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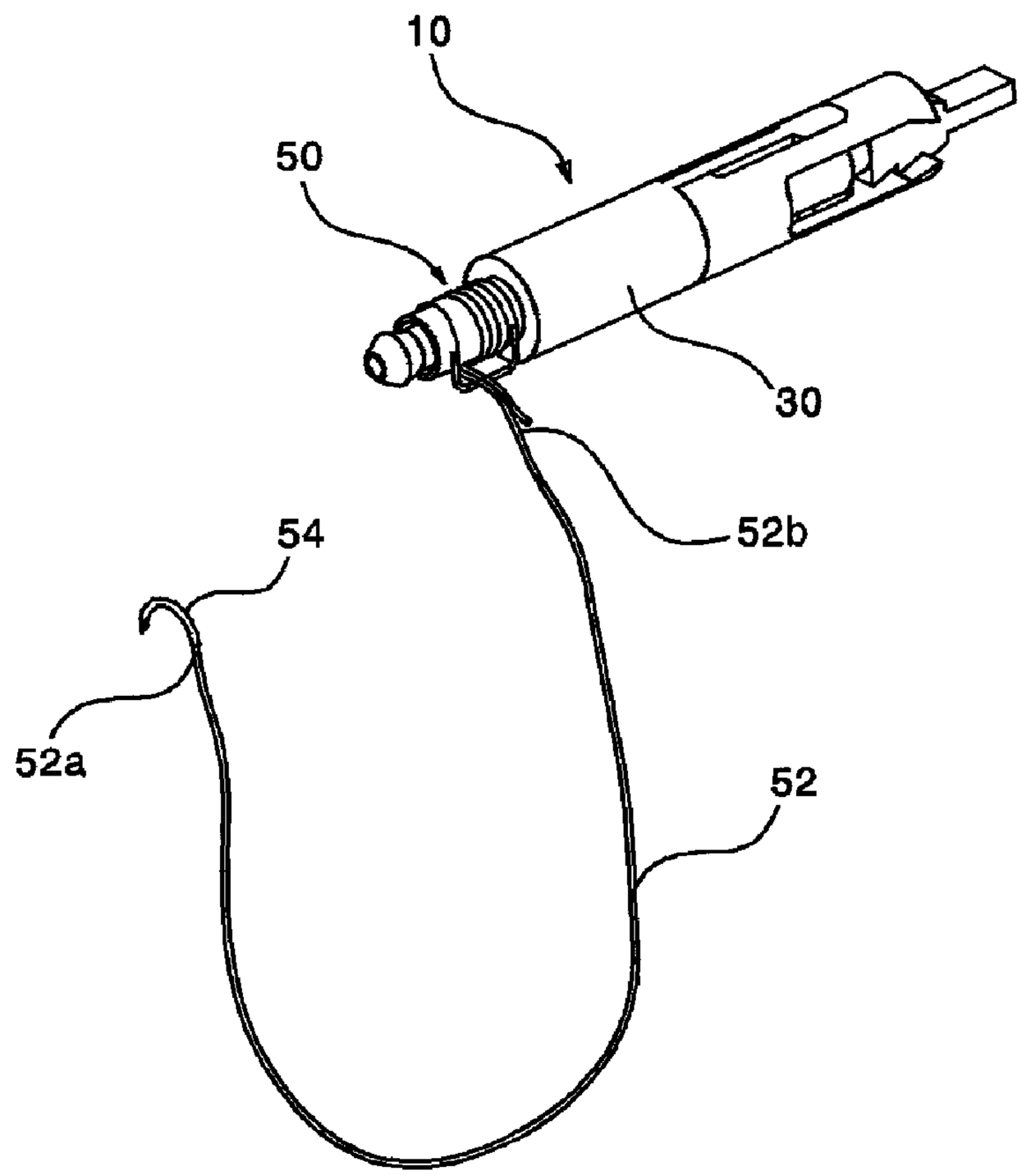


(57) Abrégé/Abstract:
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(57) Abrégé(suite)/Abstract(continued):
suture. The device includes an outer sleeve having a passageway therethrough to receive therein the elongate center pin. A suture having a suture needle is attached to a first end of the center pin and a second end of the suture is formed into a pre-formed knot mounted on the sleeve. The device includes a suture release mechanism having a passageway extending therethrough to receive the outer sleeve therein. The suture release mechanism slides along the sleeve between a first position in which the suture release mechanism is spaced from the distal end and a second position such that movement of the suture release mechanism from the first position to the second position dislodges the pre-formed knot off the sleeve. A free end of the suture, which was attached to a suture needle but cut lose after the suture has been passed through the tissue being sutured, is crimped by the crimp mechanism. The pre-formed knot is dislodged such that the crimped end of the suture is located within the pre-formed knot and pulling the suture through the knot tightens the pre-formed knot on the suture.

