Core Gel Study of the Safety 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

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Any Complication Excluding Cosmetic	15 (35.7)	20 (47.6)	7 (16.7)	0 (0.0)	42 (100.0)
	II. Cosmetic Complication					
	Hypertrophic Scarring	6 (60.0)	4 (40.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Ptosis	4 (57.1)	3 (42.9)	0 (0.0)	0 (0.0)	7 (100.0)
	Wrinkling	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Cosmetic Complication	10 (52.6)	9 (47.4)	0 (0.0)	0 (0.0)	19 (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

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	8 (32.0)	13 (52.0)	3 (12.0)	1 (4.0)	25 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Baker III, IV Capsular Contracture	0 (0.0)	4 (80.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Breast Mass	2 (66.7)	1 (33.3)	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)
	Lactation Difficulties	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)
	Necrosis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	2 (28.6)	5 (71.4)	0 (0.0)	0 (0.0)	7 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Other	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Deep Vein Thrombosis	1 (100.0)	0 (0.0)	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)
	Positive Antinuclear Antibodies Negative For Lupus	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	7 (29 2)	13 (54.2)	3 (12.5)	1 (4.2)	24 (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

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	II. Cosmetic Complication					
	Ptosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Patients with at Least One Complication	21 (20.6)	65 (63.7)	15 (14.7)	1 (1.0)	102 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	1 (5.9)	14 (82.4)	2 (11.8)	0 (0.0)	17 (100.0)
	Baker III, IV Capsular Contracture	1 (5.3)	15 (78.9)	3 (15.8)	0 (0.0)	19 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Breast Mass	8 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Pain	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Hematoma	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Implant Malposition/Displacement	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Infection	1 (7.7)	8 (61.5)	4 (30.8)	0 (0.0)	13 (100.0)
	Lymphadenopathy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)	4 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Necrosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Rheumatic Disease	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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Nipple Sensation Changes	3 (60.0)	2 (40 0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rash	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	0 (0.0)	1 (25.0)	3 (75.0)	0 (0.0)	4 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	3 (25.0)	9 (75.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Other	8 (47.1)	8 (47.1)	1 (5.9)	0 (0.0)	17 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	0 (0.0)	0 (0.0)	1 (100.0)	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)
	Dog Ear Scars From Mastectomy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lack Of Projection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	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.

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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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	19 (23.5)	46 (56.8)	15 (18.5)	1 (1.2)	81 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	14 (100.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Hypertrophic Scarring	5 (35.7)	9 (64.3)	0 (0.0)	0 (0.0)	14 (100.0)
	Ptosis	6 (66.7)	3 (33.3)	0 (0.0)	0 (0.0)	9 (100.0)
	Wrinkling	0 (0.0)	6 (100.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Any Cosmetic Complication	8 (22.9)	27 (77.1)	0 (0.0)	0 (0.0)	35 (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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	10 (17.9)	38 (67.9)	8 (14.3)	0 (0.0)	56 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	2 (25.0)	5 (62.5)	1 (12.5)	0 (0.0)	8 (100.0)
	Baker III, IV Capsular Contracture	2 (22.2)	6 (66.7)	1 (11.1)	0 (0.0)	9 (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 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Hematoma	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implant Malposition/Displacement	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Infection	1 (11.1)	4 (44.4)	4 (44.4)	0 (0.0)	9 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Necrosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Rash	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Seroma	2 (18.2)	9 (81.8)	0 (0.0)	0 (0.0)	11 (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
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Severity: Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Other	4 (36.4)	6 (54.5)	1 (9.1)	0 (0.0)	11 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	7 (16.3)	28 (65.1)	8 (18.6)	0 (0.0)	43 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	7 (100.0)	0 (0.0)	0 (0.0)	7 (100 0)
	Hypertrophic Scarring	4 (50.0)	4 (50.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Ptosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wrinkling	0 (0.0)	4 (100.0)	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).

