



Evar new device Anaconda



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Disclosure

Cook

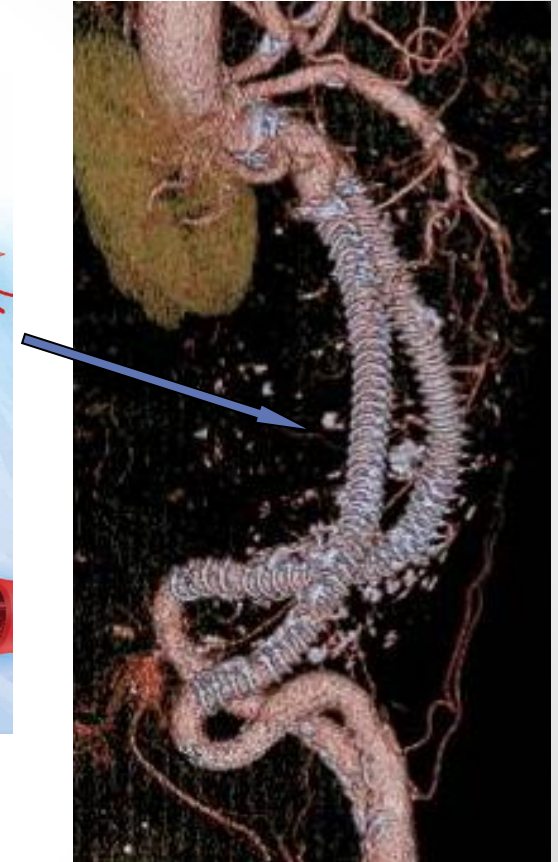
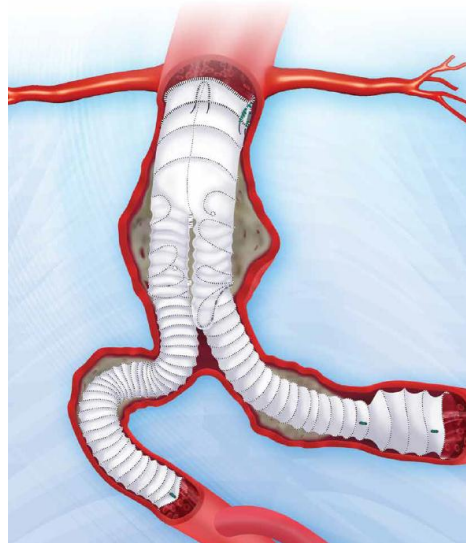
Gore

Medtronic

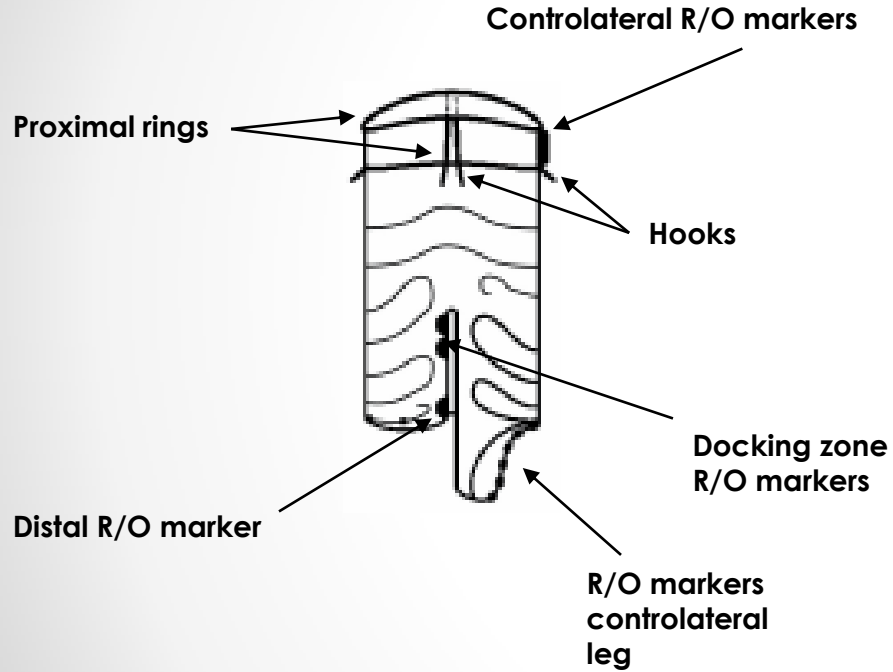
Vascutek

anaconda™ Device
AAA Stent Graft System

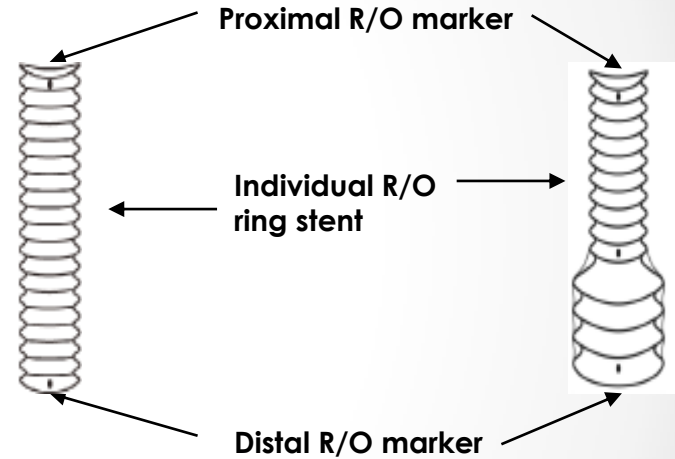
- CE Marked 2005
- 14,000 Implants world wide
 - Repositionable
 - Flexible
 - Safe and secure



