

Table 19 2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
OVERALL RECONSTRUCTION - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	36.04	37.00	3.49	27.00	40.00	57
1 Year	36.68	37.50	3.18	30.00	40.00	50
2 Year	36.60	37.00	2.98	30.00	40.00	43

  

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.50	0.00	2.89	-8.00	8.00	50
2 Year	0.88	1.00	3.50	-6.00	11.00	43

  

Overall Mean Change (b) (Standard Deviation)	0.51 ( 2.96)
p-value (c)	0.2800

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
DELAYED POST-MASTECTOMY - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	35.99	36.00	3.59	21.00	40.00	81
1 Year	36.09	37.00	4.22	15.00	40.00	67
2 Year	35.45	37.00	4.53	22.00	40.00	64
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.18	0.00	3.23	-6.00	9.00	66
2 Year	-0.65	0.00	3.36	-10.00	5.00	63
Overall Mean Change (b) (Standard Deviation)		-0.09 ( 2.91)				
p-value (c)		0.8025				

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE. TOTAL SCORE BY DEVICE PLACEMENT  
DELAYED POST-MASTECTOMY - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	35.69	36.50	3.75	30.00	40.00	16
1 Year	34.64	34.00	3.01	31.00	40.00	11
2 Year	34.30	33.00	2.41	32.00	38.00	10
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-1.45	-1.00	3.01	-8.00	2.00	11
2 Year	-0.60	-1.00	3.66	-5.00	8.00	10
Overall Mean Change (b) (Standard Deviation)		-1.12 ( 3.23)				
p-value (c)		0.2402				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
IMMEDIATE POST-MASTECTOMY - SUBMUSCULAR

Total Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	35.46	37.00	3.86	24.00	40.00	61
1 Year	35.04	35.00	3.67	27.00	40.00	56
2 Year	35.90	37.00	3.53	25.00	40.00	50
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.32	-0.50	3.95	-7.00	14.00	56
2 Year	0.30	0.00	3.52	-8.00	10.00	50
Overall Mean Change (b) (Standard Deviation)		0.22 ( 3.69)				
p-value (c)		----				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
IMMEDIATE POST-MASTECTOMY - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	36.71	37.00	1.25	35.00	39.00	7
1 Year	37.67	38.50	3.01	32.00	40.00	6
2 Year	38.00	37.00	1.41	37.00	40.00	5
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.83	2.00	3.13	-5.00	3.00	6
2 Year	1.80	2.00	1.48	0.00	4.00	5
Overall Mean Change (b) (Standard Deviation)		0.93 ( 2.91)				
p-value (c)		----				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score, the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
REVISION PATIENTS - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	36.24	37.00	3.45	29.00	40.00	108
1 Year	36.21	37.00	3.16	29.00	40.00	98
2 Year	35.87	36.00	3.74	27.00	40.00	97

  

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.05	0.00	3.07	-7.00	10.00	94
2 Year	-0.26	0.00	3.43	-11.00	10.00	94

  

Overall Mean Change (b) (Standard Deviation)	-0.10 ( 3.04)
p-value (c)	0.5614

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
REVISION PATIENTS - SUBGLANDULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	36.63	37.00	3.12	30.00	40.00	62
1 Year	36.77	38.00	3.14	30.00	40.00	57
2 Year	36.53	37.00	3.37	29.00	40.00	51

  

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.26	0.00	2.95	-7.00	10.00	57
2 Year	0.06	0.00	2.99	-7.00	7.00	51

  

Overall Mean Change (b) (Standard Deviation)	0.09 ( 2.77)
p-value (c)	0.8221

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
REVISION PATIENTS - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	36.33	37.00	4.02	28.00	40.00	27
1 Year	37.00	38.00	3.01	29.00	40.00	26
2 Year	36.00	38.00	4.29	24.00	40.00	22
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.71	0.00	3.22	-5.00	8.00	24
2 Year	-0.45	0.00	5.40	-10.00	9.00	22
Overall Mean Change (b) (Standard Deviation)		0.07 ( 4.20)				
p-value (c)		0.9007				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
OVERALL - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	35.90	37.00	3.85	20.00	40.00	490
1 Year	36.18	37.00	3.60	15.00	40.00	439
2 Year	36.11	37.00	3.84	22.00	40.00	429
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.34	0.00	3.59	-11.00	14.00	432
2 Year	0.23	0.00	3.90	-11.00	13.00	422
Overall Mean Change (b) (Standard Deviation)		0.33 ( 3.49)				
p-value (c)		0.2077				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
OVERALL - SUBGLANDULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	36.16	37.00	3.69	22.00	40.00	267
1 Year	36.47	37.00	3.64	23.00	40.00	245
2 Year	36.43	37.00	3.57	25.00	40.00	235
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.32	0.00	2.94	-8.00	10.00	243
2 Year	0.25	0.00	3.49	-14.00	9.00	234
Overall Mean Change (b) (Standard Deviation)		0.26 ( 2.92)				
p-value (c)		0.1139				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.2

ROSENBERG SELF-ESTEEM SCALE: TOTAL SCORE BY DEVICE PLACEMENT  
OVERALL - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	35.74	37.00	4.13	21.00	40.00	219
1 Year	36.51	37.50	3.59	21.00	40.00	202
2 Year	36.27	37.00	3.68	21.00	40.00	188
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.69	0.00	3.44	-8.00	10.00	199
2 Year	0.68	0.00	3.46	-10.00	11.00	187
Overall Mean Change (b) (Standard Deviation)		0.59 ( 3.26)				
p-value (c)		0.0212				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_2.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is scored as items 1 through 10. The results include only patients who had responses for all these questions used to derive the Total Score; the precise wording of each question can be found in Listing 14. Scores for items 1,2,4,6, and 7 have been reversed by subtracting the actual score from 5. Higher scores indicate higher self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.3

ROSENBERG SELF-ESTEEM SCALE: POSITIVE ATTITUDE (QUESTION 6) SCORE  
AUGMENTATION PATIENTS

Type of Visit	Positive Attitude Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	3.48	4.00	0.59	1.00	4.00	549
1 Year	3.57	4.00	0.54	1.00	4.00	503
2 Year	3.57	4.00	0.56	1.00	4.00	360

  

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	0.09	0.00	0.57	-2.00	2.00	502
2 Year	0.08	0.00	0.59	-3.00	2.00	359

  

Overall Mean Change (a) (Standard Deviation)	0.08 ( 0.54)
p-value (b)	0.0005

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_3.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.3

ROSENBERG SELF-ESTEEM SCALE: POSITIVE ATTITUDE (QUESTION 6) SCORE  
OVERALL RECONSTRUCTION

Positive Attitude Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	3.54	4.00	0.53	2.00	4.00	250
1 Year	3.51	4.00	0.55	1.00	4.00	218
2 Year	3.60	4.00	0.56	2.00	4.00	89
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.02	0.00	0.53	-1.00	2.00	217
2 Year	0.02	0.00	0.57	-1.00	1.00	88
Overall Mean Change (a) (Standard Deviation)		-0.00 ( 0.52)				
p-value (b)		0.6828				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_3.SAS

Creation Date, Time: 21JUL04 10:42

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.3

ROSENBERG SELF-ESTEEM SCALE: POSITIVE ATTITUDE (QUESTION 6) SCORE  
DELAYED POST-MASTECTOMY

Positive Attitude Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	3.54	4.00	0.52	2.00	4.00	106
1 Year	3.53	4.00	0.57	1.00	4.00	88
2 Year	3.54	4.00	0.58	2.00	4.00	28
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	0.03	0.00	0.47	-1.00	1.00	87
2 Year	0.00	0.00	0.55	-1.00	1.00	27
Overall Mean Change (a) (Standard Deviation)	0.05 ( 0.47)					
p-value (b)	0.3329					

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_3.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19 3

ROSENBERG SELF-ESTEEM SCALE: POSITIVE ATTITUDE (QUESTION 6) SCORE  
IMMEDIATE POST-MASTECTOMY

Positive Attitude Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	3.55	4.00	0.53	2.00	4.00	71
1 Year	3.48	3.00	0.50	3.00	4.00	65
2 Year	3.58	4.00	0.56	2.00	4.00	31
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.08	0.00	0.59	-1.00	2.00	65
2 Year	0.00	0.00	0.58	-1.00	1.00	31
Overall Mean Change (a) (Standard Deviation)		-0.05 ( 0.58)				
p-value (b)		----				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_3.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.3

ROSENBERG SELF-ESTEEM SCALE: POSITIVE ATTITUDE (QUESTION 6) SCORE  
REVISION PATIENTS

Positive Attitude Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	3.56	4.00	0.50	3.00	4.00	200
1 Year	3.54	4.00	0.51	2.00	4.00	181
2 Year	3.42	3.00	0.53	2.00	4.00	106
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	0.00	0.00	0.51	-1.00	1.00	177
2 Year	-0.17	0.00	0.54	-1.00	1.00	106
Overall Mean Change (a) (Standard Deviation)	-0.04 ( 0.50)					
p-value (b)	0.4382					

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_3.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 19.3

ROSENBERG SELF-ESTEEM SCALE. POSITIVE ATTITUDE (QUESTION 6) SCORE  
OVERALL

Type of Visit	Positive Attitude Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	3.51	4.00	0.56	1.00	4.00	999
1 Year	3.55	4.00	0.54	1.00	4.00	902
2 Year	3.55	4.00	0.56	1.00	4.00	555
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.04	0.00	0.55	-2.00	2.00	896
2 Year	0.02	0.00	0.58	-3.00	2.00	553
Overall Mean Change (a) (Standard Deviation)		0.04 ( 0.53)				
p-value (b)		0.0086				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T19\_3.SAS

Creation Date, Time: 21JUL04 10:42

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 20.1

FUNCTIONAL LIVING INDEX: CANCER (FLIC)  
DELAYED POST-MASTECTOMY PATIENTS

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	121.49	123.00	15.26	58.00	144.00	94
1 Year	123.12	127.00	16.81	59.00	143.00	76
2 Year	125.06	131.00	18.57	60.00	144.00	67
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	2.73	3.00	15.54	-33.00	65.00	73
2 Year	3.33	4.00	18.21	-56.00	39.00	63
Overall Mean Change (b) (Standard Deviation)		2.92 ( 15.75)				
p-value (c)		0.0353				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_1.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions; the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20.1

FUNCTIONAL LIVING INDEX. CANCER (FLIC)  
SUBTOTAL MASTECTOMY PATIENTS

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	129.14	131.00	9.08	116.00	141.00	7
1 Year	131.00	130.50	8.60	121.00	142.00	4
2 Year	133.00	133.50	8.76	124.00	141.00	4
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	1.00	0.50	3.74	-3.00	6.00	4
2 Year	1.25	1.50	6.65	-7.00	9.00	4
Overall Mean Change (b) (Standard Deviation)		2.40 ( 5.38)				
p-value (c)		0.3125				

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_1.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions; the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change

Table 20.1

FUNCTIONAL LIVING INDEX. CANCER (FLIC)  
REVISION PATIENTS HAVING AT LEAST ONE RECONSTRUCTION REVISION OR REVISION OF UNKNOWN INDICATION AND HISTORY OF CANCER

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	123.14	128.00	14.45	83.00	142.00	36
1 Year	130.06	132.00	9.01	112.00	142.00	32
2 Year	127.75	130.00	11.19	101.00	142.00	32
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	4.67	3.50	12.56	-22.00	44.00	30
2 Year	5.21	2.00	15.26	-21.00	55.00	28
Overall Mean Change (b) (Standard Deviation)		4.97 ( 13.28)				
p-value (c)		0.0381				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_1.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions; the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20.2

FUNCTIONAL LIVING INDEX: CANCER (FLIC) BY DEVICE PLACEMENT  
DELAYED POST-MASTECTOMY PATIENTS - SUBMUSCULAR

Total Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	122.51	123.50	14.37	90.00	144.00	70
1 Year	125.42	133.00	16.55	59.00	143.00	57
2 Year	124.51	132.00	19.55	60.00	144.00	55
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	3.38	3.00	13.62	-31.00	40.00	55
2 Year	2.51	2.00	19.01	-56.00	39.00	51
Overall Mean Change (b) (Standard Deviation)		2.67 ( 14.68)				
p-value (c)		0.0595				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_2.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions, the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20.2

FUNCTIONAL LIVING INDEX: CANCER (FLIC) BY DEVICE PLACEMENT  
DELAYED POST-MASTECTOMY PATIENTS - SUBPECTORAL

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	121.75	123.00	12.04	96.00	143.00	16
1 Year	116.64	116.00	13.82	91.00	138.00	11
2 Year	126.11	127.00	15.02	91.00	140.00	9

  

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-6.45	-7.00	15.31	-33.00	17.00	11
2 Year	4.56	7.00	15.91	-33.00	19.00	9

  

Overall Mean Change (b) (Standard Deviation)	-2.04 ( 14.45)
p-value (c)	0.8984

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_2.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions; the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20 2

FUNCTIONAL LIVING INDEX, CANCER (FLIC) BY DEVICE PLACEMENT  
SUBTOTAL MASTECTOMY PATIENTS - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	125.67	124.00	10.60	116.00	137.00	3
1 Year	130.00	130.00		130.00	130.00	1
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	6.00	6.00		6.00	6.00	1
Overall Mean Change (b) (Standard Deviation)		6.00 ( --- )				
p-value (c)		1.0000				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_2.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions; the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20.2

