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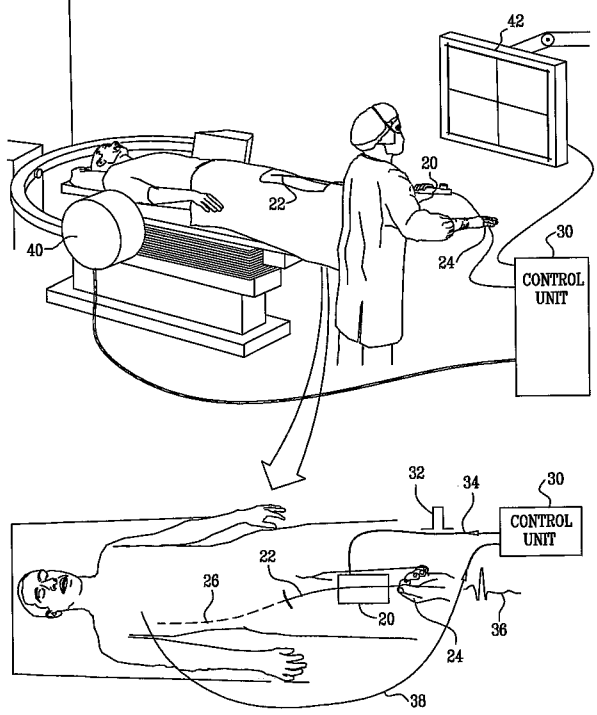
[Continued on next page]

(54) Title: STEPWISE ADVANCEMENT OF A MEDICAL TOOL

FIG. 1A



(57) Abstract: Apparatus is provided, including a sensor for sensing a phase of cyclic activity of a body system of the subject. A tool modulator of the apparatus includes a gate configured: in a first cycle of the cyclic activity, to allow movement of a tool, in response to the cyclic activity being at a first given phase thereof, following the given phase in the first cycle and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity, to inhibit the movement of the tool, and in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement, to allow movement of the tool, in response to the second cycle of the cyclic activity being at the given phase thereof. An accumulation facilitator facilitates an accumulation of the tool in the tool modulator, and/or an accumulation of energy in the tool.

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STEPWISE ADVANCEMENT OF A MEDICAL TOOL

CROSS-REFERENCES TO RELATED APPLICATIONS

The present patent application claims priority of US Provisional Patent Application No. 61/129,331 to Iddan, filed on June 19, 2008, entitled "Stepwise advancement of a medical tool," and is related to:

(a) PCT Application PCT/IL2008/000316 to Iddan, filed on March 09, 2008, entitled "Imaging and tools for use with moving organs,"

(b) US Patent Application 12/075,244 to Tolkowsky, filed March 10, 2008, entitled "Imaging for use with moving organs,"

(c) US Patent Application 12/075,214 to Iddan, filed March 10, 2008, entitled "Tools for use with moving organs," and

(d) US Patent Application 12/075,252 to Iddan, filed March 10, 2008, entitled "Imaging and tools for use with moving organs,"

all of which claim the benefit of U.S. Provisional Patent Application Nos.:

60/906,091 filed on March 8, 2007,

60/924,609 filed on May 22, 2007,

60/929,165 filed on June 15, 2007,

60/935,914 filed on September 6 2007, and

60/996,746 filed on December 4, 2007,

all entitled "Apparatuses and methods for performing medical procedures on cyclically-moving body organs," and all of which applications are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention generally relates to medical apparatus. Specifically, the present invention relates to stepwise advancement of a medical tool, within a body organ, in accordance with a motion cycle of that organ.

BACKGROUND OF THE INVENTION

Guide wires are commonly used in the course of trans-catheter endovascular interventions. Among the usages of such guide wires is the penetration of total or near-total occlusions in a blood vessel, such as an artery. In some cases, the artery moves in

accordance with a cyclical physiological cycle, such as the cardiac cycle in the case of a coronary artery, or the respiratory cycle in the case of a renal artery. In some cases, such motion of the artery also comprises a change in its geometrical shape, such as an angle at which it is bent.

PCT Application WO 08/107905 to Iddan, which is incorporated herein by reference, describes apparatus for use with a portion of a subject's body that moves as a result of cyclic activity of a body system. An imaging device acquires a plurality of image frames of the portion. A sensor senses a phase of the cyclic activity. A medical tool performs a function with respect to the portion. A control unit generates a stabilized set of image frames of the medical tool disposed within the portion, actuates the tool to perform the function, or move, in response to the sensor sensing that the cyclic activity is at a given phase thereof, and inhibits the tool from performing the action or moving in response to the sensor sensing that the cyclic activity is not at the given phase. A display facilitates use of the tool by displaying the stabilized set of image frames.

US Patent 4,545,390 to Leary describes a guide wire for guiding a very small diameter catheter, such as a coronary dilatation catheter used in coronary angioplasty techniques.

US Patent 4,758,223 to Rydell describes a hand-operated device for inflating the expander on a balloon-type catheter and for perfusing fluids through the catheter and out its distal end.

US Patent 4,723,938 to Goodin et al. describes an inflation/deflation device for an angioplasty balloon catheter which permits quick inflation to an approximate working pressure followed by a fine but slower adjustment to a final desired pressure.

The following references may be of interest:

US Patent 4,865,043 to Shimoni, US Patent 3,954,098 to Dick et al., US Patent 4,382,184 to Wernikoff, US Patent 4,016,871 to Schiff, US Patent 3,871,360 to Van Horn et al., US Patent 4,031,884 to Henzel, US Patent 4,994,965 to Crawford et al., US Patent 4,878,115 to Elion, US Patent 4,709,385 to Pfeiler, US Patent 4,270,143 to Morris, US Patent 4,758,223 to Rydell, US Patent 4,723,938 to Goodin et al., US Patent 6,937,696 to Mostafavi, US Patent 6,246,898 to Vesely et al., US Patent 6,666,863 to Wentzel et al., US Patent 5,176,619 to Segalowitz, US Patent 5,830,222 to Makower,

US Patent 4,245,647 to Randall, US Patent 4,316,218 to Gay, US Patent 4,849,906 to Chodos et al., US Patent 5,062,056 to Lo et al., US Patent 5,630,414 to Horbaschek, US Patent 6,442,415 to Bis et al., US Patent 6,473,635 to Rasche, US Patent 4,920,413 to Nakamura, US Patent 6,233,478 to Liu, US Patent 5,764,723 to Weinberger, US Patent 5,619,995 to Lobodzinski, US Patent 4,991,589 to Hongo et al., US Patent 5,538,494 to Matsuda, US Patent 5,020,516 to Biondi, US Patent 7,209,779 to Kaufman, US Patent 6,858,003 to Evans et al., US Patent 6,786,896 to Madhani et al., US Patent 6,999,852 to Green, US Patent 7,155,315 to Niemeyer et al., US Patent 5,971,976 to Wang et al., US Patent 6,377,011 to Ben-Ur, US Patent 6,711,436 to Duhaylongsod, US Patent 7,269,457 to Shafer, US Patent 6,959,266 to Mostafavi, US Patent 7,191,100 to Mostafavi, US Patent 6,708,052 to Mao et al., US Patent 7,180,976 to Wink et al., US Patent 7,085,342 to Younis et al., US Patent 6,731,973 to Voith, US Patent 6,728,566 to Subramanyan, US Patent 5,766,208 to McEwan, US Patent 6,704,593 to Stainsby, US Patent 6,973,202 to Mostafavi;

US Patent Application Publication 2006/0058647 to Strommer et al., US Patent Application Publication 2007/0173861 to Strommer, US Patent Application Publication 2007/0208388 to Jahns, US Patent Application Publication 2007/0219630 to Chu, US Patent Application Publication 2004/0176681 to Mao et al., US Patent Application Publication 2005/0090737 to Burrel et al., US Patent Application Publication 2006/0287595 to Maschke, US Patent Application Publication 2007/0142907 to Moaddeb et al., US Patent Application Publication 2007/0106146 to Altmann et al., US Patent Application Publication 2005/0054916 to Mostafavi, US Patent Application Publication 2003/0018251 to Solomon, US Patent Application Publication 2002/0049375 to Strommer et al., US Patent Application Publication 2005/0137661 to Sra, US Patent Application Publication 2005/0143777 to Sra, US Patent Application Publication 2004/0077941 to Reddy et al.;

PCT Publication WO 94/010904 to Nardella, PCT Publication WO 06/066122 to Sra, PCT Publication WO 06/066124 to Sra, PCT Publication WO 05/026891 to Mostafavi, PCT Publication WO 01/43642 to Heuscher, PCT Publication WO 03/096894 to Ho et al., PCT Publication WO 05/124689 to Manzke; and

"Catheter Insertion Simulation with Combined Visual and Haptic Feedback," by Zorcolo et al. (Center for Advanced Studies, Research and Development in Sardinia)

SUMMARY OF THE INVENTION

When a guide wire is used for penetrating an occlusion within an artery that changes its shape as a result of organ motion, it may result in (a) the guide wire being pushed along the artery, at some phases of the motion cycle, but (b) in an undesirable direction, for example, toward the wall of the artery, at other phases of the motion cycle. In some cases, the ability to penetrate the occlusion with the guide wire is therefore hindered. In other cases, advancement of the guide wire towards the wall of the artery results in a perforation or dissection of the artery's wall. Such perforation or dissection typically creates some amount of clinical risk.

