



Section A: General Study Information for Office Use Only:

| | |
|--|--|
| <p>A1. Study ID#: <input type="text" value="Label"/></p> <p>A3. Initials of Person Completing this Form: _____</p> | <p>A2. Date Form Completed: ____/____/____ Month Day Year</p> <p>A4. Patient's Last Study Visit: _____</p> |
|--|--|

SECTION B: Patient Symptoms and Treatments

B1. Based upon a review of all source documents ...

Since the last study visit for which data was collected, did the patient receive any new or continuing treatment for voiding dysfunction?

[Voiding dysfunction is defined as using a catheter to facilitate bladder emptying OR is undergoing medical or surgical therapy to facilitate bladder emptying.]

Yes..... 1 No..... 2 → **SKIP TO B2**

B1a. Circle yes or no for all **treatments received** by the patient for **voiding dysfunction** since the last study visit:

| YES | NO |
|-----|----|
|-----|----|

- i. Any catheter use..... 1 2
- ii. Urethral dilation..... 1↓ 2
 - a. Specify date: ____/____/____
Month Day Year
- iii. Tape loosening..... 1↓ 2
 - a. Specify date: ____/____/____
Month Day Year
- iv. Tape incision..... 1↓ 2
 - a. Specify date: ____/____/____
Month Day Year
- v. Urethrolysis and tape take-down..... 1↓ 2
 - a. Specify date: ____/____/____
Month Day Year
- vi. Medication 1 2
- vii. Other 1↓ 2
 - a. Specify: _____
 - b. Specify date: ____/____/____
Month Day Year

B1b. What was the date of the **first treatment of any kind** for **voiding dysfunction** since the patient's TOMUS surgery?
 ____/____/____
 Month Day Year

B2. Based upon a review of all source documents...

Since the last study visit for which data was collected, is there new or continuing evidence of vaginal prolapse?

Yes..... 1 No 2

B2a. Did the patient receive any new or continuing treatment for vaginal prolapse since the last study visit?

Yes..... 1 No 2 -> SKIP TO B3

B2b. Circle yes or no for all treatments received by the patient for vaginal prolapse since the last study visit:

| YES | NO |
|-----|----|
|-----|----|

- i. Anterior repair..... 1↓ 2
 - a. Specify date: ___ / ___ / ___
Month Day Year
- ii. Posterior repair..... 1↓ 2
 - a. Specify date: ___ / ___ / ___
Month Day Year
- iii. Enterocele repair..... 1↓ 2
 - a. Specify date: ___ / ___ / ___
Month Day Year
- iv. Vaginal vault suspension..... 1↓ 2
 - a. Specify date: ___ / ___ / ___
Month Day Year
- v. Pessary..... 1↓ 2
 - a. Specify date: ___ / ___ / ___
Month Day Year
- vi. Other..... 1↓ 2
 - a. Specify: _____
 - b. Specify date: ___ / ___ / ___
Month Day Year

B2c. What was the date of the first treatment of any kind for vaginal prolapse since the patient's TOMUS surgery?

___ / ___ / ___
Month Day Year

B3. Based upon a review of all source documents...

Since the last study visit for which data was collected, is there evidence of new or continuing urge incontinence?

Yes 1 No 2 → SKIP TO B4

B3a. Did the patient have urge incontinence symptoms prior to TOMUS surgery? (REVIEW SECTION D ON F301)

Yes (meets definition of persistent urge UI)..... 1 → SKIP TO B4

No 2

B3b. Did the patient receive any treatment for urge incontinence prior to TOMUS surgery? (REVIEW QUESTION C9 ON F302 AND QUESTION B2 ON F303)

Yes (meets definition of persistent urge UI)..... 1

No (meets definition of de novo urge UI)..... 2

B4. Did the patient receive any new or continuing treatment for urge incontinence since the last study visit?

Yes..... 1 No 2 → SKIP TO B5

B4a. Circle yes or no for all treatments received by the patient for urge incontinence since the last study visit:

| YES | NO |
|-----|----|
|-----|----|

i. Medication 1 2

ii. Pelvic Muscle Rehabilitation 1↓ 2

a. Specify date: ___/___/___
Month Day Year

iii. Behavioral Training 1↓ 2

a. Specify date: ___/___/___
Month Day Year

iv. Biofeedback 1↓ 2

a. Specify date: ___/___/___
Month Day Year

v. Other 1↓ 2

a. Specify: _____

b. Specify date: ___/___/___
Month Day Year

B4b. What was the date of the first treatment of any kind for urge incontinence since the patient's TOMUS surgery?

___/___/___
Month Day Year

B5. Based upon a review of all source documents....

Since the last study visit for which data was collected, is there new or continuing evidence of recurrent stress urinary incontinence (SUI)?

Yes 1 No 2

B5a. Did the patient receive any new or continuing treatment for recurrent SUI since the last study visit?

YES..... 1 → TREATMENT FAILURE: COMPLETE FAILURE PROTOCOL

NO 2 → SKIP TO SECTION C

B5b. Circle yes or no for all treatments received by the patient for recurrent SUI since the last study visit:

YES NO

- i. Burch colposuspension..... 1↓ 2
 - a. Specify date: ___/___/___
Month Day Year
- ii. Sling procedure 1↓ 2
 - a. Specify date: ___/___/___
Month Day Year
- iii. Tightening of previous sling..... 1↓ 2
 - a. Specify date: ___/___/___
Month Day Year
 - Additional dates: ___/___/___
Month Day Year
 - ___/___/___
Month Day Year
- iv. Needle suspension (Raz, Pereyra, Stamey, Gittes, etc.)..... 1↓ 2
 - a. Specify date: ___/___/___
Month Day Year
 - Additional dates: ___/___/___
Month Day Year
 - ___/___/___
Month Day Year
- v. Suburethral plication 1↓ 2
 - a. Specify date: ___/___/___
Month Day Year
 - Additional dates: ___/___/___
Month Day Year
 - ___/___/___
Month Day Year
- vi. Periurethral bulking agent injection 1↓ 2
 - a. Specify date: ___/___/___
Month Day Year
 - Additional dates: ___/___/___
Month Day Year
 - ___/___/___
Month Day Year

- vii. Other surgical treatment 1↓ 2
- a. Specify: _____
- b. Specify date: ____ / ____ / ____
 Month Day Year
- Additional dates: ____ / ____ / ____
 Month Day Year
- ____ / ____ / ____
 Month Day Year
- viii. Alpha-agonists 1↓ 2
- a. Specify date: ____ / ____ / ____
 Month Day Year
- ix. Other pharmacologic treatment..... 1↓ 2
- a. Specify: _____
- b. Specify date: ____ / ____ / ____
 Month Day Year
- x. Pelvic muscle rehabilitation (with or without biofeedback) 1↓ 2
- a. Specify date: ____ / ____ / ____
 Month Day Year
- xi. Device insertion, such as vaginal cone, pessary, urethral plug, patch 1↓ 2
- a. Specify: _____
- b. Specify date: ____ / ____ / ____
 Month Day Year
- Additional dates: ____ / ____ / ____
 Month Day Year
- ____ / ____ / ____
 Month Day Year
- xii. Any other treatment 1↓ 2
- a. Specify: _____
- b. Specify date: ____ / ____ / ____
 Month Day Year

B5c. What was the date of the first treatment of any kind for **recurrent SUI**? ____ / ____ / ____
 Month Day Year

SECTION C: SURGEON'S SIGNATURE

Surgeon's Signature: _____ Date: ____ / ____ / ____
 Month Day Year