



(12) PATENTANSØGNING

Patent- og
Varemærkestyrelsen

(51) Int.Cl.⁸: **A 61 B 17/04 (2009.01)** **A 61 B 17/062 (2006.01)**

(21) Patentansøgning nr: **PA 2009 70073**

(22) Indleveringsdag: **2009-07-22**

(24) Løbedag: **2009-07-22**

(41) Alm. tilgængelig: **2011-01-23**

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(54) Benævnelse: **Suturing system and assembly**

(57) Sammendrag:

A suturing assembly configured to place suture in tissue includes a handle having an actuator, a shaft coupled to the handle, and a head coupled to the shaft. The head includes a proximal portion housing a needle movable through a needle exit port and a distal end spaced apart from the proximal portion by a throat, the distal end defining a cavity. The actuator is configured to move the needle out of the needle exit port formed in the proximal portion of the head and across the throat to engage a capsule disposed in the cavity formed in the distal end of the head, the capsule attached to the suture.

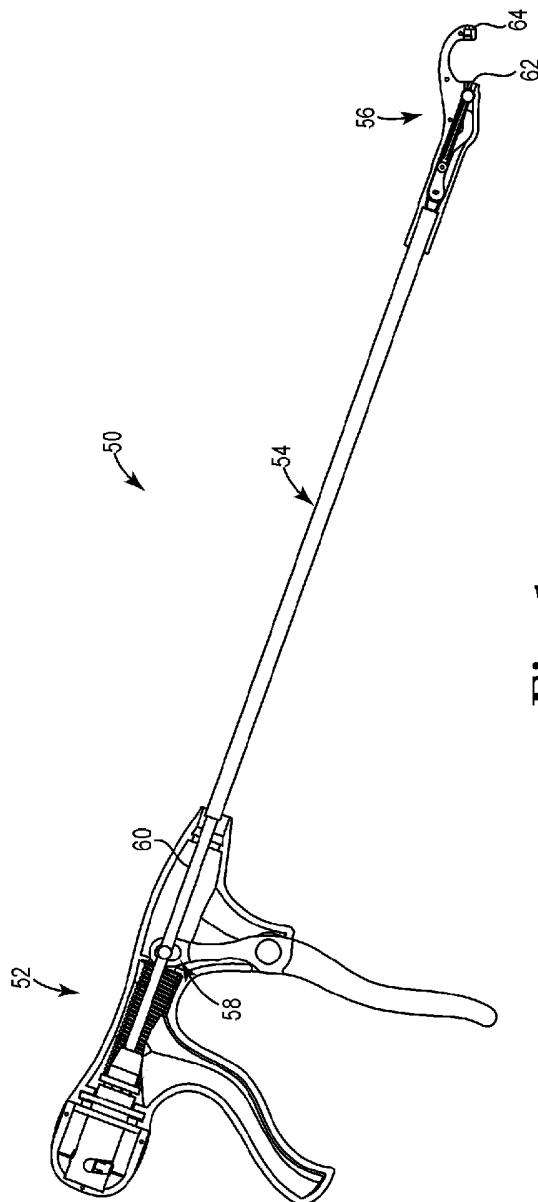


Fig. 1

WHAT IS CLAIMED IS:

1. A suturing assembly configured to place suture in tissue, the suturing assembly comprising:
 - a handle comprising an actuator;
 - a shaft coupled to the handle; and
 - a head coupled to the shaft, the head comprising a proximal portion housing a needle movable through a needle exit port and a distal end spaced apart from the proximal portion by a throat, the distal end defining a cavity;
wherein the actuator is configured to move the needle out of the needle exit port formed in the proximal portion of the head and across the throat to engage a capsule disposed in the cavity formed in the distal end of the head, the capsule attached to the suture.
2. The suturing assembly of claim 1, wherein the actuator comprises a trigger coupled to a rod disposed in the shaft, the rod extending between the handle and the needle.
3. The suturing assembly of claim 2, wherein the handle defines a major longitudinal axis and comprises a thumb brace integrally formed to extend laterally from the handle, and the trigger is spaced apart from the thumb brace and coupled to the handle at an angle of between 70-110 degrees relative to the longitudinal axis.
4. The suturing assembly of claim 2, wherein the handle defines a major longitudinal axis, and the trigger is coupled to the handle at an angle of between 0-10 degrees relative to the longitudinal axis.

5. The suturing assembly of claim 2, wherein the handle comprises a knob coupled to a proximal end portion of the handle that when turned is configured to retract the rod proximally.

6. The suturing assembly of claim 1, wherein the handle comprises an arcuate proximal end and a collar attached to the shaft, and the actuator comprises:

- a bias member disposed within the arcuate proximal end;
- a first geared rack attached between the collar and the bias member;
- a second geared rack attached to a push rod communicating with the needle;
- and
- a gear engaged between the first geared rack and the second geared rack.

7. The suturing assembly of claim 6, wherein the collar is movable toward the arcuate proximal end to move the push rod disposed within the shaft toward the head, and movement of the push rod moves the needle out of the needle exit port.

8. The suturing assembly of claim 1, wherein the handle comprises a grip and a squeezable member pinned to a distal end portion of the grip, the actuator comprising:

- a first gear disposed within the grip and communicating with a push rod disposed the shaft;
- a second gear disposed within the grip and communicating with the first gear; and
- the squeezable member comprising a geared rack engaged with the second gear;

wherein movement of the squeezable member toward the grip moves the geared rack to rotate the second gear, which rotates the first gear to translate the push rod proximally in the shaft, thus moving the needle out of the needle exit port.

9. The suturing assembly of claim 1, wherein the handle comprises:
 - a gear configured for uni-directional rotation;
 - a linkage coupled to a push rod extending between the needle and the gear;
 - a geared rack communicating with the gear; and
 - a trigger coupled to the geared rack;wherein the geared rack is configured to move longitudinally and radially away from the gear.
10. The suturing assembly of claim 9, wherein movement of the geared rack rotates the gear to move the linkage and the push rod and the needle relative to the shaft.
11. The suturing assembly of claim 9, wherein proximal movement of the geared rack disengages the geared rack from the gear, which retracts the geared rack proximally such that subsequent distal movement of the geared rack engages the geared rack with the gear, which rotates the gear to move the linkage and the push rod and the needle relative to the shaft.
12. The suturing assembly of claim 1, wherein the actuator comprises a trigger coupled to a rod disposed in the shaft, the rod extending between the handle and the needle, the handle comprising an indicator configured to indicate that the needle is movable from the needle exit port.
13. The suturing assembly of claim 1, wherein the shaft comprises a rigid shaft.
14. The suturing assembly of claim 1, wherein the shaft comprises a flexible distal end portion.

15. The suturing assembly of claim 14, wherein the shaft comprises a metal tube and the flexible distal end portion comprises a corrugated segment of the metal tube.

16. The suturing assembly of claim 14, wherein the flexible distal end portion comprises comprising a coil.

17. The suturing assembly of claim 14, wherein the shaft comprises a flexible shaft comprising a proximal end portion having a yield strength and the flexible distal end portion comprises a second yield strength that is less than the first yield strength by at least a factor of 2.

18. The suturing assembly of claim 1, comprising a rod disposed in the shaft, the rod extending between the handle and the needle;

wherein the rod comprises a coiled metal rod configured to flex laterally relative to a longitudinal axis of the shaft.

19. The suturing assembly of claim 1, wherein the shaft defines a longitudinal axis of the assembly and the distal end of the head is radially offset from the longitudinal axis.

20. The suturing assembly of claim 19, wherein the actuator is configured to move the needle longitudinally out of the needle exit port, shunt a leading end of the needle away from the longitudinal axis, and move the leading end of needle into the cavity formed in the distal end of the head.

21. The suturing assembly of claim 20, comprising a rotatable guide pin disposed in the proximal end portion of the head, the needle slideably coupled with the rotatable guide pin.

22. The suturing assembly of claim 21, wherein the actuator is configured to slide the needle through the rotatable guide pin which rotates to move the leading end of the needle away from the longitudinal axis.
23. The suturing assembly of claim 22, comprising a link disposed in a trace that is formed on an interior surface of the proximal end portion of the head, the link coupled between the actuator and a proximal end of the needle and configured to translate and rotate within the trace.
24. The suturing assembly of claim 23, wherein the actuator is configured to translate the link proximally within the trace, which rotates the link within the trace and slides the needle through the rotatable guide pin to direct a distal end of the needle away from the longitudinal axis and into the cavity.
25. The suturing assembly of claim 24, wherein the actuator comprises a trigger coupled to a rod, the rod disposed within the shaft and coupled to the link.
26. The suturing assembly of claim 1, wherein the needle comprises a substantially straight needle that is substantially aligned with the shaft when stowed within the proximal portion of the head.
27. The suturing assembly of claim 1, wherein the needle comprises a curved needle.
28. The suturing assembly of claim 1, wherein the cavity comprises a through-channel extending through the distal end of the head, the cavity sized to receive the capsule and defining a slot configured to enable the suture to pass through the distal end of the head and into the cavity.

