Form 10: Operative Measures, Version 11/15/02 (A)



Section A: General Study Information for Office Use Only:						
A1. Study ID#:	Label		A2. Visit # SurgerySURG			
A3. Date of Surgery:// A4. Date Form Completed://						
	Month Day	Year	Month Day Year			
A5. Initials of Person Completing this Form:(Certified Surgeon)						
A6. Which primary surgery was performed? Sling 1						
		Burch 2	→ SKIP TO SECTION C, PAGE 2			

		1
SECT	FION B: THE SLING PROCEDUI	RE
B1.	Length of abdominal incision:	cm
B2.	Orientation of <u>abdominal</u> incision:	Vertical 1
		Horizontal2
		Other
В3.	Orientation of <u>vaginal</u> incision:	Single midline incision 1
		2 lateral incisions
		Inverted U incision 3
		Other
B4.	Sling material used: Autologous,	Rectus fascia (required by the protocol) 1 →SKIP TO B5
	Autologous,	Fascia lata
B4a	a. Why was autologous fascia lata	used as the sling material?
		<u> </u>
B5.	Sutures for closure of harvest site:	Delayed absorbable 1
		Permanent 2
		Other
B6.	Size of sling material: a. Lengt	h cm
	b. Narro	west Width cm
	c. Wides	t Width cm

Affix ID Label Here

B7.	Suture of sling material:	Simple One Stitch per side 1
		Two Stitches per side
		Helical x3 per side
		Other
B8.	Were the sling ends folded?	Yes 1
		No 2
B9.	Were the sutures tied over o	r to the rectus fascia? Tied OVER fascia 1
		Tied TO fascia 2
B10.	Suture material used: Po	lypropylene (required by the protocol) 1 →SKIP TO B11
	Ot	her
B10		ial other than polypropylene used?
B11.	Suture gauge: 1	1 →SKIP TO SECTION D
	0	2 →SKIP TO SECTION D
	Other	
B1	1a. Why was a suture gauge	other than 1 or 0 used?
		SKIP TO SECTION D
SEC	ΓΙΟΝ C: THE BURCH F	ROCEDURE
C1.	Length of abdominal incision	n: cm
C2.	Orientation of incision:	Vertical 1
	1	Horizontal 2
		Other

Affix ID Label Here

C3. Suture material used: Polypropylene (required by the protocol)	0 04	
Other	FY: _	
C3a. Why was a suture material other than polypropylene used?		
C4. Suture gauge: 1 1 → SKIP TO C5		
0 2 →SKIP TO C5		
Other 99 → SPECIFY:		
C4a. Why was a suture gauge other than 1 or 0 used?		
C5. Number of sutures on each side? (NOTE: The number must be equal on each side.)		
2 sutures 2		
3 sutures 3		
Other		
C6. Number of suture passes through Cooper's ligament: One Pass		
Two Passes 2		
1 WO 1 455C5 2		
SECTION D: OTHER OPERATIVE INFORMATION		
SECTION D: OTHER OPERATIVE INFORMATION		
SECTION D: OTHER OPERATIVE INFORMATION D1. Were any other surgeries performed? Yes	YES	NO
SECTION D: OTHER OPERATIVE INFORMATION D1. Were any other surgeries performed? Yes	YES	NO 2
SECTION D: OTHER OPERATIVE INFORMATION D1. Were any other surgeries performed? Yes		
SECTION D: OTHER OPERATIVE INFORMATION D1. Were any other surgeries performed? Yes	1	2
SECTION D: OTHER OPERATIVE INFORMATION D1. Were any other surgeries performed? Yes	1	2 2
SECTION D: OTHER OPERATIVE INFORMATION D1. Were any other surgeries performed? Yes	1 1 1	2 2 2

