EXHIBIT 4

KD177024

MEMO

April 14, 1980

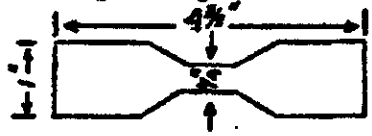
TO: FIELD FORCE

FROM: W. LYNCH, W. STITH

SUBJECT: Physical Property Testing on the Shells of Mammary Implants

As most of you know Dow Corning has come out with a new shell material for their inflatable implants which has twice the tear resistance of their former material. As far as we know this material is only being used on their inflatable mammary implants. Your physician customers may ask you why they shouldn't buy Dow implants because of this seemingly significant new feature. You should point out that when comparing different types and brands of implants, the tear strength of the shell is not a very important consideration. If your customer is comparing the properties of different inflatable, gel filled, gel/saline, and bilumen implants, there are other properties of the shell which are more important than tear strength. Explaining this to your customers necessitates knowledge on your part of the basic physical properties of the mammary implant shell and which properties are the most important. The physical properties we are talking about are: tensile strength, maximum elongation, and tear strength, plus the relationship of these factors to the shell thickness.

The tensile strength of a material is measured by cutting a standard dumbell shape sample from the material.



The sample is placed between the jaws of a tensile testing instrument, which pulls the sample until it breaks.

The force at break is recorded by the instrument. Naturally, if one sample is thicker than another the thicker sample will withstand a proportionately greater force before it breaks.

In order to make an accurate comparison between samples of different thickness the cross sectional area of each sample, before testing, is calculated. The force at break divided by the area will then give the force per unit area, most often expressed in the U.S. as lbs/in.^{2}, in Europe as kg/cm^2 or in International Metric Units as Pascals (Pa)*.

The ultimate or maximum elongation is a measure of how much the tensile test sample stretched before breaking. It is expressed as a percent increase over the original length.

Tear strength represents the force required to tear a sample in half after the sample has been nicked to a standard depth. Tear strength is calculated in pounds per inch of sample thickness.

From this discussion you should start to see that tensile strength and elongation are the most important properties. During the implantation procedure an intact implant is subjected to tremendous forces to push it through a very narrow opening into the implantation cavity. The smaller the incision and the bigger the implant, the greater the forces that will be placed on the implant. You can see why some physicians may have a much higher breakage rate than other physicians just due to the size of the implant and the size of the insertion opening. High elongation as well as ultimate tensile strength come into play here. Tear strength only comes into play when the implant shell has already been nicked or cut, which should not happen if a correct surgical procedure is being followed.

Regrettably one of the characteristics of silicone rubber is that it has a very low tear strength. Even if Dow Corning has made a shell with twice the tear strength of what they presently have, the new value will still be low compared to other materials, such as Saran Wrap. During the implantation procedure, the forces that the implant are subjected to will almost certainly result in the implant tearing once it has been nicked, even if the shell is made from the higher tear strength material. So, even if the tear strength for the D/C material is twice that of another shell, both implants still have such a relatively low tear value that the difference between the values is meaningless.

Recently we performed a study comparing the gel filled mammary implants manufactured by us and Dow Corning. This study substantiated the fact that both MEC and Dow Corning are using the same shell material for the gel filled implants.

---

* Used almost exclusively now in scientific publications.

The study consisted removing the gel from one D/C and one MEC gel implant and then performing physical property testing on the implant shells. Based on a sample size of one we did not find any significant difference between the Silastic and the Surgitek mammary implant as far as the physical properties of the shell were concerned. The results we found with the Surgitek implant were consistant with the results that we have found with previous MEC units. The results of this comparison between D/C and MEC shells were not surprising to us since, as you probably know, we purchase our mammary implant materials from Dow Corning.

I have attached a copy of our report which shows the results obtained. Feel free to use the information in this report in your sales presentations. You may also show the report to your surgeons, but do not leave them a copy of it.

W. Lynch - Consultant
W.J. Stith, Ph.D. - Vice President Scientific Affairs

EXHIBIT 5

M--000570119

CORNING

ıry 26, 1971

F. Stark

J. Boone - #113
W. Mantle - #113
G. McIntyre
G. Robertson - #113

PRODUCED BY DCC & DCW

)M: W. Koning

BJECT: Returned Mammary - Dr. Bankof

:tached is a note from Jan Varner pertaining to this "old" :yle mammary which apparently was removed following treat- ent of the patient for an infection around the implant.

