

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 15.2

TIME TO FIRST REPORT OF ANY COMPLICATION (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	131	4	1761	0.9308	0.0692	(0.0578,0.0806)
2	47	0	1714	0.9060	0.0940	(0.0809,0.1072)
3	28	2	1684	0.8912	0.1088	(0.0948,0.1229)
4	27	6	1651	0.8769	0.1231	(0.1083,0.1380)
5	15	0	1636	0.8689	0.1311	(0.1159,0.1463)
6	38	8	1590	0.8487	0.1513	(0.1352,0.1675)
7	36	4	1550	0.8294	0.1706	(0.1536,0.1875)
8	11	7	1532	0.8235	0.1765	(0.1593,0.1937)
9	11	3	1518	0.8176	0.1824	(0.1649,0.1998)
10	12	0	1506	0.8112	0.1888	(0.1712,0.2065)
11	8	1	1497	0.8068	0.1932	(0.1753,0.2110)
12	10	13	1474	0.8014	0.1986	(0.1805,0.2166)
13	33	11	1430	0.7835	0.2165	(0.1979,0.2352)
14	5	9	1416	0.7807	0.2193	(0.2006,0.2380)
15	4	4	1408	0.7785	0.2215	(0.2027,0.2403)
16	8	2	1398	0.7741	0.2259	(0.2070,0.2449)
17	3	2	1393	0.7724	0.2276	(0.2086,0.2466)
18	1	3	1389	0.7719	0.2281	(0.2091,0.2472)
19	4	2	1383	0.7696	0.2304	(0.2113,0.2495)
20	2	1	1380	0.7685	0.2315	(0.2124,0.2506)
21	2	2	1376	0.7674	0.2326	(0.2135,0.2517)
22	7	12	1357	0.7635	0.2365	(0.2173,0.2558)
23	20	146	1191	0.7514	0.2486	(0.2289,0.2682)
24	9	67	1115	0.7457	0.2543	(0.2345,0.2742)

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.

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Table 8 15.2

TIME TO FIRST REPORT OF ANY COMPLICATION (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	13	74	1028	0.7366	0.2634	(0.2431,0.2836)
26	1	36	991	0.7359	0.2641	(0.2438,0.2844)
27	2	10	979	0.7344	0.2656	(0.2453,0.2859)
28	3	6	970	0.7322	0.2678	(0.2474,0.2883)
29	2	3	965	0.7307	0.2693	(0.2489,0.2898)
30	1	8	956	0.7299	0.2701	(0.2496,0.2906)
31	1	5	950	0.7291	0.2709	(0.2503,0.2914)
32	2	5	943	0.7276	0.2724	(0.2518,0.2930)
33	2	82	859	0.7259	0.2741	(0.2534,0.2948)
34	2	64	793	0.7242	0.2758	(0.2550,0.2966)
35	5	134	654	0.7193	0.2807	(0.2596,0.3018)
36	0	236	418	0.7193	0.2807	(0.2596,0.3018)

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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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	1	0.0667	(0, 0.1929)	2	0.1444	(0, 0.3307)
I Complication Excluding Cosmetic						
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	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)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	1	0.0667	(0, 0.1929)	1	0.0667	(0, 0.1929)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	2	0.1444	(0,0.3307)	2	0.1444	(0,0.3307)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	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)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	1	0.0667	(0,0.1929)	1	0.0667	(0,0.1929)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

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(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

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CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	1	0.0667	(0,0.1929)	1	0.0667	(0,0.1929)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	1	0.0833	(0,0.2397)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	1	0.0833	(0,0.2397)

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Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

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AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	1	0.0667	(0,0.1929)	1	0.0667	(0,0.1929)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	1	0.0833	(0,0.2397)	1	0.0833	(0,0.2397)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	1	0.0833	(0,0.2397)	1	0.0833	(0,0.2397)

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(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

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AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

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CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	1	0.0833	(0,0.2397)	1	0.0833	(0,0.2397)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

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CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Patients Assessed	15	N/A	N/A	15	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

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AUGMENTATION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	1	0.0833	(0,0.2397)	1	0.0833	(0,0.2397)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	1	0.0833	(0,0.2397)	1	0.0833	(0,0.2397)
Total Patients Assessed	15	N/A	N/A	15	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

