Metal/Metal Hip Reclassification Petition 09:29 Wednesday, November 15, 2000

Age Range by Device

Table 1

		Age (Years)				
		#	Mean	Minimum	Maximum	Standard Deviation
STUDY	Device Type					
A	Metal Liner	219	55.7	18	75	12
	Poly Liner	206	57.0	30	75	12
B	Metal Liner	87	57.4	37	77	9
	Poly Liner					
C	Metal Liner	97	49.8	26	78	10
	Poly Liner	97	50.3	18	82	13

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Metal/Metal Hip Reclassification Petition 09:29 Wednesday, November 15, 2000
Distribution of Age by Device
Table 2

		Age Decade (Years)																Total
		1-19		20-29		30-39		40-49		50-59		60-69		70-79		80-89		
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n
STUDY	Device Type																	
A	Metal Liner	1	0.5	2	0.9	17	7.8	39	17.8	76	34.7	59	26.9	25	11.4	0	0	219
	Poly Liner	0	0	0	0	22	10.7	34	16.5	47	22.8	70	34.0	33	16.0	0	0	206
B	Metal Liner	0	0	0	0	3	3.4	13	14.9	33	37.9	33	37.9	5	5.7	0	0	87
	Poly Liner	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C	Metal Liner	0	0	2	2.1	11	11.3	34	35.1	36	37.1	11	11.3	3	3.1	0	0	97
	Poly Liner	1	1.0	2	2.1	16	16.5	26	26.8	33	34.0	13	13.4	4	4.1	2	2.1	97

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Metal/Metal Hip Reclassification Petition
Distribution of Device by Gender
Table 3

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		Gender				Total
		Female		Male		
		Count	%	Count	%	Count
STUDY	Device Type					
A	Metal Liner	104	47.5	115	52.5	219
	Poly Liner	79	38.3	127	61.7	206
B	Metal Liner	35	40.2	52	59.8	87
	Poly Liner					
C	Metal Liner	26	26.8	71	73.2	97
	Poly Liner	25	25.8	72	74.2	97

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Metal/Metal Hip Reclassification Petition 09:29 Wednesday, November 15, 2000

Height by Device

Table 4

		Height (Inches)				
		#	Mean	Minimum	Maximum	Standard Deviation
STUDY	Device Type					
A	Metal Liner	219	67.3	52	78	4
	Poly Liner	206	69.0	56	160	10
B	Metal Liner	80	66.0	59	75	3
	Poly Liner					
C	Metal Liner	97	69.6	60	82	4
	Poly Liner	97	69.7	59	81	4

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Metal/Metal Hip Reclassification Petition
Weight by Device
Table 5

09:29 Wednesday, November 15, 2000

		Weight (Pounds)				
		#	Mean	Minimum	Maximum	Standard Deviation
STUDY	Device Type					
A	Metal Liner	219	188.4	53	330	47
	Poly Liner	206	189.3	47	311	43
B	Metal Liner	86	175.5	110	240	28
	Poly Liner					
C	Metal Liner	97	202.6	125	396	44
	Poly Liner	97	201.7	95	300	43

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Metal/Metal Hip Reclassification Petition
Distribution of Device by Diagnosis
Table 6

09:29 Wednesday, November 15, 2000

	STUDY					
	A		B		C	
	Device Type		Device Type		Device Type	
	Metal Liner	Poly Liner	Metal Liner	Poly Liner	Metal Liner	Poly Liner
	Count	Count	Count	Count	Count	Count
Diagnosis						
AVASCULAR NECROSIS	29	33			12	14
CRYSTALLINE ARTHROPATHY	1					
DEVELOPMENTAL HIP DYSPLASIA	8	8	6			
DIASTROPHIC VARIANT					1	
LEGG PERTHES			2		2	
OSTEOARTHRITIS	164	152	74		75	72
OTHER	1	1				
OTHER - DETAIL			4			

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Metal/Metal Hip Reclassification Petition
Distribution of Device by Diagnosis
Table 6

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	STUDY					
	A		B		C	
	Device Type		Device Type		Device Type	
	Metal Liner	Poly Liner	Metal Liner	Poly Liner	Metal Liner	Poly Liner
	Count	Count	Count	Count	Count	Count
Diagnosis						
POST-TRAUMATIC ARTHRITIS	11	10	1		6	7
PROTRUSIO ACETABULUM	2					
SLIPPED CAPITAL FEMORAL EPIPHYSIS	3	2			1	3
SUBCAPITAL FRACTURE						1
Total	219	206	87		97	97

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Metal/Metal Hip Reclassification Petition
Distribution of Cases by Study and Device
Table 7

09:29 Wednesday, November 15, 2000

	Device Type		Total
	Metal Liner	Poly Liner	
	Count	Count	Count
Study			
A	219	206	425
B	87		87
C	97	97	194
Total	403	303	706

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Age Range by Device for 24+

Table 8

		Age (Years)				
		#	Mean	Minimum	Maximum	Standard Deviation
STUDY	Device Type					
A	Metal Liner	41	52.7	29	74	12
	Poly Liner	46	55.4	31	75	12
B	Metal Liner	43	56.1	37	77	9
	Poly Liner					
C	Metal Liner	39	48.7	26	68	9
	Poly Liner	42	48.6	18	66	11

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Metal/Metal Hip Reclassification Petition
Distribution of Age by Device for 24+
Table 9

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		Age Decade (Years)														Total
		1-19		20-29		30-39		40-49		50-59		60-69		70-79		
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n
STUDY	Device Type															
A	Metal Liner	0	0	1	2.4	6	14.6	10	24.4	11	26.8	9	22.0	4	9.8	41
	Poly Liner	0	0	0	0	8	17.4	7	15.2	11	23.9	14	30.4	6	13.0	46
B	Metal Liner	0	0	0	0	2	4.7	7	16.3	18	41.9	14	32.6	2	4.7	43
	Poly Liner	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C	Metal Liner	0	0	1	2.6	5	12.8	16	41.0	12	30.8	5	12.8	0	0	39
	Poly Liner	1	2.4	1	2.4	8	19.0	9	21.4	18	42.9	5	11.9	0	0	42

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Metal/Metal Hip Reclassification Petition
Distribution of Device by Gender for 24+
Table 10

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		Gender				Total
		Female		Male		
		Count	%	Count	%	Count
STUDY	Device Type					
A	Metal Liner	20	48.8	21	51.2	41
	Poly Liner	16	34.8	30	65.2	46
B	Metal Liner	17	39.5	26	60.5	43
	Poly Liner					
C	Metal Liner	11	28.2	28	71.8	39
	Poly Liner	9	21.4	33	78.6	42

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Metal/Metal Hip Reclassification Petition 09:47 Wednesday, November 15, 2000
Height by Device for 24+
Table 11

		Height (Inches)				
		#	Mean	Minimum	Maximum	Standard Deviation
STUDY	Device Type					
A	Metal Liner	41	67.2	52	78	5
	Poly Liner	46	68.2	59	76	4
B	Metal Liner	38	66.2	61	73	3
	Poly Liner					
C	Metal Liner	39	69.7	62	77	3
	Poly Liner	42	69.5	60	77	4

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Metal/Metal Hip Reclassification Petition
Weight by Device for 24+
Table 12

09:47 Wednesday, November 15, 2000

		Weight (Pounds)				
		#	Mean	Minimum	Maximum	Standard Deviation
STUDY	Device Type					
A	Metal Liner	41	189.6	53	283	48
	Poly Liner	46	189.4	47	311	48
B	Metal Liner	42	178.3	121	238	24
	Poly Liner					
C	Metal Liner	39	208.1	138	396	47
	Poly Liner	42	200.9	95	300	45

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Metal/Metal Hip Reclassification Petition
Distribution of Device by Diagnosis for 24+
Table 13

09:47 Wednesday, November 15, 2000

	STUDY					
	A		B		C	
	Device Type		Device Type		Device Type	
	Metal Liner	Poly Liner	Metal Liner	Poly Liner	Metal Liner	Poly Liner
	Count	Count	Count	Count	Count	Count
Diagnosis						
AVASCULAR NECROSIS	9	9			4	8
DEVELOPMENTAL HIP DYSPLASIA	3	3	1			
DIASTROPHIC VARIANT					1	
LEGG PERTHES			1		2	
OSTEOARTHRITIS	25	31	38		26	30
OTHER	1	1				
OTHER - DETAIL			3			
POST-TRAUMATIC ARTHRITIS	3	2			5	4

(CONTINUED)

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Metal/Metal Hip Reclassification Petition
Distribution of Device by Diagnosis for 24+
Table 13

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	STUDY					
	A		B		C	
	Device Type		Device Type		Device Type	
	Metal Liner	Poly Liner	Metal Liner	Poly Liner	Metal Liner	Poly Liner
	Count	Count	Count	Count	Count	Count
Diagnosis						
SLIPPED CAPITAL FEMORAL EPIPHYSIS					1	
Total	41	46	43		39	42

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Metal/Metal Hip Reclassification Petition
Mean Harris Hip Pain Score (44 Points Max) Over Time
Table 14

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STUDY=A

	Device Type					
	Metal Liner			Poly Liner		
	Pain Score			Pain Score		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	208	12.3	5.9	199	12.9	6.5
6 Week	185	39.0	7.6	165	39.2	6.9
6 Mos	145	40.4	7.2	129	40.9	6.4
12 Mos	107	41.3	6.2	103	41.5	5.6
24 Mos	37	42.0	5.9	44	39.6	8.5
24+ Mos	38	42.1	5.8	44	39.6	8.5
36 Mos	1	44.0				