Separately, when a guide wire is steered towards a side branch whose angle relative to the main artery varies in the course of the motion cycle, entering that side branch may require multiple, repeated attempts.

In some embodiments of the present invention, apparatus and methods are provided for the advancement of an endovascular medical tool, such as a guide wire, within a body organ, in accordance with a motion cycle of that organ. In some embodiments, a guide wire is advanced within a coronary artery in synchronization with the cardiac cycle. In some embodiments, a guide wire is advanced within a renal artery in synchronization with the respiratory cycle. In some embodiments, a guide wire is advanced within a carotid artery in synchronization with the cardiac cycle. In some embodiments, a medical tool is advanced through a bronchial lumen in synchronization with the respiratory cycle.

It is hypothesized by the inventors that embodiments of the current invention offer measures for reducing the aforementioned risk of a guide wire being advanced in an undesirable direction. For example, embodiments of the current invention may reduce the aforementioned risk of a guide wire being advanced into the wall of a blood vessel and creating a perforation or a dissection of that wall. It is also hypothesized by the inventors that advancing a guide wire in the synchronized manner described herein will, in some cases, improve the efficacy of the guide wire in penetrating an occlusion. Separately, it is also hypothesized by the inventors that advancing a guide wire in the synchronized manner described herein will, in some cases, facilitate inserting the guide

wire into a side branch, the angle of which, relative to the main lumen, varies in the course of the vessel's motion cycle.

In an embodiment, the guide wire is advanced within a coronary vessel in a stepwise manner, only at a selected phase of the cardiac cycle. In an embodiment, the selected phase of the cardiac cycle is a diastolic or end-diastolic phase, when the blood vessels are relatively further spread apart and less twisted. Compared to unsynchronized advancement of the guide wire (for example, continuous advancement of the guide wire throughout the cardiac cycle), synchronized stepwise advancement in a diastolic or end-diastolic phase typically results in the guide wire being advanced, during a greater portion of its forward motion, along the vessel and, during a lesser portion of its forward motion, towards the wall of the vessel. That, in turn, typically reduces the likelihood of the guide wire perforating or dissecting the vessel wall, and typically increases the efficacy of the guide wire penetrating a possible occlusion in the vessel.

In another embodiment, the guide wire is advanced within a carotid vessel in a stepwise manner, only at a selected phase of the cardiac cycle. In yet another embodiment, the guide wire is advanced within a renal vessel in a stepwise manner, only at a selected phase of the respiratory cycle.

The aforementioned selected phase of the cardiac cycle may be sensed by means of the patient's ECG signal, a signal derived from the patient's ECG signal, the patient's blood pressure, the patient's heartbeat, on-line processing of an image stream of the organ with which the vessel is associated, a location sensor on or within the patient's body, a displacement sensor on or within the patient's body, or any combination thereof.

The aforementioned selected phase of the respiratory cycle may be sensed by a belt placed around the patient's chest, a motion sensor, an oxygenation sensor, a displacement sensor on or within the patient's body, a location sensor on or within the patient's body, or any combination thereof.

In an embodiment, the stepwise advancement of the guide wire is achieved via a guide wire motion modulator (also referred to herein as a "guide wire modulator"). In an embodiment, the guide wire motion modulator is situated outside the patient's body, along the proximal section of the guide wire and proximally to the sheath or guiding catheter through which the guide wire is inserted into the patient's body.

There is therefore provided, in accordance with an embodiment of the present invention, apparatus for use with a portion of a body of a subject that moves as a result of cyclic activity of a body system of the subject, the apparatus including:

a sensor for sensing a phase of the cyclic activity;

a tool configured to be moved with respect to the portion of the subject's body by being pushed by a user; and

a tool modulator including:

a gate, configured:

in a first cycle of the cyclic activity, to allow movement of at least a distal portion of the tool in a distal direction, in response to the sensor sensing that the cyclic activity is at a first given phase thereof,

following the given phase in the first cycle and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity, to inhibit the movement of the distal portion of the tool, and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement, to allow movement of the at least the distal portion of the tool in the distal direction, in response to the sensor sensing that the second cycle of the cyclic activity is at the given phase thereof; and

an accumulation facilitator configured, following the given phase in the first cycle and prior to the occurrence of the given phase in the subsequent cycle of the cyclic activity, and in response to the user pushing the tool, to facilitate an accumulation selected from the group consisting of: an accumulation of the tool in the tool modulator, and an accumulation of energy in the tool.

In an embodiment, the tool modulator is configured to provide force feedback to the user that is smoothened with respect to the cyclic activity.

In an embodiment, the given phase includes a phase selected from the group consisting of a diastolic phase and an end-diastolic phase, and the gate is configured to allow movement of the distal portion of the tool in the distal direction, in response to the sensor sensing that the cyclic activity is at the selected phase.

In an embodiment, the gate is configured to allow continuous movement of the tool in a proximal direction, when the tool is being withdrawn from the portion of the subject's body.

In an embodiment, the accumulation facilitator includes a pushing element configured to push a portion of the tool at least partially in a non-distal direction, in response to the user pushing the tool in the distal direction.

In an embodiment, the accumulation facilitator is configured to facilitate accumulation of the tool in the tool modulator.

In an embodiment, the accumulation facilitator is configured to facilitate accumulation of energy in the tool.

In an embodiment, the accumulation facilitator is configured to facilitate accumulation of elastic energy in the tool.

In an embodiment, the tool includes a guide wire configured to be moved within a blood vessel of the subject.

In an embodiment:

by allowing movement of at least the distal portion of the tool in the distal direction, the gate is configured to allow movement of a distal portion of the guide wire into a side branch that branches from the blood vessel, when the side branch is at a first angle from the blood vessel, and

by inhibiting movement of at least the distal portion of the tool, the gate is configured to inhibit movement of the distal portion of the guide wire into the side branch, when the side branch is at another angle from the blood vessel.

In an embodiment, the gate, by inhibiting the movement of the distal portion of the tool, is configured to inhibit a distal portion of the guide wire from moving in an undesirable direction with respect to the blood vessel.

In an embodiment, the gate, by inhibiting the movement of the distal portion of the tool, is configured to inhibit a distal portion of the guide wire from puncturing the blood vessel.

There is further provided, in accordance with an embodiment of the present invention, a method for automatically controlling movement of a tool when the tool is

used with a portion of a body of a subject that moves as a result of cyclic activity of a body system of the subject, the method including:

sensing a phase of the cyclic activity;

in a first cycle of the cyclic activity, allowing movement of at least a distal portion of the tool in a distal direction with respect to the portion, in response to sensing that the cyclic activity is at a first given phase thereof,

following the given phase in the first cycle, and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity:

inhibiting the movement of the distal portion of the tool, and

in response to a user pushing the tool, facilitating an accumulation selected from the group consisting of: an accumulation of the tool in a housing, and an accumulation of energy in the tool; and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement of the distal portion of the tool, allowing movement of the at least the distal portion of the tool in the distal direction, in response to sensing that the second cycle of the cyclic activity is at the given phase thereof.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for use with a portion of a body of a subject that moves as a result of cyclic activity of a body system of the subject, the apparatus including:

a sensor for sensing a phase of the cyclic activity;

a guide wire configured to be moved with respect to the portion of the subject's body; and

a guide wire modulator configured:

(a) during movement of the guidewire in a distal direction with respect to the portion of the subject's body,

in a first cycle of the cyclic activity, to allow movement of at least a distal portion of the guide wire in the distal direction, in response to the sensor sensing that the cyclic activity is at a first given phase thereof,

following the given phase in the first cycle and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity, to inhibit the movement of the distal portion of the guide wire, and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement, to allow movement of the at least the distal portion of the guide wire in the distal direction, in response to the sensor sensing that the second cycle of the cyclic activity is at the given phase thereof, and

(b) during withdrawal of the guide wire from the portion of the subject's body, to allow continuous movement of the guide wire in the proximal direction.