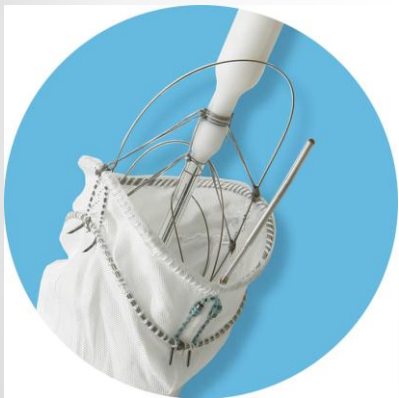
Main body



Legs



Main Body Repositionable



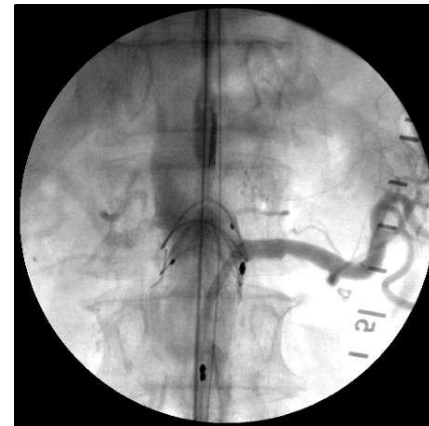
Deployed



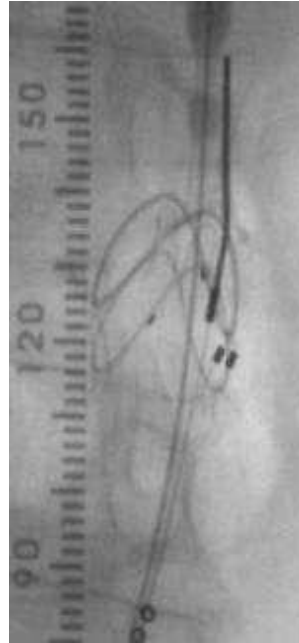
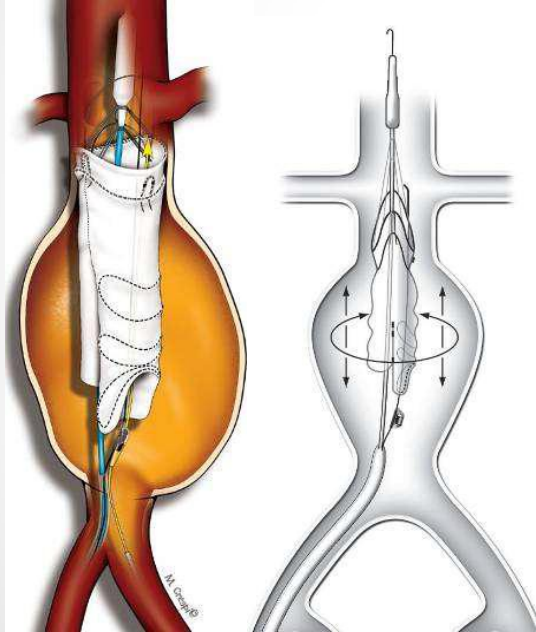
Collapsed



Re-deployed



Main Body Repositionable



Deployed



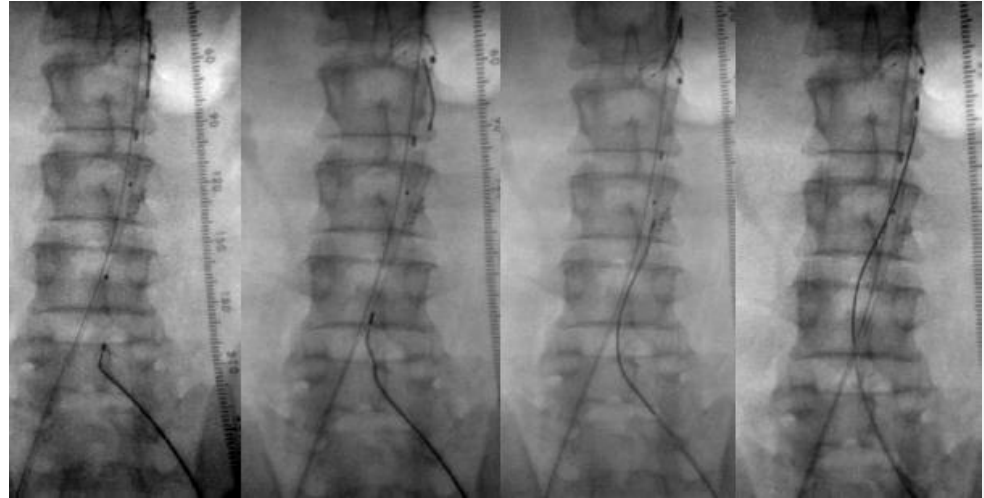
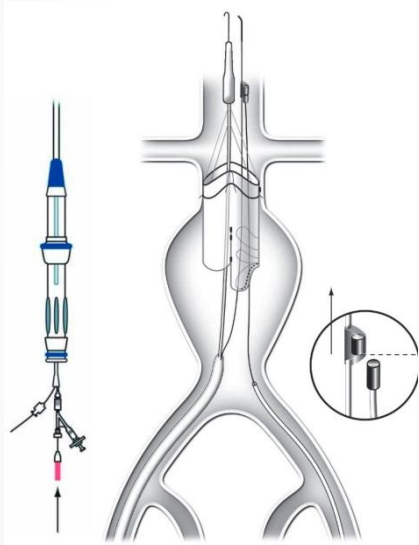
Collapsed



