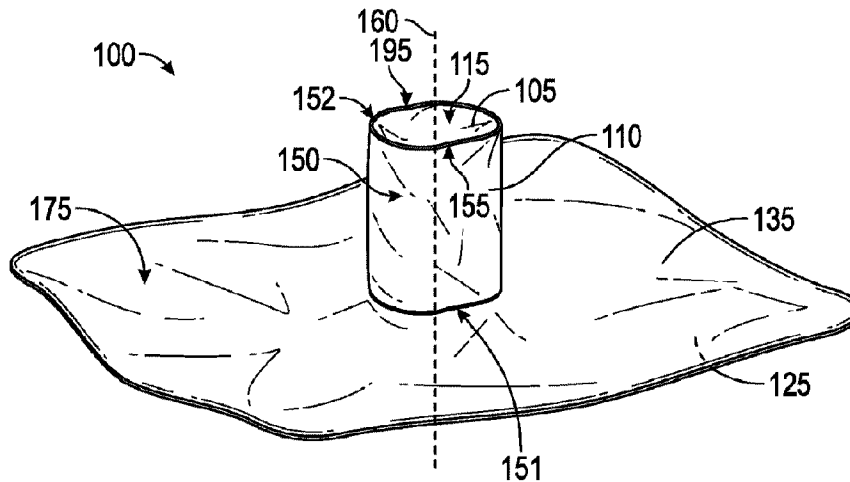




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 (72) **Inventeur/Inventor:**  
 BRESNICK, STEPHEN DAVID, US  
 (73) **Propriétaire/Owner:**  
 BRESNICK, STEPHEN DAVID, US  
 (74) **Agent:** NORTON ROSE FULBRIGHT CANADA  
 LLP/S.E.N.C.R.L., S.R.L.

(54) **Titre : BARRIERE DE PROTECTION CONTRE LE BIOFILM POUR IMPLANTS**  
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(57) **Abrégé/Abstract:**

Apparatus, systems, and methods for inserting prosthesis implants into surgically-created implant pockets in a subject and for preventing capsular contracture resulting from surgical insertion of prosthesis implants. The apparatus may include a shielding member capable of shielding an implant from at least a portion of the dissection tunnel connecting the incision to the implant pocket. The apparatus may also include a base operable to secure the shielding member during implant insertion as well as to protect the implant from the skin during insertion into the shielding member. The apparatus may also have an implant receiving member operable to receive the implant and shield the implant from the skin of the patient during insertion of the implant into the shielding member. The apparatus is capable of shielding the implant from microbial contamination, including contamination by the endogenous flora of the subject, during insertion of the implant into the surgically-created implant pocket.

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## (72) Inventor; and

(71) Applicant: **BRESNICK, Stephen David** [US/US]; 16633  
Ventura Blvd, Suite 110, Encino, California 91436 (US).

(74) Agent: **DAVIS, Kevin J.** et al.; Polsinelli PC, 1000  
Louisiana Street, Suite 6400, Houston, Texas 77002 (US).

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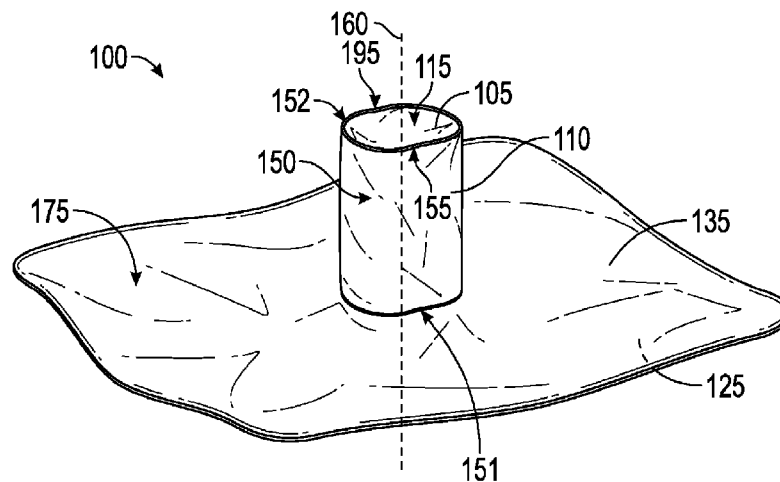


FIG. 1

(57) Abstract: Apparatus, systems, and methods for inserting prosthesis implants into surgically-created implant pockets in a subject and for preventing capsular contracture resulting from surgical insertion of prosthesis implants. The apparatus may include a shielding member capable of shielding an implant from at least a portion of the dissection tunnel connecting the incision to the implant pocket. The apparatus may also include a base operable to secure the shielding member during implant insertion as well as to protect the implant from the skin during insertion into the shielding member. The apparatus may also have an implant receiving member operable to receive the implant and shield the implant from the skin of the patient during insertion of the implant into the shielding member. The apparatus is capable of shielding the implant from microbial contamination, including contamination by the endogenous flora of the subject, during insertion of the implant into the surgically-created implant pocket.

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# **BIOFILM PROTECTION IMPLANT SHIELD**

## **FIELD OF TECHNOLOGY**

[0001] The present disclosure is directed to the insertion of prosthesis implants into a surgically-created implant pocket of a subject. In some specific instances, the present disclosure is directed to the insertion of breast implants, including un-filled implants and pre-filled implants such as silicone breast implants and pre-filled saline implants. The present disclosure is further directed to methods, devices, and systems for inserting prosthesis implants in the surgically-created implant pocket of a subject as well as methods for preventing capsular contracture resulting from surgical insertion of prosthesis implants.

## **BACKGROUND**

[0002] Capsular contracture remains the most common complication of aesthetic breast augmentation despite advances in the understanding of the biological processes which appear to be involved. Capsular contracture is characterized by the tightening and hardening of the capsule surrounding the implant. The role of biofilms in capsular contracture has been reported extensively and is believed to play an important role in the pathogenesis of capsular contracture. Recent advances in antibiotic irrigation as well as the use of skin barriers and nipple shields has assisted in the reduction of capsular contracture. Yet, despite these advances, a significant number of women develop capsular contracture following breast augmentation and require

revisional surgery or live with discomfort, deformity, or suboptimal results.

[0004] Form-stable implant studies with textured devices have shown lower capsular contracture rates compared to smooth round devices. However, anaplastic large cell lymphoma (ALCL) is an indolent lymphoma found in women with textured implants. Biofilm infection is hypothesized to be involved in the development of both capsular contracture and ALCL. It is suspected that a source of the biofilm infection may be microbes from the skin and/or exposed breast tissue of the patient that come in contact with the sterile implant during insertion into the surgically-created implant pocket. In particular, the subject's endogenous flora present at the time of the surgery, including those bacteria that may be present in the dissection tunnel connecting the skin incision to the surgically-created implant pocket or the skin surface itself, may attach to the surface of the implant during placement in the implant pocket. Following insertion of the implant, the bacteria may colonize the surface of the implant and form a biofilm. If the surface of the implant is colonized by a large number of bacteria, the subject's defenses may be overwhelmed and the biofilm may trigger a chronic inflammatory response leading to subsequent fibrosis and accelerated capsular contracture. Accordingly, methods and devices capable of shielding the implant from microbial contamination, including contamination by the endogenous flora of the subject, during insertion of the implant into the surgically-created implant pocket are desirable.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0005] In order to describe the manner in which the advantages and features of the disclosure can be obtained, reference is made to embodiments thereof which are illustrated in the appended drawings. One of skill in the art will understand that the reference numbers in the following figures are repeated throughout FIGs. 1-45 so as to refer to the same or substantially the same features. Understanding that these drawings depict only exemplary embodiments of the disclosure and are not therefore to be considered to be limiting of its scope, the principles herein are described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0006] FIG. 1 is an isometric view of the implant shield apparatus, according to an exemplary embodiment of the present disclosure;

[0007] FIG. 2 is a planar view of the implant shield apparatus, according to an exemplary embodiment of the present disclosure;

[0008] FIG. 3 is a front diagrammatic view of the implant shield apparatus showing the distal end of shielding member and the lower surface of the base, according to an exemplary embodiment of the present disclosure;

[0009] FIG. 4 is a rear diagrammatic view of the implant shield apparatus showing the proximal end of the shielding member and the upper surface of the base, according to an exemplary embodiment of the present disclosure;

[0010] FIG. 5 is an isometric view of an implant shield apparatus having a substantially circular base, according to an exemplary embodiment of the present disclosure;

[0011] FIG. 6A is a rear diagrammatic view of an implant shield apparatus in an unrolled configuration in which an end of the shielding member may be rolled on itself to form a base and a shortened shielding member, according to an exemplary embodiment of the present disclosure;

[0012] FIG. 6B is an isometric view of an implant shield apparatus in the rolled configuration in which an end of the shielding member is rolled on itself to form a base and a shortened shielding member, according to an exemplary embodiment of the present disclosure;

[0013] FIG. 7A is a rear diagrammatic view of an implant shield apparatus in the undeployed configuration in which an end of the implant shield apparatus is perforated so as to be deployable to form a base, according to an exemplary embodiment of the present disclosure;

[0014] FIG. 7B is a rear end diagrammatic view of an implant shield apparatus in the deployed configuration in which an end of the implant shield apparatus is deployed so as to form a base having a plurality of substantially rectangular flanges, according to an exemplary embodiment of the present disclosure;

[0015] FIG. 7C is an isometric view of an implant shield apparatus in the deployed configuration in which an end of the implant shield apparatus is deployed so as to form a base

having a plurality of substantially rectangular flanges, according to an exemplary embodiment of the present disclosure;

[0016] FIG. 8A is a rear diagrammatic view of an implant shield apparatus in the undeployed configuration in which an end of the implant shield apparatus is perforated so as to be deployable to form a base, according to an exemplary embodiment of the present disclosure;

[0017] FIG. 8B is a rear end diagrammatic view of an implant shield apparatus in the deployed configuration in which an end of the implant shield apparatus is deployed so as to form a base having a plurality of substantially trapezoidal flanges, according to an exemplary embodiment of the present disclosure;

[0018] FIG. 8C is an isometric view of an implant shield apparatus in the deployed configuration in which an end of the implant shield apparatus is deployed so as to form a base having a plurality of substantially trapezoidal flanges, according to an exemplary embodiment of the present disclosure;

[0019] FIG. 9 is an illustration depicting the creation of a periareolar incision in the breast of a subject; according to an exemplary embodiment of the present disclosure;

[0020] FIG. 10 is an illustration depicting the opening of the periareolar incision using two retractors, according to an exemplary embodiment of the present disclosure;

[0021] FIG. 11 is an illustration depicting insertion of the distal end of the shielding member of the implant shield into the dissection tunnel connecting the periareolar incision to the surgically-created implant pocket, according to an exemplary embodiment of the present disclosure;

[0022] FIG. 12 is an illustration depicting further insertion of the shielding member into the dissection tunnel, according to an exemplary embodiment of the present disclosure;

[0023] FIG. 13 is an illustration depicting engagement of the lower surface of the base of the implant shield with at least a portion of the skin adjacent to the incision, according to an exemplary embodiment of the present disclosure;

[0024] FIG. 14 is an illustration depicting opening of the inner bore of the shielding member and dissection tunnel using sterile retractors inserted into the inner bore of the implant

shield with the implant shield in place to provide a shielded path for the implant to the implant pocket or dissection tunnel, according to an exemplary embodiment of the present disclosure;

[0025] FIG. 15A is an illustration depicting insertion of the implant through the aperture of the base of the implant shield with the inner bore of the shielding member held open by sterile retractors inserted into the inner bore of the implant shield, according to an exemplary embodiment of the present disclosure;

[0026] FIG. 15B is an illustration depicting delivery of the implant through the aperture of the base of the implant shield with the dissection tunnel held open by sterile retractors placed in the dissection tunnel outside the shielding member of the implant shield and between the walls of the dissection tunnel and the outer surface of the shielding member, according to an exemplary embodiment of the present disclosure;

[0027] FIG. 16 is an illustration depicting disengagement of the lower surface of the base of the implant shield from the skin of the subject and removal of the shielding member from the dissection tunnel, according to an exemplary embodiment of the present disclosure;

[0028] FIG. 17 is an illustration depicting insertion of the shielding member of the implant shield into an inframammary incision in skin of the subject, rather than the periareolar incision depicted in FIGs. 9-16, according to an exemplary embodiment of the present disclosure;

[0029] FIG. 18 is an illustration depicting insertion of the terminus of a conical sleeve through the aperture of the base and into the inner bore of the shielding member while the inner bore of the shielding member is held open using sterile retractors placed inside the inner bore of the shielding member, according to an exemplary embodiment of the present disclosure;

[0030] FIG. 19 is an illustration depicting insertion of the terminus of a conical sleeve through the aperture of the base and into the inner bore of the shielding member while the dissection tunnel is held open by sterile retractors placed in the dissection tunnel between the walls of the dissection tunnel and the outer surface of the shielding member of the implant shield, according to an exemplary embodiment of the present disclosure;

[0031] FIG. 20 is an illustration depicting insertion of an implant into a conical sleeve having a terminus disposed within the inner bore of the shielding member so that the implant may be delivered to the surgical pocket while being shielded by the implant shield;

[0032] FIG. 21 is an illustration depicting the creation of an inframammary incision in the breast of a subject; according to an exemplary embodiment of the present disclosure;

[0033] FIG. 22 is an illustration depicting the opening of the inframammary incision using two retractors, according to an exemplary embodiment of the present disclosure;

[0034] FIG. 23 is an illustration depicting insertion of the distal end of the shielding member of the implant shield into the dissection tunnel connecting the inframammary incision to the surgically-created implant pocket, according to an exemplary embodiment of the present disclosure;

[0035] FIG. 24 is an illustration depicting further insertion of the shielding member into the dissection tunnel, according to an exemplary embodiment of the present disclosure;

[0036] FIG. 25 is an illustration depicting engagement of the lower surface of the base of the implant shield with at least a portion of the skin adjacent to the incision, according to an exemplary embodiment of the present disclosure;

[0037] FIG. 26 is an illustration depicting opening of the inner bore of the shielding member and dissection tunnel using sterile retractors inserted into the inner bore of the implant shield with the implant shield in place to provide a shielded path for the implant to the implant pocket or dissection tunnel, according to an exemplary embodiment of the present disclosure;

[0038] FIG. 27A is an illustration depicting insertion of the implant through the aperture of the base of the implant shield with the inner bore of the shielding member held open by sterile retractors inserted into the inner bore of the implant shield, according to an exemplary embodiment of the present disclosure;

[0039] FIG. 27B is an illustration depicting delivery of the implant through the aperture of the base of the implant shield with the dissection tunnel held open by sterile retractors placed in the dissection tunnel outside the shielding member of the implant shield and between the walls of the dissection tunnel and the outer surface of the shielding member, according to an exemplary embodiment of the present disclosure;

[0040] FIG. 28 is an illustration depicting disengagement of the lower surface of the base of the implant shield from the skin of the subject and removal of the shielding member from the dissection tunnel, according to an exemplary embodiment of the present disclosure;

[0041] FIG. 29 is a partial cross-sectional view of the periareolar insertion of an implant through the aperture of the base of an implant shield engaged with the skin of a subject and through the shielding member of the implant shield towards the implant pocket with the retractors holding open the dissection tunnel by being placed outside the shielding member, according to an exemplary embodiment of the present disclosure;

[0042] FIG. 30 is a partial cross-sectional view of the periareolar insertion of an implant through the aperture of the base of an implant shield engaged with the skin of a subject and through the shielding member of the implant shield towards the implant pocket with the retractors holding open the shielding member by being placed inside the inner bore of the shielding member, according to an exemplary embodiment of the present disclosure;

[0043] FIG. 31 is a partial cross-sectional view of the periareolar insertion of the implant shield into a distal portion of the dissection tunnel after adjusting the predetermined length of the inner bore of the shielding member based on a measured length of the dissection tunnel connecting the implant pocket to the periareolar incision on the skin of the subject, according to an exemplary embodiment of the present disclosure;

[0044] FIG. 32 is a partial cross-sectional view of the inframammary insertion of an implant through the aperture of the base of an implant shield engaged with the skin of a subject through the shielding member of the implant shield into a distal portion of the dissection tunnel and the implant pocket, according to an exemplary embodiment of the present disclosure;

[0045] FIG. 33 is an isometric view of an implant shield apparatus having a shielding member that includes both a tubular member and a conical member, according to an exemplary embodiment of the present disclosure;

[0046] FIG. 34 is a planar view of an implant shield apparatus having a shielding member that includes both a conical member and a tubular member, according to an exemplary embodiment of the present disclosure;

[0047] FIG. 35 is an isometric view of an implant shield apparatus having a shielding member comprising a conical member coupled to a base, according to an exemplary embodiment of the present disclosure;

[0048] FIG. 36 is a planar view of an implant shield apparatus having a shielding member comprising a conical member coupled to a base, according to an exemplary embodiment of the present disclosure;

[0049] FIG. 37A is a cross-sectional view of an implant shield apparatus having a shielding member having a frustoconical inner bore and an outer bore having an uniform cross-sectional width, according to an exemplary embodiment of the present disclosure;

[0050] FIG. 37B is a cross-sectional view of an implant shield apparatus that includes a shielding member having an inner bore that characterized by a uniform cross-sectional width at the distal end and a variable cross-sectional width conical inner bore at the proximal end;

[0051] FIG. 38A is a rear diagrammatic view of an implant shield apparatus having a shielding member, an implant receiving member, and a base, according to an exemplary embodiment of the present disclosure;

[0052] FIG. 38B is a rear diagrammatic view of an implant shield apparatus having a shielding member and an implant receiving member without a base, according to an exemplary embodiment of the present disclosure;

[0053] FIG. 39 is a front diagrammatic view of an implant shield apparatus having a shielding member, an implant receiving member, and a base, according to an exemplary embodiment of the present disclosure;

[0054] FIG. 40 is an illustration depicting the creation of a periareolar incision in the breast of a subject; according to an exemplary embodiment of the present disclosure;

[0055] FIG. 41 is an illustration depicting the opening of the periareolar incision using two retractors, according to an exemplary embodiment of the present disclosure;

[0056] FIG. 42 is an illustration depicting insertion of the distal end of the shielding member of an implant shield having an implant receiving member and a base into the dissection

tunnel connecting the periareolar incision to the surgically-created implant pocket, according to an exemplary embodiment of the present disclosure;

[0057] FIG. 43 is an illustration depicting further insertion of the shielding member into the dissection tunnel and engagement of the lower surface of the base of the implant shield with at least a portion of the skin of the subject adjacent to the incision, according to an exemplary embodiment of the present disclosure;

[0058] FIG. 44 is an illustration depicting engagement of the lower surface of the base of the implant shield with at least a portion of the skin adjacent to the incision with a retractor inserted between the wall of the dissection tunnel and the shielding member so as to hold open the dissection tunnel in preparation of implant insertion, according to an exemplary embodiment of the present disclosure;

[0059] FIG. 45A is an illustration depicting insertion of the implant through the proximal end of the implant receiving member of the implant shield, according to an exemplary embodiment of the present disclosure; and

[0060] FIG. 45B is an illustration depicting insertion of the implant through the proximal end of the implant receiving member of the implant shield so that the implant may be delivered through the distal end of the shielding member to the implant pocket in the subject, according to an exemplary embodiment of the present disclosure.

### **DETAILED DESCRIPTION**

[0061] It will be appreciated that numerous specific details are set forth in order to provide a thorough understanding of the embodiments described herein. However, it will be understood by those of ordinary skill in the art that the embodiments described herein can be practiced without these specific details. In other instances, methods, procedures and components have not been described in detail so as not to obscure the related relevant feature being described. Also, the description is not to be considered as limiting the scope of the embodiments described herein.

[0062] The present disclosure provides apparatus, methods, and systems for inserting prosthesis implants into surgically-created implant pockets in a subject. The presently disclosed

apparatus, methods, and systems may be used to deliver any prosthesis implants into a surgically-created implant pocket in a subject. The present disclosure is further directed to methods, devices, and systems for preventing capsular contracture resulting from surgical insertion of prosthesis implants. The prosthesis implant may include, for example, filled implants or pre-filled implants, unfilled implants, saline implants, silicone gel implants, textured implants, smooth implants, highly cohesive silicone gel implants, or oil-filled implants. The prosthesis implant may also be, for example, an implantable device, such as a pacemaker or a joint replacement prosthesis, or the prosthesis implant may be a tissue graft, such as an allograft or an autograft.

[0063] In some specific instances, the present disclosure is directed to the insertion of breast implants into the implant pocket in a breast of a subject. In such cases, the breast implant may be an un-filled breast implant or may be a pre-filled breast implant such as a pre-filled saline implant or a pre-filled silicone implant. In particular, the presently disclosed apparatus, methods, and systems are well-suited to the delivery of pre-filled breast implants which require an insertion device capable of withstanding and managing the compressive and frictional forces associated with insertion of the pre-filled implant while still being gentle enough so as to not damage the pre-filled implant during delivery to the implant pocket in the subject. The breast implant may also be, for example, a textured breast implant, a smooth breast implant, a highly cohesive silicone gel breast implant, an oil-filled breast implant, or an un-filled saline breast implant. The present disclosure is further directed to methods, devices, and systems for preventing capsular contracture resulting from surgical insertion of breast implants.

[0064] According to at least one aspect of the present disclosure, a biofilm protection implant shield apparatus useful for inserting an implant into a surgically-created implant pocket in a subject is provided. The implant shield apparatus may include a shielding member for shielding the implant from at least a portion of the dissection tunnel during insertion of the implant into the implant pocket in the subject. In some instances, the implant shield apparatus may optionally include a base that helps to secure the shielding member during insertion of the implant into the shielding member. The base also shields the implant from the skin of the subject during insertion of the implant into the shielding member. In some instances, the implant shield apparatus may further include an implant receiving member operable to receive the implant either

before or after the shielding member is inserted into the incision in the patient. In instances in which the implant shield apparatus includes an implant receiving member, the base may not be necessary as the implant receiving member may be sufficient to shield the implant from the skin of the patient during insertion of the implant into the shielding member portion of the apparatus.

[0065] The shielding member has an inner bore extending longitudinally between a proximal end and a distal end. The inner bore extends a predetermined length between the proximal end and the distal end of the shielding member. The inner bore of the shielding member may be tubular, conical, or any combination thereof. In cases in which the inner bore of the shielding member is tubular, the inner bore of the shielding member has an uniform cross-sectional width along its predetermined length. In cases in which the inner bore of the shielding member is conical, the inner bore of the shielding member has a variable cross-sectional width along its predetermined length. Typically, the conical shielding member has a wider cross-sectional width towards the proximal end of the conical shielding member. For example, the shielding member may comprise a conical member in which the cross-sectional width of the inner bore at the proximal end of the shielding member is longer than the cross-sectional width of the inner bore at the distal end of the shielding member. In such cases, the wider cross-section width the proximal end of the shielding member may facilitate or ease insertion of the implant into the shielding member.

[0066] In some instances, the shielding member may have an inner bore that is both tubular and conical. In such instances, the shielding member may comprise a tubular member and a conical member. Generally, the conical member comprises the proximal end of the shielding member while the tubular member comprises the distal end of the shielding member. Accordingly, the proximal end of the inner bore of the shielding member may have a variable cross-sectional width while the distal end of the inner bore has an uniform cross-sectional width.

[0067] The implant shield apparatus may optionally include a base that helps to secure the shielding member during insertion of the implant into the shielding member, as well as shield the sterile implant from the skin of the subject during insertion of the implant into the shielding member. The base has an upper surface and a lower surface. The lower surface of the base is operable to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket. The base may have an aperture formed therein which extends through

through the upper surface and the lower surface of the base. The base may be coupled to the proximal end of the shielding member such that the proximal end of the inner bore of the shielding member is substantially aligned with the aperture formed in the base. Therefore, when an implant is inserted into the aperture formed in the base, the implant is received in the proximal end of the inner bore of the shielding member.

[0068] In cases in which the implant shield apparatus includes an implant receiving member as well as a base, the base may extend radially from either the shielding member or the implant receiving member, or alternatively, the base may extend radially from the intersection of the shielding member and the implant receiving member. In some instances, the shielding member or the implant receiving member may extend through the base. In some cases, the shielding member or the implant receiving member may extend through an aperture formed in the base.

[0069] According to at least one aspect of the present disclosure, an apparatus for inserting an implant into a surgically-created implant pocket in a subject is provided. The apparatus may include a base having an upper surface and a lower surface. The base may have an aperture formed therein that extends through the upper surface and the lower surface of the base. The apparatus may also include a shielding member coupled with the base. The shielding member may have an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length away from the lower surface of the base. The proximal end of the shielding member may be coupled with the base and the inner bore may be substantially aligned with the aperture formed in the base. The inner bore of the shielding member is operable to receive the implant therethrough. The shielding member may have an aperture formed in the distal end of the shielding member through which the implant exits the shielding member and is received by the implant pocket of the subject. The lower surface of the base is operable to engage with a skin of the subject. For example, the base may have an adhesive disposed on the lower surface of the base. The shielding member and base may be formed from a flexible material. For example, the flexible material may be selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any

combination thereof. The predetermined length may be greater than 1 cm. For example, the predetermined length may be from about 2 cm to about 10 cm.

[0070] In at least some instances, the inner bore of the shielding member may be conical or frustoconical. The inner bore may have a larger cross-sectional width at the proximal end than the cross-sectional width of the inner bore at the distal end of the shielding member. In some instances, the inner bore may include both a conical portion and a tubular portion along its predetermined length.

[0071] In some cases, the shielding member may include a conical member. In such cases, the proximal end of the conical member may be coupled with the lower surface of the base such that the inner bore of the conical member is substantially aligned with the aperture of the base so that the conical member may receive the implant once the implant is inserted into the aperture.

[0072] In other cases, the shielding member may include both a conical member and a tubular member. In such cases, the conical member may have an inner bore, a distal end, and a proximal end, and the tubular member may have an inner bore, a distal end and a proximal end. The distal end of the conical member may be coupled with the proximal end of the tubular member such that the inner bore of the conical member is substantially aligned with the inner bore of the tubular member to form the inner bore of the shielding member. The tubular member may have a first predetermined length and the conical member may have a second predetermined length, the predetermined length of the shielding member comprising the sum of the first and second predetermined lengths.

[0073] The shielding member may have an outer surface that defines the outer bore of the shielding member. In some instances, the outer bore may be substantially tubular and the inner bore may be substantially frustoconical. In such cases, the outer bore may have a cross-sectional width that is substantially tubular and the inner bore may have a cross-sectional width that is substantially frustoconical. In other instances, the outer bore may be substantially tubular and the inner bore may include a tubular portion and a conical portion. In such instances, the tubular portion of the inner bore may include a substantially uniform cross-sectional width and the conical portion of the inner bore may include a larger cross-sectional width that is larger at the proximal end of the shielding member and decreases towards the distal end of the shielding

member. In still other cases, the inner bore may have a substantially uniform cross-sectional width over the predetermined length.

[0074] According to at least one aspect of the present disclosure, an apparatus for inserting an implant into a surgically-created implant pocket in a subject is provided. The apparatus may include a base having an upper surface and a lower surface. The base may have an aperture formed therein which extends through the upper surface and the lower surface of the base. The apparatus may also include a shielding member that is coupled to the base. The shielding member may have an inner bore extending longitudinally between a proximal end and a distal end. The inner bore may extend a predetermined length away from the lower surface of the base. The proximal end of the tubular member may be coupled with the base and the inner bore may be substantially aligned with the aperture formed in the base. The inner bore of the shielding member may be operable to receive the implant. In some instances, the shielding member may be tubular and have a substantially uniform cross-sectional width over the predetermined length of the shielding member. In such instances, the shielding member may be a tubular shielding member or otherwise comprise a tubular member.

[0075] According to another aspect of the present disclosure, an apparatus for inserting an implant into a surgically-created implant pocket in a subject is provided. The apparatus includes a base having an upper surface and a lower surface. The apparatus also includes a shielding member extending through the base. The shielding member has an inner bore, a proximal end and a distal end. The inner bore of the shielding member extends longitudinally a predetermined length away from the lower surface of the base and between the proximal end and the distal end. The inner bore is operable to receive an implant therethrough. In some cases, the shielding member may be tubular and have a substantially uniform cross-sectional width over the predetermined length. In such instances, the shielding member may be a tubular shielding member or otherwise comprise a tubular member.

[0076] According to another aspect of the present disclosure, an apparatus for inserting an implant into a surgically-created implant pocket in a subject through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject is provided. The apparatus may include a shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length. The

apparatus may further include an implant receiving member having an inner bore extending longitudinally between a proximal end and a distal end. The implant receiving member may be operable to receive the implant. The distal end of the implant receiving member may be coupled with the proximal end of the shielding member such that the inner bore of the implant receiving member is substantially aligned with the inner bore of the shielding member so that the implant may pass through the inner bore of the implant receiving member to the inner bore of the shielding member once the implant is received at the proximal end of the implant receiving member.

[0077] In some instances, the implant receiving member may be conical. The inner bore of the implant receiving member may also be conical in some instances. The inner bore of the implant receiving member may have a cross-sectional width at the proximal end of the implant receiving member that is larger than the cross-sectional width of the inner bore at the distal end of the implant receiving member. In at least some cases, the shielding member may be tubular. The inner bore of the shielding member may have a substantially uniform cross-sectional width over the predetermined length. The implant receiving member may have an outer surface and an inner surface, wherein the inner surface of the implant receiving member defines the inner bore of the implant receiving member. Likewise, the shielding member comprises an outer surface and an inner surface, wherein the inner surface of the shielding member defines the inner bore of the shielding member. The implant receiving member may have an aperture at the proximal end of the implant receiving member. The aperture may be operable to receive the implant into the inner bore of the implant receiving member. The predetermined length may be, for example, greater than 1 cm or may be from about 2 cm to about 10 cm.

[0078] The implant receiving member may be operable to shield the implant from the skin of the patient during insertion of the implant into the proximal end of the implant shielding member. The shielding member is operable to shield the implant from at least a portion of a dissection tunnel connecting an incision on a skin of the subject and the implant pocket. The implant receiving member may be further operable to mechanically propel the implant through the inner bore of the shielding member and out the distal end of the shielding member.

[0079] In some instances, the apparatus may further include a base that extends radially from one of the shielding member or the implant receiving member. In some instances, the base

may extend radially from an intersection of the shielding member and the implant receiving member. The base may include an upper surface and a lower surface, the lower surface being operable to engage a skin of the subject. The base may be integrally formed with the implant receiving member and shielding member. The shielding member, the base, and the implant receiving member may be formed from a flexible material. For example, the flexible material may be selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[0080] The presently disclosed apparatus may also be used to prevent capsular contracture in a subject resulting from surgical insertion of a breast implant in a surgically-created implant pocket through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject. The apparatus is capable of shielding the implant from microbial contamination, including contamination by the endogenous flora of the subject, during insertion of the implant into the surgically-created implant pocket.

[0081] According to at least one aspect of the present disclosure, a system is provided. The system includes an apparatus for inserting an implant into a surgically-created implant pocket in a subject as described herein. The system further includes an implant that may be inserted by the apparatus.

[0082] According to at least one other aspect of the present disclosure, a system is provided. The system includes an apparatus for inserting an implant into a surgically-created implant pocket in a subject as described herein. The system further includes a conical sleeve having an interior cavity, a first terminus, and a second terminus. The first terminus of the conical sleeve has a larger diameter than the second terminus. The second terminus is operable to be inserted into the aperture of the base, inner bore of the shielding member, or the implant receiving member of the apparatus. The conical sleeve is further operable to receive an implant into its interior cavity via the first terminus and deliver the implant through the second terminus into the aperture, inner bore, or implant receiving member of the apparatus. In at least some instances, the system further includes an implant that may be inserted by the conical sleeve.

[0083] According to at least one aspect of the present disclosure, a kit is provided. The kit includes an apparatus for inserting an implant into a surgically-created implant pocket in a

subject, as described herein. Packaged together with the apparatus, the kit further includes an implant that may be inserted by the apparatus.

[0084] According to at least one other aspect of the present disclosure, a kit is provided. The kit includes an apparatus for inserting an implant into a surgically-created implant pocket in a subject as described above. The kit further includes a conical sleeve packaged together with the apparatus. The conical sleeve has an interior cavity, a first terminus, and a second terminus. The first terminus of the conical sleeve has a larger diameter than the second terminus. The second terminus is operable to be inserted into the aperture of the base, inner bore of the shielding member, or the implant receiving member of the apparatus. The conical sleeve is further operable to receive an implant into its interior cavity via the first terminus and deliver the implant through the second terminus into the aperture, inner bore, or implant receiving member of the apparatus. In at least some instances, the kit further includes an implant packaged together with the apparatus and the conical sleeve. The implant is capable of being inserted by the conical sleeve.

[0085] According to at least one aspect of the present disclosure, a method for inserting an implant into a surgically-created implant pocket in a subject through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject is provided. The method may include providing a sterile biofilm protection implant shield. The implant shield may include a shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length. The implant shield may also include an implant receiving member having an inner bore extending longitudinally between a proximal end and a distal end. The implant receiving member may be operable to receive the implant wherein the distal end of the implant receiving member is coupled with the proximal end of the shielding member such that the inner bore of the implant receiving member is substantially aligned with the inner bore of the shielding member so that the implant may pass through the inner bore of the implant receiving member to the inner bore of the shielding member once the implant is received at the proximal end of the implant receiving member.

[0086] The method may further include inserting the distal end of the shielding member of the implant shield through the incision in the skin of subject and into the dissection tunnel such that the distal end of the shielding member is received in at least a portion of the dissection

tunnel. The method may further include causing the lower surface of the base to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket. The method may further include delivering the implant to the implant pocket by inserting the implant into the inner bore of the implant receiving member and through the inner bore and distal end of the shielding member to the implant pocket. The method may further include inserting the distal end of the shielding member into the dissection tunnel at least 1.5 cm below the incision. The method may also include measuring a length of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject and adjusting the predetermined length of the inner bore of the shielding member such that it is greater than 1 cm but equal to or less than the measured length of the dissection tunnel.

[0087] In some instances, the implant shield used in the method may have an implant receiving member that may be conical. The inner bore of the implant receiving member may also be conical in some instances. The inner bore of the implant receiving member may have a cross-sectional width at the proximal end of the implant receiving member that is larger than the cross-sectional width of the inner bore at the distal end of the implant receiving member. In at least some cases, the shielding member may be tubular. The inner bore of the shielding member may have a substantially uniform cross-sectional width over the predetermined length. The implant receiving member may have an outer surface and an inner surface, wherein the inner surface of the implant receiving member defines the inner bore of the implant receiving member. Likewise, the shielding member comprises an outer surface and an inner surface, wherein the inner surface of the shielding member defines the inner bore of the shielding member. The implant receiving member may have an aperture at the proximal end of the implant receiving member. The aperture may be operable to receive the implant into the inner bore of the implant receiving member. The predetermined length may be, for example, greater than 1 cm or may be from about 2 cm to about 10 cm.

[0088] The implant receiving member of the implant shield used in the method may be operable to shield the implant from the skin of the patient during insertion of the implant into the proximal end of the implant shielding member. The shielding member may be operable to shield the implant from at least a portion of a dissection tunnel connecting an incision on a skin of the subject and the implant pocket. The implant receiving member may be further operable to

mechanically propel the implant through the inner bore of the shielding member and out the distal end of the shielding member.

