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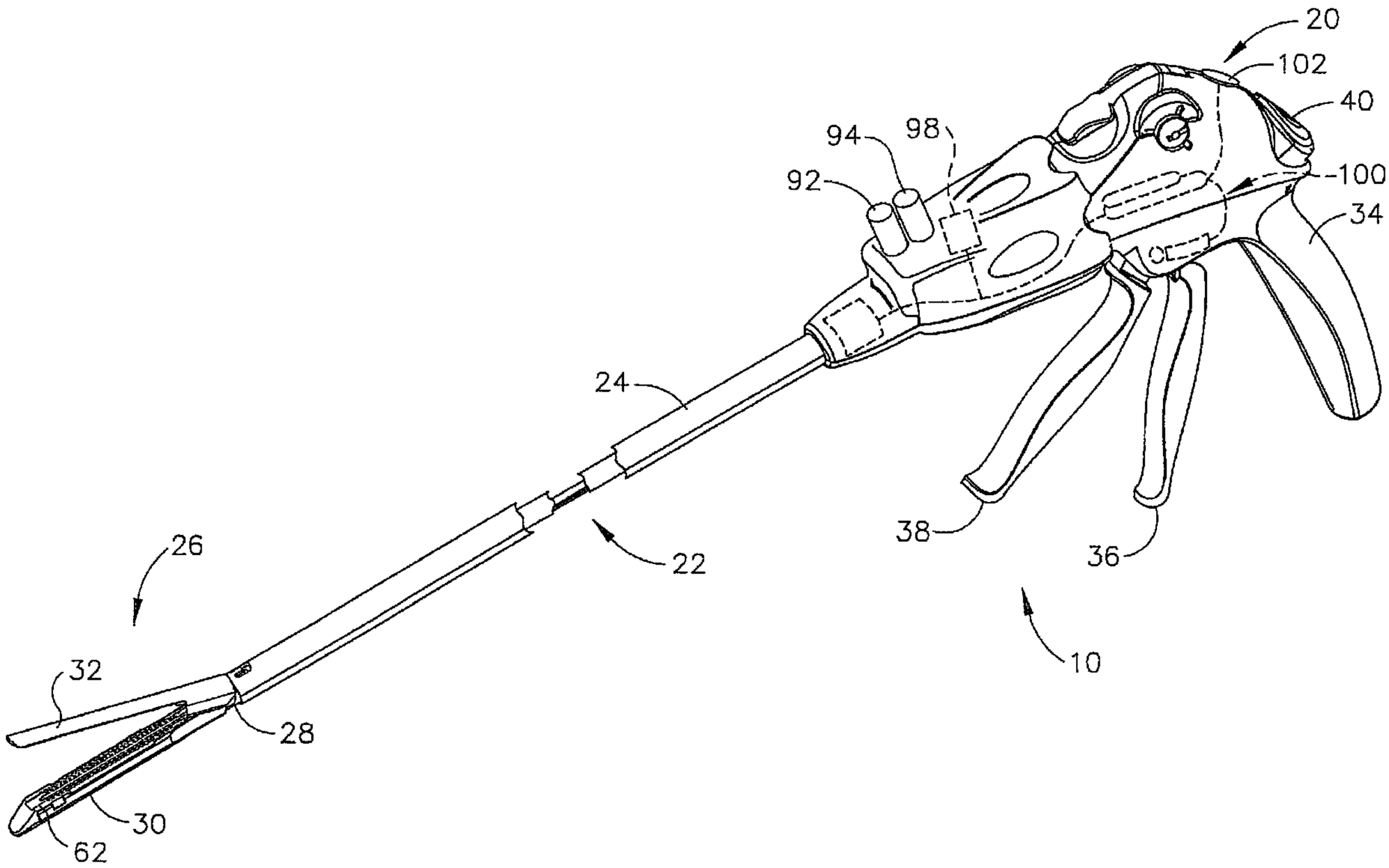
(54) Titre : AGRAFEUSES CHIRURGICALES STRUCTUREES POUR ADMINISTRER DES SUBSTANCES MEDICALES
(54) Title: SURGICAL STAPLING INSTRUMENTS STRUCTURED FOR DELIVERY OF MEDICAL AGENTS




(57) Abrégé/Abstract:
A medical agent dispensing system can be provided that may be structured for use with a surgical severing/stapling instrument that is designed for severing and stapling tissue. The dispensing system may include at least one storage reservoir structured for storing at least a component of a medical agent; a gear pump casing in communication with the storage reservoir; a screw pump auger positioned within the gear pump casing capable of rotational manipulation to move the medical agent through the gear pump casing; and, at least one agent tube in communication with the gear pump casing. The agent tube may be structured for communication with a least one agent port formed in a staple cartridge of the surgical instrument for dispensing the medical agent therethrough.

# ABSTRACT

A medical agent dispensing system can be provided that may be structured for use with a surgical severing/stapling instrument that is designed for severing and stapling tissue. The dispensing system may include at least one storage reservoir structured for storing at least a component of a medical agent; a gear pump casing in communication with the storage reservoir; a screw pump auger positioned within the gear pump casing capable of rotational manipulation to move the medical agent through the gear pump casing; and, at least one agent tube in communication with the gear pump casing. The agent tube may be structured for communication with a least one agent port formed in a staple cartridge of the surgical instrument for dispensing the medical agent therethrough.

# SURGICAL STAPLING INSTRUMENTS

# STRUCTURED FOR DELIVERY OF MEDICAL AGENTS

## FIELD OF THE INVENTION

**[0001]** The present invention generally relates to surgical instruments. The invention more particularly relates to delivery and application of medical agents in association with the use of surgical instruments to promote closure and healing of severed and stapled tissue.

## BACKGROUND

**[0002]** Conventional surgical staplers that can be used to simultaneously make longitudinal incisions in tissue and apply lines of staples on opposing sides of the incisions are known in the art. Such instruments commonly include a pair of cooperating jaw members that, when employed in endoscopic or laparoscopic applications, are capable of passing through a cannula passageway. One of the jaw members typically receives a staple cartridge having at least two laterally spaced rows of staples. The other jaw member defines an anvil having staple-forming pockets correspondingly aligned with the rows of staples in the cartridge. Such stapling instruments may also include a plurality of reciprocating wedges that pass through openings in the staple cartridge when driven and engage drivers supporting the staples to effect the firing of the staples toward the anvil and through tissue.

**[0003]** Examples of surgical staplers suitable for use with endoscopic applications are described in U.S. Patent Application No. US 2004/0232196 A1. In operation of the surgical stapler, a clinician closes or clamps the jaw members of the stapler on tissue to position the tissue

prior to firing or activation of the stapler. Once the clinician has determined that the jaw members are clamping the tissue in a desired position, then the surgical stapler can be fired by the clinician to create an incision in the tissue and at the same time staple tissue surrounding the incision. This simultaneous action of the stapler avoids complications that often arise when the severing and stapling operations are performed sequentially (or at different times) with different surgical tools (i.e., one device is used to sever the tissue, and then another device is used to staple the tissue).

