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(54) **Title:** ASYMMETRICAL DUAL PROXIMAL END INSERTION BELLOW

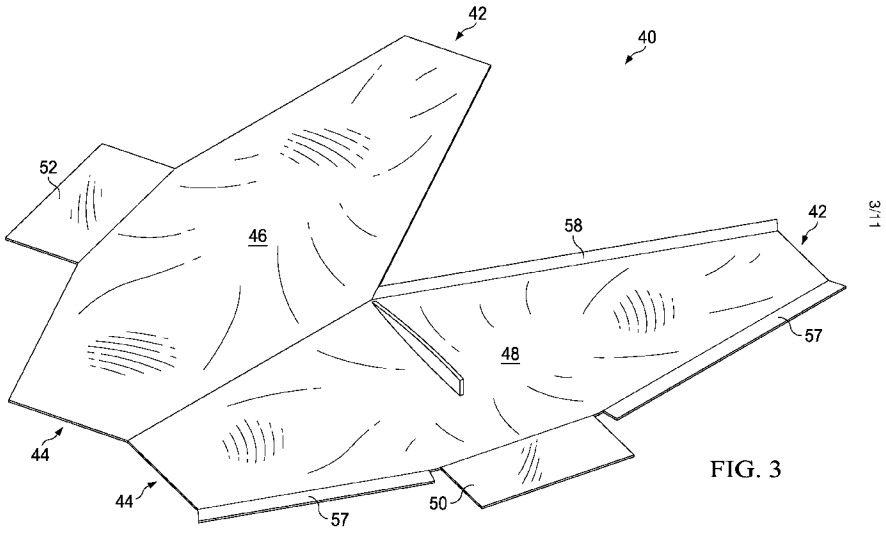

FIG. 3

(57) **Abstract:** An apparatus and method for inserting prosthesis implants into a patient pocket. The apparatus has three openings including a prosthesis opening, a large proximal opening, and a small proximal opening. The apparatus prevents infection; eases insertion and placement; and reduces complications. In use, the bellow is placed through the patient incision while allowing the bellow to be manipulated to force the prosthesis into a surgical pocket of a patient. Then the bellow is rotated so the distal end becomes the proximal end and inserted into the second incision while allowing the bellow to be manipulated to force the prosthesis into the second pocket.

[Continued on next page]

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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
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PATENT APPLICATION

TITLE: Asymmetrical Dual Proximal End Insertion Bellow

CROSS-REFERENCE TO RELATED APPLICATIONS

A claim of priority is made in this application based on Non-Provisional Application Ser. No. 15/179,983, filed June 11, 2016, which claims priority to provisional application Ser. No. 62/348,338 entitled "Opposing Proximal Insertion Ends Implant Devices" filed on June 10, 2016, the disclosures of which is hereby incorporated by reference in its entirety.

BACKGROUND — FIELD OF INVENTION

The invention is related to the apparatus and method of safely inserting two prostheses into a human body.

BACKGROUND OF THE INVENTION

The present invention is a useful and novel apparatus for advancing breast implant surgery procedures to improve surgical sterility.

Breast implants are a manufactured prosthesis used in cosmetic and reconstructive surgery. A breast implant is gelatinous with an outer casing or membrane containing a fluid such as saline or silicone.

Only about thirty percent (30%) of breast implant procedures today use an insertion device. An insertion device improves both the surgery and the patient outcome. Without an insertion device, the surgeon makes the incision, creates a pocket for the implant, retracts the incision and then manually pushes the implant into the pocket.

Different than a silicone implant, a saline implant is inserted into the pocket in an empty configuration. Once placed in the pocket, the surgeon takes the additional step of filling the membrane with a saline solution using a tube.

The incision is made in one of four places: in the armpit, in the breast fold, in the navel, or around the areola. Except for the navel insertion, one incision is made for each implant. It is preferable the incision in the patient be as short as possible. Shorter incisions are less unsightly. This goal of a shorter incision is easier to accomplish with a saline implant. A saline implant is relatively easy to insert through a short incision, as the bladder is unfilled and therefore small in size as it passes through the incision. For these inflatable implants, the surgeon rolls up the implant like a cigar and pushes it through the incision and into the pocket. In contrast, silicone implants are prefilled resulting in a more difficult and complications-susceptible operation. For these pre-filled implants, the procedure requires a larger incision length. By using an insertion device, the surgeon can assure the incision is not stretched during the operation.

After the initial incisions, the surgeon dissects a path through the tissue to the desired destination of the implant. Once that path has been created, a pocket is created for the implant superficial or deep to the pectoralis major muscle. The pocket may be formed in one of two places under the breast: subglandular (between the breast tissue and pectoralis major muscle) or subpectoral (under the pectoralis major muscle). Subglandular places the prosthesis directly behind the

mammary gland and in front of the muscle. Subpectoral places the implant partially under the pectoralis major muscle. Due to the structure of the pectoralis major muscle, a portion of the implant is not covered by the muscle.

A secondary surgery is common for patients with breast implants. In particular, patients with breast implants may require surgery to change the placement (from subglandular to subpectoral or vice versa), correct palpable folding of the implant, remove a ruptured implant; treat infection, bleeding, breast pain, contracted scar tissue forming around the implant and collections of fluid around the implant. These additional surgeries have risks due to anesthesia, infection and bleeding. The overall complication rate is about 20% for silicone gel breast augmentation with the majority of re-operations related to implant rupture (leakage), bleeding or capsular contracture.

Cellulitis, a skin-based infection, occurs in 2%-4% of patients, with some surgeons reporting much higher rates, and is usually from the bacteria normally present on the skin. Symptoms of infection include fever, pain, swelling and redness. To reduce infection, surgeons give a single dose of antibiotics before the surgery, and use an antibiotic solution in the wound before implant placement. The antibiotic solution may double as the lubrication to allow easier insertion of the implant into the pocket. However, surgeons can bring the rate of infection down further by preventing the implant from touching the patient's skin.

The implant insertion devices heretofore known suffer from a number of disadvantages:

1. Requires the surgeon to resize the insertion device mid-operation to match two different implant sizes.
2. Relies on the correctly sized trimming by the surgeon. The implant company and insertion device company have no control over the surgeon. If the surgeon does not alter the device properly,

unsafe damaging pressure may be applied to the implant during the insertion process.

3. Distal end of the device is large enough for the implant to inadvertently slip out of the device resulting in skin bacteria transferring to the implant.
4. The high cost of current implant devices encourages re-use despite the manufacturer recommendation not to do so.

SUMMARY OF THE INVENTION

An invention, which meets the needs stated above, is a system and method to insert two prostheses into a patient with maximum sterility. The method allows the surgeon to use two different size implants with a single device where each proximal end of the device receives a different size implant.

Objects and Advantages

Accordingly, besides the objects and advantages of the system for a breast implant insertion device described above, several objects and advantages of the present invention are:

a) to provide a device with two proximal ends sized for different size implants;
b) to provide the means to further improve sterility;
c) to provide a device for a procedure using two different size implants;
d) to provide a simplified insertion method;
e) to provide the means to reduce anesthesia time;
f) to provide a device that does not have to be trimmed by the surgeon;
g) to provide a single device that fits all sizes of implants;

h) to provide an easier manipulation of the implant.

Further objects and advantages of this invention will become apparent from a consideration of the drawings and the ensuing description of the drawings.

DRAWING FIGURES

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present invention and together with the description, serve to explain the principles of this invention. In the figures:

FIG **1**: Top side perspective view of an asymmetrical bellow.

FIG **2**: Bottom view of an asymmetrical bellow.

FIG **3**: Top side perspective view of an asymmetrical bellow, unassembled.

FIG **4A**: Top view of an asymmetrical bellow, with a fold along the abutted edges.

FIG **4B**: Top view of an asymmetrical bellow showing the folding of the seal folds.

FIG **4C**: Top view of an asymmetrical bellow, internal tab placed through prosthesis opening.

FIG **4D**: Top view of an asymmetrical bellow, exterior tab folded over the prosthesis opening.

FIG **5**: Front perspective view of an asymmetrical bellow with an implant being inserted through the prosthesis opening.

FIG **6**: Side perspective view of adding lubricant to the small proximal end of the asymmetrical bellow.

FIG **7A:** Right side perspective view of a asymmetrical bellow with the large proximal end inserted into the patient's right incision.

FIG **7B:** Left side perspective view of a rotated asymmetrical bellow with the small proximal end inserted into the patient's left incision.

KEY TERMS

distal: the most distant portion from the point of attachment to the body

inferior: closer to the feet

lateral: a position substantially located in any side of the longitudinal position of a patient's supine position

longitudinal: a lengthwise, or the longest, direction related to the patient's supine position

proximal: the closest portion from the point of attachment to the body

superior: closer to the head of the body

REFERENCE NUMERALS IN DRAWINGS

10 patient

20 patient's incision, opening

22 patient's breast

24 patient's pocket

28 patient's skin tissue

30 prosthesis

32 breast implant, implant

40 bellow device, bellow, asymmetrical bellow

42 small proximal end, small proximal opening

44 large proximal end, large proximal opening

46 base fold

48 initial fold

50 exterior tab

52 internal tab

54 prosthesis opening

56 seal tucks

57 tab-side seal tuck

58 abutted-side seal tuck

60 lubricant

70 retractor

72 retractor handle

74 retractor handle proximal end

76 retractor proximal end lip

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to the drawings, in which like numerals represent like elements,

FIGURES 1 - 2

Figs. 1 – 2 identify individual elements of an assembled asymmetrical dual proximal end insertion bellow **40**.

