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(54) Title: POST-LUMPECTOMY BREAST IMPLANT

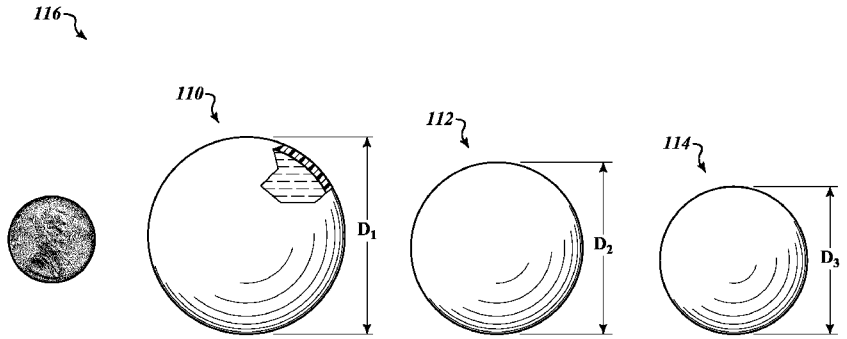

FIG.2

(57) Abstract: A post-lumpectomy breast implant can include a spherical outer shell comprising a medical-grade silicone and an inner chamber within the outer shell filled with a medical-grade silicone gel, the spherical outer shell and the inner chamber having a total volume of less than 100cc.

POST-LUMPECTOMY BREAST IMPLANT

BACKGROUND

Technical Field

The present disclosure relates generally to breast implants, and more specifically to breast implants for post-lumpectomy implantation.

Description of the Related Art

Breast implants are often used to reconstruct a patient's breast or breasts after surgery. For example, a diagnosed breast cancer patient can have breast tissue including cancerous tissue removed, or a patient identified as being at a high-risk for developing breast cancer can have breast tissue removed. In either case, the patient may desire reconstructive surgery. A variety of breast implants are available to such patients. A variety of breast implants are also available to patients seeking cosmetic breast augmentation.

BRIEF SUMMARY

A post-lumpectomy breast implant may be summarized as including a spherical outer shell comprising a medical-grade silicone and an inner chamber within the outer shell filled with a medical-grade silicone gel, the spherical outer shell and the inner chamber having a total volume of less than 100cc.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Figure 1 illustrates a cross-sectional view of a post-lumpectomy breast implant, according to one or more illustrated embodiments.

Figure 2 illustrates a kit of post-lumpectomy breast implants, according to one or more illustrated embodiments.

DETAILED DESCRIPTION

Various types of breast implants are currently commercially available. For example, saline breast implants include an outer silicone shell filled with sterile saline. Saline breast implants can be relatively safe because if they leak, the saline can be easily absorbed and expelled by the human body. Silicone breast implants include an outer silicone shell filled with a silicone gel. Silicone breast implants are often considered to provide a more natural feel

than saline breast implants. Form-stable breast implants, sometimes referred to as "gummy bear breast implants," include an outer silicone shell filled with a thicker silicone gel than other silicone breast implants. Form-stable breast implants can be firmer than other breast implants, and can allow breast implants to be manufactured in a greater variety of specifically contoured, stable shapes. Form-stable breast implants can be less likely to break than other breast implants, and can maintain their shape even if the outer silicone shell breaks.

Surgical procedures available to breast cancer patients, patients at a high risk for developing breast cancer, or other patients include mastectomy, wherein the whole breast is removed, quadrantectomy, wherein a quarter of the breast is removed, and lumpectomy, wherein a small part of the breast is removed. As used herein, a "lumpectomy" can include the removal of any small portion of a breast, and includes a biopsy. Reconstructive surgery is often performed for patients who have undergone a mastectomy, but generally is not performed for patients who have undergone a lumpectomy. Patients who have undergone a lumpectomy often choose to live with the relatively small resulting deformations (relative to deformations resulting, e.g., from a mastectomy), rather than undergo further surgical procedure(s).

Thus, breast implants designed for reconstructive applications are typically shaped and sized to replace an entire human breast or a large portion of a human breast, rather than to replace a relatively small portion of a breast removed during a lumpectomy. Similarly, breast implants designed for cosmetic surgical applications are typically shaped and sized to uniformly increase the size of a natural human breast, rather than to occupy a relatively localized portion of a human breast. Thus, typical breast implants now commercially available are not suitable for reconstructive use with lumpectomy patients.

Lack of options for suitable commercially available implants may deter lumpectomy patients from undergoing reconstructive surgery after their lumpectomy, and may deter physicians from recommending the same. Resulting lack of patient interest may in turn deter breast implant manufacturers from developing, producing, and marketing such implants. Whatever the reasons, the medical reality is that lumpectomy patients typically do not undergo reconstructive surgery after having their lumpectomy. Thus, this disclosure relates to post-lumpectomy breast implants for patients who have undergone a lumpectomy and desire reconstructive surgery.

