EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

In Re:

DOW CORNING CORPORATION,

Reorganized Debtor.

_____/

Civil Action No. 00-CV-00005-DT

(Settlement Facility Matters)

The Honorable Denise Page Hood

AFFIDAVIT OF BRIDGET SNOW-SWANTEK IN SUPPORT OF DOW CORNING CORPORATION AND THE DEBTOR'S REPRESENTATIVES' RESPONSE TO MOTION OF CLAIMANTS' ADVISORY COMMITTEE FOR DECLARATORY RELIEF REGARDING RELEASES

BEFORE ME, the undersigned authority, personally appeared Bridget Snow-Swantek, who, after being duly sworn, deposed by me stated as follows:

1. My name is Bridget Snow-Swantek. I am of sound mind, capable of making this affidavit, and personally acquainted with the facts stated in this affidavit.

2. I am currently employed in the Medical Device Operations department at Dow Corning Corporation. I supervised the Removal Assistance Program ("RAP") from approximately March 1992 through 1996 when the Removal Assistance Program announced it would close and program wrap-up occurred. Beginning in approximately August 1992 through 1994, I also served concurrently as the supervisor of the Implant Information Center. I worked in a back-up supervisory capacity in the Complaint Investigation/Medical Device Reporting Department and the Implant Information Center from late 1995 to February 1997.

3. The Implant Information Center was one resource located under the "Implant Issue Operations" organization. The Implant Information Center's Associates answered questions via telephone and provided informational brochures to patients and physicians about

breast-implant issues. For example, the Implant Information Center offered information or brochures to callers about: FDA statements and positions; Dow Corning product information, including package inserts; and answers to frequently asked questions regarding breast implants and alleged connections between breast implants and disease.

4. While the Implant Information Center was one source of information about breast implants, its Associates and informational materials told patients that their physician was the best source of information about implants, breast surgery, and related topics.

5. The Removal Assistance Program offered women an expedited way to receive financial assistance. It provided financial assistance to women who could not afford the explant procedure and who agreed with their physicians that, for medical reasons, their implants should be removed.

6. Throughout its existence, the Removal Assistance Program paid approximately $6 million to over 5,000 participants.

7. The Removal Assistance Program did not require a release of potential claims against Dow Corning.

8. The Removal Assistance Program and the Implant Information Center were separate departments within the Implant Issue Operations organization. The departments' functions, personnel, and training were separate and distinct, although they were both supervised by myself. The Implant Information Center and Removal Assistance Program shared the same toll-free number. Implant Information Center Associates initially received the calls and would pre-screen them and answer product-related questions. If appropriate, the Implant Information Center Associate would transfer the caller to a Removal Assistance Program Representative,

who would explain the Program and assist the caller in the financial assistance application process.

9. The Removal Assistance Program Representatives were well-versed in the program, but were not trained on and could not discuss implant-related issues like the Implant Information Center Associates. The Removal Assistance Program's focus was the administration of financial assistance through its streamlined process.

10. After the provisional signing of the April 1994 Global Breast Implant Litigation Settlement Agreement, Dow Corning provided written notification that the Removal Assistance Program would end in May 1995.

11. The toll-free phone number for the Customer Relations Department was different from the toll-free phone number shared by the Implant Information Center and the Removal Assistance Program. Callers to the Implant Information Center and the Removal Assistance Program who needed to speak with a Customer Relations Specialist were not transferred between the separate toll-free numbers, but rather were offered the toll-free phone number for the Customer Relations Department if appropriate.

12. Dow Corning trained its representatives to avoid automatically transferring calls regarding the Removal Assistance Program to Customer Relations Specialists. Removal Assistance Program Representatives were told to not create a bridge or path between the departments or to automatically offer the Customer Relations Department as another option.

13. An audit in approximately January 1993 found that about 16 percent of calls to the Removal Assistance Program were referred to the Customer Relations Department, generally because the caller fell outside of the Program requirements.

14. I have reviewed the CAC's Memorandum In Support Of Motion Of Claimants' Advisory Committee For Declaratory Relief That The "Receipt And Release" Document Solicited By The Dow Corning Legal Department From Unrepresented Claimants From 1992-1995 As Part Of The Removal Assistance Program (Or Represented As Part Of Such Program) Is Not A General Release. The CAC discusses an "Implant Hotline Training" transcript's reference to "a call that really belongs to the other group, the program group." The CAC appears to suggest that this shows that the Implant Hotline Associates would automatically transfer calls to the separate Customer Relations Department. However, given that protocol for the Implant Information Center was to transfer financial assistance requests to the Removal Assistance Program, the logical interpretation of this rough transcript is that the "program group" to which Ms. Williams referred was the Removal Assistance Program, not the Customer Relations Department.

15. Attached hereto as Exhibit A is a true and correct copy of a 1991 Implant Information Center informational packet, which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to make the record or to transmit information to be included in that record; and the record was made at or near the time or reasonably soon thereafter.

16. Attached hereto as Exhibit B is a true and correct copy of June 22, 1993 documents provided in Implant Information Center training, including a list of "Do's" and "Don't's", which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or

representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to make the record or to transmit information to be included in that record; and the record was made at or near the time or reasonably soon thereafter.

17. Attached hereto as Exhibit C is a true and correct copy of a document dated March 29, 1993 that outlined the Removal Assistance Program, which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to make the record or to transmit information to be included in that record; and the record was made at or near the time or reasonably soon thereafter.

18. Attached hereto as Exhibit D is a true and correct copy of a letter dated August 21, 1992, from Bridget Snow (my name at the time) to Max Dean of Dean, Dean, Segar, Hart & Shulman, which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to make the record or to transmit information to be included in that record; and the record was made at or near the time or reasonably soon thereafter.

19. Attached hereto as Exhibit E is a true and correct copy of a 1992 document entitled "Dow Corning Corporation Breast Implant Support Information", which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to

make the record or to transmit information to be included in that record; and the record was made at or near the time or reasonably soon thereafter.

20. Attached hereto as Exhibit F is a true and correct copy of handwritten notes authored by Bridget Snow on March 20, 1992, which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to make the record or to transmit information to be included in that record; and the record was made at or near the time or reasonably soon thereafter

21. Attached hereto as Exhibit G is a true and correct copy of a document revised on May 5, 1992 and entitled "For Patients Who Do Not Meet Program Requirements", which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to make the record or to transmit information to be included in that record; and the record was made at or near the time or reasonably soon thereafter.

22. Attached hereto as Exhibit H is a true and correct copy of an April 29, 1992 e-mail from Bridget Snow to Martha Biggs with a subject of "Removal Assistance Calls Referred To Customer Relations," which is a record kept by Dow Corning Corporation in the regular course of business, and it was the regular course of business of Dow Corning Corporation for an employee or representative of Dow Corning Corporation, with knowledge of the act, event, condition, opinion, or diagnosis, recorded to make the record or to transmit information to be

included in that record; and the record was made at or near the time or reasonably soon thereafter.

Bridget Snow-Swantek

Bridget Snow-Swantek

SWORN TO AND SUBSCRIBED BEFORE ME on MAY 18TH by Bridget Snow-Swantek

SHERI LITTLE-CONRAD

[Notary's typed or printed Name]

NOTARY PUBLIC FOR THE STATE OF MICHIGAN

Sheri L. Little-Conrad

(Seal) My commission expires: 9/21/07

[or Notary's Stamp]

Sheri L. Little-Conrad
Notary Public, Midland County, Michigan
My Commission Expires September 21, 2007
Acting in BAY County

EXHIBIT A

Implant Information Center

DOW CORNING

DOW CORNING WRIGHT

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

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

Implant Information Center

Dear Doctor:

There has been a great deal of publicity recently about breast implants and the FDA activity surrounding the PMA process. This, in turn, has resulted in a great many requests to Dow Corning Wright for information and we are certain to your office, as well.

In an effort to assist you in informing your patients about the risks and benefits of breast implants, the enclosed material is being provided. These materials were prepared by Dow Corning Wright and are intended for the lay reader. You may feel free to give the packets to patients or to use as a basis for discussion.

In the near future we will supply your office with a number of information packets. This will assist your patients in deciding whether or not to proceed with breast implant surgery based on the latest facts we have available. Obviously, your office can best decide how to utilize these in the best interest of your patients.

On an ongoing basis we will send an information packet with each single or pair of implants you order. Therefore, the packets will be replenished as you go.

Additional packets are available by contacting the Implant Information Center at 1-800+442-5442. The Center has a full-time staff available to answer questions from patients or doctors about our products or silicones in general.

If you would like additional technical information, we also have available copies of the clinical and non-clinical portions of Dow Corning Wright's PMAA submissions. There is a photocopying charge of 5¢ per page plus shipping. If you are interested in these materials, please contact Martha Biggs at 800+238-7188, ext. 514 for an order form.

We sincerely hope this information will be of help to you and your patients.