There is further provided, in accordance with an embodiment of the present invention, apparatus for use with a side branch of a main blood vessel, which side branch moves as a result of cyclic activity of a body system of the subject, the apparatus including:

a sensor for sensing a phase of the cyclic activity;

a guide wire configured to be moved with respect to the portion of the subject's body; and

a guide wire modulator configured:

in a first cycle of the cyclic activity, to allow movement of a distal portion of the guide wire into the side branch, in response to the sensor sensing that the cyclic activity is at a first given phase thereof, when the side branch is at a first angle from the main blood vessel,

following the given phase in the first cycle and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity, to inhibit movement of the distal portion of the guide wire into the side branch, when the side branch is at another angle from the main blood vessel, and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement, to allow movement of the at least the distal portion of the guide wire into the side branch, in response to the sensor sensing that the second cycle of the cyclic activity is at the given phase thereof, when the side branch is at the first angle from the main blood vessel.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A and 1B are schematic illustrations of respective views of a guide wire motion modulator being used by a physician, in accordance with an embodiment of the present invention;

Figs. 2 and 3 are schematic illustrations of the guide wire motion modulator in operation, in accordance with an embodiment of the present invention;

Figs. 4A and 4B are schematic illustrations of a gate of the guide wire motion modulator, in open and closed configurations, respectively, in accordance with an embodiment of the present invention;

Figs. 5A-D are schematic illustrations of a sequence of steps in the operation of the guide wire motion modulator, in accordance with an embodiment of the present invention; and

Figs. 6A-C are schematic illustrations of the forward motion of a guide wire through an occlusion in a vessel, the progress of the guide wire being modulated by a guide wire motion modulator, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1A and 1B, which are schematic illustrations of respective views of a guide wire motion modulator 20 being used by a physician, in accordance with an embodiment of the invention. In an embodiment, a tool such as a guide wire 22 is advanced by the physician's hand 24 within arterial system 26 of the patient. The actual forward motion of guide wire 22 is modulated by guide wire motion modulator 20. Guide wire motion modulator 20 receives, from control unit 30, a synchronization signal 32 over a line 34. Control unit 30 derives synchronization signal 32 from an ECG signal 36 of the patient, which is received via a line 38. In an embodiment, the guide wire motion modulator is used for advancing a coronary guide wire. Images of the advancement of guide wire 22 within arterial system 26 of the patient are typically generated by a fluoroscopy system 40 and displayed on a monitor 42. In some embodiments, guide wire 22 is inserted into arterial system 26 via a guiding catheter (not shown), the guiding catheter typically being connected to a proximal side of the apparatus.

Reference is now made to Figs. 2 and 3, which are schematic illustrations of guide wire motion modulator 20, in accordance with an embodiment of the present invention. The guide wire motion modulator comprises a housing that contains therein a mechanical gate 50 and an energy and/or material accumulation facilitator 52. Typically, gate 50 is a vise. Guide wire 22 is advanced by physician hand 24 and is inserted through gate 50. Gate 50 is activated (e.g., opened and closed), in synchronization with a measurement of a physiological cycle of the patient, such as the patient's ECG. In an embodiment, the actual forward motion of guide wire 22 is enabled when gate 50 is open and disabled when gate 50 is closed. At times when physician hand 24 pushes guide wire 22 forward while gate 50 is closed, at least some of the energy associated with the pushing of guide wire 22 is accumulated by energy and/or material accumulation facilitator 52 accumulating energy (i.e., elastic energy) in the wire, and, typically, does not result in immediate forward motion of guide wire 22 distally, past the guide wire motion modulator. As shown in Fig. 3, energy and/or material accumulation facilitator 52 typically facilitates the accumulation of a portion of guide wire 22 inside guide wire motion modulator 20. In some embodiments, energy and/or material accumulation facilitator 52 comprises a pushing element such as a knob, as shown. Energy and/or material accumulation facilitator 52 typically facilitates the accumulation of energy and/or material (such as guide wire 22) in response to the guide wire being pushed forwards while gate 50 is closed. The energy and/or material the accumulation of which is facilitated by energy and/or material accumulation facilitator 52, while the gate is closed, is typically released when the gate is subsequently opened. At least a portion of the released energy and/or material is used to advance the guide wire distally. In some embodiments, the guide wire motion modulator is used for advancing a coronary guide wire.

In some embodiments, an outer surface of accumulation facilitator 52 pushes guide wire 22 (as shown), while in other embodiments, guide wire 22 passes through a lumen (not shown) of accumulation facilitator 52, such that movement of the lumen pushes guide wire 22 and thereby facilitates the accumulation of energy and/or material.

Guide wire 22 can typically be pulled back freely when gate 50 is open, for example, when the guide wire is withdrawn from the vessel. For some applications, gate 50 is maintained open continuously during the withdrawal of guide wire 22. For example, guide wire motion modulator 20 may include a sensor (not shown), such as a

microswitch, i.e., an electric switch that is able to be actuated by very little physical force. The sensor detects when guide wire 22 is being moved in the proximal direction, and gate 50 is maintained open continuously in response to the sensor detecting that guide wire 22 is being moved in the proximal direction. The stepwise advancement of the guide wire during distal advancement of the guide wire is indicated by arrows 53 of Fig. 2. The continuous movement of the guide wire during withdrawal of the guide wire is indicated by arrow 54 of Fig. 2.

As shown in Fig. 3, guide wire 22 is advanced by physician hand 24 via guide wire motion modulator 20. Specifically, guide wire 22 is inserted via slot 60 in gate 50. The opening and closing of gate 50 is controlled via synchronization signal 32 which is transmitted to guide wire motion modulator 20 via line 34. During a selected phase in the patient's cardiac cycle, and as indicated by signal 32, gate 50 is opened so that when the physician hand 24 pushes guide wire 22 forward, the distal section of guide wire 22 is advanced within the patient's blood vessel. In some embodiments, gate 50 is opened after a defined period of time has elapsed since an event, for example, since when the gate was last closed. In some embodiments, gate 50 is opened after a period of time has elapsed since the gate was previously opened that is equal to the typical length of time of the subject's cardiac cycle. When input synchronization signal 32 indicates that the selected phase in the cardiac cycle is over, or alternatively after a defined period of time has elapsed since an event (for example, after the typical length of time of the selected phase has elapsed since gate 50 was opened), gate 50 closes. Any further pushing of guide wire 22 by physician hand 24 does not result in a forward motion of the distal section of guide wire 22 within the patient's blood vessels. Instead, while gate 50 is closed and guide wire 22 continues to be pushed forward by physician hand 24, knob 52 pushes guide wire 22 sideways (or in a different direction) within the guide wire motion modulator so that the pushing of guide wire 22 by physician hand 24 is translated into curvature of guide wire 22 within the guide wire motion modulator. In some embodiments, at least some of the energy imparted to the guide wire by the physician advancing the guide wire is stored by the guide wire in the form of elastic energy associated with the curvature of guide wire 22. In an embodiment, movement of knob 52 is activated by synchronization signal 32. In an embodiment, knob 52 and gate 50, or parts thereof, are connected rigidly to one another so that they move in tandem. In an embodiment, knob 52 and gate 50 form a single integrated component.

In an embodiment, elements of guide wire motion modulator 20 are powered by an internal power supply, such as a battery. In an embodiment, elements of the guide wire motion modulator are powered by an external power supply. In an embodiment, lines 34 and 38 are wired (as shown in Fig. 1B). In an embodiment, line 34 and/or line 38 is wireless.

Reference is now made to Figs. 4A and 4B, which are schematic illustrations of gate 50 of guide wire motion modulator 20, in open and closed configurations, respectively, in accordance with an embodiment of the present invention. In some embodiments, gate 50 is an electromagnetic gate that includes a solenoid 70. As described hereinabove, gate 50 modulates the advancement of guide wire 22. Plunger 72 enables the forward motion of guide wire 22 when in an open position as in Fig. 4A, and, typically, eliminates the forward motion of guide wire 22 when pressed into a closed position, by spring 74, as shown in Fig. 4B.

As shown in Fig. 4A, when signal 32, received via line 34, indicates that the patient's physiological cycle is at (or approximately at) the selected phase in the patient's physiological cycle, solenoid 70, which is powered by line 76, pulls plunger 72 away from guide wire 22 and enables the advancement of guide wire 22.

As shown in Fig. 4B, when signal 32 indicates that the patient's physiological cycle is no longer at the selected phase solenoid 70 releases plunger 72. Plunger 72, having been released by the solenoid, is then pushed by spring 74, such that the plunger squeezes guide wire 22 and hinders advancement of the guide wire.

In some embodiments, solenoid 70 pulls and/or releases plunger 72 after a defined period of time has elapsed since an event. For example, the solenoid may pull and/or release the plunger when a defined period of time has elapsed since the time the gate was previously opened, or closed.

Reference is now made to Figs. 5A-D, which are schematic illustrations of a sequence of steps in the operation of guide wire motion modulator 20, in accordance with an embodiment of the present invention. In Fig. 5A, input synchronization signal 32, received via line 34, indicates that the heart is the selected phase of the cardiac cycle. In an embodiment, the selected phase of the cardiac cycle is a diastolic or end-diastolic phase, when the blood vessels are relatively further spread apart and less twisted. As shown in Fig. 5A, gate 50 is open. In an embodiment, gate 50 includes one

or more voice coils that are actuated by synchronization signal 32. In the configuration shown in Fig. 5A, when physician hand 24 pushes guide wire 22 forward, distal section 80 of guide wire 22 is advanced within a portion of the vessel that is distal to the guide wire motion modulator. Knob 52 is positioned near guide wire 22 and, typically, applies substantially no force to guide wire 22.

In Fig. 5B, input synchronization signal 32, received via line 34, indicates that the selected phase in the cardiac cycle has ended, has approximately ended, or is about to end. Gate 50 closes, and knob 52 begins to apply a deforming force to guide wire 22. Since the gate is closed, any further pushing of guide wire 22 by physician hand 24 typically does not result in a forward motion of distal section 80 of guide wire 22.

