

BMP2 vs. Autograft for Critical Size Tibial Defects Inclusion/Exclusion Criteria

To be completed by the PHYSICIAN

Patient Study Number	Completed By: _____
	Clinic: _____
Visit Date (MM/DD/YY) __ __ / __ __ / __ __	Visit Schedule (<i>check appropriate box</i>) <input type="checkbox"/> Pre-Op

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: ●**

Criteria for Inclusion

Questions 01 - 09 must be answered YES for subject to be included in the study

		Yes	No
01.	Patient's age is 18-65 with an open tibia fractures involving the diaphysis	<input type="radio"/>	<input type="radio"/>
02.	Patient's tibia fracture has a circumferential bone defect of at least one centimeter in length compromising at least 50% of the circumference of the bone	<input type="radio"/>	<input type="radio"/>
03.	The definitive treatment of the patient's tibia fracture is with an intramedullary nail (may have temporary external fixation prior to IM nail placement)	<input type="radio"/>	<input type="radio"/>
04.	Patient's treatment plan includes placement of a bone graft between 6 to 10 weeks after their initial injury	<input type="radio"/>	<input type="radio"/>
05.	Patient does not have evidence of infection by clinical examination	<input type="radio"/>	<input type="radio"/>
06.	Patient was independent living and ambulation prior to injury	<input type="radio"/>	<input type="radio"/>
07.	Patient is English speaking	<input type="radio"/>	<input type="radio"/>
08.	The patient, or a designated appointee, must be willing to provide consent. The patient must be available for follow-up for at least 12 months following definitive surgical procedure	<input type="radio"/>	<input type="radio"/>
09.	Surgeon agrees to randomize patient	<input type="radio"/>	<input type="radio"/>

* Patients who smoke are eligible for inclusion

** A female of childbearing potential must have a negative pregnancy test within 72 hours prior to surgery and must agree use adequate contraception for a period of at least 1 year following implantation of rhBMP-2. Written, informed consent will be obtained from the patient or legal guardian.

*** Patients with bilateral tibia fracture; if both fractures require a bone graft, then each will be randomized separately.

Criteria for Exclusion

Questions 10-29 must be answered NO for subject to be included in the study

		Yes	No
10.	Patient is pregnant or lactating.	<input type="radio"/>	<input type="radio"/>
11.	Patient has a known hypersensitivity to rhBMP-2 or bovine type I collagen.	<input type="radio"/>	<input type="radio"/>
12.	Patient has a history of tumor, a resected or extant tumor, an active malignancy, or is undergoing treatment for malignancy.	<input type="radio"/>	<input type="radio"/>
13.	Patient is skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).	<input type="radio"/>	<input type="radio"/>
14.	Patient has inadequate neurovascular status, e.g. high risk of amputation.	<input type="radio"/>	<input type="radio"/>
15.	Patient has compartment syndrome of the affected limb.	<input type="radio"/>	<input type="radio"/>
16.	Patient has immune deficiency or history of auto-immune disease.	<input type="radio"/>	<input type="radio"/>
17.	Patient is undergoing treatment of any other investigational therapy within the month preceding implantation or planned within the 12 months following implantation.	<input type="radio"/>	<input type="radio"/>
18.	Patient is unable to return for required follow-up visits and/or medical co morbidities which preclude treatment with a general anesthetic.	<input type="radio"/>	<input type="radio"/>
19.	Patient has an active infection at the operative site, purulent drainage from the fracture or evidence of active osteomyelitis at the time of bone grafting. In addition, patients with intraoperative positive gram stain or an elevated CRP after laboratory screening for infection will be excluded.	<input type="radio"/>	<input type="radio"/>
20.	Patient has segmental defects longer than 5 cm in length.	<input type="radio"/>	<input type="radio"/>
21.	Patient has segmental defects that require more than 60 cc of bone graft.	<input type="radio"/>	<input type="radio"/>
22.	Patient requires more than one large kit of rh-BMP 2 at time of surgery.	<input type="radio"/>	<input type="radio"/>

