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Systems, apparatus and methods for passing suture through soft tissue

Abstract

An apparatus for passing suture through biological tissue. The apparatus including a jaw mechanism adapted to grasp the tissue, a needle assembly having a needle, a jaw articulation system for inducing axial articulation of the jaw mechanism, a needle articulation system for inducing articulation of the needle, a suture control system for controlling ensnarement and release of a suture, and a multifunction actuation system having an actuation trigger. The multifunction actuation system adapted to sequentially induce the axial articulation of the jaw mechanism, the ensnarement of the suture and articulation of the needle during a single continuous rotation of the trigger.

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Background/Summary

CROSS-REFERENCES TO RELATED APPLICATIONS (1) This application claims the benefit of U.S. Provisional Application No. 63/456,513, filed on Apr. 2, 2023 and U.S. Provisional Application No. 63/602,605, filed on Nov. 26, 2023.

FIELD OF THE INVENTION

(1) As is well established, suturing is a fundamental aspect of many surgical procedures; particularly, surgical procedures that involve suturing soft tissues, such as fascia, muscles, ligaments, and tendons. The process of suturing soft tissue in a surgical site often involves employing a suture passing device to pass a suture through the soft tissue in a particular pattern to secure portions of soft tissue together or one or more portions of soft tissue to an implantable device.

BACKGROUND OF THE INVENTION

(2) As is well established, suturing is a fundamental aspect of many surgical procedures;

particularly, surgical procedures that involve suturing soft tissues, such as fascia, muscles, ligaments, and tendons. The process of suturing soft tissue in a surgical site often involves employing a suture passing device to pass a suture through the soft tissue in a particular pattern to secure portions of soft tissue together or one or more portions of soft tissue to an implantable device.

(3) Conventional suture passing devices, such as the device disclosed in U.S. Pat. No. 10,383,621 to Gregoire, et al., typically include an elongated shaft and a low-profile distal clamping mechanism to allow the clamping mechanism to be deployed in a surgical site via cannulas in less invasive surgical procedures. The conventional suture passing devices also typically include a jaw mechanism with top and bottom jaw members that are sized and configured to clamp onto soft tissue and fixate the soft tissue for passage of a suture therethrough.

(4) Conventional suture passing devices are also often designed and configured to position and secure a portion of a suture proximate to the distal end of a jaw mechanism. The system for capturing a suture between the top and bottom jaw members of such devices and through soft tissue typically includes a bendable needle, which advances into and through the elongated shaft and through an opening that is disposed on the distal end of the bottom jaw member.

(5) Most bendable needles of suture passing devices include suture capture means proximate to the distal end of the needle for capturing a portion of suture, which captures the portion of suture and allows the captured portion of suture to be drawn through soft tissue by an operator.

(6) Some conventional suture passing devices also include suture retainment means that is adapted and configured to retain a portion of suture (usually in a top jaw member of a jaw mechanism) after the portion of suture has been drawn through soft tissue for manipulation by the passing device in a surgical site, e.g., forming a particular suture pattern.

(7) Although conventional suture passing devices can be employed to suture soft tissues in a surgical site with some success, there are numerous drawbacks and disadvantages associated with the use of conventional suture passing devices, which include difficulties associated with controlling the direction of suture passage and manipulating a portion of suture in a confined surgical site, and an inability to pass suture through delicate or sensitive soft tissues.

(8) A further disadvantage associated with the use of conventional suture passing devices is that such devices do not provide an operator with optimal control over articulation of a jaw mechanism or needle articulation or suture retainment and release.

(9) Although some conventional suture passing devices provide means for jointly articulating a jaw and needle, such as the device disclosed in U.S. Pat. No. 10,383,621, operators of such devices typically have minimal, if any, control over the individual timing of the jaw and needle articulation.

(10) Such devices; particularly, the suture passing device disclosed in U.S. Pat. No. 10,383,621, are also devoid of any means for controlling the timing of suture retainment and release.

(11) A major drawback and disadvantage associated with the inability to control the timing of suture retainment and release is that an operator has minimal control over suture tension in a surgical site, which can, and most instances will, adversely affect the engagement of the suture to soft tissue, and limits the types of soft tissue that can be sutured by the device.

(12) A further disadvantage associated with conventional suture passing devices that are devoid of any means for controlling the timing of suture retainment and release is that the types of suture patterns that can be created with the devices are often limited.

(13) There is thus a need for improved suture passing systems, apparatus and methods that substantially reduce or eliminate the disadvantages and drawbacks associated with conventional suture passing systems, apparatus and methods.

(14) It is thus an object of the present invention to provide improved suture passing systems, apparatus and methods that substantially reduce or eliminate the disadvantages and drawbacks associated with conventional suture passing systems, apparatus and methods.

(15) It is another object of the present invention to provide improved suture passing systems,

apparatus and methods that provide optimal control of tissue engagement, needle articulation and suture retention and release.

(16) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that provide synchronized control of tissue engagement, needle articulation and suture retention and release with a single motion of a hand actuator requiring a single hand to actuate and thus allows the operator's other hand to be free at all times for manipulation and handling of other instrumentation (i.e., cannula, camera, etc.).

(17) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that provide automated control of suture retention and release with minimal complexity.

(18) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that provide independent manual means for releasing a tissue after retainment.

(19) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that facilitate suture passage into and through a myriad of soft tissue types.

(20) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that facilitate suture passage into and through biological tissue structures having a wide range of thicknesses.

(21) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that provide enhanced suture manipulation in a surgical site.

(22) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that can be readily employed to pass suture without collateral damage to extraneous soft tissue and bone structures.

(23) It is another object of the present invention to provide improved suture passing systems, apparatus and methods that reduce the time required to conduct suturing procedures and, thereby, attendant risks to a patient.

SUMMARY OF THE INVENTION

(24) The present invention is directed to systems, apparatus and methods for passing suture through biological tissue. In one embodiment of the invention there is thus provided an apparatus for passing suture through biological tissue, the apparatus comprising: a jaw mechanism adapted to grasp biological tissue, the jaw mechanism comprising top and bottom jaw members, the top jaw member adapted to axially articulate with respect to the bottom jaw member; a needle assembly comprising a needle, the needle comprising a tissue piercing distal end configured to releasably engage a suture; a jaw articulation system adapted to induce and control the axial articulation of the top jaw member with respect to the bottom jaw member; a suture control system comprising a suture engagement ribbon, the suture control system adapted to induce and control engagement and release of the suture engagement ribbon to the suture; a needle articulation system adapted to induce and control articulation of the needle and, thereby, the needle engagement to the suture; and a multifunction actuation system, the multifunction actuation system comprising an actuation trigger, the actuation trigger adapted to rotationally articulate from a default position to a fully actuated position, the default position comprising 0° rotation of the actuation trigger, the multifunction actuation system adapted to control the jaw articulation system, suture control system and needle articulation system, the control of the jaw articulation system, suture control system and needle articulation system comprising synchronized axial articulation of the top jaw member with respect to the bottom jaw member, the suture engagement and release, and the articulation of the needle during a first single continuous rotational articulation of the trigger, the first single continuous rotational articulation of the trigger comprising rotational articulation from the default position to the fully actuated position.

(25) In a preferred embodiment, the control of the jaw articulation system, the suture control system and the needle articulation system further comprises synchronized articulation of the

needle, the suture engagement and release, and the axial articulation of the top jaw member with respect to the bottom jaw member during a second single continuous rotational articulation of the trigger, the second single continuous rotational articulation of the trigger comprising rotational articulation from the fully actuated position to the default position.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) Further features and advantages will become apparent from the following and more particular description of the preferred embodiments of the invention, as illustrated in the accompanying drawings, and in which like referenced characters generally refer to the same parts or elements throughout the views, and in which:

(2) FIGS. 1A-1C are side plan views of an embodiment of a suture passing device in various stages of deployment, in accordance with the invention;

(3) FIG. 2A is a side plan view of a notch-less tubular needle comprising a preformed memory shape, in accordance with the invention;

(4) FIG. 2B is a side plan partial sectional view of a preformed tubular needle in a retracted, constrained state, in accordance with the invention;

(5) FIG. 3A is a perspective view of a lower jaw or tip of the device shown in FIG. 1A and a suture prior to loading in the tip, in accordance with the invention;

(6) FIG. 3B is another perspective view of the tip shown in FIG. 3A showing the slot formed in the tip, in accordance with the invention;

(7) FIG. 3C is a perspective partial sectional view of the tip, tubular needle, and suture shown in FIG. 3A, in accordance with the invention;

(8) FIG. 4A is a perspective partial sectional view of the tip and tubular needle shown in FIG. 3A showing a cleat member engaged to the suture, in accordance with the invention;

(9) FIG. 4B is a perspective view of the tubular needle shown in FIG. 3A and the cleat member disposed in the lumen thereof, in accordance with the invention;

(10) FIG. 4C is a perspective view of the cleat member shown in FIG. 4B, in accordance with the invention;

(11) FIG. 5A is a perspective view of the tubular needle shown in FIG. 4B comprising another embodiment of a cleat member disposed in the lumen thereof, in accordance with the invention;

(12) FIG. 5B is a perspective view of the cleat member shown in FIG. 5A, in accordance with the invention;

(13) FIG. 5C is a perspective view of the tip, tubular needle, the embodiment of the cleat member shown in FIG. 5A, and suture, in accordance with the invention;

(14) FIG. 6A is a partial side view of the tubular needle that is extended to engage and carry the suture through the aperture of the jaw mechanism and pawl, in accordance with the invention;

(15) FIG. 6B is a perspective view of the tubular needle that is extended to carry the suture through the aperture of the jaw mechanism and pawl shown in FIG. 6A, in accordance with the invention;

(16) FIG. 6C is a perspective view of the suture captured by the pawl shown in FIG. 6A, in accordance with the invention;

(17) FIG. 6D is a side plan view of the suture captured by the pawl shown in FIG. 6A, in accordance with the invention;

(18) FIG. 7A is a perspective view of another embodiment of a suture passing device comprising two tubular needles and a jaw mechanism with the left tubular needle extended through the aperture of the jaw mechanism, in accordance with the invention;

(19) FIG. 7B is a perspective view of the hand grip, toggle switch and needle assemblies of the suture passing device shown in FIG. 7A, in accordance with the invention;

(20) FIG. 8A is a side plan view of the tip shown in FIG. 6A with a slot and floating pivot mechanism in the collapsed state, in accordance with the invention;

(21) FIG. 8B is a perspective view of the floating pivot mechanism, in accordance with the invention;

(22) FIG. 8C is a side plan view of the tip shown in FIG. 6A with a slot and floating pivot mechanism in the expanded or vertically articulated state, in accordance with the invention;

(23) FIGS. 9A-9C are side plan views of another embodiment of a suture passing device in various stages of deployment, in accordance with the invention;

(24) FIG. 10A is a side plan partial sectional view of an elongated member distal tip and jaw mechanism of the suture passing device shown in FIG. 9A prior to loading a suture, in accordance with the invention;

(25) FIG. 10B is a side plan view of a preformed tubular needle, in accordance with the invention;

(26) FIG. 10C is a side plan partial sectional view of a preformed tubular needle retracted and constrained in the guide channel of the bottom jaw member, and the jaw mechanism set at a determined gap distance, in accordance with the invention;

(27) FIG. 11A is a perspective view of the elongated member distal tip and jaw mechanism of the suture passing device shown in FIG. 10A showing the pawl feature, in accordance with the invention;

(28) FIG. 11B is a side plan sectional view of the elongated member distal tip and jaw mechanism shown in FIG. 10A showing the track for the needle, in accordance with the invention;

(29) FIG. 11C is another side view of the tubular needle shown in FIG. 10B comprising two segments to match a guide channel track profile, in accordance with the invention;

(30) FIG. 12A is a perspective view of the suture passing device shown in FIG. 10A showing the elongated member distal tip, jaw mechanism, and tubular needle extended with suture, in accordance with the invention;

(31) FIG. 12B is a perspective view of the tubular needle and cleat member shown in FIG. 10A extended to engage and carry the suture through the aperture of the jaw mechanism, and pawl, in accordance with the invention;

(32) FIG. 12C is a side plan sectional view of the elongated member distal tip, jaw mechanism, tubular needle and cleat member shown in FIG. 10A, and the suture loaded on the distal end of the tubular needle, in accordance with the invention;

