Investigational device exemption G010002
Endovascular Exclusion of TAAA or AAA utilizing Fenestrated or Branched
Data analysis plan for annual FDA report

Written: 7 December 2005
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1. Definitions of image-related events

At each follow-up imaging visit (each value of FIMG:CPEVENT), each patient is classified as follows:

endoleak, any

yes if	on follow-up fenestrated imaging form, endoleak = yes (FIMG:ENDOYN = "YES")
no if	on follow-up fenestrated imaging form, endoleak = no (FIMG:ENDOYN = "NO")
missing otherwise	

endoleak, type I

yes if	on follow-up fenestrated imaging form, type I is checked (FIMG:ENDTYP1 = 1)
no if	on follow-up fenestrated imaging form, endoleak has been answered (FIMG:ENDOYN = "YES" or FIMG:ENDOYN = "NO") AND
	on follow-up fenestrated imaging form, type I is not checked (FIMG:ENDTYP1 = NULL)
missing otherwise	

endoleak, type II

yes if	on follow-up fenestrated imaging form, type II is checked (FIMG:ENDTYP2 = 1)
no if	on follow-up fenestrated imaging form, endoleak has been answered (FIMG:ENDOYN = "YES" or FIMG:ENDOYN = "NO") AND
	on follow-up fenestrated imaging form, type II is not checked (FIMG:ENDTYP2 = NULL)
missing otherwise	

endoleak, type III

yes if	on follow-up fenestrated imaging form, type III is checked (FIMG:ENDTYP3 = 1)
no if	on follow-up fenestrated imaging form, endoleak has been answered (FIMG:ENDOYN = “YES” or FIMG:ENDOYN = “NO”) AND
	on follow-up fenestrated imaging form, type III is not checked (FIMG:ENDTYP3 = NULL)
missing otherwise	

endoleak, type IV

yes if	on follow-up fenestrated imaging form, type IV is checked (FIMG:ENDTYP4 = 1)
no if	on follow-up fenestrated imaging form, endoleak has been answered (FIMG:ENDOYN = “YES” or FIMG:ENDOYN = “NO”) AND
	on follow-up fenestrated imaging form, type IV is not checked (FIMG:ENDTYP4 = NULL)
missing otherwise	

endoleak, unknown

yes if	on follow-up fenestrated imaging form, unknown is checked (FIMG:ENDTYP5 = 1)
no if	on follow-up fenestrated imaging form, endoleak has been answered (FIMG:ENDOYN = “YES” or FIMG:ENDOYN = “NO”) AND
	on follow-up fenestrated imaging form, unknown is not checked (FIMG:ENDTYP5 = NULL)
missing otherwise	

growth notation:

- A1_p = maximum aneurysm diameter major axis on follow-up fenestrated imaging form (FIMG:DIAMEA1) at pre-discharge visit

- A1_c = maximum aneurysm diameter major axis on follow-up fenestrated imaging form (FIMG:DIAMEA1) at current visit
- A2_p = maximum aneurysm diameter minor axis on follow-up fenestrated imaging form (FIMG:DIAMEA2) at pre-discharge visit
- A2_c = maximum aneurysm diameter minor axis on follow-up fenestrated imaging form (FIMG:DIAMEA2) at current visit

aneurysm growth (only defined for visits after pre-discharge [FIMG:CPEVENT = "PRE_DISCHARGE"])

yes if	A1_c – A1_p > 5 OR
	A2_c – A2_p > 5
no if	A1_c – A1_p ≤ 5 AND
	A2_c – A2_p ≤ 5
missing otherwise	

aneurysm shrinkage (only defined for visits after pre-discharge [FIMG:CPEVENT = "PRE_DISCHARGE"])

yes if	A1_c – A1_p < -5 OR
	A2_c – A2_p < -5
no if	A1_c – A1_p ≥ -5 AND
	A2_c – A2_p ≥ -5
missing otherwise	

