

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?
 TVT-O Monarc 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)

WHICH SURG	Frequency	Percent	Cum Freq	Cum Percent
1	161	26.97	161	26.97
2	138	23.12	299	50.08
3	298	49.92	597	100.00

SECTION B: OPERATIVE INFORMATION

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

OTH SURG	Frequency	Percent	Cum Freq	Cum Percent
1	151	25.29	151	25.29
2	446	74.71	597	100.00

Circle yes or no for all types:

YES	NO
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a. Uterosacral ligament vault suspension 1 2

UT LIG SUS	Frequency	Percent	Cum Freq	Cum Percent
0: No	559	93.63	559	93.63
1: Yes	38	6.37	597	100.00

b. Sacrospinous ligament suspension 1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

c. Iliococcygeus vault suspension 1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

- d. Anterior colporrhaphy
(NB: no mesh or graft allowed in TOMUS)..... 1 2

ANT_COL	Frequency	Percent	Cum Freq	Cum Percent
0: No	544	91.12	544	91.12
1: Yes	53	8.88	597	100.00

- e. Vaginal paravaginal repair 1 2

Because the frequency of at least one category is very low, the variable was not included in the dataset

- f. Standard posterior colporrhaphy 1 2

ST_POST_COL	Frequency	Percent	Cum Freq	Cum Percent
0: No	566	94.81	566	94.81
1: Yes	31	5.19	597	100.00

- g. Defect-directed posterior repair 1 2

DEF_POST_REP	Frequency	Percent	Cum Freq	Cum Percent
0: No	561	93.97	561	93.97
1: Yes	36	6.03	597	100.00

- h. Posterior repair with allograft or autograft
(NB: no mesh allowed in TOMUS) 1 2

POST_REP	Frequency	Percent	Cum Freq	Cum Percent
0: No	591	98.99	591	98.99
1: Yes	6	1.01	597	100.00

- i. Vaginal hysterectomy..... 1 2

VAG_HYST	Frequency	Percent	Cum Freq	Cum Percent
0: No	551	92.29	551	92.29
1: Yes	46	7.71	597	100.00

- j. Oophorectomy..... 1 2

OOPH	Frequency	Percent	Cum Freq	Cum Percent
0: No	584	97.82	584	97.82
1: Yes	13	2.18	597	100.00

k. Other 1↓ 2

DIFF SURG	Frequency	Percent	Cum Freq	Cum Percent
0: No	546	91.46	546	91.46
1: Yes	51	8.54	597	100.00

ki. SPECIFY: _____

concomsx = 'Concom Surg'

concomsx	Frequency	Percent	Cum Freq	Cum Percent
0:No	446	74.71	446	74.71
1:Yes	151	25.29	597	100.00

nconcomsx= '# Concom Surgs';

nconcomsx	Frequency	Percent	Cum Freq	Cum Percent
0	446	74.71	446	74.71
1	80	13.40	526	88.11
2	35	5.86	561	93.97
3	23	3.85	584	97.82
4	9	1.51	593	99.33
5	4	0.67	597	100.00

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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

dur_surg = 'Total surgery time (in mins)'

Analysis Variable : dur_surg								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
597	0	48.4	45.0	8.0	23.0	34.0	51.0	293.0

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

dur_sling_surg = 'Mid urethral sling time (in mins)'

Analysis Variable : dur_sling_surg								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
597	0	29.1	13.9	8.0	20.0	27.0	36.0	122.0

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

YES NO

a. General..... 1 2

GEN_ANES	Frequency	Percent	Cum Freq	Cum Percent
1	427	71.52	427	71.52
2	170	28.48	597	100.00

b. Spinal 1 2

SPIN_ANES	Frequency	Percent	Cum Freq	Cum Percent
1	36	6.03	36	6.03
2	561	93.97	597	100.00

c. Epidural..... 1 2

EPI_ANES	Frequency	Percent	Cum Freq	Cum Percent
1	2	0.34	2	0.34
2	595	99.66	597	100.00

d. Sedation 1 2

SED_ANES	Frequency	Percent	Cum Freq	Cum Percent
1	163	27.30	163	27.30
2	434	72.70	597	100.00

e. Local 1↓ 2 →SKIP TO B5

LOC_ANES	Frequency	Percent	Cum Freq	Cum Percent
1	421	70.52	421	70.52
2	176	29.48	597	100.00

B4ei. Location of local anesthesia

Circle yes or no for all listed:

YES	NO
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a. Obturator 1 2

L_ANES_OB	Frequency	Percent	Cum Freq	Cum Percent
-2	176	29.48	176	29.48
1	193	32.33	369	61.81
2	228	38.19	597	100.00

b. Abdomen 1 2

L_ANES_AB	Frequency	Percent	Cum Freq	Cum Percent
-2	176	29.48	176	29.48
1	182	30.49	358	59.97
2	239	40.03	597	100.00

c. Vagina 1 2

L_ANES_VAG	Frequency	Percent	Cum Freq	Cum Percent
-2	176	29.48	176	29.48
1	352	58.96	528	88.44
2	69	11.56	597	100.00

B4eii. Medication name: _____

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

MED EPI	Frequency	Percent	Cum Freq	Cum Percent
-2	176	29.48	176	29.48
1	315	52.76	491	82.24
2	106	17.76	597	100.00

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

ANTI PRIOR	Frequency	Percent	Cum Freq	Cum Percent
1	592	99.16	592	99.16
2	5	0.84	597	100.00

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

ADDL_DOSE	Frequency	Percent	Cum Freq	Cum Percent
-2	5	0.84	5	0.84
1	51	8.54	56	9.38
2	541	90.62	597	100.00

B5bi. Why: _____

B6. Was hydrodissection performed in the retropubic space?

