



***BIOCELL® Textured  
And  
Smooth***

RTV SALINE-FILLED  
BREAST IMPLANTS

***DIRECTIONS FOR USE***

M218, Rev. \_MAY 10, 2000

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

## DEVICE DESCRIPTION

McGhan Medical RTV Saline-Filled Breast Implants are constructed from Room Temperature Vulcanized (RTV) silicone elastomer, made of polydimethylsiloxane. The device is inflated to the desired size with sterile isotonic saline before implantation. Each implant is supplied sterile with a disposable fill tube and reflux valve.

- **Round Shaped Breast Implants:**

Style 68: Smooth shell surface, anterior diaphragm valve, moderate projection.

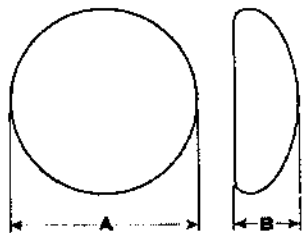
Style 168: BIOCELL® Textured shell surface, anterior diaphragm valve, moderate projection.

- **Shaped Breast Implants:**

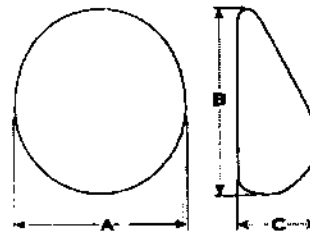
Style 163: BIOCELL® Textured shell surface, posterior diaphragm valve, full height, full projection.

Style 363: BIOCELL® Textured shell surface, anterior diaphragm valve, moderate height, full projection. *Style 363 has a ptotic shape to match an existing breast in unilateral reconstruction.*

Style 468: BIOCELL® Textured shell surface, anterior diaphragm valve, full height, moderate projection.



A = Width; B = Projection  
**ROUND**



A = Width; B = Height; C = Projection  
**SHAPED**

## 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:*

- **Infection.** Active infection anywhere in the body.
- **Breast Cancer.** Existing malignant or pre-malignant cancer of the breast 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:*

- **Adulterated Fill.** Do not place drugs or substances inside the implant other than sterile saline for injection.
- **Alteration.** Do not alter the implant or valve.
- **Do not inject** through implant shell.

- **Stacking of implants:** Do not place more than one implant per breast pocket.
- Do not allow the implant to come into 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**

McGhan Medical 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 McGhan Medical implants have not been established. McGhan Medical 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 life time 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**

McGhan Medical’s Saline-Filled Breast Implants were evaluated in four major open label, multicenter clinical studies: the 1990 Augmentation/Reconstruction Study, the Large Simple Trial (LST) (which involved 2875 patients), the 1995 Augmentation Study (which involved 901 patients), and the 1995 Reconstruction Study (which involved 237 patients). Because the 1990 study utilized devices and surgical practices that are not current, these data are not reported below. 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 based on indication.

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

Capsular Contracture III/IV	7.2	(5.8, 8.6)	12.5	(7.3, 17.8)	11.8	(7.1, 16.4)
Leakage/Deflation	3.6	(2.6, 4.5)	2.6	(0.0, 5.2)	5.4	(2.0, 8.8)
Infection	1.5	(0.9, 2.1)	6.2	(2.9, 9.5)	3.3	(1.1, 5.6)
Implant Removal with or without Replacement	6.1	(4.9, 7.3)	13.7	(8.7, 18.6)	7.8	(4.2, 11.5)

**Table 2. A95/R95: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient and By Implant.**

Additional Surgical Procedures	21.1%	(18.4, 23.8)	16.2%	(14.5, 17.9)	38.7%	(32.3, 45.0)	33.4%	(28.1, 38.7)
Breast Pain*	15.6%	(13.2, 17.9)	12.2%	(10.6, 13.7)	15.3%	(10.3, 20.2)	11.5%	(7.7, 15.2)
Wrinkling*	10.5%	(8.4, 12.6)	9.7%	(8.2, 11.1)	23.3%	(17.5, 29.1)	21.9%	(17.0, 26.9)
Asymmetry*	10.1%	(8.1, 12.1)	n/a <sup>1</sup>	n/a	33.0%	(26.6, 39.4)	n/a	n/a
Nipple Paresthesia*	9.3%	(7.4, 11.2)	7.9%	(6.6, 9.2)	<1%	<1	<1%	<1
Implant Palpability/Visibility*	9.2%	(7.2, 11.1)	8.0%	(6.7, 9.3)	20.0%	(14.5, 25.5)	18.0%	(13.4, 22.6)
Capsular Contracture III/IV or grade unknown	8.7%	(6.8, 10.6)	6.1%	(5.0, 7.3)	25.3%	(19.5, 31.2)	22.2%	(17.4, 27.0)
Loss of Nipple Sensation*	8.4%	(6.5, 10.2)	6.3%	(5.2, 7.5)	12.0%	(7.4, 16.6)	12.9%	(8.8, 17.0)
Implant Malposition*	8.2%	(6.3, 10.0)	5.5%	(4.4, 6.6)	12.2%	(7.8, 16.6)	9.5%	(6.1, 12.9)
Implant Removal for Any Reason	7.6%	(5.8, 9.4)	6.2%	(5.1, 7.3)	22.5%	(17.1, 28.0)	18.2%	(13.8, 22.5)
Skin Paresthesia*	7.2%	(5.5, 9.0)	5.7%	(4.6, 6.8)	5.6%	(2.5, 8.6)	5.4%	(2.7, 8.0)
Scarring Complications	6.4%	(4.8, 8.0)	5.1%	(4.0, 6.1)	6.0%	(2.7, 9.2)	5.3%	(2.6, 8.0)
Leakage/Deflation	5.0%	(3.5, 6.4)	2.7%	(1.9, 3.4)	6.2%	(2.9, 9.5)	4.6%	(2.2, 7.1)
Irritation/Inflammation*	2.9%	(1.8, 4.0)	2.4%	(1.7, 3.1)	6.6%	(3.3, 9.8)	5.6%	(3.0, 8.1)
Seroma	2.6%	(1.6, 3.7)	1.6%	(1.0, 2.2)	3.9%	(1.4, 6.4)	3.3%	(1.3, 5.3)
Hematoma	1.6%	(0.7, 2.4)	<1%	<1	1.3%	(0.0, 2.8)	<1%	<1
Skin Rash	1.6%	(0.8, 2.4)	1.6%	(1.0, 2.2)	3.3%	(0.9, 5.7)	2.5%	(0.7, 4.3)
Capsule Calcification*	1.2%	(0.4, 1.9)	<1%	<1	4.7%	(1.9, 7.6)	4.3%	(1.9, 6.7)
Infection	<1%	<1	<1%	<1	4.8%	(2.0, 7.5)	3.9%	(1.7, 6.1)
Delayed Wound Healing*	<1%	<1	<1%	<1	2.7%	(0.6, 4.9)	2.0%	(0.4, 3.6)
Implant Extrusion	<1%	<1	<1%	<1	2.6%	(0.6, 4.7)	2.3%	(0.6, 4.0)
Tissue/Skin Necrosis	<1%	<1	<1%	<1	3.6%	(1.1, 6.0)	2.7%	(0.8, 4.5)

