APPARATUS AND METHOD FOR TISSUE CLOSURE

RELATED APPLICATIONS

[001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 60/763,038 filed January 27, 2006, which is incorporated herein by reference.

FIELD

[002] The embodiments disclosed herein relate to a medical device for performing a procedure on tissue, such as bony tissue. Embodiments disclosed herein are appropriate for sternotomy closure, among other procedures. More particularly, embodiments disclosed herein are useful for the manipulation and control of a suture needle during sternotomy closure, and methods for using such a device.

BACKGROUND

[003] Surgical procedures present many challenges which can compromise the health of the patient as well as the health of the medical professional. For some surgical procedures, such as cardiac surgery and pneumonectomy, access to the organ is generally gained by a sternotomy, a surgical procedure in which the sternum is divided with a device such as a saw or other suitable cutting instrument. After performing the sternotomy, the sternum must be re-approximated. The medical professional typically closes the sternum using a stainless steel needle with a sharp cutting point onto which is attached a suture comprising a length of relatively inflexible stainless steel wire, or alternatively, a combination of stiff stainless steel wire and flexible stainless steel cable. The wire (or combination cable and wire) suture is manually drawn through both sides of the sternum so that sufficient length of the wire is protruding from both sides of the sternum and there is no longer any slack wire below the sternum. After removing the needle from the wire, the medical professional must manually wrap an end of one wire around the other wire either with their hands or forceps, repeatedly twisting the two ends of the wires around each other in a helical or spiral manner. The medical professional then cuts the twisted wires to a desired length and uses surgical tools to bury the sharp, cut, twisted ends of the wires into the space

between the re-approximated edges of the sternum so that the sharp, cut, twisted ends of the wire do not poke into the underside of the patient's skin. Typically, between six and eight wire sutures are placed in the sternum in order to close the sternum along its length.

[004] The prior art sternotomy closure procedures present many problems to the medical professional and the patient. Manual suturing is often difficult because the suturing needle must be forced through tough, dense bone. Manual suturing also involves the handling and manipulation of a sharp suturing needle with an instrument such as a needle forceps, which can result in inadvertent, accidental needle pricks through a surgeon's or nurse's gloves, posing a potential risk of infection for the surgeon, nurse, staff, and patient. Manipulating an inflexible wire within the chest cavity underneath the sternum and ribcage is often difficult and awkward. For example, traditionally, the surgeon must manually lift the divided sternum upward when placing a suture through the bone, placing his or her hand in significant danger of needle puncture because of the force required to penetrate the bone. In addition, medical professionals are often stuck by the sharp, cut, twisted ends of the wires, and are thus subjected to the risk of potentially fatal bloodborne infections such as HIV/AIDS and Hepatitis B and C. Furthermore, the direct handling of the needle can cause the needle to become contaminated with pathogenic bacteria that can cause onset of infection at the site of the sutures. There is also a risk of the needle penetrating the heart and adjacent vessels and structures and causing a serious and often fatal infection.

[005] Prior art sternotomy sutures for use by medical professionals are described, for example, in U.S. Patent No. 4,074,732 entitled "Wire Cutting, Stripping and Twisting Tool;" U.S. Patent No. 5,089,012 entitled "Surgical Suture, in Particular for Sternotomy Closure;" U.S. Patent No. 5,318,566 entitled "Sternotomy Cable and Method;" and U.S. Patent No. 5,830,234 entitled "Method for Double Wire Sternotomy Suture," all of which are hereby incorporated by reference herein in their entireties. Prior art sternotomy sutures require the medical professional to use their fingers or manual tools to manipulate the sutures and to provide an appropriate amount of tension to the sutures. In addition, U.S. Patent No. 6,923,819 discloses an apparatus and method for surgical suturing with thread management, the entirety of which is hereby incorporated by reference herein.

[006] Thus, it is evident that there is a need in the art for an apparatus and method for sternotomy closure that is safe, reliable, user friendly, and effective. Embodiments of the present invention seek to provide a solution for this and other problems.

SUMMARY

[007] The purpose and advantages of the present invention will be set forth in and become apparent from the description that follows. Additional advantages of the invention will be realized and attained by the methods and systems particularly pointed out in the written description and claims hereof, as well as from the appended drawings.

[008] In accordance with a first aspect of the present invention is provided a motorized suturing device comprising: a) a needle disposed in a needle track, the needle track being adapted and configured to guide the needle along a curved path about an axis of rotation substantially parallel to the longitudinal axis of the device, the needle having: i) a curved body, the curved body covering an arc less than about 330°; and ii) an engagement surface for driving the needle; and b) a housing containing a motorized drive, at least a portion of the drive being adapted and configured to reciprocate about the longitudinal axis, the drive having sufficient power to drive the needle through bony tissue of a patient.

[009] In accordance with a second aspect of the present invention, there is provided a suturing needle comprising: a) a curved generally toroidal body with a first sharp pointed end and a second end, wherein the curved body has an arcuate extent less than about 330°; b) at least one substantially planar engagement surface defined on the generally toroidal body displaced from a radially inner region of the generally toroidal body, the engagement surface being adapted and configured to receive a needle rotation drive of a suturing mechanism to facilitate driving the needle through a circular path; and c) suturing material including a flexible leader engaged to a wire suture connected to the second end of the needle.

[0010] In accordance with a third aspect of the present invention, there is provided a method for tissue re-approximation comprising: (a) releasably engaging a cartridge having a protective housing and a suturing needle to a cartridge holder assembly of a tissue closure

device; (b) placing the tissue closure device having the cartridge and the suturing needle to cause an aperture in the cartridge to be between a first side and a second side of a bony tissue segment, wherein a pointed end of the suturing needle is positioned within the protective housing before and after a complete rotation of the suturing needle about a rotational axis; (c) activating an electronic module coupled to a pusher assembly that releasably engages the suturing needle to cause motorized rotational movement of the suturing needle across the aperture in the cartridge and advance the suturing needle through the first side of the split bony tissue segment; (d) pulling a suturing material attached to the suturing needle through the first side of the split bony tissue segment; and (e) repeating steps (c) and (d) for the second side of the split bony tissue segment forming a stitch through the first side and the second side of the split tissue segment.

[0011]

[0012]

[0013] It is to be understood that both the foregoing general description and the following detailed description are exemplary and are intended to provide further explanation of the invention claimed.

[0014] The accompanying drawings, which are incorporated in and constitute part of this specification, are included to illustrate and provide a further understanding of the method and devices of the invention. Together with the description, the drawings serve to explain the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The presently disclosed embodiments will be further explained with reference to the attached drawings, wherein like structures are referred to by like numerals throughout the several views. The drawings shown are not necessarily to scale, with emphasis instead generally being placed upon illustrating the principles of the presently disclosed embodiments.

[0016] **FIG. 1** is a pictorial view of the main components of a tissue closure device provided in accordance with the invention.

[0017] **FIG. 2A** and **FIG. 2B** are perspective views of a front end assembly of the tissue closure device of FIG. 1.

[0018] **FIG. 3A** shows an expanded view of a pawl. **FIG. 3B** and **FIG. 3C** show an expanded view of a pusher assembly with the pawl in place.

[0019] **FIG. 4** shows an expanded view of a curved tissue closure needle.

[0020] **FIG. 5A** is a perspective view of the relative configuration of a tissue closure needle with respect to the pusher assembly. **FIG. 5B** and **FIG. 5C** are sectional views of the tissue closure needle and the pusher assembly.

[0021] **FIG. 6** is a perspective view of a cartridge holder assembly of the tissue closure device of FIG. 1.

[0022] **FIG. 7** shows an expanded view of a needle cartridge.

[0023] **FIG. 8A** shows an expanded view of an anti-rotate and locking bar. **FIG. 8B** shows an expanded view of the relative configuration of the anti-rotate and locking bar with respect to a suturing needle housed in a needle cartridge.

[0024] **FIG. 9** shows close-up view of an alternative cartridge locking mechanism utilizing a retractable pin incorporated into the cartridge holder assembly instead of a locking bar.

[0025] **FIG. 10** shows an isolated view of the cartridge locking pin of **FIG. 9**.

[0026] **FIG. 11** shows a cutaway view of the cartridge locking pin of **FIG. 9** engaged with the locking pin recess of the cartridge.

[0027] **FIG. 12** shows the locking pin recess of **FIG. 11** on the proximal surface of the needle cartridge.

[0028] **FIG. 13** shows an anti-rotate bar without the locking bar feature, which can be used when the locking pin feature of **FIG. 9** is incorporated into the cartridge holder assembly.

[0029] **FIG. 14A** shows a perspective view of the relative configuration of the needle cartridge with respect to the cartridge holder assembly and the anti-rotate and locking bar before the needle cartridge has been locked into place. **FIG. 14B** shows a perspective view of the relative configuration of the needle cartridge with respect to the cartridge holder assembly and the anti-rotate and locking bar after the needle cartridge has been locked into place.

[0030] **FIG. 15** shows a suture retainer on the top side of the cartridge, used to hold the suture material away from the needle, drive arm and pawl of the needle pusher assembly.

[0031] **FIG. 16** shows a rearward-leaning perspective view of the front of the cartridge, revealing the recess of the suture retainer of **FIG. 15** into which the suture can be placed.

[0032] **FIG. 17** shows the suture material in cross-section, placed within the recess of the suture retainer of **FIG. 15**.

