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 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Suture Reaction	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Other	6 (85.7)	1 (14.3)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implants Riding High	1 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Any Complication Excluding Cosmetic	89 (89.9)	10 (10.1)	0 (0.0)	0 (0.0)	0 (0.0)	99 (100.0)
	II. Cosmetic Complication						
	Asymmetry	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	10 (66.7)	5 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Ptosis	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Wrinkling	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	16 (76.2)	5 (23.8)	0 (0.0)	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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	36 (78.3)	10 (21.7)	0 (0.0)	0 (0.0)	0 (0.0)	46 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	6 (54.5)	5 (45.5)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Baker III, IV Capsular Contracture	8 (61.5)	5 (38.5)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Baker IV Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	2 (66.7)	1 (33.3)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	13 (86.7)	2 (13.3)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Other	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	27 (77.1)	8 (22.9)	0 (0.0)	0 (0.0)	0 (0.0)	35 (100.0)
	II. Cosmetic Complication						
	Hypertrophic Scarring	8 (80.0)	2 (20.0)	0 (0.0)	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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Wrinkling	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	9 (81.8)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0 0)	11 (100.0)

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Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	36 (62.1)	21 (36.2)	0 (0.0)	1 (1.7)	0 (0.0)	58 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	10 (76.9)	3 (23.1)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Baker III, IV Capsular Contracture	12 (80.0)	3 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Baker IV Capsular Contracture	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	3 (37.5)	5 (62.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Pain	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Sensation Changes	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	4 (50.0)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Rash	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Seroma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Anaphylaxis	0 (0.0)	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Any Complication Excluding Cosmetic	25 (59.5)	16 (38.1)	0 (0.0)	1 (2.4)	0 (0.0)	42 (100.0)
	II. Cosmetic Complication						
	Hypertrophic Scarring	8 (80.0)	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Ptosis	2 (28.6)	5 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Wrinkling	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Cosmetic Complication	12 (63.2)	7 (36.8)	0 (0.0)	0 (0.0)	0 (0.0)	19 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	13 (52.0)	11 (44.0)	0 (0.0)	0 (0.0)	1 (4.0)	25 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Baker III, IV Capsular Contracture	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Baker IV Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Mass	1 (33.3)	2 (66.7)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	3 (42.9)	4 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Other	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Deep Vein Thrombosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Positive Antinuclear Antibodies Negative For Lupus	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	13 (54.2)	10 (41.7)	0 (0.0)	0 (0.0)	1 (4.2)	24 (100.0)

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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.

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AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	II. Cosmetic Complication						
	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Patients with at Least One Complication	62 (60.8)	36 (35.3)	3 (2.9)	0 (0.0)	1 (1.0)	102 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	13 (76.5)	4 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Baker III, IV Capsular Contracture	14 (73.7)	5 (26.3)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Baker IV Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	6 (75.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Pain	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Implant Malposition/Displacement	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Infection	12 (92.3)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Lymphadenopathy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Miscarriage	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Necrosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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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RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Nipple Sensation Changes	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rash	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	1 (25.0)	1 (25.0)	2 (50.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	12 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Other	13 (76.5)	4 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Nipple Complications	1 (50.0)	1 (50.0)	0 (0.0)	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)	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)	0 (0.0)	1 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Skin Lesion	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	56 (69.1)	21 (25.9)	3 (3.7)	0 (0.0)	1 (1.2)	81 (100.0)
	II. Cosmetic Complication						
	Asymmetry	12 (85.7)	2 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Hypertrophic Scarring	8 (57.1)	6 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Ptosis	2 (22.2)	7 (77.8)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Wrinkling	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Any Cosmetic Complication	17 (48.6)	18 (51.4)	0 (0.0)	0 (0.0)	0 (0.0)	35 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	47 (83.9)	9 (16.1)	0 (0.0)	0 (0.0)	0 (0.0)	56 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	7 (87.5)	1 (12 5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Baker III, IV Capsular Contracture	8 (88.9)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Baker IV Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Mass	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Pain	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	2 (100.0)	0 (0.0)	0 (0.0)	0 (0 0)	0 (0.0)	2 (100.0)
	Hematoma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implant Malposition/Displacement	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Infection	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Metastatic Disease	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	1 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100 0)
	Rash	1 (100.0)	0 (0.0)	0 (0.0)	0 (0 0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Seroma	11 (100.0)	0 (0.0)	0 (0.0)	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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Other	9 (81.8)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	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)	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)	0 (0.0)	1 (100 0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	38 (88.4)	5 (11.6)	0 (0.0)	0 (0.0)	0 (0.0)	43 (100.0)
	II. Cosmetic Complication						
	Asymmetry	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Hypertrophic Scarring	6 (75.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Wrinkling	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	13 (72.2)	5 (27.8)	0 (0.0)	0 (0.0)	0 (0.0)	18 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	20 (69.0)	9 (31.0)	0 (0.0)	0 (0.0)	0 (0.0)	29 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	5 (83.3)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Baker III, IV Capsular Contracture	5 (71.4)	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Mass	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Recurrent Breast Cancer	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	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)	0 (0.0)	1 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Complication Excluding Cosmetic	16 (72.7)	6 (27.3)	0 (0.0)	0 (0.0)	0 (0.0)	22 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Ptosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wrinkling	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	5 (62.5)	3 (37.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	13 (50.0)	9 (34.6)	3 (11.5)	0 (0.0)	1 (3.8)	26 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Baker III, IV Capsular Contracture	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Mass	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Infection	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Metastatic Disease	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Rupture	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Other	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lack Of Projection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	12 (54.5)	6 (27.3)	3 (13.6)	0 (0.0)	1 (4.5)	22 (100.0)

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Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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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		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	II. Cosmetic Complication						
	Asymmetry	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ptosis	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)

