



# SALINE-FILLED & SPECTRUM® MAMMARY PROSTHESES

## *DIRECTIONS FOR USE*

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

## DEVICE DESCRIPTION

Mentor's Saline-Filled and Spectrum® Mammmary Prostheses are constructed from room temperature vulcanized silicone elastomer, made of polydimethylsiloxane. The silicone elastomer shell is inflated to the desired size with sterile isotonic saline before implantation, as well as postimplantation for the Spectrum implants. The implants are available with Siltex textured, Partially Textured (PT) or smooth surface shells.

Each implant is supplied sterile with a disposable fill tube and reflux valve. The following lists the styles of Mentor saline-filled implants.

### Saline-Filled Breast Implant Family (fixed volume):

- **Round Styles:**

- Style 1600: Smooth shell surface, anterior diaphragm valve
- Style 2600: Siltex® textured shell surface, anterior diaphragm valve

- **Contour Styles:**

- Style 2700: Siltex® textured shell surface, anterior diaphragm valve, high profile
- Style 2900: Siltex® textured shell surface, anterior diaphragm valve, moderate profile
- Style 5000: Siltex® textured shell surface, anterior diaphragm valve, tall profile
- Style 5000PT: Siltex® partially textured shell surface, anterior diaphragm valve, tall profile

### Spectrum® Breast Implant Family (post-operative adjustability):

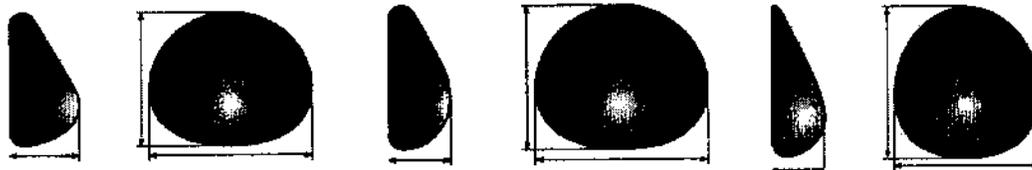
- **Round Styles:**

- Style 1400: Smooth shell surface, posterior kink plug valve
- Style 2400: Siltex® textured shell surface, posterior kink plug valve

- **Contour Styles:**

- Style 2500: Siltex® textured shell surface, posterior kink plug valve, high profile
- Style 6000: Siltex® textured shell surface, posterior kink plug valve, tall profile
- Style 6000PT: Siltex® partially textured shell surface, posterior kink plug valve, tall profile

The following diagrams illustrate the high, moderate and tall contour profiles.



Contour, high profile

Contour, moderate profile

Contour, tall profile

## 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.

## CONTRAINDICATIONS

*Patient Groups in which the product is contraindicated:*

- Active infection anywhere in the body.
- 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 make injections into the implant.
- Do not alter the implant shell or valve.
- Do not place drugs or substances inside the implant other than sterile saline for injection.
- Do not allow the implant to come in contact with Betadine®.

## **WARNINGS**

### **1. Closed Capsulotomy**

**DO NOT** treat capsular contracture by forceful external compression, which will likely result in implant damage, deflation, folds, and/or hematoma. Capsule firmness must not be treated by overexpansion of the device.

### **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 prosthesis with surgical instruments.
- Do not insert or attempt to repair a damaged prosthesis.
- 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 or valve.
- Do not contact the implant with disposable, capacitor-type cautery devices.

### **4. Proper Filling**

Follow the recommendation on the product data sheet for fill volume; do not overfill or underfill the implant.

### **5. 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.

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

## **PRECAUTIONS**

### **1. Specific Populations**

Safety & 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 of their implants.
- **Lactation** – Patients should be advised that breast implants may interfere with the ability to successfully breast feed.
- **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 valve excessively, which may cause valve leakage.

**ADVERSE EVENTS**

Mentor Corporation implants were evaluated in two prospective open label clinical studies: the Large Simple Trial (LST) (which involved 2385 patients) and the Saline Prospective Study (SPS) (which involved 1680 patients). 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 and by implant basis based on indication.

**Table 1. LST: 1-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient.**

Indication	Rate (%)	(95% CI)	Rate (%)	(95% CI)	Rate (%)	(95% CI)
Capsular Contracture III/IV	4.6%	(3.5, 5.7)	29.0%	(20.1, 37.8)	14.5%	(8.9, 20.1)
Implant Removal with or without Replacement	3.6%	(2.6, 4.5)	9.5%	(3.8, 15.3)	6.0%	(1.9, 10.2)
Leakage/Deflation	1.4%	(0.7, 2.0)	NA*	NA*	2.3%	(0.0, 4.8)
Infection	0.9%	(0.5, 1.4)	NA*	NA*	NA*	NA*

\*Insufficient numbers of patients to calculate a Kaplan-Meier risk rate.

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

Complication	By Patient (%)	95% CI (Patient)	By Implant (%)	95% CI (Implant)	By Patient (%)	95% CI (Patient)	By Implant (%)	95% CI (Implant)
Wrinkling	20.8%	(18.4, 23.2)	19.7%	(18.0, 21.4)	20.0%	(15.4, 24.5)	20.1%	(16.7, 25.1)
Reoperation	13.2%	(11.2, 15.2)	10.3%	(9.0, 11.6)	40.1%	(35.0, 45.3)	35.3%	(31.1, 39.6)
Loss of Nipple Sensation	10.2%	(8.4, 12.0)	7.5%	(6.4, 8.6)	34.5%	(29.0, 40.0)	32.4%	(27.7, 37.2)
Capsular Contracture III/IV or grade unknown	9.0%	(7.3, 10.7)	6.8%	(5.7, 7.8)	30.0%	(24.5, 34.8)	28.3%	(23.9, 32.8)
Implant Removal for Any Reason	8.1%	(6.5, 9.7)	6.4%	(5.3, 7.4)	26.8%	(22.2, 31.5)	23.5%	(19.7, 27.4)
Asymmetry	6.7%	(5.2, 8.1)	N/A	N/A	27.9%	(23.0, 32.7)	N/A	N/A
Breast Pain	5.1%	(3.8, 6.5)	3.5%	(2.8, 4.3)	17.2%	(12.5, 21.9)	14.5%	(10.8, 18.2)
Intense Nipple Sensitivity	4.8%	(3.5, 6.1)	3.8%	(3.0, 4.6)	<1%	<1%	<1%	<1%
Leakage/Deflation	3.3%	(2.2, 4.5)	2.0%	(1.4, 2.6)	9.2%	(5.7, 12.7)	7.5%	(4.6, 10.3)
Hypertrophic Scarring	2.2%	(1.3, 3.0)	1.6%	(1.0, 2.1)	4.9%	(2.6, 7.2)	4.1%	(2.3, 5.9)
Infection	1.7%	(0.97, 2.5)	<1%	(0.57, 1.4)	9.0%	(6.0, 12.1)	7.9%	(5.4, 10.3)
Implant Palpability	1.6%	(0.88, 2.4)	1.6%	(1.1, 2.1)	<1%	<1%	<1%	<1%
Hematoma	1.5%	(0.80, 2.2)	<1%	(0.47, 1.2)	1.3%	(0.16, 2.4)	<1%	(0.12, 1.7)
Ptoxis	1.5%	(0.80, 2.2)	1.4%	(0.9, 1.9)	<1%	<1%	<1%	<1%
Delayed Wound Healing	<1%	<1%	<1%	<1%	5.8%	(3.5, 8.1)	4.8%	(3.0, 6.6)
Implant Extrusion	<1%	<1%	<1%	<1%	2.4%	(0.72, 4.0)	1.7%	(0.52, 3.0)
Implant Malposition	<1%	<1%	<1%	<1%	1.1%	(0.02, 2.2)	1.0%	(0.13, 1.9)
Seroma	<1%	<1%	<1%	<1%	5.9%	(3.6, 8.3)	4.7%	(2.9, 6.5)
Tissue/Skin Necrosis	<1%	<1%	<1%	<1%	2.0%	(0.64, 3.4)	1.5%	(0.46, 2.5)
Irritation/Inflammation	<1%	<1%	<1%	<1%	7.6%	(4.6, 10.5)	5.8%	(3.5, 8.0)

**Table 3a. SPS: Types of Reoperation Procedures through 3 Years for Augmentation**

Of the 1264 augmentation patients, there were 147 (11.6%) who underwent at least one reoperation procedure over the three years of follow-up in the SPS. A total of 358 reoperation procedures were performed in augmentation patients over the three years of the SPS. The types of reoperation procedures is shown below based on the number of procedures.

Type of Reoperation Procedure for Augmentation <sup>1</sup>	N	%
Implant Removal with Replacement	116	32%
Capsule Related <sup>1</sup>	77	22%
Scar or Wound Revision	67	19%
Reposition Implant	29	8%
Saline Adjustment	27	8%
Mastopexy	23	6%
Implant Removal without Replacement	9	3%
Biopsy/Cyst Removal	6	2%
Breast Reduction or Mastectomy	3	<1%
Nipple Related <sup>2</sup>	1	<1%
<b>Total</b>	<b>358</b>	<b>100%</b>

Notes: <sup>1</sup>Capsule procedures include open capsulotomy and capsulectomy.

<sup>2</sup>These were unplanned nipple procedures.

**Table 3b. SPS: Types of Reoperation Procedures through 3 Years for Reconstruction**

Of the 416 reconstruction patients in the SPS, 149 (35.8%) underwent at least one reoperation procedure over the three years of follow-up. A total of 353 reoperation procedures were performed in reconstruction patients over the three years. The types of reoperation procedures is shown below based on the number of procedures.

