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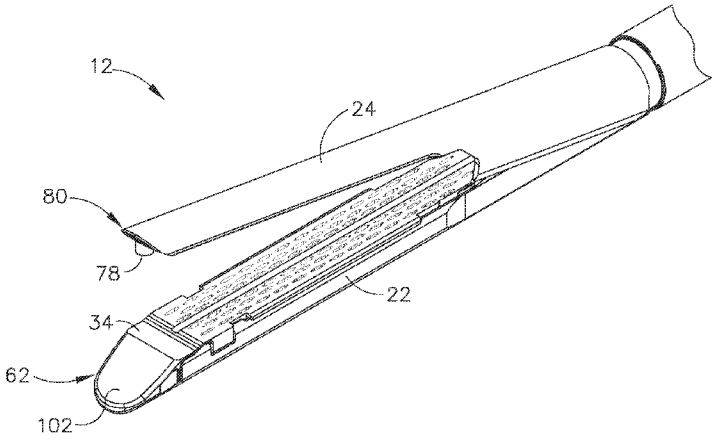

FIG. 7

(57) Abstract: In various embodiments, a staple cartridge for use in a surgical stapler is disclosed. The staple cartridge comprises a staple body comprising a proximal end and a distal end. A tissue thickness sensing module is positioned adjacent to the distal end of the staple body. The tissue thickness sensing module comprises a controller and a sensor. A power key is located removably adjacent to the staple body. The controller is configured to detect the power key and to maintain the tissue thickness sensing module in a low-power state while the power key is present. When the power key is removed, the controller transitions the tissue thickness sensing module to an active state.

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TITLE

STAPLE CARTRIDGE TISSUE THICKNESS SENSOR SYSTEM

BACKGROUND

[0001] The present disclosure relates generally to surgical instruments for endoscopic, laparoscopic, or robotic surgery. Specifically, the present disclosure relates to surgical instruments comprising an end effector configured to staple tissue.

[0002] Surgical staplers are used to simultaneously make a longitudinal incision in tissue and apply lines of staples on opposing sides of the incision. Such instruments commonly include an end effector having a pair of cooperating jaw members that, if the instrument is intended for endoscopic or laparoscopic applications, are capable of passing through a cannula passageway. In one embodiment, one of the jaw members receives a staple cartridge having at least two laterally spaced rows of staples---one on each side of a knife channel defined therein. The other jaw member can define an anvil having staple-forming pockets aligned with the rows of staples in the cartridge. The instrument can also include a plurality of cam, or lift, surfaces that, when driven distally, pass through openings in the staple cartridge and engage drivers supporting the staples to effect the firing of the staples toward the anvil. Simultaneously, a cutting instrument (or knife) is moved distally along the jaw member so that the clamped tissue is cut and fastened (e.g., stapled) at the same time.

[0003] An example of a surgical stapler suitable for endoscopic applications is described in U.S. Patent No. 7,000,818, entitled "Surgical Stapling Instrument Having Separate Distinct Closing and Firing Systems," the disclosure of which is herein incorporated by reference in its entirety. In use, a clinician is able to close the jaw members of the stapler upon tissue to position the tissue prior to firing. Once the clinician has determined that the jaw members are properly gripping tissue, the clinician can then fire the surgical stapler, thereby severing and stapling the tissue. The simultaneous severing and stapling actions avoid complications that may arise when performing such actions sequentially with different surgical tools that respectively only sever or staple.

[0004] Surgical staplers are configured to be used in an optimal tissue thickness range. Presently, clinicians must use video feeds and intuition to determine if the thickness of tissue clamped in the end effector is within the optimal tissue thickness range. Developing a proper

feel for the required thickness for a given cartridge type may take years of practice or may never occur for some clinicians. What is needed is a simple and reliable system for determining when the tissue clamped in an end effector is within the optimal tissue thickness range for a given staple cartridge.

SUMMARY

[0005] In various embodiments, a device comprising a Hall Effect sensor, a reed switch, a power source, and a controller in signal communication with the power source is disclosed. The controller is configured to detect the state of the reed switch. A magnet is removably positioned adjacent to the device. The magnet is configured to generate a magnetic field sufficient to maintain the reed switch in a saturation state. The controller detects the saturation state and maintains the device in a low-power state while the reed switch is in the saturation state. When the magnet is removed from the device, the reed switch enters a non-saturated state. The controller detects the non-saturated state of the reed switch and transitions the device from the low-power state to an active power state.

[0006] In various embodiments, a surgical end effector is disclosed. The surgical end effector comprises a staple cartridge comprising a proximal end and a distal end. The staple cartridge is configured to be used to staple tissue within an optimal tissue thickness range. An anvil is movably coupled relative to the proximal end of the staple cartridge. A tissue thickness sensing module is located adjacent to the distal end of the staple cartridge. The tissue thickness sensing module comprises a sensor and a controller. The sensor is configured to generate a tissue thickness signal indicative of a thickness of the tissue located between the anvil and the staple cartridge. The controller is in signal communication with the sensor. The controller comprises means for identifying the staple cartridge type of the staple cartridge. The staple cartridge type and the thickness of the tissue are used to determine if the thickness of the tissue located between the anvil and the staple cartridge is within the optimal tissue thickness range of the staple cartridge.

[0007] In various embodiments, a staple cartridge for use in a surgical stapler is disclosed. The staple cartridge comprises a staple body comprising a proximal end and a distal end. A tissue thickness sensing module is positioned adjacent to the distal end of the staple body. The tissue thickness sensing module comprises a controller and a sensor. A power key is located

removably adjacent to the staple body. The controller is configured to detect the power key and to maintain the tissue thickness sensing module in a low-power state while the power key is present. When the power key is removed, the controller transitions the tissue thickness sensing module to an active state.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The features of the various embodiments are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation, together with advantages thereof, may best be understood by reference to the following description, taken in conjunction with the accompanying drawings as follows:

[0009] FIGS. 1 and 2 illustrate views of an articulating surgical instrument.

[0010] FIGS. 3-6 illustrate exploded views of the end effector and shaft of the surgical instrument shown in FIGS. 1 and 2.

[0011] FIG. 7 illustrates a perspective view of an end effector comprising a tissue thickness sensing module.

[0012] FIG. 8 illustrates one embodiment of a tissue thickness sensing module.

[0013] FIGS. 9A and 9B illustrate internal views of the tissue thickness sensing module shown in FIG. 8.

[0014] FIG. 10 illustrates a block diagram of one embodiment of a tissue thickness sensing module.

[0015] FIG. 11 illustrates one embodiment of a tissue thickness sensing module configured to transmit a tissue thickness signal to a remote device.

[0016] FIG. 12 illustrates one embodiment of a tissue thickness sensing module configured to receive a power key comprising a magnet.

[0017] FIG. 13 illustrates one embodiment of Hall Effect sensor.

[0018] FIG. 14 illustrates one embodiment of a tissue thickness sensing module configured to receive a power key comprising terminal connectors.

[0019] FIG. 15 is a flow chart illustrating one embodiment of a method for maintaining a tissue thickness sensing module in a low-power state.

DETAILED DESCRIPTION

[0020] Applicant of the present application owns U.S. Patent Application entitled "Staple Cartridge Tissue Thickness Sensor System", Attorney Docket No. END7198USNP/120306, which was filed on even date herewith and which is herein incorporated by reference in its entirety.

[0021] Reference will now be made in detail to several embodiments, including embodiments showing exemplary implementations of surgical instruments comprising a tissue thickness sensing module. Wherever practicable similar or like reference numbers may be used in the figures and may indicate similar or like functionality. The figures depict exemplary embodiments of the disclosed surgical instruments and/or methods of use for purposes of illustration only. One skilled in the art will readily recognize from the following description that alternative example embodiments of the structures and methods illustrated herein may be employed without departing from the principles described herein.

[0022] It will be appreciated that the terms "proximal" and "distal" are used herein with reference to a clinician gripping the handle of an instrument. Thus, the end effector is distal with respect to the more proximal handle. It will be further appreciated that, for convenience and clarity, spatial terms such as "vertical" and "horizontal" are used herein with respect to the drawings. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute.

[0023] The instrument may be a motor-driven instrument, a hand-powered instrument, or a robotically controlled surgical instrument according to various embodiments. U.S. Patent Application Serial No. 13/782,295, entitled "Articulatable Surgical Instruments With Conductive Pathways For Signal Communication"; U.S. Patent Application Serial No. 13/782,323, entitled "Rotary Powered Articulation Joints For Surgical Instruments; U.S. Patent Application Serial No. 13/782,338, entitled "Thumbwheel Switch Arrangements For Surgical Instruments"; U.S. Patent Application Serial No. 13/782,499, entitled "Electromechanical Surgical Device with Signal Relay Arrangement"; U.S. Patent Application Serial No. 13/782,460, entitled "Multiple Processor Motor Control for Modular Surgical Instruments"; U.S. Patent Application Serial No. 13/782,358, entitled "Joystick Switch Assemblies For Surgical Instruments"; U.S. Patent Application Serial No. 13/782,481, entitled "Sensor Straightened End Effector During Removal

Through Trocar"; U.S. Patent Application Serial No. 13/782,518, entitled "Control Methods for Surgical Instruments with Removable Implement Portions"; U.S. Patent Application Serial No. 13/782,375, entitled "Rotary Powered Surgical Instruments With Multiple Degrees of Freedom"; and U.S. Patent Application Serial No. 13/782,536, entitled "Surgical Instrument Soft Stop", which were filed on March 1, 2013, are hereby incorporated by reference in their entireties.

[0024] FIGS. 1 and 2 depict a motor-driven surgical cutting and fastening instrument 10 according to various embodiments of the present disclosure. The illustrated embodiment is a linear endoscopic instrument and, in general, the embodiments of the instrument 10 described herein are linear endoscopic surgical cutting and fastening instruments. It should be noted, however, that the invention is not so limited and that according to other embodiments of the present invention, the instrument may be another type of endoscopic instrument, such as a circular or curved endocutter. U.S. Patent Application Publication No. 2008/0169332, published on July 17, 2008, entitled "Surgical Stapling Device with a Curved Cutting Member", is herein incorporated by reference in its entirety. In addition, the instrument may be a non-endoscopic surgical cutting and fastening instrument, such as a laparoscopic instrument, an open surgery instrument, or a robotic surgical instrument. In some embodiments, the surgical instrument 10 may comprise recording capabilities. U.S. Patent No. 7,845,537, which issued on December 7, 2010, entitled "Surgical Instrument Having Recording Capabilities", is herein incorporated by reference in its entirety.

[0025] The surgical instrument 10 depicted in FIGS. 1 and 2 comprises a handle 6, a shaft 8, and an end effector 12 connected to the shaft 8. In various embodiments, the end effector 12 can be articulated about an articulation pivot 14. An articulation control 16 may be provided adjacent to the handle 6 to effect rotation of the end effector 12 about the articulation pivot 14. In the illustrated embodiment, the end effector 12 is configured to act as an endocutter for clamping, severing and stapling tissue, although, in other embodiments, different types of end effectors may be used, such as end effectors for other types of surgical devices, such as graspers, cutters, staplers, clip appliers, access devices, drug/gene therapy devices, ultrasound, RF or laser devices, etc.

[0026] The handle 6 of the instrument 10 may include a closure trigger 18 and a firing trigger 20 for actuating the end effector 12. It will be appreciated that instruments having end effectors directed to different surgical tasks may have different numbers or types of triggers or other

suitable controls for operating the end effector 12. The end effector 12 is shown separated from the handle 6 by the elongate shaft 8. In one embodiment, a clinician or operator of the instrument 10 may articulate the end effector 12 relative to the shaft 8 by utilizing the articulation control 16. U.S. Patent No. 7,670,334, entitled "Surgical Instrument Having an Articulating End Effector," is incorporated herein by reference in its entirety.

[0027] The end effector 12 may include, among other things, a staple channel 22 and a pivotally translatable clamping member, such as an anvil 24, which are maintained at a spacing that assures, when the anvil 24 is in its clamped position, effective stapling and severing of tissue clamped in the end effector 12. The handle 6 includes a downwardly extending pistol grip 26, towards which a closure trigger 18 is pivotally drawn by the clinician to cause clamping or closing of the anvil 24 toward the staple channel 22 of the end effector 12 to thereby clamp tissue positioned between the anvil 24 and channel 22. The firing trigger 20 is farther outboard of the closure trigger 18. Once the closure trigger 18 is locked in the closure position, the firing trigger 20 may rotate slightly toward the pistol grip 26 so that it can be reached by the operator using one hand. Then the operator may pivotally draw the firing trigger 20 toward the pistol grip 12 to cause the stapling and severing of clamped tissue in the end effector 12. In other embodiments, different types of clamping members besides the anvil 24 could be used. The handle 6 may also include an upper portion 28 that may sit on top of the user's hand when the user grips the pistol grip portion 26 with his/her hand. The anvil 24 may include a magnet 78 located on the distal end of the anvil 24.

[0028] In operational use, the closure trigger 18 may be actuated first. Once the clinician is satisfied with the positioning of the end effector 12, the clinician may draw back the closure trigger 18 to its fully closed, locked position proximate to the pistol grip 26. Drawing back of the closure trigger 18 causes the anvil 24 to rotate downwardly, clamping the tissue between the anvil 24 and a staple cartridge 34 positioned within the channel 22. The firing trigger 20 may then be actuated. Actuation of the firing trigger 20 causes the cutting instrument in the end effector 12 to sever the clamped tissue, and causes the fasteners in the staple cartridge 34 to fasten the severed tissue. The firing trigger 20 returns to the open position (shown in FIGS. 1 and 2) when the clinician removes pressure. A release button 19 on the handle 6, when depressed, may release the locked closure trigger 18. The release button 19 may be implemented in various forms such as, for example, as disclosed in U.S. Patent App. Pub. No. 2007/0175955.

U.S. Patent App. Pub. No. 2007/0175955, entitled "Surgical cutting and fastening instrument with closure trigger locking mechanism," is incorporated herein by reference in its entirety.

[0029] The end effector 12 may include a cutting instrument, such as a knife, for example, for cutting tissue clamped in the end effector 12 when the firing trigger 20 is retracted by a user. The end effector 12 may also comprise means for fastening the tissue severed by the cutting instrument, such as staples, RF electrodes, adhesives, etc. The instrument 10 may also comprise a closure system for closing (or clamping) the end effector upon closure (or retraction) of the closure trigger 18.