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CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	3	0.1765	(0,0.3577)	3	0.1765	(0,0.3577)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.0625	(0,0.1811)	1	0.0625	(0,0.1811)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	1	0.0625	(0,0.1811)	1	0.0625	(0,0.1811)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	1	0.0588	(0,0.1707)	1	0.0588	(0,0.1707)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	2	0.1176	(0,0.2708)	2	0.1176	(0,0.2708)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	1	0.0625	(0,0.1811)	1	0.0625	(0,0.1811)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08.18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	4	0.2513	(0.0352,0.4675)	4	0.2513	(0.0352,0.4675)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.0625	(0,0.1811)	1	0.0625	(0,0.1811)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	1	0.0625	(0,0.1811)	1	0.0625	(0,0.1811)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	1	0.0588	(0,0.1707)	1	0.0588	(0,0.1707)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	2	0.1176	(0,0.2708)	2	0.1176	(0,0.2708)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	1	0.0625	(0,0.1811)	1	0.0625	(0,0.1811)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	3	0.1765	(0,0.3577)	3	0.1765	(0,0.3577)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	1	0.0714	(0,0.2063)	1	0.0714	(0,0.2063)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0714	(0,0 2063)	1	0.0714	(0,0.2063)
Any Complication Excluding Cosmetic	4	0.2513	(0.0352,0.4675)	4	0.2513	(0.0352,0.4675)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	1	0.1250	(0,0.3542)	1	0.1250	(0,0.3542)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	1	0.1250	(0,0.3542)	1	0.1250	(0,0.3542)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	1	0.0667	(0,0.1929)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	1	0.0667	(0,0.1929)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	1	0.0588	(0,0.1707)	1	0.0588	(0,0.1707)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	1	0.0667	(0,0.1929)	1	0.0667	(0,0.1929)
Explant with Replacement with Study Device	1	0.0667	(0,0.1929)	1	0.0667	(0,0.1929)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	2	0.1312	(0,0.3022)	2	0.1312	(0,0.3022)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	1	0.0588	(0,0.1707)	1	0.0588	(0,0.1707)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	1	0.0588	(0,0.1707)	2	0.1261	(0,0.2901)
Total Patients Assessed	18	N/A	N/A	18	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
RECONSTRUCTION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	1	0.0714	(0,0.2063)	1	0.0714	(0,0.2063)
Revision Of Wound Closure	1	0.0588	(0,0.1707)	1	0.0588	(0,0.1707)
Scar Revision	1	0.1667	(0,0.4649)	1	0.1667	(0,0.4649)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	2	0.1261	(0,0.2901)	2	0.1261	(0,0.2901)
Total Patients Assessed	18	N/A	N/A	18	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	1	0.0769	(0, 0.2218)	2	0.1795	(0, 0.4086)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	1	0.0769	(0, 0.2218)	2	0.1795	(0, 0.4086)
Baker III, IV Capsular Contracture	1	0.0769	(0, 0.2218)	2	0.1795	(0, 0.4086)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08.18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	3	0.2967	(0.0072,0.5862)	3	0.2967	(0.0072,0.5862)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.1667	(0,0.4649)	1	0.1667	(0,0.4649)
Baker IV Capsular Contracture	2	0.1795	(0,0.4086)	2	0.1795	(0,0.4086)
Baker III, IV Capsular Contracture	2	0.1795	(0,0.4086)	2	0.1795	(0,0.4086)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Patient Request For Removal	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	1	0.0769	(0,0.2218)	2	0.1795	(0,0.4086)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ptoisis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18 1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	1	0.1250	(0,0.3542)	1	0.1250	(0,0.3542)
Patient Request For Removal	1	0.1250	(0,0.3542)	1	0.1250	(0,0.3542)
Any Complication Excluding Cosmetic	3	0.2967	(0.0072,0.5862)	3	0.2967	(0.0072,0.5862)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	1	0.0769	(0,0.2218)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	0	0.0000	(0, 0)	1	0.0769	(0,0.2218)
Other Reoperations	0	0.0000	(0, 0)	1	0.0769	(0,0.2218)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	1	0.0769	(0,0.2218)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18 1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	2	0.1923	(0, 0.4389)	2	0.1923	(0, 0.4389)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	2	0.1923	(0, 0.4389)	2	0.1923	(0, 0.4389)
Other Reoperations	2	0.1795	(0, 0.4086)	2	0.1795	(0, 0.4086)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	1	0.0769	(0, 0.2218)	1	0.0769	(0, 0.2218)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	1	0.1111	(0, 0.3164)	1	0.1111	(0, 0.3164)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	0	0.0000	(0, 0)	1	0.0769	(0,0 2218)
Total Patients Assessed	15	N/A	N/A	15	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
REVISION PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	3	0.2967	(0.0072,0.5862)	3	0.2967	(0.0072,0.5862)
Total Patients Assessed	15	N/A	N/A	15	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	5	0.1091	(0.0186,0.1997)	7	0.1648	(0.0518,0.2779)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.0238	(0,0.0699)	1	0.0238	(0,0.0699)
Baker IV Capsular Contracture	1	0.0238	(0,0.0699)	2	0.0517	(0,0.1218)
Baker III, IV Capsular Contracture	2	0.0476	(0, 0.112)	3	0.0756	(0,0.1583)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	1	0.0213	(0,0.0625)	1	0.0213	(0,0.0625)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	2	0.0440	(0,0.1038)	2	0.0440	(0,0.1038)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	1	0.0208	(0,0.0612)	1	0.0208	(0,0.0612)
Implant Malposition/Displacement	1	0.0238	(0,0.0699)	1	0.0238	(0,0.0699)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	9	0.2237	(0.0923,0.3551)	9	0.2237	(0.0923,0.3551)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	2	0.0848	(0,0.2084)	2	0.0848	(0,0.2084)
Baker IV Capsular Contracture	2	0.0517	(0,0.1218)	2	0.0517	(0,0.1218)
Baker III, IV Capsular Contracture	3	0.0756	(0,0.1583)	3	0.0756	(0,0.1583)
Breast Pain	0	0.0000	(0,0)	0	0.0000	(0,0)
Breast Sensation Changes	0	0.0000	(0,0)	0	0.0000	(0,0)
Delayed Wound Healing	0	0.0000	(0,0)	0	0.0000	(0,0)
Extrusion	1	0.0213	(0,0.0625)	1	0.0213	(0,0.0625)
Granuloma	0	0.0000	(0,0)	0	0.0000	(0,0)
Hematoma	0	0.0000	(0,0)	0	0.0000	(0,0)
Infection	2	0.0440	(0,0.1038)	2	0.0440	(0,0.1038)
Lymphadenopathy	0	0.0000	(0,0)	0	0.0000	(0,0)
Necrosis	0	0.0000	(0,0)	0	0.0000	(0,0)
New Diagnosis of Breast Cancer	0	0.0000	(0,0)	0	0.0000	(0,0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0,0)	0	0.0000	(0,0)
Nipple Sensation Changes	1	0.0208	(0,0.0612)	1	0.0208	(0,0.0612)
Implant Malposition/Displacement	1	0.0238	(0,0.0699)	1	0.0238	(0,0.0699)
Rupture	0	0.0000	(0,0)	0	0.0000	(0,0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Patient Request For Removal	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	5	0.1091	(0.0186,0.1997)	6	0.1370	(0.0342,0.2398)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	1	0.0286	(0,0.0838)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	1	0.0286	(0,0.0838)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	2	0.0621	(0,0.1457)	2	0.0621	(0,0.1457)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0286	(0,0.0838)	1	0.0286	(0,0.0838)
Patient Request For Removal	1	0.0333	(0,0.0976)	1	0.0333	(0,0.0976)
Any Complication Excluding Cosmetic	8	0.1958	(0.0717,0.3198)	8	0.1958	(0.0717,0.3198)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	2	0.0708	(0,0.1675)	2	0.0708	(0,0.1675)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	2	0.0708	(0,0.1675)	2	0.0708	(0,0.1675)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18 1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	2	0.0488	(0,0.1147)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	1	0.0250	(0,0.0734)
Explant without Replacement	0	0.0000	(0, 0)	1	0.0244	(0,0.0716)
Other Reoperations	1	0.0217	(0,0.0639)	2	0.0462	(0,0.1089)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	1	0.0244	(0,0.0716)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	3	0.0920	(0, 0.196)	3	0.0920	(0, 0.196)
Explant with Replacement with Study Device	1	0.0250	(0,0.0734)	1	0.0250	(0,0.0734)
Explant without Replacement	2	0.0687	(0,0.1649)	2	0.0687	(0,0.1649)
Other Reoperations	5	0.1304	(0.023,0.2378)	5	0.1304	(0.023,0.2378)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	1	0.0244	(0,0.0716)	1	0.0244	(0,0.0716)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	1	0.0286	(0,0.0838)	1	0.0286	(0,0.0838)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	1	0.0217	(0,0.0639)	1	0.0217	(0,0.0639)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	1	0.0217	(0,0.0639)	3	0.0707	(0,0.1479)
Total Patients Assessed	48	N/A	N/A	48	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (PATIENT LEVEL)
OVERALL PATIENTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	1	0.0286	(0,0.0838)	1	0.0286	(0,0.0838)
Revision Of Wound Closure	1	0.0217	(0,0.0639)	1	0.0217	(0,0.0639)
Scar Revision	2	0.0748	(0,0.1777)	2	0.0748	(0,0.1777)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	6	0.1706	(0.0407,0.3005)	6	0.1706	(0.0407,0.3005)
Total Patients Assessed	48	N/A	N/A	48	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	1	0.0400	(0, 0.1168)	3	0.1360	(0, 0.2799)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	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)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	1	0.0400	(0, 0.1168)	1	0.0400	(0, 0.1168)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	3	0.1360	(0, 0.2799)	3	0.1360	(0, 0.2799)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	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)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	1	0.0400	(0, 0.1168)	1	0.0400	(0, 0.1168)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	1	0.0400	(0,0.1168)	1	0.0400	(0,0.1168)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	2	0.1000	(0,0.2315)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	2	0.1000	(0,0.2315)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	1	0.0400	(0,0.1168)	1	0.0400	(0,0.1168)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	2	0.1000	(0,0.2315)	2	0.1000	(0,0.2315)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	2	0.1000	(0,0.2315)	2	0.1000	(0,0.2315)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	2	0.1000	(0,0.2315)	2	0.1000	(0,0.2315)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Total Implants Assessed	25	N/A	N/A	25	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	2	0.1000	(0,0.2315)	2	0.1000	(0,0.2315)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	2	0.1000	(0,0.2315)	2	0.1000	(0,0.2315)
