UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

In Re:	§	**Case No. 00-CV-00005-DT**
	§	**(Settlement Facility Matters)**
Dow Corning Corporation,	§	
	§	**HON. DENISE PAGE HOOD**
Reorganized Debtor.	§	
	§	

MOTION OF DOW CORNING CORPORATION FOR A DETERMINATION THAT TISSUE EXPANDERS DO NOT CONSTITUTE BREAST IMPLANTS FOR PURPOSES OF ELIGIBILITY FOR SETTLEMENT BENEFITS UNDER THE DOW CORNING AMENDED JOINT PLAN OF REORGANIZATION

Dow Corning submits this MOTION OF DOW CORNING CORPORATION FOR A DETERMINATION THAT TISSUE EXPANDERS DO NOT CONSTITUTE BREAST IMPLANTS FOR PURPOSES OF ELIGIBILITY FOR SETTLEMENT BENEFITS UNDER THE DOW CORNING AMENDED JOINT PLAN OF REORGANIZATION in accordance with the terms of the "Stipulation and Order Establishing Procedures for Resolution of Disputes Regarding Interpretation of the Amended Joint Plan" dated June 10, 2004.

I. Background.

The Claims Administrator requested that the Plan Proponents advise whether tissue expanders were to be considered Breast Implants for purposes of the Settlement Option under the Settlement Facility and Fund Distribution Agreement (the "Settlement Facility Agreement"). The Plan Proponents submitted written position statements to the Claims Administrator in September and October 2003. The Claims Administrator held a hearing on June 22, 2004, and the Claims Administrator issued on June 28, 2004 a written determination declining to decide the issue. In accordance with the Dispute Resolution Procedures approved by the Court, Dow Corning submits this Motion.

The sole issue for determination is whether "tissue expanders" fall within the definition of Breast Implant in the Dow Corning Amended Joint Plan of Reorganization (the "Plan"). As set forth below, they do not. Dow Corning and the Claimants' Advisory Committee have been advised that some individuals who have submitted settlement claim forms to the Settlement Facility-Dow Corning Trust have submitted proof that they at one time had a tissue expander product made by Dow Corning.

In support of this Motion, Dow Corning submits the AFFIDAVIT OF EUGENE R. JAKUBCZAK IN SUPPORT OF THE MOTION OF DOW CORNING CORPORATION FOR A DETERMINATION THAT TISSUE EXPANDERS DO NOT CONSTITUTE BREAST IMPLANTS FOR PURPOSES OF ELIGIBILITY FOR SETTLEMENT BENEFITS UNDER THE DOW CORNING AMENDED JOINT PLAN OF REORGANIZATION ("Jakubczak Affidavit").

A. Summary of Argument.

The plain language of the Plan controls the determination of this issue: the Plan clearly and unequivocally states that to receive settlement benefits under Classes 5, 6.1, and 6.2 the claimants must have been implanted with a Breast Implant. Breast Implant is in turn defined as a silicone or saline-filled breast implant. In short, to receive compensation the individual claimant must have been implanted with a breast implant device. A tissue expander is not a breast implant and, thus, persons with tissue expanders simply cannot qualify for settlement benefits under the Plan. At no time during the negotiation of the Plan did the Plan Proponents discuss the possibility of authorizing persons with tissue expanders to be eligible for the Breast Implant Settlement Option. Indeed, it is important to note that none of the estimates of settlement payments presented by the Plan Proponents at the Confirmation Hearing included the possibility of individuals with tissue expanders being paid as if they had breast implants. Had the parties intended to include tissue expanders within the scope of the Breast Implant Settlement Option, it would have been a simple matter to amend the language of the definition to include tissue expanders. There is no ambiguity and no basis to conclude that tissue

expander products are the equivalent of Breast Implants for purposes of the Settlement Option.

II. Argument: The Plain Language Of The Amended Joint Plan Of Reorganization Makes It Clear That Tissue Expanders Are Not To Be Treated As Breast Implants.

A. Definition of Breast Implants.

The Amended Joint Plan of Reorganization (the "Plan") defines Breast Implant as "all silicone gel and saline-filled breast implants with silicone elastomer manufactured and either sold or otherwise distributed by the Debtor" (emphasis added). The tissue expanders manufactured by Dow Corning do not fall within the scope of this definition: to fall within the scope of this definition, the product at issue must (1) be filled with silicone gel or saline and have silicone elastomer, and (2) be a breast implant device. Tissue expanders are not breast implants. Tissue expanders are short-term devices that were used to expand body tissue in preparation for reconstructive surgery. They were not designed to function as breast implants, they have features distinctly different from breast implants and they have always been marketed and considered as an entirely different product from breast implants.

1. Tissue Expanders are Structurally and Functionally Different from Breast Implants.

a) Dow Corning tissue expanders had numerous applications and most were not designed expressly or exclusively – or even primarily – for use in the breast area. In fact, Dow Corning made over 250 different types, sizes and styles of tissue expanders. Jakubczak Affidavit ¶ 7. Tissue expanders come in a variety of sizes and shapes (e.g., rectangle, square, crescent, and round) that would be incompatible with use as a breast implant.

b) Tissue expanders were intended for short-term or intra-operative use in any part of the body (such as the arms, legs, scalp, face, back, and abdomen) that required additional tissue, primarily skin, to cover a defect or wound. The surgeon placed the device under the skin in the appropriate location and gradually, over a period of several weeks, added saline filler to the device

hypodermically to expand its volume, thus stretching the overlying skin. Jakubczak Affidavit ¶¶ 6, 8. Dow Corning tissue expanders were specifically designed, marketed and used as temporary products — not as long-term implants. Jakubczak Affidavit ¶ 10. In contrast, breast implants were designed for long-term implantation.

c) Tissue expanders were constructed with a fill valve that was accessible through the skin and could be seen and felt when inserted. In contrast, breast implants have smooth surfaces, were designed to be natural looking and did not contain protrusions or valves that could be seen or felt. Jakubczak Affidavit ¶¶ 5, 9.

