



(51) International Patent Classification:

A61B 17/00 (2006.01) A61B 17/115 (2006.01)
A61B 17/072 (2006.01) A61B 17/34 (2006.01)

(21) International Application Number:

PCT/US2012/021532

(22) International Filing Date:

17 January 2012 (17.01.2012)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

13/013,147 25 January 2011 (25.01.2011) US

(71) Applicant (for all designated States except US):
ETHICON ENDO-SURGERY, INC. [US/US]; 4545
Creek Road, Cincinnati, OH 45242 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **VOEGELE, James, W.** [US/US]; 11486 Kemperknoll Lane, Cincinnati, OH 45249 (US). **VOEGELE, Aaron, C.** [US/US]; 143 Shoemaker Drive, Loveland, OH 45140 (US).

(74) Agents: **JOHNSON, Philip S.** et al.; One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

[Continued on next page]

(54) Title: SURGICAL INSTRUMENT WITH SELECTIVELY RIGIDIZABLE FEATURES

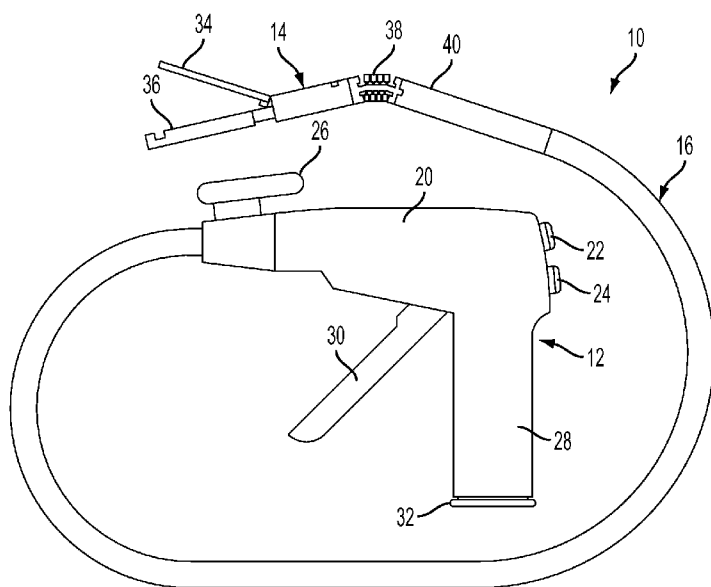


FIG. 1

(57) Abstract: Mechanisms for altering the shape of a cell or chamber of a shaft or an actuation drive of an instrument are provided. The mechanisms may selectively rigidize the shaft of surgical or diagnostic instruments. The shaft assembly includes a shaft operatively connectable to a control member, at least one cell or a set of cells defined within the shaft, a shape altering material contained within the cell or cells, and, an activation link operatively connectable to a source of activation energy for delivering activation energy to each cell for activating the shape altering material to selectively rigidize or unrigidize the shaft. An actuator for producing work is also provided that includes an element within a housing that defines a cell or a set of cells. The shape altering material is contained within the cells, and a source of activation energy operatively connected to each cell for activating the shape altering material to expand or contract the cell. The element is operatively connectable to a driving member of an instrument such that the change in the cell is translated to the driving member to facilitate the production of work.



Published:

— with international search report (Art. 21(3))

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

SURGICAL INSTRUMENT WITH SELECTIVELY RIGIDIZABLE FEATURES

BACKGROUND

i. Field of the Invention

[0001] The present application relates to methods and devices for minimally invasive surgical procedures and, more particularly, to surgical and diagnostic instruments having selectively rigidizable components.

ii. Description of the Related Art

[0002] In minimally invasive surgical and diagnostic procedures, such as laparoscopic surgery, a surgeon may place one or more small ports into a patient's abdomen to gain access into the abdominal cavity of the patient. A surgeon may use, for example, a port for insufflating the abdominal cavity to create space, a port for introducing a laparoscope for viewing, and a number of other ports for introducing surgical instruments for operating on tissue. Other minimally invasive surgical procedures include natural orifice transluminal endoscopic surgery (NOTES) wherein surgical instruments and viewing devices are introduced into a patient's body through, for example, the mouth, nose, vagina, or rectum. The benefits of minimally invasive procedures compared to open surgery procedures for treating certain types of wounds and diseases or for diagnosing certain types of conditions, are now well-known to include faster recovery time and less pain for the patient, better outcomes, and lower overall costs.

[0003] In many case, the site of interest in an internal cavity or lumen of a patient is remote from the entry port or natural orifice and an instrument having a long shaft leading from the external entry port or natural orifice to the site of interest is required. The shaft in many cases has to be flexible to allow it to be maneuvered from the port or orifice to the site of interest. That flexibility can, however, make operation of the tool at the end of the shaft, generally referred to as an end effector, difficult.

[0004] The foregoing discussion is intended only to illustrate various aspects of the related art in the field of the invention at the time, and should not be taken as a disavowal of claim scope.

SUMMARY

[0005] The use of shape altering materials to facilitate the desired functioning of various portions of instruments, such as surgical or diagnostic instruments, is described herein. In various embodiments, a shaft assembly is provided that includes a shaft, at least one cell defined within the shaft, a shape altering material contained within the at least one cell, and, an activation link operatively connectable to a source of activation energy for delivering activation energy to the at least one cell for activating the shape altering material to selectively rigidize or unrigidize the shaft.

[0006] In various embodiments, an actuator for producing work is provided that includes a housing assembly, an element within the housing that has a longitudinal axis and defines therein at least one cell, a shape altering material housed within the at least one cell, and a source of activation energy operatively connected to the cell for activating the shape altering material to effect a change in the size of the at least one cell. The element may be operatively connectable to a driving member of an instrument such that the change in the size of the cell is translated to the driving member to facilitate the production of work.

[0007] In certain preferred embodiments, one or both of the shaft assembly and the actuator may be incorporated into a surgical instrument. In these embodiments, the surgical instrument may include an end effector, a shaft assembly operatively connected to the end effector, at least one cell defined within at least one of the shaft assembly or the end effector, a shape altering material housed within the at least one cell, and, an actuation assembly for selectively activating the shape altering material to effect a change in the at least one cell.

[0008] The shape altering material may be a wax, a polymeric phase change material, a conductive plastic, an expandable foam, or a magneto rheologic fluid.

[0009] The actuation assembly may include a source of activation energy, an activation control member positioned, for example, on a control portion operatively connected to the proximal end of the instrument for selectively applying the activation energy, and a link from the control member to the at least one cell for delivering the activation energy to the cell to activate the shape altering material.

[0010] The activation energy may be light, heat, electricity, magnetism, chemical energy (exothermic or endothermic), or pneumatic energy or hydraulic energy. The source of activation energy may be an external source linked to the activation control member, such as an electric outlet or a source of radiation within a desired range of wavelengths, or an internal storage source for storing activation energy derived from an external source, such as a rechargeable battery, or a self-contained internal source, such as a replaceable battery or pressure sensor.

[0011] In certain embodiments, the shaft assembly may include an elongate shaft having a longitudinal axis and a plurality of cells formed in the shaft with each cell containing an amount of the shape altering material.

[0012] In certain embodiments, each of the plurality of cells may form a discrete pocket. The plurality of pockets may be arranged at intervals along the length of the shaft. In various embodiments, the shaft may be segmented and each pocket of the plurality of pockets is positioned between different adjacent segments along the axis of the shaft wherein selective activation of the shape altering material effects bending of the shaft in a predetermined direction. In other embodiments, the plurality of pockets may be positioned between different adjacent segments along opposing sides of the length of the shaft wherein selective activation of the shape altering material effects bending of the shaft in at least one of two predetermined directions. A further embodiment provides the plurality of pockets positioned between different adjacent segments along three equi-distant lengths of the shaft wherein selective activation of the shape altering material effects bending of the shaft in any predetermined direction through one or more 360° rotations, depending on the pitch and diameter of the shaft.

The plurality of discrete pockets may also be formed into rings around the axis of the shaft.

[0013] In alternative embodiments, each of the plurality of cells may form a column along a portion of the length of the shaft. One or more channels may be formed in the shaft for carrying the activation link to the cells.

[0014] In other embodiments, the shaft assembly may include a plurality of concentric tubes. For example, there may be in various embodiments, a plurality of concentric tubes spaced such that an annular space is defined between adjacent concentric tubes. In various embodiments, there may be an inner tube, and at least one outer tube, and an annular space defined between the inner tube and the adjacent outer tube, wherein the inner tube defines a central lumen along its length. The shaft assembly may include a plurality of elongate flexible columns alternating with a plurality of elongate cells within the annular space. In another embodiment, the shaft assembly may include a plurality of annular solid segments alternating with a plurality of annular cells within the annular space. In another embodiment, the shaft assembly may include a first coil wound in a clockwise spiral positioned within the annular space. Alternatively, or in addition, there may be a second coil wound in a counterclockwise spiral within the annular space. In the embodiment having both the first and the second coil, the coils are positioned adjacent to each other within the annular space. The annular space in this and various embodiments may define the cell containing the shape altering material.

[0015] In certain embodiments of the surgical instrument the at least one cell may be in the end effector, in addition to or instead of, in the shaft assembly. In such embodiments, the end effector may include a housing, an element within the housing having a longitudinal axis and defining therein at least one cell, a plunger movable in an axial direction through the element, wherein the plunger includes a barrier plate for dividing the cell within the element into two chambers. In this embodiment, the shape altering material may be one of the expandable foam or the phase-change material and is housed within at least one of the two chambers. Activation of the shape altering

material effects one of expansion or contraction of the shape altering material to move the plunger in one of a first or a second axial direction through the element.

[0016] In certain embodiments, each of the two chambers may contain a different shape altering material such that activation energy delivered to the two chambers effects expansion of the shape altering material in one chamber and contraction of the shape altering material in the other chamber to assist movement of the plunger in one of the first or the second axial direction. A spring may be provided within the element for biasing the plunger in a desired one of the first or the second axial direction.

[0017] The end effector may be any suitable known end effector, such as a cartridge for holding one or more tissue fasteners, such as staples or clips, wherein the plunger is positioned adjacent the tissue fastener, such that expansion of the shape altering material moves the plunger to eject a tissue fastener from the cartridge.

[0018] The end effector may, for example, be a pair of graspers having expandable jaws, such that expansion of the shape altering material moves the plunger to alter the jaws from one of an open or a closed configuration. For example, expansion may open one or both sides of the jaws and contraction of the shape altering material may move the plunger to close one or both sides of the jaws, or vice versa.

[0019] In certain embodiments, the end effector may include a cylinder defining a cylindrical space therein and having a central axial rod. The at least one cell may be formed within the cylindrical space between first and second end walls, a stationary radial wall attached to the rod, and a movable radial wall rotatably attached to the rod. When the shape altering material, for example, is a phase change material, activation effects a change of phase resulting in one of expansion or contraction of the phase change material thereby effecting rotation of the movable radial wall about the rod for the production of radial motion.

FIGURES

[0020] Various features of the embodiments described herein are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation, together with advantages thereof, may be understood in accordance with the following description taken in conjunction with the accompanying drawings as follows.

[0021] FIG. 1 is an embodiment of a surgical instrument having a shaft in a flexible mode and an end effector.

[0022] FIG. 2 is an embodiment of the surgical instrument of FIG. 1 wherein the shaft is in a rigidized mode, with a flexible configuration shown in chain line.

[0023] FIG. 3 A-A is a cross-sectional view of the shaft through the line A-A of FIG. 2.