Sincerely,

Dan M. Hayes, Jr.
President

DMH:mb0155

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

BACKGROUND INFORMATION ON

THE POSSIBLE HEALTH RISKS OF SILICONE BREAST IMPLANTS

(PREPARED DECEMBER 18, 1990)

(REVISED FEBRUARY 8, 1991)

Silicone gel-filled breast implants have been used for approximately 20 years, and at present about 2 million women in the U.S. have them. When the medical device law--the statute that gives the Food and Drug Administration (FDA) the authority to regulate products such as implants--was passed in 1976, it "grandfathered" devices that were already on the market, including breast implants. This means that the manufacturers of those products were not required to provide FDA with scientific evidence of safety and effectiveness, as they are with brand-new types of devices. That stipulation in the law is based on the premise that, generally speaking, more is known about the safety of a device that has been in use for some time than about one that is newly developed. But if questions arise over time that cast any doubt about a "grandfathered" device's safety, the law also gives FDA the authority to go back and require that its manufacturer provide us with evidence to demonstrate that it is safe and effective.

That is what FDA has chosen to do with silicone breast implants. Although it appears that most women with these implants do not suffer serious adverse effects, there are enough unanswered questions about possible risks that FDA has decided to require manufacturers to provide scientific data demonstrating their safety.

The possible risks of silicone breast implants fall into two basic categories: those related directly to the breast, and those that may involve distant parts of the body. One breast-related risk is that the implant may make it more difficult to see abnormalities in the breast when mammographic x-ray examinations are done, even if special views are made as part of the x-ray procedure. Another is the hardening, discomfort and pain that occurs in some patients, resulting from fibrous tissue growing around the implant. Still another is occasional breakage of the implant's outer envelope, causing the gel filling to be released.

Most of these breast-related effects are relatively easy to observe, and they are not unexpected. All implanted devices, from artificial hip joints to heart valves, will fail to work or will have adverse effects in a small proportion of patients--no type of device placed in the body for a long period of time can be considered perfect, and no surgical procedure is without risk. With breast implants, FDA needs more information on what percentage of patients experience these breast-related effects and how severe they are.

The possible effects of silicone breast implants on other parts of the body are far more uncertain and difficult to measure. For example, it is known that even in the absence of obvious leaks, minute quantities of the gel filling can migrate out of an intact breast implant over a long period of time and can travel throughout the body. It is not known whether this can be harmful over the long run or not. It has been suggested that these tiny amounts of silicone in the body could lead some people to develop auto-immune diseases in later years, and some scientists have raised the question of whether the silicone could have an effect on a developing fetus. But at this point there is no convincing evidence that these effects actually occur.

The long-term effect of greatest concern to most people is the possibility of cancer. That concern was aroused several years ago by a study of laboratory rats conducted by the Dow Corning Corporation, a leading manufacturer of silicone breast implants. The study showed an excess of a particular type of cancer called sarcoma in rats who had been implanted with silicone gel. FDA, too, was concerned about these results, and presented them to cancer experts within FDA and also at the National Institutes of Health.

The experts noted two reassuring facts about the study. First, sarcomas (the type of cancer produced in the rats) occur very rarely in humans; the vast majority of human breast cancers are of a distinctly different type, called carcinomas. Secondly, laboratory rats are extraordinarily susceptible to sarcomas caused by implanting foreign objects in their bodies; the experts pointed out that these animals develop sarcomas after the implantation of a wide variety of materials, most of them innocuous in humans. The experts concluded (a) that the results of the rat study are unlikely to apply to humans; (b) that although a risk from silicone breast implants cannot be completely ruled out, there are at present no convincing animal or human studies that point to such a risk; and (c) that if a cancer risk did exist from silicone breast implants, it would be very small.

To sum it up, FDA does not believe that there is cause for alarm at present about the safety of silicone breast implants. But answers are needed to the questions outlined above in order to establish once and for all just what the risks are. That is why FDA is going to require the manufacturers of the implants to supply scientific evidence of their safety. Manufacturers will have until the summer of 1991 to submit the data.

Silicone breast implants coated with polyurethane foam may pose certain additional hazards. FDA is particularly concerned that the polyurethane may break down in the body, and is conducting laboratory research to find out whether this is the case. Based on the results of this research, FDA will re-evaluate the risks and benefits associated with polyurethane-coated breast implants.

What should a woman who is contemplating a silicone breast implant do? For now, the best course of action is to discuss the situation frankly with her physician. (It is perfectly reasonable to ask the physician to see the informational material that comes with the implant, which describes possible adverse effects.) She needs to talk over the known, breast-related risks as well as the less well-understood, non-breast related risks described above, and to weigh these risks against the benefits of the procedure. That way she can make an informed decision about whether to proceed with the implant surgery.

If a woman who already has a silicone breast implant is concerned about the possible risks, she too should ask her physician's advice. Most of the readily-observed, breast-related adverse effects discussed above are well known to physicians, as are the ways to treat them. As to the possibility of effects on other parts of the body (related to the fetus, for example, or to autoimmune disease, or cancer), at this point these are only hypothetical questions. In weighing the possible long-term risks of silicone breast implants, it is important to bear in mind--and this applies to any number of substances we encounter in everyday life--that not being able to completely rule out a risk does not necessarily mean there <u>is</u> one.

MAYO CLINIC HEALTH LETTER

RELIABLE INFORMATION FOR A HEALTHIER LIFE

VOLUME 9, NUMBER 3, MARCH 1991

In this issue

Coming next month

New surgical treatment for epilepsy...Driving safety: How to cope with the challenges age brings...Food and medications: When don't they mix?

mayo

Congestive heart failure

Intensive research is leading to earlier, more effective care

With each passing second, your heart takes another beat, pumping approximately 2,000 gallons of blood to your muscles, tissues and organs each day.

What happens when your heart fails to pump as it should?

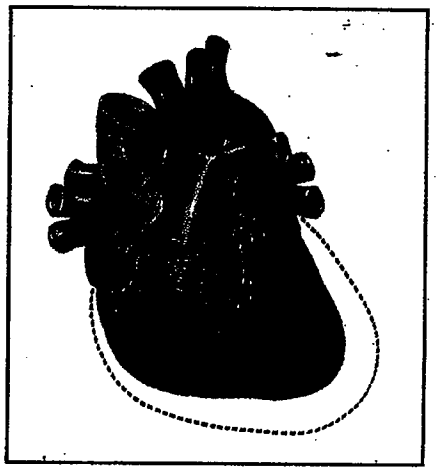
Inefficient pumping of blood results in congestive heart failure. Research suggests 10 percent of people diagnosed with congestive heart failure die within the first year. The disease is the leading cause of death among hospitalized Americans.

Intensive research into why the heart sometimes fails is uncovering new approaches for treating congestive heart failure. Doctors hope this can lead to earlier, more effective care that may improve the heart's efficiency and relieve symptoms before the illness becomes severe.

How the healthy heart works

Your circulatory system consists of your heart, arteries and veins. Your heart pumps blood to your tissues to give cells oxygen and nutrients. Arteries take blood from your heart to your tissues. Veins bring blood back to your heart.

Your heart circulates blood with two pumps, one located on the left side of your heart and one on the right side. Each pump contains an atrium (a receiving chamber) and a ventricle (an exiting chamber).



In congestive heart failure, the heart pumps less effectively and blood flows more slowly. As a result, the heart becomes enlarged (dotted lines).

Blood returning to the heart from your head, trunk, arms and legs enters the right atrium and passes into the right ventricle. From there, it is pumped to your lungs.

In the lungs, blood gives up the carbon dioxide it has carried from your tissues and absorbs oxygen. Blood flows from the lungs into the left atrium and passes into the left ventricle. This exiting chamber powerfully pumps oxygen-rich blood back out into your body.

When the pump fails

In the United States, most people with congestive heart failure suffer from chronic pump inefficiency. Ineffective pumping decreases blood flow throughout your body and allows blood to back up into the veins that return blood to your heart. ▶

One or both sides of the heart may fail:

■ *Left side* — Most forms of heart failure affect the left side. When the left-sided pump starts to fail, blood backs up into the lungs, causing them to become congested with fluid. Congestion can lead to excessive breathlessness during exertion. You may feel weak and more easily tired during or following your normal activities.

Eventually, you may also have breathing problems when lying down. Lying down allows excess fluid in the legs and feet to return to circulation. This is what may cause you to awaken in the middle of the night gasping for breath.

■ *Right side* — As the lungs become more congested, the heart's right-sided pump also becomes overloaded.

Blood backs up into your veins and causes swollen (distended) neck veins. Fluid also can build up in your liver, causing it to become enlarged. Your feet and ankles may swell. And even your fingers and hands may retain fluid, making it difficult to remove jewelry.

Causes of heart failure

Congestive heart failure is really a syndrome that can be caused by several problems:

1. Damage to the heart muscle caused by narrowed coronary arteries or a heart attack (myocardial infarction) weakens the heart's pumping action.