Continued on next page

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23.	Patient anticipated treatment plan also includes the use of other procedures to promote fracture healing, e.g. ultrasound, magnetic field or electrical stimulation.	<input type="radio"/>	<input type="radio"/>
24.	Patient's tibia fracture has been treated with addition fixation beyond the intramedullary nail, e.g. plates, wires, or screws	<input type="radio"/>	<input type="radio"/>
25.	Patient has a pathological fractures; a known history of Paget's disease or known history of heterotopic ossification.	<input type="radio"/>	<input type="radio"/>
26.	Patient has a Glasgow Coma Scale less than 15 (less than fully awake) at the time of informed consent.	<input type="radio"/>	<input type="radio"/>
27.	Patient has previous hardware in place which prevents placement of an intramedullary nail for treatment of the tibial shaft fracture.	<input type="radio"/>	<input type="radio"/>
28.	Patient not treated with an intramedullary nail.	<input type="radio"/>	<input type="radio"/>
29.	Patient is pending incarceration or is currently incarcerated	<input type="radio"/>	<input type="radio"/>

<p>30. Does the patient qualify for the study?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>	<div style="border: 2px dashed black; padding: 10px; width: fit-content; margin: auto;"> <p>Please affix randomization label here</p> </div>
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Last Name	First Name	MI	<div style="border: 1px solid black; padding: 2px;">(For Internal Use Only)</div> <div style="border: 1px solid black; padding: 2px;">Physician's Name: _____</div> <div style="border: 1px solid black; padding: 2px;">Medical Record Number _____</div>
Street Address 1 _____			
Street Address 2 _____			
City _____ State _____ Zip Code _____			
Home Phone (or primary contact) (____) _____ - _____	Work Phone (____) _____ - _____	Date of Birth (MM/DD/YYYY) ____ / ____ / ____	
Sex M/F _____	E-mail (example: johndoe@abc.com) _____		

Alternate Contact Information 1

Relationship to patient	Last Name	First Name	MI
Street Address 1 _____			Home Phone (or primary contact) (____) _____ - _____
Street Address 2 _____			
City _____ State _____ Zip Code _____			

Alternate Contact Information 2

Relationship to patient	Last Name	First Name	MI
Street Address 1 _____			Home Phone (or primary contact) (____) _____ - _____
Street Address 2 _____			
City _____ State _____ Zip Code _____			

Please continue on next page

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01a. Date of Injury ___ / ___ / ___ (MM/DD/YY)

b. Time of Injury ___ : ___ AM / PM (circle one)

02. Ethnicity

- American Indian
- Asian or Asian American
- Black or African American
- Hispanic or Latino
- Native Hawaiian or Pacific Islander
- White or Caucasian
- Other (Specify): _____

03. Side of injury

- Left Right

04. Additional upper extremity fractures

	<u>None</u>	<u>Right</u>	<u>Left</u>	<u>Bilateral</u>
a. Clavicle	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Scapula	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Humerus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Radius	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Ulna	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Wrist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Hand	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

05. Additional lower extremity fractures

	<u>None</u>	<u>Right</u>	<u>Left</u>	<u>Bilateral</u>
a. Pelvis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Acetabulum	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Femur	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Tibia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Ankle	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Foot	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

06. Additional spinal fractures

	<u>None</u>	<u>Right</u>	<u>Left</u>	<u>Bilateral</u>
a. Cervical	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Thoracic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Lumbar	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

07. Additional injuries

	<u>None</u>	<u>Right</u>	<u>Left</u>	<u>Bilateral</u>
a. Upper extremity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Lower extremity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Spine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

08. Sensation at time of presentation

<u>Location</u>	<u>Normal</u>	<u>Diminished</u>	<u>Absent</u>
a. Superficial peroneal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Deep peroneal nerve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Posterior tibial nerve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Using the AIS scoring scale, score questions 09-14 (the 6 body regions). Where multiple injuries occur in one region, use the highest scoring injury of that region.

