F311: Discharge Measures, version 03/27/06 (A)_rev08/30/07

UITN TOMUS

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Visit # Surgery ..... .TSRG

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

A4. Initials of Person Completing Section B: ____ ____ ____ (Certified Surgeon of Record)

SECTION B: ADVERSE EVENTS AND COMPLICATIONS – POST OPERATIVE

B1. Did the patient receive a **red blood cell transfusion** in the post-operative period?

Yes..... 1🡻 No ..... 2 ➔ **SKIP TO B2**

REMINDER: COMPLETE FORM 391 AS REQUIRED

B1a. Number of **autologous** units: _____ _____ units

B1b. Number of **non-autologous** units: _____ _____ units

B2. Did any adverse events or complications occur in the post-operative period? ***REVIEW BOX AT BOTTOM OF PAGE***

Yes..... 1🡻 No ..... 2 ➔ **SKIP TO SECTION C**

	Event Number (Refer to Pt AE Log)	**Event Code (Refer to Box Below)**	**If Event Code = 99, Specify**
a.	_____ _____	_____ _____➔	
b.	_____ _____	_____ _____➔	
c.	_____ _____	_____ _____➔	
d.	_____ _____	_____ _____➔	
e.	_____ _____	_____ _____➔	
f.	_____ _____	_____ _____➔	
g.	_____ _____	_____ _____➔	

REMINDER: COMPLETE SEPARATE FORM F391 FOR EACH ADVERSE EVENT OR COMPLICATION LISTED

EVENT CODES REFERENCE FOR B2

01 = Bladder Perforation
02 = Urethral Perforation
03 = Acute Renal Failure
04 = Anesthetic Complication
05 = Device Malfunction
06 = DVT
07 = Pulmonary Embolus
08 = MI
09 = CVA
10 = Death
11 = Intraoperative Bleeding
12 = Postoperative Bleeding
13 = Bowel Injury
14 = Rectal Injury
15 = Vascular Injury
16 = Mesh Complication: Erosion
17 = Mesh Complication: Exposure
18 = Surgical Site Infection: Superficial Incisional
19 = Surgical Site Infection: Deep Incisional
20 = Surgical Site Infection: Organ/Space
21 = Culture-Proven UTI
22 = Empiric UTI
23 = Recurrent UTI
24 = Fistula: Vesicovaginal
25 = Fistula: Urethrovaginal
26 = Fistula: Enterovesical
27 = Fistula: Rectovaginal
28 = Neurologic Symptoms
99 = Other

Affix ID Label Here

SECTION C: RETROGRADE FILL VOIDING TRIAL

SECTION C MAY BE COMPLETED BY A TOMUS CERTIFIED DATA COLLECTOR.

C1. Was a voiding trial completed prior to discharge?

Yes..... 1 No 2

C1a. What was the date of the last voiding trial? Date of surgery ..... 1 ➔ **SKIP TO C2**

Later than the date of surgery..... 2

Trial not done prior to discharge ..... **3 ➔ SKIP TO C1aii**

C1ai. Specify date voiding trial performed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

C1aii. Specify reason(s) the trial was not performed or performed later than the date of surgery:

Circle yes or no for all types listed:		***YES***	***NO***
a.	Concurrent surgery	1	2
b.	Bladder perforation	1	2
c.	Vaginal pack	1	2
d.	Regional anesthesia	1	2
e.	Over sedation	1	2
f.	Excessive discomfort	1	2
g.	Staffing constraints	1	2
h.	Other	1🡻	2
	Specify: _____		

C2. Was the bladder filled to 300mL or to bladder capacity <300mL?

300mL ..... 1 ➔ **SKIP TO C3**

Bladder capacity <300mL 2

Passive fill trial..... 3 ➔ **SKIP TO C3**

Trial not performed ..... 4 ➔ **SKIP TO C6**

C2a. Specify bladder capacity: **____ ____ ____ mL**

C3. Voided volume **____ ____ ____ mL** C4. PVR **____ ____ ____ mL**

C4a. Was the PVR calculated or measured? Calculated PVR 1

Measured PVR..... 2

Affix ID Label Here

C5. Outcome of the last voiding trial:

Pass..... 1

Fail 2

C6. Specify type of voiding management at discharge:

Urethral catheter..... 1

Clean intermittent self-catheterization (CISC)..... 2

Self-voiding 3

SECTION D: DISCHARGE INFORMATION

SECTION D MAY BE COMPLETED BY A TOMUS CERTIFIED DATA COLLECTOR.

D1. Date of hospital **admission**: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

D2. Date of **discharge**: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

D3. Was the patient **discharged with medications** specific to her recovery from the TOMUS surgery?

YES..... 1

NO ..... 2 ➔**SKIP TO D4**

D3a. List medications by name. Include all for which a script was written including controlled and uncontrolled medications:

MEDICATION	**NAME**
1	_____
2	_____
3	_____

D4. Date TOMUS Postoperative Instructions Distributed to Patient: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

D4a. Initials of Study Staff who Distributed TOMUS Postoperative Instructions: ___ ___ ___

D5. Initials of Person Completing Sections C and D: ___ ___ ___ (Initials) ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

SECTION E: SURGEON'S SIGNATURE

I have reviewed the above-stated information and am confirming its accuracy with my signature below.

Surgeon's Signature: _____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year