.fter examining the returned implant, Jan Varner felt that ıe was able to break through the envelope with minimal effort ınd perhaps there is some degradation of the envelope over a period of time.

I believe that Jan's sketch is not accurate,as I am unable to find the location where he broke through the envelope with his finger nail. This was probably done at the extension of the original tear. Jan appears to be loosing confidence in the stability of the envelopes physical properties over an extended period of time because of frequent comments that are being given recently by large volumes users that he calls on.

Therefore, it is important that we check out the physicals on this particular implant and report back to Jan and the customer in order to varify our product claims.

The terms, friable, disintegration and degradation are being used frequently in some areas to describe the condition of the envelope of removed SILASTIC® Mammary Prostheses.

M-570119

WJK/kfb

EXHIBIT 6

F000534

PRODUCED BY DCC AND DCW

January 15, 1976

TO: Ron Kelley
Art Rathjen

cc: Chuck Lentz — Dick Criger
Chuck Leach — Pat Meads
Bob Becker — Mel Nelson
Al Bey — John Hoyt
Bruce Ringey — Rich Steele
Jack Boone

FROM: Tom Talcott

SUBJECT: Comment on Mammary Prosthesis Quality and Request for More Information on the Scottsdale Breast Symposium

The general tone of Art's report on the Phoenix Breast Symposium was one of disappointment that we are not #1 in the market place. Disappointment that two of our units broke during augmentation surgery for the TV tape demonstrations.

During our task force assignment to get the new products to market, a large number of people spent a lot of time discussing envelope quality. We ended up saying the envelopes were "good enough" while looking at gross thin spots and flaws in the form of significant bubbles. The allowable flaws are written into our current specifications.

When will we learn at Dow Corning that making a product "just good enough" almost always leads to products that are "not quite good enough"?

Plant engineering or other effort to make uniform and flaw free envelopes would still be useful. It is unfortunate that the thinner dispersion, four dip method proved by Bartolo and Vallender in early 1974 appeared too expensive to plant personnel to even try, although a much higher acceptance rate would be obtained. I sincerly hope this experience will convince us to support programs for "high quality" rather than "just enough quality" in the future.

Art, I would also hope you can find time in your busy schedule to discuss more fully the details of the papers as they relate to theories of contracture. What was behind Frank Gerow's special call to me calling for a bleed-free, contaminant-free prosthesis now?

Tom

EXHIBIT 7

DOW CORNING

June 14, 1976

TO: WHOM IT MAY CONCERN

FROM: Gary Corbeill

MAMMARY ENVELOPE PRODUCING PROBLEMS TO DATE - 1976

We have encountered many problems in the production of mammary envelopes the first half of 1976. This memo is an attempt to summarize and put into chronological order these problems, what is being done to solve them, and the magnitude of them.

The machines used to produce mammary envelopes are designated the blue dipper and the green dipper. It should be understood that the green dipping machine is the newer of the two and has been modified to allow more control flexibility in dipping envelopes. A one-dip process is used exclusively on the green machine which, at this time, is restricted to solid mandrels due to an air leakage problem of the hollow mandrel. It should be realized that most of the round mandrels, low profile round and low profile contour mandrels are hollow which severely restricts the versatility of dipping all sizes on the green machine. The problems that I will be reviewing are to be considered exclusively problems on the blue machine. Although many problems were encountered on the green machine, these are deemed to be primarily start-up and troubleshooting rather than definite production problems. For all intents and purposes, the feasibility of dipping hollow mandrels on the green machine, reliably, is two to three months away.

Following is a list of the problems encountered, in chronological order, on the blue dipping machine:

1. February 27, 1976 - Air bubbles in the envelope were breaking, causing a high level of reject filled units. No reasons for the sudden change was found. Production changed their screening technique so that for all practical purposes, envelopes containing any air bubbles were rejected. The problem was alleviated by varying the plunge speeds on

DOW CORNING

1. (continued)

the machine. Concurrent with this problem was a brown spot on the envelope that was believed to be caused by chlorothene drying spots during the wash cycle. To solve this problem, the mandrels were dried in an inverted position so that when the pallets of mandrels were in the upright position, the spot was on the top of the mandrel and easily removed through wiping. The brown spot problem has not returned.

