

Section A: General Study Information for Office Use Only:

A1. Study ID#:

A2. Visit # Surgery.....TSRG

A3. Date of Surgery: ___/___/___
 Month Day Year

A4. Date Form Completed: ___/___/___
 Month Day Year

A5. Which Mid Urethral Sling procedure was performed?
 T₁ TVT-O T₂ Monarc T₃ TVT

A6.: Initials of Person Completing this Form: ___ ___ ___
(Certified Surgeon Investigator)

A7. Who was the Primary Surgeon? (check one response)
 Certified Investigator ___ ___ ___ (Initials)
 Certified Fellow: ___ ___ ___ (Initials)

SECTION B: OPERATIVE INFORMATION

B1. Were any other surgeries performed? Yes 1 No 2 →SKIP TO B2

Circle yes or no for all types:

	YES	NO
a. Uterosacral ligament vault suspension	1	2
b. Sacrospinous ligament suspension	1	2
c. Iliococcygeus vault suspension	1	2
d. Anterior colporrhaphy (NB: no mesh or graft allowed in TOMUS)	1	2
e. Vaginal paravaginal repair	1	2
f. Standard posterior colporrhaphy	1	2
g. Defect-directed posterior repair.....	1	2
h. Posterior repair with allograft or autograft (NB: no mesh allowed in TOMUS)	1	2
i. Vaginal hysterectomy	1	2
j. Oophorectomy	1	2
k. Other.....	1↓	2
ki. SPECIFY: _____		

B2. Record **entire** operative times. *Record in military time, i.e. 24-hour clock.*

B2a. **First** incision started: _____ : _____
hour minute

B2b. **Last** incision closed: _____ : _____
hour minute

B3. Record mid urethral sling times: *Record in military time, i.e. 24-hour clock*

B3a. **First** incision started: _____ : _____
hour minute

B3b. **Last** incision closed: _____ : _____
hour minute

B4. What type(s) of anesthesia was used? *Circle yes or no for all types listed*

	YES	NO
a. General.....	1	2
b. Spinal.....	1	2
c. Epidural	1	2
d. Sedation.....	1	2
e. Local.....	1↓	2

→SKIP TO B5

B4ei. Location of local anesthesia

Circle yes or no for all listed:

	YES	NO
a. Obturator	1	2
b. Abdomen.....	1	2
c. Vagina.....	1	2

B4eii. Medication name: _____

B4eiii. With or without epinephrine? With epinephrine..... 1 Without epinephrine..... 2

B5. Was the patient given prophylactic antibiotics **prior** to surgery? Yes 1 No..... 2 →SKIP TO B6

B5a. Record administration time closest to first incision: _____ : _____
Record in military time, i.e. 24-hour clock hour minute

B5b. Was additional dose given? Yes 1↓ No 2 →SKIP TO B6

B5bi. Why: _____

B6. Was hydrodissection performed in the retropubic space?

Yes 1

No 2

Not Applicable -1

SECTION C: ADVERSE EVENTS AND COMPLICATIONS – PERIOPERATIVE

C1. Estimated blood loss:

C1a. Entire case _____ cc

C1b. Mid-urethral sling _____ cc

REMINDER: IF MUS BLOOD LOSS > 100 CC OR ESTIMATED BLOOD LOSS FOR THE TOTAL CASE ≥ 1000 CC COMPLETE FORM 391 AS REQUIRED

C2. What measures were taken to minimize or control blood loss?

Circle yes or no for all types listed:

	YES	NO
a. Pre-incision vasoconstrictor	1	2
b. Direct pressure	1	2
c. Packing	1	2
d. Suture.....	1	2
e. Extension of incision and explorations	1↓	2
Describe: _____		
f. Other	1↓	2
Describe: _____		

C3. Did the patient receive a **red blood cell transfusion** during surgery?

Yes..... 1↓ No..... 2 → SKIP TO C4

REMINDER: COMPLETE FORM 391 AS REQUIRED

C3a. Number of **autologous** units: _____ units

C3b. Number of **non-autologous** units: _____ units

C4. Did **vaginal epithelium** perforation occur? Yes 1 No 2

C5. Results of cystoscopy: Normal..... 1 → SKIP TO C6

Abnormal..... 2

C5a. Did **bladder** perforation occur?

Yes..... 1↓ No 2 → **SKIP TO C5b**

REMINDER: COMPLETE FORM 391 AS REQUIRED

C5ai. Record location(s) of the bladder perforation(s). (*Circle yes or no for all locations listed.*)

	YES	NO
a. Lateral	1	2
b. Dome.....	1	2
c. Trigone.....	1	2

C5aii. Did the bladder perforation require management beyond removal/replacement of trocar?

Yes..... 1 No..... 2 → **SKIP TO C5b**

C5aiii. Describe: _____

C5b. Did **urethral** perforation occur?

Yes..... 1↓ No..... 2 → **SKIP TO C6**

REMINDER: COMPLETE FORM 391 AS REQUIRED

C5bi. Did the urethral perforation require management beyond removal /replacement of trocar?

Yes..... 1 No 2 → **SKIP TO C6**

C5bii. Describe: _____

C6. Did any adverse events or complications occur during surgery? **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.	_____	_____ →	
h.	_____	_____ →	
i.	_____	_____ →	
j.	_____	_____ →	

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

SECTION D: SURGEON'S SIGNATURE

I have reviewed the above-stated information and am confirming its accuracy with my signature below.

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

EVENT CODES REFERENCE FOR C6			
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		99 = Other
08 = MI	16 = Mesh Complication: Erosion		