Procedure	Number	Percentage
Capsule Related <sup>1</sup>	99	28%
Implant Removal with Replacement	66	19%
Scar or Wound Revision	47	13%
Implant Removal without Replacement	40	11%
Nipple Related <sup>2</sup>	29	8%
Saline Adjustment	23	7%
Reposition Implant	20	6%
Biopsy/Cyst Removal	2	<1%
Breast Reduction or Mastectomy	2	<1%
Mastopexy	1	<1%
<b>Total</b>	<b>353</b>	<b>100%</b>

Notes: <sup>1</sup>Capsule related includes open capsulotomy and capsulectomy.

<sup>2</sup>These nipple procedures which were not part of planned reconstruction.

**Table 4a. SPS: Reasons for Implant Removal through 3 Years for Augmentation**

Of the 1264 augmentation patients, there were 87 patients (6.9%) who had 137 implants removed over the three years of follow-up in the SPS. Of the 136 augmentation implants removed, 82% were replaced. The primary reason for implant removal is shown in the table below based on the number of implants removed.

Reason for Implant Removal	Number	Percentage
Patient Request for Size/Style Change	50	37%
Leakage/Deflation	31	23%
Capsular Contracture	22	16%
Asymmetry/Wrinkling/Sagging/Scarring	22	16%
Infection	7	5%
Hematoma/Seroma	3	2%
Breast Cancer	1	<1%
<b>Total</b>	<b>136</b>	<b>100%</b>

**Table 4b. SPS: Reasons for Implant Removal through 3 Years for Reconstruction**

Of the 416 reconstruction patients, there were 97 patients (23.3%) who had 116 implants removed over the three years of follow-up in the SPS. Of the 116 reconstruction implants removed, 60% were replaced. The primary 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	Number	Percentage
Capsular Contracture	30	26%
Infection	30	26%
Leakage/Deflation	25	22%
Asymmetry/Wrinkling/Sagging/Scarring	13	11%
Patient Request for Size/Style Change	7	6%
Necrosis/Extrusion	6	5%
Breast Pain	4	3%

Breast Cancer	1	<1%
Total	116	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 deflation/leakage, 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, sloshing), 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 several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants.
- **Cancer**  
Published studies indicate that breast cancer is no more common in women with implants than those without implants.
- **Second Generation Effects**  
There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.

## CLINICAL STUDIES OVERVIEW

### 1. STUDY DESIGN

The safety and effectiveness of Mentor Corporation Saline-filled implants were evaluated in 2 open label multicenter clinical studies: LST and SPS. Patients studied were those seeking breast augmentation or reconstruction. Follow-up was 1 year in the LST, and yearly to 3 years in the SPS. 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

The LST enrolled 2066 augmentation, 104 reconstruction, and 215 revision patients, of which 47% were available for their 1 year visit. The SPS consisted of 1264 eligible augmentation patients and 416 eligible reconstruction patients. Data are available for 76% of the eligible augmentation patients and 68% of the eligible reconstruction patients at 3 years post-implantation. There were 15 deaths in the SPS; none were related to the implant or the surgery. There were no deaths in the LST.

In the SPS, the average age at surgery was 31.9 years for augmentation patients and 45.9 years for reconstruction patients.

With respect to surgical baseline factors in the SPS, for augmentation patients, the most frequently used devices were textured, the most common incision sites were periareolar and inframammary, and the most frequent site of placement was submuscular. For reconstruction patients, the most frequently used devices were Spectrum and textured, the most common incision site was the mastectomy scar, submuscular placement was the favored site, and breast reconstruction was delayed rather than immediate in the majority of patients.

**3. SAFETY OUTCOMES**

The LST safety outcomes are presented in table 1 above.

The SPS safety outcomes for primary implantation are presented in tables 2-4 above. Complications following implant removal with replacement (i.e., revision), are not included in Tables 2-4 above.

Table 5 below shows the 3-year cumulative Kaplan-Meier adverse event rates of first occurrence following implant replacement (i.e. revision) on a by implant basis for complications occurring in at least 1% of patients. There were 113 augmentation patients and 70 reconstruction patients who underwent replacement of their implants. For those patients, follow-up data were available on 120 replacement implants in augmentation patients and 76 replaced implants in reconstruction patients.

**Table 5a: SPS: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval) Following Augmentation Implant Replacement, by Implant**

Complication Following Replacement of Augmentation Implant	3-Year Risk Rate (%)	95% CI
Reoperation	15.8%	(8.9, 22.3)
Wrinkling	14.6%	(8.0, 21.2)
Implant Removal	12.1%	(5.9, 18.3)
Capsular Contracture III/IV and grade unknown	9.1%	(3.0, 15.1)
Leakage/Deflation	4.4%	(0.0, 8.8)
Asymmetry	3.8%	(0.1, 7.5)
Breast Pain	3.0%	(0.0, 5.5)
Hematoma	1.7%	(0.0, 4.1)
Hypertrophic Scarring	2.0%	(0.0, 4.8)

**Table 5b: SPS: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval) Following Reconstruction Implant Replacement, by Implant**

Complication Following Reconstruction Implant Replacement	3-Year Risk Rate (%)	95% CI
Reoperation	30.6%	(18.4, 43.0)
Leakage/Deflation	22.6%	(9.9, 35.3)
Implant Removal	21.1%	(10.6, 31.5)
Capsular Contracture III/IV and grade unknown	18.9%	(8.5, 29.1)
Asymmetry	17.1%	(5.8, 28.3)
Wrinkling	16.0%	(5.0, 27.0)
Breast Pain	13.1%	(2.9, 23.3)
Infection	4.7%	(0.0, 9.9)

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Irritation/Inflammation	3.0%	(0.0, 7.1)
Seroma	3.0%	(0.0, 7.0)
Extrusion	1.9%	(0.0, 5.4)
Hematoma	1.5%	(0.0, 4.5)
Hypertrophic Scarring	1.6%	(0.0, 4.6)
Necrosis	1.4%	(0.0, 4.2)

**Connective Tissue Disease (CTD) and Breast Cancer**

Tables 6a and 6b summarize post-implant observations from the SPS pertaining to connective tissue/autoimmune (CTD) disease. These data should be interpreted with the precaution in that there was no comparison group of similar women without implants. Unconfirmed reports were based on self-reports by the patients. Confirmed reports were based on a diagnosis by a physician. Data pertaining to effects on offspring, mammographic detection of tumors/lesions, lactation problems, and reproduction problems were not collected in these studies. New cases of breast cancer were reported in 2 augmentation patients.

**Table 6a. SPS: Reports of CTD through 3 Years for Augmentation, By Patient.**

Reported CTD	Reports in Patients	Reports in Patients with Breast Augmentation	Prevalence
Osteoarthritis/Rheumatoid Arthritis/Unknown	1	19	4.4 <sup>a</sup>
Osteoarthritis		1	3.4 <sup>b</sup>
Rheumatoid Arthritis	1	3	1.0-1.2 <sup>c</sup>
Arthritis (type unknown)		15	-
Ankylosing spondylitis			0.3 <sup>d</sup>
Lupus Erythematosus	1		0.2 - 0.5 <sup>e</sup>
Total	2	19 <sup>f</sup>	
<sup>a</sup> Combined estimates for osteoarthritis and rheumatoid arthritis <sup>b</sup> Oliveria et al. 1995 <sup>c</sup> Chan et al. 1993; Dugowson et al. 1991 <sup>d</sup> Kaipainen-Seppanen et al. 1997 <sup>e</sup> Uramoto et al. 1999; McCarty et al. 1995 <sup>f</sup> 2 aug pts had 2 unconfirmed CTDs			

**Table 6b. SPS: Reports of CTD through 3 Years for Reconstruction, By Patient.**

CTD	Number of Patients	Number of Reports	Rate (%)
Osteoarthritis/Rheumatoid Arthritis/Unknown	4	28	4.4 <sup>a</sup>
Osteoarthritis	2	8	3.4 <sup>b</sup>
Rheumatoid Arthritis		2	1.0-1.2 <sup>c</sup>
Arthritis (type unknown)	1	18	-
Ankylosing spondylitis	1		0.3 <sup>d</sup>
Lupus Erythematosus			0.2 - 0.5 <sup>e</sup>
Total	4	28 <sup>f</sup>	

<sup>a</sup> Combined estimates for osteoarthritis and rheumatoid arthritis.  
<sup>b</sup> Oliveria et al. 1995  
<sup>c</sup> Chan et al. 1993; Dugowson et al. 1991  
<sup>d</sup> Kaipainen-Seppanen et al. 1997  
<sup>e</sup> Uramoto et al. 1999; McCarty et al. 1995  
<sup>f</sup> 7 recon pts had 2 unconfirmed CTDs

#### SUBGROUP ANALYSES

Cox-Regression analyses were performed to identify risk factors for the complications of deflation, capsular contracture (Baker Class III or IV), infection, explantation, and reoperation. Selected significant results of these analyses are summarized below:

- Deflation was significantly higher with Betadine<sup>®</sup> surgical pocket irrigation than without.
- Capsular contracture (Baker Class III or IV) rate was significantly higher in older than in younger patients.
- Capsular contracture (Baker Class III or IV) rates were lower in the inframmary approach in augmentation compared to periareolar.
- There was no difference in capsular contracture (Baker Class III or IV) rate for textured versus smooth implants.
- Spectrum Mammary Prostheses were associated with a higher implant removal and reoperation rate compared to the Saline-Filled Mammary Prostheses.

#### 4. EFFECTIVENESS OUTCOMES

For augmentation, effectiveness outcomes included breast size change, patient satisfaction, and comfort with appearance. For reconstruction, effectiveness outcomes included breast size change, level of functional living, and depression. These outcomes were reported before implantation and at three years after surgery for those patients who still had at least one of their original implants.

