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(54) **Title:** ARTICLES FOR MAINTAINING STERILITY OF A BODILY ORIFICE OR A WOUND SITE

(57) **Abstract:** The invention discloses articles for maintaining sterility of a bodily orifice or a wound. These include a sleeve for maintaining sterility of an insertable medical device. The sleeve has a cylindrical member adjustable from an extended configuration to a shortened configuration. The sleeve shields at least a portion of the medical device from contact with the human body. The cylindrical member is flexible. A flange is located upon a proximal portion of said sleeve. Also provided in the invention is a hydrogel wound dressing releasing an antimicrobial active agent.

ARTICLES FOR MAINTAINING STERILITY OF A BODILY ORIFICE OR A WOUND SITE

FIELD OF THE INVENTION

The present invention relates to a sleeve for maintaining the sterility of insertable medical devices, such as urinary catheters. The invention additionally relates to a wound dressing for preventing infection at a wound site.

BACKGROUND OF THE INVENTION

Insertion of medical devices into body orifices is often associated with infection, particularly in procedures that require prolonged insertion of the devices. For example, introduction of certain devices, such as urinary or urethral catheters, into the body often requires extended use, during which time movement of the devices with respect to surrounding tissues can lead to infection and microtrauma to the tissues. Even mild movement of the body can expose surfaces of the device to the external, non-sterile environment, and further movement can reintroduce these surfaces into the body, resulting in infection at or near the site of insertion or placement.

Even when the device has been fully sterilized prior to the procedure, microorganisms can begin to build up, a process that is facilitated by moisture within the body, and particularly moisture which exudes from the body and which can serve as a bridge between bacteria on the exterior and the sterile environment on the interior.

Insertion of medical devices is also associated with trauma to the tissue. With catheters, lubrication of surfaces to minimize friction is common practice today, as is disinfection of the orifice and surrounding skin. However, infections associated with breaching of the skin and tissue continuity are still prevalent. Such breaching of the skin and tissue can occur in many different circumstances, including, for example, insertion of a device through an orifice, insertion of a needle-dependent device, and in the presence of wounds. Insertion of a catheter through a mucosal passageway is a traumatic procedure, since the catheters are generally of a diameter that exerts considerable shear on the delicate mucosal membrane. The micro trauma breaches the integrity of the tissue, resulting in pain and infection.

Current methods for preventing infection and/or trauma to the tissue include infusion of antibiotics or other lock solutions, or coating of devices with various antimicrobials. However, coated materials tend to react with body fluids and become ineffective within a relatively short time. Coating with biomaterials having surface characteristics that discourage attachment of bacteria are also of limited benefit due to dead cells that become encrusted around the device and serve as a bacterial substrate.

Other methods for preventing infection include the use of mechanical barriers. For example, US Patent Number 4,810,247 discloses a penile cup having a passageway to receive a catheter therethrough. The lower end of the cup is constricted about the catheter to prevent fluid leakage and to prevent up-riding of the catheter. This device is designed to be placed external to the penile shaft and is attached thereto by adhesive coated elements. US Patent Number 4,811,847 discloses a package for a urinary catheter, wherein the catheter passes through a guide.

Mechanical barriers are of limited effectiveness, since they do not stop the multiplication of bacteria on the skin and under the rim confining their borders. Moreover they often provide additional moisture and warmth, which can increase the bacterial population at the site.

Hydrogels formed of synthetic and non-synthetic polymers have recently been described for use at wound sites. Hydrogels are a class of polymers that swell in the presence of moisture and may contain up to approximately 95% water by weight. In general these materials are very soft, smooth, highly lubricious, non-abrasive, and non-adhesive to tissues. A variety of techniques to produce hydrogel articles are known to those skilled in the art, including for instance, casting, molding, extrusion, pultrusion, and calendering.

International Publication No. WO 01/47549 describes a wound dressing of absorbent flexible filaments extending from a central core. The dressing is placed at a wound site, and the filaments absorb excess moisture, thus discouraging microbial growth. International Publication No. WO 05/016972 describes novel antimicrobial polymer compounds, which may be used as a wound dressing or to form an ophthalmic lens.

US Patent Number 6,475,516 describes a wound dressing having a polymeric surface, and a gelatin hydrogel covalently attached to the polymeric surface. Liposomes that

encapsulate a therapeutic agent are present within the gelatinous hydrogel. The US 6,475,516 patent describes for instance, silicone Foley catheters, which are coated with a disclosed PEG-gelatin matrix. The matrix contains liposomes encapsulating the antibiotic ciproflaxen. The coating is tightly bound to the catheter, so that upon removal of the catheter, the coating will be removed from the body. The issue of preventing micro-trauma during insertion or changing of a catheter is not addressed.

Such hydrogel polymeric materials have shown potential in reducing infection at a wound site; however they have not yet been fully developed for widespread use at a wound site or at the point of introduction of a medical device, such as a catheter.

It would thus be highly advantageous to provide articles for preventing infections, wherein extended antimicrobial treatment may be provided and trauma can be reduced at the bodily orifice or wound site.

GLOSSARY

In the present invention, the terms "medical device", or "device", refer to a medical instrument having at least one portion which is entered into the human body, either temporarily or for an extended period. These include, but are not limited to, a urinary or urethral catheter, a needle, a needle-based catheter, a surgical instrument, a surgical scope such as an endoscope, a port, or a guide wire.

The terms "proximal/distal" refer to the location of an element in relation to a medical practitioner utilizing the surgical article, wherein "proximal" refers to adjacent to the practitioner, and "distal" refers to distant from the practitioner.

The term "hydrogel" refers to a material that forms a jelly-like product when suspended in a solvent, typically water or a polar solvent. Conventional hydrogels are formulated from gelatin, pectin, or proteins such as collagen or hemoglobin, and fractions and derivatives thereof.

The term "outer perimeter", in reference to a bodily orifice or a wound, refers to the skin surrounding the orifice or wound opening.

The term "sleeve" refers to a sheath for surrounding at least a portion of a medical device and shielding the device from contact with the human body.

The term "flange" is synonymous with a skirt, a rim, and a diaphragm, and refers to a protruding edge surrounding the cylindrical member of the sleeve.

SUMMARY OF THE INVENTION

There is thus provided by the present invention, a sleeve for maintaining sterility of an insertable medical device. The sleeve comprises:

a) a cylindrical member formed of a flexible material, said cylindrical member having: a lumen, an outer side for contacting the human body, and an inner side for shielding at least a portion of a medical device placed inside said lumen from contact with the human body; said cylindrical member further having a proximal end and a distal end;

wherein said cylindrical member is adjustable from an extended configuration to a shortened configuration; said shortened configuration adapted for insertion of a medical device therein, and said extended configuration adapted for shielding at least a portion of said medical device from contact with the human body;

b) a flange located upon a proximal portion of said sleeve.

In use of the sleeve, the cylindrical member is initially in its shortened configuration. A medical device is inserted into the cylindrical member, and the cylindrical member is adjusted to the extended configuration to shield at least a portion of the medical device from contact with the human body. The flange is then positioned to cover the outer perimeter of a bodily orifice or a wound, thus maintaining sterility of the medical device.

In certain embodiments of the invention, the sleeve is formed of at least one material selected from: phthalate, polyacrylic acid, polyvinyl alcohol, polyvinyl pyrrolidone, polyoxyethylene-polyoxypropylene, polyisobutylene, an acrylic polymer, an acrylic acid polymer; styrene, a styrene isoprene block copolymer, a urethane, a silicone, butadiene, a styrene butadiene copolymer, a polyacrylate, poly(hydroxyethyl methacrylate), poly(ethylene oxide), and sub-combinations thereof.

Additionally, in one embodiment, the cylindrical member comprises:

an inner layer for contacting an insertable medical device, the inner layer formed of a synthetic polymer, and an outer layer for contacting a body tissue, the outer layer formulated as a hydrogel. In such case, the outer layer is present proximal to the flange and extends to cover a portion of the inner layer.

Optionally, the hydrogel of the outer body tissue-contacting layer (b) is formulated of at least one material selected from: alginate, cellulose, a cellulose derivative, gelatin, pectin, gum Arabic, guar gum, karaya gum, tragacanth gum, xanthan gum, bovine serum albumin, glycerin, polyethylene glycol, polylactic acid; poly(lactic-co-glycolic acid), and a plant resin.

Preferably, the hydrogel is formulated to absorb excess moisture thereby preventing microbial growth at the bodily orifice or wound.

Further, in one preferred embodiment, the hydrogel is comprised of: 10% gelatin, 6% glycerin, 20% water, and 64% of alcohol solution containing 2% comifera species gum.

Moreover, according to a preferred embodiment, the sleeve is adapted to release an antimicrobial active agent from the sleeve.

Additionally, in certain embodiments, the sleeve comprises a micropore filter layer located external to the flange, wherein the pore size of the filter prevents passage of infectious microorganisms there-through.

Still further, in one embodiment, the sleeve comprises a cylindrical extension portion extending proximally in relation to the flange. The cylindrical extension portion is adapted to remain external to the human body to cover an external area of an insertable medical device.

Preferably, the cylindrical member is sufficiently flexible to expand to a larger diameter upon insertion of an insertable medical device therein, thereby protecting the human body from shear forces occurring upon insertion of the medical device.

According to certain embodiments of the sleeve, the shortened configuration of the cylindrical member is designed so that the distal end of the cylindrical member is rolled inwards, for contacting an insertable medical device. Thus, the rolled configuration thereby converts the shear forces created during insertion of the catheter, into transverse forces. This minimizes trauma to the human body.

In some embodiments, the insertable medical device is selected from: a catheter, a needle, and a guide wire.

Additionally, in one embodiment, the cylindrical member has a wall thickness within the range of 0.1 millimeters to 1 millimeters.

