Quick Facts about

BREAST AUGMENTATION & RECONSTRUCTION

with

MENTOR® MemoryShape™ Breast Implants

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Quick Facts about
Breast Augmentation & Reconstruction
with
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ABOUT THIS BROCHURE

This brochure is intended to provide you with a high level overview of the facts about breast implant surgery with Mentor's FDA-Approved MemoryShape™ Breast Implants. This brochure is not intended to replace consultation with your surgeon. For a complete review of the benefits and risks of breast implant surgery, please read the appropriate patient educational brochure, Breast Augmentation with MENTOR® MemoryShape™ Breast Implants or Breast Reconstruction with MENTOR® MemoryShape™ Breast Implants, available from your surgeon and posted on www.mentorwwllc.com. You may also contact Mentor directly at 1 (800) MENTOR8 for a copy of the brochure.

INDICATIONS

Mentor's MemoryShape™ Breast Implants are indicated for:

- Breast augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation as well as revision surgery to correct or improve the result of primary breast augmentation surgery.
- Breast reconstruction. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery.

RISKS ASSOCIATED WITH BREAST IMPLANTS

Undergoing any type of surgery involves risks. There are a number of local complications (problems at or near the breast/surgical incision site) that may occur after your breast implant surgery.

COMPLICATIONS

Complications are defined as adverse events occurring in connection with the breast implant surgery, breast implants and/or the breast mound, and systemic diseases. The definition of a few key terms may assist the reader in understanding the complications presented below.

- MRI Cohort: A randomized subset of subjects who were to undergo MRI scans at 1, 2, 4, 6, 8, and 10 years after implant surgery.
- Non-MRI Cohort: Subjects who were not a part of the original MRI cohort but who were later asked to undergo MRI scans at 6, 8, and 10 years after implant surgery.

- Capsular Contracture Baker Grade: Normally, a healing scar forms an envelope around the implant, which, on occasion, will shrink sufficiently to squeeze the implant, producing varying degrees of firmness. The implant can feel hard, be painful and/or distorted. Capsular contracture is graded in severity on a scale of I to IV by Baker classification, with Grade I being the mildest and Grade IV being the most severe.

The tables below present the complication rates reported in Mentor's MemoryShape™ Breast Implant Core Study through 3 years and 6 years for primary augmentation and revision-augmentation patients (Table 1) and for primary reconstruction and revision-reconstruction patients (Table 2).

Table 1. Complication Rates Reported Through 3 Years and 6 Years for Primary Augmentation (N=572) and Revision-Augmentation (N=124) Patients

	Primary Augmentation		Revision-Augmentation	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Any Complication Excluding Rupture	35.0	44.8	41.0	53.3
Key Complications				
Any Reoperation	13.6	18.1	18.2	24.1
Capsular Contracture Baker Grade III, IV	1.1	2.4	5.2	9.7
Implant Removal with or without Replacement	5.0	7.0	10.8	13.6
Implant Removal with Replacement with Study Device	1.8	2.5	4.2	5.3
Implant Rupture (Based on the MRI Cohort)[1]	-	2.6	-	3.6
Infection	0.9	0.9	0.8	2.1
Other Complications Occurring at a Rate of 1% or Greater[2]				
Asymmetry[3]	0.7	0.7	1.7	1.7
Breast Pain[3]	2.2	2.4	0.9	0.9
Breast Sensation Changes[3]	2.7	3.6	2.7	2.7
Calcification[3]	0.2	0.4	0	1.1
Capsular Contracture Baker Grade II with Surgical Intervention	0.6	0.6	1.7	1.7
Capsular Contracture Baker Grade III	1.1	2.4	3.4	5.5
Capsular Contracture Baker Grade IV	0.2	0.2	1.7	4.2
Delayed Wound Healing[3]	0.2	0.2	0	1.2
Fibrocystic Disease	0.2	0.7	0	1.2
Hematoma	1.2	1.2	0	0
Hypertrophic Scarring	2.5	2.5	3.4	3.4
Implant Rotation	1.1	1.1	2.6	2.6

Table 1. *continued to next page*

Table 1. *(continued)*

	Primary Augmentation		Revision-Augmentation	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Other Complications Occurring at a Rate of 1% or Greater[2]				
Mass/Cyst	3.7	5.9	5.4	6.6
Miscarriage	0.8	1.6	0	1.1
New Diagnosis of Rheumatic Disease[4]	0.4	1.4	0.9	0.9
Nipple Complication	0.3	0.3	0	1.1
Nipple Sensation Changes[3]	3.7	4.4	5.3	5.3
Palpability-Implant[3]	0.7	0.9	2.6	3.5
Patient Dissatisfied with Aesthetic Appearance of Breast	2.2	2.8	2.6	8.1
Patient Dissatisfied with Feel of Implant	0.9	1.1	3.4	4.6
Patient Would Not Make Decision to Have Breast Surgery Again	0.4	0.6	0	1.2
Position Dissatisfaction[3]	1.8	2.0	2.7	3.7
Ptosis (Sagging)	7.9	14.6	5.3	14.4
Scarring	2.2	2.4	0	2.2
Size Change – Patient Request	3.3	3.7	6.6	6.6
Size Change – Physician Assessment Only	0.2	0.2	1.7	1.7
Skin Lesion	0.5	0.8	0	1.1
Tenderness/Soreness	0.4	0.8	0	1.3
Wound Opening (Dehiscence)	0.7	0.7	2.4	2.4
Wrinkling[3]	1.8	2.7	4.9	5.9

[1] Rupture was assessed by MRI at 1, 2, 4, and 6 years (results are provided in Table 10 of the appropriate Patient Educational Brochure); there were also 2 cases of rupture reported through 6 years in the non-MRI cohort (1 primary augmentation and 1 revision-augmentation).

