

**Section A: General Study Information for Office Use Only:**

**A1. Study ID#:**

LABEL

**A3. Date Form Completed:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

**A5. Is this Treatment Failure associated with a study visit?**

YES .....1 NO .....2 **→SKIP TO A7**

FAIL_ASSOC	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	428	97.72	428	97.72
2	10	2.28	438	100.00

**A7. Is this Treatment Failure occurring prior to the 6 Month visit?**

YES .....1 NO .....2 **→GO TO B1**

**A2. Visit:** FAILURE..... FAIL

**A4. Initials of Person Completing this Form:** \_\_\_\_\_

**A6. With which visit is this failure associated?**

F/U 2 WEEKS ..... TF2W      F/U 12 MONTHS ..... TF12  
 F/U 6 WEEKS ..... TF6W      F/U 24 MONTHS ..... TF24  
 F/U 6 MONTHS ..... TF06      **→GO TO B1**

**A6.**

FAIL_VISIT	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
-2	10	2.28	10	2.28
TF06	210	47.95	220	50.23
TF12	106	24.20	326	74.43
TF24	105	23.97	431	98.40
TF2W	2	0.46	433	98.86
TF6W	5	1.14	438	100.00

**A7.**

PRIOR_06	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
-2	428	97.72	428	97.72
1	3	0.68	431	98.40
2	7	1.60	438	100.00

**SECTION B: TREATMENT FAILURE**

Document any “**first**” failures by type below. Circle yes or no for each answer:

**YES**

**NO**

B1. Positive Stress Test.....

1↓

2

B1a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

ST_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	128	29.22	128	29.22
2	310	70.78	438	100.00

Analysis Variable : sf_days (Failure date since randomization)									
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
128	0	344.0	222.9	118.0	183.0	214.0	412.0	789.0	

B2. Self-reported stress-type UI symptoms [MESA].....

1↓

2

B2a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

MESA_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	197	44.98	197	44.98
2	241	55.02	438	100.00

Analysis Variable : mef_days (Failure date since randomization)									
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
197	0	374.8	233.8	120.0	184.0	243.0	514.0	922.0	

B3. Positive Pad Test.....

1↓

2

B3a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

PAD_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	56	12.79	56	12.79
2	382	87.21	438	100.00

Analysis Variable : pad_days (Failure date since randomization)									
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
56	0	364.0	224.3	152.0	198.0	249.0	412.0	994.0	

B4. Self-reported leakage by the 3-day Voiding Diary ..... 1↓ 2

B4a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year

VD_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	242	55.25	242	55.25
2	196	44.75	438	100.00

Analysis Variable : vf_days (Failure date since randomization)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
242	0	316.1	203.1	101.0	180.0	210.0	380.0	993.0

B5. Surgical retreatment for SUI ..... 1↓ 2

B5a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year

SURG_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	21	4.79	21	4.79
2	417	95.21	438	100.00

Analysis Variable : suf_days (Failure date since randomization)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
21	0	270.2	126.3	50.0	188.0	263.0	325.0	513.0

B6. Pharmacologic treatment for SUI ..... 1↓ 2

B6a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year

MED_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	3	0.68	3	0.68
2	435	99.32	438	100.00

Analysis Variable : mf_days (Failure date since randomization)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
3	0	294.0	279.0	44.0	44.0	243.0	595.0	595.0

B7. Behavioral treatment for SUI ..... 1↓ 2

B7a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year

BEHAV_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	10	2.28	10	2.28
2	428	97.72	438	100.00

Analysis Variable : bf_days (Failure date since randomization)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
10	0	239.6	193.0	14.0	62.0	194.0	394.0	583.0

B8. Device treatment for SUI..... 1↓ 2

B8a. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year

DEVICE_FAIL	Frequency	Percent	Cum Freq	Cum Percent
.	289	.	.	.
1	4	0.91	4	0.91
2	434	99.09	438	100.00

Analysis Variable : df_days (Failure date since randomization)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
4	0	88.0	85.8	16.0	27.0	64.0	149.0	208.0

B9. Other treatment for SUI..... 1↓ 2

B9a. Specify: \_\_\_\_\_ ↓

B9b. Date of Failure: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year

**Because the frequency of at least one category is very low, the variable was not included in the dataset**

*I have reviewed the above-stated information and am confirming its accuracy with my signature below.*

Principal Investigator's Signature: \_\_\_\_\_ Initials: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year