**[0004]** In general, application of certain medical agents to tissue incisions can promote healing, reduce the possibility of infection, and/or promote proper sealing of the incisions. If assisted by the action of such medical agents, many surgical staplers could achieve better surgical results with respect to enhanced healing, improved infection resistance, and improved sealing of tissue incisions. However, the structure of many conventional surgical staplers, and the procedures in which such staplers are employed, do not leverage the benefits of medical agents or systems that dispense medical agents.

**[0005]** In view of the foregoing, there is a need for improved surgical instruments and medical agent dispensing systems than can more effectively and efficiently promote closure, treatment, and healing of tissue incisions severed and stapled during operations involving surgical staplers.

SUMMARY

**[0006]** In accordance with the present invention, various embodiments of a medical agent dispensing system can be provided. The medical agent dispensing system may be structured for use with a surgical severing/stapling instrument structured for severing and stapling tissue. The dispensing system may include: at least one storage reservoir structured for storing at least a component of a medical agent; a gear pump casing in communication with the storage reservoir; a screw pump auger positioned within the gear pump casing capable of rotational manipulation to move the medical agent through the gear pump casing; and, at least one agent tube in communication with the gear pump casing. The agent tube may be structured for communication with a least one agent port formed in a staple cartridge of the surgical instrument for dispensing the medical agent therethrough.

**[0007]** In accordance with the invention, various embodiments of a surgical severing/stapling instrument including a medical agent dispensing system can be provided. The surgical instrument may include a handle portion including at least one storage reservoir structured for storing at least a component of a medical agent, and a shaft portion connected to the handle portion. The shaft portion may include a gear pump casing in communication with the storage reservoir, wherein the gear pump casing includes a screw pump auger extending therethrough capable of rotational manipulation to move the medical agent through the gear pump casing. The surgical instrument may also include an end effector portion operatively associated with the shaft portion that has a staple cartridge positioned removably therein. At least one agent tube may be provided in communication with the gear pump casing; and the agent tube may extend from the shaft portion to communicate with a least one agent port formed

in the staple cartridge of the surgical instrument. The agent port may be structured to permit the medical agent to be dispensed therethrough.

## BRIEF DESCRIPTION OF THE FIGURES

**[0008]** The accompanying drawings, which are incorporated into and constitute a part of this specification, illustrate embodiments of the invention. Together with the description of the embodiments provided herein, the drawings serve to explain the principles of the present invention for those skilled in the art.

**[0009]** Figure 1 depicts an three-dimensional, partially cut-away, partially schematic view of a surgical instrument that may be provided ~~in association with embodiments~~ of a medical agent dispensing system in accordance with the present invention;

**[0010]** Figure 2 illustrates a disassembled, three-dimensional view of the end effector and a shaft portion of the surgical instrument of Figure 1;

**[0011]** Figure 3 includes schematic depictions of handle, shaft and end effector portions of the surgical instrument of Figure 1;

**[0012]** Figure 4 includes an enlarged view of the shaft and end effector portions of the surgical instrument of Figure 3;

**[0013]** Figure 5 includes a enlarged view of the shaft and handle portions of the surgical instrument of Figure 3;

**[0014]** Figure 6 includes an enlarged, three-dimensional view of a screw pump auger that may be employed in accordance with various embodiments of the invention;

**[0015]** Figure 7 includes an enlarged, partially cut-away, three-dimensional view of a portion of the instrument of Figure 1;

**[0016]** Figure 8 includes an end view of the channel of the surgical instrument of Figure 2; and,

**[0017]** Figure 9 includes a process flow diagram illustrating various aspects of an example of a method for using embodiments of the medical agent dispensing system of the present invention.

DESCRIPTION

**[0018]** As applied herein, the term "tissue" may include a variety of human or animal tissues, membranes, or other organic substrates. The term "tissue" may also include any substance, substrate, or composition of matter capable of being severed and stapled by the various embodiments of surgical stapling/severing instruments described herein.

**[0019]** As applied herein, the term "medical agent" may include a variety of chemicals, liquids, high viscosity fluids, powders or other compositions of matter that may be applied to tissues. Examples of "medical agents" include, without limitation, hemostatic agents, healing agents, adhesives, sealants, antibacterial agents, infection-resistant agents, analgesics, and various other kinds of medicinal or beneficial substances.

**[0020]** With general reference to the figures, and in association with various embodiments of the invention, a surgical severing/stapling instrument 10 may be structured with a handle portion 20 that is connected to an implement portion 22. The implement portion 22 may include a shaft 24 which extends distally from the handle portion 20 and terminates in an end effector 26. The end effector 26 may include an actuator or E-beam firing mechanism ("firing bar") 28 that controls spacing between an elongated channel 30 and a pivotally translatable anvil 32 included within the end effector 26. It can be seen that the spacing between

the channel 30 and the anvil 32 may be configured to promote effective stapling and severing of tissue during use of the surgical instrument 10 by a clinician, for example.

**[0021]** The handle portion 20 of the instrument 10 may include a pistol grip 34 toward which a closure trigger 36 may be pivotally drawn by the clinician, for example, to cause clamping or closing of the anvil 32 toward the channel 30 of the end effector 26. In operation, the tissue of a patient, for example, may be clamped by the closing of the anvil 32 toward the channel 30. A firing trigger 38 positioned adjacent to the closure trigger 36 can be pivotally drawn in the direction of the pistol grip 34 to substantially simultaneously staple and sever tissue clamped in the end effector 26 of the instrument 10. In a surgical operation, the clinician first activates the closure trigger 36 to clamp the tissue of a patient, for example. Once the clinician is satisfied with the positioning of the end effector 26, the closure trigger 36 may be drawn back to a fully closed and locked position proximate to the pistol grip 34. The firing trigger 38 of the instrument 10 may then be actuated to sever and staple the clamped tissue. The firing trigger 38 may springedly return to a normal, inactivated state when the clinician removes pressure applied to the firing trigger 38. A release button 40 positioned on the proximal end of the handle portion 20 may be pressed by the clinician to release the locked closure trigger 36 to its normally open position (as shown in Figure 1).

**[0022]** In various embodiments, the distal end of the shaft 24 may include a closure tube 52 structured to receive and contain portions of the components of the end effector 26, such as the anvil 32 and the channel 30. The closure tube 52 may also be structured to receive a spine 54 extending therethrough that supports a knife shaft 56 having a distally positioned severing edge 58. The knife shaft 56 may operatively interact with the firing bar 28 at the severing edge 58 of the knife shaft 56. A knife spring 60 may be inserted within the spine 54 and structured

with a resilient downward bias that promotes proper and secure positioning of the knife shaft 56 within the spine 54. In operation, when the instrument 10 is fired, the knife shaft 56 and its severing edge 58 are moved through the channel 30 by a knife rod 61 to sever tissue clamped between the anvil 32 and the channel 30. The channel 30 may be structured to receive a removable staple cartridge 62 therein. The staple cartridge 62 may have multiple staple holes (such as illustratively representative staple holes 64, 66, 68) formed therein and through which multiple staples (not shown) may be driven that staple severed tissue when the instrument 10 is fired. In certain embodiments, the staple cartridge 62 may be an "ETS45" or "ETS60" six-row cartridge, for example, marketed by Ethicon Endo-Surgery, Inc., of Cincinnati, Ohio.

