

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
REVISION PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	10	0.1393	(0.0591,0.2195)
Baker IV Capsular Contracture	2	0.0354	( 0,0.0851)
Baker III, IV Capsular Contracture	10	0.1391	( 0.059,0.2192)
Wrinkling	0	0.0000	( 0, 0)
Total Patients Assessed	75	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8 7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
REVISION PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0526	( 0, 0.153)	3	0.1579	( 0,0.3219)	4	0.2105	(0.0272,0.3938)
Baker IV Capsular Contracture	1	0.0526	( 0, 0.153)	1	0.0526	( 0, 0.153)	1	0.0526	( 0, 0.153)
Baker III, IV Capsular Contracture	2	0.1053	( 0,0.2433)	3	0.1579	( 0,0.3219)	4	0.2105	(0.0272,0.3938)
Wrinkling	1	0.0526	( 0, 0.153)	1	0.0526	( 0, 0.153)	1	0.0526	( 0, 0.153)
Total Patients Assessed	19	N/A	N/A	19	N/A	N/A	19	N/A	N/A

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Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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.

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REVISION PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	4	0.2105	(0.0272,0.3938)
Baker IV Capsular Contracture	1	0.0526	( 0, 0.153)
Baker III, IV Capsular Contracture	4	0.2105	(0.0272,0.3938)
Wrinkling	1	0.0526	( 0, 0.153)
Total Patients Assessed	19	N/A	N/A

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

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CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
REVISION PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	4	0.1958	(0.0234,0.3681)	5	0.2460	(0.0584,0.4337)	5	0.2460	(0.0584,0.4337)
Baker IV Capsular Contracture	1	0.0476	( 0,0.1387)	1	0.0476	( 0,0.1387)	1	0.0476	( 0,0.1387)
Baker III, IV Capsular Contracture	4	0.1958	(0.0234,0.3681)	5	0.2460	(0.0584,0.4337)	5	0.2460	(0.0584,0.4337)
Wrinkling	1	0.0500	( 0,0.1455)	1	0.0500	( 0,0.1455)	2	0.1000	( 0,0.2315)
Total Patients Assessed	21	N/A	N/A	21	N/A	N/A	21	N/A	N/A

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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.

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REVISION PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	5	0.2460	(0.0584,0.4337)
Baker IV Capsular Contracture	1	0.0476	( 0,0.1387)
Baker III, IV Capsular Contracture	5	0.2460	(0.0584,0.4337)
Wrinkling	2	0.1000	( 0,0.2315)
Total Patients Assessed	21	N/A	N/A

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

(b) Based on Kaplan-Meier Estimates.

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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 8.7.5

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REVISION PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0526	( 0,0.1236)	3	0.0797	( 0,0.1662)	3	0.0797	( 0,0.1662)
Baker IV Capsular Contracture	1	0.0263	( 0,0.0772)	2	0.0534	( 0,0.1253)	2	0.0534	( 0,0.1253)
Baker III, IV Capsular Contracture	3	0.0789	( 0,0.1647)	4	0.1060	(0.0077,0.2043)	4	0.1060	(0.0077,0.2043)
Wrinkling	1	0.0263	( 0,0.0772)	1	0.0263	( 0,0.0772)	1	0.0263	( 0,0.0772)
Total Patients Assessed	38	N/A	N/A	38	N/A	N/A	38	N/A	N/A

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(b) Based on Kaplan-Meier Estimates.

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REVISION PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.1000	( 0,0.2859)	1	0.1000	( 0,0.2859)	1	0.1000	( 0,0.2859)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	1	0.1000	( 0,0.2859)	1	0.1000	( 0,0.2859)	1	0.1000	( 0,0.2859)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Patients Assessed	10	N/A	N/A	10	N/A	N/A	10	N/A	N/A

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REVISION PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.1000	( 0,0.2859)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	1	0.1000	( 0,0.2859)
Wrinkling	0	0.0000	( 0, 0)
Total Patients Assessed	10	N/A	N/A

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CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
REVISION PATIENTS  
TEXTURED SURFACE  
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Patients Assessed	1	N/A	N/A	1	N/A	N/A	1	N/A	N/A

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REVISION PATIENTS  
TEXTURED SURFACE  
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)
Total Patients Assessed	1	N/A	N/A

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Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - OTHER

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	1	0.1250	( 0,0.3542)	1	0.1250	( 0,0.3542)	1	0.1250	( 0,0.3542)
Total Patients Assessed	8	N/A	N/A	8	N/A	N/A	8	N/A	N/A

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OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - OTHER

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	1	0.1250	( 0,0.3542)
Total Patients Assessed	8	N/A	N/A

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OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	12	0.0933	(0.0431,0.1436)	16	0.1246	(0.0675,0.1817)	23	0.1833	(0.1154,0.2512)
Baker IV Capsular Contracture	1	0.0078	( 0,0.0229)	1	0.0078	( 0,0.0229)	4	0.0320	(0.0011,0.0628)
Baker III, IV Capsular Contracture	12	0.0933	( 0.043,0.1435)	16	0.1245	(0.0674,0.1817)	23	0.1832	(0.1153,0.2511)
Wrinkling	0	0.0000	( 0, 0)	1	0.0078	( 0,0.0231)	1	0.0078	( 0,0.0231)
Total Patients Assessed	130	N/A	N/A	130	N/A	N/A	130	N/A	N/A

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OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	25	0.2050	(0.1325,0.2775)
Baker IV Capsular Contracture	6	0.0644	(0.0099,0.1189)
Baker III, IV Capsular Contracture	26	0.2165	(0.1416,0.2914)
Wrinkling	1	0.0078	( 0,0.0231)
Total Patients Assessed	130	N/A	N/A

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(b) Based on Kaplan-Meier Estimates.

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OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	15	0.0466	(0.0236,0.0696)	22	0.0687	( 0.041,0.0964)	26	0.0824	( 0.052,0.1128)
Baker IV Capsular Contracture	1	0.0031	( 0,0.0092)	1	0.0031	( 0,0.0092)	2	0.0064	( 0,0.0152)
Baker III, IV Capsular Contracture	15	0.0466	(0.0235,0.0696)	22	0.0687	( 0.041,0.0964)	27	0.0856	(0.0547,0.1166)
Wrinkling	2	0.0062	( 0,0.0149)	3	0.0094	( 0,0.0199)	3	0.0094	( 0,0.0199)
Total Patients Assessed	325	N/A	N/A	325	N/A	N/A	325	N/A	N/A

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OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	27	0.0866	(0.0553, 0.118)
Baker IV Capsular Contracture	3	0.0109	( 0,0.0234)
Baker III, IV Capsular Contracture	28	0.0899	( 0.058,0.1218)
Wrinkling	3	0.0094	( 0,0.0199)
Total Patients Assessed	325	N/A	N/A