[2] The following complications occurred at a rate less than 1%: bruising, death[5], granuloma, implant movement upon muscle contraction, implant outline visible through skin, intermittent pop while wearing a certain type of bra, irritation/inflammation, lack of projection, lactation difficulties, loss of definition of inframammary fold, metastatic disease, new diagnosis of breast cancer, other: missing, numbness/tingling (paresthesia), rash, seroma, shape distortion, suture complication, swelling (excessive), thickened capsule.

[3] Mild occurrences not included.

[4] There were 10 diagnoses in 7 primary augmentation patients: spondyarthropathies (25 months post implantation), other connective tissue disease (35 months post implantation), Sjögren's syndrome (35 and 42 months post implantation), systemic lupus erythematosus (35, 42, and 44 months post implantation), fibromyalgia (36 and 37 months post implantation), and undifferentiated connective tissue disease (41 months post implantation). There was 1 diagnosis for the revision-augmentation patient: rheumatoid arthritis (11 months post implantation).

[5] All causes of death were reported by the Investigator to be unrelated to study procedure or device.

Table 2. Complication Rates Reported through 3 Years and 6 Years for Primary Reconstruction (N=191) and Revision-Reconstruction (N=68) Patients

	Primary Reconstruction		Revision-Reconstruction	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Any Complication Excluding Rupture	54.4	64.9	55.5	67.6
Key Complications				
Any Reoperation	36.1	44.5	28.4	45.4
Capsular Contracture Baker Grade III, IV	5.6	10.1	13.5	16.4
Implant Removal with or without Replacement	13.8	21.8	21.0	34.2
Implant Removal with Replacement with Study Device	6.0	7.4	4.4	10.8
Implant Rupture (Based on the MRI Cohort)[1]	-	1.6	-	0
Infection	1.6	1.6	3.0	3.0
Other Complications Occurring at a Rate of 1% or Greater[2]				
Asymmetry[3]	6.0	10.6	6.1	6.1
Breast Pain[3]	2.8	2.8	3.3	3.3
Breast Sensation Changes[3]	1.1	1.1	0	0
Capsular Contracture Baker Grade II with Surgical Intervention	1.7	4.2	1.5	3.7
Capsular Contracture Baker Grade III	4.6	9.1	13.5	13.5
Capsular Contracture Baker Grade IV	1.6	1.6	0	3.0
Death[4]	1.1	4.5	1.7	1.7
Delayed Wound Healing[3]	1.0	1.0	0	0
Excess Skin/Tissue	4.3	4.3	1.6	1.6
Gel Fracture[5]	0	0	0	2.0
Hematoma	0	0	1.5	1.5
Hypertrophic Scarring	1.1	2.4	0	0
Implant Immobility	2.4	3.8	1.9	1.9
Implant Rotation	3.4	5.1	1.5	1.5
Irritation/Inflammation	2.1	2.1	3.0	3.0
Itching	0.5	1.3	0	0
Lack of Projection	5.0	8.5	11.8	13.7
Loss of Definition of Inframammary Fold	1.7	2.3	1.5	1.5
Mass/Cyst	2.8	4.6	0	0
Metastatic Disease	2.3	2.3	1.6	1.6
Miscarriage	0.6	2.1	0	0

Table 2. *continued to next page*

Table 2. *(continued)*

	Primary Reconstruction		Revision-Reconstruction	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Other Complications Occurring at a Rate of 1% or Greater[2]				
Muscle Atrophy	0	0.6	1.5	1.5
New Diagnosis of Rheumatic Disease[6]	1.7	1.7	0	0
Nipple Sensation Changes[3]	2.3	2.9	0	0
Numbness/Tingling (Paresthesia)	0	0	3.4	3.4
Other: Missing	0	1.6	0	0
Palpability-Implant[3]	0	0.7	3.5	3.5
Patient Dissatisfied with Aesthetic Appearance of Breast	2.2	5.1	6.3	8.4
Patient Dissatisfied with Feel of Implant	1.7	1.7	1.5	3.8
Position Dissatisfaction[3]	0.5	2.1	4.9	4.9
Ptosis (Sagging)	2.9	5.8	5.0	12.2
Recurrent Breast Cancer	1.7	2.5	1.5	3.6
Redness (Erythema)	0	0	1.5	1.5
Scarring	2.9	2.9	1.5	6.5
Seroma	2.7	3.4	4.6	4.6
Shape Distortion	0	1.6	0	0
Silicone from Previous Rupture	0	0	1.5	1.5
Size Change – Patient Request	5.0	5.0	7.8	9.9
Size Change – Physician Assessment Only	2.1	2.1	0	4.8
Skin Lesion	1.1	1.8	1.8	4.3
Suture Complication	1.7	1.7	0	0
Swelling (Excessive)	0.5	0.5	1.5	1.5
Tenderness/Soreness	0.5	1.4	0	0
Wrinkling[3]	3.3	4.0	9.5	12.2

[1] Rupture was assessed by MRI at 1, 2, 4, and 6 years (results are provided in Table 10 of the appropriate Patient Educational Brochure); there were no cases of rupture reported through 6 years in the non-MRI cohort of primary reconstruction and revision-reconstruction patients.