**[0023]** Examples of the structure and operation of typical surgical stapling instruments that may be provided in association with embodiments of the present invention are disclosed in a United States published patent application to Shelton et al. entitled, "Surgical Stapling Instrument having Separate Distinct Closing and Firing Systems" (U.S. Pub. No. 2004/0232196, Serial No. 10/441,632, filed on May 20, 2003), the entirety of which is hereby incorporated by reference.

**[0024]** With regard to embodiments of a medical agent dispensing system that may be provided in conjunction with the surgical instrument 10, a pump auger casing 72 may be positioned to extend longitudinally through the spine 54, and may extend from the handle portion 20 of the instrument 10 to a lateral manifold 74. The pump auger casing 72 may be structured to receive therethrough a screw pump auger 76 that is capable of rotational manipulation when positioned within the pump auger casing 72. Figure 6 shows an example of a screw pump auger 76 that may be used in accordance with various embodiments of the invention. One or more agent tubes 78, 80 may be positioned to communicate both with the lateral manifold 74 and with

a plurality of agent ports (such as illustratively representative agent ports 82, 84, 86) formed in the staple cartridge 62 generally adjacent to the staple holes 64, 66, 68 of the cartridge 62. The agent tubes 78, 80 may be structured for communication with the agent ports 82, 84, 86 in the staple cartridge 62 as shown in the end view of the cartridge 62 of Figure 8. While a row of agent ports 82, 84, 86 is shown positioned next to both sides of a longitudinal center line of the channel 30, it can be appreciated that more or less such agent ports 82, 84, 86 may be provided in the cartridge 62. For example, more agent ports 82, 84, 86 may be provided in place of one or more of the staple holes 64, 66, 68 formed in the cartridge 62 as shown. With particular reference to Figures 3 and 5, one or more structures such as mounting blocks 79, 81 may be included within the channel 30 to facilitate securement and stability of the agent tubes 78, 80 (respectively) within the instrument 10. Also, it can be seen that the agent tubes 78, 80 (such as the left-hand side agent tube 78, as shown in Figure 4, for example) may be positioned generally adjacent to the knife shaft 56 as the agent tubes 78, 80 extend longitudinally through the shaft 24.

**[0025]** In various embodiments, the handle portion 20 may include one or more medical agent storage reservoirs 92, 94 mounted on the handle portion 20 and in communication with the casing 72. The storage reservoirs 92, 94 may contain a variety of medical agents, or components thereof, that can be beneficially applied to severed and stapled tissue by action of the dispensing system in connection with use of the surgical instrument 10. While multiple storage reservoirs 92, 94 are depicted with the instrument 10 for convenience of disclosure, certain embodiments of the invention may employ only a single storage reservoir or more than two storage reservoirs. It can be seen that employing multiple storage reservoirs 92, 94 can facilitate real-time mixing of multiple-component medical agents during operation of the medical agent dispensing system. For example, one storage reservoir 92 may contain a powder and the

other storage reservoir 94 may contain a liquid. The powder and the liquid in the storage reservoirs 92, 94 may be mixed during operation of the instrument 10, such as by directing the substances through the Y-manifold 96 (as shown in Figures 3 and 5, for example). It can be appreciated that storing and deploying components of a medical agent separately may preserve the shelf life and thus the effectiveness of the individual components. In another example, the use of multiple storage reservoirs 92, 94 permits the use of two-part adhesives, for example, in connection with operation of the dispensing system within the instrument 10.

**[0026]** Also, in various embodiments of the medical agent dispensing system of the present invention, an electric motor 98 may be included within the handle portion 20 with a mechanical linkage structured to drive rotation of the screw pump auger 76 within the pump auger casing 72 upon activation of the motor 98. Those skilled in the art will appreciate that the electric motor 98 may be any conventional battery-driven or AC-powered motor provided with specifications (e.g., a motor rating) suitable for safe and effective use of the motor 98 in association with operation of the surgical instrument 10. In certain embodiments, the electric motor 98 may be activated through conventional electrical circuitry or components 100 that can be operatively associated with the firing trigger 38, the release button 40, and/or an independent manual activation switch 102 of the instrument 10. The electrical circuitry 100 may be configured to activate the motor 98 automatically in association with the firing operation of the instrument 10, for example; and/or to activate the motor 98 manually through use of the switch 102 which may be pressed by the clinician, for example, when using the instrument 10. In certain embodiments, a mechanically driven rotary trigger, for example, may be configured to interact with the mechanical linkage operatively associated with the casing 72 to drive rotation of the screw pump auger 76 within the casing 72.

**[0027]** With reference to Figure 9, a process flow diagram illustrates a method of applying the instrument 10 with the medical agent dispensing system in a surgical procedure performed on tissue, in accordance with various embodiments of the invention. At step 202, the instrument 10 may be fired as described above to sever tissue and to apply staples to areas on both sides of an incision made in the tissue. At step 204, in connection with retraction of the knife shaft 56 from the severed/stapled tissue, the electric motor 98 may be activated to initiate rotation of the screw pump auger 76 within the pump auger casing 72 at step 206. At step 208 (which may occur substantially in parallel with step 206), the pump auger casing 72 receives a quantity of a medical agent, or components combined to create a quantity of the medical agent, from the Y-manifold 96. At step 210, the medical agent is delivered by rotational action of the screw pump auger 76 to the lateral manifold 74. At step 212, the medical agent may be driven through the agent tubes 78, 80 to be dispensed at step 214 through the plurality of agent ports 82, 84, 86 in the staple cartridge 62. Once dispensed through the plurality of agent ports 82, 84, 86, the medical agent may then cover or deluge at least a portion of tissue areas severed and stapled by action of the instrument 10 at step 202.

**[0028]** It will be appreciated that the terms "proximal" and "distal" may be used herein as convenient terms of relative orientation, such as with reference to a clinician gripping a handle of an instrument. For example, the end effector 26 may be considered "distal" with respect to the "proximal" handle portion 20 (see, e.g., Figure 1). It will be further appreciated that, for convenience and clarity of disclosure, spatial terms of relative orientation such as "vertical" and "horizontal" or "downward" and "upward" may be used herein with respect to the drawings. Those skilled in the art will appreciate, however, that surgical instruments may be

used in many orientations and positions, and such terms are not intended to be limiting and absolute.

**[0029]** Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is done so only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in the present disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

**[0030]** The examples presented herein are intended to illustrate potential and specific implementations of the present invention for those skilled in the art. No particular aspect or aspects of the examples included herein are necessarily intended to limit the scope of the present invention.

