

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

Table 8.11.2

TIME TO FIRST REPORT OF CAPSULAR CONTRACTURE ASSESSMENT OF BAKER CLASS IV (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	386	1.0000	0.0000	(0.0000,0.0000)
1	0	2	384	1.0000	0.0000	(0.0000,0.0000)
2	0	1	383	1.0000	0.0000	(0.0000,0.0000)
3	0	2	381	1.0000	0.0000	(0.0000,0.0000)
4	0	2	379	1.0000	0.0000	(0.0000,0.0000)
5	0	0	379	1.0000	0.0000	(0.0000,0.0000)
6	1	4	374	0.9973	0.0027	(0.0000,0.0079)
7	0	4	370	0.9973	0.0027	(0.0000,0.0079)
8	0	5	365	0.9973	0.0027	(0.0000,0.0079)
9	0	2	363	0.9973	0.0027	(0.0000,0.0079)
10	0	2	361	0.9973	0.0027	(0.0000,0.0079)
11	1	1	359	0.9946	0.0054	(0.0000,0.0129)
12	0	4	355	0.9946	0.0054	(0.0000,0.0129)
13	0	6	349	0.9946	0.0054	(0.0000,0.0129)
14	0	3	346	0.9946	0.0054	(0.0000,0.0129)
15	0	0	346	0.9946	0.0054	(0.0000,0.0129)
16	0	3	343	0.9946	0.0054	(0.0000,0.0129)
17	0	3	340	0.9946	0.0054	(0.0000,0.0129)
18	0	3	337	0.9946	0.0054	(0.0000,0.0129)
19	0	2	335	0.9946	0.0054	(0.0000,0.0129)
20	0	2	333	0.9946	0.0054	(0.0000,0.0129)
21	0	0	333	0.9946	0.0054	(0.0000,0.0129)
22	0	9	324	0.9946	0.0054	(0.0000,0.0129)
23	0	92	232	0.9946	0.0054	(0.0000,0.0129)
24	0	23	209	0.9946	0.0054	(0.0000,0.0129)

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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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IMPLANTS USED FOR RECONSTRUCTION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	12	197	0.9946	0.0054	(0.0000,0.0129)
26	0	6	191	0.9946	0.0054	(0.0000,0.0129)
27	0	2	189	0.9946	0.0054	(0.0000,0.0129)
28	0	0	189	0.9946	0.0054	(0.0000,0.0129)
29	0	0	189	0.9946	0.0054	(0.0000,0.0129)
30	0	2	187	0.9946	0.0054	(0.0000,0.0129)
31	0	0	187	0.9946	0.0054	(0.0000,0.0129)
32	0	2	185	0.9946	0.0054	(0.0000,0.0129)
33	0	51	134	0.9946	0.0054	(0.0000,0.0129)
34	0	24	110	0.9946	0.0054	(0.0000,0.0129)
35	0	37	73	0.9946	0.0054	(0.0000,0.0129)
36	0	37	36	0.9946	0.0054	(0.0000,0.0129)

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Table 8.11.2

TIME TO FIRST REPORT OF CAPSULAR CONTRACTURE ASSESSMENT OF BAKER CLASS IV (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	383	1.0000	0.0000	(0.0000,0.0000)
1	2	2	379	0.9948	0.0052	(0.0000,0.0125)
2	1	0	378	0.9921	0.0079	(0.0000,0.0167)
3	1	0	377	0.9895	0.0105	(0.0003,0.0207)
4	1	4	372	0.9868	0.0132	(0.0017,0.0246)
5	0	0	372	0.9868	0.0132	(0.0017,0.0246)
6	0	0	372	0.9868	0.0132	(0.0017,0.0246)
7	0	0	372	0.9868	0.0132	(0.0017,0.0246)
8	0	2	370	0.9868	0.0132	(0.0017,0.0246)
9	0	0	370	0.9868	0.0132	(0.0017,0.0246)
10	0	0	370	0.9868	0.0132	(0.0017,0.0246)
11	1	2	367	0.9842	0.0158	(0.0033,0.0284)
12	1	4	362	0.9815	0.0185	(0.0049,0.0322)
13	0	6	356	0.9815	0.0185	(0.0049,0.0322)
14	1	3	352	0.9787	0.0213	(0.0067,0.0359)
15	2	2	348	0.9731	0.0269	(0.0104,0.0433)
16	0	2	346	0.9731	0.0269	(0.0104,0.0433)
17	0	0	346	0.9731	0.0269	(0.0104,0.0433)
18	0	2	344	0.9731	0.0269	(0.0104,0.0433)
19	0	0	344	0.9731	0.0269	(0.0104,0.0433)
20	0	0	344	0.9731	0.0269	(0.0104,0.0433)
21	0	3	341	0.9731	0.0269	(0.0104,0.0433)
22	0	2	339	0.9731	0.0269	(0.0104,0.0433)
23	0	31	308	0.9731	0.0269	(0.0104,0.0433)
24	0	10	298	0.9731	0.0269	(0.0104,0.0433)

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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.

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Table 8.11.2

TIME TO FIRST REPORT OF CAPSULAR CONTRACTURE ASSESSMENT OF BAKER CLASS IV (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	24	274	0.9731	0.0269	(0.0104,0.0433)
26	0	11	263	0.9731	0.0269	(0.0104,0.0433)
27	0	8	255	0.9731	0.0269	(0.0104,0.0433)
28	0	1	254	0.9731	0.0269	(0.0104,0.0433)
29	2	1	251	0.9654	0.0346	(0.0151,0.0540)
30	0	0	251	0.9654	0.0346	(0.0151,0.0540)
31	0	5	246	0.9654	0.0346	(0.0151,0.0540)
32	1	1	244	0.9615	0.0385	(0.0176,0.0593)
33	0	20	224	0.9615	0.0385	(0.0176,0.0593)
34	0	29	195	0.9615	0.0385	(0.0176,0.0593)
35	0	28	167	0.9615	0.0385	(0.0176,0.0593)
36	0	70	97	0.9615	0.0385	(0.0176,0.0593)

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Table 8.11.2

TIME TO FIRST REPORT OF CAPSULAR CONTRACTURE ASSESSMENT OF BAKER CLASS IV (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	2	4	1890	0.9989	0.0011	(0.0000,0.0025)
2	1	1	1888	0.9984	0.0016	(0.0000,0.0034)
3	1	4	1883	0.9979	0.0021	(0.0000,0.0042)
4	2	6	1875	0.9968	0.0032	(0.0006,0.0057)
5	0	0	1875	0.9968	0.0032	(0.0006,0.0057)
6	1	10	1864	0.9963	0.0037	(0.0010,0.0065)
7	0	4	1860	0.9963	0.0037	(0.0010,0.0065)
8	2	11	1847	0.9952	0.0048	(0.0017,0.0079)
9	0	6	1841	0.9952	0.0048	(0.0017,0.0079)
10	0	2	1839	0.9952	0.0048	(0.0017,0.0079)
11	2	6	1831	0.9941	0.0059	(0.0024,0.0093)
12	2	18	1811	0.9930	0.0070	(0.0032,0.0107)
13	2	16	1793	0.9919	0.0081	(0.0040,0.0121)
14	2	10	1781	0.9908	0.0092	(0.0048,0.0135)
15	2	6	1773	0.9897	0.0103	(0.0057,0.0149)
16	0	5	1768	0.9897	0.0103	(0.0057,0.0149)
17	0	3	1765	0.9897	0.0103	(0.0057,0.0149)
18	0	5	1760	0.9897	0.0103	(0.0057,0.0149)
19	0	5	1755	0.9897	0.0103	(0.0057,0.0149)
20	0	2	1753	0.9897	0.0103	(0.0057,0.0149)
21	0	3	1750	0.9897	0.0103	(0.0057,0.0149)
22	0	20	1730	0.9897	0.0103	(0.0057,0.0149)
23	0	198	1532	0.9897	0.0103	(0.0057,0.0149)
24	0	90	1442	0.9897	0.0103	(0.0057,0.0149)

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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.

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TIME TO FIRST REPORT OF CAPSULAR CONTRACTURE ASSESSMENT OF BAKER CLASS IV (IMPLANT LEVEL)  
OVERALL IMPLANTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	100	1342	0.9897	0.0103	(0.0057,0.0149)
26	0	58	1284	0.9897	0.0103	(0.0057,0.0149)
27	0	16	1268	0.9897	0.0103	(0.0057,0.0149)
28	0	7	1261	0.9897	0.0103	(0.0057,0.0149)
29	2	3	1256	0.9881	0.0119	(0.0068,0.0169)
30	0	10	1246	0.9881	0.0119	(0.0068,0.0169)
31	0	7	1239	0.9881	0.0119	(0.0068,0.0169)
32	1	11	1227	0.9873	0.0127	(0.0073,0.0180)
33	0	113	1114	0.9873	0.0127	(0.0073,0.0180)
34	0	96	1018	0.9873	0.0127	(0.0073,0.0180)
35	0	165	853	0.9873	0.0127	(0.0073,0.0180)
36	2	316	535	0.9846	0.0154	(0.0089,0.0220)

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Table 8.12.1

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	551	1.0000	0.0000	(0.0000,0.0000)
1	0	0	551	1.0000	0.0000	(0.0000,0.0000)
2	0	0	551	1.0000	0.0000	(0.0000,0.0000)
3	0	1	550	1.0000	0.0000	(0.0000,0.0000)
4	0	0	550	1.0000	0.0000	(0.0000,0.0000)
5	0	0	550	1.0000	0.0000	(0.0000,0.0000)
6	0	3	547	1.0000	0.0000	(0.0000,0.0000)
7	0	0	547	1.0000	0.0000	(0.0000,0.0000)
8	0	2	545	1.0000	0.0000	(0.0000,0.0000)
9	0	2	543	1.0000	0.0000	(0.0000,0.0000)
10	0	0	543	1.0000	0.0000	(0.0000,0.0000)
11	0	1	542	1.0000	0.0000	(0.0000,0.0000)
12	0	5	537	1.0000	0.0000	(0.0000,0.0000)
13	0	2	535	1.0000	0.0000	(0.0000,0.0000)
14	0	2	533	1.0000	0.0000	(0.0000,0.0000)
15	0	2	531	1.0000	0.0000	(0.0000,0.0000)
16	0	0	531	1.0000	0.0000	(0.0000,0.0000)
17	0	0	531	1.0000	0.0000	(0.0000,0.0000)
18	0	0	531	1.0000	0.0000	(0.0000,0.0000)
19	0	1	530	1.0000	0.0000	(0.0000,0.0000)
20	0	0	530	1.0000	0.0000	(0.0000,0.0000)
21	0	0	530	1.0000	0.0000	(0.0000,0.0000)
22	0	4	526	1.0000	0.0000	(0.0000,0.0000)
23	0	37	489	1.0000	0.0000	(0.0000,0.0000)
24	0	28	461	1.0000	0.0000	(0.0000,0.0000)
25	1	31	429	0.9978	0.0022	(0.0000,0.0065)

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.

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Table 8.12.1

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	21	408	0.9978	0.0022	(0.0000,0.0065)
27	0	3	405	0.9978	0.0022	(0.0000,0.0065)
28	0	3	402	0.9978	0.0022	(0.0000,0.0065)
29	0	1	401	0.9978	0.0022	(0.0000,0.0065)
30	0	4	397	0.9978	0.0022	(0.0000,0.0065)
31	0	1	396	0.9978	0.0022	(0.0000,0.0065)
32	0	4	392	0.9978	0.0022	(0.0000,0.0065)
33	0	19	373	0.9978	0.0022	(0.0000,0.0065)
34	0	21	352	0.9978	0.0022	(0.0000,0.0065)
35	0	48	304	0.9978	0.0022	(0.0000,0.0065)
36	0	104	200	0.9978	0.0022	(0.0000,0.0065)

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Table 8.12 1

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	251	1.0000	0.0000	(0.0000,0.0000)
1	0	1	250	1.0000	0.0000	(0.0000,0.0000)
2	0	1	249	1.0000	0.0000	(0.0000,0.0000)
3	0	2	247	1.0000	0.0000	(0.0000,0.0000)
4	0	1	246	1.0000	0.0000	(0.0000,0.0000)
5	0	0	246	1.0000	0.0000	(0.0000,0.0000)
6	0	2	244	1.0000	0.0000	(0.0000,0.0000)
7	0	2	242	1.0000	0.0000	(0.0000,0.0000)
8	0	4	238	1.0000	0.0000	(0.0000,0.0000)
9	0	2	236	1.0000	0.0000	(0.0000,0.0000)
10	0	2	234	1.0000	0.0000	(0.0000,0.0000)
11	0	1	233	1.0000	0.0000	(0.0000,0.0000)
12	0	2	231	1.0000	0.0000	(0.0000,0.0000)
13	0	4	227	1.0000	0.0000	(0.0000,0.0000)
14	0	2	225	1.0000	0.0000	(0.0000,0.0000)
15	0	0	225	1.0000	0.0000	(0.0000,0.0000)
16	0	2	223	1.0000	0.0000	(0.0000,0.0000)
17	0	2	221	1.0000	0.0000	(0.0000,0.0000)
18	0	2	219	1.0000	0.0000	(0.0000,0.0000)
19	0	2	217	1.0000	0.0000	(0.0000,0.0000)
20	0	2	215	1.0000	0.0000	(0.0000,0.0000)
21	0	0	215	1.0000	0.0000	(0.0000,0.0000)
22	0	6	209	1.0000	0.0000	(0.0000,0.0000)
23	1	58	150	0.9938	0.0062	(0.0000,0.0182)
24	0	18	132	0.9938	0.0062	(0.0000,0.0182)
25	0	9	123	0.9938	0.0062	(0.0000,0.0182)

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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.

