

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY

A1. Study ID#: Label	A2. Date Form Completed: ____/____/____ <div style="text-align: center; font-size: small;">Month Day Year</div>
A3. Study Staff Initials: ____	A4. Patient's Last Study Visit: ____

SECTION B: TREATMENT FOR VOIDING DYSFUNCTION, URGE UI AND STRESS UI

B1. Based upon a review of all source documents (including medical records) and Data Forms...
 Did the patient receive any new or continuing treatment for **voiding dysfunction** since the last study data collection?
 (NOTE: At 3 month contact, this refers to all data obtained since surgery/treatment visit. At the 12 month visit, this refers to all data obtained since the 3 month contact).

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 data collection:

	Yes	No
i. Any catheter use	1 ↓	2
a. Specify date catheter last used: ____/____/____ <div style="text-align: center; font-size: x-small;">Month Day Year</div>		
ii. Urethral dilation.....	1 ↓	2
a. Specify date: ____/____/____ <div style="text-align: center; font-size: x-small;">Month Day Year</div>		
iii. Tape loosening.....	1 ↓	2
a. Specify date: ____/____/____ <div style="text-align: center; font-size: x-small;">Month Day Year</div>		
iv. Tape incision.....	1 ↓	2
a. Specify date: ____/____/____ <div style="text-align: center; font-size: x-small;">Month Day Year</div>		
v. Urethrolysis and tape take-down	1 ↓	2
a. Specify date: ____/____/____ <div style="text-align: center; font-size: x-small;">Month Day Year</div>		
vi. Medication.....	1 ↓	2
a. Specify date medicine last used: ____/____/____ <div style="text-align: center; font-size: x-small;">Month Day Year</div>		
vii. Other	1 ↓	2
a. Specify: _____		
b. Specify date: ____/____/____ <div style="text-align: center; font-size: x-small;">Month Day Year</div>		

REMINDER: F591 AE Form and Documentation in Section D of this Form required if condition meets definition of voiding dysfunction AE, as follows:

- Voiding Dysfunction (no time limit for reporting): Defined as a complication if one of the following criteria are met:
- Uses a catheter to facilitate bladder emptying at or beyond 6 weeks post-surgery OR
 - Has undergone medical therapy to facilitate bladder emptying at or beyond 6 weeks post-surgery OR
 - Has undergone surgical therapy to facilitate bladder emptying at anytime after study/index surgery.

B2. Based upon a review of all source documents (including medical records) and Data Forms...
Is there evidence of new or continuing **urge incontinence** since the last study data collection?
Yes..... 1 No 2

B3. Did the patient receive any new or continuing treatment for **urge incontinence** since the last study data collection?
Yes 1 No 2 → **SKIP TO B4**

B3a. Circle yes or no for all treatments received by the patient for **urge incontinence** since the last study data collection:

Yes	No
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- i. Medication..... 1 2
- ii. Pelvic Muscle Rehabilitation..... 1↓ 2
a. Specify Start Date: ___/___/___
Month Day Year
- iii. Behavioral Training..... 1↓ 2
a. Specify Start Date: ___/___/___
Month Day Year
- iv. Biofeedback..... 1↓ 2
a. Specify Start Date: ___/___/___
Month Day Year
- v. Other..... 1↓ 2
a. Specify: _____
b. Specify Date: ___/___/___
Month Day Year

B4. Based upon a review of all source documents (including medical records) and Data Forms....
Is there new or continuing evidence of **recurrent stress urinary incontinence (SUI)** since the last study data collection?
Yes..... 1 No 2

B5. Did the patient receive any new or continuing treatment for **recurrent stress urinary incontinence (SUI)** since the last study data collection?
Yes 1 No 2 → **SKIP TO SECTION C**

B5a. Circle yes or no for all treatments received by the patient for **recurrent SUI** since the last study data collection:

Yes	No
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- i. Burch colposuspension..... 1↓ 2
a. Specify date: ___/___/___
Month Day Year
- ii. Sling procedure..... 1↓ 2
a. Specify date: ___/___/___
Month Day Year

Yes No

- 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

Yes No

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

SECTION C: ADDITIONAL URODYNAMIC STUDIES

C1. Based upon a review of all source documents (including medical records) and Data Forms...

Is there evidence of any **urodynamic studies** since the last study data collection? (**NOTE:** For the UDS group, do not include the UDS completed at randomization.)

Yes..... 1 ↓

No 2 → **SKIP TO D1**

C1a. Please provide the clinical indication(s) for the additional urodynamic study(ies):

	Yes	No
i. Voiding Dysfunction?	1	2
ii. Urgency/Frequency?	1	2
iii. Urge Urinary Incontinence?	1	2
iv. Persistent/Refractory Stress Urinary Incontinence?	1	2
v. Recurrent Stress Urinary Incontinence?	1	2

SECTION D: SURGEON'S SIGNATURE

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