29. A suturing system comprising:
 - a suture assembly comprising a suture coupled to a capsule; and
 - a suturing device comprising a shaft coupled to a head, the head forming a housing for a needle that is movable through a needle exit port and a distal end spaced apart from the needle exit port by a throat, the distal end defining a cavity configured to removably retain the capsule of the suture assembly;
wherein the needle is movable from the needle exit port to the cavity formed in the distal end of the head and configured to engage the capsule of the suture assembly.
30. The suturing system of claim 29, wherein the needle is configured to snap-fit with the capsule and is retractable relative to the distal end of the head to remove the capsule from the cavity.
31. The suturing system of claim 29, wherein the needle is configured to remove the capsule from the cavity, retract in a proximal direction into the needle exit port, and park the capsule in a capsule garage formed in the needle exit port.
32. The suturing system of claim 31, wherein the suturing device comprises an actuator configured to separate the needle from the capsule, and the capsule garage is configured to frictionally retain the capsule.
33. The suturing system of claim 31, wherein the needle comprises a substantially straight needle.
34. The suturing system of claim 31, wherein the needle comprises a curved needle.

35. The suturing system of claim 29, wherein the capsule comprises a chamfered leading end, the suture extending from a trailing end of the capsule.

36. The suturing system of claim 29, wherein the shaft defines a longitudinal axis of the device and the distal end of the head is radially offset from the longitudinal axis.

37. The suturing system of claim 36, wherein the needle is configured to pass longitudinally in a first direction through the needle exit port, shunt away from the longitudinal axis in a second direction different from the first direction and into the cavity formed in the distal end of the head to engage the capsule of the suture assembly.

38. The suturing system of claim 37, wherein the needle is configured to remove the capsule from the cavity, retract in the second direction away from the cavity, move longitudinally in the first direction into the needle exit port, and park the capsule in a capsule garage formed in the needle exit port.

39. The suturing system of claim 38, comprising a handle housing a portion of an actuator and a knob threaded to a proximal end of the handle.

40. The suturing system of claim 39, wherein the knob is configured to be turned to further retract the needle into the needle exit port and separate the needle from the capsule.

41. The suturing system of claim 40, wherein the handle comprises an indicator configured to indicate that the knob has been turned.

42. The suturing system of claim 36, comprising a guide pin disposed in a proximal end portion of the head, the needle slideably coupled with the guide pin.

43. The suturing system of claim 42, comprising a link disposed in a trace that is formed on an interior surface of the proximal end portion of the head, the link coupled to the needle.

44. The suturing system of claim 43, wherein the link is configured to translate and rotate within the trace and the guide pin is rotatable to enable the needle to shunt between the first direction and the second direction.

45. The suturing system of claim 44, wherein the head comprises an arcuate neck extending between the needle exit port and the distal end of the head, the arcuate neck configured to enable a user to digitally guide the head through a tissue incision.

46. The suturing system of claim 14, wherein the shaft comprises a malleable distal end portion.

47. A suturing system comprising:

a suture device comprising a shaft coupled to a head, the head comprising a proximal end portion housing a needle movable through a needle exit port formed in the proximal end portion, and a distal end spaced apart from the proximal end portion of the head by a throat, the distal end defining a cavity;

a capsule attached to suture material, the capsule sized for retention in the cavity; and

means for moving the needle from the needle exit port, into engagement with the capsule, and removing the capsule from the cavity.

48. The suturing system of claim 47, wherein the cavity formed in the distal end of the head is aligned on an axis with the needle exit port.

49. The suturing system of claim 47, wherein the means for moving the needle from the needle exit port comprises pushing a rod disposed within the shaft, the rod communicating with the needle.

50. The suturing system of claim 49, wherein the rod is coupled to the needle by a link, the link configured to translate and to rotate relative to the head.

51. A suturing assembly comprising:
a shaft defining a longitudinal axis;
a head coupled to the shaft, the head comprising:
a proximal end portion housing a needle movable in a first direction longitudinally through a needle exit port formed in the proximal end portion, and
a distal end spaced apart from the proximal end portion of the head by a throat, the distal end defining a cavity that is radially offset from the longitudinal axis; and
means for shunting the needle laterally in a second direction away from the longitudinal axis and into the cavity formed in the distal end of the head.

52. The suturing assembly of claim 51, wherein the means for shunting the needle comprises a link disposed within a trace form on an interior surface of the proximal end portion of the head, the link coupled to a proximal end of the needle and configured to translate the needle and rotate the proximal end of the needle.

53. The suturing assembly of claim 51, wherein the means for shunting the needle further comprises a guide pin disposed within the proximal end portion of the

head, the needle configured to slide relative to the guide pin, and the guide pin rotatable to pivot the needle.

54. A method of suturing tissue, the method comprising:
 - engaging tissue with a suturing head;
 - driving a needle from a proximal end portion of the suturing head through the tissue; and
 - engaging a capsule disposed in a distal end portion of the suturing head with the needle, the capsule comprising a length of suture attached thereto.
55. The method of claim 54, further comprising:
 - removing the capsule from the cavity with the needle; and
 - retracting the capsule and the suture through a channel formed in the tissue by the needle.
56. The method of claim 55, further comprising:
 - parking the capsule in a garage formed in the proximal end portion of the suturing head.
57. The method of claim 56, further comprising:
 - removing the capsule from the garage; and
 - tying the suture to the tissue.
58. The method of claim 57, further comprising:
 - placing a second capsule in the cavity formed in the distal end of the suturing head and comprising a length of second suture attached thereto.
59. The method of claim 54, wherein driving a needle from a proximal end portion of the suturing head through the tissue comprises:

driving a needle longitudinally out in a first direction from a proximal end portion of the suturing head and through the tissue engaged in the throat; and
shunting the needle laterally away from the first direction and into a cavity formed in a distal end of the suturing head.

60. A method of suturing tissue, the method comprising:
engaging tissue in a throat of a suturing head, the throat formed between a proximal end portion and a distal end of the suturing head;
moving a needle away from the proximal end portion of the suturing head toward the distal end of the suturing head;
engaging a capsule with the needle, the capsule retained within a cavity formed in the distal end of the suturing head; and
removing the capsule from the cavity.
61. The method of claim 60, comprising moving the needle out of a needle port formed in the proximal end portion of the suturing head and across the throat.
62. The method of claim 61, comprising moving the needle out of a needle port along a substantially straight-line path entirely across the throat.
63. The method of claim 61, comprising moving the needle out of a needle port and shunting a tip of the needle from a first axis aligned with the needle exit port to a second axis aligned with the cavity.
64. The method of claim 61, comprising linearly moving a substantially straight needle out of the needle port and across the throat.

65. The method of claim 61, comprising moving a curved needle out of the needle port formed in the proximal end portion of the suturing head and across the throat in an arc.

66. The method of claim 60, wherein engaging a capsule with the needle comprises frictionally fitting a leading tip of the needle into a recess formed in the capsule.

67. The method of claim 60, wherein frictionally fitting a leading tip of the needle into a recess formed in the capsule comprises snap-fitting the leading tip of the needle into the recess formed in the capsule.

68. The method of claim 60, wherein moving a needle away from the proximal end portion of the suturing head toward the distal end of the suturing head forms a channel in the tissue, and removing the capsule from the cavity comprises pulling a blunt leading end of the capsule through the channel formed in the tissue.

69. The method of claim 68, further comprising:
a suture trailing from a trailing end of the capsule;
wherein removing the capsule from the cavity comprises pulling the suture through the channel formed in the tissue.

70. The method of claim 69, further comprising:
a needle port formed in the proximal end portion of the suturing head; and
parking the capsule within a portion of the needle port and extending the suture across the throat.

71. The method of claim 70, further comprising:
removing the capsule and the suture from the suturing head.

72. The method of claim 71, further comprising:
inserting a second capsule coupled to a second suture into the cavity formed
in the distal end of the suturing head.

