(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 April 2003 (03.04.2003)

PCT

(10) International Publication Number
WO 03/026537 A1

(51) International Patent Classification[7]: A61F 2/12

(21) International Application Number: PCT/IL02/00776

(22) International Filing Date:
19 September 2002 (19.09.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
145576 24 September 2001 (24.09.2001) IL

(71) Applicants and
(72) Inventors: **WEINBERGER, Avishai** [IL/IL]; 13A Arlozorov Street, 52481 Ramat-Gan (IL). **TUCKER, Revital** [IL/IL]; 1B Hazohar Street, 62507 Tel-Aviv (IL).

(74) Agent: **FREIMANN, Daniel**; P.O. Box 29814, 61297 Tel-Aviv (IL).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

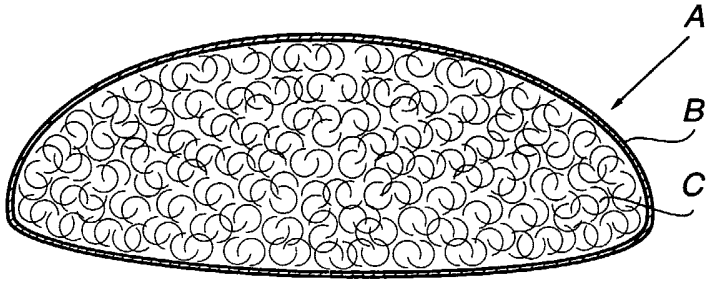
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/026537 A1

(54) Title: BREAST PROSTHESIS FILLED WITH FIBERS



(57) Abstract: A prosthesis for physical implant (A), comprising an outer envelope (B) and a filler substance that consists of a fibrous material (C). The density of the fibrous material (C) may be uniformor may vary. Preferably, the outer envelope (B) consists of rough surface silicone.

BREAST PROSTHESIS FILLED WITH FIBERS

BACKGROUND OF THE INVENTION

The present invention relates to prosthetic implants in general and prosthetic breast implants, in particular.

Breast implants, routinely in use today, characteristically have a life expectancy of up to 10-12 years. The fluid or gel implants currently in use have a tendency to 'leak', pervading neighboring tissue at a rate of approximately 1cc per year. Whereas a breast implant may rupture or leak any time after surgery the incidental rate is approximately 5% at five years increasing dramatically as the implant ages achieving a rupture rate of nearly 70% by approximately 10 years. Since most recipients have two implants, the incidence of leakage or rupture is compounded for each recipient so that nearly one in four women may require additional surgery due to complications within five years of receiving implants and three out of four women may required additional surgery by 10 years. Implant rupture or leakage can be due to an injury or just normal wear – even the pressure of a mammogram can contribute to implant rupture. Plastic surgeons usually recommend the removal of a ruptured implant even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissue. Saline implants have been known to become infected and leak, often causing infection in surrounding tissues.

Aside from the known risks associated with surgery, the repeated corrective surgeries to improve or repair the damaged prosthesis may additionally result in an unsatisfactory cosmetic outcome.

From another angle, it is well known that the female breasts tend to "sag" with age (with or without a prosthetic implant). Prosthetic implants widely in use today, are relatively heavy and difficult for the breast skin and tissue to bear – causing the breast tissue to thin and shrink. After a relatively short period of time the breast begins to "sag", which in turn causes the skin to stretch, becoming thinner. The thinner the skin becomes the easier it becomes to physically and visibly discern the implant. Sometimes the skin shows evidence of 'waves' particularly in saline solution implants, but also in silicone gel and sometimes in cohesive implants.

Another deficiency of conventional breast implants is that they are non-receptive to x-ray and ultra-sound mammary examination, periodical examinations recognized as essential to women's health. Silicone breast implants are known to be associated with calcium deposits in the breast. These calcium deposits can make it even more difficult to obtain a clear mammogram and can be mistaken for possible cancer (necessitating additional surgery or biopsy). Although the calcium deposits do not appear to be harmful, they can be indicative of a nearby cancer. Therefore, the presence of silicone implants may make it difficult to distinguish between the predictable effects of the implant and actual evidence of cancer.

