

## **Report for ANKLE DSMB: Prepared October 2009**

There have been 200 patients randomized online as of October 26, 2009. Of those, 1 patient was removed after randomization due to an ineligible fracture pattern and 2 patients withdrew consent prior to surgery bringing the total enrollment to 197.

### **Summary of Randomization**

	Randomized	Withdrew	Ineligible	Total
Treatment A	100	1		<b>99</b>
Treatment B	100	1	1	<b>98</b>

**Figure 1** presents the overall study status. **Figure 2** shows the total number of enrolled patients by month.

### **Part A: Number of Patients Included and Excluded**

**Table 1a** presents the number of patients by fracture type and treatment assignment. 100 patients have been randomized to Treatment A (**50%**) and 100 to Treatment (**50%**) **Table 1b** presents the starting dates of recruitment of the 10 centers in the study, and a month-by-month picture of the recruitment each center has achieved.

### **Part B: Patients lost to follow-up, withdrew consent, ineligible**

**Table 2a** presents the patients that were lost to follow-up, withdrew consent, or were removed due to an ineligible fracture. **Table 2b-d** shows the number of patients by center and fracture type that were lost to follow-up, withdrew consent, and were declared ineligible. There have been 22 patients lost to follow-up. 2 patients withdrew consent after randomization, and 1 patient was removed due to an ineligible fracture pattern leaving a total active enrollment of 178.

### **Part C: Patients lost to follow-up, withdrew consent, ineligible**

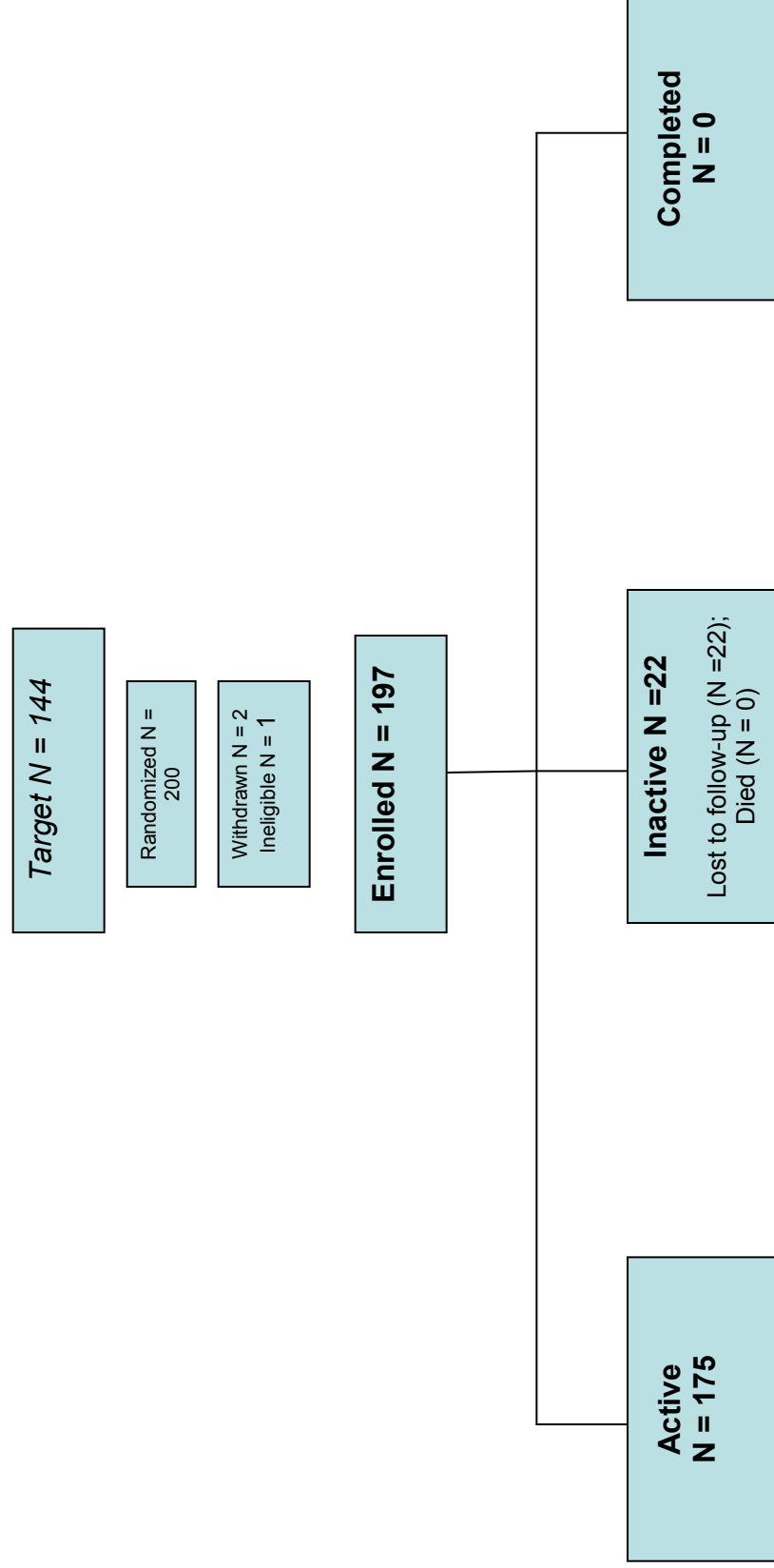
**Table 3a-b** cross-references each patient's online randomization with the treatment indicated on the Surgical Summary form. Of the 200 patients enrolled, 9 (crossed treatments) (4.5%).

