

F371: Annual Follow-Up Interview, version 03/09/09 (A)
SECTION A: GENERAL STUDY INFORMATION

A1. STUDY ID #:

LABEL

A2. VISIT # F/U 36 Months ET36 F/U 48 Months..... ET48
 F/U 60 Months ET60 F/U 72 Months..... ET72
 F/U 84 Months ET84

VISIT	Frequency	Percent	Cum Freq	Cum Percent
ET36	367	30.56	367	30.56
ET48	350	29.14	717	59.70
ET60	309	25.73	1026	85.43
ET72	148	12.32	1174	97.75
ET84	27	2.25	1201	100.00

A3. DATE INTERVIEW COMPLETED: ____ / ____ / ____
 MONTH DAY YEAR

A4. INTERVIEWER INITIALS: ____

A5. INTERVIEW TYPE? IN-PERSON 1
 TELEPHONE 2

A6. FORM VERSION USED? ENGLISH.... 1
 SPANISH 2

SECTION B: MESA

These questions ask about symptoms you may currently have related to urine leakage. For each question that I ask, please tell me the response that best represents how frequently you currently experience the symptom.

	NEVER	RARELY	SOMETIMES	OFTEN
B1. Does coughing gently cause you to lose urine? (Would you say...)	0	1	2	3

MESA_STR_1	Frequency	Percent	Cum Freq	Cum Percent
0:Never	899	74.85	899	74.85
1:Rarely	173	14.40	1072	89.26
2:Sometimes	97	8.08	1169	97.34
3:Often	32	2.66	1201	100.00

B2. Does coughing hard cause you to lose urine? (Would you say...)	0	1	2	3
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MESA_STR_2	Frequency	Percent	Cum Freq	Cum Percent
0:Never	742	61.78	742	61.78
1:Rarely	227	18.90	969	80.68
2:Sometimes	136	11.32	1105	92.01
3:Often	96	7.99	1201	100.00

B3. Does sneezing cause you to lose urine?	0	1	2	3
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MESA_STR_3	Frequency	Percent	Cum Freq	Cum Percent
0:Never	834	69.44	834	69.44
1:Rarely	175	14.57	1009	84.01
2:Sometimes	142	11.82	1151	95.84
3:Often	50	4.16	1201	100.00

B4. Does lifting things cause you to lose urine?	0	1	2	3
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MESA_STR_4	Frequency	Percent	Cum Freq	Cum Percent
0:Never	974	81.10	974	81.10
1:Rarely	106	8.83	1080	89.93
2:Sometimes	98	8.16	1178	98.08
3:Often	23	1.92	1201	100.00

B5. Does bending cause you to lose urine?	0	1	2	3
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MESA_STR_5	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
0:Never	1068	89.00	1068	89.00
1:Rarely	87	7.25	1155	96.25
2:Sometimes	36	3.00	1191	99.25
3:Often	9	0.75	1200	100.00

Frequency Missing = 1

B6. Does laughing cause you to lose urine?	0	1	2	3
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MESA_STR_6	Frequency	Percent	Cum Freq	Cum Percent
0:Never	975	81.18	975	81.18
1:Rarely	117	9.74	1092	90.92
2:Sometimes	91	7.58	1183	98.50
3:Often	18	1.50	1201	100.00

B7. Does walking briskly or jogging cause you to lose urine?	0	1	2	3
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MESA_STR_7	Frequency	Percent	Cum Freq	Cum Percent
0:Never	1015	84.51	1015	84.51
1:Rarely	75	6.24	1090	90.76
2:Sometimes	78	6.49	1168	97.25
3:Often	33	2.75	1201	100.00

B8. Does straining, if you are constipated, cause you to lose urine?	0	1	2	3
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MESA_STR_8	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
0:Never	857	71.42	857	71.42
1:Rarely	162	13.50	1019	84.92
2:Sometimes	142	11.83	1161	96.75
3:Often	39	3.25	1200	100.00

Frequency Missing = 1

B9. Does getting up from a sitting to a standing position cause you to lose urine?	0	1	2	3
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MESA_STR_9	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
0:Never	976	81.33	976	81.33
1:Rarely	112	9.33	1088	90.67
2:Sometimes	92	7.67	1180	98.33
3:Often	20	1.67	1200	100.00

