Form 31: 3 Month Follow-Up Assessment, Part I (Interview), Version 07/01/02 (A)

Section A: General Study Information for Office Use Only:

A1. STUDY ID#: LABEL

A2. VISIT # F/U 3 MONTHS. FU03

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

A4. INTERVIEWER'S INITIALS: ____ ____ ____

A5. INTERVIEW TYPE: IN-PERSON 1
TELEPHONE 2

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

SECTION B: THE MESA INTERVIEW

This first set of questions asks 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.

MESA PART I	*Never*	*Rarely*	*Sometime*	*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

MESA PART II	*Never*	*Rarely*	*Sometime*	*Often*
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? (Would you say….)	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? (Would you say….)	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

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SECTION C: ASSESSMENT OF OTHER PHYSICAL SYMPTOMS

IDENTIFY THE REFERENCE DATE FOR USE IN SECTION C and D:

DATE OF THE UITN INDEX SURGERY FROM THE VCS

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

The next set of questions asks about urinary and bowel symptoms you might currently be experiencing.

C1. Compared to before your surgery for urinary incontinence (on DATE OF SURGERY), 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 your surgery for urinary incontinence (on DATE OF 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. How would you describe the **time it takes** to urinate now, compared to before your surgery for urinary incontinence (on DATE OF SURGERY)? Would you say there's been no change, or does it seem to take more time or less time to urinate now compared to before surgery ?

NO CHANGE 1

TAKES MORE TIME 2

TAKES LESS TIME 3

C6. Next I have some questions about your <u>bowel movements.</u> Are you currently taking stool softeners?

YES..... 1

NO..... 2

C7. Do you currently have to strain to have a bowel movement?

YES..... 1

NO..... 2➔ **SKIP TO C8**

C7a. 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

More than 25% of the time? 2

C8. Do you currently have leaking or loss of control of gas?

YES..... 1

NO..... 2➔ **SKIP TO C9**

C8a. 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

C9. Do you currently have leaking or loss of control of liquid stool?

YES..... 1

NO..... 2➔ **SKIP TO C10**

C9a. 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

C10. Do you currently have leaking or loss of control of solid stool?

YES..... 1

NO..... 2➔ **SKIP TO SECTION D**

C10a. 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

SECTION D: STATUS OF PAIN AND PAIN MANAGEMENT

These next few questions are about pain and pain management.

D1. Do you take medication(s) specifically for pain related to your surgery for urinary incontinence?

YES ..... 1 ➔ **SKIP TO D3**

NO 2

*** Current medications must be recorded on the Medication Audit completed for this visit.**

D2. Do you <u>have</u> any physical pain that you feel is directly related to your surgery for urinary incontinence?

YES 1

NO ..... 2 ➔ **SKIP TO D4**

D3. Using a 10-point rating scale, where 0 is ***'no pain'*** and 10 is the ***'worst possible pain***', tell me how you would rate that pain. Remember, we want to know about pain that you feel is directly related to your surgery for urinary incontinence. (CIRCLE ONE)

0	1	2	3	4	5	6	7	8	9	10
No Pain										**Worst Possible Pain**

D4. Have you returned to full normal activities of daily life (including work, if applicable) since your surgery for urinary incontinence (ON DATE OF SURGERY)?

YES 1

NO ..... 2 ➔ **SKIP TO SECTION E**

D5. (Approximately) how many days did it take you to return to full normal activities of daily life (including work, if applicable) after surgery (ON DATE OF SURGERY)?

____ ____ DAYS

D6. How many **paid** workdays did you take off after your surgery for urinary incontinence?

____ ____ DAYS

(IF UNEMPLOYED OR RETIRED, CODE -1)

Affix ID Label Here

SECTION E: OTHER TREATMENTS / HEALTH SERVICES UTILIZATION

IDENTIFY THE REFERENCE DATE FOR USE IN SECTION E:

DATE OF THE 6-WEEK FU STUDY VISIT FROM THE 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.