### **Part D: Summary of Adverse Events**

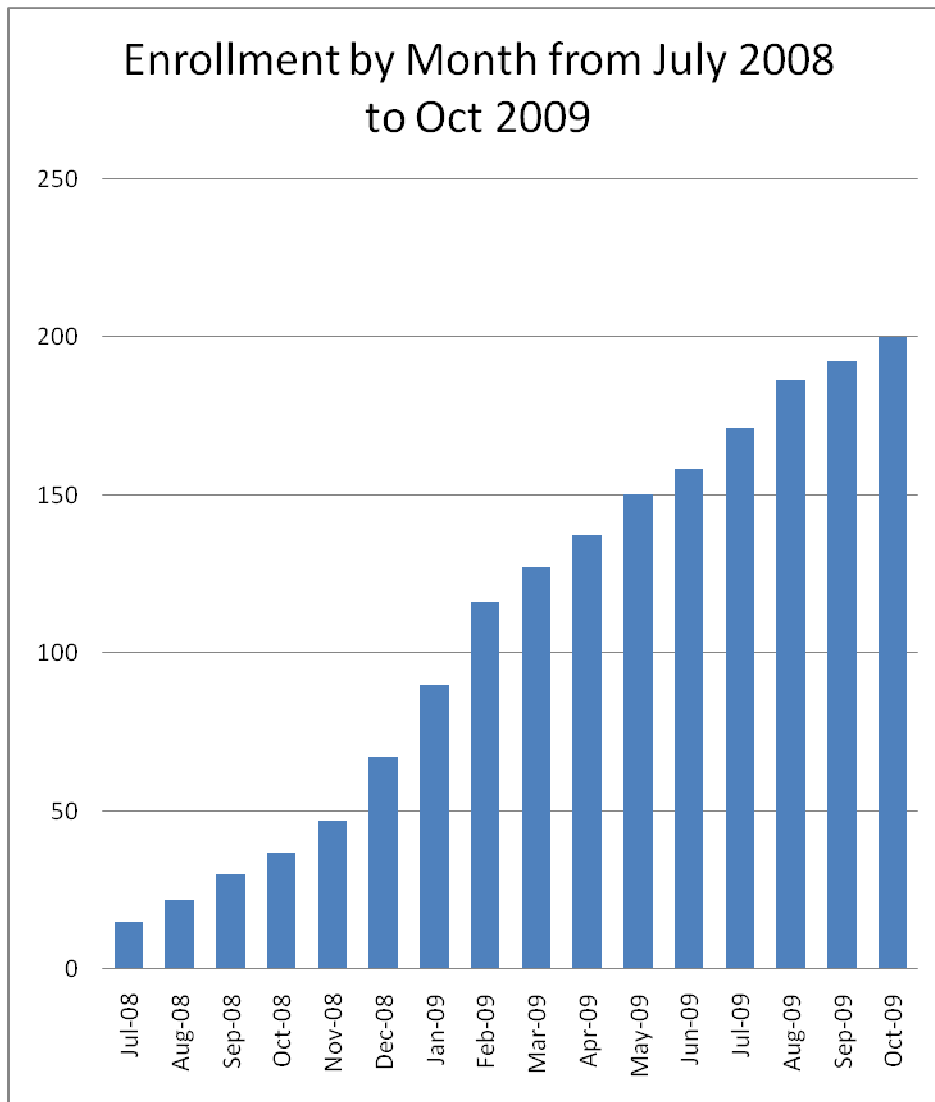
**Table 4a** shows the event rates as of May 31, 2008. There have been 18 reported Adverse Events in 11 study patients, resulting in a (8) percent AE rate in Treatment A (N=100), and a (3) percent AE rate for Treatment B (N=100). No Serious Adverse Events have been reported. Descriptions of the reported Adverse Events are presented in **Table 4b**.

