2004 FDA Workshop Homework
AAA Pre-clinical Testing

General Information

Document Numbers (IDEs and PMAs):

Applicant:

Product Name:

Check components/configurations that apply:

Implant Components/Configurations	Yes	No
Unibody bifurcated		
Modular bifurcated		
Aorto-uniiliac		
Tubular		
Aortic extension		
Iliac extension		
Branch extension		
Occluder		
Converter/bailout		
Specify others:		

Description of Device(s)

Delivery System:

Attributes	Yes	No
Deployment Mechanism		
Retract sheath		
Push through sheath		
"Ripcord"		
Specify other:		
Specify range of french sizes:		

Implant:

Attributes	Implant		Accessory Implants		Additional Accessory Implants	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**
Stent Material						
Stainless steel						
Nitinol						
Elgiloy						
Specify other:						
Graft Material						
PET						
ePTFE						
Suture/Bonding Material						
ePTFE suture						
Polyester suture						
Polypropylene suture						
Specify other:						
Stent Configuration						
Z-stents						
Braided stent						
Connecting bar						
Specify other:						
Expansion Mechanism						
Self-expanding						
Balloon-expandable						
Stent Position						
Fully supported						
Proximal and distal only						
Internally located stents						
Externally located stents						
Imbedded stents						
Specify other:						
Fixation Mechanism						
Hooks						
Barbs						
Friction only						
Fixation Site						
Suprarenal						
Infrarenal						
Specify sealing mechanism:						
Specify range of implant diameters:						
Specify range of trunk lengths (i.e., bifurcation to top of graft material):						
Specify unique device features:						

Labeling

Guidelines		
Intended Use:	**Yes**	**No**
Isolated AAA		
Isolated iliac		
AAA with iliac involvement		
Specify minimum proximal neck length:		
Specify neck diameter range:		
Specify maximum proximal neck angulation:		
Specify other nondimensional anatomical restrictions:		

Clinical Study Description

Pivotal Study

Study Features		
Intended Use:	**Yes**	**No**
Isolated AAA		
Isolated iliac		
AAA with iliac involvement		
List three most important anatomical inclusion criteria: 1. 2. 3.		
List three most important anatomical exclusion criteria: 1. 2. 3.		
Specify minimum proximal neck length:		
Specify neck diameter range:		
Specify maximum proximal neck angulation:		
Specify number of patients enrolled:		

Clinical Study Results

Pivotal Study

Table 1: Patient Accountability

Follow-up interval	Patient follow-up # (%)				Patients with adequate imaging to assess the parameter # (%)				Events occurring before next visit # (%)			
	Eligible for visit	Followed	CT	X-ray	Size Increase	Endoleak	Migration	Fracture	Conversion	Death	LTF	Not due for next visit
Peri-operative												
30 day												
6 month												
1 year												
Additional years												

Table 2: Results (data from entire study duration, by follow-up interval of observation)

	Peri-operative (<30 days) # of patients (%)	Separate column for each interval (e.g., 30 days to 6 months, 6 months to 1 year, 1 to 2 years) # of patients (%)*	Total #(%)
Total number patients			
Technically successful implant			
Perioperative (<30 days)			
Conversion for device migration**			
Proximal			
Distal			
Component			
Endoleak			
Type I			
Type III			
Follow-up			
Aneurysm related death***			
Rupture			
Adverse events due to excessive radial force (e.g., neck dilatation)			
New endoleak			
Type I			
Type III			
Continuing endoleak			
Type I			
Type III			
Size increase****			
Migration requiring second intervention			
Proximal			
Distal			
Component			
Migration without intervention**			
Proximal			
Distal			
Component			
Loss of device integrity			
Graft wear			
Suture breaks			
Seam failure			

* For your denominator, use the number of patients with data available for assessment of the parameter.
** Defined as movement of $\pm$ 10 mm.
*** Defined as any death within 30 days of initial treatment, a rupture, a conversion, or any other secondary endovascular graft procedure, or any other device related death.
**** Defined as increase of $\geq$ 5 mm.

Table 3: Identified Fractures (pivotal study cohort from both radiographic and explant observations)

		Patients with fractures #(%)	Fractures identified (# months post-implant) #(%)								Total fractures
			0-3	3-6	6-12	12-24	24-36	36-48	48-60	60+	
Connecting bar only											
Stent only											
Both	Connecting bar										
	Stent										
Hook or barb											
Total											

Table 4: Use of Adjunctive Devices (data from pivotal study duration, by follow-up interval of observation)

	Number during initial implant procedure (# devices/ # patients)	Number used during secondary procedures (# months post-implant) # devices/# patients								Total
		0-3	3-6	6-12	12-24	24-36	36-48	48-60	60+	
Aortic extension										
Iliac extension										
Branch extension										
Occluder										
Converter/ bailout										
Stents within EVG										
Specify other:										

Explant Analyses

Please provide information from all human explants.

Table 5: Sources of Explanted Devices

	Number from surgical conversion	Number from post-mortem autopsy	Total
From IDE clinical study (all phases)			
From US commercial sales			
From OUS clinical studies			
From OUS commercial sales			
Total			

Figure 1: Histogram of Implant Duration in Months for Explanted Devices

Please construct a histogram similar to the one below.