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	3	120	0.9938	0.0062	(0.0000,0.0182)
27	0	1	119	0.9938	0.0062	(0.0000,0.0182)
28	0	0	119	0.9938	0.0062	(0.0000,0.0182)
29	0	0	119	0.9938	0.0062	(0.0000,0.0182)
30	0	1	118	0.9938	0.0062	(0.0000,0.0182)
31	0	0	118	0.9938	0.0062	(0.0000,0.0182)
32	0	1	117	0.9938	0.0062	(0.0000,0.0182)
33	0	30	87	0.9938	0.0062	(0.0000,0.0182)
34	0	15	72	0.9938	0.0062	(0.0000,0.0182)
35	0	22	50	0.9938	0.0062	(0.0000,0.0182)
36	0	25	25	0.9938	0.0062	(0.0000,0.0182)

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REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	205	1.0000	0.0000	(0.0000,0.0000)
1	0	1	204	1.0000	0.0000	(0.0000,0.0000)
2	0	0	204	1.0000	0.0000	(0.0000,0.0000)
3	0	0	204	1.0000	0.0000	(0.0000,0.0000)
4	0	2	202	1.0000	0.0000	(0.0000,0.0000)
5	0	0	202	1.0000	0.0000	(0.0000,0.0000)
6	0	0	202	1.0000	0.0000	(0.0000,0.0000)
7	0	0	202	1.0000	0.0000	(0.0000,0.0000)
8	0	1	201	1.0000	0.0000	(0.0000,0.0000)
9	0	0	201	1.0000	0.0000	(0.0000,0.0000)
10	0	0	201	1.0000	0.0000	(0.0000,0.0000)
11	0	1	200	1.0000	0.0000	(0.0000,0.0000)
12	0	3	197	1.0000	0.0000	(0.0000,0.0000)
13	0	3	194	1.0000	0.0000	(0.0000,0.0000)
14	0	2	192	1.0000	0.0000	(0.0000,0.0000)
15	0	1	191	1.0000	0.0000	(0.0000,0.0000)
16	0	1	190	1.0000	0.0000	(0.0000,0.0000)
17	0	0	190	1.0000	0.0000	(0.0000,0.0000)
18	0	1	189	1.0000	0.0000	(0.0000,0.0000)
19	0	0	189	1.0000	0.0000	(0.0000,0.0000)
20	0	0	189	1.0000	0.0000	(0.0000,0.0000)
21	0	2	187	1.0000	0.0000	(0.0000,0.0000)
22	0	1	186	1.0000	0.0000	(0.0000,0.0000)
23	1	18	167	0.9945	0.0055	(0.0000,0.0161)
24	2	5	160	0.9824	0.0176	(0.0000,0.0374)
25	0	13	147	0.9824	0.0176	(0.0000,0.0374)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.12.1

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	6	141	0.9824	0.0176	(0.0000,0.0374)
27	0	4	137	0.9824	0.0176	(0.0000,0.0374)
28	1	1	135	0.9752	0.0248	(0.0007,0.0489)
29	0	1	134	0.9752	0.0248	(0.0007,0.0489)
30	0	0	134	0.9752	0.0248	(0.0007,0.0489)
31	0	3	131	0.9752	0.0248	(0.0007,0.0489)
32	0	1	130	0.9752	0.0248	(0.0007,0.0489)
33	0	12	118	0.9752	0.0248	(0.0007,0.0489)
34	0	15	103	0.9752	0.0248	(0.0007,0.0489)
35	0	16	87	0.9752	0.0248	(0.0007,0.0489)
36	0	37	50	0.9752	0.0248	(0.0007,0.0489)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.12.1

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1007	1.0000	0.0000	(0.0000,0.0000)
1	0	2	1005	1.0000	0.0000	(0.0000,0.0000)
2	0	1	1004	1.0000	0.0000	(0.0000,0.0000)
3	0	3	1001	1.0000	0.0000	(0.0000,0.0000)
4	0	3	998	1.0000	0.0000	(0.0000,0.0000)
5	0	0	998	1.0000	0.0000	(0.0000,0.0000)
6	0	5	993	1.0000	0.0000	(0.0000,0.0000)
7	0	2	991	1.0000	0.0000	(0.0000,0.0000)
8	0	7	984	1.0000	0.0000	(0.0000,0.0000)
9	0	4	980	1.0000	0.0000	(0.0000,0.0000)
10	0	2	978	1.0000	0.0000	(0.0000,0.0000)
11	0	3	975	1.0000	0.0000	(0.0000,0.0000)
12	0	10	965	1.0000	0.0000	(0.0000,0.0000)
13	0	9	956	1.0000	0.0000	(0.0000,0.0000)
14	0	6	950	1.0000	0.0000	(0.0000,0.0000)
15	0	3	947	1.0000	0.0000	(0.0000,0.0000)
16	0	3	944	1.0000	0.0000	(0.0000,0.0000)
17	0	2	942	1.0000	0.0000	(0.0000,0.0000)
18	0	3	939	1.0000	0.0000	(0.0000,0.0000)
19	0	3	936	1.0000	0.0000	(0.0000,0.0000)
20	0	2	934	1.0000	0.0000	(0.0000,0.0000)
21	0	2	932	1.0000	0.0000	(0.0000,0.0000)
22	0	11	921	1.0000	0.0000	(0.0000,0.0000)
23	2	113	806	0.9977	0.0023	(0.0000,0.0055)
24	2	51	753	0.9951	0.0049	(0.0001,0.0097)
25	1	53	699	0.9938	0.0062	(0.0008,0.0117)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.12.1

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	30	669	0.9938	0.0062	(0.0008,0.0117)
27	0	8	661	0.9938	0.0062	(0.0008,0.0117)
28	1	4	656	0.9923	0.0077	(0.0015,0.0139)
29	0	2	654	0.9923	0.0077	(0.0015,0.0139)
30	0	5	649	0.9923	0.0077	(0.0015,0.0139)
31	0	4	645	0.9923	0.0077	(0.0015,0.0139)
32	0	6	639	0.9923	0.0077	(0.0015,0.0139)
33	0	61	578	0.9923	0.0077	(0.0015,0.0139)
34	0	51	527	0.9923	0.0077	(0.0015,0.0139)
35	0	86	441	0.9923	0.0077	(0.0015,0.0139)
36	0	166	275	0.9923	0.0077	(0.0015,0.0139)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
AUGMENTATION PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19:03

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	202	1.0000	0.0000	(0.0000,0.0000)
26	0	0	202	1.0000	0.0000	(0.0000,0.0000)
27	0	0	202	1.0000	0.0000	(0.0000,0.0000)
28	0	0	202	1.0000	0.0000	(0.0000,0.0000)
29	0	0	202	1.0000	0.0000	(0.0000,0.0000)
30	0	0	202	1.0000	0.0000	(0.0000,0.0000)
31	0	0	202	1.0000	0.0000	(0.0000,0.0000)
32	0	0	202	1.0000	0.0000	(0.0000,0.0000)
33	0	0	202	1.0000	0.0000	(0.0000,0.0000)
34	0	0	202	1.0000	0.0000	(0.0000,0.0000)
35	0	0	202	1.0000	0.0000	(0.0000,0.0000)
36	0	0	202	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19:03

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19.03

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	134	1.0000	0.0000	(0.0000,0.0000)
26	0	0	134	1.0000	0.0000	(0.0000,0.0000)
27	0	0	134	1.0000	0.0000	(0.0000,0.0000)
28	0	0	134	1.0000	0.0000	(0.0000,0.0000)
29	0	0	134	1.0000	0.0000	(0.0000,0.0000)
30	0	0	134	1.0000	0.0000	(0.0000,0.0000)
31	0	0	134	1.0000	0.0000	(0.0000,0.0000)
32	0	0	134	1.0000	0.0000	(0.0000,0.0000)
33	0	0	134	1.0000	0.0000	(0.0000,0.0000)
34	0	0	134	1.0000	0.0000	(0.0000,0.0000)
35	0	0	134	1.0000	0.0000	(0.0000,0.0000)
36	0	0	134	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19:03

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
REVISION PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19:03

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	84	1.0000	0.0000	(0.0000,0.0000)
26	0	0	84	1.0000	0.0000	(0.0000,0.0000)
27	0	0	84	1.0000	0.0000	(0.0000,0.0000)
28	1	0	83	0.9881	0.0119	(0.0000,0.0351)
29	0	0	83	0.9881	0.0119	(0.0000,0.0351)
30	0	0	83	0.9881	0.0119	(0.0000,0.0351)
31	0	0	83	0.9881	0.0119	(0.0000,0.0351)
32	0	0	83	0.9881	0.0119	(0.0000,0.0351)
33	0	0	83	0.9881	0.0119	(0.0000,0.0351)
34	0	0	83	0.9881	0.0119	(0.0000,0.0351)
35	0	0	83	0.9881	0.0119	(0.0000,0.0351)
36	0	0	83	0.9881	0.0119	(0.0000,0.0351)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19:03

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
OVERALL PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19:03

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

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

Table 8.12.1A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	420	1.0000	0.0000	(0.0000,0.0000)
26	0	0	420	1.0000	0.0000	(0.0000,0.0000)
27	0	0	420	1.0000	0.0000	(0.0000,0.0000)
28	1	0	419	0.9976	0.0024	(0.0000,0.0070)
29	0	0	419	0.9976	0.0024	(0.0000,0.0070)
30	0	0	419	0.9976	0.0024	(0.0000,0.0070)
31	0	0	419	0.9976	0.0024	(0.0000,0.0070)
32	0	0	419	0.9976	0.0024	(0.0000,0.0070)
33	0	0	419	0.9976	0.0024	(0.0000,0.0070)
34	0	0	419	0.9976	0.0024	(0.0000,0.0070)
35	0	0	419	0.9976	0.0024	(0.0000,0.0070)
36	0	0	419	0.9976	0.0024	(0.0000,0.0070)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1A.SAS

Creation Date, Time: 26AUG04 19:03

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

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

Table 8.12.1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
AUGMENTATION PATIENTS

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

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19:17

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

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 8.12.1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
AUGMENTATION PATIENTS

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

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19:17

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

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 8.12.1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

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

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19:17

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

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 8.12.1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19:17

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

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 8.12.1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
REVISION PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19.17

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

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Table 8.12 1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
REVISION PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19:17

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

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 8.12.1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
OVERALL PATIENTS

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

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19:17

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

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Table 8.12.1B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (PATIENT LEVEL)  
OVERALL PATIENTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_1B.SAS

Creation Date, Time: 26AUG04 19:17

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

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Table 8 12.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
1	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
2	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
3	0	2	1125	1.0000	0.0000	(0.0000,0.0000)
4	0	0	1125	1.0000	0.0000	(0.0000,0.0000)
5	0	0	1125	1.0000	0.0000	(0.0000,0.0000)
6	0	6	1119	1.0000	0.0000	(0.0000,0.0000)
7	0	0	1119	1.0000	0.0000	(0.0000,0.0000)
8	0	4	1115	1.0000	0.0000	(0.0000,0.0000)
9	0	4	1111	1.0000	0.0000	(0.0000,0.0000)
10	0	0	1111	1.0000	0.0000	(0.0000,0.0000)
11	0	3	1108	1.0000	0.0000	(0.0000,0.0000)
12	0	10	1098	1.0000	0.0000	(0.0000,0.0000)
13	0	4	1094	1.0000	0.0000	(0.0000,0.0000)
14	0	4	1090	1.0000	0.0000	(0.0000,0.0000)
15	0	4	1086	1.0000	0.0000	(0.0000,0.0000)
16	0	0	1086	1.0000	0.0000	(0.0000,0.0000)
17	0	0	1086	1.0000	0.0000	(0.0000,0.0000)
18	0	0	1086	1.0000	0.0000	(0.0000,0.0000)
19	0	3	1083	1.0000	0.0000	(0.0000,0.0000)
20	0	0	1083	1.0000	0.0000	(0.0000,0.0000)
21	0	0	1083	1.0000	0.0000	(0.0000,0.0000)
22	0	10	1073	1.0000	0.0000	(0.0000,0.0000)
23	0	76	997	1.0000	0.0000	(0.0000,0.0000)
24	0	60	937	1.0000	0.0000	(0.0000,0.0000)

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 8.12.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	64	872	0.9989	0.0011	(0.0000,0.0032)
26	0	41	831	0.9989	0.0011	(0.0000,0.0032)
27	0	6	825	0.9989	0.0011	(0.0000,0.0032)
28	0	6	819	0.9989	0.0011	(0.0000,0.0032)
29	0	2	817	0.9989	0.0011	(0.0000,0.0032)
30	0	8	809	0.9989	0.0011	(0.0000,0.0032)
31	0	2	807	0.9989	0.0011	(0.0000,0.0032)
32	0	8	799	0.9989	0.0011	(0.0000,0.0032)
33	0	42	757	0.9989	0.0011	(0.0000,0.0032)
34	0	43	714	0.9989	0.0011	(0.0000,0.0032)
35	0	101	613	0.9989	0.0011	(0.0000,0.0032)
36	0	209	404	0.9989	0.0011	(0.0000,0.0032)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.12.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	386	1.0000	0.0000	(0.0000,0.0000)
1	0	2	384	1.0000	0.0000	(0.0000,0.0000)
2	0	1	383	1.0000	0.0000	(0.0000,0.0000)
3	0	2	381	1.0000	0.0000	(0.0000,0.0000)
4	0	2	379	1.0000	0.0000	(0.0000,0.0000)
5	0	0	379	1.0000	0.0000	(0.0000,0.0000)
6	0	4	375	1.0000	0.0000	(0.0000,0.0000)
7	0	4	371	1.0000	0.0000	(0.0000,0.0000)
8	0	5	366	1.0000	0.0000	(0.0000,0.0000)
9	0	2	364	1.0000	0.0000	(0.0000,0.0000)
10	0	2	362	1.0000	0.0000	(0.0000,0.0000)
11	0	1	361	1.0000	0.0000	(0.0000,0.0000)
12	0	4	357	1.0000	0.0000	(0.0000,0.0000)
13	0	6	351	1.0000	0.0000	(0.0000,0.0000)
14	0	3	348	1.0000	0.0000	(0.0000,0.0000)
15	0	0	348	1.0000	0.0000	(0.0000,0.0000)
16	0	3	345	1.0000	0.0000	(0.0000,0.0000)
17	0	3	342	1.0000	0.0000	(0.0000,0.0000)
18	0	3	339	1.0000	0.0000	(0.0000,0.0000)
19	0	2	337	1.0000	0.0000	(0.0000,0.0000)
20	0	2	335	1.0000	0.0000	(0.0000,0.0000)
21	0	0	335	1.0000	0.0000	(0.0000,0.0000)
22	0	9	326	1.0000	0.0000	(0.0000,0.0000)
23	1	92	233	0.9960	0.0040	(0.0000,0.0118)
24	0	23	210	0.9960	0.0040	(0.0000,0.0118)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2. Implant counts exclude events where breast side = N/A.

