### I.M.P.R.E.S.S. (Proximal Tibia) Adverse Event Form

To be completed by the PHYSICIAN

**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: ●

<table>
<thead>
<tr>
<th>COMPLETE A SEPARATE FORM FOR EACH COMPLICATION / ADVERSE EVENT</th>
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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**

  - Anaphylactic reaction
  - Atelectasis
  - Blood loss anemia
  - Cardiovascular arrhythmia
  - Congestive heart failure
  - DVT
  - GI bleeding
  - Ileus
  - Myocardial infarction

  - Other *(Specify)*: __________________________

  - Neurological deficit
  - Peripheral nerve injury
  - Pneumonia
  - Pulmonary embolism
  - Stroke/CVA
  - Thrombophlebitis
  - Urinary tract infection
  - Vascular injury

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

  - Definitely related
  - Probably not related
  - Possibly related
  - Definitely not related
  - 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)*: __________________________

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Please continue on next page
### I.M.P.R.E.S.S.  
**(Proximal Tibia)**  
**Adverse Event Form**  
To be completed by the PHYSICIAN

| Patient Study Number | Completed By: ____________________  
|----------------------|-----------------------------------|
|                      | Clinic: _________________________  
| 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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________________________________  
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