

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
TENDER LUMPS-TIBIA	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	0/ 941 ( 0)	.
	3 Year	0/ 665 ( 0)	.
PAINLESS EYE REDNESS	Baseline	1/1007 (0.10)	0.1658
	1 Year	1/ 965 (0.10)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	3/ 665 (0.45)	.
PAINFUL EYE REDNESS WITH DECREASED VISION, SMAL	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 ( 0)	.
TENDERNESS-INSERTION OF DELTOIDS	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 ( 0)	.
MUSCLE TENDERNESS	Baseline	2/1007 (0.20)	0.9160
	1 Year	2/ 965 (0.21)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	2/ 665 (0.30)	.
NAIL PITTINGS	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_12.SAS

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(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect.

Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
NAIL PITTINGS	2 Year	0/ 941 ( 0)	.
	3 Year	0/ 665 ( 0)	.
TINELS OR PHALENS SIGNS	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 ( 0)	.
SKIN RASHES	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	0/ 665 ( 0)	.

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Table 11 13

RUPTURE EVALUATION WITHIN 36 MONTHS OF IMPLANT SURGERY - BY CORRELATION WITH RHEUMATOLOGICAL SYMPTOMS - FDA Item 7b(4)

Complication Evaluation	Yes/No	New Rheumatological Symptoms		P-value (a)
		At Least One Symptoms	No Symptoms	
Silent Rupture	Yes	1	7	1.0000
	No	55	349	
Any Rupture	Yes	0	6	1.0000
	No	120	881	
Patient Dissatisfaction	Yes	6	26	0.2608
	No	113	850	
Complications	Yes	52	325	0.1605
	No	68	562	

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Creation Date, Time: 24AUG04 09:05

(a) P-value from Fisher's exact test.

Note1: Any rupture is defined as silent rupture or rupture noted at explant/removal.

Note2: Silent rupture is defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, (4) indeterminate for extracapsular silicone.

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Table 11.14

A COMPARISON BETWEEN COREGEL AND HISTORICAL CONTROLS OF CUMULATIVE INCIDENCE OF PATIENT  
REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE - FDA Item 7b(3)

Symptom Type	Implant Surgery				p-value (b)
	Historical Control		Coregel (a)		
	Number with Symptom Type	Estimated Proportion with Symptom Type	Number with Symptom Type	Estimated Proportion with Symptom Type	
FATIGUE					
Fryzek Jan 2001 (N=1369)	224	0.1636	27	0.0304	0.0000
JOINT SWELLING					
Fryzek Jan 2001 (N=1369)	184	0.1344	13	0.0142	0.0000
NUMBNESS OF FEET					
Berner 2002 (N=32)	14	0.4440	9	0.0105	0.0000
PAIN/GRITTIENESS IN EYES					
Fryzek Jan 2001 (N=1369)	38	0.0278	5	0.0051	0.0000
DRYNESS OF EYES/NOSE					
Fryzek Jan 2001 (N=1369)	98	0.0716	5	0.0052	0.0000
NECK PAIN/STIFFNESS					
Fryzek Jan 2001 (N=1369)	309	0.2257	17	0.0206	0.0000
Breiting July 2004 (N=180)	100	0.5556	17	0.0206	0.0000
PERSISTENT FEVER					
Fryzek Jan 2001 (N=1369)	54	0.0394	0	0.0000	0.0000
NIGHT SWEATS					

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Creation Date, Time: 09AUG04 18:28

(a) 36 Months after implant surgery to first occurrence of event, based on Kaplan-Meier estimates.

(b) p-value is from normal approximation test comparing proportion of patients with symptom type in CoreGel versus Historical control.

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A COMPARISON BETWEEN COREGEL AND HISTORICAL CONTROLS OF CUMULATIVE INCIDENCE OF PATIENT  
REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE - FDA Item 7b(3)

Symptom Type	Implant Surgery				p-value (b)
	Historical Control		Coregel (a)		
	Number with Symptom Type	Estimated Proportion with Symptom Type	Number with Symptom Type	Estimated Proportion with Symptom Type	
Fryzek Jan 2001 (N=1369)	263	0.1921	16	0.0181	0.0000
<b>JOINT PAIN</b>					
Berner 2002 (N=32)	20	0.6110	36	0.0400	0.0000
Fryzek Jan 2001 (N=1369)	308	0.2250	36	0.0400	0.0000
Breiting July 2004 (N=180)	66	0.3667	36	0.0400	0.0000
<b>FREQUENT MUSCLE PAIN</b>					
Berner 2002 (N=32)	16	0.5000	7	0.0072	0.0000
Fryzek Jan 2001 (N=1369)	236	0.1724	7	0.0072	0.0000
<b>NUMBNESS OF HANDS</b>					
Berner 2002 (N=32)	14	0.4440	21	0.0243	0.0000
<b>DRYNESS OF MOUTH</b>					
Berner 2002 (N=32)	9	0.2780	3	0.0032	0.0005
Fryzek Jan 2001 (N=1369)	66	0.0482	3	0.0032	0.0000
Breiting July 2004 (N=180)	52	0.2889	3	0.0032	0.0000
<b>BACK PAIN/STIFFNESS</b>					
Fryzek Jan 2001 (N=1369)	258	0.1885	17	0.0192	0.0000
Breiting July 2004 (N=180)	100	0.5556	17	0.0192	0.0000

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Creation Date, Time: 09AUG04 18:28

(a) 36 Months after implant surgery to first occurrence of event, based on Kaplan-Meier estimates.

(b) p-value is from normal approximation test comparing proportion of patients with symptom type in CoreGel versus Historical control.

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Table 11.14

A COMPARISON BETWEEN COREGEL AND HISTORICAL CONTROLS OF CUMULATIVE INCIDENCE OF PATIENT  
REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS BY SYMPTOM TYPE - FDA Item 7b(3)

Symptom Type	Implant Surgery				p-value (b)
	Historical Control		Coregel (a)		
	Number with Symptom Type	Estimated Proportion with Symptom Type	Number with Symptom Type	Estimated Proportion with Symptom Type	
DIFFICULTY SWALLOWING					
Fryzek Jan 2001 (N=1369)	32	0.0234	2	0.0022	0.0000
SEVERE RASHES					
Bernier 2002 (N=32)	7	0.2220	3	0.0032	0.0029
Breiting July 2004 (N=180)	47	0.2611	3	0.0032	0.0000
EXCESSIVE SENSITIVITY TO SUN					
Fryzek Jan 2001 (N=1369)	47	0.0343	1	0.0010	0.0000
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE					
Bernier 2002 (N=32)	12	0.3890	2	0.0020	0.0000
Breiting July 2004 (N=180)	23	0.1278	2	0.0020	0.0000
UNUSUAL HAIR LOSS					
Bernier 2002 (N=32)	9	0.2780	8	0.0105	0.0007
Fryzek Jan 2001 (N=1369)	98	0.0716	8	0.0105	0.0000
Breiting July 2004 (N=180)	9	0.0500	8	0.0105	0.0179

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Creation Date, Time: 09AUG04 18:28

(a) 36 Months after implant surgery to first occurrence of event, based on Kaplan-Meier estimates.

(b) p-value is from normal approximation test comparing proportion of patients with symptom type in CoreGel versus Historical control.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 12.1

BREAST MAMMOGRAM  
AUGMENTATION PATIENTS

Type of Visit Post-op Result		Preoperative Mammogram Result							Total n(%)
		Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	
6 Months	BIRADS 0	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.4)	1 ( 0.2)
	BIRADS 1	1 ( 25.0)	21 ( 9.9)	2 ( 5.9)	1 ( 14.3)	0 ( 0.0)	0 ( 0.0)	4 ( 1.4)	29 ( 5.4)
	BIRADS 2	0 ( 0.0)	1 ( 0.5)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.2)
	BIRADS 3	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.4)	1 ( 0.2)
	BIRADS 4	0 ( 0.0)	0 ( 0.0)	1 ( 2.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.2)
	MISSING	3 ( 75.0)	191 ( 89.7)	31 ( 91.2)	6 ( 85.7)	3 (100.0)	0 ( 0.0)	270 ( 97.8)	504 ( 93.9)
TOTAL	4 (100.0)	213 (100.0)	34 (100.0)	7 (100.0)	3 (100.0)	0 ( 0.0)	276 (100.0)	537 (100.0)	
1 Year	BIRADS 1	0 ( 0.0)	26 ( 12.3)	4 ( 11.8)	1 ( 14.3)	0 ( 0.0)	0 ( 0.0)	2 ( 0.7)	33 ( 6.2)
	BIRADS 2	0 ( 0.0)	5 ( 2.4)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 0.7)	7 ( 1.3)
	BIRADS 3	0 ( 0.0)	1 ( 0.5)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.2)
	BIRADS 4	0 ( 0.0)	1 ( 0.5)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.2)
	MISSING	4 (100.0)	179 ( 84.4)	30 ( 88.2)	6 ( 85.7)	3 (100.0)	0 ( 0.0)	266 ( 98.5)	488 ( 92.1)
	TOTAL	4 (100.0)	212 (100.0)	34 (100.0)	7 (100.0)	3 (100.0)	0 ( 0.0)	270 (100.0)	530 (100.0)
2 Year	BIRADS 0	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 33.3)	0 ( 0.0)	0 ( 0.0)	1 ( 0.2)
	BIRADS 1	0 ( 0.0)	48 ( 22.9)	5 ( 14.7)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	7 ( 2.6)	60 ( 11.5)
	BIRADS 2	0 ( 0.0)	13 ( 6.2)	3 ( 8.8)	1 ( 14.3)	0 ( 0.0)	0 ( 0.0)	2 ( 0.8)	19 ( 3.6)
	BIRADS 3	0 ( 0.0)	3 ( 1.4)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 0.8)	5 ( 1.0)
	BIRADS 4	0 ( 0.0)	1 ( 0.5)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.2)
	BIRADS 5	0 ( 0.0)	1 ( 0.5)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.2)
	MISSING	4 (100.0)	144 ( 68.6)	26 ( 76.5)	6 ( 85.7)	2 ( 66.7)	0 ( 0.0)	255 ( 95.9)	437 ( 83.4)
	TOTAL	4 (100.0)	210 (100.0)	34 (100.0)	7 (100.0)	3 (100.0)	0 ( 0.0)	266 (100.0)	524 (100.0)

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Note. Results shown are patient level results; if the patient reported different Birads scores in each breast, the patient is counted under the higher Birads score(e.g. Birads 5 is higher than Birads 4).

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Table 12.1

BREAST MAMMOGRAM  
AUGMENTATION PATIENTS

Type of Visit	Post-op Result	Preoperative Mammogram Result							Total n(%)
		Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	
3 Year	BIRADS 0	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.5)	1 ( 0.2)
	BIRADS 1	0 ( 0.0)	38 ( 22.5)	6 ( 22.2)	1 ( 25.0)	0 ( 0.0)	0 ( 0.0)	9 ( 4.5)	54 ( 13.4)
	BIRADS 2	0 ( 0.0)	13 ( 7.7)	3 ( 11.1)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	16 ( 4.0)
	BIRADS 3	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.5)	1 ( 0.2)
	BIRADS 4	0 ( 0.0)	2 ( 1.2)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 0.5)
	MISSING	4 (100.0)	116 ( 68.6)	18 ( 66.7)	3 ( 75.0)	2 (100.0)	0 ( 0.0)	187 ( 94.4)	330 ( 81.7)
	TOTAL	4 (100.0)	169 (100.0)	27 (100.0)	4 (100.0)	2 (100.0)	0 ( 0.0)	198 (100.0)	404 (100.0)

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Note. Results shown are patient level results; if the patient reported different Birads scores in each breast, the patient is counted under the higher Birads score(e.g. Birads 5 is higher than Birads 4).

