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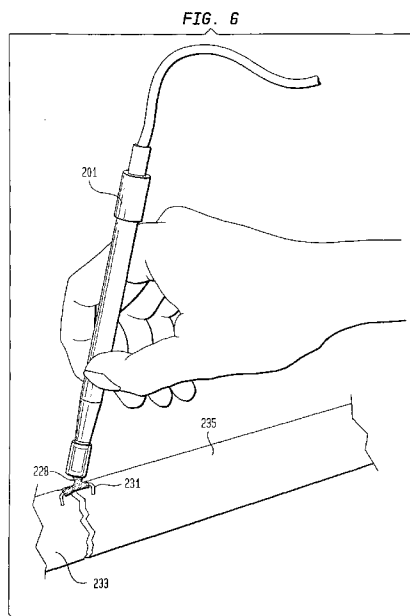
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(54) Title: METHOD AND APPARATUS FOR DELIVERING HEAT TO A SHAPE MEMORY ARTICLE



(57) Abstract: The invention pertains to a method and apparatus for heating an article (231, 413) formed of a shape memory alloy comprising the steps of providing a tool (201) having a energy probe (205), disposing a portion of a heat transfer medium (227) adjacent the energy probe, touching the heat transfer medium to a shape memory article, and activating the energy probe to heat the heat transfer medium, which heat transfer medium conductively transfers heat to the article.

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METHOD AND APPARATUS FOR DELIVERING
HEAT TO A SHAPE MEMORY ARTICLE

BACKGROUND OF THE INVENTION

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Field of the Invention

[0001] The present invention relates to a method and apparatus for heating a shape memory article to a predetermined transformation temperature.

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Brief Description of the Related Art

[0002] Shape memory articles (SMAs), comprised, for instance, substantially of NiTiNol alloy, are used in many surgical applications, including use as staples for re-attaching tissue or bone. Usually, external heat is applied to the shape memory article in order to transition it from a first shape in a martensitic, softer, morphology to a second shape in an austenitic, stiffer, morphology.

[0003] When a patient suffers an injury in which tissue or bone must be reapproximated, reattached, or fused, the injury often must be repaired by surgically securing the tissue or bone together with internal fixation devices such as plates, screws, pins, or staples. These devices are often rigid and have geometric features that enable them to reapproximate, reattach, or fuse tissues. Examples of these features include threads, grooves, overall shape of the device, and other features that provide attachment or support. Any undesired deformation of these devices could lead to increased amounts of strain and ultimate failure of the device.

[0004] Since the late 1980's, NiTiNol, a Nickel-Titanium alloy, has been increasingly utilized in a variety of medical devices and, in some cases, has become one of the materials of choice for many designers and engineers. From surgical devices to endoluminal stents and other

prostheses, the thermo-mechanical characteristics of the material and its biocompatibility have allowed its use across many medical and surgical specialties both for diagnostic and therapeutic applications.

[0005] The shape memory effect results from a reversible crystalline phase change known as martensitic transformation. Shape memory alloys can display various types of shape memory. The type of shape memory that has probably found the most use in commercial applications is commonly referred to as one-way shape memory. In one-way shape memory, an article formed of a shape memory alloy in an original shape can be substantially plastically deformed into a shape while it is in the soft, martensitic phase and it will remain in that shape, (hereinafter the deformed shape). Then, upon heating above a first temperature, the material returns to its original (prior to deformation) shape while transitioning from the soft, martensitic phase to a much stiffer austenitic phase. It should be noted that, while the article is much stiffer in the austenitic phase, it usually is still somewhat deformable, but primarily elastically, as opposed to plastically, deformable. Upon cooling below a second temperature that is below the first temperature, the material transitions back to the softer, martensitic phase, but maintains the shape it took during the transformation to the austenitic phase (i.e., its original shape) until it is acted upon by an external force or stress. Because the material is less stiff (i.e., more pliable) in its martensitic phase, it is much easier to bend (back to the deformed shape or any other shape) and it will maintain that new shape up to and until it is heated once more above its transformation temperature.

[0006] The strength and transition temperatures of SMAs can be greatly varied by changing the exact composition of the alloy and/or the thermal history of the article.

[0007] The use of shape memory staples in surgical skeletal repair enables a staple to be installed in bone or tissue in one shape while in its

martensitic phase and then be heated to cause it to transition to the much stiffer austenitic phase while shifting to another shape that, for instance, draws the tissue or bone closer together. Many medical applications use SMAs having a transition temperature for complete martensitic to
5 austenitic transformation of about 55°C. However, other medical applications utilize alloys having a complete transition temperature of about the human body temperature of 37°C.

[0008] While metallic staples have long been used for static fixation, the use of shape memory alloys (SMAs) in staples and their attendant
10 ability to apply dynamic continuous compression is a major advancement in tissue and bone uniting that potentially improves the healing process in connection with the repair, fusing, and remodeling of damaged tissue. These SMA staples are smaller and less bulky than other fixation devices, such as plates, screws, and nails. They permit smaller incisions, which
15 cause less trauma and scarring and lead to faster post-operative recovery. Also, since fewer holes need to be drilled and no screws are needed, more rapid surgical procedures are possible.

[0009] Figure 1 is a graph showing a dynamic scanning calorimetry (DSC) for one particular NiTiInol composition. DSC is useful for
20 determining the temperatures at which various substances undergo phase changes. In the case of NiTiInol or other SMA articles, DSC is utilized to understand the temperatures required for transitioning from the martensitic phase to the austenitic phase and back again. DSC measures the heat flow necessary to maintain the article at a certain temperature. The bottom
25 portion of the scan represents the state of the article at -50°C as it is subjected to increasing temperature over time. This graph shows a stable structure (martensitic morphology) during temperatures up to an austenitic start temperature (A_s) of approximately 29°C, where phase transformation to the austenitic phase theoretically begins. As
30 demonstrated by this scan and the change in heat flow, the metal is fully

transformed into its stiff, austenitic phase at the austenitic finish temperature (A_f) of approximately 50°C. The top portion of this scan represents cooling of the austenitic NiTiNol article starting at 100°C. Note that the martensitic phase recovery theoretically begins at the martensitic start temperature (M_s) of approximately 19°C and is complete at the martensitic finish temperature of approximately 0°C. This is only an example of one form of NiTiNol shape memory alloy. Other transition temperatures are achievable with different chemical compositions and thermo-mechanical treatments.

10 **[0010]** Using the exemplary material above, one can see that the device is geometrically stable in its martensitic phase up to room temperature, can be transformed to an austenitic phase via heating it to around 55°C and that it stays in a stable austenitic phase down to temperatures well below body temperature. This is very advantageous in surgical applications as devices, such as orthopedic staples, can be
15 programmed during manufacture with a clinical utility shape in the austenitic phase (the shape that it will take after heating during a surgical procedure) and then be deformed during manufacturing to an operable configuration in its martensitic phase (the shape in which it will be
20 delivered to the surgeon for insertion into the body prior to heating).

[0011] Orthopedic NiTiNol staples have been available clinically in the US for approximately ten years. The manufacturers of these devices are using various instruments and power sources for heating the staples in order to effect the transformation to the austenitic phase in vivo. Tissue
25 cautery and coagulation devices typically are available in an operating theater and are commonly used to provide heat to shape memory articles. Examples of these devices include a resistance wire driven by a voltage that essentially uncontrollably heats the wire to a temperature in excess of 600°C, sometimes reaching 1200°C. The wire is touched to the staple to
30 heat it above the transition temperature. Other forms of cautery devices

use radio frequency (RF) energy to directly heat either a monopolar or bipolar probe.

[0012] The monopolar form of cautery, often referred to as a “bovie”, utilizes the patient as one conductor and a pen-like device as the other conductor. When the pen-like device touches the patient, the circuit from the device through the patient and back to circuit ground is closed and heat is generated, preferably locally at the tip of the pen-like device, thus cauterizing or coagulating tissue. However, evidence of remote, necrotic affects have been documented. In the case of using monopolar systems to heat staples, arcing or sparking often occurs and the energy, transformed to heating the staple, is often uncontrollable.

[0013] The bipolar form of a cautery tool utilizes a handpiece that has two conductors separated or shielded from one another. When the device is energized and touches tissue, the circuit from one conductor to the other is closed through the tissue (which is conductive) and local heating at the tip of the device is used to cauterize and coagulate the tissue. When bipolar tools are used to heat shape memory staples, arcing and sparking also has been observed and the heating of the staple often is uncontrollable.