[2] The following complications occurred at a rate less than 1%: capsular contracture Baker Grade unknown, external injury not related to breast implants, necrosis, new diagnosis of breast cancer, nipple complication, symmastia, wound opening (dehiscence).

[3] Mild occurrences not included.

[4] All causes of death were reported by the Investigator to be unrelated to study procedure or device.

[5] Gel fracture occurred in 1 revision-reconstruction patient.

[6] There were 3 diagnoses in 3 primary reconstruction patients: rheumatoid arthritis (10 months post implantation), other inflammatory arthritis (11 months post implantation), and other mechanical/degenerative condition (16 months post implantation).

OTHER REPORTED CONDITIONS

There have been reports in the literature of other conditions in women with silicone gel breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause and effect relationship has been established between breast implants and the conditions listed below. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants. It should also be noted that the conditions listed below were reported by both augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

- Connective tissue diseases such as: lupus, scleroderma, rheumatoid arthritis, and fibromyalgia.
- Rheumatological signs and symptoms such as: fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes.
- Cancer, such as: breast cancer, brain cancer, respiratory/lung cancer, reproductive system cancers (cervical/vulvar cancer), lympho-hematopoietic cancers including anaplastic large cell lymphoma (ALCL), and other cancers.
- Neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis).
- Suicide
- Effects on children born to mothers with breast implants, or effects on children from breastfeeding.
- Potential health consequences of gel bleed.

IMPLANT REMOVAL

Breast implants may be removed (with or without replacement) in response to a complication or to improve the cosmetic result. In Mentor's MemoryShape™ Breast Implant Core Study, through 6 years, the most common reason for implant removal in all four study cohorts was patient request for an implant size change.

Figures 1 through 4 below present the reasons for implant removal in Mentor's MemoryShape™ Breast Implant Core Study through 3 years and 6 years. Note that the 6-year results also include any events that occurred by 3 years.