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Table 12.1

BREAST MAMMOGRAM  
RECONSTRUCTION PATIENTS

		Preoperative Mammogram Result							
Type of Visit	Post-op Result	Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	Total n(%)
6 Months	BIRADS 0	0 ( 0.0)	1 ( 1.8)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)	2 ( 0.8)
	BIRADS 1	0 ( 0.0)	7 ( 12.5)	1 ( 4.8)	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)	2 ( 3.2)	11 ( 4.5)
	BIRADS 2	0 ( 0.0)	0 ( 0.0)	2 ( 9.5)	1 ( 16.7)	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)	4 ( 1.6)
	MISSING	6 (100.0)	48 ( 85.7)	18 ( 85.7)	5 ( 83.3)	59 ( 96.7)	34 (100.0)	59 ( 95.2)	229 ( 93.1)
	TOTAL	6 (100.0)	56 (100.0)	21 (100.0)	6 (100.0)	61 (100.0)	34 (100.0)	62 (100.0)	246 (100.0)
1 Year	BIRADS 1	0 ( 0.0)	7 ( 13.0)	1 ( 4.5)	0 ( 0.0)	8 ( 13.6)	3 ( 9.4)	1 ( 1.6)	20 ( 8.3)
	BIRADS 2	0 ( 0.0)	4 ( 7.4)	1 ( 4.5)	1 ( 20.0)	1 ( 1.7)	0 ( 0.0)	0 ( 0.0)	7 ( 2.9)
	MISSING	7 (100.0)	43 ( 79.6)	20 ( 90.9)	4 ( 80.0)	50 ( 84.7)	29 ( 90.6)	60 ( 98.4)	213 ( 88.8)
	TOTAL	7 (100.0)	54 (100.0)	22 (100.0)	5 (100.0)	59 (100.0)	32 (100.0)	61 (100.0)	240 (100.0)
2 Year	BIRADS 1	0 ( 0.0)	14 ( 26.9)	2 ( 11.1)	1 ( 16.7)	8 ( 14.0)	3 ( 9.4)	2 ( 3.4)	30 ( 13.0)
	BIRADS 2	0 ( 0.0)	2 ( 3.8)	3 ( 16.7)	1 ( 16.7)	1 ( 1.8)	1 ( 3.1)	1 ( 1.7)	9 ( 3.9)
	BIRADS 3	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 3.5)	0 ( 0.0)	0 ( 0.0)	2 ( 0.9)
	MISSING	7 (100.0)	36 ( 69.2)	13 ( 72.2)	4 ( 66.7)	46 ( 80.7)	28 ( 87.5)	55 ( 94.8)	189 ( 82.2)
	TOTAL	7 (100.0)	52 (100.0)	18 (100.0)	6 (100.0)	57 (100.0)	32 (100.0)	58 (100.0)	230 (100.0)
3 Year	BIRADS 0	0 ( 0.0)	0 ( 0.0)	1 ( 11.1)	0 ( 0.0)	0 ( 0.0)	1 ( 7.7)	0 ( 0.0)	2 ( 1.7)
	BIRADS 1	0 ( 0.0)	11 ( 32.4)	1 ( 11.1)	2 ( 50.0)	3 ( 8.1)	0 ( 0.0)	0 ( 0.0)	17 ( 14.0)
	BIRADS 2	0 ( 0.0)	3 ( 8.8)	1 ( 11.1)	0 ( 0.0)	2 ( 5.4)	0 ( 0.0)	0 ( 0.0)	6 ( 5.0)
	BIRADS 3	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 5.4)	0 ( 0.0)	0 ( 0.0)	2 ( 1.7)
	BIRADS 4	0 ( 0.0)	1 ( 2.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.8)
	MISSING	2 (100.0)	19 ( 55.9)	6 ( 66.7)	2 ( 50.0)	30 ( 81.1)	12 ( 92.3)	22 (100.0)	93 ( 76.9)

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Note: Results shown are patient level results, if the patient reported different Birads scores in each breast, the patient is counted under the higher Birads score(e.g. Birads 5 is higher than Birads 4).

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Table 12.1

BREAST MAMMOGRAM  
RECONSTRUCTION PATIENTS

		Preoperative Mammogram Result							
Type of Visit	Post-op Result	Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	Total n(%)
3 Year	TOTAL	2 (100.0)	34 (100.0)	9 (100.0)	4 (100.0)	37 (100.0)	13 (100.0)	22 (100.0)	121 (100.0)

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Note: Results shown are patient level results; if the patient reported different Birads scores in each breast, the patient is counted under the higher Birads score(e.g. Birads 5 is higher than Birads 4).

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Table 12.1

BREAST MAMMOGRAM  
REVISION PATIENTS

Type of Visit Post-op Result		Preoperative Mammogram Result							Total n(%)
		Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	
6 Months	BIRADS 1	0 ( 0.0)	9 ( 9.8)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 3.4)	11 ( 5.6)
	BIRADS 2	0 ( 0.0)	2 ( 2.2)	1 ( 2.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	3 ( 1.5)
	BIRADS 3	0 ( 0.0)	1 ( 1.1)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.5)
	BIRADS 4	0 ( 0.0)	2 ( 2.2)	1 ( 2.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	3 ( 1.5)
	MISSING	1 (100.0)	78 ( 84.8)	33 ( 94.3)	0 ( 0.0)	8 (100.0)	4 (100.0)	56 ( 96.6)	180 ( 90.9)
	TOTAL	1 (100.0)	92 (100.0)	35 (100.0)	0 ( 0.0)	8 (100.0)	4 (100.0)	58 (100.0)	198 (100.0)
1 Year	BIRADS 0	0 ( 0.0)	2 ( 2.2)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 1.0)
	BIRADS 1	0 ( 0.0)	19 ( 21.1)	3 ( 8.3)	0 ( 0.0)	1 ( 12.5)	1 ( 25.0)	0 ( 0.0)	24 ( 12.3)
	BIRADS 2	0 ( 0.0)	7 ( 7.8)	5 ( 13.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 1.8)	13 ( 6.7)
	BIRADS 4	0 ( 0.0)	0 ( 0.0)	1 ( 2.8)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 1.8)	2 ( 1.0)
	BIRADS 5	0 ( 0.0)	1 ( 1.1)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.5)
	MISSING	1 (100.0)	61 ( 67.8)	27 ( 75.0)	0 ( 0.0)	7 ( 87.5)	3 ( 75.0)	54 ( 96.4)	153 ( 78.5)
TOTAL	1 (100.0)	90 (100.0)	36 (100.0)	0 ( 0.0)	8 (100.0)	4 (100.0)	56 (100.0)	195 (100.0)	
2 Year	BIRADS 0	0 ( 0.0)	0 ( 0.0)	1 ( 2.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.5)
	BIRADS 1	0 ( 0.0)	26 ( 29.2)	7 ( 20.6)	0 ( 0.0)	0 ( 0.0)	1 ( 25.0)	3 ( 5.8)	37 ( 19.8)
	BIRADS 2	0 ( 0.0)	7 ( 7.9)	9 ( 26.5)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	16 ( 8.6)
	BIRADS 4	0 ( 0.0)	0 ( 0.0)	1 ( 2.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.5)
	MISSING	1 (100.0)	56 ( 62.9)	16 ( 47.1)	0 ( 0.0)	7 (100.0)	3 ( 75.0)	49 ( 94.2)	132 ( 70.6)
	TOTAL	1 (100.0)	89 (100.0)	34 (100.0)	0 ( 0.0)	7 (100.0)	4 (100.0)	52 (100.0)	187 (100.0)
3 Year	BIRADS 1	0 ( 0.0)	22 ( 29.7)	3 ( 10.7)	0 ( 0.0)	1 ( 16.7)	0 ( 0.0)	1 ( 3.1)	27 ( 19.3)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T12\_1.SAS

Creation Date, Time: 16JUL04 13:08

Note: Results shown are patient level results; if the patient reported different Birads scores in each breast, the patient is counted under the higher Birads score(e.g. Birads 5 is higher than Birads 4).

Table 12.1

BREAST MAMMOGRAM  
REVISION PATIENTS

		Preoperative Mammogram Result							
Type of Visit	Post-op Result	Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	Total n(%)
3 Year	BIRADS 2	0 ( 0.0)	8 ( 10.8)	5 ( 17.9)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 3.1)	14 ( 10.0)
	BIRADS 3	0 ( 0.0)	2 ( 2.7)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 1.4)
	MISSING	0 ( 0.0)	42 ( 56.8)	20 ( 71.4)	0 ( 0.0)	5 ( 83.3)	0 ( 0.0)	30 ( 93.8)	97 ( 69.3)
	TOTAL	0 ( 0.0)	74 (100.0)	28 (100.0)	0 ( 0.0)	6 (100.0)	0 ( 0.0)	32 (100.0)	140 (100.0)