(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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Any Cosmetic Complication	5 (27.8)	13 (72.2)	0 (0.0)	0 (0.0)	18 (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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	8 (27.6)	16 (55.2)	5 (17.2)	0 (0.0)	29 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	0 (0.0)	5 (83.3)	1 (16.7)	0 (0.0)	6 (100.0)
	Baker III, IV Capsular Contracture	0 (0.0)	5 (71.4)	2 (28.6)	0 (0.0)	7 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Breast Mass	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	0 (0.0)	1 (100.0)	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)
	Infection	0 (0.0)	1 (100.0)	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)
	New Diagnosis of Rheumatic Disease	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Other	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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)
	Tight Benilli Suture	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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Complication Excluding Cosmetic	8 (36.4)	9 (40.9)	5 (22.7)	0 (0.0)	22 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	0 (0.0)	8 (100.0)	0 (0.0)	0 (0.0)	8 (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
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Severity: Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	9 (34.6)	13 (50.0)	3 (11.5)	1 (3.8)	26 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Baker III, IV Capsular Contracture	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Mass	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	0 (0.0)	1 (100.0)	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)
	Infection	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Metastatic Disease	1 (33.3)	0 (0.0)	2 (66.7)	0 (0.0)	3 (100.0)
	Recurrent Breast Cancer	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lack Of Projection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	6 (27.3)	12 (54.5)	3 (13.6)	1 (4.5)	22 (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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ptosis	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	5 (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.

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Table 8.2.1

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

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	6 (35.3)	10 (58.8)	0 (0.0)	1 (5.9)	17 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Baker III, IV Capsular Contracture	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	1 (100.0)	0 (0.0)	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)
	Metastatic Disease	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Necrosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0 0)	1 (100.0)
	Any Complication Excluding Cosmetic	4 (44.4)	4 (44.4)	0 (0.0)	1 (11.1)	9 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ptosis	3 (75.0)	1 (25.0)	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).

(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
RECONSTRUCTION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	3 (33.3)	6 (66.7)	0 (0.0)	0 (0.0)	9 (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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Patients with at Least One Complication	22 (25.3)	45 (51.7)	18 (20.7)	2 (2.3)	87 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	4 (12.5)	24 (75.0)	4 (12.5)	0 (0.0)	32 (100.0)
	Baker III, IV Capsular Contracture	4 (11.8)	21 (61.8)	9 (26.5)	0 (0.0)	34 (100.0)
	Baker IV Capsular Contracture	1 (10.0)	0 (0.0)	9 (90.0)	0 (0.0)	10 (100.0)
	Breast Mass	7 (63.6)	3 (27.3)	1 (9.1)	0 (0.0)	11 (100.0)
	Breast Pain	0 (0.0)	2 (50.0)	2 (50.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	0 (0.0)	3 (75.0)	0 (0.0)	1 (25.0)	4 (100.0)
	Delayed Wound Healing	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	External Injury Not Related To Breast Implants	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extrusion	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Granuloma	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (16.7)	4 (66.7)	1 (16.7)	0 (0.0)	6 (100.0)
	Implant Malposition/Displacement	0 (0.0)	4 (80.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Infection	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Inflammation	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	3 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS Creation Date, Time. 23AUG04 20:58

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Table 8.2.1

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

Time Period	Type of Complication	Severity: Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Nipple Sensation Changes	8 (47.1)	9 (52.9)	0 (0.0)	0 (0.0)	17 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Rupture	0 (0.0)	0 (0.0)	1 (25.0)	3 (75.0)	4 (100.0)
	Seroma	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	8 (66.7)	3 (25.0)	1 (8.3)	0 (0.0)	12 (100.0)
	Abnormal Mammogram	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Back And Neck Pain Related To Large Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Capsule Tear	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	False Positive For Rupture On Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Related Unplanned	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Siliconoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Symmastia	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	20 (26.0)	37 (48.1)	18 (23.4)	2 (2.6)	77 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS
Creation Date, Time: 23AUG04 20:58