Figure 1. Reasons for Implant Removal Through 3 Years and 6 Years

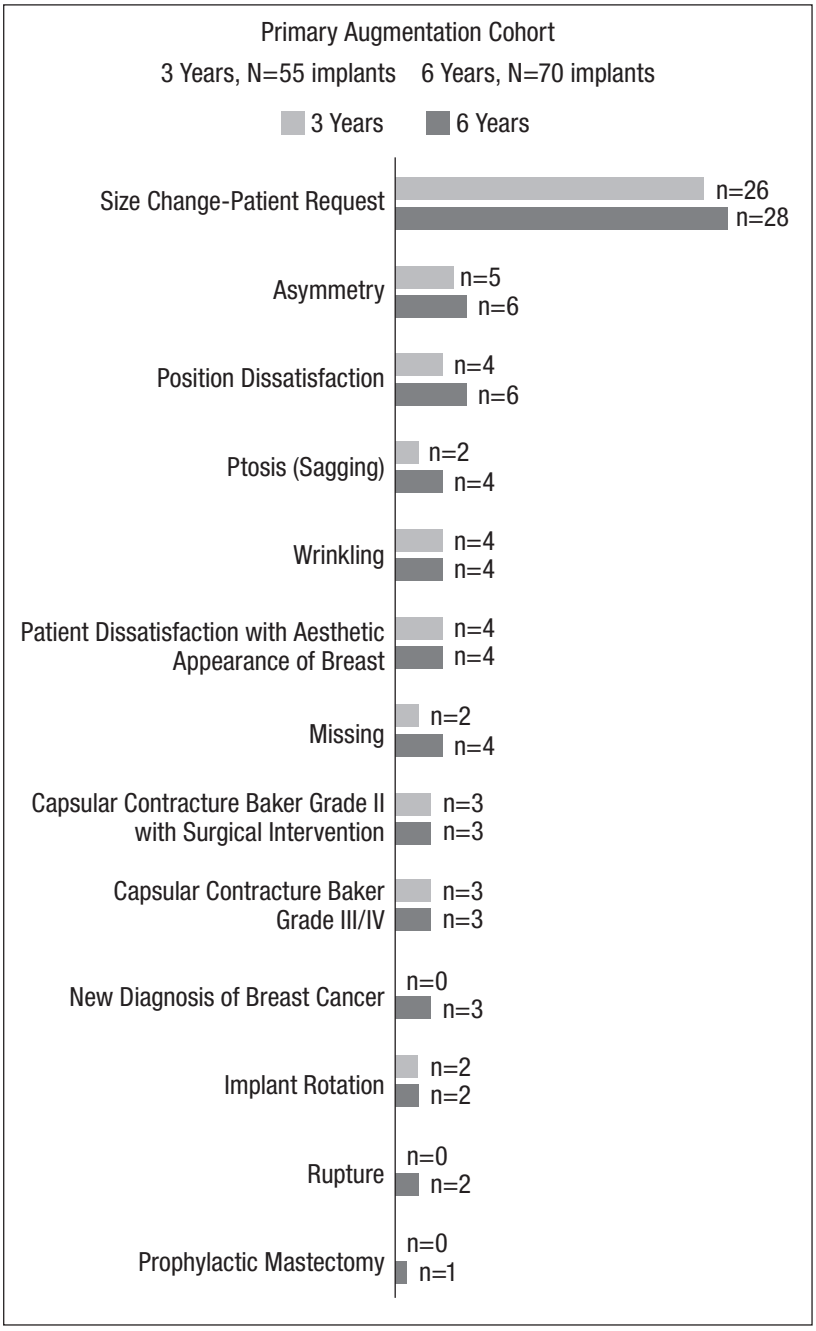


Figure 2. Reasons for Implant Removal Through 3 Years and 6 Years

