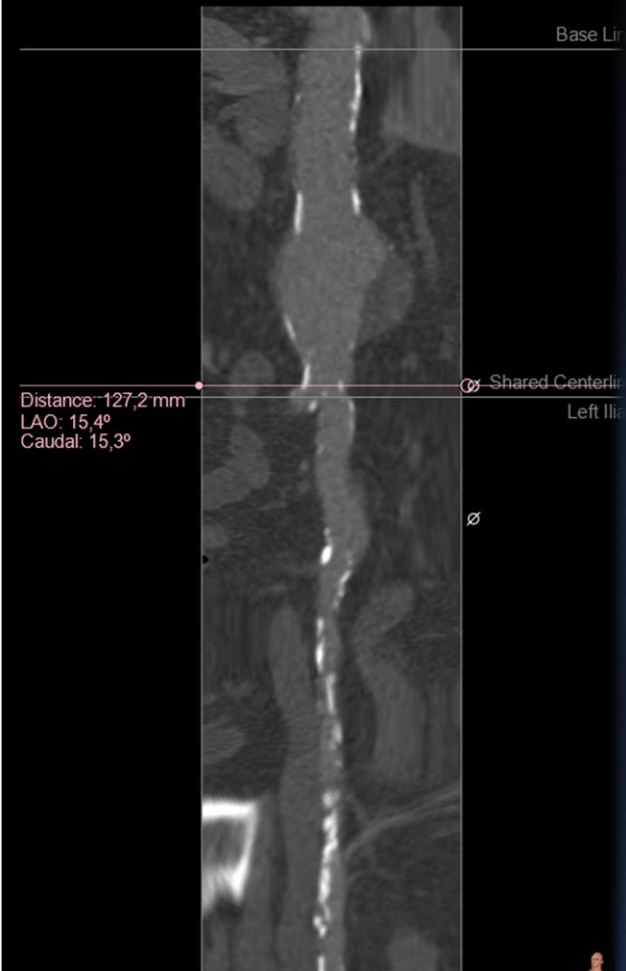
Axial View - Left Iliac (MPR)