Circle yes or no for all	types:		YES	NO
	g.	Vaginal paravaginal repair	1	2
	h.	Abdominal (retropubic) paravaginal repair	1	2
	i.	Standard posterior colporrhaphy	1	2
	j.	Defect-directed posterior repair	1	2
	k.	Posterior repair with allograft or autograft placement	1	2
	1.	Vaginal hysterectomy	1	2
	m.	Abdominal hysterectomy	1	2
	n.	Oophorectomy	1	2
	0.	Hernia repair	1	2
	p.	Other	1₩	2
		SPECIFY:		
Medical Staff Present at S D2. Surgeon of record (Ir D2a. Did a resid	nitials):	Yes 1 No 2 D2b	. SPE	CIFY I
D2c. Did a fello	w assist?	Yes 1 No	. SPE	CIFY I Y= Post-0
D3. Was a non-study sur D3a. Speci		ent? Yes		
D4. Did any other medica		onal assist? Yes 1♥ No		SKIP
D5. Record entire operat	ive times in	•	:	
		b. Last wound closed:	:	

D6 – D10. What types(s) of anesthesia was used?

	Circle yes or no for all types listed:	YES	NO
	D6. General	1	2
	D7. Spinal	1	2
	D8. Epidural	1	2
	D9. Sedation	1	2
	D10. Local	1	2
D11.	Was the patient given prophylactic antibio	otics prio s	r to curgar
D11.	Yes 1	oties prio	i to surger
	No 2	→ SKIP	TO D12
	D11a. Administration time closest to fi	rst incisio	n:
D12.	Was a local pain medication administered	l hefore ir	ncision to
D12.	Yes 1		
	No 2	- 21 2 4	
D12	w 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
D13.	Was a local pain medication administered		_
	Yes 1 No	→ D13a.	. ivicuicati
	1,0		
D14.			heter
			catheter
	No	one	
D15.	What type of wound drain was in place?	JP	
		Penros	se
		Other.	
		None.	
D16.	Results of cystoscopy: Normal		1 → SKI
	Abnormal		2
	D16a. Describe:		
	Diou. Describe.		

