

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

Table 2.1

PATIENT ACCOUNTING
AUGMENTATION PATIENTS

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Patients (theoretically due) (a)	551	551	551	551	551
Deaths	0	0	0	0	0
Discontinuations due to Explantation (b)	0	0	1	4	7
Not Yet Due For Follow-up	0	0	0	0	112
Expected Due (c)	551	551	550	547	432
Other Discontinuations	0	0	1	1	3
Missed Follow-up Visit	0	14	19	22	25
Number of Patients Included in Data Listings (Actual Included)	551	537	530	524	404
Lost to Follow-up	0	2	2	6	9
% Follow-up	100	97	96	96	94
Exclusion from Analyses (d)	0	0	2	1	2
Number of Patients Included in Summary Tables (e)	551	537	528	523	402

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T02_1.SAS

Creation Date, Time: 23AUG04 19:45

- (a) Patients who would have been examined according to implant date and follow-up schedules.
 (b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.
 For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.
 (c) Patients theoretically due minus deaths and removals without replacement.
 (d) Includes patients not having complications or reoperations in the visit year only after explanation of original study device.
 (e) Specifically, patients included in complication and reoperation tables: tables 8.1 - 10_10_A.

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Table 2.1

PATIENT ACCOUNTING
RECONSTRUCTION PATIENTS

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Patients (theoretically due) (a)	251	251	251	251	251
Deaths	0	0	0	7	9
Discontinuations due to Explantation (b)	0	1	2	6	8
Not Yet Due For Follow-up	0	0	0	0	107
Expected Due (c)	251	250	249	238	127
Other Discontinuations	0	1	3	4	6
Missed Follow-up Visit	0	3	6	4	0
Number of Patients Included in Data Listings (Actual Included)	251	246	240	230	121
Lost to Follow-up	0	0	1	1	1
% Follow-up	100	98	96	97	95
Exclusion from Analyses (d)	0	0	3	6	2
Number of Patients Included in Summary Tables (e)	251	246	237	224	119

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T02_1.SAS

Creation Date, Time: 23AUG04 19:45

(a) Patients who would have been examined according to implant date and follow-up schedules.

(b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.

For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.

(c) Patients theoretically due minus deaths and removals without replacement.

(d) Includes patients not having complications or reoperations in the visit year only after explanation of original study device.

(e) Specifically, patients included in complication and reoperation tables: tables 8.1 - 10_10_A.

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Table 2.1
PATIENT ACCOUNTING
REVISION PATIENTS

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Patients (theoretically due) (a)	205	205	205	205	205
Deaths	0	0	0	0	0
Discontinuations due to Explantation (b)	0	1	1	4	7
Not Yet Due For Follow-up	0	0	0	0	47
Expected Due (c)	205	204	204	201	151
Other Discontinuations	0	0	0	1	1
Missed Follow-up Visit	0	6	9	13	10
Number of Patients Included in Data Listings (Actual Included)	205	198	195	187	140
Lost to Follow-up	0	2	2	3	3
% Follow-up	100	97	96	93	93
Exclusion from Analyses (d)	0	0	0	1	1
Number of Patients Included in Summary Tables (e)	205	198	195	186	139

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Creation Date, Time. 23AUG04 19:45

- (a) Patients who would have been examined according to implant date and follow-up schedules.
 (b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.
 For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.
 (c) Patients theoretically due minus deaths and removals without replacement.
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 (e) Specifically, patients included in complication and reoperation tables: tables 8.1 - 10_10_A.

Table 2.1
PATIENT ACCOUNTING
OVERALL PATIENTS

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Patients (theoretically due) (a)	1007	1007	1007	1007	1007
Deaths	0	0	0	7	9
Discontinuations due to Explantation (b)	0	2	4	14	22
Not Yet Due For Follow-up	0	0	0	0	266
Expected Due (c)	1007	1005	1003	986	710
Other Discontinuations	0	1	4	6	10
Missed Follow-up Visit	0	23	34	39	35
Number of Patients Included in Data Listings (Actual Included)	1007	981	965	941	665
Lost to Follow-up	0	4	5	10	13
% Follow-up	100	98	96	95	94
Exclusion from Analyses (d)	0	0	5	8	5
Number of Patients Included in Summary Tables (e)	1007	981	960	933	660

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T02_1.SAS

Creation Date, Time: 23AUG04 19:45

- (a) Patients who would have been examined according to implant date and follow-up schedules.
- (b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.
For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.
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Table 2.2
DEVICE ACCOUNTING
IMPLANTS USED FOR AUGMENTATION

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Implants (theoretically due) (a)	1127	1127	1127	1127	1127
Deaths	0	0	0	1	1
Discontinuations due to Explantation (b)	0	0	3	7	14
Not Yet Due For Follow-up	0	0	0	0	233
Expected Due (c)	1127	1127	1124	1119	879
Other Discontinuations	0	1	0	2	4
Missed Follow-up Visit	0	54	65	71	68
Number of Implants Included in Data Listings (Actual Included)	1127	1072	1059	1046	807
Lost to Follow-up	0	6	13	19	19
% Follow-up	100	95	94	93	92
Exclusion from Analyses (d)	0	0	4	1	2
Number of Implants Included in Summary Tables (e)	1127	1072	1055	1045	805

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T02_2.SAS

Creation Date, Time: 23AUG04 19:47

- (a) Implants which would have been examined according to implant date and follow-up schedules.
 (b) A device would not be discontinued if it had failed but had not been removed.
 (c) Implants theoretically due minus deaths and removals without replacement.
 (d) Includes implants not having complications or reoperations in the visit year only after explanation of original study device.
 (e) Specifically, implants included in complication and reoperation tables: tables 8.1 - 10_10_A.

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Table 2.2
DEVICE ACCOUNTING
IMPLANTS USED FOR RECONSTRUCTION

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Implants (theoretically due) (a)	386	386	386	386	386
Deaths	0	0	0	8	13
Discontinuations due to Explantation (b)	0	1	6	9	12
Not Yet Due For Follow-up	0	0	0	0	161
Expected Due (c)	386	385	380	369	200
Other Discontinuations	0	1	8	8	11
Missed Follow-up Visit	0	9	6	9	1
Number of Implants Included in Data Listings (Actual Included)	386	375	366	352	188
Lost to Follow-up	0	0	1	1	1
% Follow-up	100	97	96	95	94
Exclusion from Analyses (d)	0	0	4	6	3
Number of Implants Included in Summary Tables (e)	386	375	362	346	185

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Creation Date, Time: 23AUG04 19:47

- (a) Implants which would have been examined according to implant date and follow-up schedules.
 (b) A device would not be discontinued if it had failed but had not been removed.
 (c) Implants theoretically due minus deaths and removals without replacement.
 (d) Includes implants not having complications or reoperations in the visit year only after explanation of original study device.
 (e) Specifically, implants included in complication and reoperation tables: tables 8.1 - 10_10_A.

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Table 2.2

DEVICE ACCOUNTING
IMPLANTS USED FOR REVISION

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Implants (theoretically due) (a)	383	383	383	383	383
Deaths	0	0	0	0	0
Discontinuations due to Explantation (b)	0	2	3	9	16
Not Yet Due For Follow-up	0	0	0	0	88
Expected Due (c)	383	381	380	374	281
Other Discontinuations	0	1	0	2	2
Missed Follow-up Visit	0	11	15	25	20
Number of Implants Included in Data Listings (Actual Included)	383	369	365	347	259
Lost to Follow-up	0	4	6	6	6
% Follow-up	100	97	96	93	92
Exclusion from Analyses (d)	0	0	0	1	2
Number of Implants Included in Summary Tables (e)	383	369	365	346	257

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Creation Date, Time: 23AUG04 19:47

- (a) Implants which would have been examined according to implant date and follow-up schedules.
 (b) A device would not be discontinued if it had failed but had not been removed.
 (c) Implants theoretically due minus deaths and removals without replacement.
 (d) Includes implants not having complications or reoperations in the visit year only after explanation of original study device.
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Table 2.2

DEVICE ACCOUNTING
IMPLANTS USED OVERALL

	Preoperative Visit	6 Month Visit	1 Year Visit	2 Year Visit	3 Year Visit
All Implants (theoretically due) (a)	1896	1896	1896	1896	1896
Deaths	0	0	0	9	14
Discontinuations due to Explantation (b)	0	3	10	23	42
Not Yet Due For Follow-up	0	0	0	0	482
Expected Due (c)	1896	1893	1886	1864	1360
Other Discontinuations	0	1	8	12	17
Missed Follow-up Visit	0	47	60	81	72
Number of Implants Included in Data Listings (Actual Included)	1896	1845	1818	1771	1271
Lost to Follow-up	0	10	20	26	26
% Follow-up	100	97	96	95	93
Exclusion from Analyses (d)	0	0	8	8	7
Number of Implants Included in Summary Tables (e)	1896	1845	1810	1763	1264

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Creation Date, Time: 23AUG04 19:47

- (a) Implants which would have been examined according to implant date and follow-up schedules.
 (b) A device would not be discontinued if it had failed but had not been removed.
 (c) Implants theoretically due minus deaths and removals without replacement.
 (d) Includes implants not having complications or reoperations in the visit year only after explanation of original study device.
 (e) Specifically, implants included in complication and reoperation tables: tables 8.1 - 10_10_A.

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Table 2.3

CUMULATIVE NUMBER OF IMPLANTS PER PATIENT AND PER BREAST
AUGMENTATION PATIENTS

	N	Mean	Minimum	Maximum
Number of Implants per Patient				
Unilateral	2	1.00	1	1
Bilateral	549	2.04	2	4
Number of Implants per Breast	1100	1.02	1	2

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Table 2.3

CUMULATIVE NUMBER OF IMPLANTS PER PATIENT AND PER BREAST
RECONSTRUCTION PATIENTS

	N	Mean	Minimum	Maximum
Number of Implants per Patient				
Unilateral	92	1.11	1	2
Bilateral	159	2.11	2	6
Number of Implants per Breast	410	1.07	1	3

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Table 2.3

CUMULATIVE NUMBER OF IMPLANTS PER PATIENT AND PER BREAST
REVISION PATIENTS

	N	Mean	Minimum	Maximum
Number of Implants per Patient				
Unilateral	24	1.00	1	1
Bilateral	181	2.10	2	4
Number of Implants per Breast	386	1.05	1	3

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Table 2.3

CUMULATIVE NUMBER OF IMPLANTS PER PATIENT AND PER BREAST
OVERALL PATIENTS

	N	Mean	Minimum	Maximum
Number of Implants per Patient				
Unilateral	118	1.08	1	2
Bilateral	889	2.06	2	6
Number of Implants per Breast	1896	1.04	1	3

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Table 2.4

Device Stratified by Surface and Size - Implant Level

Surface	Total Number of Devices	Device Volume (cc)	Catalog Number	Number Used in Study N(%)
Smooth	1195	3	3507400BCG	2 (0.2)
		125	3507125BCG	2 (0.2)
		150	3507150BCG	6 (0.5)
		175	3507175BCG	4 (0.3)
		200	3507200BCG	17 (1.4)
		225	3507225BCG	12 (1)
			3507225BC	2 (0.2)
		250	3507250BCG	40 (3.3)
			3507250BC	2 (0.2)
		275	3507275BCG	70 (5.9)
		300	3507300BC	1 (0.1)
			3507300BCG	137 (11.5)
			3507275BCG	1 (0.1)
		325	3507325BCG	106 (8.9)
			3507325BC	2 (0.2)
		330	3507300BCG	1 (0.1)
		350	3507350BCG	208 (17.4)
			3507350BC	3 (0.3)
		375	3507375BCG	103 (8.6)
		400	3507400BCG	180 (15.1)
		450	3507450BC	1 (0.1)
			3507450BCG	116 (9.7)
		500	3507500BCG	63 (5.3)
	3507500BC	1 (0.1)		
550	3507550BCG	47 (3.9)		
600	3507600BCG	34 (2.8)		
700	3507700BCG	24 (2)		
800	3507800BCG	10 (0.8)		
Sillex	701	6	3542757G	2 (0.3)
		125	3541257G	5 (0.7)

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Table 2.4

Device Stratified by Surface and Size - Implant Level

Surface	Total Number of Devices	Device Volume (cc)	Catalog Number	Number Used in Study N(%)
Siltex	701	150	3541507G	2 (0.3)
		175	3541757G	4 (0.6)
		200	3542007G	22 (3.1)
		225	3542257G	32 (4.6)
		250	3542507G	35 (5)
		275	3542757G	65 (9.3)
			3542757	2 (0.3)
		300	3543007G	81 (11.6)
			3543007	1 (0.1)
		325	3543257G	80 (11.4)
		350	3543507G	66 (9.4)
			354-3507G	1 (0.1)
		375	3543757G	80 (11.4)
			354-3757G	1 (0.1)
		400	3544007G	67 (9.6)
		450	3544507G	78 (11.1)
		500	3545007G	26 (3.7)
		550	3545507G	12 (1.7)
		600	3546007G	25 (3.6)
		700	3547007G	8 (1.1)
800	3548007G	6 (0.9)		

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Table 3

DEMOGRAPHIC SUMMARY

Variable	Augmentation Patients n (%)	Reconstruction Patients n (%)	Revision Patients n (%)	Overall n (%)
Marital Status				
Never Married	135 (24.5)	35 (13.9)	30 (14.6)	200 (19.9)
Married	312 (56.6)	173 (68.9)	126 (61.5)	611 (60.7)
Separated	17 (3.1)	5 (2.0)	4 (2.0)	26 (2.6)
Divorced	81 (14.7)	30 (12.0)	39 (19.0)	150 (14.9)
Widower	6 (1.1)	8 (3.2)	6 (2.9)	20 (2.0)
Total	551 (100.0)	251 (100.0)	205 (100.0)	1007 (100.0)
Annual Household Income				
\$0-\$20,000	18 (3.3)	6 (2.4)	8 (3.9)	32 (3.2)
\$20,000-\$40,000	91 (16.5)	27 (10.8)	32 (15.6)	150 (14.9)
\$40,000-\$60,000	110 (20.0)	44 (17.5)	31 (15.1)	185 (18.4)
above \$60,000	268 (48.6)	105 (41.8)	101 (49.3)	474 (47.1)
Missing	64 (11.6)	69 (27.5)	33 (16.1)	166 (16.5)
Total	551 (100.0)	251 (100.0)	205 (100.0)	1007 (100.0)
Race/Ethnicity				
African American	11 (2.0)	7 (2.8)	4 (2.0)	22 (2.2)
Asian	17 (3.1)	3 (1.2)	3 (1.5)	23 (2.3)
Caucasian	482 (87.5)	231 (92.0)	190 (92.7)	903 (89.7)
Other	41 (7.4)	10 (4.0)	8 (3.9)	59 (5.9)
Total	551 (100.0)	251 (100.0)	205 (100.0)	1007 (100.0)

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Table 3

DEMOGRAPHIC SUMMARY

Variable	Augmentation Patients n (%)	Reconstruction Patients n (%)	Revision Patients n (%)	Overall n (%)
Educational Level				
LESS THAN 12 YEARS	7 (1.3)	3 (1.2)	2 (1.0)	12 (1.2)
HIGH SCHOOL GRADUATE	73 (13.2)	42 (16.7)	35 (17.1)	150 (14.9)
SOME COLLEGE	215 (39.0)	66 (26.3)	76 (37.1)	357 (35.5)
COLLEGE GRADUATE	189 (34.3)	85 (33.9)	61 (29.8)	335 (33.3)
POST GRADUATE	60 (10.9)	47 (18.7)	26 (12.7)	133 (13.2)
Missing	7 (1.3)	8 (3.2)	5 (2.4)	20 (2.0)
Total	551 (100.0)	251 (100.0)	205 (100.0)	1007 (100.0)
Age Category				
<20 yrs	7 (1.3)	5 (2.0)	0 (0.0)	12 (1.2)
20-<30 yrs	163 (29.6)	13 (5.2)	20 (9.8)	196 (19.5)
30-<40 yrs	240 (43.6)	57 (22.7)	44 (21.5)	341 (33.9)
40-<50 yrs	117 (21.2)	97 (38.6)	78 (38.0)	292 (29.0)
50-<60 yrs	23 (4.2)	59 (23.5)	52 (25.4)	134 (13.3)
>=60 yrs	1 (0.2)	20 (8.0)	11 (5.4)	32 (3.2)
Total	551 (100.0)	251 (100.0)	205 (100.0)	1007 (100.0)
Age at Implantation (yrs)				
N	551	251	205	1007
Mean	34.45	45.33	44.39	39.19
Median	33.90	46.34	44.27	38.73
Standard Deviation	8.09	10.87	10.69	10.75
Minimum	18.6	18.0	20.1	18.0
Maximum	65.6	79.9	72.4	79.9

