
MENTOR SILICONE GEL-FILLED BREAST IMPLANTS

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Mentor Silicone Gel-Filled Breast Implants are silicone elastomer breast implants. The silicone gel-filled shell is constructed of successive cross-linked layers of silicone elastomer, which give the prosthesis its elasticity and integrity. The Siltex™ shell is textured to provide a disruptive surface for collagen interface.

The following lists the styles of Mentor silicone gel-filled round implants:

350-7100BC/7800BC: Moderate Profile, smooth shell surface

354-1007/8007: Moderate Profile, Siltex textured shell surface

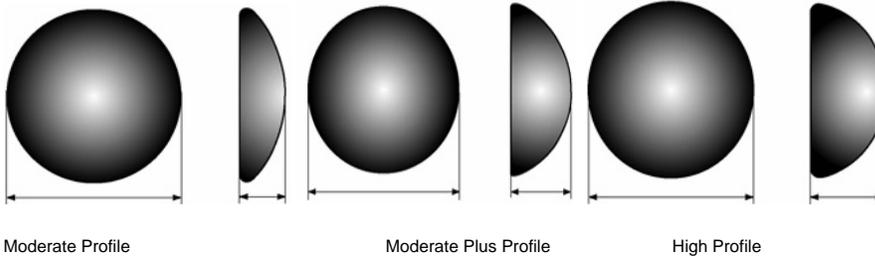
350-1001BC/8001BC: Moderate Plus Profile, smooth shell surface

354-1001/8001: Moderate Plus Profile, Siltex textured surface

350-1254BC/8004BC: High Profile, smooth shell surface

354-1007/8007: High Profile, Siltex textured surface

The following diagrams illustrate the Moderate, Moderate Plus, and High Profiles.



INDICATIONS

Breast implants are indicated for females for the following indications:

- Breast Augmentation. A woman must be at least 18 years old for breast augmentation.
- Breast Reconstruction.
- Revision.

CONTRAINDICATIONS

Patient Groups in which the product is contraindicated:

- Women with active infection anywhere in the body.
- Women with existing malignant or pre-malignant breast cancer without adequate treatment.
- Augmentation in women who are currently pregnant or nursing.

Surgical Practices in which product use is contraindicated due to compromise of product integrity:

- Stacking of implants: Do not place more than one implant per breast pocket.
- Do not alter the implant.

WARNINGS**1. Closed Capsulotomy**

DO NOT treat capsular contracture by forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.

2. Reuse

Breast implants are intended for single use only. Do not resterilize.

3. Avoiding Damage during Surgery

- Care should be taken not to damage the implant with surgical instruments.
- Do not insert or attempt to repair a damaged implant.
- Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant shell.
- Do not contact the implant with disposable, capacitor-type cautery devices.

4. Microwave Diathermy

The use of microwave diathermy in patients with breast implants is not recommended, as it has been reported to cause tissue necrosis, skin erosion, and extrusion of the implant.

5. Do not use endoscopic placement or periumbilical approach in placement of the implant.

PRECAUTIONS**1. Specific Populations**

Safety and effectiveness has not been established in patients with:

- Autoimmune diseases such as lupus and scleroderma.
- A compromised immune system (e.g., currently receiving immunosuppressive therapy).
- Patients with conditions or medications which interfere with wound healing ability (such as poorly controlled diabetes) or blood clotting (such as concurrent coumadin therapy).
- Reduced blood supply to breast tissue.

2. Mammography

Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centers and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast.

Presurgical mammography with a follow-up mammogram 6 months to 1 year following surgery may be performed to establish a baseline for future routine mammography.

3. Radiation to the Breast

Mentor has not tested the in vivo effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy may increase the likelihood of capsular contracture, necrosis, and extrusion.

4. Long-Term Effects

The long-term safety and effectiveness of Mentor implants have not been established. Mentor is monitoring the long-term (i.e., 10-year) risk of implant rupture, reoperation, implant removal, and capsular contracture.

5. Instructions to Patients:

- Reoperation – Patients should be advised that additional surgery to their breast and/or implant will be likely over the course of their life.
- Explantation – Patients should be advised that implants are not considered lifetime devices and they will likely undergo implant removal, with or without replacement, over the course of their life. Patients should also be advised that the changes to their breast following explantation are irreversible.
- Mammography – Patients should be instructed to inform their mammographers about the presence, type and placement of their implants. Patient should be advised to request a diagnostic mammography, rather than a screening mammography.
- Lactation – Patients should be advised that breast implants may interfere with the ability to successfully breast feed.
- Infection – Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain and fever. In rare instances, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms of TSS occur suddenly: a high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure which may cause fainting. Patients should be advised to contact a physician immediately for diagnosis and treatment for any of these symptoms.