(33) FIG. 13A is a perspective view of the tubular needle of the suture passing device shown in FIG. 10A with a front-loaded suture, in accordance with the invention;

(34) FIG. 13B is a side plan sectional view of the elongated member distal tip, jaw mechanism, and tubular needle shown in FIG. 10A with a front-loaded suture, in accordance with the invention;

(35) FIG. 14 is a perspective view of another embodiment of the suture passing device comprising a jaw mechanism in the open position with the tubular needle fully retracted, showing the needle shield secured to the jaw mechanism top member, in accordance with the invention;

(36) FIG. 15 is a perspective view of tubular needle of the suture passing device shown in FIG. 14 that is extending from the guide channel of the bottom jaw member and transitioning to an unconstrained configuration, in accordance with the invention;

(37) FIG. 16 is a side plan view of the jaw mechanism bottom member shown in FIG. 14 showing the suture loading slot that is disposed on a lateral side of the bottom member, in accordance with the invention;

(38) FIG. 17 is a perspective view of the jaw mechanism shown in FIG. 14 with the suture laterally loaded in the jaw mechanism bottom member, in accordance with the invention;

(39) FIG. 18 is a perspective view of a tubular needle of the suture passing device shown in FIG. 14 extended from the guide channel of the bottom jaw member and transitioned to an unconstrained configuration with a suture engaged thereto, in accordance with the invention;

(40) FIG. 19 is a perspective view of the tubular needle shown in FIG. 18 with the cleat member

engaged with the suture, in accordance with the invention;

(41) FIG. **20** is a perspective view of the elongated member distal tip and jaw mechanism of the suture passing device shown in FIG. **14**, with the tubular needle shield in the default state, in accordance with the invention;

(42) FIG. **21** is a perspective view of the jaw mechanism shown in FIG. **20** with the tubular needle shield in the deflected state, thereby, shielding the tubular needle distal end from surrounding tissue in a surgical site, in accordance with the invention;

(43) FIG. **22** is a perspective view of the jaw mechanism shown in FIG. **20** with the needle shield in the deflected state, showing a window feature in the needle shield to prevent damage to the tubular needle distal end when the needle is extended into the needle shield, in accordance with the invention;

(44) FIG. **23** is a perspective view of another embodiment of the suture passing device, in accordance with the invention;

(45) FIG. **24A** is a perspective view of a jaw mechanism of the suture passing device shown in FIG. **23**, in accordance with the invention;

(46) FIG. **24B** is a partial side plan view of the jaw mechanism shown in FIG. **24A**, in accordance with the invention;

(47) FIG. **24C** is a top plan view of the jaw mechanism shown in FIG. **24A**, in accordance with the invention;

(48) FIG. **24D** is a further top plan view of the jaw mechanism shown in FIG. **24A**, having a cut away section showing a top jaw member ribbon track and a suture retaining ribbon positioned therein, in accordance with the invention;

(49) FIG. **24E** is a partial perspective view of a system needle, in accordance with the invention;

(50) FIG. **24F** is a partial perspective view of a bottom jaw member of the jaw mechanism shown in FIG. **24A**, showing a suture positioned thereon, in accordance with the invention;

(51) FIG. **24G** is a further partial perspective view of the bottom jaw member FIG. **24F**, showing the suture captured by the system needle shown in FIG. **24E**, in accordance with the invention;

(52) FIG. **25** is a partial perspective view of another embodiment of a jaw mechanism comprising a fixed pivot, in accordance with the invention;

(53) FIGS. **26** and **27** are side plan views of the suture passing device shown in FIG. **23**, showing the jaw articulation system, suture control system, and needle articulation system of the suture passing device, in accordance with the invention;

(54) FIG. **28** is a partial side plan view of the suture passing device shown in FIG. **23**, showing the suture control system of the device, in accordance with the invention;

(55) FIG. **29A** is a further partial side plan view of the suture passing device shown in FIG. **23**, showing the suture control switch of the device positioned in an auto-engagement mode, in accordance with the invention;

(56) FIG. **29B** is a further partial side plan view of the suture passing device shown in FIG. **23**, showing the suture control switch of the device positioned in a no-engagement mode, in accordance with the invention;

(57) FIG. **30** is a table reflecting the states of the jaw articulation system, suture control system, and needle articulation system throughout various stages of actuation of the suture passing device shown in FIG. **23**, in accordance with the invention;

(58) FIG. **31A** is a perspective view of another embodiment of the suture passing device, in accordance with the invention;

(59) FIG. **31B** is a partial perspective view of the suture passing device shown in FIG. **31A**, showing a suture release tab in a default position, in accordance with the invention;

(60) FIG. **31C** is a further partial perspective view of the suture passing device shown in FIG. **31A**, showing the suture release tab in an actuated position, in accordance with the invention;

(61) FIG. **32** is a side plan view of the suture passing device shown in FIG. **31A**, showing the jaw

articulation system, suture control system, and needle articulation system of the device, in accordance with the invention;

(62) FIG. 33 is a partial side plan view of the suture passing device shown in FIG. 31A, showing the suture control system shown in FIG. 32, in accordance with the invention;

(63) FIG. 34 is a partial side plan view of the suture passing device shown in FIG. 31A, showing a stage of the suture control system during actuation of the device control system, in accordance with the invention;

(64) FIG. 35A is a perspective view of yet another embodiment of the suture passing device, showing a manual suture release tab, in accordance with the invention;

(65) FIG. 35B is a partial perspective view of the suture passing device shown in FIG. 35A, showing the manual suture release tab in a suture release position, in accordance with the invention; and

(66) FIG. 36 is a table reflecting the automatic functions, i.e., states of the jaw articulation system and needle articulation system of the suture passing device shown in FIG. 31A throughout various stages of actuation, and the manual function, i.e., suture release, of the suture passing device, in accordance with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

(67) Before describing the present invention in detail, it is to be understood that this invention is not limited to particularly exemplified systems, apparatus, structures or methods as such may, of course, vary. Thus, although a number of systems, apparatus, structures and methods similar or equivalent to those described herein can be used in the practice of the present invention, the preferred systems, apparatus, structures and methods are described herein.

(68) It is also to be understood that, although the present invention is described and illustrated in connection with endoscopic procedures, the invention is not limited to such procedures. According to the invention, the apparatus, systems and methods of the invention can also be employed in connection with a multitude of other surgical procedures, including open surgical procedures.

(69) Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one having ordinary skill in the art to which the invention pertains.

(70) Further, all publications, patents and patent applications cited herein, whether supra or infra, are hereby incorporated by reference in their entirety.

(71) As used in this specification and the appended claims, the singular forms “a”, “an” and “the” include plural referents unless the content clearly dictates otherwise. Thus, for example, reference to “an active” includes two or more such actives and the like.

(72) Further, ranges can be expressed herein as from “about” one particular value, and/or to “about” another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent “about,” it will be understood that the particular value forms another embodiment. It will be further understood that the endpoints of each of the ranges are significant both in relation to the other endpoint, and independently of the other endpoint.

(73) It is also understood that there are a number of values disclosed herein, and that each value is also herein disclosed as “approximately” that particular value in addition to the value itself. For example, if the value “10” is disclosed, then “approximately 10” is also disclosed. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “10” is disclosed then “less than or equal to 10”, as well as “greater than or equal to 10” is also disclosed.

(74) In the following detailed description, reference is made to various specific embodiments in which the invention may be practiced. These embodiments are described with sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other

embodiments may be employed, and that structural and logical changes may be made without departing from the spirit or scope of the present invention.

(75) The words used in the description to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification the generic structure, material or acts of which they represent a single species.

(76) The present invention relates generally to systems and methods for the driving of a needle or suture through or into body tissue (typically, the needle will be affixed to a suture that remains in the tissue) using a cannula, introducer or other minimally invasive means. The methods and devices described herein can be used in any number of medical procedures, including but not limited to, approximating tissue (e.g., bring separated tissue together), ligating tissue (e.g., encircling or tying off), and fixating of tissue (attaching tissue to another structure or different tissue or an implantable device).

Definitions

(77) The terms “tissue”, “soft tissue” and “biological tissue” are used interchangeably herein, and mean and include mammalian biological tissue, such as, by way of example, human abdominal tissue.

(78) The term “biological cavity”, as used herein, means and includes any cavity or space in a mammalian tissue structure.

(79) The term “surgical site”, as used herein, means and includes any space or region in a mammalian tissue structure where a surgical procedure is conducted.

(80) The terms “patient” and “subject” are used interchangeably herein, and mean and include warm blooded mammals, humans and primates; avians; domestic household or farm animals, such as cats, dogs, sheep, goats, cattle, horses and pigs; laboratory animals, such as mice, rats and guinea pigs; fish; reptiles; zoo and wild animals; and the like.

(81) The term “endoscopy”, as used herein, means and includes any minimally invasive surgical procedure conducted through at least one opening in a subject's body, including, but not limited to arthroscopy, laparoscopy, hysteroscopy and the like.

(82) The terms “one configuration,” “one embodiment,” “one aspect,” and “a configuration,” “an embodiment” and “an aspect,” as used herein, means that a particular feature, structure, or characteristic described in connection with the configuration may be included in at least one configuration and not that any particular configuration is required to have a particular feature, structure or characteristic described herein unless set forth in the claim.

(83) The phrase “in one configuration” or similar phrases employed herein do not necessarily refer to the same configuration and, unless specifically stated, do not limit the inclusion of a particular element of the invention to a single configuration. The element may thus be included in other, or all configurations discussed herein.

(84) The term “substantially”, as used herein, means and includes the complete or nearly complete extent or degree of an action, characteristic, property, state, structure, item, or result to function as indicated. For example, an object that is “substantially” enclosed would mean that the object is either completely enclosed or nearly completely enclosed. The exact allowable degree of deviation from absolute completeness may in some cases depend on the specific context, such that enclosing nearly all of the length of a lumen would be substantially enclosed, even if the distal end of the structure enclosing the lumen had a slit or channel formed along a portion thereof.

(85) Use of the term “substantially” is equally applicable when used in a negative connotation to refer to the complete or near complete lack of an action, characteristic, property, state, structure, item, or result. For example, structure which is “substantially free of” a bottom would either completely lack a bottom or so nearly completely lack a bottom that the effect would be effectively the same as if it completely lacked a bottom.

(86) The term “comprise” and variations of the term, such as “comprising” and “comprises,” means

“including, but not limited to” and is not intended to exclude, for example, other components, elements or steps.

(87) The following disclosure is provided to further explain in an enabling fashion the best modes of performing one or more embodiments of the present invention. The disclosure is further offered to enhance the understanding and appreciation for the inventive principles and advantages thereof, rather than to limit in any manner the invention. The invention is defined solely by the appended claims, including any amendments made during the pendency of this application, and all equivalents of those claims as issued.

(88) As indicated above, the present disclosure is directed to devices and methods for passing suture through biological tissue; particularly, biological tissues that are accessed via an endoscopic procedure.

(89) As is well known in the art, both open and endoscopic surgical procedures often require sutures to ligate, join or otherwise treat tissue. Generally, suture needles with attached suture strands are grasped either manually or by forceps and passed through the desired work site so a knot can be tied. Although such surgical procedures are fairly uncomplicated in open surgery procedures where most suture sites are readily accessible, surgeons must often use auxiliary devices to grasp the suture strands and pass them through desired tissue in endoscopic procedures where access to a desired suture site is not readily available.

(90) Referring now to FIG. 1A, there is illustrated one embodiment of a suture passing device, or instrument of the present invention. As illustrated in FIG. 1A, the suture passing device comprises an elongated tubular body **10**, a hand grip **20**, a tip **30**, a jaw mechanism **40**, an actuator **50** and a needle assembly **60**.

(91) According to the invention, with actuator **50**, a surgeon can seize and maintain tissue by movement of the jaw mechanism **40** against tip **30**, as shown in FIG. 1B. Using actuator **50**, a surgeon can also deploy a tubular needle **70** carrying a suture **71** through tissue, as shown in FIG. 1C and described below.

(92) Referring now to FIG. 2A, there is illustrated one embodiment of a needle of the invention, i.e., a notchless tubular needle **70**, in its natural state.