Total Implants Assessed	25	N/A	N/A	25	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	3	0.1429	(0,0.2925)	3	0.1429	(0,0.2925)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.0500	(0,0.1455)	1	0.0500	(0,0.1455)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	1	0.0500	(0,0.1455)	1	0.0500	(0,0.1455)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	1	0.0476	(0,0.1387)	1	0.0476	(0,0.1387)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	2	0.0952	(0,0.2208)	2	0.0952	(0,0.2208)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	1	0.0500	(0,0.1455)	1	0.0500	(0,0.1455)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	5	0.2800	(0.0623,0.4977)	5	0.2800	(0.0623,0.4977)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.0500	(0,0.1455)	1	0.0500	(0,0.1455)
Baker IV Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker III, IV Capsular Contracture	1	0.0500	(0,0.1455)	1	0.0500	(0,0.1455)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	1	0.0476	(0,0.1387)	1	0.0476	(0,0.1387)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	2	0.0952	(0,0.2208)	2	0.0952	(0,0.2208)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	1	0.0500	(0,0.1455)	1	0.0500	(0,0.1455)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	3	0.1429	(0,0.2925)	3	0.1429	(0,0.2925)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	1	0.0556	(0,0.1614)	1	0.0556	(0,0.1614)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0556	(0,0.1614)	1	0.0556	(0,0.1614)
Any Complication Excluding Cosmetic	4	0.2000	(0.0233,0.3767)	4	0.2000	(0.0233,0.3767)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	1	0.0909	(0,0.2608)	1	0.0909	(0,0.2608)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	1	0.0909	(0,0.2608)	1	0.0909	(0,0.2608)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	2	0.1053	(0,0.2433)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	2	0.1053	(0,0.2433)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	1	0.0476	(0,0.1387)	1	0.0476	(0,0.1387)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	2	0.1053	(0, 0.2433)	2	0.1053	(0, 0.2433)
Explant with Replacement with Study Device	2	0.1053	(0, 0.2433)	2	0.1053	(0, 0.2433)
Explant without Replacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other Reoperations	3	0.2530	(0, 0.5436)	3	0.2530	(0, 0.5436)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	1	0.0476	(0,0.1387)	1	0.0476	(0,0.1387)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	1	0.0476	(0,0.1387)	3	0.1534	(0,0.3137)
Total Implants Assessed	23	N/A	N/A	23	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR RECONSTRUCTION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	1	0.0556	(0,0.1614)	1	0.0556	(0,0.1614)
Revision Of Wound Closure	1	0.0476	(0,0.1387)	1	0.0476	(0,0.1387)
Scar Revision	1	0.1429	(0,0.4021)	1	0.1429	(0,0.4021)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	3	0.1534	(0,0.3137)	3	0.1534	(0,0.3137)
Total Implants Assessed	23	N/A	N/A	23	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time. 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	1	0.0526	(0, 0.153)	2	0.1255	(0,0.2911)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Baker IV Capsular Contracture	1	0.0526	(0, 0.153)	2	0.1255	(0,0.2911)
Baker III, IV Capsular Contracture	1	0.0526	(0, 0.153)	2	0.1255	(0,0.2911)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18 SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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.i8.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	4	0.3004	(0.0463,0.5545)	4	0.3004	(0.0463,0.5545)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.1250	(0,0.3542)	1	0.1250	(0,0.3542)
Baker IV Capsular Contracture	2	0.1255	(0,0.2911)	2	0.1255	(0,0.2911)
Baker III, IV Capsular Contracture	2	0.1255	(0,0.2911)	2	0.1255	(0,0.2911)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Malposition/Displacement	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Patient Request For Removal	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	1	0.0526	(0, 0.153)	2	0.1255	(0, 0.2911)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	2	0.1818	(0,0.4097)	2	0.1818	(0,0.4097)
Patient Request For Removal	2	0.1818	(0,0.4097)	2	0.1818	(0,0.4097)
Any Complication Excluding Cosmetic	4	0.3004	(0.0463,0.5545)	4	0.3004	(0.0463,0.5545)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	2	0.1053	(0, 0.2433)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	0	0.0000	(0, 0)	2	0.1053	(0, 0.2433)
Other Reoperations	0	0.0000	(0, 0)	1	0.0526	(0, 0.153)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision DX: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	1	0.0526	(0, 0.153)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	4	0.2679	(0.0348, 0.501)	4	0.2679	(0.0348, 0.501)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explant without Replacement	4	0.2679	(0.0348, 0.501)	4	0.2679	(0.0348, 0.501)
Other Reoperations	2	0.1255	(0, 0.2911)	2	0.1255	(0, 0.2911)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	1	0.0526	(0, 0.153)	1	0.0526	(0, 0.153)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	1	0.0769	(0, 0.2218)	1	0.0769	(0, 0.2218)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	0	0.0000	(0, 0)	2	0.1053	(0,0.2433)
Total Implants Assessed	22	N/A	N/A	22	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
IMPLANTS USED FOR REVISION - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	5	0.3393	(0.0882,0.5904)	5	0.3393	(0.0882,0.5904)
Total Implants Assessed	22	N/A	N/A	22	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time. 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	5	0.0756	(0.0118,0.1395)	8	0.1334	(0.0463,0.2205)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	1	0.0164	(0,0.0483)	1	0.0164	(0,0.0483)
Baker IV Capsular Contracture	1	0.0164	(0,0.0483)	2	0.0357	(0,0.0844)
Baker III, IV Capsular Contracture	2	0.0328	(0,0.0775)	3	0.0521	(0,0.1098)
Breast Pain	0	0.0000	(0,0)	0	0.0000	(0,0)
Breast Sensation Changes	0	0.0000	(0,0)	0	0.0000	(0,0)
Delayed Wound Healing	0	0.0000	(0,0)	0	0.0000	(0,0)
Extrusion	1	0.0147	(0,0.0433)	1	0.0147	(0,0.0433)
Granuloma	0	0.0000	(0,0)	0	0.0000	(0,0)
Hematoma	0	0.0000	(0,0)	0	0.0000	(0,0)
Infection	2	0.0306	(0,0.0724)	2	0.0306	(0,0.0724)
Lymphadenopathy	0	0.0000	(0,0)	0	0.0000	(0,0)
Necrosis	0	0.0000	(0,0)	0	0.0000	(0,0)
New Diagnosis of Breast Cancer	0	0.0000	(0,0)	0	0.0000	(0,0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0,0)	0	0.0000	(0,0)
Nipple Sensation Changes	1	0.0143	(0,0.0421)	1	0.0143	(0,0.0421)
Implant Malposition/Displacement	1	0.0164	(0,0.0483)	1	0.0164	(0,0.0483)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	12	0.2205	(0.1075,0.3334)	12	0.2205	(0.1075,0.3334)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	2	0.0592	(0,0.1466)	2	0.0592	(0,0.1466)
Baker IV Capsular Contracture	2	0.0357	(0,0.0844)	2	0.0357	(0,0.0844)
Baker III, IV Capsular Contracture	3	0.0521	(0,0.1098)	3	0.0521	(0,0.1098)
Breast Pain	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Sensation Changes	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extrusion	1	0.0147	(0,0.0433)	1	0.0147	(0,0.0433)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Infection	2	0.0306	(0,0.0724)	2	0.0306	(0,0.0724)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	1	0.0143	(0,0.0421)	1	0.0143	(0,0.0421)
Implant Malposition/Displacement	1	0.0164	(0,0.0483)	1	0.0164	(0,0.0483)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Patient Request For Removal	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	5	0.0756	(0.0118,0.1395)	6	0.0949	(0.022,0.1677)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	0	0.0000	(0, 0)	2	0.0392	(0,0.0925)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	0	0.0000	(0, 0)	2	0.0392	(0,0.0925)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	3	0.0652	(0,0.1368)	3	0.0652	(0,0.1368)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0196	(0,0.0577)	1	0.0196	(0,0.0577)
Patient Request For Removal	2	0.0455	(0, 0.107)	2	0.0455	(0, 0.107)
Any Complication Excluding Cosmetic	9	0.1573	(0.0611,0.2536)	9	0.1573	(0.0611,0.2536)
II. Cosmetic Complication						
Asymmetry	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hypertrophic Scarring	3	0.0667	(0,0.1408)	3	0.0667	(0,0.1408)
Ptosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wrinkling	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Cosmetic Complication	3	0.0667	(0,0.1408)	3	0.0667	(0,0.1408)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	0	0.0000	(0, 0)	4	0.0667	(0.0035, 0.1298)
Explant with Replacement with Study Device	0	0.0000	(0, 0)	2	0.0345	(0, 0.0814)
Explant without Replacement	0	0.0000	(0, 0)	2	0.0333	(0, 0.0788)
Other Reoperations	1	0.0152	(0, 0.0446)	2	0.0318	(0, 0.0753)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	0	0.0000	(0, 0)	1	0.0167	(0, 0.0491)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08.56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	6	0.1232	(0.0269,0.2196)	6	0.1232	(0.0269,0.2196)
Explant with Replacement with Study Device	2	0.0345	(0,0.0814)	2	0.0345	(0,0.0814)
Explant without Replacement	4	0.0919	(0.0024,0.1814)	4	0.0919	(0.0024,0.1814)
Other Reoperations	7	0.1400	(0.0403,0.2397)	7	0.1400	(0.0403,0.2397)
Biopsy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	1	0.0167	(0,0.0491)	1	0.0167	(0,0.0491)
Capsulorrhaphy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulotomy	1	0.0196	(0,0.0577)	1	0.0196	(0,0.0577)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Incision and Drainage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	1	0.0152	(0,0.0446)	1	0.0152	(0,0.0446)
Scar Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	1	0.0152	(0,0.0446)	5	0.0819	(0.013,0.1508)
Total Implants Assessed	70	N/A	N/A	70	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 8.18.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS OR REOPERATIONS AFTER EXPLANTATION WITH REPLACEMENT USING A STUDY DEVICE (IMPLANT LEVEL)
OVERALL IMPLANTS - FDA Item 13