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

Table 8.12.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	12	198	0.9960	0.0040	(0.0000,0.0118)
26	0	6	192	0.9960	0.0040	(0.0000,0.0118)
27	0	2	190	0.9960	0.0040	(0.0000,0.0118)
28	0	0	190	0.9960	0.0040	(0.0000,0.0118)
29	0	0	190	0.9960	0.0040	(0.0000,0.0118)
30	0	2	188	0.9960	0.0040	(0.0000,0.0118)
31	0	0	188	0.9960	0.0040	(0.0000,0.0118)
32	0	2	186	0.9960	0.0040	(0.0000,0.0118)
33	0	51	135	0.9960	0.0040	(0.0000,0.0118)
34	0	24	111	0.9960	0.0040	(0.0000,0.0118)
35	0	37	74	0.9960	0.0040	(0.0000,0.0118)
36	0	38	36	0.9960	0.0040	(0.0000,0.0118)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.12.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	383	1.0000	0.0000	(0.0000,0.0000)
1	0	2	381	1.0000	0.0000	(0.0000,0.0000)
2	0	0	381	1.0000	0.0000	(0.0000,0.0000)
3	0	0	381	1.0000	0.0000	(0.0000,0.0000)
4	0	4	377	1.0000	0.0000	(0.0000,0.0000)
5	0	0	377	1.0000	0.0000	(0.0000,0.0000)
6	0	0	377	1.0000	0.0000	(0.0000,0.0000)
7	0	0	377	1.0000	0.0000	(0.0000,0.0000)
8	0	2	375	1.0000	0.0000	(0.0000,0.0000)
9	0	0	375	1.0000	0.0000	(0.0000,0.0000)
10	0	0	375	1.0000	0.0000	(0.0000,0.0000)
11	0	2	373	1.0000	0.0000	(0.0000,0.0000)
12	0	6	367	1.0000	0.0000	(0.0000,0.0000)
13	0	6	361	1.0000	0.0000	(0.0000,0.0000)
14	0	4	357	1.0000	0.0000	(0.0000,0.0000)
15	0	2	355	1.0000	0.0000	(0.0000,0.0000)
16	0	2	353	1.0000	0.0000	(0.0000,0.0000)
17	0	0	353	1.0000	0.0000	(0.0000,0.0000)
18	0	2	351	1.0000	0.0000	(0.0000,0.0000)
19	0	0	351	1.0000	0.0000	(0.0000,0.0000)
20	0	0	351	1.0000	0.0000	(0.0000,0.0000)
21	0	4	347	1.0000	0.0000	(0.0000,0.0000)
22	0	2	345	1.0000	0.0000	(0.0000,0.0000)
23	2	33	310	0.9941	0.0059	(0.0000,0.0141)
24	2	10	298	0.9876	0.0124	(0.0003,0.0246)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2. Implant counts exclude events where breast side = N/A.

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

Table 8.12.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	24	274	0.9876	0.0124	(0.0003,0.0246)
26	0	12	262	0.9876	0.0124	(0.0003,0.0246)
27	0	8	254	0.9876	0.0124	(0.0003,0.0246)
28	2	1	251	0.9798	0.0202	(0.0041,0.0363)
29	0	1	250	0.9798	0.0202	(0.0041,0.0363)
30	0	0	250	0.9798	0.0202	(0.0041,0.0363)
31	0	6	244	0.9798	0.0202	(0.0041,0.0363)
32	0	1	243	0.9798	0.0202	(0.0041,0.0363)
33	0	22	221	0.9798	0.0202	(0.0041,0.0363)
34	0	26	195	0.9798	0.0202	(0.0041,0.0363)
35	0	28	167	0.9798	0.0202	(0.0041,0.0363)
36	0	71	96	0.9798	0.0202	(0.0041,0.0363)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.12.2

TIME TO FIRST REPORT OF RUPTURE (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	0	4	1892	1.0000	0.0000	(0.0000,0.0000)
2	0	1	1891	1.0000	0.0000	(0.0000,0.0000)
3	0	4	1887	1.0000	0.0000	(0.0000,0.0000)
4	0	6	1881	1.0000	0.0000	(0.0000,0.0000)
5	0	0	1881	1.0000	0.0000	(0.0000,0.0000)
6	0	10	1871	1.0000	0.0000	(0.0000,0.0000)
7	0	4	1867	1.0000	0.0000	(0.0000,0.0000)
8	0	11	1856	1.0000	0.0000	(0.0000,0.0000)
9	0	6	1850	1.0000	0.0000	(0.0000,0.0000)
10	0	2	1848	1.0000	0.0000	(0.0000,0.0000)
11	0	6	1842	1.0000	0.0000	(0.0000,0.0000)
12	0	20	1822	1.0000	0.0000	(0.0000,0.0000)
13	0	16	1806	1.0000	0.0000	(0.0000,0.0000)
14	0	11	1795	1.0000	0.0000	(0.0000,0.0000)
15	0	6	1789	1.0000	0.0000	(0.0000,0.0000)
16	0	5	1784	1.0000	0.0000	(0.0000,0.0000)
17	0	3	1781	1.0000	0.0000	(0.0000,0.0000)
18	0	5	1776	1.0000	0.0000	(0.0000,0.0000)
19	0	5	1771	1.0000	0.0000	(0.0000,0.0000)
20	0	2	1769	1.0000	0.0000	(0.0000,0.0000)
21	0	4	1765	1.0000	0.0000	(0.0000,0.0000)
22	0	21	1744	1.0000	0.0000	(0.0000,0.0000)
23	3	201	1540	0.9982	0.0018	(0.0000,0.0039)
24	2	93	1445	0.9968	0.0032	(0.0004,0.0059)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.12.2

TIME TO FIRST REPORT OF RUPTURE (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	1	100	1344	0.9961	0.0039	(0.0008,0.0069)
26	0	59	1285	0.9961	0.0039	(0.0008,0.0069)
27	0	16	1269	0.9961	0.0039	(0.0008,0.0069)
28	2	7	1260	0.9946	0.0054	(0.0017,0.0092)
29	0	3	1257	0.9946	0.0054	(0.0017,0.0092)
30	0	10	1247	0.9946	0.0054	(0.0017,0.0092)
31	0	8	1239	0.9946	0.0054	(0.0017,0.0092)
32	0	11	1228	0.9946	0.0054	(0.0017,0.0092)
33	0	115	1113	0.9946	0.0054	(0.0017,0.0092)
34	0	93	1020	0.9946	0.0054	(0.0017,0.0092)
35	0	166	854	0.9946	0.0054	(0.0017,0.0092)
36	0	318	536	0.9946	0.0054	(0.0017,0.0092)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
AUGMENTATION IMPLANTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8.12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
AUGMENTATION IMPLANTS

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

Program Name: Q:\MENTOR\CORLGEL\3YEAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8 12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
RECONSTRUCTION IMPLANTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8.12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
RECONSTRUCTION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	211	1.0000	0.0000	(0.0000,0.0000)
25	0	0	211	1.0000	0.0000	(0.0000,0.0000)
26	0	0	211	1.0000	0.0000	(0.0000,0.0000)
27	0	0	211	1.0000	0.0000	(0.0000,0.0000)
28	0	0	211	1.0000	0.0000	(0.0000,0.0000)
29	0	0	211	1.0000	0.0000	(0.0000,0.0000)
30	0	0	211	1.0000	0.0000	(0.0000,0.0000)
31	0	0	211	1.0000	0.0000	(0.0000,0.0000)
32	0	0	211	1.0000	0.0000	(0.0000,0.0000)
33	0	0	211	1.0000	0.0000	(0.0000,0.0000)
34	0	0	211	1.0000	0.0000	(0.0000,0.0000)
35	0	0	211	1.0000	0.0000	(0.0000,0.0000)
36	0	0	211	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q \MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8.12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
REVISION IMPLANTS

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

Program Name O:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8.12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	157	1.0000	0.0000	(0.0000,0.0000)
25	0	0	157	1.0000	0.0000	(0.0000,0.0000)
26	0	0	157	1.0000	0.0000	(0.0000,0.0000)
27	0	0	157	1.0000	0.0000	(0.0000,0.0000)
28	2	0	155	0.9873	0.0127	(0.0000,0.0303)
29	0	0	155	0.9873	0.0127	(0.0000,0.0303)
30	0	0	155	0.9873	0.0127	(0.0000,0.0303)
31	0	0	155	0.9873	0.0127	(0.0000,0.0303)
32	0	0	155	0.9873	0.0127	(0.0000,0.0303)
33	0	0	155	0.9873	0.0127	(0.0000,0.0303)
34	0	0	155	0.9873	0.0127	(0.0000,0.0303)
35	0	0	155	0.9873	0.0127	(0.0000,0.0303)
36	0	0	155	0.9873	0.0127	(0.0000,0.0303)

Program Name: Q:\MENTOR\COREGFI\3VFAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8.12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
OVERALL IMPLANTS

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

Program Name Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8.12.2A

TIME TO FIRST REPORT OF CONFIRMED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	785	1.0000	0.0000	(0.0000,0.0000)
25	0	0	785	1.0000	0.0000	(0.0000,0.0000)
26	0	0	785	1.0000	0.0000	(0.0000,0.0000)
27	0	0	785	1.0000	0.0000	(0.0000,0.0000)
28	2	0	783	0.9975	0.0025	(0.0000,0.0061)
29	0	0	783	0.9975	0.0025	(0.0000,0.0061)
30	0	0	783	0.9975	0.0025	(0.0000,0.0061)
31	0	0	783	0.9975	0.0025	(0.0000,0.0061)
32	0	0	783	0.9975	0.0025	(0.0000,0.0061)
33	0	0	783	0.9975	0.0025	(0.0000,0.0061)
34	0	0	783	0.9975	0.0025	(0.0000,0.0061)
35	0	0	783	0.9975	0.0025	(0.0000,0.0061)
36	0	0	783	0.9975	0.0025	(0.0000,0.0061)

Program Name: D:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2A.SAS

Creation Date, Time: 26AUG04 19:07

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
AUGMENTATION IMPLANTS

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

Program Name Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26AUG04 19:17

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
AUGMENTATION IMPLANTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26AUG04 19:17

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
RECONSTRUCTION IMPLANTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26AUG04 19.17

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
RECONSTRUCTION IMPLANTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26AUG04 19:17

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
REVISION IMPLANTS

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

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26AUG04 19:17

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	153	0.9745	0.0255	(0.0008,0.0501)
25	0	0	153	0.9745	0.0255	(0.0008,0.0501)
26	0	0	153	0.9745	0.0255	(0.0008,0.0501)
27	0	0	153	0.9745	0.0255	(0.0008,0.0501)
28	0	0	153	0.9745	0.0255	(0.0008,0.0501)
29	0	0	153	0.9745	0.0255	(0.0008,0.0501)
30	0	0	153	0.9745	0.0255	(0.0008,0.0501)
31	0	0	153	0.9745	0.0255	(0.0008,0.0501)
32	0	0	153	0.9745	0.0255	(0.0008,0.0501)
33	0	0	153	0.9745	0.0255	(0.0008,0.0501)
34	0	0	153	0.9745	0.0255	(0.0008,0.0501)
35	0	0	153	0.9745	0.0255	(0.0008,0.0501)
36	0	0	153	0.9745	0.0255	(0.0008,0.0501)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26AUG04 19:17