- Avoiding Damage during Treatment – Patients should be instructed to inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- Smoking – Patients should be informed that smoking may interfere with the healing process.
- Cosmetic Dissatisfaction – Patients should be informed that dissatisfaction with cosmetic results related to such things as scar deformity, hypertrophic scarring, asymmetry, displacement, incorrect size, unanticipated contour, and palpability may occur. Careful surgical planning and technique can minimize, but not preclude, the risk of such results. Preexisting asymmetry may not be entirely correctable. Physiological and behavioral differences among patients and variations in surgical techniques and medical treatments account for a wide variety of responses to silicone-filled breast implant surgery. Revision surgery may be indicated to maintain patient satisfaction, but carries additional considerations and risks.
- Breast Examination Techniques - Patients should be instructed to perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should be instructed not to manipulate (i.e., squeeze) the implant excessively.
- Follow-up Examinations- Patients should be instructed to have follow up examinations on an annual or biannual basis, including assessment of implant integrity.

6. Rupture

- If there is a clinical suspicion of intracapsular or extracapsular rupture, consideration should be given to performance of a Magnetic Resonance Imaging (MRI) examination. If rupture is confirmed by any means, explantation is recommended.

ADVERSE EVENTS

Mentor Corporation implants were evaluated in two prospective open label clinical studies: the Core Study (which involved 1,007 patients) and the Adjunct Study (in which 48,307 patients were enrolled as of November 2002). The cumulative Kaplan-Meier risk of first occurrence of adverse events (and 95% confidence interval) reported in greater than 1% of patients is shown in Tables 1 and 2 on a by patient basis based on indication.

Table 1. Adjunct Study 5-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient.

Complication	Revision N=1,363	Reconstruction N=394
	Rate (%) (95% CI)	Rate (%) (95% CI)
Asymmetry	27% (26,29)	42% (40,45)
Wrinkling	27% (25,28)	26% (24,29)
Breast Pain	19% (18,20)	19% (17,21)
Capsular Contracture III /IV	18% (17,20)	16% (14,18)
Explantation	13% (12,14)	11% (11,15)
Reoperation	10% (9,11)	18% (16,20)
Hypertrophic Scarring	6% (5,6)	9% (7,10)
Irritation/Inflammation	4% (3, 5)	3% (2, 4)
Lymphadenopathy	2% (1,2)	2% (1,2)
Seroma	2% (1, 2)	1% (0.9,2)
Calcification	2% (1,2)	1% (0.2,1)
Rupture	2% (1,2)	1% (0.3,1)
Infection	2% (2,2)	3% (2,3)
Hematoma	2% (2,3)	1% (0.7,2)
Extrusion	1% (0.6,1)	2% (1,2)
Necrosis	1% (0.4, 0.8)	2% (1,2)
Delayed Wound Healing	1% (1,2)	3% (2,4)

Table 2. Core Study: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient.

