

Report for ANKLE DSMB: Prepared APRIL 2011

Part A: Number of Patients Included and Excluded

There have been 242 patients randomized online as of April 04, 2011.

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

Table 1 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: Summary of Patient Randomization

Table 2a presents the number of patients by treatment assignment. 120 patients have been randomized to Treatment A (**49.6%**) and 122 to Treatment B (**50.41 %**) **Table 2b-c** cross-references each patient's online randomization with the treatment indicated on the Surgical Summary form. Of the 242 patients enrolled, 9 (crossed treatments) (3.71%).

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

Table 3a presents the patients that were lost to follow-up, withdrew consent, or were removed due to an ineligible fracture. **Table 3b-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 37 patients lost to follow-up. 15 patients withdrew consent after randomization, 5 Patients were terminated by study team and 1 patient was removed due to an ineligible fracture pattern leaving a total active enrollment of 71.

Part D: Summary of Adverse Events

Table 4a shows the event rates as of April 04, 2011. There have been 27 reported Adverse Events in 19 study patients, resulting in a (10) percent AE rate in Treatment A (N=120), and a (5.74) percent AE rate for Treatment B (N=122). There has been 1 Serious Adverse Event reported. Descriptions of the reported Adverse Events are presented in **Table 4b**.

Figure 1: Overall study status

Overall Study Status

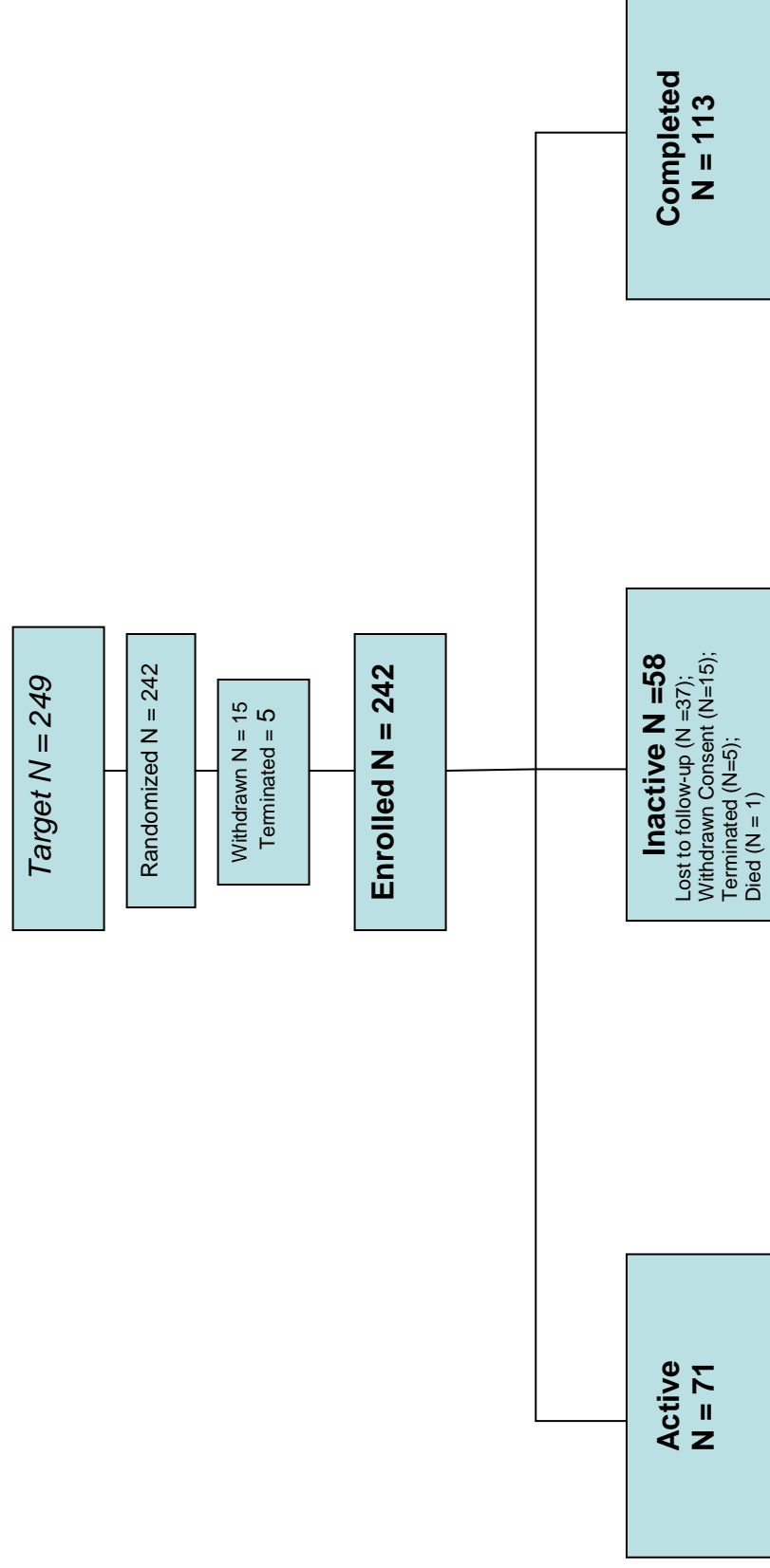


Figure 2: Cumulative enrollment by month

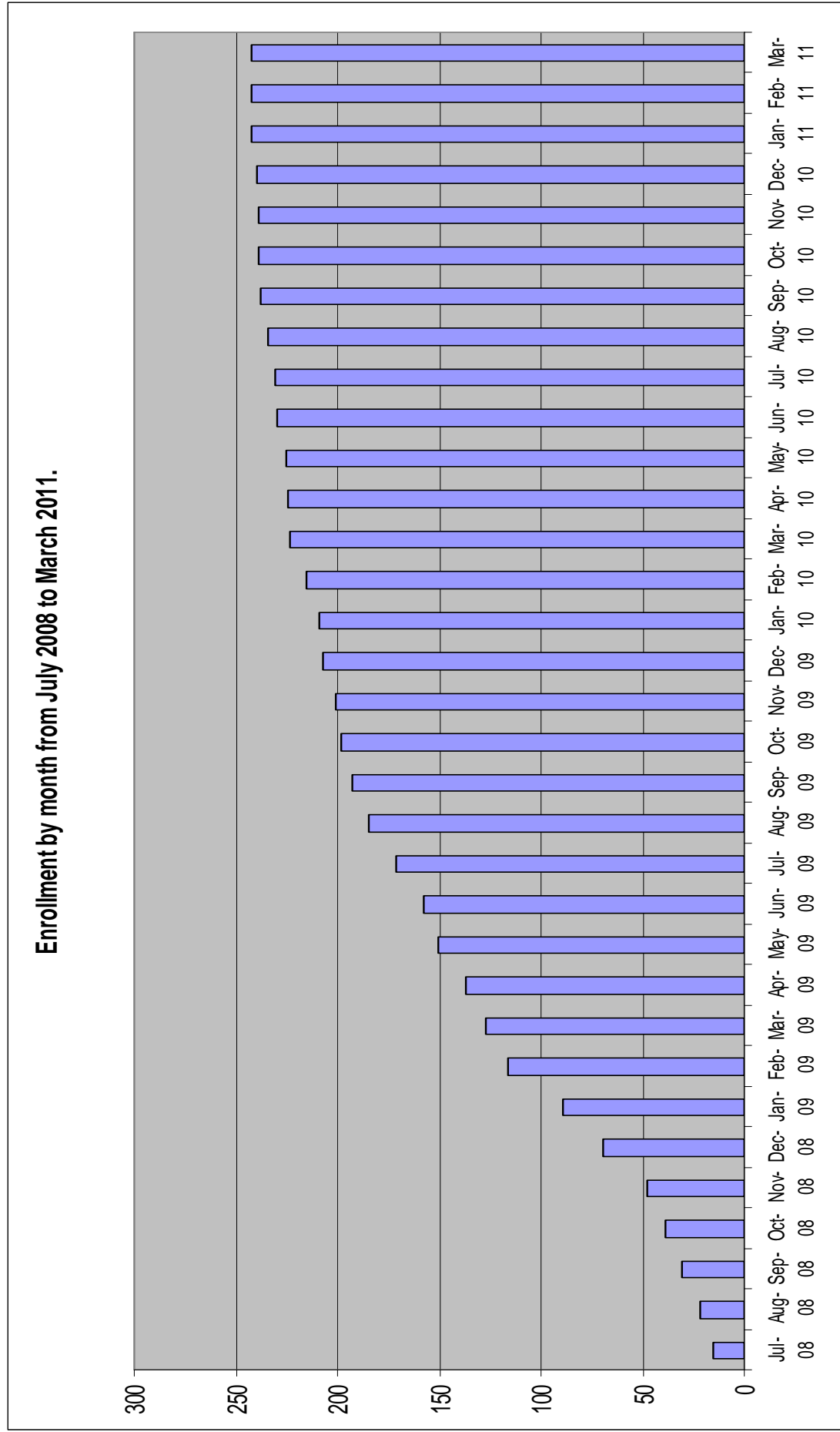


Table 1: Enrollment July 2008 through March 2009

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	2	0	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	4	3	1	4	5	1	3
06	01-Feb-09	-	-	-	-	-	-	-	0	0
07	08-Jan-09	-	-	-	-	-	-	0	6	2
08	03-Jun-08	6	2	3	2	4	10	8	12	4
09	08-Jan-09	0	0	0	0	0	0	0	0	0
