SILASTIC® MSI BRAND

Gel Saline Mammary Implant H.P.

GEL-FILLED DESIGN BY DOW CORNING WRIGHT

U.S. Patent Nos. 4,455,691, 4,472,226, 4,965,430 and Others Pending

DESCRIPTION

The SILASTIC® MSI Gel Saline Mammary Implant H.P. consists of a SILASTIC® II silicone gel-filled unit floating free within a larger micro structured high performance (H.P.) silicone elastomer envelope. The inner silicone gel-filled unit is made with a laminated silicone envelope. The laminate consists of medical grade high performance (H.P.) silicone elastomer and a fluorosilicone barrier layer. The outer lumen with its integral surface micro structure is designed to be filled with sterile normal saline through a triple seal valve. This feature provides for volume adjustment during surgery. The product nomenclature "MSI" stands for **Micro Structured Implant**. The product nomenclature "H.P." indicates the implant is fabricated from SILASTIC® brand medical grade high performance silicone elastomer which exhibits greater resistance to tear propagation than conventional silicone rubber. The fluorosilicone coating within the inner envelope provides an effective barrier to significantly reduce gel bleed. The inner envelope is filled with a transparent silicone gel.

This implant is available in a range of product sizes, providing the surgeon with versatility in satisfying specific patient requirements. Except for special order products, inner unit volume in cc's and company trademark are embossed in the envelope seal patch for easy identification.

For service and information, contact your authorized sales representative or:

Dow Corning Wright
5677 Airline Road
Arlington, TN 38002
U.S.A.
Toll free 1-800-238-7117. Outside the United States, contact your closest Dow Corning International Office.

INDICATIONS

Breast contour reconstruction and/or size augmentation following mastectomy procedures where volume adjustment is desired.

Unilateral or bilateral mammary augmentation or reconstruction, where volume adjustment during surgery is desired, to surgically correct various congenital defects or anomalies such as amastia, hypomastia, hypoplasia or for cosmetic purposes.

CONTRAINDICATIONS

A mammary implant should not be used in a patient who:

- Has a history of immunological responses or sensitization to foreign materials.
- Demonstrates psychological instability, displays a lack of understanding, or inappropriate motivation or attitude.
- Is not willing to accept the possibility of multiple surgeries for revision.
- Demonstrates inadequate or unsuitable tissue; e.g. radiation damage to tissue, ulceration, compromised vascularity, or has a history of compromised wound healing.
- May experience compromised vascularization because of implant placement.
- Demonstrates physiologic or anatomic anomalies that might result in significant post-operative complications.
- Has an active infection.

Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship.

PRECAUTIONS

1. SILASTIC® brand medical grade silicone elastomers made exclusively by Dow Corning Corporation are among the least reactive implant materials available. However, surgical glove powder, drape and sponge lint, dust, talc, skin oils and other surface contaminants deposited on an implant by improper handling may evoke foreign body reactions; e.g. excessive fluid, fibrous tissue buildup, and/or infection. There should be strict adherence to clean, aseptic techniques to prevent contamination of the implant and possible complications. Surgical gloves and instruments should be rinsed free of lint, tissue debris, etc. before handling or contacting the implant.
2. Pre-existing infection should be treated and resolved before implantation of the implant.
3. It is recommended that before implantation the prosthesis be carefully examined to assure product integrity and cleanliness.
4. The surgical approach and incision size should be evaluated by the surgeon in line with the stresses which will be placed on the implant. Certain surgical approaches may result in higher stresses on the implant during insertion and may result in more difficult insertion of the implant.

   The surgeon should select an incision size and location which allow for creation of a well-defined, dry pocket; allow for insertion of the implant without distortion; and allow for ready digital access to the pocket to ensure flat implant placement and smoothing of the implant surface.
5. The surgeon should select an implant size, implant style, pocket location, and pocket size appropriate for the patient frame size (i.e. the implant diameter is not too large for the breast and chest wall dimensions) and tissue coverage (especially when there is limited breast tissue coverage and/or limited subcutaneous fat). The submuscular plane may be preferable in patients with minimal, thin, and/or poor quality overlying tissue.

   The pocket size created by the surgeon should be of sufficient size to allow the implant to lie flat in the pocket.
6. Dow Corning Wright does not endorse or recommend the introduction of drugs into or around the implant. The action of drugs, such as vitamins, anti-inflammatory steroids, and antibiotics, in conjunction with the breast implant has not been adequately tested by the manufacturer. The risks of such usage are unknown.
7. When the surgeon treats a hematoma or serous fluid accumulation by aspiration, or performs a biopsy, care should be taken to avoid damaging the implant. These procedures present possible risk of implant puncture.
8. Microwave diathermy of a patient with a SILASTIC® MSI Gel Saline Mammary Implant H.P. is not recommended. Saline contained in the outer lumen could enhance microwave absorption, which increases the potential for local temperature increases in the implant area. Tissue necrosis, dermal erosion, and extrusion of the implant could result.

   Incidents of tissue necrosis and skin erosion with subsequent exposure or extrusion of the implant have been reported following microwave diathermy of patients with gel-filled implants.
9. This implant is intended for single patient use. DO NOT REUSE IN ANOTHER PATIENT.
10. The American College of Radiology has stated that mammography may be more difficult to perform and less effective on implanted breasts. This is because the silicone is more radiopaque to X-rays than normal breast tissue, which may possibly obscure any small malignant tumors, and because breast tissue may be compressed by the implant which may render it more difficult to detect small tumors. Factors which may affect the radiographic outcome include submammary or subpectoral implant placement, the presence and degree of capsular contracture, and a patient's anatomy as well as technical factors such as foreign body halo, the degree of tissue compression during mammography and film screen versus xeroradiography.

    The American College of Radiology recommends that to perform high quality mammography only "dedicated" or specially designed equipment be used by the mammographer. It is preferred that the mammographer have experience with the most current radiologic techniques for implanted patients that will show more breast tissue and as little implant as possible. Special diligence and use of extra tangential images customized to each patient have been reported to be beneficial when performing mammography on an implanted patient. This will increase the cost as well as increase the radiation exposure for the patient. All patients should be provided this information and be advised to inform referral physicians and radiographers of the presence of an implant.
11. Implant Life Expectancy: It is not possible to predict the life expectancy of an implanted mammary prosthesis. Performance of the implanted prosthesis is not related solely to the design, materials of composition

or fabrication of the prosthesis, but also relates to the surgical procedure with its possible attendant medical complications and consequences and to the specific medical condition, physiological, anatomical, biological and behavioral aspects of the patient. Most patients have had implants with no revisions; others have required multiple revisions.

Note: It has been reported upon removal of conventional gel implants that some have contained particulates. These have included material of varying size, texture, and coloration. Analysis has revealed many to contain triglycerides, lipids, or steroid-type compounds. These are postulated to slowly move through the silicone elastomeric shell from the surrounding tissues. The degree of such diffusion of biologicals appears to be patient-specific.

12. Animal experiments studying the micro structured surface of the SILASTIC® MSI Mammary Implant H.P. indicate a differing local tissue response dependent upon implantation site. SILASTIC® MSI micro structured implant samples placed on fatty tissue beds of rats were found to develop thinner capsules with a greater degree of capsule architecture disruption than similar implants placed in a non-fatty tissue plane. The clinical relevance of this in humans is unknown.

WARNINGS

1. Do not insert a damaged implant or attempt to repair a damaged implant.
2. The silicone mammary prosthesis should be implanted without any alterations to its original design or fabrication. Meticulous care must be taken to avoid pinching the prosthesis with instruments and avoid contacting the implant shell(s) with any sharp or pointed objects such as needles or surgical instruments. Any cut, puncture, scratch, or other compromise of the envelope(s) integrity, whether inadvertent or intentional, will cause the loss of saline with possible exposure of gel and will render the implant unusable. If the implant should accidentally rupture during insertion or be nicked with an instrument, suture needle, or the fill tube during introduction of saline into the outer lumen, remove the damaged implant and any exposed gel and replace with a new, intact, sterile implant. A surface scratch or partial penetration in the shell(s) may be enough to eventually cause subsequent rupture. Do not try to repair the implant or leave it in the surgical pocket. When inserting and positioning the implant, care should be taken to ensure the unit is flat with a minimum of surface wrinkling and to avoid excessive manipulation or undue handling with sharp, pointed or blunt objects, including retractors. Avoid extensive stretching of the envelope(s) during insertion as it may result in a local bulge in the implant shell(s).
3. Do not introduce or make injections of drugs or other materials into the implant. Injections through the implant shell(s) will compromise product integrity.

ADVERSE REACTIONS AND COMPLICATIONS

Thousands of women per year have had cosmetic or reconstructive surgery with implantation of mammary prostheses.Complications or adverse reactions have been reported. Any patient undergoing a surgical procedure is subject to unforeseen intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different. Possible risks, adverse reactions and complications associated with surgery and the use of the mammary prosthesis should be discussed with and understood by the patient prior to surgery. The adverse reactions and complications most likely to occur with the use of this product are listed below. **IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH THIS INFORMATION PRIOR TO SURGERY.**

A SILASTIC® MSI Gel Saline Mammary Implant H.P. is composed of alloplastic materials. Therefore, it is subject to possible reactions and complications including those listed herein. The patient should not be led to unrealistic expectations as to the performance or cosmetic results that the surgery and prosthesis can provide. The patient should be informed that the life expectancy of any implant is unpredictable, and that successful results cannot be guaranteed.

1. ***Asymmetry***

   Asymmetry may be attributed to pre-existing anatomic asymmetry, incorrect choice of implant shape or size, surgical technique, contracture of the fibrous capsule, seroma or hematoma, breast dysplasia developing post-operatively, discrepancy in muscle development between sides, or rupture of the implant. In the event of rupture of an implant, it is recommended that the implant be removed promptly.

