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(54) Title: SYSTEMS FOR ENDOSCOPIC SUBMUCOSAL DISSECTION

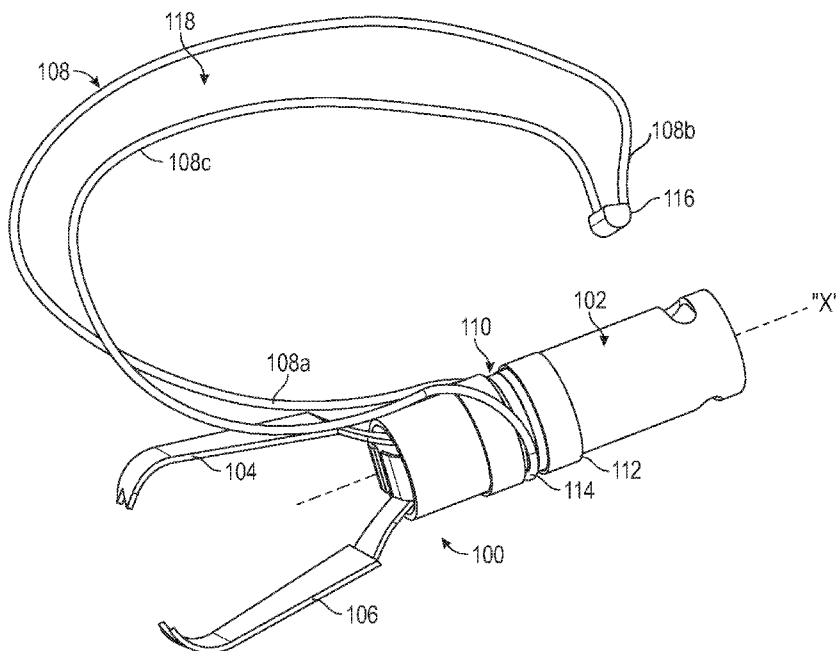


FIG. 2

(57) Abstract: A tissue clip includes an elongate body configured to be detachably coupled to a shaft of a surgical instrument, a pair of jaw members received in the elongate body, and a resilient member configured to bow outwardly from the elongate body upon deployment of the tissue clip at a surgical site.

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

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SYSTEMS FOR ENDOSCOPIC SUBMUCOSAL DISSECTION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of and priority to U.S. Provisional Application No. 62/880,287, filed on July 30, 2019, the entire contents of which being incorporated by reference herein.

FIELD

[0002] The present technology is related generally to tissue clips used in endoscopic submucosal dissection.

BACKGROUND

[0003] Endoscopic resection has been accepted as a first choice of the treatment for early stage GI carcinomas because of less invasiveness and lower cost. Endoscopic submucosal resection (ESD) allows for an en bloc resection and accurate histopathological diagnosis regardless of the size, an existence of severe fibrosis at submucosal layer, and location of a lesion. One of the benefits of ESD is lower recurrence rates compared to endoscopic mucosal resection. During some ESD's, jaw members of a tissue clip are engaged to tissue. After performing the dissection, the jaw members are disengaged from the tissue.

SUMMARY

[0004] In one aspect, the present disclosure provides a tissue clip including a proximal body portion, first and second jaw members coupled to the proximal body portion, and a resilient member. The jaw members are configured to move between an open configuration and a closed configuration to grasp tissue therebetween. The resilient member is coupled to the proximal body portion or one of the first or second jaw members. The resilient member includes a segment that is laterally spaced from the proximal body portion when the resilient member is in a deployed state.

[0005] In aspects, the resilient member may be transitionable between a stored state and the deployed state.

[0006] In aspects, the segment of the resilient member may assume a linear shape when the resilient member is in the stored state, and the segment of the resilient member may assume an arcuate shape when the resilient member is in the deployed state.

[0007] In aspects, the segment of the resilient member may bow outwardly from the proximal body portion when the resilient member is in the deployed state.