[0033] **FIG. 18** shows a top view of the needle cartridge and suture retainer of **FIG. 15**, revealing the detents of the suture retainer projections that hold the suture material within the recess.

[0034] **FIG. 19** shows a needle brace that can be installed on the needle cartridge from the outside/distal surface of the cartridge.

[0035] **FIG. 20** shows the needle brace of **FIG. 19** installed against the needle cartridge.

[0036] **FIG. 21** shows a rear perspective view of the needle brace of **FIG. 19** installed in the cartridge, revealing its positioning adjacent to the blunt and pointed ends of the suturing needle.

[0037] **FIG. 22** shows an alternative design of the needle brace of **FIG. 19**, in which the stop at the pointed end of the needle comprises a flexible tab, which can aid in securing the brace onto the cartridge.

[0038] **FIG. 23** shows the needle brace of **FIG. 22** installed onto the cartridge, showing the flexible tab snapped onto the point of the needle.

[0039] **FIG. 24** shows an electronic module of the tissue closure device of FIG. 1.

[0040] **FIGS. 25 A – H** show various perspective views of the electronic module of the tissue closure device of **FIG. 1**, including a left front perspective (**A**), front perspective (**B**), right front perspective (**C**), left rear perspective (**D**), rear perspective (**E**), right rear perspective (**F**), top perspective (**G**) and bottom perspective (**H**).

[0041] **FIG. 26A, FIG. 26B** and **FIG. 26C** show views of a tissue closure device wherein the electronic module has been encased in a housing.

[0042] **FIGS. 27 A – F** show the installation of the funnel into the back end of the handle of the suturing device, with the funnel aligned with the barrel of the handle (**A** and **D**), the funnel in position within the handle (**B** and **E**), and the electronic module of **FIG. 24** aligned with the installed funnel (**C** and **F**).

[0043] **FIGS. 28 A – F** show various perspective views of the funnel of **FIG. 27** in isolation, showing the rear (**A**), front (**B**), right side (**C**), left side (**D**), top (**E**) and bottom (**F**) of the funnel.

[0044] **FIG. 29** shows the electronic module of **FIG. 25** showing an alternative arrangement of the power and actuation buttons and indicator LED's.

[0045] **FIG. 30** shows an enlarged view of a drive wheel and a stop plate. A drive pin penetrates the stop plate and rides in a "U-shaped" track.

[0046] **FIG. 31A , FIG. 31B**, and **FIG. 31C** show segmented sectional views of the main components of the tissue closure device.

[0047] **FIG. 32A** shows an embodiment of a tissue closure needle having the tissue closing suture material attached thereto. **FIG. 32B** shows an expanded view of a crimp that houses the ends of the two materials that form a tissue closure suture material.

[0048] **FIGS. 33 A-C** show details of the construction of the pointed end of the tissue closure needle of **FIG. 4**, with the distribution of the facets (**A**), the angle of the outer curvature facet (**B**), and the resulting shape of the needle point (**C**).

[0049] **FIG. 34** shows a disposable paper and plastic film package enclosing the sterile needle cartridge of **FIG. 7**, and the suturing needle and attached suture material of **FIG. 32A**.

[0050] **FIG. 35** shows an embodiment of a tissue closure device of the presently disclosed embodiments.

[0051] **FIGS. 36 A – C** show front perspective views of an embodiment of the suturing device of **FIG. 1**, with needle cartridge attached, including left front (**A**), front (**B**), and right front (**C**) perspectives.

[0052] **FIGS. 37 A - D** show other perspective views of the suturing device of **FIG. 36**, without an attached cartridge, including left rear (**A**), right rear (**B**), bottom (**C**) and top (**D**) perspectives.

[0053] **FIG. 38** shows a further embodiment of a tissue closure device provided in accordance with the invention.

[0054] **FIGS. 39A-39D** shows the operation of the driver arm in the cartridge holder assembly operating in a rear drive mode.

[0055] **FIG. 40** shows an embodiment of a tissue closure device placed at a sternotomy site such that the device is between a first side and a second side of a split sternum.

[0056] While the above-identified drawings set forth presently disclosed embodiments, other embodiments are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of the presently disclosed embodiments.

DETAILED DESCRIPTION

[0057] Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. The method and corresponding steps of the invention will be described in conjunction with the detailed description of the system.

[0058] The devices and methods presented herein may be used for tissue closure. The present invention is particularly well suited for procedures involving bony tissue, such as sternotomy closures. As depicted, the disclosed tissue closure device, or suturing device, is a motorized, electrically powered apparatus. The power source can be battery or standard wall electrical power. The tissue closure devices disclosed herein advantageously prevent accidental needle punctures to the medical professional and readily and easily drive needles through bony tissue, eliminating the need to manually force the needles through the bone. Within the context of sternotomy closure, the disclosed devices protect the heart and adjacent vessels and structures from inadvertent needle punctures during closure and replicates the standard sternotomy closure technique. In so doing, the disclosed embodiments provide easier and more fluent manipulation of the wire or wire/cable combination within the chest cavity or other anatomy, and produce tissue closure in a time efficient manner so the patient is not subjected to health risks associated with having a tissue segment, such as the sternum, open for more time than necessary.

[0059] The main components of a tissue closure device of the presently disclosed embodiments are shown generally at **50** in **FIG. 1**. The tissue closure device **50** can be used

to produce a continuous, or more commonly, an interrupted suture so as to enable closure of the sternal halves after a sternotomy procedure, for example. As depicted, device **50** is a motorized, battery-powered apparatus designed to prevent needle punctures during sternotomy closure or other similar procedures. Device 50 delivers reliable closure using standard needles and wires and replicates standard tissue (e.g., sternotomy) closure techniques. Device 50 easily drives needles through bone as well as other tissue, thus eliminating the need to manually force the needles through the bone; and protects the heart and adjacent vessels and structures from inadvertent needle punctures during closure.

[0060] Referring to **FIG. 1**, the tissue closure device **50** includes a removable electronic module **60** including a battery pack **62**, an electric motor **61**, and a gear box **59**, as well as electronic circuits. The gear box **59** further includes a shaft that runs through a stop plate **66**, a bearing surface **68**, and a drive wheel **67**. A drive pin **63** engages the drive wheel **67** and when in use, mates with a hole in a drive plate **80** that is part of a front end assembly **70**. The bearing surface **68** acts as a lubricating surface between the stop plate **66** and the drive wheel **67**. The bearing surface **68** may be any lubricious material having a low coefficient of friction, for example fluoropolymer compounds such as those including polytetrafluoroethylene (PTFE).

[0061] The electric motor **61** preferably is compact yet powerful. In one embodiment, a DC motor can be selected from the Maxon RE-max 29 series, for example, commercially available from Maxon Precision Motors, Inc. of Fall River, MA. Model no. 226784 can be used, which weighs 159 grams, is 29 mm in size, operates on 9 volts, can generate 22 watts, and has a no-load speed rating of 7630 RPM. The gear box **59** can be selected from, for example, the Maxon Gearhead GP32C series, which is 32 mm is size. Model no. 166943 can be used, which has 3 stages, weighs 194 grams, and has a 103:1 gear reduction ratio.

[0062] As depicted, the front end assembly **70** includes a pusher assembly (not visible) and a cartridge holder assembly **72**. The pusher assembly has a drive arm that houses a drive mechanism ("pawl") and a drive shaft that runs throughout the length of the front end assembly **70** and enters the drive plate **80**. A needle cartridge **90** carrying a tissue closure needle **110** may be removably attached to a distal end **81** of the cartridge holder assembly **72**.

[0063] **FIG. 2A** and **FIG. 2B** show the front end assembly 70 including a pusher assembly 71 and the cartridge holder assembly 72 with the attached disposable needle

cartridge **90** which houses the tissue closure needle **110**. The pusher assembly **71** includes a drive shaft **73** and a drive arm **75** that is in intimate contact with the needle **110** via a pawl. The drive shaft **73** engages a spline in the drive plate **80** so the drive shaft **73** is rotationally attached to the drive plate **80**. When the electronic module is attached to the front end assembly the drive shaft **73** engages a bushing located in the drive wheel **67**. The cartridge holder assembly **72** (shown in **FIG. 2B**) includes a shaft barrel **74** and a support arm assembly **76** that is comprised of a pair of "skeletalized" arms extending along mutually divergent axes so as to provide an opening **78** to view the device **50** during its operation. The open configuration of the support arms **76** are minimal in bulk and provide a relatively wide opening **78** that allows the medical professional to directly view the aperture in the needle cartridge **90** and cartridge holder assembly **72**, the space, for example, between a first side and a second side of a split sternum and needle advancement through the space during operation of the tissue closure device **50**. Although the embodiment shown in **FIG. 2** has a plurality of support arms **76**, other variants include a support arm assembly comprising a single support arm. The improved viewing ability offered by the shape and configuration of the support arm assembly **76** enables precise device placement over the sternum in the case of a sternotomy closure procedure, and uniform advancement of the tissue closure device **50** after every stitch to provide a uniform and symmetric suture, thereby protecting the heart and adjacent vessels and structures from inadvertent needle punctures during closure.

