

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 December 2006 (21.12.2006)

PCT

(10) International Publication Number
WO 2006/135642 A1

(51) International Patent Classification:

A61B 17/064 (2006.01) A61B 17/00 (2006.01)

A61B 17/068 (2006.01) A61B 17/08 (2006.01)

(21) International Application Number:

PCT/US2006/022158

(22) International Filing Date: 7 June 2006 (07.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/689,589 10 June 2005 (10.06.2005) US

(71) Applicant (for all designated States except US): **WILSON-COOK MEDICAL INC.** [US/US]; P.O. Box 27115-4191, Winston-salem, NC 27105-4191 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **SURTI, Vihar, C.** [US/US]; 632 Timberline Ridge Lane, Winston-salem, NC 27106 (US).

(74) Agent: **DARE, Heidi, A.**; BRINKS HOFER GILSON & LIONE, P.O. Box 10087, Chicago, IL 60610 (US).

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

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

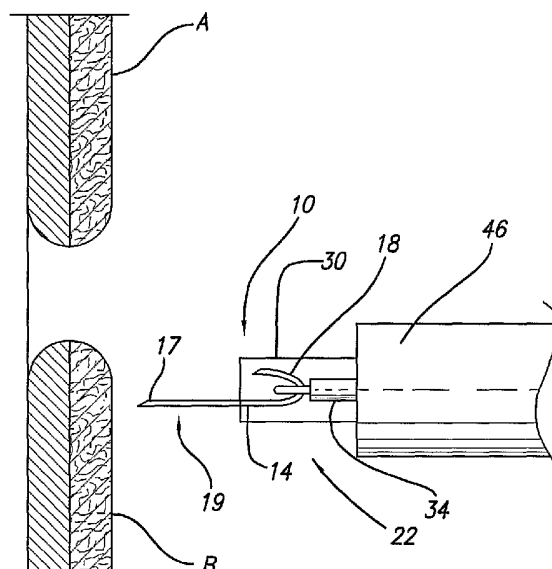
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT,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

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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

(54) Title: MEDICAL STAPLER



(57) Abstract: A stapler for delivering a staple formed from a shape memory material is disclosed. The staple includes a first tine and a second tine connected by a bridge. The staple may be disposed within the stapler in an open position with the first tine distal of the second tine. The stapler is configured to sequentially deliver the first tine and the second tine, respectively, to opposing body tissues. The stapler includes an elongate shaft (e.g., a catheter) having a working lumen and a control mechanism for delivering the staple. A drive cable extends along the working lumen of the elongate shaft. Upon warming up to a temperature at or above a transformation temperature of the shape memory material, the staple may assume a closed position, thus drawing together opposing body tissues and closing an incision.

WO 2006/135642 A1

MEDICAL STAPLER

This application claims the benefit of U.S. Provisional Patent Application No. 60/689,589, filed June 10, 2005, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0001] This disclosure generally relates to medical devices, and particularly to surgical staples and devices for delivering surgical staples.

BACKGROUND

[0002] Surgical stapling is commonly used to close surgical incisions. Surgical stapling benefits the patient by reducing the amount of time the patient is under anesthesia. It also benefits physicians by eliminating much of the time and energy that was previously spent suturing surgical incisions with traditional needle and silk, polymer, or gut thread. As a result, surgical stapling has become the procedure of choice for incision closure, especially when confronting large incisions or wounds.

[0003] Conventional staples used in surgical stapling initially were formed from stainless steel. However, properly deploying stainless steel staples proved difficult because of the substantial amount of force required to deform stainless steel staples into a closed position. A great deal of innovation was thus directed to surgical staplers. Despite this effort, surgical staplers continue to suffer from one or more of the following drawbacks. Surgical staplers are relatively heavy and bulky; they are expensive because of their complex inner workings; they often obstruct the target location for the staple; and each stapler is intended for a narrow range of procedures.

[0004] As a result of their unique characteristics, shape memory alloys ("SMAs") have become viable alternatives to stainless steel. Shape memory materials are capable of returning to a previously defined shape and size when subjected to an appropriate thermal treatment. For example, a shape memory

material having an initial configuration above a first transformation temperature may be cooled to below a second transformation temperature and then deformed to take on a different configuration. Then, upon heating above the first transformation temperature, the material may "remember" and spontaneously recover the initial configuration. The basis for this behavior is a substantially reversible phase transformation that occurs when the temperature of the material moves below and above its transformation temperatures. Using surgical staples formed from SMAs may reduce or eliminate the need to apply a substantial deforming force to fasten the staples. A shape memory surgical staple is described in U.S. Patent No. 4,485,816, to Krumme, entitled "SHAPE-MEMORY SURGICAL STAPLE APPARATUS AND METHOD FOR USE IN SURGICAL STAPLING," which is incorporated herein by reference in its entirety.

[0005] Despite the significant advance of using SMA surgical staples instead of stainless steel surgical staples, the staplers used to deliver SMA surgical staples suffer from one or more of the following drawbacks. First, such staplers are unsuitable for use in endoscopic procedures. That is, such staplers are not deliverable through the working channel of an endoscope. Accordingly, endoscopically (or laparoscopically) created incisions cannot be closed with traditional SMA staplers. Second, these staplers require that both tines of a staple be simultaneously inserted into the opposing tissues of an incision. This requires that a physician use one hand to approximate both opposing tissues of an incision and another hand to simultaneously insert the tines of the staple into the respective opposing sides. This can be particularly limiting during endoscopic procedures in which the physician needs one hand to operate the endoscope. Moreover, since both tines enter the opposing sides of the tissue simultaneously, the tines cannot be used to gather and approximate the opposing tissues. Accordingly, there is a need for a stapler and an SMA staple that resolves or improves upon any of these drawbacks.

BRIEF SUMMARY

[0006] A medical device is disclosed herein that may provide advantages over medical staplers known in the art. The medical device of the present disclosure may be suitable for use in endoscopic procedures, for example, and may allow a physician to approximate opposing tissues with one hand while operating an endoscope with the other.