In Fig. 5C, input synchronization signal 32, received via line 34, indicates that the cardiac cycle is still not at the selected phase. As a result, gate 50 is closed, and knob 52 pushes guide wire 22 sideways (or in a different direction that includes a non-forward (i.e., a non-distal) component, such as an upward or a downward component). Any further pushing of guide wire 22 by physician hand 24 typically does not result in a forward motion of distal section 80 of guide wire 22 within the vessel. Instead, any such further pushing of guide wire 22 by physician hand 24 is typically translated into further curvature of guide wire 22. Typically, the curving of the guide wire constitutes an accumulation of elastic energy within the guide wire.

In Fig. 5D, input synchronization signal 32, received via line 34, indicates that the heart is again at, or approximately at, the selected phase of the cardiac cycle. As a result, gate 50 is opened, and knob 52 is released toward its original position, as in Fig. 5A. Typically, the portion of the guide wire that became curved, straightens, thereby releasing the accumulated elastic energy in the form of forward motion of distal section 80 of the guide wire. In an embodiment, the guide wire motion modulator comprises an additional component. When gate 50 is opened, and knob 52 is released, the additional component causes the straightening of guide wire 22 to generate movement of the guide wire in the distal direction (i.e., away from the physician's hand and forward into the patient's body) and not in the proximal direction.

Typically, sequence 5A through 5D is repeated during each cardiac cycle for as long as physician hand 24 pushes guide wire 22 forward. As a result, advancement of distal section 80 of guide wire 22 within the vessel occurs, predominantly, during the

selected phase in the cardiac cycle. In some embodiments, gate 50 is configured not to open during the selected phase of every cardiac cycle of the subject. Rather, the gate is configured to open during the selected phase of every Nth cycle, e.g., every second, or third cycle. Alternatively, the gate opens in response to (a) the cardiac cycle being at the selected phase, and (b) another physiological event (e.g., the subject's respiratory cycle being at a selected phase, the subject's heart rate being within a designated range, and/or the subject's blood pressure being within a designated range).

In some embodiments, guide wire motion modulator 20 generates force feedback that does not vary with respect to the cyclic activity of the blood vessel, or force feedback that is smoothened with respect to the cyclic activity of the blood vessel. In an embodiment, physician hand 24 pushes guide wire 22 forward continuously, and, while doing so, the guide wire motion modulator provides feedback to the physician, such that the physician receives continuous sensation of guide wire 22 advancing distally. Conversely, guide wire 22 is actually advanced intermittently, in a stepwise manner and in synchronization with the patient's cardiac cycle.

Reference is now made to Figs. 6A-C, which are schematic illustrations of the forward motion of guide wire 22 through an occlusion 90 in a vessel 92, the progress of the guide wire being modulated by guide wire motion modulator 20, in accordance with an embodiment of the present invention. In an embodiment, the vessel is a coronary artery.

In Fig. 6A, input synchronization signal 32 indicates that the heart is at, or approximately at, the selected phase of the cardiac cycle. In an embodiment, the selected phase of the cardiac cycle is a diastolic or end-diastolic phase, when the coronary arteries are relatively further spread apart and less twisted. The guide wire motion modulator allows distal section 80 of guide wire 22 to advance through occlusion 90 in vessel 92.

In Fig. 6B, input synchronization signal 32 indicates that the cardiac cycle is outside the selected phase. In an embodiment, the guide wire motion modulator is configured to interpret the systolic phase of the cardiac cycle as being outside of the selected phase. In an embodiment, vessel 92 becomes twisted during the systolic phase. During this phase, even when the guide wire is pushed forward by the physician, the

guide wire motion modulator does not allow distal section 80 of the guide wire to advance through occlusion 90 in vessel 92.

In Fig. 6C, input synchronization signal 32 indicates that the heart is again at, or approximately at, the selected phase of the cardiac cycle. In an embodiment, the selected phase of the cardiac cycle is a diastolic or end-diastolic phase, when the coronary arteries are relatively further spread apart and less twisted. The guide wire motion modulator allows distal section 80 of the guide wire to advance through occlusion 90 in vessel 92, by a distance D relative to its prior position.

In Figs. 6A-C, it may be observed that the angle between main blood vessel 92 and side branch 94, which branches from the main blood vessel, is greater during diastole (as shown in Figs. 6A and 6C) than during systole (as shown in Fig. 6B). As described hereinabove, in some embodiments, guide wire motion modulator 20 is used to facilitate the insertion of guide wire 22 into a side branch, such as side branch 94. For some applications, the guide wire motion modulator allows the guide wire to advance only during a given phase of the cardiac cycle. Typically, this ensures that the angle between the side branch and the main vessel does not vary substantially while the guide wire is advanced into the side branch, thereby facilitating the insertion of the guide wire into the side branch.

US Patent Application 12/075,244, to Tolkowsky et al., filed March 10, 2008, entitled "Imaging for Use with Moving Organs," is incorporated herein by reference. In some embodiments, the apparatus and methods described herein are used in conjunction with the apparatus and methods described therein.

US Patent Application 12/075,214, to Iddan et al., filed March 10, 2008, entitled "Tools for Use with Moving Organs," is incorporated herein by reference. In some embodiments, the apparatus and methods described herein are used in conjunction with the apparatus and methods described therein.

US Patent Application 12/075,252, to Iddan et al., filed March 10, 2008, entitled "Imaging and Tools for Use with Moving Organs," is incorporated herein by reference. In some embodiments, the apparatus and methods described herein are used in conjunction with the apparatus and methods described therein.

Although embodiments relating to endovascular guide wire advancement have been described, the scope of the present invention includes applying the apparatus and

methods described herein to other medical tools or probes being moved within, or relative to, a body lumen or organ. For example, embodiments of the present invention may be applied to the advancement of an atherectomy device (e.g., a directional or a rotational atherectomy device) through a coronary artery. In a similar manner to that described with respect to guide wire 22, the advancement of the atherectomy device is synchronized with the subject's cardiac cycle. During the phase of the cardiac cycle in which advancement of the tool through the subject's blood vessel is impeded, an energy and/or material accumulation facilitator accumulates energy in the atherectomy device and/or accumulates a portion of the atherectomy device inside an atherectomy device motion modulator. Typically, the atherectomy device is advanced during a phase of the cardiac cycle during which the coronary artery is relatively straight and/or compliant (e.g., the diastolic or end-diastolic phase of the cardiac cycle). Further typically, advancing the atherectomy device during such a phase, and inhibiting advancement of the atherectomy device during other phases of the cardiac cycle, facilitates penetration of an occlusion by the atherectomy device.

Although embodiments have been described according to which the movement of a tool is synchronized with a subject's cardiac cycle, the scope of the present invention includes synchronizing the movement of a medical tool with a different physiological cycle of the subject, e.g., the subject's respiratory cycle.

In additional embodiments, the medical tool that is advanced in a stepwise manner includes any one of the following tools, or any combination thereof: a cardiovascular catheter, a stent delivery and/or placement and/or retrieval tool, a balloon delivery and/or placement and/or retrieval tool, a valve delivery and/or placement and/or retrieval tool, a graft delivery and/or placement and/or retrieval tool, a tool for the delivery and/or placement and/or retrieval of an implantable device or of parts of such device, an implantable device or parts thereof, a guide wire, a suturing tool, a biopsy tool, an aspiration tool, a navigational tool, a localization tool, a probe comprising one or more location sensors, a tissue characterization probe, a probe for the analysis of fluid, a measurement probe, an electrophysiological probe, a stimulation probe, an ablation tool, a tool for penetrating or opening partial or total occlusions in blood vessels, a drug or substance delivery tool, a chemotherapy tool, a photodynamic therapy tool, a brachytherapy tool, a local irradiation tool, a laser device, a tool for delivering energy, a tool for delivering markers or biomarkers, a tool for delivering

biological glue, an irrigation device, a suction device, a ventilation device, a device for delivering and/or placing and/or retrieving a lead of an electrophysiological device, a lead of an electrophysiological device, a pacing device, an imaging device, a sensing probe, a probe comprising an optical fiber, a robotic tool, a tool that is controlled remotely. In a particular embodiment, techniques described herein are applied to both a guide wire and another tool in this list.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. Apparatus for use with a portion of a body of a subject that moves as a result of cyclic activity of a body system of the subject, the apparatus comprising:

a sensor for sensing a phase of the cyclic activity;

a tool configured to be moved with respect to the portion of the subject's body by being pushed by a user; and

a tool modulator comprising:

a gate, configured:

in a first cycle of the cyclic activity, to allow movement of at least a distal portion of the tool in a distal direction, in response to the sensor sensing that the cyclic activity is at a first given phase thereof,

following the given phase in the first cycle and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity, to inhibit the movement of the distal portion of the tool, and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement, to allow movement of the at least the distal portion of the tool in the distal direction, in response to the sensor sensing that the second cycle of the cyclic activity is at the given phase thereof; and

an accumulation facilitator configured, following the given phase in the first cycle and prior to the occurrence of the given phase in the subsequent cycle of the cyclic activity, and in response to the user pushing the tool, to facilitate an accumulation selected from the group consisting of: an accumulation of the tool in the tool modulator, and an accumulation of energy in the tool.