<u>Region</u>	<u>AIS Score</u>
09. Head & Neck	___
10. Face	___
11. Chest	___
12. Abdomen	___
13. Extremity	___
14. External	___

AIS Score
 Minor (AIS 1)
 Moderate (AIS 2)
 Serious (AIS 3)
 Severe (AIS 4)
 Critical (AIS 5)
 Unsurvivable (AIS 6)

15. If known, please record the ISS score below

___ ISS Score

16. Primary cause of injury

- Motor vehicle accident
- Motorcycle accident
- Bicycle accident
- Pedestrian accident
- Recreational activity
- Fall from a height greater than 4 feet
- Fall from a height less than 4 feet
- Direct trauma (blunt)
- Direct trauma (penetrating)
- Crush
- Twist
- Other (Specify): _____

Please continue on next page

BMP2 vs. Autograft for Critical Size Tibial Defects

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17. High energy injury

- Yes No

18. Work related injury

- Yes No (*Skip to question 20*)

19. If "Yes", is patient currently seeking or receiving Workers' Compensation?

- Yes No (*Skip to question 20*)

20. Patient has been or is currently involved in litigation

- Yes No

21. History of smoking or tobacco use

- No (*Skip to question 25*)
 Yes, quit smoking (*Continue to question 22*)
 Yes, current smoker (*Skip to question 23*)

22. If "Yes, quit smoking", specify years tobacco free

_____ years

23. If "Yes, current smoker", specify packs smoked per day

_____ . _____ packs per day

24. If "Yes, current smoker", specify years smoked

_____ years smoked

25. History of drug or alcohol use

- Yes No (*Skip to question 28*)

26a. If "Yes", is there a history of drug or alcohol abuse?

- Yes (*Specify below*)
 No (*Skip to question 28*)

b. If "Yes", specify type of drug or alcohol abuse (*Mark all that apply*)

- Alcohol Drugs Both

27a. If "History of drug or alcohol abuse", is the patient recovered?

- Yes (*Specify below*)
 No (*Skip to question 28*)

b. If "Yes", specify years recovered

_____ years

28a. Patient's height _____ inches

b. Patient's weight _____ lbs

Current Medications (*Mark all that apply*)

29a. Type	b. Dose	c. Duration
<input type="radio"/> Steroids (examples: Cortone, Deltasone, Medrol, Predone)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Anticoagulants (examples: Coumadin, Miradon)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Anticonvulsants (examples: Phenytoin, Carbamazepine, Phenobarbital, diazepam)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Statins (examples: Lipitor, Lescol, Pravachol, Zocor)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Anti-inflammatories (examples: Anaprox, Celebrex, Motrin, Naprosyn)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Biophosphonates (examples: Actonel, Boniva, Fosamax)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Antibiotics (examples: Amoxil, Ceporex, Cydomycin, Vibramycin)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Calcium channel blockers (examples: Adalat, Cardizem, Dilacor XR, Norvasc)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Calcium or Vitamin D (examples: Cal-Citrate, Citracal, Os-Cal, Viactiv)	_____ mg/da y	____ yrs ____ mos
<input type="radio"/> Parathyroid hormone (examples: Forteo)	_____ mg/da y	____ yrs ____ mos

History of surgery

Procedure	Systemic	Extremity	Date (MM/DD/YY)
30. _____	<input type="radio"/>	<input type="radio"/>	____ / ____ / ____
31. _____	<input type="radio"/>	<input type="radio"/>	____ / ____ / ____
32. _____	<input type="radio"/>	<input type="radio"/>	____ / ____ / ____
33. _____	<input type="radio"/>	<input type="radio"/>	____ / ____ / ____
34. _____	<input type="radio"/>	<input type="radio"/>	____ / ____ / ____
35. _____	<input type="radio"/>	<input type="radio"/>	____ / ____ / ____
36. _____	<input type="radio"/>	<input type="radio"/>	____ / ____ / ____

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Patient's Current Medical History (Mark all that apply)

In question 37, please indicate the patient's personal medical history of the following conditions.

In question 38, please indicate if the patient is receiving treatment or medication for the condition.

In question 39, please indicate if the condition limits the patient's activities.

	37. <u>History</u>	38. Receiving treatment / <u>Medication</u>	39. <u>Limits activity</u>
Anemia or other blood disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Back pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cancer – metastatic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cancer – not metastatic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Circulatory disorder including ankle or leg swelling, blood clots, peripheral vascular disease, aneurysm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diabetes – diet controlled	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diabetes – medication controlled	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diabetes – insulin controlled	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heart disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
High blood pressure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History of stroke	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Kidney disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Leg pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Liver disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lung disease or asthma	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nervous system disorder including Parkinson's disease, multiple sclerosis, cerebral palsy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Obesity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Osteoarthritis/degenerative arthritis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Osteoporosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rheumatoid arthritis/lupus/ankylosing spondylitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thyroid disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ulcer or stomach disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other history (<i>Specify below</i>)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

