

Table 1: Screw Issues – Dynesys Subjects - Randomized

Patient ID (Subjects Censored Prior to Screw Issue are Noted)		Loosening, Migration, Fracture, Lucencies					AE Reporting		
ID	Visit	Onset Date	Loosening	Migration	Fracture	Lucency	Screw Issue AE Report - Description and AE Date	AE Comments	Additional AE Reporting
(b) (4) (Reoperation, Censored)	Other	7/6/2005	x				"Other - screw loosening" on AE CRF 8/10/04 (Exam Date)	CT SCAN MYELO REVEALED LOOSENING OF S1 SCREW- RESULTING IN LEG AND BACK PAIN WITH FOOT DROP	"Other - Reoperation" on 7/6/05 (Exam Date) AE CRF
(b) (4) (3-level Subject, Censored)	12MOS	2/24/2005			x		"Screw Failure/Fracture Level L4 L5 (L)" on AE CRF 2/24/05 (Exam Date)	RADIOGRAPHS TAKEN ON 2/24/05 SHOW BOTH SCREWS ARE FRACTURED AS THEN PENETRATE THE POSTERIOR PLANE OF THE VERTEBRAL BODY - NO TREATMENT PLANNED	"Screw Failure/Fracture Level L4" - noted "occ Vicodin for pain" on 3/16/06, 5/15/07 and 3/18/08 (Exam Date) AE CRFs
(b) (4)	24MOS	6/17/2005				x	"Other - screw radiolucency (L) L4" on AE CRF 6/17/05 (Exam Date)	RADIOLUCENCY NOTED ON AP XR OF LEFT L4 SCREW, PATIENT ASYMPTOMATIC	"Other- screw radiolucency (L) L4" on 7/14/06 (Exam Date) AE CRF
(b) (4)	6MOS	4/1/2004				x	"Other - L3 screw lucency" on AE CRF 4/1/04 (Exam Date)	NEW LUCENCY SURROUNDING (R) L3 SCREW, NO ABNORMAL MOTION, ASYMPTOMATIC.	"Other- L3 screw lucency" noted "observation" on 9/10/04 and 3/01/07 (Exam Date) AE CRFs
(b) (4)	36MOS	12/13/2006		x			"Device Migration Level L4" on AE CRF 12/13/06 (Exam Date)	SET SCREW L4 SCREW LOOSENED, PATIENT DOING WELL	"Device Migration Level 4" noted "Pt complains of intermittent severe low back pain, MRI ordered" on 5/02/08 (Exam Date) AE CRF

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(b) (4)	12MOS	4/20/2005				x	"Other - (L) L4 Screw Lucency" on AE CRF 4/20/05 (Exam Date)	PT IS IN FOR 12 MOS. ROUTINE FOLLOW-UP. X-RAYS DEMONSTRATE LUCENCY AROUND LEFT L4 SCREW.	"Screw Failure/Fracture Level (R) L4" - noted "On X- ray the(R) L4 screw is fractured" on 4/19/06 and 4/19/07 Exam Dare AE CRFs; "Other - (L) L4 screw lucency"- noted "X-rays demonstrates persistent lucency around the (L) L4 screw" on 4/19/06, 4/19/07 and 5/29/08 (Exam Date) AE CRFs
(b) (4)	3MOS	7/22/2004				x	"Other - (L) L4 Screw Lucency" on AE CRF 7/22/04 (Exam Date)	IT WAS NOTED ON X-RAYS DATED 7/22/04 THAT THERE APPEARS TO BE SOME LUCENCY AROUND HIS (L) L4 SCREW	"Other - (L) L4 Screw Lucency" on 10/21/04 - Noted "The lucency around the (L) L4 screw has resolved" on 10/21/04 (Exam Date) AE CRF
(b) (4)	12MOS	3/12/2004	x				"Back Pain" on AE CRF 9/03/04 (Exam Date); "Other - Screw Loosening at L4 level" on AE CRF 9/03/04 (Exam Date)	SUBJECT C/O MID-LOW BACK PAIN AND BURNING OF LEGS AND FEET NOW. CT SCAN REVEALS LOOSENING SCREWS @L4-5. DR. WELCH ADVISES REMOVAL OF HARDWARE. HE ALSO FEELS THERE MAY BE A MILD NEUROPATHY - (TOO MILD TO DIAGNOSE); X-RAY ON 2/20/04 HALO WAS NOTED AROUND L4 SCREWS, CT SCAN OF 3/12/04 CONFIRMED THIS"	"Other - Screw loosening at L4 Level" - noted NO screw loosening or Halo on 9/7/07 X-rays"
(b) (4) (Partial removal, Censored)	Other	3/21/2005	x				"Other - Loosening of pedicle screw at L3" on AE CRF 7/4/04 (Exam Date)	PEDICLE SCREW LOOSE PER CT SCAN NOTED 7-8-04	"Other - Removal of Hardware"; "Note: Pedicle Screw Loose" on 3/31/05 (Exam Date) AE CRF