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OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	10	0.0639	(0.0256,0.1022)	12	0.0771	(0.0352,0.1189)	13	0.0839	(0.0402,0.1276)
Baker IV Capsular Contracture	2	0.0128	(0.0000,0.0305)	3	0.0194	(0.0000,0.0411)	3	0.0194	(0.0000,0.0411)
Baker III, IV Capsular Contracture	11	0.0702	(0.0302,0.1103)	12	0.0768	(0.0351,0.1186)	13	0.0837	(0.0401,0.1273)
Wrinkling	2	0.0128	(0.0000,0.0305)	2	0.0128	(0.0000,0.0305)	2	0.0128	(0.0000,0.0305)
Total Patients Assessed	157	N/A	N/A	157	N/A	N/A	157	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	13	0.0839	(0.0402,0.1276)
Baker IV Capsular Contracture	3	0.0194	( 0,0.0411)
Baker III, IV Capsular Contracture	13	0.0837	(0.0401,0.1273)
Wrinkling	2	0.0128	( 0,0.0305)
Total Patients Assessed	157	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
SMOOTH SURFACE  
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Patients Assessed	4	N/A	N/A	4	N/A	N/A	4	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
SMOOTH SURFACE  
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)
Total Patients Assessed	4	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0433	(0.0094,0.0771)	9	0.0655	(0.0241,0.1068)	10	0.0729	(0.0294,0.1164)
Baker IV Capsular Contracture	2	0.0144	(0,0.0343)	2	0.0144	(0,0.0343)	2	0.0144	(0,0.0343)
Baker III, IV Capsular Contracture	7	0.0505	(0.0141, 0.087)	10	0.0727	(0.0293,0.1161)	11	0.0801	(0.0347,0.1256)
Wrinkling	2	0.0144	(0,0.0343)	2	0.0144	(0,0.0343)	5	0.0365	(0.0051,0.0679)
Total Patients Assessed	139	N/A	N/A	139	N/A	N/A	139	N/A	N/A

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	10	0.0729	(0.0294,0.1164)
Baker IV Capsular Contracture	2	0.0144	( 0,0.0343)
Baker III, IV Capsular Contracture	11	0.0801	(0.0347,0.1256)
Wrinkling	5	0.0365	(0.0051,0.0679)
Total Patients Assessed	139	N/A	N/A

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\TO8\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	4	0.0229	(0.0007, 0.045)	8	0.0461	(0.0149, 0.0773)	12	0.0708	(0.0321, 0.1095)
Baker IV Capsular Contracture	1	0.0057	(0, 0.0168)	4	0.0233	(0.0007, 0.0458)	4	0.0233	(0.0007, 0.0458)
Baker III, IV Capsular Contracture	5	0.0285	(0.0039, 0.0532)	11	0.0634	(0.0272, 0.0997)	15	0.0882	(0.0455, 0.1309)
Wrinkling	1	0.0057	(0, 0.0168)	1	0.0057	(0, 0.0168)	1	0.0057	(0, 0.0168)
Total Patients Assessed	176	N/A	N/A	176	N/A	N/A	176	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	12	0.0708	(0.0321,0.1095)
Baker IV Capsular Contracture	4	0.0233	(0.0007,0.0458)
Baker III, IV Capsular Contracture	15	0.0882	(0.0455,0.1309)
Wrinkling	2	0.0151	( 0,0.0364)
Total Patients Assessed	176	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0154	( 0,0.0453)	1	0.0154	( 0,0.0453)	2	0.0308	( 0,0.0728)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	1	0.0154	( 0,0.0453)
Baker III, IV Capsular Contracture	1	0.0154	( 0,0.0453)	1	0.0154	( 0,0.0453)	3	0.0462	( 0,0.0972)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Patients Assessed	65	N/A	N/A	65	N/A	N/A	65	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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.

Table 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	3	0.0481	( 0,0.1013)
Baker IV Capsular Contracture	1	0.0154	( 0,0.0453)
Baker III, IV Capsular Contracture	4	0.0635	(0.0031,0.1238)
Wrinkling	0	0.0000	( 0, 0)
Total Patients Assessed	65	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Patients Assessed	3	N/A	N/A	3	N/A	N/A	3	N/A	N/A

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.5

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (PATIENT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL PATIENTS  
TEXTURED SURFACE  
MIXED OR UNKNOWN DEVICE PLACEMENTS

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)
Total Patients Assessed	3	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_5.SAS

Creation Date, Time: 24AUG04 08:55

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	8	0.0465	( 0.015, 0.078)	12	0.0698	(0.0317,0.1078)	21	0.1245	(0.0745,0.1744)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	1	0.0059	( 0,0.0174)
Baker III, IV Capsular Contracture	8	0.0465	( 0.015, 0.078)	12	0.0698	(0.0317,0.1078)	21	0.1245	(0.0745,0.1744)
Wrinkling	0	0.0000	( 0, 0)	2	0.0116	( 0,0.0276)	2	0.0116	( 0,0.0276)
Total Implants Assessed	172	N/A	N/A	172	N/A	N/A	172	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	25	0.1572	(0.0997,0.2146)
Baker IV Capsular Contracture	3	0.0328	( 0,0.0711)
Baker III, IV Capsular Contracture	25	0.1572	(0.0997,0.2146)
Wrinkling	2	0.0116	( 0,0.0276)
Total Implants Assessed	172	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time. 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	8	0.0213	(0.0067,0.0359)	12	0.0320	(0.0142,0.0498)	13	0.0349	(0.0162,0.0535)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	1	0.0027	( 0,0.0081)
Baker III, IV Capsular Contracture	8	0.0213	(0.0067,0.0359)	12	0.0320	(0.0142,0.0498)	14	0.0376	(0.0183,0.0569)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	376	N/A	N/A	376	N/A	N/A	376	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6 SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: Implant counts exclude events where breast side = N/A.

Table 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	13	0.0349	(0.0162,0.0535)
Baker IV Capsular Contracture	1	0.0027	( 0,0.0081)
Baker III, IV Capsular Contracture	14	0.0376	(0.0183,0.0569)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	376	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 24AUG04 08:54

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: Implant counts exclude events where breast side = N/A.

