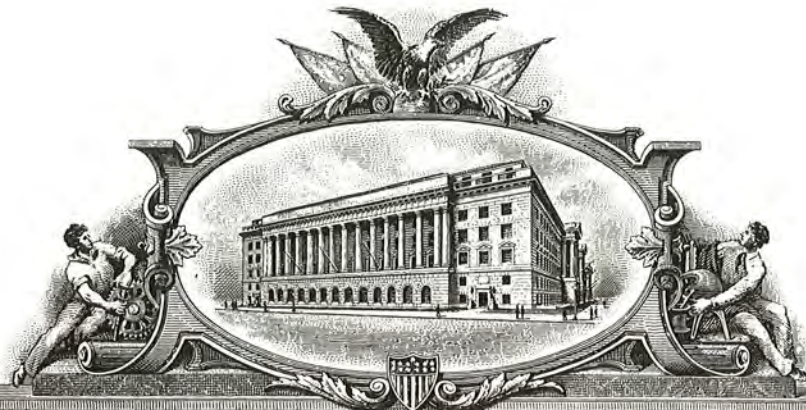




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First Named Inventor/Applicant Name:	Paul Rosenberg
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1	Transmittal of New Application	01604673.PDF	280532	no	2
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2	Application Data Sheet	01604636.PDF	1823013	no	8
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3	TrackOne Request	01604873.PDF	113929	no	2
			dcd91dfb9b912e58d8d4127e22b426b0066fda19		

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4		01605082.PDF	134380	yes	27
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Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	22
Claims	23	26
Abstract	27	27

Warnings:

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5	Drawings-only black and white line drawings	01604722.PDF	615256	no	9
			50af607f40f5d10a93f97b2b8757aa6d7f920b15		

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6	Fee Worksheet (SB06)	fee-info.pdf	40359	no	2
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UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	10401/005484-US0
	First Named Inventor	Paul Rosenberg
	Title	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE
	Express Mail Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☒ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages <u>27</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement) 5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets <u>9</u>] 6. ☐ Inventor's Oath or Declaration [Total Pages _____] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e)) a. ☐ Newly executed (original or copy) b. ☐ A copy from a prior application (37 CFR 1.63(d)) 7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required) a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee _____ 11. ☐ 37 CFR 3.73(c) Statement ☐ Power of Attorney (when there is an assignee) 12. ☐ English Translation Document (if applicable) 13. ☐ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached 14. ☐ Preliminary Amendment 15. ☐ Return Receipt Postcard (MPEP § 503) (Should be specifically itemized) 16. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed) 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☒ Other: Request for Prioritized Examination (1 page) _____ _____ _____ _____

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
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**DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF
USE THEREOF**

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FIELD OF THE INVENTION

[0002] The invention described herein generally relates to devices to assist in the placement of prosthetic implants. The invention further relates to a device that hold a prosthetic implant within a structure that is (or is generally) in the shape of a conical frustum with an opening, the interior of which comprises a lubricious coating and is of suitable dimensions to hold the prosthetic implant. The application of pressure laterally along the length of the frustum ejects the prosthetic implant through the opening and into a surgical pocket that a surgeon opens in the body of a patient.

BACKGROUND OF THE INVENTION

[0003] Prosthetic implants, in particular breast implants, have a substantial history dating back to the first recorded implant surgery done in 1895 at the University of Heidelberg, Germany. Instead of being for cosmetic purposes, the physician (Dr. Vincent Czerny) performed the procedure by taking fat from the hip of a female for implantation into her breast, which needed reconstruction after the removal of an adenoma. Accordingly, the purpose of this first “implant” was to reconstruct a breast after devastating surgery, rather than to achieve uniform enlargement.

[0004] The first real foreign substance injected into body to achieve enlargement is perhaps the injection of paraffin, which comes in a plurality of textures and is primarily composed of petroleum jelly. Dr. Robert Gesurny, an Austrian surgeon who used the material on the testicle of a soldier in an attempt to achieve a more desirable size, first discovered the use of paraffin for boosting the size of bodily objects. Inspired by the results, Dr. Gesurny went on to use the material for breast enlargement injections, universally resulting in severely compromised outcomes.

[0005] Modern silicone gel implants, which are well known to those of ordinary skill in the art today, have a long history that dates back over the past seventy years. In fact, some evidence supports Japanese prostitutes after World War II injecting their breasts with various substances, including liquid silicone. The serious worry with silicone in liquid form was that it broke apart, forming granulomas that could then migrate basically anywhere in the body. Liquid silicone is still used, but very rarely, in microscopic amounts, and only using medical-grade silicone that is completely sterile; it remains highly controversial and is associated with serious complications. Breast implants as presently known in the art — silicone as a cohesive mass inside of a polymer “bag” structure — had their debut in the 1960s, developed by Doctor Thomas Cronin and his colleague Frank Gerow.

[0006] Although removed from the market for a number of years due to a variety of concerns and complications, silicone was allowed back into breast implants in 2006, albeit in a new form. The FDA, after years of study and experiments, finally allowed silicone gel-filled implants onto the U.S. market, which are the sole breast implant option outside of saline. Today's silicone gel is designed to feel a bit like human fat: very thick, very sticky, and classified as “semi-solid”. Such technology actually represents the fifth generation of silicone implant: the

first one developed by Cronin and Gerow, with various innovations, including more secure coatings, thicker gels and more natural shapes.

[0007] When any type of implant is inserted into a surgical pocket that a surgeon opens in the body of a patient, the body reacts by forming a protective lining around the prosthetic. This biological structure is referred to as the “capsule”, “tissue capsule” or “scar capsule”, though it should be noted that the structure it is not exactly the same as scar tissue. Although a capsule formation is normal and happens regardless of whether the implant is smooth or textured, silicone or saline, some theorize that problematic capsule growth is potentially attributed to manipulation of tissue during implant placement. In addition, trauma to tissue along or adjacent to the surgical pocket may suffer from the direct formation of scar tissue due to potentially over aggressive manipulation of tissue at the entry site for the implant along the edge of the surgical pocket.

[0008] Accordingly, what is needed in the art are new devices that allow for the placement of a prosthetic implant while avoiding the unnecessary manipulation of tissue adjacent to or inside a surgical pocket to minimize the development of scar tissue and the formation of any significant capsule around the prosthetic implant.

SUMMARY OF THE INVENTION

[0009] Embodiments of the invention are directed towards a surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient. According to one embodiment, the surgical device comprises a bag shaped as a conical frustum in which a proximal end of the conical frustum is sealed and a distal end of the conical frustum is open. An elongated slit extends from the distal end towards the proximal end with a single opening formed

by the distal opening and the elongated slit being sufficiently large enough to accept the prosthetic implant into the bag.

[0010] An adhesive is applied to or otherwise affixed along a portion of the elongated slit to seal the elongated slit such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket. The elongated slit may further comprise a flap, with the adhesive affixed along the flap. While application of the adhesive may be along the entirety of the elongated slit, other embodiments apply or otherwise affix adhesive along one or more portions of the elongated slit. Sealing the elongated slit in certain embodiments allows for the formation a ridge that provides a support guide for the prosthetic implant during placement into the surgical pocket. The configuration of the surgical device of the present invention allows the device to accept and place of a variety of prosthetic implant types including, but not limited to, a breast implant, a pectoral implant, a calf implant and a gluteal implant.

[0011] The inside surface of the bag is treated or otherwise coated with a lubricious coating that, in addition to other benefits, allows the implant to freely exit the bag. While certain embodiments utilize a water activated lubricious coating on the interior of the bag, the lubricious coating is more generally any hydrophilic gel that decreases the coefficient of friction of the inside surface of the bag. According to one embodiment, the bag is composed of a polymer selected from the set of polymers consisting of medical grade vinyl, medical grade PVC, medical grade nylon and polyethylene. When utilizing medical grade vinyl in the construction of the bag, various embodiments utilize medical grade vinyl that is between .01 inches and .005 inches thick.

[0012] The outside of the bag may comprise a number of different markings or indicia that aid the surgeon in properly placing the prosthetic implant within the surgical pocket. For

example, the bag may comprise a marker, such as a circular marker, which allows the surgeon to achieve proper alignment of the prosthetic implant during placement into the surgical pocket.

Application of the marker may be in accordance with any number of processes that do not affect the integrity of the material forming the bag, such as a silkscreen process. The bag may also have a plurality of size guide lines set at varying distances from the opening in at the distal end of the bag. The surgeon can use the plurality of size guide lines to properly align a cutting device to excise excess material from the distal opening of the bag.

[0013] The lubricious coating on the inside surface of the bag is activated by exposure to water, thereby resulting in a decrease in the coefficient of friction of the inside surface of the bag. Activation of the lubricious coating may be through injection of water into the interior of the bag through the use of a syringe, or aqueous submersion of the bag. Alternatively, the surgeon or technician exposes a sheet of absorbable material placed within the bag to water, thereby allowing water to wick through the absorbable material and activate a lubricious coating on an inside surface of the bag. According to one embodiment, the sheet of absorbable material changes color when exposed to water.