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Infected Implant And Replacement With Tissue Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	1	0.0196	(0,0.0577)	1	0.0196	(0,0.0577)
Revision Of Wound Closure	1	0.0152	(0,0.0446)	1	0.0152	(0,0.0446)
Scar Revision	3	0.0702	(0,0.1491)	3	0.0702	(0,0.1491)
Skin Adjustment	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Reoperation	10	0.1967	(0.0828,0.3106)	10	0.1967	(0.0828,0.3106)
Total Implants Assessed	70	N/A	N/A	70	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_18.SAS

Creation Date, Time: 24AUG04 08:56

(a) Time from re-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 the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, 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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	2 (2.5)	2 (2.8)	2 (3.8)
Capsulectomy	18 (22.8)	18 (25.4)	15 (28.3)
Capsulorrhaphy	4 (5.1)	4 (5.6)	3 (5.7)
Capsulotomy	8 (10.1)	8 (11.3)	6 (11.3)
Implant Pocket Revision	0 (0.0)	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	14 (17.7)	14 (19.7)	8 (15.1)
Implant Removal (Without Replacement)	8 (10.1)	8 (11.3)	5 (9.4)
Implant Reposition	2 (2.5)	2 (2.8)	2 (3.8)
Incision and Drainage	11 (13.9)	10 (14.1)	10 (18.9)
Mastopexy	0 (0.0)	0 (0.0)	0 (0.0)
Nipple Related Procedure (unplanned)	1 (1.3)	1 (1.4)	1 (1.9)
Revision Of Wound Closure	3 (3.8)	3 (4.2)	3 (5.7)
Scar Revision	5 (6.3)	5 (7.0)	4 (7.5)
Skin Adjustment	3 (3.8)	3 (4.2)	2 (3.8)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Create Inframammary Fold	0 (0.0)	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)	0 (0.0)
Total Assessed with Additional Surgical Procedures	79 (100.0)	71 (100.0)	53 (100.0)

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 53 patients who had 79 additional surgical procedures during 73 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	4 (3.0)	4 (4.0)	4 (5.9)
Capsulectomy	31 (23.5)	27 (27.3)	21 (30.9)
Capsulorrhaphy	4 (3.0)	4 (4.0)	3 (4.4)
Capsulotomy	14 (10.6)	14 (14.1)	10 (14.7)
Implant Pocket Revision	2 (1.5)	2 (2.0)	1 (1.5)
Implant Removal (With Replacement)	20 (15.2)	20 (20.2)	13 (19.1)
Implant Removal (Without Replacement)	14 (10.6)	14 (14.1)	8 (11.8)
Implant Reposition	4 (3.0)	4 (4.0)	3 (4.4)
Incision and Drainage	12 (9.1)	11 (11.1)	11 (16.2)
Mastopexy	2 (1.5)	2 (2.0)	1 (1.5)
Nipple Related Procedure (unplanned)	1 (0.8)	1 (1.0)	1 (1.5)
Revision Of Wound Closure	3 (2.3)	3 (3.0)	3 (4.4)
Scar Revision	15 (11.4)	15 (15.2)	10 (14.7)
Skin Adjustment	5 (3.8)	5 (5.1)	3 (4.4)
Other	1 (0.8)	1 (1.0)	1 (1.5)
Create Inframammary Fold	0 (0.0)	0 (0.0)	0 (0.0)
Excise Breast Mass	1 (0.8)	1 (1.0)	1 (1.5)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)	0 (0.0)
Flap Coverage Of Expander	0 (0.0)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 68 patients who had 132 additional surgical procedures during 112 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)	0 (0.0)
Total Assessed with Additional Surgical Procedures	132 (100.0)	99 (100.0)	68 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09.57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 68 patients who had 132 additional surgical procedures during 112 reoperations.

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 9.1

REOPERATIVE REPORT. TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	4 (2.5)	4 (3.5)	4 (5.1)
Capsulectomy	36 (22.5)	31 (27.0)	24 (30.4)
Capsulorrhaphy	4 (2.5)	4 (3.5)	3 (3.8)
Capsulotomy	17 (10.6)	16 (13.9)	12 (15.2)
Implant Pocket Revision	2 (1.3)	2 (1.7)	1 (1.3)
Implant Removal (With Replacement)	24 (15.0)	24 (20.9)	15 (19.0)
Implant Removal (Without Replacement)	21 (13.1)	21 (18.3)	12 (15.2)
Implant Reposition	4 (2.5)	4 (3.5)	3 (3.8)
Incision and Drainage	12 (7.5)	11 (9.6)	11 (13.9)
Mastopexy	4 (2.5)	4 (3.5)	2 (2.5)
Nipple Related Procedure (unplanned)	1 (0.6)	1 (0.9)	1 (1.3)
Revision Of Wound Closure	3 (1.9)	3 (2.6)	3 (3.8)
Scar Revision	18 (11.3)	18 (15.7)	12 (15.2)
Skin Adjustment	8 (5.0)	8 (7.0)	5 (6.3)
Other	2 (1.3)	2 (1.7)	2 (2.5)
Breast Mass Excision Dx: Fibroadenoma	0 (0.0)	0 (0.0)	0 (0.0)
Create Inframammary Fold	0 (0.0)	0 (0.0)	0 (0.0)
Excise Breast Mass	2 (1.3)	2 (1.7)	2 (2.5)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)	0 (0.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 79 patients who had 160 additional surgical procedures during 134 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Flap Coverage Of Expander	0 (0.0)	0 (0.0)	0 (0.0)
Needle Aspiration	0 (0.0)	0 (0.0)	0 (0.0)
Open Incision To Rule Out Implant Rupture	0 (0.0)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)	0 (0.0)
Total Assessed with Additional Surgical Procedures	160 (100.0)	115 (100.0)	79 (100.0)
Total Assessed with Reoperation	134 (100.0)		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 79 patients who had 160 additional surgical procedures during 134 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	8 (8.1)	7 (11.5)	6 (12.5)
Capsulectomy	7 (7.1)	7 (11.5)	6 (12.5)
Capsulorrhaphy	2 (2.0)	2 (3.3)	2 (4.2)
Capsulotomy	13 (13.1)	13 (21.3)	12 (25.0)
Implant Pocket Revision	4 (4.0)	4 (6.6)	3 (6.3)
Implant Removal (With Replacement)	17 (17.2)	17 (27.9)	13 (27.1)
Implant Removal (Without Replacement)	9 (9.1)	9 (14.8)	7 (14.6)
Implant Reposition	12 (12.1)	12 (19.7)	10 (20.8)
Incision and Drainage	3 (3.0)	3 (4.9)	3 (6.3)
Mastopexy	1 (1.0)	1 (1.6)	1 (2.1)
Nipple Related Procedure (unplanned)	2 (2.0)	2 (3.3)	2 (4.2)
Revision Of Wound Closure	1 (1.0)	1 (1.6)	1 (2.1)
Scar Revision	4 (4.0)	4 (6.6)	3 (6.3)
Skin Adjustment	12 (12.1)	12 (19.7)	9 (18.8)
Other	4 (4.0)	3 (4.9)	2 (4.2)
Create Inframammary Fold	2 (2.0)	1 (1.6)	1 (2.1)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	2 (2.0)	2 (3.3)	1 (2.1)
Total Assessed with Additional Surgical Procedures	99 (100.0)	61 (100.0)	48 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 48 patients who had 99 additional surgical procedures during 66 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	10 (7.6)	9 (11.3)	8 (12.7)
Capsulectomy	10 (7.6)	10 (12.5)	9 (14.3)
Capsulorrhaphy	2 (1.5)	2 (2.5)	2 (3.2)
Capsulotomy	14 (10.6)	14 (17.5)	13 (20.6)
Implant Pocket Revision	6 (4.5)	6 (7.5)	4 (6.3)
Implant Removal (With Replacement)	23 (17.4)	23 (28.8)	18 (28.6)
Implant Removal (Without Replacement)	13 (9.8)	13 (16.3)	11 (17.5)
Implant Reposition	17 (12.9)	15 (18.8)	12 (19.0)
Incision and Drainage	3 (2.3)	3 (3.8)	3 (4.8)
Mastopexy	3 (2.3)	3 (3.8)	2 (3.2)
Nipple Related Procedure (unplanned)	2 (1.5)	2 (2.5)	2 (3.2)
Revision Of Wound Closure	1 (0.8)	1 (1.3)	1 (1.6)
Scar Revision	7 (5.3)	7 (8.8)	5 (7.9)
Skin Adjustment	14 (10.6)	14 (17.5)	10 (15.9)
Other	7 (5.3)	6 (7.5)	4 (6.3)
Create Inframammary Fold	2 (1.5)	1 (1.3)	1 (1.6)
Excise Breast Mass	0 (0.0)	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)	0 (0.0)
Flap Coverage Of Expander	1 (0.8)	1 (1.3)	1 (1.6)
Removal Of Nodule On Chest Wall	2 (1.5)	2 (2.5)	1 (1.6)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 63 patients who had 132 additional surgical procedures during 88 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Revision Of Breast / External To Pocket	2 (1.5)	2 (2.5)	1 (1.6)
Total Assessed with Additional Surgical Procedures	132 (100.0)	80 (100.0)	63 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 63 patients who had 132 additional surgical procedures during 88 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	10 (7.2)	9 (11.0)	8 (12.5)
Capsulectomy	10 (7.2)	10 (12.2)	9 (14.1)
Capsulorrhaphy	2 (1.4)	2 (2.4)	2 (3.1)
Capsulotomy	14 (10.1)	14 (17.1)	13 (20.3)
Implant Pocket Revision	6 (4.3)	6 (7.3)	4 (6.3)
Implant Removal (With Replacement)	23 (16.5)	23 (28.0)	18 (28.1)
Implant Removal (Without Replacement)	17 (12.2)	17 (20.7)	13 (20.3)
Implant Reposition	17 (12.2)	15 (18.3)	12 (18.8)
Incision and Drainage	4 (2.9)	4 (4.9)	4 (6.3)
Mastopexy	4 (2.9)	3 (3.7)	2 (3.1)
Nipple Related Procedure (unplanned)	2 (1.4)	2 (2.4)	2 (3.1)
Revision Of Wound Closure	1 (0.7)	1 (1.2)	1 (1.6)
Scar Revision	7 (5.0)	7 (8.5)	5 (7.8)
Skin Adjustment	14 (10.1)	14 (17.1)	10 (15.6)
Other	8 (5.8)	7 (8.5)	5 (7.8)
Breast Mass Excision Dx: Fibroadenoma	1 (0.7)	1 (1.2)	1 (1.6)
Create Inframammary Fold	2 (1.4)	1 (1.2)	1 (1.6)
Excise Breast Mass	0 (0.0)	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 64 patients who had 139 additional surgical procedures during 95 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Flap Coverage Of Expander	1 (0.7)	1 (1.2)	1 (1.6)
Needle Aspiration	0 (0.0)	0 (0.0)	0 (0.0)
Open Incision To Rule Out Implant Rupture	0 (0.0)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	2 (1.4)	2 (2.4)	1 (1.6)
Revision Of Breast / External To Pocket	2 (1.4)	2 (2.4)	1 (1.6)
Total Assessed with Additional Surgical Procedures	139 (100.0)	82 (100.0)	64 (100.0)
Total Assessed with Reoperation	95 (100.0)		