Re-deployed

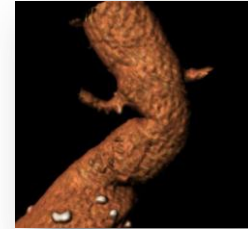
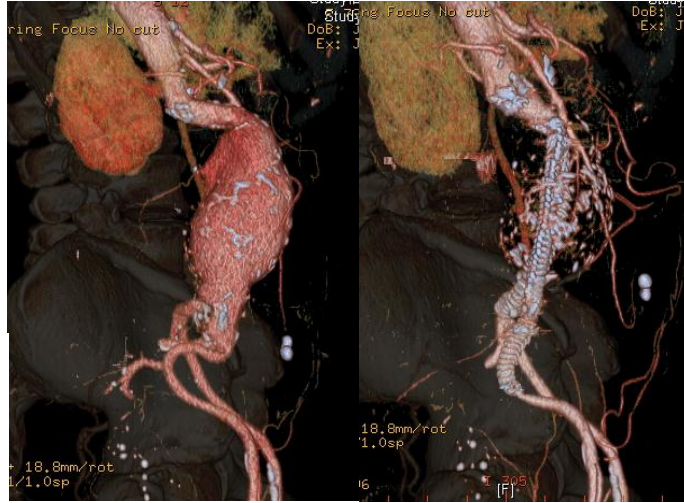
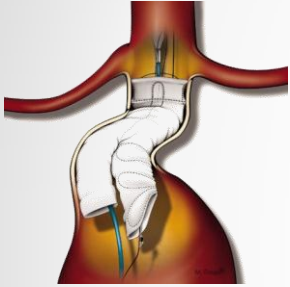
Controlateral leg catheterism

Exclusiv magnet system



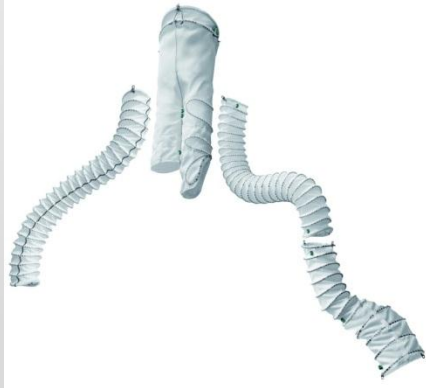
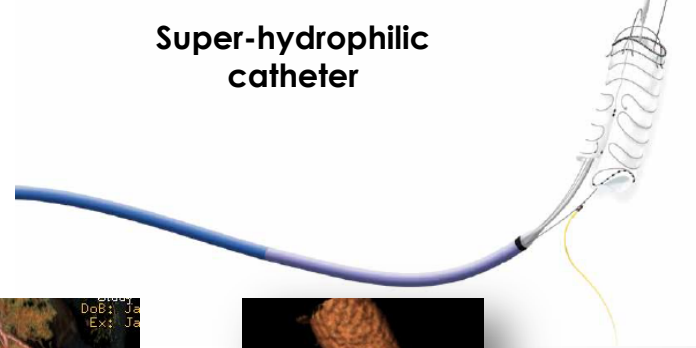
Flexibility

Difficult anatomies...



... perfect legs conformability

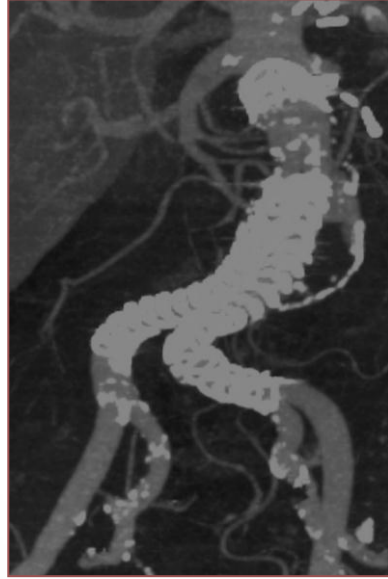
Super-hydrophilic catheter



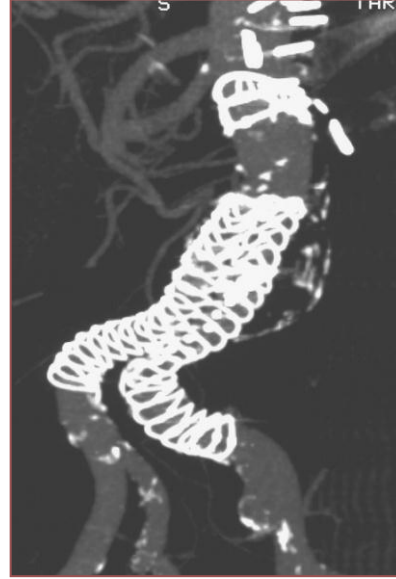
Flexibility

Difficult anatomies...