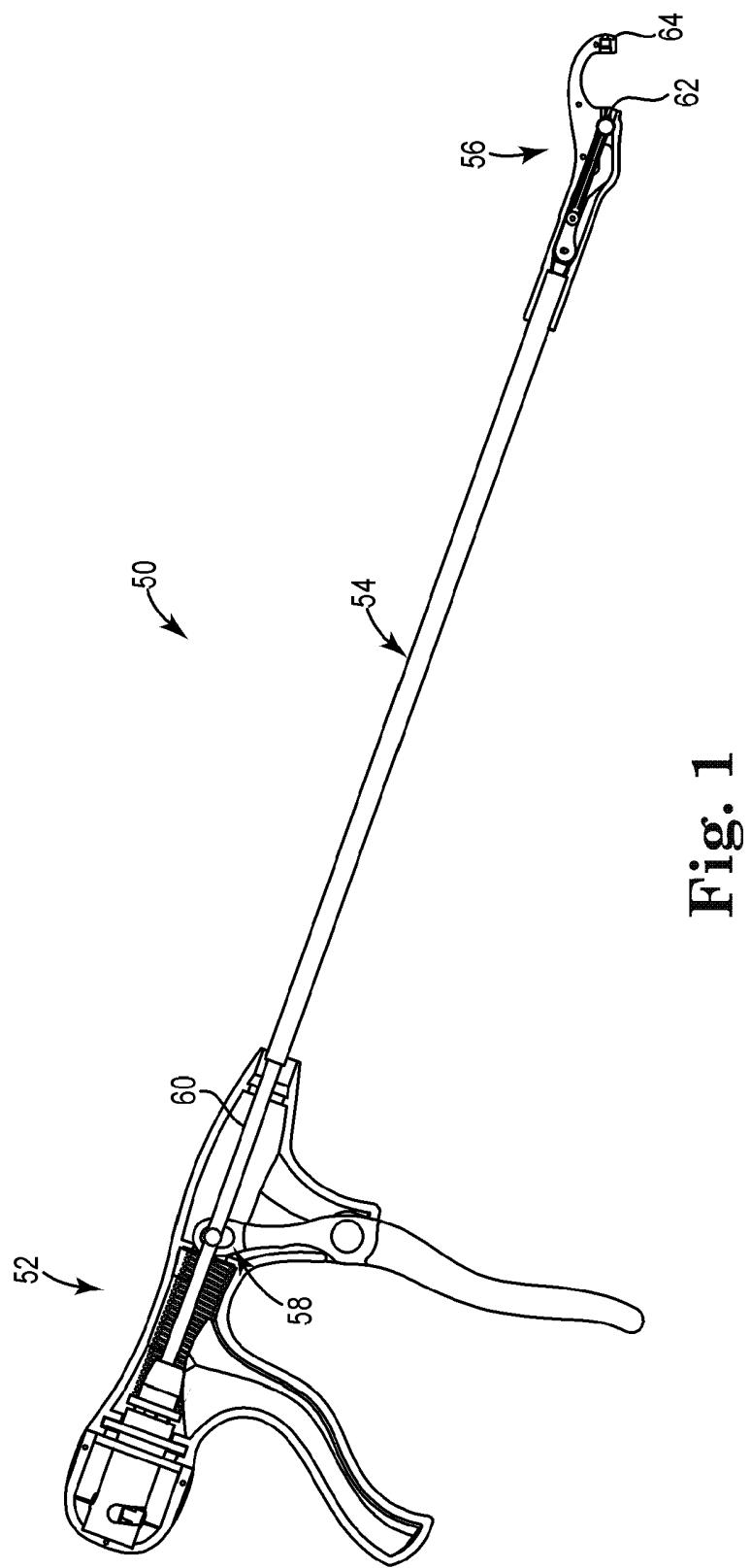


Fig. 1

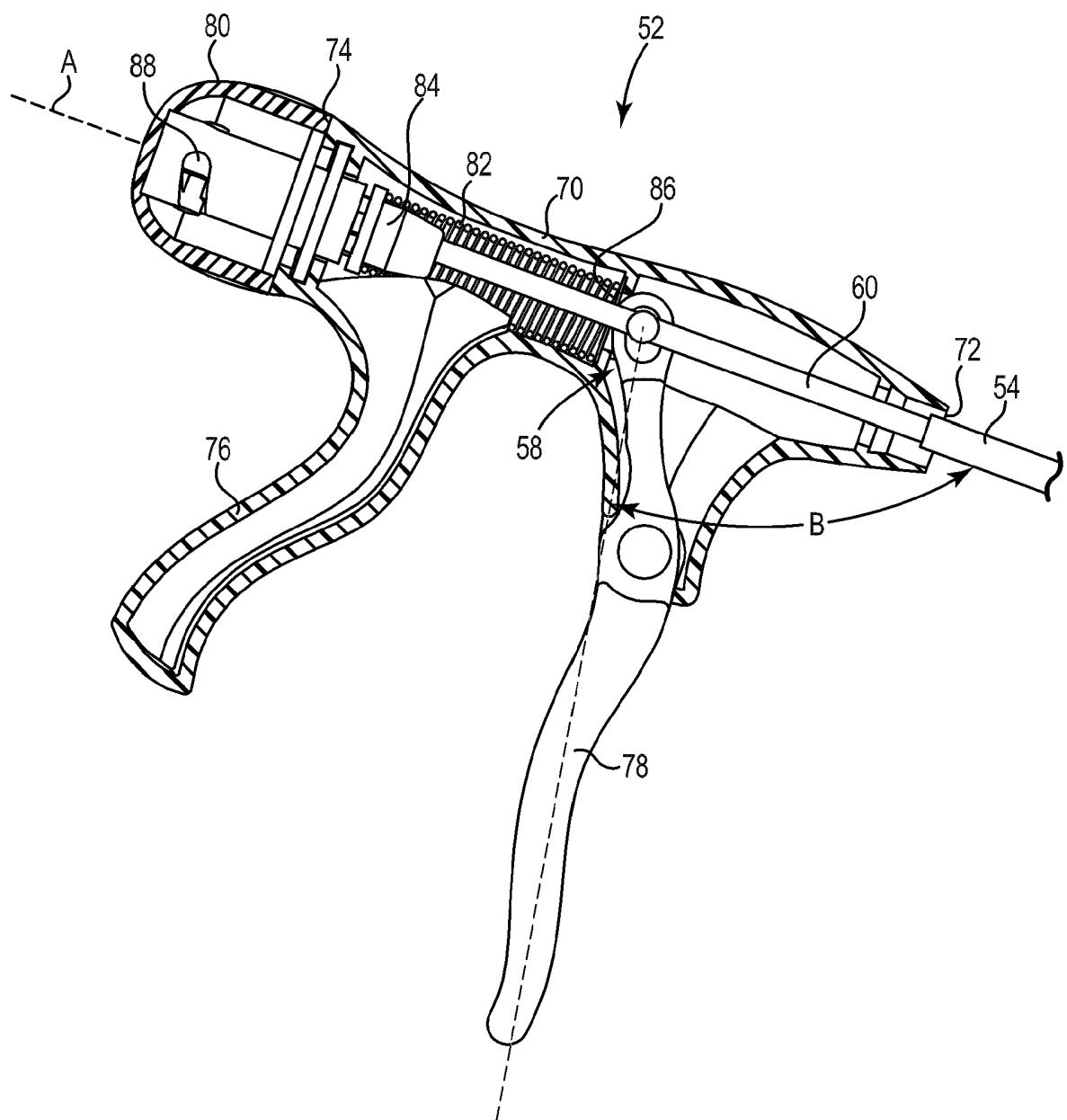


Fig. 2