[0008] In aspects, the resilient member may include a first end portion coupled to the proximal body portion and extending distally therefrom, and a second end portion extending from the segment. The segment may curve proximally and laterally from the first end portion.

[0009] In aspects, the second end portion may curve toward the proximal body portion.

[00010] In aspects, the second end portion may be disposed proximally of the first end portion.

[00011] In aspects, the resilient member may be configured to assume a looped configuration when in the deployed state.

[00012] In aspects, the resilient member may include a wire having a predefined shape.

[00013] In aspects, the resilient member may have a first end portion rotationally coupled to the proximal body portion, and a second end portion. The resilient member may be rotatable between a first position, in which the second end portion is disposed on a first side of the proximal body portion, and at least one second position, in which the second end portion is disposed on a second side of the proximal body portion.

[00014] In aspects, the proximal body portion may define an annular recess having the first end portion of the resilient member slidably received therein.

[00015] In aspects, the resilient member may include a wire wrapped about the proximal body portion.

[00016] In aspects, the first jaw member may define a pair of holes therethrough, and the resilient member may be attached to the first jaw member via the pair of holes.

[00017] In aspects, the resilient member may include first and second wires defining a gap therebetween.

[00018] In aspects, the gap may be greater than a diameter of the proximal body portion.

[00019] In another aspect of the disclosure, a method of performing an endoscopic submucosal dissection is provided. The method includes deploying a tissue clip; approximating a pair of jaw members of the tissue clip about tissue; and deploying a resilient member of the tissue clip, whereby the resilient member bows outwardly from a proximal body portion of the tissue clip to separate the grasped tissue from a gastric wall.

[00020] In aspects, the method may include rotating the resilient member about the proximal body portion to reposition the resilient member relative to the grasped tissue.

[00021] In aspects, deploying the resilient member may include transitioning the resilient member from a linear shape to an arcuate shape.

[00022] In aspects, the method may include dissecting the grasped tissue from the muscle layer while the tissue is maintained in spaced relation from the muscle layer by the resilient member.

[00023] In aspects, the method may include positioning the resilient member between the tissue and the muscle layer.

[00024] In aspects, the resilient member may assume a looped configuration after being deployed.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] Objects and features of the presently disclosed tissue clips will become apparent to those of ordinary skill in the art when descriptions of various embodiments thereof are read with reference to the accompanying drawings, of which:

[00026] FIG. 1 is a top view illustrating an exemplary embodiment of a hand-held surgical instrument;

[00027] FIG. 2 is a side perspective view illustrating a tissue clip for operation by the surgical instrument of FIG. 1;

[00028] FIG. 3 is a top view of another embodiment of a tissue clip illustrated in a stored state within a sheath of the surgical instrument of FIG. 1;

[00029] FIG. 4 is a side perspective view of the tissue clip of FIG. 3 illustrated in a deployed state; and

[00030] FIG. 5 is a perspective view illustrating yet another embodiment of a surgical tissue clip shown without a resilient member.

DETAILED DESCRIPTION

[00031] The present disclosure is generally directed to tissue clips including an elongate body, a pair of jaw members received in the elongate body and deployable therefrom, and a resilient member coupled to the jaw members or the elongate body. The resilient member is configured to assume a predefined, curved shape upon deployment of the tissue clip at a surgical site. During use, target tissue (e.g., a lesion) is grasped between the jaw members and the resilient member, in the deployed state, engages a gastric wall to separate the lesion from the gastric wall. With the resilient member maintaining the lesion in spaced relation from the gastric wall, the lesion may be dissected. In aspects, the resilient member may be swivelable about the elongate body to adjust a position thereof. These and other aspects of the present disclosure are described in greater detail below.

[00032] FIG. 1 illustrates a hand-held surgical instrument 10 for deploying a tissue clip 100 (FIG. 2). The surgical instrument 10 generally includes a handle 11, a shaft 12 extending distally from the handle 11, and a tissue clip 100 detachably coupled to a distal end portion 14 of the shaft 12. In some aspects, instead of the clip 100 being deployable from a hand-held instrument, the clip 100 may be deployed from a surgical robotic arm.