It is, therefore, the general object of the invention to overcome these and other deficiencies common to conventional breast implants.

It is a further object of the present invention to provide a lighter breast implant, such that the breast can withstand the weight of the implant for a longer period of time, thereby prolonging the attractive cosmetic effect thereof.

It is a further object of the present invention to achieve a stable breast implant design that will not 'wave'.

It is a further object of the present invention to prevent any kind of 'leakage' and subsequent penetration of body tissues.

It is yet a further object of the invention that the breast implant will not interfere with x-ray and mammogram examinations.

SUMMARY OF THE INVENTION

A prosthesis for physical implant, comprising an outer envelope and a filler of a yieldable non-liquid substance.

Preferably, the filler substance will consist of a fibrous material, e.g. cotton. The density of the fibrous material may be uniform, or may vary with respect to a different location.

Preferably the outer envelope will be of rough surface silicone.

BRIEF DESCRIPTION OF THE DRAWINGS:

These and additional constructional features and advantages of the invention will become readily understood in the light of the ensuing description of a preferred

embodiment thereof, given by way of example only with reference to the accompanying drawings, wherein –

Fig. 1 is a perspective view of a fiber filled breast implant prosthesis;

Fig. 2 is a top view of the implant prosthesis of Fig. 1;

Fig. 3 is a side view of the implant prosthesis of Fig. 1; and

Fig. 4 is a schematic cross-section of the breast implant prosthesis of Fig. 1;

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

As shown in Figs. 1-3, the prosthesis generally designated A comprises an outer envelope B of rough surface silicone, which may be of the conventional type commonly used in prevailing prosthetic implants.

Unlike the conventional implants, the envelope B is filled with a fibrous material C, preferably of cotton or synthetic fibers such as Dacron™, or Gortex™ (the latter two are currently widely used for surgical stitching procedures); however, any other fibrous material of similar character to those noted above may be employed.

The silicone envelope B is filled with the fiber content whereby the filling retains a uniform texture and density, with a flexible propensity to return to the conscripting shape of the encasing envelope.

The method employed for filling the envelope B is by encasing or "trapping" various sized fibers C or fiber aggregates. Envelope B is seamlessly and hermetically sealed to prevent direct contact with body tissue.

The 'solid' nature of the fiber implant provides a solution to the problem of 'leakage' penetrating surrounding tissue, a problem commonly associated with conventional breast implants, and will offer a greater 'lifespan' thereby diminishing the need for replacement surgery at irregular and close intervals.

The dense fibers also provide a solution to breast x-ray and mammogram examinations, since the cotton, Gortex™ , Dacron™, and similar fibers are radiolucent.

The fiber filling has a specific gravity much lower than 1gr/cm^3 and will therefore virtually eliminate the problem of 'sagging' that plagues both the natural as well as the conventional saline water or other liquid substances filled implanted breasts. The unattractive 'wavy' appearance will disappear in most if not all implants due to the especially light yet dense composition of the encased prostheses.

The fiber implants will retain a structural integrity and will provide strength and stability over significantly longer periods of time, precluding the necessity of repetitive cosmetic surgeries.

The fiber implant is virtually maintenance free and has the quality of reproducing a tactile response similar to breast tissue – providing additional attractive incentive for use as a preferred breast prosthesis for implant.

Fiber fillings also afford the unique ability to be prepared as layers with varying degrees of flexibility or firmness. This can be achieved by fusing or otherwise binding non-homogeneous layers of filling each comprised of loose, bulk, or aggregated fibers of differing strength, density, length, etc. – all with a view of achieving the optimal result for the individual patient.