2. ***Ptotic Breast***

   It is possible that, like the non-augmented breast, the augmented breast may become ptotic over time. Variability in skin elasticity and muscle tone may contribute to this result.

3. ***Breast and Nipple/Areola Sensation***

   It is reported in the medical literature that some patients undergoing breast surgery experience a significant decrease in sensation or hypersensitivity of their nipple/areolar complex, and in some cases, the breast area in general. With more extensive breast surgery there is a greater probability that the patient will experience changes in sensation to breast skin and/or nipple complex. The return of sensation varies among patients. In a few instances, it has taken as long as several years for sensation to return. There are also reports of permanent loss of nipple or breast sensation, and of cold, itchy breast areas following implantation.

4. ***Pain***

   Breast region pain of varying intensity and duration has been reported as an expected occurrence following breast implant surgery. In addition, there have been reports of pain in association with excessive capsule contracture.

5. ***Interruption of Surgical Incision Wound Healing***

Causes cited include infection, fluid accumulation and lack of drainage, hematoma, too tight a closure, too large an implant for the pocket, contamination of suture line, abscess of sutures, improper support, pressure against the wound, i.e., improperly fitted wired brassiere, trauma, use of anti-inflammatory steroids in the pocket, and placement of the prosthesis in injured areas (i.e., burned, irradiated, scarred tissue). Exposure or extrusion of the implant may occur.

6. ***Skin Sloughing/Necrosis***

Skin breakdown may be attributed to inadequate circulation due to thinness of the skin flap overlying the implant or too large an implant relative to the pocket size. It may also be attributed to trauma to the skin intra-operatively, the use of anti-inflammatory steroids, or unresolved skin deterioration or breakdown. Implant exposure and/or extrusion may result. Unresolved skin breakdown may necessitate removal of the implant. Early compromise in skin circulation necessitating post-operative implant removal has been reported in the medical literature where subcutaneous placement of the prosthesis was used for reconstruction of congenital amastia, subcutaneous mastectomy, and cancer mastectomy.

7. ***Incorrect Size, Inappropriate Location of Scars, and Misplacement or Migration of Implants***

These complications are usually iatrogenic in origin. Any surgeon performing this type of breast surgery should be familiar with the currently acceptable techniques for measuring the patient, determining implant size, and performing the surgery. Since the implant generally cannot be repositioned following closure, surgical revision may be required if the implant is misplaced or displaced.

8. ***Wrinkles, Folds, or Knuckles in Implant Shell***

Some surgeons have indicated that in some patients "wrinkles", "folds", and/or "knuckles" in the implant shell may occur and be visible and/or palpable beneath the overlying tissue. "Wrinkles" and/or "folds" are a possible clinical outcome, especially if one or more of the following conditions exists.

1) The patient is thin (i.e. little or no subcutaneous fat) or is small-framed.
2) There is no breast tissue or breast tissue is sparse.
3) The overlying tissue is of poor quality, e.g. a post-partum patient with slack, less elastic skin or a mastectomy reconstruction patient.
4) The implant is placed in the subcutaneous position.
5) The implant is of generous base dimensions and volume relative to the patient's frame size and size of the pocket which is created.
6) Saline fill of the outer lumen is insufficient.
7) Fibrous capsule contracture is present.

"Wrinkling" or a rippling of the implant shell may be most commonly seen in the infraclavicular region. "Folds" with associated "knuckles" at the ends of the folds are most commonly reported in the lateral to

medial inferior region of the implanted breast but may also be observed in the other regions as well.

Surgical revision may be desired by some patients exhibiting "wrinkles" or "folds." For some patients, these features have been reported to diminish with time. There have been reports of "folds" leading to thinning and erosion of the overlying tissue. In such cases, implant removal will likely be required.

9. ***Palpable Implant***

Palpable implants have been reported by some surgeons. It may be more readily observed in a patient with a large implant relative to pocket and/or patient frame size, when there is thin or tight overlying tissue, when the implant is placed in the subcutaneous position, and/or when contracture occurs.

10. ***Capsule Formation and Contracture***

The post-operative formation of a fibrous tissue capsule around the mammary prosthesis is a normal physiologic response to the implantation of a foreign object. Capsule formation occurs in all patients. However, each patient's capsule will vary in degree, ranging from thin to heavily thickened.

Contracture of a fibrous capsule may occur, independent of its thickness, resulting in discomfort, pain, excessive breast firmness, deflation of the outer lumen, a palpable prosthesis, wrinkles and/or folds in the prosthesis shell, and/or displacement of the prosthesis. The presence and degree of capsular contracture may effect the diagnostic value of mammographic procedures. Reported causative factors of capsular contracture include infection, hematoma, lack of drainage, implant volume, diabetes mellitus, patient's immune system, implant type, gel bleed, trauma, sterile normal saline with added preservatives, foreign body reaction, inadequate pocket dissection, and implant placement. The medical literature documents that correction may require surgical intervention. In some patients, even with further surgery and treatment by their surgeon, breast firmness may recur.

Dow Corning Wright cannot warrant the integrity of the implant if closed capsulotomy is performed. Integrity of the implant envelope(s) cannot be assured if the surgeon should choose to perform this procedure because unknown or abnormal force will be applied to the implant. Such abnormal trauma or stress to the breasts could result in prosthesis rupture with loss of saline from the outer lumen and/or extravasation of gel into surrounding tissue.

The chance of excessive capsular contracture for all augmented patients will increase with time and may necessitate reoperation. Patients who have undergone reconstructive breast surgery stand a high chance of the need for reoperation at some future date to correct excessive capsular contracture.

11. ***Deflation/Implant Rupture/Gel Extravasation***

Leakage of saline from the outer saline-filled lumen over an undefined period of time has been reported. Subsequent deflation may occur and long-term containment of saline cannot be guaranteed by Dow Corning Wright.

Rupture of implants has been reported both intra- and post-operatively. Rupture may result from the following: intra- or post-surgical trauma; excessive stresses or manipulation as may occur during normal living experiences including routine and purposeful or accidental trauma as in vigorous exercise, athletics, and intimate physical contact; mechanical damage before and during surgery, or other unknown causes at the site of implantation, including so-called spontaneous rupture. Excessive manipulation of the implant shell(s) during use as may be experienced during the performance of routine manual massage or manual exercise of the implanted breast may also produce long-term fatigue of the envelope, resulting in rupture.

If the surgeon should choose to perform manual compression of the breast (closed capsulotomy), he/she should be aware that it may lead to implant rupture or deflation due to weakening of the envelope(s) from the forces the implant may experience. The patient should be adequately informed of the possibility of implant rupture or deflation with the use of this technique and of the necessity to remove a ruptured or deflated implant should that occur. Dow Corning Wright is not responsible for the integrity of the implant if a closed capsulotomy is performed.

Medical reports state more frequent intra-operative rupture occurs with the use of too small an incision for introduction of the prosthesis.

Upon loss of shell integrity, gel may be released from the implant's inner envelope. If left in place, complications such as enlarged lymph nodes, scar formation, inflammation, granulomatous foreign body reaction, presence of foamy histiocytes, silicone mastopathy, nodule formation, or other difficulties may result. Migration of the silicone gel to adjacent or other tissue may occur.

It has been reported that if the gel material becomes inter-mixed with body fluids, the consistency of the resultant gel/body fluid mixture may become less viscous than the original gel; hence possibly more difficult to remove. In the event that a ruptured prosthesis is suspected, Dow Corning Wright recommends prompt removal of the envelopes and gel. The long-term physiological effects of uncontained gel are not completely known.

12. ***Infection***

When infection is associated with an implant site, an appropriate regimen of treatment should begin. If an infection is encountered and not brought under control, it is recommended that the implant be removed. Occasional latent infections of unknown etiology have also been reported.

A specific infection-related event, Toxic Shock Syndrome, has been referenced, or speculated upon, in rare case reports involving mammary prosthesis implantation.

13. ***Hematoma***

Meticulous hemostasis during surgery is the principal measure for prevention. Clinical literature documents that hematomas are a possible precursor to infection and increased fibrosis. If evacuation is the chosen treatment, every precaution should be taken to not damage the

prosthesis. This procedure presents possible risk of implant damage including puncture.

14. ***Serous Fluid Accumulation***

Serous fluid accumulation occurs occasionally in association with the surgical placement of any mammary prosthesis and may be accompanied by swelling and pain at the surgical site. This condition is reported to occur more frequently with surface-textured implants as a part of a normal wound healing in response to a non-smooth surface. This condition may also occur as the result of trauma. If aspiration is the surgeon's treatment of choice, every precaution should be taken to not damage the prosthesis. This procedure presents possible risk of implant damage, including puncture.

Prolonged persistent serous fluid accumulation may necessitate removal of the implant.

15. ***Calcification***

Physicians have reported so-called "calcification" of the tissue surrounding the implant. This mineralization is referred to in the medical literature as heterotopic ossification. The etiology of "calcification" is unclear. In some instances,heavy "calcification" resulting in local discomfort and breast firmness may require removal of the implant and the "calcified" capsule.

16. ***Implant Gel Bleed***

Gel bleed is the passage of small quantities of silicone through the elastomeric shells of the implant. In vitro bleed tests demonstrate that this bleed phenomenon is significantly reduced in the Dow Corning Wright SILASTIC® II and SILASTIC® MSI Mammary Implants. As a result, the envelopes of the implants will be relatively dry feeling.

The detection of small quantities of silicone in the tissue adjacent to the intact, conventional gel-filled implant and detection of small quantities of silicone in axillary lymph nodes has been reported in the medical literature. Some cellular reaction around the implant may be expected as a normal foreign body response.

Some doctors believe that silicone bleed from mammary implants may appear in breast milk. However, a study reported to the medical community indicates that milk samples from implanted and non-implanted mothers show no difference in silicone content.

