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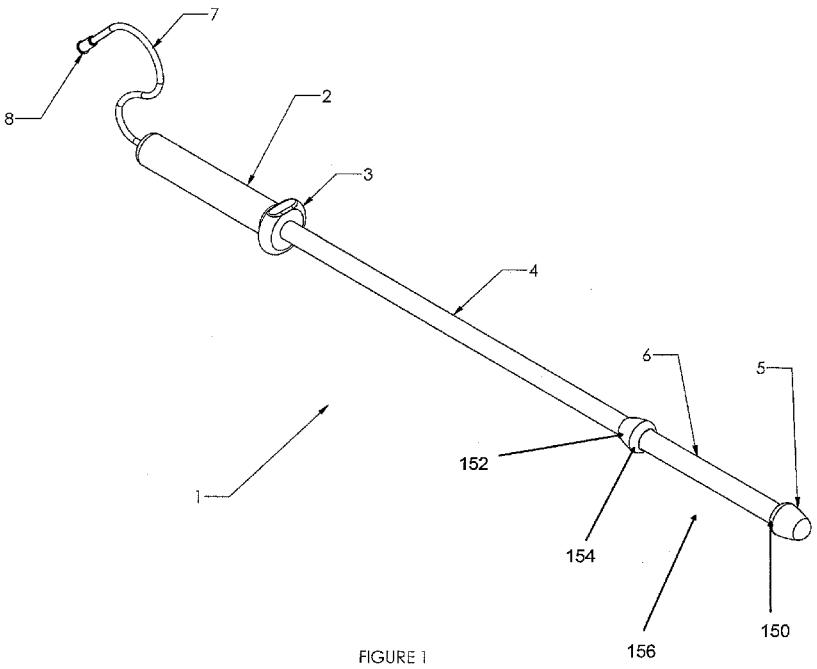

FIGURE 1

(57) Abstract: Provided herein are devices, methods, systems, and kits for the dissection of a target tissue space, delivering an implant to said target tissue space, and filling of said implant. In several embodiments, the target tissue space is the retro-mammary or retro-pectoral space and the implant to be delivered is a breast implant. In several embodiments, such implants are introduced through the umbilical region of a subject, thereby allowing trans umbilical breast augmentation to be performed.

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METHODS AND SYSTEMS FOR TRANSUMBILICAL BREAST AUGMENTATION

RELATED CASES

[0001] This application claims the benefit of U.S. Provisional Application No. 61/331,711, filed on May 5, 2010 the disclosure of which is expressly incorporated by reference herein.

BACKGROUND

[0002] Breast augmentation is a surgical procedure that has been successfully performed for many years. Traditionally, the procedure was performed with silicone gel prostheses. Recently, however, use of the silicone gel prosthesis has been reduced due to medical and legal implications associated with such prostheses. Instead, doctors have more recently been using saline-filled inflatable prostheses in breast augmentation procedures.

[0003] In the standard breast augmentation procedure using a pre-filled silicone cross-linked implant, a large proximal incision may be made on the breast (i.e. areola or nipple incision), under the breast, (inframammary crease incision), or under the arm pit (transaxillary incision). Alternatively, if an inflatable saline filled implant is to be used, a smaller incision away from the breast may be made in a region such as the umbilicus (trans-umbilical procedure TUBA) for the purpose of creating access to the retro-mammary space. This smaller, distal incision is in many cases preferred because it creates a less noticeable post surgical scar. Subsequent to the formation of the incision, the surgeon dissects a "pocket" in the retro-mammary space where an implant is thereafter implanted.

[0004] Prior to placing a saline-filled inflatable implant in the retro-mammary pocket, the surgeon must remove the implant from its sterile container. The surgeon may then fill the implant and test for the "integrity" of the implant (i.e. test to ascertain that there are no holes or other deformities in the implant). One known test used by surgeons is to squeeze the implant in its inflated state. Once the integrity of the implant has been confirmed, the surgeon empties the implant of all fluid and air, rolls the implant into a tightly-rolled "cigar-like" structure, and then forces the rolled implant (typically with the aid of an instrument) into the pocket previously formed in the retro-mammary space. Next, the surgeon fills the implant with the desired quantity of saline through a filling tube and a self-sealing valve prevents fluid from escaping the implant

once it has been filled. Once the implant is properly positioned and filled, the surgeon closes the incision and applies a dressing to the incision.

[0005] Rolling the implant into a "cigar-like" shape narrow enough to be introduced into a small distal incision for subsequent placement into a retro-mammary space is time-consuming and often difficult. It is also the principal cause of damage to the implant, which can result in post-operative deflation of the implant. If post-operative deflation occurs, a second corrective operation is required. Another cause of damage to the implant may result from the surgeon forcing the rolled implant through the incision and subcutaneous tunnel leading to the retro-mammary space. Although devices in the form of plungers, tubes and insertion sheaths have been developed to ease introduction of the rolled implant into the pocket in the retro-mammary space, none of these devices have successfully minimized the surgeon's handling of, and potential damage to, the implant.

[0006] Previously there have been two types of materials used to fill breast implants: viscous liquid silicone and saline solution. Historically, silicone filled implants were preferred for their more natural feel and appearance, but rupture or leakage of the outer casing of the implant would allow the liquid silicone to migrate within the body creating health complications. This resulted in the FDA prohibiting the use of silicone implants. Recently, cross-linked gel forms of silicone have been developed which do not migrate if the outer casing of the implant ruptures. The FDA currently allows cross-linked silicone implants, but patients receiving cross-linked silicone implants must sign off as being part of a long-term study.

[0007] Cross-linked silicone implants arrive from the manufacturer filled to a pre determined volume and must be inserted through a large incision (similar to the incisions necessary for implantation of standard silicone implants), which generally result in noticeable scars. These implants are not compatible with trans-umbilical type procedures due to their size.

[0008] Saline is a non-toxic, bio absorbable fluid that will not harm the patient if the implant were to rupture. Saline implants, which are currently the only candidate for small distal incision procedures, come from the manufacturer deflated and sealed in sterile packaging. Advantageously, because the implant can be rolled and placed in the retro mammary space in a deflated state, the saline filled implant can be introduced through a smaller incision that is less likely to produce a noticeable scar. The significant disadvantage of saline implants is that they do

not resemble natural breast tissue in mass or viscosity, thus unable to produce a more "natural" feeling and looking breast.

[0009] Saline implants are not optimal candidates for trans-umbilical procedures, or procedures requiring a delivery cannula since the silicone outer casing of the implant is naturally tacky and will not easily slide down a trans umbilical delivery tube. Therefore, significant risks associated with damage to the outer casing of the implant exist, which could ultimately result in leakage or pre-mature failure.

[0010] Therefore there exists a need for a safer, less invasive, and more efficient system and method for the placement and inflation of more "natural" looking and feeling breast implants that are safe for the patient.

SUMMARY

[0011] Typical breast augmentation methods involve the delivery of silicone implants, which are filled at the point of manufacture, and therefore require a large incision. Typically such implants are delivered via an infra-mammary, peri-areolar, and/or axillary incision. While these methods are relatively simple and short, there is typically significant risk of unsightly and undesirable scarring due to the surgical approach. Moreover, there are potential health risks due to the silicone used to fill the implant, should the integrity of the implant be compromised. A typical trans-umbilical breast augmentation method (TUBA) is advantageous in that the procedure significantly reduces scarring, but involves the use of saline to fill the implants. The fluidity of saline reduces the natural feel of the implant. Moreover, such procedures are often hampered by the lack of lubricity of the implant when being maneuvered through a delivery cannula. Thus, there remains a need for safer and more natural looking and feeling implants in conjunction with reduced surgical trauma, and reduced surgical complications to a patient during and after implantation.

[0012] As such, in several embodiments, there is provided a device for the delivery of an implant to a subject comprising an elongate outer cannula comprising a distal end, a proximal end, and at least one interior lumen, and an elongate push rod comprising a distal pushing surface, a proximal handle, and an interconnecting shaft positioned between the distal pushing surface and the proximal handle. In one embodiment, the distal end of the outer cannula comprises a passageway for receiving an implant and is configured to allow expulsion of an implant to a target tissue space. In several embodiments, an un-filled implant is rolled into a

cylindrical shape (e.g., a cigar-shape) and deposited into the distal end of the outer cannula. In some embodiments, the rolled implant is loaded from the distal end, while in other embodiments, the implant is loaded into the proximal end of the cannula and maneuvered to the distal portion of the cannula.

[0013] In one embodiment, the proximal end of the outer cannula comprises a passageway to receive at least the distal end of a push rod, and wherein the interior lumen is configured to allow longitudinal movement of a push rod within the lumen. In one embodiment the distal pushing surface is dimensioned to be positioned within the interior lumen of the outer cannula. Thus, distal application of force to the proximal handle of the push rod causes the push rod to slide longitudinally within the lumen of the outer cannula, thereby pushing an implant in a distal direction and causing it to be moved in a distal direction (either to position the implant in the device prior to delivery and/or to expel the implant into the target tissue space).

[0014] In several embodiments, at least one of the outer surface of the outer cannula and the inner surface of the interior lumen comprises a low-friction coating to facilitate delivery of the implant. Low-friction surfaces assist in positioning of the device (reduction of adhesion between the device and surrounding tissue) as well as the delivery of the implant (reduced tendency of the implant to adhere to the device, which could damage the implant). In several embodiments, the low-friction coating comprises one or more of hydrogel coatings, silane copolymer coatings, and polyvinylpyrrolidone/polyvinyl acetyl polymer blends. Physical mechanisms (e.g., raised longitudinal ribs within the lumen of the cannula) are also used in several embodiments to reduce friction.

[0015] In several embodiments, the distal end of the outer cannula comprises a beveled tip. In one embodiment the beveled tip of the outer cannula is covered by an elastomeric cover. In one embodiment the elastomeric cover comprises at least one slit to allow passage of an implant through the elastomeric cover and to a target tissue space. In several embodiments, the combination of the beveled tip and the elastomeric cover allow efficient blunt dissection of the subcutaneous tissues, but limit the damage to the tissue, as well as preventing the coring of tissue which could occlude (partially of fully) the lumen through which the implant would exit the device. In alternative embodiments, the distal tip of the outer cannula comprises an ejectable tip tethered to the device. In several such embodiments, ejection of the ejectable tip opens the distal tip of the outer cannula to allow expulsion of an implant into a target tissue space. In still

additional embodiments, the distal tip comprises a flap that protects the tissues during dissection and prevents clogging of the cannula.

[0016] In still additional embodiments, the outer cannula is movable in a longitudinal direction relative to the distal most tip of the device. Moreover, in several embodiments the distal tip of the outer cannula comprises a plurality of petals that are reversibly radially expandable and collapsible in a direction perpendicular to the longitudinal axis of the outer cannula. As such, in several embodiments, the plurality of petals is forced to collapse or expand due to the longitudinal movement of the outer cannula. As a result, expansion of the petals occurs in response to movement of the outer cannula in a distal to proximal direction, and wherein the expansion allows expulsion of an implant from the device to into a target tissue space.

[0017] In several embodiments, the distal pushing surface of the push rod comprises a substantially cylindrical element positioned to allow longitudinal movement of the push rod within the lumen of the outer cannula. In several embodiments, the cylindrical element is dimensioned to allow smooth longitudinal movement, but also prevent catching or binding of the implant by the element. In several embodiments, the distal pushing surface comprises at least one slot configured to allow passage of an implant fill tube through the distal pushing surface and back through the central lumen and out the proximal end of the device. In several embodiments, once the implant is positioned is a desired target space, the delivery device is retracted in a proximal direction, leaving the implant in the target tissue space, with the implant fill tube extending from the implant, along the subcutaneous dissection space, and out the initial incision. A port on the proximal end of the fill tube allows attachment of a filling device, as disclosed herein. After filling to the desired volume, the implant fill tube can be removed, in several embodiments, simply by applying proximally-directed force on the tube itself, which causes the tube to become disconnected from the implant. In such embodiments, the implant-tube interface comprises a one way valve, which previously allowed influx of filling media, but prevents escape of the media from the implant. In one embodiment the system further comprises a relief valve in the implant fill line, to allow drainage of any excess filling media that was delivered to the implant.

[0018] In several embodiments, there is provided a system for the delivery of an implant to a target tissue space and filling of the implant, the system comprising an implant

suitable for delivery to a target tissue space and filling after delivery/positioning in the target space, an implant delivery device as disclosed herein, an implant fill line, an implant filling solution chamber comprising an implant filling material, and a pressure source, wherein activation of the pressure source causes the implant filling material to move from the implant filling solution chamber through the implant fill line and into the implant.

[0019] In several embodiments, the implant fill line is reversibly connected to the implant and the implant filling solution chamber is in fluid connection with the implant via the implant fill line. In several embodiments, the pressure source is suitable for activation by a user in order to provide pressure to the implant filling solution chamber, thereby filling the implant in precise, measured amounts. In one embodiment the pressure source comprises a hydraulic pressure system. In one embodiment, the pressure source is suitable for delivery of a precise, predictable unit volume of filling material. In several embodiments, the pressure source comprises a pump that is configured to draw up and dispense a single solution in measured volumes. In several embodiments, a pump is configured to draw up two individual solutions, mix them, and pump the resultant combined solution to the implant in precise volumes (e.g., the pump may be the implant solution filling chamber). In several embodiments, the mixing of the individual solutions occurs during the implant procedure (e.g., once the implant is positioned, the solutions are mixed and the implant is filled in situ). In several embodiments, the two input solutions are combined in the same quantities, although, in some embodiments non-equivalent volumes are drawn up. In several embodiments, the pump is suitable for collecting, mixing, and pumping a hydrogel, precursor components of a hydrogel (that are mixed during or just prior to implant filling), saline, silicone, silicone cross-linking solutions, or combinations thereof. In some embodiments, a pump is fluidly connected to a baffled nozzle (as described below), while in some embodiments, the pump is connected directly to the implant fill line. Advantageously, in several embodiments, the pump allows on-site mixing of fill media (e.g., two components of a hydrogel). In some embodiments, a hydrogel is used for its natural feel and the ability to tailor the eventual feel of the implant (by varying the ratio of the components). Moreover, in several embodiments, the hydrogel is not cross-linked, which avoids issues with uneven feel in the implant. Additionally, in several embodiments, the hydrogel is bioabsorbable, thus providing an increased degree of safety for a patient, should the integrity of an implant become compromised.

[0020] In addition to, or in place of the pump apparatus, in several embodiments, the implant filling solution chamber is suitable for holding a hydrogel, components of a hydrogel (that are mixed during or just prior to filling), saline, silicone, silicone cross-linking solutions, or combinations thereof. In several embodiments, the implant filling solution chamber comprises at least two individual chambers containing at least two solutions for mixing during filling of the implant. In several embodiments, the system further comprises an implant fill nozzle comprises internal baffles configured for mixing of the at least two solutions during filling of the implant. In one embodiment, a hydrogel is used as the implant fill material. In several embodiments, the hydrogel comprises two parts that are mixed just prior to or during the implant filling process. In one embodiment, the pressure source functions not only to provide pressure to fill the implant, but also to mixed the component parts of the hydrogel. In some embodiments, a hydrogel is used for its natural feel and the benefits of onsite mixing (used to tailor the eventual feel of the implant). Moreover, in several embodiments, the hydrogel is not cross-linked, which avoids issues with uneven feel in the implant. Additionally, in several embodiments, the hydrogel is bioabsorbable, thus providing an increased degree of safety for a patient, should the integrity of an implant become compromised.

[0021] In several embodiments, the system further comprises an apparatus for securely holding the implant filling solution chamber. Thus, the entire system can be maneuvered into a convenient position for the physician, the patient, and support staff.

[0022] In several embodiments, there is provided a soft tissue dissection tool comprising a proximal end comprising a handle for manipulation of the device, a blunt distal-most end, an intermediate shaft communicating with the proximal end and the distal end, a reversibly inflatable balloon which may be positioned proximal to the distal-most end; and a fluid communication line in communication with the reversibly inflatable balloon.

[0023] In several embodiments, the dissection tool further comprises an indicator feature suitable for indicating the orientation of the distal portion of the device. In one embodiment the indicator comprises a notch in the proximal handle. In one embodiment the indicator comprises a light source in the distal-most end of the tool. In one embodiment the indicator comprises a magnet in the distal-most end of the tool.

[0024] In several embodiments, the reversibly inflatable balloon has an ellipsoid shape upon inflation. In several embodiments, the reversibly inflatable balloon may have an

inflated volume that is at least about 125%, at least about 150%, at least about 200% of the volume of an implant to be implanted in the tissue dissected by the tool. In several embodiments, the larger inflated volume of the balloon assists in implanting an implant, by ensuring that there is sufficient space in which to place the implant without damage to the implant due to forcibly manipulating an implant into its final position.

[0025] In several embodiments there is provided a method of preparing a tissue target space for subsequent implantation of an implant comprising introducing into the subcutaneous space of a subject a dissection tool as disclosed herein, advancing the distal end of the dissection tool along a subcutaneous pathway until the distal end of the dissection tool reaches a desired target tissue site, introducing an inflation media to the reversibly inflatable balloon, recovering the inflation media from the reversibly inflatable balloon, and withdrawing the dissection tool, thereby preparing a tissue target space for subsequent implantation of an implant. In several embodiments introduction of the inflation media causes inflation of the reversibly inflatable balloon, which serves to separate the tissue above the balloon from the tissue below the balloon, thereby creating a target tissue space for subsequent implantation of an implant. Likewise, recovery of the media causes deflation of the reversibly inflatable balloon and allows for removal of the dissection tool. In several embodiments, the target tissue space is one of the retro-pectoral or retro-mammary space and the dissection tool is introduced in the umbilical region. In several embodiments the target tissue space is prepared for the subsequent implantation of a breast implant. In one embodiment, the target tissue space is prepared in a female subject. In several embodiments, the method further comprises preparing a second target tissue space for implantation of a second implant, such as a contralateral implant.

[0026] In several embodiments the method further comprises delivering an implant to the target tissue space by a method comprising positioning an implant in an implant delivery device, directing the portion of the implant delivery device containing the implant into the vicinity of the prepared target tissue space, deploying the implant from the implant delivery device in order to implant the implant in the target tissue space; and withdrawing the implant delivery device. Moreover, in several embodiments the method further comprises filling the implant. In several embodiments the implant is filled with an implant fluid solution selected from the group consisting of a pre-mixed hydrogel, a hydrogel that is mixed just prior to or during the filling process, saline, silicone oil, silicone gel, silicone elastomer, and cross-linked

silicone. In one embodiment the implant is filled with a hydrogel material comprising two initial components, which are mixed just prior to or during the filling process.

[0027] In several such embodiments, the implant delivery device comprises an elongate outer cannula comprising a distal end, a proximal end, and an one interior lumen, wherein the distal end of the outer cannula comprises a passageway for receiving an implant and allowing expulsion of the implant to a target tissue space, wherein the proximal end of the outer cannula comprises a passageway to receive at least the distal end of a push rod, and wherein the interior lumen is configured to allow longitudinal movement of a push rod within the lumen; and an elongate push rod comprising a distal pushing surface, a proximal handle, and an interconnecting shaft positioned between the distal pushing surface and the proximal handle, wherein the distal pushing surface is dimensioned to be positioned within the interior lumen of the outer cannula, wherein distal application of force to the proximal handle of the push rod causes the push rod to advance longitudinally within the lumen of the outer cannula. As discussed above, such longitudinal movement allows the expulsion of an implant from the lumen of the outer cannula.

[0028] In several embodiments, there is provided an additional method for the single port augmentation of a breast, comprising creating an incision in the umbilical region of a subject (e.g., a single port), introducing a dissection tool into the subcutaneous space of the subject via the incision; creating a pocket in or posterior to the breast of the subject; withdrawing the dissection tool; delivering an un-filled implant to the pocket; filling the implant; and closing the umbilical incision. In several embodiments the implant is filled with hydrogel, while in several other embodiments, the implant is filled with saline, silicone, or other acceptable materials. In several embodiments, more than one solution is used to fill an implant (e.g., a multi-component filling media, such as a two-part hydrogel). In several embodiments, distinct containers are used to house an implant filling material that comprises two solutions. In several embodiments, IV bags (or other suitable sterilizable container (e.g., bottles, tubes, etc.) are used. In some embodiments, the containers are disposable, while in other embodiments, they can be cleaned, re-sterilized, and re-filled. In some embodiments, the containers are positioned in an elevated position (e.g., an IV pole, an elevated counter, etc.) in order to gravity feed the contents of each container to a central mixing area. In several embodiments, the distinct containers feed into the dual chamber described above. This is advantageous, in some embodiments, as the chamber is

the only portion of the system that needs to be cleaned and sterilized. A physician can then purchase the desired type and amount of the two solutions in pre-sterilized containers. In other embodiments, a pump draws the filling solution from the two containers and into a receiving/mixing chamber. The action of the pump thus serves not only to draw-up the two solutions, but also to mix the two solutions. In some embodiments, a single exit line from the pump mixing chamber is directly connected to an implant via an implant fill line. In other embodiments, the exit line from the pump mixing chamber is fluidly connected to a mixing nozzle comprising baffles, as disclosed herein, in order to provide additional mixing of the two solutions during delivery to the implant. In several embodiments, the pump also functions as a metering device. In some embodiments, the pump can be pre-set to receive (e.g., take up) and deliver a pre-determined amount of implant fill solution. Thus, in some embodiments, the pump controls the final volume delivered to an implant by shutting off after a specific, pre-determined volume of fill solutions has been passed through the pump. In some embodiments, the physician can fine-tune the total delivered volume, in order to achieve a desired final look and/or feel of an implant. In several embodiments, the pump is switch-actuated. In one embodiment, the switch is a foot switch (e.g., a foot pedal). In one embodiment, the switch is a hand or finger switch.

[0029] The method disclosed for placement of a breast implant is conducted in accordance with recognized sterile techniques. In several embodiments, the patient is placed in a supine position and prepped from neck to abdomen. A sterile field is then prepared generally from the patient's neck to iliac crest. A region around the breast and area of incision is completely anaesthetized to ensure patient comfort. For purpose of localized pain control, a mixture of xylocaine with epinephrine may be used. In some embodiments, the patient may also select general anesthesia where a mask and endotracheal tube is used (either in place of or in addition to local anesthesia).

[0030] A semi circular incision is created at the desired percutaneous access point, such as on the upper half of the umbilicus of the patient with, for example, a sharp tipped iris scissor in order to initiate a subcutaneous tunnel. Access may alternatively be accomplished via the axillary region or other access site. Metzenbaum or another such type of scissor may be used to further open the incision. In order to further facilitate placement of the implant into the retro-mammary space, a subcutaneous tunnel may be created using a tissue dissection tool. The tissue dissection tool has, in several embodiments, a balloon (or other object suitable for blunt tissue

dissection) located generally near the distal end. Upon insertion, the balloon is in a deflated state as the tissue dissection tool is subcutaneously inserted and used for tunneling and tissue dissection.

[0031] Prior to, or during, the creation of a subcutaneous tissue tunnel, a syringe with a long needle may be used to deliver localized anesthesia. In several embodiments, the injection needle is approximately twelve gauge in diameter, about eight inches in length, and has lateral exit ports and a blunt or closed tip to avoid the possibility of injecting into arteries or veins. In other embodiments, alternative needle dimensions are used, based either on patient-specific needs or surgeon preference.

