

First Paragraphs

Para9.1 (Enclosed Packet I Hope Is Helpful)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants. I have enclosed a packet of information which I hope you will find helpful.

Para7.1 (Thank You)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants.

Para52.1 (Thank You For Concerns And Good Wishes)

Thank you for writing the Implant Information Center with your concerns and good wishes.

Para31.1 (Letter Was Forwarded to Me, Sending Packet)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants. Your letter was forwarded to the Implant Information Center for reply. I am enclosing a packet of information which I hope you will find helpful.

Para59.1 (Tried Several Times But Could Not Reach You)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants. I tried unsuccessfully to contact you in response to the message you left on our answering machine, but have been unable to reach you. I have enclosed a packet of information which I hope you will find helpful.

Para11.1 (Letter Forwarded, Address Concerns)

Your letter has been forwarded to my attention and I would like to address the concerns you shared with us.

Para1.1 (Product ID and Package Insert W/Catalog Number Only)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants. Our records indicate that catalog number 590, which you provided, is a SILASTIC® Mammmary Implant, Low Profile Round Design (sterile), 200cc fill; No Fixation Patches. I have enclosed a Patient Information Packet which I hope you will find helpful. I have also enclosed a photocopy of the actual Package Insert which would have been provided to the physician with the implant. You may want to discuss information contained in the insert with your physician.

Para57.1 (Catalog & Lot Number, Name Of Implant)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants. I am writing to you in response to your request for information regarding catalog number P01480, lot number HH23503 280cc Mammmary Implant. The numbers which you have given indicate this implant is a SILASTIC® II Mammmary Implant H.P. Low Profile Round.

Para40.1 (Thank You For Writing, Position Statment, Packet)

Thank you for writing to the Dow Corning Corporation's Implant Information Center. I am enclosing a Dow Corning Patient Information Packet which I hope you will find helpful. I am also enclosing a summary statement on the "Study of Adjuvant Effect of Silicone Gel" that may help address your questions regarding autoimmune diseases.

Para14.1 (Testicular Implant)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled testicular implants. Although you were unable to provide a catalog or lot number, I have enclosed a photocopy of an actual package insert that would have been provided to the physician with the SILASTIC® Gel-Filled Testicular Implant II (Lattimer Design). Since the silicone gel-filled breast implant information packet includes similar product benefits and complications that would apply to testicular implants, I have also included that packet.

Para20.1 (Regards To Letter you Sent To Keith McKennon)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants. I am writing in response to your letter dated March 19, 1993, that you sent to Keith McKennon.

Para26.1 (Receive Your Letter, Safety Of Dow Corning Testiculars)

I received your letter asking for information suitable for sharing with patients with regard to the safety of Dow Corning's Gel-Filled Testicular Implant.

Para45.1 (Waiting For Your Particular Package Insert, Enclosed Is The Most Recent Package Insert)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone gel-filled breast implants. The literature we discussed is enclosed. I am waiting to receive copies of the package inserts on the particular implants identified by you. I will send those to you as soon as I receive them. Presently, I have enclosed a copy of the most recent package insert for the SILASTIC® II Gel Mammary Implants.

Para63.1 (SILASTIC® Temporomandibular Joint Implant, and SILASTIC® Block Inserts)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone products. I have enclosed a copy of a package inserts for the SILASTIC® Temporomandibular Joint Implant H.P., Wilkes Design.

Para68 (NEW) (LETTER TO DOCTORS INCLUDING STUDY OF ADJUVANT & BIBLIOGRAPHY ON BREAST IMPLANTS)

Thank you for allowing us the opportunity to provide you with information about Dow Corning Corporation and silicone breast implants. I have enclosed a packet of information which I hope you will find helpful. I have also included the following documents: "Study of Adjuvant Effect of Silicone Gel", "Adjuvancy and Breast Implants", & "Selected Bibliography on Breast Implants and Autoimmune Disease," including copies of the articles referenced in the selected Bibliography.

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MIDDLE PARAGRAPHS

Para5.1 (Catalog & Lot Number, Identify as Special Construction)

Our records for the catalog number 582, lot number HM081293, 145cc that you provided indicate this is a special construction gel-filled Mammary, round design with a fixation patch. I have enclosed a packet of information which I hope you will find helpful.

Para8.1 (Animal)

As an ethical and responsible company, Dow Corning conducts a broad range of laboratory tests to determine the safety of its products. Dow Corning uses test methodologies in accordance with standards of health and regulatory agencies worldwide. When laboratory animals must be used, they are cared for by professionals and handled with dignity. To insure animal testing is necessary and reasonable, Dow Corning has an Animal Care and Use Committee that reviews the well being of our laboratory animals and the test in which they are used.