[0024] FIG. 4 A-A is a cross-sectional view of an alternative embodiment of the shaft through the line A-A of FIG. 2.

[0025] FIG. 5 is a view of a shaft having a cell in the form of at least one column.

[0026] FIG. 6 is a view of a shaft having an alternative embodiment of cells alternating with solid sections of the shaft.

[0027] FIG. 7 is a partial sectional view of a shaft assembly having inner and outer tube layers with a shape altering material contained in between.

[0028] FIG. 8 is a side sectional view of the shaft configuration of FIG. 7 in a partially flexed or unrigidized mode.

[0029] FIG. 9 is a partial side sectional view of an embodiment of a shaft assembly configuration having inner and outer tubes with a shape altering material contained in between.

[0030] FIG. 10 is a view of the stress relationship for the individual and combined inner and outer tube members of a shaft assembly.

[0031] FIG. 11 is a curve showing the phase change characteristics of one embodiment of the shape altering material.

[0032] FIG. 12 is a view of a magneto rheological shape altering material in a flexible mode in a section of a cell.

[0033] FIG. 13 is a view of the magneto rheological shape altering material of FIG. 12 in a rigidized mode.

[0034] FIGS. 14 A-E are side sectional and cross-sectional views of alternative embodiments of sets of cells having pockets at the junctions of a segmented shaft.

[0035] FIG. 15 is a view of an alternative embodiment of an actuation cell containing a shape altering material in both chambers that effects motion in either of two directions.

[0036] FIG. 16 is a cross-sectional view of an alternative embodiment of an actuation cell containing a shape altering material that effects rotational motion.

[0037] FIG. 17 is a side sectional view and end view of an embodiment of an end effector with an actuation cell.

[0038] FIG. 18 is a side sectional view of a curved shaft having at least two columnar cells.

[0039] FIG. 19 A-D are sectional views of an alternative embodiment of a shaft having one or two coils that spiral around an annular cell in opposing directions.

[0040] FIG. 20 is a partial view of a shaft having a woven coil configuration.

[0041] FIG. 21 is a section view of an embodiment of a surgical stapler on an end-effector of a surgical instrument showing the shape altering material in a contracted

state in a cell under a stapler driver and unused staples in a stapler sled and in an expanded state in the cell under staples that have been pressed into tissue.

[0042] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate various embodiments of the invention, in one form, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DESCRIPTION

[0043] Numerous specific details are set forth to provide a thorough understanding of the overall structure, function, manufacture, and use of the embodiments as described in the specification and illustrated in the accompanying drawings. It will be understood by those skilled in the art, however, that the embodiments may be practiced without such specific details. In other instances, well-known operations, components, and elements have not been described in detail so as not to obscure the embodiments described in the specification. Those of ordinary skill in the art will understand that the embodiments described and illustrated herein are non-limiting examples, and thus it can be appreciated that the specific structural and functional details disclosed herein may be representative and do not necessarily limit the scope of the embodiments, the scope of which is defined solely by the appended claims.

[0044] Reference throughout the specification to “various embodiments,” “some embodiments,” “one embodiment,” or “an embodiment”, or the like, means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases “in various embodiments,” “in some embodiments,” “in one embodiment,” or “in an embodiment”, or the like, in places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the

features structures, or characteristics of one or more other embodiments without limitation.

[0045] It will be appreciated that the terms “proximal” and “distal” may be used throughout the specification with reference to a clinician manipulating one end of an instrument used to treat a patient. The term “proximal” refers to the portion of the instrument closest to the clinician and the term “distal” refers to the portion located furthest from the clinician. It will be further appreciated that for conciseness and clarity, spatial terms such as “vertical,” “horizontal,” “up,” and “down” may be used herein with respect to the illustrated embodiments. However, surgical instruments may be used in many orientations and positions, and these terms are not intended to be limiting and absolute.

[0046] As used herein, the term “biocompatible” includes any material that is compatible with the living tissues and system(s) of a patient by not being substantially toxic or injurious and not causing immunological rejection. “Biocompatibility” includes the tendency of a material to be biocompatible.

[0047] Body temperature as used herein means core body temperature, which is generally about 98.6 °F (37.0 °C) measured orally, but can vary depending upon factors such as exercise, sleep, food or drink consumption, the time of day, or the age or health of the individual. Adult body temperatures below about 95 °F and above about 106 °F are dangerous to life and health. Children’s body temperatures vary over a larger range. Those skilled in the art will recognize that “body temperature” is a range of temperatures around 98.6 °F (as measured orally), greater than 95 °F and less than 106 °F.

[0048] As used herein, the term “longitudinal axis”, with respect to an instrument, means the exact or approximate central axis defined by said instrument along its greater dimension, i.e., along its length, from its distal end to its proximal end, and vice versa, and is not intended to be limited to imply a straight line, wherein, for example, an instrument includes a bend angle or curves as described herein, it is intended that

"longitudinal axis" as used herein follows such bend angle or curve. As used herein, the term "axial" or "axial movement" or variants thereof, with respect to an instrument or a component of an instrument, means the movement in the direction of the longitudinal axis of such instrument.

[0049] As used herein, the term "patient," used herein, refers to any human or animal on which a surgical procedure may be performed. As used herein, the term "internal site" of a patient means a lumen, body cavity or other location in a patient's body including, without limitation, sites accessible through natural orifices or through incisions.

[0050] As used herein, the term "operatively connected" with respect to two or more components, means that operation of, movement of, or some action of one component brings about, directly or indirectly, an operation, movement or reaction in the other component or components. Components that are operatively connected may be directly connected, may be indirectly connected to each other with one or more additional components interposed between the two, or may not be connected at all, but within a position such that the operation of, movement of or action of one component effects an operation, movement or reaction in the other component in a causal manner.

[0051] The use of shape altering materials to facilitate the desired functioning of various portions of instruments, such as surgical instruments, is described herein. The shape altering material may be a wax, a polymeric phase change material, a shape memory material, an expandable foam, a magneto rheologic fluid, or a Ferro fluid. Waxes and polymer formulations, for example, can respond to activation means such as temperature, light, electrical, chemical that cause a phase change and results in expansion of the material or rigidization to change the shape of a cell or other chamber in which the material is contained.

[0052] For ease of description, the various embodiments will be shown as used with a surgical instrument, such as that shown in Fig. 1. Those skilled in the art will appreciate, however, that the shaft assembly described herein may be used with any

instrument in which it would be advantageous to selectively rigidize all or portions of an otherwise flexible shaft, or to unrigidize all or portions of an otherwise rigid shaft, or to change the rigidity of the shaft along portions thereof while in use to accommodate changing requirements, all from a control member remote from the portion of the shaft to be changed. Rigid, rigidity, or rigidize as used herein shall mean holding or maintaining a shape. Those skilled in the art will appreciate, however, that “rigid” and “unrigidize” and the like are relative terms. Rigidity, or lack thereof, is characterized by a load being distributed across the component, such as the shaft 16 described herein. Thus, rigidization by using the shape altering materials can create proportional control resulting in relatively stiffer but not necessarily completely rigid shafts having steel-like stiffness. Rigidization may also result in a completely rigid shaft 16. Rigid, rigidity, or rigidize and unrigidize or flexible, and similar terms as used herein shall include such relative increases and decreases, respectively, in stiffness and the ability to hold or maintain a shape.

[0053] Similarly, the actuator described herein for use with an end effector of a surgical instrument may be used to produce work in a similar manner in other working instruments. The two can be combined into one instrument allowing tissue access and subsequent end effector manipulation to gain tissue access for manipulation, diagnosis, or treatment.

[0054] In certain preferred embodiments, one or both of the shaft assembly and the actuator may be incorporated into a surgical instrument. In these embodiments, the surgical instrument may include a control portion, an end effector, a shaft assembly positioned between, and operatively connected to each of, the control portion and the end effector, at least one cell defined within at least one of the shaft assembly or the end effector, a shape altering material housed within the at least one cell, and, an actuation assembly for selectively activating the shape altering material to effect a change in the at least one cell. The various features may be integral in a single device, or may be separate but integrated for ease of replacement or interchangeability. For example, a single control member may be releasably attachable to a variety of different

types of end effectors and each may be releasably attachable to a variety of different shaft assemblies.

[0055] Referring to Fig. 1, a surgical instrument 10 is shown having a control member 12, a shaft 16 and an end effector 14. Any suitable end effector 14 may be used, such as a grasper, retractor or dilator, or no end effector may be used when the function of the shaft, for example, is to provide a channel for delivery of other items to a site within a patient. The illustrative end effector 14 shown in Fig. 1 is a stapler having upper and lower clamp jaws 34, 36, a rotating joint 38 for adjusting the position of the jaws 34, 36, and a drive portion 40.

[0056] Control member 12 may include a control housing 20 and a hand piece 28 with a lever 30. The control member 12 may be used to direct the angle and degree of bend in the shaft 16 and to control the work of the end-effector 14. For example, the lever 30 may be squeezed to a desired degree to effect the change in rigidity of the shaft 16 or the operation of the end effector 14. Control knobs 22, 24 and a head control dial 26 are provided in addition to lever 30 for controlling various functions of the end effector 14 or shaft 16, such as, for example, opening and closing of the jaws 34, 36, rotating the rotating joint 38, forming and ejecting a staple, or clipping, cutting, and manipulating tissue, effecting the rigidity of the shaft 16, lighting an internal body cavity or lumen, and the like. A battery compartment 32 is provided to house a rechargeable or replaceable battery. Any standard battery for use with surgical or diagnostic instruments may be used.

[0057] Fig. 2 illustrates schematically a general embodiment of the internal electronics within the control member 12. An on-off switch 44 triggers the flow of activation energy, such as an electric current, through wires 48 through the shaft 16 (and in some embodiments, the cells 116 (e.g., Figs. 3, 4, 7, 8 etc.), described in more detail below, positioned in the shaft) to the end effector 14. A light 42 may be provided to signal whether the power is on or off. A gauge 18 may be provided to show the level of power being delivered. A contact, such as ring contact 46 at head control dial 26 may be provided to further control the direction of the flow of activation energy to wires 48.

[0058] Those skilled in the art will recognize that other electronic configurations may be used and that other means of control may be used to deliver activation energy where needed in the instrument 10. The sources of activation energy may be provided by tethered means, such as electricity, in any appropriate voltage or current needed, delivered through a standard cable or wire plugged into a wall outlet or power strip to a heating element. A source of activation energy may also be provided by fluid in the form of pneumatic or hydraulic pressure, also delivered through a cable or tubing from a pressurizable source of gas (e.g., CO₂ or Argon) or liquid (e.g., pumped saline). Tubing connects to passages such as passages 118 shown in Fig. 4A-A, that egress through external holes. The media flow heats or cools the shaft, and may be the only temperature change agent or may be combined with other temperature change agents, for example, to cool a heat element. A source of activation energy may also be provided by light delivered in any wavelength suitable for use as activation signals. Fiber optics in passages with light reactive material may be turned on or off by turning off the light source or block the light path.

[0059] Activation energy may also be provided by untethered means, such as a built in or removable, replaceable battery, or a sensor, such as a piezo electric sensor, for generating signals in response to changes in pressure or motion. A handle may contain a component comprising a floating magnet within a coil (moves when handle is shaken) to create a flow of electrons that charges a capacitor for electrical dispensing i.e. to a heating coil. Untethered activation energy may also be provided by chemical energy generated, for example, from an exothermic or endothermic chemical reaction when two or more reactants, separated by suitable known means, are brought together. Passages 118 may contain reagents with a divider element that when removed, punctured, or otherwise breached, allows the reagent to mix and the reaction to take place. While reversible materials are commercially available and will be known to those skilled in the art, a one way reaction may be more practical in certain applications.