Referring now to Fig. **1**, the top side perspective view of an asymmetrical bellow **40** manufactured with a sheet material such as plastic or a flexible, surgical-grade nylon. The plastic may be strengthened or reinforced with fibers. The asymmetrical bellow **40** may be clear, or semi-transparent, in color to allow observation of the prosthesis **30** moving from bellow **40** into the patient pocket **24**.

The bellow **40** has three openings: a small proximal opening **42** for inserting a range of smaller implants into the incision **20**; a large proximal opening **44** for insertion of a range of larger implants into the patient's incision **20**; and a prosthesis opening **54**, surrounded by an exterior tab **50** and an internal tab **52**, for inserting the prosthesis **30** into the asymmetrical bellow device **40**. Each end **42,44** is considered to be proximal because the device **40** is rotated during surgery so that each end **42,44** is sequentially inserted in the patient's left and right opening **20**. Fig. 1 shows the internal tab **52** pushed through the prosthesis opening **54**, to prevent the implant from passing to the outside the bellow device **40**, and the exterior tab **50** folded over the prosthesis opening **54**. The exterior tab **50** may be folded and held in place by friction or attached by glue, adhesive, heat bond, surgical tape or other coupling mechanism. While Fig. 1 shows both tabs **50,52** folded into working position, the bellow exterior tab **50** and bellow internal tab **52** would initially be presented to the surgeon with both tabs **50, 52** outside of the bellow **40** and surrounding the prosthesis opening **54**. While the preferred embodiment shows different sized tabs **50,52** to distinguish the exterior tab **50** from the internal tab **52**, the tabs **50, 52** may be of the same size.

The asymmetrical bellow **40** is assembled using the seal tucks **56** which comprise two (2) tab-side seal tucks **57**, and one (1) abutted-side seal tuck **58**. In a preferred embodiment, the assembly may be done prior to packaging. In an alternate embodiment, the seal tucks **56** are sealed

to the base fold **46** by the patient's **10** operating team. See Fig. 4B for additional illustration of the assembly using the seal tucks **56**.

The bellow **40** prevents the breast implant **32** from touching the patient's skin tissue **28**, and prevents damage to the implant **32** during the implant **32** insertion. The asymmetrical bellow **40** may be manufactured to accommodate any breast implant **32** shape, volume, and diameter. Each proximal end **42,44** would be sized to deliver a different range of implant **32** sizes. The manufacturer may also require or suggest two specific skin incision **20** lengths to allow insertion of the implant through the bellow **40** into the incision **20**. The specifications take the burden off the surgeon to try to make shorter incisions **20**.

While the preferred embodiment of the asymmetrical dual proximal end insertion bellow would have each end **42,44** used in a single operation, the manufacturer may elect to ship a single asymmetrical device **40** for operations with the same size implants. In this latter embodiment, the surgeon would use one proximal end **42,44** for the insertion of two implants **32**.

Fig. 2 shows a bottom view of the manufactured version of the bellow **40** once the bellow fold **48** is folded over the base fold **46** along the abutted seam and the three seal tucks **56** are adhered. The manufactured bellow **40** comprises the initial fold **48** partially sealed on the periphery to the base fold **46** so that it leaves a small proximal opening **42**, a large proximal opening **44**, a bellow prosthesis opening **54**, a bellow exterior tab **50** and a bellow internal tab **52**. The large proximal end **44** is parallel to, and larger than, the device's **40** small proximal end **42**.

FIGURES 3 – 4D

Turning to Fig. 3, the illustration depicting a perspective view of an unassembled bellow device **40**. The asymmetrical bellow **40** form

comprises two simple, convex, irregular hexagons folds **46, 48** with opposing prosthesis insertion tabs **50, 52.** In a preferred embodiment the tabs **50,52** are located centrally and opposing the abutted sides of the manufactured bellow **40.** The tabs **50,52** may also be located in any position on the side opposing the assembled abutted sides. In a preferred embodiment, as shown in Figures 3 – 4D, the base fold **46** is manufactured abutted against the initial fold **48** along either edge opposing the tabbed side of the folds **46,48.** In a second embodiment the initial fold **48** and base fold **46** would be separately manufactured and assembled together at a later stage.

In the preferred embodiment, the bellow **40** would be folded along an abutted edge and manufactured with three seal tucks **56** along:

a. initial fold's **48** abutted-side edge from the abutment to the proximal end **42,44;**
b. initial fold's **48** tab-side edge from the exterior tab **50** to the small proximal end **42;**
c. initial fold's **48** tab-side edge from the exterior tab **50** to the large proximal end **44.**

In the second embodiment, the bellow **40** would be manufactured with separated initial fold **48** and base fold **46,** stacked over each other and assembled with four seal tucks **56** along:

a. initial fold's **48** abutted-side edge from the abutment to the small proximal end **42;**
b. initial fold's **48** abutted-side edge from the abutment to the large proximal end **44;**
c. initial fold's **48** tab-side edge from the exterior tab **50** to the small proximal end **42;**
d. initial fold's **48** tab-side edge from the exterior tab **50** to the large proximal end **44.**

The bellow seal tucks **56** may be folded over the opposing fold **46, 48** and attached by glue, adhesive, heat bond, surgical tape or other coupling mechanism.

In another embodiment, the seal tucks **56** may be replaced with a simple seam along the edges to bind the initial fold **48** and based fold **46** with glue, adhesive, heat bond, surgical tape or other coupling mechanism.

Figures 4A to 4D show the assembly of the asymmetrical bellow **40.** In Fig 4A, the pattern is folded along the abutted edge so that base fold **48** and initial fold **46** are stacked over each other with the tabs **50, 52** pointing in the same direction.

Then in Fig. 4B, the seal tucks **56** are folded over the opposing fold **46, 48** and sealed to the opposing fold **46, 48** with any desired manufacturing sealing technique.

With the breast implant **32** in place inside the asymmetrical bellow **40,** Fig. 4C, the internal tab **52** is pushed through the prosthesis opening **54.** The internal tab **52** prevents the implant **32** from inadvertently ejecting through the prosthesis opening **54** during the operation.

In Fig. 4D, with the internal tab **52** inside the prosthesis opening **54,** the exterior tab **50** may be pushed over the top surface of the opposing fold **46, 48.** The exterior tab **50** may be sealed to the opposing fold **46, 48** with surgical tape, heat seal, instant glue, or other forms of seals. The adhered seal **50** opposes the prosthesis opening **54** and joins the initial fold **48** and base fold **46.**

FIGURES 5 – 7B

As illustrated in Fig. 5, in the preferred embodiment a liquid lubricant **60** surrounds the breast implant **32** inside the bellow **40.** A coating of surgical lubricant **60** may be used on the inner surface of the asymmetrical bellow **40.** As an alternative, the bellow device **40**

may be provided with a coating that becomes slick when wet. In still another alterative, the prosthesis **30** may be provided with a slick surface, such as a surgical lubricant **60**. The surgeon also has the option of applying a lubricant **60** to the prosthesis **30** directly before inserting into the asymmetrical bellow **40**. The lubricant **60** may also act as an antibiotic solution.

After lubrication, the breast implant **32** is inserted into the bellow device **40** by the surgeon and nurse. To do so, the nurse opens the bellow prosthesis opening **54** by separating the tabs **50, 52**, and the surgeon slides the prosthesis **30** through the bellow prosthesis opening **54**. The team would then fold the internal tab **52** into the bellow prosthesis opening **54** to prevent the breast implant **32** from moving back out of the opening **54**. The exterior tab **50** may be left extended or folded over the opposing fold **46, 48**. If desired, the exterior tab **50** may be sealed to the opposing fold **46, 48**. In a preferred embodiment inserting the prosthesis **30** into the bellow device **40** would be completed prior to inserting the retractor **70** into the patient incision **20**. However, a surgeon could perform this step while the bellow **40** is inserted in the incision **20**.

In Fig. 6, the surgical team inserts lubricant **60** in the opposing opening **42,44** of the opening **42,44** inserted in the patient's incision **20**. The liquid lubricant **60** surrounds the breast implant **32** inside the bellow device **40**. An antibiotic solution may be used lubricant **60**.

Fig. 7A shows the patient **10** positioned in a supine position prior to an incision **20** being made in the patient's skin tissue **28**. In the figure, the incision **20** is cut in the inferior breast **22** crease. With the incision **20** opened, the surgeon then forms a pocket **24** in one of two places under the breast **22**: subglandular (between the breast **22** tissue and pectoralis muscle) or subpectoral (under the pectoralis muscle). The pocket **24** is sized to match the prosthesis **30**. By manipulating the retractor handle **72**, the retractor handle proximal

end **74** and the retractor proximal lip **76** are inserted into the incision **20** to both retract the incision **20** and hold the incision **20** open.