[0014] Another disadvantage with the mono- and bi-polar direct heating systems of the prior art is that they require significant power (between 40 and 100 Watts) to be useful since the body and the staple comprise very large electrical resistances. In order to generate the necessary heat by means of the joule effect, a significant amount of energy is required and the temperature is uncontrollable as it is a function of the staple resistance, the patient resistance, the power setting and the time of application.

[0015] Therefore, it is an object of the present invention to provide an effective, reproducible, safe, low-power, direct heating method and

apparatus to bring a shape memory article to a predetermined temperature.

Summary of the Invention

5 [0016] In accordance with a first aspect of the invention, a method is provided for heating an article formed of a shape memory alloy comprising providing a tool having an energy probe, disposing a portion of a heat transfer medium adjacent the energy probe, placing the heat transfer medium in close proximity to the article, and activating the energy probe to
10 heat the heat transfer medium, which heat transfer medium, in turn, conductively transfers the heat to the article.

[0017] In accordance with a second aspect of the invention, a surgical tool is provided for heating an article formed of a shape memory alloy comprising a body, an energy probe, a holder adjacent the energy probe,
15 and an energy source for activating the energy probe.

Brief Description of the Drawings

[0018] Figure 1 is a graphical representation of a dynamic scanning
20 calorimetry for one particular NiTiInol composition.

[0019] Figure 2 is a schematic diagram of an exemplary heating apparatus in accordance with the principles of the present invention.

[0020] Figure 3 is a cross-sectional view of the hand tool shown in Figure 2.

25 [0021] Figure 4A illustrates an exemplary surgical staple formed of a shape memory alloy in its pre-surgical, martensitic phase.

[0022] Figure 4B illustrates the same staple in its post-surgical, austenitic phase after heating above its martensitic-to-austenitic transformation temperature.

[0023] Figures 5-7 illustrate stages in a surgical procedure in accordance with one particular embodiment of the present invention.

[0024] Figure 8 is a perspective view of a tool in accordance with another embodiment of the invention.

- 5 [0025] Figure 9 is a flow diagram illustrating the steps involved in an exemplary application of the present invention for heating a surgical staple formed of a shape memory alloy.

Detailed Description of the Invention

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[0026] The present invention solves the aforementioned problems associated with the conventional art of heating an article formed of a shape memory alloy above its transition temperature by using an intermediate heat transfer medium to transfer the heat to the article. The invention is particularly suited to medical applications that utilize articles comprising shape memory alloys (hereinafter shape memory articles). The invention is even more particularly suitable for medical applications that use shape memory articles inside the body, such as tissue and bone staples (hereinafter surgical staples).

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- 20 [0027] The technique is low cost, simple, and fast, using primarily equipment that is already available in most operating rooms.

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[0028] In accordance with the invention, instead of contacting the shape memory article directly with an energy probe, which typically reaches unsafe temperatures well in excess of the temperature necessary to transform the article from its martensitic phase to its austenitic phase, the energy probe energizes an intermediate heat transfer medium to heat the medium, which, in turn, is in contact with the shape memory article. The heat travels from the heat transfer medium to the article, thereby heating the article more evenly, and with much lower power and temperatures. The heat transfer medium preferably has a steady state

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temperature above the martensitic-to-austenitic transition temperature of the article, but well below a temperature that may cause tissue damage. For instance, a water-based heat transfer medium, such as saline solution, will have a steady state temperature of about 100°C (the boiling point of water), which is well above the 37°C or 55°C needed to transition most, if not all, shape memory articles used in medical procedures, yet well below the dangerous 600°C-1200°C range of conventional techniques.

[0029] Figure 2 is a schematic diagram illustrating an exemplary embodiment of an apparatus 200 for heating a shape memory article in accordance with the present invention. Figure 3 is a cross-sectional view of the hand tool of Figure 2. In accordance with the invention, a hand-held tool 201 comprising a body 203 and a energy probe 205 is provided for generating localized heating. The tool 201 can be a purpose-built tool for use in the present invention. Alternatively, the tool can be a multi-purpose tool with other uses such as tissue cautery or ultrasonic probing.

[0030] In the embodiment illustrated in Figures 2 and 3, the tool uses a bipolar probe as the energy probe 205. This type of energy probe comprises two conductive elements, e.g., concentric tubes, 209, 210 having distal ends 209a, 210a, respectively, separated from each other by an insulator, which insulator is a electrically nonconductive polymer in the illustrated embodiment. Each concentric tube is coupled to a wire 212, 213, respectively, passing through the body 203 to an electrical connector 217a, 217b, respectively. A removable electrical cable 215 bearing a connector 216 for connecting to the instrument connectors 217a, 217b is connected to the instrument. The cable 215 is coupled via a second connector 217 to a power source 218 for generating a suitable signal to cause current to run through the conductive elements when the open circuit between the spaced ends 209a, 210a of the two conductive elements 209, 210 is closed by a conductive medium therebetween. A foot switch 208 may be provided for permitting the physician to activate

the power supply 218 to provide the electrical signal through the cable 215 to the probe 205. The signal may be a DC voltage or an alternating current. When a conductor, such as tissue or saline solution, is placed across the two ends 209a, 210a of the conductive elements, thereby
5 closing the circuit, the electrical signal can run through the conductive elements.

[0031] It should be understood that the bipolar electrical probe described above and illustrated in the Figures is merely exemplary and that the energy probe (and the accompanying power supply) may be any
10 reasonable means of generating energy to heat a heat transfer medium, including monopolar electrical probes and ultrasonic probes that heats by vibrating at ultrasonic frequency. In other embodiments, the energy probe may be a laser light source or an infrared light source that produces an
15 intense beam of light when activated, which beam strikes a heat transfer medium with a matched wavelength that absorbs the light energy and transforms it to heat.

[0032] A tube 219 is attached to the end of the instrument 201 that closely surrounds the energy probe. In certain embodiments of the invention, the tube 219 is permanently affixed to the instrument 201.
20 However, as illustrated in Figures 2 and 3, in other embodiments, the tube is removable. Specifically, in the illustrated embodiment, the tube 219 is formed of a resilient material, such a silicone, having an unbiased inner diameter, d , slightly smaller than the diameter of the shoulder 221 formed in the body 203 of the energy probe 205 so that the tube 219 can be
25 forced over the shoulder 221 whereupon it will expand to accept the shoulder and become attached to the instrument via friction. The tool body 203 may include a flange 222 defining a stop for the hole 219 so that the removable tube is always inserted to the same position.

[0033] Preferably, the distal end 219a of the tube 219 extends slightly
30 beyond the distal ends 209a, 210a of the energy probe so that the energy

probe 205 is completely within the tube 219, but close to the distal end 219a of the tube. In this manner, the energy probe 205 cannot directly contact anything, such as tissue or the shape memory article, that is not inside of tube 219. On the other hand, a bolus of heat transfer medium
5 adhered to the end of the tube 219 will be in contact with or in close proximity to the energy probe 205.

[0034] The instrument 201 is used to transfer heat to a shape memory article, such as a surgical staple 413, as illustrated in Figures 4A and 4B. Figure 4A shows the staple in its pre-surgical, martensitic shape, while
10 Figure 4B shows the staple in its post-surgical, austenitic shape after it has been heated above its transformation temperature. As should be apparent, such a staple can be installed into tissue or bone, with one tine 416 of the staple inserted in one bone fragment and the other tine 417 inserted in another bone fragment. Then, it can be heated to cause the
15 martensitic-to-austenitic transformation, changing from the shape shown in Figure 4A to the shape shown in Figure 4B, while also becoming much stiffer. This shape transformation would draw the two bone fragments closer (if they are not already in contact) and/or apply a constant dynamic force urging the bone fragments together (if they are already in contact or
20 reach contact prior to the staple 413 reaching its stress-free austenitic shape).

[0035] Figures 5-7 help illustrate a method in accordance with the principle of the present invention. For purposes of the following discussion, we shall assume that the shape memory article is a surgical
25 staple for joining two bone pieces together. In Figure 5, the staple has already been installed in the two bone pieces in its martensitic phase and awaits transformation to the austenitic phase with the accompanying change in shape to draw the two bone fragments closer together and/or apply a dynamic force urging the bone fragments together.