[0030] A longitudinally movable or rotatable drive shaft located within the shaft 8 of the instrument 10 may drive or actuate the cutting instrument and the fastening means in the end effector 12. An electric motor, located in the pistol grip portion 26 of the handle 6 of the instrument 10, may be used to drive, directly or indirectly (via a gear drive train), the drive shaft. In various embodiments, the motor may be a DC brushed driving motor having a maximum rotation of, approximately, 25,000 RPM, for example. In other embodiments, the motor may include a brushless motor, a cordless motor, a synchronous motor, a stepper motor, or any other suitable electric motor. U.S. Patent Application Publication No. 2010/0089970, published on April 15, 2010, entitled "Powered Surgical Cutting and Stapling Apparatus with Manually Retractable Firing System" and U.S. Patent No. 8,210,411, issued on July 3, 2012, entitled "Motor-Driven Surgical Cutting Instruments", are herein incorporated by reference in their entireties. A battery (or "power source" or "power pack"), such as a Lithium-ion battery, for example, may be provided in the pistol grip portion 26 of the handle 6 adjacent to the motor. The battery may supply electric power to the motor via a motor control circuit. According to various embodiments, a number of battery cells connected in series may be used as the power source to power the motor. In addition, the power source may be replaceable and/or rechargeable.

[0031] FIG. 3 is a diagram of the end effector 12 according to various embodiments of the present invention. As shown in the illustrated embodiment, the end effector 12 may include, in addition to the previously mentioned channel 22 and anvil 24, a cutting instrument 32, a sled 33, a staple cartridge 34 that is removably seated in the channel 22, and a helical screw shaft 36. The cutting instrument 32 may be, for example, a knife. The anvil 24 may be pivotably opened and closed at pivot pins 25 connected to the proximate end of the channel 22. The anvil 24 may

also include a tab 27 at its proximate end that is inserted into a component of the mechanical closure system to open and close the anvil 24. When the closure trigger 18 is actuated, that is, drawn in by a user of the instrument 10, the anvil 24 may pivot about the pivot pins 25 into the clamped or closed position, thereby clamping tissue between the channel 22 and the anvil 24. If clamping of the end effector 12 is satisfactory, the operator may actuate the firing trigger 20, which causes the knife 32 and sled 33 to travel longitudinally along the channel 22, thereby cutting the tissue clamped within the end effector 12. The movement of the sled 33 along the channel 22 causes the staples (not shown) of the staple cartridge 34 to be driven through the severed tissue and against the closed anvil 24, which turns the staples to fasten the severed tissue. In various embodiments, the sled 33 may be an integral component of the cartridge 34. The sled 33 may be part of the cartridge 34, such that when the knife 32 retracts following the cutting operation, the sled 33 does not retract with the knife 32 and remains with the at least partially fired staple cartridge 34.

[0032] FIGS. 4-5 are exploded views and FIG. 6 is a side view of the end effector 12 and shaft 8 according to various, non-limiting embodiments. As shown in the illustrated embodiment, the shaft 8 may include a proximate closure tube 40 and a distal closure tube 42 pivotably linked by pivot links 44. The distal closure tube 42 includes an opening 45 into which the tab 27 on the anvil 24 is inserted in order to open and close the anvil 24, as further described below. Disposed inside the closure tubes 40, 42 may be a proximate spine tube 46. Disposed inside the proximate spine tube 46 may be a main rotational (or proximate) drive shaft 48 that communicates with a secondary (or distal) drive shaft 50 via a bevel gear assembly 52. The secondary drive shaft 50 is connected to a drive gear 54 that engages a proximate drive gear 56 of the helical screw shaft 36. The vertical bevel gear 52b may sit and pivot in an opening 57 in the distal end of the proximate spine tube 46. A distal spine tube 58 may be used to enclose the secondary drive shaft 50 and the drive gears 54, 56. Collectively, the main drive shaft 48, the secondary drive shaft 50, and the articulation assembly (e.g., the bevel gear assembly 52a-c) are sometimes referred to herein as the "main drive shaft assembly."

[0033] A bearing 38, positioned at a distal end of the staple channel 22, receives the helical drive screw 36, allowing the helical drive screw 36 to freely rotate with respect to the channel 22. The helical screw shaft 36 may interface a threaded opening (not shown) of the knife 32 such that rotation of the shaft 36 causes the knife 32 to translate distally or proximately

(depending on the direction of the rotation) through the staple channel 22. Accordingly, when the main drive shaft 48 is caused to rotate by actuation of the firing trigger 20, the bevel gear assembly 52*a-c* causes the secondary drive shaft 50 to rotate, which in turn, because of the engagement of the drive gears 54, 56, causes the helical screw shaft 36 to rotate, which causes the knife driving member 32 to travel longitudinally along the channel 22 to cut any tissue clamped within the end effector 12. The sled 33 may be made of, for example, plastic, and may have a sloped distal surface. As the sled 33 traverses the channel 22, the sloped forward surface may push up or drive the staples in the staple cartridge 34 through the clamped tissue and against the anvil 24. The anvil 24 turns or deforms the staples, thereby stapling the severed tissue. When the knife 32 is retracted, the knife 32 and sled 33 may become disengaged, thereby leaving the sled 33 at the distal end of the channel 22.

[0034] In the illustrated embodiment, the end effector 12 uses a rotatable, helical screw shaft 36 to drive the cutting instrument 32. Such a helical screw shaft 36 may be used in embodiments where a rotating drive member is used. In other embodiments, a longitudinally reciprocating drive member may be used to power the cutting instrument, such as, for example, the longitudinally reciprocating drive member. The end effector 12 may be modified accordingly to suit such a longitudinally reciprocating drive member.

[0035] According to various embodiments, the staple cartridge 34 may comprise a tissue thickness sensing module 102 that senses the thickness of tissue clamped in the end effector 12 between the staple channel 22 (including the staple cartridge 34) and the anvil 24. According to various, non-limiting embodiments, as shown in FIG. 7, the tissue thickness sensing module 102 may be located adjacent to a distal end 62 of the staple cartridge 34, such that it is positioned distally, for example, with respect to the staples of the staple cartridge 34 when the staples are fired. FIGS. 8-9B show one embodiment of a tissue thickness sensing module 102. As shown in FIG. 8, the tissue thickness sensing module 102 may comprise an enclosure 103 to protect the elements of the tissue thickness sensing module 102 during use. FIGS. 9A and 9B illustrate one view of the tissue thickness sensing module 102 with the enclosure 103 removed. As can be seen in FIGS. 9A and 9B, the tissue thickness sensing module 102 may comprise a tissue thickness sensor 104, a controller 106, a radio module 108, a power source 110, and an antenna 112.

[0036] In some embodiments, the tissue thickness sensor 104 may be configured to generate a tissue thickness signal indicative of a thickness of tissue clamped between the staple channel 22 and the anvil 24. The tissue thickness sensor 104 may be any suitable sensor for detecting the thickness of the tissue clamped in the end effector 12. For example, the tissue thickness sensor 104 may comprise a magnetic sensor, magneto-inductive sensor, a magnetoresistive sensor (AMR, GMR), an ultrasonic sensor, a radio frequency sensor, and/or any other suitable sensor. In some embodiments, the tissue thickness sensor 104 may be configured to detect a magnetic field generated by the magnet 78 located on the distal end 80 of the anvil 24. When the clinician closes the anvil 24 by retracting the closure trigger 18, the magnet 78 rotates downwardly closer to the tissue thickness sensor 104, thereby varying the magnetic field detected by the tissue thickness sensor 104 as the anvil 24 rotates into the closed (or clamped position). The strength of the magnetic field from the magnet 78 and sensed by the tissue thickness sensor 104 is indicative of the distance between the staple cartridge 34 and the anvil 24, which is indicative of the thickness of the tissue clamped between the staple cartridge 34 and the anvil 24 when the end effector 12 is in the closed (or clamped) position. For instance, a larger distance between the staple cartridge 34 and the anvil 24, and therefore a weaker magnetic field detected by the tissue thickness sensor 104, may indicate that thick tissue is present between the staple cartridge 34 and the anvil 24, while a shorter distance between the staple cartridge 34 and the anvil 24, and therefore a stronger magnetic field detected by the tissue thickness sensor 104, may indicate that thin tissue is present between the staple cartridge 34 and the anvil 24. In some embodiments, the tissue thickness sensor 104 may comprise a Hall Effect sensor.

[0037] A controller 106 may be configured to control one or more operations of the tissue thickness sensing module 102. The controller 106 may be in signal communication with the tissue thickness sensor 104. Signal communication may comprise wired and/or wireless communication. The controller 106 may be configured to control operation of the tissue thickness sensor 104, the transmitter 108, and/or the power source 110. In some embodiments, the controller 106 may be configured to execute one or more processes to control the tissue thickness sensing module 102 and/or the end effector 12.

[0038] In some embodiments, the controller 106 may comprise identifying means for identifying the type of staple cartridge positioned within the staple channel 22. The staple cartridge 34 may be configured for use within an optimal tissue thickness range and the

controller 106 may be configured to determine whether or not a particular staple cartridge is suitable and/or preferred in a given set of circumstances. For example, in some embodiments, a staple cartridge 34 may comprise a plurality of long staples configured for use in thick tissue. In some embodiments, a staple cartridge 34 may comprise a plurality of short staples configured for use in thin tissue. When the optimal tissue thickness range for the staple cartridge 34 mandates or prefers the use of longer staples, an attempt to use a staple cartridge configured for use in thin tissue may cause the surgical instrument 2 to warn the clinician, for example, or in some instances, prevent the surgical instrument 2 from being used. The identifying means may be configured to identify the type of the staple cartridge positioned within the staple channel 22 to ensure the proper type of staple cartridge 34 is installed for the tissue being treated.

[0039] In some embodiments, the tissue thickness sensing module 102 may comprise a radio module 108. The radio module 108 may be a low-power, 2-way radio module that communicates wirelessly, using a wireless data communication protocol, with a remote device, such as, for example, a receiver located in the handle 6 of the instrument 10. According to various embodiments, the radio module 108 may communicate with the remote device using a communication frequency that is suitable for transmission through human tissue. The communications between the radio module 108 and remote device may use the MICS (Medial Implant Communication Service) frequency band (502-405 MHz), a suitable industrial, scientific and medical (ISM) radio band (such as 433 MHz center frequency or 915 MHz center frequency), a Bluetooth communication band (2.4 GHz), or any other suitable, human-tissue-permeable frequency band. In some embodiments, an antenna 112 may be in signal communication with the radio module 108. In some embodiments, the antenna 112 may be formed integrally with the radio module 108.

[0040] The tissue thickness sensing module 102 may comprise one or more power sources 110 for providing independent power to the controller 106 or the radio module 108. The power source 110 may comprise a suitable battery cell for powering the components of the tissue thickness sensing module 102, such as a Lithium-ion battery or some other suitable battery cell, for example. In some embodiments, multiple battery cells may be provided to power the components of the tissue thickness sensing module 102.

[0041] In some embodiments, the staple cartridge type signal generated by the identifying means and the tissue thickness signal generated by the tissue thickness sensor 104 may be used

to determine if the tissue clamped between the staple channel 22 and the anvil 24 is within the optimal tissue thickness range for the staple cartridge 34. In some embodiments controller 106 may be configured to determine if the tissue clamped between the staple channel 22 and the anvil 24 is within the optimal tissue thickness range. In some embodiments, a remote system, such as a remote device located in the handle 6 of the surgical instrument 10, may be configured to perform the determination or at least part of such determination.

[0042] FIG. 10 shows a block diagram of one embodiment of a tissue thickness sensing module 202. In the illustrated embodiment, the tissue thickness sensing module 202 comprises a tissue thickness sensor 204, a controller 206, a radio module 208, and a power source 210, and a reed switch 211. As shown in FIG. 10, the tissue thickness sensor 204 may be in signal communication with the controller 206. The tissue thickness sensor 204 may be any suitable sensor for determining the thickness of tissue clamped between the staple channel 22 and the anvil 24 of the surgical instrument 10. In some embodiments, the tissue thickness sensor 204 may be configured to detect a magnetic field generated by a magnet 78 located on the distal end 80 of the anvil 24. The strength of the magnetic field may be indicative of the thickness of tissue clamped in the end effector 12. In some embodiments, the tissue thickness sensor 204 may comprise a Hall Effect sensor.

[0043] The controller 206 illustrated in FIG. 10 may comprise an identifier means 214 for identifying the staple cartridge type of the staple cartridge 34. The identifier means 214 may be any suitable means useable by the controller 206 to identify the staple cartridge type. For example, in some embodiments, the identifying means 214 may comprise a memory unit. The memory unit of the controller 206 may comprise one or more solid state read only memory (ROM) and/or random access memory (RAM) units. In various embodiments, the controller 206 and the memory units may be integrated into a single integrated circuit (IC), or multiple ICs. The ROM memory units may comprise flash memory. The memory unit may store data indicative of the cartridge type of the staple cartridge 34. That is, for example, memory unit may store data indicating the type of staple cartridge 34. In some embodiments, the memory unit may store data indicative of the optimal tissue thickness range of the type of the staple cartridge 34.

[0044] In some embodiments, the identifying means 214 may comprise a first plurality of terminals formed on the proximal end of the tissue thickness sensing module 102. A second plurality of terminals may be formed on the distal end of the staple cartridge 34. A subset of the

first plurality of terminals may be in signal communication with the second plurality of terminals. The type of the staple cartridge 34 may be indicated by the subset of the first plurality of terminals that are in signal communication with the second plurality of terminals. One or more circuits may be configured to identify the subset of the first plurality of terminals in signal communication and provide a staple cartridge type signal to the controller 106 based on the identified subset.

