



US012390213B1

(12) **United States Patent**
Heneveld et al.

(10) **Patent No.:** **US 12,390,213 B1**
(45) **Date of Patent:** **Aug. 19, 2025**

(54) **SYSTEMS, APPARATUS AND METHODS
FOR PASSING SUTURE THROUGH SOFT
TISSUE**

(71) Applicant: **Passer Stitch, LLC**, Whitmore, CA
(US)

(72) Inventors: **Scott Heneveld**, Whitmore, CA (US);
John Valadez, Agua Dulce, CA (US);
Christopher Morris, Santa Clarita, CA
(US); **Justin Anderson**, Henderson, NV
(US); **Brad Topper**, Santa Clarita, CA
(US)

(73) Assignee: **Passer Stitch, LLC**, Henderson, NV
(US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 31 days.

(21) Appl. No.: **18/623,903**

(22) Filed: **Apr. 1, 2024**

Related U.S. Application Data

(60) Provisional application No. 63/602,605, filed on Nov.
26, 2023, provisional application No. 63/456,513,
filed on Apr. 2, 2023.

(51) **Int. Cl.**
A61B 17/04 (2006.01)
A61B 17/00 (2006.01)
A61B 17/06 (2006.01)
A61B 17/29 (2006.01)

(52) **U.S. Cl.**
CPC **A61B 17/0469** (2013.01); **A61B**
2017/00367 (2013.01); **A61B 2017/047**
(2013.01); **A61B 2017/2925** (2013.01); **A61B**
2017/2926 (2013.01)

(58) **Field of Classification Search**

CPC **A61B 2017/047**; **A61B 2017/294**; **A61B**
2017/00367; **A61B 2017/2925**; **A61B**
2017/2926; **A61B 2017/2936**; **A61B**
2017/2933; **A61B 2017/2934**; **A61B**
2017/2944; **A61B 17/0469**; **A61B**
17/0483; **A61B 17/0482**; **A61B 17/06004**;
A61B 17/06066

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

10,383,621 B2	8/2019	Gregoire et al.	
2008/0208221 A1 *	8/2008	Murray	A61B 17/0625 606/145
2014/0188136 A1 *	7/2014	Cournoyer	A61B 17/0401 606/144
2014/0276981 A1 *	9/2014	Hendricksen	A61B 17/0483 606/144

(Continued)

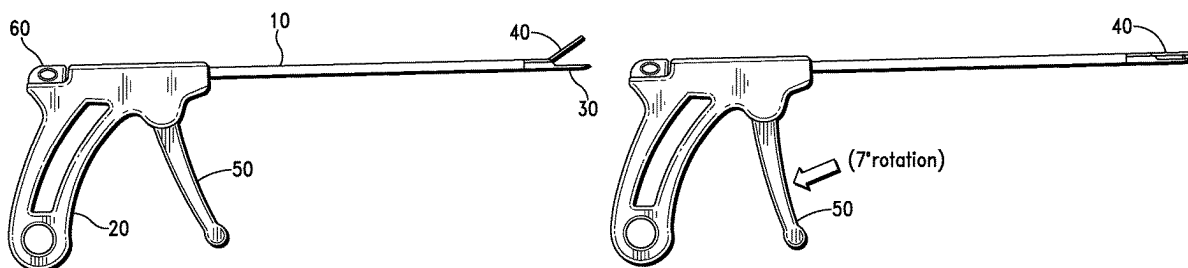
Primary Examiner — Tuan V Nguyen

(74) *Attorney, Agent, or Firm* — Francis Law Group

(57) **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.

15 Claims, 32 Drawing Sheets



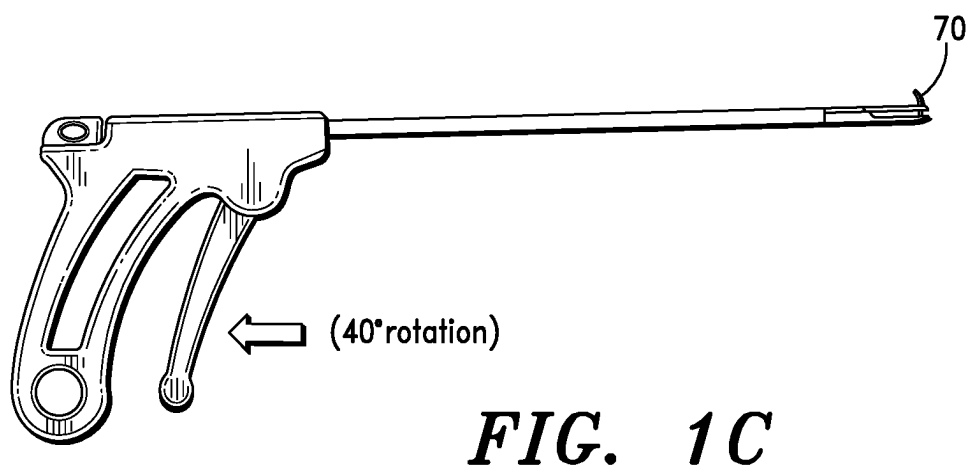
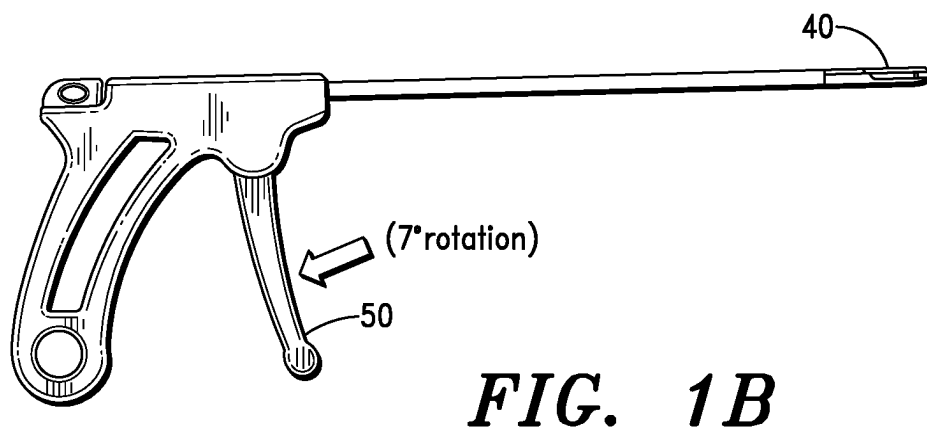
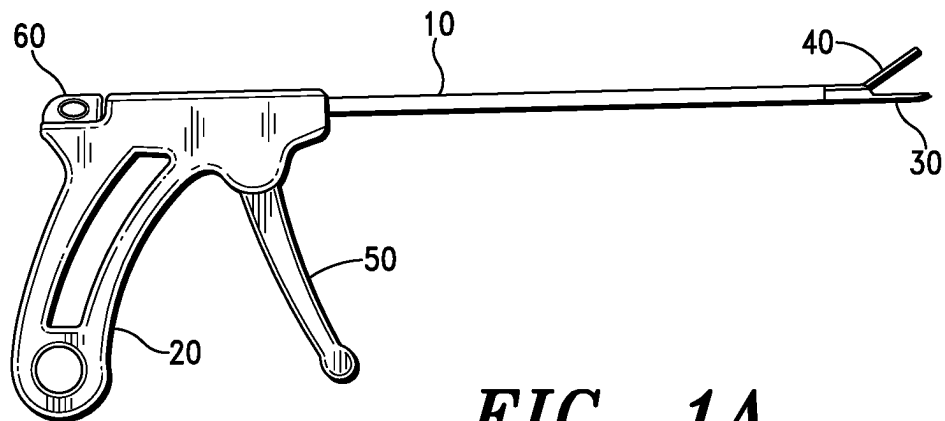
(56)

References Cited

U.S. PATENT DOCUMENTS

2014/0296880	A1 *	10/2014	Heneveld	A61B 17/0469 606/144
2017/0172565	A1	6/2017	Heneveld	
2018/0235601	A1	8/2018	Malkowski et al.	
2020/0093479	A1	3/2020	Murillo et al.	
2020/0360012	A1	11/2020	Heneveld	
2021/0000463	A1	1/2021	Murillo et al.	

