

## **Report for SOLVED DSMB: Prepared Dec 2011**

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

There have been 140 patients enrolled in SOLVED as of Dec 1, 2011. Target enrollment is 160 patients. **Figure 1** presents the overall study status. **Figure 2** shows the cumulative enrollment of patients by month. **Table 1** presents the recruitment in the 22 centers who are participating in SOLVED study, and a month-by-month picture of the recruitment each center has achieved.

### **Part B: Summary of patient randomization**

**Table 2** presents the number of patients by fracture type and treatment assignment. 74 patients were randomized to Treatment A (52.86%) and 66 were randomized to Treatment B (47.14%). There were 38 open fractures in total. 18 were randomized to Treatment A (47.37%) and 20 to Treatment B (52.63%). There were 102 closed fractures in total. 56 were randomized to Treatment A (54.9%) and 46 to Treatment B (45.1%).

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

**Table 3** shows patients with early study exits. 20 of the 140 patients enrolled have exited the study early (14.29%). 13 patients have been lost to follow-up, 4 subjects were withdrawn from the study due to non-compliance to follow up and 3 subjects expired before completing the study.

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

**Table 4a** shows the event rates as of Dec 1, 2011. There have been 52 reported Adverse Events in 35 patients resulting in a 24.32 percent AE rate in Treatment A (N=74), and a 25.75 percent AE rate for Treatment B (N=66). 24 events were definitely not related to the device, 2 were probably not related, 6 were possibly related, and 20 were definitely related. Descriptions of the reported Adverse Events are presented in **Table 4b**.