2. April 27, 1976 - The "rotten" envelope syndrome was encountered. These "rotten" spots were primarily in run areas, which is very unusual. Also, weak areas were encountered in the envelope itself. In areas of high stress, the envelope took on a wavy appearance when relaxed. Many theories were suggested such as:

(a) inhibition of the dispersion cure due to zinc stearate;

(b) inhibition of the dispersion cure due to envaporized chlorothene;

(c) "bad dispersion";

(d) room temperature and humidity conditions.

Although all theories were investigated, to some extent, none were proven conclusively to be the culprit. The problem apparently "went away" for the time being. During this period of time, the location marks on the contour mandrels were filled in to help the air bubble problem which occurred in February. At this time, a sample program was initiated which consisted of a representative sample of placed envelopes that were then filled and given to Q.C. for their inspection. If their reject level ran very high, the envelopes were scrapped and no attempt was made to fill them on a large level. This was an unusual problem in that the unfilled envelope appeared to be reliable; only after the unit was filled was this "rotten" spot apparent.

3. May 10, 1976 - A bulge problem appeared. This problem is unlike the rotten spot in that the envelopes return to shape in the bulge area. The bulge varies in size protrusion and strength, which makes it very difficult to Q.C. Again, an unfilled envelope does not exhibit this phenomenon; only when it's filled can the bulges be found. These were originally thought to be acceptable but in reality were rejected by Q.C. The sample program continued to show 100%

DOW CORNING

3. (continued)

reject units off the blue dipper. Approximate loss during this period for this problem is 20,000 placed envelopes.

4. June 7, 1976 - We began dipping with a five-dip thin dispersion process, as opposed to a three-dip thick dispersion process, and certain sizes of envelopes that we could not previously dip appear to be acceptable. The data for reject level in Q.C. is very sketchy at this time. Unfortunately, some of the critical sizes are being produced at a very, very high reject level with no relief in sight.

In summary, we have encountered many problems in the first half of 1976; problems that, for the most part, were not resolved. Total losses due to these problems are approximately 30-40,000 placed envelopes and 5-6,000 filled units. For all practical purposes, since mid April, with the exception of the five-dip process, we have not produced an acceptable envelope on the blue machine.

Thank you.

Gary Litchfield

phh

EXHIBIT 8

Rick
Suggest you
don't send
we Rose
to

August 14, 1984

TO: G. Jakubczak

cc: J. Wessel
E. Frish
J. Matherly
L. Duel

FROM: R. Dumas

SUBJECT: PROJECT REPORT - COMPLAINT ANALYSIS, PLASTIC SURGERY

SUMMARY: Project consisted of establishing methods/approaches to answering typical product complaints indicated with returned mammary implants.

In addition, a goal was set to reduce and if possible eliminate the existing backlog of 130 returned products with associated complaints outstanding through 1-1-84.

Backlog 1982 complaints accounted for 39 of total with 91 complaints registered in 1983.

Once a regular flow of completed analyses being accepted by the Business Quality Manager had been established, a specific objective was set to complete an average of one analysis per day.

Based on a project completion date of August 1, 1984, the total analyses completed would be 90 units. This number was increased to 100 as a target to exceed the goal.

During the 1st week of July, it was agreed upon to move the project completion date back to July 13th in order to begin my assignment in the orthopedics group. A total of 94 analyses had been completed by this date slightly under the target of 100 but meeting the specific objective.

Upon completion of the project, a project notebook was assembled containing example's of completed analyses as well as complaint investigation information to be used as a guide to personnel continuing this work.

Analysis Specifics:

Although the project objective was to address only the backlog complaint through 1-1-84, analyses were completed for five (5) complaints received after 1-1-84 based on litigation or specific requests from Customer Service.

Skin expanders accounted for six (6) of the 130 unit backlog and were assigned to and completed by Dave Pierce, product champion.

Priorities were set to complete the 10 gel-saline complaints in which Dow Corning was cited by FDA for failure to answer. After completing these, priority was given to the (22) remaining gel saline and (12) SILASTIC® II backlog.

Of the remaining gel mammarys completed approximately (35) were post-op and (15) pre-op in nature.

In order to facilitate retrieval of specific returned units held by TS&D, a log-in and inventory location system was established and is currently being maintained.

The practice of sending returned units to TS&D from the Medical Plant in mail envelopes via the plant mail has been changed since many of the units arrived in a smashed condition making analysis extremely difficult.