Notes: <sup>1</sup>Not applicable.

\*These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown.

**Table 3. A95/R95: Types of Additional Surgical Procedures through 4 Years**

Of the 901 augmentation patients in the A95 study, there were 201 (22.3%) who had at least one additional surgical procedure over the 4 years of follow-up. A total of 402 additional procedures were performed in A95 over 4 years. Of the 237 reconstruction patients in the R95 study, there were 95 (40.1%) who had at least one additional surgical procedure, excluding additional planned procedures such as nipple reconstruction and nipple tattoo. A total of 151 additional procedures were performed in R95 over 4 years. Table 3 shows the types of additional surgical procedures performed over 4 years in the 1995 studies based on the total number of additional procedures.

Implant Removal w/Replacement	122	30%	45	30%
Capsule Related <sup>1</sup>	78	19%	18	12%
Add/Remove Saline	45	11%	8	5%
Aspiration	28	7%	7	5%
Mastopexy	28	7%	0	0%

Scar Revision/Wound Repair	33	8%	20	13%
Reposition Implant	19	5%	6	4%
Biopsy/Lump Removal	16	4%	7	5%
Other Secondary Surgical Treatment	16	4%	19	13%
Implant Removal w/o Replacement	10	3%	17	11%
Removal of Skin Lesion or Cyst	6	2%	1	1%
Nipple-Related Procedure <sup>2</sup>	1	0%	3	2%
<b>Total</b>	<b>402</b>	<b>100%</b>	<b>151</b>	<b>100%</b>

Notes: <sup>1</sup>Capsule related includes capsulectomy, capsulotomy, and capsulorrhaphy.  
<sup>2</sup>These nipple procedures were not planned procedures.

**Table 4. A95/R95: Reasons for Implant Removal Through 4 Years**

Of the 901 augmentation patients in A95, there were 81 patients (9.0%) who had 132 implants removed over 4 years. Of the 237 reconstruction patients in R95, there were 58 patients (24.5%) who had 62 implants through 4 years. Of the 132 augmentation implants removed, 92.4% were replaced; of the 62 reconstruction implants removed, 72.6% were replaced. The primary reason for implant removal is shown below based on the number of implants removed.

Patient Request for Change Size/Style	56	43%	14	23%
Leakage/Deflation <sup>1</sup>	56	42%	19	31%
Capsular Contracture	8	6%	13	21%
Wrinkling/Asymmetry/Malposition	6	5%	6	10%
Breast Pain	3	2%	0	0%
Iatrogenic Injury	1	1%	0	0%
Infection	1	1%	6	10%
Implant Extrusion	1	1%	4	7%
<b>Total</b>	<b>132</b>	<b>100%</b>	<b>62</b>	<b>100%</b>

Notes: <sup>1</sup>Includes unreported/unknown.

## 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 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 McGhan Medical Saline-Filled Breast Implants were evaluated in four open label, multicenter clinical studies: the 1990 Augmentation/Reconstruction Study, Large Simple Trial (LST), the 1995 Augmentation Study, and the 1995 Reconstruction Study. Patients studied were those seeking implant surgery for augmentation or reconstruction of the breast. Follow-up in the 1990 and 1995 studies was yearly for 5 years, and it is currently ongoing for the 1995 studies. Safety assessments in the 1990 and 1995 studies consisted of adverse event rates and rates of secondary surgical treatment. Effectiveness assessments in the 1995 Studies consisted of patient satisfaction, breast size change, and measures of body esteem/self esteem/body image. Because the 1990 study utilized devices and surgical practices which are not current, these data are not reported below. The LST Study was designed as a one year study to assess the four safety outcomes of capsular contracture, infection, implant leakage/deflation, and implant removal for a large number of patients.

### **2. PATIENT ACCOUNTING AND BASELINE DEMOGRAPHIC PROFILE**

The LST Study enrolled 2,333 augmentation patients, 225 reconstruction patients, and 317 revision patients with an overall one-year follow-up compliance rate of 62 %. The 1995 Augmentation Study enrolled 901 augmentation patients with a three-year follow-up compliance rate of 76%. The 1995 Reconstruction Study enrolled 237 patients with a three-year follow-up compliance rate of 71%. Across the three studies, there were 14 deaths, all of which were unrelated to the implant or the implant surgery.