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Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	4 (23.5)	12 (70.6)	1 (5.9)	0 (0.0)	0 (0.0)	17 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	0 (0.0)	2 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Breast Mass	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lymphadenopathy	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Necrosis	0 (0.0)	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)	0 (0.0)	1 (100 0)
	Other	1 (50.0)	1 (50.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	2 (22.2)	6 (66.7)	1 (11.1)	0 (0.0)	0 (0.0)	9 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ptosis	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	2 (22.2)	7 (77.8)	0 (0.0)	0 (0.0)	0 (0.0)	9 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Patients with at Least One Complication	47 (54.0)	38 (43.7)	0 (0.0)	0 (0.0)	2 (2.3)	87 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	21 (65.6)	11 (34.4)	0 (0.0)	0 (0.0)	0 (0.0)	32 (100.0)
	Baker III, IV Capsular Contracture	23 (67.6)	11 (32.4)	0 (0.0)	0 (0.0)	0 (0.0)	34 (100.0)
	Baker IV Capsular Contracture	9 (90.0)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Breast Mass	5 (45.5)	6 (54.5)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Breast Pain	3 (75.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Delayed Wound Healing	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0 0)	4 (100.0)
	External Injury Not Related To Breast Implants	2 (100.0)	0 (0.0)	0 (0 0)	0 (0.0)	0 (0.0)	2 (100 0)
	Extrusion	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Granuloma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Implant Malposition/Displacement	1 (20.0)	4 (80.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Infection	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Inflammation	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Nipple Sensation Changes	12 (70.6)	5 (29.4)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Recurrent Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Rupture	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (75.0)	4 (100.0)
	Seroma	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	10 (83.3)	2 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Capsule Tear	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Related Unplanned	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	47 (61.0)	28 (36.4)	0 (0.0)	0 (0.0)	2 (2.6)	77 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	II. Cosmetic Complication						
	Asymmetry	1 (20.0)	4 (80.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	7 (58.3)	5 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Ptosis	1 (25.0)	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Wrinkling	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	11 (47.8)	12 (52.2)	0 (0.0)	0 (0.0)	0 (0.0)	23 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	40 (78.4)	11 (21.6)	0 (0.0)	0 (0.0)	0 (0.0)	51 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	14 (87.5)	2 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	16 (100.0)
	Baker III, IV Capsular Contracture	16 (88.9)	2 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100.0)
	Baker IV Capsular Contracture	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Breast Mass	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	2 (100.0)	0 (0.0)	0 (0 0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Granuloma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Implant Malposition/Displacement	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	7 (77.8)	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Seroma	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3 1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Capsule Tear	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	37 (84.1)	7 (15.9)	0 (0.0)	0 (0.0)	0 (0.0)	44 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Ptosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wrinkling	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	7 (63.6)	4 (36.4)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)

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Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	18 (60.0)	12 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	30 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	8 (66.7)	4 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Baker III, IV Capsular Contracture	9 (69.2)	4 (30.8)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Baker IV Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Recurrent Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	4 (100.0)	0 (0.0)	0 (0.0)	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)	0 (0.0)	1 (100 0)
	Muscle Spasm	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 3.1

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Complication Excluding Cosmetic	18 (64.3)	10 (35.7)	0 (0.0)	0 (0.0)	0 (0.0)	28 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hypertrophic Scarring	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	14 (41.2)	16 (47.1)	0 (0.0)	1 (2.9)	3 (8.8)	34 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	4 (40.0)	6 (60 0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Baker III, IV Capsular Contracture	5 (45.5)	6 (54.5)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Baker IV Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	1 (50.0)	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)	3 (100.0)
	Other	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Related Unplanned	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	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)	0 (0.0)	1 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Surgical Removal Of Ectopic Pregnancy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	12 (42.9)	12 (42.9)	0 (0.0)	1 (3.6)	3 (10.7)	28 (100.0)
	II. Cosmetic Complication						
	Asymmetry	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Ptosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	5 (55.6)	4 (44.4)	0 (0.0)	0 (0.0)	0 (0.0)	9 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	5 (41.7)	7 (58.3)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Baker III, IV Capsular Contracture	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Baker IV Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0 0)	0 (0.0)	2 (100.0)
	Breast Mass	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Rupture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Siliconoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	5 (50.0)	5 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (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.

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

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Patients with at Least One Complication	243 (64.6)	125 (33.2)	3 (0.8)	1 (0.3)	4 (1.1)	376 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	65 (72.2)	25 (27.8)	0 (0.0)	0 (0.0)	0 (0.0)	90 (100.0)
	Baker III, IV Capsular Contracture	71 (73.2)	26 (26.8)	0 (0.0)	0 (0.0)	0 (0.0)	97 (100.0)
	Baker IV Capsular Contracture	17 (89.5)	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Breast Mass	16 (51.6)	15 (48.4)	0 (0.0)	0 (0.0)	0 (0.0)	31 (100.0)
	Breast Pain	15 (88.2)	1 (5.9)	0 (0.0)	1 (5.9)	0 (0.0)	17 (100.0)
	Breast Sensation Changes	12 (66.7)	6 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100.0)
	Delayed Wound Healing	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	External Injury Not Related To Breast Implants	7 (77.8)	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Extrusion	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Granuloma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	23 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	23 (100.0)
	Implant Malposition/Displacement	6 (60.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100 0)
	Infection	22 (95.7)	1 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	23 (100.0)
	Inflammation	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Lactation Difficulties	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lymphadenopathy	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Metastatic Disease	0 (0.0)	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (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.