17. ***Immune Responses***

There have been reports of suspected immunological response to silicone mammary implants. Many of the case reports suggest systemic illness with joint pain, myositis, fever, and lymphadenopathy being most frequently mentioned. Additional symptoms claimed include, for example, localized inflammation and irritation at the implant area, fluid accumulation, rash, general malaise, swelling of joints, weight loss, scleroderma, chronic arthropathy, morphea, keratoconjunctivitis sicca, pyrexia, skin lesions, arthralgia, and alopecia. Some reports in the medical literature refer to various combinations of such symptoms as so-called silicone-induced human adjuvant disease.

A review of the published experimental findings and clinical experience shows that convincing evidence does not exist to support a causal relationship between exposure to silicone materials and the acquisition or exacerbation of a variety of rheumatic and connective tissue disorders. A causal relationship between mammary implants and rheumatic/connective tissue disorders such as scleroderma, scleroderma-like disorders, and other rheumatic/connective tissue disorders remains to be established.

If an immunological response is suspected and the response persists, removal of the prosthesis is recommended along with removal of the surrounding capsule tissue. Such patients should not be re-implanted.

18. ***Tumorigenesis***

During the past 28 years of clinical use, the medical literature generally indicates that the silicone mammary prosthesis is not tumorigenic. There have been case reports of ordinary breast cancer associated with the presence of mammary implants, as would be expected on statistical grounds alone. A retrospective epidemiologic study of patients with mammary implants was conducted in Los Angeles, California, by Deapen, Pike, Casagrande, and Brody. This study of over 3,100 subjects concluded that the incidence of ordinary breast cancer in women with mammary implants is no greater than statistically expected for that population. No cancers of the breast other than carcinomas were found.

Malignant sarcomas in animals (rats) associated with implanted silicone gel are to be expected on the basis of solid-state tumorigenesis or the so-called Oppenheimer effect which applies to all relatively stable alloplastic materials. Available evidence demonstrates that the induction of sarcomas (solid-state tumorigenesis) as seen in animals either does not operate in man or is, at most, a rare event. There is no evidence that silicone materials can induce breast malignancies of any type.

INSTRUCTIONS FOR USE

A. Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process.

B. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the mammary prosthesis.

C. **Surgical Procedures**

Recognition of appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Some of the surgical and implant sizing variables that have been identified by surgeons as being important include:

1) Patient frame size (e.g., the implant diameter is not too large for the breast and chest wall dimensions).
2) Tissue coverage of the implant (especially when there is limited breast tissue coverage and/or limited subcutaneous fat).

3) Surgical plane of placement (the submuscular plane may be preferable in patients with minimal, thin, and/or poor quality overlying tissue in order to minimize palpation, visibility, and/or erosion of any "wrinkles" or "folds" in the implant, if they should occur).
4) Size of implant pocket (create a pocket of adequate size and symmetry so that the implant may be placed flat and the surface of the implant adequately smoothed to assure a minimum of wrinkling at the surface).

Each surgeon must, of course, evaluate the appropriateness of the procedure based on his or her own training and experience.

Various factors must be considered by the surgeon in determining the proper size and shape of the implant used with a particular patient. The SILASTIC® MSI Gel Saline Mammary Implant H.P. is available in many standard sizes. It is advisable to have more than one size mammary implant in the operating room at the time of the surgery to allow the surgeon flexibility in determining the appropriate size implant to be used. Prior to use, the prosthesis should be carefully examined for structural integrity. A back-up implant should be available in the event of implant damage or rupture. A damaged or contaminated implant should not be used.

D. **Packaging**

The sterile mammary implant is contained pre-cleaned in a film wrap, enclosed in a double sealed blister package to provide enhanced assurance of sterility. Product is considered sterile as long as the package integrity has not been compromised. If package integrity has been compromised, resterilization is required before use of the implant. The fill tube is packaged in a clear poly bag which is inside the double sealed package above the implant.

Non-sterile Special Order SILASTIC® MSI Gel Saline Mammary Implant H.P. units are supplied pre-cleaned, packaged in a film wrap, and labeled as non-sterile.

Two patient labels for recording pertinent data, e.g. catalog number, product volume, saline fill volume, lot number, etc., are supplied. These labels should be filled out and made a part of the patient's permanent records.

E. **Recommended Procedure for Opening Package**

1. Sterile Product
   a. Firmly hold the outer package blister so that the outer cover is pointing away from the person opening the package.
   b. Grasp outer cover film at arrow position and peel back completely to end seal.
   c. Drop sterile inner package into sterile field.
   d. When implant is needed, open inner package in the same manner as the outer package, but with care not to lose control of the fill tube, also included in the blister.
   e. Remove the fill tube and lift the sterile wrapped implant from the inner blister well.

f. Remove wrap and implant is ready to use. Note that foreign body reactions can be caused by drape and sponge lint, glove powder, talc, fingerprints, and other surface contaminants. Care should be taken to prevent contamination of the SILASTIC® MSI Gel Saline Mammary Implant H.P. If the implant is contaminated, it should be cleaned and resterilized per the instructions in Section H before it is used. Handling of the sterile implant should be minimized.

g. Voids may occasionally be observed within the gel of SILASTIC® MSI Gel Saline Mammary Implants. These voids may form during the manufacturing process and consist of FREON® (dichlorodifluoromethane), the carrier gas used for sterilization. Data is on file that demonstrates that the gas is not cytotoxic. These voids are harmless to the patient and will generally dissipate with time. The use of product with bubbles within the gel does not endanger the patient or compromise the safety of the implant.

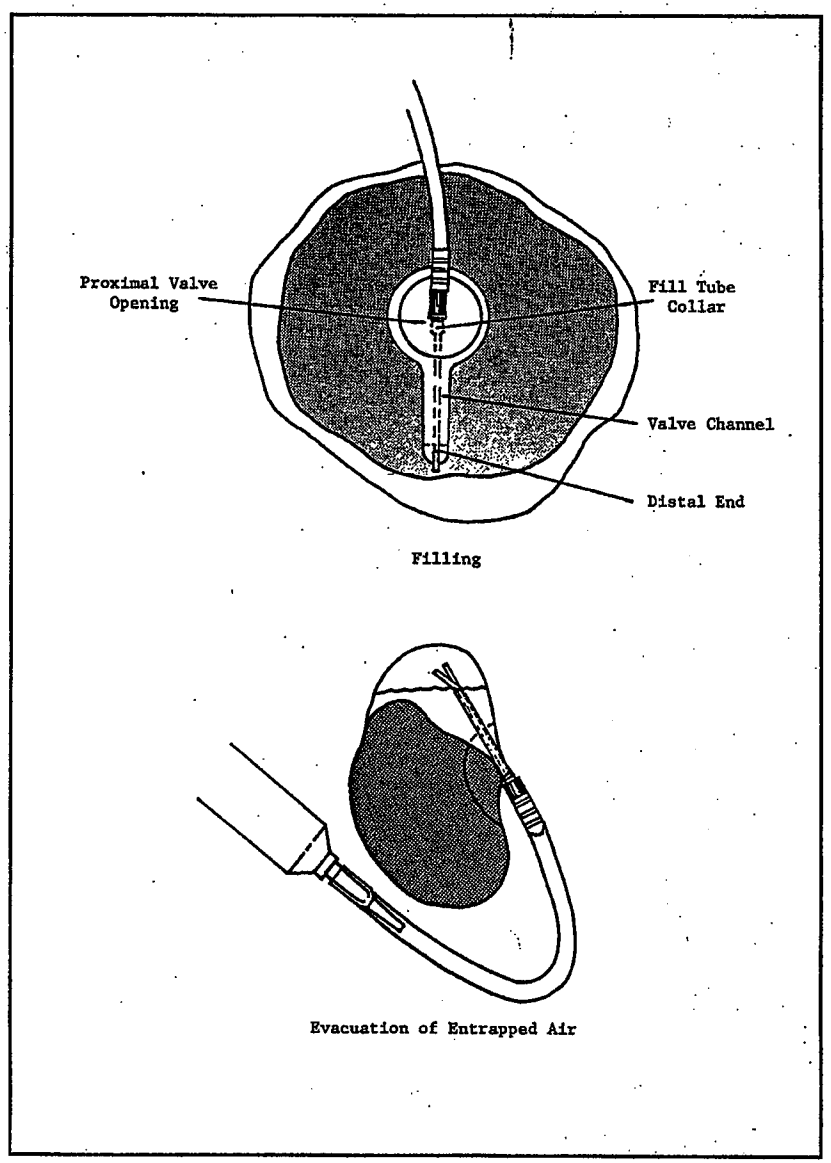
2. Non-sterile Product
   a. Open package under clean conditions.
   b. Remove the implant from wrap and sterilize per the instructions in section H.

F. **Inserting the Fill Tube (Please refer to diagrams.)**

The fill tube is inserted when evacuating trapped air, prior to (re) sterilization, and when filling or adjusting the implant with sterile normal saline prior to placement of the implant in the surgical pocket.

1. Locate the proximal valve opening (slit) at the center of the disc on the envelope surface which leads into the valve channel.
2. After wetting the fill tube tip with sterile normal isotonic saline, gently insert and pass the fill tube through the proximal opening into the valve channel. The valve channel is lubricated with silicone to facilitate entry of the fill tube. The fill tube must be inserted slowly but completely into the valve channel and through the hole at the distal end of the valve channel on the ventral surface. Gentle rotation of the fill tube during insertion may make introduction easier. When properly placed, the proximal end of the valve channel will overlap the collar of the fill tube creating a tight seal and the fill tube tip will protrude out the distal end of the valve into the interior of the outer lumen. This allows an unobstructed flow of fluid during filling and also prevents a back-flow of fluid. Extreme caution should be exercised during insertion of the fill tube and during the filling process to avoid disrupting the integrity of the inner gel unit or the outer envelope. A card enclosed in the package lists the recommended saline fill range for each product size.