E1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS RELATED TO SURGERY, OR TREATMENT OF URINARY SYMPTOMS INCLUDING URINARY TRACT INFECTIONS OR INCONTINENCE** SINCE THE 6-WEEK FOLLOW-UP VISIT? LOOK SPECIFICALLY FOR REPORTS OF COMPLICATIONS INCLUDED IN FM32. ASK,

Have you seen a doctor (nurse practitioner, physician's assistant) for any reason related to your UITN surgery or for treatment of any urinary symptoms including urinary tract infections or urinary incontinence since your last UITN study visit (on DATE OF 6-WEEK VISIT)?

YES..... 1

NO..... 2 ➔ **SKIP TO E3**

E2. DATES OF AND REASONS FOR ANY **PHYSICIAN VISITS FOR URINARY SYMPTOMS OR UITN SURGERY;** ASK,

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

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	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

†Record MR #s used here on the Visit Control Sheet

E3. IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS FOR ANY OTHER REASON** SINCE THE 6-WEEK FOLLOW-UP VISIT? LOOK SPECIFICALLY FOR REPORTS OF COMPLICATIONS INCLUDED IN FM32. ASK,

Have you seen a doctor (nurse practitioner, physician's assistant) for any other reason since your last UITN study visit (on DATE OF 6-WEEK VISIT)?

YES..... 1

NO..... 2 ➔ **SKIP TO E5**

E4. DATES OF AND REASONS FOR **ANY OTHER PHYSICIAN VISITS;** ASK,

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

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	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

†Record MR #s used here on the Visit Control Sheet

E5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY ONGOING **NON-SURGICAL** TREATMENT FOR URINARY INCONTINENCE? ASK,

Have you used or received any **non-surgical treatment(s)** for symptoms related to urine leakage / urinary incontinence since your last study visits (on DATE OF 6-WEEK VISIT)?

(**PROBE**: This would include any medications that you take or any bladder training programs that you follow or pelvic muscle exercises that you do; it would also include treatments you might receive such as acupuncture, biofeedback, electrical stimulation, or electromagnetic therapy.)

YES..... 1

NO..... 2 ➔ **SKIP TO E7**

E6. RECORD THE NAMES, CODES AND DATES OF ALL **NON-SURGICAL TREATMENTS** FOR UI. SAY,

Tell me more about that / those... (non-surgical treatments for urinary incontinence).

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

	a.	**b.**	**c.**	**d.**
	TYPE OF TREATMENT	**TREATMENT CODE***	**DATES OF TREATMENT**	**SOURCE CODE†**
1.		_____ ____	FROM: ___ ___ / ___ ___ / ___ ___ ___ ___ TO: ___ ___ / ___ ___ / ___ ___ ___ ___	_____
2.		_____ ____	FROM: ___ ___ / ___ ___ / ___ ___ ___ ___ TO: ___ ___ / ___ ___ / ___ ___ ___ ___	_____
3.		_____ ____	FROM: ___ ___ / ___ ___ / ___ ___ ___ ___ TO: ___ ___ / ___ ___ / ___ ___ ___ ___	_____

*** Current medications must also be recorded on the Medication Audit completed for this visit.**

†Record MR #s used here on the Visit Control Sheet

E7. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **EMERGENCY ROOM VISITS** SINCE HER 6 WEEK FOLLOW-UP VISIT? ASK,

Have you been to an emergency room for any reason since your last UITN study visit (on DATE OF 6-WEEK VISIT)?

YES..... 1

NO..... 2 ➔ **SKIP TO E9**

E8. 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 last UITN study visit?

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 ER VISIT**	**SOURCE CODE†**
1	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
2	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
3	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

†Record MR #s used here on the Visit Control Sheet

E9. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NEW ABDOMINAL OR PELVIC SURGERY** SINCE HER 6-WEEK FOLLOW-UP VISIT? ASK,

Have you had any new abdominal or pelvic surgery since your last UITN study visit (on DATE OF 6-WEEK VISIT)?