[0036] Thus, with reference to Figure 5, a portion of a heat transfer medium 227 is applied to the distal end 219a of the tube 219. The heat transfer medium preferably is a substance with a high coefficient of thermal conductivity so that it can absorb and release (i.e., transfer) heat rapidly. It may be a liquid, such as water, or a viscous substance such as a gel. In any case, the heat transfer medium must contain a substance, either in solution or in sufficient quantity, to render the medium excitable by the energy source embodied. In the exemplary case of heating via electrical current and the joule effect, for instance, the heat transfer medium should be electrically conductive. In such an embodiment, the heat transfer medium 227 may be a saline solution, wherein the salt in solution acts as an electrical conductor and the water in solution acts as the heat transfer medium.

[0037] In other embodiments, however, the heat transfer medium may be partially or wholly solid or a gel. On the other hand, if the energy probe is an ultrasonic probe, then an acoustic medium having good acoustic absorption would be beneficial. If the energy probe is a light source, then a heat transfer medium having a pigment with matching absorption properties to the wavelength of the light source would be a beneficial property in order to most efficiently convert the light energy into heat when the light strikes the heat transfer medium. The heat transfer medium may contain a pigment specifically added for this purpose.

[0038] Alternately or additionally, the article to be heated, such as surgical staple 413 shown in Figures 4A and 4B, may include the heat transfer medium. For instance, the heat transfer medium may be provided in the form of a coating or surface treatment of the article. Alternately, it may be dispersed in the article itself. Thus, simple activation with the energy probe of this invention will cause the heat transfer medium to heat and, in turn, heat the shape memory article to a predetermined temperature.

[0039] For reasons that will become clear in the discussion below, the heat transfer medium preferably has a steady state temperature (or maximum excitation temperature) above which it essentially cannot be heated that is at or above the martensitic-to-austenitic transformation temperature of the shape memory article, but below a temperature that might cause unnecessary tissue damage. In one embodiment, the heat transfer medium is a saline solution, which generally has a boiling point of about 100°C, thereby effectively defining a steady state excitation temperature above which it essentially cannot be heated. At 100°, the steady state temperature of this heat transfer medium is above the typical transformation temperature for a medical shape memory article, but much lower than the 600 °C to 1200°C temperatures generated for heating shape memory articles in the prior art. Note that, as a practical matter, the boiling point of saline solution of about 100°C defines a steady state heating temperature.

[0040] The heat transfer medium 227 can be applied to the distal end of the tube in a number of ways. Figure 5 illustrates one embodiment in which the heat transfer medium is applied to the end 219a of the tube 219 by dipping the tube 219 into a supply, such as a vial 225, of the heat transfer medium 227. A bolus 228 of the medium 227 sticks to the end 219a of the tube 219 due to the surface adhesion properties of liquid and viscous materials. The exact size of the bolus will depend on many factors, including the surface adhesion properties of the heat transfer medium and its viscosity, and various properties of the tube, such as its surface adhesion properties, size, wall thickness, inner diameter, outer diameter, surface roughness, etc. In fact, all of these properties of the heat transfer medium and/or tube can be engineered to help assure that a bolus of a particular size suitable to the SMA being heated is formed.

[0041] Next, with reference to Figure 6, the instrument is moved to the article, which is shown as a staple 231 already installed in its open state

into two bone fragments 233 and 235. Particularly, the distal end 219a of the tube 219 is brought to the article 231 so that the bolus 228 of heat transfer medium touches the article 231. Through contact with the article 231, the bolus of heat transfer medium partially transfers to the article 231 via the same surface adhesion that caused it to adhere to the tube 219. Next, with reference to Figure 7, the tube is left in contact with the bolus and the energy probe is then activated to heat the bolus of heat transfer medium 235 via the conversion of energy absorbed by the heat transfer medium to heat. The heat transfer medium, which is in mutual contact with the tube 219 (and possibly the energy probe 205 itself), on the one hand, and the staple 231, on the other, transfers the heat to the staple, thereby raising its temperature above the transition temperature that causes the article to transform from its martensitic phase to its austenitic phase and change shape.

[0042] Techniques also are envisioned in which the energy probe is activated to heat the heat transfer medium prior to the heat transfer medium coming in contact with the shape memory article. In some techniques, the energy probe is first activated and the heat transfer medium is brought into contact with the article. In yet other envisioned techniques, the heat transfer medium may only be brought close to the article without even contacting it.

[0043] There are many advantages inherent to an apparatus and method of using an intermediate heat transfer medium in accordance with the principles of the present invention, rather than the direct contact heating of the shape memory alloy of the conventional art. First, the heat transfer medium has a known steady state temperature. For instance, anything that is substantially water-based will have a boiling point of about 100°C and, therefore, the heat transfer medium essentially cannot be heated to a temperature greater than its boiling point, representing the steady state temperature. Hence, this provides extremely well-controlled

heating of a shape memory article, which essentially cannot be heated to a temperature greater than the steady state excitation temperature of the heat transfer medium. Furthermore, the present invention provides more uniform heating than in the conventional art. Particularly, typically, when a bolus of liquid contacts a surface, such as the surface of a shape memory article, the same surface adhesion properties of liquids that causes the bolus to stick to the end of the tube 219 also causes the bolus to spread out over the surface area of the shape memory article, thereby potentially wetting a larger portion of the article than can be directly contacted by the energy probe itself in the prior art. Hence, as the heat transfers through the heat transfer medium, it is transferred more efficiently to the shape memory article than in the prior art. Accordingly, the heat reaches the segments of the article that are further away from the contact point of the tool more quickly than in the conventional art.

15 **[0044]** In certain embodiments of the invention, the article 231 can be provided with a surface treatment that enhances the wetting of the article by the bolus of heat transfer medium when the bolus is contacted to it. Such surface treatment may include coating the article with a surfactant or wetting agent that reduces the surface tension of a liquid, allowing it to spread across and/or penetrate the surface of the article. Various suitable wicking materials, surfactants, and hydrophilic materials are widely available. Alternately, roughening of the surface or otherwise making the surface porous, or machining or otherwise forming grooves, divots, and/or pores in the surface of the article also can enhance wetting.

25 **[0045]** In certain embodiments of the invention, the article 231 may be directly coated with the heat transfer medium. The object of the heat transfer medium is to be excited by the energy absorbed into the medium and convert it into heat. In turn, because the heat transfer medium is in direct contact with the article, the heat is conducted to the article, raising the temperature of the article above the transformation temperature.

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[0046] In at least one embodiment of the invention, the distal end 219a of the tube 219 is close enough to the distal end of the energy probe 205 so that, when a bolus of the heat transfer medium adheres to the tube, the bolus is in contact with the energy probe. This provides faster, more efficient heating of the bolus. However, in other embodiments, wherein slower heating and slower vaporization may be desired, the tube can be sized, shaped, and positioned relative to the energy probe so that the energy probe is not in contact with the bolus, but heats the bolus through convective heating through the air. In embodiments in which the tube is removable, the tool can be readily adapted as desired in this regard.

[0047] The tube 219 illustrated in the drawings also is merely exemplary. Other means for holding a portion of heat transfer medium adjacent (including in contact with) the energy probe also are envisioned. For instance, the end of the energy probe may be surrounded by or wrapped in a non-woven material, in the nature of a cotton swab. In other embodiments, the tube may be formed of a woven or porous material that absorbs and/or retains fluids well. In yet other embodiments, the end of the tube 219 may contain an absorbent material that will absorb the heat transfer medium. The absorbent material may comprise a cylinder of cotton or other absorbent material having a proximal end in contact with the energy probe and a distal end extending slightly distally from the distal end 219a of the tube 219 for contacting the shape memory article.

[0048] Furthermore, the holding device need not comprise a tube and need not surround the energy probe at all. For instance, a separate component of the system might be placed in close proximity to the energy probe of the tool and have a holding element at its end for holding the heat transfer medium. The holding element may be a ball of woven or non-woven material, or simply a form having significant surface area for surface adhesion, such as a sphere or a flat waffle type configuration, preferably formed of a material having high surface adhesion properties.

This component will carry the heat transfer medium and, when placed in contact between the energy probe and the shape memory article, will wet the article as previously described.

[0049] Turning to the energy source for activating the energy probe, in one embodiment of the invention, the energy source can be programmed to provide heating in multiple bursts to help regulate the heating of the heat transfer medium. In the case of electrical resistance energy probes, the power source may provide a current through direct current (DC), alternating current (AC) or through high frequency means such as radio frequency (RF).

