F372: Follow-Up Physician Assessment, version 03/09/09 (A)

UITN
E-TOMUS

SECTION A: GENERAL STUDY INFORMATION

A1. Study ID#: Label

A2. Visit # F/U 36 Months..... ET36 F/U 48 Months..... ET48
F/U 60 Months ..... ET60 F/U 72 Months..... ET72
F/U 84 Months ET84

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

A4. Initials of Person Completing this Form: ___ ___ ___
(Certified Surgeon Investigator)

SECTION B: PATIENT SYMPTOMS AND TREATMENTS

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?

[*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 B2**

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
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)		

Affix ID Label Here

B2. 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 B3**

B2a. 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)		

B3. 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 B4**

B3a. 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 B4**

No 2

B3b. 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

B4. Did the patient receive any new or continuing <u>treatment</u> for **urge incontinence** since the last study visit?

Yes..... 1 No ..... 2➔ **SKIP TO B5**

B4a. Circle yes or no for all <u>treatments received</u> 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)		

Affix ID Label Here

B5. 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

B5a. Did the patient receive any new or continuing treatment for **recurrent SUI** since the last study visit?

Yes..... 1

No ..... 2 ➔ **SKIP TO SECTION C**

B5b. 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)		

Affix ID Label Here

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

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 other than voiding dysfunction or de novo urge incontinence 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 FE91 FOR EACH ADVERSE EVENT LISTED

EVENT CODES REFERENCE FOR C1

16 = Mesh Complication: Erosion	24 = Fistula: Vesicovaginal
17 = Mesh Complication: Exposure	25 = Fistula: Urethrovaginal
23 = Recurrent UTI	29 = Granulation Tissue
	99 = Other

SECTION D: SURGEON'S SIGNATURE

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

ADVERSE EVENT DEFINITIONS

source: section F2.a of the protocol & FE91 Attachment

Mesh Complication: Vaginal, urethral, bladder; **erosion** (defined as after primary TOMUS surgery healing, into an organ or surrounding tissue); **exposure** (defined as mesh visualized through a prior TOMUS surgery incision area with or without an inflammatory reaction). No time limit for reporting.

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. Due to TOMUS surgery or TOMUS surgery-related mesh complications.

- **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

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.