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Mean Harris Hip Pain Score (44 Points Max) Over Time
Table 14

STUDY=B

	Device Type		
	Metal Liner		
	Pain Score		
	#	Mean	STD
Interval			
Pre OP	86	10.8	6.0
6 Week	79	40.9	4.2
6 Mos	66	40.2	6.5
12 Mos	63	41.0	6.4
24 Mos	36	42.6	4.2
24+ Mos	42	42.8	3.9
36 Mos	10	43.2	1.7

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Mean Harris Hip Pain Score (44 Points Max) Over Time
Table 14

STUDY=C

	Device Type					
	Metal Liner			Poly Liner		
	Pain Score			Pain Score		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	96	16.2	7.7	97	16.5	7.5
6 Mos	85	41.1	4.9	72	40.6	6.8
12 Mos	67	41.8	4.7	53	42.2	4.3
24 Mos	34	40.5	6.3	37	41.4	6.2
24+ Mos	39	42.0	4.5	41	41.5	5.5
36 Mos	20	42.3	3.4	21	42.6	3.3
48 Mos	2	44.0	0.0	2	37.0	9.9

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Mean Harris Hip Function Score (46 Points Max) Over Time
Table 15

STUDY=A

	Device Type					
	Metal Liner			Poly Liner		
	Function Score			Function Score		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	208	24.6	7.7	199	24.4	7.6
6 Week	177	26.7	7.7	160	26.2	8.6
6 Mos	144	40.4	6.7	128	41.0	6.1
12 Mos	107	42.5	5.0	102	42.1	6.0
24 Mos	37	43.3	4.7	44	42.2	5.5
24+ Mos	38	43.3	4.6	44	42.2	5.5
36 Mos	1	43.0				

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Mean Harris Hip Function Score (46 Points Max) Over Time
Table 15

---------- STUDY=B ----------

	Device Type		
	Metal Liner		
	Function Score		
	#	Mean	STD
Interval			
Pre OP	81	26.3	9.0
6 Week	74	32.5	8.3
6 Mos	64	41.3	5.5
12 Mos	48	39.6	7.4
24 Mos	32	42.8	6.2
24+ Mos	37	43.3	5.9
36 Mos	8	46.0	0.0

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Mean Harris Hip Function Score (46 Points Max) Over Time
Table 15

STUDY=C

	Device Type					
	Metal Liner			Poly Liner		
	Function Score			Function Score		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	91	27.0	9.0	91	27.2	7.6
6 Mos	83	41.8	6.2	70	41.7	6.2
12 Mos	67	43.1	5.2	52	43.7	4.0
24 Mos	32	43.6	3.6	37	42.5	5.7
24+ Mos	34	43.3	3.8	42	43.2	4.4
36 Mos	17	42.0	4.5	22	43.5	4.0
48 Mos	1	46.0		2	39.0	9.9

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Metal/Metal Hip Reclassification Petition
Mean Harris Hip Total Score (100 Points Max) Over Time
Table 16

10:20 Wednesday, November 15, 2000

STUDY=A

	Device Type					
	Metal Liner			Poly Liner		
	Total Score			Total Score		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	205	44.1	12.4	199	44.6	12.6
6 Week	169	74.6	11.9	156	74.5	11.2
6 Mos	144	90.3	11.7	127	91.3	9.9
12 Mos	107	93.4	9.7	101	93.1	10.0
24 Mos	37	95.0	9.6	44	91.5	11.1
24+ Mos	38	95.1	9.5	44	91.5	11.1
36 Mos	1	97.0				

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Mean Harris Hip Total Score (100 Points Max) Over Time
Table 16

---------- STUDY=B ----------

	Device Type		
	Metal Liner		
	Total Score		
	#	Mean	STD
Interval			
Pre OP	81	44.4	11.7
6 Week	72	82.0	10.2
6 Mos	61	90.3	9.4
12 Mos	42	90.7	10.8
24 Mos	20	98.4	3.5
24+ Mos	25	98.4	3.2
36 Mos	6	98.7	2.1

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Mean Harris Hip Total Score (100 Points Max) Over Time
Table 16

STUDY=C

	Device Type					
	Metal Liner			Poly Liner		
	Total Score			Total Score		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	91	51.1	13.4	90	51.7	12.0
6 Mos	81	93.2	8.3	69	91.8	12.3
12 Mos	67	94.6	8.1	52	95.7	7.3
24 Mos	30	93.5	9.7	31	93.5	10.9
24+ Mos	27	94.7	8.3	29	94.1	9.2
36 Mos	13	93.8	7.9	16	96.4	5.0
48 Mos	0			1	72.0	

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Metal/Metal Hip Reclassification Petition
Harris Hip Overall Rating Over Time
Table 17

10:20 Wednesday, November 15, 2000

---------- STUDY=A ----------

Device Type: Metal Liner

	Overall Rating								Total
	0 - 69		70 - 79		80 - 89		90 - 100		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	202	98.5	3	1.5					205
6 Week	49	29.0	58	34.3	46	27.2	16	9.5	169
6 Mos	8	5.6	16	11.1	21	14.6	99	68.8	144
12 Mos	5	4.7	6	5.6	7	6.5	89	83.2	107
24 Mos	2	5.4			5	13.5	30	81.1	37
24+ Mos	2	5.3			5	13.2	31	81.6	38
36 Mos							1	100.0	1

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Overall Rating Over Time
Table 17

STUDY=A

Device Type: Poly Liner

	Overall Rating								Total
	0 - 69		70 - 79		80 - 89		90 - 100		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	196	98.5	3	1.5					199
6 Week	50	32.1	58	37.2	30	19.2	18	11.5	156
6 Mos	5	3.9	14	11.0	19	15.0	89	70.1	127
12 Mos	4	4.0	5	5.0	12	11.9	80	79.2	101
24 Mos	4	9.1	4	9.1	3	6.8	33	75.0	44
24+ Mos	4	9.1	4	9.1	3	6.8	33	75.0	44

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Metal/Metal Hip Reclassification Petition
Harris Hip Overall Rating Over Time
Table 17

10:20 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Overall Rating								Total
	0 - 69		70 - 79		80 - 89		90 - 100		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	81	100.0							81
6 Week	12	16.7	11	15.3	33	45.8	16	22.2	72
6 Mos	3	4.9	5	8.2	15	24.6	38	62.3	61
12 Mos	3	7.1	5	11.9	3	7.1	31	73.8	42
24 Mos					1	5.0	19	95.0	20
24+ Mos					1	4.0	24	96.0	25
36 Mos							6	100.0	6

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Metal/Metal Hip Reclassification Petition
Harris Hip Overall Rating Over Time
Table 17

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Overall Rating								Total
	0 - 69		70 - 79		80 - 89		90 - 100		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	81	89.0	10	11.0					91
6 Mos	2	2.5	5	6.2	12	14.8	62	76.5	81
12 Mos	1	1.5	3	4.5	10	14.9	53	79.1	67
24 Mos	2	6.7			4	13.3	24	80.0	30
24+ Mos	1	3.7	1	3.7	3	11.1	22	81.5	27
36 Mos			1	7.7	3	23.1	9	69.2	13

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Metal/Metal Hip Reclassification Petition
Harris Hip Overall Rating Over Time
Table 17

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Overall Rating								Total
	0 - 69		70 - 79		80 - 89		90 - 100		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	83	92.2	6	6.7	1	1.1			90
6 Mos	6	8.7	3	4.3	7	10.1	53	76.8	69
12 Mos	1	1.9	1	1.9	4	7.7	46	88.5	52
24 Mos	2	6.5	1	3.2	4	12.9	24	77.4	31
24+ Mos	1	3.4	1	3.4	4	13.8	23	79.3	29
36 Mos					2	12.5	14	87.5	16
48 Mos			1	100.0					1

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Pain Rating Over Time
Table 18

STUDY=A

Device Type: Metal Liner

	Pain Rating														
	Not Noted		None		Slight		Mild		Moderate		Marked		Totally Disabled		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP							4	1.8	65	29.7	134	61.2	16	7.3	219
6 Week			101	51.8	47	24.1	31	15.9	15	7.7	1	0.5			195
6 Mos			106	71.1	19	12.8	14	9.4	9	6.0	1	0.7			149
12 Mos			81	72.3	18	16.1	7	6.3	6	5.4					112
24 Mos	1	2.5	32	80.0	4	10.0	1	2.5	2	5.0					40
24+ Mos	1	2.4	33	80.5	4	9.8	1	2.4	2	4.9					41
36 Mos			1	100.0											1

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Pain Rating Over Time
Table 18

STUDY=A

Device Type: Poly Liner

	Pain Rating														Total
	Not Noted		None		Slight		Mild		Moderate		Marked		Totally Disabled		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP			1	0.5	1	0.5	2	1.0	69	33.5	116	56.3	17	8.3	206
6 Week	1	0.5	91	49.2	51	27.6	31	16.8	11	5.9					185
6 Mos	1	0.7	91	66.4	24	17.5	13	9.5	6	4.4	2	1.5			137
12 Mos			71	68.3	25	24.0	3	2.9	5	4.8					104
24 Mos			31	67.4	7	15.2	2	4.3	6	13.0					46
24+ Mos			31	67.4	7	15.2	2	4.3	6	13.0					46
36 Mos															

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Metal/Metal Hip Reclassification Petition
Harris Hip Pain Rating Over Time
Table 18