The retractor **70** assembly comprises a handle **72** located in the center, retractor handle proximal end **74**, and retractor handle proximal end lip **76**. The retractor **70** may have various shapes and sizes to match the particular application or surgeon preferences. The handle **72** of the retractor **70** is bent or angled on the ends relative to the intermediate portion. The proximal end **74** of the retractor **70** has a lip **76** that is angled relative to the end **74**. The retractor **70** is made of metal, such as stainless steel but may also be manufactured in a surgical plastic.

The retractor proximal end **74** is structured and arranged to be inserted through the incision **20** into a pocket **24** of a patient **10**. The proximal end lip **76** helps maintain the proximal end **74** of the retractor **70** beneath skin tissue **28** of a patient **10**.

The retractor **70** extends laterally from the asymmetrical bellow **40**, so as not to interfere with the surgeon manipulating the bellow **40**, with the proximal ends of the retractor **74** and proximal end lip **76** inserted into the incision **20** and located under the skin tissue **28** and moved to retract the incision **20**. The proximal end **42,44** of the bellow **40** may be lubricated with a lubricant **60** and inserted into the open incision **20**.

The asymmetrical bellow **40**, distal to the incision **20**, is squeezed and/or twisted to force the prosthesis **30** toward the proximal end **42,44** of the bellow device **40** and into the pocket **24**. The prosthesis **30** deforms to fit through the proximal opening **44**.

Once the prosthesis **30** is located inside the pocket **24**, the retractor **70** is removed from the incision **20**, followed by the bellow **40**. The incision **20** is then closed.

Finally, in Fig. 7B, showing a left-side of a patient, a retractor **70** is inserted in the second breast **22** incision **20** and moved to retract the incision **20**. The asymmetrical bellow **40** is then rotated so a new proximal end 42,44 is introduced to the incision **20** of the second breast **22**. This second proximal end **42,44** may be lubricated with a lubricant **60** and inserted into the open incision **20**.

The asymmetrical bellow **40**, distal to the incision **20**, is squeezed and/or twisted to force the prosthesis **30** toward the second proximal end **42,44** of the bellow device **40** and into the pocket **24**. The prosthesis **30** deforms to fit through the second proximal opening **42,44**.

Once the prosthesis **30** is located inside the pocket **24**, the retractor **70** is removed from the second incision **20**, followed by the bellow **40**. The incision **20** is then closed.

If the asymmetrical bellow 40 is designed for reuse, they are subjected to sterilization procedures. If the bellow 40 is designed for single use, they are disposed of. An advantage of the asymmetrical bellow **40** and method is that the implant **32** and distal openings **42,44** may be properly sized during manufacture with respect to each other so that the smallest breast implants **32** will fit through small proximal opening **42** and the larger range of implants **32** will be properly inserted through the large proximal opening **44**. This allows the proper pressure to be applied to each range of implants **32** as they deform through the proximal ends **42,44**.

The implant **32** is subject to damage if the implant **32** is mishandled. Possible mishandling includes subjecting the implant **32** to undue stresses or pressures, such as may be caused by attempting to squeeze the implant **32** through a proximal end **42** that is too small, and folding of the external silastic shell, internal fracture of the cohesive silicone gel. A surgeon may make an incision **20** in the patient **10** that is too small for the implant **32** and thus too much

force is required to squeeze the implant **32** into the pocket **24.** With this bellow device **40,** the implant **32** is protected from damage by the provision an adequate skin incision length and of the properly sized proximal end **44.** The major complication with implants **32** is capsular contracture thought to be due to sub-clinical infection. Sub-clinical infection is most likely caused by pushing the implant **32** through the skin incision **20,** dragging natural skin **28** bacteria (still present after proper skin **28** preparations) into the pocket **24** surgically created for the implant **32.** Use of this device **40** prevents the implant **32** from coming in contact with the skin tissue **28** during the insertion process.

Although the present disclosure and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the disclosure as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present disclosure. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

In the foregoing description, and the following claims, method steps and/or actions are described in a particular order for the purposes of illustration. It should be appreciated that in alternate embodiments,

the method steps and/or actions may be performed in a different order than that described. Additionally, the methods described above may be embodied in machine-executable instructions stored on one or more machine-readable mediums, such as disk drives, thumb drives or CD-ROMs. The instructions may be used to cause the machine (e.g., computer processor) programmed with the instructions to perform the method. Alternatively, the methods may be performed by a combination of hardware and software. While illustrative and presently preferred embodiments of the invention have been described in detail herein, it is to be understood that the inventive concepts may be otherwise variously embodied and employed, and that the appended claims are intended to be construed to include such variations, except as limited by the prior art.

Benefits, other advantages, and solutions to problems have been described herein with regard to specific embodiments. However, the advantages, associated benefits, specific solutions to problems, and any element(s) that may cause any benefit, advantage, or solution to occur or become more pronounced are not to be construed as critical, required, or essential features or elements of any or all the claims of the invention. As used herein, the terms “comprises”, “comprising”, or any other variation thereof, are intended to cover a non-exclusive inclusion, such that a process, method, article, or apparatus composed of a list of elements that may include other elements not expressly listed or inherent to such process, method, article, or apparatus.

ADVANTAGES

From the description above, a number of advantages become evident for the “Asymmetrical Dual Proximal End Insertion Bellow.” The present invention provides all new benefits for participating parties including manufacturers, patients and surgeons:

a) allows manufacturers to ship a single size bellow for all implant sizes;

b) allows patient's a lower risk of complications;

c) allows doctors to prevent contamination by skin bacteria, gross infection from using a proximal end twice, resulting in infection and/or capsular contracture;

d) allows doctors to eliminate the step of trimming the insertion device;

e) allows doctors to eliminate damage to the implant during the insertion process;

f) allows doctors a simplified insertion process;

g) speeds the implant insertion surgery.

CLAIMS

The invention claimed is:

1. An apparatus for inserting a prosthesis through an incision into a surgical pocket, comprising:
   a. a breast implant;
   b. a bellow comprising a bellow prosthesis opening, a small proximal opening to allow the smallest range of breast implants to exit and a large proximal opening to allow the largest range of breast implants to exit, the prosthesis opening surrounded by tabs, the bellow being semi-rigid and structured and arranged to receive the breast implant through the prosthesis opening, the bellow assembled with tab-side seal tucks and an abutted-side seal tuck;
   c. a retractor device, the retractor having a proximal end that is adjacent to the bellow proximal opening and are structured and arranged to engage an edge of a surgical pocket opening, the proximal end being fixed relative to the proximal end of the bellow.

2. An apparatus for inserting a prosthesis through an incision into a surgical pocket, comprising: a bellow formed of two simple, convex, irregular hexagons folds with opposing tabs; an initial fold abutted to a base fold along the sides opposing the tabs; the initial fold folded over the base fold along the abutted edge; an abutted-side seal tuck from the abutment to the proximal end; a tab-side seal tuck from the abutment to the small proximal end; a tab-side seal tuck from the abutment to the small proximal end;

whereby an asymmetrical bellow is formed with a bellow prosthesis opening, and two proximal openings.

3. An apparatus for inserting a prosthesis through an incision into a surgical pocket, comprising: an base fold of a simple, convex,

irregular hexagon with a tab; an initial fold of a simple, convex, irregular hexagon with a tab; the first fold stacked over the initial fold; an abutted-side seal tuck from the abutment to the small proximal end; an abutted-side seal tuck from the abutment to the small proximal end; a tab-side seal tuck from the abutment to the small proximal end; a tab-side seal tuck from the abutment to the small proximal end.

whereby an asymmetrical bellow is formed with a bellow prosthesis opening, and two proximal openings.

