

Report for IMPRESS DSMB: Prepared December 2009

Part A: Number of Patients Included and Excluded

There have been 44 patients enrolled in IMPRESS as of December 1, 2009. 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 27 centers who have are participating in IMPRESS, 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. 24 patients were randomized to Treatment A and 20 to Treatment B. Of the 17 open fractures, 8 were randomized to Treatment A (47%) and 9 to Treatment B (53%). Of the 27 closed fractures, 16 were randomized to Treatment A (59%) and 11 to Treatment B (41%).

No patients were found to have crossed over from one treatment arm to the other.

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

Table 3 shows the patients with early study exits. So far, 11 of the 44 patients enrolled have exited the study early (25.0%). 10 patients have been lost to follow-up (22.7%) and 1 patient died from injuries unrelated to the research study or device (2.3%). No patients voluntarily withdrew consent. 3 patients were randomized but were not enrolled due to discovery of an ineligible fracture patterns and were removed from the study.

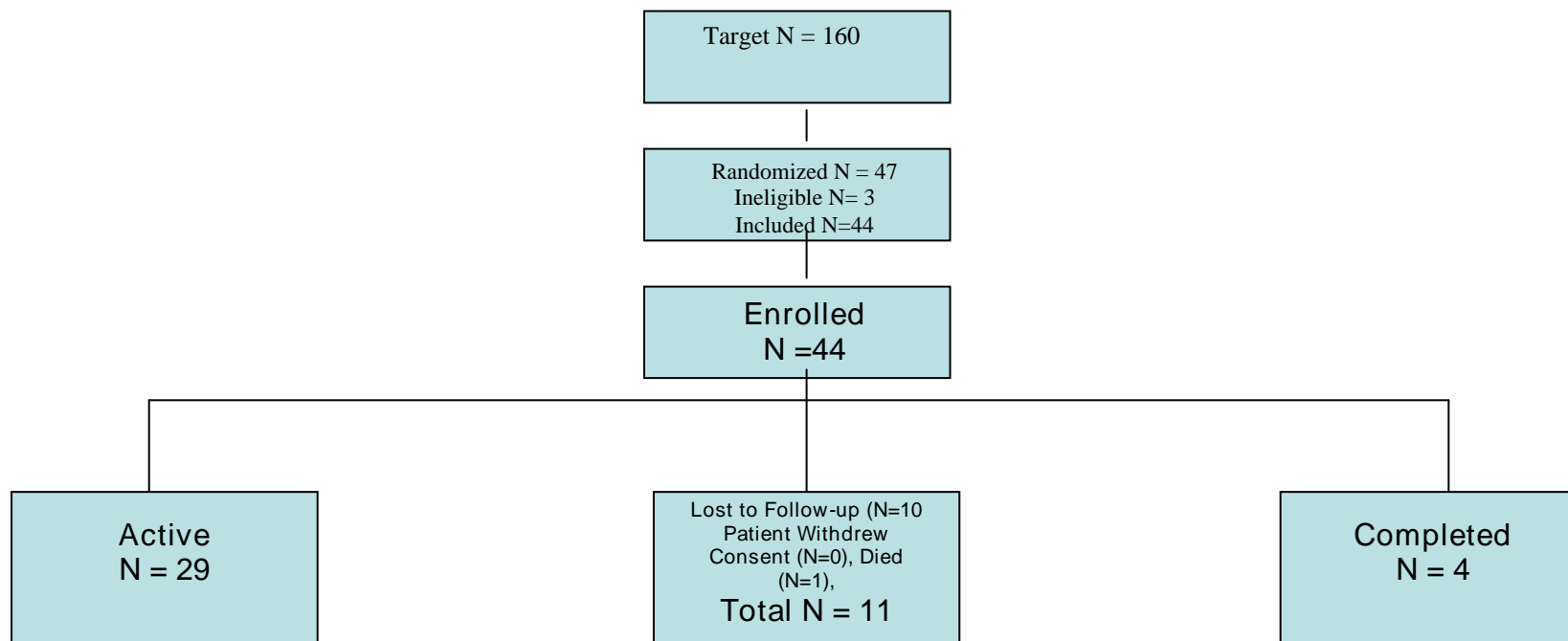
Part D: Summary of Adverse Events

Table 4a shows the event rates as of November 30, 2009. There have been 8 reported Adverse Events in 6 subjects resulting in a 12.5 percent AE rate in Treatment A , and a 15 percent AE rate for Treatment B. Of all 8 events, 3 were definitely not related to the device, 3 were possibly related, and 1 was probably not related and 1 was unknown. 3 of the events were mild, 3 events were moderate, and 2 of the events were considered serious. Of the serious events, 1 was definitely not related to the treatment and the other was probably not related to the treatment.