Figure 1 illustrates a cross-sectional view of one embodiment of a post-lumpectomy breast implant 100. Breast implant 100 includes an outer sac or shell 102 made of a medical grade silicone elastomer and an interior open space or chamber 104 filled with a medical grade clear silicone gel. The breast implant 100 can be pre-filled, that is, the chamber 104 can be filled by a manufacturer prior to the implant being shipped to a physician. In some cases, the breast implant 100 can comprise only, or consist of, the outer shell 102 and the inner chamber 104 filled with the silicone gel. The breast implant 100 can be a single-walled implant 100, and can be elastically incompressible. In other embodiments, the breast implant 100 can include any of the suitable materials and features described herein. The breast implant 100 is spherical, i.e., the outer shell 102 is spherical and the inner chamber 104 is spherical. The breast implant 100 is also relatively small compared to many commercially available breast implants. For example, the breast implant 100 can have a volume less than 100 cubic centimeters ("cc" or "ml") or a diameter D less than about 5.75 cm. The breast implant 100 can be used in reconstructive surgeries for post-lumpectomy patients.

Figure 2 illustrates three different post-lumpectomy breast implants 110, 112, and 114. Breast implants 110, 112, and 114 are the same as breast implant 100 except for their volumes, and breast implant 110 is illustrated in a partial cut-away view to show that breast implant 110 can have a structure matching that of breast implant 100. Figure 2 illustrates that the breast implants described herein can have a variety of different volumes, such as volumes ranging from 25cc to 95cc. For example, the breast implants described herein can have a volume less than 100cc, 95cc, 90cc, 85cc, 80cc, 75cc, 70cc, 65cc, 60cc, 55cc, 50cc, 45cc, 40cc, 35cc, or 30cc, and/or greater than 20cc, 25cc, 30cc, 35cc, 40cc, 45cc, 50cc, 55cc, 60cc, 65cc, 70cc, 75cc, 80cc, 85cc, or 90cc. The breast implants described herein can be generally spherical and have a diameter D less than 5.75 cm, 5.50 cm, 5.25 cm, 5.00 cm, 4.75 cm, 4.50 cm, 4.25 cm, 4.00 cm, or 3.75 cm, and/or greater than 3.50 cm, 3.75 cm, 4.00 cm, 4.25 cm, 4.50 cm, 4.75 cm, 5.00 cm, 5.25 cm, or 5.50 cm. Figure 2 also illustrates a penny for a possible example of scale.

Figure 2 also illustrates a kit 116 comprising multiple breast implants 110, 112, and 114 having different volumes and hence different diameters D_1, D_2, D_3. The kit 116 can include any suitable number of breast implants, which can have any suitable volumes. For example, the kit 116 can include a plurality of breast implants each having a different volume, the volume

of each breast implant in the kit differing from the volume of the others by at least 5cc, or at least 10cc, or at least 15cc. In some embodiments, the kit 116 may include a plurality of post-lumpectomy breast implants having different volumes within the range of 25cc to 95cc, or having different diameters within a range of 3.50 cm to 5.75 cm.

A method of treating a patient can include a physician meeting and consulting with the patient and determining that the patient is a suitable candidate for a lumpectomy. The method can also include performing the lumpectomy, thereby creating a cavity or pocket in one of the patient's breasts into which a post-lumpectomy breast implant can later be implanted. The method can also include a physician (either the same physician who performed the lumpectomy or a different physician) obtaining a kit of potentially suitable ("candidate") pre-filled post-lumpectomy breast implants, each having a different volume, and respective breast implant sizers. A breast implant sizer can include a device having a shape and volume matching that of a respective candidate post-lumpectomy breast implant, and can be temporarily inserted intraoperatively into the pocket in the patient's breast to evaluate the effect of the respective candidate breast implant on the patient's breast.

The method can also include the physician using one or more breast implant sizers of the kit to determine an appropriate size of a post-lumpectomy breast implant for use in reconstructive surgery of the patient's breast. The method can also include the physician making an initial estimate of a volume of the pocket or of a volume of a suitable post-lumpectomy breast implant, and selecting a corresponding breast implant sizer for evaluation. The method can also include the physician using the selected breast implant sizer to evaluate the effect of a respective candidate breast implant on the patient's breast. If the physician determines that the candidate breast implant is suitable for use, then the physician can proceed to implant the suitable candidate breast implant in the pocket in the patient's breast and complete the procedure. If the physician determines that the candidate breast implant is not suitable, e.g., that a larger or a smaller breast implant would be more suitable, then the physician can select another breast implant sizer accordingly and return to using the selected breast implant sizer to evaluate the suitability of a respective candidate breast implant. The physician can repeat this process until either a suitable post-lumpectomy breast implant is identified or the physician concludes that the patient is not suitable for reconstructive surgery with a post-lumpectomy breast implant.

