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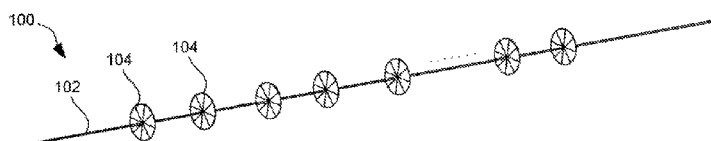


FIG. 1

(57) Abstract: Provided herein are sutures for use in a procedure applied to tissue, and methods for forming such sutures. Some sutures include bi-directional retainers, each of which can be deployed in two directions, but once deployed in one direction, resist motion in the opposite direction. Other sutures include uni-directional retainers that are conical in shape, and include tissue engaging protrusions that extend from edges and/or angled walls of the conical retainers.



SELF-RETAINING SUTURES WITH BI-DIRECTIONAL RETAINERS OR UNI-DIRECTIONAL RETAINERS

FIELD OF THE INVENTION

[0001] The present invention relates generally to self-retaining sutures for surgical procedures, methods of manufacturing self-retaining sutures for surgical procedures, and their uses.

BACKGROUND OF INVENTION

[0002] Sutures are commonly used for closing or binding together wounds in human or animal tissue, such as skin, muscles, tendons, internal organs, nerves, and blood vessels. Sutures can be formed from non-absorbable material such as silk, nylon, polypropylene, or cotton, or alternatively sutures can be formed from bio-absorbable material such as, but not limited to, homopolymers and/or copolymers of glycolide, lactide, p-dioxanone and ϵ -caprolactone.

[0003] Sutures typically consist of a filamentous suture thread with a needle with a sharp point (attachment of sutures and surgical needles is described in U.S. Patent Nos. 3,981,307, 5,084,063, 5,102,418, 5,123,911, 5,500,991, 5,722,991, 6,012,216, and 6,163,948, and U.S. Patent Application Publication No. 2004/0088003).

[0004] Self-retaining sutures (often referred to as "barbed sutures") differ from conventional sutures in that they possess numerous tiny retainers (often barbs) which anchor into the surrounding tissue following deployment, thereby eliminating the need to tie knots to affix adjacent tissues together, and have been described in, for example, U.S. Pat. No. 6,848,152 and European Patent 1 075 843. Such retainers protrude from the suture periphery and are arranged to allow passage of the self-retaining suture when drawn in one direction (with respect to the direction of protrusion of the retainer) through tissue but resist movement of the self-retaining suture when drawn in the opposite direction. Retainers can reduce slippage of the suture at least in a direction along the suture and can optionally obviate knotting of the suture.

[0005] A self-retaining suture may be unidirectional, having one or more retainers oriented in one direction along the length of the suture thread; or bidirectional,

typically having one or more retainers oriented in one direction along a portion of the thread, followed by one or more retainers oriented in another (often opposite) direction over the remainder of the thread (as described in the context of barbed retainers in U.S. Patent Nos. 5,931,855 and 6,241,747). Although any number of sequential or intermittent configurations of retainers are possible, the most common form involves a needle at one end, followed by barbs projecting “away” from the needle until the transition point (often the midpoint) of the suture is reached; at the transition point the configuration of barbs reverses itself 180° (i.e., the barbs are now facing in the opposite direction) along the remaining length of the suture thread before attaching to a second needle at the opposite end. The disclosures of all patents and patent applications mentioned herein are incorporated by reference.

[0006] Single-directional self-retaining sutures can include an end that is pointed to allow penetration and passage through tissue when drawn by the end and an opposite end that includes an anchor for engaging tissue at the initial insertion point to limit movement of the suture. Alternatively, bi-directional self-retaining sutures can include retainers grouped and extending in one direction along one portion of the suture and opposing retainers grouped and extending in an opposing direction along another portion of the suture. When implanted so that both groups of retainers are engaging tissue, the retainers can resist movement of the suture through tissue in either direction.

[0007] A surgeon may use a surgical needle with an attached suture (which can be a smooth monofilament or can be a multi-filament) to pierce the tissue alternately on opposing faces of a wound to sew the wound closed. Techniques for placement of self-retaining sutures in tissue to close or bind together wounds can include threading the self-retaining suture in straight-line patterns such as zig-zag, and curvilinear patterns such as alpha, sinusoidal, and corkscrew. A surgeon may also use self-retaining sutures to position and support tissue where there is no wound in procedures such as cosmetic surgery of the face, neck, abdominal or thoracic region among others.

[0008] More specifically, self-retaining sutures can be used in superficial and deep surgical procedures in humans and animals for closing wounds, repairing traumatic injuries or defects, joining tissues together [bringing severed tissues into approximation, closing an anatomical space, affixing single or multiple tissue layers

together, creating anastomoses between two hollow (luminal) structures, adjoining tissues, attaching or reattaching tissues to their proper anatomical location], attaching foreign elements to tissues (affixing medical implants, devices, prostheses and other functional or supportive devices), and for repositioning tissues to new anatomical locations (repairs, tissue elevations, tissue grafting and related procedures) to name but a few examples.

[0009] Sutures typically consist of a filamentous suture thread attached to a needle with a sharp point (attachment of sutures and surgical needles is described in U.S. Patent Nos. 3,981,307, 5,084,063, 5,102,418, 5,123,911, 5,500,991, 5,722,991, 6,012,216, and 6,163,948, and U.S. Patent Application Publication No. US 2004/0088003). Classically, the needle is advanced through the desired tissue on one side of the wound and then through the adjacent side of the wound to form a “loop” which is then completed by tying a knot in the suture.

[0010] Sutures materials are broadly classified as being degradable or bioabsorbable (i.e., they break down completely in the body over time), such as those composed of catgut, glycolic acid polymers and copolymers, lactic acid polymers and copolymers, and polyether-esters based copolymers such as polyglycolide or lactide copolymers with polyglycols or polyethers; or as being non-absorbable (permanent; nondegradable), such as those made of polyamide, polytetrafluoroethylene, polyethylene terephthalate, polyurethane, polyether-esters based copolymers such as polybutylene or polyethylene terephthalate with polyglycols or polyethers, metal alloys, metal (e.g., stainless steel wire), polypropylene, polyethelene, silk, and cotton. Degradable (bioabsorbable) sutures have been found to be particularly useful in situations where suture removal might jeopardize the repair or where the natural healing process renders the support provided by the suture material unnecessary after wound healing has been completed; as in, for example, completing an uncomplicated skin closure. Nondegradable (non-absorbable) sutures are used in wounds where healing may be expected to be protracted or where the suture material is needed to provide physical support to the wound for long periods of time; as in, for example, deep tissue repairs, high tension wounds, many orthopedic repairs and some types of surgical anastomoses.

[0011] Bioabsorbable sutures can be made of materials which are broken down in tissue after a given period of time, which depending on the material can be from ten days to eight weeks. The sutures are used therefore in many of the internal tissues of the body. In most cases, three weeks is sufficient for the wound to close firmly. At that time the suture is not needed any more, and the fact that it disappears is an advantage, as there is no foreign material left inside the body and no need for the patient to have the sutures removed. In rare cases, bioabsorbable sutures can cause inflammation and be rejected by the body rather than absorbed. Bioabsorbable sutures were first made from the intestines of mammals. For example, gut sutures can be made of specially prepared bovine or ovine intestine, and can be untreated (plain catgut), tanned with chromium salts to increase the suture persistence in the body (chromic catgut), or heat-treated to give more rapid absorption (fast catgut). Concern about transmitting diseases such as bovine spongiform encephalopathy, has resulted in the gut being harvested from stock which have been tested to determine that the natural polymers used as suture materials do not carry viral diseases. Bioabsorbable sutures can be made of synthetic polymer fibers, which can be monofilaments or braided.

[0012] Self-retaining sutures are designed for engaging tissue when the suture is pulled in a direction other than that in which it was originally deployed in the tissue. Knotless tissue-approximating devices having barbs have been previously described in, for example, U.S. Pat. No. 5,374,268, disclosing armed anchors having barb-like projections, while suture assemblies having barbed lateral members have been described in U.S. Pat. Nos. 5,584,859 and 6,264,675. One of the earlier patents describing a barbed suture is U.S. Pat. No. 3,716,058, which discloses a suture having one or more relatively rigid barbs at its opposite ends; the presence of the barbs just at the ends of the suture would limit the barbs' effectiveness. Sutures having a plurality of barbs positioned along a greater portion of the suture are described in U.S. Pat. No. 5,931,855, which discloses a unidirectional barbed suture, and U.S. Pat. No. 6,241,747, which discloses a bidirectional barbed suture. Methods and apparatus for forming barbs on sutures by cutting barbs into a suture body have been described in, for example, U.S. Pat. Nos. 6,848,152 and 7,225,512. Methods of manufacturing sutures

with frusto-conical retainers have also been described, for example, in European Patent 1 075 843 and U.S. Pat. Publication No. 2007/0038429.

[0013] Despite the advantages of existing self-retaining sutures, there still remains a need and desire for new and preferably improved self-retaining sutures, and method of making the same.

BRIEF SUMMARY OF INVENTION

[0014] Provided herein are sutures for use in a procedure applied to tissue, and methods for forming such sutures. In accordance with an embodiment, a suture includes an elongated suture body and plurality of retainers that are spaced apart from one another and extend from the elongated suture body between first and second ends of the suture body. In specific embodiments, the retainers are bi-directional retainers.

[0015] In accordance with an embodiment of the present invention, each bi-directional retainer is deployable through tissue in two directions generally opposite one another, but once deployed in one direction resists movement in the generally opposite direction. Advantageously, this allows the number of bi-directional retainers that are deployed in one direction and the number of bi-directional retainers that are deployed in the generally opposite direction to be decided during a surgical procedure, on-the-fly. Viewed in another way, how much of the suture is deployed through tissue in the one direction and how much of the suture is deployed through tissue in the another direction can be decided during a surgical procedure because the suture does not have a predetermined transition segment or point.

[0016] In accordance with an embodiment of the present invention, each bi-directional retainer can be collapsed in either of two directions, depending upon the direction in which the retainer is deployed through tissue. In accordance with an embodiment, each retainer collapses in a direction opposite to the direction in which the retainer is deployed through tissue. Once a retainer is collapsed due to the retainer being deployed through tissue in a first direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the first direction, and will resist motion of the elongated suture body in a second direction generally opposite the first direction.

[0017] In accordance with an embodiment of the present invention, a shape of each retainer can be transformed in either of two manners, depending upon the direction in which the retainer is deployed through tissue. Once a retainer is transformed in shape due to the retainer being deployed through tissue in a first direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the first direction, and will resist motion of the elongated suture body in a second direction generally opposite the first direction. Once a retainer is transformed in shape due to the retainer being deployed through tissue in the second direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the second direction, and will resist motion of the elongated suture body in the first direction.

[0018] In accordance with alternative embodiments of the present invention, a suture includes an elongated suture body and a plurality of conical shaped retainers spaced apart from one another and extending from the elongated suture body between first and second ends of the suture body. Additionally, tissue engaging protrusions extend from the edges of the conical shaped retainers and/or the angled walls of the conical shaped retainers.

[0019] The details of one or more embodiments are set forth in the description below. Other features, objects and advantages will be apparent from the description, the drawings, and the claims. In addition, the disclosures of all patents and patent applications referenced herein are incorporated by reference in their entirety.

