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Appendix E-1

The complication forms that were completed by one of the treating surgeons and/or research assistants under the direction of the treating surgeon at each patient's ten-week and one-year postoperative visits were used to record any adverse events, complications, and/or reoperations. ICU = intensive care unit, AVN = osteonecrosis, DVT = deep vein thrombosis, THA = total hip arthroplasty, LFCN = lateral femoral cutaneous nerve, ORIF = open reduction and internal fixation, I&D = irrigation and debridement. ■

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Appendix 1. Complication forms

Date of completion ___ / ___ / _____

Revision 7.26.10

Form completed by:

Case Identifier:

Date of Surgery:

Adverse Events / Complications/ Reoperations

Surgeon _____

1. Any post-operative complications in surgical hip? ☐1 **Yes** ☐2 **No**

2. Complication(s) Description:

Grade 1 (trivial)= A complication that requires no treatment and has no clinical relevance, there is no deviation from routine follow-up during the post-operative period. Allowed therapeutic regimens include: antiemetics, antipyretics, analgetics, diuretics, electrolytes, antibiotics, and physiotherapy

Grade 2 (moderate)= A deviation from the normal post-operative course (including unplanned clinic visits) that requires outpatient treatment either pharmacological or close monitoring as an outpatient.

Grade 3 (severe) = A complication that is treatable but requiring surgical, endoscopic, radiologic interventions or an unplanned hospital admission.

Grade 4 (severe)= A complication that is life threatening, requires ICU admission, or that is not treatable with potential for permanent disability. Complications requiring organ resection (THA).

Grade 5 (death)= Death

	Check all that apply:	Complication Grade:
AVN	_____1	_____
DVT	_____2	_____
Dislocation	_____3	_____
Pulmonary Embolism		_____
Fracture—intra-articular	_____4	_____
Fracture—posterior column	_____5	_____
Fracture—other	_____6	_____
Heterotopic Ossification (Brooker Grade)	_____7	_____
___ Grade I (Islands of bone within the soft tissues about the hip)		
___ Grade II (bone spurs leaving ≥1cm between opposing bone surfaces)		
___ Grade III (bone spurs leaving <1cm between opposing bone surfaces)		
___ Grade IV (Apparent bone ankylosis of the hip)		
Implant Failure	_____8	_____
Infection—Superficial	_____9	_____
Infection—Deep	_____10	_____
Major Nerve Palsy / Injury	_____11	_____
___ Femoral		
___ Peroneal		
___ Sciatic		
Non-Union	_____12	_____
___ Ilium		
___ Ischium		
___ Pubis		
___ Trochanter		
Sensory Nerve Dysesthesia (Pain- LFCN)	_____14	_____
Wound Dehisence	_____15	_____
Wound Hematoma	_____16	_____
Other _____	_____17	_____

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Date of completion ___ / ___ / _____ **Case Identifier:**
Revision 7.26.10 **Date of Surgery:**

3. Treatment:

_____
_____
_____
_____

3. **Any reoperations on the surgical hip (at any time point)?** ☐1 **Yes** ☐2 **No**

	Performed?		Date		
	Yes	No	M	D	Year
Arthroscopy	☐1	☐2	___ /	___ /	_____
Hardware Removal	☐1	☐2	___ /	___ /	_____
Heterotopic Bone Excision	☐1	☐2	___ /	___ /	_____
Hip Replacement	☐1	☐2	___ /	___ /	_____
Trochanteric ORIF	☐1	☐2	___ /	___ /	_____
Wound I&D	☐1	☐2	___ /	___ /	_____
Other Reoperations (Specify Other Reoperations):	☐1	☐2	___ /	___ /	_____
_____	☐1	☐2	___ /	___ /	_____
_____	☐1	☐2	___ /	___ /	_____
_____	☐1	☐2	___ /	___ /	_____

4. Outcome:
☐1 Healed/Resolved
☐2 Permanent disability:_____
☐3 Death

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Date of completion ___ / ___ / _____ **Case Identifier:**
Revision 7.26.10 **Date of Surgery:**

Adverse Event Form

General Guidance:

Report adverse events, product problems or product use errors with:

- **Medications**
- **Medical devices**
- **Combination products**
- **Human cells, tissues and cellular and tissue-based products**

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- **Death**
- **Life-threatening**
- **Hospitalization**
- **Disability or permanent damage**
- **Required intervention to prevent permanent impairment or damage**
- **Other serious (important medical events)**

(1) Adverse Event, Product Problem, or Error (check all that apply):

___1 Adverse Event
___2 Product Use Error
___3 Product Problem
___4 Problem with Different Manufacturer of Same Device

Outcomes attributed to Adverse Event (check all that apply):

____1 Death: _____ ____
(mm/dd/yyyy)
____2 Disability or Permanent Damage
____3 Hospitalization – initial or prolonged
____4 Life-threatening
____5 Other Serious (Important medical events)
____6 Required Intervention to Prevent Permanent Impairment or Damage