aneurysm stasis (only defined for visits after pre-discharge [FIMG:CPEVENT = "PRE_DISCHARGE"])

yes if	aneurysm growth = no AND
	aneurysm shrinkage = no
no if	aneurysm growth = yes OR
	aneurysm shrinkage = yes
missing otherwise	

migration notation:
- M4_p = table position of uppermost proximal stent on follow-up fenestrated imaging form (FIMG:MIGTP4) at pre-discharge visit
- M4_c = table position of uppermost proximal stent on follow-up fenestrated imaging form (FIMG: MIGTP4) at current visit
- M5_p = table position of initial appearance of full circumference of stent on follow-up fenestrated imaging form (FIMG: MIGTP5) at pre-discharge visit
- M5_c = table position of initial appearance of full circumference of stent on follow-up fenestrated imaging form (FIMG: MIGTP5) at current visit
- M1_p = table position of SMA on follow-up fenestrated imaging form (FIMG: MIGTP1) at pre-discharge visit

- M1_c = table position of SMA on follow-up fenestrated imaging form (FIMG: MIGTP1) at current visit

migration (only defined for visits after pre-discharge [FIMG:CPEVENT = "PRE_DISCHARGE"])

yes if	$\lvert (M1\_c - M4\_c) - (M1\_p - M4\_p) \rvert > 10$ OR
	$\lvert (M1\_c - M5\_c) - (M1\_p - M5\_p) \rvert > 10$
no if	$\lvert (M1\_c - M4\_c) - (M1\_p - M4\_p) \rvert \leq 10$ AND
	$\lvert (M1\_c - M5\_c) - (M1\_p - M5\_p) \rvert \leq 10$
missing otherwise	

stent fracture

yes if	on follow-up fenestrated KUB form, proximal graft stent fracture = "YES" (FKUB:DISF1 = "YES") OR
	on follow-up fenestrated KUB form, distal graft stent fracture = "YES" (FKUB:DISF2 = "YES") OR
	on follow-up fenestrated KUB form, right iliac stent fracture = "YES" (FKUB:DISF3 = "YES") OR
	on follow-up fenestrated KUB form, left iliac stent fracture = "YES" (FKUB:DISF4 = "YES") OR
	on follow-up fenestrated KUB form, occluder stent fracture = "YES" (FKUB:DISF5 = "YES") OR
	on follow-up fenestrated KUB form, converter stent fracture = "YES" (FKUB:DISF6 = "YES") OR
	on follow-up fenestrated KUB form, right iliac leg extension stent fracture = "YES" (FKUB:DISF7 = "YES") OR
	on follow-up fenestrated KUB form, left iliac leg extension stent fracture = "YES" (FKUB:DISF8 = "YES") OR
	on follow-up fenestrated KUB form, main body extension stent fracture = "YES" (FKUB:DISF9 = "YES") OR
	on follow-up fenestrated KUB form, renal stent right stent fracture = "YES" (FKUB:DISF10 = "YES") OR
	on follow-up fenestrated KUB form, renal

	stent left stent fracture = “YES” (FKUB:DISF11 = “YES”) OR
	on follow-up fenestrated KUB form, other stent fracture = “YES” (FKUB:DISF12 = “YES”)
no if	on follow-up fenestrated KUB form, proximal graft stent fracture = “NO” or “N/A” (FKUB:DISF1 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, distal graft stent fracture = “NO” or “N/A” (FKUB:DISF2 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, right iliac stent fracture = “NO” or “N/A” (FKUB:DISF3 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, left iliac stent fracture = “NO” or “N/A” (FKUB:DISF4 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, occluder stent fracture = “NO” or “N/A” (FKUB:DISF5 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, converter stent fracture = “NO” or “N/A” (FKUB:DISF6 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, right iliac leg extension stent fracture = “NO” or “N/A” (FKUB:DISF7 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, left iliac leg extension stent fracture = “NO” or “N/A” (FKUB:DISF8 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, main body extension stent fracture = “NO” or “N/A” (FKUB:DISF9 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, renal stent right stent fracture = “NO” or “N/A” (FKUB:DISF10 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, renal stent left stent fracture = “NO” or “N/A” (FKUB:DISF11 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, other stent fracture = “NO” or “N/A” (FKUB:DISF12 = “NO” or “N/A”)
missing otherwise	