## ABSTRACT

The present invention provides an anastomosis device which includes an elongate center pin having proximal and distal ends. The proximal end is configured to be graspable using a grasping tool. A grip mechanism is located at the distal end for crimping a suture. The device includes an outer sleeve having a passageway therethrough to receive therein the elongate center pin. A suture having a suture needle is attached to a first end of the center pin and a second end of the suture is formed into a pre-formed knot mounted on the sleeve. The device includes a suture release mechanism having a passageway extending therethrough to receive the outer sleeve therein. The suture release mechanism slides along the sleeve between a first position in which the suture release mechanism is spaced from the distal end and a second position such that movement of the suture release mechanism from the first position to the second position dislodges the pre-formed knot off the sleeve. A free end of the suture, which was attached to a suture needle but cut lose after the suture has been passed through the tissue being sutured, is crimped by the crimp mechanism. The pre-formed knot is dislodged such that the crimped end of the suture is located within the pre-formed knot and pulling the suture through the knot tightens the pre-formed knot on the suture.

# ANASTOMOSIS DEVICE AND METHOD OF USING THE SAME

## CROSS REFERENCE TO RELATED U.S PATENT APPLICATION

This patent application relates to U.S. provisional patent application Serial No. 61/353,993 filed on June 11, 2010, entitled **ANASTOMOSIS DEVICE AND METHOD OF USING THE SAME**, filed in English, which is incorporated herein in its entirety by reference.

## FIELD OF THE INVENTION

The present invention relates to a device for accomplishing the surgical process of anastomosis i.e. connecting two structures (commonly tubular structures) to restore continuity after resection or to bypass an unresectable disease process. More particularly the present invention relates to an anastomosis device for performing the process of connecting the structures in an end-to-end, side-to-side or an end-to-side fashion.

## BACKGROUND OF THE INVENTION

A common requirement in many surgical procedures is the resection or bypass of a diseased organ. Often the diseased section is a part of a tubular structure i.e. artery, bowel, esophagus and therefore after the resection it is required to reattach the resulting two healthy ends. This procedure is termed as anastomosis and is a fairly easy task to perform in the setting of an open surgery. However, in minimally invasive surgery where the procedure is performed through small incisions in the patient's skin, anastomosis is an extremely difficult skill to learn and execute.

Typically, anastomosis time in a MIS procedure range between half an hour up to two hours. Needless to say, the long anastomosis time has a negative impact on the patient due to increased anesthesia requirement. For the surgeon, laparoscopic anastomosis is extremely difficult to learn and perform and is very fatiguing in nature. Increased anastomosis time is also a burden on the healthcare provider as it takes up valuable operating room time and adds to the personnel cost.

U.S. Patent 6,358,258 issued to Arcia et al. discloses an anastomosis device that utilizes multiple flexible needles (designed of Nitinol material) that are deployed through multiple curved guide channels. The design utilizes multiple push rods for actuation and is suitable for end-side type anastomosis.

U.S. Patent 7,029,481 issued to Burdulis et al. discloses an anastomosis device that utilizes multiple needles that are simultaneously pierced through the tissue using a pneumatic cylinder. The needles latch onto small crimps on the opposite end and pull the sutures through the tissue upon retraction. The other end of the device utilizes multiple flexible needles deployed using curved channels and multiple push rods. The design needs custom needles as the sutures are attached to the distal tip of the needle as opposed to the proximal end found in conventional sutures.