Demographic information obtained from the 1995 Studies revealed that nearly 90% of both augmentation and reconstruction patients were Caucasian and more than half of study participants were married. The median age of the augmentation patients was 32 years (range: 19-66); for reconstruction patients the median age was 47 years (range: 25-77).

With respect to surgical baseline factors in the 1995 studies, for augmentation patients, the most frequently used devices were textured round, the most common incision sites were periareolar and inframammary, and the most frequent placement of the implant was submuscular. For reconstruction patients, the most frequently used devices were textured BioDIMENSIONAL, the most common incision site was the mastectomy scar, and the most frequent placement of the implant was submuscular.

### **3. SAFETY OUTCOMES**

The LST safety outcomes are presented in table 1 above.

The 1995 study 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 2-year cumulative Kaplan-Meier adverse event risk rates of first occurrence following implant replacement (i.e. revision) on a by implant basis. There were 69 augmentation patients (108 implants) and 37 reconstruction patients (40 implants) in the 1995 studies who had their implants removed and replaced, and who were followed for at least two years after replacement.

**Table 5a: A95/R95: 2-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval) Following Augmentation Implant Replacement, by Implant**

Adverse Event	Risk Rate (%)	95% CI
Leakage/Deflation	9.1%	(3.4, 14.7)
Capsule Contracture III/IV	7.3%	(1.5, 13)
Removal/Replacement	5.4%	(0.2, 10.5)
Infection	1.0%	(0.0, 3.0)

**Table 5b: A95/R95: 2-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval) Following Reconstruction Implant Replacement, by Implant**

Adverse Event	Risk Rate (%)	95% CI
Capsule Contracture III/IV	47.7%	(31.0, 64.5)
Removal/Replacement	25.5%	(9.8, 41.3)
Infection	7.3%	(0.0, 17.3)
Leakage/Deflation	5.3%	(0.0, 12.5)

### Reproduction/Lactation Problems, CTD, Breast Disease

Tables 6a and 6b summarize post-implant observations from the 1995 Augmentation and 1995 Reconstruction Studies pertaining to connective tissue/autoimmune (CTD) disease and breast disease (including breast carcinoma). These data should be interpreted with 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 and mammographic detection of tumors/lesions were not collected in these studies.

**Table 6a. A95/R95: Reports of CTD through 3 Years, By Patient.**

CTD	Augmentation	Reconstruction	Total	% of Total
Graves' Disease	2	1	0	0
Hyperthyroiditis	1	0	2	0
Inflammatory Bowel Disease	0	0	0	1
Lupus Erythematosus and/or Rheumatoid Arthritis	0	0	3	1
Thyroiditis	0	0	2	2
Chronic Fatigue Syndrome or Fibromyalgia	2	0	0	0
Total	5	1	7	4



**Table 6b. A95/R95: Reports of Breast Disease, By Patient.**

Breast Disease				
Benign	44	4.9%	11	4.6%
Malignant	1	0.1%	19	8.0%
Unknown Outcome	9	1.0%	1	0.4%

#### 4. **EFFECTIVENESS OUTCOMES**

Effectiveness was assessed by bra cup size change (augmentation patients only), patient satisfaction, body image, body esteem, and self concept. These outcomes were assessed for patients with both original and replacement saline devices before implantation and at three years after surgery, except for bra size, which was measured within the first year and a half after

For augmentation patients, 858 out of the original 901 patients (95%) still had implants and were in the study within 18 months after the surgery. Of these 858 patients, 330 (38.5%) increased by one cup size and 418 (48.7%) increased by two cup sizes. 31 (3.6%) did not increase their cup size.

For augmentation patients, 689 out of the original 901 patients (76%) still had implants and were in the study after three years. 655 of these 689 patients (95%) indicated being satisfied with their breast implant surgery.

The 689 augmentation patients after three years scored higher (better) than the general U.S. female population before implantation on the SF-36 and MOS-20, which measure general health related quality of life. After 3 years, augmentation patients had a worsening of their SF-36 and MOS-20 scores. The Tennessee Self-Concept Scale (which measures overall self-concept) showed no change over the 3 years. The Rosenberg Self Esteem Scale (which measures overall self-esteem) showed a slight improvement over the 3 years. The Body Esteem Scale (which measures overall self-esteem related specifically to one's body) showed no change over the 3 years. The Semantic Differential Scale (which measures attitudes about your breasts compared to attitudes about yourself) showed an increased positive attitude towards breasts compared to self.

For reconstruction patients, 169 out of the original 237 patients (71%) still had implants and were in the study after three years. 149 of these 169 patients (88%) indicated being satisfied with their breast implant surgery.

## ***Instructions for Use***

NOTE: Back-up breast implants must be available during the procedure.

DO NOT Stack more than one implant per breast pocket.

### ***Single Use***

This product is intended for single use only. Do not reuse explanted implants.

### ***Product Identification***

A product label accompanies each device within the internal product packaging. The product label provides product-specific information. The product label may be attached to the patient's chart for identification purposes. The Device Identification Card should be provided to the patient for personal reference.

### ***Surgical Planning***

Proper surgical planning such as allowance for adequate tissue coverage, implant site (i.e., submuscular vs. subglandular), incision site, implant type etc. should be made preoperatively. The surgeon must carefully evaluate implant size and contour, incision placement, pocket dissection, and implant placement criteria, with respect to the patient's anatomy and desired physical outcome. Planning should include clear delineation of aesthetic goals to ensure mutual understanding between surgeon and patient.

### ***Preliminary Product Examination***

Prior to use, examine the breast implant for any evidence of particulate contamination, damage, or loss of shell integrity.

Check the breast implant for leakage using only the sterile air already contained within the sterile breast implant.