Imagine trying to analyze a mammary flattened like a pancake inside a gel soaked mail envelope.

Also of importance was the purchase of polaroid system for taking photomicrographs. This system will be used primarily for ~~complaints in litigation~~ when deemed necessary.

Gel Saline:

Of the gel-saline units examined, the most common complaints received were of gressy surface and post-op deflation from pin hole leaks.

Due to a pattern of complaints of small pin hole tears, a process audit was conducted on 6/25/82 by Vera Parks and Betty Wade of the Quality Control Inspection lab. Vera and Betty discovered burs on the wire screen in the wash area. These were removed immediately.

Many of the pin hole leaks examined suggested origination from this source. With the gressy surface complaint, some of the returned complaints consisted of several units unopened and still in the shrink wrap.

The appearance of some of these units made me sympathize with one surgeon stating that he believed we were soaking the units in Mazola™ oil before shipping.

Since this bleed appears to be inherent in the current design of the product a standard response has been developed to answer this type of complaint.

SILASTIC® II:

The most typical complaints registered with SILASTIC® II mammary implant were found to be either Post-Op rupture or rupture during insertion.

Although the number of SILASTIC® II returns examined were only approximately 10% of the total examined. The tear propagation noted with the ruptures was found to be of a much less degree compared with the standard gel product.

Of the complaints examined and limited personal testing with the TS&D insertion tester, there is an indication that there may be more susceptibility to rupturing during insertion than that found with the standard gel unit.

Standard Gel Mammarys:

Of the standard gel mammarys complaints examined, the most typical complaints were found to be either ruptured during insertion or post-op rupture.

Noted in the majority of ruptures examined was the ease of tear propagation.

In addition non-uniformity of the envelope was noted along most tears examined, suggesting thickness variation to be a contributing factor to the rupture. Although being within thickness specifications, many units were found to vary as much as .010 within a few inches along the tears.

Recommendations:

Several units examined, specifically complaints, such as, "Implant was found to have a hole in it upon opening the sterile package" indicated the possibility of intentional damage being done to the implant in order to obtain a credit. A suggestion to eliminate this type of occurance is to give credit to surgeons admitting miss-use of the product (i.e., nicking the implant). In this situation the implant would not be sent back for analysis or logged into the complaint system.

Another major problem for the complaint investigator is the on going situation of returned product with little or no product return information (i.e., defective product). As a complaint investigator, I would like to see a policy of no properly filled out return product information summary - no credit.

CONSOLIDATE Info analysis ??

In respect to suggestions in areas that may provide product improvements, they are as follows:

1. More uniform envelope thickness - all products.

2. Reduction of bleed characteristics in gel-saline units (i.e., SILASTIC® II concept). How??

3. Increase stress resistance in SILASTIC® II. Perhaps a new H.P. formulation to increase the elongation modulus. Any samples??

Regards,

Richard Dumas

cls/g

EXHIBIT 9

MEC000020791

[redacted]

12/86

50163 R

S. Smith, M.D.
Olympia, WA

[redacted]

MEC000020792

MEDICAL DEVICE REPORT

DATE CALLED TO FDA: 12/15/86 FILE NO: 5016SR

DATE MAILED TO FDA: 12/17/86 FDA ACCESS NO: M134349

BRAND NAME: Surgitek

COMMON/USUAL NAME: Bilumen Mammary Implant

CATALOG NO: 19750-SO LOT NO: Unknown MODEL NO: N/A

SERIAL NO: N/A PMA NO: N/A

DEVICE MANUFACTURED (X) IMPORTED ( ) BY: Medical Engineering Corp.

ADDRESS: 3037 Mt. Pleasant St.

CITY: Racine STATE/COUNTRY: WI ZIP: 53404

COMMENTS:

NAME OF PERSON REPORTING TO FDA: Walter Joppy

ADDRESS: 3037 Mt. Pleasant St. TELEPHONE NO. (414)- 639- 7205

CITY: Racine STATE: WI ZIP: 53404

DESCRIPTION OF EVENT: DEATH ( ) SURGICAL INTERVENTION (X) MALFUNCTION ( ) OTHER ( )

NUMBER OF PERSONS INVOLVED: 1 DATE OF EVENT: 12/2/86

Implant deflated requiring surgical intervention to replace the implant

Code "H"

SOURCE OF REPORT:

NAME: Sherwood Smith DATE MFR/IMPORTER ALERTED: 12/10/86

FACILITY NAME: TITLE:

ADDRESS: 300-B Lilly Road Northeast TELEPHONE NO.: ( )- -

CITY: Olympia STATE/COUNTRY: WA ZIP: 98506

WILL ADDITIONAL INFORMATION BE SUBMITTED TO FDA? NO: (X) YES: ( )

IF YES, DATE INFORMATION WILL BE SUBMITTED:

COMMENTS:

HAS OR IS EVENT OCCURRING MORE FREQUENTLY THAN:

A. IS STATED IN LABELING: NO (X) YES ( ); DATA AVAILABLE/UNKNOWN AT THIS TIME ( ); DATA UNKNOWN/NOT AVAILABLE ( ).

B. IS USUAL FOR DEVICE: NO (X) YES ( ); DATA AVAILABLE/UNKNOWN AT THIS TIME ( ); DATA UNKNOWN/NOT AVAILABLE ( ).

HAS OR IS EVENT OCCURRING WITH GREATER SEVERITY THAN:

A. IS STATED IN LABELING: NO (X) YES ( ); DATA AVAILABLE/UNKNOWN AT THIS TIME ( ); DATA UNKNOWN/NOT AVAILABLE ( ).

B. IS USUAL FOR DEVICE: NO (X) YES ( ); DATA AVAILABLE/UNKNOWN AT THIS TIME ( ); DATA UNKNOWN/NOT AVAILABLE ( ).

COMMENTS:

THIS REPORT IS SUBMITTED PURSUANT TO 21 CFR PART 803 AND IS BASED ON INFORMATION SUPPLIED TO US WITHOUT OUR INDEPENDENT VERIFICATION AS TO ITS ACCURACY, COMPLETENESS, OR CASUAL RELATIONSHIP TO THE PRODUCT.

MEC000020793

PRODUCT EXPERIENCE REPORT

Information Recorded By R. Mitchell Date 8-15-86

How Reported: Date 8-15-86 ☒ Phone ☐ Letter ☐ Other (Explain)

Name of Reporter:
Claire (Individual's Name) Nurse (Title)

Reported From:
Account's Name Shannon Smith, M.D.
Address 300-B Lily Lake Rd. N.E.
City/State Olympia, Wa. 98506 Phone (206) 456-8300
Patient Name (if applicable) C.A.

Product Description	Part No.	Lot No.
W.L. Gore		

Describe reported experience in detail (attach all pertinent correspondence, letters, invoices, packing lists, RGR's, etc.)

Was a patient involved? ☒ Yes ☐ No

Date of Surgery Last Reason for Surgery Saphenous Vein Graft Occlusion

Will product be returned? ☒ Yes ☐ No RGA # Expected MEC Return Date

Is a response requested? ☐ Yes ☒ No To be directed to

Detailed Information: Received 12/10/86 on RGR # 23483
Determined by Q.A. lab that unit had a crease hole.

FOR Q.A. USE ONLY

Reviewed by Walter J. Joffrey Date 12/11/86

This P.E.R. ☐ IS ☒ IS NOT considered a Complaint

This P.E.R. ☒ IS ☐ IS NOT considered an MDR Type SURG. INTERV

If Complaint, Complaint No. Date Returned Good Rec'd

Decision approved by B.A. Lock Date 12/12/86

All Product Experience Reports must be verbally transmitted to Q.A. Supervisor, Q.A. Manager or designee on the same day information on a product concern is received. Written P.E.R.'s and product (if applicable) must be mailed Express Mail to Q.A. immediately after verbal report.

LW04152-01

1285

SERIOUS INJURY INVESTIGATION REPORT

DATE REPORTED: 12/10/86

REPORTED BY: Sherwood Smith, M.D.

PRODUCT DESCRIPTION/P.N.: 255/300cc Geo. H.P. Cont. Q.S. Bil./19750-SO

LOT NO.: Unknown

(SEE ATTACHED P.E.R.)