[0007] According to one aspect of the present invention, the medical device includes an elongate shaft having a working lumen. A staple is disposed in the working lumen in an open position. The staple includes a first tine and a second tine connected by a bridge portion. The staple comprises a shape memory material and is configured to transition from the open position to a closed position at or above a transformation temperature of the shape memory material. The first tine is disposed distal of the second tine in the working lumen.

[0008] According to another aspect of the present invention, the medical device includes a staple formed from a shape memory material. The staple has an open position and a closed position. The medical device also includes an elongate shaft having a working lumen extending at least partially therethrough. The working lumen is adapted for receiving the staple in the open position. The medical device also includes a control member extending along the lumen. The control member is adapted for delivery of the staple to a body tissue. The staple assumes the closed position when disposed in the body tissue.

[0009] In another aspect of the invention, a method of using a medical device to approximate opposing tissue portions is disclosed. The method includes providing a medical device that has an elongate shaft, a staple, and a control wire. The elongate shaft includes a proximal end, a distal end, and a working lumen extending along a longitudinal axis. The staple is disposed in an open position in the working lumen and includes a first tine and a second tine connected by a bridge portion. An end of the first tine is disposed distal of the second tine in the open position. The staple also includes a shape memory material and is configured to transition from the open position to a closed position at or above a

transformation temperature of the shape memory material. The control wire is located at least partly within the working lumen of the elongate shaft and is releasably attached to the staple. The method further comprises positioning the medical device such that the distal end of the elongate shaft is aligned with a first portion of a body tissue, and then actuating the control wire to insert the first end of the staple into the first portion of the body tissue adjacent an incision. The control wire may then be actuated to insert the second end of the staple into a second portion of the body tissue adjacent an incision, thereby causing the staple to reach the closed position and approximate the opposing tissue portions.

[0010] The foregoing paragraphs have been provided by way of general introduction, and are not intended to limit the scope of the following claims. The presently preferred embodiments, together with further advantages, will be best understood by reference to the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

[0012] Figure 1 illustrates a side view of a surgical staple according to one embodiment of the present invention;

[0013] Figure 2 illustrates a side view of a stapler with a cut-away distal portion according to one embodiment of the present invention;

[0014] Figure 3 illustrates a partial side view of a stapler, according to one embodiment of the present invention;

[0015] Figure 4 illustrates a partial side view of a stapler according to one embodiment of the present invention and a surgical incision;

[0016] Figure 5 illustrates a partial side view of a stapler according to one embodiment of the present invention and a staple deployed through one side of a surgical incision;

[0017] Figure 6 illustrates a partial side view of a stapler according to one embodiment of the present invention and a staple deployed through one tissue path;

[0018] Figure 7 illustrates a cross-sectional side view of a staple securing opposing sides of a tissue;

[0019] Figure 8 illustrates a side view of a surgical staple according to one embodiment of the present invention;

[0020] Figure 9 illustrates a side view of a surgical staple according to another embodiment of the present invention;

[0021] Figures 10A-10C illustrate the transition of a surgical staple of the present invention from an open position to a closed position;

[0022] Figures 11A-11C illustrate the transition of an alternative embodiment of a surgical staple from an open position to a closed position; and

[0023] Figure 12 is a typical transformation temperature curve for shape memory alloys.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0024] The invention is described with reference to the drawings in which like elements are referred to by like numerals. The relationship and functioning of the various elements of this invention are better understood by the following detailed description. However, the embodiments of this invention as described below are by way of example only, and the invention is not limited to the embodiments illustrated in the drawings. It should also be understood that the drawings are not to scale and in certain instances details have been omitted which are not necessary for an understanding of the present invention, such as conventional details of fabrication and assembly.

[0025] Referring now to the Figures, there is shown in Figure 1 a staple 10 having a bridge 14 connecting a first tine 17 and a second tine 18. The first and second tines 17, 18 may include first and second ends 27, 28 that are adapted to penetrate tissue. The first and second ends 27, 28 may facilitate entry of the first and second tines 17, 18 into the tissue to be approximated. By way of non-

limiting example, the ends 27, 28 may be straight or angled, and may include a sharpened or beveled point. The ends 27, 28 may also be adapted to anchor the staple in place after the ends 27, 28 have entered the tissue. For example, the ends 27, 28 may include barbs. The staple comprises a shape memory material.

[0026] As illustrated in Figure 1, the staple 10 is in a closed position 20. In the closed position 20, the first tine 17 and the second tine 18 are bent toward each other. In an open position 19 of the staple 10, as illustrated for example in Figure 2, at least one of the first tine 17 and the second tine 18 extends generally along a line of the bridge 14. In other words, at least one of the first tine 17 and the second tine 18 is not bent toward the other in the open position 19. When the staple 10 is in the closed position 20, the shape memory material may comprise a high temperature phase. According to one embodiment, the high temperature phase is austenite. When the staple 10 is in the open position 19, the shape memory material may comprise a low temperature phase. According to one embodiment, the low temperature phase is martensite.

[0027] Figure 2 further illustrates a stapler 22 that may be used to insert the staple 10. The stapler 22 may be formed, for example, from an elongate shaft (e.g., a catheter 30) having a proximal end 50 and a distal end 26. As shown in Figure 2, the distal end 26 may be configured to deliver the staple 10, which is illustrated in an open position 19. In the open position 19 within the stapler 22, the staple is disposed with an end of the first tine 17 distal of the second tine 18. In general, as will be explained in greater detail below, the catheter can be used through the working channel of an endoscope to approximate the opposing portions of a tissue using the first and second tines 17 and 18. Referring to Figures 4-7, once the first tine 17 penetrates a body tissue, the body tissue temperature causes the first tine 17 of the staple 10 to warm up and assume a closed configuration. The stapler 22 may then be used to pull the tissue with the first tine 17 inserted therein into close apposition with a second tissue for insertion of the second tine 18. The second tine 18 may then be inserted into the body tissue and assume a closed configuration upon warming up, thus drawing together

the body tissue and closing the incision. At this point, the staple 10 is in the closed position 20.