[0060] A base charged source of activation energy which stores energy from external source may also be provided in the form of a rechargeable battery, induction/capacitive coupling. For example, coils in a handle and base can be structured to act like a

transformer allowing a current to flow and charge a capacitor for electrical dispensing *i.e.* to a heating coil. Another form of based charged source of activation energy may be provided by heat transfer, that is a heat or cold sink in the handle or shaft of the instrument is charged and moved to make or break contact with an element having phase change property.

[0061] The shaft 16 is shown in a curved mode in Fig. 1 and in both linear mode in Fig. 2. Phantom chain lines in Fig. 2 show an alternative configuration wherein portions of shaft 16 may be linear and portions curved to allow the shaft 16 to bend and curve where needed to accommodate the anatomical configuration of the patient at the site of a procedure or along the path to the site of a procedure. Curvature of the shaft 16 may be in a two or three dimensional orientation or both. While in the rigid mode, the shaft 16 of an instrument 10 holds its position to create a fixed linear, curved, or serpentine path as needed for mechanical controls or accommodating a patient's anatomical features. In the flexible mode, the shaft 16 can be manipulated to a desired shape without trauma to the tissue as well as allowing easier passage through a patient's body cavity or lumen if needed.

[0062] In various embodiments of shaft 16, cells 116 are provided that contain a shape altering material. In Figs. 3 A-A and 4 A-A, alternative embodiments of a shaft configuration taken through the line A-A of Fig. 2 are shown. In Fig. 3 A-A, the shaft 16 has a central lumen 114 along the longitudinal axis 200 of shaft 16, and one cell 116 or one set of cells 116 along one side of shaft 16.

[0063] An actuation link 48, such as a wire for transmitting electrical or heat generating energy, a cable for delivering light at a desired wavelength, or a channel for delivering a pneumatic or hydraulic fluid, runs through cell 116 or set of cells 116 to deliver activation energy to each cell 116 to activate the shape altering material to effect a change in the material and thereby, a change in the rigidity of cell 116 or of one or more of the pockets 124 within the set of cells 116. See, for example, Figs. 6. The type of activation energy required will depend on the type of shape altering material used.

[0064] The shape altering material may be activated by heating when, for example, the material is a phase change material or a wax. An example of heating the phase change material or wax includes winding the activation links 48, in the form of heating elements, such as wires, around the cell 116, with the wire entering at one end of the cell 116 and exiting at another end, and winding around the cell 116 in between the entry and exits, similar to the winding of a thread in a bobbin. In another example, activation links 48 may be wound around an independent structure instead of the cell 116, but operatively linked to the cells 116 to transfer the heat to the phase change material or wax. In another example, a conductive heat resistive matrix may be formed where conductive particles are dispersed throughout the phase change material in the cell 116 and heated by application of heat to the cell 116 to spread the heat throughout the phase change material. In another embodiment, the heating elements 48 may be in the form of a self supporting coil within the phase change material.

[0065] In Fig. 4 A-A, shaft 16 has a central lumen 114, two cells 116 or two sets of cells 116 on opposite sides of shaft 16, and two passages 118 for carrying the activation links 48 through the shaft 16. The activation links 48 in this embodiment may branch off at intervals to enter each cell 116 to activate the shape altering material. The passages 118 also allow for passage of activation links 48 for end-effector controls, such as: the mechanical operation of jaws, knives, and staples, as well as the delivery of energy in any suitable form, and any combination thereof. A multi-lumen shaft 16 for example, allows for both fluid delivery for pneumatic or hydraulic control, and other activation links 48, such as wires or sensors, as appropriate.

[0066] The central lumen 114 may also be used to deliver surgical tools or instruments, such as sutures, cameras, blades, and graspers, to a site of interest. In various embodiments, shaft 16 may not have a central or an off set lumen, but may be used to deliver an end effector 14 attached to the end of shaft 16. In such a solid embodiment, cells 116, with or without separate passages 118 for activation links 48 may define the only cavities or open spaces in the solid body 120 of shaft 16.

[0067] The cells 116 in shaft 16 can be configured in a variety of different ways. As shown in Figs. 5 and 6, the cells 116 may be formed as one or more elongate columns 136, 138 running along a portion of or all of the length of shaft 16 through the shaft body 120, or may form pockets 124 that alternate with solid segments 122 in the shaft body 120 along all or a portion of the length of shaft 16. The cell 116 or set of cells 116 may run in a direction parallel to or generally parallel to the longitudinal axis, or the cell 116 or set of cells 116 may run in a spiral around a portion of, or all of the length of shaft 16. The set of cells 116 may form a plurality of discrete pockets 124 running parallel or generally parallel to the longitudinal axis 200, or spiraling around a portion of, or all of the length of shaft 16.

[0068] In various embodiments having cells 116 in the form of two or more columns 136, 138 formed in the body 120 of shaft 16, each column may contain a different shape altering material 140 or 142 that may be activated to change the degree of rigidity under different conditions. For example, one column 136 may contain a phase change material 140 that changes phase from a solid to a liquid at a first temperature, such as a predetermined body temperature, and another column 138 may contain a phase change material 142 that changes phase at a second temperature, different from the first temperature, or may contain a different kind of shape altering material, such as, for example, a wax, or an expandable foam. An example of the bending behavior of such a shaft is shown in Fig. 18, wherein the two cells 116 in the form of columns 136, 138 on opposite sides of shaft 16 contain different shape altering materials 140, 142 that are activated to change the degree of rigidity at different rates, such that one side of shaft 16 increases or decreases its length relative to the other side resulting in a curved shaft. The direction and degree of the curve can be controlled by controlling the timing and degree of activation of the shape altering materials 140 and 142 in columns 136 and 138, respectively.

[0069] Figs. 7 and 8 illustrate a shaft 16 assembly having inner and outer tubes 126 and 128, respectively, defining an annular space 130 between the inner and outer tubes 126, 128. The annular space 130 between the tubes 126 and 128 can function as the cell 116 as shown in Fig. 7, or the cell 116 can form one or more elongate columns or

discrete pockets that run along the length of annular space 130, similar to the configuration shown in Figs. 5 and 6. One or more activation links 48 may run through the annular space 130. The inner and outer tubes 126, 128 may be movable longitudinally relative to each other while the shape altering material in cell 116 is in the flexible mode, but may be constrained against relative movement when the shape altering material is in the rigidized mode.

[0070] Referring to Figs. 9 and 10, the dual tube shaft assembly offers advantages in increased moment of inertia. Referring to Fig. 9, D_1 is the outer tube 126 and D_2 is the inner tube 128, D_{1o} is the outer diameter of the outer tube 126, D_{1i} is the inner diameter of the outer tube 126, D_{2o} is the outer diameter of the inner tube 128 and D_{2i} is the inner diameter of the inner tube 128. The thickness of outer and inner tubes 126, 128 is represented by T_1 and T_2 . The thickness of the central lumen is represented as T_3 .

[0071] The combination of two tubes 126, 128 and a shape altering material creates a stiffer shaft assembly 16 than the individual tubes alone. Classic stress diagrams are shown in Fig. 10 for each tube 126, 128. In Fig. 10, T = tension and C = compression. A shape altering material, such as a phase change material in the liquid state, creates a shaft with the stiffness equal to the sum of their respective physical and dimensional properties. The shape altering materials in the solid state bond the two tubes 126, 128 together creating a stiffer structure (*i.e.*, a structure having an increased moment of inertia) which will hold the tubes 126, 128 in their relative positions at the time of rigidization, *e.g.*, straight, curved, or any desired shape.

[0072] Moment of Inertia, $I = \frac{\pi (D_o^4 - D_i^4)}{64}$,

where D_o is outside diameter, D_i is inside diameter of either the inner or the outer tube 126, 128. When acting as a solid wall when the shape altering material bonds the tubes together, the moment of inertia of the combined tubes forming the shaft assembly is greater than the sum of the moments of inertia of each tube alone.

$$I = \frac{\pi (D_{1o}^4 - D_{2i}^4)}{64} > I_{\text{tube 1}} + I_{\text{tube 2}}$$

where D_{10} is the outer diameter of the outer tube 126 and D_{2i} is the inner diameter of the inner tube 128. As the moment of inertia increases, there will be less deflection of the tubes 126, 128.

[0073] An alternative means of control can be achieved by varying the tubing wall thickness, T , to create a wide range of shaft stiffnesses. For example, concentric .062 inches thick thermo plastic rubber, such as Kynar™, or any medically approved tubing, may be used. These materials are commercially available in a variety of durometers. Tubes with a thin .005 inch layer of shape altering material, such as tetracosane, will hold the shape of shaft 16 but change the stiffness of the shaft assembly very little, whereas a .005 inch thick pvc wall and shape altering material having a .040 inch thick wall will result in a very flexible shaft when the shape altering material is liquid and a rigid shaft when the shape altering material is solid. Other suitable thermoplastic elastomeric materials are commercially available and include styrenic block copolymers, polyolefin blends, elastomeric alloys (TPE-v or TPV), thermoplastic polyurethanes, thermoplastic copolyester and thermoplastic polyamides. Examples of thermoplastic elastomeric materials products that come from block copolymers are STYROFLEX™ (BASF), KRATON™ (Shell chemicals), PELLETHANE™, ENGAGE™ (Dow Chemical), PEBAX™ (Arkema), ARNITEL™ (DSM), and HYTREL™ (E.I. Du Pont de Nemours). Commercially available elastomer alloys include: DRYFLEX™, MEDIPRENE™, SANTOPRENE™, GEOLAST™ (Monsanto), SARLINK™ (DSM), FORPRENE™, ALCRYN™ (E.I. Du Pont de Nemours) and EVOPRENE™ (AlphaGary).

[0074] When the phase change material bonds to tubing wall, the material becomes the shear member and the tubing becomes the stress member. The tubes can be treated to increase the adhesion of the phase change material. Treatment methods include, for example, cleaning, etching, or exposing the tubing to a corona arc.

[0075] Tubing material that is thin and has a higher heat transfer capacity on the exterior of the tubing is better suited for external temperature sources. In addition, or in the alternative, the tubing walls may contain fillers to change their properties. For

example, the tubing walls may contain carbon fibers to increase thermal transfer properties.

[0076] The shape altering material may be a phase change material that changes phase from gas to liquid to solid at a temperature specific to the particular material. Fig. 11, for example, shows a graph of a phase change material that is solid at room temperature and less but changes from a solid to a liquid at or near a predetermined body temperature (e.g., about 97 °– 99 °F). Other phase change materials may be a liquid or a gas at room temperature and change phase to a solid or liquid, respectively, at a temperature below room or body temperature.

[0077] A phase change with its corresponding volume change occurs when the phase change materials reach the temperature at which they change phase (e.g. melting point). At that temperature, the material absorbs large amounts of heat without changing its temperature. When the ambient temperature in the space around the phase change material drops, the phase change material solidifies, releasing its stored latent heat. Phase change materials absorb and emit heat while maintaining a nearly constant temperature. A constrained volume can create high forces.

[0078] Tissue or body temperature acts as heat sink. As previously described, the phase change temperature can be above or below body temperature depending on use of the body as a heat source or heat sink. A heating element may also be used to hold the phase change material just above or below its transition temperature to make a faster phase change trigger.