Surgeons will be able to order tailored implants manufactured to order according to specifications such as exact dimensions, shape, size, flexibility, weight, and other parameters.

It has thus been established that the invention as herein disclosed, provides for an alternative to the prevailing composition of implants in general and breast implants, in particular. The solid/non-fluid components of the implant are lightweight, shaped, elastic, long lasting and do not interfere with x-ray and mammogram examinations.

It should be appreciated that the present invention is capable of being applied in the form of a variety of embodiments, only one of which has been illustrated and described above. The invention may be embodied in other forms without departing from its spirit or essential characteristics. The described embodiment is to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes, which come within the meaning and range of equivalency of the claims, are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A prosthesis for physical implant (A), comprising an outer envelope (B) and a filler, characterized in that the filler comprises a yieldable non-liquid substance (C).
2. The implant as claimed in Claim 1 being a breast prosthesis.
3. The implant of Claim 1 the substance comprises a fibrous material.
4. The implant as claimed in Claim 3 wherein the fibrous material comprises cotton fibers.
5. The implant as claimed in Claim 3 wherein the fibrous material comprises synthetic fibers.
6. The implant as claimed in Claim 3 wherein the fibers are aggregated.
7. The implant as claimed in Claim 3 wherein the fibers are disbursed in bulk form.
8. The implant as claimed in Claim 3 wherein the fibers are evenly disbursed.
9. The implant as claimed in Claim 3 wherein the fibers are of a variable density.
10. The implant as claimed in Claim 3 wherein the fibers are layered.
11. The implant as claimed in Claim 3 wherein the fibers are shaped.
12. The implant as claimed in Claim 3 wherein the fibers are fused.
13. The implant as claimed in Claim 3 wherein the fibers are bonded.
14. The implant as claimed in Claim 1 wherein the envelope has a thin non-permeable, silicone.
15. The implant as claimed in Claim 1 wherein the envelope has a rough surface.