FUNCTIONAL LIVING INDEX: CANCER (FLIC) BY DEVICE PLACEMENT  
SUBTOTAL MASTECTOMY PATIENTS - SUBPECTORAL

Total Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	131.75	132.50	8.30	121.00	141.00	4
1 Year	131.33	131.00	10.50	121.00	142.00	3
2 Year	133.00	133.50	8.76	124.00	141.00	4
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.67	0.00	2.08	-3.00	1.00	3
2 Year	1.25	1.50	6.65	-7.00	9.00	4
Overall Mean Change (b) (Standard Deviation)		1.50 ( 5.76)				
p-value (c)		0.6250				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_2.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions, the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20.2

FUNCTIONAL LIVING INDEX: CANCER (FLIC) BY DEVICE PLACEMENT  
REVISION PATIENTS HAVING AT LEAST ONE RECONSTRUCTION REVISION OR REVISION OF UNKNOWN INDICATION AND HISTORY OF CANCER - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	122.41	127.00	15.18	83.00	142.00	32
1 Year	130.04	132.00	9.57	112.00	142.00	27
2 Year	126.82	127.50	11.58	101.00	142.00	28
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	5.00	4.50	13.22	-22.00	44.00	26
2 Year	5.24	2.00	16.06	-21.00	55.00	25
Overall Mean Change (b) (Standard Deviation)		5.15 ( 14.02)				
p-value (c)		0.0613				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_2.SAS

Creation Date, Time: 21JUL04 10:43

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions; the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20.2

FUNCTIONAL LIVING INDEX: CANCER (FLIC) BY DEVICE PLACEMENT  
REVISION PATIENTS HAVING AT LEAST ONE RECONSTRUCTION REVISION OR REVISION OF UNKNOWN INDICATION AND HISTORY OF CANCER - SUBGLANDULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	129.00	129.00		129.00	129.00	1
1 Year	132.00	132.00		132.00	132.00	1
2 Year	141.00	141.00		141.00	141.00	1
Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	3.00	3.00		3.00	3.00	1
2 Year	12.00	12.00		12.00	12.00	1
Overall Mean Change (b) (Standard Deviation)	7.50 ( --- )					
p-value (c)	1.0000					

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_2.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions, the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

Table 20.2

FUNCTIONAL LIVING INDEX: CANCER (FLIC) BY DEVICE PLACEMENT  
REVISION PATIENTS HAVING AT LEAST ONE RECONSTRUCTION REVISION OR REVISION OF UNKNOWN INDICATION AND HISTORY OF CANCER - SUBPECTORAL

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	129.00	128.00	2.65	127.00	132.00	3
1 Year	129.75	128.50	6.55	124.00	138.00	4
2 Year	132.00	132.00	2.00	130.00	134.00	3
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	2.33	4.00	9.61	-8.00	11.00	3
2 Year	1.50	1.50	4.95	-2.00	5.00	2
Overall Mean Change (b) (Standard Deviation)	2.33 ( 6.66)					
p-value (c)	0.7500					

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T20\_2.SAS

Creation Date, Time: 21JUL04 10:43

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Total is scored as the sum of all 22 questions. The results include only patients who had responses for all 22 questions, the precise wording of each question can be found in Listing 15. Scores for Questions 1,4,5,7,8,11,13,15,17, and 20 have been reversed by subtracting the actual score from 7. Higher scores indicate a higher level of functioning.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change.

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 21

GLOBAL PATIENT SATISFICATION  
AUGMENTATION PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	525 ( 97.8%)	(0.965,0.990)
	No	9 ( 1.7%)	
	Missing/Unknown	3 ( 0.6%)	
	Total	537 (100.0%)	
1 Year	Yes	497 ( 98.0%)	(0.968,0.992)
	No	10 ( 2.0%)	
	Total	507 (100.0%)	
2 Year	Yes	494 ( 98.8%)	(0.978,0.998)
	No	6 ( 1.2%)	
	Total	500 (100.0%)	
3 Year	Yes	383 ( 97.2%)	(0.956,0.988)
	No	11 ( 2.8%)	
	Total	394 (100.0%)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T21.SAS

Creation Date, Time: 23JUL04 08:53

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

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 21

GLOBAL PATIENT SATISFICATION  
OVERALL RECONSTRUCTION PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	236 ( 95.9%)	(0.947,0.996)
	No	9 ( 3.7%)	
	Missing/Unknown	1 ( 0.4%)	
	Total	246 (100.0%)	
1 Year	Yes	208 ( 95.4%)	(0.912,0.983)
	No	10 ( 4.6%)	
	Total	218 (100.0%)	
2 Year	Yes	189 ( 97.9%)	(0.942,0.999)
	No	4 ( 2.1%)	
	Total	193 (100.0%)	
3 Year	Yes	119 ( 98.3%)	(0.965,1.000)
	No	2 ( 1.7%)	
	Total	121 (100.0%)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T21.SAS

Creation Date, Time: 23JUL04 08:53

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

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 21

GLOBAL PATIENT SATISFICATION  
DELAYED POST-MASTECTOMY PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	102 ( 98.1%)	(0.954,1.000)
	No	1 ( 1.0%)	
	Missing/Unknown	1 ( 1.0%)	
	Total	104 (100.0%)	
1 Year	Yes	80 ( 92.0%)	(0.862,0.977)
	No	7 ( 8.0%)	
	Total	87 (100.0%)	
2 Year	Yes	74 ( 94.9%)	(0.900,0.998)
	No	4 ( 5.1%)	
	Total	78 (100.0%)	
3 Year	Yes	40 ( 97.6%)	(0.928,1.000)
	No	1 ( 2.4%)	
	Total	41 (100.0%)	

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T21.SAS

Creation Date, Time: 23JUL04 08:53

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

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 21

GLOBAL PATIENT SATISFICATION  
IMMEDIATE POST-MASTECTOMY PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	66 ( 93.0%)	----
	No	5 ( 7.0%)	
	Total	71 (100.0%)	
1 Year	Yes	64 ( 97.0%)	----
	No	2 ( 3.0%)	
	Total	66 (100.0%)	
2 Year	Yes	57 (100.0%)	----
	Total	57 (100.0%)	
3 Year	Yes	36 ( 97.3%)	----
	No	1 ( 2.7%)	
	Total	37 (100.0%)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T21.SAS

Creation Date, Time. 23JUL04 08:53

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

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 21

GLOBAL PATIENT SATISFICATION  
REVISION PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	186 ( 93.9%)	(0.906,0.973)
	No	12 ( 6.1%)	
	Total	198 (100.0%)	
1 Year	Yes	171 ( 93.4%)	(0.899,0.970)
	No	10 ( 5.5%)	
	Missing/Unknown	2 ( 1.1%)	
	Total	183 (100.0%)	
2 Year	Yes	163 ( 94.8%)	(0.914,0.981)
	No	9 ( 5.2%)	
	Total	172 (100.0%)	
3 Year	Yes	132 ( 96.4%)	(0.932,0.995)
	No	5 ( 3.6%)	
	Total	137 (100.0%)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T21.SAS

Creation Date, Time. 23JUL04 08.53

Note 1. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

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 21

GLOBAL PATIENT SATISFICATION  
OVERALL PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	947 ( 96.5%)	(0.957,0.980)
	No	30 ( 3.1%)	
	Missing/Unknown	4 ( 0.4%)	
	Total	981 (100.0%)	
1 Year	Yes	876 ( 96.5%)	(0.952,0.977)
	No	30 ( 3.3%)	
	Missing/Unknown	2 ( 0.2%)	
	Total	908 (100.0%)	
2 Year	Yes	846 ( 97.8%)	(0.966,0.987)
	No	19 ( 2.2%)	
	Total	865 (100.0%)	
3 Year	Yes	634 ( 97.2%)	(0.959,0.985)
	No	18 ( 2.8%)	
	Total	652 (100.0%)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T21 SAS

Creation Date, Time: 23JUL04 08.53

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	116	50	59	28
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	24 ( 4.4)	13 ( 2.4)	15 ( 2.7)	5 ( 0.9)
Baker III Capsular Contracture	24 ( 4.4)	11 ( 2.0)	13 ( 2.4)	4 ( 0.7)
Baker IV Capsular Contracture	1 ( 0.2)	2 ( 0.4)	3 ( 0.5)	1 ( 0.2)
Breast pain	6 ( 1.1)		3 ( 0.5)	
Breast Sensation Changes	8 ( 1.5)	3 ( 0.5)	2 ( 0.4)	
Granuloma	1 ( 0.2)			
Hematoma	12 ( 2.2)	1 ( 0.2)	1 ( 0.2)	
Infection	8 ( 1.5)			
Lymphadenopathy	1 ( 0.2)			
Necrosis				1 ( 0.2)
New Diagnosis of Rheumatic Disease			3 ( 0.5)	
Nipple Sensation Changes	31 ( 5.6)	15 ( 2.7)	8 ( 1.5)	7 ( 1.3)
Implant Malposition/Displacement		1 ( 0.2)		
Rupture			1 ( 0.2)	2 ( 0.4)
Seroma	4 ( 0.7)		1 ( 0.2)	
Lactation Difficulties				1 ( 0.2)
Breast Mass	1 ( 0.2)	2 ( 0.4)	8 ( 1.5)	3 ( 0.6)
Breast Rash	2 ( 0.4)		1 ( 0.2)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
External Injury Not Related To Breast Implants	2 ( 0.4)	2 ( 0.4)		2 ( 0.4)
Inflammation	2 ( 0.4)			
Miscarriage	2 ( 0.4)	3 ( 0.5)	1 ( 0.2)	
Patient Dissatisfied With Appearance		1 ( 0.2)		
Placement Damage	4 ( 0.7)			
Surgical Complications Related To Technique	4 ( 0.7)		1 ( 0.2)	
Suture Reaction	3 ( 0.5)			
Other	4 ( 0.7)	1 ( 0.2)	2 ( 0.4)	5 ( 0.9)
Anaphylaxis			1 ( 0.2)	
Deep Vein Thrombosis				1 ( 0.2)
Distortion Of Breast Shape Not Related To Capsular Contracture	1 ( 0.2)			
Explanted Due To Right Side Being Removed				2 ( 0.4)
Miscarriage R / T Natural Causes 11 Wks Pregnant				1 ( 0.2)
Mondor's Disease	2 ( 0.4)			
Positive Antinuclear Antibodies Negative For Lupus				1 ( 0.2)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Pt Requests Removal Due To Personal Reasons		1 ( 0.2)		
Rash	1 ( 0.2)			
Soft Mass Left Costal Margin			1 ( 0.2)	
Any Complication Excluding Cosmetic	99 (18.0)	36 ( 6.5)	42 ( 7.7)	25 ( 4.6)
II. Cosmetic Complication				
Asymmetry	3 ( 0.5)			
Hypertrophic Scarring	15 ( 2.7)	10 ( 1.8)	10 ( 1.8)	
Ptosis	3 ( 0.5)		7 ( 1.3)	1 ( 0.2)
Size Change - Patient Request	6 ( 1.1)	4 ( 0.7)	1 ( 0.2)	2 ( 0.4)
Wrinkling	1 ( 0.2)	1 ( 0.2)	2 ( 0.4)	
Any Cosmetic Complication	25 ( 4.5)	15 ( 2.7)	20 ( 3.6)	3 ( 0.6)
III. Reoperations				
Explant Regardless of Replacement	6 ( 1.1)	5 ( 0.9)	8 ( 1.5)	6 ( 1.1)
Explant with Replacement with Study Device	4 ( 0.7)	4 ( 0.7)	5 ( 0.9)	2 ( 0.4)
Explant without Replacement	2 ( 0.4)	1 ( 0.2)	3 ( 0.5)	4 ( 0.7)
Other Reoperations	28 ( 5.1)	16 ( 2.9)	19 ( 3.5)	12 ( 2.2)
Biopsy	1 ( 0.2)	1 ( 0.2)	2 ( 0.4)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Capsulectomy	8 ( 1.5)	7 ( 1.3)	8 ( 1.5)	4 ( 0.7)
Incision and Drainage	9 ( 1.6)	1 ( 0.2)	1 ( 0.2)	
Mastopexy			1 ( 0.2)	1 ( 0.2)
Capsulotomy	3 ( 0.5)	3 ( 0.5)	4 ( 0.7)	3 ( 0.6)
Implant Reposition	2 ( 0.4)		1 ( 0.2)	
Scar Revision	1 ( 0.2)	3 ( 0.5)	6 ( 1.1)	2 ( 0.4)
Skin Adjustment	2 ( 0.4)		1 ( 0.2)	2 ( 0.4)
Capsulorrhaphy	2 ( 0.4)	1 ( 0.2)		
Implant Pocket Revision			1 ( 0.2)	
Nipple Related Procedure (unplanned)		1 ( 0.2)		
Revision Of Wound Closure	3 ( 0.5)			
Other			1 ( 0.2)	1 ( 0.2)
Excise Breast Mass			1 ( 0.2)	1 ( 0.2)
Any Reoperation	32 ( 5.8)	20 ( 3.6)	23 ( 4.2)	14 ( 2.6)
Total Patients Assessed	551	551	549	543