U.S. Patent Application US2008/0275472, to Yossepowitch et al. discloses an anastomosis device that utilizes multiple needle deployment through the use of flexible needle and curved guide channels. The design utilizes multiple push rods and requires custom needles to function. Even

though the two ends of the design are attached through a flexible coupler, the design lacks a good suture management scheme and will suffer from suture tangling. Similar to U.S. Patent 7,029,481, the design needs custom needles as the sutures are attached to the distal tip of the needle as opposed to the proximal end found in conventional sutures.

Thus, there is a need for an automated/assisted laparoscopic anastomosis device that can reduce procedure time and operating costs. The device will also be of interest to the surgeons as it would minimize the dependence on a surgeon's dexterity and experience and will reduce the learning curve of this complex task.

## SUMMARY OF THE INVENTION

The present invention provides an anastomosis device, comprising:

a) an elongate center pin having proximal and distal ends, said proximal end structured to be manipulatable by a manipulation tool, a grip mechanism located at said distal end for gripping a suture;

b) an outer sleeve having a passageway therethrough to receive therein the elongate center pin, said sleeve being mountable by a pre-formed knot formed in a suture; and

c) a suture release mechanism having a passageway extending therethrough to receive the outer sleeve therein, said suture release mechanism being reciprocally translatable on said sleeve between a first position and a second position, and movement of said suture release mechanism from said first position to said second position dislodges said pre-formed knot off said sleeve, and with a free end of said suture being

gripped by said grip mechanism, said pre-formed knot is dislodged such that said suture is located within said pre-formed knot and pulling said free end tightens said pre-formed knot on said suture.

In another aspect of the present invention there is provided an anastomosis device, comprising:

a) an elongate center pin having proximal and distal ends, said proximal end structured to be manipulatable by a manipulation tool;

b) an outer sleeve having a passageway therethrough to receive therein the elongate center pin, said sleeve being mountable by a pre-formed knot formed in a suture;

c) a suture release mechanism having a passageway extending therethrough to receive the outer sleeve therein, said suture release mechanism being reciprocally translatable on said sleeve between a first position and a second position, and movement of said suture release mechanism from said first position to said second position dislodges said pre-formed knot off said sleeve, and with a free end of said suture being gripped by said grip mechanism, said pre-formed knot is dislodged such that said suture is located within said pre-formed knot and pulling said free end tightens said pre-formed knot on said suture; and

d) a grip mechanism located at said distal end for gripping a suture, the grip mechanism comprising a head section attached to the distal end of said elongate center pin, and a groove disposed on the head section comprising an elongate channel having a width and length and an opening thereto, wherein the opening has a width less than that of the elongate

channel, thereby allowing a suture to be inserted into the channel through the opening and to remain firmly held in place in the channel.

A further understanding of the functional and advantageous aspects of the invention can be realized by reference to the following detailed description and drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described, by way of example only, with reference to the drawings, in which:

**Figure 1** shows an exemplary embodiment of two tubular structures after the anastomosis has been performed;

**Figure 2** is a perspective view of an embodiment of an anastomosis device constructed in accordance with the present invention;

**Figure 3** is a side view of the anastomosis device of **Figure 2**;

**Figure 4** shows an exploded perspective view of the device of **Figure 2**;

**Figure 5** shows a perspective view of a laparoscopic tool that combines grasping and cutting functionality into a single tool used with the anastomosis device;

**Figure 6** shows a close up view of a portion of the grasping and cutting laparoscopic tool of **Figure 5** used with the anastomosis device;

**Figure 7** shows the close up view of a scissor actuation mechanism forming part of the grasping and cutting laparoscopic tool

**Figure 8** shows the preferred embodiment of a laparoscopic tool **200** that combines grasping functionality with a sliding push-rod tool.

**Figure 9** is a close-up view of the distal end of the combined grasper and push-rod tool according to the disclosed invention.