For reconstruction patients, 283 out of the original 416 patients (68%) still had implants and were in the study after three years. Of these 283 patients, the average increase in chest circumference was 1.5 inches.

For augmentation patients, 955 out of the original 1264 patients (76%) still had implants and were in the study after three years. Of these 955 patients, 917 (96%) experienced an increase of at least one cup size at 3 years; the average increase in chest circumference was 2.8 inches. Of the 955 patients still in the study, 860 (90%) indicated being satisfied with the general appearance of their breasts, as measured by the Breast Evaluation Questionnaire (BEQ).

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Most augmentation patients who still had their original implants and were still in the study at 3 years exhibited an improvement in the two measured subscales of the Multidimensional Body-Self Relation Questionnaire (MSBRQ) (which measures comfort with your general appearance). For augmentation patients, the Tennessee Self-Concept Scale (which measures self-concept) showed a slight increase at 3 years compared to before implantation.

## ***Instructions for Use***

**NOTE:** It is advisable to have more than one size mammary 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 prosthesis is supplied with two Patient Record Labels showing the catalog number, serial 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) and the fill volume of each prosthesis should be indicated on the label.

### **Sterilization**

Siltex and smooth-surface saline-filled mammary implants are provided sterile. This product is recommended 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 Saline-Filled Implants**

The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by the following steps:

1. Partially inflate the prosthesis with air through the fill tube, taking care not to damage the valve (see Attaching Fill Tube instructions for the Diaphragm Valve under FILLING PROCEDURE).
2. Submerge the air-filled prosthesis in sterile, pyrogen-free testing fluid (water or saline).
3. Apply mild pressure and check for possible punctures or leaks.

### **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.

### FILLING PROCEDURE- IMPLANTS WITH DIAPHRAGM VALVES

The normal position of the diaphragm valve, which is located anteriorly, is closed. A fill tube stylet, enclosed with the product, is inserted into the implant's valve system at the time of surgery and removed intraoperatively when the desired volume is reached. Air or fluid flow into or out of the prosthesis is established by inserting the fill tube stylet, which holds the diaphragm valve open.

#### Attaching Fill Tube

1. Remove and discard the protective strip between the strap closure and valve. Push the strap closure to one side of the valve opening. To insert the fill tube into the valve opening, wet the stylet tip of the fill tube in sterile, isotonic saline, and, using the thumb and forefinger to stabilize/support the valve seat while moving the strap aside, gently push the stylet tip into the valve opening as far as the fill-tube stylet flange permits. (Figure 1a) Support of the diaphragm valve together with a gentle rotation of the fill tube during insertion facilitates ease of entry. Continue to press the stylet against the prosthesis shell until air freely escapes from the prosthesis (Figures 1b & 1c).

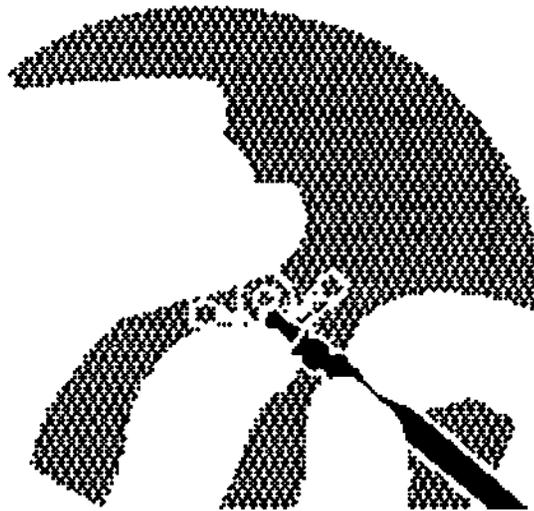


Figure 1a Stabilize and support the valve seat while moving the strap aside.

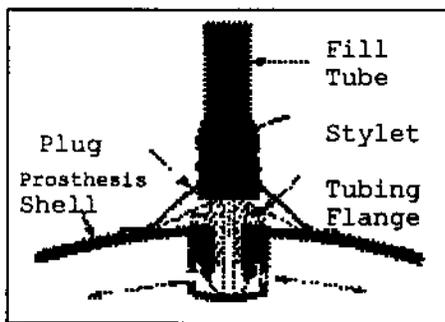


Figure 1b Diaphragm valve held open by fill tube

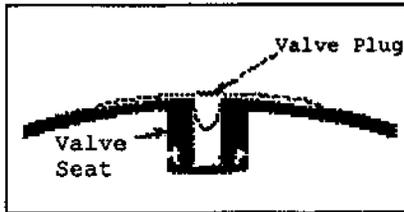


Figure 1c Strap closure in place

**Caution:** The valve system can be damaged by improper use of the fill-tube stylet. Care should be taken that the stylet enters the valve smoothly. Use the thumb and forefinger to stabilize/support the valve seat and gently push the stylet tip into the valve opening. Overstressing the valve material may result in punctures or tears and subsequent deflation may occur. Use only the fill tube stylet provided with this product. Take care not to puncture the diaphragm valve or the shell with the stylet tip. Care must also be taken when the fill tube stylet is removed to prevent damage to the valve assembly.

#### Deflation and Insertion of Implant

2. Prior to inserting the implant into the surgically prepared pocket, deflate the prosthesis completely. Attach an empty, sterile syringe to the luer-lock adapter of the fill tube and draw out as much air as possible. Remove the fill-tube stylet from the valve assembly. Fold the implant and insert it into the surgically prepared pocket. (Some surgeons prefer to leave the fill tube inserted in the implant, or partially fill the implant prior to placement. If the fill tube is left inserted in the implant, use of the enclosed two-way check valve on the luer lock will prevent air from re-entering the prosthesis through the fill tube after deflation.) Whatever method is used, evacuation of the air from the implant and the fill tube as indicated will minimize the air to be removed after prosthesis insertion.

#### Filling the Implant

3. Prior to adding fluid to the implant, the enclosed two-way check valve should be attached to the luer adapter of the fill tube (Figure 2). The two-way check valve opens when the syringe is attached and closes when the syringe is removed. The fill tube and stylet, luer-lock adapter, and check valve are used to facilitate intraoperative filling of the prosthesis and must not be implanted.

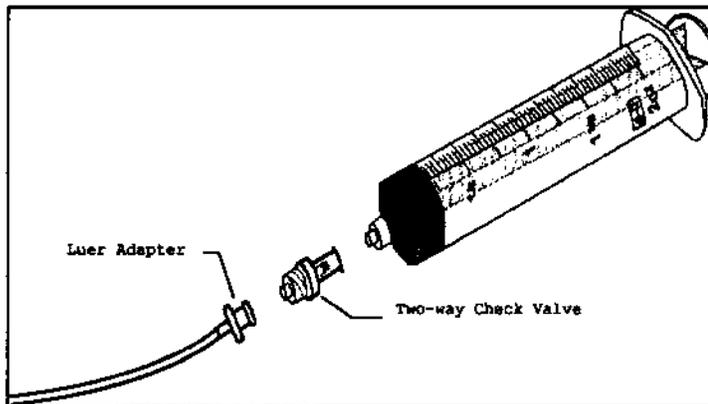


Figure 2 - Luer lock, two-way check valve and syringe assembly.

4. Use a syringe filled with sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection to fill the prosthesis to the recommended volume (see specifications on product labeling).

Only sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection drawn from its original container should be used. As it is known that bacterial infections may result from contaminated

saline, it is recommended that a new sterile saline container be used with each surgery and implant-filling procedure.

At no time should an implant be filled with less than the minimum recommended volume or with more than the maximum recommended volume (see product labeling). The suggested optimum fill capacity is the midpoint between the minimum and maximum fill volume.

**NOTE:** Should adjustment of volume be necessary, reinsert the fill tube (connected to syringe) and withdraw or add fluid as needed.

5. Entrapped air may be removed by leaving the fill tube in place after filling and using the attached syringe to draw out as much air as possible. Any remaining air will eventually diffuse out and be absorbed by tissue.
6. When removing the fill-tube assembly from the valve, support area around diaphragm valve, grasp the stylet hub and avoid pulling directly on the fill tubing.
7. Entrapped fluid in the valve opening should be removed by gently manipulating the valve between the thumb and forefinger after the fill tube has been removed. To help retard tissue ingrowth or fluid accumulation in the valve opening, always engage the strap closure (see Figure 1c).
8. At the time of wound closure, extreme care should be taken not to damage the implant with surgical instruments. Preplacement of deep sutures may help to avoid inadvertent product contact with suture needles and subsequent product damage.

#### **FILLING PROCEDURE – SPECTRUM IMPLANTS WITH KINK PLUG VALVES**

Spectrum valve is postoperatively adjustable. The silicone elastomer fill tube is inserted into the self-sealing valve at the time of manufacture. The prosthesis volume can be adjusted postoperatively via the fill tube and an injection dome. A connector system is used to join the preinserted fill tube to the injection dome. Two types of connector systems and two types of injection domes are provided with each product, and either may be used. Once the desired volume is achieved, the fill tube and injection dome are removed through a small incision under local anesthetic.

**Connector Systems (see the Connection Systems instructions provided in the connector and dome package):**

1. The Mentor True-Lock® connector does not require a suture tie.
2. The stainless steel connector does require suture material tied around tube and connector to secure the connection.