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	61	30	27	19
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	9 ( 3.6)	7 ( 2.8)	4 ( 1.6)	2 ( 0.9)
Baker III Capsular Contracture	8 ( 3.2)	6 ( 2.4)	4 ( 1.6)	2 ( 0.9)
Baker IV Capsular Contracture	1 ( 0.4)	1 ( 0.4)		
Breast pain	2 ( 0.8)	1 ( 0.4)	1 ( 0.4)	
Breast Sensation Changes		1 ( 0.4)	1 ( 0.4)	
Delayed Wound Healing	1 ( 0.4)			
Extrusion	2 ( 0.8)	1 ( 0.4)		
Hematoma	2 ( 0.8)		1 ( 0.4)	
Infection	9 ( 3.6)	1 ( 0.4)	3 ( 1.2)	
Lymphadenopathy				1 ( 0.4)
Necrosis	1 ( 0.4)			1 ( 0.4)
New Diagnosis of Rheumatic Disease		1 ( 0.4)		
Nipple Sensation Changes	2 ( 0.8)	2 ( 0.8)		1 ( 0.4)
Implant Malposition/Displacement	2 ( 0.8)	1 ( 0.4)	1 ( 0.4)	
Rupture			2 ( 0.8)	
Seroma	11 ( 4.4)		1 ( 0.4)	
Breast Mass	1 ( 0.4)	3 ( 1.2)	3 ( 1.2)	1 ( 0.4)
Breast Rash	1 ( 0.4)			

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
External Injury Not Related To Breast Implants	1 ( 0.4)			
Metastatic Disease	1 ( 0.4)		3 ( 1.2)	1 ( 0.4)
Miscarriage		2 ( 0.8)		
Patient Dissatisfied With Appearance		1 ( 0.4)		
Recurrent Breast Cancer	1 ( 0.4)	1 ( 0.4)	2 ( 0.8)	
Surgical Complications Related To Technique	3 ( 1.2)	1 ( 0.4)		
Other	8 ( 3.2)	1 ( 0.4)	2 ( 0.8)	2 ( 0.9)
Capsular Contracture Secondary To Radiation Therapy	1 ( 0.4)			
Cellulitis	1 ( 0.4)			
Deep Vein Thrombosis	1 ( 0.4)			
Distortion Of Breast Shape Not Related To Capsular Contracture		1 ( 0.4)		
Lack Of Projection			1 ( 0.4)	
Muscle Spasm	1 ( 0.4)			
Nipple Complications	1 ( 0.4)		1 ( 0.4)	
Occasional Burning Discomfort Of Skin.				1 ( 0.4)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Pain - Sternum And Under Left Arm Intermittent	1 ( 0.4)			
Skin Lesion	1 ( 0.4)			
Stitch Abscess				1 ( 0.4)
Wide Scars	1 ( 0.4)			
Any Complication Excluding Cosmetic	43 (17.1)	23 ( 9.2)	22 ( 8.9)	9 ( 3.8)
II. Cosmetic Complication				
Asymmetry	7 ( 2.8)	3 ( 1.2)	1 ( 0.4)	3 ( 1.3)
Hypertrophic Scarring	8 ( 3.2)	4 ( 1.6)	1 ( 0.4)	1 ( 0.4)
Ptosis	1 ( 0.4)	1 ( 0.4)	3 ( 1.2)	4 ( 1.7)
Size Change - Patient Request	2 ( 0.8)			2 ( 0.9)
Size Change - Physician Assessment only	3 ( 1.2)		1 ( 0.4)	
Wrinkling	4 ( 1.6)	1 ( 0.4)		1 ( 0.4)
Any Cosmetic Complication	23 ( 9.2)	8 ( 3.2)	6 ( 2.4)	11 ( 4.7)
III. Reoperations				
Explant Regardless of Replacement	7 ( 2.8)	13 ( 5.2)	8 ( 3.3)	2 ( 0.9)
Explant with Replacement with Study Device	4 ( 1.6)	9 ( 3.6)	5 ( 2.0)	
Explant without Replacement	3 ( 1.2)	4 ( 1.6)	3 ( 1.2)	2 ( 0.9)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Other Reoperations	21 ( 8.4)	22 ( 8.8)	13 ( 5.3)	2 ( 0.9)
Biopsy	4 ( 1.6)	3 ( 1.2)	2 ( 0.8)	
Capsulectomy	3 ( 1.2)	3 ( 1.2)	3 ( 1.2)	
Incision and Drainage	3 ( 1.2)			1 ( 0.4)
Mastopexy	1 ( 0.4)		1 ( 0.4)	1 ( 0.4)
Capsulotomy	5 ( 2.0)	7 ( 2.8)	1 ( 0.4)	
Implant Reposition	4 ( 1.6)	6 ( 2.4)	3 ( 1.2)	
Scar Revision	1 ( 0.4)	2 ( 0.8)	2 ( 0.8)	
Skin Adjustment	4 ( 1.6)	5 ( 2.0)	1 ( 0.4)	
Capsulorrhaphy	2 ( 0.8)			
Implant Pocket Revision		3 ( 1.2)	1 ( 0.4)	
Nipple Related Procedure (unplanned)	1 ( 0.4)	1 ( 0.4)		
Revision Of Wound Closure		1 ( 0.4)		
Other	2 ( 0.8)	1 ( 0.4)	2 ( 0.8)	
Create Inframmary Fold	1 ( 0.4)	1 ( 0.4)		
Flap Coverage Of Expander			1 ( 0.4)	
Removal Of Nodule On Chest Wall	1 ( 0.4)			
Revision Of Breast / External To Pocket			1 ( 0.4)	
Any Reoperation	25 (10.0)	27 (10.8)	16 ( 6.5)	4 ( 1.7)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Total Patients Assessed	251	249	246	234

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	54	29	40	14
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	18 ( 8.8)	13 ( 6.4)	11 ( 5.4)	5 ( 2.5)
Baker III Capsular Contracture	16 ( 7.8)	12 ( 5.9)	10 ( 4.9)	2 ( 1.0)
Baker IV Capsular Contracture	5 ( 2.4)	2 ( 1.0)	2 ( 1.0)	3 ( 1.5)
Breast pain	1 ( 0.5)	1 ( 0.5)	2 ( 1.0)	
Breast Sensation Changes	2 ( 1.0)		1 ( 0.5)	1 ( 0.5)
Delayed Wound Healing	4 ( 2.0)			
Extrusion	2 ( 1.0)	1 ( 0.5)		
Granuloma	2 ( 1.0)			
Hematoma	5 ( 2.4)		1 ( 0.5)	
Infection	1 ( 0.5)		1 ( 0.5)	
New Diagnosis of Breast Cancer		1 ( 0.5)		
New Diagnosis of Rheumatic Disease		1 ( 0.5)		
Nipple Sensation Changes	9 ( 4.4)	3 ( 1.5)	5 ( 2.5)	1 ( 0.5)
Implant Malposition/Displacement	3 ( 1.5)	1 ( 0.5)	1 ( 0.5)	
Rupture			6 ( 2.9)	2 ( 1.0)
Seroma	4 ( 2.0)			
Lactation Difficulties			1 ( 0.5)	
Breast Mass	4 ( 2.0)	2 ( 1.0)	3 ( 1.5)	2 ( 1.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22 SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
External Injury Not Related To Breast Implants	1 ( 0.5)			1 ( 0.5)
Inflammation	1 ( 0.5)	2 ( 1.0)		
Patient Dissatisfied With Appearance	1 ( 0.5)		2 ( 1.0)	
Recurrent Breast Cancer		1 ( 0.5)		
Surgical Complications Related To Technique	1 ( 0.5)	3 ( 1.5)		
Other	1 ( 0.5)	2 ( 1.0)	5 ( 2.5)	1 ( 0.5)
Abnormal Mammogram			1 ( 0.5)	
Capsule Tear	1 ( 0.5)			
False Positive For Rupture On Mammogram				1 ( 0.5)
Muscle Spasm		1 ( 0.5)		
Nipple Related Unplanned			1 ( 0.5)	
Numbness In Both Hands At Night			1 ( 0.5)	
Siliconoma				1 ( 0.5)
Skin Lesion			1 ( 0.5)	
Surgical Removal Of Ectopic Pregnancy			1 ( 0.5)	
Symmastia		1 ( 0.5)		
Any Complication Excluding Cosmetic	45 (22.0)	27 (13.2)	32 (15.7)	11 ( 5.5)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
<b>II. Cosmetic Complication</b>				
Asymmetry	1 ( 0.5)	2 ( 1.0)	1 ( 0.5)	1 ( 0.5)
Hypertrophic Scarring	6 ( 2.9)	2 ( 1.0)	5 ( 2.5)	1 ( 0.5)
Ptosis	1 ( 0.5)	1 ( 0.5)	2 ( 1.0)	1 ( 0.5)
Size Change - Patient Request	2 ( 1.0)		4 ( 2.0)	1 ( 0.5)
Wrinkling	3 ( 1.5)		1 ( 0.5)	
Any Cosmetic Complication	13 ( 6.3)	5 ( 2.5)	13 ( 6.4)	3 ( 1.5)
<b>III. Reoperations</b>				
Explant Regardless of Replacement	5 ( 2.4)	6 ( 2.9)	7 ( 3.4)	6 ( 3.0)
Explant with Replacement with Study Device	3 ( 1.5)	5 ( 2.5)	4 ( 2.0)	2 ( 1.0)
Explant without Replacement	2 ( 1.0)	1 ( 0.5)	3 ( 1.5)	4 ( 2.0)
Other Reoperations	16 ( 7.8)	14 ( 6.9)	9 ( 4.4)	9 ( 4.5)
Biopsy	3 ( 1.5)	2 ( 1.0)	1 ( 0.5)	2 ( 1.0)
Capsulectomy	3 ( 1.5)	6 ( 2.9)	1 ( 0.5)	3 ( 1.5)
Incision and Drainage	5 ( 2.4)			
Mastopexy		2 ( 1.0)		1 ( 0.5)
Capsulotomy	2 ( 1.0)	6 ( 2.9)	2 ( 1.0)	1 ( 0.5)
Implant Reposition		2 ( 1.0)	2 ( 1.0)	1 ( 0.5)
Scar Revision	1 ( 0.5)	2 ( 1.0)	2 ( 1.0)	1 ( 0.5)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Skin Adjustment	2 ( 1.0)	3 ( 1.5)	2 ( 1.0)	
Capsulorrhaphy	1 ( 0.5)	1 ( 0.5)	1 ( 0.5)	
Nipple Related Procedure (unplanned)				1 ( 0.5)
Revision Of Wound Closure	2 ( 1.0)			
Other		1 ( 0.5)	2 ( 1.0)	2 ( 1.0)
Excision Of Skin Lesion		1 ( 0.5)		
Exploration Right Breast With			1 ( 0.5)	
Evacuation Of Hematoma				
Kenalog Injection			1 ( 0.5)	
Needle Aspiration				1 ( 0.5)
Open Incision To Rule Out Implant				1 ( 0.5)
Rupture				
Any Reoperation	21 (10.2)	15 ( 7.4)	13 ( 6.4)	10 ( 5.0)
Total Patients Assessed	205	204	204	199

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	231	109	126	61
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	51 ( 5.1)	33 ( 3.3)	30 ( 3.0)	12 ( 1.2)
Baker III Capsular Contracture	48 ( 4.8)	29 ( 2.9)	27 ( 2.7)	8 ( 0.8)
Baker IV Capsular Contracture	7 ( 0.7)	5 ( 0.5)	5 ( 0.5)	4 ( 0.4)
Breast pain	9 ( 0.9)	2 ( 0.2)	6 ( 0.6)	
Breast Sensation Changes	10 ( 1.0)	4 ( 0.4)	4 ( 0.4)	1 ( 0.1)
Delayed Wound Healing	5 ( 0.5)			
Extrusion	4 ( 0.4)	2 ( 0.2)		
Granuloma	3 ( 0.3)			
Hematoma	19 ( 1.9)	1 ( 0.1)	3 ( 0.3)	
Infection	18 ( 1.8)	1 ( 0.1)	4 ( 0.4)	
Lymphadenopathy	1 ( 0.1)			1 ( 0.1)
Necrosis	1 ( 0.1)			2 ( 0.2)
New Diagnosis of Breast Cancer		1 ( 0.1)		
New Diagnosis of Rheumatic Disease		2 ( 0.2)	3 ( 0.3)	
Nipple Sensation Changes	42 ( 4.2)	20 ( 2.0)	13 ( 1.3)	9 ( 0.9)
Implant Malposition/Displacement	5 ( 0.5)	3 ( 0.3)	2 ( 0.2)	
Rupture			9 ( 0.9)	4 ( 0.4)
Seroma	19 ( 1.9)		2 ( 0.2)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Lactation Difficulties			1 ( 0.1)	1 ( 0.1)
Breast Mass	6 ( 0.6)	7 ( 0.7)	14 ( 1.4)	6 ( 0.6)
Breast Rash	3 ( 0.3)		1 ( 0.1)	
External Injury Not Related To Breast Implants	4 ( 0.4)	2 ( 0.2)		3 ( 0.3)
Inflammation	3 ( 0.3)	2 ( 0.2)		
Metastatic Disease	1 ( 0.1)		3 ( 0.3)	1 ( 0.1)
Miscarriage	2 ( 0.2)	5 ( 0.5)	1 ( 0.1)	
Patient Dissatisfied With Appearance Placement Damage	1 ( 0.1)	2 ( 0.2)	2 ( 0.2)	
Recurrent Breast Cancer	1 ( 0.1)	2 ( 0.2)	2 ( 0.2)	
Surgical Complications Related To Technique	8 ( 0.8)	4 ( 0.4)	1 ( 0.1)	
Suture Reaction	3 ( 0.3)			
Other	13 ( 1.3)	4 ( 0.4)	9 ( 0.9)	8 ( 0.8)
Abnormal Mammogram			1 ( 0.1)	
Anaphylaxis			1 ( 0.1)	
Capsular Contracture Secondary To Radiation Therapy	1 ( 0.1)			
Capsule Tear	1 ( 0.1)			
Cellulitis	1 ( 0.1)			