(93) As used throughout the specification, the term “notchless” shall refer to the absence of notches, slots, eyelets, or other such transverse openings for receiving suture as typically formed in needles of prior art suture passers.

(94) According to the invention, the needle **70** can also comprise a solid structure.

(95) As illustrated in FIG. 2A, the distal end **80** of the needle **70** is formed in a non-straight geometry.

(96) As illustrated in FIG. 2B, the needle **70** comprises a formed end **80** sheathed in a constraining channel **91**. In a preferred embodiment, the needle channel **91** also includes a curvilinear portion **90**, or guide-path, which approximates the same geometry curve as the distal end **80** of the needle **70**, thereby facilitating the consistent return of the needle **70** to its preformed curved shape each time the needle **70** exits the channel.

(97) According to the invention, the constrained state needle **70** contained in the needle assembly **60** is loaded into the handle end of the elongated tubular body **10** and advanced through a track in the tubular body **10**.

(98) FIG. 1A illustrates the hand grip **20** and actuator **50** of the suture passing device, which, as set forth in Applicant's Co-pending U.S. application Ser. No. 17/891,328, provide articulation of jaw **40** relative to tip **30**.

(99) As set forth in Co-pending U.S. application Ser. No. 17/891,328 and illustrated in FIGS. 3A and 3B, a loop of suture **71** is loaded into distal end of tip **30** with slot **31**. According to the invention, the slot **31** facilitates spring action for gripping the loop of suture **71** when the loop of suture **71** is guided into the tip **30**.

(100) In one embodiment of the invention, illustrated in FIG. 3C, tubular needle **70** pierces the loop

of suture **71** and, thereby, creates a bifurcation **72** in the suture **71**.

(101) According to the invention, when additional force is applied to the suture **71**, the bifurcation **72** advances along the shaft of the needle **70**.

(102) As further set forth in Co-pending U.S. application Ser. No. 17/891,328 and illustrated in FIG. **4A**, to prevent the bifurcation **72** from advancing along the shaft of the tubular needle **70**, in some embodiments, a prong cleat **73** is positioned in the tubular needle **70** and adapted to pierce the loop of suture **71** loop in a second location. According to the invention, the pierce of the prong cleat **73** can partially engage the thickness of the suture **71** or create a second bifurcation **74** in the suture.

(103) As illustrated in FIG. **4C**, in a preferred embodiment, the prong cleat **73** comprises a wire rod or tube that is housed within the lumen **79** of the tubular needle **70**. As further illustrated in FIG. **4C**, the prong cleat **73** comprises a sharp distal tip, which slightly extends from the lumen **79** of the tubular needle **70**, as illustrated in FIG. **4B**. The piercing action of the needle **70** and the prong cleat **73** at different locations in the suture **71** act in conjunction to stabilize the suture **71** and prevent the suture **71** from advancing along the shaft of the needle **70**.

(104) Referring back to FIG. **3C**, in another embodiment, tubular needle **70** pierces the loop of suture **71** and creates a bifurcation **72** in the suture **71**. When additional force is applied to the suture **71**, the bifurcation **72** advances along the shaft of the needle **70**. To prevent the bifurcation **72** from advancing along the shaft of the needle **70**, a lateral post cleat **75**, illustrated in FIG. **5A**, is positioned to engage the bifurcated section of the suture **71**, as illustrated in FIG. **5C**.

(105) Referring now to FIGS. **6A** and **6B**, there is illustrated a jaw mechanism **40** having an aperture **41** therein, which is sized and configured to receive tubular needle **70** and suture **71** and allow tubular needle **70** and suture **71** to pass through.

(106) As illustrated in FIGS. **6B** and **6C**, the jaw mechanism further comprises a retractable pawl **42**, which includes a window **43** that aligns with aperture **41** when the retractable pawl **42** is extended forward in the open position. When the tubular needle **70** and suture **71** are deployed within aperture **41** via actuator **50**, the retractable pawl **42** is then moved to a retracted or rearward position, as illustrated in FIG. **6C**. In some embodiments, the retractable pawl actuation mechanism includes a spring bias to provide a relatively constant force of the retractable pawl **42** against the deployed tubular needle **70** and suture **71**.

(107) As set forth in Co-pending U.S. application Ser. No. 17/891,328, upon release of the actuator **50**, a spring in the actuator mechanism returns the tubular needle **70** to the constraining channel **90**. The spring bias of the retractable pawl **42** allows the tubular needle **70** to return yet allows the retractable pawl **42** to maintain a grip on the suture **71** and pulls it in a rearward movement to become captured in between the proximal edge **44** of the aperture **41** in the jaw **40** and distal edge **47** of pawl window **43**, as is shown in FIGS. **6C** and **6D**. Complete release of the actuator **50** disengages the jaw mechanism **40** to the default open position, thus, completing the passage of suture **71** through the tissue.

(108) As further set forth in Co-pending U.S. application Ser. No. 17/891,328, in some embodiments, the suture passing device is configured to comprise two (2) or more tubular needles **70**. In one embodiment, the suture passing device can throw more than one segment of suture **71** through tissue simultaneously. An exemplar two needle suture passing device is illustrated in FIG. **7A**, which shows a left tubular needle **74** and a right tubular needle (denoted “**75**”, but not illustrated) after being released to their natural states.

(109) The segments of suture being passed by multiple tubular needles **70** can be attached to form a continuous loop of suture, thus enabling the formation of a desired suture pattern, e.g., a horizontal mattress stitch.

(110) In some embodiments of the invention, the suture passing device is configured to deploy the left needle **74** and right needle **75** independently.

(111) Referring now to FIG. **7B**, there is illustrated another embodiment of handle mechanism **20**

that is adapted to modulate multiple needles independently. As illustrated in FIG. 7B, the handle mechanism **20** comprises a switch **61** to toggle and engage one needle assembly at a time in the drive track **60**. When the switch **61** is toggled to engage the left needle assembly **64**, the jaw mechanism **40** can be actuated to grasp a desired location of tissue and the left tubular needle **74** is deployed to pass and capture suture in a first tissue location.

(112) As further set forth in Co-pending U.S. application Ser. No. 17/891,328, fully releasing the actuator **50** returns the left tubular needle **74** to its constrained state and disengages jaw mechanism **40**. The suture passing device can then be repositioned to a second desired tissue location. When the switch **61** is toggled to engage the right tubular needle **75**, the jaw mechanism **40** can be actuated to grasp a second desired location of tissue and the right needle **75** is deployed to pass and capture suture in a second tissue location. Fully releasing the actuator **50** returns the right tubular needle **75** to its constrained state and disengages jaw mechanism **40** from tissue. The suture passing device can then be removed from the cannula to expose the two ends of the suture.

(113) As further set forth in Co-pending U.S. application Ser. No. 17/891,328 and illustrated in FIGS. **8A-8C**, in some embodiments, the suture passing device described above comprises a floating pivot mechanism to facilitate a lower profile when the jaw mechanism **40** and tip **30** are separated. In some embodiments, the jaw mechanism **40** thus includes a pivot interface **36** with a linkage **35**. At the opposite end of linkage **35** is another pivot interface **37** that joins linkage **35** and drive rod **38**.

(114) As illustrated in FIGS. **8A** and **8B**, the tip **30** includes a slot **31** in which a pin **39a** slidably translates within. The pin **39a** is fixed to jaw mechanism **40**. Axial movement of drive rod **38** in relation to the tip **30** causes jaw mechanism **40** to rotate about pin **39a** in relationship to the tip **30**.

(115) As further illustrated in FIGS. **8A** and **8B**, a leaf spring **45** exerts a force on the pin **39a** to bias the pin **39a** against the lower end of slot **31**, thus, resulting in the jaw mechanism **40** being positioned in a collapsed state and the gap **92** between the inner surfaces of the tip **30** and jaw mechanism **40** being minimized.

(116) The collapsed state of the jaw mechanism **40** is advantageous for providing a minimum profile for advancing the device through an access cannula. According to the invention, the device can be configured to be advanced into the through an access cannula having a diameter in the range of 2.0 mm-15.0 mm, more preferably, in the range of 5.0 mm-8.0 mm.

(117) When the tip **30** and jaw mechanism **40** are positioned proximate tissue, advancement of the drive rod **38** causes the jaw mechanism **40** to rotate about pin **39a** to clamp onto the tissue. The resisting force of the tissue to compression between tip **30** and the jaw mechanism **40** results in a force applied to the inner surface of the jaw mechanism **40**. If the force applied to the inner surface of the jaw mechanism **40** exceeds the force of the leaf spring **45** provided to hold the pin **39a** against the lower end of slot **31**, the pin **39a** will ride up the slot **31**, and increase the gap **92** between the inner surfaces of tip **30** and the jaw mechanism **40**, as illustrated in FIG. **8C**.

(118) In some embodiments, the gap **92** between the inner surfaces of tip **30** and the jaw mechanism **40** comprises a width in the range of 0.5 mm-5.0 mm, more preferably, a width in the range of 1.5 mm-3.3 mm.

(119) Referring now to FIGS. **9A-9C**, there is shown another embodiment of a suture passing device **100** at various stages of actuation. As illustrated in FIG. **9A**, the suture passing device **100** of the present invention comprises a hand grip **102** in operative communication with elongated tubular body or member **104** having a distal end **110**.

(120) As further illustrated in FIG. **9A**, hand grip **102** comprises a proximal end **103**, an actuator **106** and a needle assembly **108**, and elongated tubular member **104** comprises a jaw mechanism **112** having top and bottom members **114a**, **114b** disposed proximate the elongated tubular member **104** distal end **110**. In a preferred embodiment, the jaw mechanism **112** top and bottom members **114a**, **114b** comprise proximal and distal ends.

(121) In a preferred embodiment, the jaw mechanism **112** of the suture passing device **100**

similarly comprises the floating pivot mechanism and pivot interface discussed above and shown in FIGS. 8A-8C to facilitate a lower profile when the top and bottom members **114a**, **114b** of jaw mechanism **112** are separated and during axial articulation of the top and bottom members **114a**, **114b**.

(122) In the noted embodiments, the jaw mechanism **112** preferably comprises first and second pins **39a**, **39b**, the proximal end of the jaw mechanism **112** top member **114a** comprises first and second pin lumens, and the proximal end of the jaw mechanism **112** bottom member **114b** comprises a third pin lumen and a pin slot **31**.

(123) Preferably, the first pin lumen and the pin slot **31**, and the second and third pin lumens are in axial alignment.

(124) In a preferred embodiment, the jaw mechanism **112** top member **114a** first pin lumen and the bottom member **114b** pin slot **31** are configured to receive and position the jaw mechanism **112** first pin **39a**, wherein, when the jaw mechanism **112** first pin **39a** is received by and positioned in the jaw mechanism **112** top member **114a** first pin lumen and the bottom member pin slot **31**, the jaw mechanism **112** top member **114a** is allowed to vertically or linearly articulate with respect to the jaw mechanism **112** bottom member **114b**.

(125) In a preferred embodiment, the jaw mechanism **112** top member **114a** second pin lumen and the bottom member **114b** third pin lumen are configured to receive and position the jaw mechanism **112** second pin **39b**, wherein, when the jaw mechanism **112** second pin **39b** is received by and positioned in the jaw mechanism **112** top member **114a** second pin lumen and the bottom member third pin lumen, the jaw mechanism **112** top member **114a** is allowed to axially or rotatably articulate with respect to the jaw mechanism **112** bottom member **114b**.

(126) According to the invention, any of the embodiments of the jaw mechanisms described herein can comprise the floating pivot mechanism and pivot interface discussed above and shown in FIGS. 8A-8C.

(127) According to the invention, the suture passing device **100** can be used to capture and maintain biological tissue by positioning the jaw mechanism **112** of the suture passing device **100** proximate the tissue applying a first radial force on the actuator **106** to transition the top and bottom members **114a**, **114b** of jaw mechanism **112** from an open configuration, as illustrated in FIG. 9A, to a closed configuration, as illustrated in FIG. 9B. A second radial force can also be applied to actuator **106** to deploy a tubular needle **116** having a suture attached thereto into and through the tissue, as illustrated in FIG. 9C and discussed in detail below.

(128) In a preferred embodiment, the actuator **106** provides axial articulation of top member **114a** relative to bottom member **114b** of jaw mechanism **112**. In some embodiments, the actuator **106** can be coupled to a return spring (not shown) that biases the actuator **106** in the open configuration shown in FIG. 9A.