* cited by examiner



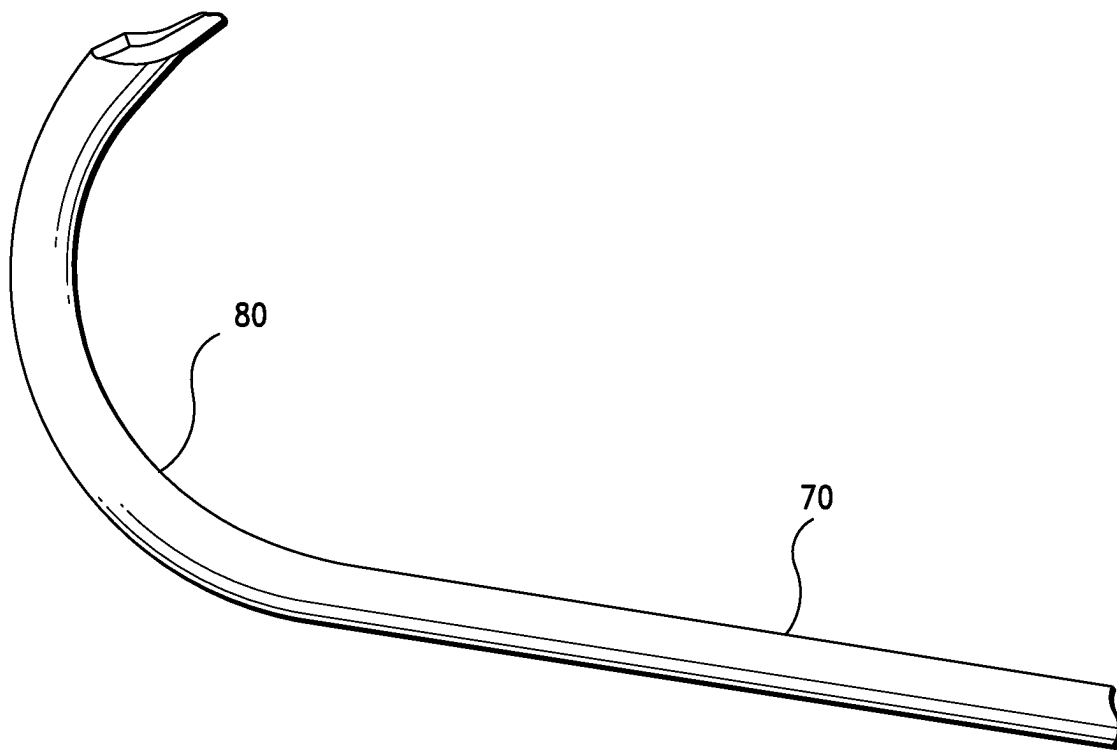


FIG. 2A

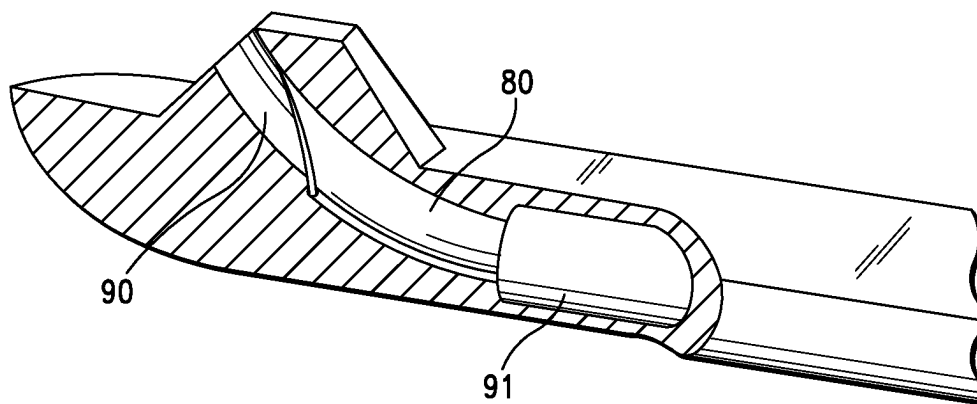


FIG. 2B

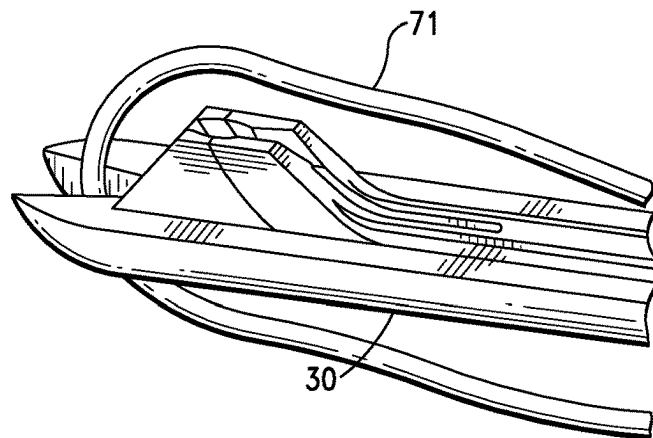


FIG. 3A

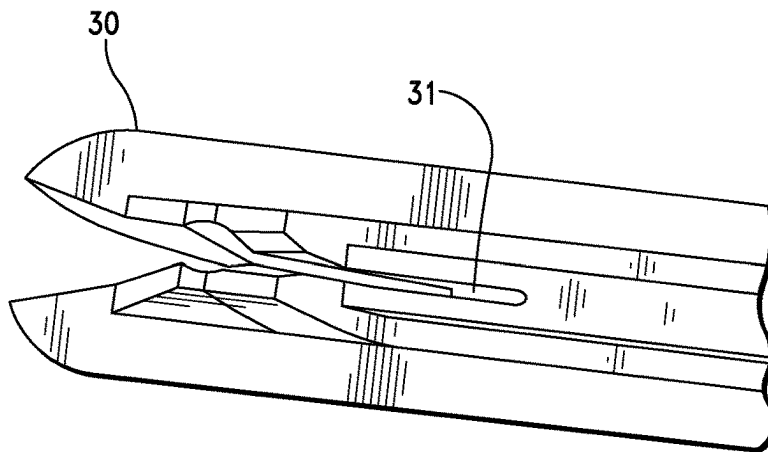


FIG. 3B

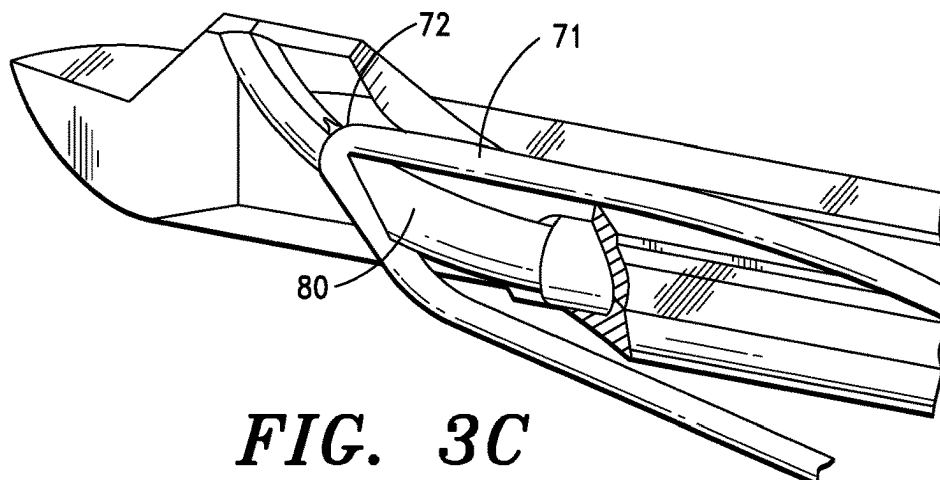


FIG. 3C

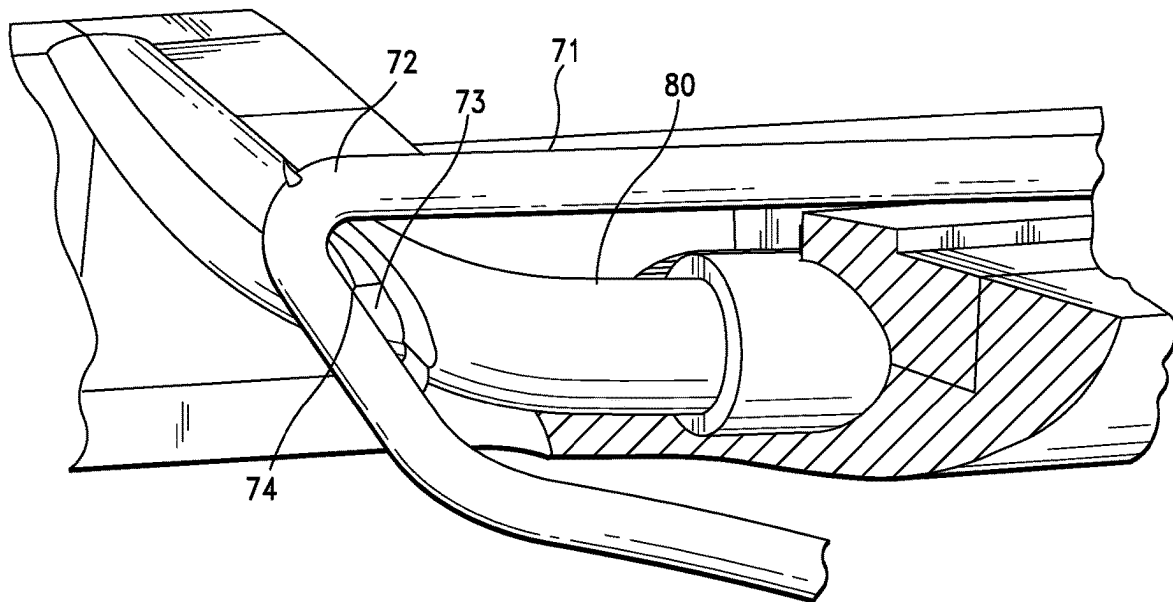


FIG. 4A

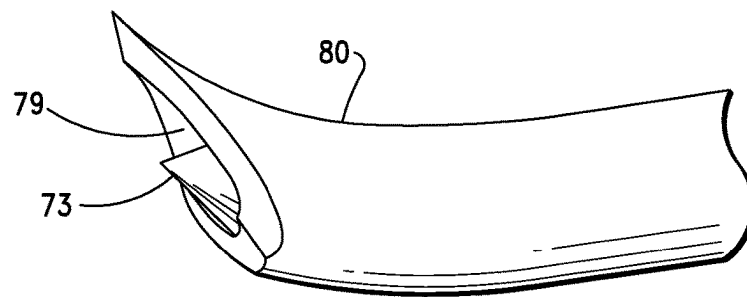


FIG. 4B

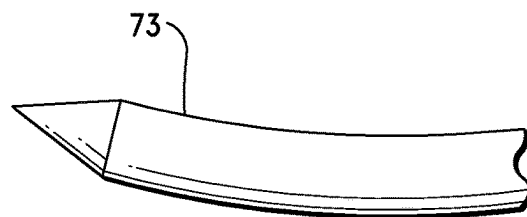


FIG. 4C

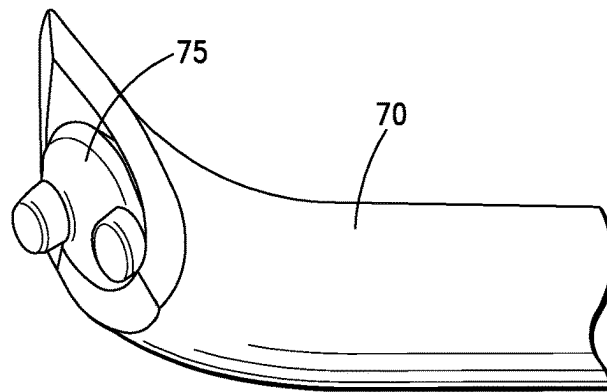


FIG. 5A

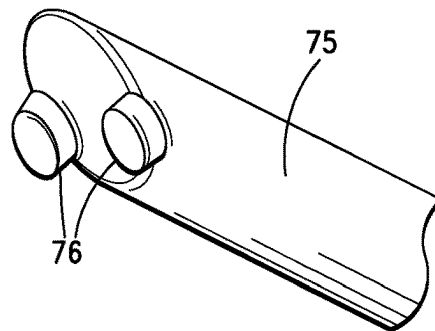


FIG. 5B

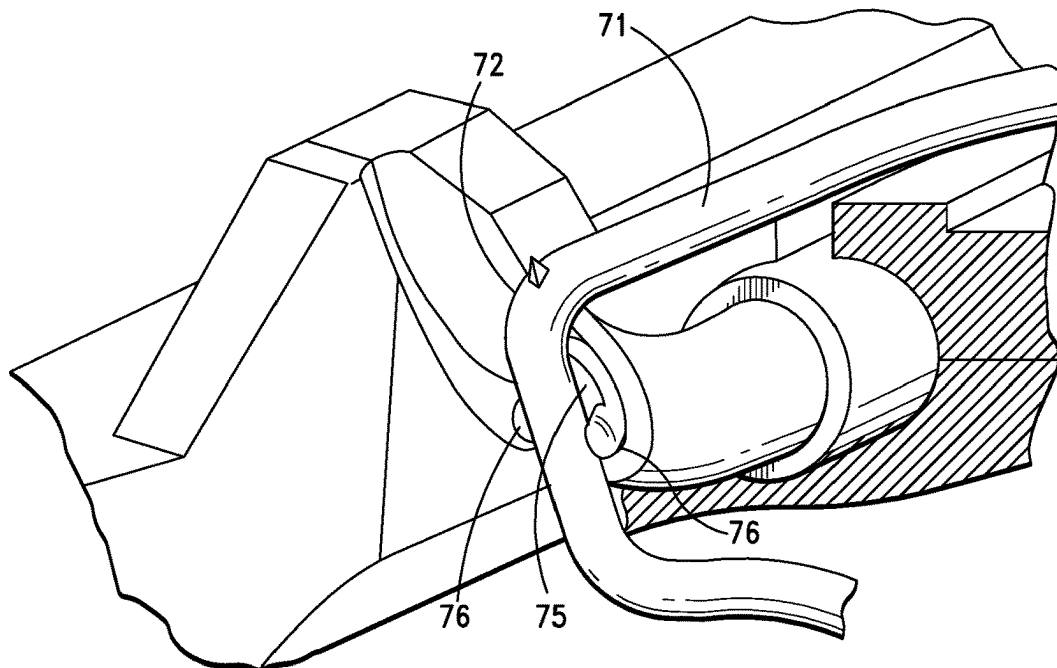