2. Tissue Expander Products are Separate and Distinct from Breast Implant Products.

a) To meet the definition of a Breast Implant the product must be filled with either silicone gel or saline. Tissue expanders were not filled with anything at the time of sale. Rather, Dow Corning tissue expanders were designed to be inflated over time through the skin. Inflation with saline generally began after implantation and could continue for up to approximately 10 weeks. Jakubczak Affidavit ¶¶ 6, 8. The tissue expander product was sold without any filling and was intended to be gradually filled over a period of time just to prepare the area for surgery. Thus, a tissue expander does not satisfy the definitional terms in the Plan.

b) To meet the definition of Breast Implant, the product must in fact *be* a breast implant. (The Plan defines "Breast Implant" as all "silicone gel or saline-filled *breast implants*. . . ." (emphasis added).) Tissue expanders were developed, marketed and sold as a product separate and distinct from breast implants. Jakubczak Affidavit ¶¶ 11-13. Tissue expanders are described as "tissue expanders" or "percutaneous skin expanders" in Dow Corning's product list and literature; they are not described as breast implants. The fact that a tissue expander may be inserted in the breast area does not transform it into a breast implant. Surely, there would be no argument that a gel-filled testicular implant that was for some reason implanted in the breast area is a breast implant

compensable under the Plan. The Plan defined the term "Breast Implant" specifically and deliberately: only those products that are named breast implants are covered by the definition. It is not reasonable to conclude that tissue expanders are breast implants or that the term "Breast Implant" as defined in the Plan was intended to incorporate tissue expanders. *See* Jakubczak Affidavit at 5-6, ¶ 14.

3. The Plan Product Identification Provisions Exclude Tissue Expanders.

a) Schedule I to the Claims Resolution Procedures (Annex A to the Settlement Facility Agreement) specifically lists the product identification requirements for eligible Breast Implant products, including model and brand names and unique identifiers. This list does not include any tissue expander products. In addition, the Plan required Dow Corning to provide to the SF-DCT specific product identification guidelines including catalogue and lot numbers that would allow the SF-DCT to confirm Breast Implant product identification. Dow Corning has provided extensive product identification manuals and lists to the SF-DCT and participated in training the SF-DCT staff in conjunction with the Tort Claimants' Committee. None of these lists or materials refers to or lists any tissue expander products. Moreover, although the parties provided numerous training sessions for the staff of the SF-DCT, at no time did these training sessions encompass product identification for tissue expander products. The product identification materials and training referred – correctly – only to breast implants and compensable "Other Products" – and not to tissue expanders. Jakubczak Affidavit ¶¶ 15, 16.

There is no ambiguity: the Plan simply does not include tissue expander devices in any of the operative terms or criteria applicable to Breast Implants, and there was never any intent to include tissue expanders within the scope of the term "Breast Implant." Had the parties wanted to include tissue expanders as compensable products under the Settlement Option, then the definition of products eligible for "Breast Implant" benefits would expressly include the term "tissue expander,"

the product identification manuals would include a section on tissue expander products, and the training would have incorporated tissue expander devices.[1]

In sum, tissue expanders are not included within the definition of Breast Implant and are not included in the acceptable product identification provisions of the Claims Resolution Procedures pertinent to Breast Implants (or to Covered Other Products, Claims Resolution Procedures § 6.03(a)). Quite simply, the Plan Proponents did not intend to include tissue expanders as products eligible for settlement benefits in the SF-DCT.

III. Defining Tissue Expanders As Breast Implants Would Be A Plan Modification.

At no point during the long and arduous Plan negotiations did the Tort Claimants' Committee advise that they believed tissue expanders were "Breast Implants." Moreover, the estimation testimony that the Plan Proponents jointly presented during the Confirmation Hearing to prove the feasibility of the Plan never included tissue expanders in the evaluation of potential settling claims and corresponding claim values. Quite simply, it was never the intention of the parties to include tissue expanders within the scope of products eligible for Breast Implant (or other) settlement benefits. The proposed change in the interpretation of "Breast Implant" at this stage would have to be viewed as a Plan modification. In fact, the parties would have to amend the product identification manuals and institute new training sessions. Allowing claimants with tissue expanders to obtain the settlement payments authorized for claims in Classes 5, 6.1, and 6.2 will increase the financial obligation of the SF-DCT. Indeed, the inclusion of such claims could result in a reduction in payments to eligible Breast Implant claimants.

[1] In fact, as the Plan was being developed in preparation for the Confirmation Hearing, Dow Corning always listed tissue expander as an "Other Product" in its list of claims filed. Attached as Exhibit A to this Motion is a chart from the exhibits to the Confirmation Hearing testimony of Dr. Frederick Dunbar. That chart lists filed Other Products claims and includes tissue expanders as an "Other Product" that is not "covered" by the Plan Settlement Option.

