

**F352: Follow-Up Physician Assessment, version 07/19/07 (C)**

**Section A: General Study Information for Office Use Only:**

A1. Study ID#:

Label

A2. Visit #

F/U 6 Months ..... TF06  
 F/U 12 Months..... TF12  
 F/U 24 Months..... TF24  
 Failure..... TFAI

VISIT	Frequency	Percent	Cum Freq	Cum Percent
TF06	545	34.82	545	34.82
TF12	535	34.19	1080	69.01
TF24	484	30.93	1564	99.94
TFAI	1	0.06	1565	100.00

A3. Date Form Completed:

\_\_\_/\_\_\_/\_\_\_  
 Month Day Year

A4. Initials of Person Completing this Form: \_\_\_\_\_

(Certified Surgeon Investigator)

**SECTION B: Patient Symptoms and Treatments**

B1. Did the patient report any **pain**?

**(REVIEW B0 ON F328 FOR THIS VISIT)**

Yes ..... 1

No ..... 2 → **SKIP TO B2**

PT_RPT_PAIN	Frequency	Percent	Cum Freq	Cum Percent
.	6	.	.	.
1	42	2.69	42	2.69
2	1517	97.31	1559	100.00

Frequency Missing = 6

B1a. Do you judge this pain to be related to the patient's TOMUS surgery?

Yes..... 1

No..... 2

Indeterminable..... 3

P_REL_SURG	Frequency	Percent	Cum Freq	Cum Percent
.	1525	.	.	.
1	11	27.50	11	27.50
2	20	50.00	31	77.50
3	9	22.50	40	100.00

Frequency Missing = 1525

B2. Did the patient receive any new or continuing treatment for this pain since the last study visit?

Yes..... 1↓ No..... 2 → **SKIP TO B3**

TX_PAIN	Frequency	Percent	Cum Freq	Cum Percent
.	2	.	.	.
1	19	1.22	19	1.22
2	1544	98.78	1563	100.00

Frequency Missing = 2

B2a. Medication? Yes ..... 1↓ No..... 2 → **SKIP TO B2b**

PAIN_MED	Frequency	Percent	Cum Freq	Cum Percent
.	1546	.	.	.
1	11	57.89	11	57.89
2	8	42.11	19	100.00

Frequency Missing = 1546

Circle yes or no for all medications listed:

	YES	NO
i. Non-steroidal and aspirin.....	1	2
ii. Narcotics.....	1	2
iii. Trigger point injections.....	1	2
iv. Other.....	1↓	2

Specify: \_\_\_\_\_

B2b. Physical Therapy? Yes ..... 1 No..... 2

PAIN PHYTH	Frequency	Percent	Cum Freq	Cum Percent
.	1546	.	.	.
1	10	52.63	10	52.63
2	9	47.37	19	100.00

Frequency Missing = 1546

B2c. Other treatment or referrals? Yes ..... 1 No..... 2 → **SKIP TO B3**

B2ci. Describe: \_\_\_\_\_

PAIN_OTH_TX	Frequency	Percent	Cum Freq	Cum Percent
.	1546	.	.	.
1	4	21.05	4	21.05
2	15	78.95	19	100.00

Frequency Missing = 1546

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B3. 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?

[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 B4**

TX_VOID_DYS	Frequency	Percent	Cum Freq	Cum Percent
1	26	1.66	26	1.66
2	1539	98.34	1565	100.00

B3a. Circle yes or no for all treatments received by the patient for **voiding dysfunction** since the last study visit:

<b>YES</b>	<b>NO</b>
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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

B3b. What was the date of the first treatment of any kind for **voiding dysfunction** since the patient's TOMUS surgery?

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

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B4. Based upon a review of all source documents and Data Forms ...

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

Yes..... 1                      No ..... 2 → **SKIP TO B5**

PRO_TREAT	Frequency	Percent	Cum Freq	Cum Percent
1	4	0.26	4	0.26
2	1561	99.74	1565	100.00

B4a. 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

B4b. What was the date of the first treatment of any kind for **vaginal prolapse** since the patient's TOMUS surgery?

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month Day Year

B5. 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 → **SKIP TO B6**

EVD_URGE	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
1	537	34.34	537	34.34
2	1027	65.66	1564	100.00

Frequency Missing = 1

B5a. 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 B6**  
 No..... 2

URGSYM_PRSRG	Frequency	Percent	Cum Freq	Cum Percent
.	1027	.	.	.
1	520	96.65	520	96.65
2	18	3.35	538	100.00

Frequency Missing = 1027

B5b. 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

TXURGE_PRSRG	Frequency	Percent	Cum Freq	Cum Percent
.	1547	.	.	.
1	3	16.67	3	16.67
2	15	83.33	18	100.00

Frequency Missing = 1547

B6. Did the patient receive any new or continuing treatment for **urge incontinence** since the last study visit?