[0064] The distal end **81** of the cartridge holder assembly **72** is where the needle cartridge **90** is disposably attached. The needle cartridge **90** comprises a circular housing that may be formed of a suitable rigid medical grade sterilizable metal or plastic material. Preferably, the material forming the cartridge **90** possesses both rigidity and a low coefficient of friction to reduce the power required to move the needle disposed within it. One such material, for example, is Lubricomp DFP22H, produced by GE Plastics, a polycarbonate containing 10% glass fill, 8% PTFE (Teflon), and 2% silicone. Constructing the cartridge from this material can provide for up to 20% more driving power at the point of the needle. The housing may be releasably retained by the distal end **81** of the cartridge holder assembly **72** by known means, such as a plurality of grooves located along on the edge of an inner lip in diametrically opposite positions that are capable of engaging the same plurality of slots correspondingly located in the distal end **81** of the cartridge holder assembly **72**. The grooves when engaged enable the needle cartridge **90** to be retained by the distal end **81** of the

cartridge holder assembly **72**. A torsion return spring 77 engages the shaft barrel 74 and the drive plate **80** and is responsible for returning the drive shaft **73** back to a "start" position such that when the electronic module **60** is attached to the front end assembly **70** the drive pin **63** will properly engage the drive plate **80** of the front end assembly **70**.

[0065] As best shown in **FIG. 31A** and **FIG. 31B**, O-rings 57 between the pusher assembly 71 and the cartridge holder assembly **72** create a separation barrier to ensure the device **50** stays sterile during operation. The first O-ring 57 seals the rotating shaft against the front end assembly. The second O-ring 57 seals closer to the housing and seals the front end assembly against the nose collar **157**. The plurality of O-rings 57 provide a sterile barrier to seal the device exterior from the interior of the handle. Alternatively, as shown in **FIG. 31C**, a Teflon seal **57A** can be used, which provides for a more durable barrier to the entry and exit of fluids and other possible contaminants. The barrier seal eliminates means of exiting of any non-sterile germs, debris, particles, etc., from the inside of the device to the sterile outside of the device front end.

[0066] **FIG. 3B** and **FIG. 3C** show expanded views of the pusher assembly including a pawl **95** (as shown in **FIG. 3A**) located at the tip, which resides in a slot in the drive arm 75 of the pusher assembly, and is connected to the drive arm 75 by a pivot pin **99**. The needle (not shown) is driven in a circular path by the pawl **95**.

[0067] **FIG. 4** shows an embodiment of the curved tissue closure needle **110** of the presently disclosed embodiments, which is particularly suitable for penetration through bony material. The needle **110** is formed as a circular split ring defining an aperture (or gap) **111**, a sharp, pointed end **112** and an opposite blunt end **113**. A cylindrical bore **114** aligned axially with respect to the needle **110**, is located at the blunt end **113**. The leading end of the suturing material for tissue closure is inserted into the bore **114** and restrained by mechanically crimping. Alternatively, the opening for accommodating the suture material can be in the form of an "eye" wherein the leading end of the suturing material may be passed through for attaching it to the needle **110**. To enable the needle **110** to penetrate to the required depth, the needle **110** preferably has an arcuate extent between about 250° and about 330°.

[0068] The needle **110** further includes two symmetric notches **115a** and **115b** along the radially rear edge, i.e. the edge proximal to the cartridge holder assembly. The notch **115b** is positioned toward the sharp pointed end **112** of the needle **110**. The notch **115a** is positioned toward the blunt end **113** of the needle **110**. The notches **115a** and **115b** are

located opposite to one another, each having a perpendicular (about 90°) segment and an angular segment that makes an angle of about 60° with the perpendicular segment. The notches **115a** and **115b** are engaged by the drive mechanism (pawl) in the cartridge holder assembly **72** and enable the needle **110** to undergo a rotational movement upon actuation of the drive mechanism, thereby causing it to penetrate and advance through the space spanning the tissue segment, such as a split sternum. A notch **116** is located on the radially outer edge ("outer notch") of the needle **110** proximally to the notch **115b** that is closer to the sharp, pointed end **112**. The outer notch **116** engages with an anti-rotate bar located in the cartridge holder assembly **72**, whereby rotation of the needle **110** in a direction opposite to the advancing direction or "needle backing-up" is prevented. The positive engagement of the needle outer notch **116** during operation prevents the needle **110** from straying out of sequence during the suturing process.

[0069] The needle **110** is enclosed within a cartridge, so the sharp pointed end **112** is not exposed. This needle position, as loaded, is referred to as the "home" position. In the home position, the needle **110** is fully contained within the cartridge housing to eliminate needle-pricks during handling of the cartridge or the loaded device. The width of the aperture in the needle cartridge is comparable to and corresponds with the width of the gap in the needle **110** so that when the needle **110** is in the home position the needle **110** does not project materially into the aperture **111**. Such an alignment causes the needle **110** to reside entirely within the needle cartridge, thereby preventing inadvertent contact of the sharp pointed end **112** with the user's fingers during handling of the disposable needle cartridge for placement on the cartridge holder assembly or disposal after use, and while operating the tissue closure device **50**. Such protection of the needle **110** in the tissue closure device **50** prevents accidental "needle-pricks" from occurring, thereby substantially reducing the risk of infection caused by pathogenic bacteria or viruses that may contaminate the needle **110** during or after use prior to disposal. The needle **110** may be rotated in a curved track of the needle cartridge about the longitudinal axis of the suturing device **50** to advance the pointed needle end **112** so that the needle **110** first spans the aperture **111** and then returns to the home position. The suturing material is attached to the needle **110**, and therefore follows the path of the needle **110**. The suturing material may then be cut and twist tied and secured by an appropriate method. Every stitch, whether a single, interrupted stitch, or one of a series of continuous, running stitches may be placed in like manner. The tissue closure, or suturing

device **50**, therefore, may be used to insert either a single stitch, or to insert a suture comprising a plurality of continuous stitches as a replacement method for a more tedious and time-consuming manual suturing process.

[0070] **FIG. 5A** provides a detailed view of the pusher assembly **71** with relation to the suturing needle **110**. The pawl at the tip of the drive arm **75** is capable of interfitting with wedge shaped notches located along the radially inner edge of the needle **110**. The drive arm **75** is capable of sweeping back and forth in an arc spanning about 190°. The drive arm rotates more than 180°, and the overdrive accounts for any design irregularities and tolerances on the needle **110** and the moving parts and ensures that the pawl will always pick up the needle notch **116**.

[0071] The advancing movement of the needle **110** during operation causes triangular slots along the radially inner edge of the needle **110** to align with the wedge-shaped pawl in the drive arm **75**, thereby causing the pawl to engage the slots due to a positive pressure exerted on the pin **99**, and to "lock" into the slots. The rotatory advancing movement of the needle **110** is therefore controlled to occur sequentially through about 190° each time the tissue closure device **50** is actuated. For each suture stitch, the needle **110** rotates through an arc of about 360°, while the drive arm **75** rotates back and forth for a total of about 760° degrees per stitch.

[0072] **FIG. 5B** and **FIG. 5C** are sectional views of the tissue closure needle and the pusher assembly. As shown in **FIG. 5B**, a flat spring **96** asserts tension on the pawl **95** to push the pawl **95** distally into the needle **110** and into the notch **115b**. When the pawl **95** is rotated, the pawl **95** picks up that notch **115b** and drives the needle **110**.

[0073] **FIG. 5C** shows the pawl **95** not engaged in the notch **115b** and engaging the surface of the needle **110**. As the pawl **95** moves along the outer surface of the needle **110**, the pawl **95** encounters the notch **115b**. The pawl tip engages the ramp for the notch **115b** and the flat spring **96** pushes the pawl **95** into the needle notch **115b**.

[0074] **FIG. 5C** shows a pawl stop **98** that permits the pawl tip to only extend a certain amount into the needle **110** to not bind the needle **110** and cause the needle **110** to stop. The pawl **95** has an angled surface that angles away from the pawl stop **98**. When the pawl **95** rotates clockwise, the pawl **95** can only turn until the angled surface contacts the pawl stop **98**. The pawl **95** contacting the pawl stop **98** is shown in **FIG. 5B**. The pawl stop

98 prevents further rotation of the pawl 95 and prevents the pawl 95 from binding the needle 110 in the cartridge 90.

[0075] FIG. 6 shows a close-up view of the distal end 81 of the cartridge holder assembly 72. The cartridge holder assembly 72 is composed of a sterilizable medical grade material which can either be a metallic material such as stainless steel to enable its reuse subsequent to sterilization following a prior use, or a sterilizable medical grade plastic material, in which case, it may be discarded and disposed after a single use. The cartridge holder assembly 72 has a cylindrical configuration with a distal edge 87 and a proximal edge 89 with respect to the device actuator handle (not shown), with an aperture 85 that corresponds in dimension and location to coincide with a substantially similar aperture located in the disposable needle cartridge. The cartridge holder assembly 72 additionally comprises a plurality of slots 82 located along on the distal edge 87 that are located opposite to one another, and are capable of engaging the same plurality of retaining clips correspondingly located in the needle cartridge housing (not shown). The cartridge holder assembly 72 further comprises a cylindrical slot (not visible) located on the distal edge 87 that is capable of engaging a pivoting pin of identical diameter correspondingly located on a gate assembly 105. The proximal edge 89 of the cartridge holder assembly 72 is attached to the shaft segment 74 by the support arm assembly 76. The gate assembly 105 prevents the needle from leaving the track and falling out into the back of the cartridge holder assembly 72. The gate assembly 105 pivots on a pivot pin 107 like a rocker switch during each actuation of the tissue closure device 50 to permit a circular movement of the drive mechanism that engages the needle. Stop pins 106 located on the cartridge holder assembly cause the gate assembly 105 to stop and reverse direction, like a "see-saw," "up-down" motion. The gate assembly 105 precludes the lateral movement and dislocation of the needle within the cartridge holder assembly 72. The gate assembly 105 is able to pivot on the pivot pin 107 so that the drive arm 75 which engages with the needle via the pawl can pass by the gate assembly 105. An anti-rotate bar 100 is capable of engaging with the needle cartridge 90 to lock it in place on the cartridge holder assembly 72 as well as to engage the needle, whereby rotation of the needle in a direction opposite to the advancing direction or "needle backing-up" is prevented.