10	09-May-08	0	0	0	0	0	0	2	1	0
Total Sites		5	5	7	8	8	8	9	10	10
Monthly Enrollment		15	7	9	7	9	21	22	27	11
Cumulative Enrollment		15	22	31	39	48	69	89	116	127

Table 1: 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	1
06	01-Feb-09	0	0	0	0	2	0	0
07	08-Jan-09	3	0	1	7	9	2	2
08	03-Jun-08	2	6	0	0	0	0	0
09	08-Jan-09	0	3	2	0	0	0	0
10	09-May-08	1	0	0	0	0	0	2
Total Sites		10	10	10	10	10	10	10
Monthly Enrollment		10	13	8	13	14	8	5
Cumulative Enrollment		137	150	158	171	185	193	198

Table 1: Enrollment through November 2009 to May 2010

Center ID	Approval Date	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10
01	10-Sep-08	0	0	0	0	0	0	0
02	27-Mar-08	0	0	1	1	2	0	0
03	6-Jun-08	0	0	0	0	0	1	0
04	26-Sep-08	0	0	0	0	0	0	0
05	26-May-08	1	1	0	0	0	0	0
06	01-Feb-09	0	1	0	0	0	0	0
07	08-Jan-09	1	1	1	0	0	0	0
08	03-Jun-08	0	0	0	2	3	0	0
09	08-Jan-09	0	3	0	0	2	0	1
10	09-May-08	1	0	0	3	1	0	0
Total Sites		10	10	10	10	10	10	10
Monthly Enrollment		3	6	2	6	8	1	1
Cumulative Enrollment		201	207	209	215	223	224	225