[0020] The details of one or more aspects or embodiments are set forth in the description below. Other features, objects and advantages will be apparent from the description, the drawings, and the claims. In addition, the disclosures of all patents and patent applications referenced herein are incorporated by reference in their entirety.

DESCRIPTION OF DRAWINGS

[0021] FIG. 1 is perspective view of a portion of a self-retaining suture according to an embodiment of the present invention, which includes bi-directional retainers.

[0022] FIGS. 2A-2C are front views of the bi-directional retainers of FIG. 1, according to various embodiments of the present invention.

[0023] FIGS. 3A-3H are cross sectional views of grooves in the bi-directional retainers of FIGS. 2A-2C, according to various embodiments of the present invention.

[0024] FIG. 4A is a perspective view of a portion of the self-retaining suture of FIG. 1, prior to it being deployed through patient tissue.

[0025] FIG. 4B is a perspective view of the self-retaining suture of FIG. 1 (and FIG. 4A), when it is initially being deployed through patient tissue.

[0026] FIG. 4C is a perspective view of the self-retaining suture of FIG. 1 (and FIGS. 4A and 4B) after it has been deployed through patient tissue.

[0027] FIG. 5 illustrates that the bi-directional retainers of FIGS. 1-4C can be deployed through patient tissue in different directions.

[0028] FIGS. 6A and 6B are front views of the bi-directional retainers that include protrusions extending from edges of the retainers, in accordance with embodiments of the present invention.

[0029] FIG. 6C is a perspective view of a suture that includes one of the bi-directional retainers of FIGS. 6A and 6B, after the retainer has been deployed through patient tissue.

[0030] FIGS. 6D and 6E are front views of the bi-directional retainers that include protrusions extending from edges of the retainers, in accordance with further embodiments of the present invention where the protrusions are corners of quadrilateral faces.

[0031] FIG. 7 is a front view of a bi-directional retainer that includes vents that prevent air from getting trapped by the retainer.

[0032] FIG. 8 illustrates an exemplary extruding and coining machine that can be used to produce the sutures described with reference to FIGS. 1-7, in accordance with an embodiment of the present invention.

[0033] FIG. 9 illustrates an exemplary filament that can be produced using the machine of FIG. 8.

[0034] FIGS. 10A-10C illustrates how a mold or die can be used to produce the sutures described with reference to FIGS. 1-7 from the filament shown in FIG. 9.

[0035] FIG. 11A illustrates a self-retaining suture that includes uni-directional retainers, according to an embodiment of the present invention.

[0036] FIGS. 11B-11E illustrate alternative retainer embodiments for the self-retaining suture of FIG. 11A.

DESCRIPTION OF INVENTION

[0037] Prior to setting forth the invention, it may be helpful to an understanding thereof to first set forth definitions of certain terms that are used hereinafter.

[0038] “Self-retaining system” refers to a self-retaining suture together with means for deploying the suture into tissue. Such deployment means include, without limitation, suture needles and other deployment devices as well as sufficiently rigid and sharp ends on the suture itself to penetrate tissue.

[0039] “Self-retaining suture” refers to a suture that does not require a knot or a suture anchor at its end in order to maintain its position into which it is deployed during a surgical procedure. These may be monofilament sutures or braided sutures, and are positioned in tissue in two stages, namely deployment and affixation, and include at least one tissue retainer.

[0040] “Tissue retainer” (or simply “retainer” or “barb”) refers to a suture element having a retainer body projecting from the suture body and a retainer end adapted to penetrate tissue. Each retainer is adapted to resist movement of the suture in a direction other than the direction in which the suture is deployed into the tissue by the surgeon, by being oriented to substantially face the deployment direction. As the tissue-penetrating end of each retainer moving through tissue during deployment faces away from the deployment direction (the direction of the passage of the suture during deployment), the tissue retainers should not catch or grab tissue during this phase. Once the self-retaining suture has been deployed, a force exerted in another direction,

often substantially opposite to the deployment direction, to affix the suture in position causes retainers to be displaced from their deployment positions of resting substantially along the suture body and causes retainer ends to penetrate into the tissue resulting in tissue being caught between the retainer and the suture body.

[0041] “Retainer configurations” refers to configurations of tissue retainers and can include features such as size, shape, surface characteristics, and so forth. These are sometimes also referred to as “barb configurations”.

[0042] “Bidirectional suture” refers to a self-retaining suture having retainers oriented in one direction at one end and retainers oriented in the other direction at the other end. A bidirectional suture is typically armed with a needle at each end of the suture thread. Many bidirectional sutures have a transitional segment located between the two barb orientations.

[0043] “Transition segment” refers to a retainer-free (barb-free) portion of a bidirectional suture located between a first set of retainers (barbs) oriented in one direction and a second set of retainers (barbs) oriented in another direction.

[0044] “Suture thread” refers to the filamentary body component of the suture, and, for sutures requiring needle deployment, does not include the suture needle. The suture thread may be monofilamentary, or, multifilamentary.

[0045] “Monofilament suture” refers to a suture comprising a monofilamentary suture thread.

[0046] “Braided suture” refers to a suture comprising a multifilamentary suture thread. The filaments in such suture threads are typically braided, twisted, or woven together.

[0047] “Degradable (also referred to as “biodegradable” or “bioabsorbable”) suture” refers to a suture which, after introduction into a tissue is broken down and absorbed by the body. Typically, the degradation process is at least partially performed in a biological system. “Degradation” refers to a chain scission process by which a polymer chain is cleaved into oligomers and monomers. Chain scission may occur through various mechanisms, including, for example, by chemical reaction (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination of these) or by a thermal or photolytic process. Polymer degradation may be characterized, for

example, using gel permeation chromatography (GPC), which monitors the polymer molecular mass changes during erosion and breakdown. Degradable suture material may include polymers such as catgut, polyglycolic acid, lactic acid polymers, polyether-esters (e.g., copolymers of polyglycolide with polyglycols, polyglycolide with polyethers, polylactic acid with polyglycols or polylactic acid with polyethers), copolymers of glycolide and lactide, copolymers of trimethylene carbonate and glycolide with diethylene glycol (e.g., MAXONTM, Tyco Healthcare Group), terpolymer composed of glycolide, trimethylene carbonate, and dioxanone (e.g., BIOSYNTM [glycolide (60%), trimethylene carbonate (26%), and dioxanone (14%)], Tyco Healthcare Group), copolymers of glycolide, caprolactone, trimethylene carbonate, and lactide (e.g., CAPROSYNTM, Tyco Healthcare Group). These sutures can be in either a braided multifilament form or a monofilament form. The polymers used in the present invention can be linear polymers, branched polymers or multi-axial polymers. Examples of multi-axial polymers used in sutures are described in U.S. Patent Application Publication Nos. 20020161168, 20040024169, and 20040116620. Degradable sutures can also include dissolvable sutures made of a dissolvable polymer, such as a polyvinyl alcohol partly deacetylated polymer, but not limited thereto. Sutures made from degradable suture material lose tensile strength as the material degrades.

[0048] “Non-degradable (also referred to as “non-absorbable”) suture” refers to a suture comprising material that is not degraded by chain scission such as chemical reaction processes (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination of these) or by a thermal or photolytic process. Non-degradable suture material includes polyamide (also known as nylon, such as nylon 6 and nylon 6.6), polyethylene terephthalate, polytetrafluoroethylene, polyether-ester (such as polybutylene or polyethylene terephthalate based copolymers with polyglycols or polyethers), polyurethane, metal alloys, metal (e.g., stainless steel wire), polypropylene, polyethelene, silk, and cotton. Sutures made of non-degradable suture material are suitable for applications in which the suture is meant to remain permanently or is meant to be physically removed from the body.

[0049] “Suture diameter” refers to the diameter of the body of the suture. It is to be understood that a variety of suture lengths may be used with the sutures described herein and that while the term “diameter” is often associated with a circular periphery, it is to be understood herein to indicate a cross-sectional dimension associated with a periphery of any shape. Suture sizing is based upon diameter. United States Pharmacopeia (“USP”) designation of suture size runs from 0 to 7 in the larger range and 1-0 to 11-0 in the smaller range; in the smaller range, the higher the value preceding the hyphenated zero, the smaller the suture diameter. The actual diameter of a suture will depend on the suture material, so that, by way of example, a suture of size 5-0 and made of collagen will have a diameter of 0.15 mm, while sutures having the same USP size designation but made of a synthetic absorbable material or a non-absorbable material will each have a diameter of 0.1 mm. The selection of suture size for a particular purpose depends upon factors such as the nature of the tissue to be sutured and the importance of cosmetic concerns; while smaller sutures may be more easily manipulated through tight surgical sites and are associated with less scarring, the tensile strength of a suture manufactured from a given material tends to decrease with decreasing size. It is to be understood that the sutures and methods of manufacturing sutures disclosed herein are suited to a variety of diameters, including without limitation 7, 6, 5, 4, 3, 2, 1, 0, 1-0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0, 8-0, 9-0, 10-0 and 11-0.

[0050] “Suture deployment end” refers to an end of the suture to be deployed into tissue; one or both ends of the suture may be suture deployment ends. The suture deployment end may be attached to deployment means such as a suture needle, or may be sufficiently sharp and rigid to penetrate tissue on its own.

[0051] “Armed suture” refers to a suture having a suture needle on at least one suture deployment end.

[0052] “Needle attachment” refers to the attachment of a needle to a suture requiring same for deployment into tissue, and can include methods such as crimping, swaging, using adhesives, and so forth. The point of attachment of the suture to the needle is known as the swage.

[0053] “Suture needle” refers to needles used to deploy sutures into tissue, which come in many different shapes, forms and compositions. There are two main types of needles, traumatic needles and atraumatic needles. Traumatic needles have channels or drilled ends (that is, holes or eyes) and are supplied separate from the suture thread and are threaded on site. Atraumatic needles are eyeless and are attached to the suture at the factory by swaging whereby the suture material is inserted into a channel at the blunt end of the needle which is then deformed to a final shape to hold the suture and needle together. As such, atraumatic needles do not require extra time on site for threading and the suture end at the needle attachment site is smaller than the needle body. In the traumatic needle the thread comes out of the needle’s hole on both sides and often the suture rips the tissues to a certain extent as it passes through. Most modern sutures are swaged atraumatic needles. Atraumatic needles may be permanently swaged to the suture or may be designed to come off the suture with a sharp straight tug. These “pop-offs” are commonly used for interrupted sutures, where each suture is only passed once and then tied. For barbed sutures that are uninterrupted, these atraumatic needles would be ideal.

[0054] Suture needles may also be classified according to their point geometry. For example, needles may be (i) “tapered” whereby the needle body is round and tapers smoothly to a point; (ii) “cutting” whereby the needle body is triangular and has sharpened cutting edge on the inside; (iii) “reverse cutting” whereby the cutting edge is on the outside; (iv) “trocar point” or “tapercut” whereby the needle body is round and tapered, but ends in a small triangular cutting point; (v) “blunt” points for sewing friable tissues; (vi) “side cutting” or “spatula points” whereby the needle is flat on top and bottom with a cutting edge along the front to one side (these are typically used for eye surgery).