Report Sheet - Right Iliac - Generated with iVY

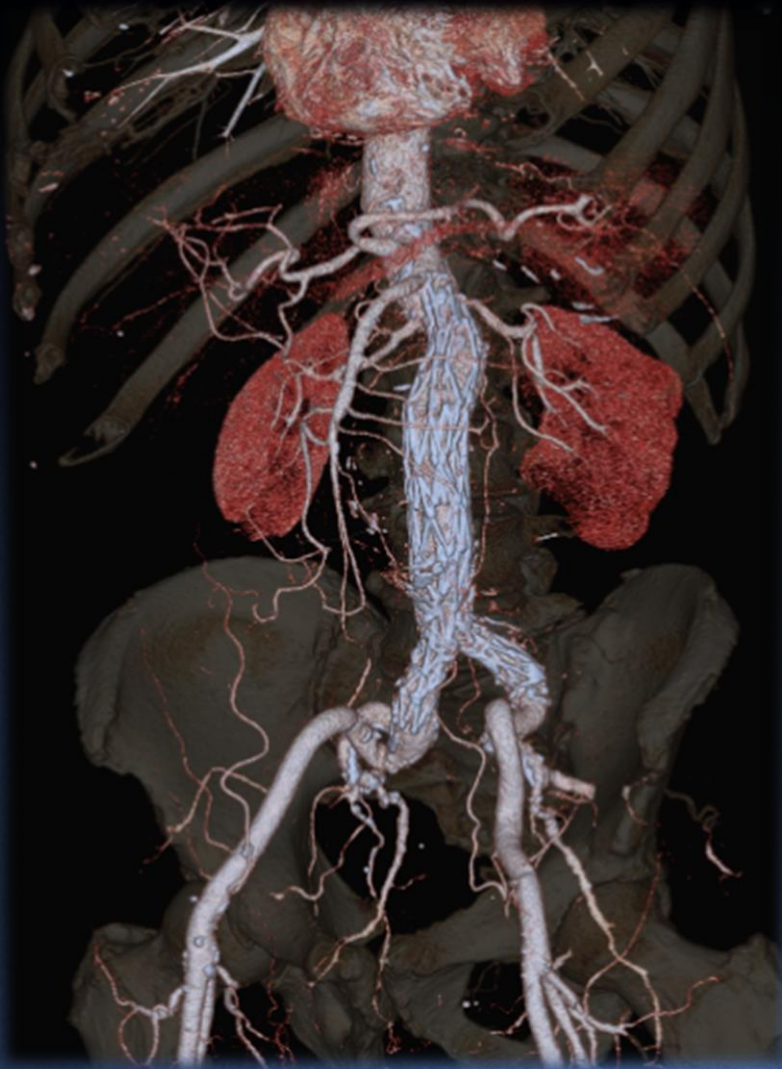


Report Sheet - Left Iliac - Generated with iVY



AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)