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Deep Vein Thrombosis	1 ( 0.1)			1 ( 0.1)
Distortion Of Breast Shape Not Related To Capsular Contracture	1 ( 0.1)	1 ( 0.1)		
Explanted Due To Right Side Being Removed				2 ( 0.2)
False Positive For Rupture On Mammogram				1 ( 0.1)
Lack Of Projection			1 ( 0.1)	
Miscarriage R / T Natural Causes 11 Wks Pregnant				1 ( 0.1)
Mondor's Disease	2 ( 0.2)			
Muscle Spasm	1 ( 0.1)	1 ( 0.1)		
Nipple Complications	1 ( 0.1)		1 ( 0.1)	
Nipple Related Unplanned			1 ( 0.1)	
Numbness In Both Hands At Night			1 ( 0.1)	
Occasional Burning Discomfort Of Skin.				1 ( 0.1)
Pain - Sternum And Under Left Arm Intermittent	1 ( 0.1)			
Positive Antinuclear Antibodies Negative For Lupus				1 ( 0.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22 SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Pt Requests Removal Due To Personal Reasons		1 ( 0.1)		
Rash	1 ( 0.1)			
Siliconoma				1 ( 0.1)
Skin Lesion	1 ( 0.1)		1 ( 0.1)	
Soft Mass Left Costal Margin			1 ( 0.1)	
Stitch Abscess				1 ( 0.1)
Surgical Removal Of Ectopic Pregnancy			1 ( 0.1)	
Symmastia		1 ( 0.1)		
Wide Scars	1 ( 0.1)			
Any Complication Excluding Cosmetic	187 (18.6)	86 ( 8.6)	96 ( 9.6)	45 ( 4.6)
II. Cosmetic Complication				
Asymmetry	11 ( 1.1)	5 ( 0.5)	2 ( 0.2)	4 ( 0.4)
Hypertrophic Scarring	29 ( 2.9)	16 ( 1.6)	16 ( 1.6)	2 ( 0.2)
Ptosis	5 ( 0.5)	2 ( 0.2)	12 ( 1.2)	6 ( 0.6)
Size Change - Patient Request	10 ( 1.0)	4 ( 0.4)	5 ( 0.5)	5 ( 0.5)
Size Change - Physician Assessment only	3 ( 0.3)		1 ( 0.1)	
Wrinkling	8 ( 0.8)	2 ( 0.2)	3 ( 0.3)	1 ( 0.1)
Any Cosmetic Complication	61 ( 6.1)	28 ( 2.8)	39 ( 3.9)	17 ( 1.7)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
<b>III. Reoperations</b>				
Explant Regardless of Replacement	18 ( 1.8)	24 ( 2.4)	23 ( 2.3)	14 ( 1.4)
Explant with Replacement with Study Device	11 ( 1.1)	18 ( 1.8)	14 ( 1.4)	4 ( 0.4)
Explant without Replacement	7 ( 0.7)	6 ( 0.6)	9 ( 0.9)	10 ( 1.0)
Other Reoperations	65 ( 6.5)	52 ( 5.2)	41 ( 4.1)	23 ( 2.4)
Biopsy	8 ( 0.8)	6 ( 0.6)	5 ( 0.5)	2 ( 0.2)
Capsulectomy	14 ( 1.4)	16 ( 1.6)	12 ( 1.2)	7 ( 0.7)
Incision and Drainage	17 ( 1.7)	1 ( 0.1)	1 ( 0.1)	1 ( 0.1)
Mastopexy	1 ( 0.1)	2 ( 0.2)	2 ( 0.2)	3 ( 0.3)
Capsulotomy	10 ( 1.0)	16 ( 1.6)	7 ( 0.7)	4 ( 0.4)
Implant Reposition	6 ( 0.6)	8 ( 0.8)	6 ( 0.6)	1 ( 0.1)
Scar Revision	3 ( 0.3)	7 ( 0.7)	10 ( 1.0)	3 ( 0.3)
Skin Adjustment	8 ( 0.8)	8 ( 0.8)	4 ( 0.4)	2 ( 0.2)
Capsulorrhaphy	5 ( 0.5)	2 ( 0.2)	1 ( 0.1)	
Implant Pocket Revision		3 ( 0.3)	2 ( 0.2)	
Nipple Related Procedure (unplanned)	1 ( 0.1)	2 ( 0.2)		1 ( 0.1)
Revision Of Wound Closure	5 ( 0.5)	1 ( 0.1)		
Other	2 ( 0.2)	2 ( 0.2)	5 ( 0.5)	3 ( 0.3)
Create Inframmary Fold	1 ( 0.1)	1 ( 0.1)		
Excise Breast Mass			1 ( 0.1)	1 ( 0.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note. Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Excision Of Skin Lesion		1 ( 0.1)		
Exploration Right Breast With Evacuation Of Hematoma			1 ( 0.1)	
Flap Coverage Of Expander			1 ( 0.1)	
Kenalog Injection			1 ( 0.1)	
Needle Aspiration				1 ( 0.1)
Open Incision To Rule Out Implant Rupture				1 ( 0.1)
Removal Of Nodule On Chest Wall	1 ( 0.1)			
Revision Of Breast / External To Pocket			1 ( 0.1)	
Any Reoperation	78 ( 7.7)	62 ( 6.2)	52 ( 5.2)	28 ( 2.9)
Total Patients Assessed	1007	1004	999	976

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	156	70	77	37
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	30 ( 2.7)	18 ( 1.6)	19 ( 1.7)	7 ( 0.6)
Baker III Capsular Contracture	29 ( 2.6)	15 ( 1.4)	17 ( 1.6)	5 ( 0.5)
Baker IV Capsular Contracture	1 ( 0.1)	3 ( 0.3)	3 ( 0.3)	2 ( 0.2)
Breast pain	9 ( 0.8)		4 ( 0.4)	
Breast Sensation Changes	11 ( 1.0)	4 ( 0.4)	2 ( 0.2)	
Granuloma	1 ( 0.1)			
Hematoma	12 ( 1.1)	1 ( 0.1)	1 ( 0.1)	
Infection	8 ( 0.7)			
Lymphadenopathy	1 ( 0.1)			
Necrosis				2 ( 0.2)
Nipple Sensation Changes	47 ( 4.3)	22 ( 2.0)	10 ( 0.9)	12 ( 1.1)
Implant Malposition/Displacement		1 ( 0.1)		
Rupture			1 ( 0.1)	2 ( 0.2)
Seroma	5 ( 0.5)		1 ( 0.1)	
Lactation Difficulties				1 ( 0.1)
Breast Mass	1 ( 0.1)	2 ( 0.2)	8 ( 0.7)	3 ( 0.3)
Breast Rash	3 ( 0.3)		1 ( 0.1)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22 SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
External Injury Not Related To Breast Implants	3 ( 0.3)	2 ( 0.2)		2 ( 0.2)
Inflammation	2 ( 0.2)			
Patient Dissatisfied With Appearance		2 ( 0.2)		
Placement Damage	4 ( 0.4)			
Surgical Complications Related To Technique	6 ( 0.5)		1 ( 0.1)	
Suture Reaction	4 ( 0.4)			
Other	4 ( 0.4)	2 ( 0.2)	1 ( 0.1)	2 ( 0.2)
Distortion Of Breast Shape Not Related To Capsular Contracture	1 ( 0.1)			
Explanted Due To Right Side Being Removed				2 ( 0.2)
Mondor's Disease	3 ( 0.3)			
Pt Requests Removal Due To Personal Reasons		2 ( 0.2)		
Soft Mass Left Costal Margin			1 ( 0.1)	
Any Complication Excluding Cosmetic	129 (11.7)	47 ( 4.3)	45 ( 4.1)	31 ( 2.9)
II. Cosmetic Complication				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22 SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Asymmetry	4 ( 0.4)			
Hypertrophic Scarring	21 ( 1.9)	14 ( 1.3)	17 ( 1.6)	
Ptosis	5 ( 0.5)		12 ( 1.1)	2 ( 0.2)
Size Change - Patient Request	11 ( 1.0)	8 ( 0.7)	2 ( 0.2)	4 ( 0.4)
Wrinkling	1 ( 0.1)	2 ( 0.2)	3 ( 0.3)	
Any Cosmetic Complication	38 ( 3.5)	24 ( 2.2)	34 ( 3.1)	6 ( 0.6)
III. Reoperations				
Explant Regardless of Replacement	9 ( 0.8)	9 ( 0.8)	12 ( 1.1)	11 ( 1.0)
Explant with Replacement with Study Device	7 ( 0.6)	7 ( 0.6)	6 ( 0.5)	4 ( 0.4)
Explant without Replacement	2 ( 0.2)	2 ( 0.2)	6 ( 0.5)	7 ( 0.6)
Other Reoperations	33 ( 3.0)	20 ( 1.8)	27 ( 2.5)	15 ( 1.4)
Biopsy	1 ( 0.1)	1 ( 0.1)	2 ( 0.2)	
Capsulectomy	10 ( 0.9)	8 ( 0.7)	11 ( 1.0)	5 ( 0.5)
Incision and Drainage	9 ( 0.8)	1 ( 0.1)	1 ( 0.1)	
Mastopexy			2 ( 0.2)	2 ( 0.2)
Capsulotomy	3 ( 0.3)	5 ( 0.5)	6 ( 0.5)	3 ( 0.3)
Implant Reposition	2 ( 0.2)		2 ( 0.2)	
Scar Revision	1 ( 0.1)	4 ( 0.4)	10 ( 0.9)	3 ( 0.3)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Skin Adjustment	3 ( 0.3)		2 ( 0.2)	3 ( 0.3)
Capsulorrhaphy	3 ( 0.3)	1 ( 0.1)		
Implant Pocket Revision			2 ( 0.2)	
Nipple Related Procedure (unplanned)		1 ( 0.1)		
Revision Of Wound Closure	3 ( 0.3)			
Other			1 ( 0.1)	1 ( 0.1)
Excise Breast Mass			1 ( 0.1)	1 ( 0.1)
Any Reoperation	40 ( 3.6)	28 ( 2.5)	35 ( 3.2)	20 ( 1.8)
Total Implants Assessed	1100	1100	1096	1084

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note. Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	74	32	28	27
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	9 ( 2.2)	8 ( 2.0)	4 ( 1.0)	2 ( 0.5)
Baker III Capsular Contracture	8 ( 2.0)	7 ( 1.7)	4 ( 1.0)	2 ( 0.5)
Baker IV Capsular Contracture	1 ( 0.2)	1 ( 0.2)		
Breast pain	3 ( 0.7)	1 ( 0.2)	1 ( 0.2)	
Breast Sensation Changes		2 ( 0.5)	1 ( 0.2)	
Delayed Wound Healing	2 ( 0.5)			
Extrusion	2 ( 0.5)	1 ( 0.2)		
Hematoma	2 ( 0.5)		1 ( 0.2)	
Infection	9 ( 2.2)	1 ( 0.2)	3 ( 0.7)	
Lymphadenopathy				1 ( 0.3)
Necrosis	1 ( 0.2)			1 ( 0.3)
Nipple Sensation Changes	3 ( 0.7)	2 ( 0.5)		1 ( 0.3)
Implant Malposition/Displacement	2 ( 0.5)	1 ( 0.2)	2 ( 0.5)	
Rupture			2 ( 0.5)	
Seroma	11 ( 2.7)		1 ( 0.2)	
Breast Mass	1 ( 0.2)	3 ( 0.7)	3 ( 0.7)	1 ( 0.3)
Breast Rash	2 ( 0.5)			

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note. Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
External Injury Not Related To Breast Implants	1 ( 0.2)			
Metastatic Disease				2 ( 0.5)
Patient Dissatisfied With Appearance		2 ( 0.5)		
Recurrent Breast Cancer	2 ( 0.5)	1 ( 0.2)	1 ( 0.2)	
Surgical Complications Related To Technique	4 ( 1.0)	1 ( 0.2)		
Other	6 ( 1.5)	1 ( 0.2)	3 ( 0.7)	3 ( 0.8)
Capsular Contracture Secondary To Radiation Therapy	1 ( 0.2)			
Cellulitis	1 ( 0.2)			
Distortion Of Breast Shape Not Related To Capsular Contracture		1 ( 0.2)		
Lack Of Projection			1 ( 0.2)	
Muscle Spasm	1 ( 0.2)			
Nipple Complications	1 ( 0.2)		2 ( 0.5)	
Occasional Burning Discomfort Of Skin.				2 ( 0.5)
Pain - Sternum And Under Left Arm Intermittent	1 ( 0.2)			