Complication*	Augmentation		Reconstruction		Revision	
	By Patient N=551		By Patient N=251		By Patient N=205	
	Rate (%)	(95% CI)	Rate (%)	(95% CI)	Rate (%)	(95% CI)
Reoperation	15.0%	(11.9, 18.0)	26.3%	(20.7, 31.9)	26.3%	(20.0, 32.6)
Nipple Sensation Changes	10.8%	(8.1, 13.4)	3.1%	(0, 6.3)	8.6%	(4.7, 12.6)
Capsular Contracture III/IV	8.2%	(5.9, 10.6)	8.8%	(4.9, 12.7)	17.2%	(11.9, 22.4)
Hypertrophic Scarring	6.3%	(4.2, 8.3)	6.4%	(3.0, 9.8)	6.0%	(2.7, 9.3)
Hematoma	2.6%	(1.2, 3.9)	1.5%	(0.0, 3.3)	3.0%	(0.6, 5.3)
Breast Mass	2.4%	(1.0, 3.7)	3.9%	(1.1, 6.6)	5.8%	(2.5, 9.1)
Breast Sensation Changes	2.2%	(1.0, 3.4)	0.9%	(0, 2.1)	2.1%	(0.05, 4.2)
Ptosis	2.2 %	(0.9, 3.4)	6.9%	(8.0, 11.8)	2.2%	(0.06, 4.3)
Breast Pain	1.7%	(0.6, 2.8)	1.7%	(0.05, 3.4)	2.0%	(0.06, 4.0)
Infection	1.5%	(0.5, 2.5)	5.3%	(2.5, 8.1)	1.0%	(0.0, 2.4)
External Injury Not Related to Breast Implants	1.4%	(0.2, 2.6)	0.4%	(0, 1.2)	1.2%	(0, 3.0)
Miscarriage	1.4%	(0.4, 2.4)	0.9 %	(0, 2.0)	0%	(0,0)
Seroma	0.9%	(0.1, 1.7)	4.9%	(2.2, 7.6)	2.0%	(0.06, 3.9)
Wrinkling	0.7%	(0.02, 1.5)	2.8%	(0.5, 5.1)	2.0%	(0.06, 4.0)
New Diagnosis of Rheumatic Disease	0.6%	(0, 1.2)	0.4%	(0, 1.2)	1.0%	(0, 2.4)
Asymmetry	0.5%	(0, 1.2)	7.1%	(3.2, 11.1)	2.7%	(.3, 5.1)
Inflammation	0.4%	(0, 0.9)	0%	(0,0)	1.5%	(0, 3.2)
Granuloma	0.2%	(0.0, 0.5)	0%	(0,0)	1.0%	(0.0, 2.3)
Implant Malposition/Displacement	0.2%	(0, 0.5)	1.7%	(0.05, 3.3)	2.5%	(0.3, 4.7)
Rupture	0.2%	(0, 0.7)	0.6%	(0, 1.8)	2.5%	(0.07, 4.9)
Lymphadenopathy	0.2%	(0, 0.5)	1.7%	(0, 5.1)	0	(0,0)
Necrosis	0.2%	(0, 0.7)	1.2%	(0, 3.1)	0%	(0,0)
Extrusion	0%	(0, 0)	1.2 %	(0, 2.6)	1.5%	(0.0, 3.1)
Recurrent Breast Cancer	0%	(0,0)	1.7%	(0.05, 3.4)	0.5%	(0, 1.5)
Metastatic Disease	0%	(0,0)	1.9%	(0.05, 3.7)	0%	(0,0)
Delayed Wound Healing	0%	(0,0)	0.4%	(0, 1.2)	2.0%	(0.06, 3.9)
Other (Non-cosmetic)	3.2%	(1.5, 4.8)	7.8%	(4.1, 11.6)	6.4%	(2.9, 9.9)

*Excludes mild occurrences of asymmetry, breast pain, calcification, position change, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Table 3a. Core Study: Types of Additional Surgical Procedures through 3 Years for Augmentation

Of the 551 augmentation patients, there were 79 (14%) who underwent at least one additional surgical procedure over the 3 years of follow-up in the Core Study. A total of 160 additional procedures in 134 reoperations were performed in augmentation patients over the 3 years of the Core Study. The types of additional surgical procedures are shown below based on the number of additional surgical procedures.

Types of Additional Surgical Procedures for Augmentation	N = 160 procedures	
	n	%
Capsulectomy	36	22.5
Implant Removal with Replacement	24	15.0
Implant Removal without Replacement	21	13.1
Scar Revision	18	11.3
Capsulotomy	17	10.6
Incision and Drainage	12	7.5
Skin Adjustment	8	5.0
Biopsy	4	2.5
Implant Reposition	4	2.5
Capsulorrhaphy	4	2.5
Mastopexy	4	2.5
Revision of Wound Closure	3	1.9
Excise Breast Mass	2	1.3
Implant Pocket Revision	2	1.3
Nipple Related Procedure (unplanned)	1	0.6
TOTAL	160	100%

Table 3b. Core Study: Types of Additional Surgical Procedures through 3 Years for Reconstruction

Of the 251 reconstruction patients in the Core Study, 64 (26%) underwent at least one reoperation over the 3 years of follow-up. A total of 139 additional surgical procedures in 95 reoperations were performed in reconstruction patients over the 3 years. The types of additional surgical procedures are shown below based on the number of additional surgical procedures.

