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 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	New Diagnosis of Rheumatic Disease	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	3 (60.0)	0 (0.0)	0 (0.0)	1 (20.0)	1 (20.0)	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	0 (0.0)	0 (0.0)	1 (25.0)	3 (75.0)	0 (0.0)	4 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	11 (91.7)	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)	12 (100.0)
	Other	9 (52.9)	1 (5.9)	4 (23.5)	3 (17.6)	0 (0.0)	17 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	0 (0.0)	0 (0.0)	1 (100.0)	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)

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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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Occasional Burning Discomfort Of Skin.	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	39 (48.1)	4 (4.9)	19 (23.5)	17 (21.0)	2 (2.5)	81 (100.0)
	II. Cosmetic Complication						
	Asymmetry	6 (42.9)	0 (0.0)	3 (21.4)	5 (35.7)	0 (0.0)	14 (100.0)
	Hypertrophic Scarring	11 (78.6)	0 (0.0)	2 (14.3)	1 (7.1)	0 (0.0)	14 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	4 (44.4)	5 (55.6)	0 (0.0)	9 (100.0)
	Wrinkling	1 (16.7)	0 (0.0)	4 (66.7)	1 (16.7)	0 (0.0)	6 (100.0)
	Any Cosmetic Complication	17 (48.6)	0 (0.0)	7 (20.0)	11 (31.4)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	34 (60.7)	3 (5.4)	8 (14.3)	11 (19.6)	0 (0.0)	56 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	1 (12.5)	2 (25.0)	3 (37.5)	2 (25.0)	0 (0.0)	8 (100.0)
	Baker III, IV Capsular Contracture	1 (11.1)	3 (33.3)	3 (33.3)	2 (22.2)	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	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Breast Pain	1 (50.0)	0 (0.0)	0 (0.0)	1 (50.0)	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	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Extrusion	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implant Malposition/Displacement	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Infection	5 (55.6)	0 (0.0)	3 (33.3)	1 (11.1)	0 (0.0)	9 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	1 (50.0)	0 (0.0)	0 (0.0)	1 (50.0)	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	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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.

Table 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Seroma	11 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (100.0)
	Other	6 (54.5)	0 (0.0)	2 (18.2)	3 (27.3)	0 (0.0)	11 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	0 (0.0)	0 (0.0)	1 (100.0)	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)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	24 (55.8)	3 (7.0)	8 (18.6)	8 (18.6)	0 (0.0)	43 (100.0)
	II. Cosmetic Complication						
	Asymmetry	3 (42.9)	0 (0.0)	1 (14.3)	3 (42.9)	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.

Note 2: At each level (Total Patients, Any Excluding Cosmetic, Any Cosmetic, individual complications) patients experiencing multiple complications with different causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

		Causality					
Time Period	Type of Complication	Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Hypertrophic Scarring	7 (87.5)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	8 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Wrinkling	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	11 (61.1)	0 (0.0)	3 (16.7)	4 (22.2)	0 (0.0)	18 (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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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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POSTOPERATIVE COMPLICATIONS BY CAUSALITY (PATIENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	8 (27.6)	1 (3.4)	9 (31.0)	11 (37.9)	0 (0.0)	29 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	0 (0.0)	1 (16.7)	3 (50.0)	2 (33.3)	0 (0.0)	6 (100.0)
	Baker III, IV Capsular Contracture	0 (0.0)	1 (14.3)	3 (42.9)	3 (42.9)	0 (0.0)	7 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Breast Mass	0 (0.0)	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Breast Pain	0 (0.0)	0 (0.0)	1 (100.0)	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)
	Extrusion	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Other	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	0 (0.0)	1 (100.0)	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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Table 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
6-12 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	5 (22.7)	1 (4.5)	8 (36.4)	8 (36.4)	0 (0.0)	22 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	3 (75.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Wrinkling	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	3 (37.5)	0 (0.0)	2 (25.0)	3 (37.5)	0 (0.0)	8 (100.0)