IV. A Comparison With The Revised Settlement Program Makes It Clear That Tissue Expanders Are Not "Breast Implants."

The Claimants' Advisory Committee has advised that the SF-DCT should deem tissue expanders to be the equivalent of Breast Implants because (1) individuals with tissue expanders made by Baxter, Bristol, or 3M are permitted to receive some settlement benefits in the Revised Settlement Program ("RSP"), and (2) the Settlement Facility Agreement states that the SF-DCT is to process claims in substantially the same manner as claims are processed in the MDL — except to the extent that criteria or guidelines are modified by the Settlement Facility Agreement.

This argument is unsupportable. Whether or not the companies involved in the RSP chose to pay settlement benefits to individuals with tissue expanders is irrelevant. The determination of eligibility for settlement benefits under the Plan is governed solely by the terms of the Plan Documents. The Plan language could not be clearer. The Plan does not include tissue expanders in the list of products eligible for settlement benefits. The SF-DCT has no authority to modify the Plan language with reference to the MDL practices or otherwise. Indeed, the Plan unequivocally states that the SF-DCT is required to adhere to the language of the Plan, and if the Plan sets forth criteria different from those of the MDL, then the SF-DCT is not permitted to alter the Plan by adopting MDL criteria.

It is useful to understand exactly how the RSP treats tissue expanders. The RSP companies, in contrast to Dow Corning, made an affirmative decision to include certain tissue expander products on the acceptable brand name/product list for the RSP. Under the RSP those products would be eligible for *some* of the benefits allowed for breast implants. In short, the RSP companies made an affirmative decision during the implementation of the RSP to add tissue expanders to the list of acceptable products by specifically including them on the product list. If Dow Corning and the Tort Claimants' Committee had wanted to include tissue expanders on the list of acceptable products, these products would have been listed on the product list just as they were in the MDL. But the Plan

Proponents did not negotiate an agreement that included tissue expanders.[2] The Claimants' Advisory Committee seeks to amend the Plan now by adding tissue expanders.

The Plan of Reorganization provides very clearly that only certain products are eligible for settlement benefits, and Schedule I of the Claims Resolution Procedures specifies the identifiers for those eligible products in detail (none of which include tissue expanders). The fact that the companies in the RSP may have by their own choice covered products other than breast implants is irrelevant.

V. A Review Of Product Literature Proves That Tissue Expanders Are Not Breast Implants.

A review of the product literature of various companies further clarifies that tissue expanders and breast implants are different products. For example, the "Gibney" product (which is listed in Exhibit G to the RSP as a CUI product) is described in the product literature as a "gel-saline filled adjustable mammary prosthesis" designed to function as both a tissue expander and permanent prosthesis. Similarly, the Becker product (listed in Exhibit G as a Mentor product) is called a "Becker Expander Mammary Prosthesis" that is converted from a tissue expander to a mammary prosthesis. The stated purpose of these products was to eliminate the two-step surgical process of first inserting a tissue expander and then undergoing additional surgery to insert the actual implant. In short, the manufacturers did not consider tissue expanders and breast implants to be one and the same — they were different products with different functions. The product descriptions noted above are attached to the Jakubczak Affidavit as Exhibit A. *See* Jakubczak Affidavit at 3, ¶ 6.

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[2] Notably, *the RSP companies did not treat Dow Corning tissue expanders as breast implants for purposes of the multiple manufacturer reduction*. Although those companies would have benefitted from such a characterization, they concluded (correctly) that Dow Corning tissue expanders were not breast implants and thus could not trigger that reduction. Thus, any argument that the RSP defines Dow Corning tissue expanders as breast implants is incorrect and contrary to the facts. In fact, the treatment of tissue expanders in the RSP confirms Dow Corning's position that a tissue expander is not a breast implant.

VI. Conclusion.

For all the foregoing reasons, Dow Corning submits that the Plan does not include, was never intended to include, and cannot be interpreted to include tissue expanders as "Breast Implants" eligible for benefits from the SF-DCT.

Respectfully submitted this 19th day of July 2004,

THE FEINBERG GROUP, LLP

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DEBTOR'S REPRESENTATIVE AND
ATTORNEY FOR DOW CORNING CORPORATION

EXHIBIT A

Reported Proofs of Claim for Covered Other Products (Includes BI Overlap)

U.S.

	Dow Corning		*DCC + Other Mfg.*		*Unknown Mfg.*		*No Response*		*Other Mfg. Only*		*Total*		
	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Total
Chin	995	760	392	187	948	2,696	158	237	533	410	3,026	4,290	7,316
Testicular	451	486	205	82	621	1,921	92	168	294	506	1,663	3,163	4,826
Hip	457	365	195	127	1,604	7,407	175	734	254	580	2,685	9,213	11,898
Knee	578	575	166	146	1,621	7,444	171	779	315	641	2,851	9,585	12,436
SJO	994	683	206	145	909	1,847	130	196	160	102	2,399	2,973	5,372
TMJ	1,514	408	828	78	1,306	1,615	200	183	1,373	273	5,221	2,557	7,778
Subtotal	*4,989*	*3,277*	*1,992*	*765*	*7,009*	*22,930*	*926*	*2,297*	*2,929*	*2,512*	*17,845*	*31,781*	*49,626*

Other

U.S.