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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Miscarriage	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Necrosis	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	5 (83.3)	0 (0.0)	1 (16.7)	0 (0 0)	6 (100.0)
	Nipple Sensation Changes	58 (73.4)	21 (26.6)	0 (0.0)	0 (0.0)	0 (0.0)	79 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Recurrent Breast Cancer	1 (20.0)	2 (40.0)	2 (40.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rupture	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	5 (83 3)	6 (100.0)
	Seroma	21 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	21 (100.0)
	Suture Reaction	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Other	33 (75.0)	11 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	44 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Anaphylaxis	0 (0.0)	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0 0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)

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POSTOPERATIVE COMPLICATIONS BY RESOLUTION (PATIENT LEVEL) - FDA Item 16
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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Dog Ear Scars From Mastectomy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Implants Riding High	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Muscle Spasm	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Complications	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Related Unplanned	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	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)	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)	0 (0.0)	1 (100.0)
	Positive Antinuclear Antibodies Negative For Lupus	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Siliconoma	1 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Wide Scars	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	217 (69.6)	87 (27.9)	3 (1.0)	1 (0.3)	4 (1.3)	312 (100.0)
	II. Cosmetic Complication						
	Asymmetry	16 (72.7)	6 (27.3)	0 (0.0)	0 (0.0)	0 (0.0)	22 (100.0)
	Hypertrophic Scarring	40 (66.7)	20 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	60 (100.0)
	Ptosis	8 (33.3)	16 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	24 (100.0)
	Wrinkling	9 (64.3)	5 (35.7)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Any Cosmetic Complication	63 (58.3)	45 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	108 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	185 (84.1)	35 (15.9)	0 (0.0)	0 (0.0)	0 (0.0)	220 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	43 (89.6)	5 (10.4)	0 (0.0)	0 (0.0)	0 (0.0)	48 (100.0)
	Baker III, IV Capsular Contracture	46 (90.2)	5 (9.8)	0 (0.0)	0 (0.0)	0 (0.0)	51 (100.0)
	Baker IV Capsular Contracture	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Breast Mass	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Breast Pain	8 (88.9)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Breast Sensation Changes	8 (80.0)	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Delayed Wound Healing	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	External Injury Not Related To Breast Implants	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Extrusion	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Granuloma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	19 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Implant Malposition/Displacement	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Infection	18 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100.0)
	Inflammation	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lymphadenopathy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Necrosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	33 (78.6)	9 (21.4)	0 (0.0)	0 (0.0)	0 (0.0)	42 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Recurrent Breast Cancer	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Seroma	19 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Suture Reaction	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Other	17 (85.0)	3 (15.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (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.

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	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)	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)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	164 (88.2)	22 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	186 (100.0)
	II. Cosmetic Complication						
	Asymmetry	10 (90.9)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Hypertrophic Scarring	20 (69.0)	9 (31.0)	0 (0.0)	0 (0.0)	0 (0.0)	29 (100.0)
	Ptosis	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Wrinkling	5 (62.5)	3 (37.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Any Cosmetic Complication	36 (72.0)	14 (28.0)	0 (0.0)	0 (0.0)	0 (0.0)	50 (100.0)

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Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	74 (70.5)	31 (29.5)	0 (0.0)	0 (0.0)	0 (0.0)	105 (100 0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	19 (65.5)	10 (34.5)	0 (0.0)	0 (0.0)	0 (0.0)	29 (100.0)
	Baker III, IV Capsular Contracture	22 (66.7)	11 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	33 (100.0)
	Baker IV Capsular Contracture	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Breast Mass	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Breast Pain	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	2 (50.0)	2 (50.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Extrusion	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0 0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Miscarriage	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	17 (85.0)	3 (15.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Recurrent Breast Cancer	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Other	6 (85.7)	1 (14.3)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	61 (71.8)	24 (28.2)	0 (0.0)	0 (0.0)	0 (0.0)	85 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	12 (75.0)	4 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (100.0)
	Ptosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Wrinkling	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Cosmetic Complication	16 (66.7)	8 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	24 (100.0)

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Table 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	63 (53.4)	46 (39.0)	3 (2.5)	2 (1.7)	4 (3.4)	118 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	17 (63.0)	10 (37.0)	0 (0.0)	0 (0.0)	0 (0.0)	27 (100.0)
	Baker III, IV Capsular Contracture	20 (66.7)	10 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	30 (100.0)
	Baker IV Capsular Contracture	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Breast Mass	4 (28.6)	10 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Breast Pain	5 (83.3)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	6 (100.0)
	Breast Sensation Changes	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hematoma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Implant Malposition/Displacement	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Infection	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Miscarriage	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	8 (61.5)	5 (38.5)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Rash	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)	4 (100.0)

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OVERALL PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Seroma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Other	6 (60.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Anaphylaxis	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Nipple Complications	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Related Unplanned	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	49 (53.3)	34 (37.0)	3 (3.3)	2 (2.2)	4 (4.3)	92 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hypertrophic Scarring	11 (68.8)	5 (31.3)	0 (0.0)	0 (0.0)	0 (0.0)	16 (100.0)
	Ptosis	4 (33.3)	8 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Wrinkling	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Any Cosmetic Complication	19 (57.6)	14 (42.4)	0 (0.0)	0 (0.0)	0 (0.0)	33 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	22 (40.7)	30 (55.6)	1 (1.9)	0 (0.0)	1 (1.9)	54 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	3 (37.5)	5 (62.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Baker III, IV Capsular Contracture	5 (45.5)	6 (54.5)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Baker IV Capsular Contracture	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lymphadenopathy	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Miscarriage	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	3 (33.3)	6 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Rupture	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	2 (100.0)
	Other	4 (57.1)	3 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Deep Vein Thrombosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	False Positive For Rupture On Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.1