2. Infected, narrowed or leaky heart valves can overload the heart.

3. Chronic alcohol abuse as well as other drugs may reduce the heart's ability to contract. Eventually, these substances cause the heart muscle to deteriorate.

4. Years of uncontrolled high blood pressure can cause the heart muscle to thicken and become stiff. Stiffness can prevent the heart from relaxing adequately to fill with blood. Chronic high blood pressure also may weaken the heart's pumping action.

Rest, diet, drugs, transplants

Treating congestive heart failure includes one or more of these approaches:

■ *Rest* — Adequate rest helps conserve energy and decreases demands on your heart. But avoid bedrest. Instead, rest in a chair periodically and avoid excessive fatigue.

■ *Diet* — Restricting sodium minimizes fluid retention. This reduces swelling in your legs and congestion in your lungs. Reduced congestion eases shortness of breath.

Digesting small meals seems to require less effort for your heart. Avoiding caffeine lowers the risk of an increased heart rate or abnormal heart rhythms.

■ *Medications* — Diuretics are almost always an integral part of early treatment, along with rest and diet.

Diuretics increase the rate at which your body makes urine. This, in turn, reduces fluid and sodium that would accumulate in your tissues. Together with a sodium restriction, diuretics relieve swelling and breathlessness.

Because some diuretics promote loss of potassium, your doctor may prescribe a potassium supplement and encourage you to eat potassium-rich foods.

Digitalis has been used for many years to mildly increase the heart's pumping action. Within the last 10 years, however, medications that dilate blood vessels (vasodilators) have advanced drug treatment and are emerging as a first-line therapy.

Three oral vasodilators that treat congestive heart failure are the angiotensin-converting enzyme inhibitors (ACE inhibitors) captopril, enalapril and lisinopril.

ACE inhibitors help in two ways. First, they decrease production of angiotensin, a hormone that constricts arteries. This allows the heart to empty more easily. Second, they decrease production of aldosterone, another hormone that causes your body to retain sodium and water.

■ *Transplantation* — At Mayo Clinic and other centers, cardiac transplant units are performing increasing numbers of heart or heart/lung transplants when conventional treatments fail. ▶

MAYO CLINIC HEALTH LETTER

Medical Editor
Charles C. Kennedy, M.D.

Associate Medical Editor
Philip T. Hagen, M.D.

Managing Editor
David E. Swanson

Staff Writers
Matthew D. Dacy
N. Nicole Spelhaug, R.D.

Customer Service Manager
Christie L. Smith

Mayo Clinic Health Letter (ISSN 0741-6245) is published monthly by Mayo Foundation for Medical Education and Research, 200 First Street SW, Rochester, MN 55905. Subscription price is $24 a year. Second-class postage paid at Rochester, MN. POSTMASTER: Send address changes to Mayo Clinic Health Letter, Subscription Services, P.O. Box 53889, Boulder, CO 80322-3889.

Focus of intensive research

As the American population ages, the incidence of congestive heart failure will increase.

Yet new approaches for treating congestive heart failure continue to evolve.

Here are some areas of research in which doctors at Mayo Clinic are involved:

■ *Implantable pump* — Doctors can insert what they call a left ventricular assist device into the chest to assist the heart's pumping action.

■ *Genetics* — Some people may inherit a heart condition called dilated cardiomyopathy. In this severe form of congestive heart failure, the heart muscle deteriorates and becomes enlarged. Although effective treatment remains unavailable, genetic research holds exciting potential.

■ *Hormones* — Mayo doctors are developing and testing new drugs to block the breakdown of a hormone called atrial natriuretic factor (ANF).

Your heart makes ANF, which causes the kidneys to rid your body of sodium. In heart failure, the heart may not make enough ANF, similar to the way the pancreas doesn't make enough insulin in diabetes.

Doctors anticipate that medication can enhance the level of ANF that the body makes.

Scientists are learning that endothelin, a hormone, is a powerful constrictor of arteries. People who have congestive heart failure frequently have elevated levels of endothelin. Control of this hormone could lead to new ways to treat heart failure.

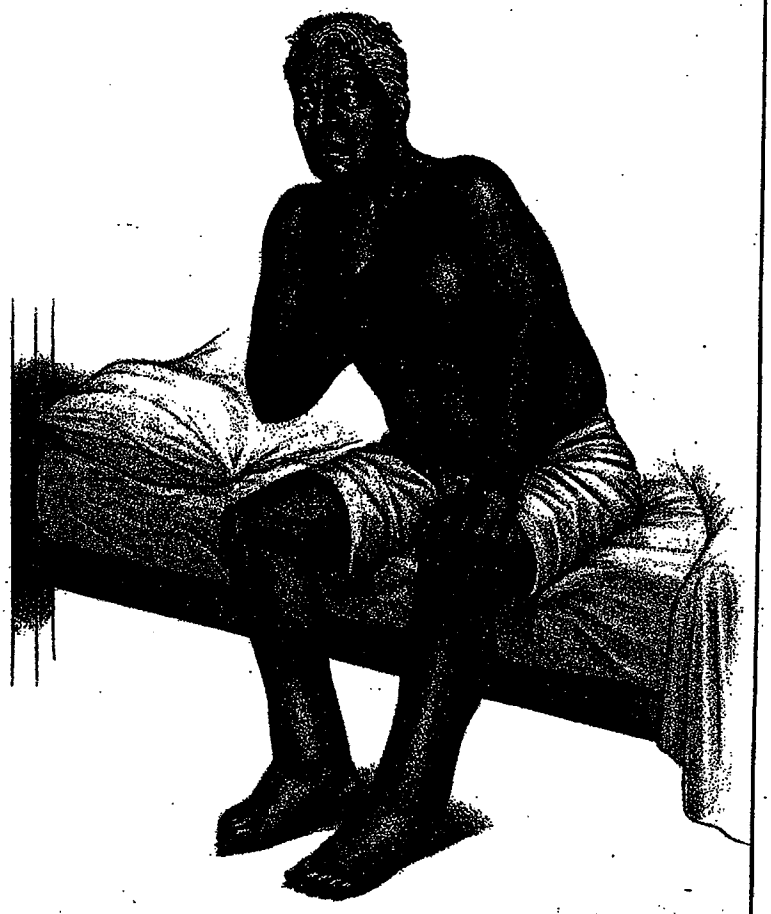
Hope for the future

Research efforts no doubt will lead to a better understanding of congestive heart failure. This may foster the development of new and improved treatments. And that could mean longer, more productive lives for people who develop the disease. □

Congestive heart failure
Know the symptoms

When your heart doesn't pump blood as efficiently as it should, excess fluid accumulates in your tissues and lungs. See your doctor if you notice any of these symptoms, especially if you have a history of heart disease:

- Fatigue, weakness and inability to exert yourself.
- Shortness of breath soon after exertion begins.
- Shortness of breath that awakens you from sleep.
- Swelling in your legs, ankles or feet.
- Rapid weight gain — a pound a day for three consecutive days.
- Swollen (distended) neck veins.
- Coughing up pinkish, blood-tinged sputum.



Colon cancer treatment

Advances in drug therapy are giving new hope to people with cancer

Each year in America, colon cancer kills more than 50,000 people.

A recently approved combination of two drugs — fluorouracil (floo'ro-ur'a-sil) and levamisole (le-vam'-i-sole) — promises to reduce that death rate.

These two medications are used as supplementary treatment following surgery for colon cancer. By killing undetectable cancer cells that may remain after surgery, they lessen the chance that cancer will recur.

A change in approach

For many years, surgery has been the mainstay of treatment for colon cancer, a killer second only to lung cancer as a cause of cancer-related deaths.

Unfortunately, the cancer often spreads (metastasizes) to lymph nodes near the tumor. Once this spread occurs, surgery is less effective.

The new combination therapy is specifically designed to prevent recurrence and further spread of colon cancer after surgery.

Although these drugs offer new hope, the medications themselves are not new. Fluorouracil, often referred to as 5-FU, is a cancer-fighting agent that has been available for three decades.

Levamisole, developed 25 years ago in Europe to kill intestinal parasites in farm animals, is given in tablet form; 5-FU is given by intravenous (IV) injection.

Fatalities reduced

Mayo Clinic researchers recently reported on their experience with this combination in two studies conducted over an 11-year period.

The treatment reduced the rate of cancer recurrence by 41 percent, and lowered the death rate by more than 30 percent.

Experts now believe the new technique could save more than 5,000 lives annually. Many specialists see it as a major advance in curing colon cancer.

During the studies, most of the 1,700 patients who participated in the research programs were treated in their home communities.

For best results, the new drug combination treatment must be started within three to five weeks of surgery.

Side effects minimal

At the doses used, unwanted effects of levamisole are infrequent and generally limited to mild nausea.

Undesirable effects of 5-FU include nausea, vomiting and a lowered white blood cell count. Less-common effects are diarrhea and sores in the mouth. A physician closely monitors the treatment.