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 64 patients who had 139 additional surgical procedures during 95 reoperations.

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 9.1

REOPERATIVE REPORT. TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period. 0 - 12 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	6 (6.9)	5 (10.9)	5 (15.6)
Capsulectomy	12 (13.8)	12 (26.1)	9 (28.1)
Capsulorrhaphy	4 (4.6)	2 (4.3)	1 (3.1)
Capsulotomy	14 (16.1)	11 (23.9)	8 (25.0)
Implant Pocket Revision	0 (0.0)	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	12 (13.8)	12 (26.1)	8 (25.0)
Implant Removal (Without Replacement)	6 (6.9)	6 (13.0)	4 (12.5)
Implant Reposition	4 (4.6)	4 (8.7)	2 (6.3)
Incision and Drainage	7 (8.0)	6 (13.0)	5 (15.6)
Mastopexy	4 (4.6)	4 (8.7)	2 (6.3)
Nipple Related Procedure (unplanned)	0 (0.0)	0 (0.0)	0 (0.0)
Revision Of Wound Closure	2 (2.3)	2 (4.3)	2 (6.3)
Scar Revision	5 (5.7)	5 (10.9)	3 (9.4)
Skin Adjustment	9 (10.3)	8 (17.4)	5 (15.6)
Other	2 (2.3)	2 (4.3)	1 (3.1)
Create Inframammary Fold	0 (0.0)	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	2 (2.3)	2 (4.3)	1 (3.1)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)	0 (0.0)
Total Assessed with Additional Surgical Procedures	87 (100.0)	46 (100.0)	32 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 32 patients who had 87 additional surgical procedures during 61 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	8 (6.7)	6 (9.2)	6 (14.0)
Capsulectomy	14 (11.8)	13 (20.0)	10 (23.3)
Capsulorrhaphy	6 (5.0)	4 (6.2)	2 (4.7)
Capsulotomy	16 (13.4)	13 (20.0)	10 (23.3)
Implant Pocket Revision	0 (0.0)	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	18 (15.1)	18 (27.7)	12 (27.9)
Implant Removal (Without Replacement)	13 (10.9)	13 (20.0)	8 (18.6)
Implant Reposition	8 (6.7)	8 (12.3)	4 (9.3)
Incision and Drainage	7 (5.9)	6 (9.2)	5 (11.6)
Mastopexy	4 (3.4)	4 (6.2)	2 (4.7)
Nipple Related Procedure (unplanned)	0 (0.0)	0 (0.0)	0 (0.0)
Revision Of Wound Closure	2 (1.7)	2 (3.1)	2 (4.7)
Scar Revision	8 (6.7)	8 (12.3)	5 (11.6)
Skin Adjustment	12 (10.1)	11 (16.9)	7 (16.3)
Other	3 (2.5)	2 (3.1)	1 (2.3)
Create Inframammary Fold	0 (0.0)	0 (0.0)	0 (0.0)
Excise Breast Mass	0 (0.0)	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	2 (1.7)	2 (3.1)	1 (2.3)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.8)	1 (1.5)	1 (2.3)
Flap Coverage Of Expander	0 (0.0)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)	0 (0.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time. 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 43 patients who had 119 additional surgical procedures during 86 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)	0 (0.0)
Total Assessed with Additional Surgical Procedures	119 (100.0)	65 (100.0)	43 (100.0)

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Creation Date, Time: 26AUG04 09.57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 43 patients who had 119 additional surgical procedures during 86 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	10 (7.1)	7 (9.0)	7 (13.7)
Capsulectomy	18 (12.8)	17 (21.8)	12 (23.5)
Capsulorrhaphy	6 (4.3)	4 (5.1)	2 (3.9)
Capsulotomy	17 (12.1)	14 (17.9)	11 (21.6)
Implant Pocket Revision	0 (0.0)	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	21 (14.9)	21 (26.9)	14 (27.5)
Implant Removal (Without Replacement)	18 (12.8)	18 (23.1)	11 (21.6)
Implant Reposition	10 (7.1)	10 (12.8)	5 (9.8)
Incision and Drainage	7 (5.0)	6 (7.7)	5 (9.8)
Mastopexy	5 (3.5)	5 (6.4)	3 (5.9)
Nipple Related Procedure (unplanned)	1 (0.7)	1 (1.3)	1 (2.0)
Revision Of Wound Closure	2 (1.4)	2 (2.6)	2 (3.9)
Scar Revision	9 (6.4)	9 (11.5)	6 (11.8)
Skin Adjustment	12 (8.5)	11 (14.1)	7 (13.7)
Other	5 (3.5)	4 (5.1)	3 (5.9)
Breast Mass Excision Dx: Fibroadenoma	0 (0.0)	0 (0.0)	0 (0.0)
Create Inframammary Fold	0 (0.0)	0 (0.0)	0 (0.0)
Excise Breast Mass	0 (0.0)	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	2 (1.4)	2 (2.6)	1 (2.0)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.7)	1 (1.3)	1 (2.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time. 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 51 patients who had 141 additional surgical procedures during 100 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
REVISION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Flap Coverage Of Expander	0 (0.0)	0 (0.0)	0 (0.0)
Needle Aspiration	1 (0.7)	1 (1.3)	1 (2.0)
Open Incision To Rule Out Implant Rupture	1 (0.7)	1 (1.3)	1 (2.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)	0 (0.0)
Total Assessed with Additional Surgical Procedures	141 (100.0)	78 (100.0)	51 (100.0)
Total Assessed with Reoperation	100 (100.0)		