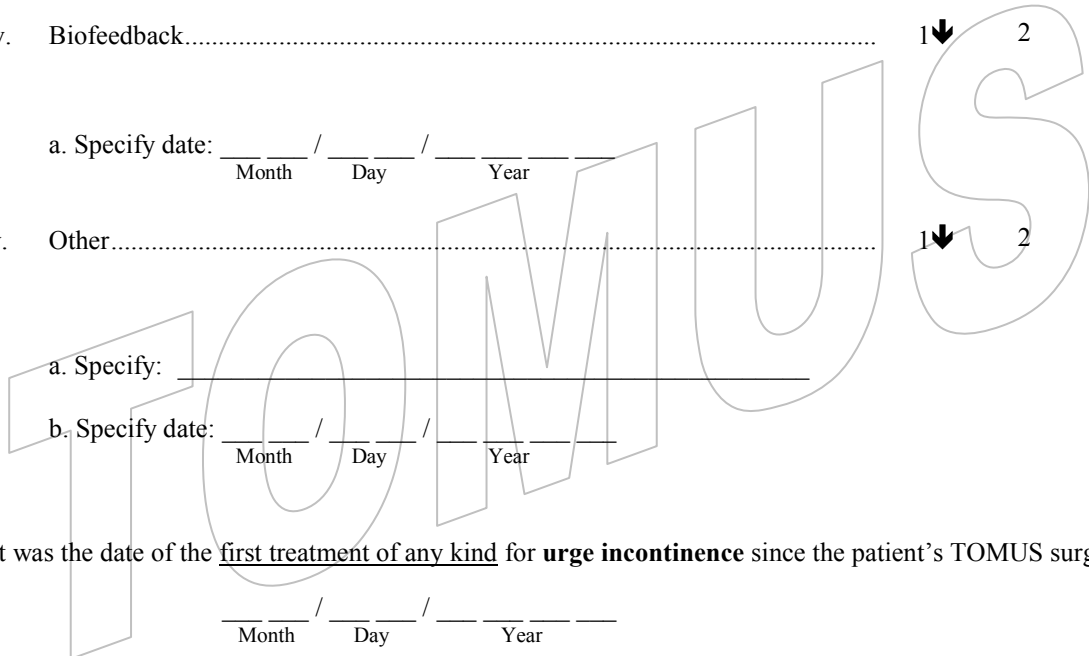
Yes..... 1 No..... 2 → **SKIP TO B7**

TXURGE_IVIS	Frequency	Percent	Cum Freq	Cum Percent
1	155	9.90	155	9.90
2	1410	90.10	1565	100.00

B6a. 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



B6b. What was the date of the first treatment of any kind for **urge incontinence** since the patient's TOMUS surgery?

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month      Day      Year

B7 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

EVD_SUI	Frequency	Percent	Cum Freq	Cum Percent
1	459	29.33	459	29.33
2	1106	70.67	1565	100.00

B7a. 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**

TX_SUI	Frequency	Percent	Cum Freq	Cum Percent
1	43	2.75	43	2.75
2	1522	97.25	1565	100.00



B7b. 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

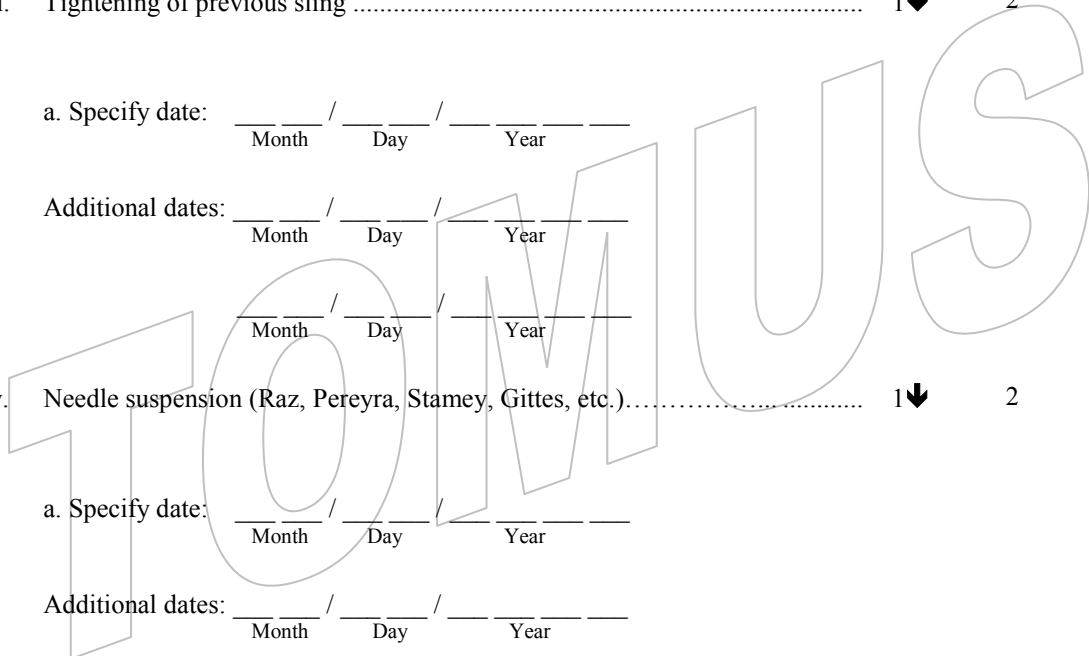
a. Specify date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month    Day    Year