[0014] Beyond the foregoing, embodiments of the present invention are directed towards a surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient. The surgical device according to the present embodiment comprises a bag shaped as a conical frustum in which a proximal end of the conical frustum is sealed and the distal end of the conical frustum is open with an elongated slit extending from the distal end towards the proximal end. As with other embodiments, an opening formed by the distal opening and the elongated slit is sufficiently large enough to accept the prosthetic implant into the bag. An adhesive along a portion of the elongated slit can seal the elongated slit such that the distal end remains open to

allow for egress of the implant from the bag for placement into the surgical pocket. Finally, a sheet of absorbable material is disposed of within the bag that when exposed to water allows the water to wick through the absorbable material and activate a lubricious coating on an inside surface of the bag.

[0015] Still further, embodiments are directed towards a surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient. The device in accordance with the present embodiment comprises a bag shaped as a conical frustum in which a proximal end of the conical frustum is sealed and the distal end of the conical frustum is open with an elongated slit extending from the distal end towards the proximal end. The distal opening and the elongated slit form a single opening that is sufficiently large enough to accept the prosthetic implant into the bag. A set of inter-lockable fastener elements disposed along opposing portions of the elongated slit seal the elongated slit such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The invention is illustrated in the figures of the accompanying drawings which are meant to be exemplary and not limiting, in which like references are intended to refer to like or corresponding parts, and in which:

[0017] Fig. 1 illustrates a top perspective view of a surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient according to one embodiment of the present invention;

[0018] Fig. 2A illustrates a top perspective view of a surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient in conjunction with a prosthetic implant according to one embodiment of the present invention;

[0019] Fig. 2B illustrates the surgical device of Fig. 2A with an implant seated with the surgical device and a partially exposed adhesive strip according to one embodiment of the present invention;

[0020] Fig. 2C illustrates the surgical device of Fig. 2A with the elongated slit sealed such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket according to one embodiment of the present invention;

[0021] Fig. 3 illustrates several exemplary prior art prosthetic implants;

[0022] Figs. 4A and 4B illustrate manipulation of a prosthetic implant through a surgical device for assisting in the placement of the prosthetic implant within a surgical pocket of a patient according to one embodiment of the present invention;

[0023] Figs. 5A and 5B illustrate placement of a prosthetic implant through a surgical device for assisting in the placement of the prosthetic implant within a surgical pocket of a patient according to one embodiment of the present invention;

[0024] Figs. 6A-6C illustrate a surgical device for assisting in the placement of the prosthetic implant within a surgical pocket that utilizes inter-lockable fastener elements in a first configuration on a pair fastener strips on each side of an elongated slit according to a one embodiment of the invention;

[0025] Figs. 7A-7C illustrate a surgical device for assisting in the placement of the prosthetic implant within a surgical pocket that utilizes inter-lockable fastener elements in a second configuration on a pair fastener strips on each side of an elongated slit according to a one embodiment of the invention; and

[0026] Fig. 8 illustrates a cross-sectional view of inter-lockable fastener elements positioned along the edges of the elongated slit and a locking slider in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0027] Subject matter will now be described more fully hereinafter with reference to the accompanying drawings, which form a part hereof, and which show, by way of illustration, exemplary embodiments in which the invention may be practiced. Subject matter may, however, be embodied in a variety of different forms and, therefore, covered or claimed subject matter is intended to be construed as not being limited to any example embodiments set forth herein; example embodiments are provided merely to be illustrative. Those of skill in the art understand that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention. Likewise, a reasonably broad scope for claimed or covered subject matter is intended. The following detailed description is, therefore, not intended to be taken in a limiting sense.

[0028] Throughout the specification and claims, terms may have nuanced meanings suggested or implied in context beyond an explicitly stated meaning. Likewise, the phrase “in one embodiment” as used herein does not necessarily refer to the same embodiment and the phrase “in another embodiment” as used herein does not necessarily refer to a different embodiment. It is intended, for example, that claimed subject matter include combinations of example embodiments in whole or in part.

[0029] Fig. 1 illustrates a top perspective view of a surgical device 100 for assisting in the placement of a prosthetic implant within a surgical pocket of a patient according to one embodiment of the present invention. The surgical device 100 comprises a bag shaped as a

conical frustum in which a proximal end 112 of the conical frustum is sealed and a distal end of the conical frustum is open 104 with an elongated slit 114 extending from the distal end towards the proximal end 112. According to one embodiment, the proximal end of the bag 100 is sealed with an RF weld. The bag 100 may be formed from a single sheet of material that is stamped or cut using a die or other suitable technique and folded around itself, or may be formed by multiple panels, e.g., front and back panels, that are joined together.

[0030] The opening 104 formed by the distal opening and the elongated slit 114 is of sufficiently large size to accept a prosthetic implant into the bag. Accordingly, manufacture of the surgical device 100 may comprise production of the surgical device in various sizes or volumes to accommodate prosthetic implants of various sizes. For example, the surgical device 100 may be sized differently to accommodate a gluteal implant as opposed to a breast or calf implant. According to one embodiment, the bag is of sufficient capacity to seat the prosthetic implant and activate the adhesive to allow the elongated slit to be sealed with the bag horizontal relative to a standing surgeon.

[0031] A technician preparing the surgical device 100 for use on a patient places the implant within the device and seals the elongated slit such that the distal end remains open to allow for egress of the implant from the bag and placement into the surgical pocket. According to the embodiment of Fig. 1, a flap 106 is formed along one side of the elongated slit 114 such that a technician can fold the flap 106 over the elongated slit 114 to form the seal. An adhesive 108 or other fastening member may be affixed along a portion of the elongated slit (which may be on the flap if present) to form a seal such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket. Advantageously, a ridge

formed by the sealed elongated slit provides a support guide for the prosthetic implant during placement into the surgical pocket.

[0032] The inside surface of the surgical device 100, which is a bag in the form of a conical frustum, is treated with a lubricious coating. Lubricity is a property that describes how slippery a surface is, more specifically, the value of its coefficient of friction. Embodiments of the present invention benefit from this type of slippery surface treatment because it reduces the insertion force that the surgeon must apply to propel or eject the prosthetic implant through the distal opening in the bag, avoiding possible puncture damage to the prosthetic implant and severe abrasion between the implant surface and the interior surface of the bag.

[0033] The lubricious coating can be applied to interior surface of the bag 100 in a number of ways. One application technique is dip coating, which entails suspending the bag from a support, lowering it into a liquid coating solution and then withdrawing. The coating sticks to the surface as the support draws the bag up and out of the solution. An alternative is spray coating, which is akin to airbrushing and involves spraying a nebulized mist over the interior surface of the bag. Film coating is another type of application process in which long rolls of material that form the bag are drawn from reel to reel through a tank of liquid coating. Other processes for the application of the lubricious coating include chemical vapor deposition and silk screening, which is primarily suitable when working with flat surfaces, such as the raw material that forms the bag.

[0034] Any of the above-described coating techniques involves a drying or curing process to permanently affix the lubricious coating to the interior surface of the bag. Two prevalent methods for curing hydrophilic coatings are heat and ultraviolet (“UV”) light. When utilizing heat-cured coatings, the bag is placed within an oven for a given period of time. Such

controlled heating accelerates drying of the coating and any necessary chemical reactions taking place within the coating (or between the coating and the bag), such as crosslinking, which allow the coating to stick to the interior surface of the bag, as well as provide durability. For embodiments that utilize lubricious coatings that use UV light for the curing step, the interior surface of the bag is exposed to UV light for a given period of time, which has the effect of stimulating any necessary chemical reactions for curing. Completion of the curing process affixes the lubricious coating to the interior surface of the bag.

[0035] The lubricious coating is hydrophilic. Hydrophilic coatings exhibit so-called “water loving” characteristics. From a chemical perspective, these coatings participate in dynamic hydrogen bonding with surrounding water. In some cases, hydrophilic coatings are also ionic, and may further exhibit negative charge, which facilitates additional aqueous interactions. Physically, these chemical interactions with water give rise to hydrogel materials that may exhibit extremely low coefficients of friction. Taken together, these chemical and physical characteristics describe a class of materials that are wettable, lubricious, and suitable for tailored biological interactions.

[0036] A technician may hydrate the interior of the bag 100 to activate the lubricious coating by injecting water into the bag through the use of a syringe 116. Alternatively, or in conjunction with the foregoing, the technician may hydrate a polymer insert (not pictured) placed within the interior of the bag 100. When hydrating the polymer insert, the insert serves to wick the fluid throughout the interior of the bag, thereby activating the lubricious coating. The polymer insert is preferably sized to follow the contours of the interior of the bag 100 and may comprise any material that suitably wicks fluid throughout its surface including, but not limited

to Lightweight Stabilizer (60% polyester/40% Rayon), Medium Weight Stabilizer (60% polyester/40% Rayon) and medium to heavyweight sew-in interfacing (100% Polyester).

[0037] Different markings on the exterior of the bag 100 assist the technician in preparing the bag for implant delivery and the surgeon in the delivery process. For example, a marker 110 on the outside of the bag allows the technician to align the prosthetic implant properly in the bag 100, such as by aligning the marker with a physical marker on the bottom of the implant. In this manner, the surgeon is aware of the bottom position of the implant upon delivery and can ensure that the implant is not delivered into the surgical pocket bottom side up. Application of the marker to the bag is in accordance with any process that permanently deposits the marker on the outer surface of the bag without harming or otherwise causing any degradation to the bag itself, e.g., through a silkscreen process, inkjet printing or hand application with suitable pens or markers. The exterior of the bag 100 may further comprise a plurality of size guide lines to properly align a cutting device when excising material from the distal opening of the bag. Excising material from the distal opening of the bag allows the technician to increase the aperture diameter of the distal opening, thereby allowing the device to accommodate larger implant sizes without causing damage to the opening 104 at the distal end of the bag 100.