[0055] Suture needles may also be of several shapes including, (i) straight, (ii) half curved or ski, (iii) 1/4 circle, (iv) 3/8 circle, (v) 1/2 circle, (vi) 5/8 circle, (v) and compound curve.

[0056] Suturing needles are described, for example, in US Patent Nos. 6,322,581 and 6,214,030 (Mani, Inc., Japan); and 5,464,422 (W.L. Gore, Newark, DE); and 5,941,899; 5,425,746; 5,306,288 and 5,156,615 (US Surgical Corp., Norwalk, CT);

and 5,312,422 (Linvatec Corp., Largo, FL); and 7,063,716 (Tyco Healthcare, North Haven, CT). Other suturing needles are described, for example, in US Patent Nos. 6,129,741; 5,897,572; 5,676,675; and 5,693,072. The sutures described herein may be deployed with a variety of needle types (including without limitation curved, straight, long, short, micro, and so forth), needle cutting surfaces (including without limitation, cutting, tapered, and so forth), and needle attachment techniques (including without limitation, drilled end, crimped, and so forth). Moreover, the sutures described herein may themselves include sufficiently rigid and sharp ends so as to dispense with the requirement for deployment needles altogether.

[0057] “Needle diameter” refers to the diameter of a suture deployment needle at the widest point of that needle. While the term “diameter” is often associated with a circular periphery, it is to be understood herein to indicate a cross-sectional dimension associated with a periphery of any shape.

[0058] “Wound closure” refers to a surgical procedure for closing of a wound. An injury, especially one in which the skin or another external or internal surface is cut, torn, pierced, or otherwise broken is known as a wound. A wound commonly occurs when the integrity of any tissue is compromised (e.g., skin breaks or burns, muscle tears, or bone fractures). A wound may be caused by an act, such as a gunshot, fall, or surgical procedure; by an infectious disease; or by an underlying medical condition. Surgical wound closure facilitates the biological event of healing by joining, or closely approximating, the edges of those wounds where the tissue has been torn, cut, or otherwise separated. Surgical wound closure directly apposes or approximates the tissue layers, which serves to minimize the volume new tissue formation required to bridge the gap between the two edges of the wound. Closure can serve both functional and aesthetic purposes. These purposes include elimination of dead space by approximating the subcutaneous tissues, minimization of scar formation by careful epidermal alignment, and avoidance of a depressed scar by precise eversion of skin edges.

[0059] “Tissue elevation procedure” refers to a surgical procedure for repositioning tissue from a lower elevation to a higher elevation (i.e. moving the tissue in a direction opposite to the direction of gravity). The retaining ligaments of the face

support facial soft tissue in the normal anatomic position. However, with age, gravitational effects achieve a downward pull on this tissue and the underlying ligaments, and fat descends into the plane between the superficial and deep facial fascia, thus allowing facial tissue to sag. Face-lift procedures are designed to lift these sagging tissues, and are one example of a more general class of medical procedure known as a tissue elevation procedure. More generally, a tissue elevation procedure reverses the appearance change that results from gravitation effects over time, and other temporal effects that cause tissue to sag, such as genetic effects. It should be noted that tissue can also be repositioned without elevation; in some procedures tissues are repositioned laterally (away from the midline), medially (towards the midline) or inferiorly (lowered) in order to restore symmetry (i.e. repositioned such that the left and right sides of the body “match”).

[0060] “Medical device” or “implant” refers to any object placed in the body for the purpose of restoring physiological function, reducing/alleviating symptoms associated with disease, and/or repairing/replacing damaged or diseased organs and tissues. While normally composed of biologically compatible synthetic materials (e.g., medical-grade stainless steel, titanium and other metals; polymers such as polyurethane, silicon, PLA, PLGA and other materials) that are exogenous, some medical devices and implants include materials derived from animals (e.g., “xenografts” such as whole animal organs; animal tissues such as heart valves; naturally occurring or chemically-modified molecules such as collagen, hyaluronic acid, proteins, carbohydrates and others), human donors (e.g., “allografts” such as whole organs; tissues such as bone grafts, skin grafts and others), or from the patients themselves (e.g., “autografts” such as saphenous vein grafts, skin grafts, tendon/ligament/muscle transplants). Medical devices that can be used in procedures in conjunction with the present invention include, but are not restricted to, orthopaedic implants (artificial joints, ligaments and tendons; screws, plates, and other implantable hardware), dental implants, intravascular implants (arterial and venous vascular bypass grafts, hemodialysis access grafts; both autologous and synthetic), skin grafts (autologous, synthetic), tubes, drains, implantable tissue bulking agents, pumps, shunts, sealants, surgical meshes (e.g., hernia repair

meshes, tissue scaffolds), fistula treatments, spinal implants (e.g., artificial intervertebral discs, spinal fusion devices, etc.) and the like.

A. Self-Retaining Sutures

[0061] Self-retaining sutures (including barbed sutures) differ from conventional sutures in that they possess numerous tissue retainers (such as barbs) which anchor into the tissue following deployment and resist movement of the suture in a direction opposite to that in which the retainers face, thereby eliminating the need to tie knots to affix adjacent tissues together (a “knotless” closure). By eliminating knot tying, associated complications are eliminated, including, but not limited to (i) spitting (a condition where the suture, usually a knot) pushes through the skin after a subcutaneous closure), (ii) infection (bacteria are often able to attach and grow in the spaces created by a knot), (iii) bulk/mass (a significant amount of suture material left in a wound is the portion that comprises the knot), (iv) slippage (knots can slip or come untied), and (v) irritation (knots serve as a bulk “foreign body” in a wound). Suture loops associated with knot tying may lead to ischemia (they create tension points that can strangulate tissue and limit blood flow to the region) and increased risk of dehiscence or rupture at the surgical wound. Knot tying is also labor intensive and can comprise a significant percentage of the time spent closing a surgical wound. Additional operative procedure time is not only bad for the patient (complication rates rise with time spent under anesthesia), but it also adds to the overall cost of the operation (many surgical procedures are estimated to cost between \$15 and \$30 per minute of operating time). Thus, knotless sutures not only allow patients to experience an improved clinical outcome, but they also save time and costs associated with extended surgeries and follow-up treatments.

[0062] Self-retaining systems for wound closure also result in better approximation of the wound edges, evenly distribute the tension along the length of the wound (reducing areas of tension that can break or lead to ischemia), decrease the bulk of suture material remaining in the wound (by eliminating knots) and reduce spitting (the extrusion of suture material – typically knots - through the surface of the skin. All

of these features are thought to reduce scarring, improve cosmesis, and increase wound strength relative to wound closures effected with plain sutures or staples.

[0063] The ability of self-retaining sutures to anchor and hold tissues in place even in the absence of tension applied to the suture is a feature that also provides superiority over plain sutures. When closing a wound that is under tension, this advantage manifests itself in several ways: (i) a multiplicity of retainers can dissipate tension along the entire length of the suture (providing hundreds of “anchor” points as opposed to knotted interrupted sutures which concentrate the tension at discrete points; this produces a superior cosmetic result and lessens the chance that the suture will “slip” or pull through); (ii) complicated wound geometries can be closed (circles, arcs, jagged edges) in a uniform manner with more precision and accuracy than can be achieved with interrupted sutures; (iii) they eliminate the need for a “third hand” which is often required for maintaining tension across the wound during traditional suturing and knot tying (to prevent “slippage” when tension is momentarily released during tying); (iv) they are superior in procedures where knot tying is technically difficult, such as in deep wounds or laparoscopic procedures; and (v) they can be used to approximate and hold the wound prior to definitive closure. As a result, self-retaining sutures provide easier handling in anatomically tight or deep places (such as the pelvis, abdomen and thorax) and make it easier to approximate tissues in laparoscopic and minimally invasive procedures; all without having to secure the closure via a knot. Greater accuracy allows self-retaining sutures to be used for more complex closures (such as those with diameter mismatches, larger defects or purse string suturing) than can be accomplished with plain sutures.

[0064] Self-retaining sutures also lend themselves to a variety of specialized indications; for example, they are suitable for tissue elevation procedures where tissue is moved from its previous location and repositioned into a new anatomical location (this is typically performed in cosmetic procedures where “drooping” tissue is elevated and fixed in a more “youthful” position; or where “out-of-position” tissue is moved back to its correct anatomical location). Such procedures include facelifts, brow lifts, breast lifts, buttocks lifts, and so forth.

[0065] A self-retaining suture may be unidirectional, having one or more retainers oriented in one direction along the length of the suture thread; or bidirectional, typically having one or more retainers oriented in one direction along a portion of the thread, followed by one or more retainers oriented in another (often opposite) direction over the remainder of the thread (as described with barbed retainers in U.S. Pat. Nos. 5,931,855 and. 6,241,747).

[0066] Although any number of sequential or intermittent configurations of retainers are possible, a common form involves a needle at one end, followed by barbs projecting “away” from the needle until the transition point (often the midpoint) of the suture is reached; at the transition point the configuration of barbs reverses itself about 180° (such that the barbs are now facing in the opposite direction) along the remaining length of the suture thread before attaching to a second needle at the opposite end (with the result that the barbs on this portion of the suture also face away from the nearest needle). Put another way, the barbs on both “halves” of a bidirectional self-retaining suture point towards the middle, with a transition segment (lacking retainers) interspersed between them, and with a needle attached to either end.

[0067] Despite the multitude of advantages of self-retaining sutures, there remains a need and desire to improve upon the design of such sutures so that a variety of common limitations can be eliminated.

B. Bi-directional Retainers

[0068] FIG. 1 shows a perspective view of a portion of a self-retaining suture 100, according to an embodiment of the present invention, that includes an elongated threadlike suture body 102 and a plurality of retainers 104 projecting from the suture body 102. The suture body 102 can include two ends, or more than two ends (e.g., three ends, four ends, or more). The self-retaining suture 100 shown in FIG. 1 has not yet been deployed through patient tissue.

[0069] As shown in FIG. 1, the retainers 104 can be generally flat prior to being deployed through tissue, e.g., during a surgical procedure. As also shown in FIG. 1, the retainers can be generally orthogonal to the suture body 102, prior to being deployed through tissue. The retainers 104 may be referred to as bi-directional retainers 104,

because they can be deployed in two directions, but once deployed in one direction, resist motion in the opposite direction, as will be appreciated from the discussion below. Advantageously, this allows the number of bi-directional retainers 104 that are deployed in one direction and the number of bi-directional retainers 104 that are deployed in the opposite direction to be decided during a surgical procedure. More specifically, prior to being deployed through tissue, each bi-directional retainer 104 is deployable through tissue in both a first direction and a second direction generally opposite the first direction. However, once a bi-directional retainer 104 is deployed through tissue in one of the first and second directions, the bi-direction retainer 104 will substantially yield to motion of the elongated suture body 102 within the tissue when the elongated suture body 102 is drawn in the one of the first and second directions, and will resist motion of the elongated suture body 102 in the other one of the first and second directions.

[0070] As can be seen from the front views in FIGS. 2A and 2B, the retainers 104 can be circular in shape (FIG. 2A), or can have other shapes such as but not limited to octagonal (FIG. 2B), hexagonal, square, and the like. Each retainer 104 include grooves 106 that extend radially from the center to the outer periphery or edge of the retainer. The grooves 106 can be continuous from the center to the outer edge, or can be discontinuous or intermittent (similar to how a perforation includes intermittent holes). The grooves 106 can cut into the retainers 104 (and thus be scores), or formed as part of a molding and/or heading process, e.g., at the same time the retainers 104 are formed. More or less grooves 106 than shown in FIGS. 2A-2C can be used. Also, as described below, each groove shown in FIGS. 2A-2C can be replaced with pairs of side-by-side grooves, or three or more side-by-side grooves.