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Table 8.2.1

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

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	5 (100.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	6 (50.0)	6 (50.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Ptosis	1 (25.0)	3 (75.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Wrinkling	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	7 (30.4)	16 (69.6)	0 (0.0)	0 (0.0)	23 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS Creation Date, Time: 23AUG04 20:58

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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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	12 (23.5)	29 (56.9)	10 (19 6)	0 (0.0)	51 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	3 (18.8)	10 (62.5)	3 (18.8)	0 (0.0)	16 (100.0)
	Baker III, IV Capsular Contracture	3 (16.7)	9 (50.0)	6 (33.3)	0 (0.0)	18 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	0 (0.0)	5 (100.0)	0 (0.0)	5 (100.0)
	Breast Mass	3 (75.0)	0 (0.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Breast Pain	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	1 (100 0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Granuloma	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	0 (0.0)	4 (80.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Implant Malposition/Displacement	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	5 (55.6)	4 (44.4)	0 (0.0)	0 (0.0)	9 (100.0)
	Seroma	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Capsule Tear	1 (100.0)	0 (0.0)	0 (0 0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	11 (25.0)	23 (52.3)	10 (22.7)	0 (0.0)	44 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	2 (33 3)	4 (66.7)	0 (0.0)	0 (0.0)	6 (100.0)
	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wrinkling	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	2 (18.2)	9 (81.8)	0 (0.0)	0 (0.0)	11 (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
REVISION PATIENTS

Time Period	Type of Complication	Severity: Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	6 (20.0)	19 (63.3)	5 (16.7)	0 (0.0)	30 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	1 (8.3)	10 (83.3)	1 (8.3)	0 (0.0)	12 (100.0)
	Baker III, IV Capsular Contracture	1 (7.7)	9 (69.2)	3 (23.1)	0 (0.0)	13 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Breast Mass	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Pain	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	0 (0.0)	1 (100.0)	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)
	Inflammation	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	3 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Other	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Back And Neck Pain Related To Large Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Complication Excluding Cosmetic	5 (17.9)	18 (64.3)	5 (17.9)	0 (0.0)	28 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hypertrophic Scarring	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	1 (20.0)	4 (80.0)	0 (0.0)	0 (0.0)	5 (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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	13 (38.2)	13 (38.2)	5 (14.7)	3 (8.8)	34 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	3 (30.0)	7 (70.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Baker III, IV Capsular Contracture	2 (18.2)	7 (63.6)	2 (18.2)	0 (0.0)	11 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Breast Mass	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (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)
	Infection	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)	3 (100.0)
	Other	3 (60.0)	1 (20.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Abnormal Mammogram	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Related Unplanned	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Surgical Removal Of Ectopic Pregnancy	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	10 (35.7)	10 (35.7)	5 (17.9)	3 (10.7)	28 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Ptosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	5 (55.6)	4 (44 4)	0 (0.0)	0 (0.0)	9 (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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	3 (25.0)	6 (50.0)	2 (16 7)	1 (8.3)	12 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Baker III, IV Capsular Contracture	2 (50.0)	1 (25.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Baker IV Capsular Contracture	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Breast Mass	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Rupture	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Other	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	False Positive For Rupture On Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Siliconoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	3 (30.0)	4 (40.0)	2 (20.0)	1 (10.0)	10 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	0 (0.0)	1 (100.0)	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).

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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
REVISION PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (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.