[0032] The tissue dissection tool is advanced subcutaneously from the incision to the retro-mammary region of the patient. Additionally, as the tissue dissection tool is advanced, a pain control mixture of xylocaine with epinephrine (or other appropriate anesthetic) may be eluted from the distal tip of the tissue separation tool. As the tissue dissection tool is advanced into the retro-mammary region, the retro-mammary area may be infused with anesthesia to control pain. The intercostal and inframammary nerves may also be blocked to further control pain. As the tissue dissection tool is advanced, the physician imparts an upward motion with the tissue dissection tool to keep the tip of the tissue dissection tool in the subcutaneous plane.

[0033] Implants are commonly placed in one of two regions: retro-pectoral, which is behind the pectoral muscle, and retro-mammary, which is in front of the pectoral muscle. If a retro-pectoral placement is desired, the physician guides the tissue dissection tool behind the breast. Once the proper retro-pectoral or retro-mammary position of the tissue dissection tool is achieved, a sterile water solution is used to inflate the dissection balloon to approximately 150 percent of the desired implant volume. The tissue dissection balloon remains inflated for a period of time to tamponade bleeding. The tissue dissection balloon is then deflated and the tip of the dissection tool is used to sweep the newly created space to separate any remaining fibrous bands and connective tissue.

[0034] If a sub-pectoral implant placement is desired, the pectoralis muscle is further separated from the surrounding substrate tissue. Furthermore, stainless steel (or other material) tissue dissection tools may be used under direct endoscopic visualization to achieve this goal. After the tissue dissection tool is removed from the patient, the breast is squeezed and manipulated to check for blood coming out of the umbilicus incision. Further inspection for

internal bleeding may be performed under direct endoscopic visualization and bleeding vessels may be clotted using electrocautery (or other suitable cautery means).

[0035] The normal breast implant size may vary from, for example, approximately 150cc's up to 650cc's with the average being from about 250cc's to about 400cc's per implant. Silicone (typically a silicone elastomer) is one of the most common implant outer shell materials and despite the relatively tacky, non-slippery surface, it is particularly well suited for use with the TUBA procedure and devices as described herein which provides for easy delivery of such materials. Silicone is also used, in several embodiments, as the inflation media. Thus, according to several methods disclosed herein, a small distal incision is used to deliver an implant that will subsequently be filled with an appropriate filling media (e.g,. hydrogel, polymer, silicone, etc.). Thus, these approaches are beneficial in at least two ways, namely 1) a patient benefits from reduced recovery time and scarring due to the use of a small incision, and 2) the devices and methods disclosed herein allow the insertion of an inflatable implant that is suitable for receiving silicone as the inflation media. Prior to Applicant's discoveries, silicone implants were not deliverable by a small incision in an un-inflated configuration, but required larger incision sizes for allowing an inflated implant to be positioned. Moreover, the methods and devices disclosed herein advantageously allow the implants to be positioned while un-inflated and subsequently inflated with any appropriate inflation media, including but not limited to, hydrogel, multi-part hydrogels, saline, silicone (e.g., oils, gels, or elastomers), cross-linked silicone, air or other gas, other suitable liquid media, combinations of the above, and the like.

[0036] A physician may then prepare the implant insertion tool by wetting generally the inside surface of the insertion cannula, for example, with a sterile solution of water, normal saline, or other inert fluid lubricant. The insertion cannula may be coated with a friction reducing agent on the inside surface to interface with the implant and on all or portions of the outside surface to facilitate easy insertion as it passes through the tunnel made by the dissection tool. Any variety of friction reducing surface structures may also be added to the insude surface of the cannula, such as axially extending ridges or other standoffs, to minimize surface area contact between the surface of the rolled implant and the inner surface of the cannula. For example, in several embodiments, the inner surface of the cannula may comprise inwardly facing axial ridges that run longitudinally along the long axis of the cannula for at least a portion of the length of the cannula. Ridges, raised surfaces, inverted grooves, partial cylinders, and the like

may also be used. Such surface features serve to reduce the degree of contact (and thus the amount of friction or resistance to movement) between the outer surface of the implant and the inner surface of the cannula. Such features may be formed during the production process of the cannula. Alternatively, such features may be incorporated into the cannula post-production. The features may also be coated with any of the friction reducing agents disclosed herein. Optionally, the distal radially outwardly extending flange 32 (see Figure 11B) may comprise a plurality of radially inwardly extending slots that are inversely matched to such features and reduce the rotational movement of the implant within the cannnula.

[0037] The preferred intent is to provide slippery surfaces on the cannula using biocompatible coatings and/or materials that are suitable for tissue contact and do not leave residue on the tissue after removal of the tool. By way of example, suitable materials for achieving low coefficients of friction suitable for the present invention may include, but are not limited to, hydrogel coatings, silane copolymer coatings, and polyvinylpyrrolidone/polyvinyl acetyl polymer blends.

[0038] A fill line is then attached to the implant (if not already as packaged). In several embodiments, all, or substantially all, the air inside the implant is removed prior to implantation. Any number of techniques capable of removing as much air as possible out of the implant may be incorporated here without departing from the scope of the claimed methods. Removal of as much air as possible out of the implant allows the implant to at least be rolled into a cigar shape, making it more compact for insertion and placement (thus requiring a smaller incision). The implant may then be placed into the insertion cannula and advanced generally adjacent to the distal end of the outer cannula through the tunnel. The user (e.g., a physician) then positions the insertion cannula subcutaneously to a position where successful deployment of the implant is achieved.

[0039] An internal push rod is then advanced through at least a portion of the center of the insertion cannula in order to allow the insertion cannula to deposit the deflated implant into the sub-mammary cavity. Once the deflated implant is manipulated into the desired position within the sub-mammary cavity, the physician may then remove the implant delivery tool. Any number of methods may be used to determine proper placement of the deflated implant (i.e. x-ray, endoscope, or manipulation of exterior breast) without departing from the scope of the present invention.

[0040] After the deflated implant has been properly placed, a preferred implant filling medium (such as saline or gel), and means of delivering the filling medium is prepared. The preferred medium and means of delivery of the implants are disclosed herein and include, for example, equipment for handling, mixing and delivering a gel material into an implant. The gel is delivered to the user as two separately packaged sterile components, which, in some embodiments, are mixed prior to or contemporaneously with filling of an implant. Each package contains a generally liquid material (or a liquid and a powder) that, when mixed, will at least partially cure to a cross-linked or non cross-linked gel. The cured gel and any additional components are biocompatible and suitable for long-term implantation in a patient. Even though the gel is contained within the implant sack, it is preferably suitable for direct contact with human tissue in the event the sack ruptures or leaks.

[0041] In those embodiments employing a cross-linked gel are advantageous in that is that the cross-linked gel will not migrate within the body if the implant sack ruptures. An advantage of the non-cross linked gel is that it will generally dissolve in the presence of bodily fluids and become bio-absorbed by the body. This also allows easier removal of the remaining damaged implant sack because it will be left generally empty. Therefore, removal will require a relatively smaller incision.

[0042] The gel components may be provided in sterile pre-filled containers, which may be used directly with the mixing/delivery equipment. Alternatively, the gel components may be provided in any type of sterile packaging (i.e. bulk or single use container) that can be transferred into containers for the use with the disclosed and claimed mixing and delivery equipment. The components of the gel may vary in composition and may require various dilutions, mixing ratios, or additives to facilitate proper curing and properties (e.g. time-to set, firmness, density, etc.). Additionally, the gel components may contain additives such as, for example, stabilizers, preservatives, antibiotics, anti-microbial agents, curing agents, radiopacity enhancing agents to permit fluoroscopic visualization, saline and/or any additives known in the art for providing benefits to implanted materials.

[0043] By way of example only, Aquadapt II Hydrogel, provided by Hydromer, Inc. of Brachburg, NJ, USA, is a suitable gel material for use with claimed methods. Aquadapt II Hydrogel is typically provided to a user in two parts which may be described as parts A and B. Parts A and B are mixed at approximately a one to one ratio, although in certain embodiments,

the mix ratio may be varied. Other ingredients may be added to Aquadapt II Hydrogel, or any gel contemplated herein to modify or enhance properties of the cured gel or to adjust the curing behavior of the gel. In several embodiments, as disclosed herein, the component solutions are mixed on-site (e.g., in the operating room), during the implantation procedure (e.g., after the un-inflated implant has been positioned). Hydrogels are particularly advantageous for on-site mixing, due to their low-toxicity and ease of handling (as compared to silicone for example, use of which may require additional safety precautions during an on-site mixing process).

[0044] Once the gel (or other fill media) has been properly prepared (e.g., mixed), the user may then transfer the gel through the fill tube in order to fill and further position the implant. After proper sizing and placement of the implant has been achieved, the physician disconnects the fill line from the implant. Again, any number of methods and/or techniques may be used to determine the proper placement and sizing of the implant. Furthermore, the breast size may be modified either by filling or removing material (i.e. fluid, gels, hydrogels) within the implant.

[0045] Thus, procedures accomplished in accordance with the present invention enable the placement of a polymer filled breast implant having a silicone or silicone like feel, but through a much smaller incision than a conventional silicone implant. For example, implants having an inflated diameter of at least about 8 cm or 10 cm can be introduced via an access incision of no more than about 6 cm, generally no more than about 4 cm and in many applications no more than about 3 cm or 2 cm. For example, a deflated, rolled or folded implant may be introduced through a cannula which is advanced through an incision of no more than about 1.5 cm or 2 cm; inflated in situ to have a diameter of at least about 10 cm by a flowable mixture of a first and second components, and then the first and second components polymerize, cross link or otherwise convert into a stable inflation media to form the final implant construct in situ. The first and second components may be advanced from respective first and second containers into a mixing chamber and then into the breast implant in a closed system, with the first and second containers located outside of the sterile field and the access incision within the sterile field. The mixing chamber may be contained in a housing positioned upstream from the cannula or within the cannula. Alternatively, mixing may be accomplished downstream from the cannula, such as within the implant.

[0046] In several embodiments, the first and second containers may be first and second compartments within a single housing, or alternatively, may be separate structures such as tubes, vials, bags or others known in the art. The first and second containers may be sold paired as a kit, each kit predetermined to produce a final media volume of any of a variety of sizes, such as within the range of from about 125 cc to about 150 cc; 150 cc to about 200 cc; 200 cc to about 300 cc or 300 cc to about 600 cc. The kit is thus configured to produce a unit volume which is associated with a particular size implant. The kit may additionally contain one or two implants, each having an inflated volume which corresponds to the volume of the media formed by the combination of the first and second components contained within the kit. The access cannula and other tools may be included within the kit.

[0047] In several embodiments, the umbilical incision is not immediately closed after the implant placement procedure is complete. Instead, the physician squeezes (or otherwise manipulates) the breasts to check for blood or serum exiting the umbilical incision. Post surgery, the patient wears a generally tight fitting bra for additional support. A steri-strip and gauze (or other suitable wound dressing) is placed over the umbilical incision. Approximately one to two hours after the completion of the procedure, the patient's breast is squeezed again to check for any bleeding or residual blood serum.

[0048] Although the devices, materials, equipment and methods described in this embodiment primarily address the transumbilical procedure, any number of procedures may be used in other embodiments to place the implant in a patient. By way of example, the disclosed methods and devices may be used to implant directly into the breast (areola or nipple incision), under the breast, (inframammary crease incision), or under the arm pit (transaxillary incision). Furthermore, it shall be appreciated that modifications to the devices and/or equipment that would be required to accommodate different approaches to placing an implant in a patient do not depart from the scope of the methods and devices disclosed and claimed herein.

[0049] Although the devices, materials, equipment, and methods described herein are described generally for use with breast implants (for the augmentation/reconstruction of breasts), this is by way of example only such that any of the devices, materials, equipment, and methods described herein may be used with any number of implants and/or with any number of methods to achieve the placement of an implant within a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0050] Figure 1 is a schematic perspective view of a dissection and/or implant sizing device in accordance with the present invention.

[0051] Figure 2 is a perspective view as in Figure 1, with a distal balloon in an inflated configuration.

[0052] Figure 3 is a side elevational view of the device of Figure 2.

[0053] Figure 4 is a cross-sectional view along the lines A-A through the balloon of Figure 3.

[0054] Figure 5 is a schematic cross-sectional representation of the device of Figure 1 after percutaneous introduction.

[0055] Figure 6 is a schematic view as in Figure 5, with the balloon at least partially inflated.

[0056] Figure 7 is a side elevational schematic view of an alternate tissue distraction and/or implant sizing device, having a working channel extending therethrough.

[0057] Figure 8 is a longitudinal cross-sectional view taken along the line E-E through the device of Figure 7.

[0058] Figure 9 is a cross-sectional view taken along the line G-G in Figure 7.

[0059] Figure 10 is a schematic perspective view of an implant deployment device in accordance with the present invention.

[0060] Figures 11A-11B depict an exploded view of the device of Figure 10, in which the implant deployment pusher (11B) has been proximally retracted from the outer tubular cannula (11A).

[0061] Figure 11c is a detailed view of the distal end of the implant deployment cannula.

[0062] Figure 12 is a side elevational view of the implant deployment device of Figure 10.

[0063] Figure 13 is a longitudinal cross-sectional view taken along the line A-A of Figure 12.

[0064] Figure 14 is a side elevational view of the implant deployment device of Figure 12, having an implant positioned therein.

[0065] Figure 15 is a longitudinal cross-sectional view taken along the line C-C in Figure 14.

[0066] Figure 16 is a perspective view of the implant deployment device of Figure 15, showing the implant distally deployed.

[0067] Figure 17 is a schematic perspective view of an alternate implant deployment device in accordance with the present invention.

[0068] Figure 18 is a longitudinal cross-sectional view of the device of Figure 17.

[0069] Figure 19 is a schematic perspective view of an alternate implant deployment device in accordance with the present invention.

[0070] Figure 20 is a detail view of the distal end of the device of Figure 19.

[0071] Figure 21 is a schematic perspective view of an alternate implant deployment device disclosed herein, having an implant partially deployed therefrom.

[0072] Figure 22 is a detail view of the distal end of the device of Figure 21.

[0073] Figure 23 is a schematic perspective view of an alternate implant deployment device disclosed herein.

[0074] Figure 24 is a detailed cross-sectional view of the distal end of the device of Figure 23.

[0075] Figure 25 is a longitudinal cross-sectional view of the device of Figure 23.

[0076] Figure 26 is a detailed perspective view of an alternate distal tip disclosed herein.

[0077] Figure 27 is a schematic perspective view of an alternate implant deployment device disclosed herein.

[0078] Figure 28 is a schematic perspective view of the device of Figure 27, showing elastic deformation of distal petals, to permit deployment of the implant therethrough.

[0079] Figure 29 is a detail view of the distal end of the device of Figure 27.

[0080] Figure 30 is a cross-sectional schematic view of an anesthesia delivery device positioned subcutaneously in a patient.

[0081] Figure 31 is a detail view of the distal end of the device of Figure 30.

[0082] Figure 32 is a schematic elevational view of an inflation media deployment system having an implant attached thereto.

[0083] Figure 33 is a schematic view of the system of Figure 32, with the implant unrolled and ready for inflation.

[0084] Figure 34 is a side elevational view of a mixing chamber in accordance with several embodiments disclosed herein.

[0085] Figure 35 is a longitudinal cross-sectional view taken along the line A-A of Figure 34.

[0086] Figure 36 is a side elevational view of a dual chamber inflation media cartridge in accordance with several embodiments disclosed herein.

[0087] Figure 37 is an elevational cross-sectional view of the cartridge of Figure 36.

[0088] Figure 38 is an elevational perspective view of the media deployment system of Figure 32, showing installation of an inflation media cartridge.

[0089] Figure 39 is a schematic view of an inflation system as in Figure 38, in communication with an inflated implant.

[0090] Figure 40 shows a detailed view of the drain valve depicted in Figure 39.

[0091] Figure 41 depicts a non-limiting example of use of multiple implant fill solution containers and a pump for filling an implant.

[0092] Figure 42 is an isometric view of a precision pump with multiple inlets and a single outlet that is used in several embodiments.

[0093] Figure 43 is a cross-sectional view of the precision pump of Figure 42 along line 43-43.

[0094] Figure 44 is a cross-sectional view of the precision pump of Figure 42, along line 44-44, shown in Figure 43.

[0095] Figure 45 illustrates the profiles of a pair of guide surfaces of the precision pump of Figure 42.

[0096] Figures 46A-46E are cross-sectional views of an adjustable cavity precision pump according to an embodiment illustrating operation of the pump in a maximum volume configuration.

[0097] Figures 47A-47E are cross-sectional views of the adjustable cavity precision pump of Figures 47A-46E illustrating operation of the pump in a reduced volume configuration.

DETAILED DESCRIPTION

[0098] Figure 1 illustrates one preferred example embodiment of a tissue dissection tool 1 which may be used to create a cavity for placement of an implant. The device 1 has a proximal handle 2 having a flange 3, which facilitates the manipulation of the tool. As used herein, the terms "device", "tool", and "dissection tool" shall be given their ordinary meaning and shall also be used interchangeably with one another, unless otherwise indicated. Also, as used herein, the term trans-umbilical breast augmentation shall be given its ordinary meaning and it shall also be used to refer to either single or multiple port breast augmentation. A filling line 7 defines a flow path travels at least the length of the tissue dissection tool 1 and may, for example, have a luer fitting 8 adapted to the proximal end of the fill line 7 to enable the attachment of a filling tool (i.e. syringe, volumetric pump). It shall be appreciated that numerous other types of fittings (e.g., press-fit, screw-type, etc.) may also be used in order to connect the filling line to a filling tool. A shaft 4 extends from the handle 2 and carries a balloon 6 adjacent to the distal end of the shaft 4. The distal end of the shaft has an obturator feature 5 which facilitates non-traumatic tissue dissection to occur while the insertion tunnel is being created. Additionally, the obturator feature 5 mechanically secures the distal end of the balloon 6 to the shaft 4. A proximally facing anular surface 150 may cooperate with a distally facing anular surface on collar 152 to define an anular recess 156 which may contain the deflated balloon. The obturator feature 5 may be felt manually through the outer tissue layer and may be used to locate the distal end of the tissue dissection tool 1 as the insertion tunnel is being created. Alternatively, the obturator 5 may be provided with a magnet, light, or any of a variety of alternative human or machine detectable indicium of location, to assist navigation of the tissue dissection tool 1. The balloon 6 is generally deflated during insertion to minimize the size of the balloon during insertion and placement. Once the balloon 6 is in the desired position within the patient, the balloon may then be used for additional tissue dissection, as will be discussed in more detail below.

[0099] Figure 2 illustrates the dissection device 1 with the balloon 6 in an inflated state. Inflation of the balloon 6 while inserted subcutaneously within a patient forces a cavity to form around the inflated balloon 6. The creation of such a cavity allows for subsequent placement of an implant. One advantage of creating a cavity prior to placement of a permanent implant is to relieve the permanent implant from generally having to form the cavity, which may cause damage to the implant, and to facilitate spatial adjustment of the implant.

[0100] Once advanced into the subcutaneous space, the distal end of the tool is not visible to the physician (unless the embodiment comprises a light or other detectable indicium of location). Thus, in some embodiments, an indicator 11 or other feature on the proximal handle 2 is positioned relative to the balloon 6 such that the user can determine the rotational orientation of the balloon 6 subcutaneously. By way of example, the indicator 11 may be a flat feature on the rounded proximal handle 2 (similar to as shown Figure 3) and oriented such that the flat area is generally parallel with the major axis 9 of the inflated balloon 6 (see also Figure 4). Any of a number of visual and/or tactile indicators and their orientation relative to the balloon 6 may be implemented into the devices disclosed herein.

[0101] Figure 4 illustrates in transverse cross section, the non circular profile of the dissection balloon 6. As the balloon 6 is inflated in the retro-mammary or retro-pectoral space, it is desired that the balloon 6 inflates generally laterally to separate the tissue planes effectively without excessively stretching the skin above. To achieve this result, the balloon 6 may be generally elliptical in transverse cross section, having a major 9 and minor axis 10. In general, the balloon 6 will have a length along major axis 9 within the range of from about 4 inches to about 6 inches, including about 4.25 inches, about 4.5 inches, about 4.75 inches, about 5.0 inches, about 5.25 inches, about 5.5 inches, about 5.75 inches, and overlapping ranges thereof. In several embodiments, the balloon length along minor axis 10 is within the range of from about 2 inches to about 4 inches, including about 2.25 inches, about 2.5 inches, about 2.75 inches, about 3.00 inches, about 3.25 inches, about 3.5 inches, about 3.75 inches, and overlapping ranges thereof. In one embodiment, the balloon dimensions are about three inches by about five inches, although other dimensions may be utilized depending upon the size of the corresponding implant.

[0102] Figure 5 illustrates one example of a dissection tool once positioned, for example, subcutaneously via percutaneous access site 158, at generally a tissue dissection site 160. As discussed above, one function of the tissue dissection tool 1 is to separate an external layer of tissue 12 from a substrate layer of tissue 13 to form a cavity at the site.

[0103] Figure 6 illustrates a tissue dissection tool generally after it has been positioned subcutaneously at the tissue dissection site. Furthermore, as shown, the tissue dissection balloon 6 has been somewhat inflated to force the dissection of the external layer of tissue 12 from the subcutaneous layer of tissue 13. Inflation of the balloon 6 bluntly separates

the tissue layers without undue force or shear that could damage surrounding tissue. Moreover, as discussed above, the inflation of the non-spherical balloon limits the stretch of the overlying tissue layers.

[0104] In general, the inflated volume of the tissue dissection balloon 6 will be at least about 250 cc, and typically within the range of from about 250 cc to about 500 cc or more. In several embodiments the inflated volume ranges from about 250 cc to about 300 cc, about 300 cc to about 350 cc, about 350 cc to about 400 cc, about 400 cc to about 450 cc, about 450 cc to about 500 cc, and overlapping ranges thereof. In use, the dissection balloon 6 may also be utilized as an implant sizing tool. For this purpose, a syringe, pump, or other source of inflation media may be provided with a calibrated volume scale to enable measurement of the exact volume of inflation media utilized to accomplish the dissection. Once positioned, the surgeon can introduce a known volume of inflation media into the balloon 6, such that dissection of the tissue layers results, and a cavity is formed. It may be desirable to inflate the balloon 6 to at least about 125%, and in some instances at least about 150% of the volume of the intended implant. Thus it may be desirable to inflate the dissection balloon to a first, desired implant volume based upon aesthetic appearance. After noting the inflation volume, in several embodiments, the dissection balloon is thereafter over inflated to at least about 125% of the intended implant size, before being deflated and removed from the patient. The volume correlated with the desired implant size may then be utilized to select an appropriate implant from a size graduated series of implants.