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

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Occasional Burning Discomfort Of Skin.	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Positive Antinuclear Antibodies Negative For Lupus	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	20 (46.5)	21 (48.8)	1 (2.3)	0 (0.0)	1 (2.3)	43 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hypertrophic Scarring	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Ptosis	0 (0.0)	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	2 (16.7)	10 (83.3)	0 (0.0)	0 (0.0)	0 (0.0)	12 (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 resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Events with at Least One Complication	192 (71.9)	74 (27.7)	0 (0.0)	0 (0.0)	1 (0.4)	267 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	43 (76.8)	13 (23.2)	0 (0.0)	0 (0.0)	0 (0.0)	56 (100.0)
	Baker III, IV Capsular Contracture	48 (78.7)	13 (21.3)	0 (0.0)	0 (0.0)	0 (0.0)	61 (100.0)
	Baker IV Capsular Contracture	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Breast Mass	6 (46.2)	7 (53.8)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Breast Pain	13 (92.9)	1 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Breast Sensation Changes	13 (72.2)	5 (27.8)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100.0)
	External Injury Not Related To Breast Implants	5 (71.4)	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Granuloma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	14 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Infection	8 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Necrosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	65 (73.0)	24 (27.0)	0 (0.0)	0 (0.0)	0 (0.0)	89 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Rash	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Suture Reaction	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	14 (77.8)	4 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Mondor's Disease	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	2 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0 0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	161 (75.9)	50 (23.6)	0 (0.0)	0 (0.0)	1 (0.5)	212 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	II. Cosmetic Complication						
	Asymmetry	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hypertrophic Scarring	38 (71.7)	15 (28.3)	0 (0.0)	0 (0.0)	0 (0.0)	53 (100.0)
	Ptosis	9 (42.9)	12 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)	21 (100.0)
	Wrinkling	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Any Cosmetic Complication	54 (66.7)	27 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	81 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Events with at Least One Complication	127 (83.6)	25 (16.4)	0 (0.0)	0 (0.0)	0 (0.0)	152 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	27 (93.1)	2 (6.9)	0 (0.0)	0 (0.0)	0 (0.0)	29 (100.0)
	Baker III, IV Capsular Contracture	28 (93.3)	2 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	30 (100.0)
	Baker IV Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Mass	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Pain	9 (90.0)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Breast Sensation Changes	9 (81.8)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	External Injury Not Related To Breast Implants	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Granuloma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	12 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Infection	8 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	36 (76.6)	11 (23.4)	0 (0.0)	0 (0.0)	0 (0.0)	47 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Seroma	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Suture Reaction	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Other	8 (72.7)	3 (27.3)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Mondor's Disease	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	114 (87.0)	17 (13.0)	0 (0.0)	0 (0.0)	0 (0.0)	131 (100.0)
	II. Cosmetic Complication						
	Asymmetry	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hypertrophic Scarring	14 (63.6)	8 (36.4)	0 (0.0)	0 (0.0)	0 (0.0)	22 (100.0)
	Ptosis	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Wrinkling	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	23 (74.2)	8 (25.8)	0 (0.0)	0 (0.0)	0 (0.0)	31 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Events with at Least One Complication	50 (79.4)	13 (20.6)	0 (0.0)	0 (0.0)	0 (0.0)	63 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	9 (60.0)	6 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Baker III, IV Capsular Contracture	12 (66.7)	6 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100.0)
	Baker IV Capsular Contracture	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	External Injury Not Related To Breast Implants	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	21 (91.3)	2 (8.7)	0 (0.0)	0 (0.0)	0 (0.0)	23 (100.0)
	Other	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Pt Requests Removal Due To Personal Reasons	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Complication Excluding Cosmetic	37 (78.7)	10 (21.3)	0 (0.0)	0 (0.0)	0 (0.0)	47 (100.0)
	II. Cosmetic Complication						
	Hypertrophic Scarring	11 (78.6)	3 (21.4)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Wrinkling	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Cosmetic Complication	13 (81.3)	3 (18.8)	0 (0.0)	0 (0.0)	0 (0.0)	16 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Events with at Least One Complication	52 (67.5)	25 (32.5)	0 (0.0)	0 (0.0)	0 (0.0)	77 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	14 (82.4)	3 (17.6)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Baker III, IV Capsular Contracture	16 (84.2)	3 (15.8)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Baker IV Capsular Contracture	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	3 (37.5)	5 (62.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Pain	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	6 (60.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Rash	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Seroma	1 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	32 (71.1)	13 (28.9)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)
	II. Cosmetic Complication						

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

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Hypertrophic Scarring	13 (76.5)	4 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Ptosis	4 (28.6)	10 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Wrinkling	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	20 (58.8)	14 (41.2)	0 (0.0)	0 (0.0)	0 (0.0)	34 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Events with at Least One Complication	18 (54.5)	14 (42.4)	0 (0.0)	0 (0.0)	1 (3.0)	33 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Baker III, IV Capsular Contracture	5 (71.4)	2 (28 6)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Baker IV Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	1 (33.3)	2 (66.7)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100 0)
	Necrosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	5 (41.7)	7 (58.3)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Other	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	18 (58.1)	12 (38.7)	0 (0.0)	0 (0.0)	1 (3.2)	31 (100.0)
	II. Cosmetic Complication						
	Ptosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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. Implant counts exclude events where breast side=N/A.

Note 2. At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR AUGMENTATION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Any Cosmetic Complication	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Events with at Least One Complication	73 (62.9)	39 (33.6)	3 (2.6)	0 (0.0)	1 (0.9)	116 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	15 (78.9)	4 (21.1)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Baker III, IV Capsular Contracture	16 (76.2)	5 (23.8)	0 (0.0)	0 (0.0)	0 (0.0)	21 (100.0)
	Baker IV Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	5 (71.4)	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Breast Pain	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	1 (50 0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100 0)
	Delayed Wound Healing	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Implant Malposition/Displacement	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Infection	12 (92.3)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Lymphadenopathy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rash	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Recurrent Breast Cancer	2 (50.0)	1 (25.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	12 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Other	13 (68.4)	4 (21.1)	2 (10.5)	0 (0.0)	0 (0.0)	19 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Any Complication Excluding Cosmetic	62 (74.7)	17 (20.5)	3 (3.6)	0 (0.0)	1 (1.2)	83 (100.0)
	II. Cosmetic Complication						
	Asymmetry	13 (81.3)	3 (18.8)	0 (0.0)	0 (0.0)	0 (0.0)	16 (100.0)
	Hypertrophic Scarring	8 (53.3)	7 (46.7)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Ptosis	2 (16.7)	10 (83.3)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Wrinkling	4 (50.0)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Any Cosmetic Complication	20 (45.5)	24 (54.5)	0 (0.0)	0 (0.0)	0 (0.0)	44 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Events with at Least One Complication	55 (85.9)	9 (14.1)	0 (0.0)	0 (0.0)	0 (0.0)	64 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	7 (87.5)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Baker III, IV Capsular Contracture	8 (88.9)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Baker IV Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Pain	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implant Malposition/Displacement	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Infection	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Necrosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Rash	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Recurrent Breast Cancer	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Seroma	11 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Other	8 (88.9)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	9 (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. Implant counts exclude events where breast side=N/A.

