F322: 2 and 6 Week Follow-Up Physician Assessment, version 08/01/07 (C)

UITN TOMUS

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit # F/U 2 Weeks.....TF2W | F/U 6 Weeks.....TF6W

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 B3**

B2. **IF B1 = YES**: Was there evidence of pain on exam? (**REVIEW F326 FOR THIS VISIT)**

Yes ..... 1 No ..... 2 ➔ **SKIP TO B2b**

B2a. Did exam findings correlate with the patient's self-report of pain?

Yes ..... 1 No 2

B2b. Do you judge this pain to be related to the patient's TOMUS surgery?

Yes..... 1 ➔ **SKIP TO B4**

No ..... 2 ➔ **SKIP TO B4**

Indeterminable ..... 3 ➔ **SKIP TO B4**

B3. **IF B1 = NO**: Was there evidence of pain on exam? (**REVIEW F326 FOR THIS VISIT)**

Yes ..... 1 No ..... 2 ➔ **SKIP TO B5** N/A..... -1 ➔ **SKIP TO B5**

B3a. Do you judge this pain to be related to the patient's TOMUS surgery?

Yes..... 1

No 2

Indeterminable 3

B4. 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 B5**

B4a. Medication? Yes ..... 1↓ No..... 2 ➔**SKIP TO B4b**

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:_____

B4b. Physical Therapy? Yes ..... 1 No 2

B4c. Other treatment or referrals? Yes ..... 1 No ..... 2 ➔**SKIP TO B5**

B4ci. Describe: _____

B5. Based upon the patient's medical history and her response to C1 on Data Form 321 OR 331…

Did the patient report any **numbness** new since surgery?

Yes..... 1 ➔ **COMPLETE F391** No 2

B6. Based upon the patient's medical history and her response to C2 on Data Form 321 OR 331…

Did the patient report any **weakness** new since surgery?

Yes..... 1 ➔ **COMPLETE F391** No 2

B7. 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 B8**

Affix ID Label Here

B7a. Circle yes or no for all <u>treatments received</u> 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)		

B7b. What was the date of the <u>first treatment of any kind</u> for **voiding dysfunction** since the patient's TOMUS surgery?

___ ___ / ___ ___ /___ ___ ___ ___
Month Day Year

B8. Based upon a review of all source documents and Data Forms …

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

Yes ..... 1 No ..... 2 ➔ **SKIP TO B9**

Affix ID Label Here

B8a. Circle yes or no for all <u>treatments received</u> 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)		

B8b. What was the date of the <u>first treatment of any kind</u> for **vaginal prolapse** since the patient's TOMUS surgery?

___ ___ / ___ ___ /___ ___ ___ ___
Month Day Year

B9. 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 B10**

B9a. 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 B10**

No 2

B9b. 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

Affix ID Label Here

B10. 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 B11**

B10a. 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)		

B10b. What was the date of the <u>first treatment of any kind</u> for **urge incontinence** since the patient's TOMUS surgery?

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B11. Based upon a review of all source documents and Data Forms….

Is there new or continuing <u>evidence</u> of **recurrent stress urinary incontinence (SUI)** since the last study visit?

Yes..... 1 No 2

B11a. Did the patient receive any new or continuing <u>treatment</u> for **recurrent SUI** since the last study visit?

YES..... 1 ➔ **TREATMENT FAILURE: COMPLETE FAILURE PROTOCOL**

NO ..... 2 ➔ **SKIP TO SECTION C**

Affix ID Label Here

B11b. 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)		
iv.	Needle suspension (Raz, Pereyra, Stamey, Gittes, etc.)……..	1	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		
v.	Suburethral plication ……..	1	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		
vi.	Periurethral bulking agent injection ……..	1	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)		
vii.	Other surgical treatment ……..	1	2
	a. Specify: _____		
	b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (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)		

B11c. What was the date of the first treatment of any kind for **recurrent SUI**? ____ ___ / ___ ___ / ___ ___ ___ (Month / Day / Year)