Program Name Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Skin Lesion	1 ( 0.2)			
Stitch Abscess				1 ( 0.3)
Any Complication Excluding Cosmetic	48 (11.7)	24 ( 5.9)	21 ( 5.2)	11 ( 2.9)
II. Cosmetic Complication				
Asymmetry	7 ( 1.7)	3 ( 0.7)	2 ( 0.5)	4 ( 1.0)
Hypertrophic Scarring	9 ( 2.2)	4 ( 1.0)	1 ( 0.2)	2 ( 0.5)
Ptosis	2 ( 0.5)	2 ( 0.5)	4 ( 1.0)	6 ( 1.6)
Size Change - Patient Request	3 ( 0.7)			4 ( 1.0)
Size Change - Physician Assessment only	5 ( 1.2)		2 ( 0.5)	
Wrinkling	5 ( 1.2)	1 ( 0.2)		1 ( 0.3)
Any Cosmetic Complication	29 ( 7.1)	9 ( 2.2)	9 ( 2.2)	17 ( 4.4)
III. Reoperations				
Explant Regardless of Replacement	10 ( 2.4)	16 ( 3.9)	9 ( 2.2)	4 ( 1.0)
Explant with Replacement with Study Device	7 ( 1.7)	10 ( 2.5)	6 ( 1.5)	
Explant without Replacement	3 ( 0.7)	6 ( 1.5)	3 ( 0.7)	4 ( 1.0)
Other Reoperations	26 ( 6.3)	25 ( 6.1)	18 ( 4.5)	2 ( 0.5)
Biopsy	5 ( 1.2)	3 ( 0.7)	2 ( 0.5)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note. Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Capsulectomy	3 ( 0.7)	4 ( 1.0)	3 ( 0.7)	
Incision and Drainage	3 ( 0.7)			1 ( 0.3)
Mastopexy	1 ( 0.2)		2 ( 0.5)	1 ( 0.3)
Capsulotomy	6 ( 1.5)	7 ( 1.7)	1 ( 0.2)	
Implant Reposition	6 ( 1.5)	6 ( 1.5)	5 ( 1.2)	
Scar Revision	2 ( 0.5)	2 ( 0.5)	3 ( 0.7)	
Skin Adjustment	6 ( 1.5)	6 ( 1.5)	2 ( 0.5)	
Capsulorrhaphy	2 ( 0.5)			
Implant Pocket Revision		4 ( 1.0)	2 ( 0.5)	
Nipple Related Procedure (unplanned)	1 ( 0.2)	1 ( 0.2)		
Revision Of Wound Closure		1 ( 0.2)		
Other	3 ( 0.7)	1 ( 0.2)	3 ( 0.7)	
Create Inframmary Fold	1 ( 0.2)	1 ( 0.2)		
Flap Coverage Of Expander			1 ( 0.2)	
Removal Of Nodule On Chest Wall	2 ( 0.5)			
Revision Of Breast / External To Pocket			2 ( 0.5)	
Any Reoperation	32 ( 7.8)	33 ( 8.1)	21 ( 5.2)	6 ( 1.6)
Total Implants Assessed	410	407	401	383

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3. 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	76	36	56	18
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	22 ( 5.7)	18 ( 4.7)	12 ( 3.1)	6 ( 1.6)
Baker III Capsular Contracture	17 ( 4.4)	16 ( 4.2)	10 ( 2.6)	2 ( 0.5)
Baker IV Capsular Contracture	5 ( 1.3)	2 ( 0.5)	3 ( 0.8)	4 ( 1.1)
Breast pain	1 ( 0.3)	1 ( 0.3)	3 ( 0.8)	
Breast Sensation Changes	3 ( 0.8)		1 ( 0.3)	1 ( 0.3)
Delayed Wound Healing	5 ( 1.3)			
Extrusion	2 ( 0.5)	1 ( 0.3)		
Granuloma	2 ( 0.5)			
Hematoma	6 ( 1.6)		1 ( 0.3)	
Infection	1 ( 0.3)		1 ( 0.3)	
New Diagnosis of Breast Cancer		1 ( 0.3)		
Nipple Sensation Changes	15 ( 3.9)	5 ( 1.3)	6 ( 1.6)	1 ( 0.3)
Implant Malposition/Displacement	5 ( 1.3)	1 ( 0.3)	1 ( 0.3)	
Rupture			8 ( 2.1)	3 ( 0.8)
Seroma	4 ( 1.0)			
Lactation Difficulties			2 ( 0.5)	
Breast Mass	4 ( 1.0)	2 ( 0.5)	3 ( 0.8)	2 ( 0.5)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
External Injury Not Related To Breast Implants	1 ( 0.3)			1 ( 0.3)
Inflammation	1 ( 0.3)	1 ( 0.3)		
Patient Dissatisfied With Appearance	2 ( 0.5)		4 ( 1.0)	
Recurrent Breast Cancer		1 ( 0.3)		
Surgical Complications Related To Technique	1 ( 0.3)	2 ( 0.5)		
Other	1 ( 0.3)	3 ( 0.8)	3 ( 0.8)	1 ( 0.3)
Abnormal Mammogram			1 ( 0.3)	
Capsule Tear	1 ( 0.3)			
False Positive For Rupture On Mammogram				1 ( 0.3)
Muscle Spasm		2 ( 0.5)		
Nipple Related Unplanned			1 ( 0.3)	
Siliconoma				1 ( 0.3)
Skin Lesion			1 ( 0.3)	
Symmastia		1 ( 0.3)		
Any Complication Excluding Cosmetic	61 (15.8)	33 ( 8.6)	40 (10.4)	13 ( 3.5)
II. Cosmetic Complication				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Asymmetry	1 ( 0.3)	2 ( 0.5)	1 ( 0.3)	1 ( 0.3)
Hypertrophic Scarring	9 ( 2.3)	3 ( 0.8)	8 ( 2.1)	1 ( 0.3)
Ptosis	2 ( 0.5)	1 ( 0.3)	4 ( 1.0)	2 ( 0.5)
Size Change - Patient Request	3 ( 0.8)		8 ( 2.1)	2 ( 0.5)
Wrinkling	5 ( 1.3)		1 ( 0.3)	
Any Cosmetic Complication	20 ( 5.2)	6 ( 1.6)	22 ( 5.7)	5 ( 1.3)
III. Reoperations				
Explant Regardless of Replacement	7 ( 1.8)	9 ( 2.3)	11 ( 2.9)	10 ( 2.7)
Explant with Replacement with Study Device	4 ( 1.0)	8 ( 2.1)	6 ( 1.6)	3 ( 0.8)
Explant without Replacement	3 ( 0.8)	1 ( 0.3)	5 ( 1.3)	7 ( 1.9)
Other Reoperations	19 ( 4.9)	24 ( 6.3)	13 ( 3.4)	13 ( 3.5)
Biopsy	3 ( 0.8)	2 ( 0.5)	1 ( 0.3)	2 ( 0.5)
Capsulectomy	3 ( 0.8)	9 ( 2.3)	1 ( 0.3)	5 ( 1.3)
Incision and Drainage	6 ( 1.6)			
Mastopexy		4 ( 1.0)		1 ( 0.3)
Capsulotomy	3 ( 0.8)	8 ( 2.1)	2 ( 0.5)	1 ( 0.3)
Implant Reposition		4 ( 1.0)	4 ( 1.0)	2 ( 0.5)
Scar Revision	1 ( 0.3)	4 ( 1.0)	3 ( 0.8)	1 ( 0.3)

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T22 SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Skin Adjustment	2 ( 0.5)	6 ( 1.6)	3 ( 0.8)	
Capsulorrhaphy	2 ( 0.5)	2 ( 0.5)	2 ( 0.5)	
Nipple Related Procedure (unplanned)				1 ( 0.3)
Revision Of Wound Closure	2 ( 0.5)			
Other		2 ( 0.5)	3 ( 0.8)	2 ( 0.5)
Excision Of Skin Lesion		2 ( 0.5)		
Exploration Right Breast With Evacuation Of Hematoma			1 ( 0.3)	
Kenalog Injection			2 ( 0.5)	
Needle Aspiration				1 ( 0.3)
Open Incision To Rule Out Implant Rupture				1 ( 0.3)
Any Reoperation	26 ( 6.7)	25 ( 6.5)	21 ( 5.5)	16 ( 4.3)
Total Implants Assessed	386	384	384	374

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22 SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
OVERALL IMPLANTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	306	138	161	82
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	61 ( 3.2)	44 ( 2.3)	35 ( 1.9)	15 ( 0.8)
Baker III Capsular Contracture	54 ( 2.8)	38 ( 2.0)	31 ( 1.6)	9 ( 0.5)
Baker IV Capsular Contracture	7 ( 0.4)	6 ( 0.3)	6 ( 0.3)	6 ( 0.3)
Breast pain	13 ( 0.7)	2 ( 0.1)	8 ( 0.4)	
Breast Sensation Changes	14 ( 0.7)	6 ( 0.3)	4 ( 0.2)	1 ( 0.1)
Delayed Wound Healing	7 ( 0.4)			
Extrusion	4 ( 0.2)	2 ( 0.1)		
Granuloma	3 ( 0.2)			
Hematoma	20 ( 1.1)	1 ( 0.1)	3 ( 0.2)	
Infection	18 ( 0.9)	1 ( 0.1)	4 ( 0.2)	
Lymphadenopathy	1 ( 0.1)			1 ( 0.1)
Necrosis	1 ( 0.1)			3 ( 0.2)
New Diagnosis of Breast Cancer		1 ( 0.1)		
Nipple Sensation Changes	65 ( 3.4)	29 ( 1.5)	16 ( 0.9)	14 ( 0.8)
Implant Malposition/Displacement	7 ( 0.4)	3 ( 0.2)	3 ( 0.2)	
Rupture			11 ( 0.6)	5 ( 0.3)
Seroma	20 ( 1.1)		2 ( 0.1)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note. Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
OVERALL IMPLANTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Lactation Difficulties			2 ( 0.1)	1 ( 0.1)
Breast Mass	6 ( 0.3)	7 ( 0.4)	14 ( 0.7)	6 ( 0.3)
Breast Rash	5 ( 0.3)		1 ( 0.1)	
External Injury Not Related To Breast Implants	5 ( 0.3)	2 ( 0.1)		3 ( 0.2)
Inflammation	3 ( 0.2)	1 ( 0.1)		
Metastatic Disease				2 ( 0.1)
Patient Dissatisfied With Appearance	2 ( 0.1)	4 ( 0.2)	4 ( 0.2)	
Placement Damage	4 ( 0.2)			
Recurrent Breast Cancer	2 ( 0.1)	2 ( 0.1)	1 ( 0.1)	
Surgical Complications Related To Technique	11 ( 0.6)	3 ( 0.2)	1 ( 0.1)	
Suture Reaction	4 ( 0.2)			
Other	11 ( 0.6)	6 ( 0.3)	7 ( 0.4)	6 ( 0.3)
Abnormal Mammogram			1 ( 0.1)	
Capsular Contracture Secondary To Radiation Therapy	1 ( 0.1)			
Capsule Tear	1 ( 0.1)			
Cellulitis	1 ( 0.1)			

Program Name O:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
OVERALL IMPLANTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Distortion Of Breast Shape Not Related To Capsular Contracture	1 ( 0.1)	1 ( 0.1)		
Explanted Due To Right Side Being Removed				2 ( 0.1)
False Positive For Rupture On Mammogram				1 ( 0.1)
Lack Of Projection			1 ( 0.1)	
Mondor's Disease	3 ( 0.2)			
Muscle Spasm	1 ( 0.1)	2 ( 0.1)		
Nipple Complications	1 ( 0.1)		2 ( 0.1)	
Nipple Related Unplanned			1 ( 0.1)	
Occasional Burning Discomfort Of Skin.				2 ( 0.1)
Pain - Sternum And Under Left Arm Intermittent	1 ( 0.1)			
Pt Requests Removal Due To Personal Reasons		2 ( 0.1)		
Siliconoma				1 ( 0.1)
Skin Lesion	1 ( 0.1)		1 ( 0.1)	
Soft Mass Left Costal Margin			1 ( 0.1)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time. 29JUL04 12.20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3. 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
OVERALL IMPLANTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Stitch Abscess				1 ( 0.1)
Symmastia		1 ( 0.1)		
Any Complication Excluding Cosmetic	238 (12.6)	104 ( 5.5)	106 ( 5.6)	55 ( 3.0)
II. Cosmetic Complication				
Asymmetry	12 ( 0.6)	5 ( 0.3)	3 ( 0.2)	5 ( 0.3)
Hypertrophic Scarring	39 ( 2.1)	21 ( 1.1)	26 ( 1.4)	3 ( 0.2)
Ptosis	9 ( 0.5)	3 ( 0.2)	20 ( 1.1)	10 ( 0.5)
Size Change - Patient Request	17 ( 0.9)	8 ( 0.4)	10 ( 0.5)	10 ( 0.5)
Size Change - Physician Assessment only	5 ( 0.3)		2 ( 0.1)	
Wrinkling	11 ( 0.6)	3 ( 0.2)	4 ( 0.2)	1 ( 0.1)
Any Cosmetic Complication	87 ( 4.6)	39 ( 2.1)	65 ( 3.5)	28 ( 1.5)
III. Reoperations				
Explant Regardless of Replacement	26 ( 1.4)	34 ( 1.8)	32 ( 1.7)	25 ( 1.4)
Explant with Replacement with Study Device	18 ( 0.9)	25 ( 1.3)	18 ( 1.0)	7 ( 0.4)
Explant without Replacement	8 ( 0.4)	9 ( 0.5)	14 ( 0.7)	18 ( 1.0)
Other Reoperations	78 ( 4.1)	69 ( 3.6)	58 ( 3.1)	30 ( 1.6)
Biopsy	9 ( 0.5)	6 ( 0.3)	5 ( 0.3)	2 ( 0.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
OVERALL IMPLANTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Capsulectomy	16 ( 0.8)	21 ( 1.1)	15 ( 0.8)	10 ( 0.5)
Incision and Drainage	18 ( 0.9)	1 ( 0.1)	1 ( 0.1)	1 ( 0.1)
Mastopexy	1 ( 0.1)	4 ( 0.2)	4 ( 0.2)	4 ( 0.2)
Capsulotomy	12 ( 0.6)	20 ( 1.1)	9 ( 0.5)	4 ( 0.2)
Implant Reposition	8 ( 0.4)	10 ( 0.5)	11 ( 0.6)	2 ( 0.1)
Scar Revision	4 ( 0.2)	10 ( 0.5)	16 ( 0.9)	4 ( 0.2)
Skin Adjustment	11 ( 0.6)	12 ( 0.6)	7 ( 0.4)	3 ( 0.2)
Capsulorrhaphy	7 ( 0.4)	3 ( 0.2)	2 ( 0.1)	
Implant Pocket Revision		4 ( 0.2)	4 ( 0.2)	
Nipple Related Procedure (unplanned)	1 ( 0.1)	2 ( 0.1)		1 ( 0.1)
Revision Of Wound Closure	5 ( 0.3)	1 ( 0.1)		
Other	3 ( 0.2)	3 ( 0.2)	7 ( 0.4)	3 ( 0.2)
Create Inframmary Fold	1 ( 0.1)	1 ( 0.1)		
Excise Breast Mass			1 ( 0.1)	1 ( 0.1)
Excision Of Skin Lesion		2 ( 0.1)		
Exploration Right Breast With Evacuation Of Hematoma			1 ( 0.1)	
Flap Coverage Of Expander			1 ( 0.1)	
Kenalog Injection			2 ( 0.1)	
Needle Aspiration				1 ( 0.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 22.2

