

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

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)

| VISIT | Frequency | Percent | Cum Freq | Cum Percent |
|-------|-----------|---------|----------|-------------|
| TF2W | 586 | 49.96 | 586 | 49.96 |
| TF6W | 587 | 50.04 | 1173 | 100.00 |

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**

| PT_RPT_PAIN | Frequency | Percent | Cum Freq | Cum Percent |
|-------------|-----------|---------|----------|-------------|
| . | 1 | . | . | . |
| 1 | 219 | 18.69 | 219 | 18.69 |
| 2 | 953 | 81.31 | 1172 | 100.00 |

Frequency Missing = 1

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

Yes..... 1

No..... 2 → **SKIP TO B2b**

| Y_EVDNCE_P | Frequency | Percent | Cum Freq | Cum Percent |
|------------|-----------|---------|----------|-------------|
| . | 955 | . | . | . |
| 1 | 131 | 60.09 | 131 | 60.09 |
| 2 | 87 | 39.91 | 218 | 100.00 |

Frequency Missing = 955

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

Yes..... 1

No..... 2

| EXAM_CORR_PT | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 1043 | . | . | . |
| 1 | 125 | 96.15 | 125 | 96.15 |
| 2 | 5 | 3.85 | 130 | 100.00 |

Frequency Missing = 1043

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

| Y_P_REL_SURG | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 955 | . | . | . |
| 1 | 127 | 58.26 | 127 | 58.26 |
| 2 | 60 | 27.52 | 187 | 85.78 |
| 3 | 31 | 14.22 | 218 | 100.00 |

Frequency Missing = 955

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

| N_EVDNCE_P | Frequency | Percent | Cum Freq | Cum Percent |
|------------|-----------|---------|----------|-------------|
| . | 956 | . | . | . |
| 1 | 5 | 2.30 | 5 | 2.30 |
| 2 | 212 | 97.70 | 217 | 100.00 |

Frequency Missing = 956

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

- Yes..... 1
 No..... 2
 Indeterminable..... 3

| N_P_REL_SURG | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 1168 | . | . | . |
| 1 | 4 | 80.00 | 4 | 80.00 |
| 3 | 1 | 20.00 | 5 | 100.00 |

Frequency Missing = 1168

B4. Did the patient receive any new or continuing treatment for this pain since the last study visit?

- Yes..... 1↓ No..... 2 → SKIP TO B5

| TX_PAIN | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| . | 949 | . | . | . |
| 1 | 58 | 25.89 | 58 | 25.89 |
| 2 | 166 | 74.11 | 224 | 100.00 |

Frequency Missing = 949

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

| PAIN_MED | Frequency | Percent | Cum Freq | Cum Percent |
|----------|-----------|---------|----------|-------------|
| . | 1115 | . | . | . |
| 1 | 55 | 94.83 | 55 | 94.83 |
| 2 | 3 | 5.17 | 58 | 100.00 |

Frequency Missing = 1115

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

| PAIN_PHYTH | Frequency | Percent | Cum Freq | Cum Percent |
|------------|-----------|---------|----------|-------------|
| . | 1115 | . | . | . |
| 1 | 6 | 10.34 | 6 | 10.34 |
| 2 | 52 | 89.66 | 58 | 100.00 |

Frequency Missing = 1115

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

B4ci. Describe: _____

| PAIN_OTH_TX | Frequency | Percent | Cum Freq | Cum Percent |
|-------------|-----------|---------|----------|-------------|
| . | 1115 | . | . | . |
| 1 | 5 | 8.62 | 5 | 8.62 |
| 2 | 53 | 91.38 | 58 | 100.00 |

Frequency Missing = 1115

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

| NEW_NUMBNESS | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| 1 | 20 | 1.71 | 20 | 1.71 |
| 2 | 1153 | 98.29 | 1173 | 100.00 |

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

| NEW_WEAKNESS | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| 1 | 33 | 2.81 | 33 | 2.81 |
| 2 | 1140 | 97.19 | 1173 | 100.00 |