**Injection Domes (used for temporary subcutaneous implantation):**

1. The micro injection dome may be used when diminished palpability is desirable. This dome is designed to withstand up to 10 total injections. It is suggested that the dome be placed in a relatively superficial location to allow ease of identification and access during subsequent filling procedures. Inflation is accomplished by using pyrogen-free, sterile Sodium Chloride USP Solution for injection. Use a 23 gauge (or finer) standard or butterfly needle. Extreme care should be taken to puncture only the center of the top surface of the micro injection dome (Figure 1).

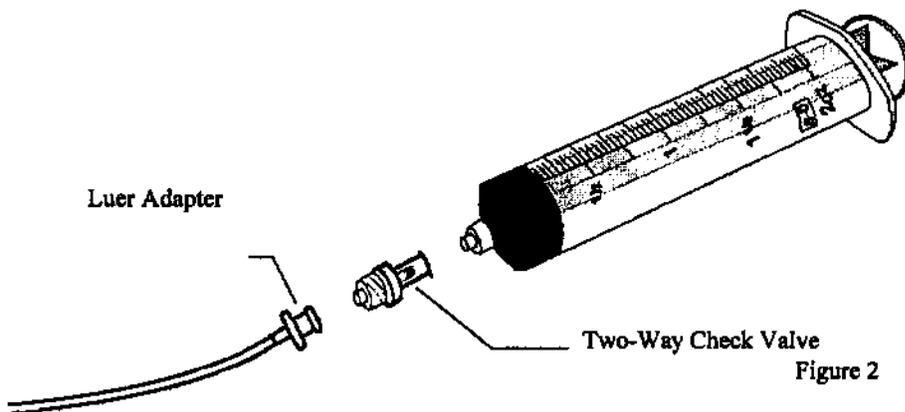
**Figure 1**

2. The standard injection dome is larger in diameter and height than the micro injection dome and can withstand up to 20 total injections.

The tube which connects the implant to the injection dome should be carefully sized to avoid kinks. Careful attachment of the fill tube to the Tru-Lock of stainless steel connector is important to prevent separation. Failure of the device to inflate may be due to kinking of the tube, leakage, separation of the components or injections which do not penetrate the injection dome.

**Filling and Connection Procedure**

1. Prior to inserting the prosthesis into the surgically prepared pocket, deflate the device completely.
2. Fold the prosthesis and insert it into the surgically prepared pocket. (Some surgeons prefer to partially fill the prosthesis prior to placement.) Whatever method is used, evacuation of air from the implant and the fill tube as indicated in Step 1 will minimize the air to be removed in Step 4.
3. Use a syringe filled with pyrogen-free, sterile Sodium Chloride USP Solution for Injection to inflate the prosthesis to the recommended volume. A luer adapter and check valve have been included to facilitate intraoperative filling of the device, and must not be implanted (Figure 2). The enclosed two-way check valve opens when a syringe is attached, and closes when the syringe is removed. Prior to adding fluid to the implant, the two-way check valve should be attached to the luer adapter of the fill tube. Only sterile, pyrogen-free, Sodium Chloride USP Solution for injection drawn from its original container should be used.



**Caution:** The prosthesis must not be filled to a volume less than or greater than specified (see product label and Inflation Table). The prosthesis must be filled to the "Final Range" before pulling fill tube.

4. Entrapped air may be removed by using the attached filling syringe. Any remaining air will eventually diffuse out and be absorbed by tissue.

NOTE: Should adjustment of volume be necessary during surgery, fluid may be added or removed per Steps 3 and 4.

5. If the device will not be postoperatively adjusted, the fill tube must be removed. The self-sealing valve will close to create the long term implant.
6. Should postoperative adjustability be desired, connect the fill tube to the injection dome after trimming the fill tube and discarding the luer adaptor and check valve. Connect the fill tube to the desired injection dome using the connector supplied with the injection dome. Care should be taken to tailor the length of the tube so that it will not kink or shorten as the implant expands.

NOTE: If the standard or micro dome with stainless steel connector are selected, nonabsorbable suture material should be tied around the tube and connector (Figure 3) to secure the connection. It is important to securely tie the fill tube both distally and proximally to the connector so the entire fill tube assembly will be removed when the injection dome is removed from the patient. Care must be taken to secure the tube to the connector with ligatures in such a manner as to avoid cutting or occluding the tube or connector. (Further detail is provided in the Connection Systems instructions located in the connector and dome package.)

Figure 3

Caution: The use of forceps or hemostats to aid in the connection and suture tying process is specifically contraindicated as tube or connector damage may lead to deflation of the device.

NOTE: If the dome pack with both domes and connector systems is selected, instructions for use for the True-Lock connector are included in the connector and dome package. Read the instructions carefully before using this connection system. It is important to securely assemble both sides of the fill tube to the connector so that the entire fill tube assembly will be removed when the injection dome is removed from the patient.

7. It is suggested that the injection dome and tube be placed high in the subcutaneous tissue adjacent to the device to allow easy identification and access during subsequent filling. The dome should be placed no less than three inches from the prosthesis to avoid damage to the device during postoperative filling. Inflation is accomplished by using sterile, pyrogen-free Sodium Chloride USP Solution for injection. Use a 23 gauge (or finer) standard or butterfly needle. Extreme care should be taken to puncture only the center of the top surface of the injection dome at an angle perpendicular  $\pm 30^\circ$  to the top surface (Figure 4).

Figure 4

8. Before closing the surgical incisions, confirm that the device is patent. This can be done by inserting the 23 gauge butterfly needle with syringe attached, into the injection dome, infusing or withdrawing fluid and observing for proper inflation/deflation of the prosthesis.

**Caution:** At the time of wound closure, extreme care should be taken not to damage the prosthesis with surgical instruments. Placement of deep sutures may help to avoid inadvertent product contact with suture needles and subsequent product damage.

#### **Postoperative Volume Adjustment**

At no time should a prosthesis be filled with less than the Temporary Minimum Volume or with more than the Final Maximum Volume (see product label and Inflation Table). Underfilled prostheses may buckle, fold or wrinkle causing crease/fold failure of the device, and subsequent deflation can occur. Additionally, inflation beyond the Final Maximum Volume can also cause crease/fold failure and deflation.

The patient must be monitored during the volume adjustment period to guard against sloughing, necrosis, wound dehiscence, etc. If at any time the overlying tissue exhibits any of these symptoms, the device should be reduced in volume (but not below the recommended Temporary Minimum Volume) by reversing the filling procedures and withdrawing fluid from the prosthesis. If signs persist, the device must be removed.

Once volume adjustments are completed, remove the injection dome and fill tube. Make a small incision at the location of the injection dome. Grasp beyond the connector and remove the tube before taking out the injection dome. This prevents the tube from dislodging and retracting back into the pocket. Do not pull on the connector while removing the tube as it may disconnect and subsequent deflation could occur. Use a slow and steady traction to remove the fill tube and thus prevent damage to the prosthesis or its self-sealing valve. Continue to pull firmly on the fill tube until the entire length of tube is withdrawn, which will be evidenced by a notch in the end of the tube.

**NOTE:** Mentor recommends timely volume adjustment of the device. Upon achievement of the desired volume adjustment result, the fill tube and injection dome must be removed. It is recommended that the duration of volume adjustment not exceed six months as tissue adhesions may make it more difficult to remove the fill tube and/or compromise valve integrity. Damage to the implant and/or leakage may result.

Mentor package insert – 5-10-00

SMOOTH & SILTEX SPECTRUM® INFLATION TABLE

Siltex Catalog Number	Smooth Catalog Number	Device Volume (cc)	Temporary* Minimum Volume (cc)	Final Minimum Volume (cc)	Final Maximum Volume (cc)	Final Volume (cc)
354-2410M		350-1410	125	105	125	150
354-2420M		350-1420	175	150	175	210
354-2430M		350-1430	225	190	225	270
354-2440M		350-1440	275	230	275	330
354-2450M		350-1450	325	275	325	390
354-2460M		350-1460	375	320	375	450
354-2470M		350-1470	425	360	425	510
354-2480M		350-1480	475	400	475	570
		350-1485	525	445	525	630
		350-1490	575	490	575	690

\* Temporary Minimum Volume must not exceed 90 days.

SILTEX® CONTOUR PROFILE® SPECTRUM INFLATION TABLE

Catalog Number	Device Volume (cc)	Temporary* Minimum Volume (cc)	Final Minimum Volume (cc)	Final Maximum Volume (cc)	Final Volume (cc)
354-2511	275	235	275	330	
354-2512	350	300	350	420	
354-2513	450	380	450	540	
354-2514	550	470	550	660	
354-2515	650	550	650	780	

\* Temporary Minimum Volume must not exceed 90 days.

SILTEX® CONTOUR PROFILE® SPECTRUM INFLATION TABLE

Catalog Number	Device Volume (cc)	Temporary* Minimum Volume (cc)	Final Minimum Volume (cc)	Final Maximum Volume (cc)	Final Volume (cc)
353-6150	150	125	150	180	
353-6200	200	170	200	240	
353-6250	250	210	250	300	
353-6300	300	255	300	360	
353-6350	350	300	350	420	
353-6400	400	340	400	480	
353-6450	450	380	450	540	
353-6500	500	425	500	600	
353-6550	550	470	550	660	
353-6600	600	510	600	720	
353-6650	650	550	650	780	
353-6700	700	595	700	840	

\* Temporary Minimum Volume must not exceed 90 days.

Mentor package insert – 5-10-00

SILTEX® CONTOUR PROFILE® PARTIALLY TEXTURED SPECTRUM INFLATION TABLE

Catalog Number	Device Volume (cc)	Temporary*		Final	
		Minimum Volume (cc)	Minimum Volume (cc)	Maximum Volume (cc)	Final Volume (cc)
353-6150PT	150	125	150	180	
353-6200PT	200	170	200	240	
353-6250PT	250	210	250	300	
353-6300PT	300	255	300	360	
353-6350PT	350	300	350	420	
353-6400PT	400	340	400	480	
353-6450PT	450	380	450	540	
353-6500PT	500	425	500	600	
353-6550PT	550	470	550	660	
353-6600PT	600	510	600	720	
353-6650PT	650	550	650	780	
353-6700PT	700	595	700	840	

Temporary Minimum Volume must not exceed 90 days.