[00033] The surgical instrument 10 includes an actuation mechanism, such as, for example, a puller (not shown) axially movable within the shaft 12. The puller may have a proximal end operably coupled to a trigger 16 of the handle 11, such that an actuation of the trigger 16 proximally translates the puller. The puller may have a distal end detachably coupled to the tissue clip 100, such that proximal translation of the puller moves the tissue clip 100 from an open configuration to a closed configuration, as will be described. It is contemplated that the surgical instrument 10 may include any suitable actuation mechanism for deploying the tissue clip 100.

[00034] With reference to FIG. 2, the tissue clip 100 has a proximal body portion 102, such as, for example, a tubular body, first and second jaw members 104, 106 received in the proximal body portion 102, and a resilient member 108 coupled to the proximal body portion 102. The proximal body portion 102 is configured to be detachably coupled to the distal end 14 of the shaft 12. In aspects, the shaft 12 may have a release latch (not shown) coupled to the proximal body portion 102 and an actuation mechanism (e.g., a pull rod, not shown) for actuating the release latch to deploy the tissue clip 100 from the shaft 12.

[00035] The first and second jaw members 104, 106 are each coupled to the proximal body portion 102. Each of the first and second jaw members 104, 106 has a proximal end portion slidably received in a hollow interior of the proximal body portion 102, and a distal end portion disposed distally of the proximal body portion 102. The distal end portion of the jaw members 104, 106 may define teeth for assisting in grasping tissue between the jaw members 104, 106. The jaw members 104, 106 may be resiliently biased toward an open configuration by a biasing member (not shown). Alternately, the jaw members 104, 106 may be devoid of a resilient bias. The jaw members 104, 106 are axially movable relative to the proximal body portion 102 from a proximal position, in which the distal end portion of the jaw members 104, 106 are approximated toward one another, and a distal position, in which the distal end portion of the jaw members 104, 106 are spaced away from one another.

[00036] The resilient member 108 of the tissue clip 100 is fabricated from a shape memory material, such as, for example, copper-aluminium-nickel or nickel-titanium. In some aspects, the resilient member 108 may be fabricated from any suitable material configured to maintain

a predefined shape. The resilient member 108 is fabricated from a wire that is folded over itself, with the folded end 114 formed into a loop to form a first end portion 108a of the resilient member 108, and the loose ends 116 of the wire being crimped together to form a second end portion 108b of the resilient member 108. The two folded portions of the wire may define a gap or aperture 118 therebetween. By spacing the two folded portions of the wire, an intermediate segment 108c of the resilient member 108 is more suitable for supporting tissue thereon. In some aspects, instead of fabricating the resilient member 108 from a folded wire, the resilient member 108 may be a thin, elongated sheet of resilient material. Other constructions of the resilient member 108 are also contemplated

[00037] The first end portion 108a of the resilient member 108 is rotationally supported on the proximal body portion 102. Specifically, the proximal body portion 102 defines an annular recess 110 having the first end portion 108a of the resilient member 108 slidably received therein. The first end portion 108a of the resilient member 108 is wrapped about the proximal body portion 102 and slidably received in the annular recess 110. As such, with the first end portion 108a of the resilient member 108 slidably received in the annular recess 110, the first end portion 108a is free to rotate about a longitudinal axis “X” defined by the proximal body portion 102 while being axially restrained to the proximal body portion 102.

[00038] The resilient member 108 assumes a looped configuration when in the deployed state. In particular, the first end portion 108a of the resilient member 108 extends distally from the annular recess 110 of the proximal body portion 102 and has a generally upwardly curved configuration. In aspects, the tissue clip 100 may have a collar 112 that clips onto the proximal body portion 102 and over the first end portion 108a of the resilient member 108 to hold the first end portion 108a in close relation with the proximal body portion 102. The intermediate segment 108c of the resilient member 108 extends from the first end portion 108a and curves laterally away from the longitudinal axis “X” of the proximal body portion 102 and in a generally proximal direction, such that in the deployed state, the intermediate segment 108c assumes an arcuate shape. The second end portion 108b of the resilient member 108 extends from the intermediate segment 108c and curves down toward the longitudinal axis “X” of the proximal body portion 102.