   Improper use of the fill tube can damage the valve system. Care must be taken to assure the fill tube enters the valve smoothly to avoid overstressing the valve material which may result in tears or punctures.
3. If alternating syringes during the filling process, the use of a hemostat close to the syringe adaptor on the fill tube will prevent



back-flow of the fluid out of the implant and minimize passage of additional air. Alternatively a 3-way valve could be used.

4. Evacuate entrapped air from the outer lumen of the unit completely. This can be accomplished by pulling negative pressure on the syringe while holding the unit such that the fill tube tip is in the air space.

G. **Removing the Fill Tube**

To remove the fill tube, hold the proximal portion of the valve in place, slowly rotate the fill tube and withdraw with a steady motion. **PRESSING THE VALVE CHANNEL FLAT WILL ASSURE BETTER CLOSURE OF THE VALVE.**

Caution: Repeated insertion and removal of the fill tube could inadvertently damage the valve and/or prevent proper sealing.

H. **To Clean and (Re) Sterilize Mammary Implants**

NOTE: THIS PRODUCT IS FOR SINGLE PATIENT USE ONLY.

1. To Clean

Should the sterile implant become contaminated before use, scrub thoroughly, but gently, with a clean soft-bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily, mild soap.

Do not use synthetic detergents or oil-based soap as these soaps may be absorbed by the implant and may subsequently leach out to cause a tissue reaction. Rinse thoroughly in hot water; follow with thorough rinses in distilled water. Be careful when removing the implant from the basin that it is not re-contaminated with floating particulates. Be certain that no soapy water has infiltrated the envelope. (Re) sterilize as follows:

2. To Sterilize (non-sterile product) or (Re) Sterilize

Each institution should establish the efficacy of its sterilization procedure by appropriate methods. If resterilization of sterile product or sterilization of non-sterile SILASTIC® MSI Gel Saline Mammary Implant H.P. is required, the following steam autoclave techniques have been effective and are provided as a guide. Do not sterilize the implant in the package and/or wrap supplied.

a. After wetting the fill tube tip with distilled water or normal saline, gently insert and pass the fill tube through the proximal opening into the valve channel and through the distal opening on the ventral surface. When properly placed, the proximal end of the fill channel will overlap the collar of the fill tube creating a tight seal and the fill tube tip will protrude out the distal end of the valve into the interior of the outer lumen. Only use the fill tube provided with this product. The implant can be damaged by improper use of the fill tube or use of a different fill tube than that designed specifically for the valve. Appropriate care should be taken to ensure that the tube enters the valve smoothly to avoid overstressing the implant and/or valve, which may result in punctures, tears or seal failure. A gentle rotation of the fill tube during insertion may make introduction easier. Ensure that

the fill tube is properly inserted to allow the release of gas from the unit.

b. Attach a syringe to the Luer receptacle of the fill tube to instill approximately 10cc of distilled water into the unit.

Evacuate entrapped air from the outer lumen of the unit completely by pulling negative pressure on the syringe while holding the unit such that the fill tube tip is in the air space. Disconnect the syringe. Leave the distilled water within the outer lumen and fill tube in position.

c. Wrap the unit in a suitable lint-free wrapping material intended for autoclave use and place in a clean open autoclave tray. Wrapping the unit too tightly may cause the fill tube to become kinked or otherwise occluded. This may prevent the venting of internal pressure from the unit resulting in enlargement and damage to the prosthesis.

d. Standard Gravity Sterilizer -

STERILIZE THIRTY (30) MINUTES at 250°F, 15 psi (121°C, 1 kg/cm² or 1.03 Bar).

Pressure differential during steam autoclaving may cause small bubbles in the gel. The bubbles will not affect the function of the implant and will dissipate with time.

e. High Speed Instrument (flash) Sterilizer -

STERILIZE FIFTEEN (15) MINUTES at 270°F, 30 psi (132°C, 2 kg/cm² or 2.07 Bar).

f. **DO NOT USE A PREVACUUM HIGH TEMPERATURE STERILIZER WHICH RAPIDLY EVACUATES THE STERILIZER CHAMBER THEN PULSES (VACUUM/STEAM) TO ACHIEVE A FAST CYCLE TIME AS THIS TYPE UNIT WILL CAUSE THE SILICONE GEL TO BUBBLE EXCESSIVELY AND THE IMPLANT TO SWELL. IF THE STEAM STERILIZATION PROCESS INCLUDES A VACUUM CYCLE WHICH CANNOT BE BYPASSED OR AVOIDED, RESTERILIZATION OF THE PRODUCT USING THAT STERILIZATION PROCESS IS NOT RECOMMENDED. DO NOT STERILIZE BY ETHYLENE OXIDE AS THE RESIDUAL STERILANT MAY CAUSE ADVERSE TISSUE REACTION.**

g. Avoid repeated sterilizations.

h. After sterilization, the center of the implant may retain heat even though the surface is cool. Be sure the implant has thoroughly cooled throughout before implantation. This may be accomplished by gently kneading the unit in sterile water or saline and allowing adequate time for cooling. Note that the mammary prosthesis may be easily ruptured while still hot from the autoclave. Care must be used during handling to avoid damage.

REFERENCES

Literature references are available upon request to:

Dow Corning Wright
Marketing Department
P.O. Box 100
Arlington, TN 38002
U.S.A.

WARRANTY

Dow Corning Wright warrants that reasonable care in selection of materials and methods of manufacture were used in fabrication of this product. Dow Corning Wright shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this product. The foregoing warranties, as conditioned and limited, are in lieu of and exclude all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise.

Dow Corning Wright neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Dow Corning Wright intends that this mammary implant product should be used only by physicians having received appropriate training in plastic surgery techniques.

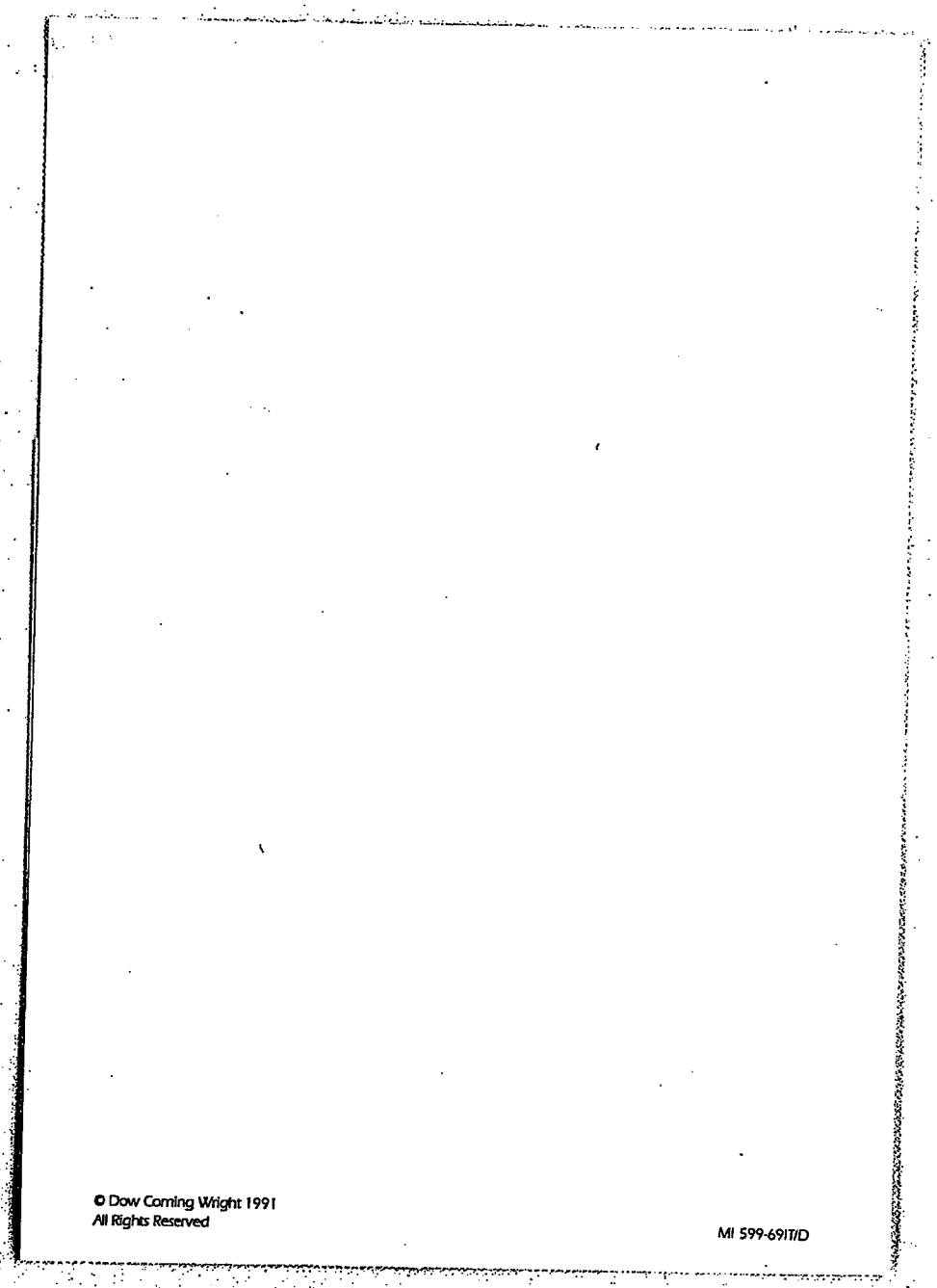
CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

SILASTIC® – This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning and its subsidiaries may identify its products with the trademark SILASTIC®. The word is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's material. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

DOW CORNING WRIGHT
5677 AIRLINE ROAD
ARLINGTON, TN 38002
U.S.A.