10:20 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Pain Rating														Total
	Not Noted		None		Slight		Mild		Moderate		Marked		Totally Disabled		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP	1	1.1					1	1.1	16	18.4	58	66.7	11	12.6	87
6 Week	6	7.1	36	42.4	37	43.5	5	5.9	1	1.2					85
6 Mos	6	8.3	33	45.8	26	36.1	2	2.8	5	6.9					72
12 Mos	4	6.0	44	65.7	12	17.9	3	4.5	4	6.0					67
24 Mos	1	2.7	28	75.7	7	18.9			1	2.7					37
24+ Mos	1	2.3	34	79.1	7	16.3			1	2.3					43
36 Mos			8	80.0	2	20.0									10

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Metal/Metal Hip Reclassification Petition
Harris Hip Pain Rating Over Time
Table 18

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Pain Rating														Total
	Not Noted		None		Slight		Mild		Moderate		Marked		Totally Disabled		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP	1	1.0	2	2.1	1	1.0	5	5.2	41	42.3	46	47.4	1	1.0	97
6 Mos			50	58.8	25	29.4	9	10.6	1	1.2					85
12 Mos			48	71.6	13	19.4	5	7.5	1	1.5					67
24 Mos			19	55.9	11	32.4	2	5.9	2	5.9					34
24+ Mos			27	69.2	10	25.6	1	2.6	1	2.6					39
36 Mos			14	70.0	5	25.0	1	5.0							20
48 Mos			2	100.0											2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Pain Rating Over Time
Table 18

STUDY=C

Device Type: Poly Liner

	Pain Rating														Total
	Not Noted		None		Slight		Mild		Moderate		Marked		Totally Disabled		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP					2	2.1	9	9.3	40	41.2	45	46.4	1	1.0	97
6 Mos			49	68.1	12	16.7	8	11.1	2	2.8	1	1.4			72
12 Mos			39	73.6	11	20.8	2	3.8	1	1.9					53
24 Mos			28	75.7	5	13.5	2	5.4	2	5.4					37
24+ Mos	1	2.4	30	71.4	6	14.3	4	9.5	1	2.4					42
36 Mos	1	4.5	16	72.7	4	18.2	1	4.5							22
48 Mos			1	50.0			1	50.0							2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Limp Rating Over Time
Table 19

STUDY=A

Device Type: Metal Liner

	Limp Rating										Total
	Not Noted		None		Slight		Moderate		Severe		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP			7	3.2	28	12.8	127	58.0	57	26.0	219
6 Week	1	0.5	42	21.5	98	50.3	52	26.7	2	1.0	195
6 Mos	1	0.7	94	63.1	37	24.8	17	11.4			149
12 Mos			82	73.2	26	23.2	3	2.7	1	0.9	112
24 Mos	1	2.5	33	82.5	6	15.0					40
24+ Mos	1	2.4	33	80.5	7	17.1					41
36 Mos					1	100.0					1

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Limp Rating Over Time
Table 19

---------- STUDY=A ----------

Device Type: Poly Liner

	Limp Rating										Total
	Not Noted		None		Slight		Moderate		Severe		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP			7	3.4	29	14.1	114	55.3	56	27.2	206
6 Week	3	1.6	36	19.5	95	51.4	45	24.3	6	3.2	185
6 Mos	2	1.5	82	59.9	45	32.8	8	5.8			137
12 Mos			80	76.9	18	17.3	6	5.8			104
24 Mos			30	65.2	13	28.3	3	6.5			46
24+ Mos			30	65.2	13	28.3	3	6.5			46
36 Mos											

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Limp Rating Over Time
Table 19

STUDY=B

Device Type: Metal Liner

	Limp Rating										Total
	Not Noted		None		Slight		Moderate		Severe		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP	5	5.7	7	8.0	16	18.4	32	36.8	27	31.0	87
6 Week	10	11.8	25	29.4	29	34.1	16	18.8	5	5.9	85
6 Mos	7	9.7	43	59.7	17	23.6	5	6.9			72
12 Mos	12	17.9	30	44.8	17	25.4	5	7.5	3	4.5	67
24 Mos	3	8.1	31	83.8	1	2.7	1	2.7	1	2.7	37
24+ Mos	2	4.7	38	88.4	1	2.3	1	2.3	1	2.3	43
36 Mos			10	100.0							10

93

Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Limp Rating Over Time
Table 19

STUDY=C

Device Type: Metal Liner

	Limp Rating												Total
	Not Noted		None		Slight		Moderate		Severe		Unable to Walk		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval													
Pre OP	1	1.0	10	10.3	31	32.0	33	34.0	19	19.6	3	3.1	97
6 Mos			55	64.7	23	27.1	7	8.2					85
12 Mos			54	80.6	10	14.9	3	4.5					67
24 Mos			28	82.4	4	11.8	2	5.9					34
24+ Mos	1	2.6	31	79.5	7	17.9							39
36 Mos			15	75.0	5	25.0							20
48 Mos	1	50.0	1	50.0									2

94

Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Limp Rating Over Time
Table 19

STUDY=C

Device Type: Poly Liner

	Limp Rating												Total
	Not Noted		None		Slight		Moderate		Severe		Unable to Walk		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval													
Pre OP			6	6.2	23	23.7	44	45.4	23	23.7	1	1.0	97
6 Mos	1	1.4	48	66.7	16	22.2	7	9.7					72
12 Mos			43	81.1	10	18.9							53
24 Mos			27	73.0	7	18.9	3	8.1					37
24+ Mos			35	83.3	5	11.9	2	4.8					42
36 Mos			19	86.4	3	13.6							22
48 Mos			1	50.0			1	50.0					2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Support Rating Over Time
Table 20

STUDY=A

Device Type: Metal Liner

	Support Rating																
	Not Noted		None		Cane,long walks		Cane,mostly		Crutch		2 Canes		2 Crutches		Walker		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval																	
Pre OP			109	49.8	27	12.3	62	28.3	5	2.3	1	0.5	12	5.5	3	1.4	219
6 Week			28	14.4	18	9.2	51	26.2	10	5.1	2	1.0	50	25.6	36	18.5	195
6 Mos	1	0.7	116	77.9	13	8.7	15	10.1	1	0.7			2	1.3	1	0.7	149
12 Mos			100	89.3	6	5.4	6	5.4									112
24 Mos	1	2.5	34	85.0	2	5.0	3	7.5									40
24+ Mos	1	2.4	35	85.4	2	4.9	3	7.3									41
36 Mos			1	100.0													1

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Support Rating Over Time
Table 20

STUDY=A

Device Type: Poly Liner

	Support Rating																
	Not Noted		None		Cane,long walks		Cane,mostly		Crutch		2 Canes		2 Crutches		Walker		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval																	
Pre OP			99	48.1	28	13.6	64	31.1	3	1.5	1	0.5	8	3.9	3	1.5	206
6 Week			32	17.3	13	7.0	39	21.1	15	8.1	1	0.5	55	29.7	30	16.2	185
6 Mos	3	2.2	111	81.0	7	5.1	10	7.3	1	0.7	1	0.7	1	0.7	3	2.2	137
12 Mos			94	90.4	5	4.8	4	3.8							1	1.0	104
24 Mos			43	93.5	2	4.3									1	2.2	46
24+ Mos			43	93.5	2	4.3									1	2.2	46
36 Mos																	

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Support Rating Over Time
Table 20

STUDY=B

Device Type: Metal Liner

	Support Rating														Total
	Not Noted		None		Cane,long walks		Cane,mostly		Crutch		2 Canes		2 Crutches		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP	1	1.1	30	34.5	13	14.9	28	32.2	7	8.0	3	3.4	5	5.7	87
6 Week	6	7.1	12	14.1	23	27.1	12	14.1	11	12.9	12	14.1	9	10.6	85
6 Mos	6	8.3	42	58.3	17	23.6	5	6.9			2	2.8			72
12 Mos	3	4.5	46	68.7	10	14.9	7	10.4					1	1.5	67
24 Mos	2	5.4	30	81.1	3	8.1	2	5.4							37
24+ Mos	2	4.7	36	83.7	3	7.0	2	4.7							43
36 Mos			10	100.0											10

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Support Rating Over Time
Table 20

STUDY=C

Device Type: Metal Liner

	Support Rating														Total
	Not Noted		None		Cane,long walks		Crutch		2 Canes		2 Crutches		Walker		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP	16	16.5	59	60.8	13	13.4	1	1.0	2	2.1	5	5.2	1	1.0	97
6 Mos	1	1.2	75	88.2	5	5.9	3	3.5			1	1.2			85
12 Mos			59	88.1	6	9.0	1	1.5			1	1.5			67
24 Mos			30	88.2	4	11.8									34
24+ Mos	2	5.1	34	87.2	3	7.7									39
36 Mos	1	5.0	16	80.0	3	15.0									20
48 Mos	1	50.0	1	50.0											2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Support Rating Over Time
Table 20

STUDY=C

Device Type: Poly Liner

	Support Rating														Total
	Not Noted		None		Cane,long walks		Crutch		2 Canes		2 Crutches		Walker		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP	15	15.5	60	61.9	14	14.4	4	4.1	2	2.1	2	2.1			97
6 Mos	4	5.6	63	87.5	3	4.2					2	2.8			72
12 Mos	1	1.9	49	92.5	3	5.7									53
24 Mos	1	2.7	34	91.9	2	5.4									37
24+ Mos			41	97.6	1	2.4									42
36 Mos			22	100.0											22
48 Mos			2	100.0											2

Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Distance Walked Rating Over Time
Table 21

STUDY=A

Device Type: Metal Liner

	Distance Walked												Total
	Not Noted		Unlimited		6 Blocks		2-3 Blocks		Indoors only		Bed & Chair		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval													
Pre OP			17	7.8	41	18.7	126	57.5	35	16.0			219
6 Week	1	0.5	56	28.7	49	25.1	72	36.9	17	8.7			195
6 Mos	2	1.3	109	73.2	22	14.8	16	10.7					149
12 Mos			90	80.4	11	9.8	11	9.8					112
24 Mos	1	2.5	31	77.5	4	10.0	4	10.0					40
24+ Mos	1	2.4	32	78.0	4	9.8	4	9.8					41
36 Mos			1	100.0									1

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Metal/Metal Hip Reclassification Petition
Harris Hip Distance Walked Rating Over Time
Table 21

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Distance Walked												
	Not Noted		Unlimited		6 Blocks		2-3 Blocks		Indoors only		Bed & Chair		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval													
Pre OP			12	5.8	37	18.0	118	57.3	37	18.0	2	1.0	206
6 Week	2	1.1	49	26.5	47	25.4	71	38.4	16	8.6			185
6 Mos	5	3.6	106	77.4	13	9.5	10	7.3	3	2.2			137
12 Mos			81	77.9	9	8.7	11	10.6	3	2.9			104
24 Mos			38	82.6	5	10.9	2	4.3	1	2.2			46
24+ Mos			38	82.6	5	10.9	2	4.3	1	2.2			46
36 Mos													

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Distance Walked Rating Over Time
Table 21

STUDY=B

Device Type: Metal Liner

	Distance Walked								Total
	Not Noted		Unlimited		6 Blocks		Indoors only		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	1	1.1	30	34.5	37	42.5	19	21.8	87
6 Week	6	7.1	49	57.6	26	30.6	4	4.7	85
6 Mos	6	8.3	54	75.0	12	16.7			72
12 Mos	5	7.5	50	74.6	10	14.9	2	3.0	67
24 Mos	3	8.1	27	73.0	5	13.5	2	5.4	37
24+ Mos	4	9.3	32	74.4	5	11.6	2	4.7	43
36 Mos	1	10.0	9	90.0					10

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Distance Walked Rating Over Time
Table 21

STUDY=C

Device Type: Metal Liner

	Distance Walked										Total
	Not Noted		Unlimited		6 Blocks		2-3 Blocks		Indoors only		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP	1	1.0	11	11.3	20	20.6	43	44.3	22	22.7	97
6 Mos			65	76.5	8	9.4	10	11.8	2	2.4	85
12 Mos			57	85.1	5	7.5	5	7.5			67
24 Mos			28	82.4	5	14.7	1	2.9			34
24+ Mos			32	82.1	4	10.3	3	7.7			39
36 Mos			14	70.0	4	20.0	2	10.0			20
48 Mos			2	100.0							2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Distance Walked Rating Over Time
Table 21

STUDY=C

Device Type: Poly Liner

	Distance Walked										Total
	Not Noted		Unlimited		6 Blocks		2-3 Blocks		Indoors only		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP			10	10.3	20	20.6	49	50.5	18	18.6	97
6 Mos	1	1.4	53	73.6	10	13.9	7	9.7	1	1.4	72
12 Mos			45	84.9	4	7.5	4	7.5			53
24 Mos			29	78.4	2	5.4	6	16.2			37
24+ Mos			33	78.6	2	4.8	7	16.7			42
36 Mos			17	77.3	1	4.5	4	18.2			22
48 Mos			1	50.0			1	50.0			2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Stair Rating Over Time
Table 22

STUDY=A

Device Type: Metal Liner

	Stair Rating										Total
	Not Noted		Normally		Normally with rail		Any method		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP			12	5.5	77	35.2	121	55.3	9	4.1	219
6 Week	2	1.0	15	7.7	70	35.9	104	53.3	4	2.1	195
6 Mos	1	0.7	85	57.0	42	28.2	21	14.1			149
12 Mos			83	74.1	22	19.6	7	6.3			112
24 Mos	1	2.5	31	77.5	4	10.0	4	10.0			40
24+ Mos	1	2.4	32	78.0	4	9.8	4	9.8			41
36 Mos			1	100.0							1

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Stair Rating Over Time
Table 22

STUDY=A

Device Type: Poly Liner

	Stair Rating										Total
	Not Noted		Normally		Normally with rail		Any method		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP			10	4.9	62	30.1	129	62.6	5	2.4	206
6 Week	2	1.1	19	10.3	56	30.3	107	57.8	1	0.5	185
6 Mos	5	3.6	73	53.3	48	35.0	11	8.0			137
12 Mos			73	70.2	26	25.0	5	4.8			104
24 Mos			33	71.7	10	21.7	3	6.5			46
24+ Mos			33	71.7	10	21.7	3	6.5			46
36 Mos											

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Stair Rating Over Time
Table 22

STUDY=B

Device Type: Metal Liner

	Stair Rating										Total
	Not Noted		Normally		Normally with rail		Any method		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP	1	1.1	8	9.2	31	35.6	45	51.7	2	2.3	87
6 Week	6	7.1	22	25.9	38	44.7	18	21.2	1	1.2	85
6 Mos	6	8.3	45	62.5	19	26.4	2	2.8			72
12 Mos	3	4.5	44	65.7	19	28.4	1	1.5			67
24 Mos	1	2.7	27	73.0	6	16.2	3	8.1			37
24+ Mos	1	2.3	34	79.1	5	11.6	3	7.0			43
36 Mos			10	100.0							10

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Stair Rating Over Time
Table 22

STUDY=C

Device Type: Metal Liner

	Stair Rating										
	Not Noted		Normally		Normally with rail		Any method		Unable		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP	2	2.1	8	8.2	47	48.5	34	35.1	6	6.2	97
6 Mos			57	67.1	26	30.6	1	1.2	1	1.2	85
12 Mos			50	74.6	17	25.4					67
24 Mos			25	73.5	9	26.5					34
24+ Mos			30	76.9	9	23.1					39
36 Mos			15	75.0	5	25.0					20
48 Mos			2	100.0							2

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Metal/Metal Hip Reclassification Petition
Harris Hip Stair Rating Over Time
Table 22

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Stair Rating										Total
	Not Noted		Normally		Normally with rail		Any method		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval											
Pre OP			5	5.2	60	61.9	30	30.9	2	2.1	97
6 Mos	1	1.4	45	62.5	25	34.7	1	1.4			72
12 Mos			41	77.4	10	18.9	2	3.8			53
24 Mos			27	73.0	9	24.3			1	2.7	37
24+ Mos			34	81.0	7	16.7			1	2.4	42
36 Mos			20	90.9	2	9.1					22
48 Mos			2	100.0							2

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Metal/Metal Hip Reclassification Petition
Harris Hip Socks/Tie Shoes Rating Over Time
Table 23

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Socks/Tie Shoes								
	Not Noted		With ease		With difficulty		Unable		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP			22	10.0	161	73.5	36	16.4	219
6 Week	7	3.6	40	20.5	77	39.5	71	36.4	195
6 Mos	3	2.0	99	66.4	42	28.2	5	3.4	149
12 Mos			81	72.3	29	25.9	2	1.8	112
24 Mos	1	2.5	34	85.0	5	12.5			40
24+ Mos	1	2.4	35	85.4	5	12.2			41
36 Mos			1	100.0					1

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Metal/Metal Hip Reclassification Petition
Harris Hip Socks/Tie Shoes Rating Over Time
Table 23

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Socks/Tie Shoes								Total
	Not Noted		With ease		With difficulty		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP			16	7.8	152	73.8	38	18.4	206
6 Week	6	3.2	31	16.8	76	41.1	72	38.9	185
6 Mos	5	3.6	97	70.8	29	21.2	6	4.4	137
12 Mos			77	74.0	23	22.1	4	3.8	104
24 Mos			31	67.4	15	32.6			46
24+ Mos			31	67.4	15	32.6			46
36 Mos									

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Socks/Tie Shoes Rating Over Time
Table 23

STUDY=B

Device Type: Metal Liner

	Socks/Tie Shoes								Total
	Not Noted		With ease		With difficulty		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	1	1.1	29	33.3	49	56.3	8	9.2	87
6 Week	6	7.1	59	69.4	12	14.1	8	9.4	85
6 Mos	6	8.3	59	81.9	6	8.3	1	1.4	72
12 Mos	3	4.5	60	89.6	3	4.5	1	1.5	67
24 Mos	1	2.7	34	91.9	2	5.4			37
24+ Mos	2	4.7	40	93.0	1	2.3			43
36 Mos	1	10.0	9	90.0					10

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Metal/Metal Hip Reclassification Petition
Harris Hip Socks/Tie Shoes Rating Over Time
Table 23

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Socks/Tie Shoes								Total
	Not Noted		With ease		With difficulty		Unable		
Interval	#	Pct	#	Pct	#	Pct	#	Pct	#
Pre OP	2	2.1	11	11.3	74	76.3	10	10.3	97
6 Mos			61	71.8	23	27.1	1	1.2	85
12 Mos			54	80.6	13	19.4			67
24 Mos			28	82.4	6	17.6			34
24+ Mos	1	2.6	31	79.5	7	17.9			39
36 Mos	1	5.0	14	70.0	5	25.0			20
48 Mos			2	100.0					2