	Dow Corning		*DCC + Other Mfg.*		*Unknown Mfg.*		*No Response*		*Other Mfg. Only*		*Total*		
	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Current	Unmani-fested	Total
Silicone Fluid	771	268	271	64	514	481	178	131	320	136	2,054	1,080	3,134
Tissue Expander	97	58	223	55	53	67	8	19	271	190	652	389	1,041
Other Implant	564	161	482	66	581	723	102	134	1,025	300	2,754	1,384	4,138
Other LJO	86	36	42	20	242	595	24	58	47	56	*441*	765	1,206
Catheter	3	1	1	0	0	2	2	0	2	0	8	3	11
Back	42	6	20	1	97	167	13	17	21	14	193	205	398
Head	3	3	3	1	17	27	4	3	1	3	28	37	65
Neck	5	1	1	2	15	27	4	2	4	3	29	35	64
Heart	1	1	1	0	8	37	3	9	1	11	14	58	72
Unknown Implant	452	315	265	122	2,661	9,347	237	756	355	305	3,970	10,845	14,815
Non-Product Response	26	3	13	1	29	16	3	2	9	6	80	28	108
No Response	203	214	119	50	92	257	387	2,223	537	353	1,338	3,097	4,435
Norplant	2,320	406	486	49	1,079	828	407	116	1,316	118	5,608	1,517	7,125
Subtotal	*4,573*	*1,473*	*1,927*	*431*	*5,388*	*12,574*	*1,372*	*3,470*	*3,909*	*1,495*	*17,169*	*19,443*	*36,612*
	9,562	4,750	3,919	1,196	12,397	35,504	2,298	5,767	6,838	4,007	35,014	51,224	86,238
		14,312		**5,115**		**47,901**		**8,065**		**10,845**	**Grand Total U.S.**		**86,238**

Source: Price Waterhouse Data (As of 12/20/98)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

In Re:	§	
	§	**Case No. 00-CV-00005-DT**
Dow Corning Corporation,	§	**(Settlement Facility Matters)**
	§	
Reorganized Debtor	§	**Hon. Denise Page Hood**
	§	

AFFIDAVIT OF EUGENE R. JAKUBCZAK IN SUPPORT OF THE MOTION OF DOW CORNING CORPORATION FOR A DETERMINATION THAT TISSUE EXPANDERS DO NOT CONSTITUTE BREAST IMPLANTS FOR PURPOSES OF ELIGIBILITY FOR SETTLEMENT BENEFITS UNDER THE DOW CORNING AMENDED JOINT PLAN OF REORGANIZATION

	§
STATE OF MICHIGAN	§
COUNTY OF BAY	§
	§

Eugene R. Jakubczak, being duly sworn, deposes and says:

1. I am currently employed by Dow Corning Corporation ("DCC"), with the title of Manager, Medical Device Operations. I make this affidavit in support of the Motion of Dow Corning Corporation for a Determination that Tissue Expanders do not constitute Breast Implants for Purposes of Eligibility for Settlement Benefits Under the Dow Corning Amended Joint Plan of Reorganization.

2. I have personal knowledge of the matters set forth herein.

3. I have been employed by DCC for 40 years. For 29 of those years I worked in the Medical Device Business. My responsibilities included but were not limited to product development, technical service and development which included design, fabrication and use of medical devices, professional interface with doctors, nurses and others in the medical profession,

interface with regulatory agencies, marketing, understanding of competitive activities associated with DCC product lines and professional relations.

4. I have personal knowledge of the implant device products developed, marketed and sold by DCC. I have personal knowledge of the specifications and uses of the various devices, the manner in which the products were marketed, the categorization of the products within DCC and the competing products made by other companies. I have personal knowledge of the specifications, characteristics and function of devices known as tissue expanders, and I have personal knowledge of the specifications, function and characteristics of the devices known as breast implants. I have personal knowledge of the terms of the Dow Corning Amended Joint Plan of Reorganization (the "Plan") that involve the definition, product identification guidelines and treatment of implanted medical devices. More specifically, I have personal knowledge of the definition of compensable breast implants under the Plan and of the types of implantable medical devices that are not eligible for settlement benefits under the Plan.

5. 1964 was the first full year that Dow Corning commercially manufactured breast implants. DCC discontinued breast implant manufacture in January 1992. Although there were various models, DCC breast implants had the following common characteristics:

1. They were made with a silicone elastomer envelope;

2. They were filled with silicone gel at the time of sale or saline before implantation into the body;

3. They were intended for long-term implantation in the breast;

4. They were designed to be natural looking, thus they did not contain any "fill valves" that would be seen or felt through the skin.

6. DCC commercially manufactured and promoted tissue expanders for sale between 1982 and December 1992. All of DCC's tissue expander products were designed and marketed to be short-term devices. The sole function of tissue expanders was, as the name implies, to stretch the skin in order to prepare the body for placement of a long-term implant device or for other reconstructive surgery. Tissue expanders were intended to be used in the body for a period of up to 10 weeks to repair a skin defect (such as a burn) or to prepare the area for further reconstructive surgery. DCC's line of Intraoperative Tissue Expanders, which were intended for surgical use to facilitate wound closure, and were not to be in place in the patient beyond the operating theatre. Thus, a DCC tissue expander for the breast was designed to be inserted into the body for only a short period of time in preparation for the later insertion of the actual breast implant. DCC never marketed tissue expander products for permanent use. As part of the market surveillance of competition, I am aware of competitive combination tissue expander/breast implant hybrid devices that were marketed for permanent implantation. Attached as Exhibit A is product literature from 2 such products. The Gibney product was marketed as an "adjustable mammary prosthesis" and the Becker product was a device that could be converted from a temporary to a long-term implant.