Table 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	11	0.0470	(0.0199,0.0741)	11	0.0470	(0.0199,0.0741)	11	0.0470	(0.0199,0.0741)
Baker IV Capsular Contracture	1	0.0043	( 0,0.0127)	3	0.0130	( 0,0.0277)	3	0.0130	( 0,0.0277)
Baker III, IV Capsular Contracture	12	0.0513	( 0.023,0.0795)	13	0.0556	(0.0262, 0.085)	13	0.0556	(0.0262, 0.085)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	235	N/A	N/A	235	N/A	N/A	235	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8 7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	11	0.0470	(0.0199,0.0741)
Baker IV Capsular Contracture	3	0.0130	( 0,0.0277)
Baker III, IV Capsular Contracture	13	0.0556	(0.0262, 0.085)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	235	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0100	( 0,0.0237)	4	0.0202	(0.0006,0.0397)	6	0.0304	(0.0064,0.0544)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	2	0.0100	( 0,0.0237)	4	0.0202	(0.0006,0.0397)	6	0.0304	(0.0064,0.0544)
Wrinkling	1	0.0050	( 0,0.0147)	1	0.0050	( 0,0.0147)	4	0.0203	(0.0006, 0.04)
Total Implants Assessed	201	N/A	N/A	201	N/A	N/A	201	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0304	(0.0064,0.0544)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	6	0.0304	(0.0064,0.0544)
Wrinkling	4	0.0203	(0.0006, 0.04)
Total Implants Assessed	201	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7 6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	1	0.0106	( 0,0.0314)	1	0.0106	( 0,0.0314)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	1	0.0106	( 0,0.0314)	1	0.0106	( 0,0.0314)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	96	N/A	N/A	96	N/A	N/A	96	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	1	0.0106	( 0,0.0314)
Baker III, IV Capsular Contracture	1	0.0106	( 0,0.0314)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	96	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	1	0.0213	( 0,0.0625)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	1	0.0213	( 0,0.0625)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	2	0.0426	( 0,0.1003)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	47	N/A	N/A	47	N/A	N/A	47	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR AUGMENTATION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0213	( 0,0.0625)
Baker IV Capsular Contracture	1	0.0213	( 0,0.0625)
Baker III, IV Capsular Contracture	2	0.0426	( 0,0.1003)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	47	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2. 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - OTHER

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	1	0.1111	( 0,0.3164)	1	0.1111	( 0,0.3164)	1	0.1111	( 0,0.3164)
Total Implants Assessed	9	N/A	N/A	9	N/A	N/A	9	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - OTHER

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	1	0.1111	( 0,0.3164)
Total Implants Assessed	9	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 24AUG04 08:54

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	7	N/A	N/A	7	N/A	N/A	7	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08.54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	7	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7 6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	5	0.0507	(0.0074, 0.094)	5	0.0507	(0.0074, 0.094)	5	0.0507	(0.0074, 0.094)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	5	0.0507	(0.0074, 0.094)	5	0.0507	(0.0074, 0.094)	5	0.0507	(0.0074, 0.094)
Wrinkling	3	0.0304	( 0,0.0643)	4	0.0409	(0.0016,0.0801)	4	0.0409	(0.0016,0.0801)
Total Implants Assessed	101	N/A	N/A	101	N/A	N/A	101	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: Implant counts exclude events where breast side = N/A.

Table 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0727	(0.0126,0.1329)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	6	0.0727	(0.0126,0.1329)
Wrinkling	4	0.0409	(0.0016,0.0801)
Total Implants Assessed	101	N/A	N/A

Program Name: Q \MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

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

(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 24AUG04 08:54

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8 7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0263	( 0,0 0772)	2	0.0550	( 0,0.1291)	2	0.0550	( 0,0.1291)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	1	0.0263	( 0,0.0772)	2	0.0550	( 0,0.1291)	2	0.0550	( 0,0.1291)
Wrinkling	2	0.0526	( 0,0.1236)	2	0.0526	( 0,0.1236)	2	0.0526	( 0,0.1236)
Total Implants Assessed	38	N/A	N/A	38	N/A	N/A	38	N/A	N/A

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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  
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Table 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0550	( 0,0.1291)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	2	0.0550	( 0,0.1291)
Wrinkling	2	0.0526	( 0,0.1236)
Total Implants Assessed	38	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8 7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
UNKNOWN DEVICE PLACEMENT

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	1	N/A	N/A	1	N/A	N/A	1	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
SMOOTH SURFACE  
UNKNOWN DEVICE PLACEMENT

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	1	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	1	0.0294	( 0,0.0862)	1	0.0294	( 0,0.0862)	1	0.0294	( 0,0.0862)
Baker III, IV Capsular Contracture	1	0.0294	( 0,0.0862)	1	0.0294	( 0,0.0862)	1	0.0294	( 0,0.0862)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	34	N/A	N/A	34	N/A	N/A	34	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	1	0.0294	( 0,0.0862)
Baker III, IV Capsular Contracture	1	0.0294	( 0,0.0862)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	34	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2. 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 8.7 6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0150	( 0, 0.0356)	6	0.0452	(0.0099,0.0806)	10	0.0784	(0.0316,0.1252)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	1	0.0076	( 0,0.0225)	1	0.0076	( 0,0.0225)
Baker III, IV Capsular Contracture	2	0.0150	( 0,0.0356)	7	0.0528	(0.0147,0.0909)	11	0.0860	(0.0372,0.1347)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	135	N/A	N/A	135	N/A	N/A	135	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2. 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	10	0.0784	(0.0316,0.1252)
Baker IV Capsular Contracture	1	0.0076	( 0,0.0225)
Baker III, IV Capsular Contracture	11	0.0860	(0.0372,0.1347)
Wrinkling	1	0.0147	( 0,0.0433)
Total Implants Assessed	135	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: Implant counts exclude events where breast side = N/A.

Table 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	61	N/A	N/A	61	N/A	N/A	61	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: Implant counts exclude events where breast side = N/A.