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	785	1.0000	0.0000	(0.0000,0.0000)
1	0	0	785	1.0000	0.0000	(0.0000,0.0000)
2	0	0	785	1.0000	0.0000	(0.0000,0.0000)
3	0	0	785	1.0000	0.0000	(0.0000,0.0000)
4	0	0	785	1.0000	0.0000	(0.0000,0.0000)
5	0	0	785	1.0000	0.0000	(0.0000,0.0000)
6	0	0	785	1.0000	0.0000	(0.0000,0.0000)
7	0	0	785	1.0000	0.0000	(0.0000,0.0000)
8	0	0	785	1.0000	0.0000	(0.0000,0.0000)
9	0	0	785	1.0000	0.0000	(0.0000,0.0000)
10	0	0	785	1.0000	0.0000	(0.0000,0.0000)
11	0	0	785	1.0000	0.0000	(0.0000,0.0000)
12	0	0	785	1.0000	0.0000	(0.0000,0.0000)
13	0	0	785	1.0000	0.0000	(0.0000,0.0000)
14	0	0	785	1.0000	0.0000	(0.0000,0.0000)
15	0	0	785	1.0000	0.0000	(0.0000,0.0000)
16	0	0	785	1.0000	0.0000	(0.0000,0.0000)
17	0	0	785	1.0000	0.0000	(0.0000,0.0000)
18	0	0	785	1.0000	0.0000	(0.0000,0.0000)
19	0	0	785	1.0000	0.0000	(0.0000,0.0000)
20	0	0	785	1.0000	0.0000	(0.0000,0.0000)
21	0	0	785	1.0000	0.0000	(0.0000,0.0000)
22	0	0	785	1.0000	0.0000	(0.0000,0.0000)
23	3	0	782	0.9962	0.0038	(0.0000,0.0081)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26Aug04 19:17

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

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

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

Table 8.12.2B

TIME TO FIRST REPORT OF SUSPECTED RUPTURE UPON EXPLANT (IMPLANT LEVEL)  
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	780	0.9936	0.0064	(0.0008,0.0119)
25	1	0	779	0.9924	0.0076	(0.0016,0.0137)
26	0	0	779	0.9924	0.0076	(0.0016,0.0137)
27	0	0	779	0.9924	0.0076	(0.0016,0.0137)
28	0	0	779	0.9924	0.0076	(0.0016,0.0137)
29	0	0	779	0.9924	0.0076	(0.0016,0.0137)
30	0	0	779	0.9924	0.0076	(0.0016,0.0137)
31	0	0	779	0.9924	0.0076	(0.0016,0.0137)
32	0	0	779	0.9924	0.0076	(0.0016,0.0137)
33	0	0	779	0.9924	0.0076	(0.0016,0.0137)
34	0	0	779	0.9924	0.0076	(0.0016,0.0137)
35	0	0	779	0.9924	0.0076	(0.0016,0.0137)
36	0	0	779	0.9924	0.0076	(0.0016,0.0137)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08\_12\_2B.SAS

Creation Date, Time: 26AUG04 19:17

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

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

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

Table 8.13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	551	1.0000	0.0000	(0.0000,0.0000)
1	9	0	542	0.9837	0.0163	(0.0058,0.0269)
2	6	0	536	0.9728	0.0272	(0.0136,0.0408)
3	4	0	532	0.9655	0.0345	(0.0192,0.0497)
4	4	0	528	0.9583	0.0417	(0.0250,0.0584)
5	4	0	524	0.9510	0.0490	(0.0310,0.0670)
6	6	1	517	0.9401	0.0599	(0.0401,0.0797)
7	4	0	513	0.9328	0.0672	(0.0463,0.0881)
8	3	1	509	0.9274	0.0726	(0.0510,0.0943)
9	4	1	504	0.9201	0.0799	(0.0573,0.1026)
10	4	0	500	0.9128	0.0872	(0.0637,0.1108)
11	3	0	497	0.9073	0.0927	(0.0685,0.1169)
12	2	4	491	0.9036	0.0964	(0.0717,0.1210)
13	3	0	488	0.8981	0.1019	(0.0766,0.1272)
14	5	2	481	0.8889	0.1111	(0.0848,0.1374)
15	2	1	478	0.8852	0.1148	(0.0881,0.1415)
16	0	0	478	0.8852	0.1148	(0.0881,0.1415)
17	3	0	475	0.8796	0.1204	(0.0931,0.1476)
18	1	0	474	0.8778	0.1222	(0.0948,0.1497)
19	0	0	474	0.8778	0.1222	(0.0948,0.1497)
20	0	0	474	0.8778	0.1222	(0.0948,0.1497)
21	0	0	474	0.8778	0.1222	(0.0948,0.1497)
22	0	1	473	0.8778	0.1222	(0.0948,0.1497)
23	1	29	443	0.8759	0.1241	(0.0965,0.1518)
24	0	25	418	0.8759	0.1241	(0.0965,0.1518)
25	3	28	387	0.8694	0.1306	(0.1022,0.1589)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	1	17	369	0.8671	0.1329	(0.1042,0.1615)
27	0	2	367	0.8671	0.1329	(0.1042,0.1615)
28	2	1	364	0.8624	0.1376	(0.1084,0.1668)
29	0	1	363	0.8624	0.1376	(0.1084,0.1668)
30	0	4	359	0.8624	0.1376	(0.1084,0.1668)
31	3	0	356	0.8552	0.1448	(0.1147,0.1749)
32	1	3	352	0.8528	0.1472	(0.1168,0.1776)
33	0	15	337	0.8528	0.1472	(0.1168,0.1776)
34	1	17	319	0.8503	0.1497	(0.1191,0.1804)
35	0	44	275	0.8503	0.1497	(0.1191,0.1804)
36	0	92	183	0.8503	0.1497	(0.1191,0.1804)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	251	1.0000	0.0000	(0.0000,0.0000)
1	3	1	247	0.9880	0.0120	(0.0000,0.0255)
2	2	0	245	0.9800	0.0200	(0.0026,0.0374)
3	4	0	241	0.9640	0.0360	(0.0129,0.0591)
4	7	0	234	0.9360	0.0640	(0.0337,0.0943)
5	4	0	230	0.9200	0.0800	(0.0464,0.1136)
6	5	1	224	0.9000	0.1000	(0.0628,0.1372)
7	4	1	219	0.8839	0.1161	(0.0764,0.1558)
8	7	0	212	0.8556	0.1444	(0.1007,0.1880)
9	5	0	207	0.8355	0.1645	(0.1185,0.2106)
10	2	1	204	0.8273	0.1727	(0.1257,0.2196)
11	0	1	203	0.8273	0.1727	(0.1257,0.2196)
12	5	0	198	0.8070	0.1930	(0.1440,0.2421)
13	4	1	193	0.7906	0.2094	(0.1587,0.2600)
14	1	2	190	0.7865	0.2135	(0.1625,0.2645)
15	0	0	190	0.7865	0.2135	(0.1625,0.2645)
16	2	0	188	0.7783	0.2217	(0.1700,0.2735)
17	2	2	184	0.7700	0.2300	(0.1776,0.2825)
18	1	1	182	0.7657	0.2343	(0.1815,0.2871)
19	2	0	180	0.7573	0.2427	(0.1892,0.2962)
20	1	1	178	0.7531	0.2469	(0.1930,0.3007)
21	1	0	177	0.7489	0.2511	(0.1969,0.3053)
22	1	4	172	0.7446	0.2554	(0.2009,0.3099)
23	0	52	120	0.7446	0.2554	(0.2009,0.3099)
24	0	10	110	0.7446	0.2554	(0.2009,0.3099)
25	0	9	101	0.7446	0.2554	(0.2009,0.3099)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	2	99	0.7446	0.2554	(0.2009,0.3099)
27	0	1	98	0.7446	0.2554	(0.2009,0.3099)
28	0	0	98	0.7446	0.2554	(0.2009,0.3099)
29	0	0	98	0.7446	0.2554	(0.2009,0.3099)
30	1	0	97	0.7370	0.2630	(0.2071,0.3190)
31	0	0	97	0.7370	0.2630	(0.2071,0.3190)
32	0	1	96	0.7370	0.2630	(0.2071,0.3190)
33	0	25	71	0.7370	0.2630	(0.2071,0.3190)
34	0	13	58	0.7370	0.2630	(0.2071,0.3190)
35	0	18	40	0.7370	0.2630	(0.2071,0.3190)
36	0	22	18	0.7370	0.2630	(0.2071,0.3190)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	205	1.0000	0.0000	(0.0000,0.0000)
1	8	0	197	0.9610	0.0390	(0.0125,0.0655)
2	2	0	195	0.9512	0.0488	(0.0193,0.0783)
3	3	0	192	0.9366	0.0634	(0.0301,0.0968)
4	4	1	187	0.9170	0.0830	(0.0452,0.1208)
5	1	0	186	0.9121	0.0879	(0.0491,0.1267)
6	3	0	183	0.8974	0.1026	(0.0611,0.1442)
7	3	0	180	0.8826	0.1174	(0.0732,0.1615)
8	3	0	177	0.8679	0.1321	(0.0857,0.1785)
9	2	0	175	0.8581	0.1419	(0.0940,0.1897)
10	1	0	174	0.8532	0.1468	(0.0983,0.1953)
11	2	0	172	0.8434	0.1566	(0.1068,0.2064)
12	0	2	170	0.8434	0.1566	(0.1068,0.2064)
13	2	3	165	0.8334	0.1666	(0.1155,0.2177)
14	2	1	162	0.8233	0.1767	(0.1243,0.2291)
15	1	1	160	0.8182	0.1818	(0.1288,0.2349)
16	2	0	158	0.8079	0.1921	(0.1378,0.2463)
17	2	0	156	0.7977	0.2023	(0.1469,0.2577)
18	1	0	155	0.7926	0.2074	(0.1515,0.2633)
19	0	0	155	0.7926	0.2074	(0.1515,0.2633)
20	0	0	155	0.7926	0.2074	(0.1515,0.2633)
21	1	1	153	0.7875	0.2125	(0.1561,0.2690)
22	0	1	152	0.7875	0.2125	(0.1561,0.2690)
23	0	14	138	0.7875	0.2125	(0.1561,0.2690)
24	0	3	135	0.7875	0.2125	(0.1561,0.2690)
25	2	8	125	0.7753	0.2247	(0.1667,0.2827)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	3	2	120	0.7567	0.2433	(0.1830,0.3036)
27	1	2	117	0.7503	0.2497	(0.1886,0.3108)
28	0	1	116	0.7503	0.2497	(0.1886,0.3108)
29	0	1	115	0.7503	0.2497	(0.1886,0.3108)
30	1	0	114	0.7438	0.2562	(0.1943,0.3181)
31	0	2	112	0.7438	0.2562	(0.1943,0.3181)
32	0	1	111	0.7438	0.2562	(0.1943,0.3181)
33	1	10	100	0.7371	0.2629	(0.2002,0.3257)
34	0	13	87	0.7371	0.2629	(0.2002,0.3257)
35	0	16	71	0.7371	0.2629	(0.2002,0.3257)
36	0	28	43	0.7371	0.2629	(0.2002,0.3257)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1007	1.0000	0.0000	(0.0000,0.0000)
1	20	1	986	0.9801	0.0199	(0.0113,0.0285)
2	10	0	976	0.9702	0.0298	(0.0193,0.0403)
3	11	0	965	0.9592	0.0408	(0.0285,0.0530)
4	15	1	949	0.9443	0.0557	(0.0415,0.0698)
5	9	0	940	0.9354	0.0646	(0.0494,0.0798)
6	14	2	924	0.9214	0.0786	(0.0619,0.0952)
7	11	1	912	0.9105	0.0895	(0.0719,0.1072)
8	13	1	898	0.8975	0.1025	(0.0838,0.1213)
9	11	1	886	0.8865	0.1135	(0.0939,0.1332)
10	7	1	878	0.8795	0.1205	(0.1004,0.1407)
11	5	1	872	0.8744	0.1256	(0.1051,0.1461)
12	7	6	859	0.8674	0.1326	(0.1116,0.1536)
13	9	4	846	0.8583	0.1417	(0.1201,0.1633)
14	8	5	833	0.8501	0.1499	(0.1277,0.1720)
15	3	2	828	0.8471	0.1529	(0.1306,0.1752)
16	4	0	824	0.8430	0.1570	(0.1345,0.1796)
17	7	2	815	0.8358	0.1642	(0.1412,0.1872)
18	3	1	811	0.8327	0.1673	(0.1441,0.1904)
19	2	0	809	0.8307	0.1693	(0.1460,0.1926)
20	1	1	807	0.8297	0.1703	(0.1470,0.1937)
21	2	1	804	0.8276	0.1724	(0.1489,0.1958)
22	1	6	797	0.8266	0.1734	(0.1499,0.1969)
23	1	95	701	0.8254	0.1746	(0.1510,0.1981)
24	0	38	663	0.8254	0.1746	(0.1510,0.1981)
25	5	45	613	0.8190	0.1810	(0.1569,0.2050)

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

Creation Date, Time. 24AUG04 08:53

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

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

Table 8 13.1

TIME TO FIRST REPORT OF ANY REOPERATION (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	4	21	588	0.8136	0.1864	(0.1619,0.2109)
27	1	5	582	0.8122	0.1878	(0.1632,0.2124)
28	2	2	578	0.8094	0.1906	(0.1658,0.2154)
29	0	2	576	0.8094	0.1906	(0.1658,0.2154)
30	2	4	570	0.8066	0.1934	(0.1684,0.2184)
31	3	2	565	0.8023	0.1977	(0.1723,0.2230)
32	1	5	559	0.8009	0.1991	(0.1736,0.2246)
33	1	50	508	0.7995	0.2005	(0.1750,0.2261)
34	1	43	464	0.7979	0.2021	(0.1764,0.2278)
35	0	78	386	0.7979	0.2021	(0.1764,0.2278)
36	0	142	244	0.7979	0.2021	(0.1764,0.2278)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.13.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
1	9	0	1118	0.9920	0.0080	(0.0028,0.0132)
2	7	0	1111	0.9858	0.0142	(0.0073,0.0211)
3	7	0	1104	0.9796	0.0204	(0.0122,0.0287)
4	5	0	1099	0.9752	0.0248	(0.0158,0.0339)
5	6	0	1093	0.9698	0.0302	(0.0202,0.0402)
6	10	2	1081	0.9610	0.0390	(0.0277,0.0504)
7	5	0	1076	0.9565	0.0435	(0.0316,0.0554)
8	4	2	1070	0.9529	0.0471	(0.0347,0.0594)
9	5	2	1063	0.9485	0.0515	(0.0386,0.0644)
10	6	0	1057	0.9431	0.0569	(0.0433,0.0704)
11	5	1	1051	0.9387	0.0613	(0.0473,0.0753)
12	4	8	1039	0.9351	0.0649	(0.0505,0.0793)
13	6	0	1033	0.9297	0.0703	(0.0554,0.0853)
14	9	4	1020	0.9216	0.0784	(0.0627,0.0942)
15	4	2	1014	0.9179	0.0821	(0.0660,0.0981)
16	0	0	1014	0.9179	0.0821	(0.0660,0.0981)
17	5	0	1009	0.9134	0.0866	(0.0701,0.1031)
18	1	0	1008	0.9125	0.0875	(0.0709,0.1040)
19	1	1	1006	0.9116	0.0884	(0.0718,0.1050)
20	0	0	1006	0.9116	0.0884	(0.0718,0.1050)
21	0	0	1006	0.9116	0.0884	(0.0718,0.1050)
22	0	6	1000	0.9116	0.0884	(0.0718,0.1050)
23	1	62	937	0.9107	0.0893	(0.0726,0.1060)
24	1	54	882	0.9097	0.0903	(0.0735,0.1071)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2. Implant counts exclude events where breast side = N/A.