The new regimen is given for about a year, but doctors still are evaluating optimal treatment time. Some believe a shorter period may suffice.

Although the new treatment clearly can help many people, it is not universally effective. Therefore, if you have colon cancer, your physician will discuss with you the therapy regimen best suited to your needs. □

Canker sore or cold sore?

Can you tell the difference? How are they treated?

Irritating, painful and repetitive. That's how many people describe canker sores and cold sores. But terminology can be confusing.

Cold sores have nothing to do with the common cold. What's more, the cause, appearance, symptoms and treatments of canker sores and cold sores differ markedly.

Canker sores — pain inside your mouth

A canker sore is an ulcer on the mucous membrane inside your mouth. Typically, you notice a burning sensation and a round, yellow spot with a red halo. Pain lessens in a few days.

Heredity, stress and infections don't cause canker sores. Food allergy is rarely involved, but some foods (such as aged cheese, nuts or citrus fruits) may cause a recur-

Canker sores

Cold sores

rence.

A minor injury like biting the inside of your mouth may prompt canker sores. But most specialists believe they are caused by an immune system response.

For relief, apply ice to the canker sore and avoid food that is irritating.

Another option is to rinse your mouth with over-the-counter preparations: Try diluted hydrogen peroxide or elixir of Benadryl.

For severe attacks, your dentist or physician may recommend a prescription mouthwash, a corticosteroid salve, or an anesthetic solution called viscous lidocaine.

Cold sores — a viral infection

Also known as fever blisters, cold sores are common. They may appear on your mouth, lips, nose, cheeks or fingers.

The herpes simplex virus 1 causes cold sores. You get cold sores from another person who has an active condition. Eating utensils, razors and towels are common means of spreading this infection.

Symptoms may not start for as long as 20 days after you were exposed, and usually last seven to 10 days. Small, fluid-filled blisters develop on a raised, red, painful area of skin.

The virus may emerge later as an active infection near the original site. Fever, menstruation and exposure to the sun may trigger a recurrence.

To diagnose a cold sore, your physician will examine the painful area. Testing your blood or material from the sore can confirm the presence of herpes simplex virus.

Most cold sores subside within a few days, but your doctor may prescribe an antiviral drug (salve or pills) for troublesome outbreaks. □

Update '91

Our views of the news

■ **Implantable contraceptive now available.** Norplant, America's first implantable contraceptive, contains a progesterone-like hormone encased in six matchstick-sized rods of rubber-like material. Rods are inserted in a fan-like arrangement under the skin of a woman's inner arm above the elbow. The hormone inhibits ovulation by blocking release of eggs for up to five years.

Norplant may represent a significant advance in birth control. But several Mayo gynecologists are not prescribing it, preferring a wait-and-see approach. Although deemed safe, Norplant may have side effects such as irregular menstrual bleeding, headache, weight gain, depression, nausea, acne, increased facial hair and benign but painful ovarian cysts. (Some of these side effects may occur with oral contraceptives as well.)

Tests show Norplant works best in women of average weight and build. Questions remain about effectiveness of doses for women who weigh more than 150 pounds or whether they will suffer more side effects. Norplant's main advantage over oral contraceptives? You don't have to remember to take it. □

■ **New test spots cancer earlier.** This test uses monoclonal antibodies — substances produced in special animal systems. Viewed under a microscope, monoclonal antibodies highlight tumor cells in bone marrow taken from the person with cancer. These antibodies are highly sensitive, being able to identify one abnormal cancer cell among 250,000 normal cells. Earlier detection improves odds of successful treatment.

Mayo oncologist Gerald S. Gilchrist, who helped develop the test, notes that researchers focused on neuroblastoma. This rare, nervous-system cancer affects about 500 children a year in America. But physicians can use the same approach to diagnose common types of cancer in adults, such as breast cancer and some forms of lung cancer, according to Dr. Gilchrist. □

■ **Injections treat impotence.** There's a new treatment option. You insert a tiny needle into the shaft of the penis and inject a prescription medication. This engorges the penis with blood, resulting in an erection.

Injections are nearly painless and produce a more natural result than vacuum devices and prosthetic implants. (See *Mayo Clinic Health Letter*, December 1989.) Side effects — painful or prolonged erections, build-up of fibrous tissue in the penile shaft or tolerance to the medications — are rare. The injections are not usually effective if you have vascular disease. Limit injections to once a day, twice a week. □

Egg substitutes

Best ways to use them while cutting your dietary cholesterol

In the spring of 1989, the U.S. Department of Agriculture (USDA) gave the egg a long-overdue break.

The USDA announced that newer, more sophisticated measurements show that an average large egg contains about 213 milligrams of cholesterol. For many years, the accepted figure had been 274 milligrams.

The American Heart Association (AHA) responded to the news by revising its egg consumption guidelines. The organization now says that to limit dietary cholesterol to 300 milligrams a day, healthy American adults can eat up to four, rather than three, egg yolks a week.

Even though this newer guideline allows more freedom for including eggs in a heart-healthy diet, the egg still is a concentrated source of cholesterol. Yet you can take advantage of the egg's culinary versatility without its cholesterol.

Substitution strategy

Whether you have high blood cholesterol or follow the AHA's recommendations for a healthy diet, these tips offer more options for enjoying egg dishes while controlling your dietary cholesterol:

■ *Use egg whites* — Substitute two egg whites for each whole egg in any recipe calling for whole eggs. An egg's cholesterol is contained entirely in its yolk. The white has protein but no cholesterol.

Because an egg white also is fat-free, some recipes such as muffins, omelettes and scrambled eggs work better if you substitute egg whites for only half the total eggs. For example, a healthier version of a standard muffin recipe that calls for two eggs is one egg plus two egg whites.

■ *Use commercial egg substitutes* — For every whole egg you replace with the white, you're left with a yolk to toss or store for future use. That's not always convenient.

A few manufacturers have solved this dilemma by offering frozen and refrigerated egg substitutes. To use them, substitute one-quarter cup of a liquid egg substitute for one whole egg. Because they're typically made entirely of egg whites, these products contain no cholesterol. Color is added to more closely resemble whole eggs. And some products contain vegetable fat to add texture to egg dishes. Add fresh herbs and spices such as onion and garlic to boost flavor.

Remember that you can pay more for egg substitutes than whole eggs. It's worth comparing brands for taste differences.

Final note

Eating no more than four egg yolks a week is only one step to controlling dietary cholesterol. □

Eggs or egg substitutes: comparing the options

Compare fat and cholesterol levels of one whole egg with the egg white only and with comparable amounts of three commercial egg substitutes. Note that dishes made with substitutes contain less fat and no cholesterol. Protein levels are about the same.

Product	Calories	Protein (grams)	Fat (grams)	Cholesterol (milligrams)
1 large egg (yolk plus white)	79	6	6	213
1 egg white (from large egg)	16	3	0	0
Ayoset Foods Second Nature, refrigerated (1/4 cup)	60	6	2	0
Fleischmann's Egg Beaters, frozen (1/4 cup)	25	5	0	0
Morningstar Farms Scramblers, frozen (1/4 cup)	60	6	3	0

This list is not comprehensive and does not represent an endorsement. We have not tested these products but rely on data supplied by manufacturers.

Breast implants

How safe are they?

Recent reports again raise questions about breast implants. We emphasize: Breast implants are safe. Here are the major concerns about breast implants — and why you should not believe them:

■ *Cancer* — An implant does not make it significantly more difficult to diagnose cancer or increase your risk of developing cancer.

Mayo researchers found that women who have mastectomy and breast-reconstruction surgery at the same time do well, in spite of common fears that implants might hide recurring cancers. Inserting a breast implant after removing cancerous tissue prevents the cost and recovery process of a follow-up operation. It also may help ease some of the psychological trauma that women can experience after the removal of one or both breasts.

■ *Other diseases* — Direct injection of silicone into your breast may lead to joint pain and flu-like symptoms. But there's no proof that implants cause such problems.

Lupus and rheumatoid arthritis are no more common in women with implants than in the general population.

In reviewing reports from around the world, fewer than 100 women with implants have been reported as having some sort of immune-system disorder. And even in these few cases, there is no evidence that breast implants were to blame.

■ *"Seeping" silicone* — Doctors have known for years that fragments of silicone may spread to the liver and spleen. But there is no known threat to your health. Even if the implant breaks, the silicone that leaks has not been proven to be dangerous.

■ *"Rejection" of silicone* — The body won't "reject" an implant as might be the case with a transplanted organ. However, if the skin covering an implant is too tight, the implant may partially break through the skin. This complication is extremely uncommon and can be corrected by surgery.

■ *Firmness* — Tissue surrounding the implant, but not the prosthesis itself, may become firm. There's no risk to your health, and surgery remedies the problem. □

Facts about implants

■ A breast implant is a silicone-rubber envelope filled with silicone gel or salt water, or a combination.

■ More than 2 million women have received implants since the early 1960s (about 25 percent after cancer surgery and the others for breast enlargement).