2. The apparatus according to claim 1, wherein the tool modulator is configured to provide force feedback to the user that is smoothened with respect to the cyclic activity.

3. The apparatus according to claim 1, wherein the given phase includes a phase selected from the group consisting of a diastolic phase and an end-diastolic phase, and wherein the gate is configured to allow movement of the distal portion of the tool in the distal direction, in response to the sensor sensing that the cyclic activity is at the selected phase.

4. The apparatus according to claim 1, wherein the gate is configured to allow continuous movement of the tool in a proximal direction, when the tool is being withdrawn from the portion of the subject's body.

5. The apparatus according to claim 1, wherein the accumulation facilitator comprises a pushing element configured to push a portion of the tool at least partially in a non-distal direction, in response to the user pushing the tool in the distal direction.

6. The apparatus according to claim 1, wherein the accumulation facilitator is configured to facilitate accumulation of the tool in the tool modulator.

7. The apparatus according to any one of claims 1-6, wherein the accumulation facilitator is configured to facilitate accumulation of energy in the tool.

8. The apparatus according to claim 7, wherein the accumulation facilitator is configured to facilitate accumulation of elastic energy in the tool.

9. The apparatus according to any one of claims 1-6, wherein the tool comprises a guide wire configured to be moved within a blood vessel of the subject.

10. The apparatus according to claim 9, wherein:

by allowing movement of at least the distal portion of the tool in the distal direction, the gate is configured to allow movement of a distal portion of the guide wire into a side branch that branches from the blood vessel, when the side branch is at a first angle from the blood vessel, and

by inhibiting movement of at least the distal portion of the tool, the gate is configured to inhibit movement of the distal portion of the guide wire into the side branch, when the side branch is at another angle from the blood vessel.

11. The apparatus according to claim 9, wherein the gate, by inhibiting the movement of the distal portion of the tool, is configured to inhibit a distal portion of the guide wire from moving in an undesirable direction with respect to the blood vessel.

12. The apparatus according to claim 11, wherein the gate, by inhibiting the movement of the distal portion of the tool, is configured to inhibit a distal portion of the guide wire from puncturing the blood vessel.

13. A method for automatically controlling movement of a tool when the tool is used with a portion of a body of a subject that moves as a result of cyclic activity of a body system of the subject, the method comprising:

sensing a phase of the cyclic activity;

in a first cycle of the cyclic activity, allowing movement of at least a distal portion of the tool in a distal direction with respect to the portion, in response to sensing that the cyclic activity is at a first given phase thereof,

following the given phase in the first cycle, and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity:

inhibiting the movement of the distal portion of the tool, and

in response to a user pushing the tool, facilitating an accumulation selected from the group consisting of: an accumulation of the tool in a housing, and an accumulation of energy in the tool; and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement of the distal portion of the tool, allowing movement of the at least the distal portion of the tool in the distal direction, in response to sensing that the second cycle of the cyclic activity is at the given phase thereof.

14. The method according to claim 13, further comprising providing force feedback to the user that is smoothened with respect to the cyclic activity.

15. The method according to claim 13, wherein the given phase includes a phase selected from the group consisting of a diastolic phase and an end-diastolic phase, and wherein allowing movement of the distal portion of the tool in the distal direction comprises allowing movement of the distal portion of the tool in the distal direction, in response to sensing that the cyclic activity is at the selected phase.

16. The method according to claim 13, further comprising allowing continuous movement of the tool in a proximal direction, when the tool is being withdrawn from the portion of the subject's body.

17. The method according to claim 13, wherein facilitating the accumulation comprises pushing a portion of the tool at least partially in a non-distal direction, in response to the user pushing the tool

18. The method according to claim 13, wherein facilitating the accumulation comprises facilitating accumulation of the tool in the housing.

19. The method according to any one of claims 13-18, wherein facilitating the accumulation comprises facilitating accumulation of energy in the tool.

20. The method according to claim 19, wherein facilitating the accumulation comprises facilitating accumulation of elastic energy in the tool.

21. The method according to any one of claims 13-18, wherein the tool includes a guide wire configured to be moved within a blood vessel of the subject, and wherein allowing movement of at least the distal portion of the tool with respect to the portion comprises allowing movement of at least a distal portion of the guide wire within the blood vessel.

22. The method according to claim 21, wherein:

allowing movement of at least the distal portion of the tool in the distal direction comprises allowing movement of a distal portion of the guide wire into a side branch that branches from the blood vessel, when the side branch is at a first angle from the blood vessel, and

inhibiting the movement of at least the distal portion of the tool comprises inhibiting movement of the distal portion of the guide wire into the side branch, when the side branch is at another angle from the blood vessel.

23. The method according to claim 21, wherein inhibiting the movement of the distal portion of the tool comprises inhibiting the guide wire from moving in an undesirable direction with respect to the blood vessel.

24. The method according to claim 23, wherein inhibiting the movement of the distal portion of the tool comprises inhibiting the guide wire from puncturing the blood vessel.

25. Apparatus for use with a portion of a body of a subject that moves as a result of cyclic activity of a body system of the subject, the apparatus comprising:

a sensor for sensing a phase of the cyclic activity;

a guide wire configured to be moved with respect to the portion of the subject's body; and

a guide wire modulator configured:

(a) during movement of the guidewire in a distal direction with respect to the portion of the subject's body,

in a first cycle of the cyclic activity, to allow movement of at least a distal portion of the guide wire in the distal direction, in response to the sensor sensing that the cyclic activity is at a first given phase thereof,

following the given phase in the first cycle and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity, to inhibit the movement of the distal portion of the guide wire, and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement, to allow movement of the at least the distal portion of the guide wire in the distal direction, in response to the sensor sensing that the second cycle of the cyclic activity is at the given phase thereof, and

(b) during withdrawal of the guide wire from the portion of the subject's body, to allow continuous movement of the guide wire in the proximal direction.

26. Apparatus for use with a side branch of a main blood vessel, which side branch moves as a result of cyclic activity of a body system of the subject, the apparatus comprising:

a sensor for sensing a phase of the cyclic activity;

a guide wire configured to be moved with respect to the portion of the subject's body; and

a guide wire modulator configured:

in a first cycle of the cyclic activity, to allow movement of a distal portion of the guide wire into the side branch, in response to the sensor sensing that the cyclic activity is at a first given phase thereof, when the side branch is at a first angle from the main blood vessel,

following the given phase in the first cycle and prior to an occurrence of the given phase in a subsequent cycle of the cyclic activity, to inhibit movement of the distal portion of the guide wire into the side branch, when the side branch is at another angle from the main blood vessel, and

in a second cycle of the cyclic activity, subsequent to the inhibiting of the movement, to allow movement of the at least the distal portion of the guide wire into the side branch, in response to the sensor sensing that the second cycle

of the cyclic activity is at the given phase thereof, when the side branch is at the first angle from the main blood vessel.

FIG. 1A

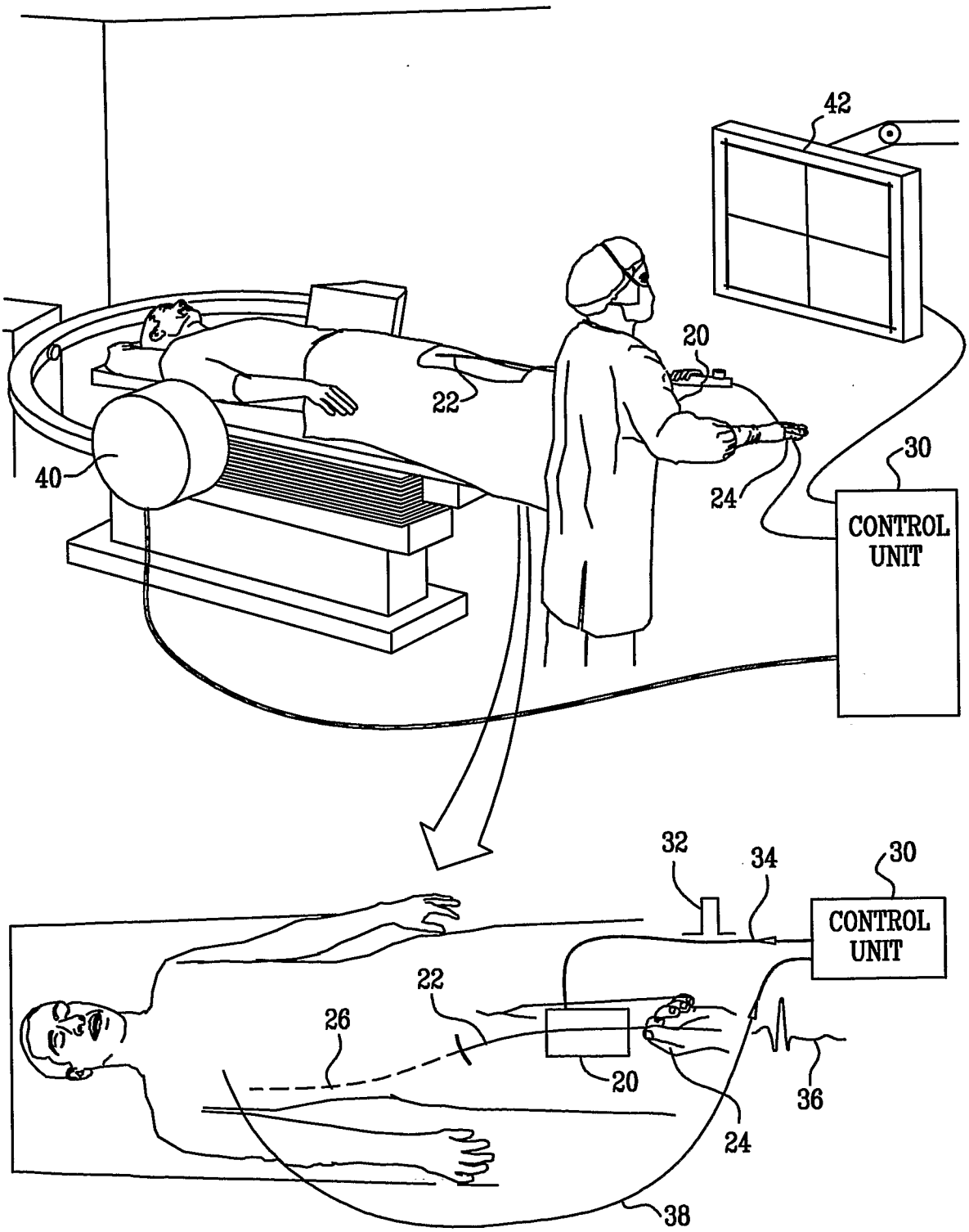
42
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FIG. 1B