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	43 (93.5)	3 (6.5)	0 (0.0)	0 (0.0)	0 (0.0)	46 (100.0)
	II. Cosmetic Complication						
	Asymmetry	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Hypertrophic Scarring	7 (87.5)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Ptosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Wrinkling	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Any Cosmetic Complication	15 (71.4)	6 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	21 (100.0)

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Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Events with at Least One Complication	20 (69.0)	9 (31.0)	0 (0.0)	0 (0.0)	0 (0.0)	29 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	7 (87.5)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Baker III, IV Capsular Contracture	7 (77.8)	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	1 (100.0)	0 (0 0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Mass	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)

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Note 2. At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Complication Excluding Cosmetic	16 (76.2)	5 (23.8)	0 (0.0)	0 (0.0)	0 (0.0)	21 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (66.7)	1 (33.3)	0 (0 0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	1 (25.0)	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Ptosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Wrinkling	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	5 (55.6)	4 (44.4)	0 (0.0)	0 (0.0)	0 (0.0)	9 (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. Implant counts exclude events where breast side=N/A.

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Events with at Least One Complication	14 (60.9)	7 (30.4)	1 (4.3)	0 (0 0)	1 (4.3)	23 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Baker III, IV Capsular Contracture	3 (75 0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Mass	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0 0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Infection	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Rupture	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Other	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lack Of Projection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Complication Excluding Cosmetic	14 (70.0)	4 (20.0)	1 (5.0)	0 (0.0)	1 (5.0)	20 (100.0)

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR RECONSTRUCTION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	II. Cosmetic Complication						
	Asymmetry	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hypertrophic Scarring	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ptosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Cosmetic Complication	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)

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IMPLANTS USED FOR RECONSTRUCTION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Events with at Least One Complication	3 (13.6)	17 (77.3)	2 (9.1)	0 (0.0)	0 (0.0)	22 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	0 (0.0)	2 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Breast Mass	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lymphadenopathy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Other	0 (0.0)	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Complication Excluding Cosmetic	1 (10.0)	7 (70.0)	2 (20.0)	0 (0.0)	0 (0.0)	10 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hypertrophic Scarring	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Ptosis	0 (0.0)	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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IMPLANTS USED FOR RECONSTRUCTION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Any Cosmetic Complication	2 (15.4)	11 (84.6)	0 (0.0)	0 (0.0)	0 (0.0)	13 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR REVISION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Events with at Least One Complication	71 (57.7)	49 (39.8)	0 (0.0)	0 (0.0)	3 (2.4)	123 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	26 (65.0)	14 (35.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (100.0)
	Baker III, IV Capsular Contracture	31 (68.9)	14 (31.1)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)
	Baker IV Capsular Contracture	12 (92.3)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Breast Mass	5 (45.5)	6 (54.5)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Breast Pain	3 (60.0)	0 (0.0)	0 (0.0)	2 (40.0)	0 (0.0)	5 (100.0)
	Breast Sensation Changes	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Delayed Wound Healing	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	External Injury Not Related To Breast Implants	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extrusion	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Granuloma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Implant Malposition/Displacement	2 (28.6)	5 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Infection	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lactation Difficulties	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	18 (72.0)	7 (28.0)	0 (0.0)	0 (0.0)	0 (0.0)	25 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Recurrent Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Rupture	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (66.7)	6 (100.0)
	Seroma	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	9 (90.0)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	False Positive For Rupture On Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Related Unplanned	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	66 (64.7)	33 (32.4)	0 (0.0)	0 (0.0)	3 (2.9)	102 (100.0)
	II. Cosmetic Complication						
	Asymmetry	1 (20.0)	4 (80.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	11 (57.9)	8 (42.1)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Ptosis	2 (28.6)	5 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	7 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Wrinkling	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Any Cosmetic Complication	16 (47.1)	18 (52.9)	0 (0.0)	0 (0.0)	0 (0.0)	34 (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. Implant counts exclude events where breast side=N/A.

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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Events with at Least One Complication	54 (77.1)	16 (22.9)	0 (0.0)	0 (0.0)	0 (0.0)	70 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	15 (88.2)	2 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Baker III, IV Capsular Contracture	20 (90.9)	2 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	22 (100.0)
	Baker IV Capsular Contracture	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Breast Mass	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Sensation Changes	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Delayed Wound Healing	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Granuloma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Implant Malposition/Displacement	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	12 (80.0)	3 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Seroma	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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. Implant counts exclude events where breast side=N/A.

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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Capsule Tear	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	49 (83.1)	10 (16.9)	0 (0.0)	0 (0.0)	0 (0.0)	59 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	6 (66.7)	3 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Ptosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Wrinkling	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	10 (62.5)	6 (37.5)	0 (0.0)	0 (0.0)	0 (0.0)	16 (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. Implant counts exclude events where breast side=N/A.