[0045] In various embodiments, the tissue thickness signal generated by the tissue thickness sensor 204 and the staple cartridge type signal generated by the identifying means 214 may be used to determine if the thickness of the tissue clamped in the end effector 12, as indicated by the tissue thickness signal, is within the optimal tissue thickness range of the staple cartridge 34, as indicated by the staple cartridge type signal. For example, the thickness of the tissue as indicated by the tissue thickness signal may be compared to an optimal tissue thickness range for the staple cartridge 34. In some embodiments, the controller 206 may be configured to determine if the measured thickness is within the optimal tissue thickness range. For example, the controller 206 may comprise a memory unit configured to store staple cartridge types and their associated optimal tissue thickness ranges. When the tissue thickness sensing module 202 enters an active state, the identifying means 214 may provide a staple cartridge type signal to the controller 206. When tissue is clamped in the end effector 12, the controller 206 may receive a tissue thickness signal from the tissue thickness sensor 204 indicating the thickness of the tissue clamped in the end effector 12. The controller 206 may access the memory unit and compare the staple cartridge type signal generated by the identifying means 214 with the stored staple cartridge types. If the staple cartridge type of the staple cartridge 34 matches a staple cartridge type stored in the memory unit, the controller 206 may access the stored optimal tissue thickness range for the staple cartridge 34. The controller 206 may compare the stored optimal tissue thickness range for the staple cartridge 34 with the tissue thickness indicated by the tissue thickness sensor 204 and may generate a status signal indicating whether the measured tissue thickness is within the optimal tissue thickness range of the staple cartridge 34. The controller 206 may provide the status signal to the radio module 208 for transmission. In some embodiments, the radio module 208 may transmit the status signal to a receiver located in the handle 6 of the surgical instrument 10. In some embodiments, the radio module 208 may transmit the status signal to a receiver

coupled to a remote device, such as, for example, an operating room video display 80 comprising a receiver 82 or a remote computer system 84 comprising a receiver 86 (see FIG. 11).

[0046] The staple cartridge 34 may comprise a staple cartridge type not recognized by the identifying means 214. In some embodiments, if the identifying means 214 is unable to identify the staple cartridge 34 inserted into the staple channel 22, the controller 206 may provide a warning to the clinician indicating that the staple cartridge is unrecognized. The warning may be any suitable warning, such as, for example, an audible warning, a visual warning, and/or a tactile warning. The warning may indicate to the clinician that the staple cartridge 34 is not recognized and that the clinician must use their discretion in the use and deployment of the inserted staple cartridge 34.

[0047] The optimal tissue thickness range for a specific staple cartridge may comprise an open-ended range. For example, in some embodiments, an optimal tissue thickness range for a specific staple cartridge may comprise any tissue thickness that is less than a maximum tissue thickness. In other embodiments, the optimal tissue thickness range for a specific staple cartridge may comprise any tissue thickness that is greater than a minimum tissue thickness. For example, a staple cartridge may comprise long staples suitable for stapling thick tissue or thin tissue. The optimal tissue thickness range for this staple cartridge may be any tissue thickness that is less than the maximum tissue thickness for the staple cartridge.

[0048] In some embodiments, the staple cartridge 34 may comprise a universal staple cartridge suitable for use in any thickness of tissue. If the identifying means 214 identifies a universal staple cartridge, the controller 206 may provide a signal to the clinician indicating that the staple cartridge 34 is a universal cartridge and therefore the thickness of tissue located between the anvil 24 and the staple cartridge 34 should not affect the operation of the surgical instrument 2.

[0049] As an example, a staple cartridge 34 may be located adjacent to a tissue thickness sensing module 202. The staple cartridge 34 and the tissue thickness sensing module may be inserted into the staple channel 22. The identifying means may identify the staple cartridge 34 as a cartridge having an optimal tissue thickness range between a first value, x1, and a second value x2. Tissue may be clamped by a clinician between the anvil 24 and the staple cartridge 34. The tissue thickness sensor 204 may generate a tissue thickness signal indicating that the thickness of the tissue clamped between the anvil 24 and the staple cartridge 34 is x. In some embodiments, the tissue thickness x may fall within the optimal tissue thickness range x1-x2 and the tissue

thickness sensing module 202 may provide an indication to the clinician that the tissue thickness x is within the optimal tissue thickness range.

[0050] In some embodiments, the tissue thickness x may fall outside the optimal tissue thickness range for the staple cartridge 34. For example, the tissue thickness x may be thinner than the lower value x1 of the optimal tissue thickness range. The surgical instrument 2 may provide a warning signal to the clinician that the tissue thickness x is lower than the optimal tissue thickness range. The surgical instrument 2 may still allow stapling if the measured tissue thickness x is thinner than the optimal tissue thickness range. As another example, the tissue thickness x may be thicker than the upper value x2 of the optimal tissue thickness range. The surgical instrument 2 may provide a warning to the clinician that the tissue thickness x is thicker than the optimal tissue thickness range. In some embodiments, the surgical instrument 2 may prevent firing the staple cartridge 34 if the measured tissue thickness x is thicker than the optimal tissue thickness range. In some embodiments, the surgical instrument may instruct the clinician to replace the staple cartridge 34 with a different cartridge type having a different optimal tissue thickness range.

[0051] In some embodiments, the controller 206 may be configured to provide the tissue thickness signal and the staple cartridge type signal to the radio module 208 for transmission to a remote device. The radio module 208 may transmit the tissue thickness signal and the staple cartridge type signal to a remote device located away from the end effector 12, such as, for example, a control circuit in the handle 6 of the surgical instrument 10 or a remote computer system 84. The remote device may be configured to perform a comparison between the received tissue thickness signal, the received staple cartridge type signal, and known optimal tissue thickness ranges. For example, the remote device may be configured to store known staple cartridges and optimal tissue thickness ranges for the known staple cartridges. The received staple cartridge type signal may be compared to the known staple cartridges. If a match is identified, the received tissue thickness signal may be compared to the optimal tissue thickness range for the staple cartridge 34. The remote device may generate a status signal indicating whether the measured tissue thickness, as indicated by the tissue thickness signal, is within the optimal tissue thickness range for the staple cartridge 34. The remote device may be updated, such as, for example, through a connection to a wired and/or wireless network. The remote device may be updated to add new staple cartridge types and optimal tissue thickness ranges or

may be updated to adjust the optimal tissue thickness range of existing staple cartridge types. By updating the remote device, staple cartridge types can be added or updated without the need to update the tissue thickness sensing module 202. In some embodiments, the remote device may receive updates periodically or may be updated whenever a new or modified cartridge is available.

[0052] In some embodiments, after the status signal has been generated by either the controller 206 or the remote device, the status signal may be used to control operation of the surgical instrument 10. For example, the status signal may be provided to a motor control circuit in the handle 6 of the surgical instrument 10. The motor control circuit may be configured to control a cutting and sealing operation of the surgical instrument 10. If the status signal indicates that the measured tissue thickness is within the optimal tissue thickness range for the staple cartridge 34, the motor control circuit may allow the cutting and sealing operation to occur. If the status signal indicates that the measured tissue thickness is not within the optimal tissue thickness range for the staple cartridge 34, the motor control circuit may prevent operation of the cutting and sealing operation and may provide a warning to the clinician indicating that the tissue thickness is not within the optimal tissue thickness range.

[0053] In some embodiments, the status signal may be displayed to a clinician through a feedback device. The feedback device may be located on the surgical instrument 10 or may be a remote device, such as an operating room video display 80. For example, in some embodiments, the surgical instrument 10 may be equipped with a light-emitting diode (LED). The LED may be activated when the status signal indicates that the tissue clamped in the end effector 12 has a thickness within the optimal tissue thickness range of the staple cartridge 34. As another example, the operating room video display 80 may be configured to display a graphical representation of the status signal, such as, for example, displaying an indicator when the measured tissue thickness is within the optimal tissue thickness range. Those skilled in the art will recognize that any suitable feedback device may be used to provide the status signal to a clinician. In some embodiments, the surgical instrument 2 may comprise a display window on the surgical instrument 2. The display window may be configured to display a representation of the status signal or the tissue thickness signal to a clinician. The display window may provide an indication of the measured tissue thickness and the optimal tissue thickness range of the staple cartridge 34.

[0054] In some embodiments, the tissue thickness sensing module 102 may be configured to receive a power key. The power key may be configured to control operation of the tissue thickness sensing module 102 prior to installation of the staple cartridge 34 into the staple channel 22. For example, in some embodiments the tissue thickness sensing module 102 may comprise a power source 110. The power source 110 may be in signal communication with the controller 106. The controller 106 may detect the presence of the power key and may maintain the power source 110 and the tissue thickness sensing module 102 in a low-power state to conserve the available energy from the power source 110.

[0055] FIG. 12 illustrates one embodiment of a thickness sensing module 302 configured to receive a power key 320. The power key 320 may comprise a magnet 378 configured to maintain the tissue thickness sensor 104 in a saturation state when the power key 320 is located adjacent to and/or connected with the tissue thickness sensing module 302. The controller 106 may detect the saturation state of the tissue thickness sensor 104 and may maintain the tissue thickness sensing module 302 in a low-power state while the tissue thickness sensor 104 is in the saturation state. The low-power state may comprise a state in which various modules of the tissue thickness sensing module 302 do not receive power or in which various operations of the tissue thickness sensing module 302 are not performed. For example, the low-power state may disconnect the controller 106, the radio module 108, and/or the tissue thickness sensor 104 from the power source 110. When the power key 320 is detached or moved away from the tissue thickness sensing module 302, the tissue thickness sensor 104 may enter a non-saturated state. When the controller 106 detects the non-saturated state, the controller 106 may transition the tissue thickness sensing module 302 into an active state for use in the surgical instrument 10. The active state may comprise a state in which all modules and functions of the tissue thickness sensing module 302 are provided with power and are operational.

[0056] In some embodiments, a device may comprise a reed switch, a power source, and a controller in signal communication with the power source. The controller may be configured to detect the state of the reed switch. A magnet may be removably located adjacent to the device. The magnet may be configured to generate a magnetic field sufficient to maintain the reed switch in a saturation state. The controller may detect the saturation state and may maintain the device in a low-power state while the reed switch is in the saturation state. When the magnet is removed from the device, the reed switch may enter a non-saturated state. The controller may

detect the non-saturated state of the reed switch and transition the device from the low-power state to an active power state.

[0057] FIG. 13 illustrates one embodiment of a Hall Effect sensor 402. The Hall Effect sensor 402 comprises a Hall Element 404, an amplifier 406, and a power source 408. The Hall Element comprises a first input terminal 410 and a second input terminal 412. The first and second input terminals 410, 412 are configured to receive a constant input current from the power source 408. When no magnetic field is present, the input current enters the first input terminal 410 and exits the second input terminal 412 with no loss of voltage potential to either side of the Hall Element 404. As a magnetic field is applied to the Hall Element 404, such as, for example, by magnet 478, a voltage potential is formed at the sides of the Hall Element 404 due to the deflection of electrons flowing through the Hall Element 404. A first output terminal 414 and a second output terminal 416 are located at opposite sides of the Hall Element 404. The first and second output terminals 414, 416 provide the voltage potential caused by the magnetic field to the amplifier 406. The amplifier 406 amplifies the voltage potential experienced by the Hall Element 404 and outputs the amplified voltage to an output terminal 418. The output of the amplifier 406 may not exceed the limits imposed by the power source 408. The upper limit of the amplifier 406 is the saturation point for the Hall Effect sensor 402. The saturation point may be selected based on the power source 408 connected to the amplifier 406. Because the saturation takes place at the amplifier 406, and not at the Hall Element 404, exposure to large magnetic filed will not damage the Hall Effect sensor 402, but instead places the Hall Effect sensor 402 into a saturation state. In some embodiments, an open emitter, an open collector, or a push-pull transistor may be added to the output of the amplifier 406.

[0058] FIG. 14 illustrates one embodiment of tissue thickness sensing module 502 configured to receive a power key 520. The tissue thickness sensing module 502 may comprise a first terminal 516 and a second terminal 518 configured to receive the power key 520. The first terminal 516 and the second terminal 518 may be in signal communication with the controller 106. The power key 520 may be configured to create a first electrical circuit state between the first terminal 516 and the second terminal 518. The first electrical circuit state may be any suitable state between the first terminal 516 and the second terminal 518, such as, for example, an open circuit, a short circuit, a specific resistance, capacitance, inductance, or any other suitable circuit state. In some embodiments, the controller 106 may detect the first electrical

circuit state between the first terminal 516 and the second terminal 518 and maintain the tissue thickness sensing module 502 in a low-power state. In some embodiments, the first electrical circuit state may prevent the power source 110 from providing power to the elements of the tissue thickness sensing module 502, such as through an open circuit, and prevent operation of the controller 106, radio module 108, or other powered elements while the power key 520 is present.

[0059] In some embodiments, the removal of the power key 520 from the first terminal 516 and the second terminal 518 may create a second electrical circuit state between the first terminal 516 and the second terminal 518. The second electrical circuit state may be any suitable circuit state between the first terminal 516 and the second terminal 518, such as, for example, an open circuit or a short circuit. The controller 106 may detect the second electrical circuit state and may transition the tissue thickness sensing module 502 into an active power state for operation with the surgical instrument 10.

[0060] For example, in some embodiments the power key 520 may be configured to create a short circuit between the first terminal 516 and the second terminal 518. The controller 106 may detect the short circuit between the first terminal 516 and the second terminal 518. The controller 106 may maintain the tissue thickness sensing module 502 in a low-power state to conserve the power source 110 while a short circuit exists between the first terminal 516 and the second terminal 518. Prior to installation of the staple cartridge 34 into the staple channel 22, the power key 520 may be removed from the tissue thickness sensing module 502. When the power key 520 is removed from the tissue thickness sensing module 502, the circuit between the first terminal 516 and the second terminal 518 may be opened. The controller 106 may detect the open circuit between the first terminal 516 and the second terminal 518 and may transition the tissue thickness sensing module 502 into an active state.

[0061] As another example, in some embodiments, the power key 520 may be configured to maintain an open circuit between the first terminal 516 and the second terminal 518. The power source 110 may be disconnected from the controller 106 and the radio module 108 when the first terminal 516 and the second terminal 518 are in an open circuit state. The staple cartridge 34 may be inserted into the staple channel 22. Once installed, a clinician may remove the power key 520 from the tissue thickness sensing module 502. When the power key 520 is removed, the circuit between the first terminal 516 and the second terminal 518 may be completed by a direct

connection between the first terminal 516 and the second terminal 518 or through an indirect connection, such as through the staple cartridge 34, the staple channel 22, or any other suitable portion of the end effector 12. For example, the first terminal 516 and the second terminal 518 may comprise a short circuit when the staple cartridge 34 is installed in the staple channel 22 and the power key 520 is removed from the tissue thickness sensing module 502. The short circuit between the first terminal 516 and the second terminal 518 may connect the power source 110 to the controller 106 and the radio module 108, causing the tissue thickness sensing module 502 to transition to an active state for use with the surgical instrument 10.

