

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

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
B2. Does coughing hard cause you to lose urine? (Would you say...)	0	1	2	3
B3. Does sneezing cause you to lose urine?	0	1	2	3
B4. Does lifting things cause you to lose urine?	0	1	2	3
B5. Does bending cause you to lose urine?	0	1	2	3
B6. Does laughing cause you to lose urine?	0	1	2	3
B7. Does walking briskly or jogging cause you to lose urine?	0	1	2	3
B8. Does straining, if you are constipated, cause you to lose urine?	0	1	2	3
B9. Does getting up from a sitting to a standing position cause you to lose urine?	0	1	2	3
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
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
B12. Do you lose urine when you suddenly have the feeling that your bladder is very full?	0	1	2	3
B13. Does washing your hands cause you to lose urine?	0	1	2	3
B14. Does cold weather cause you to lose urine?	0	1	2	3
B15. Does drinking cold beverages cause you to lose urine?	0	1	2	3

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

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

	YES	NO
a. ... strain to urinate?	1	2
b. ... bend forward to urinate?.....	1	2
c. ... lean back to urinate?.....	1	2
d. ... stand up to urinate?.....	1	2
e. ... press on your bladder to urinate?.....	1	2
f. ... push on the vagina or perineum to empty your bladder?.....	1	2
g. ... do anything else to urinate?.....	1↓	2

C2h. If yes, describe: _____

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

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

	YES	NO
a. ... a steady stream of urine?	1	2
b. ... a slow stream of urine?.....	1	2
c. ... a spurting, splitting or spraying stream of urine?	1	2
d. ... a hesitating stream of urine (stops and starts)?.....	1	2
e. ... dribbling after you have finished urinating?.....	1	2
f. ... some other description?	1↓	2

C4g. If yes, describe: _____

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

YES..... 1

NO..... 2

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

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

YES..... 1

NO..... 2 →SKIP TO SECTION D

C7a. How often did you use a catheter?

MONTHLY 1

WEEKLY..... 2

DAILY..... 3

OTHER..... 4

SPECIFY _____

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.

NO2

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

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

NO2

c. Have you had bleeding after intercourse?

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

NO2

N/A.....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)?

	<u>a. APPROXIMATE DATE</u>	<u>b. REASON FOR VISIT</u>
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 (IF SURGICAL CODE = 07)</u>	<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	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	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