Types of Additional Surgical Procedures for Reconstruction	N = 139 procedures	
	n	%
Implant Removal With Replacement	23	16.5
Implant Removal (without Replacement)	17	12.2
Implant Reposition	17	12.2
Capsulotomy	14	10.1
Skin Adjustment	14	10.1
Capsulectomy	10	7.2
Biopsy	10	7.2
Scar Revision	7	5.0
Implant Pocket Revision	6	4.3
Mastopexy	4	2.9
Incision and Drainage	4	2.9
Nipple Related Procedure (unplanned)	2	1.4
Create Inframammary fold	2	1.4
Capsulorrhaphy	2	1.4
Revision of Breast/External to Pocket	2	1.4
Removal of Nodule on Chest Wall	2	1.4
Revision of Wound Closure	1	0.7
Breast Mass Excision	1	0.7
Flap Coverage of Expander	1	0.7
TOTAL	139	100

Table 3c. Core Study: Types of Additional Surgical Procedures through 3 Years for Revision
Of the 205 revision patients in the Core Study, 51 (25%) underwent at least one additional surgical procedure over the 3 years of follow-up. A total of 141 additional surgical procedures in 100 reoperations were performed in revision patients over the 3 years. The types of additional surgical procedures are shown below based on the number of procedures.

Types of Additional Surgical Procedures for Revision	N =141 procedures	
	n	%
Implant Removal With Replacement	21	14.9
Implant Removal (Without Replacement)	18	12.8
Capsulectomy	18	12.8
Capsulotomy	17	12.1
Skin Adjustment	12	8.5
Biopsy	10	7.1
Implant Reposition	10	7.1
Scar Revision	9	6.4
Incision and Drainage	7	5.0
Capsulorrhaphy	6	4.3
Mastopexy	5	3.5
Revision of Wound Closure	2	1.4
Excision of Skin Lesion	2	1.4
Exploration of Breast with Evacuation of Hematoma	1	0.7
Open Incision to Rule out Rupture	1	0.7
Needle Aspiration	1	0.7
Nipple Related Procedure (unplanned)	1	0.7
TOTAL	141	100

Table 4a. Core Study: Reasons for Implant Removal through 3 Years for Augmentation
Of the 551 augmentation patients, there were 26 patients (5%) who had 45 implants removed over the 3 years of follow-up in the Core Study. Of the 45 augmentation implants removed, 24 implants (53%) were replaced. The reason for implant removal is shown in the table below based on the number of implants removed.

Reason for Implant Removal through 3 Years for Augmentation	N = 45 Implants Removed	
	n	%
Patient Request	27	60%
Capsular Contracture (III and IV)	5	11%
Breast Pain	2	4%
Infection	2	4%
Necrosis	2	4%
False Positive MRI for Rupture	1	2%
Wrinkling	1	2%
Right Explanted so Left Done Also	1	2%
Reason Missing	4	9%
Total	45	100%

Table 4b. Core Study: Reasons for Implant Removal through 3 Years for Reconstruction

Of the 251 reconstruction patients, there were 31 patients (12%) who had 40 implants removed over the 3 years of follow-up in the Core study. Of the 40 reconstruction implants removed, 23 (58%) were replaced. The reason for implant removal is shown in the table below based on the number of implants removed.

Reason for Implant Removal through 3 Years for Reconstruction	N = 40 Implants Removed	
	n	%
Patient Request	13	33%
Asymmetry	10	25%
Capsular Contracture (III and IV)	4	10%
Implant Reposition	3	8%
Infection	2	5%
Extrusion	2	5%
Implant Too Large	2	5%
Hematoma	1	3%
Lack of Projection	1	3%
Muscle Spasm	1	3%
Recurrent Breast Cancer	1	3%
Total	40	100%

Table 4c. Core Study: Reasons for Implant Removal through 3 Years for Revision

Of the 205 revision patients, there were 25 patients (12%) who had 39 implants removed over the 3 years of follow-up in the Core study. Of the 39 revision implants removed, 21 (54%) were replaced. The reason for implant removal is shown in the table below based on the number of implants removed.

Reason for Implant Removal through 3 Years for Revision	N = 39 Implants Removed	
	n	%
Patient Request	14	36%
Capsular Contracture (III and IV)	11	28%
Asymmetry	3	8%
Extrusion	2	5%
Symmastia	2	5%
Hypertrophic Scarring	1	3%
Infection	1	3%
Abnormal Mammogram	1	3%
Pocket Tear	1	3%
Suspected Rupture	1	3%
Reason Missing	2	5%
Total	39	100%

POTENTIAL ADVERSE EVENTS

The following is a list of potential adverse events that may occur with breast implant surgery. Some of these adverse events have been previously reported in tables 1 and 2 above. The risks include: implant rupture, additional surgery, capsular contracture, infection, Toxic Shock Syndrome, necrosis, hematoma, seroma, extrusion, breast pain, changes in nipple sensation, changes in breast sensation, dissatisfaction with cosmetic results (wrinkling, folding, displacement, asymmetry, palpability, visibility, ptosis), calcific deposits, irritation/inflammation, delayed wound healing, hypertrophic scarring, breast tissue atrophy/chest wall deformity, difficulty/inability in breast feeding, and inability to adequately visualize breast lesions with mammography.