Once a suitable post-lumpectomy breast implant is identified by the physician, the physician can implant the identified breast implant within the pocket in the patient's breast, and the physician can complete the operation. The method can include performing a lumpectomy and reconstructing the patient's breast using a post-lumpectomy breast implant in a single procedure, which can be performed in a single day. The post-lumpectomy breast implants described herein can be fabricated from silicone materials and therefore can be not bio-degradable and can prevent or resist tissue ingrowth and vascularization into the breast implant. The post-lumpectomy breast implants described herein can therefore be considered permanent and can be easily removed at a later date if removal is medically called for or otherwise desired by the patient. The post-lumpectomy breast implants described herein can also allow a physician to completely and snugly fill the pocket in the patient's breast, thereby providing pressure sufficient to prevent or reduce seroma or hematoma formation therein. The post-lumpectomy breast implants described herein can also be radiopaque, which can facilitate a physician's distinguishing between native tissue and the breast implant under x-ray.

In other embodiments, the post-lumpectomy breast implants described herein can also be used as testicular implants.

U.S. patent application Serial No. 62/248,906, filed October 30, 2015, is hereby incorporated herein by reference in its entirety.

Aspects and features of the various embodiments described above can be combined to provide further embodiments. These and other changes can be made to the embodiments in light of the above-detailed description. In general, in the following claims, the terms used should not be construed to limit the claims to the specific embodiments disclosed in the specification and the claims, but should be construed to include all possible embodiments along with the full scope of equivalents to which such claims are entitled. Accordingly, the claims are not limited by the disclosure.

CLAIMS

1. A post-lumpectomy breast implant, comprising:

a spherical outer shell comprising a medical-grade silicone; and

an inner chamber within the outer shell filled with a medical-grade silicone gel;

the spherical outer shell and the inner chamber having a total volume of less than 100cc.

2. A post-lumpectomy breast implant, consisting essentially of:

a spherical outer shell comprising a medical-grade silicone; and

an inner chamber within the outer shell filled with a medical-grade silicone gel;

the spherical outer shell and the inner chamber having a total volume of less than 100cc.

3. A post-lumpectomy breast implant, consisting of:

a spherical outer shell comprising a medical-grade silicone; and

an inner chamber within the outer shell filled with a medical-grade silicone gel;

the spherical outer shell and the inner chamber having a total volume of less than 100cc.

4. A method comprising, in a single medical procedure:

performing a lumpectomy on a breast of a patient; and

reconstructing the breast of the patient using a post-lumpectomy breast implant including:

a spherical outer shell comprising a medical-grade silicone; and

an inner chamber within the outer shell filled with a medical-grade silicone gel;

the spherical outer shell and the inner chamber having a total volume of less than 100cc.