FIG. 1

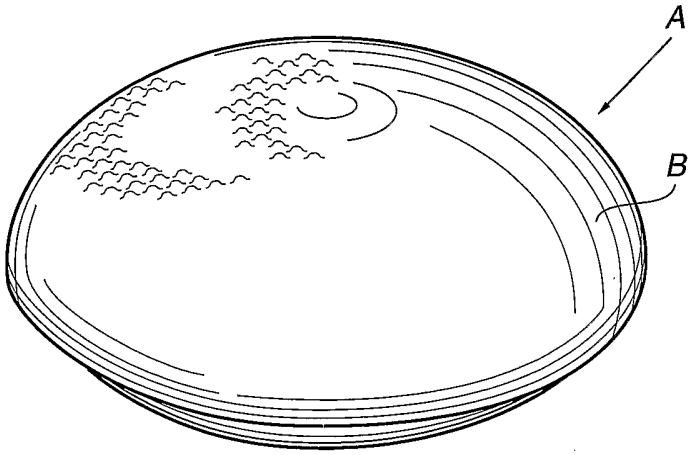


FIG. 2

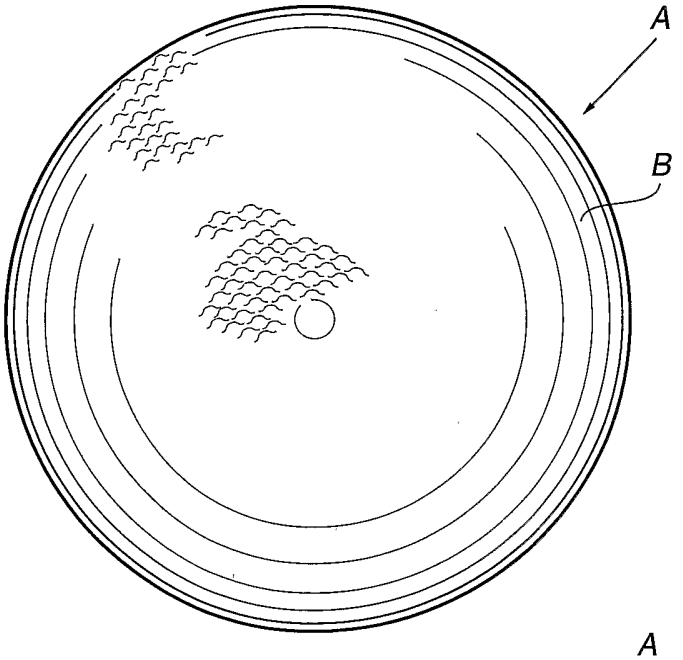
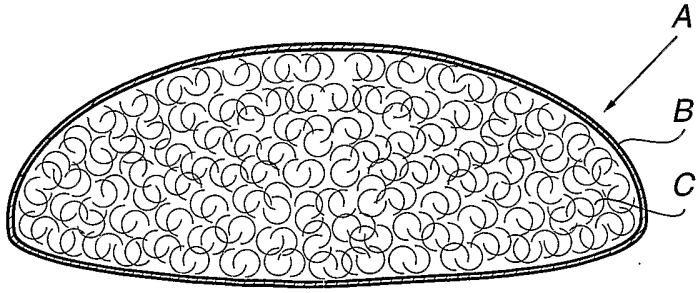


FIG. 3

FIG. 4



INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 02/00776

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 33771 A (JOHNSON JEFFERY W ;JOHNSON GERALD W (US); JOHNSON LANA LEA (US)) 15 June 2000 (2000-06-15) page 11, paragraph 3; claims 4,5; figures page 23, paragraph 2	1-9,11, 14
A	---	15
X	US 5 545 217 A (OFFRAY DENISE A ET AL) 13 August 1996 (1996-08-13) column 3, line 45 - line 60; claim 2; figures	1-3,5,6, 9-11,15

X	US 5 171 269 A (BARK JEFFREY E) 15 December 1992 (1992-12-15) column 2, line 13 - line 14; figures column 2, line 44 - line 55 column 3, line 1 - line 4	1-3,5-8, 11,14,16

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 January 2003	30/01/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Neumann, E

INTERNATIONAL SEARCH REPORT

Inter al Application No
PCT/IL 02/00776

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 676 698 A (JANZEN ERNST ET AL) 14 October 1997 (1997-10-14) column 4, line 24 - line 27; claims 3,16; figures	1-3,8, 12-14
X	US 5 961 552 A (TRINTER STEPHEN M ET AL) 5 October 1999 (1999-10-05) column 5, line 64 -column 6, line 6; claim 2; figures column 8, line 26 - line 48	1-3,5-8, 11,15

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ›nal Application No
PCT/IL 02/00776

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0033771 A	15-06-2000	AU 2477300 A	26-06-2000
		WO 0033771 A2	15-06-2000
US 5545217 A	13-08-1996	AU 690449 B2	23-04-1998
		AU 5385796 A	07-11-1996
		CA 2218497 A1	24-10-1996
		EP 0821575 A1	04-02-1998
		IL 117707 A	31-12-1999
		JP 11503652 T	30-03-1999
		WO 9632908 A1	24-10-1996
US 5171269 A	15-12-1992	NONE	
US 5676698 A	14-10-1997	AT 199311 T	15-03-2001
		AU 698087 B2	22-10-1998
		AU 7685694 A	27-03-1995
		BR 9407419 A	12-11-1996
		CA 2170753 A1	16-03-1995
		CN 1133554 A	16-10-1996
		DE 69426775 D1	05-04-2001
		DE 69426775 T2	13-09-2001
		EP 0717607 A1	26-06-1996
		JP 9502371 T	11-03-1997
		WO 9507057 A1	16-03-1995
		US 5922024 A	13-07-1999
US 5961552 A	05-10-1999	NONE	