

**DOW CORNING BREAST IMPLANT
REMOVAL ASSISTANCE PROGRAM**

AUG 6 1993

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

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

A. The Program

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

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

B. Product

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

C. Conditions

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

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

2. Product must have been implanted and removed by appropriately qualified, licensed surgeons in accordance with accepted plastic surgical procedures.
3. Patient certifies she is unable to pay for the removal surgery without the financial assistance provided under this program.
4. Completion and return of the Patient Certification Form and the Informed Consent Form prior to removal surgery.
5. Post-operative verification by the physician that Dow Corning manufactured the removed breast implant device(s).

D. Expenses

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

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

To Apply for Assistance

1. The physician or patient should contact a Dow Corning representative by phoning 1-800-442-5442 or writing to Dow Corning Corporation, P. O. Box 994, Mail#95, Midland, MI 48686.
2. The Dow Corning representative will explain the program and send
 - a. a program brochure.
 - b. a certification to be signed by the patient and her physician confirming that
 - (1) she understands and agrees to accept the risks associated with removal surgery.
 - (2) she is unable to pay for the removal surgery without the financial assistance provided under this program.
 - (3) her gel filled breast implant device(s) were manufactured by Dow Corning.
 - c. an Informed Consent Form to be reviewed and signed by the patient.
3. The patient and physician should complete the Patient Certification Form and the patient should complete the Informed Consent Form. The physician should return the completed forms to Dow Corning in the self-addressed, stamped envelope provided, prior to removal surgery.
4. Dow Corning will issue a check, made payable jointly to the patient and the physician, upon receipt of:
 - a. a written post-operative statement from the physician verifying Dow Corning as the manufacturer of the removed breast implant device(s).
 - b. the physician's statement of medical expenses directly related to the removal surgery that is not covered by insurance.