■ Implants have an impressive safety record. Under a 1988 law, manufacturers must demonstrate safety and effectiveness through scientific studies.

■ In a recent survey sponsored by the American Society of Plastic and Reconstructive Surgeons, 80 percent of women who had received implants said they would do it again without doubt. 16 percent said they "probably would," and 2 percent said they "definitely would not."

Aerobic alert

Improper exercise can harm your health

Two classic features of aerobic dance — loud music and vigorous movements — may damage sensitive parts of your inner ear and affect your hearing and balance.

On December 6, 1990, *The New England Journal of Medicine* published a letter from a New York physician who reported five case studies and a survey of 37 aerobics instructors.

The participants had a variety of problems, including a sense of "fullness" in the ear, reduced hearing at high frequencies and tinnitus (ringing in the ear).

The most common balance problem was vertigo. Other people complained of dizziness and imbalance during and after exercise.

Lower-impact alternatives

We don't want to discourage aerobic dance, but consider these tips:

1. Healthful aerobic dance limits strain on your bones, muscles and joints while exercising your cardiovascular system.

2. When jumping or jogging, land with a heel-toe motion, not flat on your feet or on the balls of your feet.

3. "Listen" to your body's signals and avoid strain in exercise where you sweep and glide, reach and sway.

4. Limit the volume of music in your dance class. Blasting your eardrums can harm your hearing.

Talk to your instructor if the music seems too loud. Buy or borrow a decibel meter to measure sound. Avoid noise levels beyond 85 to 90 decibels. □

Second opinion

We answer your questions

Q. Will saccharin in antacids or other products give me cancer or otherwise harm my health?

A. Most experts agree that saccharin doesn't measurably increase your risk of bladder cancer.

In April 1977, the Food and Drug Administration proposed a ban on saccharin. The agency had collected information indicating that male rats who were given extremely high doses of saccharin developed bladder tumors.

Saccharin does seem to be a weak promoter of cancer in animals. But studies don't link the sweetener, as typically used in the diet, to cancer in humans. □

Q. My dental fillings contain mercury. Is this a health hazard?

A. There is no convincing proof that amalgam (silver) tooth fillings are dangerous.

Recent reports linking the mercury in amalgam restorative material to Alzheimer's disease, arthritis, multiple sclerosis and memory loss touched a sensitive nerve in many of the 100 million Americans who have silver fillings. But the data fail to support such claims.

Mercury is dangerous, for example, in vapor form. You would not want to breathe large quantities. "But the mercury in dental fillings is stable and safe," explains Charles M. Reeve, a Mayo Clinic dentist. "Any vapors emitted from the fillings are negligible."

Silver fillings are less expensive than gold and stronger than composite fillings made with plastic.

Says Dr. Reeve: "There's no health reason for you to pay several hundred dollars to have your silver fillings removed." □

Q. My latest potassium blood test was 5.9, which is higher than normal. Can excess potassium cause an irregular heart beat?

A. Yes, but irregular heart beats also can result from lower-than-normal levels of potassium in the blood, which occurs more commonly.

Irregular heart beats may be occasional and of minor consequence — or they may signal a more serious health problem, such as coronary artery disease.

A potassium level of 5.9 is not excessively high. And it might be a misleading count caused by damage to red blood cells at the time your blood was drawn.

Repeat testing can confirm the finding. If you do have high levels of potassium, your doctor will look for an underlying cause.

Elevated levels of potassium are most common with kidney disease, where your kidneys can't excrete potassium normally.

Potassium-sparing diuretics, certain medications for high blood pressure, non-steroidal anti-inflammatory drugs and some salt substitutes that contain potassium can contribute to the problem. □

Q. Since I started taking two Ocuvite tablets a day, I believe my macular degeneration has improved. Can this be true?

A. There's no evidence that Ocuvite or any other vitamin or mineral supplement will prevent or correct visual loss caused by macular degeneration. But supplements can give you an upset stomach.

One tablet of Ocuvite contains 40 milligrams of zinc, which represents 270 percent of the recommended dietary allowance (RDA). It also contains 100 percent of the RDA for copper and vitamins A, C and E.

Although two tablets don't provide a dangerously high dose of vitamins and minerals, you may experience an upset stomach.

Remember this: A well-balanced diet generally provides you with adequate amounts of minerals and vitamins, making supplementation unnecessary. □

*Send your questions to: **Second Opinion, Mayo Clinic Health Letter, Box H, 200 First Street SW Rochester, MN 55905.** We appreciate every letter, but cannot publish an answer to each question or personally respond to all inquiries.*

Purpose
Mayo Clinic Health Letter provides reliable, timely information on issues relating to good health. Much of its information comes directly from the experience of Mayo's 1,100 physicians and research scientists.

Mayo Clinic Health Letter supplements the advice of your personal physician, whom you should consult for individual medical problems.

Customer Service
For subscription information, call Customer Service at:1-800-333-9037. Non-U.S. and Canadian subscribers call: (303) 447-9330. Subscription prices in USA: $24; Canada and Mexico: $29 (U.S.); all other countries: $39.

Single copies are available for $3 each. Bulk subscriptions are available at reduced rates.

Proceeds, after expenses, help strengthen Mayo programs in medical education and research.

Correspondence
Subscription inquires should be sent to:

Mayo Clinic Health Letter
Subscription Services
P.O. Box 53889
Boulder, CO 80322-3889.

Occasionally, we make our Mayo Clinic Health Letter mailing list available to carefully selected companies and organizations. If you do not wish to receive such mailings, please write us and enclose your mailing label.

Medical Essays and Index
As premiums for our readers, we publish periodic Medical Essays and an annual index. The essays cover individual health topics in depth, and the index is a handy reference to Health Letter articles published in the last five years.

For a free copy of the current index, call or write Customer Service.

MC 2019-391

Implant Information Center

Supplemental Information
To
Most Frequent Questions

Breast Cancer

Mammography

Connective Tissue Disease and Immunology

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

Silicone Breast Implants: Breast Cancer

SUMMARY

Medical researchers have shown no relationship between silicone breast implants and cancer after 30 years of use and implantation in approximately two million women.

According to the Food and Drug Administration (FDA), "...although a risk (of cancer) from silicone breast implants cannot be completely ruled out, there are at present no convincing animal or human studies that point to such a risk" and "...if a cancer risk did exist from silicone breast implants, it would be very small."

The FDA has, however, asked manufacturers of silicone breast implants to provide additional scientific evidence concerning the functions and effects of these implants on the body. Thus, researchers are continuing to conduct animal studies to further advance understanding of how the silicone breast implant interacts with the body and to be responsive to the concerns of women who are considering or have breast implants.

There are many types of cancer. Two types of cancer that can occur in women are:

- Sarcoma, which is extremely rare in humans but common in laboratory rats and
- Carcinoma, which is distinctly different from sarcoma. Carcinoma is the most common type of breast cancer in women

DO IMPLANTS CAUSE CANCER?

The possibility of silicone breast implants causing cancer in women was raised in a 1988 study of laboratory rats conducted by Dow Corning Corporation, a manufacturer of silicone breast implants. The study showed that a type of cancer called sarcoma occurred in laboratory rats that had been surgically implanted with the silicone gel used inside implants. (In women, the implant consists of an external outer shell of a rubbery silicone material known as elastomer with an inner core of silicone gel.) The results of the study were reported voluntarily to the FDA which, in turn, consulted with cancer experts at the National Institutes of Health. The experts noted several reassuring facts about the study:

- The type of cancer produced in the rats, sarcoma, occurs rarely in humans
- The vast majority of human breast cancers are of a distinctly different type called carcinomas
- Laboratory rats are extraordinarily susceptible to sarcomas
- Sarcomas can be caused in the rats by implanting many types of foreign objects like materials used in heart valves, pacemakers and hip replacement joints and other man made materials like dacron, nylon, metals and glass.[1]
- The effect of implanted objects causing sarcomas is known as "solid-state carcinogensis" which is unusual in humans.[2]

RESEARCH UPDATE

Several published studies in the medical literature have compared the number of women with both silicone implants and breast cancer to the number of women in the general population without implants who have breast cancer. This was done to determine if there is an increased incidence and risk of breast cancer in women with implants. The largest study of this kind found no increase in the breast cancer rate in women with implants.[3] The women in this study have been followed for an additional five years since the study results were issued, and there is still no sign of an increased incidence of breast cancer in these women with implants.

To date, no animal studies have shown that silicone gel or the rubbery silicone material (elastomer) that makes up the outer shell of the implant causes cancers other than sarcomas in rats. In fact, researchers have reported that silicone elastomer has no effect on the growth of a cancer artificially placed in animals.[4] Other researchers have reported that silicone gel and elastomer can actually slow the growth of tumors in animals caused by a known cancer causing chemical.[5]

THE INCIDENCE OF SARCOMA BREAST CANCER IN WOMEN

Sarcoma does occur in women without breast implants; however, the incidence is rare. A National Cancer Institute cancer registry reports 465 breast sarcomas in women between 1973 and 1986.[6] This translates to about 45 new cases each year for every 10 million women. There was no increase in new cases of sarcoma per year in the 1973 to 1986 period which could mean that breast implants are not linked to breast sarcoma. However, it is really too soon to come to this

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 or the risks associated with both.

conclusion because breast sarcoma is rare, so women must be followed for a longer time period by medical researchers.