**Figure 10** is a perspective view showing the anastomosis tool with a pre-formed knot;

**Figures 11** to **14** show various steps carried out by a surgeon using the present anastomosis tool to suturing, in which:

**Figure 11** is a perspective view showing the needle and the suture after they have been manually passed through both sides of the target vessel by the anastomosis device;

**Figure 12** is a perspective view showing the anastomosis device with a combined laparoscopic grasper and push-rod tool, with this configuration the surgeon wraps the trimmed end of the suture around a center pin head forming part of the anastomosis device preferably one or more revolutions;

**Figure 13** is a perspective view showing the pre-formed knot after it has been released from the anastomosis device onto the trimmed end of the suture;

**Figure 14** is a perspective view showing the target vessel after the knot shown released in **Figure 13** has been tightened and trimmed; and

**Figure 15** is a perspective view of a second embodiment in accordance with the present invention.

## DETAILED DESCRIPTION OF THE INVENTION

Without limitation, the majority of the systems described herein are directed to an anastomosis device for performing the process of

connecting the structures in an end-to-end, side-to-side or an end-to-side fashion, and method of using the same. As required, embodiments of the present invention are disclosed herein. However, the disclosed embodiments are merely exemplary, and it should be understood that the invention may be embodied in many various and alternative forms.

The Figures are not to scale and some features may be exaggerated or minimized to show details of particular elements while related elements may have been eliminated to prevent obscuring novel aspects. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention. For purposes of teaching and not limitation, the illustrated embodiments are directed to an anastomosis device for performing the process of connecting the structures in an end-to-end, side-to-side or an end-to-side fashion.

As used herein, the term "about", when used in conjunction with ranges of dimensions, temperatures or other physical properties or characteristics is meant to cover slight variations that may exist in the upper and lower limits of the ranges of dimensions so as to not exclude embodiments where on average most of the dimensions are satisfied but where statistically dimensions may exist outside this region. For example, in embodiments of the present invention dimensions of components of a laparoscopic anastomosis device are given but it will be understood that these are not meant to be limiting.

As used herein, the process of "anastomosis" refers to the process of reattaching two healthy ends of an anatomical tubular structure (such as blood veins, arteries, intestines etc.) after a resection has been carried out to remove a diseased or injured section. **Figure 1** shows an exemplary embodiment of two tubular structures after the anastomosis has been performed.

As used herein, the phrase "anastomosis device" refers to a device for performing process of anastomosis which forms the subject matter of the present invention.

The present invention discloses an anastomosis device that utilizes conventional sutures with a mechanism that holds a pre-formed knot to expedite the task of anastomosis. The workflow of the anastomosis device is similar to that of conventional suturing, however it facilitates easy anastomosis that is quick to perform and minimizes the dependence on a surgeon's dexterity.

**Figure 2** shows an embodiment of the anastomosis device **10** comprising four main components: center pin **12**, outer sleeve **26**, suture release mechanism **30** and locking mechanism **40**. The center pin **12** includes a head **14** rigidly attached to it on the distal end through the use of a press fit pin **16**. The outer sleeve **26** and locking mechanism **40** are rigidly attached together and therefore act as a single entity in the mechanism. The proximal end of center pin **12** includes saw tooth profile **18** that includes one or more teeth and a proximal end **20** that can be grabbed using a grasper or a similar tool. The center pin **12** can be translated with respect to the outer sleeve **26** through the use of locking mechanism **40.**

The locking mechanism **40** includes a saw-tooth profile **44** that mates with the saw-tooth profile **18** on the center pin **12.** The suture release mechanism **30** can be translated with respect to the locking mechanism **40** and is limited in its motion through the use of built in grooves **42** and a stop **34** in the locking mechanism **40**.

**Figure 3** shows the side view of the embodiment of **Figure 2**. Note that the saw-tooth profile **18** on the center pin is designed to mate with the saw-tooth profile **44** on the locking mechanism **40**. The locking mechanism **40** permits motion of the center pin **12** in the direction of arrow (as shown) and locks in the opposite direction. Since the device is a one-time use device there is no need to unlock it. At the end of its travel, the center pin **12** is butted against the outer sleeve **26** and is kept in tight contact due to the saw tooth profile **18**. In this position, the V-shaped profile on the center pin head **14** is in firm contact with the mating profile on the inside of the outer sleeve **26**. The functionality of this profile will be explained in detail later.

**Figure 4** shows the exploded view of the same embodiment as that shown in **Figures 2-3**. As shown, the center pin includes two parts; center pin body **12** and center pin tip **14** for ease of assembly. The two parts are rigidly attached to each other through the use of a press fit steel pin **16** during assembly.

