

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
25 September 2003 (25.09.2003)

PCT

(10) International Publication Number
WO 03/077730 A2

(51) International Patent Classification⁷: **A61B**

(21) International Application Number: PCT/US03/07608

(22) International Filing Date: 10 March 2003 (10.03.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/363,106 11 March 2002 (11.03.2002) US

GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv)) for US only*

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Published:
— *without international search report and to be republished upon receipt of that report*

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SURGICAL COILS AND METHODS OF DEPLOYING

(57) Abstract: Surgical coils for marking, anchoring, stapling and suturing that can be implanted in the body by deforming it to a small cross section profile and then sliding it through a low profile delivery device then deploying from an embodiment of a delivery device at a targeted site. Embodiments of surgical coils when deployed revert back to a coiled configuration and circle tissue at the target site. Can be deployed about attachment members, such as suture lines, marker lines and the like for anchoring same.



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SURGICAL COILS AND METHODS OF DEPLOYING

RELATED APPLICATIONS

This application claims the benefit of priority from U.S. Provisional Patent Application Ser. No. 60/363,106, filed by John L. Wardle on March 11, 2002, titled "Surgical Coils and Methods of Deploying" and this priority application is hereby incorporated by reference in its entirety.

BACKGROUND

Surgical stapling devices are widely used in surgical procedures to fasten body tissue quickly and efficiently by driving fasteners or staples into the tissue. In certain types of staplers, a single staple is typically formed around an anvil, e.g., skin staplers, for approximating tissue. Such staplers may employ staples having a variety of configurations, as for example a conventional U-shaped configuration and variations thereon. U-shaped staples have two opposed legs connected by a linear bridge. Therefore, the staple drivers have flat surfaces to correspond to the linear bridge portions of the staples. When deformed, such staples tend to form a B-shape, wherein the legs are curved towards the bridge and the chiseled end points are in a position to re-puncture the tissue being sutured. In such an orientation, a significant area of the deformed leg portions is not in extensive contact with the tissue.

In addition, suturing and suture line placement are necessary aspects of any surgical procedures. Surgeons have developed numerous techniques for tying sutures and placing suture lines over the years. Endoscopic surgical procedures such as arthroscopy, laparoscopy, or thoroscopy are challenged with these tasks because development of a knot or placement of a suture line in a confined space is time consuming and requires great dexterity. Currently in endoscopic procedures, either

the knots need to be tied externally to the body and inserted into the body and to the operative site using some kind of knot pushing device, or they need to be tied inside the body using long, instruments.

As such, what has been needed is to provide a device and method,
5 which, secures tissue along a greater length and does so with a reduced tendency to re-puncture the tissue being secured. What has also been needed are simple approaches for placing sutures and suture lines in confined spaces. What has also been needed are devices and methods that could also be used as sutures to attach tissue, implant devices and
10 surgical support materials for use in a wider range of none invasive surgical procedures. What has also been needed are device and methods for placing markers in tissue that do not have any sharp exposed points and do not migrate from the location of original deployment.

15 **SUMMARY**

The present invention relates to surgical coils and variety of devices that can effectively deploy surgical coils by different methods for a variety of clinical applications and indications. Techniques are also disclosed for simultaneously positioning and securing various attachment
20 elements to surgical coils. Surgical coils disclosed herein can be used in numerous clinical applications including but not limited to tissue stapling, tissue anchoring including bone and suture anchors and tissue marking.

In one embodiment having features of the invention, a medical fastener is disclosed and includes an elongate element having a
25 longitudinal axis and formed into an enclosed configuration with an overlapped portion with the elongate element making contact in the

overlapped portion, the overlapped portion having a circumferential overlap of at least 300 degrees.

In another embodiment illustrating the features of the invention, a surgical marker for marking a position within the body of a patient is disclosed and includes an elongate element having a longitudinal axis and formed into an enclosed configuration with an overlapped portion with the elongate element making contact in the overlapped portion, and a contrast material in contact with the elongate element.

In yet another embodiment, a delivery device for deployment of a surgical coil is described and comprises an elongate delivery sheath having a proximal end and a distal end, an actuator body secured to a proximal portion of the elongate delivery sheath, a first ratchet member in substantially fixed relation with the actuator body having a grip feature configured to engage an advancing ribbon for prevent substantial proximal motion of the advancing ribbon relative to the delivery sheath, an actuator slidably engaged with the actuator body, a second ratchet member having a grip feature configured to engage the advancing ribbon and being moveable with the actuator, and an advancing ribbon configured to apply axial force on an elongate element within the delivery sheath.

In another embodiment, a method for deploying a surgical coil in a patient's body is disclosed herein and includes positioning a distal end of a delivery sheath adjacent a deployment site, axially advancing a surgical coil through the delivery sheath, out of a distal port of the delivery sheath and into target tissue, and continuing to advance the surgical coil into the target tissue allowing an elongate element of the surgical coil to self-form into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

In still of another embodiment describing the features of the invention, a delivery device for simultaneous deployment of a plurality of surgical coils is disclosed and includes a delivery sheath housing, a plurality of delivery sheaths oriented and stabilized by the delivery sheath housing with each delivery sheath having a proximal end and a distal end, and plungers disposed within a plurality of the delivery sheaths, and an actuator for applying axial force to advancing members that are axially translatable with respect to the delivery sheaths for distally advancing surgical coils disposed within the delivery sheaths.

10 In another embodiment illustrating the features of the invention, a method for deploying a plurality of surgical coils in a patient's body and includes positioning distal ends of a plurality of delivery sheaths stabilized by a delivery sheath housing adjacent a deployment site, axially advancing a plurality of surgical coils through the delivery sheaths, out of distal ports of the delivery sheaths and into target tissue, and continuing to advance the surgical coils into the target tissue allowing elongate elements of the surgical coils to self-form into an enclosed configuration with an overlapped portion of each elongate element making contact with itself in the overlapped portion.

20 In yet another embodiment, a delivery device for closure of a wound site and simultaneous deployment of a plurality of surgical coils across the wound is describe herein and includes a delivery sheath housing, a plurality of delivery sheaths oriented and stabilized by the delivery sheath housing with each delivery sheath having a proximal end, a distal end and a pre-formed outward radial bias away from other delivery sheaths for at least one distal end thereof, an outer sheath slidably disposed over at least a portion of the delivery sheath housing

and delivery sheaths, and configured to constrain an outward radial displacement of the at least one distal end with the pre-formed bias when the outer sheath is disposed about the distal end with the pre-formed bias and to allow outward radial displacement of the distal end with the pre-formed bias when not disposed thereabout, plungers disposed within a plurality of the delivery sheaths for applying axial force to the delivery sheaths for distally advancing surgical coils disposed within the delivery sheaths.

In another embodiment, a method for forcing a wound closed and deploying a plurality of surgical coils across the wound to maintain closure and includes positioning distal ends of a plurality of delivery sheaths stabilized by a delivery sheath housing adjacent a deployment site with an outer sheath disposed about at least a portion of the delivery sheaths and delivery sheath housing in a proximally retracted position, advancing the distal ends of the delivery sheaths into target tissue at the deployment site with at least one delivery sheath disposed on either side of the wound, advancing the outer sheath distally in order to reduce an outward radial displacement of a distal end of at least one of the delivery sheaths thereby reducing the distance between the distal ends of at least two delivery sheaths and at least partially closing the wound, axially advancing a plurality of surgical coils through the delivery sheaths, out of distal ports of the delivery sheaths and into target tissue, and continuing to advance the surgical coils into the target tissue allowing elongate elements of the surgical coils to self-form into an enclosed configuration with an overlapped portion of each elongate element making contact with itself in the overlapped portion.

In still another embodiment describing the features of the invention, a delivery device for simultaneous deployment of a plurality of surgical

coils from within a channel and has a delivery sheath housing, a plurality of delivery sheaths oriented and stabilized by the delivery sheath housing with each delivery sheath having a proximal end and a distal end, an outer sheath slidably disposed over at least a portion of the delivery sheath housing and delivery sheaths, an expanable member disposed between distal portions of the plurality of delivery sheaths and configured to expand the distal portions of the delivery sheaths in an outward radial direction when in an expanded state, and plungers disposed within a plurality of the delivery sheaths for applying axial force to a surgical coil within the delivery sheaths for distally advancing surgical coil.

In another embodiment, a method for deploying a plurality of surgical coils from within a channel is disclosed and includes positioning distal ends of a plurality of delivery sheaths stabilized by a delivery sheath housing at a deployment site within a cavity, expanding an expandable member which is surrounded by the the plurality of delivery sheaths until distal ends of the delivery sheaths are disposed against target material, axially advancing a plurality of surgical coils through the delivery sheaths, out of distal ports of the delivery sheaths and into target material, and continuing to advance the surgical coils into the target tissue allowing elongate elements of the surgical coils to self-form into an enclosed configuration with an overlapped portion of each elongate element making contact with itself in the overlapped portion.

In still another embodiment describing the features of the invention, a delivery device for deployment of a surgical coil and attachment memberis disclosed which includes an elongate deployment shaft assembly including an elongate delivery sheath having a proximal end and a distal end, an attachment member having an attachment loop disposed adjacent a distal port of the delivery sheath which is configured

to direct a surgical coil deployed from the distal port to surround the attachment loop, and an outer sheath slidably disposed about at least a portion of the delivery sheath and attachment member, and an actuator body secured to a proximal portion of the elongate deployment shaft
5 configured to advance a surgical coil distally from the delivery sheath.

In another embodiment, a method for deploying a surgical coil and attachment member in a patient's body is described and includes positioning a distal end of a deployment shaft assembly adjacent a deployment site, axially advancing a surgical coil through a delivery
10 sheath of the deployment shaft assembly, out of a distal port of the delivery sheath, into target tissue and around an attachment loop of the attachment member, continuing to advance the surgical coil into the target tissue allowing an elongate element of the surgical coil to self-form into an enclosed configuration with an overlapped portion with the
15 elongate element making contact with itself in the overlapped portion.

In another embodiment illustrating the features of the invention, a deflectable delivery device for deployment of a surgical coil is described which includes an elongate deployment shaft assembly including an elongate delivery sheath having a proximal end, a distal end and a distal
20 end portion that can be constrained to a straightened configuration and assumes a deflected curved configuration when the restraint is removed, and an outer sheath slidably disposed about at least a portion of the delivery sheath, and an actuator body secured to a proximal portion of the elongate deployment shaft assembly including a first actuator
25 configured to advance the delivery sheath relative to the outer sheath and a second actuator configured to advance the surgical coil distally from a distal port of the delivery sheath.

In another embodiment, a method for deploying a surgical coil in a patient's body is disclosed which includes positioning a distal end of a deployment shaft assembly adjacent a deployment site, activating a first actuator to advance a delivery sheath distally from an outer sheath of the deployment shaft assembly until a distal end of the delivery sheath
5 extends beyond a distal port of the outer sheath and extends in an outward radial direction from the distal port, activating a second actuator that axially advances a surgical coil through the delivery sheath, out of a distal port of the delivery sheath, into target tissue, continuing to advance
10 the surgical coil into the target tissue allowing an elongate element of the surgical coil to self-form into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

These and other advantages of embodiments of the invention will
15 become more apparent from the following detailed description when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view, partially cut away, of a surgical
20 coil deployed within the surface of tissue holding an incision closed.

FIGS. 2 and 3 illustrate a perspective view of a surgical coil having features of the invention.

FIG. 4 is an elevational view of a surgical coil embodiment having about 90 degrees of circumferential overlap in the coils.

25 FIG. 5 is an elevational view of a surgical coil embodiment having about 360 degrees of circumferential overlap in the coils.

FIG. 6 is a perspective view of a surgical coil with no overlap in the coils and having the distal end of the elongate element of the coil engaged with the proximal end of the elongate element.

FIG. 7 is an elevational view of the surgical coil of FIG. 6.

5 FIG. 8 is an elevational view of a surgical coil, similar to the surgical coil of FIGS. 1 and 2, illustrating the tightly wound nature of the elongate element of the surgical coil which has approximately 360 degrees of circumferential overlap.

FIG. 9 is an elevational view of a surgical coil, similar to that of
10 FIG. 8, but having approximately 720 degrees of circumferential overlap.

FIG. 10 is transverse cross sectional view of the surgical coil of FIG. 8 taken along lines 10-10 of FIG. 8.

FIG. 11 is a transverse cross sectional view of the surgical coil of FIG. 9 taken along lines 11-11 of FIG. 9.

15 FIGS. 12-14 illustrate various embodiments of surgical coil winding configurations.

FIG. 15 shows a transverse cross sectional view of a surgical coil having a coil configuration similar to that of FIG. 12 illustrating an element axis of the surgical coil of about 90 degrees with respect to the
20 coil axis.

FIG. 16 shows a transverse cross sectional view of a surgical coil having a coil configuration similar to that of FIG. 13 illustrating an element axis of the surgical coil of about 45 degrees with respect to the coil axis.

25 FIG. 17 shows a perspective view of a surgical coil similar to that of FIGS. 2 and 3 in a straightened configuration.

FIG. 18 shows an alternative embodiment of a surgical coil in a straightened configuration, illustrating longitudinal slots cut into the elongate member of the surgical coil.

FIG. 19 illustrates an elevational view of a surgical coil in a
5 straightened configuration.

FIG. 20 shows a transverse cross sectional view of the elongate member of the surgical coil of FIG. 19, taken along lines 20-20 of FIG. 19.

FIGS. 21-23 illustrate transverse cross sectional views of
10 alternative embodiments of elongate members of surgical coils.

FIG. 23A is an elevational view of a surgical coil embodiment having an interlocking or self-aligning configuration.

FIG. 23B is a transverse cross sectional view of the surgical coil of FIG. 23A taken along lines 23B-23B of FIG. 23A illustrating a concave
15 transverse cross sectional configuration of the elongate element of the surgical coil.

FIG. 23C is an elevational view of a surgical coil having an embodiment of an interlocking or self-aligning coil configuration.

FIG. 23D is a transverse cross sectional view of the surgical coil of
20 FIG. 23A taken along lines 23B-23B of FIG. 23A illustrating an interlocking groove and raised ridge on the elongate element of the surgical coil.

FIG. 24 is a perspective view of a surgical coil in a partially deployed state about the axis of the surgical coil with a proximal portion of the
25 partially deployed coil in a straightened configuration.

FIG. 25 is a perspective view of a ratcheting delivery device configured to deliver and deploy surgical coils, with a thumb ring of the delivery device in a proximal retracted position.

FIG. 26 is a perspective view of the delivery device of FIG. 25 with the thumb ring of the delivery device in an advanced distal position with a surgical coil being deployed from a distal end of a delivery sheath of the delivery device.

5 FIG. 27 is an enlarged view, in perspective, of the encircled portion 27 of FIG. 26 showing a distal section of the delivery device.

FIG. 28 is a perspective view of the delivery device of FIGS. 25-27 with the thumb ring of the delivery device in a completely advanced distal position with the surgical coil being completely deployed from a distal end
10 of the delivery sheath of the delivery device.

FIG. 29 is an enlarged view of the encircled portion 29 of FIG. 28 showing the surgical coil of FIG. 28 being completely deployed from a distal end of the delivery sheath of the delivery device.

FIG. 30 is a perspective view of the delivery device of FIG. 25 with
15 the thumb ring retracted back to a proximal position and ready to deploy another surgical coil disposed within the delivery sheath.

FIG. 31 is an elevational view of the delivery device of FIG. 25.

FIG. 32 is an elevational view in partial section of the delivery device of FIG. 31 taken along lines 32-32 of FIG. 31.

20 FIG. 33 is a top view in partial section of the delivery device of FIG. 32 taken along lines 33-33 of FIG. 32.

FIG. 34 is a transverse cross sectional view of the elongate member of the surgical coil and the delivery sheath of the delivery device of FIG. 32 taken along lines 34-34 of FIG. 32.

25 FIG. 34A illustrates the distal end of a delivery sheath with an arrow indicating the angle of the sharpened distal end of the delivery sheath.

FIG. 35 is an enlarged elevational view in section of the encircled portion 35 of FIG. 32 showing the delivery device.

FIG. 36 is a transverse cross sectional view of the delivery device of FIG. 35 taken along lines 36-36 of FIG. 35.

5 FIG. 37 is a perspective view of some of the interior components of the delivery device of FIG. 25 with some of the components removed for the purposes of illustration.

FIG. 38 is an enlarged perspective view of the encircled portion 38 of FIG. 37 showing the surgical coils at a distal portion of the delivery
10 device.

FIG. 39 is a further enlarged perspective view of the encircled portion 39 of FIG. 38 showing a junction between a distal end of a first elongate member of a surgical coil and a proximal end of an elongate member of a second surgical coil.

15 FIG. 40 is an exploded view of the delivery device of FIG. 25.

FIG. 41 is a perspective view of a distal section of a delivery sheath of a delivery device and a surgical coil being formed by a coil forming member at the distal end of the delivery sheath the delivery sheath also having a directional capability that is suitable for directing the
20 deployment direction of a surgical coil having a transverse cross sectional configuration which is substantially round.

FIG. 41A is a perspective view of the distal section of the delivery sheath of FIG. 41 with the surgical coil not shown for clarity of illustration.

FIG. 41B is an elevational view in section of the delivery sheath of
25 FIG. 41A.

FIG. 41C is an elevational view in section of a delivery sheath forming a surgical coil from an elongate element during deployment of the surgical coil.

FIG. 42 illustrates a sharpened distal tip of a surgical coil penetrating tissue during deployment.

FIG. 43 illustrates a schematic view of the surgical coil of FIG. 42 in a further deployed configuration, the direction of deployment being indicated by the arrow.

FIG. 44 illustrates a schematic view of the surgical coil in a completely deployed state within tissue.

FIG. 45 shows three surgical coils deployed in a variety of deployment configurations by a variety of deployment methods with respect to tissue surfaces.

FIG. 46 is a perspective view of a ratchet delivery device that is configured to accept a surgical coil cassette for deploying a large number of surgical coils from a single delivery device.

FIG. 47 is a perspective view of the delivery device of FIG. 46 with the surgical coil cassette removed from the delivery device.

FIG. 48 is an elevational view of the delivery device of FIG. 46.

FIG. 49 is a top view in partial section of the delivery device of FIG. 48 taken along lines 49-49 of FIG. 48.

FIG. 50 is an elevational view in partial section of the delivery device of FIG. 49 taken along lines 50-50 in FIG. 49.

FIG. 51 is a transverse cross sectional view of the delivery device of FIG. 48 taken along lines 51-51 of FIG. 48.

FIG. 52 is a perspective view of the surgical coil cassette shown in FIGS. 46 and 47.

FIG. 53 is another perspective view of the surgical coil cassette shown in FIG. 52.

FIG. 54 is an enlarged perspective view of the encircled portion 54 of FIG. 52 showing the surgical coil cassette.

FIG. 55 is an enlarged perspective view of the encircled portion 55 of FIG. 53 showing the surgical coil cassette.

FIG. 56 is a top view of the delivery device shown in FIG. 46.

FIG. 57 is an enlarged elevational view of the delivery device of
5 FIG. 56 taken along lines 57-57 in FIG. 56.

FIG. 57A is an elevational view of the delivery device of FIG. 46 with the cassette inserted into the cassette slot.

FIG. 57B is an enlarged view in section of the delivery device of FIG. 57A taken along lines 57B-57B of FIG. 57A.

10 FIG. 57C is a bottom view of an advancing ribbon guide, and elongate element within the guide, of FIG. 58B without the structure surrounding the guide shown for clarity of illustration.

FIG. 57D is a transverse cross sectional view of the advancing ribbon guide of FIG. 57C taken along lines 57D-57D of FIG. 57C.

15 FIG. 57E is a transverse cross sectional view of the advancing ribbon guide of FIG. 57C taken along lines 57E-57E of FIG. 57C.

FIG. 58 is a perspective view of a vascular access port secured to chest muscle tissue by 4 surgical coils.

FIG. 59 is a perspective view of a delivery device configured to
20 deploy 8 surgical coils simultaneously with 8 delivery sheaths extended distally from the delivery device and extending toward an artificial heart valve.

FIG. 60 is a perspective view of the delivery device of FIG. 59 shown with distal ends of the 8 delivery sheaths engaged and
25 penetrating a surface of the heart valve.

FIG. 61 is a perspective view of the delivery device of FIG. 60 with the 8 surgical coils being deployed from the 8 delivery sheaths.

FIG. 62 is a perspective view of the artificial heart valve of FIG. 61 shown with the 8 surgical coils fully deployed.

FIG. 63 is a perspective view of a distal portion of a delivery device configured to deploy 2 surgical coils simultaneously in order to close a cut or incision in soft tissue.

FIG. 63A illustrates an elevational view in section of the delivery device of FIG. 63 with the delivery sheaths retracted within an outer sheath.

FIG. 64 is a perspective view of the distal portion of the delivery device of FIG. 63 shown with an outer sheath of the delivery device retracted proximally in order to allow distal ends of the delivery sheaths to be exposed and expand in a radial direction prior to engagement of tissue.

FIG. 64A illustrates an elevational view in section of the delivery device of FIG. 63 with the delivery sheaths extended from the outer sheath with the delivery sheaths expanded in an outward radial direction.

FIG. 65 is a diagrammatic view in perspective of the delivery device of FIG. 64 with the exposed delivery sheaths engaging the surface of tissue adjacent an open incision.

FIG. 66 shows the delivery device of FIG. 65 with the distal ends of the delivery sheaths penetrating the tissue adjacent the incision with the outer sheath advanced slightly distally in order to decrease the radial gap between the distal ends of the delivery sheaths and close the incision in the tissue.

FIG. 67 shows the delivery device of FIG. 66 with 2 surgical coils fully deployed from the distal ends of the delivery sheaths into the tissue across the incision.

FIG. 68 shows the two deployed surgical coils of FIG. 67 across the incision of the tissue with the delivery device removed.

FIG. 69 is a perspective view of a distal portion of a balloon delivery device which is configured to deploy multiple surgical coils to the wall of a passageway from within the passageway.

FIG. 70 is a diagrammatic view in perspective of the delivery device of FIG. 69 disposed within a passageway of an AAA stent.

FIG. 71 is a perspective view of the distal portion of the delivery device of FIG. 69 shown with an expansion balloon of the distal end of the delivery device in an expanded state forcing distal ends of multiple delivery sheaths to expand in an outward radial direction.

FIG. 72 is an enlarged view in perspective of the encircled portion 72 in FIG. 71 showing the distal end of the delivery device.

FIG. 73 is a diagrammatic view in perspective of the distal end of the delivery device shown in FIG. 72 in an expanded state within the passageway of the AAA stent with the distal ends of the delivery sheath pressed in an outward radial direction against an inside wall of the AAA stent.

FIG. 74 shows the delivery device of FIG. 73 with the surgical coils deployed from the delivery device through a proximal end of the AAA stent with the aorta adjacent the delivery device not shown for purposes of illustration.

FIG. 75 shows a perspective view of the AAA stent within an aorta of a patient with the surgical coils of FIG. 74 deployed through the proximal end of the AAA stent and the adjacent tissue of the aorta so as to secure the proximal end of the AAA stent to the aortic wall.

FIG. 76 is a diagrammatic view in perspective of a distal portion of a delivery device configured to deploy 8 surgical coils simultaneously

along and across an open incision or cut in tissue adjacent a tissue portion having an open cut.

FIG. 77 shows the delivery device of FIG. 76 with distal ends of delivery cannulae of the delivery device engaging and penetrating tissue adjacent the open cut with surgical coils being deployed while pressure is being applied to the tissue to close the cut.

FIG. 78 shows the 8 surgical coils of FIG. 77 deployed in the tissue across the cut securing the cut in a closed configuration.

FIG. 79 is a perspective view of a delivery device that is configured to deploy a surgical coil with a suture attachment.

FIG. 80 is a perspective view of the delivery device of FIG. 79.

FIG. 81 is a transverse cross sectional view of the delivery device of FIG. 79 taken along lines 81-81 of FIG. 79.

FIG. 82 is an enlarged view in perspective of encircled portion 82 shown in FIG. 80.

FIG. 83 is an enlarged view in perspective of the encircled portion 83 shown in FIG. 80 illustrating more detail of a distal end of the delivery device.

FIG. 84 is a bottom view in partial section taken along lines 84-84 of FIG. 79.

FIG. 85 is a perspective view of the delivery device of FIG. 79 with an outer sheath of the delivery device retracted proximally to expose suture alignment tubes at the distal end of the delivery device.

FIG. 86 is an enlarged view in perspective of encircled portion 86 of FIG. 85 showing more detail of the distal end of the delivery device with the suture alignment tubes exposed.

FIG. 87 is a perspective view of the delivery device illustrating a surgical coil being deployed from the distal end of a delivery sheath of the delivery device.

FIG. 88 is an enlarged view in perspective of the encircled portion
5 88 of FIG. 87 illustrating more detail of the surgical coil being deployed about a portion of the suture line and tissue (not shown) simultaneously.

FIG. 89 is a perspective view of a surgical coil deployed about a portion of a suture line within tissue (not shown) with the delivery device retracted.

10 FIG. 90 is an enlarged view in perspective of a distal portion of an alternative embodiment of a delivery device similar to the delivery device of FIG. 79 but wherein the suture alignment tubes and suture are replaced by a single leg attachment line having a fixed loop disposed adjacent a distal end of the delivery sheath with a surgical coil being
15 deployed through the fixed loop.

FIG. 91 is a perspective view of the surgical coil and single leg attachment line of FIG. 90 with the surgical coil deployed in tissue (not shown) through the fixed loop of the single leg attachment line.

20 FIG. 92 is an elevational view of a portion of bone tissue of a patient.

FIG. 93 is a transverse cross sectional view of the bone tissue of FIG. 92 taken along lines 93-93 of FIG. 92 illustrating first and second surgical coils deployed at two different sites on the bone tissue portion with attachment members extending from the bone tissue.

25 FIG. 94 is an enlarged view of encircled portion 94 of FIG. 93 illustrating the first surgical coil deployed within a cavity of the bone tissue.

FIG. 94A is an enlarged view of a delivery device deploying a surgical coil about a suture attachment member within a cavity of bone tissue.

FIG. 95 is an enlarged view of encircled portion 95 of FIG. 93 illustrating the second surgical coil deployed within a cavity of the bone tissue.

FIG. 96 is a perspective view of a distal portion of a deployment shaft assembly of a delivery device with an attachment member separated distally from the deployment shaft assembly.

FIG. 97 is a perspective view of the distal portion of the delivery shaft assembly of FIG. 96 with a retainer spring of the attachment member engaged within a proximal slot of the outer sheath.

FIG. 98 is a perspective view of the distal portion of the delivery shaft assembly of FIG. 97 (with the outer sheath not shown) illustrating a proximal stop secured to the delivery sheath.

FIG. 99 is perspective view of the distal portion of the deployment shaft assembly of FIG. 97 with the retainer spring engaged in a distal slot of the outer sheath and with a surgical coil being deployed from a distal end of the delivery sheath through a distal loop of the attachment member.

FIG. 100 illustrates a distal portion of the deployment shaft assembly of FIG. 99 with the assembly retracted proximally from the attachment member such that the retainer spring is no longer engaged with the distal slot.

FIG. 101 shows the surgical coil deployed about target tissue (not shown) and deployed about and encircling a distal loop of the attachment member.

FIG. 102 is a perspective view of a distal portion of a deployment shaft assembly configured for delivery of a plurality of surgical coils.

FIGS. 103 and 104 are perspective views of the deployment shaft assembly of FIG. 102 with an outer sheath of the assembly retracted proximally with respect to the delivery sheath housing, allowing three flexing loop wires of the attachment to expand radially outward from a longitudinal axis of the deployment shaft assembly.

FIG. 105 is a perspective view of the deployment shaft assembly of FIG. 104 with three surgical coils deployed about the respective flexing loop wires.

FIG. 106 is an end view of the deployment shaft assembly in a state of deployment shown in FIG. 102.

FIG. 107 is an end view of the deployment shaft assembly in a state of deployment shown in FIG. 105.

FIG. 108 is a perspective view of the attachment member wherein the three flexing loop wires are respectively secured to three surgical coils within tissue (not shown) and an attachment line is secured to and extending proximally from the attachment housing.

FIG. 109 is an enlarged view of the encircled portion 109 in FIG. 108.

FIG. 110 is a top view of a deployment device having a deflecting delivery sheath in a deployment shaft assembly.

FIG. 111 is an elevational view in partial section of the delivery system of FIG. 110 taken along lines 111-111 of FIG. 110.

FIG. 112 is an enlarged view in partial section of the encircled portion 112 of FIG. 111 illustrating a finger grip, pin and slot arrangement of the delivery device.

FIG. 113 is an elevational view of the delivery device of FIG. 110.

FIG. 114 is a perspective view of the delivery device of FIG. 113 wherein the sliding finger grip is positioned distally and a distal end portion of a deflecting delivery sheath is extending from a distal end of the deployment shaft assembly with a distal port of the deflecting delivery sheath being directed radially away from a longitudinal axis of the deployment shaft assembly and being radially displaced from same.

FIG. 115 is an enlarged view of the encircled portion 115 of FIG. 114.

FIG. 116 is a perspective view of the delivery device of FIG. 114 wherein a thumb ring is in an advanced distal position and a surgical coil is being deployed from a distal end of the deflecting delivery sheath.

FIG. 117 is an enlarged view of encircled portion 117 of FIG. 116 illustrating a surgical coil being deployed from a distal end of the deflecting delivery sheath.

FIG. 118 is a perspective view of the delivery device with the thumb ring fully advanced distally.

FIG. 119 is an enlarged view of encircled portion 119 illustrating a surgical coil being deployed from a distal end of the deflecting delivery sheath.

FIG. 120 is a perspective view of the delivery device with the thumb ring retracted proximally after deployment of the surgical coil as show in FIG. 118.