PRINTED IN U.S.A. 1/91
2202256-0191



MI 599-6917/D

Patient Information Booklet

Breast Implant

DOW CORNING
DOW CORNING WRIGHT
P.O. Box 994 Midland, MI 48686
1-800-442-5442 In Canada 1-800-255-2156

MI 599-691T/C

Preface

This booklet is designed for women who are considering or who have had breast implant surgery. It contains general information about silicone breast implants manufactured by Dow Corning Wright and the major benefits and risks associated with the implants.

This booklet is not the only source of information you should consider. You should ask your plastic surgeon for a copy of the package insert brochure that accompanies the implants you are considering. While the package insert is intended primarily for the physician, you should read it and ask your doctor to review it with you. You should not hesitate to ask your doctor any question concerning the implants, the surgery, your health, your body, and the risks involved as well as possible benefits.

All surgical procedures have certain risks. Your own physical condition may have a bearing on these risks. It is beyond the scope of this booklet to deal with all of these issues; they should be fully discussed with you by your doctor as they relate to you personally.

As you read this booklet, you may wish to make notes or write down questions to discuss with your doctor.

BACKGROUND INFORMATION

Silicones may be generally described as synthetic materials made up of the elements silicon, oxygen, carbon and hydrogen. These materials are frequently referred to as "polydimethylsiloxanes" or "PDMS."

The three most common elements on earth are carbon, oxygen and silicon. Silicon is never found as a free element, but usually in combination with oxygen, called silicon dioxide. It is best known as quartz, quartz rock or ordinary white sand.

To manufacture silicones, dozens of steps are required, starting with quartz rock or ordinary white sand to produce basic silicone fluid which can then be processed to a final product as a fluid, a gel or a rubber-like material called an elastomer. Special additional processing and testing are performed to manufacture medical and implant grades of silicone materials versus industrial grades.

Research was started in the early 1950's into the use of silicones for implant purposes. Animal studies were done in several species with results that showed very little adverse response. Biological safety studies continue up to the present time. To date, over 300 studies including lifetime animal studies, have been performed on the types of materials used in Dow Corning Wright breast implants.

The medical uses of silicones are many and varied. The first silicone implant, dating back to 1955, was a hydrocephalus shunt used to drain excess fluid from an infant's brain into the blood system. Over 500,000 of these have been implanted. Since then, silicones have been used for orthopedic implants, pacemaker encapsulents, drains, catheters, intra-ocular lenses, pharmaceutical, and many other medical applications.

At the request of two plastic surgeons, development work on the breast implant started in 1961 with the first Dow Corning SILASTIC® Brand breast prosthesis implanted in 1962. Since that time a number of other companies have manufactured silicone breast implants. This booklet deals only with the Dow Corning Corporation and its subsidiary, Dow Corning Wright, products. Please note that there are no references to the polyurethane foam covered implant since neither Dow Corning nor Dow Corning Wright has ever manufactured this type of device.

It has been estimated that since 1963 approximately two million women in the United States have had breast implant surgery. In 1976 Congress gave authority to the Food and Drug Administration (FDA) to regulate all medical devices to assure safety and effectiveness. Among other things, the law required FDA to classify all devices into one of three classifications according to risks. All implants are in the high risk classification unless "down-classed" by the FDA. All devices lawfully on the market before 1976 were allowed to continue on the market unless FDA determined the risks of such devices were unreasonable. While the FDA has not yet determined that silicone breast implants pose an unreasonable risk, FDA has become concerned about some problems reported by both patients and physicians. Accordingly, FDA has required that all breast implant manufacturers file all of their safety and effectiveness data as a part of the Pre-Market Approval Application (PMAA) process. The deadline for filing the PMAA's is July 9, 1991. If a company fails to file, it must cease selling the product. The FDA will study and evaluate the PMAA data submitted by each company in order to reach a decision whether or not the company will be allowed to continue selling. To date, the data available indicates that silicone implants are safe enough to continue to be available. As with all implantable devices, there are risks and it is extremely important that a patient understands the risks and can make an informed decision about having the surgery.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

TYPES OF IMPLANTS MANUFACTURED BY DOW CORNING WRIGHT

(available in various sizes and shapes)

Individual Surgeons often prefer certain types of breast implants. Discuss with your surgeon the type he or she thinks is best for you.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

1. SILASTIC® II H.P.

This is a silicone gel-filled implant with the gel contained inside a smooth-surfaced, silicone envelope. This envelope is made of a medical grade high performance (H.P.) silicone elastomer (rubber-like material) with a fluorosilicone barrier layer on its inside to reduce gel bleed through the envelope. The silicone gel is a clear, sticky, cohesive material that feels like a very thick jelly.

2. SILASTIC® II GEL SALINE H.P. (Double Lumen)

This implant consists of a SILASTIC® II H.P. implant within a larger SILASTIC® II H.P. implant shell, one of which is designed to be filled during surgery with a sterile saline (salt) solution through a triple seal valve. This valve feature allows for volume or size adjustment during surgery.

3. SILASTIC® MSI H.P. (Micro Structured Implant)

This is a silicone gel-filled implant like the SILASTIC® II H.P. except that the outer surface of the silicone elastomer envelope has micro-structured pillars which give a textured rather than smooth surface. The pillars are part of the implant envelope and are not a coating which is added on later. Animal studies and short-term clinical experience suggest that the micro-structured implant may reduce the possibility of capsule contracture (tightening of the scar around the implant). Long-term experience (over 2 years) is not yet available to prove if the risk is reduced.

4. SILASTIC® MSI GEL SALINE H.P. (Double Lumen)

This implant is like the SILASTIC® II Gel Saline H.P. but with the outer envelope having the micro-structured surface.

5. SILASTIC® CUSTOM IMPLANTS

Occasionally, the needs of a patient for breast reconstruction require that an implant be custom designed and made for her only.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

NOTE: Packaged with each implant is a printed package insert brochure which contains important information about the product, about possible risks, reported adverse reactions and complications. You should ask your doctor for a copy and ask him/her to fully discuss it with you.

Prior to your surgery, you should also ask for a photocopy of the "sticker" that comes with each implant so that you may keep it with your records. This sticker identifies the implant, its size and the manufacturer's lot number which will allow the company to trace the complete manufacturing history of that particular implant if it becomes necessary.

AUGMENTATION SURGERY

Women consider having breast augmentation in order to improve their breast size or shape because they think their breasts are too small, uneven in size or unattractive. Some women have breasts that do not fully develop or have significant change in size or shape after pregnancy, weight change or aging. The decision to have the surgery should be an individual one to please you, not someone else. There may be reasons augmentation may not be right for you and you should follow your surgeon's advice.

Most insurance companies will not cover the cost of cosmetic augmentation and may not cover the costs even if a medical problem arises during or after the procedure. You should consult with your insurance company before surgery to determine coverage or lack of coverage.

The surgery may be done in a hospital operating room, an out-patient surgical center or an accredited office surgery facility. The facility should be prepared with the appropriate staff and equipment to deal with any emergency that might occur. You should make sure the facility is properly licensed and accredited by calling your local medical society or surgeon.

You should discuss with your surgeon the type of anesthesia, whether general (fully asleep), local (awake with numbing of the area)

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

or a combination of local with mild sedation (partially awake). The risks of each type should be fully explained and understood.

There are three types of incisions used for inserting breast implants:

1. An inframammary incision is made under the breast at the fold or crease line. This is the most common incision, but with the disadvantage that the scar may be visible with some clothing, such as a bikini top.
2. A periareolar incision is made around the edge of the areola (the darker skin around the nipple) with the disadvantage that the incision may be too small to allow insertion of some implants.
3. An axillary incision is made in one of the crease lines of the armpit. This is used less often because it is more difficult to get proper placement of the implant in some patients, and if there is an implant problem, an incision on the breast may be required.

There are two locations for implant placement:

1. The subglandular (or submammary) placement is between the breast tissue and the chest wall muscles. This is the most common placement since it is easier to do and there is usually less pain after surgery. The disadvantage is that the implant may be more visible in slim women, and mammography examination may be more difficult and less effective.
2. The submuscular placement is between the muscles of the chest wall and the rib cage. The advantage is that mammography may be more effective and the breast may be more attractive in slim women. The disadvantages are that there may be more pain after surgery and the breast will move with certain muscle actions.

After the implants are in place, the incision is closed with stitches, a tape and dressing may be applied, and your surgeon will advise about the type of bra to be worn as well as other instructions. You will be told to avoid lifting, bouncing, etc., for a time period and when you will able to return to normal activities. Some doctors may advise massage exercises. You should follow your doctor's instructions. You will be advised to watch for any signs of infection, bleeding or bruising. Any symptoms or concerns should be reported immediately to your doctor.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

RECONSTRUCTIVE SURGERY

Following mastectomy (surgical removal of all or part of the breast due to disease like cancer or due to injury) patients have several choices to help restore appearance. This booklet deals only with the silicone implant choice. Your doctor can advise you about external prostheses and other surgical approaches.

Understanding why other women choose implants may help you make the decision. Your doctor can provide you with the names and contacts of women's support groups and perhaps even the names of women in your area who are willing to share their experience.

One such organization is the Y-Me National Organization for Breast Cancer Information and Support. Its headquarters can be reached at 18220 Harwood Avenue, Homewood, Illinois 60430, or by calling 1-800+221-2141.

While reconstructed breasts are not the same in appearance or feel as natural breasts, most reconstruction patients find that restoring the general size and shape helps to overcome the sense of loss patients may feel following a mastectomy.

You should fully discuss all issues with your doctor before surgery and specifically determine if you are a suitable candidate for reconstruction with a breast implant as a part of the mastectomy surgery or if you should wait for a period of time.