[0062] FIG. 15 illustrates a flow chart showing one embodiment of a method for maintaining the tissue thickness sensing module 102 in a low-power state. As shown in FIG. 15, at step 602 a controller 106 may detect a staple cartridge power key 320, 520 removably adjacent to a tissue thickness sensing module 102. The controller 106 may detect the staple cartridge power key, such as power key 320, 520 for example, through any suitable method, such as, for example, a circuit state or a sensor state. At step 604, the controller 106 maintains the tissue thickness sensing module 102 in a low-power state while the staple cartridge power key is located adjacent to, or attached to, the tissue thickness sensing module 102. At 606, the staple cartridge power key is removed from the tissue thickness sensing module 102. The controller 106 detects the removal of the staple cartridge power key and transitions the tissue thickness sensing module 102 from a low-power state to an active state at step 608.

[0063] In some embodiments, a tissue thickness sensing module 302 may comprise a tissue thickness sensor 104 configured to detect a magnetic field, such as a Hall Effect sensor, for example. The staple cartridge power key 320 may be located adjacent to the tissue thickness sensing module 302 and may comprise a magnet 378 configured to place the tissue thickness sensor 104 into a saturation state. In some embodiments, at step 604, the controller 106 in the tissue thickness sensing module 302 may detect the saturation state of the tissue thickness sensor 104. The controller 106 may maintain the tissue thickness sensing module 302 in the low-power state while the tissue thickness sensor 104 is in the saturation state. The staple cartridge power key 320 may be removed from the tissue thickness sensing module 302. The tissue thickness sensor 104 may transition from the saturation state to a non-saturated state. The controller 106 may detect the non-saturated state of the tissue thickness sensor 104 and may transition the tissue thickness sensing module 302 from the low-power state to an active state.

[0064] In some embodiments, the tissue thickness sensing module 502 may comprise a first terminal 516 and a second terminal 518 formed on the enclosure of the tissue thickness sensing module 502. The first terminal 516 and the second terminal 518 may be configured to receive the power key 520. The power key 520 may create a first electrical circuit state between the first terminal 516 and the second terminal 518. For example, the first electrical circuit state may comprise an open circuit or a short circuit. At step 604, the controller 106 may be configured to detect the presence of the power key 520 based on the first electrical circuit state. The controller 106 may maintain the tissue thickness sensing module 502 in a low-power state while the first terminal 516 and the second terminal 518 are in the first electrical circuit state. The power key 520 may be removed from the tissue thickness sensing module 502 to allow the staple cartridge 34 to be installed into the staple channel 22. In some embodiments, removing the power key 520 may cause the first terminal 516 and the second terminal 518 to transition to a second electrical circuit state, such as, a short circuit or an open circuit. The controller 106 may detect the second electrical circuit state and transition the tissue thickness sensing module 502 from the low-power state to an active state.

[0065] While various embodiments of a tissue thickness sensing module disclosed herein comprise a wireless transmitter and a power source, other embodiments are envisioned. For instance, in one embodiment, at least one conductor, such as a wire, for example, may extend through the shaft of the surgical instrument and may provide signal communication and/or power communication from the handle to the tissue thickness sensing module. In some embodiments, the controller and/or the power source may be located in the handle and may be connected to the tissue thickness sensing module through a wired connection to the controller, the power source, and/or any other components located in the handle.

[0066] While various embodiments of a tissue thickness sensing module disclosed herein are positioned distally with respect to a staple cartridge, various other embodiments are envisioned in which the tissue thickness sensing module can be positioned laterally, proximally, and/or distally with respect to a staple cartridge. In certain embodiments, a plurality of tissue thickness sensing modules can be utilized. In such embodiments, a microcontroller can be configured to interpret a plurality of tissue thickness signals from a plurality of tissue thickness sensing modules to derive the thickness of the tissue.

[0067] Various embodiments described herein are described in the context of staples removably stored within staple cartridges for use with surgical stapling instruments. In some circumstances, staples can include wires which are deformed when they contact an anvil of the surgical stapler. Such wires can be comprised of metal, such as stainless steel, for example, and/or any other suitable material. Such embodiments, and the teachings thereof, can be applied to embodiments which include fasteners removably stored with fastener cartridges for use with any suitable fastening instrument.

[0068] Various embodiments described herein are described in the context of linear end effectors and/or linear fastener cartridges. Such embodiments, and the teachings thereof, can be applied to non-linear end effectors and/or non-linear fastener cartridges, such as, for example, circular and/or contoured end effectors. For example, various end effectors, including non-linear end effectors, are disclosed in U.S. Patent Application Ser. No. 13/036,647, filed February 28, 2011, entitled SURGICAL STAPLING INSTRUMENT, now U.S. Patent Application Publication No. 2011/0226837, which is hereby incorporated by reference in its entirety. Additionally, U.S. Patent Application Ser. No. 12/893,461, filed September 29, 2012, entitled STAPLE CARTRIDGE, now U.S. Patent Application Publication No. 2012/0074198, is hereby incorporated by reference in its entirety. U.S. Patent Application Ser. No. 12/031,873, filed February 15, 2008, entitled END EFFECTORS FOR A SURGICAL CUTTING AND STAPLING INSTRUMENT, now U.S. Patent No. 7,980,443, is also hereby incorporated by reference in its entirety. U.S. Patent No. 8,393,514, entitled SELECTIVELY ORIENTABLE IMPLANTABLE FASTENER CARTRIDGE, which issued on March 12, 2013, is also hereby incorporated by reference in its entirety.

EXAMPLES

[0069] In various embodiments, a surgical end effector for treating tissue is disclosed. The surgical end effector comprises a staple cartridge. The staple cartridge comprises a proximal end and a distal end. The staple cartridge is configured to be used to staple tissue within an optimal tissue thickness range. An anvil is movably coupled relative to the proximal end of the staple cartridge. A tissue thickness sensing module is adjacent to the distal end of the staple cartridge. The tissue thickness sensing module comprises a sensor and a controller. The sensor is configured to generate a tissue thickness signal indicative of a thickness of the tissue located

between the anvil and the staple cartridge. The controller is in signal communication with the sensor. The controller comprises identifying means for identifying a staple cartridge type. The staple cartridge type and the tissue thickness signal are used to determine if the thickness is within the optimal tissue thickness range.

[0070] In some embodiments, the anvil comprises a magnet. The sensor may be configured to detect a magnetic field generated by the magnet. The sensor may comprise a Hall Effect sensor. In some embodiments, the thickness sensing module comprises a transmitter in signal communication with the controller. The transmitter may be configured to transmit the staple cartridge type and the tissue thickness signal to a receiver. The staple cartridge type and the tissue thickness signal may be received by a receiver in a surgical instrument. The receiver determines if the thickness measurement is within the optimal tissue thickness range.

[0071] In some embodiments, the controller may be configured to generate a signal indicative of whether the thickness measurement is within the optimal tissue thickness range. The transmitter may be configured to transmit the signal. In some embodiments, the thickness sensing module may comprise at least one power source configured to supply power to the controller.

[0072] In some embodiments, the identifying means may comprise a memory unit coupled to the controller. The memory unit may be configured to store the staple cartridge type. In some embodiments, the identifier means may comprise a first plurality of terminals located on the tissue thickness sensing module and a second plurality of terminals located on the distal end of the staple cartridge. A subset of the first plurality of terminals is in signal communication with the second plurality of terminals. The staple cartridge type is determined by the subset of the first plurality of terminals in signal communication with the second plurality of terminals. In some embodiments, the tissue thickness sensing module may be configured to receive a power key. The tissue thickness sensing module may comprise a first terminal and a second terminal. The first terminal and the second terminal may be configured to receive a power key configured to maintain the tissue thickness sensing module in a low-power state.

[0073] In various embodiments, a staple cartridge for use in a surgical stapler is disclosed. The staple cartridge comprises a staple body comprising a proximal end and a distal end. A plurality of staples is removably stored within the staple body. The plurality of staples is configured to be used to staple tissue within an optimal tissue thickness range. A tissue thickness module is

adjacent to the distal end of the staple channel. The tissue thickness module comprises a sensor and a controller. The sensor is configured to generate a tissue thickness signal indicative of a thickness of the tissue located between the anvil and the staple cartridge. The controller is in signal communication with the sensor. The controller comprises identifying means for identifying a staple cartridge type. The staple cartridge type and the tissue thickness signal are used to determine if the thickness of the tissue is within the optimal tissue thickness range.

[0074] In some embodiments the thickness sensing module comprises a transmitter in signal communication with the controller and at least one power source configured to supply power to the controller and the transmitter. The transmitter may be configured to transmit the staple cartridge type and the tissue thickness signal. The staple cartridge type and the tissue thickness signal may be received by a receiver in a surgical instrument. The receiver determines if the thickness of the tissue is within the optimal tissue thickness range. In some embodiments, the controller is configured to generate a signal indicative of whether the thickness of the tissue is within the optimal tissue thickness range. The transmitter may be configured to transmit the signal.

[0075] In some embodiments, the identifier means may comprise a memory unit in signal communication with the controller. The memory unit is configured to store the staple cartridge type. In some embodiments, the identifier means may comprises a first plurality of terminals located on the tissue thickness sensing module and a second plurality of terminals located on the distal end of the staple cartridge. A subset of the first plurality of terminals may be in signal communication with the second plurality of terminals. The staple cartridge type is determined by the subset of the first plurality of terminals in signal communication with the second plurality of terminals.

[0076] In some embodiments, the sensor may comprise a Hall Effect sensor. In some embodiments, the tissue thickness sensing module may be configured to receive a removable power key. The power key may be configured to maintain the tissue thickness sensing module in a low-power state. The removable power key may comprise a magnet configured to maintain the sensor in a saturation state. The low-power state may be maintained while the sensor is in the saturation state.

[0077] In various embodiments, a tissue thickness sensing module for attachment to a surgical staple cartridge configured for treatment of tissue is disclosed. The tissue thickness sensing

module comprises a sensor and a controller. The sensor is configured to detect a magnetic field indicative of a thickness of the tissue clamped against the surgical staple cartridge. The control is in signal communication with the sensor. The controller comprises an identifier means for identifying a staple cartridge type. The staple cartridge type and the thickness of the tissue are used to determine if the thickness is within an optimal tissue thickness range for the surgical staple cartridge. A transmitter is in signal communication with the controller. At least one power source is configured to supply power to the controller and the transmitter.

[0078] In various embodiments, a staple cartridge for use in a surgical stapler is disclosed. The staple cartridge comprises a staple body comprising a proximal end and a distal end. A tissue thickness sensing module is coupled to the distal end of the staple body. The tissue thickness sensing module comprises a controller and a sensor. A power key is removably positioned relative to the tissue thickness sensing module. The controller is configured to detect the power key. When the controller detects the power key, the controller maintains the tissue thickness sensing module in a low-power state. When the power key is removed, the controller transitions the tissue thickness sensing module to an active state.

[0079] In some embodiments, the sensor comprises a Hall Effect sensor and the power key comprises a magnet. The magnet is configured to maintain the Hall Effect sensor in a saturation state when the power key is positioned relative to the tissue thickness sensing module. The controller detects the saturation state of the Hall Effect sensor and maintains the low-power state while the Hall Effect sensor is in the saturation state. When the power key is removed from the tissue thickness sensing module, the Hall Effect sensor transitions to a non-saturated state. The controller detects the non-saturated state of the Hall Effect sensor and transitions the tissue thickness sensing module to the active state.

[0080] In some embodiments, the staple cartridge comprises a first terminal and a second terminal. The power key creates a first electrical circuit state between the first terminal and the second terminal. The controller detects the first electrical circuit state and maintains the tissue thickness sensing module in the low-power state while the first terminal and the second terminal are in the first electrical circuit state. When the power key is removed from the tissue thickness sensing module, the first terminal and the second terminal transition to a second electrical circuit state. The controller detects the second electrical circuit state and transitions the tissue thickness sensing module to the active state.

[0081] In some embodiments, the first electrical circuit state comprises a short circuit between the first terminal and the second terminal and the second electrical circuit state comprises an open circuit between the first terminal and the second terminal. In some embodiments, the first electrical circuit state comprises an open circuit between the first terminal and the second terminal and the second electrical circuit state comprises a short circuit between the first terminal and the second terminal. The short circuit between the first terminal and the second terminal may be established by a connection between the staple cartridge and a surgical stapler when the staple cartridge is inserted into the surgical stapler.

[0082] In various embodiments, a device comprising a Hall Effect sensor, a power source, and a controller is disclosed. The controller is configured to receive power from the power source. The controller is configured to maintain the device in a low-power state when the reed switch is in a saturation state. The controller is configured to transition the device to an active state when the Hall Effect sensor is in a non-saturation state.

[0083] In various embodiments, a method for power management of a staple cartridge assembly having a tissue thickness sensing module is disclosed. The method comprises detecting, by a controller, a power key removably positioned adjacent to the tissue thickness sensing module. The method further comprises maintaining, by the controller, a tissue thickness sensing module in a low-power state when the power key is detected. The controller transitions to an active state when the power key is removed from the tissue thickness sensing module.

[0084] In some embodiments, sensing the power key may comprise detecting, by the controller, a state of a sensor. The state of the sensor indicates whether the power key is positioned relative to said tissue thickness sensing module. The sensor may comprise a Hall Effect sensor. The state of the sensor may comprise a saturation state. In some embodiments, sensing of the power key may comprise detecting, by the controller, a first electrical circuit state between a first terminal and a second terminal. The first electrical circuit state indicates that the power key is positioned relative to the tissue thickness sensing module. The controller may be configured to detect a second electrical circuit state between the first terminal and the second terminal. The second electrical circuit state indicates that the power key is not positioned relative to the tissue thickness sensing module.

[0085] In some embodiments, the first electrical circuit state may comprise a short circuit across the first terminal and the second terminal and the second electrical circuit state may

comprise an open circuit between the first terminal and the second terminal. In some embodiments, the first electrical circuit state may comprise an open circuit between the first terminal and the second terminal and the second electrical circuit state may comprise a short circuit across the first terminal and the second terminal.

[0086] In some embodiments, the method may further comprise inserting the staple cartridge into a surgical stapler. The power key may be removed from the tissue thickness sensing module. The surgical stapler may complete a circuit connection between the first terminal and the second terminal.

[0087] In various embodiments, a method for controlling a device comprising a controller, a power source, and a reed switch is disclosed. The method comprises detecting, by the controller, a saturation state of the reed switch. The reed switch is maintained in the saturation state by a power key positioned relative to the reed switch. The power key comprises a magnet configured to generate a magnetic field sufficient to place the reed switch in the saturation state. The method further comprises maintaining, by the controller, the device in a locked state while the reed switch is in the saturation state. The locked state comprises a low-power state of the device. The method further comprises transitioning, by the controller, the device to an unlocked state, wherein the transition occurs when the power key is removed from the reed switch and the reed switch transitions to a non-saturated state. The unlocked state comprises an active state of the device.