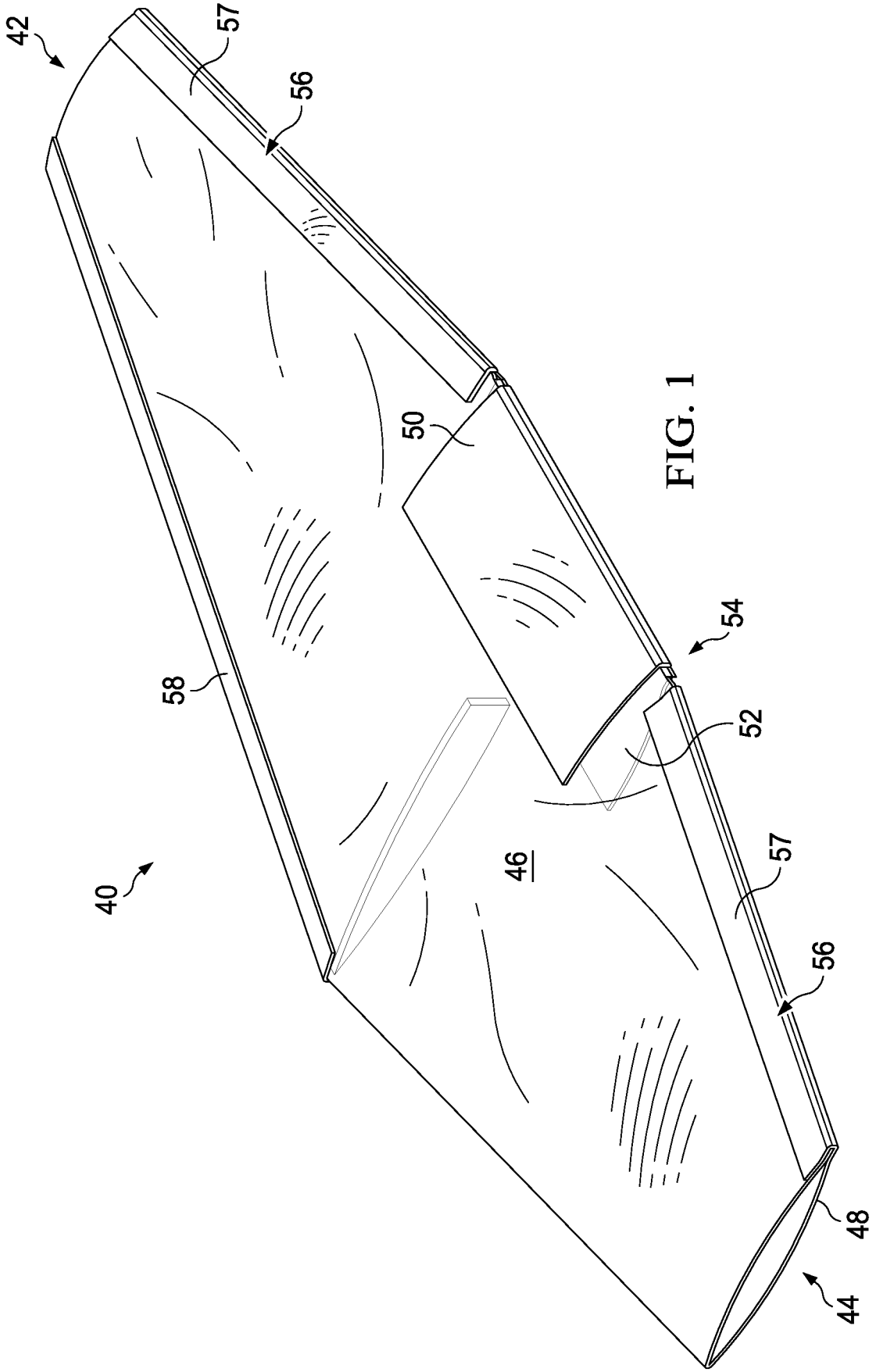

FIG. 1

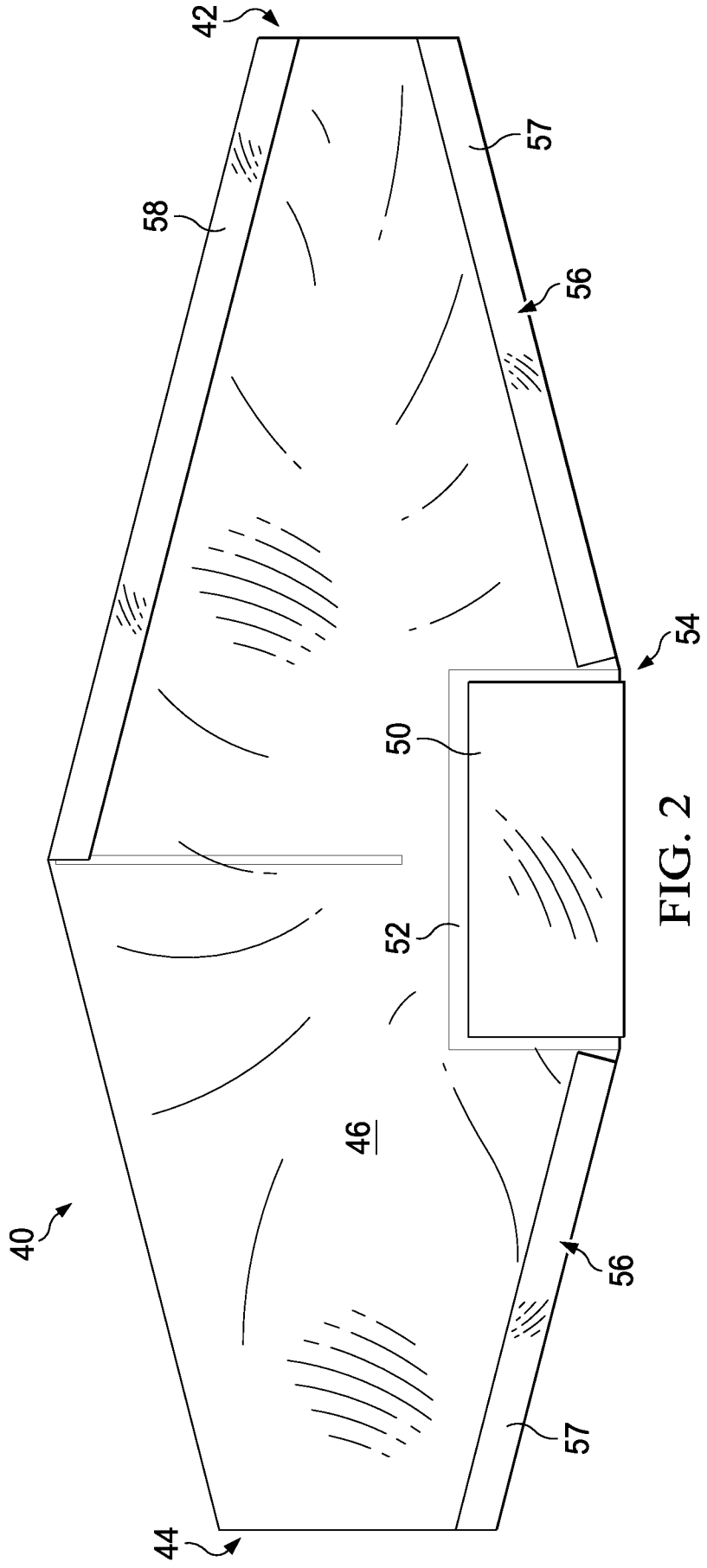

FIG. 2

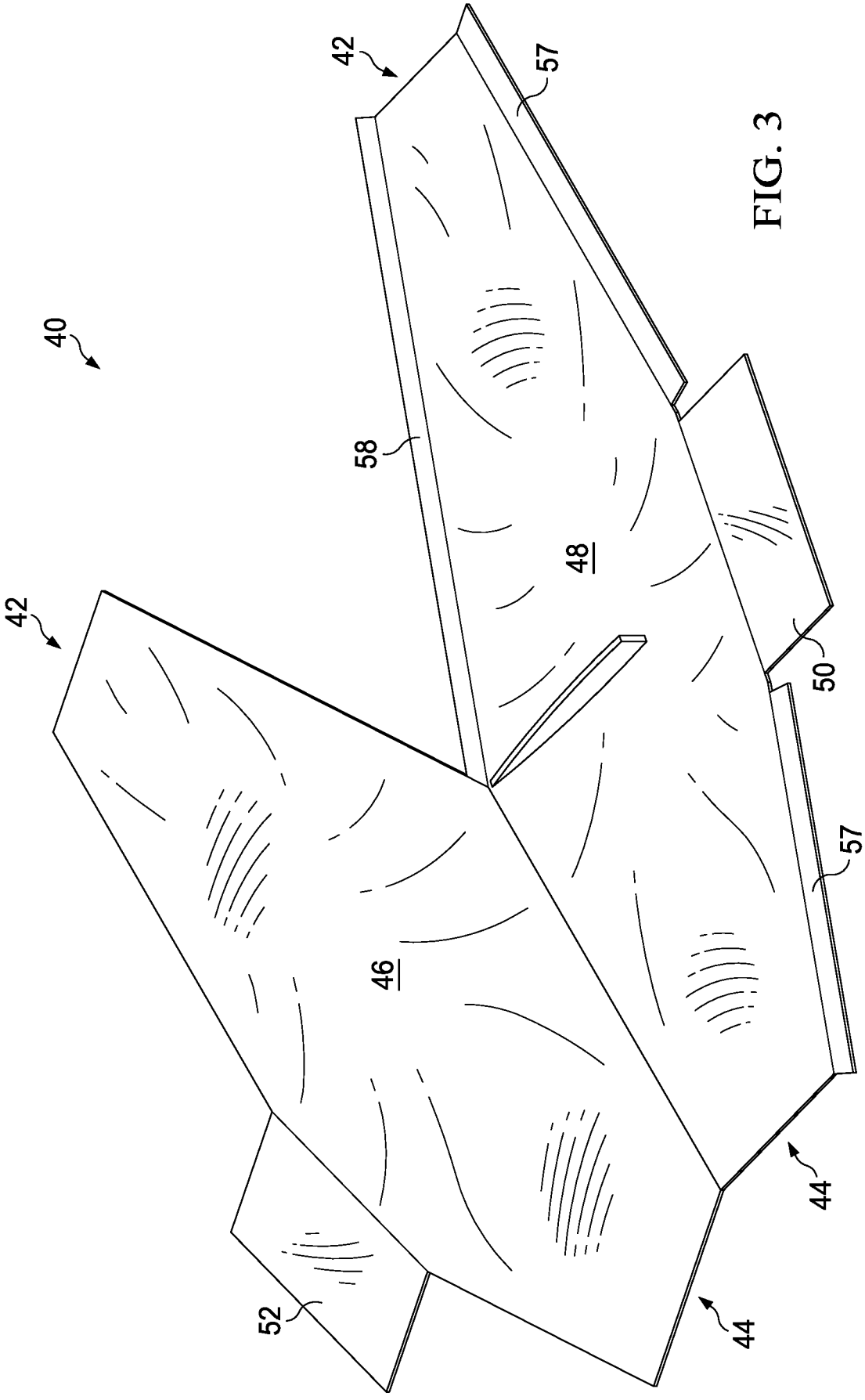

FIG. 3

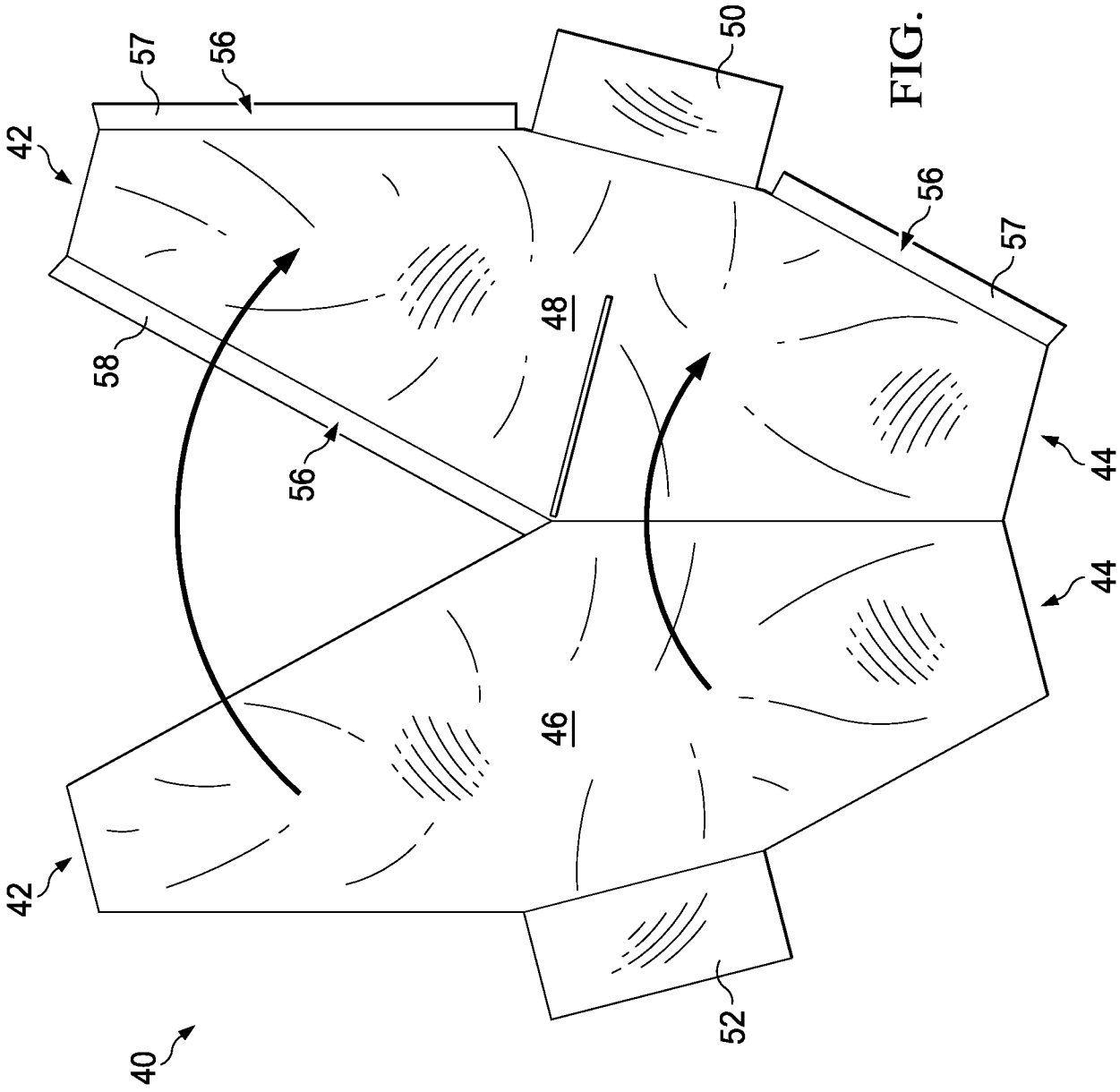

FIG. 4A

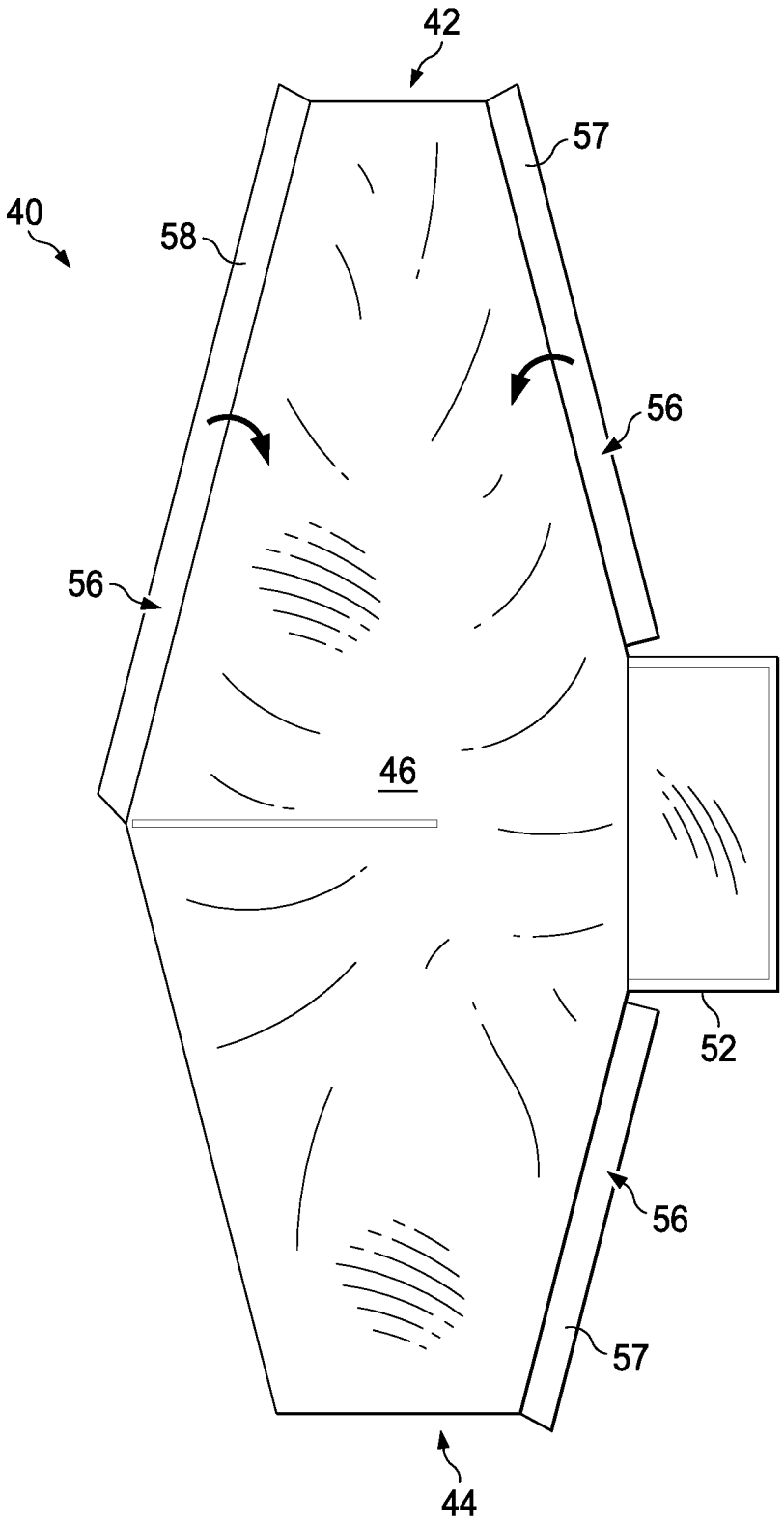

FIG. 4B

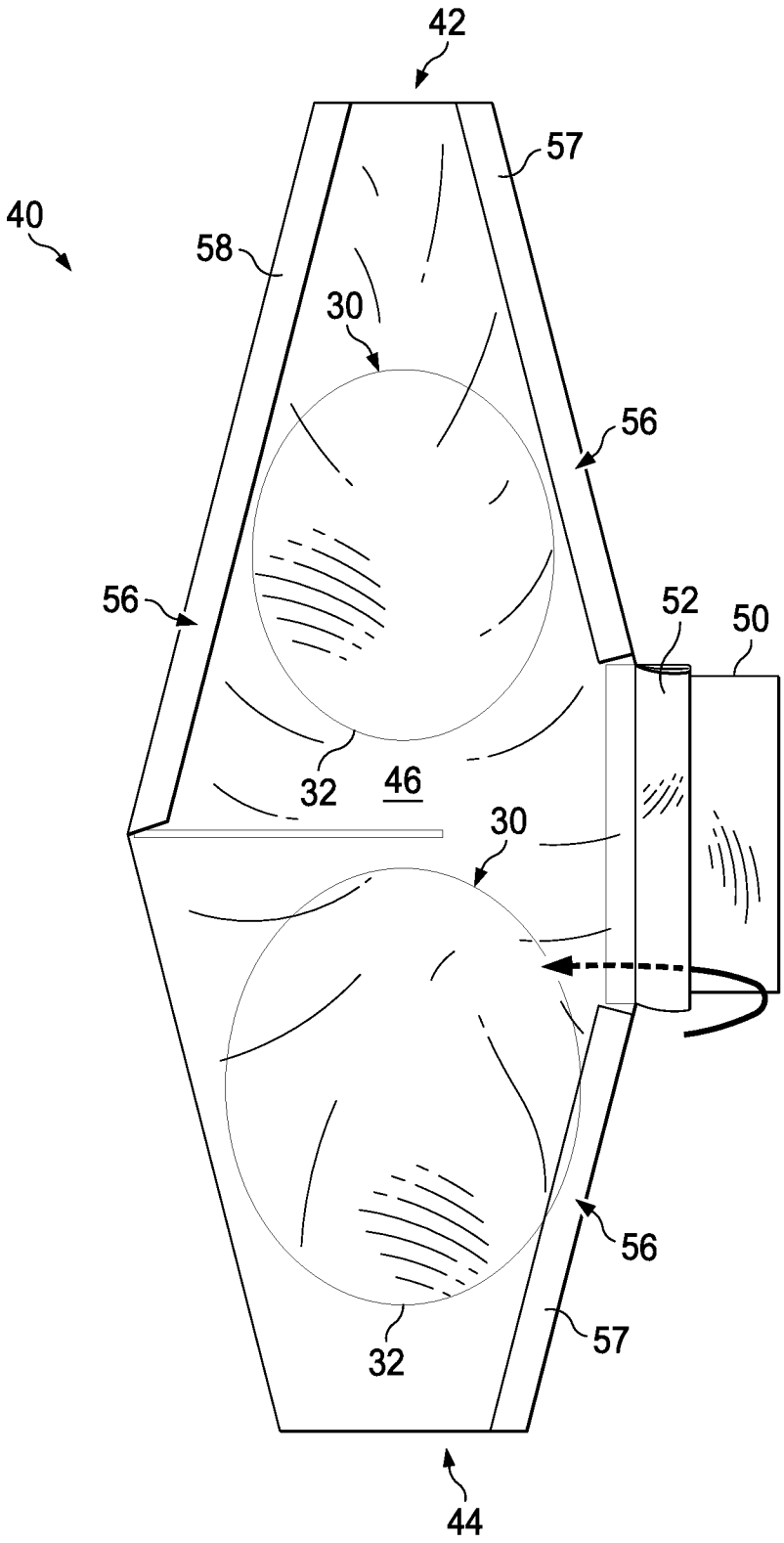

FIG. 4C

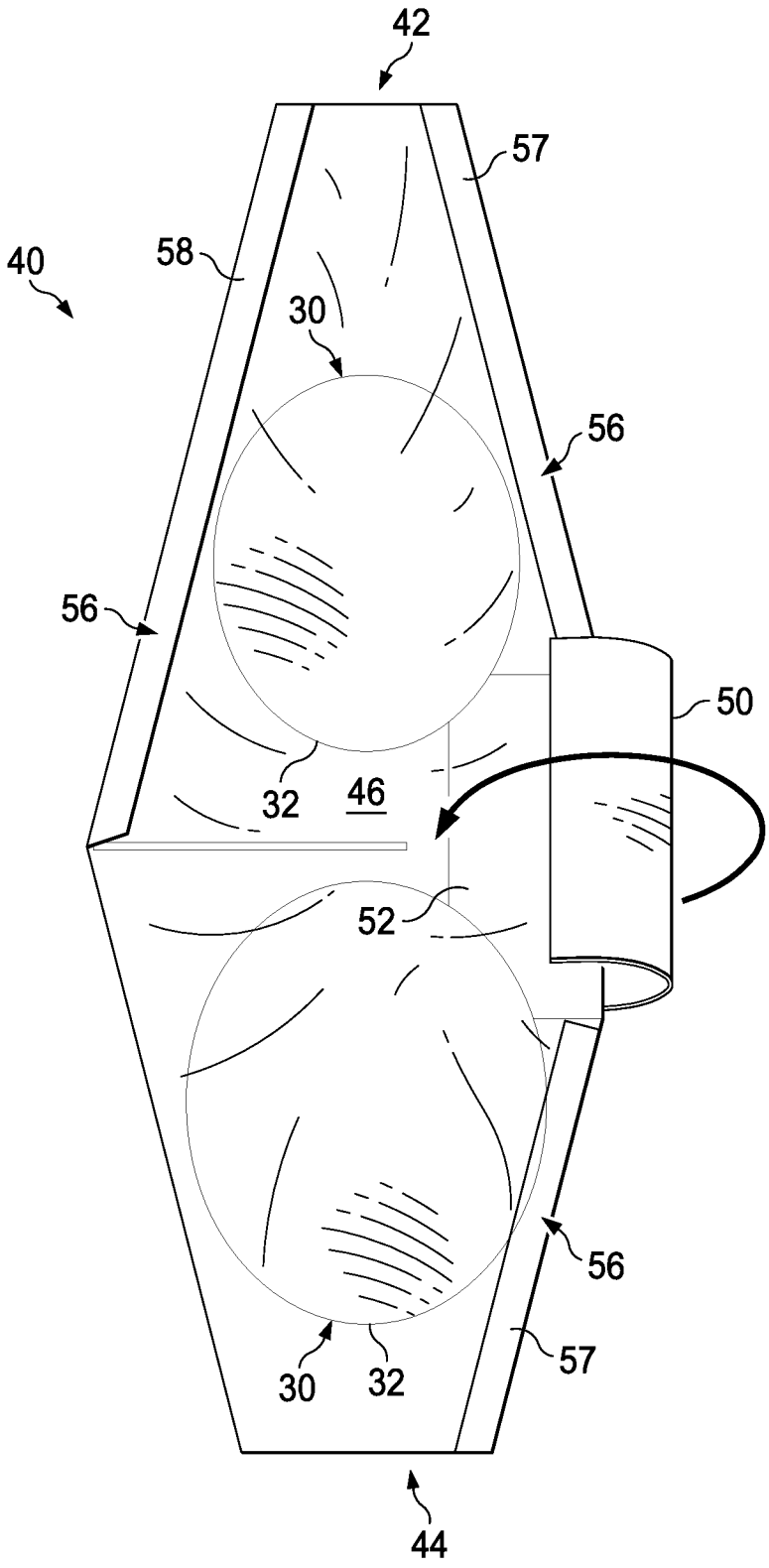

FIG. 4D

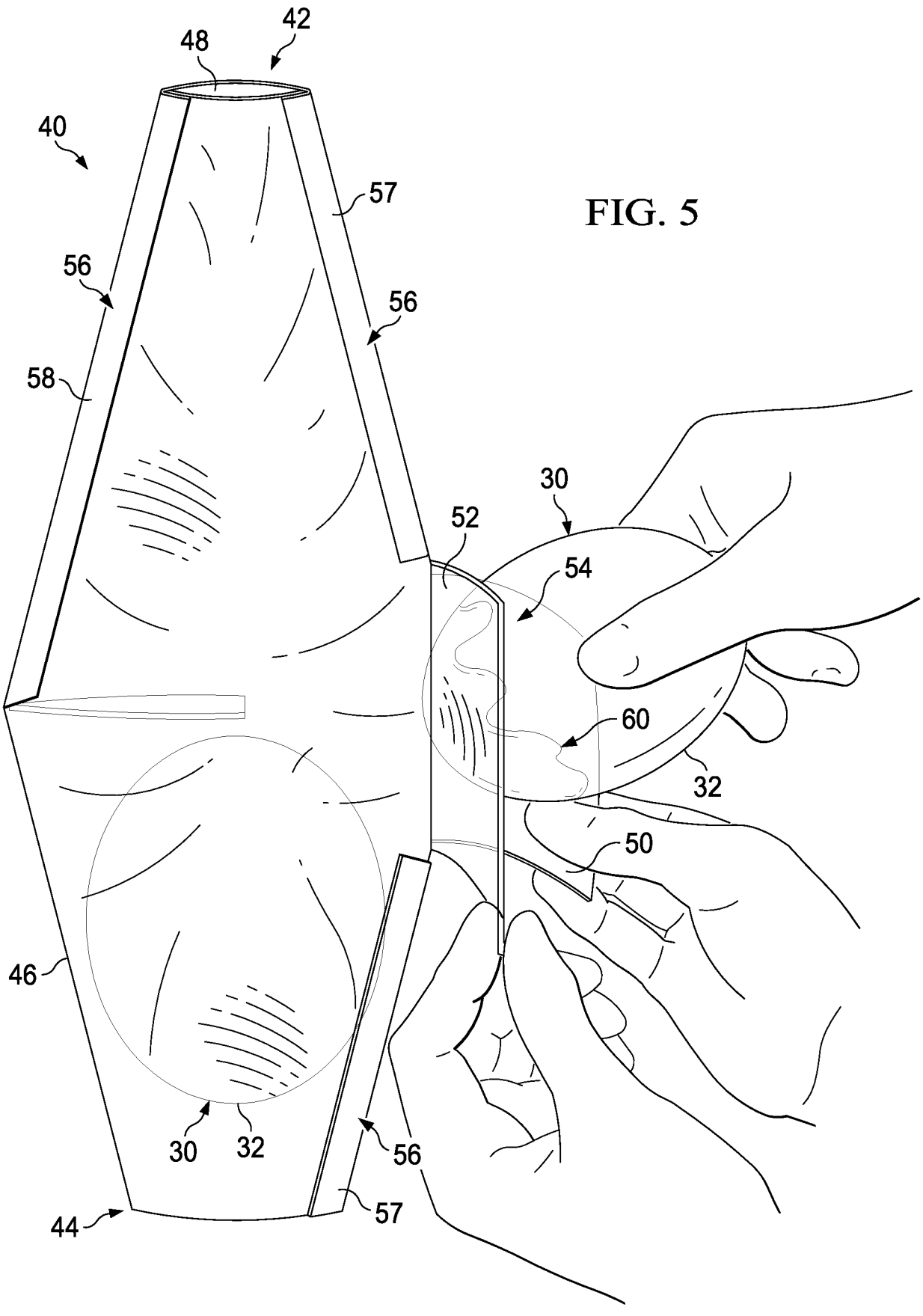

FIG. 5

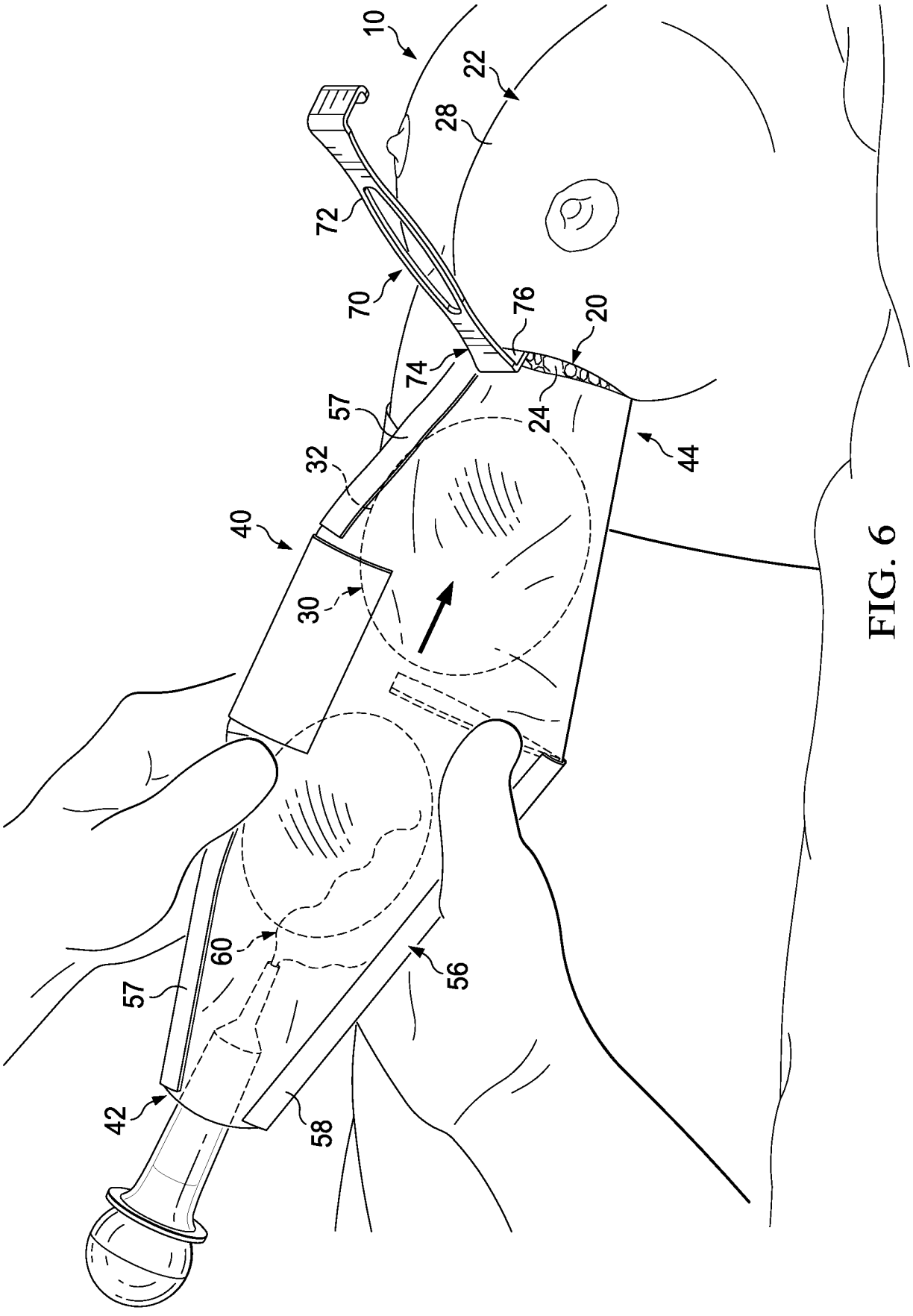

FIG. 6

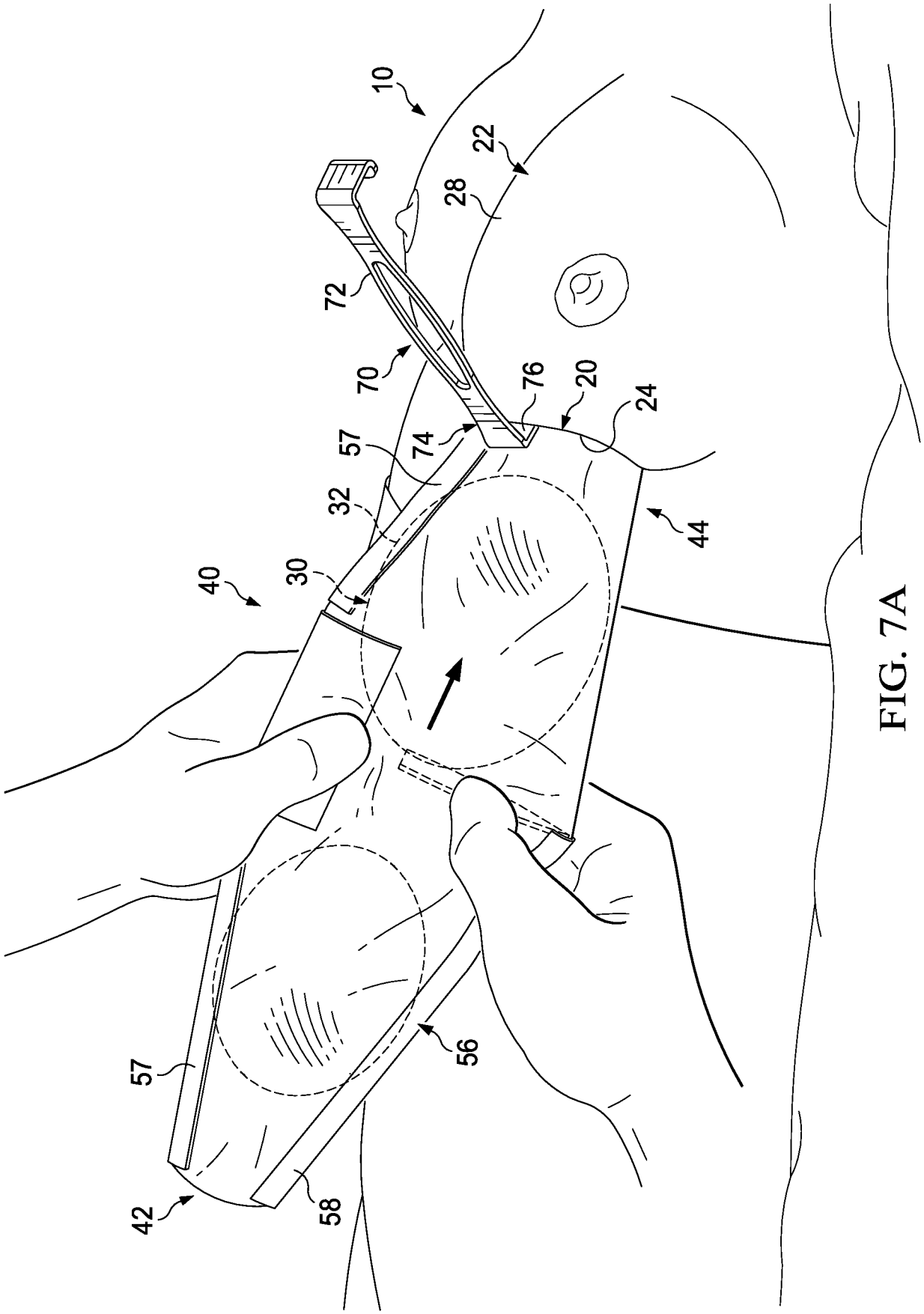

FIG. 7A

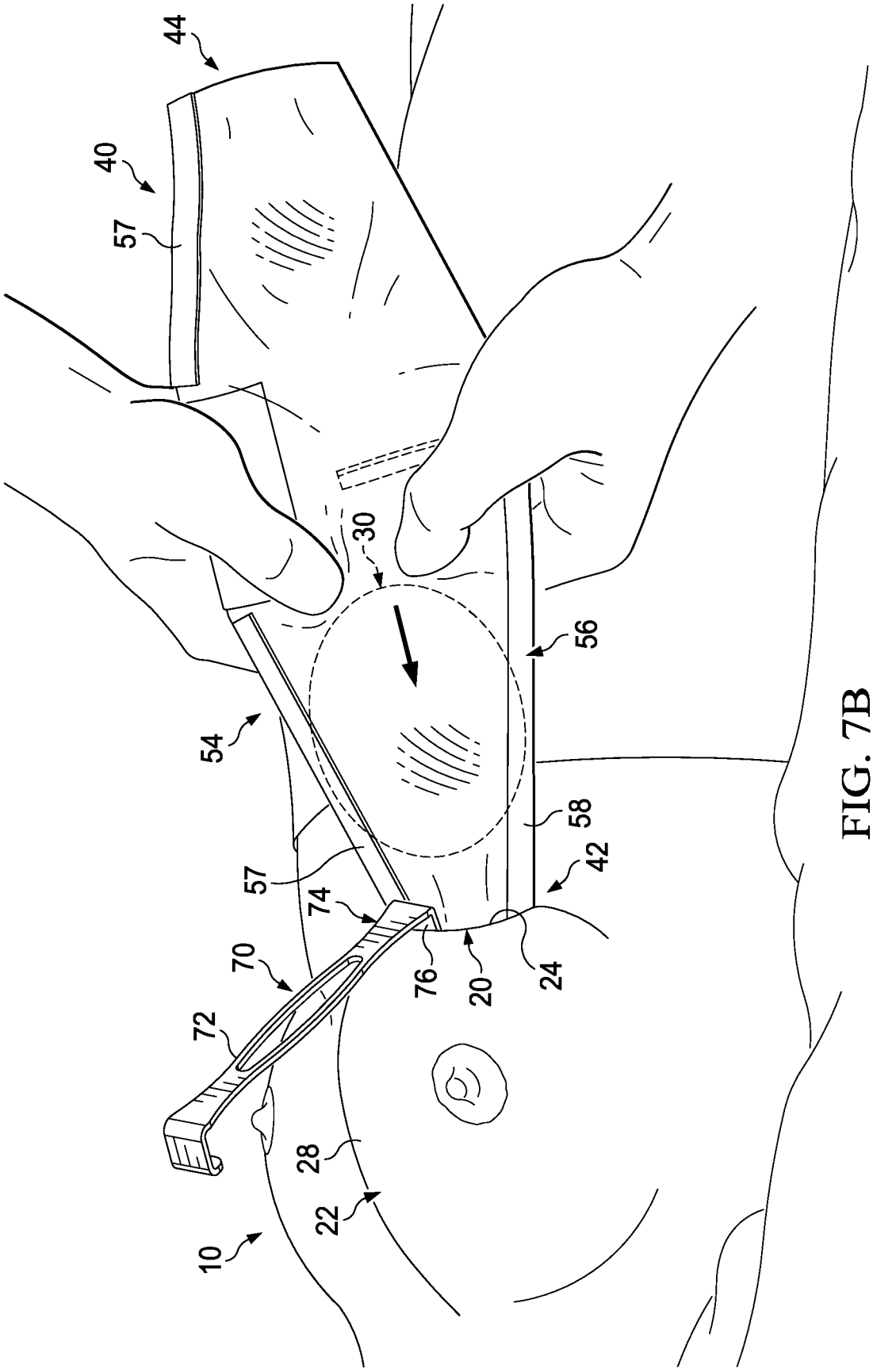

FIG. 7B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/16255

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61B17/02, 90/17; A61F2/12; A61L27/50 (2017.01)
CPC - A61B17/02, 17/3468, 17/3423, 90/40; A61F2/02, 2/12, 2/0095; A61L27/50

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)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	US 2016/0278808 A1 (ANDERSON, RG) September 28, 2016; figures 1. 6, 7a-b; paragraphs [0072], [0079]-[0082]	1-2