barb fracture

yes if	on follow-up fenestrated KUB form, barb bend is checked (FKUB:PFSNIN1 = 1) OR
	on follow-up fenestrated KUB form, proximal stent separation is checked (FKUB:PFSNIN3 = 1) OR
	on follow-up fenestrated KUB form, barb separation is checked (FKUB:PFSNIN2 = 1)
no if	on follow-up fenestrated KUB form, barb bend is not checked (FKUB:PFSNIN1 = NULL) AND
	on follow-up fenestrated KUB form, proximal stent separation is not checked (FKUB:PFSNIN3 = NULL) AND
	on follow-up fenestrated KUB form, barb separation is not checked (FKUB:PFSNIN2 = NULL)
missing otherwise	

component separation

yes if	on follow-up fenestrated KUB form, “Has component separation of the endovascular graft occurred?” = “YES” (FKUB:COMSYN = “YES”)
no if	on follow-up fenestrated KUB form, “Has component separation of the endovascular graft occurred?” = “NO” (FKUB:COMSYN = “NO”)
missing otherwise	

compression

yes if	on follow-up fenestrated KUB form, renal stent right compression = “YES” (FKUB:DEVCPR1 = “YES”) OR
	on follow-up fenestrated KUB form, renal stent left compression = “YES” (FKUB:DEVCPR2 = “YES”) OR
	on follow-up fenestrated KUB form, other stent compression = “YES” (FKUB:DEVCPR3 = “YES”)
no if	on follow-up fenestrated KUB form, renal

	stent right compression = “NO” or “N/A” (FKUB:DEVCPR1 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, renal stent left compression = “NO” or “N/A” (FKUB:DEVCPR2 = “NO” or “N/A”) AND
	on follow-up fenestrated KUB form, other stent compression = “NO” or “N/A” (FKUB:DEVCPR3 = “NO” or “N/A”)
missing otherwise	

occlusion, right iliac artery CIA

yes if	on follow-up fenestrated imaging form, right iliac artery patent CIA = “YES” (FIMG:PATCIA1 = “NO”)
no if	on follow-up fenestrated imaging form, right iliac artery patent CIA = “YES” (FIMG:PATCIA1 = “YES”)
missing otherwise	

occlusion, right iliac artery IIA

yes if	on follow-up fenestrated imaging form, right iliac artery patent IIA = “YES” (FIMG:PATIIA1 = “NO”)
no if	on follow-up fenestrated imaging form, right iliac artery patent IIA = “YES” (FIMG:PATIIA1 = “YES”)
missing otherwise	

occlusion, left iliac artery CIA

yes if	on follow-up fenestrated imaging form, left iliac artery patent CIA = “YES” (FIMG:PATCIA2 = “NO”)
no if	on follow-up fenestrated imaging form, left iliac artery patent CIA = “YES” (FIMG:PATCIA2 = “YES”)
missing otherwise	

occlusion, left iliac artery IIA

yes if	on follow-up fenestrated imaging form, left iliac artery patent IIA = “YES”