7. DCC tissue expanders were manufactured in various shapes and sizes. DCC made over 250 individual tissue expander stock-keeping units which incorporated a variety of different styles, sizes and types. Tissue expanders come in a multitude of shapes — including but not limited to square, rectangular, crescent and round. Tissue expanders find use in numerous parts of the body.

8. Tissue expanders were designed to be inserted into the body and then filled gradually with saline until the patient had an adequate amount of tissue for reconstructive surgery. As

mentioned above, the exception is DCC's Intraoperative Tissue Expanders that were filled with saline more rapidly and used only in the operating room. DCC tissue expanders were not filled with silicone gel.

9. Tissue expanders were designed with a type of valve that would allow the surgeon to inflate the expander over a period of weeks by inserting saline into the valve through the skin. The valve, containing metal, was thus easily accessible and palpable through the skin. An exception being DCC Intraoperative Tissue Expanders.

10. Product literature that accompanied tissue expander products made clear that tissue expanders were sold and to be used for the sole purpose of preparing the area for reconstructive surgery and not as long-term implants.

11. Tissue expanders are not the same as breast implants regardless of where they are inserted. DCC considered tissue expanders and breast implants to be separate and distinct products with different characteristics, uses and functions. DCC did not refer to or describe a tissue expander as a breast implant in its product literature. The term "breast implant" would not be used by DCC to refer to a tissue expander, even if that tissue expander were designed specifically for use in the breast area or was temporarily implanted in the breast area.

12. In my experience, medical professionals considered tissue expanders to be a product separate and distinct from a breast implant. It is generally understood that the term "breast implant" is used to refer solely to the implant device designed for long-term implantation in the breast.

13. In my experience, regulatory agencies also considered—and continue to consider—tissue expanders to be separate and distinct from breast implants. The United States Food and Drug Administration (FDA) for example, has historically considered tissue expanders differently than

saline breast implants. Tissue expanders remained "unclassified medical devices" while breast implants were classified in Class II based on an advisory panel recommendation in 1976, the first year the agency was empowered by the Medical Device Amendments to regulate medical devices. In June 1988, FDA reclassified breast implants into Class III. FDA continues to treat tissue expanders as distinctly different medical devices from breast implants. In their February 11, 2003 guidance document for "Saline, Silicone Gel, and Alternative Breast Implants", FDA states, "However, this guidance document does not address tissue expanders, which are unclassified devices for temporary use." In the 2004 "Breast Implant Consumer Handbook" FDA states, "It should be noted that tissue expanders, which are silicone shells filled with saline, are regulated by FDA in a different way than breast implants. This is because tissue expanders are intended for general tissue expansion for a maximum of 6 months, after which, they are to be removed. Because of this, the design specifications (e.g., thinner shell) and preclinical testing recommendations are different for tissue expanders than for breast implants. Tissue expanders are not to be confused with the third type of double lumen silicone gel-filled breast implants described in the Silicone Gel-Filled Breast Implants section below. The third type of double lumen silicone gel-filled breast implant is a permanent implant (not intended to be removed) that allows for limited tissue expansion but is regulated by FDA as a breast implant." The double lumen implant they reference is the same type of tissue expander/breast implant hybrid I mentioned in part 6, above as having been made by some of Dow Corning's competitors but not by Dow Corning.

14. The Plan defines Breast Implants as "all silicone gel and saline-filled breast implants with silicone elastomer envelopes manufactured and either sold or otherwise distributed by the Debtor." Plan at § 1.17. The fact that the definition uses the term "breast implants" to define

compensable "Breast Implants" is significant. The definition by its terms covers only products that are defined by DCC as breast implants. The definition does not include other silicone or saline-filled products with elastomer envelopes that might be implanted, albeit temporarily, into the breast. Thus, the definition was not intended to and does not include tissue expanders. If the definition were intended to include DCC tissue expanders, then the definition would have had to include the term "tissue expanders" or the alternate term "percutaneous skin expanders."

15. In the preparation of the Plan, DCC developed unique identifiers for "Breast Implants." These unique identifiers relate solely to breast implant products. I personally participated in the generation, supervision, review and approval of the "Unique Identifiers" specified in Annex A at Schedule I, Part I Section D ("Unique Product Identifiers") and at Part II Section C ("Unique Identifiers for Other Products"), to the Settlement Facility and Fund Distribution Agreement. DCC was not asked to and did not provide any unique identifiers for tissue expander products. This is consistent with DCC's understanding that tissue expanders were not incorporated into the definition of "Breast Implants."

16. I have participated in the training of the SF-DCT on three occasions in fulfillment of Annex A at Schedule I, Part I Section F ("Cooperation"). On all three occasions there was training provided on identification of DCC products. Tissue expander devices were not part of the detailed training since DCC does not consider tissue expanders to be compensable under the settlement options in the Plan.

17. I declare under penalty of perjury, under the laws of the State of Michigan, that to the best of my knowledge and recollection the foregoing is true and correct.

FURTHER AFFIANT SAYETH NOT.

Executed this 16th day of July 2004.