**Figure 1: Overall study status**

**Overall Study Status**

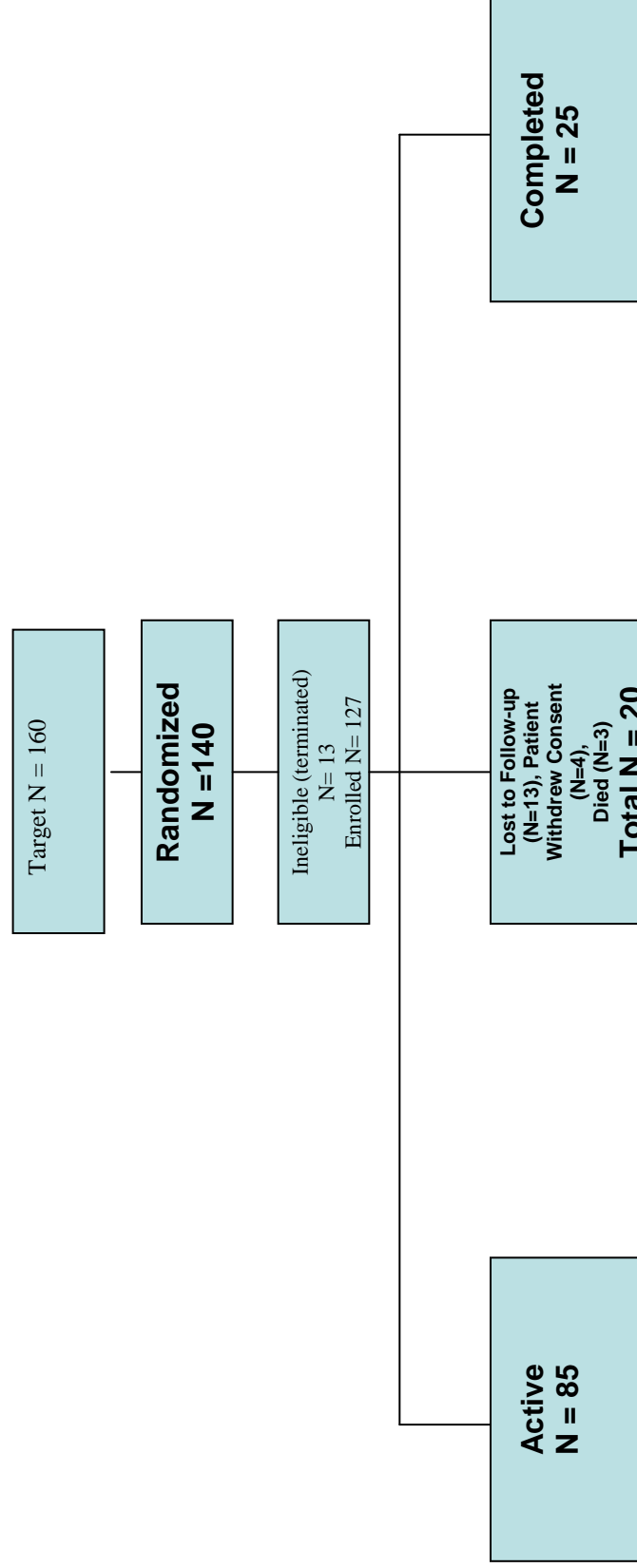
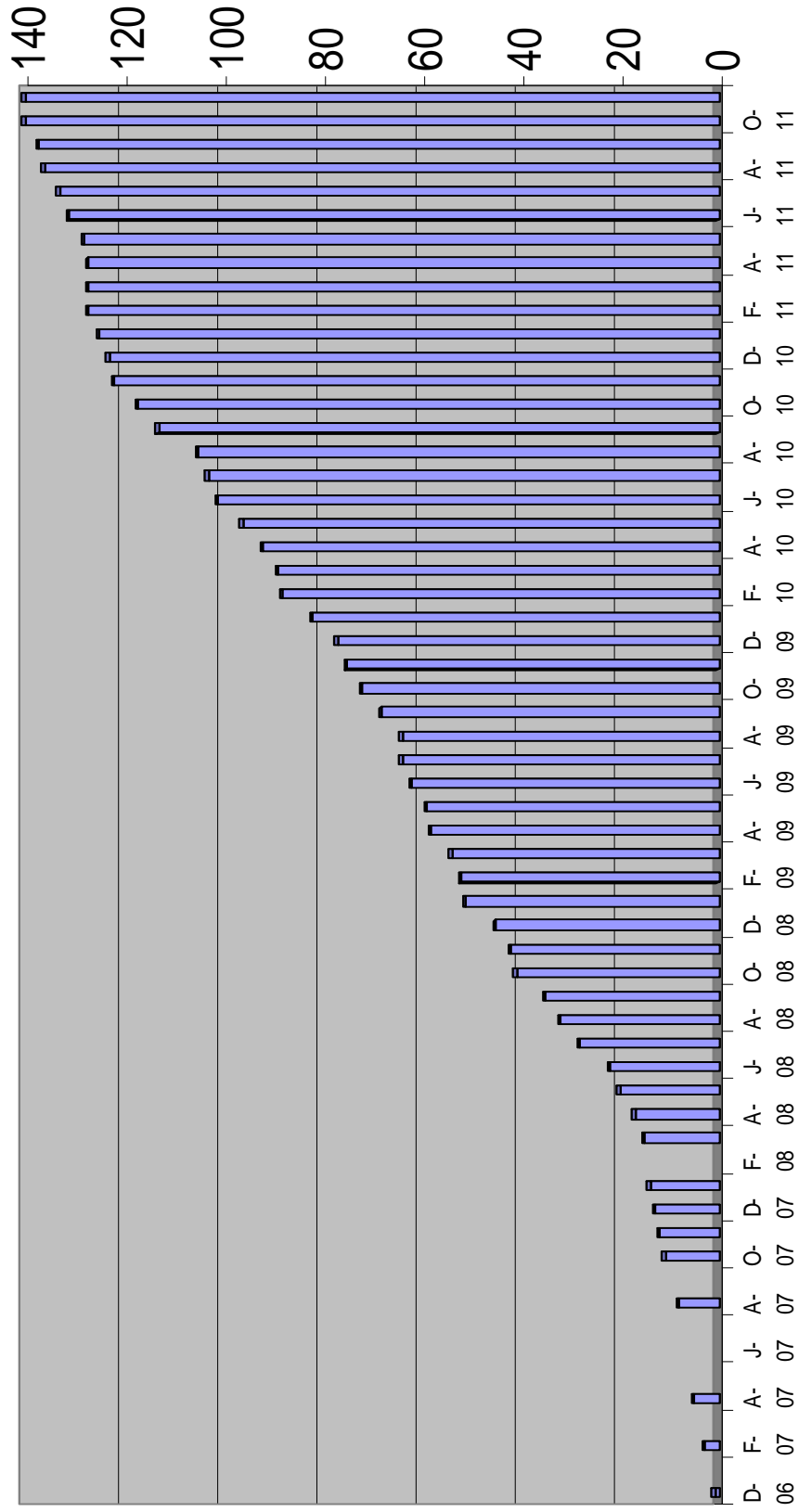