	(FIMG:PATIIA2 = “NO”)
no if	on follow-up fenestrated imaging form, left iliac artery patent IIA = “YES” (FIMG:PATIIA2 = “YES”)
missing otherwise	

occlusion, right renal

yes if	on follow-up fenestrated imaging form, right renal occluded is checked (FIMG:PATRRA = “OCCLUDED”)
no if	on follow-up fenestrated imaging form, right renal patent is checked (FIMG:PATRRA = “PATENT”)
missing otherwise	

occlusion, left renal

yes if	on follow-up fenestrated imaging form, left renal occluded is checked (FIMG:PATLRA = “OCCLUDED”)
no if	on follow-up fenestrated imaging form, left renal patent is checked (FIMG:PATLRA = “PATENT”)
missing otherwise	

occlusion, SMA

yes if	on follow-up fenestrated imaging form, SMA occluded is checked (FIMG:PATSMA = “OCCLUDED”)
no if	on follow-up fenestrated imaging form, SMA patent is checked (FIMG:PATSMA = “PATENT”)
missing otherwise	

occlusion, celiac

yes if	on follow-up fenestrated imaging form, celiac occluded is checked (FIMG:PATCEL = “OCCLUDED”)
no if	on follow-up fenestrated imaging form, celiac patent is checked (FIMG:PATCEL = “PATENT”)
missing otherwise	

2. Definitions of non-image-related events

At each follow-up visit (each value of FUP:CPEVENT) after the first follow-up visit, each patient is classified as follows:

creatinine notation:

- C_b = creatinine on subject history form (LABS:LABCRE)
- C_f = creatinine on follow-up form (FUP:LABCRE) at current visit
- C_p = creatinine on follow-up form (FUP:LABCRE) at previous visit

creatinine rise

yes if	$(C\_f - C\_b) / C\_b > 0.30$ AND
	$(C\_p - C\_b) / C\_b > 0.30$
no if	$(C\_f - C\_b) / C\_b \leq 0.30$ OR
	$(C\_p - C\_b) / C\_b \leq 0.30$
missing otherwise	

3. Summary reports for events

At selected visits, the following is reported for each event:

1. number of subjects with event = yes
2. (number of subjects with event = yes) + (number of subjects with event = no)

The selected visits are as follows:

- pre-discharge (FIMG/FUP:CPEVENT = “PRE_DISCHARGE”)
- 1 month (FIMG/FUP:CPEVENT = “1 MONTH FUP”)
- 6 months (FIMG/FUP:CPEVENT = “6 MONTH FUP”)
- 12 months (FIMG/FUP:CPEVENT = “12 MONTH FUP”)
- 24 months (FIMG/FUP:CPEVENT = “24 MONTH FUP”)
- 36 months (FIMG/FUP:CPEVENT = “3 YEAR FUP”)
- 48 months (FIMG/FUP:CPEVENT = “4 YEAR FUP”)
- other (FIMG/FUP:CPEVENT = “OTHER”)

4. Mortality

4.1. General

Each patient will have a follow-up time, defined as follows:

= months from initial procedure date (PRTH:PROCDT such that PRTH:PROTYP = "INIT IMPLANT") to death date (DTH:DTHDAT), if known to be dead
= months from initial procedure date (PRTH:PROCDT such that PRTH:PROTYP = "INIT IMPLANT") to last day of reporting period, if not known to be dead

A month will be defined as 30 days.

4.2. All-cause

All-cause mortality will be summarized in the following table:

	Follow-up time						
	1 month	6 months	12 months	24 months	36 months	48 months	60 months
Alive and in study[a]							
Dead to date[b]	before discharge:[e]						
	after discharge:[f]						
Censored to date[c]							
Survival probability[d]							

[a]Number of subjects whose follow-up times are greater than the time point.
[b]Number of subjects whose follow-up times are less than or equal to the time point and who are known to be dead.
[c]Number of subjects whose follow-up times are less than or equal to the time point and who are not known to be dead.
[d]The Kaplan-Meier estimate of the survival curve at the time point, with 95-percent confidence interval. The survival curve gives the probability of surviving past a given time.
[e]Number of subjects in this cell whose deaths occurred before discharge (PRTH:DSCHDT).
[f]Number of subjects in this cell whose deaths occurred after discharge (PRTH:DSCHDT).