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.1

BREAST MAMMOGRAM  
OVERALL PATIENTS

Type of Visit Post-op Result		Preoperative Mammogram Result							Total n(%)
		Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	
6 Months	BIRADS 0	0 ( 0.0)	1 ( 0.3)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 0.5)	3 ( 0.3)
	BIRADS 1	1 ( 9.1)	37 ( 10.2)	3 ( 3.3)	1 ( 7.7)	1 ( 1.4)	0 ( 0.0)	8 ( 2.0)	51 ( 5.2)
	BIRADS 2	0 ( 0.0)	3 ( 0.8)	3 ( 3.3)	1 ( 7.7)	1 ( 1.4)	0 ( 0.0)	0 ( 0.0)	8 ( 0.8)
	BIRADS 3	0 ( 0.0)	1 ( 0.3)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.3)	2 ( 0.2)
	BIRADS 4	0 ( 0.0)	2 ( 0.6)	2 ( 2.2)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	4 ( 0.4)
	MISSING	10 ( 90.9)	317 ( 87.8)	82 ( 91.1)	11 ( 84.6)	70 ( 97.2)	38 ( 100.0)	385 ( 97.2)	913 ( 93.1)
	TOTAL	11 ( 100.0)	361 ( 100.0)	90 ( 100.0)	13 ( 100.0)	72 ( 100.0)	38 ( 100.0)	396 ( 100.0)	981 ( 100.0)
1 Year	BIRADS 0	0 ( 0.0)	2 ( 0.6)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 0.2)
	BIRADS 1	0 ( 0.0)	52 ( 14.6)	8 ( 8.7)	1 ( 8.3)	9 ( 12.9)	4 ( 11.1)	3 ( 0.8)	77 ( 8.0)
	BIRADS 2	0 ( 0.0)	16 ( 4.5)	6 ( 6.5)	1 ( 8.3)	1 ( 1.4)	0 ( 0.0)	3 ( 0.8)	27 ( 2.8)
	BIRADS 3	0 ( 0.0)	1 ( 0.3)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.1)
	BIRADS 4	0 ( 0.0)	1 ( 0.3)	1 ( 1.1)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.3)	3 ( 0.3)
	BIRADS 5	0 ( 0.0)	1 ( 0.3)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.1)
	MISSING	12 ( 100.0)	283 ( 79.5)	77 ( 83.7)	10 ( 83.3)	60 ( 85.7)	32 ( 88.9)	380 ( 98.2)	854 ( 88.5)
	TOTAL	12 ( 100.0)	356 ( 100.0)	92 ( 100.0)	12 ( 100.0)	70 ( 100.0)	36 ( 100.0)	387 ( 100.0)	965 ( 100.0)
2 Year	BIRADS 0	0 ( 0.0)	0 ( 0.0)	1 ( 1.2)	0 ( 0.0)	1 ( 1.5)	0 ( 0.0)	0 ( 0.0)	2 ( 0.2)
	BIRADS 1	0 ( 0.0)	88 ( 25.1)	14 ( 16.3)	1 ( 7.7)	8 ( 11.9)	4 ( 11.1)	12 ( 3.2)	127 ( 13.5)
	BIRADS 2	0 ( 0.0)	22 ( 6.3)	15 ( 17.4)	2 ( 15.4)	1 ( 1.5)	1 ( 2.8)	3 ( 0.8)	44 ( 4.7)
	BIRADS 3	0 ( 0.0)	3 ( 0.9)	0 ( 0.0)	0 ( 0.0)	2 ( 3.0)	0 ( 0.0)	2 ( 0.5)	7 ( 0.7)
	BIRADS 4	0 ( 0.0)	1 ( 0.3)	1 ( 1.2)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 0.2)
	BIRADS 5	0 ( 0.0)	1 ( 0.3)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T12\_1.SAS

Creation Date, Time: 16JUL04 13:08

Note: Results shown are patient level results; if the patient reported different Birads scores in each breast, the patient is counted under the higher Birads score(e.g. Birads 5 is higher than Birads 4).

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.1

BREAST MAMMOGRAM  
OVERALL PATIENTS

		Preoperative Mammogram Result							
Type of Visit	Post-op Result	Birads 0 n(%)	Birads 1 n(%)	Birads 2 n(%)	Birads 3 n(%)	Birads 4 n(%)	Birads 5 n(%)	Missing n(%)	Total n(%)
2 Year	MISSING	12 (100.0)	236 ( 67.2)	55 ( 64.0)	10 ( 76.9)	55 ( 82.1)	31 ( 86.1)	359 ( 95.5)	758 ( 80.6)
	TOTAL	12 (100.0)	351 (100.0)	86 (100.0)	13 (100.0)	67 (100.0)	36 (100.0)	376 (100.0)	941 (100.0)
3 Year	BIRADS 0	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)	1 ( 7.7)	1 ( 0.4)	3 ( 0.5)
	BIRADS 1	0 ( 0.0)	71 ( 25.6)	10 ( 15.6)	3 ( 37.5)	4 ( 8.9)	0 ( 0.0)	10 ( 4.0)	98 ( 14.7)
	BIRADS 2	0 ( 0.0)	24 ( 8.7)	9 ( 14.1)	0 ( 0.0)	2 ( 4.4)	0 ( 0.0)	1 ( 0.4)	36 ( 5.4)
	BIRADS 3	0 ( 0.0)	2 ( 0.7)	0 ( 0.0)	0 ( 0.0)	2 ( 4.4)	0 ( 0.0)	1 ( 0.4)	5 ( 0.8)
	BIRADS 4	0 ( 0.0)	3 ( 1.1)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	3 ( 0.5)
	MISSING	6 (100.0)	177 ( 63.9)	44 ( 68.8)	5 ( 62.5)	37 ( 82.2)	12 ( 92.3)	239 ( 94.8)	520 ( 78.2)
	TOTAL	6 (100.0)	277 (100.0)	64 (100.0)	8 (100.0)	45 (100.0)	13 (100.0)	252 (100.0)	665 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T12\_1.SAS

Creation Date, Time: 16JUL04 13:08

Note. Results shown are patient level results; if the patient reported different Birads scores in each breast, the patient is counted under the higher Birads score(e.g. Birads 5 is higher than Birads 4).

Core (M) Study: Effects of Time to Effluent Entry in Revision of Round or Flat Larynx Prosthesis  
 in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.2.1

INCIDENCE OF NEW ILL-DEFINITE ABNORMAL MAMMOGRAPHY REGARDLESS OF BIOPSY RESULTS (PATIENT LEVEL)

Total with at Least One Abnormal Mammography by Indication	0-6 months (a)	6-12 months (a)	12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n (%)				
Augmentation Patients	1 ( 2.7)	1 ( 2.9)	2 ( 2.8)	2 ( 3.4)	6 ( 4.7)
Reconstruction Patients	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 4.8)	1 ( 2.0)
Revision Patients	2 ( 9.1)	2 ( 5.4)	0 ( 0.0)	0 ( 0.0)	4 ( 4.4)
Overall Patients	3 ( 4.2)	3 ( 3.2)	2 ( 1.3)	3 ( 2.6)	11 ( 4.1)

Program Name: Q:\MENTOR\MOREGEL\3YEAR\TABLES\T12\_2\_1.SAS

Creation Date, Time: 16JUL04 13:10

Note: Defined as Brads 4 (suspicious abnormality; biopsy should be considered) or Brads 5 (highly suggestive of malignancy).

(a) Includes only abnormal mammograms that were taken during the time period of interest.

Table 12.2.2

INCIDENCE OF MALIGNANT TUMOR ABNORMAL (MAMMOGRAPHY REGARDLESS OF BIOPSY RESULTS (IMPLANT LEVEL))

Total with at Least One Abnormal Mammography by Indication	0-6 months (a)	>6-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Implants n (%)				
Implants used for:					
Augmentation	2 ( 2.6)	1 ( 1.3)	2 ( 2.3)	2 ( 2.6)	7 ( 2.6)
Reconstruction	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 4.2)	1 ( 2.6)
Revision	2 ( 5.0)	2 ( 3.1)	0 ( 0.0)	0 ( 0.0)	4 ( 2.4)
Overall Implants	4 ( 3.0)	3 ( 2.8)	2 ( 0.7)	3 ( 2.4)	12 ( 2.4)

Table 12.2.3

INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY FOR TH OF PATIENTS HAVING POSITIVE OR NEGATIVE BIOPSIES (IMPLANT LEVEL)

Biopsy Result	Total with at Least One Abnormal Mammography by Indication	0-36 months (a)				
		0-6 months (a) Number of Implants n(%)	6-12 months (a) Number of Implants n(%)	12-24 months (a) Number of Implants n(%)	24-36 months (a) Number of Implants n(%)	0-36 months (a) Number of Implants n(%)
Positive	Implants used for:					
	Reconstruction	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
	Revision	0 ( 0.0)	1 ( 20.0)	0 ( 0.0)	0 ( 0.0)	1 ( 12.5)
	Overall Implants	0 ( 0.0)	1 ( 12.5)	0 ( 0.0)	0 ( 0.0)	1 ( 6.3)
Negative	Implants used for:					
	Augmentation	2 ( 40.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 10.0)
	Reconstruction	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
	Revision	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
	Overall Implants	2 ( 28.6)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 5.6)
Missing	Implants used for:					
	Augmentation	0 ( 0.0)	1 ( 1.4)	2 ( 2.4)	2 ( 4.7)	5 ( 2.0)
	Reconstruction	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 5.0)	1 ( 2.1)
	Revision	2 ( 7.7)	1 ( 1.9)	0 ( 0.0)	0 ( 0.0)	3 ( 2.0)
	Overall Implants	2 ( 1.7)	2 ( 1.4)	2 ( 0.8)	3 ( 1.6)	9 ( 2.0)

Program Name: Q:\MENTOR\COREGEL\YEAP\TABLES.T12\_2\_3.SAS

Creation Date, Time: 16 JUL 04 13:12

Note: defined as BIRADS-4 (suspect of abnormality; biopsy should be considered) or BIRADS-5 (highly suggestive of malignancy).  
(a) Includes only abnormal mammograms that were taken during the time period of interest.

Table 12.3.1

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIOPSY RESULTS (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Time from Implant Surgery(a)	Number with Event	Estimated Proportion With Event (b)	Total Patients n
6 Months	1	0.0038	264
12 Months	2	0.0076	264
24 Months	4	0.0155	264
36 Months	6	0.0263	264

Program Name: 2:\MENTOR\COREGEL\3YEAR\TABLES\T12\_3\_1.SAS

Creation Date, Time: 16/07/04 13:12

Note: Defined as Bi-rads 4 (suspicious abnormality: Further evaluation is warranted) or Bi-rads 5 (highly suggestive of malignancy).  
(a) Time to first occurrence of event.  
(b) Based on Kaplan-Meier estimates.

Core 3a Study of the Safety and Effectiveness of the Mentor Round Get-It! Breast Augmentation Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.3.1

CUMULATIVE INCIDENCE OF NEW POST-OPERATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIOPSY RESULTS (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Patients n
6 Months	0	0.0000	117
12 Months	0	0.0000	117
24 Months	0	0.0000	117
36 Months	1	0.0143	117

Program Name: Q:\MENTOR\CORE3A\BYEAP\TABLES\T12\_3\_1.SAS

Creation Date, Time: 16 JUL 04 13:12

Note: Defined as Bi-rads 4 (suspicious abnormality: biopsy should be considered) & Bi-rads 5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Note: GEI study of the safety and efficacy of the Mentor AllClear Breast-Implant Augmentary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.3.1

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIOPSY RESULTS (PATIENT LEVEL)  
REVISION PATIENTS

Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Patients n
6 Months	2	0.0147	137
12 Months	4	0.0294	137
24 Months	4	0.0294	137
36 Months	4	0.0294	137

Program Name: Q:\MENTOR\AC\_PEGE\3YEAR\TABLES\T12\_3\_1.SAS

Creation Date, Time: 16JUL04 13:12

Note: Defined as B-rads=4 (suspicious abnormality; biopsy should be considered) or B-rads=5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Core Gel Group of the Safety and Efficacy Studies of the Mammography Unit of the National Cancer Institute  
 in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 2.3.1

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIOPSY RESULTS (PATIENT LEVEL)  
 OVERALL PATIENTS

Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Patients n
6 Months	3	0.0058	518
12 Months	6	0.0117	518
24 Months	8	0.0158	518
36 Months	11	0.0249	518

Program Name: Q:\MNTOP\COREGEL\3YEAR TABLES\T12\_3\_1.SAS

Creation Date, Time: 16JUL04 13:12

Note: Defined as BIRADS 4 (suspicious abnormality; biopsy should be considered) or BIRADS 5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Table 2.3.2  
 Cumulative Incidence of New First Relative Abnormal Mammography Results Regardless of Biopsy Results (Implant Level)  
 Implants Used for Augmentation

Table 2.3.2  
 CUMULATIVE INCIDENCE OF NEW FIRST RELATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIOPSY RESULTS (IMPLANT LEVEL)  
 IMPLANTS USED FOR AUGMENTATION

Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Implants n
6 Months	2	0.0037	540
12 Months	3	0.0056	540
24 Months	5	0.0094	540
36 Months	7	0.0148	540

Program Name: Q:\MENTOR\CHEGEL\3YEAR TABLES\7.2\_3\_1.SAS

Creation Date, Time: 16JUL04 3:12

Note: Defined as Biases 4 (suspicious abnormality; biopsy should be considered) or Biases 5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Core Gel Study of the Safety and Efficacy of the Model 1000 Breast Implant in Primary Breast Augmentation in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.3.2

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIOPSY RESULTS (IMPLANT BEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Implants n
6 Months	0	0.0000	166
12 Months	0	0.0000	166
24 Months	0	0.0000	166
36 Months	1	0.0103	166

Program Name: Q:\MENTOP\COREGEL\BYLAF\TABLES\T12\_3\_1.SAS

Creation Date, Time: 16JUL04 13:12

Note: Defined as Birads-4 (suspicious abnormality; biopsy should be considered) or Birads-5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Formo S Implant in Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.3.2

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIopsy RESULTS (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Implants n
6 Months	2	0.0079	255
12 Months	4	0.0158	255
24 Months	4	0.0158	255
36 Months	4	0.0158	255

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T12\_3\_1.SAS

Creation Date, Time: 16JUL04 13:12

Note: Defined as BIRADS 4 (suspicious abnormality; biopsy should be considered) or BIRADS 5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Core Gel Study of the Safety and Efficacy of the Mentor Duet™ Breast Implant in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.3.2

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS REGARDLESS OF BIOPSY RESULTS (IMPLANT LEVEL)  
OVERALL IMPLANTS

Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Implants n
6 Months	4	0.0042	961
12 Months	7	0.0073	961
24 Months	9	0.0096	961
36 Months	12	0.0143	961

Program Name: Q:\MENTOR\COREGEL\_3YEAR\TABLES\T 2\_3\_1.SAS

Creation Date, Time: 10/08/04 13:12

Note: Defined as BIRADS-4 (suspicious abnormality; biopsy should be considered) or BIRADS-5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Core Beliefs of the Safety and Effectiveness of the New 11.1 and 11.2 Silicone Primary Prostheses  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 12.3.3

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS BY BIOPSY RESULTS (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Biopsy Result	Time from Implant Surgery(a)	Number with Event	Estimated Proportion With Event(b)	Total Implants n
Negative	6 Months	2	0.0690	29
	12 Months	2	0.0690	29
	24 Months	2	0.0690	29
	36 Months	2	0.0690	29
Missing	6 Months	0	0.0000	511
	12 Months	1	0.0020	511
	24 Months	3	0.0060	511
	36 Months	5	0.0117	511

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\TL2\_3\_3.SAS

Creation Date, Time: 16JUL04 13:12

Note: Defined as BIRADS 4 (suspicious abnormality: biopsy should be considered) or BIRADS 5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Core Data from the Safety and Effectiveness of the Mentor Form 502 Tissue Expanders, Implants in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 2.3.3

CUMULATIVE INCIDENCE OF NEW POST-OPERATIVE ABNORMAL MAMMOGRAPHY RESULTS BY BIOPSY RESULTS (INITIAL LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Biopsy Result	Time from Implant Surgery(a)	Number with Event	Estimated Proportion With Event (b)	Total Implants n
Positive	6 Months	0	0.0000	20
	12 Months	0	0.0000	20
	24 Months	0	0.0000	20
Negative	24 Months	0	0.0000	24
	36 Months	0	0.0000	24
Missing	6 Months	0	0.0000	122
	12 Months	0	0.0000	122
	24 Months	0	0.0000	122
	36 Months	1	0.0132	122

Program Name: D:\MENTOR\COREDATA\YEAR\IMPLANTS\T2\_3\_3.SAS

Creation Date, Time: 16JUN04 13:12

Note: Defined as Breast 4 (suspicious abnormality; biopsy should be considered) or Breast 5 (highly suggestive of malignancy).  
 (a) Time to first occurrence of event.  
 (b) Based on Kaplan-Meier estimates.

Core Gel: Risk of the Safety and Efficacy of the Form 2.1 and Gel 2.1 for Primary Prostheses  
 In Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 2.3.4

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS BY BIOPSY RESULTS (IMPLANT LEVEL)  
 IMPLANTS USED FOR REVISION

Biopsy Result	Time from Implant Surgery(a)	Number with Event	Estimated Proportion With Event (b)	Total Implants n
Positive	6 Months	0	0.0000	9
	36 Months	1	0.1111	9
Negative	24 Months	0	0.0000	19
	36 Months	0	0.0000	19
Missing	6 Months	4	0.0088	228
	12 Months	3	0.0133	228
	24 Months	3	0.0133	228
	36 Months	3	0.0133	228

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T12\_3\_3.SAS

Creation Date, Time: 16 JUL 04 13:12

Note: Defined as Breast 4 (suspicious abnormality; biopsy should be considered) or Breast 5 (highly suggestive of malignancy).

(a) Time to first occurrence of event.

(b) Based on Kaplan-Meier estimates.

Table 12.3.3

CUMULATIVE INCIDENCE OF NEW POSTOPERATIVE ABNORMAL MAMMOGRAPHY RESULTS BY BIOPSY RESULTS (IMPLANT LEVEL)  
 OVERALL IMPLANTS

Biopsy Result	Time from Implant Surgery (a)	Number with Event	Estimated Proportion With Event (b)	Total Implants n
Positive	6 Months	0	0.0000	29
	12 Months	0	0.0370	29
	24 Months	1	0.0370	29
	36 Months	1	0.0370	29
Negative	6 Months	0	0.0282	71
	12 Months	2	0.0282	71
	24 Months	2	0.0282	71
	36 Months	2	0.0282	71
Missing	6 Months	2	0.0023	861
	12 Months	4	0.0047	861
	24 Months	6	0.0071	861
	36 Months	9	0.0123	861

Program Name: Q:\MENTOR\CORE401\3YEAR\TABLES\T12\_3\_3.SAS

Creation Date, Time: 10JUL04 13:2

Note: Defined as Biopsy 4 (suspicious abnormality; biopsy should be considered) or Biopsy 7 (highly suggestive of malignancy).  
 (a) Time to first occurrence of event.  
 (b) Based on Kaplan-Meier estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.1

## MRI SUBSTUDY: PATIENT CHARACTERISTICS AND FINDINGS

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)
<b>Indication</b>								
Augmentation	384 (100.0)	193 (100.0)	12 ( 6.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	396 ( 54.1)	193 ( 49.0)
Reconstruction	0 ( 0.0)	0 ( 0.0)	189 ( 94.0)	121 (100.0)	1 ( 0.7)	0 ( 0.0)	190 ( 26.0)	121 ( 30.7)
Revision	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	146 ( 99.3)	80 (100.0)	146 ( 19.9)	80 ( 20.3)
Total	384 (100.0)	193 (100.0)	201 (100.0)	121 (100.0)	147 (100.0)	80 (100.0)	732 (100.0)	394 (100.0)
<b>Breast Involved</b>								
Left Only	0 ( 0.0)	0 ( 0.0)	18 ( 9.0)	18 ( 9.0)	5 ( 3.4)	5 ( 3.4)	23 ( 3.1)	23 ( 3.1)
Right Only	1 ( 0.3)	1 ( 0.3)	21 ( 10.4)	21 ( 10.4)	5 ( 3.4)	5 ( 3.4)	27 ( 3.7)	27 ( 3.7)
Bilateral	383 ( 99.7)	192 ( 50.0)	162 ( 80.6)	82 ( 40.8)	137 ( 93.2)	70 ( 47.6)	682 ( 93.2)	344 ( 47.0)
Total	384 (100.0)	193 ( 50.3)	201 (100.0)	121 ( 60.2)	147 (100.0)	80 ( 54.4)	732 (100.0)	394 ( 53.8)
<b>Placement</b>								
Submuscular	153 ( 39.8)	77 ( 39.9)	128 ( 63.7)	81 ( 66.9)	67 ( 45.6)	39 ( 48.8)	348 ( 47.5)	197 ( 50.0)
Subglandular	158 ( 41.1)	79 ( 40.9)	20 ( 10.0)	11 ( 9.1)	53 ( 36.1)	27 ( 33.8)	231 ( 31.6)	117 ( 29.7)
Subpectoral	73 ( 19.0)	37 ( 19.2)	53 ( 26.4)	31 ( 25.6)	27 ( 18.4)	14 ( 17.5)	153 ( 20.9)	82 ( 20.8)
Other	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Total	384 (100.0)	193 (100.0)	201 (100.0)	121 (100.0)	147 (100.0)	80 (100.0)	732 (100.0)	394 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_1.SAS

Creation Date, Time: 26AUG04 11:38

- (a) Figures shown are number and percent of patients with at least one breast falling in category.  
 (b) Assessment was conducted at the patient level only.  
 (c) For patients with multiple MRI scans or with differing interpretations between the local radiologist and the central MRI reader, the worst case data were summarized.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.1

## MRI SUBSTUDY: PATIENT CHARACTERISTICS AND FINDINGS

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)						
<b>Implant Type</b>								
Smooth	236 ( 61.5)	119 ( 61.7)	71 ( 35.3)	43 ( 35.5)	103 ( 70.1)	56 ( 70.0)	410 ( 56.0)	218 ( 55.3)
Textured	148 ( 38.5)	74 ( 38.3)	130 ( 64.7)	78 ( 64.5)	44 ( 29.9)	24 ( 30.0)	322 ( 44.0)	176 ( 44.7)
Total	384 (100.0)	193 (100.0)	201 (100.0)	121 (100.0)	147 (100.0)	80 (100.0)	732 (100.0)	394 (100.0)
<b>Implant Evaluation (c)</b>								
No Evidence of Rupture	383 ( 99.7)	192 ( 99.5)	198 ( 98.5)	119 ( 98.3)	142 ( 96.6)	77 ( 96.3)	723 ( 98.8)	388 ( 98.5)
Indeterminate	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Rupture	1 ( 0.3)	1 ( 0.5)	1 ( 0.5)	1 ( 0.8)	5 ( 3.4)	3 ( 3.8)	7 ( 1.0)	5 ( 1.3)
Missing	0 ( 0.0)	0 ( 0.0)	2 ( 1.0)	1 ( 0.8)	0 ( 0.0)	0 ( 0.0)	2 ( 0.3)	1 ( 0.3)
Total	384 (100.0)	193 (100.0)	201 (100.0)	121 (100.0)	147 (100.0)	80 (100.0)	732 (100.0)	394 (100.0)
<b>Type of Rupture (c)</b>								
Intracapsular	1 ( 0.3)	1 ( 0.5)	0 ( 0.0)	0 ( 0.0)	5 ( 3.4)	3 ( 3.8)	6 ( 0.8)	4 ( 1.0)
Extracapsular	0 ( 0.0)	0 ( 0.0)	1 ( 0.5)	1 ( 0.8)	0 ( 0.0)	0 ( 0.0)	1 ( 0.1)	1 ( 0.3)
N/A	383 ( 99.7)	193 (100.0)	200 ( 99.5)	120 ( 99.2)	142 ( 96.6)	78 ( 97.5)	725 ( 99.0)	391 ( 99.2)
Total	384 (100.0)	193 (100.0)	201 (100.0)	121 (100.0)	147 (100.0)	80 (100.0)	732 (100.0)	394 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_1.SAS

Creation Date, Time: 26AUG04 11:38

- (a) Figures shown are number and percent of patients with at least one breast falling in category.  
 (b) Assessment was conducted at the patient level only.  
 (c) For patients with multiple MRI scans or with differing interpretations between the local radiologist and the central MRI reader, the worst case data were summarized.