1. Submerge the breast implant in sterile saline for injection and apply gentle pressure.
2. Inspect the breast implant for any escaping air bubbles, which may indicate leakage.
3. To avoid missing any leaks due to hand position, reposition the breast implant several times and repeat the inspection.
4. Return the inspected breast implant to the inner thermoform tray and cover with lid until implanted to prevent contact with airborne and surgical field contaminants.

DO NOT test breast implant for leakage using additional, unsterile air.

DO NOT implant any device that may appear to have leaks or nicks.

DO NOT implant damaged or contaminated breast implants.

DO NOT store the breast implant with the fill tube in place, which may damage the integrity of the valve seal.

### ***Sterile Product***

Each sterile saline-filled breast implant is supplied in a sealed, double primary package. Style-specific sterile product accessories are also supplied within the product packaging. Sterility of the implant is

maintained only if the thermoform packages, including the package seals, are intact. Use standard procedures to maintain sterility during transfer of the breast implant to the sterile field. Remove the breast implant and accessories from their packages in an aseptic environment and using talc-free gloved hands.

DO NOT use the product if the thermoform packages or seals have been damaged.

DO NOT resterilize the product.

NEVER, under any circumstances, attempt to resterilize using ethylene oxide, which is known to cause adverse tissue reaction if not completely removed from the device.

Avoid unnecessary exposure of the breast implant to lint, talc, sponge, towel, skin oils, and other contaminants.

Prior to use, keep the breast implant in the inner thermoform and covered to prevent contact with airborne and surgical field particulate contaminants.

1. Peel open the lid of the outer thermoform package.
2. Invert the outer thermoform over the sterile field, allowing the sealed inner thermoform to gently fall into the field.
3. Peel open the lid of the inner package using the pull tab.
4. Gently retrieve the breast implant.

### ***Surgical Procedure***

**Breast augmentation** with saline-filled implants can be carried out through several different incisions including inframammary, periareolar, or transaxillary. The transumbilical incisional approach is not recommended. Some surgeons advocate a “no-touch” technique, which requires significant attention to minimizing contact between the patient’s skin and the implant.

Pocket dissection should be planned out preoperatively and be performed accurately and with minimal trauma. Excellent hemostasis is important to avoid postoperative hematoma. The implant may be placed subglandularly or subpectorally depending upon the balance of cosmetic and medical considerations in any given patient. The size and shape of the device may be determined preoperatively by means of dimensional planning or intraoperatively with the help of temporary sizer devices.

The implant may be filled with saline either before or after insertion. If inserted without saline, the implant may be inserted as received (i.e., filled with air), or the air may be evacuated prior to insertion. Regardless of which insertion technique is used, it is important to ultimately evacuate as much air from the implant as possible. It is also important to maintain proper orientation of any BioDIMENSIONAL<sup>®</sup> implant.

The incision for the placement of the implant should be securely closed and in several layers, whenever possible. Drains are optional.

**Breast Reconstruction** is generally carried out in the mastectomy scar. Special care must be used in breast reconstruction to make sure that appropriate amounts of healthy tissue be available to cover the implant and that the implant be properly sized and positioned based upon careful preoperative planning.

Educational materials are available through the McGhan Medical Customer Service Department to supplement surgical knowledge of the dimensional techniques intended for use with BioDIMENSIONAL® styles.

***Maintaining Hemostasis/Avoiding Fluid Accumulation***

Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly also by postoperative use of a closed drainage system. Persistent, excessive bleeding must be controlled before implantation.

Any postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination, or damage from sharp instruments.

***Technique for Using Breast Implants with Diaphragm Valve***

The fill volume range is specified on the product package labeling and data sheet.

DO NOT underfill or overfill the breast implant beyond the range specified.

DO NOT use excessive force during any of the steps in the following procedure.

DO NOT damage the breast implant with sharp surgical instruments such as needles and scalpels, or by excessive handling and manipulation during introduction into the surgical pocket.

**1. *Fill tube insertion***

Prepare the fill tube by attaching the reflux valve to the Luer adapter of the fill tube as shown in **Figure 1**. The reflux valve prevents back-flow during intraoperative filling. This two-way valve opens when a syringe is attached, and closes when the syringe is removed.

**Figure 2** shows a cross section of the diaphragm valve with the strap closure in place and the valve closed. To insert the fill tube, wet the tip of the fill tube in sterile saline for injection and push the strap closure to one side of the valve entrance.

Insert the fill tube by gently pushing the fill tube tip into the valve entrance. Do not use excessive force while inserting the fill tube tip. When the fill tube flange nears or makes contact with the implant shell, the fill tube is in the proper position and the diaphragm valve is open (**Figure 3**).

**2. *Air aspiration***

After the fill tube is properly inserted, remove any air from the breast implant by aspiration with an empty sterile syringe attached to the reflux valve on the fill tube.

**3. *Placement***

To assist with placement, a sterile BIOCELL® Delivery Assistance Sleeve is available separately. Use of this sleeve for insertion of BIOCELL® textured breast implants provides a shell/tissue interface with less friction. Insert the breast implant into one end of the sleeve. Insert the proximal end of the sleeve into the surgically-prepared pocket. With the tissue retracted, the sleeve can be twisted at its distal end to gently guide the breast implant into the pocket. Once the implant is inserted, gently remove the sleeve, and verify the correct orientation of the valve and the implant.

DO NOT use lubricants to facilitate placement, which create the risk of pocket contamination. Lubricants may also affect tissue adherence.

DO NOT use the breast implant for expansion or dissection of the pocket.

4. ***Filling***

Using a syringe filled with sterile saline for injection, inflate the implant. Fill only with sterile saline for injection, and fill to a volume within the recommended fill range specified on the product package labeling and data sheet.

NOTE: The order of filling, placement, and orientation may vary with surgeon preference and technique.