Yes 1

No 2

Not Applicable -1

RETRO_HYDRO	Frequency	Percent	Cum Freq	Cum Percent
-1	171	28.64	171	28.64
1	146	24.46	317	53.10
2	280	46.90	597	100.00

SECTION C: ADVERSE EVENTS AND COMPLICATIONS – PERIOPERATIVE

C1. Estimated blood loss:

C1a. Entire case _____ cc

C1b. Mid-urethral sling _____ cc

Analysis Variable : EBL_CASE								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
596	0	72.3	120.5	5.0	25.0	50.0	75.0	1700.0

EBL_CASE	Frequency	Percent	Cum Freq	Cum Percent
-9	1	100.00	1	100.00

Analysis Variable : EBL_SLING								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
596	0	42.9	44.4	0.0	20.0	30.0	50.0	600.0

EBL_SLING	Frequency	Percent	Cum Freq	Cum Percent
-9	1	100.00	1	100.00

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
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a. Pre-incision vasoconstrictor 1 2

PI_VASO	Frequency	Percent	Cum Freq	Cum Percent
1	369	61.81	369	61.81
2	228	38.19	597	100.00

b. Direct pressure..... 1 2

D_PRESSURE	Frequency	Percent	Cum Freq	Cum Percent
1	190	31.83	190	31.83
2	407	68.17	597	100.00

c. Packing..... 1 2

PACKING	Frequency	Percent	Cum Freq	Cum Percent
1	206	34.51	206	34.51
2	391	65.49	597	100.00

d. Suture 1 2

SUTURE	Frequency	Percent	Cum Freq	Cum Percent
1	33	5.53	33	5.53
2	564	94.47	597	100.00

e. Extension of incision and explorations..... 1↓ 2

INC_EXTENDED	Frequency	Percent	Cum Freq	Cum Percent
2	597	100.00	597	100.00

Describe: _____

f. Other..... 1↓ 2

BL_OTHER	Frequency	Percent	Cum Freq	Cum Percent
.	343	.	.	.
1	5	1.97	5	1.97
2	249	98.03	254	100.00

Describe: _____

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

Yes..... 1↓ No..... 2 → SKIP TO C4

BLOOD_TRANS	Frequency	Percent	Cum Freq	Cum Percent
1	2	0.34	2	0.34
2	595	99.66	597	100.00

REMINDER: COMPLETE FORM 391 AS REQUIRED

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

Analysis Variable : NUM_AUT								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	1.0	1.4	0.0	0.0	1.0	2.0	2.0

NUM_AUT	Frequency	Percent	Cum Freq	Cum Percent
-2	595	100.00	595	100.00

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

Analysis Variable : NUM_NONAUT								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
2	0	2.0	2.8	0.0	0.0	2.0	4.0	4.0

NUM_NONAUT	Frequency	Percent	Cum Freq	Cum Percent
-2	595	100.00	595	100.00

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

VAG_EPI_PERF	Frequency	Percent	Cum Freq	Cum Percent
1	19	3.18	19	3.18
2	578	96.82	597	100.00

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

Abnormal..... 2

CYST_RESULTS	Frequency	Percent	Cum Freq	Cum Percent
-9	1	0.17	1	0.17
1	575	96.31	576	96.48
2	21	3.52	597	100.00

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C5a. Did **bladder** perforation occur?

Yes 1↓ No..... 2 → **SKIP TO C5b**

BLAD_PER	Frequency	Percent	Cum Freq	Cum Percent
-2	575	96.31	575	96.31
1	14	2.35	589	98.66
2	8	1.34	597	100.00

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
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a. Lateral 1 2

BP_LOC_LAT	Frequency	Percent	Cum Freq	Cum Percent
-2	583	97.65	583	97.65
1	11	1.84	594	99.50
2	3	0.50	597	100.00

b. Dome 1 2

BP_LOC_DOME	Frequency	Percent	Cum Freq	Cum Percent
-2	583	97.65	583	97.65
1	4	0.67	587	98.32
2	10	1.68	597	100.00

c. Trigone 1 2

BP_LOC_TRIG	Frequency	Percent	Cum Freq	Cum Percent
-2	583	97.65	583	97.65
2	14	2.35	597	100.00

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

Yes 1 No 2 → SKIP TO C5b

BP_TROCAR	Frequency	Percent	Cum Freq	Cum Percent
-2	583	97.65	583	97.65
2	14	2.35	597	100.00

C5aiii. Describe: _____

C5b. Did **urethral** perforation occur?

Yes..... 1↓ No 2 → SKIP TO C6

URETH_PER	Frequency	Percent	Cum Freq	Cum Percent
-2	575	96.31	575	96.31
1	2	0.34	577	96.65
2	20	3.35	597	100.00

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

UP_TROCAR	Frequency	Percent	Cum Freq	Cum Percent
-2	595	99.66	595	99.66
1	2	0.34	597	100.00

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**

AE SURG	Frequency	Percent	Cum Freq	Cum Percent
1	40	6.70	40	6.70
2	557	93.30	597	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.	_____	_____ →	
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		