[0038] Figs. 2A-2C illustrate placement of an implant into and the sealing of a surgical device for assisting in the placement of the prosthetic implant within a surgical pocket of a patient. Turning to Fig. 2A, the bag 200 is set out to allow for loading of the prosthetic implant 202 into the interior of the bag 200. The distal opening 204 and elongated slit are sized to accommodate placement of the prosthetic implant 202 into the bag 200 and further align a marker on the implant with the marker on the bag 200, thereby providing the surgeon with an indication as to the orientation of the implant within the bag. According to the embodiment that

Figs. 2A-2C illustrate, a flap 208 is formed along one side of the elongated slit and covered by an adhesive backing 210 that covers an underlying adhesive until such a time as when the technician is ready to seal the elongated slit.

[0039] Continuing with Fig. 2B, the implant 202 is seated within the interior of the bag 200. Advantageously, the technician aligns a physical marker on the implant with the marker on the outside of the bag. Accordingly, the surgeon has an indication as to the orientation of the implant 202 within the bag and can maintain such orientation for the duration of the implant's movement through the bag and into a surgical pocket that the surgeon prepares to accept the implant. The technician seals the elongated slit, thereby maintaining the opening in the distal end of the bag, which the technician may further trim to increase the aperture of the opening when placing implants of various sizes. According to the present embodiment, an adhesive is applied to a flap that runs along one edge of the elongated slit.

[0040] The technician removes an adhesive backing 210 to expose an underlying adhesive 212 that seals the elongated slit by adhering the flap to the exterior surface of the bag. Fig. 2C illustrates the surgical device with the elongated slit sealed such that the distal end 216 remains open to allow for egress of the implant 202 from the bag 200 for placement into the surgical pocket. As can be seen, the flap 214 is folded over and adhered to the outside surface of the bag 200, leaving the distal opening 216 for placement in the surgical pocket during delivery of the implant 202.

[0041] Fig. 3 presents a number of prior art implants that are suitable for use with embodiments of the present invention. For example, breast 302, gluteal 308 and various calf implants 304 and 306, may be set or otherwise placed through use of various embodiments. Those of skill in the art recognize that certain aspects of the bag geometry might require slight

modification from the illustrations presented in conjunction with the embodiments depicted herein. By way of example and not limitation, when placing a gluteal implant 308, which is typically of a larger volume than a breast implant 302, the length of the bag, as well as possibly the angle at which the distal opening forms, may require commensurate increases.

[0042] As Figs. 4A and 4B illustrate, the implant is set within the bag 402 and the elongated slit 408 sealed such that sequential application of pressure by the hands 404 and 406 of the physician serve to manipulate the implant 412 out through the opening 410 in the distal end of the bag 402. As described above and further herein in connection with various embodiments of the invention, the implant is set and can further be aligned with a marker on the bag to understand alignment of the implant as the surgeon manipulates the implant along the length of the bag 402. Figs. 4A and 4B illustrate the application of a twisting motion or the sequential application of pressure laterally along the bag by the hands of the surgeon 404 and 406, typically with the proximate hand 406 applying pressure while the distal hand 404 provides support, although other hand and pressure application configurations fall within the scope of the invention. The application of pressure as such serves to drive the implant out the distal opening 410 and into a surgical pocket that the surgeon has prepared to accept the implant.

[0043] Figs. 5A and 5B continue the process illustrated by Figs. 4A and 4B in which the implant is set into a surgical pocket 502 in the body 506 of a patient. The surgeon or a technician can utilize a surgical retractor 504 to manipulate the surgical pocket 502 and properly position the surgical pocket to receive the implant. For example, a technician utilizes the surgical retractor 504 to hold open the surgical pocket 502 that the surgeon incises in the body 506 of the patient, such as under the breast. The surgeon, using the implant set in the bag with the elongated slit sealed 508, introduces the distal end of the bag into the open surgical pocket 502.

Because activated lubricious coating on the interior of the bag greatly reduces the coefficient of friction on the interior surface of the bag, manipulation by the surgeon allows the implant to be easily driven into the surgical pocket 502 with little disruption or unnecessary trauma to the surgical pocket 502 or surrounding tissues. Once the surgeon sets the implant into the surgical pocket, he or she removes the bag 508 and the wound is closed through the application of sutures, staples, glue or other techniques known to those of skill in the art suitable to close the surgical pocket.

[0044] As described above, embodiments of the invention may utilize various techniques for affixing the edges of the elongated slit to seal the elongated slit such that the distal end of the bag remains open to allow for egress of the implant from the bag. Although above-described embodiments illustrate the use of adhesives, other structures such re-closable fasteners or other adhesion or fastening techniques known to those of skill in the art may readily be utilized with the device.

[0045] Figs. 6A-6C illustrate a surgical device for assisting in the placement of the prosthetic implant within a surgical pocket that utilizes inter-lockable fastener elements in a first configuration on a pair fastener strips on each side of an elongated slit according to a one embodiment of the invention. More specifically, Figs. 6A-6C present the progression of setting a breast implant into the delivery bag, which comprises a set of inter-lockable re-closable fasteners and a slider along the edges of the elongated slit such that the elongated slit seals through fastening of the inter-lockable re-closable fasteners. The inter-lockable re-closable fasteners can also be closed by hand through alignment and application of pressure along the same.

[0046] Starting with Fig. 6A, the bag 600 is in an “open” configuration in which the elongated slit, which comprises a set of inter-lockable re-closable fasteners 606 and 608, and distal opening allow for insertion of a prosthetic implant 602 into the bag. In the embodiment that Fig. 6A illustrates, the prosthetic implant 602 is a breast implant. A slider 610, located at the end of the elongated slit closet to the proximal end of the bag, allows for roll-off closure of the set of inter-lockable re-closable fasteners. Turning to Fig. 6B, the technician places the implant 602 into the interior of the bag 600 and begins to roll off the slider 610 along the set of inter-lockable re-closable fasteners 606 and 608 in the direction of the distal opening 604. Finally, transitioning to Fig. 6C, the set of inter-lockable re-closable fasteners are locked, thereby sealing the elongated flap such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket. Although Fig. 6C illustrates the slider 610 remaining in place at the distal opening of the bag 600, the slider can also be run off the end of the bag 600 and discarded as the elongated slit is sealed with the implant 602 in place and ready for delivery.

[0047] Figs. 7A-7C illustrate a surgical device for assisting in the placement of the prosthetic implant within a surgical pocket that utilizes inter-lockable fastener elements in a second configuration on a pair fastener strips on each side of an elongated slit according to a one embodiment of the invention. More specifically, Figs. 7A-7C present the progression of setting a breast implant into the delivery bag, which comprises a set of inter-lockable re-closable fasteners and a slider along the edges of the elongated slit such that the elongated slit seals through fastening of the inter-lockable re-closable fasteners and lie flat in relation to the surface of the bag.

[0048] Starting with Fig. 7A, the bag 700 is in an “open” configuration in which the elongated slit and distal opening allow for insertion of a prosthetic implant 702 into the bag. The elongated slit comprises a set of inter-lockable re-closable fasteners 706 and 708 that lie flat in relation to the surface of the bag. In the embodiment that Fig. 7A illustrates, the prosthetic implant 702 is a breast implant. Turning to Fig. 7B, the technician places the implant 702 into the interior of the bag 700 and begins to apply pressure to the set of inter-lockable re-closable fasteners 706 and 708 in the direction of the distal opening 704. Transitioning to Fig. 6C, the technician locks the set of inter-lockable re-closable fasteners, thereby sealing the elongated flap such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket. According to the embodiment of Fig. 7A-7C, the set of inter-lockable re-closable fasteners are arranged such that the fasteners lie flat in relation to the surface of the bag, although those of skill in the art recognize that other configurations are suitable.

[0049] Fig. 8 presents a detailed cross-sectional view of one embodiment of the invention in which inter-lockable re-closable fasteners and a slider provide a mechanism for sealing the elongated slit. The elongated slit in the bag comprises a pair of opposing flexible sides 812 and 813. The side 812 has a top edge having a first fastener strip 814 attached thereto. According to one embodiment, the first fastener strip 814 has an inner surface on the inside of the bag and an outer surface on the outside of the bag. The side 813 has a top edge having a second fastener strip 815 attached thereto. The second fastener strip 815 in certain embodiments has an inner surface on the inside of the bag and an outer surface on the outside of the bag. The strips 814 and 815 may be extruded separately for attaching to the respective sides of the bag. Alternatively, the strips 814 and 815 may be extruded integrally with the sides of the bag, e.g., along the sides forming the elongated slit.

[0050] Each fastener strip may utilize one or more closure elements, but the number of closure elements on opposing strips must be equal or otherwise balanced. In accordance with the embodiment of Fig. 8, the first fastener strip has an uppermost closure element 816a and a bottommost closure element 816b. The closure elements 816a and 816b project laterally from the inner surface of fastener strip 814. Likewise, the second fastener strip 817 has at least an uppermost closure element 817a and a bottommost closure element 817b. The closure elements 817a and 817b project laterally from the inner surface of fastener strip 815. When the bag is closed, the closure elements of the first fastener strip interlock with the corresponding closure elements of the second fastener strip.