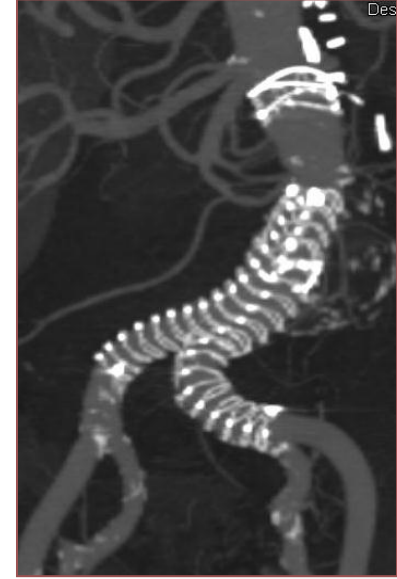
... perfect legs conformability



1 month



6 months



12 months

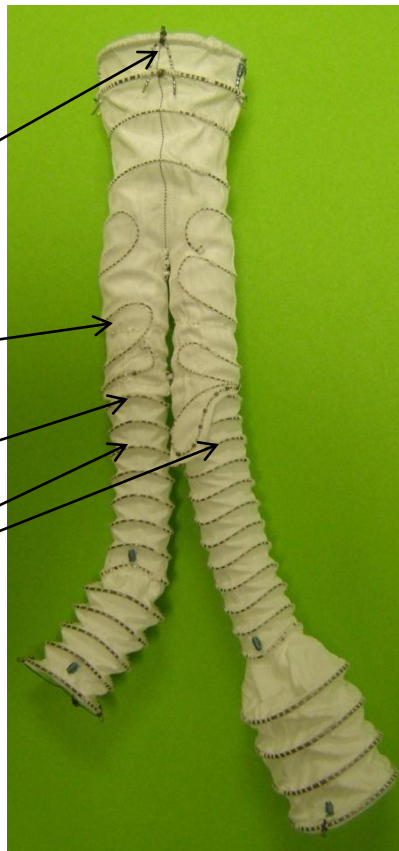
ONE-LOK™ Evolution

- 2 supported rings on the body

- Homolateral reinforced support

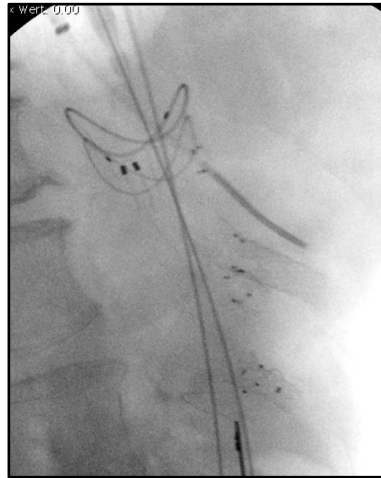
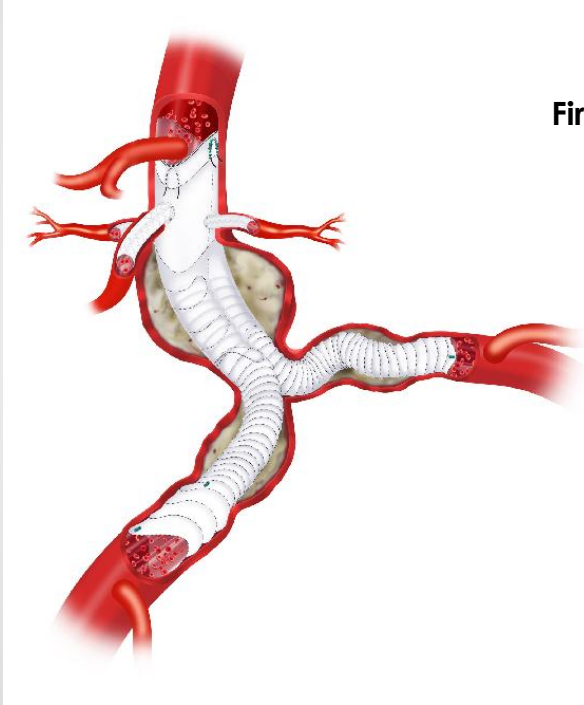
- Distal markers on homolateral access

- Universal connection (10.5mm)

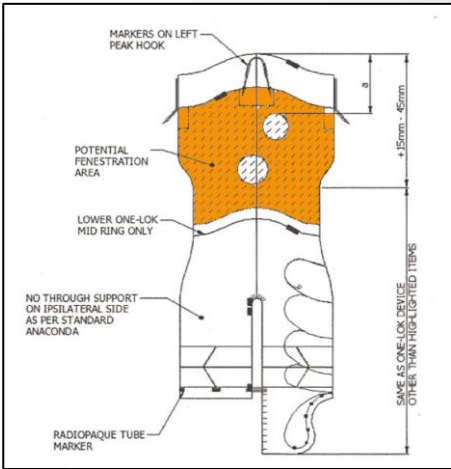
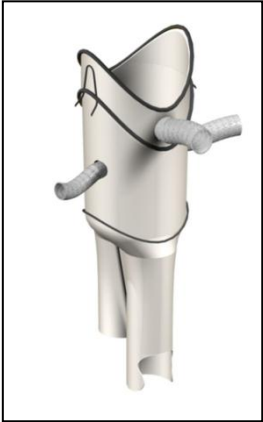
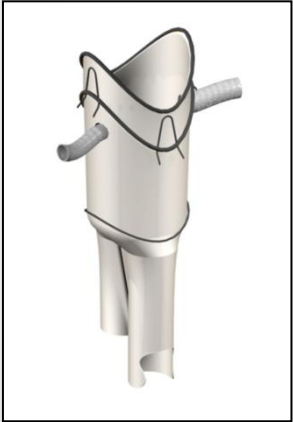