[0028] According to one embodiment, when the staple 10 is in the closed position 20, the end 27 of the first tine 17 may generally face the end 28 of the second tine 18, as shown, for example, in the configuration 68 illustrated in Figure 8. According to another embodiment, when the staple 10 is in the closed position 20, the end 27 of the first tine 17 and the end 28 of the second tine 18 may generally face the bridge portion 14, as shown, for example, in the configuration 58 illustrated in Figure 9.

[0029] In the open position 19, the staple 10 can be provided in a variety of shapes that fit within the lumen of a catheter and that allow the staple to be deployed from the distal end of the catheter. In the embodiment shown in Figure 2, the staple 10 includes a linear (straight) bridge 14 between a first tine 17 and a second tine 18. According to this embodiment, the first tine 17 is generally straight and extends along the line of the bridge 14, and the second tine 18 is bent. Specifically, the second tine 18 is curved. Alternatively, the second tine 18 may be angled. For the purposes of this disclosure, "bent" is used to refer to a curved or an angled configuration. The staple 10 may also be provided in the open position 19 with both the first and second tines 17 and 18 extending along the line of the bridge 14. In another embodiment, the first tine 17 may be bent (curved or angled), and the second tine 18 may extend along the line of the bridge 14. In some embodiments, the bridge 14 may be bent (angled or curved) in the open position 19 to facilitate insertion of the second tine 18 into the second tissue after the first tine 17 has transitioned to its closed position, as illustrated, for example, in Figures 10A-10C. In the open position 19, the bent bridge 14 may be combined with two straight first and second tines 17, 18, with a straight first tine 17 and a curved or angled second tine 18, or with a straight second tine 18 and a curved or angled first tine 17.

[0030] Preferably, in the closed position 20, both the first and second tines 17, 18 may be bent toward each other so as to approximate an incision. The first and second tines 17 and 18 may have different configurations in the closed position 20

as well as in the open position 19 (as described above). For example, in some embodiments, the first tine 17 may be curved and the second tine 18 may be angled in the closed position 20. Alternatively, the first tine 17 may be angled and the second tine may be curved in the closed position 20. The bridge 14 may be straight, angled or curved in the closed position 20.

[0031] The staple 10 may be formed from a shape memory material. A shape memory alloy including nickel and titanium, such as Nitinol, may be used. Shape memory alloys may undergo a reversible transformation between an austenitic phase and a martensitic phase at certain predetermined temperatures. The behavior of shape memory alloys depends on their transformation temperatures. Figure 12 shows a typical transformation temperature curve for a shape memory alloy. The y-axis indicates the percentage of the martensitic phase present in the material, and the x-axis indicates temperature. At point A, the shape memory material is at a temperature A_f and the structure is fully austenitic. No martensite is present in the material. Following the curve to point B, the shape memory material is cooled to a temperature of M_s , at which point the transformation to the martensitic phase begins. Further cooling leads to an increase in the percentage of martensite in the material, ultimately reaching 100% at a temperature of M_f . At this point (C), the shape memory material is fully martensitic. No austenite is present in the material. To reverse the phase transformation and return to a fully austenitic structure, the temperature of the material must be increased. Following the curve to point D, the shape memory material may be warmed to a temperature of A_s , at which point the material begins to transform to the austenitic phase. Upon further heating, the percentage of the martensitic phase in the material decreases as the transformation to austenite progresses. Ultimately, at a temperature of A_f or above, the material has completed the return transformation to the austenitic phase.

[0032] In practice, differential scanning calorimetry techniques known in the art may be used to identify the transformation temperatures of a particular shape memory material. The transformation temperatures may be affected by the alloy composition and the processing history of the material. In developing the correct

alloy composition, biological temperature compatibility may be considered in order to select suitable transformation temperatures. For example, shape memory materials can be prepared such that A_f is slightly lower than or equal to body temperature. Such materials will remember and return to their initial configuration when they come into contact with body tissue or are otherwise warmed up to about body temperature. It may be desirable to select a shape memory material for the staple 10 of the present disclosure having a value of A_f which is slightly lower than or about equal to body temperature (37°C). For example, A_f may be in the range from about 32°C to about 40°C. According to another embodiment, A_f may be in the range from about 36°C to about 38°C. Alternatively, shape memory materials having higher or lower values of A_f may be used for the staple 10. For example, it may be desirable to have A_f in the range of from about 40°C to about 60°C, e.g., 50°C. According to another embodiment, A_f may be less than 32°C.

[0033] Depending on the precise transformation temperatures (e.g., A_f) of the shape memory alloy used for the staple 10, the staple 10 may require heating or cooling from an external source during delivery within the body. For example, according to some embodiments, cooling may be desirable to prevent premature transformation to the austenitic phase and, consequently, the closed position 20. Such cooling may be carried out by, for example, periodically or continuously flushing the catheter 30 with a cool saline solution. Alternatively, the staple 10 may require heating from an external source in order to facilitate transformation to the austenitic phase and, consequently, the closed position 20. Such heating may be carried out by, for example, periodically or continuously flushing the catheter 30 with a warm saline solution. In either of these situations, the staple 10 and the heating or cooling means (e.g., saline solution) may be maintained at temperatures that are compatible with the surrounding body tissue.

[0034] In some embodiments, the shape memory material may be formed from a nickel-titanium composition (e.g., Nitinol) known in the art. The shape memory material may alternatively be formed from a composition consisting essentially of about 30 to about 52 percent titanium, up to 10 percent of one or more additional ternary alloying elements, and the balance nickel. Such ternary alloying elements

may be selected from the group consisting of palladium, platinum, chromium, iron, cobalt, vanadium, manganese, boron, copper, aluminum, tungsten, tantalum, and zirconium. In particular, the ternary element may optionally be up to 10 percent each of iron, cobalt, platinum, palladium, or chromium, and up to about 10 percent copper and vanadium. As used herein, all references to percent composition are atomic percent unless otherwise noted. Other shape memory materials may also be utilized, such as, but not limited to, irradiated memory polymers such as autocrosslinkable high density polyethylene (HDPEX). Shape memory alloys are known in the art and are discussed in, for example, "Shape Memory Alloys," *Scientific American*, Vol. 281, pp. 74-82 (November 1979).