(129) In some embodiments of the invention, the actuator **106** of the hand grip **102** comprises a spring-loaded mechanism that is configured to provide a resistance force on the actuator **106** to provide tactile feedback for the operator to indicate that the tubular needle **116** is slidably translating into and through the jaw mechanism **112**.

(130) Referring now to FIG. 10A, there are shown top and bottom members **114a**, **114b** of jaw mechanism **112** in an open configuration. As illustrated in FIG. 10A, the top member **114a** comprises a guide channel **118a** and the bottom member **114b** comprises a guide channel **118b**. In a preferred embodiment, the guide channels **118a**, **118b** are sized and configured to receive tubular needle **116** of the invention therein.

(131) As further illustrated in FIG. 10A, in a preferred embodiment, guide channel **118b** is in aligned communication with the elongated member **104** internal lumen **105**.

(132) Referring now to FIGS. 10B and 11C, there is shown tubular needle **116** in a first natural state comprising a distal end **120** and internal lumen **122**. As illustrated in FIG. 10B, the tubular needle **116** comprises a formed curvilinear portion **150**.

(133) In some embodiments, the tubular needle **116** comprises multiple curvilinear sections **150** to slidably translate into and through the guide channels **118a**, **118b**. According to the invention, the curvilinear portion **150** of the tubular needle can comprise any suitable shape where 6.0% strain is not exceeded.

(134) In a preferred embodiment, the tubular needle **116** comprises nickel-titanium alloy (Nitinol®) and is configured to transition (or deform) from an unconstrained or natural state to a constrained state, and from the constrained state back to the unconstrained state. As illustrated in FIG. **10B**, in a preferred embodiment, the unconstrained state tubular member **116** comprises formed curvilinear portion **150**.

(135) As shown in FIG. **10C**, in some embodiments, the tubular needle **116** is adapted to transition or deform into a constrained state when the curvilinear portion **150** of the tubular needle **116** is advanced through the elongated tubular member **104** internal lumen **105** and into guide channel **118b** of the jaw mechanism **112** bottom member **114b**.

(136) In some embodiments, the curvilinear portion **150** of the tubular needle **116** is adapted to reassume a curvilinear shape upon further advancement out of guide channel **118b** and into and through guide channel **118a** of the jaw mechanism **112** top member **114a**.

(137) In some embodiments, the tubular needle **116** comprises a hollow and rigid structure. In some embodiments, the tubular needle **116** comprises geometry where the area moment of inertia about the neutral bending axis is in the range of 20.0×10^{-9} to 300.0×10^{-9} inches to the 4th power, more preferably, the tubular needle comprises a geometry where the area moment of inertia about the neutral bending axis is in the range of 25.0×10^{-9} to 75.0×10^{-9} inches to the 4th power, which allows the tubular needle **116** to be driven into biological tissue with minimal deflection or skiving.

(138) According to the invention, the tubular needle **116** distal end **120** can comprise various configurations, including, but not limited to, a beveled, curved, and serrated edge, which is configured to pierce through biological tissue.

(139) In a preferred embodiment, the tubular needle **116** distal end **120** comprises a beveled edge having an angle “ α ” in the range of approximately 1° - 90° with respect to the longitudinal axis “LA” of the tubular needle **116**. More preferably, the angle “ α ” of the beveled distal end **120** is in the range of approximately 45° - 90° .

(140) In some embodiments, the needle **116** comprises a solid structure.

(141) Referring now to FIG. **10C**, there are shown top and bottom members **114a**, **114b** of jaw mechanism **112** in a closed configuration comprising tubular needle **116** disposed in the guide channel **118b** of bottom member **114b**. As illustrated in FIG. **10C**, the top and bottom members **114a**, **114b** of jaw mechanism **112** comprise a reciprocating curvilinear configuration that is configured to align guide channels **118a**, **118b** and, thereby, approximate the same curvilinear shape or configuration as the formed curvilinear portion **150** of the tubular needle **116** when the jaw mechanism **112** is in a closed configuration.

(142) As further illustrated in FIG. **10C**, when the top and bottom members **114a**, **114b** of jaw mechanism **112** are in a closed configuration the top and bottom members **114a**, **114b** are configured to be partially closed at a set distance d_i from each other.

(143) In some embodiments, the top and bottom members **114a**, **114b** are configured to fully close to facilitate passage through an access cannula.

(144) In a preferred embodiment, the needle assembly **108** and the tubular needle **116** in communication therewith are engaged to the proximal end **103** of hand grip **102** and the tubular needle **116** is slidably transitioned into and through the elongated tubular member **104** internal lumen **105** in a constrained state.

(145) Referring now to FIGS. **11A** and **11B**, there is illustrated pawl **124** of the top member **114a** of jaw mechanism **112**. As illustrated in FIGS. **11A** and **11B**, the pawl **124** comprises a distal end **126** and intersects the guide channel **118a** and, hence, the path defined by the guide channel **118a**.

(146) As further illustrated in FIG. 11A, the bottom member **114b** of jaw mechanism **112** comprises a capture lip **128** that is configured to facilitate the capture of a portion of suture **71** shown in FIG. **12B**.

(147) As further set forth in Co-pending U.S. application Ser. No. 17/891,328, in some embodiments, the pawl **124** is used as a suture capturing mechanism. Referring now to FIG. **12C**, when the tubular needle **116** guides the suture **71** into the guide channel **118a** the pawl **124** is deflected, which allows the suture **71** to be guided beyond the distal end **126** of the pawl **124** by tubular needle **116**.

(148) According to the invention, when the tubular needle **116** is retracted from the guide channel **118a** past the pawl **124**, the distal end **126** of pawl **124** exerts a closure force on the suture **71** and captures the suture **71** between the pawl **124** distal end **126** and the inner wall **119** of guide channel **118a**.

(149) Referring now to FIGS. **12B** and **12C**, there is shown suture **71** having a distal end **77** that is loaded onto the distal end **120** of the tubular needle **116**. As illustrated in FIGS. **12B** and **12C**, the distal end **120** of tubular needle **116** is configured to pierce at least a portion of suture **71**.

(150) As further illustrated in FIG. **12B**, in a preferred embodiment, the distal tip **120** of tubular needle **116** is configured to pierce and form a bifurcation **72** in the suture **71**.

(151) As illustrated in FIGS. **12B** and **12C**, in some embodiments, the tubular needle **116** comprises a cleat member **130** having a piercing distal end **132** and is positioned in the tubular needle **116** internal lumen **122** and configured to pierce and engage at least a portion of the suture **71**.

(152) In a preferred embodiment, the tubular needle **116** distal end **120** and the cleat member **130** distal end **132** are adapted to pierce and engage suture **71** at two (2) predetermined locations on the suture **71** to secure the suture **71** thereto.

(153) Referring now to FIGS. **13A** and **13B**, there is illustrated distal end **77** of suture **71** front loaded into the internal lumen **122** of the tubular needle **116** distal end **120**. As illustrated in FIGS. **13A** and **13B**, the bend in the distal end **77** of the suture **71** provides a strain relief section that functions to releasably secure the distal end **77** of the suture **71** to the tubular needle **116** distal end **120** for penetration and advancement into biological tissue. According to the invention, when the tubular needle **116** is retracted from biological tissue, at least a portion of suture **71** is captured and retained by the biological tissue.

(154) As illustrated in FIG. **13B**, in some embodiments, the suture **71** distal end **77** is engaged by the distal end **126** of pawl **124**, wherein the suture **71** distal end **77** is captured between the distal end **126** of pawl **124** and the inner wall **119** of the guide channel **118a**.

(155) Referring now to FIGS. **14-19**, there is shown another embodiment of a jaw mechanism (now denoted “**212**”) comprising top and bottom members **214a**, **214b** and a suture retriever component (or needle shield) **250** that is secured to the jaw mechanism **212** top member **214a**.

(156) As illustrated in FIGS. **14-16**, the jaw mechanism **212** bottom member **214b** similarly comprises a guide channel **218b** that is configured to receive tubular needle **116** having cleat member **130** disposed in the internal lumen **122** thereof. As further illustrated in FIGS. **14-16**, in a preferred embodiment, the guide channel **218b** comprises a curvilinear shape or geometry that is configured to approximate the same curvilinear shape or configuration as the formed curvilinear portion **150** of the tubular needle **116**.

(157) In a preferred embodiment, guide channel **218b** is in aligned communication with the elongated member **104** internal lumen **105**.

(158) As illustrated in FIG. **16**, the jaw mechanism **212** bottom member **214b** comprises a suture loading slot **232** that transects the guide channel **218b** of the bottom member **214b**.

(159) As illustrated in FIG. **17**, in a preferred embodiment, the suture **71** is loaded into the suture loading slot **232** from either lateral side, whereby the suture **71** is allowed to slidably translate therethrough and intersect a path defined by the guide channel **218b**, wherein the suture **71** can be engaged by the tubular needle **116** as it is slidably translated through guide channel **218b**.

(160) As illustrated in FIGS. **18** and **19**, in a preferred embodiment, when the tubular needle **116** comprising cleat member **130** disposed therein is slidably translated through guide channel **218b**, the cleat member **130** distal end **132** pierces and engages at least a portion of suture **71**. As the tubular needle **116** is slidably translated further through the guide channel **218b** of jaw mechanism **212** bottom member **214b**, the tubular needle **116** drives the portion of suture **71** forward and into the window **254** of the jaw **212** mechanism top member **214a**.

(161) As further illustrated in FIG. **18**, in a preferred embodiment, the curvilinear portion **150** of the tubular needle **116** is adapted to transition from a constrained state to an unconstrained state and reassume a curvilinear shape upon further advancement out of guide channel **218b**.

(162) Referring now to FIGS. **20-22**, when the tubular needle **116** is slidably translated through the guide channel **218b** and into the window **254** of the jaw mechanism **212** top member **214a**, the tubular needle **116** is guided into needle shield **250**. As illustrated in FIG. **20**, in a preferred embodiment, the needle shield **250** comprises a deflecting trapdoor mechanism that is configured to prevent the tubular needle **116** from penetrating biological tissue and bone beyond the top member **214a** and damaging the biological tissue and bone. In a preferred embodiment, the needle shield **250** is configured to deflect and flex when the tubular needle **116** distal end **120** is slidably translated into the needle shield **250**.

(163) In a preferred embodiment, the needle shield **250** of the jaw mechanism **212** top member **214a** enables antegrade and retrograde passing of suture **71** during an endoscopic procedure, which allows an operator to generate a wide variety of stitch patterns including, without limitation, modified Mason-Allen, mattress, sliding mattress, Mason-Allen, far-near-near-far, Bunnell-Mayer, three-loop pulley, locking loop, modified Kessler, simple interrupted, simple continuous, Ford interlocking, interrupted cruciate, interrupted horizontal mattress, continuous horizontal mattress, interrupted vertical mattress, quilled, interrupted or continuous Lembert, interrupted quilt, Cushing, Connel, Parker-Kerr, purse string and modified variants thereof.

(164) In some embodiments, the needle shield **250** is configured to provide a closure force that captures the suture **71** when the tubular needle **116** is retracted and the needle shield **250** is relieved from the force applied to the needle shield **250** by slidable translation of the tubular needle **116**.

(165) As illustrated in FIGS. **20-22**, in a preferred embodiment, the needle shield **250** comprises a window member **252** that is configured to protect the distal end **120** of tubular needle **116** from damage. According to the invention, the needle shield **250** can comprise other features to protect the distal end **120** of tubular needle **116**, such as a coined recess or other geometry that is configured to receive the distal end **120** of tubular needle **116** without damaging the distal end **120**.

(166) According to the invention, the window member **252** can comprise any shape or size suitable to receive the distal end **120** of tubular needle **116** without damaging the distal end **120**.

(167) Referring now to FIGS. **23-28B**, there is shown another embodiment of a suture passing device of the invention (denoted “**400**”).

(168) As illustrated in FIGS. **23** and **24A**, the suture passing device **400** similarly comprises a body **402**, comprising proximal and distal ends **401a**, **401b**, a handle **404**, a trigger **406**, and an elongated member or shaft **410** that similarly comprises a jaw mechanism (denoted “**460**” in this embodiment), which is adapted to grasp biological tissue.