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Table 4 1

PREGNANCY HISTORY AND PHYSICAL EXAMINATION SUMMARY

Variable	Augmentation Patients n(%)	Reconstruction Patients n(%)	Revision Patients n(%)	Overall n(%)
Smoking History				
Never smoked	328 (59.5)	151 (60.2)	108 (52.7)	587 (58.3)
Currently smoker	106 (19.2)	21 (8.4)	33 (16.1)	160 (15.9)
Former smoker	117 (21.2)	79 (31.5)	64 (31.2)	260 (25.8)
Total	551 (100.0)	251 (100.0)	205 (100.0)	1007 (100.0)

Table 4.2
PHYSICAL EXAMINATION AT BASELINE

Body System	Augmentation Patients n(%)	Reconstruction Patients n(%)	Revision Patients n(%)	Overall n(%)
HEENT	8 (1.5)	5 (2.0)	4 (2.0)	17 (1.7)
CARDIOVASCULAR	18 (3.3)	20 (8.0)	11 (5.4)	49 (4.9)
PULMONARY	4 (0.7)	7 (2.8)	2 (1.0)	13 (1.3)
NEUROLOGICAL	4 (0.7)	9 (3.6)	0 (0.0)	13 (1.3)
MUSCULOSKELETAL	4 (0.7)	10 (4.0)	6 (2.9)	20 (2.0)
DERMATOLOGICAL	8 (1.5)	5 (2.0)	7 (3.4)	20 (2.0)
LYMPHATIC	1 (0.2)	5 (2.0)	2 (1.0)	8 (0.8)
GENITOURINARY	6 (1.1)	3 (1.2)	3 (1.5)	12 (1.2)
GASTROINTESTINAL	8 (1.5)	5 (2.0)	2 (1.0)	15 (1.5)

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Table 5

MEDICAL HISTORY EXCLUSIVE OF CANCER

Disease Category	Augmentation Patients n(%)	Reconstruction Patients n(%)	Revision Patients n(%)	Overall n(%)
CARDIOVASCULAR DISEASE	30 (5.4)	49 (19.5)	30 (14.6)	109 (10.8)
PULMONARY DISEASE	30 (5.4)	23 (9.2)	17 (8.3)	70 (7.0)
NEUROLOGICAL DISEASE	45 (8.2)	56 (22.3)	24 (11.7)	125 (12.4)
MUSCULOSKELETAL DISEASE	11 (2.0)	20 (8.0)	11 (5.4)	42 (4.2)
DERMATOLOGICAL DISEASE	36 (6.5)	20 (8.0)	18 (8.8)	74 (7.3)
LYMPHATIC DISEASE	0 (0.0)	8 (3.2)	2 (1.0)	10 (1.0)
GENITOURINARY DISEASE	36 (6.5)	19 (7.6)	14 (6.8)	69 (6.9)
GASTROINTESTINAL DISEASE	25 (4.5)	26 (10.4)	15 (7.3)	66 (6.6)
ENDOCRINE DISEASE	23 (4.2)	41 (16.3)	20 (9.8)	84 (8.3)
ALLERGIES	228 (41.4)	132 (52.6)	93 (45.4)	453 (45.0)
PRIOR SURGERIES	389 (70.6)	195 (77.7)	155 (75.6)	739 (73.4)
OTHER	55 (10.0)	38 (15.1)	29 (14.1)	122 (12.1)

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Table 6

BREAST CANCER HISTORY

Variable	Reconstruction Patients		
	Total Mastectomy Patients (a)	Subtotal Mastectomy Patients (b)	Revision Patients (Reconstruction) (c)
	Patients n(%)	Patients n(%)	Patients n(%)
BREAST SIDE			
LEFT	79 (48.8)	4 (57.1)	16 (41.0)
RIGHT	76 (46.9)	3 (42.9)	19 (48.7)
BOTH	7 (4.3)	0 (0.0)	4 (10.3)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)
LOCATION			
UPPER LATERAL	74 (45.7)	1 (14.3)	20 (51.3)
UPPER MEDIAL	50 (30.9)	5 (71.4)	9 (23.1)
LOWER LATERAL	20 (12.3)	0 (0.0)	7 (17.9)
LOWER MEDIAL	29 (17.9)	0 (0.0)	3 (7.7)
MISSING	8 (4.9)	2 (28.6)	5 (12.8)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T06.SAS

Creation Date, Time: 16JUL04 10.49

Note: Patients may fall in more than one category; therefore, percentages may add to more than 100 percent.

(c) Includes immediate and delayed reconstruction.

(b) Includes lumpectomy and quadrantectomy.

(c) Original reconstruction due to breast cancer surgery. Includes mixed revision and revision of unknown indication.

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

Table 6

BREAST CANCER HISTORY

Variable	Reconstruction Patients		
	Total Mastectomy Patients (a)	Subtotal Mastectomy Patients (b)	Revision Patients (Reconstruction) (c)
	Patients n(%)	Patients n(%)	Patients n(%)
STAGING			
STAGE TIS	46 (28.4)	2 (28.6)	10 (25.6)
STAGE X	18 (11.1)	2 (28.6)	3 (7.7)
STAGE I	25 (15.4)	0 (0.0)	8 (20.5)
STAGE II	47 (29.0)	2 (28.6)	11 (28.2)
STAGE IIIA	13 (8.0)	0 (0.0)	1 (2.6)
STAGE IIIB	8 (4.9)	0 (0.0)	2 (5.1)
STAGE IV	1 (0.6)	0 (0.0)	1 (2.6)
MISSING	6 (3.7)	1 (14.3)	4 (10.3)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)
HISTOLOGIC TYPES			
CANCER	4 (2.5)	1 (14.3)	3 (7.7)
DUCTAL	121 (74.7)	4 (57.1)	30 (76.9)
LOBULAR	20 (12.3)	1 (14.3)	4 (10.3)
OTHER	19 (11.7)	1 (14.3)	3 (7.7)
MISSING	1 (0.6)	0 (0.0)	0 (0.0)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)

Program Name. G:\MENTOR\COREGEL\3YEAR\TABLES\T06.SAS

Creation Date, Time: 16JUL04 10:49

Note: Patients may fall in more than one category; therefore, percentages may add to more than 100 percent.

(c) Includes immediate and delayed reconstruction.

(b) Includes lumpectomy and quadrantectomy.

(c) Original reconstruction due to breast cancer surgery. Includes mixed revision and revision of unknown indication.

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

Table 6

BREAST CANCER HISTORY

Variable	Reconstruction Patients		
	Total Mastectomy Patients (a)	Subtotal Mastectomy Patients (b)	Revision Patients (Reconstruction) (c)
	Patients n(%)	Patients n(%)	Patients n(%)
DIFFERENTIATION			
POOR (G3-G4)	33 (20.4)	0 (0.0)	10 (25.6)
MODERATE (G2)	35 (21.6)	1 (14.3)	5 (12.8)
WELL (G1)	14 (8.6)	0 (0.0)	3 (7.7)
CANNOT BE ASSESSED (GX)	62 (38.3)	4 (57.1)	17 (43.6)
MISSING	19 (11.7)	2 (28.6)	5 (12.8)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)
ESTROGEN RECEPTOR			
POSITIVE	92 (56.8)	2 (28.6)	18 (46.2)
NEGATIVE	41 (25.3)	3 (42.9)	11 (28.2)
MISSING	29 (17.9)	2 (28.6)	10 (25.6)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)

Program Name Q:\MENTOR\COREGEL\3YEAR\TABLES\T06.SAS

Creation Date, Time: 16JUL04 10:49

Note: Patients may fall in more than one category; therefore, percentages may add to more than 100 percent.

(c) Includes immediate and delayed reconstruction.

(b) Includes lumpectomy and quadrantectomy.

(c) Original reconstruction due to breast cancer surgery. Includes mixed revision and revision of unknown indication.

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

Table 6

BREAST CANCER HISTORY

Variable	Reconstruction Patients		
	Total Mastectomy Patients (a)	Subtotal Mastectomy Patients (b)	Revision Patients (Reconstruction) (c)
	Patients n(%)	Patients n(%)	Patients n(%)
PROGESTERONE RECEPTOR			
POSITIVE	75 (46.3)	2 (28.6)	14 (35.9)
NEGATIVE	53 (32.7)	3 (42.9)	14 (35.9)
MISSING	34 (21.0)	2 (28.6)	11 (28.2)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)
ADJUNCTIVE THERAPY			
RADIATION	34 (21.0)	1 (14.3)	10 (25.6)
CHEMOTHERAPY	95 (58.6)	5 (71.4)	19 (48.7)
HORMONAL THERAPY	68 (42.0)	2 (28.6)	13 (33.3)
OTHER BREAST CANCER-DIRECTED THERAPY	4 (2.5)	0 (0.0)	3 (7.7)
ANY ADJUNCTIVE THERAPY			
YES	118 (72.8)	5 (71.4)	27 (69.2)
NO	41 (25.3)	2 (28.6)	11 (28.2)
MISSING	3 (1.9)	0 (0.0)	1 (2.6)
TOTAL	162 (100.0)	7 (100.0)	39 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T06.SAS

Creation Date, Time: 16JUL04 10:49

Note: Patients may fall in more than one category; therefore, percentages may add to more than 100 percent.

(c) Includes immediate and delayed reconstruction.

(b) Includes lumpectomy and quadrantectomy.

(c) Original reconstruction due to breast cancer surgery. Includes mixed revision and revision of unknown indication.

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

Table 7

OPERATIVE REPORT SUMMARY: SURGERY

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)						
Indication								
Augmentation	1100 (100.0)	551 (100.0)	26 (6.3)	0 (0.0)	1 (0.3)	0 (0.0)	1127 (59.4)	551 (54.7)
Reconstruction	0 (0.0)	0 (0.0)	384 (93.7)	251 (100.0)	2 (0.5)	0 (0.0)	386 (20.4)	251 (24.9)
Revision	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	383 (99.2)	205 (100.0)	383 (20.2)	205 (20.4)
Total	1100 (100.0)	551 (100.0)	410 (100.0)	251 (100.0)	386 (100.0)	205 (100.0)	1896 (100.0)	1007 (100.0)
Breast Involved								
Left Only	0 (0.0)	0 (0.0)	43 (10.5)	43 (17.1)	13 (3.4)	13 (6.3)	56 (3.0)	56 (5.6)
Right Only	2 (0.2)	2 (0.4)	49 (12.0)	49 (19.5)	11 (2.8)	11 (5.4)	62 (3.3)	62 (6.2)
Bilateral	1098 (99.8)	549 (99.6)	318 (77.6)	159 (63.3)	362 (93.8)	181 (88.3)	1778 (93.8)	889 (88.3)
Total	1100 (100.0)	551 (100.0)	410 (100.0)	251 (100.0)	386 (100.0)	205 (100.0)	1896 (100.0)	1007 (100.0)
Surgical Approach								
Periareolar	250 (22.7)	126 (22.9)	85 (20.7)	47 (18.7)	68 (17.6)	36 (17.6)	403 (21.3)	209 (20.8)
Inframammary	652 (59.3)	327 (59.3)	79 (19.3)	54 (21.5)	236 (61.1)	123 (60.0)	967 (51.0)	504 (50.0)
Transaxillary	182 (16.5)	91 (16.5)	0 (0.0)	0 (0.0)	6 (1.6)	3 (1.5)	188 (9.9)	94 (9.3)
Mastectomy Scar	0 (0.0)	0 (0.0)	228 (55.6)	162 (64.5)	50 (13.0)	36 (17.6)	278 (14.7)	198 (19.7)
Other	16 (1.5)	9 (1.6)	18 (4.4)	11 (4.4)	26 (6.7)	14 (6.8)	60 (3.2)	34 (3.4)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	1100 (100.0)	551 (100.0)	410 (100.0)	251 (100.0)	386 (100.0)	205 (100.0)	1896 (100.0)	1007 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T07.SAS

Creation Date, Time: 16JUL04 10:49

- (a) Figures shown are number and percent of patients with at least one breast falling in category. Percentages may exceed 100%
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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 7

OPERATIVE REPORT SUMMARY: SURGERY

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)						
Placement								
Submuscular	456 (41.5)	229 (41.6)	251 (61.2)	162 (64.5)	207 (53.6)	114 (55.6)	914 (48.2)	505 (50.1)
Subglandular	372 (33.8)	186 (33.8)	42 (10.2)	23 (9.2)	123 (31.9)	63 (30.7)	537 (28.3)	272 (27.0)
Subpectoral	272 (24.7)	136 (24.7)	107 (26.1)	62 (24.7)	56 (14.5)	29 (14.1)	435 (22.9)	227 (22.5)
Other	0 (0.0)	0 (0.0)	9 (2.2)	8 (3.2)	0 (0.0)	0 (0.0)	9 (0.5)	8 (0.8)
Missing	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.1)	1 (0.1)
Total	1100 (100.0)	551 (100.0)	410 (100.0)	251 (100.0)	386 (100.0)	205 (100.0)	1896 (100.0)	1007 (100.0)
Size of Incision (cm)								
n	1100	551	403	246	379	201	1882	998
Mean	4.3	4.3	6.9	7.2	5.5	5.6	5.1	5.3
Median	4	4	6	7	5	5	4	5
SD	1.5	1.5	3.3	3.4	2.6	2.5	2.5	2.6
Minimum	2	2	2	2	2	2	2	2
Maximum	16	16	28	28	20	20	28	28
Implant Surface								
Smooth	767 (69.7)	384 (69.7)	171 (41.7)	105 (41.8)	257 (66.6)	135 (65.9)	1195 (63.0)	624 (62.0)
Textured	333 (30.3)	167 (30.3)	239 (58.3)	146 (58.2)	129 (33.4)	70 (34.1)	701 (37.0)	383 (38.0)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	1100 (100.0)	551 (100.0)	410 (100.0)	251 (100.0)	386 (100.0)	205 (100.0)	1896 (100.0)	1007 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T07.SAS

Creation Date, Time. 16JUL04 10:49

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

Table 7

OPERATIVE REPORT SUMMARY. SURGERY

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)						
Anesthesia Type (b,c)								
General		528 (95.8)		249 (99.2)		190 (92.7)		967 (96.0)
Local		59 (10.7)		0 (0.0)		15 (7.3)		74 (7.3)
Local with Sedation		23 (4.2)		2 (0.8)		15 (7.3)		40 (4.0)
Other		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Missing		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Total		551 (100.0)		251 (100.0)		205 (100.0)		1007 (100.0)
Other Surgical Procedures at Time of Implantation (b)								
Yes		448 (81.3)		108 (43.0)		88 (42.9)		644 (64.0)
No		103 (18.7)		143 (57.0)		117 (57.1)		363 (36.0)
Missing		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Total		551 (100.0)		251 (100.0)		205 (100.0)		1007 (100.0)
Pocket Irrigation (c)								
Saline Only	461 (41.9)	232 (42.1)	135 (32.9)	90 (35.9)	153 (39.6)	82 (40.0)	749 (39.5)	404 (40.1)
Steroid	67 (6.1)	34 (6.2)	55 (13.4)	29 (11.6)	24 (6.2)	13 (6.3)	146 (7.7)	76 (7.5)
Antibiotic	593 (53.9)	297 (53.9)	242 (59.0)	141 (56.2)	216 (56.0)	114 (55.6)	1051 (55.4)	552 (54.8)
Drug	114 (10.4)	57 (10.3)	62 (15.1)	33 (13.1)	36 (9.3)	19 (9.3)	212 (11.2)	109 (10.8)
Other	301 (27.4)	152 (27.6)	113 (27.6)	64 (25.5)	79 (20.5)	41 (20.0)	493 (26.0)	257 (25.5)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T07.SAS

Creation Date, Time: 16JUL04 10.49

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

Table 7

OPERATIVE REPORT SUMMARY. SURGERY

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)						
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	1100 (100.0)	551 (100.0)	410 (100.0)	251 (100.0)	386 (100.0)	205 (100.0)	1896 (100.0)	1007 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T07.SAS

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

Table 7

OPERATIVE REPORT SUMMARY: SURGERY

Variable	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
	No. of Breasts n(%)	No. of Patients (a) n(%)						
Post-Operative Recommendation (c)								
Antibiotic	922 (83.8)	462 (83.8)	343 (83.7)	209 (83.3)	336 (87.0)	178 (86.8)	1601 (84.4)	849 (84.3)
Restricted Activities	1053 (95.7)	528 (95.8)	390 (95.1)	240 (95.6)	384 (99.5)	204 (99.5)	1827 (96.4)	972 (96.5)
Massage	643 (58.5)	322 (58.4)	190 (46.3)	106 (42.2)	197 (51.0)	105 (51.2)	1030 (54.3)	533 (52.9)
Other	253 (23.0)	127 (23.0)	75 (18.3)	44 (17.5)	107 (27.7)	56 (27.3)	435 (22.9)	227 (22.5)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	1100 (100.0)	551 (100.0)	410 (100.0)	251 (100.0)	386 (100.0)	205 (100.0)	1896 (100.0)	1007 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T07.SAS