Moreover, in one embodiment, the sleeve further comprises an adhesive for adhering the flange to an outer perimeter of a bodily orifice or a wound.

Further, in one embodiment, the sleeve material has an acidity level which deters microbial growth.

Preferably, the flange is formed of a flexible material, adapted to conform to and tightly grip the contours of the outer perimeter of a bodily orifice or a wound.

The present invention additionally provides a wound dressing for preventing infection at a wound site. The wound dressing comprises a hydrogel layer adapted to release an active antimicrobial agent. The hydrogel layer is formulated so as to tightly grip the skin and prevent entry of microorganisms beneath the hydrogel layer.

In certain embodiments of the invention, the wound dressing further comprises a micropore filter layer, having a pore size that prevents passage of infectious microorganisms there-through.

According to one preferred embodiment, the hydrogel layer comprises: 10% gelatin, 6% glycerin, 20% water, and 64% of alcohol solution containing 2% comifera species gum.

Moreover, in certain embodiments of the wound dressing, the hydrogel is comprised of at least one material selected from: alginate, cellulose, a cellulose derivative, gelatin, pectin, gum Arabic, guar gum, karaya gum, tragacanth gum, xanthan gum, polyethylene glycol, polylactic acid; poly(lactic-co-glycolic acid),, bovine serum albumin, glycerin, a plant resin, and sub-combinations thereof.

Additionally, in other embodiments, the wound dressing further comprises a layer formed of a material selected from: phthalate, polyacrylic acid polyvinyl alcohol, polyvinyl pyrrolidone, polyoxyethylene-polyoxypropylene, polyisobutylene, an acrylic polymer, an acrylic acid polymer; styrene, a styrene isoprene block copolymer, a urethane, a silicone, butadiene, a styrene butadiene copolymer, a polyacrylate, and poly(hydroxyethyl methacrylate).

Further, in one embodiment the wound dressing further comprises an outer protective layer, the protective layer having adhesive areas releasable from a peel-off membrane for ease of attachment of the protective layer.

Still further, in some embodiments, the wound dressing further comprises a second hydrogel layer, acting as a replenishing layer. This acts to hydrate the first hydrogel

layer. The second hydrogel layer is replaceable without removal of the first hydrogel layer.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and further advantages of the present invention may be better understood by referring to the following description in conjunction with the accompanying drawings in which:

FIG. 1 illustrates a prior art urethral catheter;

FIG. 2A illustrates a catheter sleeve of the invention, shown in shortened configuration prior to use;

FIG. 2B illustrates a catheter sleeve of the invention, shown in partially extended configuration during deployment;

FIG. 2C illustrates a catheter sleeve of the invention, in final extended configuration;

FIGS. 3A-3C are cross-sectional illustrations corresponding to FIGS. 2A-2C;

FIGS. 4A-4D illustrate use of the sleeve of the invention during insertion of a urinary catheter into the male urinary tract;

FIGS. 5A-5C illustrate an embodiment of the sleeve of the invention, having an extension portion;

FIGS. 6A-6B illustrate placement of the sleeve of FIG. 5, within an erect or a flaccid penis;

FIG. 7 illustrates additional layers present in the sleeve according to certain embodiments;

FIGS. 8A-8C illustrate the flexible nature of catheter sleeve;

FIG. 9 illustrates a wound dressing of the invention, used with a needle;

FIG. 10 illustrates a wound dressing of the invention, used with a venous or arterial catheter;

FIG. 11 illustrates a dressing having a slit configuration;

FIG. 12 illustrates a dressing having an adhesive in its outer perimeter;

FIG. 13 illustrates a multi-layered dressing;

FIG. 14 illustrates a dressing having concentric rings;

FIG. 15 illustrates variable aspects of the shape and elements of the dressing.

It will be appreciated that for simplicity and clarity of illustration, elements shown in the drawings have not necessarily been drawn accurately or to scale. Reference numerals may be repeated among the drawings to indicate corresponding or analogous elements. Moreover, some of the blocks depicted in the drawings may be combined into a single function.

DETAILED DESCRIPTION

In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. There is no intention to limit the invention to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting.

The present invention is directed to articles for maintaining sterility during and following an insertion procedure or wound treatment.

Reference is now made to FIG. 1, illustrating a prior art urethral catheter 50, after introduction into the male urinary tract. The difficulties associated with maintaining sterility of this standard catheter will now be described. Catheter 50 is positioned through urethra 102 running through a penile shaft 110, through a prostate 108 and into a bladder 104. An orifice 54 is positioned at a distal end 52 of catheter 50, and a balloon 56 is configured to hold catheter 50 in place when balloon 56 is inflated. It should be readily apparent that catheter 50 is any standard urethral catheter, and similar systems and methods may be used in a female body as well.

The male anatomy is generally more challenging in terms of maintaining a sterile environment, because catheter 50 may move up and down. For example, a patient's normal movements may cause the catheter to ride up in the urethra 102 sufficiently to cause a contaminated portion of catheter 50, previously located external to penile shaft 110, to enter urethra 102. This can cause contamination at the fossa navicularis 106, which may then travel upwards and contaminate the prostate 108 and urinary bladder 104.

It should be readily apparent that the urethra 102 is only one example of an internal body surface that may come into contact with a medical device. Such internal body surfaces may be existing biological surfaces, or may be surfaces created by incisions or by other medical procedures.

In order to overcome the disadvantages of prior art standard urinary catheters, and prevent infection of the urinary tract, the invention discloses a novel extendable sleeve, which shields a significant portion of the catheter from directly contacting the urinary tract. In its final extended configuration, the sleeve extends from the external penile tip, to approximately midway of the urethra. In certain embodiments, the sleeve releases an antimicrobial agent, and in certain embodiments the sleeve material absorbs excess moisture. This dual action reduces the likelihood of infection. Additionally, as the sleeve is highly flexible and smooth, it protects the urethra from micro-trauma normally associated with insertion of a urinary catheter.

Though in the following description and drawings, the invention is described in use with a urinary catheter and a needle, there is no intention to limit the invention to use with these specific medical devices. The sleeve of the invention may be used with any insertable medical device, or the wound dressing may be placed upon any relevant site of the human body.

Reference is now made to FIG. 2A, which is a perspective illustration of a sleeve 60, for use with a urinary catheter, in accordance with the present invention.

Catheter sleeve 60 is shown in Fig. 2A in its shortened configuration, prior to use. Sleeve 60 is comprised of a cylindrical member 62, which can be adjusted to extend or contract, due to the highly flexible material from which it is formed, as discussed hereinbelow. Cylindrical member 62 includes a lumen 67, a distal end 66 which can be inserted into the urethra, and a proximal end 68, which will become adjacent to the penile tip.

Outer side of cylindrical member 62 will contact the human body, while inner side, represented by lumen 67, will shield at least a portion of a catheter placed therein, from contacting the human body, as described hereinbelow in relation to Fig. 4A-4D.

In the embodiment shown, distal end 66 is rolled inwards as shown by arrows 66A, 66A.

Flange 72 is present near or at the distal end 68 of cylindrical member 62.

In use, catheter (not shown) is threaded through lumen 67 of cylindrical member 62, and catheter and sleeve 60 are brought into proximity to the penis. As catheter is inserted into the urethra, cylindrical member 62 is urged by pressure exerted from catheter tip, to extend to extended configuration.

Referring to FIG. 2B, upwards arrows illustrate pressure placed upon sleeve 60 by catheter during insertion into urethra. Sleeve 60 is illustrated in partially extended configuration.

Referring to FIG. 2C, sleeve 60 is shown in fully extended configuration, occurring after insertion of catheter is complete.

Reference is now made to FIGS. 3A-3C which are corresponding cross-sectional illustrations of the catheter sleeve of the invention.

Referring to FIG. 3A, according to one embodiment, distal end 66 of flexible cylindrical member 62 is initially rolled inwardly, and is unfurled during deployment by pushing of catheter (not shown) through lumen 67 from proximal end 68 to distal end 66. During the process of insertion of catheter, distal end 66 gradually unrolls, as depicted in FIG. 3A and 3B, until distal end 66 has completely straightened out, as shown in FIG. 3C. Rolling of distal end 66 may be done in various ways, including in a zigzag configuration, telescope configuration, or any other suitable configuration.

Reference is now made to FIGS. 4A-4C, which are schematic illustrations of the steps of using sleeve 60 with catheter 50 during insertion of catheter 50 into a penile shaft 110.

As shown in FIG. 4A, catheter sleeve 60 is initially positioned at the urethral opening of the glans penis, at the external tip 112 of penile shaft 110. Flange 72 is positioned so as to conform to external tip 112.

Distal end 66 of flexible cylindrical member 62 is initially rolled inwardly.

As shown in FIG. 4B, as catheter 50 is introduced into penile shaft 110 through catheter sleeve 60, distal end 66 of flexible cylindrical member 62 begins to unfurl or unroll distally into the urethra 102. This unrolling is caused by distal end of catheter 50 pushing up against distal end 66 of flexible distal cylindrical member 62.

As shown in FIG. 4C, catheter 50 is advanced fully through sleeve 60 and up further into the urethra 102, thus completely straightening out distal end 66 of sleeve 60.

Thus trauma upon insertion of catheter 50 is avoided by providing sleeve 60, and more particularly by its rolled up configuration. This configuration provides minimization of shear forces normally associated with insertion of a catheter, converting these forces to transverse forces instead, which are much less traumatic to the body tissue.

Finally, as shown in FIG. 4D, when catheter 50 is fully in place, a portion of catheter 50 is in direct contact with body tissue 100 (in this case urethra 102, prostate 108 and bladder 104), this portion referred to as a tissue contacting portion 42; a portion of catheter 50 is exposed to the air and is outside of the body, this portion referred to as an exposed portion 44, and a portion of catheter 50 is in contact with sleeve 60, this portion referred to as sleeve contacting portion 46.