Table 4b contains the descriptions of the reported Adverse Events

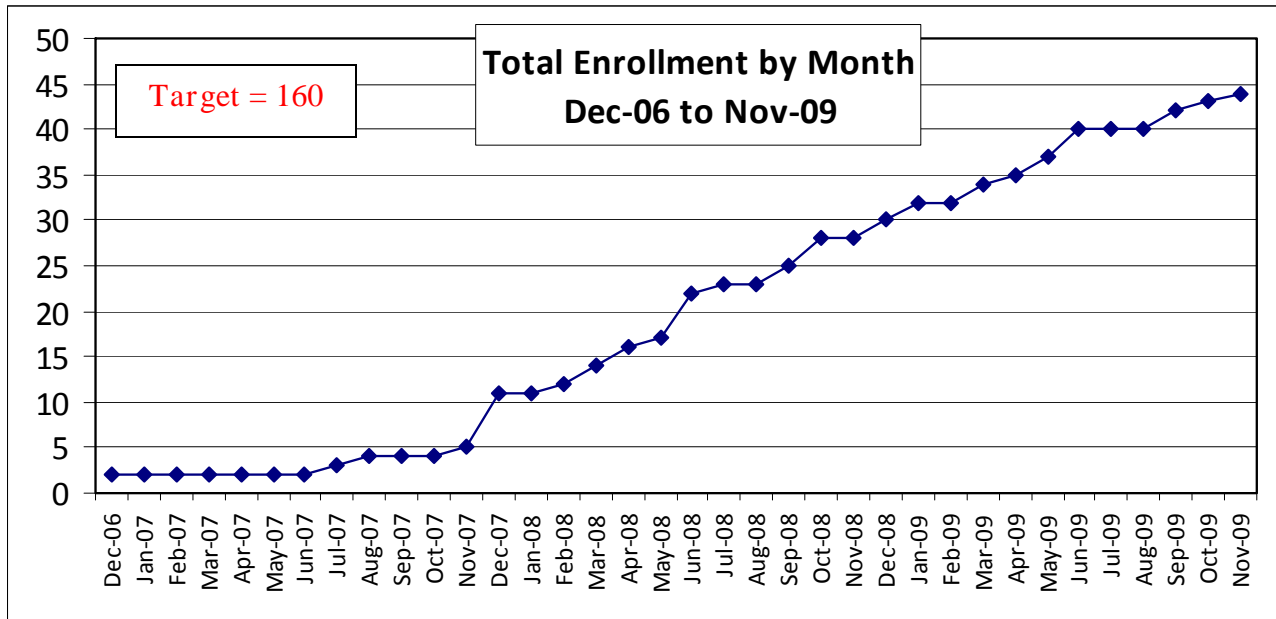
Figure 1: Overall study status

### Overall Study Status



Part A: Number of Patients Included and Excluded

Figure 2: Cumulative enrollment by month:



Part A: Number of Patients Included and Excluded

Table 1: Enrollment by Site. Dec. 2006 through November 2009:

Site #	IRB Date	Enrollment															
		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	
01	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0	
02	Dec-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
03	Oct-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
04	May-07	X	X	X	X	X	0	0	0	0	0	0	0	0	0	0	
05	Nov-06	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
06	Mar-07	X	X	X	X	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	0	0	0	0	0	0	0	0	0	0	0	
10	May-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	0	0	0	0	0	
12	Mar-07	X	X	X	0	0	0	0	0	0	0	0	0	1	0	0	
13	Mar-07	X	X	X	0	0	0	0	0	1	0	0	0	0	0	0	
14	Dec-06	2	0	0	0	0	0	0	0	0	0	0	0	1	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	0	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	2	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	
21	Jun-07	X	X	X	X	X	X	0	0	0	0	0	0	0	0	0	
22	Apr-07	X	X	X	X	0	0	0	1	0	0	0	0	0	0	0	
23	Jul-07	X	X	X	X	X	X	X	0	0	0	0	0	2	0	1	
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	
26	Aug-08	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
27	Apr-07	X	X	X	X	0	0	0	0	0	0	0	0	0	0	0	
<b>Enrolled</b>		<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>6</b>	<b>0</b>	<b>1</b>	
<b>Cumulative</b>		<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>5</b>	<b>11</b>	<b>11</b>	<b>12</b>	
<i>Total Sites</i>		<i>4</i>	<i>4</i>	<i>4</i>	<i>8</i>	<i>13</i>	<i>17</i>	<i>19</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	<i>21</i>	