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=388) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
0-36 Months	Total with At Least One Complication N (%)	388 (100.0%)	261 (23.7%)	187 (33.9%)
	Explant with or without Replacement	45 (11.6%)	45 (4.1%)	26 (4.7%)
	Other Reoperations	101 (26.0%)	87 (7.9%)	67 (12.2%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	69 (17.8%)	56 (5.1%)	41 (7.4%)
	Baker III, IV Capsular Contracture	78 (20.1%)	61 (5.5%)	44 (8.0%)
	Baker IV Capsular Contracture	9 (2.3%)	9 (0.8%)	7 (1.3%)
	Breast Mass	14 (3.6%)	12 (1.1%)	12 (2.2%)
	Breast Pain	13 (3.4%)	13 (1.2%)	9 (1.6%)
	Breast Sensation Changes	17 (4.4%)	17 (1.5%)	12 (2.2%)
	External Injury Not Related To Breast Implants	7 (1.8%)	7 (0.6%)	6 (1.1%)
	Granuloma	1 (0.3%)	1 (0.1%)	1 (0.2%)
	Hematoma	15 (3.9%)	14 (1.3%)	14 (2.5%)
	Implant Malposition/Displacement	1 (0.3%)	1 (0.1%)	1 (0.2%)
	Infection	9 (2.3%)	8 (0.7%)	8 (1.5%)
	Inflammation	2 (0.5%)	2 (0.2%)	2 (0.4%)
	Lactation Difficulties	1 (0.3%)	1 (0.1%)	1 (0.2%)
	Lymphadenopathy	1 (0.3%)	1 (0.1%)	1 (0.2%)
	Miscarriage	7 (1.8%)		7 (1.3%)
	Necrosis	2 (0.5%)	2 (0.2%)	1 (0.2%)
	New Diagnosis of Rheumatic Disease	3 (0.8%)		3 (0.5%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

Implants/patients reporting more than one complication or reoperation under type of cosmetic complication, complication excluding cosmetic, or any reoperation are counted only once for that type. * Complications resulting from planned second stage surgery in reconstruction or revision patients.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=388) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
0-36 Months	Nipple Sensation Changes	94 (24.2%)	88 (8.0%)	57 (10.3%)
	Placement Damage	4 (1.0%)	4 (0.4%)	4 (0.7%)
	Rash	5 (1.3%)	4 (0.4%)	4 (0.7%)
	Rupture	1 (0.3%)	1 (0.1%)	1 (0.2%)
	Seroma	7 (1.8%)	6 (0.5%)	5 (0.9%)
	Suture Reaction	4 (1.0%)	4 (0.4%)	3 (0.5%)
	Other	20 (5.2%)	16 (1.5%)	15 (2.7%)
	Anaphylaxis	2 (0.5%)		1 (0.2%)
	Deep Vein Thrombosis	1 (0.3%)		1 (0.2%)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (0.3%)	1 (0.1%)	1 (0.2%)
	Ecchymosis	2 (0.5%)	2 (0.2%)	2 (0.4%)
	Excessive Implant Movements	2 (0.5%)	2 (0.2%)	1 (0.2%)
	Explanted Due To Right Side Being Removed	2 (0.5%)	2 (0.2%)	2 (0.4%)
	Implants Riding High	2 (0.5%)	2 (0.2%)	1 (0.2%)
	Inframammary Fold Too High	1 (0.3%)	1 (0.1%)	1 (0.2%)
	Mondor's Disease	3 (0.8%)	3 (0.3%)	2 (0.4%)
	Positive Antinuclear Antibodies Negative For Lupus	1 (0.3%)		1 (0.2%)
	Pt Requests Removal Due To Personal Reasons	2 (0.5%)	2 (0.2%)	1 (0.2%)
	Soft Mass Left Costal Margin	1 (0.3%)	1 (0.1%)	1 (0.2%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

Implants/patients reporting more than one complication or reoperation under type of cosmetic complication, complication excluding cosmetic, or any reoperation are counted only once for that type. * Complications resulting from planned second stage surgery in reconstruction or revision patients.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=388) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
0-36 Months	Any Complication Excluding Cosmetic	306 (78.9%)	207 (18.8%)	154 (27.9%)
	II. Cosmetic Complication			
	Asymmetry	4 (1.0%)	4 (0.4%)	3 (0.5%)
	Hypertrophic Scarring	52 (13.4%)	52 (4.7%)	34 (6.2%)
	Ptosis	19 (4.9%)	19 (1.7%)	11 (2.0%)
	Wrinkling	7 (1.8%)	6 (0.5%)	4 (0.7%)
	Any Cosmetic Complication	82 (21.1%)	79 (7.2%)	50 (9.1%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	45 (28.1%)	45 (39.1%)	26 (32.9%)
	Explant with Replacement with Study Device	24 (15.0%)	24 (20.9%)	15 (19.0%)
	Explant without Replacement	21 (13.1%)	21 (18.3%)	12 (15.2%)
	Other Additional Surgical Procedures	101 (63.1%)	87 (75.7%)	67 (84.8%)
	Biopsy	4 (2.5%)	4 (3.5%)	4 (5.1%)
	Capsulectomy	36 (22.5%)	31 (27.0%)	24 (30.4%)
	Capsulorrhaphy	4 (2.5%)	4 (3.5%)	3 (3.8%)
	Capsulotomy	17 (10.6%)	16 (13.9%)	12 (15.2%)
	Excise Breast Mass	2 (1.3%)	2 (1.7%)	2 (2.5%)
	Implant Pocket Revision	2 (1.3%)	2 (1.7%)	1 (1.3%)

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Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=388) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
0-36 Months	Implant Reposition	4 (2.5%)	4 (3.5%)	3 (3.8%)
	Incision and Drainage	12 (7.5%)	11 (9.6%)	11 (13.9%)
	Mastopexy	4 (2.5%)	4 (3.5%)	2 (2.5%)
	Nipple Related Procedure (unplanned)	1 (0.6%)	1 (0.9%)	1 (1.3%)
	Revision Of Wound Closure	3 (1.9%)	3 (2.6%)	3 (3.8%)
	Scar Revision	18 (11.3%)	18 (15.7%)	12 (15.2%)
	Skin Adjustment	8 (5.0%)	8 (7.0%)	5 (6.3%)
	Any Additional Surgical Procedures	160 (100.0%)	115 (100.0%)	79 (100.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

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Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=190) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
0-6 Months	Total with At Least One Complication N (%)	190 (100.0%)	149 (13.5%)	113 (20.5%)
	Explant with or without Replacement	11 (5.8%)	11 (1.0%)	7 (1.3%)
	Other Reoperations	33 (17.4%)	33 (3.0%)	28 (5.1%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	31 (16.3%)	29 (2.6%)	24 (4.4%)
	Baker III, IV Capsular Contracture	32 (16.8%)	30 (2.7%)	24 (4.4%)
	Baker IV Capsular Contracture	1 (0.5%)	1 (0.1%)	1 (0.2%)
	Breast Mass	1 (0.5%)	1 (0.1%)	1 (0.2%)
	Breast Pain	9 (4.7%)	9 (0.8%)	6 (1.1%)
	Breast Sensation Changes	11 (5.8%)	11 (1.0%)	8 (1.5%)
	External Injury Not Related To Breast Implants	3 (1.6%)	3 (0.3%)	2 (0.4%)
	Granuloma	1 (0.5%)	1 (0.1%)	1 (0.2%)
	Hematoma	12 (6.3%)	12 (1.1%)	12 (2.2%)
	Infection	9 (4.7%)	8 (0.7%)	8 (1.5%)
	Inflammation	2 (1.1%)	2 (0.2%)	2 (0.4%)
	Lymphadenopathy	1 (0.5%)	1 (0.1%)	1 (0.2%)
	Miscarriage	2 (1.1%)		2 (0.4%)
	Nipple Sensation Changes	47 (24.7%)	47 (4.3%)	31 (5.6%)
	Placement Damage	4 (2.1%)	4 (0.4%)	4 (0.7%)
	Rash	4 (2.1%)	3 (0.3%)	3 (0.5%)
	Seroma	6 (3.2%)	5 (0.5%)	4 (0.7%)

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=190) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
0-6 Months	Suture Reaction	4 (2.1%)	4 (0.4%)	3 (0.5%)
	Other	10 (5.3%)	10 (0.9%)	7 (1.3%)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (0.5%)	1 (0.1%)	1 (0.2%)
	Ecchymosis	2 (1.1%)	2 (0.2%)	2 (0.4%)
	Excessive Implant Movements	2 (1.1%)	2 (0.2%)	1 (0.2%)
	Implants Riding High	2 (1.1%)	2 (0.2%)	1 (0.2%)
	Mondor's Disease	3 (1.6%)	3 (0.3%)	2 (0.4%)
	Any Complication Excluding Cosmetic	158 (83.2%)	129 (11.7%)	99 (18.0%)
	II. Cosmetic Complication			
	Asymmetry	4 (2.1%)	4 (0.4%)	3 (0.5%)
	Hypertrophic Scarring	21 (11.1%)	21 (1.9%)	15 (2.7%)
	Ptosis	5 (2.6%)	5 (0.5%)	3 (0.5%)
	Wrinkling	2 (1.1%)	1 (0.1%)	1 (0.2%)
Any Cosmetic Complication	32 (16.8%)	30 (2.7%)	21 (3.8%)	
III. Additional Surgical Procedures				
Explant with or without Replacement	11 (23.9%)	11 (26.2%)	7 (21.2%)	
Explant with Replacement with Study Device	7 (15.2%)	7 (16.7%)	4 (12.1%)	

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AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=190) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
0-6 Months	Explant without Replacement	4 (8.7%)	4 (9.5%)	3 (9.1%)
	Other Additional Surgical Procedures	33 (71.7%)	33 (78.6%)	28 (84.8%)
	Biopsy	1 (2.2%)	1 (2.4%)	1 (3.0%)
	Capsulectomy	10 (21.7%)	10 (23.8%)	8 (24.2%)
	Capsulorrhaphy	3 (6.5%)	3 (7.1%)	2 (6.1%)
	Capsulotomy	3 (6.5%)	3 (7.1%)	3 (9.1%)
	Implant Reposition	2 (4.3%)	2 (4.8%)	2 (6.1%)
	Incision and Drainage	9 (19.6%)	9 (21.4%)	9 (27.3%)
	Revision Of Wound Closure	3 (6.5%)	3 (7.1%)	3 (9.1%)
	Scar Revision	1 (2.2%)	1 (2.4%)	1 (3.0%)
	Skin Adjustment	3 (6.5%)	3 (7.1%)	2 (6.1%)
	Any Additional Surgical Procedures	46 (100.0%)	42 (100.0%)	33 (100.0%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=72) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
6-12 Months	Total with At Least One Complication N (%)	72 (100.0%)	61 (5.5%)	46 (8.3%)
	Explant with or without Replacement	11 (15.3%)	11 (1.0%)	6 (1.1%)
	Other Reoperations	21 (29.2%)	20 (1.8%)	16 (2.9%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	15 (20.8%)	15 (1.4%)	11 (2.0%)
	Baker III, IV Capsular Contracture	18 (25.0%)	18 (1.6%)	13 (2.4%)
	Baker IV Capsular Contracture	3 (4.2%)	3 (0.3%)	2 (0.4%)
	Breast Mass	2 (2.8%)	2 (0.2%)	2 (0.4%)
	Breast Sensation Changes	4 (5.6%)	4 (0.4%)	3 (0.5%)
	External Injury Not Related To Breast Implants	2 (2.8%)	2 (0.2%)	2 (0.4%)
	Hematoma	2 (2.8%)	1 (0.1%)	1 (0.2%)
	Implant Malposition/Displacement	1 (1.4%)	1 (0.1%)	1 (0.2%)
	Miscarriage	3 (4.2%)		3 (0.5%)
	Nipple Sensation Changes	22 (30.6%)	22 (2.0%)	15 (2.7%)
	Other	2 (2.8%)	2 (0.2%)	1 (0.2%)
	Pt Requests Removal Due To Personal Reasons	2 (2.8%)	2 (0.2%)	1 (0.2%)
	Any Complication Excluding Cosmetic	56 (77.8%)	45 (4.1%)	35 (6.4%)
	II. Cosmetic Complication			
	Hypertrophic Scarring	14 (19.4%)	14 (1.3%)	10 (1.8%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=72) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
6-12 Months	Wrinkling	2 (2.8%)	2 (0.2%)	1 (0.2%)
	Any Cosmetic Complication	16 (22.2%)	16 (1.5%)	11 (2.0%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	11 (33.3%)	11 (36.7%)	6 (28.6%)
	Explant with Replacement with Study Device	7 (21.2%)	7 (23.3%)	4 (19.0%)
	Explant without Replacement	4 (12.1%)	4 (13.3%)	2 (9.5%)
	Other Additional Surgical Procedures	21 (63.6%)	20 (66.7%)	16 (76.2%)
	Biopsy	1 (3.0%)	1 (3.3%)	1 (4.8%)
	Capsulectomy	8 (24.2%)	8 (26.7%)	7 (33.3%)
	Capsulorrhaphy	1 (3.0%)	1 (3.3%)	1 (4.8%)
	Capsulotomy	5 (15.2%)	5 (16.7%)	3 (14.3%)
	Incision and Drainage	2 (6.1%)	1 (3.3%)	1 (4.8%)
	Nipple Related Procedure (unplanned)	1 (3.0%)	1 (3.3%)	1 (4.8%)
	Scar Revision	4 (12.1%)	4 (13.3%)	3 (14.3%)
	Any Additional Surgical Procedures	33 (100.0%)	30 (100.0%)	21 (100.0%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=87) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
12-24 Months	Total with At Least One Complication N (%)	87 (100.0%)	75 (6.8%)	58 (10.5%)
	Explant with or without Replacement	12 (13.8%)	12 (1.1%)	8 (1.5%)
	Other Reoperations	30 (34.5%)	27 (2.5%)	19 (3.4%)
	I Complication Excluding Cosmetic			
	Baker III Capsular Contracture	17 (19.5%)	17 (1.5%)	13 (2.4%)
	Baker III, IV Capsular Contracture	20 (23.0%)	19 (1.7%)	15 (2.7%)
	Baker IV Capsular Contracture	3 (3.4%)	3 (0.3%)	3 (0.5%)
	Breast Mass	8 (9.2%)	8 (0.7%)	8 (1.5%)
	Breast Pain	4 (4.6%)	4 (0.4%)	3 (0.5%)
	Breast Sensation Changes	2 (2.3%)	2 (0.2%)	2 (0.4%)
	Hematoma	1 (1.1%)	1 (0.1%)	1 (0.2%)
	Miscarriage	1 (1.1%)		1 (0.2%)
	New Diagnosis of Rheumatic Disease	3 (3.4%)		3 (0.5%)
	Nipple Sensation Changes	10 (11.5%)	10 (0.9%)	8 (1.5%)
	Rash	1 (1.1%)	1 (0.1%)	1 (0.2%)
	Seroma	1 (1.1%)	1 (0.1%)	1 (0.2%)
	Other	4 (4.6%)	2 (0.2%)	3 (0.5%)
	Anaphylaxis	2 (2.3%)		1 (0.2%)
	Inframammary Fold Too High	1 (1.1%)	1 (0.1%)	1 (0.2%)
	Soft Mass Left Costal Margin	1 (1.1%)	1 (0.1%)	1 (0.2%)

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=87) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
12-24 Months	Any Complication Excluding Cosmetic	55 (63.2%)	45 (4.1%)	42 (7.6%)
	II. Cosmetic Complication			
	Hypertrophic Scarring	17 (19.5%)	17 (1.5%)	10 (1.8%)
	Ptosis	12 (13.8%)	12 (1.1%)	7 (1.3%)
	Wrinkling	3 (3.4%)	3 (0.3%)	2 (0.4%)
	Any Cosmetic Complication	32 (36.8%)	32 (2.9%)	19 (3.4%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	12 (22.6%)	12 (34.3%)	8 (34.8%)
	Explant with Replacement with Study Device	6 (11.3%)	6 (17.1%)	5 (21.7%)
	Explant without Replacement	6 (11.3%)	6 (17.1%)	3 (13.0%)
	Other Additional Surgical Procedures	30 (56.6%)	27 (77.1%)	19 (82.6%)
	Biopsy	2 (3.8%)	2 (5.7%)	2 (8.7%)
	Capsulectomy	13 (24.5%)	11 (31.4%)	8 (34.8%)
	Capsulotomy	6 (11.3%)	6 (17.1%)	4 (17.4%)
	Excise Breast Mass	1 (1.9%)	1 (2.9%)	1 (4.3%)
	Implant Pocket Revision	2 (3.8%)	2 (5.7%)	1 (4.3%)
	Implant Reposition	2 (3.8%)	2 (5.7%)	1 (4.3%)
	Incision and Drainage	1 (1.9%)	1 (2.9%)	1 (4.3%)