Fenestrated Evolution

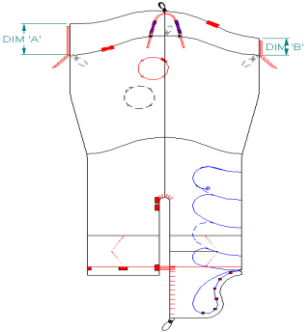
First implant – June 2010



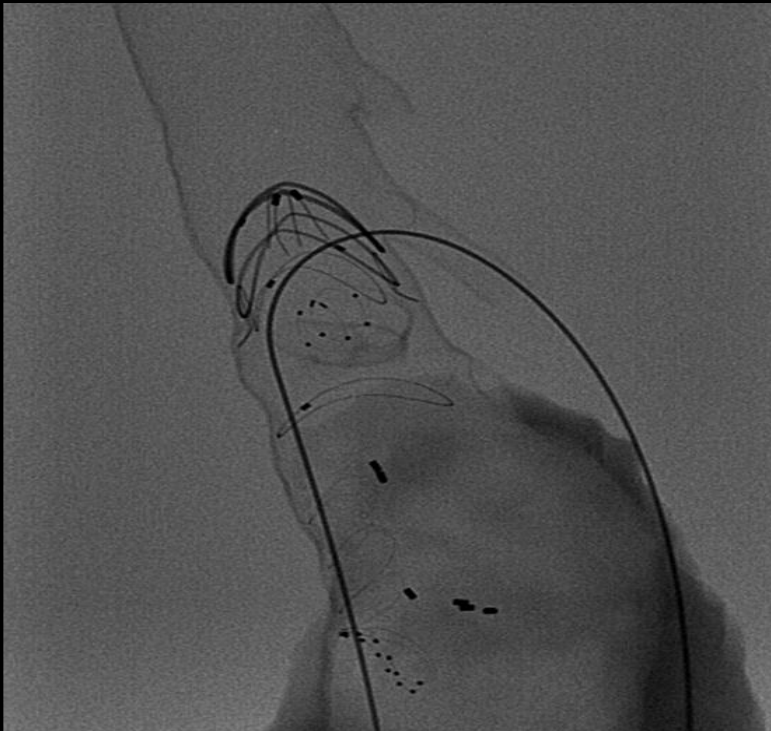
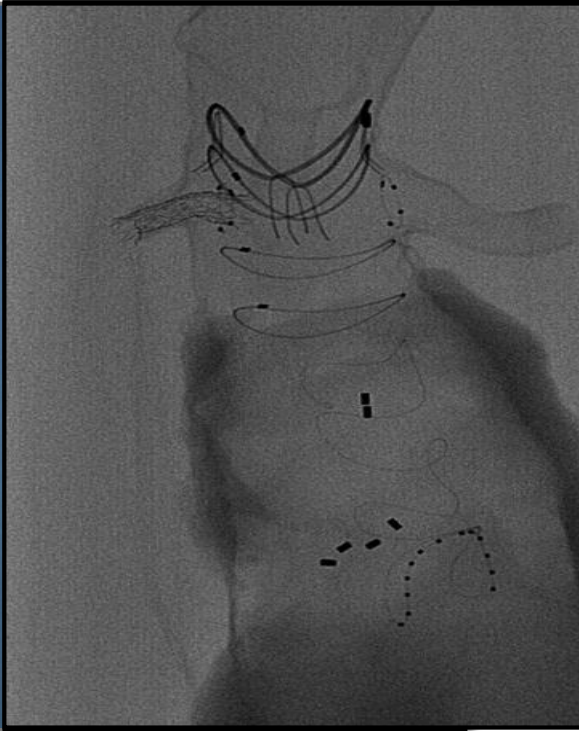
Fenestrated evolution



Totally "home made" fenestration area & number of windows



Flow model



Clinical results

ANACONDA

- Phase II FDA trial - 195 cases, 1 year
- European multicentre study - 61 cases, 5 years - Rödel SG et al. EurJ VascEndovascSurg. 2009
- Italian study - 127 cases, 4 years - Antonio Freyrie
- Italian registry - 983 cases, 3 years - Antonio Freyrie/Andrea Stella
- Vascutek PMS registry - 290 cases, 3 years
- Ring-stents supported infrarenal aortic endograft fits well in abdominal aneurysms with tortuous anatomy. Freyrie A et al Cardiovasc Surg 2010; 51:467-74.
- West of Scotland Anaconda registry - 106 cases – Majumder B Scottish Med J. 2012
- French cohorte - 150 cases, 3 years - Dominique Midy
- EPIANA French study - 180 cases - enrolling

FENESTRATED ANACONDA

- European registry – 190 cases, since 2 years
- Windows 3 study - 20 cases - enrolling

Clinical results

State of the Registry

Cases: 983

Males: 907 (92.3%)

Females: 76 (7.7%)

Mean age: 76.8 yrs (range 50 -94 yrs)

Preoperative Clinical Data

ASA	N° cases	%
2	154	15.6
3	732	74.4
4	97	9.8

Hypertension	81.9%
CPOD	53.1%
Coronary disease	42.7%
Renal insuff	13.2%
Diabetes	15.5%
Cerebro-vascular disease	11.2%
PAOD	18.1%