[0071] FIGS. 3A-3F, which illustrate alternative cross sectional portions of the retainers 104, show various embodiments of the grooves 106. Each retainer 104 has two generally planer sides, which can be referred to as first and second sides, left and right sides, or the like. As shown in FIGS. 3A and 3D, only one side of the retainer 104 can include grooves 106, or as shown in FIGS. 3C and 3F only the other side of the retainer 104 can include grooves 106. Alternatively, as shown in FIGS. 3B and 3E, both sides of the retainer 104 can include grooves 106. Where both sides of the retainer

104 includes grooves, the grooves 106 on one side can mirror the grooves on the other side. Alternatively, grooves 106 can be on both sides of the retainer 104 that do not mirror one another, as can be appreciated from FIG. 2C, where solid lines 106 represent grooves on one side, and dashed lines 106 represent grooves on the other side. Notice that the shape of the grooves 106 in FIGS. 3A-3C differ from the shape of the grooves 106 in FIGS. 3D-3F. A pair of grooves can be side-by-side, as shown in FIG. 3G, or three or more grooves can be side-by-side to form a sinusoidal wave of grooves, as shown in FIG. 3H. In specific embodiments, the grooves can have uniform thickness and/or depth. In other embodiments, the grooves can have varying thickness and/or depth, e.g. to allow for greater deformation near the center of each retainer 104. For a more specific example, each groove can have a greatest thickness and/or depth near the center or opening 116 of the retainer, and be narrowest and/or shallowest at the outer edge of the retainer. While in FIGS. 3A-3H the grooves 106 are shown as being generally triangular in shape, other shapes are also possible, such as, but not limited to square shaped, U-shaped, and the like.

[0072] As can be appreciated from FIGS. 1 and 4A, the sides of the retainers 104 are initially generally perpendicular to the suture body 102. This also means that the grooves 106 are initially generally perpendicular to the suture body 102. However, once the suture is used in a surgical procedure, and threaded through patient tissue, the resistance provided by the patient tissue will cause the retainers 104 to collapse, as can be appreciated from FIGS. 4B and 4C. FIG. 4B shows the retainer 104 as it initially begins to collapse. FIG. 4C shows the retainer 104 after it has been collapsed, i.e., in its collapsed position. The grooves 106 act as fold or collapse lines, so that the retainer 104 collapses in a controlled manner. The collapse occurs in a somewhat accordion fashion in that the folding along the grooves 106 alternates back and forth.

[0073] Each retainer 104 can be collapsed in either of two directions, depending upon the direction in which the retainer is deployed through tissue. The retainer 104 can collapse in the direction of the grooves, but may also collapse in the direction opposite of the grooves. In other words, if the grooves are on the right side of the retainer 104, and the suture body 102 with the retainer is pulled through tissue (i.e., deployed) in a leftwardly direction, the retainer 104 will collapse rightwardly, as shown

in FIGS. 4B and 4C. However, if the same suture body 102 is initially pulled through tissue (i.e., deployed) in a rightwardly direction, the retainer 104 will collapse leftwardly, even though the grooves are only on the right side of the retainer 104. In other words, each retainer 104 collapses in a direction opposite to the direction in which the retainer is deployed through tissue.

[0074] Once in the collapsed position (e.g., as shown in FIG. 4C), the retainer 104 substantially yields to motion of the elongated suture body 102 within the tissue when the suture 100 is drawn in the suture deployment direction that caused the retainer to collapse, and resists motion if the suture 100 is drawn in a direction opposite the suture deployment direction. For example, it can be appreciated from FIG. 4C that the collapsed retainer 104 can be readily pulled through tissue in the direction of the arrow, but would resist motion in a direction opposite the arrow. Stated more generally, once a bi-directional retainer 104 is collapsed due to the retainer being deployed through tissue in a first direction, that retainer 104 will substantially yield to motion of the elongated suture body 102 within the tissue when the elongated suture body 102 is drawn in the first direction, and will resist motion of the elongated suture body 102 in a second direction generally opposite the first direction. More generally, each bi-directional retainer 104 can be deployed in either of two directions, and once deployed, yields to motion in the direction in which the retainer was deployed through tissue, and resists motion in the direction opposite the deployment direction.

[0075] Self-retaining sutures 100 that include the bi-directional retainers 104 can be used unidirectionally or bidirectionally. If intended to be used unidirectionally, the self-retaining sutures can include an end that is pointed or has a needle to allow penetration and passage through tissue when drawn by the end and an opposite end that includes in some embodiments an anchor for engaging tissue at the initial insertion point to limit movement of the suture. If intended to be used bi-directionally, more than one end of the suture can include a point or needle for tissue penetration. In other words, a bidirectional suture can be armed with a needle at each end of the suture thread.

[0076] Conventionally, a bi-directional self-retaining suture include a group of retainers extending toward one deployment direction along one portion of the suture

and opposing retainers grouped and extending toward an opposing deployment direction along another portion of the suture. Also, conventionally a bi-directional self-retaining suture includes a transitional segment located between the two groups of retainers. A problem with such conventional bi-directional self-retaining sutures is that a surgeon needs to be cognizant of the location of the transitional segment when deploying the suture. Further, if the transitional segment is in the middle of the suture, the suture length on one side of the transitional segment may be shorter than is desired by the surgeon in some instances.

[0077] Additionally, the marking of the transition point of conventional bi-directional self retaining sutures is not always satisfactory. A drawback of current bi-directional self retaining sutures is that there are additional manufacturing and technical hurdles to achieve effective marking of the transition point. Further, a transition point may not always be at a location desired by certain doctors and/or appropriate or optimal for certain procedures.

[0078] Bi-directional self-retaining sutures 100 that include the bi-directional retainers 104 overcome the aforementioned deficiencies of conventional bi-directional self-retaining sutures. This is because bi-directional self-retaining sutures 100 that include the bi-directional retainers 104 can be deployed in either direction, but once deployed, resist movement in the direction opposite to the deployment rejection. For example, if a suture includes N spaced apart retainers 104, any where from all to none (i.e., M, where $0 \leq M \leq N$) of the retainers 104 can be collapsed in one direction by drawing all or part of the suture through patient tissue in a first direction, while the remaining retainers 104 (i.e., N-M) can be collapsed in the opposite direction by drawing the remaining portion of the suture through patient tissue in a second direction. Thereafter, i.e., once collapsed, each of the retainers 104 will resist movement in the direction opposite to its deployment direction. For example, M retainers 104 can resist movement in a first direction, and N-M retainers 104 can resist movement in a second direction opposite the first direction, where the variable M can be selected on-the-fly. Stated another way, the number of bi-directional retainers 104 that are deployed in one direction and the number of bi-directional retainers 104 that are deployed in the opposite direction can be decided during a surgical procedure. This can be appreciated

from the illustration in FIG. 5. Further, unlike conventional bi-directional self-retaining sutures where a transitional segment is typically included between two groups of retainers that are deployable in opposite directions, with the bi-directional self-retaining sutures 100 that include the bi-directional retainers 104 a transitional segment need not be included. Additionally, the same bi-directional self-retaining suture 100 that includes the bi-directional retainers 104 can be efficiently and effectively used regardless of the desired and/or optimal transition point. Additionally, if the suture includes a needle at two ends of the suture body, a doctor can change the transition point at any time during a procedure. For example, the doctor can stitch with one needle and then when he is done, no matter how much of the suture has been used so far, the doctor can then start stitching with the other needle for the rest of the suture. This is beneficial over a suture having a fixed symmetrical or asymmetrical transition segment, because the transition segment can be anywhere the doctor selects for any procedure and at anytime time during the procedure.

[0079] FIGS. 6A and 6B illustrate that the retainers 104 can include protrusions 108 along the outer edge of the retainers. The protrusions 108 provide for increased engagement of the retainers 104 with tissue. FIG. 6C illustrates one of the retainers 104 of FIG. 6A after it has been deployed through tissue and collapsed. It can be appreciated from FIG. 6C that if the suture body 102 were pulled in a direction opposite the arrow, the protrusions would stick into patient tissue, providing for even further resistance to movement in the direction opposite the arrow. As shown in FIGS. 6D and 6E, the protrusions 108 can be portions of quadrilateral faces 610. The quadrilateral faces 610 can be perfect rhomboids, as shown in FIG. 6E. By varying the dimension of each quadrilateral (and possibly rhomboidal) face 610, different final geometries can be achieved.

[0080] FIG. 7 illustrates that the retainers 104 can includes one or more vents 110 that prevent air from getting trapped by the retainers 104 as the retainers are deployed through patient tissue. This is advantageous, because it is believed that tissue will heal more quickly if there is no trapped air behind the retainer 104. Further, the vents provide for further anchoring of patient tissue.

[0081] The retainers 104 can be preformed and thereafter attached to the suture body 102. In an embodiment, each of the bi-directional retainers 104 includes an opening 116 therethrough. The suture body 102 can be threaded through the openings 116 of the retainers 104, and the retainers 104 can be attached to the suture body 102 such that the retainers 104 are spaced apart from one another. In an embodiment, the retainers 104 can be attached to the suture body 102 using an adhesive. Exemplary adhesives that can be used include, but are not limited to, cyanoacrylates (e.g., octylcyanoacrylate), fibrin sealants, gelatin glue, synthetic N-hydroxysuccinimide based adhesives and acrylic adhesives. Alternatively, externally activated adhesives can be used, such as materials from the polymerizable groups, such as acrylic and methacrylic functionalities, acrylamide, methacrylamide, itaconate and styrene groups, which will exhibit an adhesive quality upon exposure to high-frequency radiation (e.g., ultraviolet light or other high-frequency waves). Other adhesives which can be used include permanent silicone room temperature vulcanizing adhesives, free radical generating adhesives such as benzoyl peroxide and the like. In other embodiments, the retainers 104 are attached to the suture body 102 by melting the retainers 104 to the suture body 102. In other words, the retainers can be heat-bonded to the suture body 102. In some embodiments, the retainers 104 are attached to the suture body 102 by fusing the retainers 104 to the suture body 102 using welding, such as, but not limited to, ultrasonic welding or laser welding. In other words, the retainers 104 can be weld-bonded to the suture body 102. Alternatively, the retainers 104 are attached to the suture body 102 using a solvent, e.g., by partly or completely dissolving a portion of the retainers 104 into the suture body 102 and/or vice versa. In other words, the retainers can be solvent-bonded to the suture body 102.

[0082] Alternatively, the retainers 104 can be formed as an integral portion of (i.e., as a one piece structure with) the suture body 102, e.g., using extrusion, molding and/or heading processes. FIGS. 8, 9 and 10A-10C will be used to explain an exemplary process that can be used to produce the self retaining suture 100 include bi-directional retainers 104.