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=87) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
12-24 Months	Mastopexy	2 (3.8%)	2 (5.7%)	1 (4.3%)
	Scar Revision	10 (18.9%)	10 (28.6%)	6 (26.1%)
	Skin Adjustment	2 (3.8%)	2 (5.7%)	1 (4.3%)
	Any Additional Surgical Procedures	53 (100.0%)	35 (100.0%)	23 (100.0%)

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=39) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
24-36 Months	Total with At Least One Complication N (%)	39 (100.0%)	32 (2.9%)	25 (4.5%)
	Explant with or without Replacement	11 (28.2%)	11 (1.0%)	6 (1.1%)
	Other Reoperations	17 (43.6%)	15 (1.4%)	12 (2.2%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	6 (15.4%)	5 (0.5%)	4 (0.7%)
	Baker III, IV Capsular Contracture	8 (20.5%)	7 (0.6%)	5 (0.9%)
	Baker IV Capsular Contracture	2 (5.1%)	2 (0.2%)	1 (0.2%)
	Breast Mass	3 (7.7%)	3 (0.3%)	3 (0.5%)
	External Injury Not Related To Breast Implants	2 (5.1%)	2 (0.2%)	2 (0.4%)
	Lactation Difficulties	1 (2.6%)	1 (0.1%)	1 (0.2%)
	Miscarriage	1 (2.6%)		1 (0.2%)
	Necrosis	2 (5.1%)	2 (0.2%)	1 (0.2%)
	Nipple Sensation Changes	15 (38.5%)	12 (1.1%)	7 (1.3%)
	Rupture	1 (2.6%)	1 (0.1%)	1 (0.2%)
	Other	4 (10.3%)	2 (0.2%)	4 (0.7%)
	Deep Vein Thrombosis	1 (2.6%)		1 (0.2%)
	Explanted Due To Right Side Being Removed	2 (5.1%)	2 (0.2%)	2 (0.4%)
	Positive Antinuclear Antibodies Negative For Lupus	1 (2.6%)		1 (0.2%)
	Any Complication Excluding Cosmetic	37 (94.9%)	30 (2.7%)	24 (4.4%)

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Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Events (N=39) n (%)	Implants (N=1100) n (%) (a)	Patients (N=551) n (%) (a)
24-36 Months	II. Cosmetic Complication			
	Ptosis	2 (5.1%)	2 (0.2%)	1 (0.2%)
	Any Cosmetic Complication	2 (5.1%)	2 (0.2%)	1 (0.2%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	11 (39.3%)	11 (55.0%)	6 (42.9%)
	Explant with Replacement with Study Device	4 (14.3%)	4 (20.0%)	2 (14.3%)
	Explant without Replacement	7 (25.0%)	7 (35.0%)	4 (28.6%)
	Other Additional Surgical Procedures	17 (60.7%)	15 (75.0%)	12 (85.7%)
	Capsulectomy	5 (17.9%)	5 (25.0%)	4 (28.6%)
	Capsulotomy	3 (10.7%)	3 (15.0%)	3 (21.4%)
	Excise Breast Mass	1 (3.6%)	1 (5.0%)	1 (7.1%)
	Mastopexy	2 (7.1%)	2 (10.0%)	1 (7.1%)
	Scar Revision	3 (10.7%)	3 (15.0%)	2 (14.3%)
	Skin Adjustment	3 (10.7%)	3 (15.0%)	2 (14.3%)
Any Additional Surgical Procedures	28 (100.0%)	20 (100.0%)	14 (100.0%)	

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Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=185) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
0-36 Months	Total with At Least One Complication N (%)	185 (100.0%)	121 (29.5%)	102 (40.6%)
	Explant with or without Replacement	40 (21.6%)	40 (9.8%)	31 (12.4%)
	Other Reoperations	74 (40.0%)	66 (16.1%)	53 (21.1%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	22 (11.9%)	18 (4.4%)	17 (6.8%)
	Baker III, IV Capsular Contracture	24 (13.0%)	20 (4.9%)	19 (7.6%)
	Baker IV Capsular Contracture	2 (1.1%)	2 (0.5%)	2 (0.8%)
	Breast Mass	8 (4.3%)	8 (2.0%)	8 (3.2%)
	Breast Pain	5 (2.7%)	5 (1.2%)	4 (1.6%)
	Breast Sensation Changes	3 (1.6%)	3 (0.7%)	2 (0.8%)
	Delayed Wound Healing	3 (1.6%)	2 (0.5%)	1 (0.4%)
	External Injury Not Related To Breast Implants	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Extrusion	3 (1.6%)	3 (0.7%)	3 (1.2%)
	Hematoma	3 (1.6%)	3 (0.7%)	3 (1.2%)
	Implant Malposition/Displacement	5 (2.7%)	5 (1.2%)	4 (1.6%)
	Infection	14 (7.6%)	13 (3.2%)	13 (5.2%)
	Lymphadenopathy	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Metastatic Disease	6 (3.2%)	2 (0.5%)	4 (1.6%)
	Miscarriage	2 (1.1%)		2 (0.8%)
	Necrosis	2 (1.1%)	2 (0.5%)	2 (0.8%)
	New Diagnosis of Rheumatic Disease	1 (0.5%)		1 (0.4%)

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Note 1. Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2. Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=185) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
0-36 Months	Nipple Sensation Changes	6 (3.2%)	6 (1.5%)	5 (2.0%)
	Rash	3 (1.6%)	2 (0.5%)	1 (0.4%)
	Recurrent Breast Cancer	5 (2.7%)	4 (1.0%)	4 (1.6%)
	Rupture	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Seroma	15 (8.1%)	12 (2.9%)	12 (4.8%)
	Other	20 (10.8%)	18 (4.4%)	17 (6.8%)
	Capsular Contracture Secondary To Radiation Therapy	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Cellulitis	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Deep Vein Thrombosis	1 (0.5%)		1 (0.4%)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Dog Ear Scars From Mastectomy	2 (1.1%)	2 (0.5%)	1 (0.4%)
	Extra Skin	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Lack Of Projection	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Loss Of Inframammary Fold	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Muscle Spasm	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Nipple Complications	3 (1.6%)	3 (0.7%)	2 (0.8%)
	Occasional Burning Discomfort Of Skin.	2 (1.1%)	2 (0.5%)	1 (0.4%)
	Pain - Sternum And Under Left Arm Intermittent	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Skin Lesion	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Stitch Abscess	1 (0.5%)	1 (0.2%)	1 (0.4%)

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=185) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
0-36 Months	Tight Benilli Suture	1 (0.5%)	1 (0.2%)	1 (0.4%)
	Wide Scars	1 (0.5%)		1 (0.4%)
	Any Complication Excluding Cosmetic	131 (70.8%)	87 (21.2%)	81 (32.3%)
	II. Cosmetic Complication			
	Asymmetry	16 (8.6%)	16 (3.9%)	14 (5.6%)
	Hypertrophic Scarring	17 (9.2%)	16 (3.9%)	14 (5.6%)
	Ptosis	14 (7.6%)	14 (3.4%)	9 (3.6%)
	Wrinkling	7 (3.8%)	7 (1.7%)	6 (2.4%)
	Any Cosmetic Complication	54 (29.2%)	45 (11.0%)	35 (13.9%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	40 (28.8%)	40 (48.8%)	31 (48.4%)
	Explant with Replacement with Study Device	23 (16.5%)	23 (28.0%)	18 (28.1%)
	Explant without Replacement	17 (12.2%)	17 (20.7%)	13 (20.3%)
	Other Additional Surgical Procedures	74 (53.2%)	66 (80.5%)	53 (82.8%)
Biopsy	10 (7.2%)	9 (11.0%)	8 (12.5%)	
Breast Mass Excision Dx: Fibroadenoma	1 (0.7%)	1 (1.2%)	1 (1.6%)	
Capsulectomy	10 (7.2%)	10 (12.2%)	9 (14.1%)	

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RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=185) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
0-36 Months	Capsulorrhaphy	2 (1.4%)	2 (2.4%)	2 (3.1%)
	Capsulotomy	14 (10.1%)	14 (17.1%)	13 (20.3%)
	Create Inframmary Fold	2 (1.4%)	1 (1.2%)	1 (1.6%)
	Flap Coverage Of Expander	1 (0.7%)	1 (1.2%)	1 (1.6%)
	Implant Pocket Revision	6 (4.3%)	6 (7.3%)	4 (6.3%)
	Implant Reposition	17 (12.2%)	15 (18.3%)	12 (18.8%)
	Incision and Drainage	4 (2.9%)	4 (4.9%)	4 (6.3%)
	Mastopexy	4 (2.9%)	3 (3.7%)	2 (3.1%)
	Nipple Related Procedure (unplanned)	2 (1.4%)	2 (2.4%)	2 (3.1%)
	Removal Of Nodule On Chest Wall	2 (1.4%)	2 (2.4%)	1 (1.6%)
	Revision Of Breast / External To Pocket	2 (1.4%)	2 (2.4%)	1 (1.6%)
	Revision Of Wound Closure	1 (0.7%)	1 (1.2%)	1 (1.6%)
	Scar Revision	7 (5.0%)	7 (8.5%)	5 (7.8%)
	Skin Adjustment	14 (10.1%)	14 (17.1%)	10 (15.6%)
	Any Additional Surgical Procedures	139 (100.0%)	82 (100.0%)	64 (100.0%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=92) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
0-6 Months	Total with At Least One Complication N (%)	92 (100.0%)	66 (16.1%)	56 (22.3%)
	Explant with or without Replacement	10 (10.9%)	10 (2.4%)	7 (2.8%)
	Other Reoperations	26 (28.3%)	26 (6.3%)	21 (8.4%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	8 (8.7%)	8 (2.0%)	8 (3.2%)
	Baker III, IV Capsular Contracture	9 (9.8%)	9 (2.2%)	9 (3.6%)
	Baker IV Capsular Contracture	1 (1.1%)	1 (0.2%)	1 (0.4%)
	Breast Mass	1 (1.1%)	1 (0.2%)	1 (0.4%)
	Breast Pain	3 (3.3%)	3 (0.7%)	2 (0.8%)
	Delayed Wound Healing	3 (3.3%)	2 (0.5%)	1 (0.4%)
	External Injury Not Related To Breast Implants	1 (1.1%)	1 (0.2%)	1 (0.4%)
	Extrusion	2 (2.2%)	2 (0.5%)	2 (0.8%)
	Hematoma	2 (2.2%)	2 (0.5%)	2 (0.8%)
	Implant Malposition/Displacement	2 (2.2%)	2 (0.5%)	2 (0.8%)
	Infection	10 (10.9%)	9 (2.2%)	9 (3.6%)
	Metastatic Disease	1 (1.1%)		1 (0.4%)
	Necrosis	1 (1.1%)	1 (0.2%)	1 (0.4%)
	Nipple Sensation Changes	3 (3.3%)	3 (0.7%)	2 (0.8%)
	Rash	3 (3.3%)	2 (0.5%)	1 (0.4%)
	Recurrent Breast Cancer	2 (2.2%)	2 (0.5%)	1 (0.4%)
	Seroma	14 (15.2%)	11 (2.7%)	11 (4.4%)

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RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=92) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)	
0-6 Months	Other	12 (13.0%)	10 (2.4%)	11 (4.4%)	
	Capsular Contracture Secondary To Radiation Therapy	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Cellulitis	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Deep Vein Thrombosis	1 (1.1%)		1 (0.4%)	
	Dog Ear Scars From Mastectomy	2 (2.2%)	2 (0.5%)	1 (0.4%)	
	Extra Skin	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Loss Of Inframammary Fold	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Muscle Spasm	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Nipple Complications	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Pain - Sternum And Under Left Arm Intermittent	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Skin Lesion	1 (1.1%)	1 (0.2%)	1 (0.4%)	
	Wide Scars	1 (1.1%)		1 (0.4%)	
		Any Complication Excluding Cosmetic	69 (75.0%)	48 (11.7%)	43 (17.1%)
		II. Cosmetic Complication			
		Asymmetry	7 (7.6%)	7 (1.7%)	7 (2.8%)
	Hypertrophic Scarring	9 (9.8%)	9 (2.2%)	8 (3.2%)	
	Ptosis	2 (2.2%)	2 (0.5%)	1 (0.4%)	
	Wrinkling	5 (5.4%)	5 (1.2%)	4 (1.6%)	

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RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=92) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
0-6 Months	Any Cosmetic Complication	23 (25.0%)	21 (5.1%)	18 (7.2%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	10 (20.8%)	10 (31.3%)	7 (28.0%)
	Explant with Replacement with Study Device	7 (14.6%)	7 (21.9%)	4 (16.0%)
	Explant without Replacement	3 (6.3%)	3 (9.4%)	3 (12.0%)
	Other Additional Surgical Procedures	26 (54.2%)	26 (81.3%)	21 (84.0%)
	Biopsy	5 (10.4%)	5 (15.6%)	4 (16.0%)
	Capsulectomy	3 (6.3%)	3 (9.4%)	3 (12.0%)
	Capsulorrhaphy	2 (4.2%)	2 (6.3%)	2 (8.0%)
	Capsulotomy	6 (12.5%)	6 (18.8%)	5 (20.0%)
	Create Inframmary Fold	1 (2.1%)	1 (3.1%)	1 (4.0%)
	Implant Reposition	6 (12.5%)	6 (18.8%)	4 (16.0%)
	Incision and Drainage	3 (6.3%)	3 (9.4%)	3 (12.0%)
	Mastopexy	1 (2.1%)	1 (3.1%)	1 (4.0%)
	Nipple Related Procedure (unplanned)	1 (2.1%)	1 (3.1%)	1 (4.0%)
	Removal Of Nodule On Chest Wall	2 (4.2%)	2 (6.3%)	1 (4.0%)
	Scar Revision	2 (4.2%)	2 (6.3%)	1 (4.0%)
	Skin Adjustment	6 (12.5%)	6 (18.8%)	4 (16.0%)
	Any Additional Surgical Procedures	48 (100.0%)	32 (100.0%)	25 (100.0%)

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=36) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
6-12 Months	Total with At Least One Complication N (%)	36 (100.0%)	30 (7.3%)	29 (11.6%)
	Explant with or without Replacement	16 (44.4%)	16 (3.9%)	13 (5.2%)
	Other Reoperations	25 (69.4%)	25 (6.1%)	22 (8.8%)
I. Complication Excluding Cosmetic				
	Baker III Capsular Contracture	7 (19.4%)	7 (1.7%)	6 (2.4%)
	Baker III, IV Capsular Contracture	8 (22.2%)	8 (2.0%)	7 (2.8%)
	Baker IV Capsular Contracture	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Breast Mass	3 (8.3%)	3 (0.7%)	3 (1.2%)
	Breast Pain	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Breast Sensation Changes	2 (5.6%)	2 (0.5%)	1 (0.4%)
	Extrusion	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Implant Malposition/Displacement	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Infection	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Miscarriage	2 (5.6%)		2 (0.8%)
	New Diagnosis of Rheumatic Disease	1 (2.8%)		1 (0.4%)
	Nipple Sensation Changes	2 (5.6%)	2 (0.5%)	2 (0.8%)
	Recurrent Breast Cancer	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Other	2 (5.6%)	2 (0.5%)	2 (0.8%)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Tight Benilli Suture	1 (2.8%)	1 (0.2%)	1 (0.4%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