**Figure 5** shows an embodiment of a laparoscopic tool **100** that combines grasping and cutting functionality into a single tool. The tool **100** includes a slender grasping/cutting end **102** that is inserted into the patient's body cavity and a proximal end **104** that includes two levers **110**

and **112** for the grasping action and a cutting (scissor) actuation mechanism **124**. As with a conventional laparoscopic grasper, the opening and closing of the grasper levers **110** and **112** causes either one or both grasper tips **106** and **108** to open and close, respectively. The scissor actuation mechanism **124** is preferably utilized while the grasper tips **106** and **108** are in its closed position. The forward motion (towards the distal end) of the scissor actuation mechanism **124** causes the outer sleeve **120** of the instrument to move in a forward direction and vice versa.

**Figure 6** shows the close up view of the embodiment of a combined grasping and cutting laparoscopic tool **100**. Utilizing this tool, the suture can be grasped using the graspers **106** and **108** in a conventional manner. The scissor actuation mechanism **124** can then be translated that will result in the translation of sleeve **120** and therefore scissor edge **122** along the grasper surface, resulting in cutting of the suture.

**Figure 7** shows the close up view of the scissor actuation mechanism **124**. The forward (towards the distal end of the laparoscopic instrument) motion of the lever **124** causes the scissor tip **122** to translate forward against the grasper surface and results in cutting of the suture.

**Figure 8** shows an embodiment of a laparoscopic tool **200** that combines grasping functionality with a sliding push-rod tool. The tool **200** includes a slender end **202** that is inserted into the patient's body cavity and a proximal end **204** that includes two levers **210** and **212** for grasping action and an actuation mechanism **224** for the push-rod. As with a conventional laparoscopic grasper, opening and closing of the grasper levers **210** and **212** causes one or both grasper tips **206** and **208** to open

and close, respectively. The push-rod actuation mechanism **224** is utilized while the grasper tips **206** and **208** are in its closed position. The forward motion (towards the distal end) of the push-rod actuation mechanism **224** causes the outer sleeve **220** (and push-rod tip **222**) of the instrument to move in a forward direction. The preferred method of use for this tool will be described in details later.

**Figure 9** shows a close-up view of the distal end **202** of the combined grasper and push-rod tool **200**.

**Figure 10** shows the anastomosis tool **10** with a suture **52** and a pre-formed knot **50** formed on the proximal end **52b** of the suture. Knot **50** is preferably a type of slip knot that once slid on suture **52**, is prone to unwinding. It can be seen that the anastomosis device **10** is designed as a one-time-use disposable device and is supplied with the needle **54** and suture **52** with a pre-formed knot **50**. Various means can be provided on the device to ensure that knot does not accidently slip from the device during handling. One preferred method will be to provide a groove on the suture release mechanism **30** and the proximal end **52b** of the suture **52** can be latched in this groove to avoid accidental slippage of the knot. The suture can then be removed from this groove by the surgeon using the laparoscopic grasper after the needle has been passed through both ends of the target anatomy and the anastomosis device is ready to be deployed. Other means of constraining the knot can be utilized without changing the scope of the invention. The preferred method of performing an anastomosis according to disclosed invention will now be described in detail.

One method of performing anastomosis using the disclosed embodiments herein requires the use of two laparoscopic ports on the patient's body. A third laparoscopic port is utilized to obtain images of the target anatomy using an endoscope that is connected to an external monitor for visualization. As a first step, the surgeon introduces the anastomosis device **10** (including the suture **52** and needle **54**) into the patient's body cavity through one of the ports. For this task, the surgeon can utilize a laparoscopic tool **100** or **200** to aid in easy insertion. As a next step, the surgeon introduces the combined laparoscopic grasping and cutting tool **100** (**Figure 5**) and the combined laparoscopic grasping and push-rod tool **200** (**Figure 8**) through the two ports into the patient's body cavity. In a manner similar to conventional anastomosis, the surgeon then utilizes both hands and left and right graspers **100** and **200** to pass the needle through two ends of the organs to be connected.

**Figure 11** shows the needle and the suture after they have been manually passed through both sides of the target vessel **60**. **Figure 11** also shows an exemplary opening **62** in vessel **60**. The objective of anastomosis is to approximate vessel **60** such that the two sides **64a** and **64b** of the opening **62** are in firm contact with each other and form a leak-proof seal after the anastomosis has been completed. After passing the needle through two sides **64a** and **64b**, the surgeon utilizes the laparoscopic tools **100** and **200** and the scissor mechanism **122** (on the combined grasper and cutting tool **200**) to cut needle **54** from the distal end **52a** of suture **52**. Optionally, the surgeon can remove needle **54** from the body through one of the laparoscopic ports at this time.