[0076] FIG. 7 shows a close-up view of a disposable needle cartridge 90 of the presently disclosed embodiments, which is preferably offered in a sterilized sealed package.

The needle cartridge **90** comprises a circular housing **91** that may be formed of a suitable rigid medical grade sterilizable metal or plastic material. The material forming the cartridge **90** preferably has both rigidity and a low coefficient of friction to reduce the power required to move the needle disposed within it. One such material, for example, is Lubricomp DFP22H, produced by GE Plastics, a polycarbonate containing 10% glass fill, 8% PTFE (Teflon), and 2% silicone. Constructing the cartridge from this material can provide for up to 20% more needle driving power at the point of the needle. The housing **91** may be releasably retained by the cartridge holder assembly at the distal end of suturing device **50** by known means, such as a plurality of grooves **94** in diametrically opposite positions that are capable of engaging with the plurality of slots on the distal edge of the cartridge holder assembly. The needle cartridge **90** further comprises a groove **93** that is capable of engaging the anti-rotate and locking bar **100** correspondingly located on the cartridge holder assembly.

[0077] While the grooves **94** when engaged enable the needle cartridge **90** to be retained by the cartridge holder assembly, the groove **93** when engaged with the anti-rotate and locking bar **100** causes an aperture **97** defined in the needle cartridge **90** to be aligned with the corresponding aperture in the cartridge holder assembly. The needle cartridge **90** further comprises a circular groove or "track" **92** that is inscribed in the inside surface of the housing **91**, which lies in a plane that is perpendicular to the longitudinal axis of both the housing **91** and that of the suturing device **50**. The aperture **97** interrupts the track **92**.

[0078] The arcuate suturing needle **110** composed of medical grade stainless steel or similar material is slidably positioned in the track **92**. The radius of the arc defining the arcuate needle **110** is approximately equal to the circumference to the needle cartridge **90** at the aperture **97** therein. The needle **110** normally resides in a "home" position in the track **92** such that the gap in the arcuate needle **110** is in alignment with the aperture **97** in the cartridge **90**. The sharp, pointed end of the needle **110** is situated on one side and entirely within the confines of the housing aperture **97**; the pointed end of the needle **110** is, therefore, shielded by the cartridge housing **91**. The blunt end of the needle **110** that is attached to a suturing material is located at the opposite side of the aperture **97**. The sharp, pointed end of the needle **110** is, therefore, wholly contained within the cartridge **90** and does not protrude beyond the housing of the cartridge **90**. Thus, the sharp pointed end of the needle **110** is not exposed to the user.

[0079] **FIG. 8A** shows a close-up view of the anti-rotate and locking bar **100**. As shown in **FIG. 8B**, the anti-rotate and locking bar **100** includes a cartridge locking surface **101**, which makes contact with the needle cartridge **90** and locks it into place, and an anti-rotate surface **102**, which contacts the needle **110**. A coil spring **104** engages the cartridge holder assembly 72 and allows the anti-rotate and locking bar **100** to move up and down so as to lock or un-lock the needle cartridge **90** into place on the cartridge holder assembly 72.

[0080] **FIGS. 14A** and **14B** show an enlarged view of the distal end **81** of the cartridge holder assembly 72. In **FIG. 14A**, the needle cartridge **90** is in a non-locked position. In order to lock the needle cartridge **90**, the needle cartridge **90** needs to be rotated counter clockwise. To unlock the needle cartridge **90** from the distal end **81** of the cartridge holder assembly 72, the anti-rotate and locking bar **100** may be pressed down to engage the coil spring and this will allow the anti-rotate and locking bar **100** to pivot at pivot pin **103**.

[0081] **FIG 9** shows an alternative cartridge locking mechanism. A locking pin **200** is slidably disposed within the cartridge holder assembly 72. A handle and button **203** connected to the locking pin **200** allows the operator to slide the pin **200** proximally along the slot **204** from a position that protrudes from the distal edge **87** of the cartridge holder assembly 72 to a fully retracted position (not shown). As shown in the cross-sectional view of **FIG. 11**, the locking pin **200** is biased to protrude from the distal edge **87** of the cartridge holder assembly 72 by virtue of the spring **201** situated on the proximal end of the locking pin **200**. When the needle cartridge **90** is secured to the cartridge holder assembly 72, whereby the grooves **94** are fully engaged with the slots **82**, a locking pin recess **202** on the mating surface of the cartridge **90** aligns with the pin **200**, allowing the pin **200** to protrude and engage the recess **202**, thereby locking the needle cartridge **90** rotationally onto the cartridge holder assembly 72. The locking pin recess **202** is formed to be slightly larger but with a similar cross-sectional shape as the locking pin **200**. In one embodiment, the cross-sectional shape of the locking pin **200** and the shape of the locking pin recess **202** are circular. To release the cartridge from the cartridge holder assembly, a user can engage the handle and button **203** attached to the pin **200** and slide the pin **200** proximally to retract it from the locking pin recess **202**. Upon retracting the locking pin **200**, the user can rotate the needle cartridge 90 to disengage the grooves **94** from the slots **82**, and thereby remove the cartridge from the cartridge holder assembly 72. The locking pin recess **202** is more clearly

seen in **FIG. 12**, a perspective view of a portion of the mating or proximal surface of the needle cartridge **90**.

[0082] The anti-rotate and locking bar **100** engages the outer notch of the needle **110** to prevent rotation of the needle **110** and prevent "needle backing-up" and thereby precluding the needle **110** from straying out of sequence. **FIG. 14B** shows the needle cartridge **90** locked into position both rotationally and axially.

[0083] The construction of the anti-rotate and locking bar **100** can be simplified if the cartridge locking function is achieved with a locking pin **200**. The arm leading to the locking surface **101** of the anti-rotate and locking bar **100**, can be eliminated, resulting in a purely anti-rotate bar **300**, as shown in **FIG. 13**. The anti-rotate bar **300** can comprise an anti-rotate surface **302** that makes contact with the needle **110**. The anti-rotate bar **300** is biased by spring **304** to engage the anti-rotate surface **302** with the outer notch **116** of needle **110** to prevent reverse rotation of the needle **110**.

[0084] As shown in **FIG. 15**, the cartridge **90** can be equipped with a suture retainer **400** to keep the suture material **138** from interfering with the rotation of the needle **110** during operation of the suturing device **50**. The suture retainer **400** helps to keep the suture material **138** away from the needle track **92** of the cartridge **90**. A front perspective view of the needle retainer **400** is shown in **FIG. 16**. The projections **401** help the operator to guide the suture material **138** into the needle retainer recess **402** of the cartridge **90**. As shown in **FIG. 17**, the detents **403** of the needle retainer **400** cause the passageway to the needle retainer recess **402** to be slightly smaller than the diameter of the suture material **138**, allowing the operator to press-fit the suture material **138** into the needle retainer recess **402**. This is also shown in **FIG. 18**, illustrating how the detents **403** provide a slightly narrower passageway for the suture material into and out of the needle retainer recess **402**. This feature prevents the suture material **138** from unintentionally slipping out of the needle retainer **400**.

[0085] The needle cartridge **90** can also be equipped with a needle brace **500**, as shown in **FIG. 19**. Positioning a needle brace **500** against the cartridge **90** can prevent inadvertent movement of the needle **110** within the cartridge **90** during handling of the cartridge **90** and suture material **138** prior to loading the cartridge **90** onto the cartridge holder assembly **72**. This keeps the needle **110** from straying within the track to a position placing it out of proper sequence for initiation of the first actuation cycle of the suturing device **50**. The

needle brace **500** has a flange **501** that contacts the outside (distal) surface of the needle cartridge **90** holding the brace in position, as shown in **FIG. 20**. The needle brace **500** has a body **502** whose outside radial dimension conforms to the inside radial dimension of the cartridge **90**, allowing a shoulder feature **503** of needle brace **500** to be situated near the inside (proximal) surface of cartridge **90** and adjacent to the hub or blunt end of needle **110** seated within the cartridge **90**, as shown in **FIG. 21**. The needle **110** is thus prevented from rotating within its track in a reverse direction. Similarly, the pointed end of needle **110** is prevented from moving forward in its track by the presence of the vertical segment **504** of body **502** of needle brace **500**, which closely conforms to the inside radial dimension of cartridge **90** and blocks the forward movement of needle **110** in its track. With the needle brace **500** in position, an individual can manipulate the cartridge/needle/suture assembly without fear of inadvertently moving the needle within the track of cartridge **90**. Such movement could potentially position the needle out of proper sequence for activation after it is placed on the cartridge holder assembly **72**. The needle brace **500** may be formed of a suitable rigid medical grade disposable metal or plastic material.