[0088] Various embodiments of surgical instruments and robotic surgical systems are described herein. It will be understood by those skilled in the art that the various embodiments described herein may be used with the described surgical instruments and robotic surgical systems. The descriptions are provided for example only, and those skilled in the art will understand that the disclosed embodiments are not limited to only the devices disclosed herein, but may be used with any compatible surgical instrument or robotic surgical system.

[0089] Reference throughout the specification to "various embodiments," "some embodiments," "one example embodiment," or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one example embodiment. Thus, appearances of the phrases "in various embodiments," "in some embodiments," "in one example embodiment," or "in an embodiment" in places throughout the specification are not necessarily all referring to the same embodiment.

Furthermore, the particular features, structures, or characteristics illustrated or described in connection with one example embodiment may be combined, in whole or in part, with features, structures, or characteristics of one or more other embodiments without limitation.

[0090] While various embodiments herein have been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications may readily appear to those skilled in the art. For example, each of the disclosed embodiments may be employed in endoscopic procedures, laparoscopic procedures, as well as open procedures, without limitations to its intended use.

[0091] It is to be understood that at least some of the figures and descriptions herein have been simplified to illustrate elements that are relevant for a clear understanding of the disclosure, while eliminating, for purposes of clarity, other elements. Those of ordinary skill in the art will recognize, however, that these and other elements may be desirable.

[0092] While several embodiments have been described, it should be apparent, however, that various modifications, alterations and adaptations to those embodiments may occur to persons skilled in the art with the attainment of some or all of the advantages of the disclosure. For example, according to various embodiments, a single component may be replaced by multiple components, and multiple components may be replaced by a single component, to perform a given function or functions. This application is therefore intended to cover all such modifications, alterations and adaptations without departing from the scope and spirit of the disclosure as defined by the appended claims.

[0093] Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

CLAIMS

What is claimed is:

1. A staple cartridge for use in a surgical stapler, the staple cartridge comprising:

a staple body comprising a proximal end and a distal end;

a tissue thickness sensing module coupled to said distal end of said staple body, wherein said tissue thickness sensing module comprises:

a controller; and

a sensor; and

a power key removably positioned relative to said tissue thickness sensing module, wherein said controller is configured to detect said power key, wherein, when said controller detects said power key, said controller maintains said tissue thickness sensing module in a low-power state, and wherein, when said power key is removed, said controller transitions said tissue thickness sensing module to an active state.

2. The staple cartridge of claim 1, wherein:

said sensor comprises a Hall Effect sensor; and

wherein said power key comprises a magnet, wherein said magnet is configured to maintain said Hall Effect sensor in a saturation state when said power key is positioned relative to said tissue thickness sensing module, and wherein said controller detects said saturation state of said Hall Effect sensor and maintains said low-power state while said Hall Effect sensor is in said saturation state.

3. The staple cartridge of claim 2, wherein, when said power key is removed from said tissue thickness sensing module, said Hall Effect sensor transitions to a non-saturated state, and wherein said controller detects said non-saturated state of said Hall Effect sensor and transitions said tissue thickness sensing module to said active state.

4. The staple cartridge of claim 1, comprising:

a first terminal and a second terminal;

wherein said power key creates a first electrical circuit state between said first terminal and said second terminal, wherein said controller detects said first electrical circuit state and maintains said low-power state while said first terminal and said second terminal are in said first electrical circuit state.

5. The staple cartridge of claim 4, wherein, when said power key is removed from said tissue thickness sensing module, said first terminal and said second terminal transition to a second electrical circuit state, and wherein said controller detects said second electrical circuit state and transitions said tissue thickness sensing module to said active state.

6. The staple cartridge of claim 5, wherein said first electrical circuit state comprises a short circuit between said first terminal and said second terminal, and wherein said second electrical circuit state comprises an open circuit between said first terminal and said second terminal.

7. The staple cartridge of claim 5, wherein said first electrical circuit state comprises an open circuit between said first terminal and said second terminal, and wherein said second electrical circuit state comprises a short between said first terminal and said second terminal.

8. The staple cartridge of claim 7, wherein said short between said first terminal and said second terminal is established by a connection between said staple cartridge and a surgical stapler when said staple cartridge is inserted into said surgical stapler.

9. A device comprising:

a reed switch;

a power source; and

a controller configured to receive power from said power source, wherein said controller is configured to maintain said device in a low-power state when said reed switch is in a saturation state, and wherein said controller is configured to transition said device to an active state when said reed switch is in a non-saturation state.

10. A method for power management of a staple cartridge assembly having a tissue thickness sensing module, the method comprising:

detecting, by a controller, a power key removably positioned adjacent to said tissue thickness sensing module;

maintaining, by said controller, a tissue thickness sensing module in a low-power state when said power key is detected; and

transitioning, by said controller, said tissue thickness sensing module to an active state when said power key is removed from said tissue thickness sensing module.

11. The method of claim 10, wherein said sensing of said power key comprises:

detecting, by said controller, a state of a sensor, wherein said state of said sensor indicates said power key is positioned relative to said tissue thickness sensing module.

12. The method of claim 11, wherein said sensor comprises a reed switch and said state comprises a saturation state.

13. The method of claim 10, wherein said sensing of said power key comprises:

detecting, by said controller, a first electrical circuit state between a first terminal and a second terminal, wherein said first electrical circuit state indicates that said power key is positioned relative to said tissue thickness sensing module.

14. The method of claim 13, comprising:

detecting, by said controller, a second electrical circuit state between said first terminal and said second terminal, wherein said second electrical circuit state indicates that said power key is not positioned relative to said tissue thickness sensing module.

15. The method of claim 14, wherein said first electrical circuit state comprises a short circuit across said first terminal and said second terminal, and wherein said second electrical circuit state comprises an open circuit between said first terminal and said second terminal.

16. The method of claim 14, wherein said first electrical circuit state comprises an open circuit between said first terminal and said second terminal, and wherein said second electrical circuit state comprises a short circuit across said first terminal and said second terminal.

17. The method of claim 16, comprising:

inserting said staple cartridge into a surgical stapler;

removing said power key from said tissue thickness sensing module; and

completing, by said surgical stapler, a circuit connection between said first terminal and said second terminal.

18. A method for controlling a device comprising a controller, a power source, and a reed switch sensor, the method comprising:

detecting, by said controller, a saturation state of said reed witch, wherein said reed switch is maintained in said saturation state by a power key positioned relative to said reed switch, and wherein said power key comprises a magnet configured to generate a magnetic field sufficient to place said reed switch in said saturation state;

maintaining, by said controller, said device in a locked state while said reed switch is in said saturation state, wherein said locked state comprises a low-power state of said device; and

transitioning, by said controller, said device to an unlocked state, wherein said transition occurs when said power key is removed from said reed switch and said reed switch is in a non-saturated state, and wherein said unlocked state comprises an active state of said device.