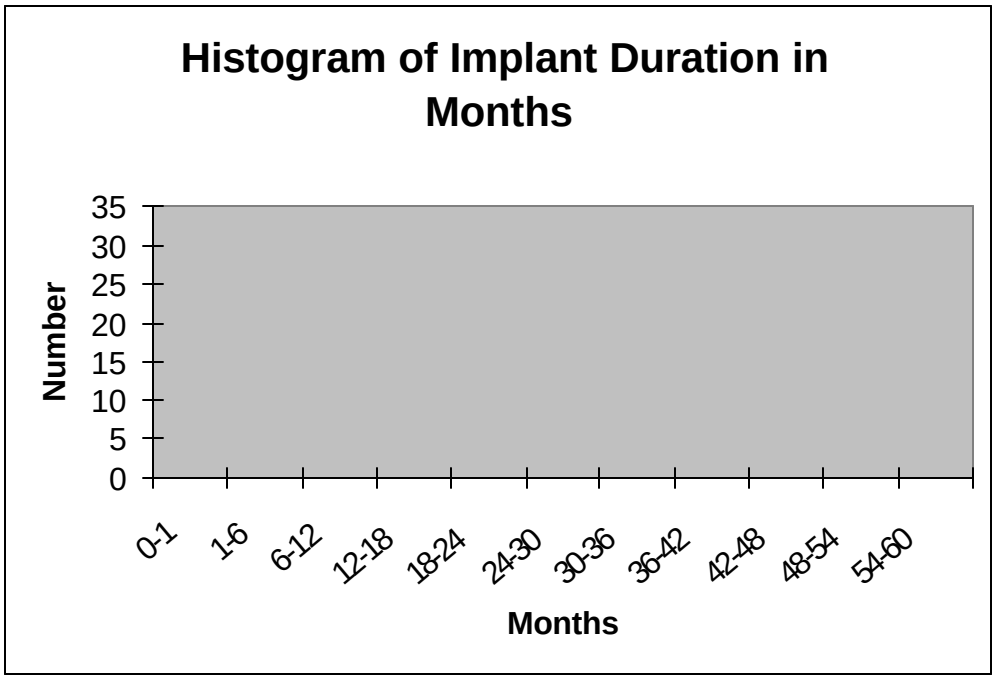

Table 6: Reasons for Explant

	Number of occurrences – implant duration less than or equal to 1 month	Number of occurrences – implant duration greater than 1 month	Total
Increase in AAA size			
Incidental autopsy			
Rupture			
Post implant			
At the time of implant			
Endoleak			
Type I			
Type III			
Component separation			
Implantation difficulties			
Limb occlusion			
Aortoenteric fistula			
Symptomatic AAA			
Infection			
Migration			
Disease progression			
Specify additional reasons:			

Table 7: Explant Observations

7a: Fractures														
	Number of Explants	Duration of Implantation (# months post-implant)												Total
		0-1	1-6	6-12	12-18	18-24	24-30	30-36	36-42	42-48	48-54	54-60	60+	
Connecting bar only														
Stent only														
Both: Connecting bar														
Both: Stent														
Hook or barb														
Total														

7b: Additional Observations														
	Number of Explants	Duration of Implantation (# months post-implant)												Total
		0-1	1-6	6-12	12-18	18-24	24-30	30-36	36-42	42-48	48-54	54-60	60+	
Graft material wear														
Suture breaks														
List additional anomalies														
Total														

Session 1 – Animal Studies: A Retrospective and Prospective Evaluation

Please provide **brief** preliminary answers to the following questions which form the basis for the objectives of this session:

1a. Describe animal studies previously conducted using the following tables:

Table 8: Summary of Animal Study

Please complete the following table for **each** animal study reported to FDA.

Study Features			
Purpose of studies and questions intended to be answered by study			
Animal species			
Sample size	Number of Animals	Number of Implants	
Test article(s)	Straight	Bifurcated	
Implantation site(s)	Aorta	Aorto-iliac	Iliac
Controls	Yes	No	
Interim sacrifice periods (e.g., 2 week, 1 month, 3 month)			
Follow-up duration			
Methods of assessment			
Results*			
Conclusions			

*Please state whether qualitative and/or quantitative analyses (e.g., morphometric analysis, inflammation and injury scoring, gross and histological measurements) were conducted. Identify any anomalies observed during explant analysis.

Table 9: Performance Attributes and Failure Modes Addressed

In the following table, please indicate whether the following were evaluated.

Attributes and Failure Modes	**Yes**	**No**
Delivery and deployment		
Corrosion		
Biological responses		
Patency		
Migration		
Proximal		
Distal		
Component		
Endoleak		
Type I		
Type III		
Rupture		
Adverse events due to excessive radial force (e.g., neck dilatation)		
Size increase		
Loss of device integrity		
Graft wear		
Suture breaks		
Seam failure		

1b. Describe what has not been adequately evaluated in animal studies using the following table:

Table 10: Clinical Failure Modes

Failure Modes	Observed in animal study		Observed in clinical study		Identify characteristics not addressed in animal study that may have been important in evaluating each failure mode
	Yes	No	Yes	No	
Migration					
Endoleak					
Rupture					
Excessive radial force					
Size increase					
Loss of device integrity					
Graft or suture					
Metallic components					
Specify other:					

1c. What are the additional limitations of current animal models (e.g., strong taper, size, configuration)?