[0079] Using available phase change diagrams, the phase change transition temperature can be used to control the shape altering characteristics from a rigidized to an unrigidized or flexed mode back to a rigidized mode or *vice versa*, as desired.

[0080] If the phase change material body is in the liquid phase at body temperature, then the device will be flexible. Cooling the phase change material will make it solid and stiffen the shaft 16. The patient's body temperature will change the phase change material back to liquid and the shaft 16 will regain flexibility.

[0081] If the phase change material body is in the solid phase at the predetermined body temperature, the shaft 16 will be rigid. Heating the phase change material to the appropriate temperature above the body temperature will change the phase to liquid and create a flexible condition in the cells 116 and thereby in the portion of shaft 16 where the cells 116 are positioned. Exposure of the phase change material again to the predetermined body temperature will hasten the return to the solid and rigid state. If, however, the transition temperature includes the body temperature, the energy needed to create the phase change is less and opens the kinds of activation sources available.

[0082] To cause a phase change material to alter states, energy to heat or cool the material is needed. Brittle phase change materials will fracture if overstressed, potentially limiting tissue contact pressure damage, but will re-crystallize and regain its rigid structure after being re-melted. Phase change materials with crystalline properties, such as tetracosane, are stiffer than polymers like paraffin. High purity phase change materials have greater stiffness than impure or blended materials.

[0083] Exemplary phase change materials include water.

[0084] Exemplary shape memory materials include metals, for example, NITENOL™ and plastics VERIFLES™ (styrene) manufactured by Cornerstone Research Group.

[0085] Exemplary waxes include Paraffin and tetracosane.

[0086] Exemplary expandable foams are commercially available from Cornerstone Research Group.

[0087] The shape altering material may alternatively be a magneto rheological material. Referring to Figs. 12 and 13, a carrier oil with magnetic particles 132 dispersed throughout may be contained in the cells 116. Upon activation, the magnetic particles 132 line up and form chains along magnetic flux lines 134. The magneto rheological material may be used in the embodiment of cells 116 shown in Figs. 5 and 6, for example, wherein the magneto rheological material would be contained in the columnar cell 116 shown in Fig. 5 or in the pockets 124 shown in Fig. 6.

[0088] Magneto rheological materials are fluids that contain micrometer sized magnetic particles (in the range of about 0.1 to 10 μm) in a carrier fluid, such as an oil, usually mixed with a surfactant. Surfactants in the carrier fluid reduce the rate and degree to which the magnetic particles 132 come out of suspension in the carrier fluid. When there is no applied magnetic field, the magnetic particles are in suspension and randomly distributed in the carrier fluid. In this mode, the shaft 16 will be flexible. When subjected to a magnetic field, the fluid increases its viscosity to become a viscoelastic solid and the magnetic particles align in chains along lines of magnetic flux perpendicular to the longitudinal axis of the cell 116, which, in most cases, is parallel to the longitudinal axis 200 of the shaft 16. When the fluid is contained between two poles, the chain of particles restricts movement of the fluid along the longitudinal axis of the cell 116. The restriction on movement of the fluid effectively increases its viscosity, rigidizing the cell 116 and the portion of shaft 16 in which the cell 116 is positioned. Any of the commercially available magneto rheological materials may be used as the shape altering material in cells 116. An alternate material is a Ferro fluid with smaller particles which will provide a more dense suspension.

[0089] The shaft is flexible when introduced at some entry point of a patient's body. A magnet can be positioned and turned on and off to give momentary stiffening of the shaft 16 for maneuvering. The flexible state allows the shaft to take shape, when, for example, a vaginal entry device needs to drape over the sacral prominence without applying pressure to compress tissue and nerves. The magnet may be external, internal or built into the shaft. A magnet built into the shaft could allow an external controller to control any or all segments of the shaft subject to magnetic zones created by loops of wire to create a magnetic field.

[0090] For example, to apply a magnetic field to activate the magneto rheological material when used in cells 116, an external magnet may be used, such as the type of external magnetic control device used in magnetic anchoring and guidance systems (MAGS). MAGS, which have been developed for use in minimally invasive procedures, generally include an internal device attached in some manner to a surgical instrument, laparoscope or other camera or viewing device, and an external hand held device for

controlling the movement of the internal device. Each of the external and internal devices has magnets which are magnetically coupled to each other across, for example, a patient's abdominal wall. The external device of such a system and its associated magnets may be used to apply the magnetic field to the magneto rheological material in the cells 116. An internal magnet to establish a localized magnetic field. The strength of the magnetic field may be adjusted by adjusting the height of the external magnet or alternatively, the field intensity if using an electromagnet.

[0091] In various embodiments, shown in Figs. 14 A-E, the shaft 16 may be segmented. In a similar manner, the rotating joint 38 of the end-effector 14 is shown as segmented. Although described with specific reference to the shaft 16, the following description of segmented sections applies to both the shaft and a bendable or twistable section of the end-effector 14, such as but not limited to the rotating joint 38 shown in FIGS. 1 and 2. One or more shaft 16 segments 102 will have a means, such as a flexible membrane lining for the segmented shaft, to allow separation at the junctions 110 between shaft segments 102 while maintaining a closed shaft. Separation of the edges at the junctions of adjacent segments 102 at one point will cause the adjacent segments 102 to angulate on one side creating a curved section of shaft 16. Controlling multiple segments 102 individually or in some combination will enable controlling the length and degree of curve. In certain embodiments, each of the plurality of cells 116 may form a discrete pocket 124 arranged at intervals along the length of the shaft 16, with each pocket 124 being positioned at the junction 110 between a different adjacent segment 102 along the longitudinal axis 200 of a solid (*i.e.*, without a central lumen) shaft 16. See Fig. 14 A. Selective activation of the shape altering material in one or more of the pockets 124 effects bending of the shaft 16 in a predetermined direction along a desired portion of the shaft 16.

[0092] In other embodiments, as shown in Fig. 14 B, side to side motion of a shaft 16 can be provided by having two sets of cells 116 arranged along opposing sides of the length of the shaft 16 such that there are two pockets 124 positioned on opposite sides (*e.g.*, at about 180° from each other) of the junction 110 between adjacent segments 102 of shaft 16. Selective activation of the shape altering material in this embodiment

effects bending of the shaft 16 in at least one of two predetermined directions along a desired portion of the shaft 16.

[0093] A further embodiment shown in Fig. 14 C provides three sets of cells 116 arranged equi-distant from each other (e.g., at about 120° from each other) such that there are three pockets 124 positioned equi-distant from each other around the circumference of the juncture 110 of adjacent segments 102 of shaft 16. Selective activation of the shape altering material in this embodiment effects bending or twisting of the shaft 16 in any predetermined direction within 360°. In each of the foregoing embodiments, the pockets 124 may be positioned at either regular or irregular intervals of segments 102 along all or a portion of the length of the shaft 16. By way of example, a pair of pockets 124 in the embodiment having two sets of cells 116 may be positioned regularly at every junction 110 between adjacent segments 102 or at the junctions 110 between every second, third or fourth shaft segment 102. Alternatively, there may be pairs of pockets 124 (or one, three or more pockets) at every junction 110 of adjacent segments 102 for several segments in a row, followed several unpocketed segments, followed by pairs of pockets 124 or single columns of pockets 124 at every other junction 110 of shaft segments 102, or in any desired pattern suitable for the intended use of the instrument and shaft.

[0094] Segmented shafts allow for flexibility. An alternative to the segmented shaft with a flexible inner lining is a ball and socket design which enables a load to create increased friction to hold the shape. A cable may run through the center of the ball and socket arrangement. Referring to Fig. 14 A, a central activation link 48 when expanded by the shape altering material, such as a phase change material, pneumatic or hydraulic fluid, or chemical means, creates the friction needed to lock the segments 102 in place. Having two or more off-center lines that are simultaneously expanded like those shown in Figs. 14 B or C, will provide an alternate shape holding configuration. Multiple lines allow higher forces to be created or allow a smaller expansion member to maintain a lower force.

[0095] An alternate form shown in Fig. 14 D that can be used to either curve or tighten an assembly is a ring (continuous or segmented) with one, two or three activation links 48 that, depending on how they are activated, enables a curved or linear response. The plurality of discrete pockets 124 may be formed into rings positioned around the longitudinal axis 200 of the shaft 16, for example, at the juncture 110 of adjacent shaft segments 102, or where the shaft 16 is not segmented, at either regular or irregular intervals along all or a portion of the length of the shaft 16.

[0096] Fig. 14 E shows an embodiment of a series of pockets 124 in four sets of cells 116. In this embodiment, there may be a split shaft 16 or the sets of cells 116 may be used in, for example, the jaws of a grasper or another type of an end effector 14 having facing sections that would benefit from changing between a flexible and a rigid shape. Two sets of cells 116, arranged in off-set rows of pockets 124, are placed in each half shaft 16 or end effector 14 section.

[0097] The segmented motion can be achieved by the expansion of shape memory plastics or phase change materials such as wax. Use of more conventional power means such as reversible chemical reaction, pneumatic or hydraulic fluids may be used as well. To give a faster return after diminishing the elongation source, a wire 48 with springs applies a return to the shortened (straight) position.

[0098] In an alternative embodiment of shaft 16 and cells 116, coiled tubes may be used. Coils are flexible and can perform well in compression. Expansion of coils, however, will make the shaft 16 poor in tension. Fig. 19 shows a shaft 16 construction having a continuous annular cell 116 and oppositely wound coils 146 and 148 housed therein. One coil 146 is wound in a clockwise direction and the other coil 148 is wound in a counterclockwise direction. Either one of the two coils may be wound inside the other of the two coils. The dual coil construction, particularly when combined with a shape altering material, prevents the shaft from being crushed. A shape altering material, such as a phase change material, is placed in the annular cell 116 in between the coils 146 and 148, thus enabling the coils 146, 148 to become one stronger structure that can then be used to perform with greater tension and compression. By

varying the coil material, wire size, mandrel diameter, and pitch, a large range of flexible properties, limited only by the available volume, can be created.

[0099] Referring to Fig. 20, an alternative configuration for the shaft 16 and cell 116 provides a woven wire pattern 144 in the annular cell 116 that has some give before engagement in tension, compression and torque. Integration with a shape altering material, such as a phase change material, can make the shaft 16 behave like a solid shaft and eliminate twisting of the shaft 16.

[0100] Various embodiments of the cells in their capacity as an actuator assembly may include one or more linear pushing and/or pulling cells 80 that may be used as an alternative to the mechanical drive system used for example in surgical stapler systems. A volume change in the cell 80 may be channeled to a smaller diameter section to increase the linear travel of a plunger 86, as described below. The volume of the actuator cell 80 or set of cells 80 and the activation energy input to each cell may be varied to accommodate a variety of end effectors 14 of any size or length of actuation.

[0101] Fig. 15 illustrates an example of a cell 116 used as an actuation cell 80 for the production of work by enabling pushing, pulling, or a reciprocating pushing and pulling motion. Actuation cell 80 is defined between a first end wall 88 and a second end wall 90. An axially movable plunger 86 having a mid plate 94 and a rod 96 is positioned in actuation cell 80, dividing cell 80 into a first chamber 82 and a second chamber 84. In the embodiment shown in Fig. 15, both chambers 82 and 84 contain a shape altering material. In other embodiments of the actuation cell 80, only one of the chambers 82 or 84 may contain a shape altering material. Seals 92 prevent leakage of the shape altering material from one chamber into the adjacent chamber. An activation link 48 as described previously is operatively connected to the cell 80 to activate a change in the shape altering material.

