F552: Follow-Up Physician Assessment, version 04/21/09 (B)_rev090909

UITN ValUE

Section A: General Study Information for Office Use Only

A1. Study ID#: Label

A2. Visit # F/U 3 Months V03M
F/U 12 Months V12M

A3. Date Form Completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

A4. Initials of Certified Surgeon Investigator: ___ ___ ___

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: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		
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
a. Specify date medicine last used: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		
vii. Other	1🡻	2
a. Specify: _____		
b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		

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
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
i.	Burch colposuspension	1🡻	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		
ii.	Sling procedure	1🡻	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		

Affix ID Label Here

		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
vi. No Clinical Indication - Local Routine Post-Op Care	1	2
vii. Other	1 ↓	2

viii. Specify if Other: _____

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SECTION D: ADVERSE EVENTS

SECTION D SHOULD BE COMPLETED AFTER ALL OTHER VISIT COMPONENTS.
REFER TO 591 AE FORM ATTACHMENT DOCUMENT FOR GUIDANCE.

D1. Did any adverse events occur since the last study data collection?

Yes..... 1🡻 No ..... 2 ➔ **SKIP TO SECTION E**

	Event Number (Refer to Pt AE Log)	Event Code (Refer to F591 Attachment)	If Event Code = 99, Specify
a.	_____ _____	_____ _____➔	
b.	_____ _____	_____ _____➔	
c.	_____ _____	_____ _____➔	
d.	_____ _____	_____ _____➔	
e.	_____ _____	_____ _____➔	

REMINDER: COMPLETE SEPARATE FORM F591 FOR EACH ADVERSE EVENT LISTED

SECTION E: SURGEON'S SIGNATURE

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