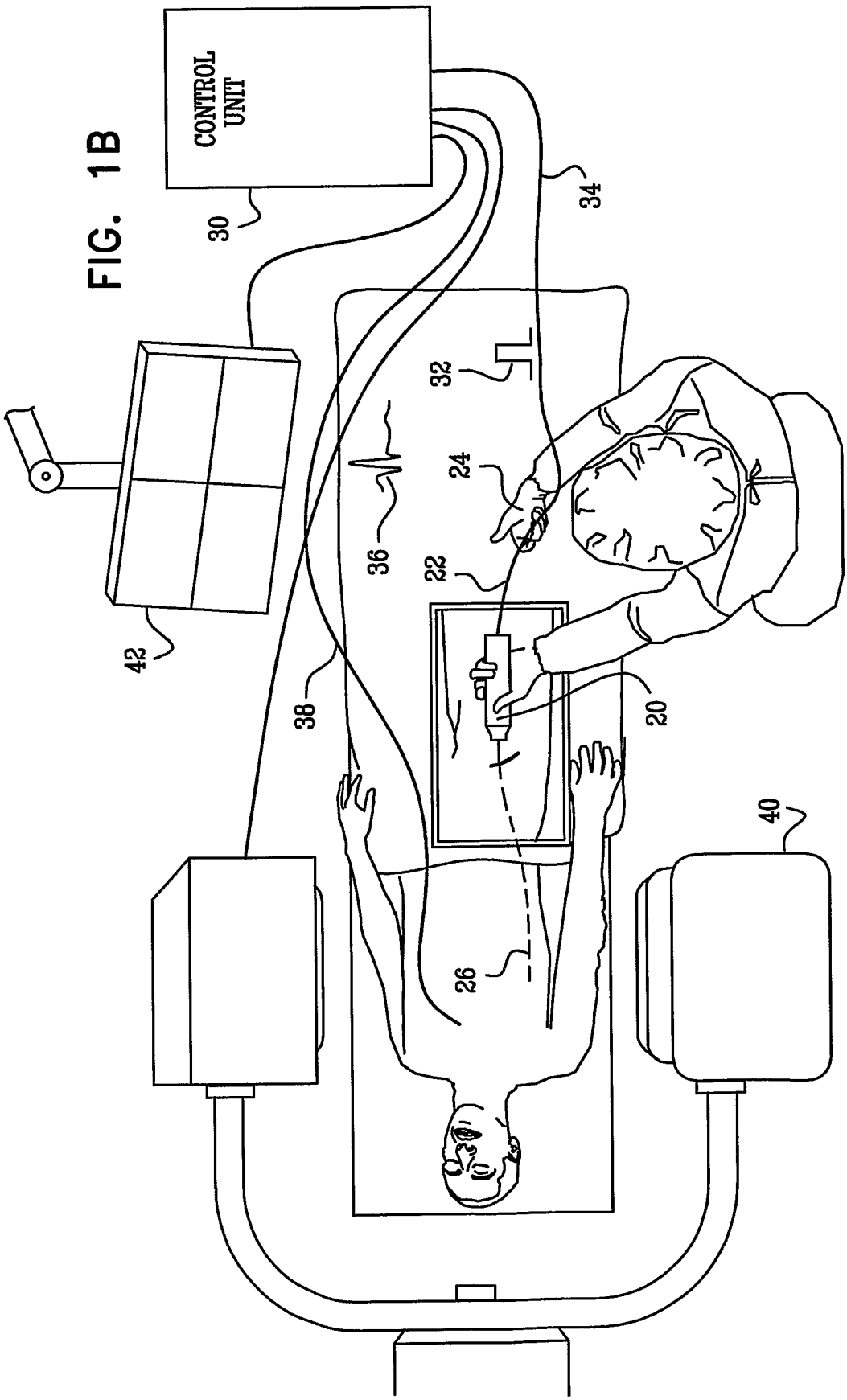


FIG. 2

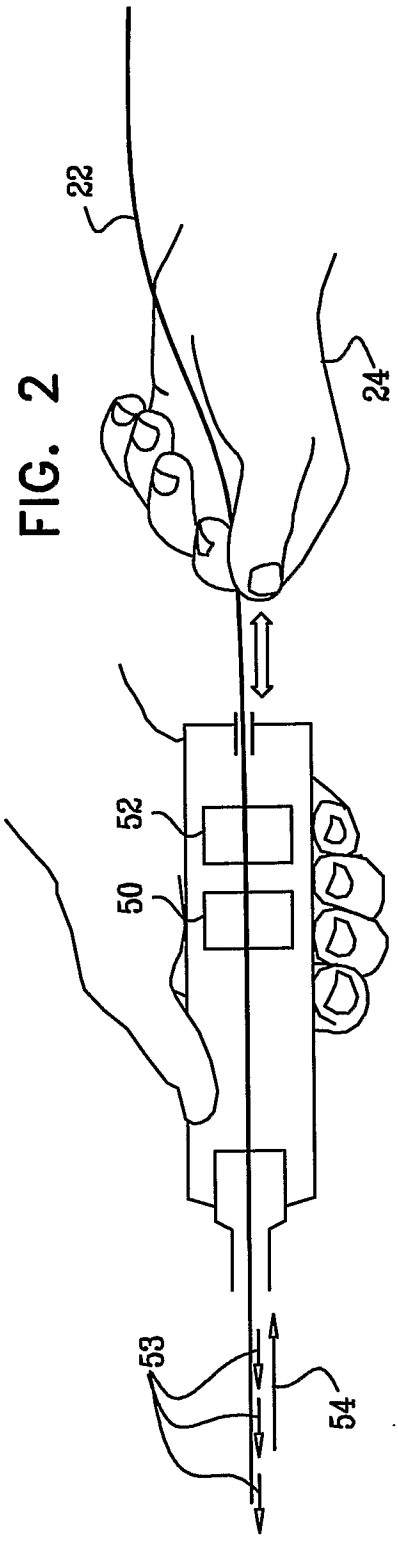
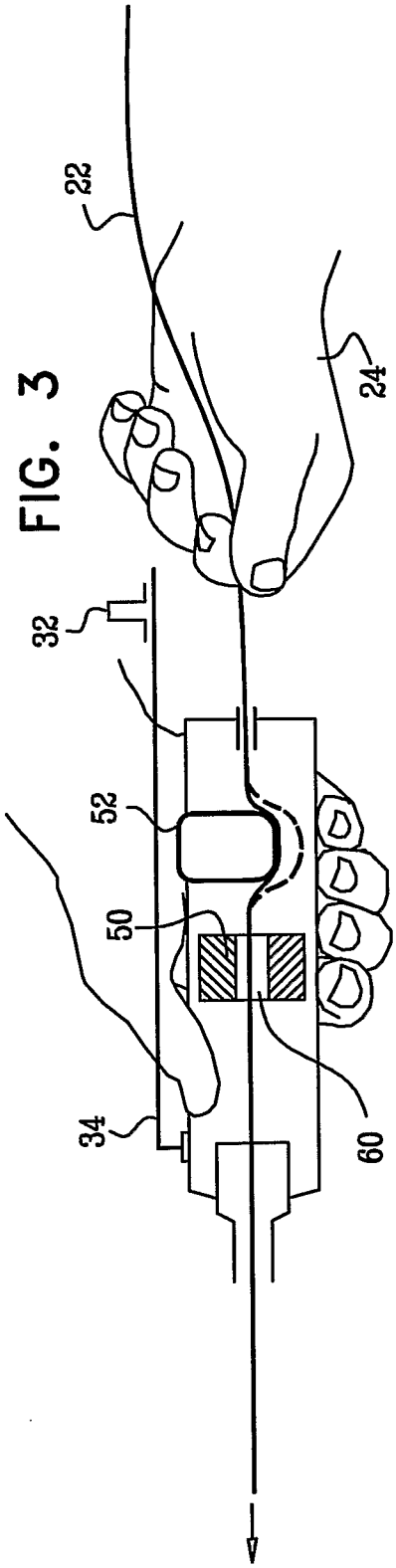


