Form 32: 3 Month Follow-Up Assessment, Part II, 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 Form Completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

A4. Initials of Person Completing this Form: ____ ____ ____
(Certified Surgeon)

SECTION B: Post-Discharge Complications

REMINDER: COMPLETE ADVERSE EVENT FORMS AS REQUIRED

DATE OF THE 6-WEEK STUDY VISIT	REFERENCE DATE:
DATE OF COMPLETION OF FORM 22 (6-WEEK F/U VISIT FROM VCS):	___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

B1. Were any **wound complications** newly identified since the patient's 6-week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes 1

No evidence ..... 2➔ **SKIP TO B2**

Circle yes or no for all types listed:	*YES*	*NO*
a. Separation	1	2
b. Hematoma	1	2
c. Infection	1	2
d. Infected hematoma	1	2
e. Abscess	1	2
f. Hernia	1	2
g. Sling erosion	1	2
h. Seroma	1	2
i. Other	1↓	2
Specify: _____		

B1j. Were there any treatments for this / these wound complications?

Yes..... 1

No ..... 2 ➔ **SKIP TO B2**

B1k. Describe these treatments: _____

B2. Were any **organ injuries** newly identified since the patient's 6-week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes 1

No evidence ..... 2 ➔ **SKIP TO B3**

Circle yes or no for all types:		***YES***	***NO***
a.	Bladder injury	1	2
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🡻	2
	Specify:_____		
i.	Other	1🡻	2
	Specify:_____		

B2j. Were there any treatments for this / these organ injury complication(s)?

Yes 1

No..... 2 ➔ **SKIP TO B3**

B2k. Describe these treatments: _____

B3. Were any **cardiovascular events** newly identified since the patient's 6-week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes 1

No evidence ..... 2 ➔ **SKIP TO B4**

Circle yes or no for all types:		***YES***	***NO***
a.	Deep vein thrombosis?	1	2
b.	Myocardial infarction?	1	2
c.	Cerebrovascular accident?	1	2
d.	Other	1🡻	2
	Specify: _____		

B3e. Were there any <u>treatments</u> for this / these CV events?

Yes 1

No ..... 2 ➔ **SKIP TO B4**

B3f. Describe these <u>treatments</u>: _____

B4. Were any **febrile morbidities** <u>newly</u> <u>identified</u> since the patient's 6-week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes 1

No evidence ..... 2 ➔**SKIP TO B5**

Circle yes or no for all types listed:		***YES***	***NO***
a.	Unexplained fever: ≥ 101˚ f (38.3 ˚ C)	1	2
b.	Pelvic cellulitis	1	2
c.	Culture-proven urinary tract infection	1	2
d.	Sepsis	1	2
e.	Infection at SP catheter site	1	2
f.	Other	1🡻	2
	Specify: _____		

B4g. Were there any <u>treatments</u> for this /these febrile morbidity complications?

Yes 1

No..... 2 ➔ **SKIP TO B5**

B4h. Describe these <u>treatments</u>: _____

_____

Affix ID Label Here

B5. Were any **pulmonary events** newly identified since the patient's 6-week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes 1

No evidence ..... 2 ➔ **SKIP TO B6**

Circle yes or no for all types listed:	***YES***	***NO***
a. Atelectasis	1	2
b. Pulmonary edema	1	2
c. Pneumonia	1	2
d. Pulmonary embolus	1	2
e. Aspiration pneumonia	1	2
f. Laryngospasm	1	2
g. Other🡻	1	2
Specify: _____		

B5h. Were there any treatments for this / these pulmonary events?

Yes 1

No ..... 2 ➔ **SKIP TO B6**

B5i. Describe these treatments: _____

B6. Were **any other complications of the surgery**, of any kind, newly identified since the patient's 6-week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes 1

No evidence ..... 2 ➔ **SKIP TO B7**

B6a. Describe: _____

B6b. Were there any treatments for this / these other post-discharge complications?

Yes 1

No ..... 2 ➔ **SKIP TO B7**

B6c. Describe these treatments: _____

Affix ID Label Here

B7. Has the patient had a red blood cell transfusion since her 6-week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes..... 1

No evidence..... 2 ➔ **SKIP TO B8**

B7a. Number of **autologous** units: _____ _____ **units**

B7b. Number of **non-autologous** units: _____ _____ **units**

B8. Has the patient developed vaginal prolapse since her 6 week follow-up visit (on DATE OF 6-WEEK VISIT)?

Yes 1

No evidence ..... 2 ➔**SKIP TO C1**

B8a. Describe**:** _____

_____

SECTION C: SUMMARY OF ADVERSE EVENTS/UNTOWARD OUTCOMES

C1. 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 31 AND COMPLETE ADVERSE EVENT FORM(S), IF REQUIRED**

No evidence 2