1. Date of Event **M M D D Y Y Y Y** ☐☐ ☐☐ ☐☐☐☐
2. Date of this Report **M M D D Y Y Y Y** ☐☐ ☐☐ ☐☐☐☐
3. Describe Event, Problem, or Product Use Error

_____
_____
_____
_____
_____
_____

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Date of completion ___ / ___ / _____ **Case Identifier:**
Revision 7.26.10 **Date of Surgery:**

4. Relevant Tests/Laboratory Data, Including Dates

5. Other **Relevant** History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

(2) Suspect Products

1. Brand Name _____
2. Common Device Name _____
3. Manufacturer Name, City and State _____
4. Model # _____ Lot # _____
   Catalog # _____ Expiration Date _____
   Serial # _____ Other # _____
5. If implanted, give date **M M** **D D** **Y Y Y Y**
6. If explanted, give date **M M** **D D** **Y Y Y Y**
7. Is this a single-use device that was reprocessed and reused on a patient?
   ☐ 1 **Yes** ☐ 2 **No**

   If YES, enter name and address or reprocessor

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TABLE E-1 Modified Clavien-Dindo Classification Scheme*

Grade	Definition†	Specific Complication†
I	A complication that requires no treatment and has no clinical relevance; there is no deviation from routine follow-up during the postoperative period; allowed therapeutic regimens include: antiemetics, antipyretics, analgesics, diuretics, electrolytes, antibiotics, and physiotherapy	Asymptomatic Brooker grade-I or II heterotopic ossification; postoperative fever, nausea, constipation, minor UTI; wound problem not requiring a change in postoperative care
II	A deviation from the normal postoperative course (including unplanned clinic visits) that requires outpatient treatment: either pharmacologic or close monitoring as an outpatient	Superficial wound infection (additional clinic visits); transient neurapraxia from positioning or surgical retraction that resolves under close observation; nerve palsy requiring bracing and close observation (complete resolution); trochanteric delayed union
III	A complication that is treatable but requires surgical, endoscopic, or radiographic interventions or an unplanned hospital admission	Trochanteric nonunion; fracture; deep infection; surgical hematoma; clinically significant heterotopic ossification that requires surgical excision; deep vein thrombosis (admission and anticoagulation)
IV	A complication that is life-threatening, requires ICU admission, or is not treatable with potential for permanent disability; a complication that requires organ resection (THA)	Osteonecrosis; permanent nerve injury; major vascular injury; pulmonary embolism; CNS complications; organ dysfunction
V	Death	

*Reproduced, with modification, 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. Ann Surg. 2004 Aug;240(2):205-13, with permission from Wolters Kluwer Lippincott Williams & Wilkins; and from: Sink EL, Leunig M, Zaltz I, Gilbert JC, Clohisy J; Academic Network for Conservational Hip Outcomes Research Group. Reliability of a complication classification system for orthopaedic surgery. Clin Orthop Relat Res. 2012 Aug;470(8):2220-6. Epub 2012 Apr 19. Reproduced with permission. †UTI = urinary tract infection, ICU = intensive care unit, THA = total hip arthroplasty, and CNS = central nervous system.

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TABLE E-2 Selected Historical Reports of Complications Following Periacetabular Osteotomy

Study	Year	No. of Hips	Complications *(no. of patients)*					
			Neurovascular Injury	Nounion or Delayed Union	Heterotopic Ossification	Deep Infection	LFCN*	Intraoperative Fracture
Ganz et al.[10]	1988	75	1	2	4		Frequent	
Matta et al.[12]	1999	66		11	9		1	
Davey and Santore[16]	1999	70	1	10	3		15	
Crockarell et al.[15]	1999	21	2	3	5			3
Trumble et al.[17]	1999	123	3		22	2		
McKinley[18]	2003	36	1		1			
Naito et al.[26]	2005	128		3			27	1
Clohisy et al.[28]	2005	16		2				
Peters et al.[19]	2006	73	4	11		2		
Biedermann et al.[20]	2008	60	6	8	13		20	4
Millis et al.†	2009	87	1	1				
Teratani et al.‡	2010	46		1				
Thawrani et al.[21]	2010	83		5			4	
Karashima et al.§	2011	191		2	2			9
Howie et al.[30]	2012	26	1	1				

*LFCN = lateral femoral cutaneous nerve. †Millis MB, Kain M, Sierra R, Trousdale R, Taunton MJ, Kim YJ, Rosenfeld SB, Kamath G, Schoenecker P, Clohisy JC. Periacetabular osteotomy for acetabular dysplasia in patients older than 40 years: a preliminary study. Clin Orthop Relat Res. 2009 Sep;467(9):2228-34. ‡Teratani T, Naito M, Kiyama T, Maeyama A. Periacetabular osteotomy in patients fifty years of age or older. J Bone Joint Surg Am. 2010 Jan;92(1):31-41. §Karashima H, Naito M, Shiramizu K, Kiyama T, Maeyama A. A periacetabular osteotomy for the treatment of severe dysplastic hips. Clin Orthop Relat Res. 2011 May;469(5):1436-41.