In addition to these potential adverse events, there have been concerns with certain systemic diseases.

- **Connective Tissue Disease**

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. A review of recent long term epidemiological studies of women with and without implants, together with the review of a number of previously conducted epidemiological studies, indicates that these diseases are no more common in women with implants than those in women without implants.

- **Cancer**

Published medical literature indicates that:

1. Patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer;
2. Early detection of hidden breast cancer is possible in women with breast implants;
3. Submuscular placement of breast implants allows for greater visualization of breast tissue during mammography;
4. Mammography exams should be performed and interpreted by radiologists experienced in the evaluation of women with breast implants and should include additional views (i.e., Eklund views using displacement techniques);
5. The current recommendation for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants; and
6. A recently published review of four large scale incidence follow-up studies that included more than 10,000 women with cosmetic implants followed for up to 29 years concluded that there is no significant excess of breast cancer incidence among women with cosmetic breast implants.

- **Second Generation Effects**

There have been concerns raised regarding potential damaging effects on children born of mothers with implants. Two large, well-controlled, population-based epidemiological studies (one from Sweden and one from Denmark) have found no evidence to support an association of maternal silicone breast implants and adverse health outcomes in offspring. A review of the published literature on this issue suggests that the literature may be insufficient to draw definitive conclusions.

CLINICAL STUDIES OVERVIEW

1. STUDY DESIGN

The safety and effectiveness of Mentor Corporation silicone gel-filled implants were evaluated in 2 open label multicenter clinical studies: the Core Study and the Adjunct Study.

The Adjunct Study was designed to gather safety data regarding short-term, post implantation complications associated with Mentor's silicone gel-filled breast implants. Patients studied were those seeking reconstruction, revision of an existing implant for medical reasons, or treatment of severe breast deformities. The safety assessment was based on the reported incidence of capsular contracture, seroma, infection and rupture. The secondary objective of the study was to provide data concerning potential complications in addition to those reported in the safety assessment. Follow-up was at 1, 3 and 5 years and is currently on-going.

The Core Study was designed as a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision patients. Patient follow-up was at 6 months, 12 months, 24 months, and annually through 10 years, and is currently on-going. Safety endpoints consisted of complication rates. Effectiveness was assessed by patient satisfaction, breast size change, and measures of body esteem/self-esteem/body image.

2. PATIENT ACCOUNTING AND BASELINE DEMOGRAPHIC PROFILE

As of November 2002, the Adjunct Study enrolled a total of 48,307 patients, consisting of 13,288 reconstruction patients, 34,205 revision patients, and 814 patients for which the indication was unknown. Of the reconstruction patients available to be seen, 11% returned for their 5-year visit. Of the revision patients available to be seen, 10% returned for their 5-year visit.

The Core Study consisted of 551 eligible augmentation patients, 251 eligible reconstruction patients, and 205 eligible revision patients. Data are available for 94% of the eligible augmentation patients, 95% of the eligible reconstruction patients, and 93% of the revision patients at 3 years post-implantation.

Demographic information in the Core Study is as follows. With regard to race, 90% of the Core Study patients were Caucasian, 2% were Asian, 2% were African American, and 6% were other. The mean age at surgery was 34 years for augmentation patients, 45 years for reconstruction patients, and 44 years for revision patients. Most of the Core Study patients were married (56% of the augmentation patients, 69% of the reconstruction patients, and 61% of the revision patients). Approximately 80% had some college education.

With respect to surgical baseline factors in the Core Study, for augmentation patients, the most frequently used devices were smooth surface implants, the most common incision site was inframammary, and the most frequent site of placement was submuscular. For reconstruction patients, the most frequently used devices were textured surface implants, the most common incision site was the mastectomy scar, and submuscular placement was the favored site. For revision patients, the most frequently used devices were smooth surface implants, the most common incision sites were inframammary, and submuscular placement was the favored site.

3. SAFETY OUTCOMES

The Adjunct Study safety outcomes are presented in Table 1 above.

The Core Study safety outcomes for primary implantation are presented in Tables 2-4 above.

Breast Disease:

There was one patient (0.05%) who was newly diagnosed with breast cancer through 3 years postimplantation. The incidences of recurrence of breast cancer and of breast mass are shown in Table 2 above.