FIG. 5C

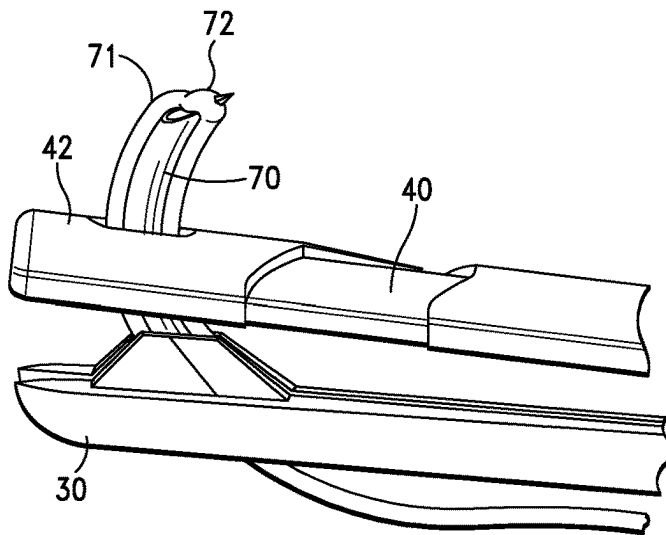


FIG. 6A

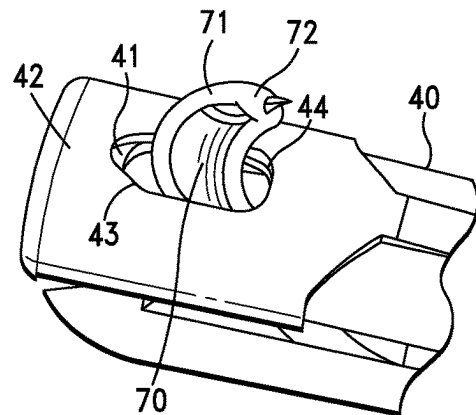


FIG. 6B

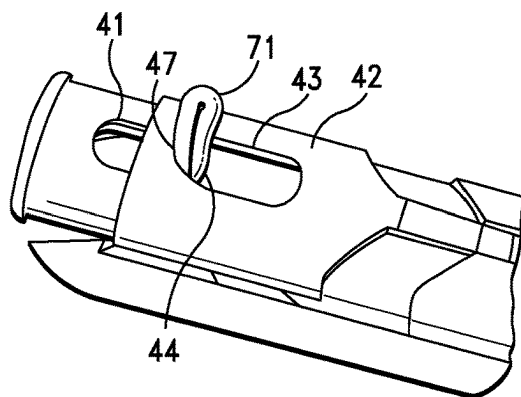


FIG. 6C

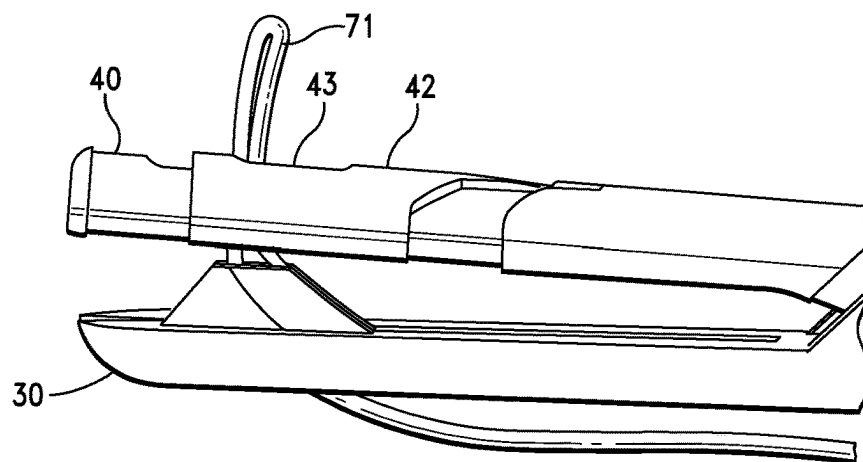


FIG. 6D

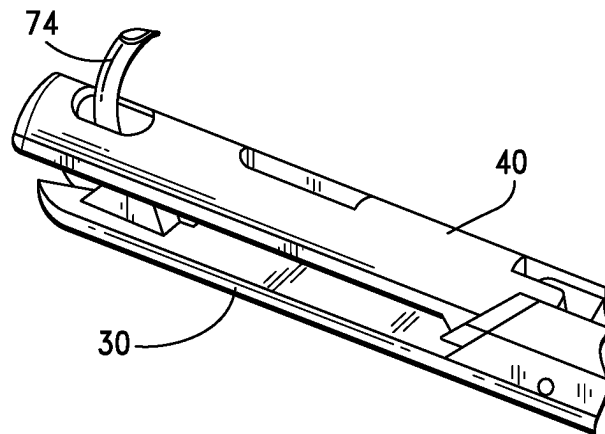


FIG. 7A

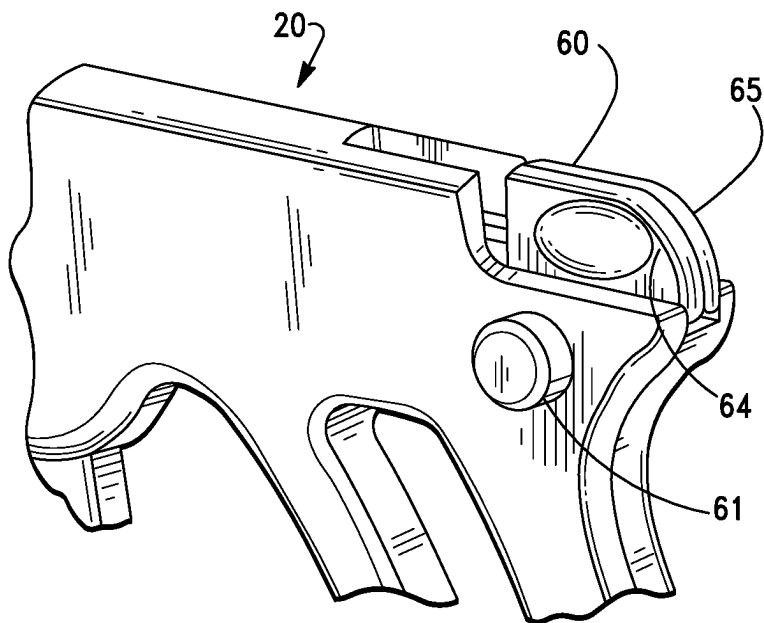


FIG. 7B

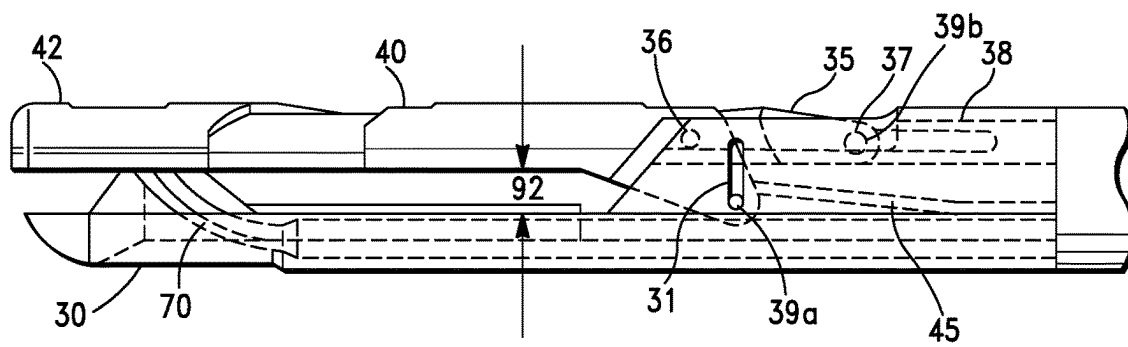


FIG. 8A

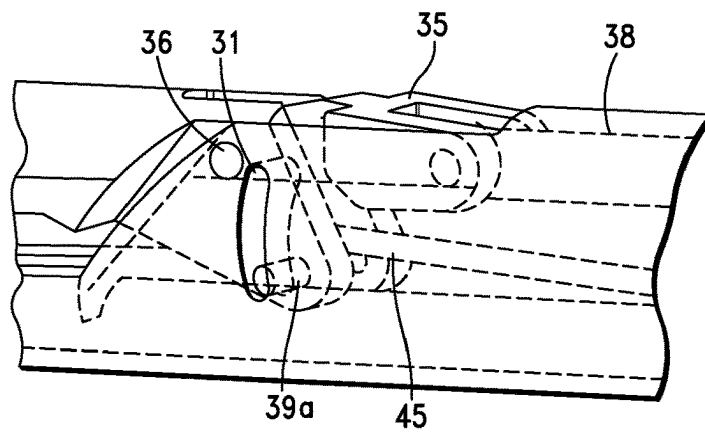


FIG. 8B

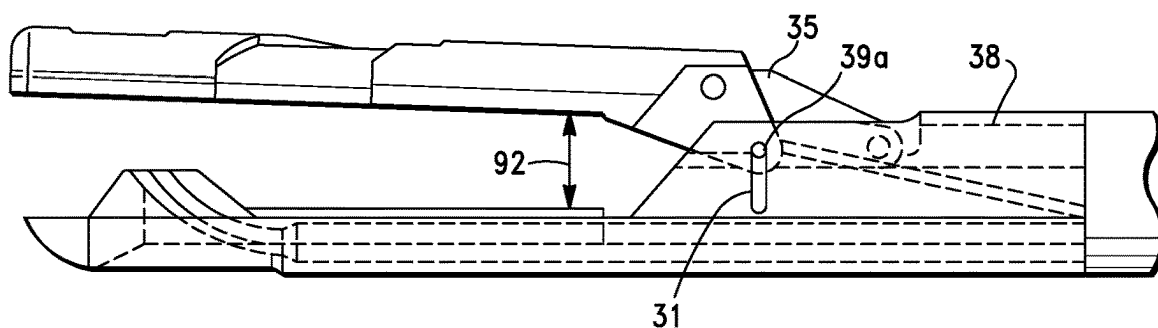


FIG. 8C

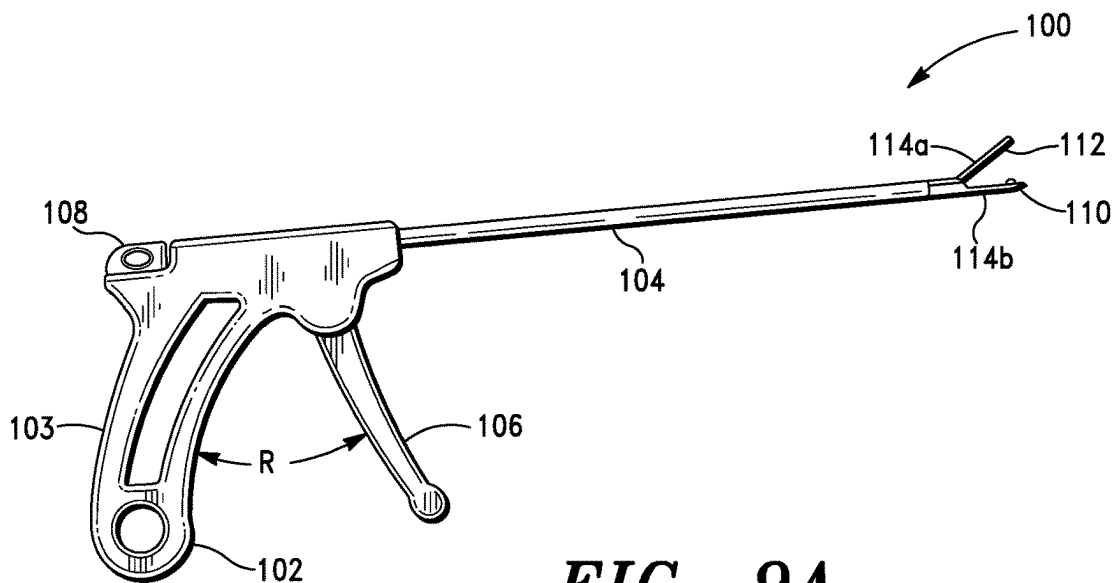


FIG. 9A

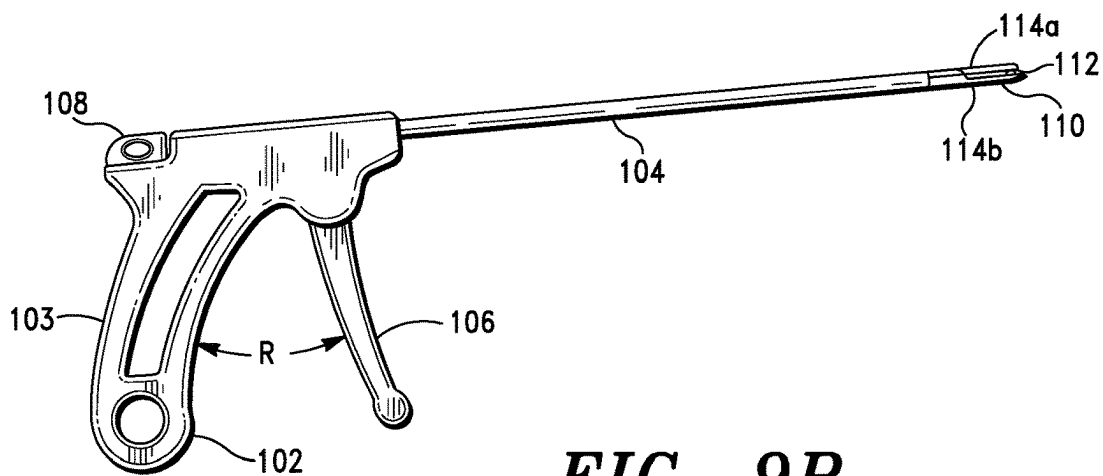


FIG. 9B