[0050] Due to the nature of the invention, very little power is needed to generate the heat required to transform the shape memory article. Power on the order of 4-10 watts should be sufficient to generate the necessary amount of heat, as opposed to many prior art systems that require approximately 40-100 Watts of power. Due to the lowered power requirements, it is possible to provide a tool in accordance with the invention in the form of a self-contained, battery-powered, hand-held tool without the need for a separate power source.

[0051] The present invention is extremely effective using commonly available saline solutions as the heat transfer medium. However, operation of the invention can be improved by specifically engineering the heat transfer medium to have particularly beneficial properties. For instance, the medium can be engineered to have a specific resistance or conductivity. On the other hand, if the energy probe is an ultrasonic probe, the medium can be selected or engineered to have particularly desirable acoustic properties. Likewise, in the case of acoustic heating, the tube can be selected or engineered to provide certain acoustic properties, such as a certain acoustic resonance, or certain acoustic focusing.

[0052] In yet other embodiments, in which the energy probe is not a physical probe, but rather a light beam, such as a laser light beam or an infrared light beam, contact between the energy probe, per se, and the bolus is not an issue. However in such embodiments, the heat transfer medium may be adapted to contain pigment having a color that is highly absorbent of the light of the particular wavelength of the light source in order to efficiently excite the pigment, thus heating the heat transfer medium.

[0053] In addition, depending on the particular application, therapeutic agents, such as antibiotics, may be added or incorporated into the medium to facilitate healing, pain relief, infection reduction, etc.

[0054] In certain other embodiments of the invention, the heat transfer medium may be encapsulated in a shell in the manner of gel capsule pills or actually wholly comprised of a solid. The shell material preferably is selected so that it also will break down (thereby releasing the heat transfer medium) during heating. Alternately, embodiments are envisioned in which the heat transfer medium is itself a solid ball of gel capsule material. A solid ball of the heat transfer medium may be attached to the end of the tube or other holding device by an adhesive or by its inherent tackiness. In fact, the heat transfer medium can be any substance, in solution, mixture or other form, that can be caused to be heated to a predetermined temperature by the energy delivered by an energy probe. Additionally, the heat transfer medium may start out as a gel or solid at room temperature and transform upon heating to a flowable substance for wetting the shape memory article.

[0055] In yet other embodiments of the invention, the heat transfer medium may be supplied to the end of the tube by or through the instrument itself (rather than by dipping the end of the instrument into a supply of the medium). Such an embodiment is illustrated in Figure 8. For instance, a supply tube 801 may run along the side of the body 803

(alternately, it may run through the body of the instrument 800) with the distal end 801a of the tube positioned adjacent the end of the energy probe 805 and deliver a quantity of heat transfer medium 228 to the operative site. The proximal end 801b of the tube 801 may be coupled to
5 a reservoir 850 of the heat transfer medium and supplied through the supply tube 801 to the distal tip 801a of the tube. The reservoir 850 is illustrated schematically as a block. However, it may be located directly in or on the hand-held tool 800. Alternately, it may be provided integral with the power supply, such as power supply 218 of Figure 2. Even further, the
10 reservoir may be free-standing and/or remotely located from the hand-held portion of the tool, with the supply tube extending from the proximal end of the tool to the remote reservoir. In one particular embodiment, the heat transfer medium may be advanced through the supply tube via gravity feed. However, in other embodiments, it may be forced through the
15 supply tube by a pump, such as a peristaltic pump. In other embodiments, the heat transfer medium may be provided through a spray nozzle near the end of the tube.

[0056] Figure 8 also illustrates that the tool 800 may be battery powered by self-contained batteries 811 because it requires relatively low
20 power to operate, as previously mentioned. Particularly, Figure 8 illustrates an embodiment in which two batteries 811 (shown in phantom since they are inside the body) are contained within the body of the instrument 800. A switch 816 is provided for selectively energizing the probe from the battery power. If the tool is battery powered so that it
25 operates without connection to a separate power source, signal processing also may be provided within the body of the tool for conditioning the power supplied to the probe. Specifically, an Application Specific Integrated Circuit (ASIC), microcontroller, microprocessor, analog circuit, digital signal processor or any combination thereof may be
30 provided within the body 803 of the instrument for pulsing the power to the probe when the button is activated, turning the power off a certain time

period after the button is activated, activating an LED to indicate when the probe is energized, etc.

[0057] The invention has many other advantages. For instance, it is small and handheld. It requires very low power to energize and heat the heat transfer medium. It also provides a highly controllable amount of heating of the shape memory article and the results are highly reproducible. Also, the heating is more uniform over the volume of the article.

[0058] Figure 9 is a flow diagram illustrating one preferred implementation of a method in accordance with the present invention. In accordance with this implementation, the procedure starts at step 901. In step 902, the surgeon places the staple or other shape memory article into the position where it is to be transformed. In step 903, the surgeon applies a portion of the heat transfer medium to the tip of the tube. Next, in step 905, the surgeon touches the tip of the tube containing the heat transfer medium to the article.

[0059] In step 907, the surgeon activates the energy probe and, in step 909, this causes the heat transfer medium to heat up. In turn, this causes the heat transfer medium to heat the article above its martensitic transformation temperature and transform in shape. If desired, steps 903-911 may be repeated one or more times to assure transformation. The process ends at step 913.

[0060] Having thus described a few particular embodiments of the invention, various alterations, modifications, and improvements will readily occur to those skilled in the art. Such alterations, modifications, and improvements as are made obvious by this disclosure are intended to be part of this description though not expressly stated herein, and are intended to be within the spirit and scope of the invention. Accordingly, the foregoing description is by way of example only, and not limiting. The

invention is limited only as defined in the following claims and equivalents thereto.

Claims

1. A method of heating an article formed of a shape memory alloy comprising:
 - 5 providing a tool having an energy probe;
 disposing a portion of a heat transfer medium adjacent the energy probe;
 placing the heat transfer medium in close proximity to an article formed of a shape memory alloy; and
 - 10 activating the energy probe to heat the heat transfer medium, which heat transfer medium transfers the heat to the article.
2. The method of claim 1 wherein the heat transfer medium has a predetermined steady state temperature above a martensitic to austenitic transformation temperature of the shape memory article.
- 15 3. The method of claim 1 wherein the heat transfer medium is a fluid.
4. The method of claim 1 wherein the heat transfer medium is a saline solution.
- 20 5. The method of claim 1 wherein the heat transfer medium is viscous.
6. The method of claim 1 wherein the placing comprises contacting the heat transfer medium to the article.
- 25 7. The method of claim 6 wherein the placing causes wetting of the article due to surface adhesion between the heat transfer medium and the article.
- 30 8. The method of claim 1 wherein the disposing comprises disposing the heat transfer medium in contact with the energy probe.

9. The method of claim 8 wherein the energy probe comprises first and second electrically conductive probes and wherein the heat transfer medium is electrically and thermally conductive such that the first probe, the heat transfer medium, and the second probe form a closed circuit loop, and wherein the activating step comprises causing electrical current to flow through the circuit loop to heat the heat transfer medium.
10. The method of claim 1 wherein the heat transfer medium has a steady state excitation temperature no greater than about 100°C.
11. The method of claim 1 wherein the disposing comprises dipping the tool into a supply of the heat transfer medium such that a portion of the heat transfer medium is retained adjacent the energy probe.
12. The method of claim 1 wherein the activating comprises a plurality of consecutive energy excitation cycles.
13. The method of claim 1 further comprising:
providing the article with surface features to assist in wetting of the staple by the heat transfer medium via surface adhesion.
14. The method of claim 1 further comprising:
coating the article with a substance that facilitates wetting of the article by the heat transfer medium.
15. The method of claim 1 wherein the disposing comprises providing the heat transfer medium through the tool.

16. The method of claim 1 wherein the disposing comprises surface adhering the heat transfer medium to a tube within which the energy probe is positioned.
- 5 17. A tool for heating an article formed of a shape memory alloy comprising:
a body;
an energy probe;
a holder adjacent the energy probe for holding a portion of a heat
10 transfer medium to be heated by the energy probe.
18. The tool of claim 17 wherein the holder comprises a wicking material.
19. The tool of claim 17 wherein the holder comprises a tube surrounding
15 the energy probe.
20. The tool of claim 19 wherein the tube has a distal end and the energy probe has a distal end and wherein the distal end of the tube extends distally beyond the distal end of the energy probe.
20
21. The tool of claim 20 wherein the tube is removable.
22. The tool of claim 17 in combination with an article formed of a shape memory alloy, the article including surface treatment to enhance wetting of
25 the article by the heat transfer medium.
23. The tool of claim 22 wherein the treatment comprises a coating of hydrophilic material.