BMP2 vs. Autograft for Critical Size Tibial Defects Fracture Characteristics Form

To be completed by the PHYSICIAN

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01. "Open" fracture, select Gustillo Type (*See description below*)

- I
- II
- IIIA
- IIIB
- IIIC

Type I Wound \leq 1.0 cm in length and clean
Type II Wound $>$ 1.0 cm without extensive soft tissue damage, flaps or avulsions
Type IIIA Extensive soft tissue injury or flaps with soft tissue coverage of bone OR segmental (caused by high energy trauma) irrespective of the size of the wound
Type IIIB Requiring flap coverage
Type IIIC Vascular injury requiring repair

02. Specify wound length

____ mm

03. Location of fracture in diaphysis.

- Proximal 1/3
- Middle 1/3
- Distal 1/3

04. Is the fibula fractured?

- Yes
- No

05. Location of fibula fracture.

- Proximal 1/3
- Middle 1/3
- Distal 1/3

06. Bone Loss Assessment (radiographic)

AP radiograph:
Length ____ (cm)

Lateral radiograph:
Length ____ (cm)
Cortical width ____ (cm)

06. Bone Loss Assessment (continued)

Circumferential bone loss:

50% _____

75% _____

100% _____

07. Bone Loss Assessment (intraoperative)

Pre debridement:

Length ____ (cm)

Width ____ (cm)

Depth ____ (cm)

Post debridement:

Length ____ (cm)

Width ____ (cm)

Depth ____ (cm)

08. OTA Classification (see attached illustration)

Location:

_____ Diaphyseal Segment (42)

_____ Simple (A)

_____ Wedge (B)

_____ Complex (C)

Subtype:

_____ Simple (42-A)

_____ Spiral (42-A1)

_____ Oblique ($\geq 30^\circ$) (42-A2)

_____ Transverse ($\leq 30^\circ$) (42-A3)

_____ Wedge (42-B)

_____ Spiral Wedge (42-B1)

_____ Bending Wedge (42-B2)

_____ Fragmented Wedge (42-B3)

_____ Complex (42-C)

_____ Spiral (42-C1)

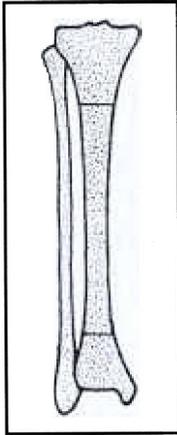
_____ Segmented (42-C2)

_____ Irregular (42-C3)

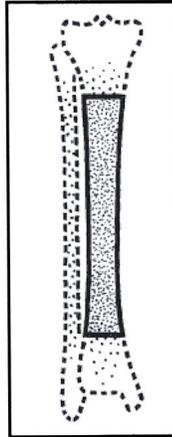
***BMP2 vs. Autograft for
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Fracture Characteristics Form***
To be completed by the PHYSICIAN

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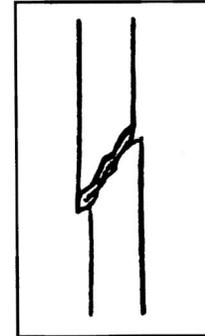
BONE:
TIBIA/FIBULA (4)



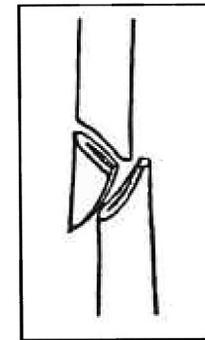
Location:
Diaphyseal segment (42)



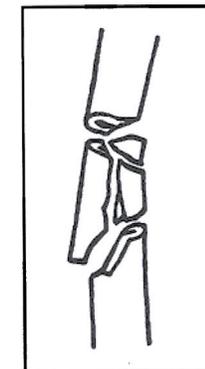
Types:
A. Simple (42-A)



B. Wedge (42-B)



C. Complex (42-C)



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Fracture Characteristics Form

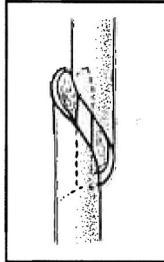
To be completed by the **PHYSICIAN**

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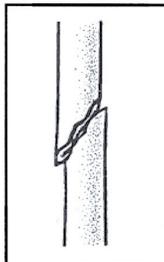
Groups:

