

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

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

VISIT	Frequency	Percent	Cum Freq	Cum Percent
V03M	585	52.00	585	52.00
V12M	540	48.00	1125	100.00

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 and Data Forms...

Did the patient receive any new or continuing treatment for **voiding dysfunction** since the last study visit?

Yes 1

No 2 → **SKIP TO B2**

VOID_TX	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	127	11.29	127	11.29
2:No	998	88.71	1125	100.00

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

CATHETER	Frequency	Percent	Cum Freq	Cum Percent
.	998	.	.	.
1:Yes	125	98.43	125	98.43
2:No	2	1.57	127	100.00

Frequency Missing = 998

Analysis Variable : rando_dt_CATHETER_D									
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
124	1001	-40.2	50.6	-392.0	-43.5	-30.5	-19.0	-5.0	

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

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 the 6 week visit OR
- Has undergone medical therapy to facilitate bladder emptying at or beyond the 6 week visit OR
- Has undergone surgical therapy to facilitate bladder emptying at anytime after study/index surgery.

B2. Based upon a review of all source documents and Data Forms...

Is there evidence of new or continuing **urge incontinence** since the last study visit?

Yes 1 No 2

URGE_EVID	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	315	28.00	315	28.00
2:No	810	72.00	1125	100.00

B3. Did the patient receive any new or continuing treatment for **urge incontinence** since the last study visit?

Yes 1 No 2 → **SKIP TO B4**

URGE_TX	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	115	10.22	115	10.22
2:No	1010	89.78	1125	100.00

B3a. 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 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 and Data Forms
Is there new or continuing evidence of **recurrent stress urinary incontinence (SUI)** since the last study visit?

Yes 1 No..... 2

SUI	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	209	18.58	209	18.58
2:No	916	81.42	1125	100.00

B5. Did the patient receive any new or continuing treatment for **recurrent stress urinary incontinence (SUI)** since the last study visit?

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 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: ____/____/____

Yes	No
-----	----

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 and Data Forms...

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

Yes..... 1 ↓ No..... 2 → **SKIP TO D1**

UDS	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	36	3.20	36	3.20
2:No	1089	96.80	1125	100.00

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

UDS_NCI	Frequency	Percent	Cum Freq	Cum Percent
.	1090	.	.	.
1:Yes	25	71.43	25	71.43
2:No	10	28.57	35	100.00

Frequency Missing = 1090

vii. Other 1 ↓ 2

UDS_OTH	Frequency	Percent	Cum Freq	Cum Percent
.	1090	.	.	.
1:Yes	2	5.71	2	5.71
2:No	33	94.29	35	100.00

Frequency Missing = 1090

viii. Specify if Other: _____

UDS_OTH_SP	Frequency	Percent	Cum Freq	Cum Percent
.	1125	100.00	1125	100.00

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 visit?

Yes..... 1 ↓ No..... 2 → **SKIP TO SECTION E**

AE OCCUR	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	98	8.71	98	8.71
2:No	1027	91.29	1125	100.00

	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

PI_SIGN	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	1125	100.00	1125	100.00

Analysis Variable : rando_dt_PI_SIGN_D									
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
1125	0	-239.8	141.2	-550.0	-378.0	-190.0	-100.0	-56.0	