[0105] Figures 7-9 illustrate additional embodiments of a dissection tool 110 which allows the physician to pass an accessory device through the dissection tool to perform a function at the distal end of the tool (e.g., in the tissue cavity formed). Among other accessory devices, a physician can utilize a tissue cutting tool, irrigation and/or aspiration tool, endoscope or other visualization device to tailor, clean, and/or inspect the cavity produced by the dissection tool 110. In such embodiments, the shaft 111 of the dissection tool 110 includes at least two continuous longitudinal lumens 14, 15 (as shown in Figure 9) which extend axially along the length of the shaft 111. In several embodiments, the diameters of the lumens 14, 15 are the same. In several embodiments, the dissection device is modular, thereby allowing a shaft 111 having lumens of varying diameter to be used. For example, in some embodiments, the lumen diameter required to pass first device (a cutting device) is distinct from a second lumen diameter

required to pass a second device (e.g., an irrigation device) or to conduct irrigation or aspiration. Thus, in some embodiments, based on physician preference, a shaft 111 having internal lumens 14, 15 of the size required to accommodate the accessory devices or functions preferred by that physician may be connected to the proximal handle and distal end of the dissection tool.

[0106] The dissection tool 110 may also be provided with a deflectable distal zone, to facilitate separation of adjacent tissue planes within or below the breast, without requiring a lateral sweeping of the length of the access cannula. For example, a distal zone having a length of at least about 2 cm or 4 cm and generally no more than about 10 cm or about 12 cm may be provided with a laterally flexible side wall. This may be accomplished by providing a plurality of transverse slots extending around at least about 50% of the circumference of the cannula from a first side of the cannula, leaving a relatively axially incompressible spine on an opposite side of the cannula. One or two or more axially reciprocally movable control elements such as pull wires are attached to the cannula at or beyond the distal end of the deflectable zone and extend proximally to a control carried by the proximal end of the cannula. Proximal retraction of a pull wire can cause axial compression of the slotted side of the cannula, resulting in lateral deflection of the deflectable zone. Deflection can be accomplished through an angle of at least about 45 degrees, and in some embodiments at least about 90 degrees from the linear axis of the cannula, in either one or both directions. Sweeping the deflection zone back and forth at the desired implant site may be accomplished as a site preparation step prior to implant deployment.

[0107] The distal tip of the dissection tool comprises at least one distal opening 31 (see Figure 8) that is in communication with at least one of the longitudinal lumens 14, 15. By way of example, the larger lumen 14 may be used as a pathway for an endoscope or other tool to travel through the dissection tool 110 and exit the distal end through the distal opening 31 for viewing the creation of a subcutaneous cavity, conducting a biopsy or lumpectomy, or other diagnostic or therapeutic procedure. The proximal handle 113 of the dissection tool 110, may have at least one proximal opening 16 to allow the insertion of various items (such as, for example, an endoscope) to be inserted into at least one of the longitudinal lumens 14, 15 extending through the shaft 111. By way of further example, an inflation line 114 may be in communication with to the second longitudinal lumen 15 to allow fluid (e.g., gel, saline, water, or gas) to be delivered to the balloon. Thus, the distal end of inflation lumen 15 is in fluid communication with the balloon 6 in several embodiments.

[0108] Figures 10-15 illustrate several embodiments of an implant delivery tool 18 for facilitating subcutaneous insertion of a device (e.g., an implant) into a patient (see Figure 10). In some embodiments, the implant delivery tool is a multi-part tool comprising an hollow, tubular, outer cannula 21 comprising a proximal handle 24 having a flange 25 and a distal tip 26. The outer cannula 21 is configured to receive a push rod comprising a longitudinal shaft 30 that is dimensioned to travel within the inner diameter of the outer cannula 21. The push rod further comprises a proximal handle 29. As described below, activation (e.g., distal advancement) of the push rod within a cannula 21 having an implant loaded therein can be performed by a physician to accomplish ejection of the implant from the distal tip of the cannula into the target site of a subject.

[0109] The distal tip 26 of the outer cannula 21 has an opening for removably receiving an implant therein. The implant is loaded into the central lumen contained within the distal end 26 of the outer cannula 21 of the implant delivery tool 18 (for clarity, this chamber is not expressly illustrated). Preferably, the implant is loaded into the chamber by the physician or other personnel at the clinical site, rather than at a remote point of manufacture. By loading the implant into the distal end of the delivery tool 18, the axial length of travel of the implant within the central lumen of delivery tool 18 during the deployment step can be minimized. Minimizing the travel distance within the implant delivery tool 18, along with the coatings described elsewhere below, enhances control and reduces damage to the implant during the implant deployment process.

[0110] The distal opening to the implant chamber is preferably removably covered, to facilitate distal advance through the tissue tract while reducing trauma (e.g., coring) of the surrounding tissue, as will be appreciated by those of skill in the art. In the illustrated embodiment, the cannula 21 has a generally beveled face 115 with a cover such as an elastomeric membrane116 (see e.g., Figure 11C). In several embodiments, the elastomeric cover 116 has a slit 27, which generally aligns with the longitudinal axis of the outer cannula 21. Both ends of the slit 27 terminate in a circular cut out 34, which facilitates the opening of the slit to allow ejection of the implant from the delivery device to the implant site. Moreover, the circular cutouts reduce the tendency for the slit 27 to rip during the ejection process.

[0111] As described above, delivery tool 18 comprises a push rod (see Figure 11B, the push rod is identified as element 28) which longitudinally travels within the external cannula

21 once the distal end of the push rod is inserted into the proximal opening 36 (the proximal opening of the outer cannula 21 is illustrated in Figure 13) of the outer cannula 21. The push rod consists of a longitudinal shaft 30 with a proximal handle 29 to facilitate the manipulation of the push rod, which may be used to eject a device (e.g., an implant) from the, for example, implant delivery tool 18. As shown in Figure 11B, the push rod 28 comprises a distal radially outwardly extending flange 32 that is slightly smaller in diameter than the internal diameter of the central lumen 35 extending throughout the length of the outer cannula 21 (see e.g., Figure 13). Longitudinal movement of the push rod in a proximal to distal direction causes the distal surface of the flange to contact the proximal end of an implant within the distal portion of the outer cannula, thereby further assisting in the ejection of a device (e.g., an implant) from, for example, the implant delivery tool 18.

[0112] A radially inwardly extending slot 33 in the peripheral edge of the flange 32 and partially along the longitudinal axis of the shaft 30 enables the accommodation of, for example, an implant fill line 38 (see, for example, Figure 15). A luer fitting (or other appropriate type of fitting) 39 may be adapted to the proximal end of the implant fill line 38 to allow the attachment of a syringe or other suitable fluid filling device. The distal end of the fluid fill line 38 connects to an implant 37.

[0113] In several embodiments, the internal surface which defines the central lumen 35 of the outer cannula is coated with a material 40 (e.g., hydrogel coatings, saline copolymer coatings, parylene, PTFE), along at least a distal portion thereof (e.g., the portion wherein an implant would be positioned), which dramatically decreases the coefficient of friction between the implant 37 and the internal surface of the outer cannula. In addition to coatings on the interior surface of the outer cannula which interfaces with an implant, in some embodiments, a coating (or coatings) are applied to at least a portion of the outer surface of the outer cannula in order to facilitate easy insertion and maneuverability of the cannula through the surgical pathway made by the dissection tool. In such embodiments, a slippery (e.g., low-friction) surface is provided on at least a portion of the cannula through use of one or more biocompatible coatings or materials that are suitable for tissue contact but that will leave little or no residue on the tissue after removal of the tool. By way of example, suitable materials for achieving low coefficients of friction include, but are not limited to, hydrogel coatings, saline copolymer coatings, or polyvinylpyrrolidone/polyvinyl acetyl polymer blends and others disclosed herein.

[0114] In addition, at least a portion of the surface of the implant may be provided with a corresponding friction reducing coating, for reducing frication between the implant and the cannula 21. The width of the coating, measured transversely to the longitudinal axis of the cannula 21 may be less that about 150%, often less than about 110%, and in some embodiments, between about 50% and 110% of the circumference of the implant when in the rolled configuration for placement within the cannula 21.

[0115] Figure 16 illustrates one example of the implant 37 at least partially deployed from the implant delivery tool 18. The deployment of the implant 37 from the implant delivery tool 18 is accomplished by advancing the internal push rod by application of proximal to distal force on the push rod handle 29, causing the push rod to move longitudinally through the delivery tool 18 and forcing the implant 37 to distally advance. Once the push rod has forced the implant 37 to become completely deployed from the implant delivery tool 18, the implant may then be further positioned and filled for permanent implantation. Furthermore, the implant 37 is preferably deployed generally into the cavity previously formed by a tissue dissection tool (such as the tissue dissection tool 1 described above).

[0116] Figs. 17 and 18 illustrate an additional embodiment of an implant delivery tool (depicted as 41 in Figure 17). Prior to delivery (e.g., implantation) of an implant to a target site in a patient, an implant is pre-loaded in a tubular cavity 45 contained within the distal end 42 of the implant delivery tool 41. In several embodiments, as shown in Figure 17, the extreme distal end 43 of the implant delivery tool comprises an ejectable tip 44. The ejectable tip, is secured to the implant delivery tool 41 with a core wire, central tubular support or other flexible or rigid tether 46 (see, e.g., Figure 18). The ejectable tip 44 facilitates insertion of the implant delivery tool and prevents any dislodged pieces of tissue from becoming trapped in the distal tubular cavity 45. The ejectable tip 44 may readily eject from the distal end of the implant delivery tool 41 as the implant is ejected from the implant delivery tool 41.

[0117] Figures 19-22 illustrate an additional implant delivery tool (shown as 47 in Figure 19). As shown generally in Figure 19, the delivery tool 47 comprises a proximal handle 48 attached to a longitudinal shaft 118. An outer sheath 50 over the shaft 118 terminates near the distal end 51 of the tool. The outer sheath 50 includes a generally circular aperture 52 at its distal end (element 49, which is shown in more detail in Figure 20). A plurality of distal petals 54 extend from the longitudinal shaft 118 are curved with generally non-traumatic distal ends 53.

The petals protect at least a portion of the rolled breast implant 55 (see, e.g., Figure 22). When the outer sheath 50 is proximally retracted by the physician relative to the petals 54, the rolled implant 55 is revealed and distally ejected through the petals 54 into the retro-mammary or retro-pectoral space.

[0118] Figure 23 illustrates another embodiment of an implant delivery tool (shown generally as 55) which includes a beveled distal tip 119 that facilitates insertion of the delivery tool and placement of an implant. A flap 57 covers the open distal beveled tip 119 and further facilitates insertion of the implant delivery tool 55. Additionally, the flap 57 serves to generally prevent tissue, blood or other body fluids from entering the distal end of the implant delivery tool 55 as it becomes inserted into a retro mammary space or retro-pectoral space. A flange 58 (see Figures 24 and 26) on the inner portion of the flap 57 keeps the flap centered and properly located on the beveled distal tip 119 The flange 58 at least partially mates with the inner diameter 59 of the implant delivery tube 59.

[0119] Figures 27 through 29 illustrate alternate distal tip configurations. It shall be appreciated that the devices disclosed herein are readily combinable by one of ordinary skill in the art. In other words, one of ordinary skill in the art could select a distal tip, shaft, and proximal handle that are best suited to the implant procedure to be performed and/or based on her preference. The distal tips shown in Figures 27 through 29 have a generally hemispherical shape. In several embodiments, a plurality of longitudinal cuts 64 through the distal tip 62 facilitates the ejection of an implant from the distal tip 61 of the implant delivery tool. As the rolled implant 65 is ejected from the delivery tool, the cuts 64 allow the distal tip 62 to flare open (shown in Figure 28 as element 63) thereby allowing the rolled implant 65 to be completely ejected from the distal tip 61 of a delivery device. The delivery device is withdrawn generally simultaneously with the ejection of the implant 65 in order to deposit the implant 65 into the preformed cavity (for example, as described above).

[0120] Figures 30 and 31 illustrate various embodiments of a blunt tipped needle 66 delivering an anesthetic to the trans-umbilical tunnel prior to insertion of a tissue dissection tool. For example, a syringe 67 adapted to be connected to the blunt tipped needle 66 may be filled with a xylocaine/epinephrine mixture 68. By way of further example, the needle 66 may be approximately 12 gauge in diameter and at least about eight inches long. The needle may have a

closed distal tip 69 with a plurality of holes 70 through the sidewall along a delivery zone to allow the anesthetic mixture 68 to flood the subcutaneous region.

[0121] Figure 32 illustrates one embodiment of a delivery system 71 used to mix a solution (e.g., a filling media) and subsequently (or simultaneously) fill an implant. In several embodiments, the delivery system comprises an apparatus 75 for holding a material solution chamber 72. The apparatus 75 may be attached to a portable I.V. pole 76 or other such device that is easily positionable near the patient. A delivery line 77 attaches to the solution chamber 72 mixing nozzle 79 to allow the implant filling material to be delivered to the implant 78 which has been inserted and positioned within a patient. In several embodiments, a hydraulic foot pedal 73 may be connected to the apparatus 75 (via a hydraulic or gas cylinder 74) to allow the physician to mix and deliver the implant filling material to the implant within the patient.

[0122] Figure 33 further illustrates the delivery system. In one embodiment, a hydraulic cylinder 74, attached to the delivery apparatus 75, is connected to a hydraulic foot pedal 73 via a high pressure hydraulic line 82. The implant 78 illustrated in Figure 33 is shown unrolled, as it would be after ejection from a delivery device and prior to inflation. The implant 78 generally comprises first and second side walls, having a general circular periphery. The first and second side walls are bonded together along the periphery, to form an enclosure. At least one valve is provided in communication with the enclosed volume, for permitting filling with, but resisting the escape of, inflation media. In the illustrated embodiment, the delivery line 77 is removably connected to a fill port 101 which is positioned at the center of the first side wall. The fill port may be positioned elsewhere on the implant, such as on the peripheral edge of the implant so that the delivery line extends away from the implant within the plane of the deflated implant. The fill port may be provided with any of a variety of valves, for permitting infusion of inflation media into the enclosed chamber but resisting escape of inflation media following removal of the delivery line 77. Any of a variety of duckbill valves, flap valves collapsible tubular valves and the like may be utilized, taking into account the desire to optimize the function of the valve while minimize the ability to tactilely detect its presence.

[0123] Figures 34-35 illustrate various mixing nozzle 79 embodiments. In one embodiment, the mixing nozzle 79 has a proximal, female threaded end 83, which may attach to a male threaded distal fitting 91 on the distal end of the solution chamber 72 (see Figure 36). The mixing nozzle consists of a hollow cylindrical structure 85 which contains a series of baffles

87 along the length of its interior 86. The distal tip 84 of the mixing nozzle 79 is designed to connect to the implant fill line 77.

[0124] Figures 36-37 illustrate features of the filling material solution chamber 72. In several embodiments, the implant filling material may comprises two components. In several embodiments, the material solution chamber comprises two associated chambers, one chamber for each of the solutions. Each chamber 80, 81 includes of a cylindrical or other geometry storage lumen 92, 93 with a plunger opening 89 for the placement of a drive plunger 102. Each lumen 92, 93 has associated distal openings 90 which feed into an either permanently affixed or removable mixing nozzle 79. Markings 88 on the external surface of the solution chamber 72 are used to indicate the volume of implant filling material that has been delivered to the implant positioned within patient. In several embodiments, distinct containers are used to house an implant filling material that comprises two solutions. A non-limiting example is shown in Figure 41. In several embodiments, first 165 and second 170 sterilizable container (e.g., IV bags bottles, tubes, etc.) are used to contain a first 165' and second 170' solution. In some embodiments, the containers are disposable, while in other embodiments, they can be cleaned, re-sterilized, and re-filled. In some embodiments, the containers are positioned in an elevated position via a support device 175 (e.g., an IV pole, an elevated counter, etc.) in order to gravity feed the contents of each container to a central mixing area. In several embodiments, the distinct containers feed into the dual chamber described above. This is advantageous, in some embodiments, as the chamber is the only portion of the system that needs to be cleaned and sterilized. A physician can then purchase the desired type and amount of the two solutions in pre-sterilized containers.

[0125] In other embodiments, a pump 180 draws the filling solution from the first 165 and second 170 containers (via solution feed lines 166 and 171, respectively) and into a receiving/mixing chamber 181. The action of the pump thus serves not only to draw up the two solutions, but also to mix the two solutions. In some embodiments, a single exit line from the pump mixing chamber is directly connected to an implant 78 via an implant fill line 77. In other embodiments, the exit line from the pump mixing chamber is fluidly connected to a mixing nozzle comprising baffles, as disclosed herein, in order to provide additional mixing of the two solutions during delivery to the implant. In several embodiments, the pump also functions as a metering device. In some embodiments, the pump can be pre-set to receive and deliver a pre-

determined amount of implant fill solution. Thus, in some embodiments, the pump controls the final volume delivered to an implant by shutting off after a specific, pre-determined volume of fill solutions has been passed through the pump. In some embodiments, the physician can fine-tune the total volume, in order to achieve a desired final look and/or feel of an implant. In several embodiments, the pump is switch-actuated. In one embodiment, the switch is a foot switch 73 (e.g., a foot pedal). In one embodiment, the switch is a hand or finger switch.

[0126] Figs. 42-44 illustrate a non-limiting embodiment of a precision pump 400. The precision pump 400 is a volume displacement pump wherein a cavity is formed between a pin 401 and a piston 402. A barrel cam feature 403 at one end or along the length of the piston 402 controls the linear translation of the piston 402 along its central axis. Although shown in this embodiment as having a barrel cam 403 which assists in controlling the linear translation of the piston 402 along its central axis, other driving mechanisms can be implemented in some embodiments. As the piston axially travels away from the pin 401, a cavity 404 is formed. As illustrated in Figures 42 and 43, the precision pump 400 can include more than one inlet port 440, 441 for enabling the addition of more than one type of fluid to enter through different inlet ports and fill the cavity 404 (best shown in Fig. 43). Once the fluids are contained within the cavity 404, the fluids are able to mix and subsequently dispense out of the outlet port 442. Although precision pump 400 is shown as having two inlet ports and a single outlet port, other numbers of inlet ports and outlet ports may be incorporated into the system in some embodiments.

[0127] The axial translation of the piston 402 determines the size of the cavity 404, and thus the volume of fluid which will be transferred from each of the inlet ports 440, 441 to at least one of the outlet ports 442. By way of example only and as illustrated in Fig 44, rotation of the motor or input shaft 407 (which is coupled to the piston 402) can be transferred to the to the piston 202. The barrel cam 403 can urge axial translation of the piston 402 as the piston 402 rotates. During one complete revolution of the motor shaft 407, the piston 402 axially and rotationally travels. As the piston 402 axially and rotationally travels, the fluid pathway 412 in the valve seal 410 is aligned with each of the inlet ports 440, 441 and outlet port 442. Various fluids are allowed to enter the cavity 404 as the fluid pathway 412 is aligned with each of the inlet ports 440, 441. The various fluids are able to mix while contained in the cavity and then subsequently dispensed out of the outlet port 442 when the fluid pathway 412 is aligned with the

outlet port 442. The filling and dispensing of the cavity 404 is in part due to the axial translation of the piston 402.

[0128] The amount of fluid drawn into the cavity 404 from each of the inlet ports 440, 441 can be varied to meet the desired volume ratios of fluids to be mixed within the cavity 404. The amount of fluid drawn into and dispensed from the cavity 404 can be varied by adjusting the profile of the guide surfaces 454, 456. For example, greater deviations of the tangent of the guide surface from perpendicular to the axis of rotation of the cam 403 over the portion of the cam 403 that interacts with the pin 458 during alignment of the pocket 411 with an input or output can result in larger draws into or dispensings from the cavity 404.

[0129] Figure 45 illustrates exemplifying profiles of guide surfaces 454, 456. The profiles of the guide surfaces are represented in Figure 45as though the guide surfaces, which extend around the circumference of barrel cam 203, were laid flat. Thus, the guide surfaces 454, 456 appear in Figure 45 to have ends, when in fact they are continuous (in the illustrated embodiment).

[0130] The guide surfaces 454, 456 of Figure 45 are configured to draw fluid into the cavity 404 from two inlets and dispense fluid through one outlet. Where the pin 458 interacts with the vertical portions (as Figure 45 is oriented) of the guide surfaces, fluid is neither drawn into nor dispensed from the cavity 404. These vertical portions correspond to orientations of the seal 410 and piston 402 where the first pocket 411 is in fluid communication with no outlet or inlet. When the first pocket 411 and fluid pathway 412 are in fluid communication with an inlet or outlet, fluid can be drawn into or dispensed from the cavity. The rate of fluid draw or dispensation is influenced by the deviation of the tangent of the guide profile from vertical (again, as Figure 45 is oriented). A greater deviation from vertical causes the piston 402 to translate axially more rapidly as the pin 458 moves over that portion of the guide surface 454, 456. Therefore, the amount of fluid drawn into or dispensed from any port can be determined by alteration of the profile of the guide surface over that portion of the guide surfaces that interacts with the pin 458 when the fluid pathway is in fluid communication with that port. Thus, the amount and rate of transfer of fluid between inputs and outputs can be programmed by the profile of the guide surfaces 454, 456.

[0131] Preferably, the pin 458 engages only one of the guide surfaces 454, 456 at a time. Thus, although the spacing between the guide surfaces is shown to be generally constant in

Figure 45, other configurations can result in the same translation of the piston 402 as it rotates. In some embodiments, a constant or generally constant spacing between the guide surfaces, for example as shown constant in Figure 45, can allow the transfer rate of fluid in forward and reverse operation of the pump to be the same or substantially the same. In some embodiments, the spacing between the guide surfaces can vary along the guide surfaces such that forward and reverse operation of the pump transfer fluid at different rates.

[0132] Although shown in this embodiment to have a single outlet port 442, the precision pump 400 can have more than one outlet port. A precision pump 400 with more than one outlet port can be configured or controlled so that various volumes are dispensed from each of the outlet ports which can be useful in a number of different applications (e.g. biologics assays, laboratory analysis).

[0133] The housing 420 can comprise a passage 428 to permit venting of the housing. Venting the housing can, in some embodiments, prevent or inhibit pressure from developing within the housing that would interfere with the desired movement of the piston 402.

[0134] The pin or plunger 401 can be fixed to the housing 420 by a rod or screw advanced through the hole 429.

[0135] Figs. 46(A)-(E) and 47(A)-(E) illustrate an exemplifying embodiment of a precision pump 800 wherein a cavity adjustment feature enables the adjustment of the maximum volume of the cavity formed within the pump. The pump 800 comprises a spring loaded piston post or pin 801 that dictates the volume of the cavity formed within the precision pump 800 and can be adjusted to reduce or enlarge the cavity 804 formed at the furthest (retracted) extent of the stroke piston 802. Therefore, the volume of fluid that is transferred through the precision pump 800 with each stroke of the piston can be tuned or calibrated to the desired dispensing volume.

[0136] The precision pump 800 comprises a spring-loaded pin or plunger 801. The pin or plunger 801 is movably positioned within the housing 820. A cap, plug, or stop 818 is adjustably attached to the housing 820. A spring 816 is positioned within the housing 820 to engage the stop 818 and the pin 801 on a side of the pin that is opposite the piston 802, and urges the pin 801 toward the piston 802.

[0137] The pin 801 and stop 818 can be configured such that when the pin 801 is fully advanced the pin is seated against stop 818. For example, the pin 801 can comprise a shoulder 822 and the stop 818 can comprise a rim 824, the shoulder and the rim being sized and

shaped to engage one another when the pin 801 is advanced by the spring 816 toward the rim 824. Thus, movement the stop 818 into or out of the housing 820 adjusts the maximum distance the pin 801 can advance in the direction of the piston 802.