Connective Tissue Disease (CTD):

CTDs were reported in some Core Study patients through 3 years. These data should be interpreted with the precaution in that there was no comparison group of similar women without implants. Table 5 summarizes post-implant observations from the Core Study pertaining to confirmed reports of CTD that were based on a diagnosis by a physician.

Table 5. Core Study: Number of Confirmed Reports of CTD through 3 Years, By Patient

Rheumatic Disease	Augmentation Patients	Reconstruction Patients	Revision Patients
Hashimoto Thyroiditis	1	0	0
Fibromyalgia	0	1	1
Pyoderma Gangrenosum	0	0	1
Rheumatoid Arthritis	1	0	0
Hypothyroidism	1	0	0
TOTAL	3	1	2

4. EFFECTIVENESS OUTCOMES

Effectiveness was assessed based primarily on changes in circumferential breast size and bra cup size, and secondarily, based on changes in the results of quality of life questionnaire results and global patient satisfaction. The Tennessee Self-Concept Scale (TSCS), the SF-36 Health Survey Scale, the Bode Esteem Scale, the Rosenberg Self-Esteem Scale, the Manitoba Cancer Treatment & Research Foundation Functional Living Index: Cancer (FLIC) (cancer patients only), and Global Patient Satisfaction were used to assess effectiveness. Global patient satisfaction was assessed by whether the patient would have the surgery again.

Implantation of the Mentor Silicone Gel-Filled Breast Implants resulted in a significant increase in circumferential chest size and bra cup size in augmentation patients, and restoration of the chest mound in reconstruction and revision patients. For patients overall, and for all indications, the changes in circumferential breast size were positive and highly significant. The average increase in circumferential breast size for patients overall was 5.5 cm. The average increase in circumferential breast size was 7.1 cm for augmentation patients, 3.3 cm for reconstruction patients, and 1.9 cm for revision patients.

Among augmentation patients, greater than 97% had an increase in bra cup size of at least one step (e.g., from A to B cup size) at each of the various follow-up visits. The overall average increase in breast cup size was 1.7 cup sizes

The results of the Tennessee Self-Concept Scale (which measures self-concept) showed that there was a decrease across follow-up visits among revision patients, suggesting a decline in self-concept as measured by this assessment. The changes for augmentation patients and reconstruction patients were not significant. When the total score of Tennessee Self-Concept Scale was analyzed by device placement, for submuscular placement, a statistically significant overall mean increase was observed for augmentation patients, no significant difference was observed for reconstruction patients, and a statistically significant overall mean decrease was observed for revision patients.

On the SF-36 Health Survey, at baseline, the overall population scored significantly higher than did the general United States female population on all eight subcategories. The study patients also scored significantly higher than the United States female population on the Mental Component Score (MCS) and Physical Component Score (PCS). The results for some of the subscales showed scores that decreased slightly, but statistically significantly, from preoperative to postoperatively, indicating a slight worsening in physical and mental health. However, the magnitude of these changes was slight, and postoperatively the study patients continued to score statistically higher for all eight subcategories and the MCS and PCS as compared to the United States female population.

The results of the Body Esteem Scale showed there was no significant change in body esteem among the augmentation and reconstruction patients. Among revision patients, there was a statistically significant decrease, indicating a worsening of body esteem in revision patients.

The Rosenberg Self-Esteem Scale showed significant overall mean increases in augmentation patients, indicating improvement in self-esteem. There were no changes among the reconstruction patients and revision patients. When the results are stratified by device placement, statistically significant increases were noted for augmentation patients having a device implanted using a submuscular approach.

The Functional Living Index: Cancer (FLIC) showed a significant overall mean increase in delayed post-mastectomy patients, indicating an improved functioning postoperatively.

Global Patient Satisfaction indicated that, at the 3-year follow-up visit, 97% of patients said they would have the implant surgery again. The results were similar for augmentation patients (97%), reconstruction patients (98%) and revision patients (96%). Furthermore, 95% of patients who had a reoperation indicated that they would have breast implant surgery again.

5. Investigation of Long-Term Silicone Gel-Filled Implant Integrity and Observational Analysis of Potential Health Consequences of Rupture

A study was designed and conducted by Dr. David T. Sharpe, and Dr. Nicholas Collis, Bradford Royal Infirmary, U.K., to evaluate Mentor silicone gel-filled breast implant integrity in implants that have been in place for 4-12 years, as determined by Magnetic Resonance Imaging ("MRI") and confirmed at explantation. An observational analysis of the potential health consequences of implant rupture was included in this study. The study methods, results, and conclusions are summarized below.