Table 13.1

MRI SUBSTUDY: PATIENT CHARACTERISTICS AND FINDINGS

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)
<b>Condition of Rupture (c)</b>								
Uncollapsed	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	2 ( 1.4)	1 ( 1.3)	2 ( 0.3)	1 ( 0.3)
Partially Collapsed	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Fully Collapsed	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Missing	1 ( 0.3)	1 ( 0.5)	1 ( 0.5)	1 ( 0.8)	3 ( 2.0)	2 ( 2.5)	5 ( 0.7)	4 ( 1.0)
N/A	383 ( 99.7)	192 ( 99.5)	200 ( 99.5)	120 ( 99.2)	142 ( 96.6)	77 ( 96.3)	725 ( 99.0)	389 ( 98.7)
Total	384 (100.0)	193 (100.0)	201 (100.0)	121 (100.0)	147 (100.0)	80 (100.0)	732 (100.0)	394 (100.0)
<b>Soft Tissue Evaluation (Extracapsular Silicone) (c)</b>								
No Evidence of Rupture	384 (100.0)	193 (100.0)	199 ( 99.0)	120 ( 99.2)	143 ( 97.3)	77 ( 96.3)	726 ( 99.2)	390 ( 99.0)
Indeterminate	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	1 ( 0.7)	1 ( 1.3)	1 ( 0.1)	1 ( 0.3)
Definite	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)	3 ( 2.0)	2 ( 2.5)	3 ( 0.4)	2 ( 0.5)
Missing	0 ( 0.0)	0 ( 0.0)	2 ( 1.0)	1 ( 0.8)	0 ( 0.0)	0 ( 0.0)	2 ( 0.3)	1 ( 0.3)
Total	384 (100.0)	193 (100.0)	201 (100.0)	121 (100.0)	147 (100.0)	80 (100.0)	732 (100.0)	394 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_1.SAS

Creation Date, Time: 26AUG04 11:38

- (a) Figures shown are number and percent of patients with at least one breast falling in category.
- (b) Assessment was conducted at the patient level only.
- (c) For patients with multiple MRI scans or with differing interpretations between the local radiologist and the central MRI reader, the worst case data were summarized.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2

## CUMULATIVE INCIDENCE OF RUPTURE BY TYPE OF DIAGNOSIS - MRI SUBSTUDY

Patient Indication	Types of Diagnosis (a)	Time from Implant Surgery (Month) (b)	Patients		Implants	
			Estimated Proportion with Event (c)	Total Patients (n)	Estimated Proportion with Event (c)	Total Implants (n)
AUGMENTATION PATIENTS	MRI Diagnosis of Rupture Excluding Explanted Determined to be Intact or Rupture Noted at Explantation	12	0.0000	202	0.0000	417
		24	0.0000	202	0.0000	417
		36	0.0050	202	0.0024	417
RECONSTRUCTION PATIENTS	MRI Diagnosis of Rupture Excluding Explanted Determined to be Intact or Rupture Noted at Explantation	12	0.0000	134	0.0000	211
		24	0.0075	134	0.0047	211
		36	0.0075	134	0.0047	211
REVISION PATIENTS	MRI Diagnosis of Rupture Excluding Explanted Determined to be Intact or Rupture Noted at Explantation	12	0.0000	84	0.0000	157
		24	0.0357	84	0.0255	157
		36	0.0476	84	0.0382	157
OVERALL PATIENTS	MRI Diagnosis of Rupture Excluding Explanted Determined to be Intact or Rupture Noted at Explantation	12	0.0000	420	0.0000	785
		24	0.0095	420	0.0064	785
		36	0.0143	420	0.0102	785

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2.SAS

Creation Date, Time: 25AUG04 18:57

(a) Rupture noted by either the local radiologist or the central MRI reader.

(b) Time from implant surgery to first occurrence of event.

(c) Based on Kaplan-Meier estimates.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	202	1.0000	0.0000	(0.0000,0.0000)
1	0	0	202	1.0000	0.0000	(0.0000,0.0000)
2	0	0	202	1.0000	0.0000	(0.0000,0.0000)
3	0	0	202	1.0000	0.0000	(0.0000,0.0000)
4	0	0	202	1.0000	0.0000	(0.0000,0.0000)
5	0	0	202	1.0000	0.0000	(0.0000,0.0000)
6	0	0	202	1.0000	0.0000	(0.0000,0.0000)
7	0	0	202	1.0000	0.0000	(0.0000,0.0000)
8	0	0	202	1.0000	0.0000	(0.0000,0.0000)
9	0	0	202	1.0000	0.0000	(0.0000,0.0000)
10	0	0	202	1.0000	0.0000	(0.0000,0.0000)
11	0	0	202	1.0000	0.0000	(0.0000,0.0000)
12	0	0	202	1.0000	0.0000	(0.0000,0.0000)
13	0	0	202	1.0000	0.0000	(0.0000,0.0000)
14	0	0	202	1.0000	0.0000	(0.0000,0.0000)
15	0	0	202	1.0000	0.0000	(0.0000,0.0000)
16	0	0	202	1.0000	0.0000	(0.0000,0.0000)
17	0	0	202	1.0000	0.0000	(0.0000,0.0000)
18	0	0	202	1.0000	0.0000	(0.0000,0.0000)
19	0	0	202	1.0000	0.0000	(0.0000,0.0000)
20	0	0	202	1.0000	0.0000	(0.0000,0.0000)
21	0	0	202	1.0000	0.0000	(0.0000,0.0000)
22	0	0	202	1.0000	0.0000	(0.0000,0.0000)
23	0	0	202	1.0000	0.0000	(0.0000,0.0000)
24	0	0	202	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	0	201	0.9950	0.0050	(0.0000,0.0146)
26	0	0	201	0.9950	0.0050	(0.0000,0.0146)
27	0	0	201	0.9950	0.0050	(0.0000,0.0146)
28	0	0	201	0.9950	0.0050	(0.0000,0.0146)
29	0	0	201	0.9950	0.0050	(0.0000,0.0146)
30	0	0	201	0.9950	0.0050	(0.0000,0.0146)
31	0	0	201	0.9950	0.0050	(0.0000,0.0146)
32	0	0	201	0.9950	0.0050	(0.0000,0.0146)
33	0	0	201	0.9950	0.0050	(0.0000,0.0146)
34	0	0	201	0.9950	0.0050	(0.0000,0.0146)
35	0	0	201	0.9950	0.0050	(0.0000,0.0146)
36	0	0	201	0.9950	0.0050	(0.0000,0.0146)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	134	1.0000	0.0000	(0.0000,0.0000)
1	0	0	134	1.0000	0.0000	(0.0000,0.0000)
2	0	0	134	1.0000	0.0000	(0.0000,0.0000)
3	0	0	134	1.0000	0.0000	(0.0000,0.0000)
4	0	0	134	1.0000	0.0000	(0.0000,0.0000)
5	0	0	134	1.0000	0.0000	(0.0000,0.0000)
6	0	0	134	1.0000	0.0000	(0.0000,0.0000)
7	0	0	134	1.0000	0.0000	(0.0000,0.0000)
8	0	0	134	1.0000	0.0000	(0.0000,0.0000)
9	0	0	134	1.0000	0.0000	(0.0000,0.0000)
10	0	0	134	1.0000	0.0000	(0.0000,0.0000)
11	0	0	134	1.0000	0.0000	(0.0000,0.0000)
12	0	0	134	1.0000	0.0000	(0.0000,0.0000)
13	0	0	134	1.0000	0.0000	(0.0000,0.0000)
14	0	0	134	1.0000	0.0000	(0.0000,0.0000)
15	0	0	134	1.0000	0.0000	(0.0000,0.0000)
16	0	0	134	1.0000	0.0000	(0.0000,0.0000)
17	0	0	134	1.0000	0.0000	(0.0000,0.0000)
18	0	0	134	1.0000	0.0000	(0.0000,0.0000)
19	0	0	134	1.0000	0.0000	(0.0000,0.0000)
20	0	0	134	1.0000	0.0000	(0.0000,0.0000)
21	0	0	134	1.0000	0.0000	(0.0000,0.0000)
22	0	0	134	1.0000	0.0000	(0.0000,0.0000)
23	1	0	133	0.9925	0.0075	(0.0000,0.0220)
24	0	0	133	0.9925	0.0075	(0.0000,0.0220)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	133	0.9925	0.0075	(0.0000,0.0220)
26	0	0	133	0.9925	0.0075	(0.0000,0.0220)
27	0	0	133	0.9925	0.0075	(0.0000,0.0220)
28	0	0	133	0.9925	0.0075	(0.0000,0.0220)
29	0	0	133	0.9925	0.0075	(0.0000,0.0220)
30	0	0	133	0.9925	0.0075	(0.0000,0.0220)
31	0	0	133	0.9925	0.0075	(0.0000,0.0220)
32	0	0	133	0.9925	0.0075	(0.0000,0.0220)
33	0	0	133	0.9925	0.0075	(0.0000,0.0220)
34	0	0	133	0.9925	0.0075	(0.0000,0.0220)
35	0	0	133	0.9925	0.0075	(0.0000,0.0220)
36	0	0	133	0.9925	0.0075	(0.0000,0.0220)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
REVISION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	84	1.0000	0.0000	(0.0000,0.0000)
1	0	0	84	1.0000	0.0000	(0.0000,0.0000)
2	0	0	84	1.0000	0.0000	(0.0000,0.0000)
3	0	0	84	1.0000	0.0000	(0.0000,0.0000)
4	0	0	84	1.0000	0.0000	(0.0000,0.0000)
5	0	0	84	1.0000	0.0000	(0.0000,0.0000)
6	0	0	84	1.0000	0.0000	(0.0000,0.0000)
7	0	0	84	1.0000	0.0000	(0.0000,0.0000)
8	0	0	84	1.0000	0.0000	(0.0000,0.0000)
9	0	0	84	1.0000	0.0000	(0.0000,0.0000)
10	0	0	84	1.0000	0.0000	(0.0000,0.0000)
11	0	0	84	1.0000	0.0000	(0.0000,0.0000)
12	0	0	84	1.0000	0.0000	(0.0000,0.0000)
13	0	0	84	1.0000	0.0000	(0.0000,0.0000)
14	0	0	84	1.0000	0.0000	(0.0000,0.0000)
15	0	0	84	1.0000	0.0000	(0.0000,0.0000)
16	0	0	84	1.0000	0.0000	(0.0000,0.0000)
17	0	0	84	1.0000	0.0000	(0.0000,0.0000)
18	0	0	84	1.0000	0.0000	(0.0000,0.0000)
19	1	0	83	0.9881	0.0119	(0.0000,0.0351)
20	0	0	83	0.9881	0.0119	(0.0000,0.0351)
21	0	0	83	0.9881	0.0119	(0.0000,0.0351)
22	0	0	83	0.9881	0.0119	(0.0000,0.0351)
23	1	0	82	0.9762	0.0238	(0.0000,0.0564)
24	2	0	80	0.9524	0.0476	(0.0021,0.0932)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
REVISION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	80	0.9524	0.0476	(0.0021,0.0932)
26	0	0	80	0.9524	0.0476	(0.0021,0.0932)
27	0	0	80	0.9524	0.0476	(0.0021,0.0932)
28	1	0	79	0.9405	0.0595	(0.0089,0.1101)
29	0	0	79	0.9405	0.0595	(0.0089,0.1101)
30	0	0	79	0.9405	0.0595	(0.0089,0.1101)
31	0	0	79	0.9405	0.0595	(0.0089,0.1101)
32	0	0	79	0.9405	0.0595	(0.0089,0.1101)
33	0	0	79	0.9405	0.0595	(0.0089,0.1101)
34	0	0	79	0.9405	0.0595	(0.0089,0.1101)
35	0	0	79	0.9405	0.0595	(0.0089,0.1101)
36	0	0	79	0.9405	0.0595	(0.0089,0.1101)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time. 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
OVERALL PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	420	1.0000	0.0000	(0.0000,0.0000)
1	0	0	420	1.0000	0.0000	(0.0000,0.0000)
2	0	0	420	1.0000	0.0000	(0.0000,0.0000)
3	0	0	420	1.0000	0.0000	(0.0000,0.0000)
4	0	0	420	1.0000	0.0000	(0.0000,0.0000)
5	0	0	420	1.0000	0.0000	(0.0000,0.0000)
6	0	0	420	1.0000	0.0000	(0.0000,0.0000)
7	0	0	420	1.0000	0.0000	(0.0000,0.0000)
8	0	0	420	1.0000	0.0000	(0.0000,0.0000)
9	0	0	420	1.0000	0.0000	(0.0000,0.0000)
10	0	0	420	1.0000	0.0000	(0.0000,0.0000)
11	0	0	420	1.0000	0.0000	(0.0000,0.0000)
12	0	0	420	1.0000	0.0000	(0.0000,0.0000)
13	0	0	420	1.0000	0.0000	(0.0000,0.0000)
14	0	0	420	1.0000	0.0000	(0.0000,0.0000)
15	0	0	420	1.0000	0.0000	(0.0000,0.0000)
16	0	0	420	1.0000	0.0000	(0.0000,0.0000)
17	0	0	420	1.0000	0.0000	(0.0000,0.0000)
18	0	0	420	1.0000	0.0000	(0.0000,0.0000)
19	1	0	419	0.9976	0.0024	(0.0000,0.0070)
20	0	0	419	0.9976	0.0024	(0.0000,0.0070)
21	0	0	419	0.9976	0.0024	(0.0000,0.0070)
22	0	0	419	0.9976	0.0024	(0.0000,0.0070)
23	2	0	417	0.9929	0.0071	(0.0000,0.0152)
24	2	0	415	0.9881	0.0119	(0.0015,0.0223)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.1