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

Table 8.13.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	5	60	817	0.9044	0.0956	(0.0783,0.1130)
26	1	34	782	0.9033	0.0967	(0.0793,0.1142)
27	0	5	777	0.9033	0.0967	(0.0793,0.1142)
28	3	3	771	0.8998	0.1002	(0.0824,0.1181)
29	0	2	769	0.8998	0.1002	(0.0824,0.1181)
30	0	8	761	0.8998	0.1002	(0.0824,0.1181)
31	4	0	757	0.8950	0.1050	(0.0866,0.1233)
32	1	7	749	0.8938	0.1062	(0.0877,0.1246)
33	0	38	711	0.8938	0.1062	(0.0877,0.1246)
34	2	37	672	0.8913	0.1087	(0.0899,0.1274)
35	0	93	579	0.8913	0.1087	(0.0899,0.1274)
36	0	194	385	0.8913	0.1087	(0.0899,0.1274)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.13.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	386	1.0000	0.0000	(0.0000,0.0000)
1	3	2	381	0.9922	0.0078	(0.0000,0.0166)
2	2	0	379	0.9870	0.0130	(0.0017,0.0244)
3	5	0	374	0.9740	0.0260	(0.0101,0.0420)
4	9	0	365	0.9505	0.0495	(0.0278,0.0712)
5	4	0	361	0.9401	0.0599	(0.0362,0.0836)
6	7	2	352	0.9218	0.0782	(0.0513,0.1050)
7	6	2	344	0.9061	0.0939	(0.0647,0.1231)
8	8	0	336	0.8851	0.1149	(0.0830,0.1469)
9	6	0	330	0.8693	0.1307	(0.0970,0.1645)
10	4	1	325	0.8587	0.1413	(0.1064,0.1762)
11	0	1	324	0.8587	0.1413	(0.1064,0.1762)
12	6	0	318	0.8428	0.1572	(0.1207,0.1937)
13	5	2	311	0.8295	0.1705	(0.1327,0.2083)
14	1	3	307	0.8268	0.1732	(0.1352,0.2112)
15	0	0	307	0.8268	0.1732	(0.1352,0.2112)
16	3	0	304	0.8187	0.1813	(0.1425,0.2200)
17	3	3	298	0.8106	0.1894	(0.1500,0.2288)
18	1	2	295	0.8079	0.1921	(0.1525,0.2317)
19	2	0	293	0.8024	0.1976	(0.1575,0.2377)
20	1	1	291	0.7997	0.2003	(0.1600,0.2406)
21	1	0	290	0.7969	0.2031	(0.1625,0.2436)
22	1	6	283	0.7941	0.2059	(0.1651,0.2466)
23	1	84	198	0.7911	0.2089	(0.1678,0.2499)
24	0	14	184	0.7911	0.2089	(0.1678,0.2499)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.13 2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	12	172	0.7911	0.2089	(0.1678,0.2499)
26	1	4	167	0.7864	0.2136	(0.1718,0.2554)
27	0	1	166	0.7864	0.2136	(0.1718,0.2554)
28	0	0	166	0.7864	0.2136	(0.1718,0.2554)
29	0	0	166	0.7864	0.2136	(0.1718,0.2554)
30	1	0	165	0.7817	0.2183	(0.1757,0.2609)
31	0	0	165	0.7817	0.2183	(0.1757,0.2609)
32	0	2	163	0.7817	0.2183	(0.1757,0.2609)
33	0	45	118	0.7817	0.2183	(0.1757,0.2609)
34	0	21	97	0.7817	0.2183	(0.1757,0.2609)
35	0	34	63	0.7817	0.2183	(0.1757,0.2609)
36	0	35	28	0.7817	0.2183	(0.1757,0.2609)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2. Implant counts exclude events where breast side = N/A.

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

Table 8.13.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	383	1.0000	0.0000	(0.0000,0.0000)
1	9	0	374	0.9765	0.0235	(0.0083,0.0387)
2	4	0	370	0.9661	0.0339	(0.0158,0.0521)
3	3	0	367	0.9582	0.0418	(0.0217,0.0618)
4	6	2	359	0.9425	0.0575	(0.0342,0.0809)
5	1	0	358	0.9398	0.0602	(0.0363,0.0840)
6	3	0	355	0.9320	0.0680	(0.0428,0.0933)
7	5	0	350	0.9188	0.0812	(0.0538,0.1085)
8	5	0	345	0.9057	0.0943	(0.0650,0.1236)
9	2	0	343	0.9005	0.0995	(0.0695,0.1296)
10	2	0	341	0.8952	0.1048	(0.0741,0.1355)
11	4	0	337	0.8847	0.1153	(0.0832,0.1473)
12	1	4	332	0.8821	0.1179	(0.0856,0.1503)
13	3	6	323	0.8740	0.1260	(0.0927,0.1593)
14	3	2	318	0.8658	0.1342	(0.0999,0.1684)
15	1	2	315	0.8631	0.1369	(0.1023,0.1715)
16	3	0	312	0.8549	0.1451	(0.1096,0.1806)
17	3	0	309	0.8467	0.1533	(0.1170,0.1897)
18	3	0	306	0.8384	0.1616	(0.1244,0.1987)
19	0	0	306	0.8384	0.1616	(0.1244,0.1987)
20	0	0	306	0.8384	0.1616	(0.1244,0.1987)
21	2	2	302	0.8330	0.1670	(0.1294,0.2047)
22	0	2	300	0.8330	0.1670	(0.1294,0.2047)
23	0	29	271	0.8330	0.1670	(0.1294,0.2047)
24	1	8	262	0.8298	0.1702	(0.1321,0.2082)

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 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 8.13.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	2	16	244	0.8232	0.1768	(0.1380,0.2156)
26	5	6	233	0.8063	0.1937	(0.1529,0.2345)
27	2	5	226	0.7992	0.2008	(0.1592,0.2423)
28	0	1	225	0.7992	0.2008	(0.1592,0.2423)
29	0	1	224	0.7992	0.2008	(0.1592,0.2423)
30	2	0	222	0.7921	0.2079	(0.1656,0.2503)
31	0	4	218	0.7921	0.2079	(0.1656,0.2503)
32	0	1	217	0.7921	0.2079	(0.1656,0.2503)
33	2	19	196	0.7848	0.2152	(0.1721,0.2584)
34	0	23	173	0.7848	0.2152	(0.1721,0.2584)
35	0	28	145	0.7848	0.2152	(0.1721,0.2584)
36	0	59	86	0.7848	0.2152	(0.1721,0.2584)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.13.2

TIME TO FIRST REPORT OF ANY REOPERATION (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	21	2	1873	0.9889	0.0111	(0.0064,0.0158)
2	13	0	1860	0.9821	0.0179	(0.0120,0.0239)
3	15	0	1845	0.9741	0.0259	(0.0187,0.0330)
4	20	2	1823	0.9636	0.0364	(0.0280,0.0449)
5	11	0	1812	0.9577	0.0423	(0.0332,0.0513)
6	20	4	1788	0.9472	0.0528	(0.0428,0.0629)
7	16	2	1770	0.9387	0.0613	(0.0505,0.0721)
8	17	2	1751	0.9297	0.0703	(0.0588,0.0819)
9	13	2	1736	0.9228	0.0772	(0.0652,0.0893)
10	12	1	1723	0.9164	0.0836	(0.0711,0.0961)
11	9	2	1712	0.9116	0.0884	(0.0756,0.1012)
12	11	12	1689	0.9057	0.0943	(0.0811,0.1075)
13	14	8	1667	0.8982	0.1018	(0.0882,0.1155)
14	13	9	1645	0.8912	0.1088	(0.0948,0.1229)
15	5	4	1636	0.8884	0.1116	(0.0973,0.1258)
16	6	0	1630	0.8852	0.1148	(0.1004,0.1292)
17	11	3	1616	0.8792	0.1208	(0.1061,0.1355)
18	5	2	1609	0.8765	0.1235	(0.1086,0.1384)
19	3	1	1605	0.8748	0.1252	(0.1102,0.1401)
20	1	1	1603	0.8743	0.1257	(0.1107,0.1407)
21	3	2	1598	0.8727	0.1273	(0.1122,0.1424)
22	1	14	1583	0.8721	0.1279	(0.1128,0.1430)
23	2	175	1406	0.8710	0.1290	(0.1139,0.1442)
24	2	76	1328	0.8697	0.1303	(0.1151,0.1456)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8 13 2

TIME TO FIRST REPORT OF ANY REOPERATION (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	7	88	1233	0.8650	0.1350	(0.1195,0.1506)
26	7	44	1182	0.8600	0.1400	(0.1241,0.1559)
27	2	11	1169	0.8585	0.1415	(0.1255,0.1575)
28	3	4	1162	0.8563	0.1437	(0.1275,0.1599)
29	0	3	1159	0.8563	0.1437	(0.1275,0.1599)
30	3	8	1148	0.8541	0.1459	(0.1296,0.1623)
31	4	4	1140	0.8511	0.1489	(0.1324,0.1654)
32	1	10	1129	0.8503	0.1497	(0.1331,0.1662)
33	2	102	1025	0.8488	0.1512	(0.1345,0.1678)
34	2	81	942	0.8472	0.1528	(0.1360,0.1696)
35	0	155	787	0.8472	0.1528	(0.1360,0.1696)
36	0	288	499	0.8472	0.1528	(0.1360,0.1696)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\108\_SURV.SAS

Creation Date, Time: 24AUG04 08:53

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

Note 2. Implant counts exclude events where breast side = N/A.

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

Table 8.14.1

TIME TO FIRST REPORT OF EXPLANATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	551	1.0000	0.0000	(0.0000,0.0000)
1	0	0	551	1.0000	0.0000	(0.0000,0.0000)
2	2	0	549	0.9964	0.0036	(0.0000,0.0087)
3	1	0	548	0.9946	0.0054	(0.0000,0.0116)
4	0	0	548	0.9946	0.0054	(0.0000,0.0116)
5	0	0	548	0.9946	0.0054	(0.0000,0.0116)
6	4	1	543	0.9873	0.0127	(0.0034,0.0221)
7	1	0	542	0.9855	0.0145	(0.0045,0.0245)
8	1	1	540	0.9836	0.0164	(0.0058,0.0269)
9	1	1	538	0.9818	0.0182	(0.0070,0.0293)
10	0	0	538	0.9818	0.0182	(0.0070,0.0293)
11	2	0	536	0.9782	0.0218	(0.0096,0.0340)
12	1	4	531	0.9763	0.0237	(0.0110,0.0364)
13	2	0	529	0.9727	0.0273	(0.0137,0.0410)
14	0	2	527	0.9727	0.0273	(0.0137,0.0410)
15	0	1	526	0.9727	0.0273	(0.0137,0.0410)
16	0	0	526	0.9727	0.0273	(0.0137,0.0410)
17	1	0	525	0.9708	0.0292	(0.0151,0.0433)
18	0	0	525	0.9708	0.0292	(0.0151,0.0433)
19	1	0	524	0.9690	0.0310	(0.0165,0.0456)
20	0	0	524	0.9690	0.0310	(0.0165,0.0456)
21	0	0	524	0.9690	0.0310	(0.0165,0.0456)
22	0	4	520	0.9690	0.0310	(0.0165,0.0456)
23	2	34	484	0.9652	0.0348	(0.0194,0.0501)
24	1	26	457	0.9632	0.0368	(0.0210,0.0526)
25	0	31	426	0.9632	0.0368	(0.0210,0.0526)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.14 1