Figure 2: Cumulative enrollment by month:

## Total enrollment by month Dec 06 - Dec 11.

Target = 160



**Table 1: Enrollment by Site, Dec. 2006 through Dec 2011:**

Site #	IRB Approval	Dec-06	Jan-07	Feb-07	Mar-07	Apr-07	May-07	Jun-07	Jul-07	Aug-07	Sep-07	Oct-07	Nov-07	Dec-07	Jan-08	Feb-08
02	Dec-06	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
03	Oct-06	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
04	May-07	X	X	X	X	X	0	0	0	1	0	0	0	0	0	0
05	Nov-06	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
06	Sep-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	Jun-07	X	X	X	X	X	X	0	0	0	0	0	0	0	0	0
08	Apr-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0
09	Apr-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
11	Jul-07	X	X	X	X	X	X	X	0	0	0	1	0	0	0	0
12	Mar-07	X	X	X	0	1	0	0	0	0	0	0	1	0	0	0
13	Mar-07	X	X	X	0	1	0	0	0	0	0	0	0	0	0	0
14	Dec-06	1	0	2	0	0	0	0	0	0	0	0	0	0	0	0
15	May-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
16	Mar-07	X	X	X	0	0	0	0	0	0	0	1	0	0	0	0
17	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0
18	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0
19	Jun-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
20	Jun-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
22	Apr-07	X	X	X	X	0	0	0	0	1	0	0	0	0	0	0
23	Jul-07	X	X	X	X	X	X	X	0	0	0	0	0	0	0	0
24	Mar-07	X	X	X	0	0	0	0	0	0	0	0	0	0	0	0
25	May-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
28	Oct-07	X	X	X	X	X	X	X	X	X	X	0	0	0	0	0
29	Nov-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Enrollment</b>		<b>1</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>3</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>0</b>
<i>Total Sites</i>		5	5	5	9	11	14	15	17	17	17	18	18	18	18	18

Table 1 continued:

Site #	Approval Date	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09	Jun-09
02	Dec-06	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
03	Oct-06	1	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0
04	May-07	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
05	Nov-06	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	1
06	Sep-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	Jun-07	0	0	1	1	1	1	0	0	0	0	0	0	1	0	0	0
08	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	X
09	Apr-08	X	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
11	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	Mar-07	0	0	1	0	1	0	1	0	0	0	1	1	0	1	0	0
13	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	Dec-06	0	0	1	0	1	0	1	2	0	0	2	0	0	2	0	0
15	May-08	X	X	0	1	1	0	0	2	0	1	2	0	0	0	1	1
16	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
17	May-07	0	0	0	0	0	1	0	0	0	0	1	0	1	0	0	0
18	May-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	Jun-08	X	X	X	0	0	0	0	0	0	0	0	0	0	0	0	1
20	Jun-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0
22	Apr-07	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
23	Jul-07	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
24	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	May-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0
28	Oct-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	Nov-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Enrollment</b>		<b>1</b>	<b>2</b>	<b>3</b>	<b>2</b>	<b>6</b>	<b>4</b>	<b>3</b>	<b>6</b>	<b>1</b>	<b>3</b>	<b>6</b>	<b>1</b>	<b>2</b>	<b>4</b>	<b>1</b>	<b>3</b>
<b>Total Sites</b>		<b>18</b>	<b>19</b>	<b>20</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>21</b>	<b>22</b>	<b>22</b>