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		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Events with at Least One Complication	22 (62.9)	13 (37.1)	0 (0.0)	0 (0.0)	0 (0.0)	35 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	9 (60.0)	6 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Baker III, IV Capsular Contracture	11 (64.7)	6 (35.3)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Baker IV Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Pain	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Inflammation	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	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)	0 (0.0)	5 (100.0)
	Recurrent Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Muscle Spasm	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Complication Excluding Cosmetic	21 (65.6)	11 (34.4)	0 (0.0)	0 (0.0)	0 (0.0)	32 (100.0)

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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hypertrophic Scarring	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Ptosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (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. Implant counts exclude events where breast side=N/A.

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Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Events with at Least One Complication	19 (43.2)	19 (43.2)	0 (0.0)	2 (4.5)	4 (9.1)	44 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	4 (40.0)	6 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Baker III, IV Capsular Contracture	6 (50.0)	6 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Baker IV Capsular Contracture	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	1 (33.3)	0 (0.0)	0 (0.0)	2 (66.7)	0 (0.0)	3 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lactation Difficulties	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	5 (83.3)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)	4 (100.0)
	Other	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Related Unplanned	0 (0.0)	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)	0 (0.0)	1 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_32.SAS Creation Date, Time: 23AUG04 20:59

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

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR REVISION

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Any Complication Excluding Cosmetic	15 (45.5)	12 (36.4)	0 (0.0)	2 (6.1)	4 (12.1)	33 (100.0)
	II. Cosmetic Complication						
	Asymmetry	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	4 (50.0)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Ptosis	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	7 (50.0)	7 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_32.SAS Creation Date, Time: 23AUG04 20:59

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

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR REVISION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Events with at Least One Complication	7 (46.7)	8 (53.3)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Baker III, IV Capsular Contracture	3 (60.0)	2 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Baker IV Capsular Contracture	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Rupture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Other	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Siliconoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	7 (58.3)	5 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
IMPLANTS USED FOR REVISION

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Ptosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Cosmetic Complication	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (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. Implant counts exclude events where breast side=N/A.

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Events with at Least One Complication	336 (66.4)	162 (32.0)	3 (0.6)	0 (0.0)	5 (1.0)	506 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	84 (73.0)	31 (27.0)	0 (0.0)	0 (0.0)	0 (0.0)	115 (100.0)
	Baker III, IV Capsular Contracture	95 (74.8)	32 (25.2)	0 (0.0)	0 (0.0)	0 (0.0)	127 (100.0)
	Baker IV Capsular Contracture	22 (91.7)	2 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	24 (100.0)
	Breast Mass	16 (51.6)	15 (48.4)	0 (0.0)	0 (0.0)	0 (0.0)	31 (100.0)
	Breast Pain	19 (82.6)	2 (8.7)	0 (0.0)	2 (8.7)	0 (0.0)	23 (100.0)
	Breast Sensation Changes	17 (68.0)	8 (32.0)	0 (0.0)	0 (0.0)	0 (0.0)	25 (100.0)
	Delayed Wound Healing	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	External Injury Not Related To Breast Implants	8 (80.0)	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Extrusion	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Granuloma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	24 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	24 (100.0)
	Implant Malposition/Displacement	8 (61.5)	5 (38.5)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Infection	22 (95.7)	1 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	23 (100.0)
	Inflammation	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Lactation Difficulties	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lymphadenopathy	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Necrosis	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)

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POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	New Diagnosis of Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	87 (73.1)	32 (26.9)	0 (0.0)	0 (0.0)	0 (0.0)	119 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Recurrent Breast Cancer	2 (40.0)	2 (40.0)	1 (20.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rupture	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (75.0)	8 (100.0)
	Seroma	22 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	22 (100.0)
	Suture Reaction	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	36 (76.6)	9 (19.1)	2 (4.3)	0 (0.0)	0 (0.0)	47 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Dog Ear Scars From Mastectomy	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)

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POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Extra Skin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lack Of Projection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	0 (0 0)	2 (100.0)	0 (0 0)	0 (0.0)	2 (100.0)
	Mondor's Disease	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Muscle Spasm	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Complications	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Related Unplanned	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Siliconoma	1 (100.0)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	289 (72.8)	100 (25.2)	3 (0.8)	0 (0.0)	5 (1.3)	397 (100.0)
	II. Cosmetic Complication						
	Asymmetry	18 (72 0)	7 (28.0)	0 (0.0)	0 (0.0)	0 (0.0)	25 (100.0)
	Hypertrophic Scarring	57 (65.5)	30 (34 5)	0 (0.0)	0 (0.0)	0 (0.0)	87 (100.0)
	Ptosis	13 (32.5)	27 (67.5)	0 (0.0)	0 (0.0)	0 (0.0)	40 (100.0)
	Wrinkling	12 (63.2)	7 (36.8)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Any Cosmetic Complication	90 (56.6)	69 (43.4)	0 (0.0)	0 (0.0)	0 (0.0)	159 (100.0)

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Table 8 3 2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Events with at Least One Complication	236 (82.5)	50 (17.5)	0 (0.0)	0 (0 0)	0 (0.0)	286 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	49 (90.7)	5 (9.3)	0 (0.0)	0 (0.0)	0 (0.0)	54 (100.0)
	Baker III, IV Capsular Contracture	56 (91.8)	5 (8.2)	0 (0.0)	0 (0.0)	0 (0.0)	61 (100.0)
	Baker IV Capsular Contracture	7 (100.0)	0 (0.0)	0 (0.0)	0 (0 0)	0 (0.0)	7 (100.0)
	Breast Mass	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Breast Pain	11 (84.6)	2 (15.4)	0 (0.0)	0 (0.0)	0 (0 0)	13 (100.0)
	Breast Sensation Changes	12 (85.7)	2 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Delayed Wound Healing	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	External Injury Not Related To Breast Implants	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Extrusion	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Granuloma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hematoma	20 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Implant Malposition/Displacement	4 (57.1)	3 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Infection	18 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100 0)
	Inflammation	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lymphadenopathy	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	51 (78.5)	14 (21.5)	0 (0.0)	0 (0.0)	0 (0.0)	65 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Recurrent Breast Cancer	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Seroma	20 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Suture Reaction	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	18 (81.8)	4 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	22 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Mondor's Disease	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Muscle Spasm	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8 3 2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Nipple Complications	0 (0.0)	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Skin Lesion	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	206 (87.3)	30 (12 7)	0 (0.0)	0 (0.0)	0 (0.0)	236 (100.0)
	II. Cosmetic Complication						
	Asymmetry	11 (91.7)	1 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Hypertrophic Scarring	27 (69.2)	12 (30.8)	0 (0.0)	0 (0.0)	0 (0.0)	39 (100.0)
	Ptosis	7 (77.8)	2 (22.2)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Wrinkling	6 (54.5)	5 (45.5)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Any Cosmetic Complication	48 (70.6)	20 (29.4)	0 (0.0)	0 (0.0)	0 (0.0)	68 (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. Implant counts exclude events where breast side=N/A.