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	2	19	405	0.9586	0.0414	(0.0244,0.0584)
27	0	3	402	0.9586	0.0414	(0.0244,0.0584)
28	1	2	399	0.9562	0.0438	(0.0262,0.0614)
29	0	1	398	0.9562	0.0438	(0.0262,0.0614)
30	0	4	394	0.9562	0.0438	(0.0262,0.0614)
31	1	0	393	0.9538	0.0462	(0.0281,0.0644)
32	0	4	389	0.9538	0.0462	(0.0281,0.0644)
33	1	18	370	0.9513	0.0487	(0.0299,0.0675)
34	1	19	350	0.9487	0.0513	(0.0319,0.0707)
35	0	48	302	0.9487	0.0513	(0.0319,0.0707)
36	0	103	199	0.9487	0.0513	(0.0319,0.0707)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.14.1

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	251	1.0000	0.0000	(0.0000,0.0000)
1	0	1	250	1.0000	0.0000	(0.0000,0.0000)
2	1	0	249	0.9960	0.0040	(0.0000,0.0118)
3	2	0	247	0.9880	0.0120	(0.0000,0.0255)
4	2	0	245	0.9800	0.0200	(0.0026,0.0374)
5	0	0	245	0.9800	0.0200	(0.0026,0.0374)
6	2	1	242	0.9720	0.0280	(0.0076,0.0485)
7	3	1	238	0.9599	0.0401	(0.0157,0.0644)
8	6	0	232	0.9357	0.0643	(0.0338,0.0947)
9	2	0	230	0.9277	0.0723	(0.0401,0.1045)
10	1	1	228	0.9236	0.0764	(0.0434,0.1094)
11	0	1	227	0.9236	0.0764	(0.0434,0.1094)
12	1	0	226	0.9195	0.0805	(0.0466,0.1143)
13	3	1	222	0.9073	0.0927	(0.0566,0.1288)
14	0	2	220	0.9073	0.0927	(0.0566,0.1288)
15	0	0	220	0.9073	0.0927	(0.0566,0.1288)
16	1	1	218	0.9032	0.0968	(0.0600,0.1336)
17	0	2	216	0.9032	0.0968	(0.0600,0.1336)
18	1	1	214	0.8990	0.1010	(0.0635,0.1386)
19	2	0	212	0.8906	0.1094	(0.0705,0.1484)
20	1	1	210	0.8864	0.1136	(0.0740,0.1533)
21	0	0	210	0.8864	0.1136	(0.0740,0.1533)
22	1	6	203	0.8820	0.1180	(0.0776,0.1583)
23	0	57	146	0.8820	0.1180	(0.0776,0.1583)
24	0	16	130	0.8820	0.1180	(0.0776,0.1583)
25	0	9	121	0.8820	0.1180	(0.0776,0.1583)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.14.1

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	3	118	0.8820	0.1180	(0.0776,0.1583)
27	1	1	116	0.8745	0.1255	(0.0829,0.1681)
28	0	0	116	0.8745	0.1255	(0.0829,0.1681)
29	0	0	116	0.8745	0.1255	(0.0829,0.1681)
30	1	0	115	0.8670	0.1330	(0.0883,0.1778)
31	0	0	115	0.8670	0.1330	(0.0883,0.1778)
32	0	1	114	0.8670	0.1330	(0.0883,0.1778)
33	0	30	84	0.8670	0.1330	(0.0883,0.1778)
34	0	15	69	0.8670	0.1330	(0.0883,0.1778)
35	0	21	48	0.8670	0.1330	(0.0883,0.1778)
36	0	24	24	0.8670	0.1330	(0.0883,0.1778)

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

Creation Date, Time: 24AUG04 08 53

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

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

Table 8.14.1

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	205	1.0000	0.0000	(0.0000,0.0000)
1	1	0	204	0.9951	0.0049	(0.0000,0.0144)
2	1	0	203	0.9902	0.0098	(0.0000,0.0232)
3	0	0	203	0.9902	0.0098	(0.0000,0.0232)
4	3	1	199	0.9755	0.0245	(0.0033,0.0456)
5	0	0	199	0.9755	0.0245	(0.0033,0.0456)
6	0	0	199	0.9755	0.0245	(0.0033,0.0456)
7	1	0	198	0.9706	0.0294	(0.0062,0.0525)
8	2	0	196	0.9608	0.0392	(0.0126,0.0658)
9	0	0	196	0.9608	0.0392	(0.0126,0.0658)
10	1	0	195	0.9559	0.0441	(0.0159,0.0722)
11	1	0	194	0.9510	0.0490	(0.0194,0.0786)
12	2	2	190	0.9411	0.0589	(0.0266,0.0912)
13	0	3	187	0.9411	0.0589	(0.0266,0.0912)
14	0	1	186	0.9411	0.0589	(0.0266,0.0912)
15	0	1	185	0.9411	0.0589	(0.0266,0.0912)
16	2	0	183	0.9309	0.0691	(0.0341,0.1040)
17	1	0	182	0.9259	0.0741	(0.0380,0.1103)
18	2	0	180	0.9157	0.0843	(0.0459,0.1227)
19	0	0	180	0.9157	0.0843	(0.0459,0.1227)
20	1	0	179	0.9106	0.0894	(0.0500,0.1288)
21	1	1	177	0.9055	0.0945	(0.0540,0.1349)
22	0	1	176	0.9055	0.0945	(0.0540,0.1349)
23	0	18	158	0.9055	0.0945	(0.0540,0.1349)
24	1	4	153	0.8997	0.1003	(0.0585,0.1421)
25	1	12	140	0.8938	0.1062	(0.0631,0.1493)

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

Creation Date, Time: 24AUG04 08.53

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

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

Table 8.14.1

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	2	3	135	0.8810	0.1190	(0.0730,0.1649)
27	0	3	132	0.8810	0.1190	(0.0730,0.1649)
28	0	1	131	0.8810	0.1190	(0.0730,0.1649)
29	0	1	130	0.8810	0.1190	(0.0730,0.1649)
30	1	0	129	0.8742	0.1258	(0.0783,0.1732)
31	0	2	127	0.8742	0.1258	(0.0783,0.1732)
32	0	1	126	0.8742	0.1258	(0.0783,0.1732)
33	1	10	115	0.8673	0.1327	(0.0837,0.1817)
34	0	15	100	0.8673	0.1327	(0.0837,0.1817)
35	0	16	84	0.8673	0.1327	(0.0837,0.1817)
36	0	35	49	0.8673	0.1327	(0.0837,0.1817)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.14 1

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1007	1.0000	0.0000	(0.0000,0.0000)
1	1	1	1005	0.9990	0.0010	(0.0000,0.0029)
2	4	0	1001	0.9950	0.0050	(0.0006,0.0093)
3	3	0	998	0.9920	0.0080	(0.0025,0.0134)
4	5	1	992	0.9871	0.0129	(0.0059,0.0199)
5	0	0	992	0.9871	0.0129	(0.0059,0.0199)
6	6	2	984	0.9811	0.0189	(0.0105,0.0273)
7	5	1	978	0.9761	0.0239	(0.0144,0.0333)
8	9	1	968	0.9671	0.0329	(0.0218,0.0439)
9	3	1	964	0.9641	0.0359	(0.0244,0.0474)
10	2	1	961	0.9621	0.0379	(0.0261,0.0497)
11	3	1	957	0.9591	0.0409	(0.0286,0.0531)
12	4	6	947	0.9551	0.0449	(0.0321,0.0577)
13	5	4	938	0.9500	0.0500	(0.0365,0.0635)
14	0	5	933	0.9500	0.0500	(0.0365,0.0635)
15	0	2	931	0.9500	0.0500	(0.0365,0.0635)
16	3	1	927	0.9470	0.0530	(0.0391,0.0669)
17	2	2	923	0.9449	0.0551	(0.0409,0.0692)
18	3	1	919	0.9419	0.0581	(0.0436,0.0727)
19	3	0	916	0.9388	0.0612	(0.0463,0.0761)
20	2	1	913	0.9367	0.0633	(0.0481,0.0784)
21	1	1	911	0.9357	0.0643	(0.0491,0.0795)
22	1	11	899	0.9347	0.0653	(0.0500,0.0807)
23	2	109	788	0.9326	0.0674	(0.0518,0.0830)
24	2	46	740	0.9301	0.0699	(0.0540,0.0858)
25	1	52	687	0.9289	0.0711	(0.0550,0.0872)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.14.1

TIME TO FIRST REPORT OF EXPLANATION REGARDLESS OF REPLACEMENT (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	4	25	658	0.9234	0.0766	(0.0598,0.0935)
27	1	7	650	0.9220	0.0780	(0.0610,0.0951)
28	1	3	646	0.9205	0.0795	(0.0622,0.0967)
29	0	2	644	0.9205	0.0795	(0.0622,0.0967)
30	2	4	638	0.9177	0.0823	(0.0647,0.1000)
31	1	2	635	0.9162	0.0838	(0.0659,0.1016)
32	0	6	629	0.9162	0.0838	(0.0659,0.1016)
33	2	58	569	0.9133	0.0867	(0.0684,0.1049)
34	1	49	519	0.9117	0.0883	(0.0698,0.1068)
35	0	85	434	0.9117	0.0883	(0.0698,0.1068)
36	0	162	272	0.9117	0.0883	(0.0698,0.1068)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.14.2

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
1	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
2	2	0	1125	0.9982	0.0018	(0.0000,0.0042)
3	2	0	1123	0.9965	0.0035	(0.0001,0.0070)
4	0	0	1123	0.9965	0.0035	(0.0001,0.0070)
5	0	0	1123	0.9965	0.0035	(0.0001,0.0070)
6	7	2	1114	0.9902	0.0098	(0.0040,0.0155)
7	2	0	1112	0.9885	0.0115	(0.0053,0.0178)
8	2	2	1108	0.9867	0.0133	(0.0066,0.0200)
9	2	2	1104	0.9849	0.0151	(0.0080,0.0222)
10	0	0	1104	0.9849	0.0151	(0.0080,0.0222)
11	3	1	1100	0.9822	0.0178	(0.0101,0.0255)
12	2	8	1090	0.9804	0.0196	(0.0115,0.0277)
13	4	0	1086	0.9768	0.0232	(0.0144,0.0320)
14	0	4	1082	0.9768	0.0232	(0.0144,0.0320)
15	1	2	1079	0.9759	0.0241	(0.0151,0.0331)
16	0	0	1079	0.9759	0.0241	(0.0151,0.0331)
17	1	0	1078	0.9750	0.0250	(0.0158,0.0341)
18	0	0	1078	0.9750	0.0250	(0.0158,0.0341)
19	2	1	1075	0.9732	0.0268	(0.0173,0.0363)
20	0	0	1075	0.9732	0.0268	(0.0173,0.0363)
21	0	0	1075	0.9732	0.0268	(0.0173,0.0363)
22	0	10	1065	0.9732	0.0268	(0.0173,0.0363)
23	2	71	992	0.9714	0.0286	(0.0188,0.0384)
24	2	57	933	0.9694	0.0306	(0.0205,0.0408)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.14.2

TIME TO FIRST REPORT OF EXPLANATION REGARDLESS OF REPLACEMENT (IMPLANT LEVEL)  
IMPLANTS USED FOR AUGMENTATION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	64	869	0.9694	0.0306	(0.0205,0.0408)
26	4	37	828	0.9648	0.0352	(0.0242,0.0462)
27	0	6	822	0.9648	0.0352	(0.0242,0.0462)
28	2	4	816	0.9625	0.0375	(0.0261,0.0490)
29	0	2	814	0.9625	0.0375	(0.0261,0.0490)
30	0	8	806	0.9625	0.0375	(0.0261,0.0490)
31	2	0	804	0.9601	0.0399	(0.0280,0.0519)
32	0	8	796	0.9601	0.0399	(0.0280,0.0519)
33	1	41	754	0.9589	0.0411	(0.0290,0.0533)
34	2	40	712	0.9563	0.0437	(0.0311,0.0563)
35	0	101	611	0.9563	0.0437	(0.0311,0.0563)
36	0	208	403	0.9563	0.0437	(0.0311,0.0563)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.14 2

TIME TO FIRST REPORT OF EXPLANATION REGARDLESS OF REPLACEMENT (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	386	1.0000	0.0000	(0.0000,0.0000)
1	0	2	384	1.0000	0.0000	(0.0000,0.0000)
2	1	0	383	0.9974	0.0026	(0.0000,0.0077)
3	2	0	381	0.9922	0.0078	(0.0000,0.0166)
4	4	0	377	0.9818	0.0182	(0.0048,0.0316)
5	0	0	377	0.9818	0.0182	(0.0048,0.0316)
6	3	2	372	0.9739	0.0261	(0.0101,0.0420)
7	4	2	366	0.9635	0.0365	(0.0177,0.0553)
8	7	0	359	0.9450	0.0550	(0.0321,0.0778)
9	2	0	357	0.9398	0.0602	(0.0364,0.0841)
10	1	1	355	0.9371	0.0629	(0.0385,0.0872)
11	0	1	354	0.9371	0.0629	(0.0385,0.0872)
12	2	1	351	0.9318	0.0682	(0.0429,0.0934)
13	4	2	345	0.9212	0.0788	(0.0517,0.1059)
14	0	3	342	0.9212	0.0788	(0.0517,0.1059)
15	0	0	342	0.9212	0.0788	(0.0517,0.1059)
16	1	2	339	0.9185	0.0815	(0.0540,0.1090)
17	0	3	336	0.9185	0.0815	(0.0540,0.1090)
18	1	2	333	0.9157	0.0843	(0.0563,0.1122)
19	2	0	331	0.9102	0.0898	(0.0610,0.1186)
20	1	1	329	0.9075	0.0925	(0.0633,0.1217)
21	0	0	329	0.9075	0.0925	(0.0633,0.1217)
22	1	9	319	0.9047	0.0953	(0.0657,0.1250)
23	0	90	229	0.9047	0.0953	(0.0657,0.1250)
24	0	21	208	0.9047	0.0953	(0.0657,0.1250)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.14.2