**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 for examination and analyses.

**RETURNED GOODS AUTHORIZATION**

• **U.S. Customers**

Authorization must be received from Mentor prior to the return of merchandise. Merchandise returned must have all manufacturer's seals intact and be returned within 30 days from date of invoice to be eligible for credit or replacement. Please contact the Mentor Customer Service Department for details. To obtain a Return Authorization number call (800) 235-5731, or FAX (805) 967-7108. 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:

- ***Saline-Filled Breast Implant Surgery: Making an Informed Decision.***  
This brochure can be used to facilitate patient education in the risks and benefits of saline-filled breast implant surgery. The patient should be advised to wait a week after reviewing and considering this information before deciding whether to have augmentation surgery.
- ***Device Identification Card***  
Enclosed with each saline-filled breast implant is a Device Identification Card. To complete the Device Identification Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. Patients should be provided with these cards 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  
3041 Skyway Circle North  
Irving, TX 75038 USA



## **MENTOR**

For customer service or to return product, please call  
(800) 235-5731 in USA; outside USA call (805) 879-6000

**Manufacturer**  
Mentor  
Irving, TX 75038 USA

## SALINE-FILLED BREAST IMPLANT SURGERY: MAKING AN INFORMED DECISION

### So You're Considering Saline-Filled Breast Implant Surgery

The purpose of this brochure is to assist you in making an informed decision about breast augmentation and breast reconstruction surgery. This educational brochure is set up to help you talk with your doctor, as well as provide you with general information on breast implant surgery and give you specific details about Mentor breast implants.

### What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Situated beneath the breast is the pectoralis major muscle or chest muscle. Factors such as pregnancy, (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age combine to stretch the skin, which may cause the breast to droop or sag.



### What is a Saline-Filled Breast Implant?

A breast implant is a sac (implant shell) of silicone elastomer (rubber), which is surgically implanted under your chest tissues, and then filled with saline, a salt water solution, through a valve.



In augmentation surgery a breast implant can be placed either over the pectoralis muscle (subglandularly) or partially under this muscle (submuscularly), depending on the thickness of your breast tissue and its ability to adequately cover the breast implant. In reconstruction following mastectomy, a breast implant is most often placed submuscularly. Reconstruction following mastectomy may involve a two-stage

procedure, which includes placement of a tissue expander for several months prior to placement of the breast implant.

The silicone elastomer (rubber) contains the following substances: 1) small amounts (parts per million) of various smaller silicones; 2) small amounts (50 - 100 parts per million) of metals like tin and platinum and very trace amounts of other metals; 3) trace amounts of volatile materials like xylene and other organic compounds; and 4) considerable amounts (approximately 20 parts per hundred) of finely powdered silica that is tightly bound to the silicone rubber pouch.

### **Are You Eligible for Saline-Filled Breast Implants?**

*Implants are to be used for females for the following indications:*

- **Breast Augmentation** – This procedure is done to increase the size and proportions of a woman's breasts. **A woman must be at least 18 years old for breast augmentation.**
- **Breast Reconstruction** – This procedure is done to restore a woman's breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect.

### **What Are Important Factors for You to Consider When Deciding to Have Saline-Filled Implants?**

- ⇒ Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one time surgery. You are likely to need additional surgery and doctor visits over the course of your life.
- ⇒ Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.
- ⇒ Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- ⇒ Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breast from sagging after pregnancy.
- ⇒ With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- ⇒ For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

**Augmentation** - Insurance does not cover breast augmentation and may not cover reoperation (additional surgery) and additional doctor's visits following augmentation.

**Reconstruction** - Most insurance covers the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional doctor's visits following reconstruction may not be covered, depending on the policy.

## Who is Not Eligible for Breast Implants?

### *Implants are contraindicated for women with:*

- Existing malignant or pre-malignant cancer of your breast without adequate treatment
- Active infection anywhere in your body
- Augmentation in women who are currently pregnant or nursing

## What are Contraindications, Warnings, and Precautions for You to Consider?

### *Surgical practices that are contraindicated in breast implantation:*

- Placement of drugs/substances inside the implant other than sterile saline
- Any contact of the implant with Betadine®
- Injection through implant shell
- Alteration of the implant
- Stacking of implants: more than one implant per breast per breast pocket

### *Safety and effectiveness has not been established in patients with the following conditions:*

- Autoimmune diseases such as lupus and scleroderma
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (e.g., currently receiving immunosuppressive therapy)
- Reduced blood supply to breast tissue

### *Further considerations:*

- **Pre-implantation Mammography** - You may wish to undergo a preoperative mammogram and another one 6 months to one year after implantation to establish a baseline.
- **Interference with Mammography** - The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.
- **Distinguishing the implant from breast tissue during breast self-examination** - You should perform breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps or suspicious lesions (sores) should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant.
- **Long Term Effects** - The long term safety and effectiveness of breast implants have not been studied; however, Mentor is monitoring the long term (i.e., 10 year) chance of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant). Mentor is also conducting mechanical testing to assess the long-term likelihood of implant rupture. We will update this brochure with this information and timeframes later.
- **Capsule Procedures** - You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule is not recommended as this may result in breakage of the implant.

## What Types of Breast Implant Are Available from Mentor?

Implants come in a variety of shapes, surface textures, and sizes. There are 2 types/families of implants filled with saline – one referred to as Saline-Filled and the other referred to as Spectrum. The Saline-Filled family of implants has a self-sealing valve located on the front (anterior) of the implant that is used

for filling the device. The Spectrum family has a valve on the back (posterior) of the implant that allows saline to be added after surgery (postoperative adjustability). The implants are available with Siltex textured, Partially Textured (PT) or smooth surface shells. It should be noted that although smooth surface and Siltex-textured surface implants have been evaluated in Mentor's clinical studies, the recently introduced PT implants were not included in these studies.

Below is a description of Mentor implant styles. Be sure to familiarize yourself with the different features of breast implants and to discuss the most appropriate type(s) of implants for you with your surgeon.

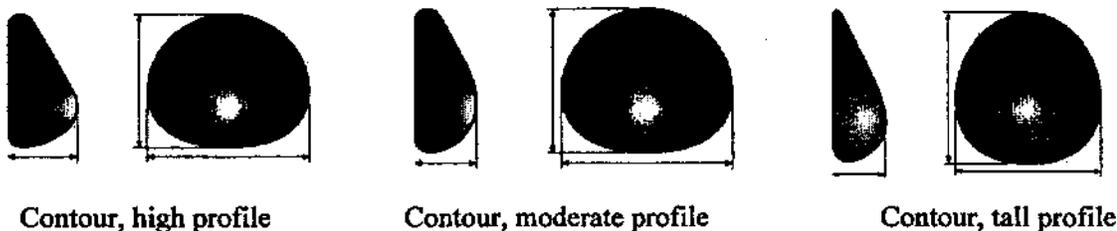
**Saline-Filled Breast Implant Family (fixed volume):**

- **Round Styles:**
  - Style 1600: Smooth shell surface, anterior filling valve
  - Style 2600: Siltex® textured shell surface, anterior filling valve
  
- **Contour Styles:**
  - Style 2700: Siltex® textured shell surface, anterior filling valve, high profile
  - Style 2900: Siltex® textured shell surface, anterior filling valve, moderate profile
  - Style 5000: Siltex® textured shell surface, anterior filling valve, tall profile
  - Style 5000PT: Siltex® partially textured shell surface, anterior filling valve, tall profile

**Spectrum® Breast Implant Family (post-operative adjustment of volume):**

- **Round Styles:**
  - Style 1400: Smooth shell surface, posterior filling valve
  - Style 2400: Siltex® textured shell surface, posterior filling valve
  
- **Contour Styles:**
  - Style 2500: Siltex® textured shell surface, posterior filling valve, high profile
  - Style 6000: Siltex® textured shell surface, posterior filling valve, tall profile
  - Style 6000PT: Siltex® partially textured shell surface, posterior filling valve, tall profile

The following diagrams illustrate the high, moderate and tall contour profiles.



**What Are the Breast Implant Complications?**

Undergoing any surgical procedure may involve the risk of complications such as the effects of anesthesia, infection, swelling, redness, bleeding, and pain.

In addition, there are potential complications specific to breast implants. These complications include:

- **Deflation/Rupture**

Breast implants deflate when the saline solution leaks either through an unsealed or damaged valve, or through a break in the implant shell. Implant deflation can occur immediately or progressively over a period of days and is noticed by loss of size or shape of the implant. Some implants deflate (or rupture) in the first few months after being implanted and some deflate after several years. Causes of

deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate/rupture.

Deflated implants necessitate additional surgery to remove and to possibly replace the implant.

- **Capsular Contracture**

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture is more common following infection, hematoma, and seroma. It is also more common with subglandular placement. Symptoms range from firmness and mild discomfort, to pain, distortion, palpability of the implant, and/or displacement of the implant.

Additional surgery is needed in cases where pain and/or firmness is severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself.

Capsular contracture may happen again after these additional surgeries.

- **Pain**

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your doctor about severe pain.