[0086] The needle brace **500** can be secured within the inner circumference of the cartridge **90**, either through a frictional 'press' fit, or through tabs placed along the periphery of the needle brace **500**, which can cooperate with corresponding depressions (not shown) along the inner circumference of the cartridge **90**. In a further refinement of the needle brace **500**, the vertical segment **504** can be constructed so that it forms a tab **504A** as shown in **FIG. 22**. The tab **504A** is constructed of material with sufficient elastic properties to be somewhat bendable. The Lubricomp plastic material referenced earlier, for example, possesses this characteristic. With the pointed end of needle **110** positioned at the end of the track of cartridge **90**, installing needle brace **500** causes the tab **504A** to bend slightly and snap into position over the tip of the needle **112**, thereby locking the needle brace **500** into position, as shown in **FIG. 23**. A user can remove the needle brace **500** by applying sufficient force to overcome the elastic resistance of the tab **504a**.

[0087] **FIG. 24** is an exploded perspective view of the removable electronic module **60** which is a battery-operated electro-mechanical assembly. The electronic module **60** includes the battery pack **62** and the electric motor **61** which includes the gear box **59** and an output shaft **58**, as well as electronic circuits. The battery **62** is preferably re-chargeable and provides the power for the electronic module **60**. The battery **62** should have a minimum

battery life of about 400 discharge cycles and be able to perform 18 sutures (or 36 total cycles) through a tissue segment such as the sternum. The motor **61** provides the rotational force necessary for the tissue closure device **50** to function. An electronics board controls the operation of the electronic module **60** based on user controlled power and actuation buttons. Indicators are provided to provide feedback to the user of the current status of the electronic module **60**. A microprocessor and firmware control the starting, stopping, and torque of the electric motor **61**. The electronics also includes the recharging circuit for the battery pack **62**. The electronic module **60** may be provided as non-sterile and may be attached to the front end assembly prior to surgery by an aseptic technique. The electronic module **60** may be removed from the front end assembly following a procedure for cleaning, battery charging and storage. Additional views of the electronic module **60** are shown in **FIG. 25(A)** to **25(H)**.

[0088] **FIGS. 26A** and **26B** show the tissue closure device **50** wherein the removable electronic module **60** has been enclosed in a thermoplastic enclosure **150** and a thermoplastic housing **151**. A door **152**, locked by a clamp latch **153**, provides entry and exit for the removable electronic module **60**. The handle **160** of the device has the door **152** at the proximal end where the removable electronic module **60** is inserted. When the non-sterile battery pack is installed, the door **152** needs to be closed and sealed. The door **152** is sealed using an O-ring or Teflon seal similar to the front end of the device to prevent the egress of any non-sterile germs from the inside the device into the sterile operating field.

[0089] In order to facilitate the placement of a non-sterile electronic module **60** into a sterile handle **160**, a funnel **600** can be provided, which is temporarily placed within the opening of the proximal end of the handle **160**, as shown in **FIGS. 27(A –F)**. The funnel **600** operates as a physical barrier between the person (e.g. circulating nurse) who handles the non-sterile electronic module **60** and the person (e.g. surgical scrub nurse) who handles the sterile components of the suturing device **50**. The sterile components include the handle **160**, the door **152**, the latch **153**, the nose collar **157**, the shaft segment **74**, cartridge holder assembly **72**, and cartridge **90**. The funnel **600** is initially sterile when inserted into the handle **160**. As shown in **FIGS. 28(A-F)**, the funnel **600** has a proximal barrel **601** and a distal barrel **602**, each shaped in cross-section to conform to the cross-sectional shape of the handle **160** and corresponding electronic module **60**. The proximal **601** and distal **602** barrels of the funnel **600** are separated by a flange **603** broad enough to form a barrier between the

hand of the person inserting the electronic module **60** and the rest of the suturing device **50**. An arrow **604** can be printed or engraved on the surface of the flange to direct the user in installing the funnel **600** in the proper vertical orientation. The arrow **604** or other suitable printing **605** on the flange **603** can also help the user distinguish the proximal **601** from the distal **602** barrels of the funnel **600**. The distal barrel **602** can fit within the handle **160**, as shown in **FIG. 27B** and **27E**. The electronic module **60** can be passed through the cavity of the funnel **600**, as shown in **FIG. 27C** and **27F**. Once the electronic module has passed through the funnel **600**, and has been inserted into the handle **160**, the funnel **600** is no longer considered to be sterile and can be removed. The door **152** can then be closed in a sterile manner and secured with the latch **153**, also securing the proximal end of the electronic module **60** in place. The outer surfaces of the suturing device **50** remain sterile, a condition facilitated by the use of the funnel **600**. In an alternative embodiment, the funnel **600** can have a sterile drape (preferably disposable) attached to the periphery of the flange **603** in order to extend the barrier separating the sterile from the non-sterile components and personnel. The mode of attachment of the drape to the flange **603** can include, for example, a high strength adhesive that resists breakdown by heat, moisture and sterilizing gas.

[0090] As shown in **FIGS. 26A** through **26C**, a silicone keypad is encapsulated into the enclosure **150** and provides two buttons, one for power **154**, and one for actuation **155**. An alternative electronic module **60** with a different arrangement of the keypad buttons is shown in **FIG. 29**, in which the Power-on/Power-off button **154A** is separated from the actuation button **155A** by the LED indicator **156**. The electronic keypad **154A** and **155A**, and LED indicator **156** are integral to the battery/motor/gear box unit, and form the electronic module **60**, as shown in **FIG. 29**. The Power-on / Power-off button **154** enables the electronic module to either be turned on or off. The actuation button **155** may be depressed which would run the electronic module through one cycle. One cycle consists of a 360° needle **110** rotation accomplished through two 190° rotations of the output shaft **58**. The electronic module **60** interfaces with the enclosure **150** through the stop plate **66** mounted to the front of the electronic module **60**. The stop plate **66** has flat faces and a taper to engage into the enclosure **150**. This provides the connection to capture the torque applied within the unit so that the operator does not have to oppose the torque of the suturing operation (anti-rotation feature). The stop plate **66** also limits the rotation travel of the output shaft **58** to about 190°. A drive wheel is attached to the output shaft of the electronic module **60**. The

drive wheel contains a drive pin which engages with the drive plate of the front end assembly **70**. The drive pin supplies the torque to the front end assembly **70** to drive the needle **110** through the tissue. The drive wheel also contains two permanent magnets. These magnets are preferably used in conjunction with a Hall effect sensor **162** to detect the rotational extents of travel. A nose collar **157** attaches the front end assembly **70** to the housing **151** via screws **158** or some other means for mechanical engagement.

[0091] Three indicators (LEDs) **156** show the status of the unit: Power (Green), Error (Red) & Low Battery (Yellow). The housing **151** and keypad provide an exterior surface that is capable of sustaining hospital wipe-down procedures, but is not sterilizable in an autoclave. The electronic module software and operating features cause the needle driver arm to automatically move to its home position (reverse motion limit) when the Power-on /Power-off button **154** is initially activated (depressed). The unit will turn itself off after 10 minutes of inactivity in the event it is stored with the power on. Depressing the Power-on /Power-off button **154** during an actuation cycle will be ignored by the software. When the electronic module is switched On, the On LED indicator will illuminate and remain illuminated until switched Off. In one embodiment, triggering an actuation cycle to drive the needle through tissue by depressing the actuation button **155** will cause the device **50** to automatically power off at the end of the cycle. Once switched On or Off, the electronic module will stay in that condition until deliberately switched to the opposite condition, unless there is an error mode, the electronic module times-out from inactivity, or an actuation cycle has occurred. The electronic module has an Error LED (color red) to indicate an Error Mode. The electronic module also has a Low Battery LED (color Yellow) which indicates the internal battery needs to be charged. The actuation button **155** must be depressed for the device **50** to drive the tissue closure needle **110**. The actuation cycle begins when the actuation button **155** is depressed. The actuation button **155** does not have to remain depressed (i.e. the actuation cycle will complete if the button is released). The actuation button **155** only requires one depression to rotate the needle **110** 360° (the needle driver arm will automatically rotate 190° twice to accomplish rotating the needle **110** the full 360°) The actuation button **155** is operable so long as the device **50** is On and not already in a suturing sequence. The actuation button **155** must be released and the Power-on button **154** re-depressed before depression of the Actuation button **155** will again begin the next suturing cycle. The electronic Hall effect sensor **162** combined with the firmware sense the extent of the about 190 degree rotations

utilizing the permanent magnets in the drive wheel. Once the end of motion is detected the firmware modifies the torque applied to the motor to create a soft-stop. Some of the Error Modes that may occur during operation are listed in Table 1.