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

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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

B7c. What was the date of the first treatment of any kind for **recurrent SUI**? \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

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**SECTION C: Adverse Events or Complications**

**SECTION C SHOULD BE COMPLETED AFTER ALL OTHER VISIT COMPONENTS.**

C1. Did any adverse events or complications other than voiding dysfunction, urge incontinence, or pain occur since the last study visit? **REVIEW BOX AT BOTTOM OF PAGE**

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

AE_LSTVIS	Frequency	Percent	Cum Freq	Cum Percent
1	61	3.90	61	3.90
2	1504	96.10	1565	100.00

	Event Number (Refer to Pt AE Log)	Event Code (Refer to Box Below)	If Event Code = 99, Specify
a.	_____	_____ →	

PI_SIG	Frequency	Percent	Cum Freq	Cum Percent
1	1565	100.00	1565	100.00

EVENT_NUM	Frequency	Percent	Cum Freq	Cum Percent
.	1504	.	.	.
1	35	57.38	35	57.38
2	12	19.67	47	77.05
3	8	13.11	55	90.16
4	5	8.20	60	98.36
5	1	1.64	61	100.00

Frequency Missing = 1504

b.	_____	_____ →	
c.	_____	_____ →	
d.	_____	_____ →	
e.	_____	_____ →	
f.	_____	_____ →	
g.	_____	_____ →	

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F391 FOR**

**EACH ADVERSE EVENT OR COMPLICATION LISTED\***

Affix ID Label Here

EVENT CODES REFERENCE FOR C1	
16 = Mesh Complication: Erosion	23 = Recurrent UTI
17 = Mesh Complication: Exposure	24 = Fistula: Vesicovaginal
18 = Surgical Site Infection: Superficial Incisional	25 = Fistula: Urethrovaginal
19 = Surgical Site Infection: Deep Incisional	26 = Fistula: Enterovesical
20 = Surgical Site Infection: Organ/Space	27 = Fistula: Rectovaginal
	29=Granulation Tissue
	99 = Other

**SECTION D: SURGEON'S SIGNATURE**

Surgeon's Signature: \_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Month Day Year

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## ADVERSE EVENT DEFINITIONS

source: section H2.h of the protocol

- Mesh Complication: Vaginal, urethral, bladder; erosion (defined as after primary healing, into an organ or surrounding tissue); exposure (defined as mesh visualized through a prior incision area with or without an inflammatory reaction). No time limit for reporting.
  - Surgical Site Infection (based on 1992 CDC definition): No time limit for reporting. One of the following criteria must be met:
    - Evidence of any of the following signs at the surgical incision site: purulent drainage, pain or tenderness, localized swelling, redness or heat.
    - Deliberate opening of the wound unless culture negative.
    - Evidence of infection on re-operation or imaging study.
    - Diagnosis of infection by physician, confirmed by study surgeon.
- Surgical site infections will be subcategorized into the following types:
1. Superficial Incisional: Involves only the skin and subcutaneous tissues at the incision site(s).
  2. Deep Incisional: Involves deep soft tissue (e.g. fascial and muscle layers) at the operative site(s).
  3. Organ/space: Organs or spaces, other than the incision, that were opened or manipulated during the operative procedure (includes pelvic abscess, peritonitis).
- Recurrent UTI: Presumed UTI with treatment,  $\geq 3$  in 1 year AFTER 6 week visit. No time limit for reporting.
  - Fistula: No time limit for reporting.
    - Vesicovaginal: connection between bladder and vagina resulting in passage of urine per vaginum
    - Urethrovaginal: connection between urethra and vagina resulting in passage of urine per vaginum
    - Enterovesical: connection between bladder and bowel, may be diagnosed by pneumaturia, charcoal study, or cystoscopy
    - Rectovaginal: connection between the rectum and the vagina resulting in the passage of stool per vaginum.
- NOTE: Foreign body reaction in space of Retzius resulting in vaginal discharge or bleeding or granulation tissue in vagina is NOT a fistula.
- Granulation Tissue: At or beyond the 6 week visit, granulation at the TOMUS surgical site. (If at or beyond 6 weeks there is granulation at a concomitant surgery site, that should be reported as an “other” [code 99] adverse event.) No time limit for reporting.