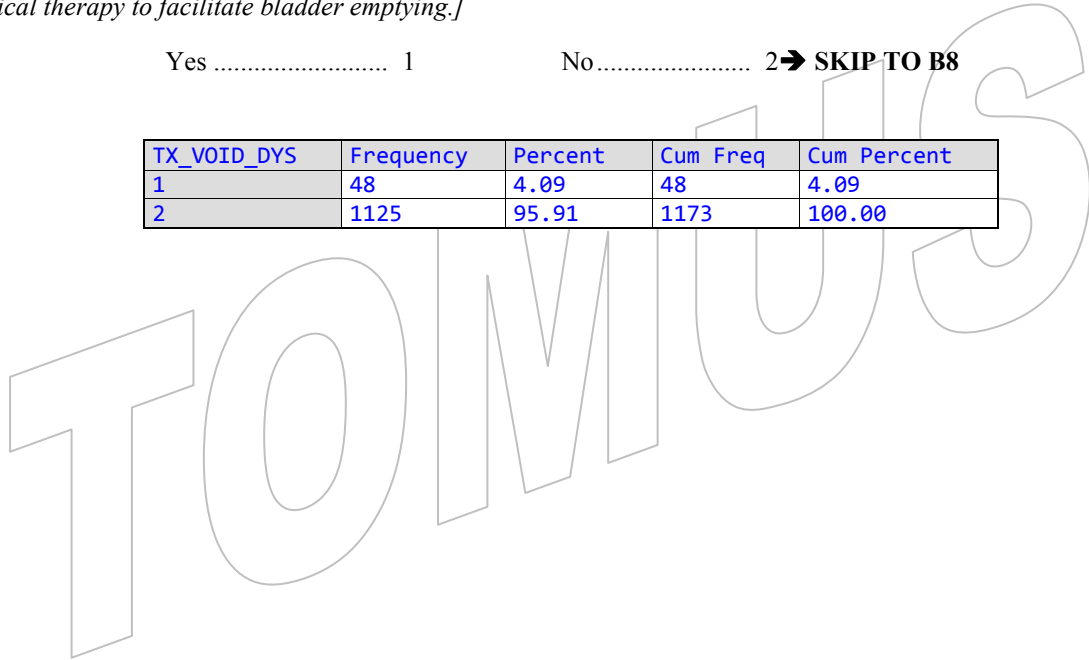
B7. Based upon a review of all source documents and Data Forms...

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**

| TX_VOID_DYS | Frequency | Percent | Cum Freq | Cum Percent |
|-------------|-----------|---------|----------|-------------|
| 1 | 48 | 4.09 | 48 | 4.09 |
| 2 | 1125 | 95.91 | 1173 | 100.00 |



B7a. 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

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

___/___/___
Month Day Year

| Analysis Variable : VDFR_days | | | | | | | | |
|-------------------------------|--------|------|------|---------|----------------|--------|----------------|---------|
| N | N Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 47 | 0 | 5.7 | 10.7 | 0.0 | 0.0 | 1.0 | 6.0 | 48.0 |

| VDFR_days | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| . | 1126 | 100.00 | 1126 | 100.00 |

F322: B8. Is there new evidence of vaginal prolapse

B8. 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 B9**

| EVD_PRO | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| . | 755 | . | . | . |
| 2 | 418 | 100.00 | 418 | 100.00 |

Frequency Missing = 755

B8a. 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

| pro_treat | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| 2 | 1173 | 100.00 | 1173 | 100.00 |

- 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 first treatment of any kind 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

| EVD_URGE | Frequency | Percent | Cum Freq | Cum Percent |
|----------|-----------|---------|----------|-------------|
| 1 | 248 | 21.14 | 248 | 21.14 |
| 2 | 925 | 78.86 | 1173 | 100.00 |

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

| URGSYM_PRSRG | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 925 | . | . | . |
| 1 | 236 | 95.16 | 236 | 95.16 |
| 2 | 12 | 4.84 | 248 | 100.00 |

Frequency Missing = 925

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

| TXURGE_PRSRG | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 1161 | . | . | . |
| 2 | 12 | 100.00 | 12 | 100.00 |

Frequency Missing = 1161

B10. Did the patient receive any new or continuing treatment for **urge incontinence** since the last study visit?

Yes..... 1 No..... 2 → **SKIP TO B11**

| TXURGE_IVIS | Frequency | Percent | Cum Freq | Cum Percent |
|-------------|-----------|---------|----------|-------------|
| 1 | 43 | 3.67 | 43 | 3.67 |
| 2 | 1130 | 96.33 | 1173 | 100.00 |

B10a. 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

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

___/___/___
Month Day Year

| Analysis Variable : URGEFR_days | | | | | | | | |
|---------------------------------|------|------|------|---------|----------------|--------|----------------|---------|
| N | Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 43 | 0 | 25.2 | 14.0 | 1.0 | 14.0 | 17.0 | 38.0 | 55.0 |

| URGEFR_days | Frequency | Percent | Cum Freq | Cum Percent |
|-------------|-----------|---------|----------|-------------|
| . | 1130 | 100.00 | 1130 | 100.00 |

B11. 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 | 101 | 8.61 | 101 | 8.61 |
| 2 | 1072 | 91.39 | 1173 | 100.00 |

B11a. 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 | 8 | 0.68 | 8 | 0.68 |
| 2 | 1165 | 99.32 | 1173 | 100.00 |

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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: ___/___/___