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (IMPLANT LEVEL)  
IMPLANTS USED FOR RECONSTRUCTION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	12	196	0.9047	0.0953	(0.0657,0.1250)
26	0	6	190	0.9047	0.0953	(0.0657,0.1250)
27	2	1	187	0.8951	0.1049	(0.0728,0.1371)
28	0	0	187	0.8951	0.1049	(0.0728,0.1371)
29	0	0	187	0.8951	0.1049	(0.0728,0.1371)
30	2	0	185	0.8855	0.1145	(0.0800,0.1489)
31	0	0	185	0.8855	0.1145	(0.0800,0.1489)
32	0	2	183	0.8855	0.1145	(0.0800,0.1489)
33	0	51	132	0.8855	0.1145	(0.0800,0.1489)
34	0	24	108	0.8855	0.1145	(0.0800,0.1489)
35	0	36	72	0.8855	0.1145	(0.0800,0.1489)
36	0	37	35	0.8855	0.1145	(0.0800,0.1489)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.14.2

TIME TO FIRST REPORT OF EXPLANATION REGARDLESS OF REPLACEMENT (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	383	1.0000	0.0000	(0.0000,0.0000)
1	2	0	381	0.9948	0.0052	(0.0000,0.0124)
2	1	0	380	0.9922	0.0078	(0.0000,0.0167)
3	0	0	380	0.9922	0.0078	(0.0000,0.0167)
4	4	2	374	0.9817	0.0183	(0.0049,0.0318)
5	0	0	374	0.9817	0.0183	(0.0049,0.0318)
6	0	0	374	0.9817	0.0183	(0.0049,0.0318)
7	2	0	372	0.9764	0.0236	(0.0084,0.0388)
8	3	0	369	0.9685	0.0315	(0.0139,0.0490)
9	0	0	369	0.9685	0.0315	(0.0139,0.0490)
10	1	0	368	0.9659	0.0341	(0.0159,0.0523)
11	2	0	366	0.9607	0.0393	(0.0198,0.0588)
12	3	4	359	0.9527	0.0473	(0.0260,0.0686)
13	0	6	353	0.9527	0.0473	(0.0260,0.0686)
14	0	2	351	0.9527	0.0473	(0.0260,0.0686)
15	0	2	349	0.9527	0.0473	(0.0260,0.0686)
16	3	0	346	0.9445	0.0555	(0.0324,0.0785)
17	1	0	345	0.9418	0.0582	(0.0346,0.0818)
18	4	0	341	0.9309	0.0691	(0.0435,0.0948)
19	0	0	341	0.9309	0.0691	(0.0435,0.0948)
20	1	0	340	0.9281	0.0719	(0.0457,0.0980)
21	2	2	336	0.9227	0.0773	(0.0503,0.1044)
22	0	2	334	0.9227	0.0773	(0.0503,0.1044)
23	0	33	301	0.9227	0.0773	(0.0503,0.1044)
24	2	9	290	0.9164	0.0836	(0.0554,0.1118)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2. Implant counts exclude events where breast side = N/A.

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

Table 8.14.2

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (IMPLANT LEVEL)  
IMPLANTS USED FOR REVISION

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	23	266	0.9133	0.0867	(0.0579,0.1155)
26	4	7	255	0.8995	0.1005	(0.0691,0.1319)
27	0	7	248	0.8995	0.1005	(0.0691,0.1319)
28	0	1	247	0.8995	0.1005	(0.0691,0.1319)
29	0	1	246	0.8995	0.1005	(0.0691,0.1319)
30	1	0	245	0.8958	0.1042	(0.0721,0.1362)
31	0	4	241	0.8958	0.1042	(0.0721,0.1362)
32	0	1	240	0.8958	0.1042	(0.0721,0.1362)
33	2	19	219	0.8884	0.1116	(0.0782,0.1450)
34	0	27	192	0.8884	0.1116	(0.0782,0.1450)
35	0	28	164	0.8884	0.1116	(0.0782,0.1450)
36	0	69	95	0.8884	0.1116	(0.0782,0.1450)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.14.2

TIME TO FIRST REPORT OF EXPLANATION REGARDLESS OF REPLACEMENT (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	2	2	1892	0.9989	0.0011	(0.0000,0.0025)
2	4	0	1888	0.9968	0.0032	(0.0006,0.0057)
3	4	0	1884	0.9947	0.0053	(0.0020,0.0085)
4	8	2	1874	0.9905	0.0095	(0.0051,0.0139)
5	0	0	1874	0.9905	0.0095	(0.0051,0.0139)
6	10	4	1860	0.9852	0.0148	(0.0094,0.0202)
7	8	2	1850	0.9810	0.0190	(0.0129,0.0252)
8	12	2	1836	0.9746	0.0254	(0.0183,0.0325)
9	4	2	1830	0.9725	0.0275	(0.0201,0.0349)
10	2	1	1827	0.9714	0.0286	(0.0211,0.0361)
11	5	2	1820	0.9687	0.0313	(0.0234,0.0391)
12	7	13	1800	0.9650	0.0350	(0.0267,0.0433)
13	8	8	1784	0.9607	0.0393	(0.0305,0.0481)
14	0	9	1775	0.9607	0.0393	(0.0305,0.0481)
15	1	4	1770	0.9602	0.0398	(0.0310,0.0487)
16	4	2	1764	0.9580	0.0420	(0.0329,0.0511)
17	2	3	1759	0.9569	0.0431	(0.0339,0.0523)
18	5	2	1752	0.9542	0.0458	(0.0364,0.0553)
19	4	1	1747	0.9520	0.0480	(0.0383,0.0577)
20	2	1	1744	0.9509	0.0491	(0.0393,0.0589)
21	2	2	1740	0.9498	0.0502	(0.0403,0.0601)
22	1	21	1718	0.9493	0.0507	(0.0408,0.0607)
23	2	194	1522	0.9482	0.0518	(0.0418,0.0619)
24	4	87	1431	0.9456	0.0544	(0.0441,0.0647)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.14.2

TIME TO FIRST REPORT OF EXPLANTATION REGARDLESS OF REPLACEMENT (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	1	99	1331	0.9449	0.0551	(0.0447,0.0655)
26	8	50	1273	0.9392	0.0608	(0.0498,0.0719)
27	2	14	1257	0.9377	0.0623	(0.0511,0.0736)
28	2	5	1250	0.9362	0.0638	(0.0524,0.0753)
29	0	3	1247	0.9362	0.0638	(0.0524,0.0753)
30	3	8	1236	0.9339	0.0661	(0.0544,0.0778)
31	2	4	1230	0.9324	0.0676	(0.0557,0.0794)
32	0	11	1219	0.9324	0.0676	(0.0557,0.0794)
33	3	111	1105	0.9301	0.0699	(0.0578,0.0820)
34	2	91	1012	0.9284	0.0716	(0.0593,0.0839)
35	0	165	847	0.9284	0.0716	(0.0593,0.0839)
36	0	314	533	0.9284	0.0716	(0.0593,0.0839)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2. Implant counts exclude events where breast side = N/A.

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

Table 8.15.1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	551	1.0000	0.0000	(0.0000,0.0000)
1	63	0	488	0.8857	0.1143	(0.0878,0.1409)
2	15	0	473	0.8584	0.1416	(0.1125,0.1707)
3	11	1	461	0.8385	0.1615	(0.1308,0.1923)
4	11	0	450	0.8185	0.1815	(0.1493,0.2137)
5	3	0	447	0.8130	0.1870	(0.1544,0.2196)
6	10	1	436	0.7948	0.2052	(0.1715,0.2389)
7	15	0	421	0.7675	0.2325	(0.1972,0.2678)
8	3	1	417	0.7620	0.2380	(0.2024,0.2736)
9	6	1	410	0.7510	0.2490	(0.2129,0.2851)
10	1	0	409	0.7492	0.2508	(0.2146,0.2870)
11	2	0	407	0.7455	0.2545	(0.2181,0.2909)
12	4	4	399	0.7382	0.2618	(0.2251,0.2986)
13	12	1	386	0.7159	0.2841	(0.2463,0.3218)
14	1	2	383	0.7141	0.2859	(0.2481,0.3237)
15	2	1	380	0.7103	0.2897	(0.2517,0.3276)
16	0	0	380	0.7103	0.2897	(0.2517,0.3276)
17	1	0	379	0.7085	0.2915	(0.2535,0.3296)
18	2	0	377	0.7047	0.2953	(0.2571,0.3335)
19	1	0	376	0.7029	0.2971	(0.2589,0.3354)
20	3	0	373	0.6973	0.3027	(0.2643,0.3412)
21	0	0	373	0.6973	0.3027	(0.2643,0.3412)
22	2	1	370	0.6935	0.3065	(0.2678,0.3451)
23	6	23	341	0.6818	0.3182	(0.2791,0.3573)
24	4	19	318	0.6737	0.3263	(0.2869,0.3658)
25	3	22	293	0.6671	0.3329	(0.2932,0.3727)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.15 1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	12	281	0.6671	0.3329	(0.2932,0.3727)
27	1	2	278	0.6647	0.3353	(0.2954,0.3752)
28	0	2	276	0.6647	0.3353	(0.2954,0.3752)
29	1	1	274	0.6623	0.3377	(0.2977,0.3777)
30	1	4	269	0.6598	0.3402	(0.3000,0.3803)
31	0	0	269	0.6598	0.3402	(0.3000,0.3803)
32	1	1	267	0.6574	0.3426	(0.3023,0.3829)
33	0	12	255	0.6574	0.3426	(0.3023,0.3829)
34	2	12	241	0.6521	0.3479	(0.3073,0.3885)
35	0	37	204	0.6521	0.3479	(0.3073,0.3885)
36	0	69	135	0.6521	0.3479	(0.3073,0.3885)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.15.1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	251	1.0000	0.0000	(0.0000,0.0000)
1	22	1	228	0.9120	0.0880	(0.0529,0.1231)
2	16	0	212	0.8480	0.1520	(0.1075,0.1965)
3	3	0	209	0.8360	0.1640	(0.1181,0.2098)
4	3	1	205	0.8240	0.1760	(0.1288,0.2232)
5	3	0	202	0.8119	0.1881	(0.1396,0.2365)
6	9	2	191	0.7756	0.2244	(0.1727,0.2762)
7	4	2	185	0.7593	0.2407	(0.1876,0.2938)
8	1	2	182	0.7552	0.2448	(0.1914,0.2982)
9	2	0	180	0.7469	0.2531	(0.1991,0.3072)
10	5	0	175	0.7261	0.2739	(0.2183,0.3294)
11	4	0	171	0.7095	0.2905	(0.2339,0.3471)
12	2	1	168	0.7012	0.2988	(0.2417,0.3559)
13	3	2	163	0.6887	0.3113	(0.2535,0.3691)
14	1	2	160	0.6844	0.3156	(0.2575,0.3736)
15	1	0	159	0.6802	0.3198	(0.2616,0.3781)
16	3	0	156	0.6673	0.3327	(0.2737,0.3916)
17	1	1	154	0.6630	0.3370	(0.2778,0.3961)
18	1	0	153	0.6587	0.3413	(0.2819,0.4007)
19	1	0	152	0.6544	0.3456	(0.2860,0.4052)
20	1	1	150	0.6501	0.3499	(0.2901,0.4097)
21	2	0	148	0.6415	0.3585	(0.2983,0.4187)
22	2	3	143	0.6327	0.3673	(0.3067,0.4279)
23	4	43	96	0.6115	0.3885	(0.3264,0.4505)
24	1	10	85	0.6048	0.3952	(0.3324,0.4579)
25	2	6	77	0.5901	0.4099	(0.3454,0.4744)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.15.1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	1	1	75	0.5824	0.4176	(0.3522,0.4830)
27	0	0	75	0.5824	0.4176	(0.3522,0.4830)
28	0	0	75	0.5824	0.4176	(0.3522,0.4830)
29	1	0	74	0.5746	0.4254	(0.3591,0.4916)
30	0	0	74	0.5746	0.4254	(0.3591,0.4916)
31	0	0	74	0.5746	0.4254	(0.3591,0.4916)
32	0	0	74	0.5746	0.4254	(0.3591,0.4916)
33	1	19	54	0.5647	0.4353	(0.3674,0.5032)
34	0	9	45	0.5647	0.4353	(0.3674,0.5032)
35	2	10	33	0.5393	0.4607	(0.3873,0.5341)
36	0	18	15	0.5393	0.4607	(0.3873,0.5341)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.15.1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	205	1.0000	0.0000	(0.0000,0.0000)
1	22	1	182	0.8923	0.1077	(0.0652,0.1503)
2	6	0	176	0.8629	0.1371	(0.0900,0.1843)
3	6	0	170	0.8334	0.1666	(0.1154,0.2177)
4	7	2	161	0.7988	0.2012	(0.1461,0.2562)
5	4	0	157	0.7790	0.2210	(0.1640,0.2780)
6	6	0	151	0.7492	0.2508	(0.1912,0.3104)
7	5	0	146	0.7244	0.2756	(0.2141,0.3371)
8	2	0	144	0.7145	0.2855	(0.2234,0.3477)
9	2	0	142	0.7046	0.2954	(0.2327,0.3582)
10	4	0	138	0.6847	0.3153	(0.2513,0.3793)
11	2	0	136	0.6748	0.3252	(0.2607,0.3897)
12	1	1	134	0.6698	0.3302	(0.2654,0.3949)
13	6	2	126	0.6396	0.3604	(0.2942,0.4266)
14	1	1	124	0.6345	0.3655	(0.2991,0.4319)
15	0	0	124	0.6345	0.3655	(0.2991,0.4319)
16	2	1	121	0.6242	0.3758	(0.3090,0.4427)
17	0	0	121	0.6242	0.3758	(0.3090,0.4427)
18	0	0	121	0.6242	0.3758	(0.3090,0.4427)
19	0	0	121	0.6242	0.3758	(0.3090,0.4427)
20	0	0	121	0.6242	0.3758	(0.3090,0.4427)
21	1	1	119	0.6190	0.3810	(0.3140,0.4481)
22	1	0	118	0.6138	0.3862	(0.3190,0.4535)
23	4	7	107	0.5926	0.4074	(0.3393,0.4754)
24	1	2	104	0.5871	0.4129	(0.3446,0.4813)
25	3	5	96	0.5700	0.4300	(0.3610,0.4991)