5. ***Residual Air***

After filling is completed, aspirate any residual air bubbles. Then use gentle traction to remove the fill tube from the valve, taking care to avoid damage to shell or valve.

6. ***Diaphragm Valve Closure***

Use gentle traction to remove the fill tube from the valve, taking care to avoid damage to shell or valve. Verify that the diaphragm valve is clear of particulates. Once the fill tube tip is removed the diaphragm valve is closed. To help retard tissue ingrowth or fluid accumulation in the valve entrance, engage the strap closure as follows: using the thumb and forefinger, compress the valve seat and the strap to snap the valve plug into place as shown in Figure 2.

### ***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.

### ***Specific Product Information***

#### ***BIOCELL® Delivery Assistance Sleeve***

Sterile BIOCELL® Delivery Assistance Sleeves are available from your McGhan Medical Sales Representative or Customer Service Department at 800.624.4261.

#### ***Returned Goods Policy***

Product returns should be handled through a McGhan Medical Sales Representative or through the McGhan Medical Customer Service Department at 800.624.4261. Return value is based on time

limitations. All package seals must be intact to be eligible for return. Returned products may be subject to a restocking charge. Certain products are non-returnable, including custom and optional products.

### ***Reporting and Return of Explanted Devices***

Explanted devices associated with a complaint or serious injury should be reported and returned to McGhan Medical Corporation. In the event of such an explantation, please contact the McGhan Medical Customer Service Department at 800.624.4261 for a Product Field Report (PFR) Kit and explant return instructions.

### ***ConfidencePlus™ Breast Implant Replacement Program***

The McGhan Medical ConfidencePlus™ Breast Implant Replacement Program provides lifetime replacement and limited financial reimbursement in the event of loss of product integrity, subject to certain conditions as fully discussed in the ConfidencePlus™ literature. For more information, please contact the McGhan Medical Customer Affairs Department at 800.624.4261.

### ***Product Ordering***

To order directly in the U.S.A or for product information, please contact your local McGhan Medical Sales Representative or the McGhan Medical Customer Service Department at McGhan Medical Corporation at 800.624.4261.

BIOCELL, BioDIMENSIONAL and BIOSPAN are registered trademarks of McGhan Medical Corporation.

ConfidencePlus is a trademark of McGhan Medical Corporation.

These products are covered by one or more of the following U.S. Patents: 4,455,691; 4,472,226 and 4,859,712 and/or foreign patents corresponding thereto.

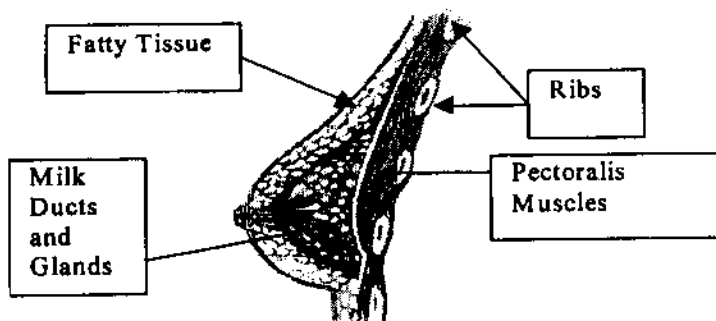
## SALINE-FILLED BREAST IMPLANT SURGERY: MAKING AN INFORMED DECISION

### 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 McGhan Medical Saline-Filled Breast Implants.

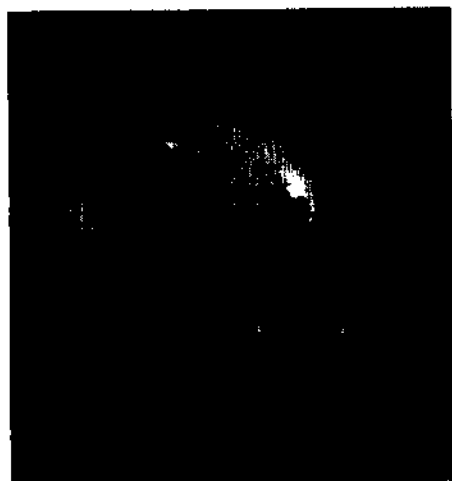
### What Gives the Breast Its Shape?

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 (chest muscle) of the chest wall. 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 tissues, and then filled with sterile 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, McGhan Medical 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). McGhan 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 McGhan Medical?

Implants come in a variety of shapes, surface textures, and sizes. All McGhan Medical implants have a self-sealing (diaphragm) valve that is used for filling the device. Depending on the style, the filling valve may be located on the front (anterior) or the back (posterior) of the implant.

Below is a description of McGhan Medical breast 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.

- **Round Shaped Breast Implants:**

Style 68: Smooth shell surface, anterior filling valve, moderate projection.

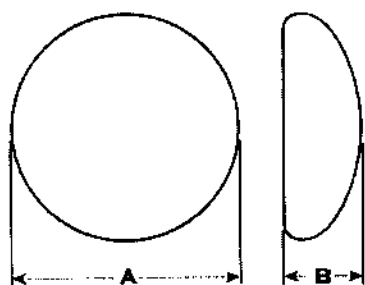
Style 168: BIOCELL® Textured shell surface, anterior filling valve, moderate projection.

- **Shaped Breast Implants:**

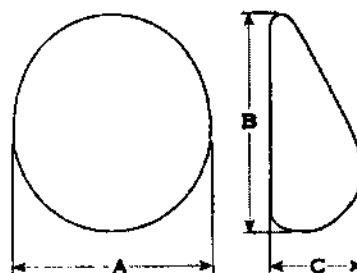
Style 163: BIOCELL® Textured shell surface, posterior filling valve, full height, full projection.

Style 363: BIOCELL® Textured shell surface, anterior filling valve, moderate height, full projection.