Information concerning the cohort evaluated in this study is provided below:

Number of NHS women with cosmetic subglandular Mentor Siltex silicone gel-filled breast implants	204
Number of NHS women with cosmetic subglandular Mentor Siltex silicone gel-filled breast implants who underwent MRI examination included in the patient level analysis	101
Number of women who underwent MRI examination, but were excluded from patient level analysis because one of their implants was removed prior to the MRI examination, but their remaining implant was included in the implant level analysis	2
Number of implants evaluated by MRI and included in implant-level analysis	204
Mean age at implantation	30.6±5.6 years
Mean age at MRI examination	40.0±6.1 years
Mean implant duration	8.8±2.5 years
Mean implant size	
Right	225±35 cc
Left	221±35 cc

The results of the MRI evaluation are presented below:

	Patient	Implant
Number of MRI-identified silent ruptures	12 (11.9%)	19 (9.3%)
Number of ruptures confirmed at surgery	9 (8.9%)	11 (5.4%)
Mean age of implants at MRI-identified rupture (excluding implants confirmed as intact)		9.2±1.5 years
Mean age of implants at confirmed rupture		9.1±1.6 years
Number of extracapsular ruptures	0	0

Of the patients with at least one ruptured implant who underwent rheumatological examination, only one woman reported possible rheumatological effects (one possible episode of "myalgic encephalitis"), which was not considered by the evaluating rheumatologist to be implant related. Blood analyses revealed no abnormal findings.

In this study, the confirmed overall rupture rate was 8.9% (by patient) and 5.4% (by implant). No ruptures were observed until approximately 7 years after implantation, and, based on the modeling conducted, the rupture rate slowly increased thereafter until, at 12 years, the rate was approximately 12%. The average age of the implant at confirmed rupture was 9.1±1.6 years, which demonstrates the durability of Mentor's silicone gel-filled implants. Importantly, of the confirmed ruptures, none were extracapsular, and with the possible exception of one woman, none of the women with ruptured implants experienced adverse health consequences.

PRECLINICAL STUDIES OVERVIEW

Device Gel Bleed Testing

Gel bleed testing of sterile Smooth Moderate Profile Silicone Gel-Filled Breast Implants was performed using the suggested test method in ASTM F703-96, Appendix X2. This method provides a worst case estimate of the amount of silicone gel diffusion through a shell. The results of such testing can be used for "comparison of gel bleed diffusion rates of various product configurations in a laboratory setting" (ASTM F703-96). ASTM standard clearly states, that "The results of this bleed test method can not be correlated with the actual physiological performance of an implant since the chemical gradient is not replicated."

All PMA models use the same materials and design for the shell and gel-filler; as a result, the gel bleed rate measured from one smooth device is indicative of the bleed rate of the other smooth device styles as well. The data obtained in this test demonstrate a relatively low bleed rate (starting at 0.0035 g/cm²/week and decreasing to 0.0011 g/cm²/week at week 15) that became relatively constant after approximately five weeks.

An in vitro bleed test was also performed to quantitatively and qualitatively analyze the silicone compounds and platinum which bleeds into a physiological fluid. An intact 125cc Smooth Round Moderate Profile device was immersed in porcine serum (at 370C) for 120 days. Porcine serum was chosen to simulate the composition, including lipid content, of the extracellular fluid within the

fibrous capsule that is in direct contact with the implant in the patient. Aliquots of the serum were analyzed at different time points for low molecular weight (LMW) siloxane compounds (<1500 molecular weight) by gas chromatography/mass spectroscopy and for platinum by inductively coupled plasma/mass spectrometry. The results indicate that only the LMW siloxanes D4, D5, and D6 and platinum diffused into the serum in measurable quantities. Of all the detectable LMW siloxanes in serum, D5 was the highest at 2.8 µg. In total, only 4.3 µg of the three siloxanes was detected (all at about background levels). Platinum levels followed an increasing trend in the serum peaking at 4.1 µg by sixty days and then remained constant thereafter. These bleed data suggest that the amount of gel-filled mammary bleed under physiological conditions is much less than that seen in the standard test suggested in ASTM F703-96.

Iatrogenic Effects

Iatrogenic events, inadvertently induced by a physician or surgeon or by medical treatment or diagnostic procedures, may contribute to premature implant failure. A study has been completed to evaluate iatrogenic events and subsequent effect on fatigue lifetime. This included surgical insertion procedure, mammography and sharp instrument damage caused by scalpel or suture needle. Smooth Round Moderate Profile Gel-filled Mammary Implants were subjected to cyclic fatigue analysis following induced iatrogenic events. Surgical insertion and mammography procedures showed no effect on implant fatigue lifetime. Sharp instrument damage induced with scalpel and suture needle showed a significant reduction of fatigue lifetime.