[00039] In use, with the tissue clip 100 coupled to the shaft 12 and the jaw members 104, 106 in the open configuration, the tissue clip 100 is positioned adjacent tissue (e.g., a lesion). The tissue is positioned between the jaw members 104, 106, whereupon the puller of the surgical instrument 10 retracts the jaw members 104, 106 proximally through the proximal body portion 102. An inner wall of the proximal body portion 102 acts on the jaw members

104, 106 to move the jaw members 104, 106 toward the closed configuration about the tissue. With the tissue grasped between the jaw members 104, 106, the puller is further retracted to detach the puller from the jaw members 104, 106, thereby releasing the proximal body portion 102 of the tissue clip 100 from the shaft 12 and leaving the tissue clip 100 at the surgical site. Other mechanisms for releasing the tissue clip 100 from the shaft 12 are also contemplated.

[00040] Upon releasing tissue clip 100 from the shaft 12, the resilient member 108 of the tissue clip 100 is allowed to transition from a stored state, in which the resilient member 108 is constrained within the shaft 12, to a deployed state. In the stored state, the resilient member 108 assumes a generally linear shape, and in the deployed state, the resilient member 108 moves toward its predefined, arcuate shape, in which the resilient member 108 bows outwardly from the proximal body portion 102.

[00041] After, during, or prior to grasping the tissue with the jaw members 104, 106, the resilient member 108 is positioned between the tissue and a muscle layer of a gastric wall, whereby the outward resilient bias of the resilient member 108 separates the grasped tissue from the gastric wall. To change an orientation of the resilient member 108 to better position the resilient member 108 between the grasped tissue and the gastric wall, the first end portion 108a of the resilient member 108 may be rotated about the proximal body portion 102. During rotation of the first end portion 108a, the intermediate segment 108c and the second end portion 108b is moved to a different side of the proximal body portion 102 until the desired orientation is achieved. With the tissue being maintained in spaced relation from the muscle layer by the resilient member 108, the grasped tissue may be dissected from the muscle layer.

[00042] FIGS. 3 and 4 illustrate another embodiment of a tissue clip 200 deployable from the surgical instrument 10. The tissue clip 200 is similar to tissue clip 100 and will only be described in detail to elucidate differences between the two clips. The tissue clip 200 includes a proximal body portion, such as, for example, a tubular body 202, first and second jaw member 204, 206 received in the proximal body portion 202, and a resilient member 208. The proximal body portion 202 is configured to be detachably coupled to the distal end 14 of the shaft 12. As shown in FIG. 3, the surgical instrument 10 may have a sheath 20 detachably coupled to the shaft 14 and configured to encapsulate the resilient member 208 to selectively maintain the resilient member 208 in a stored, linear state. The tissue clip 200 differs from the tissue clip 100 by having the resilient member 208 directly attached to the jaw member 204. In aspects, the resilient member 208 may be formed from a folded wire, or

in some aspects two discreet wires, having the folded end 210 non-rotatably fixed to the jaw member 204.

[00043] In aspects, the resilient member 208 consists of a single wire having two ends 208a, 208b that are attached to one another with a crimp 212. The jaw member 204 has a pair of holes 214a, 214b extending through a thickness thereof. Each of the holes 214a, 214b are spaced from one another a selected distance extending along a width of the jaw member 204. It is contemplated that the distance between the holes 214a, 214b in the jaw member 204 are selected so that two sections 209a, 209b of the single wire 208 are spaced from one another by a greater distance than the diameter of the tubular body 202 when deployed. In this way, upon the resilient member 208 engaging tissue, the resilient member 208 balances the tissue clip 200, thereby preventing the tissue clip 200 from rotating out of engagement with the tissue.

