



SE	CTION A: C	GENERAL ST	UDY INFOR	RMATION FO	OR OFFICE USE ONLY:	
A1. STUDY ID#:	LABEL			A2.	VISIT # F/U 2 Weeks TF2W	
A3. DATE INTERVIEW COM	IPLETED: MOI	NTH DAY	/YEAR	A4.	INTERVIEWER INITIALS:	
A5. INTERVIEW TYPE?		1		A6.	FORM VERSION USED? ENGLISH	
	int_type 1 2	Frequency 565 24	Percent 95.93 4.07	Cum Freq 565 589	Cum Percent 95.93 100.00	
SECTION B: BLADDER AND BOWEL SYMPTOMS						
B1. Compared to before your surgery for urinary incontinence, have you had an increase in your frequency of urination? YES						
	UR_FREQ	Frequency	Percent	Cum Freq	Cum Percent	
	1	137	23.26	137	23.26	
	2 452 76.74 589 100.00					
B2. Do you currently h	ave to					
YES NO						
a strain to uring	ate?		•••••		1 2	
	STRAIN_UR	Frequency	Percent	Cum Freq	Cum Percent	
	1	34	5.77	34	5.77	
	2	555	94.23	589	100.00	
h hend forwar	d to urinate?				1 2	

BEND_UR	Frequency	Percent	Cum Freq	Cum Percent
1	84	14.26	84	14.26
2	505	85.74	589	100.00

LEAN_UR	Frequency	Percent	Cum Freq	Cum Percent
1	35	5.94	35	5.94
2	554	94.06	589	100.00

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STAND_UR	Frequency	Percent	Cum Freq	Cum Percent
1	9	1.53	9	1.53
2	580	98.47	589	100.00

2

PRESS_UR	Frequency	Percent	Cum Freq	Cum Percent
1	12	2.04	12	2.04
2	577	97.96	589	100.00

f. ... push on the vagina or perineum to empty your bladder? 1 2

PUSH_UR	Frequency	Percent	Cum Freq	Cum Percent
1	5	0.85	5	0.85
2	584	99.15	589	100.00

OTH_ACC_UR	Frequency	Percent	Cum Freq	Cum Percent
1	23	3.90	23	3.90
2	566	96.10	589	100.00

B2h. If yes, describe:

В3.	How bothered are your surgery? Would you	•	ay you now ui	rınate compar	ed to how yo	ou urinated prior t	to the
	Not at all bo	thered		. 1			
	Slightly both	nered		. 2			
	Moderately	bothered		. 3			
	Greatly both	ered		. 4			
							_
		UR_BOTH	Frequency	Percent	Cum Freq	Cum Percent	
		1	463	78.61	463	78.61	
		2	92	15.62	555	94.23	
		3	26	4.41	581	98.64	Affix ID Label Here
		4	8	1.36	589	100.00	
B4.	Would you describe a a steady strea	-				TES NO 1 2	
	9	STEADY_STR	Frequency	Percent	Cum Freq	Cum Percent	\neg / /
	1	_	495	84.04	495	84.04	
	2	2	94	15.96	589	100.00	
b.	a slow stream of u					2	-
		SLOW_STR	Frequency	Percent	Cum Freq	Cum Percent	
		2	257 332	43.63 56.37	257 589	43.63 100.00	
		2	332	30.37	369	100.00	_
c.	a spurting, splitting	g or sprayin	g stream of u	rine?	1	2	_
		SPURT_STR	Frequency	Percent	Cum Freq	Cum Percent	
		1	97	16.47	97	16.47	
		2	492	83.53	589	100.00	
d.	a hesitating stream	of urine (st	ops and starts	s)?	1	2	
	Г	HESIT STR	Frequency	Percent	Cum Freq	Cum Percent	
		1	166	28.18	166	28.18	
		2	423	71.82	589	100.00	
	_		1	'			
e.	dribbling after you	have finish	ed urinating?		1	2	
		DRIB_STR	Frequency	Percent	Cum Freq	Cum Percent	1
		1	187	31.75	187	31.75	
		2	402	68.25	589	100.00	
			<u> </u>				
f.	some other descrip	tion?			1	4 2	

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OTH_STR	Frequency	Percent	Cum Freq	Cum Percent
1	38	6.45	38	6.45
2	551	93.55	589	100.00

B3g. If yes, describe:

B5.	Do you currently	v experience a	feeling of incon	nplete bladder	emptying?