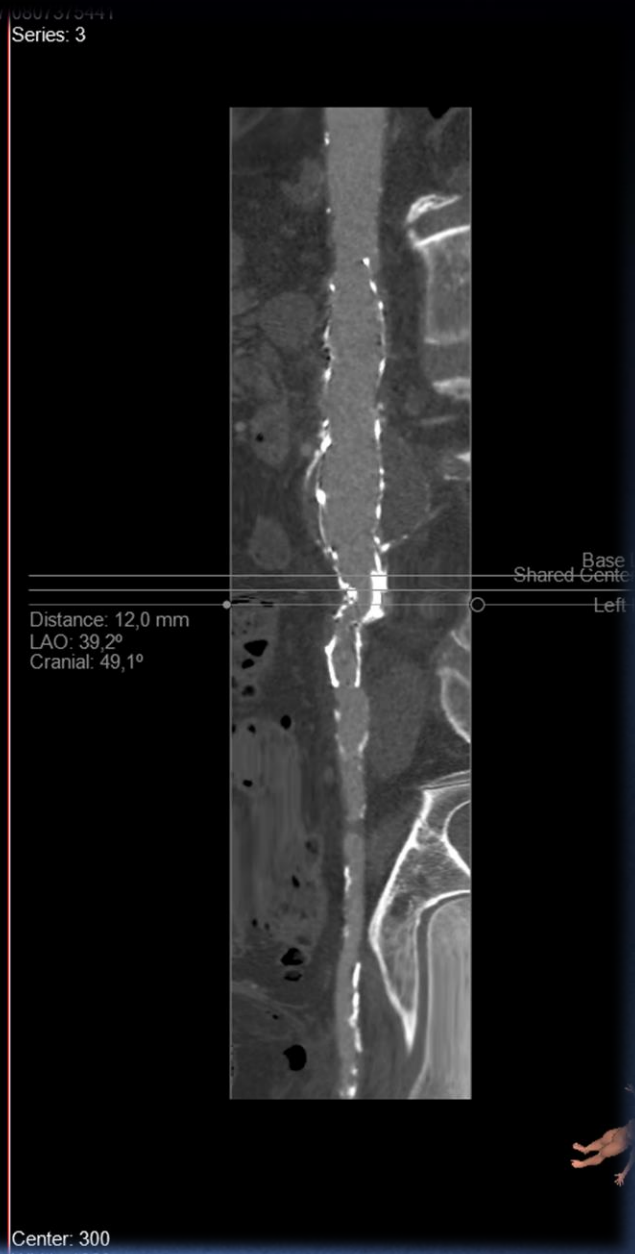
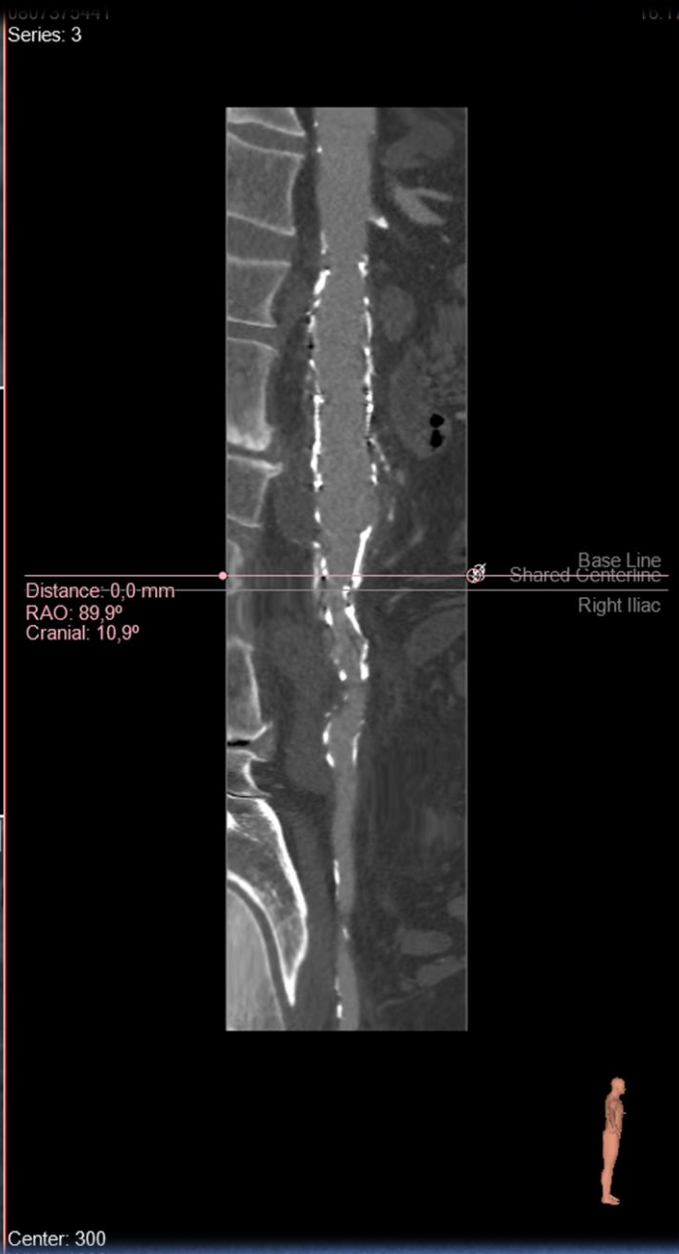
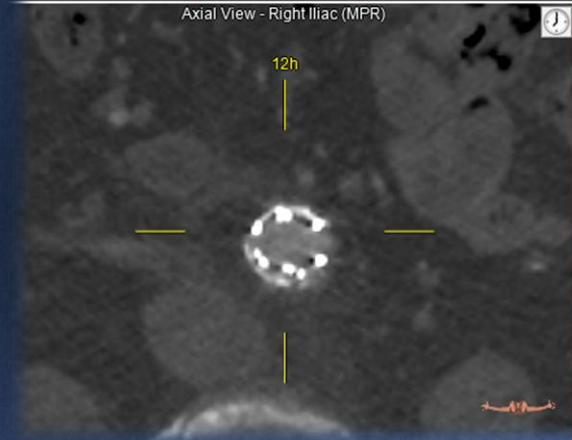
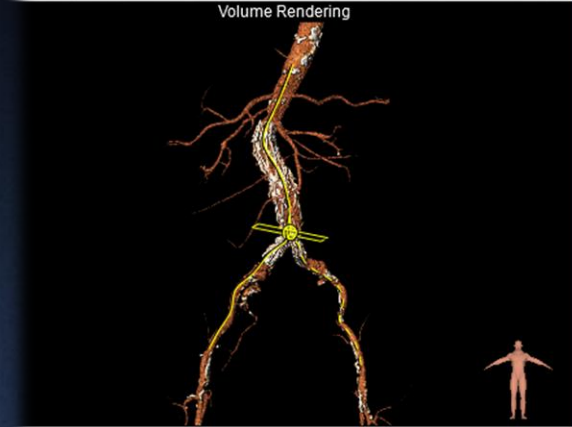
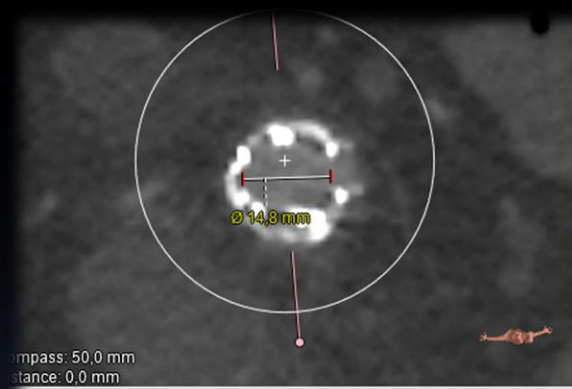
AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*





AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)

AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.