Session 2 – Sealing and Fixation Effectiveness

Please provide **brief** preliminary answers to the following questions which form the basis for the objectives of this session:

2. Using the following table, identify preclinical testing conducted to evaluate sealing and fixation effectiveness:

Table 11: Summary of Preclinical Testing for Sealing and Fixation Effectiveness

	Testing Conducted	Potential Improvements
Simulated Use		
Purpose of test		
Attributes evaluated quantitatively		
Attributes evaluated qualitatively		
Description of model		
Pressure		
Flow		
Tortuosity/angulated neck		
Material of mock artery		
Fluid type, if any		
Pumping mechanism		
Did testing include cuffs and extenders?		
Acceptance criteria and justification		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		
Migration Resistance		
Description of model		
Pressure		
Flow		
Temperature		
Material of mock artery		
Configuration (e.g., straight, angulated)		
Rate of crosshead speed/rate of separation (mm/min)		
Oversizing		
Sample selection		
Length of junction or overlap		
Did testing include cuffs and extenders?		
Acceptance criteria and justification		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		
Pull Test for Modular Components		
Description of model		
Pressure		

Flow		
Temperature		
Material of mock artery		
Configuration (e.g., straight, angulated)		
Rate of crosshead speed/rate of separation (mm/min)		
Oversizing		
Sample selection		
Length of junction or overlap		
Did testing include cuffs and extenders?		
Acceptance criteria and justification		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		
Radial Force		
Description of model		
What method was chosen to test (e.g., from ISO Standard Annex D 5.3.15)		
Length of prosthesis in fixture		
Did testing include measurement under expansion?		
Did testing include measurement under compression?		
Acceptance criteria with justification		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		
Other Tests (e.g., computer simulation)		
Description of model		
Acceptance criteria with justification		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		

Session 3 – Device Integrity, Fatigue and Durability

Please provide **brief** preliminary answers to the following questions which form the basis for the objectives of this session:

3. Using the following table, identify preclinical testing conducted to evaluate device integrity, fatigue and durability.

Table 12: Summary of Preclinical Testing for Device Integrity, Fatigue and Durability

	Testing Conducted	Potential Improvements
Strength of Stent/Attachment System to Graft Bond		
Description of test		
Acceptance criteria and justification		
Did testing include cuffs and extenders?		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		
Corrosion		
Description of tests		
Acceptance criteria and justification		
What characteristics were not addressed (e.g., galvanic corrosion)?		
What failure modes seen clinically were not predicted in this test?		
Fatigue and Durability		
Failure modes intended to be evaluated		
Description of model		
Pressure		
Flow		
Temperature		
Material of mock artery		
Assumed compliance of abdominal aorta		
Compliance of mock artery		
Assumed compliance of abdominal aorta with graft in place		
Configuration (e.g., straight, angulated)		
Method of displacement measurement		
Amount of displacement		
Test frequency		
Oversizing		
Sample selection		
Length of junction or overlap		
Did testing include cuffs and extenders?		
Acceptance criteria and justification		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., fractures, suture breaks, wear)?		

Stress Strain/Analysis		
Description of model		
How were material properties established?		
Boundary conditions		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		
Other Tests (e.g., computer simulation)		
Description of model		
Acceptance criteria with justification		
What characteristics were not addressed (e.g., neck angulation, changes in morphology, tortuosity, atherosclerotic/diseased vessels)?		
What failure modes seen clinically were not predicted in this test (e.g., migration, separation of components)?		

Session 4 – Clinical and Preclinical Performance: Past, Present and Future

4a. Rank order the most challenging anatomical limitations in endovascular grafting in 2001 and 2004.

Table 13: Anatomical Limitations

Characteristic	2001	2004
Proximal neck angulation		
Proximal neck shape		
Proximal neck length		
Calcification in proximal neck		
Thrombus in proximal neck		
Calcification at distal attachment site		
Distal attachment site length		
Distal attachment site tortuosity		
Thrombus at distal attachment site		
Thrombus in aneurysm sack		
Access vessel size		
Access vessel morphology (e.g., calcification, tortuosity)		
Accessory renal arteries		
Narrow distal aorta		
Involvement of iliac artery (i.e., extent of iliac aneurysmal disease)		
Physician training		
Physician ego		
Specify other:		

4b. Rank order the most critical failure modes in 2001 and 2004.

Table 14: Critical Failure Modes

Failure Mode	2001	2004
Aneurysm rupture		
Type I endoleak		
Endotension		
Migration		
Stent fracture		
Graft wear holes		
Suture breaks		
Component separation		
Seam failure		
Limb occlusion		

4c. What do you think we have learned between 2001 and 2004?
4d. Has your testing strategy changed since 2001?
4e. Are you performing any new testing now that you weren't performing three years ago? Why? If no, why not?