YES...... 1

NO...... 2

INC_EMPTY	Frequency	Percent	Cum Freq	Cum Percent
1	110	18.68	110	18.68
2	479	81.32	589	100.00

B6. How would you describe the **time it takes** to urinate now, compared to before your surgery? Would you say there's been no change, or does it seem to take more or less time to urinate now compared to before the surgery?

NO CHANGE 1

TAKES LESS TIME TO URINATE

		\ /		
UR_TIME	Frequency	Percent	Cum Freq	Cum Percent
•	3	•	•	•
1	209	35.67	209	35.67
2	263	44.88	472	80.55
3	114	19.45	586	100.00

B7. These next few questions ask about any symptoms of bowel incontinence you may have.

Do you have to strain to have a bowel movement?

YES..... 1

NO...... 2 → SKIP TO B8

STR_BM	Frequency	Percent	Cum Freq	Cum Percent
1	153	25.98	153	25.98
2	436	74.02	589	100.00

B7a. How often do you have to strain to have a bowel movement? Would you say....

Less than or equal to 25% of the time? 1

OFT_STR_BM	Frequency	Percent	Cum Freq	Cum Percent
•	436	•	•	•
1	74	48.37	74	48.37
2	79	51.63	153	100.00

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B8. Do you have leaking or loss of control of gas? YES 1

NO...... 2 → SKIP TO B9

GAS_LK	Frequency	Percent	Cum Freq	Cum Percent
1	152	25.81	152	25.81
2	437	74.19	589	100.00

B8a. How **often** does this happen? Would you say....

OFT_GAS_LK	Frequency	Percent	Cum Freq	Cum Percent
	437	•	•	•
1	10	6.58	10	6.58
2	32	21.05	42	27.63
3	60	39.47	102	67.11
4	50	32.89	152	100.00

B9. Do you have leaking or loss of control of liquid stool?

YES..... 1

NO...... 2 → SKIP TO B10

LIQ_STOOL_LK	Frequency	Percent	Cum Freq	Cum Percent
1	34	5.77	34	5.77
2	555	94.23	589	100.00

B9a. How **often** does this happen? Would you say....

less than once a month? ______1

more than once a month but less than once a week?............ 2

more than once a week but less than every day?..... 3

every day?......4

OFT_LIQ_LK	Frequency	Percent	Cum Freq	Cum Percent
•	555	•	•	•
1	22	64.71	22	64.71
2	5	14.71	27	79.41
3	7	20.59	34	100.00

B10. Do you have leaking or loss of control of solid stool?

YES..... 1

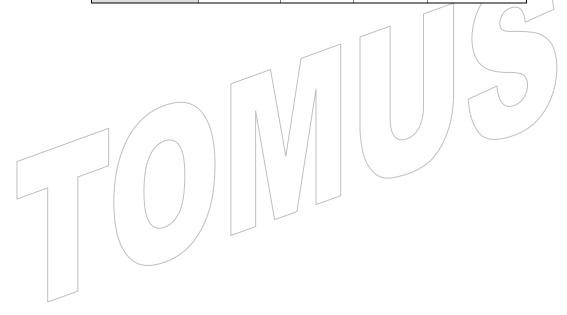
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SOL_STOOL_LK	Frequency	Percent	Cum Freq	Cum Percent
1	7	1.19	7	1.19
2	582	98.81	589	100.00

B10a. How **often** does this happen? Would you say....

less than once a month?	1
more than once a month but less than once a week?	2
more than once a week but less than every day?	3
every day?	4

OFT_SOLID_LK	Frequency	Percent	Cum Freq	Cum Percent
•	582	•	•	•
1	5	71.43	5	71.43
3	2	28.57	7	100.00



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SECTION C: NEUROLOGIC SYMPTOMS

INSTRUCTIONS: We also want to know if you have any numbness or weakness in your lower abdomen or your pelvic area or in your lower extremities.