4.3. AAA-related

Deaths will be classified as AAA-related based on the following definition:

yes if	death occurs within 30 days of any procedure (initial or secondary) OR
	on the death form, "procedure caused or contributed to death" = yes (DTH:DTCYNP = "YES" and DTH:DTHCTX = "PROCEDURE CAUSED OR CONTRIBUTED TO DEATH") OR
	on the death form, "device caused or contributed to death" = yes (DTH:DTCYNP = "YES" and DTH:DTHCTX = "DEVICE CAUSED OR CONTRIBUTED TO DEATH")
no if	death does not occur within 30 days of any procedure (initial or secondary) AND
	on the death form, "procedure caused or contributed to death" = no (DTH:DTCYNP = "NO" and DTH:DTHCTX = "PROCEDURE CAUSED OR CONTRIBUTED TO DEATH") AND
	on the death form, "device caused or contributed to death" = no (DTH:DTCYNP = "NO" and DTH:DTHCTX = "DEVICE CAUSED OR CONTRIBUTED TO DEATH")
missing otherwise	

AAA-related mortality will be summarized in the following table:

	Follow-up time						
	1 month	6 months	12 months	24 months	36 months	48 months	60 months
Alive and in study[a]							
Dead of AAA to date[b]	before discharge:[e]						
	after discharge:[f]						
Censored to date[c]							
Survival probability[d]							

[a]Number of subjects whose follow-up times are greater than the time point.
[b]Number of subjects whose follow-up times are less than or equal to the time point, who are known to be dead, and whose deaths are AAA-related.
[c]Number of subjects whose follow-up times are less than or equal to the time point and who are not known to be dead, are dead of a cause unrelated to AAA, or are dead of an unknown cause.
[d]The Kaplan-Meier estimate of the survival curve at the time point, with 95-percent confidence interval. The survival curve gives the probability of surviving past a given time.
[e]Number of subjects in this cell whose deaths occurred before initial discharge (PRTH:DSCHDT such that PRTH:PROTYP = “INIT IMPLANT”).
[f]Number of subjects in this cell whose deaths occurred after initial discharge (PRTH:DSCHDT such that PRTH:PROTYP = “INIT IMPLANT”).

5. Secondary interventions

Each patient will have a follow-up time, defined as follows:

= months from date of initial procedure (PRTH:PROCDT such that PRTH:PROTYP = "INIT IMPLANT") to date of first secondary intervention (PRTH:PROCDT such that PRTH:PROTYP = "ADD ENDO"), if any secondary interventions

= months from initial procedure date (PRTH:PROCDT such that PRTH:PROTYP = "INIT IMPLANT") to death date (DTH:DTHDAT), if no secondary interventions and known to be dead

= months from initial procedure date (PRTH:PROCDT such that PRTH:PROTYP = "INIT IMPLANT") to last day of reporting period, if no secondary interventions and not known to be dead

A month will be defined as 30 days.

Secondary interventions will be summarized in the following table:

	Follow-up time						
	1 month	6 months	12 months	24 months	36 months	48 months	60 months
Alive, in study, and free of secondary interventions[a]							
Has experienced at least one secondary intervention[b]							
Censored to date[c]							
Survival probability[d]							

[a]Number of subjects whose follow-up times are greater than the time point.
[b]Number of subjects whose follow-up times are less than or equal to the time point and who experienced at least one secondary intervention.
[c]Number of subjects whose follow-up times are less than or equal to the time point and and who have not experienced any secondary interventions.
[d]The Kaplan-Meier estimate of the survival curve at the time point, with 95-percent confidence interval. The survival curve gives the probability of surviving past a given time.

6. Validation

A random sample of approximately 5 percent of the subjects will be drawn, and these subjects' data will be audited. Auditing will consist of comparing the data on the remote data capture screens, which are considered source data, to the following derived data sets:

1. the web report "patient event report"
2. the web report "follow-up time for survival analysis"
3. the statistician's working mortality data sets
4. the statistician's working secondary intervention data sets

Auditing will be done by people uninvolved in producing the derived data sets.