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(b) (4)	3WKS	12/5/2003	x				"Screw Failure/Fracture level L4 L5 (L)" on AE CRF 12/05/03 (Exam Date)	PATIENT COMPLAINS OF BACK AND LEFT LEG PAIN. X-RAY SHOWS L4-5 LOOSENING AT SCREW.	"Screw Failure/Fracture level L4 L5 (L)" noted - "X-ray views show Left L4 screw loose; 1/19/04 revision and reposition of L4-5 pedicle screw; (L) L4 screw removed and replaced and spacer was replaced" on 01/19/04 (Exam Date) CRF
(b) (4)	24MOS					x	"Back and Leg Pain" with crossed out "Other - MVA screw loosening" on AE CRF 3/14/06 (Exam Date)	PATIENT HAD MVA ON 6/18/04 AND SINCE THEN HE HAS BACK PAIN AND @ LE PAIN (NO NOTES OF SCREW ISSUES ON CRF WITH THE EXCEPTION OF CORRECTED/CROSSED OUT "SCREW LOOSENING" ON FRONT OF CRF	
(b) (4)	36MOS	4/27/2007				x	"Other - Asymptomatic (L) L4 screw radiolucency" on AE CRF 4/27/07 (Exam Date)	NEW RADIOGRAPHIC LUCENCY AROUND LEFT L4 SCREW	
(b) (4)	24MOS	2/16/2007			x		"Screw failure/Fracture level L5" on AE CRF 2/16/07 (Exam Date)	LEG AND BACK PAIN (NO NOTES ON SCREW FAILURE OR RADIOGRAPHIC ISSUES IN COMMENTS ON AE CRF)	
(b) (4)	12MOS	9/10/2004		x			"Device migration Level L2' on AE CRF 9/10/04 (Exam Date)	SCREW LOOSING WITH LATERAL MIGRATION LEFT L2 PEDICLE- BACK PAIN	"Device migration Level L2' with "L2 screw moving laterally" noted on 11/01/04 (Exam Date) AE CRF; "Device migration Level L2" with "Device Explanted" noted on 11/16/04 (Exam Date) CRF

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(b) (4)	12MOS	6/4/2005	x				"Other - loosening of upper screws at L4 and one of S1 screws" on AE CRF 6/9/05 (Exam Date)	X-RAYS AT 12 MOS VISIT SHOW EVIDENCE OF SOME LOOSENING OF THE UPPER SCREWS AT L4 AS WELL AS ONE OF THE S1 SCREWS. NONE ARE PULLED OUT. SUBJECT STATED SHE FELL ON SOME STEPS & STRUCK HER LOWER BACK.	"Other - L4 to S1 revision and fusion - removal of Dynesys due to loosening of screws" on 2/23/06 (Exam Date) AE CRF

Table 2: Table 1: Screw Issues – Dynesys Subjects – Roll-in

Patient ID (Subjects Censored Prior to Screw Issue are Noted)		Loosening, Migration, Fracture, Lucencies					AE Reporting		
ID	Visit	Onset Date	Loosening	Migration	Fracture	Lucency	Screw Issue AE Report - Description and AE Date	AE Comments	Additional AE Reporting
(b) (4)	12MOS	2/7/2005				x	"Other - (R) L4 screw lucency" on AE CRF 2/07/05 (Exam Date)	PT. WAS IN FOR ROUTINE 12 MOS. FOLLOW UP X- RAYS OBTAINED SHOWED LUCENCY AROUND RIGHT L4 SCREW	

Table 3: Screw Issues - *Silhouette* Subjects - Randomized

Patient ID (Subjects Censored Prior to Screw Issue are Noted)		Loosening, Migration, Fracture, Lucencies					AE Reporting		
ID	Visit	Onset Date	Loosening	Migration	Fracture	Lucency	Screw Issue AE Report - Description and AE Date	AE Comments	Additional AE Reporting
(b) (4) (Reoperation)	Other	6/17/2004	x				"Screw Failure/Fracture Level (L) L4" on AE CRF 6/17/04 (Exam Date)	AT RE-OP THE LEFT L4 SCREW WAS LOOSE AND WOBBLY (NOTED - THE SCREW WAS REMOVED.)	"Pseudoarthrosis" Note "Pseudoarthrosis was discovered during surgery posterior lateral fusion" on 10/21/04 (Exam Date) AE CRF
(b) (4) (Other - Discontinued)	24MOS	7/11/2007	x				"Other -radiographic loosening of screws" on AE CRF 7/11/06 (Exam Date)	RADIOGRAPHS LOOSEN NOTED ON FILM @ L3 & L5	
(b) (4)	6MOS	12/15/2004	x				"Other - Asymptomatic screw loosening" on AE CRF 12/15/04 (Exam Date)	ASYMPTOMATIC SCREW LOOSENING L4 R	"Other - screw loosening" on 6/29/05 (Exam Date) CRF; "Other - asymptomatic screw loosening" on 6/5/06 (Exam Date) CRF
(b) (4)	6MOS	1/12/2005	x				"Other - L4 screw loosening" on AE CRF 01/12/05 (Exam Date)	PEDICLE SCREW LOOSENING L4 ON RIGHT, (PSEUDOARTHROSIS, BONE GROWTH STIMULATOR ORDERED DUE TO CHEMOTHERAPY INFLUENCE)	Patient transferred to hospice care due to breast cancer; withdrawn from study 5/29/07
(b) (4)	24MOS	9/13/2006	x				"Other - screw loosening" on AE CRF 9/13/06 (Exam Date)	SCREW LOOSENING (BILATERAL) AT S1	AE Comment on 9/13/06 - "Patient being forwarded to surgery on 01/30/07"+M46; Pt withdrew consent on 1/26/07 - transferred to new physician