One advantage of the invention is thus readily apparent, as sleeve 60 will shield and prevent direct contact between a significant area of the catheter 50, and the urethra. Sleeve contacting portion 46 separates tissue-contacting portion 42 of catheter from exposed portion 44. If catheter 50 does not stay fully in place, causing exposed portion 44 to at least partially enter penile shaft 110, exposed portion 44 will contact sleeve 60 and will be prevented from touching any of body tissue 100. In this way, contamination may be avoided, and sterility of the catheter is maintained.

Flange 72 is advantageous in providing a spatial barrier for preventing contamination, since the urethral opening and catheter 50, are now covered and thus protected from exposure to the external non-sterile exposed portion of penile shaft 110.

In one preferred embodiment, flange 72 is formed of a flexible material, which can readily conform to the contours of the outer perimeter of the bodily orifice or a wound. Thus, flange 72 will preferably tightly grip external skin, and will prevent entry of

microorganisms beneath the flange from adjacent non-sterile skin areas, which could occur in prior art loose dressings.

Optionally, the outer edges of flange 72 may be provided with adhesive to ensure adherence of flange 72 to the outer perimeter of a bodily orifice or a wound.

In one preferred embodiment, sleeve 60 releases an antimicrobial active agent. The antimicrobial active agent may be bonded or applied to sleeve 60 in any manner known in the art. Sleeve 60 may be impregnated with the antimicrobial agent, pre-treated or coated with the antimicrobial active agent. Non-limiting examples of antimicrobial active agents are an alcohol such as ethanol or isopropynol, a chloride active agent such as chlorhexidin, iodine, a heavy metal compound such as silver nitrate, or an antibiotic. Preferably, release of the antimicrobial active agent continues over the course of several days or weeks.

In one embodiment, the acidity level of the sleeve is such as will discourage microbial growth. For instance, the sleeve material may be formulated to have a pH level of approximately pH=5.

In some embodiments, cylindrical member 62 and flange 72 are configured from the same piece of material. In other embodiments, two different materials are attached by glue or other attachment means.

In certain embodiments, the polymeric material of the sleeve is selected from: phthalate, polyacrylic acid, polyvinyl alcohol, polyvinyl pyrrolidone, polyoxyethylene-polyoxypropylene, polyisobutylene, an acrylic polymer, an acrylic acid polymer; styrene, a styrene isoprene block copolymer, a urethane, a silicone, butadiene, a styrene butadiene copolymer, a polyacrylate, poly(hydroxyethyl methacrylate), and combinations thereof.

The thickness of the material forming the sleeve walls, and the diameter of the final sleeve, may be quite small (i.e., in a range of 0.1 to 1 millimeters, or on the order of several millimeters, for example). The sleeve requires no rigidity and is held open by the catheter or other medical device placed inside.

Reference is now made to FIGS. 5A-5C, illustrating a catheter sleeve 60, having a cylindrical extension portion, according to one embodiment of the invention.

Referring to FIG. 5A, catheter sleeve 60 further includes a cylindrical extension portion 74 extending proximally from the flange 72. Extension portion 74 is configured to extend over an additional portion of catheter 50, and is adapted to remain external to the human body, as best shown in FIG. 7A, described hereinbelow.

Cylindrical extension portion 74 may be outwardly rollable, such that initially extension portion 74 is rolled up with a proximal end positioned within the rolled up portion.

Referring to FIGS. 5B and 5C, once catheter 50 is in place, extension portion 74 is gradually unrolled until proximal end 76 is in its fully extended proximal position as shown in FIG 5C.

Reference is now made to FIGS. 6A and 6B, illustrating advantages of cylindrical extension portion. FIGS. 6A and 6B are schematic illustrations of catheter 50 within catheter sleeve 60 in an erect penile shaft 110 and a flaccid penile shaft 110, respectively. When an erection is lost, an area of catheter 50 that is normally within urethra may become exposed. Upon further erection of penile shaft 110, the newly exposed portion will again contact urethra, leading to potential contamination. By providing catheter sleeve 60, and more particularly extension portion 74, exposed portion 44 is shielded and prevented from contacting urethra upon, for example, a new erection.

In some embodiments (not shown), the extension portion 74 may be variable in length. During insertion, the extension layer may be attached to the medical device, while still allowing for movement of device. Extension portion 74 may have an accordion-like configuration, or a spring-like configuration, for example. Thus, if an end of extension portion 74 is attached to the medical insertable device, the device is still free to move, and the movements will not breach the sleeve.

Reference is now made to FIG. 7. In some embodiments, catheter sleeve 60 is further comprised of, a micropore filter layer 24, which is present external to the flange 72. The pore size of the filter layer is such that prevents passage of infectious microorganisms through the filter. In Fig. 7, filter layer 24 extends over flange 72 as

well as over cylindrical extension portion 74. Micropore filter layer may be formed of cellulose acteate, nitrate, or any porous material known in the art for preventing passage of microorganisms therethrough. Filter layer 24 mimics shape and configuration of flange 72 and of cylindrical extension portion 74, however for simplicity, only right side of filter layer 24 is illustrated in Fig. 7.

In alternative embodiment, layer 24, also termed an "outer layer", is comprised of a hydrogel material. Layer 24 will contact the body tissue at the entry site of medical device, and will cover a portion of cylindrical member 62. In this embodiment, cylindrical member 62 is formed of a synthetic polymer, and is termed an "inner layer". The inner layer will contact the insertable medical device.
The lengths of the outer and inner layers may vary relative to one another. Although in Fig. 7 the outer layer 24 is illustrated as shorter than the inner layer 62, this is merely for illustrative purposes and is not intended to limit the scope of the invention.

Optionally, when catheter device is to be changed, outer layer 24 of hydrogel can be removed, while inner layer of synthetic polymer can be left within the urethra. This prevents micro-trauma typically associated with changing of a catheter device. This option is not available in prior art coated catheters, whose coating is tightly bound to the catheter, and cannot be left within the urethra to ease of re-insertion of a catheter.

A hydrogel absorbs excess moisture, thereby preventing microbial growth at the bodily orifice or wound. A hydrogel is typically sufficiently flexible to expand to a larger diameter upon insertion of an insertable medical device therein, thus protecting the human body from shear forces occurring upon insertion of a medical device. This aspect of the invention is discussed further hereinbelow in relation to FIG. 8.

In certain embodiments, the hydrogel is formed of at least one of the following: alginate, cellulose, a cellulose derivative, gelatin, gum Arabic, guar gum, karaya gum, tragacanth gum, xanthan gum, polyethylene glycol, polylactic acid; and poly(lactic-co-glycolic acid).

In a particular embodiment, the cellulose derivative is selected from carboxymethyl cellulose; ethyl cellulose; hydroxyethyl cellulose; hydroxylpropyl

cellulose; hydroxypropylmethyl cellulose; methyl cellulose; methylhydroxy cellulose; cellulose acetate, and combinations thereof.

In a particular embodiment, the polymer is gelatin. In a particular embodiment, the gelatin is crosslinked. In particular embodiments the cross linking is achieved by a chemical cross linker, or by a physical method, such as UV irradiation, gamma irradiation, microwave irradiation or a thermal effect. A suitable degree of cross-linking is in the range 5% to100%.

In a particular embodiment, the gelatin has a Bloom strength in the range of 100 to 400. In particular embodiments, the gelatin is present in an amount of 0.5 to 20 %(w/w), or in an amount of 0.5 to 2 %(w/w), based on the total weight of the formulation.

In a particular embodiment, the gel is a semisolid gel or a soft gel. In a particular embodiment, the gel is a thixotropic gel. In a particular embodiment, the gel is anhydrous.

Optionally, the hydrogel may additionally comprise one or more material selected from: bovine serum albumin, chitosan, gelatin, glycerin, and a plant resin.

One preferred hydrogel composition comprises:10% gelatin, 6% glycerin, 20% water, 64% of absolute alcohol solution containing 2% comifera species gum.

This composition will tightly grip the skin, forming a continuum with the skin and prevent entry of infectious microorganisms beneath the hydrogel from the surrounding non-sterile skin environment. In contrast, prior art hydrogels suffer from the disadvantage that they are relatively loose and allow migration of infectious microorganisms from the surrounding non-sterile skin, beneath the edges of the hydrogel layer.

Reference is now made to FIGS. 8A-8C, which are illustrations of catheter sleeve 60 illustrating flexible nature of catheter sleeve. As shown in FIG. 8A, flexible cylindrical member 62 has an initial narrow diameter d_1. As shown in FIG. 8B, insertion of device 50 causes an increase in the overall diameter along the length of flexible cylindrical member portion by gradually stretching or pushing the walls of flexible cylindrical

member portion 62 outwardly in a lateral direction as device 50 moves along an interior surface thereof. In a final configuration, as shown in FIG. 8C, the diameter d_2 of flexible cylindrical member 62 is greater overall than the initial diameter d_1 of flexible cylindrical member 62. This minimizes friction between the insertable medical device 50 and the surrounding body tissue.

In summary, the sleeve of the invention thus protects the urinary tract from infection, by acting as a spatial barrier, and in certain embodiments, by releasing an active antimicrobial agent. The flexible nature of the sleeve, and the preferred configuration of a rolled up distal end, act to protect the urinary tract from micro-trauma normally associated with insertion of a urinary catheter. The sleeve may be left within to ease re-insertion of a new catheter. The cylindrical extension portion and the flange provide additional protection against infection.

Reference is now made to FIG. 9, which is an illustration of a wound dressing 80 and a needle 90 for insertion into a body, in accordance with additional embodiments of the present invention. Wound dressing 80 may be, for example, a patch, and may include both dynamic properties and spatial properties. Wound dressing 80 is comprised of active layer 14 which is formed of a hydrogel that releases an antimicrobial active agent. Active layer 14 of hydrogel is formulated so as to tightly grip the skin and prevent entry of microorganisms beneath said hydrogel layer. This is contrast to prior art hydrogels, which suffer from the disadvantage that they are relatively loose and allow migration of infectious microorganisms from the surrounding non-sterile skin, beneath the edges of the hydrogel layer.