24. The tool of claim 22 wherein the treatment comprises at least one surface variation on a surface of the article selected from the group comprising grooves, corrugations, roughening, and protrusions.

5 25. The tool of claim 17 wherein the energy probe comprises a light source.

26. The tool of claim 17 wherein the energy probe comprises an ultrasonic probe.

10

27. The tool of claim 17 wherein the holder is adapted relative to the energy probe such that the portion of the heat transfer medium contacts the energy probe when disposed in the holder.

15 28. The tool of claim 17 wherein the tool comprises a body adapted to be hand held tool, the tool further comprising a battery to provide energy for energizing the energy probe.

20 29. The tool of claim 17 wherein the energy probe utilizes less than 20 watts when activated.

30. The tool of claim 29 wherein the energy probe utilizes between about 4 and 10 watts when activated.

25 31. The tool of claim 17 further comprising a circuit for causing energy to be delivered to the energy probe in pulse when the switch is operated to activate the energy probe.

30 32. The tool of claim 17 further comprising a tube for delivering the heat transfer medium adjacent the energy probe, the tube having a proximal end and a distal end, the distal end of the tube positioned adjacent the

energy probe and the proximal end of the tube connected to a reservoir of the heat transfer medium.

33. The tool of claim 32 wherein the reservoir is located in the body.

5

34. The tool of claim 32 wherein the reservoir is located remotely of the body and energy probe.

35. A medical article comprising:

10 a shape memory alloy; and
 a heat transfer medium.

36. The medical article of claim 35 wherein the heat transfer medium is in the form of a coating on the medical article.

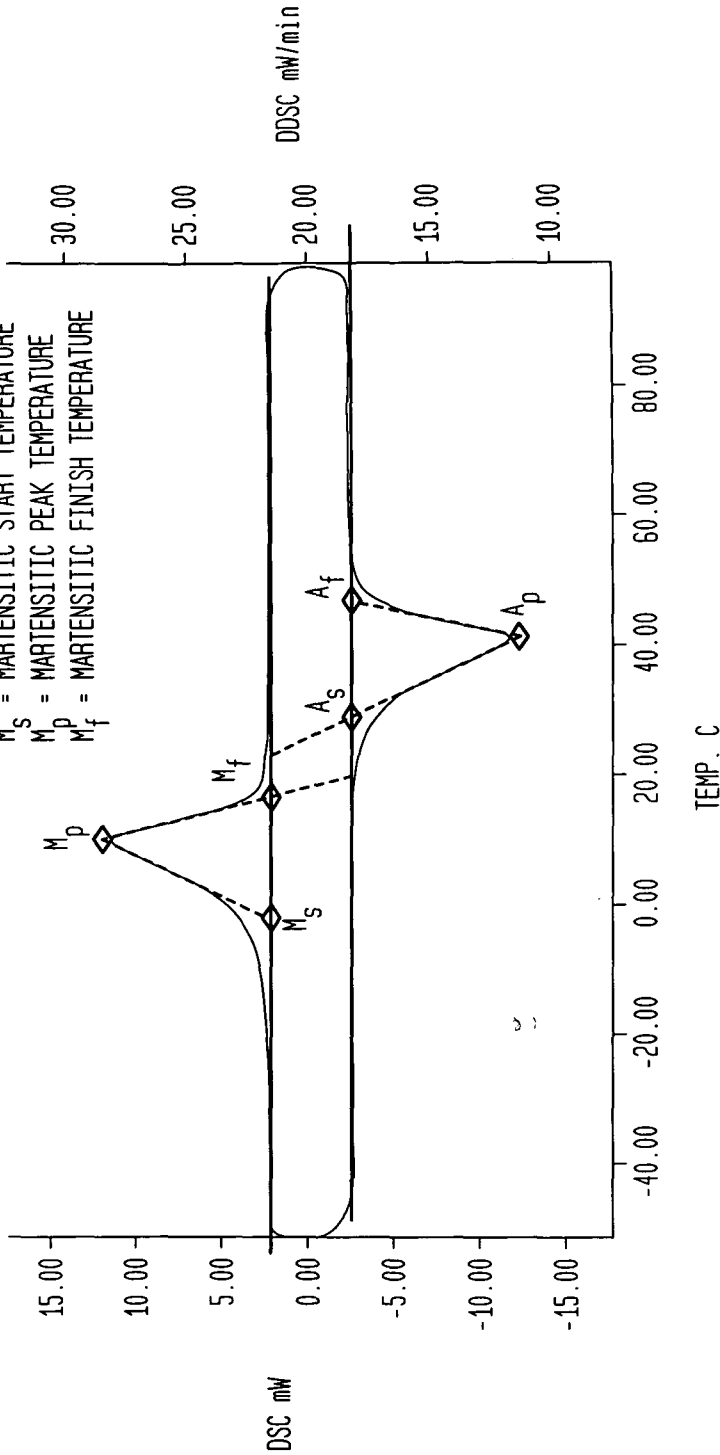
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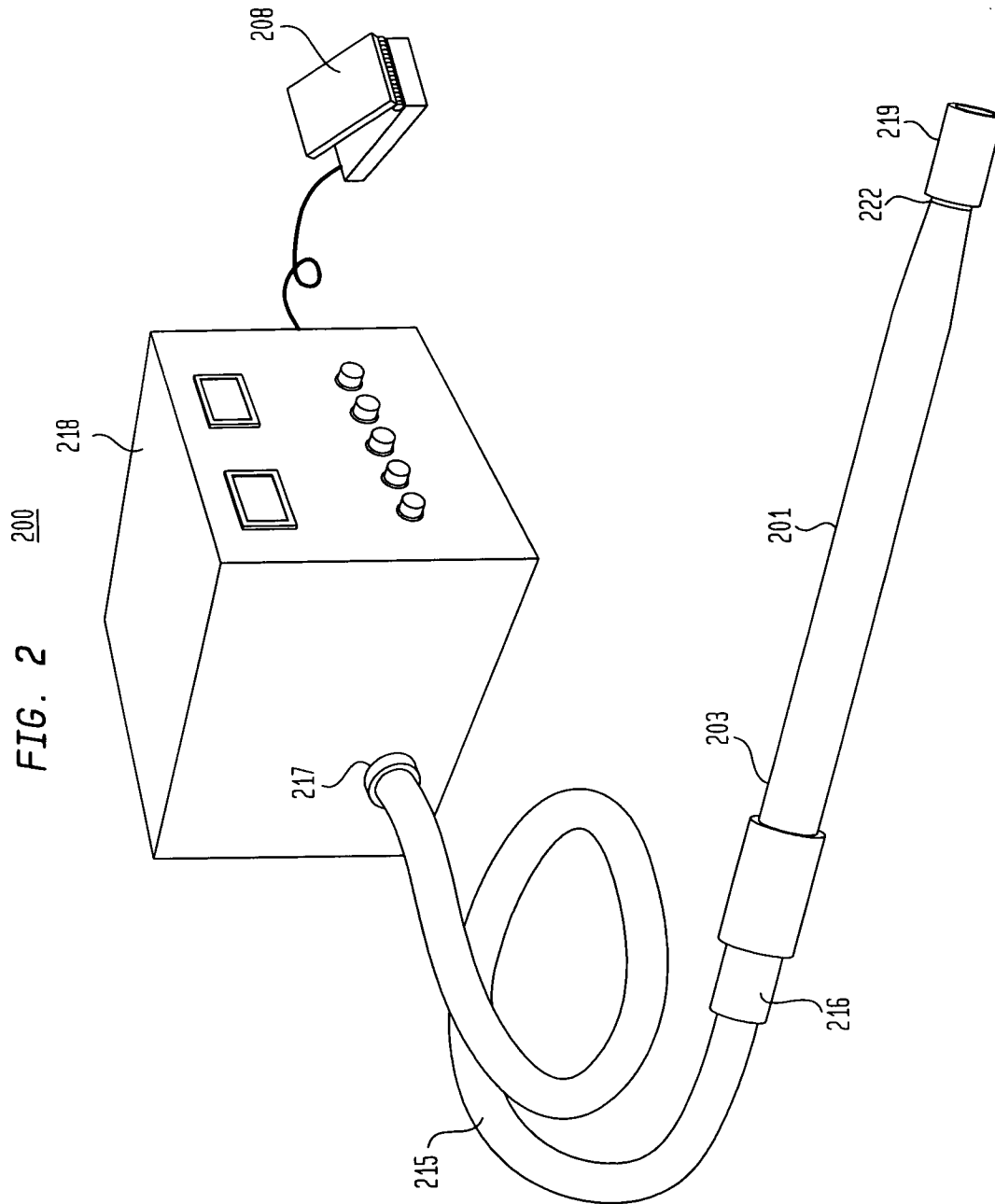
37. The medical article of claim 36 wherein the medical article is a tissue or bone staple.