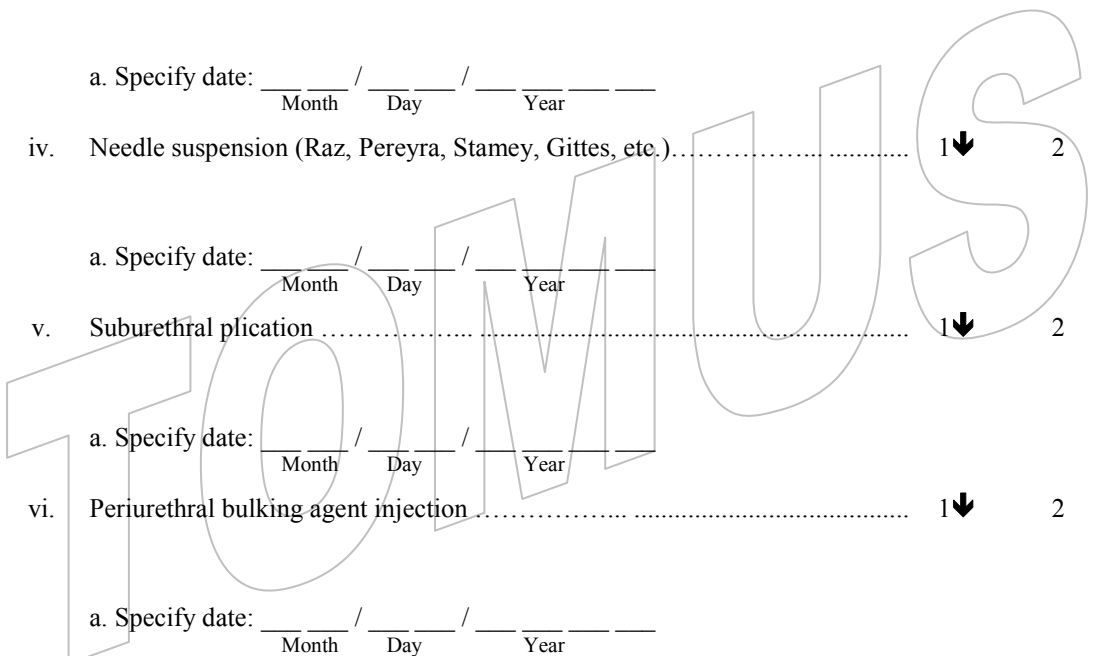
viii. Alpha-agonists 1↓ 2

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

| Analysis Variable : SUI_days | | | | | | | | | |
|------------------------------|------|------|------|---------|----------------|--------|----------------|---------|--|
| N | Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum | |
| 8 | 0 | 31.9 | 22.7 | 10.0 | 15.0 | 27.0 | 42.0 | 77.0 | |

| SUI_days | Frequency | Percent | Cum Freq | Cum Percent |
|----------|-----------|---------|----------|-------------|
| . | 1165 | 100.00 | 1165 | 100.00 |

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**

| AE_LSTVIS | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| 1 | 145 | 12.36 | 145 | 12.36 |
| 2 | 1028 | 87.64 | 1173 | 100.00 |

| | 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. | _____ | _____ → | |

| EVENT_NUM | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| . | 1028 | . | . | . |
| 1 | 93 | 64.14 | 93 | 64.14 |
| 2 | 35 | 24.14 | 128 | 88.28 |
| 3 | 12 | 8.28 | 140 | 96.55 |
| 4 | 3 | 2.07 | 143 | 98.62 |
| 5 | 2 | 1.38 | 145 | 100.00 |

Frequency Missing = 1028

| EVENT_NUM | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| . | 1028 | 87.64 | 1028 | 87.64 |
| 12 | 2 | 0.17 | 1030 | 87.81 |
| 16 | 2 | 0.17 | 1032 | 87.98 |
| 17 | 6 | 0.51 | 1038 | 88.49 |
| 18 | 2 | 0.17 | 1040 | 88.66 |
| 21 | 41 | 3.50 | 1081 | 92.16 |
| 22 | 26 | 2.22 | 1107 | 94.37 |
| 28 | 48 | 4.09 | 1155 | 98.47 |
| 29 | 2 | 0.17 | 1157 | 98.64 |
| 99 | 16 | 1.36 | 1173 | 100.00 |

Frequency Missing = 1028

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

D1. Is this field signed by the Surgeon

| PI_SIG | Frequency | Percent | Cum Freq | Cum Percent |
|--------|-----------|---------|----------|-------------|
| 1 | 1173 | 100.00 | 1173 | 100.00 |

Surgeon's Signature: _____

Date: ____ / ____ / ____
Month Day Year

| Analysis Variable : Days | | | | | | | | |
|--------------------------|--------|------|------|---------|----------------|--------|----------------|---------|
| N | N Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 1173 | 0 | 37.8 | 24.9 | 8.0 | 17.0 | 38.0 | 48.0 | 211.0 |

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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.