Affix ID Label Here

SECTION C: Post-Discharge 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

01 = Bladder Perforation	09 = CVA	17 = Mesh Complication: Exposure	23 = Recurrent UTI
02 = Urethral Perforation	10 = Death	18 = Surgical Site Infection: Superficial Incisional	24 = Fistula: Vesicovaginal
03 = Acute Renal Failure	11 = Intraoperative Bleeding	19 = Surgical Site Infection: Deep Incisional	25 = Fistula: Urethrovaginal
04 = Anesthetic Complication	12 = Postoperative Bleeding	20 = Surgical Site Infection: Organ/Space	26 = Fistula: Enterovesical
05 = Device Malfunction	13 = Bowel Injury	21 = Culture-proven UTI	27 = Fistula: Rectovaginal
06 = DVT	14 = Rectal Injury	22 = Empiric UTI	28 = Neurologic Symptoms
07 = Pulmonary Embolus	15 = Vascular Injury		29 = Granulation Tissue
08 = MI	16 = Mesh Complication: Erosion		99 = Other

SECTION D: SURGEON'S SIGNATURE

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

ADVERSE EVENT DEFINITIONS

source: section H2.h of the protocol

- Bladder Perforation: Unplanned piercing made through the bladder, recognized intraoperatively.
- Urethral Perforation: Unplanned piercing or creation of an opening in the urethra, recognized intraoperatively.
- Acute Renal Failure: As diagnosed by a nephrology consult. 6 week reporting limit.
- Anesthetic Complication 6 week reporting limit.
- Deep Venous Thrombosis: Initiation of anticoagulation therapy for a thromboembolic event. 6 week reporting limit.
- Pulmonary Embolus: Diagnosed within 6 weeks of surgery or at any time secondary to a DVT that was diagnosed within 6 weeks of surgery.
- Myocardial Infarction: Documented by ECG changes or elevation of cardiac enzymes, as confirmed by cardiology consult, within 6 weeks of surgery.
- Cerebrovascular Accident: Documented by CT scan or neurologic consultation within 6 weeks after surgery.
- Death: 6 week reporting limit.
- Bleeding: Intraoperative: pelvic and obturator vessels, abdominal wall; Estimated blood loss (EBL) greater than 100 cc attributable to the placement of the midurethral sling OR estimated blood loss for the total case greater than or equal to 1000 cc and/or requiring intraoperative blood transfusion.
  Postoperative: pelvis, thigh, vagina, abdominal wall; Bleeding from a wound or from a contained space that resulted in intervention. 6 week reporting limit.
- Bowel Injury: Confirmation of injury to small or large bowel by laparotomy or imaging studies. 6 week reporting limit.
- Rectal Injury: Perforation of the rectum. 6 week reporting limit.
- Vascular Injury: Injury to a major blood vessel, diagnosed by imaging study or surgical intervention. 6 week reporting limit.
- Device Malfunction: Any abnormal occurrence attributable specifically to the sling device during placement, i.e. trocar releases from sling material, abnormality of the protective sleeve surrounding the sling material, etc. Recognized intraoperatively.
- 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).
- UTI - Empiric: Prior to 6-weeks, patient receives antibiotic therapy for symptoms thought to be secondary to UTI. 6 week reporting limit.
- UTI - Culture-Proven: Prior to 6-weeks,patient receives antibiotic therapy for symptoms of urinary tract infection subsequently associated with a positive culture. 6 week reporting limit.
- 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.

- Neurologic Symptoms: 6 week reporting limit.
  - New paresthesias or alteration in motor function that develop between surgery and the 6 week visit. Will be considered a neurological complication related to surgery if the patient answers "yes" to either of following two questions (questions will be asked at baseline, 2-week and 6-week visits):

    1. Do you have any numbness in your legs or pelvic area that has developed since surgery? If yes, describe location and magnitude.

       a. Location: Patient to mark body map. Body map will have areas labeled that correspond to the following data points.
          - Suprapubic
          - Groin
          - Vulva
          - Upper leg
          - Lower leg

       b. Magnitude: Measured by answering the following question: "How bothersome is the numbness that you described and relate to your surgery?" Response categories are: *not at all bothersome*, *slightly bothersome*, *moderately bothersome* and *greatly bothersome*.

    2. Do you have any weakness in your legs or pelvic area that has developed since surgery? If yes, questions noted above will be used to get information about location and magnitude.

- 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.