

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

Table 13.2.1

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

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

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

Creation Date, Time: 24AUG04 15:53

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

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Table 13.2.1

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

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

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Table 13.2.1

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

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

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

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 (1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or  
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Table 13.2.1

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

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

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Table 13.2.1

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

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

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

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

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Table 13.2.1

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

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

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OVERALL PATIENTS

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

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