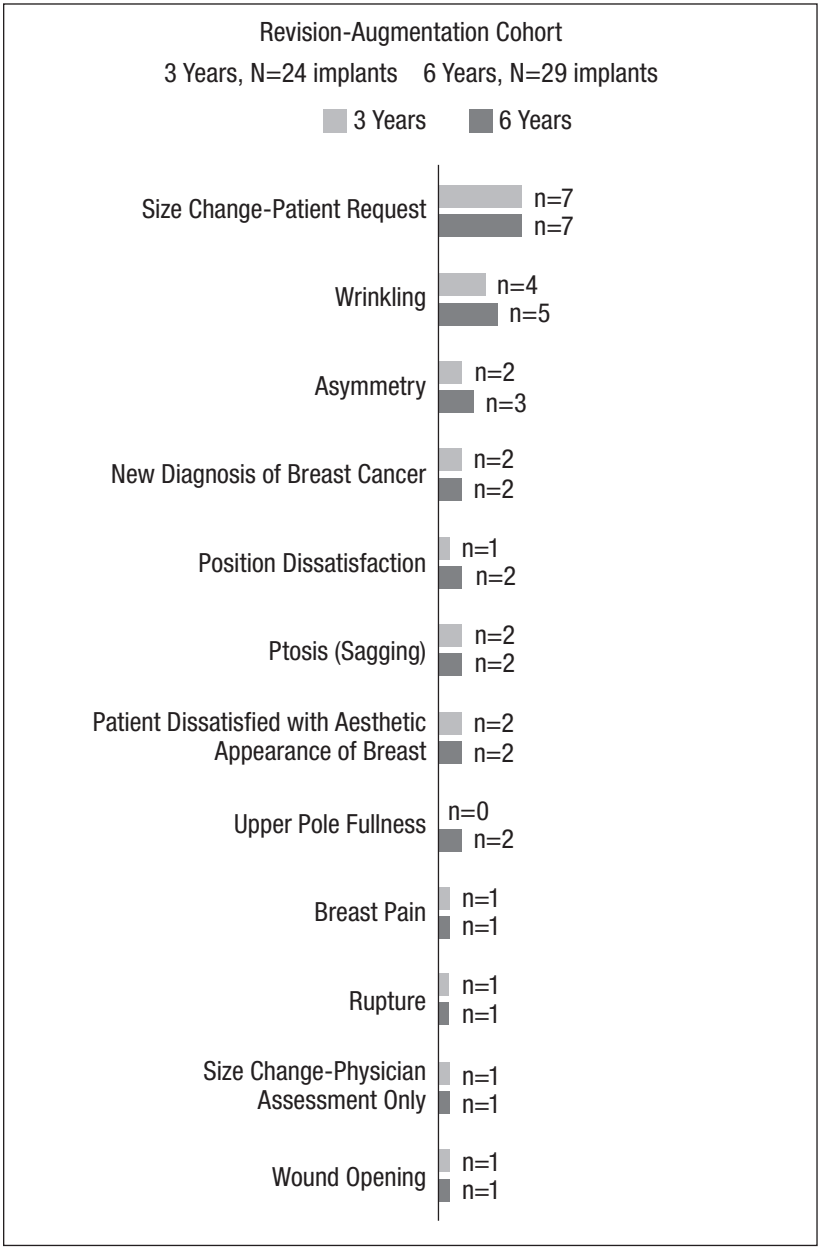


Figure 3. Reasons for Implant Removal Through 3 Years and 6 Years

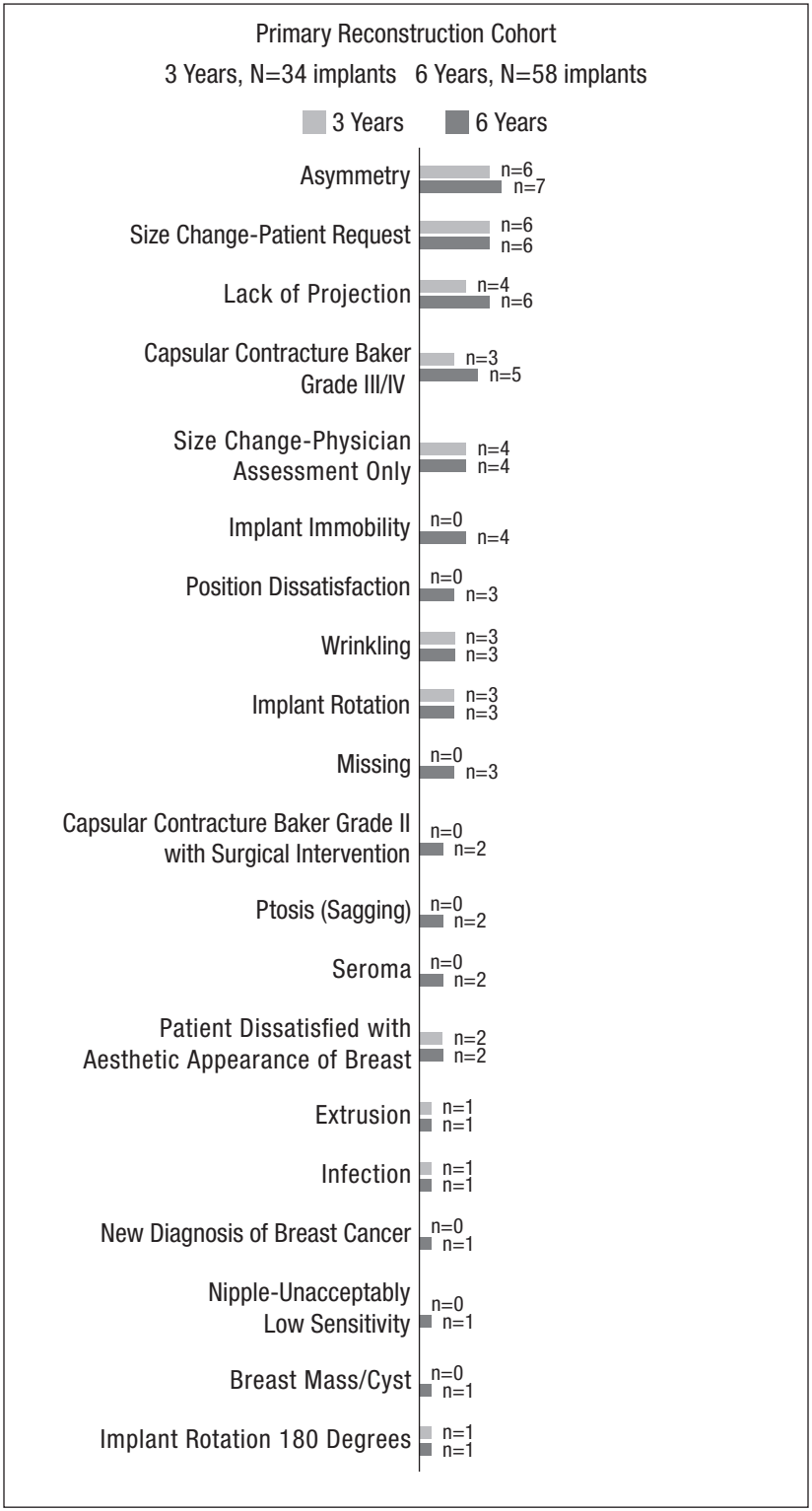
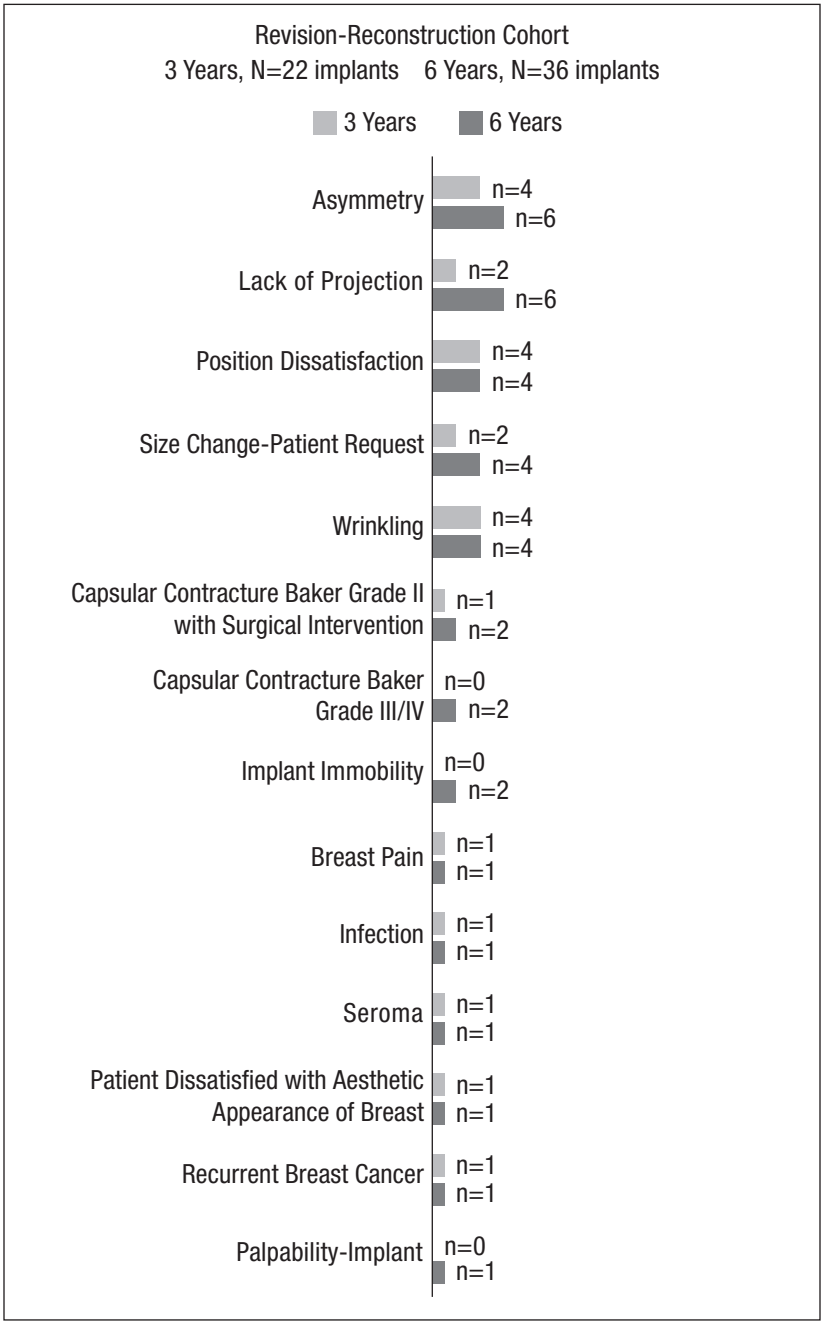