[0102] In the embodiment wherein both chambers 82, 84 contain shape altering materials, each chamber may contain a shape altering material different from the material in the adjacent chamber. As described above, the adjacent chambers 82, 84

may contain two different phase change materials, or two different expandable foams that are activated at different temperatures, or may contain two different kinds of shape altering materials that are activated under different conditions, or may contain the same or different shape altering materials with separate activation links to each chamber 82, 84 to effect a change in the state of the material at different times or to effect different changes in the state of the material at the same time.

[0103] When the shape altering material in chamber 82 is activated to cause the material to expand, the expanding material pushes mid plate 94 of plunger 86 in direction 78 (to the right in Fig. 15). The shape altering material in chamber 84 must be able to be compressed or must not fill the entire chamber. Pushing plate 94 pushes rod 96 in direction 78. When used in an end effector 14, rod 96 will be operatively connected to a component, such as a gear, a ramp, a movable platform, a pivot point, or the like, that performs or causes to be performed some work. Pushing rod 96 will apply force to the component to trigger the desired performance.

[0104] Similarly, when the shape altering material in chamber 84 is activated to cause the material to expand, the expanding material pulls mid plate 94 of plunger 86 in direction 76 (to the left in Fig. 15). The shape altering material in chamber 82 must be able to be compressed or must not fill the entire chamber. Pulling plate 94 pulls rod 96 in direction 76. The component in the end effector 14 to which rod 96 is operatively connected may be pulled back, to end the performance of the work or may be pulled back to rest the component for the next application of force sufficient to trigger the performance of work.

[0105] In certain embodiments, a spring 106 as shown in Fig. 17, can be incorporated adjacent to an end wall 88 or 90 of the actuation cell 80, or in one of the chambers 82 or 84 when only one chamber 82 or 84 contains the shape altering material. The spring 106 may be used to bias the plunger 86 toward the position in which the shape altering material in the adjacent chamber is in an unexpanded mode. The spring 106 may return the plunger 86 in a one way motion or return it to a neutral position in an actuation cell 80 configured for two way motion, like the cell 80 shown in Fig. 15. Spring

106 may be of any type of biasing member, such as a tension spring, a compression spring, a rotational spring, a leaf spring, or bellview washer.

[0106] Fig. 16 illustrates the cross sectional view of an embodiment of an actuation cell 80 that enables the production of work in a circular configuration for rotational applications. Examples of rotational motion are in plane axial rotation, a cam, or a screw. The degree of rotation may be any fractional or greater turn. In this embodiment of actuation cell 80, the plunger 86 includes a central rod 96, a fixed radial wall 98 and a movable radial wall 94. The shape altering material is contained in the cell 80 between the fixed and movable radial walls 98, 94. An activation link 48 as described previously is operatively connected to the cell 80 to activate a change in the shape altering material.

[0107] Activation of the shape altering material may expand the material forcing the rotational movement of movable radial wall 94 in a counterclockwise direction, as shown by the arrow in Fig. 16. Activation of the shape altering material may alternatively cause the shape altering material to contract. Movable radial wall 94 may be biased in the clockwise direction back into the contracted position by a spring or other biasing member, as described above, or by activation of a second shape altering material in the manner described with regard to Fig. 15. Those skilled in the art will recognize that, depending on the location of the shape altering material within cell 80 relative to fixed and movable radial wall 98, 94, the expansion and contraction of the shape altering material may cause rotation of the movable wall in a clockwise or counterclockwise direction, respectively. Those skilled in the art will appreciate that the movable radial wall 94 does not have to be in the center of the cell 80 and further, that the cell 80 may be partitioned to have one, two or more divisions, or chambers in the cells 80 in cross section.

[0108] The degree of axial, linear or rotational motion may be controlled by segmented heating elements or proportional resistance, with for example, a potentiometer or a rheostat, or by way of dynamic computer control. In this embodiment, the control member 12 may be operatively connected to an external

computer, or may incorporate computer chips controllable with the various controls on control member 12, as described above.

[0109] Surface temperatures below 140 °F are not known to harm tissue, but temperatures at or above that temperature may. Therefore, when the speed and action of the plunger 86 is triggered by a thermal response, insulation of the area surrounding the actuation cell 80 is provided to avoid harm to tissue. Similarly, insulation may be provided around portions of shaft 16 if such high temperatures are used to trigger changes in rigidity.

[0110] An example of the type of work that may be triggered by the activation of the shape altering material in an actuation cell 80 is a surgical stapler. Referring to Fig. 17, an end effector 14 in the form of a surgical stapler with a jaw drive is shown. The end effector 14 shown includes a drive portion 40 and a rotating joint 38 from which extend rotating jaws 50 and ribbon drives 52 for stapling and cutting operations. Drive portion 40 that houses an actuation cell 80 which is divided into first and second chambers 56 and 72, respectively, by leading end walls 88a and 88b and mid plates 94a and 94b of plunger 86. First chamber 56 contains a shape altering material and second chamber 72 contains a spring 106 for biasing the mid plate 94 a, b of plunger 86 distally, in direction 76. The mechanical spring 106 maintains the rotating jaws 50 in a normally open position, when the activation energy is not applied. Seals 92, such as O-rings, are positioned in the space between each of the adjacent wall 88 a, b and plate sections 94 a, b. Plunger 86 includes a center rod 96 that extends from the leading end wall 88 through mid plate walls 90 through end wall 90 into a shaft 16 of an instrument 10 (not shown in this view. See Figs. 1 and 2). Rod 96 includes a channel 58 along the longitudinal axis of rod 96 through which run the activation links 48 and ribbon drives 52 for stapling and cutting. Two activation links 48 branch off into actuation cell 80. The remaining activation links 48 continue forward, distally to the rotating jaw drives 50 and ribbon drives 52.

[0111] Activation of the shape altering material in the manner described in any of the embodiments described herein causes the material to expand, exerting force on the mid

plate 94 a of plunger 86, thereby pulling the plunger 86 and its narrow channel 58 in the proximal direction (direction 78 in Fig. 17) allowing rotating drives 50 to expand outwardly, away from each other in a more open position. When the activation energy is discontinued or changed such that the shape altering material contracts, spring 106 pushes mid plate sections 94 a, b forward in the distal direction (direction 76 in Fig. 17) to squeeze rotating drives 50 into channel 58 forcing the drives 50 inwardly, towards each other in a more closed position. The actuation cell 80 in the embodiment of Fig. 17 can be configured such that the rotating jaws will be normally closed and powered to open.

[0112] The actuation cells 80 described herein can easily be adapted to numerous end effectors 14. For example, referring to Figs. 1 and 2, the jaws 34, 36 can be configured to be normally closed and powered to open, or normally open and powered to close. The jaws 34, 36 may be configured to open in a non-symmetrical fashion. One jaw arm 34 or 36 may be fixed and the other movable.

[0113] The drive portion 40 and shaft 16 may be configured in any diameter with the limitation being that deliverable forces will be less with smaller diameters. A practical size range is from 2 mm to 12 mm diameters. Other dimensions may be used depending on the application.

[0114] In another embodiment, staple drivers 206 may sit on a platform or stapler sled 260 positioned in the bottom portion 236 of the end effector 14, above an actuation cell 280. End-effectors that comprise staplers and stapler drives are shown in U.S. Patent No. 7,794,475, which is incorporated herein by reference. Instead of the driving mechanism shown in the prior art stapler systems, a shape altering material in an actuation cell 280 may be provided, which, when heated by a heating element 208 which may be connected directly or indirectly to an activation energy source 248, changes phase from solid to liquid, or more generally, changes from a contracted to an expanded state. The change to the expanded state changes the volume of cell 280, which applies force to the staple drivers 206 and ejects the staple 200 into tissue 300. The top portion 234 of the end effector 14 presses the staple into a closed position,

designated by staples 202, as illustrated in the Fig. 21. In another embodiment, a knife (not shown) may be incorporated as part of the platform of the stapler sled that is raised when the shape altering material expands. The knife may be part of the same driver as the staple or may be independently raised with its own driver, activation source, and control. Surgical staples and knives of this kind are commercially available and well known in the art, so will not be described in detail herein.

[0115] When the shape altering material is an expandable foam, when heated, the foam can expand to forty times its volume to drive staple formation. The activation energy source may be any of the means identified herein. The expandable foam material may be any suitable known foam, such as the foam product available from Cornerstone Research Group, Inc; of Dayton, Ohio. One property of an expandable foam is a time delay from activation to expansion. This delay can be adjusted from seconds to minutes. Staplers are typically clamped on tissue 300 for a minute before firing the staples 200. As such, the foam may be selected and its activation controlled to provide a built in delay mechanism.

[0116] Those skilled in the art will appreciate that other configurations of foam expansion for pushing staples and cutting tissue directly or indirectly may be provided within the scope of the subject matter described and claimed herein.

[0117] In an alternative embodiment, a tapered wedge, similar to ramp 250 in Fig. 21, and a driver with wings may be provided. The wings (one side or two) have volume expansion causing a movement along the stapler sled's 260 long axle thereby moving the driver up the ramp (inclined plane) to drive the staple 200 out of the sled 260. This is a linear expansion that drives a sled 260 that sequentially fires staples 200 and cuts tissue 300. In yet another embodiment, a rotational cell, such as the cell shown in Fig. 16, may be used to raise the staple driver and knife.

[0118] Variations of the concept allow for multiple configurations wherein a number of extruded holes may be provided to accommodate cells of the phase change material

and activation means. An offset activation may be used to allow a slower reaction time thereby gradually increasing or decreasing the degree of rigidity over time.

[0119] Although the Figures and description herein primarily reference shaft and cell components as being circular in cross section, those skilled in the art will recognize that other configurations may be used. For example, the shaft and cells or one of them, may form, in cross section, an oval, a square, a rectangle, a triangle or another polygonal shape, or an irregular shape. Conforming changes in configuration would be made in any appropriate end walls, movable walls, plungers and plunger mid plates of the cells 116 or 80.

[0120] Except as otherwise noted, the articles "a", "an", and "the" mean "one or more".

[0121] Except as otherwise noted, all amounts including quantities, percentages, portions, and proportions, are understood to be modified by the word "about", and amounts are not intended to indicate significant digits.

[0122] The dimensions and values disclosed herein are not to be understood as being strictly limited to the exact numerical values recited. Instead, unless otherwise specified, each such dimension is intended to mean both the recited value and a functionally equivalent range surrounding that value. For example, a dimension disclosed as "40 mm" is intended to mean "about 40 mm".

[0123] It should be understood that every maximum numerical limitation given throughout this specification includes every lower numerical limitation, as if such lower numerical limitations were expressly written herein. Every minimum numerical limitation given throughout this specification will include every higher numerical limitation, as if such higher numerical limitations were expressly written herein. Every numerical range given throughout this specification will include every narrower numerical range that falls within such broader numerical range, as if such narrower numerical ranges were all expressly written herein.

[0124] The embodiments of the devices described herein may be introduced inside a patient using minimally invasive or open surgical techniques. In some instances it may be advantageous to introduce the devices inside the patient using a combination of minimally invasive and open surgical techniques. Minimally invasive techniques may provide more accurate and effective access to the treatment region for diagnostic and treatment procedures. To reach internal treatment regions within the patient, the devices described herein may be inserted through natural openings of the body such as the mouth, anus, and/or vagina, for example. Minimally invasive procedures performed by the introduction of various medical devices into the patient through a natural opening of the patient are known in the art as NOTES™ procedures. Some portions of the devices may be introduced to the tissue treatment region percutaneously or through small – keyhole – incisions.