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Table 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	8 (30.8)	1 (3.8)	11 (42.3)	5 (19.2)	1 (3.8)	26 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	3 (75.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Baker III, IV Capsular Contracture	3 (75.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Breast Mass	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Breast Pain	0 (0.0)	0 (0.0)	1 (100.0)	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	1 (33.3)	0 (0.0)	2 (66.7)	0 (0.0)	0 (0.0)	3 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	1 (33.3)	2 (66.7)	0 (0.0)	3 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Seroma	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Other	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Lack Of Projection	0 (0.0)	1 (100.0)	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)

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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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Table 8.5 1

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

		Causality					
Time Period	Type of Complication	Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Any Complication Excluding Cosmetic	8 (36.4)	1 (4.5)	8 (36.4)	4 (18.2)	1 (4.5)	22 (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	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	1 (20.0)	0 (0.0)	3 (60.0)	1 (20.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number of Patients with at Least One Complication	7 (41.2)	0 (0.0)	4 (23.5)	5 (29.4)	1 (5.9)	17 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Baker III, 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)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Other	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	4 (44.4)	0 (0.0)	2 (22.2)	2 (22.2)	1 (11.1)	9 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Ptosis	0 (0.0)	0 (0.0)	2 (50.0)	2 (50.0)	0 (0.0)	4 (100.0)
	Wrinkling	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	3 (33.3)	0 (0.0)	2 (22.2)	4 (44.4)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 5.1

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

		Causality					
Time Period	Type of Complication	Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Total Number of Patients with at Least One Complication	35 (40.2)	15 (17.2)	25 (28.7)	10 (11.5)	2 (2.3)	87 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	3 (9.4)	13 (40.6)	14 (43.8)	2 (6.3)	0 (0.0)	32 (100.0)
	Baker III, IV Capsular Contracture	3 (8.8)	15 (44.1)	14 (41.2)	2 (5 9)	0 (0.0)	34 (100.0)
	Baker IV Capsular Contracture	2 (20.0)	6 (60.0)	2 (20.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Breast Mass	1 (9.1)	0 (0.0)	6 (54.5)	4 (36.4)	0 (0.0)	11 (100.0)
	Breast Pain	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Breast Sensation Changes	3 (75.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Delayed Wound Healing	2 (50.0)	0 (0.0)	0 (0.0)	2 (50.0)	0 (0.0)	4 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Extrusion	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Granuloma	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Hematoma	2 (33.3)	0 (0.0)	1 (16.7)	3 (50.0)	0 (0.0)	6 (100.0)
	Implant Malposition/Displacement	2 (40.0)	0 (0.0)	3 (60.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Infection	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Inflammation	0 (0.0)	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Lactation Difficulties	0 (0 0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

		Causality					
Time Period	Type of Complication	Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	New Diagnosis of Rheumatic Disease	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	13 (76.5)	0 (0.0)	2 (11.8)	2 (11.8)	0 (0.0)	17 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Rupture	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	3 (75.0)	4 (100.0)
	Seroma	3 (75.0)	0 (0.0)	0 (0.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Other	1 (8.3)	1 (8.3)	4 (33 3)	6 (50.0)	0 (0.0)	12 (100.0)
	Abnormal Mammogram	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Back And Neck Pain Related To Large Implants	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Capsule Tear	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	False Positive For Rupture On Mammogram	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Siliconoma	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Symmastia	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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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POSTOPERATIVE COMPLICATIONS BY CAUSALITY (PATIENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Any Complication Excluding Cosmetic	26 (33.8)	15 (19.5)	24 (31.2)	10 (13.0)	2 (2.6)	77 (100.0)
	II. Cosmetic Complication						
	Asymmetry	1 (20.0)	0 (0.0)	3 (60.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	9 (75.0)	0 (0.0)	1 (8.3)	2 (16.7)	0 (0.0)	12 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	2 (50.0)	2 (50.0)	0 (0.0)	4 (100.0)
	Wrinkling	1 (25.0)	2 (50.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	11 (47.8)	2 (8.7)	5 (21.7)	5 (21.7)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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.