[0035] Briefly, the staple 10 may be formed into any desired closed position 20 while the shape memory material is in the austenitic phase by, for example, shaping on a mandrel. Then, the staple 10 may be provided in the open position 19 for being received by the lumen of the catheter 30 for delivery to body tissue. Generally, providing the staple 10 in the open position 19 involves cooling the staple 10 to a temperature at or below M_f of the shape memory material. This cooling effects a complete transformation of the shape memory material from the high temperature phase (austenite) to the low temperature phase (martensite) (see Figure 12). Once the staple 10 has a fully martensitic structure, the staple 10 may be deformed into the open position 19 from the closed position 20. Elastic (recoverable) strains of up to about 8% may be obtainable from nickel-titanium shape memory alloys.

[0036] After deformation, if the temperature of the staple 10 is kept below about A_s , the staple may remain in the open position 19. If the temperature of the staple 10 is raised to A_f or above, then the staple 10 may completely transform to the austenitic phase and remember (return to) its closed position 20. At temperatures below A_f and at or above A_s , the staple may partially transform to the austenitic phase and exhibit some change in its configuration without completely transforming to the closed position 20. In other words, the staple may be partly martensitic and partly austenitic within this temperature range. It may be desirable for the staple to be delivered to the body tissue at a temperature within this range

(below A_f but at or above A_s) in order to exploit the higher rigidity of the austenitic phase compared to the more deformable martensitic phase. The enhanced rigidity may be useful for the initial penetration of body tissue by the ends 27, 28 of the staple 10, for example. Alternatively, it may be advantageous in some embodiments to maintain the staple 10 at a temperature below A_s during delivery.

[0037] The staple 10 may transition from the open position 19 in the catheter 30 to the closed position 20 in a tissue in a stepwise fashion, wherein the first tine 17 transitions to the austenitic phase prior to the second tine 18. Figures 4-7, 10A-10C and 11A-11C show exemplary staples transitioning from the open position 19 to the closed position 20. In the open position 19, the first tine 17 of the staple 10 is disposed distal of the second tine 18 within the lumen of the catheter 30 (see Figure 4). Upon being heated to a temperature of A_f or higher, the first tine 17 may transition to its final (closed) configuration, as shown for example in Figures 5, 10B, and 11B. The heating may occur as the first tine 18 is being inserted into body tissue, for example, or by some other means. The second tine 18 may remain in its initial configuration after the first tine 17 has transitioned to the final configuration. The second tine 18 may then be heated to a temperature of A_f or higher upon entry into the body tissue (or by other means) and transition to its final (closed) configuration. Consequently, the staple 10 reaches the closed position 20, shown in Figures 7, 10C, and 11C.

[0038] Referring now to Figures 2-3, the delivery catheter 30 includes a proximal end 50 and a distal end 26. The proximal end 50 is used to control the catheter 30 and to actuate the stapler 22. Operation of the delivery catheter 30 takes place via the proximal end 50 (Figure 2), which is provided with a conventional handle (not shown). As will become apparent to a person of ordinary skill, a wide variety of handle mechanisms could be used with the disclosed medical stapler. For example, the handle can be a thumb ring, a scissors-type handle, a pin vise, or any other conventional handle suitable for moving a sheath relative to a control wire. In general, the handle is used to actuate the control wire,

which in turn controls the stem movement. That is, the handle is connected to and causes the control wire to move relative to the catheter 30 or vice versa.

[0039] As illustrated in Figures 2-3, the stapler 22 has a control wire 34 that extends to the distal end 26 of the catheter 30. The control wire 34 can be formed from a rigid material such as stainless steel or plastic. The distal end of the control wire 34 is provided with a hook 38. The hook 38 is configured to catch and clasp (i.e., secure) the staple 10 during delivery and insertion, thereby preventing the staple 10 from inadvertently sliding out of the stapler 22. The distal end 26 further includes a slot 42 (Figure 3), which allows the staple to rotate during insertion as described in greater detail below. Any device known to one of skill in the art may be used to manipulate the staple 10 for insertion into the tissue.

[0040] Figures 4-6 illustrate a method of approximating opposing tissues with the staple 10 and the stapler 22. As shown in Figure 4, an endoscope 46 is navigated to the site of opposing tissues A and B. Once the endoscope 46 is adjacent opposing tissues A and B, the physician actuates the catheter handle to move the control wire 34 distally, i.e., toward opposing tissues A and B. Stapler 22 is then moved toward tissue B, as shown in Figure 5, so that the second tine 18 penetrates or pierces the tissue. When the second tine 18 of the staple 10 penetrates tissue B, the exposure to body temperature causes the second tine 18 of the staple to assume its closed configuration. After the second tine 18 assumes its closed position, the physician can move the distal end of the stapler 22 towards tissue A using the second tine 18 in tissue B to pull tissue B towards tissue A. As illustrated in Figure 6, a portion of the staple 10 may extend through the slot 42 as the tissue B is approximated with tissue A allowing the staple 10 to be rotated after the second tine 18 is inserted into tissue B. At this point in the procedure, the physician can insert the first tine 17 into tissue A. Once the first tine 17 is heated by exposure to body temperature, the first tine 17 assumes its closed configuration, and the control wire 34 can be moved distally and laterally relative to the staple 10 to disengage the hook 38 from the staple 10. When the temperature of the staple 10 reaches or exceeds A_f , the staple 10 assumes the closed position 20 illustrated in Figure 7, thereby approximating opposing tissues A and B.