[0089] In some instances, the implant shield used in the method may further include a base that extends radially from one of the shielding member or the implant receiving member. In some instances, the base may extend radially from an intersection of the shielding member and the implant receiving member. The base may include an upper surface and a lower surface, the lower surface being operable to engage a skin of the subject. The base may be integrally formed with the implant receiving member and shielding member. The shielding member, the base, and the implant receiving member may be formed from a flexible material. For example, the flexible material may be selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[0090] According to at least one aspect of the present disclosure, a method for inserting an implant into a surgically-created implant pocket in a subject through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject is disclosed. The method may include providing a sterile biofilm protection implant shield. The implant shield may include a base having an upper surface and a lower surface. The base may further have an aperture formed therein and extending through the upper surface and the lower surface. The implant shield may also have a shielding member coupled with the base. The shielding member may have an inner bore extending longitudinally between a proximal end and a distal end. The inner bore may extend a predetermined length away from the lower surface of the base. The proximal end of the shielding member may be coupled with the base and the inner bore may be substantially aligned with the aperture formed in the base. The inner bore may be operable to receive the implant therethrough. The method may further include inserting the distal end of the shielding member of the implant shield through the incision in the skin of subject and into the dissection tunnel such that the distal end of the shielding member is received in at least a portion of the dissection tunnel or the implant pocket. The method may further include causing the lower surface of the base to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket. The method may also include delivering the implant to the implant pocket by inserting the implant through the aperture of the base and through the inner

bore and distal end of the shielding member to the implant pocket. The method may also be used to prevent capsular contracture in a subject resulting from surgical insertion of a breast implant in a surgically created implant pocket through a dissection tunnel connecting the implant pocket to an incision on the skin of the patient.

[0091] FIG. 1 depicts an isometric view of a biofilm protection implant shield apparatus 100 for inserting an implant into a surgically-created implant pocket in a subject, according to an exemplary embodiment of the present disclosure. As depicted in FIG. 1, implant shield 100 may include a base 175 having an upper surface 125 and a lower surface 135. The implant shield 100 includes an aperture 120 (not shown in FIG. 1; see FIG. 4) formed in the base 175 and extending through the upper surface 125 and the lower surface 135.

[0092] Implant shield 100 further includes a shielding member 150 coupled with the base 175. The shielding member 150 has an inner surface 105, an outer surface 110, a proximal end 151 and a distal end 152. As depicted in FIG. 1, the proximal end 151 is coupled with the base 175 while the distal end 152 of shielding member 150 extends away from the base 175. The shielding member 150 has an inner bore 115 defined by inner surface 105. The outer surface 110 defines an outer bore 195 of shielding member 150 that includes the cross-sectional width of the inner bore 115 as well as the thickness of the wall of the shielding member 150 at the particular portion of along the outer surface 110 that the outer bore 195 is determined. The distal end 152 of the shielding member 150 has an aperture 155 that is substantially aligned with inner bore 115 and aperture 120 of the base 175 when the shielding member 150 is extended. As shown in FIG. 1, the inner bore 115 has a longitudinal axis 160 extending therethrough. The longitudinal axis 160 extends substantially perpendicular to the base 175. The inner bore 115 extends longitudinally along the longitudinal axis 160 between the proximal end 151 and the distal end 152 a predetermined length 165 (not shown in FIG. 1; see FIG. 2) away from the lower surface 135 of the base 175. Therefore, the shielding member 150 also extends along the longitudinal axis 160 and substantially orthogonally from the base 175.

[0093] As depicted in FIG. 1, the base 175 extends away from shielding member 150 in a direction substantially perpendicular to the longitudinal axis 160. The inner bore 115 is substantially aligned with the aperture 120 formed in the base 175. In at least some instances, the base 175 extends away from shielding member 150 in substantially the same plane as the

aperture 120. The aperture 120 and inner bore 115 of shielding member 150 are operable to receive the implant. The proximal end 151 of shielding member 150 is also operable to receive an implant therethrough. The distal end 152 of shielding member 150 is operable to be inserted into an incision in the skin of the subject and further operable to be extended the predetermined length 165 such that the distal end 152 is received into at least a portion of the surgically-created implant pocket or a distal portion of the dissection tunnel connecting an incision in the skin of the subject to the implant pocket. In some instances, at least a portion of the inner bore 115 of the shielding member 150 may extend a second predetermined length above the upper surface 125 of the base 175 (not shown in FIGs. 1-4).

[0094] The shielding member 150 of biofilm protection implant shield apparatus 100 is operable to extend along at least a portion of the dissection tunnel during use. The shielding member 150 is also operable to deliver the implant to the implant pocket or a distal portion of the dissection tunnel without the implant contacting the incision site or at least a portion of the dissection tunnel. In some instances, the shielding member 150 of apparatus 100 may be operable to shield the implant from touching any portion of the dissection tunnel or incision site.

[0095] While FIGs. 1-4 depict shielding member 150 as having an inner bore 115 that is tubular with a substantially uniform cross-sectional width 157 along its predetermined length 165 (refer to FIG. 2), the shielding member 150 may have an inner bore 115 that is tubular, conical, or any combination thereof. In cases in which the inner bore 115 of the shielding member 150 is tubular, the inner bore 115 of the shielding member 150 has an uniform cross-sectional width 157 along its predetermined length 165. In cases in which the inner bore 115 of the shielding member 150 is conical, the inner bore 115 of the shielding member 150 has a variable cross-sectional width 157 along its predetermined length 165. Typically, if the shielding member 150 has a inner bore 115 that is conical, the inner bore 115 has a wider cross-sectional width 157 towards the proximal end 151 of the shielding member 150. For example, the cross-sectional width 157 of the inner bore 115 at the proximal end 151 of the shielding member 150 may be longer than the cross-sectional width 157 of the inner bore 115 at the distal end 152 of the shielding member 150. In such cases, the wider cross-section width 157 at the proximal end 151 of the shielding member 150 may facilitate or ease insertion of the implant into the shielding member 150.

[0096] In some instances, the shielding member 150 may have an inner bore 115 that is both tubular and conical. In such instances, the shielding member 150 may comprise a tubular member and a conical member. When the shielding member 150 has an inner bore 115 that is both tubular and conical, the conical member generally comprises the proximal end 151 of the shielding member 150 while the tubular member comprises the distal end 152 of the shielding member 150. Accordingly, the proximal end 151 of the inner bore 115 of the shielding member 150 may have a variable cross-sectional width 157 while the distal end 152 of the inner bore 115 has an uniform cross-sectional width 157.

[0097] In at least some instances, the shielding member 150 and/or inner bore 115 of the shielding member 150 is substantially cylindrical in cross-sectional shape. In some instances, the shielding member 150 and/or inner bore 115 of the shielding member 150 may be elliptical in cross-sectional shape. In some cases, the inner bore 115 of shielding member 150 is not tapered along the predetermined length 165. In at least some instances, the distal end 152 has substantially the same cross-sectional width as the cross-sectional width of the proximal end 151. In such cases, the cross-sectional width 157 of the inner bore 115 at the distal end 152 of the shielding member is substantially the same as the cross-sectional width 157 of the inner bore at the proximal end 151 of the shielding member. In some cases, the aperture 155 of the distal end 152 of shielding member 150 has substantially the same cross-sectional width as the cross-sectional width of aperture 120 in base 175. In some cases, the cross-sectional width of the aperture 120 in base 175 may be substantially the same as the cross-sectional width 157 of the proximal end 151 of the inner bore 115 of the tubular member 150.

[0098] The cross-sectional width 157 of the inner bore 115 of the shielding member 150 may be any cross-sectional width suitable to receive and facilitate insertion of an implant into the implant pocket of a subject. For example, the cross-sectional width 157 of the inner bore 115 of the shielding member 150 may be from about 3 cm to about 12 cm, or from 3.5 cm to about 9 cm, or from about 3.5 cm to about 8.5 cm, or from about 5 cm to about 8 cm. In at least some instances, the cross-sectional width 157 of the inner bore 115 may be selected based on the size of the implant. In general, pre-filled breast implants are from about 9 cm to about 16 cm (most commonly from about 11 cm to about 12 cm) in diameter but deform and elongate when inserted into the aperture 120 and inner bore 115 of apparatus 100.

[0099] As used herein, the term "cross-sectional width" shall include the longest distance between two points on the circumference or edge of the cross-section of an object having a circular and/or non-circular cross-section. The two points may be located on the interior or exterior surface circumference or edge of the cross-section of the object. It should be recognized that "cross-sectional width" of objects having a substantially circular cross-section may be referred to as the "diameter" of the object. The terms "cross-sectional width" and "diameter" may be used interchangeably for objects having a substantially circular cross-section. Understanding that the presently disclosed devices and apparatus, or portions thereof, may be deformable or collapsible or formed from collapsible or deformable materials, the cross-sectional width, as referred to herein, is generally measured in the open and/or extended configuration, such as that typical during use.

[00100] While FIGs. 1-4 depict the inner bore 115 of the shielding member 150 as substantially circular in cross-sectional profile, inner bore 115 may have any cross-sectional profile, including conical, elliptical, oval, or circular. Likewise, the outer bore 195 or outer profile of the shielding member 150, as defined by outer surface 110 of the shielding member 150, may be conical, elliptical, oval, or circular. In at least some instances the distal end 152 and the proximal end 151 of inner bore 115 have the same cross-sectional profile, wherein the cross-sectional profile is selected from the group consisting of circular, elliptical, and oval. For example, in cases in which the distal end 152 and the proximal end 151 of inner bore 115 have the same cross-sectional profile, the cross-sectional profile of both the distal end 152 and the proximal end 151 of inner bore 115 could have an elliptical cross-sectional profile, or both could have a circular cross-sectional profile, or both could have an elliptical cross-sectional profile. In other cases, the distal end 152 of inner bore 115 may have a cross-sectional profile that is different than the cross-sectional profile of the proximal end 151. For example, in such cases, the distal end 152 may have a cross-sectional profile that is elliptical while the proximal end 151 may have a circular cross-sectional profile. In cases in which the distal end 152 and the proximal end 151 of inner bore have different cross-sectional profiles, they may still have the substantially the same cross-sectional width. It should be recognized that when the cross-sectional profile of a portion of the inner bore 115 is circular, elliptical, or oval, the three-dimensional profile (*e.g.*, the

exterior profile or shape) of a corresponding portion of shielding member 150 may also be, respectively, circular, elliptical, or oval.

[00101] According to at least one aspect of the present disclosure, the base 175 is operable to engage the skin of the subject so as to enable the shielding member 150 to stay in place during implant insertion as well as to enable the shielding member 150 to better resist the frictional forces created by insertion of the implant into the inner bore 115 so that the shielding member 150 is operable to shield the implant from the dissection tunnel during transit of the implant along the inner bore to the implant pocket. The lower surface 135 of base 175 is operable to engage the skin of the subject adjacent to an incision so as to resist movement of the base 175 when the implant is inserted into the aperture 120 and the inner bore 115 of shielding member 150. During use, the aperture 120 and inner bore 115 of shielding member 150 substantially overlies at least a portion of the incision. In at least some instances, the lower surface 135 is operable to frictionally engage the skin of a subject. In such cases, the frictional engagement resists movement of the base 175 relative to the skin of the subject during use. In at least some instances, the lower surface 135 may include a textured surface.

[00102] In some cases, the lower surface 135 may include a surface operable to engage the skin of a subject once it is wetted with a liquid or a fluid. In such cases, the liquid may be, for example, an aqueous solution, water, a saline solution, or any combination thereof. Other liquids or fluids may also be used to wet the lower surface 135 so long as the wetting of the lower surface by that liquid or fluid provides for sufficient engagement of lower surface 135 with the skin of the subject such that movement of the base 175 is resisted during use. In at least some instances, the liquid or fluid may be disposed on the lower surface 135 of base 175 or may be applied or otherwise disposed on the skin of the subject.

[00103] In other cases, an adhesive may be disposed on the lower surface 135. Any adhesive may be used so long as the adhesive provides for sufficient engagement of lower surface 135 with the skin of the subject such that movement of the base 175 is resisted during use. In some instances, the adhesive may be applied to the skin of the subject prior to engagement of the lower surface 135 of base 175 with the skin of the subject.

[00104] In at least some instances, a removable backing (not shown in FIGs. 1-4) may be included on the lower surface 135 of base 175. The removable backing may serve to protect or

otherwise keep clean the lower surface 135 prior to use. In instances in which an adhesive is disposed on the lower surface 135, the removable backing may cover and protect the adhesive prior to use.

[00105] The shielding member 150 is operable to deliver the implant subdermally to the implant pocket, or a distal portion of the dissection tunnel, through the predetermined length 165 of inner bore 115 of the shielding member 150. In at least some instances, the predetermined length 165 may be determined based on a distance between an incision in the skin of a patient and a surgically-created implant pocket formed below the skin. In other cases, the predetermined length 165 may be based on a distance between an incision in the skin and the length of the dissection tunnel or portion of a dissection tunnel connecting the incision to the surgically-created implant pocket. In some instances, the predetermined length 165 between the proximal end 151 and the distal end 152 extends the inner bore 115 operably to deliver an implant subdermally through the aperture 120 and inner bore 115 and into the surgically-created implant pocket or a distal portion of the dissection tunnel or when the lower surface 135 of base 175 is adjacently engaged with the skin of a subject and the distal end 152 is received into at least a portion of the implant pocket or distal portion of the dissection tunnel.

[00106] The predetermined length 165 of the inner bore 115 of the shielding member 150 may be adjusted based on the desired depth of insertion into the dissection tunnel, the size of the implant used, the location of the incision, and the characteristics of the subject's breast. In at least some instances, the predetermined length 165 of the inner bore 115 may have a predetermined length 165 equal to or less than the measured length of the dissection tunnel. In some instances, the predetermined length 165 of the inner bore 115 of the shielding member 150 may be greater than 1 cm, or greater than 1.5 cm, or greater than 2cm, or greater than 2.5 cm, or greater than 3 cm, or greater than 3.5 cm, or greater than 4 cm, or greater than 4.5 cm, or greater than 5 cm, or greater than 5.5 cm, or greater than 6 cm, or greater than 6.5 cm, or greater than 7 cm, or greater than 7.5 cm, or greater than 8 cm. In other instances, the predetermined length 165 may be from about 2 cm to about 10 cm, or from about 3 cm to about 10 cm, or from about 2 cm to about 8 cm, or from about 2 cm to about 5 cm, or from about 3 cm to about 8 cm.

[00107] The biofilm protection implant shield apparatus 100, including shielding member 150 and base 175, may be made of any suitable flexible material. For example, the flexible

material may include, but is not limited to, plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof. In some cases, the shielding member 150 and base 175 may be formed from the same material. In some instances, the flexible material may be resistant to stretching. In some instances, the shielding member 150 and the base 175 may be integrally formed. In some instances, the flexible material may be a transparent or semi-transparent flexible material.

[00108] In other instances, biofilm protection implant shield apparatus 100, including shielding member 150 and base 175, may be stretchable and/or made of a flexible material that is stretchable. As used herein, the term “stretchable” refers to a material, or property of a device or device component, that may be extensible or elastomeric. That is, a stretchable material, or a stretchable device or device component, may be extended, deformed, or the like, without breaking, and may or may not significantly retract after removal of an extending force. As used herein, the terms “elastomeric” or “elastic” are used interchangeably to refer to that property of a material (or device or device component) where upon removal of an elongating force, the material (or device or device component) is capable of recovering to substantially is unstretched size and shape or the material exhibits a significant retractive force. As used herein, the term “extensible” refers to that property of a material (or device or device component) where upon removal of an elongating force, the material (or device or device component) experiences a substantially permanent deformation or the material does not exhibit a significant retractive force.

[00109] In particular, shielding member 150 may be stretchable and/or comprise a stretchable material. Stretchability of the shielding member 150 provides the advantage that when retractors are placed inside of the shielding member 150 during use to open up the dissection tunnel, the shielding member 150 may stretch to allow greater opening of the dissection tunnel as well as engagement of the walls of the dissection tunnel thereby providing effective shielding for the implant as well as reducing the frictional forces associated with implant insertion. The stretchability of the shielding member 150 also provides the advantage of stretching during insertion of the implant so as to reduce the forces associated with implant insertion and to facilitate transit of the implant to the implant pocket while providing the implant

shielding function, whether retractors are placed within shielding member 150 during use or not. In at least some instances, the shielding member 150 may be elastic or comprise an elastic material. In other instances, the shielding member 150 may be extensible or comprise an extensible material.

[00110] In at least some instances, the shielding member 150 may be made of a material that is different than the material that makes up the base 175. For example, while it is advantageous in at least some instances that the shielding member be stretchable or made of a stretchable material, base 175 does not necessarily need to be stretchable or made of a stretchable material. In other instances, base 175 may comprise the same material as shielding member 150 but the stretchability of shielding member 150 is determined by the thickness of the material. In other words, shielding member 150 may be constructed of a material that is thin enough to be stretchable during use while the base 175 may be constructed of the same material but may not be stretchable due to the chosen thickness of the base 175.

[00111] In some cases, the inner bore 115 may include a lubricant along the inner surface 105 that defines the inner bore 115. In such cases, the lubricant along the inner surface 105 of the inner bore 115 may facilitate insertion and passage of the implant into and through aperture 120 and inner bore 115. In some instances, the outer surface 110 of the shielding member 150 may include a lubricant. In such cases, the lubricant on the outer surface 110 may facilitate insertion of the shielding member 150 into the dissection tunnel. The lubricant may be, for example, a sterile lubricant selected from the group consisting of a surgical lubricant, a water-based lubricating jelly, a dry lubricant, a powdered lubricant, a moisture-activated lubricant, and any combination thereof. The lubricant may be disposed on the inner surface 105 and/or the outer surface 110 at the time of manufacturing and packing. In other instances, the lubricant may be applied to the inner surface 105 and/or the outer surface 110 by a physician or technician prior to use so long as the surfaces and the lubricant remain sterile.

[00112] In some instances, the inner bore 115 or inner surface 105 of shielding member 150 may include a lubricating coating or a friction-reducing coating that serves a similar function as the lubricant described above. In some cases, the outer surface 110 of the shielding member 150 may include a lubricating coating or a friction-reducing coating that also serves the same or similar function as the lubricant described above.

[00113] FIG. 2 is a planar view of the biofilm protection implant shield apparatus 100, according to an exemplary embodiment of the present disclosure. As depicted in FIG. 2, biofilm protection implant shield apparatus 100 includes base 175 and shielding member 150 extending through the base 175 to form aperture 120 (not shown in FIG. 2; see FIG. 4). The shielding member 150 has an inner bore 115, a proximal end 151 and a distal end 152. The base 175 radially extends from at least a portion of the proximal end 151 of shielding member 150. The inner bore 115 has a longitudinal axis 160 therethrough which extends substantially perpendicular and/or orthogonally to the base 175. As shown in FIG. 2, the inner bore 115 extends longitudinally a predetermined length 165 away from the lower surface 135 of the base 175 and between the proximal end 151 and the distal end 152. The shielding member 150 likewise extends along the longitudinal axis 160 a predetermined length 165 away from the lower surface 135 of the base 175 and substantially perpendicular and/or orthogonally to the base 175.

[00114] FIG. 3 is a front diagrammatic view of the biofilm protection implant shield apparatus 100 showing the distal end 152 of shielding member 150 and the lower surface 135 of the base 175, according to an exemplary embodiment of the present disclosure. As depicted in FIG. 3, the proximal end 151 of shielding member 150 is coupled with base 175 of the biofilm protection implant shield apparatus 100. The distal end 152 of the shielding member 150 comprises aperture 155 through which an implant may exit after transiting through at least a portion of the dissection tunnel during delivery to the implant pocket. FIG. 4 is a rear diagrammatic view of the biofilm protection implant shield apparatus 100 showing base 175 having an aperture 120 formed therein and extending through the upper surface 125 and the lower surface 135.

[00115] The base 175 can have any shape, configuration, diameter, or thickness so long as the base 175 is operable to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket, and/or is operable to engage the skin of the subject adjacent to an incision so as to resist movement of the base 175 when the implant is inserted into the aperture 120 and the inner bore 115 of shielding member 150, and/or is operable to substantially protect the implant from contamination from the microbial flora that may be present on the skin of the subject during insertion of the implant into the aperture 120 and the inner bore

115 of shielding member 150. For example, in at least some instances, the base 175 may be substantially rectangular as shown in FIGs. 1-4, or the base 175 may be, for example, substantially circular as shown in FIG. 5.

[00116] As depicted in FIG. 2, the base 175 may have a diameter 167. As used herein, the diameter 167 of base 175 is defined as the minimum distance between two opposite outer edges of the base 175 when the base 175 is fully extended away from the shielding member 150 (*e.g.*, the same position or configuration as when the base is engaged with the skin of the subject). For example, as shown in FIG. 2, the diameter 167 of base 175 is the distance between first outer edge 136 and an opposite second outer edge 137. The base 175 may have any diameter sufficient to be operable to engage the skin of the subject and to resist movement of the base 175 when the implant is inserted into the aperture 120 and the inner bore 115 of the shielding member 150. The base 175 may also have any diameter sufficient to substantially protect the implant from contamination from the microbial flora that may be present on the skin of the subject during insertion of the implant into aperture 120. In at least some instances, the base 175 may have a diameter 167 that is at least 3 times greater than the cross-sectional width 157 of the inner bore 115 of the shielding member 150 and/or the aperture 120 and/or the outer bore 195 of the shielding member 150. In other instances, the base 175 may have a diameter 167 that is from about 3 times to about 5 times the cross-sectional width 157 of the inner bore 115 of the shielding member 150 and/or the aperture 120 and/or the outer bore 195 of the shielding member 150. For example, if the cross-sectional width 157 of the inner bore 115 is 5 cm, then the diameter 167 of the base 175 may be from about 15 cm to about 25 cm. In other instances, the diameter 167 of base 175 may be from about 9 cm to about 60 cm, or from about 10.5 cm to about 45 cm, or from about 10.5 cm to about 42.5 cm, or from about 15 cm to about 24 cm, or from about 20 cm to about 32 cm, or from about 25 cm to about 40 cm.

[00117] The base 175 may also have a radial length 169, as shown in FIG. 2. As used herein, the radial length 169 of base 175 is defined as the distance between an outer edge (*e.g.*, outer edges 136,137) of the base 175, when the base 175 is fully extended away from the shielding member 150 (*e.g.*, the same position or configuration as when the base is engaged with the skin of the subject), and the outer surface 110 of the proximal end 151 of the shielding member 150 where it is coupled to the base 175. Accordingly, the radial length 169 of the base

175 is the length that the base 175 extends away from the shielding member 150. The base 175 may have any radial length sufficient to be operable to engage the skin of the subject and to resist movement of the base 175 when the implant is inserted into the aperture 120 and the inner bore 115 of the shielding member 150. The base 175 may also have any radial length sufficient to substantially protect the implant from contamination from the microbial flora that may be present on the skin of the subject during insertion of the implant into aperture 120. In at least some instances, the base 175 may have a radial length 169 that is greater than or equal to the cross-sectional width 157 of the inner bore 115 of the shielding member 150 and/or the aperture 120 and/or the outer bore 195 of the shielding member 150. In other instances, the base 175 may have a radial length 169 from about one (1) to about two (2) times the cross-sectional width 157 of the inner bore 115 of the shielding member 150 and/or the aperture 120 and/or the outer bore 195 of the shielding member 150. For example, if the cross-sectional width 157 of the inner bore 115 is 5 cm, then the radial length 169 of the base 175 may be from about 5 cm to about 10 cm. In other instances, the radial length of base 175 may be from about 3 cm to about 12 cm, or from about 3.5 cm to about 18 cm, or from about 3.5 cm to about 17 cm, or from about 5 cm to about 8 cm, or from about 10 cm to about 16 cm, or from about 5 cm to about 16 cm.

[00118] Base 175 may have sufficient thickness to provide structural support or rigidity to the biofilm protection implant shield apparatus 100 such that the implant may be easily inserted into aperture 120 and such that the base sufficiently resists the forces associated with implant insertion to provide stability for the shielding member 150 when the base 175 is engaged with the skin of the subject. Base 175 may also have sufficient thickness to provide enough structural support and rigidity to resist movement of the base relative to the skin of the subject, to which the base 175 is engaged, during insertion of the implant into aperture 120 and passage of the implant through the inner bore 115 of the shielding member 150. In some instances, the base 175 may have a thickness (*e.g.*, the distance or thickness between the lower surface 135 and the upper surface 125 of base 175) that is substantially the same as the thickness of the shielding member 150. In other instances, the base 175 may have a thickness that is substantially thicker than the thickness of the shielding member 150. In other instances, the base 175 may have a thickness that is substantially thinner than the thickness of the shielding member 150. In such instances, the shielding member 150 may be thicker than the thickness of the base 175 so that the

shielding member 150 has sufficient rigidity or structural integrity to facilitate insertion into the dissection tunnel while resisting the forces created by insertion of the implant into the inner bore 115 such that the shielding member 150 is operable to shield the implant from the dissection tunnel during transit of the implant along the inner bore to the implant pocket.

[00119] Importantly, base 175 operably engages with the skin of the subject such that apparatus 100 does not need to be held by a surgeon or assistant during insertion of the implant into aperture 120 and inner bore 115, even during insertion of pre-filled breast implants which are accompanied by much higher forces of insertion. Apparatus 100 is particularly suited to the delivery of pre-filled breast implants because base 175 is operable to protect the implant from contamination from the skin while stabilizing the shielding member 150 and resisting movement during pre-filled implant insertion, which is accompanied by large compressional and frictional forces associated with deformation of the pre-filled implant during insertion and transit along the length of the inner bore 115 to the implant pocket. Base 175 does not displace from the skin of the subject during implant insertion even during insertion of pre-filled implants and when the base 175 or any other portion of the device is not held by a surgeon or assistant.

[00120] In some instances, apparatus 100 may include a shielding member 150 that is operable to form a base 175 or otherwise deploy or transition to form a base 175. For example, as shown in FIGs. 6A and 6B, the proximal end 151 of shielding member 150 may be operable to be folded or rolled on itself to form a shortened shielding member 150 and a base 175. In such instances, the base 175 may be formed from successive folds of the proximal end 151 of shielding member 150, as shown in FIG. 6B. Other configurations may be possible in which the shielding member 150 may be deployed or transitioned to form a base 175. All such configurations in which the shielding member 150 may be transitioned from the undeployed configuration shown in FIG. 6A to the deployed configuration shown in FIG. 6B having a suitable base 175 formed from the shielding member 150 are within the scope and spirit of the present disclosure. In at least some instances the length of the inner bore 115 of shielding member 150 may be adjusted by forming the base 175 such that the inner bore 115 has a predetermined length 165 equal to or less than the length of the dissection tunnel.

[00121] As depicted in FIGs 7A-7C, apparatus 100 may include a perforated or perforable portion 170 at the proximal end 151 of shielding member 150 that is operable to form a base 175

or otherwise deploy or transition to form a base 175 by the deployment or splaying out of a plurality of flanges 177. FIG. 7A depicts device 100 in the undeployed configuration in which the plurality of flanges 177 are substantially parallel to the longitudinal axis 160. As shown in FIG. 7A, the perforated or perforable portion 170 at the proximal end 151 of shielding member 150 may be perforated, or perforable, or otherwise comprise a plurality of flanges 177. In at least some instances, a plurality of flanges 177 may be integrally formed on the proximal end 151 of shielding member 150. In some cases, the proximal end 151 of shielding member 150 may be perforated or scored so that a plurality of flanges 177 may be easily separated or formed upon tearing of the perforations or scored portions of shielding member 150.

[00122] FIGs. 7B and 7C depict apparatus 100 in the deployed configuration in which the plurality of flanges 177 are splayed out to form base 175 by transitioning from the parallel to longitudinal axis 160 undeployed arrangement in FIG. 7A to the base arrangement in FIG. 7B. As depicted in FIG. 7B, the plurality of flanges 177 extend outward from shielding member 150 such that flanges 177 are perpendicular to the shielding member 150. FIG. 7C depicts the transitioning of the plurality of flanges 177 from the undeployed arrangement depicted in FIG. 7A to the base arrangement in which the plurality of flanges 177 are substantially perpendicular to the longitudinal axis 160. In at least some instances, an adhesive may be disposed on the lower surface 135 of each of the plurality of flanges 177. In some instances, the lower surface 135 of each of the plurality of flanges 177 may also include a removable backing that serves to protect or otherwise keep clean the lower surface 135 of each of the plurality of flanges 177 prior to use. In instances in which an adhesive is disposed on the lower surfaces 135, the removable backing may cover and protect the adhesive prior to use.

[00123] The plurality of flanges 177 may have any shape so long as they are operable to form base 175 as described herein. While the plurality of flanges 177 are depicted in FIGs. 7A-7C as substantially rectangular in shape, the plurality of flanges 177 may have any other shape including a substantially trapezoidal shape depicted in FIGs. 8A-8C.

[00124] The present disclosure also provides a system that includes the biofilm protection implant shield apparatus 100 and an implant capable of being inserted by the biofilm protection implant shield apparatus. The present disclosure further provides a system that includes the biofilm protection implant shield apparatus 100 and a conical sleeve. The conical sleeve has an

interior cavity, a first terminus, and a second terminus. The first terminus of the conical sleeve has a larger diameter than the second terminus. Therefore the conical sleeve is tapered along its length. The second terminus of the conical sleeve is operable to be inserted into the aperture 120 or inner bore 115 of the shielding member 150 of the apparatus 100. The conical sleeve is further operable to receive an implant into its interior cavity via the first terminus and deliver the implant through the second terminus into the inner bore 115 of the apparatus 100 when the lower surface 135 of the base 175 is engaged with the skin of the subject. In at least some instances, the system further includes an implant that may be inserted by the conical sleeve.

[00125] The present disclosure also provides a kit that includes the biofilm protection implant shield apparatus 100 packaged together with an implant capable of being inserted by the biofilm protection implant shield apparatus. The present disclosure further provides a kit that includes the biofilm protection implant shield apparatus 100 packaged together with a conical sleeve. The conical sleeve has an interior cavity, a first terminus, and a second terminus. The first terminus of the conical sleeve has a larger diameter than the second terminus. Therefore the conical sleeve is tapered along its length. The second terminus of the conical sleeve is operable to be inserted into the aperture 120 or inner bore 115 of the shielding member 150 of the apparatus 100. The conical sleeve is further operable to receive an implant into its interior cavity via the first terminus and deliver the implant through the second terminus into the inner bore 115 of the apparatus 100 when the lower surface 135 of the base 175 is engaged with the skin of the subject. In at least some instances, the kit further includes an implant that may be inserted by the conical sleeve.

[00126] The apparatus, systems, kits, and methods of the present disclosure may be used with any implants. For example, the implant may be, but is not limited to, filled implants, unfilled implants, saline implants, silicone gel implants, textured implants, smooth implants, highly cohesive silicone gel implants, oil-filled implants, and prosthesis implants. The subject may be any subject in need of an implant. The subject may be, for example, but not limited to, a mammal or a human. In some cases, the subject may be a human and the implant may be a breast implant. While FIGs. 9-32 and 40-45 illustrate methods of using the presently disclosed apparatus and techniques of using the apparatus for inserting a breast implant into a human subject, one of skill in the art will understand and appreciated the depicted methods may be used

for any type of implant in any type of subject in need thereof. FIGs. 9-32 illustrate methods for inserting an implant into a surgically-created implant pocket in a subject using the biofilm protection implant shield apparatus 100 disclosed herein. FIGs. 9-16, 18-20, and 29-31 depict methods for use of the presently disclosed biofilm protection implant shield apparatus 100 in the case of a periareolar incision and implant insertion, whereas FIGs. 17, 21-28, and 32 depict methods for use of the implant shield apparatus 100 in the case of an inframammary incision and implant insertion. FIGs. 40-45 illustrate methods of using the biofilm protection implant shield apparatus 100 when the apparatus 100 includes a implant receiving member 3800.

[00127] In order for the implant to be inserted into the surgically-created implant pocket it must first pass through the incision in the skin of the subject and through the dissection tunnel connecting the implant pocket to the incision. As depicted in FIG. 9, a periareolar incision 510 in the skin 501 of the subject is created by scalpel 515.

[00128] FIG. 10 depicts the use of retractors 651, 652 to open the periareolar incision 510 and to facilitate full surgical dissection of the implant pocket and the dissection tunnel connecting the implant pocket to the incision. Apparatus 100 is a shield rather than a retractor and is not capable of dilating the incision or holding open the incision during use like a retractor. However, unlike a retractor, the shielding member 150 of apparatus 100 is much quicker and easier to insert into the incision and dissection tunnel and therefore requires less manipulation. The less required manipulation and speed and ease of use of apparatus 100 results in less contamination risk to the implant and greater effectiveness of biofilm shielding. Additionally, since the distal end 152 of the shielding member 150 does not include or require a retracting member, apparatus 100 provides for easy adjustment of the predetermined length 165 prior to use by cutting the distal end 152 of the shielding member 150 to the desired predetermined length 165. Apparatus 100 may be used in conjunction with separate retractors, such as retractors 651, 652 shown in FIG. 11, which allows the dissection tunnel and implant pocket to be opened up and reduces the resistance of the implant to insertion as well as reduces the external force required for insertion and delivery of the implant to the implant pocket.

[00129] While FIG. 11 depicts the use of retractors during use of apparatus 100, one of skill in the art will understand that in other instances, apparatus 100 may be used without retractors particularly depending on the type, nature, and size of the implant being inserted. Additionally,

shielding member 150 may be stretchable or comprise a stretchable material providing for expansion of the dissection tunnel during insertion of the implant into the inner bore 115 of the stretchable shielding member 150. In such cases, the shielding member 150 may stretch to accommodate the implant as well as to engage the walls of the dissection tunnel so that the dissection tunnel is opened sufficient for implant insertion while the shielding member 150 shields the implant from the dissection tunnel or a portion thereof. The stretchability of the shielding member 150 also provides the advantage that when retractors are placed inside of the shielding member 150 during use to open up the dissection tunnel, the shielding member 150 may stretch to allow greater opening of the dissection tunnel as well as engagement of the walls of the dissection tunnel thereby providing effective shielding for the implant as well as reducing the frictional forces associated with implant insertion. The stretchability of the shielding member 150 also provides the advantage of stretching during insertion of the implant so as to reduce the forces associated with implant insertion and to facilitate transit of the implant to the implant pocket while providing the implant shielding function, whether retractors are placed within shielding member 150, placed between the shielding member 150 and the walls of the dissection tunnel, or not used at all.

[00130] As depicted in FIG. 11, the incision 510 and the dissection tunnel are further opened using retractors 651, 652 to facilitate insertion of the shielding member 150 of apparatus 100. In particular, the distal end 152 of the shielding member 150 is inserted through the incision 510 and into the dissection tunnel using any suitable sterile insertion tool, such as forceps 725. As shown in FIG. 12, the shielding member 150 is further inserted into the dissection tunnel such that the distal end 152 of the shielding member 150 is received in at least a portion of the dissection tunnel or the implant pocket.