Eugene R. Jakubczak

Subscribed and sworn to before
me this 16th day of July 2004.

Christine M. Fitak

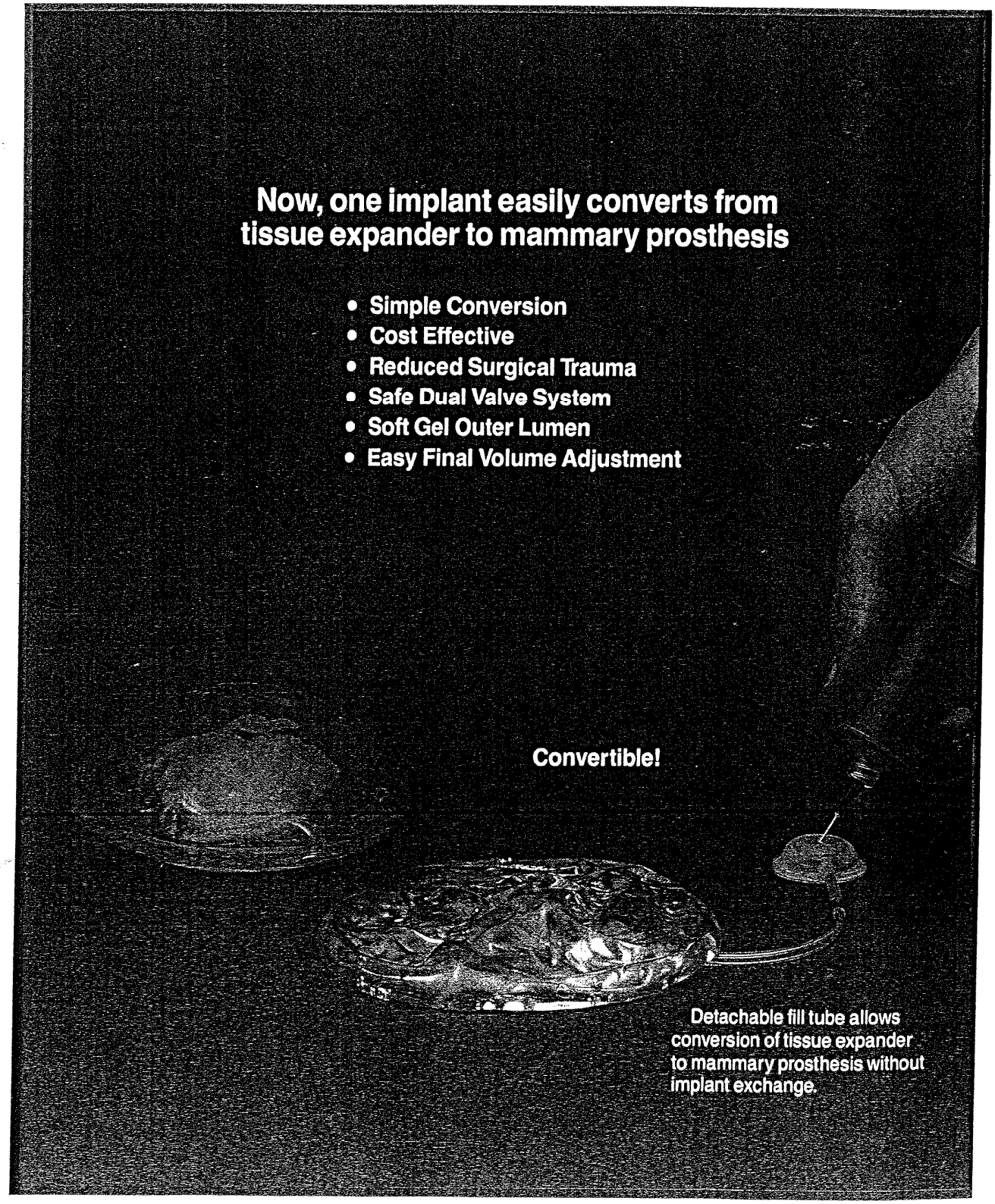
Notary Public in the State of Michigan

My commission expires:

Christine M. Fitak
Notary Public, Midland County, Michigan
My Commission Expires April 30, 2007
Acting In Bay County

EXHIBIT A

The Mentor Becker Expander/Mammary Prosthesis



MENTOR CORPORATION

Toll Free (800) 235-5731

Becker Expander/Mammary Prosthesis

The Becker Expander/Mammary Prosthesis represents the logical next step in tissue expansion for breast reconstruction. Tissue expansion itself has given you a dramatic new method of confining reconstructive breast surgery to the immediate breast area minimizing the need for tissue transfer and flap scars in the abdominal or dorsal region. This design allows for an even simpler course of going from mastectomy to the reconstructed breast.

Now the Becker Prosthesis eliminates one more step. This implant can be easily converted from tissue expander to mammary prosthesis without the time, trauma and cost of a replacement surgery. You need only fill this implant to its final volume and then, through a small incision at the remote reservoir, remove the fill tube and injection dome. The Becker Expander/Mammary Prosthesis is left in place for the final result.