[0041] Any other undisclosed or incidental details of the construction or composition of the various elements of the disclosed embodiment of the present invention are not believed to be critical to the achievement of the advantages of the present invention, so long as the elements possess the attributes needed for them to perform as disclosed. Certainly, one skilled in the medical arts would be able to conceive of a wide variety of staple shapes and delivery system configurations and successful combinations thereof. The selection of these and other details of construction are believed to be well within the ability of one of even rudimentary skills in this area, in view of the present disclosure. Illustrative embodiments of the present invention have been described in considerable detail for the purpose of disclosing a practical, operative structure whereby the invention may be practiced advantageously. The designs described herein are intended to be exemplary only. The novel characteristics of the invention may be incorporated in other structural forms without departing from the spirit and scope of the invention. The invention encompasses embodiments both comprising and consisting of the elements described with reference to the illustrative embodiments. Unless otherwise indicated, all ordinary words and terms used herein shall take their customary meaning as defined in *The New Shorter Oxford English Dictionary*, 1993 edition. All technical terms shall take on their customary meaning as established by the appropriate technical discipline utilized by those normally skilled in that particular art area. All medical terms shall take their meaning as defined by *Stedman's Medical Dictionary*, 27th edition.

CLAIMS

1. A medical device, comprising:

an elongate shaft having a working lumen; and

a staple disposed in an open position in the working lumen, the staple comprising a first tine and a second tine connected by a bridge portion, the staple further comprising a shape memory material and being configured to transition from the open position to a closed position at or above a transformation temperature of the shape memory material,

wherein the first tine is disposed distal of the second tine in the working lumen.
2. The medical device according to claim 1, wherein an end of the first tine or and end of the second tine is bent toward the other tine in the open position.
3. The medical device according to claim 1, wherein at least one of the first tine and the second tine extend generally along a line of the bridge portion in the open position.
4. The medical device according to claim 1, wherein the staple is disposed in the closed position after delivery to a body tissue.
5. The medical device according to claim 4, wherein the first tine and the second tine are bent toward each other in the closed position, thereby enabling closure of an incision.
6. The medical device according to claim 1, further comprising a control mechanism extending through the working lumen of the elongate shaft.
7. The medical device according to claim 1, wherein the transformation temperature of the shape memory material is in the range of from about 32°C to about 40°C.

8. The medical device of claim 1, wherein the shape memory material is a shape memory alloy.
9. The medical device of claim 8, wherein the shape memory alloy comprises nickel and titanium.
10. The medical device according to claim 1, wherein the elongate shaft further comprises a proximal portion and a distal portion, and a slot disposed along the distal portion, the slot being configured to allow a portion of the staple to pass therethrough.
11. A medical device, comprising:
 - a staple formed from a shape memory material and having an open position and a closed position;
 - an elongate shaft having a working lumen extending at least partially therethrough, the working lumen being adapted for receiving the staple in the open position; and
 - a control member extending along the lumen, the control member being adapted for delivery of the staple to a body tissue, wherein the staple assumes the closed position when disposed in the body tissue.
12. The medical device according to claim 11, wherein the control member is adapted for delivery of the staple to the body in sequential stages.
13. The medical device according to claim 11, wherein the staple further comprises a first tine and a second tine connected by a bridge portion, and wherein an end of the first tine is disposed distal of the second tine when the staple is received in the lumen in the open position.
14. The medical device according to claim 11, wherein the shape memory material comprises a high temperature phase and a low temperature phase.

15. The medical device according to claim 14, wherein the staple comprises the low temperature phase of the shape memory material in the open position and the high temperature phase of the shape memory material in the closed position.

16. The medical device of claim 11, wherein the elongate shaft further comprises a axial slot in a distal portion of the elongate shaft, the slot being configured to allow a portion of the staple to pass therethrough.

17. A method of approximating opposing tissue portions, comprising the steps of

- a) providing a medical device, the medical device comprising:
an elongate shaft having a proximal end, a distal end, and a working lumen extending along a longitudinal axis;
a staple disposed in an open position in the working lumen, the staple comprising a first tine and a second tine connected by a bridge portion, the staple further comprising a shape memory material and being configured to transition from the open position to a closed position at or above a transformation temperature of the shape memory material, wherein an end of the first tine is disposed distal of the second tine in the working lumen; and
a control wire located at least partly within the working lumen of the elongate shaft, wherein the control wire is releasably attached to the staple;
- b) positioning the medical device such that the distal end of the elongate shaft is aligned with a first portion of a body tissue;
- c) actuating the control wire to insert the first end of the staple into the first portion of the body tissue adjacent an incision; and
- d) actuating the control wire to insert the second end of the staple into a second portion of the body tissue adjacent an incision, thereby approximating the opposing tissue portions.

18. The method according to claim 17, further comprising extending the staple through a slot in the elongate shaft to facilitate insertion of the second end of the staple.

19. The method according to claim 17, further comprising manipulating one of the elongate shaft and the control wire to move the staple to draw the first portion of the body tissue toward a second portion of the body tissue adjacent an incision.

20. The method according to claim 17, further comprising introducing the medical device through an endoscope to a target site in a body prior to positioning the medical device.