INVESTIGATED BY:

Walter J. Joyce - Q.A. Supervisor
TITLE

10/16/86
DATE

APPROVED BY:

B A Lou
TITLE

10/16/86
DATE

SERIOUS INJURY INVESTIGATION AND ACTION RECOMMENDED

1. Pull trace card.
2. Check manufacturing and inspection procedures.
3. Have Q.A. Lab evaluate unit.

ACTION TAKEN

1. Trace card cannot be pulled as the lot number is unknown.
2. Manufacturing and inspection procedures are performed on all units to check for holes in the shells prior to packaging.
3. Q.A. Lab determined that the unit had a crease hole.
4. R & D also evaluated the unit, and the Q.A. Lab findings were confirmed.
5. The occurrence of crease holes in mammary implants is a state-of-the-art concern.
6. A statement in our package insert warns, "Implant may rupture and/or deflate due to material fatigue (i.e. crease fold phenomenon). If this phenomenon does occur, additional surgery may be required to remove..."
7. Additionally, we have decreased the recommended fill volume in our bilumen mammary implants to minimize the amount of fluid loss.

MEC000020796

MEDICAL ENGINEERING CORPORATION
RETURNED GOODS REPORT

23483

Authorization # _____

Date Received 12/10/86 Date Recorded 12/10/86 Recorded By D. Maiuri

Received From (Name) Olympia Plastic Surgeons

Address 300-B Lilly Rd. N.E., Olympia, Wa. 98506

	Qty.	Lot No.	Product No.	Product Description	Pkg. Seals Intact
1.	1 ea	unk.	19750-50	255/300 Gen H.P. Cont. Bil. QS.	yes
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

EVALUATION AND DISPOSITION

I. MISCELLANEOUS INFORMATION

☒ Q.A. Lab Review Date 12/10/86 By Whom D. Ost

☐ Feedback Required To Whom _____

Q.A. Special Info./Comments cc: B. Ulfsch

II. Q.A. SUMMARY

☐ Complaint # _____ ☒ Investigation MDR 50163R ☒ Product has been Used

☐ Legal Dept.

Condition: 1. Crease hole, cause unknown

By Walter J. Ogay Date 12/11/86

III. CUSTOMER SERVICE REVIEW AND DISPOSITION

☐ Remove from Consignment ☐ Issue Credit for $ _____

☐ Return to Customer ☐ No Credit

☐ No action required - reason _____

☐ Endotek Repair - forwarded to technician

Comments: _____

Disposition by _____ Date _____

IV. QUALITY ASSURANCE FINAL DISPOSITION

☐ Repackage, Resterilize and Restock ☐ Reinspect

☐ Product Destroyed ☐ Restock ☐ Rebox and Restock

☐ Retain until notified by _____

Other - Describe: _____

By _____ Date _____

Form LW04101-01-A

8/84

OPERATION REPORT

NAME: A.L. [redacted]

Date: December 2, 1986

PREOPERATIVE DIAGNOSIS: Previous breast reconstruction with loss of outer lumen right implant and severe capsule contracture.

FINAL DIAGNOSIS: Same.

OPERATION: Open operative capsulotomy and implant exchange.

OPERATIVE PROCEDURE: (1 hour 30 min)

The patient was appropriately premedicated and she was taken to surgery where she was positioned and monitored and sedated with intravenous Versed. Local anesthesia was then achieved using 1/2% Xylocaine with 1:200,000 to perform a IV level intercostal block plus local infiltration. She was then appropriately prepped and draped.

The scar was excised and dissection carried down to the capsule which was entered. Clear serous yellow fluid was encountered and this was cultured. The implant was then removed and the outer shell seen to have failed. The implant was to be returned to the manufacturer. The pocket was then incised using cutting cautery incising the periphery of the capsule and re-establishing a large submuscular pocket using both sharp and blunt dissection. Hemostasis was achieved with the cautery. The capsule was then removed from the entire inferior half of the anterior aspect of the pocket and radial capsulotomy performed over the superior half. The new implant was then filled to 360 cc. by adding 30 cc. to the central lumen and the implant inserted. Hemostasis was checked and the wound was closed in layers using Vicryl and Prolene. A bulky outer dressing was applied and the patient returned to Recovery having tolerated the procedure well.

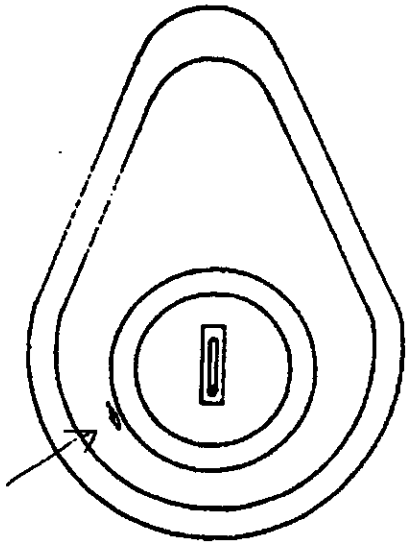
Sherwood P. Smith, M.D.