INSTRUCTIONS FOR USE

The implantation of silicone gel-filled breast implants involves a variety of surgical techniques. Therefore, the surgeon is advised to use the method which her/his own practice and discretion dictate to be best for the patient.

NOTE: It is advisable to have more than one size breast implant in the operating room at the time of surgery to allow for flexibility in determining the appropriate size implant to be used. A backup implant should also be available.

Do Not stack more than one implant per breast pocket.

Recording Procedure

Each breast implant is supplied with two Patient Record Labels showing the catalog number and lot number for that unit. One of these pressure sensitive labels should be attached directly to the Patient ID Card, and one to the patient's chart. The implanted position (left or right side) should be indicated on the label.

Sterilization

Mentor's silicone gel-filled breast implants are provided sterile. They are sterilized by dry heat. This product is for single use only. Do not resterilize.

Implant Selection

Some of the important surgical and implant sizing variables that have been identified include the following:

- The implant should not be too small or too large in comparison to the patient's chest wall dimensions.
- Available tissue must provide adequate coverage of the implant.
- Submuscular placement of the implant may be preferable in patients with thin or poor quality tissue.
- A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
- Avoid too small of an incision.
- The higher profile of the Siltex shell should be considered in surgical approach.

Testing Procedure For Silicone Gel-Filled Implants

The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by gently manipulating the prosthesis with hand and fingers, while carefully examining for rupture or leakage sites.

Maintaining hemostasis/Avoiding fluid accumulation

Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, the implantation with the device should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination, or damage from sharp instruments.

POSTOPERATIVE CARE

Mentor recommends that the patient be wrapped superiorly with an elastic (Ace) bandage, taped laterally, and wear a surgical bra 24 hours a day to help prevent shifting of the implant.

DEVICE RETRIEVAL EFFORTS

Mentor requests that any explanted devices be sent to Mentor Corporation, Product Evaluation Department, 3041 Skyway Circle North, Irving, TX 75038 USA for examination and analysis.

PRODUCT EVALUATION

Mentor requires that any complications or explantation resulting from the use of this device be brought to the immediate attention of the Product Evaluation Department at Mentor, 3041 Skyway Circle North, Irving, TX 75038 USA.

RETURNED GOODS AUTHORIZATION

- U.S. Customers

Merchandise returned must have all manufacturers seals intact and must be returned within 60 days from date of invoice to be eligible for credit or replacement. Please contact Mentor Customer Service Department for details. Returned products may be subject to restocking charges.

- International Customers

Authorization for return of merchandise should be obtained from your respective dealer. Other conditions noted above also apply.

Information a Physician Should Provide to the Patient

Breast implantation is an elective procedure and the patient must be well counseled on the risk-benefit relationship. The surgeon should provide each prospective patient with the following:

- **Silicone Gel-Filled Breast Implant Surgery: Making an Informed Decision.**
This brochure can be used to facilitate patient education in the risks and benefits of silicone gel-filled breast implant surgery. The patient should be advised to wait a week after reviewing and considering this information before deciding whether to have surgery.
- **Patient ID Card**
Enclosed with each gel-filled breast implant is a Patient ID Card. To complete the Patient ID Card, stick one Patient Record Label for each implant on the back of the Patient ID Card. Patient Record Labels are located on the internal product packaging attached to the label. If a Patient Record Label is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. The patient should be provided with the Patient ID Card for personal reference.

PRODUCT ORDER INFORMATION

U.S. Customers

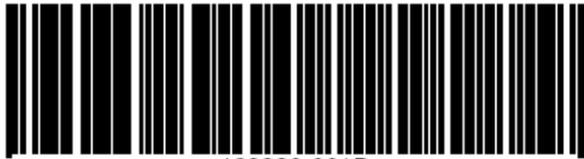
To order directly in the USA, please contact the Mentor Customer Service Department at Mentor, 201 Mentor Drive, Santa Barbara, CA 93111; Toll free telephone (800) 235-5731, FAX (805) 967-7108.

International Customers

For product information or to order directly, contact your local Mentor products distributor or the International Customer Service Department at Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA; (805) 879-6000; FAX (805) 967-7108.

REFERENCES

Literature references are available upon request from:
Mentor Marketing Services, Literature Department
201 Mentor Drive
Santa Barbara, CA 93111 USA



For customer service call (800) 235-5731 in USA; outside of USA contact your local Mentor representative.

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