Optionally, dressing 80 may further include replenishing layer 29, which prevents dehydration of active layer 14. Replenishing layer 29 may be formulated as a hydrogel as well. Replenishing layer 29 may be of different composition than active layer 14, or may be of similar composition. Replenishing layer 29 may be replaced without removal of the active layer 14, thus preventing exposure of the wound site to the external environment.

Wound dressing 80 preferably includes a micropore filter layer (not shown) having a pore size, which prevents passage of infectious microorganisms there through.

Device entry point 36 is at a distance from edges 34. Upon insertion of needle 90 into the body (vein, muscle, etc.), needle 90 must first pass through wound dressing at device entry point 36. Device entry point 36 may be a designated area, or may be chosen at will during the insertion procedure. In some embodiments, needle 90 may comprise a connecting portion 92. Connecting portion 92 is comprised of the same material as active layer 14 or of replenishing layer 29, and thus forms an additional lock between needle 90 and the exposed environment.
Optionally, dressing or certain portions thereof, are transparent.

In some embodiments, active layer 14 is a porous polymeric gel, and active agent includes molecules suspended in the polymeric gel. For example, active layer 14 may be comprised of polyurethane, latex, silicone, Teflon, or any other polymer. Active layer 14 may be configured as a porous hydrogel and may further include gelatin, hyaluronic acid, chitosan, etc. In other embodiments, active layer 14 may be a porous polymer combined with alcohol or ethanol. In yet additional embodiments, active layer 14 may be comprised of cross-linked, natural, synthetic or any combination thereof of materials, including for example, cotton fibers, powder such as talc, or sponge-like materials. Active agent may include, for example, ethanol or alcohol and medicaments such as antibiotics or any other anti-contamination or disinfectant substances. In some embodiments, active layer 14 may be comprised of a woven or unwoven sponge-like material. In some embodiments, active layer 14 is a filter membrane designed to keep bacteria from entering body tissue opening 101. The ability to keep bacteria out depends on pore size, and as such, active layer 14 may include pores as small as 0.05 microns, for example. Active layer 14 may be an extremely thin layer, designed to be in direct contact with device 40 or skin, for example. Active layer may be as thin as 0.1 mm or even less, and in some embodiments is in a range of 0.1 mm to 1 mm. In other embodiments, active layer 14 may be several millimeters in thickness. In some embodiments, an additional protective layer may be used, wherein the protective layer allows for diffusion of treatment composition from active layer 14 and through the

protective layer to the body tissue. The protective layer may be comprised of polymeric or other synthetic materials as well.

Reference is now made to FIG. 10. In some embodiments, needle 90 is a portion of a venous or arterial catheter, as shown in FIG. 10. A replenishing layer may further be added to a shaft of the catheter, for providing an additional barrier.

Reference is now made to FIG. 11, illustrating a dressing 12 that can be added to a shaft of a catheter after the catheter is in place. Dressing 12 includes a slit 140 for fitting around a shaft. Thus, dressing 12 may be placed around a shaft of the catheter and up against the skin. After positioning of dressing 12 in place, in some embodiments, edges of slit 140 can be adhered together. Similarly, a slit configuration may be used for replenishing layer (not shown).

Reference is now made to FIG. 12, which is a schematic illustration of a wound dressing 12 in accordance with yet additional embodiments of the present invention. An outer perimeter 48 is positioned at an outer edge of dressing 12, wherein outer perimeter 48 includes adhesive material for attaching dressing 10 to the skin. A typical wound dressing may be placed on top of dressing 12 of the invention and adhered thereto.

Reference is now made to FIG. 13, which is a schematic illustration of wound dressing 10 in accordance with additional embodiments of the present invention. Dressing 12 may be comprised of multiple layers, separated from one another by impermeable membranes 130 so as to prevent diffusion and mixing of various compositions of treatment solution within each of the layers. Each layer may include a composition for a different action. For example, one layer may include a disinfectant which is known to be effective against a particular microorganism, a second layer will have a different disinfectant, and a third layer will have a polymer with a basic pH for hindering growth of normal skin saprophites (which favor an acidic environment), for example. In order for each layer to be able to contact the skin, a first layer 132 which is closest to the skin may be smaller than a second layer 134, which is further from the skin, which in turn may be smaller than a third layer 136, which is on top of the first and second layers 132 and 134. It should be readily apparent that the number of layers may vary and is not

limited to the embodiment shown herein. Additional examples of compositions which may be incorporated into some of the layers include emulsifiers to facilitate penetration into hydrophobic islands of bacteria embedded in lipids and keratinocytes, acids, antioxidants, chelators, humectants, oxidizing or reducing agents, keratinolytic agents or combinations thereof.

Reference is now made to FIG. 14, which is an illustration of another embodiment of the present invention. In this embodiment, dressing 12 is comprised of rings, each of which is permeated with a different solution. This creates a graded barrier system whereby the area of dressing 12 which are closer to body tissue opening 101 have more potent solutions that outer areas, for example.

Reference is now made to FIG. 15. Dressing 12 may have any shape required. Dressing 12 has a surface portion with edges 34 and a body tissue opening contact area 21, which may be a device entry point for insertion of device 50 therethrough, or which may be, for example, a wound-contacting point. Edges 34 are positioned at a suitable distance D from body tissue opening contact area 21 such that a spatial barrier or protection zone 23 is provided between body tissue opening contact area 21 and areas of potential contamination.

It should be apparent that many modifications, substitutions, changes, and equivalents might occur to those of ordinary skill in the art. For example, the present invention may be used with a catheter for expansion of a balloon and/or delivery of a stent, or with a catheter for drug delivery at an ostium, for cauterization, or for any other treatment.

Having described the present invention with regard to certain specific embodiments thereof, it is to be understood that the description is not meant as a limitation, since further modifications will now suggest themselves to those skilled in the art, and it is intended to cover such modifications as fall within the scope of the appended claims.

CLAIMS

1. A sleeve for maintaining sterility of an insertable medical device, said sleeve comprising:
    a) a cylindrical member formed of a flexible material, said cylindrical member having: a lumen, an outer side for contacting the human body, and an inner side for shielding at least a portion of a medical device placed inside said lumen from contact with the human body; said cylindrical member further having a proximal end and a distal end;
    wherein said cylindrical member is adjustable from an extended configuration to a shortened configuration; said shortened configuration adapted for insertion of a medical device therein, and said extended configuration adapted for shielding at least a portion of said medical device from contact with the human body;
    b) a flange located upon a proximal portion of said sleeve.
2. The sleeve according to claim 1, wherein said sleeve is formed of at least one material selected from: phthalate, polyacrylic acid, polyvinyl alcohol, polyvinyl pyrrolidone, polyoxyethylene-polyoxypropylene, polyisobutylene, an acrylic polymer, an acrylic acid polymer; styrene, a styrene isoprene block copolymer, a urethane, a silicone, butadiene, a styrene butadiene copolymer, a polyacrylate, poly(hydroxyethyl methacrylate), poly(ethylene oxide), and sub-combinations thereof.
3. The sleeve according to claim 1, wherein in said cylindrical member:
    a) said inner side is an inner layer formed of a synthetic polymer, said inner layer for contacting an insertable medical device,
    b) said outer side is an outer layer is formulated as a hydrogel, said outer layer for contacting a body tissue;
    wherein said outer layer (b) is present proximal to said flange and extends to cover a portion of said inner layer (a).
4. The sleeve according to claim 3, wherein the hydrogel of said outer body tissue-contacting layer (b) is formulated of at least one material selected from: alginate, cellulose, a cellulose derivative, gelatin, pectin, gum Arabic, guar gum, karaya gum, tragacanth gum, xanthan gum, bovine serum albumin, glycerin, polyethylene glycol, polylactic acid; poly(lactic-co-glycolic acid), and a plant resin.

5. The sleeve according to claim 3, wherein said hydrogel is formulated to absorb excess moisture thereby preventing microbial growth at said bodily orifice or wound.
6. The sleeve according to claim 3, wherein said hydrogel is comprised of: 10% gelatin, 6% glycerin, 20% water, and 64% of alcohol solution containing 2% comifera species gum.
7. The sleeve according to claim 1, wherein said sleeve is adapted to release an antimicrobial active agent from said sleeve.
8. The sleeve according to claim 1, further comprising a micropore filter layer located external to said flange, wherein the pore size of said filter prevents passage of infectious microorganisms there-through.
9. The sleeve according to claim 1, further comprising a cylindrical extension portion extending proximally in relation to said flange, wherein said cylindrical extension portion is adapted to remain external to the human body to cover an external area of an insertable medical device.
10. The sleeve according to claim 1, wherein said cylindrical member is sufficiently flexible to expand to a larger diameter upon insertion of an insertable medical device therein, thereby protecting the human body from shear forces occurring upon insertion of said medical device.
11. The sleeve according to claim 1, wherein in said shortened configuration of said cylindrical member, the distal end of said cylindrical member is rolled inwards, for contacting an insertable medical device, said rolled configuration thereby converting shear forces into transverse forces thus minimizing trauma to the human body.
12. The sleeve according to claim 1, wherein said insertable medical device is selected from: a catheter, a needle, and a guide wire.
13. The sleeve according to claim 1, wherein said cylindrical member has a wall thickness within the range of 0.1 millimeters, to 1 millimeters.
14. The sleeve according to claim 1, further comprising an adhesive for adhering said flange to an outer perimeter of a bodily orifice or a wound.
15. The sleeve according to claim 1, wherein said sleeve material has an acidity level which deters microbial growth.