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Metal/Metal Hip Reclassification Petition
Harris Hip Socks/Tie Shoes Rating Over Time
Table 23

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Socks/Tie Shoes								
	Not Noted		With ease		With difficulty		Unable		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	1	1.0	11	11.3	75	77.3	10	10.3	97
6 Mos	1	1.4	58	80.6	12	16.7	1	1.4	72
12 Mos			50	94.3	3	5.7			53
24 Mos			32	86.5	5	13.5			37
24+ Mos			32	76.2	10	23.8			42
36 Mos			15	68.2	7	31.8			22
48 Mos			1	50.0	1	50.0			2

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Metal/Metal Hip Reclassification Petition
Harris Hip Sitting Rating Over Time
Table 24

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Sitting								Total
	Not Noted		Comfortable 1 hour		High chair,1/2 hour		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	1	0.5	108	49.3	90	41.1	20	9.1	219
6 Week	1	0.5	167	85.6	25	12.8	2	1.0	195
6 Mos	1	0.7	139	93.3	9	6.0			149
12 Mos			107	95.5	5	4.5			112
24 Mos	1	2.5	36	90.0	3	7.5			40
24+ Mos	1	2.4	37	90.2	3	7.3			41
36 Mos			1	100.0					1

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Metal/Metal Hip Reclassification Petition
Harris Hip Sitting Rating Over Time
Table 24

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Sitting								Total
	Not Noted		Comfortable 1 hour		High chair,1/2 hour		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP			100	48.5	89	43.2	17	8.3	206
6 Week	3	1.6	143	77.3	37	20.0	2	1.1	185
6 Mos	5	3.6	123	89.8	9	6.6			137
12 Mos			96	92.3	8	7.7			104
24 Mos			42	91.3	4	8.7			46
24+ Mos			42	91.3	4	8.7			46
36 Mos									

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Sitting Rating Over Time
Table 24

STUDY=B

Device Type: Metal Liner

	Sitting								Total
	Not Noted		Comfortable 1 hour		High chair,1/2 hour		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	1	1.1	28	32.2	42	48.3	16	18.4	87
6 Week	6	7.1	51	60.0	28	32.9			85
6 Mos	6	8.3	57	79.2	9	12.5			72
12 Mos	5	7.5	54	80.6	8	11.9			67
24 Mos	3	8.1	30	81.1	4	10.8			37
24+ Mos	4	9.3	36	83.7	3	7.0			43
36 Mos	1	10.0	9	90.0					10

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Metal/Metal Hip Reclassification Petition
Harris Hip Sitting Rating Over Time
Table 24

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Sitting								
	Not Noted		Comfortable 1 hour		High chair,1/2 hour		Unable		Total
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP	2	2.1	57	58.8	25	25.8	13	13.4	97
6 Mos			81	95.3	4	4.7			85
12 Mos			65	97.0	2	3.0			67
24 Mos			33	97.1	1	2.9			34
24+ Mos	2	5.1	36	92.3	1	2.6			39
36 Mos	1	5.0	18	90.0	1	5.0			20
48 Mos	1	50.0	1	50.0					2

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Metal/Metal Hip Reclassification Petition
Harris Hip Sitting Rating Over Time
Table 24

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Sitting								Total
	Not Noted		Comfortable 1 hour		High chair,1/2 hour		Unable		
	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval									
Pre OP			55	56.7	37	38.1	5	5.2	97
6 Mos	1	1.4	67	93.1	4	5.6			72
12 Mos			52	98.1	1	1.9			53
24 Mos			37	100.0					37
24+ Mos			41	97.6	1	2.4			42
36 Mos			21	95.5	1	4.5			22
48 Mos			2	100.0					2

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Metal/Metal Hip Reclassification Petition
Harris Hip Public Transport Rating Over Time
Table 25

10:20 Wednesday, November 15, 2000

---------- STUDY=A ----------

Device Type: Metal Liner

	Public Transport						Total
	Not Noted		Able to enter		Not able to enter		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP			215	98.2	4	1.8	219
6 Week	3	1.5	191	97.9	1	0.5	195
6 Mos	2	1.3	146	98.0	1	0.7	149
12 Mos			112	100.0			112
24 Mos	1	2.5	39	97.5			40
24+ Mos	1	2.4	40	97.6			41
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Harris Hip Public Transport Rating Over Time
Table 25

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Public Transport						Total
	Not Noted		Able to enter		Not able to enter		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP			200	97.1	6	2.9	206
6 Week	4	2.2	178	96.2	3	1.6	185
6 Mos	5	3.6	130	94.9	2	1.5	137
12 Mos	1	1.0	103	99.0			104
24 Mos			46	100.0			46
24+ Mos			46	100.0			46
36 Mos							

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Metal/Metal Hip Reclassification Petition
Harris Hip Public Transport Rating Over Time
Table 25

10:20 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Public Transport						Total
	Not Noted		Able to enter		Not able to enter		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP	2	2.3	80	92.0	5	5.7	87
6 Week	7	8.2	77	90.6	1	1.2	85
6 Mos	7	9.7	65	90.3			72
12 Mos	10	14.9	56	83.6	1	1.5	67
24 Mos	3	8.1	34	91.9			37
24+ Mos	4	9.3	39	90.7			43
36 Mos	1	10.0	9	90.0			10

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Metal/Metal Hip Reclassification Petition
Harris Hip Public Transport Rating Over Time
Table 25

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Public Transport						Total
	Not Noted		Able to enter		Not able to enter		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP	2	2.1	77	79.4	18	18.6	97
6 Mos			85	100.0			85
12 Mos			67	100.0			67
24 Mos			34	100.0			34
24+ Mos	1	2.6	38	97.4			39
36 Mos	1	5.0	19	95.0			20
48 Mos			2	100.0			2

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Metal/Metal Hip Reclassification Petition
Harris Hip Public Transport Rating Over Time
Table 25

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Public Transport						Total
	Not Noted		Able to enter		Not able to enter		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP			81	83.5	16	16.5	97
6 Mos	2	2.8	70	97.2			72
12 Mos			53	100.0			53
24 Mos			36	97.3	1	2.7	37
24+ Mos			42	100.0			42
36 Mos			22	100.0			22
48 Mos			2	100.0			2

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Metal/Metal Hip Reclassification Petition
Harris Hip Deformity Score Over Time
Table 26

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Deformity Score						Total
	Not Noted		Deformity		Absence of Deformity		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP	11	5.0	48	21.9	160	73.1	219
6 Week	18	9.2	7	3.6	170	87.2	195
6 Mos	5	3.4	3	2.0	141	94.6	149
12 Mos	5	4.5	2	1.8	105	93.8	112
24 Mos	3	7.5	1	2.5	36	90.0	40
24+ Mos	3	7.3	1	2.4	37	90.2	41
36 Mos					1	100.0	1

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Metal/Metal Hip Reclassification Petition
Harris Hip Deformity Score Over Time
Table 26

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Deformity Score						Total
	Not Noted		Deformity		Absence of Deformity		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP	7	3.4	35	17.0	164	79.6	206
6 Week	25	13.5	6	3.2	154	83.2	185
6 Mos	9	6.6	4	2.9	124	90.5	137
12 Mos	2	1.9	1	1.0	101	97.1	104
24 Mos	2	4.3			44	95.7	46
24+ Mos	2	4.3			44	95.7	46
36 Mos							

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Metal/Metal Hip Reclassification Petition
Harris Hip Deformity Score Over Time
Table 26

10:20 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Deformity Score				
	Deformity		Absence of Deformity		Total
	#	Pct	#	Pct	#
Interval					
Pre OP	9	10.3	78	89.7	87
6 Week	3	3.5	82	96.5	85
6 Mos	2	2.8	70	97.2	72
12 Mos			67	100.0	67
24 Mos			37	100.0	37
24+ Mos			43	100.0	43
36 Mos			10	100.0	10

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Metal/Metal Hip Reclassification Petition
Harris Hip Deformity Score Over Time
Table 26

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Deformity Score						Total
	Not Noted		Deformity		Absence of Deformity		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP			8	8.2	89	91.8	97
6 Mos	2	2.4			83	97.6	85
12 Mos					67	100.0	67
24 Mos	2	5.9			32	94.1	34
24+ Mos	8	20.5			31	79.5	39
36 Mos	5	25.0			15	75.0	20
48 Mos	1	50.0			1	50.0	2

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Metal/Metal Hip Reclassification Petition
Harris Hip Deformity Score Over Time
Table 26

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Deformity Score						Total
	Not Noted		Deformity		Absence of Deformity		
	#	Pct	#	Pct	#	Pct	#
Interval							
Pre OP			9	9.3	88	90.7	97
6 Mos	1	1.4			71	98.6	72
12 Mos					53	100.0	53
24 Mos	6	16.2			31	83.8	37
24+ Mos	12	28.6			30	71.4	42
36 Mos	5	22.7			17	77.3	22
48 Mos	1	50.0			1	50.0	2

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Score Over Time
Table 27

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Range of Motion Score														Total
	Not Noted		1		2		3		4		5		6		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP	13	5.9	2	0.9	9	4.1	35	16.0	114	52.1	34	15.5	12	5.5	219
6 Week	17	8.7					2	1.0	39	20.0	94	48.2	43	22.1	195
6 Mos	3	2.0							9	6.0	49	32.9	88	59.1	149
12 Mos	3	2.7							4	3.6	26	23.2	79	70.5	112
24 Mos	2	5.0									7	17.5	31	77.5	40
24+ Mos	2	4.9									7	17.1	32	78.0	41
36 Mos													1	100.0	1