[0125] Endoscopic minimally invasive surgical and diagnostic medical procedures are used to evaluate and treat internal organs by inserting a small tube into the body. The endoscope may have a rigid or a flexible tube. A flexible endoscope may be introduced either through a natural body opening (e.g., mouth, anus, and/or vagina) or via a trocar through a relatively small – keyhole – incision incisions (usually 0.5 - 2.5cm). The endoscope can be used to observe surface conditions of internal organs, including abnormal or diseased tissue such as lesions and other surface conditions and capture images for visual inspection and photography. The endoscope may be adapted and configured with working channels for introducing medical instruments to the treatment region for taking biopsies, retrieving foreign objects, and/or performing surgical procedures.

[0126] Preferably, the various embodiments of the devices described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK® bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized

instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility. Other sterilization techniques can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, and/or steam.

[0127] Although the various embodiments of the devices have been described herein in connection with certain disclosed embodiments, many modifications and variations to those embodiments may be implemented. For example, different types of end effectors may be employed. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modification and variations.

[0128] Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

WHAT IS CLAIMED IS:

1. A surgical instrument comprising:
 - an end effector;
 - a shaft assembly positioned operatively connected to the end effector;
 - at least one cell defined within at least one of the shaft assembly or the end effector;
 - a shape altering material housed within the at least one cell;
 - an actuation assembly for selectively activating the shape altering material to effect a change in the at least one cell.
2. The surgical instrument recited in claim 1 wherein the shape altering material is selected from the group consisting of wax, a polymeric phase change material, an expandable foam, conductive plastic, and a magneto rheologic fluid.
3. The surgical instrument recited in claim 1 wherein the shape altering material is a phase change material that changes phase from a solid to a liquid at a predetermined body temperature.
4. The surgical instrument recited in claim 1 wherein the actuation assembly comprises:
 - a source of activation energy;
 - an activation control member for selectively applying the activation energy;
 - a link from the control member to the at least one cell for delivering the activation energy to the cell to activate the shape altering material.

5. The surgical instrument recited in claim 4 wherein the source of activation energy is selected from the group consisting of an external source linked to the activation control member, an internal storage source for storing activation energy derived from an external source, and a self-contained internal source.
6. The surgical instrument recited in claim 4 wherein the activation energy is selected from the group consisting of light, heat, electricity, magnetism, exothermic chemical energy, pneumatic energy, and hydraulic energy.
7. The surgical instrument recited in claim 1 wherein the at least one cell is in the shaft assembly.
8. The surgical instrument recited in claim 7 wherein the shaft assembly comprises an elongate shaft having a longitudinal central axis, and there are a plurality of cells formed in the shaft, each cell containing the shape altering material.
9. The surgical instrument recited in claim 8 wherein each of the plurality of cells comprises a discrete pocket, the plurality of pockets being arranged at intervals along the length of the shaft.
10. The surgical instrument recited in claim 9 wherein at least a portion of the shaft is segmented and each pocket of the plurality of pockets is positioned between different adjacent segments along the central axis of the shaft wherein selective activation of the shape altering material effects bending of the shaft in a predetermined direction.
11. The surgical instrument recited in claim 9 wherein at least a portion of the shaft is segmented and each pocket of the plurality of pockets is positioned between different adjacent segments along opposing sides of the length of the shaft wherein selective activation of the shape altering material effects bending of the shaft in at least one of two predetermined directions.
12. The surgical instrument recited in claim 9 wherein at least a portion of the shaft is segmented and each pocket of the plurality of pockets is positioned between different

adjacent segments along three equi-distant lengths of the shaft wherein selective activation of the shape altering material effects bending of the shaft in any predetermined direction within 360°.

13. The surgical instrument recited in claim 9 wherein the plurality of discrete pockets from rings around the central axis of the shaft.

14. The surgical instrument recited in claim 8 wherein each of the plurality of cells form a column along a portion of the length of the shaft.

15. The surgical instrument recited in claim 14 further comprising one or more channels formed in the shaft for carrying the activation link to the cells.

16. The surgical instrument recited in claim 7 wherein the shaft assembly comprises an inner tube, at least one outer tube, and an annular space defined between the inner and at least one outer tube, the inner tube defining a central lumen along its length;

at least one coil wound in one of a clockwise or a counterclockwise spiral positioned within the annular space; and,

the annular space defining the cell and housing the shape altering material therein.

17. The surgical instrument recited in claim 1 wherein the at least one cell is in the end effector.

18. The surgical instrument recited in claim 17 wherein the end effector comprises:

a housing;

an element within the housing having a longitudinal axis and defining therein the at least one cell;

a plunger movable in an axial direction through the element within the housing, the plunger comprising a barrier plate for dividing the cell within the element into two chambers;

wherein the shape altering material comprises one of the wax, the expandable foam, or the phase-change material, and is housed within at least one of the two chambers, wherein activation of the shape altering material effects one of expansion or contraction of the shape altering material to move the plunger in one of a first or a second axial direction through the element.

19. An actuator for producing work, the actuator comprising:

a housing assembly for use in a surgical instrument;

an element within the housing having a longitudinal axis and defining therein at least one cell, the element being operatively connectable to a driving member of the surgical instrument; and

a shape altering material housed within the at least one cell, wherein the shape altering material is selected from the group consisting of wax, a polymeric phase change material, conductive plastic, and an expandable foam;

a source of activation energy operatively connected to the cell for activating the shape altering material to effect a change in the size of the at least one cell, wherein the change is translated to the driving member, wherein the activation energy is selected from the group consisting of light, heat, electricity, magnetism, exothermic chemical energy, pneumatic energy, and hydraulic energy.

20. A shaft assembly comprising:

an elongate shaft having a longitudinal axis operatively connectable to a control member;

a plurality of cells formed in the shaft;

a shape altering material housed within the at least one cell, the shape altering material being selected from the group consisting of wax, a polymeric phase change material, an expandable foam, conductive plastic, and a magneto rheologic fluid; and,

an activation link operatively connectable to a source of activation energy for delivering activation energy to each cell for activating the shape altering material to selectively rigidize or unrigidize the shaft;

wherein a surgical instrument is operatively connected to the shaft for selectively activating and deactivating the shape altering material..