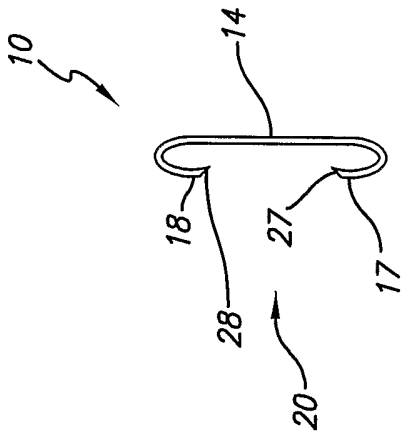


FIG. 1

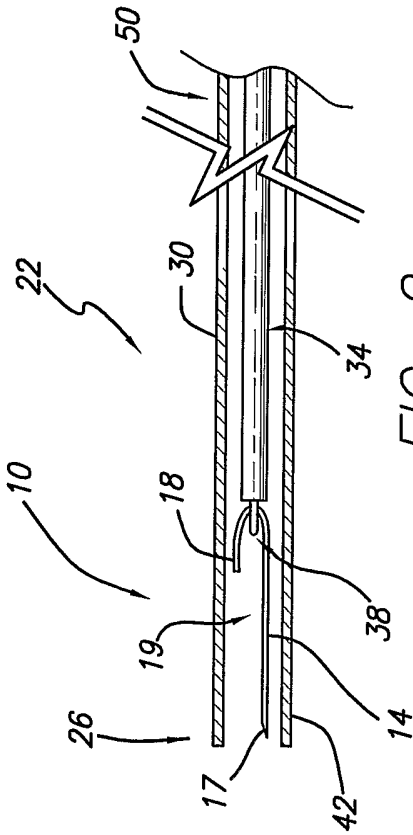


FIG. 2

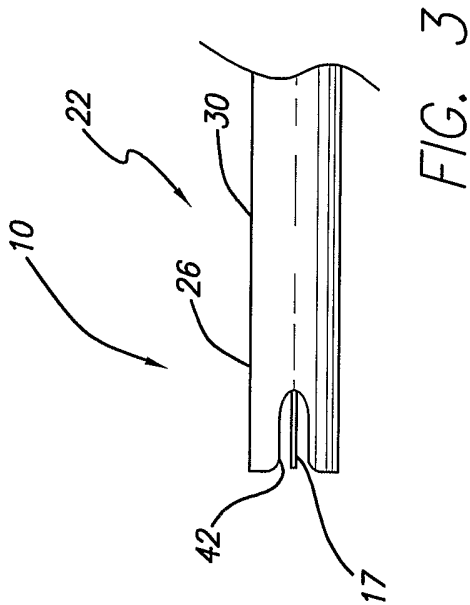
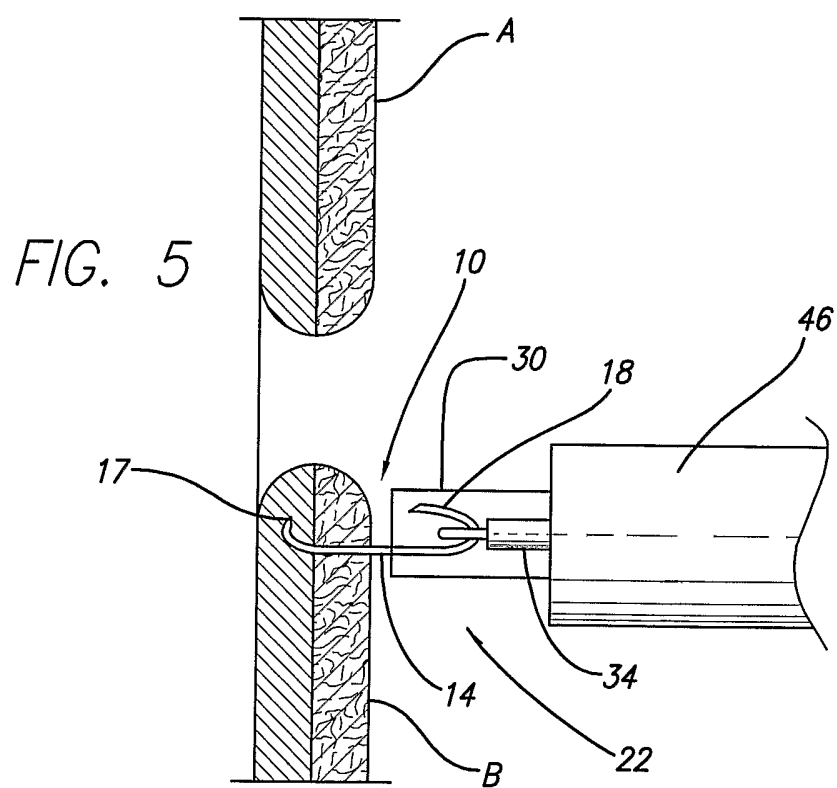
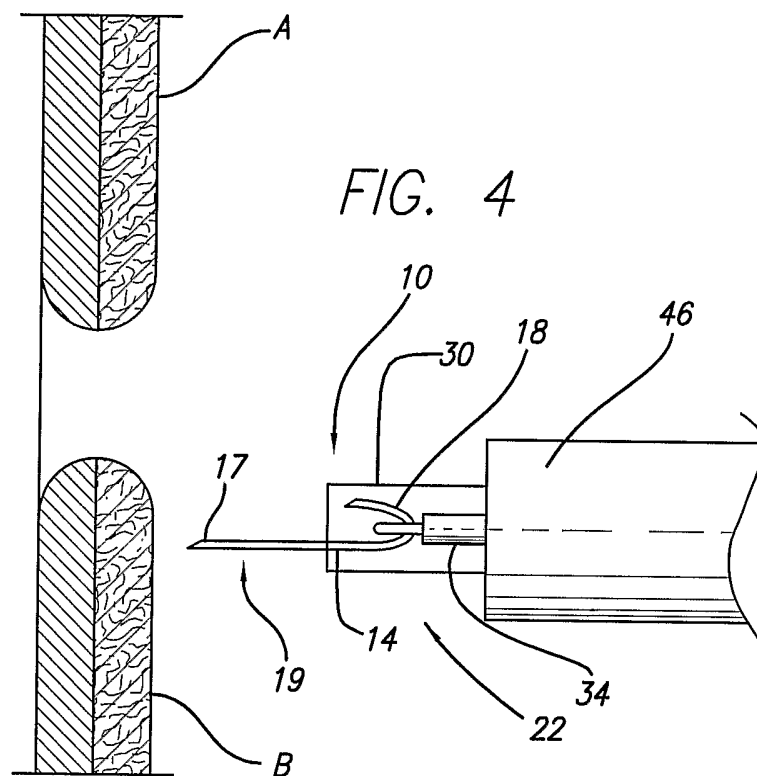