FIG. 121 is an enlarged view of encircled portion 121 of FIG. 120 illustrating the surgical coil fully deployed in adjacent tissue (not shown).

FIG. 122 is a schematic view in partial section of tissue with a distal portion of a mammatome biopsy device disposed within a lesion of the tissue with a distal portion of a delivery sheath extending radially from

a lateral aperture in the mammatome and a surgical marking coil being deployed from the distal portion of the delivery sheath into the lesion.

FIG. 123 is a perspective view of a distal portion of a mammatome biopsy device with a lateral aperture with a distal portion of a delivery
5 sheath extending radially from the lateral aperture in the mammatome and a surgical marking coil being deployed from the distal portion of the delivery sheath into the lesion.

FIG. 124 is a perspective view of a deployment pattern for surgical coil markers illustrating a plurality of surgical coil markers deployed at a
10 distal extremity and several radially extended positions which can serve to define the boundaries of a suspect tissue mass for imaging by medical imaging methods.

FIG. 125 is an elevational view of the deployment pattern for surgical coil markers of FIG. 124 illustrating a plurality of surgical coil
15 markers deployed at a distal extremity, proximal extremity and radially extended positions which can serve to define the boundaries of a suspect tissue mass for imaging by medical imaging methods.

FIG. 126 is a top view of an embodiment of a surgical coil shape forming jig.

20 FIG. 127 is a transverse cross sectional view of the shape forming jig of FIG. 126 taken along lines 127-127 of FIG. 126.

FIG. 128 is top view of the shape forming jig of FIG. 126 with a portion of metallic ribbon material inserted into the jig.

FIG. 129 is a transverse cross sectional view of the jig and metallic
25 ribbon material of FIG. 128 taken along lines 128-128 of FIG. 127.

FIG. 130 is a perspective view of the jig of FIG. 129 illustrating removal of the metallic ribbon material after shape setting of the ribbon material.

FIG. 131 is a perspective view of a punch and die configured to cut the shape formed metallic ribbon shown if FIG. 130, which is shown disposed within the die, to length and form a sharp distal tip and wedged proximal end of a surgical coil.

5 FIG. 132 is an elevational view in partial section of the punch and die shown if FIG. 130, with a non-shape formed portion of the metallic ribbon disposed within the die.

10 FIG. 133 is a perspective view of the punch and die of FIG. 131 with the punch partially inserted into the die adjacent the shape formed portion of the metallic ribbon material which has been pulled into the die to align the shape formed portion with the die cavities.

FIG. 135 is a bottom view of the punch and die of FIG. 134 with the shape formed portion of the metallic ribbon material aligned with the die cavities.

15

DETAILED DESCRIPTION

Embodiments of surgical coils are disclosed which can secure tissue along a significant length and do so with a minimal tendency to re-puncture the tissue being secured. Embodiments of the present device
20 also place surgical coils that complete a full circular path and can be used as sutures to attach tissue, implant devices and surgical support materials in addition to being made small in profile in order to make a wide range of non-invasive surgical procedures possible.

25 Suturing and suture line placement are necessary aspects of most surgical procedures. Embodiments of the current device provide devices and methods for placing sutures and suture lines in confined spaces. Suture anchors can be used to mount suture to bone for subsequent

attachment of ligaments, tendons, or other tissue. Some known suture anchors are inserted into pre-drilled holes in the bone, while others are "self-tapping" and are threaded into the bone through the bone surface. In either case, ridges, which extend outwardly from the exterior surface of the suture anchor facilitate retention of the anchor in the bone tissue.

Anchors of this type typically use up a large surface area relative to the size of the suture and so the number of anchors that can be used in any single location of placement is limited due to the confined surgical space at the site of installation. Another limitation of these known anchors is that they only can only be reliably used when the full length of the anchor is embedded in bone. Embodiments of the current invention provide devices and methods for reliable bone anchoring sutures that require minimal bone surface disruption space and skill to install and can also be reliably attached to thin cross sections of bone.

It is desirable and often necessary to perform procedures for detecting, sampling, and testing lesions and other abnormalities in the tissue of humans particularly in the diagnosis and treatment of patients with cancerous tumors, pre-malignant condition and other diseases or disorders. It can be of considerable benefit in many circumstances to be able to permanently mark the location or margins of such a lesion prior to or immediately after removing a sample of the tissue for testing. Marking tissue of a lesion prior to removal helps to ensure that the entire lesion is excised, if desired. Alternatively, a lesion is inadvertently removed in its entirety, marking the biopsy site immediately after the procedure would enable reestablishment of its location for future identification.

Known tissue marking devices and methods typically attach a micro-staple device to an internal wall of a cavity of a biopsy site, these types of staples, clips or open medical screws can be easily dislodged in

some circumstances, and, as such, can be unreliable in accurately defining a target site. In addition, they generally have sharp exposed points that can be a hazard to a surgeon who subsequently has to remove the marked area. A marker with sharp exposed points can
5 puncture or tear a surgical glove along with the surgeon's skin. As a result, both physician and patient are at risk of transmitted immunodeficiency virus or hepatitis, as well as other high risk contagions. Embodiments of the present invention provide reliable marking methods and markers with little or no exposed sharp points.

10 In addition, in some clinical settings identification and localization of a suspect mass is performed by a radiologist who, using current methods, places a localization wire or "Kopan's" wires into the breast of a patient to define and locate the tissue mass to be removed. A hollow needle, containing the localization wire, is inserted into the breast under
15 local anesthesia. The localization wire is inserted while the breast is under compression during the imaging procedure, until the distal end of the localization wire passes through the suspect mass. The localization wire is anchored distally beyond the mass by means such as a barb or hook at the distal end of the wire.

20 The needle is then removed from the body, leaving the wire in place and extending from the body as a marker for the surgeon. However, this type of known localization wire can move relative to the lesion when the breast is released from compression. Specifically, the distal end of the wire often migrates and thus shifts position with respect
25 to the targeted tissue mass. This may lead to inaccurate placement of the incision for the biopsy, with the result that either an excess of tissue outside of the target tissue mass is removed, or less than all of the target

tissue mass is removed. In addition, the wire is sometimes inadvertently severed, or pulled out during surgery.

In addition, there is frequently a day or two time delay between placement of the localization wire and surgical removal of the suspect
5 tissue mass so the patient may have to tolerate a localization wire protruding from the breast during this time period. Embodiments of the present invention provide devices and methods for reliable tissue anchoring that will not migrate from a target tissue mass, and can include a flexible attachment line for a surgeon to follow to the target lesion and
10 which can be left in place and not inconvenience a patient excessively while waiting for surgery.

FIG. 1 shows an embodiment of a surgical coil 10 deployed across a cut 12 in a portion of tissue 14 serving to hold the cut in the tissue portion closed. The surgical coil 10 is shown in more detail in the
15 perspective views of FIGS. 2 and 3, wherein an elongate element 16 having a ribbon-like configuration is coiled upon itself with a significant amount of overlap or circumferential overlap of adjacent portions of the elongate element 16. In some embodiments of the surgical coil 10, the overlapped portions of elongate element 16 are tightly coiled and in
20 contact with each other. A wedge shaped tissue penetrating distal tip 18 is configured on a distal end 20 of an elongate element 16 of the surgical coil 10. A wedge shaped recess 22 is formed into a proximal end 24 of the elongate element 16 of the surgical coil 10.

FIGS. 4 and 5 demonstrate circumferential overlap of coil
25 embodiments. FIG. 4 shows an embodiment of a surgical coil 26 having about 90 degrees of circumferential overlap. The circumferential overlap is delineated by the angle formed between a line 28 drawn from an axis 30 of the surgical coil 26 to a first end 32 of an elongate element 34, and

a line 36 drawn from the axis 30 to a second end 38 of the elongate element 34, inclusive of full rotational angles, i.e., 360 degrees for each full rotation of overlap of the elongate element 34 of the surgical coil 26. FIG. 5 illustrates a surgical coil 40 having about 360 degrees of circumferential overlap.

FIGS. 6 and 7 illustrate a surgical coil 42 having substantially no circumferential overlap wherein the proximal end 44 of an elongate element 46 of the surgical coil 42 directly engages a distal end 48 of the elongate element 46 of the surgical coil 42 in a smooth and continuous circular configuration. Such a configuration may be useful as a surgical coil marker where the surgical coil 42 is not likely to be subjected to high stress loads.

FIGS. 8-11 illustrate two additional embodiments of surgical coils. FIG. 8 is a side or elevational view of a surgical coil 50 having about 360 degrees of circumferential overlap. A transverse cross sectional view of the surgical coil 50 of FIG. 8 can be seen in FIG. 10 which shows a transverse cross section of the elongate element 52 of the surgical coil 50. As can be seen from both FIG. 8 and FIG. 10, a junction between overlapped adjacent portions of the elongate element 52 are in close contact, forming a tightly wound surgical coil 50. FIGS. 9 and 11 illustrate similar views of a surgical coil 56 having a circumferential overlap of about 700 degrees to about 740 degrees. FIGS. 8 and 10 illustrate surgical coil 50 having a circumferential overlap of about 360 degrees, however, similar and useful embodiments may have a circumferential overlap of at least about 300 degrees. Other surgical coil 50 embodiments may have a circumferential overlap of about 300 to about 420 degrees, more specifically, about 340 to about 380 degrees.

Still other embodiments of surgical coils 50 may have a circumferential overlap of about 350 degrees to about 750 degrees.

FIGS. 12-14 show three different embodiments of surgical coils having element axes forming differing angles with respect to an axis of the respective surgical coils. FIG. 15 illustrates a transverse cross sectional view of the surgical coil 58 of FIG. 12 with an element axis 60 that forms an angle of about 90 degrees with an axis 62 of the surgical coil 58. The element axis line 60 is formed by a line extending through a longitudinal axis 64 of the elongate element 66 of the surgical coil 58 on each side of the section shown in FIG. 15. In FIG. 15, such a line 60 is shown making an angle of about 90 degrees with the coil axis 62.

FIG. 16 illustrates a transverse cross sectional view of the surgical coil 68 of FIG. 13 with an element axis 70 that forms an angle of about 45 degrees with an axis 72 of the surgical coil 68. Such a surgical coil 68 has a somewhat conical configuration overall. FIG. 14 shows a surgical coil 74 embodiment wound similar to a tightly wound coil spring having an element axis that is substantially parallel to an axis (not shown) of the coil 74, or put another way, forming a zero angle with an axis of the coil. Such a coil would have a substantially cylindrical configuration.

FIGS. 17-19 illustrate various embodiments of elongate elements of surgical coils in a straightened configuration. FIG. 17 shows an elongate element 76 having a wedge shaped trocar-like tissue cutting distal tip 78 and a wedge shaped recess 80 at a proximal end 82. FIG. 18 shows an elongate element 84 having a plurality of axially consecutive longitudinal slots 86 cut into the elongate element 84. Such slots 86 can be formed into one surface 88 of the elongate element 84, or may extend completely through the elongate element 84. Such slots or cavities 86 may be used to hold image contrast materials such as radiopaque

materials or materials that can be readily imaged by ultrasonic imaging, MRI imaging or any other suitable imaging technique. The slots or cavities 86 could also be used to hold bioactive agents such as antibiotic agents, growth factors, anti-inflammatory agents and the like. The
5 cavities 86 can have configurations other than the slots 86 shown, which are merely illustrative. The cavities 86 and any material disposed within them may also be covered with a gas or liquid permeable membrane (not shown) which may be used to regulate the rate of delivery or elution of the agents.

10 FIG. 20 is a transverse cross sectional view of the elongate element 76 of FIG. 19. The elongate element 76 has a major transverse dimension 90 and a minor transverse dimension 92 and has a substantially oval configuration overall, but with a somewhat flattened top surface 94 and bottom surface 96. In some embodiments of elongate
15 elements 76, a length of the major transverse dimension 90 may be at least about 2 times a length of the minor transverse dimension 92, in other embodiments at least 3 times the length of the minor transverse dimension 92. In still other embodiments, the major transverse dimension of the elongate element 76 may have a length of about 2 to
20 about 8 times the length of the minor transverse dimension 92, specifically, about 3 to about 6 times the length of the minor transverse dimension 92. FIGS. 21-23 illustrate transverse cross sections of other embodiments of elongate elements. FIG. 21 shows a transverse cross section of an elongate element 98 having a substantially round cross
25 section, FIG. 22 illustrates an elongate element 100 with a substantially rectangular transverse cross section, and FIG. 23 illustrates a transverse cross section of an elongate element 102 similar to that of the elongate element 76 of FIG. 20, but with a longitudinal cavity or lumen 104

extending through the elongate element 102. The lumen 104 of elongate element 102 may be used as a cavity for image contrast materials or bioactive agents as discussed above and may have one or more openings (not shown) that may optionally be covered with permeable
5 membranes (not shown).

FIGS. 23A-23D illustrate two embodiments of surgical coils which have elongate elements that interlock when deployed. FIG. 23A shows a surgical coil 106 having approximately 360 degrees of circumferential overlap and a curved elongate element 108 with an interlocking cross
10 sectional configuration. FIG. 23B is a transverse cross sectional view of the surgical coil 106 of FIG. 23A which illustrates the curved elongate element 108. The elongate element 108 has a concave inner surface 110 which interlocks laterally with a convex outer surface 112 when the inner surface 110 and outer surface 112 are in a tightly coiled
15 configuration as shown in FIG. 23B. FIG. 23C illustrates an embodiment of a surgical coil 114 with an elongate element 116 having an interlocking configuration. FIG. 23D is a transverse cross sectional view of the surgical coil 114 of FIG. 23C which shows a raised ridge 118 extending longitudinally on a first surface 120 of the elongate element 116 which is
20 configured to mate and interlock with a groove 122 extending longitudinally along a second surface 124 of the elongate element 116. An interlocking engagement between the raised ridge 118 and groove 122 can be seen in FIG. 23D where two adjacent overlapped portions of the elongate element 116 are in contact with each other.

25 FIG. 24 shows an elongate element 126 partially deployed and formed into a surgical coil 130 about an axis 132 of the surgical coil 130. A proximal portion of the elongate element 128 is in a substantially straightened configuration as may be the case inside a delivery sheath of

a delivery system (not shown). In some embodiments, a series of elongate elements may be loaded into a delivery sheath which constrains the elongate elements 126 into a substantially straightened configuration for deployment.

5 Surgical coils 10 intended for placement in tissue can be fabricated with a distal point to facilitate tissue penetration when the coil 10 is ejected or deployed from the delivery device. After deployment, embodiments of the surgical coil 10 assume a self-forming coiled shape. In doing so the surgical coil 10 creates full circumferential path through
10 adjacent tissue that the coil 10 traps itself within. In a deployed configuration, both ends of an elongate element 16 of the surgical coil 10 can be in contact with each other in overlapped portions as shown in FIGS. 2 and 3. As such, movement of the surgical coil 10 is limited to rotation of the coil 10 about its own axis because the tissue captured
15 within the axis of the surgical coil prevents translation of the surgical coil 10 through tissue.

In some applications surgical coils 10 are required to support a pulling force from another component to which it has been secured. Such other components may be referred to as attachments throughout this
20 document. These attachments can include sutures and can be easily joined to the coil 10 as part of the surgical coil deployment process as discussed in more detail below.

Surgical coils 10 may be configured so that any pointed or sharp ends 18 do not protrude away from and are encased within the surgical
25 coil 10. Surgical coils 10 with this feature are shown generally in FIGS. 2, 14, 23A and 23C. This feature can help to protect medical staff from accidentally sticking themselves on sharp edges when palpating a tissue mass having a surgical coil 10 disposed therein during or after surgical

removal of the tissue mass. This feature also prevents the surgical coil 10 from opening up if it rotates by not allowing an end of an elongate element 16 of a surgical coil 10 to core another path and deviate from the original target site.

5 Surgical coils 10 can be made from a variety of materials including those that exhibit either great elasticity or shape memory properties. Suitable materials for fabrication include but are not limited to nickel titanium alloys (Nitinol), stainless steel, Elgiloy, MP35N or other high strength biocompatible materials. The cross section profile of the
10 elongate element 16 of the surgical coils 10 illustrated in the embodiments of FIGS. 1-22 may be oval or round but can be any other suitable shape.

 Various clinical applications or indications can require a specific surgical coil configuration. The number of rotations or amount of
15 circumferential overlap that the surgical coil 10 will have can be dependant on whether or not it has to support any load, such as a tensile load, from an attachment, and, if so, the amount of load the surgical coil 10 is required to support and the strength of tissue surrounding the surgical coil 10.

20 Surgical coils 10 can vary significantly in the various dimensions and configurations, depending on the intended use. One embodiment of a surgical coil has 50 an outside diameter 134, see Fig. 8, from about .060" to about .300", and a transverse dimension of about .002" to about .040". The number coil rotations for one embodiment can range from
25 about 1 to about 5, which corresponds to a circumferential overlap of about 0 to about 1,440 degrees. The circumferential overlap of surgical coil embodiments creates a complete circular structure that is enclosed and prevents attachments, such as sutures and marking devices from

pulling out or slipping out of the ring-like structure of the surgical coils. Surgical coils having no circumferential overlap could allow attachments to slip or pull through the joint between ends of the structure if a force is applied to the attachment. In addition, the size and strength of a surgical coil can be dependent on the type of tissue within which it is being
5 deployed. For example, in strong fibrous tissue, such as muscle or tendon, a small surgical coil can be used. However, for soft tissue deployment, a larger surgical coil which encompasses or encircles a larger amount of tissue may be necessary in order to adequately anchor
10 or fix the surgical coil in the tissue.

In some embodiments, it is desirable that the inside diameter 135 of the surgical coil 50 (see FIG. 8) be as small as possible. The smaller the inside diameter 135 for a given surgical coil 50, generally the higher the pull or tensile force it can withstand before opening up or otherwise
15 mechanically failing. In addition, pull force performance may be substantially increased by adding more revolutions of coiled material and increasing the overall coil thickness (stacking the coils). The surgical coil 56 configuration shown in FIG. 9 with an additional wind or 720° of circumferential overlap can have an increase in pull force performance of
20 approx 50% in comparison to the configuration of the surgical coil 50 shown in FIG. 8.

Many variations of surgical coil wind geometries are contemplated, as illustrated in FIGS. 12-14. In addition to variations in surgical coil wind geometries, embodiments are shown that add slots 86
25 to the surgical elongate element 84 as shown in FIG. 18 (the surgical coil is shown here flattened out to clearly show the slots) and or use a hollow structure, a cross section of which is illustrated in FIG. 23. These slotted or hollow features could be used as reservoirs for drugs and the surgical

coil used for site-specific drug delivery. The slots 86 shown in FIG. 18 may also make the device more visible with ultrasound imaging systems and the like. The surgical coil 10 embodiments of FIGS. 1-11 have a "V" groove at the proximal end of the surgical coils 10 which may be used
5 for embodiments of delivery methods.

Surgical coils 10 may be used as tissue markers with a small dimensional configuration. One embodiment of a surgical coil marker 42 can have an outer diameter of about .060" to about .100". In addition, if a surgical 42 coil is to be used as a marker and will not be subjected to
10 significant stresses, the surgical coil marker can have a low number of coil rotations or small to non-existent amount of circumferential overlap. Surgical coil markers 42 used to identify specific target areas within tissue are generally not required to carry any load and need only to be large enough to be detected by suitable medical imaging devices.
15 Surgical coils 10 used as soft tissue or bone anchors may be larger than surgical coil markers, with some embodiments having an outer diameter of about .100" to about .300". Such surgical coils can have 2 or more coil rotations, i.e., 360 degrees or more of circumferential overlap, and can be attached to a second component or attachment member if desired.
20 Such a surgical coil anchor may be used to anchor itself at a specific target tissue area and support the joined attachment.

Surgical coils 10 used for suturing and stapling applications may have a wide range of dimensions and configurations. Such embodiments may have to keep a wound closed so circumferential overlap is required
25 to support the load between two sections of tissue being held together. The outer diameter of some embodiments can be from about 0.06 inch to about 0.30 inch. Circumferential overlap of at least about 90 degrees may be suitable for these applications. A surgical coil 10 for these

indications may perform both the function of suturing and stapling, and so, can be considered a hybrid device. Metallic suture materials are often desirable in applications where a permanent suture is required because they generally produce low tissue reactivity. However, metallic sutures
5 are rarely used due to difficulty in tying reliable knots and cutting the metallic material. A surgical coil 10 used for suturing eliminates the need to tie a knot or cut the material and provides full circular fixation of tissue within the surgical coil.

FIGS. 25-45 illustrate an embodiment of a delivery device 138 and
10 methods of using the delivery device 138 for deployment of surgical coils 140. FIG. 25 is a perspective view of an embodiment of a delivery device 138 having an elongate delivery sheath 142 with a proximal end 144 a distal end and a delivery actuator 148 secured to the proximal end 144 of the delivery sheath 142. As shown in FIG. 34A, an embodiment of the
15 delivery sheath can have a sharpened distal end with an angle indicated by arrow 143, of about 15 to about 30 degrees. The delivery sheath is an elongate hollow tube having a sharpened distal tip 150 shown in FIG. 27. The delivery sheath 142 has an interior lumen 152, shown in FIG. 34, which is configured to constrain an elongate element 154 of a surgical
20 coil 140 and allow the constrained elongate element 154 to be advanced through the lumen 152 of the delivery sheath 142 to a deployment site. For the configuration shown, the delivery sheath 142 can be made from any suitable high strength metal, composite or polymer.

Suitable metals include stainless steel, Nitinol, MP35N and the like.
25 The delivery actuator 148 has an elongate cylindrically shaped body portion 156 with a proximal flange 158 and a distal flange 160. The body portion 156 has an internal bore 162 that is sized to accept a cylindrical actuator 164 in sliding relation to the body portion 156. A thumb ring 166

is disposed at a proximal end 168 of the cylindrical actuator 164 to facilitate the grip of an operator of the delivery device 138. The body portion 156 and cylindrical actuator 164 can be made from a variety of suitable medical grade materials, including metals, composites and
5 polymers. Specifically, polymers such as ABS plastic, PVC, polycarbonate and the like may be used.

Referring to FIG. 33, a limit pin 170 is secured to the body portion 156 and slidingly engages a slot 172 in the cylindrical actuator 164 that is configured to limit the relative travel between the cylindrical actuator 164
10 and the body portion 156. An advancing ribbon 174 is coiled in a compartment 176 adjacent the thumb ring 166 and has a distal end 178 which extends into a proximal end 180 of the delivery sheath 142 and contacts a proximal end 182 of an elongate element 184 disposed in the delivery sheath 142 ready for deployment, as shown in FIG. 40.

15 Referring to FIGS. 32 and 35, a first or distal ratchet member 186 having a bias member, such as spring 188, is fixed relative to the body portion 156 with regard to relative axial movement and is configured to translate in a radial direction under force of the spring 188 in order for the first ratchet member 186 to releasably engage the advancing ribbon 174 and
20 prevent proximal translation of the advancing ribbon 174. The advancing ribbon 174 has a series of notches 190 which are configured to releasably engage the first ratchet member 186. A second ratchet member 192 having a bias member, such as spring 194, is disposed on the cylindrical actuator 164 proximally of the first ratchet member 186.

25 The second ratchet member 192 is configured to engage the advancing ribbon 174 similarly to the first ratchet member 186 and moves axially with the cylindrical actuator 165 while the slot 196 within which the second ratchet member 192 is disposed allows radial motion.

When the cylindrical actuator 164 is advanced distally, the second ratchet member 192 engages one of the notches 190 in the advancing ribbon 174 and translates the advancing ribbon 174 forward in a distal direction until the limit pin 170 engages a proximal end 198 of the limit slot 172 of the cylindrical actuator 164. At this point, the first ratchet member 186 engages another notch 190 in the advancing ribbon 174 and prevents proximal translation of the advancing ribbon 174. Referring to FIG. 40, during the distal advancement of the advancing ribbon 174, the distal end 178 of the advancing ribbon 174 pushes against a proximal end 182 of the proximal most elongate element 184 loaded within the lumen 152 of the delivery sheath 142 and advances the proximal most elongate element 184 which then translates the distal motion to a distal most elongate element 200. The distal translation movement deploys the distal most elongate element 200 during the advancement cycle as shown in FIGS. 42-44. Thereafter, the cylindrical actuator 164 can then be proximally retracted and the delivery device 138 is then ready to begin another surgical coil deployment cycle.

For the delivery device 138, a feature to enable elongate elements 184 to be deployed that may be important is the ability of elongate elements 184 to push against each other axially without compromising the sharp distal tip of the elongate element 184 pushing on an elongate element ahead of it. In FIG. 39, a first elongate 202 element has a distal tip 204 engaged with a proximal end 206 of a second elongate element 208. In the embodiments shown, a wedge shaped recess 210 of the second elongate element 208 has a wedge recess angle that is less than a wedge angle of the sharpened distal tip 204 of the first elongate element 202. Such a configuration serves to protect the sharpened distal tip 204 of the first elongate element 202 from being dulled due to contact

with the proximal end 206 of the second elongate element 208. The amount of force to move an elongate element through a delivery sheath can be significant because of the frictional force generated by the elongate element pushing against the constraining force of the delivery
5 sheath.

A surgical coil 140 being deployed from a distal end 146 of the delivery sheath 142 as shown in FIGS. 42-44 can be a self-forming member, wherein the elongate element 154 returns to a coiled configuration, that is the configuration in a relaxed state, as the elongate
10 element 154 exits the distal end 146 of the delivery sheath 142 and the constraint of the delivery sheath 142 is removed. Alternatively, the distal end 146 of the delivery sheath 142 may include, or be disposed adjacent, a coil forming member 212 which strains an elongate element into a coiled configuration as it is deployed through the delivery sheath 142, as
15 can be seen in FIGS. 41B-41C. In this embodiment, an elongate element 214 has a substantially straight or non-coiled configuration in a relaxed state without any constraints thereon. As the elongate element 214 is pushed out of the delivery sheath 216, it passes through or by a coil forming member 212 which permanently strains the material of the
20 elongate element 214 which then assumes a coiled configuration outside the delivery sheath 216 as shown in FIG. 41C. For the embodiment of FIGS. 41-41C, the coil forming member 212 is a bent portion of a distal section 218 of the delivery sheath 216, however, any other suitable arrangement could be used. The coil forming member 212 can also
25 serve to add directional capability that is suitable for directing the deployment direction of a surgical coil having a transverse cross sectional configuration which is substantially round.

FIG. 45 illustrates a variety of deployment methods and configurations that could be used with the delivery device 138 and similar devices discussed herein. The delivery device 138 has the capability to serially deliver a plurality of surgical coils in a variety of configurations with respect to a tissue surface. A surgical coil 220 is shown deployed in an inner surface 222 of a patient's chest cavity 224 with a portion of the surgical coil 220 exposed. The surgical coil 220 has been delivered by a delivery sheath 226 introduced through a cannula member 228. Another surgical coil 230 is shown disposed beneath the inner surface 222 of the chest cavity 224 with no portion of the surgical coil 230 exposed. The surgical coil 230 having been deployed by a delivery sheath 226 having a sharpened tissue penetrating distal tip 232 which has penetrated an anterior wall 234 of the chest cavity 224 and been advanced into and beneath the inner surface 222 of a posterior wall 236 of the chest cavity 224. Finally, another surgical coil 238 has been deployed in the anterior wall 234 of the chest cavity 224 by inserting a sharpened delivery sheath 226 through the anterior chest wall portion 234 and deploying the surgical coil 238 from within the chest wall. A portion of the surgical coil is exposed above the inner surface 222 of the chest cavity 224.

Embodiments of delivery devices 138 and 240 shown in FIGS. 25 and 46 may use low profile delivery sheaths in the form of hollow needles with sharpened distal ends to deliver surgical coils to the target site. The delivery sheath 142 is a straight tube with a distal tissue penetrating point 150, as shown in FIG. 29, and is stiffer than a surgical coil 140 to be delivered therethrough. The geometry of the distal point of the delivery sheath 142 can be important in some embodiments. The distal point 150 needs to easily penetrate tissue while also providing clearance for the surgical coil 140 as it is being delivered without substantial

restriction to assume the relaxed geometry of the surgical coil 140. For some delivery sheath 142 embodiments, the distal point can have an angle of about 25 degrees. As seen in FIG. 34A and the discussion thereof, other angles can also be used. Delivery sheaths 142 may have
5 an internal profile that can slidably receive an elongate element 154 of surgical coils 140 along their full length, as shown in FIG. 34, and will straighten them out into a substantially straight configuration in doing so. Surgical coils 140 can be pre-loaded into the delivery sheath 142 prior to use. The maximum number of surgical coils 140 that a delivery sheath
10 142 can accommodate is limited by its length, however, some applications may require only a single surgical coil 140 be used. In a delivery device 138 having a multiple coil 140 configuration, surgical coils 140 can be stacked end to end within the delivery sheath 142. A surgical coil 140 configuration to preserve a sharpness of a tissue penetrating
15 point of an elongate element 154 of a surgical coil 140 from damage by a proximal end of an adjacent elongate element of a surgical coil 140 is shown in FIGS. 38 and 39.

The delivery device 138 configuration shown in FIGS. 33-40 uses a ratchet system with a moving ratchet member 192 and a fixed spring
20 ratchet member 186. When the thumb ring 186 is moved distally the moving ratchet teeth (FIG. 35) grip in the notches 190 of the advancing ribbon and move it also. The fixed spring ratchet 186 at this time slides up and over the notches 190 of the advancing ribbon 174 (the wave profile spring compresses to facilitate this). When the thumb ring 166 is
25 returned to the proximal position the moving ratchet 192 slides over the advancing ribbon 174 while the fixed spring ratchet 186 stops any motion of the advancing ribbon 174. The distance of travel of the thumb ring 166 equals the length of a surgical coil 140 so that each time the thumb ring

166 is fully depressed a surgical coil 140 is ejected from the device 138. The advancing ribbon 174 has a profile that is slidably fits the sheath 142 and can be advanced the full length of the delivery sheath 142.