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Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=36) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
6-12 Months	Any Complication Excluding Cosmetic	25 (69.4%)	22 (5.4%)	22 (8.8%)
	II. Cosmetic Complication			
	Asymmetry	3 (8.3%)	3 (0.7%)	3 (1.2%)
	Hypertrophic Scarring	5 (13.9%)	4 (1.0%)	4 (1.6%)
	Ptosis	2 (5.6%)	2 (0.5%)	1 (0.4%)
	Wrinkling	1 (2.8%)	1 (0.2%)	1 (0.4%)
	Any Cosmetic Complication	11 (30.6%)	9 (2.2%)	8 (3.2%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	16 (31.4%)	16 (48.5%)	13 (48.1%)
	Explant with Replacement with Study Device	10 (19.6%)	10 (30.3%)	9 (33.3%)
	Explant without Replacement	6 (11.8%)	6 (18.2%)	4 (14.8%)
	Other Additional Surgical Procedures	25 (49.0%)	25 (75.8%)	22 (81.5%)
	Biopsy	3 (5.9%)	3 (9.1%)	3 (11.1%)
	Capsulectomy	4 (7.8%)	4 (12.1%)	3 (11.1%)
	Capsulotomy	7 (13.7%)	7 (21.2%)	7 (25.9%)
	Create Inframmary Fold	1 (2.0%)	1 (3.0%)	1 (3.7%)
	Implant Pocket Revision	4 (7.8%)	4 (12.1%)	3 (11.1%)
	Implant Reposition	6 (11.8%)	6 (18.2%)	6 (22.2%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=36) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
6-12 Months	Nipple Related Procedure (unplanned)	1 (2.0%)	1 (3.0%)	1 (3.7%)
	Revision Of Wound Closure	1 (2.0%)	1 (3.0%)	1 (3.7%)
	Scar Revision	2 (3.9%)	2 (6.1%)	2 (7.4%)
	Skin Adjustment	6 (11.8%)	6 (18.2%)	5 (18.5%)
	Any Additional Surgical Procedures	51 (100.0%)	33 (100.0%)	27 (100.0%)

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=33) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
12-24 Months	Total with At Least One Complication N (%)	33 (100.0%)	25 (6.1%)	26 (10.4%)
	Explant with or without Replacement	10 (30.3%)	10 (2.4%)	9 (3.6%)
	Other Reoperations	20 (60.6%)	18 (4.4%)	13 (5.2%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	5 (15.2%)	4 (1.0%)	4 (1.6%)
	Baker III, IV Capsular Contracture	5 (15.2%)	4 (1.0%)	4 (1.6%)
	Breast Mass	3 (9.1%)	3 (0.7%)	3 (1.2%)
	Breast Pain	1 (3.0%)	1 (0.2%)	1 (0.4%)
	Breast Sensation Changes	1 (3.0%)	1 (0.2%)	1 (0.4%)
	Hematoma	1 (3.0%)	1 (0.2%)	1 (0.4%)
	Implant Malposition/Displacement	2 (6.1%)	2 (0.5%)	1 (0.4%)
	Infection	3 (9.1%)	3 (0.7%)	3 (1.2%)
	Metastatic Disease	3 (9.1%)		3 (1.2%)
	Recurrent Breast Cancer	2 (6.1%)	1 (0.2%)	2 (0.8%)
	Rupture	1 (3.0%)	1 (0.2%)	1 (0.4%)
	Seroma	1 (3.0%)	1 (0.2%)	1 (0.4%)
	Other	3 (9.1%)	3 (0.7%)	2 (0.8%)
	Lack Of Projection	1 (3.0%)	1 (0.2%)	1 (0.4%)
	Nipple Complications	2 (6.1%)	2 (0.5%)	1 (0.4%)
	Any Complication Excluding Cosmetic	26 (78.8%)	20 (4.9%)	22 (8.8%)

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=33) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
12-24 Months	II. Cosmetic Complication			
	Asymmetry	2 (6.1%)	2 (0.5%)	1 (0.4%)
	Hypertrophic Scarring	1 (3.0%)	1 (0.2%)	1 (0.4%)
	Ptosis	4 (12.1%)	4 (1.0%)	3 (1.2%)
	Any Cosmetic Complication	7 (21.2%)	7 (1.7%)	5 (2.0%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	10 (30.3%)	10 (45.5%)	9 (52.9%)
	Explant with Replacement with Study Device	6 (18.2%)	6 (27.3%)	5 (29.4%)
	Explant without Replacement	4 (12.1%)	4 (18.2%)	4 (23.5%)
	Other Additional Surgical Procedures	20 (60.6%)	18 (81.8%)	13 (76.5%)
	Biopsy	2 (6.1%)	2 (9.1%)	2 (11.8%)
	Capsulectomy	3 (9.1%)	3 (13.6%)	3 (17.6%)
	Capsulotomy	1 (3.0%)	1 (4.5%)	1 (5.9%)
	Flap Coverage Of Expander	1 (3.0%)	1 (4.5%)	1 (5.9%)
	Implant Pocket Revision	2 (6.1%)	2 (9.1%)	1 (5.9%)
	Implant Reposition	5 (15.2%)	5 (22.7%)	3 (17.6%)
	Mastopexy	2 (6.1%)	2 (9.1%)	1 (5.9%)
	Revision Of Breast / External To Pocket	2 (6.1%)	2 (9.1%)	1 (5.9%)
	Scar Revision	3 (9.1%)	3 (13.6%)	2 (11.8%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=33) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
12-24 Months	Skin Adjustment	2 (6.1%)	2 (9.1%)	1 (5.9%)
	Any Additional Surgical Procedures	33 (100.0%)	22 (100.0%)	17 (100.0%)

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=24) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
24-36 Months	Total with At Least One Complication N (%)	24 (100.0%)	23 (5.6%)	17 (6.8%)
	Explant with or without Replacement	4 (16.7%)	4 (1.0%)	2 (0.8%)
	Other Reoperations	3 (12.5%)	3 (0.7%)	3 (1.2%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	2 (8.3%)	2 (0.5%)	2 (0.8%)
	Baker III, IV Capsular Contracture	2 (8.3%)	2 (0.5%)	2 (0.8%)
	Breast Mass	1 (4.2%)	1 (0.2%)	1 (0.4%)
	Lymphadenopathy	1 (4.2%)	1 (0.2%)	1 (0.4%)
	Metastatic Disease	2 (8.3%)	2 (0.5%)	1 (0.4%)
	Necrosis	1 (4.2%)	1 (0.2%)	1 (0.4%)
	Nipple Sensation Changes	1 (4.2%)	1 (0.2%)	1 (0.4%)
	Other	3 (12.5%)	3 (0.7%)	2 (0.8%)
	Occasional Burning Discomfort Of Skin.	2 (8.3%)	2 (0.5%)	1 (0.4%)
	Stitch Abscess	1 (4.2%)	1 (0.2%)	1 (0.4%)
	Any Complication Excluding Cosmetic	11 (45.8%)	11 (2.7%)	9 (3.6%)
	II. Cosmetic Complication			
	Asymmetry	4 (16.7%)	4 (1.0%)	3 (1.2%)
	Hypertrophic Scarring	2 (8.3%)	2 (0.5%)	1 (0.4%)
	Ptosis	6 (25.0%)	6 (1.5%)	4 (1.6%)

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RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Events (N=24) n (%)	Implants (N=410) n (%) (a)	Patients (N=251) n (%) (a)
24-36 Months	Wrinkling	1 (4.2%)	1 (0.2%)	1 (0.4%)
	Any Cosmetic Complication	13 (54.2%)	13 (3.2%)	9 (3.6%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	4 (57.1%)	4 (57.1%)	2 (40.0%)
	Explant without Replacement	4 (57.1%)	4 (57.1%)	2 (40.0%)
	Other Additional Surgical Procedures	3 (42.9%)	3 (42.9%)	3 (60.0%)
	Breast Mass Excision Dx: Fibroadenoma	1 (14.3%)	1 (14.3%)	1 (20.0%)
	Incision and Drainage	1 (14.3%)	1 (14.3%)	1 (20.0%)
	Mastopexy	1 (14.3%)	1 (14.3%)	1 (20.0%)
	Any Additional Surgical Procedures	7 (100.0%)	7 (100.0%)	5 (100.0%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=216) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
0-36 Months	Total with At Least One Complication N (%)	216 (100.0%)	124 (32.1%)	87 (42.4%)
	Explant with or without Replacement	39 (18.1%)	39 (10.1%)	25 (12.2%)
	Other Reoperations	77 (35.6%)	59 (15.3%)	41 (20.0%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	47 (21.8%)	41 (10.6%)	32 (15.6%)
	Baker III, IV Capsular Contracture	62 (28.7%)	46 (11.9%)	34 (16.6%)
	Baker IV Capsular Contracture	15 (6.9%)	13 (3.4%)	10 (4.9%)
	Breast Mass	12 (5.6%)	11 (2.8%)	11 (5.4%)
	Breast Pain	6 (2.8%)	5 (1.3%)	4 (2.0%)
	Breast Sensation Changes	5 (2.3%)	5 (1.3%)	4 (2.0%)
	Delayed Wound Healing	5 (2.3%)	5 (1.3%)	4 (2.0%)
	External Injury Not Related To Breast Implants	2 (0.9%)	2 (0.5%)	2 (1.0%)
	Extrusion	3 (1.4%)	3 (0.8%)	3 (1.5%)
	Granuloma	2 (0.9%)	2 (0.5%)	2 (1.0%)
	Hematoma	7 (3.2%)	7 (1.8%)	6 (2.9%)
	Implant Malposition/Displacement	7 (3.2%)	7 (1.8%)	5 (2.4%)
	Infection	2 (0.9%)	2 (0.5%)	2 (1.0%)
	Inflammation	3 (1.4%)	2 (0.5%)	3 (1.5%)
	Lactation Difficulties	2 (0.9%)	2 (0.5%)	1 (0.5%)
	New Diagnosis of Breast Cancer	1 (0.5%)	1 (0.3%)	1 (0.5%)
	New Diagnosis of Rheumatic Disease	2 (0.9%)		2 (1.0%)

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=216) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
0-36 Months	Nipple Sensation Changes	27 (12.5%)	25 (6.5%)	17 (8.3%)
	Recurrent Breast Cancer	1 (0.5%)	1 (0.3%)	1 (0.5%)
	Rupture	6 (2.8%)	6 (1.6%)	4 (2.0%)
	Seroma	4 (1.9%)	4 (1.0%)	4 (2.0%)
	Other	16 (7.4%)	11 (2.8%)	12 (5.9%)
	Abnormal Mammogram	1 (0.5%)	1 (0.3%)	1 (0.5%)
	Back And Neck Pain Related To Large Implants	1 (0.5%)		1 (0.5%)
	Capsule Tear	1 (0.5%)	1 (0.3%)	1 (0.5%)
	False Positive For Rupture On Mammogram	1 (0.5%)	1 (0.3%)	1 (0.5%)
	Muscle Spasm	2 (0.9%)	2 (0.5%)	1 (0.5%)
	Nipple Related Unplanned	1 (0.5%)	1 (0.3%)	1 (0.5%)
	Numbness In Both Hands At Night	1 (0.5%)		1 (0.5%)
	Siliconoma	1 (0.5%)	1 (0.3%)	1 (0.5%)
	Skin Lesion	1 (0.5%)	1 (0.3%)	1 (0.5%)
	Surgical Removal Of Ectopic Pregnancy	1 (0.5%)		1 (0.5%)
	Symmastia	3 (1.4%)	3 (0.8%)	2 (1.0%)
	Symmastia And Implant Malposition	2 (0.9%)	1 (0.3%)	1 (0.5%)
	Any Complication Excluding Cosmetic	175 (81.0%)	103 (26.7%)	77 (37.6%)
II. Cosmetic Complication				
	Asymmetry	5 (2.3%)	5 (1.3%)	5 (2.4%)

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Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

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Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=216) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
0-36 Months	Hypertrophic Scarring	21 (9.7%)	19 (4.9%)	12 (5.9%)
	Ptosis	9 (4.2%)	7 (1.8%)	4 (2.0%)
	Wrinkling	6 (2.8%)	6 (1.6%)	4 (2.0%)
	Any Cosmetic Complication	41 (19.0%)	35 (9.1%)	23 (11.2%)
III. Additional Surgical Procedures				
	Explant with or without Replacement	39 (27.7%)	39 (50.0%)	25 (49.0%)
	Explant with Replacement with Study Device	21 (14.9%)	21 (26.9%)	14 (27.5%)
	Explant without Replacement	18 (12.8%)	18 (23.1%)	11 (21.6%)
	Other Additional Surgical Procedures	77 (54.6%)	59 (75.6%)	41 (80.4%)
	Biopsy	10 (7.1%)	7 (9.0%)	7 (13.7%)
	Capsulectomy	18 (12.8%)	17 (21.8%)	12 (23.5%)
	Capsulorrhaphy	6 (4.3%)	4 (5.1%)	2 (3.9%)
	Capsulotomy	17 (12.1%)	14 (17.9%)	11 (21.6%)
	Excision Of Skin Lesion	2 (1.4%)	2 (2.6%)	1 (2.0%)
	Exploration Right Breast With Evacuation Of Hematoma	1 (0.7%)	1 (1.3%)	1 (2.0%)
	Implant Reposition	10 (7.1%)	10 (12.8%)	5 (9.8%)
	Incision and Drainage	7 (5.0%)	6 (7.7%)	5 (9.8%)
	Mastopexy	5 (3.5%)	5 (6.4%)	3 (5.9%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

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Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=216) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
0-36 Months	Needle Aspiration	1 (0.7%)	1 (1.3%)	1 (2.0%)
	Nipple Related Procedure (unplanned)	1 (0.7%)	1 (1.3%)	1 (2.0%)
	Open Incision To Rule Out Implant Rupture	1 (0.7%)	1 (1.3%)	1 (2.0%)
	Revision Of Wound Closure	2 (1.4%)	2 (2.6%)	2 (3.9%)
	Scar Revision	9 (6.4%)	9 (11.5%)	6 (11.8%)
	Skin Adjustment	12 (8.5%)	11 (14.1%)	7 (13.7%)
	Any Additional Surgical Procedures	141 (100.0%)	78 (100.0%)	51 (100.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=94) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
0-6 Months	Total with At Least One Complication N (%)	94 (100.0%)	71 (18.4%)	51 (24.9%)
	Explant with or without Replacement	7 (7.4%)	7 (1.8%)	5 (2.4%)
	Other Reoperations	22 (23.4%)	19 (4.9%)	16 (7.8%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	17 (18.1%)	17 (4.4%)	16 (7.8%)
	Baker III, IV Capsular Contracture	23 (24.5%)	22 (5.7%)	18 (8.8%)
	Baker IV Capsular Contracture	6 (6.4%)	5 (1.3%)	5 (2.4%)
	Breast Mass	4 (4.3%)	4 (1.0%)	4 (2.0%)
	Breast Pain	2 (2.1%)	1 (0.3%)	1 (0.5%)
	Breast Sensation Changes	3 (3.2%)	3 (0.8%)	2 (1.0%)
	Delayed Wound Healing	5 (5.3%)	5 (1.3%)	4 (2.0%)
	External Injury Not Related To Breast Implants	1 (1.1%)	1 (0.3%)	1 (0.5%)
	Extrusion	2 (2.1%)	2 (0.5%)	2 (1.0%)
	Granuloma	2 (2.1%)	2 (0.5%)	2 (1.0%)
	Hematoma	6 (6.4%)	6 (1.6%)	5 (2.4%)
	Implant Malposition/Displacement	5 (5.3%)	5 (1.3%)	3 (1.5%)
	Infection	1 (1.1%)	1 (0.3%)	1 (0.5%)
	Inflammation	1 (1.1%)	1 (0.3%)	1 (0.5%)
	Nipple Sensation Changes	15 (16.0%)	15 (3.9%)	9 (4.4%)
	Seroma	4 (4.3%)	4 (1.0%)	4 (2.0%)
	Other	3 (3.2%)	2 (0.5%)	2 (1.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=94) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)	
0-6 Months	Capsule Tear	1 (1.1%)	1 (0.3%)	1 (0.5%)	
	Symmastia And Implant Malposition	2 (2.1%)	1 (0.3%)	1 (0.5%)	
	Any Complication Excluding Cosmetic	77 (81.9%)	59 (15.3%)	44 (21.5%)	
	II. Cosmetic Complication				
	Asymmetry	1 (1.1%)	1 (0.3%)	1 (0.5%)	
	Hypertrophic Scarring	9 (9.6%)	9 (2.3%)	6 (2.9%)	
	Ptosis	2 (2.1%)	2 (0.5%)	1 (0.5%)	
	Wrinkling	5 (5.3%)	5 (1.3%)	3 (1.5%)	
	Any Cosmetic Complication	17 (18.1%)	17 (4.4%)	11 (5.4%)	
	III. Additional Surgical Procedures				
	Explant with or without Replacement	7 (22.6%)	7 (26.9%)	5 (23.8%)	
	Explant with Replacement with Study Device	4 (12.9%)	4 (15.4%)	3 (14.3%)	
	Explant without Replacement	3 (9.7%)	3 (11.5%)	2 (9.5%)	
Other Additional Surgical Procedures					
Biopsy	3 (9.7%)	3 (11.5%)	3 (14.3%)		
Capsulectomy	3 (9.7%)	3 (11.5%)	3 (14.3%)		
Capsulorrhaphy	2 (6.5%)	2 (7.7%)	1 (4.8%)		

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=94) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
0-6 Months	Capsulotomy	3 (9.7%)	3 (11.5%)	2 (9.5%)
	Incision and Drainage	7 (22.6%)	6 (23.1%)	5 (23.8%)
	Revision Of Wound Closure	2 (6.5%)	2 (7.7%)	2 (9.5%)
	Scar Revision	1 (3.2%)	1 (3.8%)	1 (4.8%)
	Skin Adjustment	3 (9.7%)	2 (7.7%)	2 (9.5%)
	Any Additional Surgical Procedures	31 (100.0%)	26 (100.0%)	21 (100.0%)

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Creation Date, Time. 26AUG04 12:37

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=47) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
6-12 Months	Total with At Least One Complication N (%)	47 (100.0%)	36 (9.3%)	30 (14.6%)
	Explant with or without Replacement	11 (23.4%)	11 (2.8%)	7 (3.4%)
	Other Reoperations	29 (61.7%)	24 (6.2%)	14 (6.8%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	17 (36.2%)	16 (4.1%)	12 (5.9%)
	Baker III, IV Capsular Contracture	19 (40.4%)	18 (4.7%)	13 (6.3%)
	Baker IV Capsular Contracture	2 (4.3%)	2 (0.5%)	2 (1.0%)
	Breast Mass	2 (4.3%)	2 (0.5%)	2 (1.0%)
	Breast Pain	1 (2.1%)	1 (0.3%)	1 (0.5%)
	Extrusion	1 (2.1%)	1 (0.3%)	1 (0.5%)
	Implant Malposition/Displacement	1 (2.1%)	1 (0.3%)	1 (0.5%)
	Inflammation	2 (4.3%)	1 (0.3%)	2 (1.0%)
	New Diagnosis of Breast Cancer	1 (2.1%)	1 (0.3%)	1 (0.5%)
	New Diagnosis of Rheumatic Disease	2 (4.3%)		2 (1.0%)
	Nipple Sensation Changes	5 (10.6%)	5 (1.3%)	3 (1.5%)
	Recurrent Breast Cancer	1 (2.1%)	1 (0.3%)	1 (0.5%)
	Other	6 (12.8%)	5 (1.3%)	4 (2.0%)
	Back And Neck Pain Related To Large Implants	1 (2.1%)		1 (0.5%)
	Muscle Spasm	2 (4.3%)	2 (0.5%)	1 (0.5%)
	Symmastia	3 (6.4%)	3 (0.8%)	2 (1.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12.37

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Note 3: 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 sensation changes, nipple complications, and wrinkling.