Y --- A	US 2016/0095697 A1 (ANDERSON, RG) April 6, 2016; figures 3, 7; paragraphs [0073]-[0075], [0076], [0078], [0111]-[0114]	1 --- 2-3
Y --- A	CA 2861438 A1 (KELLER MEDICAL, INC.) August 22, 2013; paragraphs [0019]; claim 5; figure 3c	1 --- 2-3
A	US 2015/0374478 A1 (ANDERSON, RG) December 30, 2015; figure 1; paragraphs [0057]-[0058]	2-3
A	US 5199795 A (RUSSO, JD et al.) April 3, 1993; figure 1b; column 6, lines 49-55	2-3
A	AMEEN, S "No-Touch Breast Implant Insertion Device' Faculty of Health Sciences, University of Cape Town, disseration. January 22, 2016, introduction and literature review.	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
8 June 2017 (08.06.2017)	28 JUN 2017
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/16255

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.:
because they relate to subject matter not required to be searched by this Authority, namely:

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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fee must be paid.

Group I: Claim 1 is directed toward a apparatus for inserting a prosthesis through an incision into a surgical pocket, comprising: a breast implant, a bellow comprising a bellow prosthesis opening, a small proximal opening to allow the smallest range of breast implants to exit and a large proximal opening to allow the largest range of breast implants to exit.

Group II: Claims 2-3 are directed toward an apparatus for inserting a prosthesis through an incision into a surgical pocket, comprising: a bellow formed of two simple, convex, irregular hexagons folds with opposing tabs and an initial fold abutted to a base fold along the sides opposing the tabs.

-***-Continued Within the Next Supplemental Box-***-

1. ☒ As all required additional 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 additional fees, this Authority did not invite payment of 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
