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(12) United States Patent
Mohammadpour et al.

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(54) **LINEAR TISSUE CLIPPING DEVICE**

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(73) Assignee: **UNITED STATES ENDOSCOPY GROUP, INC.**, Mentor, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 283 days.

(21) Appl. No.: **18/199,912**

(22) Filed: **May 19, 2023**

(65) **Prior Publication Data**

US 2023/0371956 A1 Nov. 23, 2023

Related U.S. Application Data

(60) Provisional application No. 63/344,354, filed on May 20, 2022.

(51) **Int. Cl.**
A61B 17/128 (2006.01)
A61B 17/12 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/1285*** (2013.01); *A61B 2017/12004* (2013.01)

(58) **Field of Classification Search**
CPC ... A61B 17/1285; A61B 17/10; A61B 17/083; A61B 2017/12004; A61B 2017/0034; A61B 2017/00477; A61B 2017/00269; A61B 2017/00818; A61B 2017/00867
See application file for complete search history.

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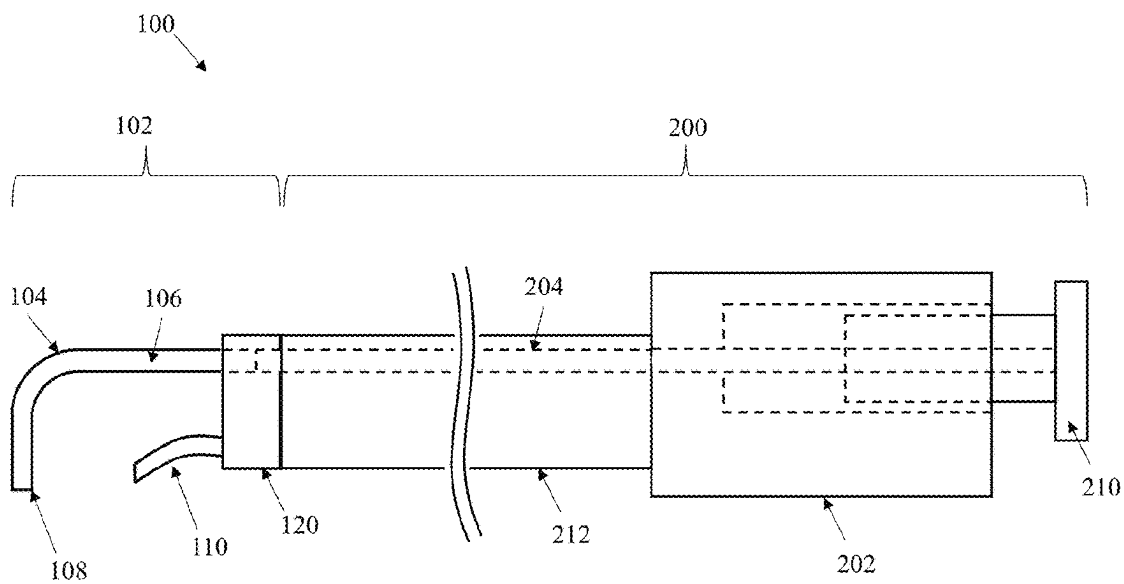
Primary Examiner — Ryan J. Severson
(74) *Attorney, Agent, or Firm* — Calfee, Halter & Griswold LLP

(57) **ABSTRACT**

A tissue clipping device for clipping tissue and methods of using the same. The device includes a tissue clipping assembly for clipping tissue and a drive assembly operable to control the operation of the tissue clipping assembly. The tissue clipping assembly includes a distal arm that is linearly extendable and retractable to clip tissue. The tissue clipping assembly may be decoupled from the drive assembly after tissue is clipped. Additional clipping assemblies may be deployed with the drive assembly to close larger defects.

20 Claims, 57 Drawing Sheets



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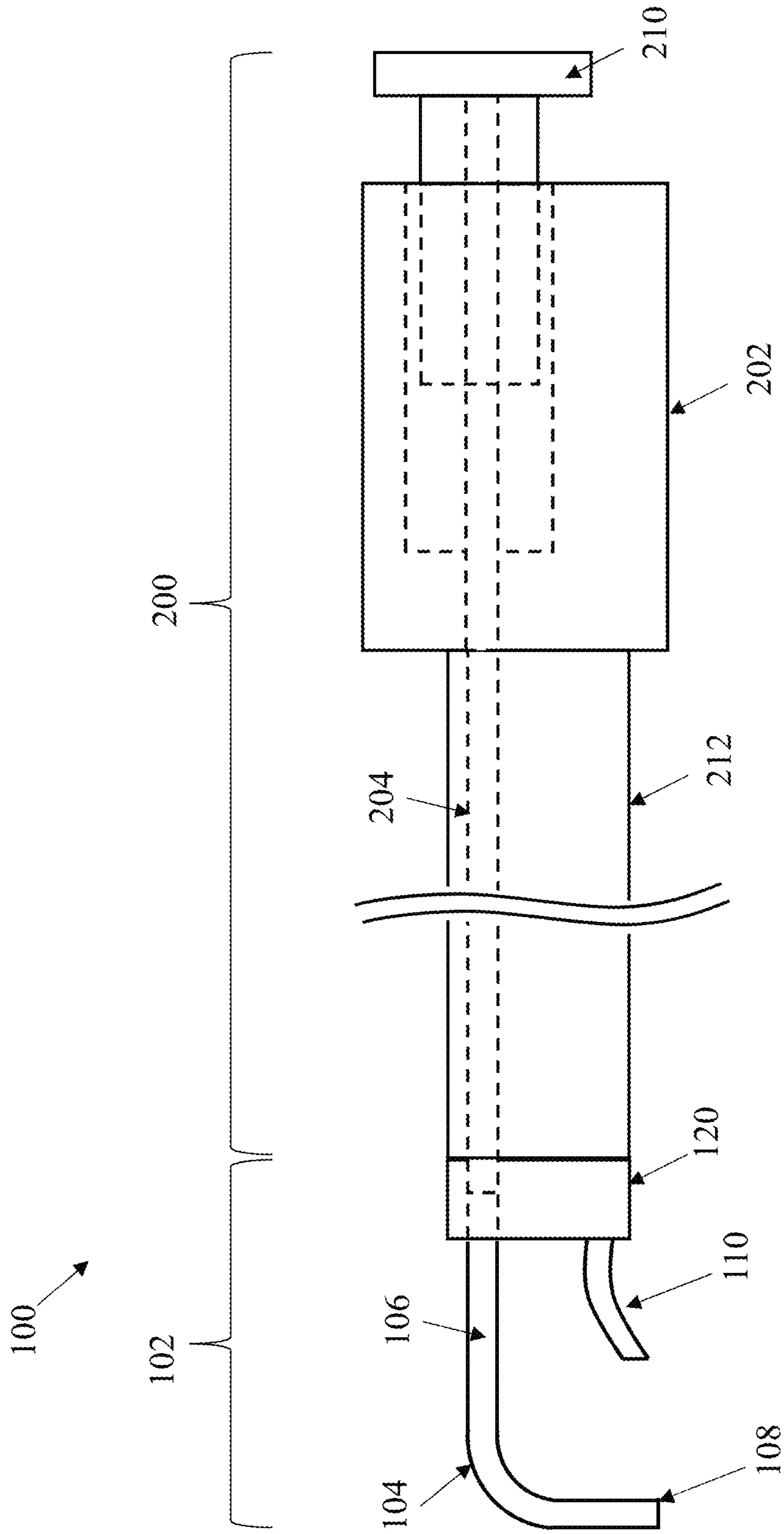


FIG. 1

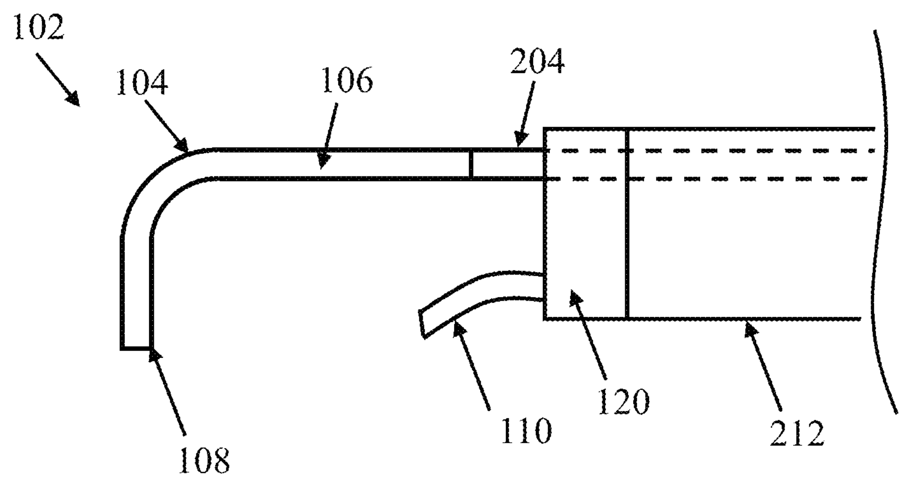
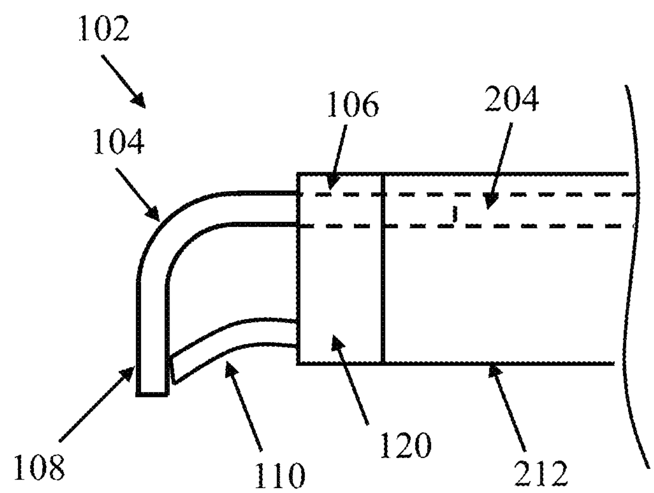


FIG. 2A



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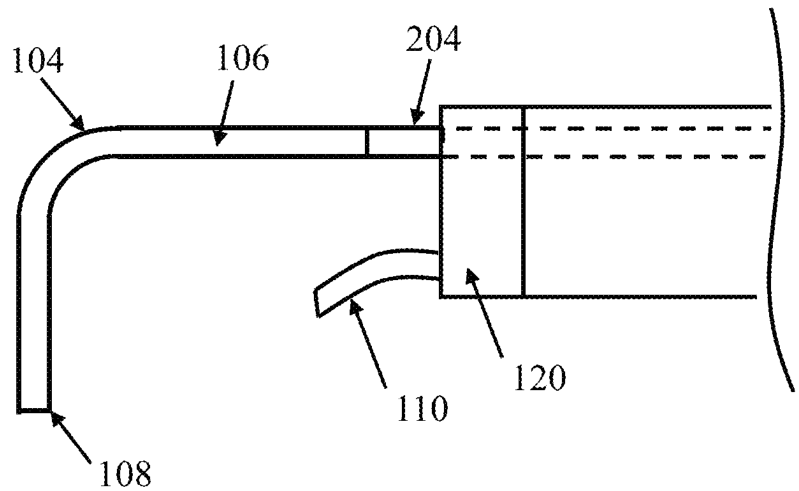


FIG. 3A

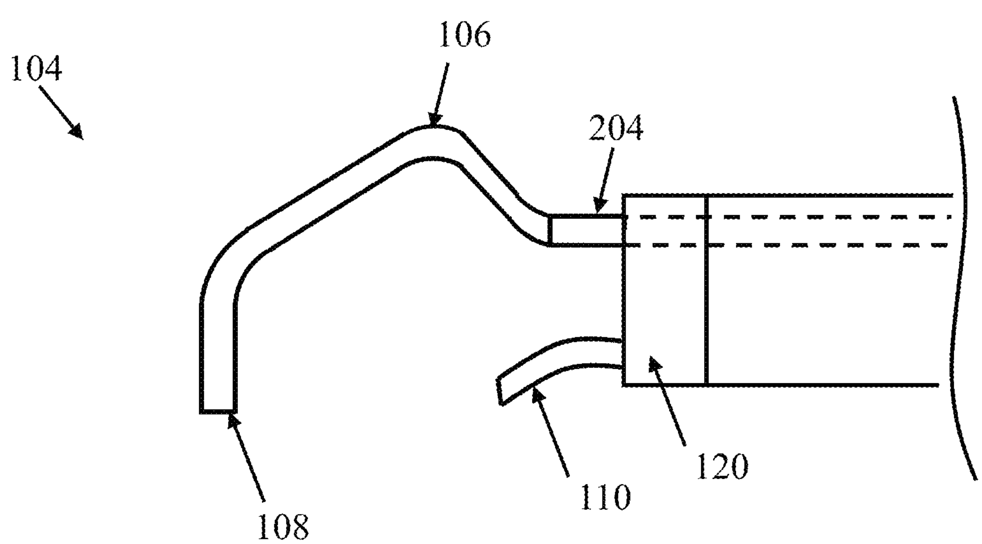
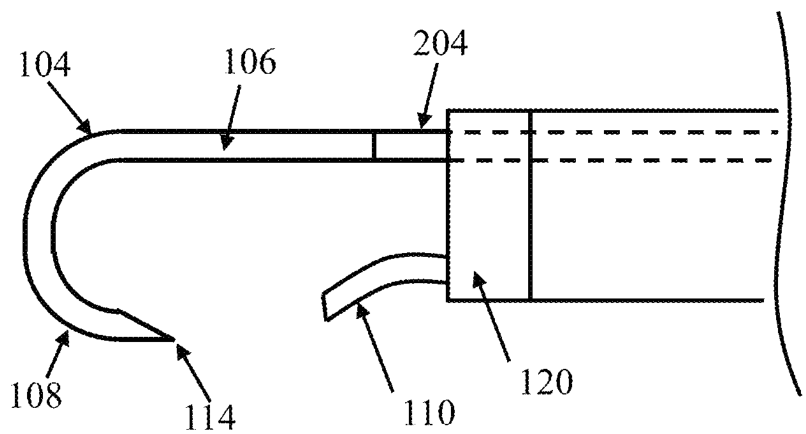


FIG. 3B



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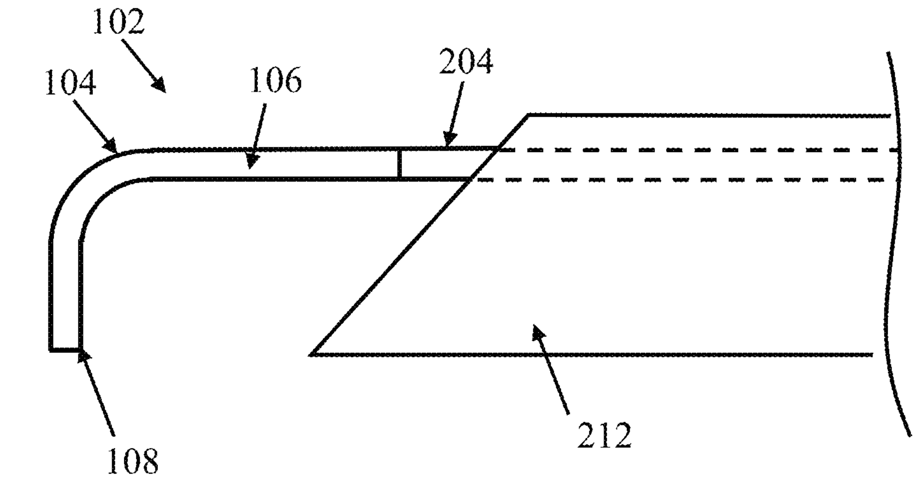

FIG. 4A

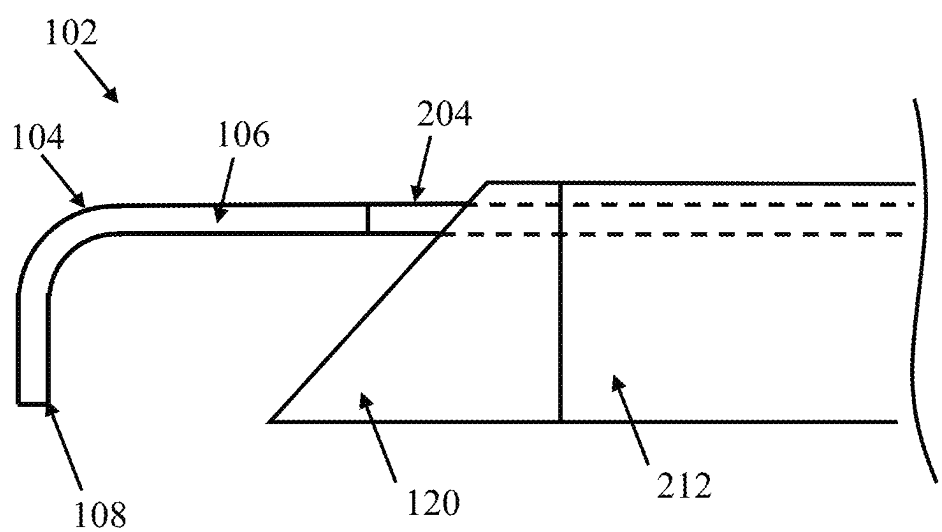

FIG. 4B

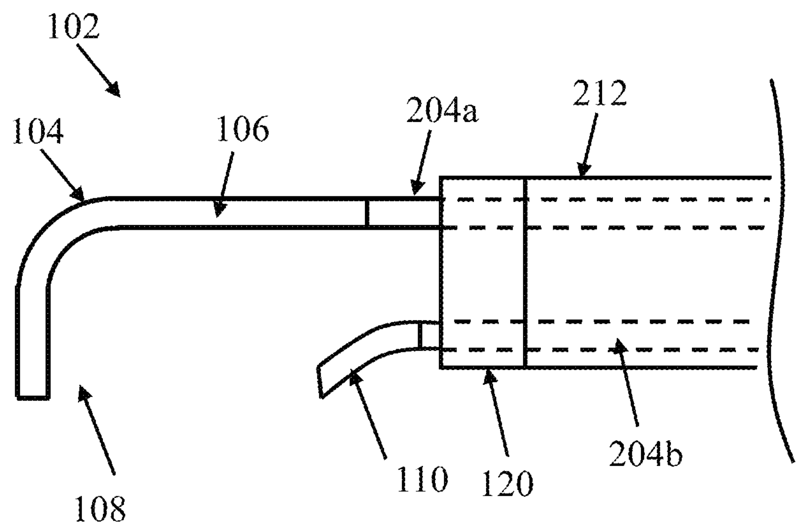

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FIG. 5A

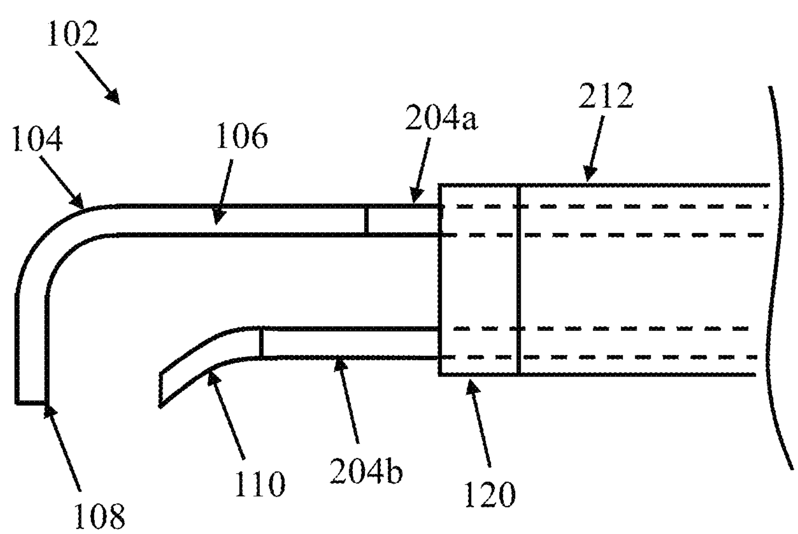

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FIG. 5B

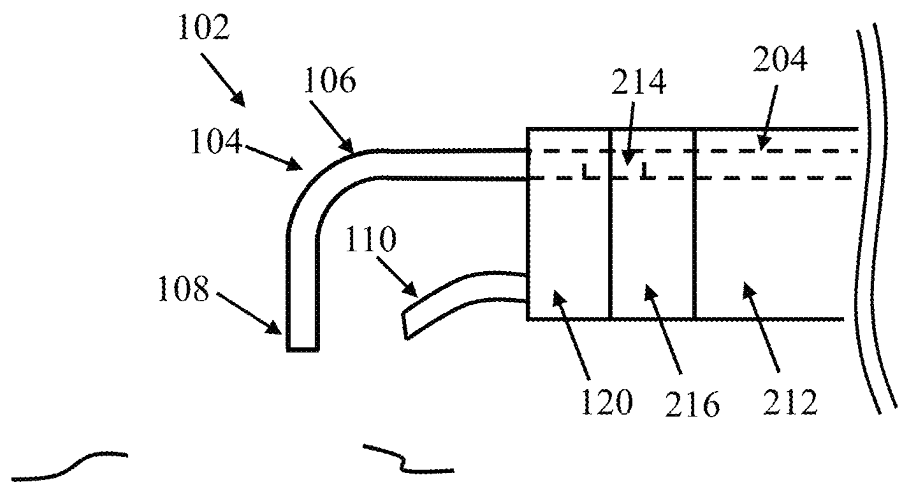
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FIG. 6A

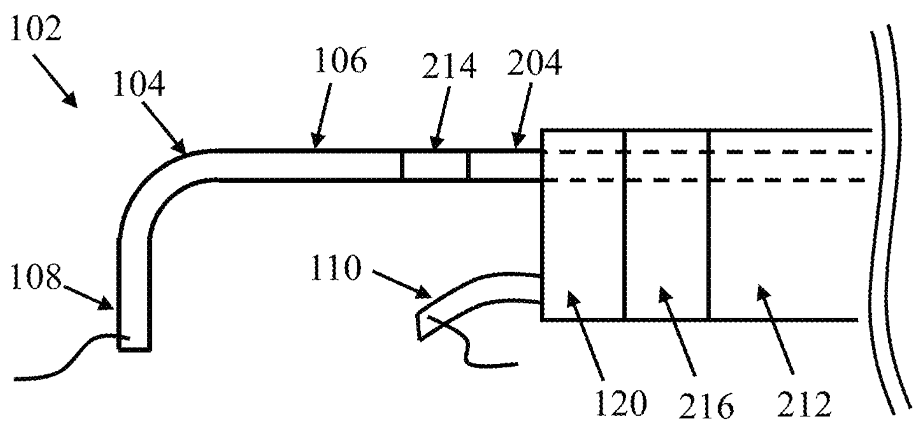
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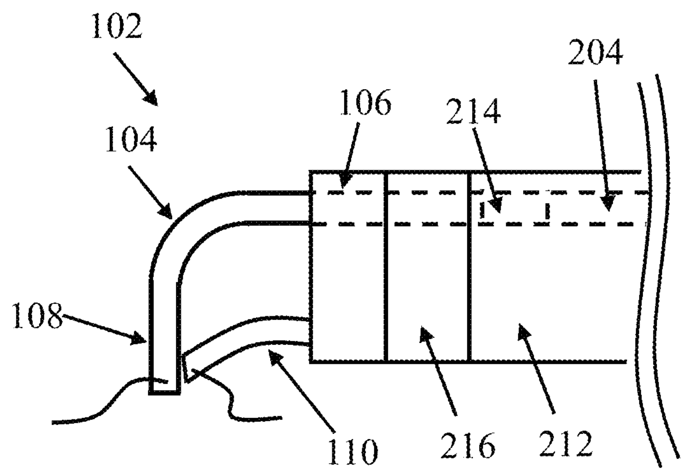
FIG. 6B



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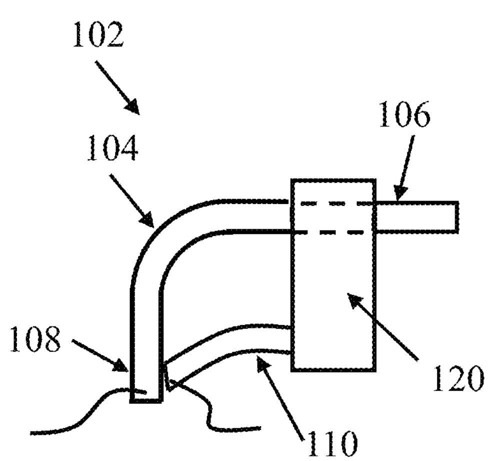
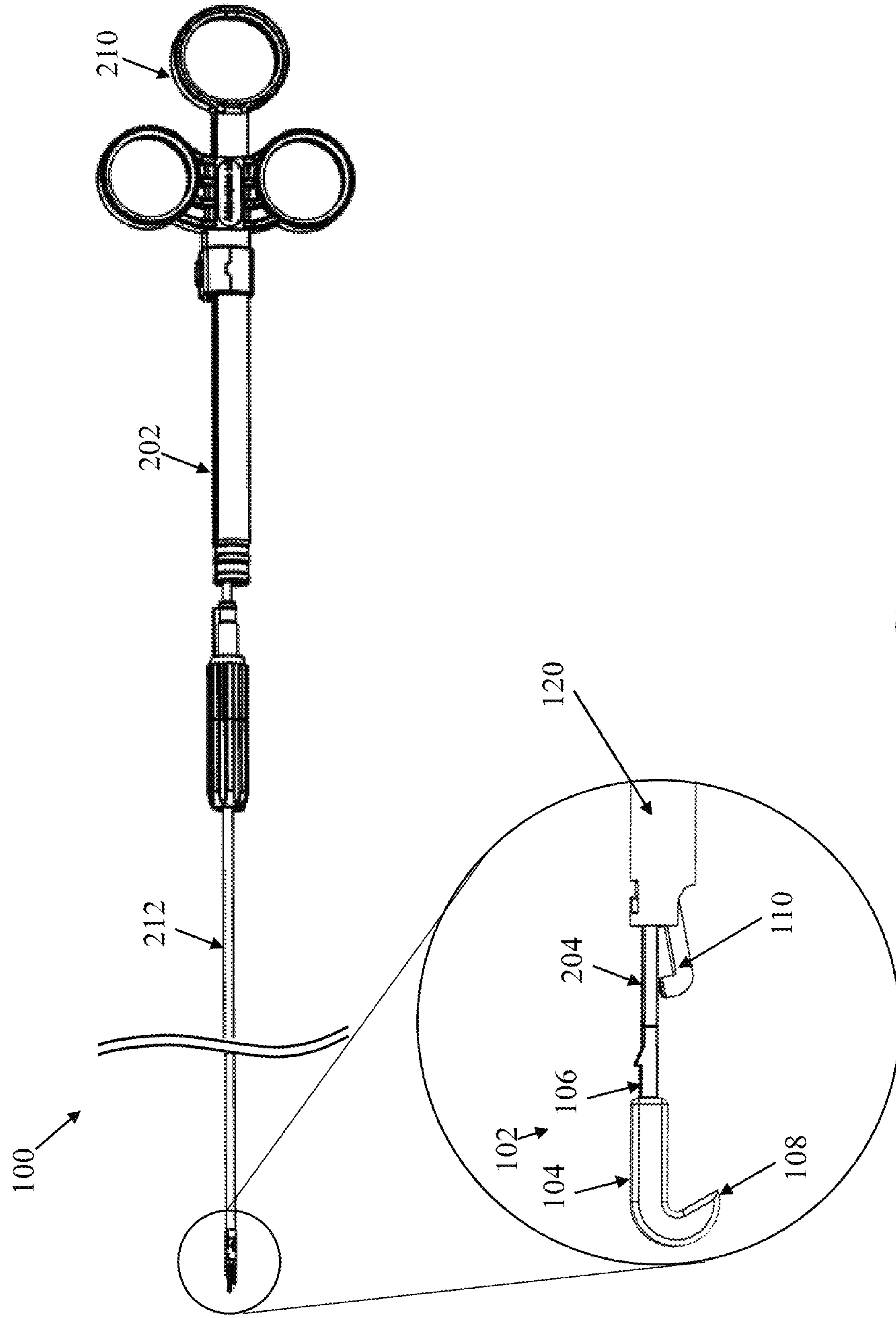


FIG. 6D



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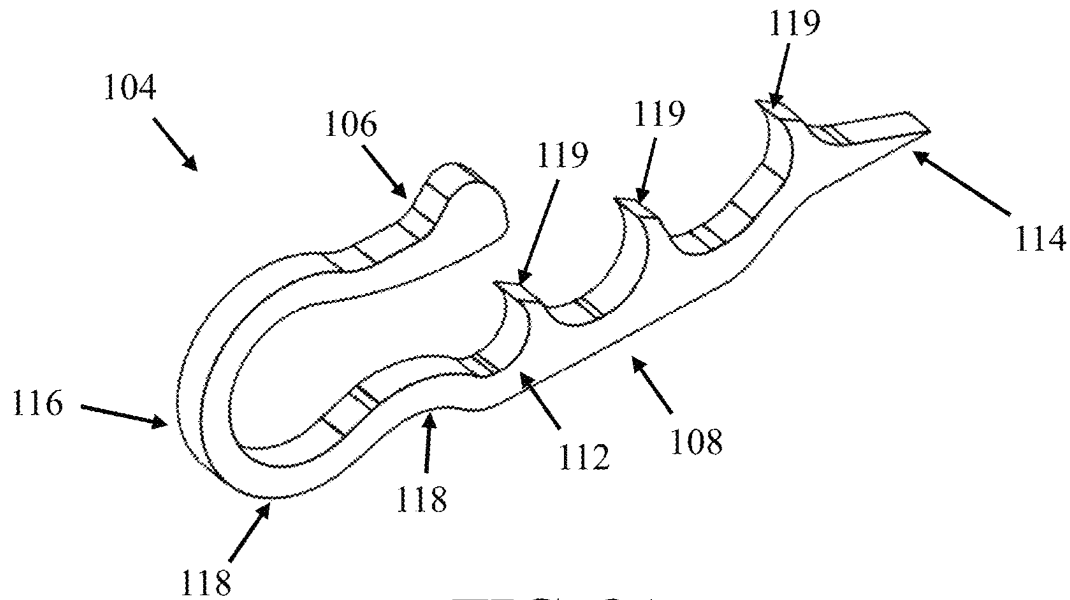
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FIG. 8A

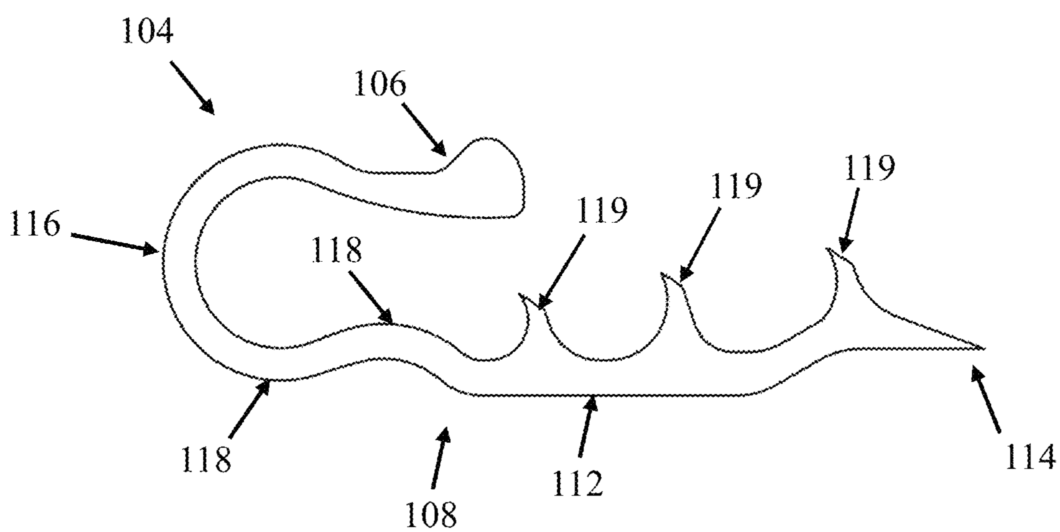
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FIG. 8B

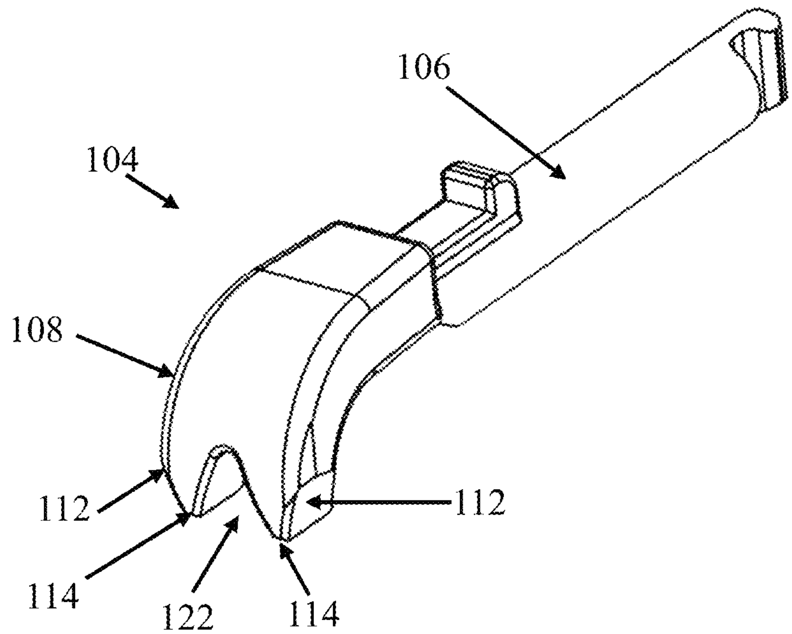
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FIG. 9A

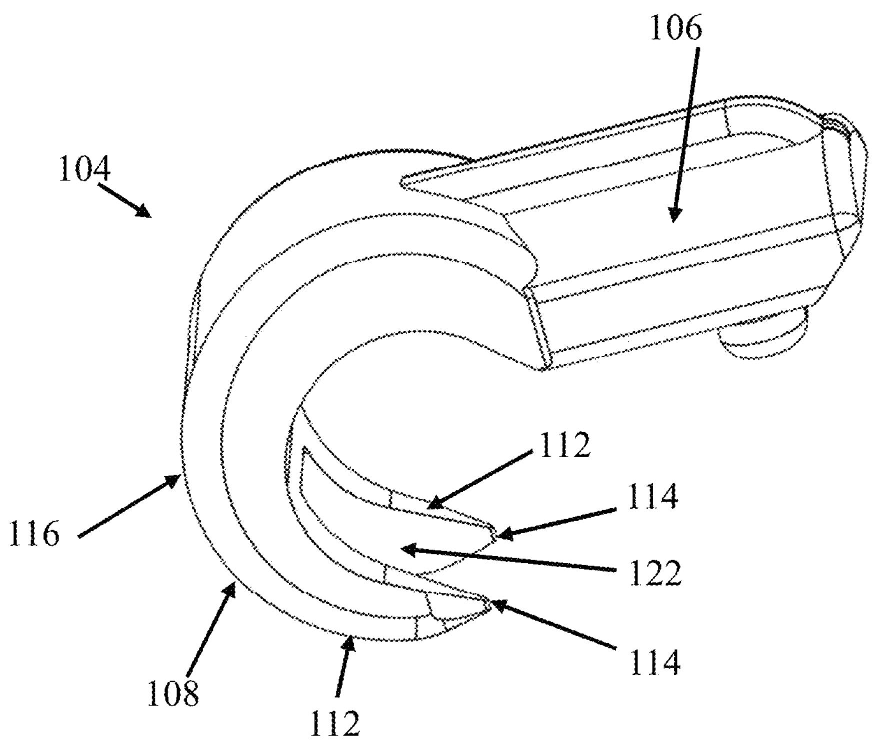
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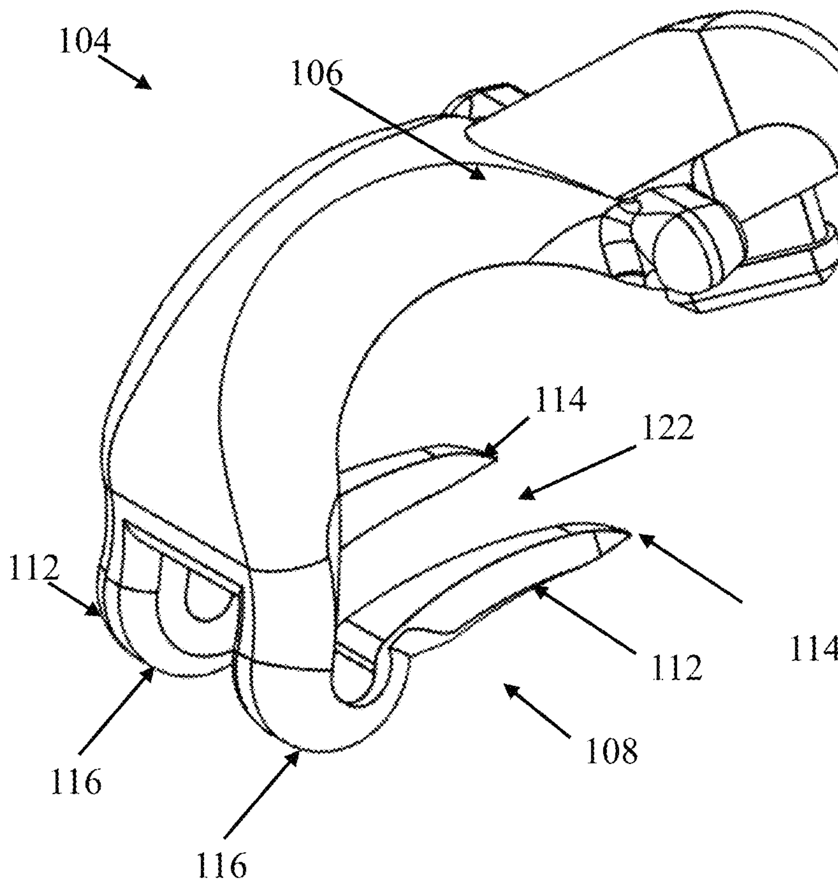
FIG. 9B



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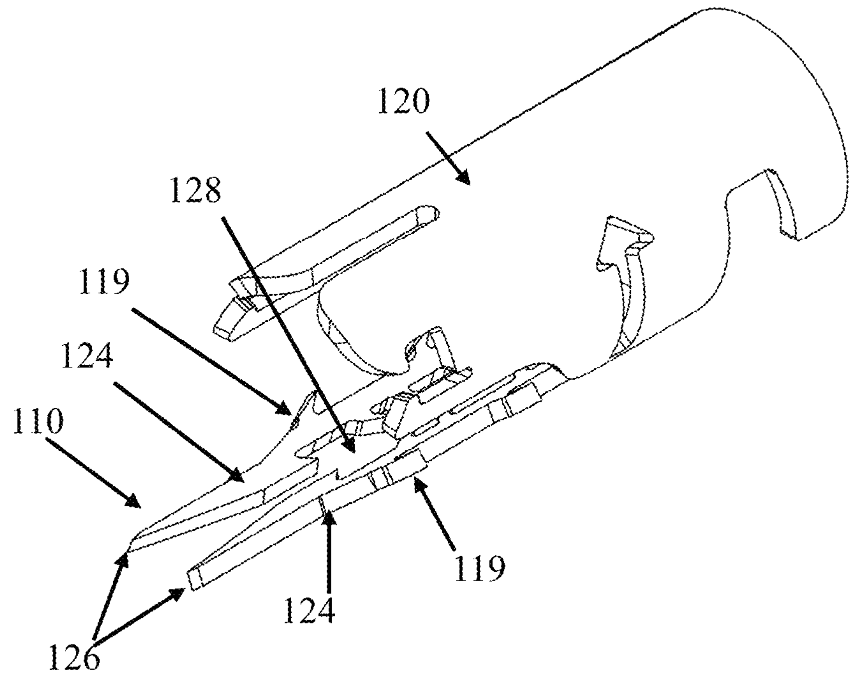

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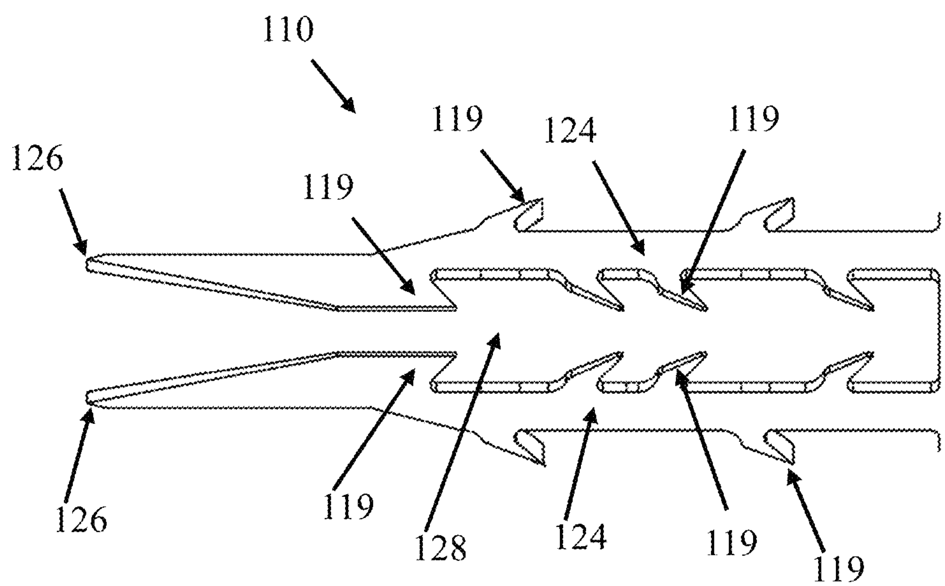