[0138] Figures 46(A) and 47(A) show the piston 802 in a position of farthest advancement toward the stop 818. Figures 46(B) and 47(B) show the piston 802 in a position retracted from the position of farthest advancement toward the stop 818. Figures 46(C) and 47(C) show the piston 802 in a position farthest retraction from the pin 801. Figures 46(D) and 47(D) show the piston 802 in a position advanced toward the pin 801 from the position of farthest retraction from the pin 801. Figures 46(E) and 47(E) illustrate the piston 802 returned to the position of farthest advancement toward the stop 818.

[0139] Figures 46(A)-(E) illustrate operation of the pump 800 when the stop 818 is adjusted for transfer of a maximum volume of fluid. As illustrated in Figure 46(E), when the piston 802 is at its most advanced position in the direction of the stop 818, the cavity 804 has closed and has no volume, or approximately no volume.

[0140] Figures 47(A)-(E) illustrate operation of the pump 800 when the stop 818 is adjusted for transfer of less than a maximum volume of fluid. As illustrated in Figure 47(D), before the piston 802 is at its most advanced position in the direction of the stop 818, the cavity 804 has closed and has no volume, or approximately no volume. If the spring-loaded pin or plunger 801 engages the piston 802 and the piston 802 is advanced toward the stop 818, the plunger 801 will move with the piston 802 against the force of the spring 816 to retract into a recess in the stop, as illustrated in Figure 47(E), for example.

[0141] The stop 818 can comprise threads that cooperate with threads of the housing 820 for adjustment of the stop 818 relative to the housing 820. Other types of connections between the stop 818 and the housing 820 can be used in some embodiments.

[0142] The stop 818 can be adjusted during manufacturing for precision of fluid transferred with each revolution then fixed or be adjustable by a user to vary the rate of flow of the pump. In some embodiments, a fluid flow meter can be connected to an outlet of the pump and the stop 818 can be adjusted until the desired flow rate is attached. In some embodiments, the maximum volume of the cavity can be adjusted during operation of the pump. In some embodiments, the pump can comprise indicators corresponding to specific fluid flow rates to facilitate adjustment after manufacturing.

[0143] In addition to the containers described above being disposable (e.g., single-use), in several embodiments, the pump is also single use. Kits comprising the fluid components, all necessary tubing, the fluid containers, the pump, and one or more implants may be purchased. Alternatively each of these elements may be purchased independently. Additional information on pumps that are suitable for use in several embodiments of the disclosed methods, devices, and systems may be found in International Application PCT/US2010/051707, which is incorporated in its entirety by reference herein.

[0144] In several embodiments, the pump is advantageous in that it is disposable, and an entire new set of equipment that comes in contact with the implant fill solution may be purchased as a pre-sterilized kit. For example, a kit may comprise, in several embodiments, a pair of sterile hydrogel component containers (e.g.,. component A and component B), fluid lines for conveying component A and component B to a pump, a pump, an implant fill line, and an implant. In several such embodiments, all of the above recited components are pre-sterilized, thereby increasing ease of use by and end-user.

[0145] Figure 38 illustrates one example of a loading technique for positioning the material solution chamber within the delivery apparatus 75. Stabilizer plates 94, 95 for the stabilization of the mixing nozzle 79 are slideably positionable along a central support such as chassis plate 97 of the holding apparatus 75 into a loading position. When the plates are positioned in the loading position (shown in Figure 38), the solution chamber 72 can be lifted to a position which allows the solution chamber to be inserted upward (arrow 97) and inward (arrow 98) into the apparatus 75. The stabilizer plates 94, 95 are then returned which secures the solution chamber 72 to the apparatus 75, thereby allowing operation of the delivery system (e.g., via the foot pedal) to allow the filling material solution to be delivered to the patient. See Figure 39.

[0146] Figures 39-40 illustrate methods for regulating the amount of filling material delivered to the patient's implant 78. By way of example only, each completed stroke of the hydraulic foot pedal 73 delivers a precise, predictable unit volume of filling material to the patient's implant 78 via the delivery line 77. For example, each stroke of the foot petal may deliver a unit volume within the range of from about 5 cc or about 10 cc to about 50 cc. The delivered volume per stroke may be adjustable, to accommodate different physician preference. For example, in several embodiments, the stroke volume can be about 25 cc, about 50 cc, about

75 cc, about 100 cc, about 150 cc, or greater. In addition, the stroke volume can be adjusted in fine increments to achieve small differences in filling volumes between implants (e.g., to account for variations in tissue thickness between a patient's left and right breast and achieve a uniform look). In any event the total volume delivered to the implant may be determined by visually observing the volumetric scale appearing on the side wall of chambers 80 and/or 81, or on the side wall of the solution chamber 72 or by a volume indicator located anywhere else along the length of the flow path between the source of inflation media and the patient.

[0147] In several embodiments, a relief syringe 99 is attached to a drain valve 100 (see figure 40) in the filling material delivery line 77. In order to allow fine tuning of the eventual implant size, or release overfill volume, material may be withdrawn from the implant by inducing suction with the relief syringe 99. The excess filling material may be drawn into the relief syringe 99 and subsequently disposed.

[0148] The various components of the delivery system are provides in for sale individually and/or in kits. For example, one time use disposable dual chamber solution containers 72 may be preloaded at the point of manufacture with a desired volume of media and packaged together with a mixing chamber. The prefilled volume of inflation media in the container may correspond to the maximum likely volume for a given procedure, or containers may be obtainable having different preload volumes. In several embodiments, containers (e.g., IV bags, bottles, tubes, etc.) containing presterilized inflation media are provided to an end user of the system. In other embodiments, containers containing presterilized inflation media are available for purchase distinct from the delivery system.

[0149] The sizing balloon, delivery device and implant may be packaged as a kit, separate from one another or together with a container of inflation media and mixing chamber.

[0150] In several embodiments, these kits and systems are particularly advantageous, from the perspective of the physician, a supplier, and a patient. From the physician perspective, the single port breast augmentation is a simple procedure which reduces the risk of patient scarring, implant damage, and other complications. An increased demand for the procedure results, in several embodiments, as well as an ability for the physician to increase the number of procedures safely performed. From a patient perspective, the single port breast augmentation methods and systems disclosed result in less scarring, reduced risk of implant rupture (due to the implantation and subsequent filling of an implant), increased safety in the event of a rupture (in

those embodiments employing a bioabsorbable hydrogel), reduced cost, procedure time and recovery time, among other benefits (such as more natural look and feel of the implants). From a supplier perspective, a simple, multi-component system provides the opportunity to sell the components individually as needed, or market the system together as a whole. Advantageously (for all three parties), the ability to provide or receive a complete, pre-sterilized, disposable, system reduces risks to the patient (procedure is simpler and safer), risks to the physician (decreased burden of maintaining multiple components or requirement for sterilization equipment), and risks to the supplier (mixing and matching of multi-supplier components which may not be optimized). Thus, several embodiments of the methods and devices disclosed herein answer the long-felt, but previously unmet need, for safe, natural feeling and looking, low-scarring breast augmentation.

WHAT IS CLAIMED IS:

1. A device for the delivery of an implant to a subject, said device comprising:

an elongate outer cannula comprising:

a distal end,

a proximal end, and

an interior lumen,

wherein said distal end of said outer cannula comprises a passageway for receiving an implant and allowing expulsion of said implant to a target tissue space,

wherein said proximal end of said outer cannula comprises a passageway to receive at least the distal end of a push rod, and

wherein said interior lumen is configured to allow longitudinal movement of a push rod within said lumen; and

an elongate push rod comprising:

a distal pushing surface,

a proximal handle, and

an interconnecting shaft positioned between the distal pushing surface and the proximal handle,

wherein said distal pushing surface is dimensioned to be positioned within said interior lumen of said outer cannula,

wherein application of force to said proximal handle of said push rod causes said push rod to slide longitudinally within said lumen of said outer cannula.

2. The device of Claim 1, wherein at least one of the outer surface of the outer cannula and the inner surface of the interior lumen comprises a low-friction coating to facilitate delivery of the implant.

3. The device of Claim 2, wherein the low-friction coating comprises at least one of hydrogel coatings, silane copolymer coatings, and polyvinylpyrrolidone/polyvinyl acetyl polymer blends.

4. The device of Claim 1, wherein said distal end of said outer cannula comprises a beveled tip.

5. The device of Claim 4, wherein said beveled tip of said outer cannula is covered by an elastomeric cover.

6. The device of Claim 5, wherein said elastomeric cover comprises at least one slit to allow passage of an implant through said elastomeric cover.

7. The device of Claim 1, wherein said distal pushing surface of said push rod is carried by a cylindrical element positioned to allow longitudinal movement of the push rod within the lumen of the outer cannula.

8. The device of Claim 1, wherein said distal pushing surface comprises at least one slot configured to allow passage of an implant fill tube through said distal pushing surface.

9. The device of Claim 1, wherein said distal tip of said outer cannula comprises an ejectable tip tethered to said device.

10. The device of Claim 9, wherein ejection of said ejectable tip opens the distal tip of said outer cannula to allow expulsion of an implant into a target tissue space.

11. The device of Claim 1, wherein said outer cannula is movable in a longitudinal direction relative to the distal most tip of the device.

12. The device of Claim 11, wherein said distal tip of said outer cannula comprises a plurality of petals that are reversibly radially expandable and collapsible in a direction perpendicular to the longitudinal axis of the outer cannula.

13. The device of Claim 12, wherein said plurality of petals collapse or expand in response to said longitudinal movement of said outer cannula.

14. The device of Claim 13, wherein expansion of said petals occurs in response to movement of the outer cannula in a distal to proximal direction, and wherein said expansion allows expulsion of an implant from the device to into a target tissue space.

15. A system for the delivery of an implant to a target tissue space and filling of said implant, the system comprising:

an implant suitable for delivery to a target tissue space,

wherein said implant is suitable for filling after being positioned in said target tissue space;

an implant delivery device according to any one of Claims 1-12,

an implant fill line,

wherein said implant fill line is reversibly connected to said implant;

an implant filling solution chamber comprising an implant filling material,

wherein said implant filling solution chamber is in fluid connection with said implant via said implant fill line,

a pressure source,

wherein said pressure source is suitable for activation by a user in order to provide pressure to said implant filling solution chamber,

wherein activation of said pressure source causes said implant filling material to move from said implant filling solution chamber through said implant fill line and into said implant.

16. The system according to Claim 15, wherein said implant filling solution chamber is suitable for holding a pre-mixed hydrogel, individual unmixed hydrogel components, saline, silicone, silicone, silicone cross-linking solutions, or combinations thereof.

17. The system according to Claim 15, wherein said implant filling solution chamber comprises at least two individual chambers.

18. The system according to Claim 17, further comprising an implant fill nozzle comprises internal baffles configured for mixing of said at least two solutions during filling of said implant.

19. The system according to Claim 15, wherein said pressure source comprises a hydraulic pressure system.

20. The system according to Claim 15, wherein said pressure source is suitable for delivery of a precise, predictable unit volume of filling material

21. The system according to Claim 15, further comprises an apparatus for securely holding said implant filling solution chamber.

22. The system according to Claim 15, further comprising a relief valve in said implant fill line.

23. A soft tissue dissection tool comprising:

a proximal end comprising a handle for manipulation of the device,

a blunt distal-most end;

an intermediate shaft communicating with said proximal end and said distal end;

a reversibly inflatable balloon positioned proximal to said distal-most end; and

fluid communication line in communication with said reversibly inflatable balloon.

24. The dissection tool of Claim 23, further comprising an indicator feature, wherein said indicator feature is suitable for indicating the orientation of the distal portion of the device.

25. The dissection tool of Claim 24, wherein said indicator comprises a notch in said proximal handle.

26. The dissection tool of Claim 24, wherein said indicator comprises a light source in said distal-most end of said tool.

27. The dissection tool of Claim 24, wherein said indicator comprises a magnet in said distal-most end of said tool.

28. The dissection tool of Claim 23, wherein said reversibly inflatable balloon has an ellipsoid shape upon inflation.

29. The dissection tool of Claim 23, wherein said reversibly inflatable balloon has inflated volume that is up to about 200% of the volume of an implant to be implanted in the tissue dissected by the tool.

30. A method of preparing a tissue target space for subsequent implantation of an implant comprising;

introducing into the subcutaneous space of a subject a dissection tool according to any one of Claims 23-29;

advancing the distal end of said dissection tool along a subcutaneous pathway until the distal end of said dissection tool reaches a desired target tissue site;

introducing an inflation media to said reversibly inflatable balloon,

wherein introduction of said inflation media causes inflation of said reversibly inflatable balloon,

wherein inflation of said reversibly inflatable balloon separates the tissue above said balloon from the tissue below said balloon, thereby creating a target tissue space for subsequent implantation of an implant;

recovering said inflation media from said reversibly inflatable balloon,

wherein said recovery causes deflation of said reversibly inflatable balloon; and

withdrawing said dissection tool, thereby preparing a tissue target space for subsequent implantation of an implant.

31. The method of Claim 30, wherein said target tissue space is one of the retro-pectoral, or retro-mammary space and said dissection tool is introduced in the umbilical region.

32. The method of Claim 31, wherein said target tissue space is prepared for the subsequent implantation of a breast implant.

33. The method of Claim 32, wherein said target tissue space is prepared in a female subject.

34. The method of Claim 30, further comprising preparing a second target tissue space for implantation of a second implant.

35. The method of Claim 30, further comprising delivering an implant to said target tissue space by a method comprising:

positioning an implant in an implant delivery device;

directing the portion of said implant delivery device containing said implant into said prepared target tissue space;

removing the implant from said implant delivery device in order to implant said implant in said target tissue space; and

withdrawing said implant delivery device.

36. The method of Claim 35, further comprising filling said implant.

37. The method of Claim 36, wherein said implant is filled with an implant fluid solution selected from the group consisting of a hydrogel, saline, silicone oil, silicone gel, silicone elastomer, and cross-linked silicone.

38. The method of Claim 37, wherein said implant is filled with a hydrogel, wherein said hydrogel comprises two unmixed parts, and wherein said two parts are mixed during the implant filling process.

39. The method of Claim 35, wherein said the implant delivery device comprises:

an elongate outer cannula comprising:

a distal end,

a proximal end, and

an one interior lumen,

wherein said distal end of said outer cannula comprises a passageway for receiving an implant and allowing expulsion of said implant to a target tissue space,

wherein said proximal end of said outer cannula comprises a passageway to receive at least the distal end of a push rod, and

wherein said interior lumen is configured to allow longitudinal movement of a push rod within said lumen; and

an elongate push rod comprising:

a distal pushing surface,

a proximal handle, and

an interconnecting shaft positioned between the distal pushing surface and the proximal handle,

wherein said distal pushing surface is dimensioned to be positioned within said interior lumen of said outer cannula,

wherein application of force to said proximal handle of said push rod causes said push rod to slide longitudinally within said lumen of said outer cannula.

40. A method for the trans-umbilical augmentation of a breast, comprising:

creating an incision in the umbilical region of a subject,

introducing a dissection tool according to Claim 22 into the subcutaneous space of said subject via said incision;

creating a pocket in the breast of said subject;

withdrawing said dissection tool;

delivering an un-filled implant to said pocket;

filling said implant;

closing said umbilical incision.

41. The method of Claim 40, wherein said implant is filled with a hydrogel.

42. The method of Claim 40, wherein said implant is filled with saline.

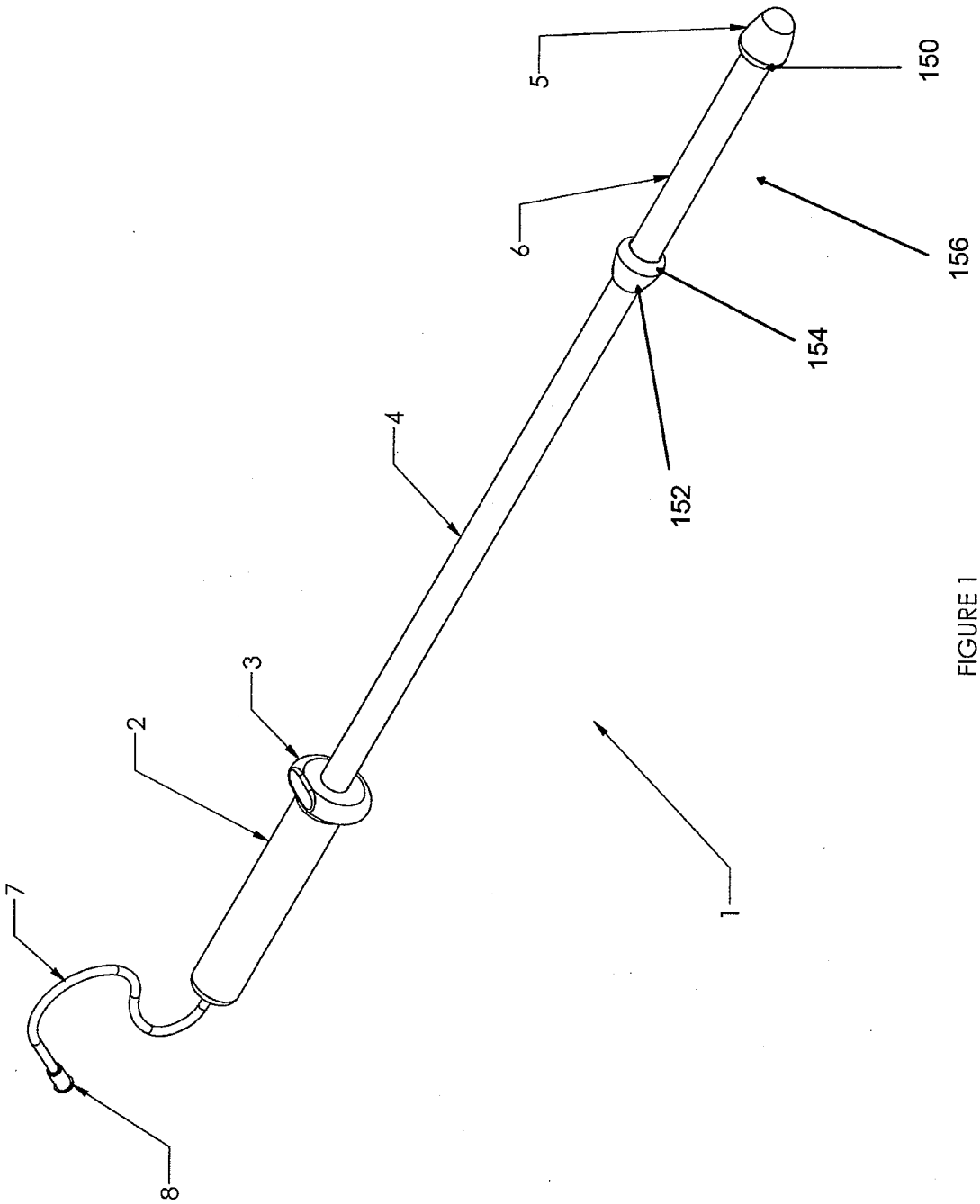


FIGURE 1

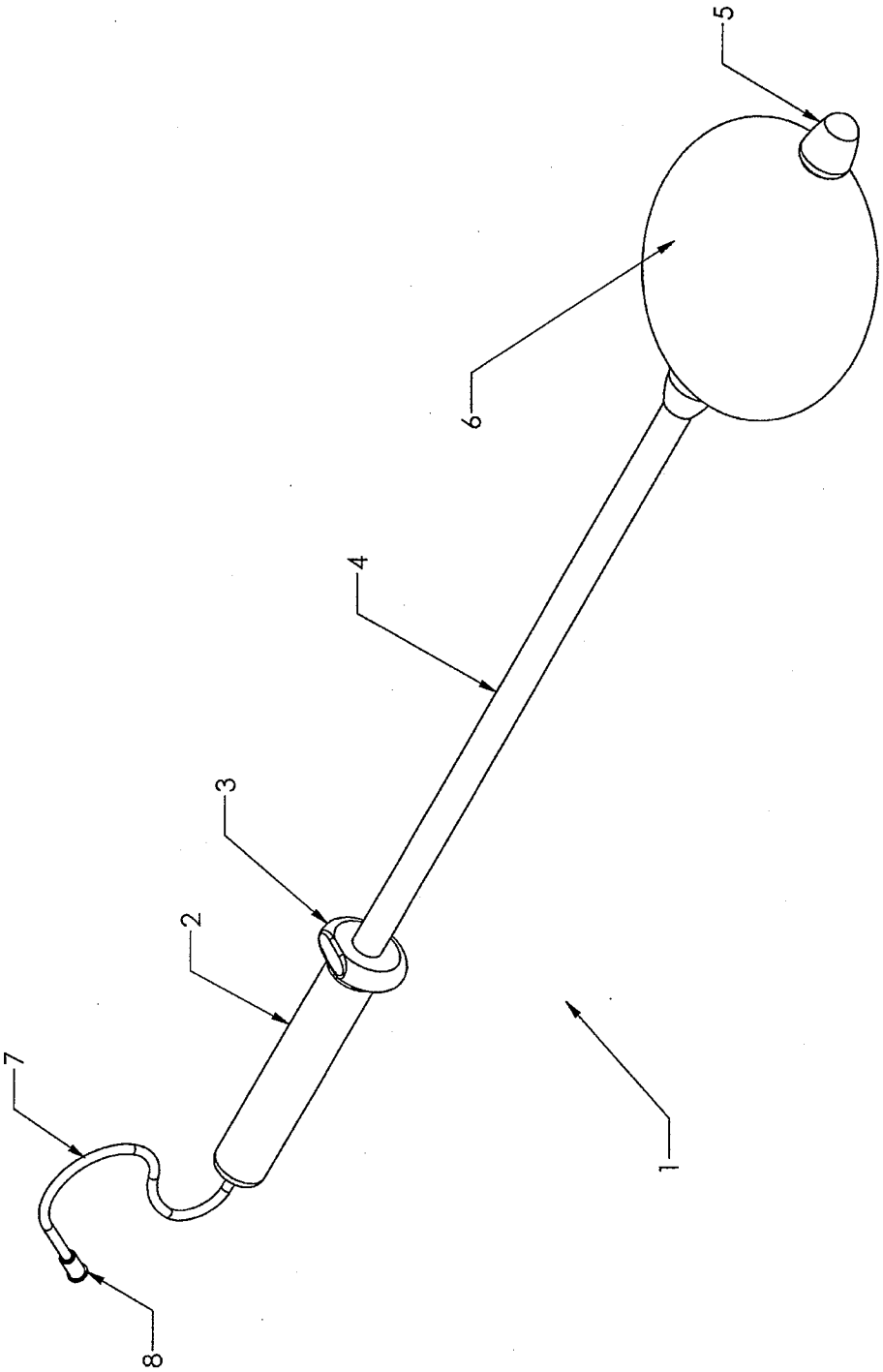


FIGURE 2

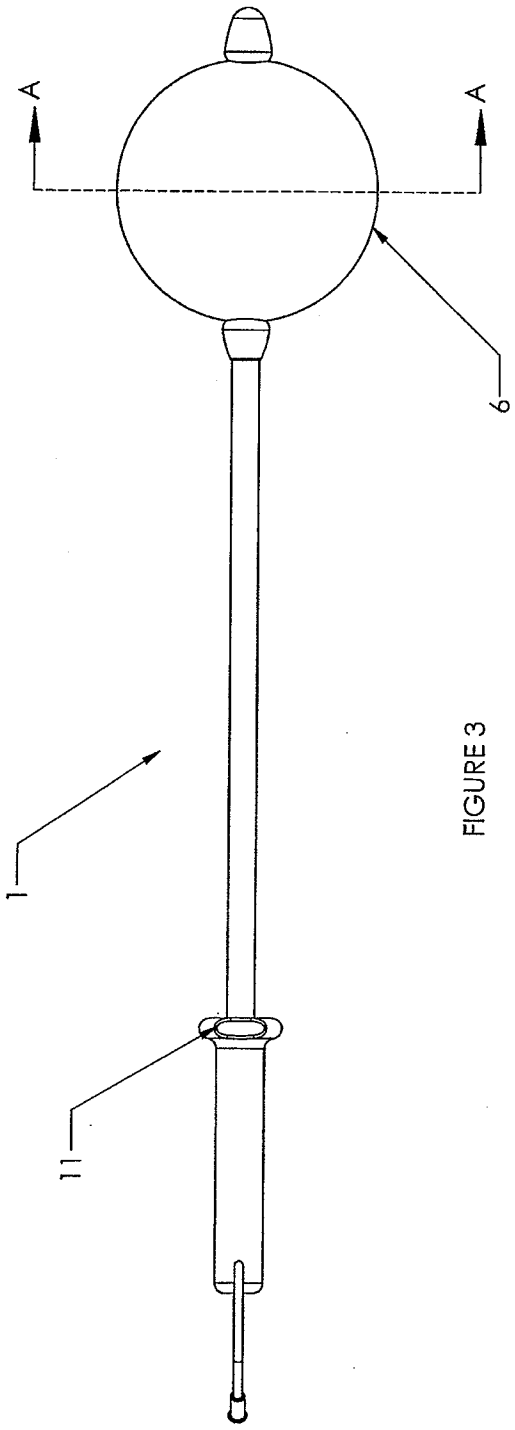
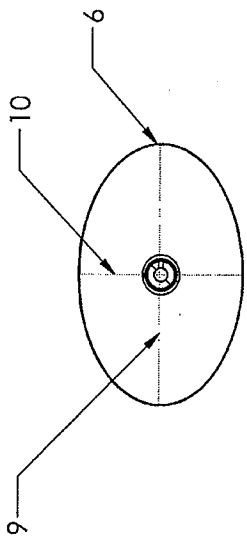