# AFX Experience

Narrow iliac access 9 Fr / 19 Fr  
Start a percutaneous learning curve

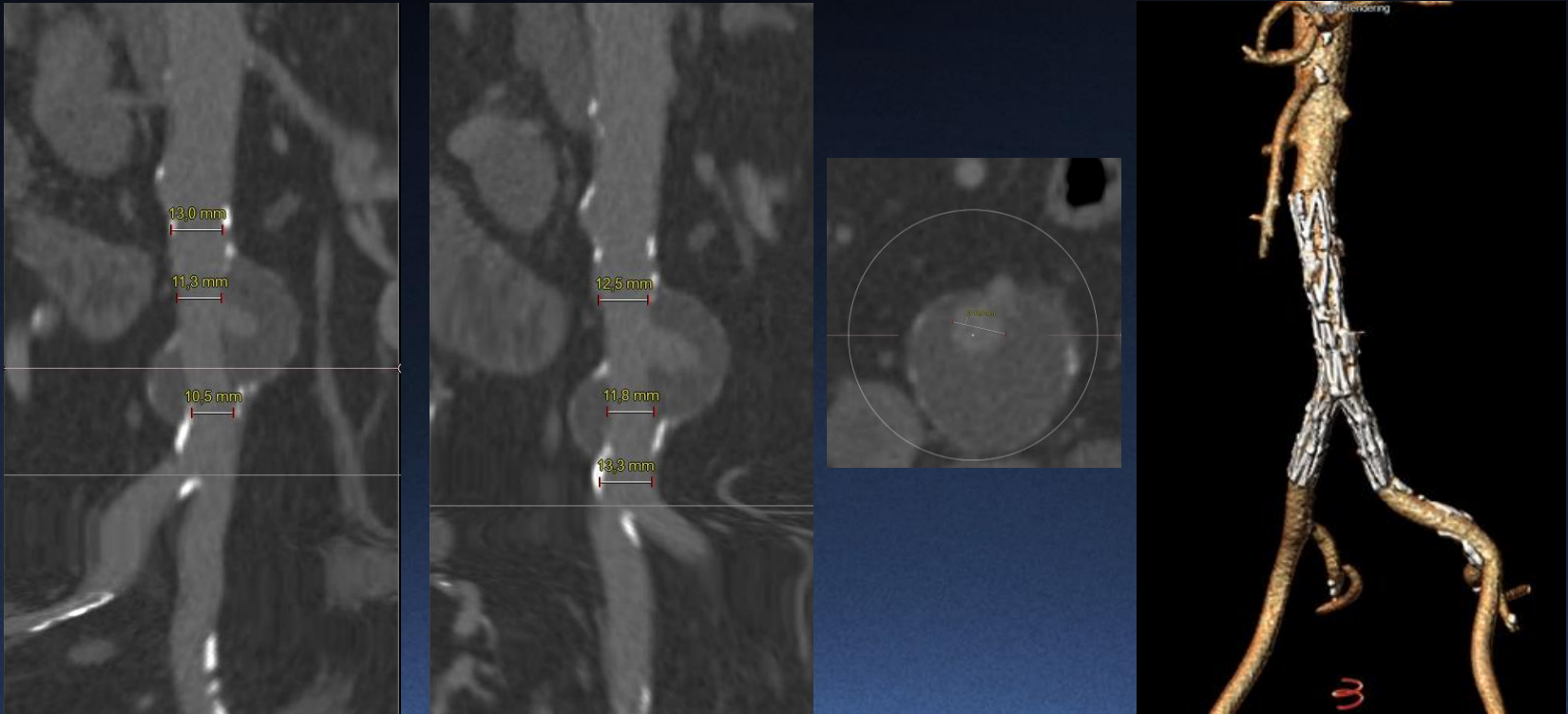


*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# AFX Experience

## Sacciform aneurysms / PAUs



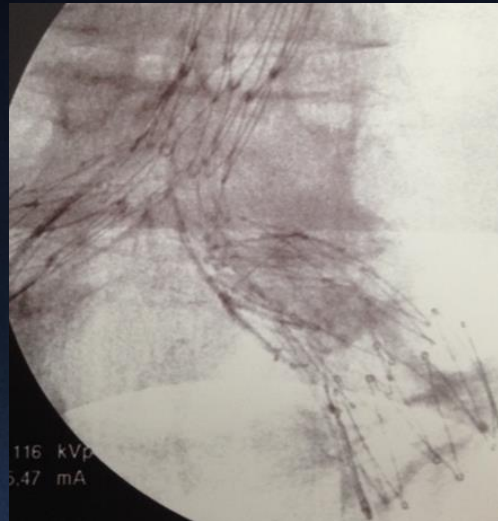