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Score Over Time
Table 27

10:20 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Range of Motion Score														Total
	Not Noted		1		2		3		4		5		6		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval															
Pre OP	6	2.9	3	1.5	8	3.9	37	18.0	101	49.0	38	18.4	13	6.3	206
6 Week	22	11.9							48	25.9	82	44.3	33	17.8	185
6 Mos	7	5.1							8	5.8	44	32.1	78	56.9	137
12 Mos	2	1.9							8	7.7	32	30.8	62	59.6	104
24 Mos	2	4.3							1	2.2	13	28.3	30	65.2	46
24+ Mos	2	4.3							1	2.2	13	28.3	30	65.2	46
36 Mos															

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Score Over Time
Table 27

10:20 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Range of Motion Score												Total
	Not Noted		2		3		4		5		6		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval													
Pre OP	1	1.1	3	3.4	23	26.4	47	54.0	13	14.9			87
6 Week	10	11.8			2	2.4	26	30.6	25	29.4	22	25.9	85
6 Mos	10	13.9					12	16.7	21	29.2	29	40.3	72
12 Mos	11	16.4					10	14.9	11	16.4	35	52.2	67
24 Mos	15	40.5					1	2.7	3	8.1	18	48.6	37
24+ Mos	17	39.5							3	7.0	23	53.5	43
36 Mos	4	40.0									6	60.0	10

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Score Over Time
Table 27

10:20 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Range of Motion Score												Total
	Not Noted		2		3		4		5		6		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval													
Pre OP			3	3.1	9	9.3	41	42.3	37	38.1	7	7.2	97
6 Mos	2	2.4					8	9.4	23	27.1	52	61.2	85
12 Mos							2	3.0	15	22.4	50	74.6	67
24 Mos	2	5.9					3	8.8	8	23.5	21	61.8	34
24+ Mos	9	23.1					2	5.1	7	17.9	21	53.8	39
36 Mos	6	30.0					1	5.0	1	5.0	12	60.0	20
48 Mos	1	50.0									1	50.0	2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Score Over Time
Table 27

STUDY=C

Device Type: Poly Liner

	Range of Motion Score												Total
	Not Noted		2		3		4		5		6		
	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#	Pct	#
Interval													
Pre OP	1	1.0	1	1.0	10	10.3	50	51.5	26	26.8	9	9.3	97
6 Mos	1	1.4	1	1.4			7	9.7	11	15.3	52	72.2	72
12 Mos							2	3.8	10	18.9	41	77.4	53
24 Mos	6	16.2							6	16.2	25	67.6	37
24+ Mos	12	28.6							5	11.9	25	59.5	42
36 Mos	5	22.7							2	9.1	15	68.2	22
48 Mos	1	50.0									1	50.0	2

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Degrees Over Time
Table 28

STUDY=A

	Device Type								
	Metal Liner			Poly Liner			ALL		
	Flexion			Flexion			Flexion		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	217	81.9	18.2	206	85.0	17.2	423	83.4	17.8
6 Week	184	94.6	10.6	168	94.2	11.3	352	94.4	10.9
6 Mos	149	104.0	10.8	135	102.2	10.7	284	103.2	10.8
12 Mos	112	107.6	12.1	104	104.7	15.4	216	106.2	13.8
24 Mos	39	106.5	9.3	46	105.9	13.0	85	106.2	11.4
24+ Mos	40	106.4	9.2	46	105.9	13.0	86	106.1	11.4
36 Mos	1	100.0					1	100.0	

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=A

	Device Type								
	Metal Liner			Poly Liner			ALL		
	Abduction			Abduction			Abduction		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	213	21.4	18.2	204	21.1	17.9	417	21.2	18.0
6 Week	183	35.3	15.8	167	34.5	15.1	350	34.9	15.5
6 Mos	149	42.2	16.1	134	40.7	15.0	283	41.5	15.6
12 Mos	112	42.7	14.6	104	41.5	15.0	216	42.1	14.8
24 Mos	39	45.0	16.1	46	42.7	17.2	85	43.8	16.7
24+ Mos	40	45.0	15.9	46	42.7	17.2	86	43.8	16.6
36 Mos	1	45.0					1	45.0	

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Degrees Over Time
Table 28

STUDY=A

	Device Type						ALL		
	Metal Liner			Poly Liner					
	Adduction			Adduction			Adduction		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	209	12.2	9.2	200	12.4	9.4	409	12.3	9.3
6 Week	179	19.4	8.5	163	18.5	8.5	342	19.0	8.5
6 Mos	146	23.4	9.2	131	22.6	9.4	277	23.0	9.3
12 Mos	110	24.5	8.0	102	24.6	9.6	212	24.6	8.8
24 Mos	38	23.4	8.0	44	24.1	8.8	82	23.8	8.4
24+ Mos	39	23.3	7.9	44	24.1	8.8	83	23.7	8.4
36 Mos	1	20.0					1	20.0	

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=A

	Device Type						ALL		
	Metal Liner			Poly Liner					
	External Rotation			External Rotation			External Rotation		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	216	17.6	12.7	206	17.1	12.8	422	17.4	12.7
6 Week	184	24.7	10.3	167	23.6	9.9	351	24.2	10.1
6 Mos	149	32.3	11.3	133	32.7	10.1	282	32.5	10.7
12 Mos	112	34.1	10.7	104	33.5	12.4	216	33.8	11.6
24 Mos	39	38.3	12.6	46	35.0	9.5	85	36.5	11.1
24+ Mos	40	38.3	12.4	46	35.0	9.5	86	36.5	11.0
36 Mos	1	35.0					1	35.0	

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=A

	Device Type						ALL		
	Metal Liner			Poly Liner					
	Internal Rotation			Internal Rotation			Internal Rotation		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	213	-0.4	11.4	206	0.2	10.0	419	-0.1	10.7
6 Week	185	13.8	9.0	169	13.6	10.4	354	13.7	9.7
6 Mos	147	17.9	11.4	134	19.1	11.6	281	18.5	11.5
12 Mos	109	21.6	12.6	102	20.4	11.1	211	21.0	11.9
24 Mos	38	25.9	13.9	44	24.2	10.8	82	25.0	12.3
24+ Mos	39	26.4	14.1	44	24.2	10.8	83	25.2	12.4
36 Mos	1	45.0					1	45.0	

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=B

	Device Type					
	Metal Liner			ALL		
	Flexion			Flexion		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	86	81.8	17.5	86	81.8	17.5
6 Week	77	92.9	18.2	77	92.9	18.2
6 Mos	63	105.5	16.1	63	105.5	16.1
12 Mos	58	109.9	17.3	58	109.9	17.3
24 Mos	24	113.3	15.5	24	113.3	15.5
24+ Mos	29	116.6	14.3	29	116.6	14.3
36 Mos	7	123.6	12.8	7	123.6	12.8

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=B

	Device Type					
	Metal Liner			ALL		
	Abduction			Abduction		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	86	16.0	11.0	86	16.0	11.0
6 Week	76	31.8	11.4	76	31.8	11.4
6 Mos	63	36.8	13.2	63	36.8	13.2
12 Mos	58	41.0	15.5	58	41.0	15.5
24 Mos	24	48.3	14.5	24	48.3	14.5
24+ Mos	29	50.2	13.5	29	50.2	13.5
36 Mos	7	50.0	14.7	7	50.0	14.7

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=B

	Device Type					
	Metal Liner			ALL		
	Adduction			Adduction		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	86	10.8	8.1	86	10.8	8.1
6 Week	77	19.7	9.7	77	19.7	9.7
6 Mos	62	23.5	10.3	62	23.5	10.3
12 Mos	56	27.0	10.4	56	27.0	10.4
24 Mos	22	30.7	8.2	22	30.7	8.2
24+ Mos	26	32.3	8.2	26	32.3	8.2
36 Mos	6	36.7	5.2	6	36.7	5.2

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=B

	Device Type			ALL		
	Metal Liner					
	External Rotation			External Rotation		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	86	10.9	9.5	86	10.9	9.5
6 Week	77	22.7	10.2	77	22.7	10.2
6 Mos	63	26.4	9.9	63	26.4	9.9
12 Mos	58	28.1	10.9	58	28.1	10.9
24 Mos	24	34.0	8.2	24	34.0	8.2
24+ Mos	29	34.8	7.1	29	34.8	7.1
36 Mos	7	34.3	6.7	7	34.3	6.7

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Metal/Metal Hip Reclassification Petition
Harris Hip Range of Motion Degrees Over Time
Table 28

10:20 Wednesday, November 15, 2000

STUDY=B

	Device Type					
	Metal Liner			ALL		
	Internal Rotation			Internal Rotation		
	#	Mean	STD	#	Mean	STD
Interval						
Pre OP	86	5.3	8.0	86	5.3	8.0
6 Week	75	16.0	8.7	75	16.0	8.7
6 Mos	63	18.2	9.6	63	18.2	9.6
12 Mos	56	20.6	12.8	56	20.6	12.8
24 Mos	22	26.8	8.2	22	26.8	8.2
24+ Mos	26	27.5	6.8	26	27.5	6.8
36 Mos	6	27.5	7.6	6	27.5	7.6