(169) As illustrated in FIGS. **24A** and **24B**, the jaw mechanism **460** similarly comprises top and bottom jaw members **462**, **464**. As further illustrated in FIGS. **24A** and **24B**, the bottom jaw member **464** similarly comprises a guide channel **478** that is configured to receive a needle of the invention; preferably, needle **170** illustrated in FIG. **24E** and discussed below, thereon, and a suture loading slot **472** that similarly allows a suture **71**, to be loaded therein from either lateral side of the jaw mechanism **460**, as illustrated in FIG. **24F**, whereby the suture **71** can be engaged by the needle **170** as it slidably translates through guide channel **478**, as illustrated in FIG. **24G**.

(170) Referring now to FIG. **24E**, there is shown a plan view of needle **170**. As illustrated in FIG. **24E**, the needle **170** comprises a suture ensnarement end **171** comprising a suture piercing region

171a and a suture retaining region **171b**, the suture piercing region **171a** and a suture retaining region **171b** forming a suture seat **171c** therebetween, which is configured to seat a suture therein, as illustrated in FIG. **24G**.

(171) As illustrated in FIG. **24E**, the needle **170** further comprises a curvilinear region (denoted “CR”) disposed on the distal end thereof.

(172) In a preferred embodiment, the curvilinear portion “CR” of needle **170** comprises a bend radius that is in the range of approximately 10.0% to 80.0% greater than the track radius of the guide channel **478**.

(173) As illustrated in FIGS. **24B** and **24C**, in a preferred embodiment, the top jaw member **462** of the jaw mechanism **460** comprises a side wall opening **476** and hook **481**, which facilitates suture capture in a surgical site.

(174) As further illustrated in FIG. **24B**, in a preferred embodiment, the bottom jaw member **464** comprises a raised suture guide region **475** proximate the distal end **473b** of the jaw mechanism **460** and side wall opening **476**, which is sized and configured to restrict access of a suture, e.g., suture **71**, into the jaw mechanism **460** from the distal end **473b** thereof and, hence, further facilitate suture capture from a lateral side of the jaw mechanism **460**.

(175) As further illustrated in FIGS. **24A** and **24B**, in one embodiment, the jaw mechanism **460** further comprises the aforementioned floating pivot mechanism (denoted “451”).

(176) In the noted embodiment, the floating pivot mechanism **451** thus comprises a first pin **453**, which is sized and configured to be positioned in a first pin lumen (not shown) in the top jaw member **462**, a second pin **455**, which is sized and configured to be positioned in a second pin lumen **457** in the top jaw member **462**, a third pin lumen in link **452**, and a floating pin slot **456** in the bottom jaw member **464**.

(177) According to the invention, the floating pivot mechanism **451** operates in a similar manner and provides the same features and advantages as the floating pivot mechanism illustrated in FIGS. **8A** and **8C**, and discussed above.

(178) Referring now to FIG. **25**, in some embodiments, the jaw mechanism **460** comprises a simple pin **453** that defines a pivot point, wherein the top and bottom jaw members **462**, **464** are in pivotal communication and the top jaw member **462** axially articulates with respect to the bottom jaw member **464**.

(179) As discussed in detail below, a seminal feature of the suture passing device **400** is the multifunction actuation system (denoted “405”), which is configured to provide at least the following synchronized functions during a single continuous rotational (or angular) articulation of trigger **406** from a default position, i.e., 0° rotation, to a fully actuated position: (i) articulation of the system jaw mechanism, in this instance, jaw mechanism **460**, (ii) suture control, i.e., suture engagement, retainment and release, by the jaw mechanism **460**, and (iii) translation and positioning of the device needle, in this instance, needle **170**. The multifunction actuation system **405** is also configured to provide the same functions in reverse order during continuous rotational articulation of the trigger **406** from the fully actuated position to the default position, i.e., upon release of the trigger **406**.

(180) Referring now to FIGS. **23** and **26**, in one embodiment of the invention, the multifunction actuation system **405** comprises a trigger **406**, a trigger arm/ring gear **426** and a pinion gear **424**.

(181) As illustrated in FIG. **26**, the trigger arm/ring gear **426** is engaged to the proximal end **419** of the trigger **406** and comprises an open ring gear region **409** comprising a plurality of teeth **421** that are sized and configured to cooperate with the teeth **425** on the pinion gear **424**, whereby rotational articulation of the trigger **406** induces rotation of the pinion gear **424**.

(182) Jaw Articulation

(183) In a preferred embodiment, the suture passing system **400** comprises a jaw articulation system **444**, which is adapted to cooperate with the multifunction actuation system **405** to provide articulation of the jaw mechanism **460** illustrated in FIG. **24A**.

(184) As illustrated in FIG. 26, the jaw articulation system **444** comprises a jaw rack **428**, jaw lever **412**, jaw driver **436** and jaw driver rod **416**. In a preferred embodiment, the jaw rack **428** is sized and configured to be disposed in and slidably translate within the lower internal compartment **405c** of the device frame **403**.

(185) As further illustrated in FIG. 26, in a preferred embodiment, the jaw rack **428** comprises a plurality of teeth **431** on the proximal end **423a**, which are also sized and configured to cooperate with the teeth **425** on the pinion gear **424**, and a jaw rack slot **429** on the distal end **423b** of the jaw rack **428** that is sized and configured to receive pin **413c** of the jaw lever **412**, whereby the pin **413c** is allowed to slidably translate within the jaw rack slot **429**.

(186) In a preferred embodiment, the jaw lever **412** is rotatably connected to the frame **403** of the suture passing device **400** via pin **413b**, whereby rotational articulation of the trigger **406** induces linear translation of the jaw rack **428** and, thereby, rotation of the jaw lever **412** about pin **413b**.

(187) As further illustrated in FIG. 26, the jaw lever **412** is also rotatably connected to the jaw driver **436** (via pin **413a**), which is coupled to the distal end **411b** of the jaw drive rod **416**, and the jaw drive rod **416** is coupled to the jaw driver **436** via a retaining ring **434**.

(188) In a preferred embodiment, the jaw articulation system **444** further comprises a jaw spring **438**, which, as illustrated in FIG. 26, is positioned proximate the jaw driver **436** to accommodate variances in thickness of tissue being grasped by the jaw mechanism **460** and provide sufficient jaw mechanism closing force.

(189) As further illustrated in FIG. 26, in some embodiments, the jaw rack slot **429** of the jaw rack **428** comprises an angled section **449b** at the proximal end **427a** of the jaw rack slot **429**.

(190) According to the invention, when the trigger **406** is initially rotationally articulated (or rotated) from an initial or default position, i.e., 0° rotation, which is illustrated in FIG. 23, toward handle **404**, i.e., pulled inwardly, the jaw rack **428** is slidably translated toward proximal end **401a** of the device **400**, i.e., frame **403** thereof, wherein pin **413c** translates through the angled section **449b** the jaw rack slot **429**, whereby the jaw lever **412** rotates (i.e., in a counterclockwise direction) and the jaw driver **436** and jaw drive rod **416** traverse toward the distal end **401b** of the device frame **403** and induce a transition of the jaw mechanism **460** from its default open configuration to a closed configuration.

(191) In a preferred embodiment, the trigger **406** is spring biased wherein, when the trigger **406** is released, the trigger **406** rotates away from the device handle **404** toward the default position, whereby the pinion gear **424** rotates in an opposite (i.e., clockwise) direction, whereby linear translation of the jaw rack **428**, rotation of the jaw lever **412** about pin **413b** and linear translation of the jaw driver **436** and jaw drive rod **416** coupled thereto are reversed and the jaw mechanism **460** transitions from the closed configuration to the default open configuration.

(192) Articulation of the jaw mechanism **460** from an open configuration to a closed configuration is thus provided by the multifunction actuator **405** via rotational articulation of the trigger **406** in a first direction toward the device handle **404**, and from the closed configuration to the open configuration via rotational articulation of the trigger **406** in a second direction away from the device handle **404**, i.e., release of the trigger **406**.

(193) Suture Control

(194) In a preferred embodiment, the suture passing system **400** further comprises a suture control system **413**, which is also adapted to cooperate with the multifunction actuation system **405** to control suture engagement, retainment and release by the jaw mechanism **460**.

(195) Referring back to FIG. 24D, in a preferred embodiment, the suture control system **413** comprises an elongated suture retaining ribbon **450**, which extends through the elongated shaft **410**, into and through a ribbon slot **454** of the top jaw member **462**, and across a window **470** disposed proximate the distal end **474b** of the top jaw member **462**, when the ribbon **450** is in an extended suture engagement position.

(196) As discussed in detail below and illustrated in FIG. 24A, in a preferred embodiment, when

the trigger **406** of the multifunction actuator **405** is in the default position, (i.e., 0° rotation) illustrated in FIG. 23, the suture retaining ribbon **450** is in the extended suture engagement position, whereby a suture, e.g., suture **71**, cannot be drawn through the window **470** of the top jaw member **462** by a system needle.

(197) When the trigger **406** is rotationally articulated toward the device handle **404**, at the proper sequenced timing, the suture retaining ribbon **450** is retracted from jaw member window **470**, as illustrated in FIG. 24D, whereby a suture can be drawn through the window **470** of the top jaw member **462** by a system needle. Thereafter, when the trigger **406** is rotationally articulated away from the device handle **404**, i.e., released, the suture retaining ribbon **450** is advanced and extends across the jaw member window **470** to the suture engagement position, whereby the suture retaining ribbon **450** engages the suture and draws the suture toward a distal wall **477** of the jaw member window **470**, wherein the suture is positioned on and retained against the distal wall **477** of jaw member window **470**.

(198) As illustrated in FIGS. 24C and 24D, in a preferred embodiment, the distal wall **477** of jaw member window **470** comprises a recess **479** adapted to receive the suture, whereby, when the suture retaining ribbon **450** engages the suture and draws or pushes the suture toward a distal wall **477** of the jaw member window **470**, the suture seats in the recess **479** in the distal wall **477** and creates a strain relief to promote greater retention capacity of the suture.

(199) According to the invention, when a suture is retained by the suture retaining ribbon **450** of the suture control system **413**, the suture can be manipulated by an operator of the device **400** in a surgical site to construct a desired stitch pattern, such as one of the aforementioned stitch patterns.

(200) As discussed below, according to the invention, the suture retaining ribbon **450** can also be retracted in the ribbon slot **454** of the top jaw member **462** by the operator to release a suture disposed in the jaw member window **470** and, hence, jaw mechanism **460**. The suture can be recaptured and drawn into the jaw member window **470** thereafter by the jaw mechanism **460** via the side wall opening **476** in the top jaw member **462** for retainment by the suture retaining ribbon **450** to continue constructing a desired stitch pattern.

(201) Referring now to FIGS. 26 and 27, the suture control system **413** further comprises a capture lever **414** and suture control switch **408**, which, as also discussed in detail below, is configured and adapted to modulate suture retaining ribbon **450** translation and, thereby, suture engagement, retainment and release.

(202) As illustrated in FIGS. 27 and 28, in a preferred embodiment, the suture retaining ribbon **450** is engaged to the distal end **417b** of the capture lever **414**.

(203) As further illustrated in FIGS. 27 and 28, the capture lever **414** is rotatably engaged to the frame **403** via pin **415a** and the proximal end **417a** of the capture lever **414** is coupled to capture lever spring **440** via pin **415c**.

(204) According to the invention, the pin **415a** defines a pivot point on the frame **403** and, as illustrated in FIG. 28, converts rotational movement of the capture lever **414** (denoted by arrow “R.sub.1”) to slidable translation of the ribbon **450** towards the proximal end **402a** or distal end **402b** of the device frame **403** (denoted by arrow “L.sub.1”).

(205) As further illustrated in FIG. 27, the distal end **417b** of the capture lever **414** is sized and configured to abut tabs **442a**, **442b** disposed on the bottom surface **407b** of the suture control switch **408** (see also FIGS. 29A and 29B).

(206) Referring back to FIG. 26, the capture lever **414** is also adapted to communicate with the needle rack **430** via pin **415b**, which, as discussed below, is sized and configured to abut the proximal end **437a** of the needle rack recess **447** in the needle rack **430**, when the needle rack **430** translates toward the distal end **402b** of the device frame **403**.