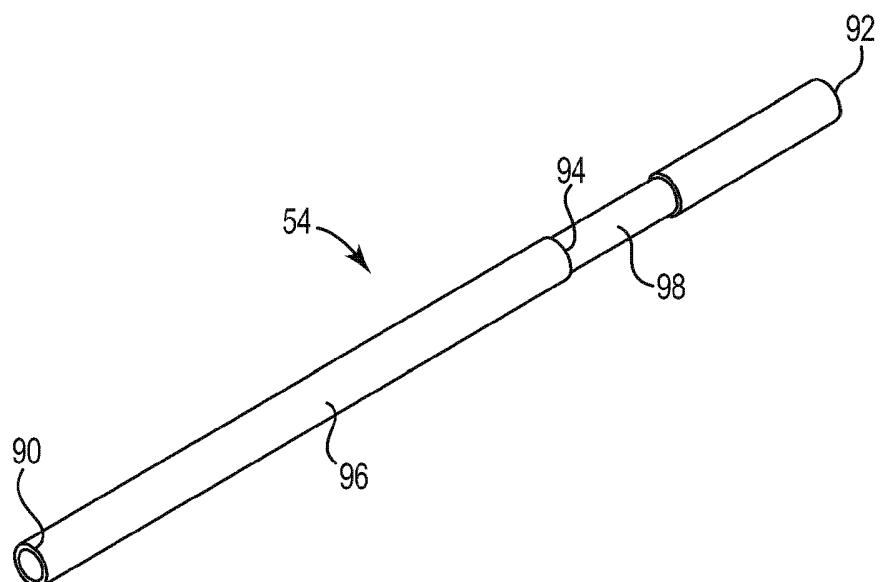


Fig. 3

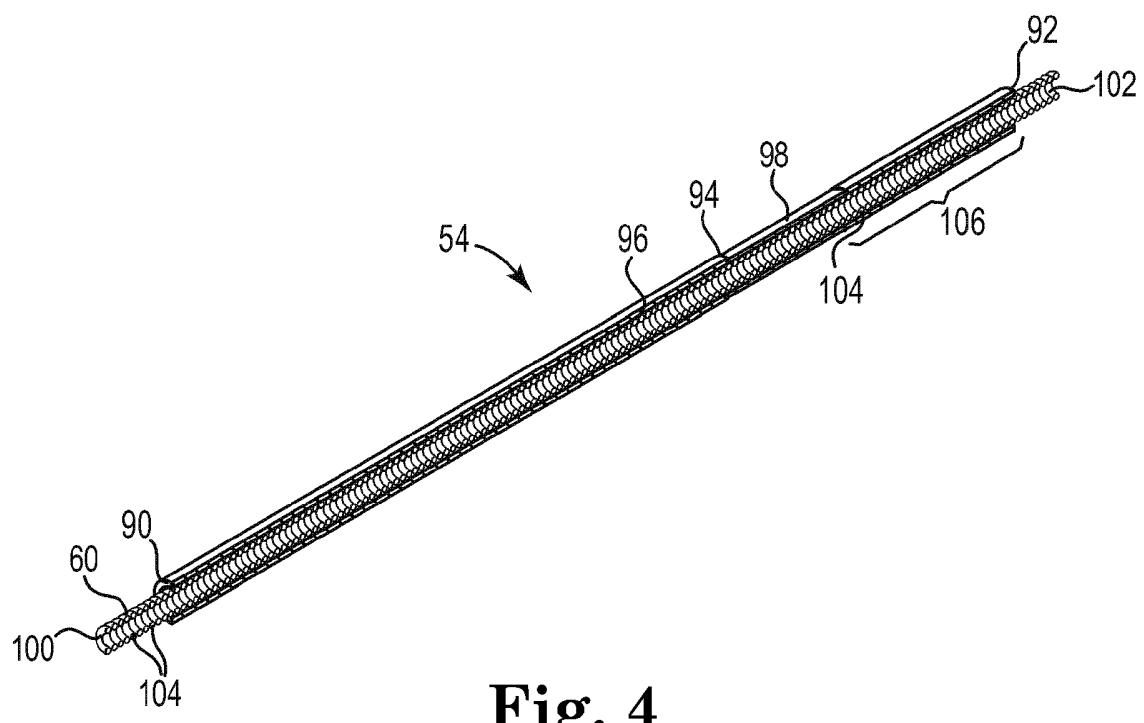
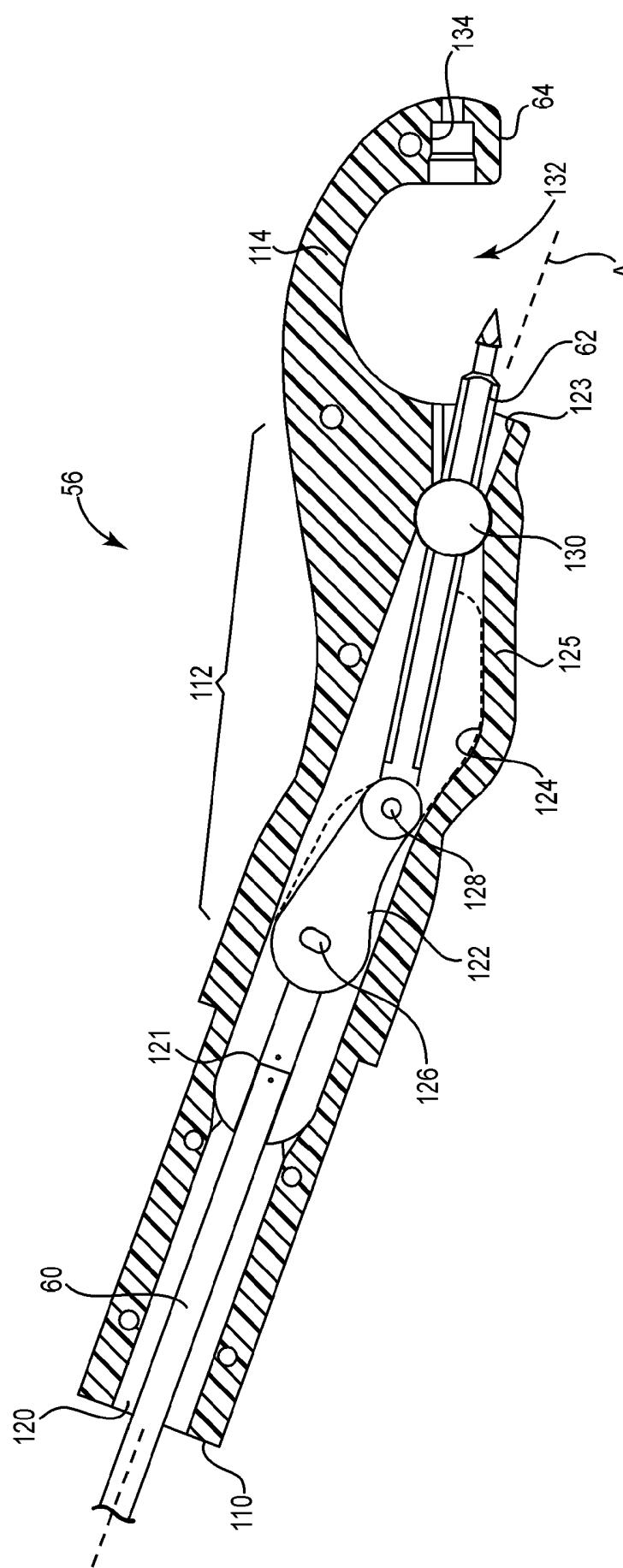