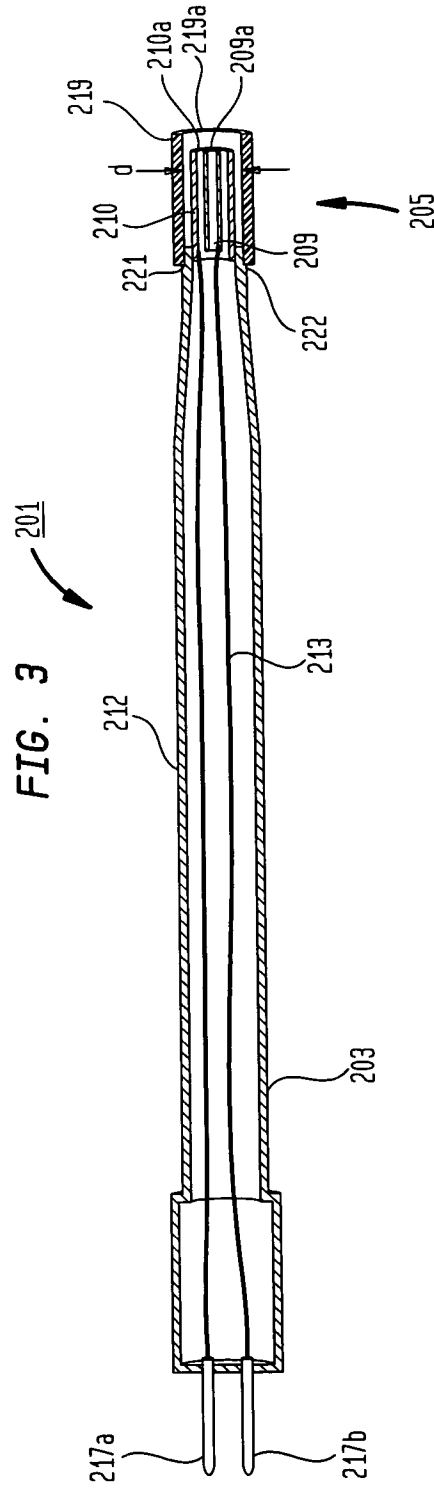
38. The medical article of claim 37 wherein the heat transfer medium is a
20 gel.

FIG. 1

A_s = AUSTENITIC START TEMPERATURE
A_p = AUSTENITIC PEAK TEMPERATURE
A_f = AUSTENITIC FINISH TEMPERATURE
M_s = MARTENSITIC START TEMPERATURE
M_p = MARTENSITIC PEAK TEMPERATURE
M_f = MARTENSITIC FINISH TEMPERATURE







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FIG. 4A

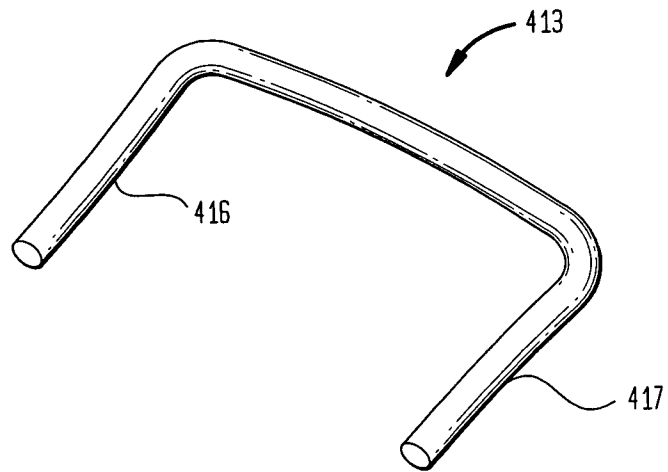
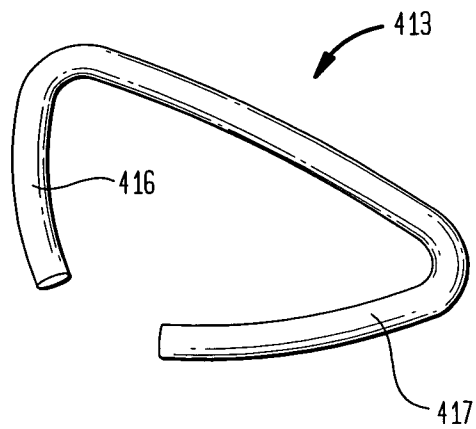
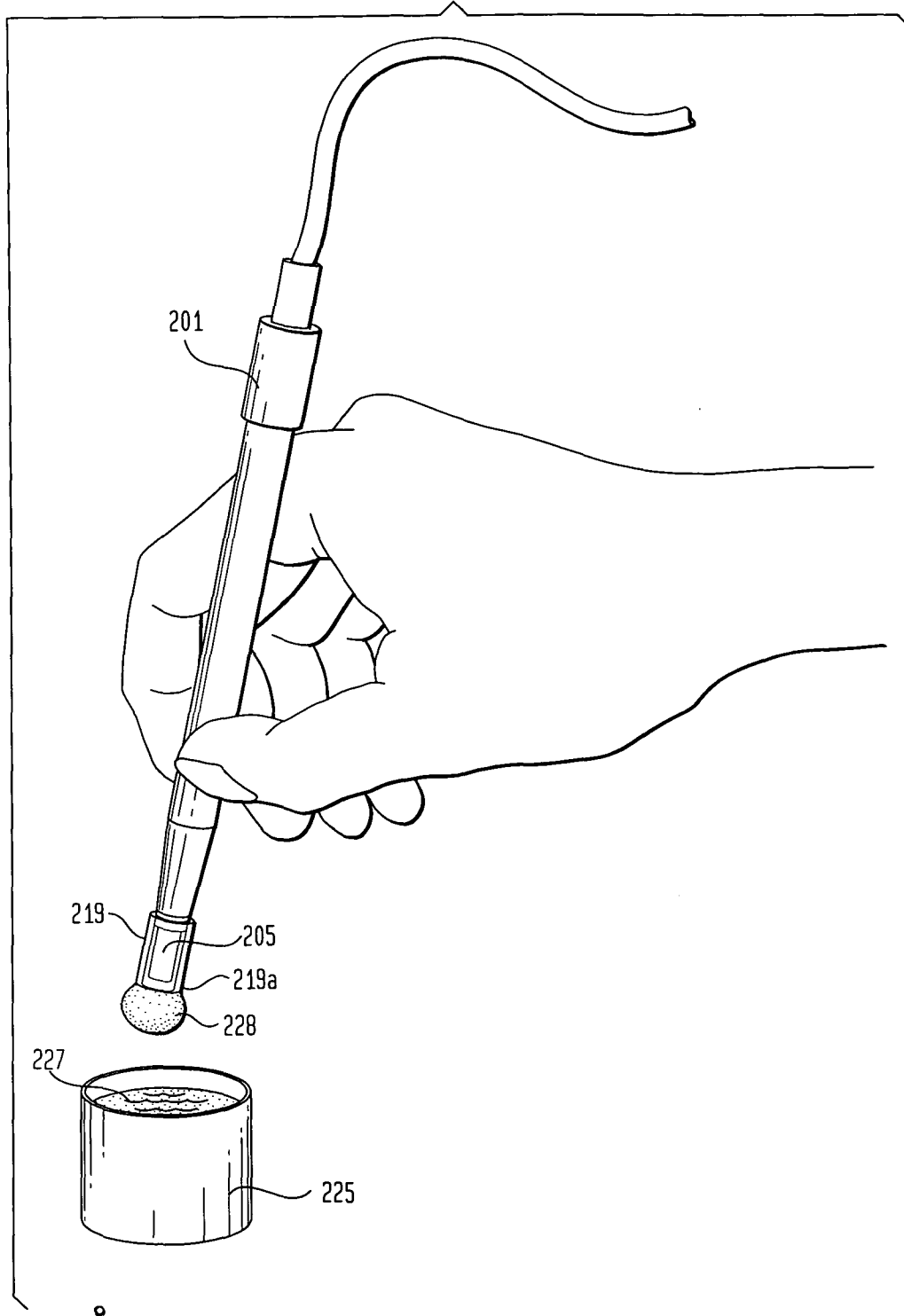