(207) As further illustrated in FIGS. 27 and 28, the proximal end (or lip) **437a** of the needle rack recess **447** is preferably positioned a predetermined dwell distance from pin **415b** of the capture lever **414**, whereby the capture lever **414** is initially stationary, i.e., suture control system **413** is in

dwelling.

(208) As indicated above, in a preferred embodiment, when the trigger **406** of the multifunction actuator **405** is in the default position, (i.e., 0° rotation), the suture retaining ribbon **450** is in an extended position, whereby a suture cannot be drawn through the window **470** of the top jaw member **462** by a system needle.

(209) During initial rotational articulation of the system trigger **406** toward the handle **404**, the needle rack **430** translates toward the distal end **402b** of the device frame **403** until pin **415b** abuts the proximal end (or lip) **437a** of the needle rack recess **447** (i.e., the suture control system **413** is in dwell). During further rotation of the system trigger **406** toward the handle **404** and, thereby, further translation of the needle rack **430** toward the distal end **402b** of the device frame **403** (after pin **415b** abuts the proximal end **437a** of the needle rack recess **447**), clockwise rotation (R.sub.1) of the capture lever **414** is induced (as illustrated in FIG. 26), which retracts the suture retaining ribbon **450** toward the proximal end **402a** of the device frame **403**, and, hence, proximal end **473a** of the jaw mechanism **460**, whereby a suture, in this instance, suture **71** can be drawn into the jaw member window **470**.

(210) When the trigger **406** is rotationally articulated away from the device handle **404**, i.e., is released, the needle rack **430** translates toward the proximal end **402a** of the device frame **403** and the capture lever **414** rotates in a counterclockwise direction, wherein the suture retaining ribbon **450** advances, engages the suture **71** and retains the suture **71** in the jaw member window **470**.

(211) During translation of the needle rack **430** toward the distal end **402b** of the device frame **403**, pin **415b** the capture lever **414** sits on and translates over the top proximal surface **431** of the needle rack **430**, i.e., the top proximal surface **431** of the needle rack **430** functions as a dwell feature to maintain the capture lever **414** in a stationary state, whereby the suture retaining ribbon **450** is maintained in the retracted position while the needle advances the suture.

(212) As indicated above and illustrated in FIG. 28, in a preferred embodiment, the proximal end **417a** of the capture lever **414** is coupled to capture lever spring **440**, which is adapted to rotatably bias the capture lever **414** in a counterclockwise direction, whereby the suture retaining ribbon **450** is extended forward in slot **454** and across the jaw member window **470**.

(213) As indicated above and illustrated in FIGS. 23 and 27, in a preferred embodiment, the suture control system **413** further comprises a suture control switch **408**, which is adapted to modulate suture engagement, more specifically, control engagement of and interaction between the suture retaining ribbon **450** and suture **71**.

(214) As illustrated in FIG. 28, the distal end **417b** of the capture lever **414** is sized and configured to abut tabs **442a**, **442b** disposed on the bottom surface **407b** of the suture control switch **408** to facilitate communication by and between the capture lever **414** and the suture control switch **408**.

(215) As discussed in detail below, the suture control switch **408** enables an operator to interact with and modulate the position of the capture lever **414** and, thereby, set the suture control function of the suture control system **413** and, hence, suture passing device **400** between two (2) modes: (1) an “auto-engagement” mode, i.e., engagement and, thereby, interaction of the suture retaining ribbon **450** with the suture **71**, which is illustrated in FIG. 29A, and a (2) “no-engagement” mode, i.e., no engagement of ribbon **450** to suture **71**, and, hence, no interaction therebetween, as illustrated in FIG. 29B.

(216) As illustrated in FIGS. 29A and 29B, in a preferred embodiment, an operator can manually translate (or move) the suture control switch **408**, i.e., advance or retract the switch **408** in a linear direction, along the top surface **407a** of the suture passing device body **402** to switch the suture control system **413** from the “auto-engagement” mode (i.e., first switch position illustrated in FIG. 29A) to the “no-engagement” mode (i.e., second switch position illustrated in FIG. 29B), as denoted by arrow “M.sub.2”, and from the “no-engagement” mode to the “auto-engagement” mode.

(217) Referring back to FIGS. 24D and 27, the ribbon **450** extends from the capture lever **414**

through the elongated shaft **410** and into and through the ribbon slot **454** of the top jaw member **462**, and, when extended, across jaw member window **470** disposed proximate the distal end **474b** of the top jaw member **462**.

(218) According to the invention, when the trigger **406** of the multifunction actuator **405** is in the default position, i.e., at 0° of rotation, and the suture control system **413** is in “auto-engagement” mode illustrated in FIG. **29A**, the capture lever **414** is preferably spring biased in a fully rotated counterclockwise direction, as illustrated in FIGS. **27** and **28**, whereby the suture retaining ribbon **450** is fully advanced through the elongated shaft **410**, into and through the ribbon slot **454** of the top jaw member **462**, and across the jaw member window **470**.

(219) According to the invention, when the suture control system **413** is in “auto-engagement” mode and the trigger **406** of the multifunction actuator **405** is rotated a first defined angle, e.g., between 5.0° to 15.0°, from the default position, as indicated above, the distal end **417b** of the capture lever **414** is rotated in a clockwise direction, wherein the suture retaining ribbon **450** is retracted from the jaw member window **470** and, thereby, allows the needle **170** with suture **71** attached thereto to traverse therethrough.

(220) After the needle **170** has passed a suture **71** into and through biological tissue and through the jaw member window **470**, the trigger **406** is rotated away from the handle **404**, i.e., is released, whereby the trigger **406** and, hence, multifunction actuator **405** return to the default position, i.e., 0° of rotation.

(221) As indicated above, when the trigger **406** returns to the default position, the capture lever **414** rotates (i.e., in a counterclockwise direction), the suture retaining ribbon **450** is advanced through the elongated shaft **410**, into and through the ribbon slot **454** of the top jaw member **462**, and across the jaw member window **470**, whereby the suture retaining ribbon **450** engages the suture **71** and draws the suture **71** toward and retains the suture **71** in the jaw member window **470**.

(222) As set forth below, according to the invention, the suture control switch **408** can also be manually moved to the “no-engagement” position illustrated in FIG. **29B** to disengage the suture retaining ribbon **450** from the suture **71** and, hence, release the suture **71**.

(223) Referring to FIG. **29B**, when the suture control switch **408** is manually moved to the “no-engagement” position, the distal tab member **442b** of the switch **408** contacts the distal end **417b** of the capture lever **414** and rotates the capture lever **414** in a clockwise direction, whereby the suture retaining ribbon **450** retracts from the jaw member window **470** and disengages from the suture **71**, wherein the suture **71** is released from the distal wall **477** of the jaw member window **470**.

(224) As illustrated in FIG. **29B**, in a preferred embodiment, the distal tab member **442b** is sized and configured to contact the distal end **417b** of the capture lever **414**, whereby the capture lever **414** is locked in the “no-engagement” position and the suture retaining ribbon **450** is thereby locked in a retracted position. Rotation of the capture lever **414** and, hence, translation of the suture retaining ribbon **450** through the jaw member slot **454** and window **470** is also abated.

(225) According to the invention, the suture control switch **408** can subsequently be manually moved from the “no-engagement” mode to the “auto-engagement” mode to unlock the capture lever **414** and allow translation of the suture retaining ribbon **450** through the jaw member slot **454** and window **470**, i.e., release the ribbon **450** from its retracted position.

(226) Control of a suture, i.e., ensnarement, retainment and release, can thus also be effectuated by the multifunction actuator **405** via simple rotational articulation of the trigger **406**.

(227) Needle Articulation

(228) In a preferred embodiment, the suture passing system **400** further comprises a needle articulation system **441**, which is also adapted to cooperate with the multifunction actuation system **405** to induce and control articulation of the system needle; preferably, needle **170** illustrated in FIG. **24E**.

(229) Referring back to FIG. **26**, in addition to needle **170**, the needle articulation system **441** comprises a needle rack **430**, needle support tube **418**, which is sized and configured to receive the

needle **170** therein, and proximal and distal needle holders **432a**, **432b**, which are coupled to the needle support tube **418**.

(230) In a preferred embodiment, the needle rack **430** is sized and configured to be disposed in and slidably translate within the upper internal compartment **405b** of the device frame **403**. As also illustrated in FIG. **26**, the needle rack **430** further comprises a plurality of teeth **439** on the distal end **433b** of the needle rack **430**, which are also sized and configured to cooperate with the teeth **425** on the pinion gear **424**.

(231) As further illustrated in FIG. **26**, the needle rack **430** further comprises a needle rack slot **445** that is sized and configured to receive the distal needle holder **432b**, whereby, as discussed below, the distal needle holder **432b** is allowed to slidably translate therein and provide a needle articulation system **441** dwell, i.e., a predetermined distance and, hence, delay in function.

(232) In a preferred embodiment, the proximal needle holder **432a** is coupled to the needle support tube **418** and needle **170** and is positioned in the upper internal compartment **405b** of the device frame **403**, whereby, upon rotational articulation of the trigger **406** toward the handle **404** and, thereby, linear translation of the needle rack **430** (and, thereby, needle support tube **418** and needle **170**), the proximal needle holder **432a** abuts a proximal interior wall **405i** of the device frame **403** and functions as a positive stop for the needle support tube **418** and needle **170**, and, hence, needle translation.

(233) As further illustrated in FIG. **26**, in a preferred embodiment, the proximal needle holder **432a** is coupled to a needle assembly cable **422**, which is sized to be drawn across two (2) pulley members **420a**, **420b** and coupled to a return spring (not shown) that provides tension to retract the needle **170** to a default retracted position when the trigger **406** is released from a fully actuated position.

(234) In a preferred embodiment, during rotational articulation of the trigger **406** toward the handle **404**, the needle rack **430** and, thereby, needle support tube **418** (and, hence, needle **170** disposed therein) remain stationary, i.e., needle articulation system in dwell until the distal needle holder **432b** abuts a proximal end region **435a** of the needle rack slot **445**, and, thereafter, during further rotational articulation of the trigger **406** (i.e., toward the handle **404**), needle rack **430** and, thereby, needle support tube **418** and needle **170** advance toward the distal end **402b** of the device frame **403** and the needle **170**, advances out of the elongated shaft **410**.

(235) In a preferred embodiment, during rotational articulation of the trigger **406** away from the handle **404**, i.e., upon release of the trigger **406**, the needle rack **430** and, thereby, needle support tube **418** and needle **170**, advance toward the proximal end **402a** of the device frame **403** and the needle **170** retracts into the elongated shaft **410**.

(236) According to the invention, articulation of the needle **170** is thus also provided by the multifunction actuator **405** via simple rotational articulation of the trigger **406**.

(237) As reflected in FIG. **30**, the multifunction actuation system **405** of suture passing device **400** thus sequentially (i) articulates and positions the system jaw mechanism, in this instance, jaw mechanism **460**, (ii) controls the ensnarement, retainment and release of a suture, and (iii) articulates and positions the system needle, in this instance, needle **170** during continuous rotational articulation of the trigger **406** from a default position, i.e., 0° rotation, toward the device handle **404** to a fully actuated position, and sequentially provides the same functions in reverse order during continuous rotational articulation of the trigger **406** from the fully actuated position to the default position, i.e., upon release of the trigger **406**.

(238) As further reflected in FIG. **30**, the noted functions are provided during six (6) distinct stages of the noted articulations of the system trigger **406**. Referring now to FIG. **31A**, there is shown another embodiment of suture passing device **400** (now denoted “500”), which similarly comprises a multifunction actuation system **505** that is configured to similarly provide at least the following synchronized functions during a single continuous rotational (or angular) articulation of the system trigger from a default position, i.e., 0° rotation to a fully actuated position: (i) articulation of the

system jaw mechanism, (ii) suture control, i.e., suture engagement, retainment and release, by the jaw mechanism, and (iii) translation and positioning of the device needle. The multifunction actuation system **505** is similarly also configured to provide the same functions in reverse order during continuous rotational articulation of the system trigger from the fully actuated position to the default position.

(239) As illustrated in FIG. **31A**, the suture passing device **500** thus similarly comprises a body **502**, handle **504** and an elongated member or shaft **510**. In a preferred embodiment, the elongated member shaft **510** similarly includes jaw mechanism **460**, whereby the suture passing device **500** similarly comprises aforementioned features and advantages associated therewith.