C1. First, I'll ask about numbness. Do you have any **numbness** in your lower abdomen or your pelvic area or your legs?

YES..... 1*

NO...... 2

2 **→** SKIP TO C2

NUMBNESS	Frequency	Percent	Cum Freq	Cum Percent
1	29	4.92	29	4.92
2	560	95.08	589	100.00

REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

SHOW ATTACHED BODY MAPS 1, 2, 4, AND 6 FOR MARKING NUMBNESS:

Here are 4 pictures of those areas. The specific areas we're asking about are circled on the pictures. Take a minute to look at the pictures and mark Xs to show where you feel numbness.

WHEN THE PATIENT COMPLETES HER MARKINGS, INSPECT THE PICTURES AND COMPLETE C1a-e.

C1a. DID THE PATIENT MARK ANY Xs IN THE SUPRAPUBIC AREA (PICTURE #1)?

YES

NO |....\..

→ SKIP TO C11

\				
NUM_SUP	Frequency	Percent	Cum Freq	Cum Percent
	560	•	•	•
1	13	44.83	13	44.83
2	16	55.17	29	100.00

C1ai. SHOW PICTURE #1: How bothersome is the numbness in **this** location? Would you say...

not at all bothersome 1

moderately bothersome 3

greatly bothersome 4

NUM_SUP_BOTH	Frequency	Percent	Cum Freq	Cum Percent
•	576	•	•	•
1	11	84.62	11	84.62
2	2	15.38	13	100.00

C1b. DID THE PATIENT MARK ANY Xs IN THE **GROIN** AREA? (PICTURE #2)

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NUM_GRO	Frequency	Percent	Cum Freq	Cum Percent
•	560	•		•
1	5	17.24	5	17.24
2	24	82.76	29	100.00

C1bi. SHOW PICTURE #2: How bothersome is the numbness in **this** location? Would you say...

not at all bothersome 1

slightly bothersome 2

moderately bothersome 3

greatly bothersome 4

NUM_GRO_BOTH	Frequency	Percent	Cum Freq	Cum Percent
•	584			•
2	2	40.00	2	40.00
3	1	20.00	3	60.00
4	2	40.00	5	100.00

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C1c. DID THE PATIENT MARK ANY Xs IN THE VULVAR AREA? (PICTURE #4)

NUM_VUL	Frequency	Percent	Cum Freq	Cum Percent
•	560	•	•	•
1	4	13.79	4	13.79
2	25	86.21	29	100.00

C1ci. SHOW PICTURE #4: How bothersome is the numbness in **this** location? Would you say...

not at all bothersome 1

moderately bothersome 3

greatly bothersome 4

NUM_VUL_BOTH	Frequency	Percent	Cum Freq	Cum Percent
•	585			
1	1	25.00	1	25.00
2	1	25.00	2	50.00
3	1	25.00	3	75.00
4	1	25.00	4	100.00

C1d. DID THE PATIENT MARK ANY Xs IN THE UPPER LEG AREA? (PICTURE #6)

NO.	∤	لمهرو	2	7	SKIP	10	Cle

NUM_UL	Frequency	Percent	Cum Freq	Cum Percent
•	560	•	•	•
1	10	34.48	10	34.48
2	19	65.52	29	100.00

C1di. SHOW PICTURE #6 FOR NUMBNESS:

How bothersome is the numbness in this location? Would you say...

not at all bothersome 1

slightly bothersome 2

moderately bothersome 3

greatly bothersome 4

NUM_UL_BOTH	Frequency	Percent	Cum Freq	Cum Percent
•	579			
2	7	70.00	7	70.00
3	1	10.00	8	80.00
4	2	20.00	10	100.00