In one embodiment of use, the distal end 146 of the delivery
5 sheath 142 is placed at a target site, a thumb ring 166 of the cylindrical actuator 164 is then moved distally as shown in FIG. 26 which pushes an advancing ribbon 174 (see figs. 35 and 57) which in turn pushes the most proximal surgical coil 174 which then ejects the most distal surgical coil 200 a from the device 138 as shown in fig. 27. Drawings of two
10 configurations of this device 138 and 240 are provided. FIGS. 33-40 show a configuration that will eject or deploy only the number of surgical coils 140 that are pre-loaded into the delivery sheath 142. FIGS. 46-57 show a configuration that houses surgical coils 242 in a cassette 244 and therefore the number of coils 242 can be delivered is limited only by the
15 number of coils 242 the cassette 244 can accommodate.

There are varieties of techniques that can be employed with these low profile delivery devices 138 and 240 to access target sites. The delivery sheath 142 can be used in the same manner as a hypodermic needle is for drug delivery (direct incision). Alternatively they can be
20 placed within the working channel of an endoscope or cannula. All methods allow the physician to completely or partially implant a coil in tissue at an anterior or posterior location. Some illustrations of delivery techniques are shown in FIG. 45. Fully implanted coils 230 are typically used for tissue marking or site specific drug delivery with drug coated or
25 impregnated coils 220 and 238, partially implanted coils can be used to attach suture lines for procedures such as bladder neck suspension or to create a group of purse string sutures. Coils can be delivered so that they interlock in linear or radial patterns to create palpable masses or linked

as group for strong tissue anchor point. Embodiments can also be used to suture in place devices or components such as pacemakers, pacemaker leads, catheters or tissue supporting surgical materials such as Gore-Tex or hernia patch materials. An example of this use is
5 illustrated in FIG. 58.

The delivery device 240 configuration shown in FIGS. 46-57 uses a surgical coil cassette 244 to store a plurality of elongate elements 246 of surgical coils 242. The surgical coil cassette 244 fits into a slot 248 in the delivery actuator 250, as shown in FIG. 47. An advancing ribbon 252 is
10 slidingly disposed within an advancing ribbon guide 275. An advancing shuttle 273 is coupled to a cylindrical actuator 254 with the thumb ring 256 and moves in direct relationship with it. The cassette 244 has multiple slots 258 that accommodate surgical coils 242. The coils 242 are positioned so that the distal end 260 and proximal ends 262 extend into
15 the side grooves 264 of the cassette 244 as shown in FIGS. 54, 55, and 57. Springs 266 shown in Fig. 46, surround spring posts 267 and are in compression and bias the cassette 244 away from the delivery actuator 250, in doing so the ends of the surgical coil 242 are forced to contact the stops 268, as shown in Fig. 57, and in alignment with the lumen of the
20 delivery sheath 270 and advancing ribbon 252. When the thumb ring 256 is moved distally, the cylindrical actuator 254 is advanced distally which in turn advances an advancing shuttle 273. The axial motion of the cylindrical actuator 254 is limited by a limit pin 271 which is secured to the delivery actuator and engages a slot 271A in the cylindrical
25 actuator. The advancing shuttle, the axial movement of which is shown by arrow 277, engages a slot or slots in the advancing ribbon 252, as shown in FIGS. 57C-57D, and pushes a surgical coil 272 out of the cassette 244 and into the delivery sheath 270. When the thumb rings 256

is returned to the proximal position and the advancing ribbon 252 has been pulled out of the cassette 244 another surgical coil will be brought into contact with the stops 268. This procedure is repeated until the first coil 242 that was pushed out of the cassette 244 is aligned with the distal tip 274 of the delivery sheath 270. The device 240 can then be used to deliver surgical coils 242 to the target site and each full depression of the thumb ring 256 will eject a surgical coil 242.

The drawings shown illustrate an oval cross section of the surgical coils 242 and delivery sheath 270 however, surgical coils 242 made from materials with a round cross-sections that are deployed via a round cross-sections delivery needles can also be used. Surgical coils 242 having a circular cross-section have the disadvantage in that they are not self aligning, however an alignment feature can be provided to ensure that as the surgical coil it is deployed from the delivery sheath 270, it is correctly orientated. If a self- coring tip (also known as hubber tip as shown in Fig. 41) or slots 276 are provided longitudinally along the axis at the distal end of the delivery sheath the coil when it contacts this alignment feature 276 will take the path of least resistance and orient itself.

Delivery devices can be configured to deliver a plurality of surgical coils 10 simultaneously and in a variety of deployment patterns or configurations. Examples can include radial, linear, radial interlocking, linear interlocking, back to back in the same delivery tube, i.e., 2 surgical coils deployed together in opposite directions or back to front in the same delivery sheath, i.e., 2 coils deployed together in the same direction.

In one modality of deployment, FIG. 58 shows a vascular access port 278 secured to a portion of chest muscle 280 by four deployed surgical coils 282. Figs. 59-62 show the distal end 284 of a delivery

device 286 that has 8 delivery sheaths 288 that deploy 8 surgical coils 290 simultaneously to suture an artificial heart valve 292 to the annulus of the atrium 294. The method of use may follow the sequence of the figures, wherein, in FIG. 60 the delivery device 286 is positioned with the delivery sheaths 288 disposed within tissue 294 adjacent the heart valve 292. In FIG. 61, the surgical coils 290 are being deployed from the distal ports (not shown) of the 8 delivery sheaths 288. In FIG. 62, the delivery device has been proximally retracted, and the heart valve 292 secured to the heart tissue 294 by the surgical coils 290.

FIGS. 63-68 show another embodiment of a delivery device 296 and method where the distal end 298 of the delivery device 296 can deploy two surgical coils 300 simultaneously from opposing sides of a tissue cut 302 and can be used as a stapling or suturing device for the closure of tissue incisions or cuts. The method of use can follow the sequence of FIGS. 65-68. FIG. 63 shows a distal portion 304 of a deployment shaft assembly 306 wherein the distal ends of a first delivery sheath 312 and a second delivery sheath 314 are disposed within and radially constrained by an outer sheath 316. FIG. 64 shows the deployment shaft assembly 306 with the outer sheath 316 proximally retracted and the distal ends 308 and 310 of the delivery sheaths 312 and 314 in a radially expanded and relaxed state.

The deployment shaft assembly 306 is then advanced towards target tissue, such as tissue which has a cut therein. The sharpened distal tips 308 and 310 of the first and second delivery sheaths 312 and 314 are then forced into tissue on opposite sides of the cut and the outer sheath 316 then advanced distally. This motion of the outer sheath 316 reasserts the radial constraint on the distal ends 308 and 310 of the delivery sheaths 312 and 314 and pulls both the distal ends 308 and 310

of the delivery sheaths 312 and 314 and the tissue on opposite sides of the cut closer together as shown in FIG. 66. A first surgical coil 300 and a second surgical coil 301 are then deployed from first and second distal ports 318 and 320 of the delivery sheaths 312 and 314 into the tissue as shown in FIG. 67, with the cut in the tissue being permanently closed at the end of the procedure as shown in FIG. 68. The delivery device 296 has a low profile that facilitates placement through an endoscope, cannula or a confined space. A portion of the coils 300 and 301 are shown exposed on the external surface of the tissue, however, the coils 300 and 301 can be placed deeper and remain completely implanted in the tissue.

FIGS. 69-75 show another embodiment of a delivery device where a distal end of the delivery device can deploy a radial pattern of surgical coils that are not on a specific or fixed radius. The delivery device 322 is a low profile catheter that can be readily passed through a natural body track or channel, e.g., artery, vein, GI tract, urethra etc. A distal portion 324 of the delivery device 322 is configured to be expanded as necessary for a given indication. An expansion member 326, such as an expandable balloon can be used to expand a distal portion of the delivery sheaths 328 of the delivery device 322. A balloon expansion method is shown which allows the delivery device to accommodate anatomical and device size variations.

FIGS. 69-75 show how the delivery device 322 may be used to attach the leg of a stent or stent-graft 330 that may be used to treat an abdominal aortic aneurysm (AAA). The method of use may follow the sequence of the figures. This delivery device 322 is not, however, limited to the AAA application only. For example, the delivery device 322 could also be used to attach vascular grafts to artery walls or place a radial

pattern of coils in the GI tract of a patient that could subsequently be used to make a purse string suture prior to cutting away a portion of the patient's colon.

In FIG. 70, the delivery device 322 is shown being advanced into a
5 AAA stent 330 over a guidewire 332. The balloon at the distal end 334 of the delivery device 322, which is disposed within the circumferential configuration of delivery sheaths 328, is then expanded which forces the distal ends of the delivery sheaths 328 against an inside surface 336 of the AAA stent 330 as shown in FIGS. 71, 72 and 73. The AAA stent can
10 be positioned within a patient's artery or other vessel either before or after the balloon 326 is expanded. Once positioned, surgical coils 338 are deployed from distal ports 340 of the delivery sheaths 328 as shown in FIG. 74 and the surgical coils 338 then penetrate the material of the AAA stent 330 and the adjacent tissue of the body vessel 342 as shown
15 in FIG. 75. The surgical coils 338 deployed may penetrate the wall of the vessel 342 completely, or may be embedded in the wall of the vessel 342 and not break an outside surface 343 of the vessel 342.

FIGS. 76-78 show another embodiment of a delivery device 344 where a distal end of delivery device 344 can deploy a linear pattern of
20 surgical coils 348 simultaneously from opposing directions and may be used as a stapling or suturing device for the closure of tissue incisions or cuts. The method of use for the delivery device 344 may follow the sequence of the FIGS. 76-78. The delivery device 344 could be used for rapid closure of cuts or wounds. FIGS. 76-78 show a portion of the
25 surgical coils 348 exposed on an external surface 350 of the tissue, however, the surgical coils 348 can also be placed deeper in the tissue 352 and remain completely implanted beneath a surface of the tissue 352. In FIG. 76 a delivery sheath housing 354 securing 8 delivery

sheaths 356 in fixed relation is disposed adjacent a portion of tissue 352 having a cut in the surface thereof. FIG. 77 shows the sharpened distal tips 358 of the delivery sheaths 356 penetrating the tissue 352 with the surgical coils 348 being deployed from distal ports 360 of the delivery sheaths 356. FIG. 78 shows the cut in the tissue 352 secured in a closed position by the 8 surgical coils 348. Note that the configuration of the delivery sheath housing 354 could include an arrangement similar to that of FIG. 63 with an outer sheath 316 that could be activated to squeeze the cut of the tissue 352 closed by advancing same over radially expanded distal portions of the delivery sheaths 356. One alternative of this method is to use manual closure of the wound or cut 352 during deployment of the surgical coils 348.

Embodiments of devices and methods are also contemplated for attaching items to surgical coils in conjunction with a the coil deployment process. Some of the items that can be attached to a surgical coil during deployment include, but are not limited to, suture lines, anchor lines, electrical leads & catheters. These attachments can be attached at the surface of tissue or implanted in tissue at any depth when the coils are placed or deployed as shown in FIG. 45.

FIGS. 79-91 show devices for and methods of making an attachment to a variety of tissue types by use of a surgical coil as an anchor member. The delivery device 362 shown in FIGS. 79-109 can have features similar or identical to features of the delivery device 138 shown in FIGS. 25-41C. The delivery device 362 shown in FIG. 79 has a deployment shaft assembly 364, a delivery actuator housing 366, a delivery sheath actuator 368 slidably engaged with the delivery actuator housing 366 and a cylindrical actuator 370 slidably engaged with the delivery sheath actuator 368. Such a delivery device 362 may be used

for deployment of a surgical coil attachment 372, where the attachment 372 (for example, a length of flexible suture) may be enclosed within alignment tubes 374 disposed within an outer sheath 376 of the deployment shaft assembly 364. The suture 372 can be fed through a
5 side port 378 of the delivery actuator housing 364 of the delivery device 362 as shown in FIG. 80. The side port 378 feeds into a deployment shaft assembly 364 where it may be placed alongside a surgical coil delivery sheath 380 within an outer sheath 376 of a deployment shaft assembly 364.

10 FIG. 82 illustrates a stop 382 which is used to control a distal position of distal ends 384 of the alignment tubes 374, which in turn determines the distal position of an attachment loop 386 of the suture 372, relative to a distal port 388 of the surgical coil delivery sheath 380 (see FIG. 83). A distal portion of the alignment tubes 374 may have a
15 pre-bend or other bias towards an outward radial direction and upward direction that is constrained by an inside surface 390 of the outer sheath 376. The bias of the alignment tubes may be configured to position the attachment loop 386 at or near the center of a surgical coil being deployed from the delivery sheath. The deployment shaft assembly 364
20 may be advanced to a target site while the components at a distal end of the deployment shaft assembly 364 of the delivery device 362 are positioned as shown in FIG. 83. The target site may be accessed by a variety of methods, such as those shown in FIG. 45, as well as others. A sharpened distal tip 394 of the outer sheath 376 of the deployment shaft
25 assembly 364 may be used to penetrate soft tissue in order to access the target site.

When the target site has been accessed, the outer sheath 376 is moved proximally as shown in FIG. 85 and the distal ends 384 of the

alignment tubes 374 are then exposed and released from a constrained state. An incision that the outer sheath 376 made prior to being moved proximally allows the alignment tubes 374 to spread as shown in FIG. 86. An elongate element 396 of a surgical coil 398 is then deployed from a distal port 388 of the delivery sheath 380 and captures the attachment loop 386 of the suture as shown in FIG. 88. The delivery device 362 can then be removed, and in doing so, the suture is allowed to pull out of the alignment tubes and is left attached to the surgical coil 398 as shown in Fig. 89. This method provides a means to place and anchor suture lines 372 in tissue at difficult to access or confined places at any desired depth.

Figs. 90 and 91 show another embodiment of a delivery device 400 where a single leg attachment line 402 with a fixed attachment loop 404 at a distal end thereof, is attached by a similar method but without the need for the alignment tubes 374 of the delivery device 362 shown in FIGS. 79-89 above. The attachment loop 404 may be made of a stiff material (e.g. metals, such as stainless steel or high strength polymers or composites) which ensures that an opening is provided for a surgical coil 408 to pass through during deployment of the surgical coil 408 and thereby be captured. When the delivery device 400 is proximally retracted or removed, the attachment line 402 is allowed to pull through the outer sheath 410 and remain attached to the surgical coil 408. A proximal portion 412 of the attachment 402 can be made of a variety of materials and have a variety of configurations e.g. stainless steel, flexible or stiff plastic, suture material, single or multi filament strand, and the like.

Referring to FIGS. 92-95, a surgical coil anchor 414 can be used in applications such as anchoring ligaments or tendons, when performing soft tissue surgical reconstruction, ruptured tendons, or torn ligaments,

and other indications in which a surgeon wants to reconstruct or repair connective tissue with respect to the bone tissue. In one embodiment, a surgical coil anchor 414 is placed through a pre-drilled pilot hole 416 disposed in bone tissue 418 of a patient, having a diameter much smaller than an outer diameter of the surgical coil anchor 414 as shown in FIGS. 92-95. The deployment shaft assembly 364 of the delivery device 362 is subsequently introduced into the pilot hole 416 and the surgical coil anchor 414 is deployed therein along with a suitable attachment member 372 into the bone 418. A ligament or tendon may then be sutured and anchored to the bone tissue 418 using the anchor attachment 414. The anchor attachment 414 can be a piece of suture, wire or the like.

A bone-drilling device (not shown) can be used that permits the drill to adjust its approach angle while maintaining the same entry point at the bone surface 420. Multiple passes of the drill can be made into the bone at the same entry point 418 at varying angles to produce a small round profile hole 416 at the surface 420 of the bone 418 tapering to an incrementally larger oval profile hole or cavity 422 beneath the surface 420 of the bone tissue 418 as seen in FIG. 93. The round entry hole 416 is made large enough to accept a distal end 392 of a delivery device 362 while part of the oval profile cavity 422 beneath the surface 420 of the bone tissue 418 is made large enough to accommodate a surgical coil anchor 414.

Alternatively a straight pilot hole 424 can be drilled through a thin section of bone tissue 418 and into the bone marrow 426 as shown in FIG. 94. Thereafter, the delivery device 362 can be introduced through the pilot hole 424 into the marrow 426 and the surgical coil anchor 414 deployed along with an attachment member 372 into the bone marrow 426.

Yet another embodiment of a delivery device installs an attachment member from a distal end of the delivery device as shown in FIGS. 96-101. This method allows shorter attachment members 428 to be used, which can optionally be dispensed from a cassette for sterility and convenience if required. The delivery device 362 used for the deployment shaft assembly 430 shown in FIGS. 96-101 can be the same or similar to the delivery device 362 discussed above and shown in FIGS. 79-91. An outer sheath 432 of the deployment shaft assembly 430 has a proximal slot 434 and a distal slot 436 which are configured to engage a retainer spring 438 of the attachment member 428. The attachment member 428 is relatively short in axial length and has an attachment loop 440 at the distal end.

The attachment member 442 is loaded into a distal port 444 of the outer sheath 432 until a proximal end of the attachment member 442 rests against a stop 448 which is fixed to an outside surface 450 of a delivery sheath 452 disposed within the outer sheath 432 at which point the retainer spring 438 also engages the proximal slot 434 in the outer sheath 432. The deployment shaft assembly 430 is then advanced to a target site, and the outer sheath 432 retracted relative to the attachment member 428 and delivery sheath 452 until the retainer spring 438 on the attachment member 428 engages the distal slot 436 of the outer sheath 432 as shown in FIG. 99. A surgical coil 454 is then deployed from a distal port 456 of the delivery sheath 452 through the attachment loop 440 of the attachment member 428 as shown in FIG. 99. The deployment shaft assembly 430 is thereafter retracted proximally leaving the attachment member 428 secured to the tissue at the target site or captured by bone tissue 418 if deployed in a cavity 422 formed in bone tissue 418, or the like as shown in FIGS. 100 and 101.

Referring to Figs. 102-109, another embodiment of a delivery device 458 uses an attachment member 460 that can be joined to multiple surgical coils 462 simultaneously. The delivery device 458 can be used to anchor an attachment member 460 to a target tissue site and
5 allow a surgeon to locate and excise a pathologically suspect tissue mass or other tissue of interest. The attachment member has three resilient attachment loops 459 disposed adjacent distal ports of three respective delivery sheaths 461. When the attachment loops 459 are constrained within an outer sheath 463, they assume a constrained first
10 outer diameter as illustrated in FIG. 106. When released from the constraint of the outer sheath 463, as shown in FIG. 107, the attachment loops then assume a relaxed state having a greater outer diameter, greater than an outer diameter of the outer sheath 463 in some embodiments. The attachment loops are then positioned at or near the
15 center of surgical coils 462 which can then be deployed from the delivery sheaths 461 as shown in FIG. 105 and 107. Once deployed, the surgical coils 462 will not migrate from the target site. This can be important for certain indications, specifically in breast biopsy procedures where the breast may be compressed during placement of the surgical coils 462.
20 This, movement of the surgical coils 462 is prevented when compression is released from at the breast at the completion of the imaging procedure, or if the attachment leg 464 is inadvertently shifted after the procedure. The attachment leg 464 that extends out of the patient's body can be flexible, making it more tolerable for a patient awaiting surgery.

25 FIGS. 110-125 show an embodiment of a deflecting delivery device 466. The delivery device 466 may have features that are the same as or similar to those of the delivery devices 138 and 362 discussed above. The method of deployment may follow the sequence in FIGS. 114-121.

The delivery device 466 is similar to the low profile single coil needle delivery devices 138 and 362 shown in FIGS. 25 and 46 with the addition of a surgical coil delivery sheath 468 having a preformed curve 470 at a distal end 472 thereof as shown in FIG. 115. The coil delivery sheath
5 468 can be made from materials that exhibit either great elasticity or shape memory properties. Suitable materials for fabrication of the coil delivery tube include, but are not limited to, nickel titanium alloys (Nitinol), stainless steel, elgiloy, and MP35N.

The delivery device 466 also has an additional outer sheath 474
10 that has a close sliding fit with the delivery sheath 468. This outer sheath 474 can be moved relative to the delivery sheath 468 by repositioning the finger grip 476 shown in FIGS. 110-113. When the finger grip 476 is in the proximal position the deflecting delivery sheath 468 will be completely covered and straightened by the outer sheath 474. In this position the
15 device 466 can be used in the same manner as the low profile single coil delivery devices 138 and 240. When the finger grip 476 is moved distally, however, the delivery sheath 468 exits a distal end of the outer sheath 474 and is allowed to assume its natural relaxed shape or configuration as shown in FIG. 115. Subsequently, the shape of the delivery sheath
20 468 will redirect the placement of any surgical coils 478 ejected or deployed relative to the centerline axis of the delivery device 466.

One clinical application that would benefit from this embodiment of the delivery device 466 is the marking of biopsy sites and tissue masses. One method of clinical use is illustrated in FIGS. 122 and 123. A
25 mammatome 480 is a device frequently used to biopsy breast abnormalities. Part of the procedure often entails placing one or more markers 478 in wall of a biopsy cavity 482. Previously used designs of these markers 478 frequently are dislodged from the placement site by

the cut out or lateral aperture 484 of the mammatome device 480. In order to prevent this, the deflecting delivery device 466 may place the markers 478 in the tissue 486 around the target tissue 482 of the biopsy site not within the target tissue. Thus, the marker or markers 478 will not
5 be dislodged during the biopsy procedure. This method provides assurance that the marker or markers 478 remain fixed after deployment.

Another method of deploying markers 478 is shown in FIGS. 124 and 125 where a delivery device 466 is placed in a pathologically suspect tissue mass 488. It is often desirable to be able to accurately mark the
10 location prior to surgery to ensure that the suspect mass 488 is totally excised. It has become common practice when dealing with breast cancer to remove not only the suspect mass 488 but also a 1cm margin surrounding the suspect mass 488. FIGS. 124 and 125 show the deflecting delivery device 466 being used to place surgical coils 478 at
15 this margin boundary 490. Using a single insertion entry site for the delivery device 466, multiple surgical coils 478 can be deployed within a lesion or target tissue 488. The delivery device 466 can be used with the delivery sheath 468 undeflected to mark the anterior and posterior boundary 490, by simply keeping the outer sheath 474 in a distal position
20 as shown in FIG. 113.

The deflecting delivery sheath 468 can then be advanced and a surgical coil 478 placed at both boundaries as shown in FIGS. 124 and 125. The deflection of the delivery sheath 468 is correctly sized in this embodiment to ensure that the surgical coil 478 is position 1cm off the
25 centerline 500 as shown in FIG. 125. After deployment of a surgical coil 478, the delivery sheath 468 is retracted, the delivery device 466 is rotated, once again the delivery sheath 468 is advanced and another surgical coil 478 deployed at a new location. This process is repeated as

many times as is necessary to correctly identify the perimeter 490 of the suspect target tissue mass 488. The maximum deflection angle shown in FIGS. 110-125 is approximately 90 degrees, however, the amount of deflection can be increased or decreased for this or other embodiments.

5 Referring to FIGS. 126-135, an embodiment of a method and tools for manufacturing surgical coils are illustrated. FIGS. 126-130 illustrate a shape forming jig 502 for shape setting a piece of ribbon material 504, such as metallic Nitinol ribbon material, into a coil configuration. The jig 502 has a cylindrical cavity 506 with an inside diameter that defines an
10 outside diameter of a coil produced by the jig 502. An access slot 508 communicates from the cylindrical cavity 506 to an outer wall 510 of the jig body 502. Both the cylindrical cavity 506 and the access slot 508 are open at a top surface 512 of the jig 502 to facilitate removal of the heat set ribbon 504, as shown in FIG. 130. A post member 514 is positioned
15 in the center of the cylindrical cavity 506 which is cylindrically shaped and together with the cylindrical cavity 506 of the jig 502 body forms a circular slot 516 in communication with the access slot 508.

 The access slot 508 meets the circular slot 516 in a tangential orientation which allows a piece of metallic ribbon 504 to be inserted from
20 outside the jig 502, through the access slot 508 and into the circular slot 516 as shown in FIG. 128. As the ribbon material enters the circular slot 504, it begins to follow the curvature of the cylindrical cavity 506 and is bounded radially by an inside surface 518 of the cylindrical cavity 506 and an outside surface 520 of the post member 514. The metallic ribbon
25 504 is forced into the circular slot 516 until a desired amount of circumferential overlap is formed in the coil configuration of the ribbon material 504. The entire jig 502 and metallic ribbon 504 may then be placed within a heat source so as to heat treat the Nitinol ribbon material

504 to take a set in the coiled configuration and assume the desired mechanical properties for a surgical coil 522.

In some embodiments of surgical coils 522, it is desired that the material of the surgical coil have superelastic properties. Heat treatment
5 parameters that can be used include subjecting the coiled ribbon material 504 in the jig 502 to a temperature of about 400 to about 500 degrees C for several minutes. More specifically, subjecting the ribbon material 504 to a temperature of about 480 to about 500 degrees C for about 1 to about 5 minutes. One embodiment of an alloy that can be used for this
10 process includes a Nitinol alloy having about 55.7 to about 55.9 composition by weight nickel, with the remainder or balance being tin. Another Nitinol alloy that is suitable includes an alloy having about 55.5 to about 55.7 composition by weight nickel, with the balance being tin. Such compositions may undergo cold working processes prior to the heat
15 treatment discussed above.

Once the metallic ribbon material 504 has been heat treated and removed from the jig 502, it can then be inserted into a constraint slot 524 of a punch 526 and die 528 as shown in FIGS. 131-135, which is configured to cut the shape-formed ribbon 504, or elongate element 530
20 to length and produce a proximal end 532 and distal end 534 having a desired configuration. FIG. 131 illustrates the metal punch member 526 and a metal die member 528 which can be manufactured from any appropriate material, such as tool steel or the like. The punch member 526 has a first punch element 536 and a second punch element 538.
25 The first punch element 536 is configured to cut the ribbon material 504 into a sharp wedge tipped configuration in order to form the sharp pointed, tissue penetrating wedge shaped distal tip 540 of an elongate element 530 as discussed above. The second punch element 538 is

configured to cut a wedge shaped "V" in the ribbon material 504 in order to produce the wedge shaped proximal end 542 of an elongate element 530, also as discussed above.

Once the punch 526 and die 528 has been activated and the
5 proximal and distal ends 532 and 534 respectively of a shape formed elongate element 530 are formed, the elongate element 530 can then be forced from the constraint slot 524 of the punch 526 and die 528 with another piece of ribbon 504 or the like. It may be desirable to load the newly formed elongate element 530 of a surgical coil directly into another
10 constraining device configured for storage or sterilization of the elongate element 530.

The apparatus and methods of the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. Embodiments can be combined to create other
15 embodiments for example combining the deflecting delivery system embodiment with the attachment embodiment to create a deflecting attachment coil delivery device. The described embodiments are to be considered in all respects only as illustrative and not restrictive. Accordingly, it is not intended that the invention be limited, except as by
20 the appended claims.

What is claimed is:

1. A medical fastener comprising:
an elongate element having a longitudinal axis;
5 the elongate element formed into an enclosed configuration
with an overlapped portion with the elongate element making
contact in the overlapped portion; and
the overlapped portion having a circumferential overlap of at
least 300 degrees.
- 10 2. The medical fastener of claim 1 wherein the longitudinal axis
of the elongate element lies substantially in a plane.
3. The medical fastener of claim 1 wherein the circumferential
overlap of the overlapped portion is about 300 to about 600 degrees.
4. The medical fastener of claim 1 wherein the enclosed
15 configuration of the elongate element is substantially circular.
5. The medical fastener of claim 1 wherein the enclosed
configuration of the elongate element is substantially elliptical.
6. The medical fastener of claim 1 wherein the elongate
element has a transverse cross section that is substantially rectangular.
- 20 7. The medical fastener of claim 1 wherein the elongate
element has a transverse cross section that is substantially elliptical.
8. The medical fastener of claim 1 wherein the elongate
element further comprises a distal end having a reduced transverse
dimension which is configured to engage a hollow portion of a proximal
25 end of another elongate element so as to eliminate or reduce relative
transverse movement between the proximal end and distal end when the
ends are engaged.

9. The medical fastener of claim 8 wherein the distal end of the elongate element comprises a sharpened chisel shaped configuration.

10. The medical fastener of claim 9 wherein the proximal end of the elongate element comprises a wedge shaped cut out configured to
5 engage the chisel shaped configuration of the the distal end.

11. The medical fastener of claim 8 wherein the elongate element has a major transverse dimension of about 0.01 inch to about 0.100 inch.

12. The medical fastener of claim 11 wherein the elongate element has a minor transverse dimension of about 0.005 inch to about
10 0.050 inch.

13. The medical fastener of claim 1 wherein the elongate element is comprised of a solid material.

14. The medical fastener of claim 1 wherein the elongate element is hollow with a longitudinal lumen extending from a distal end of
15 the elongate member to a proximal end of the elongate member.

15. The medical fastener of claim 10 wherein the wedge is configured to protect the sharp distal tip of the elongate member.

16. The medical fastener of claim 1 wherein the elongate element further comprises an interlocking configuration.

20 17. The medical fastener of claim 16 wherein the elongate element further comprises a longitudinal groove in a first surface of the elongate element and a longitudinal ridge, configured to mate with the longitudinal groove on a second surface opposite the first surface.

25 18. The medical fastener of claim 1 wherein the elongate element is comprised of a material that is configured to self-forming from a constrained substantially straightened state to the enclosed configuration with an overlapped portion with the elongate element making contact in the overlapped portion.