Figure 4. Reasons for Implant Removal Through 3 Years and 6 Years



MENTOR® MEMORYSHAPE™ BREAST IMPLANT CONTINUED ACCESS STUDY

The tables below present the complication rates reported in Mentor's MemoryShape™ Breast Implant Continued Access Study through 3 years for primary augmentation and revision-augmentation patients (Table 3) and for primary reconstruction and revision-reconstruction patients (Table 4).

Table 3. Complication Rates Reported Through 3 Years for Primary Augmentation (N=2379) and Revision-Augmentation (N=555) Patients

	Primary Augmentation %	Revision-Augmentation %
Any Complication	13.6	19.9
Key Complications		
Any Reoperation	7.3	14.1
Capsular Contracture Baker Grade III/IV	0.4	0.5
Implant Removal with or without Replacement	3.0	7.9
Implant Removal with Replacement with Study Device	1.1	2.4
Infection	0.6	1.2
Other Complications ≥ 1%[1]		
Mass/Cyst	1.4	1.2
Seroma	< 1	2.0
Implant Rotation	< 1	1.5
Hematoma	< 1	1.3

[1] The following complications were reported and occurred at a rate less than 1%: capsular contracture Baker II with surgical intervention, capsular contracture Baker III, capsular contracture Baker IV, breast sensation changes, breast pain, bruising, calcification, cidp, contact dermatitis, contour irregularities, death[2], delayed wound healing, double bubble, drainage, erythema, excess skin/tissue, external injury to breast, extrusion, immobile implant, irritation/inflammation, lack of projection, lactation difficulties, loss of definition of inframammary fold, low breast volume, Lyme disease, lymphadenopathy, lymphoma, miscarriage, Mondor's disease, multiple sclerosis, necrosis, nerve pain, neuropathic pain, new diagnosis of breast cancer, new diagnosis of rheumatic disease, nipple complication, nipple sensation changes, other: missing, palpability-implant, patient dissatisfied with aesthetic appearance of breast, patient dissatisfied with feel of breast, patient dissatisfaction, patient dissatisfied with breast size, patient requested removal, position dissatisfaction, rib pain, scarring, sensation changes, skin complication, skin lesion, small cell lung cancer, sternal pain, suture complication, swelling (excessive), symmastia, wound dehiscence.

[2] All causes of death were reported by the Investigator to be unrelated to study procedure or device.

Table 4. Complication Rates Reported Through 3 Years for Primary Reconstruction (N=444) and Revision-Reconstruction (N=259) Patients

	Primary Augmentation %	Revision-Augmentation %
Any Complication	26.5	22.3
Key Complications		
Any Reoperation	21.0	15.3
Capsular Contracture Baker Grade III/IV	2.5	3.9
Implant Removal with or without Replacement	11.8	8.2
Implant Removal with Replacement with Study Device	7.3	3.2
Infection	1.8	0.8
Other Complications ≥ 1%[1]		
Baker III Capsular Contracture	1.9	2.9
Implant Rotation	1.8	< 1
Death[2]	1.6	< 1
Baker II Capsular Contracture w/Surgical Intervention	1.5	2.1
Seroma	1.3	< 1
Wound Dehiscence	1.2	0.0
Position Dissatisfaction	< 1	2.5
Baker IV Capsular Contracture	< 1	1.0

[1] The following complications were reported and occurred at a rate less than 1%: atrophy, breast pain, calcification, contour irregularities, contralateral explant due to wound dehiscence, delayed wound healing, erythema, excess skin/tissue, external injury not related to breast implants, extrusion, hematoma, implant removal due to contralateral breast cancer, irritation/inflammation, lack of projection, mass/cyst, metastatic cancer, necrosis, new diagnosis of breast cancer, new diagnosis of rheumatic disease, nipple complication, other: missing, palpability-implant, patient dissatisfied with aesthetic appearance of breast, patient requested removal, pregnancy complication - ectopic, recurrent breast cancer, rupture, scarring, skin complication, small 2-mm opening down to the implant r breast, swelling (excessive), tightness of skin over implant.

[2] All causes of death were reported by the Investigator to be unrelated to study procedure or device.

CA Study: Main Reasons for Reoperation

Patients may require a reoperation for a number of reasons such as size and/or style change or in response to a complication. In addition, patients often require more than one surgical procedure to complete their reconstruction such as skin or nipple-related procedures.