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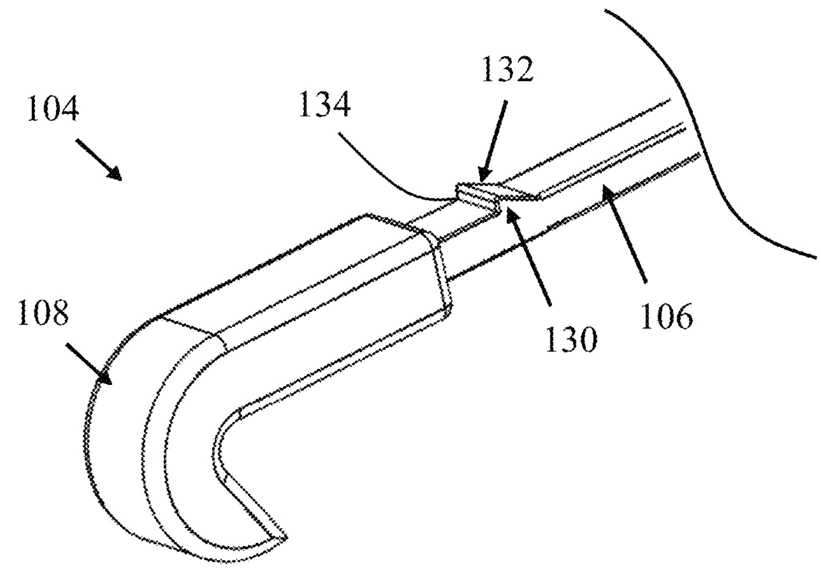
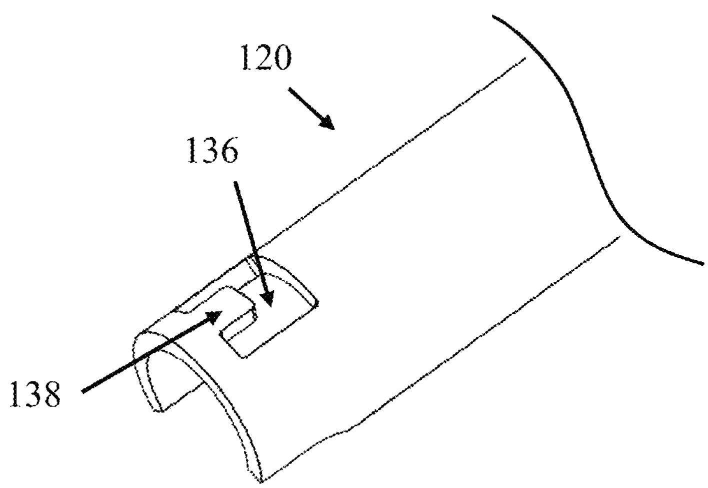


FIG. 11A



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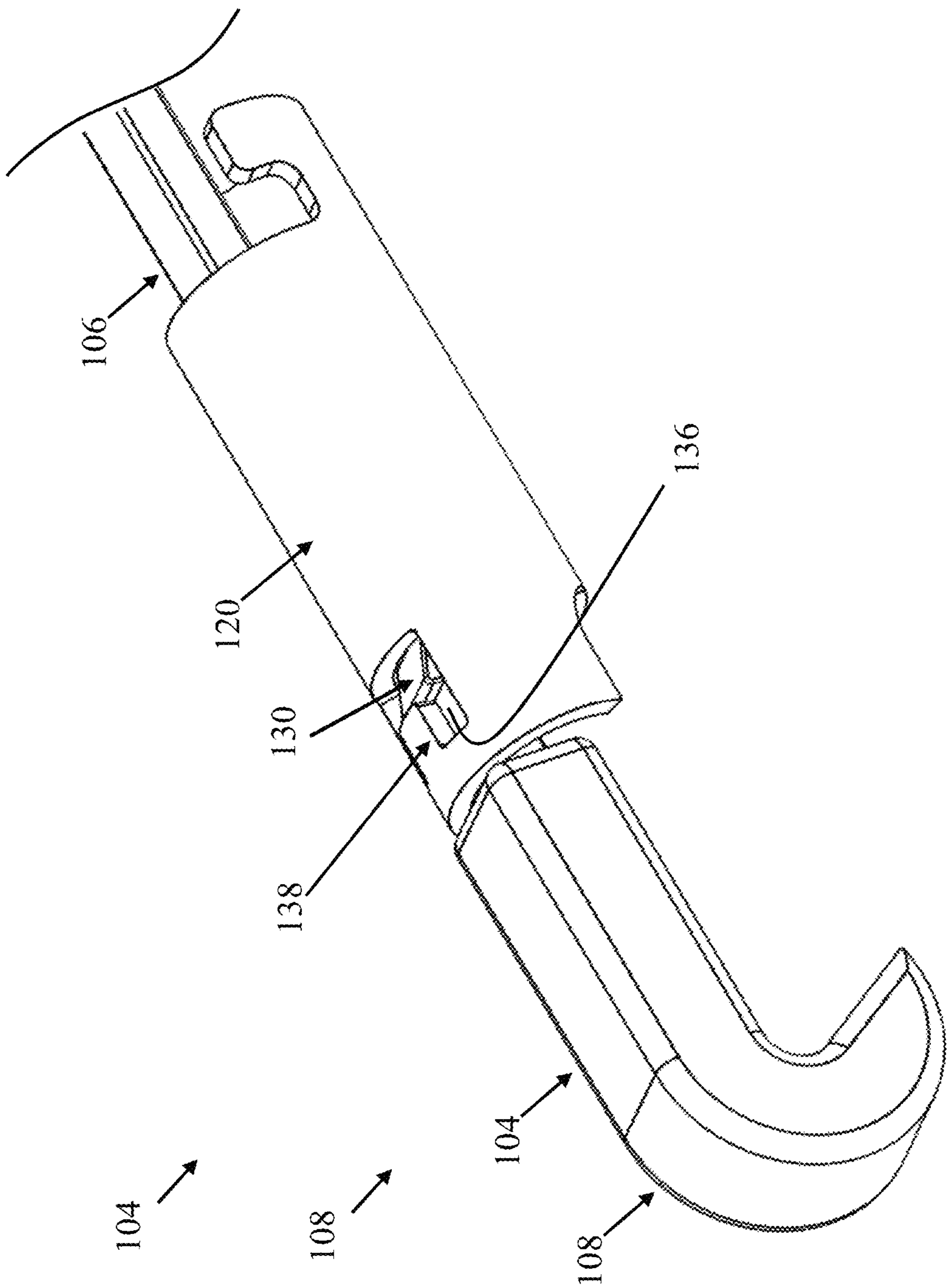

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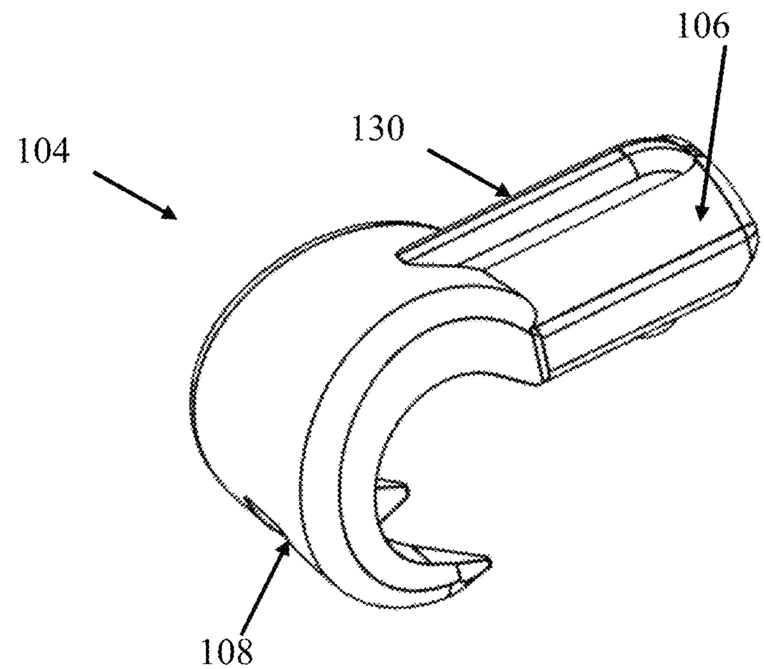
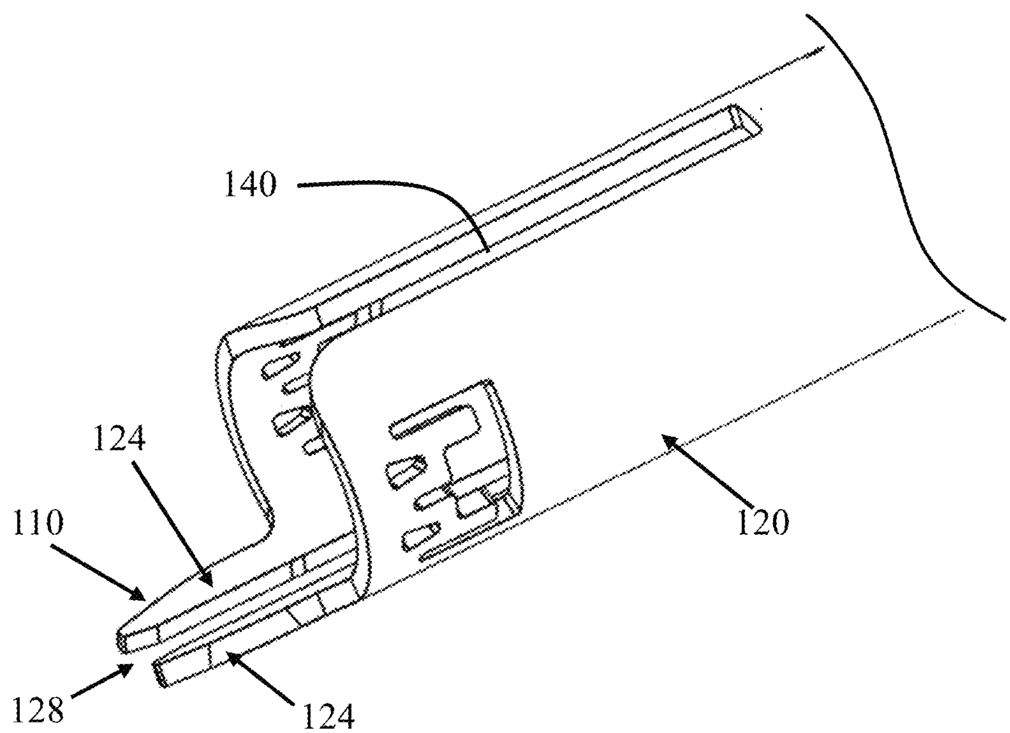


FIG. 12A



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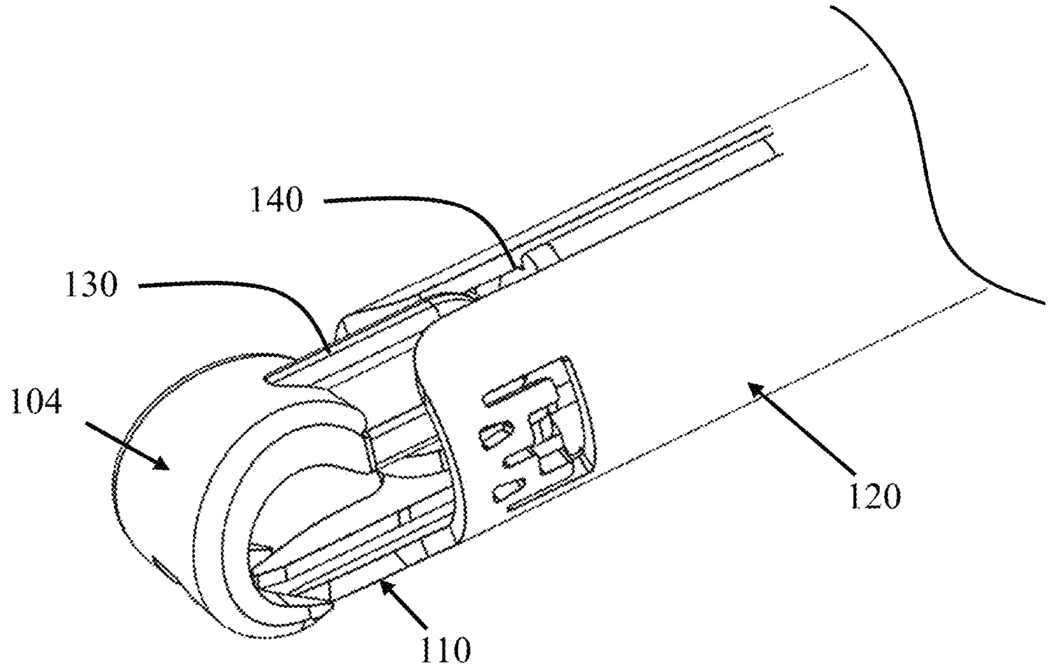

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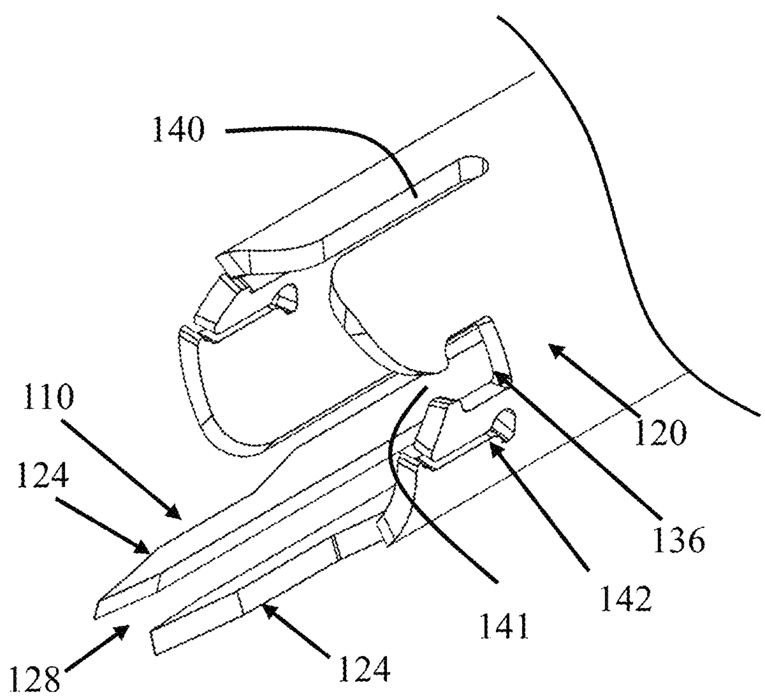


FIG. 13

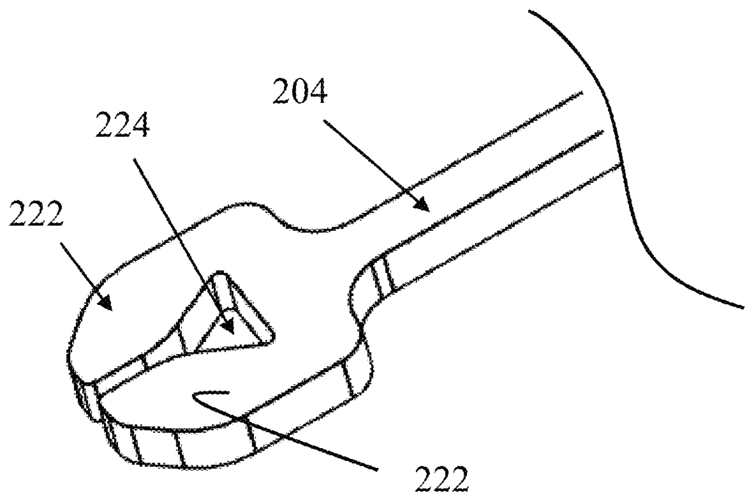
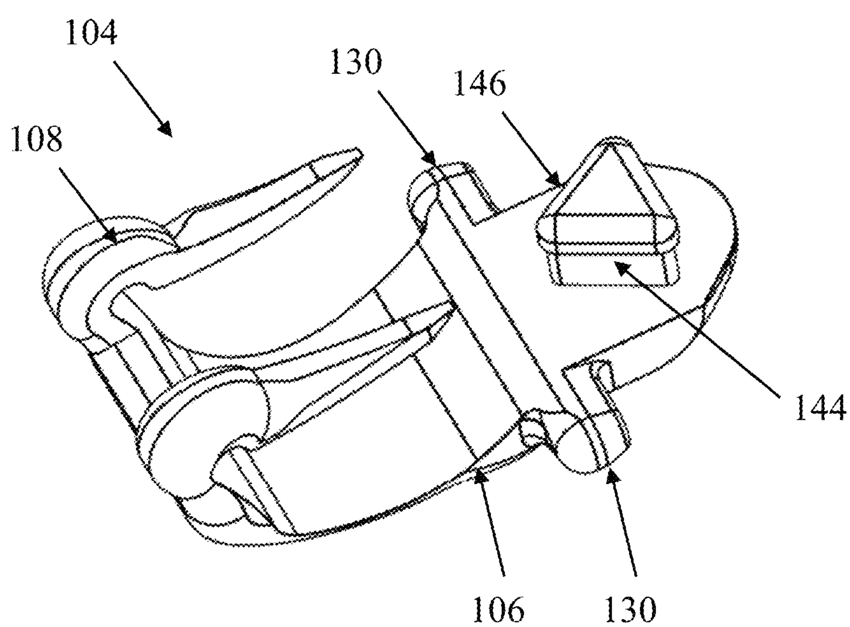


FIG. 14A



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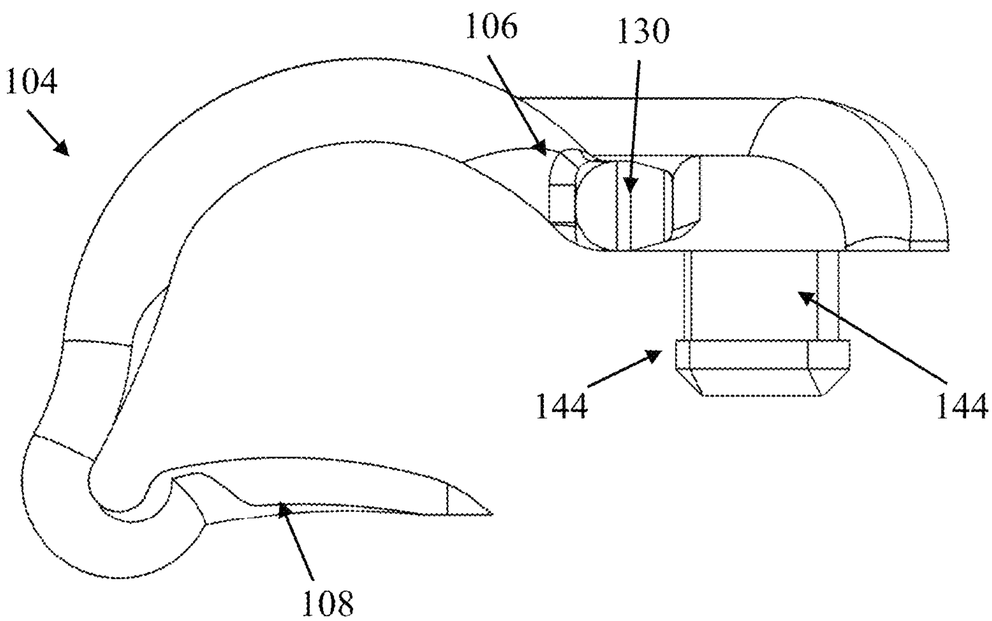


FIG. 14C

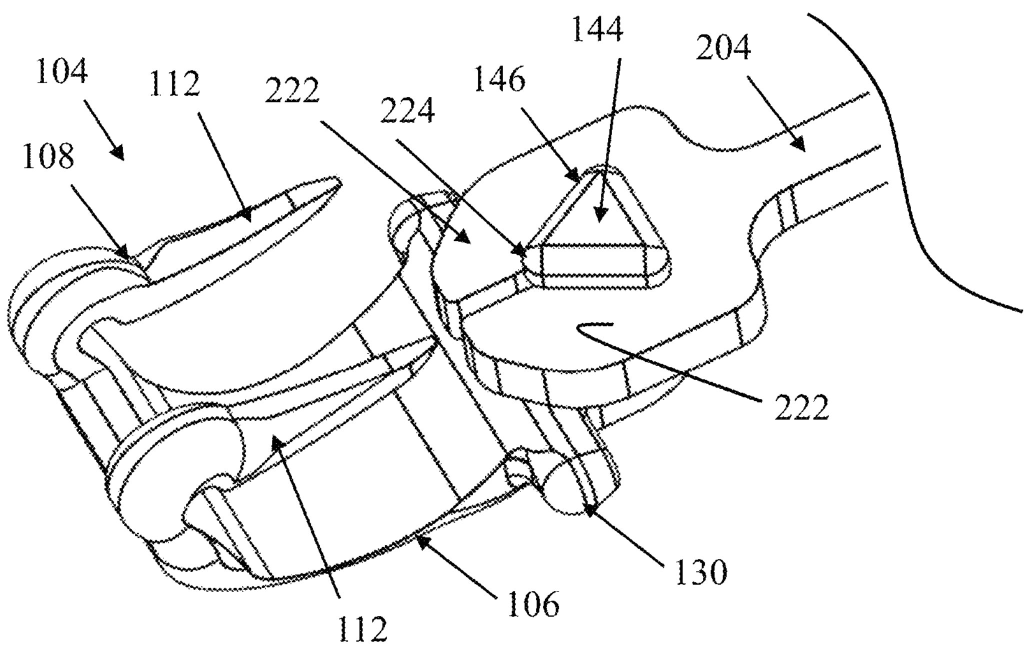
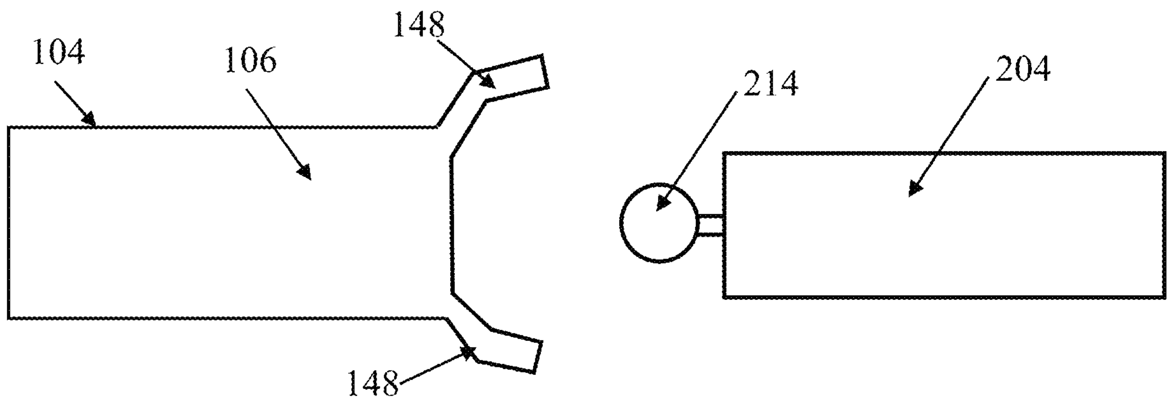


FIG. 14D



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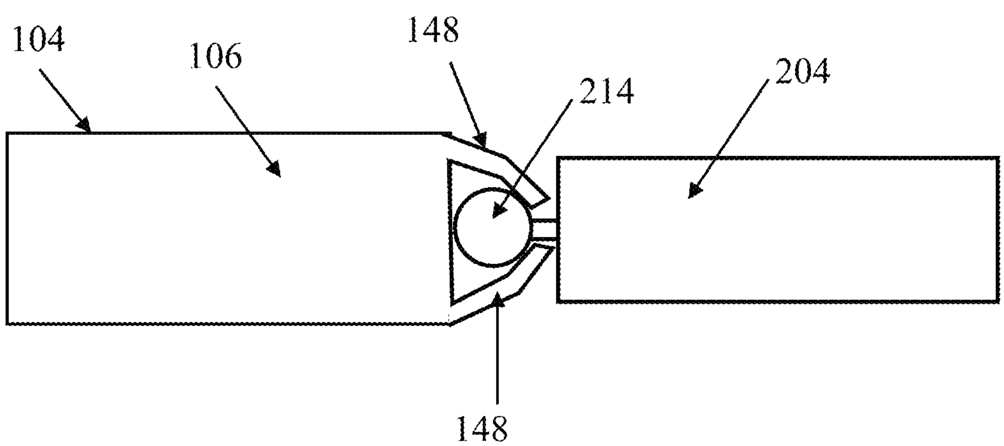


FIG. 15B

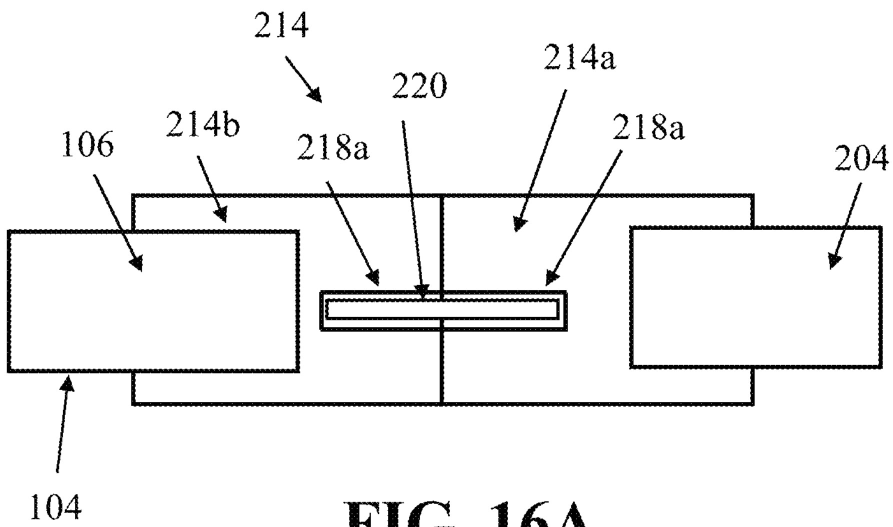


FIG. 16A

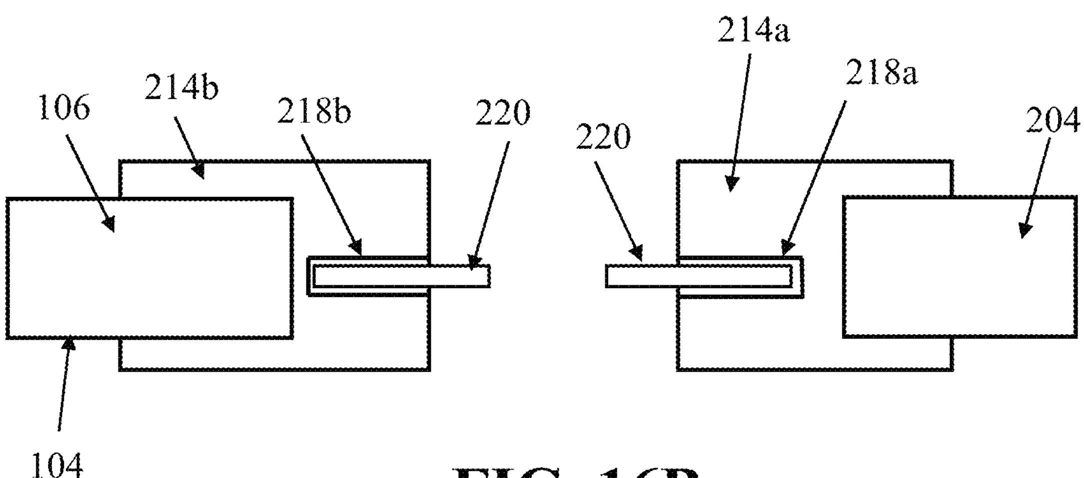


FIG. 16B

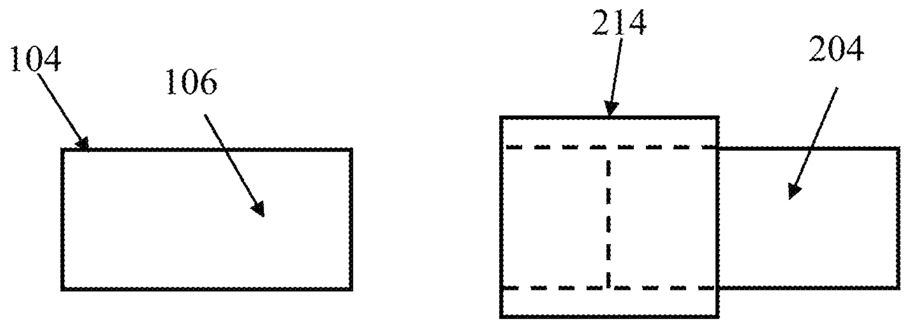
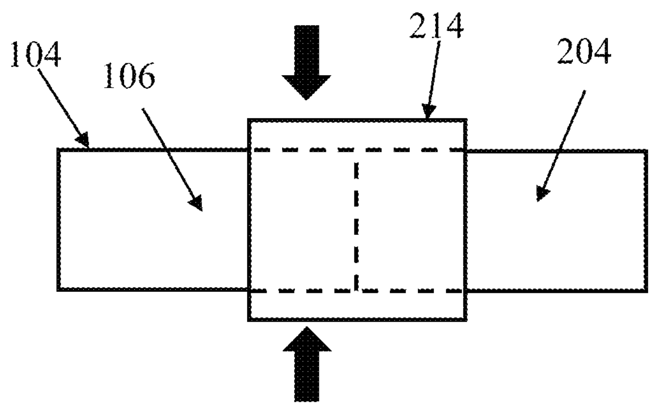


FIG. 17A



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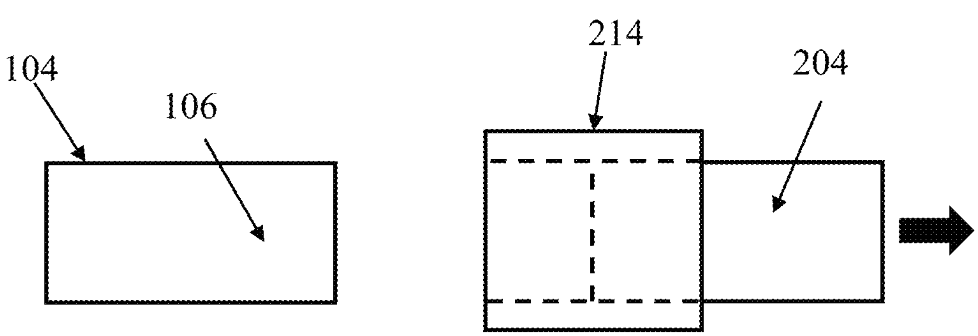

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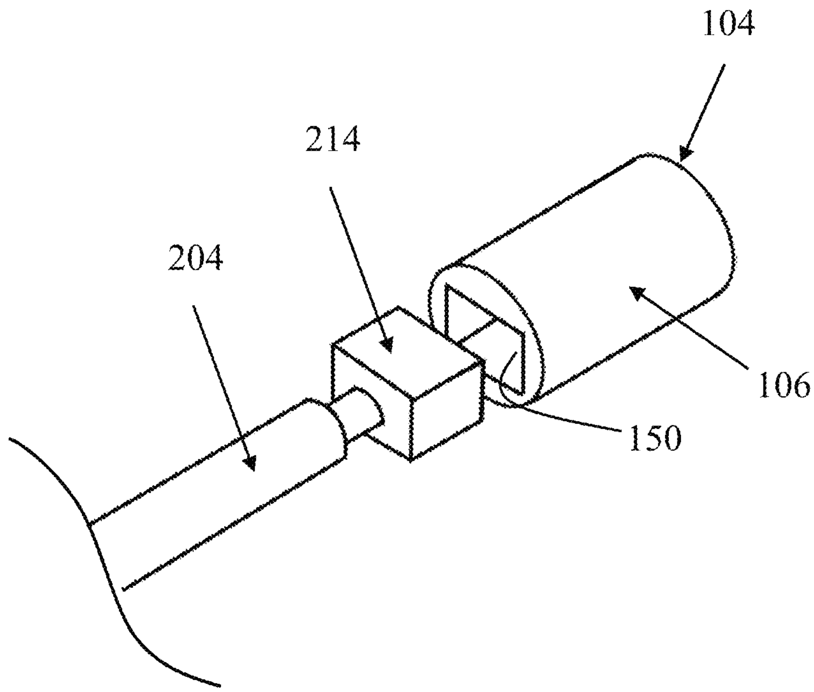

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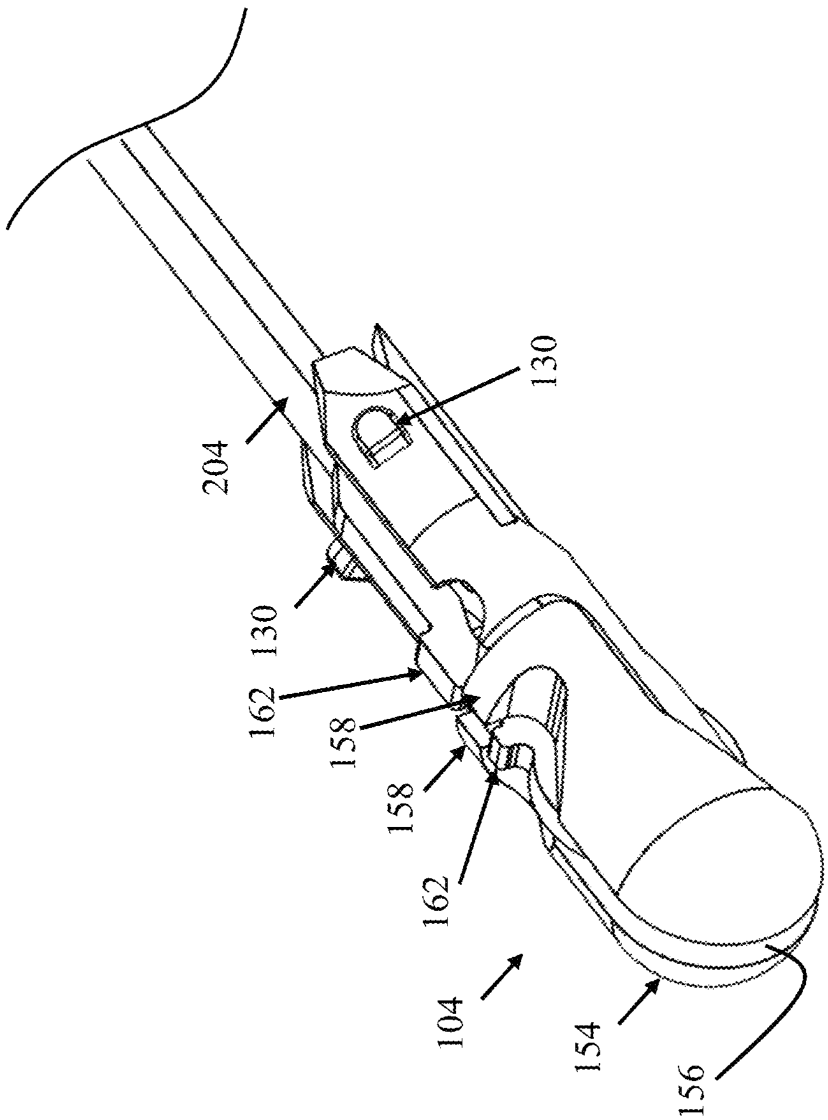


FIG. 19A

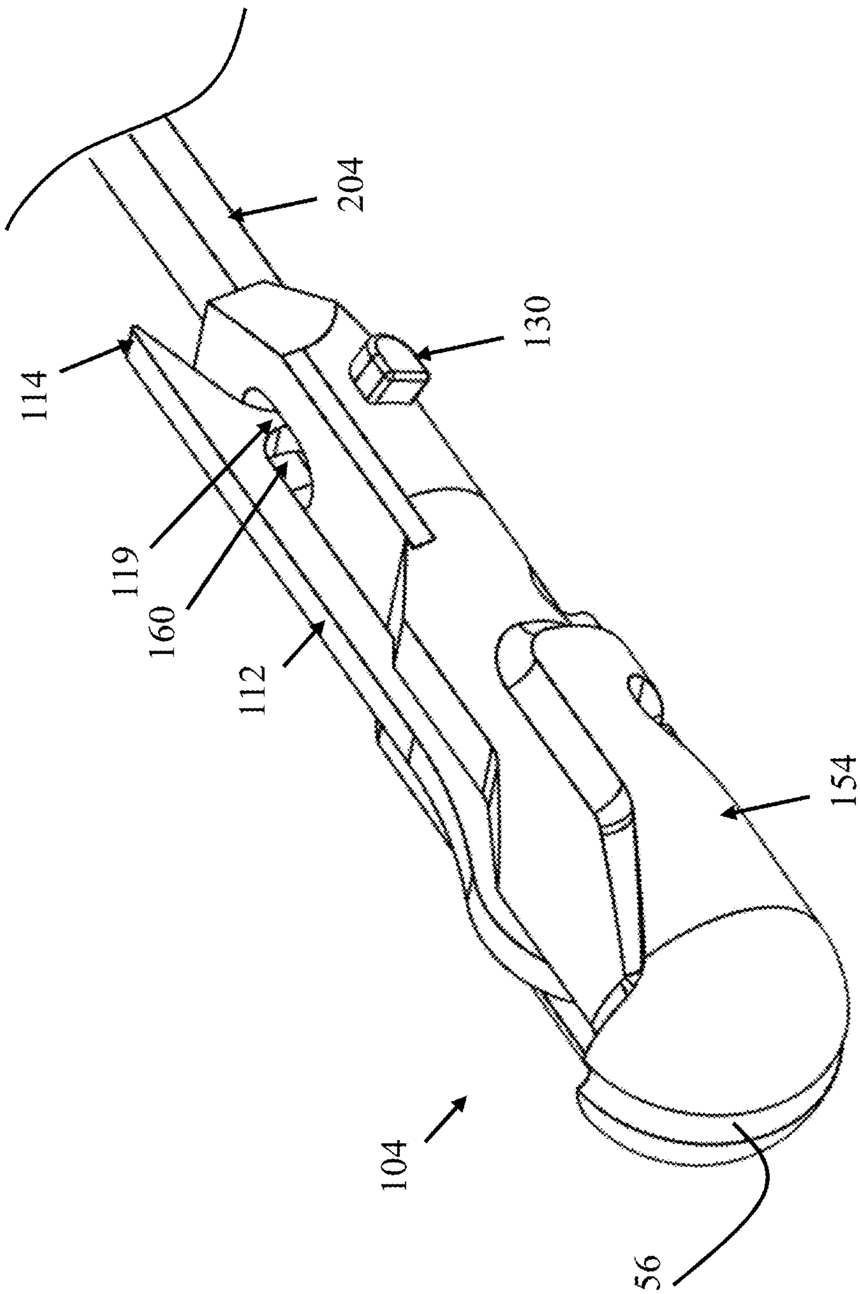
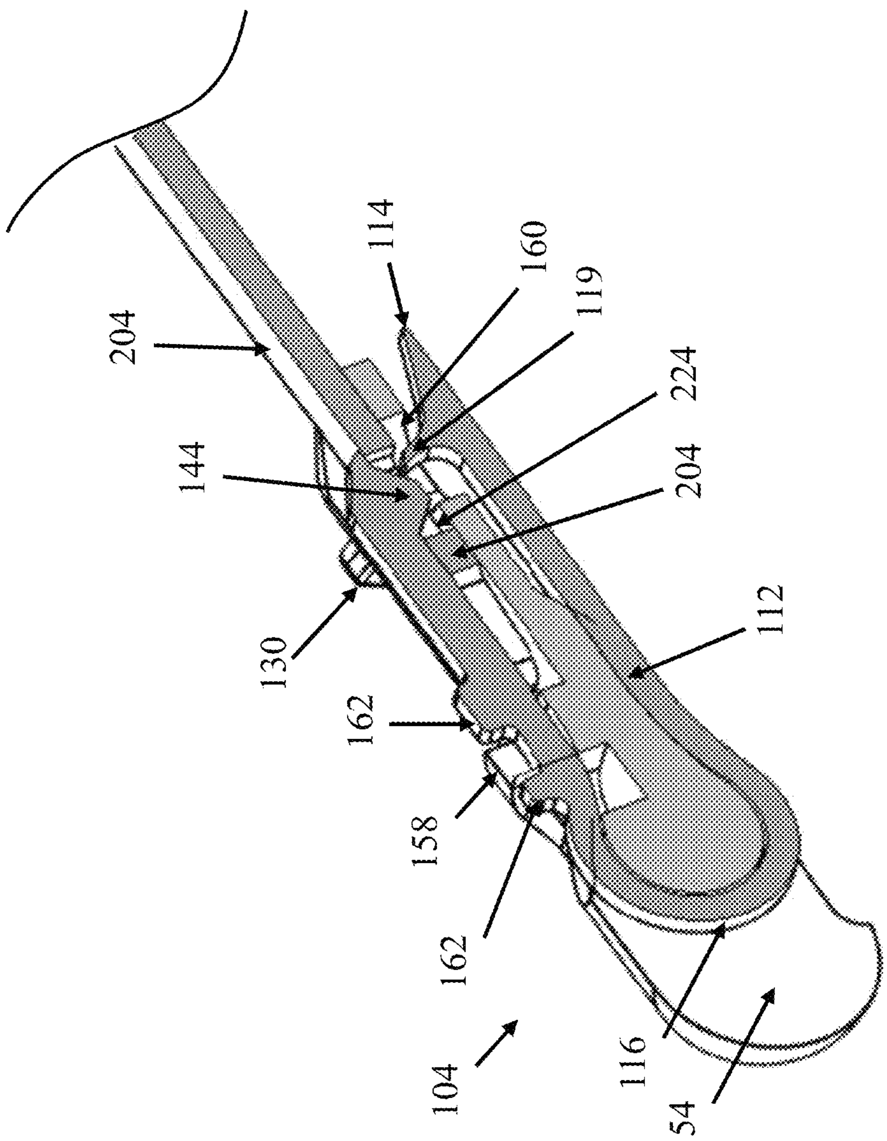