LED:	Power Green	Error Red	Low Battery Yellow	REM Status:
Off Mode	OFF	OFF	OFF	Unit is off and will not actuate
On Mode	ON	OFF	OFF	Unit is ready for use
Actuating	ON	OFF	OFF	Unit is actuating through a cycle.
Error Mode	ON	ON	OFF	Indicates an error occurred. Mechanism will return to home position and not actuate if actuation button is depressed.
Recharge Required	ON	OFF	ON	Battery needs to be recharged upon completion of surgery. i.e. unit can do 6 more complete sutures.
Battery drained	ON	ON	ON	Battery is drained. Unit will not actuate. Needs to be recharged.
Charging Battery	OFF	OFF	Blinking	Charging cycle. Device will not turn on or actuate while in this mode. Blinking rate TBD.
Battery Fully Charged	OFF	OFF	ON	Battery charging cycle is completed

Table 1

[0092] **FIG. 30** is a close-up view of the stop plate **66** and drive wheel **67** (shown as transparent), permanent magnets **65**, the drive pin **63** and the gear **59** shaft. At the center of the stop plate **66** there is a hole which provides the entry point for the gear **59** shaft. The stop plate **66** is attached to the gear box **59** by screws **69**. The stop plate **66** comprises a "U-shaped" track **64** in which the drive pin **63** rides. As the device is actuated, such that the electronic module causes rotation, the drive pin **63** will ride along the track **64** until the drive pin **63** reaches a stopping point. The track **64** provides the mechanical stops that limit the rotation of the device **50**. The permanent magnets **65** are used in conjunction with the Hall effect sensor **162** located at a distal end of an electronics board **161** located inside the removable electronic module **60** to detect the rotational extents of travel. The electronic Hall effect sensor **162** combined with the firmware sense the extent of the about 190 degree rotations utilizing the magnets **65** in the drive wheel **67**. Once the end of motion is detected the firmware modifies the torque applied to the motor **61** to create a soft-stop.

[0093] FIG. 26C shows the Hall effect sensor **162** located on the electronics board **161** that is used to detect the rotational position of the drive wheel **67**. When the rotation is nearing the stopping point, the magnets **65** pass adjacent to the Hall effect sensor **162**, sending a signal to the control electronics that the needle **110** will soon be stopping. At that point the motor torque is reduced. The motor continues to drive to the mechanical stopping point at the reduced torque level. When the drive pin 63 hits the mechanical stopping point, the control electronics sense the current spike that is caused by the motor not turning any more and shut off the power to the motor. At least two magnets **65** are positioned in the drive wheel **67** to sense the approach to stopping points at both ends of the arc traveled by the drive wheel **67**.

[0094] FIGS. **31A** and **31B** show the main components of the suturing device **50**. In FIG. **31A** the electronic module **60** has been drawn disengaged from the front end assembly **70**. During the disengaged stage, the torsion return spring **77** is extended to allow the pusher assembly **71** to return to a "home" position. In the home position, the drive plate **80** returns to a start position, such that a hole **84** in the drive plate **80** is ready to accept the drive pin **63**. As shown in FIG. **31B** the electronic module **60** has been attached to the front end assembly **70**. When the electronic module **60** is connected, the drive shaft **73** engages a bushing **67a** located in the drive wheel **67**; the drive pin **63** engages the hole **84** in the drive plate **80** and the device **50** is ready.

[0095] FIG. **32A** shows the curved suturing needle **110** having a tissue closing material attached. The needle **110** is formed as a circular split ring with the aperture (or gap) **111**, the sharp, pointed end **112** and the opposite blunt end **113**. The cylindrical bore **114** aligned axially with respect to the needle **110**, is located at the blunt end **113**. A flexible leader **136** of the tissue closing suture material is inserted into the blunt end **113** and can be restrained by mechanical engagement, for example mechanical crimping. Those skilled in the art will recognize that the flexible leader **136** may engage the needle **110** by any type of mechanical engagement including, but not limited to, welding, soldering, or laser welding. For example, the assembly comprising the flexible leader **136** inserted into the bore **114** of the needle can be immobilized in a clamp, and the junction circumferentially welded with a YAG laser welder or other suitable laser welder. The junction between the flexible leader and wire monofilament suture similarly can be welded or laser-welded. A suture-needle assembly welded in this manner can provide a smoother transition between the needle and

flexible leader, and between the flexible leader and the monofilament suture than mechanical crimping, which facilitates drawing the suture material through the tissue. Thus it is easier to pass the suture through the first side of the divided sternum, for example, while maneuvering the device **50** in preparation for placing a suture in the second side of the divided sternum. To enable the needle **110** to penetrate to the required depth, the needle **110** preferably has an arcuate extent between about 250° and about 330°.

[0096] For suturing through bone, it may be preferable to have a triple-faceted (or 'cutting-edge') needle point as shown in **FIG. 33A**, each facet occupying approximately 120° of the circumference of the needle shaft. As shown in **FIG. 33B**, One of the facets can be oriented to face the outside curvature of the needle, in which case the outside-facing facet can be cut at a shallower angle than the other two facets, preferably at an angle of approximately 21° with respect to the long axis of the needle shaft. The resulting cutting surface of the needle point as shown in **FIG. 33C** will have a shorter cutting height, leading to more efficient penetration of bony or other dense tissue. Alternatively, when placing the sutures around the outer or lateral edge of the sternum, the needle tip can be configured with a 'blunt taper-point' or 'ball-point'. The rounded tip and conical shape of the leading component of the needle shaft permits less traumatic penetration through softer tissues. Other applications may require sharper tipped 'taper-point' needles, or even 'reverse-cutting edge' needles.

[0097] The needle **110** has two symmetric notches **115a** and **115b** along the radially rear edge, i.e. the edge proximal to the cartridge holder assembly. The notch **115b** is positioned toward the sharp pointed end **112** of the needle **110**. The notch **115a** is positioned toward the blunt end **113** of the needle **110**. The notches **115a** and **115b** are located opposite to one another, each having a perpendicular (about 90°) segment and an angular segment that makes an angle of about 60° with the perpendicular segment. The notches **115a** and **115b** are engaged by the drive mechanism (pawl) in the cartridge holder assembly **72** and enable the needle **110** to undergo a rotational movement upon actuation of the drive mechanism, causing the needle **110** to penetrate and advance through the space spanning the split sternum, or other tissue location. A notch **116** is located on the radially outer edge ("outer notch") of the needle **110** proximally to the notch **115b** that is closer to the sharp pointed end **112**. The outer notch **116** engages with an anti-rotate and locking bar located in the cartridge holder assembly **72**, whereby rotation of the needle **110** in a direction opposite to the advancing

direction or "needle backing-up" is prevented. The positive engagement of the needle outer notch **116** during operation prevents the needle **110** from straying out of sequence during the suturing process. In addition, the blunt end or hub **113** of the needle **110** can also engage the anti-rotate bar **100** (or **300**, if the device has a separate locking pin), as seen in **FIG. 39C**, to prevent the needle **110** from reversing direction after it has traversed the aperture in the needle cartridge **90**.

[0098] The needle **110** is enclosed within a cartridge, so the sharp pointed end **112** is not exposed. This needle position, as loaded, is referred to as the "home" position. In the home position, the needle **110** is fully contained within the cartridge housing to eliminate needle-pricks during handling of the cartridge or the loaded device. The width of the aperture in the needle cartridge is comparable to and corresponds with the width of the gap in the needle **110** so that when the needle **110** is in the home position the needle **110** does not project materially into the aperture **111**. Such an alignment causes the needle **110** to reside entirely within the needle cartridge, thereby preventing inadvertent contact of the sharp pointed end **112** with the user's fingers during handling of the disposable needle cartridge for placement on the cartridge holder assembly or disposal after use, and while operating the suturing device **50**. Such protection of the needle **110** in the suturing device **50** prevents accidental "needle-pricks" from occurring, thereby substantially reducing the risk of infection caused by pathogenic bacteria or viruses that may contaminate the needle **110** during or after use prior to disposal. The needle **110** may be rotated in a curved track of the needle cartridge about the longitudinal axis of the suturing device **50** to advance the pointed needle end **112** so that the needle **110** first spans the aperture **111** and then returns to the home position.

[0099] **FIG. 32B** shows an expanded view of a crimp **137** that houses the ends of the two materials that form a tissue closure suture material. The tissue closing material includes the flexible leader **136** attached to a wire suture **138** by means of the crimp **137**. The crimp has an opening on each end, a first opening **137a** accepts the flexible leader **136** and a second opening **137b** accepts the wire suture **138**. The flexible leader **136** is placed into the first opening **137a** and then the crimp **137** is mechanically crimped to engage the flexible leader **136**. The wire suture **138** is placed into the second opening **137b** and then the crimp **137** is mechanically crimped to engage the wire suture **138**. Those skilled in the art will recognize that the crimp **137** may engage the flexible leader **136** and the wire suture **138** by any type of mechanical engagement including, but not limited to, welding, soldering, or laser welding.

The crimp **137** has a curved shape to make it easier to slide through the holes. The crimp **137** is streamlined and low profile to travel through tissue, cartilage or bone.