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Table 8 1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=47) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
6-12 Months	Any Complication Excluding Cosmetic	41 (87.2%)	33 (8.5%)	28 (13.7%)
	II. Cosmetic Complication			
	Asymmetry	2 (4.3%)	2 (0.5%)	2 (1.0%)
	Hypertrophic Scarring	3 (6.4%)	3 (0.8%)	2 (1.0%)
	Ptosis	1 (2.1%)	1 (0.3%)	1 (0.5%)
	Any Cosmetic Complication	6 (12.8%)	6 (1.6%)	5 (2.4%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	11 (19.6%)	11 (40.7%)	7 (43.8%)
	Explant with Replacement with Study Device	8 (14.3%)	8 (29.6%)	5 (31.3%)
	Explant without Replacement	3 (5.4%)	3 (11.1%)	2 (12.5%)
	Other Additional Surgical Procedures	29 (51.8%)	24 (88.9%)	14 (87.5%)
	Biopsy	3 (5.4%)	2 (7.4%)	2 (12.5%)
	Capsulectomy	9 (16.1%)	9 (33.3%)	6 (37.5%)
	Capsulorrhaphy	2 (3.6%)	2 (7.4%)	1 (6.3%)
	Capsulotomy	11 (19.6%)	8 (29.6%)	6 (37.5%)
	Excision Of Skin Lesion	2 (3.6%)	2 (7.4%)	1 (6.3%)
	Implant Reposition	4 (7.1%)	4 (14.8%)	2 (12.5%)
	Mastopexy	4 (7.1%)	4 (14.8%)	2 (12.5%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

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REVISION PATIENTS

Time Period	Type of Complication	Events (N=47) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
6-12 Months	Scar Revision	4 (7.1%)	4 (14.8%)	2 (12.5%)
	Skin Adjustment	6 (10.7%)	6 (22.2%)	3 (18.8%)
	Any Additional Surgical Procedures	56 (100.0%)	27 (100.0%)	16 (100.0%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=56) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
12-24 Months	Total with At Least One Complication N (%)	56 (100.0%)	44 (11.4%)	34 (16.6%)
	Explant with or without Replacement	13 (23.2%)	13 (3.4%)	8 (3.9%)
	Other Reoperations	14 (25.0%)	11 (2.8%)	8 (3.9%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	11 (19.6%)	10 (2.6%)	10 (4.9%)
	Baker III, IV Capsular Contracture	15 (26.8%)	12 (3.1%)	11 (5.4%)
	Baker IV Capsular Contracture	4 (7.1%)	3 (0.8%)	2 (1.0%)
	Breast Mass	3 (5.4%)	3 (0.8%)	3 (1.5%)
	Breast Pain	3 (5.4%)	3 (0.8%)	2 (1.0%)
	Breast Sensation Changes	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Hematoma	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Implant Malposition/Displacement	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Infection	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Lactation Difficulties	2 (3.6%)	2 (0.5%)	1 (0.5%)
	Nipple Sensation Changes	6 (10.7%)	6 (1.6%)	5 (2.4%)
	Rupture	4 (7.1%)	4 (1.0%)	3 (1.5%)
	Other	5 (8.9%)	3 (0.8%)	5 (2.4%)
	Abnormal Mammogram	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Nipple Related Unplanned	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Numbness In Both Hands At Night	1 (1.8%)		1 (0.5%)
	Skin Lesion	1 (1.8%)	1 (0.3%)	1 (0.5%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12.37

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REVISION PATIENTS

Time Period	Type of Complication	Events (N=56) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
12-24 Months	Surgical Removal Of Ectopic Pregnancy	1 (1.8%)		1 (0.5%)
	Any Complication Excluding Cosmetic	42 (75.0%)	33 (8.5%)	28 (13.7%)
	II. Cosmetic Complication			
	Asymmetry	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Hypertrophic Scarring	8 (14.3%)	8 (2.1%)	5 (2.4%)
	Ptosis	4 (7.1%)	4 (1.0%)	2 (1.0%)
	Wrinkling	1 (1.8%)	1 (0.3%)	1 (0.5%)
	Any Cosmetic Complication	14 (25.0%)	14 (3.6%)	9 (4.4%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	13 (40.6%)	13 (61.9%)	8 (61.5%)
	Explant with Replacement with Study Device	6 (18.8%)	6 (28.6%)	4 (30.8%)
	Explant without Replacement	7 (21.9%)	7 (33.3%)	4 (30.8%)
	Other Additional Surgical Procedures	14 (43.8%)	11 (52.4%)	8 (61.5%)
	Biopsy	2 (6.3%)	1 (4.8%)	1 (7.7%)
	Capsulectomy	2 (6.3%)	1 (4.8%)	1 (7.7%)
	Capsulorrhaphy	2 (6.3%)	2 (9.5%)	1 (7.7%)
	Capsulotomy	2 (6.3%)	2 (9.5%)	2 (15.4%)

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Note 1. Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2. Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8 1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=56) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
12-24 Months	Exploration Right Breast With Evacuation Of Hematoma	1 (3.1%)	1 (4.8%)	1 (7.7%)
	Implant Reposition	4 (12.5%)	4 (19.0%)	2 (15.4%)
	Scar Revision	3 (9.4%)	3 (14.3%)	2 (15.4%)
	Skin Adjustment	3 (9.4%)	3 (14.3%)	2 (15.4%)
	Any Additional Surgical Procedures	32 (100.0%)	21 (100.0%)	13 (100.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

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Note 1. Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2. Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3. 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 sensation changes, nipple complications, and wrinkling.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=19) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
24-36 Months	Total with At Least One Complication N (%)	19 (100.0%)	15 (3.9%)	12 (5.9%)
	Explant with or without Replacement	8 (42.1%)	8 (2.1%)	5 (2.4%)
	Other Reoperations	12 (63.2%)	12 (3.1%)	8 (3.9%)
I. Complication Excluding Cosmetic				
	Baker III Capsular Contracture	2 (10.5%)	2 (0.5%)	2 (1.0%)
	Baker III, IV Capsular Contracture	5 (26.3%)	5 (1.3%)	4 (2.0%)
	Baker IV Capsular Contracture	3 (15.8%)	3 (0.8%)	2 (1.0%)
	Breast Mass	3 (15.8%)	2 (0.5%)	2 (1.0%)
	Breast Sensation Changes	1 (5.3%)	1 (0.3%)	1 (0.5%)
	External Injury Not Related To Breast Implants	1 (5.3%)	1 (0.3%)	1 (0.5%)
	Nipple Sensation Changes	1 (5.3%)	1 (0.3%)	1 (0.5%)
	Rupture	2 (10.5%)	2 (0.5%)	1 (0.5%)
	Other	2 (10.5%)	1 (0.3%)	1 (0.5%)
	False Positive For Rupture On Mammogram	1 (5.3%)	1 (0.3%)	1 (0.5%)
	Siliconoma	1 (5.3%)	1 (0.3%)	1 (0.5%)
	Any Complication Excluding Cosmetic	15 (78.9%)	12 (3.1%)	10 (4.9%)
II. Cosmetic Complication				
	Asymmetry	1 (5.3%)	1 (0.3%)	1 (0.5%)
	Hypertrophic Scarring	1 (5.3%)	1 (0.3%)	1 (0.5%)

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Creation Date, Time: 26AUG04 12:37

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Events (N=19) n (%)	Implants (N=386) n (%) (a)	Patients (N=205) n (%) (a)
24-36 Months	Ptosis	2 (10.5%)	2 (0.5%)	1 (0.5%)
	Any Cosmetic Complication	4 (21.1%)	3 (0.8%)	2 (1.0%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	8 (36.4%)	8 (57.1%)	5 (55.6%)
	Explant with Replacement with Study Device	3 (13.6%)	3 (21.4%)	2 (22.2%)
	Explant without Replacement	5 (22.7%)	5 (35.7%)	3 (33.3%)
	Other Additional Surgical Procedures	12 (54.5%)	12 (85.7%)	8 (88.9%)
	Biopsy	2 (9.1%)	2 (14.3%)	2 (22.2%)
	Capsulectomy	4 (18.2%)	4 (28.6%)	2 (22.2%)
	Capsulotomy	1 (4.5%)	1 (7.1%)	1 (11.1%)
	Implant Reposition	2 (9.1%)	2 (14.3%)	1 (11.1%)
	Mastopexy	1 (4.5%)	1 (7.1%)	1 (11.1%)
	Needle Aspiration	1 (4.5%)	1 (7.1%)	1 (11.1%)
	Nipple Related Procedure (unplanned)	1 (4.5%)	1 (7.1%)	1 (11.1%)
	Open Incision To Rule Out Implant Rupture	1 (4.5%)	1 (7.1%)	1 (11.1%)
	Scar Revision*	1 (4.5%)	1 (7.1%)	1 (11.1%)
	Any Additional Surgical Procedures	22 (100.0%)	14 (100.0%)	9 (100.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=789) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-36 Months	Total with At Least One Complication N (%)	789 (100.0%)	506 (26.7%)	376 (37.3%)
	Explant with or without Replacement	124 (15.7%)	124 (6.5%)	82 (8.1%)
	Other Reoperations	252 (31.9%)	212 (11.2%)	161 (16.0%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	138 (17.5%)	115 (6.1%)	90 (8.9%)
	Baker III, IV Capsular Contracture	164 (20.8%)	127 (6.7%)	97 (9.6%)
	Baker IV Capsular Contracture	26 (3.3%)	24 (1.3%)	19 (1.9%)
	Breast Mass	34 (4.3%)	31 (1.6%)	31 (3.1%)
	Breast Pain	24 (3.0%)	23 (1.2%)	17 (1.7%)
	Breast Sensation Changes	25 (3.2%)	25 (1.3%)	18 (1.8%)
	Delayed Wound Healing	8 (1.0%)	7 (0.4%)	5 (0.5%)
	External Injury Not Related To Breast Implants	10 (1.3%)	10 (0.5%)	9 (0.9%)
	Extrusion	6 (0.8%)	6 (0.3%)	6 (0.6%)
	Granuloma	3 (0.4%)	3 (0.2%)	3 (0.3%)
	Hematoma	25 (3.2%)	24 (1.3%)	23 (2.3%)
	Implant Malposition/Displacement	13 (1.6%)	13 (0.7%)	10 (1.0%)
	Infection	25 (3.2%)	23 (1.2%)	23 (2.3%)
	Inflammation	5 (0.6%)	4 (0.2%)	5 (0.5%)
	Lactation Difficulties	3 (0.4%)	3 (0.2%)	2 (0.2%)
	Lymphadenopathy	2 (0.3%)	2 (0.1%)	2 (0.2%)
	Metastatic Disease	6 (0.8%)	2 (0.1%)	4 (0.4%)

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=789) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-36 Months	Miscarriage	9 (1.1%)		9 (0.9%)
	Necrosis	4 (0.5%)	4 (0.2%)	3 (0.3%)
	New Diagnosis of Breast Cancer	1 (0.1%)	1 (0.1%)	1 (0.1%)
	New Diagnosis of Rheumatic Disease	6 (0.8%)		6 (0.6%)
	Nipple Sensation Changes	127 (16.1%)	119 (6.3%)	79 (7.8%)
	Placement Damage	4 (0.5%)	4 (0.2%)	4 (0.4%)
	Rash	8 (1.0%)	6 (0.3%)	5 (0.5%)
	Recurrent Breast Cancer	6 (0.8%)	5 (0.3%)	5 (0.5%)
	Rupture	8 (1.0%)	8 (0.4%)	6 (0.6%)
	Seroma	26 (3.3%)	22 (1.2%)	21 (2.1%)
	Suture Reaction	4 (0.5%)	4 (0.2%)	3 (0.3%)
	Other	56 (7.1%)	45 (2.4%)	44 (4.4%)
	Abnormal Mammogram	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Anaphylaxis	2 (0.3%)		1 (0.1%)
	Back And Neck Pain Related To Large Implants	1 (0.1%)		1 (0.1%)
	Capsular Contracture Secondary To Radiation Therapy	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Capsule Tear	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Cellulitis	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Deep Vein Thrombosis	2 (0.3%)		2 (0.2%)
	Distortion Of Breast Shape Not Related To Capsular Contracture	2 (0.3%)	2 (0.1%)	2 (0.2%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=789) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-36 Months	Dog Ear Scars From Mastectomy	2 (0.3%)	2 (0.1%)	1 (0.1%)
	Ecchymosis	2 (0.3%)	2 (0.1%)	2 (0.2%)
	Excessive Implant Movements	2 (0.3%)	2 (0.1%)	1 (0.1%)
	Explanted Due To Right Side Being Removed	2 (0.3%)	2 (0.1%)	2 (0.2%)
	Extra Skin	1 (0.1%)	1 (0.1%)	1 (0.1%)
	False Positive For Rupture On Mammogram	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Implants Riding High	2 (0.3%)	2 (0.1%)	1 (0.1%)
	Inframammary Fold Too High	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Lack Of Projection	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Loss Of Inframammary Fold	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Mondor's Disease	3 (0.4%)	3 (0.2%)	2 (0.2%)
	Muscle Spasm	3 (0.4%)	3 (0.2%)	2 (0.2%)
	Nipple Complications	3 (0.4%)	3 (0.2%)	2 (0.2%)
	Nipple Related Unplanned	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Numbness In Both Hands At Night	1 (0.1%)		1 (0.1%)
	Occasional Burning Discomfort Of Skin.	2 (0.3%)	2 (0.1%)	1 (0.1%)
	Pain - Sternum And Under Left Arm Intermittent	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Positive Antinuclear Antibodies Negative For Lupus	1 (0.1%)		1 (0.1%)
	Pt Requests Removal Due To Personal Reasons	2 (0.3%)	2 (0.1%)	1 (0.1%)
	Siliconoma	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Skin Lesion	2 (0.3%)	2 (0.1%)	2 (0.2%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=789) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-36 Months	Soft Mass Left Costal Margin	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Stitch Abscess	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Surgical Removal Of Ectopic Pregnancy	1 (0.1%)		1 (0.1%)
	Symmastia	3 (0.4%)	3 (0.2%)	2 (0.2%)
	Symmastia And Implant Malposition	2 (0.3%)	1 (0.1%)	1 (0.1%)
	Tight Benlli Suture	1 (0.1%)	1 (0.1%)	1 (0.1%)
	Wide Scars	1 (0.1%)		1 (0.1%)
	Any Complication Excluding Cosmetic	612 (77.6%)	397 (20.9%)	312 (31.0%)
	II. Cosmetic Complication			
	Asymmetry	25 (3.2%)	25 (1.3%)	22 (2.2%)
	Hypertrophic Scarring	90 (11.4%)	87 (4.6%)	60 (6.0%)
	Ptosis	42 (5.3%)	40 (2.1%)	24 (2.4%)
	Wrinkling	20 (2.5%)	19 (1.0%)	14 (1.4%)
	Any Cosmetic Complication	177 (22.4%)	159 (8.4%)	108 (10.7%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	124 (28.2%)	124 (45.1%)	82 (42.3%)
	Explant with Replacement with Study Device	68 (15.5%)	68 (24.7%)	47 (24.2%)
	Explant without Replacement	56 (12.7%)	56 (20.4%)	36 (18.6%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=789) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-36 Months	Other Additional Surgical Procedures	252 (57.3%)	212 (77.1%)	161 (83.0%)
	Biopsy	24 (5.5%)	20 (7.3%)	19 (9.8%)
	Breast Mass Excision Dx. Fibroadenoma	1 (0.2%)	1 (0.4%)	1 (0.5%)
	Capsulectomy	64 (14.5%)	58 (21.1%)	45 (23.2%)
	Capsulorrhaphy	12 (2.7%)	10 (3.6%)	7 (3.6%)
	Capsulotomy	48 (10.9%)	44 (16.0%)	36 (18.6%)
	Create Inframmary Fold	2 (0.5%)	1 (0.4%)	1 (0.5%)
	Excise Breast Mass	2 (0.5%)	2 (0.7%)	2 (1.0%)
	Excision Of Skin Lesion	2 (0.5%)	2 (0.7%)	1 (0.5%)
	Exploration Right Breast With Evacuation Of Hematoma	1 (0.2%)	1 (0.4%)	1 (0.5%)
	Flap Coverage Of Expander	1 (0.2%)	1 (0.4%)	1 (0.5%)
	Implant Pocket Revision	8 (1.8%)	8 (2.9%)	5 (2.6%)
	Implant Reposition	31 (7.0%)	29 (10.5%)	20 (10.3%)
	Incision and Drainage	23 (5.2%)	21 (7.6%)	20 (10.3%)
	Mastopexy	13 (3.0%)	12 (4.4%)	7 (3.6%)
	Needle Aspiration	1 (0.2%)	1 (0.4%)	1 (0.5%)
	Nipple Related Procedure (unplanned)	4 (0.9%)	4 (1.5%)	4 (2.1%)
	Open Incision To Rule Out Implant Rupture	1 (0.2%)	1 (0.4%)	1 (0.5%)
	Removal Of Nodule On Chest Wall	2 (0.5%)	2 (0.7%)	1 (0.5%)
	Revision Of Breast / External To Pocket	2 (0.5%)	2 (0.7%)	1 (0.5%)
	Revision Of Wound Closure	6 (1.4%)	6 (2.2%)	6 (3.1%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12.37