FIG. 19B



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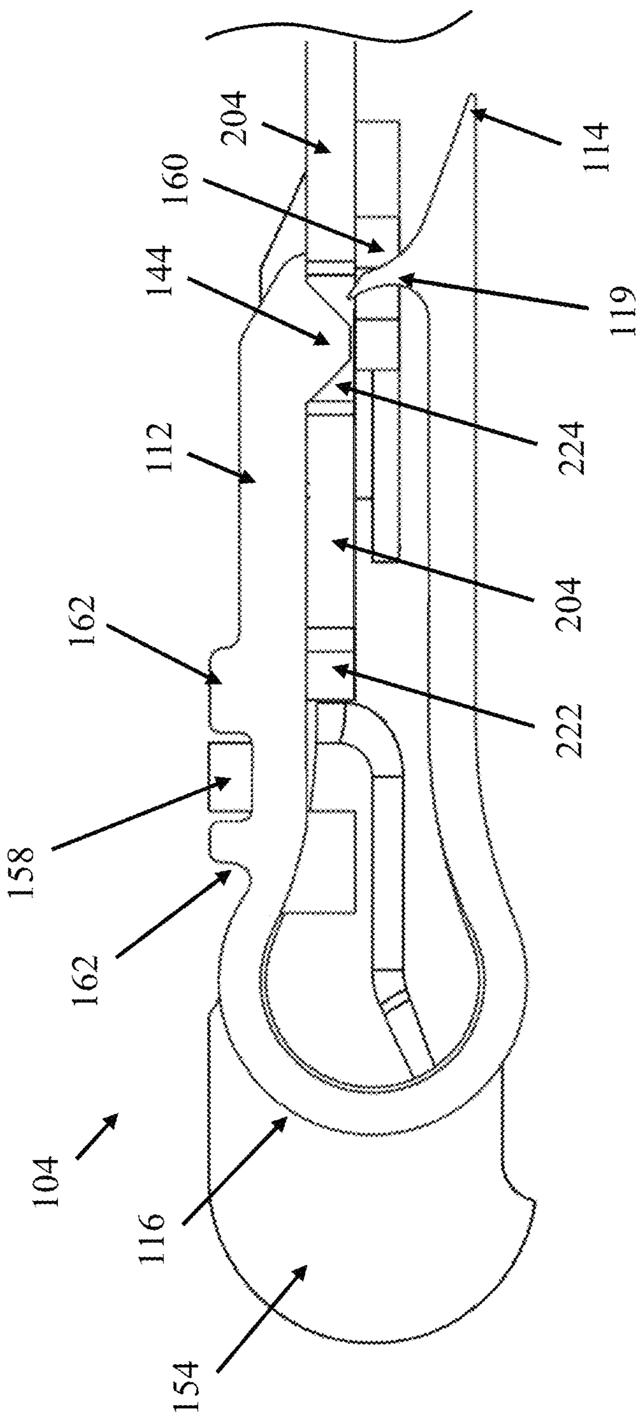