Figure 1: Overall study status

## Overall Study Status



**Figure 2: Cumulative enrollment by month**



**Table 1a: Enrollment by Fracture Type and Treatment Assignment**

<b>Center ID</b>	<b>Treatment A</b>	<b>Treatment B</b>	<b>Total</b>
<b>01</b>	12	11	23
<b>02</b>	10	9	19
<b>03</b>	3	3	6
<b>04</b>	0	0	0
<b>05</b>	23	24	47
<b>06</b>	0	2	2
<b>07</b>	16	16	32
<b>08</b>	30	30	60
<b>09</b>	3	2	5
<b>10</b>	3	3	6
<b>TOTAL</b>	<b>100</b>	<b>100</b>	<b>200</b>

**Table 1b: Enrollment July 2008 through March 2009**

CenterID	Approval Date	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09
01	10-Sep-08	-	-	2	1	4	3	5	5	1
02	27-Mar-08	5	1	0	1	1	4	2	1	1
03	6-Jun-08	0	0	0	0	0	0	0	1	0
04	26-Sep-08	-	-	-	0	0	0	0	0	0
05	26-May-08	4	4	3	3	1	3	6	1	3
06	08-Jan-09	-	-	-	-	-	-	0	6	2
07	03-Jun-08	6	2	3	2	4	10	8	11	4
08	01-Feb-09	-	-	-	-	-	-	-	0	0
09	27-May-08	0	0	0	0	0	0	2	1	0
<b>Total Sites</b>		<b>5</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>7</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>9</b>
<b>Monthly Enrollment</b>		<b>15</b>	<b>7</b>	<b>8</b>	<b>7</b>	<b>10</b>	<b>20</b>	<b>23</b>	<b>26</b>	<b>11</b>
<b>Cumulative Enrollment</b>		<b>15</b>	<b>22</b>	<b>30</b>	<b>37</b>	<b>47</b>	<b>67</b>	<b>90</b>	<b>116</b>	<b>127</b>

**Table 1b: Enrollment April 2009 through October 2009**

Center ID	Approval Date	April-09	May-09	June-09	July-09	Aug-09	Sep-09	Oct-09
01	10-Sep-08	0	1	1	0	0	0	0
02	27-Mar-08	0	0	0	2	0	1	0
03	6-Jun-08	2	0	0	2	0	1	0
04	26-Sep-08	0	0	0	0	0	0	0
05	26-May-08	2	3	4	2	3	4	0
06	16-Feb-09	0	0	0	0	2	0	0
07	08-Jan-09	3	0	1	7	9	2	2
08	01-Feb-09	2	6	0	0	0	0	0
09	27-May-08	0	3	2	0	0	0	0
10	16-Feb-09	1	0	0	0	0	0	2
	<b>Total Sites</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>
	<b>Monthly Enrollment</b>	<b>10</b>	<b>13</b>	<b>8</b>	<b>13</b>	<b>14</b>	<b>8</b>	<b>4</b>
	<b>Cumulative Enrollment</b>	<b>137</b>	<b>150</b>	<b>158</b>	<b>171</b>	<b>185</b>	<b>193</b>	<b>197</b>

**Table 2a: Patients lost to follow-up, withdrew consent, ineligible**

<b>Subject-ID</b>	<b>Center-ID</b>	<b>Date of Enrollment</b>	<b>Date of Last Follow-up</b>	<b>Reason</b>
03-***-0001	02	01-Jul-08	12-Aug-08	Lost to follow-up
03-***-0005	02	31-Jul-08	19-Aug-08	Lost to follow-up
03-***-0012	05	15-Aug-08	N/A	Withdrew consent
03-***-0007	07	11-Aug-08	No f/u	Lost to follow-up
03-***-0015	07	02-Nov-08	No f/u	Lost to follow-up
03-***-0025	07	18-Dec-08	N/A	Withdrew consent
03-***-0038	07	02-Feb-08	N/A	Ineligible
03-***-0017	01	04-Feb-09	30-April-09	Lost to f/u
03-***-0021	01	04-Mar-09	26-May-09	Lost to f/u
03-***-0001	03	16-Feb-09	NO F/U	Lost to f/u
03-***-0002	03	17-April-09	29-April-09	Lost to f/u
03-***-0004	03	07-Jul-09	NO F/U	Lost to f/u
03-***-0003	06	04-Feb-09	05-Feb-09	Lost to f/u
03-***-0006	06	12-Feb-09	12-May-09	Lost to f/u
03-***-0011	07	12-Sep-08	08-Dec-08	Lost to f/u
03-***-0012	07	06-Oct-08	12-Jan-09	Lost to f/u
03-***-0014	07	01-Nov-08	18-Dec-08	Lost to f/u
03-***-0020	07	15- Dec-08	29-Jan-09	Lost to f/u
03-***-0028	07	31-Dec-08	03-April-09	Lost to f/u
03-***-0035	07	18-Jan-09	02-Mar-09	Lost to f/u
03-***-0049	07	01-Mar-09	26-Aug-09	Lost to f/u
03-***-0004	09	20-April-09	02-Jun-09	Lost to f/u