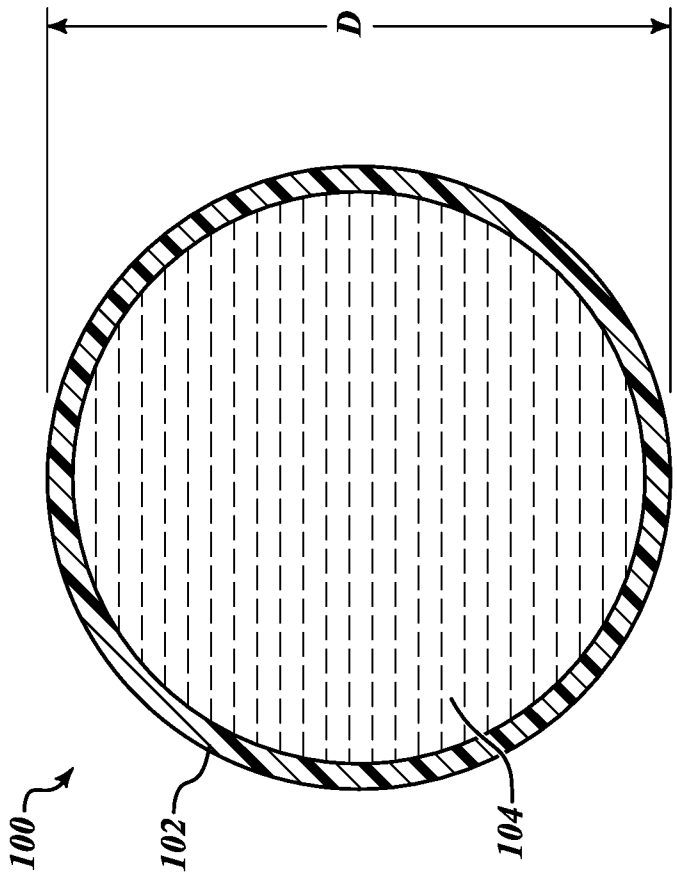

FIG.1

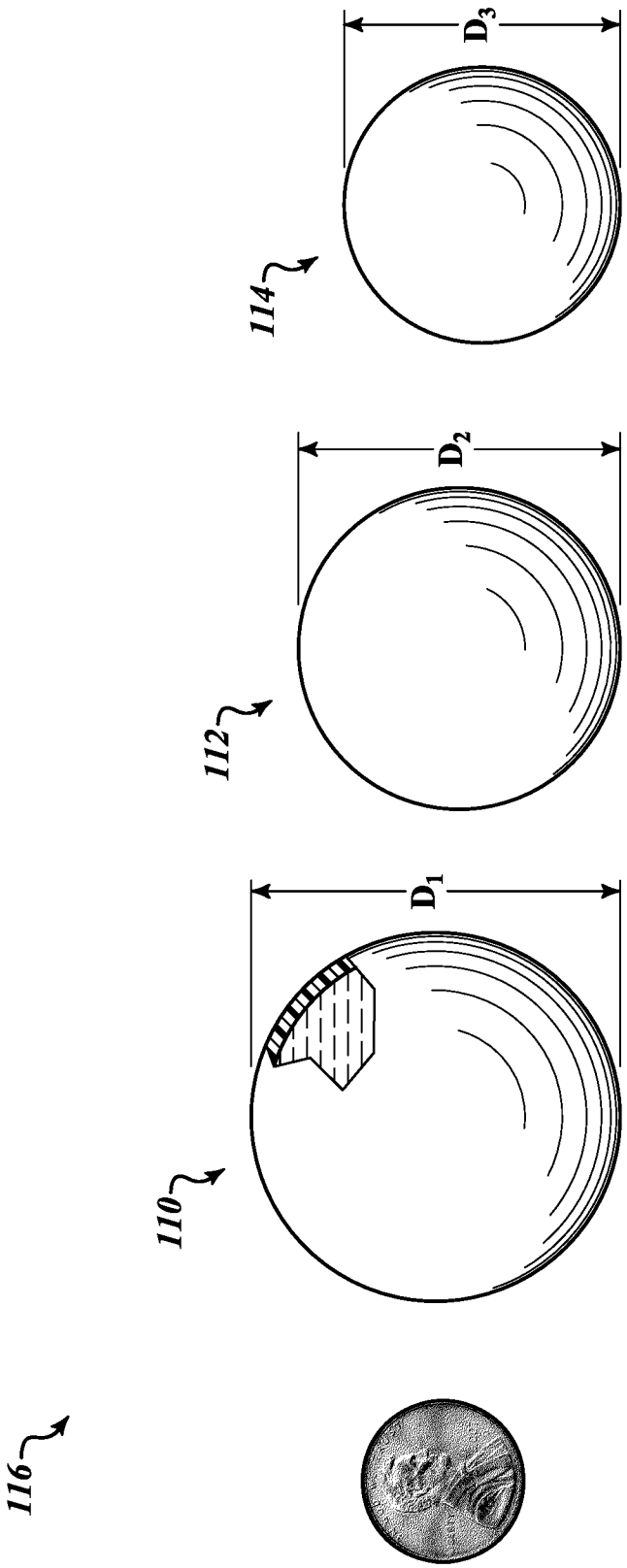

FIG.2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/058931

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 4
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 4 pertains to a method for treatment of the human body by surgery and thus relates to a subject matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/058931

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/12(2006.01)i, A61L 27/02(2006.01)i

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)
A61F 2/12; A61F 2/02; A61L 27/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: breast implant, lumpectomy, outer shell, inner chamber, silicone, silicone gel

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006-0282164 A1 (SEASTROM, J.) 14 December 2006 See paragraphs [0035]-[0068]; claims 1-24; figures 1-12.	1-3
X	US 5922024 A (JANZEN, E. et al.) 13 July 1999 See column 2, line 56 - column 7, line 7; claims 1-11; figure 1.	1-3
A	US 2014-0100656 A1 (INNOVATIVE BIOLOGICS LLC) 10 April 2014 See the whole document.	1-3
A	US 8668737 B2 (CORBITT, JR., J. D.) 11 March 2014 See the whole document.	1-3
A	US 2013-0226296 A1 (TRANSMED7, LLC) 29 August 2013 See the whole document.	1-3

☐ Further documents are listed in the continuation of Box C.

☒ See patent family 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 application or patent 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
06 February 2017 (06.02.2017)	**07 February 2017 (07.02.2017)**

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2016/058931

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 9039763 B2	26/05/2015
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