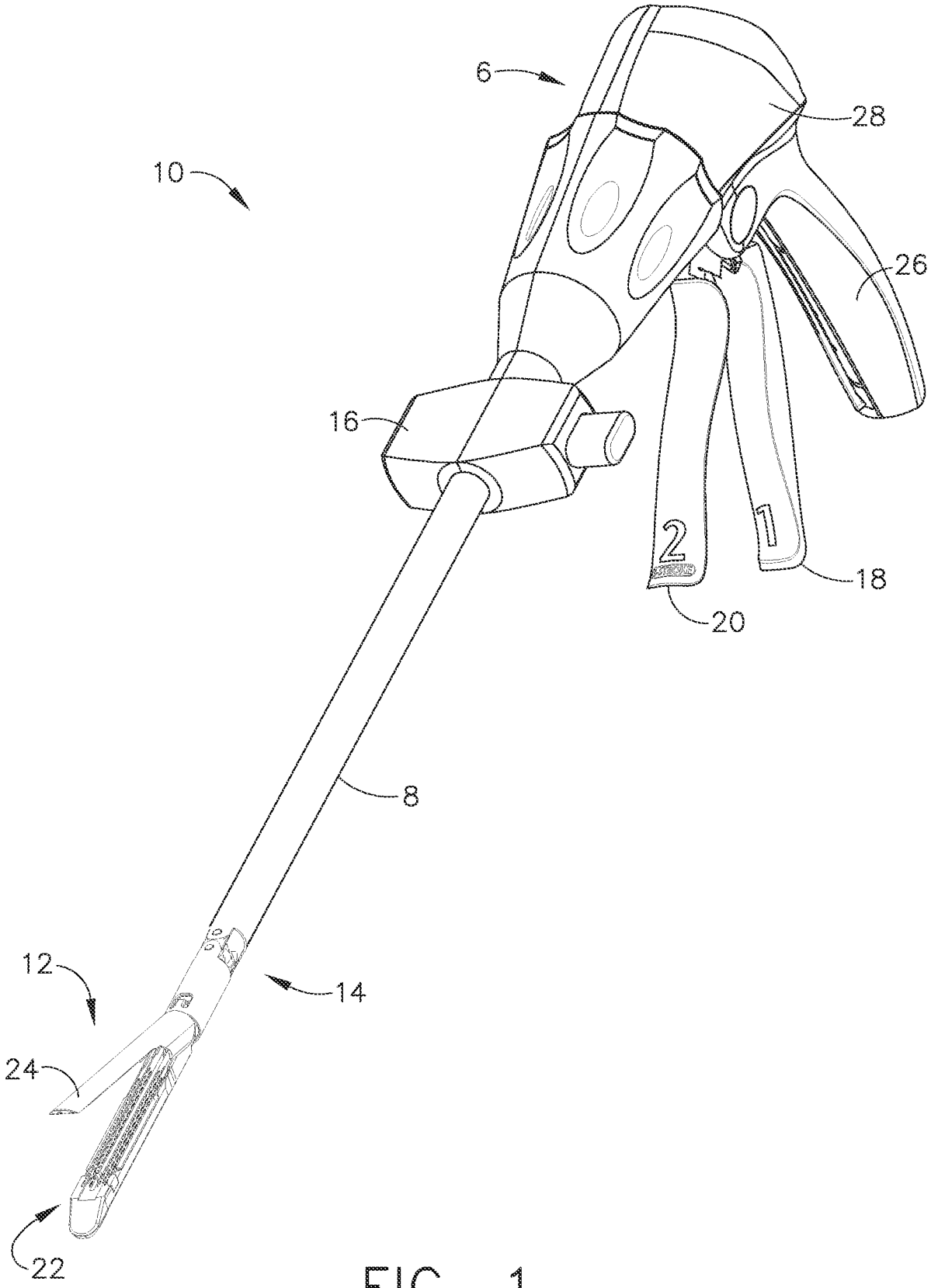

FIG. 1

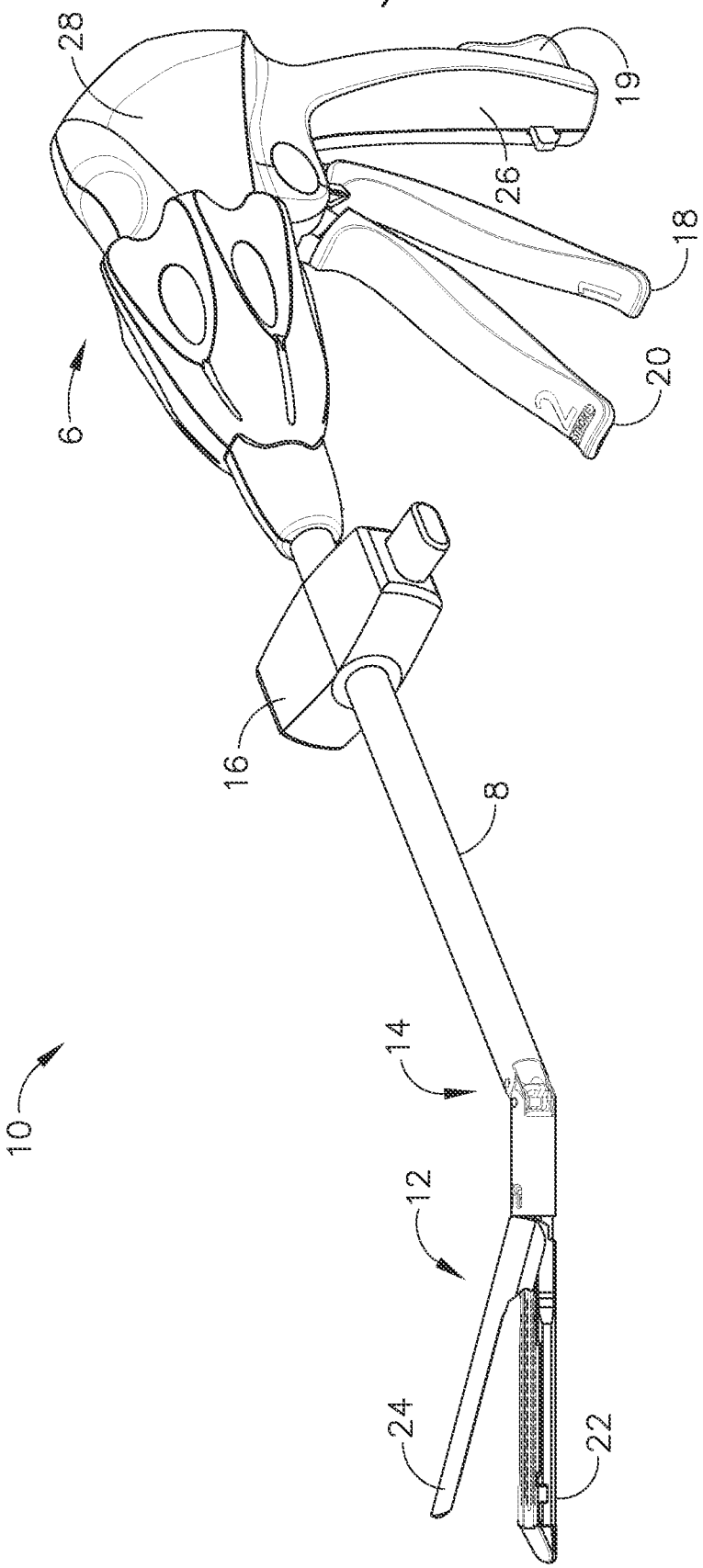

FIG. 2

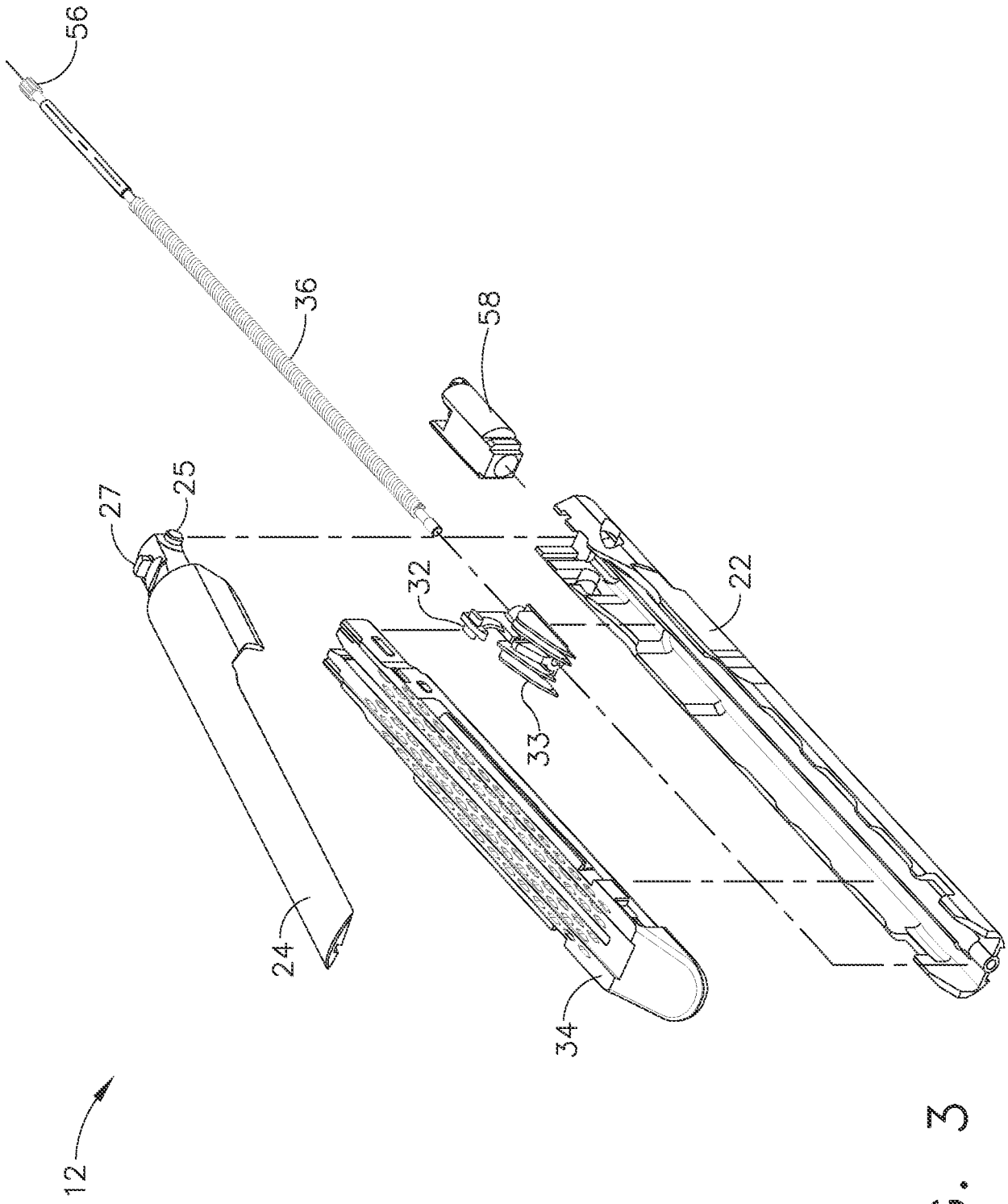

FIG. 3

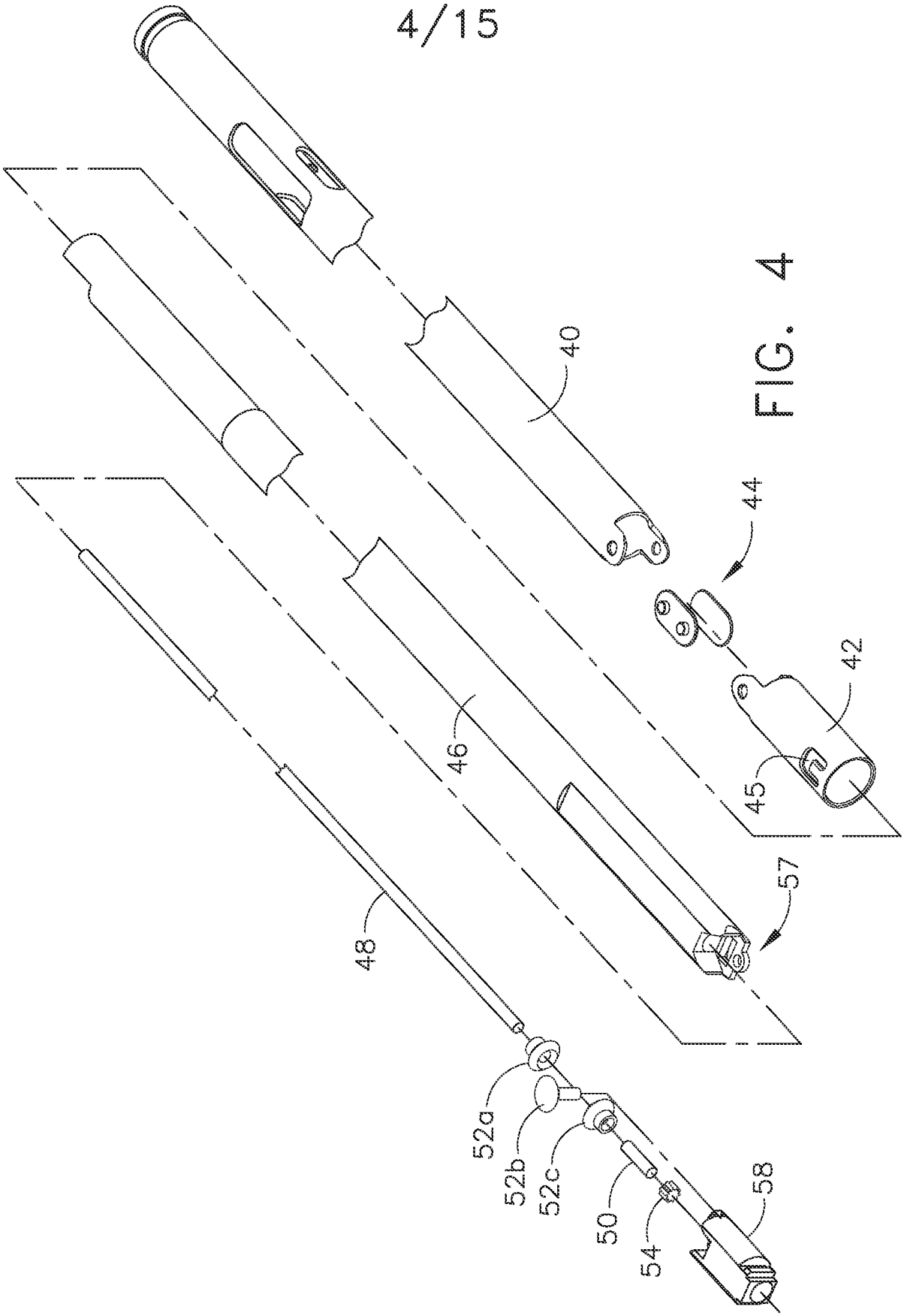

FIG. 4

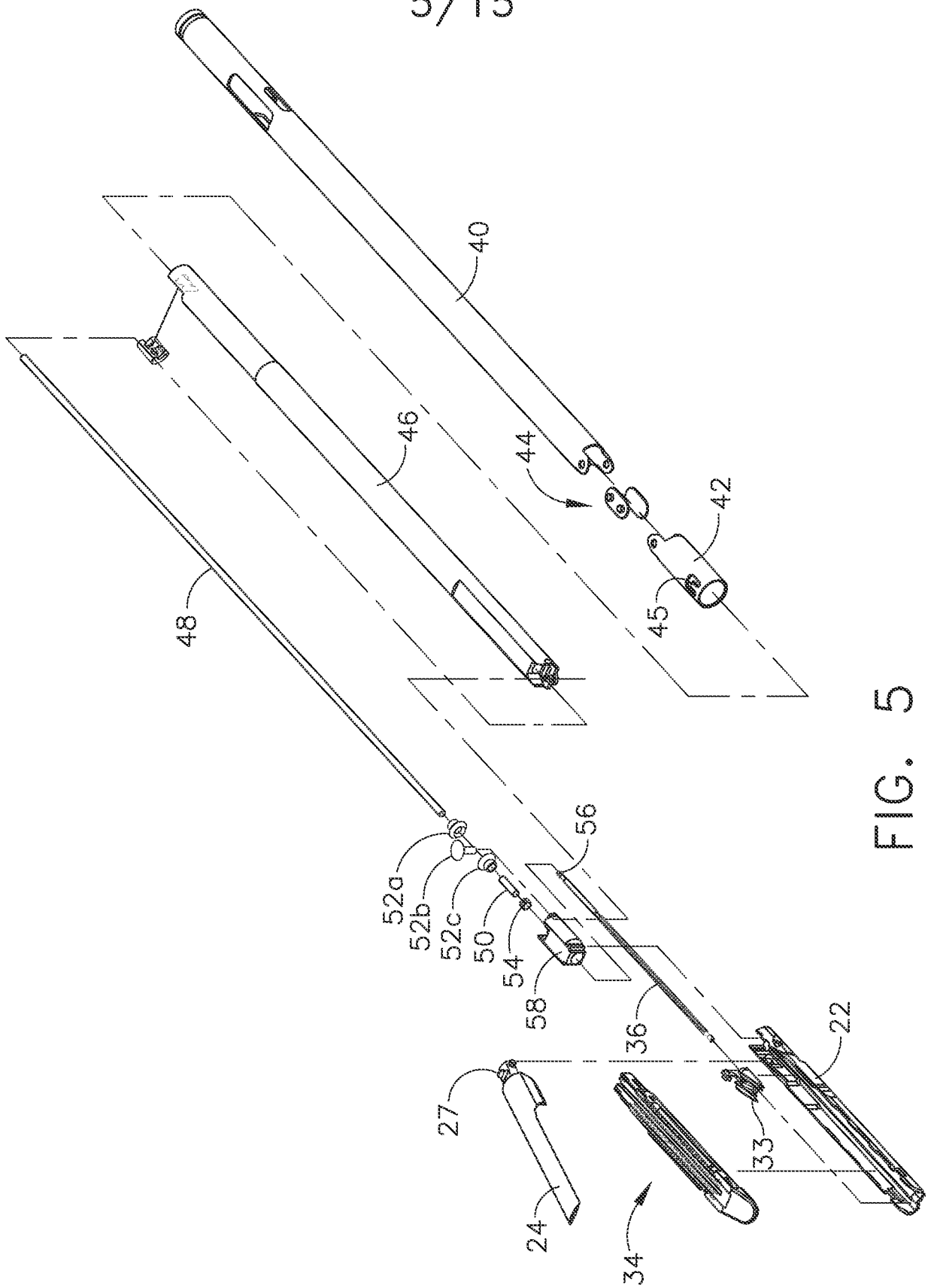

FIG. 5

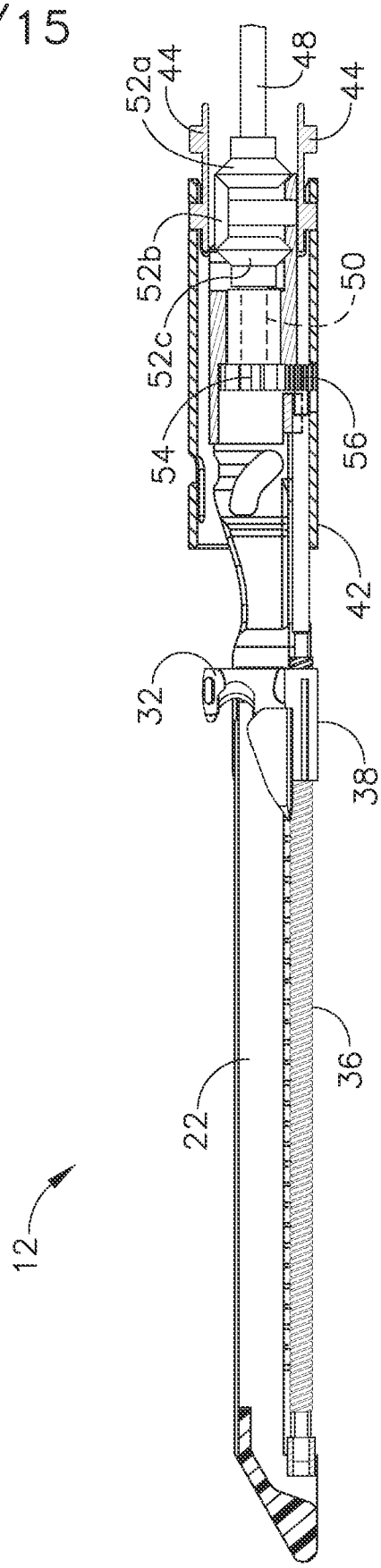

FIG. 6

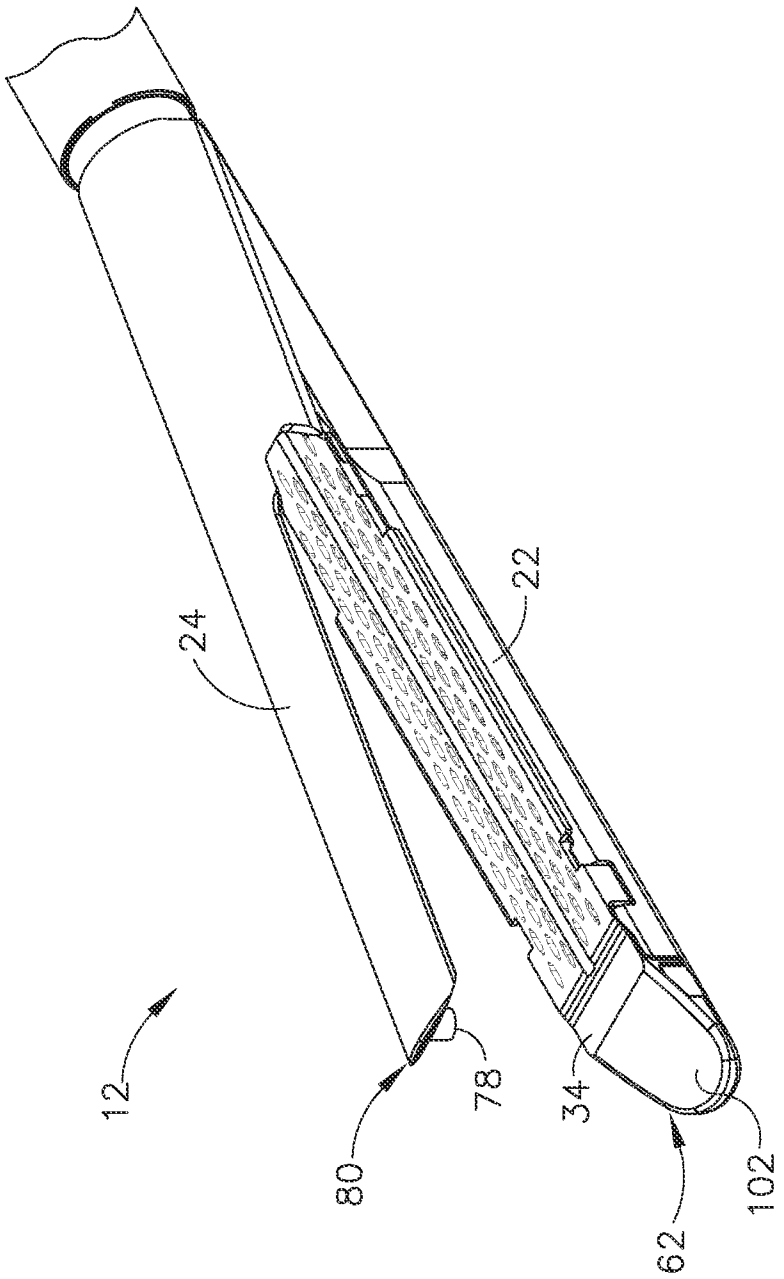