**Table 1 continued:**

Site #	Approval Date	Jul-09	Aug09	Sep-09	Oct-09	Nov09	Dec-09	Jan10	Feb-10	Mar10	Apr-10	May10	Jun-10
02	Dec-06	0	0	0	1	0	0	2	0	0	0	0	0
03	Oct-06	2	0	0	0	0	1	0	0	0	0	0	0
04	May-07	0	0	0	0	0	0	0	0	0	0	0	X
05	Nov-06	0	0	0	1	1	1	0	1	0	0	0	1
06	Sep-06	X	X	X	X	X	X	X	X	X	X	X	X
07	Jun-07	0	0	0	0	0	0	0	0	0	0	1	0
08	Apr-07	X	X	X	X	X	X	X	X	X	X	X	X
09	Apr-08	0	0	2	0	0	0	0	0	0	0	0	1
11	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0
12	Mar-07	0	0	0	0	1	0	0	0	0	2	0	0
13	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0
14	Dec-06	0	0	0	1	0	0	0	2	0	0	0	1
15	May-08	0	0	2	1	0	0	1	2	0	0	0	1
16	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0
17	May-07	0	0	0	0	0	0	0	0	0	0	0	0
18	May-07	0	0	0	0	0	0	0	0	0	0	0	0
19	Jun-08	0	0	0	0	0	0	2	1	0	0	0	1
20	Jun-09	0	0	0	0	0	0	0	0	0	0	0	0
22	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0
23	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0
24	Mar-07	0	0	0	0	0	0	0	0	0	1	2	0
25	May-07	0	0	0	0	1	0	0	0	0	0	1	0
28	Oct-07	0	0	0	0	0	0	0	0	0	0	0	0
29	Nov-09	X	X	X	X	0	0	0	0	1	0	0	0
<b>Enrollment</b>		<b>2</b>	<b>0</b>	<b>4</b>	<b>4</b>	<b>3</b>	<b>2</b>	<b>5</b>	<b>6</b>	<b>1</b>	<b>3</b>	<b>4</b>	<b>5</b>
<i>Total Sites</i>		22	22	22	22	23	23	23	23	23	23	23	22

**Table 1 continued:**

Site #	Approval Date	10-Jul	10-Aug	10-Sep	10-Oct	10-Nov	10-Dec	11-Jan	11-Feb	11-Mar	11-Apr	11-May	11-Jun
2	6-Dec	0	0	0	0	0	0	0	0	0	0	0	0
3	6-Oct	0	0	0	0	0	0	0	0	0	0	0	0
4	7-May	0	0	0	0	0	0	0	0	0	0	0	0
5	6-Nov	0	0	1	1	0	0	0	0	0	0	0	0
6	6-Sep	X	X	X	X	X	X	X	X	X	X	X	X
7	7-Jun	0	0	1	0	0	0	0	0	0	0	0	0
8	7-Apr	X	X	X	X	X	X	X	X	X	X	X	X
9	8-Apr	0	0	1	0	1	0	1	1	0		0	0
11	7-Jul	0	0	0	0	0	0	0	0	0	0	0	0
12	7-Mar	0	0	1	0	0	1	0	0	0	0	0	1
13	7-Mar	0	0	0	0	0	0	0	0	0	0	0	0
14	6-Dec	1	1	1	1	1	0	0	1	0	0	1	1
15	8-May	0	0	1	1	0	0	1	0	0	0	0	0
16	7-Mar	0	0	0	0	0	0	0	0	0	0	0	0
17	7-May	0	0	0	1	1	0	0	0	0	0	0	0
18	7-May	0	0	0	0	1	0	0	0	0	0	0	0
19	8-Jun	0	0	1	0	1	0	0	0	0	0	0	1
20	9-Jun	0	0	0	0	0	0	0	0	0	0	0	0
22	7-Apr	0	0	0	0	0	0	0	0	0	0	0	0
23	7-Jul	0	0	0	0	0	0	0	0	0	0	0	0
24	7-Mar	1	2	0	0	0	0	0	0	0	0	0	0
25	7-May	0	0	0	0	0	0	0	0	0	0	0	0
28	7-Oct	0	0	0	0	0	0	0	0	0	0	0	0
29	9-Nov	0	0	0	0	0	0	0	0	0	0	0	0
<b>Enrollment</b>		<b>2</b>	<b>3</b>	<b>7</b>	<b>4</b>	<b>5</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>3</b>
<b>Total Sites</b>		<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>	<b>22</b>

**Table 1 continued:**

Site #	Approval										
	Date	11-Jul	11-Aug	11-Sep	11-Oct	11-Nov					
2	6-Dec	0	0	0	0	0					
3	6-Oct	0	0	0	0	0					
4	7-May	0	0	0	0	0					
5	6-Nov	0	0	0	0	0					
6	6-Sep	X	X	X	X	X					
7	7-Jun	0	0	0	0	0					
8	7-Apr	X	X	X	X	X					
9	8-Apr	0	0	0	0	0					
11	7-Jul	0	0	0	0	0					
12	7-Mar	0	0	0	0	0					
13	7-Mar	0	0	0	0	0					
14	6-Dec	1	2	0	0	2					
15	8-May	1	1	1	0	0					
16	7-Mar	0	0	0	0	0					
17	7-May	0	0	0	0	0					
18	7-May	0	0	0	0	0					
19	8-Jun	0	0	0	0	0					
20	9-Jun	0	0	0	0	0					
22	7-Apr	0	0	0	0	0					
23	7-Jul	0	0	0	0	0					
24	7-Mar	1	0	0	0	1					
25	7-May	0	0	0	0	0					
28	7-Oct	0	0	0	0	0					
29	9-Nov	0	0	0	0	0					
<b>Enrollment</b>		<b>2</b>	<b>3</b>	<b>1</b>	<b>3</b>	<b>0</b>					
<i>Total Sites</i>		22	22	22	22	22					