Of the primary augmentation patients through 3 years, 137 of 2379 (5.8%) patients had a total of 327 additional surgical procedures. Of the revision-augmentation patients through 3 years, 66 of 555 (11.9%) patients had a total of 151 additional

surgical procedures. Of the primary reconstruction patients through 3 years, 76 of 444 (17.1%) patients had a total of 208 additional surgical procedures. In the revision-reconstruction patients through 3 years, 31 of 259 (12.0%) patients had a total of 87 additional surgical procedures.

Table 5 provides the types of additional surgical procedures performed in the CA study. Percentages are based upon the number of patients with a given procedure divided by the total number of patients with an additional procedure for that cohort (Primary Augmentation, Revision-Augmentation, Primary Reconstruction or Revision-Reconstruction).

The most common type of additional procedure across all four cohorts was Explant with or without Replacement with a Study Device. There were 54 of the 137 (39.4%) primary augmentation patients who had any additional procedure who fit this category. There were 41 of the 76 (53.9%) primary reconstruction patients who had any additional procedure who fit this category.

Table 5. Types of Additional Surgical Procedures Through 3 Years for Patients in the Continued Access Study

Type of Additional Surgical Procedure	Primary Augmentation (N=137*) n (%)	Revision-Augmentation (N=66*) n (%)	Primary Reconstruction (N=76*) n (%)	Revision-Reconstruction (N=31*) n (%)
Explant with or without Replacement with Study Device	54 (39.4)	36 (54.5)	41 (53.9)	17 (54.8)
Explant with Replacement with Study Device	19 (13.9)	11 (16.7)	24 (31.6)	6 (19.4)
Explant without Replacement with Study Device	36 (26.3)	25 (37.9)	17 (22.4)	11 (35.5)
Biopsy	7 (5.1)	4 (6.1)	3 (3.9)	1 (3.2)
Capsulectomy	13 (9.5)	8 (12.1)	12 (15.8)	10 (32.3)
Incision and Drainage	25 (18.2)	20 (30.3)	11 (14.5)	2 (6.5)
Mastopexy	16 (11.7)	4 (6.1)	4 (5.3)	2 (6.5)
Capsulotomy	12 (8.8)	7 (10.6)	13 (17.1)	8 (25.8)
Implant Reposition	18 (13.1)	6 (9.1)	8 (10.5)	3 (9.7)
Scar Revision	22 (16.1)	4 (6.1)	8 (10.5)	2 (6.5)
Skin Adjustment	3 (2.2)	1 (1.5)	10 (13.2)	0 (0.0)

Table 5. *continued to next page*

Table 5. *(continued)*

Type of Additional Surgical Procedure	Primary Augmentation (N=137*) n (%)	Revision-Augmentation (N=66*) n (%)	Primary Reconstruction (N=76*) n (%)	Revision-Reconstruction (N=31*) n (%)
Capsulorraphy	4 (2.9)	1 (1.5)	0 (0.0)	1 (3.2)
Additional Procedures for Breast Reconstruction	1 (0.7)	0 (0.0)	8 (10.5)	0 (0.0)
Dermis Placed	0 (0.0)	0 (0.0)	4 (5.3)	2 (6.5)
Excision of Mass/Cyst	1 (0.7)	0 (0.0)	1 (1.3)	0 (0.0)
Cyst Aspiration	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)
Mastectomy	2 (1.5)	1 (1.5)	0 (0.0)	1 (3.2)
Nipple Procedure	4 (2.9)	2 (3.0)	4 (5.3)	0 (0.0)
Pocket Revision	8 (5.8)	0 (0.0)	2 (2.6)	1 (3.2)
Biopsy and Tissue Adjustment	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)
Exploration	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)
Fat Grafting	0 (0.0)	2 (3.0)	11 (14.5)	7 (22.6)
Fat Grafting and Dermis Placed	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Mastectomy and Dermis Placed	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
IMF revision	1 (0.7)	1 (1.5)	2 (2.6)	0 (0.0)
Incision Revision	0 (0.0)	1 (1.5)	3 (3.9)	0 (0.0)
Skin Biopsy	1 (0.7)	1 (1.5)	0 (0.0)	1 (3.2)
Laser Hair Removal	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Liposuction	0 (0.0)	0 (0.0)	2 (2.6)	0 (0.0)
Port Removal	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
Removal of Implant, Washout, Debridement and Replacement	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)

Table 5. *continued to next page*

Table 5. *(continued)*

Type of Additional Surgical Procedure	Primary Augmentation (N=137*) n (%)	Revision-Augmentation (N=66*) n (%)	Primary Reconstruction (N=76*) n (%)	Revision-Reconstruction (N=31*) n (%)
Implant Removed, Pocket Irrigated, Implant Placed Back in Pocket	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Tissue Expander Placement, Wound Debridement, and Collagen Grafting	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Wound Debridement	1 (0.7)	0 (0.0)	2 (2.6)	0 (0.0)

* The number of subjects with additional procedures is given in the column header and is used as the denominator in the calculation of percentages.

For a more detailed review of potential complications, please refer to Section 4, Risks Associated with Breast Implants, of the appropriate Patient Educational Brochure for breast augmentation or reconstruction with MENTOR® MemoryShape™ Breast Implants.