**[0031]** It is to be understood that the figures and descriptions of the present invention have been simplified to illustrate elements that are relevant for a clear understanding of the present invention, while eliminating, for purposes of clarity, other elements. Those of ordinary skill in the art will recognize, however, that these and other elements may be desirable in a typical computer system or database system. However, because such elements are well known in the art and because they do not facilitate a better understanding of the present invention, a discussion of such elements may not be provided herein.

**[0032]** Any element expressed herein as a means for performing a specified function is intended to encompass any way of performing that function including, for example, a combination of elements that perform that function. Furthermore the invention, as defined by such means-plus-function claims, resides in the fact that the functionalities provided by the various recited means are combined and brought together in a manner as defined by the appended claims. Therefore, any means that can provide such functionalities may be considered equivalents to the means shown herein.

**[0033]** In various embodiments of the present invention disclosed herein, a single component may be replaced by multiple components, and multiple components may be replaced by a single component, to perform a given function or functions. Except where such substitution would not be operative to practice embodiments of the present invention, such substitution is within the scope of the present invention.

**[0034]** While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications may readily appear to those skilled in the art. The present invention has been discussed in terms of endoscopic procedures and apparatus. However, use herein of terms such as "endoscopic" should not be construed to limit the present invention to a surgical stapling and severing instrument for use only in conjunction with an endoscopic tube (i.e., trocar). On the contrary, it is believed that surgical instruments structured in accordance with the present invention may find use in many surgical procedures, including but not limited to laparoscopic procedures and open procedures. Moreover, the unique and novel aspects of the embodiments of the present invention may find

utility when used in connection with other forms of stapling apparatuses without departing from the spirit and scope of the present invention.

# CLAIMS

WHAT IS CLAIMED IS:

1. A medical agent dispensing system structured for use with a surgical severing/stapling instrument structured for severing and stapling tissue, the dispensing system comprising:

at least one storage reservoir structured for storing at least a component of a medical agent;

a gear pump casing in communication with the storage reservoir;

a screw pump auger positioned within the gear pump casing, the screw pump auger being capable of rotational manipulation to move the medical agent through the gear pump casing; and,

at least one agent tube in communication with the gear pump casing, the agent tube being structured for communication with a least one agent port formed in a staple cartridge of the surgical instrument for dispensing the medical agent therethrough.

2. The dispensing system of Claim 1, wherein the medical agent includes a hemostatic agent.

3. The dispensing system of Claim 1, wherein the medical agent includes an adhesive.

4. The dispensing system of Claim 1, wherein the pump auger casing is positioned to extend longitudinally through a spine of the surgical instrument.

5. The dispensing system of Claim 1, wherein the pump auger casing is in communication with the agent tube through a lateral manifold.

6. The dispensing system of Claim 5, wherein the agent tube is in communication with both the lateral manifold and a plurality of the agent ports.

7. The dispensing system of Claim 1, further comprising at least a second agent tube in communication with the gear pump casing, wherein the first agent tube communicates with a first plurality of agent ports formed in the staple cartridge, and the second agent tube communicates with a second plurality of agent ports formed in the staple cartridge.

8. The dispensing system of Claim 1, further comprising at least one agent port being formed generally adjacent to at least one staple hole of the staple cartridge.

9. The dispensing system of Claim 1, further comprising at least a second storage reservoir in communication with the gear pump casing, the second storage reservoir being structured for storing at least a component of the medical agent.

10. The dispensing system of Claim 9, wherein the component stored in the first storage reservoir and the component in the second storage reservoir are designed to be combined to form the medical agent.

11. The dispensing system of Claim 9, further comprising a Y-manifold in communication with both the first storage reservoir and the second storage reservoir.

12. The dispensing system of Claim 1, further comprising an electric motor structured to drive rotation of the screw pump auger within the pump auger casing.

13. The dispensing system of Claim 1, further comprising a mechanically driven rotary trigger configured to drive rotation of the screw pump auger within the pump auger casing.

14. A surgical severing/stapling instrument including a medical agent dispensing system, the instrument comprising:

a handle portion including at least one storage reservoir structured for storing at least a component of a medical agent;

a shaft portion connected to the handle portion, the shaft portion including a gear pump casing in communication with the storage reservoir, the gear pump casing including a screw pump auger extending therethrough capable of rotational manipulation to move the medical agent through the gear pump casing;

an end effector portion operatively associated with the shaft portion, the end effector including a channel having a staple cartridge positioned removably therein;

at least one agent tube in communication with the gear pump casing, the agent tube extending from the shaft portion to communicate with a least one agent port formed in the staple cartridge for dispensing the medical agent therethrough.

15. The instrument of Claim 14, wherein the medical agent includes a hemostatic agent.

16. The instrument of Claim 14, wherein the medical agent includes an adhesive.

17. The instrument of Claim 14, wherein the pump auger casing is in communication with the agent tube through a lateral manifold.

18. The instrument of Claim 14, further comprising at least a second agent tube in communication with the gear pump casing, wherein the first agent tube communicates with a first plurality of agent ports formed in the staple cartridge, and the second agent tube communicates with a second plurality of agent ports formed in the staple cartridge.

19. The instrument of Claim 14, further comprising the handle portion including at least a second storage reservoir in communication with the gear pump casing, the second storage reservoir being structured for storing at least a component of the medical agent.

20. The instrument of Claim 19, wherein the component stored in the first storage reservoir and the component in the second storage reservoir are designed to be combined to form the medical agent.