- **Additional Surgeries**

Women should understand there is a high chance they will need to have additional surgery at some point to replace or remove the implant. Also, problems such as deflation, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. Those who do not may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

- **Dissatisfaction with Cosmetic Results**

Dissatisfying results such as wrinkling, asymmetry implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised scar) scarring, and/or sloshing may occur. Careful surgical planning and technique can minimize but not always prevent such results.

- **Infection**

Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved.

In rare instances, Toxic Shock Syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment.

- **Hematoma/Seroma**  
Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery, however this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.
- **Changes in Nipple and Breast Sensation**  
Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect sexual response or the ability to nurse a baby. (See the paragraph on breast-feeding below.)
- **Breast Feeding**  
At this time it is not known if a small amount of silicone may diffuse (pass through) from the saline-filled breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting *silicone* levels in breast milk, a study measuring *silicon* (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants.  
  
With respect to the ability to successfully breast feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast feed compared to 7% without implants. The periareolar incision site may significantly reduce the ability to successfully breast feed.
- **Calcium Deposits in the Tissue Around the Implant**  
Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery to biopsy and/or removal of the implant to distinguish them from cancer.
- **Delayed Wound Healing**  
In some cases, the incision site fails to heal normally.
- **Extrusion**  
Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.
- **Necrosis**  
Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.
- **Breast Tissue Atrophy/Chest Wall Deformity**  
The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

In addition to these common complications, there are have been concerns with rarer diseases, of which you should be aware:

- **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 several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.
- **Cancer**  
Published studies indicate that breast cancer is no more common in women with implants than those without implants.
- **Second Generation Effects**  
There have been concerns raised regarding potential damaging effects on children born of mothers with implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.

### **What Are the Risks Based on Mentor's Clinical Studies?**

Mentor conducted clinical testing of its saline-filled breast implants to determine the short-term and most common risks of their implants. These were assessed in the following studies:

- Saline Prospective Study (SPS)
- The Large Simple Trial (LST)

The LST was designed to determine the 1-year risk of capsular contracture, infection, deflation, and implant removal. There were 2,066 augmentation patients, 104 reconstruction patients, and 215 revision patients enrolled. Of these enrolled patients, 47% returned for their 1-year visit.

The SPS was designed as a 3-year study to assess all complications with breast implants as well as patient satisfaction, body image, and self concept. Patients were followed annually and data through 3 years are available. The SPS enrolled 1,264 augmentation patients and 428 reconstruction patients. 76% of augmentation patients and 68% of reconstruction patients returned for their 3-year visit. The outcomes of the patients lost to follow-up are not known.

### **What Is A Cumulative Risk Rate?**

The complication risk information obtained from the clinical studies are reported in the form of estimated risk rates for each complication at three years following implant surgery for the SPS, and at one year after implant surgery for the LST Study. These cumulative risk rates describe the risk or chance of developing a first occurrence of a complication in a patient through 3 years for the SPS and through 1 year for the LST. For example, a 1-year cumulative risk rate of 2% for infection means that approximately 2 patients out of 100 will experience at least one infection at some time during the first year after implantation. This 1-year cumulative risk rate does not mean that 2% of the patients still have an infection at one year. Risk rates are reported on both a by-patient and by-implant basis because many patients have two implants.

These risk rates do not provide the risk or chance of developing multiple occurrences of the same complication, nor do they provide information on how long a complication lasted, how severe the complication was, or what treatment (if any) was needed for the complication to resolve. These are issues which you discuss with your surgeon, and which you should understand prior to having an implant.

**What Were the 1-Year Cumulative Complication Risk Rates of First Occurrence from the LST?**

Complication	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year
Capsular Contracture	5%	3%	29%	23%	15%	10%
Infection	1%	1%	NA	NA	NA	NA
Implant Leakage/Deflation	1%	1%	NA	NA	2%	1%
Implant Removal	4%	3%	10%	8%	6%	5%

NA: Not Available or insufficient data to perform an analysis of risk of that complication.

\* Data on 47% of the patients in the study.

**What Were the 3-Year Cumulative Complication Risk Rates of First Occurrence from the SPS?**

The cumulative risk rates of first occurrence which occurred in at least 1% of the patients are shown in the following tables, including all levels of severity (mild to severe):

Augmentation

Complication	1 Year	3 Year
Wrinkling	21%	20%
Reoperation	13%	10%
Loss of Nipple Sensation	10%	8%
Capsular Contracture III/IV or grade unknown	9%	7%
Implant Removal	8%	6%
Asymmetry	7%	5%
Intense Nipple Sensation	5%	4%
Breast Pain	5%	4%
Leakage/Deflation	3%	2%
Implant Palpability	2%	2%
Infection	2%	1%
Breast Sagging	2%	1%
Scarring Complications	2%	2%

Reconstruction

Complication	1 Year	3 Year
Reoperation	40%	35%
Loss of Nipple Sensation	35%	32%
Capsular Contracture III/IV or grade unknown	30%	28%
Asymmetry	28%	25%
Implant Removal	27%	24%
Wrinkling	20%	21%
Breast Pain	17%	15%
Infection	9%	8%
Leakage/Deflation	9%	7%

### What Were the 1-Year Cumulative Complication Risk Rates of First Occurrence from the LST?

Complication	1-Year Risk Rate					
	Augmentation		Reconstruction		Revision	
	By Patient	By Implant	By Patient	By Implant	By Patient	By Implant
Capsular Contracture	5%	3%	29%	23%	15%	10%
Infection	1%	1%	NA	NA	NA	NA
Implant Leakage/Deflation	1%	1%	NA	NA	2%	1%
Implant Removal	4%	3%	10%	8%	6%	5%

NA: Not Available or insufficient data to perform an analysis of risk of that complication.

\* Data on 47% of the patients in the study.

### What Were the 3-Year Cumulative Complication Risk Rates of First Occurrence from the SPS?

The cumulative risk rates of first occurrence which occurred in at least 1% of the patients are shown in the following tables, including all levels of severity (mild to severe):

#### Augmentation

Augmentation Complications	3-Year Risk Rate	
	By Patient N=1264	By Implant N=2526
Wrinkling	21%	20%
Reoperation	13%	10%
Loss of Nipple Sensation	10%	8%
Capsular Contracture III/IV or grade unknown	9%	7%
Implant Removal	8%	6%
Asymmetry	7%	5%
Intense Nipple Sensation	5%	4%
Breast Pain	5%	4%
Leakage/Deflation	3%	2%
Implant Palpability	2%	2%
Infection	2%	1%
Breast Sagging	2%	1%
Scarring Complications	2%	2%

#### Reconstruction

Reconstruction Complications	3-Year Risk Rate	
	By Patient N=416	By Implant N=572
Reoperation	40%	35%
Loss of Nipple Sensation	35%	32%
Capsular Contracture III/IV or grade unknown	30%	28%
Asymmetry	28%	25%
Implant Removal	27%	24%
Wrinkling	20%	21%
Breast Pain	17%	15%
Infection	9%	8%
Leakage/Deflation	9%	7%

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Irritation/Inflammation	8%	6%
Delayed Wound Healing	6%	5%
Seroma	6%	5%
Scarring Complications	5%	4%
Extrusion	2%	2%
Necrosis	2%	1%
Hematoma	1%	1%
Position Change	1%	1%

**What Were the Types of Additional Surgical Treatments Performed?**

The following table provides of the types of additional surgical treatments that were performed through the 3 years. There were a total of 358 reoperation procedures in augmentation patients and 353 procedures in reconstruction patients (excluding those that were planned reconstruction such as nipple reconstruction) through 3 years. The most common type of additional surgery was removal with replacement.

Augmentation

Type of Additional Surgical Treatment	N = 358 procedures	
	n	%
Implant Removal with Replacement	116	32%
Capsule Related	77	22%
Scar or Wound Revision	67	19%
Reposition Implant	29	8%
Saline Adjustment	27	8%
Mastopexy	23	6%
Implant Removal without Replacement	9	3%
Biopsy/Cyst Removal	6	2%
Breast Reduction or Mastectomy	3	<1%
Nipple Related	1	<1%
<b>Total</b>	<b>358</b>	<b>100%</b>

Reconstruction

Type of Additional Surgical Treatment	N = 353 procedures	
	n	%
Capsule Related	99	28%
Implant Removal with Replacement	66	19%
Scar or Wound Revision	47	13%
Implant Removal without Replacement	40	11%
Nipple Related	29	8%
Saline Adjustment	23	7%
Reposition Implant	20	6%
Biopsy/Cyst Removal	2	<1%
Breast Reduction or Mastectomy	2	<1%
Mastopexy	1	<1%
<b>Total</b>	<b>353</b>	<b>100%</b>

**What Were the Reasons for Implant Removal?**

The following tables detail the main reasons for implant removal among augmentation and reconstruction patients in the SPS on a by-Patient basis. There were 136 augmentation implants and 116 reconstruction implants removed over the 3 years.