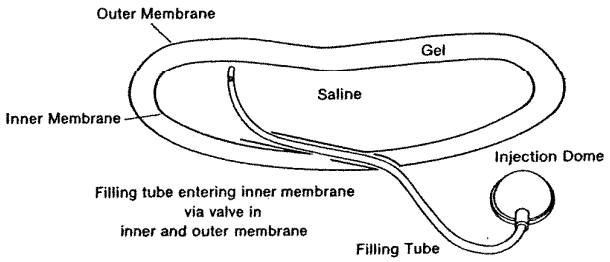
Features

Implanted Detachable Fill Tube—The fill tube of this unique prosthesis can be removed through a small incision from the dual valve system by traction on the injection dome.

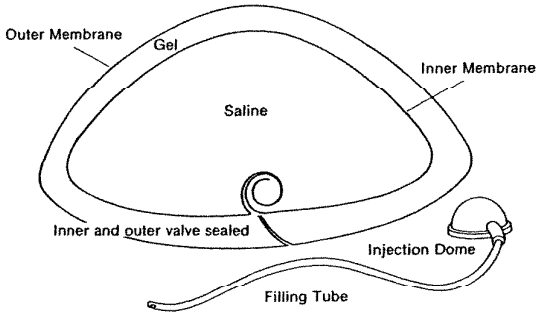
Dual Valve System—Two valves have been incorporated into this design to allow access through both shells and the gel lumen into the center saline expansion chamber. Added anti-leak protection is accomplished by this configuration.

Soft Gel Outer Lumen—The outer chamber of gel will minimize shell wrinkles while lubricating both envelopes to guard against "crease-fold failure."

Partially Filled Implant



Implant Filled to Desired Volume



Designed with
Hilton Becker, MD
Suite 504
2617 North Flagler Drive
West Palm Beach, Florida 33407

U.S. Patent Pending

Catalog Number	Size cc's	Outer Gel Fill Volume	Suggested Saline Volume	Nominal Total Volume	Diameter	Projection
350-0150	150	40 cc	110 cc	150±25 cc	10.3 cm	2.9 cm
350-0200	200	50 cc	150 cc	200±25 cc	10.9 cm	3.4 cm
350-0250	250	60 cc	190 cc	250±25 cc	11.6 cm	3.6 cm
350-0300	300	75 cc	225 cc	300±25 cc	13.2 cm	4.0 cm
350-0350	350	90 cc	260 cc	350±25 cc	13.6 cm	4.2 cm
350-0400	400	100 cc	300 cc	400±25 cc	14.3 cm	4.2 cm
350-0450	450	115 cc	335 cc	450±25 cc	15.0 cm	4.5 cm
350-0500	500	125 cc	375 cc	500±25 cc	15.0 cm	4.8 cm
350-0550	550	140 cc	410 cc	550±25 cc	16.0 cm	5.0 cm
350-0600	600	150 cc	450 cc	600±25 cc	16.0 cm	5.2 cm

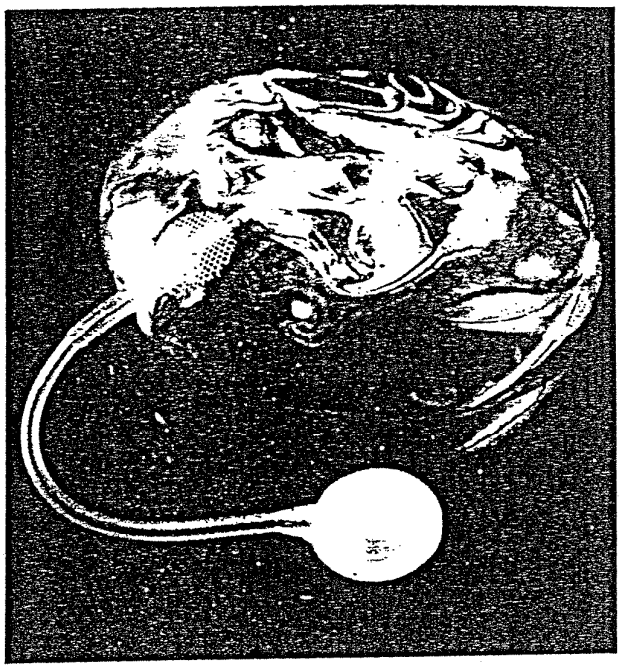
MENTOR CORPORATION
600 Pine Avenue
Goleta, California 93117
(805) 967-3451 **Toll Free (800) 235-5731**

585-132 Effective June 1985

GEL-SALINE FILLED ADJUSTABLE MAMMARY PROSTHESIS

Gibney RDL-Xpand™

SWEP0055012



ADVANTAGES

Combines the benefits of a tissue expander with a Reverse Double Lumen mammary prosthesis.

Requires only one surgical procedure. Ease of introduction through a small incision in comparison to comparable size gel prosthesis.

Two unique fill valves. Initial filling via CUI patented* posterior fill valve. Subsequent insufflations using CUI detachable fill port with unique dual stage needlestop.

Gel/Saline ratio provides lubrication of envelope to lessen chance of shell erosion. In addition, the gel enhances simulation of tactile characteristics of natural tissue.

DESCRIPTION

The RDL-Xpand is an adjustable volume mammary prosthesis which serves as a tissue expander until the remote fill port is detached and removed leaving a reverse double lumen mammary prosthesis in place. The RDL-Xpand's outer lumen is gel filled and the inner lumen is saline fillable. The inner lumen may be initially filled through the patented posterior fill valve, with additional percutaneous insufflations via the remote fill port. Saline may be removed through the same port. Once the desired volume of saline has been attained, the remote fill port may be detached, leaving the reverse double lumen mammary prosthesis in place.