[00131] The distal end 152 of the shielding member 150 is generally inserted into the dissection tunnel to a depth greater than 1 cm below the incision so as to sufficiently shield the implant during insertion into the dissection tunnel and implant pocket. In general, it is not necessary for the shielding member 150 to shield the implant from the entire length of the dissection tunnel since often only a portion of the dissection tunnel is formed through breast tissue (glandular tissue) which may be colonized by microbes, thereby posing a risk of microbial contamination to the otherwise sterile implant. Often, the remaining portions of the dissection

tunnel are formed through sterile muscle or adipose tissue that do not pose a significant contamination risk to the implant during its transit to the implant pocket. Generally, the upper dissection tunnel comprises breast tissue and/or glandular tissue while the lower dissection tunnel comprises tissue other than breast or glandular tissue, such as muscle or adipose tissue. As used herein, the upper dissection tunnel refers to the portion of the dissection tunnel beginning at the incision in the skin of the patient and extending downward for so long as the walls of the dissection tunnel are formed through breast and/or glandular tissue. The lower dissection tunnel, as used herein, refers to the portion of the dissection tunnel beginning at the first instance of tissue other than breast and/or glandular tissue, such as muscle or adipose tissue and extending to the implant pocket. Therefore, the upper dissection tunnel is the upper most portion of the dissection tunnel connecting the incision in the skin of the patient to the lower dissection tunnel which in turn extends to the implant pocket. The length of the upper dissection tunnel can be measured intraoperatively and used to determine the predetermined length of the inner bore 115 and shielding member 150. In at least some instances, the distal end 152 of shielding member 150 is inserted into the dissection tunnel such that the entire length of the upper dissection tunnel is shielded from the implant during transit of the implant to the implant pocket. In such cases, the distal end 152 is inserted into the dissection tunnel to a depth equal to or greater than the length of the upper dissection tunnel. In other instances, the distal end 152 may be inserted into the dissection tunnel such that at least a portion of the upper dissection tunnel is shielded from the implant during transit of the implant to the implant pocket.

[00132] In at least some instances, the distal end 152 of the shielding member 150 is inserted greater than 1.5 cm, or greater than 2cm, or greater than 2.5 cm, or greater than 3 cm, or greater than 3.5 cm, or greater than 4 cm, or greater than 4.5 cm, or greater than 5 cm, or greater than 5.5 cm, or greater than 6 cm, or greater than 6.5 cm, or greater than 7 cm, or greater than 7.5 cm, or greater than 8 cm, below the incision. In at least some instances, the distal end 152 of the shielding member 150 is inserted into the dissection tunnel to a depth of from about 2 cm to about 10 cm, or from about 3 cm to about 10 cm, or from about 2 cm to about 8 cm, or from about 2 cm to about 5 cm, or from about 3 cm to about 8 cm, below the incision. The depth of insertion will generally depend on the size of the implant used, the location of the incision, and the characteristics of the subject's breast. In at least some instances, insertion of the implant into

the shielding member 150 may extend the distal end 152 of the shielding member 150 deeper into the dissection tunnel such that the implant is shielded from a greater portion of the dissection tunnel during its transit to the implant pocket.

[00133] In at least some instances, the predetermined length 165 of the inner bore 115 of the shielding member 150 may be adjusted based on the desired depth of insertion into the dissection tunnel. In such instances, intraoperative measurements of the length of the dissection tunnel may be used to determine the predetermined length 165 of the inner bore 115 of the shielding member 150 necessary to shield the implant from at least a portion of the dissection tunnel. In such cases, the predetermined length 165 of the inner bore 115 may be adjusted or cut to a predetermined length 165 equal to or less than the measured length of the dissection tunnel.

[00134] Once the shielding member 150 is sufficiently inserted into the dissection tunnel, the base 175 of apparatus 100 may be engaged with the surface of the skin 501 of the subject so that apparatus 100 may be anchored in place during insertion of the implant. As shown in FIG. 13, the lower surface 135 (opposite of upper surface 125) of base 175 is engaged with the skin 501 of the subject. As described above, the lower surface 135 of the base 175 may be engaged with the skin 501 of the subject by any number of techniques, including, but not limited to, frictional engagement by a textured surface or by wetting with a suitable liquid and by attaching to the skin 501 of the subject using an adhesive exposed by the removal of a removable backing. Once apparatus 100 is securely engaged with the skin 501 of the subject, aperture 120 and inner bore 115 substantially overlie at least a portion of the incision. In some instances, the distal end 152 of the shielding member 150 may be further positioned by inserting the insertion tool or retractors through the aperture 120 of the base 175 and within the inner bore 115 of shielding member 150. In this manner, the distal end 152 may be further inserted such that it is sufficiently received in a portion of either the dissection tunnel or the implant pocket.

[00135] In FIG. 14, the aperture 120 and the inner bore 115 of the shielding member 150 are opened up by sterile retractors 1001, 1002 so that the implant 1100 may be inserted into the aperture 120 and inner bore 115 of the apparatus 100, as shown in FIGs. 15A and 15B. As depicted in FIGs. 15A and 15B there are at least two methods by which the dissection tunnel may be opened sufficient for implant insertion into the breast. In FIG. 15A, the retractors 1001, 1002 are placed through aperture 120 and into inner bore 115 of the shielding member 150 in

order to open the dissection tunnel and the inner bore 115 in order to facilitate insertion of implant 1100. FIG. 15B depicts an alternative method in which retractors 1001, 1002 are placed in the dissection tunnel outside the shielding member 150 and in between the walls of the dissection tunnel and the outer surface 110 of shielding member 150.

[00136] After the implant 1100 is inserted into the implant pocket while being shielded from the endogenous flora of the subject by biofilm protection implant shield apparatus 100, as described above, the base 175 of the apparatus 100 may be disengaged from the skin 501 of the subject and the shielding member 150 may be withdrawn from the dissection tunnel, as depicted in FIG. 16. While FIGs. 9-16 depict the use of periareolar incision carrying out the presently disclosed methods and techniques, any suitable incision may be used and still be within the spirit and scope of the present disclosure. For example, the incision may be a periareolar incision, an inframammary incision, an axillary incision, a vertical incision, and a transumbilical incision, or any other incision that may be made for the purpose of breast implant insertion. FIG. 17 depicts the non-limiting example of apparatus 100 used in the context of an inframammary incision in the skin of a subject in which the lower surface 135 (opposite of upper surface 125) of base 175 is engaged with the skin 501 of the subject and aperture 120 and inner bore 115 substantially overlie at least a portion of the inframammary incision.

[00137] FIGs. 18-20 depict an alternative embodiment for inserting the implant 1100 into the aperture 120 of the shielding member 150 of implant shield apparatus 100 once the lower surface 135 of the base 175 is engaged with the skin 501 of the subject. As depicted in FIGs. 18-20, a conical sleeve 1800 may be used to deliver the implant 1100 through aperture 120 and into inner bore 115 of shielding member 150. The conical sleeve 1800 may have an interior cavity 1815, a first terminus 1805, and a second terminus 1810, where the first terminus 1805 has a larger diameter than the second terminus 1810. The second terminus 1810 of conical sleeve 1800 may be inserted into the aperture 120 and inner bore 115 of the shielding member 150 of apparatus 100, as depicted in FIG. 18. The conical sleeve 1800 is operable to receive implant 1100 into its interior cavity 1815 via the first terminus 1805 and deliver the implant 1100 through the second terminus 1810 into the inner bore 115 of apparatus 100, as shown in FIGs. 19-20.

[00138] FIGs. 21-28 illustrate methods for the use of the presently disclosed biofilm protection implant shield apparatus 100 in the case of inframammary incision and implant insertion. As depicted in FIG. 21, an inframammary incision 2110 in the skin 501 of the subject is created by scalpel 515. FIG. 22 depicts the use of retractors 651, 652 to open the inframammary incision 2110 and to facilitate full surgical dissection of the implant pocket and the dissection tunnel connecting the implant pocket to the incision. As depicted in FIG. 23, the inframammary incision 2110 and the dissection tunnel are further opened using retractors 651, 652 to facilitate insertion of the shielding member 150 of apparatus 100. In particular, the distal end 152 of the shielding member 150 is inserted through the incision 2110 and into the dissection tunnel using any suitable sterile insertion tool, such as forceps 725. As shown in FIG. 24, the shielding member 150 is further inserted into the dissection tunnel such that the distal end 152 of the shielding member 150 is received in at least a portion of the dissection tunnel or the implant pocket.

[00139] Once the shielding member 150 is sufficiently inserted into the dissection tunnel, the base 175 of apparatus 100 may be engaged with the surface of the skin 501 of the subject so that apparatus 100 may be anchored in place during insertion of the implant. As shown in FIG. 25, the lower surface 135 (opposite of upper surface 125) of base 175 is engaged with the skin 501 of the subject. As described above, the lower surface 135 of the base 175 may be engaged with the skin 501 of the subject by any number of techniques, including, but not limited to, frictional engagement by a textured surface or by wetting with a suitable liquid and by attaching to the skin 501 of the subject using an adhesive exposed by the removal of a removable backing. Once apparatus 100 is securely engaged with the skin 501 of the subject, aperture 120 and inner bore 115 substantially overlie at least a portion of the incision. In some instances, the distal end 152 of the shielding member 150 may be further positioned by inserting the insertion tool or retractors through the aperture 120 of the base 175 and within the inner bore 115 of shielding member 150. In this manner, the distal end 152 may be further inserted such that it is sufficiently received in a portion of either the dissection tunnel or the implant pocket.

[00140] In FIG. 26, the aperture 120 and the inner bore 115 of the shielding member 150 are opened up by sterile retractors 1001, 1002 so that the implant 1100 may be inserted into the aperture 120 and inner bore 115 of the apparatus 100, as shown in FIGs. 27A and 27B. As

depicted in FIGs. 27A and 27B there are at least two methods by which the dissection tunnel may be opened sufficient for implant insertion into the breast. In FIG. 27A, the retractors 1001, 1002 are placed through aperture 120 and into inner bore 115 of the shielding member 150 in order to open the dissection tunnel and the inner bore 115 in order to facilitate insertion of implant 1100. FIG. 27B depicts an alternative method in which retractors 1001, 1002 are placed in the dissection tunnel outside the shielding member 150 and in between the walls of the dissection tunnel and the outer surface 110 of shielding member 150.

[00141] After the implant 1100 is inserted into the implant pocket while being shielded from the endogenous flora of the subject by biofilm protection implant shield apparatus 100, as described above, the base 175 of the apparatus 100 may be disengaged from the skin 501 of the subject and the shielding member 150 may be withdrawn from the dissection tunnel, as depicted in FIG. 28.

[00142] FIGs. 29-32 are partial cross-sectional views illustrating methods for the use of the presently disclosed biofilm protection implant shield apparatus 100. In particular, FIG. 29 depicts periareolar insertion of an implant 1100 through aperture 120 of base 175 of the implant shield apparatus 100. As depicted in FIG. 29, the lower surface 135 of base 175 is engaged with the skin 501 of the subject while the dissection tunnel 2910 is held open by retractors 1001, 1002 placed outside the shielding member 150 and between the outer surface 110 of the shielding member 150 and the walls 2915 of dissection tunnel 2910. As shown in FIG. 29, insertion of the implant 1100 through aperture 120 and into the inner bore 115 of shielding member 150 provides for shielding of the implant 1100 from contamination by the breast tissue 2975 comprising the upper dissection tunnel 2911 and the endogenous flora of the subject during transit through the dissection tunnel 2910 to the implant pocket 2950. The lower dissection tunnel 2912 is formed by pectoral muscle tissue 2980, as shown by FIG. 29.

[00143] FIG. 30 depicts a similar periareolar insertion as shown in FIG. 29, except that retractors 1101, 1102, are placed inside of the inner bore 115 of shielding member 150 so as to hold open the inner bore 115 during insertion of the implant 1100 through aperture 120 of shielding member 150. As depicted in FIG. 30, shielding member 150 having outer surface 110 shields the implant 1100 from contamination by the breast tissue 2975 and the endogenous flora

of the subject during transit of the implant 1100 through the dissection tunnel 2910 to the implant pocket 2950.

[00144] FIG. 31 depicts insertion of the distal end 152 of shielding member 150 into the dissection tunnel 2910 connecting a periareolar incision to the implant pocket 2950. As shown in FIG. 31, the distal end 152 of the shielding member 150 is generally inserted into the dissection tunnel to a depth greater than 1 cm below the incision so as to sufficiently shield the implant 1100 during insertion into the dissection tunnel 2910 and implant pocket 2950. The shielding member 150 and inner bore 115 of shielding member 150 have a predetermined length 165 that may be adjusted (e.g., from about 1.5 cm to about 10 cm) based on the length of the dissection tunnel 2910, the desired depth of insertion into the dissection tunnel 2910, the size of the implant used, the location of the incision, and the characteristics of the subject's breast.

[00145] FIG. 32 depicts a partial cross-sectional view of the inframammary insertion of an implant 1100 through the aperture 120 of the base 175 of an implant shield 100 engaged with the skin 501 of a subject. As depicted in FIG. 32, the implant 1100 transits the inner bore 115 of shielding member 150 which shields the implant 1100 from at least a portion of the dissection tunnel 2910 as the implant 1100 exits the aperture 155 of the shielding member 150 and enters the implant pocket 2950.

[00146] According to at least one aspect of the present disclosure, the implant shield apparatus 100 may include a shielding member 150 that has an inner bore 115 that is conical or an inner bore that is a combination of conical and tubular. For example, implant shield apparatus 100 may include a conical member 280, for example, as shown in FIGs. 33-36. The conical member 280 may have an inner bore 285 similar to inner bore 115 of tubular member 150 except that the inner bore 285 of conical member 280 is tapered or has a variable (e.g., non-uniform) cross-sectional width over its predetermined length 196. Conical member 280 may have a proximal end 281 and a distal end 282. The proximal end 281 may have a larger cross-sectional width than the distal end 282 such that the cross-sectional width of the inner bore 285 of conical member 280 decreases along its predetermined length 296 from the proximal end 281 to the distal end 282. The outer bore 297 as defined by outer surface 210 of conical member 280 may also be conical or tapered such that the outer bore 297 has a greater cross-sectional width at the proximal end 281 than the distal end 282 of conical member 280. As shown in FIGs. 33-36, the

proximal end 281 of conical member 280 may substantially overlie aperture 120 in base 175 such that the inner bore 285 of the conical member 280 is continuous with the aperture 120 such that when an implant is inserted into aperture 120 of base 175 it will be received in the proximal end 281 of inner bore 285 of the conical member 280. In at least some instances, the conical or tapered characteristics of conical member 280 may ease insertion of the implant into aperture 120 of base 175 and facilitate transit of the implant to the implant pocket while being shielded from at least a portion of the dissection tunnel by shielding member 150 of implant shield apparatus 100.

[00147] In some instances, the shielding member 150 of implant shield apparatus 100 may have an inner bore 115 that is both tubular and conical. In such instances, the shielding member may comprise a tubular member 250 and a conical member 280, for example, as depicted in FIGs. 33-34. As shown in FIG. 33, the conical member 280 may comprises the proximal end 151 of the shielding member 150 while the tubular member 250 may comprise the distal end 152 of the shielding member 150. Accordingly, the proximal end 151 of the inner bore 115 of the shielding member 150 may have a variable cross-sectional width while the distal end 152 of the inner bore 115 may have an uniform cross-sectional width, as shown in FIGs. 33-34. As shown in FIGs. 33-34, the inner bore 285 of conical member 280 may have a greater cross-sectional width at the proximal end 151 of shielding member 150 (proximal end 281 of conical member 280) corresponding to the aperture 120 in base 175 as compared to the opposite distal end 282 of the conical member 280, thus providing for easier insertion of the implant into the aperture 120 and shielding member 150.

[00148] As shown in FIGs. 33-34, the proximal end 281 of conical member 280 may be coupled with the lower surface 135 of base 175 such that the inner bore 285 of the conical member 280 is substantially aligned with the aperture 120 of base 175 so that the conical member 280 may receive the implant once the implant is inserted into aperture 120. The distal end 282 of conical member 280 may be coupled with the proximal end 251 of tubular member 250 such that the inner bore 285 of the conical member 280 is substantially aligned with the inner bore 215 of the tubular member 250 to form inner bore 115 of shielding member 150. Aperture 155 of shielding member 150 is formed in the distal end 252 of the tubular member 250. As shown in FIG. 34, the tubular member 250 may have a predetermined length 295 while

the conical member may have a predetermined length 296. Therefore, in such cases, the predetermined length 165 of shielding member 150 comprises the predetermined length 295 of tubular member 250 together with the predetermined length 296 of conical member 280.

[00149] As shown in FIGs. 35-36, shielding member 150 may have an inner bore 115 that is conical. In such cases, the shielding member 150 may comprise a conical member 280 having an outer surface 210 and an inner bore 285. The proximal end 281 of conical member 280 may be coupled with the lower surface 135 of base 175 while the distal end 282 of conical member 280 forms the aperture 155 of the shielding member 150. The proximal end 281 of conical member 280 may have a larger cross-sectional width than the distal end 282 such that the cross-sectional width of the inner bore 285 of conical member 280 decreases along its predetermined length 296 from the proximal end 281 to the distal end 282. The outer bore 298 as defined by outer surface 210 of conical member 280 may also be conical or tapered such that the outer bore 298 has a greater cross-sectional width at the proximal end 281 than the distal end 282 of conical member 280. The proximal end 281 of conical member 280 may substantially overlies aperture 120 in base 175 such that the inner bore 285 of the conical member 280 is continuous with the aperture 120 such that when an implant is inserted into aperture 120 of base 175 it will be received in the proximal end 281 of inner bore 285 of the conical member 280. In at least some instances, the conical or tapered characteristics of conical member 280 may ease insertion of the implant into aperture 120 of base 175 and facilitate transit of the implant to the implant pocket while being shielded from at least a portion of the dissection tunnel by shielding member 150 of implant shield apparatus 100.

[00150] In some instances, the outer bore 195 as defined by outer surface 110 of shielding member 150 may have the same cross-sectional shape as the inner bore 115 of the shielding member 150, for example, as shown in FIGs. 1-8 and 33-36. However, in other cases, the outer bore 195 of shielding member 150 may have a different cross-sectional shape than the inner bore 115 of the shielding member. For example, as shown in FIGs. 37A and 37B, the outer bore 195 and outer surface 110 of shielding member 150 may have a tubular shape and cross-section with a uniform cross-sectional width, while the inner bore 115 is conical or a combination of tubular and conical.

[00151] As depicted in FIG. 37A, shielding member 150 may have an outer bore 195 as defined by outer surface 110 that is tubular, for example, characterized by a uniform cross-sectional width. However, the inner bore 115 of shielding member 150 may be frustoconical or conical, as defined by inner surface 105, having a variable cross-sectional width that is wider (greater) at the proximal end 151 of shielding member 150 and narrower (less) as the distal end 152 of the shielding member 150. In such cases, the conical inner bore 115 allows easy insertion of the implant at the proximal end 151 of the shielding member 150 while the narrower distal end 152 provides enough resistance to cause full extension of the shielding member into the dissection tunnel during implant insertion so as ensure effective shielding over the entire predetermined length 165 of the shielding member 150. Meanwhile, the tubular shape of the outer bore 195 and outer surface 110 of the shielding member 150 provides for easy insertion of the distal end 152 of the shielding member 150 into the dissection tunnel prior to implant insertion.

[00152] The shielding member 150 may also have an inner bore 115 that is both tubular and conical, as shown in FIG. 37B. As depicted in FIG. 37B, the shielding member 150 may have an outer bore 195 and outer surface 110 that is tubular while having an inner bore 115 that comprises a tubular portion 3701 defined by inner surface 105 and a conical portion 3702 defined by inner surface 107. In such cases, the conical portion 3702 defined by inner surface 107 facilitates easy insertion of the implant at the proximal end 151 of the shielding member 150 while the tubular portion 3701 at the distal end 152 of inner bore 115 defined by inner surface 105 provides enough resistance to cause full extension of the shielding member into the dissection tunnel during implant insertion so as ensure effective shielding over the entire predetermined length 165 of the shielding member 150. Meanwhile, the tubular shape of the outer bore 195 and outer surface 110 of the shielding member 150 provides for easy insertion of the distal end 152 of the shielding member 150 into the dissection tunnel prior to implant insertion.

[00153] In some instances, the implant shield apparatus 100 may further include an implant receiving member 3800 as shown in FIGs. 38A-B and 39. The implant receiving member 3800 is operable to receive the implant either before or after the distal end 152 of the shielding member 150 is inserted into the incision in the patient. For example, as shown in FIG. 38A,

implant shield apparatus 100 includes shielding member 150, base 175, and implant receiving member 3800. Implant receiving member 3800 has an outer surface 3810 and an inner surface 3805 defining an inner bore 3815. The implant receiving member 3800 also has an aperture 3820 at the proximal end 3801 of the implant receiving member 3800. The aperture 3820 is operable to receive an implant into the inner bore 3815 of the implant receiving member 3800. The distal end 3802 of the implant receiving member 3800 is coupled with the proximal end 151 of the shielding member 150 such that the inner bore 3815 of the implant receiving member is substantially aligned with the inner bore 115 of the shielding member 150 so that the implant may pass through the inner bore 3815 of the implant receiving member 3800 to the inner bore 115 of the shielding member 150. In at least some instances, the implant receiving member 3800 is operable to receive the implant such that apparatus 100 is loaded with the implant without the implant being passing or otherwise being disposed in the inner bore 115 of the shielding member 150 until mechanical force is applied to the implant receiving member 3800 by a user. In this manner, an implant may be received by the implant receiving member 3800 prior to insertion of the distal end 152 of the shielding member 150 into the dissection tunnel of the subject.

[00154] The implant receiving member 3800 is operable to receive the sterile implant and deliver it to the inner bore 115 of the shielding member 150 which in turn shields the sterile implant from at least a portion of the dissection tunnel. The implant receiving member 3800 therefore, facilitates easy insertion into the shielding member 150 and/or minimizes handling of the sterile implant during insertion into the shielding member 150. In at least some instances, the implant receiving member 3800 provides a means for mechanically propelling the implant through the inner bore 115 of the shielding member and out aperture 155 (see FIG. 39) for delivery of the implant to the implant pocket with minimal contact time with any portion of the dissection tunnel that is not shielded.

[00155] As shown in FIG. 38A, the implant shield apparatus 100 may further include a base 175 base that extends radially from either the shielding member 150 or the implant receiving member 3800, or alternatively, the base 175 may extend radially from the intersection of the shielding member 150 and the implant receiving member 3800. In some instances, the shielding member 150 or the implant receiving member 3800 may extend through the base 175. In some cases, the shielding member 150 or the implant receiving member 3800 may extend through an

aperture, such as aperture 120, formed in the base 175. In at least some instances, the base 175 is integrally formed with implant receiving member 3800 and shielding member 150. In all cases, the base 175 is secured or coupled with shielding member 150, receiving member 3800, or an intersection connecting shielding member 150 and implant receiving member 3800, such that the base 175 is fixed with respect to the shielding member 150 and implant receiving member 3800. The base 175 engages with the skin of the subject as described herein so that the distal end 152 of the shielding member 150 remains secured and disposed in the dissection tunnel or portion thereof during insertion of the implant into the implant pocket of the subject. In some instances, the implant receiving member 3800 may be loaded with the implant prior to insertion of the distal end 152 of the shielding member 150 into at least a portion of the dissection tunnel of the patient and the engagement of the base 175 with the skin of the subject. In other cases, the distal end 152 of the shielding member 150 is inserted into the dissection tunnel and the base 175 is engaged with the skin of the subject prior to the insertion of the implant into the implant receiving member 3800.

[00156] The implant receiving member 3800 and its inner bore 3815 may be conical, tubular, or any combination thereof. For example, the inner bore 3815 of the implant receiving member 3800 may be tubular and have a uniform cross-sectional width over the length of the inner bore 3815 between the proximal end 3801 and the distal end 3815 of the implant receiving member 3815. In other cases, such as that shown in FIG. 38A, the inner bore 3815 of the implant receiving member 3815 may be conical having a cross-sectional width at the proximal end 3801 of the implant receiving member 3800 that is larger than the cross-sectional width of the inner bore 3815 at the distal end 3802 of the implant receiving member 3815.

[00157] In at least some instances, the distal end 3802 of the implant receiving member 3800 is coupled to the upper surface 125 of the base 175 while the lower surface 135 of the base 175 is coupled with the proximal end 151 of the shielding member 150 such that the lower surface 135 of the base is operable to be engaged with the skin of a subject when the distal end 152 of the shielding member 150 is inserted into the incision and dissection tunnel of the subject.

[00158] In instances in which the implant shield apparatus 100 includes an implant receiving member 3800, the base 175 may not be necessary as the implant receiving member 3800 may be sufficient to shield the implant from the skin of the patient during insertion of the

implant into the shielding member 150 of the apparatus 100. FIG. 38B depicts implant shield apparatus 100 having a implant receiving member 3800 and a shielding member 150 without a base. In some instances, the implant receiving member 3800 may be loaded with the implant prior to insertion of the distal end 152 of the shielding member 150 into at least a portion of the dissection tunnel of the patient. In other cases, the distal end 152 of the shielding member 150 is inserted into the dissection tunnel prior to the insertion of the implant into the implant receiving member 3800.

[00159] FIGs. 40-45 illustrate the use of an implant shield apparatus 100 that includes an implant receiving member 3800. While FIGs. 40-45 illustrate a method of using an apparatus 100 that includes a base 175, it should be recognized that a similar method may be used in the case of an apparatus 100 that does not include a base 175 to deliver an implant into an implant pocket of a subject. FIG. 40 illustrates the creation of a periareolar incision 510 in the skin 501 of the subject by scalpel 515. FIG. 41 depicts the use of retractors 651, 652 to open the periareolar incision 510 and to facilitate full surgical dissection of the implant pocket and the dissection tunnel connecting the implant pocket to the incision. As depicted in FIG. 42, the incision 510 and the dissection tunnel are further opened using retractors 651, 652 to facilitate insertion of the shielding member 150 of apparatus 100. In particular, the distal end 152 of the shielding member 150 is inserted through the incision 510 and into the dissection tunnel using any suitable sterile insertion tool, such as forceps 725. As depicted in FIG. 42, the implant may already be loaded (*e.g.*, the implant has been received in the implant receiving member 3800) into the implant receiving member 3800 (but not yet inserted into the inner bore 115 of the shielding member 150) prior to insertion of the distal end 152 of the shielding member 150 into the dissection tunnel and engagement of base 175 with the skin of the subject. In other cases, the distal end 152 of the shielding member 3800 may be inserted into the dissection tunnel and the base 175 engaged with the skin of the subject prior to insertion of the implant into the implant receiving member 3800.

[00160] As shown in FIG. 43, the shielding member 150 is further inserted into the dissection tunnel such that the distal end 152 of the shielding member 150 is received in at least a portion of the dissection tunnel or the implant pocket. As described above, the distal end 152 of the shielding member 150 is generally inserted into the dissection tunnel to a depth greater than 1

cm below the incision so as to sufficiently shield the implant during insertion into the dissection tunnel and implant pocket. Once the shielding member 150 is sufficiently inserted into the dissection tunnel, the base 175 of apparatus 100 may be engaged with the surface of the skin 501 of the subject so that apparatus 100 may be anchored in place during delivery of the implant to the implant pocket in the subject. In cases in which a base 175 is not included in the apparatus 100, the engagement of the base 175 with the skin is simply not performed and the method proceeds as otherwise depicted in FIGs. 40-45. As shown in FIG. 44, the mechanical force is applied to the implant receiving member 3800 by the user such that the implant is propelled through the distal end 3802 of the implant receiving member 3800 and into the inner bore 115 of the shielding member 150 so that the implant may transit through the inner bore 115 of the shielding member 150 and exit aperture 155 at the distal end 152 of the shielding member 150 thereby delivering the implant 1100 to the implant pocket in the subject.

[00161] FIGs. 45A and 45B illustrates the alternative method in which the distal end 152 of the shielding member 150 is inserted into the dissection tunnel of the subject, and optionally the base 175 is engaged with the skin of the subject, prior to insertion of the implant 1100 into the proximal end 3801 of the implant receiving member 3800. As shown in FIG. 45B, the implant 1100 is loaded into the proximal end 3801 of the implant receiving member 3800 with the base 175 engaged with the skin of the subject. The user may then apply mechanical force to the implant receiving member 3800 such that the implant is propelled through the distal end 3802 of the implant receiving member 3800 and into the inner bore 115 of the shielding member 150 so that the implant may transit through the inner bore 115 of the shielding member 150 and exit aperture 155 at the distal end 152 of the shielding member 150 thereby delivering the implant 1100 to the implant pocket in the subject.

### **STATEMENTS OF THE PRESENT DISCLOSURE**

[00162] Numerous examples are provided herein to enhance understanding of the present disclosure. A specific set of statements are provided as follows.

[00163] Statement 1: An apparatus for inserting an implant into a surgically-created implant pocket in a subject, the apparatus comprising: a base having an upper surface and a lower

surface, the base having an aperture formed therein and extending through the upper surface and the lower surface; and a shielding member coupled with the base, the shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length away from the lower surface of the base; wherein the proximal end of the shielding member is coupled with the base and the inner bore is substantially aligned with the aperture formed in the base; and wherein the inner bore is operable to receive the implant therethrough.

[00164] Statement 2: The apparatus according to Statement 1, wherein the inner bore has a longitudinal axis therethrough, the shielding member extending along the longitudinal axis.

[00165] Statement 3: The apparatus according to Statement 1 or Statement 2, wherein the inner bore extends longitudinally along a longitudinal axis a predetermined length away from the lower surface of the base.

[00166] Statement 4: The apparatus according to Statement 2 or Statement 3, wherein the longitudinal axis extends substantially perpendicular to the base.

[00167] Statement 5: The apparatus according to Statement 1, wherein the shielding member extends longitudinally along a longitudinal axis substantially perpendicular to the base.

[00168] Statement 6: The apparatus according to any one of the preceding Statements 1-5, wherein the shielding member extends substantially orthogonally from the base.

[00169] Statement 7: The apparatus according to any one of the preceding Statements 1-6, wherein the base extends away from the shielding member in a direction substantially perpendicular to the longitudinal axis.

[00170] Statement 8: The apparatus according to any one of the preceding Statements 1-7, wherein the shielding member is substantially cylindrical in cross-sectional shape.

[00171] Statement 9: The apparatus according to any one of the preceding Statements 1-7, wherein the shielding member is elliptical in cross-sectional shape.

[00172] Statement 10: The apparatus according to any one of the preceding Statements 1-9, wherein at least a portion of the inner bore of shielding member extends a second predetermined length above the upper surface of the base.

[00173] Statement 11: The apparatus according to any one of the preceding Statements 1-10, wherein the lower surface of the base is operable to engage with a skin of the subject.

[00174] Statement 12: The apparatus according to any one of the preceding Statements 1-11, wherein the lower surface of the base is operable to engage a skin of the subject adjacent to an incision, wherein the inner bore of shielding member substantially overlies at least a portion of the incision.

[00175] Statement 13: The apparatus according to any one of the preceding Statements 1-12, wherein the lower surface of the base is operable to engage with a skin of the subject so as to resist movement of the base with respect to the skin when engaged with the skin.

[00176] Statement 14: The apparatus according to any one of the preceding Statements 1-13, wherein the lower surface is operable to frictionally engage the skin of a subject, wherein the frictional engagement resists movement of the base relative to the skin.

[00177] Statement 15: The apparatus according to any one of the preceding Statements 1-14, wherein the lower surface comprises a textured surface.

[00178] Statement 16: The apparatus according to any one of the preceding Statements 1-15, wherein the lower surface comprises a surface operable to frictionally engage the skin of a subject once wetted.

[00179] Statement 17: The apparatus according to any one of the preceding Statements 1-15, wherein a fluid is disposed on one of the lower surface and/or the skin of the patient, the fluid operable to form a frictional engagement between the lower surface and the skin.

[00180] Statement 18: The apparatus according to any one of the preceding Statements 1-15, wherein an adhesive is disposed on the lower surface.

[00181] Statement 19: The apparatus according to Statement 18, wherein the lower surface further comprises a removable backing, the removable backing operable to expose the adhesive.

[00182] Statement 20: The apparatus according to any one of the preceding Statements 1-19, wherein the predetermined length is determined based on a distance between an incision in the skin of a patient and a surgically-created implant pocket formed below the skin.

[00183] Statement 21: The apparatus according to any one of the preceding Statements 1-20,

wherein the predetermined length between the proximal end and the distal end extends the inner bore operably to deliver an implant subdermally through the aperture and inner bore and into the surgically-created implant pocket when the lower surface of base is adjacently engaged with the skin of a patient and the distal end is received into at least a portion of the implant pocket.

[00184] Statement 22: The apparatus according to any one of the preceding Statements 1-21, wherein the proximal end of shielding member is operable to receive an implant therethrough.

[00185] Statement 23: The apparatus according to Statement 22, wherein the shielding member is further operable to deliver the implant subdermally to the implant pocket through the predetermined length of inner bore of the shielding member.

[00186] Statement 24: The apparatus according to any one of the preceding Statements 1-23, wherein the distal end of shielding member is operable to be inserted into an incision in the skin of the subject, and the shielding member is operable to be extended the predetermined length such that the distal end is received into at least a portion of the surgically-created implant pocket.

[00187] Statement 25: The apparatus according to Statement 24, wherein shielding member extends along at least a portion of a dissection tunnel formed between the incision and the implant pocket.

[00188] Statement 26: The apparatus according to Statement 24 or Statement 25, wherein the shielding member is operable to deliver the implant to the implant pocket through a dissection tunnel connecting the incision to the implant pocket without the implant contacting the dissection tunnel.

[00189] Statement 27: The apparatus according to any one of the preceding Statements 1-26, wherein the shielding member comprises an inner surface and an outer surface, the inner surface defining the inner bore of shielding member.

[00190] Statement 28: The apparatus according to any one of the preceding Statements 1-27, wherein the shielding member and the base are formed from the same material.

[00191] Statement 29: The apparatus according to any one of the preceding Statements 1-28, wherein the shielding member and base are formed from a flexible material.

[00192] Statement 30: The apparatus according to Statement 29, wherein the flexible material

is resistant to stretching.

[00193] Statement 31: The apparatus according to Statement 29, wherein the flexible material is capable of stretching.

[00194] Statement 32: The apparatus according to Statement 29, wherein the flexible material is operable to stretch when an implant is inserted and/or physically manipulated through the longitudinal length of the inner bore of the shielding member.

[00195] Statement 33: The apparatus according to any one of Statements 29-32, wherein the flexible material is selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[00196] Statement 34: The apparatus according to any one of the preceding Statements 1-33, wherein the shielding member and the base are integrally formed.

[00197] Statement 35: The apparatus according to any one of the preceding Statements 1-34, wherein the inner bore of shielding member is not tapered along the predetermined length.

[00198] Statement 36: The apparatus according to any one of the preceding Statements 1-35, wherein the implant is selected from the group consisting of a breast implant, a pre-filled breast implant, a pre-filled saline breast implant, a pre-filled silicone breast implant, an un-filled breast implant, a saline breast implant, a silicone breast implant, a textured breast implant, a smooth breast implant, a highly cohesive silicone gel breast implant, an oil-filled breast implant, and an un-filled saline breast implant.

[00199] Statement 37: The apparatus according to any one of the preceding Statements 1-36, wherein the inner bore comprises a lubricant.

[00200] Statement 38: The apparatus according to any one of the preceding Statements 1-36, wherein the inner surface of the shielding member comprises a lubricant.

[00201] Statement 39: The apparatus according to any one of the preceding Statements 1-36, wherein the outer surface of the shielding member comprises a lubricant.

[00202] Statement 40: The apparatus according to any one of the preceding Statements 37-39, wherein the lubricant is a sterile lubricant selected from the group consisting of a surgical

lubricant, a water-based lubricating jelly, a dry lubricant, a powdered lubricant, a moisture-activated lubricant, and any combination thereof.

[00203] Statement 41: The apparatus according to any one of the preceding Statements 1-40, wherein the inner bore comprises a lubricating coating or a friction-reducing coating.

[00204] Statement 42: The apparatus according to any one of the preceding Statements 1-36, wherein the inner surface of the shielding member comprises a lubricating coating or a friction-reducing coating.

[00205] Statement 43: The apparatus according to any one of the preceding Statements 1-36, wherein the outer surface of the shielding member comprises a lubricating coating or a friction-reducing coating.