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=789) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-36 Months	Scar Revision	34 (7.7%)	34 (12.4%)	23 (11.9%)
	Skin Adjustment	34 (7.7%)	33 (12.0%)	22 (11.3%)
	Any Additional Surgical Procedures	440 (100.0%)	275 (100.0%)	194 (100.0%)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08.1.SAS

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=376) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-6 Months	Total with At Least One Complication N (%)	376 (100.0%)	286 (15.1%)	220 (21.8%)
	Explant with or without Replacement	28 (7.4%)	28 (1.5%)	19 (1.9%)
	Other Reoperations	81 (21.5%)	78 (4.1%)	65 (6.5%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	56 (14.9%)	54 (2.8%)	48 (4.8%)
	Baker III, IV Capsular Contracture	64 (17.0%)	61 (3.2%)	51 (5.1%)
	Baker IV Capsular Contracture	8 (2.1%)	7 (0.4%)	7 (0.7%)
	Breast Mass	6 (1.6%)	6 (0.3%)	6 (0.6%)
	Breast Pain	14 (3.7%)	13 (0.7%)	9 (0.9%)
	Breast Sensation Changes	14 (3.7%)	14 (0.7%)	10 (1.0%)
	Delayed Wound Healing	8 (2.1%)	7 (0.4%)	5 (0.5%)
	External Injury Not Related To Breast Implants	5 (1.3%)	5 (0.3%)	4 (0.4%)
	Extrusion	4 (1.1%)	4 (0.2%)	4 (0.4%)
	Granuloma	3 (0.8%)	3 (0.2%)	3 (0.3%)
	Hematoma	20 (5.3%)	20 (1.1%)	19 (1.9%)
	Implant Malposition/Displacement	7 (1.9%)	7 (0.4%)	5 (0.5%)
	Infection	20 (5.3%)	18 (0.9%)	18 (1.8%)
	Inflammation	3 (0.8%)	3 (0.2%)	3 (0.3%)
	Lymphadenopathy	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Metastatic Disease	1 (0.3%)		1 (0.1%)
	Miscarriage	2 (0.5%)		2 (0.2%)

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Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=376) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-6 Months	Necrosis	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Nipple Sensation Changes	65 (17.3%)	65 (3.4%)	42 (4.2%)
	Placement Damage	4 (1.1%)	4 (0.2%)	4 (0.4%)
	Rash	7 (1.9%)	5 (0.3%)	4 (0.4%)
	Recurrent Breast Cancer	2 (0.5%)	2 (0.1%)	1 (0.1%)
	Seroma	24 (6.4%)	20 (1.1%)	19 (1.9%)
	Suture Reaction	4 (1.1%)	4 (0.2%)	3 (0.3%)
	Other	25 (6.6%)	22 (1.2%)	20 (2.0%)
	Capsular Contracture Secondary To Radiation Therapy	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Capsule Tear	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Cellulitis	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Deep Vein Thrombosis	1 (0.3%)		1 (0.1%)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Dog Ear Scars From Mastectomy	2 (0.5%)	2 (0.1%)	1 (0.1%)
	Ecchymosis	2 (0.5%)	2 (0.1%)	2 (0.2%)
	Excessive Implant Movements	2 (0.5%)	2 (0.1%)	1 (0.1%)
	Extra Skin	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Implants Riding High	2 (0.5%)	2 (0.1%)	1 (0.1%)
	Loss Of Inframammary Fold	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Mondor's Disease	3 (0.8%)	3 (0.2%)	2 (0.2%)

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=376) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-6 Months	Muscle Spasm	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Nipple Complications	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Pain - Sternum And Under Left Arm Intermittent	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Skin Lesion	1 (0.3%)	1 (0.1%)	1 (0.1%)
	Symmastia And Implant Malposition	2 (0.5%)	1 (0.1%)	1 (0.1%)
	Wide Scars	1 (0.3%)		1 (0.1%)
	Any Complication Excluding Cosmetic	304 (80.9%)	236 (12.4%)	186 (18.5%)
	II. Cosmetic Complication			
	Asymmetry	12 (3.2%)	12 (0.6%)	11 (1.1%)
	Hypertrophic Scarring	39 (10.4%)	39 (2.1%)	29 (2.9%)
Ptosis	9 (2.4%)	9 (0.5%)	5 (0.5%)	
Wrinkling	12 (3.2%)	11 (0.6%)	8 (0.8%)	
Any Cosmetic Complication	72 (19.1%)	68 (3.6%)	50 (5.0%)	
III. Additional Surgical Procedures				
Explant with or without Replacement	28 (22.4%)	28 (28.0%)	19 (24.1%)	
Explant with Replacement with Study Device	18 (14.4%)	18 (18.0%)	11 (13.9%)	
Explant without Replacement	10 (8.0%)	10 (10.0%)	8 (10.1%)	

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=376) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
0-6 Months	Other Additional Surgical Procedures	81 (64.8%)	78 (78.0%)	65 (82.3%)
	Biopsy	9 (7.2%)	9 (9.0%)	8 (10.1%)
	Capsulectomy	16 (12.8%)	16 (16.0%)	14 (17.7%)
	Capsulorrhaphy	7 (5.6%)	7 (7.0%)	5 (6.3%)
	Capsulotomy	12 (9.6%)	12 (12.0%)	10 (12.7%)
	Create Inframmary Fold	1 (0.8%)	1 (1.0%)	1 (1.3%)
	Implant Reposition	8 (6.4%)	8 (8.0%)	6 (7.6%)
	Incision and Drainage	19 (15.2%)	18 (18.0%)	17 (21.5%)
	Mastopexy	1 (0.8%)	1 (1.0%)	1 (1.3%)
	Nipple Related Procedure (unplanned)	1 (0.8%)	1 (1.0%)	1 (1.3%)
	Removal Of Nodule On Chest Wall	2 (1.6%)	2 (2.0%)	1 (1.3%)
	Revision Of Wound Closure	5 (4.0%)	5 (5.0%)	5 (6.3%)
	Scar Revision	4 (3.2%)	4 (4.0%)	3 (3.8%)
	Skin Adjustment	12 (9.6%)	11 (11.0%)	8 (10.1%)
	Any Additional Surgical Procedures	125 (100.0%)	100 (100.0%)	79 (100.0%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=155) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
6-12 Months	Total with At Least One Complication N (%)	155 (100.0%)	127 (6.7%)	105 (10.4%)
	Explant with or without Replacement	38 (24.5%)	38 (2.0%)	26 (2.6%)
	Other Reoperations	75 (48.4%)	69 (3.6%)	52 (5.2%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	39 (25.2%)	38 (2.0%)	29 (2.9%)
	Baker III, IV Capsular Contracture	45 (29.0%)	44 (2.3%)	33 (3.3%)
	Baker IV Capsular Contracture	6 (3.9%)	6 (0.3%)	5 (0.5%)
	Breast Mass	7 (4.5%)	7 (0.4%)	7 (0.7%)
	Breast Pain	2 (1.3%)	2 (0.1%)	2 (0.2%)
	Breast Sensation Changes	6 (3.9%)	6 (0.3%)	4 (0.4%)
	External Injury Not Related To Breast Implants	2 (1.3%)	2 (0.1%)	2 (0.2%)
	Extrusion	2 (1.3%)	2 (0.1%)	2 (0.2%)
	Hematoma	2 (1.3%)	1 (0.1%)	1 (0.1%)
	Implant Malposition/Displacement	3 (1.9%)	3 (0.2%)	3 (0.3%)
	Infection	1 (0.6%)	1 (0.1%)	1 (0.1%)
	Inflammation	2 (1.3%)	1 (0.1%)	2 (0.2%)
	Miscarriage	5 (3.2%)		5 (0.5%)
	New Diagnosis of Breast Cancer	1 (0.6%)	1 (0.1%)	1 (0.1%)
	New Diagnosis of Rheumatic Disease	3 (1.9%)		3 (0.3%)
	Nipple Sensation Changes	29 (18.7%)	29 (1.5%)	20 (2.0%)
	Recurrent Breast Cancer	2 (1.3%)	2 (0.1%)	2 (0.2%)

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Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=155) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
6-12 Months	Other	10 (6.5%)	9 (0.5%)	7 (0.7%)
	Back And Neck Pain Related To Large Implants	1 (0.6%)		1 (0.1%)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (0.6%)	1 (0.1%)	1 (0.1%)
	Muscle Spasm	2 (1.3%)	2 (0.1%)	1 (0.1%)
	Pt Requests Removal Due To Personal Reasons	2 (1.3%)	2 (0.1%)	1 (0.1%)
	Symmastia	3 (1.9%)	3 (0.2%)	2 (0.2%)
	Tight Benilli Suture	1 (0.6%)	1 (0.1%)	1 (0.1%)
	Any Complication Excluding Cosmetic	122 (78.7%)	100 (5.3%)	85 (8.4%)
	II Cosmetic Complication			
	Asymmetry	5 (3.2%)	5 (0.3%)	5 (0.5%)
	Hypertrophic Scarring	22 (14.2%)	21 (1.1%)	16 (1.6%)
	Ptosis	3 (1.9%)	3 (0.2%)	2 (0.2%)
	Wrinkling	3 (1.9%)	3 (0.2%)	2 (0.2%)
	Any Cosmetic Complication	33 (21.3%)	31 (1.6%)	24 (2.4%)
III. Additional Surgical Procedures				
Explant with or without Replacement	38 (27.1%)	38 (42.2%)	26 (40.6%)	
Explant with Replacement with Study Device	25 (17.9%)	25 (27.8%)	18 (28.1%)	

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=155) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
6-12 Months	Explant without Replacement	13 (9.3%)	13 (14.4%)	8 (12.5%)
	Other Additional Surgical Procedures	75 (53.6%)	69 (76.7%)	52 (81.3%)
	Biopsy	7 (5.0%)	6 (6.7%)	6 (9.4%)
	Capsulectomy	21 (15.0%)	21 (23.3%)	16 (25.0%)
	Capsulorrhaphy	3 (2.1%)	3 (3.3%)	2 (3.1%)
	Capsulotomy	23 (16.4%)	20 (22.2%)	16 (25.0%)
	Create Inframmary Fold	1 (0.7%)	1 (1.1%)	1 (1.6%)
	Excision Of Skin Lesion	2 (1.4%)	2 (2.2%)	1 (1.6%)
	Implant Pocket Revision	4 (2.9%)	4 (4.4%)	3 (4.7%)
	Implant Reposition	10 (7.1%)	10 (11.1%)	8 (12.5%)
	Incision and Drainage	2 (1.4%)	1 (1.1%)	1 (1.6%)
	Mastopexy	4 (2.9%)	4 (4.4%)	2 (3.1%)
	Nipple Related Procedure (unplanned)	2 (1.4%)	2 (2.2%)	2 (3.1%)
	Revision Of Wound Closure	1 (0.7%)	1 (1.1%)	1 (1.6%)
	Scar Revision	10 (7.1%)	10 (11.1%)	7 (10.9%)
	Skin Adjustment	12 (8.6%)	12 (13.3%)	8 (12.5%)
	Any Additional Surgical Procedures	140 (100.0%)	90 (100.0%)	64 (100.0%)

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Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=176) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
12-24 Months	Total with At Least One Complication N (%)	176 (100.0%)	144 (7.6%)	118 (11.7%)
	Explant with or without Replacement	35 (19.9%)	35 (1.8%)	25 (2.5%)
	Other Reoperations	64 (36.4%)	56 (3.0%)	40 (4.0%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	33 (18.8%)	31 (1.6%)	27 (2.7%)
	Baker III, IV Capsular Contracture	40 (22.7%)	35 (1.8%)	30 (3.0%)
	Baker IV Capsular Contracture	7 (4.0%)	6 (0.3%)	5 (0.5%)
	Breast Mass	14 (8.0%)	14 (0.7%)	14 (1.4%)
	Breast Pain	8 (4.5%)	8 (0.4%)	6 (0.6%)
	Breast Sensation Changes	4 (2.3%)	4 (0.2%)	4 (0.4%)
	Hematoma	3 (1.7%)	3 (0.2%)	3 (0.3%)
	Implant Malposition/Displacement	3 (1.7%)	3 (0.2%)	2 (0.2%)
	Infection	4 (2.3%)	4 (0.2%)	4 (0.4%)
	Lactation Difficulties	2 (1.1%)	2 (0.1%)	1 (0.1%)
	Metastatic Disease	3 (1.7%)		3 (0.3%)
	Miscarriage	1 (0.6%)		1 (0.1%)
	New Diagnosis of Rheumatic Disease	3 (1.7%)		3 (0.3%)
	Nipple Sensation Changes	16 (9.1%)	16 (0.8%)	13 (1.3%)
	Rash	1 (0.6%)	1 (0.1%)	1 (0.1%)
	Recurrent Breast Cancer	2 (1.1%)	1 (0.1%)	2 (0.2%)
	Rupture	5 (2.8%)	5 (0.3%)	4 (0.4%)

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=176) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)	
12-24 Months	Seroma	2 (1.1%)	2 (0.1%)	2 (0.2%)	
	Other	12 (6.8%)	8 (0.4%)	10 (1.0%)	
	Abnormal Mammogram	1 (0.6%)	1 (0.1%)	1 (0.1%)	
	Anaphylaxis	2 (1.1%)		1 (0.1%)	
	Inframammary Fold Too High	1 (0.6%)	1 (0.1%)	1 (0.1%)	
	Lack Of Projection	1 (0.6%)	1 (0.1%)	1 (0.1%)	
	Nipple Complications	2 (1.1%)	2 (0.1%)	1 (0.1%)	
	Nipple Related Unplanned	1 (0.6%)	1 (0.1%)	1 (0.1%)	
	Numbness In Both Hands At Night	1 (0.6%)		1 (0.1%)	
	Skin Lesion	1 (0.6%)	1 (0.1%)	1 (0.1%)	
	Soft Mass Left Costal Margin	1 (0.6%)	1 (0.1%)	1 (0.1%)	
	Surgical Removal Of Ectopic Pregnancy	1 (0.6%)		1 (0.1%)	
		Any Complication Excluding Cosmetic	123 (69.9%)	98 (5.2%)	92 (9.1%)
	II. Cosmetic Complication				
	Asymmetry	3 (1.7%)	3 (0.2%)	2 (0.2%)	
	Hypertrophic Scarring	26 (14.8%)	26 (1.4%)	16 (1.6%)	
	Ptosis	20 (11.4%)	20 (1.1%)	12 (1.2%)	
	Wrinkling	4 (2.3%)	4 (0.2%)	3 (0.3%)	
	Any Cosmetic Complication	53 (30.1%)	53 (2.8%)	33 (3.3%)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