FIG. 3



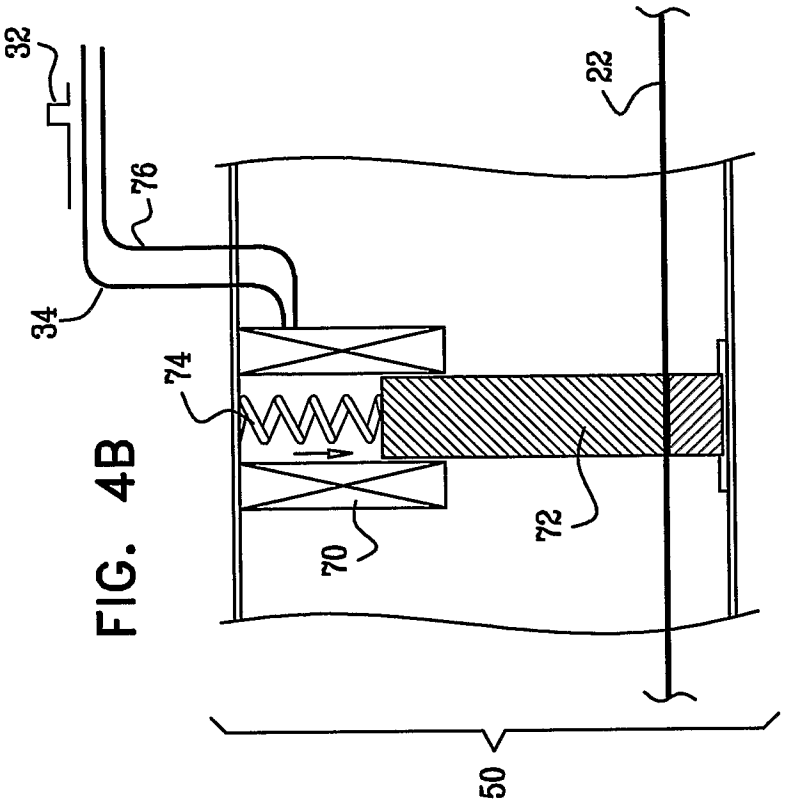


FIG. 4B

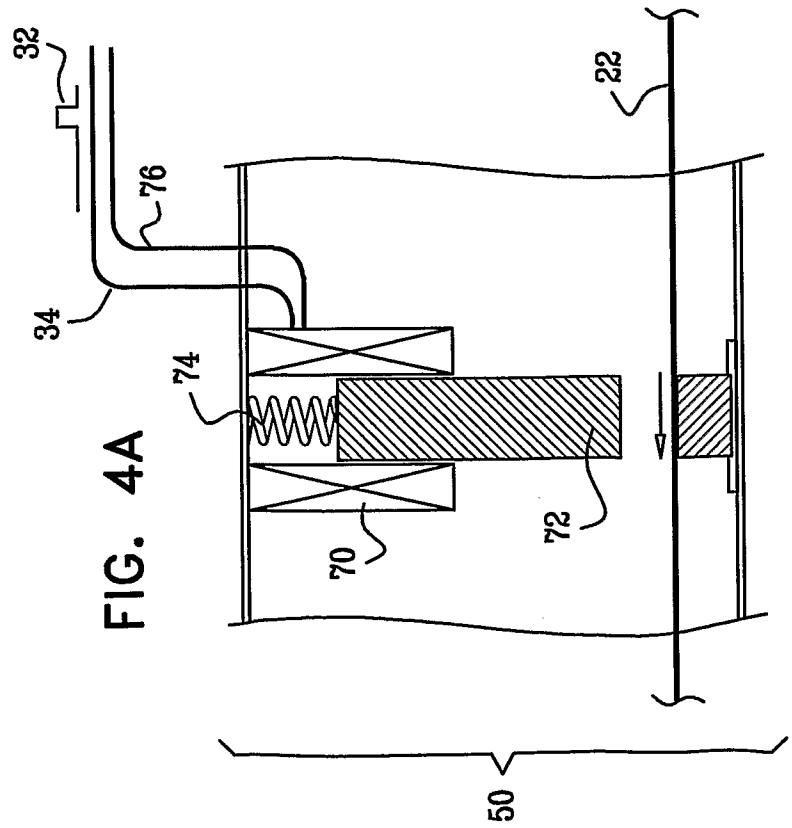


FIG. 4A

FIG. 5A

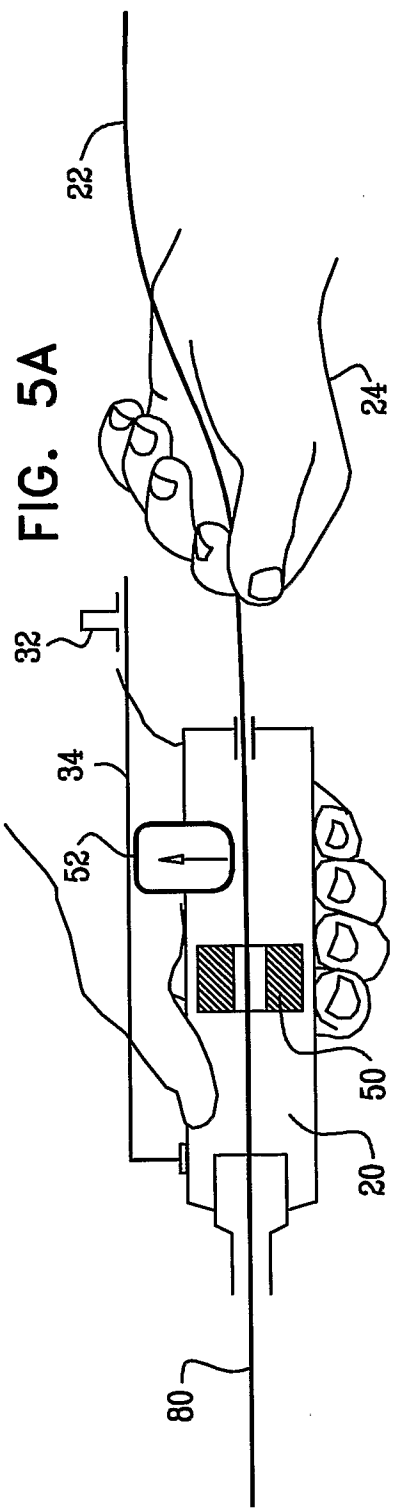


FIG. 5B

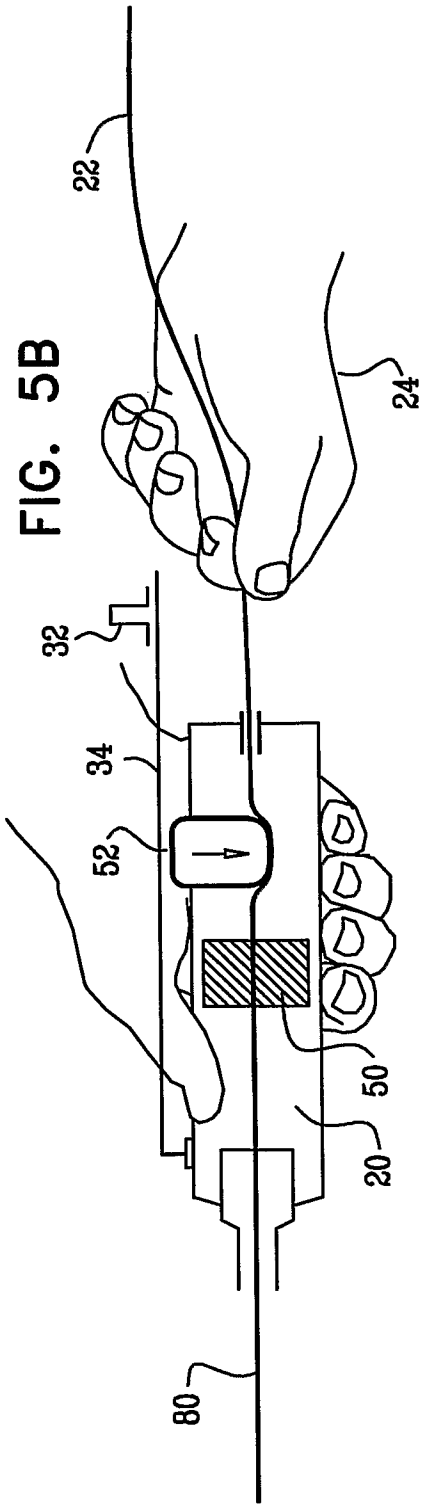


FIG. 5C

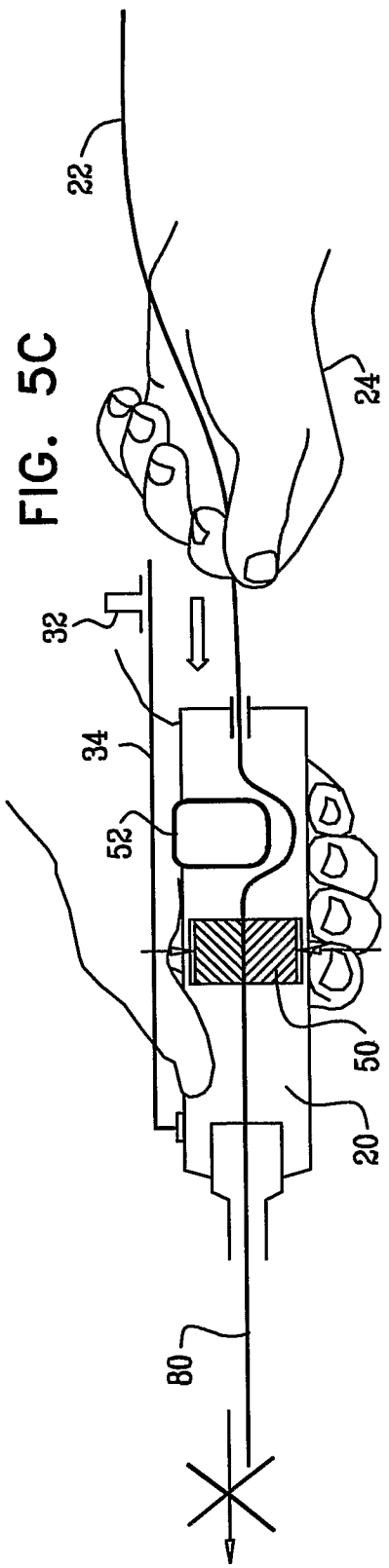
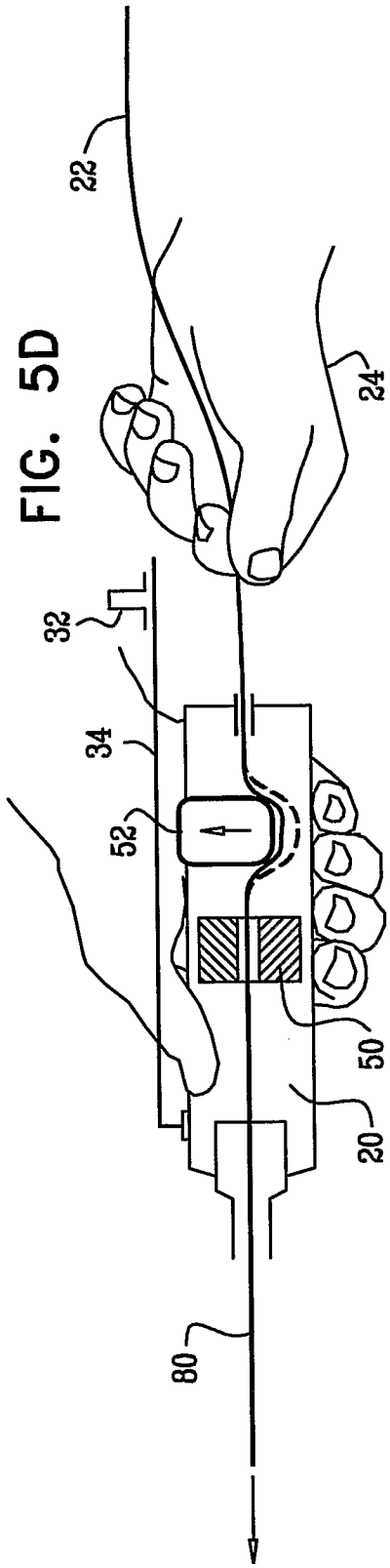


FIG. 5D



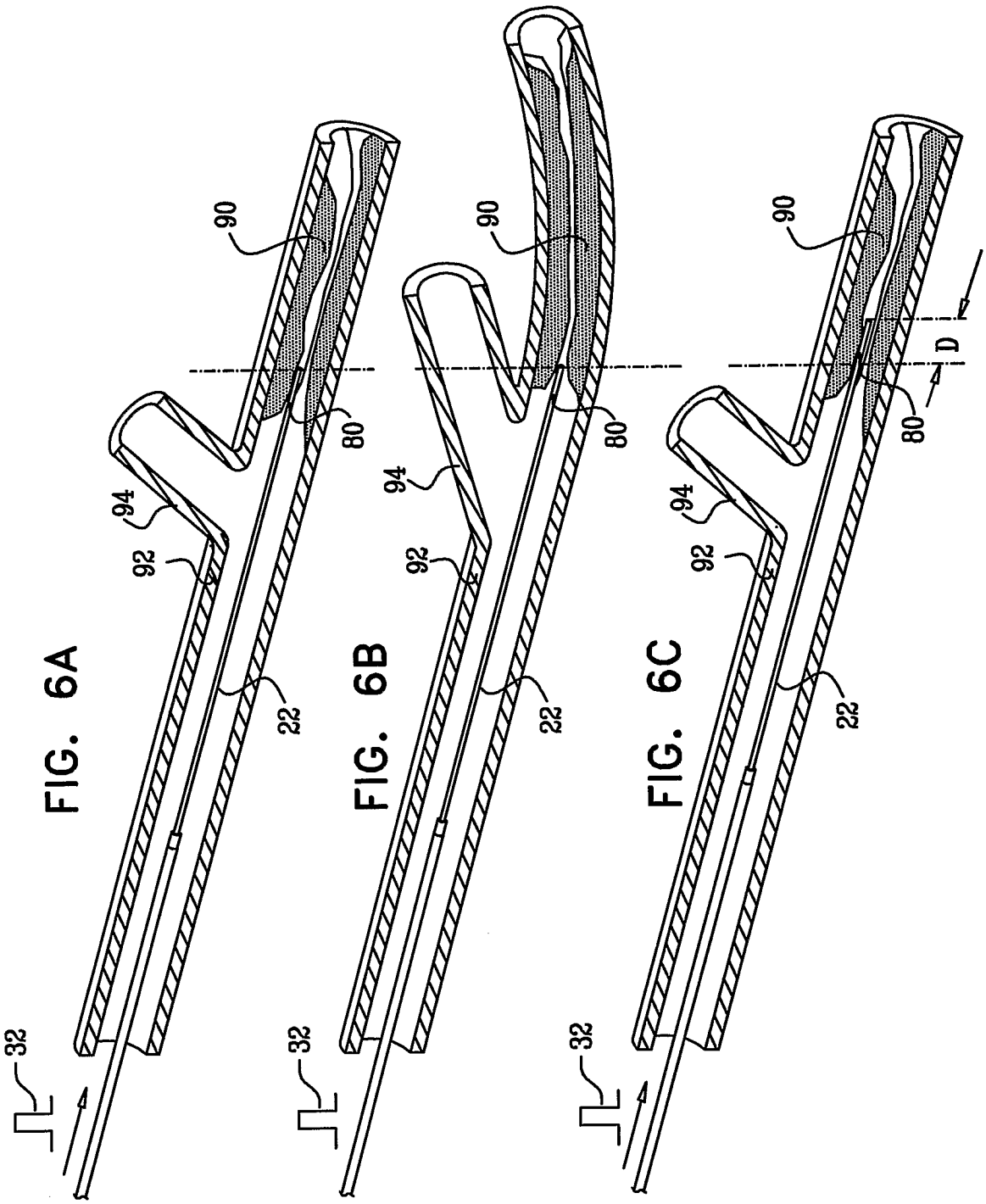


FIG. 6A

FIG. 6B

FIG. 6C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 09/00610

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 25/01 (2009.01)
USPC - 604/528
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)
IPC(8) - A61M 25/01 (2009.01)
USPC - 604/528

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) - A61M 25/00, 25/08, 25/09 (2009.01); A61B 5/103, 5/11, 5/113 (2009.01)
USPC - 600/587, 534, 500, 527; 604/264, 523, 164.13

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,EPAB,JPAB); Google Patents; Google Scholar
Search Terms Used: cyclic, cycle, body, patient, subject, sensor, monitor, tracker, phase, synchronized, guide, wire, guidewire, accumulator, capacitor, diastolic, cardiac, respiratory, energy

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 5,295,486 A (WOLLSCHLAGER et al.) 22 March 1994 (22.03.1994) col 2, ln 54-58; col 3, ln 16-37; col 4, ln 34-47	25 ---------- 1-24, 26
Y	US 2002/0188307 A1 (PINTOR et al.) 12 December 2002 (12.12.2002) para [0094], [0130], [0140], [0145], [0168]	1-24, 26
Y	US 5,486,192 A (WALINSKY et al.) 23 January 1996 (23.01.1996) col 2, ln 43-56	3, 7-12/(3), 15, 19-24/(15)

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 August 2009 (26.08.2009)	08 SEP 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)