[0083] Referring to FIG. 8, a monofilament 220 can be formed by extrusion and coining. As shown in FIG. 8, an extruder 210 receives pellets of polymer 212 in hopper 214. The polymer is melted and pushed by screw 216 through extrusion die 218 to form filament 220 of melted polymer 212. The filament 220 initially has a uniform cross-section in the shape of the hole in the extrusion die 218. The extruded filament passes through an air gap 219 where the filament cools and polymer 212 solidifies somewhat. The extruded filament 220 is passed to coining machine 230 where filament 220 passes between two rollers 232, 234. The filament may optionally be quenched, drawn and/or tempered before and/or after the coining process. Rollers 232, 234 have a patterned surface which presses the material of filament 220 into the desired shape shown in FIG. 9. This coining process can be conducted at a temperature that is between 20-80% of the melting point of the polymer. In preferred embodiments, the coining process is conducted at temperatures above the glass transition temperature of the polymer and below the onset of melting temperature. In the configuration illustrated in FIG. 8, each of rollers 232, 234 has hemispherical indentations 236 on its outer surface such that as filament 220 passes through the rollers it takes on the shape shown in FIG. 9.

[0084] As shown in FIG. 9, the resulting filament 220 has intermittent hemispherical nodules 230. As can be appreciated from FIGS. 10A-10C, a mold or die 250 can be used in a molding and/or heading process to shape, coin or otherwise produce the bi-directional retainers 104 described above with reference to FIG. 1-7. The grooves 106 in the retainers 104 can be generated using the mold or die 250, or cut or machined into the retainers 104 thereafter, e.g., using a blade or the like.

[0085] FIGS. 2A, 2B, 6A and 6B discussed above illustrate alternative shapes for the bi-directional retainers 104. These are just a few possible shapes for the bi-direction retainers 104, which are not meant to be limiting. In other words, other shaped bi-directional retainers 104 are possible, and within the scope of the present invention.

[0086] The self-retaining suture 100 can include bi-directional retainers 104 of different sizes, which are designed for various surgical applications. For example, different retainers 104 can have different diameters. Relatively larger retainers are

desirable for joining fat and soft tissues, whereas relatively smaller retainers are desirable for joining fibrous tissues. Use of a combination of large, medium, and/or small retainers on the same suture helps to ensure maximum anchoring properties when retainers sizes are customized for each tissue layer. The periodicity of the retainers 104 can be random or organized. The order of occurrence and the size of the groups may be altered to maximize tissue engagement strength.

[0087] The retainers 104 can be made of the same material as the suture body 102, or of a different material. In specific embodiments, the retainers 104 are made of a material that has a higher elastic constant (and thus stiffer) and/or a larger plastic zone (and thus more permanently deformable) than the material from which the suture body 102 is made. Also, the suture body 102 can be made of a material that is more flexible and/or more elastic than the material from which the retainers 104 are made. Furthermore the retainers 104 can have a greater toughness than the suture body to withstand the excess bending forces applied to them. Alternatively, the retainers 104 and the suture body 102 can be made of the same type of material, but the retainers when formed can be treated to increase their stiffness and strength, e.g., by appropriate annealing cycles (heating to a certain temperature and cooling at a certain rate) of the retainers 104, e.g., using techniques similar to those taught in U.S. Patent No. 5,007,922, which is incorporated herein by reference.

[0088] The retainers 104 and the suture body 102 can both be made of bio-absorbable material, examples of which were provided above. Alternatively, the retainers 104 and the suture body 102 can both be made of non-absorbable material, examples of which were provided above. In still other embodiments, the retainers 104 can be bio-absorbable, while the suture body 102 is non-absorbable, or vice versa. In another embodiment of this invention the retainers 104 and/or the suture body 102 can be partially bio-absorbable, or a number of the retainers 104 can be bioabsorbable while the remaining retainers 104 are not bio-absorbable. Additionally, the suture body 102 can be made of a material having a greater tensile strength than the material used to make the retainers 104, or vice versa.

C. Uni-Directional Retainers

[0089] Protrusions similar to protrusions 108 can also be provided on uni-directional retainers, as shown in FIGS. 11A-11E. In FIG. 11A, a self-retaining suture 1100 includes retainers 1104 that have a conical shape and include protrusions 1108. In FIGS. 11A-11D, the protrusions 1108 extend from ends 1112 of the main body of the conical retainer 1104. The retainers 1104 yield to motion of the elongated suture body within the tissue when the suture is drawn in the suture deployment direction represented by the arrow, and resists motion if the suture is drawn in a direction opposite the suture deployment direction (a direction opposite the arrow). If the suture 1100 were pulled in a direction opposite the arrow, the protrusions 1108 would stick into patient tissue, providing for even further resistance to movement in the direction opposite the arrow.

[0090] FIGS. 11B-11E illustrate some variations on retainer 1104. The retainer 1104 of FIG. 11B is similar to the retainer 1104 of FIG. 8, but includes a greater number of protrusions 1108. FIG. 11C illustrates that an angle of the protrusions 1108 of the retainers 1104 can be different (e.g., more or less obtuse) than the angle of the wall 1114 of the conical main body of the retainer 1104. The retainer 1104 of FIG. 11D is similar to the retainer 1104 of FIG. 11C, but includes a greater number of protrusions 1108. FIG. 11C also illustrates that the retainer 1104 can include one or more vents 1110 in the angled walls 1114, where the vents prevent air from getting trapped by the retainers 1104 as the retainers are employed through patient tissue. This is advantageous, because it is believed that tissue will heal more quickly if there is no trapped air behind the retainer 1104. Further, the vents provide for further anchoring of the tissue. Such vents 1110 can be included in any of the retainers 1104 of FIGS. 11A-11E. Venting can also be provided by forming conical retainers from a mesh, perforated or porous material. The retainer 1104 of FIG. 11E includes protrusions 1108 that extend from the angled wall 1114 of the conical main body of the retainer 1104. In each embodiment, the retainers 1104 yield to motion of the elongated suture body within the tissue when the suture is drawn in a first suture deployment direction, and resists motion if the suture is drawn in a direction opposite the suture deployment direction. When the retainers 1104 are pulled in a direction opposite their deployment

direction, the protrusions 1108 will stick into patient tissue, providing for even further resistance to movement in the direction opposite the deployment direction.

[0091] While the conical retainers 1104 can have a circular cross section, the cross section may alternatively be elliptical, or some other shape. Also, it is noted that the instead of the angled walls 1114 being curved, it's possible that they are faceted. Further, the term conical is meant to encompass frusto-conical.

[0092] The retainers 1104 can be preformed and thereafter attached to a suture body 1102. In an embodiment, each of the retainers 1104 includes an opening 1116 therethrough. The suture body 1102 can be threaded through the openings 1116 of the retainers 1104, and the retainers 1104 can be attached to the suture body 1102 such that the retainers 104 are spaced apart from one another. The retainers can be attached to the suture body 1102 using an adhesive, by heat-bonding, by weld-bonding, by solvent-bonding, etc. Alternatively, the retainers 1104 can be formed as an integral portion of (i.e., as a one piece structure with) the suture body 1102, e.g., using extrusion, molding, machining and/or heading processes, e.g., in a manner similar to that described above with reference to FIGS. 8-10C.

[0093] The walls of the retainers 1104 are angled such that the retainers substantially yield to motion of the elongated suture body within the tissue when the suture is drawn in one suture deployment direction and resist motion if the suture is drawn in an opposite suture deployment direction. The self-retaining sutures 1100 can be unidirectional or bidirectional. If unidirectional sutures, the self-retaining sutures can include an end that is pointed or has a needle to allow penetration and passage through tissue when drawn by the end and an opposite end that includes in some embodiments an anchor for engaging tissue at the initial insertion point to limit movement of the suture. If bi-directional, the self-retaining sutures 1100 can include retainers 1104 grouped and extending toward one deployment direction along one portion of the suture and opposing retainers 1104 grouped and extending toward an opposing deployment direction along another portion of the suture. Accordingly, when such a bidirectional suture is implanted, both groups of retainers are engaging tissue, and the retainers can resist movement of the suture through tissue in either direction. Also, a bidirectional suture can be armed with a needle at each end of the suture thread.

A bidirectional suture can also have a transitional segment located between the two groups of retainers.

[0094] The self-retaining suture 1100 of can include retainers 1104 of different sizes, which are designed for various surgical applications. For example, different retainers 1104 can have different cross-sectional diameters. Relatively larger retainers are desirable for joining fat and soft tissues, whereas relatively smaller retainers are desirable for joining fibrous tissues. Use of a combination of large, medium, and/or small retainers on the same suture helps to ensure maximum anchoring properties when retainers sizes are customized for each tissue layer. The periodicity of the retainers 104 can be random or organized. The order of occurrence and the size of the groups may be altered to maximize tissue engagement strength.

[0095] The retainers 1104 can be made of the same material as the suture body 1102, or of a different material. In specific embodiments, the retainers 1104 are made of a material that has a higher elastic constant (and thus stiffer) and/or a larger plastic zone (and thus more permanently deformable) than the material from which the suture body 1102 is made. Also, the suture body 1102 can be made of a material that is more flexible and/or more elastic than the material from which the retainers 1104 are made. Furthermore the retainers 1104 can have a greater toughness than the suture body to withstand the excess bending forces applied to them. Alternatively, the retainers 1104 and the suture body 1102 can be made of the same type of material, but the retainers when formed can be treated to increase their stiffness and strength, e.g., by appropriate annealing cycles (heating to a certain temperature and cooling at a certain rate) of the retainers 1104, e.g., using techniques similar to those taught in U.S. Patent No. 5,007,922, which is incorporated herein by reference.

[0096] The retainers 1104 and the suture body 1102 can both be made of bio-absorbable material, examples of which were provided above. Alternatively, the retainers 1104 and the suture body 1102 can both be made of non-absorbable material, examples of which were provided above. In still other embodiments, the retainers 1104 can be bio-absorbable, while the suture body 1102 is non-absorbable, or vice versa. In another embodiment of this invention the retainers 1104 and/or the suture body 1102 can be partially bio-absorbable, or a number of the retainers 1104 can be bioabsorbable

while the remaining retainers 1104 are not bio-absorbable. Additionally, the suture body 1102 can be made of a material having a greater tensile strength than the material used to make the retainers 1104, or vice versa.

D. Materials for Manufacture of Self-Retaining Sutures

[0097] The suture bodies and retainers described above can be made of any suitable biocompatible material, and may be further treated with any suitable biocompatible material, whether to enhance the sutures' strength, resilience, longevity, or other qualities, or to equip the sutures to fulfill additional functions besides joining tissues together, repositioning tissues, or attaching foreign elements to tissues.

[0098] The retainers described above may also incorporate materials that further promote tissue engagement. For example, forming the retainers of tissue engagement-promoting materials can enhance the ability of the sutures to stay in place. One such class of tissue engagement-promoting materials are porous polymers that can be extruded to form suture bodies, including both microporous polymers and polymers that can be extruded with bubbles (whether bioabsorbable or nonbioabsorbable). Retainers synthesized with such materials can have a three-dimensional lattice structure that increases tissue engagement surface area and permits tissue infiltration into the suture body itself, thus having a primary structure that promotes successful suture use. Moreover, by optimizing pore size, fibroblast ingrowth can be encouraged, further facilitating anchoring of the retainers in the tissue. Alternatively pro-fibrotic coatings or agents may be used to promote more fibrous tissue encapsulation of the retainers and therefore better engagement. Exemplary profibrotic materials, which can be used to form retainers 204 and/or which can be applied to retainers, to promote tissue growth, are disclosed in U.S. Patent No. 7,166,570, entitled "Medical implants and fibrosis-inducing agents," which is incorporated herein by reference.

