I.M.P.R.E.S.S.
(Proximal Tibia)
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

○ Anaphylactic reaction
○ Atelectasis
○ Blood loss anemia
○ Cardiovascular arrhythmia
○ Congestive heart failure
○ DVT
○ GI bleeding
○ Ileus
○ Myocardial infarction
○ Neurological deficit
○ Peripheral nerve injury
○ Pneumonia
○ Pulmonary embolism
○ Stroke/CVA
○ Thrombophlebitis
○ Urinary tract infection
○ Vascular injury

○ Other *(Specify)*: _____

06. Relationship of "Systemic" complication to surgery

○ Definitely related
○ Possibly related
○ Unknown
○ Probably not related
○ Definitely not related

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

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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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