Table 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR RECONSTRUCTION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0189	( 0,0.0555)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	1	0.0189	( 0,0.0555)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	61	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time. 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0741	( 0.017,0.1311)	9	0.1111	(0.0427,0.1796)	11	0.1399	(0.0629,0.2169)
Baker IV Capsular Contracture	1	0.0123	( 0,0.0364)	1	0.0123	( 0,0.0364)	4	0.0529	(0.0024,0.1035)
Baker III, IV Capsular Contracture	7	0.0864	(0.0252,0.1476)	10	0.1235	(0.0518,0.1951)	12	0.1518	(0.0724,0.2312)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	81	N/A	N/A	81	N/A	N/A	81	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	12	0.1558	(0.0741,0.2375)
Baker IV Capsular Contracture	6	0.0908	(0.0201,0.1615)
Baker III, IV Capsular Contracture	15	0.2015	(0.1089,0.2941)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	81	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time. 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	3	0.0222	( 0, 0.047)	10	0.0748	(0.0302,0.1194)	13	0.0986	(0.0476,0.1495)
Baker IV Capsular Contracture	1	0.0074	( 0,0.0217)	1	0.0074	( 0,0.0217)	1	0.0074	( 0,0.0217)
Baker III, IV Capsular Contracture	4	0.0295	( 0.001, 0.058)	10	0.0746	(0.0301, 0.119)	13	0.0984	(0.0475,0.1492)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	138	N/A	N/A	138	N/A	N/A	138	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time. 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2. 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	13	0.0986	(0.0476,0.1495)
Baker IV Capsular Contracture	2	0.0192	( 0,0.0462)
Baker III, IV Capsular Contracture	13	0.0984	(0.0475,0.1492)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	138	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0270	( 0,0.0793)	3	0.0811	( 0, 0.169)	5	0.1368	(0.0253,0.2482)
Baker IV Capsular Contracture	1	0.0270	( 0,0.0793)	1	0.0270	( 0,0.0793)	1	0.0270	( 0,0.0793)
Baker III, IV Capsular Contracture	2	0.0541	( 0,0.1269)	4	0.1081	(0.0081,0.2082)	5	0.1360	(0.0251,0.2468)
Wrinkling	1	0.0270	( 0,0.0793)	1	0.0270	( 0,0.0793)	1	0.0270	( 0,0.0793)
Total Implants Assessed	37	N/A	N/A	37	N/A	N/A	37	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	5	0.1368	(0.0253,0.2482)
Baker IV Capsular Contracture	1	0.0270	( 0,0.0793)
Baker III, IV Capsular Contracture	5	0.1360	(0.0251,0.2468)
Wrinkling	1	0.0270	( 0,0.0793)
Total Implants Assessed	37	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	4	0.0977	(0.0067,0.1888)	5	0.1228	(0.0219,0.2237)	5	0.1228	(0.0219,0.2237)
Baker IV Capsular Contracture	1	0.0238	( 0,0.0699)	2	0.0488	( 0,0.1149)	2	0.0488	( 0,0.1149)
Baker III, IV Capsular Contracture	5	0.1216	(0.0216,0.2217)	6	0.1467	(0.0381,0.2553)	6	0.1467	(0.0381,0.2553)
Wrinkling	2	0.0500	( 0,0.1175)	2	0.0500	( 0,0.1175)	3	0.0750	( 0,0.1566)
Total Implants Assessed	42	N/A	N/A	42	N/A	N/A	42	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	5	0.1228	(0.0219,0.2237)
Baker IV Capsular Contracture	2	0.0488	( 0,0.1149)
Baker III, IV Capsular Contracture	6	0.1467	(0.0381,0.2553)
Wrinkling	3	0.0750	( 0,0.1566)
Total Implants Assessed	42	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	2	0.0294	( 0,0.0696)	4	0.0597	( 0.003,0.1165)	4	0.0597	( 0.003,0.1165)
Baker IV Capsular Contracture	1	0.0147	( 0,0.0433)	2	0.0299	( 0,0.0706)	2	0.0299	( 0,0.0706)
Baker III, IV Capsular Contracture	3	0.0441	( 0,0.0929)	5	0.0745	(0.0116,0.1373)	5	0.0745	(0.0116,0.1373)
Wrinkling	1	0.0147	( 0,0.0433)	1	0.0147	( 0,0.0433)	1	0.0147	( 0,0.0433)
Total Implants Assessed	68	N/A	N/A	68	N/A	N/A	68	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7 6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	4	0.0597	( 0.003,0.1165)
Baker IV Capsular Contracture	2	0.0299	( 0,0.0706)
Baker III, IV Capsular Contracture	5	0.0745	(0.0116,0.1373)
Wrinkling	1	0.0147	( 0,0.0433)
Total Implants Assessed	68	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0588	( 0,0.1707)	1	0.0588	( 0,0.1707)	1	0.0588	( 0,0.1707)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	1	0.0588	( 0,0.1707)	1	0.0588	( 0,0.1707)	1	0.0588	( 0,0.1707)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	17	N/A	N/A	17	N/A	N/A	17	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
IMPLANTS USED FOR REVISION  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0588	( 0,0.1707)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	1	0.0588	( 0,0.1707)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	17	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08.54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - OTHER

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	1	0.1111	( 0,0.3164)	1	0.1111	( 0,0.3164)	1	0.1111	( 0,0.3164)
Total Implants Assessed	9	N/A	N/A	9	N/A	N/A	9	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - OTHER

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	1	0.1111	( 0, 0.3164)
Total Implants Assessed	9	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	14	0.0544	(0.0267,0.0821)	21	0.0818	(0.0483,0.1153)	32	0.1282	(0.0866,0.1698)
Baker IV Capsular Contracture	1	0.0039	(0,0.0115)	1	0.0039	(0,0.0115)	5	0.0201	(0.0027,0.0375)
Baker III, IV Capsular Contracture	15	0.0583	(0.0297,0.0869)	22	0.0856	(0.0514,0.1199)	33	0.1319	(0.0898,0.1739)
Wrinkling	0	0.0000	(0,0)	2	0.0078	(0,0.0186)	2	0.0078	(0,0.0186)
Total Implants Assessed	260	N/A	N/A	260	N/A	N/A	260	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7 6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	37	0.1551	(0.1085,0.2016)
Baker IV Capsular Contracture	9	0.0528	(0.0161,0.0896)
Baker III, IV Capsular Contracture	40	0.1703	(0.1214,0.2193)
Wrinkling	2	0.0078	( 0,0.0186)
Total Implants Assessed	260	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08 54

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

(b) Based on Kaplan-Meier Estimates.

Note. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	16	0.0262	(0.0135,0.0389)	27	0.0446	(0.0281, 0.061)	31	0.0518	( 0.034,0.0696)
Baker IV Capsular Contracture	1	0.0016	( 0,0.0048)	1	0.0016	( 0,0.0048)	2	0.0034	( 0, 0.008)
Baker III, IV Capsular Contracture	17	0.0279	(0.0148,0.0409)	27	0.0445	(0.0281, 0.061)	32	0.0535	(0.0354,0.0716)
Wrinkling	3	0.0049	( 0,0.0105)	4	0.0066	(0.0002, 0.013)	4	0.0066	(0.0002, 0.013)
Total Implants Assessed	615	N/A	N/A	615	N/A	N/A	615	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2. 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	32	0.0541	(0.0358,0.0723)
Baker IV Capsular Contracture	3	0.0057	( 0,0.0123)
Baker III, IV Capsular Contracture	33	0.0557	(0.0372,0.0743)
Wrinkling	4	0.0066	(0.0002, 0.013)
Total Implants Assessed	615	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	13	0.0420	(0.0197,0.0644)	16	0.0520	(0.0272,0.0768)	18	0.0590	(0.0325,0.0854)
Baker IV Capsular Contracture	2	0.0065	( 0,0.0155)	4	0.0131	(0.0003,0.0259)	4	0.0131	(0.0003,0.0259)
Baker III, IV Capsular Contracture	15	0.0485	(0.0246,0.0725)	19	0.0618	(0.0349,0.0888)	20	0.0653	(0.0376, 0.093)
Wrinkling	3	0.0097	( 0,0.0207)	3	0.0097	( 0,0.0207)	3	0.0097	( 0,0.0207)
Total Implants Assessed	310	N/A	N/A	310	N/A	N/A	310	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6 SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	18	0.0590	(0.0325,0.0854)
Baker IV Capsular Contracture	4	0.0131	(0.0003,0.0259)
Baker III, IV Capsular Contracture	20	0.0653	(0.0376, 0.093)
Wrinkling	3	0.0097	( 0,0.0207)
Total Implants Assessed	310	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
UNKNOWN DEVICE PLACEMENT