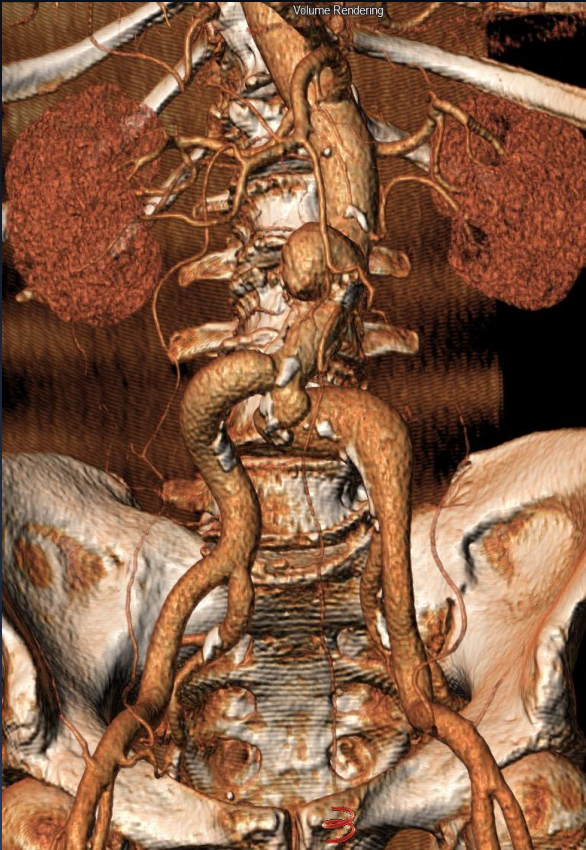
*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# AFX Experience

## Sacciform Aneurysms / PAUs Tortuous / Complex Bifurcation



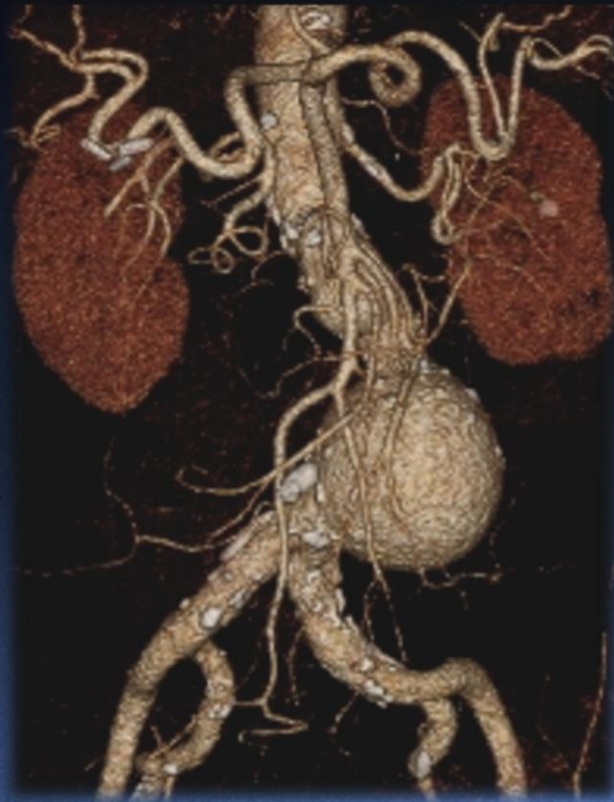
*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# AFX Experience