19. A medical fastener comprising:
an elongate element having a longitudinal axis;
the elongate element formed into an enclosed configuration
with an overlapped portion with the elongate element making contact in
5 the overlapped portion;
the overlapped portion having a circumferential overlap of at
least 300 degrees; and
the longitudinal axis of the elongate element lying
substantially in a plane.
- 10 20. The medical fastener of claim 19 wherein the circumferential
overlap of the overlapped portion is about 300 to about 600 degrees.
21. The medical fastener of claim 19 wherein the enclosed
configuration of the elongate element is substantially circular.
22. The medical fastener of claim 19 wherein the enclosed
15 configuration of the elongate element is substantially elliptical.
23. The medical fastener of claim 19 wherein the elongate
element has a transverse cross section that is substantially rectangular.
24. The medical fastener of claim 19 wherein the elongate
element further comprises a distal end having a reduced transverse
20 dimension which is configured to engage a hollow portion of a proximal
end of another elongate element so as to eliminate or reduce relative
transverse movement between the proximal end and distal end when the
ends are engaged.
25. The medical fastener of claim 24 wherein the distal end of
25 the elongate element comprises a sharpened chisel shaped
configuration.

26. The medical fastener of claim 25 wherein the proximal end of the elongate element comprises a wedge shaped cut out configured to engage the chisel shaped configuration of the the distal end.

27. The medical fastener of claim 23 wherein the elongate
5 element has a major transverse dimension of about 0.01 inch to about 0.100 inch.

28. The medical fastener of claim 27 wherein the elongate element has a minor transverse dimension of about 0.005 inch to about 0.050 inch.

10 29. The medical fastener of claim 19 wherein the elongate element is comprised of a solid material.

30. The medical fastener of claim 19 wherein the elongate element is hollow with a longitudinal lumen extending from a distal end of the elongate member to a proximal end of the elongate member.

15 31. The medical fastener of claim 26 wherein the wedge is configured to protect the sharp distal tip of the elongate member.

32. The medical fastener of claim 19 wherein the elongate element further comprises an interlocking configuration.

20 33. The medical fastener of claim 32 wherein the elongate element further comprises a longitudinal groove in a first surface of the elongate element and a longitudinal ridge, configured to mate with the longitudinal groove on a second surface opposite the first surface.

25 34. The medical fastener of claim 19 wherein the elongate element is comprised of a material that is configured to self-forming from a constrained substantially straightened state to the enclosed configuration with the overlapped portion of the elongate element making contact with itself in the overlapped portion.

35. A surgical marker for marking a position within the body of a patient comprising:

an elongate element having a longitudinal axis and formed into an enclosed configuration with an overlapped portion with the elongate
5 element making contact in the overlapped portion; and

a contrast material in contact with the elongate element.

36. The surgical marker of claim 35 wherein the overlapped portion has a circumferential overlap of at least 300 degrees.

37. The surgical marker of claim 35 wherein the elongate element
10 comprises at least one cavity disposed therein.

38. The surgical marker of claim 37 wherein the elongate element comprises a hollow transverse cross section forming the at least one cavity therein.

39. The surgical marker of claim 37 wherein the cavity is
15 enclosed.

40. The surgical marker of claim 37 wherein the cavity contains a bioactive agent for delivery to adjacent tissue.

41. The surgical marker of claim 37 wherein the cavity contains the image contrast material.

20 42. The surgical marker of claim 35 wherein the image contrast material comprises a radiopaque material.

43. The surgical marker of claim 35 wherein the image contrast material comprises ultrasound contrast material.

25 44. The surgical marker of claim 35 wherein the image contrast material comprises MRI contrast material.

45. The surgical marker of claim 35 wherein the elongate element is comprised of a material that is configured to self-forming from a constrained substantially straightened state to the enclosed

configuration with the overlapped portion of the elongate element making contact with itself in the overlapped portion.

46. A surgical marker for marking a position within the body of a patient, comprising:

5 an elongate element having a longitudinal axis and formed into an enclosed configuration with a distal end engaged with a proximal end of the elongate element; and

a contrast material in contact with the elongate element.

47. The surgical marker of claim 46 wherein the distal end
10 comprises a wedge shaped pointed tip which is engaged with a wedge shaped cut out in the proximal end of the elongate member.

48. The surgical marker of claim 46 wherein the elongate element has at least one cavity disposed therein.

49. The surgical marker of claim 48 wherein the elongate element
15 has a hollow transverse cross section forming the at least one cavity therein.

50. The surgical marker of claim 48 wherein the cavity is enclosed.

51. The surgical marker of claim 48 wherein the cavity contains
20 a bioactive agent for delivery to adjacent tissue.

52. The surgical marker of claim 48 wherein the cavity contains image contrast material.

53. The surgical marker of claim 46 wherein the image contrast material comprises a radiopaque material.

25 54. The surgical marker of claim 46 wherein the image contrast material comprises ultrasound contrast material.

55. The surgical marker of claim 46 wherein the image contrast material comprises MRI image contrast material.

56. The surgical marker of claim 46 wherein the elongate element is comprised of a material that is configured to self-forming from a constrained and substantially straightened state to the enclosed configuration with the distal end engaged with the proximal end of the
5 elongate element.

57. A delivery device for deployment of a surgical coil, comprising:

- an elongate delivery sheath having a proximal end and a distal end;
- 10 an actuator body secured to a proximal portion of the elongate delivery sheath;
- a first ratchet member in substantially fixed relation with the actuator body having a grip feature configured to engage an advancing ribbon for prevent substantial proximal motion of the
- 15 advancing ribbon relative to the delivery sheath;
- an actuator slidably engaged with the actuator body;
- a second ratchet member having a grip feature configured to engage the advancing ribbon and being moveable with the actuator; and
- 20 an advancing ribbon configured to apply axial force on an elongate element within the delivery sheath.

58. The delivery device of claim 57 wherein the actuator is configured to slide relative to the actuator body a length equal to or greater than a length of an elongate element of a surgical coil to be
25 deployed.

59. The delivery device of claim 57 wherein the delivery sheath comprises a cannula with a sharpened distal tip.

60. The delivery device of claim 59 wherein the cannula comprises a stainless steel hypodermic tube with a sharpened distal tip configured to penetrate tissue.

61. The delivery device of claim 57 wherein the delivery sheath
5 has a length of about 5 to about 20 cm.

62. The delivery device of claim 57 further comprising a surgical coil cassette having a plurality of surgical coils disposed therein and wherein the actuator body has an aperture configured to receive the surgical coil cassette and load surgical coils into the delivery sheath in
10 serial.

63. The delivery device of claim 62 wherein the surgical coil cassette comprises a plurality of longitudinal slots for individually storing a plurality of surgical coils in a constrained substantially straight configuration and a plurality of biasing springs coupled to the cassette for
15 advancing the cassette after each surgical coil is loaded from the cassette into the delivery sheath.

64. The delivery device of claim 57 wherein the distal end of the delivery sheath further comprises a shape forming member for forming an elongate element into an enclosed configuration with an overlapped
20 portion with the elongate element making contact with itself in the overlapped portion.

65. A method for deploying a surgical coil in a patient's body, comprising:

25 positioning a distal end of a delivery sheath adjacent a deployment site;

axially advancing a surgical coil through the delivery sheath, out of a distal port of the delivery sheath and into target tissue; and

continuing to advance the surgical coil into the target tissue allowing an elongate element of the surgical coil to self-form into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

5

66. The method of claim 65 wherein the the elongate element self-forms into a closed configuration having a circumferential overlap of at least about 300 degrees.

67. The method of claim 65 wherein an element axis of the elongate element forms an angle of about 90 degrees with respect to a coil axis.

10

68. The method of claim 65 wherein the elongate element is advanced from the delivery sheath until a proximal end of the elongate element is ejected from the delivery sheath and the surgical coil is fully deployed in the target tissue disconnected from the delivery sheath.

15

69. The method of claim 65 wherein the delivery sheath is configured to constrain the elongate element to a substantially straight configuration prior to ejection from the distal end of the deliver sheath.

70. A method for deploying a surgical coil in a patient's body, comprising:

20

positioning a distal end of a delivery sheath adjacent a deployment site;

axially advancing a surgical coil through the delivery sheath until a distal end of an elongate element of the surgical coil contacts a coil forming member; and

25

continuing to advance the elongate member past the coil forming member and into the target tissue with the coil forming member shaping the elongate element into an enclosed

configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

71. The method of claim 70 wherein the elongate element is advanced from the delivery sheath until the surgical coil has a circumferential overlap of at least about 300 degrees.

72. The method of claim 70 wherein the elongate element is advanced from the delivery sheath until a proximal end of the elongate element is ejected from the delivery sheath and the surgical coil is fully deployed in the target tissue disconnected from the delivery sheath.

73. The method of claim 70 wherein the coil forming member comprises a bent distal tip of the delivery sheath.

74. A delivery device for simultaneous deployment of a plurality of surgical coils, comprising:

a delivery sheath housing;

a plurality of delivery sheaths oriented and stabilized by the delivery sheath housing with each delivery sheath having a proximal end and a distal end; and

plungers disposed within a plurality of the delivery sheaths;

and

an actuator for applying axial force to advancing members that are axially translatable with respect to the delivery sheaths for distally advancing surgical coils disposed within the delivery sheaths.

75. The delivery device of claim 74 wherein the actuator is configured to slide relative to the delivery sheath a length equal to or greater than a length of an elongate element of a surgical coil to be deployed.

76. The delivery device of claim 74 wherein the delivery sheaths comprise a cannulas with sharpened distal tips.

77. The delivery device of claim 76 wherein the cannulas comprise stainless steel hypodermic tubes with a sharpened distal tips
5 configured to penetrate tissue.

78. The delivery device of claim 74 wherein the delivery sheaths have a length of about 5 to about 20 cm.

79. The delivery device of claim 74 wherein the distal end of at least one delivery sheath further comprises a shape forming member for
10 forming an elongate element of a surgical coil into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

80. The delivery device of claim 74 wherein the delivery sheath housing is a substantially tubular member with the delivery sheaths
15 evenly spread about a wall of the tubular member and a longitudinal axis of the delivery sheaths is substantially parallel to a longitudinal axis of the tubular member.

81. The delivery device of claim 74 wherein the delivery sheath housing is a cylinder and the delivery sheaths are evenly spread about
20 an outer perimeter of the cylinder and a longitudinal axis of the delivery sheaths is substantially parallel to a longitudinal axis of the cylinder.

82. The delivery device of claim 74 wherein the delivery sheaths are arranged in two substantially parallel rows within the delivery sheath housing in a rectangular configuration with a longitudinal axis of each of
25 the delivery sheaths being substantially parallel to each of the other delivery sheaths.

83. A method for deploying a plurality of surgical coils in a patient's body, comprising:

positioning distal ends of a plurality of delivery sheaths
stabilized by a delivery sheath housing adjacent a deployment site;
axially advancing a plurality of surgical coils through the
delivery sheaths, out of distal ports of the delivery sheaths and into
5 target tissue; and

continuing to advance the surgical coils into the target tissue
allowing elongate elements of the surgical coils to self-form into an
enclosed configuration with an overlapped portion of each elongate
element making contact with itself in the overlapped portion.

10 84. The method of claim 83 wherein the the elongate elements
self-form into a closed configuration having a circumferential overlap of at
least about 300 degrees.

85. The method of claim 83 wherein an element axis of the
elongate elements form an angle of about 90 degrees with respect to a
15 coil axis.

86. The method of claim 83 wherein the elongate elements are
advanced from the delivery sheaths until proximal ends of the elongate
elements are ejected from the delivery sheath and the surgical coil is fully
deployed in the target tissue disconnected from the delivery sheaths.

20 87. The method of claim 83 wherein the delivery sheaths are
configured to constrain the elongate elements to a substantially straight
configuration prior to ejection from the distal end of the deliver sheaths.

88. A delivery device for closure of a wound site and
simultaneous deployment of a plurality of surgical coils across the
25 wound, comprising:

a delivery sheath housing;

a plurality of delivery sheaths oriented and stabilized by the
delivery sheath housing with each delivery sheath having a

proximal end, a distal end and a pre-formed outward radial bias away from other delivery sheaths for at least one distal end thereof;

5 an outer sheath slidably disposed over at least a portion of the delivery sheath housing and delivery sheaths, and configured to constrain an outward radial displacement of the at least one distal end with the pre-formed bias when the outer sheath is disposed about the distal end with the pre-formed bias and to allow outward radial displacement of the distal end with the pre-formed
10 bias when not disposed thereabout;

plungers disposed within a plurality of the delivery sheaths for applying axial force to the delivery sheaths for distally advancing surgical coils disposed within the delivery sheaths.

89. The delivery device of claim 88 wherein the plungers are
15 configured to slide relative to the delivery sheaths a length equal to or greater than a length of an elongate element of surgical coils to be deployed.

90. The delivery device of claim 88 wherein the delivery sheaths comprise a cannulas with sharpened distal tips.

20 91. The delivery device of claim 90 wherein the cannulas comprise stainless steel hypodermic tubes with a sharpened distal tips configured to penetrate tissue.

92. The delivery device of claim 88 wherein the delivery sheaths have a length of about 5 to about 20 cm.

25 93. The delivery device of claim 88 wherein the distal end of at least one delivery sheath further comprises a shape forming member for forming an elongate element of a surgical coil into an enclosed

configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

94. The delivery device of claim 88 wherein the delivery sheath housing is a cylinder and the delivery sheaths are evenly spread about
5 an outer perimeter of the cylinder and a longitudinal axis of the delivery sheaths is substantially parallel to a longitudinal axis of the cylinder.

95. A method for forcing a wound closed and deploying a plurality of surgical coils across the wound to maintain closure, comprising:

10 positioning distal ends of a plurality of delivery sheaths stabilized by a delivery sheath housing adjacent a deployment site with an outer sheath disposed about at least a portion of the delivery sheaths and delivery sheath housing in a proximally retracted position;

15 advancing the distal ends of the delivery sheaths into target tissue at the deployment site with at least one delivery sheath disposed on either side of the wound;

advancing the outer sheath distally in order to reduce an outward radial displacement of a distal end of at least one of the
20 delivery sheaths thereby reducing the distance between the distal ends of at least two delivery sheaths and at least partially closing the wound;

axially advancing a plurality of surgical coils through the delivery sheaths, out of distal ports of the delivery sheaths and into
25 target tissue; and

continuing to advance the surgical coils into the target tissue allowing elongate elements of the surgical coils to self-form into an

enclosed configuration with an overlapped portion of each elongate element making contact with itself in the overlapped portion.

96. The method of claim 95 wherein the the elongate elements self-form into a closed configuration having a circumferential overlap of at
5 least about 300 degrees.

97. The method of claim 95 wherein an element axis of the elongate elements form an angle of about 90 degrees with respect to a coil axis.

98. The method of claim 95 wherein the elongate elements are
10 advanced from the delivery sheaths until proximal ends of the elongate elements are ejected from the delivery sheath and the surgical coil is fully deployed in the target tissue disconnected from the delivery sheaths.

99. The method of claim 95 wherein the delivery sheaths are configured to constrain the elongate elements to a substantially straight
15 configuration prior to ejection from the distal end of the deliver sheaths.

100. A delivery device for simultaneous deployment of a plurality of surgical coils from within a channel, comprising:

a delivery sheath housing;

a plurality of delivery sheaths oriented and stabilized by the
20 delivery sheath housing with each delivery sheath having a proximal end and a distal end;

an outer sheath slidably disposed over at least a portion of the delivery sheath housing and delivery sheaths;

an expanable member disposed between distal portions of
25 the plurality of delivery sheaths and configured to expand the distal portions of the delivery sheaths in an outward radial direction when in an expanded state; and

plungers disposed within a plurality of the delivery sheaths for applying axial force to a surgical coil within the delivery sheaths for distally advancing surgical coil.

5 101. The delivery device of claim 100 wherein the plungers are configured to slide relative to the delivery sheaths a length equal to or greater than a length of an elongate element of surgical coils to be deployed.

10 102. The delivery device of claim 100 wherein the delivery sheaths comprise cannulas with sharpened distal tips.

 103. The delivery device of claim 102 wherein the cannulas comprise stainless steel hypodermic tubes with a sharpened distal tips configured to penetrate tissue.

15 104. The delivery device of claim 100 wherein the delivery sheaths have a length of about 5 to about 20 cm.

 105. The delivery device of claim 100 wherein the distal end of at least one delivery sheath further comprises a shape forming member for forming an elongate element of a surgical coil into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

20 106. The delivery device of claim 100 wherein the delivery sheath housing is a cylinder and the delivery sheaths are evenly spread about an outer perimeter of the cylinder and a longitudinal axis of the delivery sheaths is substantially parallel to a longitudinal axis of the cylinder.

25 107. The delivery device of claim 100 wherein the expandable member is a balloon.

 108. A method for deploying a plurality of surgical coils from within a channel, comprising:

positioning distal ends of a plurality of delivery sheaths stabilized by a delivery sheath housing at a deployment site within a cavity;

5 expanding an expandable member which is surrounded by the the plurality of delivery sheaths until distal ends of the delivery sheaths are disposed against target material;

axially advancing a plurality of surgical coils through the delivery sheaths, out of distal ports of the delivery sheaths and into target material; and

10 continuing to advance the surgical coils into the target tissue allowing elongate elements of the surgical coils to self-form into an enclosed configuration with an overlapped portion of each elongate element making contact with itself in the overlapped portion.

109. The method of claim 108 wherein the the elongate elements
15 self-form into a closed configuration having a circumferential overlap of at least about 300 degrees.

110. The method of claim 108 wherein an element axis of the elongate elements form an angle of about 90 degrees with respect to a coil axis.

20 111. The method of claim 108 wherein the elongate elements are advanced from the delivery sheaths until proximal ends of the elongate elements are ejected from the delivery sheath and the surgical coil is fully deployed in the target tissue disconnected from the delivery sheaths.

25 112. The method of claim 108 wherein the delivery sheaths are configured to constrain the elongate elements to a substantially straight configuration prior to ejection from the distal end of the deliver sheaths.

113. The method of claim 108 wherein expansion of the expandable member comprises inflation of a balloon.

114. The method of claim 108 wherein the cavity comprises a body lumen and the target material comprises tissue and further comprising expanding the expandable member until distal ends of the delivery sheaths are disposed against the tissue with a desired force.

5 115. The method of claim 108 wherein the cavity comprises an intracorporeal prosthesis and the target material comprises a wall material of the prosthesis and further comprising expanding the expandable member until distal ends of the delivery sheaths are disposed adjacent the wall of the prosthesis.

10 116. A delivery device for deployment of a surgical coil and attachment member, comprising:

an elongate deployment shaft assembly including an elongate delivery sheath having a proximal end and a distal end, an attachment member having an attachment loop disposed adjacent a distal port of the delivery sheath which is configured to direct a surgical coil deployed from the distal port to surround the attachment loop, and an outer sheath slidably disposed about at least a portion of the delivery sheath and attachment member; and

15

an actuator body secured to a proximal portion of the elongate deployment shaft including an actuator configured to advance a surgical coil distally from the delivery sheath.

20

117. The delivery device of claim 116 further comprising

a first ratchet member in substantially fixed relation with the actuator body having a grip feature configured to engage an advancing ribbon for prevent substantial proximal motion of the advancing ribbon relative to the delivery sheath;

25

an actuator slidably engaged with the actuator body;

a second ratchet member having a grip feature configured to engage the advancing ribbon and being moveable with the actuator; and

5 an advancing ribbon configured to apply axial force on an elongate element within the delivery sheath.

118. The delivery device of claim 116 wherein the actuator is configured to slide relative to the actuator body a length equal to or greater than a length of an elongate element of a surgical coil to be deployed.

10 119. The delivery device of claim 116 wherein the delivery sheath comprises a cannula with a sharpened distal tip.

120. The delivery device of claim 119 wherein the cannula comprises a stainless steel hypodermic tube with a sharpened distal tip configured to penetrate tissue.

15 121. The delivery device of claim 116 wherein the deployment shaft assembly has a length of about 5 to about 20 cm.

122. The delivery device of claim 116 further comprising a surgical coil cassette having a plurality of surgical coils disposed therein and wherein the actuator body has an aperture configured to receive the surgical coil cassette and load surgical coils into the delivery sheath in serial.

20 123. The delivery device of claim 122 wherein the surgical coil cassette comprises a plurality of longitudinal slots for individually storing a plurality of surgical coils in a constrained substantially straight configuration and a plurality of biasing springs coupled to the cassette for advancing the cassette after each surgical coil is loaded from the cassette into the delivery sheath.

124. The delivery device of claim 116 wherein the distal end of the delivery sheath further comprises a shape forming member for forming an elongate element into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in
5 the overlapped portion.

125. The delivery device of claim 116 wherein the attachment loop comprises a loop formed at a distal end of single solid attachment member.

126. The delivery device of claim 116 wherein the delivery device
10 further comprises two suture alignment tubes extending within the outer sheath and having distal end ports disposed adjacent the distal port of the delivery sheath and wherein the attachment loop comprises a length of suture material extending between distal ports of the suture alignment tubes.

15 127. The delivery device of claim 126 wherein distal ends of the suture alignment tubes have an outward radial bias that can be constrained by the outer sheath when the outer sheath is disposed about said distal ends.

20 128. A method for deploying a surgical coil and attachment member in a patient's body, comprising:

positioning a distal end of a deployment shaft assembly adjacent a deployment site;

25 axially advancing a surgical coil through a delivery sheath of the deployment shaft assembly, out of a distal port of the delivery sheath, into target tissue and around an attachment loop of the attachment member;

continuing to advance the surgical coil into the target tissue allowing an elongate element of the surgical coil to self-form into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped
5 portion.

129. The method of claim 128 wherein the the elongate element self-forms into a closed configuration having a circumferential overlap of at least about 300 degrees.

130. The method of claim 128 wherein an element axis of the
10 elongate element forms an angle of about 90 degrees with respect to a coil axis.

131. The method of claim 128 wherein the elongate element is advanced from the delivery sheath until a proximal end of the elongate element is ejected from the delivery sheath and the surgical coil is fully
15 deployed in the target tissue disconnected from the delivery sheath and encircling the attachment loop of the attachment member.

132. The method of claim 128 wherein the delivery sheath is configured to constrain the elongate element to a substantially straight configuration prior to ejection from the distal end of the deliver sheath.

20 133. The method of claim 128 further comprising proximally withdrawing the deployment shaft assembly leaving the surgical coil in place secured to the attachment loop.

134. The method of claim 128 wherein the deployment shaft assembly further comprises two suture alignment tubes extending within
25 the outer sheath and having distal end ports disposed adjacent the distal port of the delivery sheath and wherein the attachment loop comprises a length of suture material extending between distal ports of the suture alignment tubes.

135. The method of claim 134 distal ends of the suture alignment tubes have an outward radial bias that can be constrained by the outer sheath when the outer sheath is disposed about said distal ends and further comprising proximally withdrawing the outer sheath and
5 expanding distal ends of the suture alignment tubes in an outward radial orientation prior to deploying the surgical coil from the distal port of the delivery sheath.

136. The method of claim 128 wherein the deployment shaft assembly comprises a plurality of delivery sheaths and a plurality of
10 surgical coils are deployed about a plurality of attachment loops.

137. The method of claim 128 further comprising pre-forming a cavity in target tissue prior to positioning the distal end of the deployment shaft assembly adjacent a deployment site in the cavity and further comprising deploying the surgical coil within the cavity such that the
15 surgical coil is trapped in the cavity and the attachment member extends from the cavity.

138. The method of claim 137 wherein the cavity is formed in bone tissue and the surgical coil is deployed within and trapped by bone tissue.

20 139. The method of claim 137 wherein the cavity is formed in bone and bone marrow and the surgical coil is disposed at least partially within bone marrow.

140. A deflectable delivery device for deployment of a surgical coil, comprising:

25 an elongate deployment shaft assembly including an elongate delivery sheath having a proximal end, a distal end and a distal end portion that can be constrained to a straightened configuration and assumes a deflected curved configuration when

the restraint is removed, and an outer sheath slidably disposed about at least a portion of the delivery sheath; and

an actuator body secured to a proximal portion of the elongate deployment shaft assembly including a first actuator
5 configured to advance the delivery sheath relative to the outer sheath and a second actuator configured to advance the surgical coil distally from a distal port of the delivery sheath.

141. The delivery device of claim 140 further comprising:

a first ratchet member in substantially fixed relation with a
10 second actuator body having a grip feature configured to engage an advancing ribbon for prevent substantial proximal motion of the advancing ribbon relative to the delivery sheath;

the second actuator slidably engaged with the second actuator body;

15 a second ratchet member having a grip feature configured to engage the advancing ribbon and being moveable with the second actuator; and

an advancing ribbon configured to apply axial force on an elongate element within the delivery sheath.

20 142. The delivery device of claim 141 wherein the second actuator is configured to slide relative to the actuator body a length equal to or greater than a length of an elongate element of a surgical coil to be deployed.

143. The delivery device of claim 140 wherein the delivery sheath
25 comprises a cannula with a sharpened distal tip.

144. The delivery device of claim 143 wherein the cannula comprises a stainless steel hypodermic tube with a sharpened distal tip configured to penetrate tissue.

145. The delivery device of claim 140 wherein the deployment shaft assembly has a length of about 5 to about 20 cm.

146. The delivery device of claim 140 further comprising a surgical coil cassette having a plurality of surgical coils disposed therein
5 and wherein the actuator body has an aperture configured to receive the surgical coil cassette and load surgical coils into the delivery sheath in serial.

147. The delivery device of claim 146 wherein the surgical coil cassette comprises a plurality of longitudinal slots for individually storing
10 a plurality of surgical coils in a constrained substantially straight configuration and a plurality of biasing springs coupled to the cassette for advancing the cassette after each surgical coil is loaded from the cassette into the delivery sheath.

148. The delivery device of claim 140 wherein the distal end of
15 the delivery sheath further comprises a shape forming member for forming an elongate element into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

149. A method for deploying a surgical coil in a patient's body,
20 comprising:

positioning a distal end of a deployment shaft assembly adjacent a deployment site;

activating a first actuator to advance a delivery sheath distally from an outer sheath of the deployment shaft assembly
25 until a distal end of the delivery sheath extends beyond a distal port of the outer sheath and extends in an outward radial direction from the distal port;

activating a second actuator that axially advances a surgical coil through the delivery sheath, out of a distal port of the delivery sheath, into target tissue;

5 continuing to advance the surgical coil into the target tissue allowing an elongate element of the surgical coil to self-form into an enclosed configuration with an overlapped portion with the elongate element making contact with itself in the overlapped portion.

10 150. The method of claim 149 wherein the the elongate element self-forms into a closed configuration having a circumferential overlap of at least about 300 degrees.

151. The method of claim 149 wherein an element axis of the elongate element forms an angle of about 90 degrees with respect to a coil axis.

15 152. The method of claim 149 wherein the elongate element is advanced from the delivery sheath until a proximal end of the elongate element is ejected from the delivery sheath and the surgical coil is fully deployed in the target tissue disconnected from the delivery sheath in a position radially displaced from a longitudinal axis of the deployment
20 shaft assembly.

153. The method of claim 149 wherein the delivery sheath is configured to constrain the elongate element to a substantially straight configuration prior to ejection from the distal end of the deliver sheath.

25 154. The method of claim 149 further comprising proximally withdrawing the deployment shaft assembly leaving the surgical coil in place in the target tissue.

155. The method of claim 149 wherein the deployment shaft assembly comprises a mammatome trocar having a lateral aperture

which is positioned adjacent the deployment site by tissue penetration during distal advancement.

156. The method of claim 149 further comprising repeating the surgical coil deployment with a plurality of surgical coils in different
5 positions which are arranged to define the boundary of a suspect tissue mass.

157. The method of claim 156 wherein the surgical coils are deployed in a substantially spherical configuration about a suspect tissue mass defining a margin about the suspect tissue mass of about 0.5 to
10 about 1.5 cm.

158. The method of claim 149 wherein the surgical coil comprises an image contrast material and further comprising imaging the deployment site after deployment of a surgical coil.

