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

UITN TOMUS

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

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 ⬇

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

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

B2a. Document follow-up efforts below:

i. _____

ii. _____

iii. _____ ➔**Skip to B5**

B3. For patient who **withdrew consent**, date consent withdrawn: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B3a. Date last study data collected: ___ ___ / ___ ___ / ___ ___ ___ ___ ➔**Skip to B5**
Month Day Year

B4. For **administrative decision** or **other**, date last study data collected: ___ ___ / ___ ___ / ___ ___ ___ ___ ➔**Skip to B5**
Month Day Year

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

SECTION C: PRINCIPAL INVESTIGATOR'S SIGNATURE

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

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