## Sacciform Aneurysms Predictable Catheterism Complexity



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# AFX Experience

Proximal angulated aortic Neck  
Predictable catheterism complexity / Rigidity



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# AFX Experience

Proximal angulated aortic Neck  
Predictable catheterism complexity / Rigidity



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# AFX Experience

## Isolated iliac aneurysm Without proximal iliac neck

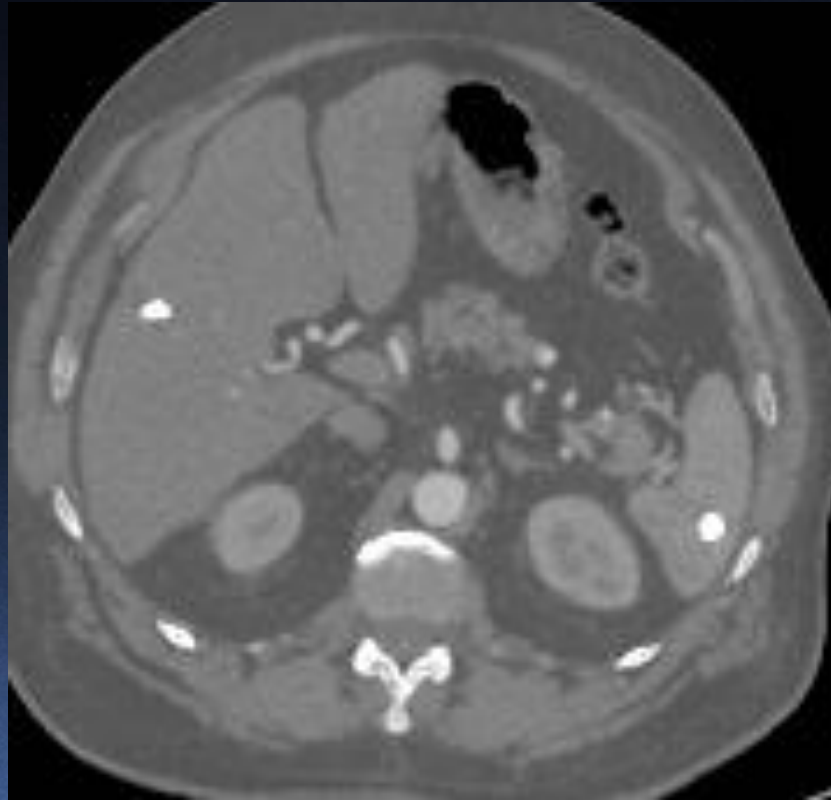


*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# AFX Experience

## Isolated iliac aneurysm Without proximal iliac neck



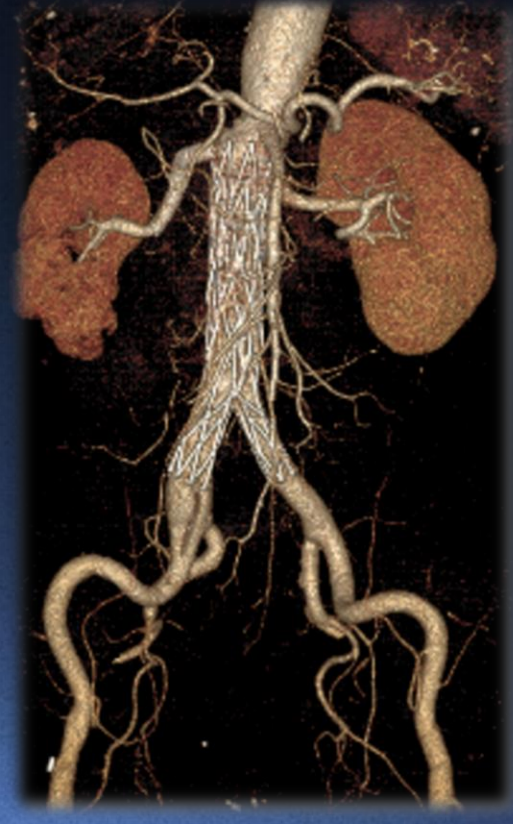
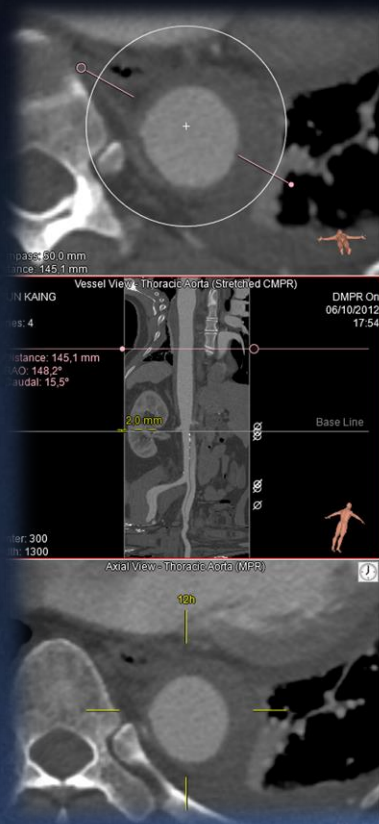
*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# AFX Experience