[0099] One such microporous polymer is ePTFE (expanded polytetrafluoroethylene). Self-retaining sutures incorporating ePTFE (and related microporous materials) are well-suited to uses requiring a strong and permanent lift (such as breast lifts, face lifts, and other tissue repositioning procedures), as tissue

infiltration of the suture results in improved fixation and engraftment of the suture and the surrounding tissue thus providing superior hold and greater longevity of the lift.

[00100] Additionally, self-retaining sutures described herein may be provided with compositions to promote healing and prevent undesirable effects such as scar formation, infection, pain, and so forth. This can be accomplished in a variety of manners, including for example: (a) by directly affixing to the suture a formulation (e.g., by either spraying the suture with a polymer/drug film, or by dipping the suture into a polymer/drug solution), (b) by coating the suture with a substance such as a hydrogel which will in turn absorb the composition, (c) by interweaving formulation-coated thread (or the polymer itself formed into a thread) into the suture structure in the case of multi-filamentary sutures, (d) by inserting the suture into a sleeve or mesh which is comprised of, or coated with, a formulation, or (e) constructing the suture itself with a composition. Such compositions may include without limitation anti-proliferative agents, anti-angiogenic agents, anti-infective agents, fibrosis-inducing agents, anti-scarring agents, lubricious agents, echogenic agents, anti-inflammatory agents, cell cycle inhibitors, analgesics, and anti-microtubule agents. For example, a composition can be applied to the suture before the retainers are formed, so that when the retainers engage, the engaging surface is substantially free of the coating. In this way, tissue being sutured contacts a coated surface of the suture as the suture is introduced, but when the retainer engages, a non-coated surface of the retainer contacts the tissue. Alternatively, the suture may be coated after or during formation of retainers on the suture if, for example, a fully-coated rather than selectively-coated suture is desired. In yet another alternative, a suture may be selectively coated either during or after formation of retainers by exposing only selected portions of the suture to the coating. The particular purpose to which the suture is to be put or the composition may determine whether a fully-coated or selectively-coated suture is appropriate; for example, with lubricious coatings, it may be desirable to selectively coat the suture, leaving, for instance, the tissue-engaging surfaces of the sutures uncoated in order to prevent the tissue engagement function of those surfaces from being impaired. On the other hand, coatings such as those comprising such compounds as anti-infective agents may suitably be applied to the entire suture, while coatings such as those comprising

fibrosing agents may suitably be applied to all or part of the suture (such as the tissue-engaging surfaces). The purpose of the suture may also determine the sort of coating that is applied to the suture; for example, self-retaining sutures having anti-proliferative coatings may be used in closing tumour excision sites, while self-retaining sutures with fibrosing coatings may be used in tissue repositioning procedures and those having anti-scarring coatings may be used for wound closure on the skin. As well, the structure of the suture may influence the choice and extent of coating; for example, sutures having an expanded segment may include a fibrosis-inducing composition on the expanded segment to further secure the segment in position in the tissue. Coatings may also include a plurality of compositions either together or on different portions of the suture, where the multiple compositions can be selected either for different purposes (such as combinations of analgesics, anti-infective and anti-scarring agents) or for their synergistic effects.

E. Clinical Uses

[0100] In addition to the general wound closure and soft tissue repair applications described in the preceding sections, self-retaining sutures can be used in a variety of other indications.

[0101] Self-retaining sutures described herein may be used in various dental procedures, i.e., oral and maxillofacial surgical procedures and thus may be referred to as “self-retaining dental sutures.” The above-mentioned procedures include, but are not limited to, oral surgery (e.g., removal of impacted or broken teeth), surgery to provide bone augmentation, surgery to repair dentofacial deformities, repair following trauma (e.g., facial bone fractures and injuries), surgical treatment of odontogenic and non-odontogenic tumors, reconstructive surgeries, repair of cleft lip or cleft palate, congenital craniofacial deformities, and esthetic facial surgery. Self-retaining dental sutures may be degradable or non-degradable, and may typically range in size from USP 2-0 to USP 6-0.

[0102] Self-retaining sutures described herein may also be used in tissue repositioning surgical procedures and thus may be referred to as “self-retaining tissue repositioning sutures”. Such surgical procedures include, without limitation, face lifts,

neck lifts, brow lifts, thigh lifts, and breast lifts. Self-retaining sutures used in tissue repositioning procedures may vary depending on the tissue being repositioned; for example, sutures with larger and further spaced-apart retainers may be suitably employed with relatively soft tissues such as fatty tissues.

[0103] Self-retaining sutures described herein may also be used in microsurgical procedures that are performed under a surgical microscope (and thus may be referred to as “self-retaining microsutures”). Such surgical procedures include, but are not limited to, reattachment and repair of peripheral nerves, spinal microsurgery, microsurgery of the hand, various plastic microsurgical procedures (e.g., facial reconstruction), microsurgery of the male or female reproductive systems, and various types of reconstructive microsurgery. Microsurgical reconstruction is used for complex reconstructive surgery problems when other options such as primary closure, healing by secondary intention, skin grafting, local flap transfer, and distant flap transfer are not adequate. Self-retaining microsutures have a very small caliber, often as small as USP 9-0 or USP 10-0, and may have an attached needle of corresponding size. They may be degradable or non-degradable.

[0104] Self-retaining sutures as described herein may be used in similarly small caliber ranges for ophthalmic surgical procedures and thus may be referred to as “ophthalmic self-retaining sutures”. Such procedures include but are not limited to keratoplasty, cataract, and vitreous retinal microsurgical procedures. Ophthalmic self-retaining sutures may be degradable or non-degradable, and have an attached needle of correspondingly-small caliber.

[0105] Self-retaining sutures can be used in a variety of veterinary applications for a wide number of surgical and traumatic purposes in animal health.

[0106] Although the embodiments of the present invention has been shown and described in detail with regard to only a few exemplary embodiments of the invention, it should be understood by those skilled in the art that it is not intended to limit the invention to the specific embodiments disclosed. Various modifications, omissions, and additions may be made to the disclosed embodiments without materially departing from the novel teachings and advantages of the invention, particularly in light of the foregoing teachings. Accordingly, it is intended to cover all such modifications,

omissions, additions, and equivalents as may be included within the spirit and scope of the invention as defined by the following claims.

CLAIMS

What is claimed:

1. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of bi-directional retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;
wherein, prior to being deployed through tissue, each said bi-directional retainer is deployable through tissue in both a first direction and a second direction generally opposite the first direction; and
wherein once a said bi-directional retainer is deployed through tissue in one of the first and second directions, the bi-direction retainer will substantially yield to motion of said elongated suture body within the tissue when said elongated suture body is drawn in the one of the first and second directions, and will resist motion of said elongated suture body in the other one of the first and second directions.
2. The suture of claim 1, wherein the number of said bi-directional retainers that are deployed in the first direction and the number of said bi-directional retainers that are deployed in the second direction can be decided during a procedure.
3. The suture of claim 1, wherein how much of the suture is deployed through tissue in the first direction and how much of the suture is deployed through tissue in the second direction can be decided during a procedure because the suture does not have a predetermined transition segment or point.
4. The suture of claim 1, wherein:
once a said bi-direction retainer is deployed through tissue in the first direction, the bi-direction retainer will substantially yield to motion of said elongated suture body within the tissue when said elongated suture body is drawn in the first direction, and

will resist motion of said elongated suture body in the second direction generally opposite the first direction; and

once a said bi-direction retainer is deployed through tissue in the second direction, the bi-direction retainer will substantially yield to motion of said elongated suture body within the tissue when said elongated suture body is drawn in the second direction, and will resist motion of said elongated suture body in the first direction.

5. The suture of claim 4, wherein:

if the entire said suture body is deployed through tissue in the first direction, then all of the plurality of bi-directional retainers will substantially yield to motion of said elongated suture body within the tissue when said elongated suture body is drawn in the first direction, and will resist motion of said elongated suture body in the second direction generally opposite the first direction; and

if a first portion of said elongated suture body is deployed through tissue in the first direction and a second portion of said elongated suture body is deployed through tissue in the second direction generally opposite the first direction, then

those of said bi-directional retainers extending from the first portion of said suture body will substantially yield to motion of said elongated suture body within the tissue when said elongated suture body is drawn in the first direction, and will resist motion of said elongated suture body in the second direction generally opposite the first direction, and

those of said bi-directional retainers extending from the second portion of said suture body will substantially yield to motion of said elongated suture body within the tissue when said elongated suture body is drawn in the second direction, and will resist motion of said elongated suture body in the first direction.

6. The suture of claim 1, wherein:

each said bi-directional retainer can be collapsed in either of two directions, depending upon the direction in which the bi-directional retainer is deployed through tissue;

once a said bi-directional retainer is collapsed due to the bi-directional retainer being deployed through tissue in the first direction, the bi-directional retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the first direction, and will resist motion of the elongated suture body in the second direction generally opposite the first direction; and

once a said bi-directional retainer is collapsed due to the bi-directional retainer being deployed through tissue in the second direction, the bi-directional retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the second direction, and will resist motion of the elongated suture body in the first direction.

7. The suture of claim 6, wherein a said bi-directional retainer collapses in a direction opposite to the direction in which the bi-directional retainer is deployed through tissue.

8. The suture of claim 7, wherein:

if the entire said elongated suture body is deployed through tissue in a first direction, then all of the plurality of bi-directional retainers will collapse in a second direction opposite the first direction; and

if a first portion of said elongated suture body is deployed through tissue in the first direction and a second portion of said elongated suture body is deployed through tissue in the second direction generally opposite the first direction, then those of said bi-directional retainers extending from the first portion will collapse in the second direction, and those of said retainers extending from the second portion will collapse in the first direction.

9. The suture of claim 6, wherein each said bi-directional retainer include grooves that guide how the bi-directional retainer collapses.

10. The suture of claim 9, wherein said grooves of a said bi-directional retainer extend radially, from a location at which the bi-directional retainer is attached to said elongated suture body, to an outer edge of the bi-directional retainer.

11. The suture of claim 1, wherein said bi-directional retainers include vents to prevent air from getting trapped as said bi-directional retainers are deployed through tissue.

12. The suture of claim 1, wherein said bi-directional retainers, prior to being deployed through tissue, extend generally radially from and generally perpendicular to said elongated suture body.

13. The suture of claim 1, wherein said elongated suture body and said bi-directional retainers comprise a one piece structure.

14. The suture of claim 1, wherein:
each of said bi-directional retainers includes an opening therethrough;
said suture body is threaded through said openings of said bi-directional retainers; and
said bi-directional retainers are attached to said suture body such that said bi-directional retainers are spaced apart from one another between said first and second ends of said elongated suture body.

15. The suture of claim 14, wherein said bi-directional retainers are attached to said suture body in at least one of the following manners:
said bi-directional retainers are adhesive-bonded to said elongated suture body;
said bi-directional retainers are weld-bonded to said elongated suture body;
said bi-directional retainers are solvent-bonded to said elongated suture body;
and
said bi-directional retainers are heat-bonded to said elongated suture body.

16. The suture of claim 1, further comprising tissue engaging protrusions that extend from edges of said bi-directional retainers.

17. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of bi-directional retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;
wherein each said bi-directional retainer is deployable through tissue in two directions generally opposite one another, but once deployed in one direction resists movement in the generally opposite direction.

18. The suture of claim 17, wherein the number of said bi-directional retainers that are deployed in one direction and the number of said bi-directional retainers that are deployed in the generally opposite direction can be decided during a procedure.

19. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of transformable retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;
wherein, prior to being deployed through tissue, each said transformable retainer is deployable through tissue in both a first direction and a second direction generally opposite the first direction; and
wherein a shape of each said transformable retainer can be transformed in either of two manners, depending upon the direction in which the retainer is deployed through tissue;
once a said retainer is transformed in shape due to the retainer being deployed through tissue in the first direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the first direction, and will resist motion of the elongated suture body in the second direction generally opposite the first direction; and

once a said retainer is transformed in shape due to the retainer being deployed through tissue in the second direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the second direction, and will resist motion of the elongated suture body in the first direction.

20. The suture of claim 19, wherein the number of said transformable retainers that are deployed in one direction and the number of said transformable retainers that are deployed in the generally opposite direction can be decided during a procedure.

21. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of transformable retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;
wherein a shape of each said transformable retainer is transformed when the retainer is deployed through tissue.

22. The suture of claim 21, wherein if a said retainer is transformed in shape due to the retainer being deployed through tissue in a first direction, then the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the first direction, and will resist motion of the elongated suture body in a second direction generally opposite the first direction.

23. The suture of claim 22, wherein if a said retainer is transformed in shape due to the retainer being deployed through tissue in the second direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the second direction, and will resist motion of the elongated suture body in the first direction.

24. The suture of claim 21, wherein each said transformable retainer is deployable through tissue in two directions generally opposite one another, but once the shape of

the retainer is transformed due to the retainer being deployed through tissue in one direction the retainer resists movement in the generally opposite direction.

25. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;

wherein

each said retainer includes grooves, perforations, or other fold lines along which the retainer can bend when the retainer is deployed through tissue;

prior to being deployed through tissue, each said retainer is deployable through tissue in both a first direction and a second direction generally opposite the first direction;

once a said retainer is deployed through tissue in the first direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the first direction, and will resist motion of the elongated suture body in the second direction generally opposite the first direction; and

once a said retainer is deployed through tissue in the second direction, the retainer will substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the second direction, and will resist motion of the elongated suture body in the first direction.

26. The suture of claim 25, wherein the number of said retainers that are deployed in one direction and the number of said retainers that are deployed in the generally opposite direction can be decided during a procedure.

27. The suture of claim 25, wherein how much of the suture is deployed through tissue in the first direction and how much of the suture is deployed through tissue in the second direction can be decided during a procedure because the suture does not have a predetermined transition segment or point.

28. The suture of claim 25, wherein said grooves, perforations, or other fold lines of a said retainer extend radially, from a location at which the retainer is attached to said elongated suture body, to an outer edge of the retainer.
29. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of conical shaped retainers spaced apart from one another and extending from said elongated suture body between said first and second ends; and
tissue engaging protrusions that extend from at least one of
edges of the conical shaped retainers, and
angled walls of the conical shaped retainers.
30. The suture of claim 29, wherein the tissue engaging protrusions extend from the edges of the conical shaped retainers.
31. The suture of claim 29, wherein the tissue engaging protrusions extend from the angled walls of the conical shaped retainers.
32. The suture of claim 29, wherein:
the elongated suture body includes first and second longitudinal portions;
a first group of said retainers extend from the first longitudinal portion and substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in a first direction and resist motion of the elongated suture body in a second direction generally opposite the first direction; and
a second group of said retainers extend from the second longitudinal portion and substantially yield to motion of the elongated suture body within the tissue when the elongated suture body is drawn in the second direction and resist motion of the elongated suture body in the first direction.

33. The suture of claim 29, wherein said conical shaped retainers include vents to prevent air from getting trapped by the retainers.
34. The suture of claim 33, wherein said vents extend through the angled walls of said conical shaped retainers.
35. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of conical shaped retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;
wherein said conical shaped retainers include vents to prevent air from getting trapped by the retainers.
36. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of conical shaped retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;
wherein said conical shaped retainers are formed from a mesh material.
37. The suture of claim 36, wherein openings in the mesh material prevent air from getting trapped by the retainers.
38. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and
a plurality of conical shaped retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;
wherein said conical shaped retainers are perforated or porous to prevent air from getting trapped by the retainers.
39. A suture to be used in a procedure applied to tissue, comprising:
an elongated suture body including first and second ends; and

a plurality retainers spaced apart from one another and extending from said elongated suture body between said first and second ends;

wherein said retainers are perforated or porous or made from a mesh material to prevent air from getting trapped by the retainers.

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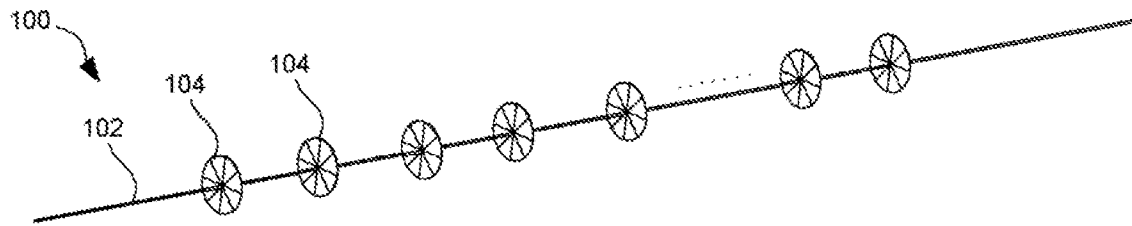


FIG. 1

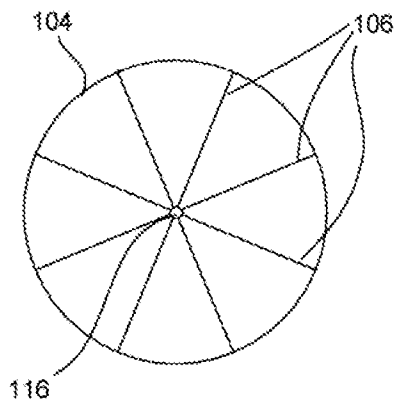


FIG. 2A

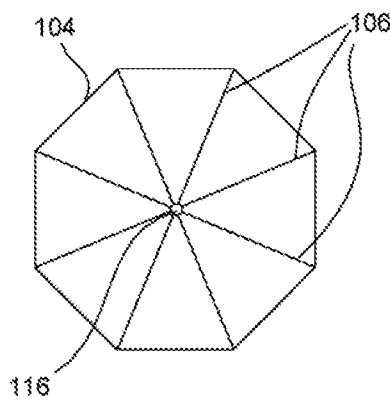


FIG. 2B

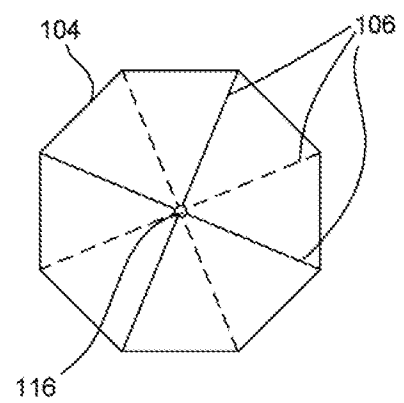


FIG. 2C



FIG. 3A



FIG. 3B

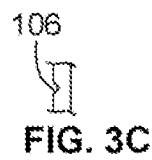


FIG. 3C

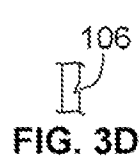


FIG. 3D



FIG. 3E



FIG. 3F



FIG. 3G



FIG. 3H

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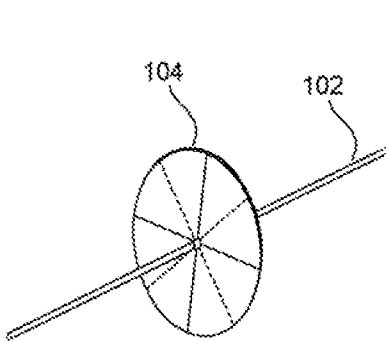