Fig. 4



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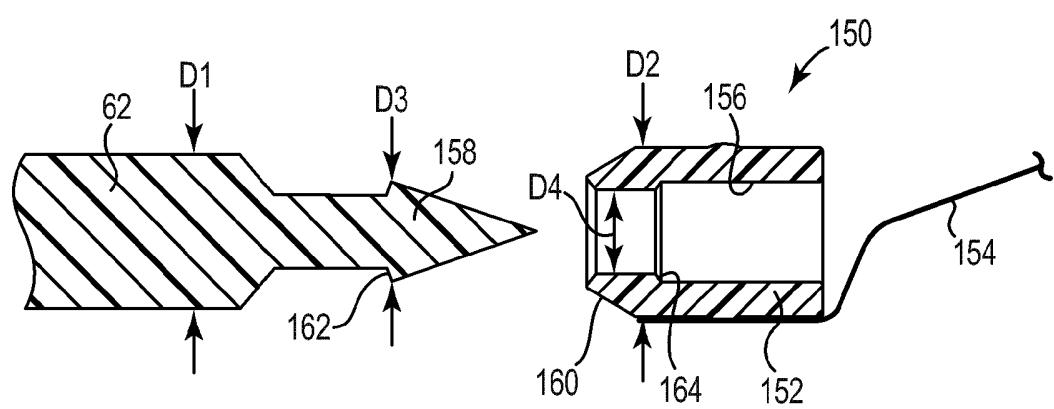
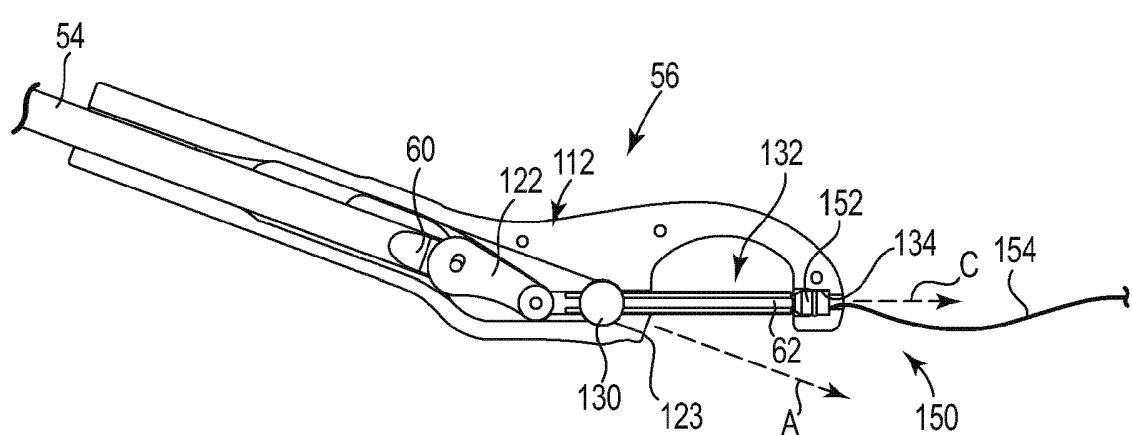
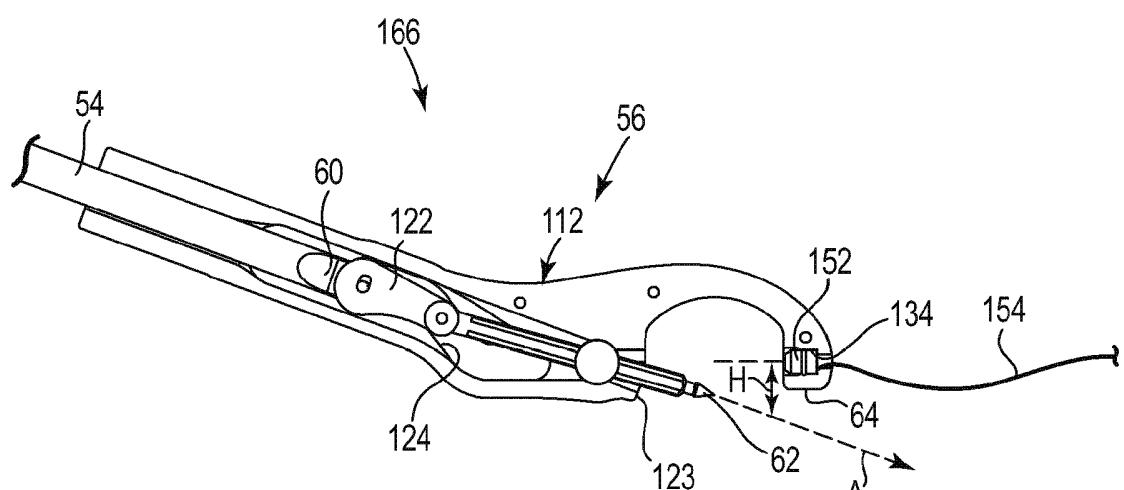
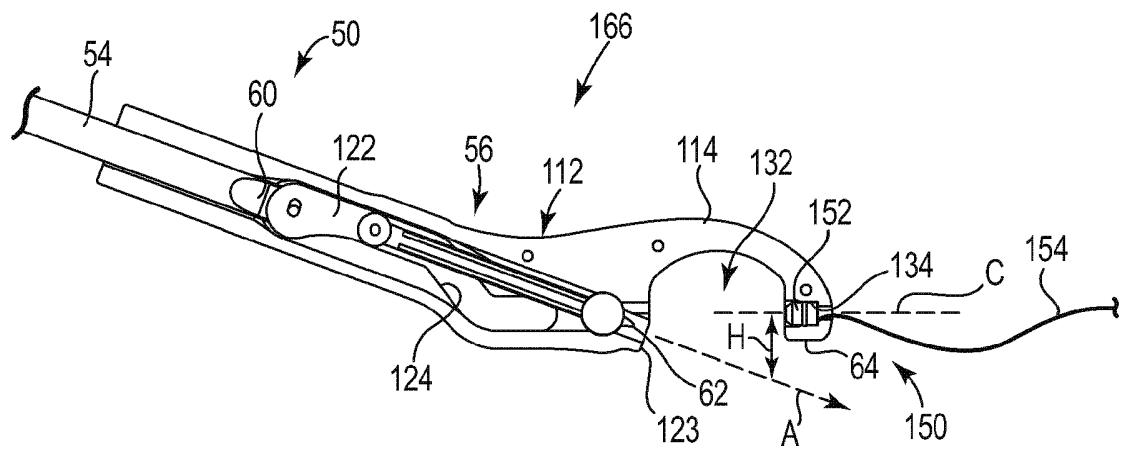
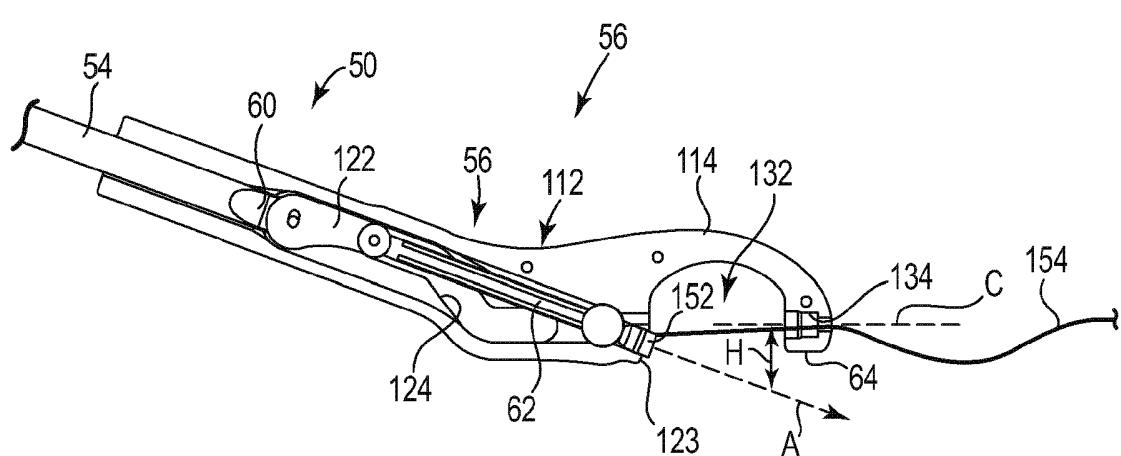
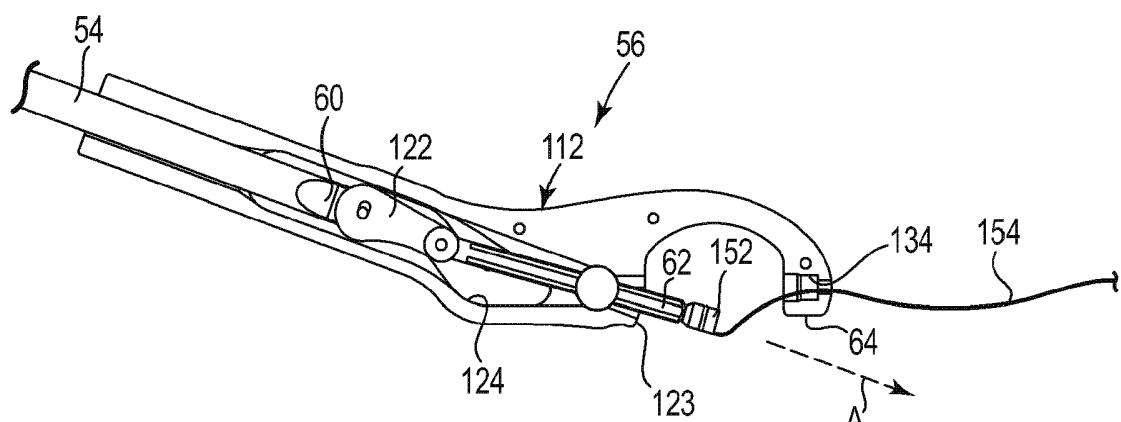
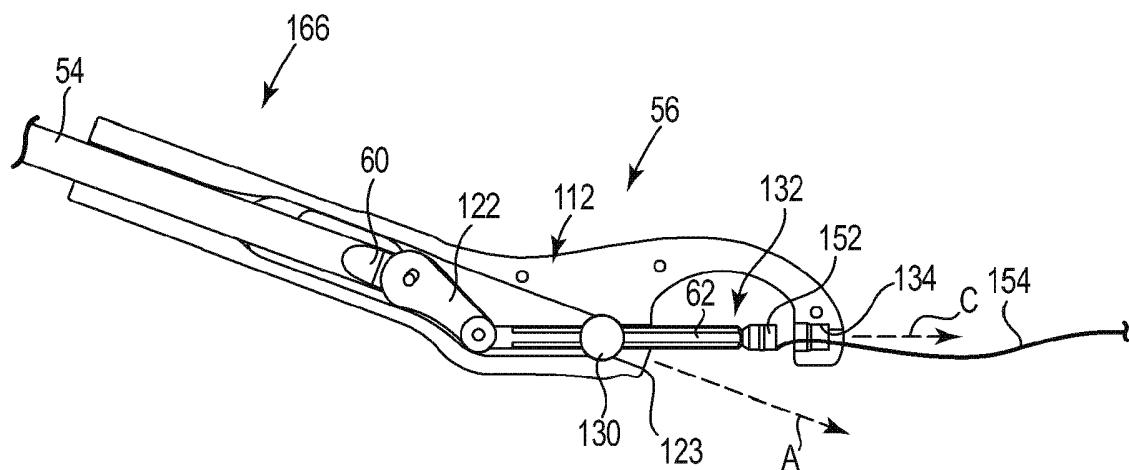