SPS/em

MEC000020798

TEARDROP, GEORGIADE
OVAL BILUMEN Quin Seal
VOLUME 255/300 Ges. H.P. Cont. Bil. QS.

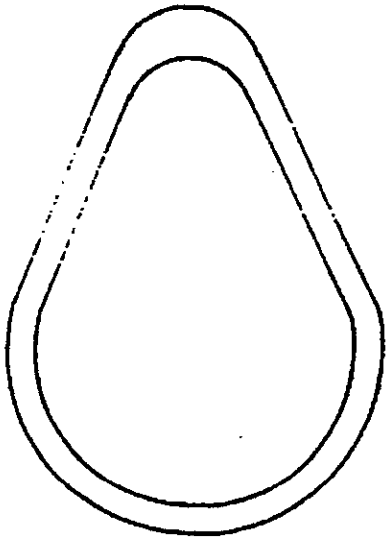
DATE : 12-10-86
COMPLAINT NO. : _____
R.G.R. NO. : 23483
LOT NO. : unk.



SEAL – UP

PICTORIAL REPRESENTATION
OF AFFECTED AREA(S)

1. Grease hole, cause unk.
2. _____
3. _____
4. _____



SEAL – DOWN

SAMPLE THICKNESS AT AFFECTED AREA

1. _____
2. _____
3. _____
4. _____

FORM NO. LM09109–01

COMPLETED BY: B. Conf 12-1
Wash. D.C.

MEC 000020798

EXHIBIT 10

DOW CORNING BREAST IMPLANT REMOVAL ASSISTANCE PROGRAM

Patient Certification

JUN 26 1992

Patient Name: [redacted]
Address: [redacted]
Phone: [redacted]

Physician Who Will Perform Implant Removal Surgery Name: Dr. Thomas D. Gant
Address: 21810 76th Ave W Edmonds Wa 98020
Phone: 206-775-2200

Physician Who Performed Implant Surgery Name: Dr. Thomas D Gant
Address: 21510 76th Ave W Edmonds Wa 98020
Phone: 206-775-2200
Approximate month and year of implant surgery: 7-91

Dr. Thomas D Gant and I agree my breast implant device(s) should be removed.

I have discussed the removal surgery with Dr. Thomas D. Gant, and I understand and agree to accept the risks associated with the removal surgery.

I am certain Dow Corning manufactured the silicone gel filled breast implant device(s) I intend to have removed. I understand this program only applies if the post-operative verification performed by my physician identifies Dow Corning as the device manufacturer.

I am unable to pay for the breast implant removal surgery without the financial assistance provided under this program.

Sherry A. Aguilar
Patient's signature

6-18-92
Date

Physician's signature

6/23/92
Date

☒ Please check the box if you are willing to have your physician return your removed implant(s) to Dow Corning to be used in a physical and chemical testing program. Results of this test program will be made available to you upon request. Dow Corning does not test human fluids or tissues.

Program Representative Initials MS

DATE CALLED
REPRESENTATIVE inks

BREAST IMPLANT REMOVAL ASSISTANCE PROGRAM

EXPLANT RETURN CHECKLIST

PATIENT [redacted]

DOCTOR Thomas D Grant TELEPHONE NO. 206-775-22

Jeri

RETURNING EXPLANT YES X NO ___

INFECTIOUS DISEASE YES ___ NO X DISEASE IF KNOWN ___

PRODUCT SIL@1 SIZE OF EXPLANT 360cc

CATALOG NO. P014-0360 LOT NUMBER HH080752

DOUBLE LUMEN YES ___ NO X

COMMENTS not removed yet zip⇒98026

DATE COPY OF PATIENT FILE SENT TO EXPLANT TESTING JUL 01 1992

TO BE COMPLETED BY EXPLANT TESTING PROGRAM

DATE EXPLANTS RECEIVED ___

ASCENSION NUMBER ___

DATE NOTICE OF RECEIPT MADE TO REMOVAL ASSISTANCE ___

COMMENTS ___

06/05/92