F591: Adverse Event, version 09/08/08 (A) _rev08/19/10

UITN ValUE

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. Study ID #: LABEL

A2. Date Form Completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

A3. Initials of Study Staff Completing this Form: ____ ____ ____

A4. Time Form Completed: ____ ____ : ____ ____ (Use Military Time)

SECTION B: ADVERSE EVENT INFORMATION

B1. Is this the initial report of an Adverse Event? ☐1Yes ☐2No

B2. Specify Event Number: _____ _____ **Refer to Pt AE Log. For Follow-Up Events, Use Event # From Initial Report**

B3. Describe Event: _____

_____

_____

_____

_____ **IF ADDITIONAL SPACE NEEDED, USE AN ADDITIONAL COMMENTS ATTACHMENT SHEET**

B4. Adverse Event Code (See Attachment): _____ _____ ➔

If code 99, Complete B4a.
If code 18, 19, or 20, Complete B4b.
If code 21, Complete B4c and B4d.
Otherwise, Skip to B5.

B4a. Specify Other: _____ ➔**SKIP TO B5**

B4b. Code 18/19/20 Location: ☐1Suburethral➔**B5** ☐2 Trocar Site➔ (Specify: _____)➔**B5** ☐3Other➔ (Specify: _____)➔**B5**

B4c. Code 21 Culture Results Organism (check all that apply): ☐ *E.Coli* ☐ *Proteus klebsiella* ☐ *Enterobacter* ☐ Other ➔ (Specify: _____)

B4d. Code 21 Culture Results CFU (check highest if >1): ☐1<10,000/mL ☐2 10,000-99,999/mL ☐3 >100,000/mL

B5. Date of Onset: ____ ____ / ____ ____ / ____ ____ ____ ____ (Month / Day / Year)

B6. Is event related to: ☐1Study Surgery➔ ☐2 Concomitant Surgery➔ ☐3Indeterminable➔ ☐4Not Related➔

B6a. Specify: _____

B7. ACTION TAKEN:

(Circle Yes or No for each)	YES	NO	
a. Medication	1➔	2	If yes, specify: _____
b. Surgery	1➔	2	If yes, specify: _____
c. Endoscopy	1➔	2	If yes, specify: _____
d. Radiologic	1➔	2	If yes, specify: _____
e. Other	1➔	2	If yes, specify: _____
f. None	1	2	

B8. GRADE: ____ ____ ____ ____

≥III ➔**SAE**

B9. SYSTEM: ____ ____

B10. STATUS/OUTCOME:
- ☐ 1 = Resolved ➔ Date of Resolution: ____ ____/____ ____/____ ____ ____ ____
- ☐ 2 = Ongoing
- ☐ 3 = Death ➔**Complete Death Form**
- ☐-8 = Unknown ➔**Explain in B3 & on AE Log**

B11. Is this event Grade III or higher? (Refer to B8) ☐1Yes➔ ☐2No

FAX FORM W/IN 72 HRS TO M. MIHOVA/DCC (617) 673–9515 & J. KUSEK/NIDDK (301) 480-3510

Principal Investigator's Signature: _____ Initials: ____ ____ ____ Date: ____ ____/____ ____/____ ____ ____ ____ (Month / Day / Year)

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EVENT CODES

01 = Bladder Perforation	09 = CVA	17 = Mesh Complication: Exposure (i.e. vagina)	23 = Recurrent UTI
02 = Urethral Perforation	10 = Death	18 = Surgical Site Infection: Superficial Incisional	24 = Fistula: Vesicovaginal
03 = Acute Renal Failure	11 = Intraoperative Bleeding	19 = Surgical Site Infection: Deep Incisional	25 = Fistula: Urethrovaginal
04 = Anesthetic Complication	12 = Postoperative Bleeding	20 = Surgical Site Infection: Organ/Space	26 = Fistula: Enterovesical
05 = Device Malfunction	13 = Bowel Injury	21 = Culture-Proven UTI	27 = Fistula: Rectovaginal
06 = DVT	14 = Rectal Injury	22 = Empiric UTI	28 = Granulation Tissue
07 = Pulmonary Embolus	15 = Vascular Injury		29 = Voiding Dysfunction
08 = MI	16 = Mesh Complication: Erosion (i.e. into an organ)		99 = Other

SEVERITY[1] GRADING

Grade		Definition
I		Any deviation from the normal intraoperative or postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside (silver nitrate = grade I)
II		Requiring pharmacological treatment with drugs other than such allowed for grade I complications
	IIa	Oral or topical administration of drugs other than such allowed for grade I, including antibiotics for wound or bladder infections (e.g. premarin cream = IIa)
	IIb	IV administration of drugs other than such allowed for grade I, including antibiotics; blood transfusions and total parenteral nutrition are also included
III		Requiring surgical, endoscopic or radiological intervention
	IIIo	Additional surgical measures required during study/index procedure (includes cystotomies and vag. epithelium perfs)
	IIIa	Intervention not under general anesthesia (includes in-office diagnostic cysto)
	IIIb	Intervention under general anesthesia
IV		Life-threatening complication (including CNS complications)* requiring IC/ICU management
	IVa	Single organ dysfunction (including dialysis)
	IVb	Multiorgan dysfunction
V		Death of a patient
Suffix "d"		If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

[1]Modified from*:* Dindo D, Demartines N, Clavien PA. Classification of surgical complications. A new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Annals of Surgery* 2004; 240:205-213.

