

S.O.L.V.E.D

(Distal Femur)

Inclusion/Exclusion Criteria

To be completed by the PHYSICIAN

(For Internal Use Only)

Patient Study Number: _____	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="margin: 0 5px;">/</div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="margin: 0 5px;">/</div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> </div>	Visit Schedule (check appropriate box) <input checked="" type="checkbox"/> Pre-Op

USE TO SCREEN ALL DISTAL FEMUR FRACTURES

Complete pages 1-3 for all patients presenting with distal femur fractures. DO NOT randomize patient unless consent is obtained and patient meets all inclusion and exclusion criteria.

SCREENING INFORMATION:

Date (MM/DD/YY) ____ ____ / ____ ____ / ____ ____

Site Name: _____

Completed By: _____

Fracture Type: ☐ Open
 ☐ Closed

INCLUSION CRITERIA: *Must answer questions 1-6 “YES” for patient to qualify*

1.	Skeletally mature	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2.	Fracture of the metaphyseal distal femur with or without intraarticular extension and with or without a TKA	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3.	Fracture requiring operative treatment amenable to either IM nail or plate	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4.	Surgeon agreed to randomize patient	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5.	Informed consent obtained	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6.	Patient is English speaking	<input type="checkbox"/> Yes	<input type="checkbox"/> No

For any “NO” answers, please provide a brief description:

S.O.L.V.E.D

(Distal Femur)

Inclusion/Exclusion Criteria

To be completed by the PHYSICIAN

(For Internal Use Only)

Patient Study Number: _____	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> <div style="border: 1px solid black; width: 30px; height: 30px; display: flex; align-items: center; justify-content: center;"> </div> </div>	Visit Schedule (check appropriate box) <input checked="" type="checkbox"/> Pre-Op

EXCLUSION CRITERIA: *Must answer questions 1-13 “NO” for patient to qualify*

1.	Fracture of the metaphyseal distal femur with intraarticular comminution	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2.	Fracture with vascular injury (Gustillo Type IIIC injury) requiring repair	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3.	Pathological fracture	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4.	Known metabolic bone disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5.	Contralateral distal femur fractures (bilateral injury) or ipsilateral lower extremity injury that would compromise function of the knee	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6.	Retained hardware or existing deformity in the affected limb that would complicate IM nailing or plating	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7.	Symptomatic knee arthritis	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8.	Soft tissue injuries compromising either treatment method with nail or plate	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9.	Surgical delay greater than 3 weeks for closed fractures or 24 hours for open fractures	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10.	Immunocompromised	<input type="checkbox"/> Yes	<input type="checkbox"/> No
11.	Unable to comply with postoperative rehabilitation protocols or instructions (i.e. head injured or mentally impaired)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12.	Current or impending incarceration	<input type="checkbox"/> Yes	<input type="checkbox"/> No
13.	Unlikely to follow-up in surgeon’s estimation	<input type="checkbox"/> Yes	<input type="checkbox"/> No

For any “YES” answers, please provide a brief description:

S.O.L.V.E.D
(Distal Femur)
Inclusion/Exclusion Criteria
 To be completed by the PHYSICIAN

(For Internal Use Only)

Patient Study Number:	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) <div style="display: flex; justify-content: space-around;"> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div>/</div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div>/</div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> <div><div style="border: 1px solid black; width: 20px; height: 20px;"></div></div> </div>	Visit Schedule <i>(check appropriate box)</i> <input checked="" type="checkbox"/> Pre-Op

POST – SCREENING DATA CAPTURE

1. Does the patient qualify for the study?
☐ Yes
☐ No

2. If the patient qualified, was the patient randomized?
☐ Yes
 - ➔ To Nail ☐
 - ➔ To Plate ☐☐ No, patient initially consented to randomization, but withdrew consent prior to randomization
☐ No, patient did not sign the consent form

3. Why did the eligible patient choose NOT to participate in the study? (mark all that apply)
☐ Not applicable
☐ Not interested
☐ Too much work
☐ Other: _____