CONCLUSION

Animal studies have raised only the issue of an association between silicone gel and sarcoma in laboratory rats. To date, studies have found no association between sarcomas and women with implants. An increase in one cancer type in animals caused by a chemical or material does not necessarily mean that other types of cancer will be caused by the same chemical or material in humans.

In that regard, the FDA and National Institutes of Health (NIH) cancer experts have concluded that:

- The results of the laboratory rat study are unlikely to apply to humans
- Although a risk from silicone breast implants cannot be completely ruled out, there are at present no convincing animal or human studies that point to such a risk
- If a cancer risk did exist from silicone breast implants, it would be very small

Researchers and physicians are continuing to study implants and remain responsive to the concerns of women who have or are considering breast implants. Additional animal studies are being conducted to advance an understanding of how the silicone breast implant interacts with the body.

FOR MORE INFORMATION

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 or the risks associated with both.

SELECTED REFERENCES

The following references are available from your hospital or medical school library.

1. Brand KG, Johnson KH, Buoen LC. Foreign body tumorigenesis. CRC Critical Review in Toxicology 1976, Volume 4, page 353.
2. Turner FC. Sarcomas at sites of subcutaneously implanted bakelite discs in rats. Journal of the National Cancer Institute 1941, Volume 2, page 81.
3. Deapen DM, Pike MC, Casagrande JT, Brody GS. The relationship between breast cancer and augmentation mammaplasty: An epidemiologic study. Plastic and Reconstructive Surgery 1986, Volume 77, page 361.
4. Habal MB, Powel RD. Biophysical evaluation of the tumorigenic response to implanted polymers. Journal of Biomedical Materials Research 1980, Volume 14, page 447.
5. Dreyfuss DA, Singh S, Dowlatshahi K, Krizek TJ. Silicone implants as an anticarcinogen. Surgical Forum 1987, Volume 38, page 587.
6. May DS, Stroup NE. The incidence of sarcomas of the breast among women in the United States, 1973-1986. Plastic and Reconstructive Surgery 1991, Volume 87, page 193.

Silicone Breast Implants: Mammography

SUMMARY

Mammography is an essential screening and diagnostic procedure for the detection of breast cancer. In America, one out of every nine women will develop breast cancer during her lifetime, regardless of whether they have silicone breast implants. Studies differ as to whether mammography can be effectively performed in the presence of breast implants. In most instances, special placement techniques and more x-rays are necessary for women with implants in order to obtain a picture of the breast tissue. Women who have breast implants should seek out radiologists and technicians who are experienced in taking x-rays of patients with implants.

DETECTING BREAST CANCER

Breast implants make it difficult for physicians to detect lumps in the breasts by mammography because x-rays cannot pass through silicone gel. For this reason, some mammary tissue is blocked from imaging by the breast implant.

The positioning of the implant can help make a difference in viewing the breast tissue through mammography. If the implant is placed behind the muscle of the chest wall, the x-ray views can be better than if the implant is placed in front of the muscle of the chest wall and behind the mammary gland. Even if there is chest muscle between the implant and the mammary gland, imaging can be of poorer quality because the volume of the implant compresses mammary tissue. In general, the more mammary gland tissue present in a breast, the less blocking there will be.

It is important for women to tell the examining physician or x-ray technician the type of implant and its placement (in front of or behind the chest wall muscle) before the mammogram is taken.

TECHNIQUE USED IN MAMMOGRAPHY

While many surgeons and radiologists have concluded that the implanted breast can be properly imaged, it is generally agreed that mammography is more difficult to perform when an implant is present.

For the woman with breast implants, it is probably best to supplement the usual screening mammogram with additional x-ray views in order to obtain the most comprehensive pictures of the breast tissue. In addition to regular Breast Self-Examination (BSE), a manual examination by a physician should be done periodically at intervals recommended by a woman's physician. Again, a record of the type of implant and the implant's placement is important for both the personal physician and the radiologist or technician performing the mammogram.

X-rays of the implanted breast often can be improved by using a modified mammography procedure called displacement mammography in addition to the usual compression method.[1]

Displacement involves compressing the mammary tissue while pushing the implant away from the tissue and against the chest wall. Your physician should be able to recommend radiologists and technicians experienced in mammography of women with breast implants.

EFFECTIVENESS OF MAMMOGRAPHY IN WOMEN WITH IMPLANTS

One group of researchers has shown data that neither compression nor displacement mammography is as effective in the presence of breast implants as it is with the unimplanted breast. They claim that as a result, breast cancer is detected at a later stage in these women, when the cancer has grown large enough to be seen easily.[2,3] A number of other studies, however, have found that implants have no influence on the stage at which breast cancer was diagnosed.[4,5] One study of more than 3,000 implanted women found implants to have no influence on disease stage at diagnosis compared to women without implants.[6]

CONCLUSION

The American Cancer Society recommends a "baseline" mammogram for all women between the ages of 35 and 40 and additional mammograms every two years following. Women who are thinking of having breast implants may want to have a mammogram taken before implantation and then another immediately after to serve as a reference baseline. Women who have a history of breast cancer in their family should consult their physician for a recommended schedule of mammograms.

All women should practice regular BSE techniques as instructed by her physician. The surgeon who performs the implantation can show the patient the best technique for BSE with implants.

FOR MORE INFORMATION

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.

Information on breast self-examination and mammography guidelines is available from the American Cancer Society, 1599 Clifton Road, NE, Atlanta, GA 30329. (404) 320-3333.

SELECTED REFERENCES

The following references are available from your hospital or medical school library.

1. Eklund GW, Busby RC, Miller SH, Job JS. Improved imaging of the augmented breast. American Journal of Radiology 1988; Volume 151, page 469.
2. Silverstein MJ, Handel N, Gamagami P, Waisman JR, Gierson ED, Rosser RJ, Steyskal R, Colburn W. Breast cancer in women after augmentation mammoplasty. Archives of Surgery 1988; Volume 123, page 681.
3. Silverstein MJ, Handel N, Gamagami P, Waisman JR, Gierson ED, Lewinsky B. Breast cancer diagnosis and prognosis in women following augmentation with silicone gel-filled prostheses (Abstract). Conference on silicone in medical devices, Baltimore, February 1-2, 1991, page 18.
4. Mitnick JS, Harris MN, Roses DF. Mammographic detection of carcinoma in patients with augmentation prostheses. Surgical Gynecology and Obstetrics 1989; Volume 168, page 30.
5. Robertson CL, Kopans DB, McCarty KA, Hart NE. Nonpalpable lesions in the augmented breast: preoperative localization. Radiology 1989, Volume 173, page 873.
6. Deapen DM, Pike MC, Casagrande JT, Brody GS. The relationship between breast cancer and augmentation mammaplasty: A epidemiologic study. Plastic and Reconstructive Surgery 1986, Volume 77, page 361.

Silicone Breast Implants: Connective Tissue Disease And Immunology

SUMMARY

It cannot be said with assurance whether silicone breast implants are associated with diseases of the immune system, or whether abnormalities in the immune system cause connective tissue disease.

The body's natural defense system is called the immune system. Normally, the immune system attacks only those things foreign to the body, including any kind of implant made of any kind of materials like metal, plastic, TEFLON,® silicone and so forth. There are several diseases that can occur when the immune system goes awry. This includes some types of connective tissue diseases. (Connective tissue in the human body binds tissues and organs together. Examples of connective tissues includes skin, bones and cartilage.) The number of cases of connective tissue disease reported in women with silicone breast implants is small and likely within the number expected by chance alone.

SCLERODERMA, RHEUMATOID ARTHRITIS, LUPUS

According to the Food and Drug Administration (FDA), to date, there is no convincing evidence that silicone breast implants can cause connective tissue diseases including:

- Scleroderma – a hardening and thickening of the skin often on the legs and arms
- Rheumatoid arthritis – swelling and inflammation of the tissue around the joints
- Lupus – also known as systemic lupus erythematosus, this rare disease is characterized by inflammation and damage to the connective tissues of the body that can occur in one or several sites like the skin, joints, muscles, blood vessels, and/or the membranes that surround the lungs and heart.

"HUMAN ADJUVANT DISEASE"

Some reports of suspected immune system responses to silicone breast implants have been called human adjuvant disease or HAD. The symptoms for HAD reportedly include inflammation and irritation at the implant site, fluid accumulation, rash, general tiredness, swelling of the joints, weight loss, fever, skin sores, joint pain and hair loss.