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Degrees Over Time
Table 28

STUDY=C

	Device Type						ALL		
	Metal Liner			Poly Liner					
	Flexion			Flexion			Flexion		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	97	80.5	17.7	97	79.0	18.8	194	79.7	18.2
6 Mos	83	94.6	12.5	72	94.1	16.2	155	94.3	14.3
12 Mos	67	96.3	13.1	53	98.4	11.0	120	97.2	12.2
24 Mos	32	93.9	13.0	31	97.1	12.1	63	95.5	12.5
24+ Mos	31	93.9	13.5	30	98.2	9.2	61	96.0	11.7
36 Mos	15	91.0	6.3	17	95.0	5.6	32	93.1	6.2
48 Mos	1	95.0		1	95.0		2	95.0	0.0

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Degrees Over Time
Table 28

STUDY=C

	Device Type						ALL		
	Metal Liner			Poly Liner					
	Abduction			Abduction			Abduction		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	97	24.0	15.2	96	23.4	11.5	193	23.7	13.5
6 Mos	83	39.3	12.5	71	40.6	13.6	154	39.9	13.0
12 Mos	67	43.3	13.6	53	41.4	12.4	120	42.4	13.1
24 Mos	32	45.0	15.8	31	45.9	13.9	63	45.4	14.8
24+ Mos	31	44.7	15.2	30	45.7	13.1	61	45.2	14.1
36 Mos	15	49.2	12.8	17	49.4	12.9	32	49.3	12.7
48 Mos	1	59.0		1	59.0		2	59.0	0.0

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Degrees Over Time
Table 28

STUDY=C

	Device Type						ALL		
	Metal Liner			Poly Liner					
	Adduction			Adduction			Adduction		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	97	14.0	12.4	96	14.5	10.6	193	14.3	11.5
6 Mos	83	23.2	10.2	71	25.0	12.6	154	24.1	11.4
12 Mos	67	28.1	13.5	53	25.9	11.6	120	27.1	12.7
24 Mos	32	29.4	16.2	31	31.2	16.6	63	30.3	16.3
24+ Mos	30	31.0	17.2	30	29.3	16.2	60	30.2	16.6
36 Mos	14	36.6	18.0	17	30.5	14.6	31	33.3	16.3
48 Mos	1	59.0		1	59.0		2	59.0	0.0

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Degrees Over Time
Table 28

STUDY=C

	Device Type								
	Metal Liner			Poly Liner			ALL		
	External Rotation			External Rotation			External Rotation		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	97	19.3	13.5	96	21.1	12.7	193	20.2	13.1
6 Mos	83	31.6	12.1	71	34.5	12.0	154	32.9	12.1
12 Mos	67	35.8	13.5	53	36.9	13.1	120	36.3	13.3
24 Mos	32	40.2	14.1	31	39.4	15.3	63	39.8	14.6
24+ Mos	31	41.6	14.2	30	39.0	15.3	61	40.3	14.7
36 Mos	15	46.2	14.3	17	38.5	14.8	32	42.1	14.9
48 Mos	1	59.0		1	59.0		2	59.0	0.0

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Metal/Metal Hip Reclassification Petition 10:20 Wednesday, November 15, 2000
Harris Hip Range of Motion Degrees Over Time
Table 28

STUDY=C

	Device Type						ALL		
	Metal Liner			Poly Liner					
	Internal Rotation			Internal Rotation			Internal Rotation		
	#	Mean	STD	#	Mean	STD	#	Mean	STD
Interval									
Pre OP	97	11.5	14.0	96	13.4	15.1	193	12.5	14.5
6 Mos	83	23.7	11.7	71	25.5	13.6	154	24.5	12.6
12 Mos	67	27.7	14.7	53	28.6	17.6	120	28.1	15.9
24 Mos	32	28.6	18.1	31	29.4	15.2	63	29.0	16.6
24+ Mos	31	30.4	18.5	30	31.0	17.0	61	30.7	17.6
36 Mos	15	35.5	18.3	17	32.6	15.8	32	34.0	16.8
48 Mos	1	59.0	.	1	59.0	.	2	59.0	0.0

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 29

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Femoral Stem Subsidence						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	193	99.0	1	0.5	195
6 Mos			148	100.0			148
12 Mos	2	1.8	110	98.2			112
24 Mos			38	100.0			38
24+ Mos			39	100.0			39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 29

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Femoral Stem Subsidence						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	2	1.1	181	98.9			183
6 Mos	1	0.7	139	98.6	1	0.7	141
12 Mos	1	0.9	105	99.1			106
24 Mos			48	100.0			48
24+ Mos			48	100.0			48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 29

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Femoral Stem Subsidence						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	25	34.7	47	65.3			72
6 Mos			58	98.3	1	1.7	59
12 Mos	1	1.6	60	98.4			61
24 Mos			31	100.0			31
24+ Mos			37	100.0			37
36 Mos			9	100.0			9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 29

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Femoral Stem Subsidence						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	94	97.9	2	2.1			96
6 Mos	1	1.3	75	93.8	4	5.0	80
12 Mos			63	95.5	3	4.5	66
24 Mos			30	90.9	3	9.1	33
24+ Mos			34	94.4	2	5.6	36
36 Mos			14	93.3	1	6.7	15
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 29

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Femoral Stem Subsidence						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	91	95.8	4	4.2			95
6 Mos	1	1.5	64	97.0	1	1.5	66
12 Mos			50	96.2	2	3.8	52
24 Mos			30	96.8	1	3.2	31
24+ Mos	2	5.9	30	88.2	2	5.9	34
36 Mos	2	12.5	13	81.3	1	6.3	16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 30

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Femoral Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	192	98.5	2	1.0	195
6 Mos			146	98.6	2	1.4	148
12 Mos	1	0.9	110	98.2	1	0.9	112
24 Mos			38	100.0			38
24+ Mos			39	100.0			39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 30

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Femoral Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	181	98.9	1	0.5	183
6 Mos	1	0.7	138	97.9	2	1.4	141
12 Mos			102	96.2	4	3.8	106
24 Mos			44	91.7	4	8.3	48
24+ Mos			44	91.7	4	8.3	48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 30

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Femoral Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	32	44.4	38	52.8	2	2.8	72
6 Mos	2	3.4	54	91.5	3	5.1	59
12 Mos	2	3.3	55	90.2	4	6.6	61
24 Mos	2	6.5	27	87.1	2	6.5	31
24+ Mos	2	5.4	32	86.5	3	8.1	37
36 Mos			8	88.9	1	11.1	9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 30

10:09 Wednesday, November 15, 2000

---------- STUDY=C ----------

Device Type: Metal Liner

	Femoral Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week			93	96.9	3	3.1	96
6 Mos			78	97.5	2	2.5	80
12 Mos			61	92.4	5	7.6	66
24 Mos			27	81.8	6	18.2	33
24+ Mos			32	88.9	4	11.1	36
36 Mos			14	93.3	1	6.7	15
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 30

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Femoral Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week			89	93.7	6	6.3	95
6 Mos			62	93.9	4	6.1	66
12 Mos			46	88.5	6	11.5	52
24 Mos			25	80.6	6	19.4	31
24+ Mos	1	2.9	27	79.4	6	17.6	34
36 Mos	1	6.3	10	62.5	5	31.3	16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 31

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Femoral Radiolucency (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	193	99.0	1	0.5	195
6 Mos			147	99.3	1	0.7	148
12 Mos	1	0.9	109	97.3	2	1.8	112
24 Mos	1	2.6	36	94.7	1	2.6	38
24+ Mos	1	2.6	37	94.9	1	2.6	39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 31

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Femoral Radiolucency (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	2	1.1	181	98.9			183
6 Mos	1	0.7	140	99.3			141
12 Mos	1	0.9	104	98.1	1	0.9	106
24 Mos			47	97.9	1	2.1	48
24+ Mos			47	97.9	1	2.1	48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 31

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Femoral Radiolucency (Lateral View)		
	Not Noted		Total
	#	Pct	#
Interval			
6 Week	72	100.0	72
6 Mos	59	100.0	59
12 Mos	61	100.0	61
24 Mos	31	100.0	31
24+ Mos	37	100.0	37
36 Mos	9	100.0	9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 31

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Femoral Radiolucency (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	2	2.1	94	97.9			96
6 Mos			80	100.0			80
12 Mos	1	1.5	63	95.5	2	3.0	66
24 Mos			30	90.9	3	9.1	33
24+ Mos	1	2.8	33	91.7	2	5.6	36
36 Mos	1	6.7	13	86.7	1	6.7	15
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 31

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Femoral Radiolucency (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week			94	98.9	1	1.1	95
6 Mos	1	1.5	64	97.0	1	1.5	66
12 Mos			48	92.3	4	7.7	52
24 Mos	1	3.2	27	87.1	3	9.7	31
24+ Mos	3	8.8	30	88.2	1	2.9	34
36 Mos	3	18.8	11	68.8	2	12.5	16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 32

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Resorption of Shaft (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	193	99.0	1	0.5	195
6 Mos			147	99.3	1	0.7	148
12 Mos	1	0.9	111	99.1			112
24 Mos			38	100.0			38
24+ Mos			39	100.0			39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 32

10:09 Wednesday, November 15, 2000

---------- STUDY=A ----------

Device Type: Poly Liner

	Resorption of Shaft (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	182	99.5			183
6 Mos	1	0.7	140	99.3			141
12 Mos			106	100.0			106
24 Mos			48	100.0			48
24+ Mos			48	100.0			48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 32

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Resorption of Shaft (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	23	31.9	49	68.1			72
6 Mos			59	100.0			59
12 Mos	2	3.3	59	96.7			61
24 Mos	1	3.2	29	93.5	1	3.2	31
24+ Mos	1	2.7	35	94.6	1	2.7	37
36 Mos			9	100.0			9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 32