TIME TO FIRST REPORT OF SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4c  
OVERALL PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	0	414	0.9857	0.0143	(0.0029,0.0256)
26	0	0	414	0.9857	0.0143	(0.0029,0.0256)
27	0	0	414	0.9857	0.0143	(0.0029,0.0256)
28	1	0	413	0.9833	0.0167	(0.0044,0.0289)
29	0	0	413	0.9833	0.0167	(0.0044,0.0289)
30	0	0	413	0.9833	0.0167	(0.0044,0.0289)
31	0	0	413	0.9833	0.0167	(0.0044,0.0289)
32	0	0	413	0.9833	0.0167	(0.0044,0.0289)
33	0	0	413	0.9833	0.0167	(0.0044,0.0289)
34	0	0	413	0.9833	0.0167	(0.0044,0.0289)
35	0	0	413	0.9833	0.0167	(0.0044,0.0289)
36	0	0	413	0.9833	0.0167	(0.0044,0.0289)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_1.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
AUGMENTATION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	417	1.0000	0.0000	(0.0000,0.0000)
1	0	0	417	1.0000	0.0000	(0.0000,0.0000)
2	0	0	417	1.0000	0.0000	(0.0000,0.0000)
3	0	0	417	1.0000	0.0000	(0.0000,0.0000)
4	0	0	417	1.0000	0.0000	(0.0000,0.0000)
5	0	0	417	1.0000	0.0000	(0.0000,0.0000)
6	0	0	417	1.0000	0.0000	(0.0000,0.0000)
7	0	0	417	1.0000	0.0000	(0.0000,0.0000)
8	0	0	417	1.0000	0.0000	(0.0000,0.0000)
9	0	0	417	1.0000	0.0000	(0.0000,0.0000)
10	0	0	417	1.0000	0.0000	(0.0000,0.0000)
11	0	0	417	1.0000	0.0000	(0.0000,0.0000)
12	0	0	417	1.0000	0.0000	(0.0000,0.0000)
13	0	0	417	1.0000	0.0000	(0.0000,0.0000)
14	0	0	417	1.0000	0.0000	(0.0000,0.0000)
15	0	0	417	1.0000	0.0000	(0.0000,0.0000)
16	0	0	417	1.0000	0.0000	(0.0000,0.0000)
17	0	0	417	1.0000	0.0000	(0.0000,0.0000)
18	0	0	417	1.0000	0.0000	(0.0000,0.0000)
19	0	0	417	1.0000	0.0000	(0.0000,0.0000)
20	0	0	417	1.0000	0.0000	(0.0000,0.0000)
21	0	0	417	1.0000	0.0000	(0.0000,0.0000)
22	0	0	417	1.0000	0.0000	(0.0000,0.0000)
23	0	0	417	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15.53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
AUGMENTATION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	417	1.0000	0.0000	(0.0000,0.0000)
25	1	0	416	0.9976	0.0024	(0.0000,0.0071)
26	0	0	416	0.9976	0.0024	(0.0000,0.0071)
27	0	0	416	0.9976	0.0024	(0.0000,0.0071)
28	0	0	416	0.9976	0.0024	(0.0000,0.0071)
29	0	0	416	0.9976	0.0024	(0.0000,0.0071)
30	0	0	416	0.9976	0.0024	(0.0000,0.0071)
31	0	0	416	0.9976	0.0024	(0.0000,0.0071)
32	0	0	416	0.9976	0.0024	(0.0000,0.0071)
33	0	0	416	0.9976	0.0024	(0.0000,0.0071)
34	0	0	416	0.9976	0.0024	(0.0000,0.0071)
35	0	0	416	0.9976	0.0024	(0.0000,0.0071)
36	0	0	416	0.9976	0.0024	(0.0000,0.0071)

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
 (1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
 (4) indeterminate for extracapsular silicone

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
RECONSTRUCTION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	211	1.0000	0.0000	(0.0000,0.0000)
1	0	0	211	1.0000	0.0000	(0.0000,0.0000)
2	0	0	211	1.0000	0.0000	(0.0000,0.0000)
3	0	0	211	1.0000	0.0000	(0.0000,0.0000)
4	0	0	211	1.0000	0.0000	(0.0000,0.0000)
5	0	0	211	1.0000	0.0000	(0.0000,0.0000)
6	0	0	211	1.0000	0.0000	(0.0000,0.0000)
7	0	0	211	1.0000	0.0000	(0.0000,0.0000)
8	0	0	211	1.0000	0.0000	(0.0000,0.0000)
9	0	0	211	1.0000	0.0000	(0.0000,0.0000)
10	0	0	211	1.0000	0.0000	(0.0000,0.0000)
11	0	0	211	1.0000	0.0000	(0.0000,0.0000)
12	0	0	211	1.0000	0.0000	(0.0000,0.0000)
13	0	0	211	1.0000	0.0000	(0.0000,0.0000)
14	0	0	211	1.0000	0.0000	(0.0000,0.0000)
15	0	0	211	1.0000	0.0000	(0.0000,0.0000)
16	0	0	211	1.0000	0.0000	(0.0000,0.0000)
17	0	0	211	1.0000	0.0000	(0.0000,0.0000)
18	0	0	211	1.0000	0.0000	(0.0000,0.0000)
19	0	0	211	1.0000	0.0000	(0.0000,0.0000)
20	0	0	211	1.0000	0.0000	(0.0000,0.0000)
21	0	0	211	1.0000	0.0000	(0.0000,0.0000)
22	0	0	211	1.0000	0.0000	(0.0000,0.0000)
23	1	0	210	0.9953	0.0047	(0.0000,0.0140)