Frequency Missing = 1

B10. Some women receive very little warning and suddenly find that they are losing, or are about to lose urine beyond their control. How often does this happen to you?	0	1	2	3
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MESA_URG_1	Frequency	Percent	Cum Freq	Cum Percent
0:Never	651	54.20	651	54.20
1:Rarely	328	27.31	979	81.52
2:Sometimes	167	13.91	1146	95.42
3:Often	55	4.58	1201	100.00

B11. If you can't find a toilet or find that the toilet is occupied, and you have an urge to urinate, how often do you end up losing urine or wetting yourself?	0	1	2	3
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MESA_URG_2	Frequency	Percent	Cum Freq	Cum Percent
0:Never	670	55.79	670	55.79
1:Rarely	303	25.23	973	81.02
2:Sometimes	159	13.24	1132	94.25
3:Often	69	5.75	1201	100.00

B12. Do you lose urine when you suddenly have the feeling that your bladder is very full?	0	1	2	3
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MESA_URG_3	Frequency	Percent	Cum Freq	Cum Percent
0:Never	713	59.37	713	59.37
1:Rarely	229	19.07	942	78.43
2:Sometimes	205	17.07	1147	95.50
3:Often	54	4.50	1201	100.00

B13. Does washing your hands cause you to lose urine?	0	1	2	3
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MESA_URG_4	Frequency	Percent	Cum Freq	Cum Percent
0:Never	1057	88.01	1057	88.01
1:Rarely	81	6.74	1138	94.75
2:Sometimes	47	3.91	1185	98.67
3:Often	16	1.33	1201	100.00

B14. Does cold weather cause you to lose urine?	0	1	2	3
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MESA_URG_5	Frequency	Percent	Cum Freq	Cum Percent
0:Never	1082	90.09	1082	90.09
1:Rarely	61	5.08	1143	95.17
2:Sometimes	41	3.41	1184	98.58
3:Often	17	1.42	1201	100.00

B15. Does drinking cold beverages cause you to lose urine?	0	1	2	3
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MESA_URG_6	Frequency	Percent	Cum Freq	Cum Percent
0:Never	1126	93.76	1126	93.76
1:Rarely	51	4.25	1177	98.00
2:Sometimes	20	1.67	1197	99.67
3:Often	4	0.33	1201	100.00

SECTION C: BLADDER SYMPTOMS

C1. Compared to before your surgery for urinary incontinence, have you had an increase in your frequency of urination?

YES..... 1

NO 2

FREQUEN_URIN	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	186	15.49	186	15.49
2: No	1015	84.51	1201	100.00

C2. Do you **currently** have to...

YES NO

a. ... strain to urinate? 1 2

STRAIN_UR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	71	5.91	71	5.91
2: No	1130	94.09	1201	100.00

b. ... bend forward to urinate? 1 2

BEND_UR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	188	15.65	188	15.65
2: No	1013	84.35	1201	100.00

c. ... lean back to urinate? 1 2

LEAN_UR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	58	4.83	58	4.83
2: No	1143	95.17	1201	100.00

d. ... stand up to urinate? 1 2

STAND_UR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	18	1.50	18	1.50
2: No	1183	98.50	1201	100.00

e. ... press on your bladder to urinate? 1 2

PRESS_UR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	54	4.50	54	4.50
2: No	1147	95.50	1201	100.00

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

PUSH_UR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	36	3.00	36	3.00
2: No	1165	97.00	1201	100.00

g. ... do anything else to urinate?..... 1↓ 2

C2h. If yes, describe: _____

OTH_ACC_UR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	49	4.08	49	4.08
2: No	1152	95.92	1201	100.00

C3. How bothered are you by the way you now urinate compared to how you urinated prior to the surgery? Would you say...

Not at all bothered..... 1

Slightly bothered..... 2

Moderately bothered 3

Greatly bothered..... 4

URINE_BOTHER	Frequency	Percent	Cum Freq	Cum Percent
1: Not at all bothered	926	77.10	926	77.10
2: Slightly bothered	197	16.40	1123	93.51
3: Moderately bothered	47	3.91	1170	97.42
4: Greatly bothered	31	2.58	1201	100.00

C4. Would you describe your **current** urine stream as...