IMPORTANT FACTORS TO CONSIDER

Before you have surgery, you should have a detailed conversation with all of your doctors (primary care doctor, surgeon, and any specialists you see) about breast implant surgery in light of your medical history.

CONTRAINDICATIONS

Breast implant surgery should NOT be performed in:

- Women with active infection anywhere in their bodies,
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions,
- Women who are pregnant or nursing.

PRECAUTIONS

CAUTION: Notify your doctor if you have any of the following conditions as the risks of breast implant surgery may be higher if you have any of these conditions:

- An autoimmune disease,
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
- Planned chemotherapy following breast implant placement,

- Planned radiation therapy to the breast following breast implant placement,
- Conditions that interfere with wound healing and/or blood clotting,
- Reduced blood supply to breast tissue, or
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery.

WARNINGS

WARNING – Below is a list of warnings associated with breast implant surgery. For a more detailed review of warnings, please refer to Section 3.4, Warnings, of the appropriate Patient Educational Brochure.

- Smoking can make it harder for your body to heal. Do not smoke before your breast implant surgery or while you are recovering.
- Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery.
- Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone.
- Breast implants may interfere with your ability to produce milk (lactate) for breast-feeding.
- Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. Be sure to notify the technologist that you have breast implants prior to the procedure.
- Your implants could rupture without you noticing any change in your breasts (called a “silent” rupture). Because silent ruptures can occur and because they are difficult to detect, you should have an MRI 3 years after your breast implant surgery and then every 2 years after that.
- Routine self-examination of your breasts may be more difficult with implants. However, you should still perform an examination of your breasts every month for cancer screening.
- After undergoing breast implant surgery, you may experience changes in your healthcare insurance. Be sure to check with your insurance company about potential issues and understand the complete extent of your health coverage before having breast implant surgery.

For a complete review of the risks and benefits please read the appropriate Mentor Patient Educational Brochure for breast augmentation or reconstruction, ***Breast Augmentation with MENTOR® MemoryShape™ Breast Implants*** *or* ***Breast Reconstruction with MENTOR® MemoryShape™ Breast Implants****.*

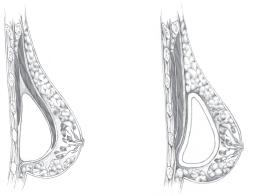
BREAST IMPLANT SURGERY – UNDERSTANDING THE PROCEDURE

Before your breast implant surgery, you and your plastic surgeon will discuss the implant placement and surgical incision options, as well as your expected postoperative care.

IMPLANT PLACEMENT

Your surgeon will consult with you and suggest where the breast implant is to be placed. Implants are placed beneath your breast tissue, either on top of the chest muscle (subglandular placement) or underneath part or all of the chest muscle (submuscular placement).

Figure 5. Implant Placement



Submuscular Subglandular

INCISION SITES

Your surgeon will suggest the best incision site option for your particular surgery. There are 3 common incision sites to consider:

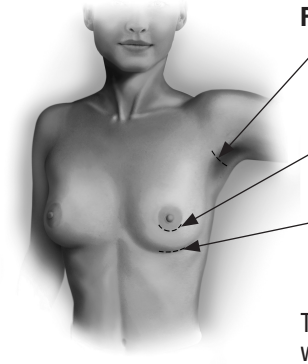


Figure 6. Incision Sites

- Axillary – the incision is made in the armpit, which gives the surgeon easier access to the chest muscle,
- Periareolar – an incision is made around the nipple, and
- Inframammary – the most common incision, made under your breast at the crease where the breast meets the body.

The incision with the MemoryShape™ Breast Implant will be longer than the one typically made for breast augmentation with a saline or round silicone gel breast implant.

For breast reconstruction after a mastectomy, your doctor will choose the incision sites based on the type of mastectomy surgery that is planned for you. Sometimes, a doctor will recommend placing an implant in the opposite breast after a unilateral (one breast only) mastectomy and reconstruction to create better symmetry. If you have an unaffected breast implanted to match a reconstructed breast, you may be able to choose the incision site (refer to Figure 6).

POSTOPERATIVE CARE

In the weeks after your breast implant surgery, the skin over your breasts may feel tight as it adjusts to your new breast size. After your stitches are removed, your doctor may tell you to massage your incision site(s) with a cream or lotion to keep the skin from drying out; this may make you more comfortable as well. Use the product(s) he or she recommends.

Your doctor may have special directions about avoiding exercise or activities that compress or put pressure on your breasts during the first weeks after surgery. Follow your doctor's directions.

BREAST IMPLANTS ARE NOT LIFETIME DEVICES

Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. It is likely that you will need other surgery related to your breast implants over the course of your life. Patients may require a reoperation for a number of reasons, including size and/or style change, implant removal (with or without replacement), capsular contracture procedures, incision and drainage, implant repositioning, scar revision, or to address some of the complications mentioned in Table 1 and Table 2 above.

ADDITIONAL INFORMATION

For additional information or if you have questions regarding the MENTOR® MemoryShape™ Breast Implants, please visit Mentor's website at www.mentorwwllc.com or call **Mentor at 1 (800) MENTOR8**.

Additional information about silicone gel breast implants can be obtained from the United States Food and Drug Administration (FDA) at www.fda.gov/breastimplants

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MENTOR®

For customer service, call (800) 235-5731 in USA; outside of USA, call (805) 879-6000, or contact your local representative.

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