

F378: Final Status, version 02/05/09 (A)

SECTION A: GENERAL STUDY INFORMATION

A1. Study ID#: A2. Date Form Completed: ____ / ____ / ____
 Month Day Year

A3. Initials of Person Completing this Form: ____ A4. Patient's Last Study Visit: ____

LAST_VISIT	Frequency	Percent	Cum Freq	Cum Percent
ET36	21	5.20	21	5.20
ET48	46	11.39	67	16.58
ET60	174	43.07	241	59.65
ET72	124	30.69	365	90.35
ET84	27	6.68	392	97.03
ETOM	12	2.97	404	100.00

SECTION B: FINAL STUDY STATUS

B1. What was the patient's final study status?

Completed study 1 →Skip to B5

Lost to follow-up..... 2 →Skip to B2

Withdrew consent 3 →Skip to B3

Administrative decision 4 →Skip to B1a

Death..... 5 → Skip to B5 & Complete Death Form

Other 6 ↓

FINAL_STATUS_cat	Frequency	Percent	Cum Freq	Cum Percent
1: Completed study	292	72.28	292	72.28
2: Lost to follow-up	61	15.10	353	87.38
3: Withdrew consent/4: Administrative Decision/5: Death	51	12.62	404	100.00

B1a. Specify **administrative decision** or **other**: _____ →Skip to B4

B2. For patient **lost to follow-up**, date last study data collected: ____ / ____ / ____
 Month Day Year

Analysis Variable : rando_dt_LOST_D								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
61	343	-1416	415.9	-2270	-1540	-1468	-1097	-723.0

B2a. Document follow-up efforts below:

- i. _____
- ii. _____
- iii. _____

→ Skip to B5

B3. For patient who **withdrew consent**, date consent withdrawn:

____ / ____ / ____
Month Day Year

Analysis Variable : rando_dt_CONS_WDRAW									
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
16	388	-1742	340.5	-2248	-1903	-1807	-1502	-1111	

B3a. Date last study data collected:

____ / ____ / ____
Month Day Year

→ Skip to B5

Analysis Variable : rando_dt_WDRAW_D									
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
16	388	-1329	321.2	-1836	-1498	-1479	-1101	-730.0	

B4. For **administrative decision** or **other**, date last study data collected:

____ / ____ / ____
Month Day Year

→ Skip to B5

Analysis Variable : rando_dt_ADMIN_D									
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
34	370	-1653	193.4	-1943	-1845	-1602	-1470	-1375	

B5. Additional Comments: _____

 _____ → If B1=1, Skip to Section C

B6. Did the patient receive any new or continuing treatment for **voiding dysfunction**, **vaginal prolapse**, **urge incontinence** or **stress incontinence** since the last study visit for which data was collected?

YES 1 → COMPLETE F398

NO 2

CONT_TREAT	Frequency	Percent	Cum Freq	Cum Percent
.	292	.	.	.
1: Yes	1	0.89	1	0.89
2: No	111	99.11	112	100.00

Frequency Missing = 292

SECTION C: PRINCIPAL INVESTIGATOR'S SIGNATURE

I have reviewed and agree with the above-stated information.

Principal Investigator's Signature: _____ Date: _____ / _____ / _____
Month Day Year

Analysis Variable : rando_dt_PI_SIG_D								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
404	0	-2038	276.9	-2599	-2218	-2022	-1841	-1088