FIGURE 3



SECTION A-A

FIGURE 4

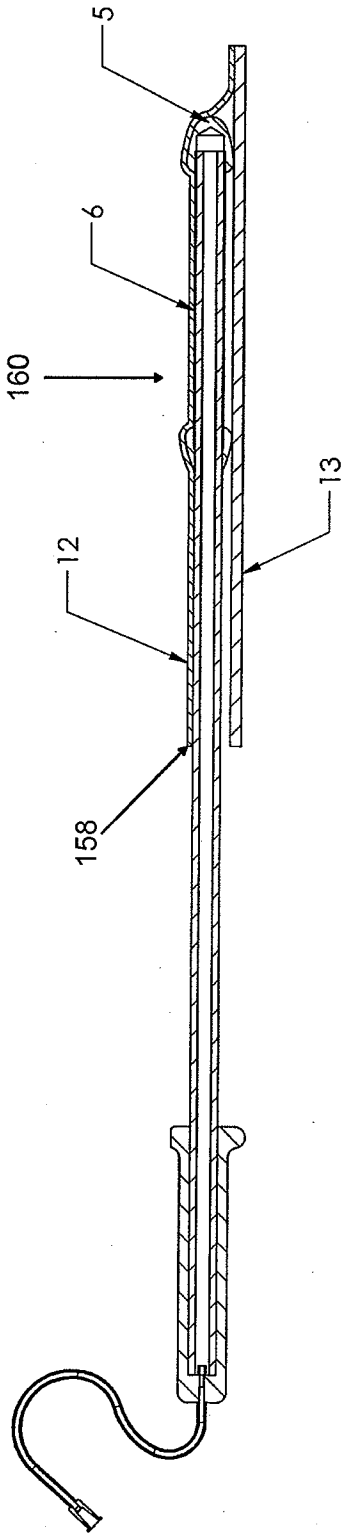


FIGURE 5

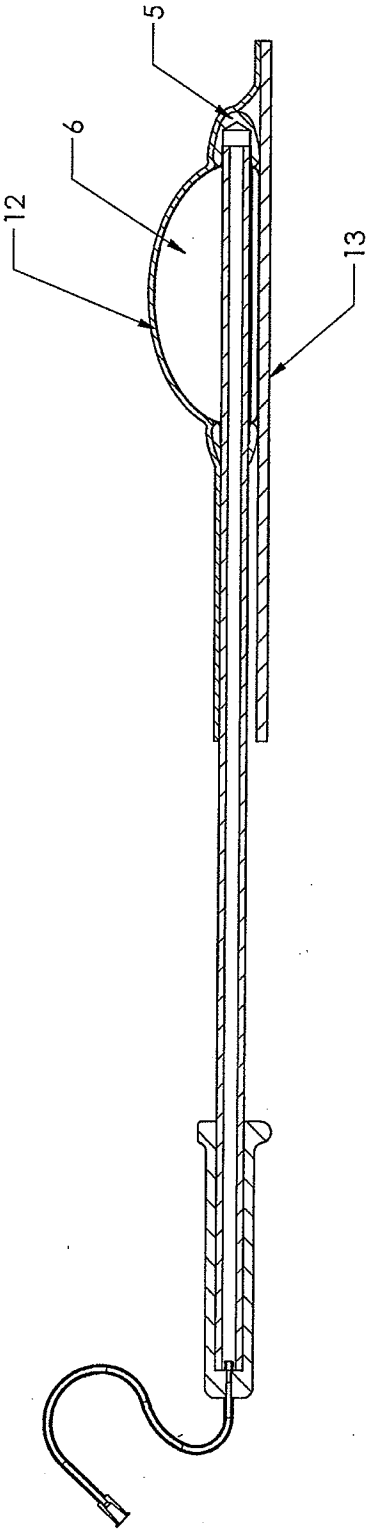


FIGURE 6

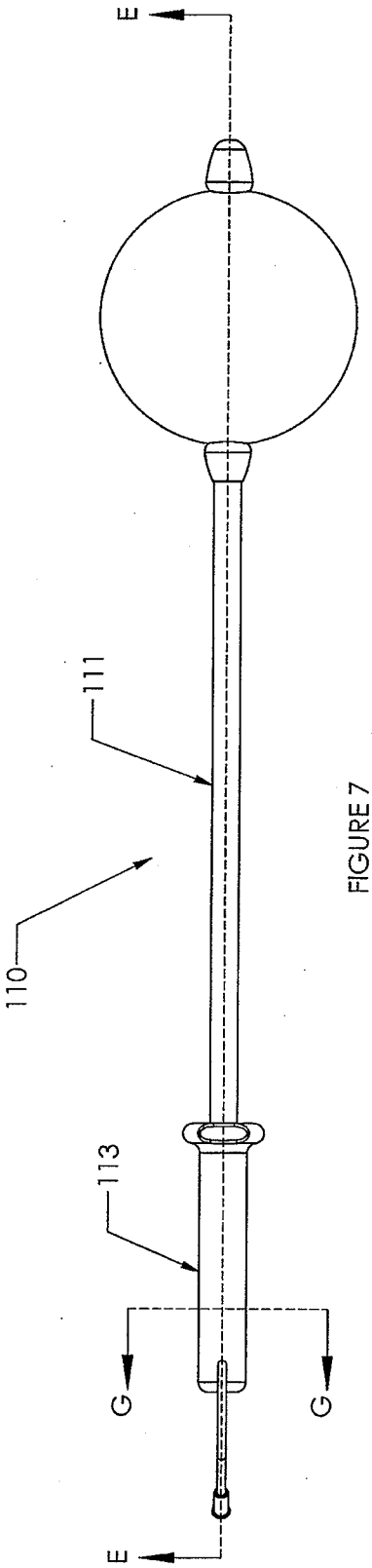
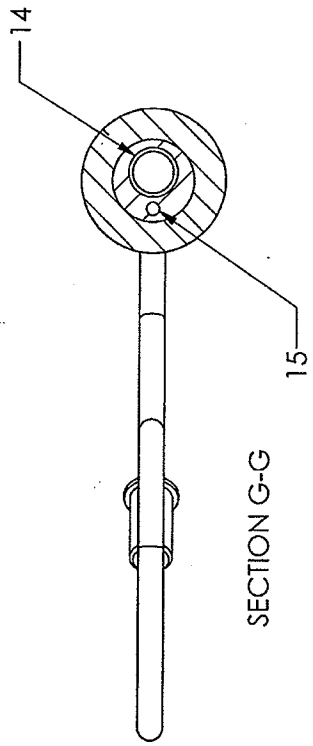


FIGURE 7



SECTION G-G

FIGURE 9

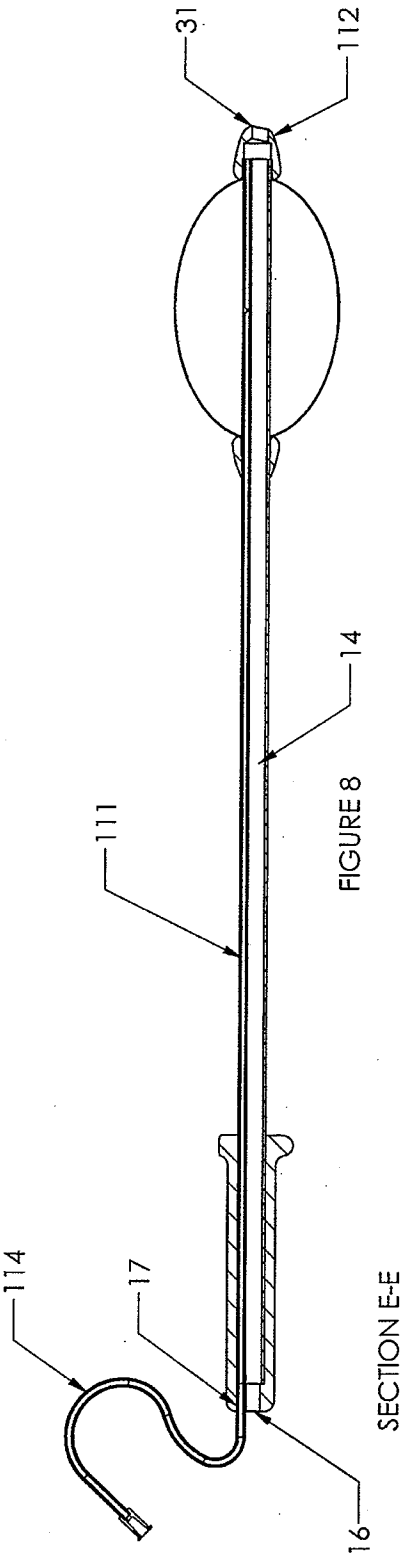


FIGURE 8

SECTION E-E

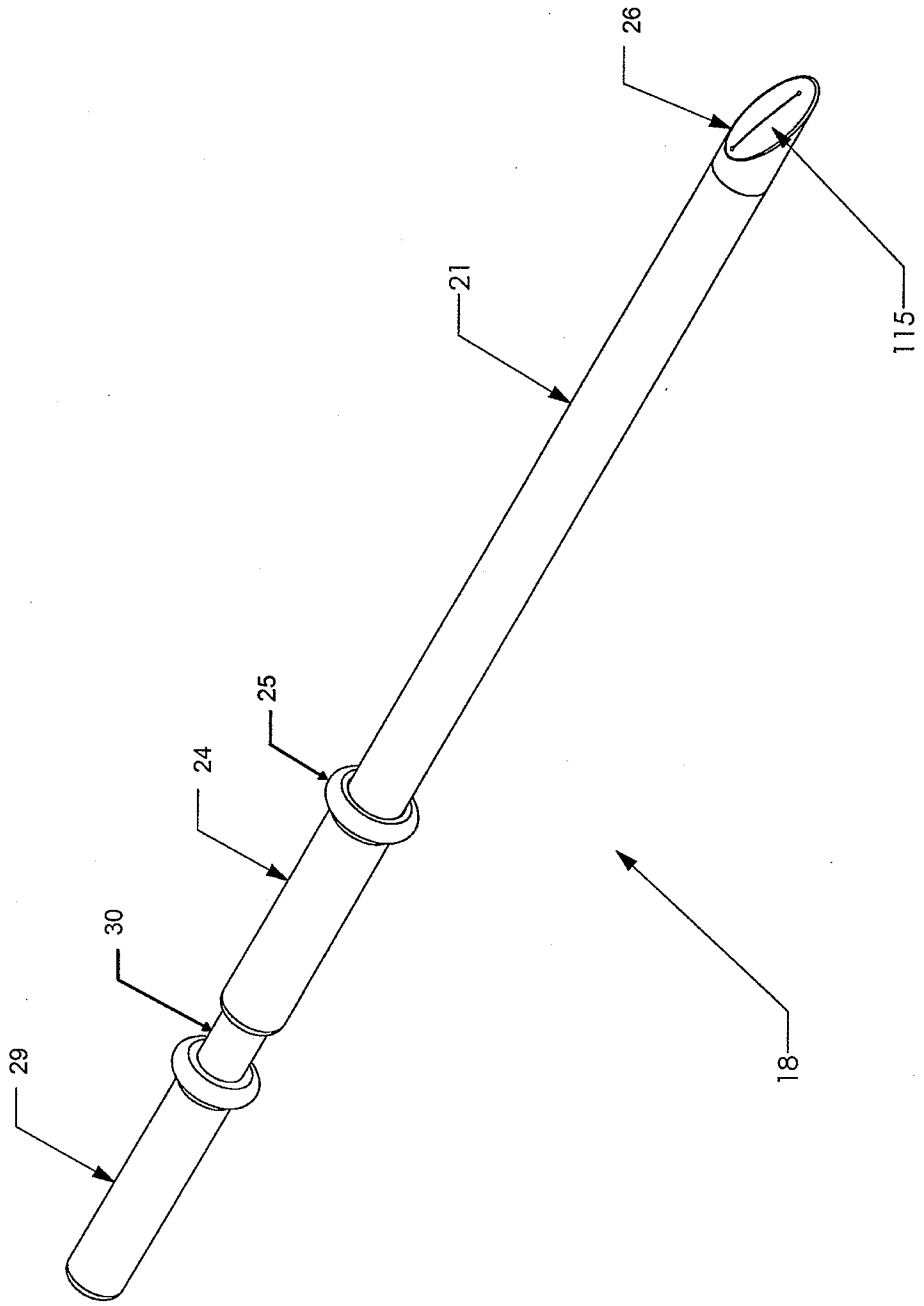


FIGURE 10

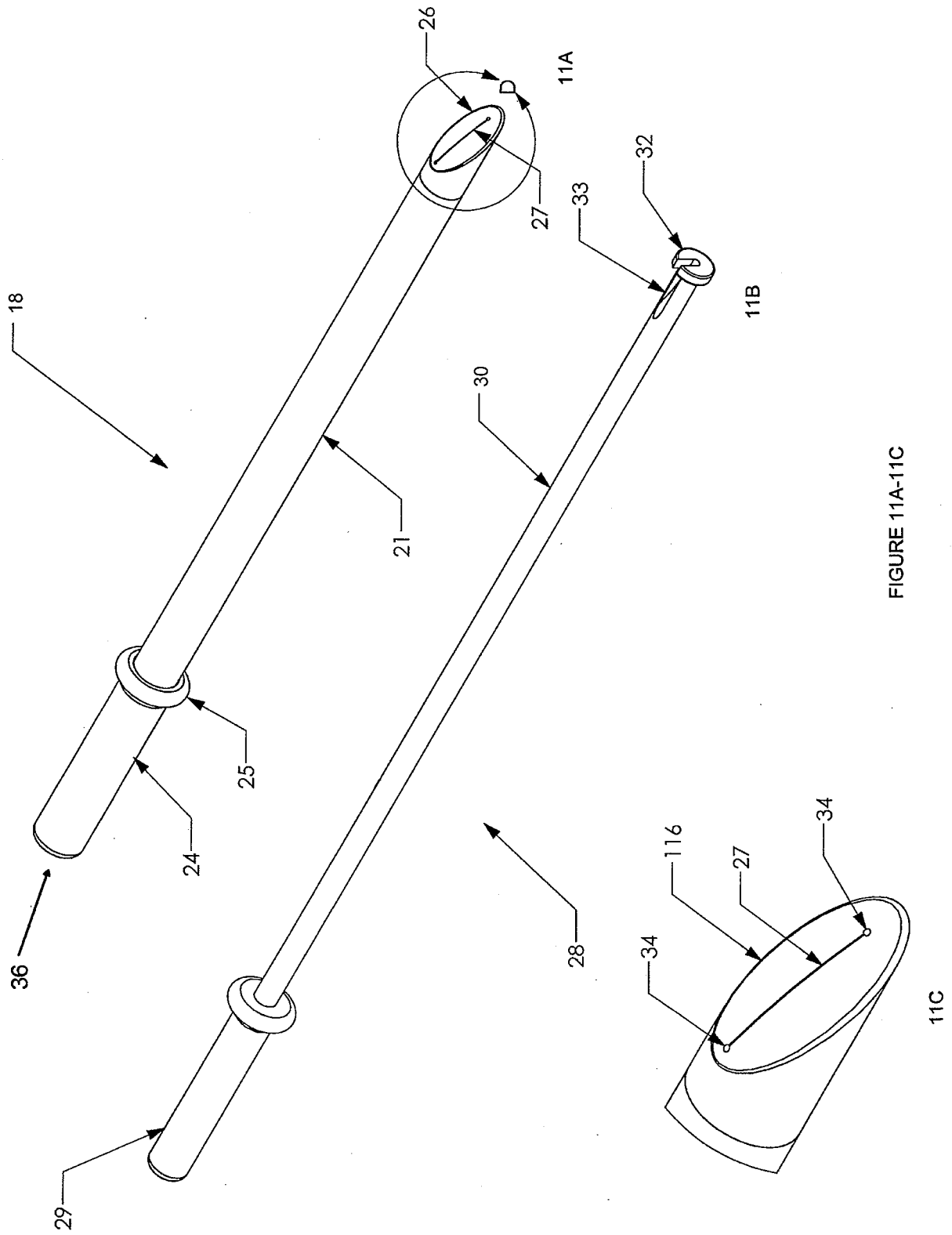


FIGURE 11A-11C

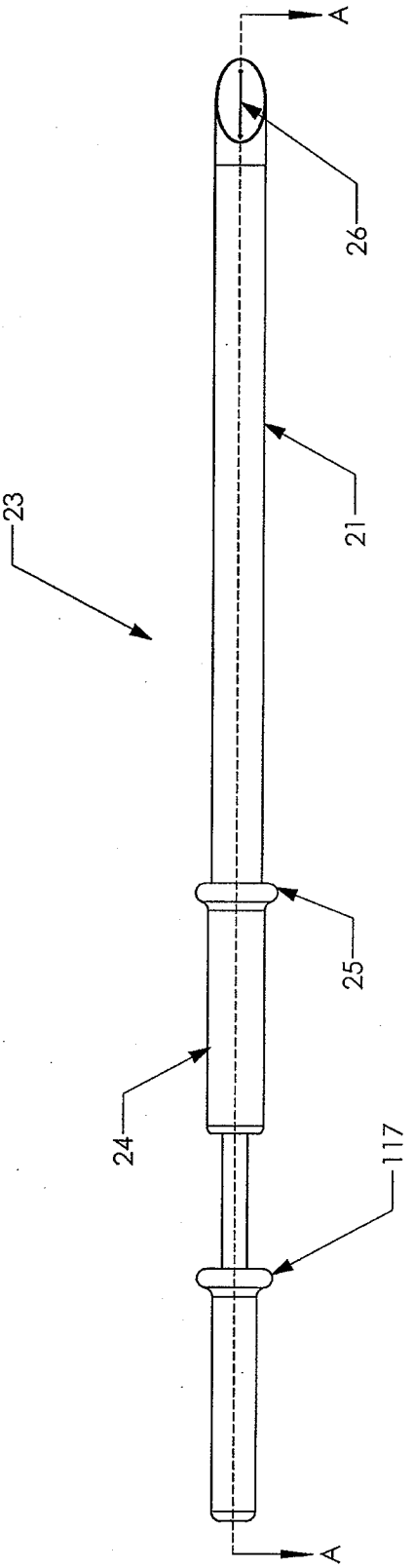
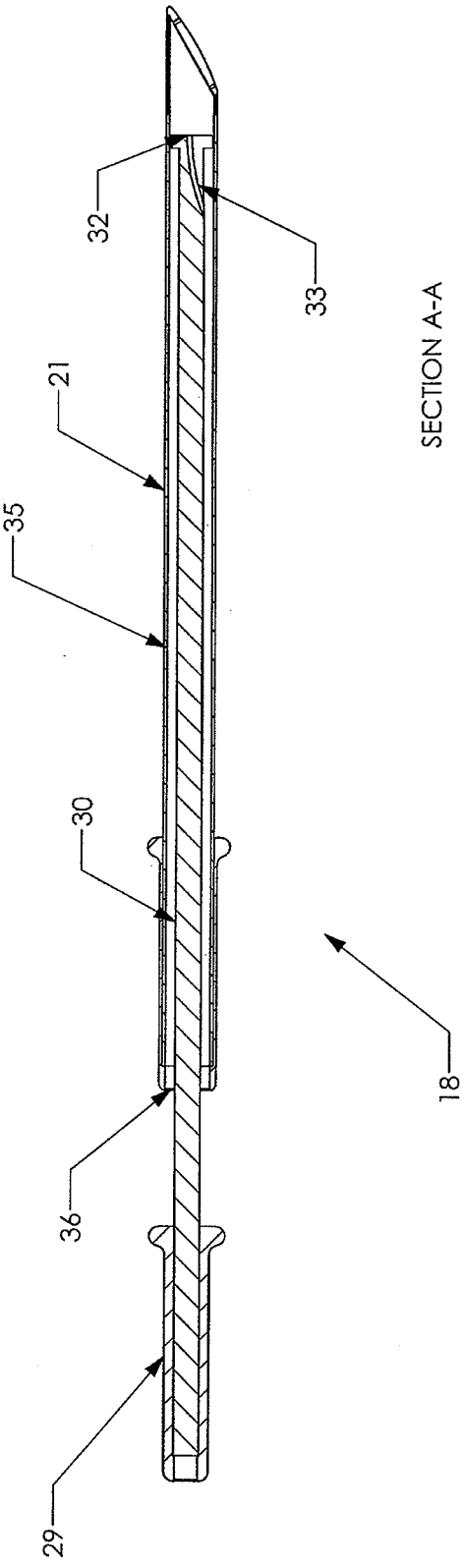