FIG. 19D

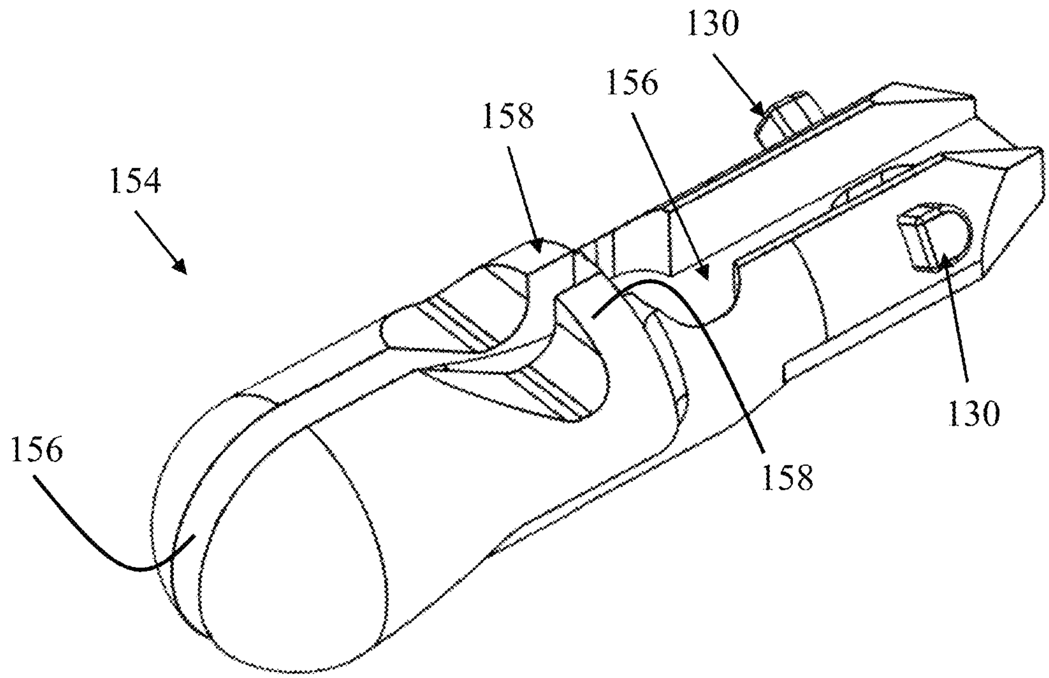


FIG. 19E

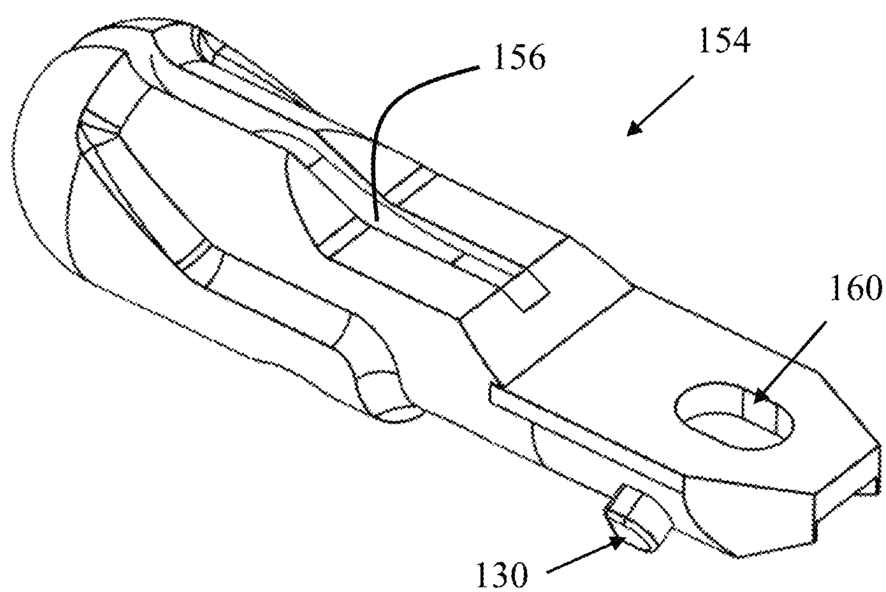


FIG. 19F

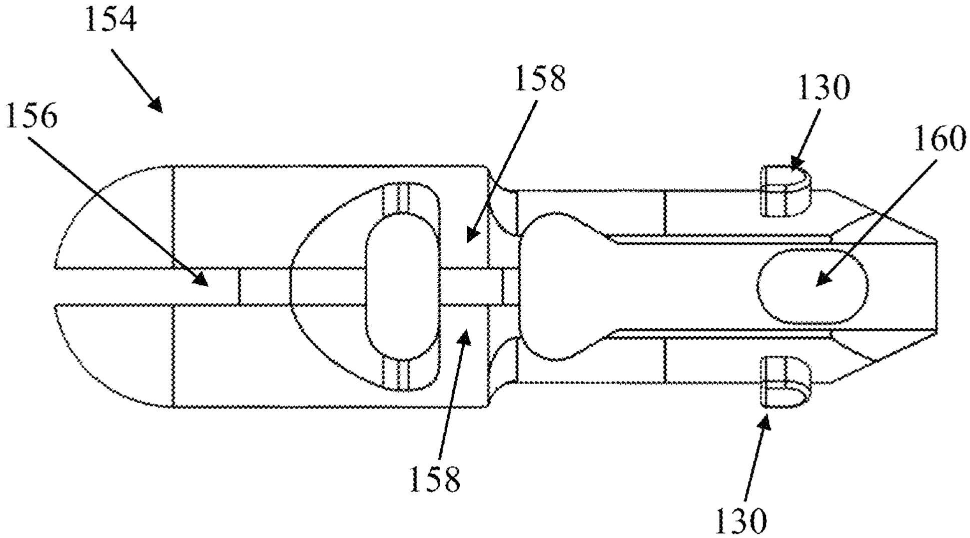


FIG. 19G

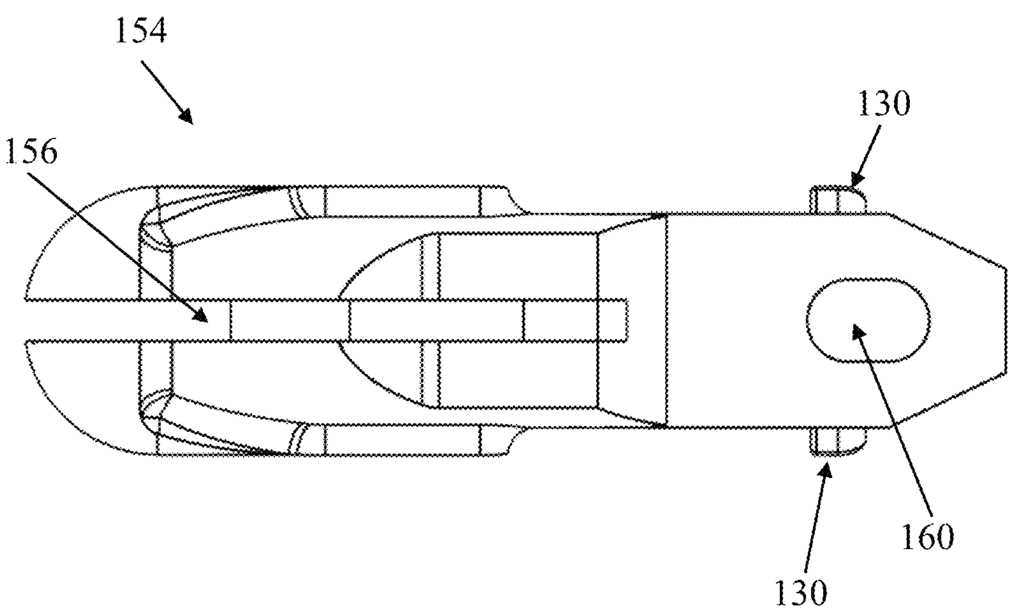


FIG. 19H

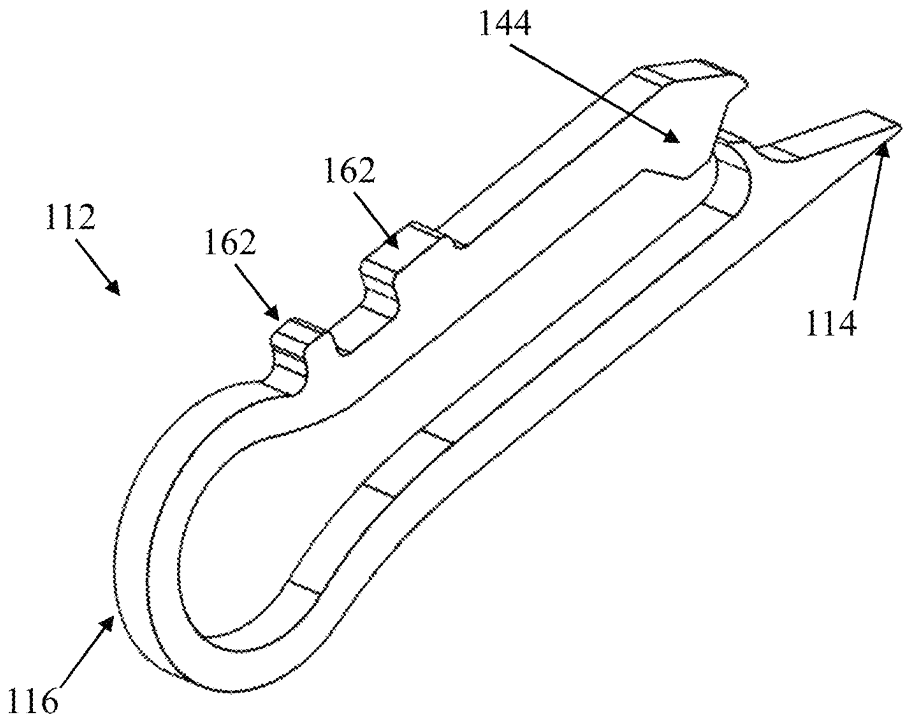


FIG. 19I

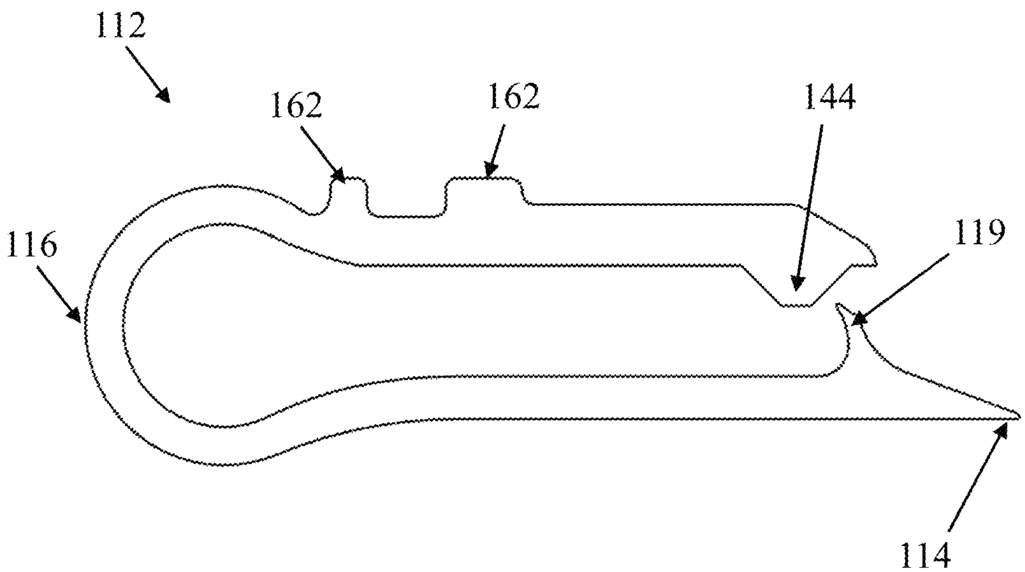


FIG. 19J

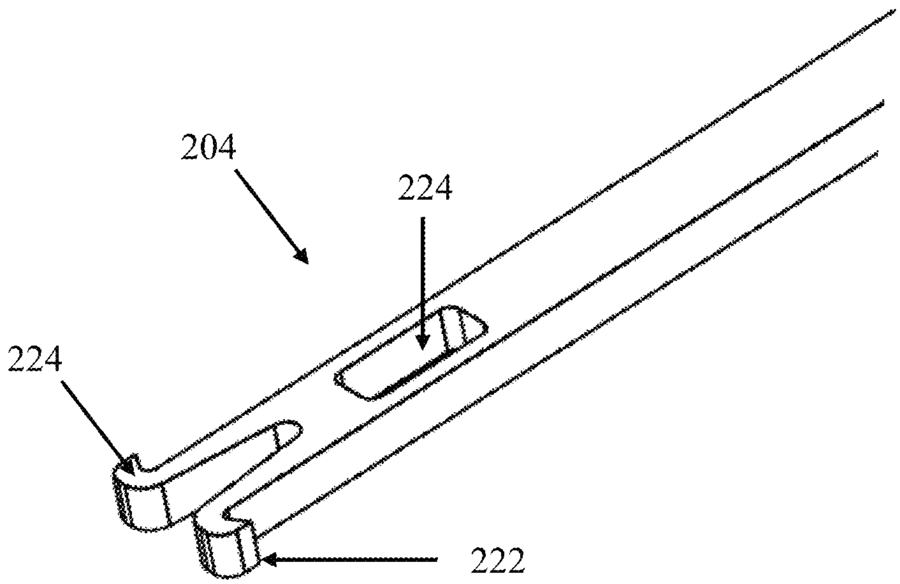


FIG. 19K

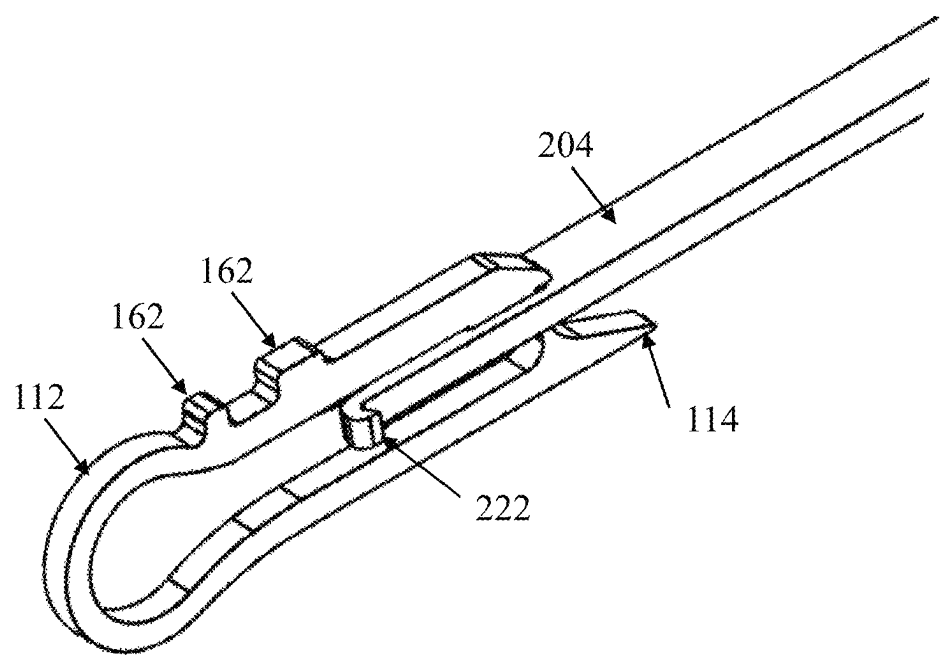


FIG. 19L

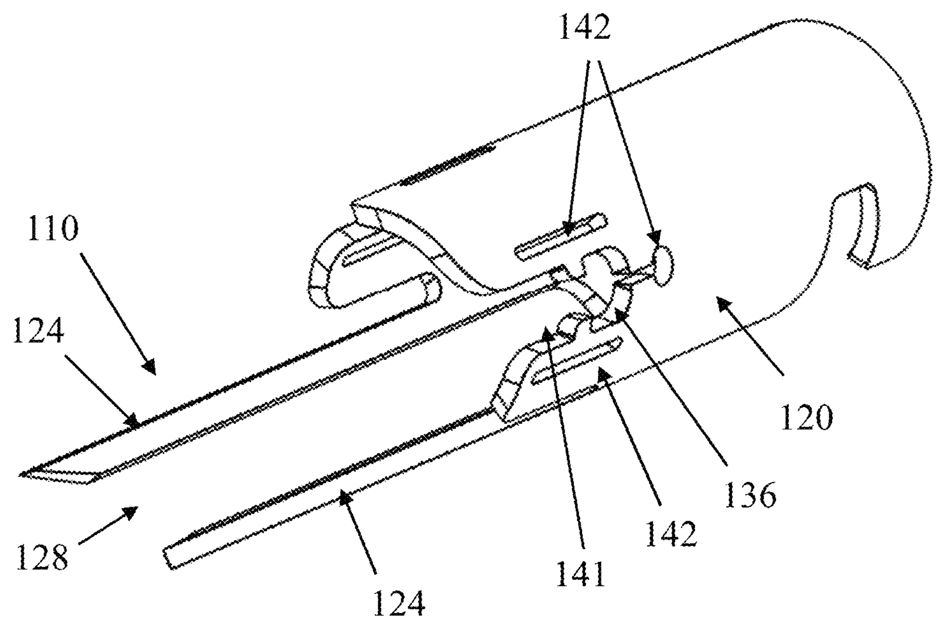


FIG. 19M

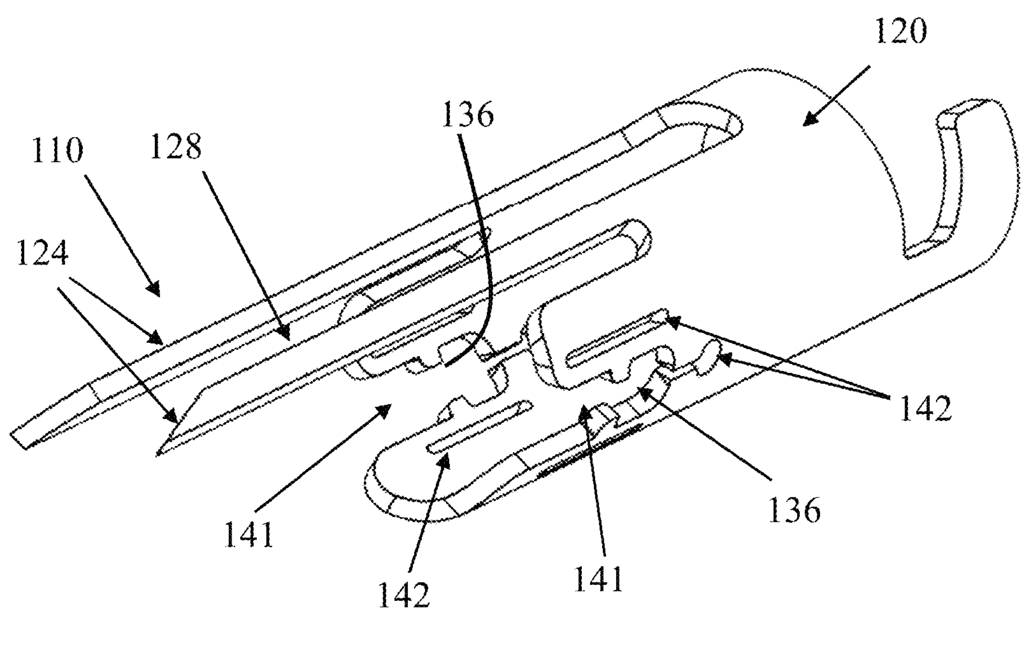


FIG. 19N

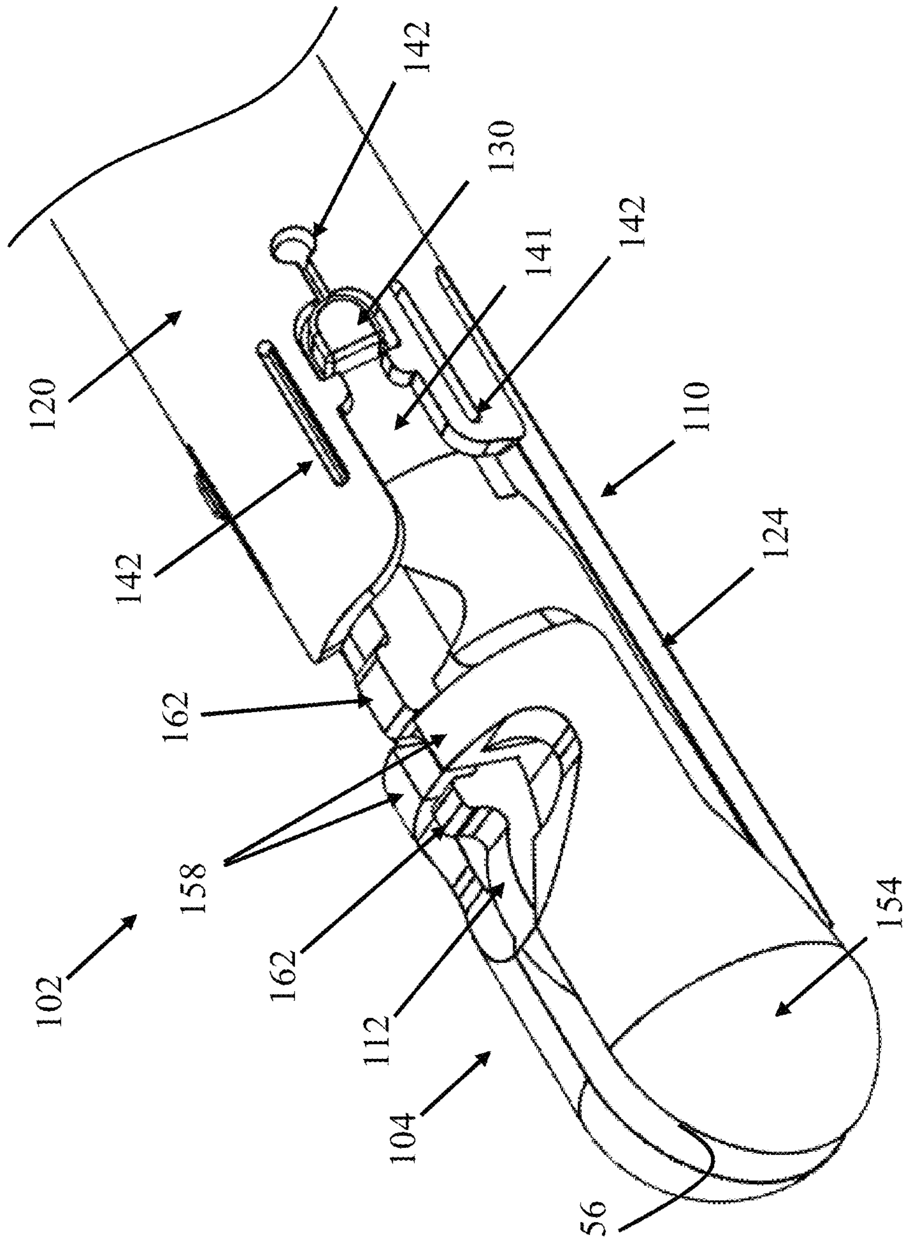


FIG. 19O

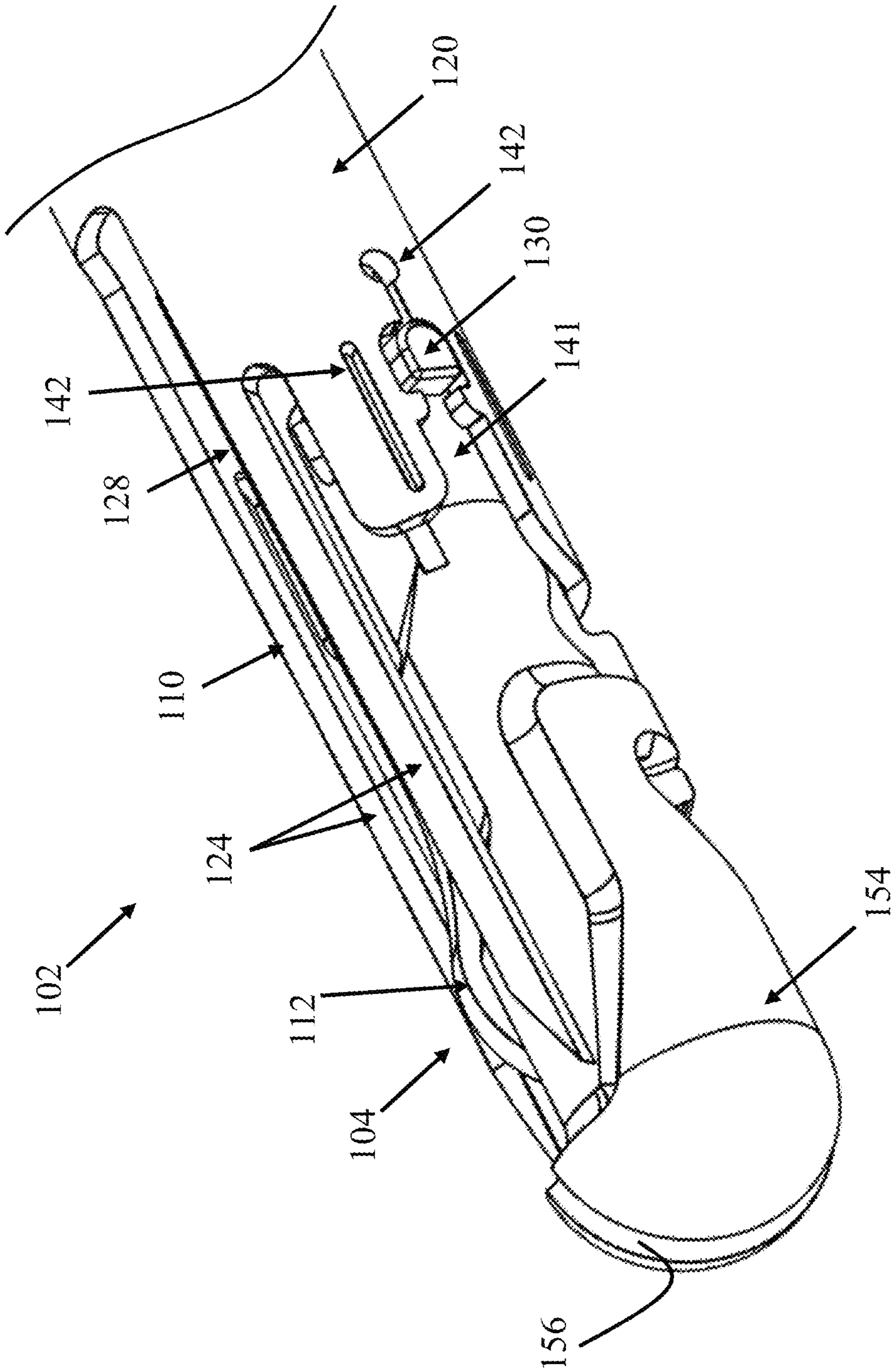


FIG. 19P

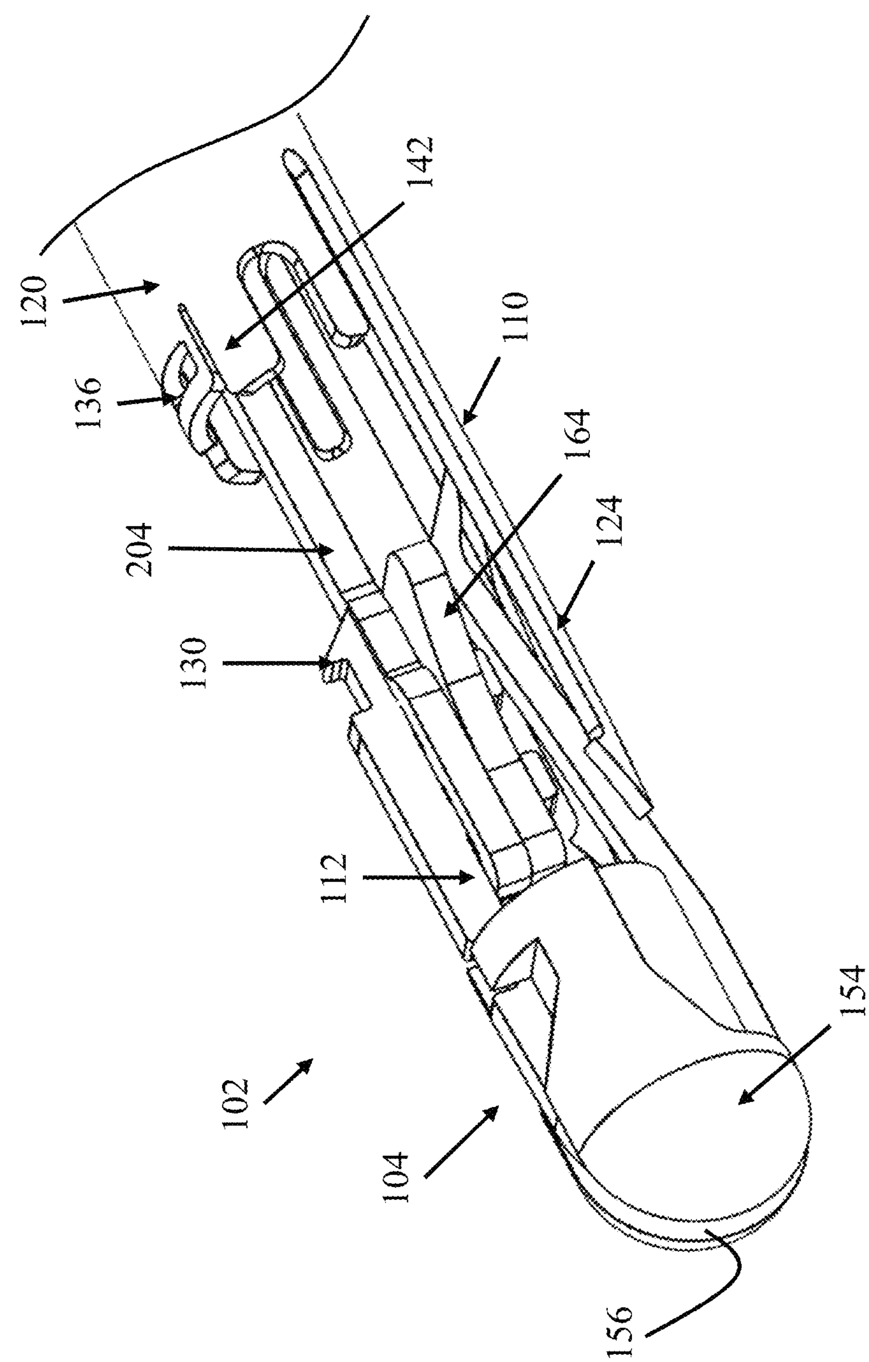


FIG. 20A

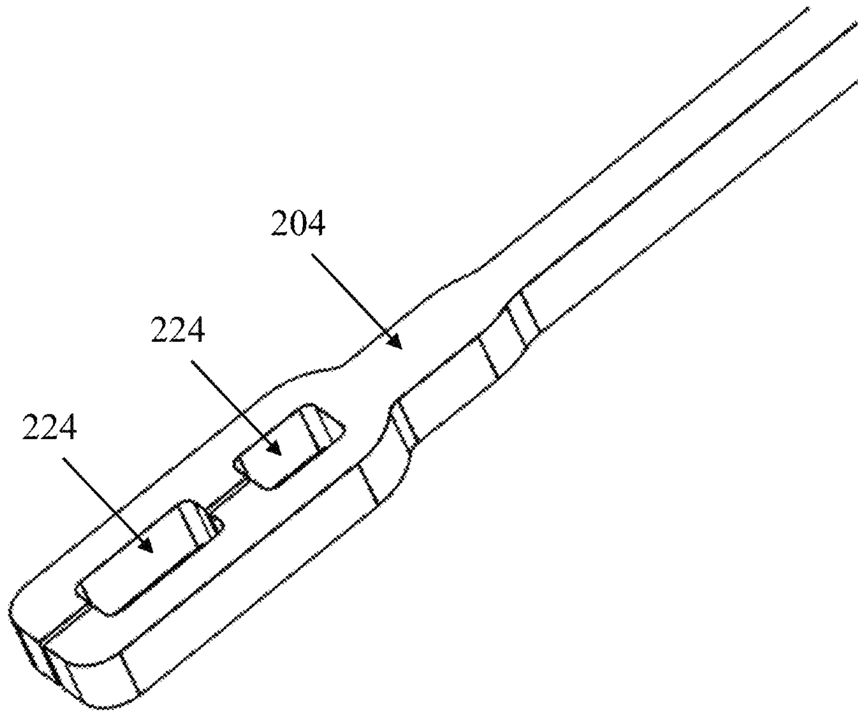


FIG. 20B

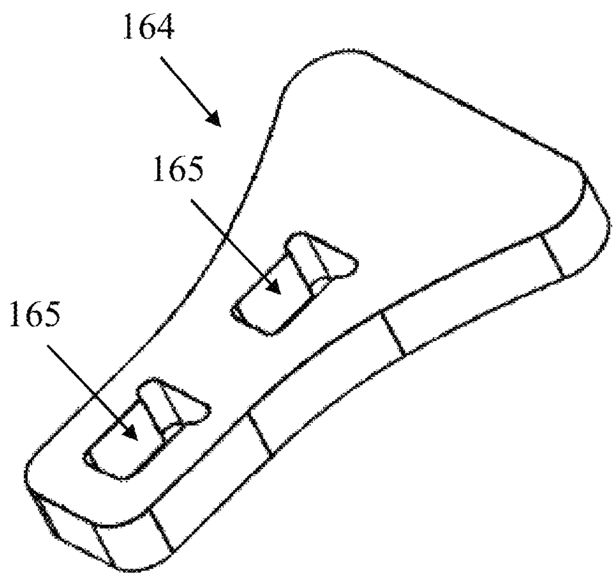


FIG. 20C

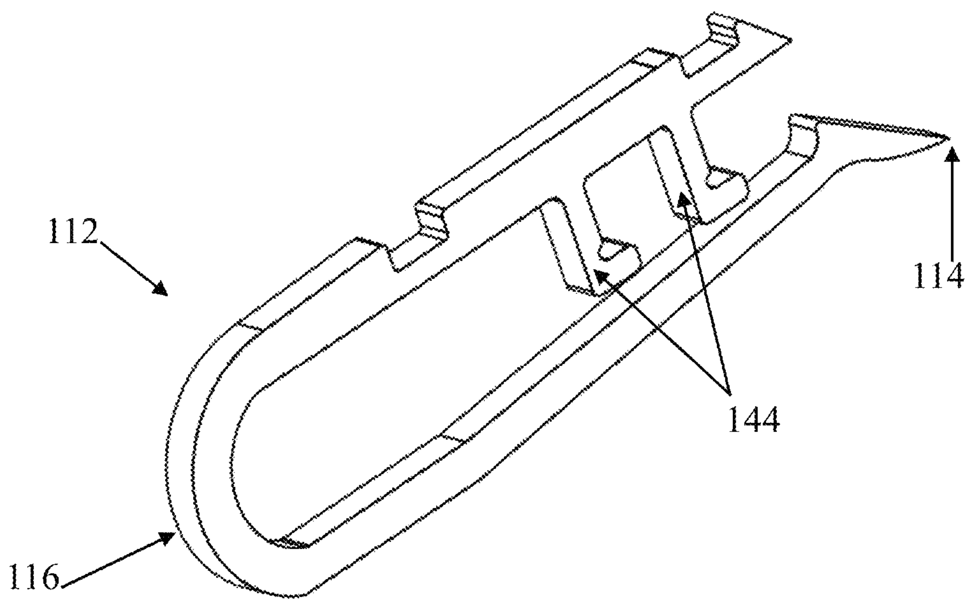


FIG. 20D

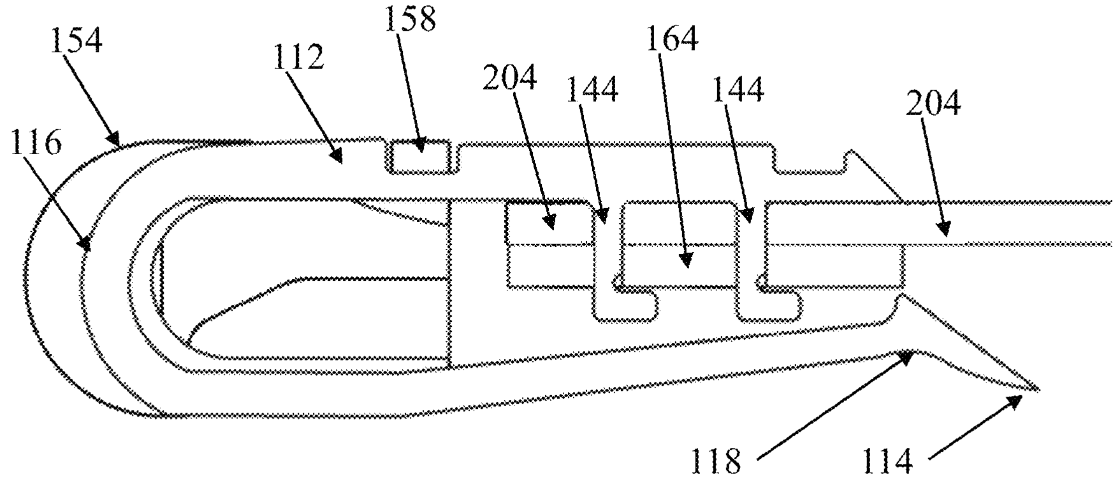


FIG. 20E

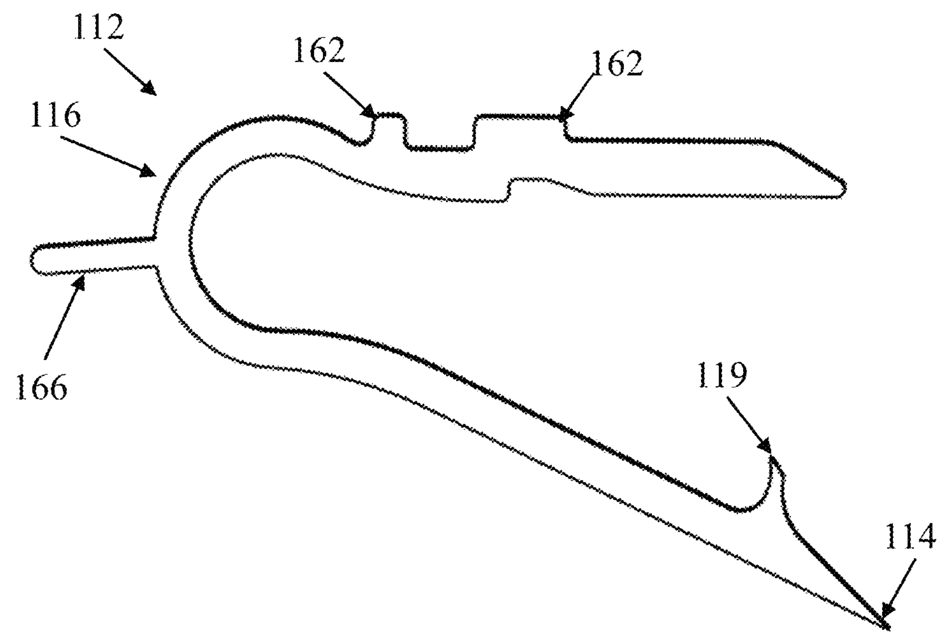


FIG. 21A

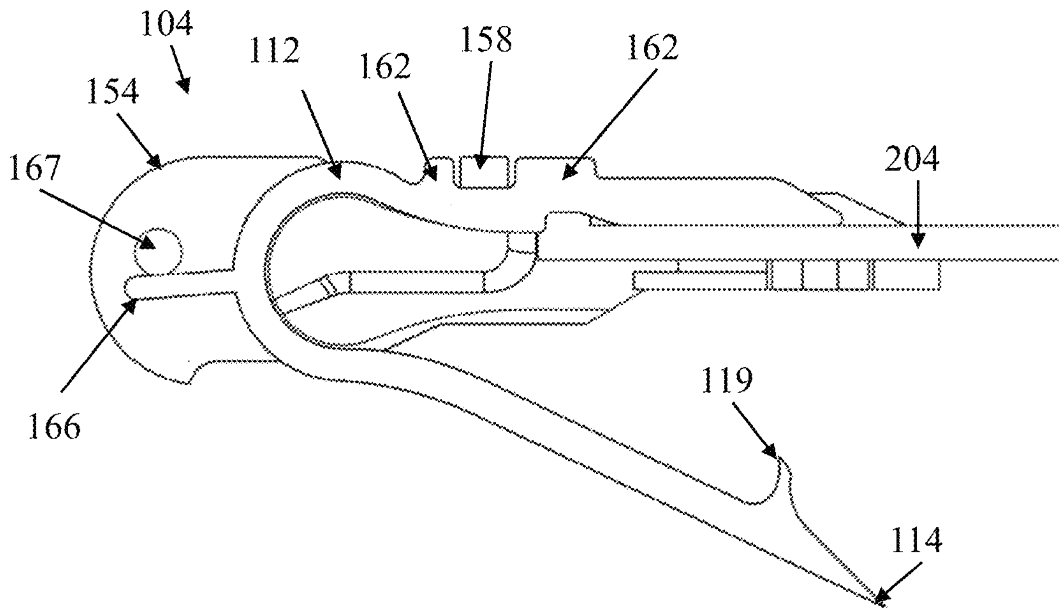


FIG. 21B

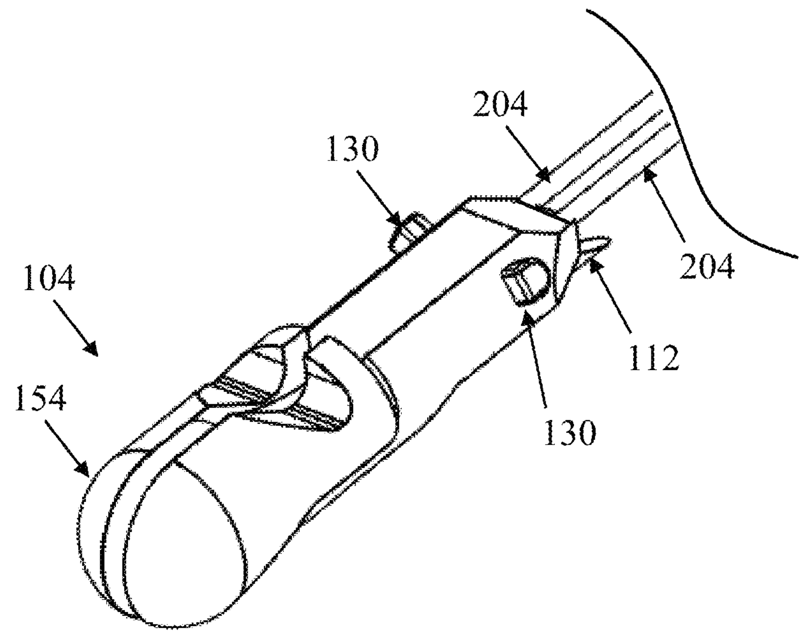


FIG. 22A

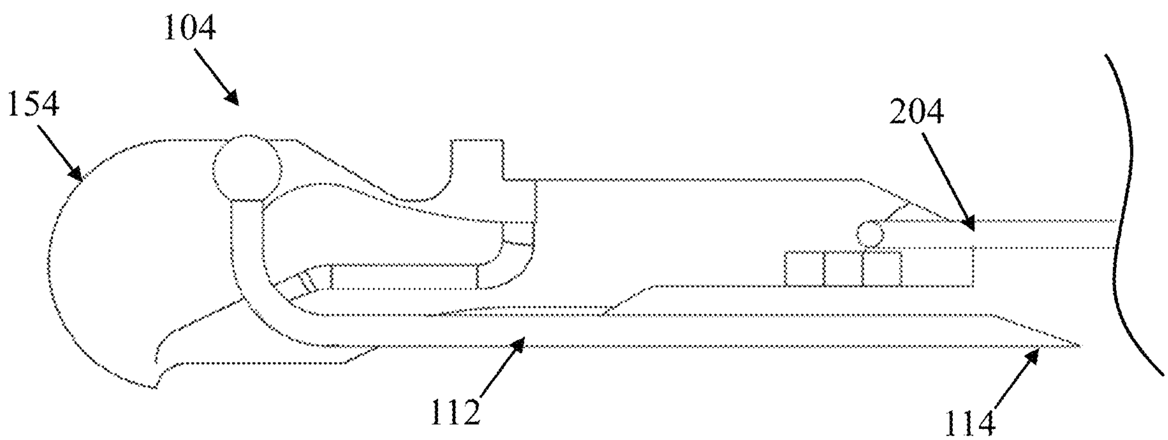


FIG. 22B

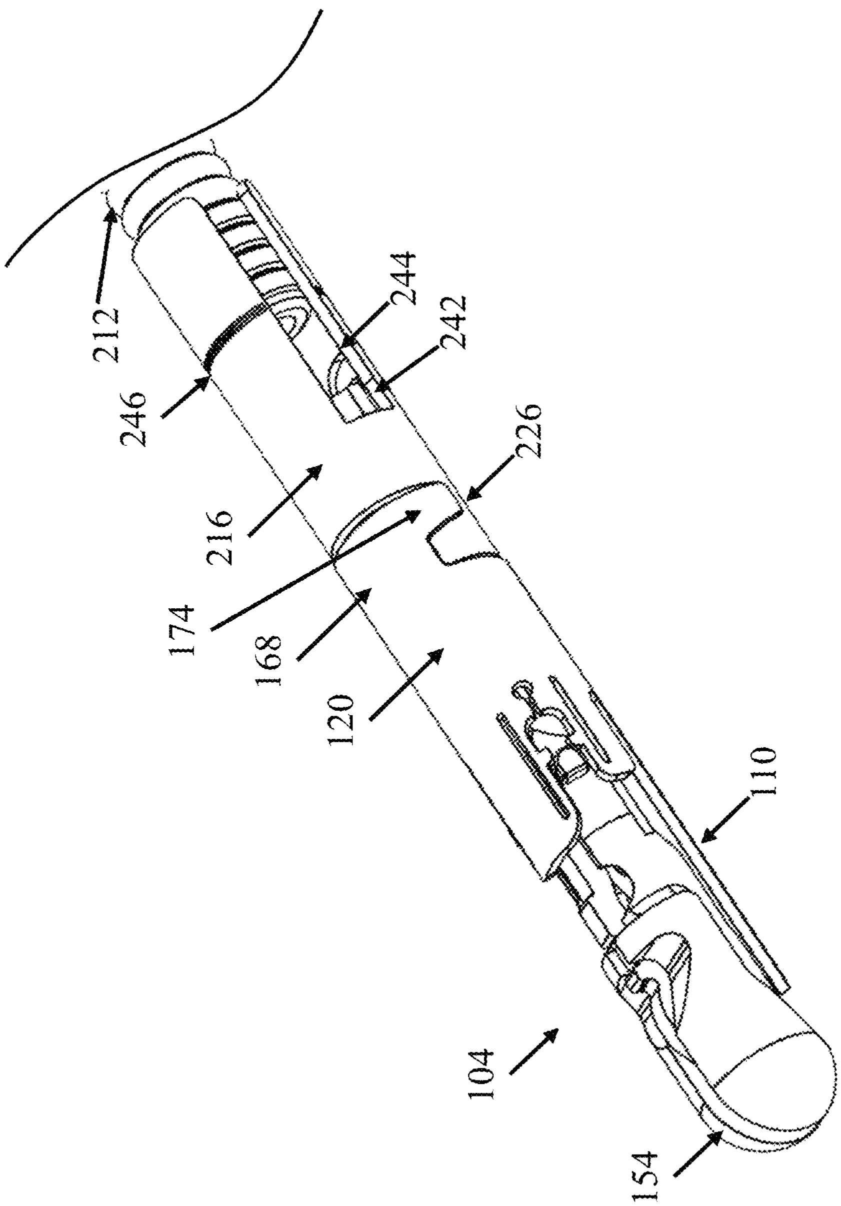


FIG. 23

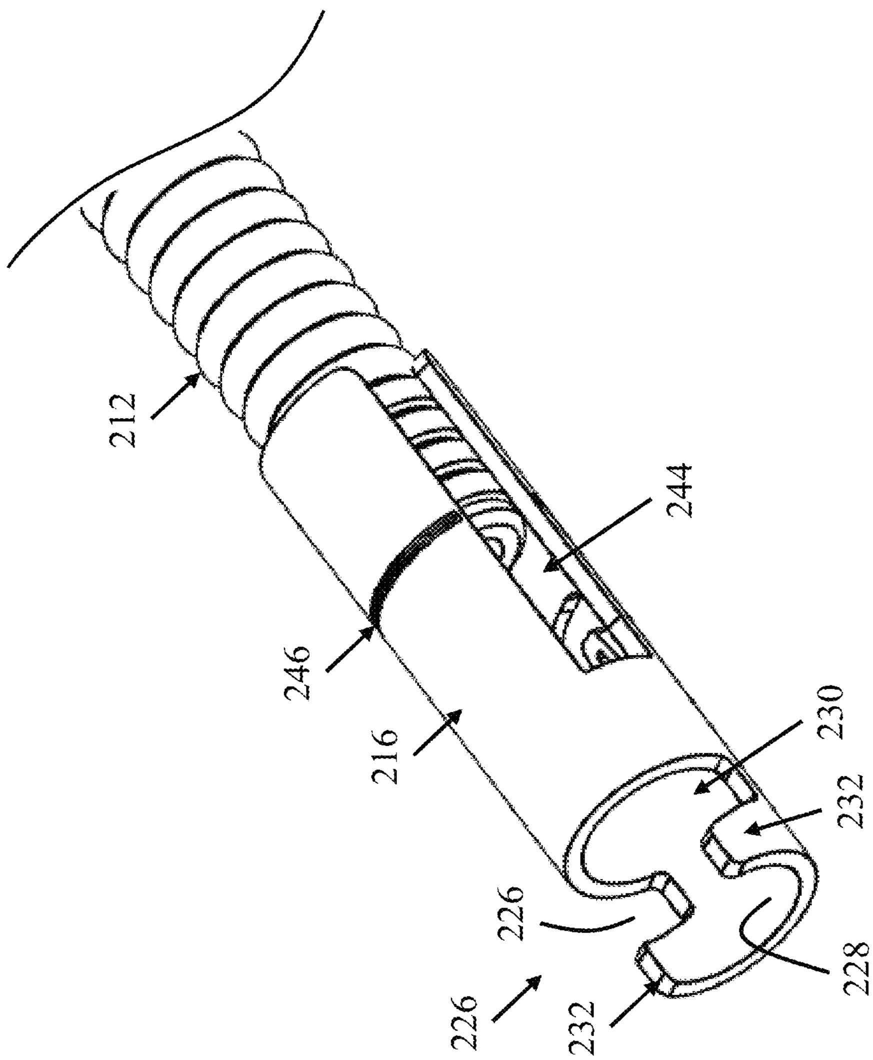


FIG. 24A

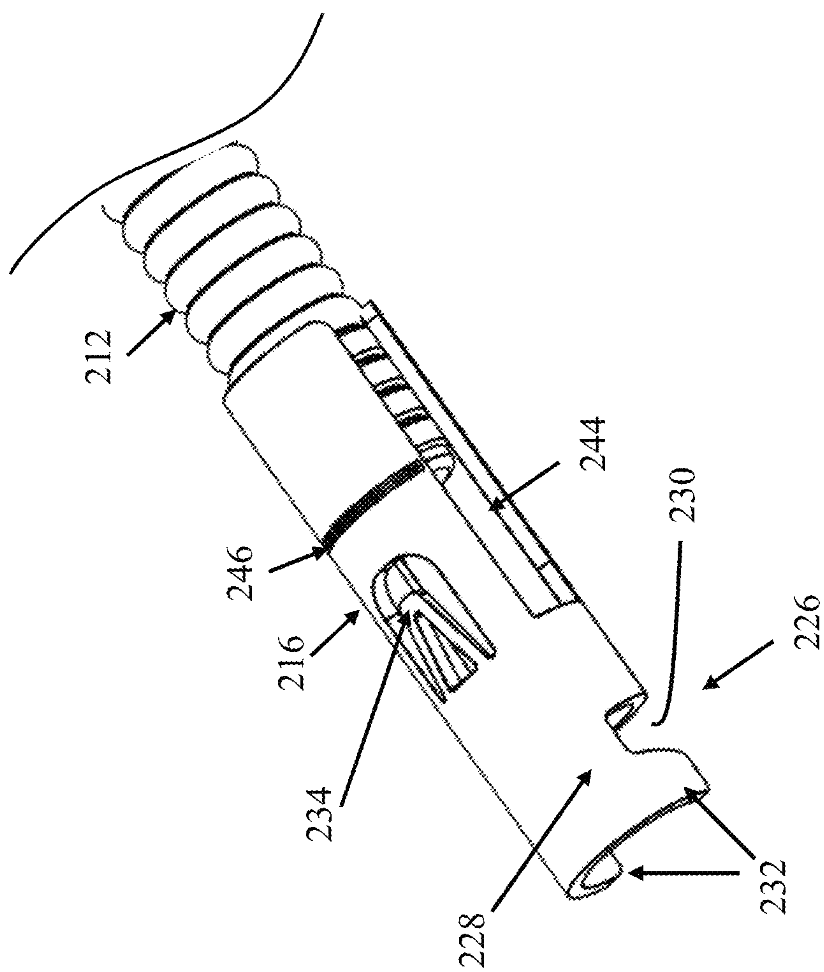


FIG. 24B

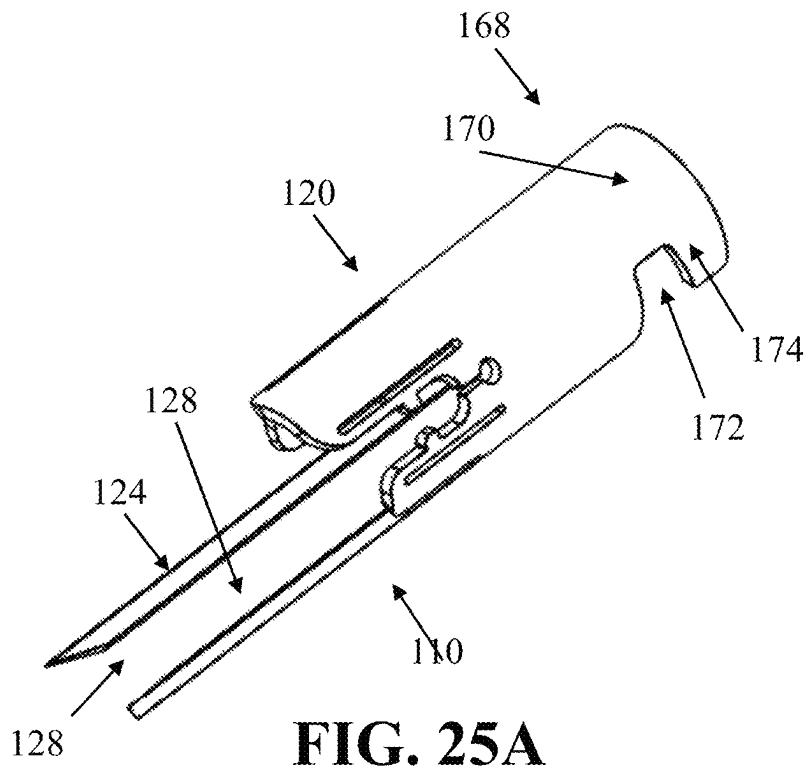


FIG. 25A

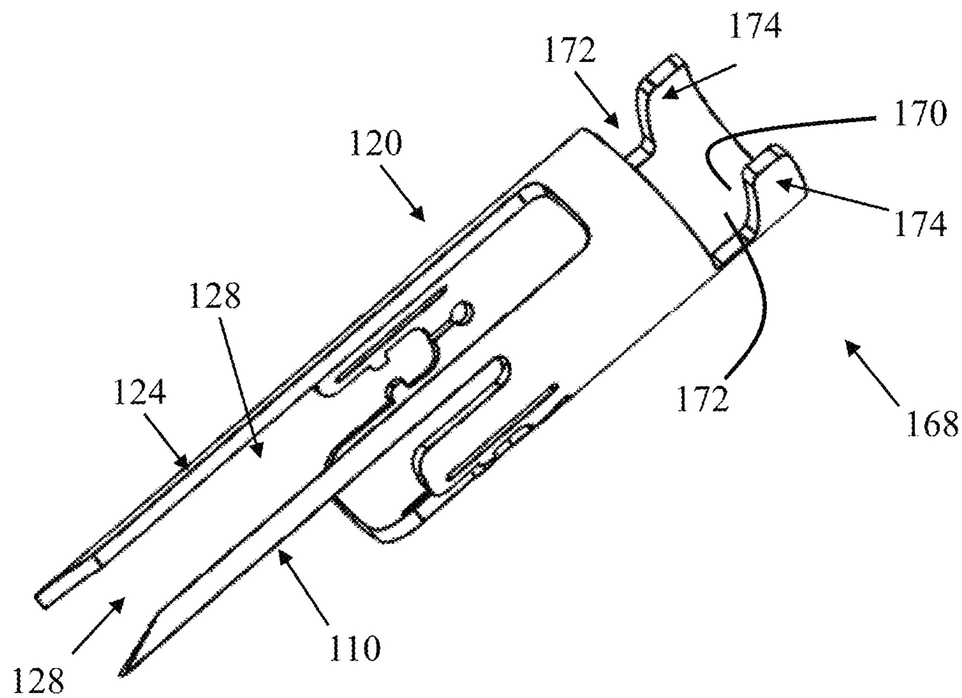


FIG. 25B

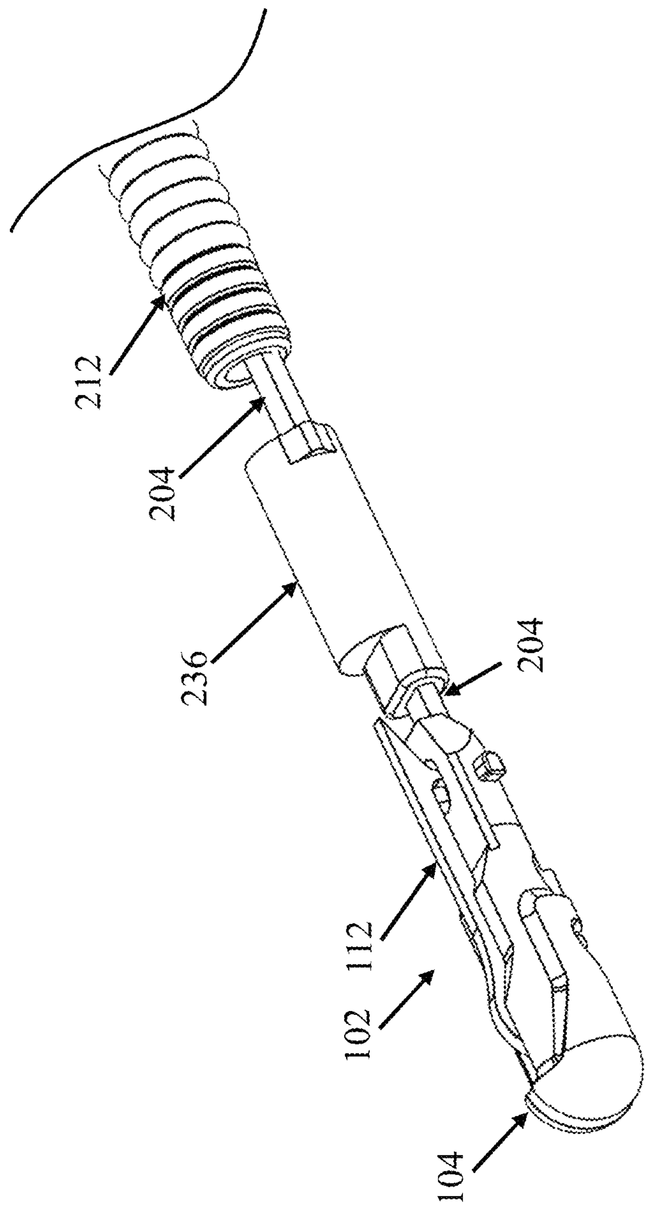


FIG. 26

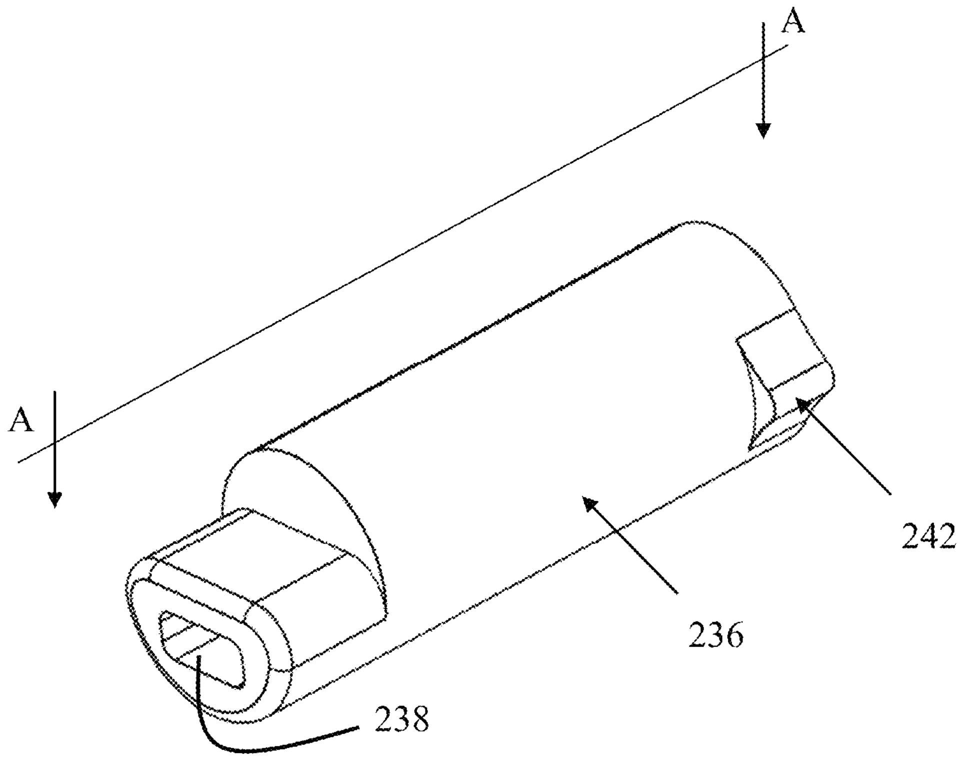


FIG. 27A

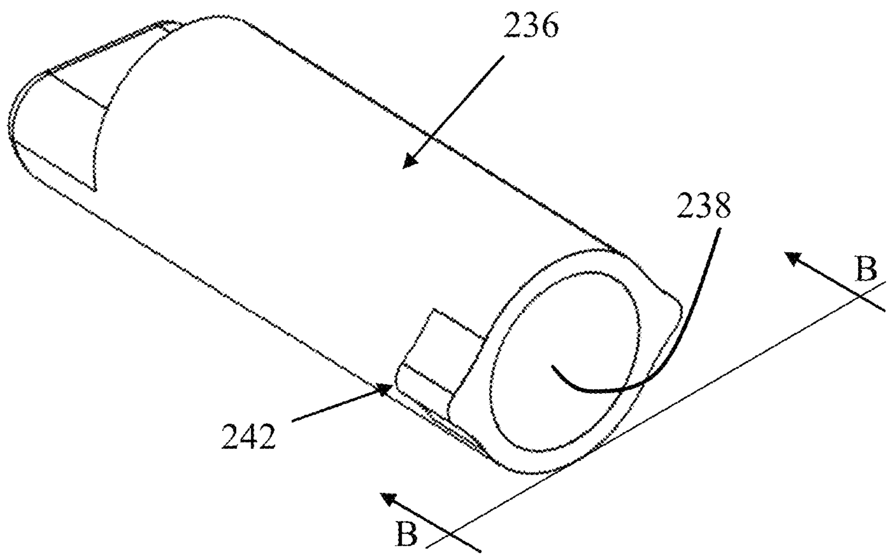


FIG. 27B

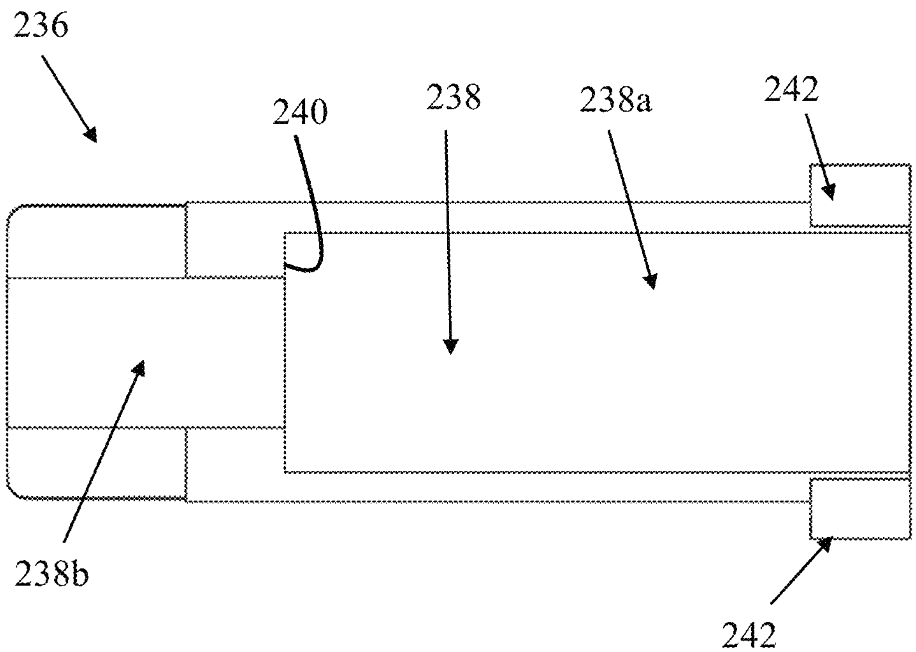


FIG. 27C

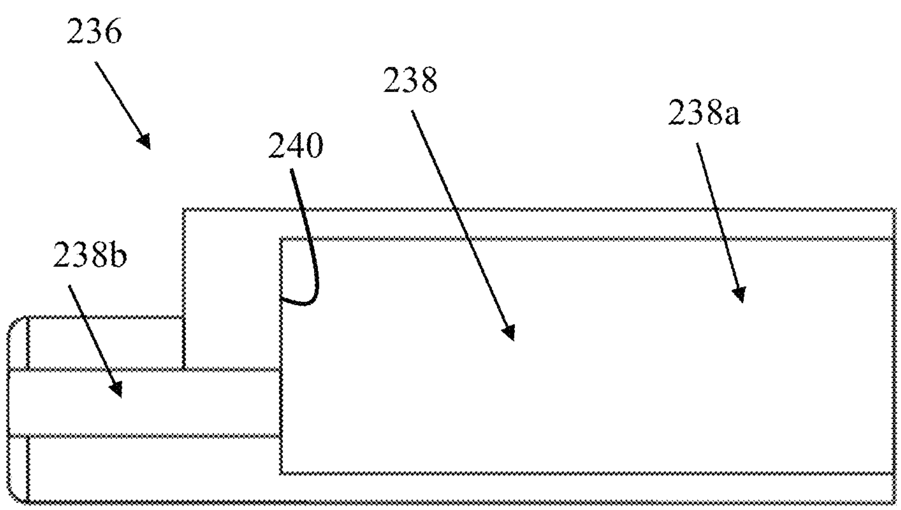


FIG. 27D

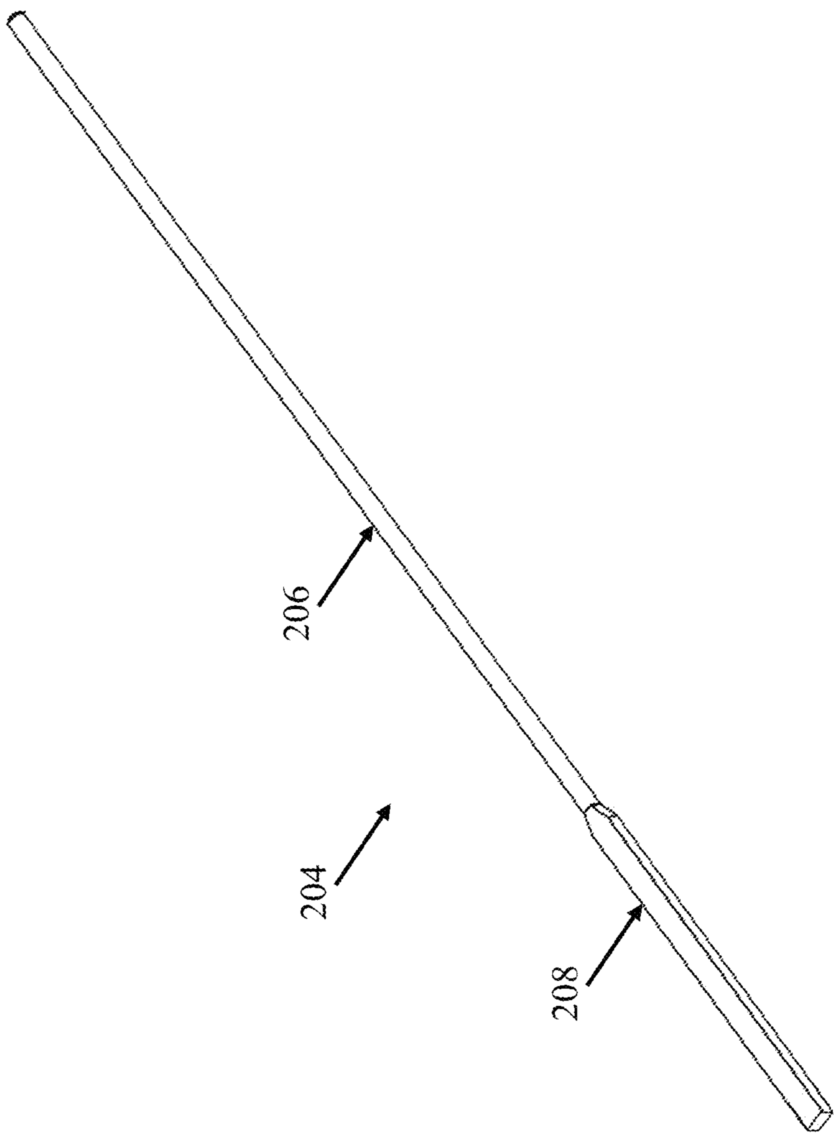


FIG. 28A

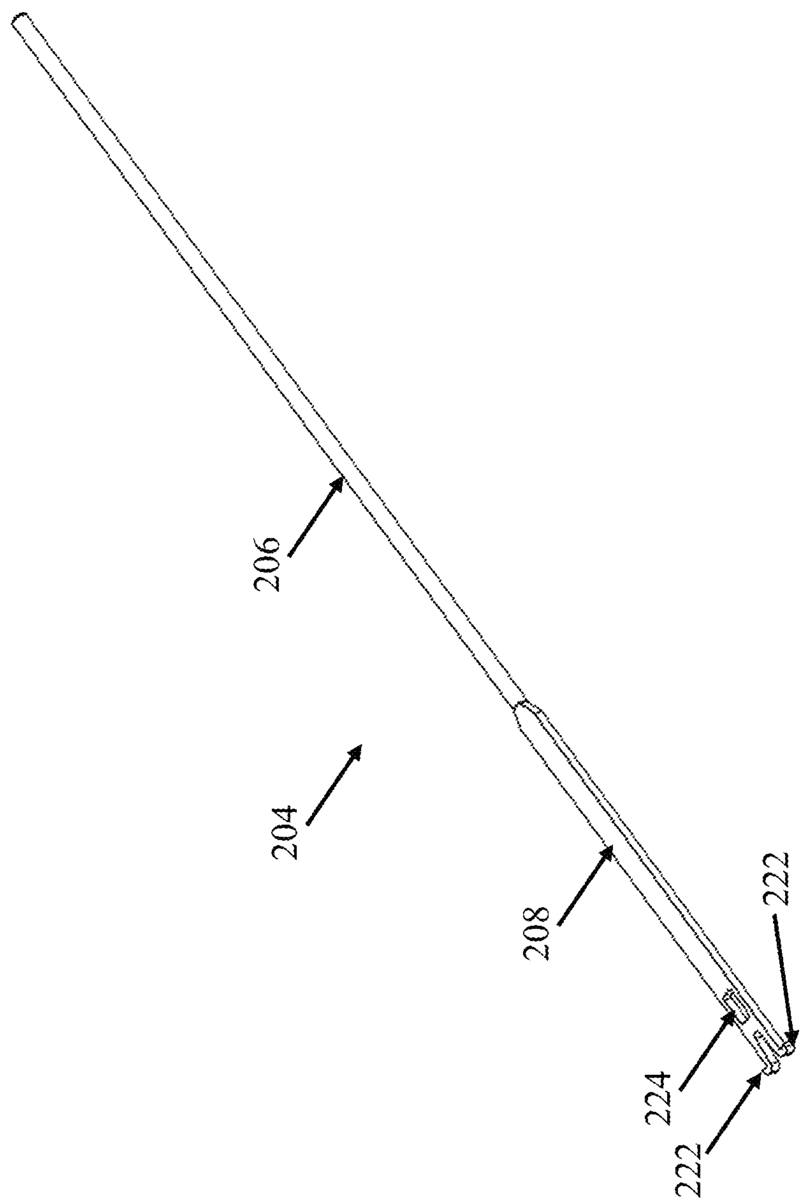


FIG. 28B

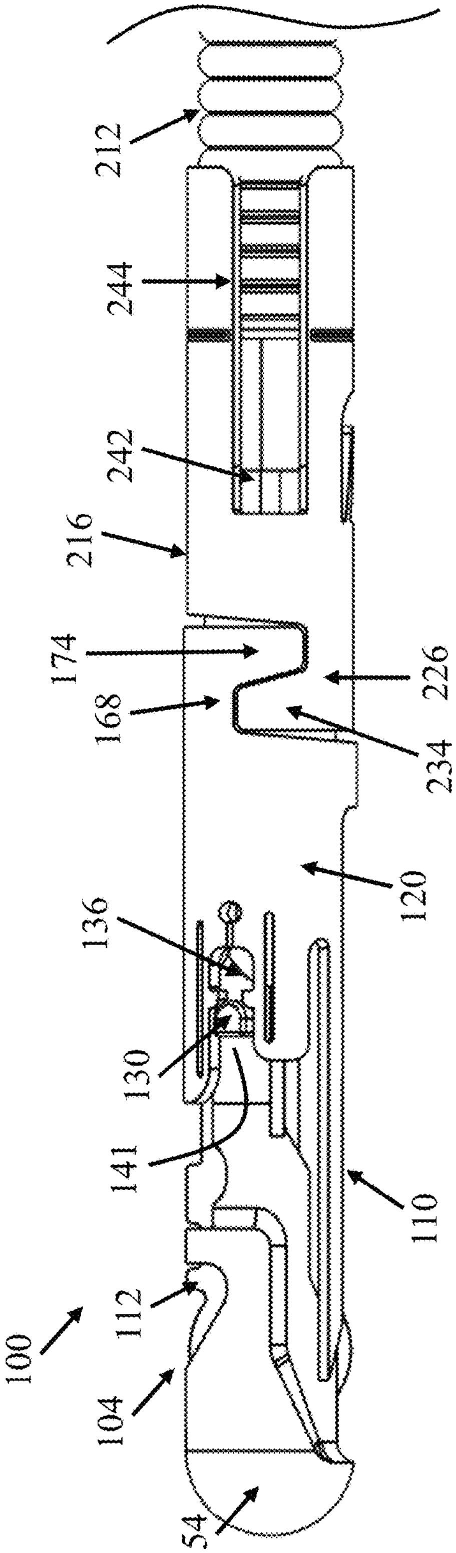


FIG. 29A

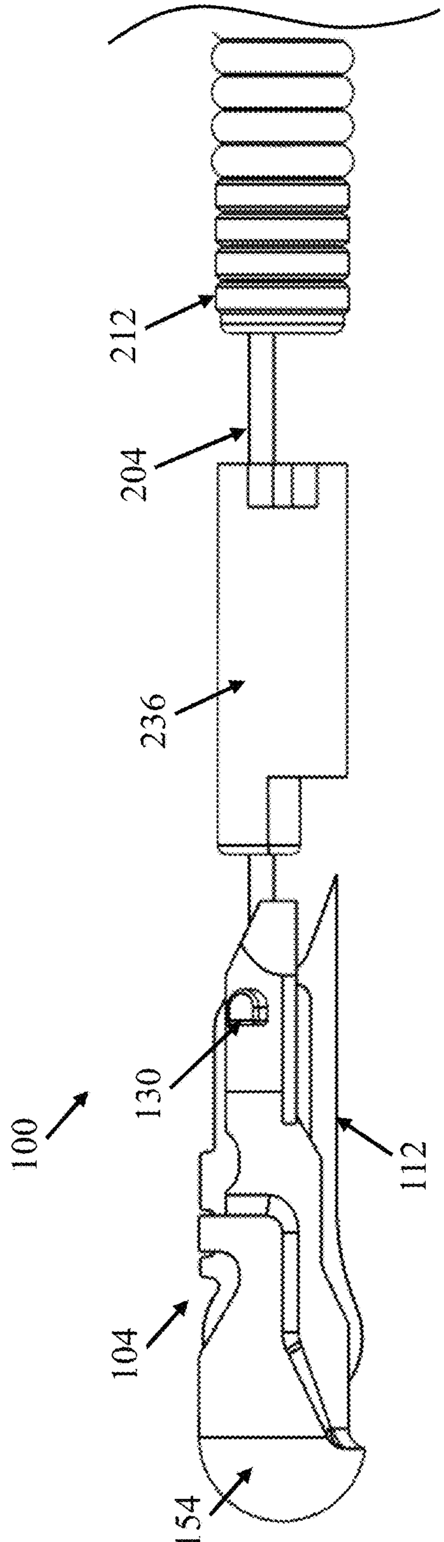


FIG. 29B

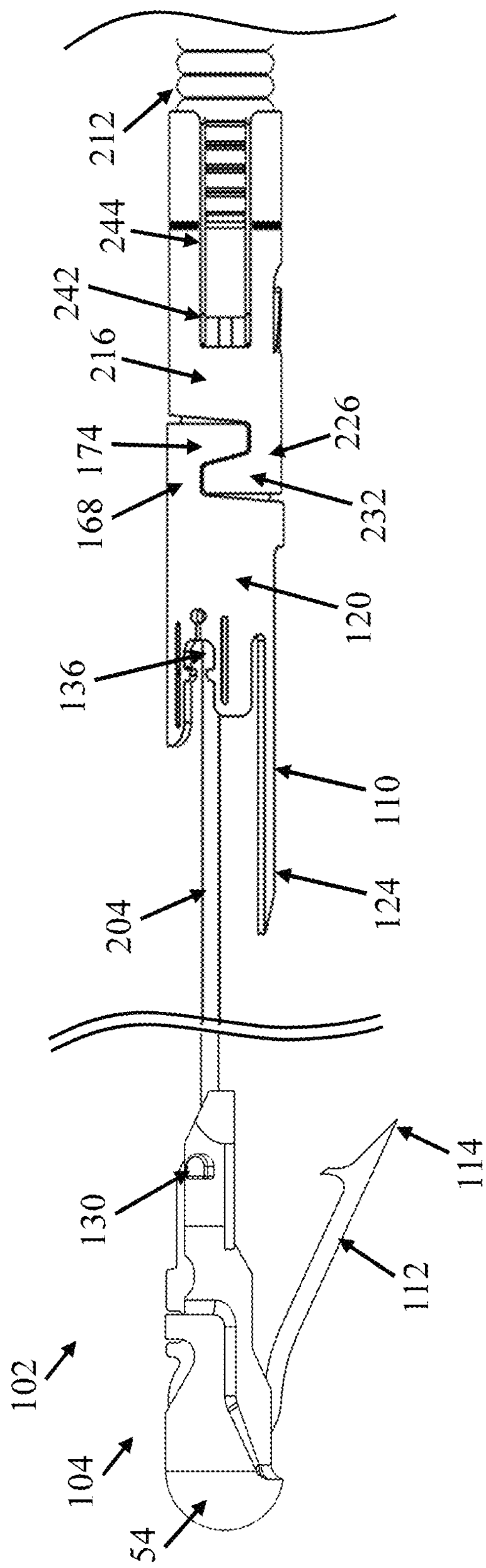


FIG. 30A

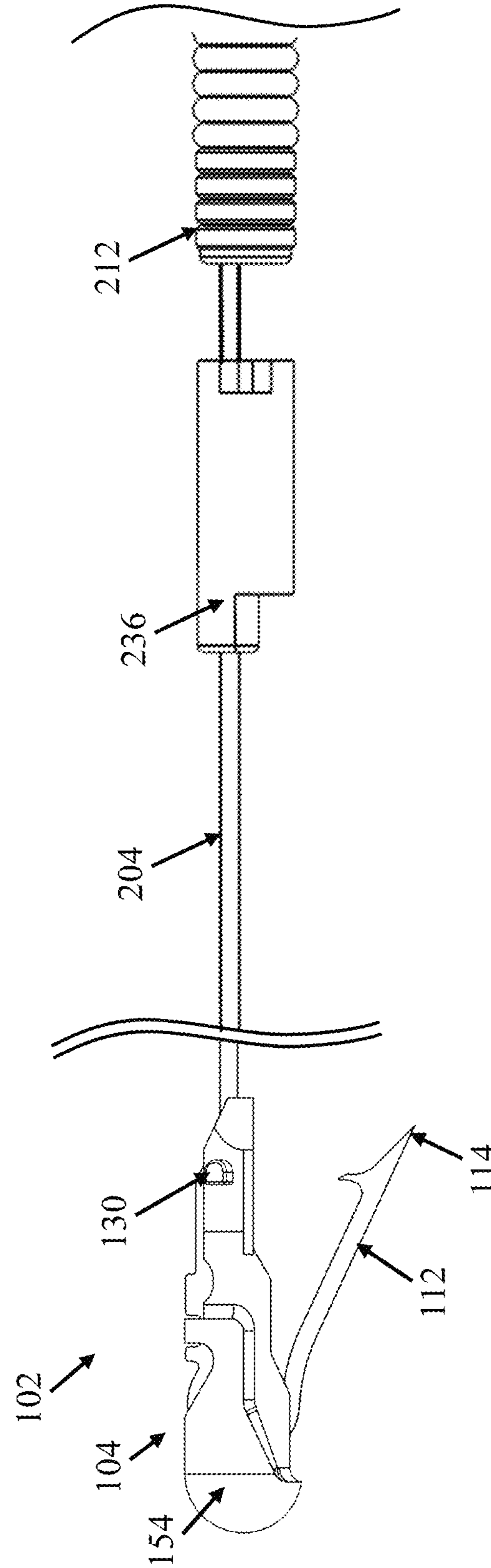


FIG. 30B

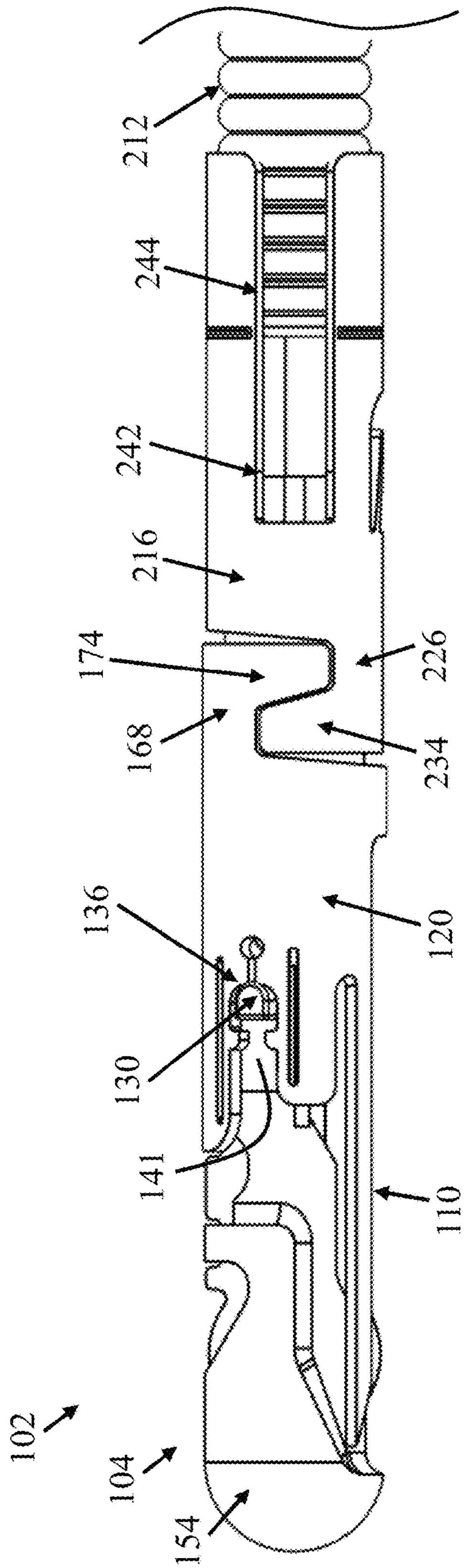


FIG. 31A

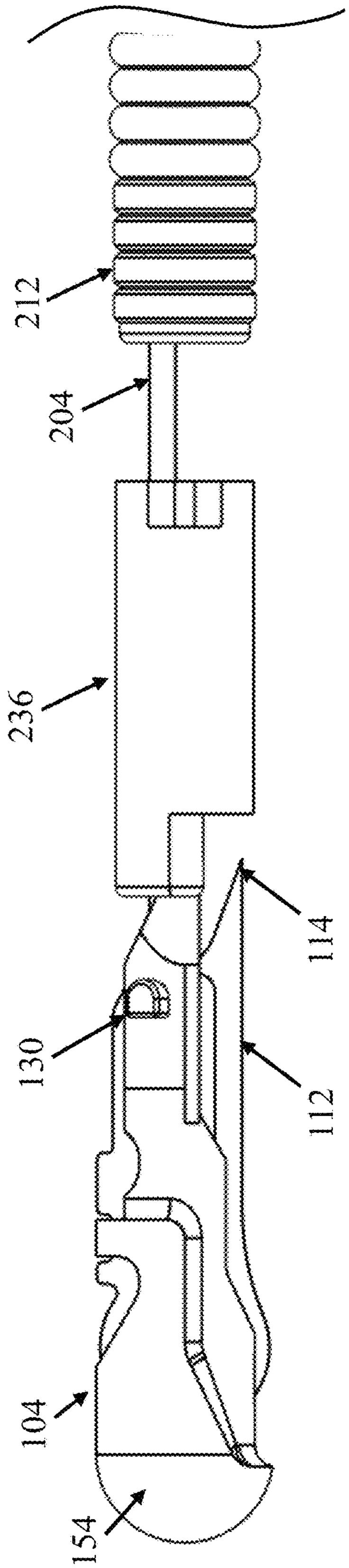
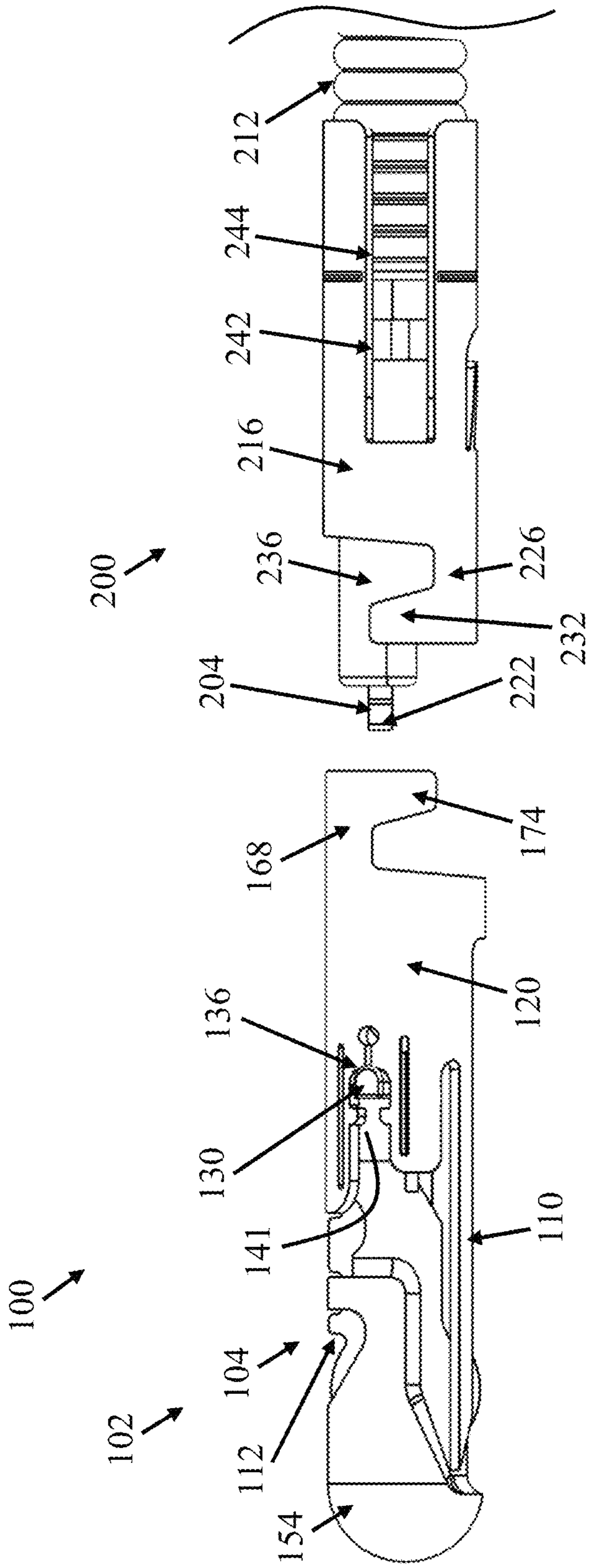


FIG. 31B


212
244
242
216
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232
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174
168
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136
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102
112
154

FIG. 32

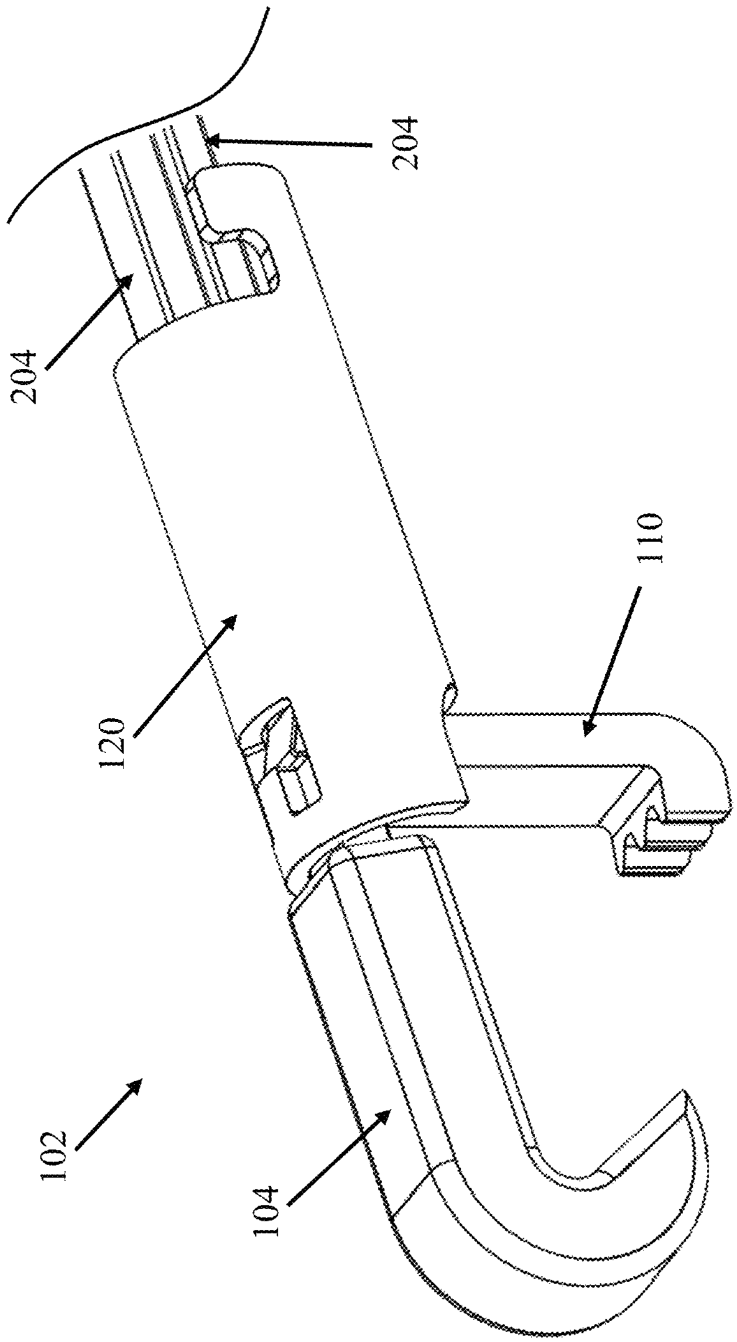

FIG. 33A

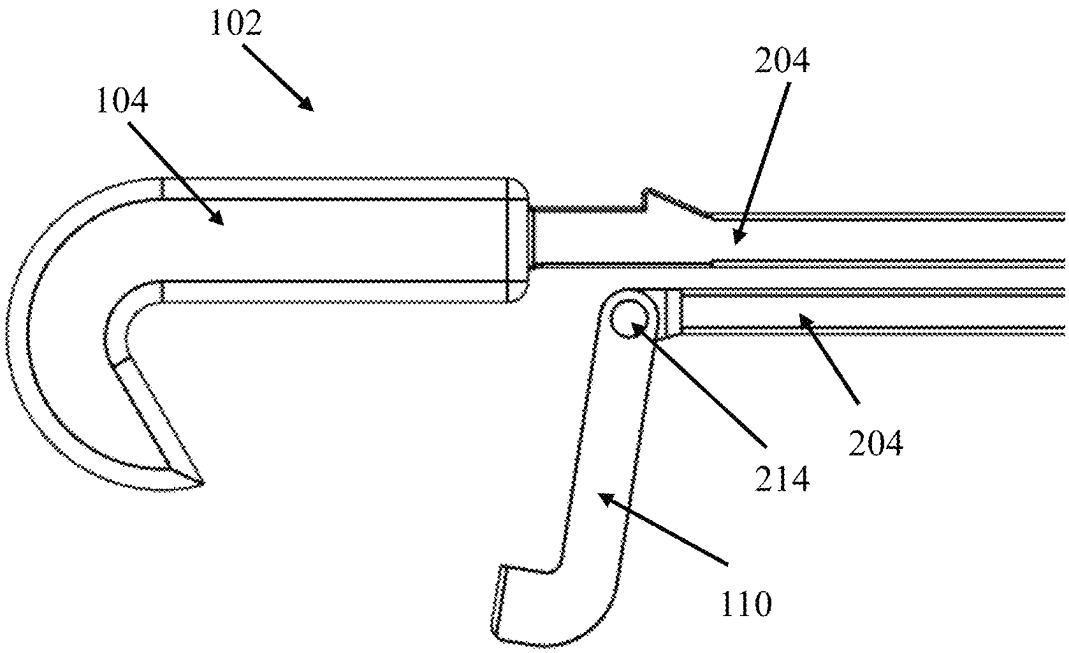

FIG. 33B

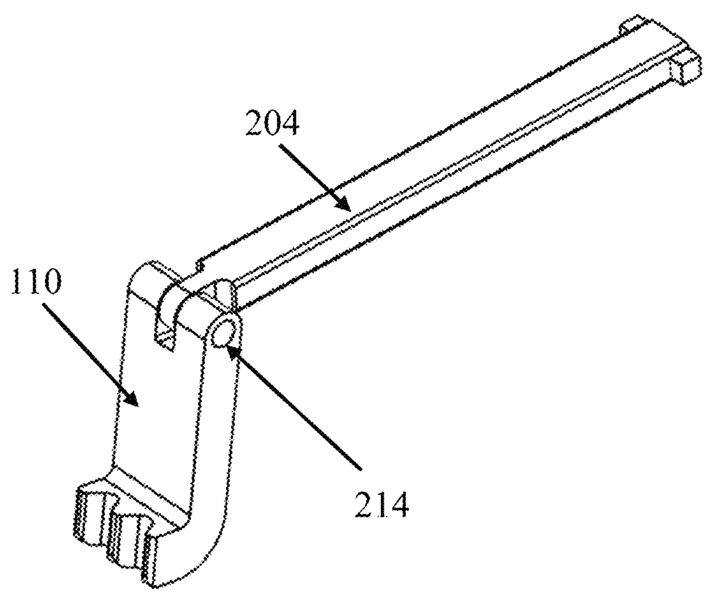

FIG. 33C

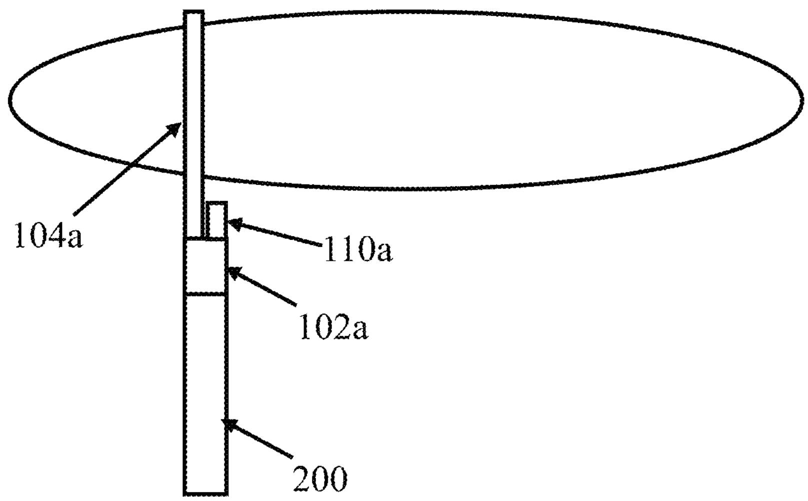

FIG. 34A

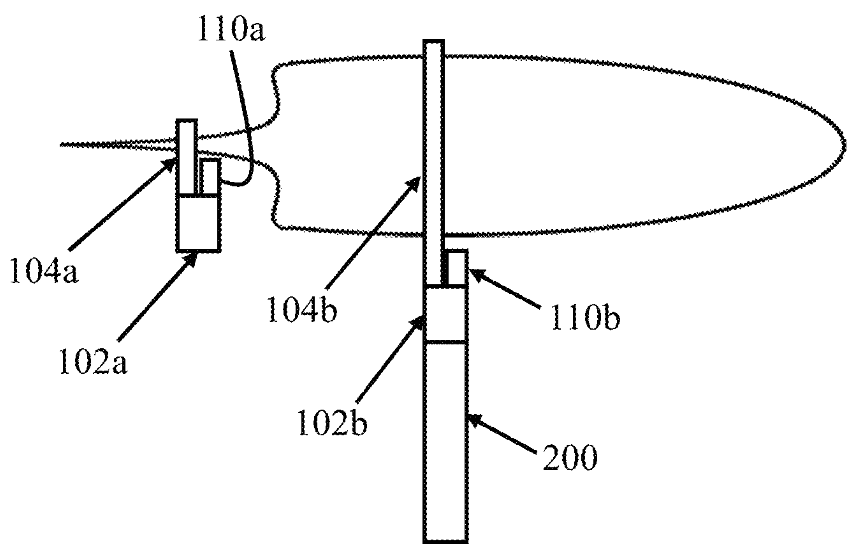

FIG. 34B

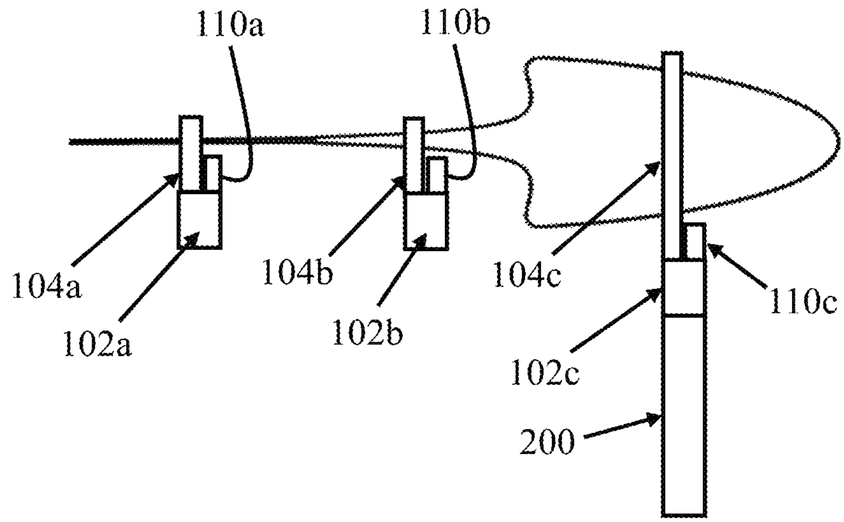

FIG. 34C

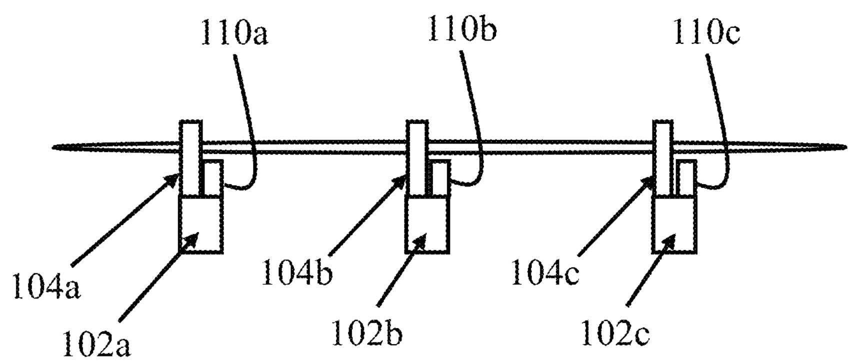

FIG. 34D

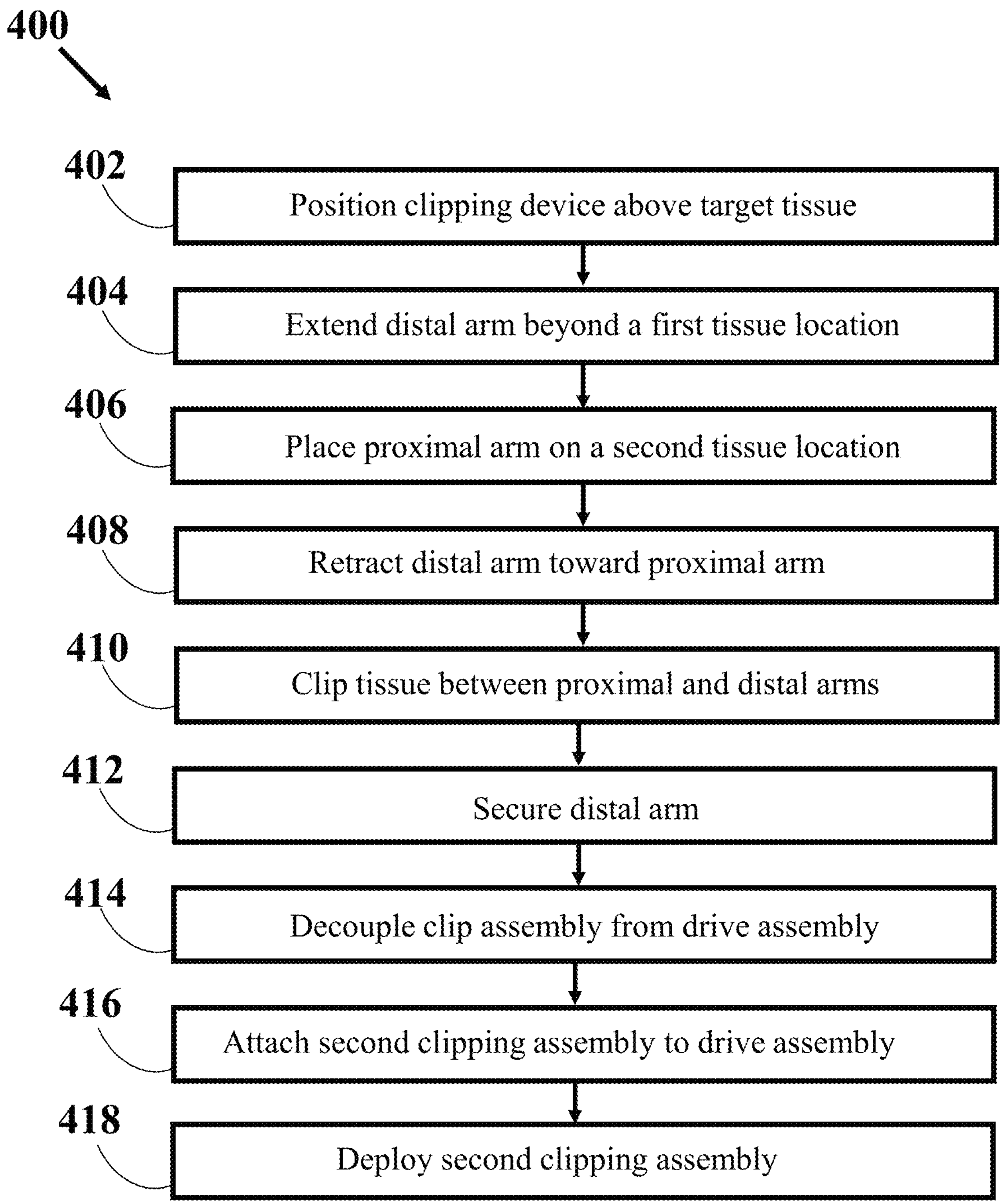
400
402
Position clipping device above target tissue
404
Extend distal arm beyond a first tissue location
406
Place proximal arm on a second tissue location
408
Retract distal arm toward proximal arm
410
Clip tissue between proximal and distal arms
412
Secure distal arm
414
Decouple clip assembly from drive assembly
416
Attach second clipping assembly to drive assembly
418
Deploy second clipping assembly

FIG. 35

LINEAR TISSUE CLIPPING DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority to U.S. Provisional Patent Application No. 63/344,354, filed on May 20, 2022, the entire disclosure of which is incorporated herein by reference as though recited herein it its entirety.

TECHNICAL FIELD

The present disclosure relates generally to surgical devices and, more specifically, to a linear tissue clipping device that allows for improved tissue recruitment.

BACKGROUND

Tissue recruitment devices are used in various parts of the body, including the gastrointestinal, urinary, and vascular systems, to recruit tissue, such as tissue from the luminal wall. The tissue recruitment devices may be deployed using an endoscope to recruit tissue such that it may be treated. The tissue recruitment devices may be used with hemostatic devices to treat internal bleeding or defects. Conventional hemostatic devices, such as clamps, clips, staples, and sutures, may be applied around recruited tissue to apply constrictive forces to the tissue, such as to apply a constrictive force to prevent bleeding.

Conventional tissue recruitment devices and hemostatic devices are operated from a position substantially above and perpendicular to the target tissue. However, such tissue recruitment devices and hemostatic devices may be difficult to properly position or operate to recruit and close tissue. For example, the target tissue may be located at a site which is difficult or impossible to access from a conventional perpendicular approach. This may increase the time of the procedure and limit the efficiency of the tissue recruitment and the closure of the target tissue, such as resulting in the recruitment device not adequately recruiting the target tissue and/or the hemostatic device not adequately closing the target tissue.

Accordingly, there are unmet needs for an improved recruiting device and an improved hemostatic device that is conducive for use in a non-perpendicular approach.

SUMMARY

This summary is meant to provide some examples and is not intended to be limiting of the scope of the invention in any way. For example, any feature included in an example of this summary is not required by the claims, unless the claims explicitly recite the features. Also, the features, components, steps, concepts, etc. described in examples in this summary and elsewhere in this disclosure can be combined in a variety of ways. The description herein relates to systems, assemblies, methods, devices, apparatuses, combinations, etc. that may be utilized for hemostatic closure of defects, perforations, ulcers, and other pathologies of the body requiring hemostasis. Various features and steps as described elsewhere in this disclosure may be included in the examples summarized here. Further, the treatment techniques, methods, operations, steps, etc. described or suggested herein can be performed on a living animal or on a non-living simulation, such as on a cadaver, simulator (e.g., with the body parts, tissue, etc. being simulated), etc.

In one example embodiment, a medical device for clipping tissue is provided. The medical device includes a catheter and a collar having a proximal arm extending in a distal direction. A proximal end of the collar is coupled with the distal end of the catheter. The medical device also includes a distal arm having an extending portion and a grasping portion, and a drive element extending through the catheter and coupled with the distal arm. The drive element is operable to linearly translate the distal arm through the collar. The medical device is operable to clip tissue between the proximal arm and the distal arm by linearly retracting the distal arm toward the proximal arm.

In one example embodiment, a medical device for clipping tissue is provided. The medical device includes a tissue clipping assembly operable to clip tissue and including a distal arm, a collar, and a proximal arm. The medical device also includes a drive assembly operable to actuate the tissue clipping assembly and including a handle, a catheter, and a drive element. A proximal end of the drive element is secured to the handle and a distal end of the drive element is operably coupled with a proximal end of the distal arm. The drive element is operable to linearly translate the distal arm to clip tissue between the distal arm and the proximal arm. The tissue clipping assembly is operably decoupled from the drive assembly after the tissue clipping assembly has clipped tissue.

In one example embodiment, a method for treating a defect with a tissue recruiting device is provided. The method includes the steps of positioning a tissue clipping assembly above the defect, linearly extending a distal arm of the tissue clipping assembly to grasp a first side of the defect via a drive assembly, grasping a second side of the defect with a proximal arm of the tissue clipping assembly, retracting the distal arm toward the proximal arm, clipping tissue between the distal and proximal arms, and decoupling the tissue clipping assembly from the drive assembly.