(240) Referring now to FIG. **32**, in a preferred embodiment, the multifunction actuation system **505** similarly comprises a trigger **506**, a trigger arm/ring gear **526** and a pinion gear **524**.

(241) As illustrated in FIG. **32**, the trigger arm/ring gear **526** is similarly engaged to the distal end **519** of the trigger **506** and comprises an open ring gear region **509** comprising a plurality of teeth **521** that are sized and configured to cooperate with the teeth **525** on the pinion gear **524**, whereby rotational articulation of the trigger **506** induces rotation of the pinion gear **524**.

(242) As further illustrated in FIG. **32**, the trigger arm/ring gear **526** comprises an outer ring gear surface **582**, which is radially concentric with the rotational articulation of the trigger arm/ring gear **526**, and preferably includes a first region **531a**, a second region **531b** and a third region **531c**.

(243) In a preferred embodiment, the trigger arm/ring gear **526** is also coupled to jaw lever **512** and the jaw lever bearing **580** associated therewith via pin **513c**.

(244) In a preferred embodiment, the trigger arm/ring gear **526** further comprises a ring gear slot **529** that is sized and configured to receive pin **513c** therein and allow the pin **513c** to translate therethrough.

(245) As further illustrated in FIG. **32**, the jaw lever **512** is also rotatably coupled to the frame **503** via pin **513b** and, as discussed below, the jaw driver **536** via pin **513a**.

(246) Jaw Articulation

(247) In a preferred embodiment, the suture passing system **500** similarly comprises a jaw articulation system **544**, which is adapted to cooperate with the multifunction actuation system **505** to provide articulation of the jaw mechanism **460**.

(248) As illustrated in FIG. **32**, the jaw articulation system **544** comprises a jaw driver **536** that is sized and configured to be seated in and slidably translate within compartment **505a** of the device frame **503**.

(249) In a preferred embodiment, the jaw driver **536** comprises a distal opening that is sized and configured to receive the distal end **511b** of jaw drive rod **516**, which is disposed inside the elongated member **510**. As illustrated in FIG. **32**, the distal end **511b** of the jaw drive rod **516** is preferably coupled to the jaw driver **536**.

(250) As further illustrated in FIG. **32**, in a preferred embodiment, the jaw articulation system **544** similarly comprises a jaw spring **538a** that is sized and configured to accommodate the dimensional variance of any article, e.g., biological tissue, disposed between top and bottom jaw members **462**, **464** of the jaw mechanism **460** (e.g., various thicknesses of biological tissue), and provide adequate clamping force of the jaw mechanism **460**.

(251) As further illustrated in FIG. **32**, in a preferred embodiment, the jaw articulation system **544** further comprises a jaw return spring **538b** that is disposed on the distal end **511b** of the jaw drive rod **516** proximate the jaw driver **536**. In a preferred embodiment, jaw return spring **538b** is sized and configured to bias or preload the jaw driver **536** to a default position.

(252) As indicated above and illustrated in FIG. **32**, the jaw lever **512** is coupled to the jaw driver **536** via pin **513a** and to the frame **503** via pin **513b**, which defines a pivot point on the frame **503** that converts rotational movement of the jaw lever **512** to slidable translation of the jaw driver **536** within compartment **505a** of device frame **503**.

(253) As also indicated above, in a preferred embodiment, the trigger arm/ring gear **526** comprises

a ring gear slot **529** that is sized and configured to receive pin **513c** therein and allow the pin **513c** to translate therethrough.

(254) In a preferred embodiment, the jaw lever **512** comprises a jaw lever bearing **580** in communication with the pin **513c** to reduce frictional forces that are generated when the pin **513c** slidably translates within the ring gear slot **529** of the trigger arm/ring gear **526**.

(255) As illustrated in FIG. **32**, in a preferred embodiment, the ring gear slot **529** comprises a linear region **527a** (or first segment of a cam path) and a radial region **527b** (or second segment of the cam path). According to the invention, when the pin **513c** is disposed in the ring gear slot **529** and the trigger **506** is initially rotationally articulated (or rotated) in a first direction from a default toward the device handle **504**, i.e., pulled inwardly, pin **513c** slidably translates through the linear region **527a** of the ring gear slot **529** and induces counterclockwise rotation of the jaw lever **512**, and, thereby, translation of the jaw driver **536** within compartment **505a** toward the distal end **502b** of the device frame **503**, wherein the jaw mechanism **460** similarly transitions from the default open configuration to the closed configuration.

(256) When the trigger **506** is further rotated toward the handle **504** (e.g., the trigger is rotated approx. 8.4°), the pin **513c** translates from the linear region **527a** to the radial region **527b** of the ring gear slot **529**, whereby the jaw lever **512** and, thereby, jaw driver assembly **536** (and, hence, jaw driver **537**) cease linear translation and remain in a constant fixed position, wherein the jaw mechanism **460** is maintained in the closed configuration, i.e., jaw articulation system **544** in dwell.

(257) In a preferred embodiment, the trigger **506** is similarly spring biased wherein, when the trigger **506** is released, the trigger rotates away from the device handle **504**, i.e., toward the initial or default position illustrated in FIG. **31A**, whereby the pin **513c** translates back through the radial region **527b** of the ring gear slot **529** and into and through the linear region **527a** of the ring gear slot **529**, wherein clockwise rotation of the jaw lever **512** is induced, and, thereby, translation of the jaw driver **536** within compartment **505a** toward the proximal end **502a** of the device frame **503**, wherein the jaw mechanism **460** similarly transitions from the closed configuration to the default open configuration.

(258) As indicated above, the jaw return spring **538b** biases the jaw driver **536** back to a default position to maintain the jaw mechanism **460** in the default open configuration.

(259) Articulation of the jaw mechanism **460** from an open configuration to a closed configuration is thus similarly provided by multifunction actuator **505** of suture passing system **500** via rotational articulation of the system trigger **506** in a first direction toward the device handle **504**, and from the closed configuration to the open configuration via rotational articulation of the trigger **506** in a second direction away from the device handle **504**, i.e., release of the trigger **506**.

(260) Suture Control

(261) In a preferred embodiment, the suture passing system **500** similarly further comprises a suture control system **513**, which is also adapted to cooperate with the multifunction actuation system **505** to control suture engagement, retainment and release by the jaw mechanism **460**.

(262) In a preferred embodiment, the suture control system **513** similarly comprises an elongated suture retaining ribbon (denoted “550” in this embodiment), which similarly extends into and through the jaw mechanism **460**, as described above, and suture control switch **408**.

(263) As illustrated in FIGS. **32** and **33**, the suture control system **513** further comprises a capture lever **514**, which is rotatably engaged to the frame **503** via pin **515b**. As further illustrated in FIGS. **32** and **33**, suture capture ribbon **550** is attached to the distal end **517b** of the capture lever **514** and the proximal end **517a** of the capture lever **514** is coupled to capture lever spring **540** via pin **515c**.

(264) According to the invention, pin **515b** similarly defines a pivot point on the frame **503** and, thus, similarly converts rotational movement of the capture lever **514** to slidable translation of the suture retaining ribbon **550** towards the proximal end **502a** or distal end **502b** of the device frame **503**.

(265) As further illustrated in FIGS. **32** and **33**, and discussed in detail below, the capture lever **514**

is also in communication with the trigger arm/ring gear **526** via pin **515a**, which is sized and configured to abut and traverse over the outer ring gear surface **582** of the trigger arm/ring gear **526**.

(266) The trigger arm/ring gear **526** is similarly in communication with the pinion gear **524**, wherein, when the trigger **506** is rotationally articulated in a first direction from a default position toward the device handle **504**, i.e., pulled inwardly, the trigger arm/ring gear **526** rotates, which slidably translates pin **515a** of the capture lever **514** along outer ring gear surface **582** of the trigger arm/ring gear **526**, and, as discussed above, also advances the jaw lever **512** and, thereby, jaw driver **536** and jaw driver rod **516**.

(267) According to the invention, when the trigger **506** of the multifunction actuator **505** is in the default position (i.e., 0° rotation) illustrated in FIG. **31A**, the suture retaining ribbon **550** is similarly in an extended position, whereby a suture cannot be drawn through the window **470** of the top jaw member **462** by a system needle.

(268) During the noted translation (or movement) of the pin **515a** of the capture lever **514** along outer ring gear surface **582** of the trigger arm/ring gear **526**, the pin **515a** provides three (3) distinct stages of capture lever **514** articulation: (i) an initial stage, which is illustrated in FIG. **33**, wherein the pin **515a** traverses over the first region **531a** of the outer ring gear surface **582** during initial articulation of the trigger **506** (e.g., rotation from ~0°-8.0°), wherein rotational articulation of the capture lever **514** is not induced (i.e., suture control system **513** is in dwell), (ii) a second stage, which is illustrated in FIG. **34**, wherein the pin **515a** traverses over the second region **531b** of the outer ring gear surface **582** during further articulation of the trigger **506** (e.g., rotation from ~8.0°-11.5°), wherein the trigger arm/ring gear **526** induces rotation of the capture lever **514** (i.e., in a clockwise direction) and, thereby, retraction of ribbon **550** engaged thereto toward the proximal end **501a** of the device body **502**, and (iii) a third stage, wherein the pin **515a** traverses over the third region **531c** of the outer ring gear surface **582** during further articulation of the trigger **506** (e.g., rotation >11.5°), wherein further rotation of the capture lever **514** is not induced and the capture lever **514** and, thereby, suture capture ribbon **550** engaged thereto are in a static state in the retracted position.

(269) In a preferred embodiment, the distal end **517b** of capture lever **514** is similarly sized and configured to abut tabs **442a**, **442b** disposed on the bottom surface of the suture control switch **408** and similarly cooperate therewith.

(270) As described in detail above, suture control switch **408** facilitates the above discussed ribbon engagement modes of the invention: (i) the “auto-engagement” mode and (ii) the “no-engagement” mode.

(271) Referring again to FIG. **31A**, in a preferred embodiment, the suture passing device **500** further comprises a suture release tab **590**, which, as discussed in detail below, is adapted to cooperate with the capture lever **514** and, thereby, suture control system **513**.

(272) As illustrated in FIG. **31A**, in a preferred embodiment, the suture release tab **590** is disposed externally on the device body **502** to facilitate easy access thereto by an operator.

(273) As illustrated in FIG. **32**, the suture release tab **590** is coupled to capture lever **514** via pin **592**.

(274) According to the invention, in a preferred embodiment, actuation of the suture release tab **590** by a manual force on the tab **590** in a direction denoted by “F.sub.1” transitions the tab **590** from a default first tab position, which is illustrated in FIG. **31B**, to a second tab position, which is illustrated in FIG. **31C**, rotates the capture lever **514** and, thereby, translates the suture capture ribbon **550** engaged thereto into the retracted position, i.e., toward the proximal end **502a** of the device frame **503** (and, hence, proximal end **473a** of the jaw mechanism **460**).

(275) Actuation of the suture release tab **590** can thus be used by an operator to selectively disengage the suture capture ribbon **550** from suture **71** and release suture **71** from the distal wall **477** of the top jaw member window **470** when disposed therein.

(276) Control of a suture, i.e., ensnarement, retainment and release, can thus also be effectuated by the multifunction actuator **505** via simple rotational articulation of the trigger **506**.

(277) In this embodiment, release of a suture **71** can also be readily effectuated by an operator by manual actuation of an external suture release tab **590**.

(278) Needle Articulation

(279) In a preferred embodiment, the suture passing system **500** similarly further comprises a needle articulation system **541**, which is also adapted to cooperate with the multifunction actuation system **505** to control articulation of the system needle, in this instance, needle **170**.

(280) As further illustrated in FIG. **32**, in addition to needle **170**, the suture passing device **500** comprises needle rack **530**, needle support tube **518**, which is similarly sized and configured to receive the needle **170** therein, and proximal and distal needle holders **532a**, **532b**, which are coupled to the needle support tube **518** and needle **170**.

(281) In a preferred embodiment, the needle rack **530** is similarly sized and configured to be disposed in and slidably translate within an upper internal compartment **505b** of the device frame **503**. As additionally illustrated in FIG. **33**, the needle rack **530** further comprises a plurality of teeth **539** on the proximal end **533a** of the rack **530**, which are also sized and configured to cooperate with the teeth **525** on the pinion gear **524**.