Dow Corning actively participates globally in several industry organizations that obtain and share data, thereby greatly reducing the number of animal studies performed by individual companies. We also actively seek and use those test methods that are acceptable alternatives to live animal tests. Dow Corning's commitment to animal welfare minimizes the number of animals used.

As a person who is also very interested in animal welfare, I hope I have addressed your concerns.

Para48.1 (MSI Composition -vs- Foam Implant And Removal)

The SILASTIC® MSI Implant H.P. is a registered trademark of Dow Corning Corporation. MSI stands for micro-structured implant. The MSI consists of thousands of very small columnar-shaped pillars which are made as an integral part of the shell. The pillars are not pasted or glued on, but are made as a part of and at the same time as the shell. The micro-structured surface of the MSI implant is designed to alter the structure of the scar tissue so that contracture may be less frequent. The micro-structured surface does not interfere with removal of the implant.

Polyurethane implants were never manufactured or distributed by Dow Corning Wright or Dow Corning Corporation.

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Para12.1 (Question On Doctor, Is He Plastic Surgeon, 800 Numbers)

Just as you seek a specialist in other fields of medicine, a plastic surgeon is a specialist when it comes to breast implants. I would urge you to contact a plastic surgeon of your choice. On the enclosed list you will find a telephone number for the American Society of Plastic and Reconstructive Surgeons (ASPRS) and the American Academy of Cosmetic Surgeons (AACS). Either source will send you a list of plastic surgeons located near you. If you are concerned about the problems described in you letter, please do not delay in seeking medical attention.

Para13.1 (Question On Manufacturer, How To Find Lot and Catalog Number)

Although you do not know who manufactured your implants, I have enclosed a packet of information on silicone gel-filled breast implants in general and Dow Corning Corporation's products specifically. I would encourage you to contact the doctor who performed this surgery or the facility in which it was performed to get this information. If you do indeed have a Dow Corning Corporation's implant, you may be able to obtain a catalog and lot number from your implanting physician which will identify your specific implant. Should you discover that you have another manufacturer's implant, I have enclosed a listing of other manufacturers' telephone numbers.

Para36.1 (Sending Packet, 800 Numbers To Someone With Other Manufacturers Implants)

I have enclosed a packet of information on silicone gel-filled implants generally and on Dow Corning Corporation's implants specifically. In the packet you will find a list of other manufacturers' telephone numbers. I would suggest that you call the 800 number to obtain information from the manufacturer of your implants.

Para16.1 (Silicone In The Brainstem)

I referred your questions regarding silicone in the brainstem to our Technical Director. He reported that there have not been reports of finding silicone in the brainstem and that no research done by Dow Corning or others has found an association between silicone gel-filled breast implants and seizure states.

Para22.1 (When Production Began On Testiculars, Statistics of Rupture)

The post-operative complaints received by Dow Corning Corporation from 1979 - March, 1992, Generally indicate problems occur at a rate of less than 1 in 5000 .

Para42.1 (Testicular Implants)

Enclosed please find an information packet on silicone gel-filled implants and Dow Corning Corporation's implants specifically. Some of the information in this packet, including benefits and complications, will also apply to testicular implants. I have also included a package insert for Dow Corning Corporation's SILASTIC® Brand Gel-Filled Testicular Implants II (Lattimer Design). This information is specific to our testicular implants.

Para33.1 (Biosafety Studies-Testicular)

Dow Corning Corporation has completed many biosafety studies on the materials that are used in the manufacture of our silicone gel-filled implants. These biosafety studies are applicable and appropriate for testicular implants. I am enclosing the order form for use in obtaining the biological and safety data.

Para37.1 (No Convincing Scientific Evidence, Ten Million Research, Both Sides)

To date, there is no convincing scientific evidence that silicone gel-filled breast implants cause connective tissue disease such as rheumatoid arthritis. However, the FDA states there is insufficient evidence to rule out the possibility that these complications could occur and that more studies should be done. Dow Corning committed publicly on March 19, 1992 to contribute at least ten million dollars for continued research and studies to add to the knowledge base about silicone gel-filled breast implants. Our most recent estimate indicates that Dow Corning will actually spend closer to fifteen to twenty million dollars on this research.