[00044] During manufacturing and/or assembly of the tissue clip 200, the two ends 208a, 208b of the single wire 208 are each respectively passed upwardly through the corresponding holes 214a, 214b in the jaw member 204 to establish a friction-fit engagement between the folded end 210 of the wire 208 and the jaw member 204. After passing the single wire/resilient member 208 through the holes 214a, 214b of the jaw member 204, the two ends 208a, 208b of the wire 208 are crimped together, thereby giving the resilient member 208 an enclosed loop shape. Attaching the resilient member 208 to the jaw member 204 via the holes 214a, 214b is a relatively cheap, easy, and effective means of coupling the resilient member 208 to the remainder of the tissue clip 200.

[00045] With reference to FIG. 5, another embodiment of a tissue clip 300 is illustrated. The tissue clip 300 is configured to be deployed from the surgical instrument 10 (FIG. 1) and is similar to tissue clip 200. The tissue clip 300 includes a pair of jaw members 302, 304 and a resilient member or wire 208 (FIG. 4) configured to be fixed to one of the jaw members 302, 304. Each of the jaw members 302, 304 has a body member 306 having a generally semi-hemispherical shape along a length thereof and a distal tip 308 that curves inwardly toward the other. Each of the jaw members 302, 304 has serrations 310 along the entire outer peripheral edge of the jaw members 302, 304 to assist with grasping tissue. The body member 306 of at least one of the jaw members 302 has a cutout 312 that forms a tab 314 and a pair of holes 312a, 312b for receipt of the resilient member 208 (FIG. 4).

[00046] During manufacturing and/or assembly of the surgical tissue clip 300, the tab 314 is bent outwardly and the folded end 210 of the resilient wire 208 is passed over the tab 314 and inserted into the holes 312a, 312b. The tab 314 is then folded down to capture the folded

end 210 of the resilient member 208 in the holes 312a, 312b. In this way, the opposing ends 208a, 208b (FIG. 4) of the resilient member 208 may be crimped before attaching the resilient member 208 to the jaw member 302.

[00047] It should be understood that various aspects disclosed herein may be combined in different combinations than the combinations specifically presented in the description and accompanying drawings. It should also be understood that, depending on the example, certain acts or events of any of the processes or methods described herein may be performed in a different sequence, may be added, merged, or left out altogether (e.g., all described acts or events may not be necessary to carry out the techniques).

WHAT IS CLAIMED IS:

1. A tissue clip, comprising:
a proximal body portion;
first and second jaw members coupled to the proximal body portion and configured to move between an open configuration and a closed configuration to grasp tissue therebetween;
and
a resilient member coupled to the proximal body portion or one of the first or second jaw members, the resilient member including a segment that is laterally spaced from the proximal body portion when the resilient member is in a deployed state.
2. The tissue clip according to claim 1, wherein the resilient member is transitionable between a stored state and the deployed state.
3. The tissue clip according to claim 2, wherein the segment of the resilient member assumes a linear shape when the resilient member is in the stored state, and the segment of the resilient member assumes an arcuate shape when the resilient member is in the deployed state.
4. The tissue clip according to claim 2, wherein the segment of the resilient member bows outwardly from the proximal body portion when the resilient member is in the deployed state.
5. The tissue clip according to claim 1, wherein the resilient member includes:
a first end portion coupled to the proximal body portion and extending distally therefrom, the segment curving proximally and laterally from the first end portion;
and
a second end portion extending from the segment.
6. The tissue clip according to claim 5, wherein the second end portion curves toward the proximal body portion.
7. The tissue clip according to claim 6, wherein the second end portion is disposed proximally of the first end portion.

8. The tissue clip according to claim 1, wherein the resilient member is configured to assume a looped configuration when in the deployed state.

9. The tissue clip according to claim 1, wherein the resilient member includes a wire having a predefined shape.

10. The tissue clip according to claim 1, wherein the resilient member has a first end portion rotationally coupled to the proximal body portion, and a second end portion, such that the resilient member is rotatable between a first position, in which the second end portion is disposed on a first side of the proximal body portion, and at least one second position, in which the second end portion is disposed on a second side of the proximal body portion.