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INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=176) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
12-24 Months	III. Additional Surgical Procedures			
	Explant with or without Replacement	35 (29.7%)	35 (44.9%)	25 (47.2%)
	Explant with Replacement with Study Device	18 (15.3%)	18 (23.1%)	14 (26.4%)
	Explant without Replacement	17 (14.4%)	17 (21.8%)	11 (20.8%)
	Other Additional Surgical Procedures	64 (54.2%)	56 (71.8%)	40 (75.5%)
	Biopsy	6 (5.1%)	5 (6.4%)	5 (9.4%)
	Capsulectomy	18 (15.3%)	15 (19.2%)	12 (22.6%)
	Capsulorrhaphy	2 (1.7%)	2 (2.6%)	1 (1.9%)
	Capsulotomy	9 (7.6%)	9 (11.5%)	7 (13.2%)
	Excise Breast Mass	1 (0.8%)	1 (1.3%)	1 (1.9%)
	Exploration Right Breast With Evacuation Of Hematoma	1 (0.8%)	1 (1.3%)	1 (1.9%)
	Flap Coverage Of Expander	1 (0.8%)	1 (1.3%)	1 (1.9%)
	Implant Pocket Revision	4 (3.4%)	4 (5.1%)	2 (3.8%)
	Implant Reposition	11 (9.3%)	11 (14.1%)	6 (11.3%)
	Incision and Drainage	1 (0.8%)	1 (1.3%)	1 (1.9%)
	Mastopexy	4 (3.4%)	4 (5.1%)	2 (3.8%)
	Revision Of Breast / External To Pocket	2 (1.7%)	2 (2.6%)	1 (1.9%)
	Scar Revision	16 (13.6%)	16 (20.5%)	10 (18.9%)
	Skin Adjustment	7 (5.9%)	7 (9.0%)	4 (7.5%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

Implants/patients reporting more than one complication or reoperation under type of cosmetic complication, complication excluding cosmetic, or any reoperation are counted only once for that type. * Complications resulting from planned second stage surgery in reconstruction or revision patients

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=176) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
12-24 Months	Any Additional Surgical Procedures	118 (100.0%)	78 (100.0%)	53 (100.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=82) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
24-36 Months	Total with At Least One Complication N (%)	82 (100.0%)	70 (3.7%)	54 (5.4%)
	Explant with or without Replacement	23 (28.0%)	23 (1.2%)	13 (1.3%)
	Other Reoperations	32 (39.0%)	30 (1.6%)	23 (2.3%)
	I. Complication Excluding Cosmetic			
	Baker III Capsular Contracture	10 (12.2%)	9 (0.5%)	8 (0.8%)
	Baker III, IV Capsular Contracture	15 (18.3%)	14 (0.7%)	11 (1.1%)
	Baker IV Capsular Contracture	5 (6.1%)	5 (0.3%)	3 (0.3%)
	Breast Mass	7 (8.5%)	6 (0.3%)	6 (0.6%)
	Breast Sensation Changes	1 (1.2%)	1 (0.1%)	1 (0.1%)
	External Injury Not Related To Breast Implants	3 (3.7%)	3 (0.2%)	3 (0.3%)
	Lactation Difficulties	1 (1.2%)	1 (0.1%)	1 (0.1%)
	Lymphadenopathy	1 (1.2%)	1 (0.1%)	1 (0.1%)
	Metastatic Disease	2 (2.4%)	2 (0.1%)	1 (0.1%)
	Miscarriage	1 (1.2%)		1 (0.1%)
	Necrosis	3 (3.7%)	3 (0.2%)	2 (0.2%)
	Nipple Sensation Changes	17 (20.7%)	14 (0.7%)	9 (0.9%)
	Rupture	3 (3.7%)	3 (0.2%)	2 (0.2%)
	Other	9 (11.0%)	6 (0.3%)	7 (0.7%)
	Deep Vein Thrombosis	1 (1.2%)		1 (0.1%)
	Explanted Due To Right Side Being Removed	2 (2.4%)	2 (0.1%)	2 (0.2%)
	False Positive For Rupture On Mammogram	1 (1.2%)	1 (0.1%)	1 (0.1%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

Implants/patients reporting more than one complication or reoperation under type of cosmetic complication, complication excluding cosmetic, or any reoperation are counted only once for that type. * Complications resulting from planned second stage surgery in reconstruction or revision patients.

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

Table 8.1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=82) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
24-36 Months	Occasional Burning Discomfort Of Skin.	2 (2.4%)	2 (0.1%)	1 (0.1%)
	Positive Antinuclear Antibodies Negative For Lupus	1 (1.2%)		1 (0.1%)
	Siliconoma	1 (1.2%)	1 (0.1%)	1 (0.1%)
	Stitch Abscess	1 (1.2%)	1 (0.1%)	1 (0.1%)
	Any Complication Excluding Cosmetic	63 (76.8%)	53 (2.8%)	43 (4.3%)
	II. Cosmetic Complication			
	Asymmetry	5 (6.1%)	5 (0.3%)	4 (0.4%)
	Hypertrophic Scarring	3 (3.7%)	3 (0.2%)	2 (0.2%)
	Ptosis	10 (12.2%)	10 (0.5%)	6 (0.6%)
	Wrinkling	1 (1.2%)	1 (0.1%)	1 (0.1%)
	Any Cosmetic Complication	19 (23.2%)	18 (0.9%)	12 (1.2%)
	III. Additional Surgical Procedures			
	Explant with or without Replacement	23 (40.4%)	23 (56.1%)	13 (46.4%)
	Explant with Replacement with Study Device	7 (12.3%)	7 (17.1%)	4 (14.3%)
	Explant without Replacement	16 (28.1%)	16 (39.0%)	9 (32.1%)
Other Additional Surgical Procedures	32 (56.1%)	30 (73.2%)	23 (82.1%)	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1. Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively.

Note 3: 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

Implants/patients reporting more than one complication or reoperation under type of cosmetic complication, complication excluding cosmetic, or any reoperation are counted only once for that type. * Complications resulting from planned second stage surgery in reconstruction or revision patients.

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

Table 8 1

INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND ADDITIONAL SURGICAL PROCEDURES - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Events (N=82) n (%)	Implants (N=1896) n (%) (a)	Patients (N=1007) n (%) (a)
24-36 Months	Biopsy	2 (3.5%)	2 (4.9%)	2 (7.1%)
	Breast Mass Excision Dx: Fibroadenoma	1 (1.8%)	1 (2.4%)	1 (3.6%)
	Capsulectomy	9 (15.8%)	9 (22.0%)	6 (21.4%)
	Capsulotomy	4 (7.0%)	4 (9.8%)	4 (14.3%)
	Excise Breast Mass	1 (1.8%)	1 (2.4%)	1 (3.6%)
	Implant Reposition	2 (3.5%)	2 (4.9%)	1 (3.6%)
	Incision and Drainage	1 (1.8%)	1 (2.4%)	1 (3.6%)
	Mastopexy	4 (7.0%)	4 (9.8%)	3 (10.7%)
	Needle Aspiration	1 (1.8%)	1 (2.4%)	1 (3.6%)
	Nipple Related Procedure (unplanned)	1 (1.8%)	1 (2.4%)	1 (3.6%)
	Open Incision To Rule Out Implant Rupture	1 (1.8%)	1 (2.4%)	1 (3.6%)
	Scar Revision	4 (7.0%)	4 (9.8%)	3 (10.7%)
	Skin Adjustment	3 (5.3%)	3 (7.3%)	2 (7.1%)
		Any Additional Surgical Procedures	57 (100.0%)	41 (100.0%)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_1.SAS

Creation Date, Time: 26AUG04 12:37

Note 1: Excludes complications or reoperations that occurred after explantation. Implant counts exclude events where breast side=N/A.

Note 2: Percentages are based on the total number of events, total number of implants, and total number of patients in the population, respectively

Note 3: 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 sensation changes, nipple complications, and wrinkling.

(a) Implant/patients frequencies of individual complications or reoperations reflect the number of implants/patients having at least one occurrence of that particular complication or reoperation. Consequently implants/patients may be counted under more than one complication or reoperation.

Implants/patients reporting more than one complication or reoperation under type of cosmetic complication, complication excluding cosmetic, or any reoperation are counted only once for that type. * Complications resulting from planned second stage surgery in reconstruction or revision patients.

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

Table 8.2.1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
0-36 Months	Total Number of Patients with at Least One Complication	79 (42.2)	81 (43.3)	26 (13.9)	1 (0.5)	187 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	13 (31.7)	27 (65.9)	1 (2.4)	0 (0.0)	41 (100.0)
	Baker III, IV Capsular Contracture	13 (29.5)	28 (63.6)	3 (6.8)	0 (0.0)	44 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	4 (57.1)	3 (42.9)	0 (0.0)	7 (100.0)
	Breast Mass	9 (75.0)	3 (25.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Breast Pain	0 (0.0)	4 (44.4)	5 (55.6)	0 (0.0)	9 (100.0)
	Breast Sensation Changes	0 (0.0)	9 (75.0)	3 (25.0)	0 (0.0)	12 (100.0)
	External Injury Not Related To Breast Implants	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Granuloma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	8 (57.1)	5 (35.7)	1 (7.1)	0 (0.0)	14 (100.0)
	Implant Malposition/Displacement	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Infection	4 (50.0)	3 (37.5)	1 (12.5)	0 (0.0)	8 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lactation Difficulties	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lymphadenopathy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	7 (100.0)	0 (0.0)	7 (100.0)
	Necrosis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS

Creation Date, Time: 23AUG04 20:58

Note 1: Excludes complications that occurred after explantation, 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 sensation changes, nipple complications, and wrinkling.

Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different severities are counted only once under the greatest severity (ordered as severe, moderate, mild, missing).

(a) Percentages are based upon the total number of patients having at least one complication, having at least one non-cosmetic complication, one cosmetic complication, or each specific complication, as appropriate.

Core Gel Study of the Safety 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 2 1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
0-36 Months	Nipple Sensation Changes	20 (35.1)	32 (56.1)	5 (8.8)	0 (0.0)	57 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	4 (80.0)	0 (0.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Suture Reaction	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Other	9 (60.0)	5 (33.3)	1 (6.7)	0 (0.0)	15 (100.0)
	Anaphylaxis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ecchymosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Explanted Due To Right Side Being Removed	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implants Riding High	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Mondor's Disease	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Positive Antinuclear Antibodies Negative For Lupus	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS

Creation Date, Time: 23AUG04 20:58

Note 1: Excludes complications that occurred after explantation, 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 sensation changes, nipple complications, and wrinkling.

Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications
with different severities are counted only once under the greatest severity (ordered as severe, moderate, mild, missing).

(a) Percentages are based upon the total number of patients having at least one complication, having at least one non-cosmetic complication, one
cosmetic complication, or each specific complication, as appropriate.

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

Table 8.2.1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
0-36 Months	Any Complication Excluding Cosmetic	59 (38.3)	68 (44.2)	26 (16.9)	1 (0.6)	154 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	22 (64.7)	12 (35.3)	0 (0.0)	0 (0.0)	34 (100.0)
	Ptosis	6 (54.5)	5 (45.5)	0 (0.0)	0 (0.0)	11 (100.0)
	Wrinkling	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	27 (54.0)	23 (46.0)	0 (0.0)	0 (0.0)	50 (100.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21 SAS

Creation Date, Time. 23AUG04 20:58

Note 1: Excludes complications that occurred after explantation, 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,
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cosmetic complication, or each specific complication, as appropriate.

Core Gel Study of the Safety 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 2.1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
0-6 Months	Total Number of Patients with at Least One Complication	50 (44.2)	49 (43.4)	14 (12.4)	0 (0.0)	113 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	9 (37.5)	15 (62.5)	0 (0.0)	0 (0.0)	24 (100.0)
	Baker III, IV Capsular Contracture	8 (33.3)	16 (66.7)	0 (0.0)	0 (0.0)	24 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Mass	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Pain	0 (0.0)	2 (33.3)	4 (66.7)	0 (0.0)	6 (100.0)
	Breast Sensation Changes	0 (0.0)	5 (62.5)	3 (37.5)	0 (0.0)	8 (100.0)
	External Injury Not Related To Breast Implants	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Granuloma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	7 (58.3)	4 (33.3)	1 (8.3)	0 (0.0)	12 (100.0)
	Infection	4 (50.0)	3 (37.5)	1 (12.5)	0 (0.0)	8 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lymphadenopathy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	8 (25.8)	18 (58.1)	5 (16.1)	0 (0.0)	31 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Seroma	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS

Creation Date, Time: 23AUG04 20.58

Note 1: Excludes complications that occurred after explantation, 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 sensation changes, nipple complications, and wrinkling.

Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different severities are counted only once under the greatest severity (ordered as severe, moderate, mild, missing).

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

Table 8.2.1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
0-6 Months	Suture Reaction	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Other	4 (57.1)	3 (42.9)	0 (0.0)	0 (0.0)	7 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ecchymosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implants Riding High	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Mondor's Disease	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Complication Excluding Cosmetic	41 (41.4)	44 (44.4)	14 (14.1)	0 (0.0)	99 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	9 (60.0)	6 (40.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Ptosis	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	3 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
Any Cosmetic Complication	10 (47.6)	11 (52.4)	0 (0.0)	0 (0.0)	21 (100.0)	

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Note 1: Excludes complications that occurred after explantation, 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 sensation changes, nipple complications, and wrinkling.

Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications
with different severities are counted only once under the greatest severity (ordered as severe, moderate, mild, missing).

(a) Percentages are based upon the total number of patients having at least one complication, having at least one non-cosmetic complication, one
cosmetic complication, or each specific complication, as appropriate.

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

Table 8.2 1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
6-12 Months	Total Number of Patients with at Least One Complication	27 (58.7)	15 (32.6)	4 (8.7)	0 (0.0)	46 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	7 (63.6)	4 (36.4)	0 (0.0)	0 (0.0)	11 (100.0)
	Baker III, IV Capsular Contracture	7 (53.8)	5 (38.5)	1 (7.7)	0 (0.0)	13 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Breast Mass	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	External Injury Not Related To Breast Implants	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	10 (66.7)	5 (33.3)	0 (0.0)	0 (0.0)	15 (100.0)
	Other	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	19 (54.3)	12 (34.3)	4 (11.4)	0 (0.0)	35 (100.0)
	II. Cosmetic Complication					
	Hypertrophic Scarring	8 (80.0)	2 (20.0)	0 (0.0)	0 (0.0)	10 (100.0)

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Note 1: Excludes complications that occurred after explantation, 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 sensation changes, nipple complications, and wrinkling.

Note 2. At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different severities are counted only once under the greatest severity (ordered as severe, moderate, mild, missing).

(a) Percentages are based upon the total number of patients having at least one complication, having at least one non-cosmetic complication, one cosmetic complication, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.2.1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
6-12 Months	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	8 (72.7)	3 (27.3)	0 (0.0)	0 (0.0)	11 (100.0)

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Note 1: Excludes complications that occurred after explantation, 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 sensation changes, nipple complications, and wrinkling.

Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different severities are counted only once under the greatest severity (ordered as severe, moderate, mild, missing).

(a) Percentages are based upon the total number of patients having at least one complication, having at least one non-cosmetic complication, one cosmetic complication, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.2.1

POSTOPERATIVE COMPLICATIONS BY SEVERITY (PATIENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Severity				Total (a) n (100%)
		Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	
12-24 Months	Total Number of Patients with at Least One Complication	23 (39.7)	28 (48.3)	7 (12.1)	0 (0.0)	58 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	5 (38.5)	7 (53.8)	1 (7.7)	0 (0.0)	13 (100.0)
	Baker III, IV Capsular Contracture	5 (33.3)	8 (53.3)	2 (13.3)	0 (0.0)	15 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Breast Mass	7 (87.5)	1 (12.5)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Pain	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Breast Sensation Changes	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	2 (25.0)	6 (75.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Rash	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Seroma	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Other	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Anaphylaxis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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