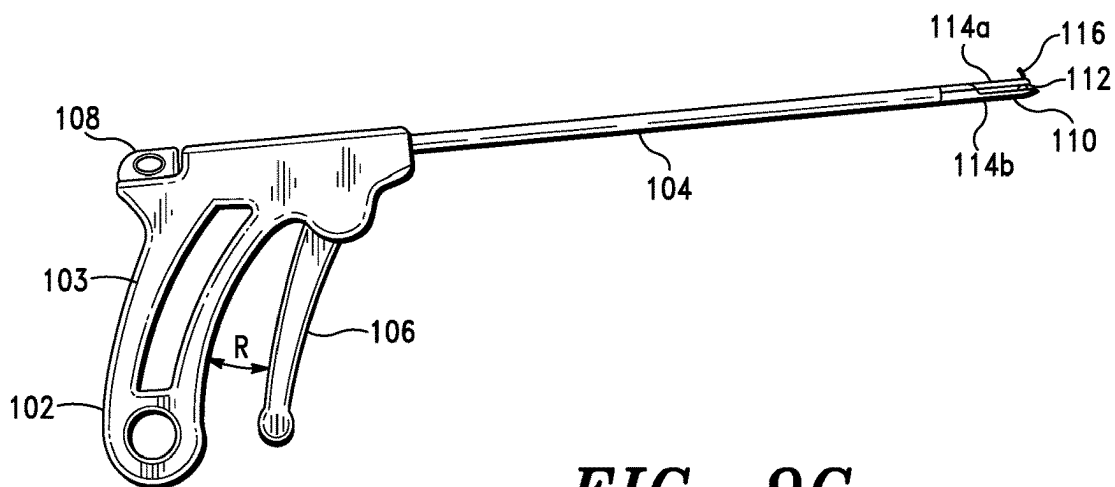


FIG. 9C

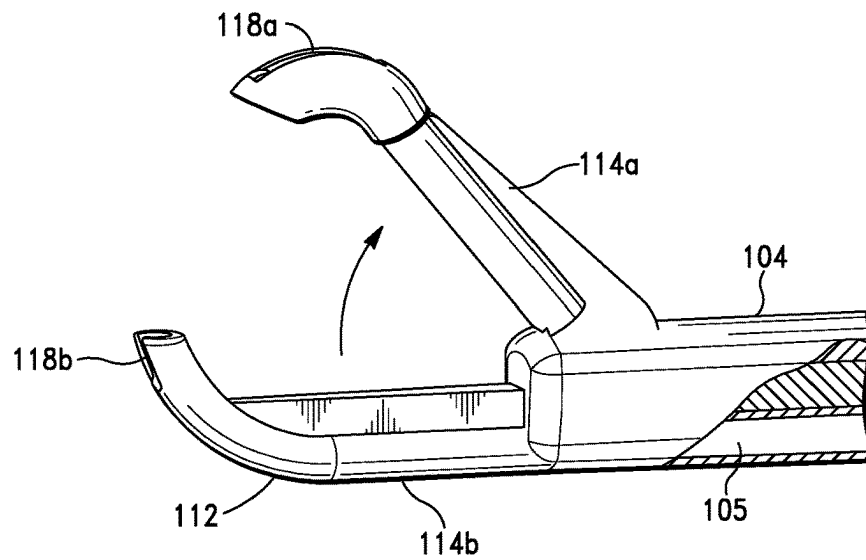


FIG. 10A

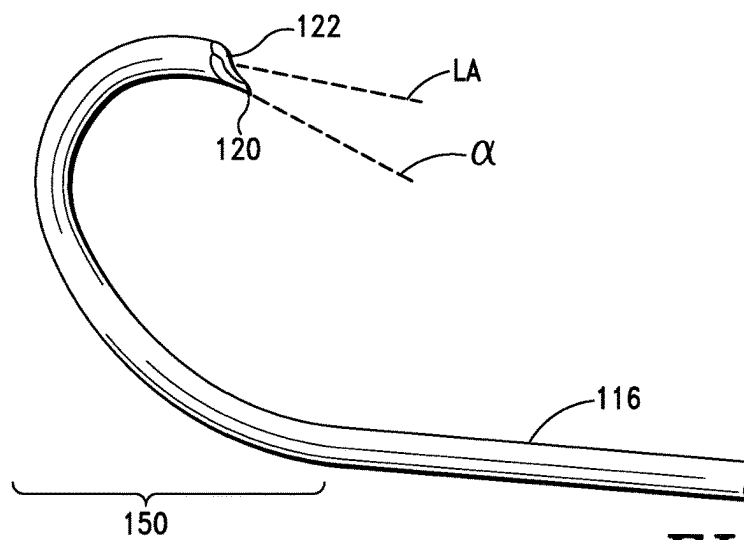


FIG. 10B

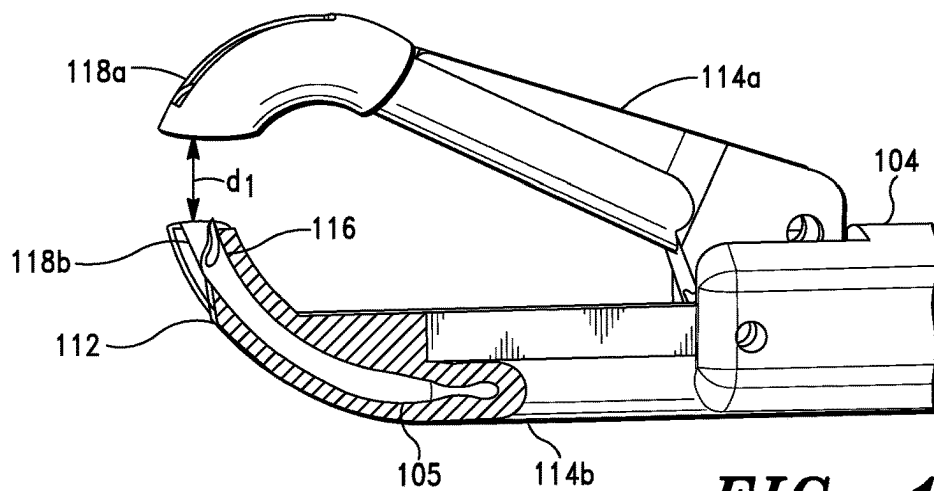


FIG. 10C

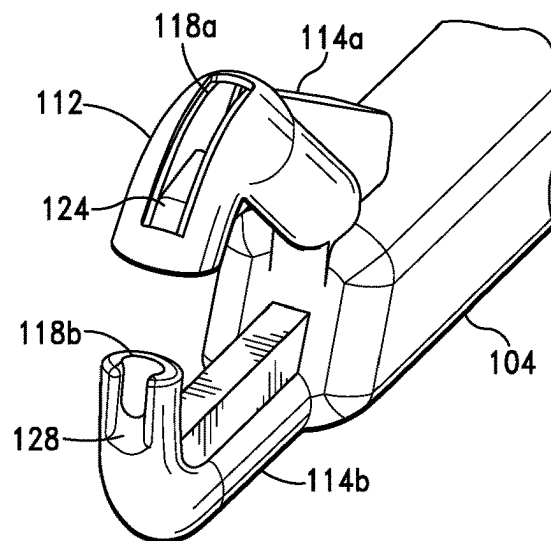


FIG. 11A

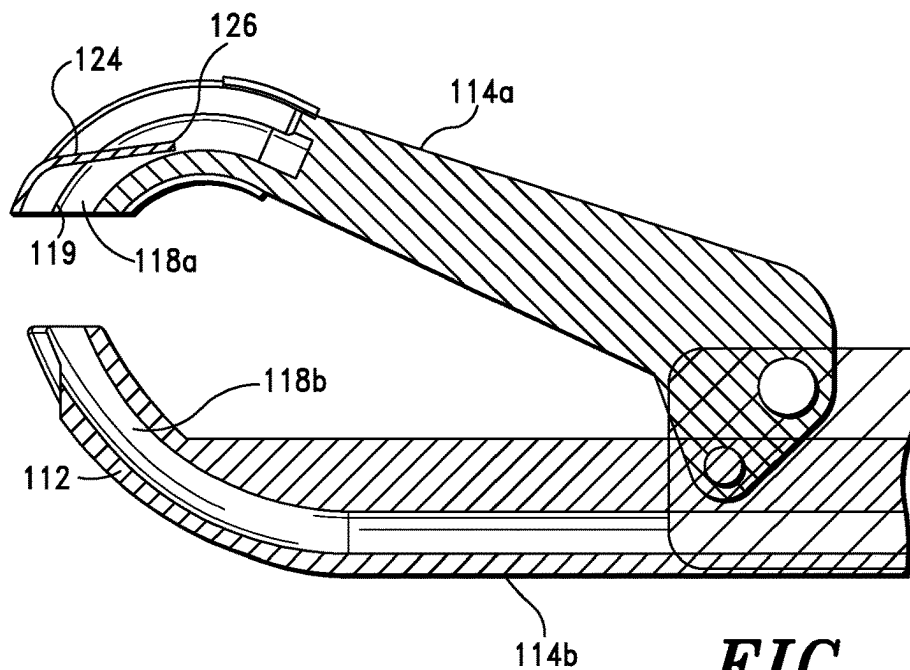


FIG. 11B

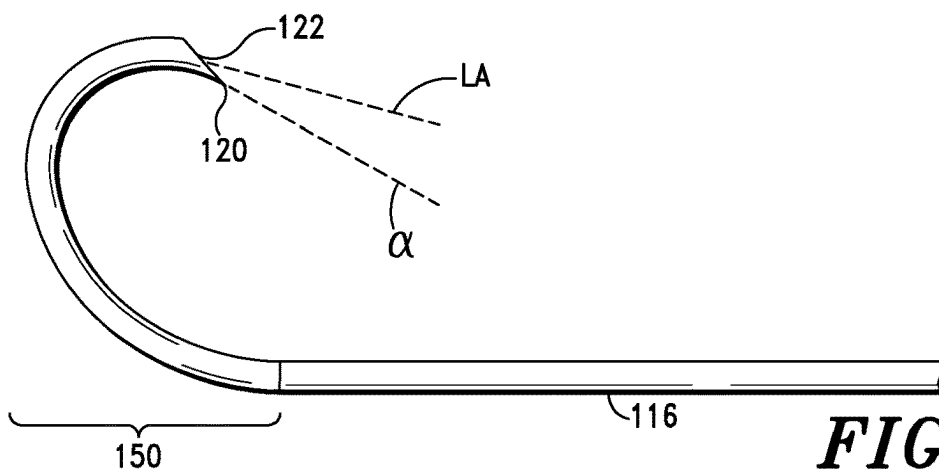


FIG. 11C

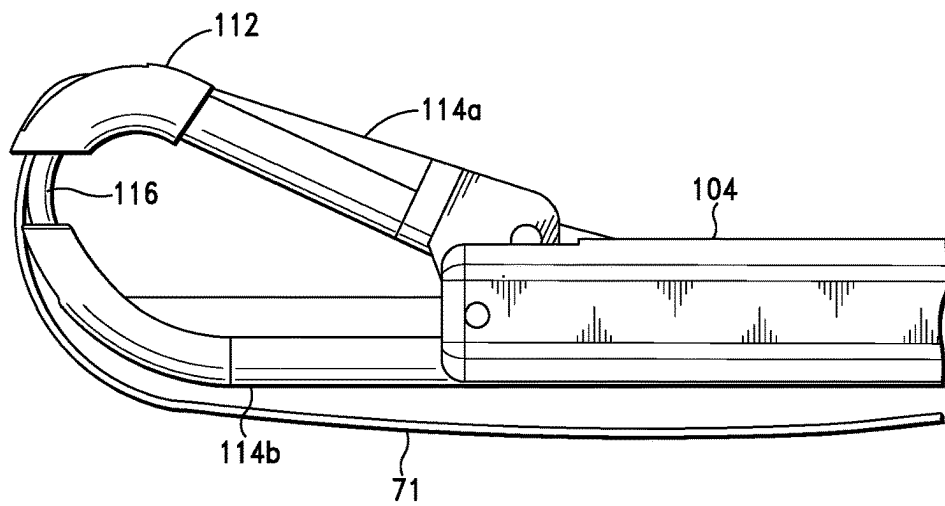


FIG. 12A

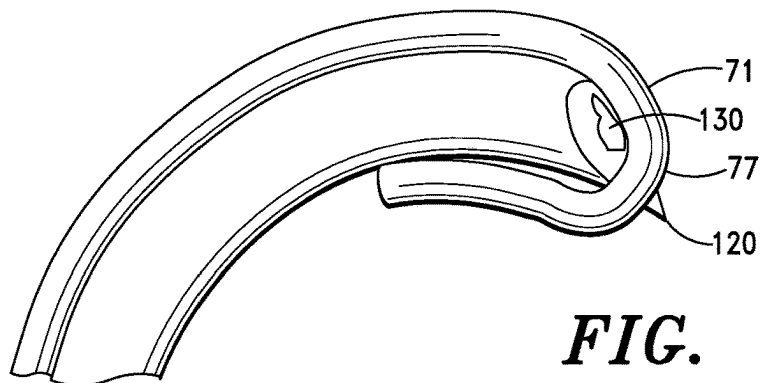


FIG. 12B

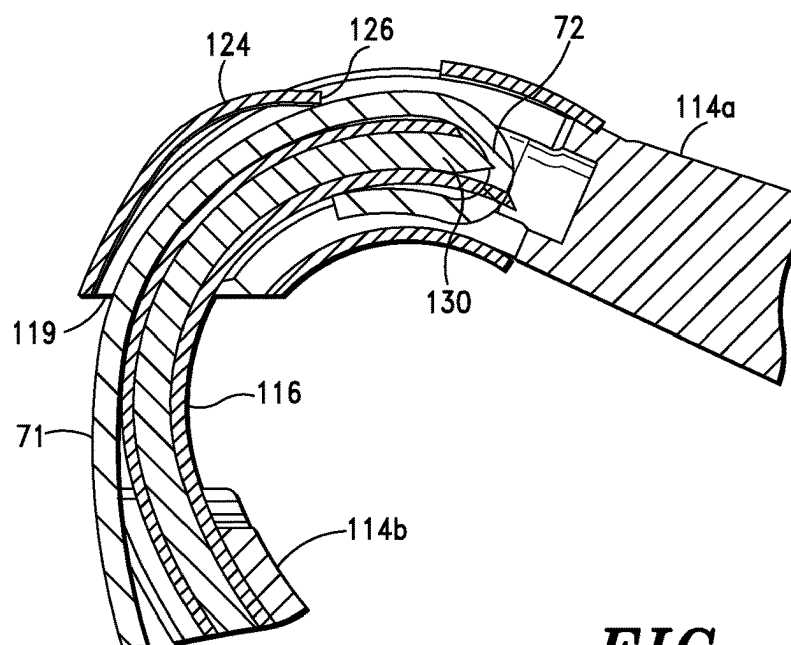
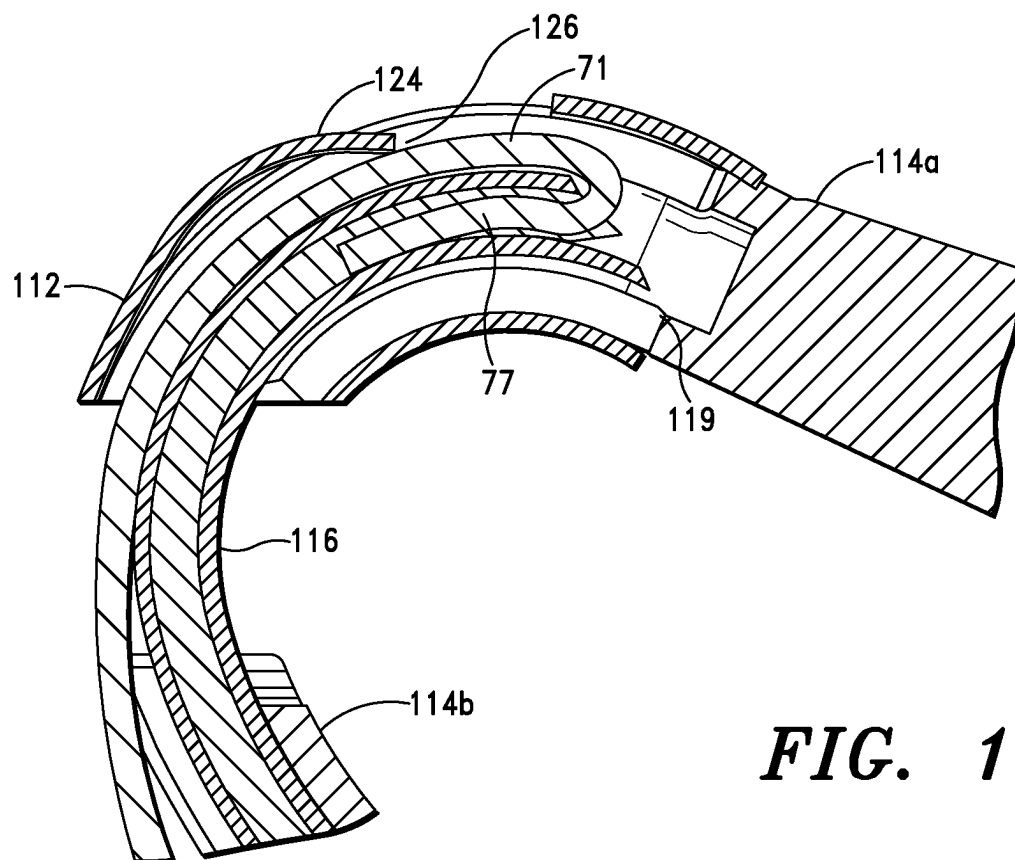
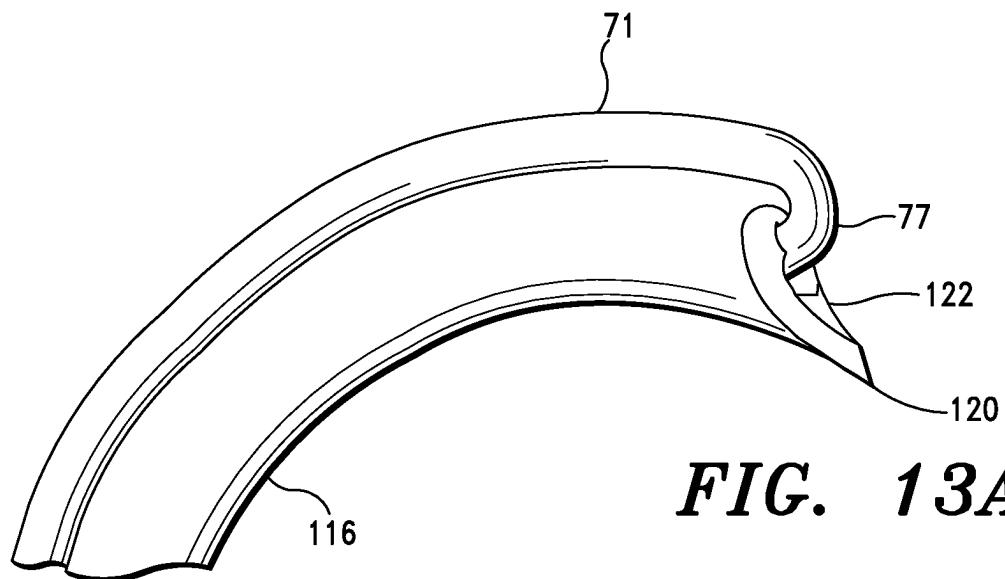