FIG. 4A

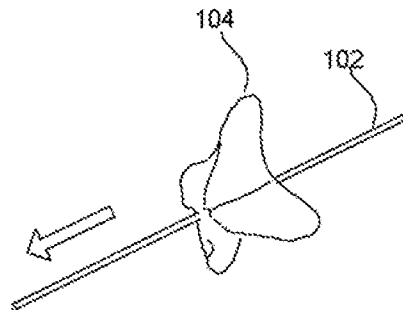


FIG. 4B

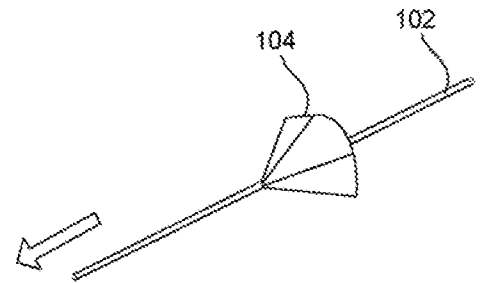


FIG. 4C

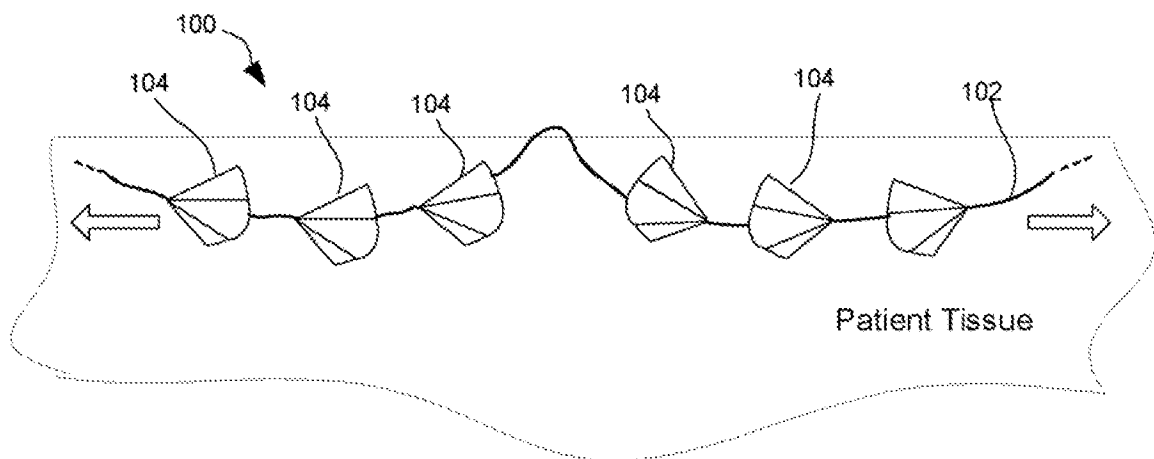


FIG. 5

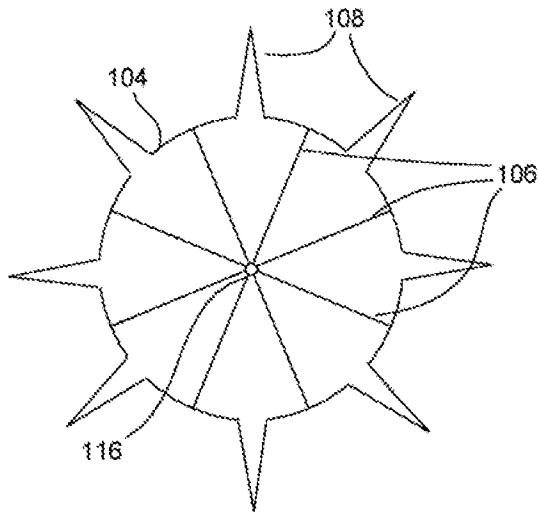


FIG. 6A

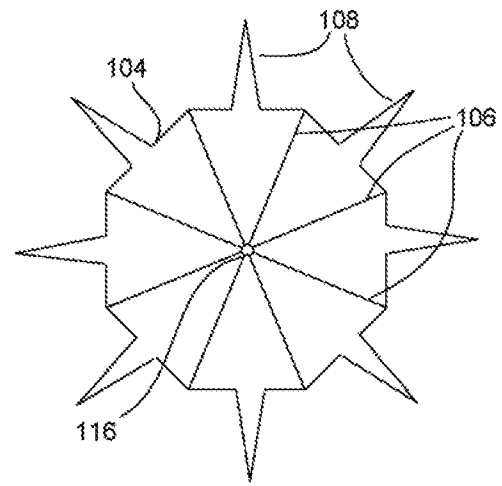


FIG. 6B

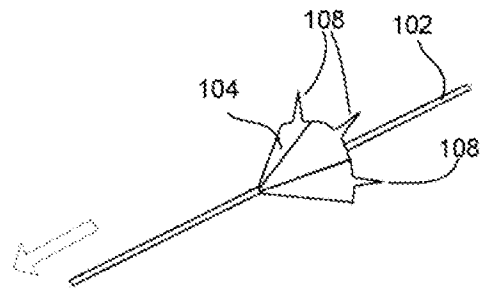


FIG. 6C

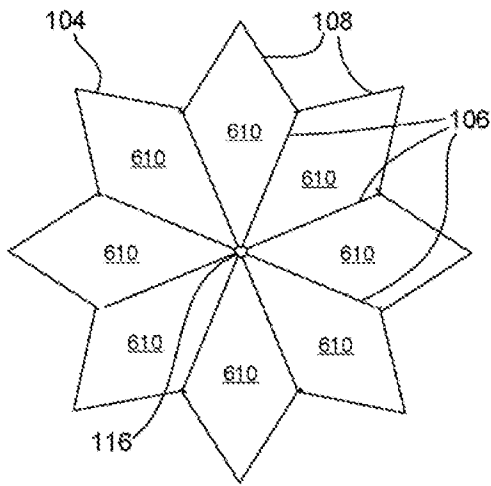


FIG. 6D

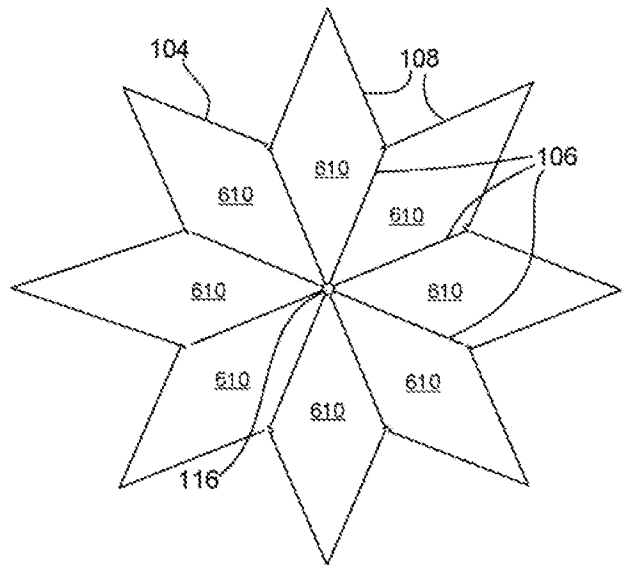


FIG. 6E

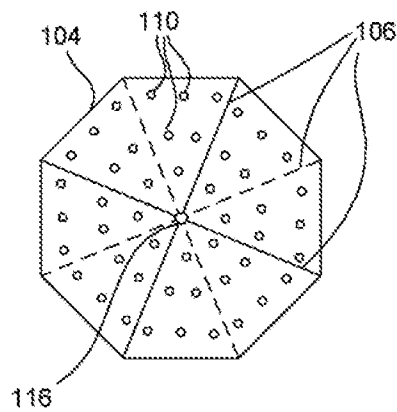
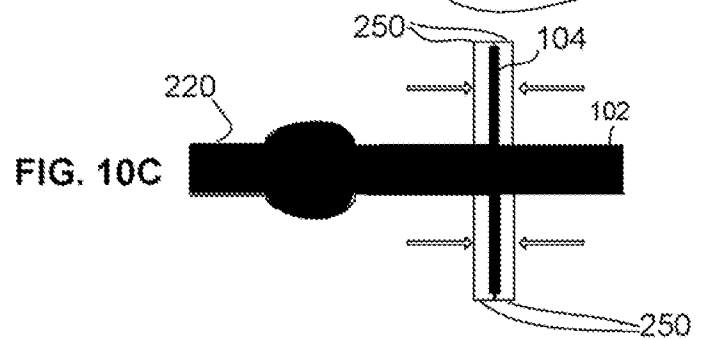
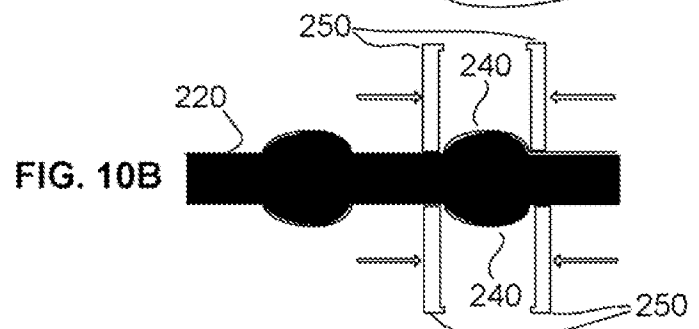
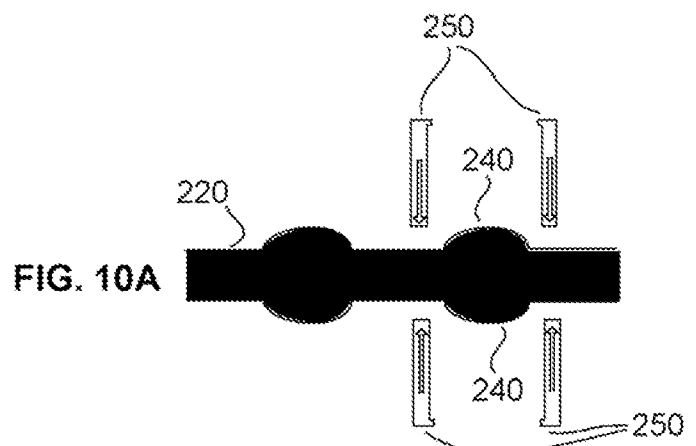
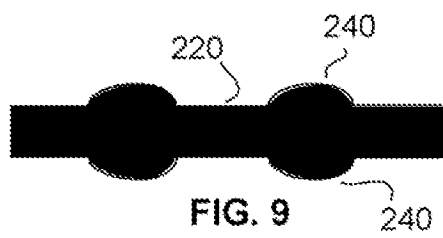
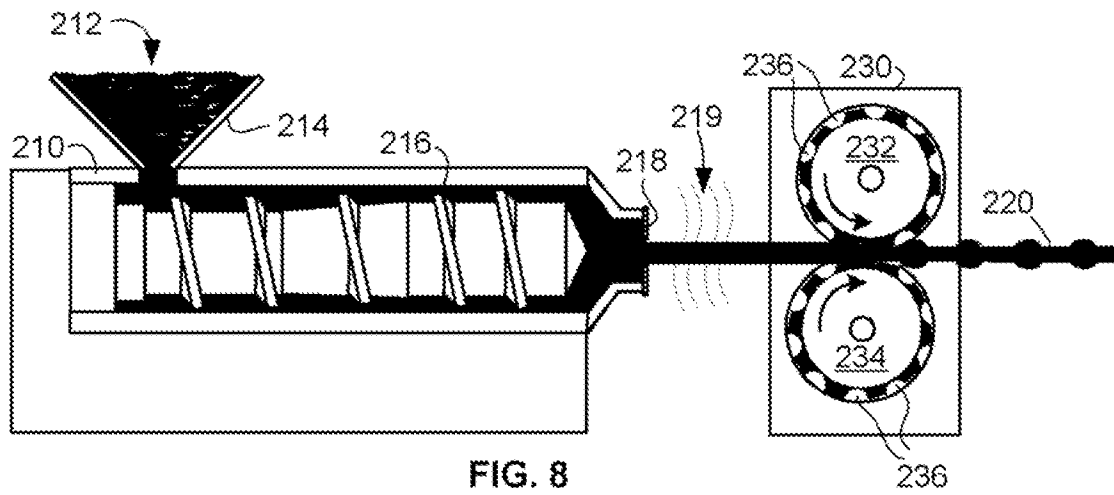


FIG. 7

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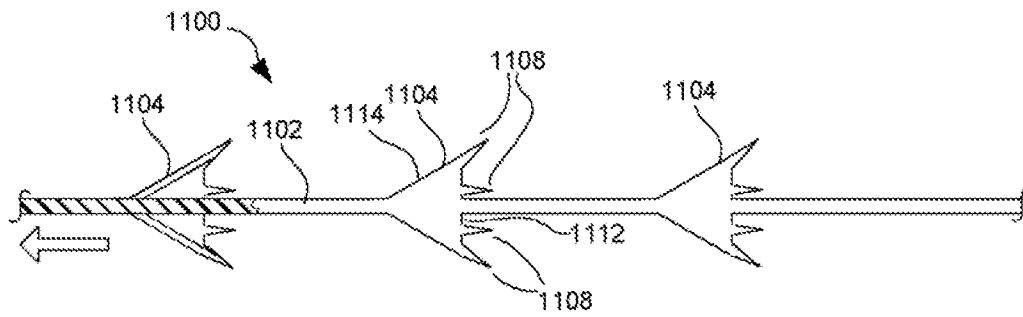


FIG. 11A

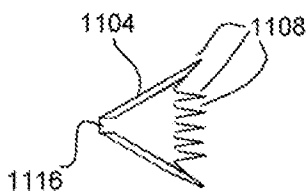


FIG. 11B

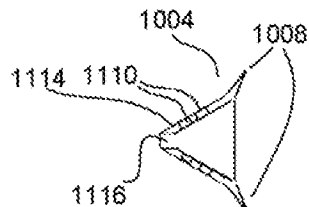


FIG. 11C

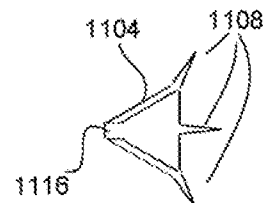


FIG. 11D

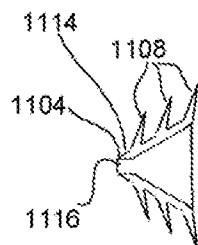


FIG. 11E