Program Name: Q \MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
RECONSTRUCTION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	210	0.9953	0.0047	(0.0000,0.0140)
25	0	0	210	0.9953	0.0047	(0.0000,0.0140)
26	0	0	210	0.9953	0.0047	(0.0000,0.0140)
27	0	0	210	0.9953	0.0047	(0.0000,0.0140)
28	0	0	210	0.9953	0.0047	(0.0000,0.0140)
29	0	0	210	0.9953	0.0047	(0.0000,0.0140)
30	0	0	210	0.9953	0.0047	(0.0000,0.0140)
31	0	0	210	0.9953	0.0047	(0.0000,0.0140)
32	0	0	210	0.9953	0.0047	(0.0000,0.0140)
33	0	0	210	0.9953	0.0047	(0.0000,0.0140)
34	0	0	210	0.9953	0.0047	(0.0000,0.0140)
35	0	0	210	0.9953	0.0047	(0.0000,0.0140)
36	0	0	210	0.9953	0.0047	(0.0000,0.0140)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	157	1.0000	0.0000	(0.0000,0.0000)
1	0	0	157	1.0000	0.0000	(0.0000,0.0000)
2	0	0	157	1.0000	0.0000	(0.0000,0.0000)
3	0	0	157	1.0000	0.0000	(0.0000,0.0000)
4	0	0	157	1.0000	0.0000	(0.0000,0.0000)
5	0	0	157	1.0000	0.0000	(0.0000,0.0000)
6	0	0	157	1.0000	0.0000	(0.0000,0.0000)
7	0	0	157	1.0000	0.0000	(0.0000,0.0000)
8	0	0	157	1.0000	0.0000	(0.0000,0.0000)
9	0	0	157	1.0000	0.0000	(0.0000,0.0000)
10	0	0	157	1.0000	0.0000	(0.0000,0.0000)
11	0	0	157	1.0000	0.0000	(0.0000,0.0000)
12	0	0	157	1.0000	0.0000	(0.0000,0.0000)
13	0	0	157	1.0000	0.0000	(0.0000,0.0000)
14	0	0	157	1.0000	0.0000	(0.0000,0.0000)
15	0	0	157	1.0000	0.0000	(0.0000,0.0000)
16	0	0	157	1.0000	0.0000	(0.0000,0.0000)
17	0	0	157	1.0000	0.0000	(0.0000,0.0000)
18	0	0	157	1.0000	0.0000	(0.0000,0.0000)
19	2	0	155	0.9873	0.0127	(0.0000,0.0303)
20	0	0	155	0.9873	0.0127	(0.0000,0.0303)
21	0	0	155	0.9873	0.0127	(0.0000,0.0303)
22	0	0	155	0.9873	0.0127	(0.0000,0.0303)
23	2	0	153	0.9745	0.0255	(0.0008,0.0501)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note. Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	151	0.9618	0.0382	(0.0082,0.0682)
25	0	0	151	0.9618	0.0382	(0.0082,0.0682)
26	0	0	151	0.9618	0.0382	(0.0082,0.0682)
27	0	0	151	0.9618	0.0382	(0.0082,0.0682)
28	2	0	149	0.9490	0.0510	(0.0166,0.0854)
29	0	0	149	0.9490	0.0510	(0.0166,0.0854)
30	0	0	149	0.9490	0.0510	(0.0166,0.0854)
31	0	0	149	0.9490	0.0510	(0.0166,0.0854)
32	0	0	149	0.9490	0.0510	(0.0166,0.0854)
33	0	0	149	0.9490	0.0510	(0.0166,0.0854)
34	0	0	149	0.9490	0.0510	(0.0166,0.0854)
35	0	0	149	0.9490	0.0510	(0.0166,0.0854)
36	0	0	149	0.9490	0.0510	(0.0166,0.0854)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	785	1.0000	0.0000	(0.0000,0.0000)
1	0	0	785	1.0000	0.0000	(0.0000,0.0000)
2	0	0	785	1.0000	0.0000	(0.0000,0.0000)
3	0	0	785	1.0000	0.0000	(0.0000,0.0000)
4	0	0	785	1.0000	0.0000	(0.0000,0.0000)
5	0	0	785	1.0000	0.0000	(0.0000,0.0000)
6	0	0	785	1.0000	0.0000	(0.0000,0.0000)
7	0	0	785	1.0000	0.0000	(0.0000,0.0000)
8	0	0	785	1.0000	0.0000	(0.0000,0.0000)
9	0	0	785	1.0000	0.0000	(0.0000,0.0000)
10	0	0	785	1.0000	0.0000	(0.0000,0.0000)
11	0	0	785	1.0000	0.0000	(0.0000,0.0000)
12	0	0	785	1.0000	0.0000	(0.0000,0.0000)
13	0	0	785	1.0000	0.0000	(0.0000,0.0000)
14	0	0	785	1.0000	0.0000	(0.0000,0.0000)
15	0	0	785	1.0000	0.0000	(0.0000,0.0000)
16	0	0	785	1.0000	0.0000	(0.0000,0.0000)
17	0	0	785	1.0000	0.0000	(0.0000,0.0000)
18	0	0	785	1.0000	0.0000	(0.0000,0.0000)
19	2	0	783	0.9975	0.0025	(0.0000,0.0061)
20	0	0	783	0.9975	0.0025	(0.0000,0.0061)
21	0	0	783	0.9975	0.0025	(0.0000,0.0061)
22	0	0	783	0.9975	0.0025	(0.0000,0.0061)
23	3	0	780	0.9936	0.0064	(0.0008,0.0119)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.2

TIME TO FIRST REPORT OF SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4c  
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	778	0.9911	0.0089	(0.0023,0.0155)
25	1	0	777	0.9898	0.0102	(0.0032,0.0172)
26	0	0	777	0.9898	0.0102	(0.0032,0.0172)
27	0	0	777	0.9898	0.0102	(0.0032,0.0172)
28	2	0	775	0.9873	0.0127	(0.0049,0.0206)
29	0	0	775	0.9873	0.0127	(0.0049,0.0206)
30	0	0	775	0.9873	0.0127	(0.0049,0.0206)
31	0	0	775	0.9873	0.0127	(0.0049,0.0206)
32	0	0	775	0.9873	0.0127	(0.0049,0.0206)
33	0	0	775	0.9873	0.0127	(0.0049,0.0206)
34	0	0	775	0.9873	0.0127	(0.0049,0.0206)
35	0	0	775	0.9873	0.0127	(0.0049,0.0206)
36	0	0	775	0.9873	0.0127	(0.0049,0.0206)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_2.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	202	1.0000	0.0000	(0.0000,0.0000)
1	0	0	202	1.0000	0.0000	(0.0000,0.0000)
2	0	0	202	1.0000	0.0000	(0.0000,0.0000)
3	0	0	202	1.0000	0.0000	(0.0000,0.0000)
4	0	0	202	1.0000	0.0000	(0.0000,0.0000)
5	0	0	202	1.0000	0.0000	(0.0000,0.0000)
6	0	0	202	1.0000	0.0000	(0.0000,0.0000)
7	0	0	202	1.0000	0.0000	(0.0000,0.0000)
8	0	0	202	1.0000	0.0000	(0.0000,0.0000)
9	0	0	202	1.0000	0.0000	(0.0000,0.0000)
10	0	0	202	1.0000	0.0000	(0.0000,0.0000)
11	0	0	202	1.0000	0.0000	(0.0000,0.0000)
12	0	0	202	1.0000	0.0000	(0.0000,0.0000)
13	0	0	202	1.0000	0.0000	(0.0000,0.0000)
14	0	0	202	1.0000	0.0000	(0.0000,0.0000)
15	0	0	202	1.0000	0.0000	(0.0000,0.0000)
16	0	0	202	1.0000	0.0000	(0.0000,0.0000)
17	0	0	202	1.0000	0.0000	(0.0000,0.0000)
18	0	0	202	1.0000	0.0000	(0.0000,0.0000)
19	0	0	202	1.0000	0.0000	(0.0000,0.0000)
20	0	0	202	1.0000	0.0000	(0.0000,0.0000)
21	0	0	202	1.0000	0.0000	(0.0000,0.0000)
22	0	0	202	1.0000	0.0000	(0.0000,0.0000)
23	0	0	202	1.0000	0.0000	(0.0000,0.0000)
24	0	0	202	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following.  
 (1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
 (4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	0	201	0.9950	0.0050	(0.0000,0.0146)
26	0	0	201	0.9950	0.0050	(0.0000,0.0146)
27	0	0	201	0.9950	0.0050	(0.0000,0.0146)
28	0	0	201	0.9950	0.0050	(0.0000,0.0146)
29	0	0	201	0.9950	0.0050	(0.0000,0.0146)
30	0	0	201	0.9950	0.0050	(0.0000,0.0146)
31	0	0	201	0.9950	0.0050	(0.0000,0.0146)
32	0	0	201	0.9950	0.0050	(0.0000,0.0146)
33	0	0	201	0.9950	0.0050	(0.0000,0.0146)
34	0	0	201	0.9950	0.0050	(0.0000,0.0146)
35	0	0	201	0.9950	0.0050	(0.0000,0.0146)
36	0	0	201	0.9950	0.0050	(0.0000,0.0146)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following.  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	134	1.0000	0.0000	(0.0000,0.0000)
1	0	0	134	1.0000	0.0000	(0.0000,0.0000)
2	0	0	134	1.0000	0.0000	(0.0000,0.0000)
3	0	0	134	1.0000	0.0000	(0.0000,0.0000)
4	0	0	134	1.0000	0.0000	(0.0000,0.0000)
5	0	0	134	1.0000	0.0000	(0.0000,0.0000)
6	0	0	134	1.0000	0.0000	(0.0000,0.0000)
7	0	0	134	1.0000	0.0000	(0.0000,0.0000)
8	0	0	134	1.0000	0.0000	(0.0000,0.0000)
9	0	0	134	1.0000	0.0000	(0.0000,0.0000)
10	0	0	134	1.0000	0.0000	(0.0000,0.0000)
11	0	0	134	1.0000	0.0000	(0.0000,0.0000)
12	0	0	134	1.0000	0.0000	(0.0000,0.0000)
13	0	0	134	1.0000	0.0000	(0.0000,0.0000)
14	0	0	134	1.0000	0.0000	(0.0000,0.0000)
15	0	0	134	1.0000	0.0000	(0.0000,0.0000)
16	0	0	134	1.0000	0.0000	(0.0000,0.0000)
17	0	0	134	1.0000	0.0000	(0.0000,0.0000)
18	0	0	134	1.0000	0.0000	(0.0000,0.0000)
19	0	0	134	1.0000	0.0000	(0.0000,0.0000)
20	0	0	134	1.0000	0.0000	(0.0000,0.0000)
21	0	0	134	1.0000	0.0000	(0.0000,0.0000)
22	0	0	134	1.0000	0.0000	(0.0000,0.0000)
23	1	0	133	0.9925	0.0075	(0.0000,0.0220)
24	0	0	133	0.9925	0.0075	(0.0000,0.0220)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following.  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	133	0.9925	0.0075	(0.0000,0.0220)
26	0	0	133	0.9925	0.0075	(0.0000,0.0220)
27	0	0	133	0.9925	0.0075	(0.0000,0.0220)
28	0	0	133	0.9925	0.0075	(0.0000,0.0220)
29	0	0	133	0.9925	0.0075	(0.0000,0.0220)
30	0	0	133	0.9925	0.0075	(0.0000,0.0220)
31	0	0	133	0.9925	0.0075	(0.0000,0.0220)
32	0	0	133	0.9925	0.0075	(0.0000,0.0220)
33	0	0	133	0.9925	0.0075	(0.0000,0.0220)
34	0	0	133	0.9925	0.0075	(0.0000,0.0220)
35	0	0	133	0.9925	0.0075	(0.0000,0.0220)
36	0	0	133	0.9925	0.0075	(0.0000,0.0220)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3.SAS