16. The sleeve according to claim 1, wherein said flange is formed of a flexible material, adapted to conform to and tightly grip the contours of the outer perimeter of a bodily orifice or a wound.
17. Use of the sleeve of claim 1, wherein said cylindrical member is initially in its shortened configuration, a medical device is inserted into said cylindrical member, and upon insertion of said medical device, said cylindrical member is adjusted to said extended configuration to shield at least a portion of said medical device from contact with the human body; and said flange is positioned to cover the outer perimeter of a bodily orifice or a wound, thus maintaining sterility of said medical device.
18. A wound dressing for preventing infection at a wound site, comprising a hydrogel layer adapted to release an active antimicrobial agent, wherein said hydrogel layer is formulated so as to tightly grip the skin and prevent entry of microorganisms beneath said hydrogel layer.
19. The wound dressing according to claim 18, further comprising a micropore filter layer wherein the pore size of said filter prevents passage of infectious microorganisms therethrough.
20. The wound dressing according to claim 18, wherein said hydrogel layer comprises: 10% gelatin, 6% glycerin, 20% water, and 64% of alcohol solution containing 2% comifera species gum.
21. The wound dressing according to claim 18, wherein said hydrogel is comprised of at least one material selected from: alginate, cellulose, a cellulose derivative, gelatin, pectin, gum Arabic, guar gum, karaya gum, tragacanth gum, xanthan gum, polyethylene glycol, polylactic acid; poly(lactic-co-glycolic acid),, bovine serum albumin, glycerin, a plant resin, and sub-combinations thereof.
22. The wound dressing according to claim 18, further comprising a layer formed of a material selected from: phthalate, polyacrylic acid polyvinyl alcohol, polyvinyl pyrrolidone, polyoxyethylene-polyoxypropylene, polyisobutylene, an acrylic polymer, an acrylic acid polymer; styrene, a styrene isoprene block copolymer, a urethane, a silicone, butadiene, a styrene butadiene copolymer, a polyacrylate, and poly(hydroxyethyl methacrylate).

23. The wound dressing according to claim 18, further comprising an outer protective layer, said protective layer having adhesive areas releasable from a peel-off membrane for ease of attachment of said protective layer.
24. The wound dressing according to claim 18, further comprising a second hydrogel layer, acting as a replenishing layer, for hydrating said first hydrogel layer, wherein said second hydrogel layer is replaceable without removal of said first hydrogel layer.