FIGURE 12



SECTION A-A

FIGURE 13

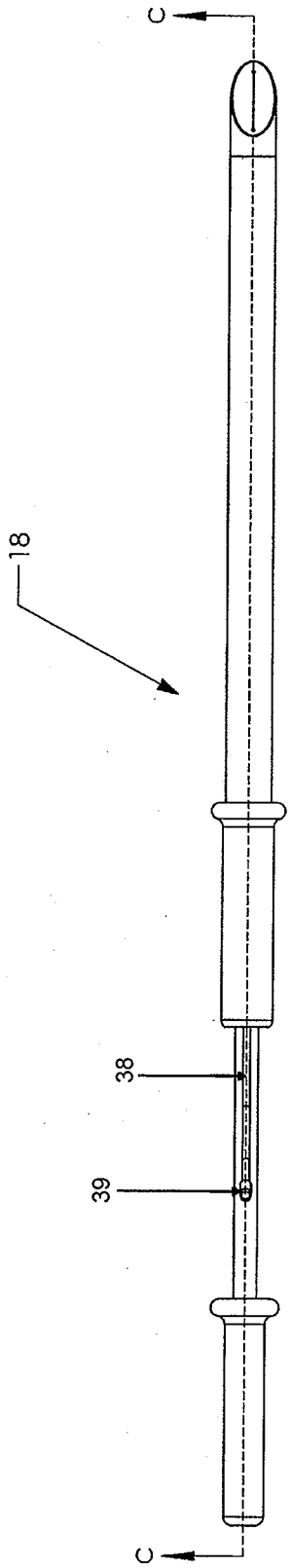
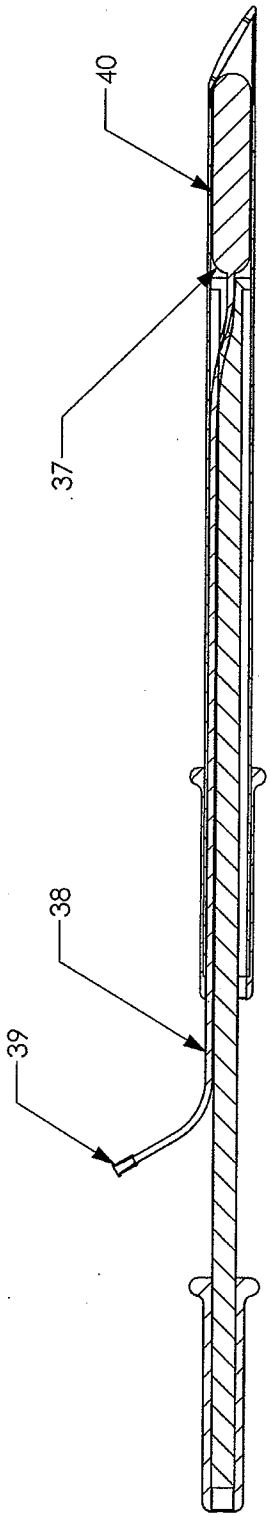