SYSTEM CATEGORIES

	System Categories	Examples
01	**ALLERGIES**	Drug reaction
02	**CONSTITUTIONAL**	Fevers/chills, fatigue, dizziness, headache
03	**DERMATOLOGIC**	(Not related to wound), rash, ecchymosis, tape reaction, candida
04	**GI**	Ileus, enterovesical fistula, gastritis, constipation, nausea after 24 hours post-op
05	**GU**	Vesicovaginal fistula, urethrovaginal fistula, cystitis, pyelonephritis, bladder injury, dysuria, stones, suprapubic pain
06	**MUSCULOSKELETAL**	Aches/pains, back pain
07	**NEUROLOGIC**	Weakness, paralysis, numbness, CVA, sciatica
08	**PSYCHIATRIC**	Depression, suicidal thoughts, hallucinations, delirium
09	**PULMONARY**	Pneumonia, atelectasis, (not PE)
10	**CARDIOVASCULAR**	MI, a-fib, CHF, arrhythmia
11	**VASCULAR/HEMATOLOGIC**	Blood vessel injury, thromboembolic event (DVT & PE), bleeding, DIC
12	**PELVIC**	Pain, dyspareunia
13	**WOUND**	Infection, mesh erosion, discharge, chronic sinus, hernia
14	**ANESTHETIC COMPLICATION**	Spinal headache, laryngospasm, hoarseness, failed intubation

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ADVERSE EVENT DEFINITIONS

- Bladder Perforation: Unplanned piercing made through the bladder, recognized intraoperatively.
- Urethral Perforation: Unplanned piercing or creation of an opening in the urethra, recognized intraoperatively.
- Acute Renal Failure: As diagnosed by a nephrology consult. 6 week reporting limit.
- Anesthetic Complication 6 week reporting limit.
- Device Malfunction: Any abnormal occurrence attributable specifically to the sling device during placement, i.e. trocar releases from sling material, abnormality of the protective sleeve surrounding the sling material, etc. Recognized intraoperatively.
- Deep Venous Thrombosis: Initiation of anticoagulation therapy for a thromboembolic event. 6 week reporting limit.
- Pulmonary Embolus: Diagnosed within 6 weeks of surgery or at any time secondary to a DVT that was diagnosed within 6 weeks of surgery.
- Myocardial Infarction: Documented by ECG changes or elevation of cardiac enzymes, as confirmed by cardiology consult, within 6 weeks of surgery.
- Cerebrovascular Accident: Documented by CT scan or neurologic consultation within 6 weeks after surgery.
- Death 6 week reporting limit.
- Bleeding: Intraoperative: pelvic and obturator vessels, abdominal wall; Estimated blood loss (EBL) greater than 500 cc.
  Postoperative: pelvis, thigh, vagina, abdominal wall; Bleeding from a wound or from a contained space that resulted in intervention. 6 week reporting limit.
- Bowel Injury: Confirmation of injury to small or large bowel by laparotomy or imaging studies. 6 week reporting limit.
- Rectal Injury: Perforation of the rectum. 6 week reporting limit.
- Vascular Injury: Injury to a major blood vessel, diagnosed by imaging study or surgical intervention. 6 week reporting limit.
- Mesh Complication: Vaginal, urethral, bladder; erosion (defined as after primary healing, into an organ or surrounding tissue); exposure (defined as mesh visualized through a prior incision area with or without an inflammatory reaction). No time limit for reporting.
- Surgical Site Infection (based on 1992 CDC definition): No time limit for reporting. One of the following criteria must be met:
  - Evidence of any of the following signs at the surgical incision site: purulent drainage, pain or tenderness, localized swelling, redness or heat.
  - Deliberate opening of the wound unless culture negative.
  - Evidence of infection on re-operation or imaging study.
  - Diagnosis of infection by physician, confirmed by study surgeon.

  Surgical site infections will be subcategorized into the following types:
  1. Superficial Incisional: Involves only the skin and subcutaneous tissues at the incision site(s).
  2. Deep Incisional: Involves deep soft tissue (e.g. fascial and muscle layers) at the operative site(s).
  3. Organ/space: Organs or spaces, other than the incision, that were opened or manipulated during the operative procedure (includes pelvic abscess, peritonitis).
- UTI - Empiric: Prior to 6-weeks, patient receives antibiotic therapy for symptoms thought to be secondary to UTI. 6 week reporting limit. (Reminder: If culture sent and comes back negative, event should be rescinded. If positive, revise event code to "21" (i.e. culture-proven) accordingly and add culture data.)
- UTI – Culture-Proven: Prior to 6-weeks, patient receives antibiotic therapy for symptoms of urinary tract infection subsequently associated with a positive culture. 6 week reporting limit.
- Recurrent UTI: Presumed UTI with treatment, ≥3 in 1 year AFTER 6 weeks post-surgery. No time limit for reporting.

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- Fistula No time limit for reporting.
    - Vesicovaginal: connection between bladder and vagina resulting in passage of urine per vaginum
    - Urethrovaginal: connection between urethra and vagina resulting in passage of urine per vaginum
    - Enterovesical: connection between bladder and bowel, may be diagnosed by pneumaturia, charcoal study, or cystoscopy
    - Rectovaginal: connection between the rectum and the vagina resulting in the passage of stool per vaginum.

  NOTE: Foreign body reaction in space of Retzius resulting in vaginal discharge or bleeding or granulation tissue in vagina is NOT a fistula.
- Granulation Tissue: At or beyond 6-weeks post-surgery, granulation at the study/index surgical site. (If at or beyond 6 weeks there is granulation at a concomitant surgery site, that should be reported as an "other" [code 99] adverse event.) No time limit for reporting.
- Voiding Dysfunction (no time limit for reporting): Defined as a complication if one of the following criteria are met:
    - Uses a catheter to facilitate bladder emptying at or beyond 6 weeks post-surgery OR
    - Has undergone medical therapy to facilitate bladder emptying at or beyond 6 weeks post-surg. OR
    - Has undergone surgical therapy to facilitate bladder emptying at anytime after study/index surgery.