Of the 136 implants removed among augmentation patients, 82% were replaced. Of the 116 implants removed among reconstruction patients, 60% were replaced. The most common reason for implant

removal was patient request for a size or shape change for augmentation patients, and was correction of capsular contracture and infection for reconstruction patients

Augmentation

Main Reason for Augmentation Implant Removal through 5 Years	N = 136 Implants Removed	
	n	%
Leakage/Deflation	31	23%
Capsular Contracture	22	16%
Infection	7	5%
Hematoma/Seroma	3	2%
Asymmetry/Wrinkling/Sagging/Scarring	22	16%
Patient Request for Size/Style Change	50	37%
Breast Cancer	1	<1%
<b>Total</b>	<b>136</b>	<b>100%</b>

\* Patients having more than one reason for implant removal are counted only once using the following hierarchy: Deflation, Contracture, Infection, Necrosis/Extrusion, Hematoma/Seroma, Asymmetry, Breast Pain, Patient Request, Other

Reconstruction

Main Reason for Reconstruction Implant Removal through 5 Years	N = 116 Implants Removed	
	n	%
Capsular Contracture	30	26%
Infection	30	26%
Leakage/Deflation	25	22%
Asymmetry/Wrinkling/Sagging/Scarring	13	11%
Patient Request for Size/Style Change	7	6%
Necrosis/Extrusion	6	5%
Breast Pain	4	3%
Breast Cancer	1	<1%
<b>Total</b>	<b>116</b>	<b>100%</b>

\* Patients having more than one reason for implant removal are counted only once using the following hierarchy: deflation, Contracture, Infection, Necrosis/Extrusion, Hematoma/Seroma, Asymmetry, Breast Pain, Patient Request, Other

**What are the Complication Risk Rates After Implant Replacement?**

For those women in the SPS who had an implant removed and replaced and for which there was follow-up information, the cumulative first occurrence risk of complications were higher than for the initial implantation. The cumulative risk rates of first occurrence following implant replacement are shown below on a by implant basis for complications occurring in at least 1% of patients (severity was not assessed).

Augmentation

Complication Following Replacement of Augmentation Implant	3-Year Risk Rate N = 120 Implants
Reoperation	16%
Wrinkling	15%
Implant Removal	12%
Capsular Contracture III/IV or grade unknown	8%
Leakage/Deflation	4%
Asymmetry	4%

Mentor Patient Labeling - 5-10-00

Breast Pain	3%
Hematoma	2%
Scarring Complications	2%

Reconstruction

Reason for Reoperation	% of Patients
Reoperation	31%
Leakage/Deflation	23%
Implant Removal	21%
Capsular Contracture III/IV or grade unknown	17%
Asymmetry	17%
Wrinkling	16%
Breast Pain	13%
Infection	5%
Irritation/Inflammation	3%
Seroma	3%
Extrusion	2%
Hematoma	2%
Scarring Complications	2%
Necrosis	1%

What about Systemic or Rare Events?

Connective tissue disease (CTD) and breast disease were reported in some patients through three years after implantation in the SPS. New cases of breast cancer were reported in 2 augmentation patients. The incidence of confirmed new cases of connective tissue disease was in the range of what would be expected based in the literature in a diverse population of this magnitude over a 3 year period, as illustrated by the following table. Unconfirmed reports were based on self-reports by the patients. Confirmed reports were based on a diagnosis by a physician.

Augmentation

Rheumatic Disease	Number of Reports of CTD in Augmentation Patients in the SPS Study		
	No. of Confirmed Reports in Patients	No. of Unconfirmed Reports in Patients	No. of Reports in 54,434 in Disease Population
Osteoarthritis/Rheumatoid Arthritis/Unknown	1	19	4.4 <sup>a</sup>
Osteoarthritis		1	3.4 <sup>b</sup>
Rheumatoid Arthritis	1	3	1.0-1.2 <sup>c</sup>
Arthritis (type unknown)		15	-
Ankylosing spondylitis			0.3 <sup>d</sup>
Lupus Erythematosus	1		0.2 - 0.5 <sup>e</sup>
Total	2	19 <sup>f</sup>	

<sup>a</sup>Combined estimates for osteoarthritis and rheumatoid arthritis  
<sup>b</sup>Oliveria et al. 1995  
<sup>c</sup>Chan et al. 1993; Dugowson et al. 1991  
<sup>d</sup>Kaipainen-Seppanen et al. 1997  
<sup>e</sup>Uramoto et al. 1999; McCarty et al. 1995  
<sup>f</sup>2 aug pts had 2 unconfirmed CTDs

**Reconstruction**

Condition (ICD-9-CM)	No. of Confirmed Revisions	No. of Unconfirmed Revisions	No. of Revisions Reported by Device Patients
Osteoarthritis/Rheumatoid Arthritis/Unknown	4	28	4.4 <sup>a</sup>
Osteoarthritis	2	8	3.4 <sup>b</sup>
Rheumatoid Arthritis		2	1.0-1.2 <sup>c</sup>
Arthritis (type unknown)	1	18	-
Ankylosing spondylitis	1		0.3 <sup>d</sup>
Lupus Erythematosus			0.2 - 0.5 <sup>e</sup>
Total	4	28 <sup>f</sup>	

<sup>a</sup> Combined estimates for osteoarthritis and rheumatoid arthritis  
<sup>b</sup> Oliveria et al. 1995  
<sup>c</sup> Chan et al. 1993; Dugowson et al. 1991  
<sup>d</sup> Kaipainen-Seppanen et al. 1997  
<sup>e</sup> Uramoto et al. 1999; McCarty et al. 1995  
<sup>f</sup> 7 recon pts had 2 unconfirmed CTDs

**What Are the Benefits of Breast Implants in the SPS?**

The SPS measured a variety of outcomes that assessed the benefits of the implants. For augmentation, these outcomes included breast size change, as well as satisfaction and comfort with appearance. For reconstruction, these outcomes included breast size change. These outcomes were assessed before implantation and at three years after surgery for those patients who still had their original implants.

For reconstruction patients, 283 out of the original 416 patients (68%) still had implants and were in the study after three years. Of these 283 patients, the average increase in chest circumference was 1.5 inches.

For augmentation patients, 955 out of the original 1264 patients (76%) still had implants and were in the study after three years. Of these 955 patients, 917 (96%) experienced an increase of at least one cup size at 3 years; the average increase in chest circumference was 2.8 inches. Of the 955 patients still in the study, 860 (90%) indicated being satisfied with the general appearance of their breasts, as measured by the Breast Evaluation Questionnaire (BEQ).

Most augmentation patients who still had their original implants and were still in the study at 3 years exhibited an improvement in the two measured subscales of the Multidimensional Body-Self Relation Questionnaire (MSBRQ) (which measures comfort with your general appearance). For augmentation patients, the Tennessee Self-Concept Scale (which measures self-concept) showed a slight increase at 3 years compared to before implantation.

**How Do the Benefits and Risks Information from the Clinical Studies Relate to Me?**

While every patient experiences their own individual benefits and risks from the implants, this information indicates that while most women experienced at least one complication over the 3 year period, most women were satisfied with their implants. The chance of additional surgery through 3 years is about 1 in 8 for augmentation and 1 in 2.5 for reconstruction, with implant removal with replacement as the most common reason for additional surgery. The chance of implant removal with or without replacement over 3 years is about 1 in 12 for augmentation and about 1 in 4 for reconstruction.

## Other Factors To Consider In Breast Implantation

- **Choosing a Surgeon**

When choosing an experienced surgeon who is experienced with breast implantation, you should know the answers to the following questions:

1. How many breast augmentation or reconstruction implantation procedures does he/she perform per year?
2. How many years has he/she performed breast implantation procedures?
3. Is he/she board certified, and if so, with which board?
4. In which states is he/she licensed to practice surgery? Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients either by request or on the world wide web.
5. What is the most common complication he/she encounters with breast implantation?
6. What is his/her reoperation rate with breast implantation and what is the most common type of reoperation he/she performs?

Familiarize yourself with the following options in breast implant surgery and be prepared to discuss with your surgeon the following issues:

- **Implant Shape and Size**

Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). You should be aware that contoured implants that are placed submuscularly may assume a round shape after implantation.

Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant. If you desire a breast implant size too large for your tissue, the doctor may warn you that breast implant edges may be apparent or visible post-operatively. You may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

- **Surface Texturing**

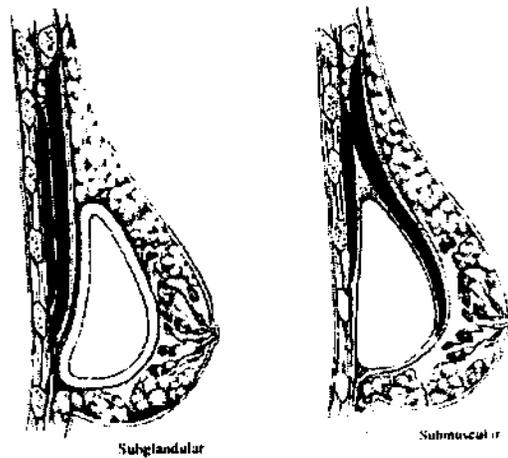
Textured surface implants were designed to reduce the chance of capsular contracture. Some information in the literature with small numbers of patients suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with Mentor implants shows no difference in the likelihood of developing capsular contracture with textured implants compared to smooth surfaced implants (see "What Are the Risks Based on Mentor's Clinical Studies?" below).

- **Palpability**

The following may cause implants to be more palpable (more easily felt): textured implants, larger implants, subglandular placement, and the amount of skin/tissue available to cover the implant.

- **Implant Placement**

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the pros and cons of the implant placement selected for you.



The **submuscular placement** may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have some reoperation procedures than the subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less capsular contracture, and easier imaging of the breast with mammography.

The **subglandular placement** may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with mammography.

- **Incision Sites**

To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. You should discuss with your surgeon, the pros and cons for the incision site specifically recommended for you, depending on whether you will be having augmentation or reconstruction.

**Augmentation Incision Sites** - There are three common incision sites: under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary). If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a “pocket” for the breast implant.

- Periareolar – This incision is most concealed, but is associated with a higher likelihood of inability to successfully breastfeed, as compared to the other incision sites.
- Inframammary – This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.
- Axillary – This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.
- Umbilical/endoscopic – This incision site has not been studied and is not recommended.



**Reconstruction Incision Sites** - Most implants in breast reconstruction use the mastectomy scar either immediately (during the mastectomy procedure) or after tissue expansion. These issues are discussed below in the special considerations for reconstruction section.