Style 468: BIOCELL® Textured shell surface, anterior filling valve, full height, moderate projection.



A = Width; B = Projection  
**Round Breast Implant**



A = Width; B = Height; C = Projection  
**Shaped Breast Implant**

## 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 may be 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 complications, there are have been concerns with certain systemic 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 McGhan Medical's Clinical Studies?

McGhan Medical 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:

- The Large Simple Trial (LST)
- The 1995 Augmentation Study (A95)
- The 1995 Reconstruction Study (R95)

The Large Simple Trial was designed to determine the 1-year risk of capsular contracture, infection, implant leakage/deflation, and implant replacement/removal. There were 2,333 patients enrolled for augmentation, 225 for reconstruction, and 317 for revision (replacement of existing implants). Of these enrolled patients, 62% returned for their 1-year follow-up visit.

The A95 and R95 Studies were designed as 5-year studies to assess a variety of safety outcomes as well as patient satisfaction, body image, body esteem, and self concept. Patients were followed annually and data through three years after implantation are currently available. The A95 Study enrolled 901 augmentation patients, with 76% returning for their 3-year follow-up visit. The R95 Study enrolled 237 reconstruction patients, with 71% returning for their 3-year follow-up visit.

### What Is A Cumulative Risk Rate?

The complication risk information obtained from each of the three clinical studies is reported in the form of estimated risk rates for each type of complication at one year after implant surgery for the LST Study and at three years following implant surgery for the A95 and R95 Studies. These cumulative risk rates describe the risk or chance of developing a first occurrence of a complication through 1 year for the LST Study and through three years for the A95 and R95 Studies. For example, a one-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 lasts, how severe the complication is, or what treatment (if any) is needed for the complication to resolve. These are issues that you should discuss with your surgeon and that you should understand prior to having breast implant surgery.

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

Capsular Contracture	7%	5%	13%	11%	12%	8%
Infection	2%	1%	6%	6%	3%	2%
Implant Leakage/Deflation	4%	2%	3%	2%	5%	4%
Implant Removal	6%	5%	14%	11%	8%	6%

\*Data on 62% of the patients enrolled in the study

**What Were the 3-Year Cumulative Complication Risk Rates of First Occurrence from the A95 and R95 Studies?**

The cumulative risk rates of first occurrence which occurred in at least 1% of the patients are shown in the following tables:

Augmentation

Additional Surgical Treatment	21%	16%
Breast Pain*	16%	12%
Wrinkling*	11%	10%
Asymmetry*	10%	n/a
Capsular Contracture III/IV	9%	6%
Implant Palpability/Visibility*	9%	8%
Intense Nipple Sensation*	9%	8%
Implant Malposition	8%	6%
Loss of Nipple Sensation*	8%	6%
Implant Removal for Any Reason	8%	6%
Intense Skin Sensation*	7%	6%
Scarring Complications	6%	5%
Leakage/Deflation	5%	3%
Irritation/Inflammation*	3%	2%
Seroma	3%	2%
Hematoma	2%	1%
Skin Rash	2%	2%
Capsule Calcification*	1%	1%
Delayed Wound Healing*	1%	< 1%

- Notes: 1. n/a = Not applicable  
 2. \*These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown in this table.

Reconstruction

Additional Surgical Treatment	39%	33%
Asymmetry*	33%	n/a
Capsular Contracture III/IV	25%	22%
Implant Removal for Any Reason	23%	18%
Wrinkling*	23%	22%

Implant Palpability/Visibility*	20%	18%
Breast Pain*	15%	12%
Implant Malposition	12%	10%
Loss of Nipple Sensation*	12%	13%
Irritation/Inflammation*	7%	6%
Intense Skin Sensation*	6%	5%
Scarring Complications	6%	5%
Leakage/Deflation	6%	5%
Infection	5%	4%
Capsule Calcification*	5%	4%
Tissue/Skin Necrosis	4%	3%
Seroma	4%	3%
Skin Rash	3%	3%
Other Complications	3%	2%
Delayed Wound Healing*	3%	2%
Implant Extrusion	3%	2%
Hematoma	1%	1%

- Notes:
1. n/a = Not applicable
  2. \*These complications were assessed with severity ratings. Only the rates for moderate, severe, or very severe (excludes mild and very mild ratings) are shown in this table.

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

The following table provides a breakdown for the 1995 Augmentation and 1995 Reconstruction Studies of the types of additional surgical treatments that were performed through three years after implantation on a by-implant basis. There were a total of 402 additional surgical procedures performed in the augmentation patients and 151 additional procedures (excluding planned nipple reconstruction and nipple tattoo procedures) in the reconstruction patients through 3 years. The most common type of additional surgical treatment was implant removal with replacement.

#### Augmentation

Implant Removal With Replacement	122	30%
Capsule Procedure	78	19%
Change Saline Fill	45	11%
Scar Revision/Wound Repair	33	8%
Mastopexy	28	7%
Aspiration	28	7%
Reposition Implant	19	5%
Biopsy/Lump Removal	16	4%
Other Secondary Surgical Treatment	16	4%
Implant Removal Without Replacement	10	3%
Removal of Skin Lesion or Cyst	6	2%
Nipple-Related Procedure	1	0%
<b>Total</b>	<b>402</b>	<b>100%</b>

Reconstruction

Implant Removal With Replacement	45	30%
Scar Revision/Wound Repair	20	13%
Other Secondary Surgical Treatment	19	13%
Capsule Procedure	18	12%
Implant Removal Without Replacement	17	11%
Change Saline Fill	8	5%
Aspiration	7	5%
Biopsy/Lump Removal	7	5%
Reposition Implant	6	4%
Nipple-Related Procedure	3	2%
Removal of Skin Lesion or Cyst	1	1%
<b>Total</b>	<b>151</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 1995 Studies on a by-implant basis. Of the 132 devices removed among augmentation patients, 92.4% were replaced. Of the 62 devices removed among reconstruction patients, 72.6% were replaced. The most common reason for implant removal was patient request for a size or style change for augmentation patients, and was leakage/deflation for reconstruction patients.