FIG. 7

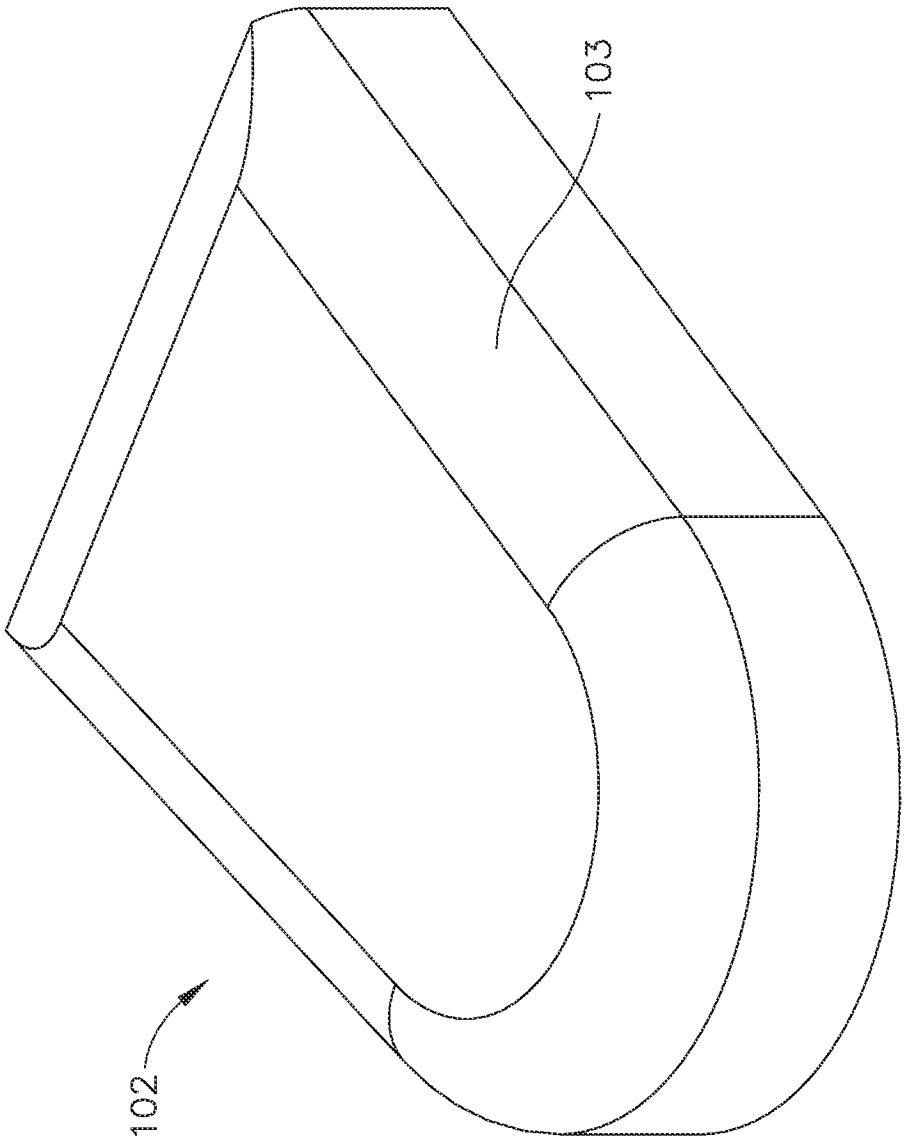

FIG. 8

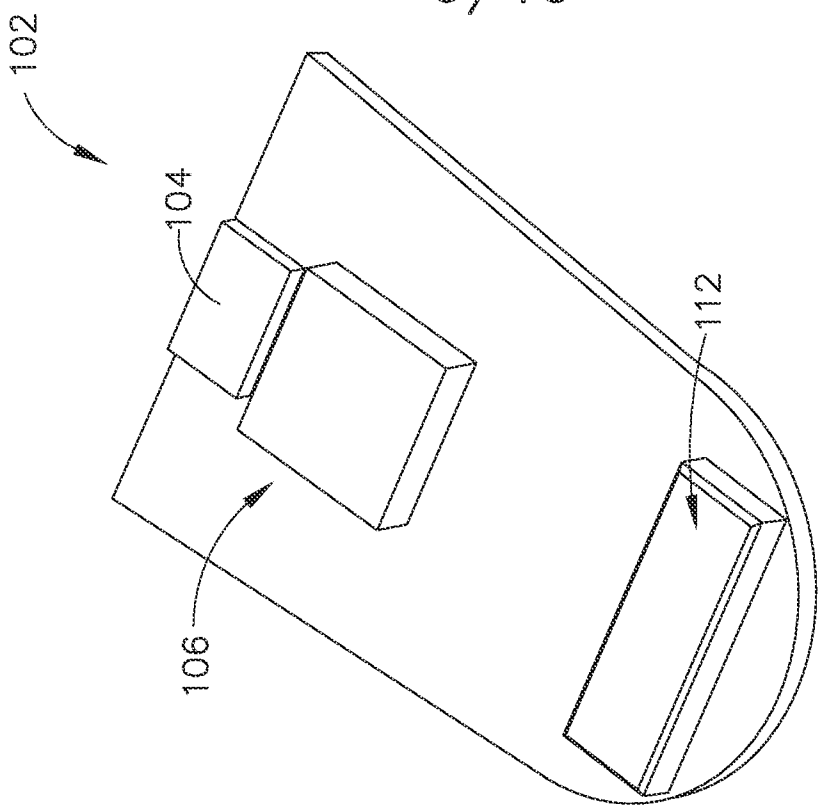

FIG. 9B

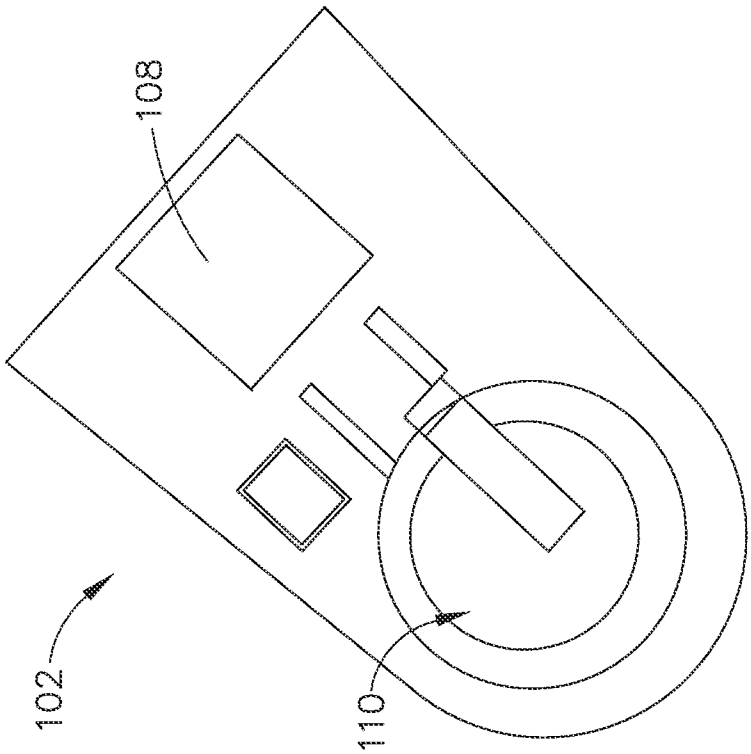

FIG. 9A

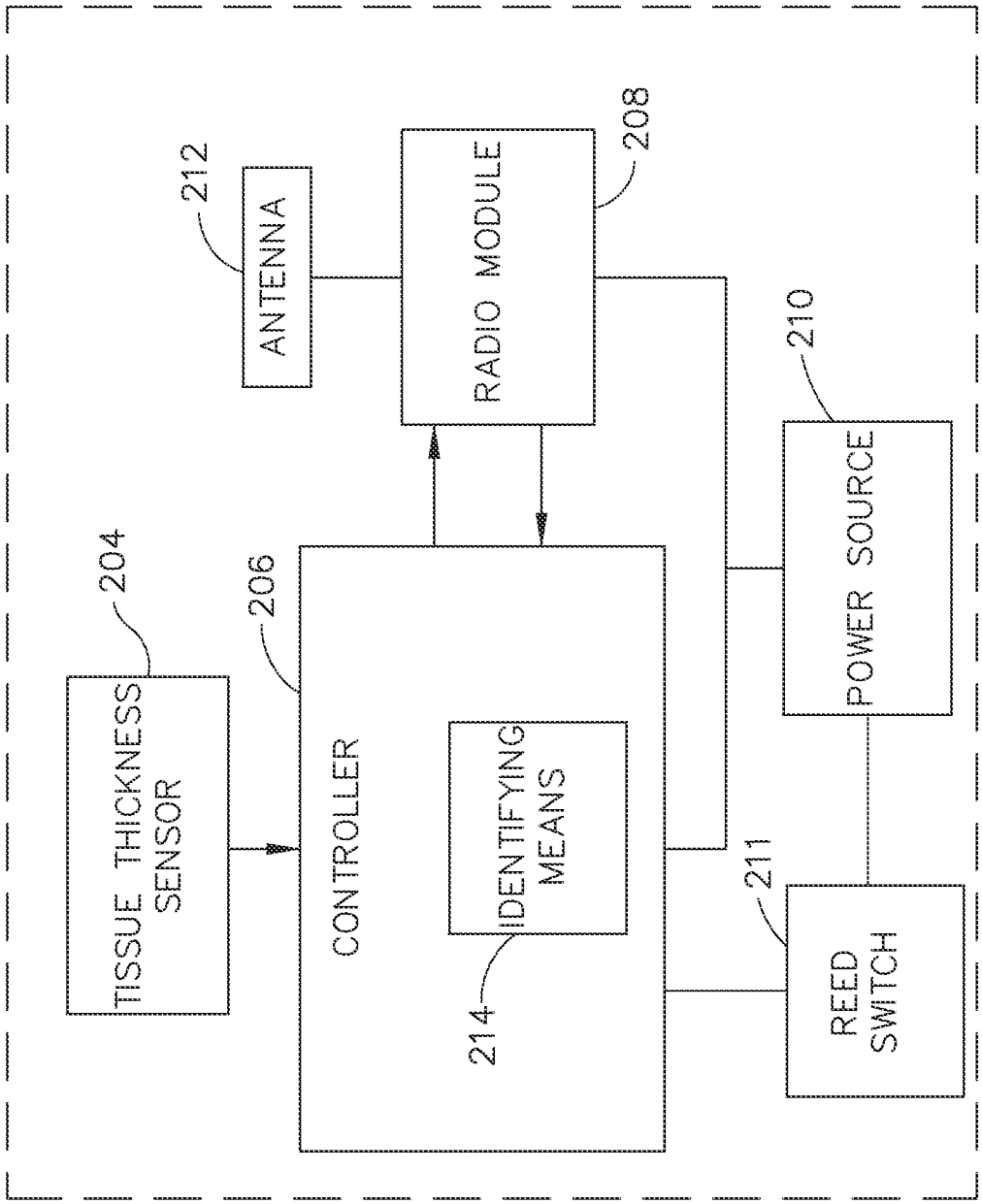
212
ANTENNA
RADIO MODULE
208
210
POWER SOURCE
204
206
TISSUE THICKNESS SENSOR
CONTROLLER
IDENTIFYING MEANS
214
211
REED SWITCH