FIG. 4B



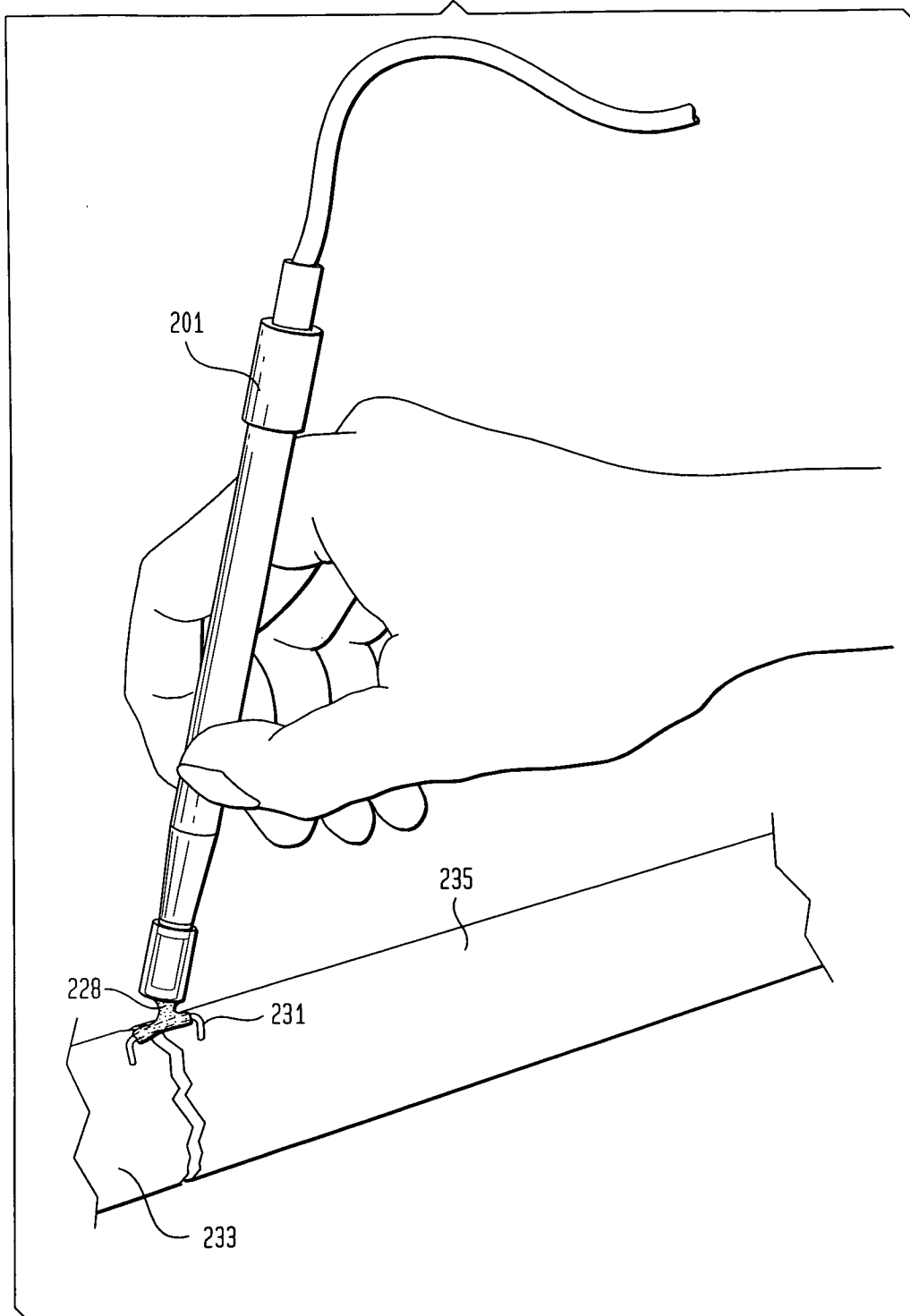
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FIG. 5



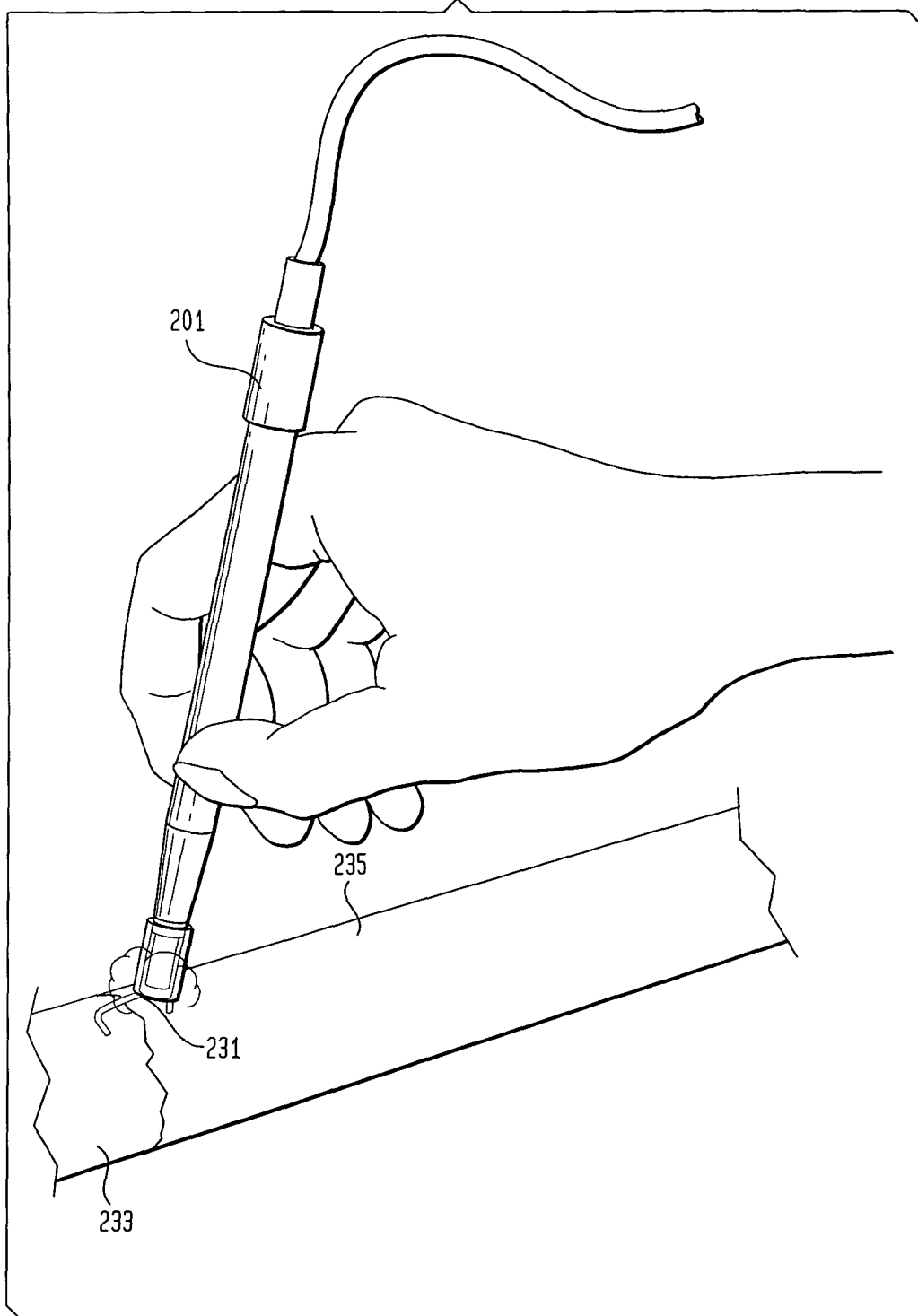
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FIG. 6