Augmentation

Leakage/Deflation	56	42%
Patient Request for Size/Style Change	56	43%
Capsular Contracture III/IV	8	6%
Wrinkling/Assymetry/Malposition	6	5%
Breast Pain	3	2%
Infection	1	1%
Implant Extrusion	1	1%
Injury during Surgery	1	1%
<b>Total</b>	<b>132</b>	<b>100%</b>



Reconstruction

Leakage/Deflation	19	31%
Patient Request for Size/Style Change	14	23%
Capsular Contracture III/IV or grade unknown	13	21%
Wrinkling/Assymetry/Malposition	6	10%
Infection	6	10%
Implant Extrusion	4	7%
<b>Total</b>	<b>62</b>	<b>100%</b>

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

There were 69 augmentation patients (108 implants) and 37 reconstruction patients (40 implants) in the 1995 studies who had their implants removed and replaced and were followed for at least two years after replacement. The by-implant 2-year cumulative risk rates of first occurrence are shown below.

Augmentation

Leakage/Deflation	9%
Capsule Contracture III/IV	7%
Removal/Replacement	5%
Infection	1%

Reconstruction

Capsule Contracture III/IV or grade unknown	48%
Removal/Replacement	26%
Infection	7%
Leakage/Deflation	5%

**What About Systemic or Rare Events?**

Connective tissue and breast diseases were reported in some patients through three years after implantation in the A95/R95 Studies (see table below) without such a report before implantation. Without a comparison group of women with similar characteristics (such as age, race, etc.), but without breast implants, no conclusions can be made regarding an association between breast implants and these systemic events. Unconfirmed reports were based on self-reports by the patients. Confirmed reports were based on a diagnosis by a physician.

Benign	4.9%	4.6%
Malignant	0.1%	8.0%
Unknown Outcome	1.0%	0.4%

Note: The percentage of patients reported is based on the total number of enrolled patients.

Graves' Disease	2	1	0	0
Hyperthyroiditis	1	0	2	0
Inflammatory Bowel Disease	0	0	0	1
Lupus Erythematosus and/or Rheumatoid Arthritis	0	0	3	1
Thyroiditis	0	0	2	2
Chronic Fatigue Syndrome or Fibromyalgia	2	0	0	0
Total	5	1	7	4

### What Are the Benefits of Breast Implants in the A95/R95 Studies?

The benefits of saline-filled breast implants in the A95/R95 Studies were assessed by a variety of outcomes, including bra cup size change (augmentation patients only), patient satisfaction, body image, body esteem, and self concept. These outcomes were assessed for patients with both original and replacement saline devices before implantation and at three years after surgery, except for bra size, which was measured within the first year and a half after surgery.

For augmentation patients, 858 out of the original 901 patients (95%) still had implants and were in the study within 18 months after the surgery. Of these 858 patients, 330 (38.5%) increased by one cup size and 418 (48.7%) increased by two cup sizes. 31 (3.6%) did not increase their cup size.

For augmentation patients, 689 out of the original 901 patients (76%) still had implants and were in the study after three years. 655 of these 689 patients (95%) indicated being satisfied with their breast implant surgery.

The 689 augmentation patients after three years scored higher (better) than the general U.S. female population before implantation on the SF-36 and MOS-20, which measure general health related quality of life. After 3 years, augmentation patients had a worsening of their SF-36 and MOS-20 scores. The Tennessee Self-Concept Scale (which measures overall self-concept) showed no change over the 3 years. The Rosenberg Self Esteem Scale (which measures overall self-esteem) showed a slight improvement over the 3 years. The Body Esteem Scale (which measures overall self-esteem related specifically to one's body) showed no change over the 3 years. The Semantic Differential Scale (which measures attitudes about your breasts compared to attitudes about yourself) showed an increased positive attitude towards breasts compared to self.

For reconstruction patients, 169 out of the original 237 patients (71%) still had implants and were in the study after three years. 149 of these 169 patients (88%) indicated being satisfied with their breast implant surgery.

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

While every patient experiences her own individual benefits and risks following breast implant surgery, the clinical study data indicate that most women can expect to experience a least one complication at some point through three years after implant surgery. Most women also can expect to be satisfied with their breast implant surgery. The chance of additional surgical treatment through three years is about 1 in 5 for augmentation patients and 1 in 2.5 for reconstruction patients, with implant removal with replacement as the most common reason for additional surgery. The chance of implant removal, with or without replacement, over three years is about 1 in 10 for augmentation and about 1 in 5 for reconstruction patients.

### **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**

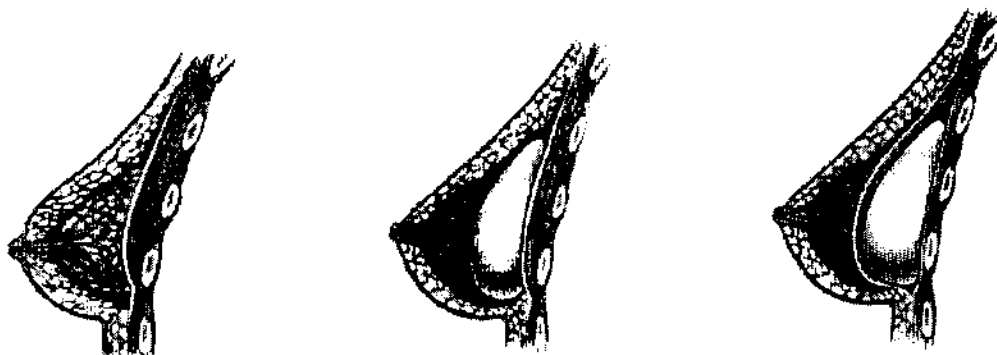
Textured surface implants were designed to reduce the chance of capsular contracture. Some information in the literature with small numbers of patients suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with McGhan Medical 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 McGhan Medical'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.