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	1	N/A	N/A	1	N/A	N/A	1	N/A	N/A

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
SMOOTH SURFACE  
UNKNOWN DEVICE PLACEMENT

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	0	0.0000	( 0, 0)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)
Baker III, IV Capsular Contracture	0	0.0000	( 0, 0)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	1	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08.54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	6	0.0217	(0.0045,0.0389)	9	0.0328	(0.0117, 0.054)	11	0.0403	( 0.017,0.0636)
Baker IV Capsular Contracture	2	0.0072	( 0,0.0173)	3	0.0109	( 0,0.0232)	3	0.0109	( 0,0.0232)
Baker III, IV Capsular Contracture	8	0.0290	(0.0092,0.0487)	11	0.0401	(0.0169,0.0633)	13	0.0475	(0.0223,0.0728)
Wrinkling	3	0.0109	( 0,0.0231)	3	0.0109	( 0,0.0231)	7	0.0257	(0.0069,0.0445)
Total Implants Assessed	277	N/A	N/A	277	N/A	N/A	277	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8 7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBGLANDULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	11	0.0403	( 0.017,0.0636)
Baker IV Capsular Contracture	3	0.0109	( 0,0.0232)
Baker III, IV Capsular Contracture	13	0.0475	(0.0223,0.0728)
Wrinkling	7	0.0257	(0.0069,0.0445)
Total Implants Assessed	277	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08.54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	4	0.0134	(0.0004,0.0265)	10	0.0339	(0.0132,0.0545)	14	0.0484	(0.0236,0.0732)
Baker IV Capsular Contracture	1	0.0033	(0,0.0099)	4	0.0136	(0.0004,0.0269)	4	0.0136	(0.0004,0.0269)
Baker III, IV Capsular Contracture	5	0.0168	(0.0022,0.0313)	13	0.0440	(0.0206,0.0674)	17	0.0586	(0.0315,0.0856)
Wrinkling	1	0.0033	(0,0.0099)	1	0.0033	(0,0.0099)	1	0.0033	(0,0.0099)
Total Implants Assessed	299	N/A	N/A	299	N/A	N/A	299	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBMUSCULAR

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	14	0.0484	(0.0236,0.0732)
Baker IV Capsular Contracture	4	0.0136	(0.0004,0.0269)
Baker III, IV Capsular Contracture	17	0.0586	(0.0315,0.0856)
Wrinkling	2	0.0086	( 0,0.0209)
Total Implants Assessed	299	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2. 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	6 Months (a)			12 Months (a)			24 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	1	0.0080	( 0,0.0236)	1	0.0080	( 0,0.0236)	2	0.0160	( 0, 0.038)
Baker IV Capsular Contracture	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	1	0.0080	( 0,0.0236)
Baker III, IV Capsular Contracture	1	0.0080	( 0,0.0236)	1	0.0080	( 0,0.0236)	3	0.0240	( 0,0.0508)
Wrinkling	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)	0	0.0000	( 0, 0)
Total Implants Assessed	125	N/A	N/A	125	N/A	N/A	125	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time: 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.7.6

CUMULATIVE INCIDENCE OF SELECTED COMPLICATIONS (IMPLANT LEVEL) - BY SURFACE AND DEVICE PLACEMENT  
OVERALL IMPLANTS  
TEXTURED SURFACE  
DEVICE PLACEMENT - SUBPECTORAL

Type of Complication or Reoperation	36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Baker III Capsular Contracture	3	0.0250	( 0, 0.053)
Baker IV Capsular Contracture	1	0.0080	( 0,0.0236)
Baker III, IV Capsular Contracture	4	0.0330	(0.0011,0.0649)
Wrinkling	0	0.0000	( 0, 0)
Total Implants Assessed	125	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_7\_6.SAS

Creation Date, Time. 24AUG04 08:54

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

(b) Based on Kaplan-Meier Estimates.