[0051] When the bag is open, the first and second fastener strips 814 and 815 are separated from each other on the respective sides. Closure elements 816a, 817a, 816b, and 817b have a complimentary cross-sectional shape that achieves closure by pressing the fastener strips together. The slider 810 accomplishes the pressing action through actuation, which straddles the fastener strips 814 and 815 and is adapted to close or open the closure elements 816 and 817 of the re-closable fastener. The slider 810 moves between a closed position and an open position. Thus, when the slider 810 reaches the closed position at distal end of the bag, the bag is closed and the closure elements interlock throughout a portion of the length of the elongated slit. When the slider reaches the open position at the end of the elongated slit closest to the proximal end of the bag, the bag is open and the closure elements are disengaged throughout substantially the entire length of the elongated slit. Those of skill in the art recognize that it is sufficient for at least the bottommost closure elements to interlock with each other throughout substantially their entire length in order for the elongated slit to be closed. Preferably, although not necessarily, the uppermost closure elements also interlock with each other.

[0052] As indicated, the slider is operative to interlock the closure elements of the fastener strip on each side of the elongated slit. As Fig. 8 illustrates, the slider 810 comprises an inverted U-shaped member having a top 820 for moving along the top edges of the fastener strips 814 and 815. The slider 810 has sidewalls 821 and 822 depending from the top 820. Sidewalls 821 and 822 extend downward along the outer surface of the fastener strips 814 and 815, to a point at or below the closure elements 816 and 817, so that at least a portion of the closure elements 816 and 817 are held between the side walls 821 and 822. Sidewalls 821 and 822 cooperate with the fastener strips 814 and 815 so that the fastener strips 814 and 815 are received between the side walls 821 and 822 as the slider moves between the open and closed position.

[0053] According to one embodiment, sidewalls 821 and 822 extend from a separating end of the slider to a pinching end of the slider, such that the sidewalls 821 and 822 are spaced farther apart at the separating end than at the pinching end. The closer spacing at the pinching end acts to pinch, or squeeze the fastening strips together, thereby forcing the closure element 816 and 817 into an interlocking relationship. A user can squeeze fastener strips together all at once, e.g., uppermost closure elements 816a and 817a are pressed together at approximately the same time that bottommost closure elements 816b and 817b are pressed together. Alternatively, the fastener strips can interlock by application of force in a rolling action along the length of the elongated slit.

[0054] A given fastener strip optionally comprises an additional structure for maintaining the slider in straddling relation with the fastener strips. In the embodiment of Fig. 8, the structure comprises a ridge 825 on the outer surface of a given fastener strips 814 and 815, and shoulders on the sidewalls of the slider. The shoulders project inwardly at a point at or below the closure elements 816 and 817. The shoulders act as structure that provides for maintaining the slider in a

straddling relation with the fastener strips by grasping the lower surfaces of the ridges 825. The ridges 825 thus act as handles for the slider to hold onto, such that the slider 810 maintains the straddling relation with the fastener strips along the entire length of the elongated slit. Ridges 825 extend along the length of the outer surface of fastener strips 814 and 815 at a point at or below the closure elements and can be attached to the fastener strips by any desired means, such as, for example, by extruding with the fastener strips, heating, gluing, or snapping in place. The ridges can also result from the difference in thicknesses between a given fastener strip and the bag.

[0055] The slider 810 may be made in multiple parts and welded together or the parts may be constructed to be snapped together; the slider 810 may also comprise one-piece construction. Fabrication of the slider can be in accordance with any desired method, such as, for example, injection-molding, extrusion, material deposit fabrication (3D printing) or any other suitable method known to those of ordinary skill in the art. The slider 810 can be molded from any suitable plastic such, for example, as nylon, polypropylene, polystyrene, polyketone, polybutylene terephthalate, high-density polyethylene, polycarbonate, or ABS. The slider can be clear, opaque, or colored. It should be noted by those of skill in the art

[0056] Figures 1 through 8 are conceptual illustrations allowing for an explanation of the present invention. Those of skill in the art should understand that various aspects of the embodiments of the present invention could be implemented using different materials, fasteners and minor design modifications. Notably, the figures and examples above are not meant to limit the scope of the present invention to a single embodiment, as other embodiments are possible by way of interchange of some or all of the described or illustrated elements. Moreover, where certain elements of the present invention can be partially or fully implemented using known

components, only those portions of such known components that are necessary for an understanding of the present invention are described, and detailed descriptions of other portions of such known components are omitted so as not to obscure the invention.

[0057] In the present specification, an embodiment showing a singular component should not necessarily be limited to other embodiments including a plurality of the same component, and vice-versa, unless explicitly stated otherwise herein. Moreover, applicants do not intend for any term in the specification or claims to be ascribed an uncommon or special meaning unless explicitly set forth as such. Further, the present invention encompasses present and future known equivalents to the known components referred to herein by way of illustration.

[0058] The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying knowledge within the skill of the relevant art(s) (including the contents of the documents cited and incorporated by reference herein), readily modify and/or adapt for various applications such specific embodiments, without undue experimentation, without departing from the general concept of the present invention. Such adaptations and modifications are therefore intended to be within the meaning and range of equivalents of the disclosed embodiments, based on the teaching and guidance presented herein. It is to be understood that the phraseology or terminology herein is for the purpose of description and not of limitation, such that the terminology or phraseology of the present specification is to be interpreted by the skilled artisan in light of the teachings and guidance presented herein, in combination with the knowledge of one skilled in the relevant art(s).

[0059] While various embodiments of the present invention have been described above, it should be understood that they have been presented by way of example, and not limitation. It would be apparent to one skilled in the relevant art(s) that various changes in form and detail

could be made therein without departing from the spirit and scope of the invention. Thus, the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

CLAIMS

What is claimed is:

1. A surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient, the surgical device comprising:

a bag shaped as a conical frustum in which a proximal end of the bag is sealed and a distal end of the bag is open with the bag having an elongated slit extending from the distal end towards the proximal end, the bag further having a single opening formed by the distal opening and the elongated slit, the single opening configured to accept the prosthetic implant into the bag; and

an adhesive affixed along a portion of the elongated slit to seal the elongated slit such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket.

2. The surgical device of claim 1, wherein the prosthetic implant is selected from the set of prosthetic implants consisting of a breast implant, a pectoral implant, a calf implant and a gluteal implant.

3. The surgical device of claim 1, wherein an inside surface of the bag is treated with a lubricious coating.

4. The surgical device of claim 3, wherein the lubricious coating is water activated.

5. The surgical device of claim 3, wherein the lubricious coating comprises a hydrophilic gel that decreases a coefficient of friction of the inside surface of the bag.

6. The surgical device of claim 1, wherein the bag is composed of a polymer selected from the set of polymers consisting of medical grade vinyl, medical grade PVC, medical grade nylon and polyethylene.

7. The surgical device of claim 6, wherein the medical grade vinyl is between .01 inches and .005 inches thick.
8. The surgical device of claim 1, wherein the adhesive is affixed entirely along the elongated slit.
9. The surgical device of claim 1, wherein a ridge formed by the sealed elongated slit provides a support guide for the prosthetic implant during placement into the surgical pocket.
10. The surgical device of claim 1, wherein the elongated slit comprises a flap with the adhesive affixed along the flap.
11. The surgical device of claim 1, comprising a marker on the bag to properly align the prosthetic implant for placement into the surgical pocket.
12. The surgical device of claim 11, wherein the marker is printed on the bag.
13. The surgical device of claim 1, wherein the proximal end of the bag is sealed with an RF weld.
14. The surgical device of claim 1, comprising a plurality of size guide lines to properly align a cutting device for excision of excess material from the distal opening of the bag.
15. The surgical device of claim 14, wherein the plurality of size guide lines are printed on the bag.
16. The surgical device of claim 1, wherein the bag is of sufficient capacity to seat the prosthetic implant and activate the adhesive to allow the elongated slit to be sealed with the bag horizontal relative to a standing surgeon.
17. The surgical device of claim 1, comprising a sheet of absorbable material placed within the bag that when exposed to water allows the water to wick through the absorbable material and activate a lubricious coating on an inside surface of the bag.

18. The surgical device of claim 17 wherein the sheet of absorbable material changes color when exposed to water.

19. A surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient, the surgical device comprising:

a bag shaped as a conical frustum in which a proximal end of the bag is sealed and the distal end of the bag is open with, the bag having an elongated slit extending from the distal end towards the proximal end, the bag further having a single opening formed by the distal opening and the elongated slit, the opening configured to accept the prosthetic implant into the bag;

a sheet of absorbable material placed within the bag that when exposed to water allows the water to wick through the absorbable material and activate a lubricious coating on an inside surface of the bag; and

an adhesive affixed along a portion of the elongated slit to seal the elongated slit such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket.

20. A surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient, the surgical device comprising:

a bag shaped as a conical frustum in which a proximal end of the bag is sealed and the distal end of the bag is open with, the bag having an elongated slit extending from the distal end towards the proximal end, the bag further having a single opening formed by the distal opening and the elongated slit, the opening configured to accept the prosthetic implant into the bag; and

a set of inter-lockable fastener elements disposed along opposing portions of the elongated slit, the set of inter-lockable fastener elements configured to seal the elongated slit

such that the distal end remains open to allow for egress of the implant from the bag for placement into the surgical pocket.