[00206] Statement 44: The apparatus according to any one of the preceding Statements 1-43, wherein the predetermined length of the inner bore is equal to or less than a measured length of the dissection tunnel.

[00207] Statement 45: The apparatus according to any one of the preceding Statements 1-43, wherein the predetermined length of the inner bore is equal to or less than a measured length of the upper dissection tunnel.

[00208] Statement 46: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 1 cm.

[00209] Statement 47: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 1.5 cm.

[00210] Statement 48: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 2 cm.

[00211] Statement 49: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 2.5 cm.

[00212] Statement 50: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 3 cm.

[00213] Statement 51: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 3.5 cm.

[00214] Statement 52: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 4 cm.

[00215] Statement 53: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 4.5 cm.

[00216] Statement 54: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is greater than 5 cm.

[00217] Statement 55: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is from about 1.5 cm to about 10 cm.

[00218] Statement 56: The apparatus according to any one of the preceding Statements 1-45, wherein the predetermined length of the inner bore is from about 1.5 cm to about 5 cm or from about 3 cm to about 8 cm.

[00219] Statement 57: The apparatus according to any one of the preceding Statements 1-56, wherein the distal end of the shielding member comprises a second aperture that is substantially aligned with the inner bore and the aperture of the base when the shielding member is extended.

[00220] Statement 58: The apparatus according to any one of the preceding Statements 1-57, wherein the inner bore has a substantially uniform cross-sectional width over the predetermined length.

[00221] Statement 59: The apparatus according to any one of the preceding Statements 1-58, wherein the distal end has substantially the same cross-sectional width as the cross-sectional width of the proximal end.

[00222] Statement 60: The apparatus according to any one of the preceding Statements 1-59, wherein the cross-sectional width of the inner bore at the distal end of the shielding member is substantially the same as the cross-sectional width of the inner bore at the proximal end of the shielding member.

[00223] Statement 61: The apparatus according to any one of the preceding Statements 57-60, wherein the second aperture at the distal end of the shielding member has substantially the same cross-sectional width as the cross-sectional width of the aperture in the base.

[00224] Statement 62: The apparatus according to any one of the preceding Statements 1-57,

wherein the inner bore is conical.

[00225] Statement 63: The apparatus according to any one of the preceding Statements 1-57, wherein the shielding member comprises a conical member.

[00226] Statement 64: The apparatus according to any one of the preceding Statements 1-57, wherein the inner bore has a larger cross-sectional width at the proximal end than the cross-sectional width of the inner bore at the distal end of the shielding member.

[00227] Statement 65: The apparatus according to any one of the preceding Statements 1-57, wherein the inner bore comprises a conical portion and a tubular portion along its predetermined length.

[00228] Statement 66: The apparatus according to any one of the preceding Statements 1-57, wherein the shielding member comprises a conical member and a tubular member.

[00229] Statement 67: The apparatus according to Statement 66, wherein the conical member has an inner bore, a distal end, and a proximal end, and the tubular member has an inner bore, a distal end and a proximal end, wherein the proximal end of the conical member is coupled with the lower surface of the base such that the inner bore of the conical member is substantially aligned with the aperture of the base so that the conical member may receive the implant once the implant is inserted into aperture.

[00230] Statement 68: The apparatus according to Statement 67, wherein the distal end of the conical member is coupled with the proximal end of the tubular member such that the inner bore of the conical member is substantially aligned with the inner bore of the tubular member to form the inner bore of the shielding member.

[00231] Statement 69: The apparatus according to Statement 68, wherein the aperture of the shielding member is formed in the distal end of the shielding member.

[00232] Statement 70: The apparatus according to Statement 66 or Statement 69, wherein, the tubular member has a first predetermined length and the conical member has a second predetermined length, the predetermined length of the shielding member comprising the sum of the first and second predetermined lengths.

[00233] Statement 71: The apparatus according to any one of the preceding Statements 1-70,

wherein the distal end and the proximal end of the inner bore have the same cross-sectional profile, wherein the cross-sectional profile is selected from the group consisting of circular, elliptical, and oval.

[00234] Statement 72: The apparatus according to any one of the preceding Statements 1-70, wherein the distal end and the proximal end of the inner bore have a different cross-sectional profile, wherein the cross-sectional profile is selected from the group consisting of circular, elliptical, and oval.

[00235] Statement 73: The apparatus according to Statement 72, wherein the distal end and the proximal end of the inner bore have substantially the same cross-sectional width.

[00236] Statement 74: The apparatus according to any one of the preceding Statements 1-61, wherein the shielding member comprises an outer surface, the outer surface defining an outer bore, wherein the outer bore is substantially tubular and the inner bore is substantially frustoconical.

[00237] Statement 75: The apparatus according to any one of the preceding Statements 1-61, wherein the shielding member comprises an outer surface, the outer surface defining an outer bore, wherein the outer bore comprises a cross-sectional width that is substantially tubular and the inner bore comprises a cross-sectional width that is substantially frustoconical.

[00238] Statement 76: The apparatus according to any one of the preceding Statements 1-61, wherein the shielding member comprises an outer surface, the outer surface defining an outer bore, wherein the outer bore is substantially tubular and the inner bore comprises a tubular portion and a conical portion.

[00239] Statement 77: The apparatus according to Statement 76, wherein the tubular portion of the inner bore comprises a substantially uniform cross-sectional width and the conical portion of the inner bore comprises a larger cross-sectional width that is larger at the proximal end of the shielding member and decreases towards the distal end of the shielding member.

[00240] Statement 78: An apparatus for inserting an implant into a surgically-created implant pocket in a subject, the apparatus comprising: a base having an upper surface and a lower surface; and a shielding member extending through the base, the shielding member having an inner bore, a proximal end and a distal end, the inner bore extending longitudinally a

predetermined length away from the lower surface of the base and between the proximal end and the distal end; and wherein the shielding member comprises a first aperture at the proximal end and a second aperture at the distal end, wherein the inner bore is operable to receive an implant at the first aperture and deliver the implant therethrough at the second aperture.

[00241] Statement 79: The apparatus according to Statement 78, wherein the base radially extends from at least a portion of the proximal end of the shielding member.

[00242] Statement 80: The apparatus according to Statement 78 or Statement 79, wherein the inner bore has a longitudinal axis therethrough, the shielding member extending along the longitudinal axis.

[00243] Statement 81: The apparatus according to any one of the preceding Statements 78-66, wherein the inner bore extends longitudinally along a longitudinal axis a predetermined length away from the lower surface of the base.

[00244] Statement 82: The apparatus according to Statement 80 or Statement 81, wherein the longitudinal axis extends substantially perpendicular to the base.

[00245] Statement 83: The apparatus according to any one of the preceding Statements 78-82, wherein the shielding member extends longitudinally along a longitudinal axis substantially perpendicular to the base.

[00246] Statement 84: The apparatus according to any one of the preceding Statements 78-83, wherein the shielding member extends substantially orthogonally from the base.

[00247] Statement 85: The apparatus according to any one of the preceding Statements 78-84, wherein the base extends away from the shielding member in a direction substantially perpendicular to the longitudinal axis.

[00248] Statement 86: The apparatus according to any one of the preceding Statements 78-85, wherein the shielding member is substantially cylindrical in cross-sectional shape.

[00249] Statement 87: The apparatus according to any one of the preceding Statements 78-85, wherein the shielding member is elliptical in cross-sectional shape.

[00250] Statement 88: The apparatus according to any one of the preceding Statements 78-87, wherein at least a portion of the inner bore of shielding member extends a second predetermined

length above the upper surface of the base.

[00251] Statement 89: The apparatus according to any one of the preceding Statements 78-88, wherein the lower surface of the base is operable to engage with a skin of the subject.

[00252] Statement 90: The apparatus according to any one of the preceding Statements 78-89, wherein the lower surface of the base is operable to engage a skin of the subject adjacent to an incision, wherein the inner bore of shielding member substantially overlies at least a portion of the incision.

[00253] Statement 91: The apparatus according to any one of the preceding Statements 78-90, wherein the lower surface of the base is operable to engage with a skin of the subject so as to resist movement of the base with respect to the skin when engaged with the skin.

[00254] Statement 92: The apparatus according to any one of the preceding Statements 78-91, wherein the lower surface is operable to frictionally engage the skin of a subject, wherein the frictional engagement resists movement of the base relative to the skin.

[00255] Statement 93: The apparatus according to any one of the preceding Statements 78-92, wherein the lower surface comprises a textured surface.

[00256] Statement 94: The apparatus according to any one of the preceding Statements 78-93, wherein the lower surface comprises a surface operable to frictionally engage the skin of a subject once wetted.

[00257] Statement 95: The apparatus according to any one of the preceding Statements 78-93, wherein a fluid is disposed on one of the lower surface and/or the skin of the patient, the fluid operable to form a frictional engagement between the lower surface and the skin.

[00258] Statement 96: The apparatus according to any one of the preceding Statements 78-93, wherein an adhesive is disposed on the lower surface.

[00259] Statement 97: The apparatus according to Statement 96, wherein the lower surface further comprises a removable backing, the removable backing operable to expose the adhesive.

[00260] Statement 98: The apparatus according to any one of the preceding Statements 78-97, wherein the predetermined length is determined based on a distance between an incision in the skin of a patient and a surgically-created implant pocket formed below the skin.

[00261] Statement 99: The apparatus according to any one of the preceding Statements 78-98, wherein the predetermined length between the proximal end and the distal end extends the inner bore operably to deliver an implant subdermally through the first aperture, inner bore, and second aperture into the surgically-created implant pocket when the lower surface of base is adjacently engaged with the skin of a patient and the distal end is received into at least a portion of the implant pocket.

[00262] Statement 100: The apparatus according to any one of the preceding Statements 78-99, wherein the proximal end of the shielding member is operable to receive an implant therethrough.

[00263] Statement 101: The apparatus according to Statement 100, wherein the shielding member is further operable to deliver the implant subdermally to the implant pocket through the predetermined length of inner bore of the shielding member.

[00264] Statement 102: The apparatus according to any one of the preceding Statements 78-101, wherein the distal end of the shielding member is operable to be inserted into an incision in the skin of the subject, and the shielding member is operable to be extended the predetermined length such that the distal end is received into at least a portion of the surgically-created implant pocket.

[00265] Statement 103: The apparatus according to Statement 102, wherein shielding member extends along at least a portion of a dissection tunnel formed between the incision and the implant pocket.

[00266] Statement 104: The apparatus according to Statement 102 or Statement 103, wherein the shielding member is operable to deliver the implant to the implant pocket through a dissection tunnel connecting the incision to the implant pocket without the implant contacting the dissection tunnel.

[00267] Statement 105: The apparatus according to any one of the preceding Statements 78-104, wherein the shielding member comprises an inner surface and an outer surface, the inner surface defining the inner bore of the shielding member.

[00268] Statement 106: The apparatus according to any one of the preceding Statements 78-105, wherein the shielding member and the base are formed from the same material.

[00269] Statement 107: The apparatus according to any one of the preceding Statements 78-106, wherein the shielding member and base are formed from a flexible material.

[00270] Statement 108: The apparatus according to Statement 107, wherein the flexible material is resistant to stretching.

[00271] Statement 109: The apparatus according to Statement 107, wherein the flexible material is capable of stretching.

[00272] Statement 110: The apparatus according to Statement 107, wherein the flexible material is operable to stretch when an implant is inserted and/or physically manipulated through the longitudinal length of the inner bore of the shielding member.

[00273] Statement 111: The apparatus according to any one of the preceding Statements 107-110, wherein the flexible material is selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[00274] Statement 112: The apparatus according to any one of the preceding Statements 78-111, wherein the shielding member and the base are integrally formed.

[00275] Statement 113: The apparatus according to any one of the preceding Statements 78-112, wherein the inner bore of the shielding member is not tapered along the predetermined length.

[00276] Statement 114: The apparatus according to any one of the preceding Statements 78-113, wherein the inner bore comprises a lubricant.

[00277] Statement 115: The apparatus according to any one of the preceding Statements 78-113, wherein the inner surface of the shielding member comprises a lubricant.

[00278] Statement 116: The apparatus according to any one of the preceding Statements 78-113, wherein the outer surface of the shielding member comprises a lubricant.

[00279] Statement 117: The apparatus according to any one of the preceding Statements 114-116, wherein the lubricant is a sterile lubricant selected from the group consisting of a surgical lubricant, a water-based lubricating jelly, a dry lubricant, a powdered lubricant, a moisture-activated lubricant, and any combination thereof.

[00280] Statement 118: The apparatus according to any one of the preceding Statements 78-117, wherein the inner bore comprises a lubricating coating or a friction-reducing coating.

[00281] Statement 119: The apparatus according to any one of the preceding Statements 78-117, wherein the inner surface of the shielding member comprises a lubricating coating or a friction-reducing coating.

[00282] Statement 120: The apparatus according to any one of the preceding Statements 78-117, wherein the outer surface of the shielding member comprises a lubricating coating or a friction-reducing coating.

[00283] Statement 121: The apparatus according to any one of the preceding Statements 78-120, wherein the predetermined length of the inner bore is equal to or less than a measured length of the dissection tunnel.

[00284] Statement 122: The apparatus according to any one of the preceding Statements 78-120, wherein the predetermined length of the inner bore is equal to or less than a measured length of the upper dissection tunnel.

[00285] Statement 123: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 1 cm.

[00286] Statement 124: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 1.5 cm.

[00287] Statement 125: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 2 cm.

[00288] Statement 126: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 2.5 cm.

[00289] Statement 127: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 3 cm.

[00290] Statement 128: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 3.5 cm.

[00291] Statement 129: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 4 cm.

[00292] Statement 130: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 4.5 cm.

[00293] Statement 131: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is greater than 5 cm.

[00294] Statement 132: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is from about 1.5 cm to about 10 cm.

[00295] Statement 133: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is from about 1.5 cm to about 5 cm.

[00296] Statement 134: The apparatus according to any one of the preceding Statements 78-122, wherein the predetermined length of the inner bore is from about 3 cm to about 8 cm.

[00297] Statement 135: The apparatus according to any one of the preceding Statements 78-134, wherein the second aperture that is substantially aligned with the first aperture when the shielding member is fully extended.

[00298] Statement 136: The apparatus according to any one of the preceding Statements 78-135, wherein the inner bore has a substantially uniform cross-sectional width over the predetermined length.

[00299] Statement 137: The apparatus according to any one of the preceding Statements 78-135, wherein the distal end has substantially the same cross-sectional width as the cross-sectional width of the proximal end.

[00300] Statement 138: The apparatus according to any one of the preceding Statements 78-137, wherein the cross-sectional width of the inner bore at the distal end of the shielding member is substantially the same as the cross-sectional width of the inner bore at the proximal end of the shielding member.

[00301] Statement 139: The apparatus according to any one of the preceding Statements 78-138, wherein the second aperture has substantially the same cross-sectional width as the first aperture.

[00302] Statement 140: The apparatus according to any one of the preceding Statements 78-135, wherein the inner bore is conical.

[00303] Statement 141: The apparatus according to any one of the preceding Statements 78-135, wherein the shielding member comprises a conical member.

[00304] Statement 142: The apparatus according to any one of the preceding Statements 78-135, wherein the inner bore has a larger cross-sectional width at the proximal end than the cross-sectional width of the inner bore at the distal end of the shielding member.

[00305] Statement 143: The apparatus according to any one of the preceding Statements 78-135, wherein the inner bore comprises a conical portion and a tubular portion along its predetermined length.

[00306] Statement 144: The apparatus according to any one of the preceding Statements 78-135, wherein the shielding member comprises a conical member and a tubular member.

[00307] Statement 145: The apparatus according to Statement 144, wherein the conical member has an inner bore, a distal end, and a proximal end, and the tubular member has an inner bore, a distal end and a proximal end, wherein the proximal end of the conical member is coupled with the lower surface of the base such that the inner bore of the conical member is substantially aligned with the aperture of the base so that the conical member may receive the implant once the implant is inserted into aperture.

[00308] Statement 146: The apparatus according to Statement 145, wherein the distal end of the conical member is coupled with the proximal end of the tubular member such that the inner bore of the conical member is substantially aligned with the inner bore of the tubular member to form the inner bore of the shielding member.

[00309] Statement 147: The apparatus according to Statement 146, wherein the aperture of the shielding member is formed in the distal end of the shielding member.

[00310] Statement 148: The apparatus according to Statement 145 or Statement 147, wherein, the tubular member has a first predetermined length and the conical member has a second predetermined length, the predetermined length of the shielding member comprising the sum of the first and second predetermined lengths.

[00311] Statement 149: The apparatus according to any one of the preceding Statements 78-148, wherein the distal end and the proximal end of the inner bore have the same cross-sectional

profile, wherein the cross-sectional profile is selected from the group consisting of circular, elliptical, and oval.

[00312] Statement 150: The apparatus according to any one of the preceding Statements 78-148, wherein the distal end and the proximal end of the inner bore have a different cross-sectional profile, wherein the cross-sectional profile is selected from the group consisting of circular, elliptical, and oval.

[00313] Statement 151: The apparatus according to Statement 150, wherein the distal end and the proximal end of the inner bore have substantially the same cross-sectional width.

[00314] Statement 152: The apparatus according to any one of the preceding Statements 78-151, wherein the shielding member comprises an outer surface, the outer surface defining an outer bore, wherein the outer bore is substantially tubular and the inner bore is substantially frustoconical.

[00315] Statement 153: The apparatus according to any one of the preceding Statements 78-151, wherein the shielding member comprises an outer surface, the outer surface defining an outer bore, wherein the outer bore comprises a cross-sectional width that is substantially tubular and the inner bore comprises a cross-sectional width that is substantially frustoconical.

[00316] Statement 154: The apparatus according to any one of the preceding Statements 78-151, wherein the shielding member comprises an outer surface, the outer surface defining an outer bore, wherein the outer bore is substantially tubular and the inner bore comprises a tubular portion and a conical portion.

[00317] Statement 155: The apparatus according to Statement 154, wherein the tubular portion of the inner bore comprises a substantially uniform cross-sectional width and the conical portion of the inner bore comprises a larger cross-sectional width that is larger at the proximal end of the shielding member and decreases towards the distal end of the shielding member.

[00318] Statement 156: The apparatus according to any one of the preceding Statements 78-155, wherein the first aperture and the second aperture have the same cross-sectional profile, wherein the cross-sectional profile is selected from the group consisting of circular, elliptical, and oval.

[00319] Statement 157: The apparatus according to any one of the preceding Statements 78-155, wherein the first aperture and the second aperture have a different cross-sectional profile, wherein the cross-sectional profile is selected from the group consisting of circular, elliptical, and oval.

[00320] Statement 158: The apparatus according to Statement 157, wherein the first aperture and the second aperture have substantially the same cross-sectional width.

[00321] Statement 159: A system comprising: an apparatus for inserting an implant into a surgically-created implant pocket in a subject according to any one of the preceding Statements 1-158, 165, 273-295, 350-381, and 390; and an implant.

[00322] Statement 160: A system comprising: an apparatus for inserting an implant into a surgically-created implant pocket in a subject according to any one of the preceding Statements 1-158, 165, 273-295, 350-381, and 390; and a conical sleeve having a an interior cavity, a first terminus, and a second terminus, wherein the first terminus has a larger diameter than the second terminus; wherein the second terminus is operable to be inserted into the aperture or inner bore of the shielding member of the apparatus, the conical sleeve further operable to receive an implant into its interior cavity via the first terminus and deliver the implant through the second terminus into the inner bore of the apparatus.

[00323] Statement 161: The system according to Statement 160, further comprising an implant.

[00324] Statement 162: A kit comprising: an apparatus for inserting an implant into a surgically-created implant pocket in a subject according to any one of Statements 1-158, 165, 273-295, 350-381, and 390; and an implant; wherein the apparatus and the implant are packaged together.

[00325] Statement 163: A kit comprising: an apparatus for inserting an implant into a surgically-created implant pocket in a subject according to any one of Statements 1-158, 165, 273-295, 350-381, and 390; and a conical sleeve having a an interior cavity, a first terminus, and a second terminus, wherein the first terminus has a larger diameter than the second terminus; wherein the second terminus is operable to be inserted into the aperture or inner bore of the shielding member of the apparatus, the conical sleeve further operable to receive an implant into

its interior cavity via the first terminus and deliver the implant through the second terminus into the inner bore of the apparatus; wherein the apparatus and the implant are packaged together.

[00326] Statement 164: The kit according to Statement 163, further comprising an implant.

[00327] Statement 165: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-381, wherein the implant is selected from the group consisting of a filled implant or a pre-filled implant, an unfilled implant, a saline implant, a silicone gel implant, a textured implant, a smooth implant, a highly cohesive silicone gel implant, an oil-filled implant, a pacemaker, a joint replacement prosthesis, an allograft, an autograft, and a prosthesis implant.

[00328] Statement 166: The system according to any one of the preceding Statements 159-161, wherein the implant is selected from the group consisting of a filled implant or a pre-filled implant, an unfilled implant, a saline implant, a silicone gel implant, a textured implant, a smooth implant, a highly cohesive silicone gel implant, an oil-filled implant, a pacemaker, a joint replacement prosthesis, an allograft, an autograft, and a prosthesis implant.

[00329] Statement 167: The kit according to any one of the preceding Statements 162-164, wherein the implant is selected from the group consisting of a filled implant or a pre-filled implant, an unfilled implant, a saline implant, a silicone gel implant, a textured implant, a smooth implant, a highly cohesive silicone gel implant, an oil-filled implant, a pacemaker, a joint replacement prosthesis, an allograft, an autograft, and a prosthesis implant.

[00330] Statement 168: A method for inserting an implant into a surgically-created implant pocket in a subject through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject, the method comprising: providing a sterile biofilm protection implant shield, the implant shield comprising: a base having an upper surface and a lower surface, the base further having an aperture formed therein and extending through the upper surface and the lower surface; and a shielding member coupled with the base, the shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length away from the lower surface of the base; wherein the proximal end of the shielding member is coupled with the base and the inner bore is substantially aligned with the aperture formed in the base; and wherein the inner bore is operable to receive the

implant therethrough and has a substantially uniform cross-sectional width over the predetermined length; inserting the distal end of the shielding member of the implant shield through the incision in the skin of subject and into the dissection tunnel such that the distal end of the shielding member is received in at least a portion of the dissection tunnel or the implant pocket; causing the lower surface of the base to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket; and delivering the implant to the implant pocket by inserting the implant through the aperture of the base and through the inner bore and distal end of the shielding member to the implant pocket.

[00331] Statement 169: The method according to Statement 168, further comprising: opening the dissection tunnel using one or more retractors during inserting the shielding member of the implant shield into the implant pocket or a portion of a dissection tunnel.

[00332] Statement 170: The method according to Statement 168 or Statement 169, wherein inserting the shielding member of the implant shield into the implant pocket or a portion of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject comprises inserting the shielding member or a distal end thereof using forceps or a similar device.

[00333] Statement 171: The method according to any one of the preceding Statements 168-170, further comprising: causing the lower surface of the base to engage the skin of the subject so as to resist movement of the base with respect to the skin when engaged with the skin.

[00334] Statement 172: The method according to Statement 171, wherein the base is frictionally engaged with the skin of the subject.

[00335] Statement 173: The method according to Statement 171 or Statement 172, further comprising wetting the lower surface of the base to cause the engagement with the skin of the subject.

[00336] Statement 174: The method according to Statement 171, wherein the base is engaged with the skin of the subject by an adhesive disposed on the lower surface of the base.

[00337] Statement 175: The method according to Statement 174, further comprising: exposing the adhesive disposed on the lower surface of the base by removing a removable backing disposed on the lower surface of the base.

[00338] Statement 176: The method according to any one of the preceding Statements 168-175, further comprising: attaching the lower surface of the base to the skin of the subject so as to arrest movement of the base with respect to the skin during use.

[00339] Statement 177: The method according to any one of the preceding Statements 171-175, wherein the aperture substantially overlies at least a portion of the incision.

[00340] Statement 178: The method according to any one of the preceding Statements 168-177, further comprising: inserting the shielding member of the implant shield into the implant pocket or a portion of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject, such that the lower surface of the base substantially engages with at least a portion of the skin adjacent to the incision; and extending the shielding member of the implant shield through the full length of the dissection tunnel such that the distal end extends at least partially into the implant pocket.

[00341] Statement 179: The method according to Statement 178, wherein the shielding member of the implant shield is extended through the dissection tunnel using one or more retractors inserted through the aperture and into the inner bore of the shielding member.

[00342] Statement 180: The method according to Statement 178, wherein the shielding member of the implant shield is extended through the dissection tunnel using one or more retractors placed outside the aperture and between the shielding member and a tissue forming the dissection tunnel.

[00343] Statement 181: The method according to any one of the preceding Statements 178-180, wherein prior to delivering the implant to the implant pocket, the method further comprises: inserting one or more retractors through the aperture and into the inner bore of the tubular member so as to open the inner bore and dissection tunnel for implant insertion.

[00344] Statement 182: The method according to any one of the preceding Statements 168-181, wherein the implant is delivered to the implant pocket such that the entire tissue path between an incision on the subject's skin and the implant pocket is shielded from the tissue forming a dissection tunnel connecting the incision to the implant pocket.

[00345] Statement 183: The method according to any one of the preceding Statements 168-182, wherein the implant does not contact the tissue forming the dissection tunnel during

delivery to the implant pocket.

[00346] Statement 184: The method according to any one of the preceding Statements 168-182, wherein the implant shield substantially minimizes the contact of the implant with the tissue forming the dissection tunnel.

[00347] Statement 185: The method according to any one of the preceding Statements 168-184, wherein the inner bore of the shielding member forms a sterile path by which the implant may be inserted and delivered to the implant pocket.

[00348] Statement 186: The method according to any one of the preceding Statements 168-185, wherein the inner bore of the shielding member forms a sterile path, through which the implant may be delivered, from an incision in a skin of the patient to the implant pocket through a dissection tunnel connecting the incision to the implant pocket.

[00349] Statement 187: The method according to any one of the preceding Statements 168-186, further comprising: causing the lower surface of the base to disengage from the skin of subject; and removing the shielding member and implant shield from the subject.

[00350] Statement 188: The method according to any one of the preceding Statements 168-187, further comprising: closing the incision.

[00351] Statement 189: The method according to any one of the preceding Statements 168-188, further comprising: selecting a biofilm protection implant shield having an inner bore with a cross-sectional width greater than the diameter of the implant.

[00352] Statement 190: The method according to any one of the preceding Statements 168-189, further comprising: sterilizing the biofilm protection implant shield.

[00353] Statement 191: The method according to any one of the preceding Statements 168-190, further comprising: selecting a biofilm protection implant shield having a predetermined length of the inner bore of the shielding member sufficiently long that the shielding member is operable to shield the implant from the upper dissection tunnel and/or a substantial length of the dissection tunnel upon insertion of the implant into the inner bore of the shielding member and transit of the implant to the implant pocket in a subject.

[00354] Statement 192: The method according to Statement 191, wherein the substantial

length of the dissection tunnel corresponds to at least the entire portion of the dissection tunnel that comprises breast tissue.

[00355] Statement 193: The method according to any one of the preceding Statements 168-190, further comprising: selecting a biofilm protection implant shield having a predetermined length of the inner bore of the shielding member equal to or less than a length of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject.

[00356] Statement 194: The method according to any one of the preceding Statements 168-190, further comprising: selecting a biofilm protection implant shield having a predetermined length of the inner bore of the shielding member equal to or greater than a length of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject.

[00357] Statement 195: The method according to any one of the preceding Statements 168-190, further comprising: measuring a length of a dissection tunnel and/or upper dissection tunnel connecting the implant pocket to an incision on a skin of the subject; and adjusting the predetermined length of the inner bore of the shielding member such that it has a length equal to or less than the length of the dissection tunnel or upper dissection tunnel.

[00358] Statement 196: The method according to Statement 195, wherein adjusting the predetermined length comprises cutting the shielding member such that the predetermined length of the inner bore of the shielding member has a length equal to or less than the length of the dissection tunnel or upper dissection tunnel.

[00359] Statement 197: The method according to any one of the preceding Statements 168-190, further comprising: measuring a length of a dissection tunnel or upper dissection tunnel connecting the implant pocket to an incision on a skin of the subject; and adjusting the predetermined length of the inner bore of the shielding member such that it has a length equal to or greater than the length of the dissection tunnel or upper dissection tunnel.

[00360] Statement 198: The method according to Statement 197, wherein adjusting the predetermined length comprises cutting the shielding member such that the predetermined length of the inner bore of the shielding member has a length equal to or greater than the length of the dissection tunnel or upper dissection tunnel.

[00361] Statement 199: The method according to any one of the preceding Statements 168-

198, further comprising: creating an incision in the skin of the subject; and surgically-creating an implant pocket and a dissection tunnel connecting the incision to the surgically-created implant pocket.

[00362] Statement 200: The method according to any one of the preceding Statements 168-199, wherein delivering the implant to the implant pocket comprises: providing a conical sleeve having a an interior cavity, a first terminus, and a second terminus, wherein the first terminus has a larger diameter than the second terminus; placing the implant into the interior cavity of the conical sleeve; inserting the second terminus through the aperture of the base and into the inner bore of the shielding member such that the terminus of the conical sleeve is received in the implant shield proximal to the implant pocket; and applying pressure to the conical sleeve such that the implant exits the second terminus of the conical sleeve and is delivered to the implant pocket.

[00363] Statement 201: The method according to Statement 200, wherein the conical sleeve is a tapered sleeve.

[00364] Statement 202: The method according to any one of the preceding Statements 168-201, wherein the subject is a mammal.

[00365] Statement 203: The method according to any one of the preceding Statements 168-201, wherein the subject is a human.

[00366] Statement 204: The method according to any one of the preceding Statements 168-203, wherein the implant is selected from the group consisting of a breast implant, a pre-filled implant, a pre-filled saline breast implant, a pre-filled silicone breast implant, an un-filled breast implant, a saline breast implant, a silicone breast implant, a textured breast implant, a smooth breast implant, a highly cohesive silicone gel breast implant, an oil-filled breast implant, and an un-filled saline breast implant.

[00367] Statement 205: The method according to any one of the preceding Statements 168-204, wherein the incision is a periareolar incision.

[00368] Statement 206: The method according to any one of the preceding Statements 168-204, wherein the incision is an inframammary incision.

[00369] Statement 207: The method according to any one of the preceding Statements 168-204, wherein the incision is an axillary incision.

[00370] Statement 208: The method according to any one of the preceding Statements 168-204, wherein the incision is a transumbilical incision.

[00371] Statement 209: The method according to any one of the preceding Statements 168-204, wherein the incision is a vertical incision.

[00372] Statement 210: A method of preventing capsular contracture in a subject resulting from surgical insertion of a breast implant in a surgically created implant pocket through a dissection tunnel connecting the implant pocket to an incision on the skin of the patient, the method comprising: providing a sterile biofilm protection implant shield, the implant shield comprising: a base having an upper surface and a lower surface, the base further having an aperture formed therein and extending through the upper surface and the lower surface; and a shielding member coupled with the base, the shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length away from the lower surface of the base; wherein the proximal end of the shielding member is coupled with the base and the inner bore is substantially aligned with the aperture formed in the base; and wherein the inner bore is operable to receive the implant therethrough and has a substantially uniform cross-sectional width over the predetermined length; inserting the distal end of the tubular member of the implant shield through the incision in the skin of subject and into the dissection tunnel such that the distal end of the shielding member is received in at least a portion of the dissection tunnel or the implant pocket; causing the lower surface of the base to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket; and delivering the implant to the implant pocket by inserting the implant through the aperture of the base and through the inner bore and distal end of the shielding member to the implant pocket.

[00373] Statement 211: The method according to Statement 210, further comprising: opening the dissection tunnel using one or more retractors during inserting the shielding member of the implant shield into the implant pocket or a portion of a dissection tunnel.

[00374] Statement 212: The method according to Statement 210, wherein inserting the

shielding member of the implant shield into the implant pocket or a portion of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject comprises inserting the shielding member or a distal end thereof using forceps or a similar device.

[00375] Statement 213: The method according to Statement 210, further comprising: causing the lower surface of the base to engage the skin of the subject so as to resist movement of the base with respect to the skin when engaged with the skin.

[00376] Statement 214: The method according to Statement 213, wherein the base is frictionally engaged with the skin of the subject.

[00377] Statement 215: The method according to Statement 213, wherein the base is engaged with the skin of the subject by an adhesive disposed on the lower surface of the base.

[00378] Statement 216: The method according to Statement 215, further comprising: exposing the adhesive disposed on the lower surface of the base by removing a removable backing disposed on the lower surface of the base.

[00379] Statement 217: The method according to any one of the preceding Statements 210-216, further comprising: attaching the lower surface of the base to the skin of the subject so as to arrest movement of the base with respect to the skin during use.

[00380] Statement 218: The method according to any one of the preceding Statements 210-217, wherein the aperture substantially overlies at least a portion of the incision.

[00381] Statement 219: The method according to any one of the preceding Statements 210-218, further comprising: inserting the shielding member of the implant shield into the implant pocket or a portion of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject, such that the lower surface of the base substantially engages with at least a portion of the skin adjacent to the incision; and extending the shielding member of the implant shield through the full length of the dissection tunnel such that the distal end extends at least partially into the implant pocket.

[00382] Statement 220: The method according to Statement 219, wherein the shielding member of the implant shield is extended through the dissection tunnel using one or more retractors inserted through the aperture and into the inner bore of the shielding member.

[00383] Statement 221: The method according to Statement 219, wherein the shielding member of the implant shield is extended through the dissection tunnel using one or more retractors placed outside the aperture and between the shielding member and a tissue forming the dissection tunnel.

[00384] Statement 222: The method according to any one of the preceding Statements 219-221, wherein prior to delivering the implant to the implant pocket, the method further comprises: inserting one or more retractors through the aperture and into the inner bore of the shielding member so as to open the inner bore and dissection tunnel for implant insertion.

[00385] Statement 223: The method according to any one of the preceding Statements 210-222, wherein the implant is delivered to the implant pocket such that the entire tissue path between an incision on the subject's skin and the implant pocket is shielded from the tissue forming a dissection tunnel connecting the incision to the implant pocket.

[00386] Statement 224: The method according to any one of the preceding Statements 210-223, wherein the implant does not contact the tissue forming the dissection tunnel during delivery to the implant pocket.

[00387] Statement 225: The method according to any one of the preceding Statements 210-223, wherein the implant shield substantially minimizes the contact of the implant with the tissue forming the dissection tunnel.

[00388] Statement 226: The method according to any one of the preceding Statements 210-225, wherein the inner bore of the shielding member forms a sterile path by which the implant may be inserted and delivered to the implant pocket.

[00389] Statement 227: The method according to any one of the preceding Statements 210-226, wherein the inner bore of the shielding member forms a sterile path, through which the implant may be delivered, from an incision in a skin of the patient to the implant pocket through a dissection tunnel connecting the incision to the implant pocket.

[00390] Statement 228: The method according to any one of the preceding Statements 210-227, further comprising: causing the lower surface of the base to disengage from the skin of subject; and removing the shielding member and implant shield from the subject.

[00391] Statement 229: The method according to any one of the preceding Statements 210-228, further comprising: closing the incision.

[00392] Statement 230: The method according to any one of the preceding Statements 210-229, further comprising: selecting a biofilm protection implant shield having an inner bore with a cross-sectional width great than the diameter of the implant.

[00393] Statement 231: The method according to any one of the preceding Statements 210-230, further comprising: sterilizing the biofilm protection implant shield.