Creation Date, Time: 24AUG04 15.53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
REVISION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	84	1.0000	0.0000	(0.0000,0.0000)
1	0	0	84	1.0000	0.0000	(0.0000,0.0000)
2	0	0	84	1.0000	0.0000	(0.0000,0.0000)
3	0	0	84	1.0000	0.0000	(0.0000,0.0000)
4	0	0	84	1.0000	0.0000	(0.0000,0.0000)
5	0	0	84	1.0000	0.0000	(0.0000,0.0000)
6	0	0	84	1.0000	0.0000	(0.0000,0.0000)
7	0	0	84	1.0000	0.0000	(0.0000,0.0000)
8	0	0	84	1.0000	0.0000	(0.0000,0.0000)
9	0	0	84	1.0000	0.0000	(0.0000,0.0000)
10	0	0	84	1.0000	0.0000	(0.0000,0.0000)
11	0	0	84	1.0000	0.0000	(0.0000,0.0000)
12	0	0	84	1.0000	0.0000	(0.0000,0.0000)
13	0	0	84	1.0000	0.0000	(0.0000,0.0000)
14	0	0	84	1.0000	0.0000	(0.0000,0.0000)
15	0	0	84	1.0000	0.0000	(0.0000,0.0000)
16	0	0	84	1.0000	0.0000	(0.0000,0.0000)
17	0	0	84	1.0000	0.0000	(0.0000,0.0000)
18	0	0	84	1.0000	0.0000	(0.0000,0.0000)
19	0	0	84	1.0000	0.0000	(0.0000,0.0000)
20	0	0	84	1.0000	0.0000	(0.0000,0.0000)
21	0	0	84	1.0000	0.0000	(0.0000,0.0000)
22	0	0	84	1.0000	0.0000	(0.0000,0.0000)
23	1	0	83	0.9881	0.0119	(0.0000,0.0351)
24	2	0	81	0.9643	0.0357	(0.0000,0.0754)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3 SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
 (1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
 (4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
REVISION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	81	0.9643	0.0357	(0.0000,0.0754)
26	0	0	81	0.9643	0.0357	(0.0000,0.0754)
27	0	0	81	0.9643	0.0357	(0.0000,0.0754)
28	1	0	80	0.9524	0.0476	(0.0021,0.0932)
29	0	0	80	0.9524	0.0476	(0.0021,0.0932)
30	0	0	80	0.9524	0.0476	(0.0021,0.0932)
31	0	0	80	0.9524	0.0476	(0.0021,0.0932)
32	0	0	80	0.9524	0.0476	(0.0021,0.0932)
33	0	0	80	0.9524	0.0476	(0.0021,0.0932)
34	0	0	80	0.9524	0.0476	(0.0021,0.0932)
35	0	0	80	0.9524	0.0476	(0.0021,0.0932)
36	0	0	80	0.9524	0.0476	(0.0021,0.0932)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13 2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
OVERALL PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	420	1.0000	0.0000	(0.0000,0.0000)
1	0	0	420	1.0000	0.0000	(0.0000,0.0000)
2	0	0	420	1.0000	0.0000	(0.0000,0.0000)
3	0	0	420	1.0000	0.0000	(0.0000,0.0000)
4	0	0	420	1.0000	0.0000	(0.0000,0.0000)
5	0	0	420	1.0000	0.0000	(0.0000,0.0000)
6	0	0	420	1.0000	0.0000	(0.0000,0.0000)
7	0	0	420	1.0000	0.0000	(0.0000,0.0000)
8	0	0	420	1.0000	0.0000	(0.0000,0.0000)
9	0	0	420	1.0000	0.0000	(0.0000,0.0000)
10	0	0	420	1.0000	0.0000	(0.0000,0.0000)
11	0	0	420	1.0000	0.0000	(0.0000,0.0000)
12	0	0	420	1.0000	0.0000	(0.0000,0.0000)
13	0	0	420	1.0000	0.0000	(0.0000,0.0000)
14	0	0	420	1.0000	0.0000	(0.0000,0.0000)
15	0	0	420	1.0000	0.0000	(0.0000,0.0000)
16	0	0	420	1.0000	0.0000	(0.0000,0.0000)
17	0	0	420	1.0000	0.0000	(0.0000,0.0000)
18	0	0	420	1.0000	0.0000	(0.0000,0.0000)
19	0	0	420	1.0000	0.0000	(0.0000,0.0000)
20	0	0	420	1.0000	0.0000	(0.0000,0.0000)
21	0	0	420	1.0000	0.0000	(0.0000,0.0000)
22	0	0	420	1.0000	0.0000	(0.0000,0.0000)
23	2	0	418	0.9952	0.0048	(0.0000,0.0113)
24	2	0	416	0.9905	0.0095	(0.0002,0.0188)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following.  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.3

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (PATIENT LEVEL) - FDA Item 4d  
OVERALL PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	0	415	0.9881	0.0119	(0.0015,0.0223)
26	0	0	415	0.9881	0.0119	(0.0015,0.0223)
27	0	0	415	0.9881	0.0119	(0.0015,0.0223)
28	1	0	414	0.9857	0.0143	(0.0029,0.0256)
29	0	0	414	0.9857	0.0143	(0.0029,0.0256)
30	0	0	414	0.9857	0.0143	(0.0029,0.0256)
31	0	0	414	0.9857	0.0143	(0.0029,0.0256)
32	0	0	414	0.9857	0.0143	(0.0029,0.0256)
33	0	0	414	0.9857	0.0143	(0.0029,0.0256)
34	0	0	414	0.9857	0.0143	(0.0029,0.0256)
35	0	0	414	0.9857	0.0143	(0.0029,0.0256)
36	0	0	414	0.9857	0.0143	(0.0029,0.0256)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_3.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d  
AUGMENTATION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	417	1.0000	0.0000	(0.0000,0.0000)
1	0	0	417	1.0000	0.0000	(0.0000,0.0000)
2	0	0	417	1.0000	0.0000	(0.0000,0.0000)
3	0	0	417	1.0000	0.0000	(0.0000,0.0000)
4	0	0	417	1.0000	0.0000	(0.0000,0.0000)
5	0	0	417	1.0000	0.0000	(0.0000,0.0000)
6	0	0	417	1.0000	0.0000	(0.0000,0.0000)
7	0	0	417	1.0000	0.0000	(0.0000,0.0000)
8	0	0	417	1.0000	0.0000	(0.0000,0.0000)
9	0	0	417	1.0000	0.0000	(0.0000,0.0000)
10	0	0	417	1.0000	0.0000	(0.0000,0.0000)
11	0	0	417	1.0000	0.0000	(0.0000,0.0000)
12	0	0	417	1.0000	0.0000	(0.0000,0.0000)
13	0	0	417	1.0000	0.0000	(0.0000,0.0000)
14	0	0	417	1.0000	0.0000	(0.0000,0.0000)
15	0	0	417	1.0000	0.0000	(0.0000,0.0000)
16	0	0	417	1.0000	0.0000	(0.0000,0.0000)
17	0	0	417	1.0000	0.0000	(0.0000,0.0000)
18	0	0	417	1.0000	0.0000	(0.0000,0.0000)
19	0	0	417	1.0000	0.0000	(0.0000,0.0000)
20	0	0	417	1.0000	0.0000	(0.0000,0.0000)
21	0	0	417	1.0000	0.0000	(0.0000,0.0000)
22	0	0	417	1.0000	0.0000	(0.0000,0.0000)
23	0	0	417	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_4.SAS

Creation Date, Time: 24AUG04 15.53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d  
AUGMENTATION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	417	1.0000	0.0000	(0.0000,0.0000)
25	1	0	416	0.9976	0.0024	(0.0000,0.0071)
26	0	0	416	0.9976	0.0024	(0.0000,0.0071)
27	0	0	416	0.9976	0.0024	(0.0000,0.0071)
28	0	0	416	0.9976	0.0024	(0.0000,0.0071)
29	0	0	416	0.9976	0.0024	(0.0000,0.0071)
30	0	0	416	0.9976	0.0024	(0.0000,0.0071)
31	0	0	416	0.9976	0.0024	(0.0000,0.0071)
32	0	0	416	0.9976	0.0024	(0.0000,0.0071)
33	0	0	416	0.9976	0.0024	(0.0000,0.0071)
34	0	0	416	0.9976	0.0024	(0.0000,0.0071)
35	0	0	416	0.9976	0.0024	(0.0000,0.0071)
36	0	0	416	0.9976	0.0024	(0.0000,0.0071)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_4.SAS

Creation Date, Time. 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:  
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d  
RECONSTRUCTION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	211	1.0000	0.0000	(0.0000,0.0000)
1	0	0	211	1.0000	0.0000	(0.0000,0.0000)
2	0	0	211	1.0000	0.0000	(0.0000,0.0000)
3	0	0	211	1.0000	0.0000	(0.0000,0.0000)
4	0	0	211	1.0000	0.0000	(0.0000,0.0000)
5	0	0	211	1.0000	0.0000	(0.0000,0.0000)
6	0	0	211	1.0000	0.0000	(0.0000,0.0000)
7	0	0	211	1.0000	0.0000	(0.0000,0.0000)
8	0	0	211	1.0000	0.0000	(0.0000,0.0000)
9	0	0	211	1.0000	0.0000	(0.0000,0.0000)
10	0	0	211	1.0000	0.0000	(0.0000,0.0000)
11	0	0	211	1.0000	0.0000	(0.0000,0.0000)
12	0	0	211	1.0000	0.0000	(0.0000,0.0000)
13	0	0	211	1.0000	0.0000	(0.0000,0.0000)
14	0	0	211	1.0000	0.0000	(0.0000,0.0000)
15	0	0	211	1.0000	0.0000	(0.0000,0.0000)
16	0	0	211	1.0000	0.0000	(0.0000,0.0000)
17	0	0	211	1.0000	0.0000	(0.0000,0.0000)
18	0	0	211	1.0000	0.0000	(0.0000,0.0000)
19	0	0	211	1.0000	0.0000	(0.0000,0.0000)
20	0	0	211	1.0000	0.0000	(0.0000,0.0000)
21	0	0	211	1.0000	0.0000	(0.0000,0.0000)
22	0	0	211	1.0000	0.0000	(0.0000,0.0000)
23	1	0	210	0.9953	0.0047	(0.0000,0.0140)

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Creation Date, Time: 24AUG04 15:53

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d  
RECONSTRUCTION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	210	0.9953	0.0047	(0.0000,0.0140)
25	0	0	210	0.9953	0.0047	(0.0000,0.0140)
26	0	0	210	0.9953	0.0047	(0.0000,0.0140)
27	0	0	210	0.9953	0.0047	(0.0000,0.0140)
28	0	0	210	0.9953	0.0047	(0.0000,0.0140)
29	0	0	210	0.9953	0.0047	(0.0000,0.0140)
30	0	0	210	0.9953	0.0047	(0.0000,0.0140)
31	0	0	210	0.9953	0.0047	(0.0000,0.0140)
32	0	0	210	0.9953	0.0047	(0.0000,0.0140)
33	0	0	210	0.9953	0.0047	(0.0000,0.0140)
34	0	0	210	0.9953	0.0047	(0.0000,0.0140)
35	0	0	210	0.9953	0.0047	(0.0000,0.0140)
36	0	0	210	0.9953	0.0047	(0.0000,0.0140)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13\_2\_4.SAS

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d  
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	157	1.0000	0.0000	(0.0000,0.0000)
1	0	0	157	1.0000	0.0000	(0.0000,0.0000)
2	0	0	157	1.0000	0.0000	(0.0000,0.0000)
3	0	0	157	1.0000	0.0000	(0.0000,0.0000)
4	0	0	157	1.0000	0.0000	(0.0000,0.0000)
5	0	0	157	1.0000	0.0000	(0.0000,0.0000)
6	0	0	157	1.0000	0.0000	(0.0000,0.0000)
7	0	0	157	1.0000	0.0000	(0.0000,0.0000)
8	0	0	157	1.0000	0.0000	(0.0000,0.0000)
9	0	0	157	1.0000	0.0000	(0.0000,0.0000)
10	0	0	157	1.0000	0.0000	(0.0000,0.0000)
11	0	0	157	1.0000	0.0000	(0.0000,0.0000)
12	0	0	157	1.0000	0.0000	(0.0000,0.0000)
13	0	0	157	1.0000	0.0000	(0.0000,0.0000)
14	0	0	157	1.0000	0.0000	(0.0000,0.0000)
15	0	0	157	1.0000	0.0000	(0.0000,0.0000)
16	0	0	157	1.0000	0.0000	(0.0000,0.0000)
17	0	0	157	1.0000	0.0000	(0.0000,0.0000)
18	0	0	157	1.0000	0.0000	(0.0000,0.0000)
19	0	0	157	1.0000	0.0000	(0.0000,0.0000)
20	0	0	157	1.0000	0.0000	(0.0000,0.0000)
21	0	0	157	1.0000	0.0000	(0.0000,0.0000)
22	0	0	157	1.0000	0.0000	(0.0000,0.0000)
23	2	0	155	0.9873	0.0127	(0.0000,0.0303)

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