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
OVERALL IMPLANTS

Type of Complication or Reoperation	Incidence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Open Incision To Rule Out Implant Rupture				1 ( 0.1)
Removal Of Nodule On Chest Wall	2 ( 0.1)			
Revision Of Breast / External To Pocket			2 ( 0.1)	
Any Reoperation	98 ( 5.2)	86 ( 4.5)	77 ( 4.1)	42 ( 2.3)
Total Implants Assessed	1896	1891	1881	1841

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T22.SAS

Creation Date, Time: 29JUL04 12:20

(1) Defined as a patient reporting at least one new occurrence of the complication or reoperation in question during each specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	116	94	96	45
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	24 ( 4.4)	22 ( 4.0)	26 ( 4.7)	13 ( 2.4)
Baker III Capsular Contracture	24 ( 4.4)	21 ( 3.8)	22 ( 4.0)	13 ( 2.4)
Baker IV Capsular Contracture	1 ( 0.2)	3 ( 0.5)	5 ( 0.9)	1 ( 0.2)
Breast pain	6 ( 1.1)	1 ( 0.2)	4 ( 0.7)	2 ( 0.4)
Breast Sensation Changes	8 ( 1.5)	9 ( 1.6)	6 ( 1.1)	1 ( 0.2)
Granuloma	1 ( 0.2)			
Hematoma	12 ( 2.2)	1 ( 0.2)	1 ( 0.2)	
Infection	8 ( 1.5)	1 ( 0.2)		
Lymphadenopathy	1 ( 0.2)			
Necrosis				1 ( 0.2)
New Diagnosis of Rheumatic Disease			3 ( 0.5)	
Nipple Sensation Changes	31 ( 5.6)	34 ( 6.2)	30 ( 5.5)	11 ( 2.0)
Implant Malposition/Displacement		1 ( 0.2)		
Rupture			1 ( 0.2)	2 ( 0.4)
Seroma	4 ( 0.7)		1 ( 0.2)	
Lactation Difficulties				1 ( 0.2)
Breast Mass	1 ( 0.2)	2 ( 0.4)	9 ( 1.6)	3 ( 0.6)

Program Name: Q:\MENTOR\COREGEL\3YFAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Breast Rash	2 ( 0.4)		1 ( 0.2)	
External Injury Not Related To Breast Implants	2 ( 0.4)	2 ( 0.4)		2 ( 0.4)
Inflammation	2 ( 0.4)	1 ( 0.2)		
Miscarriage	2 ( 0.4)	3 ( 0.5)	1 ( 0.2)	
Patient Dissatisfied With Appearance		1 ( 0.2)	1 ( 0.2)	
Placement Damage	4 ( 0.7)			
Surgical Complications Related To Technique	4 ( 0.7)	1 ( 0.2)	1 ( 0.2)	
Suture Reaction	3 ( 0.5)	1 ( 0.2)		
Other	4 ( 0.7)	2 ( 0.4)	3 ( 0.5)	6 ( 1.1)
Anaphylaxis			1 ( 0.2)	
Deep Vein Thrombosis				1 ( 0.2)
Distortion Of Breast Shape Not Related To Capsular Contracture	1 ( 0.2)	1 ( 0.2)	1 ( 0.2)	1 ( 0.2)
Explanted Due To Right Side Being Removed				2 ( 0.4)
Miscarriage R / T Natural Causes 11 Wks Pregnant				1 ( 0.2)
Mondor's Disease	2 ( 0.4)			

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time. 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23 1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Positive Antinuclear Antibodies Negative For Lupus				1 ( 0.2)
Pt Requests Removal Due To Personal Reasons		1 ( 0.2)		
Rash	1 ( 0.2)			
Soft Mass Left Costal Margin			1 ( 0.2)	
Any Complication Excluding Cosmetic	99 (18.0)	72 (13.1)	73 (13.3)	37 ( 6.8)
II. Cosmetic Complication				
Asymmetry	3 ( 0.5)	2 ( 0.4)		
Hypertrophic Scarring	15 ( 2.7)	18 ( 3.3)	18 ( 3.3)	5 ( 0.9)
Ptosis	3 ( 0.5)	2 ( 0.4)	8 ( 1.5)	3 ( 0.6)
Size Change - Patient Request	6 ( 1.1)	5 ( 0.9)	2 ( 0.4)	2 ( 0.4)
Wrinkling	1 ( 0.2)	1 ( 0.2)	2 ( 0.4)	
Any Cosmetic Complication	25 ( 4.5)	26 ( 4.7)	28 ( 5.1)	10 ( 1.8)
III. Reoperations				
Explant Regardless of Replacement	6 ( 1.1)	5 ( 0.9)	8 ( 1.5)	6 ( 1.1)
Explant with Replacement with Study Device	4 ( 0.7)	4 ( 0.7)	5 ( 0.9)	2 ( 0.4)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Explant without Replacement	2 ( 0.4)	1 ( 0.2)	3 ( 0.5)	4 ( 0.7)
Other Reoperations	28 ( 5.1)	16 ( 2.9)	19 ( 3.5)	12 ( 2.2)
Biopsy	1 ( 0.2)	1 ( 0.2)	2 ( 0.4)	
Capsulectomy	8 ( 1.5)	7 ( 1.3)	8 ( 1.5)	4 ( 0.7)
Incision and Drainage	9 ( 1.6)	1 ( 0.2)	1 ( 0.2)	
Mastopexy			1 ( 0.2)	1 ( 0.2)
Capsulotomy	3 ( 0.5)	3 ( 0.5)	4 ( 0.7)	3 ( 0.6)
Implant Reposition	2 ( 0.4)		1 ( 0.2)	
Scar Revision	1 ( 0.2)	3 ( 0.5)	6 ( 1.1)	2 ( 0.4)
Skin Adjustment	2 ( 0.4)		1 ( 0.2)	2 ( 0.4)
Capsulorrhaphy	2 ( 0.4)	1 ( 0.2)		
Implant Pocket Revision			1 ( 0.2)	
Nipple Related Procedure (unplanned)		1 ( 0.2)		
Revision Of Wound Closure	3 ( 0.5)			
Other			1 ( 0.2)	1 ( 0.2)
Excise Breast Mass			1 ( 0.2)	1 ( 0.2)
Any Reoperation	32 ( 5.8)	20 ( 3.6)	23 ( 4.2)	14 ( 2.6)
Total Patients Assessed	551	551	549	543

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	61	52	41	19
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	9 ( 3.6)	11 ( 4.4)	8 ( 3.3)	2 ( 0.9)
Baker III Capsular Contracture	8 ( 3.2)	9 ( 3.6)	8 ( 3.3)	2 ( 0.9)
Baker IV Capsular Contracture	1 ( 0.4)	2 ( 0.8)		
Breast pain	2 ( 0.8)	1 ( 0.4)	1 ( 0.4)	
Breast Sensation Changes		1 ( 0.4)	1 ( 0.4)	
Delayed Wound Healing	1 ( 0.4)			
Extrusion	2 ( 0.8)	1 ( 0.4)		
Hematoma	2 ( 0.8)		1 ( 0.4)	1 ( 0.4)
Infection	9 ( 3.6)	2 ( 0.8)	3 ( 1.2)	
Lymphadenopathy				1 ( 0.4)
Necrosis	1 ( 0.4)			1 ( 0.4)
New Diagnosis of Rheumatic Disease		1 ( 0.4)		
Nipple Sensation Changes	2 ( 0.8)	3 ( 1.2)	2 ( 0.8)	1 ( 0.4)
Implant Malposition/Displacement	2 ( 0.8)	2 ( 0.8)	2 ( 0.8)	
Rupture			2 ( 0.8)	
Seroma	11 ( 4.4)		1 ( 0.4)	
Breast Mass	1 ( 0.4)	3 ( 1.2)	4 ( 1.6)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note. Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Breast Rash	1 ( 0.4)			
External Injury Not Related To Breast Implants	1 ( 0.4)			
Metastatic Disease	1 ( 0.4)		3 ( 1.2)	1 ( 0.4)
Miscarriage		2 ( 0.8)		
Patient Dissatisfied With Appearance		1 ( 0.4)		
Recurrent Breast Cancer	1 ( 0.4)	2 ( 0.8)	3 ( 1.2)	
Surgical Complications Related To Technique	3 ( 1.2)	2 ( 0.8)		
Other	8 ( 3.2)	4 ( 1.6)	4 ( 1.6)	2 ( 0.9)
Capsular Contracture Secondary To Radiation Therapy	1 ( 0.4)	1 ( 0.4)	1 ( 0.4)	
Cellulitis	1 ( 0.4)			
Deep Vein Thrombosis	1 ( 0.4)			
Distortion Of Breast Shape Not Related To Capsular Contracture		1 ( 0.4)		
Lack Of Projection			1 ( 0.4)	
Muscle Spasm	1 ( 0.4)	1 ( 0.4)		
Nipple Complications	1 ( 0.4)		1 ( 0.4)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Occasional Burning Discomfort Of Skin.				1 ( 0.4)
Pain - Sternum And Under Left Arm Intermittent	1 ( 0.4)			
Skin Lesion	1 ( 0.4)			
Stitch Abscess				1 ( 0.4)
Wide Scars	1 ( 0.4)	1 ( 0.4)	1 ( 0.4)	
Any Complication Excluding Cosmetic	43 (17.1)	32 (12.9)	31 (12.6)	9 ( 3.8)
II. Cosmetic Complication				
Asymmetry	7 ( 2.8)	10 ( 4.0)	3 ( 1.2)	3 ( 1.3)
Hypertrophic Scarring	8 ( 3.2)	9 ( 3.6)	5 ( 2.0)	1 ( 0.4)
Ptosis	1 ( 0.4)	1 ( 0.4)	4 ( 1.6)	4 ( 1.7)
Size Change - Patient Request	2 ( 0.8)	1 ( 0.4)	1 ( 0.4)	2 ( 0.9)
Size Change - Physician Assessment only	3 ( 1.2)	3 ( 1.2)	1 ( 0.4)	
Wrinkling	4 ( 1.6)	3 ( 1.2)		1 ( 0.4)
Any Cosmetic Complication	23 ( 9.2)	25 (10.0)	14 ( 5.7)	11 ( 4.7)
III. Reoperations				
Explant Regardless of Replacement	7 ( 2.8)	13 ( 5.2)	8 ( 3.3)	2 ( 0.9)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Explant with Replacement with Study Device	4 ( 1.6)	9 ( 3.6)	5 ( 2.0)	
Explant without Replacement	3 ( 1.2)	4 ( 1.6)	3 ( 1.2)	2 ( 0.9)
Other Reoperations	21 ( 8.4)	22 ( 8.8)	13 ( 5.3)	2 ( 0.9)
Biopsy	4 ( 1.6)	3 ( 1.2)	2 ( 0.8)	
Capsulectomy	3 ( 1.2)	3 ( 1.2)	3 ( 1.2)	
Incision and Drainage	3 ( 1.2)			1 ( 0.4)
Mastopexy	1 ( 0.4)		1 ( 0.4)	1 ( 0.4)
Capsulotomy	5 ( 2.0)	7 ( 2.8)	1 ( 0.4)	
Implant Reposition	4 ( 1.6)	6 ( 2.4)	3 ( 1.2)	
Scar Revision	1 ( 0.4)	2 ( 0.8)	2 ( 0.8)	
Skin Adjustment	4 ( 1.6)	5 ( 2.0)	1 ( 0.4)	
Capsulorrhaphy	2 ( 0.8)			
Implant Pocket Revision		3 ( 1.2)	1 ( 0.4)	
Nipple Related Procedure (unplanned)	1 ( 0.4)	1 ( 0.4)		
Revision Of Wound Closure		1 ( 0.4)		
Other	2 ( 0.8)	1 ( 0.4)	2 ( 0.8)	
Create Inframmary Fold	1 ( 0.4)	1 ( 0.4)		
Flap Coverage Of Expander			1 ( 0.4)	
Removal Of Nodule On Chest Wall	1 ( 0.4)			

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2. Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Revision Of Breast / External To Pocket			1 ( 0.4)	
Any Reoperation	25 (10.0)	27 (10.8)	16 ( 6.5)	4 ( 1.7)
Total Patients Assessed	251	249	246	234