Table 1: Enrollment through Jun 2010 to Dec 2010

Center ID	Approval Date	Jun-10	Jul-10	Aug-10	Sep-10	Oct-10	Nov-10	Dec-10
01	10-Sep-08	0	0	0	0	0	0	0
02	27-Mar-08	1	0	1	2	1	0	0
03	6-Jun-08	1	1	0	0	0	0	0
04	26-Sep-08	0	0	0	0	0	0	0
05	26-May-08	0	0	0	0	0	0	0
06	01-Feb-09	0	0	1	0	0	0	0
07	08-Jan-09	0	0	0	0	0	0	0
08	03-Jun-08	1	0	0	0	0	0	0
09	08-Jan-09	2	0	1	2	0	0	1
10	09-May-08	0	0	0	0	0	0	0
Total Sites		10	10	10	10	10	10	10
Monthly Enrollment		5	1	3	4	1	0	1
Cumulative Enrollment		230	231	234	238	239	239	240

Table 1: Enrollment through Jan 2011 to Mar 2011

Center ID	Approval Date	Jan-11	Feb-11	Mar-11
01	10-Sep-08	0	0	0
02	27-Mar-08	1	0	0
03	6-Jun-08	0	0	0
04	26-Sep-08	0	0	0
05	26-May-08	0	0	0
06	01-Feb-09	0	0	0
07	08-Jan-09	0	0	0
08	03-Jun-08	0	0	0
09	08-Jan-09	1	0	0
10	09-May-08	0	0	0
Total Sites		10	10	10
Monthly Enrollment		2	0	0
Cumulative Enrollment		242	242	242

Table 2a: Enrollment by Treatment Assignment

Center ID	Treatment A	Treatment B	Total
01	12	11	23
02	15	14	29
03	5	4	9
04	0	0	0
05	25	25	50
06	1	2	3
07	17	19	36
08	33	33	66
09	7	8	15
10	5	6	11
TOTAL	120	122	242

Table 2b : Patients with different randomized treatment than indicated on surgical summary

Subject ID	Site	Randomized Treatment	Surgical Summary
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 2c: Summary of patients that crossed treatment groups by Center

Center	Number of Patients Enrolled	Crossed from A to B	Crossed from B to A
01	23	0	0
02	29	1	0
03	9	2	0
04	0	0	0
05	50	1	1
06	35	0	0
07	66	1	1
08	4	1	1
09	15	0	0
10	11	0	0
TOTAL	242	6	3

Table 3a: Patients lost to follow-up, withdrew consent, ineligible

Subject-ID	Center-ID	Date of Enrollment	Date of Last Follow-up	Reason
03-***-0001	01	29-Sep-08	16-Dec-08	Lost to f/u
03-***-0002	01	30-Sep-08	08-Jan-09	Lost to f/u
03-***-0004	01	10-Nov-08	13-Jan-2009	Lost to f/u
03-***-0005	01	17-Nov-08	31-Dec-2008	Lost to f/u
03-***-0008	01	10-Dec-08	07-May-2009	Lost to f/u
03-***-0009	01	9-Dec-08	10-Feb-2009	Lost to f/u
03-***-0012	01	6-Jan-09	22-Jan-09	Lost to f/u
03-***-0014	01	15-Jan-09	No follow up	Lost to f/u
03-***-0015	01	15-Jan-09	29-Jan-09	Lost to f/u
03-***-0018	01	10-Feb-09	19-Mar-09	Lost to f/u
03-***-0019	01	13-Feb-09	No follow up	Lost to f/u
03-***-0020	01	17-Feb-09	19-Mar-09	Lost to f/u
03-***-0017	01	4-Feb-09	30-Apr-09	Lost to f/u
03-***-0021	01	4-Mar-09	26-May-09	Lost to f/u
03-***-0001	02	1-Jul-08	12-Aug-08	Lost to f/u
03-***-0003	02	23-Jul-08	13-Jan-09	Lost to f/u
03-***-0005	02	31-Jul-08	19-Aug-08	Lost to f/u
03-***-0006	02	4-Aug-08	3-Feb-09	Lost to f/u
03-***-0018	02	28-Jul-09	No F/u	Withdrew Consent.
03-***-0001	03	16-Feb-09	NO F/U	Lost to f/u
03-***-0002	03	17-Apr-09	29-Apr-09	Terminated
03-***-0004	03	7-Jul-09	NO F/U	Withdrew Consent.
03-***-0001	05	11-Jul-08	8-Aug-08	Lost to f/u
03-***-0003	05	18-Jul-08	03-feb-09	Lost to f/u
03-***-0009	05	19-Sep-08	10-Oct-08	Lost to f/u