**Breast before augmentation**

**Breast after  
subglandular augmentation**

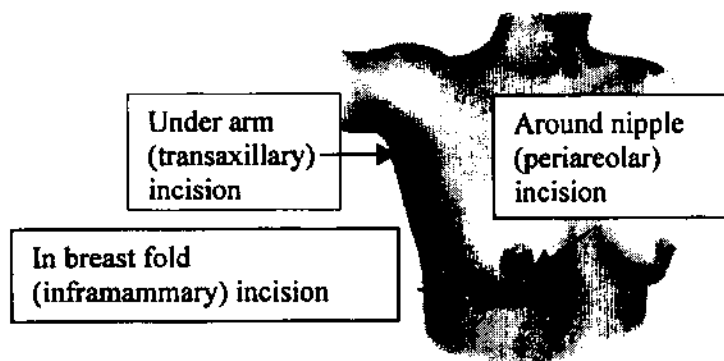
**Breast after  
submuscular augmentation**

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 this information 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.

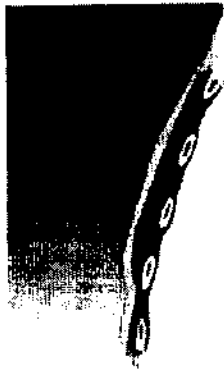
### **What Is the Breast Implant Reconstruction Procedure?**

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

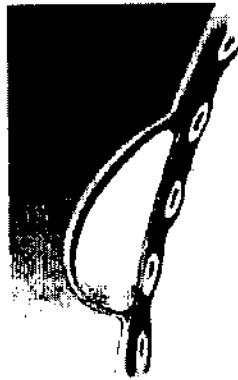
Immediate one-stage breast reconstruction may be done at the time of your mastectomy. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the one-stage reconstruction.

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

Breast reconstruction with McGhan Medical 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.



**Side View. Breast  
Tissue Removed**



**Side View. Expander  
Inserted and Filled.**

- **Stage 1: Tissue Expansion**

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.

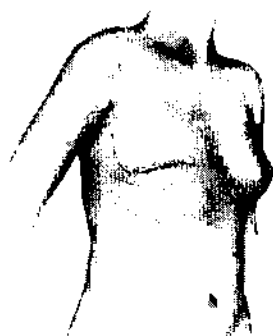
Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally one to two hours. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activity after two to three weeks.

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.

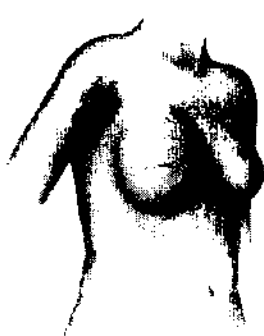
- **Stage 2: Placing the Breast Implant**

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.

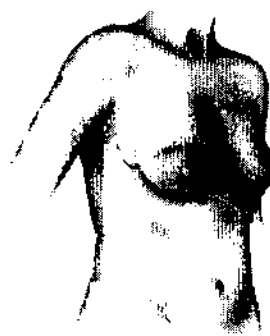




**Post Mastectomy**



**Stage 1: Tissue Expander**



**Stage 2: Breast Implant  
And Nipple/Areola  
Reconstruction**

### **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.

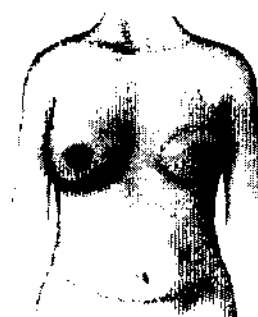
### The TRAM Flap (Pedicle or Free)



Post Mastectomy



TRAM Flap



Final Result with  
Nipple/Areola Reconstruction

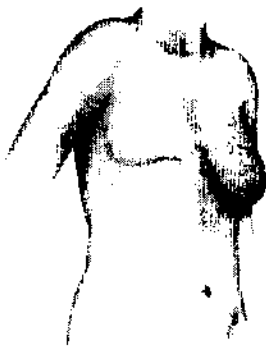
During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

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

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.

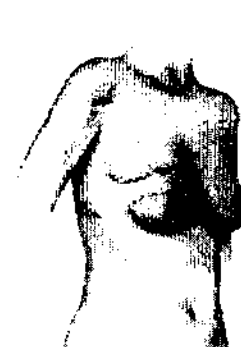
The Latissimus Dorsi flap procedure typically takes two to four hours of surgery under general anesthesia. Typically, the hospital stay is two to three days. You can resume daily activity after two to three weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in 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.



Post Mastectomy



View Showing Back Scar



Latissimus Dorsi Flap

### **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. You may have additional questions as well.

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. You may have additional questions as well.

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. 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 McGhan. For more detailed information on the preclinical and clinical studies conducted by McGhan, 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).

McGhan Medical	1-800-624-4426	<a href="http://www.mcghan.com">www.mcghan.com</a>
Institute of Medicine Report on the Safety of Silicone Implants		<a href="http://www.nap.edu/catalog/9618.html">www.nap.edu/catalog/9618.html</a>
Food and Drug Administration	1-888-INFO-FDA or 301-827-3990	
	<a href="http://www.fda.gov/cdrh/breastimplants/">http://www.fda.gov/cdrh/breastimplants/</a>	

### 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://cancer.net.nci.nih.gov">cancer.net.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>