Tibia/Fibula, diaphyseal, simple
(42-A)

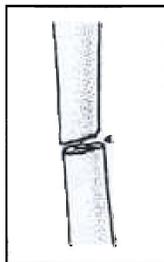
1. Spiral (42-A1)



2. Oblique ($\geq 30^\circ$) (42-A2)



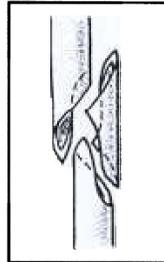
3. Transverse ($< 30^\circ$) (42-A3)



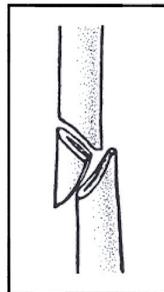
A

Tibia/Fibula, diaphyseal, wedge
(42-B)

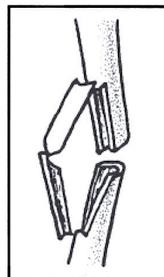
1. Spiral wedge (42-B1)



2. Bending wedge (42-B2)



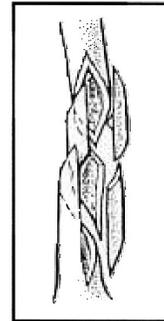
3. Fragmented wedge (42-B3)



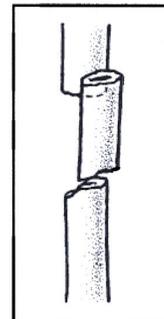
B

Tibia/Fibula, diaphyseal, complex
(42-C)

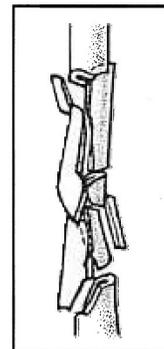
1. Spiral (42-C1)



2. Segmented (42-C2)



3. Irregular (42-C3)



C

BMP2 vs. Autograft for Critical Size Tibial Defects

Surgical Summary

To be completed by the **PHYSICIAN**

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ___ / ___ / ___	Visit Schedule (<i>check appropriate box</i>) <input type="checkbox"/> Day of Surgery

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: ●**

Component Details

- 01. Length** ___ ___ mm
- 02. Diameter** ___ . ___ mm
- 03. Material**
 Stainless steel Titanium
- 04. Manufacturer**
 DePuy
 Smith & Nephew
 Stryker
 Synthes
 Zimmer
 Other (*Specify*): _____
- 05. Proximal locking**
 Number of screws _____
- 06. Distal locking**
 Number of screws _____
- 07. Date and time of irrigation and debridement**
 a. Date ___ / ___ / ___ (MM/DD/YY)
 b. Time ___ : ___ AM / PM (circle one)
- 08. Date and time of definitive fixation**
 a. Date ___ / ___ / ___ (MM/DD/YY)
 b. Time ___ : ___ AM / PM (circle one)
- 09. Stabilization prior to definitive fixation**
 Brace External fixation
 Plaster / fiberglass Traction
 Other (*Specify*): _____
- 10. Length of surgery** (*skin to skin*) ___ ___ minutes

- 11. Fasciotomy performed** (*Mark all that apply*)
 None Posterior
 Anterior Lateral
- 12. Did the patient have abdominal surgery?**
 Yes No
- 13. Did the patient have any other surgical procedures?**
 Yes (*Specify below*) No

- 14. Planned secondary surgeries** (*Mark all that apply*)
 None
 Flap coverage
 Irrigation and debridement
 VAC placement
 Other (*Specify below*)

- 15. Cancellous chips**
 a. Amount of cancellous chips inserted ___ ___ (cc)
 b. Brand of cancellous chips used:

- 16. Radiographic alignment on post-operative films**
 a. ___ ° Varus or Valgus
 b. ___ ° Anterior angulation or Posterior angulation
- 17a. Rotational alignment of affected extremity**
 Normal (*Skip to question 41*)
 Internally rotated
 Externally rotated
 b. If “Internally” or “Externally” rotated, specify degrees ___ °
- 18a. Leg length discrepancy**
 None (*Skip to question 42*)
 Affected leg shorter than unaffected leg
 Affected leg longer than unaffected leg
 b. If ‘Short’ or ‘Long’, specify discrepancy
 ___ mm