FIGURE 14



SECTION C-C

FIGURE 15

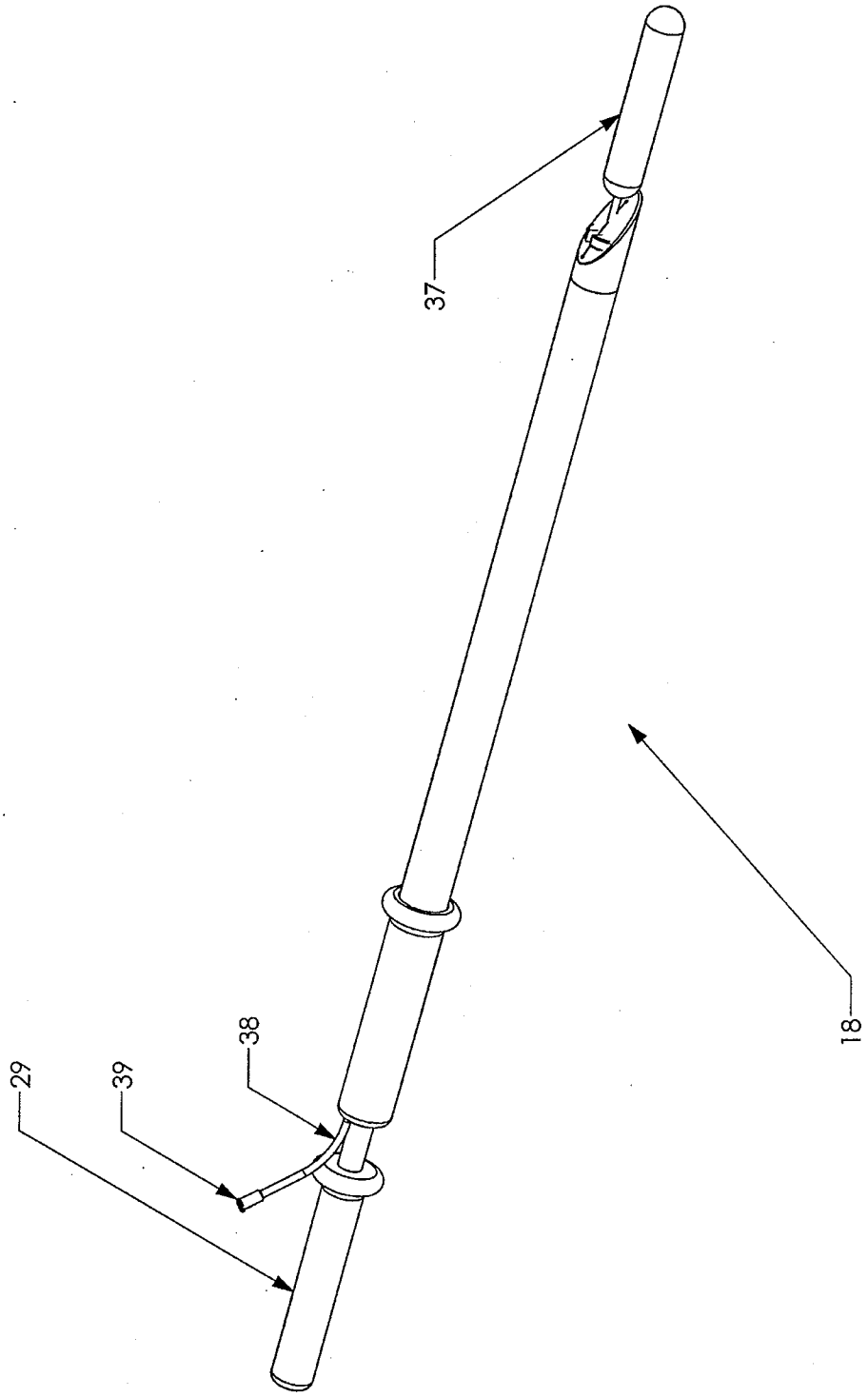


FIGURE 16

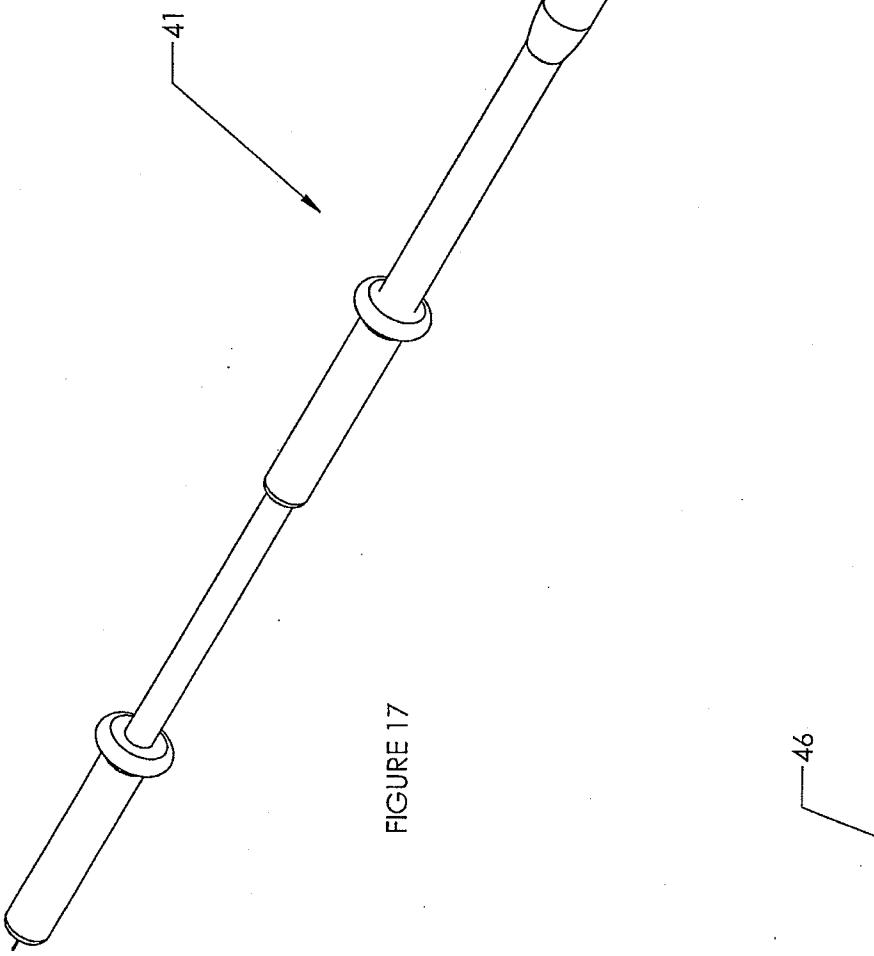


FIGURE 17

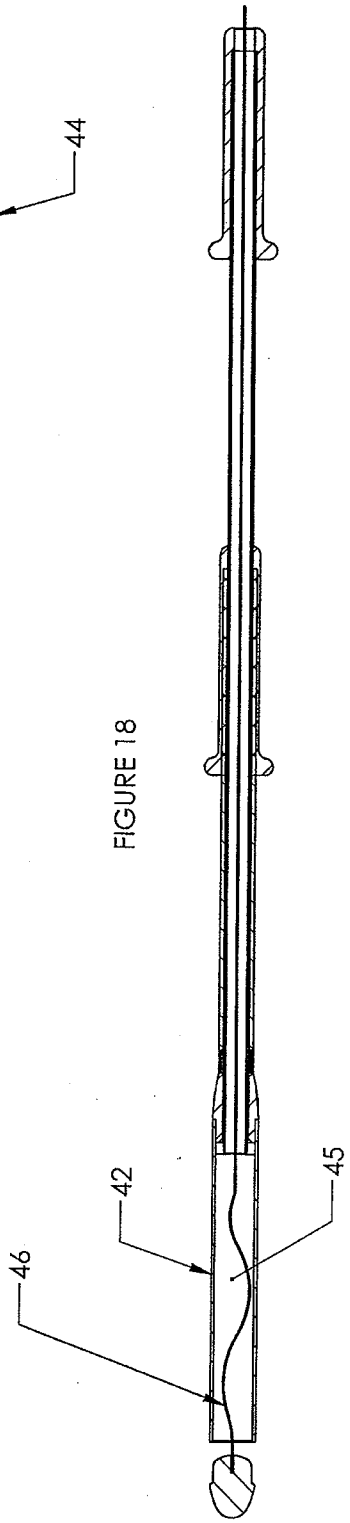


FIGURE 18

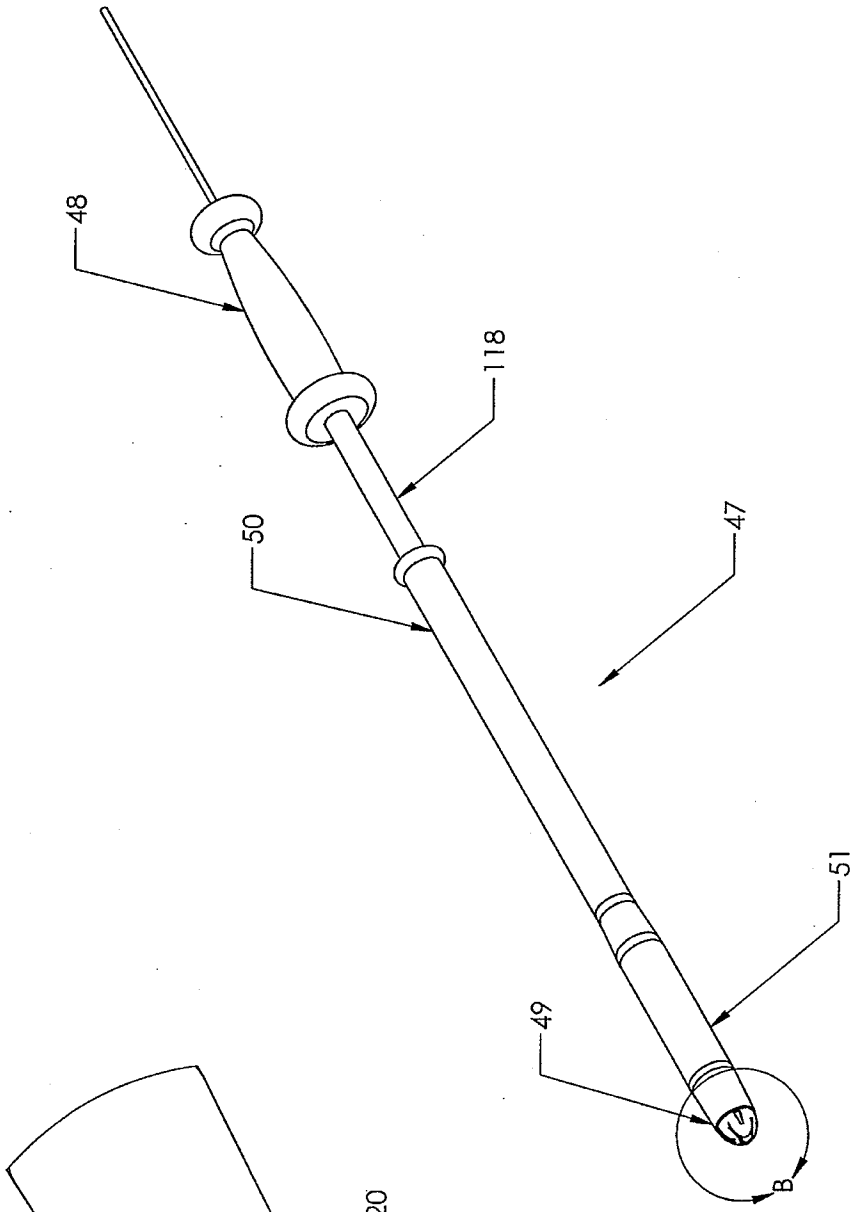


FIGURE 19

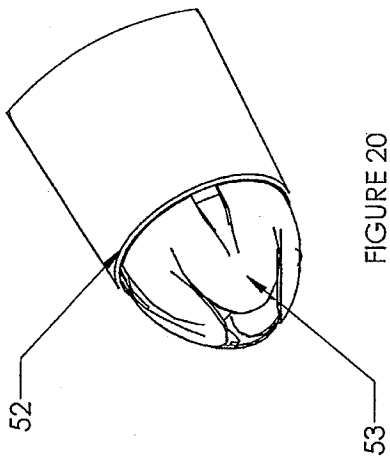


FIGURE 20

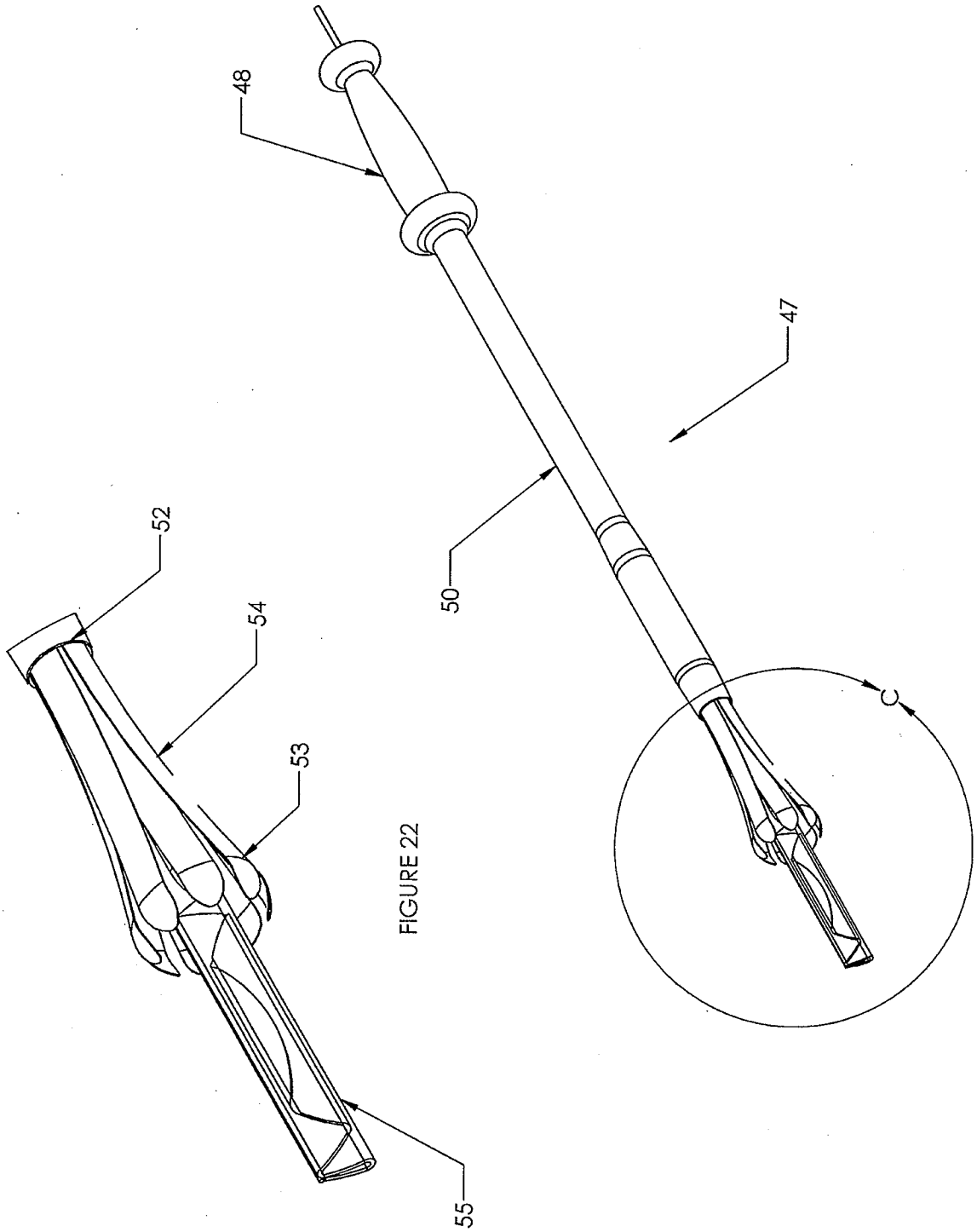


FIGURE 21

FIGURE 22

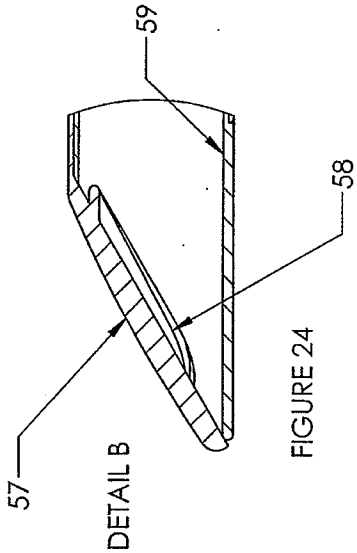


FIGURE 24

FIGURE 23

FIGURE 26

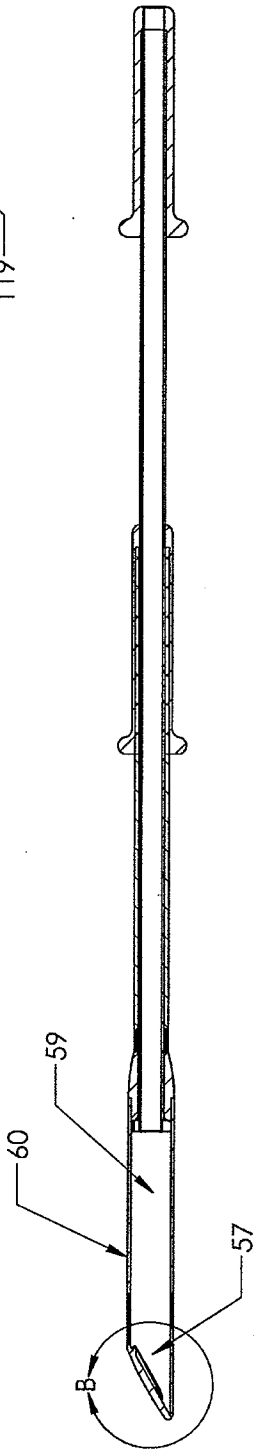


FIGURE 25

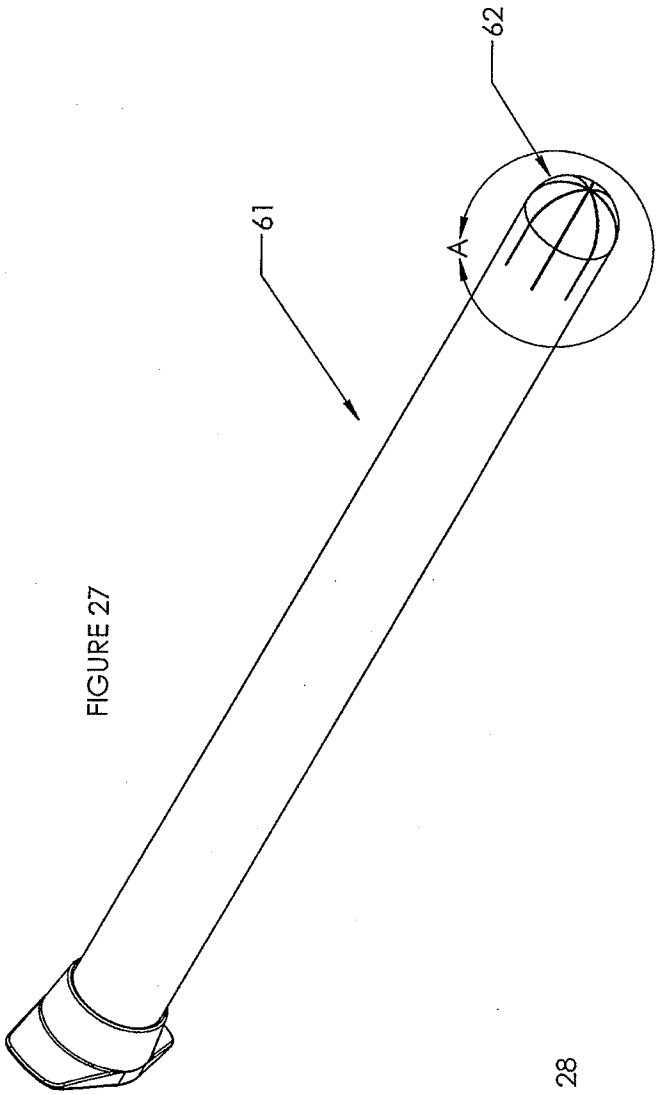


FIGURE 27

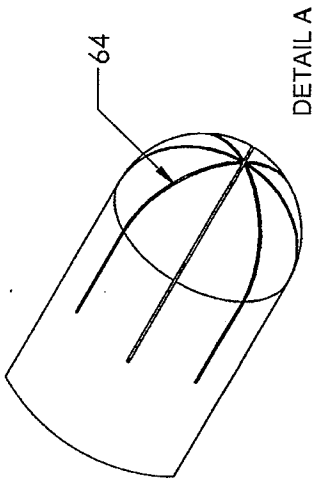


FIGURE 29

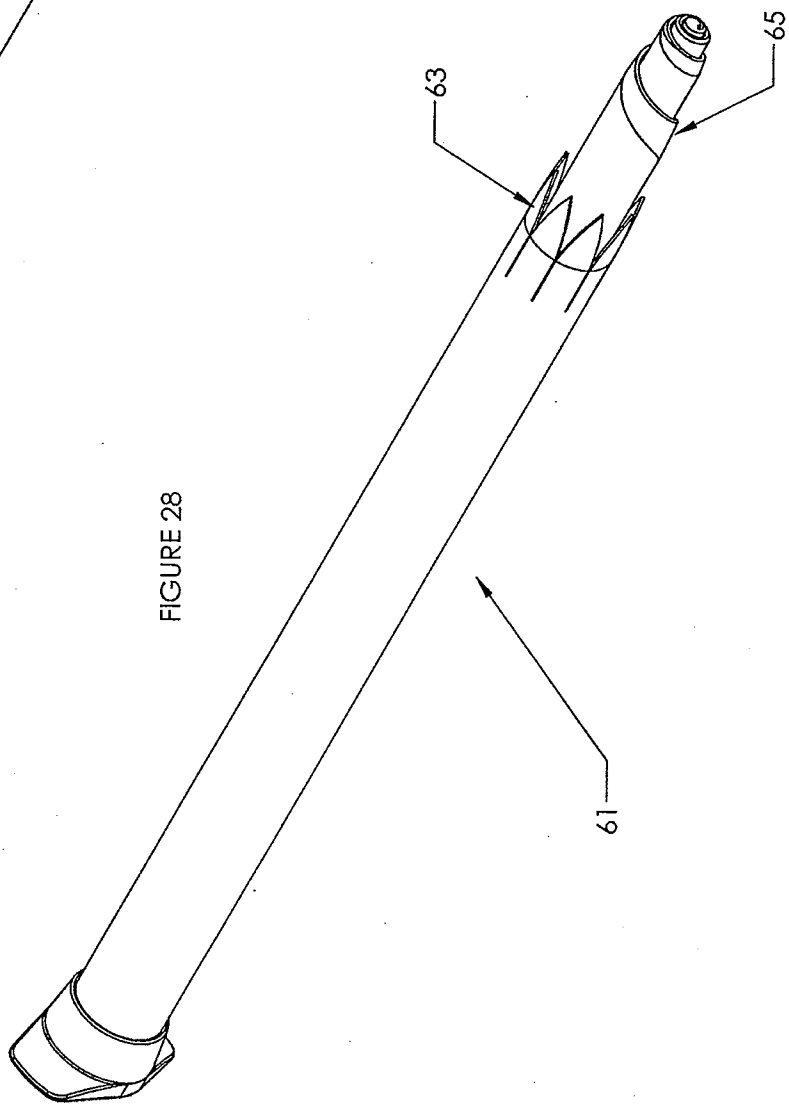


FIGURE 28

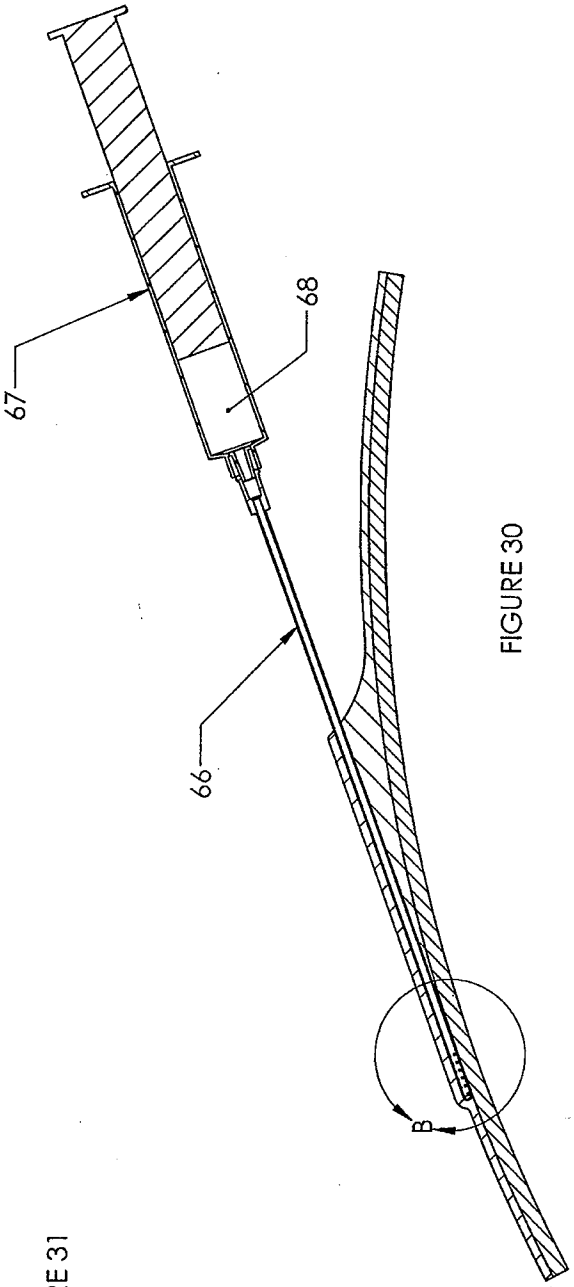
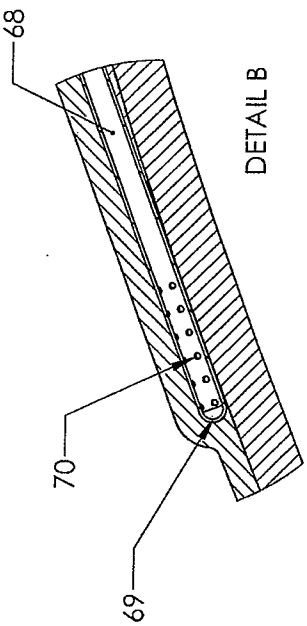


