

F591: ATTACHMENT

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

SEVERITY¹ 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 perms)
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, subarachnoidal bleeding, but excluding transient ischemic attacks. CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.	

¹Modified 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:
 - o Evidence of any of the following signs at the surgical incision site: purulent drainage, pain or tenderness, localized swelling, redness or heat.
 - o Deliberate opening of the wound unless culture negative.
 - o Evidence of infection on re-operation or imaging study.
 - o 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.

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