These and other objects, features, and advantages of the present disclosure will become apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify various aspects of implementations of the present disclosure, a more particular description of the certain examples and implementations will be made by reference to various aspects of the appended drawings. These drawings depict only example implementations of the present disclosure and are therefore not to be considered limiting of the scope of the disclosure. Moreover, while the Figures can be drawn to scale for some examples, the Figures are not necessarily drawn to scale for all examples. Examples and other features and advantages of the present disclosure will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** is a schematic illustration of a tissue clipping device;

FIGS. **2**A and **2**B are schematic illustrations depicting the operation of the tissue clipping assembly according to one embodiment;

FIG. **3**A is a schematic illustration of a tissue clipping assembly for use with a tissue clipping device according to one embodiment;

FIG. **3**B is a schematic illustration of a tissue clipping assembly for use with a tissue clipping device according to one embodiment;

FIG. **3**C is a schematic illustration of a tissue clipping assembly for use with a tissue clipping device according to one embodiment;

FIG. **4**A is a schematic illustration of the distal end of a tissue clipping device according to one embodiment;

FIG. **4**B is a schematic illustration of the distal end of a tissue clipping device according to another embodiment;

FIGS. **5**A and **5**B are schematic illustrations depicting the operation of the tissue clipping assembly according to another embodiment;

FIGS. **6**A through **6**D are schematic illustrations showing a tissue clipping operation with a tissue clipping device;

FIG. **7** is a side view of a tissue clipping device according to one embodiment;

FIG. **8**A is a perspective view of a distal arm according to one embodiment;

FIG. **8**B is a side view of the distal arm of FIG. **8**A;

FIG. **9**A is a perspective view of a distal arm according to another embodiment;

FIG. **9**B is a perspective view of a distal arm according to another embodiment;

FIG. **9**C is a perspective view of a distal arm according to another embodiment;

FIG. **10**A is a perspective view of a collar with a proximal arm according to one embodiment;

FIG. **10**B is a bottom view of the proximal arm of FIG. **10**A;

FIG. **11**A is a perspective view of a distal arm according to one embodiment;

FIG. **11**B is a perspective view of a collar according to one embodiment for use with the distal arm of FIG. **11**A;

FIG. **11**C is a perspective view of the distal arm of FIG. **11**A in a locked position in the collar of FIG. **11**B;

FIG. **12**A is a perspective view of a distal arm according to another embodiment;

FIG. **12**B is a perspective view of a collar according to another embodiment for use with the distal arm of FIG. **12**A;

FIG. **12**C is a perspective view of distal arm of FIG. **12**A retracted into a guiding slot of the collar of FIG. **12**B;

FIG. **13** is a perspective view of a collar according to another embodiment;

FIG. **14**A is a perspective view of a distal end of a drive element according to one embodiment;

FIGS. **14**B and **14**C are perspective and side views of a distal arm for use with the drive element of FIG. **14**A;

FIG. **14**D is a perspective view of the drive element of FIG. **14**A coupled with the distal arm of FIGS. **14**A-**14**B;

FIGS. **15**A and **15**B are schematic illustrations showing a distal arm coupled to a drive element via a coupler according to one embodiment;

FIGS. **16**A and **16**B are schematic illustrations showing a distal arm coupled to a drive element via a coupler according to another embodiment;

FIGS. **17**A-**17**C are schematic illustrations showing a distal arm coupled to a drive element via a coupler according to another embodiment;

FIG. **18** is a perspective view of a drive element coupling with a distal arm via a coupler according to another embodiment;

FIGS. **19**A and **19**B are top and bottom perspective views of a distal arm with a housing according to one embodiment;

FIG. **19**C is a perspective cross section view of the distal arm of FIGS. **19**A-**19**B;

FIG. **19**D is a side cross section view of the distal arm of FIGS. **19**A-**19**B;

FIGS. **19**E-**19**H are various views of the housing of the distal arm of FIGS. **19**A-**19**B;

FIGS. **19**I and **19**J show various views of a distal tine of the distal arm of FIGS. **19**A-**19**B;

FIG. **19**K is a perspective view of a distal portion of a drive element for use with the housing of FIGS. **19**E-**19**H and the distal tine of FIGS. **19**I-**19**J;

FIG. **19**L is a perspective view of the drive element of FIG. **19**K coupled with the distal tine of FIGS. **19**I-**19**J;

FIGS. **19**M and **19**N are top and bottom views of a coupler for use with the distal arm of FIGS. **19**A-**19**B;

FIGS. **19**O and **19**P are top and bottom perspective views of the distal arm of FIGS. **19**A-**19**B in a locked position with the coupler of FIGS. **19**M and **19**N;

FIG. **20**A is a perspective view of a distal arm with a housing according to another embodiment;

FIG. **20**B is a perspective view of a distal portion of a drive element for use with the housing of FIG. **20**A;

FIG. **20**C is a perspective view of a housing coupler for use with the housing of FIG. **20**A;

FIG. **20**D is a perspective view of a distal tine for use with the housing of FIG. **20**A;

FIG. **20**E is a cross-sectional side view of the housing of FIG. **20**A;

FIG. **21**A is a side view of a distal tine for use with a housing according to one embodiment;

FIG. **21**B is a cross-sectional side view of the distal tine of FIG. **21**A coupled with a housing;

FIG. **22**A is a perspective view of a distal arm according to another embodiment;

FIG. **22**B is a cross-sectional view of the distal arm of FIG. **22**A;

FIG. **23** is a perspective view of a tissue clipping assembly coupled with a catheter according to one embodiment;

FIGS. **24**A and **24**B are top and bottom perspective views of the catheter of FIG. **23** coupled with a connector;

FIGS. **25**A and **25**B are top and bottom perspective views of the collar of the tissue clipping assembly of FIG. **23**;

FIG. **26** is a bottom perspective view of the tissue clipping assembly of FIG. **23** with the collar and connector removed;

FIGS. **27**A and **27**B are front and rear perspective views of an alignment spacer for use with the tissue clipping assembly of FIG. **23**;

FIG. **27**C is a cross-sectional view of the alignment spacer of FIGS. **27**A-**27**B taken along the line B-B of FIG. **27**B;

FIG. **27**D is a cross-sectional view of the alignment spacer of FIGS. **27**A-**27**B taken along the line A-A of FIG. **27**A;

FIG. **28**A is a perspective view of a drive element according to one embodiment;

FIG. **28**B is a perspective view of a drive element according to another embodiment;

FIG. **29**A is a side view of the tissue clipping assembly of FIG. **23** in a set position;

FIG. **29**B is a side view of the tissue clipping assembly of FIG. **29**A with the collar and connector removed;

FIG. **30**A is a side view of the tissue clipping assembly of FIG. **23** in an extended position;

FIG. **30**B is a side view of the tissue clipping assembly of FIG. **30**A with the collar and connector removed;

FIG. **31**A is a side view of the tissue clipping assembly of FIG. **23** in a closed and locked position;

FIG. **31**B is a side view of the tissue clipping assembly of FIG. **31**A with the collar and connector removed;

FIG. **32** is a side view of the tissue clipping assembly of FIG. **23** in a deployed position;

FIG. **33**A is a perspective view of a tissue clipping assembly according to another embodiment;

FIG. **33**B is a side view of the tissue clipping assembly of FIG. **33**A with the collar removed;

FIG. **33**C is a perspective view of the tissue clipping assembly of FIG. **33**B with the distal arm removed;

FIGS. **34**A-**34**D are schematic illustrations depicting a methodology for clipping tissue with a tissue clipping device using multiple tissue clipping assemblies; and

FIG. **35** is an illustrative example depicting a methodology for clipping tissue with a tissue clipping device.