IntraOperative Data

Anesthesia:

local: 3.3%

loco-regional: 54.1%

general: 39.6%

Pre-implant iliac PTA/ stenting:

4.7%

PeriOperative Data

Intensive care	189 cases	19.2%
Mean hospitalization	4.6 days	
Post-implant fever ($> 38^{\circ}$)	194 cases	19.3%

Preoperative Morphological Data

AAA diameter: mean 55.2 mm (± 20.8)

Proximal aortic neck:

- mean length: 25.6 mm
- mean diameter: 23.8 mm
- severe angle ($>60^\circ$): 6.6%

Distal aortic diameter:

≤ 20 mm: 6.5%

Right/Left Iliac axes (1966):

severe proximal tortuosity: 1.5%

severe distal tortuosity: 4.1%

IntraOperative Data

Main Body repositioning:

All cases	21%
Neck length = 15 mm	32.3%
Neck length >15mm	17.4%

Chi-Square P=0.011

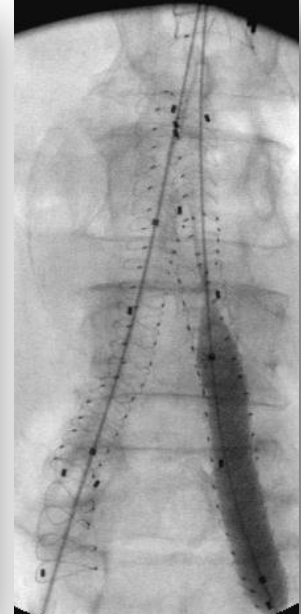
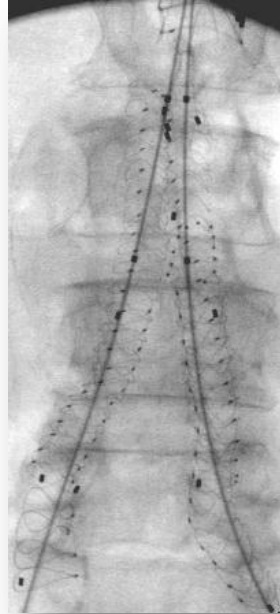
IntraOperative Data

Ballooning:

Main body: 11.1%

Docking zone: 23.8%

Iliac leg: 56.7%



IntraOperative Data

Adjunctive perioperative procedures

	%	N° cases
Proximal cuff	0,4%	4
Renal stenting		3
Endograft Stenting	2,3 %	23
Hypogastric embolization		12
Sac thrombization	4,7 %	46
Femoral EA		5
Fem-Fem bypass		2

PostOperative Data: 30 days

N. Cases (%)

Death	11 (1.1%)
Surgical Conversion	11 (1.1%)
Iliac leg thrombosis	16 (1.6%)
Native iliac artery thrombosis	8 (0.8%)

PostOperative Data: 30 days

Details of the 11 cases of 30-days deaths

case	Age (yrs)	ASA class	Post-op day of death	Surgical conversion	Cause of death
1	78	2	1	Yes	Iliac lesion
2	76	3	3	No	Cardiac arrest
3	72	3	1	Yes	Cardiac arrest
4	71	3	26	Yes	Multi-organ failure
5	85	3	2	No	Not reported
6	78	4	15	No	Intestinal infarction
7	72	4	16	No	Myocardial infarction
8	75	3	15	No	Septicemia
9	79	4	Not reported	No	Not reported
10	83	3	4	No	Coagulopathy
11	81	3	12	no	Multi-organ failure

PostOperative Data: 30 days

30-days death

	Cases	Death	%
Total	983	11	1.1
Successful implantation	972	8	0.8
Surgical conversion	11	3	27.2

Chi-Square $P < 0.001$

PostOperative Data: 30 days

Endoleaks	N Cases (%)
Type I	8 (0.8%)
Type II	103 (10.4%)
Type III	1 (0.1%)
Total	112 (11.3%)