[00100] The flexible leader **136** has a diameter (gauge) that is larger or equal to the diameter of the wire suture **138**. The flexible leader **136** may be formed from a stainless steel material or by some other braided or monofilament material. In an embodiment, the flexible leader **136** is formed from wire cable. In an embodiment, the length of the flexible leader **136** is between about 8 inches to about 18 inches. The flexible leader **136** may be longer than 18 inches. The flexible leader **136** acts to improve ease of suture manipulation within the thorax, for example (under the sternum) during placement of each of the series of wire sternum closure sutures and thus make sternum closure faster and easier. The wire cable **138** may be formed from wire suture, such as stainless steel, made available in varying wire sizes, such as, for example, 5, 6, and 7. In an embodiment, the length of the wire suture **138** is at least 18 inches and may be longer than 18 inches. As shown in **FIG. 34**, the cartridge **90**, needle **110** and suture material **138** can form the components of a sterile kit, packaged in appropriate plastic/reinforced paper material **700**, which preferably can be peeled open to lay out the components onto a sterile field. The bottom web of the package can be thermoformable transparent plastic film, such as polyamide/polyethylene or polypropylene/polyethylene. This allows the contents of the sealed package to be visible. The top web can be sterilizable paper, such as Tyvek®, with a basic weight of about 60 gm/m^2 or more, allowing it to be permeable to sterilizing gas, so that the cartridge **90**, needle **110** and suture material **138** can be sterilized from within the package. The top and bottom webs are sealed along the periphery of the package using a suitable adhesive. The package preferably can be opened by hand, using peel-open corners and peelable seams.

[00101] The suturing device **50** is designed to be held in the dominant hand of the medical professional. **FIG. 35** shows an embodiment of a suturing device having a ergonomic handle **160**. **FIGS. 36A-C** show aspects of the front side of the device **50** with cartridge **90** attached. **FIGS. 37A-D** show aspects of the rear sides (**FIG. 37A** and **37B**), the bottom side (**FIG. 37C**) and the top side (**FIG. 37D**) of suturing device **50** without the cartridge **90**. **FIG. 38** shows an embodiment of a suturing device having a pistol-like handle **160**. The handle **160** is supplied non-sterile to the medical professional. The hospital or office is responsible for sterilizing the device **50** by techniques known in the art, such as gravity steam sterilization, Steris and ETO. In an embodiment shown in **FIG. 35**, the

electronic module **60** has been surrounded by a hollow handle/body that includes an activator button and may also include flush ports along the handle/body in order to provide a port of entry for cleaning fluids or suction such that the device **50** can be cleaned prior to or after use. In an embodiment shown in **FIG. 38**, the electronic module **60** has been surrounded by a different hollow handle that includes an activator button and may also include flush ports along the handle/body in order to provide a port of entry for cleaning fluids or suction such that the device **50** can be cleaned prior to or after use. Those skilled in the art will recognize that the battery pack **62** and electric motor **61** can be placed anywhere in the handle and be within the scope and spirit of the presently disclosed embodiments.

[00102] **FIGS. 39A, 39B, 39C** and **39D** show serial views of the "rear-drive" needle operating drive mechanism operating within the distal end of the cartridge holder assembly. The "rear-drive" mechanism comprises the drive arm **75** connected to a drive shaft that is capable of circular motion so as to "sweep" along the circular inner edge of the cartridge holder assembly. **FIG. 39A** shows the needle **110** in the "home" position. Initially, the pawl **95** has not made contact with the needle **110**. The drive arm **75** moves to engage a notch **115a** in the needle **110** (referred to as rest position). As shown in **FIG. 39B**, the gate assembly **105** is resting at stop pin **106**. Actuation of the device causes the drive shaft to rotate about 190° in a counterclockwise direction (referred to as position # 1), thereby causing the drive arm **75** to move circularly from its "home" rest position and move up to and past the gate assembly **105**, causing the gate assembly to pivot clockwise in the process so that the gate assembly **105** is now resting at the other stop pin **106**. The needle **110** is prevented from moving backwards by the anti-rotate and locking bar **100**. The needle **110**, in this position, is referred to as in a "penetrating-state" of the needle **110** cycle. As shown in **FIG. 39C**, the pawl **95** has been disengaged from the notch **115a** and the drive arm **75** continues to move circularly until it comes to rest once again in the "home" position, about 190° clockwise from position # 1 (this new position is referred to as position # 2). The pawl **95** then engages the notch **115b**. The gate assembly **105** has pivoted counterclockwise to rest again at the other stop pin **106**. **FIG. 39D** shows the pawl **95** engaged in the notch **115b** and the drive arm **75** continuing to move circularly until it is about 190° clockwise from position # 2 (this new position is referred to as position #3). The gate assembly **105** has pivoted clockwise again to rest at stop pin **106**. The needle **110** is pulled through the space between the tissue gap (e.g.,

split sternum) and the closing material follows. The drive arm 75 then returns back to the start home position by rotating 190° clockwise to the position shown in **FIG. 39A.**

[00103] In an embodiment, the handle of the suturing device **50** does not contain batteries, but is powered by electric power provided from outside the sterile field of the operating room (OR). In this external electric power embodiment, the device is configured with an autoclavable motor in the handle and a sterilizable power cord attached to the handle. The device would be connected with the sterilizable cord to a power supply unit that is located outside the sterile field in the operating room. That power unit would be plugged into wall power, and be able to convert the wall power (i.e., 120 volts or 240 volts) to voltage levels appropriate for the motor. The sterilizable cord transmits power to the hand-held unit which contains the motor and the needle driving mechanics. In addition, the control electronics could also be located in the external power unit rather than inside the handle. This change in configuration would reduce the size of the handle.

[00104] The suturing device **50** of the presently disclosed embodiments can be used for any procedure in which bony tissue or dense soft tissue closure is required. The tissue chosen should be sufficiently compliant to permit penetration by one of the variety of needle tips that can be used with the device. Other possible uses could include, for example, repair of injuries or incisions involving the attachment points of the rotator cuff, quadriceps tendon, patellar tendon or Achilles tendon, and rib reapproximation after lateral thoracotomy. In some of these cases, it may be advantageous to use non-metallic suture material attached to a needle that is compatible with the cartridge **90**, cartridge holder assembly **72**, and pusher assembly **71** of the device **50**. The non-metallic suture material can include, for example, braided or monofilament nylon, prolene or dacron, natural material such as silk or catgut, and synthetic absorbable material such as polyglycolic acid, polyglactin, polyglyconate or polydioxone.

[00105] Using a sternotomy procedure as an example, prior to the procedure, the handle of device **50** is sterilized in a hospital autoclave and delivered to the operating room in the same manner as any other piece of sterile surgical equipment. The battery pack **62** of the electronic module **60** has been charged using a charger and is brought into the non-sterile area of the operating room. As part of the routine set up of the surgical field in the operating room, a surgical scrub nurse will open the sterile package containing the sterilized handle of device **50**. The scrub nurse will then open the rear portal of the handle and will use standard

practice aseptic technique to present the open portal of the handle to a circulating nurse who is located outside of the sterile operating field. At this time, the scrub nurse can grasp a sterile funnel **600** by the flange **603** and insert it into the handle **160** of the device **50**. The circulating nurse will take the fully charged electronic module **60** and install the module **60** into the open rear portal of the handle **160** using standard aseptic technique. The circulating nurse can then grasp the flange **603** of the funnel **600** and withdraw it from the handle **160**, being careful not to make contact with any other component of the device **50**. To assist in this procedure, the circulating nurse can withdraw the funnel **600** by using a sterile forceps or clamp to grasp the flange **603**. The scrub nurse will close the portal, securing and sealing the electronic module **60** into the handle. The reusable device **50** is now ready for the loading of the disposable suture cartridge **90**.

[00106] When it is time to close the sternum, the scrub nurse will open the sterile disposable suture cartridges **90** that will be used in the case (a typical package will be a 6-pack). One suture cartridge **90** is loaded onto the cartridge holder assembly **72** of the device **50**. The device **50** is checked to make sure that the power light **154** is OFF, none of the LED lights **156** should be illuminated. The 10 o'clock and 2 o'clock slots on the needle cartridge **90** are aligned with the 10 o'clock and 2 o'clock tabs on the cartridge holder assembly **72**. The needle cartridge **90** is aligned with the cartridge holder assembly **72**, pushed onto the cartridge holder assembly **72**, and then rotated counterclockwise to lock the needle cartridge **90** in place. The locking pin **200** comes into alignment with the locking pin recess **202** of the cartridge **90**, at which point the locking pin **200** can engage the locking pin recess **202**. The needle brace **500**, if present, can be removed from the cartridge **90** after it has been secured to the cartridge holder assembly **72**. The Power On button **154** is then turned on. The green LED will come on, indicating the device **50** is ready. The actuation button **155** is then pressed to cycle the needle **110** once, prior to placing the device **50** in the surgeon's hand. The device **50** should cycle twice, causing the needle **110** to rotate one revolution. The device **50** is now ready to be used to place the first suture. The scrub nurse will hand the device **50** to the surgeon who will perform the suture placement process. Sutures are placed at the surgeon's discretion from top to bottom of the sternum. Typically about six to eight sutures are used to close the sternum. As an additional measure to enhance its operational safety, the device **50** can be programmed to have each actuation cycle require the operator to press the Power-on button **154** before pressing the actuation button **155**.