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 51 patients who had 141 additional surgical procedures during 100 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	16 (6.0)	14 (7.9)	13 (9.8)
Capsulectomy	37 (14.0)	37 (20.8)	30 (22.6)
Capsulorrhaphy	10 (3.8)	8 (4.5)	6 (4.5)
Capsulotomy	35 (13.2)	32 (18.0)	26 (19.5)
Implant Pocket Revision	4 (1.5)	4 (2.2)	3 (2.3)
Implant Removal (With Replacement)	43 (16.2)	43 (24.2)	29 (21.8)
Implant Removal (Without Replacement)	23 (8.7)	23 (12.9)	16 (12.0)
Implant Reposition	18 (6.8)	18 (10.1)	14 (10.5)
Incision and Drainage	21 (7.9)	19 (10.7)	18 (13.5)
Mastopexy	5 (1.9)	5 (2.8)	3 (2.3)
Nipple Related Procedure (unplanned)	3 (1.1)	3 (1.7)	3 (2.3)
Revision Of Wound Closure	6 (2.3)	6 (3.4)	6 (4.5)
Scar Revision	14 (5.3)	14 (7.9)	10 (7.5)
Skin Adjustment	24 (9.1)	23 (12.9)	16 (12.0)
Other	6 (2.3)	5 (2.8)	3 (2.3)
Create Inframammary Fold	2 (0.8)	1 (0.6)	1 (0.8)
Excision Of Skin Lesion	2 (0.8)	2 (1.1)	1 (0.8)
Removal Of Nodule On Chest Wall	2 (0.8)	2 (1.1)	1 (0.8)
Total Assessed with Additional Surgical Procedures	265 (100.0)	178 (100.0)	133 (100.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 133 patients who had 265 additional surgical procedures during 200 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	22 (5.7)	19 (7.8)	18 (10.3)
Capsulectomy	55 (14.4)	50 (20.5)	40 (23.0)
Capsulorrhaphy	12 (3.1)	10 (4.1)	7 (4.0)
Capsulotomy	44 (11.5)	41 (16.8)	33 (19.0)
Implant Pocket Revision	8 (2.1)	8 (3.3)	5 (2.9)
Implant Removal (With Replacement)	61 (15.9)	61 (25.0)	43 (24.7)
Implant Removal (Without Replacement)	40 (10.4)	40 (16.4)	27 (15.5)
Implant Reposition	29 (7.6)	27 (11.1)	19 (10.9)
Incision and Drainage	22 (5.7)	20 (8.2)	19 (10.9)
Mastopexy	9 (2.3)	9 (3.7)	5 (2.9)
Nipple Related Procedure (unplanned)	3 (0.8)	3 (1.2)	3 (1.7)
Revision Of Wound Closure	6 (1.6)	6 (2.5)	6 (3.4)
Scar Revision	30 (7.8)	30 (12.3)	20 (11.5)
Skin Adjustment	31 (8.1)	30 (12.3)	20 (11.5)
Other	11 (2.9)	9 (3.7)	6 (3.4)
Create Inframammary Fold	2 (0.5)	1 (0.4)	1 (0.6)
Excise Breast Mass	1 (0.3)	1 (0.4)	1 (0.6)
Excision Of Skin Lesion	2 (0.5)	2 (0.8)	1 (0.6)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.3)	1 (0.4)	1 (0.6)
Flap Coverage Of Expander	1 (0.3)	1 (0.4)	1 (0.6)
Removal Of Nodule On Chest Wall	2 (0.5)	2 (0.8)	1 (0.6)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09.57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 174 patients who had 383 additional surgical procedures during 286 reoperations.

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 9.1

REOPERATIVE REPORT. TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Revision Of Breast / External To Pocket	2 (0.5)	2 (0.8)	1 (0.6)
Total Assessed with Additional Surgical Procedures	383 (100.0)	244 (100.0)	174 (100.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 174 patients who had 383 additional surgical procedures during 286 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Biopsy	24 (5.5)	20 (7.3)	19 (9.8)
Capsulectomy	64 (14.5)	58 (21.1)	45 (23.2)
Capsulorrhaphy	12 (2.7)	10 (3.6)	7 (3.6)
Capsulotomy	48 (10.9)	44 (16.0)	36 (18.6)
Implant Pocket Revision	8 (1.8)	8 (2.9)	5 (2.6)
Implant Removal (With Replacement)	68 (15.5)	68 (24.7)	47 (24.2)
Implant Removal (Without Replacement)	56 (12.7)	56 (20.4)	36 (18.6)
Implant Reposition	31 (7.0)	29 (10.5)	20 (10.3)
Incision and Drainage	23 (5.2)	21 (7.6)	20 (10.3)
Mastopexy	13 (3.0)	12 (4.4)	7 (3.6)
Nipple Related Procedure (unplanned)	4 (0.9)	4 (1.5)	4 (2.1)
Revision Of Wound Closure	6 (1.4)	6 (2.2)	6 (3.1)
Scar Revision	34 (7.7)	34 (12.4)	23 (11.9)
Skin Adjustment	34 (7.7)	33 (12.0)	22 (11.3)
Other	15 (3.4)	13 (4.7)	10 (5.2)
Breast Mass Excision Dx: Fibroadenoma	1 (0.2)	1 (0.4)	1 (0.5)
Create Inframammary Fold	2 (0.5)	1 (0.4)	1 (0.5)
Excise Breast Mass	2 (0.5)	2 (0.7)	2 (1.0)
Excision Of Skin Lesion	2 (0.5)	2 (0.7)	1 (0.5)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.2)	1 (0.4)	1 (0.5)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time. 26AUG04 09:57

Note 1. Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2. Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3. Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4. There were 194 patients who had 440 additional surgical procedures during 329 reoperations.

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 9.1

REOPERATIVE REPORT: TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 10
OVERALL PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Additional Surgical Procedures n(%)	No. of Implants n(%)	No. of Patients n(%)
Flap Coverage Of Expander	1 (0.2)	1 (0.4)	1 (0.5)
Needle Aspiration	1 (0.2)	1 (0.4)	1 (0.5)
Open Incision To Rule Out Implant Rupture	1 (0.2)	1 (0.4)	1 (0.5)
Removal Of Nodule On Chest Wall	2 (0.5)	2 (0.7)	1 (0.5)
Revision Of Breast / External To Pocket	2 (0.5)	2 (0.7)	1 (0.5)
Total Assessed with Additional Surgical Procedures	440 (100.0)	275 (100.0)	194 (100.0)
Total Assessed with Reoperation	329 (100.0)		

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_1.SAS

Creation Date, Time: 26AUG04 09:57

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Within capsulotomies, there were 6 closed capsulotomy reoperations involving 3 implants and 2 patients in revision patients.

Note 3: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Note 4: There were 194 patients who had 440 additional surgical procedures during 329 reoperations.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	5 (6.8)	5 (7.0)	4 (7.5)
BREAST MASS	1 (1.4)	1 (1.4)	1 (1.9)
BREAST PAIN	0 (0.0)	0 (0.0)	0 (0.0)
CAPSULAR CONTRACTURE III/IV	22 (30.1)	22 (31.0)	16 (30.2)
DELAYED WOUND HEALING	1 (1.4)	1 (1.4)	1 (1.9)
EXTRUSION	1 (1.4)	1 (1.4)	1 (1.9)
HEMATOMA	10 (13.7)	9 (12.7)	9 (17.0)
HYPERTROPHIC SCARRING	4 (5.5)	4 (5.6)	3 (5.7)
IMPLANT MALPOSITION/DISPLACEMENT	1 (1.4)	1 (1.4)	1 (1.9)
INFECTION	3 (4.1)	3 (4.2)	3 (5.7)
IRRITATION/INFLAMMATION	0 (0.0)	0 (0.0)	0 (0.0)
NIPPLE RELATED (UNPLANNED)	0 (0.0)	0 (0.0)	0 (0.0)
PATIENT REQUEST	19 (26.0)	19 (26.8)	10 (18.9)
PTOSIS	2 (2.7)	2 (2.8)	1 (1.9)
SEROMA	1 (1.4)	1 (1.4)	1 (1.9)
WRINKLING	1 (1.4)	1 (1.4)	1 (1.9)
OTHER	2 (2.7)	2 (2.8)	2 (3.8)
BREAST / SKIN LESIONS	0 (0.0)	0 (0.0)	0 (0.0)
EXTRA SKIN BUMP	0 (0.0)	0 (0.0)	0 (0.0)
GRANULOMA	0 (0.0)	0 (0.0)	0 (0.0)
MUSCLE SPASM	0 (0.0)	0 (0.0)	0 (0.0)
POCKET TEAR	0 (0.0)	0 (0.0)	0 (0.0)
RECURRENT BREAST CANCER	0 (0.0)	0 (0.0)	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time. 03NOV04 10:19

- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)	0 (0.0)	0 (0.0)
SUTURE REACTION	1 (1.4)	1 (1.4)	1 (1.9)
SYMMASTIA	0 (0.0)	0 (0.0)	0 (0.0)
TEAR IN CAPSULE	1 (1.4)	1 (1.4)	1 (1.9)
TIGHT BUNILLI SUTURE	0 (0.0)	0 (0.0)	0 (0.0)
MISSING	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL ASSESSED WITH REOPERATION	73 (100.0)	71 (100.0)	53 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time: 03NOV04 10:19

- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
 Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
 Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9 2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	5 (4.5)	5 (5.1)	4 (5.9)
BREAST MASS	3 (2.7)	3 (3.0)	3 (4.4)
BREAST PAIN	2 (1.8)	2 (2.0)	1 (1.5)
CAPSULAR CONTRACTURE III/IV	36 (32.1)	33 (33.3)	24 (35.3)
DELAYED WOUND HEALING	1 (0.9)	1 (1.0)	1 (1.5)
EXTRUSION	1 (0.9)	1 (1.0)	1 (1.5)
HEMATOMA	11 (9.8)	10 (10.1)	10 (14.7)
HYPERTROPHIC SCARRING	12 (10.7)	12 (12.1)	8 (11.8)
IMPLANT MALPOSITION/DISPLACEMENT	3 (2.7)	3 (3.0)	2 (2.9)
INFECTION	3 (2.7)	3 (3.0)	3 (4.4)
IRRITATION/INFLAMMATION	0 (0.0)	0 (0.0)	0 (0.0)
NIPPLE RELATED (UNPLANNED)	0 (0.0)	0 (0.0)	0 (0.0)
PATIENT REQUEST	26 (23.2)	26 (26.3)	14 (20.6)
PTOSIS	2 (1.8)	2 (2.0)	1 (1.5)
SEROMA	1 (0.9)	1 (1.0)	1 (1.5)
WRINKLING	3 (2.7)	3 (3.0)	2 (2.9)
OTHER	3 (2.7)	3 (3.0)	3 (4.4)
BREAST / SKIN LESIONS	0 (0.0)	0 (0.0)	0 (0.0)
EXTRA SKIN BUMP	0 (0.0)	0 (0.0)	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	1 (0.9)	1 (1.0)	1 (1.5)
GRANULOMA	0 (0.0)	0 (0.0)	0 (0.0)
LACK OF PROJECTION	0 (0.0)	0 (0.0)	0 (0.0)
MUSCLE SPASM	0 (0.0)	0 (0.0)	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time: 03NOV04 10:19

- Note 1. Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)	0 (0.0)	0 (0.0)
POCKET TEAR	0 (0.0)	0 (0.0)	0 (0.0)
RECURRENT BREAST CANCER	0 (0.0)	0 (0.0)	0 (0.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)	0 (0.0)	0 (0.0)
SUTURE REACTION	1 (0.9)	1 (1.0)	1 (1.5)
SYMMASTIA	0 (0.0)	0 (0.0)	0 (0.0)
TEAR IN CAPSULE	1 (0.9)	1 (1.0)	1 (1.5)
TIGHT BUNILLI SUTURE	0 (0.0)	0 (0.0)	0 (0.0)
MISSING	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL ASSESSED WITH REOPERATION	112 (100.0)	99 (100.0)	68 (100.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time: 03NOV04 10.19

- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
 Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
 Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	5 (3.7)	5 (4.3)	4 (5.1)
BREAST MASS	4 (3.0)	4 (3.5)	4 (5.1)
BREAST PAIN	2 (1.5)	2 (1.7)	1 (1.3)
CAPSULAR CONTRACTURE III/IV	43 (32.1)	37 (32.2)	28 (35.4)
DELAYED WOUND HEALING	1 (0.7)	1 (0.9)	1 (1.3)
EXTRUSION	1 (0.7)	1 (0.9)	1 (1.3)
HEMATOMA	11 (8.2)	10 (8.7)	10 (12.7)
HYPERTROPHIC SCARRING	15 (11.2)	15 (13.0)	10 (12.7)
IMPLANT MALPOSITION/DISPLACEMENT	3 (2.2)	3 (2.6)	2 (2.5)
INFECTION	3 (2.2)	3 (2.6)	3 (3.8)
IRRITATION/INFLAMMATION	0 (0.0)	0 (0.0)	0 (0.0)
NECROSIS	2 (1.5)	2 (1.7)	1 (1.3)
NIPPLE RELATED (UNPLANNED)	0 (0.0)	0 (0.0)	0 (0.0)
PATIENT REQUEST	31 (23.1)	31 (27.0)	17 (21.5)
PTOSIS	5 (3.7)	5 (4.3)	3 (3.8)
SEROMA	1 (0.7)	1 (0.9)	1 (1.3)
WRINKLING	3 (2.2)	3 (2.6)	2 (2.5)
OTHER	4 (3.0)	4 (3.5)	4 (5.1)
ABNORMAL MAMMOGRAM	0 (0.0)	0 (0.0)	0 (0.0)
BREAST / SKIN LESIONS	0 (0.0)	0 (0.0)	0 (0.0)
EXTRA SKIN BUMP	0 (0.0)	0 (0.0)	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	1 (0.7)	1 (0.9)	1 (1.3)
GRANULOMA	0 (0.0)	0 (0.0)	0 (0.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2 SAS

Creation Date, Time: 03NOV04 10:19

- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
LACK OF PROJECTION	0 (0.0)	0 (0.0)	0 (0.0)
MUSCLE SPASM	0 (0.0)	0 (0.0)	0 (0.0)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)	0 (0.0)	0 (0.0)
POCKET TEAR	0 (0.0)	0 (0.0)	0 (0.0)
RECURRENT BREAST CANCER	0 (0.0)	0 (0.0)	0 (0.0)
RIGHT EXPLANTED SO LEFT DONE ALSO	1 (0.7)	1 (0.9)	1 (1.3)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)	0 (0.0)	0 (0.0)
SUSPECTED RUPTURE	0 (0.0)	0 (0.0)	0 (0.0)
SUTURE REACTION	1 (0.7)	1 (0.9)	1 (1.3)
SYMMASTIA	0 (0.0)	0 (0.0)	0 (0.0)
TEAR IN CAPSULE	1 (0.7)	1 (0.9)	1 (1.3)
TIGHT BUNILLI SUTURE	0 (0.0)	0 (0.0)	0 (0.0)
TOO LARGE	0 (0.0)	0 (0.0)	0 (0.0)
MISSING	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL ASSESSED WITH REOPERATION	134 (100.0)	115 (100.0)	79 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time: 03NOV04 10:19

- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
 Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
 Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	15 (22.7)	15 (24.6)	13 (27.1)
BREAST MASS	6 (9.1)	5 (8.2)	4 (8.3)
BREAST PAIN	1 (1.5)	1 (1.6)	1 (2.1)
CAPSULAR CONSTRICTURE III/IV	6 (9.1)	6 (9.8)	4 (8.3)
DELAYED WOUND HEALING	0 (0.0)	0 (0.0)	0 (0.0)
EXTRUSION	2 (3.0)	2 (3.3)	2 (4.2)
HEMATOMA	1 (1.5)	1 (1.6)	1 (2.1)
HYPERTROPHIC SCARRING	0 (0.0)	0 (0.0)	0 (0.0)
IMPLANT MALPOSITION/DISPLACEMENT	7 (10.6)	7 (11.5)	7 (14.6)
INFECTION	4 (6.1)	4 (6.6)	4 (8.3)
IRRITATION/INFLAMMATION	0 (0.0)	0 (0.0)	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (3.0)	2 (3.3)	2 (4.2)
PATIENT REQUEST	10 (15.2)	10 (16.4)	6 (12.5)
PTOSIS	1 (1.5)	1 (1.6)	1 (2.1)
SEROMA	1 (1.5)	1 (1.6)	1 (2.1)
WRINKLING	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	8 (12.1)	7 (11.5)	6 (12.5)
BREAST / SKIN LESIONS	1 (1.5)	1 (1.6)	1 (2.1)
EXTRA SKIN BUMP	1 (1.5)	1 (1.6)	1 (2.1)
GRANULOMA	0 (0.0)	0 (0.0)	0 (0.0)
MUSCLE SPASM	1 (1.5)	1 (1.6)	1 (2.1)
POCKET TEAR	0 (0.0)	0 (0.0)	0 (0.0)
RECURRENT BREAST CANCER	2 (3.0)	1 (1.6)	1 (2.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time: 03NOV04 10.19

- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
 Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
 Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (3.0)	2 (3.3)	1 (2.1)
SUTURE REACTION	0 (0.0)	0 (0.0)	0 (0.0)
SYMMASTIA	0 (0.0)	0 (0.0)	0 (0.0)
TEAR IN CAPSULE	0 (0.0)	0 (0.0)	0 (0.0)
TIGHT BUNILLI SUTURE	1 (1.5)	1 (1.6)	1 (2.1)
MISSING	2 (3.0)	2 (3.3)	2 (4.2)
TOTAL ASSESSED WITH REOPERATION	66 (100.0)	61 (100.0)	48 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time: 03NOV04 10:19

- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction
 Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
 Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	20 (22.7)	19 (23.8)	16 (25.4)
BREAST MASS	8 (9.1)	7 (8.8)	6 (9.5)
BREAST PAIN	1 (1.1)	1 (1.3)	1 (1.6)
CAPSULAR CONSTRICTURE III/IV	10 (11.4)	10 (12.5)	8 (12.7)
DELAYED WOUND HEALING	0 (0.0)	0 (0.0)	0 (0.0)
EXTRUSION	2 (2.3)	2 (2.5)	2 (3.2)
HEMATOMA	1 (1.1)	1 (1.3)	1 (1.6)
HYPERTROPHIC SCARRING	3 (3.4)	3 (3.8)	2 (3.2)
IMPLANT MALPOSITION/DISPLACEMENT	11 (12.5)	11 (13.8)	9 (14.3)
INFECTION	4 (4.5)	4 (5.0)	4 (6.3)
IRRITATION/INFLAMMATION	0 (0.0)	0 (0.0)	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (2.3)	2 (2.5)	2 (3.2)
PATIENT REQUEST	11 (12.5)	11 (13.8)	7 (11.1)
PTOSIS	3 (3.4)	3 (3.8)	2 (3.2)
SEROMA	1 (1.1)	1 (1.3)	1 (1.6)
WRINKLING	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	9 (10.2)	8 (10.0)	7 (11.1)
BREAST / SKIN LESIONS	1 (1.1)	1 (1.3)	1 (1.6)
EXTRA SKIN BUMP	1 (1.1)	1 (1.3)	1 (1.6)
FALSE POSITIVE MRI FOR RUPTURE	0 (0.0)	0 (0.0)	0 (0.0)
GRANULOMA	0 (0.0)	0 (0.0)	0 (0.0)
LACK OF PROJECTION	1 (1.1)	1 (1.3)	1 (1.6)
MUSCLE SPASM	1 (1.1)	1 (1.3)	1 (1.6)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.

Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT. PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)	0 (0.0)	0 (0.0)
POCKET TEAR	0 (0.0)	0 (0.0)	0 (0.0)
RECURRENT BREAST CANCER	2 (2.3)	1 (1.3)	1 (1.6)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (2.3)	2 (2.5)	1 (1.6)
SUTURE REACTION	0 (0.0)	0 (0.0)	0 (0.0)
SYMMASTIA	0 (0.0)	0 (0.0)	0 (0.0)
TEAR IN CAPSULE	0 (0.0)	0 (0.0)	0 (0.0)
TIGHT BUNILLI SUTURE	1 (1.1)	1 (1.3)	1 (1.6)
MISSING	2 (2.3)	2 (2.5)	2 (3.2)
TOTAL ASSESSED WITH REOPERATION	88 (100.0)	80 (100.0)	63 (100.0)

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- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
 Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
 Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	20 (21.1)	19 (23.2)	16 (25.0)
BREAST MASS	9 (9.5)	8 (9.8)	7 (10.9)
BREAST PAIN	1 (1.1)	1 (1.2)	1 (1.6)
CAPSULAR CONSTRUCTURE III/IV	10 (10.5)	10 (12.2)	8 (12.5)
DELAYED WOUND HEALING	0 (0.0)	0 (0.0)	0 (0.0)
EXTRUSION	2 (2.1)	2 (2.4)	2 (3.1)
HEMATOMA	2 (2.1)	2 (2.4)	2 (3.1)
HYPERTROPHIC SCARRING	3 (3.2)	3 (3.7)	2 (3.1)
IMPLANT MALPOSITION/DISPLACEMENT	11 (11.6)	11 (13.4)	9 (14.1)
INFECTION	4 (4.2)	4 (4.9)	4 (6.3)
IRRITATION/INFLAMMAION	0 (0.0)	0 (0.0)	0 (0.0)
NECROSIS	0 (0.0)	0 (0.0)	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (2.1)	2 (2.4)	2 (3.1)
PATIENT REQUEST	13 (13.7)	13 (15.9)	8 (12.5)
PTOSIS	4 (4.2)	3 (3.7)	2 (3.1)
SEROMA	1 (1.1)	1 (1.2)	1 (1.6)
WRINKLING	0 (0.0)	0 (0.0)	0 (0.0)
OTHER	11 (11.6)	10 (12.2)	8 (12.5)
ABNORMAL MAMMOGRAM	0 (0.0)	0 (0.0)	0 (0.0)
BREAST / SKIN LESIONS	1 (1.1)	1 (1.2)	1 (1.6)
EXTRA SKIN BUMP	1 (1.1)	1 (1.2)	1 (1.6)
FALSE POSITIVE MRI FOR RUPTURE	0 (0.0)	0 (0.0)	0 (0.0)
GRANULOMA	0 (0.0)	0 (0.0)	0 (0.0)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.

Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9 2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
LACK OF PROJECTION	1 (1.1)	1 (1.2)	1 (1.6)
MUSCLE SPASM	1 (1.1)	1 (1.2)	1 (1.6)
PATIENT DISSATISFIED WITH APPEARANCE	0 (0.0)	0 (0.0)	0 (0.0)
POCKET TEAR	0 (0.0)	0 (0.0)	0 (0.0)
RECURRENT BREAST CANCER	2 (2.1)	1 (1.2)	1 (1.6)
RIGHT EXPLANTED SO LEFT DONE ALSO	0 (0.0)	0 (0.0)	0 (0.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (2.1)	2 (2.4)	1 (1.6)
SUSPECTED RUPTURE	0 (0.0)	0 (0.0)	0 (0.0)
SUTURE REACTION	0 (0.0)	0 (0.0)	0 (0.0)
SYMMASTIA	0 (0.0)	0 (0.0)	0 (0.0)
TEAR IN CAPSULE	0 (0.0)	0 (0.0)	0 (0.0)
TIGHT BUNILLI SUTURE	1 (1.1)	1 (1.2)	1 (1.6)
TOO LARGE	2 (2.1)	2 (2.4)	1 (1.6)
MISSING	2 (2.1)	2 (2.4)	2 (3.1)
TOTAL ASSESSED WITH REOPERATION	95 (100.0)	82 (100.0)	64 (100.0)

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- Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
- Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
- Note 3: Percentages are based upon Total Assessed with Reoperation.

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 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	1 (1.6)	1 (2.2)	1 (3.1)
BREAST MASS	4 (6.6)	4 (8.7)	4 (12.5)
BREAST PAIN	0 (0.0)	0 (0.0)	0 (0.0)
CAPSULAR CONSTRUCTURE III/IV	21 (34.4)	15 (32.6)	11 (34.4)
DELAYED WOUND HEALING	4 (6.6)	3 (6.5)	3 (9.4)
EXTRUSION	3 (4.9)	3 (6.5)	3 (9.4)
HEMATOMA	4 (6.6)	3 (6.5)	3 (9.4)
HYPERTROPHIC SCARRING	2 (3.3)	2 (4.3)	1 (3.1)
IMPLANT MALPOSITION/DISPLACEMENT	2 (3.3)	2 (4.3)	1 (3.1)
INFECTION	0 (0.0)	0 (0.0)	0 (0.0)
IRRITATION/INFLAMMATION	1 (1.6)	1 (2.2)	1 (3.1)
NIPPLE RELATED (UNPLANNED)	2 (3.3)	2 (4.3)	1 (3.1)
PATIENT REQUEST	5 (8.2)	5 (10.9)	3 (9.4)
PTOSIS	0 (0.0)	0 (0.0)	0 (0.0)
SEROMA	1 (1.6)	1 (2.2)	1 (3.1)
WRINKLING	2 (3.3)	2 (4.3)	1 (3.1)
OTHER	9 (14.8)	7 (15.2)	5 (15.6)
BREAST / SKIN LESIONS	2 (3.3)	2 (4.3)	1 (3.1)
EXTRA SKIN BUMP	0 (0.0)	0 (0.0)	0 (0.0)
GRANULOMA	1 (1.6)	1 (2.2)	1 (3.1)
MUSCLE SPASM	0 (0.0)	0 (0.0)	0 (0.0)
POCKET TEAR	1 (1.6)	1 (2.2)	1 (3.1)
RECURRENT BREAST CANCER	1 (1.6)	1 (2.2)	1 (3.1)

Program Name: Q:\MENTOR\COREGEL\3YEAR\RQ\T09_2.SAS

Creation Date, Time: 03NOV04 10:19

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.

Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.

Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)	0 (0.0)	0 (0.0)
SUTURE REACTION	0 (0.0)	0 (0.0)	0 (0.0)
SYMMASTIA	4 (6.6)	2 (4.3)	1 (3.1)
TEAR IN CAPSULE	0 (0.0)	0 (0.0)	0 (0.0)
TIGHT BUNILLI SUTURE	0 (0.0)	0 (0.0)	0 (0.0)
MISSING	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL ASSESSED WITH REOPERATION	61 (100.0)	46 (100.0)	32 (100.0)

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Note 3: Percentages are based upon Total Assessed with Reoperation.