Para47.1 (Reinforcement Of No Convincing Evidence)

I would like to reinforce the fact that, to date, there is no convincing evidence that silicone gel-filled breast implants can cause connective tissue diseases, such as scleroderma. In fact, the American Medical Association's Scleroderma Task Force reports that there is insufficient evidence that breast implants cause connective tissue diseases. Published studies confirm that connective tissue diseases appear to be no more common in women with breast implants than in the general population.

Para27.1 (Competitors)

I am unable to provide answers to the specific questions you raised about your Surgitek implants. I have, however, enclosed a packet of information regarding silicone gel-filled implants and Dow Corning products specifically. A list of other manufacturers' telephone numbers is contained in the information provided.

Para 28.1 (Quote From Package Insert About Immunological Response)

Dow Corning Corporation states in its package insert that if an immunological response is suspected and the response persists, removal of the implant device is recommended along with removal of the surrounding capsule tissue. The package insert also states that such patients should not be re-implanted.

Para29.1 (Request For Studies)

In response to your request for information on research studies, I have enclosed an order form to obtain biological and safety data. There is a charge of .05 per page to cover copying and you may order those segments pertaining to your area of interest. Checks should be made payable to Dow Corning Corporation and forwarded to the address contained on the order form.

Para65 (Info. Being Sent Under Separate Cover)

We are in receipt of your order form and check for the biological and safety data. The information you ordered is being mailed under separate cover.

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Para66 (Summary of Scientific Studies and Internal Company Documents)

As promised in our telephone conversation of ~, 1993, I am sending a copy of the "Summary of Scientific Studies and Internal Company Documents Concerning Silicone Breast Implants", that was released to the general public on February 10, 1992.

Para67 (Summary of Breast Milk Analysis)

In response to your letter/telephone conversation of December 14, 1993, I am enclosing a copy of the "Summary of Breast Milk Analysis."

Para46.1 (Highlighted Capsular Contracture And Rupture)

Thank you for your recent inquiry concerning capsular contracture and rupture. I have enclosed a package of information on silicone gel-filled implants in general and Dow Corning Corporation Implants specifically. I have highlighted the passages in our patient information packet that discuss these items of interest.

Para43 (Rupture)

If you suspect that you have a ruptured implant, Dow Corning recommends that you consult your physician. If the rupture is confirmed, prompt surgery is recommended to remove the implant.

Para34.1 (Question On Special Implant Not Ours "Vogue")

I am enclosing a packet of information which I hope you will find helpful. Please note that this packet deals with silicone gel-filled breast implants in general and Dow Corning Corporation products specifically. In your letter you state that during your second surgery you received a sponge covered implant. I would encourage you to contact the doctor who performed your surgery or the facility in which it was performed to determine the manufacturer of your implants.

Para39.1 (Package Insert, Certain Time Frame)

Although you were unable to identify the catalog and lot number of your implants, in accordance with your request, I've enclosed a photocopy of our package insert on SILASTIC® Mammmary Prosthesis that was provided to physicians with products during the 1969 time period.

Para41.1 (Whirlpools and Saunas)

To date, we have received no reports that using whirlpools or saunas have caused a detrimental effect on silicone gel-filled breast implants.

Para 44.1 (Leakage on SWANSON Foot Implant, Flexible Hinge Toe Implant)

In accordance with our telephone conversation on November 15th, 1993, I want to confirm that SILASTIC® SWANSON Foot Implants are not silicone gel-filled and thus, silicone gel bleed does not occur with this device. Relative to your request for information, enclosed please find a package insert for a SWANSON Design Foot Implant and a data sheet from our SILASTIC® H.P. 100 SWANSON Flexible Hinge Toe Implant.

Para49.1 (Mammography)

To help address your concerns, you should ask the facility that will be doing your mammogram if the technicians are trained to work with implant patients and if they have advanced diagnostic equipment. Also, you may want to call the breast Radiological Society of North America to see if the facility is accredited. Their number is (708) 571-2670.

Para60.1 (Trust in Product, Reasons For Exiting Market)

Please allow this letter to respond to your question of why Dow Corning has chosen to cease the production of silicone gel-filled breast implants. Our reasons for not resuming production and sales are based on market conditions and are not related to issues of science or safety. Dow Corning remains satisfied that our implants produced over the years have filled an important need for thousands of women and do not represent an unreasonable risk.

Para64.1 (Weight Of Implant In Grams)

Please allow this letter to respond to your inquiry on how to convert the volume of a 200cc implant into its weight in grams. Generally, $1 \text{ cc} = 0.97 \text{ grams}$, thus the weight of the implant would approximate 194 grams (0.97×200). You should, however, be aware that the above volume weight is based on an approximate and not exact volume.

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