15

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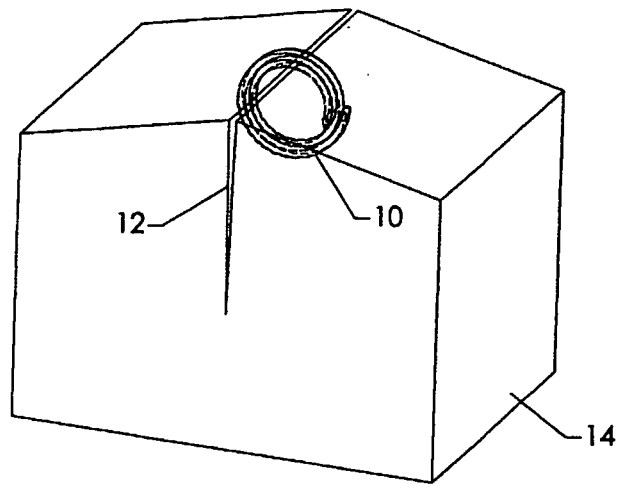


FIG 1

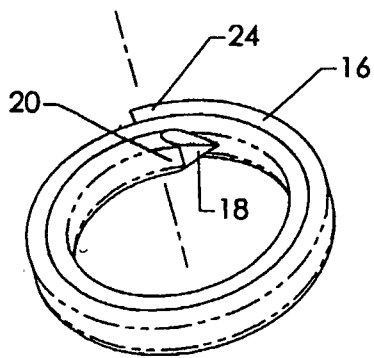


FIG 2

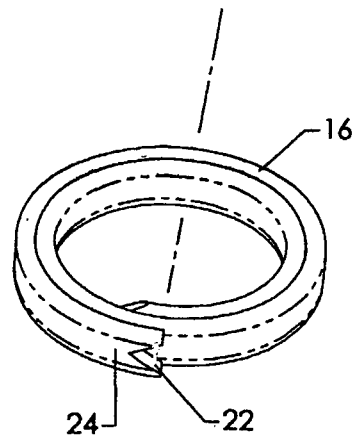


FIG 3

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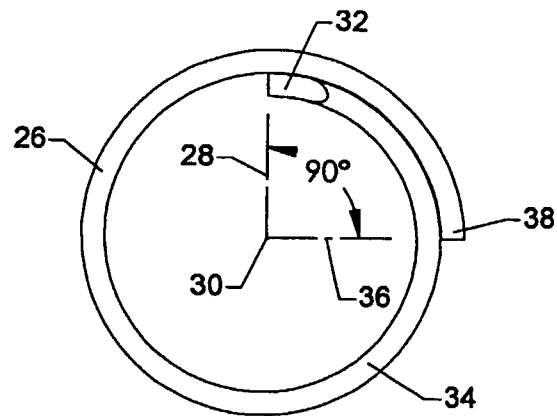


FIG 4

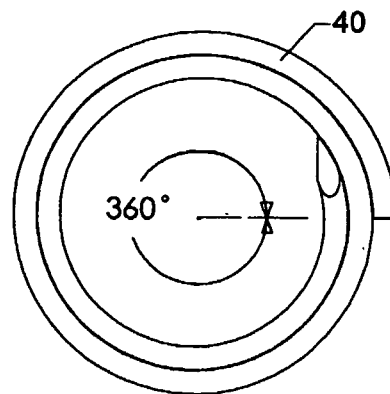
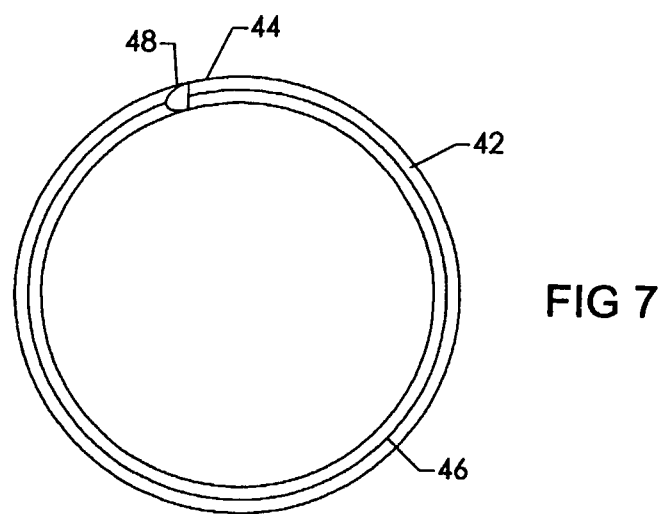
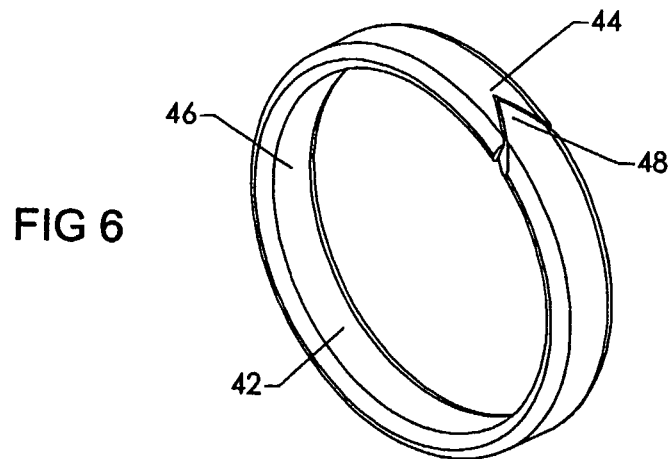


FIG 5

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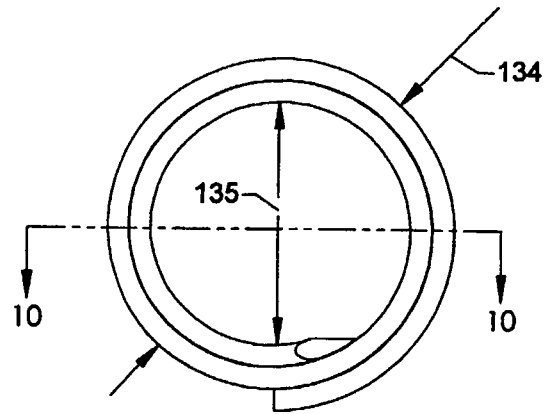


FIG 8

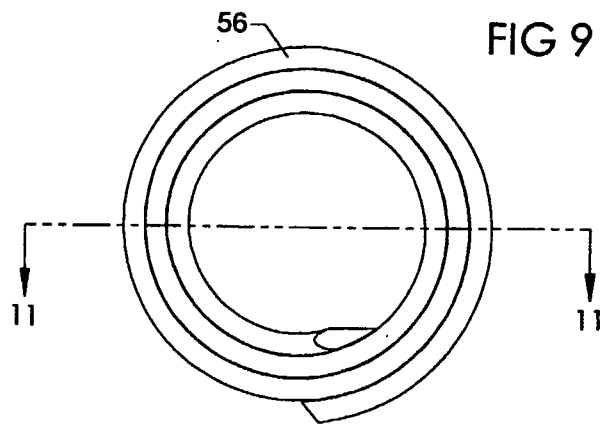


FIG 9

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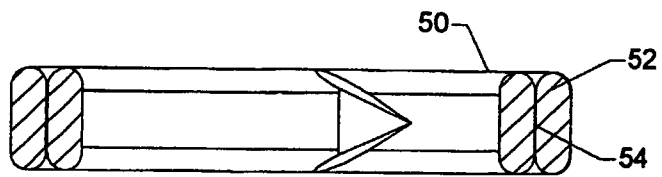


FIG 10

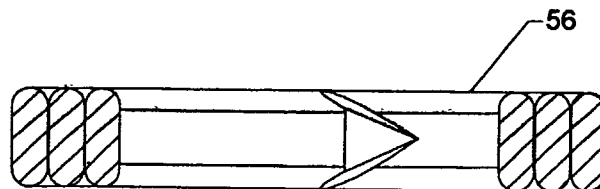


FIG 11

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FIG 12

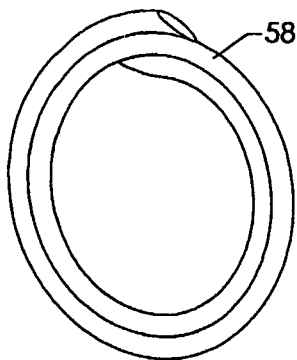


FIG 14

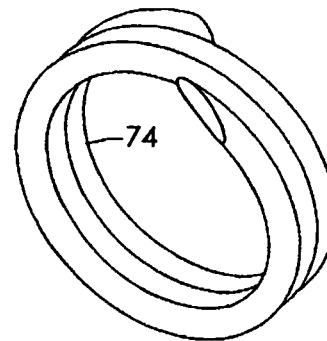
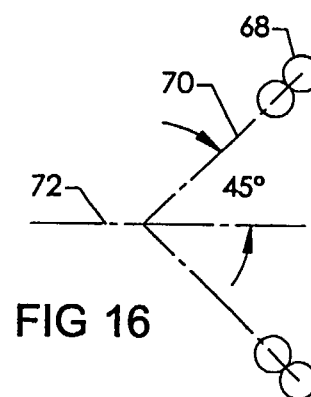
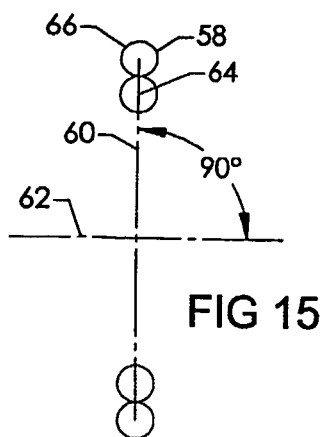
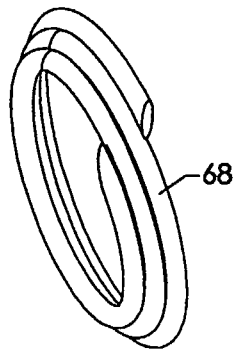
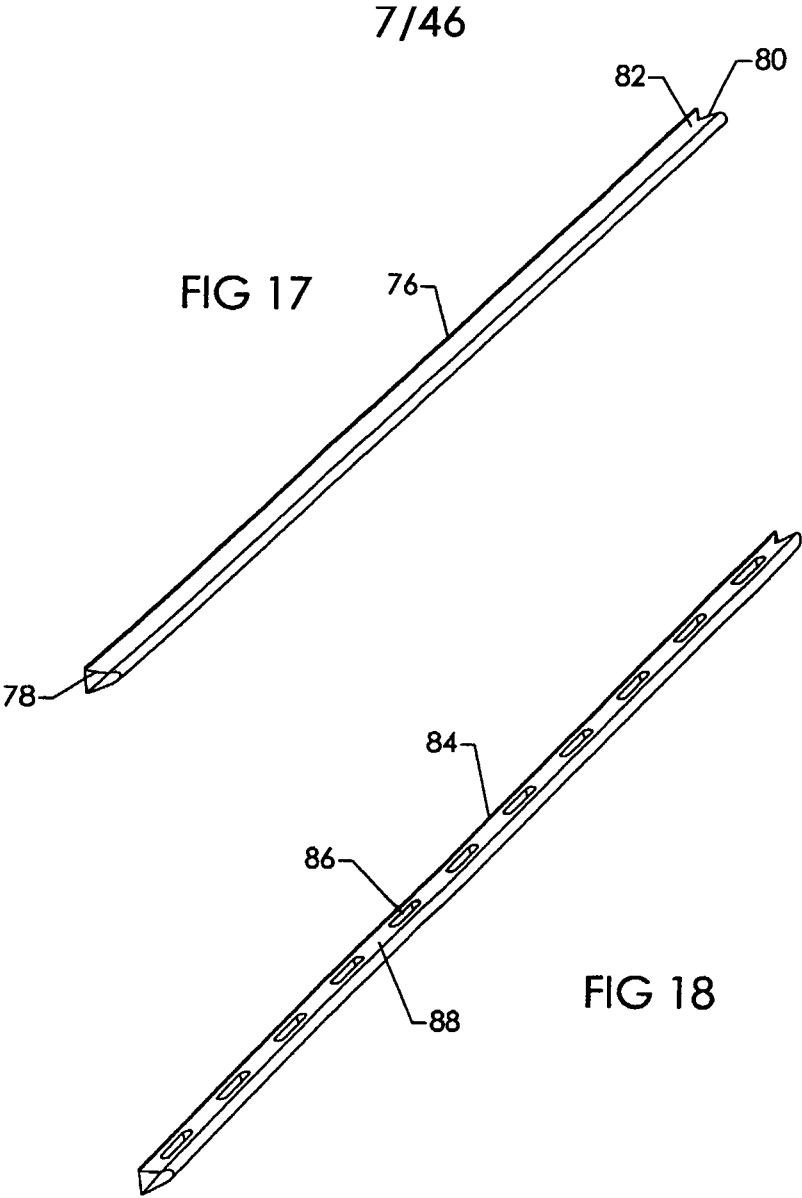


FIG 13





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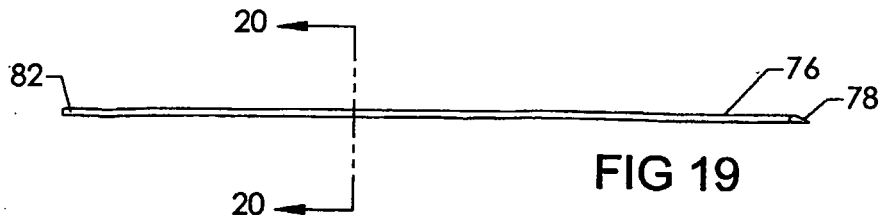


FIG 19

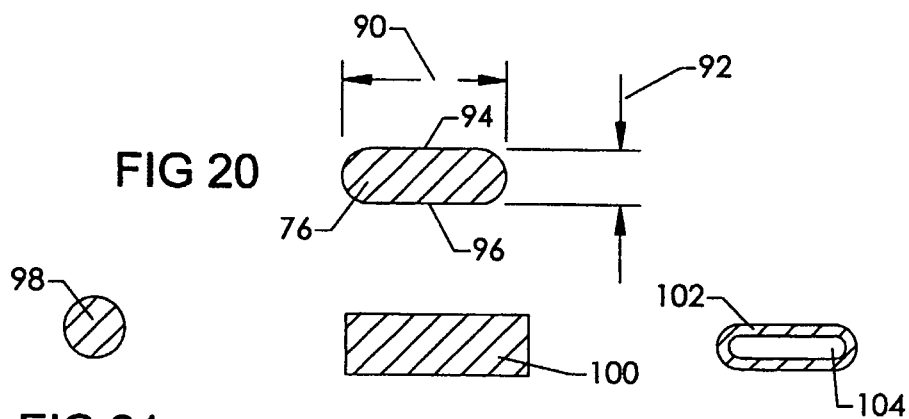


FIG 21

FIG 22

FIG 23

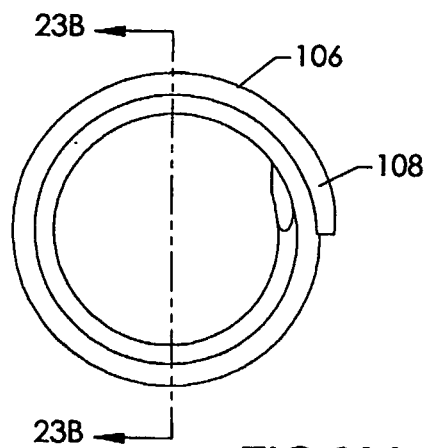


FIG 23A

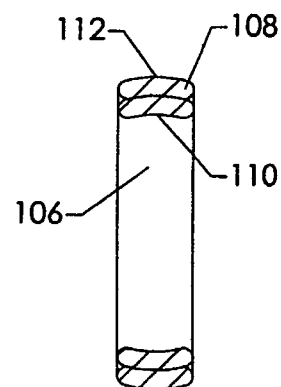


FIG 23B

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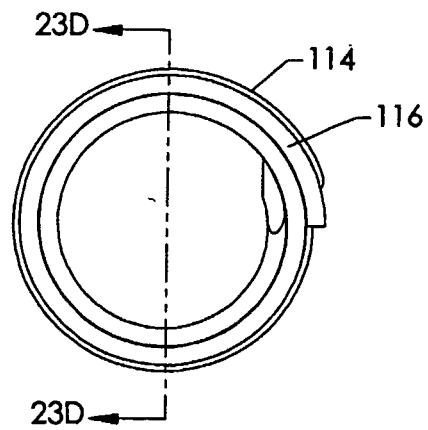


FIG 23C

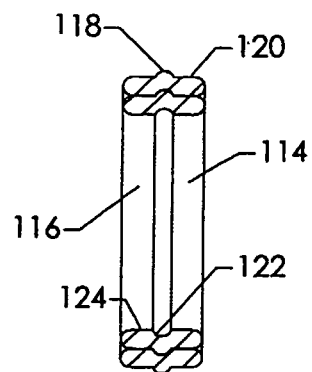


FIG 23D

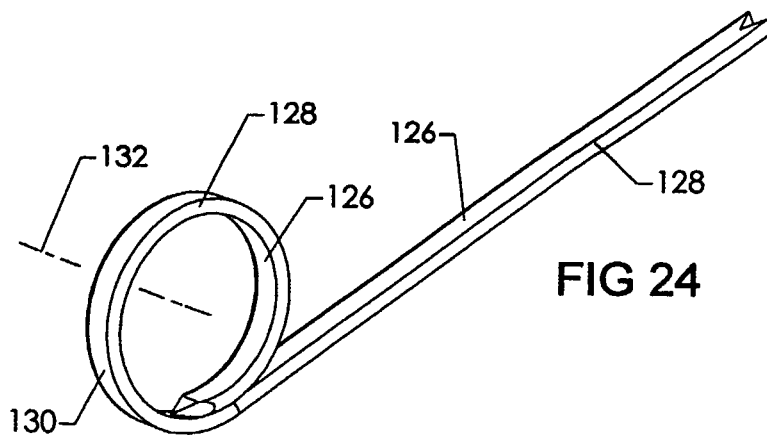
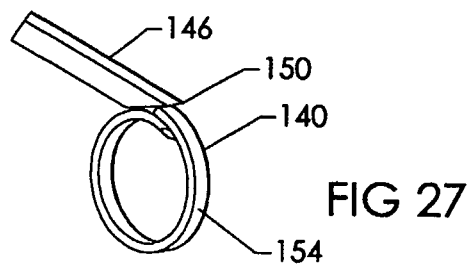
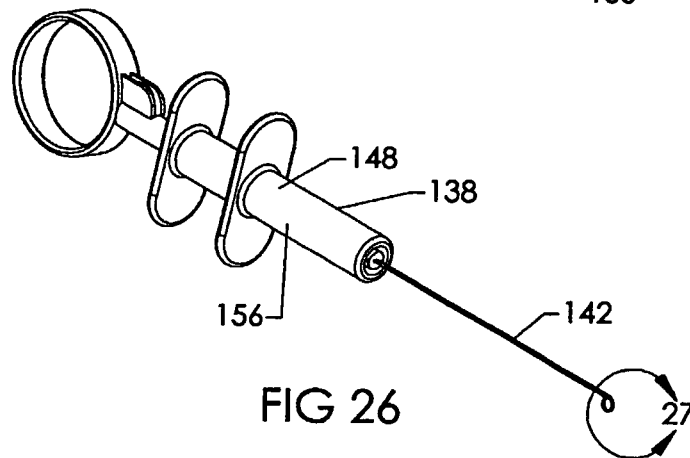
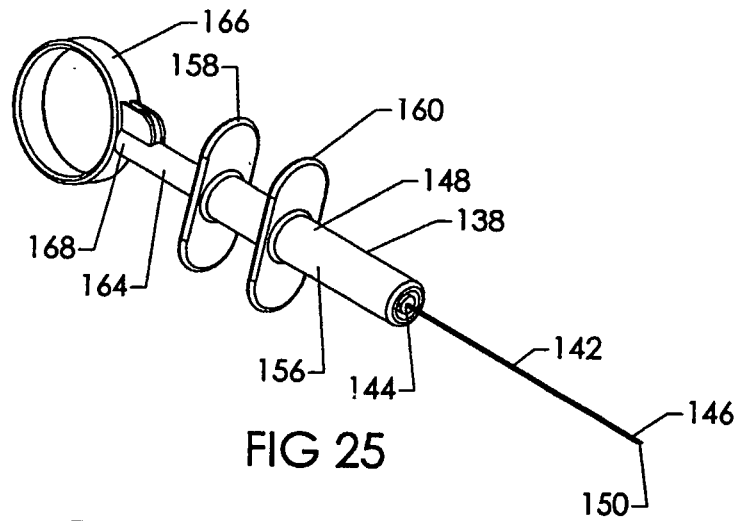
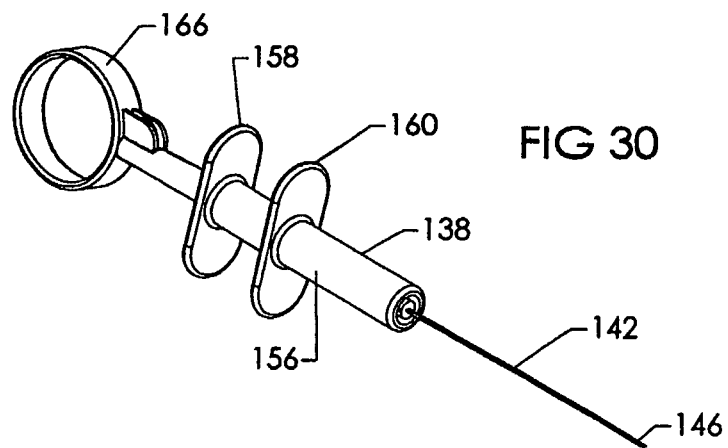
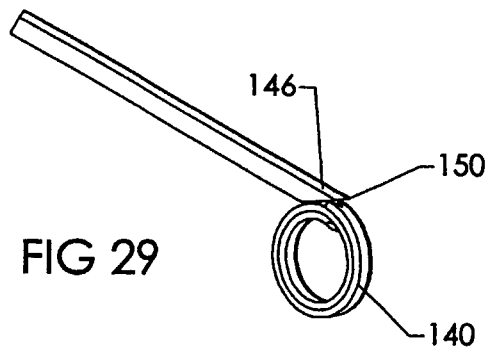
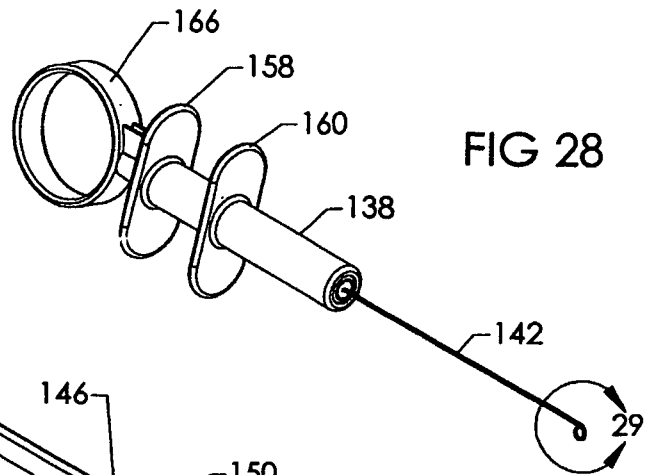


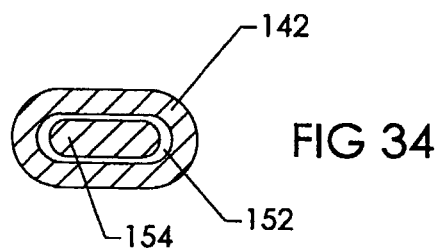
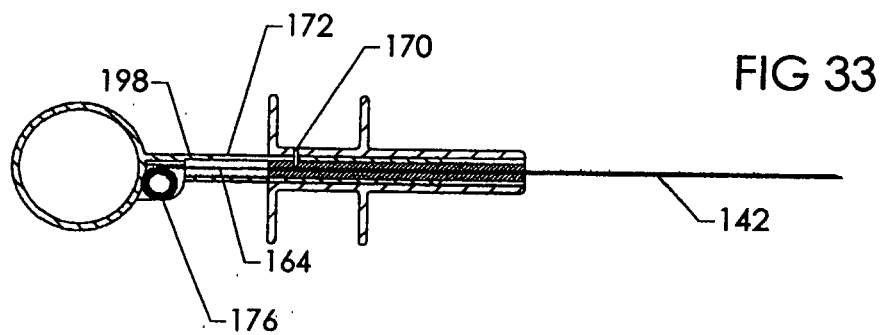
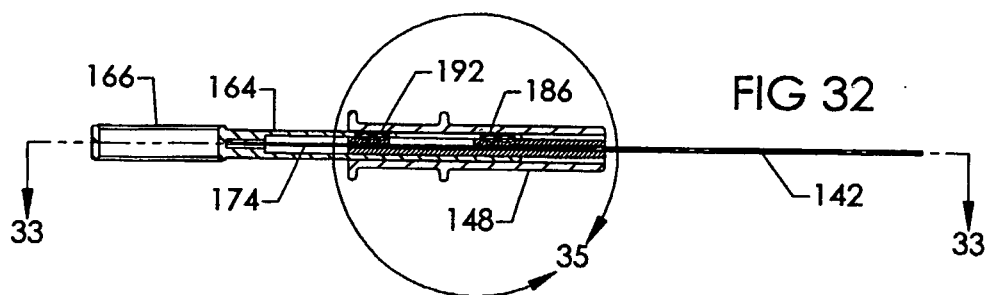
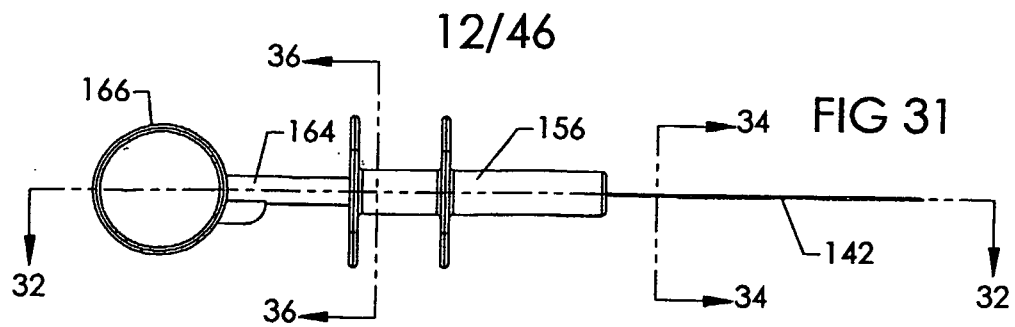
FIG 24

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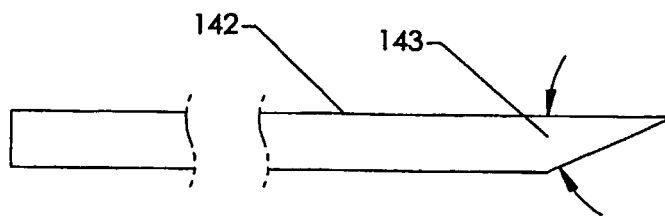
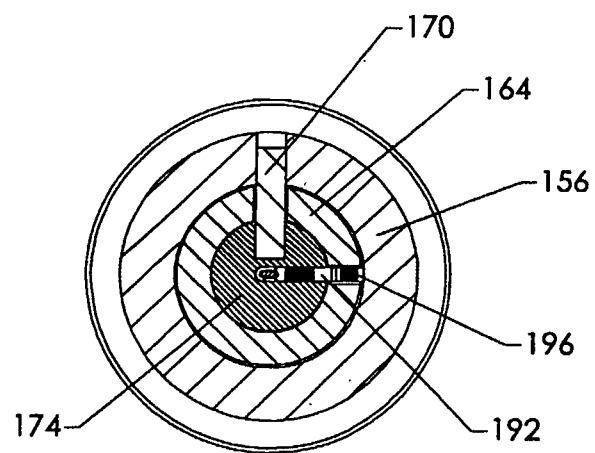
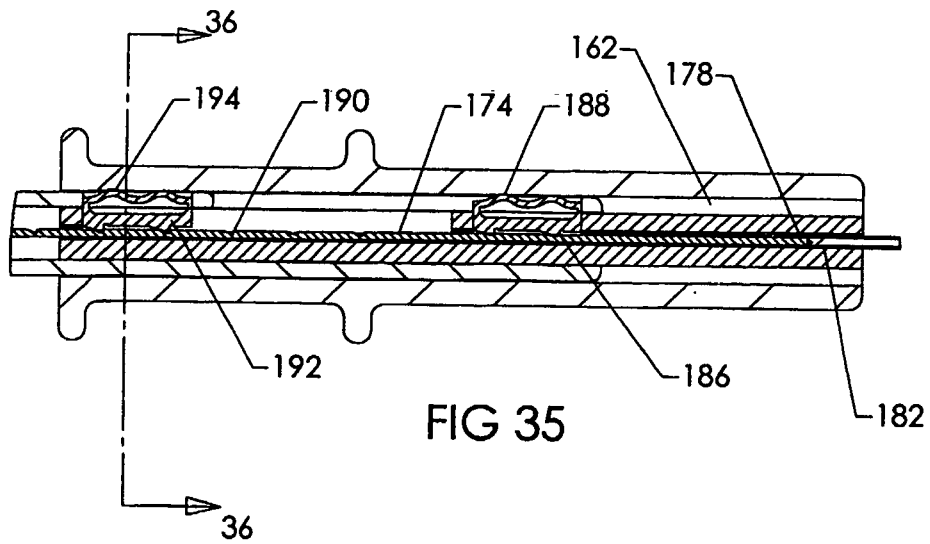
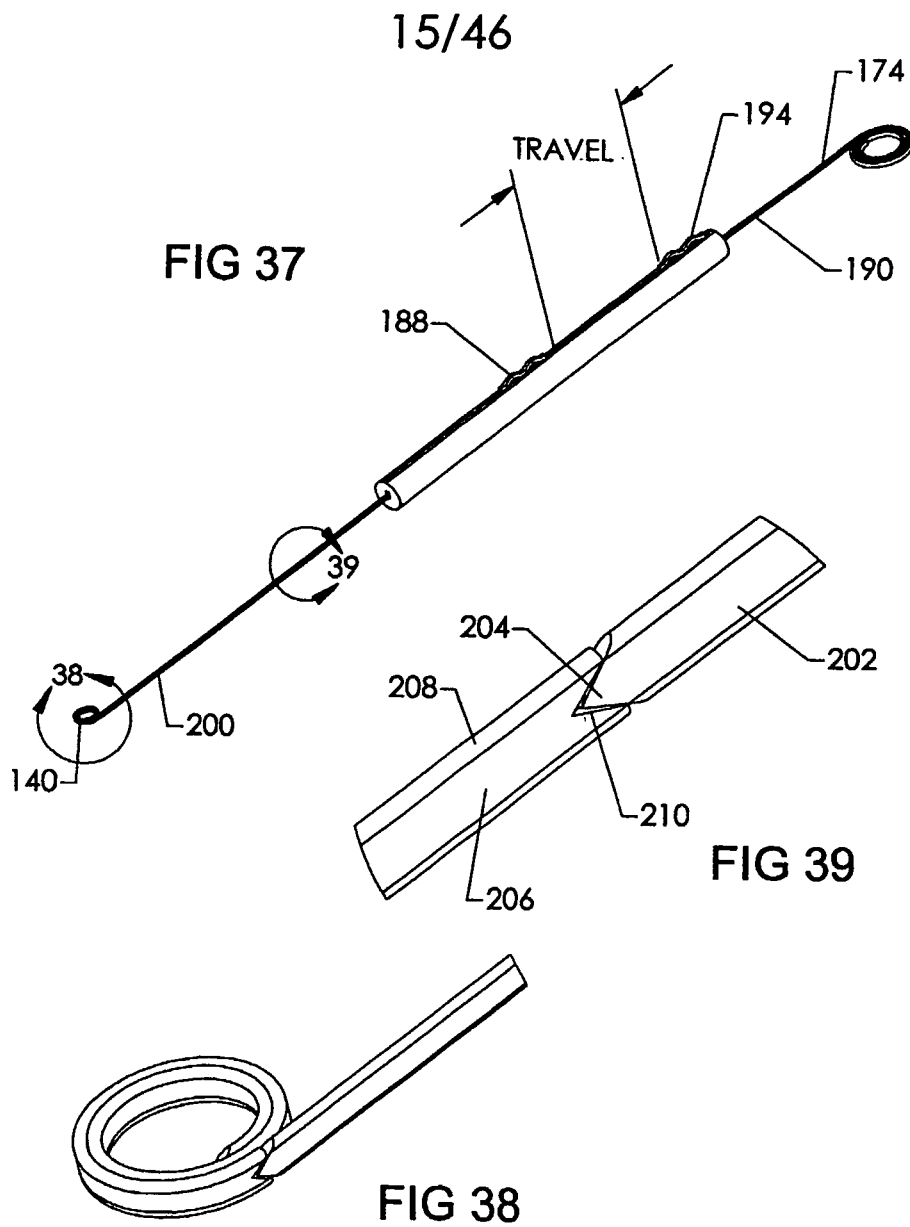