FIG. 12C



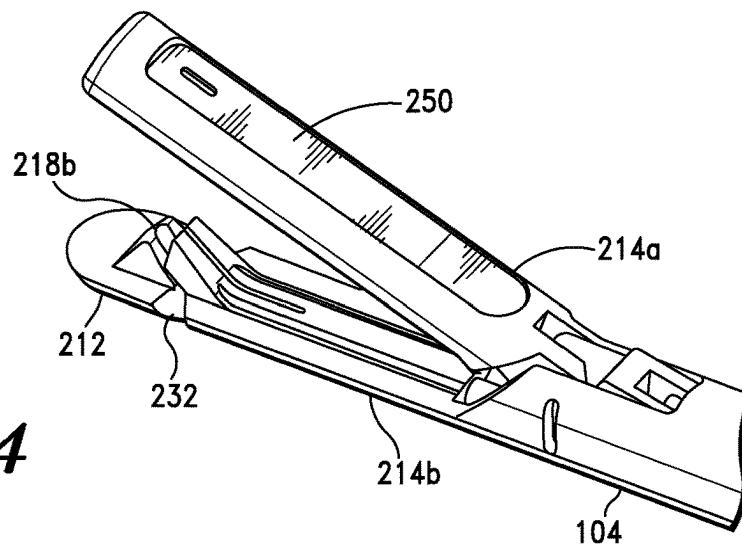


FIG. 14

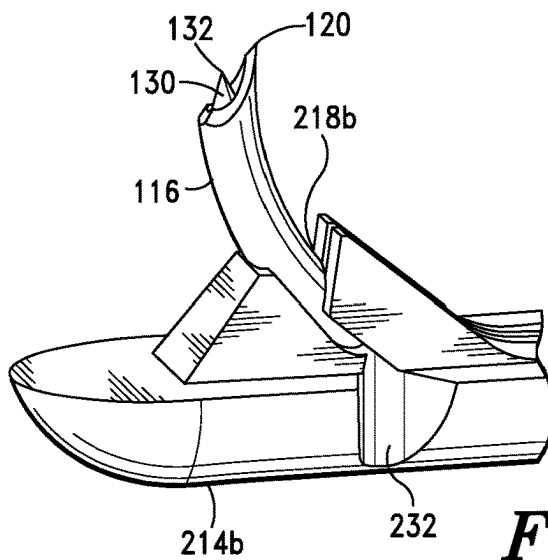


FIG. 15

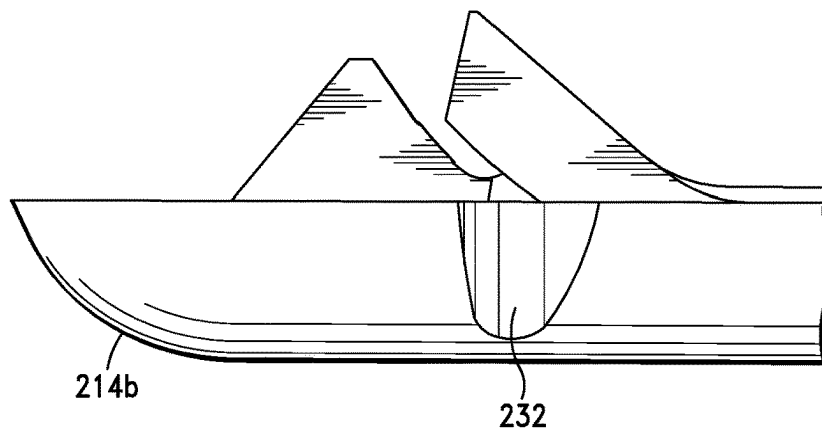


FIG. 16

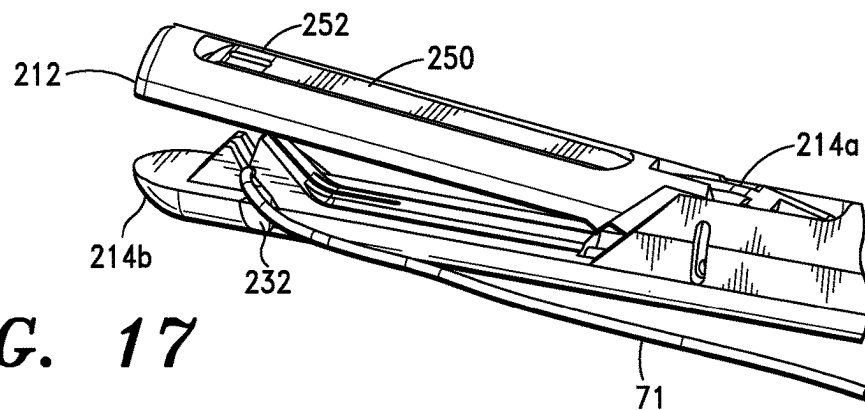


FIG. 17

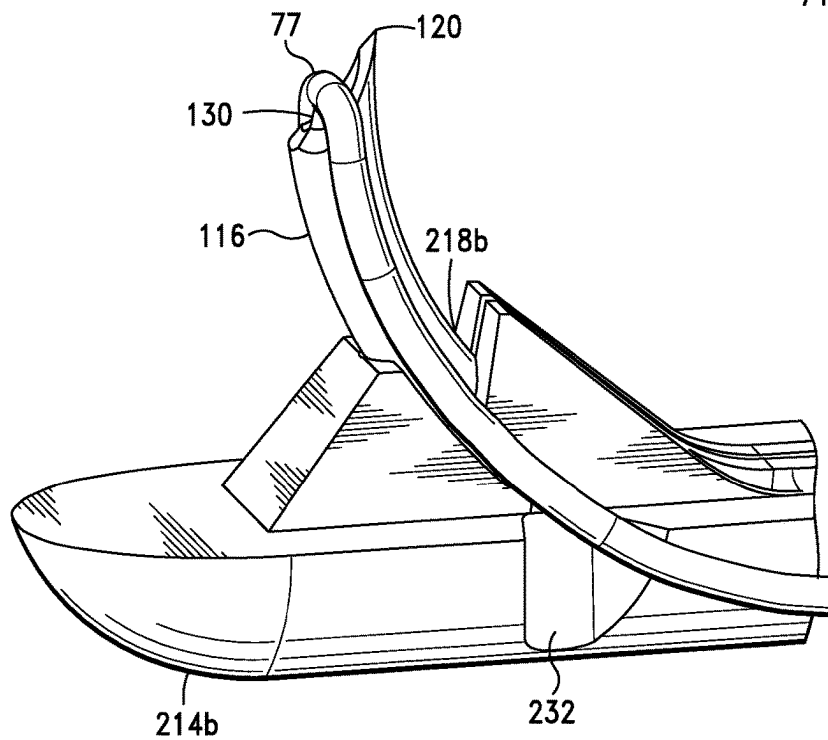


FIG. 18

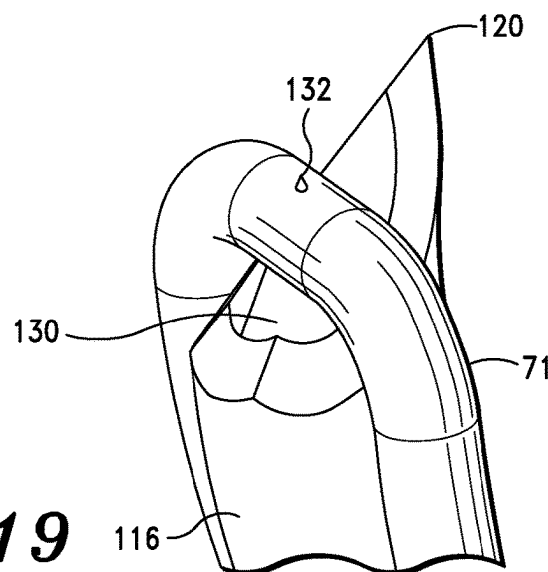


FIG. 19

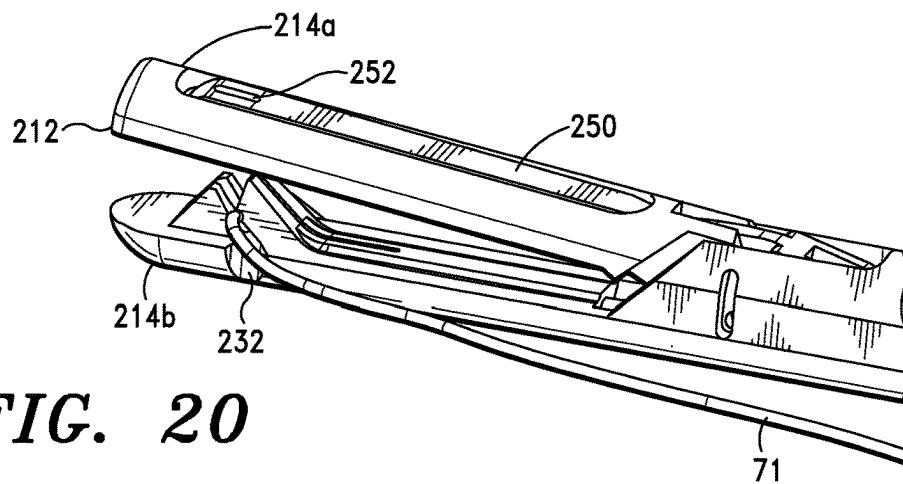


FIG. 20

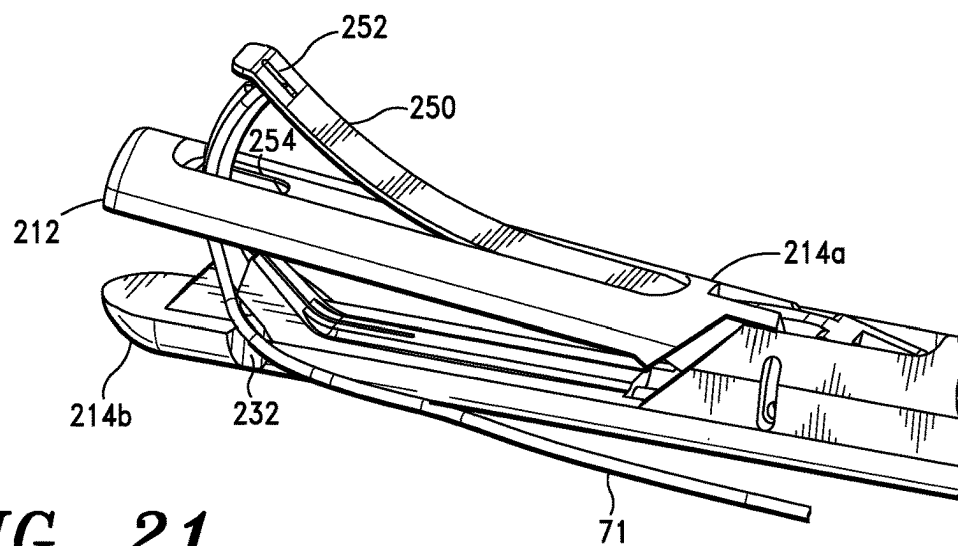


FIG. 21

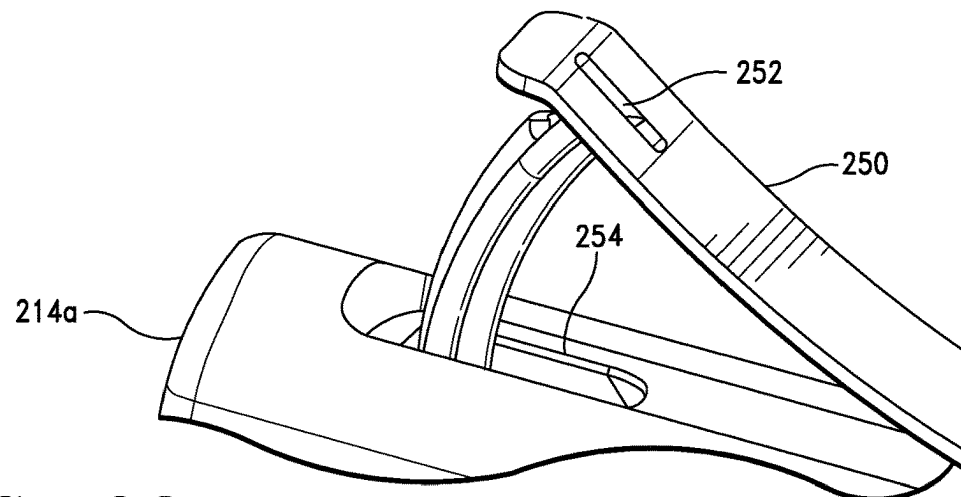


FIG. 22

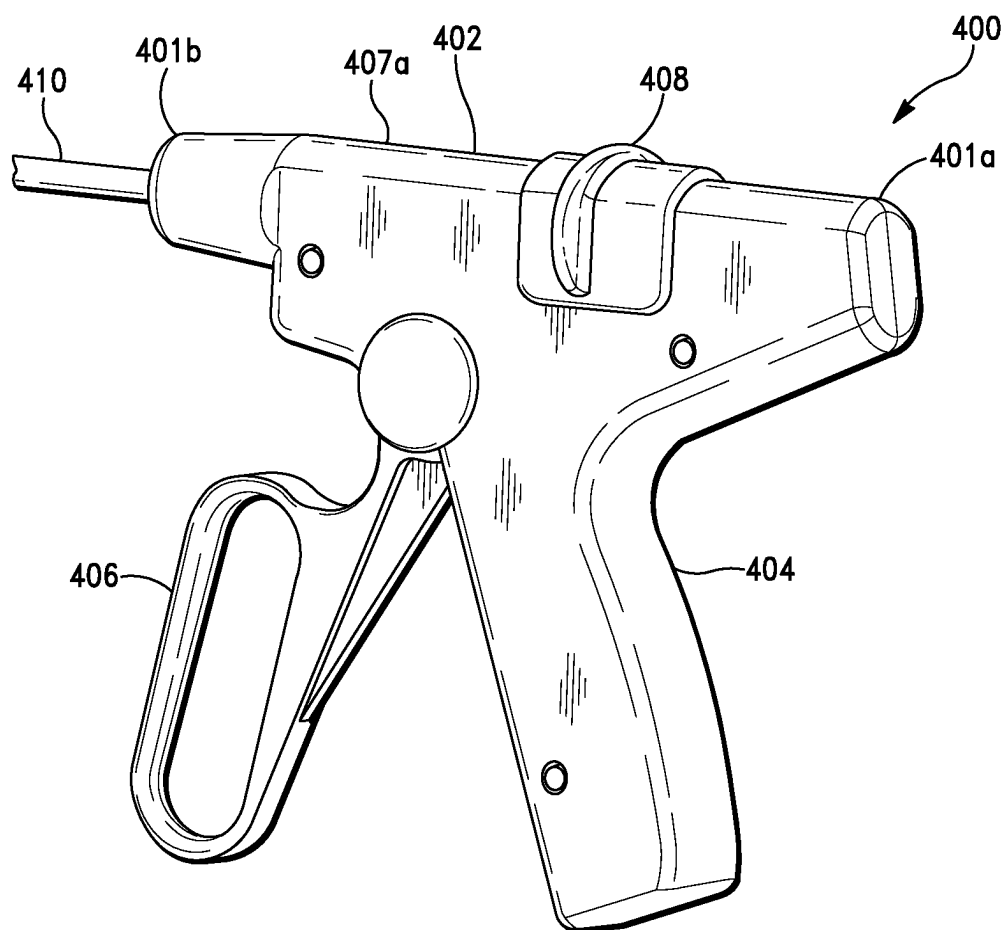


FIG. 23

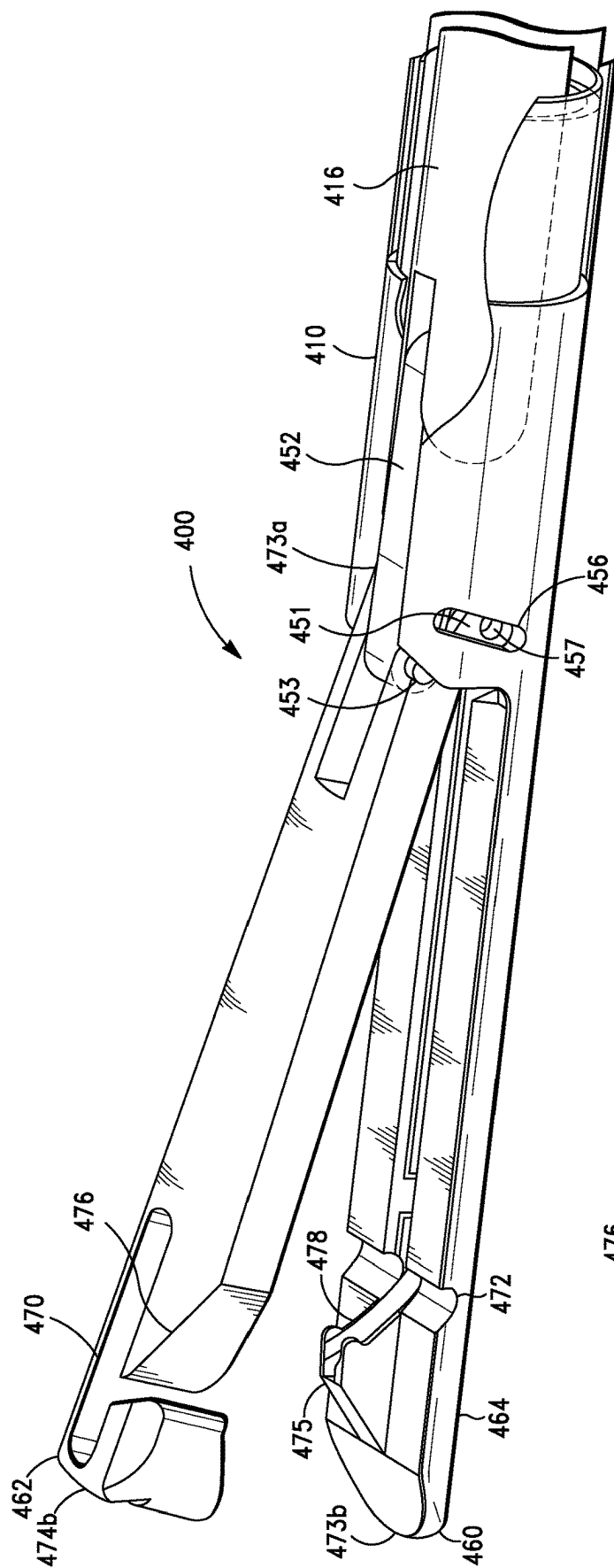


FIG. 24A