**Table 2: Randomization by Fracture Type and Treatment Assignment:**

Site #	Treatment A			Treatment B			Total		
	Open	Closed	Total	Open	Closed	Total	Open	Closed	Total
2	0	4	4	0	2	2	0	6	6
3	0	4	4	0	3	3	0	7	7
4	1	1	2	0	0	0	1	1	2
5	3	2	5	5	2	7	8	4	12
7	2	3	5	1	1	2	3	4	7
8	0	0	0	0	0	0	0	0	0
9	0	5	5	0	4	4	0	9	9
11	0	0	0	0	1	1	0	1	1
12	5	3	8	4	2	6	9	5	14
13	0	0	0	0	1	1	0	1	1
14	4	11	15	3	10	13	7	21	28
15	2	9	11	2	9	11	4	18	22
16	0	1	1	0	1	1	0	2	2
17	0	2	2	1	2	3	1	4	5
18	0	1	1	0	0	0	0	1	1
19	0	5	5	1	3	4	1	7	8
20	0	0	0	0	0	0	0	0	0
22	0	2	2	0	0	0	0	2	2
23	0	1	1	0	1	1	0	2	2
24	1	2	3	2	3	5	3	5	8
25	0	1	1	0	1	1	0	2	2
28	0	0	0	0	0	0	0	0	0
29	0	0	0	1	0	1	1	0	1
<b>TOTAL</b>	<b>18</b>	<b>56</b>	<b>74</b>	<b>20</b>	<b>46</b>	<b>66</b>	<b>38</b>	<b>102</b>	<b>140</b>

**Table 3: Patients lost to follow-up & withdrawn from study:**

<b>Pt ID</b>	<b>Reason</b>
03-0001	Reason Unknown - Lost to follow-up
04-0002	Reason Unknown - Lost to follow-up
05-0002	Patient Incarcerated - lost to follow-up
05-0007	Patient Incarcerated - lost to follow-up
09-0004	Reason unknown - lost to follow-up
11-0001	Reason Unknown - lost to follow-up
14-0001	Patient withdrawn due to non-compliance
12-0001	Patient moved - lost to follow-up
12-0004	Reason unknown - patient lost to follow-up
12-0007	Reason unknown - patient lost to follow-up
15-0005	Transportation issue - lost to follow-up
15-0008	Transportation issue - lost to follow-up
15-0004	Patient withdrawn(by the study team)
16-0001	Reason unknown-Lost to follow up.
16-0002	Patient Terminated- Mental illness.
17-0002	Patient withdrawn(by the study team)
23-0002	Subject went to local orthopedist-lost to follow-up.

**Table 4a: Adverse Event rates by treatment and fracture type:**

	Total Events	Patients	Total Enrolled	Rate
<b>Treatment A</b>	<b>28</b>	<b>18</b>	<b>74</b>	<b>24.32%</b>
Open	8	5	18	27.77%
Closed	20	13	56	23.21%
<b>Treatment B</b>	<b>24</b>	<b>17</b>	<b>66</b>	<b>25.75%</b>
Open	5	3	20	15.00%
Closed	19	14	46	30.43%
<b>Total</b>	<b>52</b>	<b>35</b>	<b>140</b>	<b>25.00%</b>
Open	12	8	38	21.05%
Closed	39	27	102	26.47%