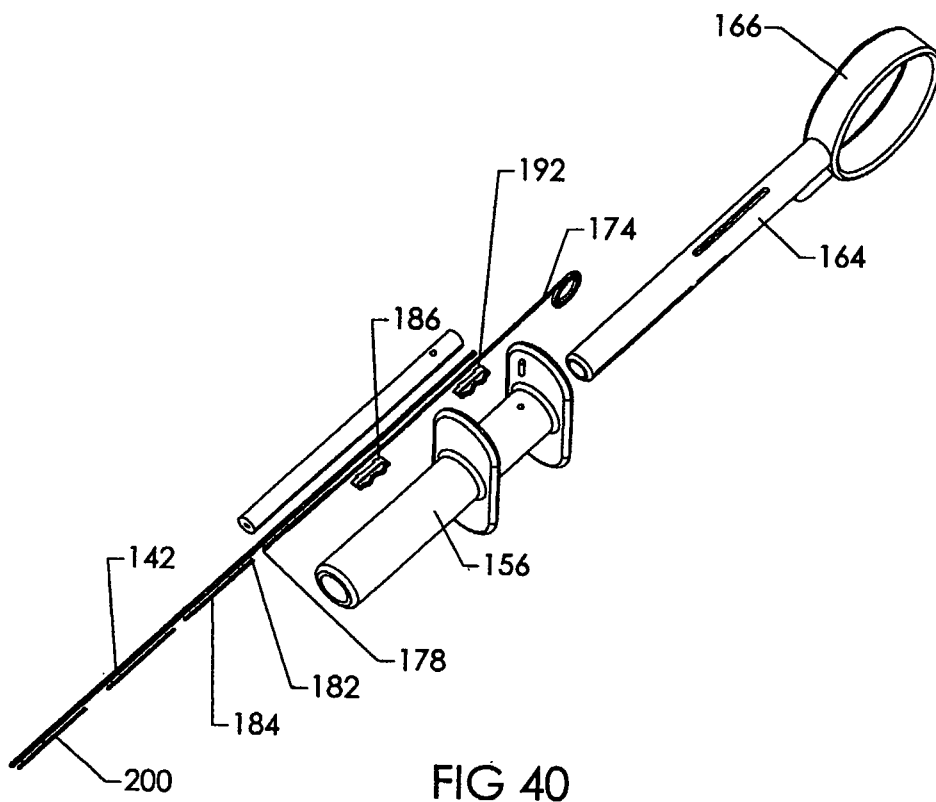
FIG 34A

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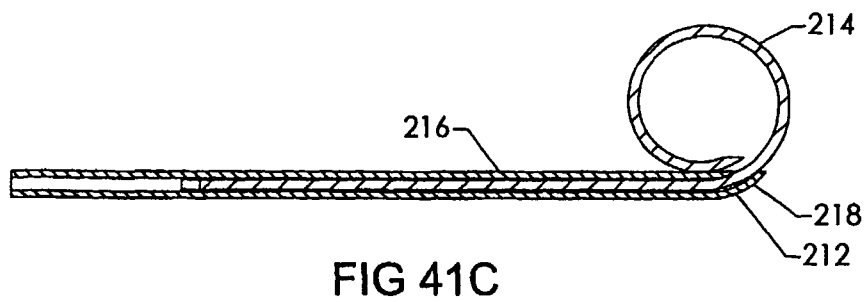
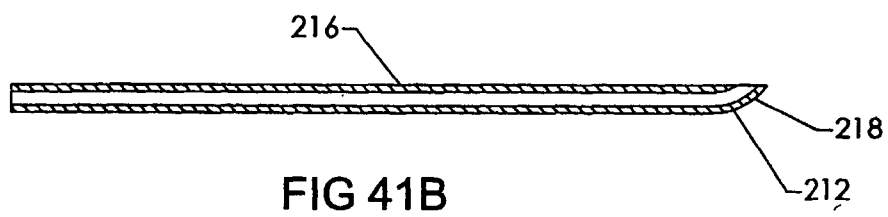
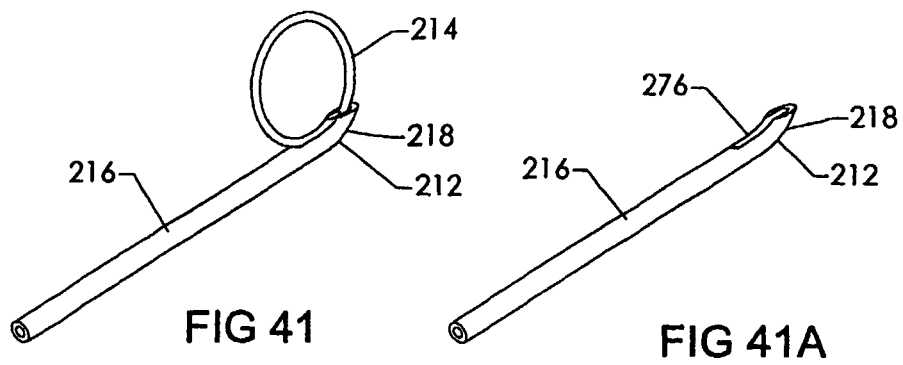




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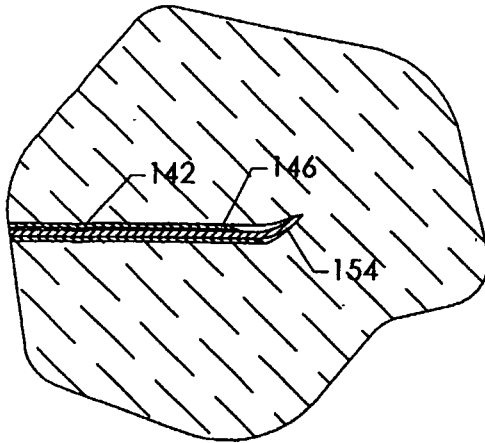


FIG 42

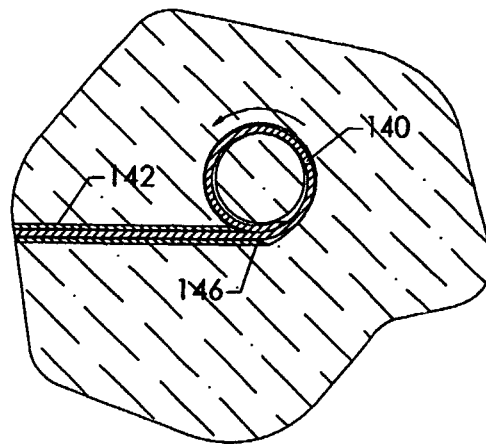


FIG 43

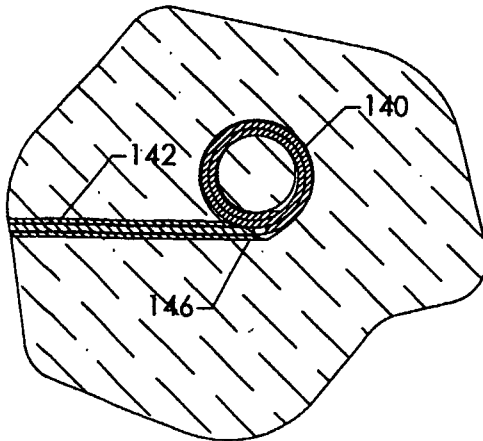


FIG 44

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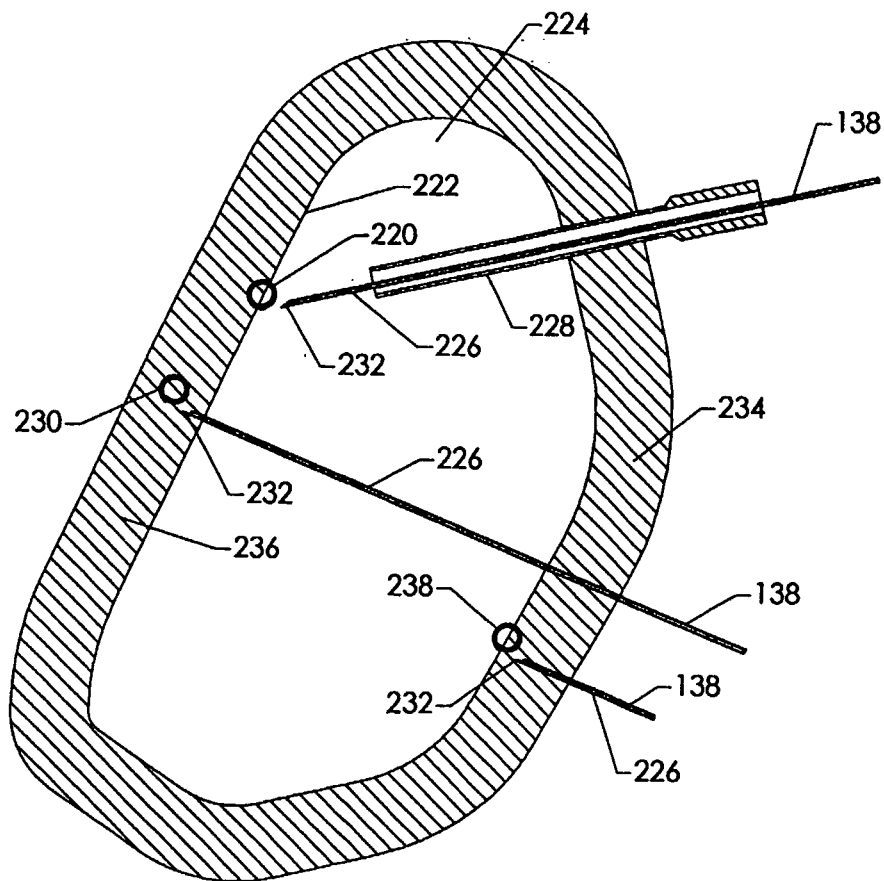
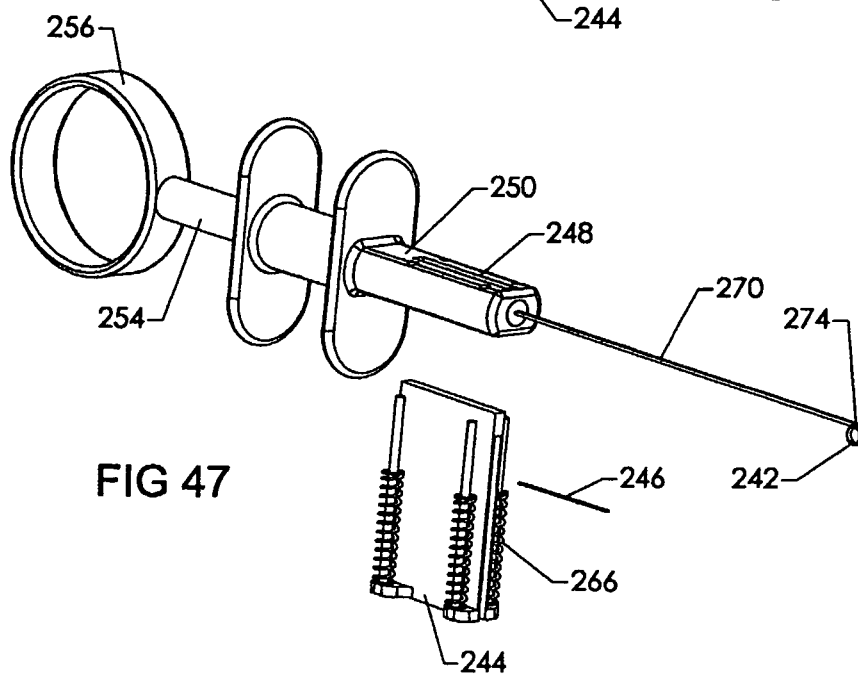
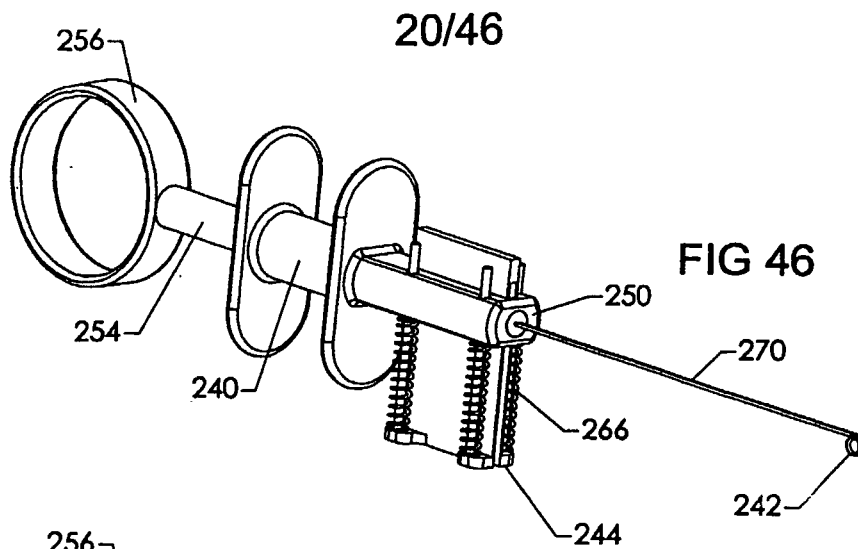
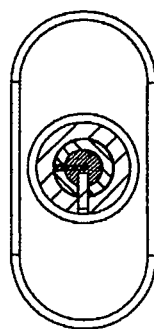
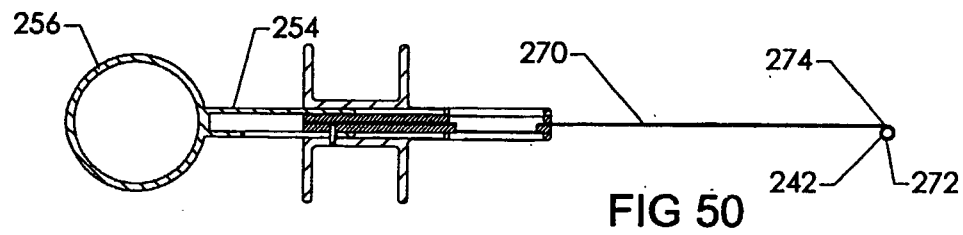
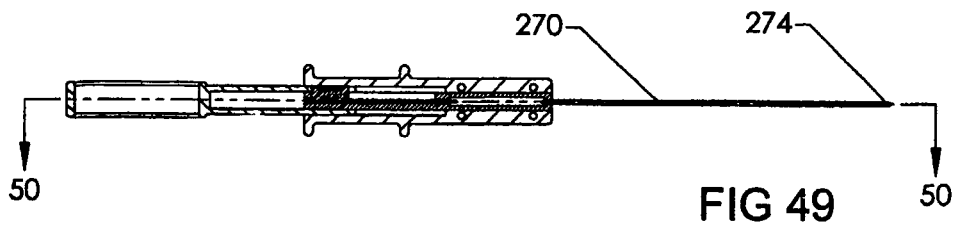
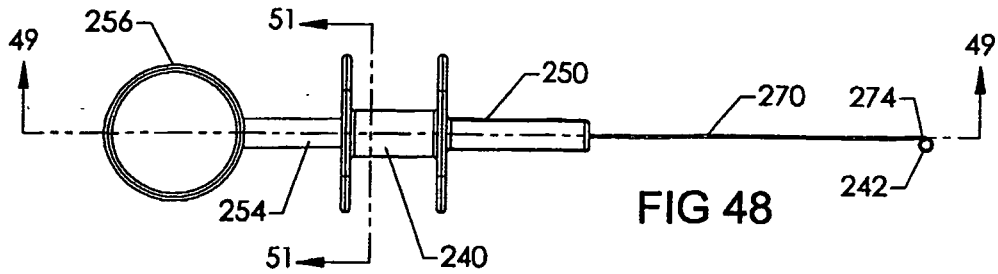


FIG 45



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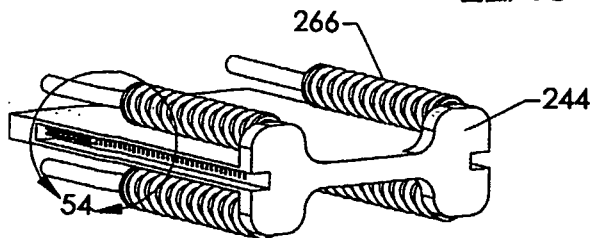


FIG 52

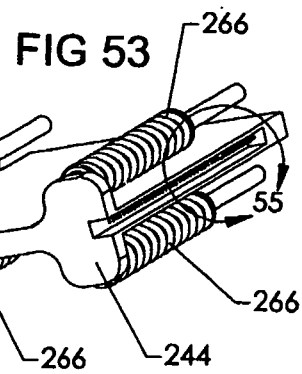


FIG 53

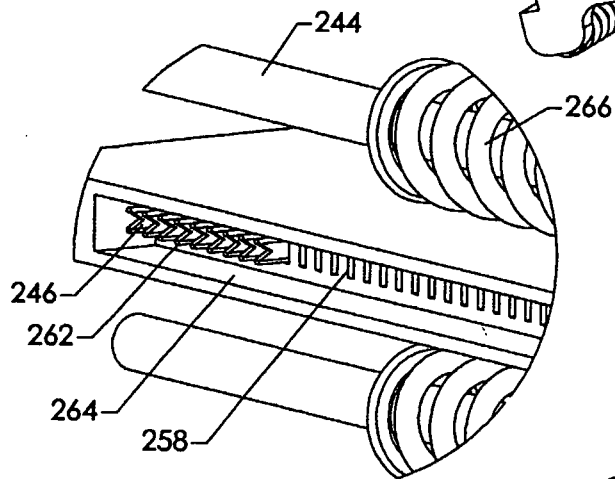


FIG 54

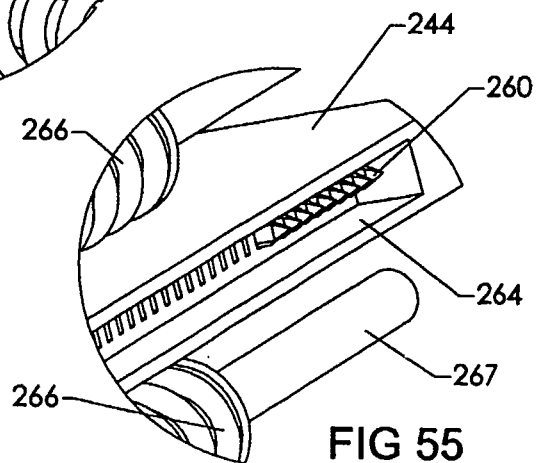


FIG 55

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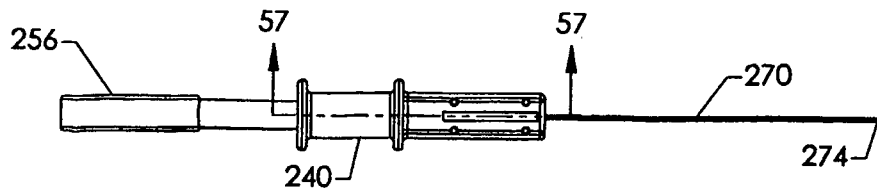


FIG 56

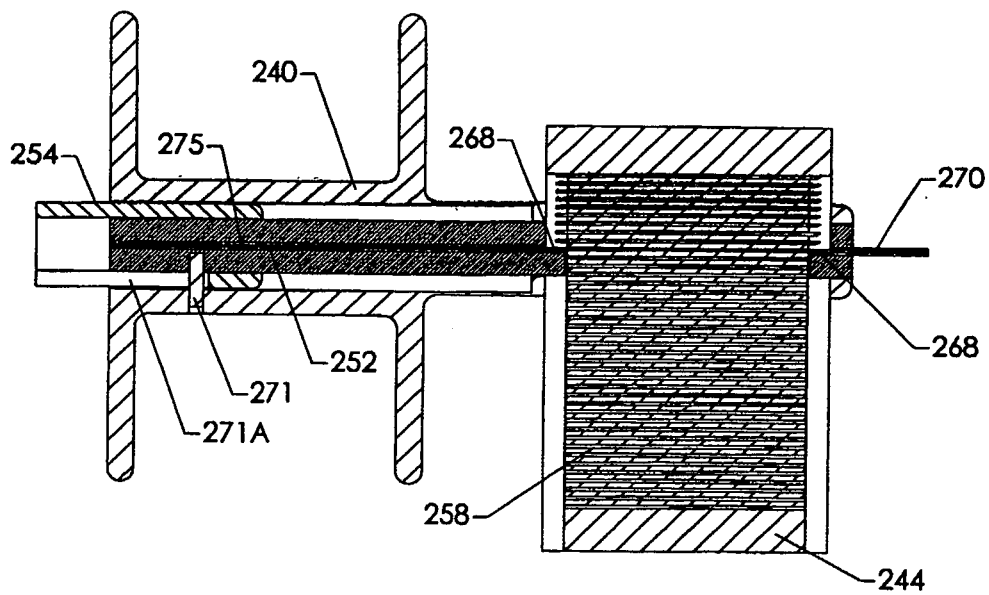
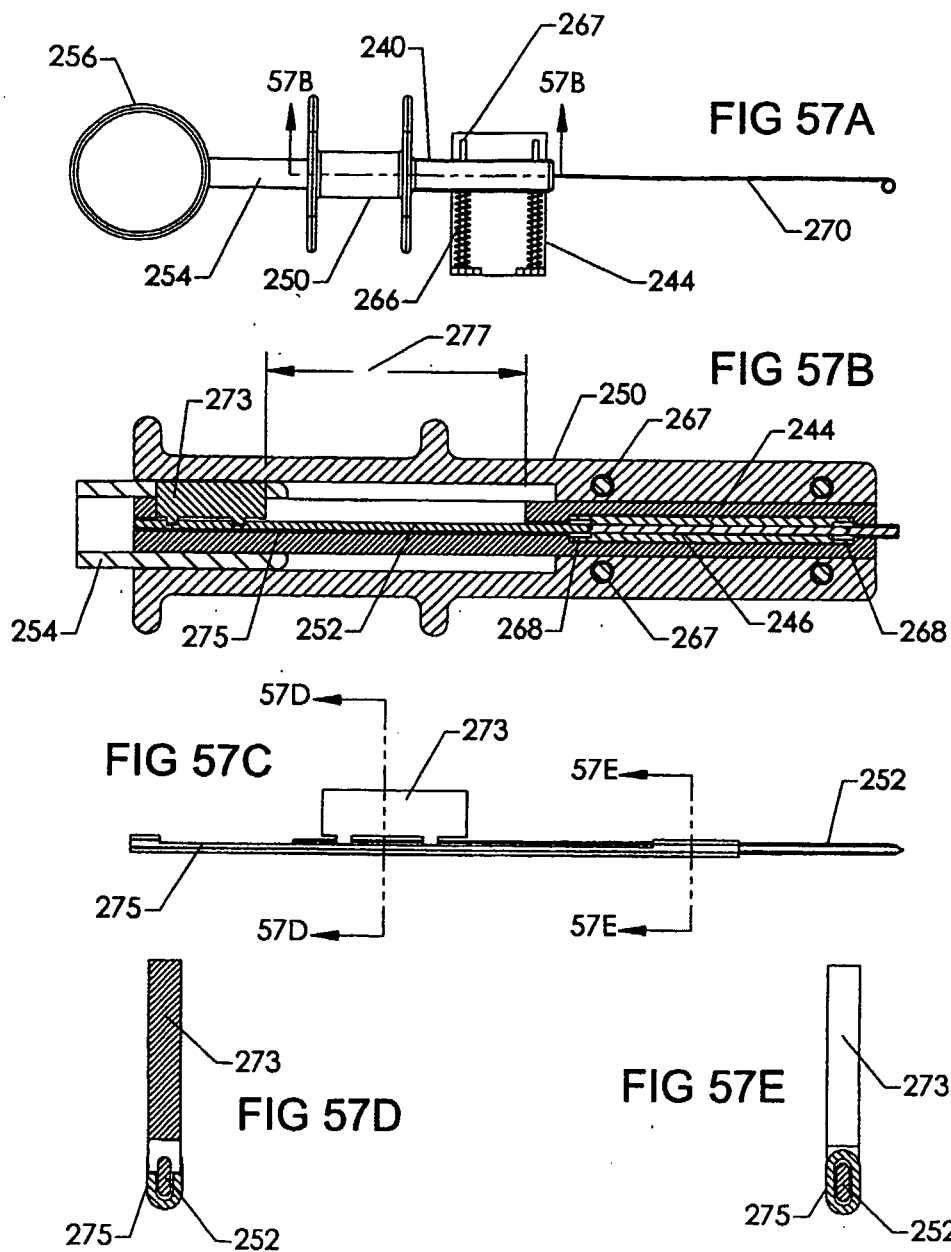