*U.S. Patent #4,178,643

COX-UPHOFF INTERNATIONAL
930 W. 16th ST., Suite B-1
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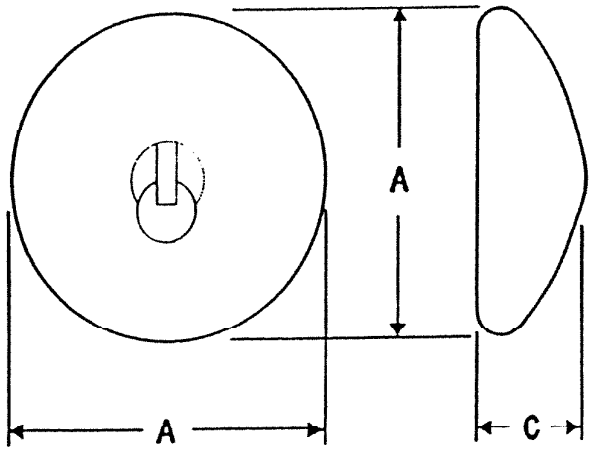
COX-UPHOFF INTERNATIONAL

Printed in U.S.A.
120,090—8605

SPECIFICATIONS

The RDL-Xpand adjustable mammary prosthesis is available in the following sizes. Complete instructions for use are included with each prosthesis.



Cat. No.	Total Volume (cc)	Recom. Saline Volume (cc) Inner Lumen	Gel Volume (cc) Lumen	W/Recom. Amt. Saline A Diam.	C Height
RDL/X-200:200	400	200	200	13.1	5.8
RDL/X-250:250	500	250	250	14.1	5.2
RDL/X-300:300	600	300	300	14.0	6.1
RDL/X-350:350	700	350	350	15.3	6.3

SUPPLIED STERILE

The RDL-Xpand is supplied with a protective outer container to serve as a dust cover and double-wrapped sterile packaging. It is intended that the protective cover and outer sterile wrapper can be opened by the circulating nurse so that the item with intact inner most wrapping can be presented aseptically to the scrubbed person.

Each prosthesis is supplied with a label for attachment of pertinent data to the patient's record and a package insert data sheet giving resterilization instructions and other details relating to the professional use of this prosthesis.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

CUI Corporation warrants that reasonable care was used in the selection of materials and method of manufacture of its products, and will provide a replacement of this product if investigation by CUI indicates it was defective at time of shipment.

No other warranties are expressed or implied as to merchantability or fitness for a particular purpose.

CUI representatives, distributors or their representatives may not change any of the foregoing.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:	§	Case No. 00-CV-00005-DT
	§	(Settlement Facility Matters)
DOW CORNING CORPORATION,	§	
	§	HON. DENISE PAGE HOOD
REORGANIZED DEBTOR	§	
	§	

ESTIMATE OF TIME, EXHIBITS AND WITNESSES REQUIRED FOR HEARING ON MOTION OF DOW CORNING CORPORATION FOR A DETERMINATION THAT TISSUE EXPANDERS DO NOT CONSTITUTE BREAST IMPLANTS FOR PURPOSES OF ELIGIBILITY FOR SETTLEMENT BENEFITS UNDER THE DOW CORNING AMENDED JOINT PLAN OF REORGANIZATION

Pursuant to paragraph 2(E) of the Fourth Amended Case Management and Administrative Order entered by the Court on November 1, 2001, the Reorganized Debtor estimates its hearing requirements on the MOTION OF DOW CORNING CORPORATION FOR A DETERMINATION THAT TISSUE EXPANDERS DO NOT CONSTITUTE BREAST IMPLANTS FOR PURPOSES OF ELIGIBILITY FOR SETTLEMENT BENEFITS UNDER THE DOW CORNING AMENDED JOINT PLAN OF REORGANIZATION:

Hearing Time:	☐ < 30 min.	■ 30-60 min.	☐ > 60 min.
No. of Witnesses:	■ 0	☐ 1-5	☐ > 5
No. of Exhibits:	■ 0	☐ 1-5	☐ > 5
Importance of Matter:[1]	■ A	☐ B	☐ C

The Reorganized Debtor reserves the right to modify this Estimate of Time, Exhibits and Witnesses, if necessary, as further discovery takes place.

Respectfully submitted this 19th day of July 2004.

THE FEINBERG GROUP, LLP

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Detroit, MI 48207-3192
Tel.: 313-446-1530
Fax: 313-259-0450

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[1] **A: Crucial that it be heard on the date fixed;**
B: Prefer matter be heard, but accommodations can be made; and
C: Matter can wait

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE:	§	**CASE NO. 00-CV-00005-DT**
	§	**(Settlement Facility Matters)**
DOW CORNING CORPORATION,	§	
	§	**HON. DENISE PAGE HOOD**
REORGANIZED DEBTOR	§	

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2004 a true and correct copy of the below listed pleading was served via overnight delivery and either e-mail or telecopy upon the parties listed below.

1. MOTION OF DOW CORNING CORPORATION FOR A DETERMINATION THAT TISSUE EXPANDERS DO NOT CONSTITUTE BREAST IMPLANTS FOR PURPOSES OF ELIGIBILITY FOR SETTLEMENT BENEFITS UNDER THE DOW CORNING AMENDED JOINT PLAN OF REORGANIZATION.

THE FEINBERG GROUP, LLP

By: _____
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