Referring now to **Figure 12**, the next step requires the surgeon to grasp the disclosed anastomosis device **10** (from the proximal end **20**) using the combined laparoscopic grasper and push-rod tool **200.** Using the other hand and the laparoscopic grasper/cutter **100**, the surgeon wraps the trimmed end of the suture **52** around the center pin head **14** preferably one or more revolution. With the wrapped suture in its place around the center pin head **14**, the surgeon actuates the push-rod mechanism **222** that grips the trimmed end of the suture between the center pin head **14** and the outer sleeve **26**. The locking action of the saw-tooth profile **18** and **44** on the center pin **12** and the locking mechanism **40** ensures that the suture **52** stays tightly gripped between the center pin head **14** and the outer sleeve **26**. With the center pin **12** firmly held by the laparoscopic grasper and push-rod tool **200**, the surgeon utilizes the other laparoscopic tool **100** to actuate the suture release mechanism **30** (by applying a sliding force towards the distal end of the disclosed anastomosis device **10**). The suture release mechanism **30** can have notched profile on its surface to aid in application of the proper sliding force. This step essentially slides the pre-formed knot **50** from the outer sleeve **26** on to the trimmed section of the suture **52** (that has already been passed through the target vessel **60**).

**Figure 13** shows the pre-formed knot **50** after it has been released onto the trimmed end **52a** of the suture **52**. The surgeon can now release the anastomosis device **10** from the laparoscopic grasper/push-rod tool **200**. The surgeon can then utilize both graspers **100** and **200** to tighten the knot **50** on the trimmed section **52a** of the suture. The diameter of the outer sleeve **26** is preferably twice the diameter of the suture **52** and therefore

knot **50** is fairly well formed as it is released from the outer sleeve **26**. From this point onwards, the surgeon can utilize one grasper (for example **200**) to hold the trimmed end **52a** of the suture **52** and the other grasper **100** to slide the knot **50** towards the target vessel **60** to tighten the knot and complete the anastomosis. Once the wound closure is tight enough (as judged by the surgeon), the surgeon can utilize the cutting tool **122** to trim the suture **52** to the desired length and remove the disclosed anastomosis device **10** (which is also holding the remaining suture **52** gripped on the center pin **12**) from the patient's body. Optionally, the surgeon may remove needle **54** from the body through one of the laparoscopic ports at this time.

**Figure 14** shows the target vessel **60** after the knot **50** has been tightened and trimmed. These steps are repeated with a new anastomosis device **10** introduced each time and a new knot **50** being applied until a proper anastomosis of the anatomy is achieved. A typical end-to-end anastomosis could require 6 to 8 sutures for proper approximation of the anatomy. In embodiments herein, the task of releasing pre-formed knot from the outer sleeve requires the surgeon to use both hands. However, this task can also be completed with one hand through redesign of the laparoscopic grasper/push-rod **200** through inclusion of another concentric shaft to actuate suture release mechanism **30** without changing the scope of the invention. In addition to the knot **50** shown in the disclosed invention, other forms of knots can be utilized without changing the scope of the invention.

**Figure 15** is a perspective view of a further embodiment of the anastomosis device **300**. **Figure 15** shows this embodiment, which

includes two components **302** (composed of profiles **302a-302f** and **314**) and **304**. Profile **302a** on the distal end is designed to host a pre-formed knot **50** (similar to **Figure 10**), profile **302c** includes two guiding grooves **314** and profile **302d** is the flatted proximal end that can be held utilizing tool **200** (**Figure 8**). The distal end also includes a profile **302b** (preferably cylindrical) that consists of an opening **302e** and a gripping mechanism with a groove **302f**. This gripping mechanism is designed to allow a suture to be lockably placed therein. Component **304** includes two substantially narrow profiles **306**, and two end-stops **308**. Each of the end-stops **308** is designed to slidably fit inside the corresponding guiding groove **314** and can translate linearly with component **304**.