FIG. 3

2/6



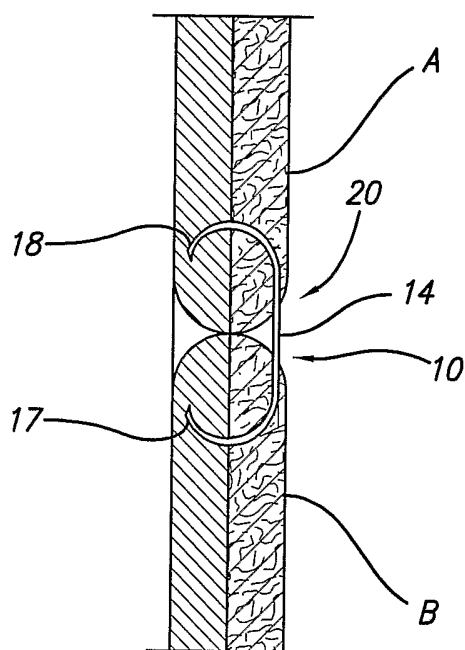
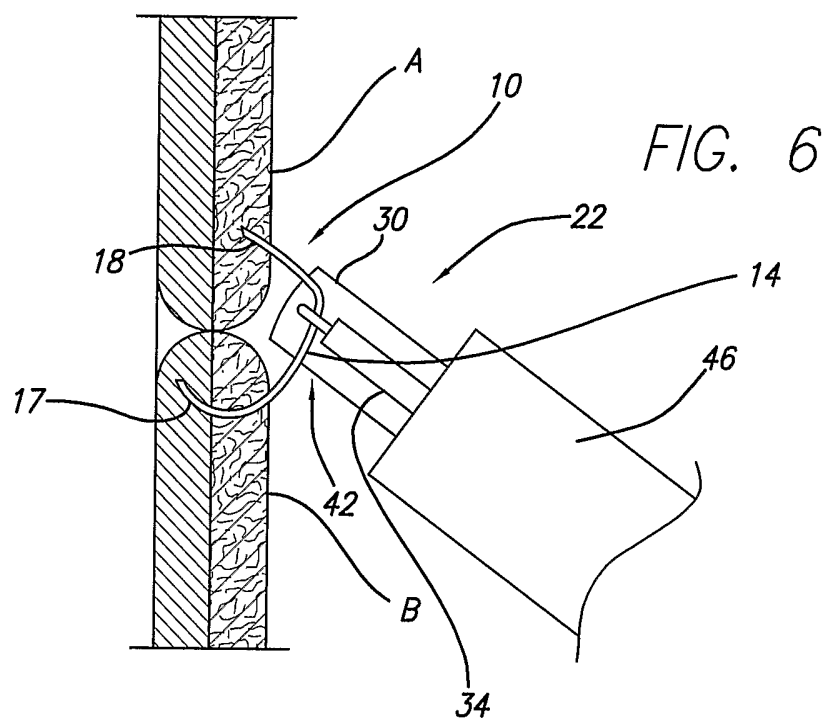