Your expectations about size, shape, scars, sensation, and risks need to be fully discussed with your doctor so that you do not have false expectations.

Reconstructive surgery will be done while under general anesthesia and usually takes from two to seven hours. Your surgeon will discuss with you

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

the extent of surgery expected, the type of anesthesia, your general health condition and what you should expect during recovery.

Depending on the amount of skin and tissue left after mastectomy, your surgeon may require a tissue expander be implanted first to create additional skin. The tissue expander is a silicone elastomer (rubber) envelope that is implanted where extra skin is needed. Over a period of several weeks, the surgeon periodically fills the expander with sterile salt water and the skin grows as a result of the pressure just as it does during pregnancy or weight gain. When an adequate amount of tissue has grown, the expander is removed and the breast implant inserted.

The type of implant used may be one of the types described on previous pages of this booklet.

Most insurance companies cover the costs of breast reconstruction during or after mastectomy. You should check with your insurance company to confirm coverage.

SURGICAL RISKS

As with any surgery, breast augmentation or reconstruction poses risks that you should know about, such as hematoma, infection, fluid accumulation and skin necrosis.

A hematoma is a blood clot which forms as a result of a leak in a blood vessel. If this happens, you may have swelling, pain, and discoloration and possibly an increased risk of capsular contracture.

Signs of infection–pain, redness, swelling, and fever– should be reported to your doctor immediately. Infection is an infrequent problem but may be troublesome or even serious if it occurs. Nearly all infections occur within a few days of surgery.

Infections around the implant are usually treated with medication. If this is ineffective, the implant must then be removed. Most women have to wait until the infection has cleared before the implant can be replaced.

Serous fluid accumulation may occur immediately following surgery or later during the healing process, giving the breast a full or swollen feeling. This should be reported to your doctor.

Skin decay, called necrosis, occurs when there is not enough blood to supply the skin. This may happen because the implant size is too large for the available tissue or remaining tissue has been changed by a mastectomy.

Necrosis may result from radiation treatments, steroid drugs used to reduce capsular contracture, an implant that is too large for the available space, and smoking.

In some cases, the surgeon may have to remove the implant to prevent infection.

If necrosis is severe enough, the implant may come through the skin.

If you suspect a hematoma, infection, fluid accumulation or necrosis, tell your doctor immediately.

POSTOPERATIVE RECOVERY

After surgery, you can expect some swelling, discoloration, pain and tenderness to occur, but they should disappear with time. If a flap procedure was done, you will also feel pain in the places where skin and tissue was removed to form the flap. If the pain becomes a problem, your surgeon can order some medicine for you. The length of your stay in the hospital or clinic will vary, depending on the type of surgery you have and your general health.

Your surgeon may advise you to massage your breast to reduce capsular contracture or pain. Instructions will include proper technique, as well as how often and how long to massage.

Your surgeon will tell you when you can return to your normal routine. This will depend on how fast healing takes place and how well you feel. Check with your surgeon about any limits to your activities and follow up visits.

COMPLICATIONS

Capsular Contracture:

A capsule is a layer of scar tissue that normally forms around any artificial material that is

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

placed in the body. Capsular contracture occurs when the scar tissue shrinks around an implant, squeezing it so that it feels firm, or in some cases, hard.

This is the most frequently reported problem relating to breast implant surgery. No one knows why some women develop capsular contracture and some others don't, or why in the same woman one breast may contract and the other doesn't.

Contracture occurs in various degrees, from barely detectable firmness to a hard breast. It may be severe enough to be bothersome–even painful–and may cause deformity.

This condition may occur in one or both breasts and to a different degree on either side. It may develop anytime, even years later, although it is most likely to occur in the first several months after surgery. Even if it's treated successfully, capsular contracture can recur.

To relieve or reduce the firmness or a contracture, doctors use a procedure called a capsulotomy. There are two types of capsulotomy: "closed" and "open."

During "closed" capsulotomy your doctor tries to break up the scar tissue by forcefully squeezing the hardened breast. This doesn't always work and may result in bruising, bleeding, or in rupture of the implant. If the implant ruptures, you may need surgery to remove and replace it. Because of the risk of rupture, we do not recommend this procedure.

The other procedure called "open" capsulotomy, involves surgery under anesthesia. The surgeon removes the implant and either makes many cuts in the capsule to loosen it or removes all or part of it. If an implant is inserted again, the surgeon inserts the same implant or a new one in the breast pocket.

Gel Bleed:

Gel bleed is the "sweating" of small amounts of silicone fluid through the outside covering (envelope) of the implant. This free silicone may then move slowly into the surrounding scar tissue, the nearby breast tissue and muscle, and even the lymph nodes in the armpit.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

Breakage/Rupture of the Implant With Leakage:

Your breast implant may break or rupture, sometimes for no apparent reason. You might have a rupture and not know it, because the scar tissue surrounding your implant can keep the gel from spreading (migrating). If you have had a hard blow to the breast, such as an auto accident, or if you notice a change in the appearance or feel of your breast, you should consult you doctor. A mammogram may be useful in some, but not all, cases to determine if an implant has been ruptured.

If the capsule tears or ruptures as a result of a severe injury such as receiving a strong blow to the chest or having a closed capsulotomy, the gel can be a serious problem. It may be squeezed or may ooze into the surrounding body tissues. Movement or migration of large amounts of silicone gel, however, is believed to be uncommon.

If migration occurs, the free gel may cause inflammation, tenderness and swelling around the ruptured implant, as well as lumps on the chest, arms, and abdomen. Prompt surgery is recommended to remove the implant and as much of the silicone gel as possible. If all of the silicone is not removed, it may leave lumps, called granulomas.

Interference With Tumor Detection:

Because silicone gel causes a shadow on an X-ray, silicone implants and free-floating silicone may mask the presence of breast cancer during routine mammography (X-ray of the breast.) If you have breast implants, you should always tell the radiologist before having a mammogram so special techniques can be used.

Granulomas:

Certain body cells can surround a droplet of silicone in quantities large enough to form a lump called a granuloma. It may be difficult to tell the difference between silicone granulomas and other breast lumps. A suspicious breast lump should be removed and examined (biopsied) to determine if it if cancerous. If a biopsy is to be performed, be sure that your doctor knows that you have breast implants.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

If you discover any lump or suspect a rupture, you should be checked by your doctor immediately.

Asymmetry:

While the goal of the surgery is to create a symmetrical (balanced) look to your breasts, a number of factors may cause asymmetry (unevenness). These may include capsular contracture, implant shifting, use of steroids in the implant pocket, uneven placement, different size implants inserted, a pre-existing anatomic asymmetry and differences in the rate of healing between the two breasts.

If your breasts were uneven to start with, the implants may improve this, but not always completely.

Changes in the Nipple and Breast Sensation:

Following surgery, some women report that their nipples and breasts become either painfully sensitive or lose sensitivity. Others, who have submammary implants, have reported that, compared to the rest of the body, their breasts feel cooler to the touch.

These changes may be temporary or permanent. Either condition can have a bearing on sexual response and the comfort level of nursing. You should discuss this with your doctor before surgery.

Movement of Implant:

The implant usually will not move out of the pocket unless there is a severe injury or contracture. Once dislocated, it can be uncomfortable and can distort your breast appearance/shape. You might need another operation to correct the problem.

FURTHER STUDIES NEEDED

Birth Defects and Problems with Nursing:

Scientists have yet to determine the effect, if any, of breast implants on a pregnant woman or her unborn baby. Animal studies have shown no adverse effect. Many women with breast implants are able to nurse. Some women have problems nursing, but it's not known if the problems are related to breast implants.

Current studies show no indication that silicone leaks into the milk of mothers who have breast implants, but little research has been done in this area.

Cancer:

Whether or not implants cause cancer is a concern to many people.

Studies of women with breast implants so far show no increased risk of cancer, but these studies are incomplete. Long-term studies are continuing.

Some life-time rodent studies have shown a 25% incidence of a type of cancer called "sarcoma" which is expected to occur when solid objects of artificial material are implanted in rodents. Most breast cancers are "carcinomas" not "sarcomas." Both Dow Corning Wright and FDA scientists have reviewed these studies and concluded that they are not likely to indicate an increase in risk to humans, and that if there is a risk, it is likely to be very small.

Auto-Immune Diseases:

A small number of women have reported symptoms of rare forms of auto-immune diseases (often called connective tissue diseases) such as Lupus and Scleroderma. These are diseases in which cells attack other cells in the body, causing a wide variety of problems. Scientists are studying the issue to determine if there is a true connection between the implants and these diseases.

OTHER IMPORTANT INFORMATION

Breast Examinations:

If you decide to have breast implant surgery, it is important to continue to have your breasts examined for breast cancer.

You should become familiar with your new breast shape and feel and continue to examine your breasts yourself each month. You should have routine physical exams, including breast examinations, as recommended by your doctor.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

If you don't know how to check your own breasts, have your doctor or other qualified health professional show you a proper method. You could also contact the American Cancer Society for breast self-exam instructions. If you have had an implant, be sure that you receive special instructions.

Mammography:

Mammography is an X-ray exam of the breast. Mammography can detect a small cancer in the breast before it is large enough to be felt. Studies have shown that the smaller the cancer, the better the chance for survival and cure.

The American College of Radiology (ACR) , a professional society of physicians who specialize in diagnosis and treatment through the use of X-ray equipment, has warned that "mammography may be more difficult to perform and less effective on implanted breasts."

This is because the implant shows up as a dense shadow on the X-ray hiding the breast tissue and possibly hiding any small cancerous tumors. However, you should not be discouraged from having a mammogram. It may detect a tumor in that part of your breast not hidden by the implant.

It is easier to X-ray the breast when the implant is placed behind the chest wall muscle rather than when the implant is located in front of the muscle.

