



TOMUS

F380: Final Status, version 12/11/06 (B)

Section A: General Study Information for Office Use Only:

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

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

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 | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| 1 | 493 | 82.58 | 493 | 82.58 |
| 2 | 53 | 8.88 | 546 | 91.46 |
| 3 | 33 | 5.53 | 579 | 96.98 |
| 4 | 1 | 0.17 | 580 | 97.15 |
| 5 | 5 | 0.84 | 585 | 97.99 |
| 6 | 12 | 2.01 | 597 | 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 : lost_days (Days from randomization) | | | | | | | | |
|---|--------|-------|-------|---------|----------------|--------|----------------|---------|
| N | N Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 53 | 0 | 293.7 | 212.4 | 17.0 | 64.0 | 340.0 | 416.0 | 905.0 |

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 For patient who **withdrew consent**, date consent withdrawn: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 : cw_days (Days from randomization) | | | | | | | | |
|---|--------|-------|-------|---------|----------------|--------|----------------|---------|
| N | N Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 33 | 0 | 560.8 | 236.0 | 160.0 | 302.0 | 695.0 | 751.0 | 933.0 |

B3a. Date last study data collected:

____/____/____
Month Day Year

➔Skip to B5

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

____/____/____
Month Day Year

➔Skip to B5

| Analysis Variable : adm_days (Days from randomization) | | | | | | | | |
|--|--------|-------|------|---------|----------------|--------|----------------|---------|
| N | N Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 13 | 0 | 357.2 | 91.3 | 155.0 | 354.0 | 374.0 | 407.0 | 478.0 |

B5. Additional Comments: _____

 _____ **→If A4=TBAS or B1=1, skip to Section C**

B6. For randomized patients, 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 F381**

NO..... 2

| CONT_TREAT | Frequency | Percent | Cum Freq | Cum Percent |
|------------|-----------|---------|----------|-------------|
| . | 1 | . | . | . |
| -2 | 493 | 82.72 | 493 | 82.72 |
| 1 | 2 | 0.34 | 495 | 83.05 |
| 2 | 101 | 16.95 | 596 | 100.00 |

SECTION C: PRINCIPAL INVESTIGATOR'S SIGNATURE

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

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