FIG 57

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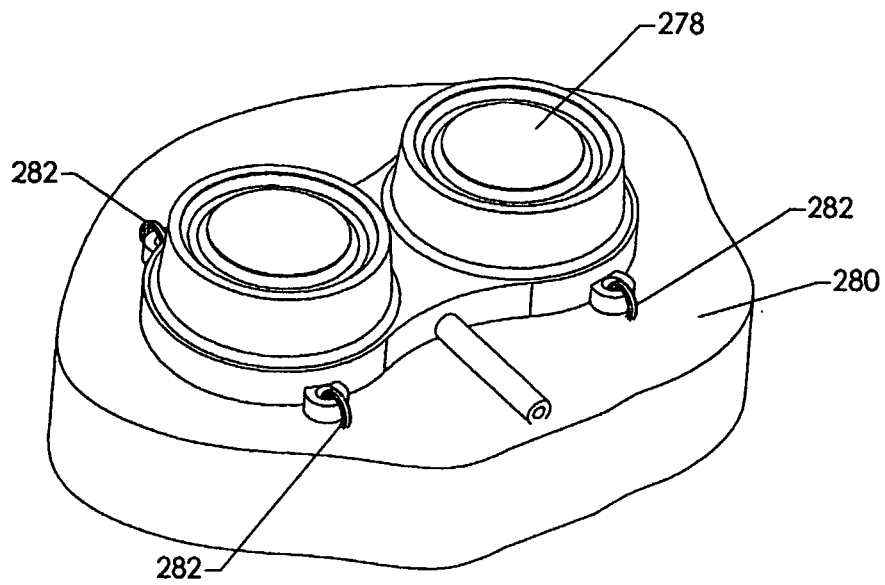
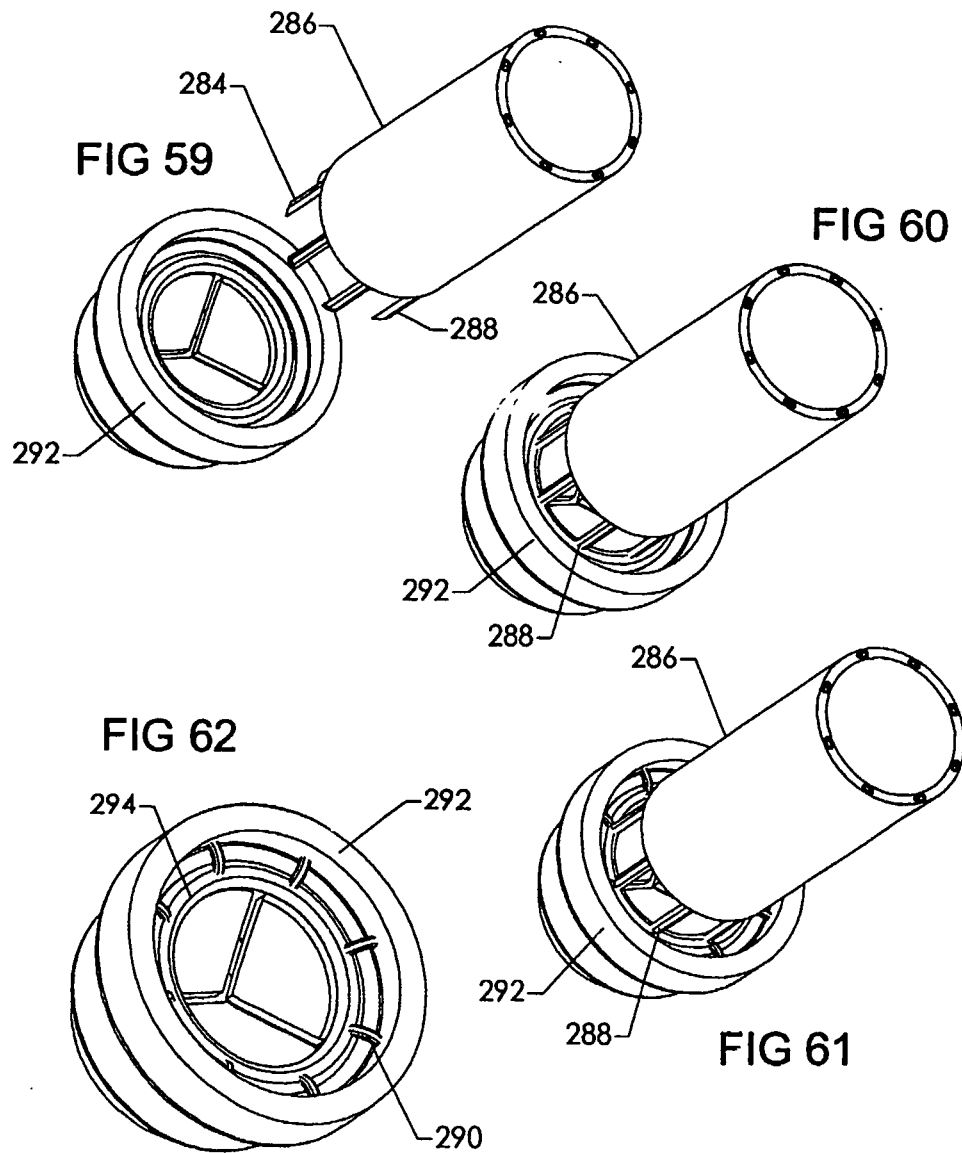
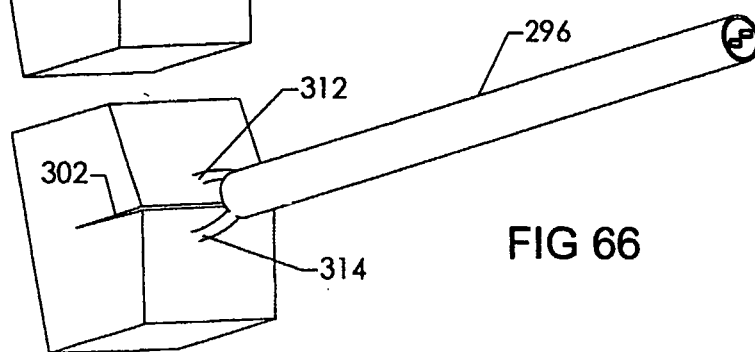
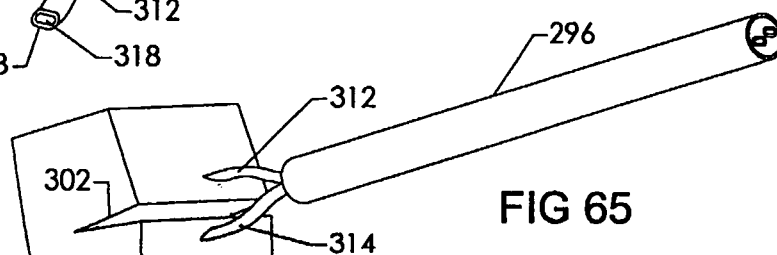
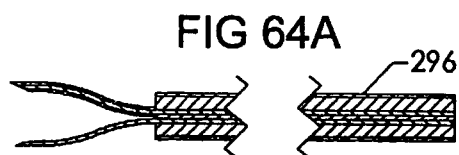
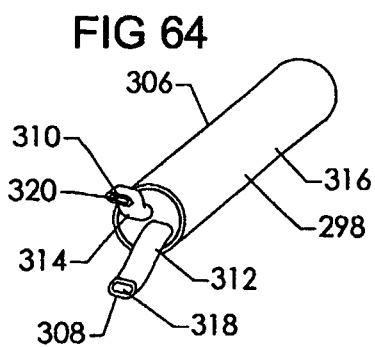
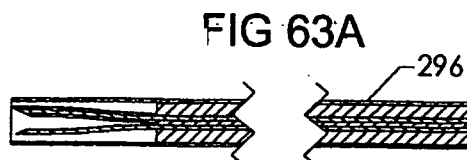
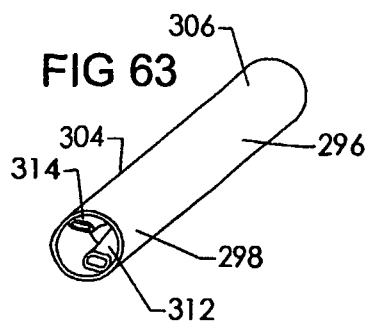


FIG 58

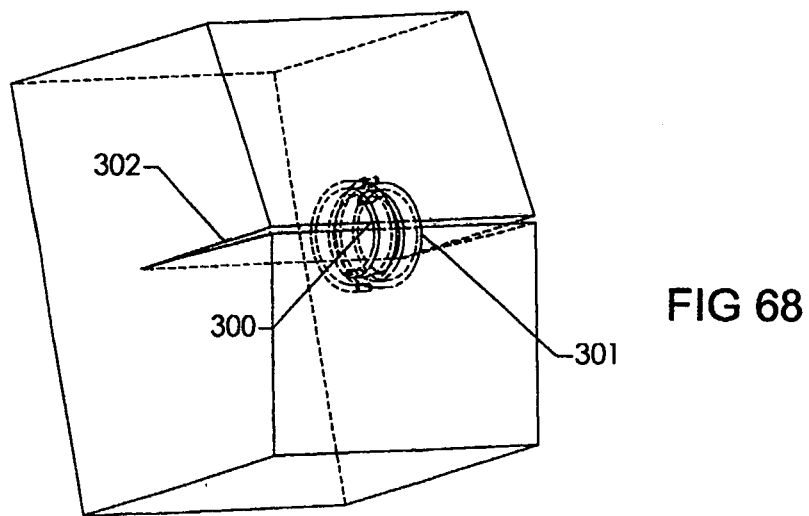
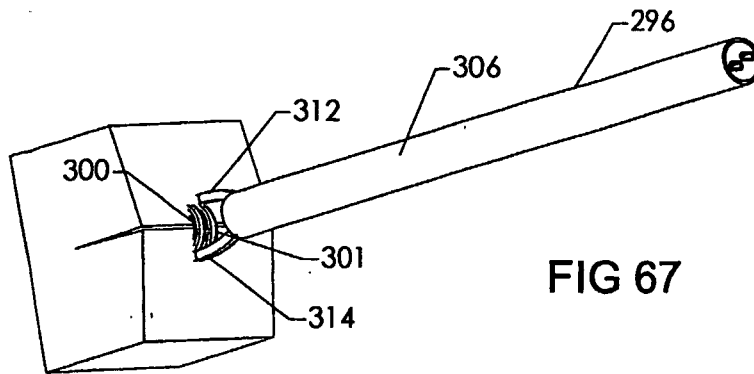
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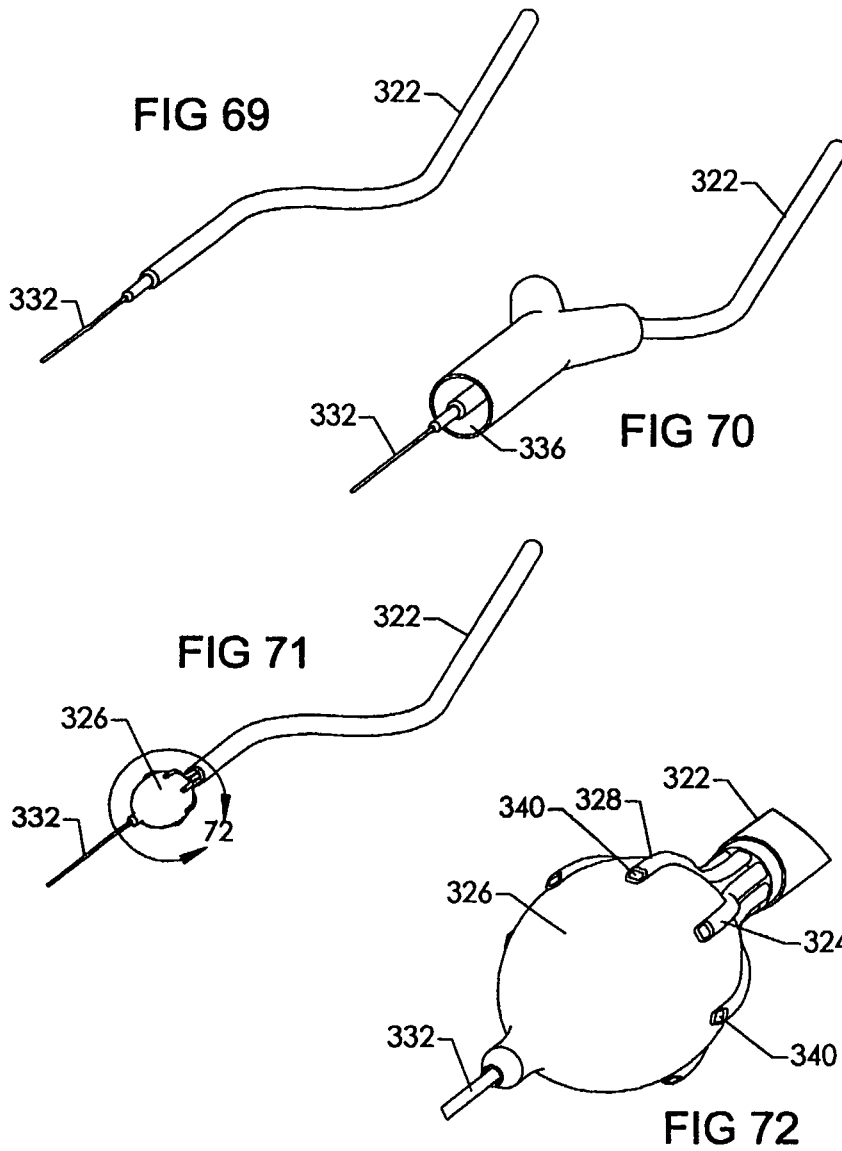
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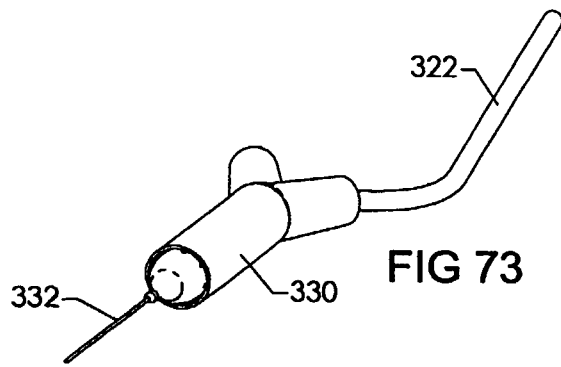


FIG 73

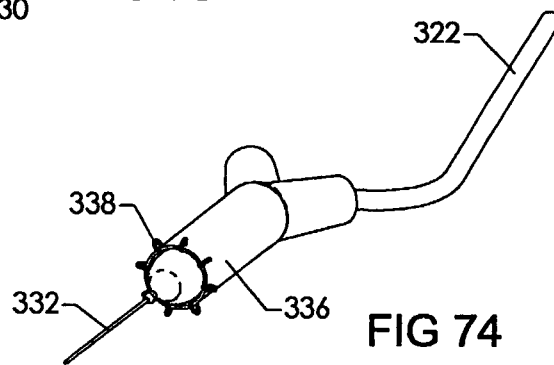


FIG 74

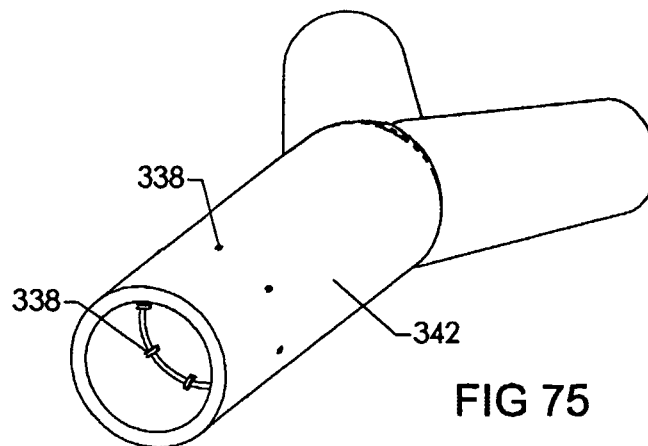


FIG 75

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FIG 76

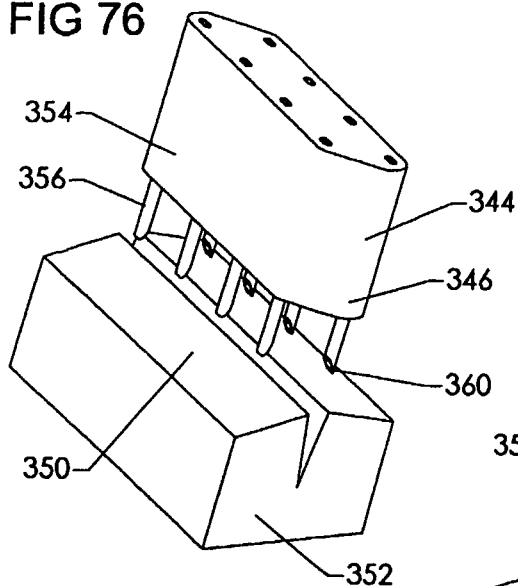


FIG 77

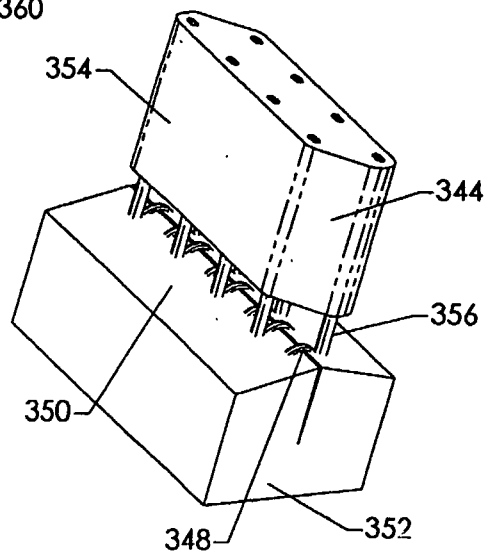
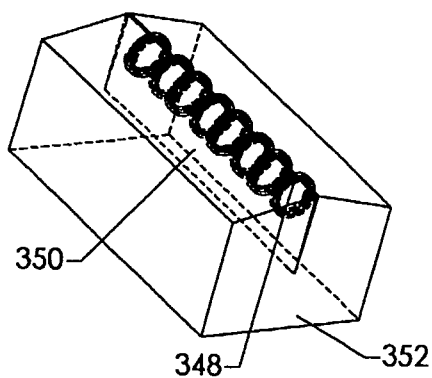
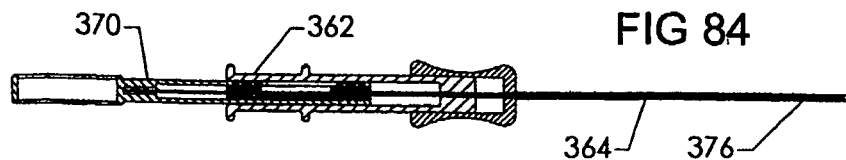
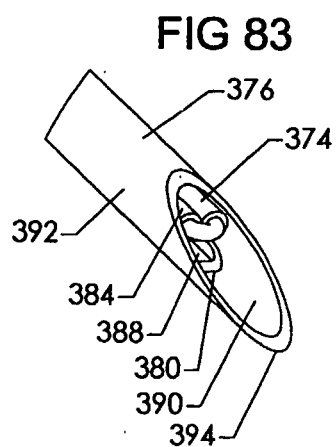
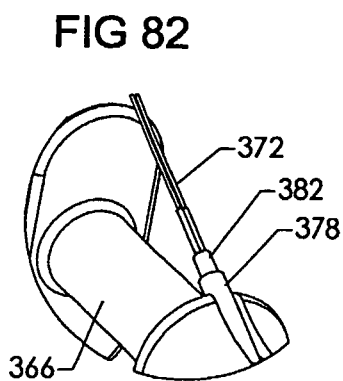
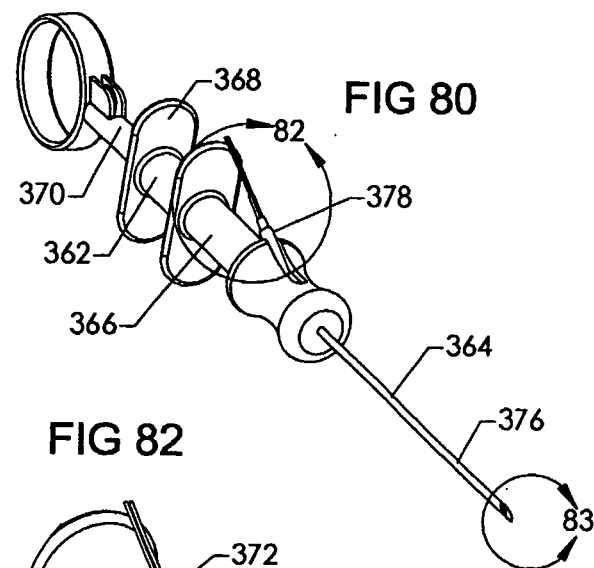
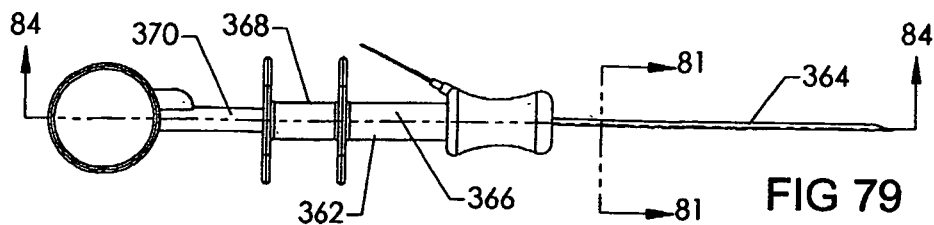


FIG 78



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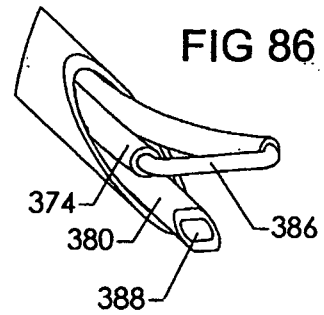
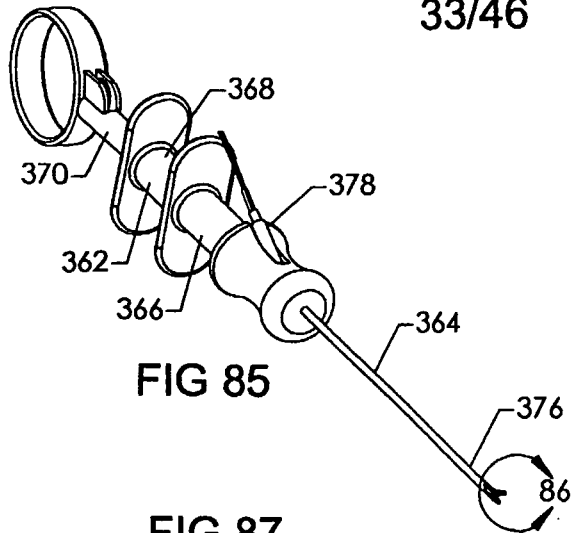


FIG 87

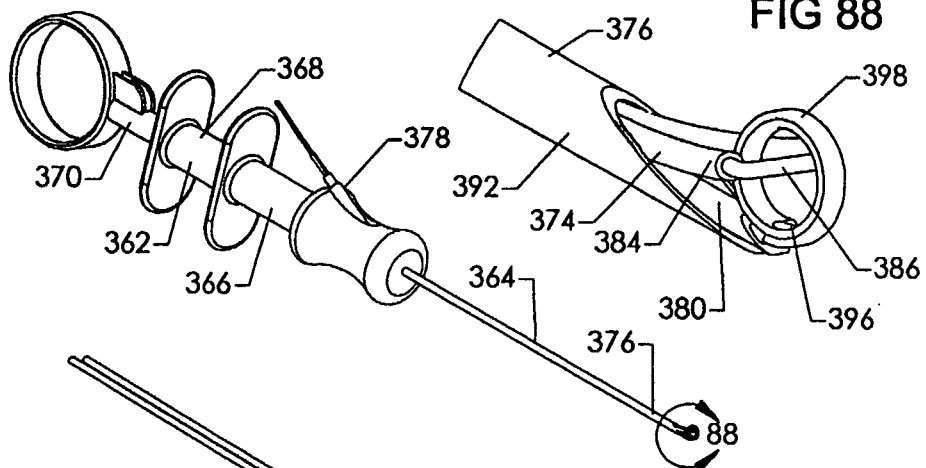
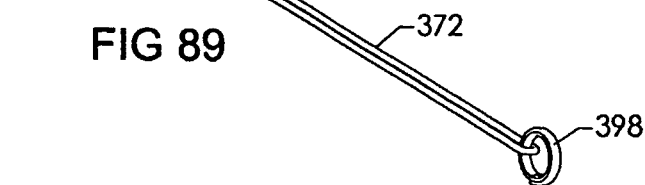


FIG 89



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FIG 90

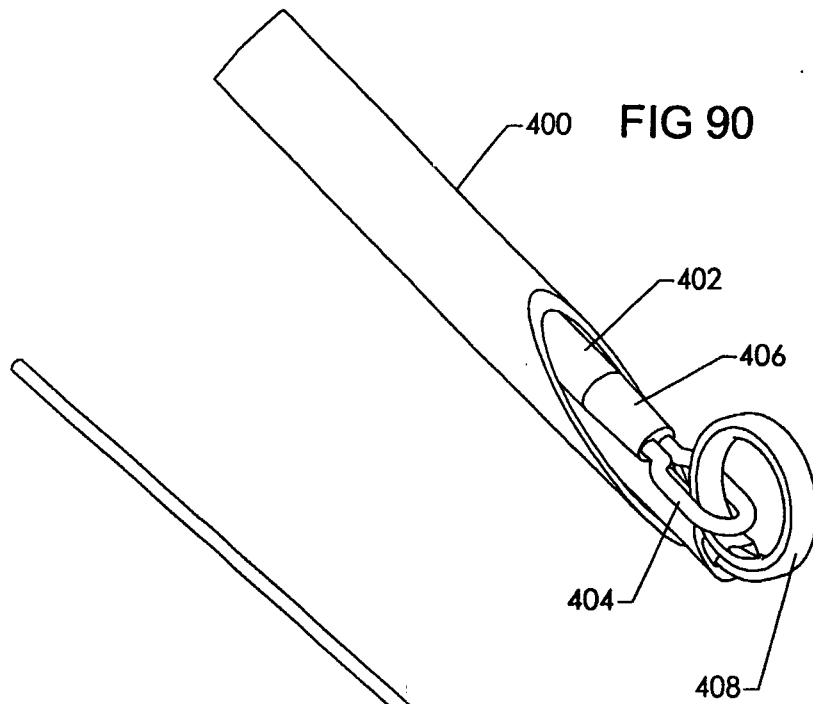
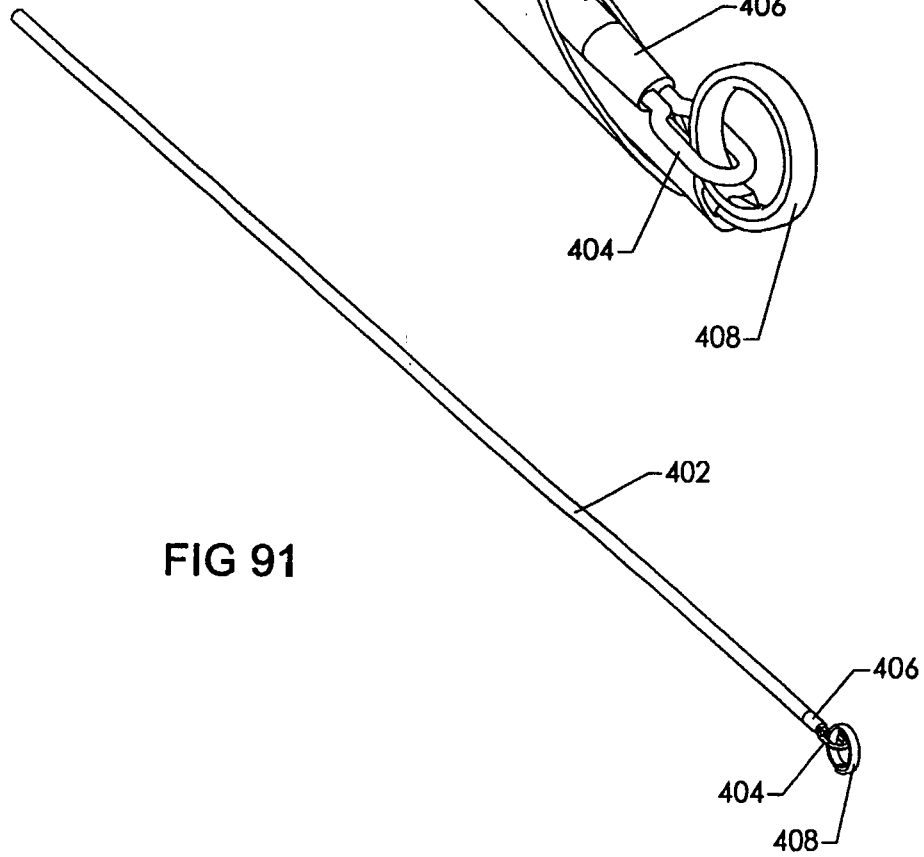


FIG 91



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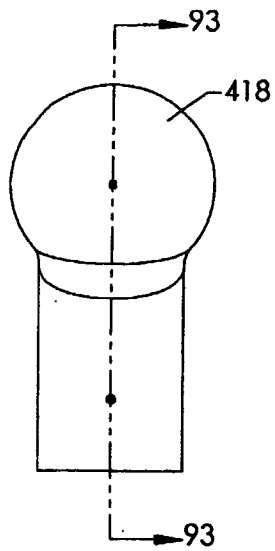