(282) As further illustrated in FIG. **32**, the needle rack **430** further comprises a needle rack slot **545** that is sized and configured to receive the distal needle holder **532b**, whereby the distal needle holder **532b** is similarly allowed to slidably translate therein and provide a needle articulation system dwell.

(283) In a preferred embodiment, the proximal needle holder **532a** is coupled to the needle support tube **518** and is positioned in the upper internal compartment **505b** of the frame **503**, whereby, upon rotational articulation of the trigger **506** toward the handle **504** and, thereby, linear translation of the needle rack **530** (and, thereby, needle support tube **518** and needle **170**), the proximal needle holder **532a** similarly abuts a proximal interior wall **505i** of the device frame **503** and functions as a positive stop for the needle support tube **518**, and, hence, needle translation.

(284) As further illustrated in FIG. **32**, in a preferred embodiment, the proximal needle holder **532a** is similarly coupled to a needle assembly cable **522**, which is sized to be drawn across two (2) pulley members **520a**, **520b** and coupled to a return spring **595** that provides tension to retract the needle **170** to a default retracted position when the trigger **506** is released from a fully actuated position.

(285) In a preferred embodiment, during rotational articulation of the trigger **506**, i.e., toward the handle **504**, the needle rack **530** and, thereby, needle support tube **518** (and, hence, needle **170** disposed therein) similarly remain stationary (the needle **170** being in a default retracted position within the needle support tube **518**) until the distal needle holder **532b** abuts a proximal surface **535a** of the needle rack slot **545**, and, thereafter, during further rotational articulation of the trigger **506**, needle rack **530** and, thereby, needle support tube **518** advance toward the distal end **502b** of the device frame **503** and the needle **170** similarly advances out of the elongated shaft **510**.

(286) In a preferred embodiment, during rotational articulation of the trigger **506** away from the handle **504**, i.e., upon release of the trigger **506**, the needle rack **530** and, thereby, needle support tube **518** and needle **170** similarly advance toward the proximal end **502a** of the device frame **503** and the needle **170** retracts into the elongated shaft **510**.

(287) According to the invention, articulation of the needle **170**, i.e., translation and positioning thereof, is thus similarly provided by the multifunction actuation system **505** via simple rotational articulation of the trigger **506**.

(288) According to the invention, the multifunction actuation system **505** and, hence, suture passing device **500** is similarly adapted to sequentially (i) articulate and position the system jaw mechanism, in this instance, jaw mechanism **460**, (ii) control the ensnarement, retainment and release of a suture, and (iii) articulate and position the system needle, in this instance, needle **170**

during continuous rotational articulation of the trigger **506** from a default position to a fully actuated position, and sequentially provide the same functions in reverse order during continuous rotational articulation of the trigger **506** from the fully actuated position to the default position, as also set forth in FIG. **30**.

(289) As also indicated above, the suture passing device **500** is further adapted to manually effectuate ribbon **550** articulation and, thereby, suture **71** release via simple actuation of an external suture release tab **590**, which is readily accessible to an operator.

(290) Referring now to FIGS. **35A** and **35B**, there is shown yet another embodiment of a suture passing device of the invention (denoted “**600**”).

(291) As illustrated in FIGS. **35A** and **35B**, the device similarly comprises a housing **602**, handle **604** and the elongated member **510**. According to the invention, the device **600** also comprises the jaw mechanism **460**, needle assembly and suture retaining ribbon **550** of device **500**, discussed above.

(292) In a preferred embodiment, the device **600** also similarly comprises the multifunction actuation system **505**, and, as reflected in FIG. **36**, the jaw articulation system **544** and needle articulation system **541** of suture passing device **500** discussed above.

(293) As further illustrated in FIGS. **35A** and **35B**, the device **600** does not include the suture control switch **408** (and, hence, functions and features associated therewith).

(294) As discussed in detail below, in this embodiment, control of suture engagement and release is provided by a manual suture release system.

(295) As illustrated in FIGS. **35A** and **35B**, the manual release system comprises an external suture release tab **690**, which is similarly disposed on the device housing **602**, whereby the tab **690** is readily accessible by an operator (i.e., easily actuated by an operator's thumb).

(296) In a preferred embodiment, the suture retaining ribbon **550** is similarly fully advanced through the elongated shaft (denoted **510** in this embodiment), into and through the ribbon slot **454** of the top jaw member **462**, and across the jaw member window **470**, whereby suture access therein is abated.

(297) In a preferred embodiment, the manual suture release system is configured and adapted to cooperate with the suture capture ribbon **550**, whereby, upon manual actuation of the suture release tab **690** via application of a force in a downward direction, as denoted by arrow “F.sub.2” (and holding the tab **690** in the actuated position), and rotational articulation of the trigger **606** toward the handle **604**, the suture retaining ribbon **550** retracts, allowing access of a suture into the jaw member window **470**.

(298) According to the invention, the manual suture release system is also configured and adapted to retract the suture capture ribbon **550** and allow access of a suture into the jaw member window **470** upon “simultaneous” manual actuation of the suture release tab **690** and rotational articulation of the trigger **606** toward the handle **604**.

(299) In a preferred embodiment, upon a simple release of the tab **690**, the suture retaining ribbon **550** extends to its default position and engages and retains the suture in the recess or opening in the distal wall **477** of the jaw member window **470**.

(300) Upon manual actuation of the suture release tab **690** thereafter and rotational articulation of the trigger **606** toward the handle **604**, the suture retaining ribbon **550** can again be retracted to effectuate release of the suture from the distal wall **477** of the jaw member window **470**.

(301) Suture passing device **600**, thus, effectuates simple suture control, i.e., engagement and release, through simple one-handed operation via two (2) actuators.

(302) As will readily be appreciated by one having ordinary skill in the art, the present invention provides numerous advantages compared to prior art systems and methods for passing suture through biological tissue. Among the advantages are the following: The provision of suture passing systems that can be readily employed to effectively approximate, ligate, fixate and/or close biological tissue; The provision of suture passing systems that provide an enhanced degree of

control of tissue engagement, needle articulation and suture retention by an operator with minimal complexity; The provision of suture passing systems that provide synchronized control of tissue engagement, needle articulation and suture retention with a single motion of a hand actuator; The provision of suture passing systems that include independent manual means for releasing a tissue after retainment; The provision of suture passing systems that facilitate suture passage into and through a myriad of soft tissue types; The provision of suture passing systems that facilitate suture passage into and through biological tissue structures having a wide range of thicknesses; The provision of suture passing systems that provide enhanced suture manipulation in a surgical site; The provision of suture passing systems that can be readily employed to endure multiple use cycles with limited impact on suture passing efficacy; The provision of suture passing systems that can be readily employed to enable antegrade and retrograde passing of suture during endoscopic surgical procedures; The provision of suture passing systems that can be readily employed to enable an operator to generate high tensile strength stitch patterns during an endoscopic procedure, such as a modified Mason-Allen stitch; The provision of suture passing systems that can be readily employed to pass suture without collateral damage to extraneous soft tissue and bone structures; and The provision of suture passing systems that reduce the time required to conduct suturing procedures and, thereby, attendant risks to a patient.

(303) Without departing from the spirit and scope of this invention, one of ordinary skill can make various changes and modifications to the invention to adapt it to various usages and conditions. As such, these changes and modifications are properly, equitably, and intended to be, within the full range of equivalence of the following claims.

Claims

1. A suture passing device, comprising: a jaw mechanism adapted to grasp biological tissue and engage a suture, said jaw mechanism comprising top and bottom jaw members, said top jaw member adapted to axially articulate with respect to said bottom jaw member; a needle assembly comprising a needle, said needle comprising a tissue piercing distal end configured to releasably engage a suture; a jaw articulation system adapted to induce and control said axial articulation of said top jaw member with respect to said bottom jaw member; a suture control system adapted to control access of said suture into said jaw mechanism and said engagement of said suture by said jaw mechanism, said suture control system further adapted to control release of said suture by said jaw mechanism after said engagement by said jaw mechanism; a needle articulation system adapted to induce and control articulation of said needle and, thereby, said needle engagement to said suture; and a multifunction actuation system, said multifunction actuation system comprising an actuation trigger, said actuation trigger adapted to rotationally articulate from a default position to a fully actuated position, said default position comprising 0° rotation of said actuation trigger, said multifunction actuation system adapted to control said jaw articulation system, said suture control system and said needle articulation system, said control of said jaw articulation system, said suture control system and said needle articulation system comprising synchronized said axial articulation of said top jaw member with respect to said bottom jaw member, said access of said suture into said jaw mechanism, and said articulation of said needle during a first single continuous rotational articulation of said actuation trigger, said first single continuous rotational articulation of said actuation trigger comprising rotational articulation from said default position to said fully actuated position.

2. The device of claim 1, wherein said control of said jaw articulation system, said suture control system and said needle articulation system further comprises synchronized said articulation of said needle, said suture engagement by said jaw mechanism, and said axial articulation of said top jaw member with respect to said bottom jaw member during a second single continuous rotational articulation of said actuation trigger, said second single continuous rotational articulation of said

actuation trigger comprising rotational articulation from said fully actuated position to said default position.

3. The device of claim 1, wherein said needle assembly is in communication with said jaw mechanism and adapted to cooperate with said jaw mechanism.

4. The device of claim 1, wherein said device further comprises an elongated tubular member in communication with said jaw mechanism and said needle assembly, said elongated tubular member comprising an internal lumen configured to receive said needle therein and advance said needle therefrom when said needle is said articulated by said multifunction actuation system.

5. The device of claim 4, wherein said top jaw member of said jaw mechanism comprises a ribbon slot and jaw member window adapted to receive said suture therein, said ribbon slot in communication with said elongated tubular member.

6. The device of claim 5, wherein said suture control system comprises a suture retaining ribbon in communication with said multifunction actuation system, said suture retaining ribbon comprising first and second configurations, said first configuration comprising a default extended configuration and said second configuration comprising a retracted configuration.

7. The device of claim 6, wherein said suture retaining ribbon is adapted to transition from said default extended configuration to said retracted configuration, and from said retracted configuration to said default extended configuration.

8. The device of claim 7, wherein said suture retaining ribbon extends from said multifunction actuation system, through said elongated tubular member, through said ribbon slot and, when said suture retaining ribbon is in said default extended configuration, over said jaw member window in said top jaw member.

9. The device of claim 7, wherein, when said suture retaining ribbon is in said extended configuration, said suture is restricted from entering said jaw member window.

10. The device of claim 9, wherein, during said first single continuous rotational articulation of said actuation trigger, said suture retaining ribbon said transitions from said default extended configuration to said retracted configuration, whereby access to said jaw member window by said suture is provided.

11. The device of claim 10, wherein, during said second single continuous rotational articulation of said actuation trigger, said suture retaining ribbon said transitions from said retracted configuration to said default extended configuration, whereby, when said suture is disposed in said jaw member window, said suture retaining ribbon engages said suture and retains said suture in said jaw member window.

12. The device of claim 11, wherein said multifunction actuation system further comprises a suture mode switch adapted to selectively provide multiple ribbon/suture engagement modes.

13. The device of claim 12, wherein said multiple ribbon/suture engagement modes comprise an auto-engagement mode, wherein said suture retaining ribbon is allowed to said transition from said retracted configuration to said default extended configuration, whereby, when said suture is disposed in said jaw member window, said suture retaining ribbon engages said suture during said second single continuous rotational articulation of said actuation trigger, and during said first single continuous rotational articulation of said actuation trigger said suture retaining ribbon is allowed to said transition from said default extended configuration to said retracted configuration, whereby said suture retaining ribbon disengages from said suture.

14. The device of claim 13, wherein said multiple ribbon/suture engagement modes comprise a no-engagement mode, wherein said suture retaining ribbon is maintained in said retracted configuration, whereby, when said suture is disposed in said jaw member window, said suture retaining ribbon does not transition from said retracted configuration to said default extended configuration and, thereby engage said suture during said second single continuous rotational articulation of said trigger.

15. The device of claim 13, wherein said multifunction actuation system further comprises a suture

release switch adapted to release said suture from said jaw member window when said engaged by said suture retaining ribbon.