[00394] Statement 232: The method according to any one of the preceding Statements 210-230, further comprising: selecting a biofilm protection implant shield having a predetermined length of the inner bore of the shielding member sufficiently long that the shielding member is operable to shield the implant from the upper dissection tunnel and/or a substantial length of the dissection tunnel upon insertion of the implant into the inner bore of the shieldig member and transit of the implant to the implant pocket in a subject.

[00395] Statement 233: The method according to Statement 232, wherein the substantial length of the dissection tunnel corresponds to at least the entire portion of the dissection tunnel that comprises breast tissue.

[00396] Statement 234: The method according to any one of the preceding Statements 210-231, further comprising: selecting a biofilm protection implant shield having a predetermined length of the inner bore of the shielding member equal to or less than a length of a dissection tunnel or an upper dissection tunnel connecting the implant pocket to an incision on a skin of the subject.

[00397] Statement 235: The method according to any one of the preceding Statements 210-231, further comprising: selecting a biofilm protection implant shield having a predetermined length of the inner bore of the shielding member equal to or greater than a length of a dissection tunnel or an upper dissection tunnel connecting the implant pocket to an incision on a skin of the subject.

[00398] Statement 236: The method according to any one of the preceding Statements 210-231, further comprising: measuring a length of a dissection tunnel or upper dissection tunnel connecting the implant pocket to an incision on a skin of the subject; and adjusting the

predetermined length of the inner bore of the shielding member such that it has a length equal to or less than the length of the dissection tunnel or upper dissection tunnel.

[00399] Statement 237: The method according to Statement 236, wherein adjusting the predetermined length comprises cutting the shielding member such that the predetermined length of the inner bore of the shielding member has a length equal to or less than the length of the dissection tunnel or upper dissection tunnel.

[00400] Statement 238: The method according to any one of the preceding Statements 210-231, further comprising: measuring a length of a dissection tunnel or upper dissection tunnel connecting the implant pocket to an incision on a skin of the subject; and adjusting the predetermined length of the inner bore of the shielding member such that it has a length equal to or greater than the length of the dissection tunnel or upper dissection tunnel.

[00401] Statement 239: The method according to Statement 238, wherein adjusting the predetermined length comprises cutting the shielding member such that the predetermined length of the inner bore of the shielding member has a length equal to or greater than the length of the dissection tunnel or upper dissection tunnel.

[00402] Statement 240: The method according to any one of the preceding Statements 210-239, further comprising: creating an incision in the skin of the subject; and surgically-creating an implant pocket and a dissection tunnel connecting the incision to the surgically-created implant pocket.

[00403] Statement 241: The method according to any one of the preceding Statements 210-240, wherein delivering the implant to the implant pocket comprises: providing a conical sleeve having a an interior cavity, a first terminus, and a second terminus, wherein the first terminus has a larger diameter than the second terminus; placing the implant into the interior cavity of the conical sleeve; inserting the second terminus through the aperture of the base and into the inner bore of the shielding member such that the terminus of the conical sleeve is received in the implant shield proximal to the implant pocket; and applying pressure to the conical sleeve such that the implant exits the second terminus of the conical sleeve and is delivered to the implant pocket.

[00404] Statement 242: The method according to Statement 241, wherein the conical sleeve is

a tapered sleeve.

[00405] Statement 243: The method according to any one of the preceding Statements 210-242, wherein the subject is a mammal.

[00406] Statement 244: The method according to any one of the preceding Statements 210-242, wherein the subject is a human.

[00407] Statement 245: The method according to any one of the preceding Statements 210-244, wherein the implant is selected from the group consisting of a breast implant, a pre-filled breast implant, a pre-filled saline breast implant, a pre-filled silicone breast implant, an un-filled breast implant, a saline breast implant, a silicone breast implant, a textured breast implant, a smooth breast implant, a highly cohesive silicone gel breast implant, an oil-filled breast implant, and an un-filled saline breast implant.

[00408] Statement 246: The method according to any one of the preceding Statements 210-245, wherein the incision is a periareolar incision.

[00409] Statement 247: The method according to any one of the preceding Statements 210-245, wherein the incision is an inframammary incision.

[00410] Statement 248: The method according to any one of the preceding Statements 210-245, wherein the incision is an axillary incision.

[00411] Statement 249: The method according to any one of the preceding Statements 210-246, wherein the incision is a transumbilical incision.

[00412] Statement 250: The method according to any one of the preceding Statements 210-246, wherein the incision is a vertical incision.

[00413] Statement 251: The method according to any one of the preceding Statements 168-250, wherein the implant is selected from the group consisting of a filled implant or a pre-filled implant, an unfilled implant, a saline implant, a silicone gel implant, a textured implant, a smooth implant, a highly cohesive silicone gel implant, an oil-filled implant, a pacemaker, a joint replacement prosthesis, an allograft, an autograft, and a prosthesis implant.

[00414] Statement 252: The method according to any one of the preceding Statements 168-251, wherein the implant is an unfilled implant and the implant has a cross-sectional width

smaller than the cross-sectional width of the tubular member of the implant shield.

[00415] Statement 253: The method according to any one of the preceding Statements 168-251, wherein the implant has a cross-sectional width smaller than the cross-sectional width of the tubular member of the implant shield due to the deformation forces during insertion of the implant into the aperture and inner bore of the implant shield.

[00416] Statement 254: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted greater than 1.5 cm below the incision.

[00417] Statement 255: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted greater than 2 cm below the incision.

[00418] Statement 256: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted greater than 2.5 cm below the incision.

[00419] Statement 257: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted greater than 3 cm below the incision.

[00420] Statement 258: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted greater than 3.5 cm below the incision.

[00421] Statement 259: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted greater than 4.5 cm below the incision.

[00422] Statement 260: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted greater than 5 cm below the incision.

[00423] Statement 261: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted into the dissection tunnel to a

depth of from about 2 cm to about 10 cm below the incision.

[00424] Statement 262: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted into the dissection tunnel to a depth of from about 2 cm to about 5 cm below the incision.

[00425] Statement 263: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted into the dissection tunnel to a depth of from about 3 cm to about 8 cm below the incision.

[00426] Statement 264: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted such that at least 1.5 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00427] Statement 265: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted such that at least 2 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00428] Statement 266: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted such that at least 2.5 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00429] Statement 267: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted such that at least 3 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00430] Statement 268: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted such that at least 3.5 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00431] Statement 269: The method according to any one of the preceding Statements 168-

253, wherein the distal end of the shielding member is inserted such that at least 4 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00432] Statement 270: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted such that at least 4.5 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00433] Statement 271: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted such that at least 5 cm of the length of the dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00434] Statement 272: The method according to any one of the preceding Statements 168-253, wherein the distal end of the shielding member is inserted into the dissection tunnel such that the entire upper dissection tunnel is shielded from the implant during insertion of the implant into the implant pocket.

[00435] Statement 273: An apparatus for inserting an implant into a surgically-created implant pocket in a subject through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject, the apparatus comprising: a shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length; and an implant receiving member having an inner bore extending longitudinally between a proximal end and a distal end, the implant receiving member operable to receive the implant; wherein the distal end of the implant receiving member is coupled with the proximal end of the shielding member such that the inner bore of the implant receiving member is substantially aligned with the inner bore of the shielding member so that the implant may pass through the inner bore of the implant receiving member to the inner bore of the shielding member once the implant is received at the proximal end of the implant receiving member.

[00436] Statement 274: The apparatus according to Statement 273, wherein the implant receiving member is conical.

[00437] Statement 275: The apparatus according to Statement 273, wherein the inner bore of the implant receiving member is conical.

[00438] Statement 276: The apparatus according to any one of the preceding Statements 273-275, wherein the inner bore of the implant receiving member comprises a cross-sectional width at the proximal end of the implant receiving member that is larger than the cross-sectional width of the inner bore at the distal end of the implant receiving member.

[00439] Statement 277: The apparatus according to any one of the preceding Statements 273-276, wherein the shielding member is tubular.

[00440] Statement 278: The apparatus according to any one of the preceding Statements 273-277, wherein the inner bore of the shielding member has a substantially uniform cross-sectional width over the predetermined length.

[00441] Statement 279: The apparatus according to any one of the preceding Statements 273-278, wherein the implant receiving member comprises an outer surface and an inner surface, wherein the inner surface of the implant receiving member defines the inner bore of the implant receiving member.

[00442] Statement 280: The apparatus according to any one of the preceding Statements 273-279, wherein the shielding member comprises an outer surface and an inner surface, wherein the inner surface of the shielding member defines the inner bore of the shielding member.

[00443] Statement 281: The apparatus according to any one of the preceding Statements 273-280, wherein the implant receiving member comprises an aperture at the proximal end of the implant receiving member, the aperture operable to receive the implant into the inner bore of the implant receiving member.

[00444] Statement 282: The apparatus according to any one of the preceding Statements 273-281, wherein the implant receiving member is operable to shield the implant from the skin of the patient during insertion of the implant into the proximal end of the implant shielding member.

[00445] Statement 283: The apparatus according to any one of the preceding Statements 273-282, wherein the shielding member is operable to shield the implant from at least a portion of a dissection tunnel connecting an incision on a skin of the subject and the implant pocket.

[00446] Statement 284: The apparatus according to any one of the preceding Statements 273-283, wherein the implant receiving member is operable to mechanically propel the implant through the inner bore of the shielding member and out the distal end of the shielding member.

[00447] Statement 285: The apparatus according to any one of the preceding Statements 273-284, further comprising a base that extends radially from one of the shielding member or the implant receiving member, wherein the base comprises an upper surface and a lower surface, the lower surface being operable to engage a skin of the subject.

[00448] Statement 286: The apparatus according to any one of the preceding Statements 273-284, further comprising a base that extends radially from an intersection of the shielding member and the implant receiving member, wherein the base comprises an upper surface and a lower surface, the lower surface being operable to engage a skin of the subject.

[00449] Statement 287: The apparatus according to Statement 285 or Statement 286, wherein the base is integrally formed with the implant receiving member and the shielding member.

[00450] Statement 288: The apparatus according to any one of the preceding Statements 285-287, wherein the lower surface of the base is operable to engage a skin of the subject so that the distal end of the shielding member remains secured and disposed in a portion of a dissection tunnel connecting the implant pocket to an incision in the skin of the subject during insertion of the implant into the implant pocket.

[00451] Statement 289: The apparatus according to any one of the preceding Statements 285-288, wherein the distal end of the implant receiving member is coupled with the upper surface of the base and the lower surface of the base is coupled with the proximal end of the shielding member such that the lower surface of the base is operable to be engaged with the skin of a subject when the distal end of the shielding member is inserted into an incision and dissection tunnel of the subject.

[00452] Statement 290: The apparatus according to any one of the preceding Statements 273-289, wherein the shielding member and the implant receiving member are formed from a flexible material.

[00453] Statement 291: The apparatus according to Statement 290, wherein the flexible material is selected from the group consisting of plastic-containing fabrics, polymers, plastics,

mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[00454] Statement 292: The apparatus according to any one of the preceding Statements 285-291, wherein the shielding member, the base, and the implant receiving member are formed from a flexible material.

[00455] Statement 293: The apparatus according to Statement 292, wherein the flexible material is selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[00456] Statement 294: The apparatus according to any one of the preceding Statements 273-293, wherein the predetermined length is greater than 1 cm.

[00457] Statement 295: The apparatus according to any one of the preceding Statements 273-294, wherein the predetermined length is from about 2 cm to about 10 cm.

[00458] Statement 296: A method for inserting an implant into a surgically-created implant pocket in a subject through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject, the method comprising: providing a sterile biofilm protection implant shield, the implant shield comprising: a base having an upper surface and a lower surface, the base further having an aperture formed therein and extending through the upper surface and the lower surface; and a shielding member coupled with the base, the shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length away from the lower surface of the base; wherein the proximal end of the shielding member is coupled with the base and the inner bore is substantially aligned with the aperture formed in the base; and wherein the inner bore is operable to receive the implant therethrough; inserting the distal end of the shielding member of the implant shield through the incision in the skin of subject and into the dissection tunnel such that the distal end of the shielding member is received in at least a portion of the dissection tunnel; causing the lower surface of the base to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket; and delivering the implant to the implant pocket by inserting the implant through the aperture of the base and through the inner bore and distal end of

the shielding member to the implant pocket.

[00459] Statement 297: The method according to Statement 296, further comprising: inserting the shielding member of the implant shield into a portion of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject, such that the lower surface of the base substantially engages with at least a portion of the skin adjacent to the incision; and inserting the distal end of the shielding member into the dissection tunnel at least 1.5 cm below the incision.

[00460] Statement 298: The method according to Statement 296 or Statement 297, further comprising: measuring a length of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject; and adjusting the predetermined length of the inner bore of the shielding member such that it is greater than 1 cm but equal to or less than the measured length of the dissection tunnel.

[00461] Statement 299: The method according to any one of the preceding Statements 296-298, wherein delivering the implant to the implant pocket comprises: providing a conical sleeve having a an interior cavity, a first terminus, and a second terminus, wherein the first terminus has a larger diameter than the second terminus; placing the implant into the interior cavity of the conical sleeve; inserting the second terminus through the aperture of the base and into the inner bore of the shielding member such that the terminus of the conical sleeve is received in the implant shield proximal to the implant pocket; and applying pressure to the conical sleeve such that the implant exits the second terminus of the conical sleeve and is delivered to the implant pocket.

[00462] Statement 300: A method for inserting an implant into a surgically-created implant pocket in a subject through a dissection tunnel connecting the implant pocket to an incision on the skin of the subject, the method comprising: providing a sterile biofilm protection implant shield, the implant shield comprising: a shielding member having an inner bore extending longitudinally between a proximal end and a distal end, the inner bore extending a predetermined length; and an implant receiving member having an inner bore extending longitudinally between a proximal end and a distal end, the implant receiving member operable to receive the implant; wherein the distal end of the implant receiving member is coupled with the proximal end of the shielding member such that the inner bore of the implant receiving member is substantially aligned with the inner bore of the shielding member so that the implant may pass through the

inner bore of the implant receiving member to the inner bore of the shielding member once the implant is received at the proximal end of the implant receiving member; inserting the distal end of the shielding member of the implant shield through the incision in the skin of subject and into the dissection tunnel such that the distal end of the shielding member is received in at least a portion of the dissection tunnel; causing the lower surface of the base to substantially engage with at least a portion of the skin adjacent to an incision leading to the implant pocket; and delivering the implant to the implant pocket by inserting the implant into the inner bore of the implant receiving member and through the inner bore and distal end of the shielding member to the implant pocket.

[00463] Statement 301: The method according to Statement 300, wherein the implant receiving member is conical.

[00464] Statement 302: The method according to Statement 300, wherein the inner bore of the implant receiving member is conical.

[00465] Statement 303: The method according to Statement 300, wherein the inner bore of the implant receiving member is conical.

[00466] Statement 304: The method according to any one of the preceding Statements 300-303, wherein the inner bore of the implant receiving member comprises a cross-sectional width at the proximal end of the implant receiving member that is larger than the cross-sectional width of the inner bore at the distal end of the implant receiving member.

[00467] Statement 305: The method according to any one of the preceding Statements 300-304, wherein the shielding member is tubular.

[00468] Statement 306: The method according to any one of the preceding Statements 300-305, wherein the inner bore of the shielding member has a substantially uniform cross-sectional width over the predetermined length.

[00469] Statement 307: The method according to any one of the preceding Statements 300-306, wherein the implant receiving member comprises an outer surface and an inner surface, wherein the inner surface of the implant receiving member defines the inner bore of the implant receiving member.

[00470] Statement 308: The method according to any one of the preceding Statements 300-307, wherein the shielding member comprises an outer surface and an inner surface, wherein the inner surface of the shielding member defines the inner bore of the shielding member.

[00471] Statement 309: The method according to any one of the preceding Statements 300-308, wherein the implant receiving member comprises an aperture at the proximal end of the implant receiving member, the aperture operable to receive the implant into the inner bore of the implant receiving member.

[00472] Statement 310: The method according to any one of the preceding Statements 300-309, wherein the implant receiving member is operable to shield the implant from the skin of the patient during insertion of the implant into the proximal end of the implant shielding member.

[00473] Statement 311: The method according to any one of the preceding Statements 300-310, wherein the shielding member is operable to shield the implant from at least a portion of a dissection tunnel connecting an incision on a skin of the subject and the implant pocket.

[00474] Statement 312: The method according to any one of the preceding Statements 300-311, wherein the implant receiving member is operable to mechanically propel the implant through the inner bore of the shielding member and out the distal end of the shielding member.

[00475] Statement 313: The method according to any one of the preceding Statements 300-312, further comprising a base that extends radially from one of the shielding member or the implant receiving member, wherein the base comprises an upper surface and a lower surface, the lower surface being operable to engage a skin of the subject.

[00476] Statement 314: The method according to any one of the preceding Statements 300-312, further comprising a base that extends radially from an intersection of the shielding member and the implant receiving member, wherein the base comprises an upper surface and a lower surface, the lower surface being operable to engage a skin of the subject.

[00477] Statement 315: The method according to Statement 313 or Statement 314, wherein the base is integrally formed with the implant receiving member and the shielding member.

[00478] Statement 316: The method according to any one of the preceding Statements 313-315, wherein the lower surface of the base is operable to engage a skin of the subject so that the

distal end of the shielding member remains secured and disposed in a portion of a dissection tunnel connecting the implant pocket to an incision in the skin of the subject during insertion of the implant into the implant pocket.

[00479] Statement 317: The method according to any one of the preceding Statements 313-316, wherein the distal end of the implant receiving member is coupled with the upper surface of the base and the lower surface of the base is coupled with the proximal end of the shielding member such that the lower surface of the base is operable to be engaged with the skin of a subject when the distal end of the shielding member is inserted into an incision and dissection tunnel of the subject.

[00480] Statement 318: The method according to any one of the preceding Statements 300-317, wherein the shielding member and the implant receiving member are formed from a flexible material.

[00481] Statement 319: The method according to Statement 318, wherein the flexible material is selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[00482] Statement 320: The method according to any one of the preceding Statements 313-319, wherein the shielding member, the base, and the implant receiving member are formed from a flexible material.

[00483] Statement 321: The method according to Statement 320, wherein the flexible material is selected from the group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

[00484] Statement 322: The method according to any one of the preceding Statements 300-321, wherein the predetermined length is greater than 1 cm.

[00485] Statement 323: The method according to any one of the preceding Statements 300-322, wherein the predetermined length is from about 2 cm to about 10 cm.

[00486] Statement 324: The method according to any one of the preceding Statements 300-

323, further comprising inserting the distal end of the shielding member into the dissection tunnel at least 1.5 cm below the incision.

[00487] Statement 325: The method according to any one of the preceding Statements 300-324, further comprising: measuring a length of a dissection tunnel connecting the implant pocket to an incision on a skin of the subject; and adjusting the predetermined length of the inner bore of the shielding member such that it is greater than 1 cm but equal to or less than the measured length of the dissection tunnel.

[00488] Statement 326: The method according to any one of the preceding Statements 168-272 and 296-325, wherein the base extends away from the shielding member in substantially the same plane as the aperture of the base.

[00489] Statement 327: The method according to any one of the preceding Statements 168-272, 296-325, and 326, wherein the cross-sectional width of the inner bore of the shielding member is from about 3 cm to about 12 cm.

[00490] Statement 328: The method according to any one of the preceding Statements 168-272, 296-325, and 326, wherein the cross-sectional width of the inner bore of the shielding member is from about 5 cm to about 8 cm.

[00491] Statement 329: The method according to any one of the preceding Statements 168-272, 296-325, and 326, wherein the cross-sectional width of the inner bore of the shielding member is from about 3.5 cm to about 9 cm.

[00492] Statement 330: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is at least three times greater than the cross-sectional width of the inner bore of the shielding member.

[00493] Statement 331: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is at least three times greater than the cross-sectional width of the aperture of the base.

[00494] Statement 332: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is at least three times greater than the cross-sectional width of the outer bore of the shielding member.

[00495] Statement 333: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is from about three (3) to five (5) times greater than the cross-sectional width of the inner bore of the shielding member.

[00496] Statement 334: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is from about three (3) to five (5) times greater than the cross-sectional width of the aperture of the base.

[00497] Statement 335: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is from about three (3) to five (5) times greater than the cross-sectional width of the outer bore of the shielding member.

[00498] Statement 336: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is from about 9 cm to about 60 cm.

[00499] Statement 337: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is from about 10.5 cm to about 45 cm.

[00500] Statement 338: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a diameter that is from about 15 cm to about 40 cm.

[00501] Statement 339: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length that is greater than or equal to the cross-sectional width of the inner bore of the shielding member.

[00502] Statement 340: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length that is greater than or equal to the cross-sectional width of the aperture of the base.

[00503] Statement 341: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length that is greater than or equal to the cross-sectional width of the outer bore of the shielding member.

[00504] Statement 342: The method according to any one of the preceding Statements 168-

272, 296-325, and 326-329, wherein the base comprises a radial length that from about one (1) to about two (2) times cross-sectional width of the inner bore of the shielding member.

[00505] Statement 343: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length that from about one (1) to about two (2) times the cross-sectional width of the aperture of the base.

[00506] Statement 344: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length that from about one (1) to about two (2) times the cross-sectional width of the outer bore of the shielding member.

[00507] Statement 345: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length from about 3 cm to about 12 cm.

[00508] Statement 346: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length from about 3 cm to about 18 cm.

[00509] Statement 347: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length from about 5 cm to about 8 cm.

[00510] Statement 348: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length from about 10 cm to about 16 cm.

[00511] Statement 349: The method according to any one of the preceding Statements 168-272, 296-325, and 326-329, wherein the base comprises a radial length from about 5 cm to about 16 cm.

[00512] Statement 350: The apparatus according to any one of the preceding Statements 1-158, 165, and 273-295, wherein the base extends away from the shielding member in substantially the same plane as the aperture of the base.

[00513] Statement 351: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350, wherein the cross-sectional width of the inner bore of the shielding

member is from about 3 cm to about 12 cm.

[00514] Statement 352: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350, wherein the cross-sectional width of the inner bore of the shielding member is from about 5 cm to about 8 cm.

[00515] Statement 353: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350, wherein the cross-sectional width of the inner bore of the shielding member is from about 3.5 cm to about 9 cm.

[00516] Statement 354: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is at least three times greater than the cross-sectional width of the inner bore of the shielding member.

[00517] Statement 355: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is at least three times greater than the cross-sectional width of the aperture of the base.

[00518] Statement 356: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is at least three times greater than the cross-sectional width of the outer bore of the shielding member.

[00519] Statement 357: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is from about three (3) to five (5) times greater than the cross-sectional width of the inner bore of the shielding member.

[00520] Statement 358: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is from about three (3) to five (5) times greater than the cross-sectional width of the aperture of the base.

[00521] Statement 359: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is from about three (3) to five (5) times greater than the cross-sectional width of the outer bore of the shielding member.

[00522] Statement 360: The apparatus according to any one of the preceding Statements 1-

158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is from about 9 cm to about 60 cm.

[00523] Statement 361: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is from about 10.5 cm to about 45 cm.

[00524] Statement 362: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a diameter that is from about 15 cm to about 40 cm.

[00525] Statement 363: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length that is greater than or equal to the cross-sectional width of the inner bore of the shielding member.

[00526] Statement 364: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length that is greater than or equal to the cross-sectional width of the aperture of the base.

[00527] Statement 365: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length that is greater than or equal to the cross-sectional width of the outer bore of the shielding member.

[00528] Statement 366: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length that from about one (1) to about two (2) times cross-sectional width of the inner bore of the shielding member.

[00529] Statement 367: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length that from about one (1) to about two (2) times the cross-sectional width of the aperture of the base.

[00530] Statement 368: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length that from about one (1) to about two (2) times the cross-sectional width of the outer bore of the shielding member.

[00531] Statement 369: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length from about 3 cm to

about 12 cm.

[00532] Statement 370: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length from about 3 cm to about 18 cm.

[00533] Statement 371: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length from about 5 cm to about 8 cm.

[00534] Statement 373: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length from about 10 cm to about 16 cm.

[00535] Statement 374: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-353, wherein the base comprises a radial length from about 5 cm to about 16 cm.

[00536] Statement 375: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member is stretchable.

[00537] Statement 376: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member comprises a stretchable material.

[00538] Statement 378: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member is elastic.

[00539] Statement 379: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member comprises an elastic material.

[00540] Statement 380: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member is extensible.

[00541] Statement 381: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member comprises an extensible material.

[00542] Statement 382: The method according to any one of the preceding Statements 168-272 and 296-349, wherein the shielding member is operable to stretch during insertion of the

implant into the inner bore of the shielding member.

[00543] Statement 383: The method according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member is stretchable.

[00544] Statement 384: The method according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member comprises a stretchable material.

[00545] Statement 385: The method according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member is elastic.

[00546] Statement 386: The method according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member comprises an elastic material.

[00547] Statement 387: The method according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member is extensible.

[00548] Statement 388: The method according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, wherein the shielding member comprises an extensible material.

[00549] Statement 389: The method according to any one of the preceding Statements 1-158, 165, 273-295, and 350-374, and 382-388, wherein the aperture of the base has a cross-sectional width that is substantially the same as the cross-sectional width of the proximal end of the inner bore of the tubular member.

[00550] Statement 390: The apparatus according to any one of the preceding Statements 1-158, 165, 273-295, and 350-381, wherein the aperture of the base has a cross-sectional width that is substantially the same as the cross-sectional width of the proximal end of the inner bore of the tubular member.

What is claimed is:

1. An apparatus for inserting a breast implant into a surgically-created implant pocket in a breast of a subject, the apparatus comprising:

a base having an upper surface and a lower surface, the base having an aperture formed therein and extending through the upper surface and the lower surface, wherein the aperture is operable to receive the breast implant therethrough; and

a tubular shielding member coupled with the base, the tubular shielding member having an inner bore extending longitudinally between a proximal end having a proximal opening and a distal end having a distal opening, the inner bore extending a predetermined length away from the lower surface of the base;

wherein the proximal end of the tubular shielding member is coupled with the lower surface of the base and the distal end of the tubular member extends a predetermined length away from the lower surface of the base;

wherein the inner bore of the tubular shielding member is aligned with the aperture formed in the base;

wherein the inner bore is operable to receive the breast implant therethrough and has a uniform cross-sectional width over the predetermined length;

wherein the upper surface of the base forms the proximal most end of the apparatus and the distal end of the tubular shielding member forms the distal most end of the apparatus; and

wherein the base comprises a diameter that is at least three times greater than a cross-sectional width of the inner bore of the tubular shielding member.

2. The apparatus according to claim 1, wherein the lower surface of the base is operable to frictionally engage a skin of the subject, wherein the frictional engagement resists movement of the base relative to the skin.

3. The apparatus according to claim 2, wherein an adhesive is disposed on the lower surface of the base.

4. The apparatus according to claim 1, wherein the tubular shielding member and base are formed from a flexible material.

5. The apparatus according to claim 4, wherein the flexible material is selected from a group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

6. The apparatus according to claim 1, wherein the predetermined length is determined based on a distance between an incision in the skin of the subject and a surgically-created implant pocket formed below the skin, and wherein the predetermined length is greater than 1 cm.

7. The apparatus according to claim 6, wherein the predetermined length is from about 2 cm to about 10 cm.

8. The apparatus according to claim 1, wherein the base extends away from the shielding member in the same plane as the aperture of the base.

9. An apparatus for shielding an implant from a dissection tunnel in a subject during insertion of the implant into a surgically-created implant pocket connected to an incision in the skin of the subject by the dissection tunnel, the apparatus comprising:

a base having an upper surface and a lower surface, the base having an aperture formed therein and extending through the upper surface and the lower surface, wherein the aperture is operable to receive the implant therethrough; and

a tubular shielding member coupled with the base, the tubular shielding member having an inner bore extending longitudinally between a proximal end having a proximal opening and a distal end having a distal opening, the inner bore extending a predetermined length away from the lower surface of the base;

wherein the proximal end of the tubular shielding member is coupled with the lower surface of the base and the distal end of the tubular shielding member extends a predetermined length away from the lower surface of the base, the distal end of the tubular member operable to be inserted into the dissection tunnel in the subject connecting the incision in the skin of the subject to the surgically-created implant pocket;

wherein the inner bore of the tubular shielding member is aligned with the aperture formed in the base;

wherein the inner bore is operable to receive the implant therethrough and has a uniform cross-sectional width over the predetermined length;

wherein the upper surface of the base forms the proximal most end of the apparatus and the distal end of the tubular member forms the distal most end of the apparatus; and

wherein the base comprises a diameter that is at least three times greater than a cross-sectional width of the inner bore of the tubular member.

10. The apparatus according to claim 9, wherein the tubular shielding member is operable to shield the implant from at least a portion of a dissection tunnel connecting an incision on a skin of the subject and the implant pocket.

11. The apparatus according to claim 9, wherein the lower surface of the base is operable to engage a skin of the subject so that the distal end of the tubular shielding member remains secured and disposed in a portion of a dissection tunnel connecting the implant pocket to an incision in the skin of the subject during insertion of the implant into the implant pocket.

12. The apparatus according to claim 9, wherein the distal end of the implant receiving member

is coupled with the upper surface of the base and the lower surface of the base is coupled with the proximal end of the shielding member such that the lower surface of the base is operable to be engaged with the skin of a subject when the distal end of the shielding member is inserted into an incision and dissection tunnel of the subject.

13. The apparatus according to claim 9, wherein the shielding member and base are formed from a flexible material.

14. The apparatus according to claim 13, wherein the flexible material is selected from a group consisting of plastic-containing fabrics, polymers, plastics, mylar, vinyls, polyvinyl chloride, ethylene and alpha-olefin copolymers, silicone, solid silicone, silicone rubber, and any combination thereof.

15. The apparatus according to claim 9, wherein the predetermined length is greater than 1 cm.

16. The apparatus according to claim 9, wherein the predetermined length is from about 2 cm to about 10 cm.

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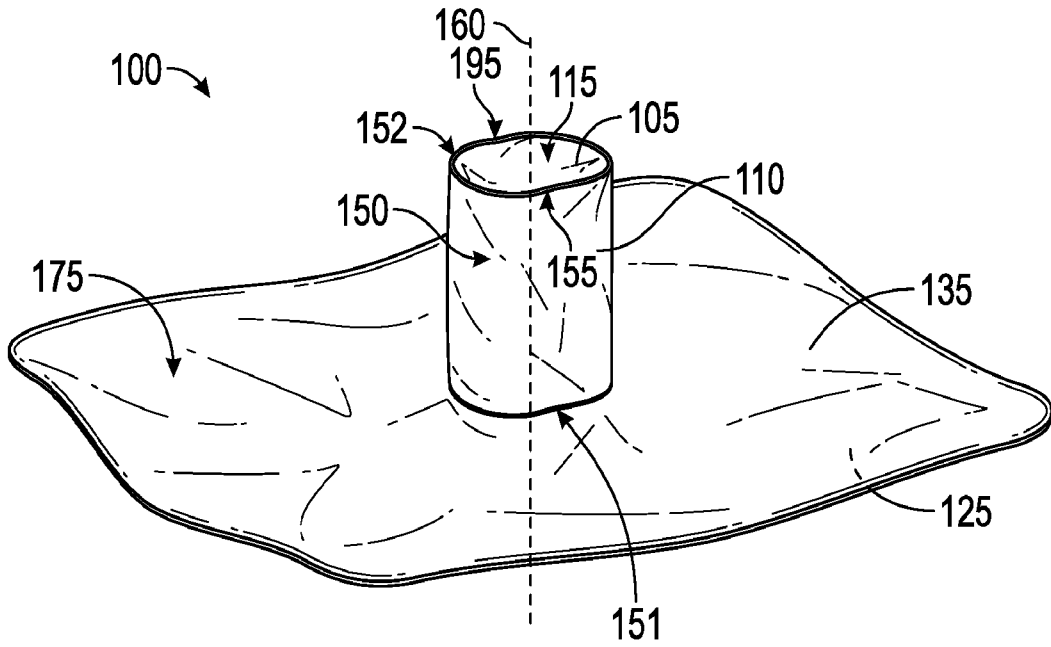


FIG. 1

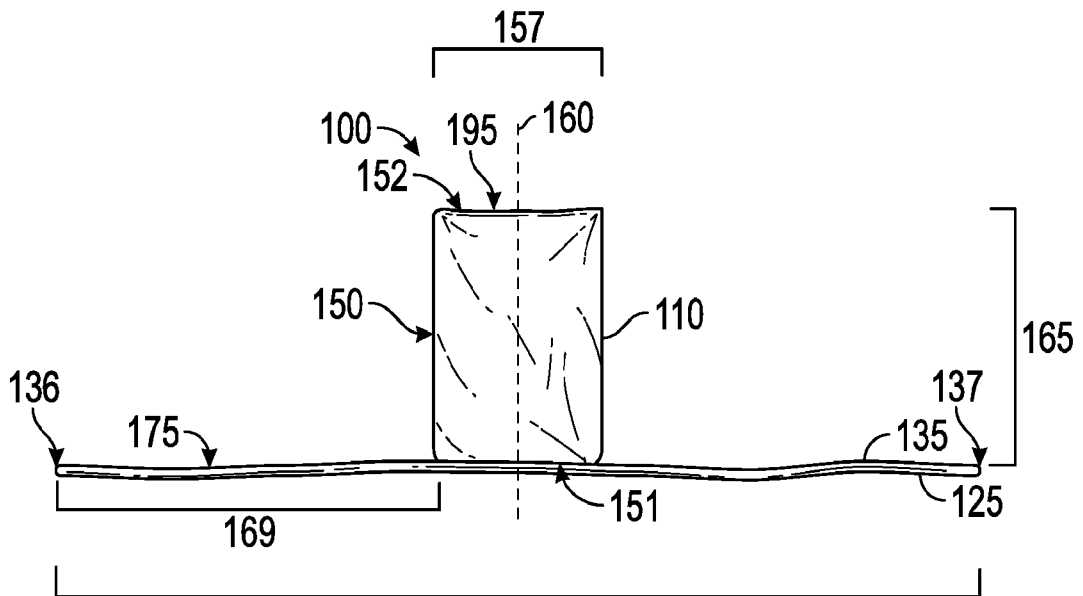


FIG. 2

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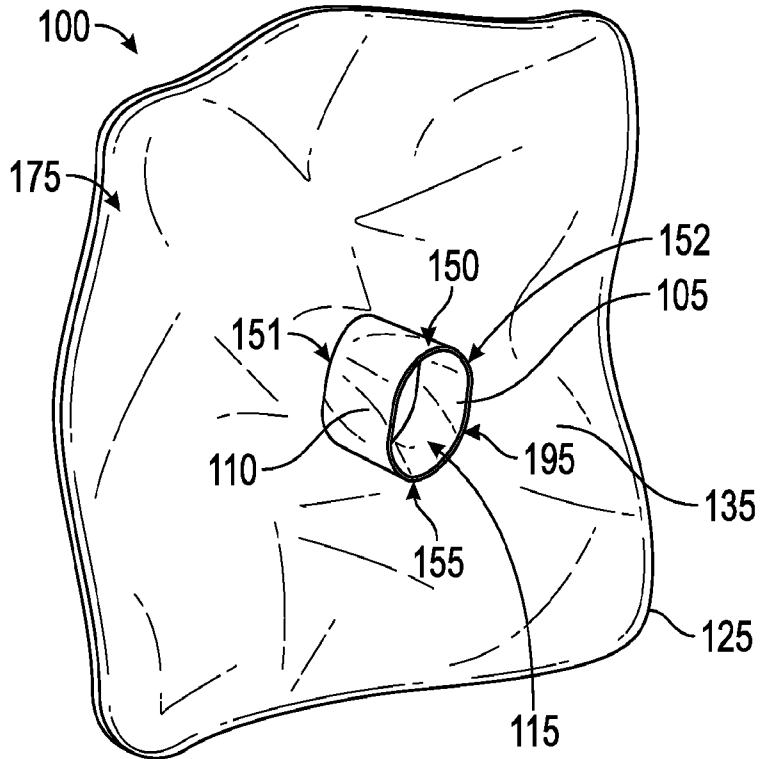