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Resorption of Shaft (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	99.0	1	1.0			96
6 Mos			78	97.5	2	2.5	80
12 Mos			65	98.5	1	1.5	66
24 Mos			30	90.9	3	9.1	33
24+ Mos			34	94.4	2	5.6	36
36 Mos			15	100.0			15
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 32

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Resorption of Shaft (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	100.0					95
6 Mos			65	98.5	1	1.5	66
12 Mos			52	100.0			52
24 Mos			31	100.0			31
24+ Mos	1	2.9	33	97.1			34
36 Mos	1	6.3	15	93.8			16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 33

10:09 Wednesday, November 15, 2000

---------- STUDY=A ----------

Device Type: Metal Liner

	Resorption of Shaft (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	193	99.0	1	0.5	195
6 Mos			147	99.3	1	0.7	148
12 Mos	2	1.8	110	98.2			112
24 Mos	1	2.6	37	97.4			38
24+ Mos	1	2.6	38	97.4			39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 33

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Resorption of Shaft (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	182	99.5			183
6 Mos	1	0.7	140	99.3			141
12 Mos			106	100.0			106
24 Mos			48	100.0			48
24+ Mos			48	100.0			48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 33

10:09 Wednesday, November 15, 2000

---------- STUDY=B ----------

Device Type: Metal Liner

	Resorption of Shaft (Lateral View)		
	Not Noted		Total
	#	Pct	#
Interval			
6 Week	72	100.0	72
6 Mos	59	100.0	59
12 Mos	61	100.0	61
24 Mos	31	100.0	31
24+ Mos	37	100.0	37
36 Mos	9	100.0	9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 33

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Resorption of Shaft (Lateral View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	99.0	1	1.0			96
6 Mos			80	100.0			80
12 Mos	1	1.5	65	98.5			66
24 Mos			32	97.0	1	3.0	33
24+ Mos	1	2.8	35	97.2			36
36 Mos	1	6.7	14	93.3			15
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 33

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Resorption of Shaft (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	100.0					95
6 Mos	1	1.5	64	97.0	1	1.5	66
12 Mos			52	100.0			52
24 Mos	1	3.2	30	96.8			31
24+ Mos	3	8.8	31	91.2			34
36 Mos	3	18.8	13	81.3			16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 34

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Hypertrophy of Shaft (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	2	1.0	193	99.0			195
6 Mos			147	99.3	1	0.7	148
12 Mos	1	0.9	111	99.1			112
24 Mos			36	94.7	2	5.3	38
24+ Mos			37	94.9	2	5.1	39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 34

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Hypertrophy of Shaft (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	182	99.5			183
6 Mos	1	0.7	140	99.3			141
12 Mos			106	100.0			106
24 Mos			48	100.0			48
24+ Mos			48	100.0			48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 34

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Hypertrophy of Shaft (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	23	31.9	48	66.7	1	1.4	72
6 Mos			56	94.9	3	5.1	59
12 Mos	2	3.3	53	86.9	6	9.8	61
24 Mos	1	3.2	30	96.8			31
24+ Mos	1	2.7	36	97.3			37
36 Mos			9	100.0			9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 34

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Hypertrophy of Shaft (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	99.0	1	1.0			96
6 Mos			77	96.3	3	3.8	80
12 Mos			61	92.4	5	7.6	66
24 Mos			30	90.9	3	9.1	33
24+ Mos			31	86.1	5	13.9	36
36 Mos			13	86.7	2	13.3	15
48 Mos					1	100.0	1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 34

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Hypertrophy of Shaft (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	100.0					95
6 Mos			63	95.5	3	4.5	66
12 Mos	1	1.9	44	84.6	7	13.5	52
24 Mos			27	87.1	4	12.9	31
24+ Mos	1	2.9	30	88.2	3	8.8	34
36 Mos	1	6.3	14	87.5	1	6.3	16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 35

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Hypertrophy of Shaft (Lateral View)				Total
	Not Noted		No		
	#	Pct	#	Pct	#
Interval					
6 Week	2	1.0	193	99.0	195
6 Mos			148	100.0	148
12 Mos	2	1.8	110	98.2	112
24 Mos			38	100.0	38
24+ Mos			39	100.0	39
36 Mos			1	100.0	1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 35

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Hypertrophy of Shaft (Lateral View)				Total
	Not Noted		No		
	#	Pct	#	Pct	#
Interval					
6 Week	1	0.5	182	99.5	183
6 Mos	1	0.7	140	99.3	141
12 Mos			106	100.0	106
24 Mos			48	100.0	48
24+ Mos			48	100.0	48
36 Mos					

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 35

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Hypertrophy of Shaft (Lateral View)		
	Not Noted		Total
	#	Pct	#
Interval			
6 Week	72	100.0	72
6 Mos	59	100.0	59
12 Mos	61	100.0	61
24 Mos	31	100.0	31
24+ Mos	37	100.0	37
36 Mos	9	100.0	9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 35

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Hypertrophy of Shaft (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	99.0	1	1.0			96
6 Mos			78	97.5	2	2.5	80
12 Mos	1	1.5	63	95.5	2	3.0	66
24 Mos			32	97.0	1	3.0	33
24+ Mos	1	2.8	33	91.7	2	5.6	36
36 Mos	1	6.7	13	86.7	1	6.7	15
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 35

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Hypertrophy of Shaft (Lateral View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	100.0					95
6 Mos	1	1.5	64	97.0	1	1.5	66
12 Mos	1	1.9	50	96.2	1	1.9	52
24 Mos	1	3.2	30	96.8			31
24+ Mos	3	8.8	31	91.2			34
36 Mos	3	18.8	12	75.0	1	6.3	16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 36

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Endosteal Cavitation - Lysis (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	2	1.0	193	99.0			195
6 Mos			147	99.3	1	0.7	148
12 Mos	1	0.9	110	98.2	1	0.9	112
24 Mos			38	100.0			38
24+ Mos			39	100.0			39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 36

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Endosteal Cavitation - Lysis (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	182	99.5			183
6 Mos	1	0.7	139	98.6	1	0.7	141
12 Mos			106	100.0			106
24 Mos			47	97.9	1	2.1	48
24+ Mos			47	97.9	1	2.1	48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 36

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Endosteal Cavitation - Lysis (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	24	33.3	48	66.7			72
6 Mos			59	100.0			59
12 Mos			61	100.0			61
24 Mos			30	96.8	1	3.2	31
24+ Mos			36	97.3	1	2.7	37
36 Mos			9	100.0			9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 36

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Endosteal Cavitation - Lysis (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	99.0	1	1.0			96
6 Mos			79	98.8	1	1.3	80
12 Mos			65	98.5	1	1.5	66
24 Mos			32	97.0	1	3.0	33
24+ Mos			35	97.2	1	2.8	36
36 Mos			15	100.0			15
48 Mos					1	100.0	1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Femoral Stem
Table 36

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Endosteal Cavitation - Lysis (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	95	100.0					95
6 Mos			66	100.0			66
12 Mos			51	98.1	1	1.9	52
24 Mos			31	100.0			31
24+ Mos			32	94.1	2	5.9	34
36 Mos			14	87.5	2	12.5	16
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 37

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Metal Liner

	Acetabular Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	1	0.5	193	99.0	1	0.5	195
6 Mos			145	98.0	3	2.0	148
12 Mos	2	1.8	104	92.9	6	5.4	112
24 Mos			36	94.7	2	5.3	38
24+ Mos			37	94.9	2	5.1	39
36 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 37

10:09 Wednesday, November 15, 2000

STUDY=A

Device Type: Poly Liner

	Acetabular Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	3	1.6	170	92.9	10	5.5	183
6 Mos	2	1.4	131	92.9	8	5.7	141
12 Mos	1	0.9	99	93.4	6	5.7	106
24 Mos			45	93.8	3	6.3	48
24+ Mos			45	93.8	3	6.3	48
36 Mos							

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 37

10:09 Wednesday, November 15, 2000

STUDY=B

Device Type: Metal Liner

	Acetabular Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week	12	16.7	59	81.9	1	1.4	72
6 Mos			57	96.6	2	3.4	59
12 Mos	1	1.6	57	93.4	3	4.9	61
24 Mos			29	93.5	2	6.5	31
24+ Mos	1	2.7	32	86.5	4	10.8	37
36 Mos	1	11.1	5	55.6	3	33.3	9

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 37

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Metal Liner

	Acetabular Radiolucency (AP View)						Total
	Not Noted		No		Yes		
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week			79	82.3	17	17.7	96
6 Mos			75	93.8	5	6.3	80
12 Mos			61	92.4	5	7.6	66
24 Mos			24	72.7	9	27.3	33
24+ Mos			28	77.8	8	22.2	36
36 Mos			12	80.0	3	20.0	15
48 Mos			1	100.0			1

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Metal/Metal Hip Reclassification Petition
Radiographic Evaluation of the Acetabular Cup
Table 37

10:09 Wednesday, November 15, 2000

STUDY=C

Device Type: Poly Liner

	Acetabular Radiolucency (AP View)						
	Not Noted		No		Yes		Total
	#	Pct	#	Pct	#	Pct	#
Interval							
6 Week			82	86.3	13	13.7	95
6 Mos	1	1.5	65	98.5			66
12 Mos			46	88.5	6	11.5	52
24 Mos			26	83.9	5	16.1	31
24+ Mos			31	91.2	3	8.8	34
36 Mos			15	93.8	1	6.3	16
48 Mos			1	100.0			1

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