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	54	46	56	23
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	18 ( 8.8)	20 ( 9.8)	16 ( 7.8)	7 ( 3.5)
Baker III Capsular Contracture	16 ( 7.8)	19 ( 9.3)	16 ( 7.8)	4 ( 2.0)
Baker IV Capsular Contracture	5 ( 2.4)	4 ( 2.0)	4 ( 2.0)	4 ( 2.0)
Breast pain	1 ( 0.5)	1 ( 0.5)	3 ( 1.5)	1 ( 0.5)
Breast Sensation Changes	2 ( 1.0)	2 ( 1.0)	3 ( 1.5)	1 ( 0.5)
Delayed Wound Healing	4 ( 2.0)			
Extrusion	2 ( 1.0)	1 ( 0.5)		
Granuloma	2 ( 1.0)	1 ( 0.5)		
Hematoma	5 ( 2.4)		1 ( 0.5)	
Infection	1 ( 0.5)		1 ( 0.5)	
New Diagnosis of Breast Cancer		1 ( 0.5)		
New Diagnosis of Rheumatic Disease		1 ( 0.5)		
Nipple Sensation Changes	9 ( 4.4)	9 ( 4.4)	11 ( 5.4)	3 ( 1.5)
Implant Malposition/Displacement	3 ( 1.5)	2 ( 1.0)	2 ( 1.0)	
Rupture			6 ( 2.9)	2 ( 1.0)
Seroma	4 ( 2.0)			
Lactation Difficulties			1 ( 0.5)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Breast Mass	4 ( 2.0)	3 ( 1.5)	5 ( 2.5)	2 ( 1.0)
External Injury Not Related To Breast Implants	1 ( 0.5)			1 ( 0.5)
Inflammation	1 ( 0.5)	2 ( 1.0)	1 ( 0.5)	1 ( 0.5)
Patient Dissatisfied With Appearance	1 ( 0.5)		2 ( 1.0)	
Recurrent Breast Cancer		1 ( 0.5)		
Surgical Complications Related To Technique	1 ( 0.5)	4 ( 2.0)	1 ( 0.5)	
Other	1 ( 0.5)	2 ( 1.0)	6 ( 2.9)	2 ( 1.0)
Abnormal Mammogram			1 ( 0.5)	1 ( 0.5)
Capsule Tear	1 ( 0.5)			
False Positive For Rupture On Mammogram				1 ( 0.5)
Muscle Spasm		1 ( 0.5)	1 ( 0.5)	
Nipple Related Unplanned			1 ( 0.5)	
Numbness In Both Hands At Night			1 ( 0.5)	
Siliconoma				1 ( 0.5)
Skin Lesion			1 ( 0.5)	
Surgical Removal Of Ectopic Pregnancy			1 ( 0.5)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Symmastia		1 ( 0.5)		
Any Complication Excluding Cosmetic	45 (22.0)	43 (21.1)	47 (23.0)	17 ( 8.5)
II. Cosmetic Complication				
Asymmetry	1 ( 0.5)	2 ( 1.0)	1 ( 0.5)	1 ( 0.5)
Hypertrophic Scarring	6 ( 2.9)	4 ( 2.0)	8 ( 3.9)	3 ( 1.5)
Ptosis	1 ( 0.5)	2 ( 1.0)	3 ( 1.5)	2 ( 1.0)
Size Change - Patient Request	2 ( 1.0)		3 ( 1.5)	1 ( 0.5)
Wrinkling	3 ( 1.5)	2 ( 1.0)	1 ( 0.5)	
Any Cosmetic Complication	13 ( 6.3)	10 ( 4.9)	15 ( 7.4)	6 ( 3.0)
III. Reoperations				
Explant Regardless of Replacement	5 ( 2.4)	6 ( 2.9)	7 ( 3.4)	6 ( 3.0)
Explant with Replacement with Study Device	3 ( 1.5)	5 ( 2.5)	4 ( 2.0)	2 ( 1.0)
Explant without Replacement	2 ( 1.0)	1 ( 0.5)	3 ( 1.5)	4 ( 2.0)
Other Reoperations	16 ( 7.8)	14 ( 6.9)	9 ( 4.4)	9 ( 4.5)
Biopsy	3 ( 1.5)	2 ( 1.0)	1 ( 0.5)	2 ( 1.0)
Capsulectomy	3 ( 1.5)	6 ( 2.9)	1 ( 0.5)	3 ( 1.5)
Incision and Drainage	5 ( 2.4)			

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
REVISION PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Mastopexy		2 ( 1.0)		1 ( 0.5)
Capsulotomy	2 ( 1.0)	6 ( 2.9)	2 ( 1.0)	1 ( 0.5)
Implant Reposition		2 ( 1.0)	2 ( 1.0)	1 ( 0.5)
Scar Revision	1 ( 0.5)	2 ( 1.0)	2 ( 1.0)	1 ( 0.5)
Skin Adjustment	2 ( 1.0)	3 ( 1.5)	2 ( 1.0)	
Capsulorrhaphy	1 ( 0.5)	1 ( 0.5)	1 ( 0.5)	
Nipple Related Procedure (unplanned)				1 ( 0.5)
Revision Of Wound Closure	2 ( 1.0)			
Other		1 ( 0.5)	2 ( 1.0)	2 ( 1.0)
Excision Of Skin Lesion		1 ( 0.5)		
Exploration Right Breast With Evacuation Of Hematoma			1 ( 0.5)	
Kenalog Injection			1 ( 0.5)	
Needle Aspiration				1 ( 0.5)
Open Incision To Rule Out Implant Rupture				1 ( 0.5)
Any Reoperation	21 (10.2)	15 ( 7.4)	13 ( 6.4)	10 ( 5.0)
Total Patients Assessed	205	204	204	199

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	231	192	193	87
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	51 ( 5.1)	53 ( 5.3)	50 ( 5.0)	22 ( 2.3)
Baker III Capsular Contracture	48 ( 4.8)	49 ( 4.9)	46 ( 4.6)	19 ( 1.9)
Baker IV Capsular Contracture	7 ( 0.7)	9 ( 0.9)	9 ( 0.9)	5 ( 0.5)
Breast pain	9 ( 0.9)	3 ( 0.3)	8 ( 0.8)	3 ( 0.3)
Breast Sensation Changes	10 ( 1.0)	12 ( 1.2)	10 ( 1.0)	2 ( 0.2)
Delayed Wound Healing	5 ( 0.5)			
Extrusion	4 ( 0.4)	2 ( 0.2)		
Granuloma	3 ( 0.3)	1 ( 0.1)		
Hematoma	19 ( 1.9)	1 ( 0.1)	3 ( 0.3)	1 ( 0.1)
Infection	18 ( 1.8)	3 ( 0.3)	4 ( 0.4)	
Lymphadenopathy	1 ( 0.1)			1 ( 0.1)
Necrosis	1 ( 0.1)			2 ( 0.2)
New Diagnosis of Breast Cancer		1 ( 0.1)		
New Diagnosis of Rheumatic Disease		2 ( 0.2)	3 ( 0.3)	
Nipple Sensation Changes	42 ( 4.2)	46 ( 4.6)	43 ( 4.3)	15 ( 1.5)
Implant Malposition/Displacement	5 ( 0.5)	5 ( 0.5)	4 ( 0.4)	
Rupture			9 ( 0.9)	4 ( 0.4)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23 1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Seroma	19 ( 1.9)		2 ( 0.2)	
Lactation Difficulties			1 ( 0.1)	1 ( 0.1)
Breast Mass	6 ( 0.6)	8 ( 0.8)	18 ( 1.8)	5 ( 0.5)
Breast Rash	3 ( 0.3)		1 ( 0.1)	
External Injury Not Related To Breast Implants	4 ( 0.4)	2 ( 0.2)		3 ( 0.3)
Inflammation	3 ( 0.3)	3 ( 0.3)	1 ( 0.1)	1 ( 0.1)
Metastatic Disease	1 ( 0.1)		3 ( 0.3)	1 ( 0.1)
Miscarriage	2 ( 0.2)	5 ( 0.5)	1 ( 0.1)	
Patient Dissatisfied With Appearance	1 ( 0.1)	2 ( 0.2)	3 ( 0.3)	
Placement Damage	4 ( 0.4)			
Recurrent Breast Cancer	1 ( 0.1)	3 ( 0.3)	3 ( 0.3)	
Surgical Complications Related To Technique	8 ( 0.8)	7 ( 0.7)	2 ( 0.2)	
Suture Reaction	3 ( 0.3)	1 ( 0.1)		
Other	13 ( 1.3)	8 ( 0.8)	13 ( 1.3)	10 ( 1.0)
Abnormal Mammogram			1 ( 0.1)	1 ( 0.1)
Anaphylaxis			1 ( 0.1)	
Capsular Contracture Secondary To Radiation Therapy	1 ( 0.1)	1 ( 0.1)	1 ( 0.1)	

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Capsule Tear	1 ( 0.1)			
Cellulitis	1 ( 0.1)			
Deep Vein Thrombosis	1 ( 0.1)			1 ( 0.1)
Distortion Of Breast Shape Not Related To Capsular Contracture	1 ( 0.1)	2 ( 0.2)	1 ( 0.1)	1 ( 0.1)
Explanted Due To Right Side Being Removed				2 ( 0.2)
False Positive For Rupture On Mammogram				1 ( 0.1)
Lack Of Projection			1 ( 0.1)	
Miscarriage R / T Natural Causes 11 Wks Pregnant				1 ( 0.1)
Mondor's Disease	2 ( 0.2)			
Muscle Spasm	1 ( 0.1)	2 ( 0.2)	1 ( 0.1)	
Nipple Complications	1 ( 0.1)		1 ( 0.1)	
Nipple Related Unplanned			1 ( 0.1)	
Numbness In Both Hands At Night			1 ( 0.1)	
Occasional Burning Discomfort Of Skin.				1 ( 0.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Pain - Sternum And Under Left Arm Intermittent	1 ( 0.1)			
Positive Antinuclear Antibodies Negative For Lupus				1 ( 0.1)
Pt Requests Removal Due To Personal Reasons		1 ( 0.1)		
Rash	1 ( 0.1)			
Siliconoma				1 ( 0.1)
Skin Lesion	1 ( 0.1)		1 ( 0.1)	
Soft Mass Left Costal Margin			1 ( 0.1)	
Stitch Abscess				1 ( 0.1)
Surgical Removal Of Ectopic Pregnancy			1 ( 0.1)	
Symmastia		1 ( 0.1)		
Wide Scars	1 ( 0.1)	1 ( 0.1)	1 ( 0.1)	
Any Complication Excluding Cosmetic	187 (18.6)	147 (14.6)	151 (15.1)	63 ( 6.5)
II. Cosmetic Complication				
Asymmetry	11 ( 1.1)	14 ( 1.4)	4 ( 0.4)	4 ( 0.4)
Hypertrophic Scarring	29 ( 2.9)	31 ( 3.1)	31 ( 3.1)	9 ( 0.9)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Ptoxis	5 ( 0.5)	5 ( 0.5)	15 ( 1.5)	9 ( 0.9)
Size Change - Patient Request	10 ( 1.0)	6 ( 0.6)	6 ( 0.6)	5 ( 0.5)
Size Change - Physician Assessment only	3 ( 0.3)	3 ( 0.3)	1 ( 0.1)	
Wrinkling	8 ( 0.8)	6 ( 0.6)	3 ( 0.3)	1 ( 0.1)
Any Cosmetic Complication	61 ( 6.1)	61 ( 6.1)	57 ( 5.7)	27 ( 2.8)
III. Reoperations				
Explant Regardless of Replacement	18 ( 1.8)	24 ( 2.4)	23 ( 2.3)	14 ( 1.4)
Explant with Replacement with Study Device	11 ( 1.1)	18 ( 1.8)	14 ( 1.4)	4 ( 0.4)
Explant without Replacement	7 ( 0.7)	6 ( 0.6)	9 ( 0.9)	10 ( 1.0)
Other Reoperations	65 ( 6.5)	52 ( 5.2)	41 ( 4.1)	23 ( 2.4)
Biopsy	8 ( 0.8)	6 ( 0.6)	5 ( 0.5)	2 ( 0.2)
Capsulectomy	14 ( 1.4)	16 ( 1.6)	12 ( 1.2)	7 ( 0.7)
Incision and Drainage	17 ( 1.7)	1 ( 0.1)	1 ( 0.1)	1 ( 0.1)
Mastopexy	1 ( 0.1)	2 ( 0.2)	2 ( 0.2)	3 ( 0.3)
Capsulotomy	10 ( 1.0)	16 ( 1.6)	7 ( 0.7)	4 ( 0.4)
Implant Reposition	6 ( 0.6)	8 ( 0.8)	6 ( 0.6)	1 ( 0.1)
Scar Revision	3 ( 0.3)	7 ( 0.7)	10 ( 1.0)	3 ( 0.3)
Skin Adjustment	8 ( 0.8)	8 ( 0.8)	4 ( 0.4)	2 ( 0.2)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29.JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Capsulorrhaphy	5 ( 0.5)	2 ( 0.2)	1 ( 0.1)	
Implant Pocket Revision		3 ( 0.3)	2 ( 0.2)	
Nipple Related Procedure (unplanned)	1 ( 0.1)	2 ( 0.2)		1 ( 0.1)
Revision Of Wound Closure	5 ( 0.5)	1 ( 0.1)		
Other	2 ( 0.2)	2 ( 0.2)	5 ( 0.5)	3 ( 0.3)
Create Inframmary Fold	1 ( 0.1)	1 ( 0.1)		
Excise Breast Mass			1 ( 0.1)	1 ( 0.1)
Excision Of Skin Lesion		1 ( 0.1)		
Exploration Right Breast With Evacuation Of Hematoma			1 ( 0.1)	
Flap Coverage Of Expander			1 ( 0.1)	
Kenalog Injection			1 ( 0.1)	
Needle Aspiration				1 ( 0.1)
Open Incision To Rule Out Implant Rupture				1 ( 0.1)
Removal Of Nodule On Chest Wall	1 ( 0.1)			
Revision Of Breast / External To Pocket			1 ( 0.1)	
Any Reoperation	78 ( 7.7)	62 ( 6.2)	52 ( 5.2)	28 ( 2.9)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.1