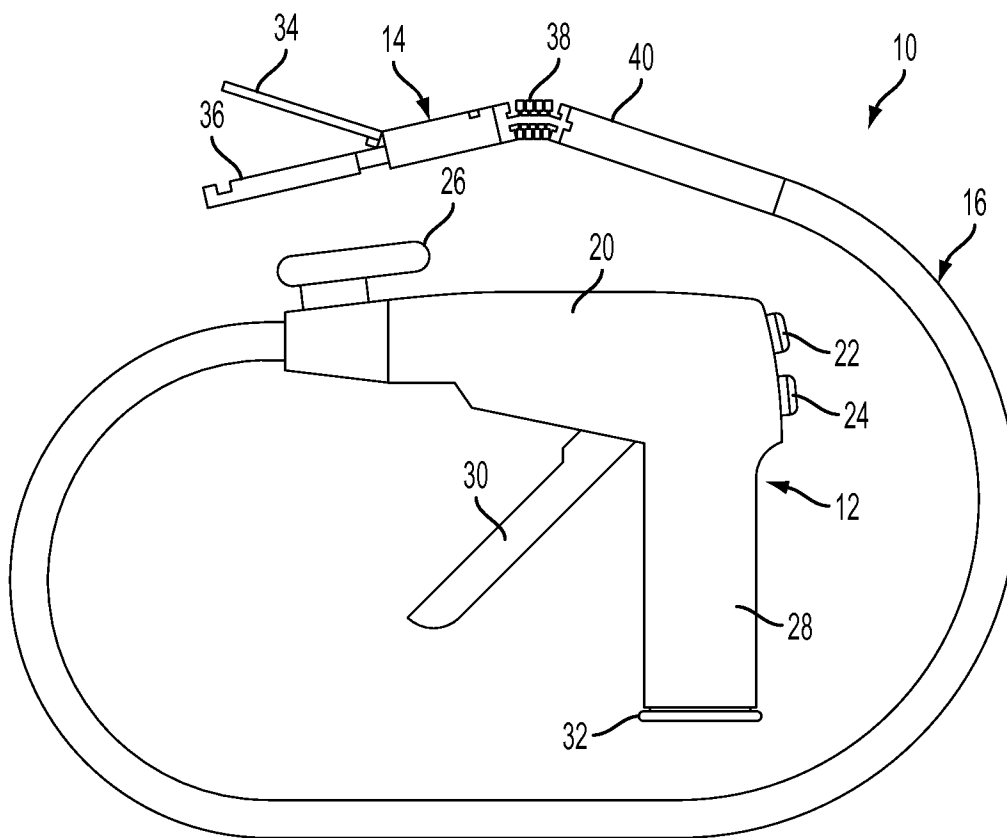


FIG. 1

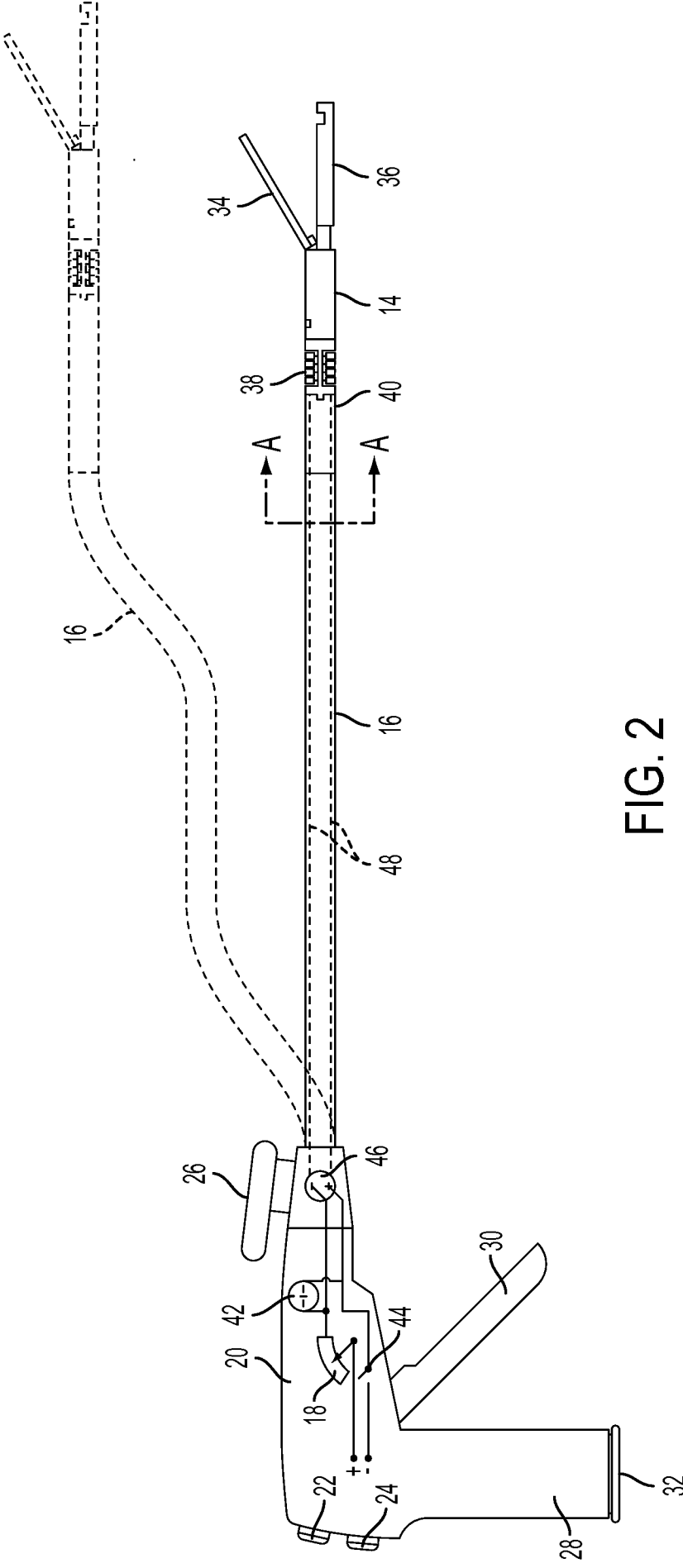


FIG. 2

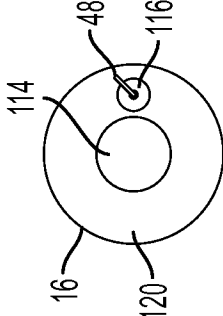


FIG. 3A-A

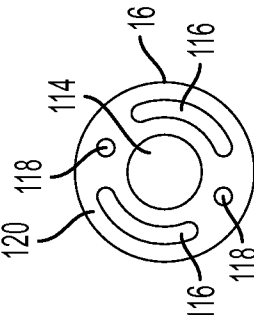


FIG. 4A-A

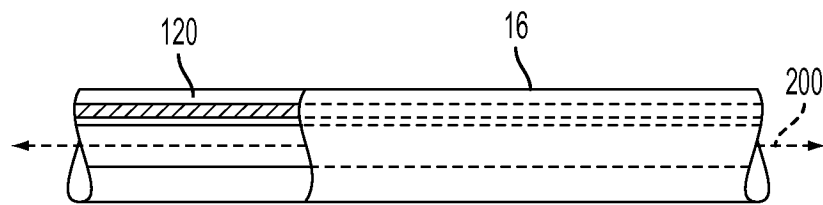


FIG. 5

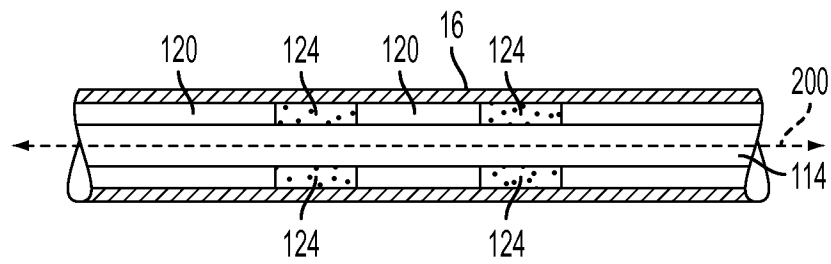


FIG. 6

4/11

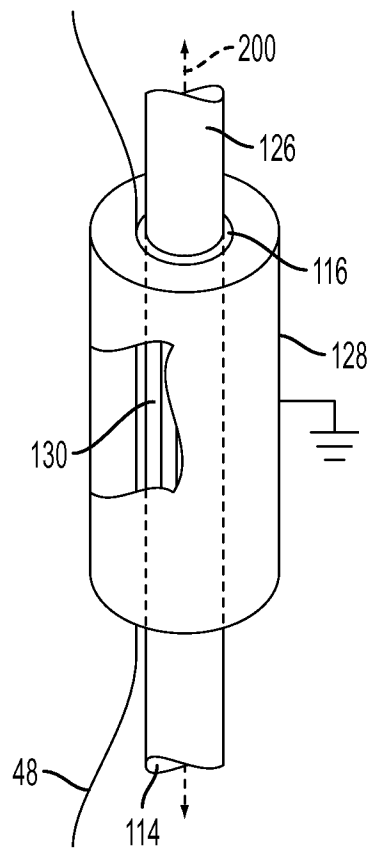


FIG. 7

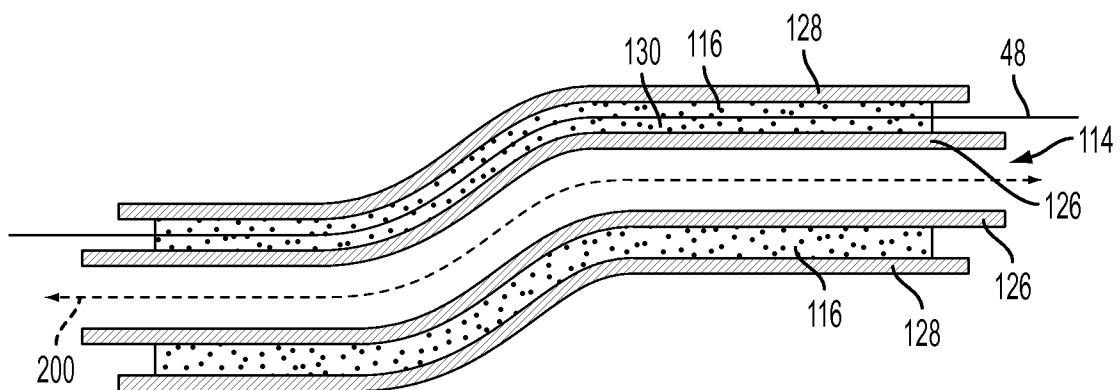


FIG. 8

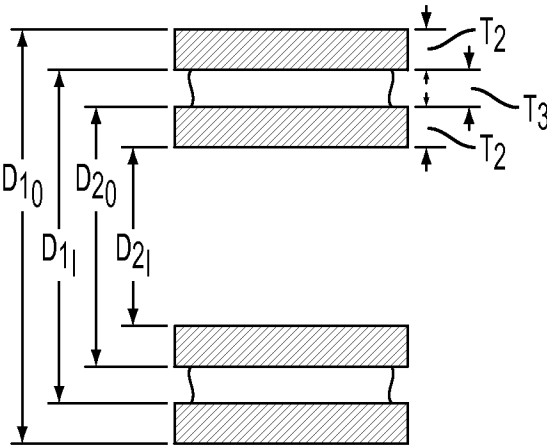


FIG. 9

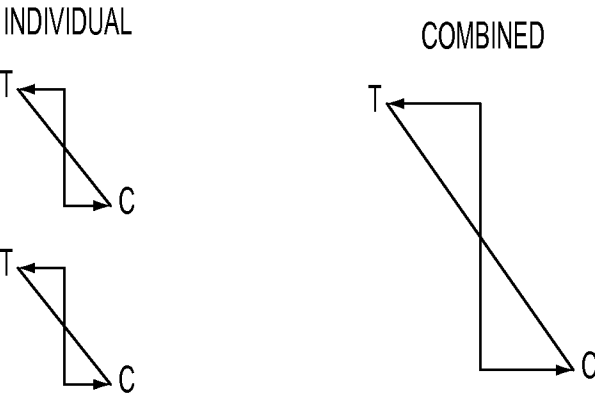


FIG. 10

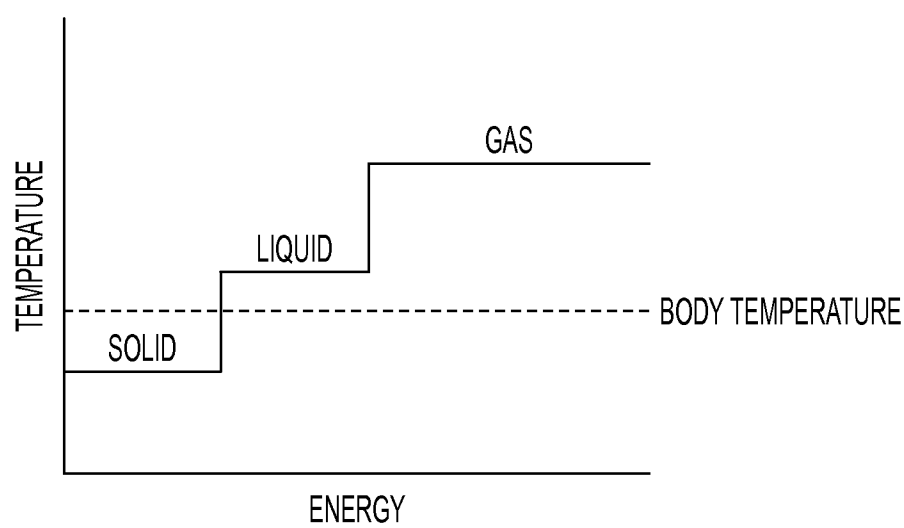


FIG. 11

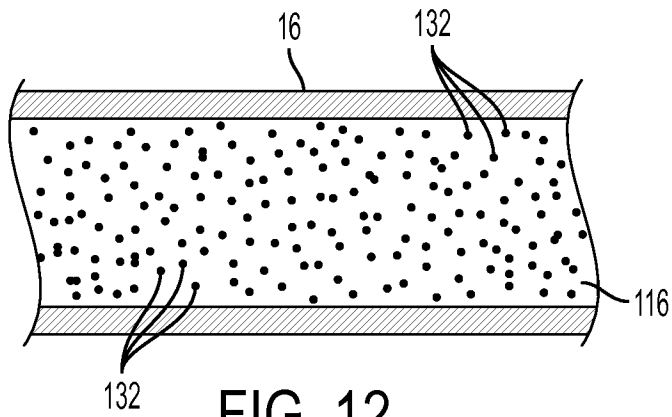


FIG. 12

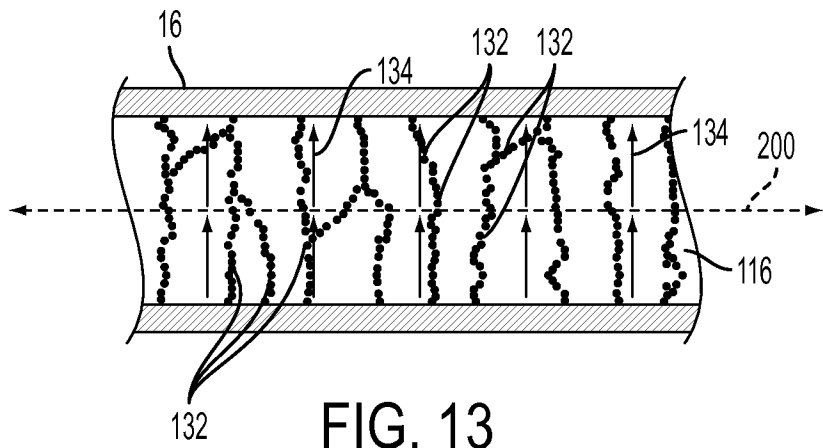


FIG. 13

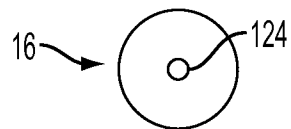
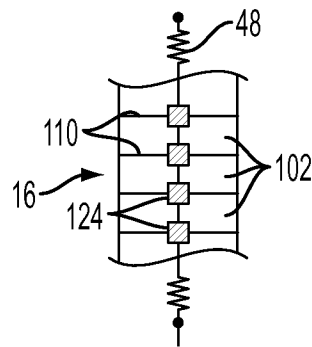