FIGURE 30



DETAIL B

FIGURE 31

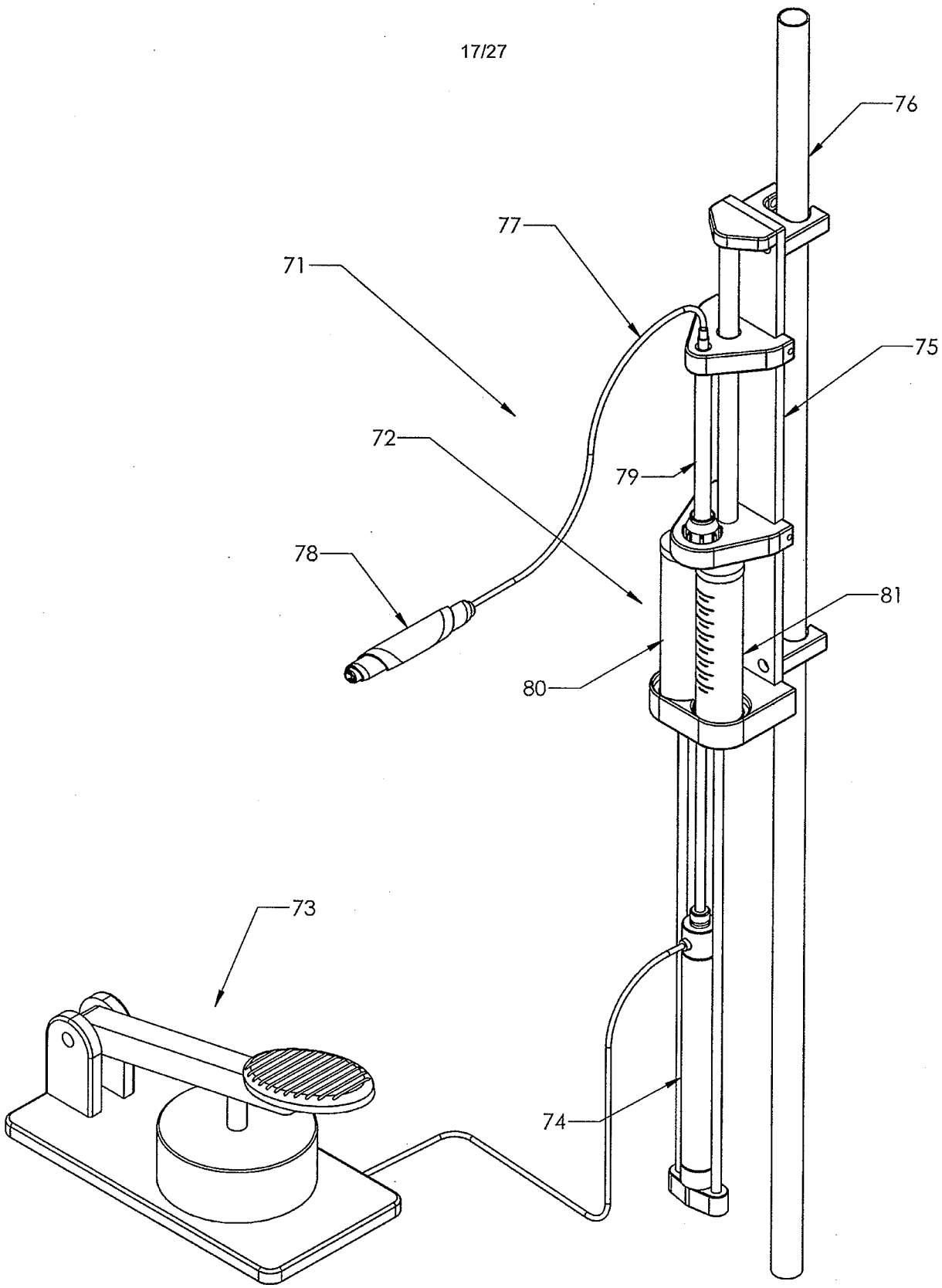


FIGURE 32

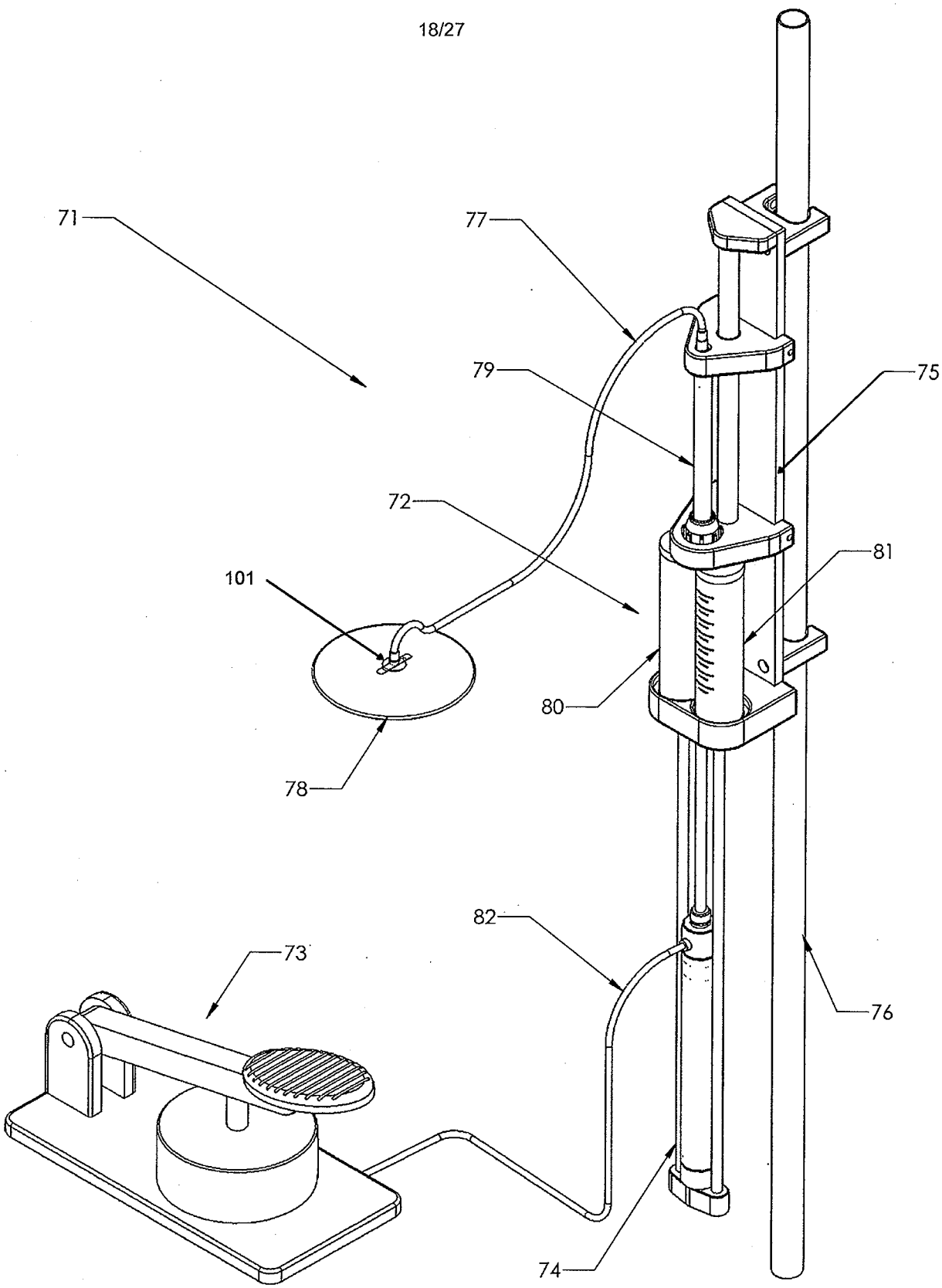


FIGURE 33

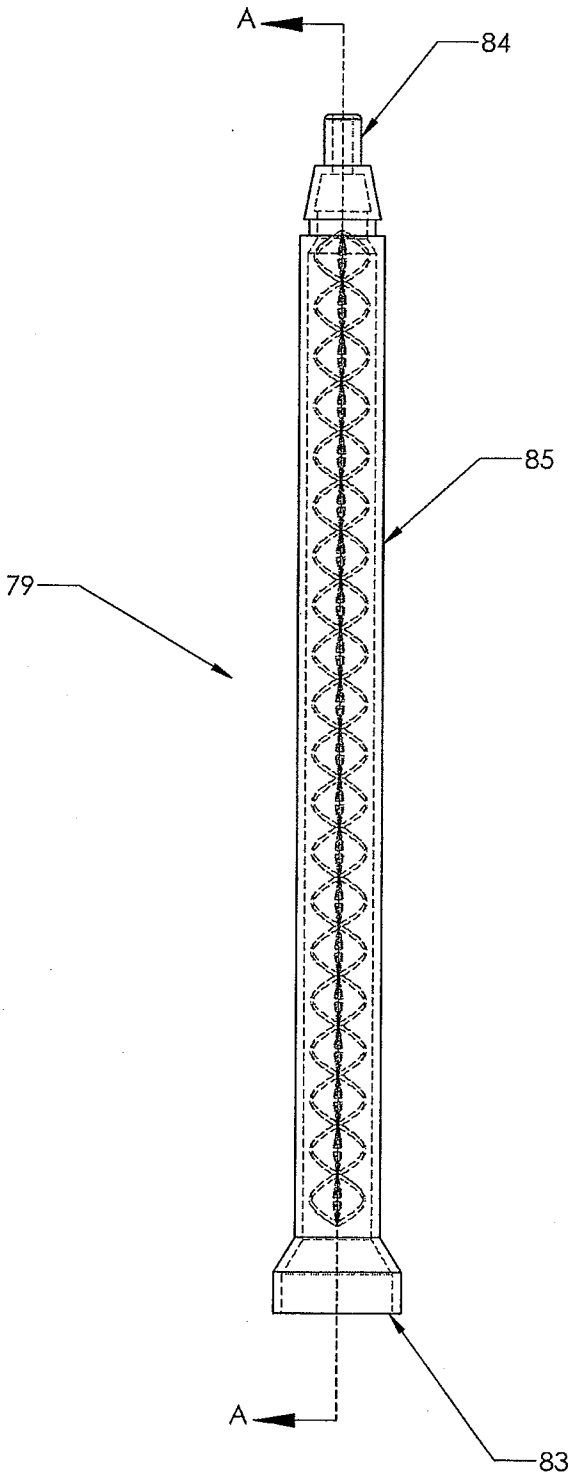


FIGURE 34

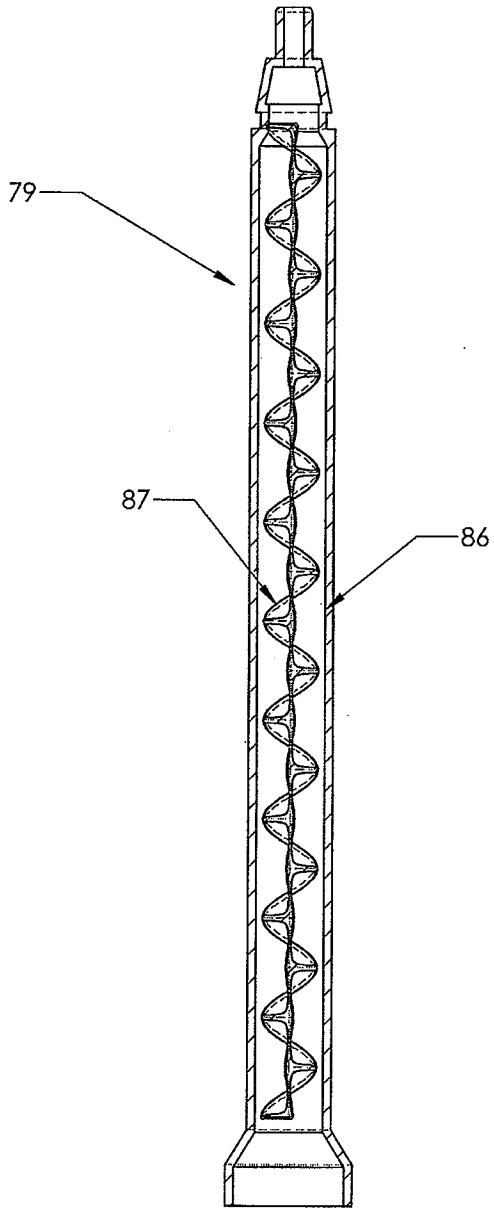


FIGURE 35

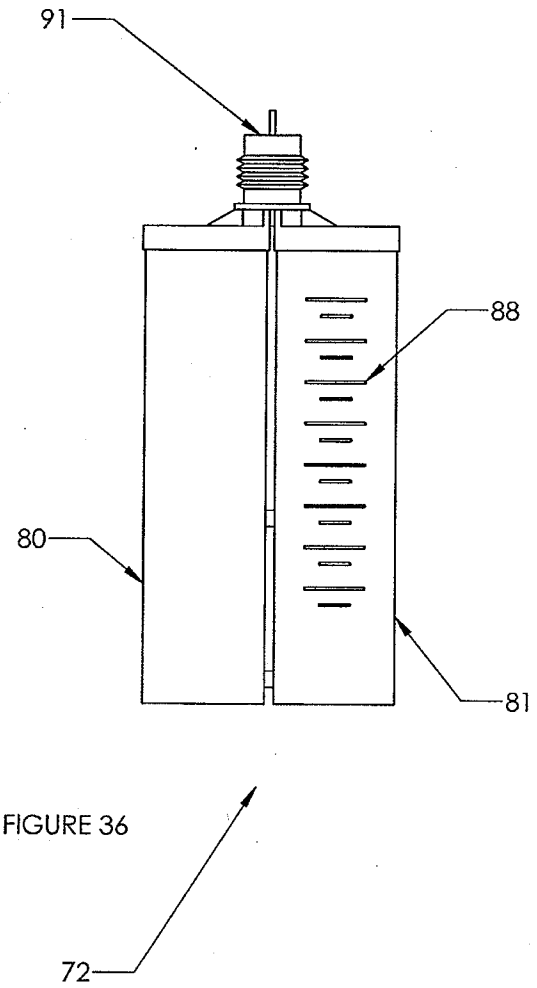


FIGURE 36

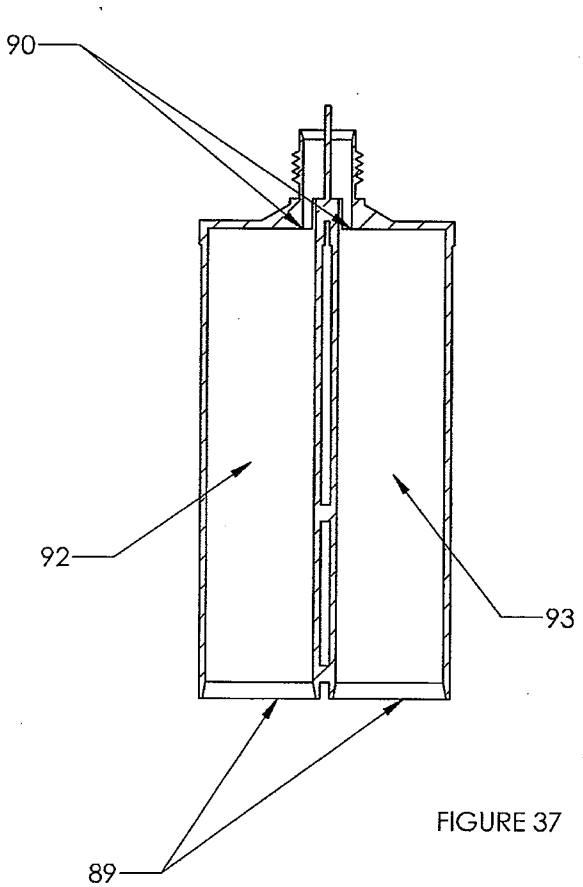


FIGURE 37

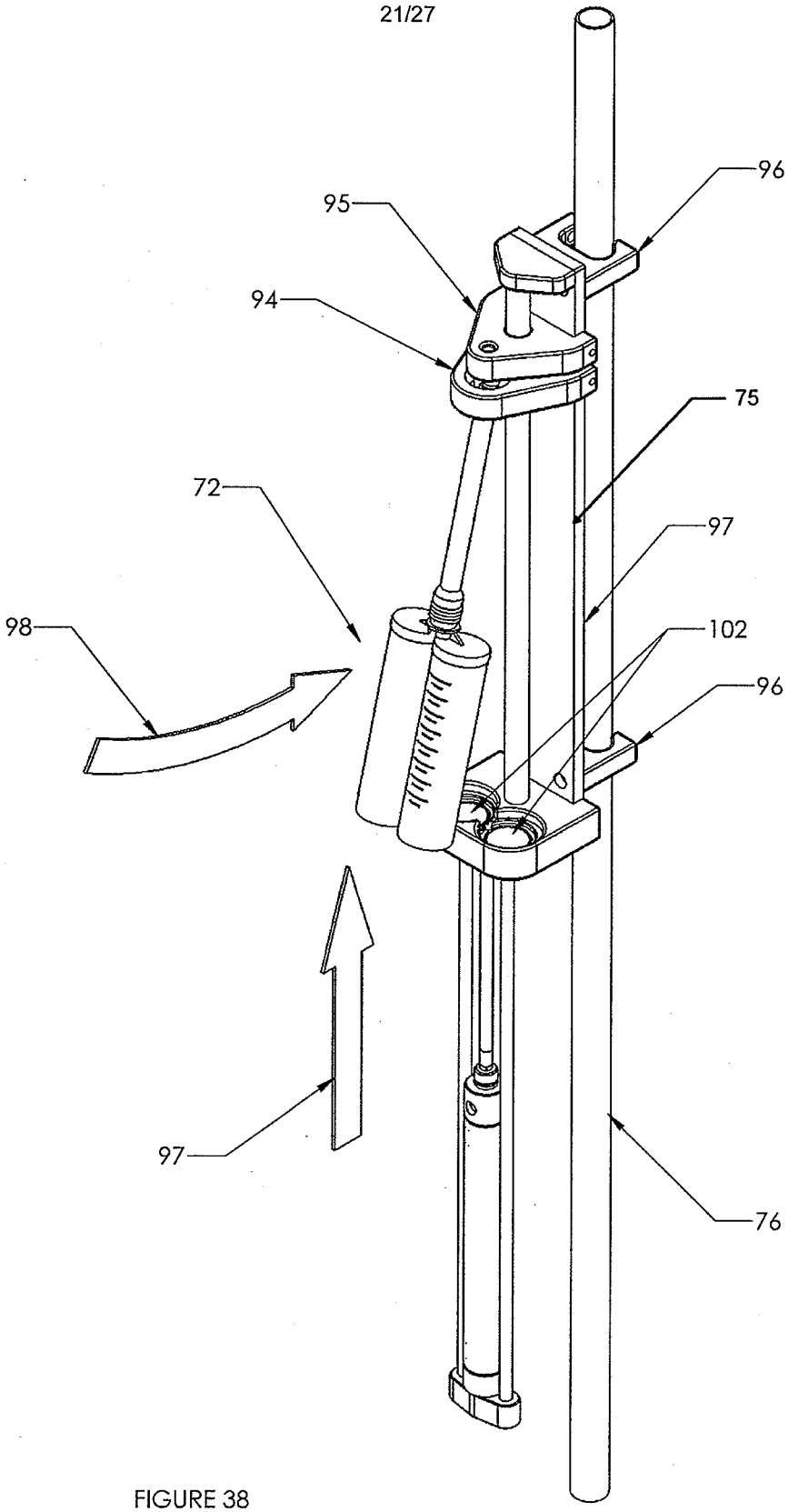


FIGURE 38

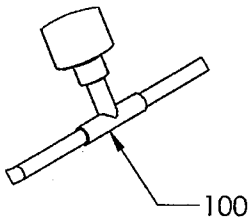


FIGURE 40

FIGURE 39

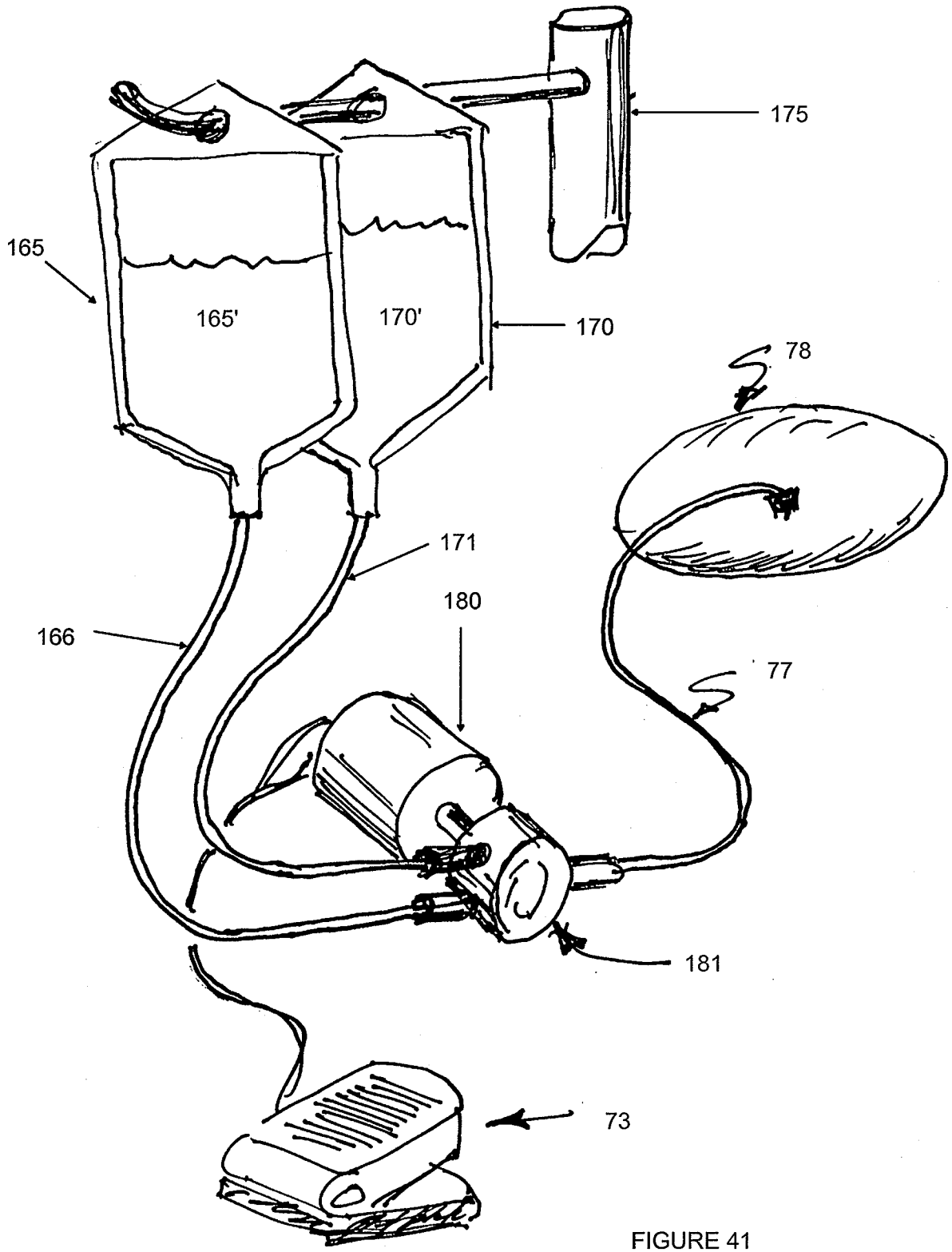


FIGURE 41

FIGURES 42-44

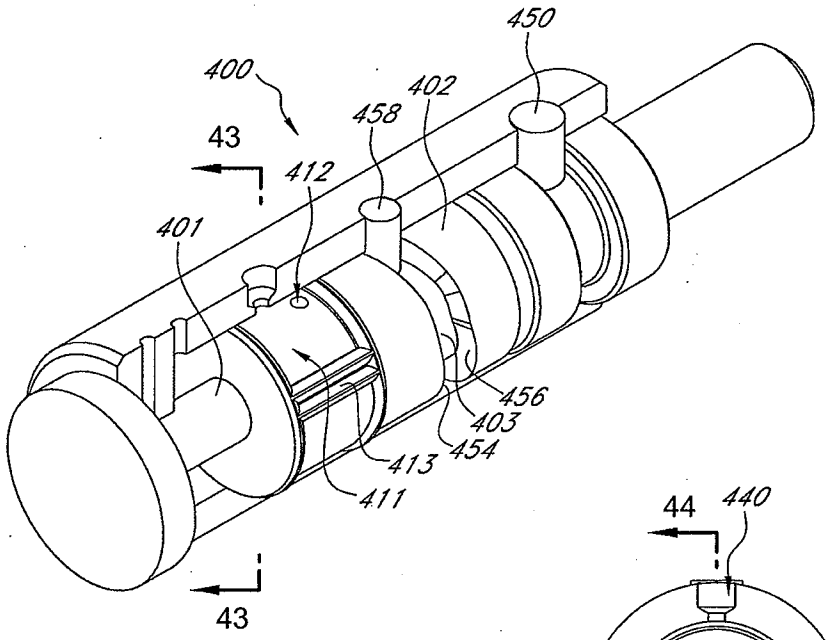


FIGURE 42

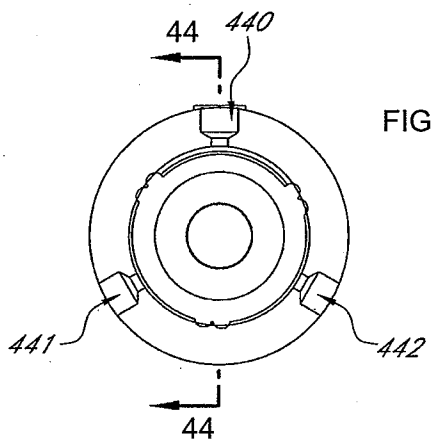


FIGURE 43

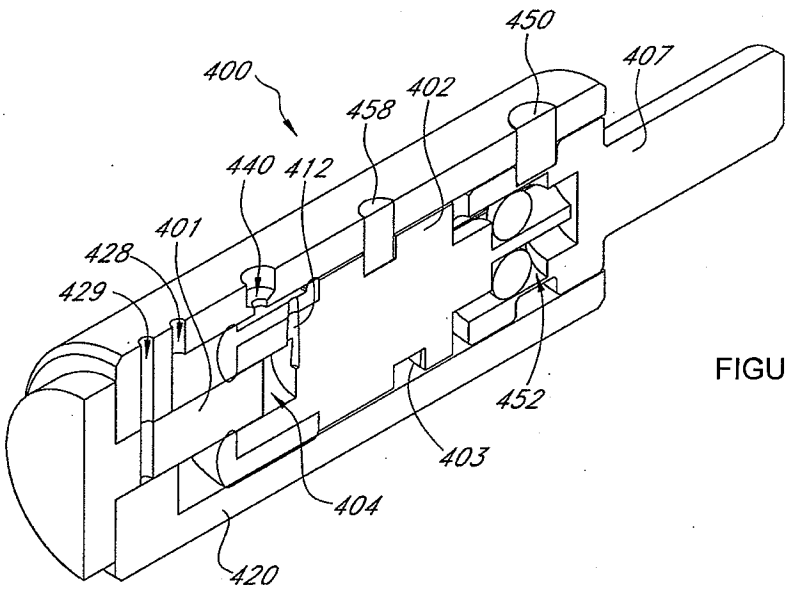


FIGURE 44

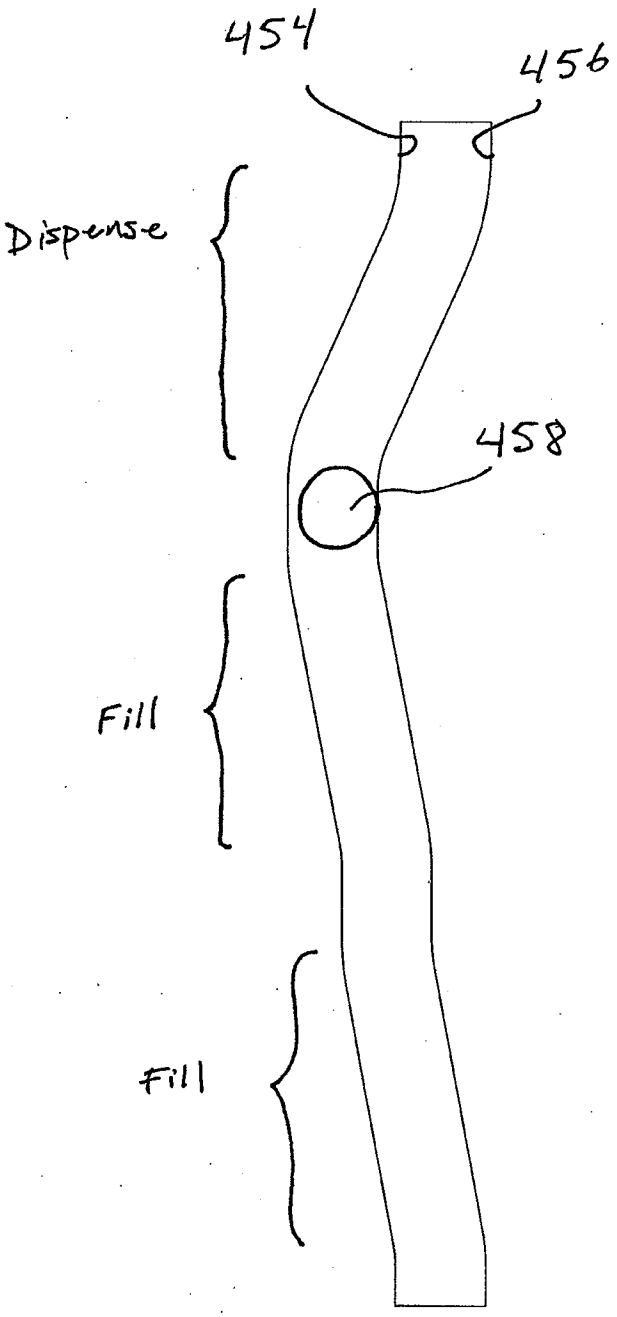
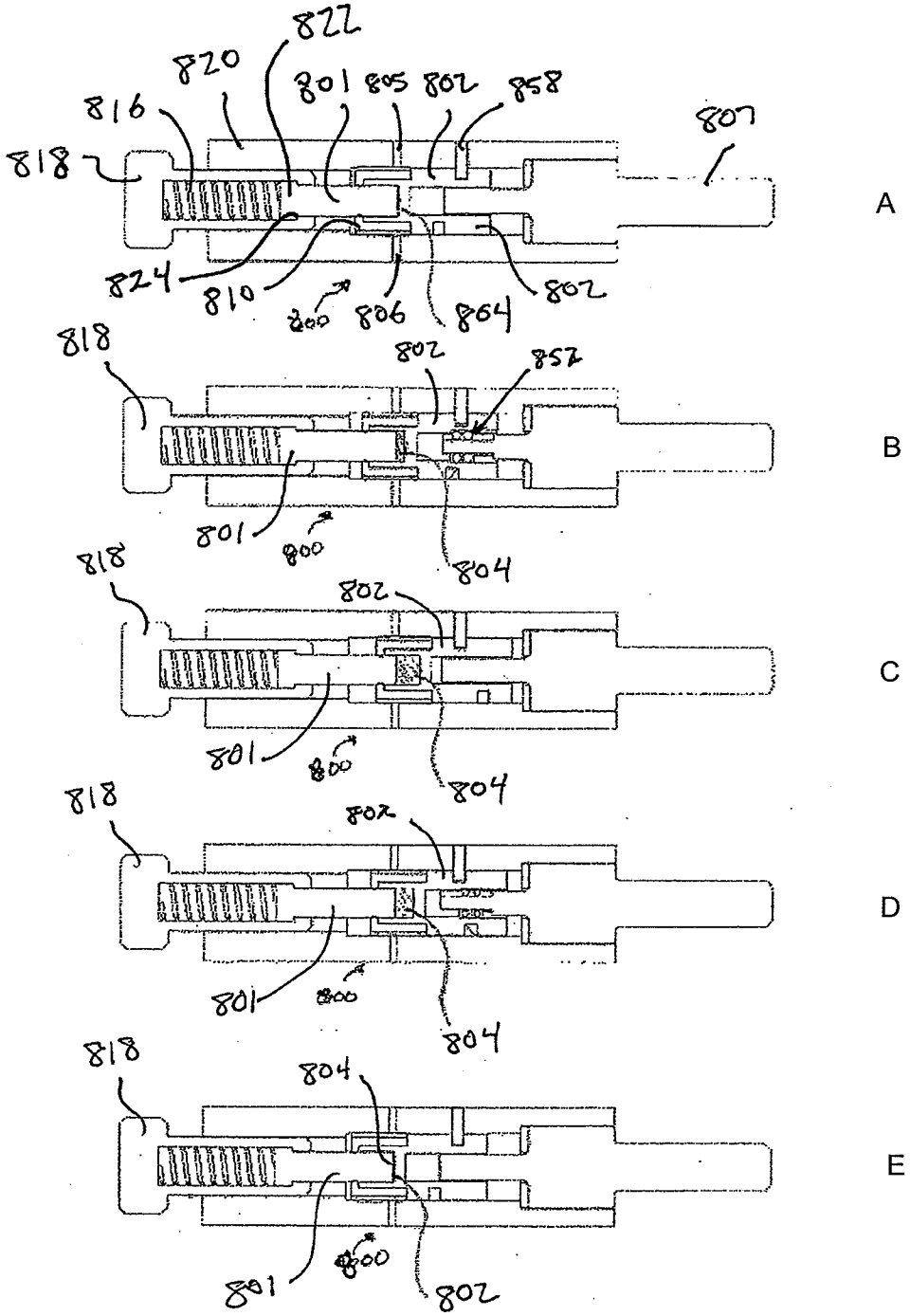
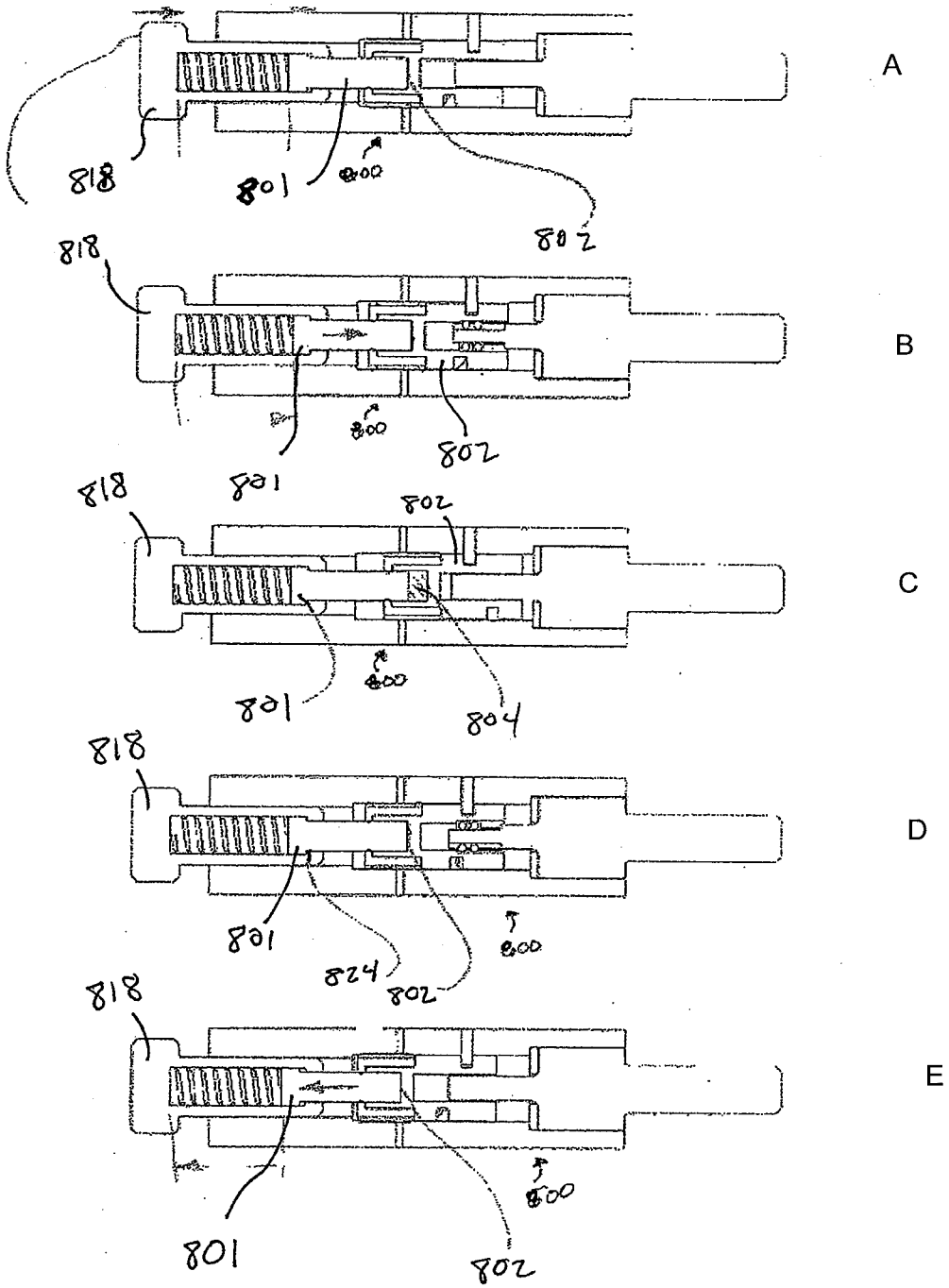


FIGURE 45



FIGURES 46A-46E



FIGURES 47A-47E

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 11/35411

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/12 (2011.01)
USPC - 623/8
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 623/8

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 128/897, 898; 606/190, 191, 192; 623/7, 8, 66.1 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(PGPB, USPT, EPAB, JPAB); Google
Search Terms Used: fluid, hold$3, lock$3, secur$3, holder, breast, augmentation, implant, fill$3, hydraulic, baffle, mix$3, combin$5, valve, tip, plug, eject$4, hydrogel, silane copolymer, polyvinylpyrrolidone, polyvinyl acetyl, coat$3, cannula, introducer, obturator, lumen ..

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0299401 A1 (TILSON) 03 December 2009 (03.12.2009) fig 154A, 154B, 156, 159, 161, 162, 171B, para [0093], [0610], [0612]-[0613], [0615], [0617]-[0621], [0631]-[0632], [0637]-[0638]	1, 4-8, 11-14, 15/(1, 4-8, 11-14)-17/(1, 4-8, 11-14), 19/(1, 4-8, 11-14)-20/(1, 4-8, 11-14), 22/(1, 4-8, 11-14)
---		---
Y		2-3, 9-10, 15/(2-3, 9-10)-17/(2-3, 9-10), 18, 19/(2-3, 9-10)-20/(2-3, 9-10), 21, 22/(2-3, 9-10)
Y	US 2006/0135981 A1 (LENKER et al) 22 June 2006 (22.06.2006) para [0098]	2-3, 15/(2-3)-22/(2-3)
Y	US 5,941,910 A (SCHINDLER et al) 24 August 1999 (24.08.1999) fig 3, col 7, ln 27-29, col 7, ln 42-49, col 8, ln 1-14	9-10, 15/(9-10)-22/(9-10)
Y	US 2010/0100115 A1 (SOETERMANS et al) 22 April 2010 (22.04.2010) para [0058]	18
Y	US 2009/0099588 A1 (MAKOWER et al) 16 April 2009 (16.04.2009) para [0164]	21

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 October 2011 (09.10.2011)	19 OCT 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 11/35411

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

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

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

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid. Group I: Claims 1-22; directed to a device for the delivery of an implant to a subject. Group II: Claims 23-42; directed to a soft tissue dissection tool. The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Group I is an elongate outer cannula, which is not present in Group II. The special technical feature of Group II is a reversibly inflatable balloon, which is not present in Group I. The only elements of commonality between the groups are those of a proximal end, a distal end, a proximal handle, and an interconnecting shaft positioned between the distal end and a proximal portion, which are known in the prior art (ref. US 2008/0058926 A1 to Solomon; Fig. 22; para [0088]--"dissector 2200 includes a dissector handle 2202 and a bent portion 2204. The bent portion 2204 includes a plurality of grooves 2206 with sharp edges to facilitate dissection"). Accordingly, unity of invention is lacking under PCT Rule 13.1.

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-22

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.