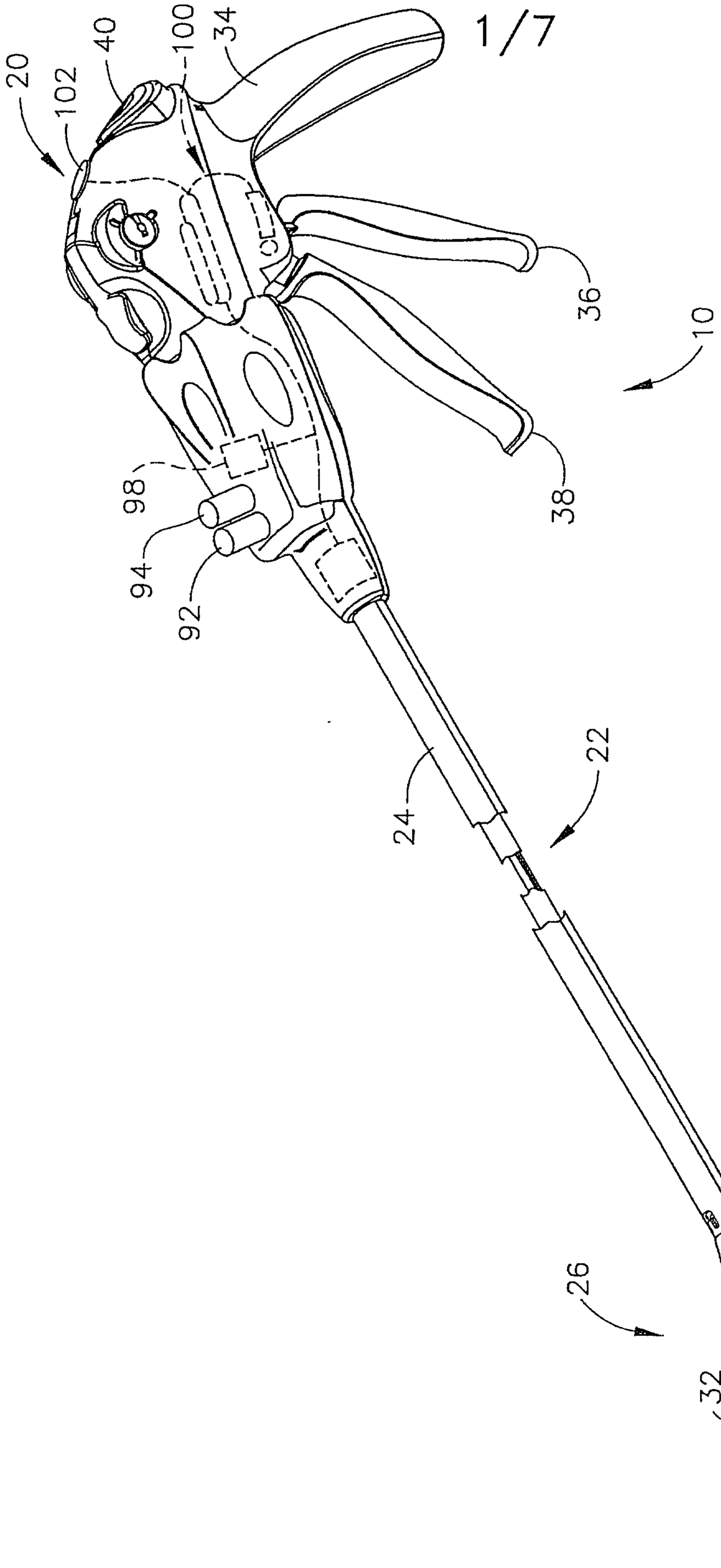



FIG. 1

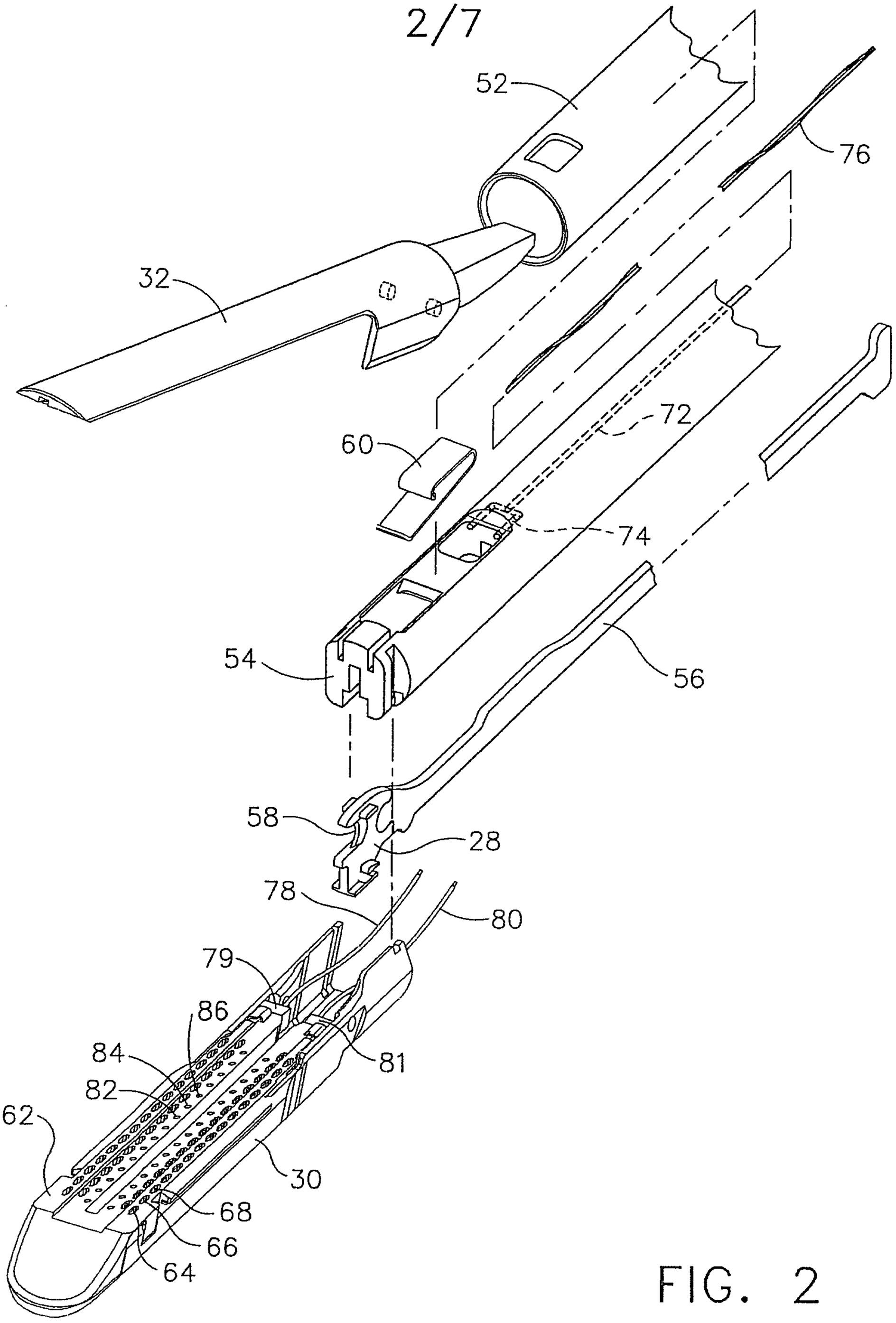



FIG. 2

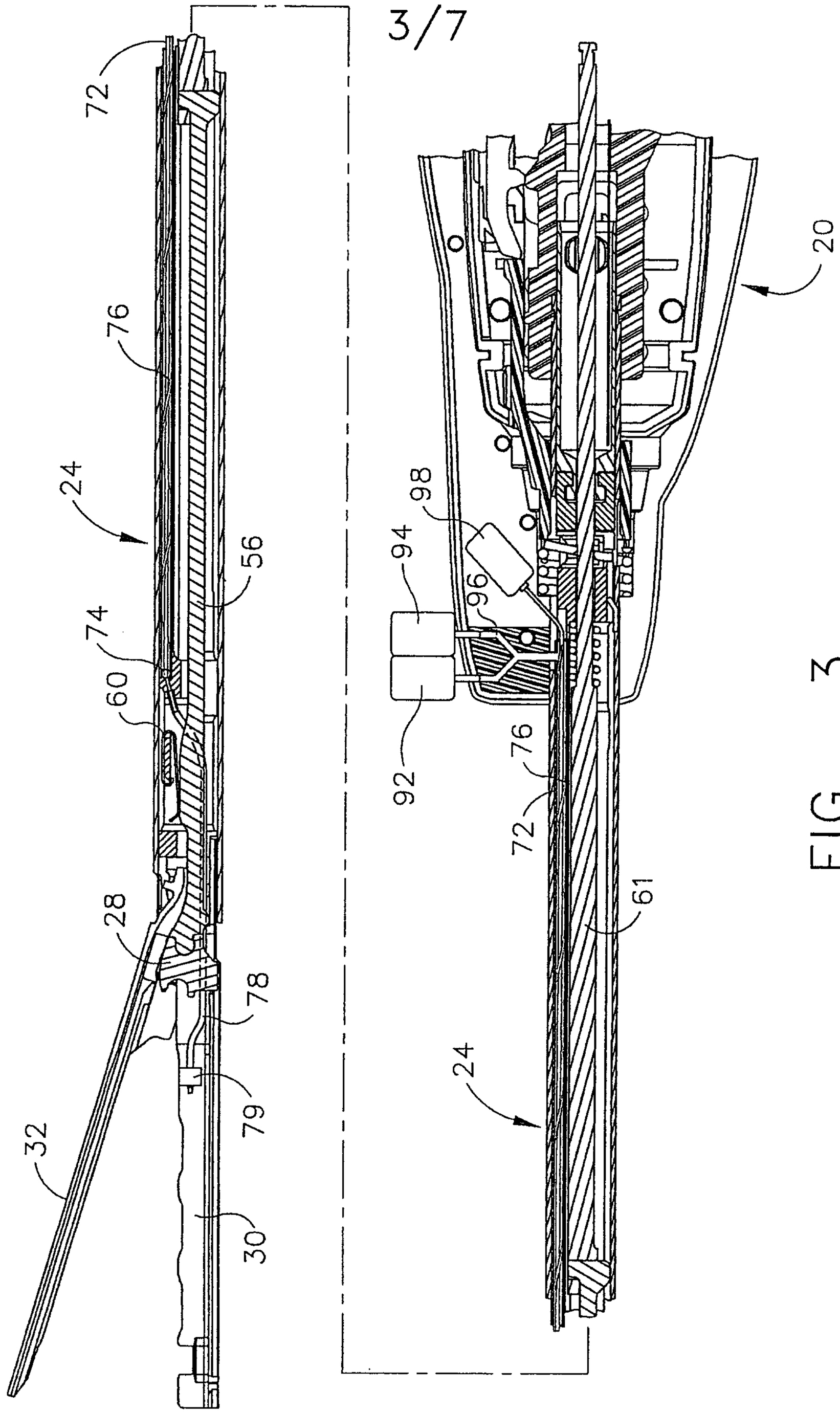



FIG. 3

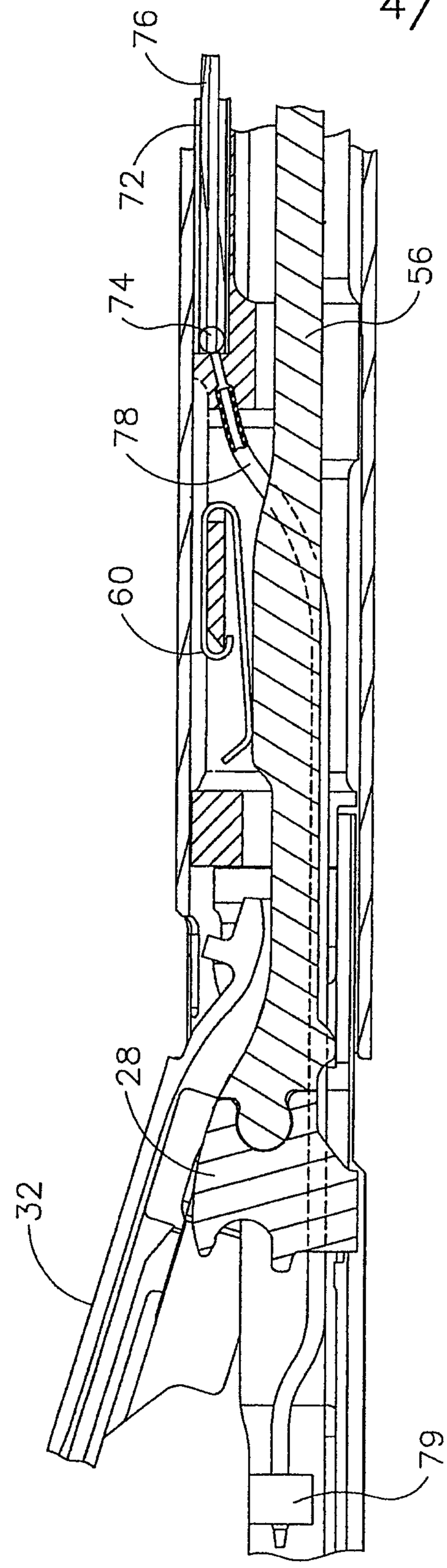