Information on patent family members

International application No.
PCT/US17/16255

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

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Group I has at least a breast implant; a bellow comprising a bellow prosthesis opening, a small proximal opening to allow the smallest range of breast implants to exit and a large proximal opening to allow the largest range of breast implants to exit, the prosthesis opening surrounded by tabs, the bellow being semi-rigid and structured and arranged to receive the breast implant through the prosthesis opening, a retractor device, the retractor having a proximal end that is adjacent to the bellow proximal opening and are structured and arranged to engage an edge of a surgical pocket opening, and the proximal end being fixed relative to the proximal end of the bellow that Group II does not have.

Group II has at least a bellow formed of two simple, convex, irregular hexagons folds with opposing tabs; an initial fold abutted to a base fold along the sides opposing the tabs, whereby an asymmetrical bellow is formed with a bellow prosthesis opening, and two proximal openings that Group I does not have.

The common technical features of Groups I and II are at least a bellow, the bellow assembled with tab-side seal tucks and an abutted-side seal tuck. These common features are disclosed by US 2015/0374478 A1 to ANDERSON, R (hereinafter 'Anderson'). Anderson discloses a bellow (bellow 40, figure 1, paragraph [0084]), the bellow assembled with tab-side seal tuck and an abutted-side seal tuck (bellow 40 includes seals 56 for initial fold 48 of flap 52 (tab-side seal tuck) and bellow base fold 46 (abutted-side seal tuck), figure 1, paragraphs [0082]-[0085]).

Since the common technical features are previously disclosed by the Anderson reference, these common features are not special and so Groups I and II lack unity.