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C1e. DID THE PATIENT MARK ANY Xs IN THE **LOWER LEG** AREA? (PICTURE #6)

NUM_LL	Frequency	Percent	Cum Freq	Cum Percent
•	560	•	•	•
1	6	20.69	6	20.69
2	23	79.31	29	100.00

C1ei. SHOW PICTURE #6 FOR NUMBNESS:

How bothersome is the numbness in **this** location? Would you say...

not at all bothersome 1

slightly bothersome 2

moderately bothersome 3

greatly bothersome 4

			1		
NUM_LL_BOTH	Frequency	Percent	Cum Freq	Cum Percent	_
	583				
2	2	33.33	2	33.33	
3	2	33.33	4	66.67	
4	2	33.33	6	100.00	

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C2. Next, I'll ask about weakness. Do you have any **weakness** in your legs?

WEAKNESS	Frequency	Percent	Cum Freq	Cum Percent
1	36	6.11	36	6.11
2	553	93.89	589	100.00

REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

SHOW PICTURE # 6 FOR WEAKNESS: Here is a (another) picture of the legs. Look at the picture and mark Xs to show where you feel weakness.

WHEN THE PATIENT COMPLETES HER MARKINGS, INSPECT THE PICTURE AND FINISH C2 a-b.

C2a. DID THE PATIENT MARK ANY Xs IN THE **UPPER LEG** AREA?

WEAK_UL	Frequency	Percent	Cum Freq	Cum Percent
	553		•	•
1	27	75.00	27	75.00
2	9	25.00	36	100.00

C2ai. SHOW PICTURE #6 FOR WEAKNESS: POINT TO Xs MARKED ON UPPER LEG. How bothersome is the weakness in **this** location? Would you say...

not at all bothersome 1

slightly bothersome 2

moderately bothersome 3

greatly bothersome 4

WEAK_UL_BOTH	Frequency	Percent	Cum Freq	Cum Percent
	562	•	•	•
1	3	11.11	3	11.11
2	9	33.33	12	44.44
3	11	40.74	23	85.19
4	4	14.81	27	100.00

C2b. DID THE PATIENT MARK ANY Xs IN THE **LOWER LEG** AREA?

WEAK_LL	Frequency	Percent	Cum Freq	Cum Percent
	553	•	•	•
1	17	47.22	17	47.22
2	19	52.78	36	100.00

C2bi. SHOW PICTURE #6 FOR WEAKNESS: POINT TO Xs MARKED ON LOWER LEG. How bothersome is the weakness in **this** location? Would you say...

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not at all bothersome	1
slightly bothersome	2
moderately bothersome	3
greatly bothersome	4

WEAK_LL_BOTH	Frequency	Percent	Cum Freq	Cum Percent
•	572	•		
1	2	11.76	2	11.76
2	9	52.94	11	64.71
3	3	17.65	14	82.35
4	3	17.65	17	100.00

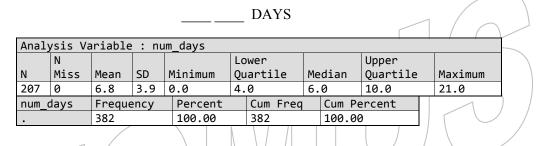


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SECTION D: RESUMPTION OF ACTIVITIES

D1.	Have you return	ed to full norma	al activities of	daily life (in	ncluding worl	k, if applicable) si	nce your surgery?
	YES	1					
	NO	2 →	SKIP TO D	2			
		RETURN ACT	Frequency	Percent	Cum Freq	Cum Percent	l
		1	209	35.48	209	35.48	
		2	380	64.52	589	100.00	

D1a. (Approximately) how many days did it take you to return to full normal activities of daily life (including work, if applicable) after surgery?



D1b. How many paid workdays did you take off after surgery?