- **Surgical Setting and Anesthesia**

**Augmentation** - Augmentation surgery is usually performed on an outpatient basis, either in a hospital operating room, surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia is also an option. The surgery usually lasts one to two hours. Your surgeon will make an incision and create a pocket for the breast implant. Then, the breast implant will be placed in the pocket, filled, and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.

**Reconstruction** - Reconstruction surgery is usually performed on an inpatient basis in an operating room. General anesthesia is most often used. See the section on special considerations for reconstruction for details regarding immediate versus delayed surgery and other reconstruction options such as use of tissue flaps.

- **Post-operative Care**

**Augmentation** - You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size.

Post-operative care may involve the use of a post-operative bra, compression bandage, or jog bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although you should avoid any strenuous activities that could raise your pulse and blood pressure for at least a couple of weeks. Your surgeon may also recommend breast massage exercises.

**Reconstruction** - Depending on the type of surgery you have (i.e., immediate or delayed), the post-operative recovery period will vary. See the section on special considerations for reconstruction below.

**Note:** For both augmentation and reconstruction, if you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

## **Special Considerations for Breast Augmentation**

### **What Are the Alternatives to Breast Augmentation?**

- Accept your breasts as they are
- Wear a padded bra or external prostheses

You are advised to wait a week after reviewing and considering the information in this brochure before deciding whether to have augmentation surgery.

## **Special Considerations for Breast Reconstruction**

### **Should You Have Breast Reconstruction?**

Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may consider consulting your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral for the names of experienced, board certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

### **What Are the Alternatives to Breast Reconstruction?**

You may choose not to undergo breast reconstruction. In this case, you may or may not decide to wear an external breast form (prosthesis) inside your bra. Breast forms are available in a variety of shapes, sizes, and materials such as foam, cotton, and silicone. Custom prostheses are also available to match the size and shape of your breast.

### **What Are the Choices in Reconstructive Procedures?**

The type of breast reconstruction procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals. Women with small or medium sized breasts are the best candidates for breast reconstruction.

Breast reconstruction can be accomplished by the use of a prosthesis (a breast implant, either silicone gel or saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a section of skin, fat and/or muscle which is moved from your stomach, back or other area of your body, to the chest area, and shaped into a new breast.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. For example, because the nipple is often removed with the breast tissue in mastectomy, the nipple is often reconstructed by using a skin graft from the opposite breast or by tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

### **Breast Reconstruction with Breast Implants**

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make them more alike (maximize symmetry) or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. Reduction mammoplasty involves removal of breast tissue and skin.

If it is important to you not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

### **The Timing of Your Breast Implant Reconstruction**

The following description applies to reconstruction following mastectomy but similar considerations apply to reconstruction following breast trauma or for reconstruction for congenital defects. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction). Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which will eventually be replaced with a breast implant. It is important to know that any type of surgical breast reconstruction may take several steps to complete.

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of complications such as deflation with immediate reconstruction, and your initial operative time and recuperative time may be longer.

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy, or if you just need more time to consider your options.

There are medical, financial and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your surgeon, plastic surgeon, and oncologist, the pros and cons with the options available in your individual case.

### **Surgical Considerations to Discuss with your Doctor**

Discuss the advantages and disadvantages of the following options with your surgeon and your oncologist:

- **Immediate Reconstruction:**

One-stage immediate reconstruction with a breast implant (implant only).

Two-stage immediate reconstruction with a tissue expander followed by delayed reconstruction several months later with a breast implant.

- **Delayed Reconstruction:**

Two-stage delayed reconstruction with a tissue expander followed several months later by replacement with a breast implant.

### **What Is the Breast Implant Reconstruction Procedure?**

- **One-Stage Immediate Breast Implant Reconstruction**

Immediate one-stage breast reconstruction may be done at the time of your mastectomy. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the one-stage reconstruction.

- **Two-Stage (Immediate or Delayed) Breast Implant Reconstruction**

Breast reconstruction with Mentor saline-filled breast implant usually occurs as a two-stage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.

### Stage 1: Tissue Expansion



Mastectomy Scar



Expander/implant with remote injection dome



Tissue expander with integral injection dome



Final result with implant

During a mastectomy, the general surgeon often removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast-shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy. The tissue expander creates a new breast shaped pocket for a breast implant.

Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally one to two hours. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activity after two to three weeks.

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure or discomfort after each filling of the expander, which subsides as the tissue expands. Tissue expansion typically lasts four to six months.

#### - Stage 2: Placing the Breast Implant

After the tissue expander is removed, the unfilled breast implant is placed in the pocket, and then filled with sterile saline fluid. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.

### Breast Reconstruction Without Implants: Tissue Flap Procedures

The breast can be reconstructed by surgically moving a section of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks.

The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements.

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and possibly on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

It is important for you to be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method.

### **The TRAM Flap (Pedicle or Free)**



Step 1: Mastectomy is performed and the donor site is marked



Step 2: The flap of rectus muscle and tissue is funneled to the breast



Step 3: Final Result

During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

A pedicle TRAM flap procedure typically takes three to six hours of surgery under general anesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is two to five days. You can resume normal daily activity after six to eight weeks. Some women, however, report that it takes up to one year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the abdominal area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.

## The Latissimus Dorsi Flap With or Without Breast Implants



A skin flap and muscle are taken from donor site in the back.



The tissue is tunneled to the mastectomy and used to create a breast mound.



An implant can also be used to create the breast mound.

During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the Latissimus Dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.

The Latissimus Dorsi flap procedure typically takes two to four hours of surgery under general anesthesia. Typically, the hospital stay is two to three days. You can resume daily activity after two to three weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may also have additional scars on your reconstructed breast.

### What Questions Do You Ask Your Surgeon about Breast Augmentation?

The following list of questions may help you to remind you of topics to discuss with your doctor.

1. What are the risks and complications associated with having breast implants?
2. How many additional operations in my implanted breast(s) can I expect over my lifetime?
3. How will my breasts look if I opt to have the implants removed without replacement?
4. What shape, size, surface texturing, incision site, and placement site is recommended for me?
5. How will my ability to breast feed be affected?
6. How can I expect my implanted breasts to look over time?
7. How can I expect my implanted breasts to look after pregnancy? After breastfeeding?
8. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breasts?
9. What alternate procedures or products are available if I choose not to have breast implants?
10. Do you have before and after photos I can look at for each procedure and what results are reasonable for me?

### What Questions Do You Ask Your Surgeon about Breast Reconstruction?

The following list of questions may help to remind you of topics to discuss with your doctor.

1. What are all my options for breast reconstruction?
2. What are the risks and complications of each type of breast reconstruction surgery and how common are they?
3. What if my cancer recurs or occurs in the other breast?
4. Will reconstruction interfere with my cancer treatment?
5. How many steps are there in each procedure, and what are they?
6. How long will it take to complete my reconstruction?

7. How much experience do you have with each procedure?
8. Do you have before and after photos I can look at for each procedure and what results are reasonable for me?
9. What will my scars look like?
10. What kind of changes in my implanted breast can I expect over time?
11. What kind of changes in my implanted breast can I expect with pregnancy?
12. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breast?
13. Can I talk with other patients about their experiences?
14. For staged reconstruction, what is the estimated total cost of each procedure?
15. How much will my health insurance carrier to cover, especially any complication that may require surgery?
16. How much pain or discomfort will I feel, and for how long?
17. How long will I be in the hospital?
18. Will I need blood transfusions, and can I donate my own blood?
19. When will I be able to resume my normal activity (or sexual activity, or athletic activity)?

### **If You Experience a Problem, Should You Report It?**

If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to FDA. You are encouraged to report any adverse events through their health professionals. Although reporting by physicians or other health professionals is preferred, women may also report any serious problem directly through the MedWatch voluntary reporting system. An adverse event is serious and should be reported when it results in an initial or prolonged hospitalization, disability, congenital anomaly, or medical or surgical intervention.

To report, use MedWatch form 3500 which may be obtained through FDA's website at <http://www.fda.gov/medwatch/index.html>. You may also call 1-888-463-INFOFDA (1-888-463-6332), from 10:00am – 4:00pm Eastern Time, Monday through Friday to receive an additional FDA MedWatch Package. Keep a copy of the MedWatch form completed by your doctor for your records.

### **What Are Other Sources of Additional Information?**

#### **General Resources about Implants:**

Upon request, you will be provided with a copy of the Directions for Use (package insert). You can request a copy from your surgeon or from Mentor. For more detailed information on the preclinical and clinical studies conducted by Mentor, you are referred to the Summary of Safety and Effectiveness Data for this product at <http://www.fda.gov/>.

You will be given a device identification card with the style and serial number of your breast implant(s).

Mentor Corporation

Institute of Medicine Report on the Safety of Silicone Implants

Food and Drug Administration

1-800-MENTOR8

1-888-INFO-FDA or 301-827-3990

<http://www.fda.gov/cdrh/breastimplants/>

[www.mentorcorp.com](http://www.mentorcorp.com)

[www.nap.edu/catalog/9618.html](http://www.nap.edu/catalog/9618.html)

**Breast Reconstruction Resources**

The following list of resources may help you to find more information and support for your breast reconstruction decision.

National Cancer Institute	1-800-4-CANCER	<a href="http://canceret.nci.nih.gov">canceret.nci.nih.gov</a>
American Cancer Society (Reach to Recovery)	1-800-ACS-2345	<a href="http://www.cancer.org">www.cancer.org</a>
Y-ME National Organization for Breast Cancer Information and Support	1-800-221-2141	<a href="http://www.y-me.org">www.y-me.org</a>