To perform high quality mammography only "dedicated" or specially designed equipment should be used. If you have a breast implant, ask your plastic surgeon to recommend a mammographer who is experienced in using a special technique that will show more breast tissue. It is very important to tell the technician you have a breast implant to assure that the proper technique is used.

This technique involves pressing the implant against the chest wall while the breast tissue is gently pulled away and in front of the implant. It usually involves extra X-rays of the breast and increased radiation exposure. It may be more difficult if there is a capsular contracture.

The ACR and the American Cancer Society (ACS) recommend the following mammography guidelines for healthy women with breast implants:

- Women 35 years or older with no significant risk factors should have a mammography exam before surgery.
- After surgery, women between the ages of 40 and 49 should have mammograms every two years and every year after 50.
- If you are at high risk of getting breast cancer, your doctor may adjust your mammography schedule to meet your personal needs. For more information about breast cancer risk factors, contact your local chapter of ACS.

X-raying of the reconstructed breast requires special techniques also. No mammogram is necessary if all breast tissue including areola and nipple have been removed. This should be discussed with your doctor.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

CONCLUSION

This booklet is provided to help you understand the benefits and risks of breast implant surgery. It does not and cannot answer all possible questions nor can it put into perspective your own personal situation. It is intended to give you an overview of the major issues and remind you to seek more detailed and specific information from your doctor.

If you have the implant surgery done and have a complication or problem, it should be reported to your doctor and to Dow Corning Wright at the numbers given below. If desired, you may contact the Food and Drug Administration through the U.S. Pharmacopeia at the number given below. Your report should have the following information available if known:

- Manufacturer's name
- Product brand name and catalog number
- Product style, size and lot number
- Date of implant surgery
- Date of problem
- Nature or description of problem
- Name and address of surgeon
- Your name, address and telephone numbers

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

To call or write Dow Corning Wright:
P.O. Box 100
Arlington, Tennessee 38002
Telephone 1-800+442-5442
In Canada 1-800+255-2156
To Call U.S. Pharmacopeia (for FDA):
Telephone: 1-800+638-6725

SILASTIC® – This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning may identify its products with the trademark SILASTIC®. The word is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's material. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

Your physician is the most important source of information about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about silicone breast implants, breast surgery and the risks associated with both.

EXHIBIT B

I M P L A N T I N F O R M A T I O N C E N T E R T R A I N I N G

MONDAY JUNE 21, 1993

8:00 - 8:15 WELCOME - REVIEW OF TRAINING AGENDA - BRIDGET SNOW

8:15 - 9:15 HISTORY OF DC IN MEDICAL DEVICE/MEDICAL MATERIAL BUSINESS
EUGENE (GENE) JAKUBCZAK

9:15 - 10:00 WHAT IS INFO CENTER? WHY DO WE EXIST? - BRIDGET SNOW
* Background/Caller Activity/Associate Responsibilities
* View Connie Chung Video (15 minutes)
* View Primetime Live 6/3/93(20 minutes)

10:00 - 10:15 BREAK

10:15 - 11:00 HISTORY OF IMPLANTS AND DOW CORNING IMPLANTS SPECIFICALLY
GERRY HAAS
* View Mammary Implant Production Video
* Handout Varifil(R)

11:00 - 12:00 SURGICAL PROCEDURES - Bridget Snow
*Video 3 APPROACHES TO BREAST AUGMENTATION
USING SILASTIC II MAMMARY IMPLANTS (15 MINUTES)
*Video INTRAOPERATIVE TISSUE EXPANSION Dr. Saski (30 MINUTES)

12:00 - 1:00 LUNCH

1:00 - 3:00 MEDICAL TERMINOLOGY AND COMPLICATIONS (PACKAGE INSERT)
PRESENTED BY REGISTERED NURSES IN COMPLAINT ANALYSIS

3:00 - 3:15 BREAK

3:15 - 5:00 IMPLANT INFORMATION CENTER LITERATURE PACKET
AND PERTINENT KEY ISSUES - BRIDGET SNOW

TUESDAY JUNE 22, 1993

8:00 - 9:15 OTHER KEY ISSUES/GENERAL QUESTIONS & ANSWERS - BRIDGET SNOW

9:15 - 9:30 BREAK

9:30 - 11:00 MEDICAL MATTERS - DR. MYRON HARRISON
* Lymph/Immune System
* Autoimmune
* Si in the Body
* Adjuvant Study
* Breast Milk

11:00 - 12:00	ATTNY CLIENT PRIVILEDGE/LIABILITY OF ASSOCIATES LEGAL DO'S AND DONT'S - BARBARA ANDERSON
12:00 - 1:00	LUNCH
1:00 - 2:30	TEST DATA - DR. ROBERT LEVIER * Completed Studies - Summary * In-progress Studies * Future Plans * Biological & Safety Data (10,000 pages)
2:30 - 2:45	BREAK
2:45 - 3:45	COMPLAINT FILES AND MDR REPORTING - DEBRA GRUBBS Food, Drug and Cosmetic Act of 1906 as amended * Good Manufacturing Practices (GMP's) Medical Device Reporting Act of 1984 as amended Safe Medical Devices Act of 1990
3:45 - 4:30	FDA - BRIDGET SNOW
4:30 - 5:00	WRAP UP QUESTIONS & ANSWERS

WEDNESDAY JUNE 23, 1993
(IIC ASSOCIATES ONLY)

8:00 - 9:00	OPEN
9:00 - 11:00	IIC PROCEDURES MANUAL - TONI DEWALD (to include demo of telephone usage)
11:00 - 1:30	OPEN
1:30 - 2:30	DO'S AND DONT'S - VICKI WESTBROOK MONITORING PROCEDURES RESOURCE LIST DATA BASE CODING CORRESPONDENCE FORM LETTER BOOK
2:30 - 3:30	HOW TO FIND A CORRECT PACKAGE INSERT - SANDY MENDYK HOW TO READ A LOT NUMBER HOW TO USE THE CATALOG NOTEBOOK GRIFFIN BELL
3:30 - 3:45	BREAK
3:45 - 4:45	MDL ORDER - BRIDGET SNOW BREAST IMPLANT REMOVAL ASSISTANCE PROGRAM CUSTOMER RELATIONS 10,000 PAGES AND 800 PAGES
4:45 - 5:00	WRAP-UP AND QUESTIONS AND ANSWERS - BRIDGET SNOW

6-23-93
Vicki Westbrook

DO'S

1. State Dow Corning Wright Implant Information Center and your full name.

2. Ask if caller is an implant patient (not applicable if Doctor, Lawyer, or if caller has received implant other than a breast implant). — OR Lay Representative

3. Read recording statement and ask if caller wants to be recorded.

4. Be Certain the caller has your name and telephone number so they can reach you again. If necessary, do a "supplemental" call report if they call again. — It will be in Letter

5. Encourage patients to discuss questions and concerns with their doctors.

6. Offer to send the Patient Information Packet.

7. Stick to the facts. Be open about what we do and do not know. Use the information in the Patient Information Packet and other approved materials.

8. Provide other sources of credible information (see reference list) including ASPRS, FDA other manufacturers, etc.

10. Do respect the caller's right to privacy. Treat the details of each call as confidential to be discussed only with those who have a need to know.

11. Do try to address the caller's immediate concerns during the conversation and then offer to follow-up with the written information, if needed.

12. Be sympathetic and human. Take as much time as the caller needs.

13. Do be sensitive to the caller's tone of voice and hidden agenda.
    Note: You do not have to talk to caller if it is an obscene phone call or if caller is using profane language.

6/22/93

*

DONT'S

1. Do not guess or speculate about an answer. If you do not know the answer, offer to find out and call back. Contact resource person for assistance.

2. Do not talk about other manufacturers' products. Stick to silicone in general or Dow Corning's products. Give 800 number for manufacturers if caller has a question.

3. Do not give personal opinions. Any opinion you express is the opinion of the company. (NOTE: You can answer questions based on your factual personal experience. for example - Have you ever had surgery? Do you have implants? Do you know anyone who has implants? etc. After you answer these questions, tell caller you are concerned with them.)

4. Do not commit to what the company will or will not do. Your job is to provide information and not to practice law, medicine, science or marketing.

5. Ask for information needed for call report. If they do not want to give their name or their doctor's name or any other information, do not press.

6. Do not read to the caller. Answer questions in you own words but be certain that your explanation is consistent with the Patient Information Packet.

7. Do not get on the telephone if you are upset, tired, uncertain of some fact, etc. Calls can be extremely stressful and you will not do yourself or the caller any good if you are upset or "stressed out".

6/22/93

EXHIBIT C

DOW CORNING BREAST IMPLANT REMOVAL ASSISTANCE PROGRAM

In February 1992, FDA provided the following advice to women with silicone gel-filled implants. **"It is important to bear in mind that most women do not experience serious problems with their implants. At this time, FDA is not recommending women have their implants removed if they are not experiencing any problems. But women with implants should be on the alert for potential problems. If they experience any symptoms they feel may be related to the implants, they should contact their personal physicians or plastic surgeons, as they would with any illness."**

Dow Corning supports this statement by the FDA. Furthermore, Dow Corning believes that silicone gel-filled breast implant devices serve an important medical purpose and that unnecessary removal could result in surgical complications or harm which otherwise would not occur. Although it does not encourage, and in fact strongly discourages, unnecessary surgery, Dow Corning recognizes that each woman, in consultation with her physician, must make her own decision. For those women who agree with their physicians that for medical reasons the implant(s) should be removed, but who are unable to pay for the removal surgery without financial assistance, Dow Corning has designed a financial support program described in detail below. This program applies to patients who reside in the United States.