## Aortic Dissections Exclusion of distal re-entry tears



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# AFX Experience

## Complex Ruptured Aneurysms No Catheterism



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# Large Anatomic Applicability



- **Narrow distal Aorta < 16 mm**

- No more AUI + Fem-Fem bypass
- No Leg Competition



- **Narrow iliac access with 9Fr**

- No AUI + Fem-fem bypass
- Possibility of later cross-over revascularizations



- **Percutaneous Learning curve**

- Homolateral Sheath 19 Fr
- Controlateral Sheath 9 Fr

*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# Large Anatomic Applicability



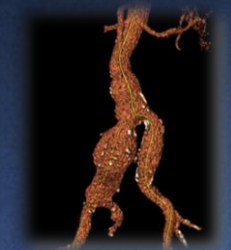
## ■ Sacciform Aneurysms / PAUs

- Narrow Calcified Aorta
- More stable than an aortic tube
- No Catheterism



## ■ Proximal Angulated Necks

- Rigidity in the aortic Neck
- No catheterism
- *Additional infrarenal extension for sufficient Overlap*

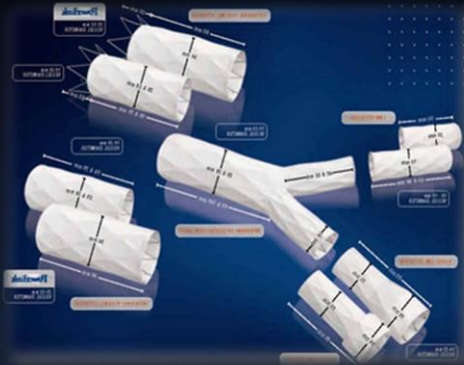


## ■ Isolated Iliac Aneurysms

- Creates a Proximal iliac neck
- In a Narrow healthy Aorta



# Large Clinical Applicability



## ■ Simple Inventory

- Bifurcated Body : 22 / 25 / 28 mm
- Proximal Extensions : 25 / 28 / 34 mm
- Distal Extensions : 20 / 25 mm



## ■ Limited Emergency Stock of 6 pieces

- Simplified Sizing
- Standardized Procedure without catheterism

# EVAR Experience HEGP 2005/2015

## 1 year results

<b>381 elective patients / IFU</b>	<b>81 COOK</b>	<b>44 GORE</b>	<b>84 Endurant</b>	<b>96 AFX</b>
Survival	96 %	90 %	94 %	98 %
Type I	6 %	2 %	1 %	3 %
Type II	21 %	30 %	15 %	12 %
Type III	4 %	2 %	1 %	1 %
Redo Endo	15 %	16 %	6 %	4 %
Open Conversion	6 %	9 %	5 %	1 %