Note: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of 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 2: 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	551	1.0000	0.0000	(0.0000,0.0000)
1	6	0	545	0.9891	0.0109	(0.0022,0.0196)
2	2	0	543	0.9855	0.0145	(0.0045,0.0245)
3	0	1	542	0.9855	0.0145	(0.0045,0.0245)
4	0	0	542	0.9855	0.0145	(0.0045,0.0245)
5	0	0	542	0.9855	0.0145	(0.0045,0.0245)
6	0	3	539	0.9855	0.0145	(0.0045,0.0245)
7	0	0	539	0.9855	0.0145	(0.0045,0.0245)
8	0	1	538	0.9855	0.0145	(0.0045,0.0245)
9	0	2	536	0.9855	0.0145	(0.0045,0.0245)
10	0	0	536	0.9855	0.0145	(0.0045,0.0245)
11	0	1	535	0.9855	0.0145	(0.0045,0.0245)
12	0	5	530	0.9855	0.0145	(0.0045,0.0245)
13	0	2	528	0.9855	0.0145	(0.0045,0.0245)
14	0	2	526	0.9855	0.0145	(0.0045,0.0245)
15	0	1	525	0.9855	0.0145	(0.0045,0.0245)
16	0	0	525	0.9855	0.0145	(0.0045,0.0245)
17	0	0	525	0.9855	0.0145	(0.0045,0.0245)
18	0	0	525	0.9855	0.0145	(0.0045,0.0245)
19	0	1	524	0.9855	0.0145	(0.0045,0.0245)
20	0	0	524	0.9855	0.0145	(0.0045,0.0245)
21	0	0	524	0.9855	0.0145	(0.0045,0.0245)
22	0	4	520	0.9855	0.0145	(0.0045,0.0245)
23	0	37	483	0.9855	0.0145	(0.0045,0.0245)
24	0	28	455	0.9855	0.0145	(0.0045,0.0245)
25	0	31	424	0.9855	0.0145	(0.0045,0.0245)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	21	403	0.9855	0.0145	(0.0045,0.0245)
27	0	2	401	0.9855	0.0145	(0.0045,0.0245)
28	0	3	398	0.9855	0.0145	(0.0045,0.0245)
29	0	1	397	0.9855	0.0145	(0.0045,0.0245)
30	0	4	393	0.9855	0.0145	(0.0045,0.0245)
31	0	1	392	0.9855	0.0145	(0.0045,0.0245)
32	0	4	388	0.9855	0.0145	(0.0045,0.0245)
33	0	19	369	0.9855	0.0145	(0.0045,0.0245)
34	0	19	350	0.9855	0.0145	(0.0045,0.0245)
35	0	47	303	0.9855	0.0145	(0.0045,0.0245)
36	0	103	200	0.9855	0.0145	(0.0045,0.0245)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note Excludes planned second stage surgeries, and 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
 RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	251	1.0000	0.0000	(0.0000,0.0000)
1	5	1	245	0.9800	0.0200	(0.0026,0.0374)
2	1	0	244	0.9760	0.0240	(0.0050,0.0430)
3	2	0	242	0.9680	0.0320	(0.0102,0.0538)
4	0	1	241	0.9680	0.0320	(0.0102,0.0538)
5	1	0	240	0.9640	0.0360	(0.0129,0.0591)
6	0	2	238	0.9640	0.0360	(0.0129,0.0591)
7	1	2	235	0.9599	0.0401	(0.0157,0.0644)
8	0	3	232	0.9599	0.0401	(0.0157,0.0644)
9	0	2	230	0.9599	0.0401	(0.0157,0.0644)
10	0	2	228	0.9599	0.0401	(0.0157,0.0644)
11	0	1	227	0.9599	0.0401	(0.0157,0.0644)
12	0	1	226	0.9599	0.0401	(0.0157,0.0644)
13	1	3	222	0.9556	0.0444	(0.0187,0.0700)
14	1	2	219	0.9513	0.0487	(0.0218,0.0755)
15	1	0	218	0.9470	0.0530	(0.0249,0.0811)
16	0	2	216	0.9470	0.0530	(0.0249,0.0811)
17	0	1	215	0.9470	0.0530	(0.0249,0.0811)
18	0	2	213	0.9470	0.0530	(0.0249,0.0811)
19	0	2	211	0.9470	0.0530	(0.0249,0.0811)
20	0	2	209	0.9470	0.0530	(0.0249,0.0811)
21	0	0	209	0.9470	0.0530	(0.0249,0.0811)
22	0	6	203	0.9470	0.0530	(0.0249,0.0811)
23	0	57	146	0.9470	0.0530	(0.0249,0.0811)
24	0	18	128	0.9470	0.0530	(0.0249,0.0811)
25	0	9	119	0.9470	0.0530	(0.0249,0.0811)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	2	117	0.9470	0.0530	(0.0249,0.0811)
27	0	2	115	0.9470	0.0530	(0.0249,0.0811)
28	0	0	115	0.9470	0.0530	(0.0249,0.0811)
29	0	0	115	0.9470	0.0530	(0.0249,0.0811)
30	0	1	114	0.9470	0.0530	(0.0249,0.0811)
31	0	0	114	0.9470	0.0530	(0.0249,0.0811)
32	0	1	113	0.9470	0.0530	(0.0249,0.0811)
33	0	28	85	0.9470	0.0530	(0.0249,0.0811)
34	0	14	71	0.9470	0.0530	(0.0249,0.0811)
35	0	21	50	0.9470	0.0530	(0.0249,0.0811)
36	0	25	25	0.9470	0.0530	(0.0249,0.0811)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note. Excludes planned second stage surgeries, and 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	205	1.0000	0.0000	(0.0000,0.0000)
1	1	1	203	0.9951	0.0049	(0.0000,0.0145)
2	0	0	203	0.9951	0.0049	(0.0000,0.0145)
3	0	0	203	0.9951	0.0049	(0.0000,0.0145)
4	0	2	201	0.9951	0.0049	(0.0000,0.0145)
5	0	0	201	0.9951	0.0049	(0.0000,0.0145)
6	0	0	201	0.9951	0.0049	(0.0000,0.0145)
7	0	0	201	0.9951	0.0049	(0.0000,0.0145)
8	0	1	200	0.9951	0.0049	(0.0000,0.0145)
9	0	0	200	0.9951	0.0049	(0.0000,0.0145)
10	0	0	200	0.9951	0.0049	(0.0000,0.0145)
11	0	1	199	0.9951	0.0049	(0.0000,0.0145)
12	0	3	196	0.9951	0.0049	(0.0000,0.0145)
13	0	3	193	0.9951	0.0049	(0.0000,0.0145)
14	0	2	191	0.9951	0.0049	(0.0000,0.0145)
15	0	1	190	0.9951	0.0049	(0.0000,0.0145)
16	0	1	189	0.9951	0.0049	(0.0000,0.0145)
17	0	0	189	0.9951	0.0049	(0.0000,0.0145)
18	0	1	188	0.9951	0.0049	(0.0000,0.0145)
19	0	0	188	0.9951	0.0049	(0.0000,0.0145)
20	1	0	187	0.9898	0.0102	(0.0000,0.0243)
21	0	2	185	0.9898	0.0102	(0.0000,0.0243)
22	0	1	184	0.9898	0.0102	(0.0000,0.0243)
23	0	18	166	0.9898	0.0102	(0.0000,0.0243)
24	0	5	161	0.9898	0.0102	(0.0000,0.0243)
25	0	13	148	0.9898	0.0102	(0.0000,0.0243)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
 REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	6	142	0.9898	0.0102	(0.0000,0.0243)
27	0	4	138	0.9898	0.0102	(0.0000,0.0243)
28	0	1	137	0.9898	0.0102	(0.0000,0.0243)
29	0	1	136	0.9898	0.0102	(0.0000,0.0243)
30	0	0	136	0.9898	0.0102	(0.0000,0.0243)
31	0	3	133	0.9898	0.0102	(0.0000,0.0243)
32	0	1	132	0.9898	0.0102	(0.0000,0.0243)
33	0	12	120	0.9898	0.0102	(0.0000,0.0243)
34	0	17	103	0.9898	0.0102	(0.0000,0.0243)
35	0	16	87	0.9898	0.0102	(0.0000,0.0243)
36	0	36	51	0.9898	0.0102	(0.0000,0.0243)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08.53