[00107] To commence the sternotomy closure, any embodiment of the sternotomy closure device **50** is placed at the site of the sternotomy such that the device **50** is between a first side and a second side of a split sternum, the typical starting point is around the manubrium 170 (or head) of the sternum as shown in **FIG. 40**. The surgeon will elevate one side of the divided sternum with his or her left hand. The surgeon places and aligns the opening (aperture) of the needle cartridge **90** over the cut edge of the sternum locating the penetration point he desires for the suture under the top of the cartridge opening. The surgeon can also use the lower edge of the cartridge holder assembly **72** to elevate the divided sternum during the suturing, obviating the need to place his or her hand under the sternum. The needle will enter the sternum from the exterior (outside) of the patient. The surgeon presses the Power-on button **154** prior to positioning the device **50**, and then presses the actuation button **155** while holding the device **50** in the desired location. When the button **155** is pressed, the following actions occur: The electronic controller starts the motor and gearbox rotating clockwise. This motion is transferred from the inside of the electronic module to the drive shaft by the following chain of components: Gearbox shaft to drive wheel to drive plate to the drive shaft to the drive arm. The drive arm holds the pawl. The pawl engages the rear drive notch of the needle. As the drive arm rotates through a first half circular arc, the pawl pushes the needle through a first half of one rotation. This is the stroke that penetrates the sternum. When the drive arm reaches the end of a stroke, the drive arm stops. The drive arm will then reverse direction and return to a start position. As soon as the drive arm reaches the start position, the drive arm stops again. The drive arm now starts to rotate clockwise again. The pawl picks up the front needle notch and pulls the needle through the completion of a stroke. When the drive arm reaches the end of this stroke, the drive arm stops. The drive arm will then reverse direction and return to a start position. As soon as the drive arm reaches a start position, it stops again, and the device **50** automatically powers down. The needle is now completely driven through the one side of the sternum. The flexible leader has been pulled into and through the hole created by the needle. The surgeon will now rotate the device **50** handle clockwise pulling the leader through the one side of the sternum. The surgeon's left hand may be used to assist pulling the flexible leader through the sternum. The surgeon will now elevate the other side of the sternum. The surgeon places and aligns the opening of the needle cartridge **90** over the sternum bone locating the penetration point he desires for the suture under the bottom of the needle

cartridge opening. After the surgeon presses the Power-on button **154**, followed by the actuation button **155**, the needle will enter the sternum from the interior (inside) of the patient. The steps are repeated. At this point, the flexible leader has passed through this side of the sternum. The surgeon may press the cartridge locking surface **101** located on the anti-rotate and locking bar and rotate the needle cartridge **90** clockwise to remove the needle cartridge **90** from the device **50**.

[00108] The device **50** may be passed to the scrub nurse for loading of a second needle cartridge **90**. The surgeon will now use both hands to pull the flexible leader and suture through both sides of the sternum following standard practice for any sternum closure suture. The needle, flexible leader and crimp ferrule are removed from the monofilament suture using standard practices. The surgeon now moves on to place a second suture. The process continues for all remaining sutures that the surgeon chooses to place, typically to an area near the xiphoid process **172**. After all desired sutures are placed, the sternum closure is completed using standard surgical techniques. The device **50** may be prepared for cleaning, sterilization and charging. A typical procedure may include: The clean up personnel will wipe down the outside of the device **50** with a disinfectant. The rear portal will be opened and the electronic module will be removed. The electronic module goes to non-sterile equipment storage for charging on the dedicated charger. The device handle will be cleaned to according to a validated cleaning protocol. The device handle will be sterilized according to a validated sterilization protocol.

[00109] A Teflon seal **57A** or an O-ring seal **57** between the pusher assembly and the cartridge holder assembly **72** provide a sterility barrier so that when the pusher assembly is driving the needle, the drive shaft will rotate within the Teflon seal **57A** or O-ring **57** which will prevent anything from migrating down the drive shaft and finding its way inside the handle of the tissue closure device **50**.

[00110] A method for sternum re-approximation is provided herein. The method includes (a) releasably engaging a cartridge having a protective housing and a suturing needle to a cartridge holder assembly of a sternotomy closure device; (b) placing the sternotomy closure device having the cartridge and the suturing needle to cause an aperture in the cartridge to be between a first side and a second side of a split sternum, wherein a pointed end of the suturing needle is positioned within the protective housing before and after a complete rotation of the suturing needle about a rotational axis; (c) activating an electronic

module coupled to a pusher assembly that releasably engages the suturing needle to cause rotational movement of the suturing needle across the aperture in the cartridge and advance the suturing needle through the first side of the split sternum; (d) pulling a suturing material attached to the suturing needle through the first side of the split sternum; and (e) repeating steps (c) and (d) for the second side of the split sternum forming a stitch through the first side and the second side of the split sternum. Steps (b) through (e) are repeated until a length of the first side and the second side of the split sternum have been re-approximated.

[00111] All patents, patent applications, and published references cited herein are hereby incorporated by reference in their entirety. It will be appreciated that various of the above-disclosed and other features and functions, or alternatives thereof, may be desirably combined into many other different systems or applications. Various presently unforeseen or unanticipated alternatives, modifications, variations, or improvements therein may be subsequently made by those skilled in the art which are also intended to be encompassed by the following claims. Thus, it is intended that the present invention include modifications and variations that are within the scope of the appended claims and their equivalents.

CLAIMS

What is claimed is:

1. A motorized suturing device comprising:

a) a needle disposed in a needle track, the needle track being adapted and configured to guide the needle along a curved path about an axis of rotation substantially parallel to the longitudinal axis of the device, the needle having:

i) a curved body, the curved body covering an arc less than about 330°; and

ii) an engagement surface for driving the needle; and

b) a housing containing a motorized drive, at least a portion of the drive being adapted and configured to reciprocate about the longitudinal axis, the drive having sufficient power to drive the needle through bony tissue of a patient.

2. The motorized suturing device of Claim 1, wherein a substantial portion of the motorized drive is removable from the sternotomy closure device as a module to facilitate sterilization of the device when the module is not installed.

3. The motorized suturing device of any of the preceding Claim 2, wherein the module comprises:

a) a power source for providing power to the suturing device; and

b) an electric motor adapted and configured to provide a sufficient force to rotate the needle about the longitudinal axis through bony tissue.

4. The motorized suturing device of Claim 2, wherein the module is received by a compartment within the housing, and wherein the compartment is sealed from the external environment.

5. The motorized suturing device of Claim 4, wherein the module may be removed from the compartment by opening a door at a proximal end of the housing.

6. The motorized suturing device of Claim 4, further comprising a funnel that may be removably disposed in the compartment when the module is being installed to maintain sterility.

7. The motorized suturing device of Claim 2, wherein the module includes a gear box to provide increased torque to advance the needle through bony tissue.

8. The motorized suturing device of Claim 7, wherein the gear box provides a reduction in gearing of about 100:1.

9. The motorized suturing device of Claim 1, wherein the engagement surface for driving the needle is defined on a surface displaced from a radially inner region of the curved body.

10. The motorized suturing device of Claim 1, wherein the needle includes suturing material disposed at a trailing end thereof, the suturing material including a flexible leader engaged to a wire suture.

11. The motorized suturing device of Claim 1, further comprising a cartridge for housing the needle, the cartridge including:

a) a housing having a curved shape, an inner wall and an outer wall;

b) a track defined in the inner wall of the housing whereby the suturing needle follows a curved path along the track during a revolution of the suturing needle; and

c) an aperture in the housing that intercepts the track, wherein the housing shields the pointed end of the suturing needle during at least a portion of the revolution of the suturing needle.

12. A suturing needle comprising:

a) a curved generally toroidal body with a first sharp pointed end and a second end, wherein the curved body has an arcuate extent less than about 330°;

b) at least one substantially planar engagement surface defined on the generally toroidal body displaced from a radially inner region of the generally toroidal body, the engagement surface being adapted and configured to receive a needle rotation drive of a suturing mechanism to facilitate driving the needle through a circular path; and

c) suturing material including a flexible leader engaged to a wire suture connected to the second end of the needle.

13. The suturing needle of Claim 12, wherein the flexible leader has a diameter larger than a diameter of the wire suture.

14. The suturing needle of Claim 12, wherein the flexible leader is a wire cable.

15. The suturing needle of Claim 12, wherein the engagement surface is formed at least in part by a notch formed in the generally toroidal body.

16. The suturing needle of Claim 12, further comprising a cartridge for housing the needle, the cartridge including:

a) a housing having a curved shape, an inner wall and an outer wall;

b) a track defined in the inner wall of the housing whereby the suturing needle follows a curved path along the track during a revolution of the suturing needle; and

c) an aperture in the housing that intercepts the track, wherein the housing shields the pointed end of the suturing needle during at least a portion of the revolution of the suturing needle.

17. The suturing needle of Claim 16, wherein the needle, leader and cartridge are contained in a sterilizable package that permits viewing of the package contents.

18. A method for tissue re-approximation comprising:

(a) releasably engaging a cartridge having a protective housing and a suturing needle to a cartridge holder assembly of a tissue closure device;

(b) placing the tissue closure device having the cartridge and the suturing needle to cause an aperture in the cartridge to be between a first side and a second side of a bony tissue segment, wherein a pointed end of the suturing needle is positioned within the protective housing before and after a complete rotation of the suturing needle about a rotational axis;

(c) activating an electronic module coupled to a pusher assembly that releasably engages the suturing needle to cause motorized rotational movement of the suturing needle

across the aperture in the cartridge and advance the suturing needle through the first side of the split bony tissue segment;

(d) pulling a suturing material attached to the suturing needle through the first side of the split bony tissue segment; and

(e) repeating steps (c) and (d) for the second side of the split bony tissue segment forming a stitch through the first side and the second side of the split tissue segment.

19. The method of claim 18 wherein steps (b) through (e) are repeated until a length of the first side and the second side of the split bony tissue segment have been re-approximated.

20. The method of claim 18 wherein the tissue segment is a split sternum requiring reapproximation.