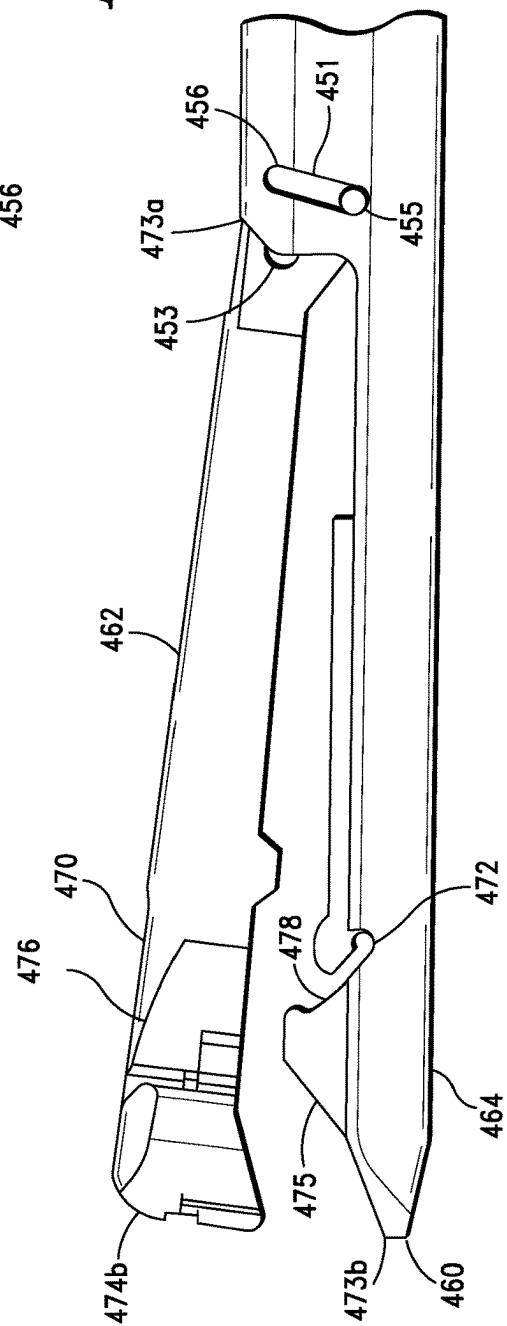


FIG. 24B

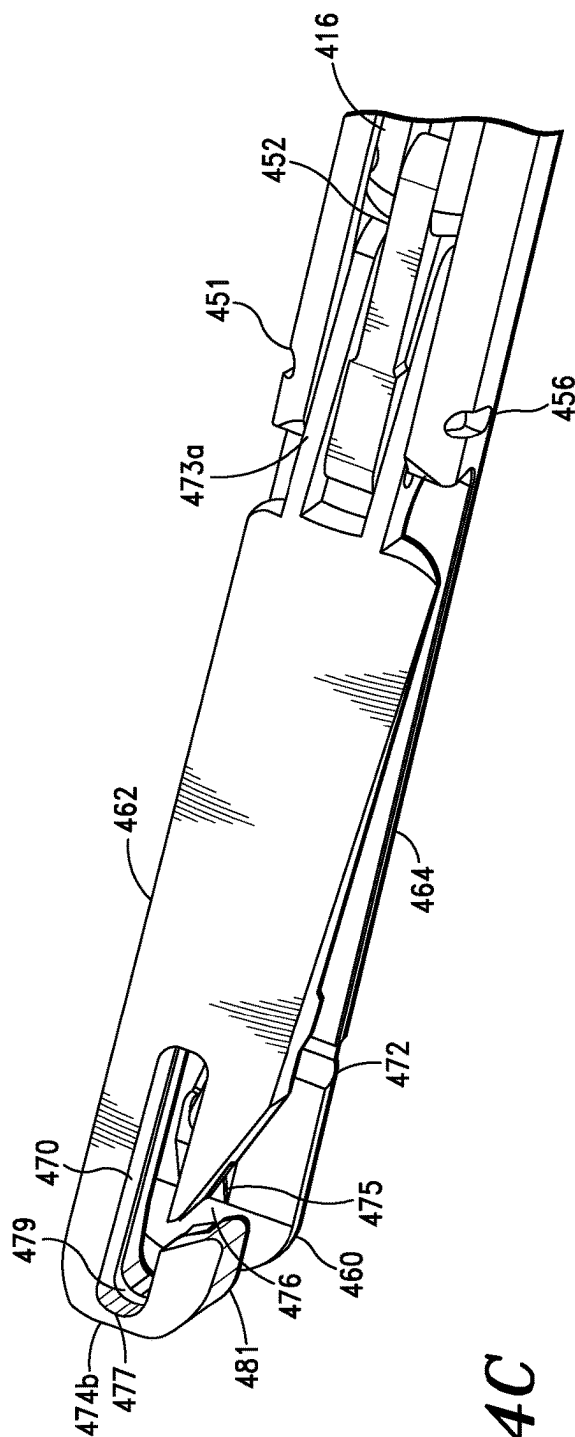


FIG. 24C

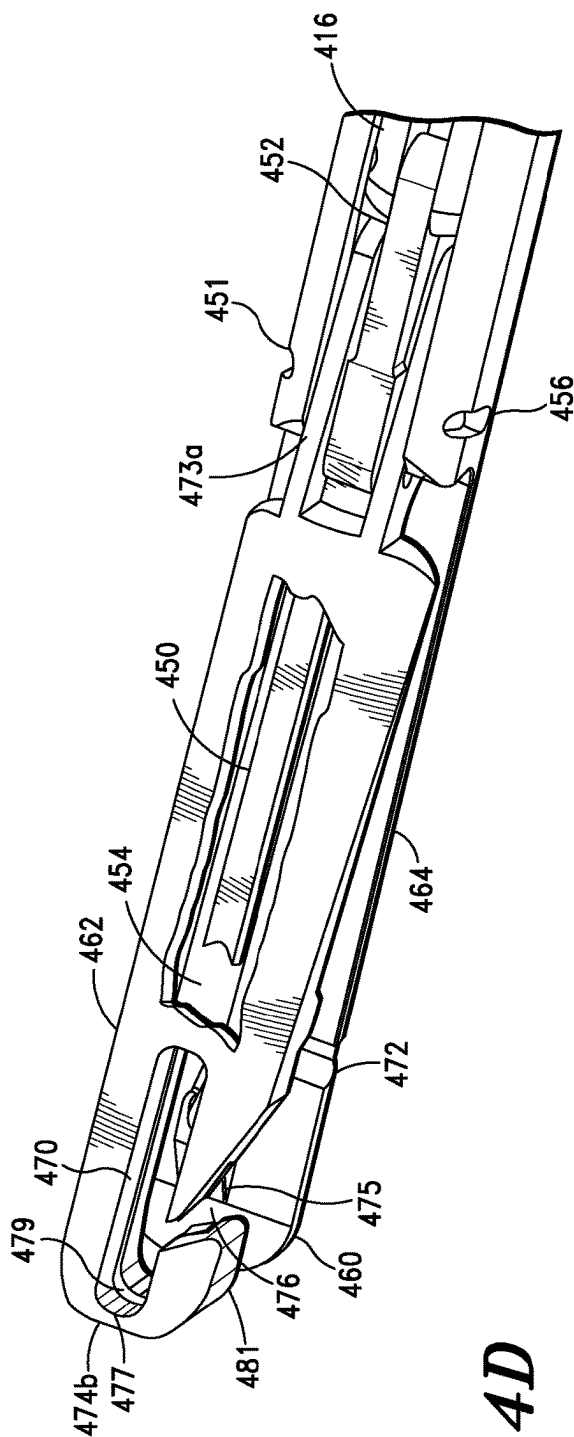


FIG. 24D

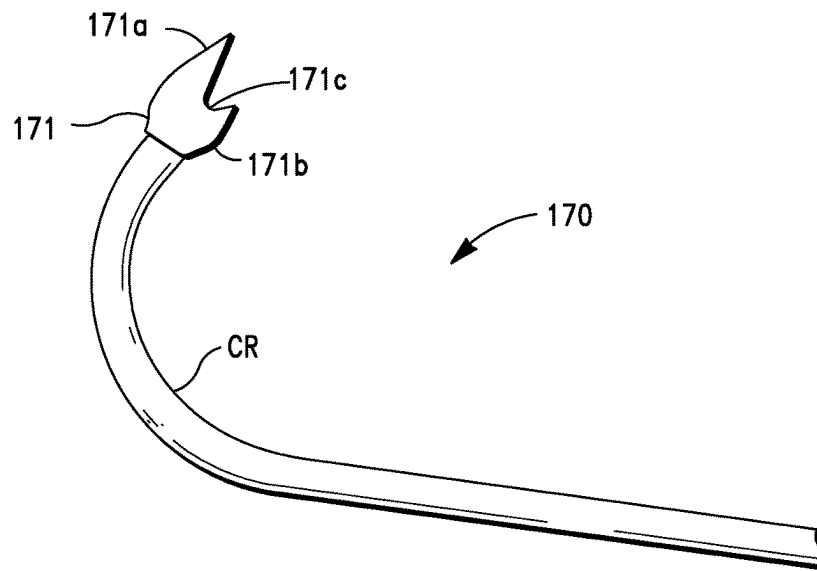


FIG. 24E

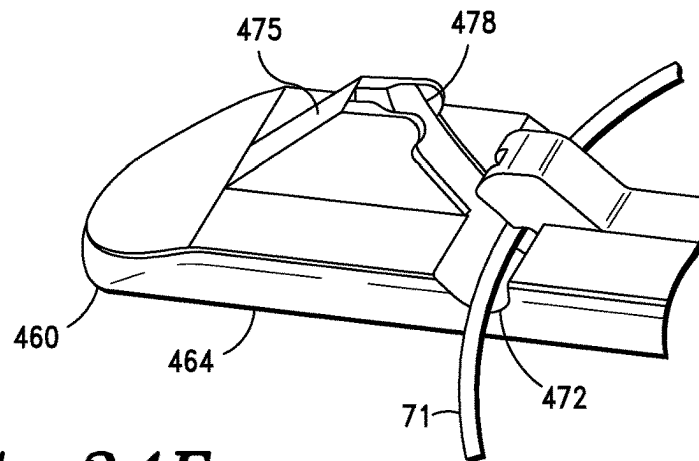


FIG. 24F

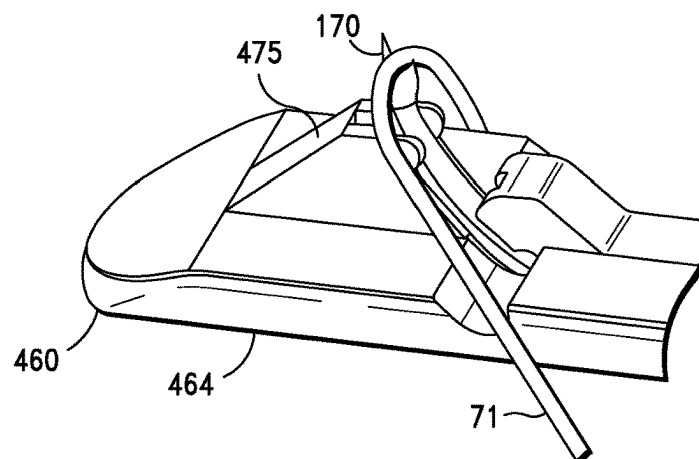


FIG. 24G

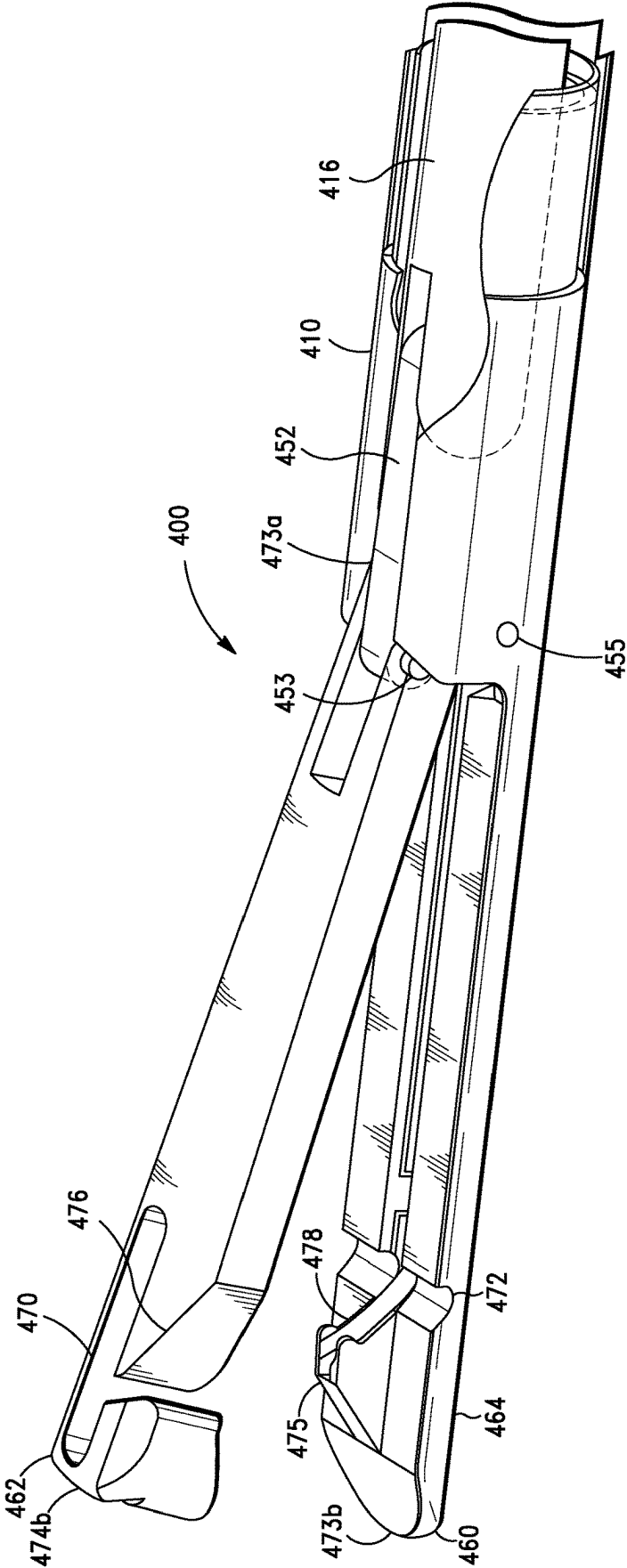


FIG. 25

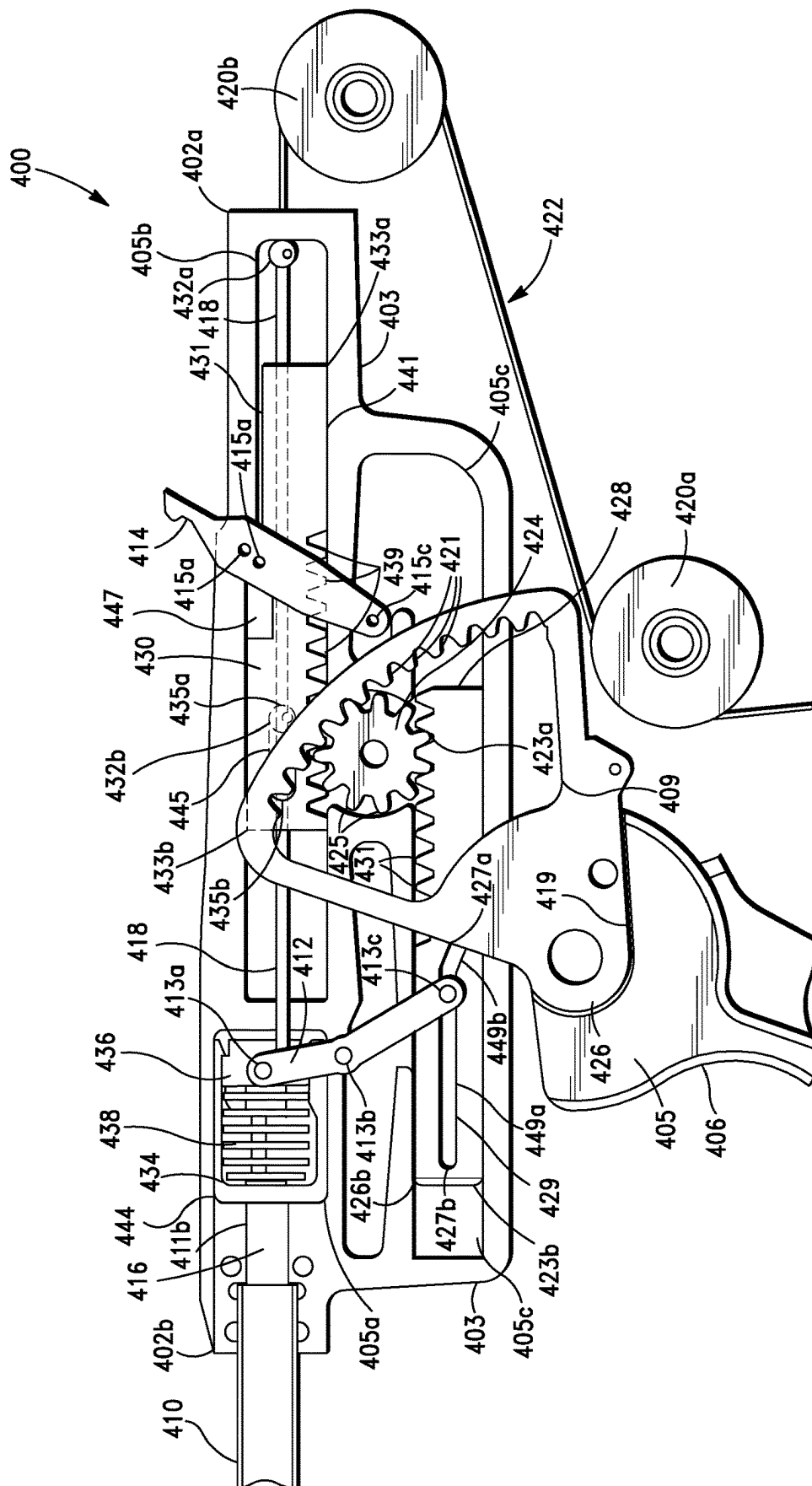


FIG. 26

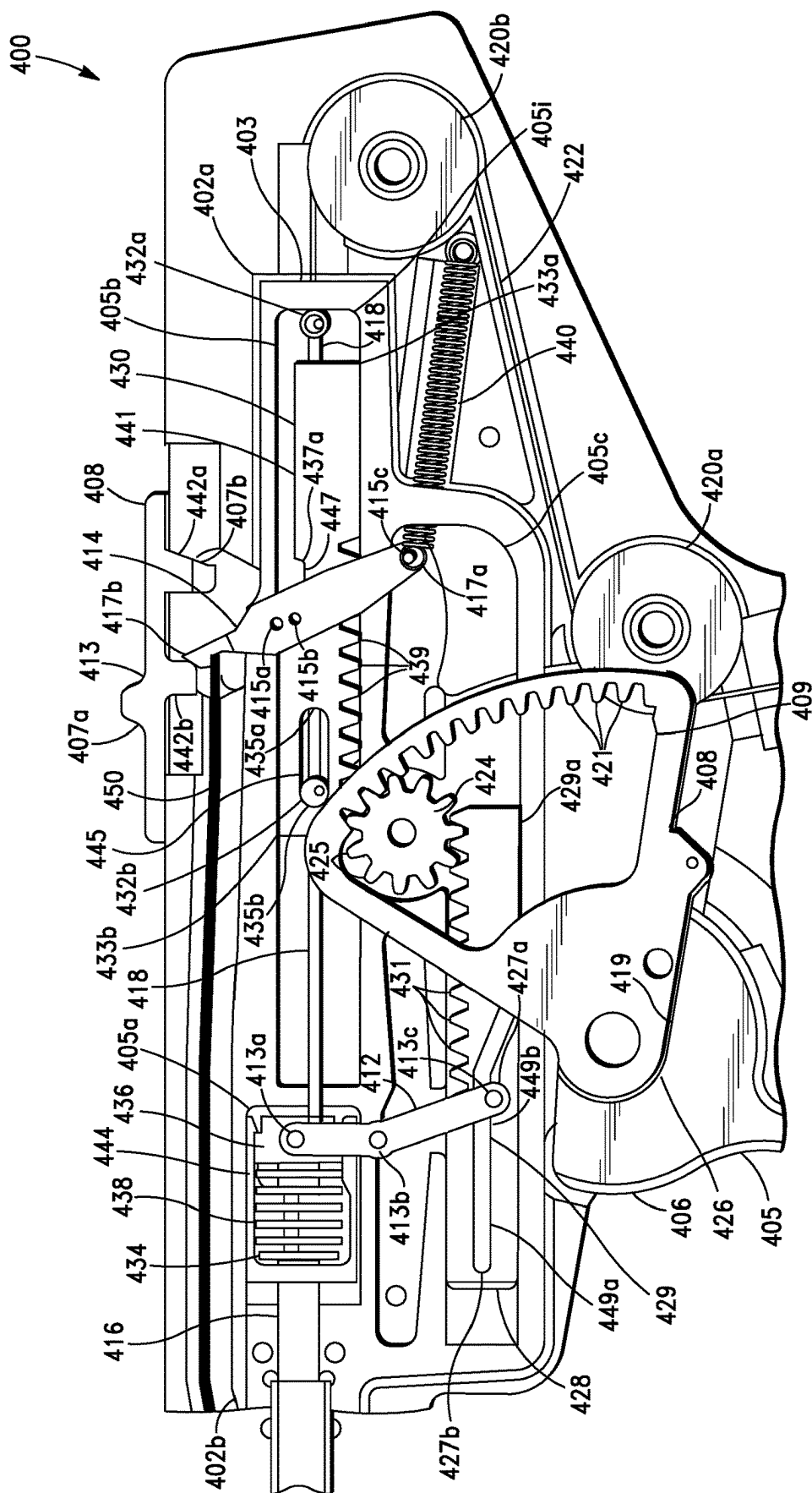


FIG. 27

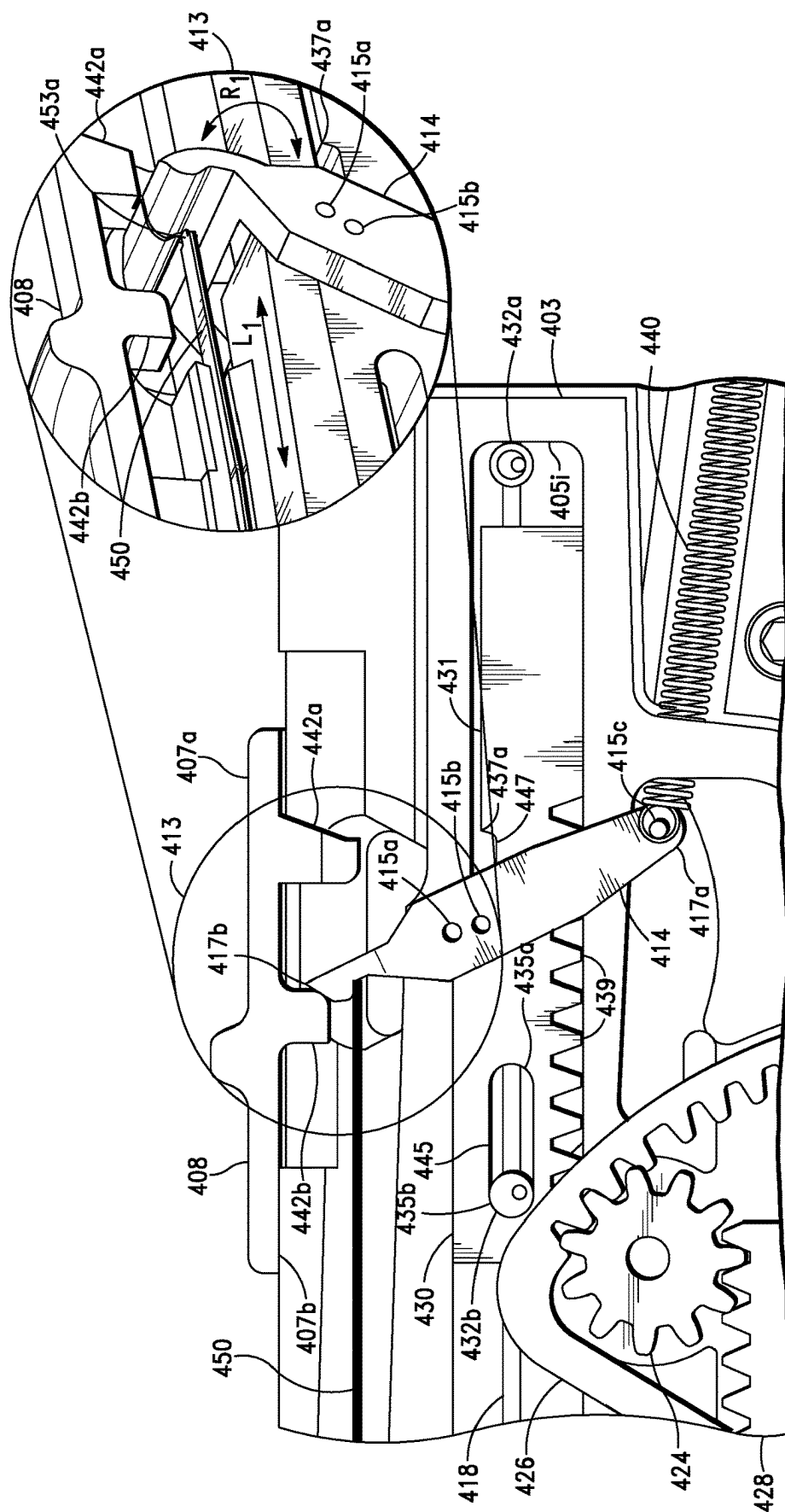


FIG. 28

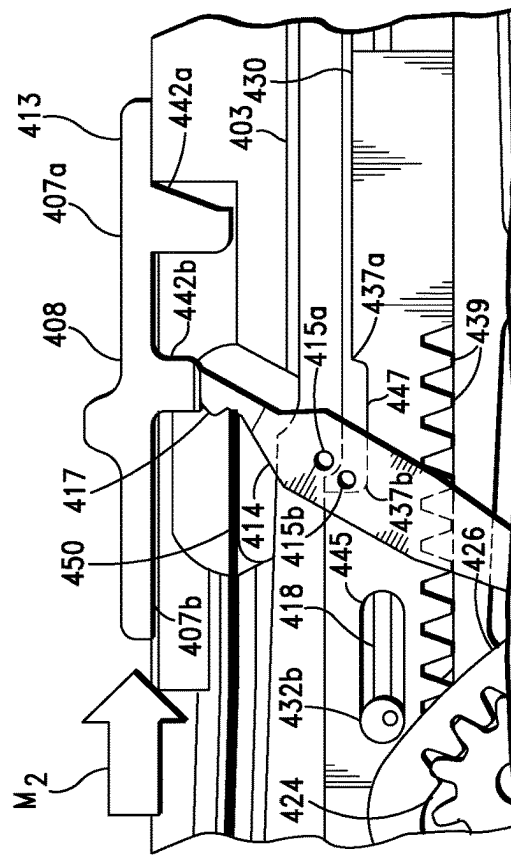


FIG. 29B

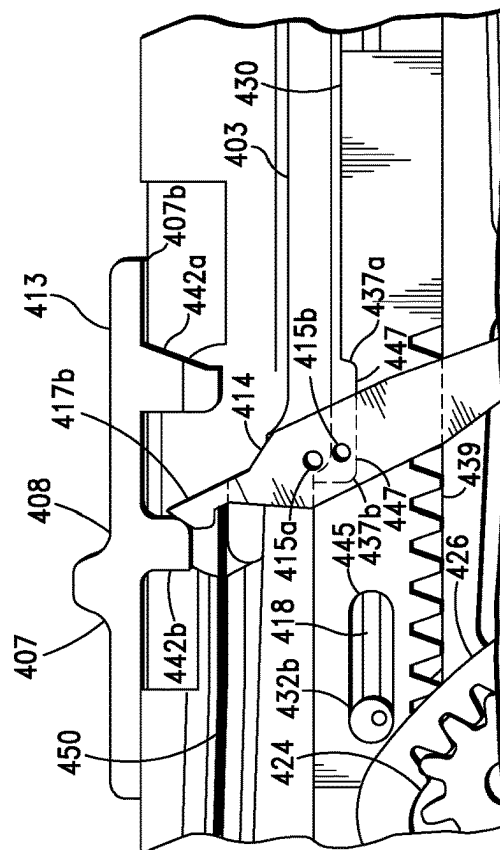


FIG. 29A

Synchronized Suture Passing Device Functions

Needle Articulation System			
Trigger Actuation	Jaw Articulation System	Suture Control System	
Stage 1	Default State—A*	stationary (in dwell)	stationary (in dwell)
Stage 2	A*—B*	gear driven retracted	stationary (in dwell)
Stage 3	B*—Fully Actuated	stationary (in dwell)	forward gear driven
Stage 4	Fully Actuated—B*	stationary (in dwell)	gear driven retracted
Stage 5	B*—A*	forward gear driven	spring retracted
Stage 6	A*—Default State	stationary (in dwell)	spring retracted

TRIGGER
ACTUATION
(CLOSING)

TRIGGER
ACTUATION
(RETURNING)