DAYS **SKIP TO E1**

(IF UNEMPLOYED OR RETIRED, CODE -1)

Analy	Analysis Variable : paid_days										
	N					Low	er			Upper	
N	Miss	Mean	SD	Mi	nimum	Qua	rtile	Med	ian	Quartile	Maximum
134	0	4.4	3.7	0.	.0	1.0		4.0		7.0	14.0
paid	_days	Frequ	equency Percent		Percent	:	Cum Fre	q	Cum I	Percent	
•		455			100.00		455		100.0	90	

D2. If you have not returned to work, is that because your work includes activities such as heavy lifting, which you were advised not to do?

YES..... 1

NO..... 2

(IF UNEMPLOYED OR RETIRED, CODE -1)

WK_HVY_ACT	Frequency	Percent	Cum Freq	Cum Percent
	295	•	•	•
1	203	69.05	203	69.05
2	91	30.95	294	100.00

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SECTION E: HEALTH SERVICES UTILIZATION

E1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS** SINCE SURGERY? ASK,

Have you seen a doctor (nurse practitioner, physician's assistant) for any reason since your surgery?

YES..... 1

NO...... 2 → SKIP TO E3

PHYS_VISIT	Frequency	Percent	Cum Freq	Cum Percent
1	196	33.28	196	33.28
2	393	66.72	589	100.00

E2. DATES OF AND REASONS FOR ANY PHYSICIAN VISITS; ASK,

What was (were) the (approximate) date(s) and reason(s) for the physician (NP, PA) visit(s) since your surgery?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ♥

	a.	b.	c.
	APPROXIMATE DATE	REASON FOR THE VISIT	SOURCE CODE
1			
2			
3			

E3. DOES THE PATIENT REPORT-OR IS THERE EVIDENCE OF ANY **EMERGENCY ROOM VISITS** SINCE HER SURGERY? ASK,

Have you been to an emergency room for any reason since your surgery?

YES...... 1

NO...... 2 → SKIP TO E5

ER_VISIT	Frequency	Percent	Cum Freq	Cum Percent
1	16	2.72	16	2.72
2	573	97.28	589	100.00

E4. DATES OF AND REASONS FOR ANY **EMERGENCY ROOM** VISIT(S), ASK,

What was (were) the (approximate) date(s) and reason(s) for the emergency room visit(s) since your surgery?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ♥

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	a.	b.	c.
	APPROXIMATE DATE	REASON FOR THE ER VISIT	SOURCE CODE
1	//		
2	/		
3	/		



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E5.	DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY NEW ABDOMINAL OR PELVIC
	SURGERY SINCE HER UITN SURGERY? ASK,

Have you had any new abdominal or pelvic surgery since your surgery?

YES...... 1

NO...... 2 → SKIP TO E7

NEW_SURG	Frequency	Percent	Cum Freq	Cum Percent
1	5	0.85	5	0.85
2	584	99.15	589	100.00

E6. DATES OF AND DESCRIPTION OF NEW ABDOMINAL OR PELVIC SURGERIES. ASK,

Tell me more about these surgeries.

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ♥

	a.	b.	c.	d.	e.
	DATE OF SURGERY	SURGICAL CODE	SPECIFY (IF SURGICAL CODE = 07)	NAME OF SURGERY	SOURCE CODE
1.					
2.					
3.					

E7. OTHER THAN ANY DESCRIBED ABOVE IN E6, DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **HOSPITAL ADMISSIONS** SINCE HER SURGERY? ASK,

Have you been <u>hospitalized</u> for any (other) reason since your surgery?

YES..... 1

NO...... 2 → SKIP TO E9

HOS_ADMIT	Frequency	Percent	Cum Freq	Cum Percent
1	6	1.02	6	1.02
2	583	98.98	589	100.00

E8. DATES OF AND REASONS FOR HOSPITAL ADMISSIONS. ASK,

What was (were) the (approximate) date(s) and reason for each hospitalization that occurred since your surgery?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ♥

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	a.	b.	c.
	APPROXIMATE DATE	REASON FOR HOSPITALIZATION	SOURCE CODE
1	//		
2	/		
3	/		



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E9. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF **ANY ANTIBIOTICS** PRESCRIBED SINCE DISCHARGE?