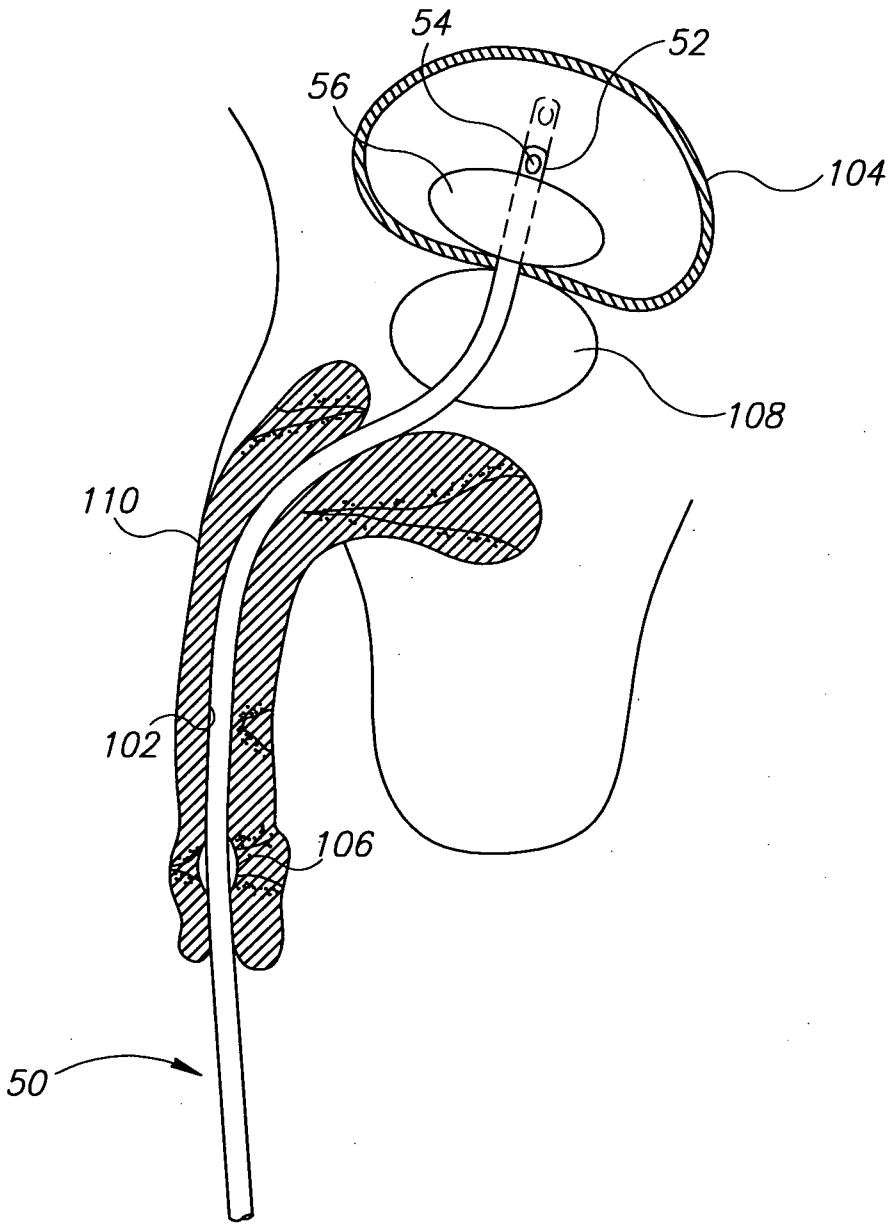

FIG.1

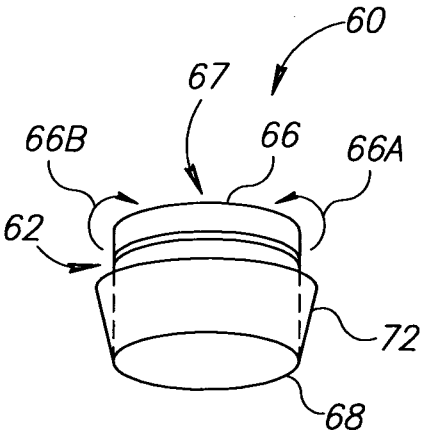

FIG.2A

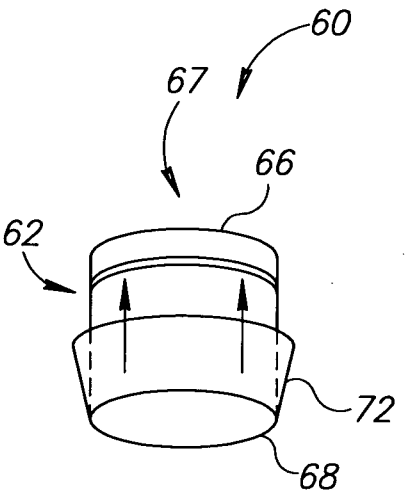

FIG.2B

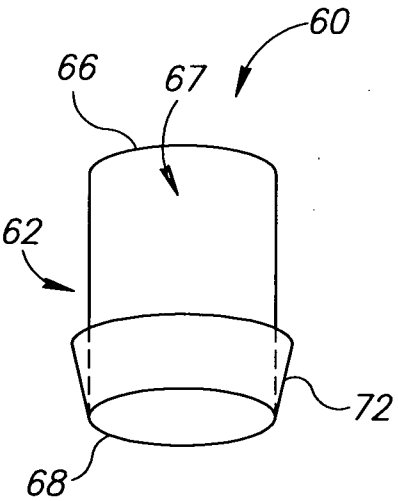

FIG.2C

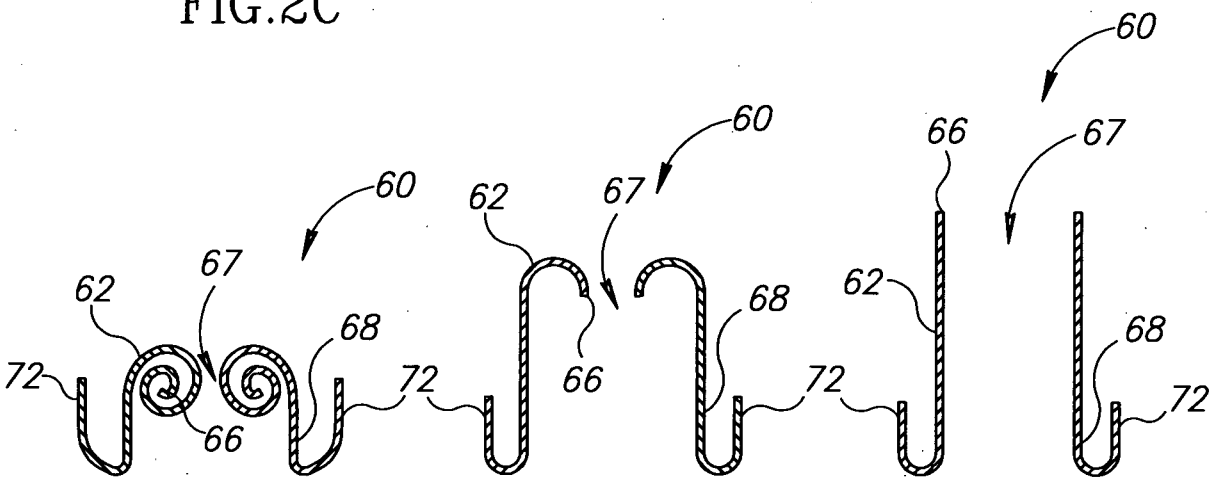

FIG.3A FIG.3B FIG.3C

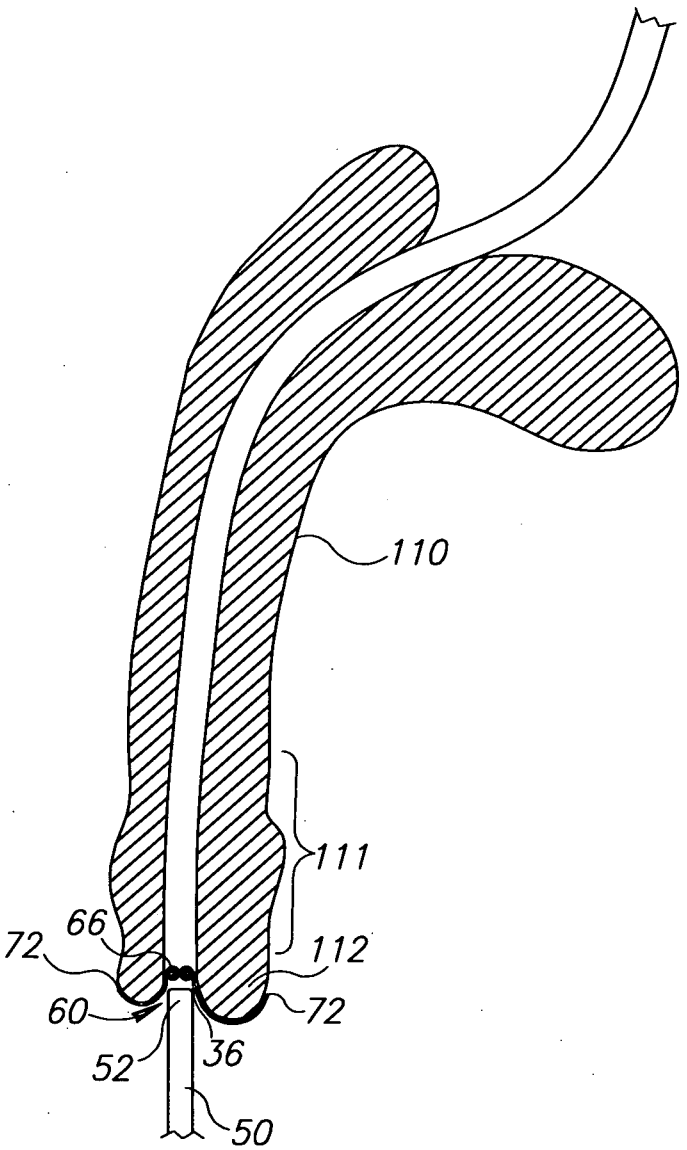

FIG.4A

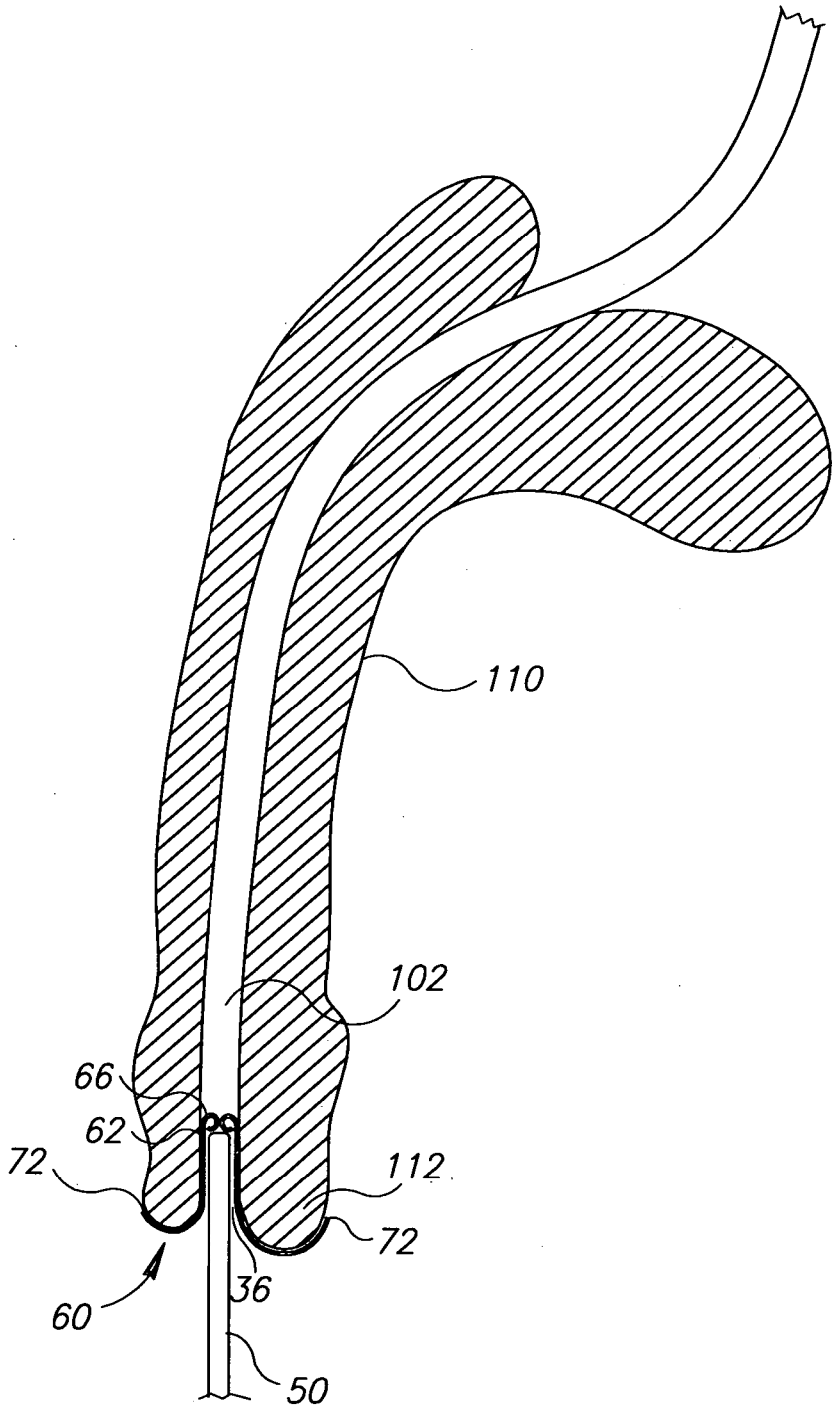

FIG.4B

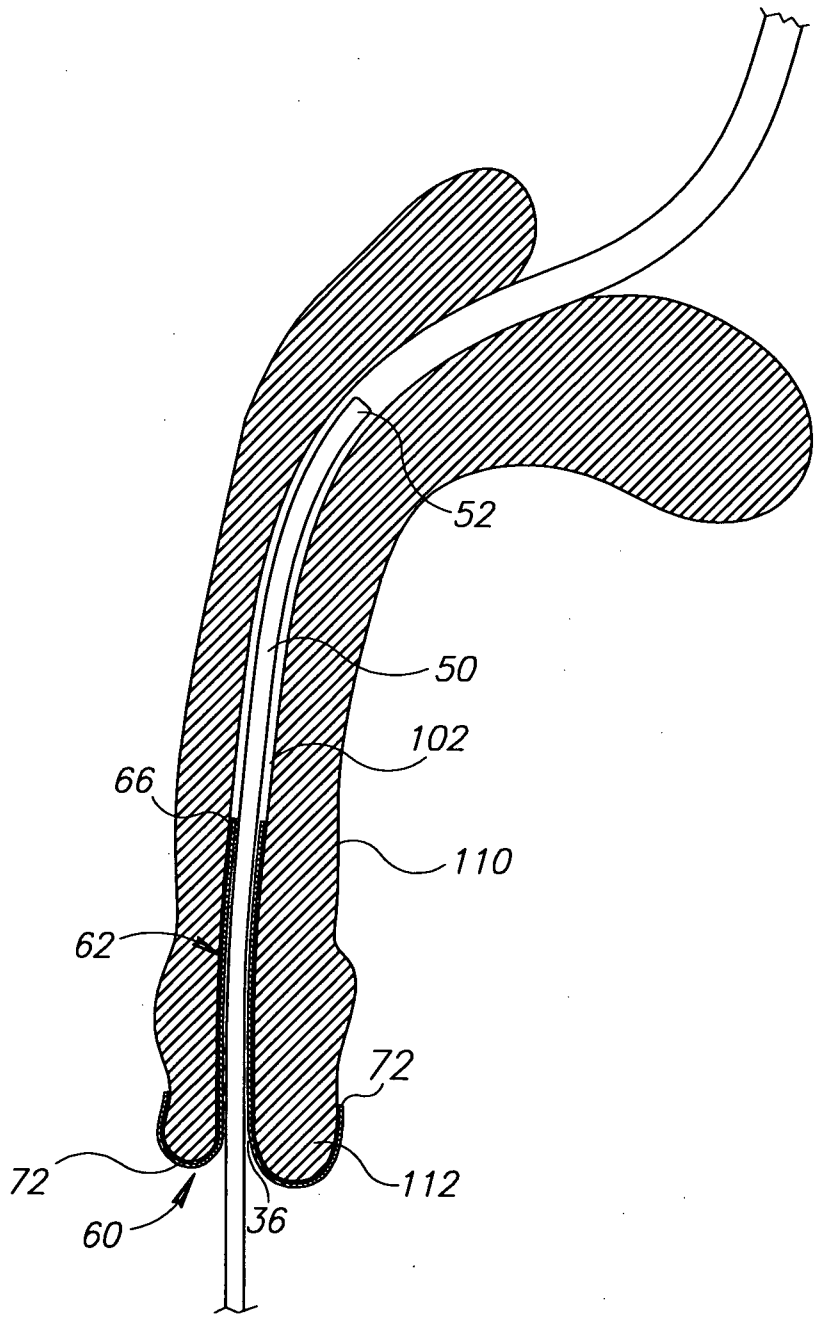

FIG.4C