SECTION E: OPERATIVE COMPLICATIONS DURING SURGERY

REMINDER: COMPLETE ADVERSE EVENT FORMS AS REQUIRED

a. Bladder injury b. Urethral injury 1 2 c. Ureteral injury 1 2 d. Fistula 1 2 e. Intestinal injury 1 2 f. Rectal injury 1 2 g. Vascular injury 1 2 h. Nerve injury 1 4 2 Specify site: i. Other 1	b. Urethral injury c. Ureteral injury d. Fistula e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: Vere there any treatments for organ injuries that occurred during surgery? Yes	b. Urethral injury c. Ureteral injury d. Fistula e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: I Vere there any treatments for organ injuries that occurred during surgers	s or no for	all types listed:	YES	NO
c. Ureteral injury d. Fistula e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: 1	c. Ureteral injury 1 2 d. Fistula 1 2 e. Intestinal injury 1 2 f. Rectal injury 1 2 g. Vascular injury 1 2 h. Nerve injury 1 ♥ 2 Specify site:	c. Ureteral injury d. Fistula e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: j. Were there any treatments for organ injuries that occurred during surgers	a.	Bladder injury	1	2
d. Fistula e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: 1	d. Fistula e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: 1	d. Fistula e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: Were there any treatments for organ injuries that occurred during surgestimates and the state of the	b.	Urethral injury	1	2
e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: 1	e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: j. Were there any treatments for organ injuries that occurred during surgery? Yes	e. Intestinal injury f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: j. Were there any treatments for organ injuries that occurred during surgers.	c.	Ureteral injury	1	2
f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: 1 2 4 2 Specify site: 5 Specify: 1 4 2 Specify: 1 5 2 Specify: 1 7 2 Specify: 1 8 2 Specify: 1 9 2 Specify: 1 9 2 Specify: 1 1 9 2 Specify: 1 1 1 1 2 Specify: 1 1 2 Specify: 1 1 2 Specify: 1 2 2 Specify: 1 1 2 2 Specify: 1 2 2 Specify: 1 1 2 2 Specify: 1 2 2 Specify: 1 1 2 2 Specify: 1 2 2 Specify: 1 2 2 Specify: 1 1 2 2 Specify: 1 2 2 Specify: 1 1 2 2 Specify: 1 2 2 2 2 Specify: 1 2 2 2 2 Specify: 1 2 2 2 2 2 Specify: 1 3 2 2 2 2 Specify: 1 3 2 2 2 Specify: 1 4 2 2 2 Specify: 1 5 2 2 2 Specify: 1 5 2 2 2 2 Specify: 1 5	f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: j. Were there any treatments for organ injuries that occurred during surgery? Yes	f. Rectal injury g. Vascular injury h. Nerve injury Specify site: i. Other Specify: 1	d.	Fistula	1	2
g. Vascular injury h. Nerve injury Specify site: i. Other Specify: Specify: 1	g. Vascular injury h. Nerve injury Specify site: i. Other Specify: j. Were there any treatments for organ injuries that occurred during surgery? Yes	g. Vascular injury h. Nerve injury Specify site: i. Other Specify: Specify: 1 2 4 2 5 2 5 2 5 2 5 3 5 3 6 4 7 6 7 7 5 7 8 6 7 9 7 9 8 7 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9	e.	Intestinal injury	1	2
h. Nerve injury Specify site: i. Other Specify: Specify: Were there any treatments for organ injuries that occurred during surgery? Yes	h. Nerve injury Specify site: i. Other Specify: Specify: 1	h. Nerve injury Specify site: i. Other Specify: j. Were there any treatments for organ injuries that occurred during surgetimes.	f.	Rectal injury	1	2
Specify site: i. Other Specify: Specify: Specify: 1	Specify site:	Specify site: i. Other Specify: Specify: j. Were there any treatments for organ injuries that occurred during surgestime.	g.	Vascular injury		2
i. Other 1	i. Other 1	i. Other 1	h.		1♥	2
Specify:	j. Were there any treatments for organ injuries that occurred during surgery? Yes	j. Were there any treatments for organ injuries that occurred during surg				
Were there any treatments for organ injuries that occurred during surgery? Yes	j. Were there any treatments for organ injuries that occurred during surgery? Yes	j. Were there any treatments for organ injuries that occurred during surg	i.	Other	1₩	2
Yes 1	Yes 1			Specify:		
No 2 → SKIP TO E2	No 2 → SKIP TO E2		Were there ar	y treatments for organ inju		during s
		No	Yes	-		

ircle yes or n	o for all types listed:	YES	NO	
	a. Myocardial infarction	1	2	
	b. Cerebrovascular accident	1	2	
	c. Other	1₩	2	
	Specify:			
No.		at occurred durin	10 Surgery	ing surgery?
No.		at occurred durii	ng surgery	
No.	2 → SKIP TO E3			

Were any cardiovascular complications recognized intra-operatively?

E2.

E3	3b. Were there any treatments for any other complications of any kind that occurred during surgery?
	Yes 1
	No
F.2	
E3	Sc. Describe any treatments for any other operative complications:
E4	Estimated blood loos.
E4.	Estimated blood loss: ml
E5.	Did the patient receive a red blood cell transfusion during surgery?
	Yes 1
	No
	E5a. Number of autologous units: units
	E5b. Number of non-autologous units: units
E6.	Did the patient experience an anesthetic complication requiring admission to the ICU?
	Yes 1
	No 2
E7.	Did the patient expire ?
	Yes 1
	No 2
* <i>RE</i>	EMINDER: COMPLETE ADVERSE EVENT FORMS & DEATH FORM AS REQUIRED
SECT	ΓΙΟΝ F: SURGEON'S SIGNATURE
Surge	eon's Signature: Date:/
	Month Day Year