7. Web reports

7.1. General

All reports are available in Excel or PDF format and can be limited in any of the following ways:

1. whether to exclude compassionate use cases (default: do not exclude)
    a. exclude (CLNO:COMPYN = "NO")
    b. do not exclude (all cases)
2. type of device (default: all subjects):
    a. fenestrated (PRTH:FORMTP1 = 1)
    b. visceral (PRTH:FORMTP2 = 1)
    c. hypogastric (PRTH:FORMTP3 = 1)
3. maximum subject number (default: all subjects)
4. maximum enrollment date (default: date on which the report is generated), which has the following effects:
    a. a subject can be included only if his procedure date (PRTH:PROCDT) is less than or equal to the maximum
    b. a follow-up form can be used only if the visit date (FIMG:APPTDT or FUP:EV_DT) is less than or equal to the maximum
    c. a subject can be counted as dead only if his death date (DTH:DTHDAT) is less than or equal to the maximum
    d. a secondary intervention can be counted only if the procedure date (PRTH:PROCDT) is less than or equal to the maximum
    e. the maximum is considered the last day of the reporting period in the definitions of follow-up time in sections 4 and 5

Events are reported at the following visits:

- pre-discharge (FIMG/FUP:CPEVENT = "PRE_DISCHARGE")
- 1 month (FIMG/FUP:CPEVENT = "1 MONTH FUP")
- 6 months (FIMG/FUP:CPEVENT = "6 MONTH FUP")
- 12 months (FIMG/FUP:CPEVENT = "12 MONTH FUP")
- 24 months (FIMG/FUP:CPEVENT = "24 MONTH FUP")
- 36 months (FIMG/FUP:CPEVENT = "3 YEAR FUP")
- 48 months (FIMG/FUP:CPEVENT = "4 YEAR FUP")
- other (FIMG/FUP:CPEVENT = "OTHER")

7.2. Events: Summary report

All events will be included in a single report, which will have one column for each visit and two rows for each event, as follows:

event		visit		
		pre-discharge	1-month	(etc.)
endoleak, any	number yes	#	#	
	number yes or no	#	#	
endoleak, type I	number yes	#	#	
	number yes or no	#	#	
(etc.)				

7.3. Events: Patient-level data set

Each event will have its own report, with one column for each visit and one row for each subject, as follows:

event = endoleak, any

patient	visit		
	pre-discharge	1-month	(etc.)
1	0/1/missing	0/1/ missing	
2	0/1/ missing	0/1/ missing	
(etc.)			

event = endoleak, type I

patient	visit		
	pre-discharge	1-month	(etc.)
1	0/1/ missing	0/1/ missing	
2	0/1/ missing	0/1/ missing	
(etc.)			

(etc.)

7.4. Mortality and secondary interventions

The summary reports will consist of the tables described in sections 4 and 5. The patient-level reports will have one row for each subject and the following columns:

Mortality:

1. study ID (CLNO:PT)
2. Cleveland Clinic ID (CLNO:CLINNO)
3. procedure date (PRTH:PROCDT)
4. discharge date (PRTH:DSCHDAT)
5. date of end of follow-up period, as defined in section 4.1
6. length of follow-up period in months, as defined in section 4.1
7. indicator of whether subject is dead (0 = no, 1 = yes)
8. indicator of whether death is AAA-related, as defined in section 4.3 (0 = no, 1 = yes, NULL = not dead)

Secondary interventions:

1. study ID (CLNO:PT)
2. Cleveland Clinic ID (CLNO:CLINNO)
3. procedure date (PRTH:PROCDT)
4. discharge date (PRTH:DSCHDAT)
5. date of end of follow-up period, as defined in section 5
6. length of follow-up period in months, as defined in section 5
7. indicator of whether subject has had at least one secondary intervention (0 = no, 1 = yes)