FIG. 7

4/6

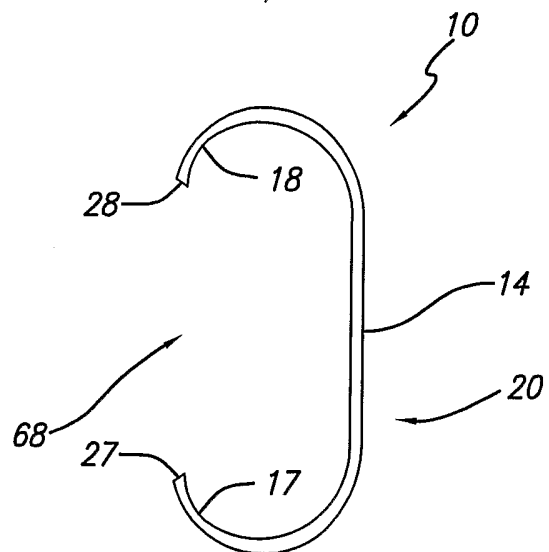


FIG. 8

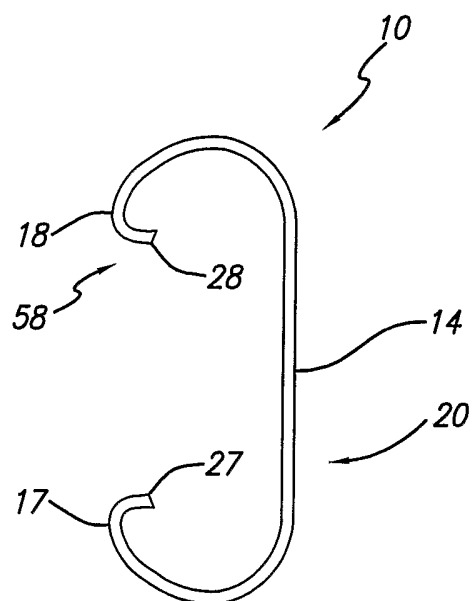


FIG. 9

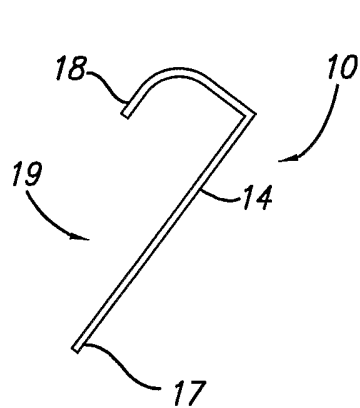


FIG. 10A

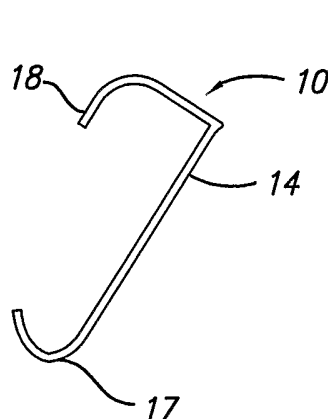


FIG. 10B

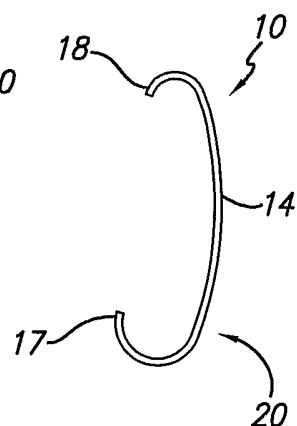


FIG. 10C

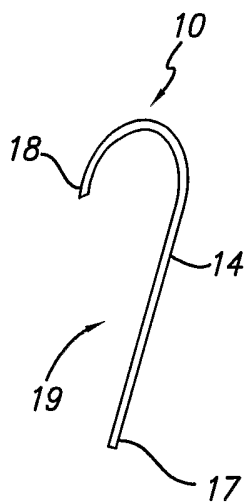


FIG. 11A

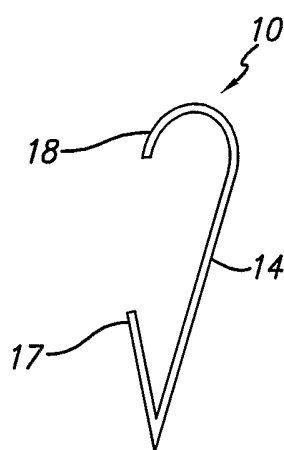


FIG. 11B

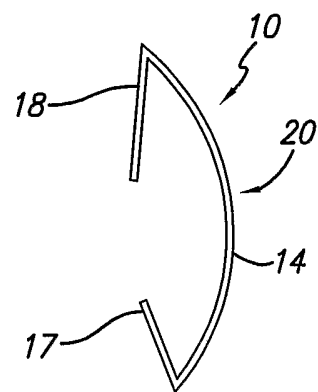
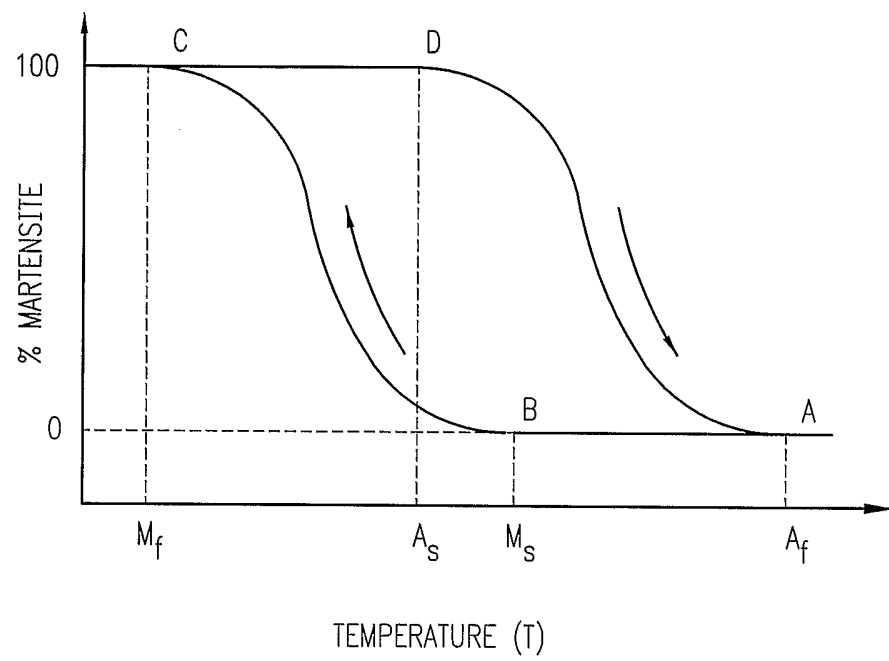


FIG. 11C

*FIG. 12*

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/022158

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/064 A61B17/068
ADD. A61B17/00 A61B17/08

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 practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 199 038 A (ETHICON ENDO-SURGERY, INC) 24 April 2002 (2002-04-24) paragraph [0034] - paragraph [0038] -----	1-9, 11-15
A	EP 1 100 381 A (ANSON MEDICAL LIMITED) 23 May 2001 (2001-05-23) paragraph [0020] -----	1
A	EP 1 016 378 A (JACOBS, ROBERT A) 5 July 2000 (2000-07-05) paragraph [0019] - paragraph [0021] -----	1
A	US 2005/080454 A1 (DREWS MICHAEL J ET AL) 14 April 2005 (2005-04-14) paragraph [0045] paragraph [0069] paragraph [0078] - paragraph [0079] ----- -/--	1

☒ 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 document 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

29 September 2006

Date of mailing of the international search report

23/10/2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Angeli, Markus

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/022158

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 2005/021054 A1 (AINSWORTH STEPHEN ET AL) 27 January 2005 (2005-01-27) paragraph [0037] - paragraph [0039] paragraph [0043]</p> <p>-----</p>	10,16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/022158

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/022158

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1199038	A	24-04-2002	AU 782940 B2	08-09-2005
			AU 8144101 A	02-05-2002
			CA 2359391 A1	19-04-2002
			CN 1356092 A	03-07-2002
			DE 60113940 T2	27-07-2006
			ES 2248244 T3	16-03-2006
			JP 2002200087 A	16-07-2002
			MX PA01010703 A	19-05-2003
			US 6773438 B1	10-08-2004
EP 1100381	A	23-05-2001	AT 303101 T	15-09-2005
			AU 766645 B2	23-10-2003
			AU 5183499 A	28-02-2000
			DE 69927035 D1	06-10-2005
			DE 69927035 T2	08-06-2006
			DK 1100381 T3	19-12-2005
			ES 2249024 T3	16-03-2006
			WO 0007506 A2	17-02-2000
			JP 2002522107 T	23-07-2002
EP 1016378	A	05-07-2000	NONE	
US 2005080454	A1	14-04-2005	AU 2004285424 A1	12-05-2005
			CA 2541171 A1	12-05-2005
			EP 1670364 A2	21-06-2006
			WO 2005041784 A2	12-05-2005
US 2005021054	A1	27-01-2005	WO 2005011468 A2	10-02-2005