**Table2b: Ineligible Patients by Fracture Type and Treatment Assignment**

CenterID	Treatment A	Treatment B	Total
01	0	0	0
02	0	0	0
03	0	0	0
04	0	0	0
05	0	0	0
06	0	0	0
07	0	1	1
08	0	0	0
09	0	0	0
<b>TOTAL</b>	<b>0</b>	<b>1</b>	<b>0</b>

**Table2c Withdrawn Patients by Fracture Type and Treatment Assignment**

CenterID	Treatment A	Treatment B	Total
01	0	0	0
02	0	1	1
03	0	0	0
04	0	0	0
05	1	0	1
06	0	0	0
07	0	1	1
08	0	0	0
09	0	0	0
<b>TOTAL</b>	<b>1</b>	<b>1</b>	<b>2</b>

**Table 2d: Patients Lost to Follow-up by Fracture Type and Treatment Assignment**

CenterID	Treatment A	Treatment B	Total
01	0	2	2
02	0	2	2
03	2	1	3
05	1	0	1
06	1	1	2
07	4	7	11
09	0	1	1
<b>TOTAL</b>	<b>8</b>	<b>14</b>	<b>22</b>

**Table 3a : Patients with different randomized treatment than indicated on surgical summary**

<b>Subject ID</b>	<b>Site</b>	<b>Randomized Treatment</b>	<b>Surgical Summary</b>
03-***-0016	02	A	B
03-***-0003	05	A	B
03-***-0008	05	B	A
03-***-0034	05	A	B
03-***-0027	07	A	B
03-***-0014	07	B	A
03-***-0054	08	A	B
03-***-0047	08	B	A

**Table 3b: Summary of patients that crossed treatment groups by Center**

<b>Center</b>	<b>Number of Patients Enrolled</b>	<b>Crossed from A to B</b>	<b>Crossed from B to A</b>
<b>01</b>	23	0	0
<b>02</b>	19	1	0
<b>03</b>	6	2	0
<b>04</b>	0	0	0
<b>05</b>	47	1	1
<b>06</b>	2	0	0
<b>07</b>	32	1	1
<b>08</b>	60	1	1
<b>09</b>	5	0	0
<b>10</b>	6	0	0
<b>TOTAL</b>	<b>200</b>	<b>6</b>	<b>3</b>

	# Patients with Events	Total Patients (Rate%)
Treatment A	13	100 (13)
Treatment B	5	100 (5)
<b>Total</b>	18	200 (9)

**Table 4a: Adverse Event rates by treatment**

**Table 4b: Adverse Event descriptions**  
*Total Events = 18*

Subject-ID	Center ID	Date	Description of Event	Severity of Event	Device Related?
03-***-0009	02	17-Feb-09	NECROSIS/WOUND SLOUGH	MILD	POSSIBLY RELATED
03-***-0006	05	9-Sep-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	30-Sep-08	DEEP INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	6-Oct-08	DEEP INFECTION	MODERATE	POSSIBLY RELATED
03-***-0006	05	30-Oct-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0001	07	9-Jul-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0001	07	11-Jul-08	DVT	MODERATE	POSSIBLY RELATED
03-***-0001	07	31-Jul-08	DVT	MODERATE	POSSIBLY RELATED
03-***-0002	07	4-Nov-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0010	07	13-Sep-08	MAYOCARDIAL INFARCTION	MODERATE	DEFINITELY NOT RELATED

<b>03-***-0010</b>	07	20-Nov-08	FRACTURED OTHER ANKLE (RIGHT)	MODERATE	DEFINITELY NOT RELATED
<b>03-***-0010</b>	07	19-Feb-09	Non-Union	SEVERE	POSSIBLY RELATED
<b>03-***-0026</b>	07	01-Apr-09	CONSTRUCT LOOSENING-DISTAL TO FRACTURE	NOT SERIOUS	POSSIBLY RELATED
<b>02-***-0001</b>	06	28-JUL-09	SURGICAL SITE/ORTHOAEDIC	MILD	PROBOLY NOT RELATED
<b>02-***-0022</b>	06	09-Sep-09	INFECTION MINOR	MILD	POSSIBLY RELATED
<b>02-***-0025</b>	06	15- SEP-09	DEEP INFECTION	MODERATE	NOT RELATED
<b>02-***-0027</b>	06	17-AUG-09	PATIENT REQUIRED A LATERAL PLATE WHEN RANDOMIZED TO ANTIGLIDE	NOT SERIOUS	DEFINITELY NOT RELATED
<b>03-***-0005</b>	07	03-AUG-09	PAINFUL IMPALNT - PLATE	MILD	DEFINITELY RELATED