FIG. 3

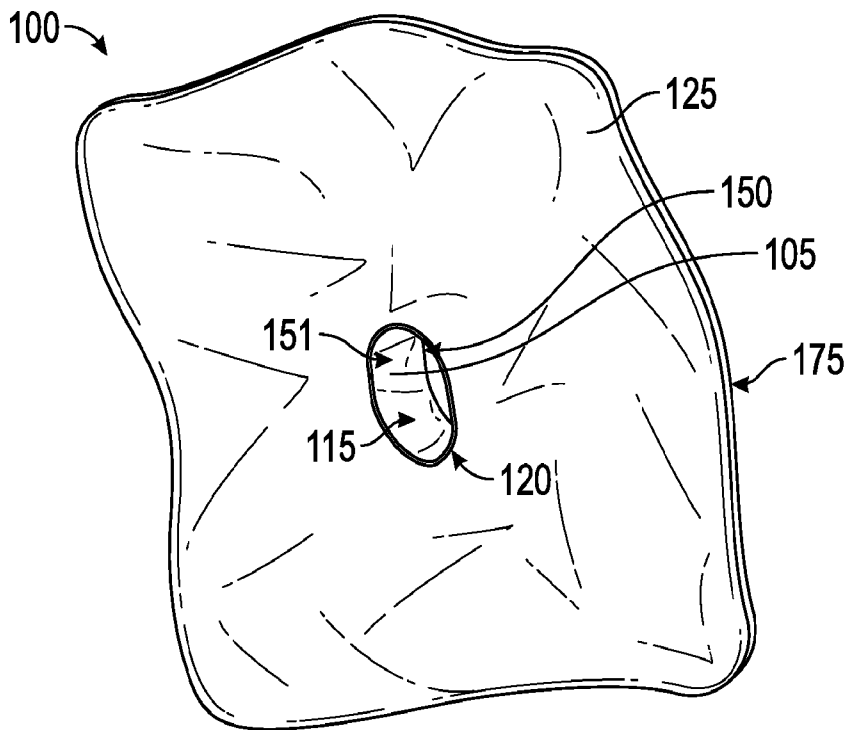


FIG. 4

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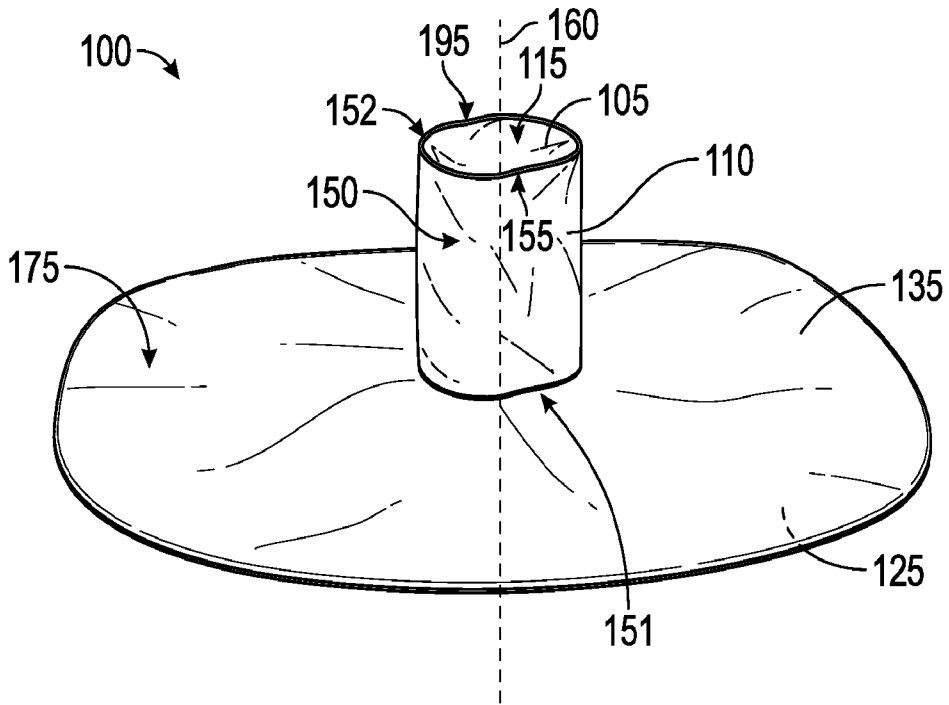


FIG. 5

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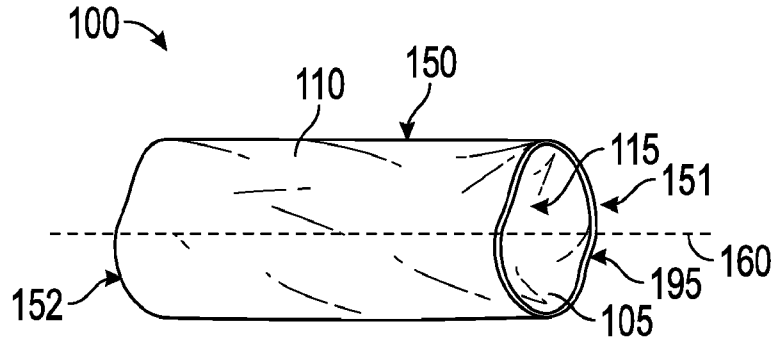


FIG. 6A

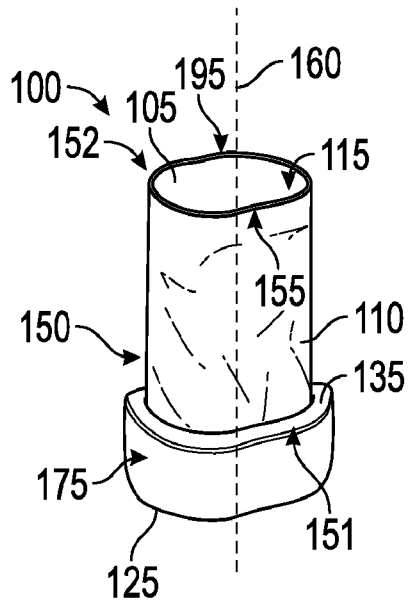


FIG. 6B

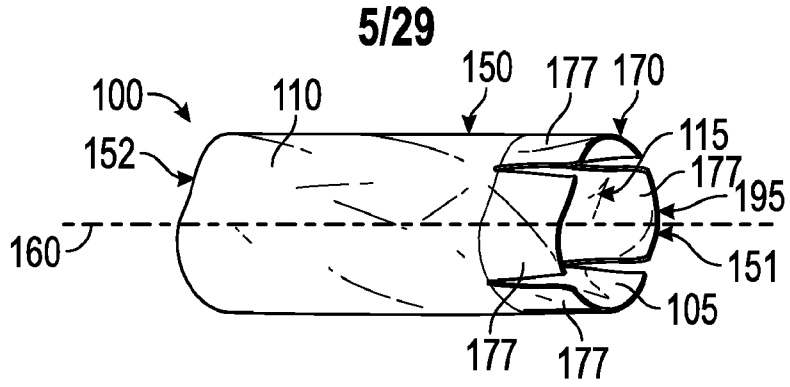


FIG. 7A

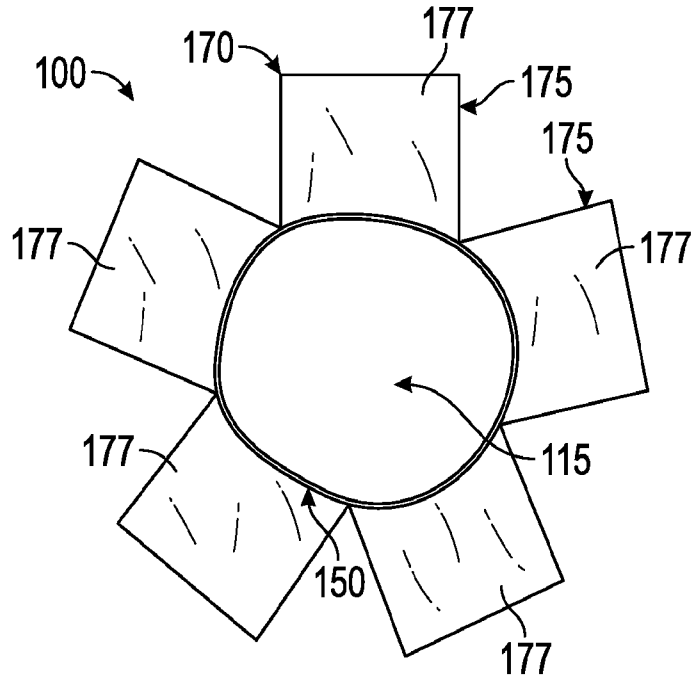


FIG. 7B

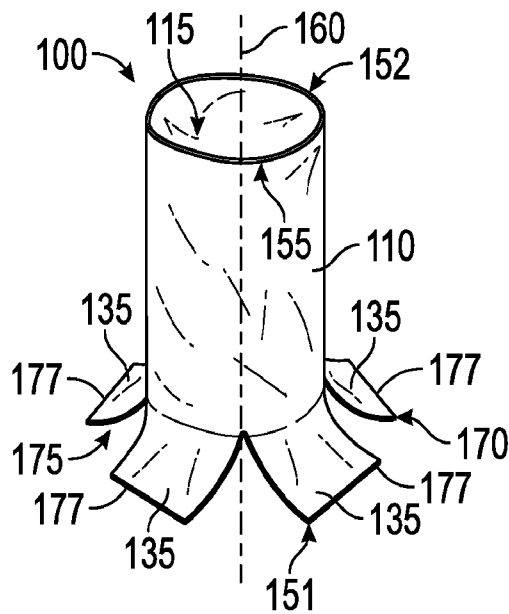


FIG. 7C

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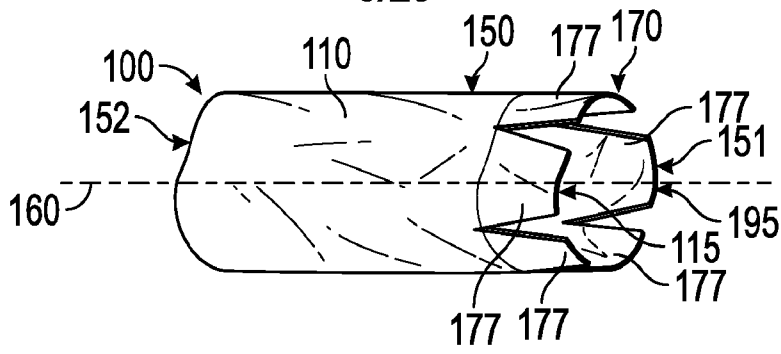


FIG. 8A

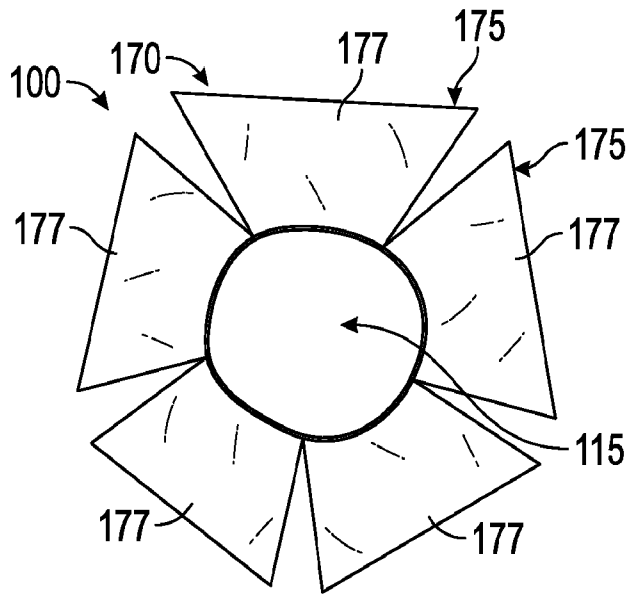


FIG. 8B

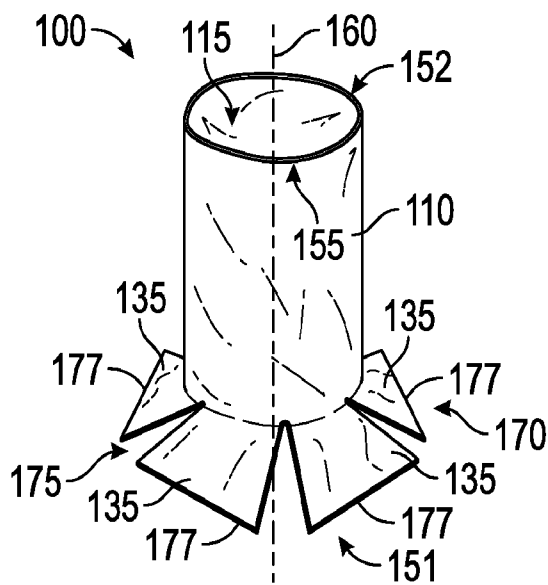


FIG. 8C

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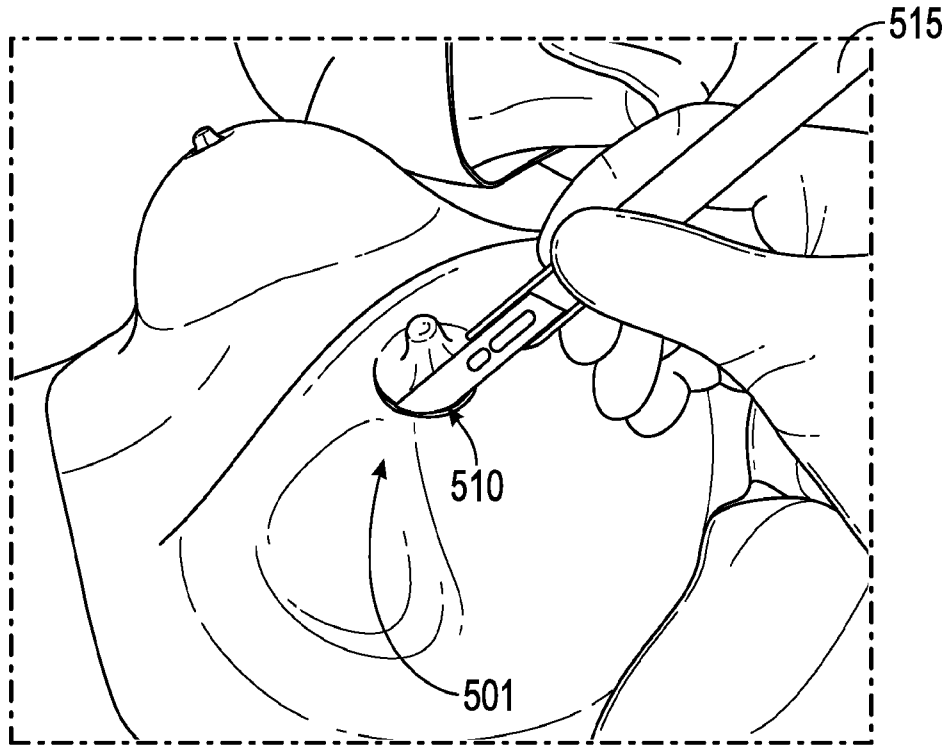


FIG. 9

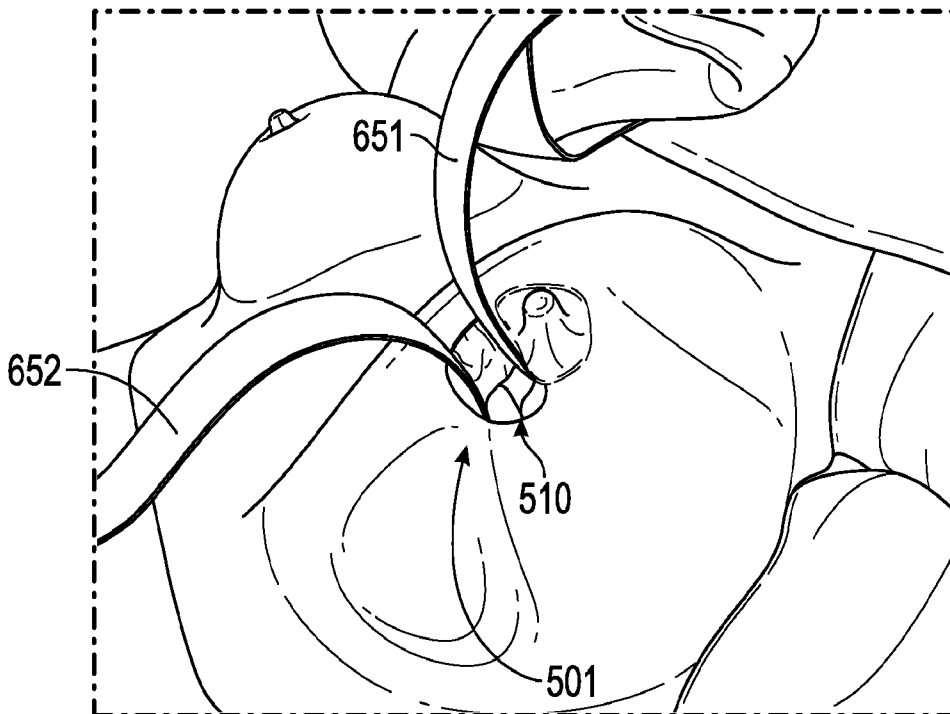


FIG. 10

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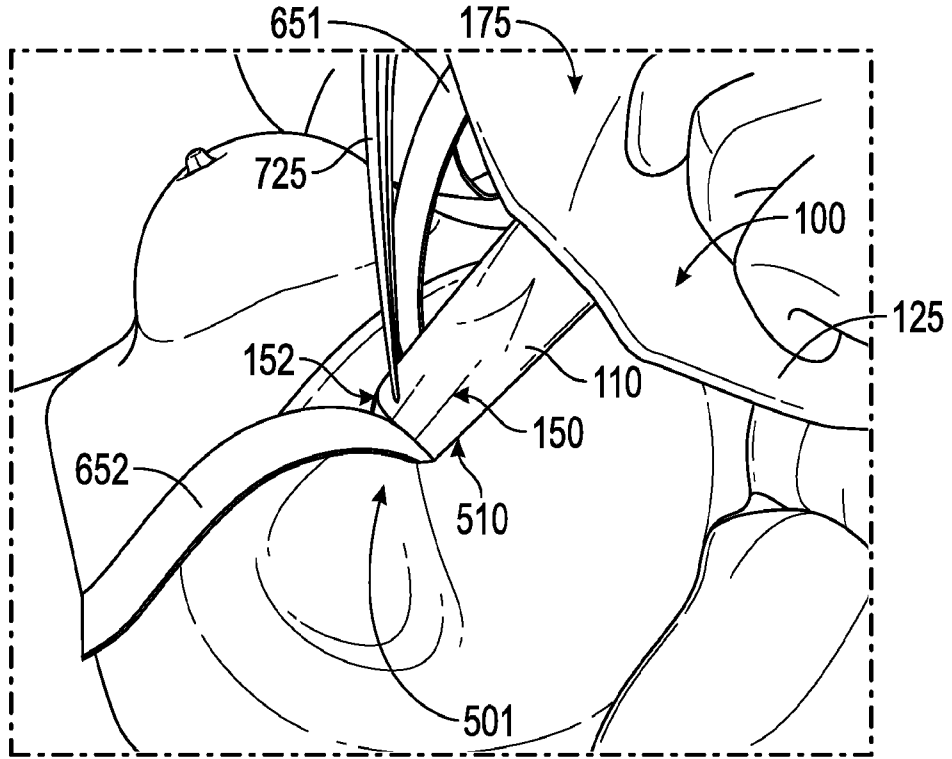


FIG. 11

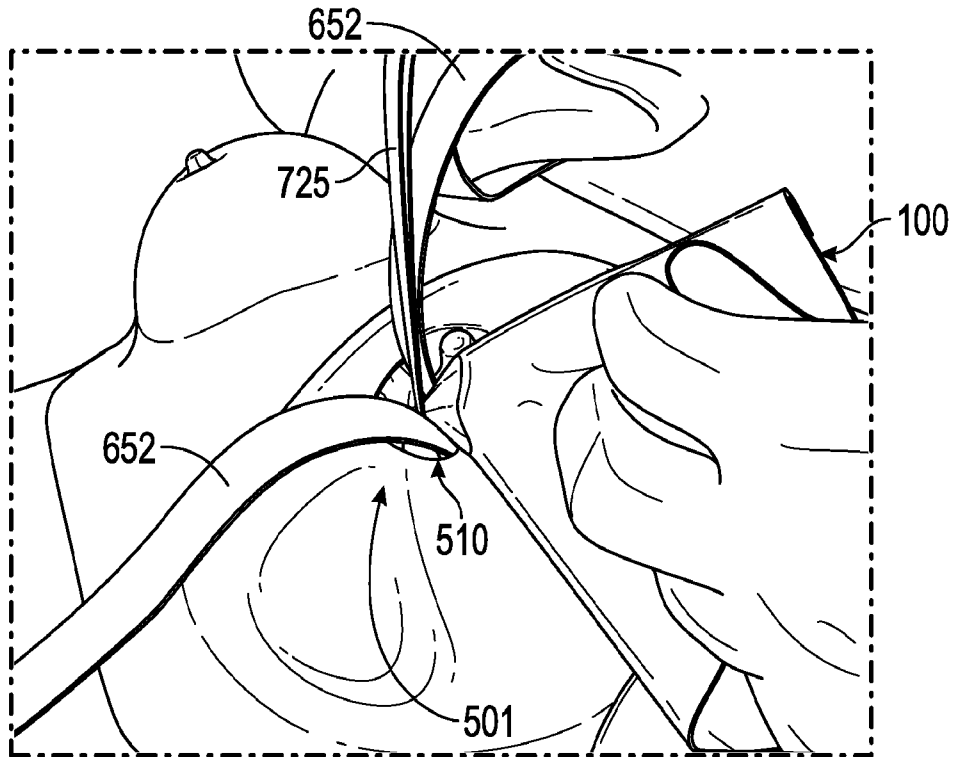


FIG. 12

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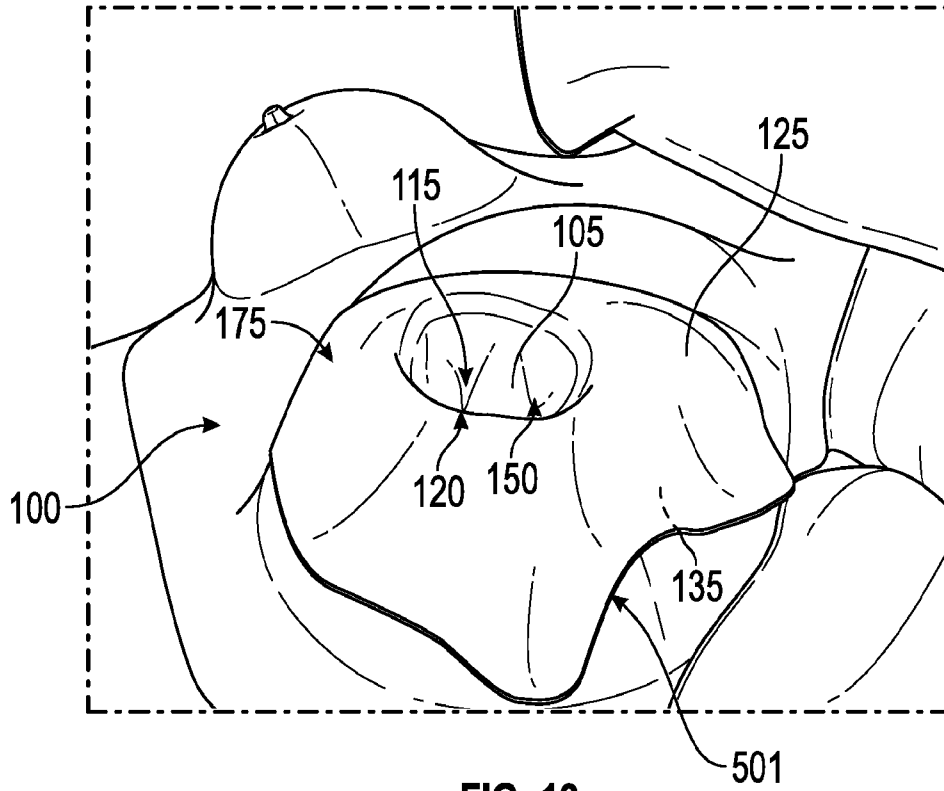


FIG. 13

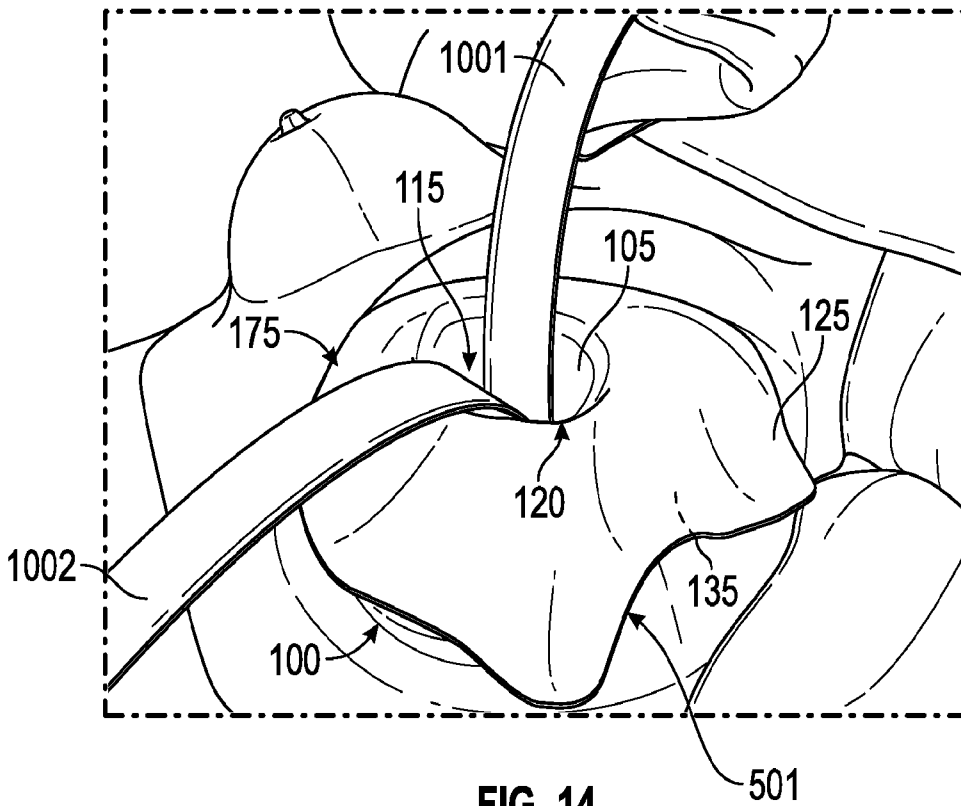


FIG. 14

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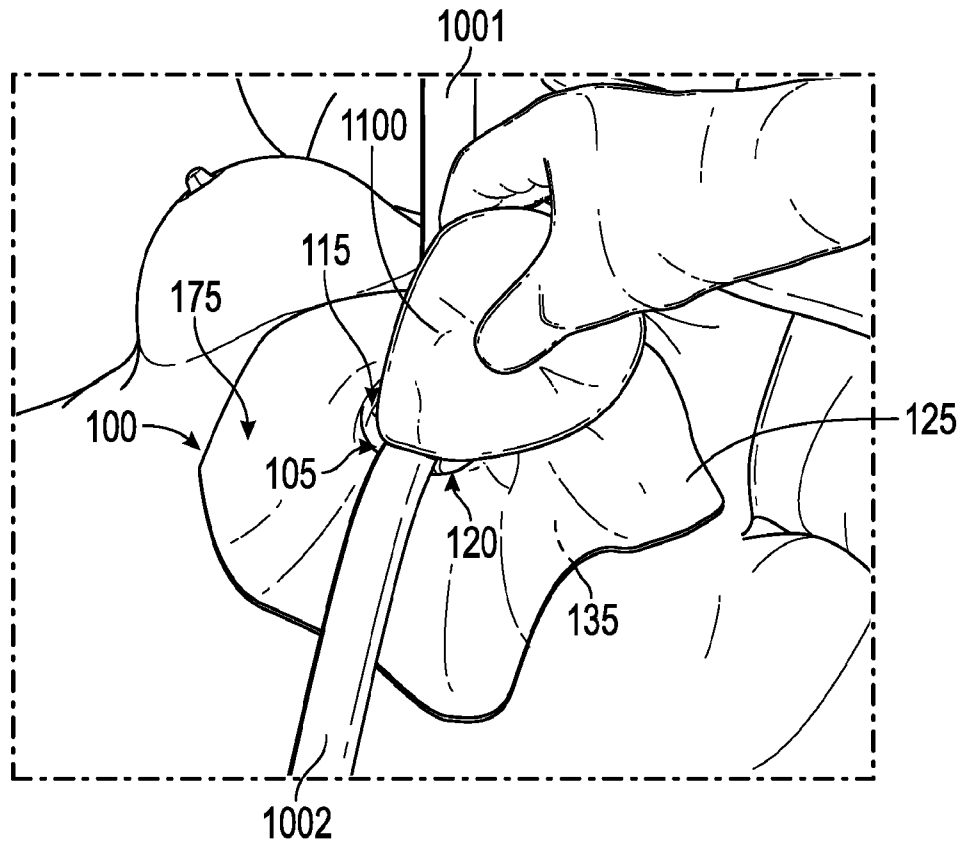


FIG. 15A

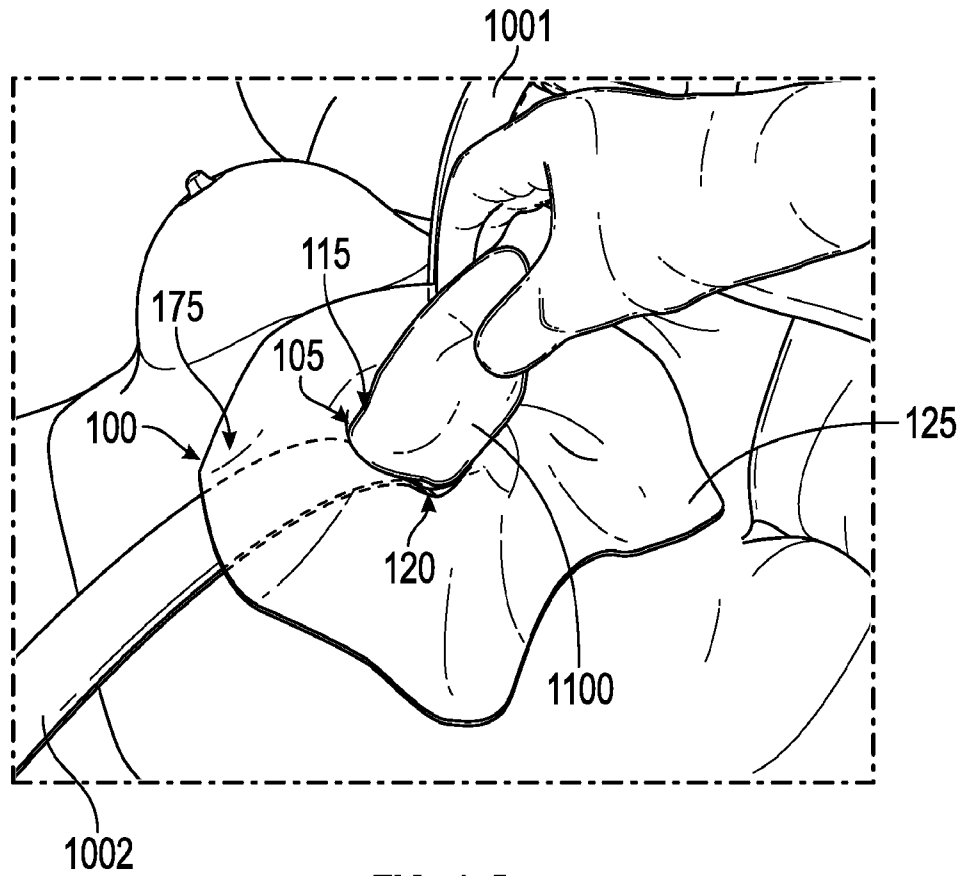


FIG. 15B

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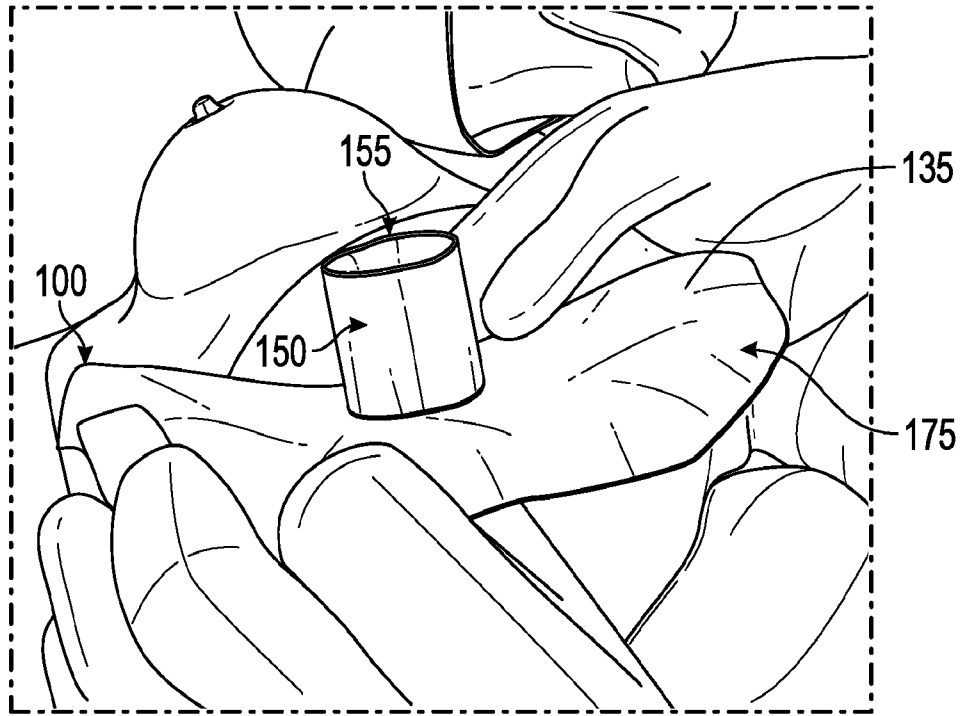