11. The tissue clip according to claim 10, wherein the proximal body portion defines an annular recess having the first end portion of the resilient member slidably received therein.

12. The tissue clip according to claim 1, wherein the first jaw member defines a pair of holes therethrough, the resilient member being attached to the first jaw member via the pair of holes.

13. The tissue clip according to claim 1, wherein the resilient member includes first and second wires defining a gap therebetween.

14. The tissue clip according to claim 13, wherein the gap is greater than a diameter of the proximal body portion.

15. A method of performing an endoscopic submucosal dissection, comprising:
deploying a tissue clip;
approximating a pair of jaw members of the tissue clip about tissue; and
deploying a resilient member of the tissue clip, whereby the resilient member bows outwardly from a proximal body portion of the tissue clip to separate the grasped tissue from a gastric wall.

16. The method according to claim 15, further comprising rotating the resilient member about the proximal body portion to reposition the resilient member relative to the grasped tissue.

17. The method according to claim 15, wherein deploying the resilient member includes transitioning the resilient member from a linear shape to an arcuate shape.

18. The method according to claim 15, further comprising dissecting the grasped tissue from the muscle layer while the tissue is maintained in spaced relation from the muscle layer by the resilient member.

19. The method according to claim 15, further comprising positioning the resilient member between the tissue and the muscle layer.