**Table 4b: Adverse Event descriptions:**

Pt #	FX Type	Treatment	Description	Related to Device?
3-0006	CLOSED	NAIL	Painful Implant-Nail	Definitely related
3-0006	CLOSED	NAIL	Pulmonary Embolism	Definitely not related.
4-0001	OPEN	NAIL	Construct loosening - distal to femur	Definitely related
4-0001	OPEN	NAIL	Painful Implant Screw.	Definitely related
4-0002	CLOSED	NAIL	Decreased gastric motility	Definitely not related
4-0002	CLOSED	NAIL	Vitral hemorrhage	Definitely not related
5-0002	OPEN	NAIL	Painful implant - screw	Definitely related
5-0005	CLOSED	NAIL	Leg Swelling	Definitely not related.
7-0006	OPEN	NAIL	Pulmonary Embolism	Definitely not related.
9-0002	CLOSED	NAIL	Left shoulder pain	Definitely not related
9-0002	CLOSED	NAIL	Abdominal hernia	Definitely not related
9-0002	CLOSED	NAIL	Fracture Ankle and Distal Fibula on opposite leg during hospital stay for Femur Fracture.	Definitely not related
9-0004	CLOSED	NAIL	Congestive Heart Failure	Definitely not related
12-0010	OPEN	NAIL	Construct loosening - distal to femur	Definitely related

**Adverse Event description (Continued)**

<b>Pt #</b>	<b>FX Type</b>	<b>Treatment</b>	<b>Description</b>	<b>Related to Device?</b>
12-0010	OPEN	NAIL	Construct loosening - Proximal to fracture.	Definitely related
15-0003	CLOSED	NAIL	Painful Implant-Nail	Definitely related
15-0009	CLOSED	NAIL	Open wound right heel, infected, retained suture	Definitely not related.
17-0001	CLOSED	NAIL	Contra lateral Knee TKA	Definitely not related
17-0001	CLOSED	NAIL	Painful implant - Nail	Definitely related
22-0001	CLOSED	NAIL	Painful implant - screw	Definitely related
23-0001	CLOSED	NAIL	Infection - deep	Possibly related
23-0001	CLOSED	NAIL	Infection - deep	Possibly related
09-0002	CLOSED	NAIL	Painful Implant-Screw	Definitely related
12-0011	OPEN	NAIL	Painful Implant-Screw	Definitely related
12-0011	OPEN	NAIL	Construct Loosening-Distal to fracture.	Definitely related.
14-0007	CLOSED	NAIL	Death-Unknown reason.	Definitely not related.
15-0014	CLOSED	NAIL	Death-Colon Cancer	Definitely not related.

Pt #	FX Type	Treatment	Description	Related to Device?
19-0008	CLOSED	NAIL	Pulmonary Embolism	Definitely Not related.
3-0002	CLOSED	PLATE	Painful implant - plate	Definitely related
3-0002	CLOSED	PLATE	Hardware irritation	Definitely related
3-0004	CLOSED	PLATE	perforated bowel	Definitely not related
3-0004	CLOSED	PLATE	pulmonary embolism	Probably not related
3-0004	CLOSED	PLATE	Cardiovascular Arrhythmia	Definitely not related
3-0005	CLOSED	PLATE	Fractured implant plate	Definitely related
5-0004	CLOSED	PLATE	Painful implant - plate	Definitely related
9-0001	CLOSED	PLATE	Neurological Deficit	Definitely not related
9-0001	CLOSED	PLATE	Urinary Tract Infection	Definitely not related
9-0003	CLOSED	PLATE	Right Calcaneus Fracture.	Definitely not related
9-0003	CLOSED	PLATE	Right Femoral Non-union	Possibly related
11-0001	CLOSED	PLATE	painful implant - screw & Arthrofibrosis	Definitely related
12-0001	OPEN	PLATE	Painful implant - plate, Arthrofibrosis	Possibly related

Pt #	FX Type	Treatment	Description	Related to Device?
15-0006	OPEN	PLATE	DVT	Definitely not related
15-0007	CLOSED	PLATE	DVT	Definitely not related
15-0013	CLOSED	PLATE	Painful Implant-Screw	Definitely related
09-0006	CLOSED	PLATE	Respiratory Failure, Cardiac arrest-Death.	Definitely not related
14-0009	CLOSED	PLATE	Cardiac Arrhythmia	Definitely not related.
25-0001	CLOSED	PLATE	Painful Implant-Screw	Definitely related
24-0008	CLOSED	PLATE	Death-Cardiac and respiratory events.	Definitely Not Related.
15-0016	OPEN	PLATE	Painful Plate	Definitely related
15-0016	OPEN	PLATE	Non Union-Fractured Plate	Possibly Related.
15-0020	CLOSED	PLATE	Failed Fixation: Component Removal	Possibly Related
12-0001	OPEN	PLATE	Infection - deep, Non-union	Probably not related