YES NO

a. ... a steady stream of urine?..... 1 2

STEADY_STR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	990	82.43	990	82.43
2: No	211	17.57	1201	100.00

b. ... a slow stream of urine? 1 2

SLOW_STR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	356	29.64	356	29.64
2: No	845	70.36	1201	100.00

c. ... a spurting, splitting or spraying stream of urine? 1 2

SPURT_STR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	311	25.90	311	25.90
2: No	890	74.10	1201	100.00

d. ... a hesitating stream of urine (stops and starts)? 1 2

HESIT_STR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	338	28.14	338	28.14
2: No	863	71.86	1201	100.00

e. ... dribbling after you have finished urinating? 1 2

DRIB_STR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	478	39.80	478	39.80
2: No	723	60.20	1201	100.00

f. ... some other description? 1↓ 2

C4g. If yes, describe: _____

OTH_STR	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	26	2.16	26	2.16
2: No	1175	97.84	1201	100.00

C5. Do you currently experience a feeling of incomplete bladder emptying?

YES 1

NO 2

INC_BLADDER	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	279	23.23	279	23.23
2: No	922	76.77	1201	100.00

C6. 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 MORE TIME TO URINATE 2

TAKES LESS TIME TO URINATE 3

UR_TIME	Frequency	Percent	Cum Freq	Cum Percent
1: No change	642	53.46	642	53.46
2: Takes more time to urinate	429	35.72	1071	89.18
3: Takes less time to urinate	130	10.82	1201	100.00

C7. Have you used a catheter to empty your bladder since your last study visit?

YES 1

NO 2 ➔ **SKIP TO SECTION D**

CATH_EMPTY	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	17	1.42	17	1.42
2: No	1184	98.58	1201	100.00

C7a. How often did you use a catheter?

MONTHLY 1

WEEKLY 2

DAILY 3

OTHER 4

SPECIFY _____

CATH_EMP_OFT	Frequency	Percent	Cum Freq	Cum Percent
.	1184	.	.	.
1: Monthly	1	5.88	1	5.88
2: Weekly	1	5.88	2	11.76
3: Daily	4	23.53	6	35.29
4: Other	11	64.71	17	100.00

Frequency Missing = 1184

SECTION D: OTHER SYMPTOMS

D1. ASK, In the past year, ...

a. Have you had more than 1 urinary tract infection?

YES 1 ➔ **NOTE:** Check for Code 23 AEs;
Complete FE91 as needed.

NO 2

ONE_UTI	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	125	10.41	125	10.41
2: No	1076	89.59	1201	100.00

b. Have you had any vaginal discharge or bleeding that was concerning to you?

YES 1 ➔ **NOTE:** Check for AEs; Complete FE91 as needed.

NO 2

VAG_DISC_BLE	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	35	2.91	35	2.91
2: No	1166	97.09	1201	100.00

c. Have you had bleeding after intercourse?

YES.....1 ➔NOTE: Check for AEs; Complete
FE91 as needed.

NO.....2

N/A.....3

BLEED_INTERC	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	26	2.16	26	2.16
2: No	781	65.03	807	67.19
3: N/A	394	32.81	1201	100.00

d. Have you had pain during vaginal intercourse?

YES.....1 ➔NOTE: Check for AEs; Complete
FE91 as needed.

NO.....2

N/A.....3

PAIN_INTERC	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	131	10.91	131	10.91
2: No	670	55.79	801	66.69
3: N/A	400	33.31	1201	100.00

e. Has your partner complained of pain during vaginal intercourse?

YES.....1 ➔NOTE: Check for AEs; Complete
FE91 as needed.

NO.....2

N/A.....3

PART_PAIN	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	15	1.25	15	1.25
2: No	785	65.36	800	66.61
3: N/A	401	33.39	1201	100.00

f. Have you noticed any blood in your urine?

YES.....1 ➔NOTE: Check for AEs; Complete
FE91 as needed.

NO.....2

BLOOD_URINE	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	35	2.91	35	2.91
2: No	1166	97.09	1201	100.00

g. Have you had any physical pain that you feel is
directly related to your study surgery?