Fig. 6





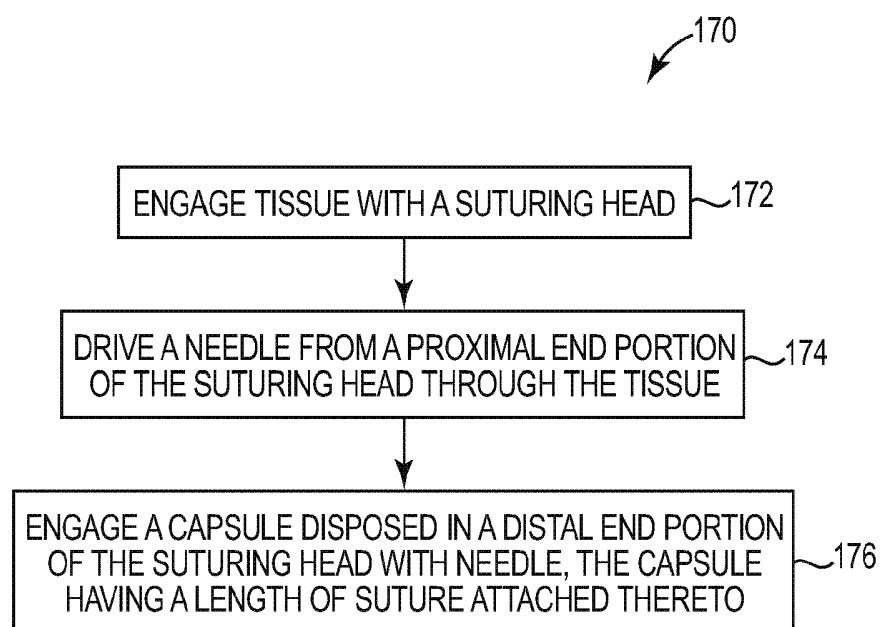


Fig. 8

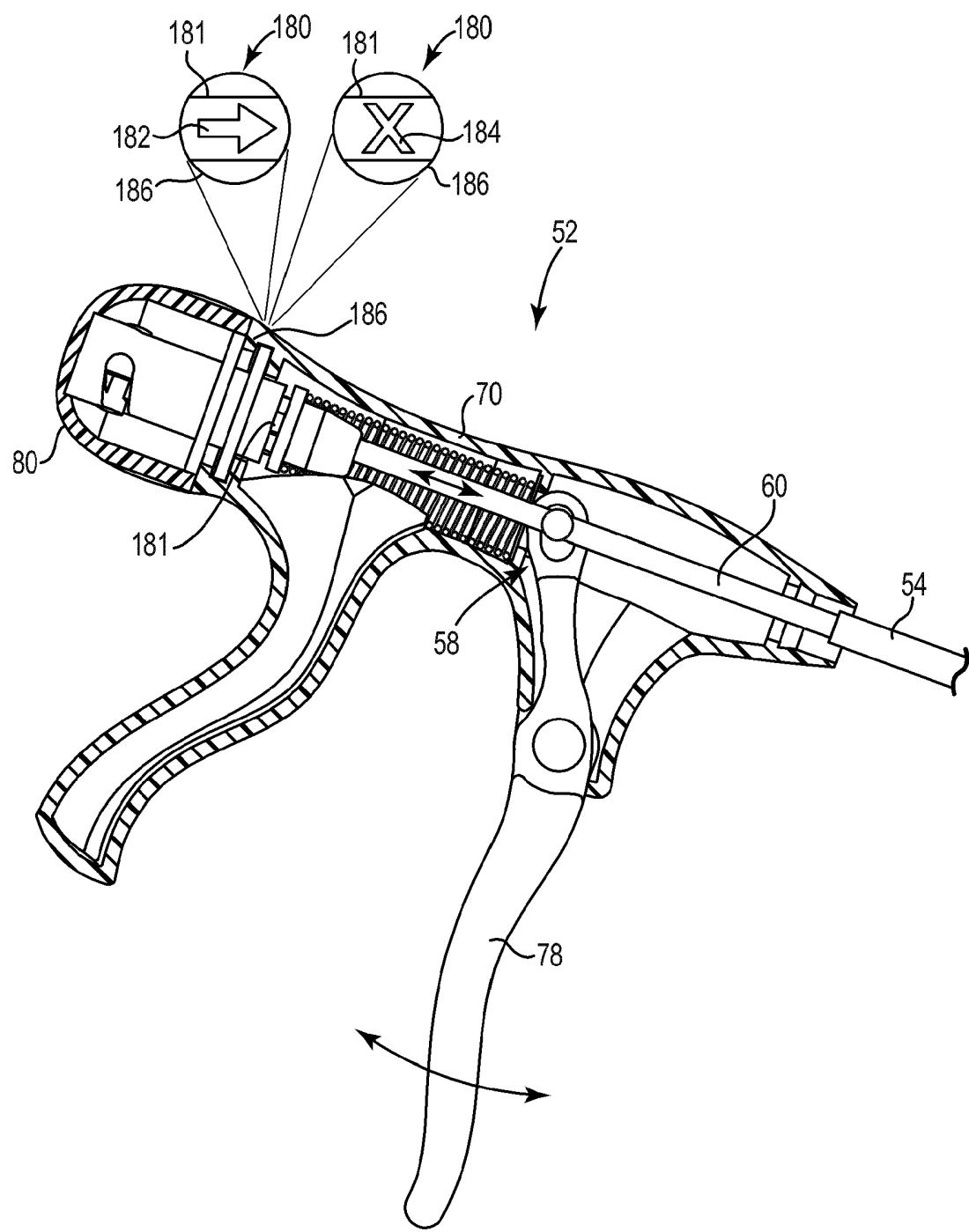


Fig. 9A

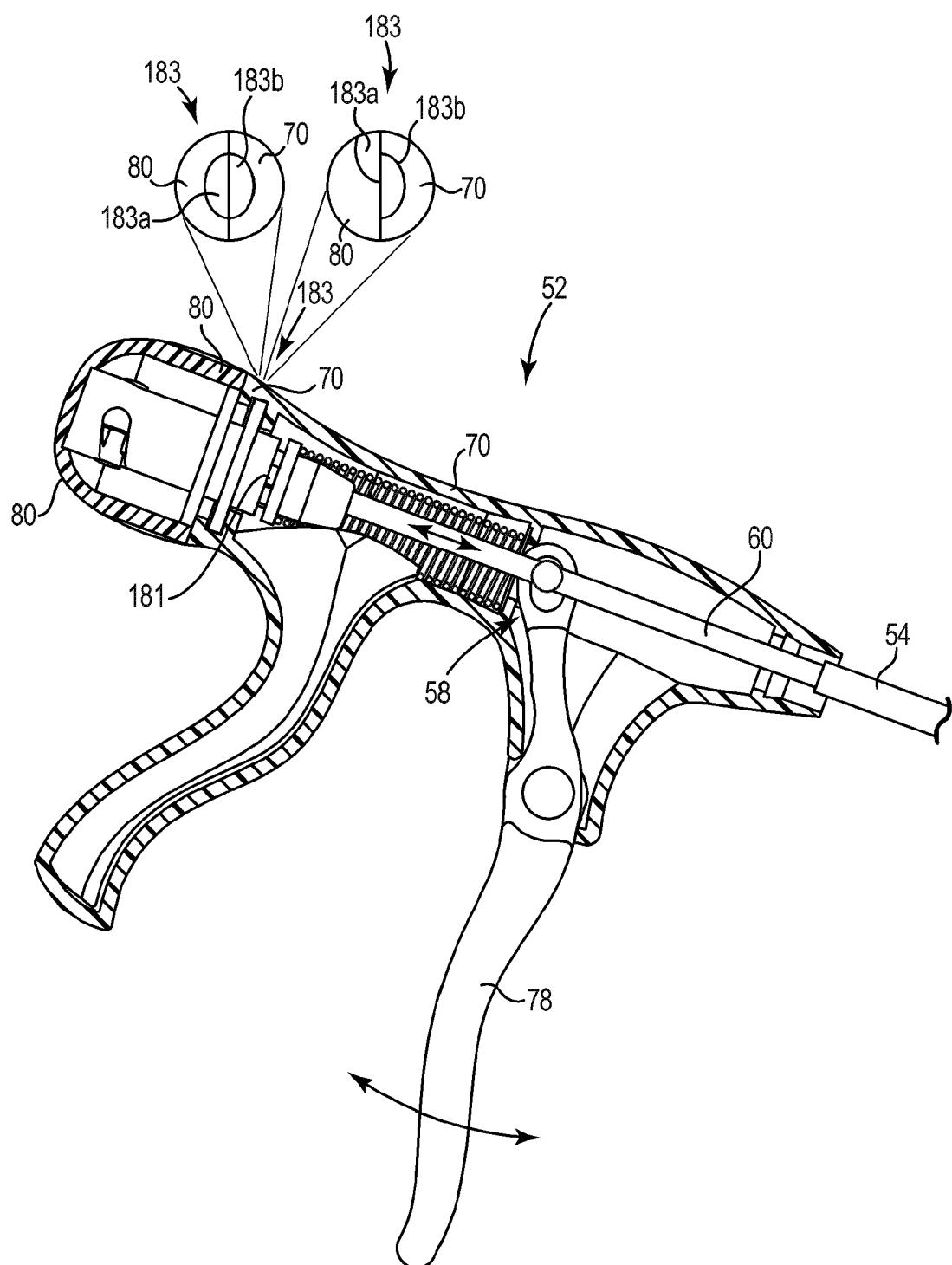


Fig. 9B

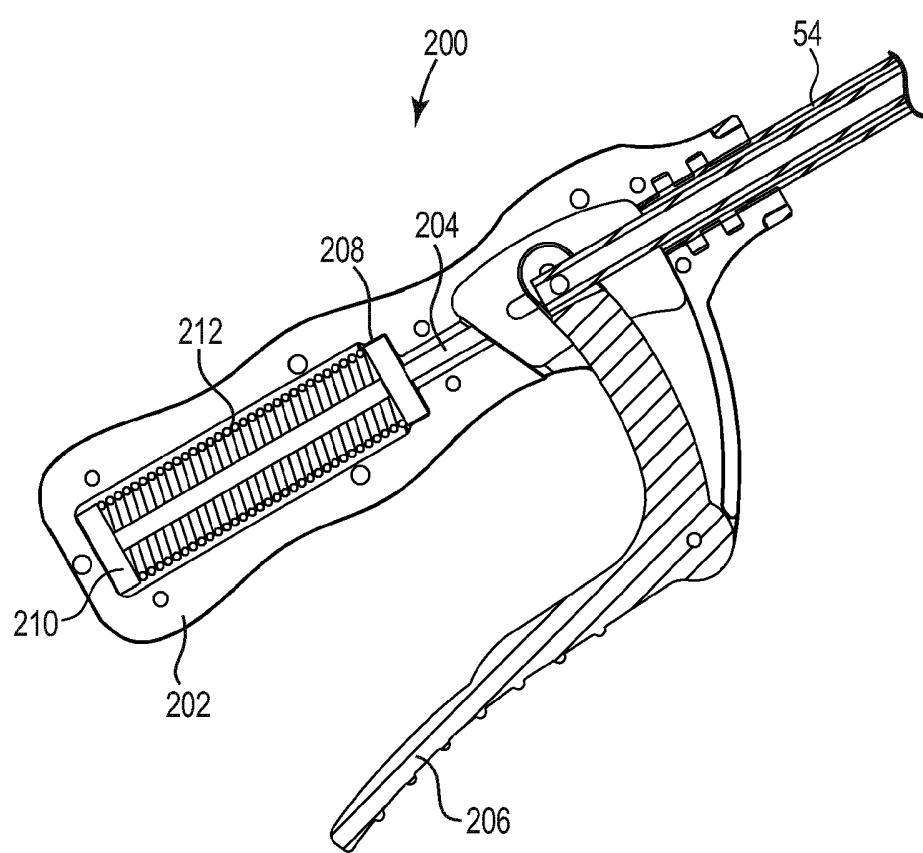