ABSTRACT OF THE DISCLOSURE

A surgical device for assisting in the placement of a prosthetic implant within a surgical pocket of a patient such that placement minimizes tissue stress along and inside the surgical pocket. The surgical device comprises a bag shaped as a conical frustum in which a proximal end of the conical frustum is sealed and a distal end of the conical frustum is open, with an elongated slit extending from the distal end towards the proximal end. An opening formed by the distal opening and the elongated slit is sufficiently large enough to accept the prosthetic implant into the bag. According to one embodiment, an adhesive is affixed along a portion of the elongated slit to seal the elongated slit such that the distal end remains open, thereby allowing for egress of the implant from the bag and placement into the surgical pocket.

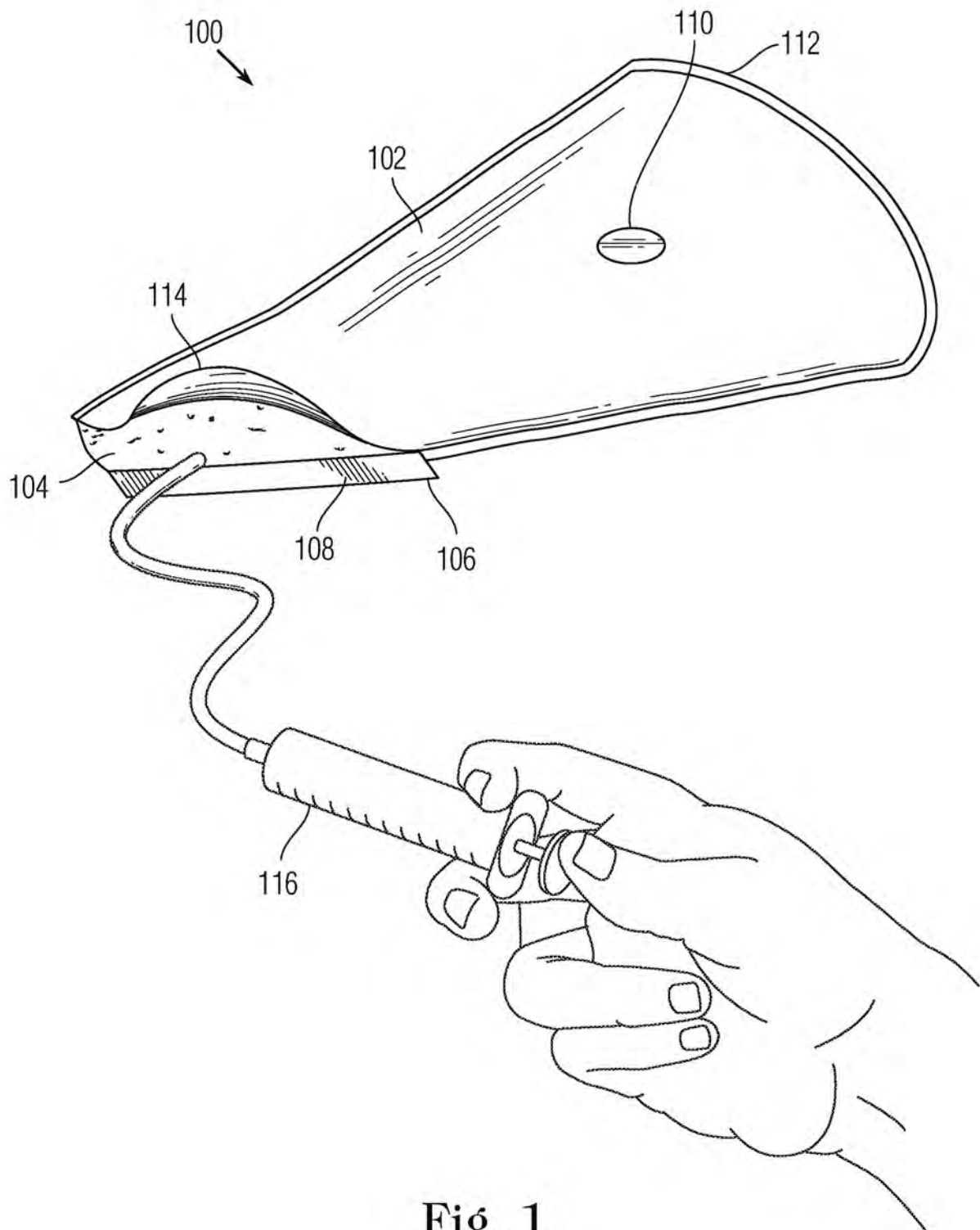
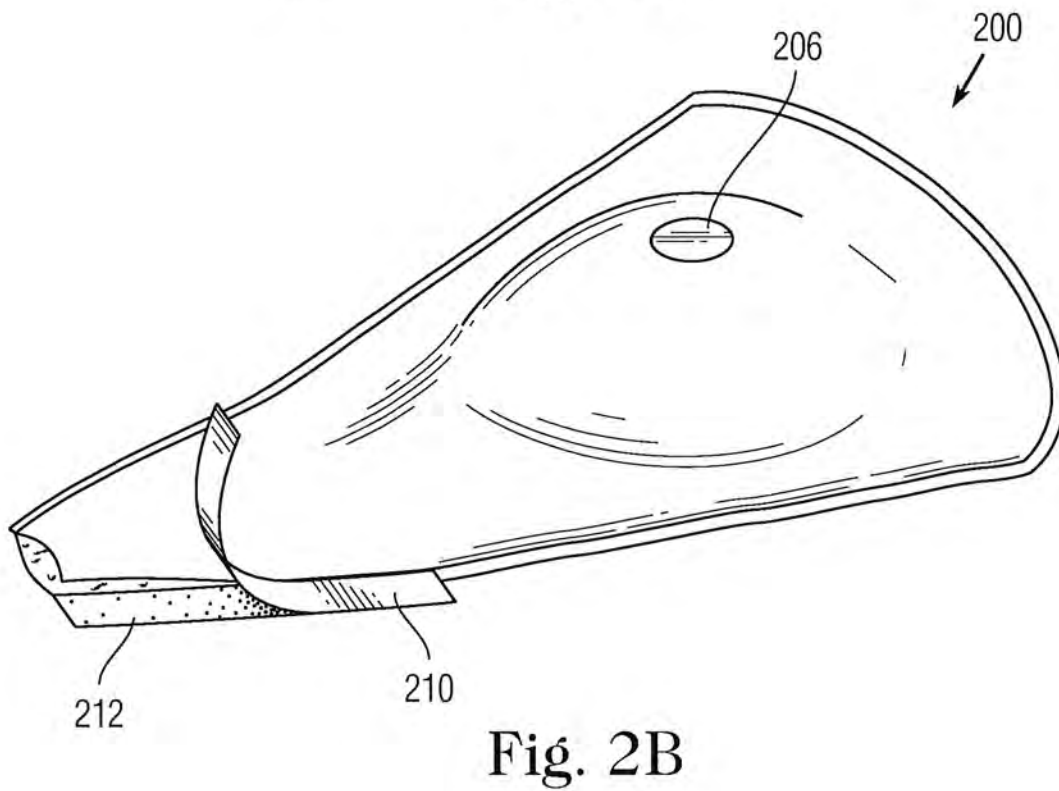
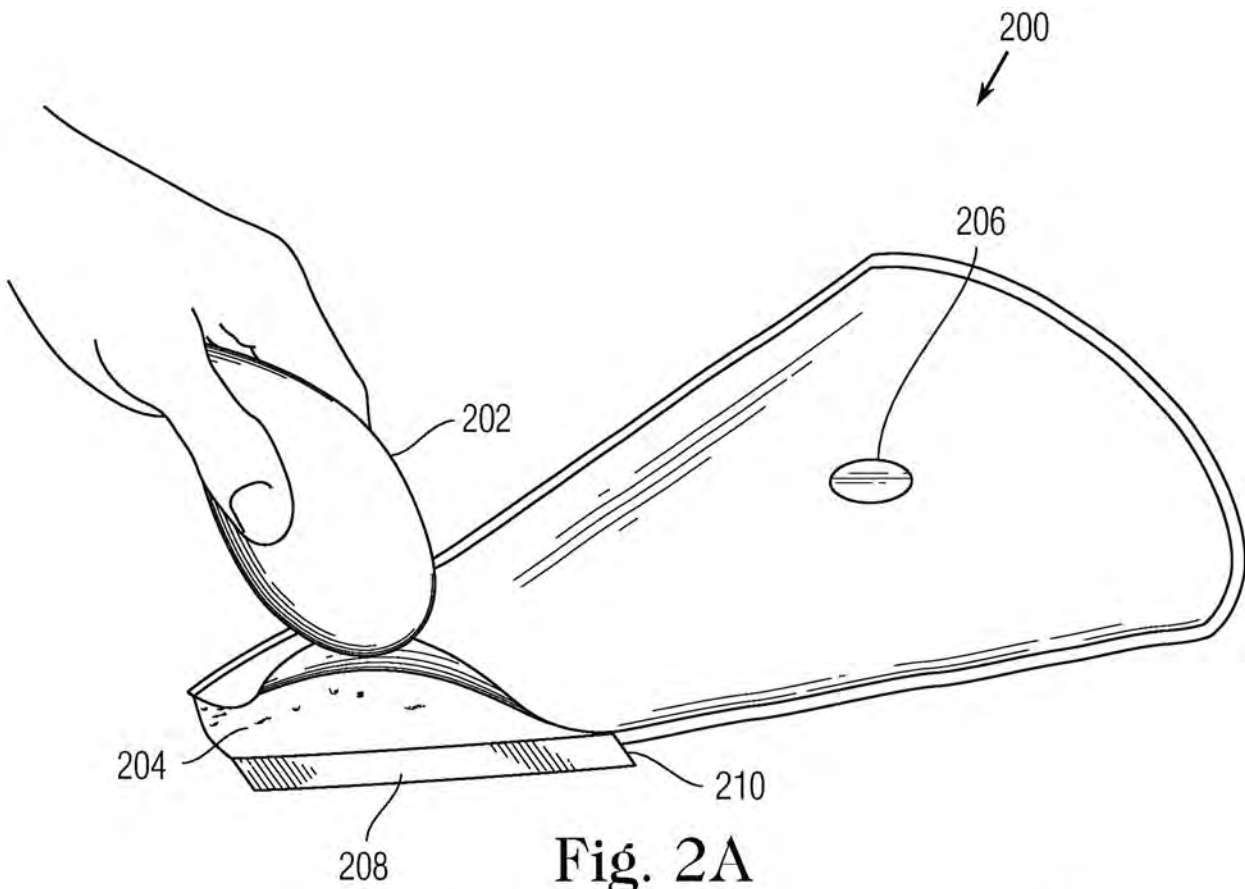