FIG 92

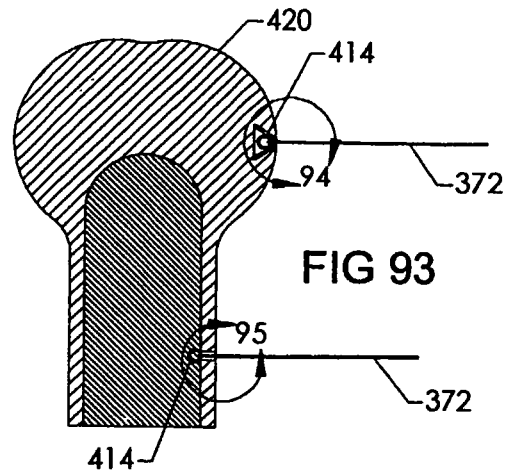


FIG 93

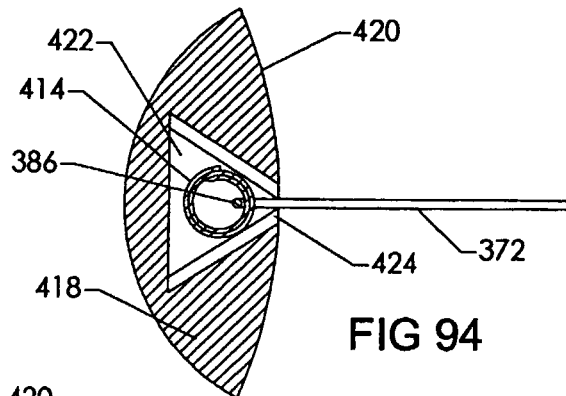


FIG 94

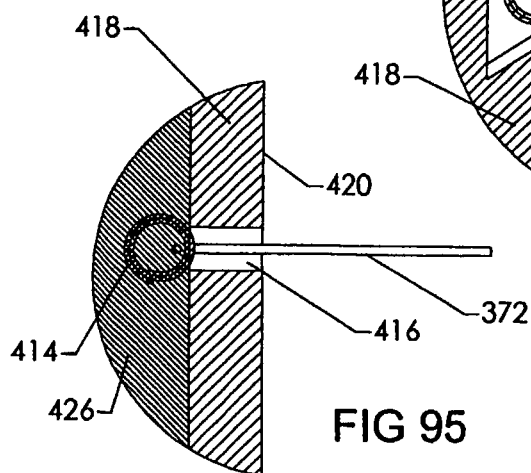


FIG 95

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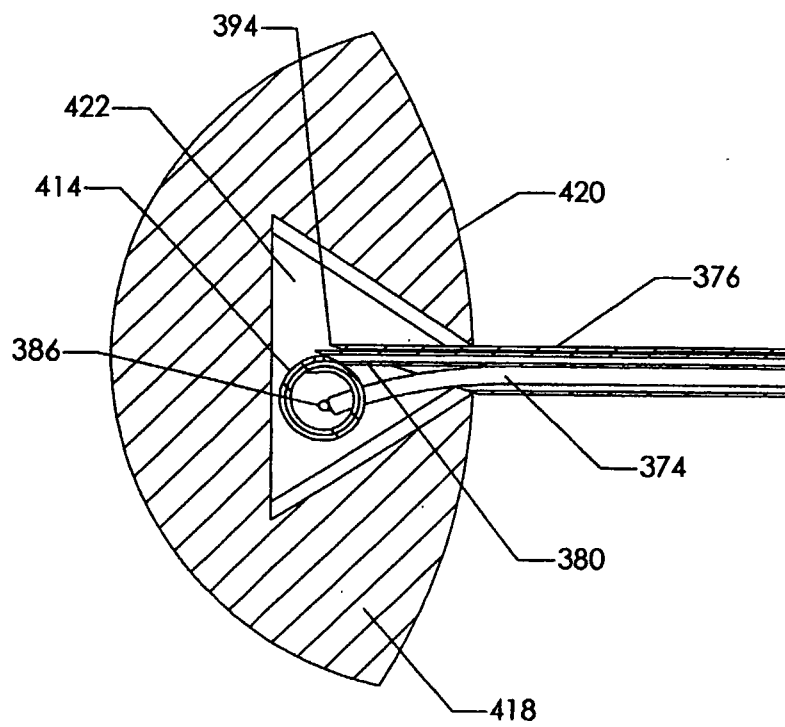
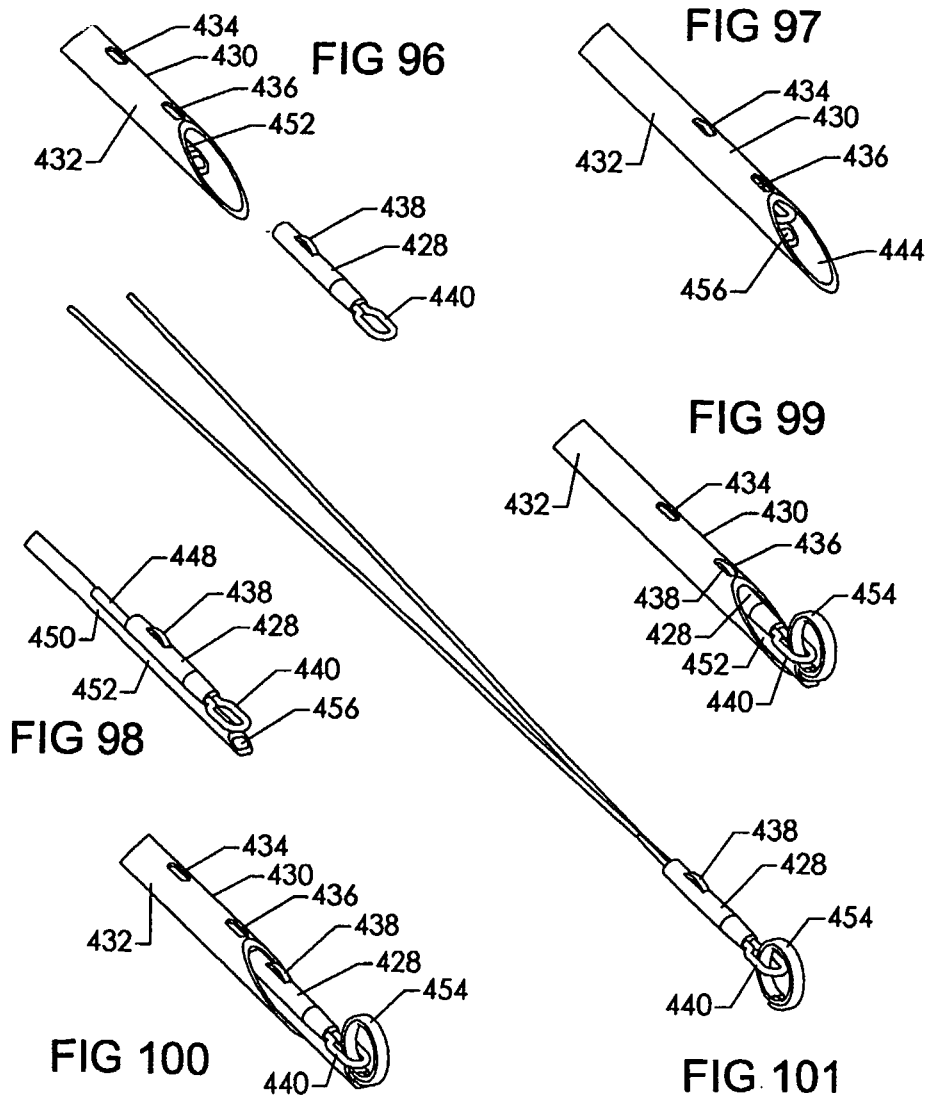
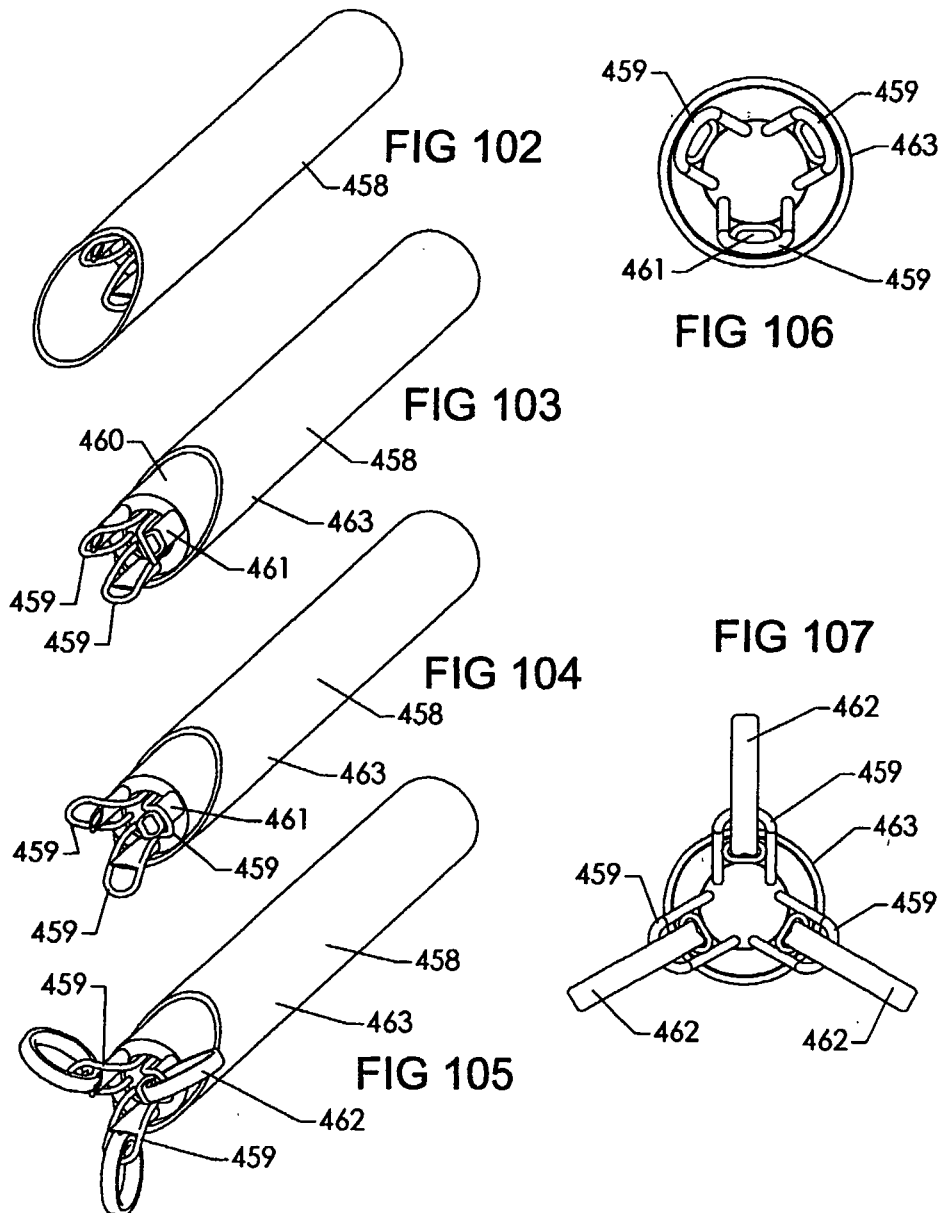


FIG 94A

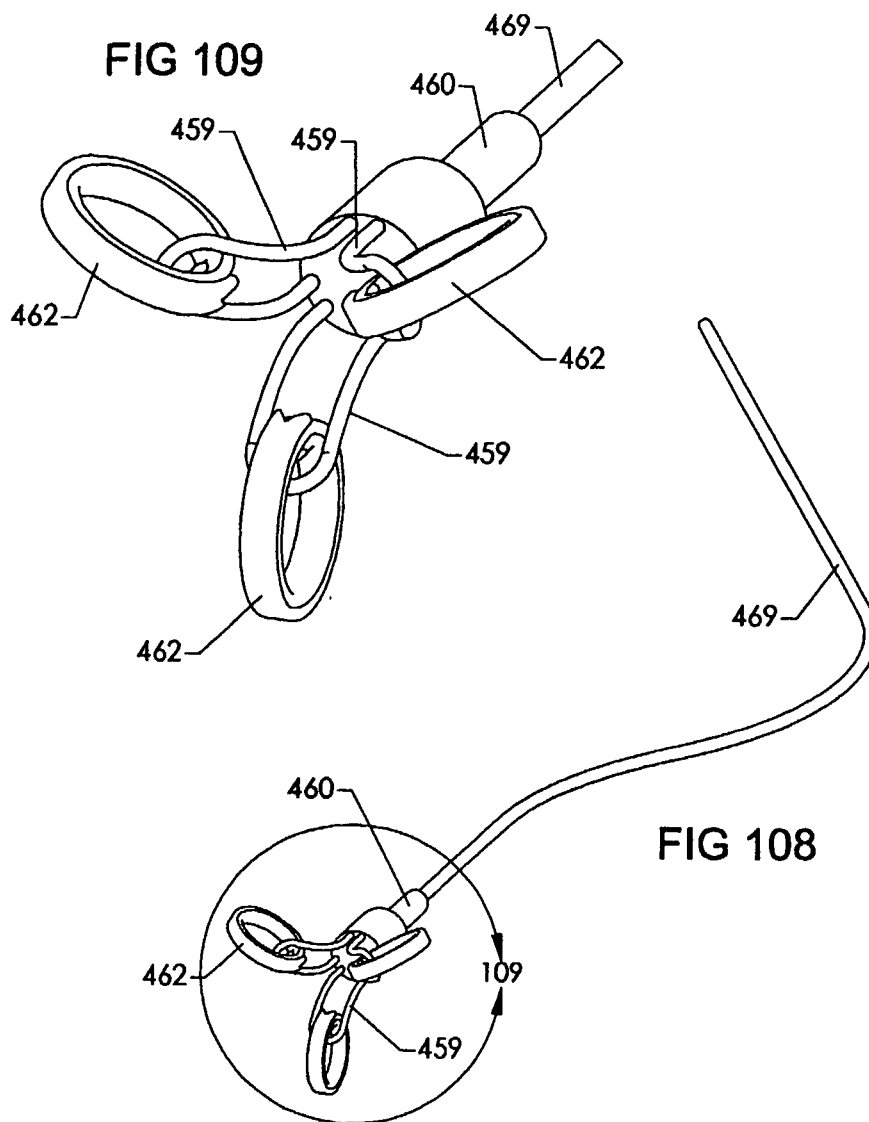
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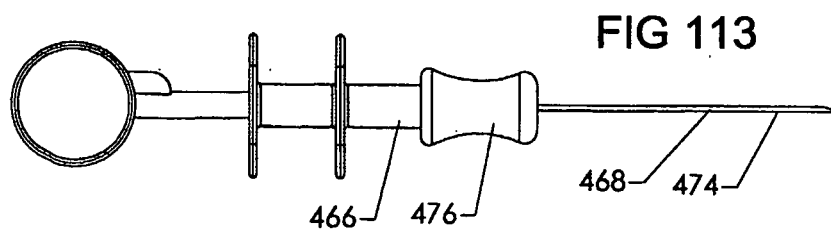
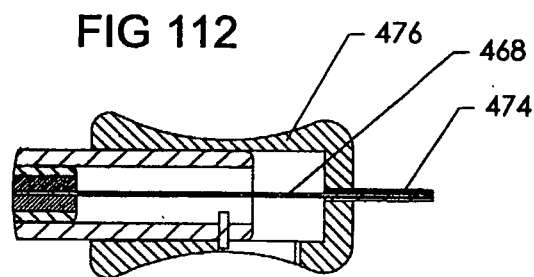
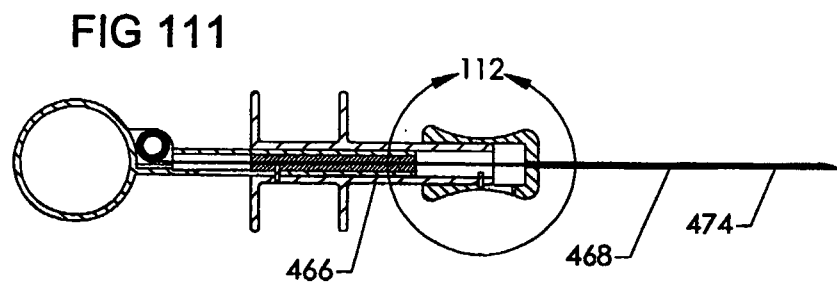
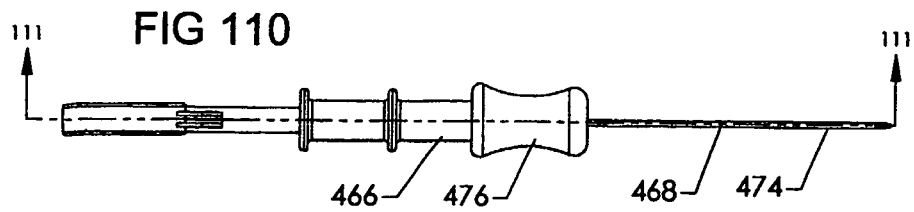
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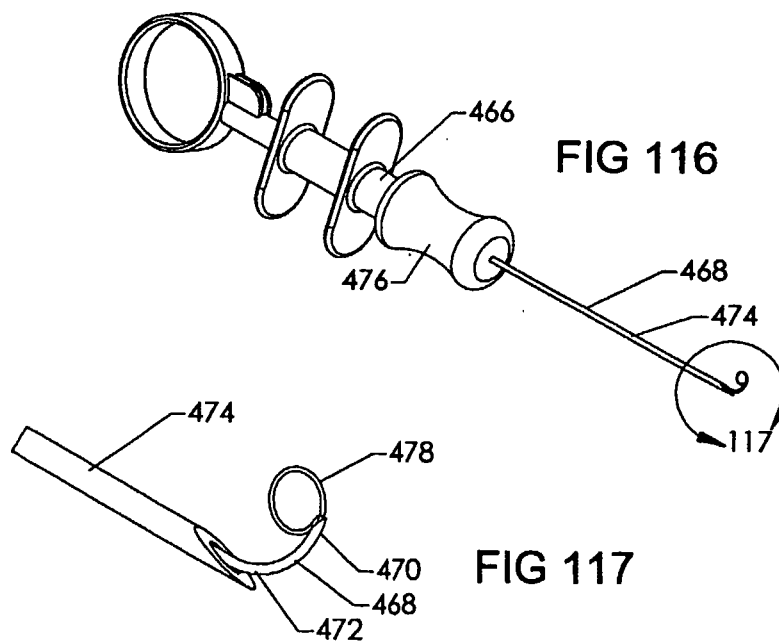
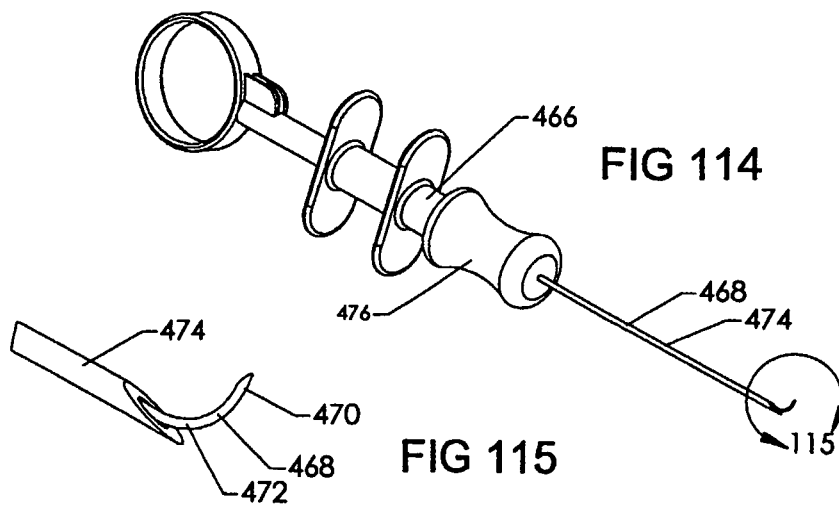
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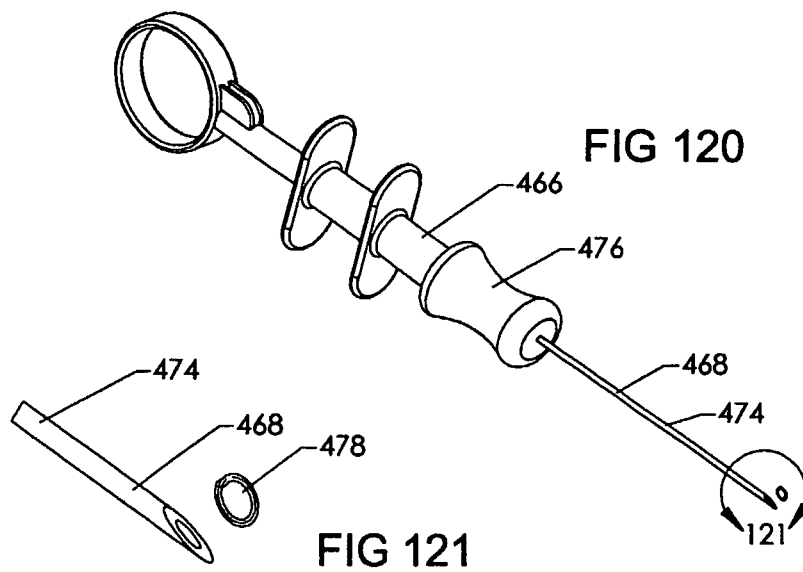
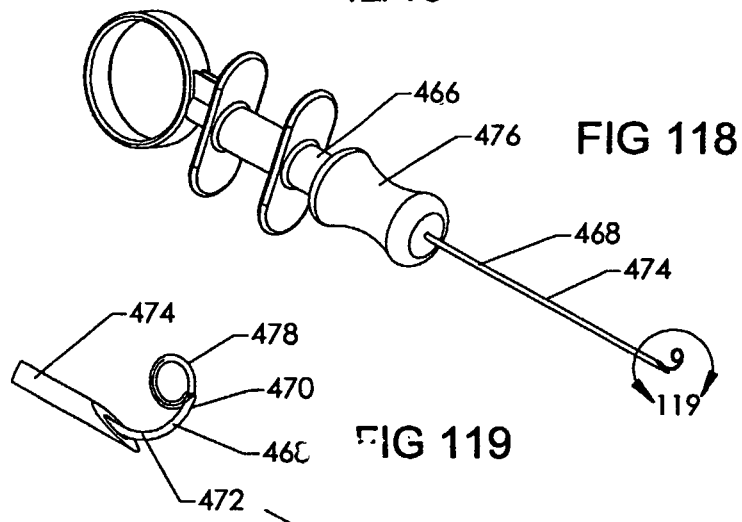
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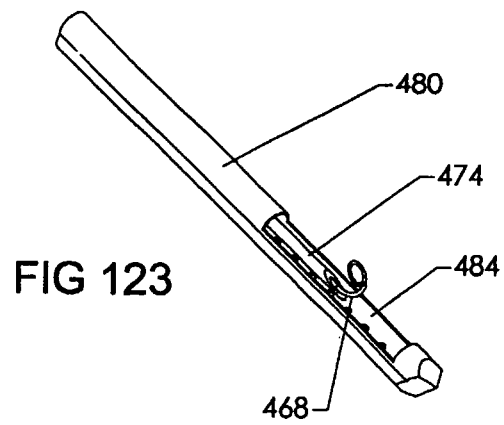
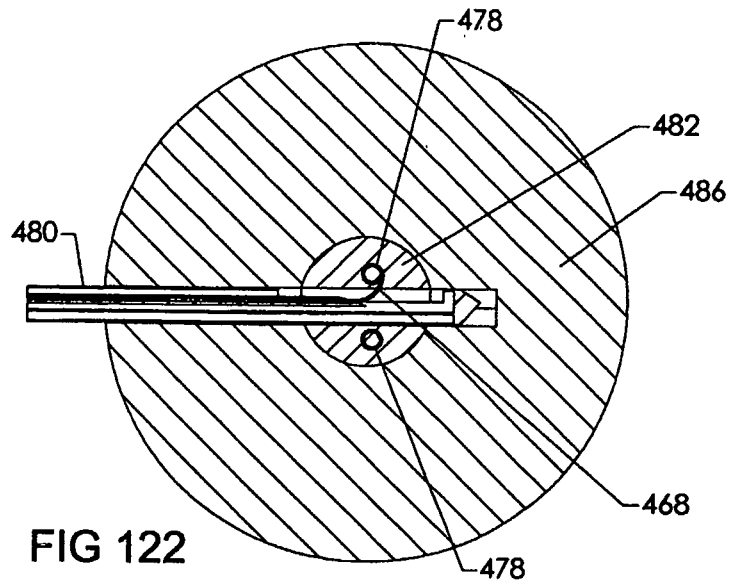
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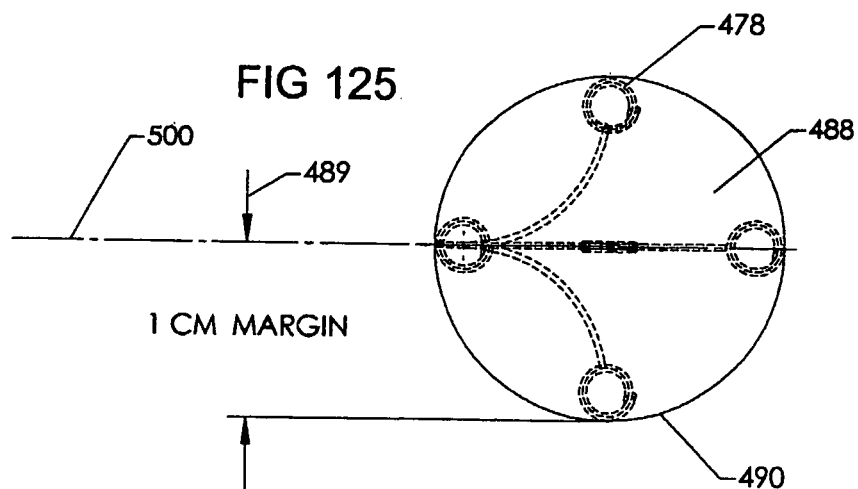
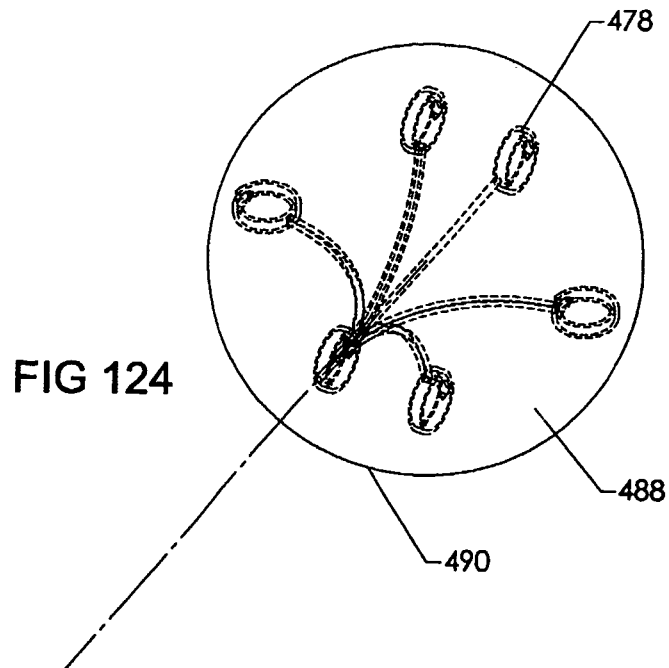
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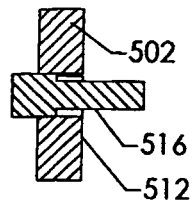


FIG 127

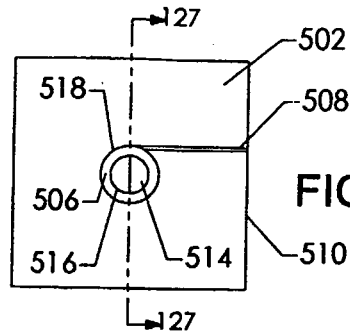


FIG 126

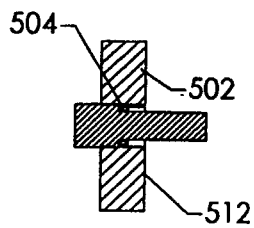


FIG 129

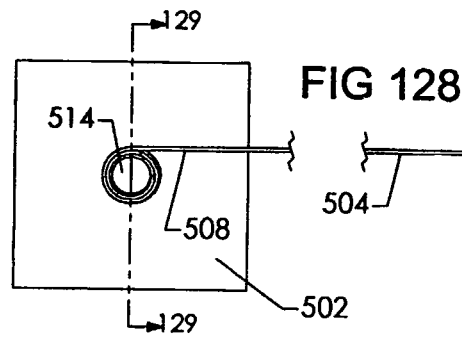


FIG 128

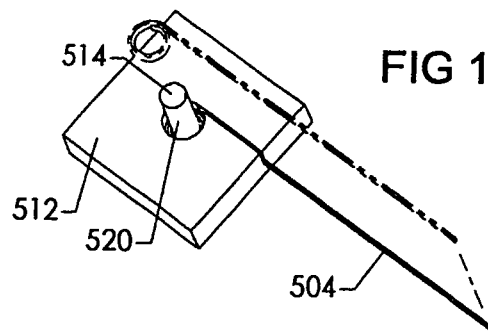


FIG 130

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FIG 131

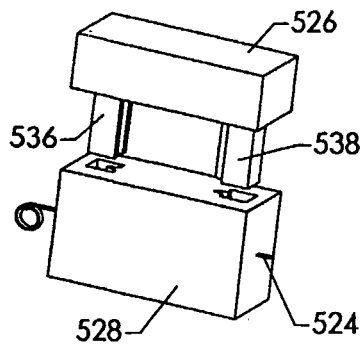


FIG 132

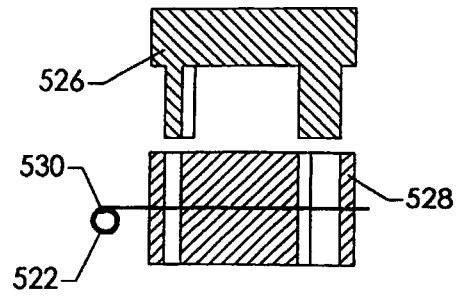


FIG 133

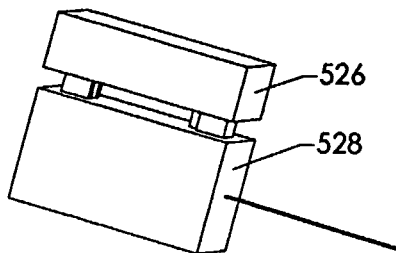


FIG 134

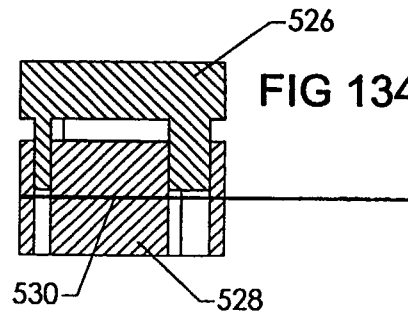


FIG 135

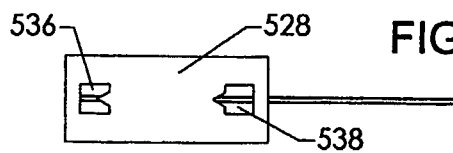
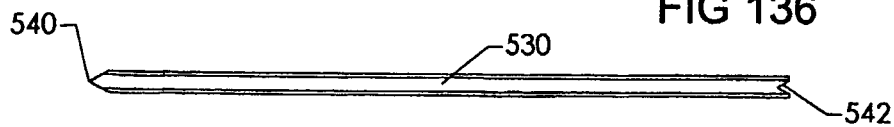


FIG 136



专利名称(译)	手术线圈和部署方法		
公开(公告)号	EP1494611A2	公开(公告)日	2005-01-12
申请号	EP2003744658	申请日	2003-03-10
[标]申请(专利权)人(译)	沃德尔约翰·L·		
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IPC分类号	A61B10/00 A61B10/02 A61B17/00 A61B17/04 A61B17/06 A61B17/064 A61B17/068 A61B17/072 A61B17/22 A61B19/00 A61F2/06 A61F2/24 A61D1/00 A61B17/08		
CPC分类号	A61B17/068 A61B10/0275 A61B17/06109 A61B17/0644 A61B17/072 A61B2017/00867 A61B2017/0409 A61B2017/0414 A61B2017/0416 A61B2017/0443 A61B2017/061 A61B2017/0649 A61B2017/0688 A61B2017/22061 A61B2090/3908 A61B2090/3916 A61B2090/3983 A61B2090/3987 A61F2/07 A61F2/2409 A61F2002/065		
代理机构(译)	绿色，MARK CHARLES		
优先权	60/363106 2002-03-11 US		
外部链接	Espacenet		

摘要(译)

用于标记，锚定，缝合和缝合的外科线圈，其可以通过使其变形为小的横截面轮廓而植入体内，然后使其滑过低轮廓的输送装置，然后从输送装置的实施例部署在目标部位。当展开时，外科线圈的实施例恢复到盘绕构型并且在目标部位处环绕组织。可以围绕附接构件展开，例如缝合线，标记线等，以用于锚固它们。