Note 2. At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Events with at Least One Complication	92 (72.4)	35 (27.6)	0 (0.0)	0 (0.0)	0 (0.0)	127 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	25 (65.8)	13 (34.2)	0 (0.0)	0 (0.0)	0 (0.0)	38 (100.0)
	Baker III, IV Capsular Contracture	30 (68.2)	14 (31.8)	0 (0.0)	0 (0.0)	0 (0.0)	44 (100.0)
	Baker IV Capsular Contracture	5 (83.3)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Breast Mass	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Breast Pain	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	External Injury Not Related To Breast Implants	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extrusion	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	25 (86.2)	4 (13.8)	0 (0.0)	0 (0.0)	0 (0.0)	29 (100.0)
	Recurrent Breast Cancer	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Other	8 (88.9)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	9 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Pt Requests Removal Due To Personal Reasons	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	74 (74.0)	26 (26.0)	0 (0.0)	0 (0.0)	0 (0.0)	100 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	15 (71.4)	6 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	21 (100.0)
	Ptosis	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Wrinkling	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	21 (67.7)	10 (32.3)	0 (0.0)	0 (0.0)	0 (0.0)	31 (100.0)

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Events with at Least One Complication	85 (59.0)	51 (35.4)	1 (0.7)	2 (1.4)	5 (3 5)	144 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	21 (67.7)	10 (32.3)	0 (0.0)	0 (0.0)	0 (0.0)	31 (100.0)
	Baker III, IV Capsular Contracture	25 (71.4)	10 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	35 (100.0)
	Baker IV Capsular Contracture	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Breast Mass	4 (28.6)	10 (71.4)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Breast Pain	6 (75.0)	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	8 (100.0)
	Breast Sensation Changes	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hematoma	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Implant Malposition/Displacement	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Infection	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Lactation Difficulties	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	11 (68.8)	5 (31.3)	0 (0.0)	0 (0.0)	0 (0.0)	16 (100.0)
	Rash	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)	5 (100.0)
	Seroma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Other	6 (75.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Abnormal Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Lack Of Projection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Related Unplanned	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Soft Mass Left Costal Margin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	61 (62.2)	29 (29.6)	1 (1.0)	2 (2.0)	5 (5.1)	98 (100.0)
	II. Cosmetic Complication						
	Asymmetry	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	17 (65.4)	9 (34.6)	0 (0.0)	0 (0.0)	0 (0.0)	26 (100.0)
	Ptosis	6 (30.0)	14 (70.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Wrinkling	3 (75.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	29 (54.7)	24 (45.3)	0 (0.0)	0 (0.0)	0 (0.0)	53 (100.0)

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Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Events with at Least One Complication	28 (40.0)	39 (55.7)	2 (2.9)	0 (0.0)	1 (1.4)	70 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	4 (44.4)	5 (55.6)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Baker III, IV Capsular Contracture	8 (57.1)	6 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Baker IV Capsular Contracture	4 (80.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Breast Mass	3 (50.0)	3 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Breast Sensation Changes	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lymphadenopathy	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	5 (35.7)	9 (64.3)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Rupture	2 (66.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)	3 (100.0)
	Other	4 (50.0)	2 (25.0)	2 (25.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	False Positive For Rupture On Mammogram	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	2 (100.0)	0 (0.0)	0 (0 0)	0 (0.0)	2 (100.0)
	Siliconoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

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

Table 8.3.2

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (IMPLANT LEVEL) - FDA Item 16
OVERALL IMPLANTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	26 (49.1)	24 (45.3)	2 (3.8)	0 (0.0)	1 (1.9)	53 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (40 0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Ptosis	0 (0.0)	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Wrinkling	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	2 (11.1)	16 (88.9)	0 (0.0)	0 (0.0)	0 (0.0)	18 (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. Implant counts exclude events where breast side=N/A.

Note 2: At each level (Total Implants, Any Excluding Cosmetic, Any Cosmetic, individual complications) implants experiencing multiple complications with different resolutions are counted only once under the greatest resolution (ordered as died, ongoing, resolved, unknown, missing).