Fig. 1



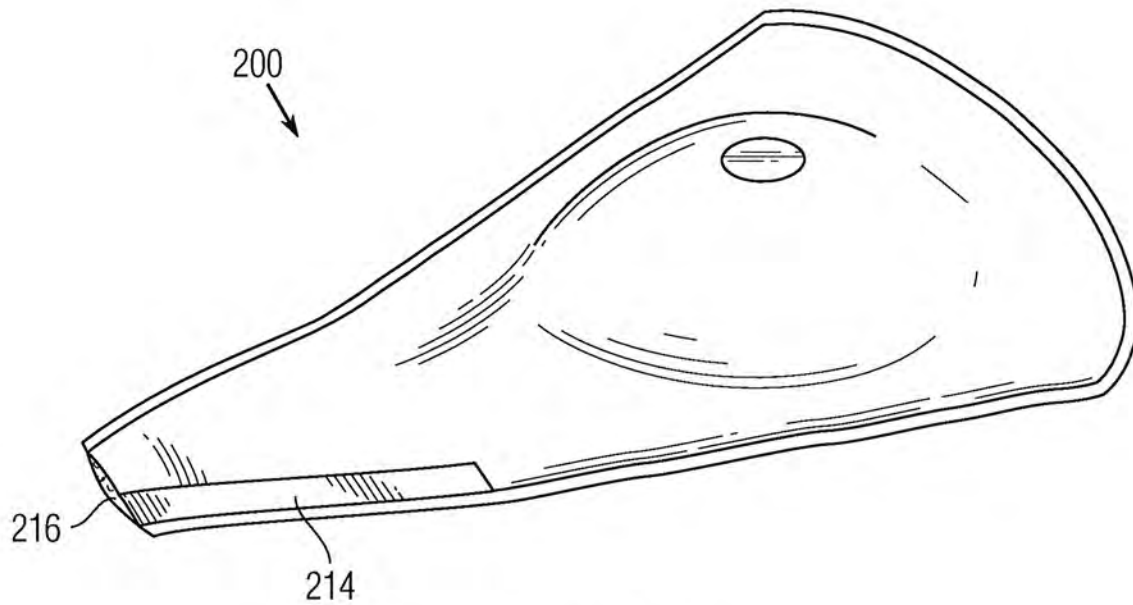


Fig. 2C

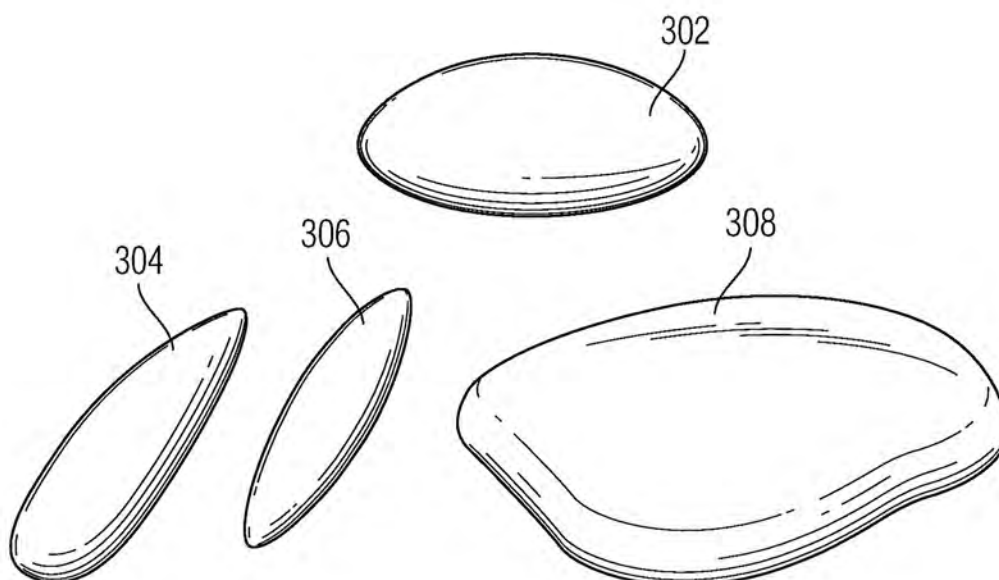


Fig. 3

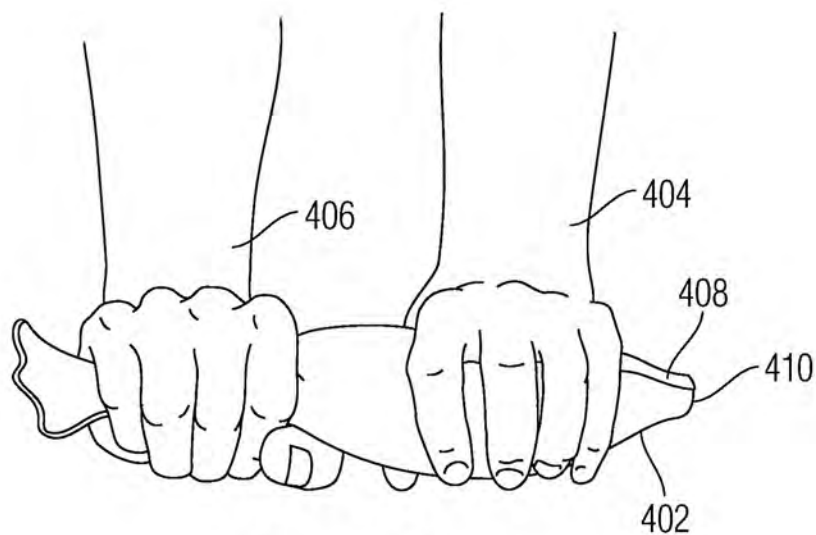


Fig. 4A

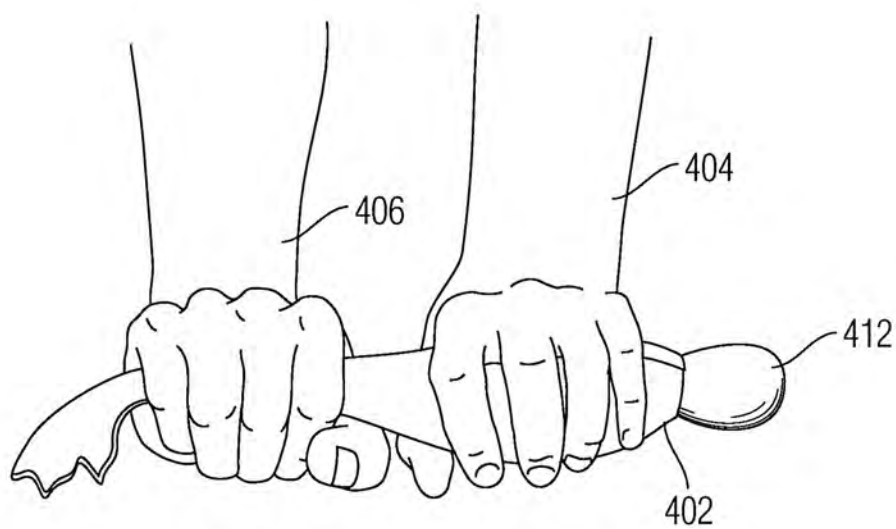


Fig. 4B

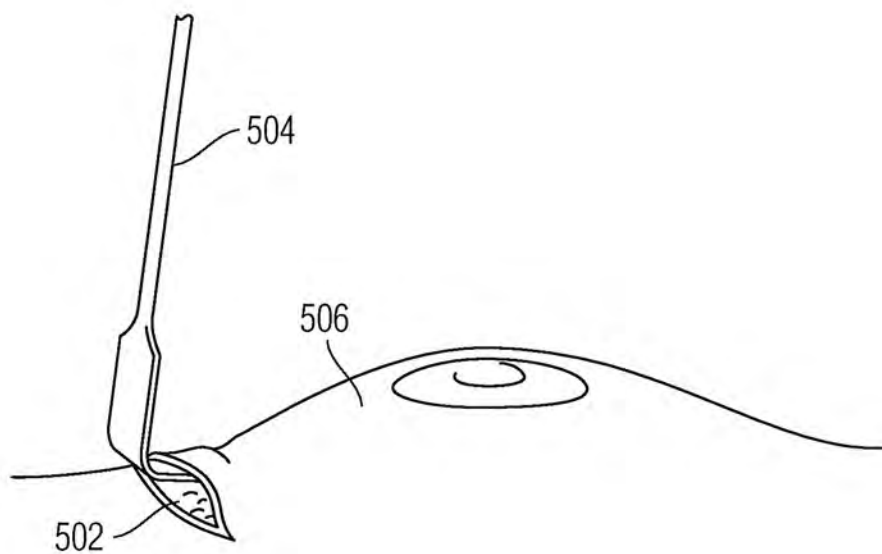


Fig. 5A

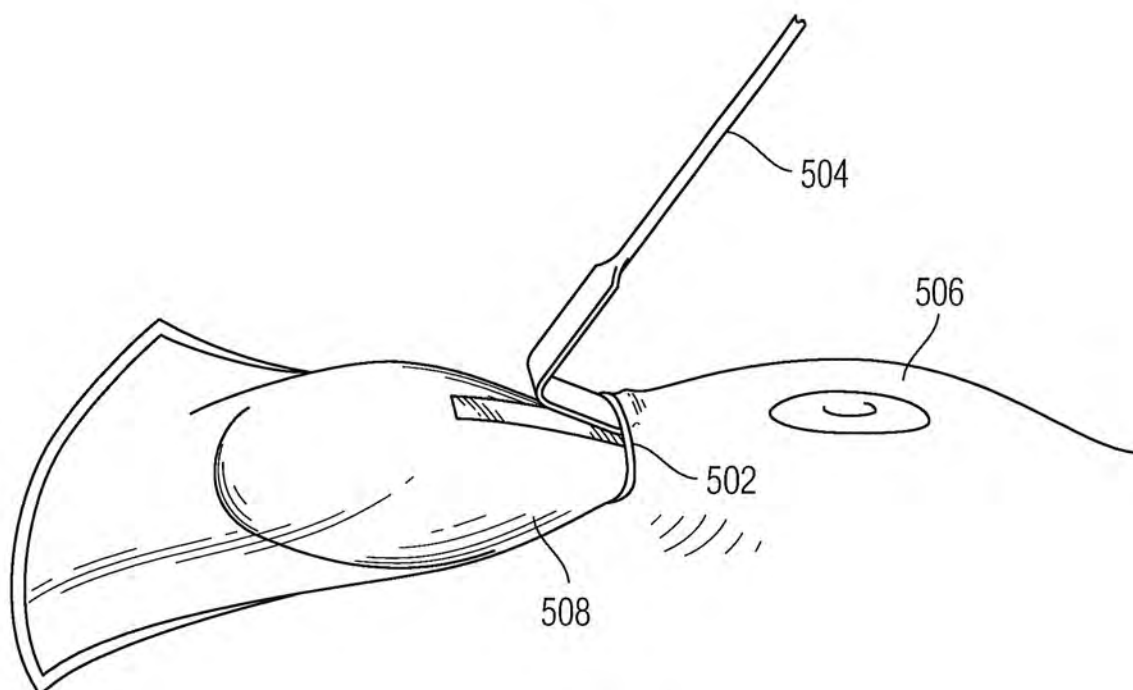


Fig. 5B

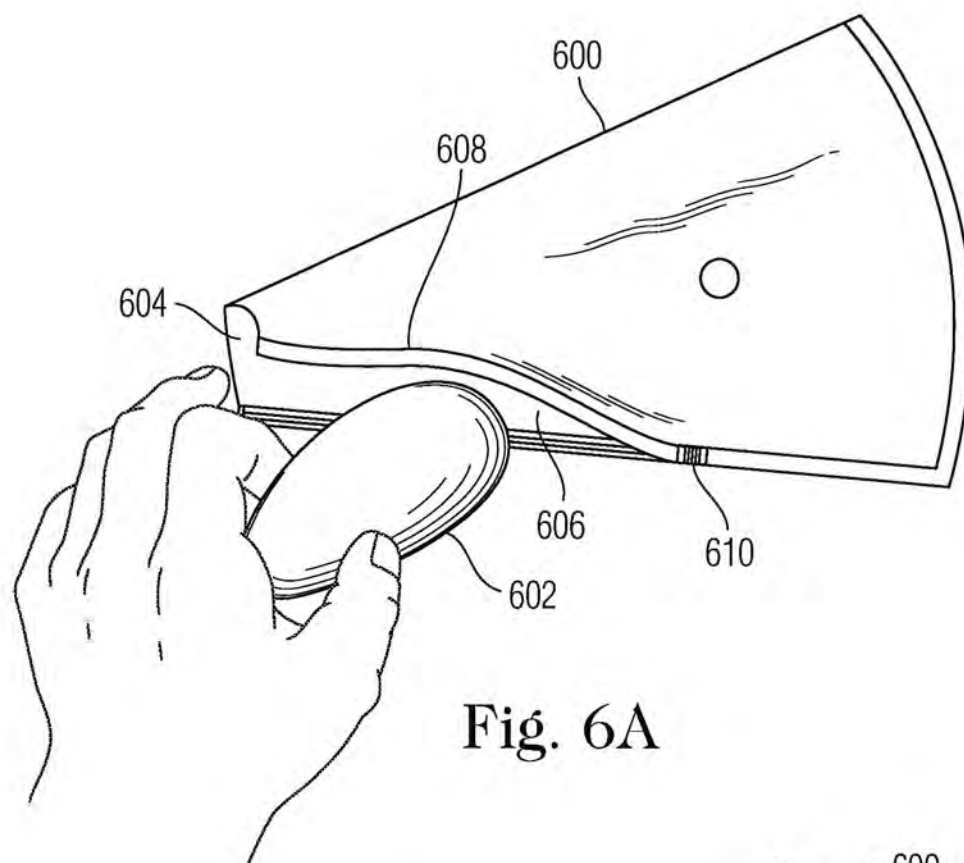


Fig. 6A

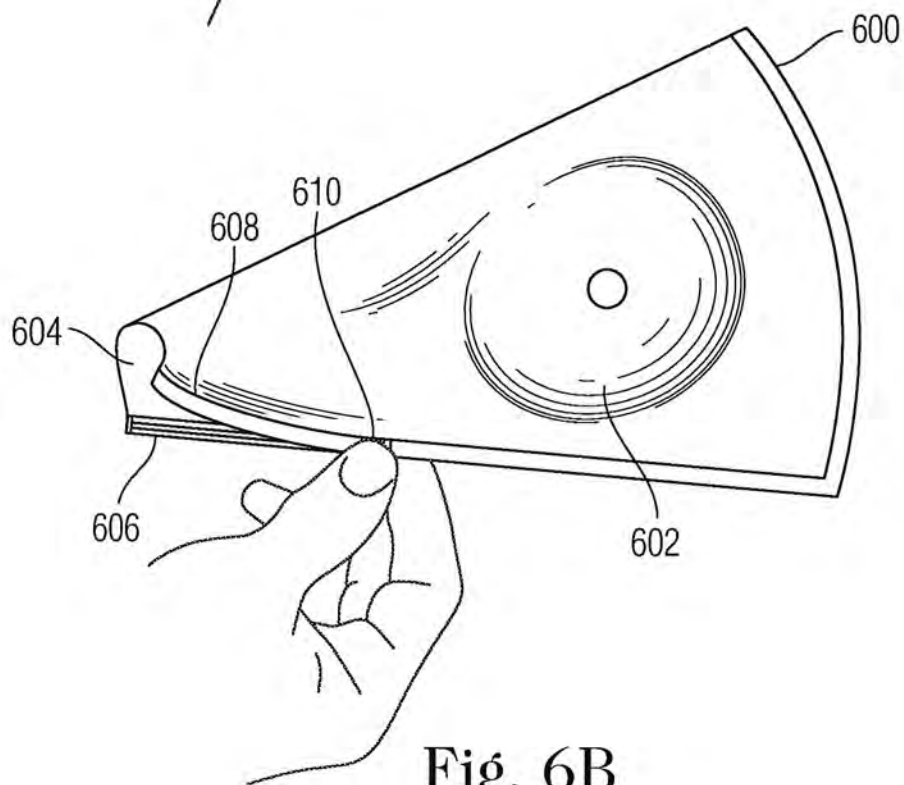


Fig. 6B

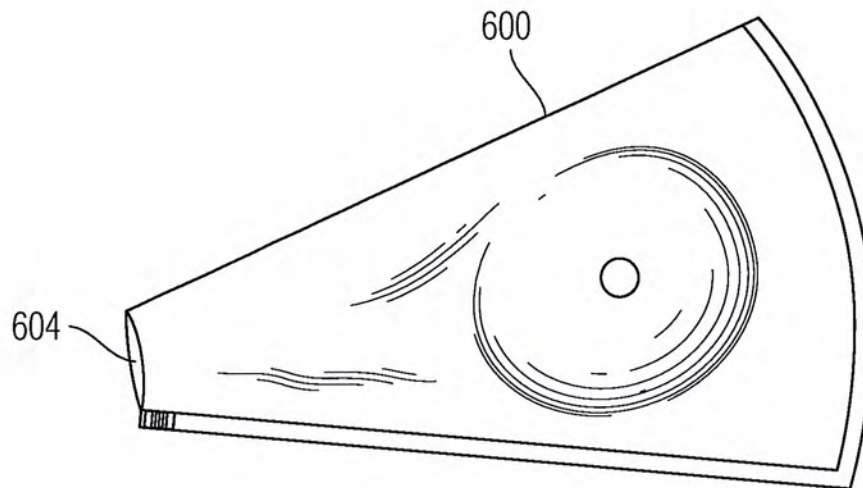


Fig. 6C

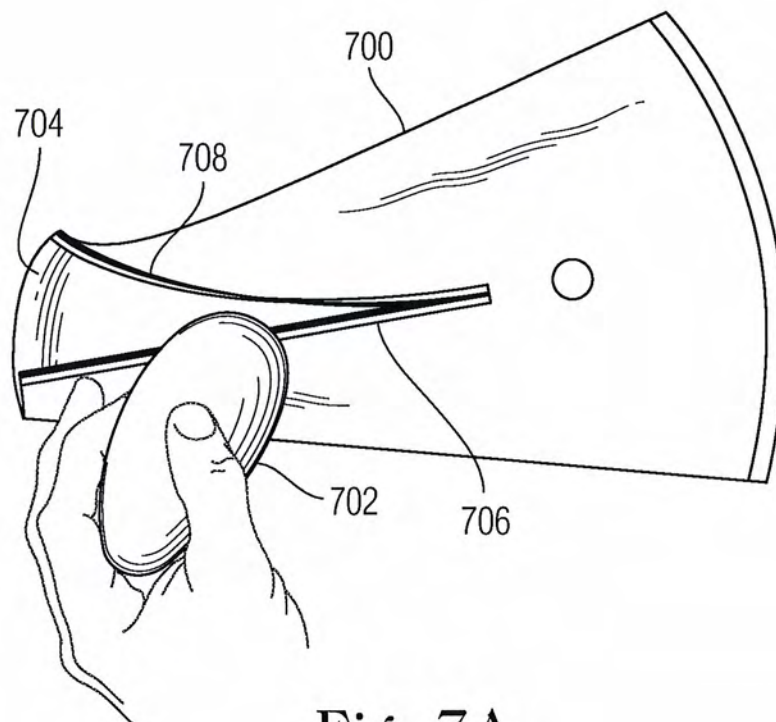


Fig. 7A

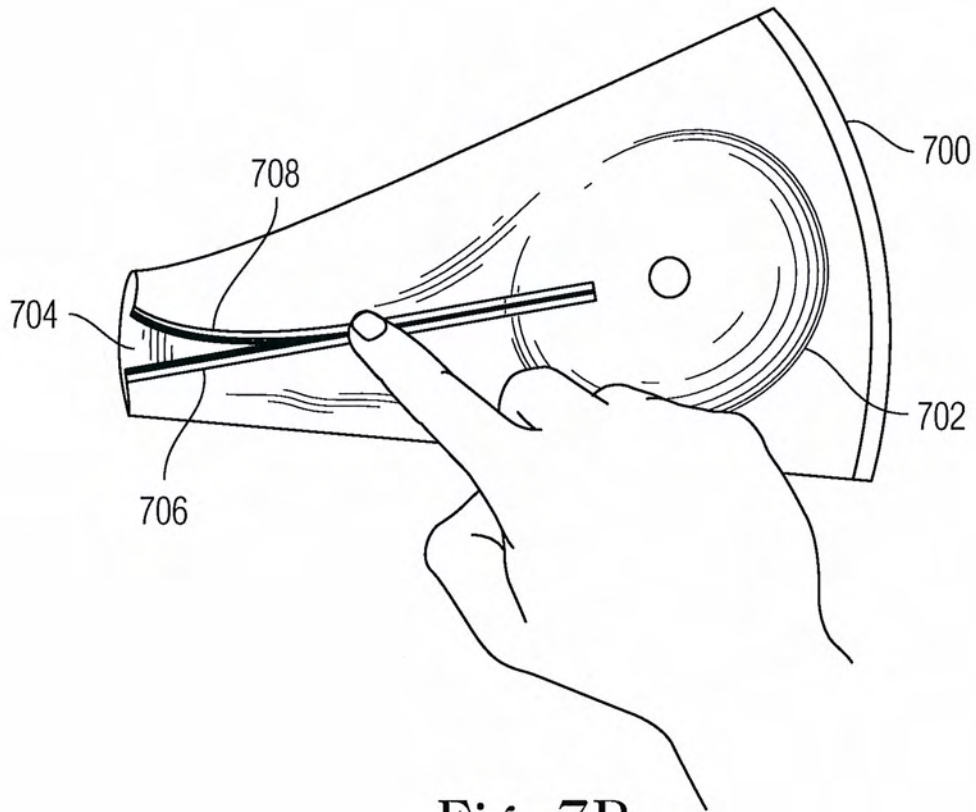


Fig. 7B

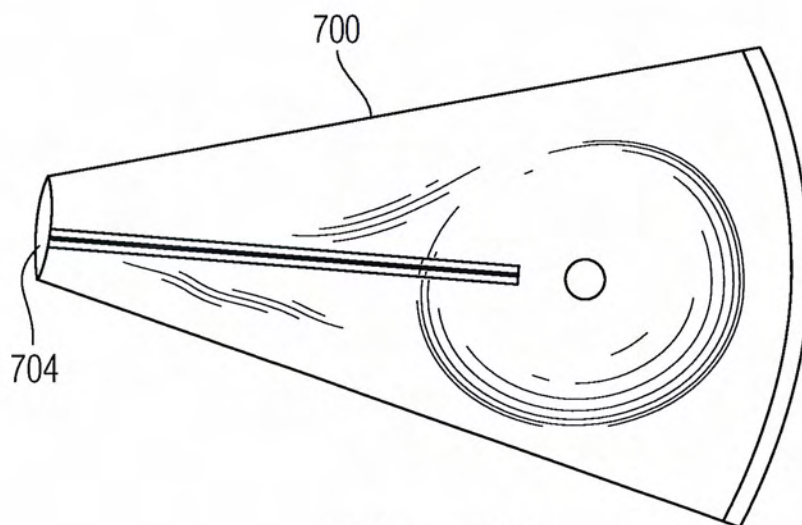


Fig. 7C

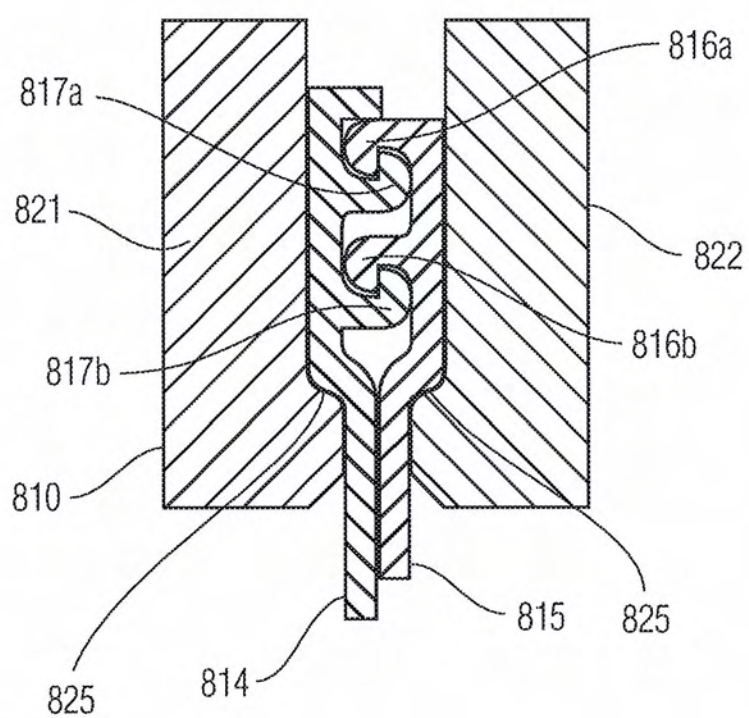


Fig. 8

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10401/005484-US0
		Application Number	
Title of Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

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	Paul		Rosenberg			
Residence Information (Select One) • US Residency Non US Residency Active US Military Service						
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Application Information:

Title of the Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		