Table 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number of Patients with at Least One Complication	22 (43.1)	10 (19.6)	12 (23.5)	7 (13.7)	0 (0.0)	51 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	1 (6.3)	8 (50.0)	6 (37.5)	1 (6.3)	0 (0.0)	16 (100.0)
	Baker III, IV Capsular Contracture	1 (5.6)	10 (55.6)	6 (33.3)	1 (5.6)	0 (0.0)	18 (100.0)
	Baker IV Capsular Contracture	1 (20.0)	3 (60.0)	1 (20.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Breast Mass	0 (0.0)	0 (0.0)	2 (50.0)	2 (50.0)	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	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Delayed Wound Healing	2 (50.0)	0 (0.0)	0 (0.0)	2 (50.0)	0 (0.0)	4 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Hematoma	2 (40.0)	0 (0.0)	1 (20.0)	2 (40.0)	0 (0.0)	5 (100.0)
	Implant Malposition/Displacement	2 (66.7)	0 (0.0)	1 (33.3)	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	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	8 (88.9)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)	9 (100.0)
	Seroma	3 (75.0)	0 (0.0)	0 (0.0)	1 (25.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Other	0 (0.0)	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Capsule Tear	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	18 (40.9)	10 (22.7)	9 (20.5)	7 (15.9)	0 (0.0)	44 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	4 (66.7)	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	6 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wrinkling	1 (33.3)	1 (33.3)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	5 (45.5)	1 (9.1)	4 (36.4)	1 (9.1)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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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POSTOPERATIVE COMPLICATIONS BY CAUSALITY (PATIENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number of Patients with at Least One Complication	7 (23.3)	5 (16.7)	13 (43.3)	5 (16.7)	0 (0.0)	30 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	1 (8.3)	5 (41.7)	6 (50.0)	0 (0.0)	0 (0.0)	12 (100.0)
	Baker III, IV Capsular Contracture	2 (15.4)	5 (38.5)	6 (46.2)	0 (0.0)	0 (0.0)	13 (100.0)
	Baker IV Capsular Contracture	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Pain	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Extrusion	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Nipple Sensation Changes	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Other	1 (25.0)	0 (0.0)	2 (50.0)	1 (25.0)	0 (0.0)	4 (100.0)
	Back And Neck Pain Related To Large Implants	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	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	0 (0.0)	0 (0.0)	2 (100.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Any Complication Excluding Cosmetic	6 (21.4)	5 (17.9)	12 (42.9)	5 (17.9)	0 (0.0)	28 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hypertrophic Scarring	1 (50.0)	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	1 (20.0)	0 (0.0)	3 (60.0)	1 (20.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, 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 8.5.1

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

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number of Patients with at Least One Complication	8 (23.5)	4 (11.8)	11 (32.4)	8 (23.5)	3 (8.8)	34 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	2 (20.0)	2 (20.0)	4 (40.0)	2 (20.0)	0 (0.0)	10 (100.0)
	Baker III, IV Capsular Contracture	2 (18.2)	3 (27.3)	4 (36.4)	2 (18.2)	0 (0.0)	11 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Mass	0 (0.0)	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Breast Pain	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Hematoma	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Implant Malposition/Displacement	0 (0 0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Infection	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lactation Difficulties	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Sensation Changes	4 (80.0)	0 (0.0)	1 (20.0)	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	0 (0.0)	0 (0.0)	2 (40.0)	3 (60.0)	0 (0.0)	5 (100.0)
	Abnormal Mammogram	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Nipple Related Unplanned	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	0 (0.0)	1 (100.0)	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 causalities are counted only once under the most severe causality (ordered as procedure related, device related, unknown, other, missing).

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Table 8.5 1

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

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	5 (17.9)	3 (10.7)	11 (39.3)	6 (21.4)	3 (10.7)	28 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Hypertrophic Scarring	4 (80.0)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	5 (100 0)
	Ptosis	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	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	4 (44.4)	1 (11.1)	0 (0.0)	4 (44.4)	0 (0.0)	9 (100.0)

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