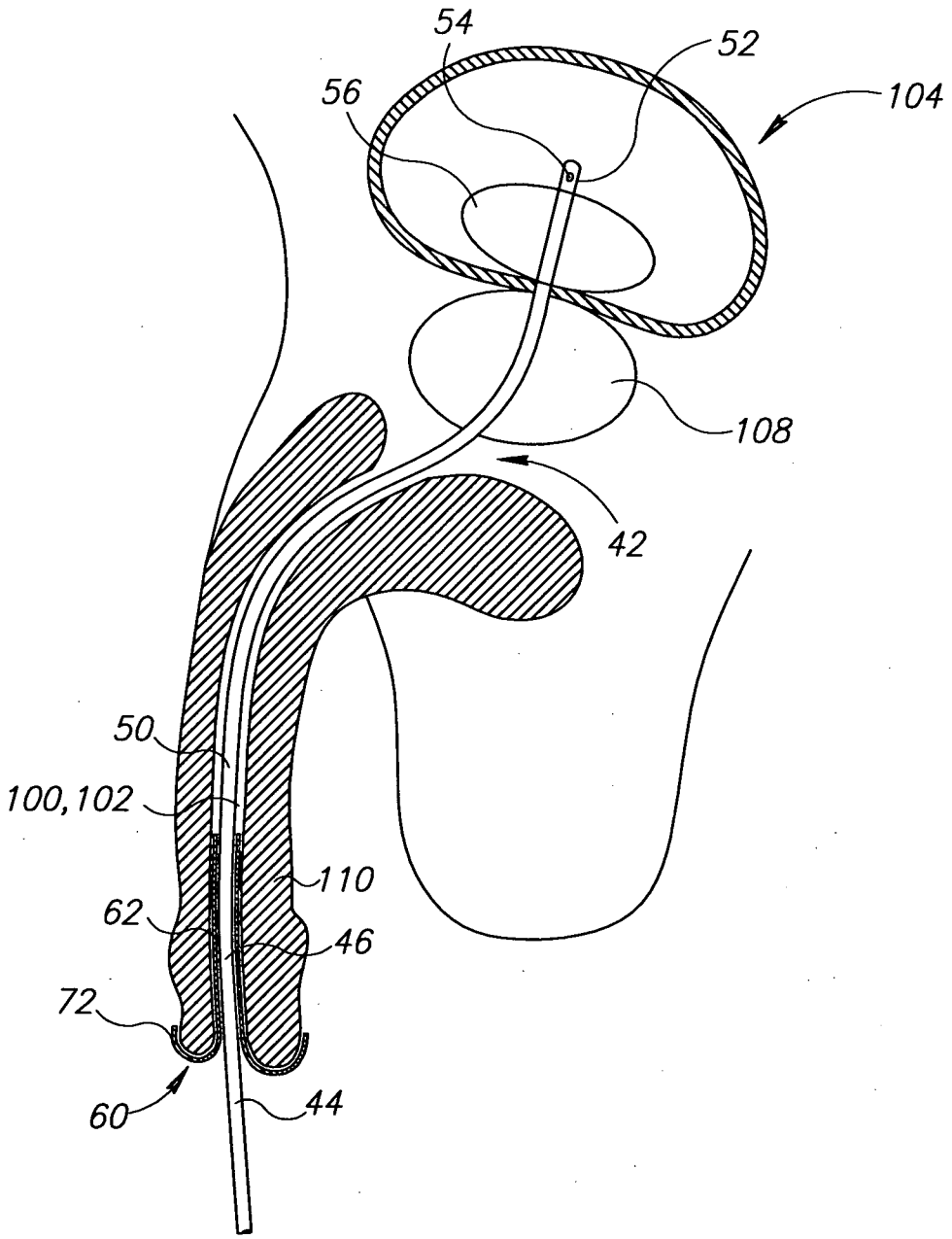

FIG.4D

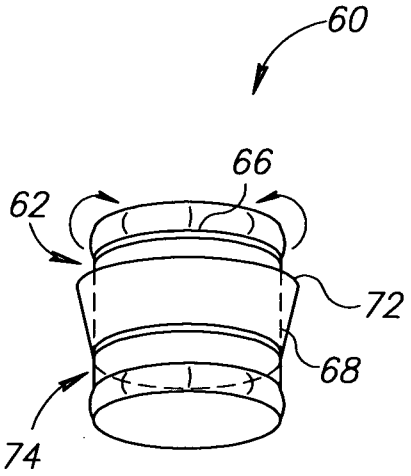

FIG.5A

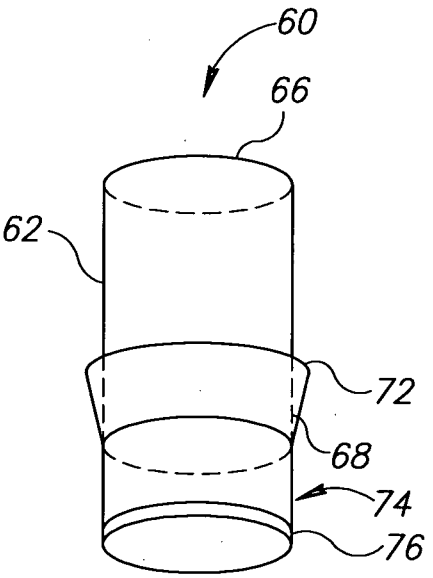

FIG.5B

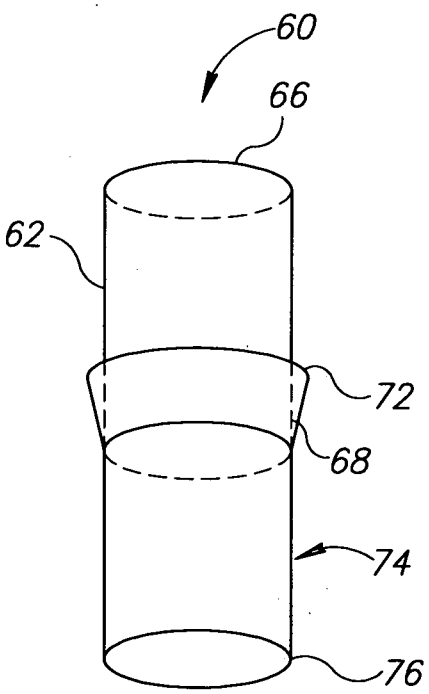

FIG.5C

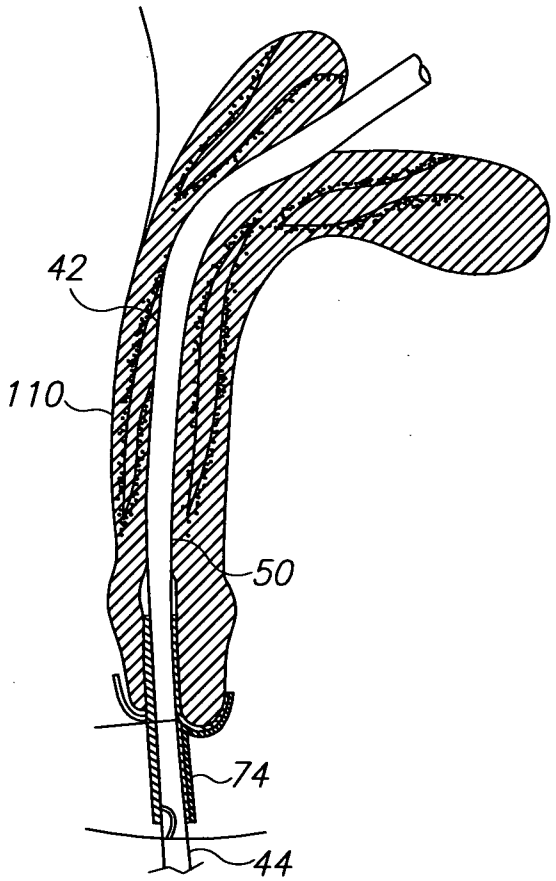

FIG.6A

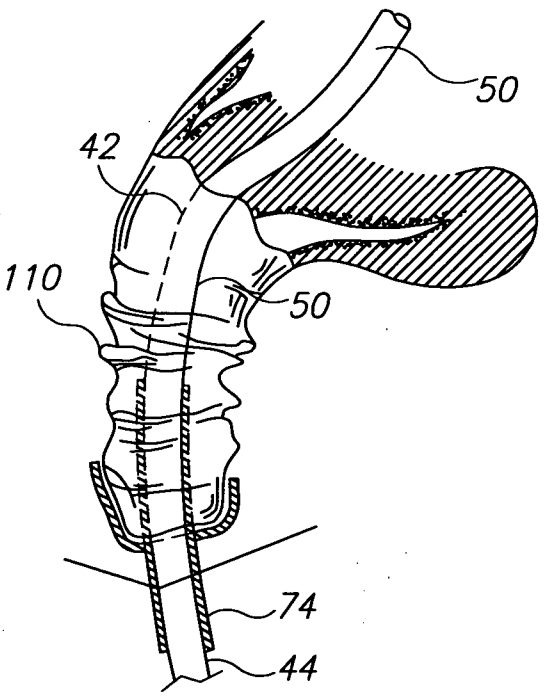

FIG.6B

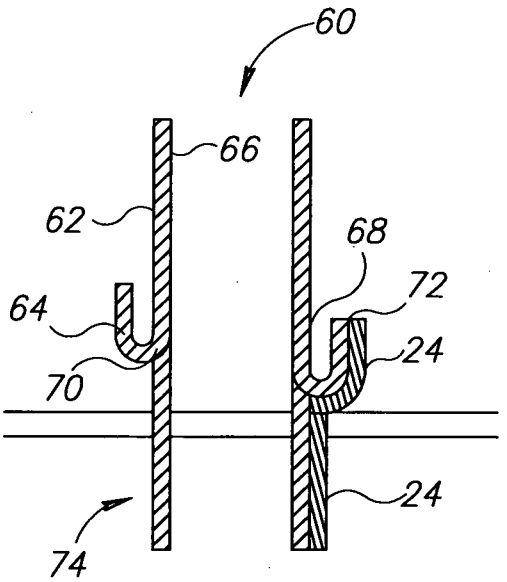

FIG.7

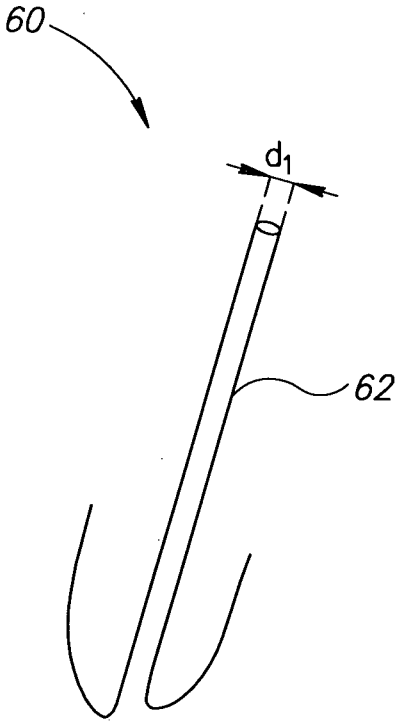

FIG.8A

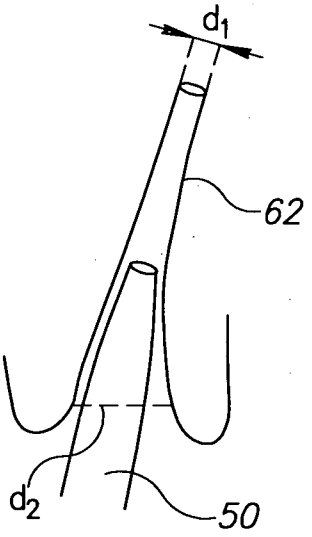