Fig. 10

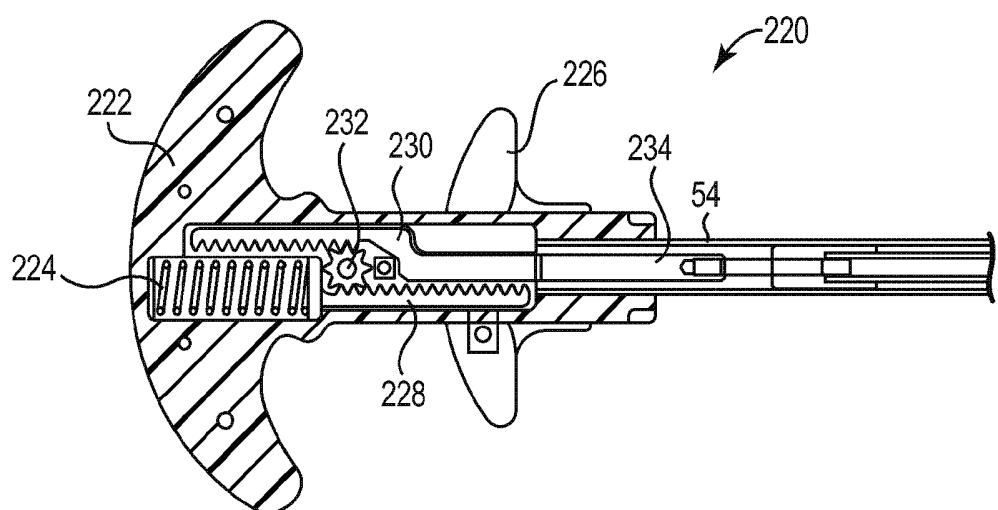


Fig. 11

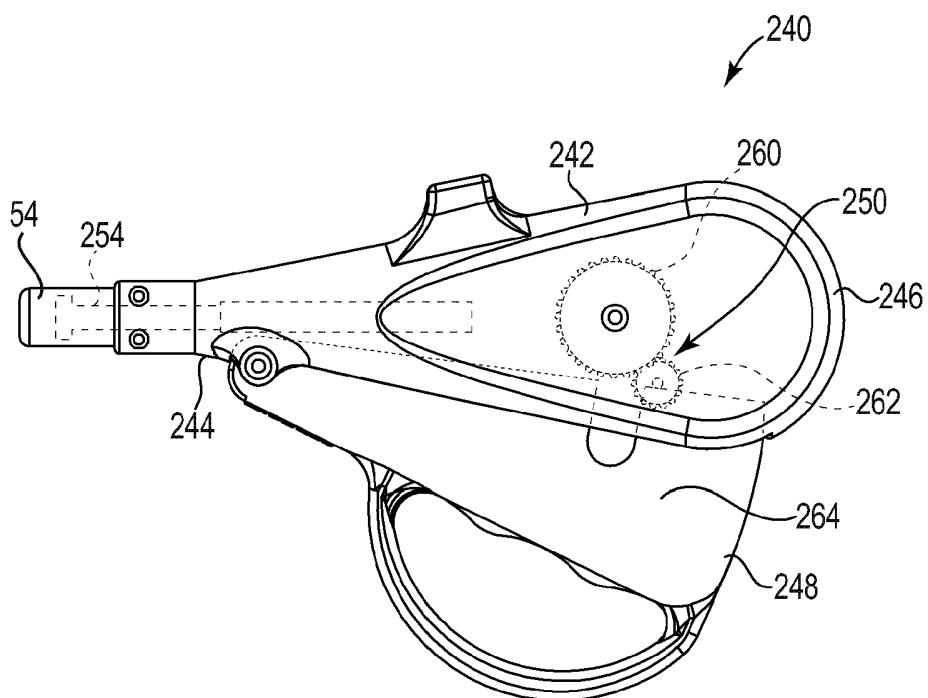


Fig. 12

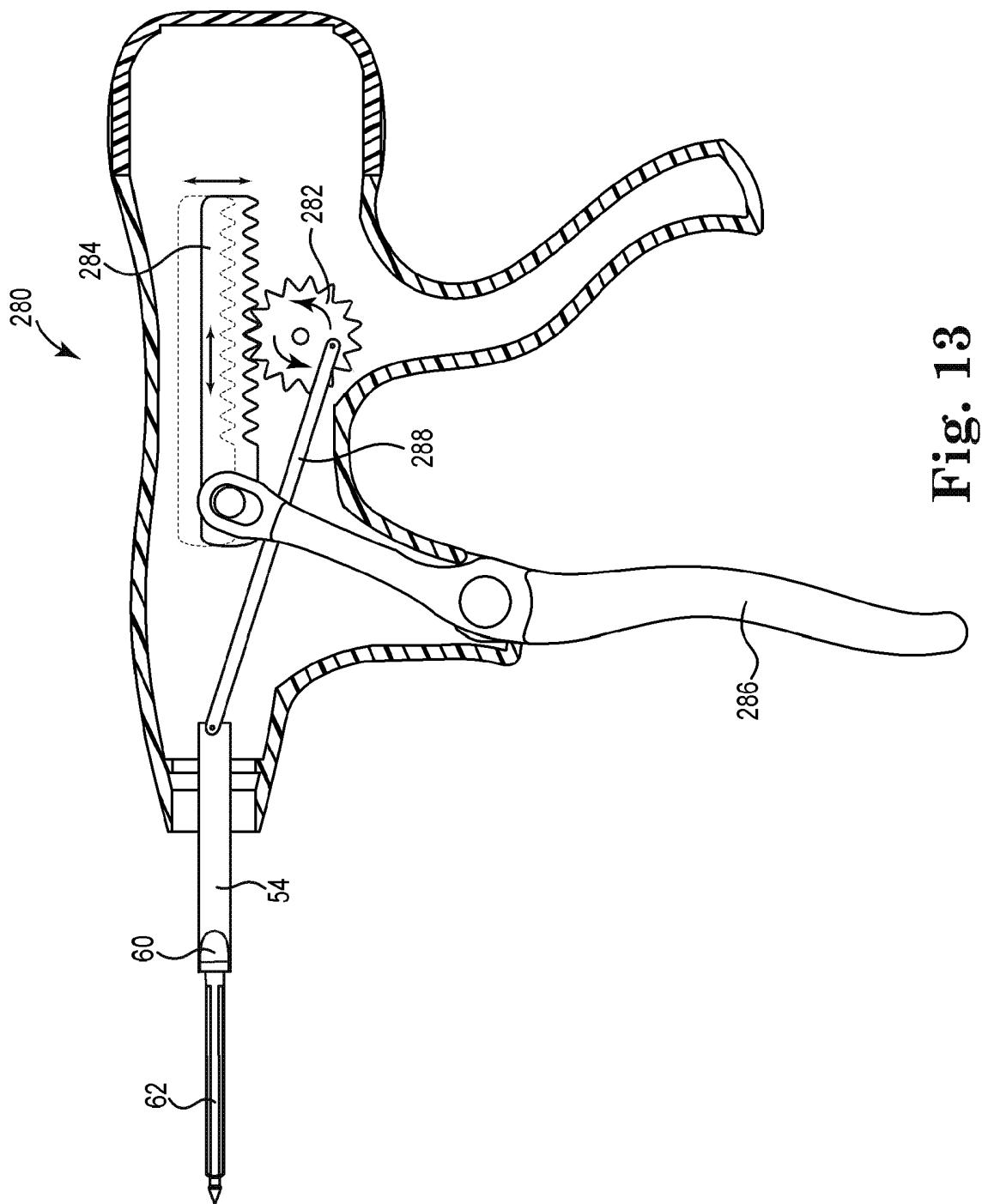


Fig. 13