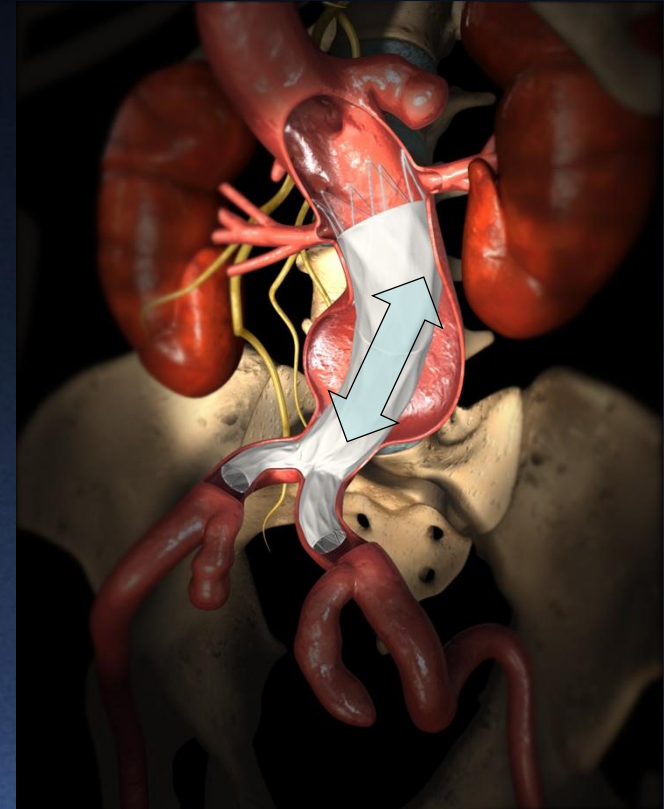
*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*



# Conclusions

- Mature Stentgraft
  - Reliable Long term Results
- Standardized deployment Process
  - Reproducible
  - Reliable
- Anatomic Fixation
  - No Catheterism
  - No Iliac leg conflict
  - Possible Cross Over
- Large Anatomic / Clinical Applicability



*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*

# Type III endoleak: Cumulative Rate across EVAR Devices at 3 years

INDEPENDENT,  
SYSTEMATIC REVIEW of  
**12** articles  
including  
**26,000** patients  
at 3-year follow up.

Type III endoleak	EVAR	95% CI: 3.8%, 4.3%
Maitrias, 2016, JVS	<b>12%</b> (3/28)	Multicenter, Prospective (France)
Kouvelos, 2015, JVS	<b>6%</b> (36/641)	Systematic review, 26 articles (Greece)
Sirignano, 2015, JVIR	<b>0.5%</b> (1/191)	Single center; Prospective (Italy)
Zhou, 2014, JVS	<b>1%</b> (2/213)	VA study, single center (Palo Alto, CA)
Chaar, 2012 JVS	<b>5%</b> (2/44)	Single center; Retrospective (Pgh, PA)
Jim, 2011, JET	<b>0%</b> (0/156)	Multicenter, Prospective Talent trial
Gambardella, 2010 Annals	<b>0.4%</b> (1/238)	Single center; Retrospective (Ireland)
Mehta, 2010, JVS	<b>0.3%</b> (5/1768)	Single center, Retrospective (Albany, NY)
AbuRahma, 2009, JVS	<b>0.4%</b> (1/238)	Single center; Retrospective (WV)
Hobo, 2006, JVS	<b>5%</b> (138/2846)	Eurostar Registry
Drury, 2005, BJS	<b>4%</b> (832/19804)	Systematic review, 61 articles (UK)
Haulon, 2003, EJVES	<b>6%</b> (6/96)	Single center; Prospective (France)

Summary of outcomes from an independent, systematic cumulative rate data synthesis comparing published rates specific to EVAR devices. Analysis conducted in February, 2016. Publication dates range from 2000 – 2016. Across 66 publications and 97,000 patients, 12 articles across 26,000 patients report Type III endoleak rates. Rates reflect incidence from implant through 3 years. Data on file.

AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)

AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.



# Cumulative Event Rates by AFX Product Version

	AFX Product Version		
	AFX System + Strata	AFX System + Duraply™	AFX2 System
Type IIIa Endoleak Rate	1.54% (366/23,828)	0.20% (34/17,139)	0.02% (1/4,143)
Type IIIb Endoleak Rate	1.34% (320/23,828)	0.19% (33/17,139)	0% (0/4,143)

*AFX® Endovascular AAA System Not Currently for sale in the European Economic Area (EEA)*

*AFX is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography.*