Since your surgery, has a doctor prescribed any antibiotics?

YES 1

NO 2 → SKIP TO E11

ANTIBIOTICS	Frequency	Percent	Cum Freq	Cum Percent
1	109	18.51	109	18.51
2	480	81.49	589	100.00

E10. RECORD EACH ANTIBIOTIC BY NAME

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ♥

	a.	b.	c.	d.	e.
	ANTIBIOTIC NAME (PRINT NAME PRECISELY)		IS THE PATIENT STILL TAKING THIS MEDICATION?	REASON PRESCRIBED	SOURCE CODE†
1			YES1 NO2		
2			YES1 NO2		
3			YES1 NO2		

E11. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF **ANY MEDICATION** PRESCRIBED FOR THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS SINCE DISCHARGE? ASK,

Since your surgery, has a doctor prescribed any medication for the treatment of lower urinary tract symptoms?

YES 1

MED_TX_UT	Frequency	Percent	Cum Freq	Cum Percent
1	16	2.72	16	2.72
2	573	97.28	589	100.00

E12. RECORD EACH MEDICATION BY NAME

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ♥

	a.	b.	c.	d.	e.
	MEDICATION NAME (PRINT NAME PRECISELY)		IS THE PATIENT STILL TAKING THIS MEDICATION?	REASON PRESCRIBED	SOURCE CODE†
1			YES 1 NO2		
2			YES 1 NO2		
3			YES 1 NO2		

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REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

: SOURCE DOCUMENT REVIEW ATTESTATION

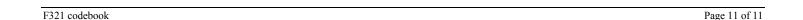
F1. Initials of Interviewer/Data Collector who completed a thorough review of all source documents (i.e. inpatient medical records, clinic charts, etc.) for any pertinent study information since the last study visit (e.g. adverse events, retreatments, interim visits, etc.):

F2. Date Review Completed:



Analy	ysis Va	ariable	: da	ys				
	N				Lower		Upper	
N	Miss	Mean	SD	Minimum	Quartile	Median	Quartile	Maximum
589	0	16.0	3.9	8.0	14.0	15.0	18.0	36.0

F3. Signature of Data Collector Completing F1:



Attachment

	SURGERY CODES
00	Urethrolysis/Tape Takedown
01	Abdominoplasty
02	Anterior repair
03	Cesarean delivery
04	Femoral hernia repair
05	Hysterectomy
06	Inguinal hernia repair
07	Laparoscopy
08	Posterior repair
09	Removal of an ectopic pregnancy
10	Removal of an ovarian cyst
11	Removal of both ovaries
12	Removal of one ovary
13	Supracervical hysterectomy
14	Tubal ligation
15	D and C (dilatation and curettage)
16	Colpopexy (abdominal)
17	Colpopexy (vaginal)
31	Enterocele repair
32	Vaginal vault suspension
18	UNKNOWN TYPE
19	OTHER

SLING REVISION CODES			
60	Tape loosening		
61	Tape incision		

	SURGERY FOR UI CODES
20	Anterior repair, Kelly plication, suburethral plication
21	Collagen injection
22	Durasphere injection
23	Other periurethral bulking agent
24	Laparoscopic Burch colposuspension
25	Marshall-Marchetti-Krantz (MMK) bladder suspension
26	Needle suspensions: Raz, Pereyra, Gittes
27	Open Burch colposuspension
28	Sling procedure (autologous or cadaveric)
29	Sling procedures (synthetic material)
30	Tightening of previous sling
38	UNKNOWN TYPE
39	OTHER

TREATMENT CODES	
40	Medicine (drug treatment)
41	Bladder training (including behavior changes involving the timing of urination or changes in fluid intake)
42	Pelvic muscle exercices (Kegel exercises)
43	Electrical stimulation
44	Electromagnetic therapy
45	Biofeedback
46	Acupuncture or other alternative medicine techniques
58	UNKNOWN TYPE
59	OTHER TYPE

F321 codebook Attachment