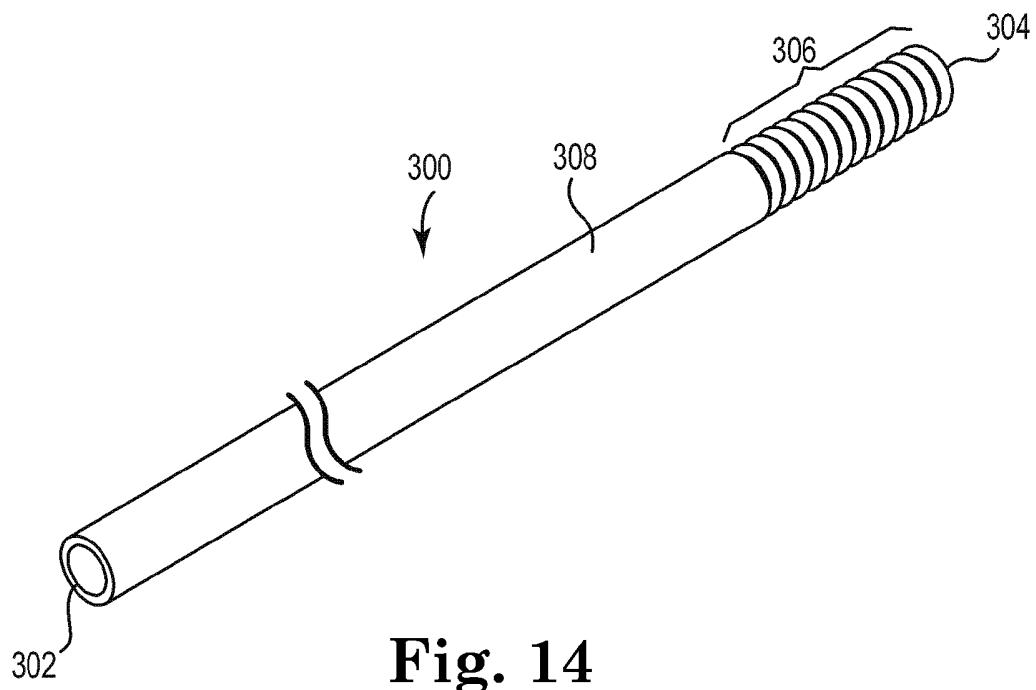


Fig. 14

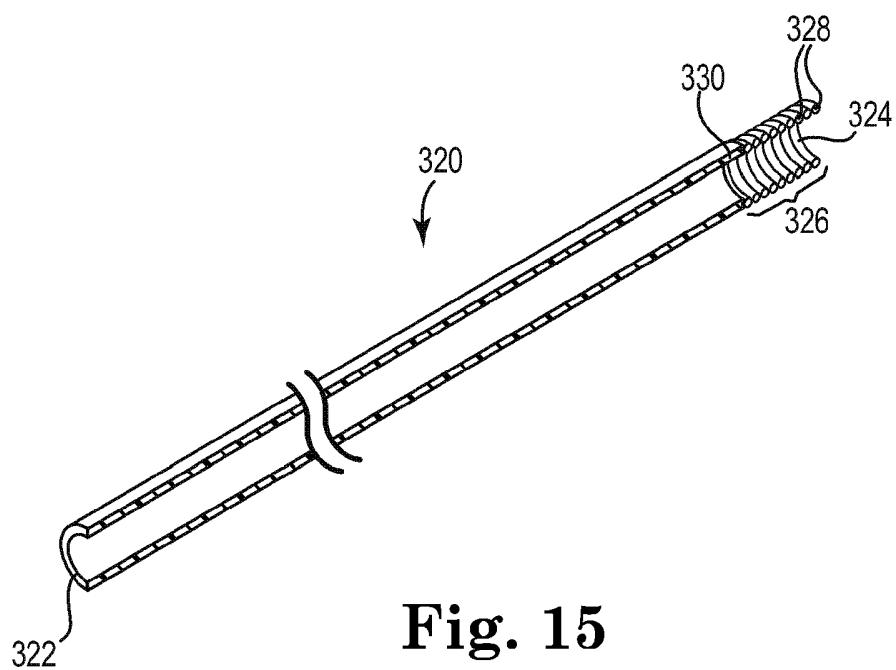


Fig. 15

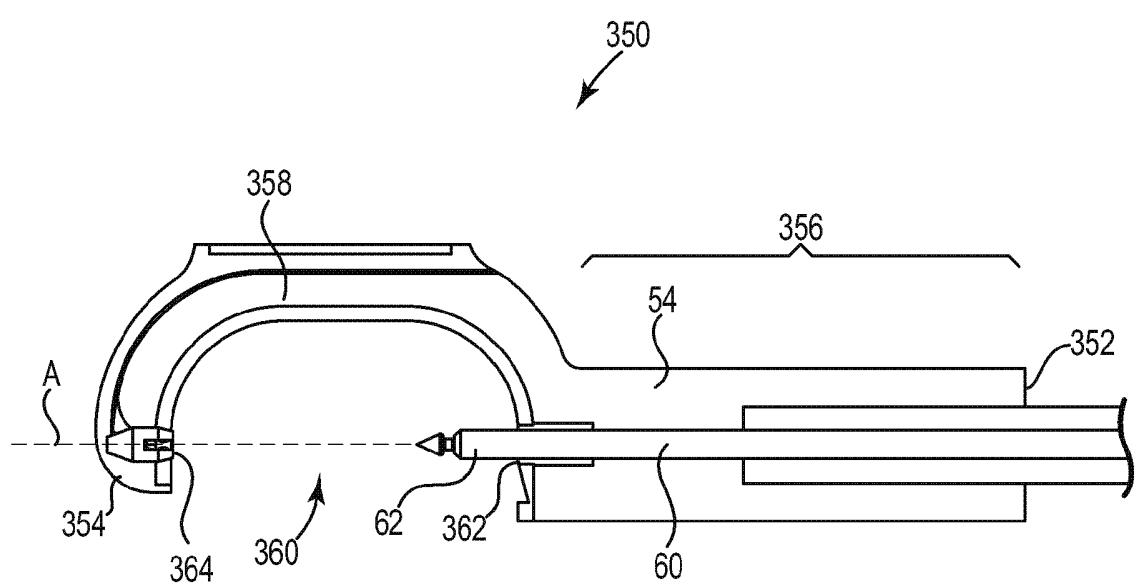


Fig. 16

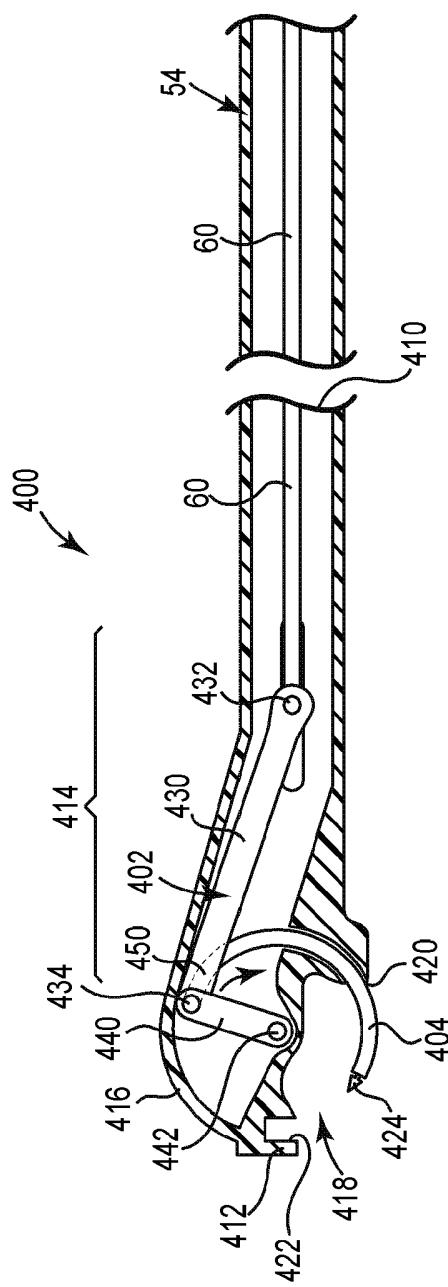


Fig. 17