Note. Excludes planned second stage surgeries, and 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
 OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1007	1.0000	0.0000	(0.0000,0.0000)
1	12	2	993	0.9881	0.0119	(0.0052,0.0187)
2	3	0	990	0.9851	0.0149	(0.0074,0.0224)
3	2	1	987	0.9831	0.0169	(0.0089,0.0249)
4	0	3	984	0.9831	0.0169	(0.0089,0.0249)
5	1	0	983	0.9821	0.0179	(0.0097,0.0261)
6	0	5	978	0.9821	0.0179	(0.0097,0.0261)
7	1	2	975	0.9811	0.0189	(0.0105,0.0273)
8	0	5	970	0.9811	0.0189	(0.0105,0.0273)
9	0	4	966	0.9811	0.0189	(0.0105,0.0273)
10	0	2	964	0.9811	0.0189	(0.0105,0.0273)
11	0	3	961	0.9811	0.0189	(0.0105,0.0273)
12	0	9	952	0.9811	0.0189	(0.0105,0.0273)
13	1	8	943	0.9800	0.0200	(0.0113,0.0286)
14	1	6	936	0.9790	0.0210	(0.0121,0.0299)
15	1	2	933	0.9780	0.0220	(0.0129,0.0312)
16	0	3	930	0.9780	0.0220	(0.0129,0.0312)
17	0	1	929	0.9780	0.0220	(0.0129,0.0312)
18	0	3	926	0.9780	0.0220	(0.0129,0.0312)
19	0	3	923	0.9780	0.0220	(0.0129,0.0312)
20	1	2	920	0.9769	0.0231	(0.0138,0.0324)
21	0	2	918	0.9769	0.0231	(0.0138,0.0324)
22	0	11	907	0.9769	0.0231	(0.0138,0.0324)
23	0	112	795	0.9769	0.0231	(0.0138,0.0324)
24	0	51	744	0.9769	0.0231	(0.0138,0.0324)
25	0	53	691	0.9769	0.0231	(0.0138,0.0324)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note. Excludes planned second stage surgeries, and 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 8.8.1

TIME TO FIRST REPORT OF INFECTION (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	29	662	0.9769	0.0231	(0.0138,0.0324)
27	0	8	654	0.9769	0.0231	(0.0138,0.0324)
28	0	4	650	0.9769	0.0231	(0.0138,0.0324)
29	0	2	648	0.9769	0.0231	(0.0138,0.0324)
30	0	5	643	0.9769	0.0231	(0.0138,0.0324)
31	0	4	639	0.9769	0.0231	(0.0138,0.0324)
32	0	6	633	0.9769	0.0231	(0.0138,0.0324)
33	0	59	574	0.9769	0.0231	(0.0138,0.0324)
34	0	50	524	0.9769	0.0231	(0.0138,0.0324)
35	0	84	440	0.9769	0.0231	(0.0138,0.0324)
36	0	164	276	0.9769	0.0231	(0.0138,0.0324)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
1	6	0	1121	0.9947	0.0053	(0.0011,0.0096)
2	2	0	1119	0.9929	0.0071	(0.0022,0.0120)
3	0	2	1117	0.9929	0.0071	(0.0022,0.0120)
4	0	0	1117	0.9929	0.0071	(0.0022,0.0120)
5	0	0	1117	0.9929	0.0071	(0.0022,0.0120)
6	0	6	1111	0.9929	0.0071	(0.0022,0.0120)
7	0	0	1111	0.9929	0.0071	(0.0022,0.0120)
8	0	3	1108	0.9929	0.0071	(0.0022,0.0120)
9	0	4	1104	0.9929	0.0071	(0.0022,0.0120)
10	0	0	1104	0.9929	0.0071	(0.0022,0.0120)
11	0	3	1101	0.9929	0.0071	(0.0022,0.0120)
12	0	10	1091	0.9929	0.0071	(0.0022,0.0120)
13	0	4	1087	0.9929	0.0071	(0.0022,0.0120)
14	0	4	1083	0.9929	0.0071	(0.0022,0.0120)
15	0	3	1080	0.9929	0.0071	(0.0022,0.0120)
16	0	0	1080	0.9929	0.0071	(0.0022,0.0120)
17	0	0	1080	0.9929	0.0071	(0.0022,0.0120)
18	0	0	1080	0.9929	0.0071	(0.0022,0.0120)
19	0	3	1077	0.9929	0.0071	(0.0022,0.0120)
20	0	0	1077	0.9929	0.0071	(0.0022,0.0120)
21	0	0	1077	0.9929	0.0071	(0.0022,0.0120)
22	0	10	1067	0.9929	0.0071	(0.0022,0.0120)
23	0	76	991	0.9929	0.0071	(0.0022,0.0120)
24	0	60	931	0.9929	0.0071	(0.0022,0.0120)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note. Excludes planned second stage surgeries, and 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 2: 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
 IMPLANTS USED FOR AUGMENTATION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	64	867	0.9929	0.0071	(0.0022,0.0120)
26	0	41	826	0.9929	0.0071	(0.0022,0.0120)
27	0	5	821	0.9929	0.0071	(0.0022,0.0120)
28	0	6	815	0.9929	0.0071	(0.0022,0.0120)
29	0	2	813	0.9929	0.0071	(0.0022,0.0120)
30	0	8	805	0.9929	0.0071	(0.0022,0.0120)
31	0	2	803	0.9929	0.0071	(0.0022,0.0120)
32	0	8	795	0.9929	0.0071	(0.0022,0.0120)
33	0	42	753	0.9929	0.0071	(0.0022,0.0120)
34	0	41	712	0.9929	0.0071	(0.0022,0.0120)
35	0	100	612	0.9929	0.0071	(0.0022,0.0120)
36	0	208	404	0.9929	0.0071	(0.0022,0.0120)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note. Excludes planned second stage surgeries, and 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 2. 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	386	1.0000	0.0000	(0.0000,0.0000)
1	5	2	379	0.9870	0.0130	(0.0017,0.0244)
2	1	0	378	0.9844	0.0156	(0.0032,0.0280)
3	2	0	376	0.9792	0.0208	(0.0065,0.0351)
4	0	2	374	0.9792	0.0208	(0.0065,0.0351)
5	1	0	373	0.9765	0.0235	(0.0083,0.0386)
6	0	4	369	0.9765	0.0235	(0.0083,0.0386)
7	1	4	364	0.9739	0.0261	(0.0101,0.0421)
8	0	4	360	0.9739	0.0261	(0.0101,0.0421)
9	0	2	358	0.9739	0.0261	(0.0101,0.0421)
10	0	2	356	0.9739	0.0261	(0.0101,0.0421)
11	0	1	355	0.9739	0.0261	(0.0101,0.0421)
12	0	3	352	0.9739	0.0261	(0.0101,0.0421)
13	1	5	346	0.9711	0.0289	(0.0121,0.0457)
14	1	3	342	0.9683	0.0317	(0.0140,0.0494)
15	1	0	341	0.9655	0.0345	(0.0161,0.0530)
16	0	3	338	0.9655	0.0345	(0.0161,0.0530)
17	0	2	336	0.9655	0.0345	(0.0161,0.0530)
18	0	3	333	0.9655	0.0345	(0.0161,0.0530)
19	0	2	331	0.9655	0.0345	(0.0161,0.0530)
20	0	2	329	0.9655	0.0345	(0.0161,0.0530)