Peri-operative data from randomized Trials and Registries

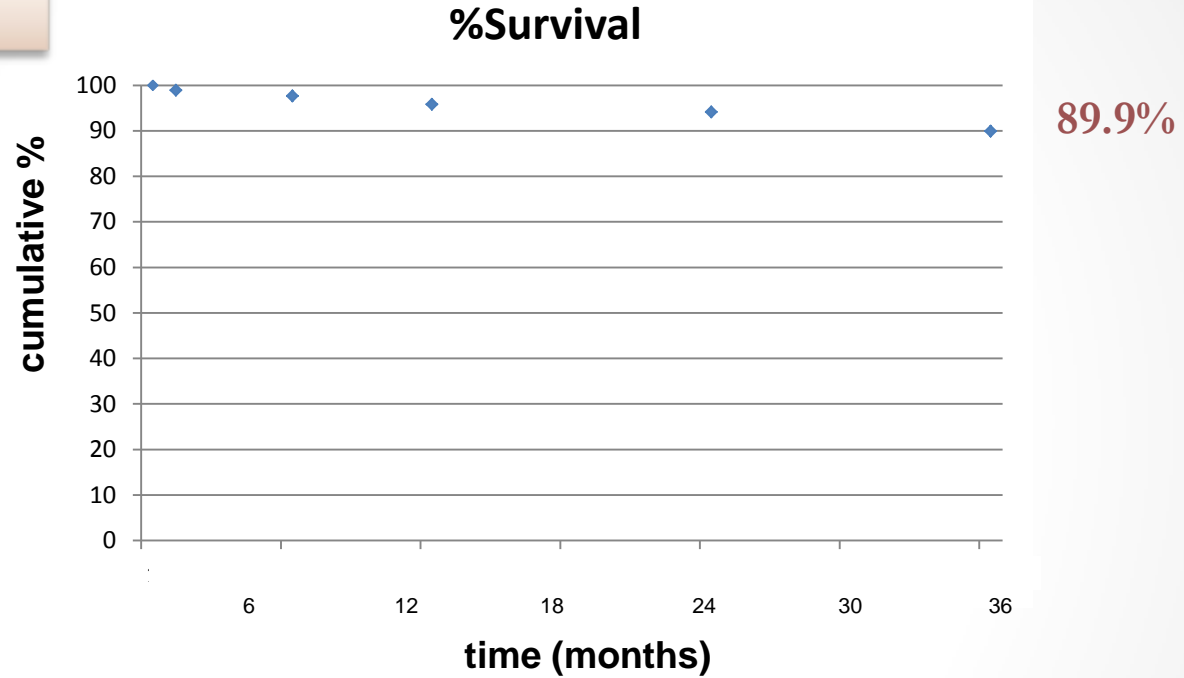
Study	EVAR cases	Mean age (yrs)	Mean AAA diameter (mm)	ASA \geq 3	30-days death	30-days conversion
Randomized Trials						
EVAR1(2004)	531	74.2	65	/	1.7 %	1.8 %
DREAM (2004)	171	70.7	60.6	8.2 %	1.2 %	1.8%
ACE (2011)	150	68.9	55.2	24 %	1.3 %	/
Registries						
EUROSTAR (2000)	2464	70.5	56.5	50.8 %	3.2 %	1.3 %
Anaconda Italian Registry (2012)	983	76.8	55.2	84.2 %	1.1%	1.1%

Follow-Up

Cases in follow-up

	<i>6 m</i>	<i>1 y</i>	<i>2 yrs</i>	<i>3 yrs</i>
cases	685	532	436	183
%	69.6	54.1	44.3	18.6

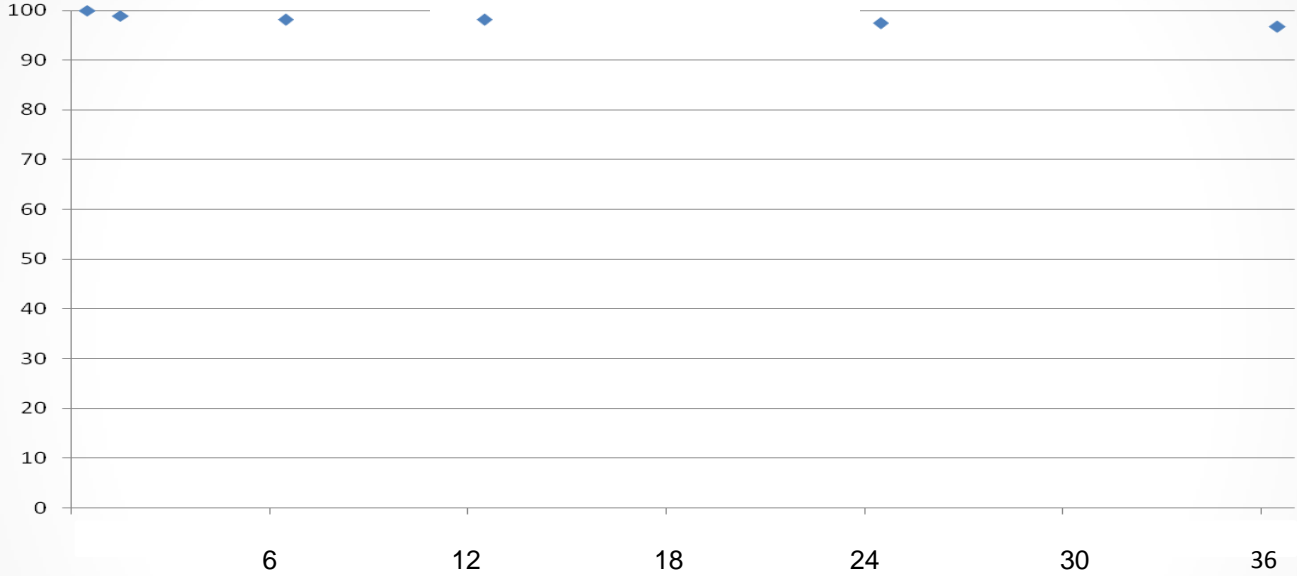
Survival



	1 month	6 months	12 months	24 months	36 months
Survival (%)	98.9	97.6	95.8	94.1	89.9
Patients at risk	964	685	532	436	183