It can be seen that device **300** has substantially simplified design as compared to device **10** (**Figure 2**) at the same time exhibiting similar functionality. The functioning of device **300** will now be described in detail. Similar to device **10**, device **300** is also packaged as one-time use disposable with the suture **52** and is introduced into the patient's body cavity in a similar fashion. Once the distal end **52a** of the suture (containing needle **54**) has been passed through two ends of the anatomy, the needle **54** is trimmed using the laparoscopic tool **100**. The surgeon then utilizes tool **200** and firmly holds device **300** at profile **302d** using graspers **206** and **208**. Once the device is firmly held, the surgeon utilizes tool **100** to hold free end **52a** of suture **52** and inserts it into the gripping mechanism groove **302f**. The insertion of suture **52** into groove **302f** is assisted by the chamfered profile **302e**. The gripping mechanism groove **302f** is dimensioned to lockably contain the suture once it is positioned inside the

groove. The surgeon then actuates push-rod **220** on tool **200** that causes push-rod tip **222** to linearly translate and come in contact with surface **310** (on end-stop **308**). As the push-rod is actuated further, a distal acting force on surface **310** causes component **304** to translated with respect to component **302** and causes preformed knot **50** to slide off profile **302a**. The surgeon then releases the grasper from proximal end **302d** and utilizes graspers on tools **100** and **200** to tighten the knot. The process is repeated for each anastomosis device **300** until a proper anastomosis is accomplished. It can be noted that various profiles and sizes for gripping mechanism groove **302f** can be utilized without changing the scope of the invention.

The disclosed embodiments herein utilize a novel mechanical device that holds a pre-formed knot for easy and quick anastomosis. The embodiments disclosed herein minimize the dependence on a surgeon's dexterity and experience in performing the anastomosis. Thus, novice surgeons will be able learn and produce quality laparoscopic anastomosis in a short time using the disclosed invention.

The system design is simple and therefore it can be mass produced at low cost using existing fabrication techniques.

The design utilizes conventional needles and sutures and therefore does not require custom materials as needed in some prior art.

Manual suturing is still the most widely accepted method of conducting anastomosis, and the similar workflow of the disclosed embodiments will be easily adapted to by surgeons.

Further, the disclosed embodiments have a good market potential that is evident from the fact that even after centuries of technological development, only a handful of automated/assisted anastomosis devices exist in the market. Most of these devices are designed for open surgery and find little or no use in a minimally invasive surgery (MIS) approach. MIS has already become a preferred surgical approach due to its benefits to the patient and it is evident that the number of procedures performed through this approach will increase exponentially in the coming years. At the same time, without any improvement to the laparoscopic anastomosis technique, present anastomosis times of the order of hours will have a huge social and financial burden. Thus an anastomosis device that can potentially reduce anastomosis time from hours to minutes has high market value.

The disclosed embodiments have advantages over existing devices and technologies in terms of their simplicity, close resemblance to manual suturing and low cost. Most of the existing technologies utilize custom designed needles/sutures whereas the disclosed embodiments utilize standardized off-the-shelf needle and sutures. In addition, the mechanical components of the disclosed embodiments can be constructed using materials such as plastics and can be produced at a low cost using standardized manufacturing process (injection molding etc.). The disclosed embodiments are suitable for all types of anastomosis (end-end, end-side and side-side) for vessels with varying diameters.

As used herein, the terms “comprises”, “comprising”, “includes” and “including” are to be construed as being inclusive and open ended, and not exclusive. Specifically, when used in this specification including claims, the

terms “comprises”, “comprising”, “includes” and “including” and variations thereof mean the specified features, steps or components are included. These terms are not to be interpreted to exclude the presence of other features, steps or components.

The foregoing description of the preferred embodiments of the invention has been presented to illustrate the principles of the invention and not to limit the invention to the particular embodiment illustrated. It is intended that the scope of the invention be defined by all of the embodiments encompassed within the following claims and their equivalents.

