

F510: Operative Data, version 09/08/2008 (A)

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY

A1. Study ID#:

A2. Visit # Surgery.....VSRG

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

A4. Initials of Certified Surgeon Investigator: ____

SECTION B: OPERATIVE INFORMATION

B1. Date of Surgery: ___/___/___
Month Day Year

Analysis Variable : rando_dt SURG_DATE								
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
586	0	-28.2	30.0	-402.0	-36.0	-22.5	-13.0	-1.0

B2. Primary Surgeon Initials: _____

B3. Did a fellow assist with this case? Yes..... 1 ↓ No 2

FELLOW_ASSIS	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	292	49.83	292	49.83
2:No	294	50.17	586	100.00

B3a. Initials of fellow who assisted: _____

- B4. Which SUI procedure was performed?
- Midurethral Sling 1 → SKIP TO B4b
 - Traditional Sling..... 2 → SKIP TO B4c
 - Retropubic Urethropexy..... 3 → SKIP TO B5
 - Urethral Bulking Injection 4 → SKIP TO B4d
 - Other Surgical Procedure 5 ↓

B4a. If Other, specify: _____ → SKIP TO B5

WHICH_SURG_cat	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
1:Midurethral Sling	555	94.87	555	94.87
2:Traditional Sling/Retropubic Urethropexy/Urethral Bulking Injection	30	5.13	585	100.00

Frequency Missing = 1

B4b. What kind of midurethral sling? Retropubic 1
 Transobturator 2
 Minisling 3

WHICH_MIDURE_cat	Frequency	Percent	Cum Freq	Cum Percent
.	31	.	.	.
1:Retropubic	378	68.11	378	68.11
2:Transobturator/Minisling	177	31.89	555	100.00

Frequency Missing = 31

B4c. What kind of traditional sling? Autologous 1 **SKIP TO B5**

- Allogenic 2
- Xenograft 3
- Synthetic 4
- Collagen 1
- Non-collagen material 2 ↓

B4d. What kind of urethral bulking injection?

B4di. Specify: _____

B5. Were any modifications made to the conventional (typical) way that this surgery is usually performed?
 Yes 1 ↓ No 2

B5a. If Yes, specify: _____

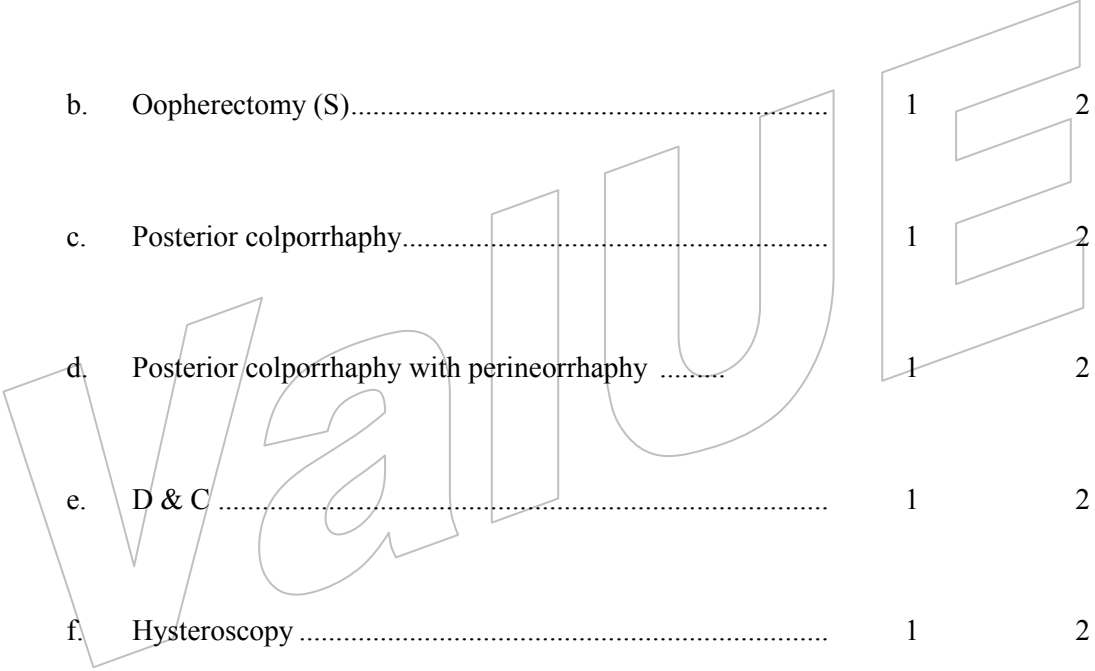
B6. Were any concomitant surgeries performed? Yes 1 ↓ No 2

CONCOMI_SURG	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	95	16.21	95	16.21
2:No	491	83.79	586	100.00

Circle Yes or No for each type:

YES	NO
-----	----

- | | | |
|---|-----|---|
| a. Hysterectomy (not for prolapse)..... | 1 ↓ | 2 |
| ai. Type of hysterectomy: | | |
| Vaginal 1 | | |
| Abdominal 2 | | |
| Laparoscopic 3 | | |
| Laparoscopic-assisted vaginal hysterectomy 4 | | |
| b. Oophorectomy (S)..... | 1 | 2 |
| c. Posterior colporrhaphy..... | 1 | 2 |
| d. Posterior colporrhaphy with perineorrhaphy | 1 | 2 |
| e. D & C | 1 | 2 |
| f. Hysteroscopy | 1 | 2 |
| g. Cone biopsy | 1 | 2 |



CONC_CONEBIO	Frequency	Percent	Cum Freq	Cum Percent
.	491	.	.	.
2:No	95	100.00	95	100.00

Frequency Missing = 491

- h. Endometrial biopsy 1 2
- i. Vaginal biopsy 1 2
- j. Vulvar biopsy..... 1 2

CONC_VULVAR	Frequency	Percent	Cum Freq	Cum Percent
.	491	.	.	.
2:No	95	100.00	95	100.00

Frequency Missing = 491

- k. Tubal sterilization 1 2
- l. Adenexal surgery 1 2

CONC_ADX_SUR	Frequency	Percent	Cum Freq	Cum Percent
.	491	.	.	.
2:No	95	100.00	95	100.00

Frequency Missing = 491

- m. Other 1↓ 2

mi. If Other, specify: _____

B7. Were any other unplanned, medically necessary surgeries performed?

- Yes 1 ↓
- No 2

B7a. If Yes, specify: _____

B8. Results of cystoscopy: Normal 1 ➔ SKIP TO C1
Abnormal 2
Not Done 3 ➔ SKIP TO C1

B8a. If abnormal, describe: _____

SECTION C: ADVERSE EVENTS

C1. Did any adverse events occur during surgery? Yes..... 1↓ No..... 2 ➔ SKIP TO SECTION D

AE_SURG	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	35	5.97	35	5.97
2:No	551	94.03	586	100.00

REVIEW BOX BELOW. COMPLETE SEPARATE FORM 591 FOR EACH AE LISTED.

	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.	_____	_____ ➔	

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

SURG_SIG	Frequency	Percent	Cum Freq	Cum Percent
1:Yes	586	100.00	586	100.00

Analysis Variable : rando_dt_SURG_SIG_D									
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
586	0	-35.8	33.8	-410.0	-42.0	-29.0	-17.0	-1.0	

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 = Granulation Tissue
07 = Pulmonary Embolus	15 = Vascular Injury		29 = Voiding Dysfunction
08 = MI	16 = Mesh Complication: Erosion		99 = Other