DETAILED DESCRIPTION

The following description refers to the accompanying drawings, which illustrate specific embodiments of the present disclosures, and describes exemplary embodiments in accordance with the general inventive concepts and is not intended to limit the scope of the invention or the claims in any way. Indeed, the invention as described by the claims is broader than and not limited by the exemplary embodiments set forth herein, and the terms used in the claims have their full ordinary meaning.

The general inventive concepts will be understood more fully from the detailed description given below and from the accompanying drawings of the various exemplary aspects and implementations of the disclosure. This should not be taken to limit the general inventive concepts to the specific aspects or implementations, which are being provided for explanation and understanding only. Example embodiments of the present disclosure are directed to devices and methods for clipping tissue. Various embodiments of devices and systems for clipping tissue are disclosed herein, and any combination of these options can be made unless specifically excluded. In other words, individual components of the disclosed devices and systems can be combined unless mutually exclusive or otherwise physically impossible.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art encompassing the general inventive concepts. The terminology set forth in this detailed description is for describing particular embodiments only and is not intended to be limiting of the general inventive concepts. As used in this detailed description and the appended claims, the singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise.

As described herein, when one or more components are described as being connected, joined, affixed, coupled, attached, or otherwise interconnected, such interconnection can be direct as between the components or can be indirect such as through the use of one or more intermediary components. Also, as described herein, reference to a "member," "component," or "portion" shall not be limited to a single structural member, component, or element, but can include an assembly of components, members, or elements.

Unless otherwise indicated, all numbers, such as for example, numbers expressing measurements or physical characteristics, used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless otherwise indicated, the numerical properties set forth in the specification and claims are approximations that may vary depending on the suitable properties sought to be obtained in embodiments of the invention. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the general inventive concepts are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical values, however, inherently contain certain errors necessarily resulting from error found in their respective measurements. Also, as described herein, the terms "substantially" and "about" are defined as at least close to (and includes) a given value or state (preferably within 10% of, more preferably within 1% of, and most preferably within 0.1% of).

In discussing the exemplary embodiments herein, the terms "proximal" and "distal" may often be used. These terms are used to describe a position or a direction with reference to the operator of the instrument. For example, the proximal position or proximal direction is toward the user or operator of the instrument, and the distal position or direction is away from the user or operator of the instrument, i.e., position or direction toward the object which the operator is attempting to grasp, retain, and/or view. Additionally, relative positional terms such as "up" or "down" and "above" or "below" refer to the position of the component in the context of the figures. Such relative positional terms are used only to facilitate the description and are not meant to be limiting.

The present invention provides a tissue clipping device which may be used in a linear procedural approach parallel to target tissue, such as parallel to the luminal wall. The tissue clipping device may be used closing lesions and/or acutely for hemostasis, such as in endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), full thickness perforations, or upper/lower GI bleeding. The tissue clipping device may be configured to better approximate tissue than standard tissue recruiting devices, such as tissue in the GI tract, such as the colon, small bowel, and esophagus. The tissue clipping device may also be configured to recruit tissue over larger defects than standard tissue recruiting devices and hemostatic clips. For example, the tissue clipping device of the present disclosure may be configured to approximate tissue defects having a width or diameter greater than 10 mm. In some embodiments, the tissue clipping device is configured to approximate tissue defects between 20 mm and 30 mm in width or diameter. The tissue clipping device may be configured to effectively grasp tissue across defects greater than 30 mm in width or diameter. The tissue clipping device may reduce the number of hemostatic devices needed to close a defect. The tissue clipping device may be usable in locations and positions which are less amenable to conventional tissue recruiting devices, such as splenic or hepatic flexures or other articulated positions. In some embodiments, the tissue clipping device may be a sterile, single use device.

A functional block diagram for a tissue clipping device **100** is illustrated in FIG. **1**. The tissue clipping device **100** includes a tissue clipping assembly **102** at a distal end and a drive assembly **200** at a proximal end and coupled with a proximal end of the tissue clipping assembly **102**. The tissue clipping device **100** is operable to linearly clip tissue, such as in a direction parallel to the tissue. It will be understood that the linear movement and operation of the tissue clipping device **100** refers to a direction substantially parallel to the angle of insertion and operation of the device **100**, such as a direction substantially parallel to a distal end of an endoscope, a distal end of a catheter, and/or a surface of the tissue.

The tissue clipping assembly **102** is operable to clip tissue in a linear direction. The tissue clipping assembly **102** includes a distal arm **104** and a proximal arm **110**. The distal arm **104** is distally extendable and proximally retractable relative to the proximal arm **110** to clip tissue between the distal and proximal arms **104**, **110**. The distal arm **104** includes an extending portion **106** extending generally linearly in a distal direction and a grasping portion **108** extending from the extending portion **106**. The grasping portion **108** is operable to grasp target tissue such that it may clipped between the distal arm **104** and the proximal arm **110**. The proximal arm **110** is disposed proximally to the distal arm **104**, such as proximally from the grasping portion **108** of the distal arm **104**. It will be understood that the clipping of the tissue clipping assembly **102** encompasses grasping, grabbing, pinching, hooking, or otherwise securing tissue.

In the illustrated embodiment, the extending portion **106** of the distal arm **104** extends substantially straight, the grasping portion **108** extends substantially downward (e.g., in a direction substantially perpendicular to the linear movement of the tissue clipping assembly **102**), and the proximal arm **110** extends distally and downwardly. However, it will be understood that the distal and proximal arms **104**, **110** may have other shapes and configurations. For example, the grasping portion **108** of the distal arm **104** may extend proximally toward the proximal arm **110** and the proximal arm **110** may extend substantially distally.

The drive assembly **200** includes a handle **202** operably by a user to control the tissue clipping assembly **102**. The drive assembly **200** also includes one or more drive elements **204** coupling the tissue clipping assembly **102** and the handle **202** such that a user may control the tissue clipping assembly **102**, such as to clip tissue, via the handle **202**. Each drive element **204** may be configured to transfer translational movement to the tissue clipping assembly **102**. In some embodiments, the drive elements **204** are configured to transfer rotational movement to the tissue clipping assembly **102**. Each drive element **204** may be a solid cable, a hollow tube, a drive cable, a torque cable/shaft, a hypotube, a spring sheath, a catheter, or other device configured to control a component of the tissue clipping assembly **102**, or any combination thereof. In some embodiments, the distal ends of the drive elements **204** are fixed to the tissue clipping assembly **102**. In other embodiments, the distal ends of the drive elements **204** may be operably decoupled from the tissue clipping assembly **102**, as described below.

In the illustrated embodiment, the tissue clipping device **100** includes one drive element **204** with a distal end coupled with the proximal end of the distal arm **104**, such as to the proximal end of the extending portion **106** of the distal arm **104**, and operable to transmit linear and rotational movement to the distal arm **104**. However, it will be understood that the tissue clipping device **100** may include more than one drive element **204**. For example, the tissue clipping device **100** may include a second drive element **204** coupled with the proximal arm **110** to control the linear and/or rotational positions of the proximal arm **110** (see FIGS. **3**A-**3**B).

The handle **202** may include a control actuator **210** coupled to the proximal end of each drive element **204**. Each control actuator **210** may be operable to control the position and rotation of the coupled drive element **204**, such as to control the position and rotation of the tissue clipping assembly **102**. For example, a user may linearly translate and rotate the control actuator **210** to linearly translate and rotate a portion of the tissue clipping assembly **102** via one of the drive elements **204**. In the illustrated embodiment, the control actuator **210** is a rotational wheel that is linearly slidable within a portion of the handle **202** to control the rotation and translation of the drive element **204**. The control actuators **210** may be any suitable device a user may actuate to control the position and/or rotation of one of the drive elements **204**. For example, the control actuators **210** may be push buttons, wheels, toggles, switches, levers, triggers, sliders, or the like, or any combination thereof.

The drive assembly **200** also includes a catheter **212** extending distally from the handle **202**. The catheter **212** may include one or more lumens extending the length of the catheter **212**. The catheter **212** may be sized, shaped, and configured to cover one or more components of the tissue clipping device **100**, such as when the device **100** is disposed through an endoscope. The tissue clipping assembly **102** and the drive elements **204** may be extended through the catheter **212**, such as through the endoscope, to the desired location in a body. In some embodiments, the proximal arm **110** is coupled to the distal end of the catheter **212**. It will be understood that the catheter **212** may be a tube, such as polymer tubing, a sheath, a coil, such as a stainless steel coil, or a composite shaft, such as a braided or coiled polymer, or any combination thereof.

In some embodiments, the catheter **302** comprises polyether ether-ketone (PEEK), a thermos-plastic material, nylon, Pellethane, polytetrafluoroethylene (PTFE), polyimide, composite metal and/or include polymer tubing, metal tubing, metal coils, or a reinforced composite sheath containing a coil and/or braid, or combinations thereof. In a preferred embodiment, the catheters **212** are metal spring sheaths configured to resist compression and operational forces exerted on the catheters **212** by the one or more drive elements **204** as described below. In some embodiments, the catheter **212** is configured to translate and/or rotate the tissue clipping assembly **102**, such that an operator may control the position and/or orientation of the tissue clipping assembly **102**. In some embodiments, the **212** includes a liner or coating, such as a PTFE liner and/or coating, Polyimide, HDPE, or other lubricious polymer, or any combination thereof, disposed in the one or more lumens to increase the resiliency of the catheter **212** and/or to decrease friction between the one or more drive element **204** and the catheter **212**. In some embodiments, the liner is a separate component from the catheter **212** and is disposed between an outer surface of the drive element **204** and an inner surface of the catheter **212**.

In some embodiments, the tissue clipping assembly **102** includes a collar **120** operably coupled with the distal end of the catheter **212**. The collar **120** may be a substantially tubular ring through which distal arm **104** and the drive element **204** may be extended and retracted. In some embodiments, the proximal arm **110** is coupled to the distal end of the collar **120**. The proximal arm **110** and the collar **120** may be combined into a single component. In some embodiments, the collar **120** may be operably decoupled from the catheter **212**, such as after the tissue clipping assembly **102** has clipped tissue such that the tissue clipping assembly **102** may continue to clip the tissue closed.

The tissue clipping device **100** may be used with any suitable or conventional endoscopic or laparoscopic surgical equipment. For purposes of this disclosure, the tissue clipping device **100** is described in the context of use with an endoscope, such as a colonoscope, gastroscope, duodenoscope, enteroscope, or sigmoidoscope type apparatus of conventional or suitable construction. However, the tissue clipping device **100** may also be used in other manners, such as in any minimally invasive procedure with a suitable natural or artificially created orifice in the body. The scope is provided with an elongated body having a controllably flexible projecting end region. Surgical instruments, such as the device **100**, may be introduced through an instrument channel, such as an accessory channel, which extends through the scope body, for recruiting tissue targeted by the surgeon manipulating the scope. The tissue clipping assembly **102** may be sized, shaped, and configured such that it may be disposed through a single instrument or accessory channel of the endoscope.

The tissue clipping assembly **102** may be operated by a user at a proximal end of the endoscope via one or more drive elements **204** extending through a channel located within and extending through the endoscope, such as via the drive assembly **200**. However, the device **100** may also be used without an endoscope, such as in minimally invasive procedure with a suitable natural or artificially created orifice in the body. The tissue clipping device **100** is constructed and configured such that it may also be inserted into a subject through an orifice or small incision and operated to clip tissue, such as to a tissue defect.

As shown in FIGS. **2A-2B**, the distal arm **104** may be actuated by one of the drive elements **204** to extend from and retract into the catheter **212**, such as to clip tissue. The drive element **204** coupled with the distal arm **104**, such as the proximal end of the extending portion **106** of the distal arm **104**, may be distally extended, such as via the handle **202**, to distally extend the distal arm **104**. In some embodiments, the distal arm **104** and the proximal arm **110** comprise wire, such as a flat wire.

The distal arm **104** may be linearly extended such that the grasping portion **108** of the distal arm **104** is spaced apart from the proximal arm **110**, the collar **120**, and the catheter **212**. The tissue clipping assembly **102** may be in an extended or open position when the distal arm **104** is spaced apart from the proximal arm **110** (FIG. **2A**). In some embodiments, the distal arm **104** may be distally extended from the catheter **212** between about 1 cm and about 3 cm. In some embodiments, the drive element **204** may also be rotated, such as via the handle **202**, to rotate the distal arm **104**, such as to position the grasping portion **108** of the distal arm **104** to clip target tissue.

When the tissue clipping assembly **102** is in the open position, the distal and proximal arms **104**, **110** may be properly positioned relative to the target tissue. The grasping portion **108** of the distal arm **104** may be extended and placed such that it is disposed on a first side of a defect. The proximal arm **110** may be placed on a second side of the defect substantially opposite the first side. In some embodiments, the grasping portion **108** of the distal arm **104** is at least partially inserted into tissue on the first side of the defect and the proximal arm **110** is at least partially inserted into tissue on the second side of the defect such that the distal and proximal arms **104**, **110** are each secured in the tissue. In some embodiments, the grasping portion **108** of the distal arm **104** and/or the proximal arm **110** include barbs, tines, or other projections configured to further secure the tissue to the grasping portion **108** of the distal arm **104** and/or the proximal arm **110**.

The drive element **204** may also be retracted, such as via the handle **202**, to retract the distal arm **104** toward the proximal arm **110**, the collar **120**, and/or the distal end of the catheter **212**. As shown in FIG. **2B**, the distal arm **104** may be retracted such that the tissue clipping assembly **102** is in a closed or clipping position in which the grasping portion **108** of the distal arm **104** substantially contacts or abuts the distal end of the proximal arm **110**, such as to clip tissue. The retraction of the distal arm **104** toward the proximal arm **110** may pull the secured tissue from the first side of the defect to the secured tissue on the second side of the defect, such as to close the defect. In some embodiments, the distal and/or proximal arms **104**, **110** may be locked in the closed position, as described below. In some embodiments, the distal and proximal arms **104**, **110** may be decoupled from the drive assembly **200** when the tissue clipping assembly **102** is in the closed position, such as to keep the defect closed. In other embodiments, a hemostatic closure device may be deployed around the clipped tissue to apply a circumferential force around the tissue to maintain the closure of the tissue.

Referring to FIGS. **3A-3C**, the distal arm **104** may have a variety of configurations, such as to increase the ability of the distal arm **104** to clip or otherwise grasp tissue. As shown in FIG. **3A**, the grasping portion **108** of the distal arm **104** may be radially elongated (e.g., extend farther downwardly). The grasping portion **108** of the distal arm **104** may have a length such that the grasping portion **108** extends below the catheter **212** and/or the proximal arm **110**. The distal arm **104** may comprise a flexible, superelastic, and/or shape memory material, such as stainless steel or Nitinol, such that the grasping portion **108** may be bent or flexed toward the extending portion **106** when the distal arm **104** is extended through the catheter **212** and such that the distal arm **104** may regain its shape when the grasping portion **108** is extended through the distal end of the catheter **212**.

As shown in FIG. **3B**, the extending portion **106** of the distal arm **104** may be bent or otherwise flexed upwardly. The upward extension of the extending portion **106** may provide additional space to grasp tissue, such as when the distal and proximal arms **104**, **110** are positioned on opposite sides of a defect. The distal arm **104** may comprise a flexible or shape memory material, such as Nitinol, such that the extending portion **106** may be bent or flexed downwardly when the distal arm **104** is extended through the catheter **212** and such that the extending portion **106** may regain its shape when the extending portion **106** is extended through the distal end of the catheter **212**.

As shown in FIG. **3C**, the grasping portion **108** of the distal arm **104** may be curved or bent proximally toward the proximal arm **110**. The orientation of the grasping portion **108** toward the proximal arm **110** may increase the ability of the distal arm **104** to grasp tissue, such as tissue on a first side of a defect, as described below. In some embodiments, the end of the grasping portion **108** may be pointed to increase the ability of the grasping portion **108** of the distal arm **104** to pierce and/or grasp tissue during the clipping operation.

While the distal arm **104** has been described as being retractable to clip tissue against the proximal arm **110**, it will be understood that the device **100** may have other configurations and assemblies. For example, as shown in FIGS. **4A** and **4B**, the distal end of the catheter **212** (FIG. **4A**) or the distal end of the collar **120** (FIG. **4B**) may be angled such that the bottom of the catheter **212** or the collar **120** protrudes distally. The catheter **212** or the collar **120** may be angled such that the bottom of the distal end extends about 3 cm from the top of the distal end.

The distal protrusion of the catheter **212** or the collar **120** may operate substantially similarly to the proximal arm **110** described in FIGS. **1-3B**. For example, the distal arm **104** may be extended, such as via the drive element **204**, and secured in tissue on a first side of a defect and the protrusion of the catheter **212** or collar **120** may be secured in tissue on the second side of the defect. The distal arm **104** may then be retracted, such as via the drive element **204**, toward the protrusion of the catheter **212** or collar **120** such that the secured tissue from the first side of the defect is brought toward the secured tissue on the second side of the defect, such as to close the defect. In embodiments where the distal end of the collar **120** is angled to secure tissue on one side of the defect, the distal arm **104** and the collar **120** may be secured together and decoupled from the drive assembly **200**, such as to keep the defect closed.

In some embodiments, the proximal arm **110** may be extendable and retractable similarly to the distal arm **104**. As shown in FIGS. **5**A and **5**B, the proximal end of the distal arm **104**, such as the proximal end of the extending portion **106**, is coupled with a first drive element **204***a* and the proximal end of the proximal arm **110** is coupled with a second drive element **204***b*. The proximal arm **110** may be linearly translated and rotated via the second drive element **204***b*, such as via a second control actuator **210** of the handle **202**, to position the proximal arm **110** and clip tissue. For example, the distal arm **104** may be translated and/or rotated to secure tissue on a first side of a defect and the proximal arm **110** may be translated and/or rotated to secure tissue on a second side of the defect. The distal arm **104** may then be retracted toward the catheter **212** and/or the proximal arm **110** may be extended from the catheter **212** to close the defect. In some embodiments, the distal arm **104** and the proximal arm **110** rotate together via the same drive element **204**. In other embodiments, the proximal arm **110** opens via extension of the distal arm **104**. In some embodiments, the distal arm **104** and the proximal arm **110** may be operated such that the distance between the distal end of the proximal arm **110** and the grasping portion **108** of the distal arm **104** is between about 0.5 cm and about 3 cm.

The proximal arm **110** of any of the other tissue clipping devices **100** may be actuatable by a drive element **204**. For example, the proximal arm **110** of FIGS. **1**-**3**B may be actuatable by a drive element **204**. In embodiments with two drive elements **204**, the catheter **212** may include two lumens with one drive element **204** disposed through each lumen. In embodiments with one drive element **204**, the catheter **212** may include a single lumen through which the tissue clipping assembly **102** is extended.

Referring to FIGS. **6**A-**6**D, the tissue clipping assembly **102** may be maneuvered, such as via the drive assembly **200**, to grasp tissue in two locations, such as on opposite sides of a defect, and clip the tissue together. The tissue clipping assembly **102** may be decoupled from the drive assembly **200** to maintain the closure of the tissue via the tissue clipping assembly **102**. The tissue clipping assembly **102** may be moved to a locked position before the tissue clipping assembly **102** is decoupled from the drive assembly **200**.

As shown in FIG. **6**A, the tissue clipping assembly **102** may be oriented substantially above target tissue, such as an identified defect. For example, the endoscope and/or the catheter **212** may be manipulated such that the tissue clipping assembly **102** is in the desired position substantially above the tissue. The grasping portion **108** of the distal arm **104** may be positioned near the distal end of the catheter **212**. The drive assembly **200** may include a coupler **214** which operably couples the distal end of the drive element **204** to the proximal end of the extending portion **106** of the distal arm **104**. The drive assembly **200** may also include a connector **216** which operably couples the distal end of the catheter **212** to the proximal end of the collar **120**. The connector **216** may be fixed to the distal end of the catheter **212** or may be included as a component of the catheter **212**.

As shown in FIG. **6**B, the distal arm **104** may be extended, such as via the drive element **204**, such that the grasping portion **108** of the distal arm **104** secures tissue at a first location, such as on a first side of the defect. The coupler **214** may be configured to transmit the translational and rotational movement of the drive element **204** to the distal arm **104** such that the distal arm **104** may be properly positioned. The proximal arm **110** may be maneuvered, such as via the catheter **212** and/or the endoscope such that the proximal arm **110** secures tissue at a second location, such as on a second side of the defect.

As shown in FIG. **6**C, the tissue clipping assembly **102** may appose the tissue from the two locations, such as to close the defect. The distal arm **104** may be retracted, such as via the drive element **204**, to the closed position such that the tissue from the first location is brought toward the tissue at the second location. The position and rotation of the distal arm **104** may be locked or otherwise maintained in the closed position such that the tissue remains clipped. For example, the collar **120** may provide a frictional, interference, or compressive force against the distal arm **104** which maintains the distal arm **104** in the closed position.

As shown in FIG. **6**D, the tissue clipping assembly **102** may be decoupled from the drive assembly **200**. The distal arm **104** may be decoupled from the drive element **204** and the collar **120** may be decoupled from the catheter **212**. The coupler **214** may decouple the drive element **204** from the distal arm **104** such that the drive element **204** and coupler **214** may be retracted from the distal arm **104**. The connector **216** may decouple the collar **120** from the catheter **212** such that the catheter **212** may be retracted from the collar **120**, as described below. The drive assembly **200** may be withdrawn from the body and the tissue clipping assembly **102** may remain in position to continue to clip the tissue. Optionally, the drive assembly **200** of the device **100** may be loaded with a second tissue clipping assembly **102** such that the second tissue clipping assembly **102** may be deployed to clip tissue at a different location, such as to close a larger defect.

Referring now to FIGS. **7**, a tissue clipping device **100** is shown according to one embodiment. The handle **202** includes the control actuator **210** which is operable to control the movement of the distal arm **104** via the drive element **204**. The distal arm **104** may be extended from and retracted into the collar **120**, such as to clip tissue against the proximal arm **110** of the tissue clipping assembly **102**. The collar **120** may be coupled with the distal end of the catheter **212**. In some embodiments, the collar **120** is releasably coupled with the catheter **212**, such as described below.

A user may grasp the handle **202** and manipulate the control actuator **210** to maneuver the distal arm **104** via the drive element **204**. The distal arm **104** may be extended from the collar **120** across target tissue. The proximal arm **110** may be positioned to grasp tissue at a first side of the target tissue and the distal arm **104** may be positioned to grasp tissue at a second side of the tissue, such as opposite the first side. The distal arm **104** may be retracted to the closed position to clip tissue between the distal arm **104** and the proximal arm **110**. In some embodiments, the distal arm **104** may be retracted to recruit tissue into the collar **120** when the tissue clipping assembly **102** clips tissue. In some embodiments, the collar **120** may be decoupled from the catheter **212** such that the tissue clipping assembly **102** continues to clip the tissue after the drive assembly **200** is withdrawn from the body.

In the illustrated embodiment, the handle **202** includes one control actuator **210** coupled to the distal arm **104** via the drive element **204**. However, it will be understood that the device **100** may have other configurations and assemblies. For example, the handle **202** may include a second control actuator **210** coupled to a second drive element **204** to operable control the position of the proximal arm **110**.

The proximal arm **110** and/or the distal arm **104** may be sized, shaped, and configured to more securely grasp tissue, such as to better grasp tissue as the tissue clipping assembly **102** is moved to the closed position and/or to more securely retain the distal and proximal arms **104**, **110** in the tissue when the tissue clipping assembly **102** clips tissue, such as when then tissue clipping assembly **102** clips sides of a defect together.

In some embodiments, as shown in FIGS. **8**A and **8**B, the distal arm **104** is configured to increase the grasp and securement of the distal arm **104** on tissue. The grasping portion **108** of the distal arm **104** includes one or more distal tines **112** configured to increase the grasp of the distal arm **104** on target tissue. The distal tines **112** may extend substantially proximally toward the proximal arm **110**, such as to grasp and recruit tissue as the distal arm **104** is proximally retracted during the tissue clipping operation. Each distal tine **112** may include a tip **114** at the proximal end that is operable to pierce tissue. The tip **114** may be sized, shaped, and configured to drive the distal tine **112** into tissue. The distal tine(s) **112** may be integral with the distal arm **104** or may be an additional component attached to the distal arm **104**. In some embodiments, the distal tines **112** comprise stainless steel, Nitinol, ceramic, polymer, or other suitable composite material, or any combination thereof. In some embodiments, the grasping portion **108** of the distal arm **104** has a length between about 1 mm and about 7 mm, such as between about 3 mm and about 6 mm, such as about 5 mm.

In some embodiments, at least a portion of the distal arm **104**, such as the distal tine(s) **112**, is flexible such that the distal arm **104** may flex when the distal arm **104** is maneuvered to grasp tissue. The distal arm **104** may be flexible such to allow the distal tine(s) **112** to be placed against tissue during the tissue clipping operation. For example, the distal arm **104** may be flexible such that the distal tines **112** may be oriented downwardly toward the target tissue, such as at an angle, such that the distal arm **104** may grasp tissue at the second side of the target tissue. The distal arm **104** may also be stiff enough such that the distal arm **104** may retain the grasped tissue, such as during the tissue clipping operation, and to clip tissue against the proximal arm **110**.

In some embodiments, the distal end of the one or more distal tines **112** may be sized, shaped, or configured to reduce trauma to tissue as the distal arm **104** is extended from the catheter **212** and/or to prevent damage to the catheter **212** and/or the endoscope, such as when extending the tissue clipping assembly **102** through the catheter **212** and/or endoscope. For example, the distal end of the distal tines **112** may each include a rounded portion **116** configured to deflect tissue and reduce damage to the catheter **212** and/or the endoscope when the tissue clipping assembly **102** is extended through the catheter **212** and/or the endoscope. In some embodiments, the rounded portions **116** of the distal tines **112** also extend beneath the tip **114**, such as to lift the distal tines **112** in relation to the surface of the tissue when the distal arm **104** is retracted from the clipped tissue. The rounded portions **116** may also shroud the proximal arm **110** when the distal arm **104** is disposed near the proximal arm **110** such as to protect the proximal arm **110** when the tissue clipping assembly **102** is extended through the catheter **212** and/or endoscope and to protect users from the proximal arm **110** during handling. The rounded portions **116** may be configured such that the tissue clipping assembly **102** is atraumatic when the distal arm **104** is disposed near the proximal arm **110**, such as when the tissue clipping assembly **102** is in the closed position, such as to protect the operator, the endoscope, the catheter **212**, and/or the patient.

The distal tines **112** may also include one or more bends **118** along a length of the distal tine **112**. The bends **118** may be configured such that the tip **114** of the distal tine **112** is inserted into tissue when the distal arm **104** is retracted during the tissue clipping operation. The bends **118** may also be configured such that the tip **114** and the distal tine **112** are driven away from live tissue as the distal arm **104** is proximally retracted during the tissue clipping operation. The bends **118** may further be sized, shaped, and configured to increase the flexibility of the distal arm **104** as the distal arm **104** grasps tissue and to strengthen the distal arm **104** when the distal arm **104** grasps and recruits tissue. For example, the bends **118** may be configured and arranged to prevent the distal tine **112** from pivoting radially outwardly about the rounded portion **116** during the tissue clipping operation. The bends **118** and/or the tip **114** of the distal tine **112** may also be sized, shaped, and configured to guide the distal tines **112** into tissue. For example, one or more sides of the distal tine **112** (e.g., top and/or bottom) may be chamfered or tapered toward the tip **114** such that the distal tine **112** is guided into tissue when the tip **114** is inserted into tissue and the distal arm **104** is proximally retracted (see FIG. **19**D).

In the illustrated embodiment, the distal arm **104** is substantially linear. However, it will be understood that the distal arm **104** may have other suitable shapes and configurations. For example, the grasping portion **108** may include one or more radial bends **118** (e.g., left and right), such as to increase the ability of the distal arm **104** to be inserted into tissue and/or to increase the ability of the distal arm **104** to grasp tissue during the tissue clipping operation. Further, the distal arm **104** may include a hypotube with shorter tines on either side of the distal tine **112**.

In some embodiments, the distal tines **112** are further configured to better grasp tissue. For example, one or more distal tines **112** may include one or more barbs **119**. The barbs **119** may extend substantially laterally from one or both sides of the respective distal tine **112**. The barbs **119** may be arranged and configured to assist with securing the distal tine(s) **112**, such as within tissue during the clipping procedure. The barbs **119** may be sized, shaped, and configured to be inserted into tissue and to sufficiently prevent the distal tine **112** from being retracted from the tissue, such as after the tissue clipping assembly **102** has been deployed in the closed position.

In the illustrated embodiment, the barbs **119** extend from the top of the distal tine **112**. However, it will be understood that the distal arm **104** may have other configurations and assemblies. For example, the distal arm **104** may also include barbs **119** extending downwardly from the distal tine(s) **112** and/or the distal arm **104** may include barbs **119** extending from one or more sides of the distal tine(s) **112**.

The distal arm **104** may include more than one distal tine **112** to grasp and recruit tissue during the tissue clipping operation. As shown in FIGS. **9**A-**9**C, the distal arm **104** includes two distal tines **112**, each having a tip **114**. The distal tines **112** may have other shapes, sizes, and configurations than the distal tine **112** of FIGS. **8**A and **8**B, such as based upon the location of the target tissue to be clipped. For example, the distal tines **112** may be oriented substantially downwardly (FIG. **9**A). The distal tines **112** may also be rounded and shorter such that the grasping portion **108** of the distal arm **104** forms a semi-circle (FIG. **9**B).

The distal tines **112** may also include rounded portions **116** extending distally and downwardly from the remainder of the distal tine **112** (FIG. **9**C) to reduce trauma to the tissue when the distal arm **104** is extended from the collar **120** and/or prevent damage to the catheter **212** and/or the endoscope such as when extending the tissue clipping assembly **102** through the catheter **212** and/or endoscope. The rounded portions **116** may also extend beneath the remainder of the distal tines **112**, such as to lift the distal tines **112** in relation to the surface of the tissue when the distal arm **104** is retracted to clip tissue. The rounded portion(s) **116** may also shroud the proximal arm **110** when the distal arm **104** is disposed near the proximal arm **110** such as to protect the proximal arm **110** when the tissue clipping assembly **102** is extended through the catheter **212** and/or endoscope and to protect users from the proximal arm **110** during handling. The rounded portions **116** may be configured such that the tissue clipping assembly **102** is atraumatic when the distal arm **104** is disposed near the proximal arm **110**, such as when the tissue clipping assembly **102** is in the closed position, such as to protect the operator, the endoscope, the catheter **212**, and/or the patient. Further, the distal arm **104** may include more than two distal tines **112**.

The distal tines **112** may be separated by a distal gap **122**. The distal gap(s) **122** may separate the distal tines **112** such that each distal tine **112** may separately grasp tissue. The distal gap(s) **122** may also be sized, shaped, and configure to receive a portion of the proximal arm **110** when the tissue clipping assembly **102** is in the closed position such that the distal arm **104** and proximal arm **110** overlap in the closed position. For example, the tissue clipping assembly **102** may be maneuvered, such as via the drive assembly **200**, to grasp tissue on opposite sides of target tissue with the distal and proximal arms **104**, **110** and the proximal arm **110** may extend distally into the distal gap **122** when then tissue clipping assembly **102** is moved to the closed position.

In some embodiments, as shown in FIGS. **10**A and **10**B, the proximal arm **110** includes one or more proximal tines **124** configured to increase the grasp of the proximal arm **110** on target tissue, such as on the first side of target tissue. The proximal tines **124** may be attached to or integrally formed with the proximal arm **110**. The proximal tines **124** may extend distally from the collar **120** and may be operable to further increase the grasp of the proximal arm **110** on tissue. In embodiments in which the proximal arm **110** is integral with the collar **120**, the proximal tines **124** may be integral with the collar **120**. In some embodiments, the proximal tines **124** comprise stainless steel, Nitinol, ceramic, polymer, or composite material, or any combination thereof.

The proximal tines **124** may each include a tip **126** at a distal end of the proximal tine **124** that is operable to pierce tissue. The tips **126** of the proximal tines **124** may be inserted into tissue at a first side of target tissue to grasp tissue during the tissue clipping operation. In some embodiments, the proximal tines **124** may be substantially arcuate. For example, the proximal tines **124** may extend from the distal end of the collar **120** such that the upper surfaces of the proximal tines **124** substantially correspond to the shape of the inner surface of the collar **120**.

In some embodiments, the proximal tines **124** are further configured to better grasp tissue. The more proximal tines **124** may also include one or more barbs **119**. The barbs **119** may extend substantially laterally from one or more sides of the respective proximal tine **124** The barbs **119** may be arranged and configured to assist with securing the proximal tine(s) **124**, such as within tissue during the clipping procedure. For example, the barbs **119** may be arranged and configured to be inserted into tissue and to prevent or otherwise restrict the proximal arm **110** from being retracted from the tissue.

In the illustrated embodiment, the proximal arm **110** includes two proximal tines **124**. However, it will be understood that the proximal arm **110** may have other configurations and assemblies. For example, the proximal arm **110** may include one or three or more proximal tines **124**.

In some embodiments, the proximal tines **124** of the proximal arm **110** define one or more proximal gaps **128** between the proximal tines **124**. The proximal gaps **128** may increase the ability of the proximal arm **110** to grasp tissue. For example, the proximal gaps **128** between the proximal tines **124** may allow each proximal tine **124** to separately grasp tissue. The proximal gaps **128** may also be sized, shaped, and configure to receive a portion of the distal arm **104**, such as the distal tines **112**, when the tissue clipping assembly **102** is in the closed position. For example, the tissue clipping assembly **102** may be maneuvered, such as via the drive assembly **200**, to grasp tissue on opposite sides of target tissue with the distal and proximal arms **104**, **110** and the distal tines **112** may extend into the proximal gaps **128** when then tissue clipping assembly **102** is moved to the closed position. In some embodiments, the proximal tines **124** are shaped and configured such that the proximal gaps **128** are narrower near the distal end of the proximal arm **110** to increase the ability of the proximal arm **110** to be inserted into tissue, such as to allow the proximal tines **124** to be inserted into tissue substantially simultaneously. The distal tines **112** may also be configured such that the distal gaps **122** are narrower near the proximal end of distal arm **104** to increase the ability of the distal arm **104** to be inserted into tissue, such as to allow the distal tines **112** to be inserted into tissue substantially simultaneously. In other embodiments, the proximal gaps **128** are wider near the distal end of the proximal arm **110** and/or the distal gaps **122** are wider near the proximal end of the distal arm **104**, such as to allow each proximal tine **124** and/or distal tine **112** to separately grasp tissue.

While the proximal gaps **128** have been described as being formed between the proximal tines **124**, it will be understood that the proximal arm **110** may include additional proximal gaps **128** and/or the proximal gaps **128** may be formed in other manners. For example, the proximal arm **110** may include one or more proximal gaps **128** extending along the proximal arm **110**, such as within the proximal tines **124**. Further, the collar **120** may also be configured to include one or more proximal gaps **128** such as extending into the collar **120**.

In some embodiments, at least a portion of the proximal arm **110**, such as portions of the proximal tines **124**, may be flexible such that the proximal arm **110** may flex when the proximal arm **110** is maneuvered to grasp tissue. The proximal arm **110** may be flexible such to allow the proximal tine(s) **124** to be placed against tissue during the tissue clipping operation. For example, the proximal arm **110** may be flexible such that the proximal tines **124** may be oriented downwardly toward the target tissue, such as at an angle, such that the proximal arm **110** may grasp tissue at the first side of the target tissue and such that the distal arm **104** may be maneuvered to grasp tissue at the second side of the target tissue. The proximal arm **110** may also be stiff enough such that the proximal arm **110** may retain the grasped tissue, such as during the tissue clipping operation, and clip tissue against the distal arm **104**.

Referring now to FIGS. **11**A-**13**, the tissue clipping device **100** is configured such that the collar **120** is operable to lock the position of the distal arm **104** when the distal arm **104** is fully retracted toward the catheter **212**, such as when the distal arm **104** is moved to the closed position. The collar **120** may maintain the position of the distal arm **104** when the distal arm **104** is in the locked position, such as to allow the distal arm **104** to continue to clip tissue against the proximal arm **110**. In some embodiments, after the position of the distal arm **104** has been retracted to the locked position and secured relative to the collar **120**, the distal arm **104** may be decoupled from the drive element **204**. In some embodiments, the force required to lock the distal arm **104** with the collar **120** is between about 0.1 pounds and about 6 pounds, such as between about 2 pounds and about 4 pounds. In some embodiments, the force required to lock the distal arm **104** with the collar is about 2 pounds or greater, such as to prevent unintentional locking of the distal arm **104**.

In some embodiments, as shown in FIGS. **11A-13**, the extending portion **106** of the distal arm **104** includes one or more locking projections **130** extending outwardly from the outer surface of the extending portion **106**. The locking projection **130** may be sized, shaped, and configured to couple the distal arm **104** with the collar **120** when the distal arm **104** is moved to the locked position, such as when the tissue clipping assembly **102** is moved to the closed position. The locking projection **130** may be positioned and configured, such as being spaced apart from the distal end of the distal arm **104** and/or extending to a distance from the outer surface of the distal arm **104**, such as to prevent scratching or otherwise injuring tissue during the tissue clipping operation. In some embodiments, the locking projection **130** is initially bent radially inwardly to avoid damage to tissue when the distal arm **104** is extended and the locking projection **130** extends radially outwardly when the distal arm **104** is in the locked position in the collar **120**.

The collar **120** includes or defines one or more receiving portions **136** configured to operably receive the locking projection **130** of the distal arm **104** when the distal arm **104** is moved to the locked position. The receiving portion(s) **136** may be disposed along a length of the collar **120** corresponding to the position of the locking projection **130** when the distal arm **104** is moved to the closed position. When the distal arm **104** is moved to the locked position, the locking projection **130** may extend into receiving portion **136** of the collar **120** to maintain the position of the distal arm **104** relative to the collar **120**. The receiving portion **136** and the locking projection **130** may be sized, shaped, and configured such that the locking projection **130** is prevented from withdrawing from the receiving portion **136**, such as to maintain the distal arm **104** in the closed position after the tissue clipping assembly **102** is decoupled from the drive assembly **200**. The locking projection **130** may remain in the receiving portion **136** of the collar **120** after the tissue clipping assembly **102** is deployed from the drive assembly **200**, such as to keep the tissue clipping assembly **102** in the closed position to clip tissue.

In some embodiments, the locking projection **130** includes a ramp portion **132** at a proximal end and a shoulder portion **134** at a distal end. The ramp portion **132** may be configured to permit the locking projection **130** to be moved into the receiving portion **136** of the collar **120**. For example, the ramp portion **132** may be angled or sloped such that the locking projection **130** may slide beneath the inner surface of the collar **120** as the distal arm **104** is retracted into the collar **120** to position the locking projection **130** in the receiving portion **136**. The shoulder portion **134** may be configured to retain the locking projection **130** in the receiving portion **136** of the collar **120** such that the distal arm **104** is prevented from moving distally relative to the collar **120** (e.g., to lock the distal arm **104** with the collar **120** prior to releasing the tissue clipping assembly **102**). For example, the shoulder portion **134** may abut a side of the receiving portion **136** to prevent the locking projection **130** from retracting from the receiving portion **136**.

In some embodiments, the collar **120** includes one or more locking tabs **138** extending into the receiving portion **136** to retain the locking projection **130** in the receiving portion **136** of the collar **120**. The locking tabs **138** may be flexed or bent radially inwardly to retain the locking projection **130** in the receiving portion **136**. In the illustrated embodiment, the collar **120** includes one locking tab **138** extending proximally into the receiving portion **136**. However, it will be understood that the collar **120** may have other configurations and assemblies. For example, the collar **120** may include two or more locking tabs **138**, and the locking tabs **138** may extend proximally, distally, or laterally into the receiving portion **136**.

In some embodiments, as shown in FIGS. **12A-12C**, the collar **120** may include one or more guiding slots **140** extending from the distal end of the collar **120**. The guiding slots **140** may be operable to align the distal arm **104** as the distal arm **104** is retracted into the collar **120**, such as when the distal arm **104** is retracted into the locked position. In some embodiments, the guiding slots **140** extend distally into receiving portions **136** (not shown). In some embodiments, the guiding slots **140** operate as the receiving portions **136** and lock the distal arm **104** in the closed position. In some embodiments, the guiding slot is separate from the receiving portion **136** and aligns other locking projections **130** with the receiving portion(s) **136** of the collar **120**.

During the tissue clipping operation, one of the locking projections **130** of the distal arm **104** may be received in the guiding slot **140** of the collar **120** when the distal arm **104** is retracted. One of the locking projections **130** or another portion of the distal arm **104** may extend into the guiding slot **140** of the collar **120**, such as when the distal arm **104** is oriented in the desired position. In some embodiments, the distal ends of the guiding slot **140** are flared or rounded such as to guide the locking projection **130** into the guiding slot **140** and orient the distal arm **104** into the desired position as the distal arm **104** is proximally retracted. The disposition of the locking projection **130** in the guiding slot **140** may also orient the distal arm **104** during the tissue clipping operation, such as to prevent the distal arm **104** from unintentionally rotating during operation.

