



Section A: General Study Information for Office Use Only:

A1. Study ID#:

Label

A2. Visit # F/U 6 weeks.....FU6W

A3. Date Form Completed: ___/___/___
Month Day Year

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

SECTION B: Post-Discharge Complications Per Physician's Assessment(s)

SECTION B SHOULD BE COMPLETED FOLLOWING THE PATIENT EXAMINATION BY THE SURGEON.

****REMINDER: COMPLETE ADVERSE EVENT FORMS AS REQUIRED****

B1. Were any **wound complications** newly identified since the patient's discharge after her UITN surgery?

Yes..... 1

No..... 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 discharge after her UITN surgery?

Yes 1

No..... 2 → **SKIP TO B3**

Circle yes or no for all types:

	<i>YES</i>	<i>NO</i>
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 complications** newly identified since the patient's discharge after her UITN surgery?

Yes 1

No 2 ➔ **SKIP TO B4**

Circle yes or no for all types:

	<i>YES</i>	<i>NO</i>
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 treatments for this /these CV complications?

Yes 1

No 2 ➔ **SKIP TO B4**

B3f. Describe these treatments: _____

B4. Were any **febrile morbidities** newly identified since the patient's discharge after her UITN surgery?

Yes..... 1

No 2 → **SKIP TO B5**

Circle yes or no for all types listed:

		<i>YES</i>	<i>NO</i>
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 treatments for this /these febrile morbidity complications?

Yes..... 1

No..... 2 → **SKIP TO B5**

B4h. Describe these treatments: _____

B5. Were any **pulmonary complications** newly identified since the patient's discharge after her UITN surgery?

Yes..... 1

No 2 ➔ **SKIP TO B6**

Circle yes or no for all types listed:

	<i>YES</i>	<i>NO</i>
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↓ Specify: _____	1	2

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

Yes..... 1

No 2 ➔ **SKIP TO B6**

B5i. Describe these treatments: _____

B6. Were **any other complications**, of any kind, newly identified since the patient's discharge after surgery?

Yes..... 1

No 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: _____

B7. Has the patient had a red blood cell transfusion since discharge after her UITN surgery?

Yes..... 1

No 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 discharge after her UITN surgery?

Yes 1

No 2 ➔ **SKIP TO SECTION C**

B8a. Describe: _____

SECTION C: SUMMARY OF ADVERSE EVENTS/COMPLICATIONS

C1. As indicated by the responses recorded for the preceding questions, is there any evidence of any **adverse events or complications** related to the patient’s UITN surgery or any study procedures?

Yes..... 1 ➔ **REMINDER: DOCUMENT ON FORM 21 AND COMPLETE ADVERSE EVENT FORM(S), IF REQUIRED**

No evidence 2