(a) Percentages are based upon the total number of implants 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 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Complications	301 (77.6)	85 (21.9)	0 (0.0)	1 (0.3)	1 (0.3)	388 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	56 (81.2)	13 (18.8)	0 (0.0)	0 (0.0)	0 (0.0)	69 (100.0)
	Baker III, IV Capsular Contracture	65 (83.3)	13 (16 7)	0 (0.0)	0 (0.0)	0 (0.0)	78 (100.0)
	Baker IV Capsular Contracture	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Breast Mass	7 (50.0)	7 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Breast Pain	13 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (100.0)
	Breast Sensation Changes	13 (76.5)	4 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	External Injury Not Related To Breast Implants	5 (71.4)	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Granuloma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	15 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Infection	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Miscarriage	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Necrosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	69 (73.4)	25 (26.6)	0 (0.0)	0 (0.0)	0 (0.0)	94 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

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Table 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution: Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Rash	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	7 (100.0)	0 (0.0)	0 (0.0)	0 (0 0)	0 (0.0)	7 (100.0)
	Suture Reaction	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	13 (65.0)	7 (35.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Anaphylaxis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Deep Vein Thrombosis	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Mondor's Disease	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Positive Antinuclear Antibodies Negative For Lupus	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	2 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	244 (79.7)	60 (19 6)	0 (0.0)	1 (0.3)	1 (0.3)	306 (100.0)
	II. Cosmetic Complication						

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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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, 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 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Asymmetry	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hypertrophic Scarring	38 (73.1)	14 (26.9)	0 (0.0)	0 (0.0)	0 (0.0)	52 (100.0)
	Ptosis	8 (42.1)	11 (57.9)	0 (0.0)	0 (0.0)	0 (0.0)	19 (100.0)
	Wrinkling	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Any Cosmetic Complication	57 (69.5)	25 (30.5)	0 (0.0)	0 (0.0)	0 (0.0)	82 (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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Table 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Complications	166 (87.4)	24 (12.6)	0 (0.0)	0 (0.0)	0 (0.0)	190 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	29 (93.5)	2 (6.5)	0 (0.0)	0 (0.0)	0 (0.0)	31 (100.0)
	Baker III, IV Capsular Contracture	30 (93.8)	2 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	32 (100.0)
	Baker IV Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Mass	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Breast Pain	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Breast Sensation Changes	9 (81.8)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	External Injury Not Related To Breast Implants	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Granuloma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	12 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Infection	9 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (100.0)
	Inflammation	2 (100.0)	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Miscarriage	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	36 (76.6)	11 (23.4)	0 (0.0)	0 (0.0)	0 (0.0)	47 (100.0)
	Placement Damage	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Seroma	6 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Suture Reaction	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	8 (80.0)	2 (20.0)	0 (0.0)	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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

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Table 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Mondor's Disease	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Complication Excluding Cosmetic	141 (89.2)	17 (10.8)	0 (0.0)	0 (0.0)	0 (0.0)	158 (100.0)
	II. Cosmetic Complication						
	Asymmetry	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hypertrophic Scarring	14 (66.7)	7 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	21 (100.0)
	Ptosis	5 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Wrinkling	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Cosmetic Complication	25 (78.1)	7 (21.9)	0 (0.0)	0 (0.0)	0 (0.0)	32 (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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, 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 8.3 3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Complications	59 (81.9)	13 (18.1)	0 (0.0)	0 (0.0)	0 (0.0)	72 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	9 (60.0)	6 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Baker III, IV Capsular Contracture	12 (66.7)	6 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	18 (100.0)
	Baker IV Capsular Contracture	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	3 (75.0)	1 (25.0)	0 (0.0)	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)	0 (0 0)	2 (100.0)
	Hematoma	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implant Malposition/Displacement	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0 0)	1 (100.0)
	Miscarriage	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	20 (90.9)	2 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	22 (100.0)
	Other	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Pt Requests Removal Due To Personal Reasons	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Any Complication Excluding Cosmetic	46 (82.1)	10 (17.9)	0 (0 0)	0 (0.0)	0 (0.0)	56 (100.0)
	II. Cosmetic Complication						
	Hypertrophic Scarring	11 (78.6)	3 (21.4)	0 (0.0)	0 (0.0)	0 (0.0)	14 (100.0)
	Wrinkling	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

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Table 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

		Resolution					
Time Period	Type of Complication	Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Cosmetic Complication	13 (81.3)	3 (18.8)	0 (0.0)	0 (0.0)	0 (0.0)	16 (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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

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Table 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Complications	55 (63.2)	31 (35.6)	0 (0.0)	1 (1.1)	0 (0.0)	87 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	14 (82.4)	3 (17.6)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Baker III, IV Capsular Contracture	17 (85.0)	3 (15.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (100.0)
	Baker IV Capsular Contracture	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Mass	3 (37.5)	5 (62.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Pain	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Miscarriage	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	6 (60.0)	4 (40.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Rash	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Seroma	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	1 (25.0)	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Anaphylaxis	0 (0.0)	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)	0 (0.0)	1 (100.0)
	Surgical Complication Related To Technique	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	36 (65.5)	18 (32.7)	0 (0.0)	1 (1.8)	0 (0.0)	55 (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.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, 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 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	II. Cosmetic Complication						
	Hypertrophic Scarring	13 (76.5)	4 (23.5)	0 (0.0)	0 (0.0)	0 (0.0)	17 (100.0)
	Ptosis	3 (25.0)	9 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Wrinkling	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	19 (59.4)	13 (40.6)	0 (0.0)	0 (0.0)	0 (0.0)	32 (100.0)

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Table 8.3.3

POSTOPERATIVE COMPLICATIONS BY RESOLUTION (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Resolution					
		Resolved n (%)	Ongoing n (%)	Died n (%)	Unknown n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Complications	21 (53.8)	17 (43.6)	0 (0.0)	0 (0.0)	1 (2.6)	39 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	4 (66.7)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (100.0)
	Baker III, IV Capsular Contracture	6 (75.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Baker IV Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	1 (33.3)	2 (66.7)	0 (0.0)	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)	0 (0.0)	2 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0 0)	1 (100 0)
	Miscarriage	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Necrosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	7 (46.7)	8 (53.3)	0 (0.0)	0 (0.0)	0 (0.0)	15 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Other	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Deep Vein Thrombosis	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Explanted Due To Right Side Being Removed	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Positive Antinuclear Antibodies Negative For Lupus	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	21 (56.8)	15 (40.5)	0 (0.0)	0 (0.0)	1 (2.7)	37 (100.0)
	II. Cosmetic Complication						
	Ptosis	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)

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