The Scleroderma Task Force, sponsored by the American Medical Association (AMA) has concluded that there is insufficient evidence that breast implants cause connective tissue disease and that there is no reason for surgeons to discourage women from considering breast implants or to suggest removal of implants in women who already have them. Both the FDA and the Scleroderma Task Force of the American Medical Association (AMA) have concluded and reported that there is no definite diagnosis for "Human Adjuvant Disease," that the term is non-descriptive, and that its use should be avoided.

However, if an immune system response is suspected and the response persists, it is recommended as a precaution that the silicone breast implant, and surrounding capsule tissue, be removed. The patient should not be reimplanted.

RESEARCH DATA RESULTS

The first cases of possible connective tissue disease were published in Japan in 1964. The study reported on two women who had developed arthritis-like symptoms such as sore joints following the injection of liquid paraffin into their breasts. Over the last 26 years, more than 100 cases have been published in the medical literature on women who have developed connective tissue disease. [1,2,3]

About two-thirds of these cases reported in medical journals concern women who received injections of paraffin or silicone directly into the breast. Only one-third of the women in the reported cases had silicone breast implant devices. Most of the implanted women were diagnosed as having either scleroderma or HAD. Some of the women are reported to have recovered after the breast implants were removed, while the condition of the others did not improve.

HOW COMMON IS CONNECTIVE TISSUE DISEASE?

Connective tissue diseases like scleroderma and lupus are quite rare. The Arthritis Foundation estimates that the number of new cases per year of scleroderma in this country is about 10 per million population. Scleroderma is two to four times more common in women than men and it increases with age. This suggests that there will be from 70 to 90 new cases of scleroderma this year.

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 or the risks associated with both.

The Scleroderma Foundation estimates there are 700,000 cases of connective tissue disease currently in the United States ranging from relatively non life-threatening diseases like Raynard's Syndrome (a circulatory system disorder that affects the fingers and causes them to become extremely sensitive to cold) to life-threatening scleroderma. The majority of these cases are in women.

The total number of scleroderma cases reported for women with breast implants in the last 26 years does not appear to exceed the number expected by chance alone. Caution is needed, however, because reliable statistics for all connective tissue diseases simply do not exist.

RESEARCH STUDIES SHOW CONFLICTING REPORTS

Some researchers believe that silicone materials can stimulate the immune system to react to the body's own tissue.[4] Their reasoning cites a tissue reaction to silicone known as "granuloma". A silicone-related granuloma occurs when minute quantities of silicone seep out of an implant. This is known as gel bleed.

The body's natural reaction to any foreign matter, be it a pacemaker or a small silicone particle, is to surround the material with white blood cells which in turn eventually form a scar-like tissue at the site. Some researchers believe that the presence of a granuloma means that there must be an immune reaction. However, noted immunologists (doctors who specialize in the body's immune system) disagree. These experts conclude that the local tissue reaction is just an inflammation unrelated to immune reactions.[5] Most of the animal studies reported so far are incomplete or inconclusive in one way or another. For example, the possibility of silicone causing allergies has been raised by one group of researchers, while other experts believe that there is no effect on the immune system based on their animal studies. [6,7,8]

CONCLUSION

According to the U.S. Food and Drug Administration, "... it is known that even in the absence of obvious leaks, minute quantities of the gel filling can migrate out of an intact breast implant over a long period of time. It has been suggested by some physicians that these tiny amounts of silicone in the body could lead some people to develop autoimmune diseases in later years, and some scientists have raised the question of whether the silicone could have an effect on a developing fetus. But at this point there is no convincing evidence that these effects actually occur."

Manufacturers have found no evidence that silicone gel or silicone rubber causes allergic reactions, and so far, there appear to be no effects on the immune system in terms of general stimulation or blocking of the immune system. More animal research is needed to determine if there is or is not a definite effect of silicone materials on the immune system.

FOR MORE INFORMATION

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.

SELECTED REFERENCES

The following references are available from your hospital or medical school library.

1. Weisman, MH, Vecchione, D, Albert, LT, and Moore, MR. Connective-tissue disease following breast augmentation: A preliminary test of the human adjuvant disease hypothesis. Plastic and Reconstructive Surgery. 1988. Volume 82, page 626.
2. Weiner, SR, Suzuki, SM, Clemens, PJ, and Paulus, HE. Scleroderma (PSS) after augmentation mammaplasty (AM). Arthritis and Rheumatism. 1989. Volume 32, No. 4 (Supplement), page S 79.
3. Martinez-Osuna, P, Espinoza, LR, Gresh, JP, Seleznick, M, Germain, B, and Vasey, FB. Arthritis & Rheumatism. 1990. Volume 33, No. 9 (Supplement), page S 156.
4. Heggers, JP, Kossovsky, N, Parsons, RW, Robson, MC, Pelley, RP, and Raines, TJ. Biocompatibility of silicone implants. Annals of Plastic Surgery. 1983. Volume 11, page 38.
5. Boros, X. Allergy, 3rd edition. Principles and Practice by Middleton, Reed, Ellis, Atkinson and Youner. Published by Mosby, St. Louis. 1988, page 275.
6. Smith, Jr, D, Sazy, J, Crissman, J, Niu, X-T, Robson, M, and Heggers, J. Immunogenic potential of carpal implants. Journal of Surgical Research. 1990. Volume 48, page 13.
7. Brantley, SK, Davidson, SF, St. Arnold, PA, Johnson, MB, Talbot, PJ, Grogan, JB, Cuchens, MA, Hsu, HS, and Das, SK. Assessment of the lymphocyte response to silicone. Plastic and Reconstructive Surgery. 1990. Volume 86, page 1131.
8. Brantley, SK, Davidson, S, Johnson, M, St. Arnold, P, and Das, K. The effects of prior exposure to silicone on capsule formation, histology, and pressure. Annals of Plastic Surgery. 1990. Volume 25, page 44.

Silicone Breast Implants: Benefits And Complications

SUMMARY

Thousands of women each year have silicone breast implant cosmetic or reconstructive surgery with few or no complications.

A recent survey conducted by the American Society of Plastic and Reconstructive Surgeons (ASPRS) found that 92 percent of American women who have breast implants report that they are satisfied with the results of their implant surgery. Among the women surveyed, 35 percent say they sought the procedure for reconstruction after cancer or other diseases.

That is not to say that silicone breast implant surgery is without risks. According to the Food and Drug Administration (FDA), "...All implanted devices, from artificial hip joints to heart valves, will fail to work or will have adverse effects in a small proportion of patients — no type of device placed in the body for a long period of time can be considered perfect, and no surgical procedure is without risk."

Silicone breast implants may cause complications or adverse reactions. Patients differ in tolerance to surgery, medication and implantation of a foreign object. Possible risks, adverse reactions and complications associated with surgery and breast implants should be discussed with the surgeon and understood by the woman prior to surgery.

BENEFITS

The benefits to silicone breast implants are many and varied including:

- Symmetrical form and contour to the breast
- Enlargement and balance in breast size
- Correcting drooping breasts (ptosis)
- Reconstruction following mastectomy
- Psychological benefits like improved self-image and self-esteem.[1,2]

SATISFACTION SURVEY

Recently, the American Society of Plastic and Reconstructive Surgeons (ASPRS) surveyed 592 women about their level of satisfaction with results of their breast augmentation or breast reconstruction.[3] The results show that women generally are satisfied with their breast implant surgery. According to the ASPRS:

- Sixty-five percent of the women had breast augmentation and 35 percent had breast reconstruction
- Nine women in 10 were satisfied with the results of their surgery. If given the opportunity to decide again, 82% of these women would still choose breast implants
- About 10 percent of the women who had breast augmentation have at some time considered having the implants removed
- Nearly 25 percent of the women who had breast reconstruction following mastectomy have considered implant removal

Regarding Breast firmness:

- Fifty-six percent of the women who had breast augmentation thought their breasts were soft and natural
- Twenty-nine percent said their breasts were slightly firm
- Ten percent felt their breasts were moderately hard
- Five percent said their breasts were hard and probably require additional treatment from a physician

The results for women with breast reconstruction were similar but 20 percent had moderately firm breasts and six percent had hard breasts.

The level of satisfaction for women following mastectomy is understandable because the natural breast cannot be duplicated and there is often extensive scarring after undergoing the very trying experience of having a breast removed.

COMPLICATIONS

A woman seeking advice about breast implants should not be led to unrealistic expectations as to the performance or cosmetic results of the implant surgery. She also should be informed that the life expectancy of a given implant is unpredictable and that the patient's satisfaction cannot be guaranteed.

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 or the risks associated with both.