FIG. 4

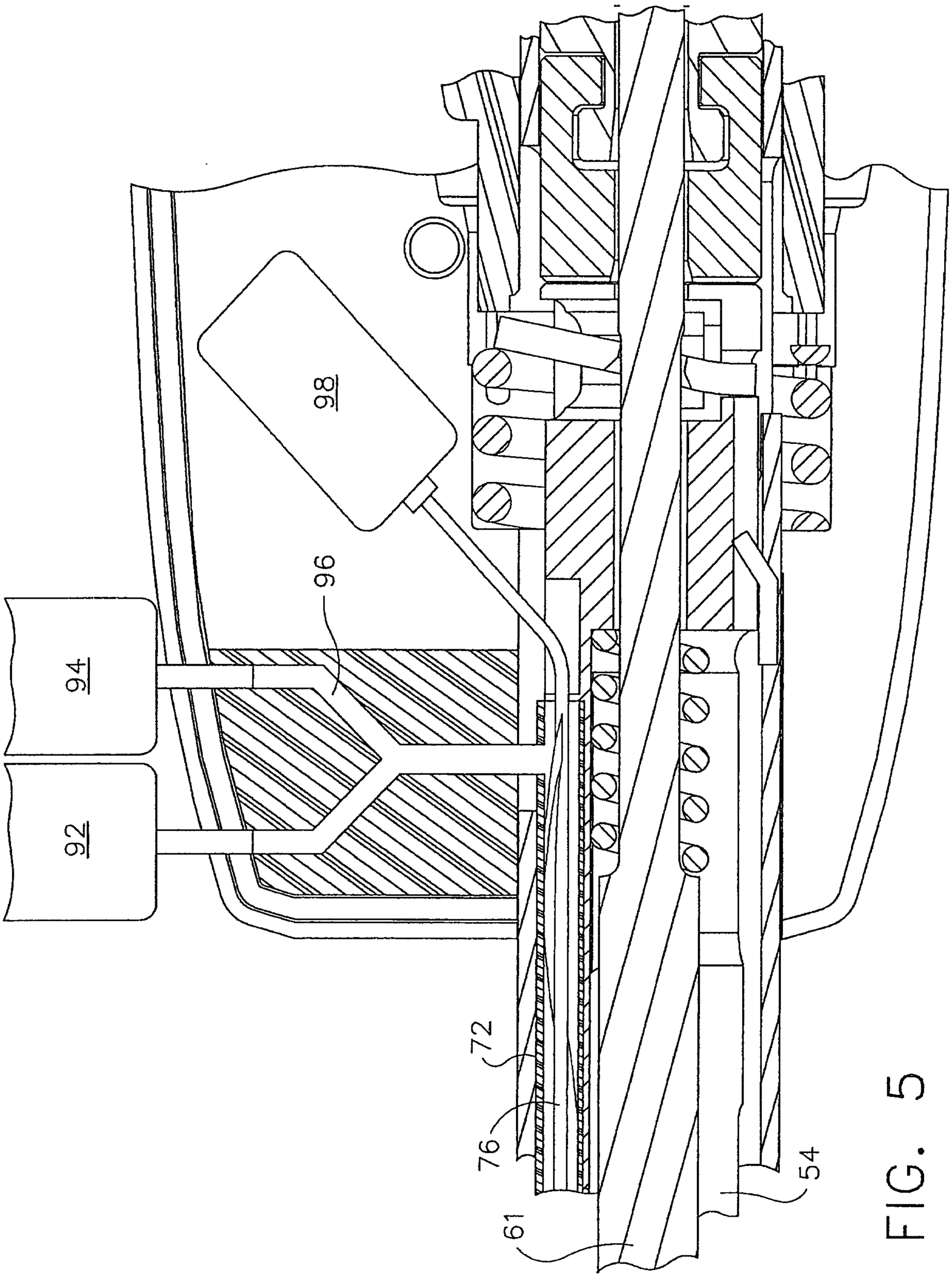



FIG. 5

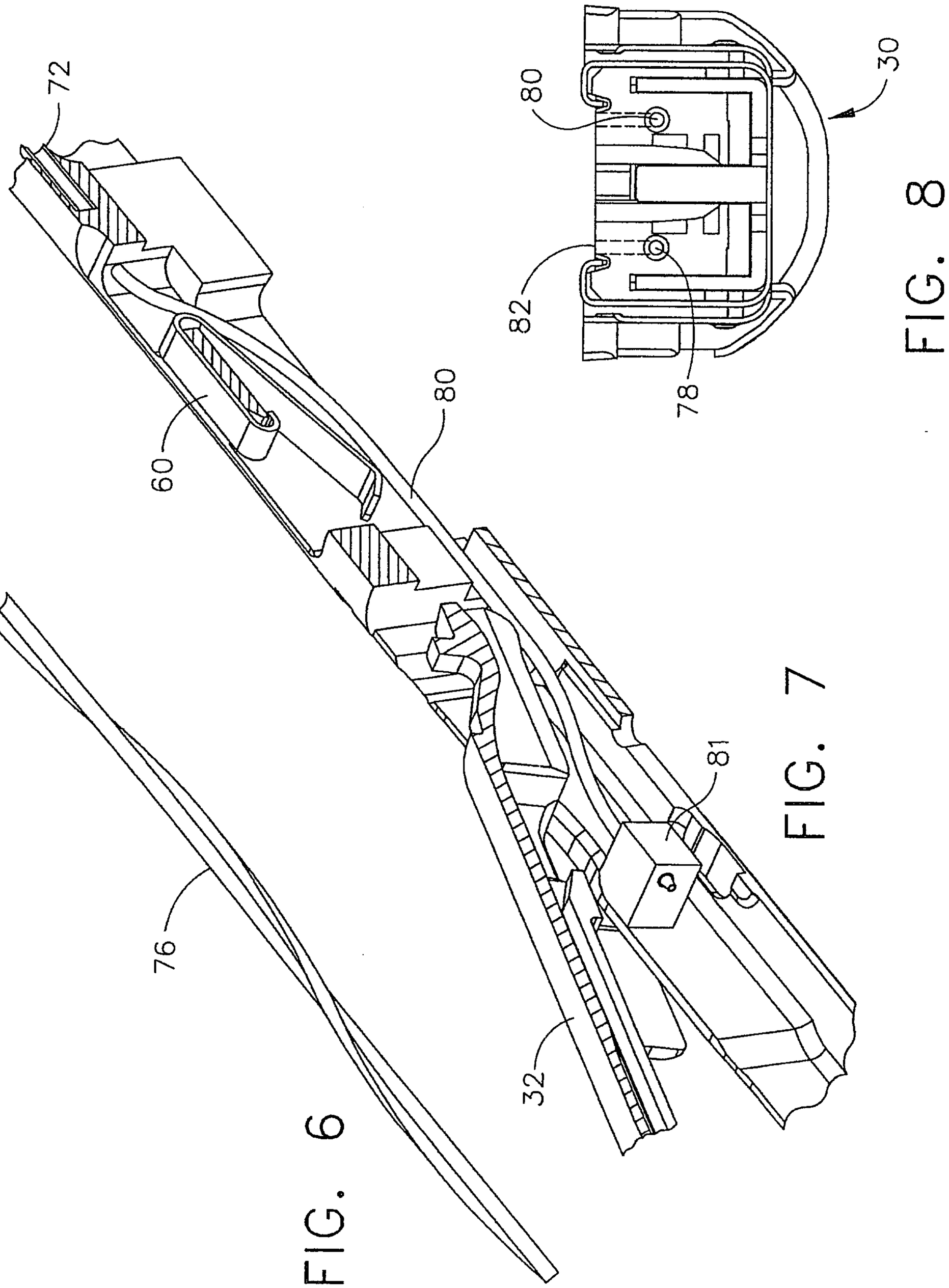



FIG. 6

FIG. 7

FIG. 8

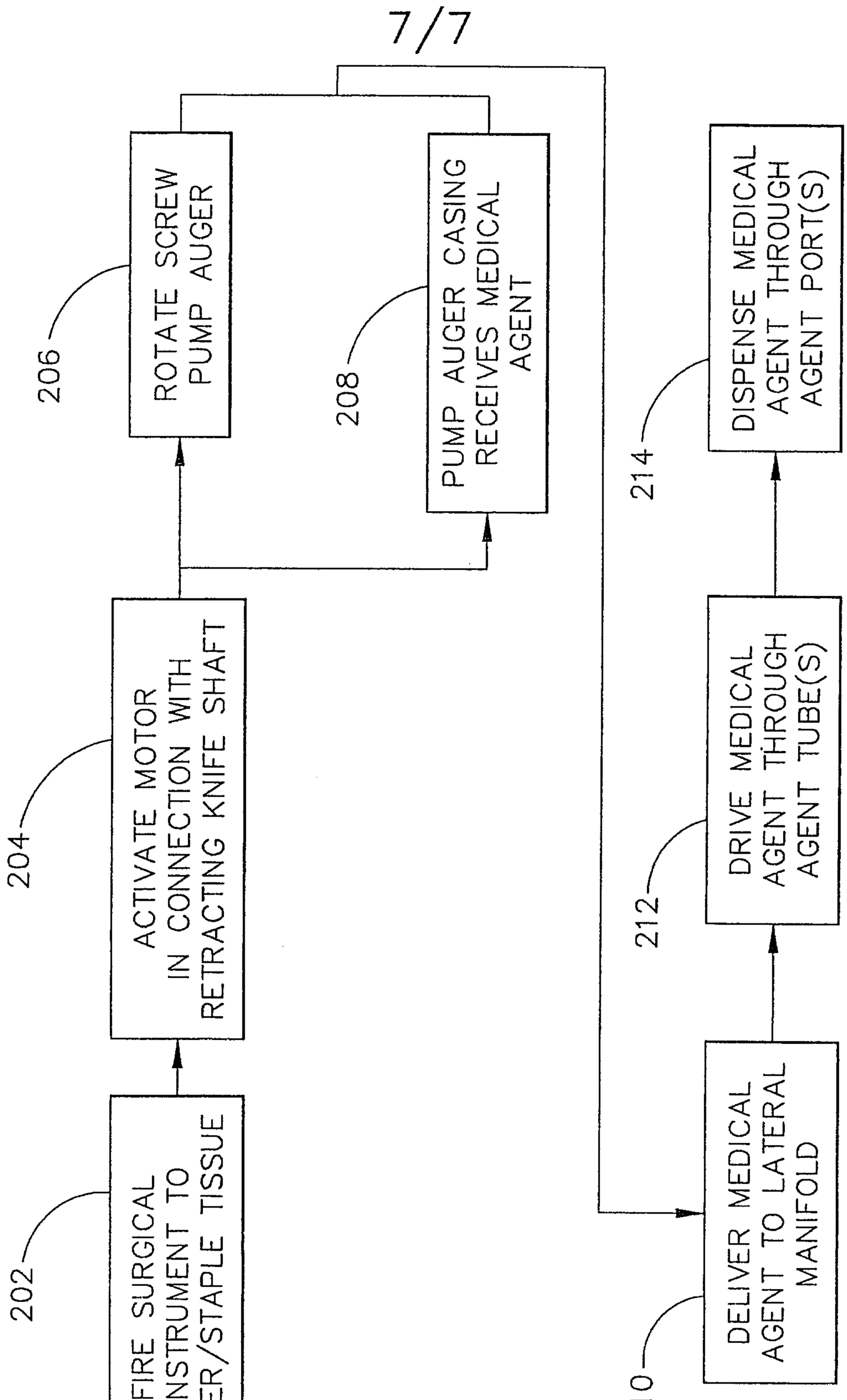
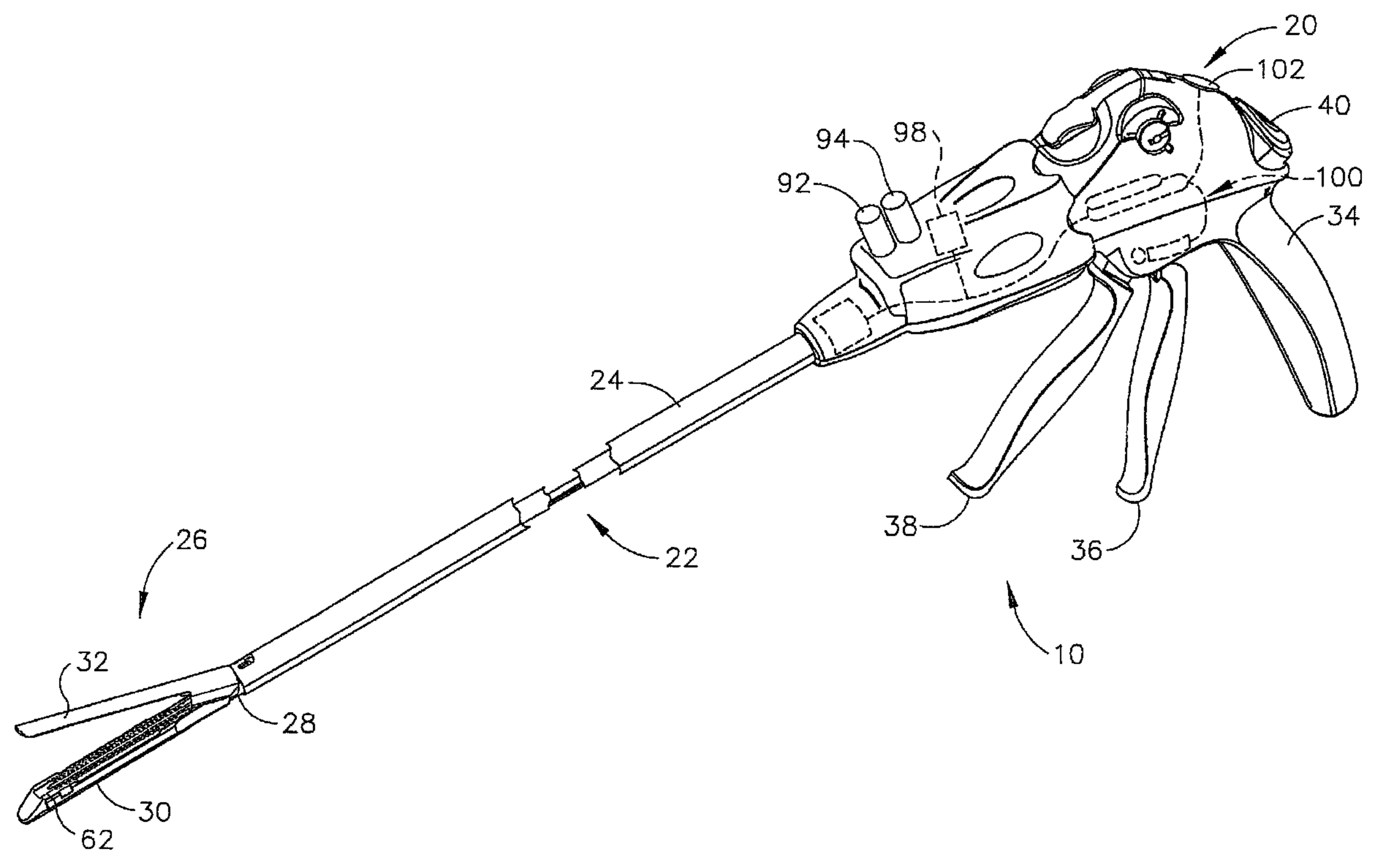

202
FIRE SURGICAL INSTRUMENT TO SEVER/STAPLE TISSUE
204
ACTIVATE MOTOR IN CONNECTION WITH RETRACTING KNIFE SHAFT
206
ROTATE SCREW PUMP AUGER
208
PUMP AUGER CASING RECEIVES MEDICAL AGENT
210
DELIVER MEDICAL AGENT TO LATERAL MANIFOLD
212
DRIVE MEDICAL AGENT THROUGH AGENT TUBE(S)
214
DISPENSE MEDICAL AGENT THROUGH AGENT PORT(S)

FIG. 9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