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

UITN TOMUS

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 <u>treatment</u> 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: _____

Affix ID Label Here

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

Affix ID Label Here

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

Affix ID Label Here

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**

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

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

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**

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)

Affix ID Label Here

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 <u>first treatment of any kind</u> for **recurrent SUI**? ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Affix ID Label Here

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
17 = Mesh Complication: Exposure
18 = Surgical Site Infection: Superficial Incisional
19 = Surgical Site Infection: Deep Incisional
20 = Surgical Site Infection: Organ/Space
23 = Recurrent UTI
24 = Fistula: Vesicovaginal
25 = Fistula: Urethrovaginal
26 = Fistula: Enterovesical
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 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.