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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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Patients with at Least One Complication	122 (32.4)	191 (50.8)	59 (15.7)	4 (1.1)	376 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	18 (20.0)	65 (72.2)	7 (7.8)	0 (0.0)	90 (100.0)
	Baker III, IV Capsular Contracture	18 (18.6)	64 (66.0)	15 (15.5)	0 (0.0)	97 (100.0)
	Baker IV Capsular Contracture	1 (5.3)	5 (26.3)	13 (68.4)	0 (0.0)	19 (100.0)
	Breast Mass	24 (77.4)	6 (19.4)	1 (3.2)	0 (0.0)	31 (100.0)
	Breast Pain	0 (0.0)	10 (58.8)	7 (41.2)	0 (0.0)	17 (100.0)
	Breast Sensation Changes	0 (0.0)	14 (77.8)	3 (16.7)	1 (5.6)	18 (100.0)
	Delayed Wound Healing	0 (0.0)	5 (100.0)	0 (0.0)	0 (0.0)	5 (100.0)
	External Injury Not Related To Breast Implants	4 (44.4)	5 (55.6)	0 (0.0)	0 (0.0)	9 (100.0)
	Extrusion	0 (0.0)	5 (83.3)	1 (16.7)	0 (0.0)	6 (100.0)
	Granuloma	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	9 (39.1)	12 (52.2)	2 (8.7)	0 (0 0)	23 (100.0)
	Implant Malposition/Displacement	0 (0.0)	9 (90.0)	1 (10.0)	0 (0.0)	10 (100.0)
	Infection	6 (26.1)	11 (47.8)	6 (26.1)	0 (0.0)	23 (100.0)
	Inflammation	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Lactation Difficulties	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lymphadenopathy	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Metastatic Disease	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)	4 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS Creation Date, Time: 23AUG04 20:58

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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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Miscarriage	0 (0.0)	0 (0.0)	9 (100.0)	0 (0.0)	9 (100.0)
	Necrosis	1 (33.3)	1 (33.3)	1 (33.3)	0 (0.0)	3 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	1 (16.7)	4 (66.7)	1 (16.7)	0 (0.0)	6 (100.0)
	Nipple Sensation Changes	31 (39.2)	43 (54.4)	5 (6.3)	0 (0.0)	79 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	2 (40.0)	2 (40.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Recurrent Breast Cancer	0 (0.0)	1 (20.0)	4 (80.0)	0 (0.0)	5 (100.0)
	Rupture	0 (0.0)	0 (0.0)	1 (16.7)	5 (83.3)	6 (100.0)
	Seroma	7 (33.3)	13 (61.9)	1 (4.8)	0 (0.0)	21 (100.0)
	Suture Reaction	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Other	25 (56.8)	16 (36.4)	3 (6.8)	0 (0.0)	44 (100.0)
	Abnormal Mammogram	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Anaphylaxis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Back And Neck Pain Related To Large Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Capsule Tear	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	2 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS Creation Date, Time: 23AUG04 20:58

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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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Distortion Of Breast Shape Not Related To Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Dog Ear Scars From Mastectomy	0 (0.0)	1 (100.0)	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)
	Extra Skin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	False Positive For Rupture On Mammogram	1 (100.0)	0 (0.0)	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)
	Lack Of Projection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	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)
	Muscle Spasm	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Complications	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Related Unplanned	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Occasional Burning Discomfort Of Skin	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (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)

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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Siliconoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Stitch Abscess	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)
	Surgical Removal Of Ectopic Pregnancy	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Symmastia	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	98 (31.4)	151 (48.4)	59 (18.9)	4 (1.3)	312 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	22 (100.0)	0 (0.0)	0 (0.0)	22 (100.0)
	Hypertrophic Scarring	33 (55.0)	27 (45.0)	0 (0.0)	0 (0.0)	60 (100.0)
	Ptosis	13 (54.2)	11 (45.8)	0 (0.0)	0 (0.0)	24 (100.0)
	Wrinkling	0 (0.0)	14 (100.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Any Cosmetic Complication	42 (38.9)	66 (61.1)	0 (0.0)	0 (0.0)	108 (100.0)