Subject-ID	Center-ID	Date of Enrollment	Date of Last Follow-up	Reason
03-***-0018	05	18-Dec-08	19-Mar-09	Lost to f/u
03-***-0022	05	16-Jan-09	07-Apr-09	Lost to f/u
03-***-0026	05	27-Feb-09	16-Apr-09	Lost to f/u
03-***-0029	05	30-Mar-09	30-Mar-09	Lost to f/u
03-***-0044	05	24-Sep-09	16-Feb-10	Lost to f/u
03-***-0012	05	30-Sep-08	N/A	Terminated
03-***-0007	08	11-Aug-08	No f/u	Lost to f/u
03-***-0008	08	26-Aug-08	19-Nov-08	Withdrew consent
03-***-0011	08	12-Sep-08	8-Dec-08	Lost to f/u
03-***-0012	08	6-Oct-08	6-Oct-08	Withdrew consent
03-***-0015	08	2-Nov-08	No f/u	Lost to f/u
03-***-0016	08	2-Nov-08	11-May-09	Withdrew consent
03-***-0020	08	15-Dec-08	29-Jan-09	Withdrew consent
03-***-0021	08	15-Dec-08	9-Mar-09	Lost to f/u
03-***-0024	08	18-Dec-08	10-Jun-09	Withdrew consent
03-***-0025	08	18-Dec-08	No f/u	Withdrew consent
03-***-0028	08	31-Dec-08	3-Apr-09	lost to f/u
03-***-0029	08	1-Jan-09	2-Apr-09	lost to f/u
03-***-0034	08	9-Jan-09	19-Mar-09	Withdrew consent
03-***-0035	08	18-Jan-09	2-Mar-09	Lost to f/u
03-***-0036	08	20-Jan-09	15-Jul-09	Withdrew consent
03-***-0037	08	1-Feb-09	31-Jul-09	Withdrew consent
03-***-0038	08	2-Feb-09	No F/U	in eligible
03-***-0039	08	2-Feb-09	28-May-09	Withdrew consent
03-***-0045	08	14-Feb-09	11-Jun-09	Withdrew consent
03-***-0046	08	17-Feb-09	7-May-09	Withdrew consent
03-***-0002	09	6-May-09	No F/u	Withdrew consent

Subject-ID	Center-ID	Date of Enrollment	Date of Last Follow-up	Reason
03-***-0005	09	03-Jun-09	12-Jun-09	Lost to f/u
03-***-0004	10	20-Apr-09	2-Jun-09	Lost to f/u
03-***-0002	10	27-Jan-09	28-Jul-09	Lost to f/u
03-***-0005	10	21-Oct-09	9-Dec-09	Terminated
03-***-0006	10	22-Oct-09	7-Dec-09	Terminated

Table3b: 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	0	0
08	0	1	1
09	0	0	0
10	0	0	0
TOTAL	0	1	1

Table3c Withdrawn Patients by Fracture Type and Treatment Assignment

CenterID	Treatment A	Treatment B	Total
01	0	0	0
02	0	1	1
03	1	0	1
04	0	0	0
05	0	0	0
06	0	0	0
07	0	0	0
08	6	6	12
09	0	1	1
10	0	0	0
TOTAL	7	8	15

Table 3d: Patients Lost to Follow-up by Fracture Type and Treatment Assignment

CenterID	Treatment A	Treatment B	Total
01	5	9	14
02	1	3	4
03	0	1	1
05	3	5	8
06	0	0	0
07	0	0	0
08	2	5	7
09	1	0	1
10	1	1	2
TOTAL	13	24	37