YES.....1

NO.....2

PHYS_PAIN	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	49	4.08	49	4.08
2: No	1152	95.92	1201	100.00

SECTION E: HEALTH SERVICES FOR UI, OTHER URINARY SYMPTOMS & COMPLICATIONS

FOR REFERENCE IN SECTION E: DATE OF LAST STUDY VISIT (FROM VCS):

____ / ____ / ____
Month Day Year

This next series of questions asks about any health care or treatments that you may have received since your last study visit that are related to your incontinence surgery and/or symptoms.

- E1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS RELATED TO STUDY SURGERY, OR TREATMENT OF UI SYMPTOMS INCLUDING UTIs, DIFFICULTY EMPTYING OR INCONTINENCE** SINCE THE LAST FOLLOW-UP VISIT? LOOK FOR EVIDENCE OF AEs. ASK,
Have you seen a doctor (nurse practitioner, physician's assistant) for any reason related to your study surgery or for treatment of any urinary symptoms including urinary tract infections, difficulty emptying your bladder or urinary incontinence since your last study visit (on DATE OF LAST VISIT)?

YES..... 1

NO 2 ➔ SKIP TO E3

- E2. DATES OF AND REASONS FOR **PHYSICIAN (NP, PA) VISITS**; ASK,
What was (were) the (approximate) date(s) and reason(s) for these physician (NP, PA) visit(s)?

	a. APPROXIMATE DATE	b. REASON FOR VISIT
1	____ / ____ / ____	_____
2	____ / ____ / ____	_____
3	____ / ____ / ____	_____

- E3. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **EMERGENCY ROOM VISITS** SINCE THE LAST FOLLOW-UP VISIT RELATED TO STUDY SURGERY OR URINARY SYMPTOMS? ASK,

Have you been to an emergency room for any reason related to your study surgery, incontinence or difficulty emptying your bladder since your last study visit (on DATE OF LAST VISIT)?

YES..... 1

NO 2 ➔ SKIP TO E5

- E4. DATES OF AND REASONS FOR ANY **EMERGENCY ROOM VISIT(S)**, ASK,
What was (were) the (approximate) date(s) and reason(s) for these emergency room visit(s)?

	a. APPROXIMATE DATE	b. REASON FOR VISIT
1	____ / ____ / ____	_____
2	____ / ____ / ____	_____
3	____ / ____ / ____	_____

- E5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NEW SURGERIES** SINCE THE LAST STUDY VISIT? ASK, Have you had any new surgeries due to pelvic, gynecologic, incontinence or any other urinary symptoms issues since your last study visit (on DATE OF LAST VISIT)?

YES..... 1 ➔ **ALSO DOCUMENT ON F372 IF APPLICABLE**

NO 2 ➔ **SKIP TO E7**

- E6. DATES OF AND DESCRIPTION OF NEW SURGERIES. ASK, Tell me more about these surgeries.

	<u>a. NAME OF SURGERY</u>	<u>b. SURG CODE</u>	<u>c. SPECIFY</u> (IF SURGICAL CODE = 07)	<u>d. DATE OF SURGERY</u>
1		_____		___ / ___ / _____
2		_____		___ / ___ / _____
3		_____		___ / ___ / _____

- E7. OTHER THAN ANY IN E6, DOES PATIENT REPORT OR IS THERE EVIDENCE OF ANY **HOSPITAL ADMISSIONS** RELATED TO UI OR URINARY SYMPTOMS SINCE LAST VISIT? ASK, Have you been hospitalized for any (other) reason related to your study surgery or urinary symptoms since your last study visit (on DATE OF LAST VISIT)?

YES..... 1

NO 2 ➔ **END FORM**

- E8. **ADMISSION DATES AND REASONS.** ASK, What was (were) the (approximate) date(s) and reason for each hospitalization noted?

	<u>a. APPROXIMATE DATE</u>	<u>b. REASON FOR HOSPITALIZATION</u>
1	___ / ___ / _____	_____
2	___ / ___ / _____	_____

REMINDER: COMPLETE ADVERSE EVENT FORMs (FE91) AS NECESSARY

Attachment

SURGERY CODES	
00	Urethrolisis/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	Enterocoele repair
32	Vaginal vault suspension
18	UNKNOWN TYPE
19	OTHER

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

SLING REVISION CODES	
60	Tape loosening
61	Tape incision