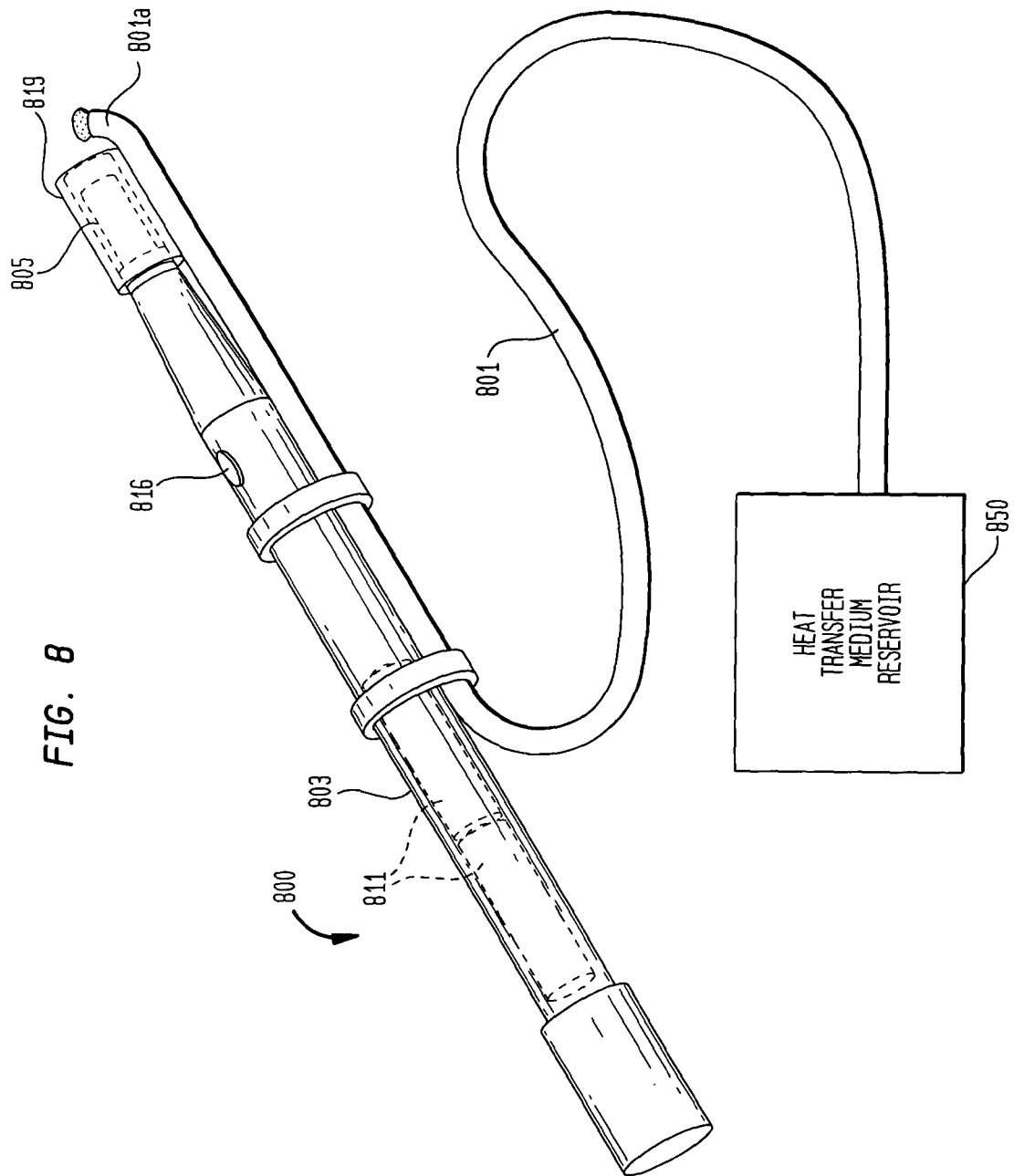


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FIG. 7

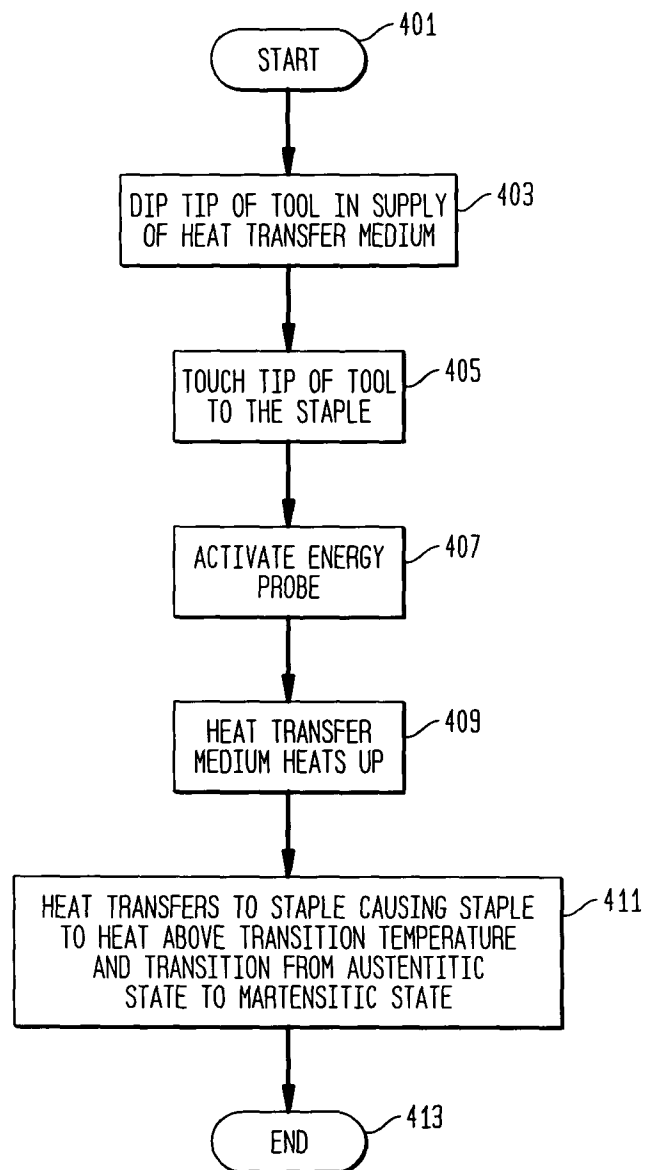


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FIG. 9



INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/026305

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/064 A61B17/068

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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/044951 A (INTELIFUSE INC [US]; ASHMAN RICHARD B [US]; ANTOINE EUGENE JR [US]; ST) 19 April 2007 (2007-04-19) paragraphs [0001], [0008], [0016]; figure 1	17, 19, 22, 25-31, 35, 37
X	WO 2005/065561 A (SCIMED LIFE SYSTEMS INC [US]; GARABEDIAN ROBERT J [US]; KELLY AMY C [U] 21 July 2005 (2005-07-21) pages 2, 3, 32; figure 19	17-19, 25-34
X	WO 01/62136 A (STRYKER INSTR [US]) 30 August 2001 (2001-08-30) pages 19-22 - page 22, lines 16-21; figures 17-24	17, 19-21, 24, 27-34

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

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- *Z* document member of the same patent family

Date of the actual completion of the international search

6 October 2008

Date of mailing of the international search report

22/10/2008

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Authorized officer

Assion, Jean-Charles

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/026305

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 778 549 A (MBA SA [FR]) 19 November 1999 (1999-11-19) pages 2,4; figures 1,4 -----	17,19, 22, 25-31, 35,37
X	US 4 485 816 A (KRUMME JOHN F [US]) 4 December 1984 (1984-12-04) columns 3,4; figures 3,4 -----	17, 27-31, 35,37
X	US 3 868 956 A (ALFIDI RALPH J ET AL) 4 March 1975 (1975-03-04) column 8; figures 1,3,15 -----	17-22, 24,27, 29-31,35
X	WO 2007/106263 A (TRUSTEES OF THE UNIVERSITY OF [US]; SHAFIRSTEIN GAL [US]) 20 September 2007 (2007-09-20) figures 4,10,12,17 -----	17,19, 24-31
X	WO 2007/078978 A (INTRINSIC THERAPEUTICS INC [US]; BOYAJIAN THOMAS [US]; VELAGIC ALMIR []) 12 July 2007 (2007-07-12) paragraph [0067] -----	35-37
A		24
X	US 2007/093869 A1 (BLOOM ELIOT [US] ET AL) 26 April 2007 (2007-04-26) paragraph [0033] -----	35-37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/026305

Box No. 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.: 1-16
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
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
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 No. 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 additional fees.
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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/026305

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			EP 1968464 A2	17-09-2008
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US 2007093869	A1	26-04-2007	NONE	