FIG. 10

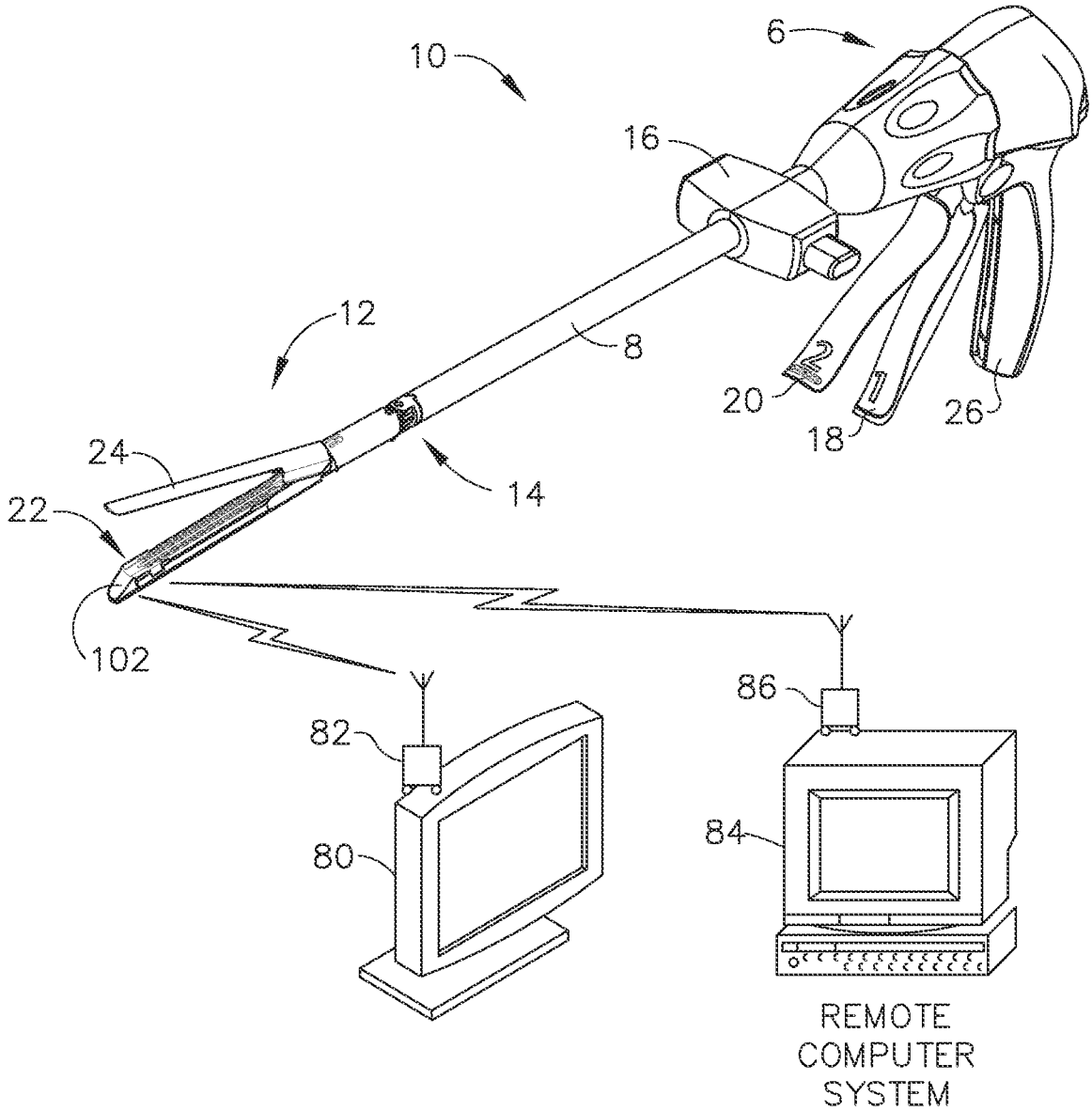
10
6
16
12
8
20
18
26
24
14
22
102
82
86
80
84
REMOTE
COMPUTER
SYSTEM

FIG. 11

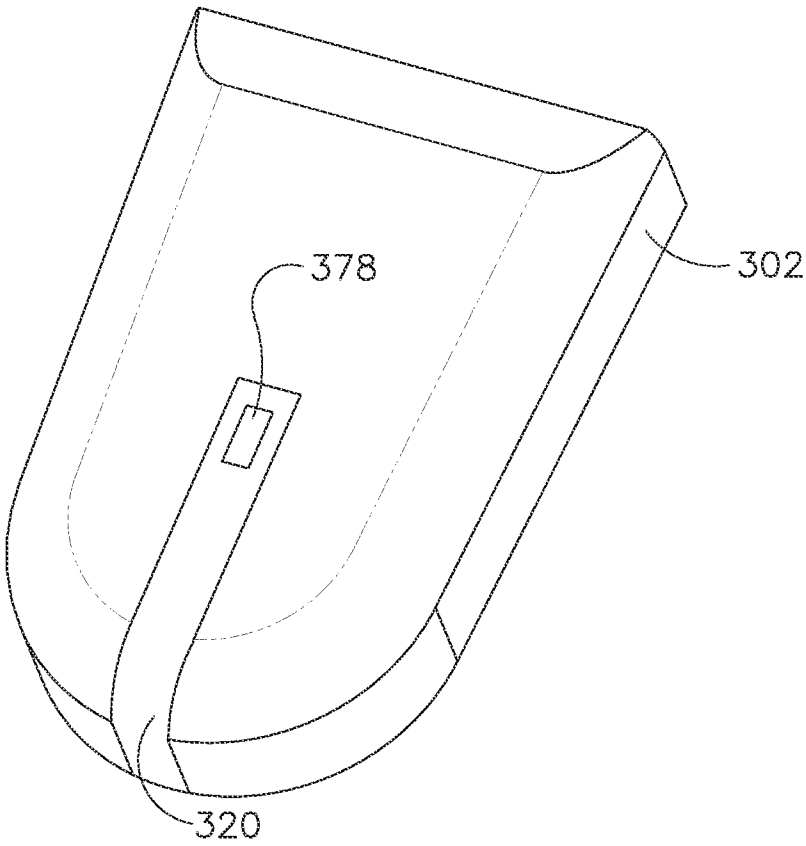

FIG. 12

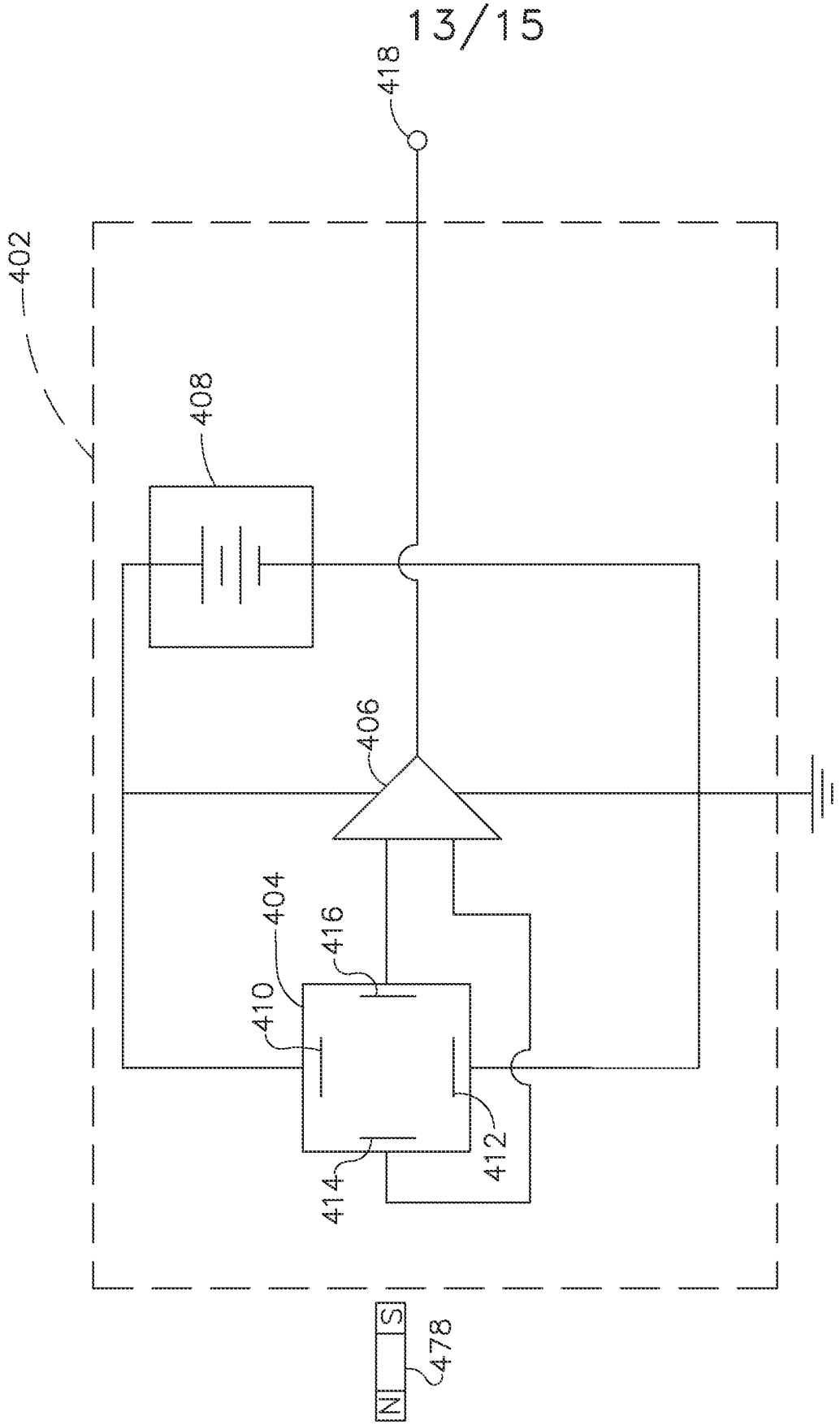

FIG. 13

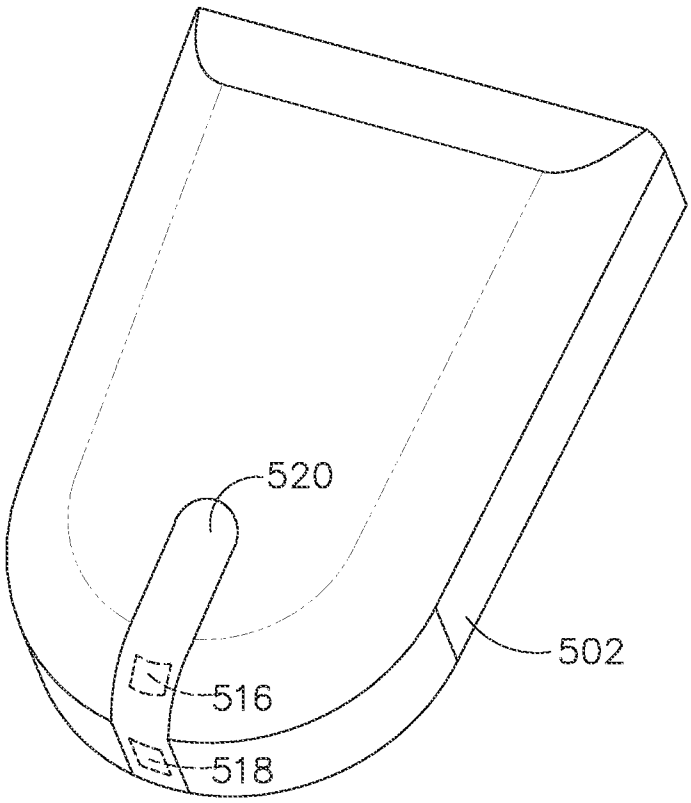

FIG. 14

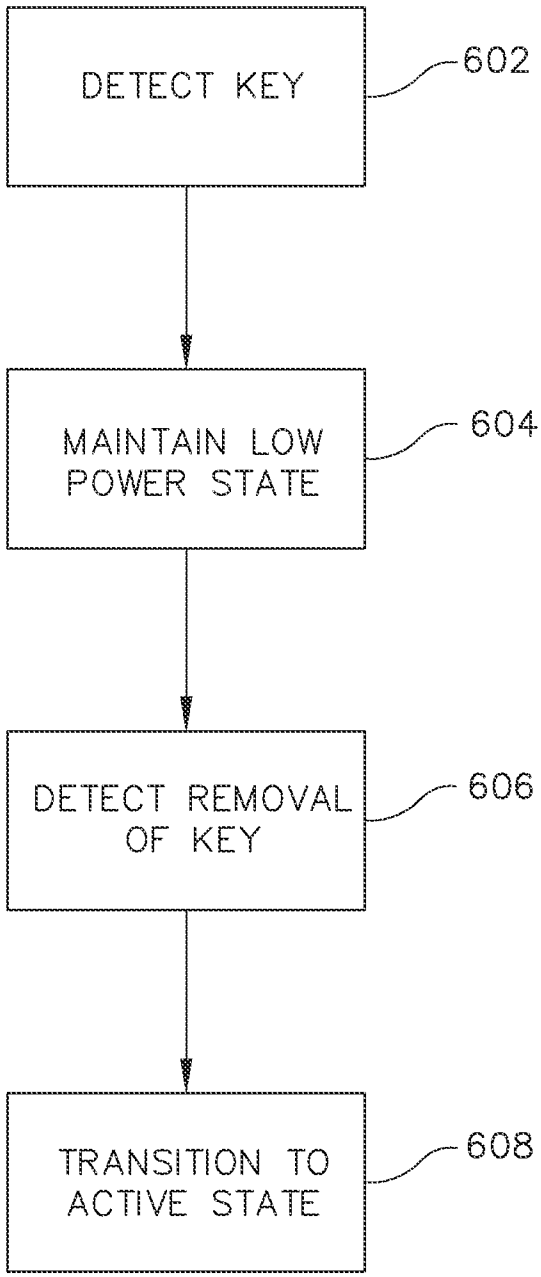
DETECT KEY
602
MAINTAIN LOW POWER STATE
604
DETECT REMOVAL OF KEY
606
TRANSITION TO ACTIVE STATE
608

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/018932

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/072 A61B19/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B G06F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	US 2012/078071 A1 (BOHM SEBASTIAN [US] ET AL) 29 March 2012 (2012-03-29) paragraph [0162] - paragraph [0166]; figures 1,5A	9,18
X	WO 2012/160163 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]; EGGERT ILONA [DE]; O'HARE AIDAN MICHA) 29 November 2012 (2012-11-29) page 13, line 31 - page 16, line 19; figures 2-4	9,18

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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

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"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
5 June 2014	23/06/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Roudaut, Tanguy

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/018932

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 2011/155781 A1 (SWENSGARD BRETT E [US] ET AL) 30 June 2011 (2011-06-30) paragraph [0030] - paragraph [0038] paragraph [0045] - paragraph [0046]; figures 7-12	1-18
X,P	WO 2013/062978 A2 (ETHICON ENDO SURGERY INC [US]; MONSON GAVIN M [US]; TREES GREGORY A [U) 2 May 2013 (2013-05-02) page 34, line 32 - page 36, line 14; figures 1,7,8,41-47	9,18

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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