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

Creation Date, Time: 24AUG04 08.53

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

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

Table 8.15.1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
REVISION PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	0	2	94	0.5700	0.4300	(0.3610,0.4991)
27	0	1	93	0.5700	0.4300	(0.3610,0.4991)
28	1	1	91	0.5638	0.4362	(0.3669,0.5055)
29	0	1	90	0.5638	0.4362	(0.3669,0.5055)
30	0	0	90	0.5638	0.4362	(0.3669,0.5055)
31	0	2	88	0.5638	0.4362	(0.3669,0.5055)
32	0	1	87	0.5638	0.4362	(0.3669,0.5055)
33	0	4	83	0.5638	0.4362	(0.3669,0.5055)
34	0	9	74	0.5638	0.4362	(0.3669,0.5055)
35	0	15	59	0.5638	0.4362	(0.3669,0.5055)
36	0	21	38	0.5638	0.4362	(0.3669,0.5055)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8 15.1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1007	1.0000	0.0000	(0.0000,0.0000)
1	107	2	898	0.8936	0.1064	(0.0873,0.1255)
2	37	0	861	0.8568	0.1432	(0.1216,0.1649)
3	20	1	840	0.8369	0.1631	(0.1403,0.1860)
4	21	3	816	0.8159	0.1841	(0.1601,0.2081)
5	10	0	806	0.8059	0.1941	(0.1696,0.2185)
6	25	3	778	0.7809	0.2191	(0.1935,0.2447)
7	24	2	752	0.7568	0.2432	(0.2167,0.2698)
8	6	3	743	0.7507	0.2493	(0.2225,0.2761)
9	10	1	732	0.7406	0.2594	(0.2322,0.2865)
10	10	0	722	0.7305	0.2695	(0.2420,0.2970)
11	8	0	714	0.7224	0.2776	(0.2499,0.3054)
12	7	6	701	0.7153	0.2847	(0.2567,0.3127)
13	21	5	675	0.6938	0.3062	(0.2776,0.3348)
14	3	5	667	0.6907	0.3093	(0.2806,0.3380)
15	3	1	663	0.6876	0.3124	(0.2836,0.3412)
16	5	1	657	0.6824	0.3176	(0.2887,0.3465)
17	2	1	654	0.6803	0.3197	(0.2907,0.3486)
18	3	0	651	0.6772	0.3228	(0.2937,0.3518)
19	2	0	649	0.6751	0.3249	(0.2958,0.3540)
20	4	1	644	0.6710	0.3290	(0.2998,0.3582)
21	3	1	640	0.6678	0.3322	(0.3029,0.3614)
22	5	4	631	0.6626	0.3374	(0.3080,0.3668)
23	14	73	544	0.6468	0.3532	(0.3233,0.3830)
24	6	31	507	0.6396	0.3604	(0.3304,0.3905)
25	8	33	466	0.6292	0.3708	(0.3404,0.4013)

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

Creation Date, Time: 24AUG04 08:53

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

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

Table 8.15.1

TIME TO FIRST REPORT OF ANY COMPLICATION (PATIENT LEVEL)  
OVERALL PATIENTS

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
26	1	15	450	0.6278	0.3722	(0.3417, 0.4027)
27	1	3	446	0.6264	0.3736	(0.3430, 0.4041)
28	1	3	442	0.6250	0.3750	(0.3444, 0.4056)
29	2	2	438	0.6222	0.3778	(0.3471, 0.4086)
30	1	4	433	0.6207	0.3793	(0.3485, 0.4100)
31	0	2	431	0.6207	0.3793	(0.3485, 0.4100)
32	1	2	428	0.6193	0.3807	(0.3499, 0.4115)
33	1	35	392	0.6177	0.3823	(0.3514, 0.4132)
34	2	30	360	0.6145	0.3855	(0.3545, 0.4166)
35	2	62	296	0.6110	0.3890	(0.3577, 0.4202)
36	0	108	188	0.6110	0.3890	(0.3577, 0.4202)

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Creation Date, Time: 24AUG04 08:53

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

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

Table 8.15.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	1127	1.0000	0.0000	(0.0000,0.0000)
1	81	0	1046	0.9281	0.0719	(0.0568,0.0870)
2	22	0	1024	0.9086	0.0914	(0.0746,0.1082)
3	16	2	1006	0.8944	0.1056	(0.0877,0.1235)
4	13	0	993	0.8828	0.1172	(0.0984,0.1359)
5	5	0	988	0.8784	0.1216	(0.1025,0.1407)
6	15	4	969	0.8650	0.1350	(0.1150,0.1549)
7	26	0	943	0.8418	0.1582	(0.1368,0.1795)
8	6	3	934	0.8365	0.1635	(0.1419,0.1851)
9	6	3	925	0.8311	0.1689	(0.1470,0.1908)
10	2	0	923	0.8293	0.1707	(0.1487,0.1927)
11	2	1	920	0.8275	0.1725	(0.1504,0.1946)
12	5	8	907	0.8230	0.1770	(0.1547,0.1993)
13	21	2	884	0.8039	0.1961	(0.1728,0.2193)
14	3	4	877	0.8012	0.1988	(0.1754,0.2222)
15	3	3	871	0.7984	0.2016	(0.1781,0.2251)
16	0	0	871	0.7984	0.2016	(0.1781,0.2251)
17	2	0	869	0.7966	0.2034	(0.1798,0.2270)
18	1	0	868	0.7957	0.2043	(0.1807,0.2279)
19	3	1	864	0.7929	0.2071	(0.1833,0.2308)
20	2	0	862	0.7911	0.2089	(0.1851,0.2327)
21	0	0	862	0.7911	0.2089	(0.1851,0.2327)
22	2	6	854	0.7893	0.2107	(0.1868,0.2346)
23	9	54	791	0.7806	0.2194	(0.1951,0.2438)
24	7	45	739	0.7735	0.2265	(0.2018,0.2511)

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Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.15.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	6	51	682	0.7669	0.2331	(0.2081,0.2581)
26	0	27	655	0.7669	0.2331	(0.2081,0.2581)
27	1	5	649	0.7657	0.2343	(0.2092,0.2593)
28	1	5	643	0.7646	0.2354	(0.2103,0.2606)
29	1	2	640	0.7634	0.2366	(0.2114,0.2618)
30	1	8	631	0.7622	0.2378	(0.2126,0.2631)
31	1	0	630	0.7610	0.2390	(0.2137,0.2644)
32	2	4	624	0.7585	0.2415	(0.2160,0.2669)
33	0	34	590	0.7585	0.2415	(0.2160,0.2669)
34	2	30	558	0.7560	0.2440	(0.2184,0.2697)
35	0	83	475	0.7560	0.2440	(0.2184,0.2697)
36	0	159	316	0.7560	0.2440	(0.2184,0.2697)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.15.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	386	1.0000	0.0000	(0.0000,0.0000)
1	23	2	361	0.9402	0.0598	(0.0361,0.0836)
2	16	0	345	0.8985	0.1015	(0.0713,0.1317)
3	3	0	342	0.8907	0.1093	(0.0781,0.1405)
4	4	2	336	0.8802	0.1198	(0.0873,0.1523)
5	4	0	332	0.8697	0.1303	(0.0966,0.1640)
6	14	4	314	0.8328	0.1672	(0.1298,0.2045)
7	3	4	307	0.8249	0.1751	(0.1370,0.2132)
8	1	3	303	0.8222	0.1778	(0.1395,0.2162)
9	2	0	301	0.8167	0.1833	(0.1444,0.2221)
10	4	0	297	0.8059	0.1941	(0.1544,0.2338)
11	5	0	292	0.7923	0.2077	(0.1669,0.2485)
12	3	2	287	0.7842	0.2158	(0.1744,0.2572)
13	4	4	279	0.7732	0.2268	(0.1846,0.2690)
14	1	3	275	0.7704	0.2296	(0.1872,0.2720)
15	1	0	274	0.7676	0.2324	(0.1898,0.2750)
16	5	0	269	0.7536	0.2464	(0.2028,0.2899)
17	1	2	266	0.7508	0.2492	(0.2054,0.2929)
18	0	2	264	0.7508	0.2492	(0.2054,0.2929)
19	1	1	262	0.7480	0.2520	(0.2081,0.2959)
20	0	1	261	0.7480	0.2520	(0.2081,0.2959)
21	1	0	260	0.7451	0.2549	(0.2108,0.2990)
22	2	6	252	0.7393	0.2607	(0.2162,0.3052)
23	4	74	174	0.7253	0.2747	(0.2289,0.3204)
24	1	16	157	0.7209	0.2791	(0.2328,0.3254)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.15.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	3	10	144	0.7065	0.2935	(0.2453,0.3416)
26	1	3	140	0.7016	0.2984	(0.2496,0.3471)
27	1	0	139	0.6966	0.3034	(0.2540,0.3528)
28	0	0	139	0.6966	0.3034	(0.2540,0.3528)
29	1	0	138	0.6916	0.3084	(0.2584,0.3584)
30	0	0	138	0.6916	0.3084	(0.2584,0.3584)
31	0	0	138	0.6916	0.3084	(0.2584,0.3584)
32	0	0	138	0.6916	0.3084	(0.2584,0.3584)
33	2	37	99	0.6787	0.3213	(0.2692,0.3735)
34	0	17	82	0.6787	0.3213	(0.2692,0.3735)
35	5	25	52	0.6295	0.3705	(0.3062,0.4348)
36	0	27	25	0.6295	0.3705	(0.3062,0.4348)

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

Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.15.2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	383	1.0000	0.0000	(0.0000,0.0000)
1	27	2	354	0.9292	0.0708	(0.0450,0.0965)
2	9	0	345	0.9056	0.0944	(0.0650,0.1237)
3	9	0	336	0.8820	0.1180	(0.0856,0.1504)
4	10	4	322	0.8555	0.1445	(0.1092,0.1798)
5	6	0	316	0.8396	0.1604	(0.1235,0.1973)
6	9	0	307	0.8157	0.1843	(0.1453,0.2234)
7	7	0	300	0.7971	0.2029	(0.1625,0.2434)
8	4	1	295	0.7864	0.2136	(0.1723,0.2548)
9	3	0	292	0.7784	0.2216	(0.1797,0.2634)
10	6	0	286	0.7624	0.2376	(0.1947,0.2804)
11	1	0	285	0.7598	0.2402	(0.1972,0.2833)
12	2	3	280	0.7544	0.2456	(0.2022,0.2890)
13	8	5	267	0.7327	0.2673	(0.2227,0.3120)
14	1	2	264	0.7299	0.2701	(0.2253,0.3149)
15	0	1	263	0.7299	0.2701	(0.2253,0.3149)
16	3	2	258	0.7215	0.2785	(0.2332,0.3238)
17	0	0	258	0.7215	0.2785	(0.2332,0.3238)
18	0	1	257	0.7215	0.2785	(0.2332,0.3238)
19	0	0	257	0.7215	0.2785	(0.2332,0.3238)
20	0	0	257	0.7215	0.2785	(0.2332,0.3238)
21	1	2	254	0.7187	0.2813	(0.2358,0.3268)
22	3	0	251	0.7102	0.2898	(0.2439,0.3357)
23	7	18	226	0.6901	0.3099	(0.2629,0.3569)
24	1	6	219	0.6870	0.3130	(0.2658,0.3602)

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Creation Date, Time: 24AUG04 08:53

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

Note 2: Implant counts exclude events where breast side = N/A.

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

Table 8.15 2

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

Months Following Procedure	Number With Event	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	4	13	202	0.6743	0.3257	(0.2778,0.3736)
26	0	6	196	0.6743	0.3257	(0.2778,0.3736)
27	0	5	191	0.6743	0.3257	(0.2778,0.3736)
28	2	1	188	0.6673	0.3327	(0.2843,0.3811)
29	0	1	187	0.6673	0.3327	(0.2843,0.3811)
30	0	0	187	0.6673	0.3327	(0.2843,0.3811)
31	0	5	182	0.6673	0.3327	(0.2843,0.3811)
32	0	1	181	0.6673	0.3327	(0.2843,0.3811)
33	0	11	170	0.6673	0.3327	(0.2843,0.3811)
34	0	17	153	0.6673	0.3327	(0.2843,0.3811)
35	0	26	127	0.6673	0.3327	(0.2843,0.3811)
36	0	50	77	0.6673	0.3327	(0.2843,0.3811)

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.