Part A: Number of Patients Included and Excluded

Table 1 continued:

Site #	IRB 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
		01	May-07	1	1	0	0	0	0	0	0	0	0	0	0	0
02	Dec-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
03	Oct-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
04	May-07	0	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	0	0	0	0	0	0
06	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	Jun-07	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
08	Apr-07	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
09	Apr-08	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	May-08	X	X	0	0	0	0	0	0	0	0	0	0	1	0	0
11	Jul-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
12	Mar-07	0	0	0	1	0	0	1	1	0	1	0	0	1	0	0
13	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	Dec-06	0	0	1	2	0	0	0	0	0	1	1	0	0	0	1
15	May-08	X	X	0	2	0	0	1	0	0	0	0	0	0	0	0
16	Mar-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	May-07	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
18	May-07	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
20	May-09	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0
21	Jun-07	0	0	0	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	0	1	0
23	Jul-07	0	1	0	0	0	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
25	May-07	X	X	X	X	X	X	X	X	X	X	X	X	X	X	0
26	Aug-08	X	X	X	X	X	0	0	1	0	0	0	0	0	0	0
27	Apr-07	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Enrolled</b>		<b>2</b>	<b>2</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>2</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>2</b>
<b>Cumulative</b>		<b>14</b>	<b>16</b>	<b>17</b>	<b>22</b>	<b>23</b>	<b>23</b>	<b>25</b>	<b>28</b>	<b>28</b>	<b>30</b>	<b>32</b>	<b>32</b>	<b>34</b>	<b>35</b>	<b>37</b>
<b>Total Sites</b>		<b>21</b>	<b>21</b>	<b>23</b>	<b>24</b>	<b>24</b>	<b>25</b>	<b>25</b>	<b>25</b>	<b>25</b>	<b>25</b>	<b>25</b>	<b>25</b>	<b>25</b>	<b>25</b>	<b>27</b>

Part A: Number of Patients Included and Excluded

Table 1 Continued

Site #	IRB Date	Jun-09	Jul-09	Aug-09	Sep-09	Oct-09	Nov-09
01	May-07	0	0	0	0	0	0
02	Dec-06	0	0	0	0	0	0
03	Oct-06	0	0	0	0	0	0
04	May-07	0	0	0	0	0	0
05	Nov-06	0	0	0	0	0	1
06	Mar-07	0	0	0	0	0	0
07	Jun-07	0	0	0	0	0	0
08	Apr-07	0	0	0	0	0	0
09	Apr-08	0	0	0	0	0	0
10	May-08	1	0	0	0	0	0
11	Jul-07	0	0	0	0	0	0
12	Mar-07	0	0	0	1	0	0
13	Mar-07	0	0	0	0	0	0
14	Dec-06	1	0	0	0	1	0
15	May-08	1	0	0	1	0	0
16	Mar-07	0	0	0	0	0	0
17	May-07	0	0	0	0	0	0
18	May-07	0	0	0	0	0	0
19	Jun-08	0	0	0	0	0	0
20	May-09	0	0	0	0	0	0
21	Jun-07	0	0	0	0	0	0
22	Apr-07	0	0	0	0	0	0
23	Jul-07	0	0	0	0	0	0
24	Mar-07	0	0	0	0	0	0
25	May-07	0	0	0	0	0	0
26	Aug-08	0	0	0	0	0	0
27	Apr-07	0	0	0	0	0	0
	<b>Enrolled</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>1</b>
	<b>Cumulative</b>	<b>40</b>	<b>40</b>	<b>40</b>	<b>42</b>	<b>43</b>	<b>44</b>
	<b>Total Sites</b>	<b>27</b>	<b>27</b>	<b>27</b>	<b>27</b>	<b>27</b>	<b>27</b>

Part B: Summary of patient randomization

Table 2: Enrollment by Fracture Type and Treatment Assignment:

Site #	Treatment A			Treatment B			Total		
	Open	Closed	Total	Open	Closed	Total	Open	Closed	Total
01	0	1	1	0	1	1	0	2	2
02	0	0	0	0	0	0	0	0	0
03	0	0	0	0	0	0	0	0	0
04	0	0	0	0	0	0	0	0	0
05	0	1	1	0	1	1	0	2	2
06	0	0	0	0	0	0	0	0	0
07	1	0	1	1	0	1	2	0	2
08	0	1	1	0	0	0	0	1	1
09	0	0	0	0	0	0	0	0	0
10	0	2	2	0	0	0	0	2	2
11	0	0	0	0	1	1	0	1	1
12	2	1	3	3	1	4	5	2	7
13	0	1	1	0	0	0	0	1	1
14	1	4	5	2	4	6	3	8	11
15	2	1	3	1	1	2	3	2	5
16	0	0	0	0	0	0	0	0	0
17	0	1	1	0	0	0	0	1	1
18	0	0	0	1	1	2	1	1	2
19	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0
22	0	1	1	1	0	1	1	1	2
23	1	2	3	0	1	1	1	3	4
24	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0
26	1	0	1	0	0	0	1	0	1
27	0	0	0	0	0	0	0	0	0
TOTAL	8	16	24	9	11	20	17	27	44

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

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

Site #	Pt ID	Date of Enrollment	Date of Last Follow-up	Reason
01	1-01	3/5/2008	5/23/2008	Patient moved away
05	5-01	11/5/2007	1/4/2008	Reason unknown - patient lost to follow-up
08	8-01	1/5/2009	no follow-up	Patient is mentally Impaired and has not been able to comply with F/Us
12	12-02	6/6/2008	8/5/2008	Reason unknown - patient lost to follow-up
14	14-03	11/3/2007	no follow-up	Patient moved away
16	16-01	10/23/2008	-	Patient withdrawn (by study team)
17	17-01	7/29/2008	-	Patient withdrawn (by study team)
22	22-01	7/11/2007	no follow-up	Reason unknown - patient lost to follow-up
22	22-02	1/20/2009	-	Patient withdrawn (by study team)
23	23-01	11/20/2007	1/3/2008	Reason unknown - patient lost to follow-up
23	23-02	12/28/2007	no follow-up	Reason unknown - patient lost to follow-up
23	23-03	2/10/2008	6/30/2008	Reason unknown - patient lost to follow-up
23	23-04	4/6/2008	no follow-up	Reason unknown - patient lost to follow-up
23	23-01	10/20/2008	-	Patient deceased

Part D: Summary of Adverse Events

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

	<b>Total Events</b>	<b>Total Patients w/ Events</b>	<b>Enrollment (Adverse Event Rate%)</b>
<b>Treatment A</b>	<b>5</b>	<b>3</b>	<b>24 (12.5)</b>
Open	1	1	8 (12.5)
Closed	4	2	16 (12.5)
<b>Treatment B</b>	<b>3</b>	<b>3</b>	<b>20 (15.0)</b>
Open	1	1	9 (11.1)
Closed	2	2	11 (18.2)
<b>Total</b>	<b>8</b>	<b>6</b>	<b>44 (13.6)</b>
Open	2	2	17 (11.8)
Closed	6	4	27 (14.8)

Table 4b: Adverse Event descriptions:

Site #	Patient ID	Treatment	Fx Type	AE Date	Related	Severity	Unexpected	Description
01	1-01	A	CLOSED	5/23/2008	Possibly	Mod	NO	30 DEGREE APEX ANTERIOR ANGULATION NOTED ON XRAY - R TIBIA
01	1-01	A	CLOSED	9/15/2008	Def Not	Mod	NO	INFECTION - DEEP
01	1-01	A	CLOSED	6/23/2009	Def Not	Mod	NO	WOUND BREAKDOWN RIGHT PROXIMAL TIBIA SURGICAL SITE.
01	1-02	B	CLOSED	4/19/2008	Def Not	Sev	NO	ASPIRATION PNEUMONIA
12	12-03	B	CLOSED	3/24/2009	Possibly	Mild	NO	NON-UNION
14	14-01	A	CLOSED	11/6/2007	Possibly	Mild	NO	PAINFUL IMPLANT - SCREW
22	22-03	B	OPEN	6/3/2009	Unknown	Mild	NO	INFECTION – SUPERFICIAL
26	26-01	A	OPEN	10/28/2008	Def Not	Sev	NO	MULTITRAUMA/STROKE/I NTRACRANIAL HYPERTENSION