21	0	0	329	0.9655	0.0345	(0.0161,0.0530)
22	0	9	320	0.9655	0.0345	(0.0161,0.0530)
23	0	91	229	0.9655	0.0345	(0.0161,0.0530)
24	0	23	206	0.9655	0.0345	(0.0161,0.0530)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note. Excludes planned second stage surgeries, and 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 2. 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
 IMPLANTS USED FOR RECONSTRUCTION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	12	194	0.9655	0.0345	(0.0161,0.0530)
26	0	5	189	0.9655	0.0345	(0.0161,0.0530)
27	0	3	186	0.9655	0.0345	(0.0161,0.0530)
28	0	0	186	0.9655	0.0345	(0.0161,0.0530)
29	0	0	186	0.9655	0.0345	(0.0161,0.0530)
30	0	2	184	0.9655	0.0345	(0.0161,0.0530)
31	0	0	184	0.9655	0.0345	(0.0161,0.0530)
32	0	2	182	0.9655	0.0345	(0.0161,0.0530)
33	0	49	133	0.9655	0.0345	(0.0161,0.0530)
34	0	23	110	0.9655	0.0345	(0.0161,0.0530)
35	0	36	74	0.9655	0.0345	(0.0161,0.0530)
36	0	38	36	0.9655	0.0345	(0.0161,0.0530)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 2: 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	383	1.0000	0.0000	(0.0000,0.0000)
1	1	2	380	0.9974	0.0026	(0.0000,0.0078)
2	0	0	380	0.9974	0.0026	(0.0000,0.0078)
3	0	0	380	0.9974	0.0026	(0.0000,0.0078)
4	0	4	376	0.9974	0.0026	(0.0000,0.0078)
5	0	0	376	0.9974	0.0026	(0.0000,0.0078)
6	0	0	376	0.9974	0.0026	(0.0000,0.0078)
7	0	0	376	0.9974	0.0026	(0.0000,0.0078)
8	0	2	374	0.9974	0.0026	(0.0000,0.0078)
9	0	0	374	0.9974	0.0026	(0.0000,0.0078)
10	0	0	374	0.9974	0.0026	(0.0000,0.0078)
11	0	2	372	0.9974	0.0026	(0.0000,0.0078)
12	0	6	366	0.9974	0.0026	(0.0000,0.0078)
13	0	6	360	0.9974	0.0026	(0.0000,0.0078)
14	0	4	356	0.9974	0.0026	(0.0000,0.0078)
15	0	2	354	0.9974	0.0026	(0.0000,0.0078)
16	0	2	352	0.9974	0.0026	(0.0000,0.0078)
17	0	0	352	0.9974	0.0026	(0.0000,0.0078)
18	0	2	350	0.9974	0.0026	(0.0000,0.0078)
19	0	0	350	0.9974	0.0026	(0.0000,0.0078)
20	1	0	349	0.9945	0.0055	(0.0000,0.0130)
21	0	4	345	0.9945	0.0055	(0.0000,0.0130)
22	0	2	343	0.9945	0.0055	(0.0000,0.0130)
23	0	33	310	0.9945	0.0055	(0.0000,0.0130)
24	0	10	300	0.9945	0.0055	(0.0000,0.0130)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 2: 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	24	276	0.9945	0.0055	(0.0000,0.0130)
26	0	12	264	0.9945	0.0055	(0.0000,0.0130)
27	0	8	256	0.9945	0.0055	(0.0000,0.0130)
28	0	1	255	0.9945	0.0055	(0.0000,0.0130)
29	0	1	254	0.9945	0.0055	(0.0000,0.0130)
30	0	0	254	0.9945	0.0055	(0.0000,0.0130)
31	0	6	248	0.9945	0.0055	(0.0000,0.0130)
32	0	1	247	0.9945	0.0055	(0.0000,0.0130)
33	0	22	225	0.9945	0.0055	(0.0000,0.0130)
34	0	29	196	0.9945	0.0055	(0.0000,0.0130)
35	0	28	168	0.9945	0.0055	(0.0000,0.0130)
36	0	70	98	0.9945	0.0055	(0.0000,0.0130)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 2 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
OVERALL IMPLANTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1896	1.0000	0.0000	(0.0000,0.0000)
1	12	4	1880	0.9937	0.0063	(0.0028,0.0099)
2	3	0	1877	0.9921	0.0079	(0.0039,0.0119)
3	2	2	1873	0.9910	0.0090	(0.0047,0.0132)
4	0	6	1867	0.9910	0.0090	(0.0047,0.0132)
5	1	0	1866	0.9905	0.0095	(0.0051,0.0139)
6	0	10	1856	0.9905	0.0095	(0.0051,0.0139)
7	1	4	1851	0.9900	0.0100	(0.0056,0.0145)
8	0	9	1842	0.9900	0.0100	(0.0056,0.0145)
9	0	6	1836	0.9900	0.0100	(0.0056,0.0145)
10	0	2	1834	0.9900	0.0100	(0.0056,0.0145)
11	0	6	1828	0.9900	0.0100	(0.0056,0.0145)
12	0	19	1809	0.9900	0.0100	(0.0056,0.0145)
13	1	15	1793	0.9894	0.0106	(0.0060,0.0152)
14	1	11	1781	0.9888	0.0112	(0.0064,0.0159)
15	1	5	1775	0.9883	0.0117	(0.0068,0.0166)
16	0	5	1770	0.9883	0.0117	(0.0068,0.0166)
17	0	2	1768	0.9883	0.0117	(0.0068,0.0166)
18	0	5	1763	0.9883	0.0117	(0.0068,0.0166)
19	0	5	1758	0.9883	0.0117	(0.0068,0.0166)
20	1	2	1755	0.9877	0.0123	(0.0073,0.0173)
21	0	4	1751	0.9877	0.0123	(0.0073,0.0173)
22	0	21	1730	0.9877	0.0123	(0.0073,0.0173)
23	0	200	1530	0.9877	0.0123	(0.0073,0.0173)
24	0	93	1437	0.9877	0.0123	(0.0073,0.0173)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 2: 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 8.8.2

TIME TO FIRST REPORT OF INFECTION (IMPLANT LEVEL)  
OVERALL IMPLANTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	100	1337	0.9877	0.0123	(0.0073,0.0173)
26	0	58	1279	0.9877	0.0123	(0.0073,0.0173)
27	0	16	1263	0.9877	0.0123	(0.0073,0.0173)
28	0	7	1256	0.9877	0.0123	(0.0073,0.0173)
29	0	3	1253	0.9877	0.0123	(0.0073,0.0173)
30	0	10	1243	0.9877	0.0123	(0.0073,0.0173)
31	0	8	1235	0.9877	0.0123	(0.0073,0.0173)
32	0	11	1224	0.9877	0.0123	(0.0073,0.0173)
33	0	113	1111	0.9877	0.0123	(0.0073,0.0173)
34	0	93	1018	0.9877	0.0123	(0.0073,0.0173)
35	0	164	854	0.9877	0.0123	(0.0073,0.0173)
36	0	316	538	0.9877	0.0123	(0.0073,0.0173)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

Note: Excludes planned second stage surgeries, and 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 2. Implant counts exclude events where breast side = N/A.