



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

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**

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

Yes..... 1

No..... 2

Indeterminable..... 3

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**

B2a. Medication?

Yes 1 ↓

No..... 2 → **SKIP TO B2b**

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

B2c. Other treatment or referrals?

Yes 1

No 2 → **SKIP TO B3**

B2ci. Describe: _____

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

B3a. 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

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

___/___/___
Month Day Year

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**

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

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

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

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

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

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**

	Event Number (Refer to Pt AE Log)	Event Code (Refer to Box Below)	If Event Code = 99, Specify
a.	_____	_____ →	
b.	_____	_____ →	
c.	_____	_____ →	
d.	_____	_____ →	
e.	_____	_____ →	
f.	_____	_____ →	
g.	_____	_____ →	

REMINDER: COMPLETE SEPARATE FORM F391 FOR EACH ADVERSE EVENT OR COMPLICATION LISTED

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

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, ≥ 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 vaginam
 - **Urethrovaginal:** connection between urethra and vagina resulting in passage of urine per vaginam
 - **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 vaginam.
- 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.