Some adverse reactions and complications that can occur with silicone breast implants are listed below:

Potential Complications

- Infection is a risk in any surgery
- Swelling of tissue because of bleeding, known as hematoma, is another risk common to any type of surgery
- Poor wound healing can be due to infection, fluid accumulation, hematoma, the stitches being too tight, too large an implant, diabetes, improper support and/or pressure against the healing scar tissue (i.e., improperly fitted underwire bra).
- A breakdown of the skin, known as necrosis, may be due to the thinness of the skin flap over the implant or skin trauma during surgery. If unresolved, this situation may mean the implant must be removed.
- Incorrect implant size, inappropriate location of scars, or misplacement of implants can be caused by improper measurements of the patient's body frame.
- Wrinkling of the implant is sometimes visible through the overlying skin, particularly when the implant is inappropriately sized relative to the pocket or frame of the patient, when a fibrous capsule contracts, or, in the case of the salt water-filled implant, where not enough salt water is injected into the implant at the time of surgery.
- Drooping of the breasts (ptotic breasts) can occur over time just as with breasts not implanted.

CAPSULE FORMATION AND CONTRACTURE

The body reacts to the implantation of any foreign material like pacemakers, heart valves, hip joints, etc., by forming scar tissue or hard fibrous tissue around the device. With breast implants, this is called "capsule formation" and it occurs in all patients to varying degrees of thickness.

This fibrous capsule may contract around the breast implant and, in some cases, result in discomfort, pain, extreme sensitivity to touch, excessive firmness, wrinkling of the implant and movement or displacement of the implant. The presence and degree of contracture also may affect the ability of physicians to read mammograms.

There is no known specific cause of capsular contracture. It is believed, however, that many factors can contribute to it, including infection, hematoma, lack of drainage around the site of the incisions, improper implant size, and the body's reaction to the implant.

There are two ways to treat capsular contracture. In a technique known as "closed capsulotomy," the surgeon squeezes the hardened tissue by hand in order to break it. Implant manufacturers do not recommend this procedure because this abnormal stress can result in bleeding and can rupture the implant. In "open capsulotomy," the doctor surgically breaks up the scar tissue. Even if capsular contracture is relieved, it can recur.

IMPLANT RUPTURES

Implants have ruptured both during and after surgery for a variety of reasons including:

- Damage to the implant before or during the initial implant surgery
- Injury
- Excessive stress or particularly vigorous exercise
- Trauma such as a car accident
- As a result of the capsulotomy
- Because of insertion of a biopsy needle

In the event of rupture, implant manufacturers recommend that the implant be removed promptly.

NIPPLE AND BREAST SENSATION

Change in nipple and breast sensation is unpredictable. There can be heightened, decreased or even loss of sensation in the nipple or the breast. Subsequent return of sensation varies among patients. While most patients recover feeling, in a few instances it has taken as long as several years for sensation to return, and there are also reports of permanent loss.[4]

IMPLANT GEL BLEEDING

Gel bleed is the passage of minute amounts of silicone through the outside shell of the implant. The body's normal response to foreign matter is to form a scar around it. These small areas of tissue reaction have been detected in the tissue adjacent to the implant and in the lymph nodes under the arms. This reaction is not cancerous nor cancer causing.

There is now no convincing evidence that gel bleed causes harm to the body. According to the FDA, "...it is known that even in the absence of obvious leaks, minute quantities of the gel filling can migrate out of an intact breast implant over a long period of time and can travel throughout the body. It is not known whether this can be harmful over the long run or not. It has been suggested that these tiny amounts of silicone in the body could lead some people to develop autoimmune diseases in later years, and some scientists have raised the question of whether the silicone could have an effect on a developing fetus. But at this point there is no convincing evidence that these effects actually occur."[5]

CALCIFICATION

Physicians have reported calcification, a hardening due to calcium deposits, of the tissue surrounding the implant. In some instances, heavy calcification resulting in discomfort and breast firmness may require removal of the implant and calcified tissue.

CONNECTIVE TISSUE DISEASE/HUMAN ADJUVANT DISEASE

To date, there is no convincing evidence that silicone breast implants can cause connective tissue diseases like scleroderma (a hardening and thickening of the skin), or rheumatoid arthritis (the swelling and inflammation of the tissue around the joints), or systemic lupus erythematosus (an inflammation and damage to the connective tissues of the body that can occur in one or several sites like the skin, joints, muscles, blood vessels, or the membranes that surround the lungs and heart).

In addition, there have been some reports of suspected immune system responses to silicone breast implants that have been called human adjuvant disease or HAD. The symptoms for HAD reportedly include inflammation and irritation at the implant site, fluid accumulation, rash, general tiredness, swelling of the joints, weight loss, fever, skin sores, joint pain and hair loss. The Scleroderma Task Force, sponsored by the American Medical Association (AMA), has concluded that there is insufficient evidence that breast implants cause connective tissue disease and that there is no reason for surgeons to discourage women from considering breast implants or to suggest removal of implants in women who already have them.

CONCLUSION

The body normally reacts in varying degrees to any implanted object, whether it is a heart valve, pacemaker or a breast implant. One of the most common complications in breast implant surgery is contracture, with some surgeons reporting very little or no incidence while others report some degree of contracture in many patients. Still others report that the number of patients with contracture has declined over time although just why this has happened is not clear.[5]

It is recommended that women seek out Board Certified Plastic and Reconstructive Surgeons who are experienced in implant surgery and are familiar with the currently acceptable techniques for measuring the patient along with determining implant size.

FOR MORE INFORMATION

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.

SELECTED REFERENCES

The following references are available from your hospital or medical school library.

1. Johnson, CH, et al. Oncological aspects of immediate breast reconstruction following mastectomy for malignancy. Archives of Surgery 1989, Volume 124, page 819.
2. Hetter, GP. Satisfactions and dissatisfactions of patients with augmentation mammaplasty. Plastic and Reconstructive Surgery 1979, Volume 64, page 151.
3. Patient Satisfaction Survey, American Society of Plastic and Reconstructive Surgeons, Inc. 1990. Not yet published.
4. Courtiss, EH, Goldwyn, RM. Breast sensation before and after plastic surgery 1976. Volume 58, Pages 1-13.
5. Biggs, TM, Yarish, RS. Augmentation mammaplasty: a comparative analysis. Plastic and Reconstructive Surgery 1990, Volume 85, page 368.

Package Inserts

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

SILASTIC® MSI Brand

Mammary Implant H.P.

Gel-Filled Design By Dow Corning Wright

Nos. 4,455,691; 4,472,226; 4,965,430 and Others Pending

Description

The SILASTIC® MSI Mammary Implant H.P. is a silicone gel-filled breast implant made with a micro structured silicone envelope. The silicone envelope consists of medical grade high performance (H.P.) silicone elastomer with an integral surface micro structure and a fluorosilicone barrier laminated to the inner surface of the envelope. 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 envelope provides an effective barrier to significantly reduce gel bleed. The envelope is filled with 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, the unit volume in cc's, implant style, and company name 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.

Unilateral or bilateral mammary augmentation or reconstruction 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 with 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 a 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 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 Mammary Implant H.P. is not recommended. Microwave diathermy, under normal conditions, does not appear to alter gel-filled implants. However, 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 with any sharp or pointed objects such as needles or surgical instruments. Any cut, puncture, scratch, or other compromise of the envelope integrity, whether inadvertent or intentional, will expose the silicone gel and will render the implant unusable. If the implant should accidently rupture during insertion or be nicked with an instrument or suture needle, 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 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 during insertion as it may result in a local bulge in the implant shell.

3. Do not introduce or make injections of drugs or other materials into the implant. Injections through the implant shell 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 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 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, 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 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) Fibrous capsule contracture is present.

"Wrinkles" 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.

3. ***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.

1. ***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, 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, 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 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 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.

Implant Rupture/Gel Extravasation

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 or during surgery, or other unknown causes at the site of implantation, including so-called spontaneous rupture. Excessive manipulation of the implant shell 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 due to weakening of the envelope from the forces the implant may experience. The patient should be adequately informed of the possibility of implant rupture with the use of this technique, and of the necessity to remove a ruptured 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 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 envelope 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 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 shell 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 Implant H.P. 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 responses 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 the 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 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 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 and cleanliness. A back-up implant should be available in the event of implant damage/rupture or contamination. 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.

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

Two patient labels to record pertinent data, e.g. catalog number, product 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 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.

   e. 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 Mammary Implant H.P. If the implant is contaminated, it should be cleaned and resterilized per the instructions in Section F before it is used. Handling of the sterile implant should be minimized.

   g. Voids may occasionally be observed within the gel of SILASTIC® MSI 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 F.

F. **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. (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 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. Wrap the unit in a suitable lint-free wrapping material for autoclave use and place in a clean open autoclave tray.

   b. Standard Gravity Sterilizer—**STERILIZE THIRTY (30) MINUTES AT 250°F, 15psi (121°C, 1 kg/cm^2 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.

   c. High Speed Instrument (flash) Sterlizer—**STERILIZE FIFTEEN (15) MINUTES AT 270°F, 30psi (132°C, 2 kg/cm^2 or 2.07 Bar).**

   d. **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.**

   e. Avoid repeated sterilizations.

   f. 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.

106928
Rev. 3
6/91
2124017-0691

12