20. The method according to claim 15, wherein the resilient member assumes a looped configuration after being deployed.

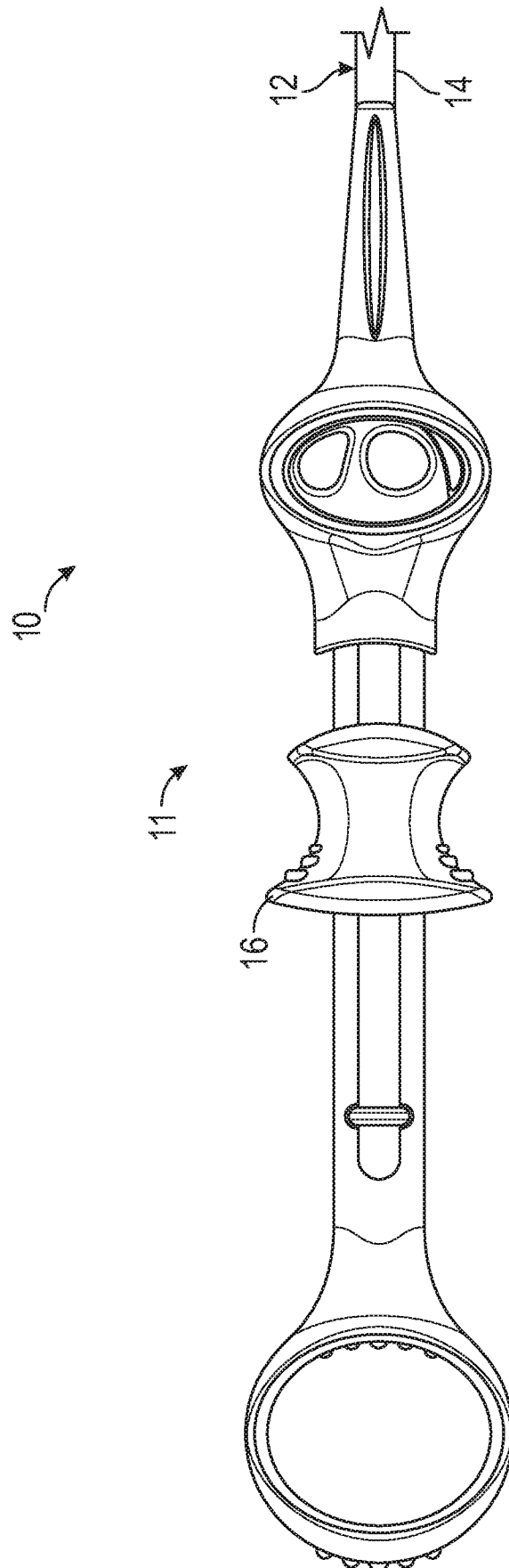


FIG. 1

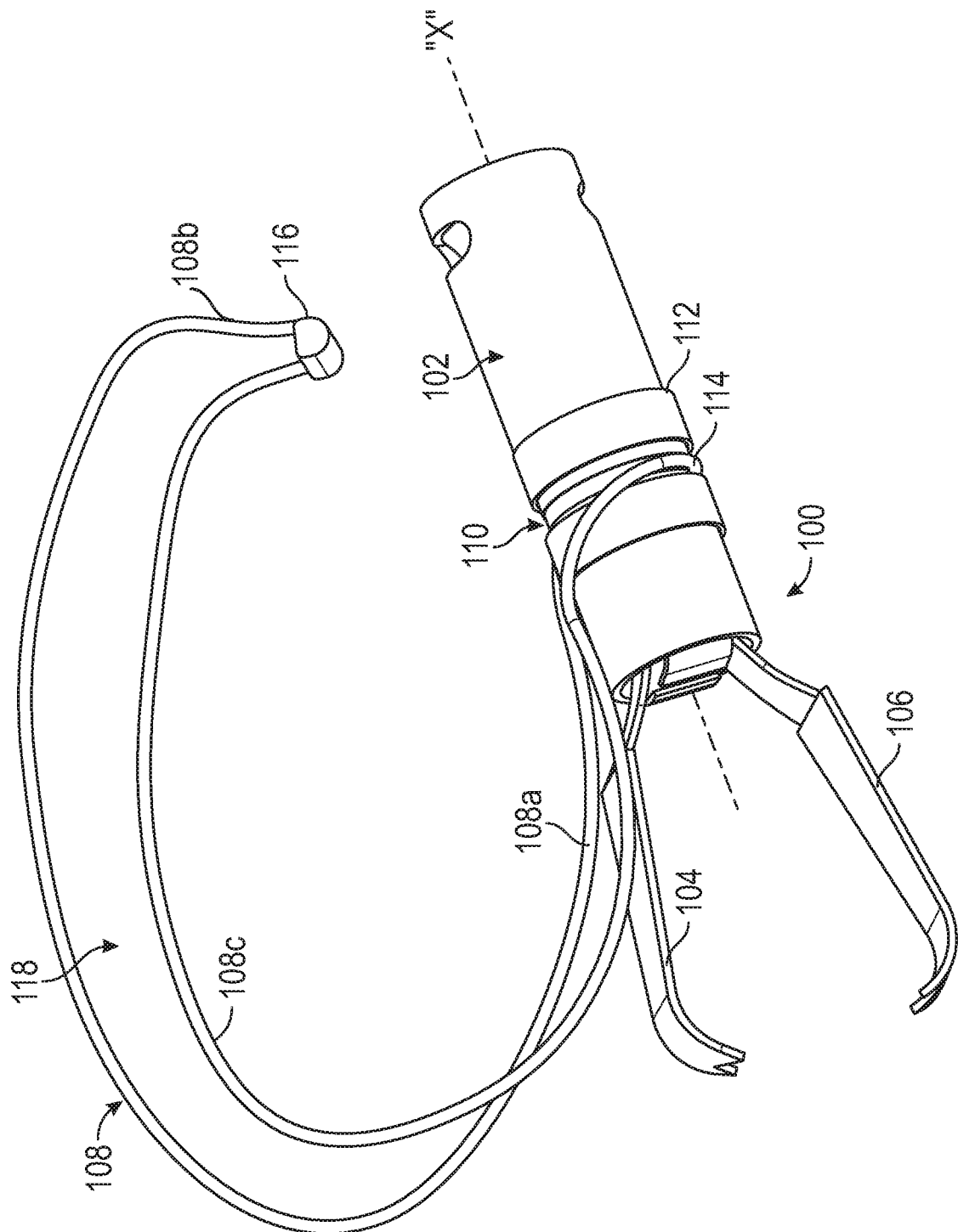


FIG. 2



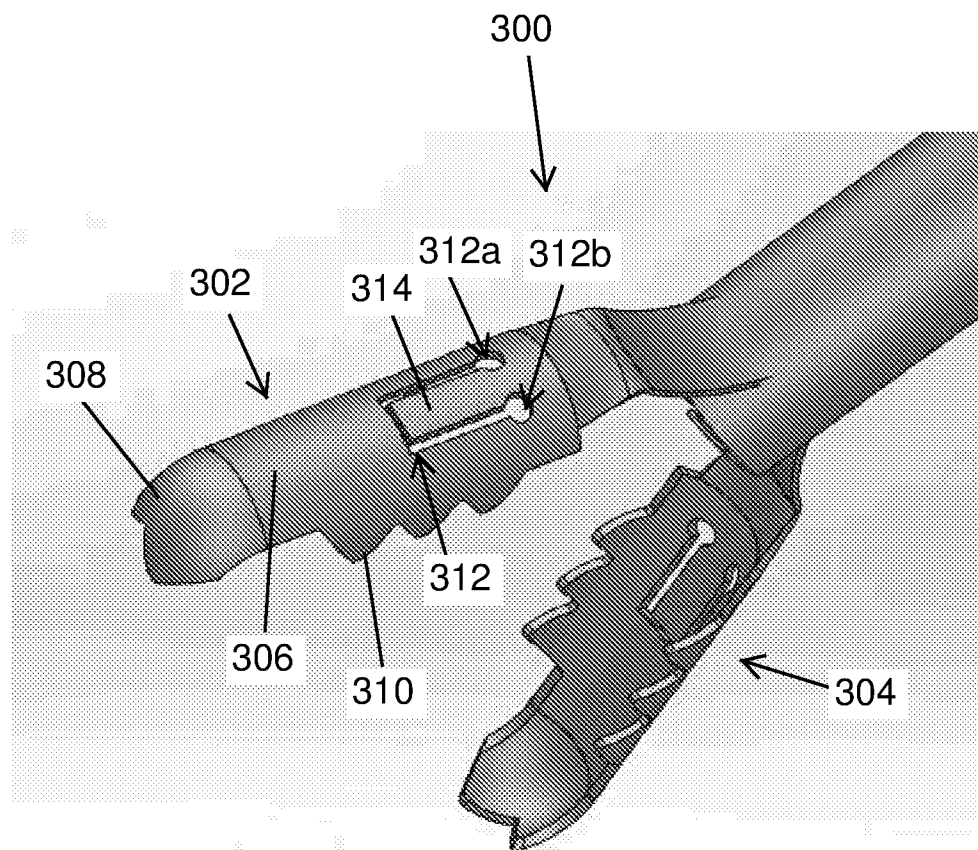


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/044157

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/08 A61B17/10 A61B17/122 A61B17/128 A61B90/00
A61B17/02
ADD. A61B17/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018/279869 A1 (WALES RYAN V [US] ET AL) 4 October 2018 (2018-10-04) paragraphs [0057] - [0065]; figures 9A-9G -----	1-4,8,9, 12-14
X	US 2019/216463 A1 (DOBASHI AKIRA [JP] ET AL) 18 July 2019 (2019-07-18) paragraphs [0077] - [0084]; figures 19, 20 -----	1-4, 8-10,13, 14
X	US 2018/035997 A1 (SMITH PAUL [US] ET AL) 8 February 2018 (2018-02-08) paragraphs [0054], [0055], [0132] - [0150]; figures 19A-25B -----	1,2,13, 14



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 October 2020

Date of mailing of the international search report

04/11/2020

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/044157

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15-20
because they relate to subject matter not required to be searched by this Authority, namely:
Pursuant to Article 17(2)(a)(i) PCT, this Authority is not required to search the subject-matter of claims 15-20, since the method of treating a patient as defined in claim 15 is a method for treatment of the human or animal body by therapy and surgery (Rule 39.1(iv)).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2020/044157

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