Surgical Conversion

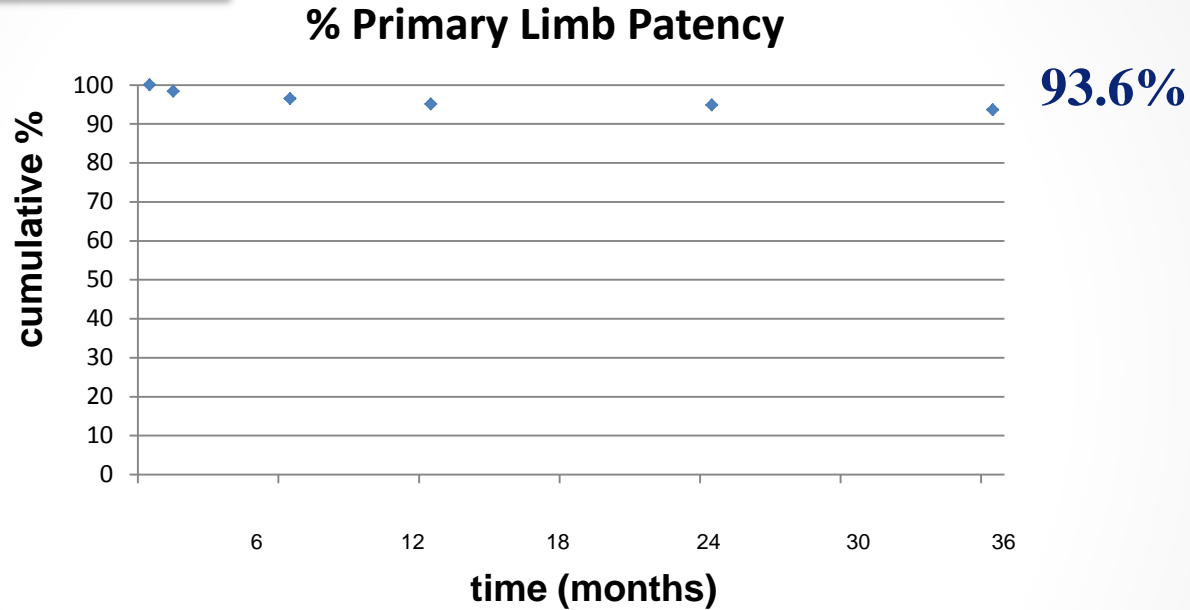
% Conversion free



96.7%

	1 month	6 months	12 months	24 months	36 months
Conversion free (%)	98.9	98.1	98.1	97.4	96.7
Patients at risk	964	685	532	436	183

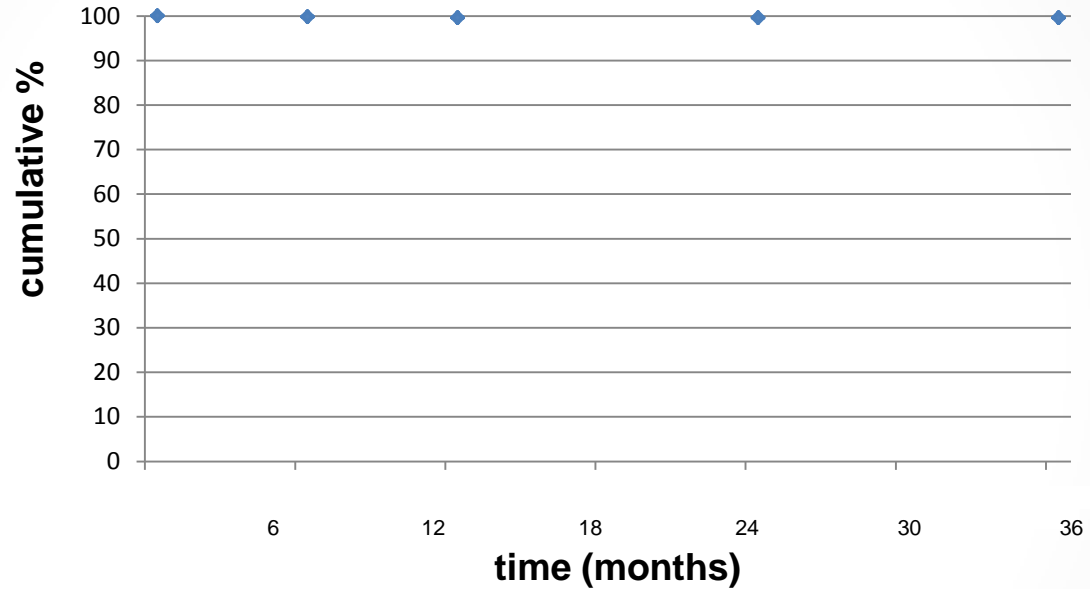
Primary Limb Patency



	1 month	6 months	12 months	24 months	36 months
Primary Limb Patency (%)	98.4	96.5	95.1	94.8	93.6
Patients at risk	964	685	532	436	183

Endograft migration

% Endograft migration free



	6 month	12 months	24 months	36 months
Endograft displacement (%)	99.8	99.6	99.6	99.6
Patients at risk	685	532	436	183

Follow-Up

Endoleaks

	<i>6 m</i> 685	<i>1 y</i> 532	<i>2 yrs</i> 436	<i>3 yrs</i> 183
Type I <i>(new cases)</i>	2 (0.3%)	2 (0.4%)	1 (0.2%)	2 (1.0%)
All Endoleaks	95 (13.8%)	57 (10.7%)	36 (8.2%)	23 (12.5%)

Follow-Up

AAA sac evolution

	<i>6 m</i> 685	<i>1 y</i> 532	<i>2 yrs</i> 436	<i>3 yrs</i> 183
Decreased	337 (49.1%)	340 (63.9%)	306 (70.1%)	138 (75.4%)
Increased	21 (3.0%)	19 (3.5%)	13 (2.9%)	7 (3.8%)

Conclusion



- Anaconda Endograft is a safe system to treat AAA.
- AAA with severe neck angulation can be treated by a ring-stent endograft with results similes of those with more favourable anatomy.
- Good mid-term results in terms of technical and clinical success.