Table 4a: Adverse Event rates by treatment

	# Patients with Events	Total Patients (Rate%)
Treatment A	12	120 (10.0)
Treatment B	7	122 (5.74)
Total	19	242 (7.85)

Table 4b: Adverse Event descriptions

Total Events = 26

Subject-ID	Center ID	Treatment	Date	Description of Event	Severity of Event	Device Related?
06-***-0003	06	A	05-Jul-10	PAINFUL IMPLANT-SCREW,PLATE	MILD	DEFINITELY RELATED
10-***-0009	10	A	20-SEP-10	SUBJECT EXPIRED DUE TO CANCER.	SERIOUS	DEFINITELY NOT RELATED
08-***-0062	08	A	2-SEP-10	PAINFUL IMPLANT-SCREW	MILD	DEFINITELY RELATED
08-***-0062	08	A	2-SEP-10	DEVELOPED EQUINOUS CONTRACTURE	MILD	DEFINITELY RELATED
08-***-0057	08	A	4-May-10	PAINFUL IMPLANT-SCREW	MILD	DEFINITELY RELATED
03-***-0006	05	A	9-Sep-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	A	30-Sep-08	DEEP INFECTION	MILD	POSSIBLY RELATED
03-***-0006	05	A	6-Oct-08	DEEP INFECTION	MODERATE	POSSIBLY RELATED
03-***-0006	05	A	30-Oct-08	SUPERFICIAL INFECTION	MILD	POSSIBLY RELATED
03-***-0001	08	A	9-Jul-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0001	08	A	11-Jul-08	DVT	MODERATE	POSSIBLY RELATED
03-***-0001	08	A	31-Jul-08	DVT	MODERATE	POSSIBLY RELATED

03-***-0002	08	A	4-Nov-08	INFECTED SUPERFICIAL WOUND (not at surgical site)	MILD	DEFINITELY NOT RELATED
03-***-0026	08	A	01-Apr-09	CONSTRUCT LOOSENING-DISTAL TO FRACTURE	NOT SERIOUS	POSSIBLY RELATED
02-***-0001	07	A	28-JUL-09	SURGICAL SITE/ORTHOPAEDIC	MILD	PROBABLY NOT RELATED
02-***-0022	07	A	09-Sep-09	INFECTION MINOR	MILD	POSSIBLY RELATED
02-***-0027	07	A	17-Aug-09	PATIENT REQUIRED A LATERAL PLATE WHEN RANDOMIZED TO ANTIGLIDE	NOT SERIOUS	DEFINITELY NOT RELATED
03-***-0005	08	A	03-Aug-09	PAINFUL IMPALNT -PLATE	MILD	DEFINITELY RELATED
03-***-0010	08	B	13-Sep-08	MYOCARDIAL INFARCTION	MODERATE	DEFINITELY NOT RELATED
03-***-0010	08	B	20-Nov-08	FRACTURED OTHER ANKLE (RIGHT)	MODERATE	DEFINITELY NOT RELATED
03-***-0010	08	B	19-Feb-09	Non-Union	SEVERE	POSSIBLY RELATED
03-***-0009	02	B	17-Feb-09	NECROSIS/WOUND SLOUGH	MILD	POSSIBLY RELATED
02-***-0025	07	B	15-Sep-09	DEEP INFECTION	MODERATE	NOT RELATED
02-***-0017	02	B	01-Jul-10	Anterior Tendonitis	NOT SERIOUS	PROBABLY NOT RELATED
03-***-0007	03	B	5-May-10	Neurological deficit-peripheral injury	MODERATE	DEFINITELY NOT RELATED
03-***-0029	03	B	27-Feb-11	Necrosis/Wound Slough	MILD	POSSIBLY RELATED
06-***-0017	06	B	14-Jul-10	Painful Implant-Screw	MILD	DEFINITELY RELATED