FIG. 14A

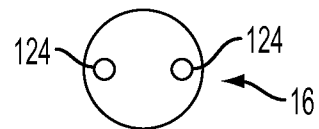
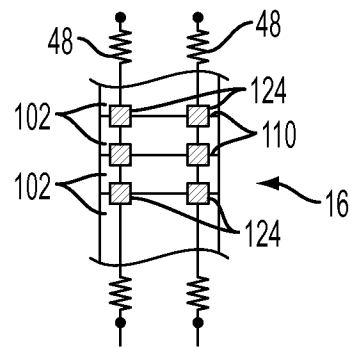


FIG. 14B

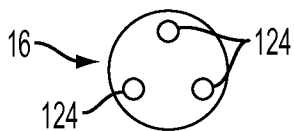
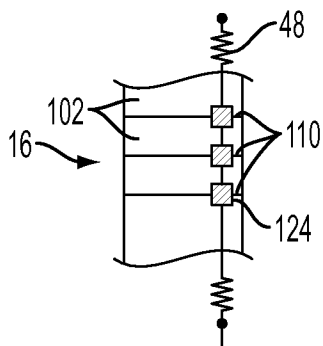


FIG. 14C

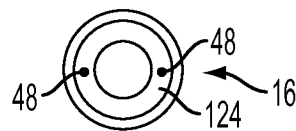
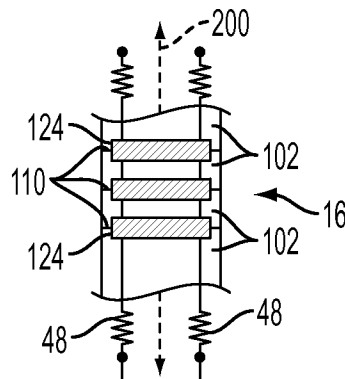


FIG. 14D

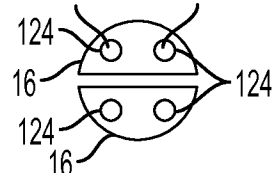
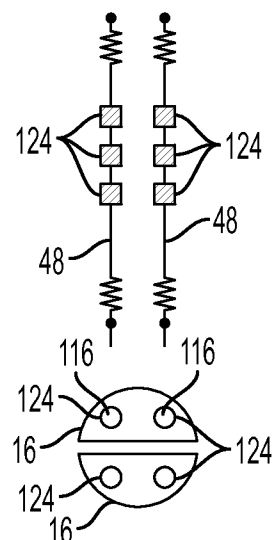


FIG. 14E

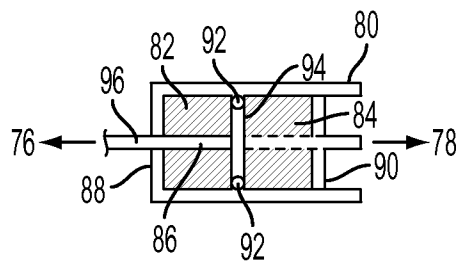


FIG. 15

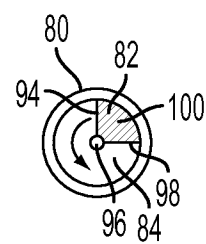


FIG. 16

9/11

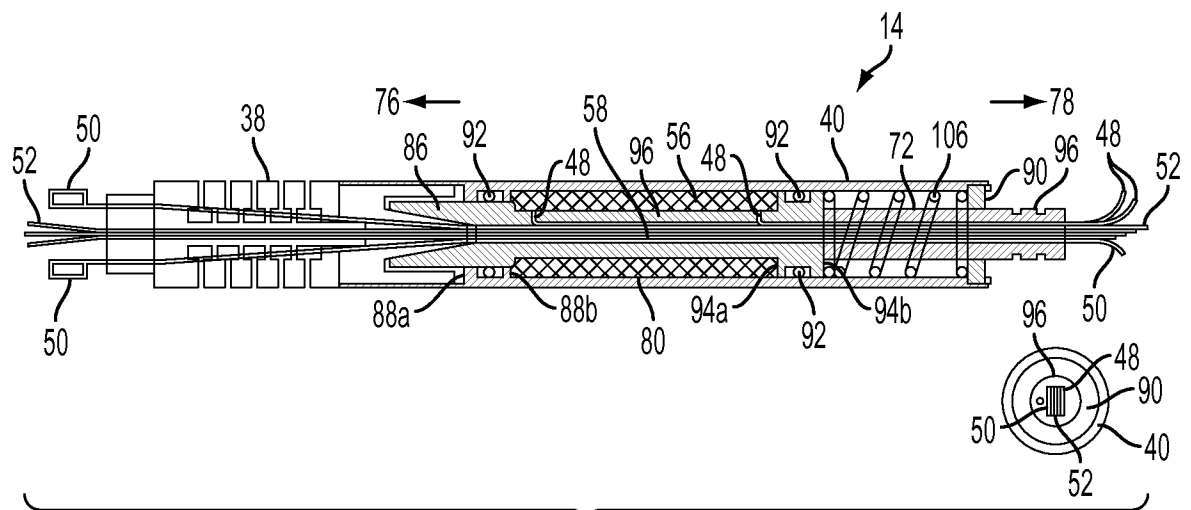


FIG. 17

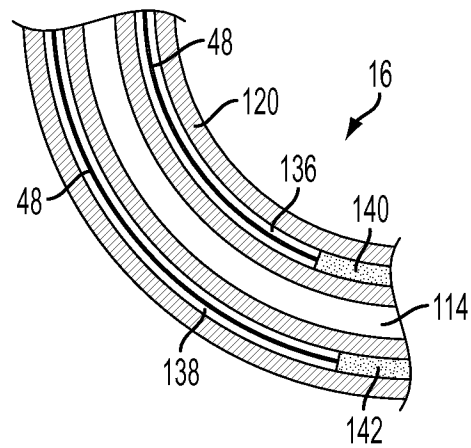


FIG. 18

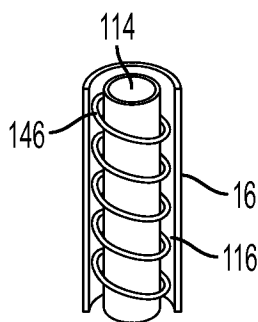


FIG. 19A

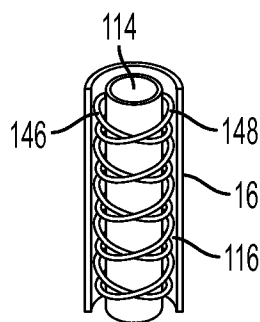


FIG. 19B

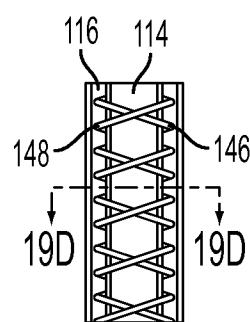


FIG. 19C

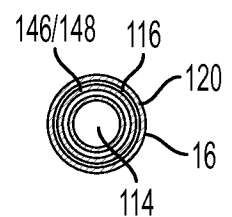


FIG. 19D

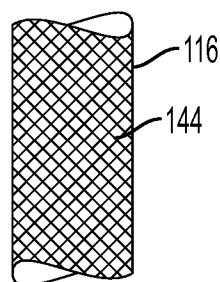


FIG. 20

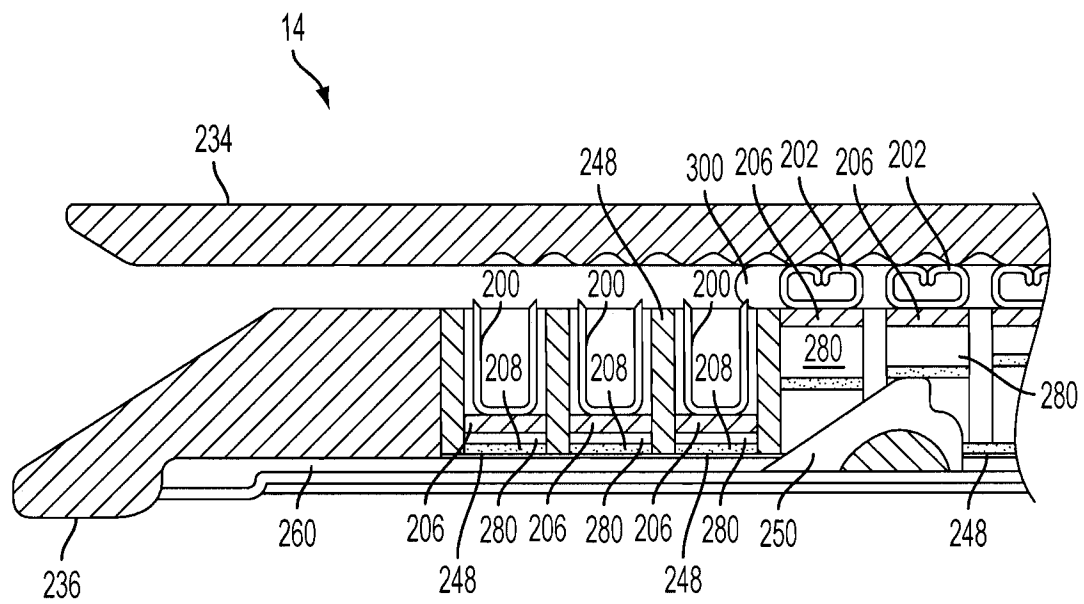


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/021532

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 A61B17/072 A61B17/115 A61B17/34
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/002665 A1 (PARIHAR SHAILENDRA K [US] ET AL) 1 January 2004 (2004-01-01)	1-12,14, 15,17-19
Y	paragraphs [0167] - [0169], [0181] - [0185] - paragraphs [0195] - [0197], [0199] - [0200]; figures 9,19a,23,24a,b,27a,b,29a-c,30	13,16,20
Y	US 5 970 581 A (CHADWICK BARRY W [US] ET AL) 26 October 1999 (1999-10-26) column 4, lines 20-36; figures 2-4	13,16,20
A	WO 2007/135577 A2 (KONINKL PHILIPS ELECTRONICS NV [NL]; PHILIPS CORP [US]; ECK KAI [NL]) 29 November 2007 (2007-11-29) page 3, line 33 - page 4, line 8; figures 1-6	1-20



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

28 June 2012

Date of mailing of the international search report

06/07/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Lee, Ronan

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/021532

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004002665	A1	01-01-2004	AU 2003243446 A1 19-01-2004
			US 2004002665 A1 01-01-2004
			WO 2004002310 A1 08-01-2004

US 5970581	A	26-10-1999	AR 018893 A1 12-12-2001
			AT 411142 T 15-10-2008
			AU 741407 B2 29-11-2001
			AU 4336999 A 10-01-2000
			BR 9911489 A 20-03-2001
			CA 2335555 A1 29-12-1999
			CN 1312760 A 12-09-2001
			CZ 20004871 A3 15-08-2001
			EP 1094954 A1 02-05-2001
			HK 1038905 A1 09-03-2007
			JP 2002518221 A 25-06-2002
			PL 344997 A1 19-11-2001
			RU 2211151 C2 27-08-2003
			TW 517022 B 11-01-2003
			US 5970581 A 26-10-1999
			WO 9966781 A1 29-12-1999
			ZA 200007643 A 24-12-2001

WO 2007135577	A2	29-11-2007	CA 2652785 A1 29-11-2007
			CN 101448542 A 03-06-2009
			EP 2026864 A2 25-02-2009
			JP 2009538167 A 05-11-2009
			KR 20090019794 A 25-02-2009
			RU 2008150476 A 27-06-2010
			TW 200803941 A 16-01-2008
			US 2009234278 A1 17-09-2009
			WO 2007135577 A2 29-11-2007