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (PATIENT LEVEL)  
OVERALL PATIENTS

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Total Patients Assessed	1007	1004	999	976

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	156	132	130	59
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	30 ( 2.7)	30 ( 2.7)	32 ( 2.9)	16 ( 1.5)
Baker III Capsular Contracture	29 ( 2.6)	27 ( 2.5)	28 ( 2.6)	16 ( 1.5)
Baker IV Capsular Contracture	1 ( 0.1)	4 ( 0.4)	5 ( 0.5)	2 ( 0.2)
Breast pain	9 ( 0.8)	1 ( 0.1)	5 ( 0.5)	2 ( 0.2)
Breast Sensation Changes	11 ( 1.0)	13 ( 1.2)	8 ( 0.7)	2 ( 0.2)
Granuloma	1 ( 0.1)			
Hematoma	12 ( 1.1)	1 ( 0.1)	1 ( 0.1)	
Infection	8 ( 0.7)	1 ( 0.1)		
Lymphadenopathy	1 ( 0.1)			
Necrosis				2 ( 0.2)
Nipple Sensation Changes	47 ( 4.3)	50 ( 4.5)	42 ( 3.8)	16 ( 1.5)
Implant Malposition/Displacement		1 ( 0.1)		
Rupture			1 ( 0.1)	2 ( 0.2)
Seroma	5 ( 0.5)		1 ( 0.1)	
Lactation Difficulties				1 ( 0.1)
Breast Mass	1 ( 0.1)	2 ( 0.2)	9 ( 0.8)	3 ( 0.3)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Breast Rash	3 ( 0.3)		1 ( 0.1)	
External Injury Not Related To Breast Implants	3 ( 0.3)	2 ( 0.2)		2 ( 0.2)
Inflammation	2 ( 0.2)	1 ( 0.1)		
Patient Dissatisfied With Appearance		2 ( 0.2)	2 ( 0.2)	
Placement Damage	4 ( 0.4)			
Surgical Complications Related To Technique	6 ( 0.5)	2 ( 0.2)	1 ( 0.1)	
Suture Reaction	4 ( 0.4)	2 ( 0.2)		
Other	4 ( 0.4)	3 ( 0.3)	2 ( 0.2)	3 ( 0.3)
Distortion Of Breast Shape Not Related To Capsular Contracture	1 ( 0.1)	1 ( 0.1)	1 ( 0.1)	1 ( 0.1)
Explanted Due To Right Side Being Removed				2 ( 0.2)
Mondor's Disease	3 ( 0.3)			
Pt Requests Removal Due To Personal Reasons		2 ( 0.2)		
Soft Mass Left Costal Margin			1 ( 0.1)	
Any Complication Excluding Cosmetic	129 (11.7)	99 ( 9.0)	90 ( 8.2)	47 ( 4.3)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
<b>II. Cosmetic Complication</b>				
Asymmetry	4 ( 0.4)	2 ( 0.2)		
Hypertrophic Scarring	21 ( 1.9)	24 ( 2.2)	27 ( 2.5)	7 ( 0.6)
Ptosis	5 ( 0.5)	3 ( 0.3)	14 ( 1.3)	5 ( 0.5)
Size Change - Patient Request	11 ( 1.0)	10 ( 0.9)	4 ( 0.4)	4 ( 0.4)
Wrinkling	1 ( 0.1)	2 ( 0.2)	3 ( 0.3)	
Any Cosmetic Complication	38 ( 3.5)	38 ( 3.5)	45 ( 4.1)	16 ( 1.5)
<b>III. Reoperations</b>				
Explant Regardless of Replacement	9 ( 0.8)	9 ( 0.8)	12 ( 1.1)	11 ( 1.0)
Explant with Replacement with Study Device	7 ( 0.6)	7 ( 0.6)	6 ( 0.5)	4 ( 0.4)
Explant without Replacement	2 ( 0.2)	2 ( 0.2)	6 ( 0.5)	7 ( 0.6)
Other Reoperations	33 ( 3.0)	20 ( 1.8)	27 ( 2.5)	15 ( 1.4)
Biopsy	1 ( 0.1)	1 ( 0.1)	2 ( 0.2)	
Capsulectomy	10 ( 0.9)	8 ( 0.7)	11 ( 1.0)	5 ( 0.5)
Incision and Drainage	9 ( 0.8)	1 ( 0.1)	1 ( 0.1)	
Mastopexy			2 ( 0.2)	2 ( 0.2)
Capsulotomy	3 ( 0.3)	5 ( 0.5)	6 ( 0.5)	3 ( 0.3)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Implant Reposition	2 ( 0.2)		2 ( 0.2)	
Scar Revision	1 ( 0.1)	4 ( 0.4)	10 ( 0.9)	3 ( 0.3)
Skin Adjustment	3 ( 0.3)		2 ( 0.2)	3 ( 0.3)
Capsulorrhaphy	3 ( 0.3)	1 ( 0.1)		
Implant Pocket Revision			2 ( 0.2)	
Nipple Related Procedure (unplanned)		1 ( 0.1)		
Revision Of Wound Closure	3 ( 0.3)			
Other			1 ( 0.1)	1 ( 0.1)
Excise Breast Mass			1 ( 0.1)	1 ( 0.1)
Any Reoperation	40 ( 3.6)	28 ( 2.5)	35 ( 3.2)	20 ( 1.8)
Total Implants Assessed	1100	1100	1096	1084

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	74	59	46	27
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	9 ( 2.2)	12 ( 2.9)	9 ( 2.2)	2 ( 0.5)
Baker III Capsular Contracture	8 ( 2.0)	10 ( 2.5)	9 ( 2.2)	2 ( 0.5)
Baker IV Capsular Contracture	1 ( 0.2)	2 ( 0.5)		
Breast pain	3 ( 0.7)	1 ( 0.2)	1 ( 0.2)	
Breast Sensation Changes		2 ( 0.5)	1 ( 0.2)	
Delayed Wound Healing	2 ( 0.5)			
Extrusion	2 ( 0.5)	1 ( 0.2)		
Hematoma	2 ( 0.5)		1 ( 0.2)	1 ( 0.3)
Infection	9 ( 2.2)	2 ( 0.5)	3 ( 0.7)	
Lymphadenopathy				1 ( 0.3)
Necrosis	1 ( 0.2)			1 ( 0.3)
Nipple Sensation Changes	3 ( 0.7)	3 ( 0.7)	2 ( 0.5)	1 ( 0.3)
Implant Malposition/Displacement	2 ( 0.5)	2 ( 0.5)	3 ( 0.7)	
Rupture			2 ( 0.5)	
Seroma	11 ( 2.7)		1 ( 0.2)	
Breast Mass	1 ( 0.2)	3 ( 0.7)	4 ( 1.0)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Breast Rash	2 ( 0.5)			
External Injury Not Related To Breast Implants	1 ( 0.2)			
Metastatic Disease				2 ( 0.5)
Patient Dissatisfied With Appearance		2 ( 0.5)		
Recurrent Breast Cancer	2 ( 0.5)	3 ( 0.7)	3 ( 0.7)	
Surgical Complications Related To Technique	4 ( 1.0)	2 ( 0.5)		
Other	6 ( 1.5)	3 ( 0.7)	4 ( 1.0)	3 ( 0.8)
Capsular Contracture Secondary To Radiation Therapy	1 ( 0.2)	1 ( 0.2)	1 ( 0.2)	
Cellulitis	1 ( 0.2)			
Distortion Of Breast Shape Not Related To Capsular Contracture		1 ( 0.2)		
Lack Of Projection			1 ( 0.2)	
Muscle Spasm	1 ( 0.2)	1 ( 0.2)		
Nipple Complications	1 ( 0.2)		2 ( 0.5)	
Occasional Burning Discomfort Of Skin.				2 ( 0.5)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Pain - Sternum And Under Left Arm Intermittent	1 ( 0.2)			
Skin Lesion Stitch Abscess	1 ( 0.2)			1 ( 0.3)
Any Complication Excluding Cosmetic	48 (11.7)	33 ( 8.1)	31 ( 7.7)	11 ( 2.9)
II. Cosmetic Complication				
Asymmetry	7 ( 1.7)	10 ( 2.5)	4 ( 1.0)	4 ( 1.0)
Hypertrophic Scarring	9 ( 2.2)	10 ( 2.5)	5 ( 1.2)	2 ( 0.5)
Ptosis	2 ( 0.5)	2 ( 0.5)	6 ( 1.5)	6 ( 1.6)
Size Change - Patient Request	3 ( 0.7)	1 ( 0.2)	1 ( 0.2)	4 ( 1.0)
Size Change - Physician Assessment only	5 ( 1.2)	5 ( 1.2)	2 ( 0.5)	
Wrinkling	5 ( 1.2)	3 ( 0.7)		1 ( 0.3)
Any Cosmetic Complication	29 ( 7.1)	29 ( 7.1)	18 ( 4.5)	17 ( 4.4)
III. Reoperations				
Explant Regardless of Replacement	10 ( 2.4)	16 ( 3.9)	9 ( 2.2)	4 ( 1.0)
Explant with Replacement with Study Device	7 ( 1.7)	10 ( 2.5)	6 ( 1.5)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12.21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Explant without Replacement	3 ( 0.7)	6 ( 1.5)	3 ( 0.7)	4 ( 1.0)
Other Reoperations	26 ( 6.3)	25 ( 6.1)	18 ( 4.5)	2 ( 0.5)
Biopsy	5 ( 1.2)	3 ( 0.7)	2 ( 0.5)	
Capsulectomy	3 ( 0.7)	4 ( 1.0)	3 ( 0.7)	
Incision and Drainage	3 ( 0.7)			1 ( 0.3)
Mastopexy	1 ( 0.2)		2 ( 0.5)	1 ( 0.3)
Capsulotomy	6 ( 1.5)	7 ( 1.7)	1 ( 0.2)	
Implant Reposition	6 ( 1.5)	6 ( 1.5)	5 ( 1.2)	
Scar Revision	2 ( 0.5)	2 ( 0.5)	3 ( 0.7)	
Skin Adjustment	6 ( 1.5)	6 ( 1.5)	2 ( 0.5)	
Capsulorrhaphy	2 ( 0.5)			
Implant Pocket Revision		4 ( 1.0)	2 ( 0.5)	
Nipple Related Procedure (unplanned)	1 ( 0.2)	1 ( 0.2)		
Revision Of Wound Closure		1 ( 0.2)		
Other	3 ( 0.7)	1 ( 0.2)	3 ( 0.7)	
Create Inframmary Fold	1 ( 0.2)	1 ( 0.2)		
Flap Coverage Of Expander			1 ( 0.2)	
Removal Of Nodule On Chest Wall	2 ( 0.5)			

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Revision Of Breast / External To Pocket			2 ( 0.5)	
Any Reoperation	32 ( 7.8)	33 ( 8.1)	21 ( 5.2)	6 ( 1.6)
Total Implants Assessed	410	407	401	383

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: 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 23.2

PREVALENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS BY TIME PERIOD (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Type of Complication or Reoperation	Prevalence (1) at Each Time Period			
	<=6 Months	>6 - <=12 Months	>12 - <=24 Months	>24 - <=36 Months
	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)	Number With Event n(%)
Any Complication	76	66	79	30
I. Complication Excluding Cosmetic				
Baker III, IV Capsular Contracture	22 ( 5.7)	29 ( 7.6)	18 ( 4.7)	10 ( 2.7)
Baker III Capsular Contracture	17 ( 4.4)	26 ( 6.8)	16 ( 4.2)	5 ( 1.3)
Baker IV Capsular Contracture	5 ( 1.3)	5 ( 1.3)	5 ( 1.3)	5 ( 1.3)
Breast pain	1 ( 0.3)	1 ( 0.3)	4 ( 1.0)	1 ( 0.3)
Breast Sensation Changes	3 ( 0.8)	3 ( 0.8)	4 ( 1.0)	1 ( 0.3)
Delayed Wound Healing	5 ( 1.3)			
Extrusion	2 ( 0.5)	1 ( 0.3)		
Granuloma	2 ( 0.5)	1 ( 0.3)		
Hematoma	6 ( 1.6)		1 ( 0.3)	
Infection	1 ( 0.3)		1 ( 0.3)	
New Diagnosis of Breast Cancer		1 ( 0.3)		
Nipple Sensation Changes	15 ( 3.9)	15 ( 3.9)	15 ( 3.9)	4 ( 1.1)
Implant Malposition/Displacement	5 ( 1.3)	3 ( 0.8)	3 ( 0.8)	
Rupture			8 ( 2.1)	3 ( 0.8)
Seroma	4 ( 1.0)			
Lactation Difficulties			2 ( 0.5)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T23.SAS

Creation Date, Time: 29JUL04 12:21

(1) Defined as a patient having the complication or reoperation in question during each specific time period, regardless of whether the event was newly reported during the specific time period.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Note 3: Implant counts exclude events where breast side = N/A.