In some embodiments, the guiding slot **140** may be configured to guide one of locking projections **130** into the receiving portion **136** of the collar **120** to couple the distal arm **104** with the collar **120**. For example, the receiving portion **136** may be connected with the proximal end of the guiding slot or the guiding slot **140** may orient the distal arm **104** during retraction such that one of the other locking projections **130** extends into the receiving portion **136**. In other embodiments, the guiding slot **140** may be configured to retain the locking projections **130** to maintain the distal arm **104** in the locked position. For example, the proximal portion of the guiding slot **140** may be narrower to provide a compression fit on the locking projection **130** to maintain the distal arm **104** in the locked position.

In some embodiments, as shown in FIG. **13**, the collar **120** may include setting recesses **141** at the distal end of the collar **120** and in line with the receiving portions **136**. Each setting recess **141** may be configured to allow the tissue clipping assembly **102** to be moved near the closed position and to allow the operator to observe the clipping of the tissue with the tissue clipping assembly **102** before the distal arm **104** is locked with the collar **120**. The setting recesses **141** may be a distally opening channel or groove in the distal end of the collar **120**. The collar **120** may narrower between the setting recesses **141** and the receiving portions **136**, such as to prevent accidental locking of the distal arm **104** and to maintain the distal arm **104** in the locked position when one of the locking projections **130** are disposed in the receiving portions **136**. In some embodiments, the device **100** may be extended through the catheter **212** and/or the endoscope with the locking projection(s) **130** disposed in the setting recess (es) **141**.

During operation, the distal arm **104** may be retracted, such as via the drive element **204**, such that the locking projection **130** of the distal arm **104** is disposed in the setting recess **141**. The operator may observe the clipping of the tissue with the tissue clipping assembly **102** to determine if the tissue clipping assembly **102** is properly clipping tissue. The operator may regrasp tissue with the distal and proximal arms **104**, **110** if it is determined that the tissue clipping assembly **102** is not properly grasping tissue. Alternatively, the distal arm **104** may be retracted, such as via the drive element **204** to move the locking projection **130** of the distal arm **104** into the receiving portion **136** if it is determined that the tissue clipping assembly **102** is properly grasping tissue. The distal arm **104** may remained locked with the collar **120** when the locking projection(s) **130** are moved from the setting recess(es) **141** to the receiving portion(s) **136** of the collar **120**.

In the illustrated embodiment, the collar **120** includes setting recesses **141** and receiving portions **136** on both sides of the collar **120** and a guiding slot **140** at the top of the collar **120**. The collar **120** also includes a stress relief **142** on one side of each setting recess **141** and receiving portion **136** pair. The stress relief **142** may permit the collar **120** to flex, bend, or compress such that the locking projection **130** may be moved from the setting recess **141** to the receiving portion **136**. The collar **120** may regain its shape after the locking projection **130** is disposed in the receiving portion **136** to maintain the distal arm **104** in the locked position. The stress reliefs **142** may be grooves or cut outs which permit the collar **120** to flex, bend, or compress. Further, it will be understood that any of the features of the collar **120** of FIG. **13** may be incorporated into any of the collars **120** described herein.

Referring now to FIGS. **14A-18**, the one or more drive elements **204** may be operably coupled with the tissue clipping assembly **102**, such as the distal arm **104**, in a variety of manners such that the drive elements **204** may be decoupled from the tissue clipping assembly **102**, such as after the tissue clipping assembly **102** clips tissue. In some embodiments, the drive element **204** is operably coupled directly to the proximal end of the distal arm **104**. In other embodiments, the drive element **204** is operably coupled to the proximal end of the distal arm **104** via one or more couplers **214**. The one or more couplers **214** may be fixed to the distal end of the drive element **204** via welding, crimping, swaging, soldering, adhesives, fasteners, or the like. The coupler **214** may also be integral with the drive element **204**.

In some embodiments, the drive element **204** may be decoupled from the distal arm **104** by proximally retracting the drive element **204** with sufficient force, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions. In some embodiments, the proximal force applied to the drive element **204**, such as a force applied by the operator via the handle **202**, to decouple the drive element **204** from the distal arm **104** is between about 10 pounds and about 25 pounds such that the force applied to the coupling between the drive element **204** and the distal arm **104** is between about 5 pounds and about 10 pounds.

In some embodiments, the distal end of the drive element **204** is sized, shaped, and configured to operably couple with the distal arm **104** during operation of the distal arm **104** and to operably decouple from the distal arm **104** after the tissue clipping assembly **102** has been moved to the closed position. As shown in FIGS. **14A-14D**, the distal end of the drive element **204** includes two prongs **222** extending distally from the remainder of the drive element **204**. The prongs **222** may be shaped and configured to define a coupling area **224** between the prongs **222**. The prongs **222** may be closer together at the distal end such that the distal opening to the coupling area **224** is narrower than the proximal portion of the coupling area **224**.

The distal arm **104**, such as the extending portion **106**, includes one or more coupling projections **144** configured to be operably received in the coupling area **224** defined by the prongs **222** of the drive element **204**. The coupling projection **144** may extend from the extending portion **106** of the distal arm **104** in a manner to increase the recruitment of tissue, such as during the clipping operation, by increasing the space beneath the grasping portion **108** of the distal arm **104** in which tissue may be grasped. For example, the coupling projection **144** may extend a distance below the extending portion **106** to increase the space beneath and/or proximal to the distal tines **112** such that the distal tines **112** may grasp tissue.

The coupling projection(s) **144** and the prongs **222** may be sized, shaped, and configured such that the coupling projection **144** may be operably received in the coupling area **224** defined between the prongs **222** during operation and operably released from the coupling area **224**, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions. The coupling projection **144** may be inserted through the distal opening between the prongs **222** and be disposed in the coupling area **224** defined by the prongs **222**. The distal ends of the prongs **222** may extend around a distal portion of the coupling projection **144** to operably retain the coupling projection **144** in the coupling area **224**. In some embodiments, the prongs **222** snap fit around the coupling projection **144** to retain the coupling projection **144** in the coupling area **224**. When the coupling projection **144** is disposed in the coupling area **224** and the prongs **222** extend distally around the coupling projection **144**, the coupling projection **144** may be retained in the coupling area **224** and the distal arm **104** may be coupled with the drive element **204** such that linear and/or rotational movement of the drive element **204** is transferred to the distal arm **104**. The prongs **222** may be sized, shaped, and configured to retain the coupling projection **144** in the coupling area **224** and maintain the coupling of the drive element **204** and the distal arm **104** during the tissue clipping operation. In some embodiments, the prongs **222** are configured to bias radially inwardly around the coupling projection **144** such that the prongs **222** retain the coupling projection **144** in the coupling area **224** during operation.

The coupling projection **144** may also be withdrawn from the coupling area **224** to decouple the distal arm **104** from the drive element **204**, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions. The drive element **204** may be proximally retracted, such as via the handle **202**, with sufficient force such that the prongs **222** are proximally retracted from the coupling projection **144** and the coupling projection **144** is pulled out of the coupling area **224** and through the distal opening between the prongs **222**. The prongs **222** may flex or bend radially outwardly, such as by contacting wider proximal portions of the coupling projection **144**, as the drive element **204** is retracted such that the prongs **222** release the coupling projection **144** from the coupling area **224**. The force required to pull the tissue clipping assembly **102** out of the coupling area **224** defined by the prongs **222** may be greater than the force required to recruit tissue with the distal arm **104** such that the distal arm **104** is not prematurely decoupled from the drive element **204**. After the prongs **222** are retracted proximally from the coupling projection **144**, the distal arm **104** may be decoupled from the drive element **204** and the drive element **204** may be withdrawn from the distal arm **104**, such as with the tissue clipping assembly **102** in the closed and locked positions and clipping tissue.

In some embodiments, the coupling projection **144** includes a shoulder **146** extending outwardly from the remainder of the coupling projection **144**. The shoulder **146** of the coupling projection **144** may be spaced apart from the remainder of the distal arm **104** and sized, shaped, and configured to receive the drive element **204** between the shoulder **146** and the outer surface of the distal arm **104** from which the coupling projection **144** extends. The shoulder **146** may abut the top or bottom of the drive element **204**, such as the top and bottom of the prongs **222**, such that the distal end of the drive element **204** is substantially prevented from sliding off the top or bottom of the coupling projection **144**. For example, in the illustrated embodiment, the shoulder **146** is disposed at the bottom of the coupling projection **144** such that the prongs **222** may be disposed around the remainder of the coupling projection **144** and such that the shoulder **146** abuts the bottom of the drive element **204**, thereby preventing the prongs **222** from slipping off the bottom of the coupling projection **144**.

In the illustrated embodiment, the coupling projection **144** is oriented substantially downwardly from the extending portion **106** and is substantially triangular and pointed distally with the proximal end being wider than the proximal end. The narrower distal end of the coupling projection **144** may permit the coupling projection **144** to be withdrawn from the coupling area **224** defined by the prongs **222** of the drive element **204**, such as after the tissue clipping assembly **102** has clipped tissue, to decouple the distal arm **104** from the drive element **204**. For example, the narrower distal end of the coupling projection **144** may be angled such that the prongs **222** radially separate as the drive element **204** is retracted relative to the coupling projection **144**. However, it will be understood that the coupling projection **144** may have other shapes and configurations. For example, the coupling projection **144** may have a circular, elliptical, ovular, rectangular, or other suitable shape and the coupling projection **144** may be oriented substantially upwardly from the extending portion **106**.

While the prongs **222** have been described as forming a part of the distal end of the drive element **204**, it will be understood that the drive assembly **200** may have other assemblies and configurations. For example, the prongs **222** may be formed on a coupler **214** that is fixed to the distal end of the drive element **204** such that the distal end of the drive element **204** may be releasably coupled with the distal arm **104** via the coupler **214**.

In some embodiments, as shown in FIGS. **15**A and **15**B, the proximal end of the distal arm **104**, such as the proximal end of the extending portion **106**, includes one or more tabs **148** configured to operably couple the distal arm **104** with the drive element **204**. The tabs **148** extend from the proximal end of the distal arm **104** and are flexible or pivotable to operably couple the distal arm **104** with the drive element **204**. The drive element **204** may include or be coupled with a coupler **214**. The coupler **214** may be sized, shaped, and configured to be operably retained by the tabs **148** of the distal arm **104** to couple the distal arm **104** with the drive element **204**.

In the illustrated embodiment, the coupler **214** has a substantially spherical coupling portion at a distal end configured to couple with the tabs **148** of the distal arm **104**. In some embodiments, the coupler **214** is welded to the distal end of the drive element **204**. In some embodiments, the coupler **214** includes a neck portion fixed to the distal end of the drive element **204** such that the drive element **204** may control the position and/or rotation of the distal arm **104**. In some embodiments, the coupler **214** is rectangular, helical, obround, asymmetric, or otherwise shaped to provide translational and/or rotational force to the distal arm **104** when coupled between the drive element **204** and the distal arm **104**.

The tabs **148** of the distal arm **104** may be configured to flex or bend around the coupler **214**, such as the spherical coupling portion of the coupler **214**, to couple the drive element **204** with the distal arm **104**. The bent tabs **148** may prevent or otherwise restrict the coupler **214** from being retracted from distal arm **104** during the tissue clipping operation. For example, the tabs **148** may be sized and shaped to substantially cover a proximal side of the coupler **214**. Additionally, the tabs **148** may remain disposed around the coupler **214** during operation such that linear and/or rotational motion of the drive element **204** may be transferred to the distal arm **104**.

The tabs **148** may be flexed outwardly to decouple the drive element **204** from the distal arm **104**, such as after the tissue clipping assembly **102** has been moved to the closed position. The drive element **204** may be retracted proximally with sufficient force, such as via the handle **202**, to disengage the tabs **148** from retaining the coupler **214** to the distal arm **104**. The drive element **204** may be retracted with a force sufficient to retract the coupler **214** such that the tabs **148** bend radially outwardly and no longer surround the coupling portion of the coupler **214**. The force required to release the tabs **148** may be greater than the force required to recruit tissue with the distal arm **104**. After tabs **148** have bent radially outwardly, the drive element **204** and the coupler **214** may be retracted proximally from the distal arm **104**, such as with the tissue clipping assembly **102** clipping tissue.

Additionally or alternatively, the distal end of the drive element **204** may include one or more detents extending radially into the outer surface of the drive element **204** which are each configured to receive a tab **148** extending from the proximal end of the extending portion **106** of the distal arm **104**. The tabs **148** of the distal arm **104** may be pivoted or flexed such that the tabs extend into the detents to operably couple the drive element **204** with the distal arm **104**. The tabs **148** may be disengaged by proximally retracting the drive element **204** relative to the distal arm **104** to bend the tabs **148** out of the detents, thereby decoupling the drive element **204** from the distal arm **104**.

In some embodiments, the proximal end of the distal arm **104** may include a bore or recess configured to receive the coupler **214**, such as the spherical coupler. The coupler **214** may be inserted into the bore of the distal arm **104** and the distal arm **104** may be connected the coupler **214**, such as by crimping, swaging, or welding the distal arm **104** around the coupler **214** to couple the drive element **204** and the distal arm **104**. The drive element **204** may be decoupled from the distal arm **104** by retracting the drive element **204** relative to the distal arm **104** to break or otherwise disrupt the one or more connections, such as the crimp, such that the coupler **214** may be retracted from the distal arm **104**.

In some embodiments, the distal arm **104** may be coupled with the drive element **204** by a frangible coupling. The distal arm **104** may be coupled with the drive element **204** until a sufficient proximal force is applied to the drive element **204**, such as via the handle **202**, to break or otherwise disrupt the coupling between the drive element **204** and the distal arm **104**, such as after the tissue clipping assembly **102** has been moved to the closed position to clip tissue.

As shown in FIGS. **16**A and **16**B, the coupler **214** may be substantially cylindrical with a first portion **214***a* fixed around the distal end of the drive element **204** and a second portion **214***b* fixed around the proximal portion of the distal arm **104**, such as fixed around the proximal portion of the extending portion **106** of the distal arm **104**. The coupler **214** includes a channel **218** extending into the coupler **214**, such as with a first channel portion **218***a* extending proximally into the first portion **214***a* from a distal end of the first portion **214***a* and a second channel portion **218***b* extending distally into the second portion **214***b* from a proximal end of the second portion **214***b*. A coupling link **220** extends into and is secured in the channel **218**, such as with a proximal portion of the coupling link **220** secured in the first channel portion **218***a* and a distal portion of the coupling link **220** secured in the second channel portion **218***b*. When secured, the coupling link **220** may operably couple the drive element **204** with the distal arm **104**. In some embodiments, the coupling link **220** is laser welded into the first and second channel portions **218***a*, **218***b* of the channel **218**.

The coupling link **220** may be sized, shaped, and configured such that translation and/or rotation of the drive element **204** is transmitted to the distal arm **104** when the coupling link **220** couples the drive element **204** and the distal arm **104**. The coupling link **220** may also be sized, shaped, and configured such that it breaks when subjected to a desired tensile load, such as the force applied to the coupling link **220** when the tissue clipping assembly **102** is in the closed position and the drive element **204** is proximally retracted. When the coupling link **220** is broken, the distal arm **104** may be decoupled from the drive element **204** such that the drive element **204** may be retracted from the distal arm **104**. In some embodiments, the coupling link **220** comprises stainless steel or Nitinol, or combinations thereof.

While the coupler **214** of FIGS. **16**A and **16**B has been described as including a first portion **214***a* disposed around the drive element **204**, a second portion **214***b* disposed around the distal arm **104**, and a channel **218**, it will be understood that the coupler **214** may have other configurations and assemblies. For example, the coupler **214** may form the coupling link **220** by directly coupling the distal end of the drive element **204** with the proximal end of the distal arm **104**. The coupling link **220** may be operable to transmit the movement and/or rotation of the drive element **204** to the distal arm **104** when the coupling link **220** couples the drive element **204** and the distal arm **104**. The coupling link **220** may also be configured to break and thereby decouple the drive element **204** from the distal arm **104** when the coupling link **220** is subjected to a desired tensile load, as described above. Additionally or alternatively, a portion of the distal arm **104** and/or a portion of the drive element **204** may be frangible such that the drive element **204** may be coupled with the distal arm **104** during operation and broken under a predetermined load to decouple the distal arm **104** from the drive element **204**.

As shown in FIGS. **17**A-**17**C, the drive assembly **200** may include a coupler **214** that is substantially tubular and disposed around the distal end of the drive element **204**. The coupler **214** may be a hypotube. The coupler **214** may be disposed around the distal end of the drive element **204** such that a portion of the coupler **214** extends distally beyond the distal end of the drive element **204** (FIG. **17**A). The coupler **214** may be fixed to the drive element **204** via a swage, such as a swaging the inner surface of the coupler **214** to the drive element **204**. The coupler **214** may also be crimped or welded to the drive element **204**. The proximal end of the distal arm **104**, such as the proximal end of the extending portion **106**, may be inserted into distal end of the coupler **214** and the coupler **214** may be operably secured with the distal arm **104**. The distal end of the coupler **214** may be connected, such as via crimping, distally to the proximal end of distal arm **104** (FIG. **17**B) such that distal arm **104** is coupled with the drive element **204** via the coupler **214**, such as to maneuver the distal arm **104** to grasp tissue.

The coupler **214** may operably decouple the distal arm **104** from the drive element **204**, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions to clip tissue. The drive element **204** may be retracted proximally with sufficient force to break or otherwise disrupt the connection, such as the crimp, between the coupler **214** and the distal arm **104**. When the connection (e.g., the crimp) of the coupler **214** to the distal arm **104** is broken or disrupted, the distal arm **104** may be decoupled from the drive element **204** (FIG. **17**C). The force required to break or disrupt the connection may be less than the force required to pull the tissue clipping assembly **102** from the tissue. After connection has been broken, the drive element **204** and the coupler **214** may be retracted from the distal arm **104**, such as with the tissue clipping assembly **102** clipping tissue. While the coupler **214** has been described as being connected to the distal arm **104** via a crimp, it will be understood that the coupler **214** may be connected to the distal arm **104** in other manners, such as via swaging, soldering, and welding.

Further, it will be understood that the proximal end of the distal arm **104** may be further coupled with the distal end of the drive element **204** within the coupler **214**. For example, the proximal end of the distal arm **104**, such as the proximal end of the extending portion **106**, may be configured to operably interlock with the distal end of the drive element **204** (see FIG. **9**A).

In some embodiments, the coupler **214** has a size, shape, and configuration that permits the coupler **214** to be inserted into and interlocked with a portion of the distal arm **104** until the coupler **214** is moved to an unlocked position. As shown in FIG. **18**, the proximal end of the distal arm **104**, such as the proximal end of the extending portion **106**, includes a coupling bore **150** extending distally into the distal arm **104**. The coupling bore **150** may be a bore with a proximal opening which substantially corresponds to a shape of the coupler **214**. The distal portion of the coupling bore **150** may have a width or diameter larger than the proximal opening of the coupling bore **150**. The coupler **214** may be inserted into the coupling bore **150** in a position corresponding to the shape of the proximal opening. After the coupler **214** is inserted through the proximal opening into the coupling bore **150**, the coupler **214** may be rotated to operably secure the coupler **214** in the coupling bore **150**.

In some embodiments, the coupling bore **150** is configured such that the coupler **214** may be rotated a predetermined amount in the coupling bore **150** such that the coupler **214** operably locks in place in the coupling bore **150**. For example, rotating the coupler **214** may cause the cross section of the coupler **214** to have a shape which prevents the coupler **214** from being retracted from the proximal opening of the coupling bore **150**. The coupling bore **150** may include one or more locking elements which prevent or otherwise restrict the coupler **214** from rotating or translating in the coupling bore **150** during operation of the distal arm **104**. For example, the coupling bore **150** may include one or more tabs which bend once the coupler **214** is properly disposed in the coupling bore **150** and restrict the opposite rotation of the coupler **214** to operably retain the coupler **214** in position in the coupling bore **150**. In some embodiments, the coupler **214** may be magnetically locked in the coupling bore **150** until a sufficient force is exerted on the drive element **204** to overcome the magnetic attraction.

The coupler **214** may be interlocked with the coupling bore **150** of the distal arm **104** such that the distal arm **104** may be translated and/or rotated via the drive element **204** during operation. The coupler **214** may be rotated in the coupling bore **150**, such as via the drive element **204**, such that the coupler **214** may be retracted from the coupling bore **150** to decouple the drive element **204** from the distal arm **104**, such as after the tissue clipping assembly **102** clips tissue. For example, the coupler **214** may be rotated in a direction opposite the direction the coupler **214** is rotated to lock the coupler **214** in the coupling bore **150** such that the cross section of the coupler **214** is aligned with the proximal opening of the coupling bore **150**.

In the illustrated embodiment, the coupler **214** is a substantially rectangular block and the proximal opening of the coupling bore **150** is similarly rectangular. However, it will be understood that the coupler **214** and the proximal opening of the coupling bore **150** may have any suitable shapes and configurations. For example, the coupler **214** may be ovular, elliptical, triangular, pentagonal, hooked, or any other suitable shape. Further, while the coupler **214** has been described as extending from the distal end of the drive element **204**, it will be understood that the distal end of the drive element **204** may be sized, shaped, and configured to function similarly to the coupler **214** of FIG. **18**.

In other embodiments, the coupler **214** may be substantially spherical and the coupling bore **150** may be sized, shaped, and configured to operably receive the coupler **214** in a ball-and-socket connection. The coupler **214** may be inserted, such as via a snap fit or press fit, into the coupling bore **150** of the distal arm **104** to retain the coupler **214** in the coupling bore **150** during operation. The coupling bore **150** may be sized, shaped, and configured to retain the coupler **214**, such as having a narrower opening, such that the distal arm **104** may be controlled via the drive element **204** during operation. The coupler **214** may be retracted with a sufficient force, such as sufficient force to overcome the snap fit, to release the coupler **214** from the coupling bore **150** to thereby decouple the drive element **204** from the distal arm **104**.

While the coupler **214** of FIG. **18** has been described as having a shape which may be correspond to the shape of the proximal opening of the coupling bore **150** of the distal arm **104**, it will be understood that the coupler **214** may have other configurations such that coupler **214** may be retained in the coupling bore **150**. For example, the coupler **214** may form or include the coupling link **220** that is deformable such that the coupling link **220** may couple the distal arm **104** to couple the drive element **204**. The opening of the receiving portion **136** may be narrower than the distal portion of the coupling bore **150**. The coupling link **220** be inserted into the coupling bore **150** and may bend or deform in the coupling bore **150** such that the coupling link **220** has a width greater than the proximal opening of the coupling bore **150** thereby coupling the drive element **204** and the distal arm **104** and preventing the coupling link **220** from being retracted from the coupling bore **150** during operation. The drive element **204** may be proximally retracted with sufficient force to pull the coupling link **220** out of the deformed state such that the coupling link **220** may be retracted from the coupling bore **150** to decouple the drive element **204** from the distal arm **104**. The coupling link **220** may comprise a shape memory and/or superelastic material, such as Nitinol.

Further, the distal end of the drive element **204** may be sized, shaped, and configured to operably couple with the proximal end of the distal arm **104**. For example, the distal end of the drive element **204** may be bent into a shape, such as an L-shape, which is received through a portion of the distal arm **104**. The distal arm **104** may be linearly extendable and retractable when the drive element **204** is disposed through the portion of the distal arm **104**. After the tissue clipping assembly **102** has been moved to the closed position, the shape of the distal end of the drive element **204** may be pulled out of the distal arm **104** such that the drive element **204** is decoupled from the distal arm **104**, such as by lifting the L-shaped bend out of a receiving portion of the distal arm **104**. Furthermore, it will be understood that the distal arm **104** may be operably coupled with the drive element **204** in other manners, such as described below.

In embodiments in which the distal arm **104** is releasably coupled with the drive element **204**, the drive assembly **200** may include one or more components configured to further maintain the coupling of the distal arm **104** and the drive element **204** during operation. For example, the drive assembly **200** may include a sheath or tube disposed around the drive element **204** and substantially covering the coupling of the drive element **204** to the distal arm **104**. The sheath or tube may extend to the proximal end of the distal arm **104** to prevent or otherwise restrict the distal arm **104** from decoupling from the drive element **204** during the tissue clipping operation. In some embodiments, the sheath or tube has a distal portion operably interlocked with a proximal portion. When the distal arm **104** is decoupled from the drive element **204**, the distal portion may decouple from the proximal portion, such as by proximal retraction of the drive element **204**.

While the coupler **214** has been described as being a part of the drive assembly **200** and attached to the distal end of the drive element **204**, it will be understood that the coupler **214** may be part of the tissue clipping assembly **102** and be attached to the proximal end of the distal arm **104**. Additionally, it will be understood that any of methods of coupling described above may be switched such that the coupling component(s) of the drive element **204** is disposed on the tissue clipping assembly **102** and vice versa. Further, in embodiments in which the proximal arm **110** is translatable by a drive element **204**, it will be understood that the proximal end of the proximal arm **110** may similarly be coupled with the drive element **204** such that the proximal arm **110** may be decoupled from the drive element **204**.

Referring now to FIGS. **19A-21B** the distal arm **104** includes a housing **154** toward the distal end of the distal arm **104**. The housing **154** may be configured to reduce trauma to tissue as the distal arm **104** is extended from the catheter **212** and/or to prevent damage to the catheter **212** and/or the endoscope, such as when extending the tissue clipping assembly **102** through the catheter **212** and/or endoscope. The housing **154** may deflect tissue such that the extension of the distal arm **104** is substantially atraumatic when the distal arm **104** is extended from the collar **120**. The housing **154** may shroud the proximal arm **110**, such as when the tissue clipping assembly **102** is in the closed position, such as to protect the operator, the endoscope, the catheter **212**, and/or the patient. The housing **154** may also be configured to operably lock with the collar **120** to secure the distal arm **104** in the closed and locked positions. In some embodiments, the housing **154** and/or the distal tine **112** of the distal arm **104** are releasably coupled to the distal end of the drive element **204**.

As shown in FIGS. **19**A-**19**P, the housing **154** of the distal arm **104** includes a tine channel **156** operable to receive the distal tine **112** therein. The tine channel **156** may be substantially linear and extend around the top, front, and bottom of the housing **154** to substantially correspond to the shape of the distal tine **112**. The tine channel **156** may be sized, shaped, and configured to receive at least a portion of the distal tine **112** therein. In some embodiments, the distal tine **112** is snap fit or press fit into the tine channel **156** to secure the distal tine **112** in the tine channel **156**. Additionally or alternatively, the distal tine **112** may be secured in the tine channel **156** via welding, crimping, swaging, soldering, adhesives, fasteners, or the like.

The housing **154** may include one or more housing extensions **158** extending radially outwardly from and at least partially laterally across the tine channel **156**. The housing extensions **158** may be sized, shaped, and configured to prevent the distal tine **112** from being retracted from the tine channel **156**. For example, the housing extensions may be operable to abut an outer surface of the distal tine **112** disposed in the tine channel **156** to prevent the distal tine **112** from moving radially out of the tine channel **156**. The housing extensions **158** may be crimped, swaged, pressed, or otherwise mechanically deformed such as to hold the distal tine **112** in place relative the housing **154** and within the tine channel **156**.

The distal tine **112** may include one or more retaining tabs **162** extending radially outwardly from the remainder of the distal tine **112**. The retaining tabs **162** may be disposed at a location along the distal tine **112** and extend outwardly from the remainder of the distal tine **112** to retain the distal tine **112** in the tine channel **156**. The retaining tabs **162** may extend radially outwardly above a bottom surface of the housing extensions **158**. The retaining tabs **162** may be sized, shaped, positioned, and configured to abut the proximal and distal sides of the housing extensions **158**. The retaining tabs **162** may be disposed on both sides of the housing extensions **158** to prevent or otherwise restrict the distal tine **112** from translating linearly within the tine channel **156** relative to the housing **154**.

The distal tine **112** and/or the housing **154** may be configured to releasably couple with the distal end of the drive element **204**. As shown in FIG. **19**K, the distal end of the drive element **204** may include a coupling area **224** proximally inset from the prongs **222**. The coupling area **224** may be sized, shaped, and configured to receive a portion of the distal tine **112** and/or the housing **154** to releasably couple the distal arm **104** to the drive element **204** such that the position of the distal arm **104** may be controlled by the drive element **204**.

As shown in FIGS. **19**I and **19**J, the coupling projection **144** of the distal tine **112** extends downwardly from the upper portion of the distal tine near the proximal end of the distal tine **112**. The proximal and/or distal sides of the coupling projection **144** may be sloped or rounded, such as to permit the coupling projection **144** to be withdrawn from the coupling area **224** defined by the drive element **204**, as described below.

As shown in FIGS. **19**C and **19**D, the coupling projection **144** may extend into the coupling area **224** defined by the drive element **204** to couple the distal arm **104** with the drive element **204**. The coupling projection **144** may extend substantially from the proximal end of the coupling area **224** to the distal end of the coupling area **224** such that the movement of the drive element **204** is translated to the distal arm **104**.

The distal arm **104** may be decoupled from the drive element **204** by applying sufficient proximal force to the drive element **204** to withdraw the coupling projection **144** from the coupling area **224**, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions. The drive element **204** may be proximally retracted such that the distal end of the coupling projection **144** contacts the distal side of the coupling area **224**. The side of the coupling projection **144** may be sized, shaped, and configured such that the distal tine **112** moves upwardly by virtue of the contact between the distal of the coupling projection **144** and the distal side of the coupling area **224** as the drive element **204** is proximally retracted. In the illustrated embodiment, the sides of the coupling projection **144** are angled or sloped. However, it will be appreciated that the coupling projection **144** may have other shapes and configurations. For example, the sides of the coupling projection **144** may be rounded. The drive element **204** may be proximally retracted such that the coupling projection **144** is lifted out of the coupling area **224**. The drive element **204** may be decoupled from the distal arm **104** when the coupling projection **144** is removed from the coupling area **224** and the drive element **204** is proximally retracted.

While the distal tine **112** has been described as releasably coupling with the distal end of the drive element **204**, it will be understood that the distal arm **104** may have other configurations and assemblies. For example, the coupling projection **144** may be disposed on the housing **154** to be operably received in the coupling area **224** defined by the drive element **204**.

In some embodiments, the housing **154** also includes a lateral passage **160** near the proximal end of the housing **154**. The lateral passage **160** may be sized, shaped, and configured to at least partially receive one of the barbs **119** of the distal tine **112** therethrough. The disposition of the barb **119** in the lateral passage **160** may permit the distal tine **112** to substantially close in the tine channel **156** of the housing **154**.

As shown in FIGS. **19**A-**19**C and **19**E-**19**H, the locking projections **130** of the distal arm **104** may be disposed on the outer surface of the housing **154**, such as at a proximal end of the housing **154**. As shown in FIGS. **19**M-**19**O, the housing **154** may be retracted into and locked with the collar **120**, such as when the tissue clipping assembly **102** is moved to the closed and locked positions. The collar **120** includes setting recesses **141** at a distal end of the collar **120** and extending into the receiving portions **136**. The setting recesses **141** and receiving portions **136** may be positioned corresponding to the position of the locking projections **130** of the housing **154**. The distal arm **104** may be retracted such that the locking projections **130** are disposed in the setting recesses **141**, such as to orient the distal arm **104** and ensure the tissue clipping assembly **102** is properly clipping tissue.

The distal arm **104** may be proximally retracted, such as via the drive element **204**, to move the locking projections **130** into the receiving portions **136** of the collar to move the distal arm **104** to the closed and locked positions. The collar **120** may also include stress reliefs **142** disposed on both sides of the setting recesses **141** and the receiving portions **136** and at the distal end of the receiving portions **136** to permit the locking projections **130** to move from the setting recesses **141** to the receiving portions **136** of the collar **120**. In some embodiments, as shown in FIG. **19**P, the distal tine **112** may be disposed between the proximal tines **124** of the proximal arm **110** as the distal arm **104** is retracted such that the proximal tines **124** operate as the guiding slot **140**.

As shown in FIGS. **19**O and **19**P, the housing **154** may substantially surround the proximal tines **124** of the proximal arm **110** when the tissue clipping assembly **102** is in the closed and locked positions. The housing **154** may be sized, shaped, and configured to maintain the clipping of tissue between the distal and proximal arms **104**, **110** and to reduce trauma to surrounding tissue when the tissue clipping assembly **102** is in the closed and locked positions.

As shown in FIGS. **20**A-**20**E, the housing **154** may include a drive coupler **164** configured to further couple the distal arm **104** with the drive element **204**. As shown in FIG. **20**B, the drive element **204** may define one or more coupling areas **224** along the distal end of the drive element **204**. As shown in FIG. **20**C, the drive coupler **164** may be substantially triangular with a wider proximal end and include one or more projection apertures **165** extending from a top of the drive coupler **164** to a bottom of the drive coupler **164**. The projection apertures **165** may substantially correspond to the position of the coupling areas **224** of the drive element **204**. As shown in FIG. **20**D, the distal tine **112** includes one or more coupling projections **144** extending substantially downwardly. The coupling projections **144** may be sized and positioned corresponding to the coupling areas **224** of the drive element **204** and the projection apertures **165** of the drive coupler **164**. The coupling projections **144** may be substantially L-shaped with the elongated portion extending proximally.

As shown in FIG. **20**E, when the distal tine **112** is coupled with the housing **154**, the coupling projections **144** may extend through the coupling areas **224** of the drive element **204** and the projection apertures **165** of the drive coupler **164** to couple the distal arm **104** to the drive element **204**. The elongated portion of the coupling projections **144** may partially extend along the bottom surface of the drive coupler **164**, such as to prevent the drive coupler **164** from sliding off the coupling projections **144**. The drive coupler **164** may maintain the coupling of the drive element **204** and the distal arm **104** by preventing the drive element **204** from prematurely sliding off the coupling projections **144**. When the tissue clipping assembly **102** is moved to the closed and locked positions, the drive element **204** may be manipulated such that the coupling projections **144** are retracted through the drive coupler **164** and the drive element **204** to decouple the drive element **204** from the distal arm **104**.

Further, it will be understood that the distal tine **112** may have a variety of configurations to maintain the distal tine **112** in the tine channel **156**. For example, as shown in FIGS. **20**D-**20**E, the top portion of the distal tine **112** may include a notch to receive the housing extension **158** therein. The disposition of the housing extension **158** in the notch may maintain the translational position of the distal tine **112** relative to the tine channel **156** and may prevent the distal tine **112** from moving radially out of the tine channel **156**.

In some embodiments, the distal arm **104**, such as the housing **154**, may be sized, shaped, and configured to limit the flexing or rotation of the one or more distal tines **112**, such as to limit the flexing or rotation of the distal tine **112** about the rounded portions **116** of the distal tines **112**. As shown in FIGS. **21**A and **21**B, the distal tine **112** may include a flange **166** extending radially outwardly (e.g., proximally) from the rounded portion **116**. The housing **154** may include a stop **167** radially outward (e.g., proximal) from the tine channel **156**. As the bottom portion of the distal tine **112**, such as the tip **114**, flexes downwardly, such as into tissue, the flange **166** may abut the stop **167**. The abutment between the flange **166** and the stop **167** may prevent the bottom portion of the distal tine **112**, such as the tip **114**, from flexing further downward. For example, the abutment between the flange **166** and the stop **167** may prevent the distal tine **112** from opening beyond a point from which the distal tine **112** cannot return to a closed position to clip tissue. Additionally or alternatively, the rounded portion **116** of the distal tine **112** may be thicker and/or comprise a stiffer material to prevent the distal tine **112** from opening too far. Further, the housing **154** may include one or more housing extensions **158** extending across the tine channel **156** at a bottom side of the housing **154** to similarly prevent the distal tine **112** from opening too far during the tissue clipping operation.

In some embodiments, the distal arm **104** and/or the drive element **204** may be configured to simplify the device **100** and/or to reduce the overall cost of the device **100**. As shown in FIGS. **22**A and **22**B, the distal arm **104** may include a single bent distal tine **112**. In some embodiments, the distal tine **112** may be a bent and cut tube or Nitinol wire. The distal tine **112** may have a spherical end which is secured in the housing **154**. The housing **154** may be coupled with the distal end of the drive element **204**, such as via a frangible coupling. The distal end of the drive element **204** may comprise two or more wires, such as stainless steel or Nitinol wires, instead of a single element with a substantially rectangular cross section, as described in more detail below.

While the housing **154** has been described as housing one distal tine **112**, it will be understood that the housing **154** may have other configurations. For example, the housing **154** may include two or more tine channels **156** such that the housing **154** may be used with two or more distal tines **112**. Further, any of the housings **154** may be used with any of the other distal tines **112** described herein, such as the distal tines of FIG. **8**A-**8**B.

Referring now to FIGS. **23**-**32**, the collar **120** of the tissue clipping assembly **102** may be operably coupled with the catheter such that the collar **120** may be decoupled from the catheter **212**, such as after the tissue clipping assembly **102** clips tissue. The distal end of the catheter **212** may be coupled directly or indirectly with the proximal end of the collar **120** during operation. The catheter **212** may be decoupled from the collar **120** after the tissue clipping assembly **102** has been moved to the closed position, such as via continued proximal retraction of the drive element **204**.

As shown in FIG. **23**-**24**, the drive assembly **200** may include a connector **216** configured to operably couple the distal end of the catheter **212** with the proximal end of the collar **120**. The connector **216** may couple the catheter **212** with the collar **120** while the tissue clipping assembly **102** is maneuvered to clip tissue. The connector **216** may also decouple the catheter **212** from the collar **120** after the tissue clipping assembly **102** has been moved to the closed and locked positions, such as to deploy the tissue clipping assembly **102** in the body to maintain the clipping of the tissue. The connector **216** may be a substantially hollow cylinder operable to slidably receive the drive element **204** therethrough.

In some embodiments, the proximal end of the connector **216** is fixed to the distal end of the catheter **212** such that the connector **216** remains coupled with the catheter **212** after the drive assembly **200** is decoupled from the tissue clipping assembly **102**. The proximal end of the connector **216** may be coupled to the distal end of the catheter **212** via adhesives, welding, fasteners, heat bonding, or the like. In an exemplary embodiment, the proximal end of the connector **216** is welded to the distal end of the catheter **212**. In other embodiments, the connector **216** is included as an integral part of the distal portion of the catheter **212**.

The distal end of the connector **216** is operable to couple with the proximal end of the collar **120**. As shown in FIG. **23**-**25**B, the connector **216** includes a connecting portion **226** at a distal end of the connector **216** operable to couple with the collar **120**. The connecting portion **226** of the connector **216** includes one or more connecting projections **228** and defines one or more receiving areas **230**. The connecting projections **228** of the collar **120** may extend distally from the remainder of the connector **216** and may be substantially arcuate.

The collar **120** may also include a connecting portion **168** at a proximal end of the collar **120** operable to couple with the connecting portion **226** of the connector **216**. The connecting portion **168** of the collar **120** may also include one or more connecting projections **170** and define one or more receiving areas **172**. The connecting projections **170** of the collar **120** may extend proximally from the remainder of the collar **120** and may be substantially arcuate.

The connecting projections **170** of the collar **120** and the receiving areas **230** defined by the connector **216** may be sized, shaped, and configured such that the connecting projections **170** of the collar **120** may be received in the receiving areas **230** of the connector **216** to couple the collar **120** with the connector **216**. The connecting projections **228** of the connector **216** and the receiving areas **172** defined by the collar **120** may also be sized, shaped, and configured such that the connecting projections **228** of the connector **216** may be received in the receiving areas **172** of the collar **120** to couple the collar **120** with the connector **216**. The connecting projections **170** of the collar **120** may be received in the receiving areas **230** of the connector **216** and the connecting projections **228** of the connector **216** may be received in the receiving areas **172** of the collar **120** to operably couple the collar **120** to the connector **216**. The connecting projections **170** and receiving areas **172** of the collar **120** and the connecting projections **228** and the receiving areas **230** of the collar **120** may operably interlock together to operably couple the collar **120** with the connector **216**. The connecting portion **168** of the collar **120** may linearly overlap with the connecting portion **226** of the connector **216** when the connector **216** is coupled with the collar **120**. For example, the connecting projections **170** of the collar **120** may extend proximally beyond a portion of the connecting projections **228** of the connector **216** and connecting projections **228** of the connector **216** may extend distally beyond a portion of the connecting projections **170** of the collar **120** when the connector **216** is coupled with the collar **120**. The collar **120** may be translated and/or rotated with the catheter **212** when the collar **120** is coupled with the connector **216**.

The connecting projections **170** of the collar **120** may each include lateral flanges **174** extending laterally (e.g., radially) from the proximal end of the connecting projection **170**. The lateral flanges **174** of the collar **120** may be operable to retain the connecting projection **170** in the corresponding receiving area **230** of the connector **216** during operation. The lateral flanges **174** of the connecting projections **170** of the collar **120** may be sized, shaped, and configured to be received in the receiving areas **230** of the connector **216** and to laterally (e.g., radially) extend proximally behind a portion of the connector **216**. The extension of the lateral flanges **174** of the connecting projections **170** of the collar **120** proximally behind a portion of the connector **216** may operably interlock the collar **120** with the connector **216** and prevent the collar **120** from moving distally relative to the connector **216**.