FIG.8B

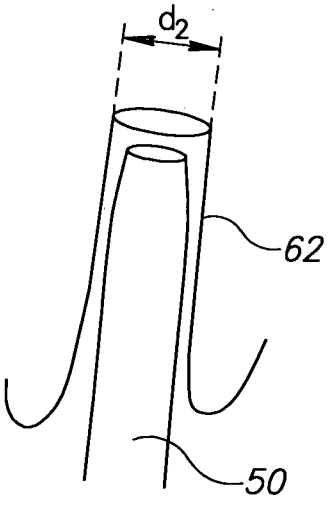

FIG.8C

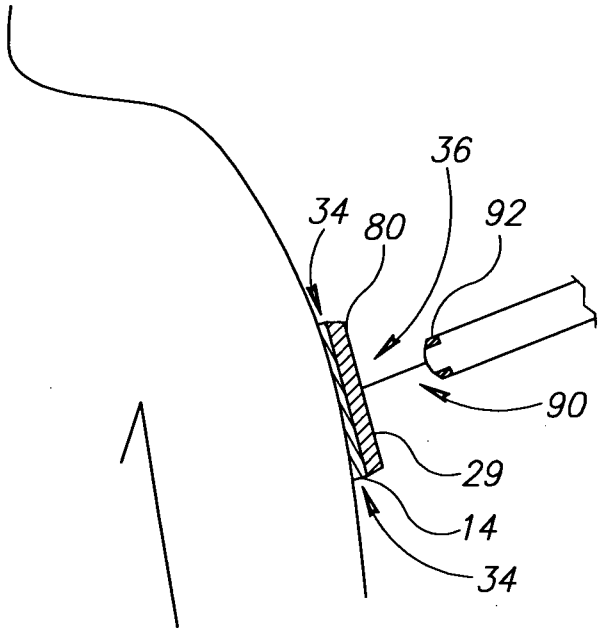

FIG.9

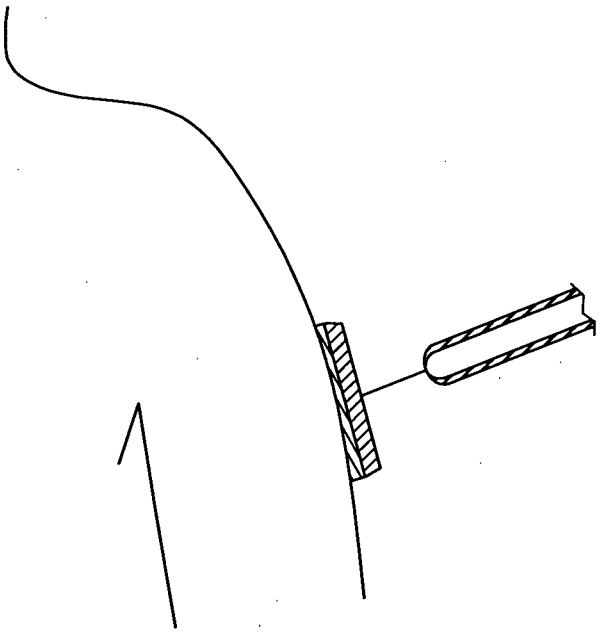

FIG.10

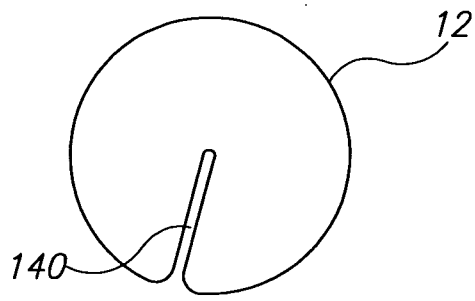

FIG.11

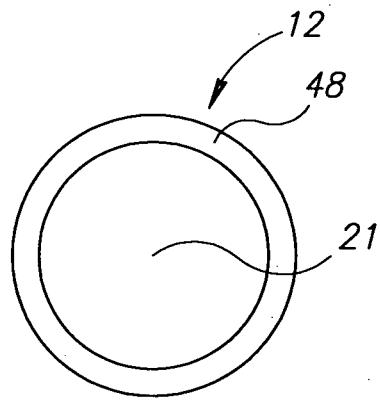

FIG.12

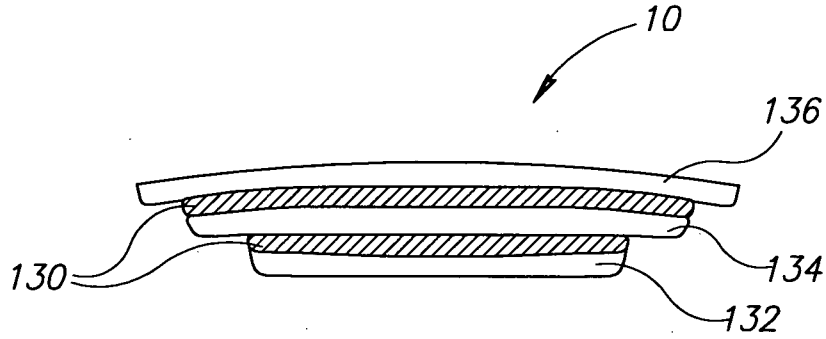

FIG.13

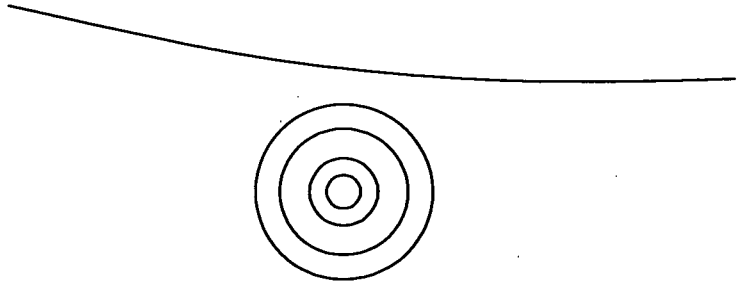

FIG.14

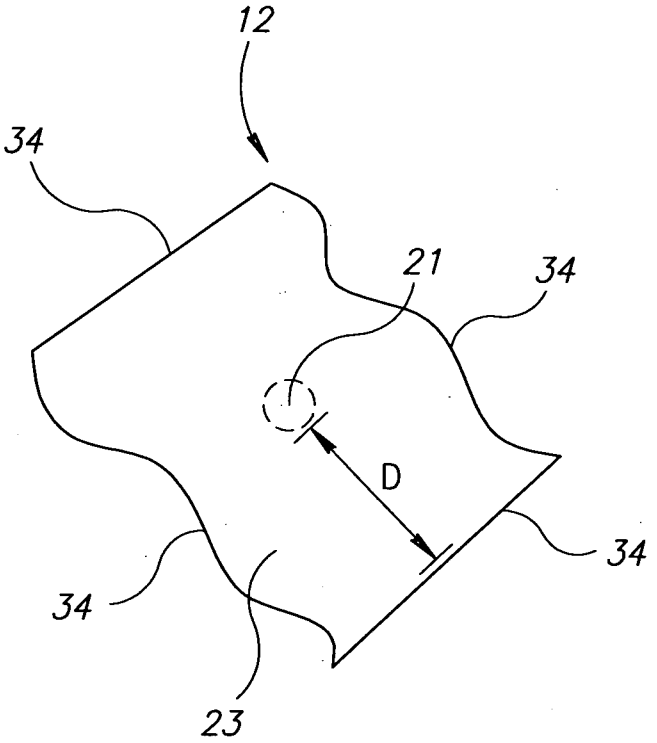

FIG.15