

# S.O.L.V.E.D

## (Distal Femur)

### Adverse Event Form

To be completed by the PHYSICIAN

(For Internal Use Only)

Patient Study Number	Completed By: _____
	Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (As Needed)

**Directions:** Answer every question by filling in the correct circle or writing in the information. If you need to change an answer, completely erase or cross out the incorrect mark, initial, and fill in the correct information. **Mark only one answer for each question, unless otherwise instructed. Shade circles like this: ●**

#### COMPLETE A SEPARATE FORM FOR EACH COMPLICATION / ADVERSE EVENT

**01. Date of occurrence (MM/DD/YY)**

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

**02. Did this complication occur perioperatively?**

☐ Yes      ☐ No

**03. Severity of the event**

- ☐ Mild – does not interfere with ADL
- ☐ Moderate – interferes some with ADL
- ☐ Severe – incapacitating, unable to perform ADL

**04. Type of complication/adverse event**

- ☐ Surgical site / Orthopaedic (*Skip to question 07*)
- ☐ Systemic
- ☐ Other event (*Specify*): \_\_\_\_\_

**05. If “Systemic” complication, specify below**

- |   |   |
|---|---|
| <input type="radio"/> Anaphylactic reaction           | <input type="radio"/> Neurological deficit    |
| <input type="radio"/> Atelectasis                     | <input type="radio"/> Peripheral nerve injury |
| <input type="radio"/> Blood loss anemia               | <input type="radio"/> Pneumonia               |
| <input type="radio"/> Cardiovascular arrhythmia       | <input type="radio"/> Pulmonary embolism      |
| <input type="radio"/> Congestive heart failure        | <input type="radio"/> Stroke/CVA              |
| <input type="radio"/> DVT                             | <input type="radio"/> Thrombophlebitis        |
| <input type="radio"/> GI bleeding                     | <input type="radio"/> Urinary tract infection |
| <input type="radio"/> Ileus                           | <input type="radio"/> Vascular injury         |
| <input type="radio"/> Myocardial infarction           |   |
| <input type="radio"/> Other ( <i>Specify</i> ): _____ |   |

**06. Relationship of “Systemic” complication to surgery**

- |  |  |
|--|--|
| <input type="radio"/> Definitely related | <input type="radio"/> Probably not related   |
| <input type="radio"/> Possibly related   | <input type="radio"/> Definitely not related |
| <input type="radio"/> Unknown            |  |

**07. If “Surgical site/Orthopaedic” complication, specify below**

- ☐ Compartment syndrome
- ☐ Construct loosening – proximal to fracture
- ☐ Construct loosening – distal to fracture
- ☐ Fractured implant – nail
- ☐ Fractured implant – plate
- ☐ Fractured implant – screw(s)
- ☐ Hematoma
- ☐ Infection – deep
- ☐ Infection – superficial
- ☐ Necrosis/would slough
- ☐ Non-union
- ☐ Painful implant – nail
- ☐ Painful implant – plate
- ☐ Painful implant – screw
- ☐ Peripheral nerve injury
- ☐ Peri-implant fracture
- ☐ Other (*Specify*): \_\_\_\_\_

*Please continue on next page*

**S.O.L.V.E.D**  
(*Distal Femur*)  
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Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (As Needed)

**08. Was the complication device related?**

- ☐ Definitely related
- ☐ Possibly related
- ☐ Unknown
- ☐ Probably not related
- ☐ Definitely not related

**09. Was re-hospitalization required?**

- ☐ No (*Skip to question 11*)
- ☐ Yes, for systemic complication
- ☐ Yes, for surgical site / orthopaedic complication

**10. If “Yes”, re-admission date (MM/DD/YY)**

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

**11. If “Surgical site / orthopaedic complication”, what treatment was required? (*Mark all that apply*)**

- ☐ None
- ☐ Antibodies
- ☐ Bone graft
- ☐ Fasciotomy
- ☐ Irrigation & debridement
- ☐ Revision/component removal
- ☐ Other treatment (*Specify below*)

**12. If revision was required, indicate the procedure (*Mark all that apply*)**

- ☐ Bone graft
- ☐ Exchange nailing
- ☐ Plate addition or exchange
- ☐ Removal of screws or pins
- ☐ Other (*Specify below*)

**13a. Outcome of adverse event**

- ☐ Resolved (*Specify date below*)
- ☐ Unresolved

**b. If “Resolved”, specify date (MM/DD/YY)**

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

**14. If “Resolved”, effect on patient**

- ☐ Temporary
- ☐ Lasting
- ☐ Death (*Specify date below*)

\_\_\_\_ / \_\_\_\_ / \_\_\_\_ (MM/DD/YY)

**15. Please provide additional details of the adverse event, if needed.**

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