The connecting projections **228** of the connector **216** may also include lateral flanges **232** extending laterally from the distal end of the connecting projections **228**. The lateral flanges **232** of the connector **216** may be operable to retain the respective connecting projection **228** in the corresponding receiving area **172** of the collar **120** during operation. The lateral flanges **232** of the connecting projections **228** of the connector **216** may be sized, shaped, and configured to be received in the receiving areas **172** of the collar **120** and to laterally (e.g., radially) extend distally behind a portion of the collar **120**. The extension of the lateral flanges **232** of the connecting projections **228** of the connector **216** distally behind a portion of the collar **120** may operably interlock the connector **216** with the collar **120** and prevent the connector **216** from moving proximally relative to the collar **120**.

In some embodiments, the lateral flanges **174** of the connecting projections **170** of the collar **120** are disposed proximally behind the lateral flanges **232** of the connecting projections **228** of the connector **216** when the connecting projections **170** of the collar **120** are disposed in the receiving areas **230** of the connector **216**. The lateral flanges **232** of the connecting projections **228** of the connector **216** may be disposed distally behind the lateral flanges **174** of the connecting projections **170** of the collar **120** when the connecting projections **228** of the connector **216** are disposed in the receiving areas **172** of the collar **120**. The linear overlap of the lateral flanges **174** of the collar **120** and the lateral flanges **232** of the connector **216** may further secure the coupling between the connector **216** and the collar **120**.

In the illustrated embodiment, the collar **120** and the connector **216** have one connecting projection **170**, **228** and two receiving areas **172**, **230**. However, it will be understood that the collar **120** and the connector **216** may have any suitable number of connecting projections **170**, **228** and receiving areas **172**, **230** to operably interlock the collar **120** with the connector **216**.

The connecting projections **170** of the collar **120** may be decoupled from the receiving areas **230** of the connector **216** and the connecting projections **228** of the connector **216** may be decoupled from the receiving areas **172** of the collar **120** to decouple the connector **216** from the collar **120**. The connecting projections **170** of the collar **120** may be moved laterally and/or flexed radially outwardly from the receiving areas **230** of the connector **216** and the connecting projections **228** of the connector **216** may be moved laterally and/or flexed radially outwardly from the receiving areas **172** of the collar **120**. For example, connecting projections **228** of the connector **216** and/or the connecting projections **170** of the collar **120** may be moved or flexed radially outwardly via sufficient proximal retraction of the drive element **204**, as described below. After the connecting projections **170** of the collar **120** are removed from the receiving areas **230** of the connector **216** and the connecting projections **228** of the connector **216** are removed from the receiving areas **172** of the collar **120**, the connector **216** may be decoupled from the collar **120**. After the connector **216** is decoupled from the collar **120**, the connector **216** and the catheter **212** may be withdrawn from the collar **120**.

While the catheter **212** has been described as being releasably coupled to the collar **120** via the connector **216**, it will be understood that the catheter **212** may be coupled with the collar **120** in other manners. For example, the connector **216** may be incorporated into the distal end of the catheter **212** and the catheter **212** may include a coupling portion operable to connect with the connecting portion **168** of the collar **120**.

As shown in FIGS. **26-27**D, the drive assembly **200** may include an alignment adapter or spacer **236** configured to substantially maintain the orientation of the distal arm **104** during operation and to operably decouple the collar **120** from the connector **216**, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions.

The alignment spacer **236** may be substantially cylindrical and sized, shaped, and configured to linearly slide within the inner surfaces of the collar **120** and the connector **216**. The alignment spacer **236** may define a drive passage **238** extending through the length of the alignment spacer **236**. The drive passage **238** may be sized, shaped, and configured to receive a portion of the drive element **204** therethrough such that the drive element **204** is translatable through the drive passage **238**.

The alignment spacer **236** may be disposed in an operational position within and between the collar **120** and the connector **216** when the collar **120** and the connector **216** are coupled to maintain the coupling of the collar **120** and the connector **216**. The alignment spacer **236** may be disposed within the collar **120** and the connector **216** such that the outer surface of the alignment spacer **236** abuts the inner surfaces of the collar **120** and the connector **216**. The outer surface of the alignment spacer **236** may abut the inner surfaces of the connecting portions **168**, **226** of the collar **120** and the connector **216** to prevent the collar **120** and the connector **216** from decoupling. For example, the outer surface of the alignment spacer **236** may simultaneously abut the connecting projections **170** of the collar **120** and the connecting projections **228** of the connector **216** to prevent the connecting projections **170** of the collar **120** from moving out of the receiving areas **230** of the connector **216** and to prevent the connecting projections **228** of the connector **216** from moving out of the receiving areas **172** of the collar **120**. The distal end of the alignment spacer **236** may be disposed near the proximal end of the distal arm **104** when the alignment spacer **236** is in the operational position and the distal arm **104** is in the set position. During operation, the positioning of the alignment spacer **236** near the collar **120** may assist in guiding the distal arm **104** to recruit tissue.

The alignment spacer **236** may also be linearly translatable within the collar **120** and the connector **216** to decouple the connector **216** from the collar **120**. The alignment spacer **236** may be linearly translated, such as proximally, from beneath the connecting portions **168**, **226** of the collar **120** and the connector **216** such that the alignment spacer **236** no longer supports the coupling between the collar **120** and the connector **216**. For example, the alignment spacer **236** may be proximally retracted entirely into the connector **216**. Without the support of the alignment spacer **236**, the connector **216** may be moved, such as via the catheter **212**, such that the connecting projections **228** of the connector **216** are moved out of the receiving areas **172** of the collar **120** and vice versa, thereby decoupling the collar **120** from the connector **216** and the catheter **212**.

Referring now to FIGS. **28**A and **28**B, the drive element **204** may include a proximal portion **206** which may be coupled to the handle **202**, such as to the control actuator **210**, and a distal portion **208** which may be operably coupled with the tissue clipping assembly **102**, such as via the coupler **214**. The proximal portion **206** may be sized, shaped, and configured to extend through the catheter **212** and transmit translational and rotational movement from the handle **202** toward the tissue clipping assembly **102**. In some embodiments, the proximal portion **206** of the drive element **204** may be sized, shaped, and configured to decrease friction applied to the catheter **212** when the tissue clipping device **100** is operated. In an exemplary embodiment, the proximal portion **206** of the drive element **204** is configured to allow the distal arm **104** to flexibly recruit tissue and the distal portion **208** is configured to guide the distal arm **104** linearly out of and into the collar **120**. The proximal portion **206** of the drive element **204** may be a toque shaft which may be translated and rotated by an operator, such as via the handle **202**.

The distal end of the distal portion **208** of the drive element **204** may be coupled with the tissue clipping assembly **102**, such as with the proximal end of the distal arm **104**. The distal portion **208** may be sized, shaped, and configured to increase control of the distal arm **104** as the distal arm **104** is operated to clip tissue. The distal portion **208** of the drive element **204** may have a different cross section than the proximal portion **206** of the drive element **204**. In some embodiments, the distal portion **208** of the drive element **204** has a wider cross section than the proximal portion **206** of the drive element **204**, such as to decouple the drive assembly **200** from the tissue clipping assembly **102**, as described below. In some embodiments, the distal portion **208** of the drive element **204** has a substantially rectangular cross section and comprises stainless steel or Nitinol. In other embodiments, the distal portion **208** of the drive element **204** includes multiple wires spaced laterally apart and extending in parallel toward the tissue clipping assembly **102**.

While the proximal portion **206** of the drive element **204** has been described as having a circular cross section and the distal portion **208** of the drive element **204** has been described as having a rectangular cross section, it will be understood that the drive element **204** may have other shapes and configurations. For example, both the proximal and distal portions **206**, **208** of the drive element **204** may have a substantially circular cross section or both the proximal and distal portions **206**, **208** may have a substantially rectangular cross section. The distal portion **208** may also be wider to guide the linear extension and retraction of the distal arm **104** relative to the proximal arm **110**. For example, the wider distal portion **208** may make the distal portion **208** stronger such that the distal portion **208** remains substantially in line with the distal opening of the alignment spacer **236** as the distal arm **104** is linearly extended and retracted, such as during the tissue clipping operation. The distal portion **208** may remain relatively in lace as the proximal portion **206** is maneuvered by an operator. For example, the distal portion **208** may be stiffer than the proximal portion **206**.

The distal end of the proximal portion **206** of the drive element **204** may be fixed to the proximal end of the distal portion **208** of the drive element **204**. In an exemplary embodiment, the distal end of the proximal portion **206** is welded to the proximal end of the distal portion **208**. In other embodiments, the distal end of the proximal portion **206** is coupled with the proximal end of the distal portion **208** via adhesives, solder, fasteners, or other suitable means known in the art to couple the proximal portion **206** to the distal portion **208**. In an exemplary embodiment, the proximal and distal portions **206**, **208** are integral.

In some embodiments, the proximal portion **206** of the drive element **204** has a length nearly corresponding to the distance which the distal arm **104** is to be extended from the catheter **212**. For example, the drive assembly **200** may be configured to limit the distal extension of the proximal portion **206** of the drive element **204** such that the extension length of the distal arm **104** is substantially equivalent to the length of the distal portion **208** of the drive element **204**. In embodiments, where the distal arm **104** is configured to be extended about 3 cm from the catheter **212**, the distal portion **208** of the drive element **204** may have a length of about 3 cm or slightly larger. The distal portion **208** may have a length similar to or longer than the length of the distal tine **112** such that the distal arm **104** may be effectively guided relative to the collar **120**.

Referring back to FIGS. **27**C-**27**D, the drive passage **238** of the alignment spacer **236** may be sized, shaped, and configured to permit a proximal portion of the distal portion **208** of the drive element **204** to be distally extended through the drive passage **238** and such that the alignment spacer **236** may be proximally retracted when the drive element **204** is proximally retracted, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions. The drive passage **238** may include a proximal portion **238***a* at the proximal end and a distal portion **238***b* at the distal end. The proximal portion **238***a* of the drive passage **238** may be sized, shaped, and configured to receive the distal end of the proximal portion **206** of the drive element **204** therein and to allow the distal portion **208** of the drive element **204** to translate therethrough. The distal portion **238***b* of the drive passage **238** may be sized, shaped, and configured to permit the distal portion **208** of the drive element **204** to translate therethrough. The distal portion **238***b* of the drive passage **238** may also be sized, shaped, and configured to prevent the proximal portion **206** of the drive element **204** from extending therein. The distal portion **238***b* of the drive passage **238** may also be sized, shaped, and configured to prevent a distal portion of the drive element **204**, such as the prongs **222**, from extending therethrough.

In some embodiments, the cross section of the proximal portion **238***a* of the drive passage **238** is wider than the distal portion **238***b* of the drive passage **238**. In some embodiments, the cross section of the proximal portion **238***a* of the drive passage **238** corresponds to the cross section of the proximal portion **206** of the drive element **204** (e.g., circular). In some embodiments, the cross section of the distal portion **238***b* of the drive passage **238** corresponds to the cross section of the distal portion **208** of the drive element **204** (e.g., rectangular).

In some embodiments, the alignment spacer **236** includes a shoulder **240** disposed at the distal end of the proximal portion **238***a* of the drive passage **238**. The shoulder **240** may be configured to abut the distal end of the proximal portion **206** of the drive element **204**. The shoulder **240** may be configured to prevent the proximal portion **206** of the drive element **204** from extending into the distal portion **238***b* of the drive passage **238** while allowing the distal portion **208** of the drive element **204** to extend into the distal portion **238***b* of the drive passage **238**. The drive element **204** may also include a stop feature which abuts the shoulder **240** to prevent the proximal portion **206** of the drive element **204** from extending into the distal portion **238***b* of the drive passage **238**.

The alignment spacer **236** may be disposed between the connecting portions **168**, **226** of the collar **120** and the connector **216** when the device **100** is extended into the body and when the tissue clipping assembly **102** is maneuvered to clip tissue (e.g., the operational position), such as to maintain the coupling of the collar **120** and the connector **216**. The alignment spacer **236** may allow the distal portion **208** of the drive element **204** to be extended through the drive passage **238** such that the distal arm **104** may be operated to grasp tissue as described above. The alignment spacer **236** may also prevent the proximal portion **206** of the drive element **204** from extending through the drive passage **238**, such as to control the extension length of the distal arm **104**. The cross section of the distal portion **238***b* of the drive passage **238** may substantially correspond to the cross section of the distal portion **208** of the drive element **204** such that the orientation of the distal portion **208** of the drive element **204** substantially corresponds to the orientation of the alignment spacer **236**, such as to prevent the distal portion **208** of the drive element **204** and the distal arm **104** from rotating or twisting when the distal portion **208** is distally extended. In some embodiments, the distal end of the alignment spacer **236** is narrower to increase the stiffness of the alignment spacer **236** around the distal portion **238***b* of the drive passage **238**.

In some embodiments, the alignment spacer **236** includes one or more ridges **242** extending radially outwardly from an outer surface of the alignment spacer **236**. The ridges **242** may extend radially outward from a proximal portion of the alignment spacer **236**. The ridges **242** may extend into slots **244** extending along a length of the connector **216** (see FIGS. **23**-**24**B). The ridges **242** may be retained in the slots **244** of the connector **216** to maintain the orientation of the alignment spacer **236** during operation, such as to maintain the orientations of the distal portion **208** of the drive element **204** and the distal arm **104** during the tissue clipping operation. For example, the slots **244** may permit linear translation of the alignment spacer **236** but prevent rotation of the alignment spacer **236** when the ridges **242** are disposed in the slots **244**.

The slots **244** of the connector **216** may also control the linear translation of the alignment spacer **236**. For example, the alignment spacer **236** may be prevented from translating distally through the connector **216** when the ridges **242** abut the distal ends of the slots **244**. In some embodiments, the distal ends of the slots **244** may be positioned such that the alignment spacer **236** is in the operational position between the connecting portions **168**, **226** of the collar **120** and the connector **216** when the ridges **242** abut the distal ends of the slots **244** (e.g., the alignment spacer **236** may only translate proximally). In another embodiment, the slots **244** have narrower portions that abut the ridges **242** thereby preventing the alignment spacer **236** from being moved proximally until a sufficient force is delivered to the alignment spacer **236** via the drive element **204**. The force required to proximally retract the alignment spacer **236** may be between about 1 pound and about 10 pounds, such as between about 2 pounds and about 4 pounds.

In some embodiments, as shown in FIG. **24**B, the connector **216** includes a retention tab **234** configured to operably retain the alignment spacer **236** in the operational position to maintain the coupling between the collar **120** and the connector **216**. The retention tab **234** may be bent or flexed radially inwardly to abut the proximal end of the alignment spacer **236** when the alignment spacer **236** is in the operational position. The abutment between the retention tab **234** and the alignment spacer **236** may prevent the alignment spacer **236** from proximally retracting during the tissue clipping operation. The retention tab **234** may flex or bend radially outwardly when the alignment spacer **236** is retracted with sufficient force, such as via the drive element **204**, such that the retention tab **234** no longer abuts the alignment spacer **236**, thereby allowing the alignment spacer **236** to be proximally retracted. In some embodiments, the connector **216** includes fiducials **246** extending between the slots **244** which aid in assembly and provide a visual cue to an operator that the connector **216** is disposed properly on the catheter **216**. The fiducials **246** may also be flexible such as to allow the connector **216** to flex or bend, such as to place the proximal end of the connector **216** around the distal end of the catheter **212**.

The alignment spacer **236** may be proximally retracted from between the connecting portions **168**, **226** of the collar **120** and the connector **216** by proximal retraction of the drive element **204**, such as after the tissue clipping assembly **102** has been moved to the closed and locked positions. After the distal end of the drive element **204** is decoupled from the tissue clipping assembly **102**, the drive element **204** may be proximally retracted through the drive passage **238** of the alignment spacer **236**. The drive element **204** may be retracted until a distal portion of the drive element **204**, such as the prongs **222**, abut the distal end of the alignment spacer **236**. The drive element **204** may then be retracted with sufficient proximal force, such as via the handle **202**, that the abutment between the drive element **204** and the alignment spacer **236** proximally retracts the alignment spacer **236**. For example, the drive element **204** may be retracted with sufficient force to flex the retention tab **234** radially outwardly such that the alignment spacer **236** may be proximally retracted with the drive element **204**. After the alignment spacer **236** is proximally retracted from the operational position, the collar **120** may be decoupled from the connector **216** and the catheter **212** such that the tissue clipping assembly **102** is decoupled from the drive assembly **200**.

While the drive element **204** has been described with a distal portion **208** having a flat, rectangular cross section to control the orientation and deflection of the distal arm **104** during operation, it will be understood that the distal portion **208** may have other configurations and assemblies. For example, the distal portion **208** of the drive element **204** may include two or more wires, such as stainless steel or Nitinol wires, extending in parallel to the distal arm **104**, such as shown in FIG. **22**A.

Referring now to FIGS. **29**A-**32**, the tissue clipping device **100** may be operated to clip tissue with the tissue clipping assembly **102** and the tissue clipping assembly **102** may be decoupled from the drive assembly **200**, such as to deploy the tissue clipping assembly **102** in the body to maintain closure of the tissue. The tissue clipping assembly **102** may be inserted into a position above and substantially parallel to target tissue, such as an identified defect. The tissue clipping assembly **102** may be operated via the drive assembly **200** to linearly clip tissue, such as to clip together opposing sides of a defect. The tissue clipping assembly **102** may be moved to a closed position and locked position to continue to clip tissue. The tissue clipping assembly **102** may be decoupled from drive assembly **200**, such as to maintain closure of the defect with the tissue clipping assembly **102**. FIGS. **29**B, **30**B, and **31**B show the tissue clipping device **100** without the collar **120** and the connector **216** to show the inner components of the tissue clipping assembly **102** and the drive assembly **200**.

As shown in FIGS. **29**A-**29**B, the tissue clipping assembly **102** may be extended through the catheter **212**, such as through an endoscope, to a desired location, such as above a defect. The distal arm **104** of the tissue clipping assembly **102** may be coupled with the distal end of the drive element **204**. The distal arm **104** and the drive element **204** may extend through the collar **120** and the proximal arm **110** may also extend from the distal end of the collar **120**. The locking projections **130** of the distal arm **104** may be disposed in the setting recesses **141** of the collar **120** such that the tissue clipping assembly **102** is in the set position. The distal arm **104** may include the housing **154** which substantially shrouds the proximal arm **110**. The collar **120** is operably coupled with the distal end of the catheter **212** via the connector **216**. The connecting portion **168** of the collar **120** may operably couple with the connecting portion **226** of the connector **216** and the alignment spacer **236** may be disposed between the connecting portions **168**, **226** to maintain the coupling between the collar **120** and the connector **216**. The drive element **204** extends through the alignment spacer **236** and is operably coupled with the distal arm **104**.

As shown in FIGS. **30**A-**30**B, the distal arm **104** may be linearly extended (e.g., parallel to the surface of the tissue) from the collar **120** to the extended configuration such that the tissue clipping assembly **102** may be positioned on opposite sides of target tissue. The drive element **204** may be distally extended, such as via the handle **202**, to linearly extend the distal arm **104**. The tissue clipping device **100** may be maneuvered such that the proximal arm **110**, such as the proximal tines **124**, grasps tissue at a first tissue location and such that the distal arm **104**, such as the distal tine **112**, grasps tissue at a second tissue location. The second tissue location may be substantially opposite the first location. In some embodiments, the distal tine **112** of the distal arm **104** may flex a distance radially outwardly (e.g., downwardly) such that the distal tine **112** may grasp tissue.

As shown in FIGS. **31**A-**31**B, the distal arm **104** may be proximally retracted to clip tissue between the distal arm **104** and the proximal arm **110** and the tissue clipping assembly **102** may be moved to the closed and locked positions such that the position of the distal arm **104** is maintained relative to the collar **120**. The distal arm **104** may be proximally retracted by proximally retracting the drive element **204**, such as via the handle **202**. The retraction of the distal arm **104** may clip tissue between the distal and proximal arms **104**, **110**. In some embodiments, before the tissue clipping assembly **102** is moved to the locked position, the tissue clipping assembly **102** may be proximally retracted to the set position shown in FIGS. **29**A-**29**B such that the operator may confirm the tissue clipping assembly **102** is properly clipping tissue. The tissue clipping assembly **102** may be moved to the closed and locked positions by proximally retracting the distal arm **104** via the drive element **204** such that the locking projections **130** are moved into the receiving portions **136**. The disposition of the locking projections **130** in the receiving portions **136** may secure the position of the distal arm **104** in the closed position relative to the collar **120**. In some embodiments, the distal arm **104**, such as the housing **154**, may shroud the proximal arm **110** to prevent trauma to tissue. The distal tine **112** may be closed relative to the proximal arm **110**. In some embodiments, the distal arm **104** linearly overlaps with the proximal arm **110** to clip tissue in the closed position. In some embodiments, the distal arm **104** is operable to recruit tissue into the collar **120** when the tissue clipping assembly **102** is moved to the closed position.

As shown in FIG. **32**, the tissue clipping assembly **102** may be decoupled from the drive assembly **200** such as to deploy the tissue clipping assembly **102** in the closed clipping position in the tissue. After the tissue clipping assembly **102** has been moved to the closed and locked positions, the drive element **204** may be proximally retracted with sufficient force to decouple the distal arm **104** from the drive element **204**. The drive element **204** may be retracted further such that the drive element **204** abuts the distal end of the alignment spacer **236**. The drive element **204** may be proximally retracted with sufficient force such that the alignment spacer **236** is pulled proximally from its position maintaining the coupling between the collar **120** and the connector **216**. The connector **216** may then be decoupled from the collar **120**, such as via maneuvering the catheter **212**. With the tissue clipping assembly **102** decoupled from the drive assembly **200**, the tissue clipping assembly **102** may be deployed in the body such that the tissue clipping assembly **102** continues to clip tissue. The drive assembly **200** may then be withdrawn from the body. In some embodiments, the tissue clipping assembly **102** deployed in the body to clip tissue has a length between about 5.0 mm and about 30.0 mm, such as between about 10.0 mm and about 20.0 mm, such as about 14 mm. For example, the tissue clipping assembly **102** may have a length which reduces abrasion of surrounding tissue and premature dislodgement of the tissue clipping assembly **102** when the tissue clipping assembly **102** is deployed.

While the alignment spacer **236** has been described as being a singular component with a drive passage **238** with a proximal portion **238***a* and a distal portion **238***b*, it will be understood that the tissue clipping device **100** may have other assemblies and configurations. For example, as shown in FIG. **33**, the tissue clipping assembly **102** may include a first alignment spacer operable to limit the linear extension of the proximal portion **206** of the drive element **204** and a second alignment spacer operable to control the orientation of the distal portion **208** of the drive element **204** and to abut the distal end of the drive element **204** as the drive element is retracted. However, the inclusion of a single alignment spacer **236** as described above may allow the tissue clipping device **100**, the tissue clipping assembly **102**, and/or the drive assembly **200** to have a smaller profile.

In some embodiments, as shown in FIGS. **33**A-**33**C, the proximal arm **110** may be pivotable about the distal end of the collar **120**. The proximal end of the proximal arm **110** may be coupled with a drive element **204** which may open and close the proximal arm **110** via linear extension and retraction of the drive element **204**. For example, the proximal arm **110** may be opened when the tissue clipping assembly **102** is placed in position relative to the target tissue and the proximal arm **110** may be close to grasp tissue on one side of the target tissue.

The proximal arm **110** may be decoupled from the drive element **204**, such as after the tissue clipping assembly **102** has been moved to the closed position. For example, the proximal arm **110** may be pivotably coupled with the distal end of the drive element **204** via a pin or link such that the proximal arm **110** may pivot about the link and which breaks under a predetermined force to decouple the proximal arm **110** from the drive element **204**. In other embodiments, the drive element **204** coupled to the proximal arm **110** may be decoupled from the drive element **204** in any of the manners described above. The position of the proximal arm **110** may be fixed relative to the collar **120**, such as described above.

In some embodiments, the tissue clipping device **100**, such as the tissue clipping assembly **102** and/or the drive assembly **200**, may include markings or other indicia to assist operators in positioning and operating the tissue clipping device **100**. For example, the collar **120** may include one or more indicia indicative of an orientation of the tissue clipping device **100**. Additionally, the connector **216** may also include one or more indicia indicative of an orientation of the tissue clipping device **100**. For example, one or more of the indicia of the collar **120** and the connector **216** may be arrows indicative of the extension direction of the distal arm **104** and one or more indicia of the collar **120** may be arrows indicating the orientation of the device **100** such that the tissue clipping assembly **102** is properly oriented to clip tissue. In some embodiments, the collar **120** also includes indicia or other markings that aid in the assembly and/or manufacture of the tissue clipping device **100**.

The tissue clipping device **100** may be operable with multiple tissue clipping assemblies **102**, such as to clip multiple tissue locations. After a first tissue clipping assembly **102** is deployed to clip tissue, a second tissue clipping assembly **102** may be coupled to the drive assembly **200** such that the drive assembly **200** may deploy the second tissue clipping assembly **102** to clip tissue. The second tissue clipping assembly **102** may be substantially similar to the first tissue clipping assembly **102** or may have a different size, shape, or configuration, such as based upon differences in tissue deployment location. The deployment of multiple tissue clipping assemblies **102** may permit the tissue clipping device **100** to close larger defects or lesions than conventional recruiting devices and hemostatic clips. For example, the device **100** may be used to clip elongated sections of tissue, such as elongated or oval lesions, using multiple tissue clipping assemblies **102**.

Referring now to FIGS. **34**A-**34**D, the tissue clipping device **100** may be operable to deploy multiple tissue clipping assemblies **102** to clip target tissue, such as to close an elongated defect.

As shown in FIG. **34**A, after the target tissue, such as the defect, in a body has been identified, the endoscope and/or the tissue clipping device **100** may be positioned above and facing toward the tissue. The device **100** may be positioned on a first side of the target tissue and at one end of the target tissue. The tissue clipping device **100** includes a first tissue clipping assembly **102***a* coupled to the drive assembly **200**. The first tissue clipping assembly **102***a* includes a first distal arm **104***a* and a first proximal arm **110***a*. The first distal arm **104***a* may be linearly extended across the width of the tissue past the second side of the target tissue opposite the first side. The device **100** may be operated to grasp tissue at the second side of the tissue with the first distal arm **104***a* and to grasp tissue at the first side of the tissue with the first proximal arm **110***a*. The device **100** may then be operated to clip the sides of the tissue with the distal and proximal arms **104***a*, **110***a*, as described above.

While the tissue clipping device **100** has been described as clipping two opposing sides of a defect together, it will be understood that the device **100** may be used in other manners. For example, the distal arm **104** may be extended to recruit tissue from the center of a defect to the proximal arm **110** positioned at a side of the defect. The device **100** may then clip half of the defect, such as to create two more manageable defects. The device **100** may be used to further close the defect, such as with additional tissue clipping assemblies **102**, or a hemostatic closure mechanism may be deployed to close the defect.

As shown in FIG. **34**B, the drive assembly **200** may be decoupled from the first tissue clipping assembly **102***a*, the drive assembly **200** may be withdrawn from the body, and the tissue clipping device **100** may be reloaded with a second tissue clipping assembly **102***b*. The collar **120** of the second tissue clipping assembly **102***b* may be coupled to the distal end of the connector **216** and the distal arm **104***b* of the second tissue clipping assembly **102***b* may be coupled drive element **204**, as described above. For example, the operator may reach through the slots **244** of the connector **216** to reset the alignment spacer **236** to the operational position to maintain the coupling between the connector **216** and the collar **120** of the second tissue clipping assembly **102**.

The tissue clipping device **100** may be reinserted into the body, such as through the endoscope, and positioned above and facing toward the target tissue at a position spaced apart from the first tissue clipping assembly **102***a*. The device **100** may then be operated to clip the sides of the tissue with the distal and proximal arms **104***b*, **110***b* of the second tissue clipping assembly **102***b*. The second tissue clipping assembly **102***b* may be positioned such that the target tissue is substantially clipped or otherwise closed between the first and second tissue clipping assemblies **102***a*, **102***b*.

As shown in FIG. **34**C, the drive assembly **200** may be decoupled from the second tissue clipping assembly **102***b*, the drive assembly **200** may be withdrawn from the body, and the tissue clipping device **100** may be reloaded with a third tissue clipping assembly **102***c*. The tissue clipping device **100** may be reinserted into the body, such as through the endoscope, and positioned above and facing toward the target tissue at a position spaced apart from the second tissue clipping assembly **102***b* on an opposite side of the first tissue clipping assembly **102***a*, such as at the other end of the target tissue. The device **100** may then be operated to clip the sides of the tissue with the distal and proximal arms **104***c*, **110***c* of the third tissue clipping assembly **102***c*. The third tissue clipping assembly **102***c* may be positioned such that the target tissue is substantially clipped or otherwise closed between the second and third tissue clipping assemblies **102***b*, **102***c*.

As shown in FIG. **34**D, the drive assembly **200** may be decoupled from the third tissue clipping assembly **102***c* and withdrawn from the body. The tissue clipping assemblies **102***a*, **102***b*, **102***c* may be deployed to clip the first and second sides of the target tissue along the length of the target tissue. The tissue clipping assemblies **102** may be deployed to substantially close the length of the target tissue, such as to close a defect which would conventionally require more clips to close.

In the illustrated embodiment, the tissue clipping device **100** is operated to deploy three tissue clipping assemblies **102***a*, **102***b*, **102***c* to clip together an elongated section of tissue. However, it will be understood that the tissue clipping method shown in FIGS. **34**A-**34**D is merely an illustrative example. For example, the tissue clipping device **100** may be used with one, two, or four or more tissue clipping assemblies **102** to clip together a section of tissue.

FIG. **35** illustrates an exemplary methodology **400** relating to clipping tissue, such as to close a defect. While the methodology is shown as being a series of acts that are performed in a sequence, it is to be understood and appreciated that the methodology is not limited by the order of the sequence. For example, some acts can occur concurrently with another act. Further, in some instances, not all acts may be required to implement the methodology described herein.

At step **402**, a clipping device is positioned above target tissue, such as a defect. The tissue may be identified using one or more cameras operably connected to an endoscope. The clipping device may include a tissue clipping assembly that is positioned above the target tissue. The tissue clipping assembly may be coupled to a drive assembly such that a user may control the position and rotation of the tissue clipping assembly. The tissue clipping assembly and portions of the drive assembly may be extended through an endoscope to the desired location.

At step **404**, a distal arm of the tissue clipping assembly is extended beyond a first tissue location, such as beyond a first side of the identified defect. The distal arm may be extended from a distal end of the endoscope and a distal end of a catheter of the drive assembly. The distal arm may be extended via a drive element, such as via a handle, to linearly translate and rotate the distal arm beyond the first tissue location. The distal arm may be extended such that a grasping portion of the distal arm is positioned linearly beyond (e.g., distally to) the tissue at the first location. The distal arm, such as the grasping portion of the distal arm, may be inserted into the tissue at the first location to graspingly secure the tissue at the first location.

In some embodiments, one or more tines of the distal arm are oriented to face and grasp the tissue at the first location. The orientation of the tines may be achieved using one or more indicia, such as arrows on the clip to indicate the top of the tissue clipping device.

In some embodiments, the tissue at the first location may be pulled or dragged proximally toward a second tissue location by proximally retracting the endoscope and/or catheter of the drive assembly without actuating the tissue clipping device. This may permit the tissue clipping device to close defects larger than an actual opening of the tissue clipping device.

At step **406**, a proximal arm of the tissue clipping device is placed on tissue at a second location. The second location may be substantially proximal to the first location, such as a second side of the defect opposite the first side of the defect. The proximal arm may be positioned at the second location via the catheter. The proximal arm may be inserted into the tissue at the second location to graspingly secure the tissue at the second location. In some embodiments, one or more tines of the proximal arm are oriented to face and grasp the tissue at the second location. In some embodiments, the proximal arm is fixedly attached to a collar of the tissue clipping assembly.

At step **408**, the distal arm is retracted toward the proximal arm. The distal arm may be linearly retracted toward the proximal arm such that the tissue grasped by the distal arm at the first location is pulled toward the tissue grasped by the proximal arm at the second location. In some embodiments, the proximal arm remains fixed in position at the second location. Optionally, if it is determined that the tissue is not grasped properly, the distal arm and/or the proximal arm may be maneuvered to release the tissue such that tissue may be regrasped.

At step **410**, tissue is clipped between the proximal and distal arms. The distal arm may be retracted toward the proximal arm such that the tissue grasped at the first location is substantially adjacent to the tissue grasped at the second location. The distal arm may be retracted such that the distal arm substantially abuts the proximal arm to clip the tissue between the distal arm and the proximal arm. For example, the retraction of the distal arm grasping tissue at a first side of a defect toward the proximal arm grasping tissue at a second side of the defect may substantially close the defect. The distal arm may be retracted toward the proximal arm such that the tissue clipping assembly is moved to a closed position, as described above. In some embodiments, tissue recruited by the distal arm is disposed in the collar when the tissue is clipped between the proximal and distal arms.

At step **412**, the distal arm is secured relative to the other components of the tissue clipping assembly. The distal arm may be secured in position to maintain the tissue clipping assembly in the closed position such that the tissue clipping assembly keeps the tissue clipped. In some embodiments, the distal arm includes one or more tabs which are lockingly received in the collar of the tissue clipping assembly to secure the position of the distal arm in the collar. The proximal arm may be integral with the collar.

At step **414**, the tissue clipping assembly may be decoupled from the drive assembly, such as to deploy the tissue clipping assembly in the body, such as to maintain the clipping of the tissue. The distal arm may be decoupled from the drive element and the collar may be decoupled from the catheter to decouple the tissue clipping assembly from the drive assembly. The distal arm may be decoupled from the drive element via continued proximal retraction of the drive element. For example, the distal arm may be operably coupled to the distal end of the drive element via a coupler or coupling projection that decouples the distal arm from the drive element when the distal arm is in the closed position and the drive element is proximally retracted, as described above. The collar may also be decoupled from the catheter via continued proximal retraction of the drive element, as described above. After the tissue clipping assembly is decoupled from the drive assembly, the tissue clipping assembly may remain in the body to continue to clip the tissue and the drive assembly may be withdrawn from the body. The endoscope may also be withdrawn from the body.

In some embodiments, the distal end of the catheter is coupled with a connector that operably couples the catheter to the proximal end of the collar. During operation, and alignment spacer may be disposed within the coupling between the collar and the connector, such as in abutment with the connecting portions of the collar and the connector, such that the alignment spacer maintains the coupling between the collar and the connector, as described above. When the distal arm is in the closed position, further proximal retraction of the drive element may move the alignment spacer such that the alignment member no longer maintains the coupling of the collar and the connector such that the collar may be decoupled from the catheter.

As described above, the drive element may have a proximal portion with a narrower cross section than a distal portion of the drive element. The proximal portion may operably be coupled to the distal arm during operation, such as to linearly translate the distal arm. After the tissue clipping assembly has been moved to the closed position, such as to clip tissue, the drive element may be proximally retracted such that the distal end of the drive element decouples from the distal arm and the proximal portion of the drive wire is retracted from the alignment spacer. Further proximal retraction of the drive element may cause a distal end of the drive element to abut or otherwise contact an alignment spacer. Proximal retraction of the drive element may pull the alignment spacer proximally such that the alignment spacer no longer maintains the coupling of the collar and the connector such that the collar may be decoupled from the connector.

At step **416**, a second tissue clipping assembly may optionally be attached to the drive assembly. The second tissue assembly may be substantially similar to the first tissue clipping assembly. The drive element of the drive assembly may be coupled with the distal arm of the second tissue clipping assembly and the catheter may be coupled with a collar of the tissue clipping assembly such that the tissue clipping assembly may be maneuvered by the drive assembly, as described above.

At step **418**, the second tissue clipping assembly may be deployed via the drive assembly to clip tissue at a second location. Steps **402** through **414** may be repeated with the second tissue clipping assembly to deploy the second issue clipping assembly. In some embodiments, the second tissue clipping assembly is deployed substantially parallel to the first tissue clipping assembly to clip tissue adjacent and/or parallel to the tissue clipped by the first tissue clipping assembly. For example, the second tissue clipping assembly may clip tissue across a width of the identified defect at a location spaced apart from the first tissue clipping assembly to clip tissue along a length of a larger defect.

Steps **416** and **418** may be repeated with additional tissue clipping assemblies as desired. For example, additional tissue clipping assembly or assemblies may be deployed in line with and spaced apart from the first and second tissue clipping assemblies, such as to close larger defects. The additional tissue clipping assemblies may be deployed to clip tissue across a width of the identified defect at a location spaced apart from the first and second tissue clipping assemblies to clip tissue along the length of a larger defect.

It is to be understood that the detailed description is intended to be illustrative, and not limiting to the embodiments described. Other embodiments will be apparent to those of skill in the art upon reading and understanding the above description. Moreover, in some instances, elements described with one embodiment may be readily adapted for use with other embodiments. Therefore, any products, methods and/or systems described herein are not limited to the specific details, the representative embodiments, and/or the illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of the general aspects of the present disclosure.

Additionally, the components and materials described hereinafter as making up the various embodiments are intended to be illustrative and not restrictive. It should be appreciated that many suitable components and materials that would perform the same or a similar function as the materials described herein are intended to be embraced within the scope of embodiments of the present disclosure.

We claim:

1. A medical device for clipping tissue, the device comprising:

a catheter;

a collar having a proximal arm extending in a distal direction, a proximal end of the collar being coupled with a distal end of the catheter;

a distal arm having an extension portion and a grasping portion; and

a drive element extending through the catheter and coupled with the distal arm;

wherein the drive element is operable to linearly translate the distal arm through the collar; and

wherein the medical device is operable to clip tissue between the proximal arm and the distal arm by linearly retracting the distal arm toward the proximal arm.

2. The medical device of claim **1**, wherein the distal arm has a distal tine with a tip and barbs configured to grasp tissue.

3. The medical device of claim **1**, wherein the proximal arm has a proximal tine with a tip and barbs configured to grasp tissue.

4. The medical device of claim 1, wherein the proximal arm is fixed to the collar.

5. The medical device of claim 1, wherein the distal arm includes a locking projection configured to be received in a receiving portion of the collar to lock the distal arm in a closed position.

6. The medical device of claim 1, wherein distal arm includes a housing configured to shroud the proximal arm when the tissue clipping device is in a closed position.

7. The medical device of claim 1, wherein the proximal arm is pivotable about the collar.

8. A medical device for clipping tissue, the device comprising:
- a tissue clipping assembly operable to clip tissue, the tissue clipping assembly comprising:
  - a distal arm;
  - a collar; and
  - a proximal arm;
- a drive assembly operable to actuate the tissue clipping assembly, the drive assembly comprising:
  - a handle;
  - a catheter; and
  - a drive element with a proximal end secured to the handle and a distal end operably coupled with a proximal end of the distal arm; and
- wherein the drive element is operable to linearly translate the distal arm to clip tissue between the distal arm and the proximal arm; and
- wherein the tissue clipping assembly is operably decoupled from the drive assembly after the tissue clipping assembly has clipped tissue.

9. The medical device of claim 8, wherein the drive element has a proximal portion extending through the catheter and a distal portion coupled with the distal arm, wherein the distal portion has a rectangular cross section.

10. The medical device of claim 8, wherein the distal arm includes a coupling projection configured to releasably couple the distal arm with the drive element.

11. The medical device of claim 8, wherein the drive assembly further comprises a coupler operable to couple the drive element with the distal arm.

12. The medical device of claim 8, wherein the drive assembly further comprises a connector operable to couple the catheter with the collar.

13. The medical device of claim 12, wherein the drive assembly further comprises an alignment spacer operable to maintain the coupling of the connector and the collar.

14. The medical device of claim 8, wherein the distal arm is decoupled from the drive element and the collar is decoupled from the catheter by proximal retraction of the drive element.

15. A method for treating a defect with a tissue recruiting device, the method comprising the steps of:
- positioning a tissue clipping assembly above the defect;
- linearly extending a distal arm of the tissue clipping assembly to grasp a first side of the defect via a drive assembly;
- grasping a second side of the defect with a proximal arm of the tissue clipping assembly;
- retracting the distal arm toward the proximal arm;
- clipping tissue between the distal and proximal arms; and
- decoupling the tissue clipping assembly from the drive assembly.

16. The method of claim 15, further comprising the step of locking the distal arm in a collar of the tissue clipping assembly.

17. The method of claim 15, wherein the distal arm is coupled to a handle of the drive assembly by a drive element.

18. The method of claim 17, wherein the distal arm is coupled with the drive element via a coupler.

19. The method of claim 15, wherein the collar is operably coupled to a catheter and the collar is decoupled from the catheter by proximal retraction of the drive element.

20. The method of claim 15, further comprising the step of attaching a second tissue clipping assembly to the drive assembly.

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