FIG. 16

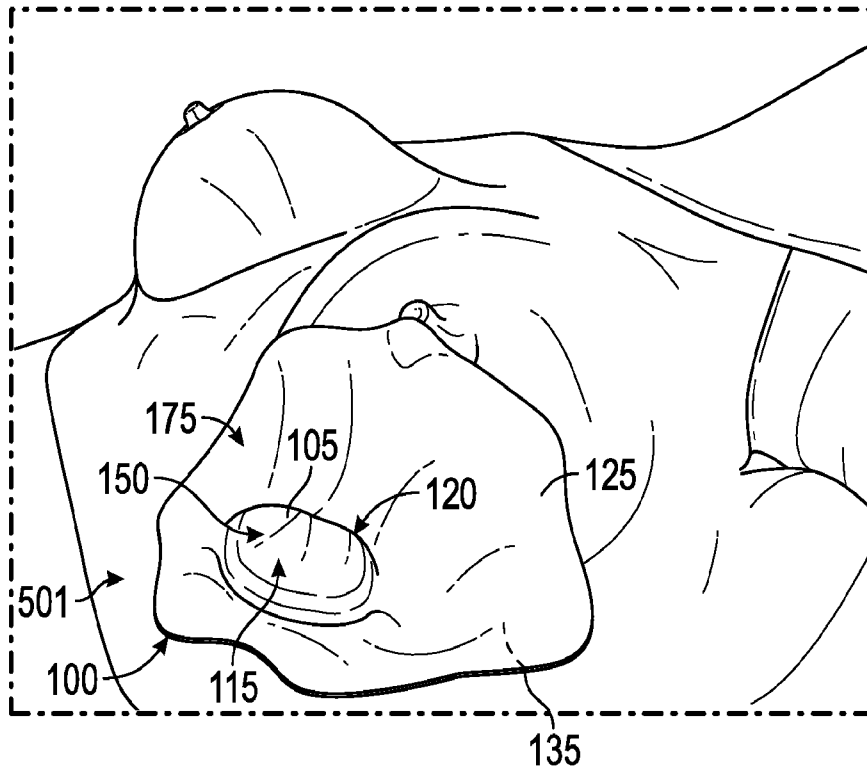


FIG. 17

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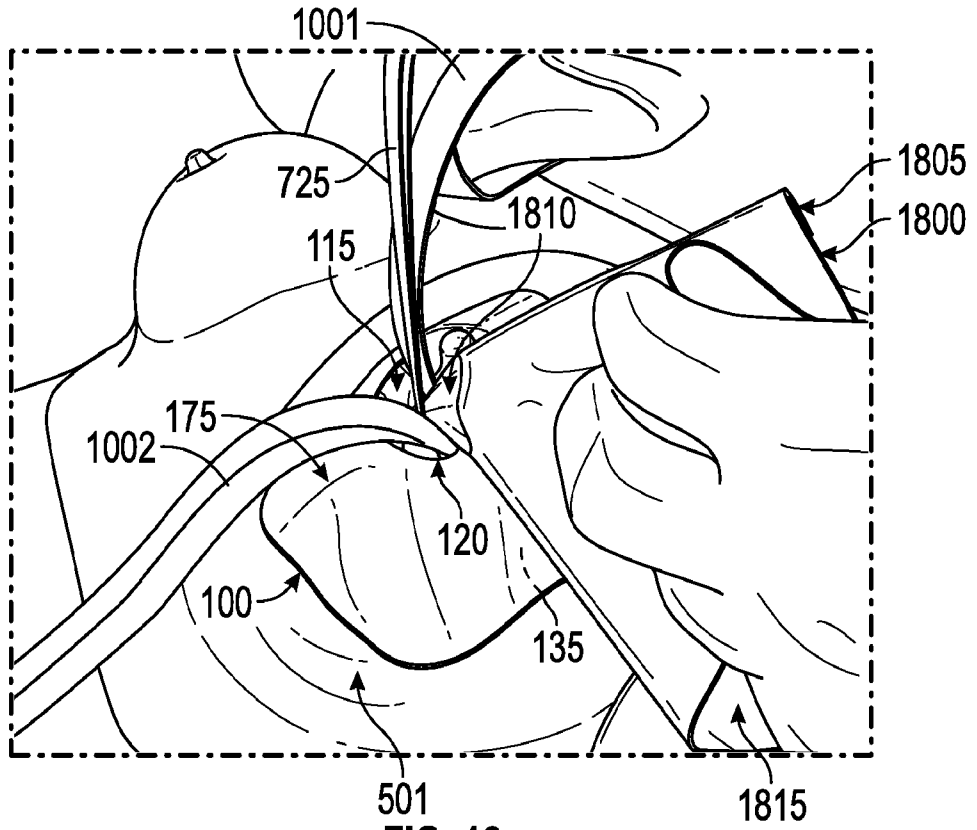


FIG. 18

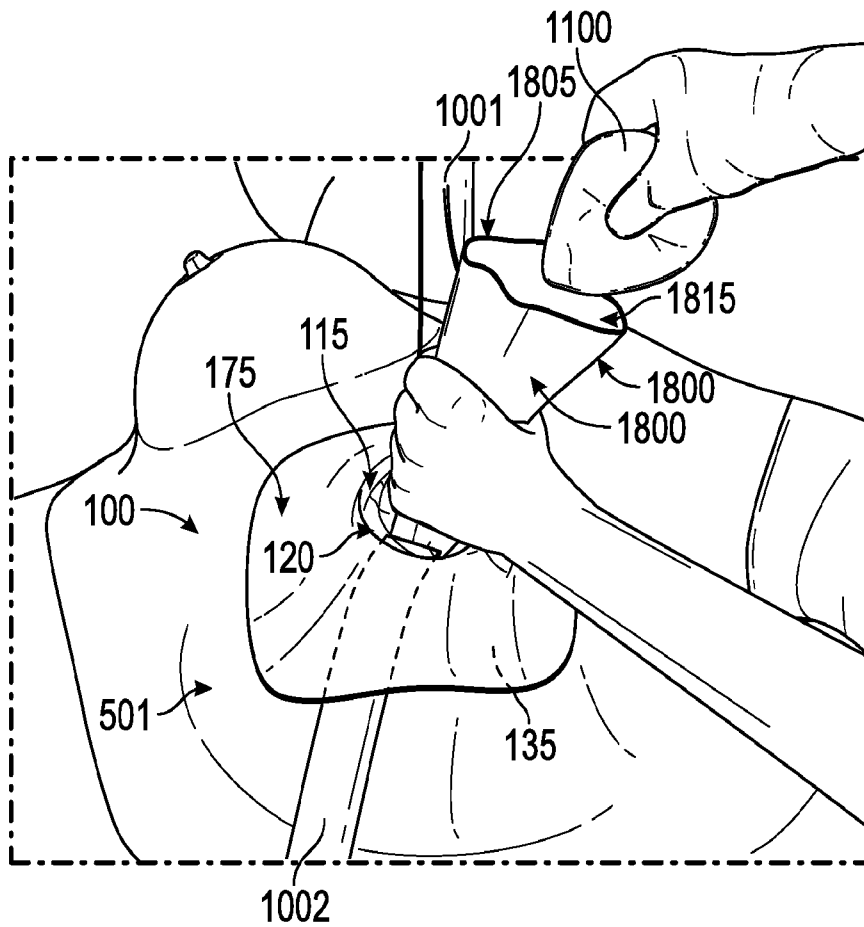


FIG. 19

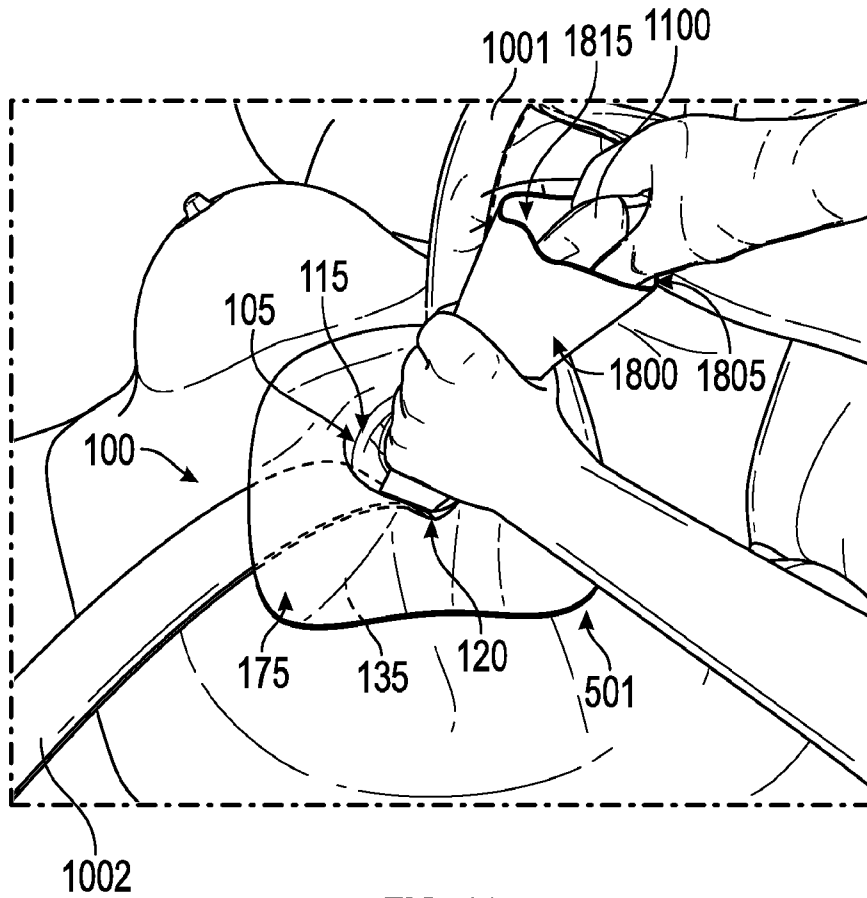


FIG. 20

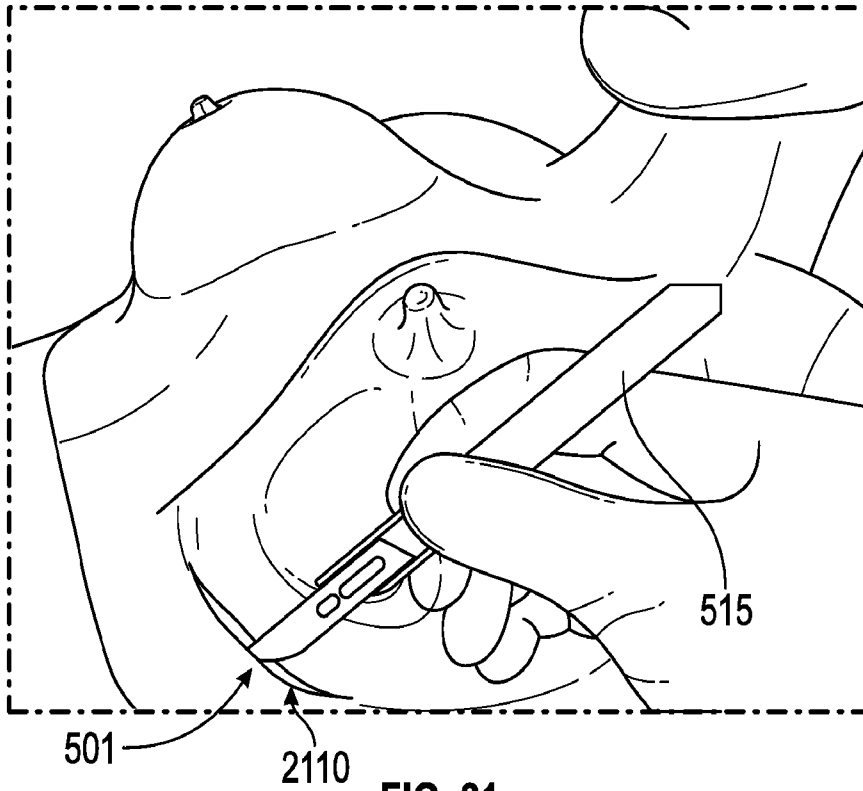


FIG. 21

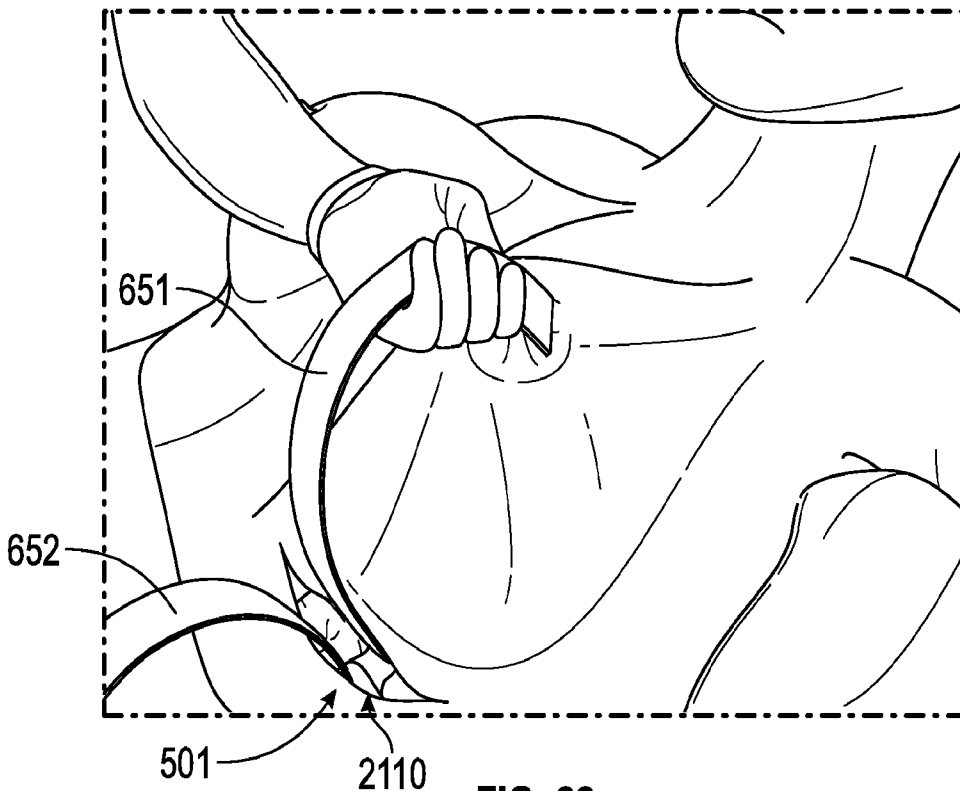


FIG. 22

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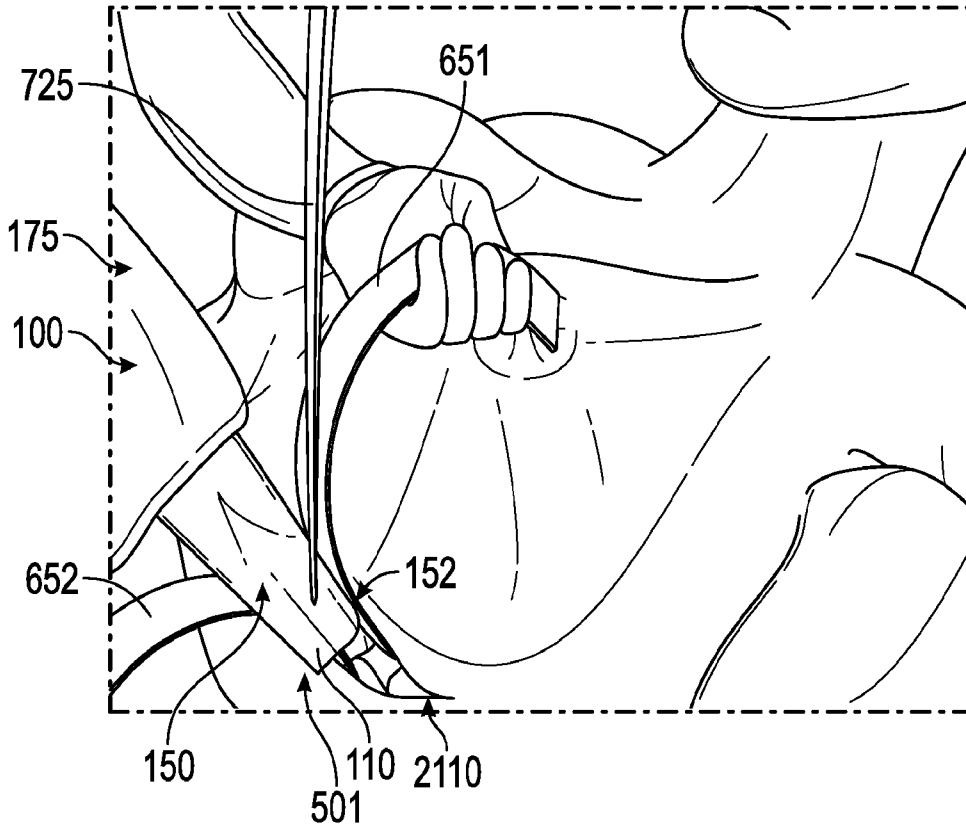


FIG. 23

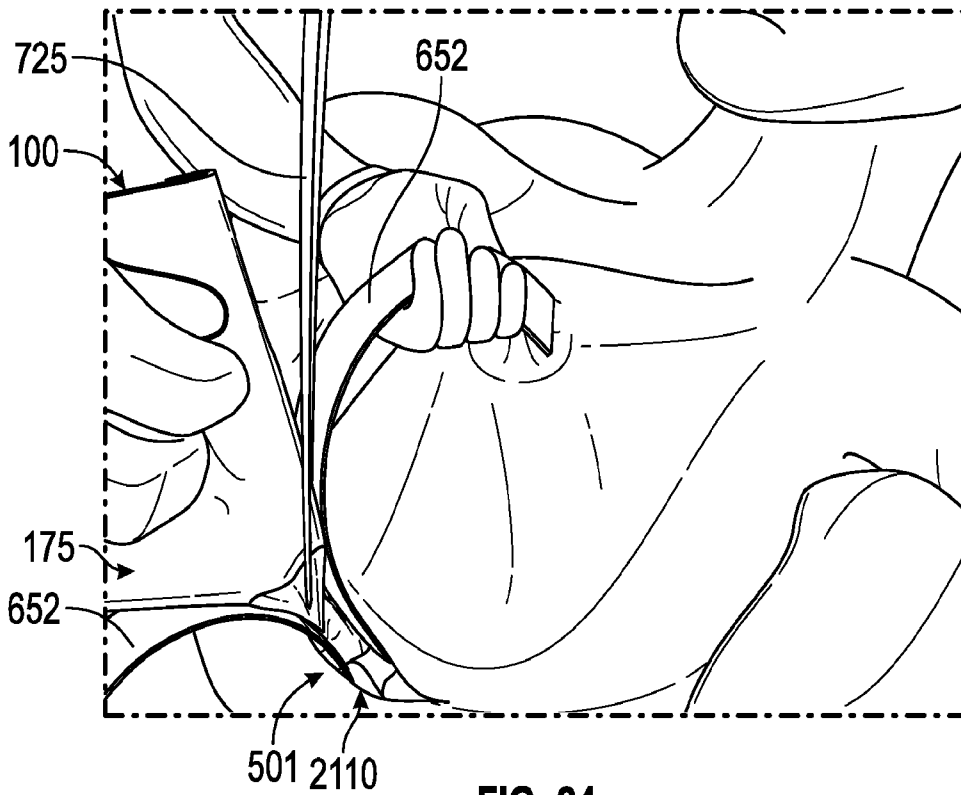


FIG. 24

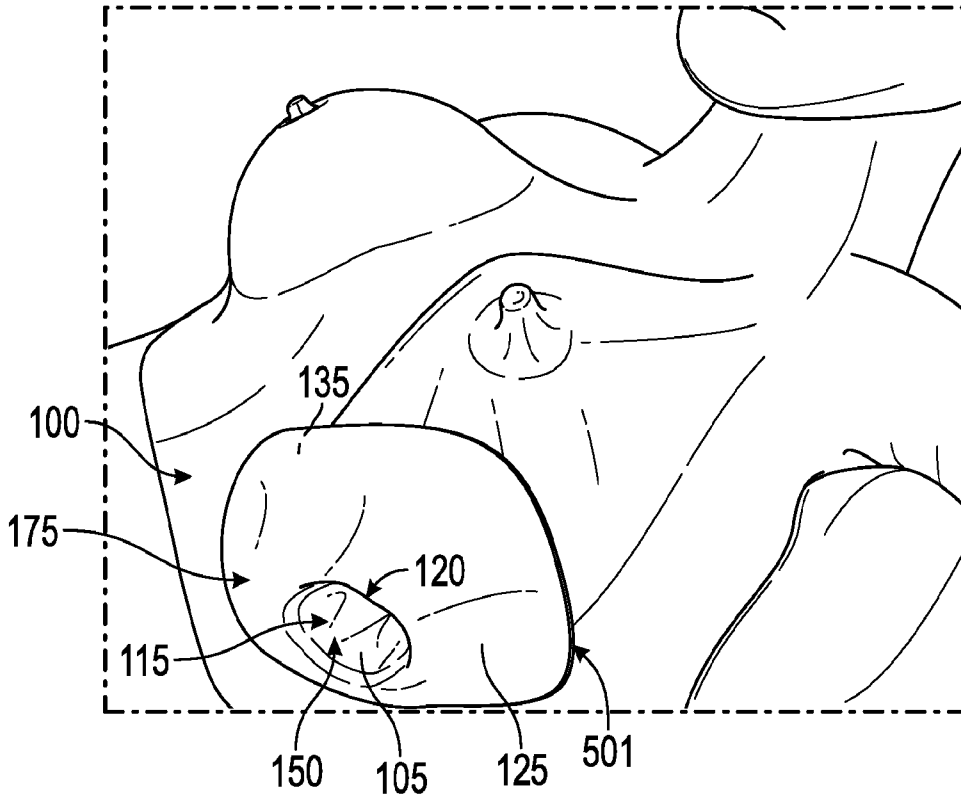


FIG. 25

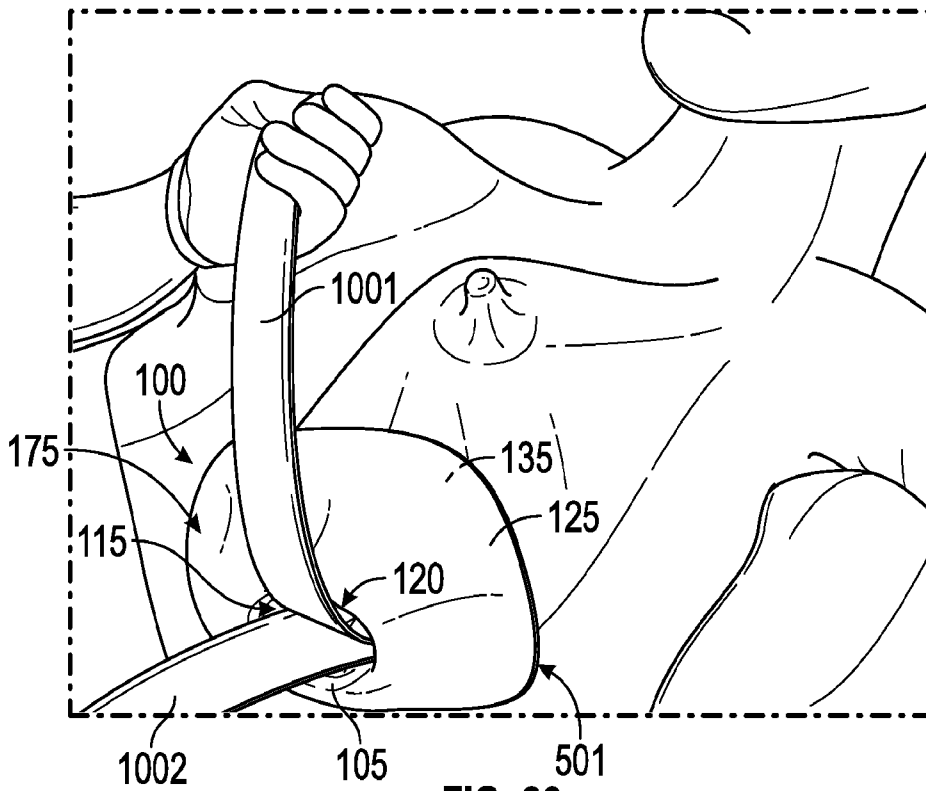


FIG. 26

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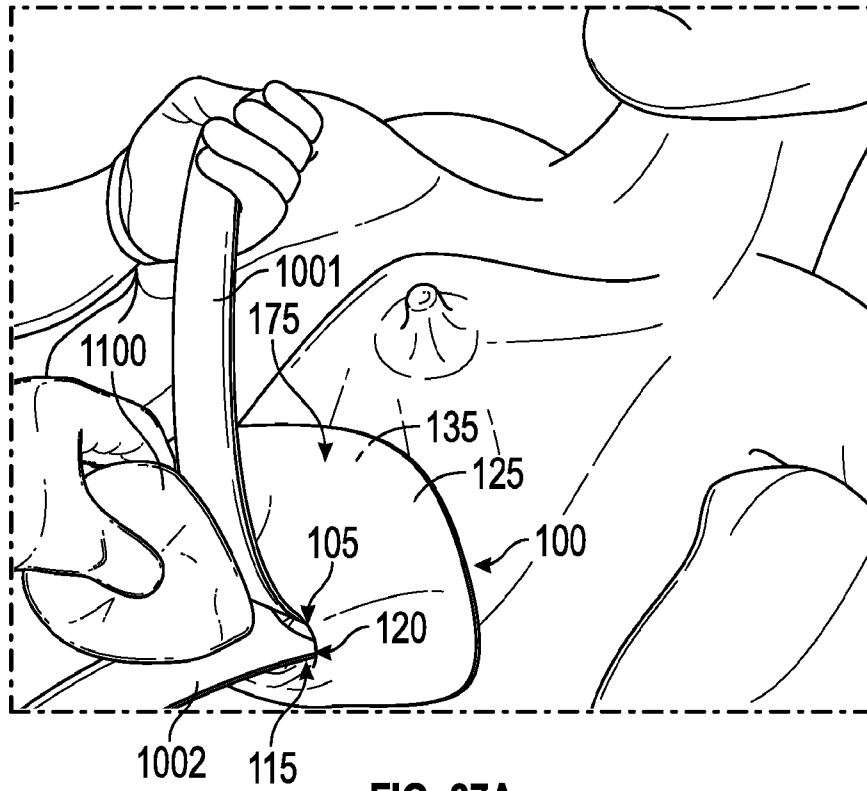


FIG. 27A

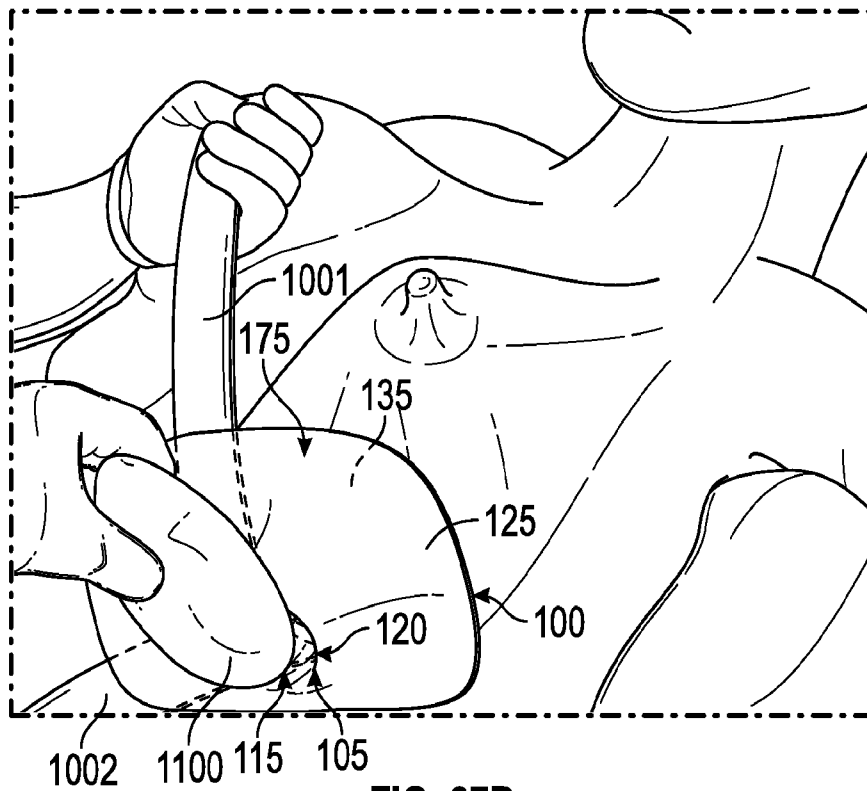


FIG. 27B

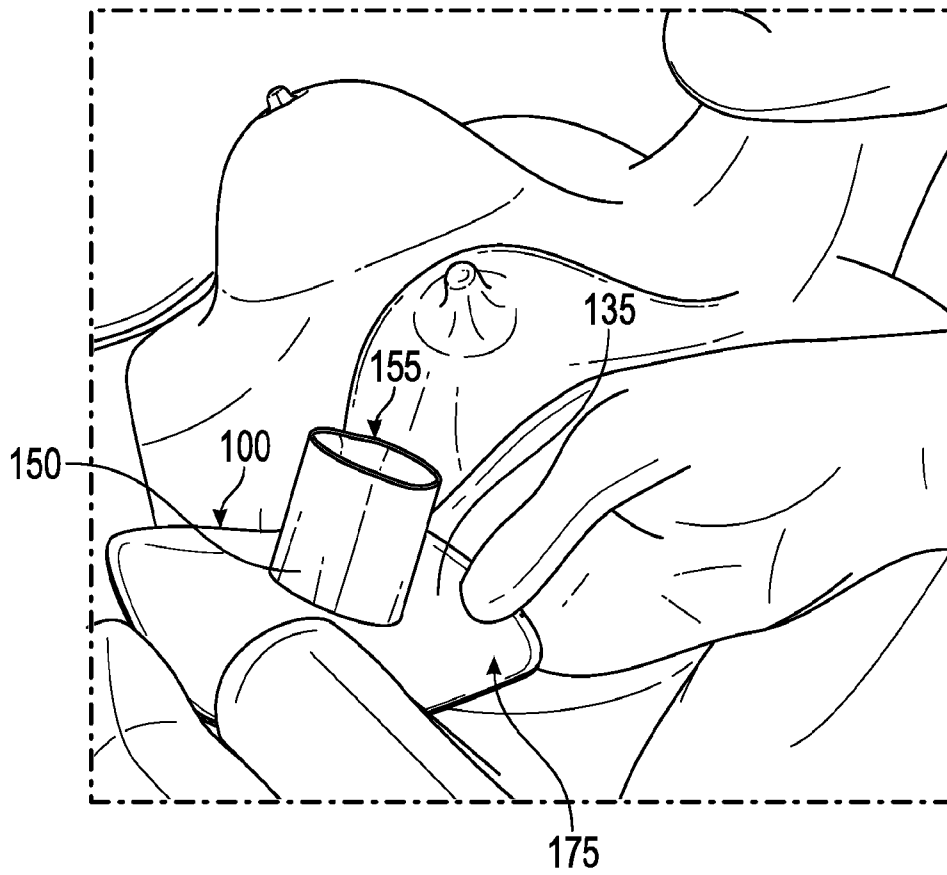


FIG. 28



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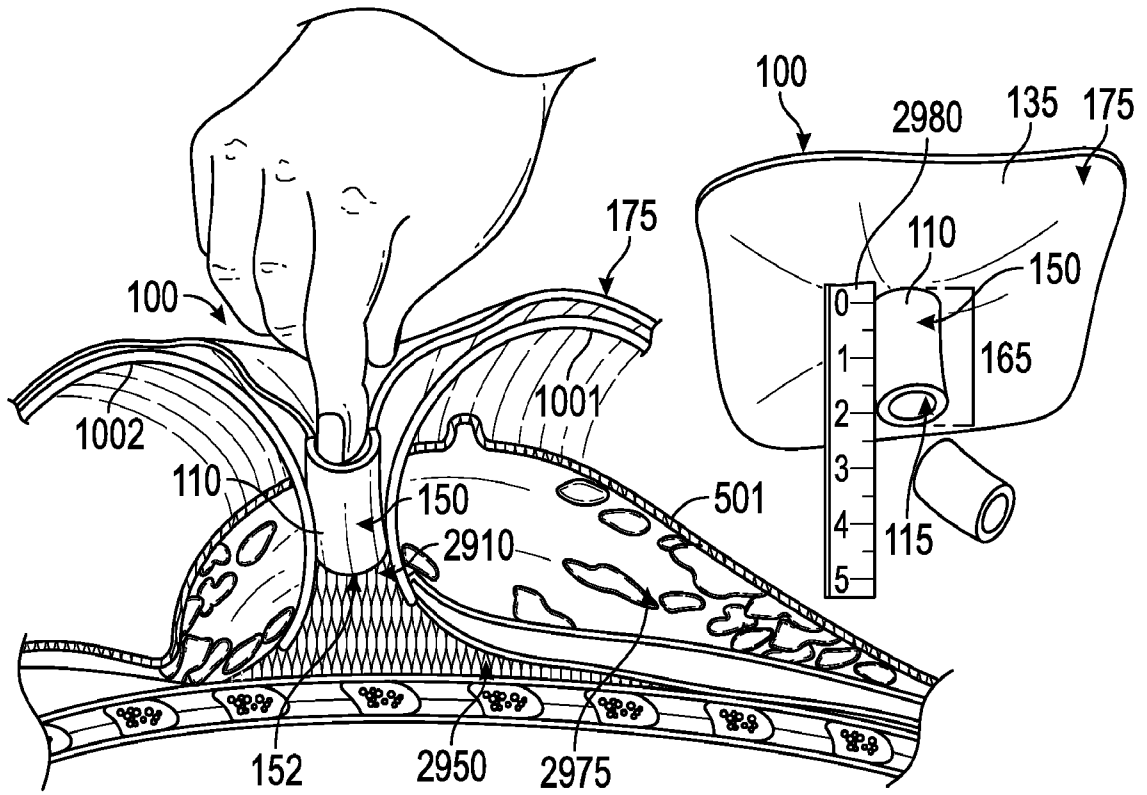