Attorney Docket Number	10401/005484-US0	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	9	Suggested Figure for Publication (if any)	1

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10401/005484-US0
		Application Number	
Title of Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button. Add			

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10401/005484-US0
		Application Number	
Title of Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10401/005484-US0
		Application Number	
Title of Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10401/005484-US0
		Application Number	
Title of Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant	1	Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.		
Clear		
☒ Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.		Person who shows sufficient proprietary interest
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:		
Name of the Deceased or Legally Incapacitated Inventor:		
If the Applicant is an Organization check here. ☒		
Organization Name	Proximate Concepts LLC	
Mailing Address Information For Applicant:		
Address 1	1567 Palisade Ave	
Address 2		
City	Fort Lee	State/Province NJ
Country	US	Postal Code 07024
Phone Number		Fax Number
Email Address		
Additional Applicant Data may be generated within this form by selecting the Add button. Add		

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10401/005484-US0
		Application Number	
Title of Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		

Assignee	1
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Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1				
Address 2				
City		State/Province		
Country ⁱ		Postal Code		
Phone Number		Fax Number		
Email Address				

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is **not** checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/peter busch/		Date (YYYY-MM-DD)	2016-11-15
First Name	Peter	Last Name	Busch	Registration Number
				72966

Additional Signature may be generated within this form by selecting the Add button.

Add

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	10401/005484-US0
		Application Number	
Title of Invention	DEVICE FOR THE DELIVERY OF A PROSTHETIC IMPLANT AND METHOD OF USE THEREOF		

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.