YES..... 1

NO..... 2 ➔ **SKIP TO E11**

E10. 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.**
	NAME OF SURGERY	**SURGICAL CODE**	**SPECIFY (IF SURGICAL CODE = 07)**	**DATE OF SURGERY**	**SOURCE CODE†**
1.		____ ____		___ ___ / ___ ___ / ___ ___ ___ ___	_____
2.		____ ____		___ ___ / ___ ___ / ___ ___ ___ ___	_____
3.		____ ____		___ ___ / ___ ___ / ___ ___ ___ ___	_____

†Record MR #s used here on the Visit Control Sheet

E11. OTHER THAN ANY DESCRIBED ABOVE IN E9, DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **HOSPITAL ADMISSIONS** SINCE HER 6 WEEK FOLLOW-UP VISIT? ASK,

Have you been hospitalized for any (other) reason since your last UITN study visit (on DATE OF 6-WEEK VISIT)?

YES..... 1

NO..... 2 ➔ **SKIP TO E13**

E12. DATES OF AND REASONS FOR **HOSPITAL ADMISSIONS**. ASK,

What was (were) the (approximate) date(s) and reason for each hospitalization that occurred since your last UITN study visit?

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 HOSPITALIZATION**	**SOURCE CODE†**
1	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
2	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____
3	___ ___ / ___ ___ / ___ ___ ___ ___	_____	_____

†Record MR #s used here on the Visit Control Sheet

E13. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF **ANY ANTIBIOTICS** PRESCRIBED SINCE HER 6-WEEK FOLLOW-UP VISIT? ASK ABOUT ANTIBIOTICS SHE REPORTED TAKING AT HER 6-WEEK FOLLOW-UP VISIT. (SEE THE PATIENT'S VCS.) ASK,

Since your last UITN study visit, has a doctor prescribed any antibiotics (on DATE OF 6-WEEK VISIT)?

YES 1

NO ..... 2 ➔ **SKIP TO SECTION F**

E14. 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)	**NUMBER OF DAYS TAKEN**	**IS THE PATIENT STILL TAKING THIS MEDICATION?**	**REASON PRESCRIBED**	**SOURCE CODE†**
1		_____ _____	YES..... 1 NO 2		_____
2		_____ _____	YES..... 1 NO 2		_____
3		_____ _____	YES..... 1 NO 2		_____

*** Current medications must also be recorded on the Medication Audit completed for this visit.**

†Record MR #s used here on the Visit Control Sheet

Affix ID Label Here

SECTION F: SUMMARY OF ADVERSE EVENTS/UNTOWARD OUTCOMES

F1. AS INDICATED BY THE RESPONSES RECORDED FOR THE PRECEDING QUESTIONS, IS THERE ANY EVIDENCE OF ANY **ADVERSE EVENTS OR UNTOWARD OUTCOMES** RELATED TO THE PATIENT'S UITN SURGERY OR ANY STUDY PROCEDURES SINCE HER 6 WEEK FOLLOW-UP VISIT (on DATE OF 6-WEEK VISIT)?

YES..... 1➔ **REMINDER: DOCUMENT ON FORM 32 AND COMPLETE ADVERSE EVENT FORM(S), IF REQUIRED**

NO..... 2

Attachment

PELVIC SURGERY CODES	
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
18	UNKNOWN TYPE
19	OTHER

PELVIC SURGERY FOR UI CODES	
20	Anterior repair, Kelly plication, suburethral plication
21	Collagen injection
22	Durasphere injection
23	Laparoscopic Burch colposuspension
24	Marshall-Marchetti-Krantz (MMK) bladder suspension
25	Needle suspensions: Raz, Pereyra, Gittes
26	Open Burch colposuspension
27	Sling procedure
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