FIG. 30

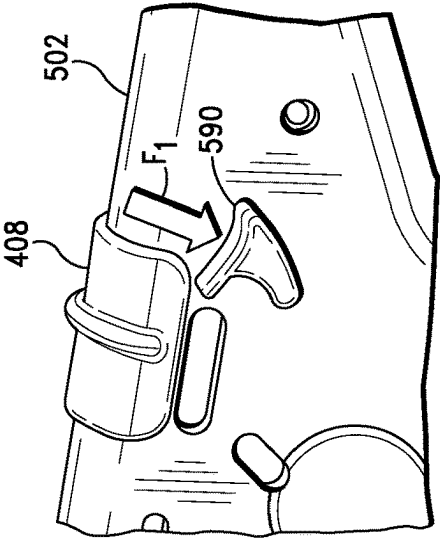


FIG. 31B

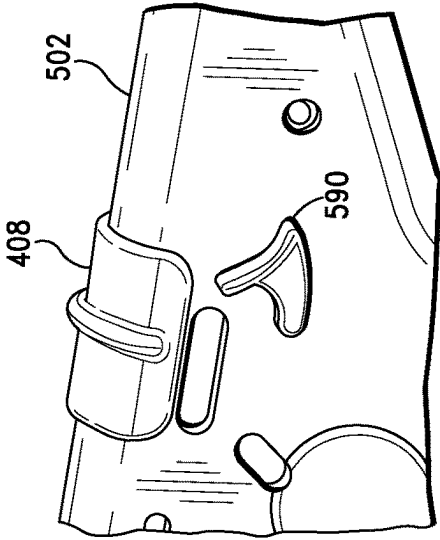


FIG. 31C

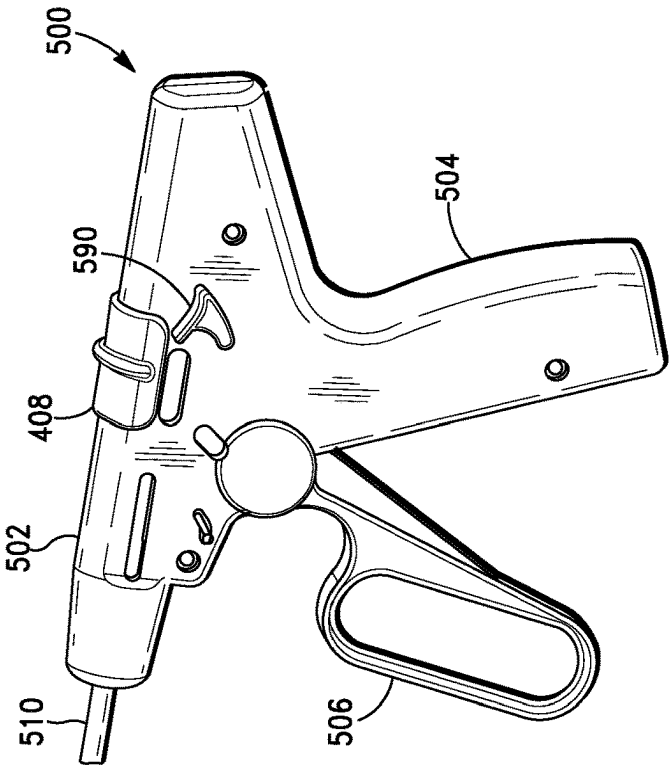


FIG. 31A

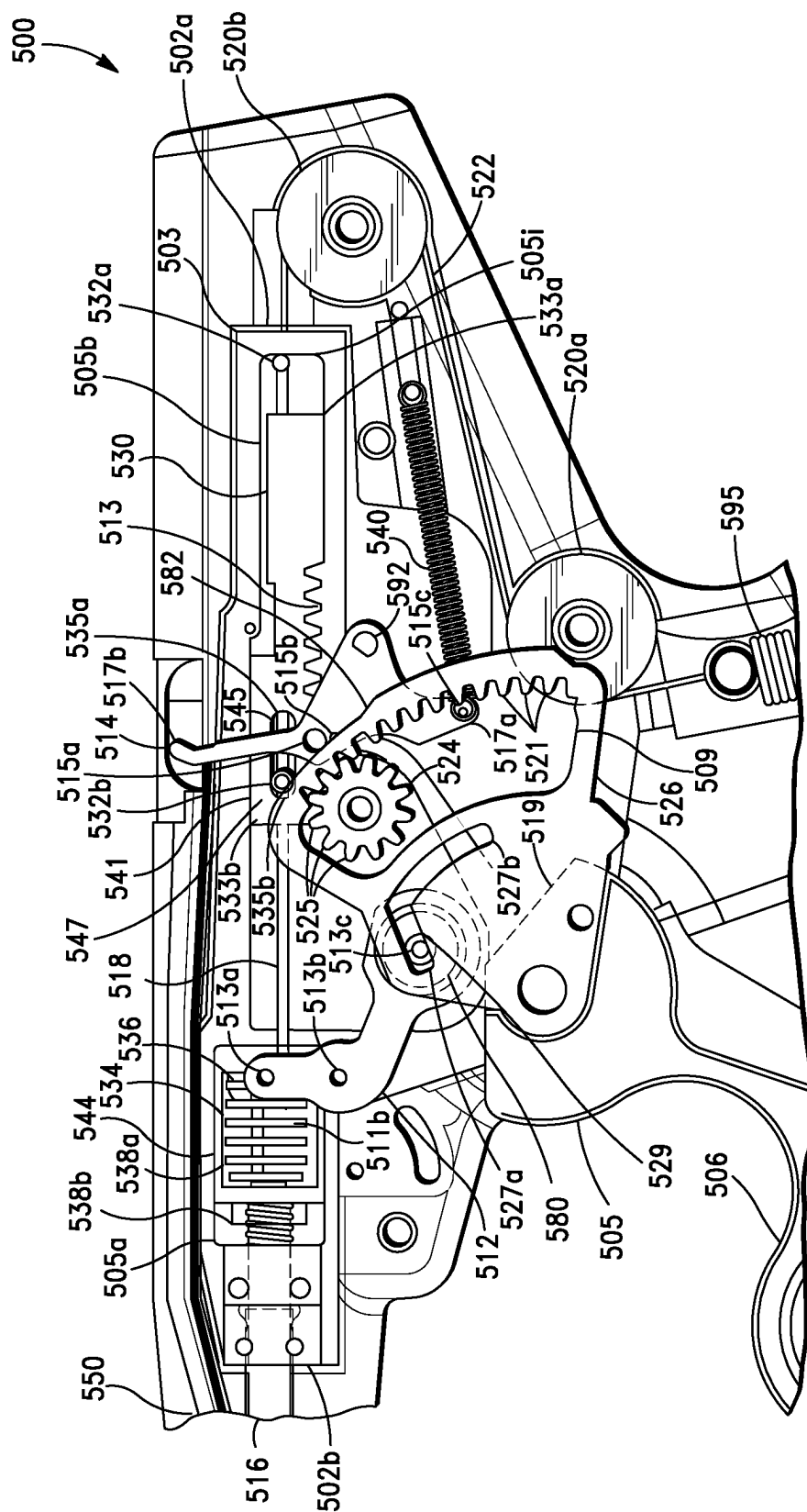


FIG. 32

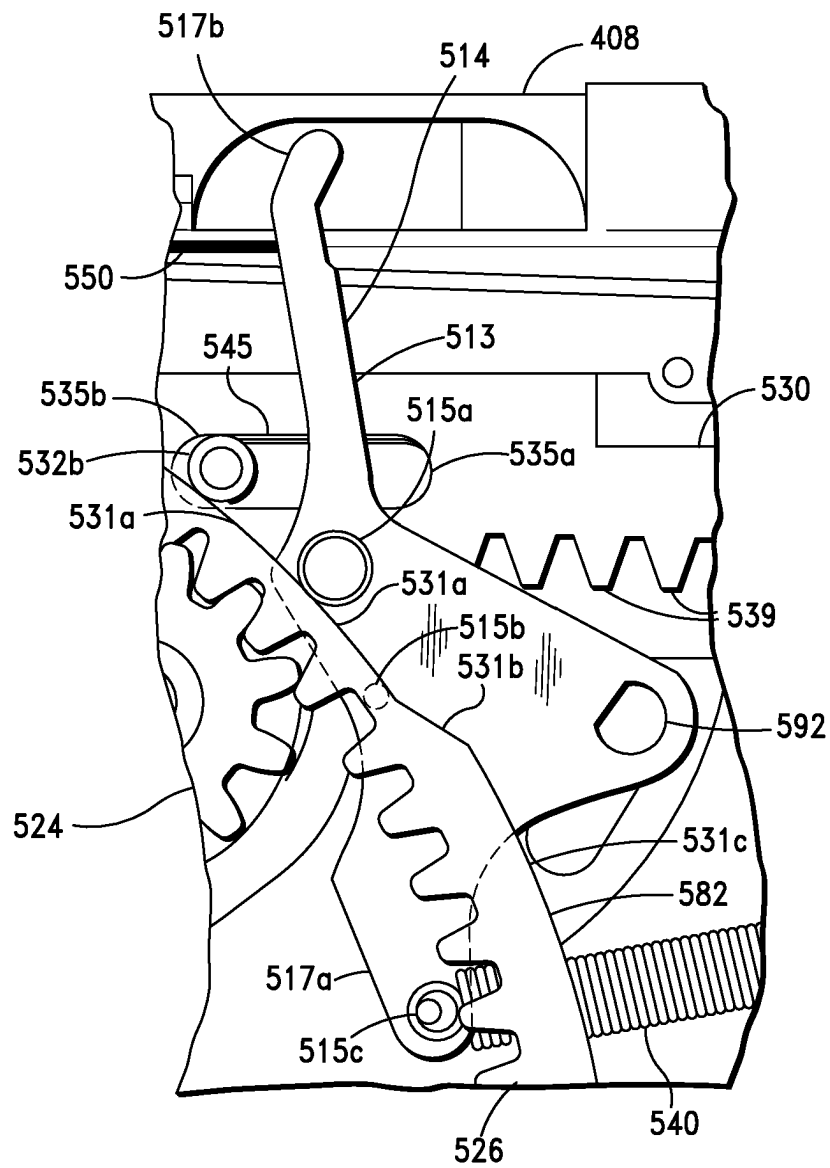


FIG. 33

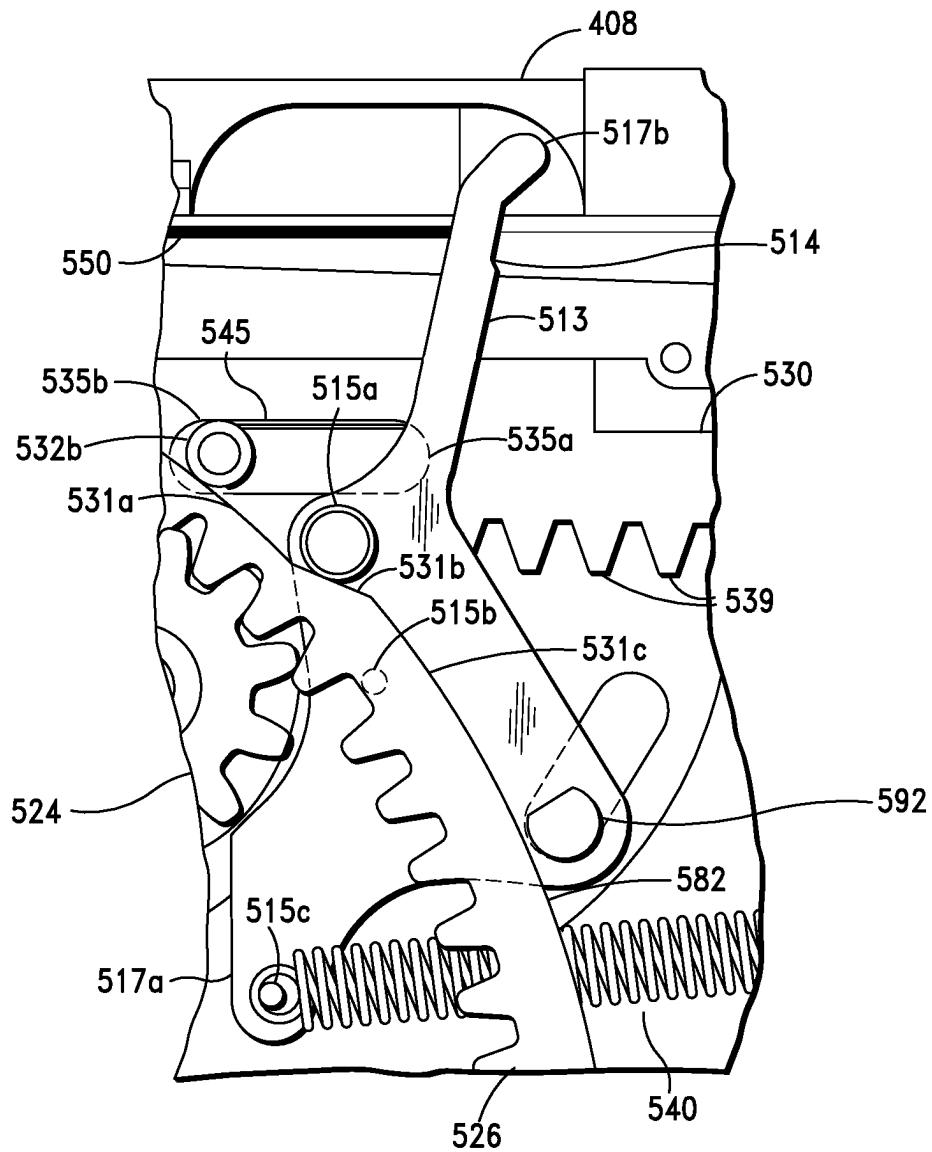


FIG. 34

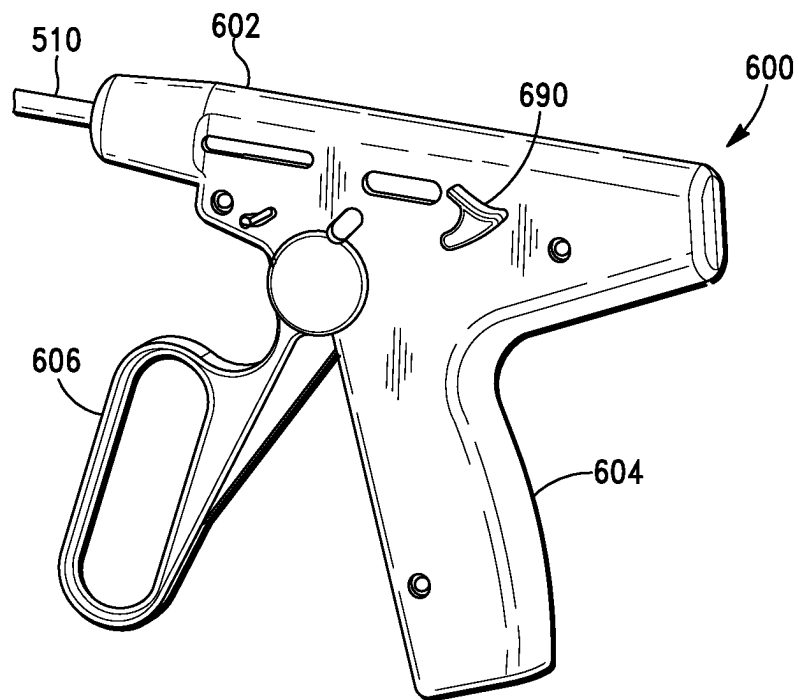


FIG. 35A

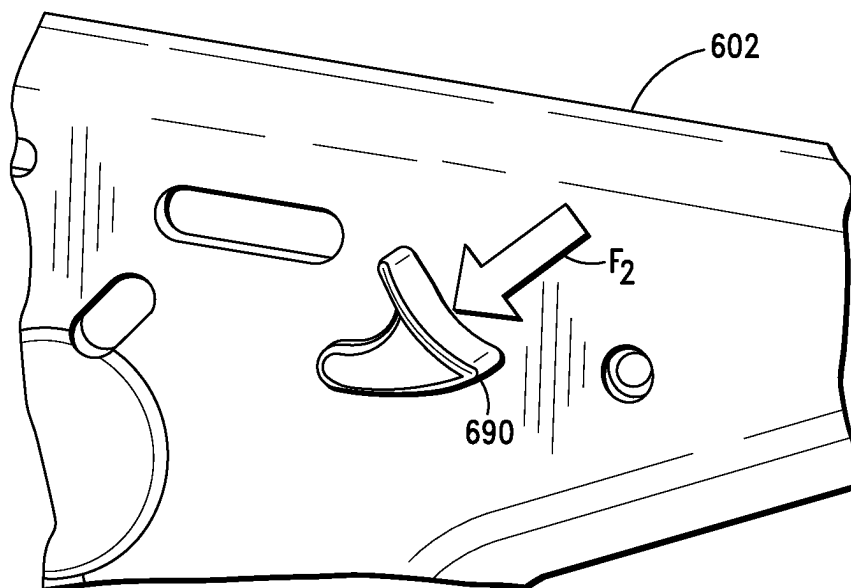


FIG. 35B

Suture Passing Device Functions
With Manual Suture Release System

AUTOMATIC FUNCTIONS			INDEPENDENT FUNCTIONS	
Needle Articulation System			MANUALLY ACTIVATED Suture Release System	
ACTUATION TRIGGER	Needle Articulation System	Jaw Articulation System		
Stage 1	stationary (in dwell)	forward gear driven		
Stage 2	stationary (in dwell)	stationary (in dwell)		
Stage 3	forward gear driven	stationary (in dwell)		
Stage 4	gear driven retracted	stationary (in dwell)		
Stage 5	spring retracted	stationary (in dwell)		
Stage 6	spring retracted	gear driven retracted		

TRIGGER ACTUATION (CLOSING)

TRIGGER ACTUATION (RETURNING)

FIG. 36

SYSTEMS, APPARATUS AND METHODS FOR PASSING SUTURE THROUGH SOFT TISSUE

CROSS-REFERENCES TO RELATED APPLICATIONS

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

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

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.

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.

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.

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.

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.

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 control-

ling 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.).

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.

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.

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.

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.

3

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.

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.

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

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.
- 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.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features and advantages will become apparent from the following and more particular description of the

4

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:

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;

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

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

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;

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;

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

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;

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;

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

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;

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

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;

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;

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;

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

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

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;

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;

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;

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

5

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;

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;

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;

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

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;

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;

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;

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;

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;

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;

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;

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;

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;

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;

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;

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;

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;

6

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;

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;

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;

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;

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;

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

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

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

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

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;

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

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;

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;

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

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;

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;

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;

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;

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;

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

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;

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;

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;

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;

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;

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;

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

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

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.

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.

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.

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

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.

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.

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.

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.

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.

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

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.

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

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.

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.

The term “endoscopy”, as used herein, means and includes any minimally invasive surgical procedure con-

ducted through at least one opening in a subject's body, including, but not limited to arthroscopy, laparoscopy, hysteroscopy and the like.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

According to the invention, the needle 70 can also comprise a solid structure.

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

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.

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.

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.

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.

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.

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

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.

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

11

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**.

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.

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.

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**.

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.

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.

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.

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

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.

12

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.

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**.

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**.

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.

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.

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.

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.

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**.

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

13

end 110. In a preferred embodiment, the jaw mechanism 112 top and bottom members 114a, 114b comprise proximal and distal ends.

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.

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.

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

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.

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.

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.

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.

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.

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.

Referring now to FIG. 10A, there are shown top and bottom members 114a, 114b of jaw mechanism 112 in an

14

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.

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.

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.

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.

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.

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.

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.

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} - 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} - 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.

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.

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°.

In some embodiments, the needle 116 comprises a solid structure.

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

15

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.

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 di from each other.

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

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.

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**.

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.

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**.

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**.

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**.

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**.

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**.

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.

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.

16

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**.

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**.

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**.

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

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**.

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**.

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**.

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**.

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**.

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.

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.

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.

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.

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

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.

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.

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.

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

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

Jaw Articulation

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.

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.

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

19

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**.

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**.

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**.

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.

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**.

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.

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.

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**.

Suture Control

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**.

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

20

the distal end **474b** of the top jaw member **462**, when the ribbon **450** is in an extended suture engagement position.

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.

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**.

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.

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.

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.

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.

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**.

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**.

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 "R₁") to slidably translation of the ribbon **450** towards the proximal end **402a** or distal end **402b** of the device frame **403** (denoted by arrow "L₁").

As further illustrated in FIG. 27, the distal end **417b** of the capture lever **414** is sized and configured to abut tabs **442a**,

21

442b disposed on the bottom surface 407b of the suture control switch 408 (see also FIGS. 29A and 29B).

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.

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 dwell.

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.

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 (R₁) 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.

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.

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.

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.

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.

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

22

control switch 408 to facilitate communication by and between the capture lever 414 and the suture control switch 408.

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.

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 “M₂”, and from the “no-engagement” mode to the “auto-engagement” mode.

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.

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.

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.

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.

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.

As set forth below, according to the invention, the suture control switch 408 can also be manually moved to the

23

“no-engagement” position illustrated in FIG. 29B to disengage the suture retaining ribbon 450 from the suture 71 and, hence, release the suture 71.

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.

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.

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.

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.

Needle Articulation

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.

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.

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.

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.

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

24

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

Jaw Articulation

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

Suture Control

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.

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.

27

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.

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.

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.

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.

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.

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.

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.

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.

Referring again to FIG. 31A, in a preferred embodiment, the suture passing device 500 further comprises a suture

28

release tab 590, which, as discussed in detail below, is adapted to cooperate with the capture lever 514 and, thereby, suture control system 513.

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.

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

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 “F₁” 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).

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.

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.

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.

Needle Articulation

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.

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.

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.

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.

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.

29

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.

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.

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.

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.

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, retention 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.

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.

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

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.

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.

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).

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

As illustrated in FIGS. 35A and 35B, the manual release system comprises an external suture release tab 690, which

30

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).

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.

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 "F₂" (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.

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.

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.

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.

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

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;

31

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.

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.

What is claimed is:

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

32

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 con-

tinuous 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. 5

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

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. 20

* * * * *