A. The Program

The Breast Implant Removal Assistance Program is designed for a woman who has agreed with her physician that for medical reasons her Dow Corning gel filled breast implant device(s) should be removed and who is unable to pay for the removal surgery without the financial assistance provided under this program. The program is effective for removal surgery performed as of January 6, 1992, and will remain in effect for the foreseeable future to allow women to make an informed decision regarding removal surgery. At least one years notice will be given prior to termination of this program.

The surgeon, as primary intermediary, is responsible for providing the patient with appropriate risk information prior to surgery.

B. Product

The program will apply to all Dow Corning gel filled breast implant devices implanted prior to January 6, 1992.

C. Conditions

The following conditions must be met in order for the Breast Implant Removal Assistance Program to apply:

1. Product must have been used only as intended and in accordance with Dow Corning literature current to the date of implantation.

2. Product must have been implanted and removed by appropriately qualified, licensed surgeons in accordance with accepted plastic surgical procedures.

3. Patient certifies she is unable to pay for the removal surgery without the financial assistance provided under this program.

4. Completion and return of the Patient Certification Form and the Informed Consent Form prior to removal surgery.

5. Post-operative verification by the physician that Dow Corning manufactured the removed breast implant device(s).

D. Expenses

Dow Corning agrees to pay up to $1,200 of the medical expenses directly related to removal surgery that are not covered by insurance. This program is not intended to cover costs related to breast implant replacement.

Participation in this program will not require a release of your potential claims against Dow Corning.

To Apply for Assistance

1. The physician or patient should contact a Dow Corning representative by phoning 1-800-442-5442 or writing to Dow Corning Corporation, P. O. Box 994, Mail #95, Midland, MI 48686.

2. The Dow Corning representative will explain the program and send
   a. a program brochure.
   b. a certification to be signed by the patient and her physician confirming that
      (1) she understands and agrees to accept the risks associated with removal surgery.
      (2) she is unable to pay for the removal surgery without the financial assistance provided under this program.
      (3) her gel filled breast implant device(s) were manufactured by Dow Corning.
   c. an Informed Consent Form to be reviewed and signed by the patient.

3. The patient and physician should complete the Patient Certification Form and the patient should complete the Informed Consent Form. The physician should return the completed forms to Dow Corning in the self-addressed, stamped envelope provided, prior to removal surgery.

4. Dow Corning will issue a check, made payable jointly to the patient and the physician, upon receipt of:
   a. a written post-operative statement from the physician verifying Dow Corning as the manufacturer of the removed breast implant device(s).
   b. the physician's statement of medical expenses directly related to the removal surgery that is not covered by insurance.

EXHIBIT D

DOW CORNING

[redacted]

August 21, 1992

Max Dean
Dean, Dean, Segar, Hart
& Shulman, P.C.
1616 Genesee Towers
120 East First Street
Flint, MI 48502-1957

Dear Mr. Dean:

I am writing in response to your letter of June 10, 1992 and various telephone calls between you and Linda Abbott of Dow Corning's Implant Removal Assistance Program. I appreciate the opportunity to respond to the questions in your letter.

The documents used in the Dow Corning Implant Removal Program were prepared to assist in implementing a removal program for women with a desire and medical need for removal of Dow Corning implants, if they could not otherwise afford the costs attendant to such a procedure. The program thus contemplates that participants will be involved with their respective surgeons in discussions related to potential complications of removal surgery, the normal course of which includes a patient's acknowledgment of the inherent risks of all surgical procedures and/or the particular risks of the contemplated procedure. The language of the Removal Assistance Program documents, including references to an informed understanding of the potential risks of surgery, are consistent with this purpose.

With regard to the program not requiring a release of a participant's potential claims against Dow Corning, this language is in our view clear and straightforward. Dow Corning has consistently stated that participants in the program need not execute a release of liability to participate, and nothing in the written documents for the program constitutes such a release.

I hope that this letter is responsive to your client's questions.

Very truly yours,

Bridget Snow

Bridget Snow, Supervisor
Removal Assistance Program
1-800-442-5442

EXHIBIT E

Dow Corning Corporation

Breast Implant Support

Information

DOW CORNING

On March 19, 1992 Dow Corning made a decision to exit the silicone breast implant business. Dow Corning understands the need for continuing information to doctors and patients and, in response to this need, we have established sources of information and support.

IMPLANT INFORMATION CENTER

The Implant Information Center provides information to patients concerning Dow Corning® silicone breast implants and our related support programs. The service provides an 800 number with operators on staff who will provide information in response to the most frequently asked questions from patients.

You may contact this service by calling 1-800-442-5442 in the U.S. or 1-800-255-2156 in Canada.

IMPLANT REMOVAL ASSISTANCE PROGRAM

In February of 1992 the Food and Drug Administration provided the following advice to women with silicone gel-filled implants. "It is important to bear in mind that most women do not experience serious problems with their implants. At this time, FDA is not recommending women have their implants removed if they are not experiencing any problems. But women with implants should be on the alert for potential problems. If they experience any symptoms they feel may be related to the implants, they should contact their personal physicians or plastic surgeons, as they would with any illness."

The Breast Implant Removal Assistance Program is designed for a woman who has agreed with her physician that for medical reasons her Dow Corning® gel-filled or gel-saline breast device(s) should be removed and who is unable to pay for the removal surgery without the financial assistance provided under this program. Participation in this program does not require a release of potential claims against Dow Corning. The program provides up to $1200 for medical expenses. The $1200 must be used for removal surgery performed on or after January 6, 1992. The Breast Implant Removal Program will remain in effect for the foreseeable future to allow women to make an informed decision regarding removal surgery. At least one year's notice will be given prior to termination of this program.

Contact with the Breast Implant Removal Assistance program can be made by calling 1-800-442-5442 in the U.S. or by calling 1-800-255-2156 in Canada. Ask to be connected to the Implant Removal Assistance Program.

CUSTOMER RELATIONS DEPARTMENT

For patients who may have experienced problems with their Dow Corning® implants or who are not eligible for the Implant Removal Assistance Program, Dow Corning offers a more formal product claims procedure:

The formal claims process is based upon evaluation of the removed, sterilized implants (if available), in combination with the relevant medical records. If a product failure appears to be related to our materials or our workmanship, we will assume financial responsibility for the reasonable uninsured, out-of-pocket expenses associated with the corrective surgery. Additional expenses associated with the corrective surgery will be considered on a case-by-case basis. The patient will be required to sign a release.

To contact the Customer Relations Department call 1-800-446-3845.

WARRANTY PROGRAM

The P.R.E.P.® warranty program covers Silastic® II and/or MSI™ implants inserted on or after 11-1-86. The warranty extends for 5 years from the original date of implantation and provides up to $600.00 for each breast implant plus the cost of replacement implants. No release is required.

To contact call the Customer Relations Department at 1-800-446-3845.

PROFESSIONAL RELATIONS

Dow Corning maintains an 800 number and personnel to answer questions from doctors or other healthcare professionals concerning more detailed implant related questions or concerns.

You can access the Professional Relations Department by calling 1-800-437-7056.

RESEARCH SUPPORT

Dow Corning has established support for the research programs necessary to address questions raised by the FDA advisory panel. It has established the following:

$10 Million Research Fund

$500,000 Matching Grant with the Plastic Surgery Education Foundation

This research support is aimed at providing additional scientific information on silicone breast implants.

EXHIBIT F

covered w/ staff 3/20/98

DON'T

(1) don't mention complications just ideas in head

(2) don't mention IF this program doesn't work forward you to Claims — Have Someone from Customer relations Call

(3) [redacted]

(4) [redacted] Status [illegible] it

(5) Order lunch (?) Friday

(6) Job - leave blank & SS fill out

(7) [redacted]

(8) Mail file

EXHIBIT G

DOW CORNING

[redacted]

3/30/92

FOR PATIENTS WHO DO NOT MEET PROGRAM REQUIREMENTS

We appreciate your call about our Implant Removal Program. We have carefully defined the program and are sorry that the facts of your situation do not meet the requirements. We have a more formal claims procedure with more complex criteria which may be of value to you. We cannot advise you on whether you should call or not, but if you choose to do so, the number is 1-800-238-7188.

IF YOU CHOOSE TO CALL THIS NUMBER, PLEASE TELL THE OPERATOR THAT YOU ALREADY TALKED TO A REMOVAL ASSISTANCE PROGRAM REPRESENTATIVE.

REV. 5/5/92

EXHIBIT H

From: BMSNOW --MIDVM01 Date and time 04/29/92 19:12:46
To: MJBIGGS --MIDVM01

Note From: Bridget M. Snow - 6145
REMOVAL ASSISTANCE - MAIL #95
SUBJECT: REMOVAL ASSISTANCE CALLS REFERRED TO CUSTOMER RELATIONS

MARTHA, WOULD YOU PLEASE COPY LYNN ON THE FOLLOWING:

LYNN, CONFIRMING OUR TELEPHONE DISCUSSION THIS AFTERNOON, HERE ARE SOME ADDITIONAL PATIENT NAMES THAT WERE REFERRED TO CUSTOMER RELATIONS AND ENDED UP BACK WITH REMOVAL ASSISTANCE.

PLEASE FOLLOW-UP WITH:

1) Rosemary Battles
(817) 569-4507
Initially given Mem # 4/21/92
Mdr'd 4/15/92 - Notice to Anderson 4/15/92

2) Christine Conklin
301 Island Shores Dr.
West Palm Beach, FL 33413
(407) 641-1823 ...you can leave msg on answering machine if she is not there.
Initially referred to Mem 4/21

3) Leslie Gums
4312 Mesaview Dr.
Mesquite, TX 75150
(214) 681-4513
MDR'd by us on 3/23, Notice to Zurich on 4/16
Initailly referred to Mem on 4/10

cc: MJWILDES--MIDVM01 TKBUTLER--MIDVM01
DABENNET--MIDVM01 MKSTAMAS--MIDVM01

Bridget