FIG. 31

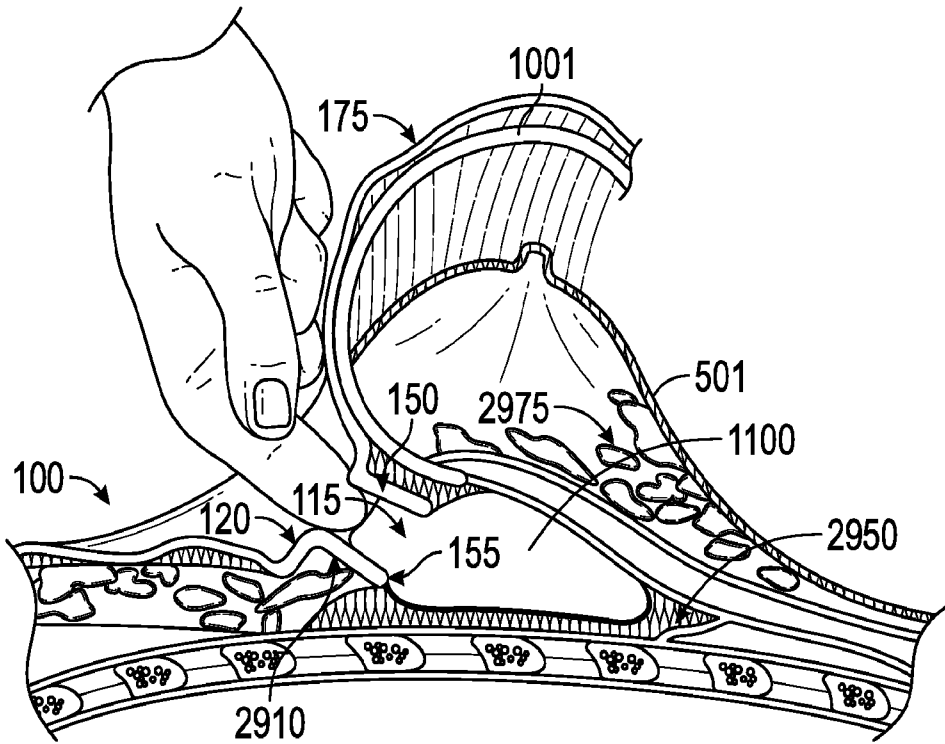


FIG. 32

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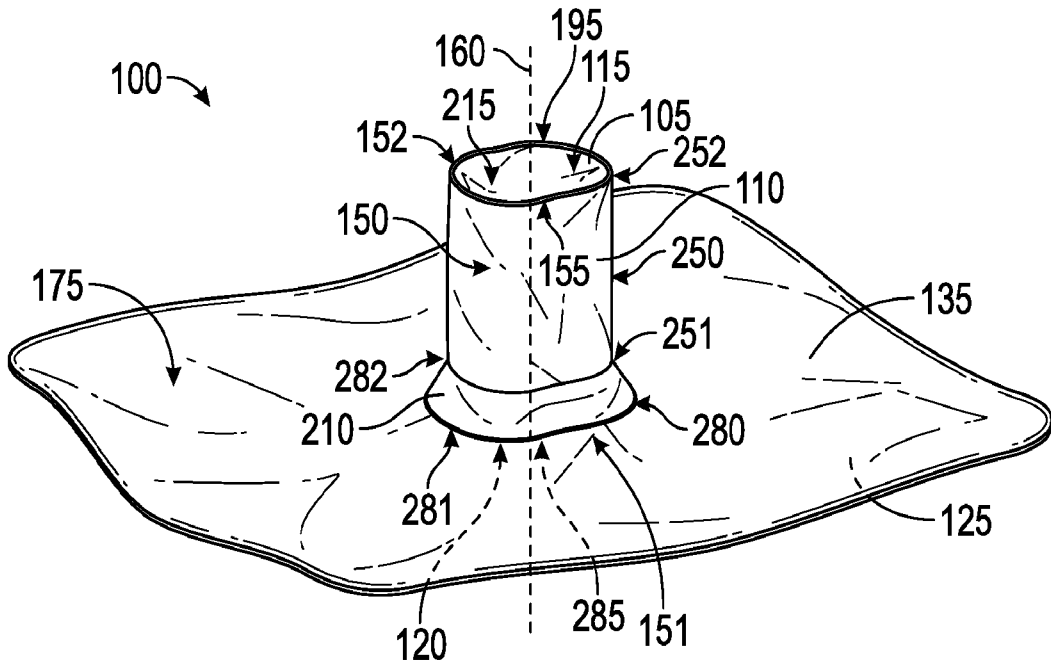


FIG. 33

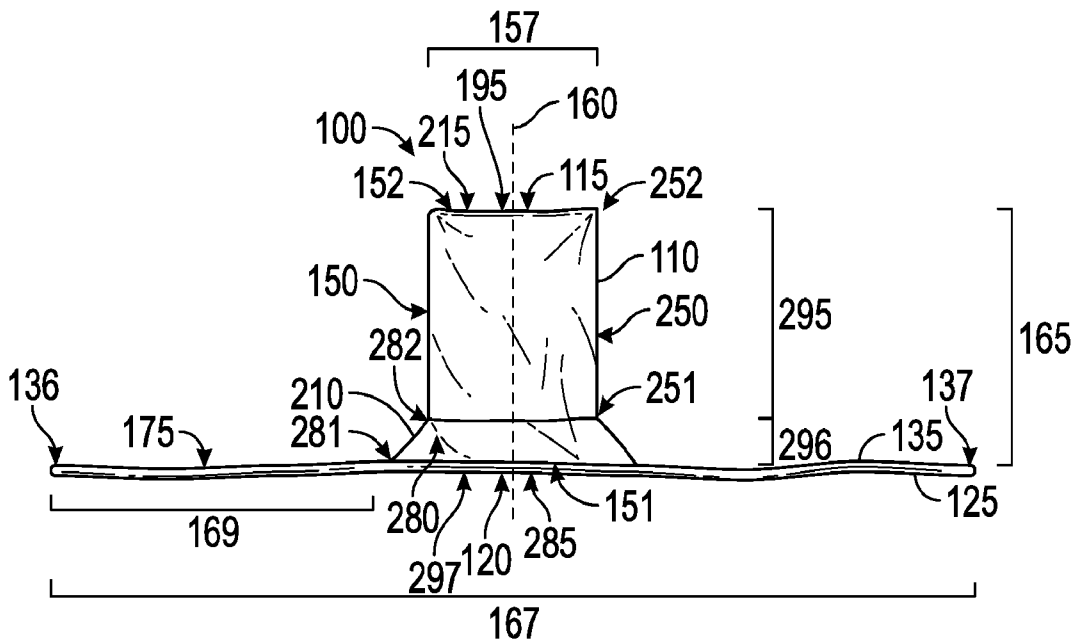


FIG. 34

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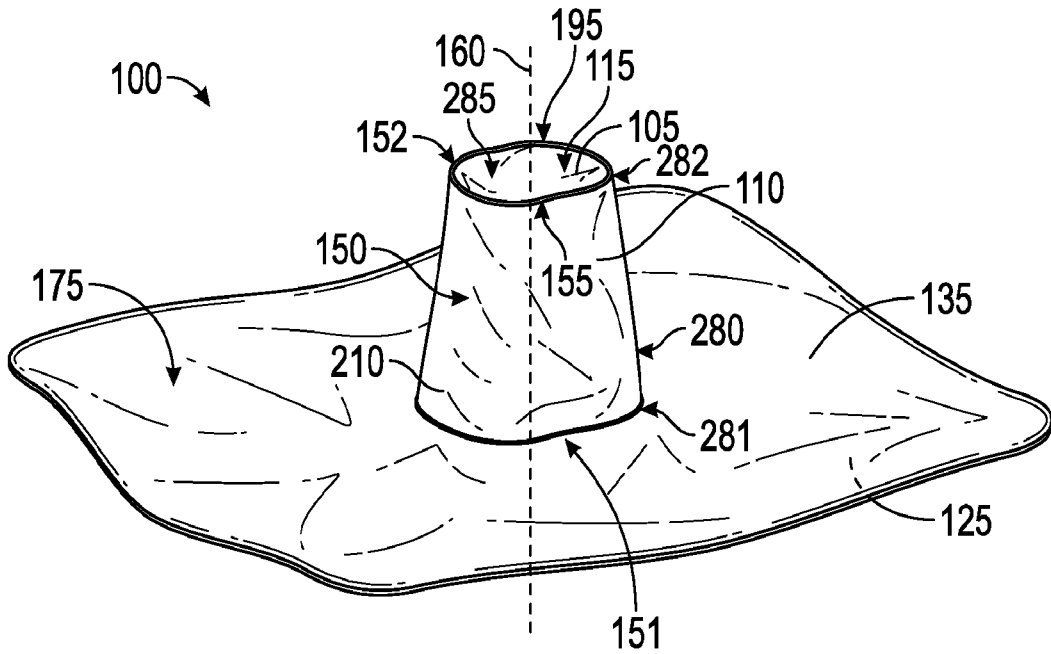


FIG. 35

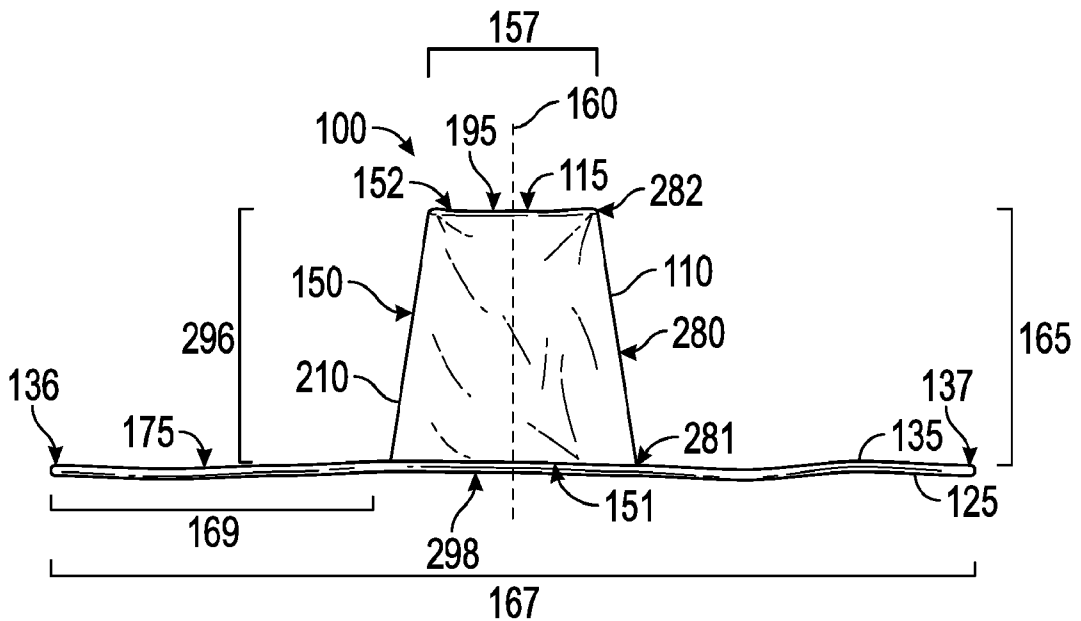
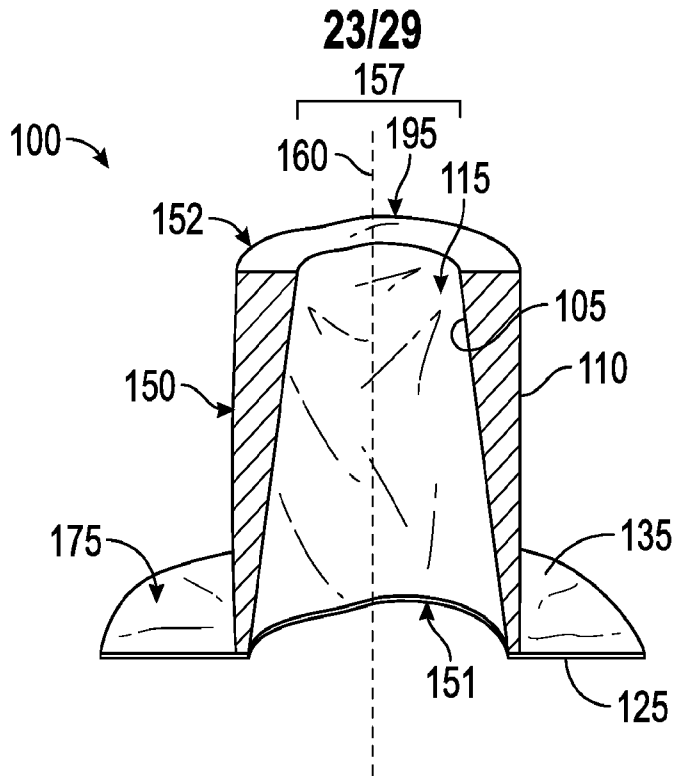
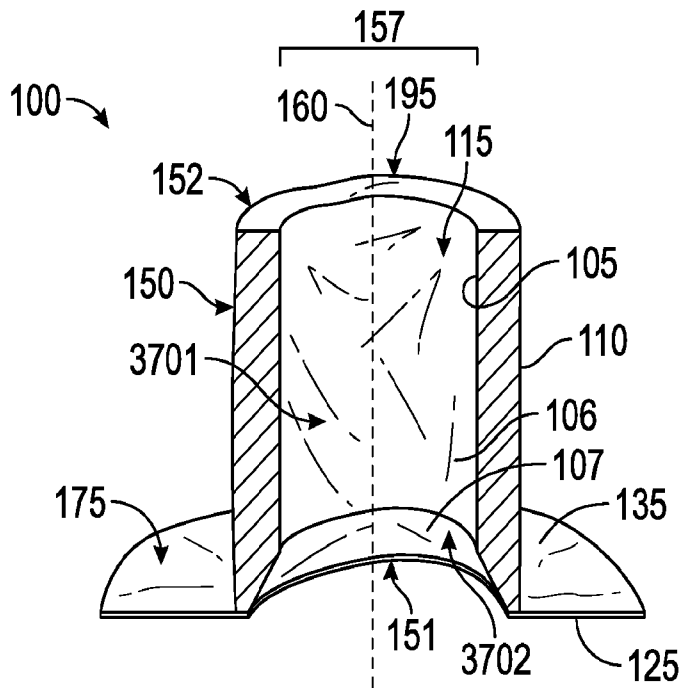


FIG. 36



**FIG. 37A**



**FIG. 37B**

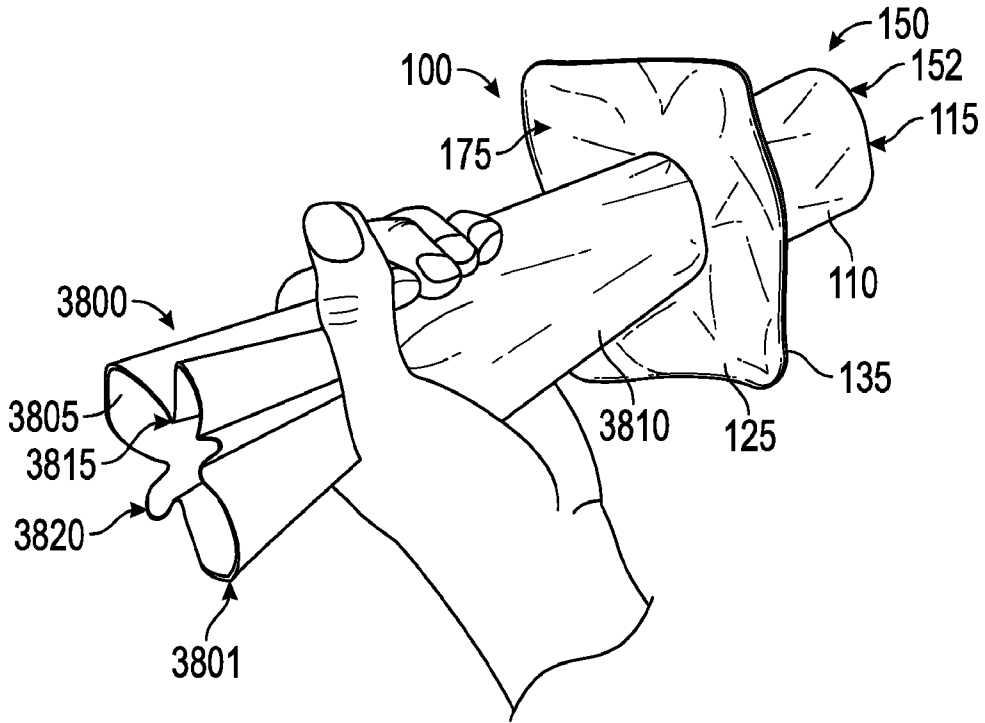


FIG. 38A

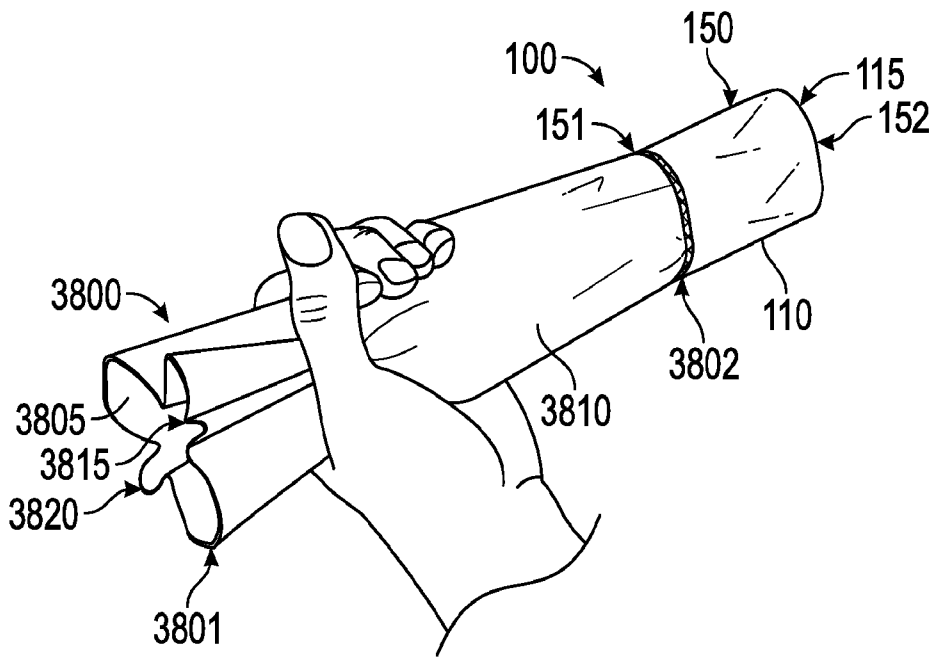


FIG. 38B

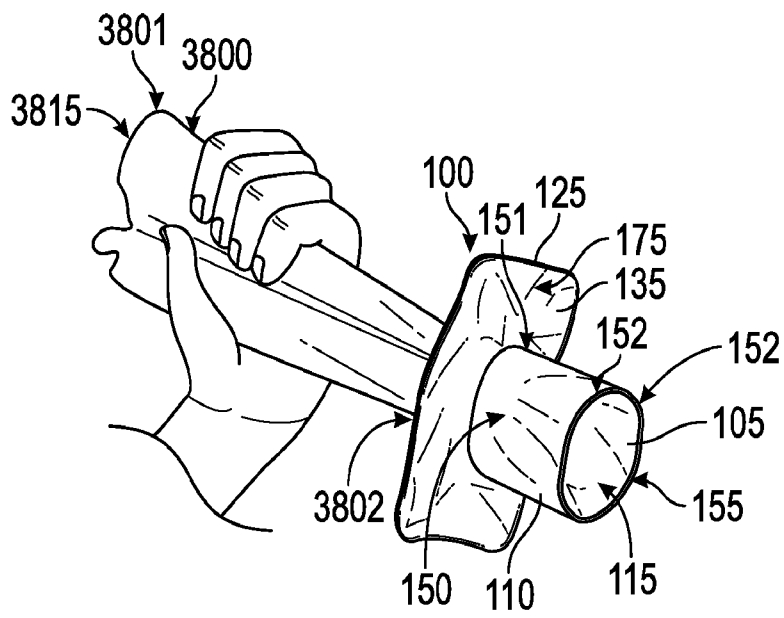


FIG. 39

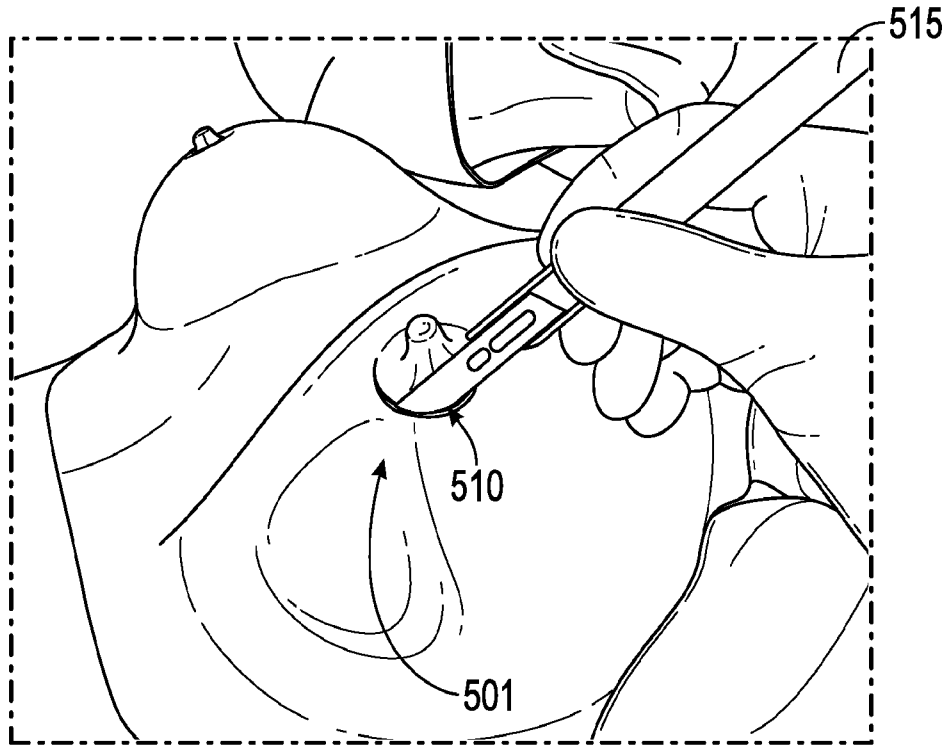


FIG. 40

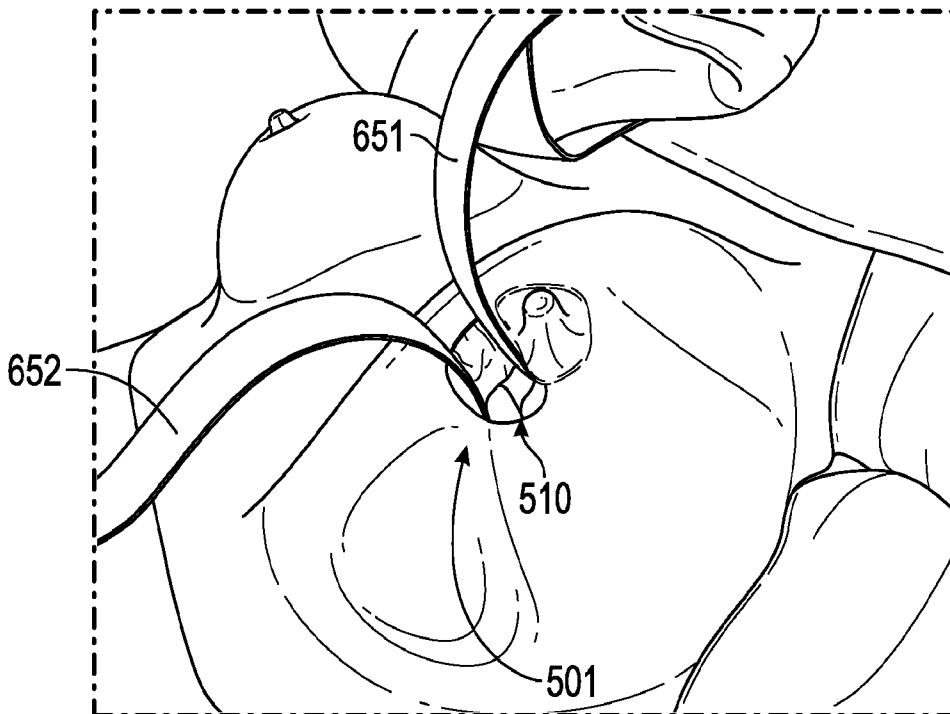


FIG. 41

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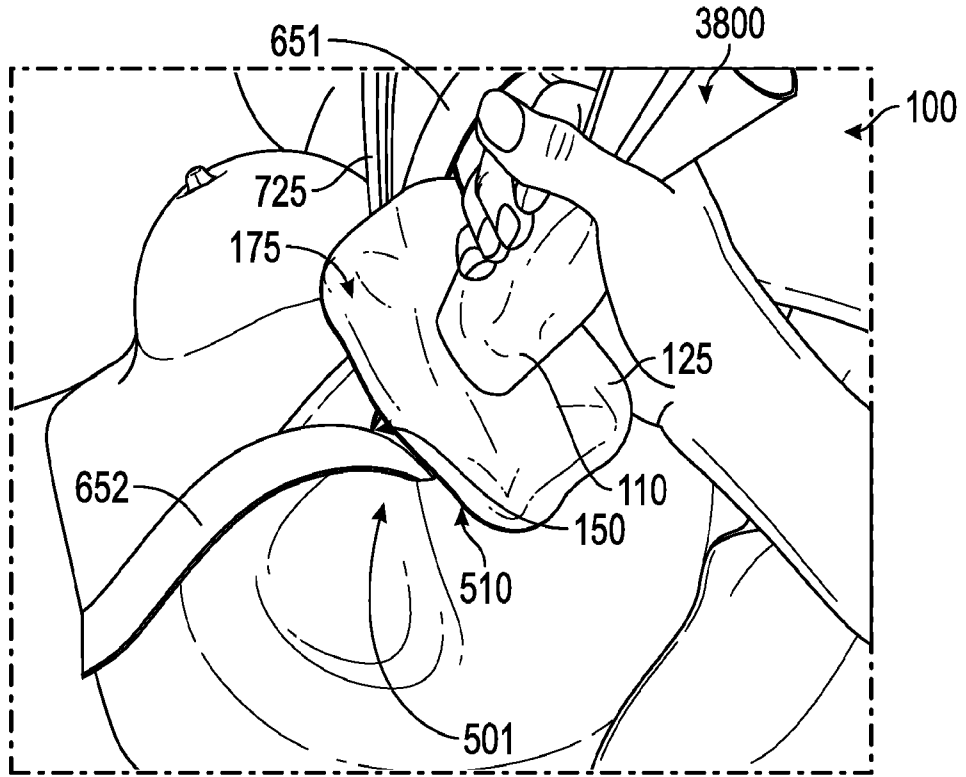


FIG. 42

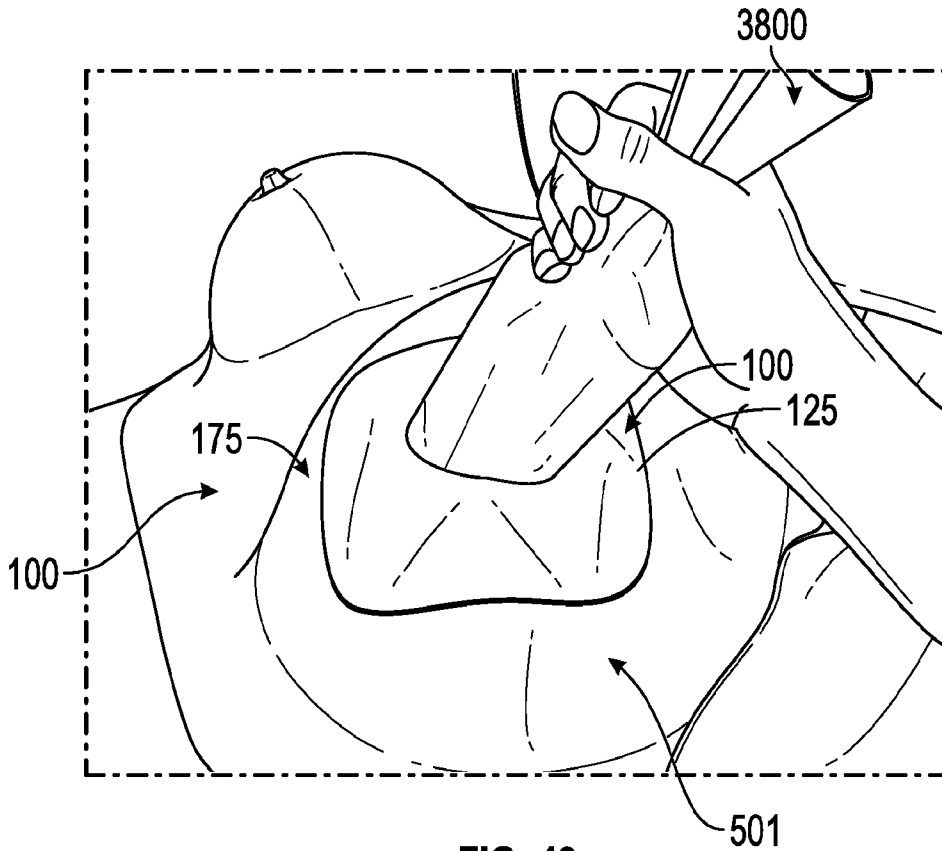
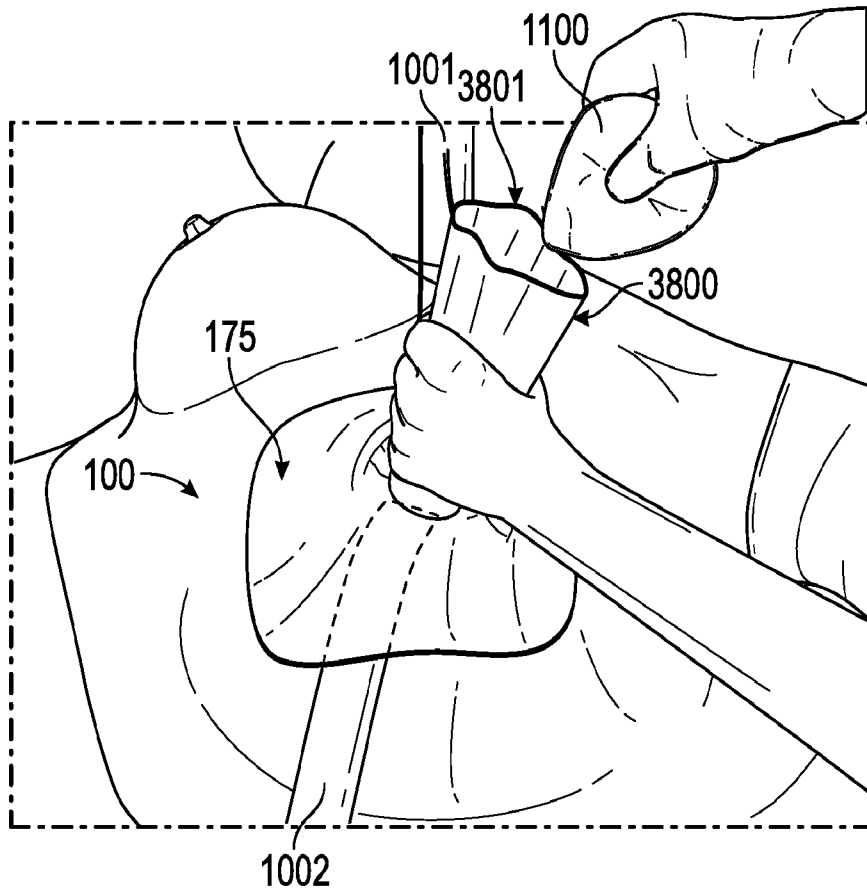
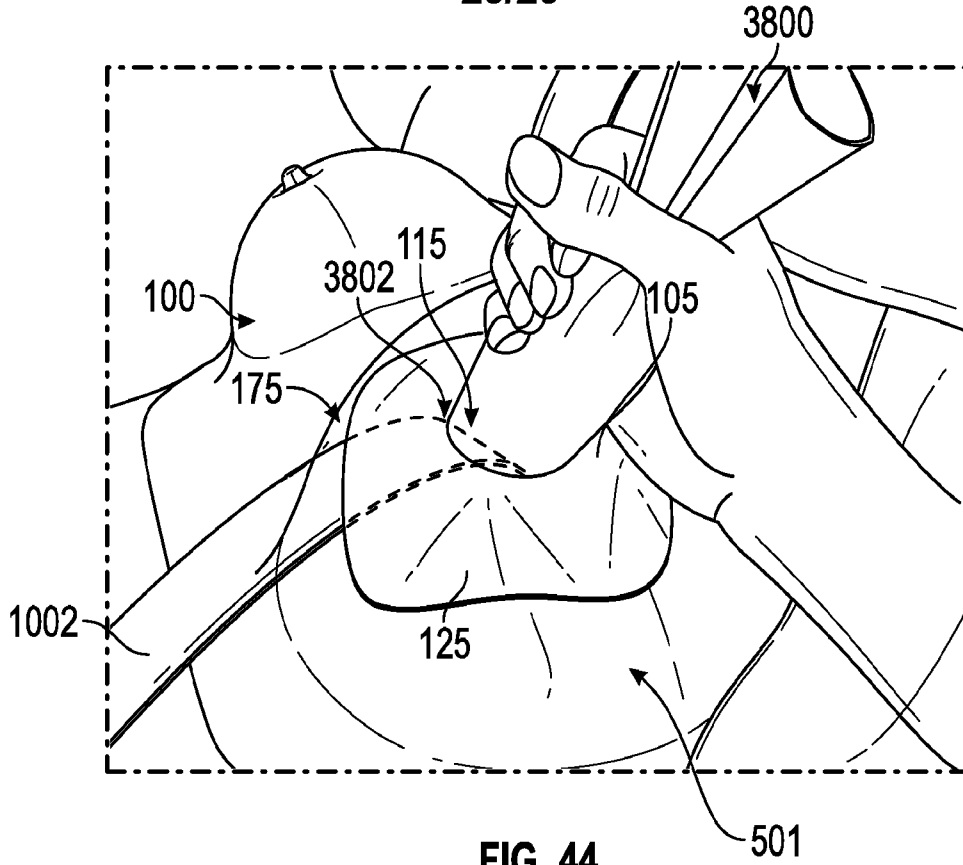


FIG. 43

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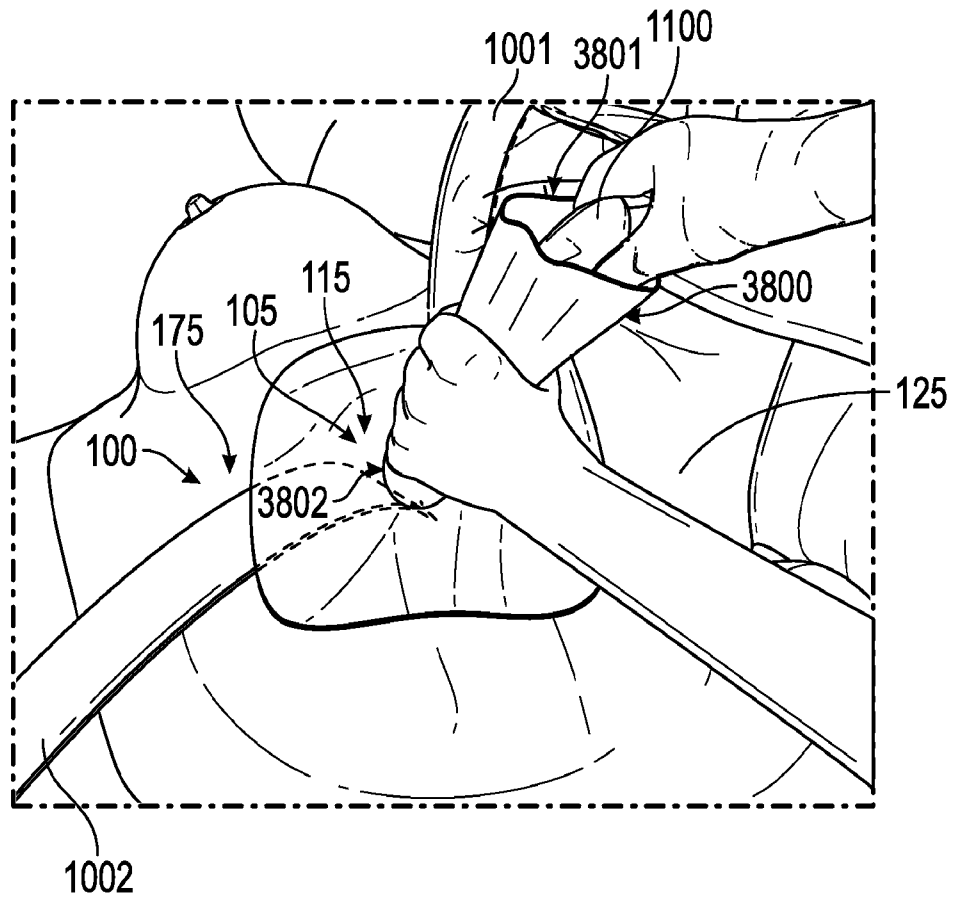


FIG. 45B