Program Name: G:\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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	72 (32.7)	116 (52.7)	32 (14.5)	0 (0.0)	220 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	14 (29.2)	30 (62.5)	4 (8.3)	0 (0.0)	48 (100.0)
	Baker III, IV Capsular Contracture	13 (25.5)	31 (60.8)	7 (13.7)	0 (0.0)	51 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	2 (28.6)	5 (71 4)	0 (0.0)	7 (100.0)
	Breast Mass	5 (83.3)	0 (0.0)	1 (16.7)	0 (0.0)	6 (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)	7 (70.0)	3 (30.0)	0 (0.0)	10 (100.0)
	Delayed Wound Healing	0 (0.0)	5 (100.0)	0 (0.0)	0 (0.0)	5 (100.0)
	External Injury Not Related To Breast Implants	1 (25.0)	3 (75.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Extrusion	0 (0.0)	3 (75.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Granuloma	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	7 (36.8)	10 (52.6)	2 (10.5)	0 (0.0)	19 (100.0)
	Implant Malposition/Displacement	0 (0.0)	4 (80.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Infection	6 (33.3)	7 (38 9)	5 (27.8)	0 (0.0)	18 (100.0)
	Inflammation	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Lymphadenopathy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Necrosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	14 (33.3)	23 (54.8)	5 (11.9)	0 (0.0)	42 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	2 (50.0)	1 (25.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Seroma	6 (31.6)	13 (68.4)	0 (0.0)	0 (0.0)	19 (100.0)
	Suture Reaction	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Other	9 (45.0)	10 (50.0)	1 (5.0)	0 (0.0)	20 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Capsule Tear	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	0 (0.0)	0 (0.0)	1 (100.0)	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)
	Dog Ear Scars From Mastectomy	0 (0.0)	1 (100.0)	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)
	Extra Skin	1 (100.0)	0 (0.0)	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)
	Loss Of Inframammary Fold	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).

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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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Mondor's Disease	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Muscle Spasm	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	59 (31.7)	95 (51.1)	32 (17.2)	0 (0.0)	186 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	11 (100.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Hypertrophic Scarring	15 (51.7)	14 (48.3)	0 (0.0)	0 (0.0)	29 (100.0)
	Ptosis	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Wrinkling	0 (0.0)	8 (100.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Any Cosmetic Complication	17 (34.0)	33 (66.0)	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

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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
OVERALL PATIENTS

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	41 (39.0)	50 (47.6)	14 (13.3)	0 (0.0)	105 (100.0)
	I. Complication Excluding Cosmetic					
	Baker III Capsular Contracture	8 (27.6)	19 (65.5)	2 (6.9)	0 (0.0)	29 (100.0)
	Baker III, IV Capsular Contracture	8 (24.2)	19 (57.6)	6 (18.2)	0 (0.0)	33 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	1 (20.0)	4 (80.0)	0 (0.0)	5 (100.0)
	Breast Mass	5 (71.4)	2 (28.6)	0 (0.0)	0 (0.0)	7 (100.0)
	Breast Pain	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
	External Injury Not Related To Breast Implants	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extrusion	0 (0.0)	2 (100.0)	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)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Infection	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	5 (100.0)	0 (0.0)	5 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	13 (65.0)	7 (35.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)

Program Name. Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS Creation Date, Time: 23AUG04 20:58

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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

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

		Severity				
Time Period	Type of Complication	Mild n (%)	Moderate n (%)	Severe n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Other	5 (71.4)	2 (28 6)	0 (0.0)	0 (0.0)	7 (100.0)
	Back And Neck Pain Related To Large Implants	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)
	Muscle Spasm	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)
	Symmastia	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	32 (37.6)	39 (45.9)	14 (16.5)	0 (0.0)	85 (100.0)
	II. Cosmetic Complication					
	Asymmetry	0 (0.0)	5 (100.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	9 (56.3)	7 (43.8)	0 (0.0)	0 (0.0)	16 (100.0)
	Ptosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Wrinkling	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Cosmetic Complication	9 (37.5)	15 (62.5)	0 (0.0)	0 (0.0)	24 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_21.SAS Creation Date, Time: 23AUG04 20:58

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(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.