**THEREFORE WHAT IS CLAIMED IS:**

1. An anastomosis device, comprising:

a) an elongate center pin having proximal and distal ends, said proximal end structured to be manipulatable by a manipulation tool, a grip mechanism located at said distal end for gripping a suture;

b) an outer sleeve having a passageway therethrough to receive therein the elongate center pin, said sleeve being mountable by a pre-formed knot formed in a suture; and

c) a suture release mechanism having a passageway extending therethrough to receive the outer sleeve therein, said suture release mechanism being reciprocally translatable on said sleeve between a first position and a second position, and movement of said suture release mechanism from said first position to said second position dislodges said pre-formed knot off said sleeve, and with a free end of said suture being gripped by said grip mechanism, said pre-formed knot is dislodged such that said suture is located within said pre-formed knot and pulling said free end tightens said pre-formed knot on said suture.

2. The anastomosis device according to claim 1 wherein said grip mechanism comprises:

a head section attached to the distal end of said elongate center pin, said head section having a circumferential groove to receive therein a suture,

said elongate center pin including a saw tooth profile spaced from said manipulatable proximal end that includes one or more teeth; and

a locking mechanism located at one end of the outer sleeve, said locking mechanism including a saw-tooth profile that mates with the saw-tooth profile spaced from the proximal end of said elongate center pin, wherein said locking mechanism permits motion of the center pin into the outer sleeve and locks in the opposite direction, and wherein at the end of its travel, the elongate center pin is butted against a distal end of the outer sleeve and is kept in tight contact thereto thereby firmly holding the suture in place.

3. The anastomosis device according to claim 1 wherein said grip mechanism comprises:

a head section attached to the distal end of said elongate center pin; and

a groove disposed on the head section comprising an elongate channel having a width and length and an opening thereto, wherein the opening has a width less than that of the elongate channel, thereby allowing a suture to be inserted into the channel through the opening and to remain firmly held in place in the channel.

4. The anastomosis device according to claim 3 wherein said head section further includes a chamfered opening used to guide a suture towards said groove.

5. The anastomosis device according to claim 2, 3 or 4 wherein said suture release mechanism comprises a pair of elongate arms each terminated by a stop attached thereto having a width wider than a width of each of the arms, said locking mechanism including a pair of grooves to receive therein said arms with attached stops, with said grooves having an opening at one end thereof having a width to accept the arms therein but not said stops, such that said suture release mechanism can be translated with respect to the locking mechanism between said first and second positions and is limited in its motion through the use of said grooves in the locking mechanism and said stops on said arms.

6. The anastomosis device according to any one of claims 1 to 5 further comprising a suture having a suture needle attached to a first end thereof and a second end of the suture being formed into said pre-formed knot mounted on said outer sleeve.

7. An anastomosis device, comprising:

a) an elongate center pin having proximal and distal ends, said proximal end structured to be manipulatable by a manipulation tool;

b) an outer sleeve having a passageway therethrough to receive therein the elongate center pin, said sleeve being mountable by a pre-formed knot formed in a suture;

c) a suture release mechanism having a passageway extending therethrough to receive the outer sleeve therein, said suture release mechanism being reciprocally translatable on said sleeve between a first position and a second position, and movement of said suture release mechanism from said first position to said second position dislodges said pre-formed knot off said sleeve, and with a free end of said suture being gripped by said grip mechanism, said pre-formed knot is dislodged such that said suture is located within said pre-formed knot and pulling said free end tightens said pre-formed knot on said suture; and

d) a grip mechanism located at said distal end for gripping a suture, the grip mechanism comprising a head section attached to the distal end of said elongate center pin, and a groove disposed on the head section comprising an elongate channel having a width and length and an opening thereto, wherein the opening has a width less than that of the elongate channel, thereby allowing a suture to be inserted into the channel through the opening and to remain firmly held in place in the channel.

8. The anastomosis device according to claim 7 wherein said head section further includes a chamfered opening used to guide a suture towards said groove.

9. The anastomosis device according to claim 7 or 8 wherein said suture release mechanism comprises a pair of elongate arms each terminated by a stop attached thereto having a width wider than a width of each of the arms, said locking mechanism including a pair of grooves to receive therein said arms with attached stops, with said grooves having an opening at one end thereof having a width to accept the arms therein but not said stops, such that said suture release mechanism can be translated with respect to the locking mechanism between said first and second positions and is limited in its motion through the use of said grooves in the locking mechanism and said stops on said arms.

10. The anastomosis device according to any one of claims 7 to 9 further comprising a suture having a suture needle attached to a first end thereof and a second end of the suture being formed into said pre-formed knot mounted on said outer sleeve.

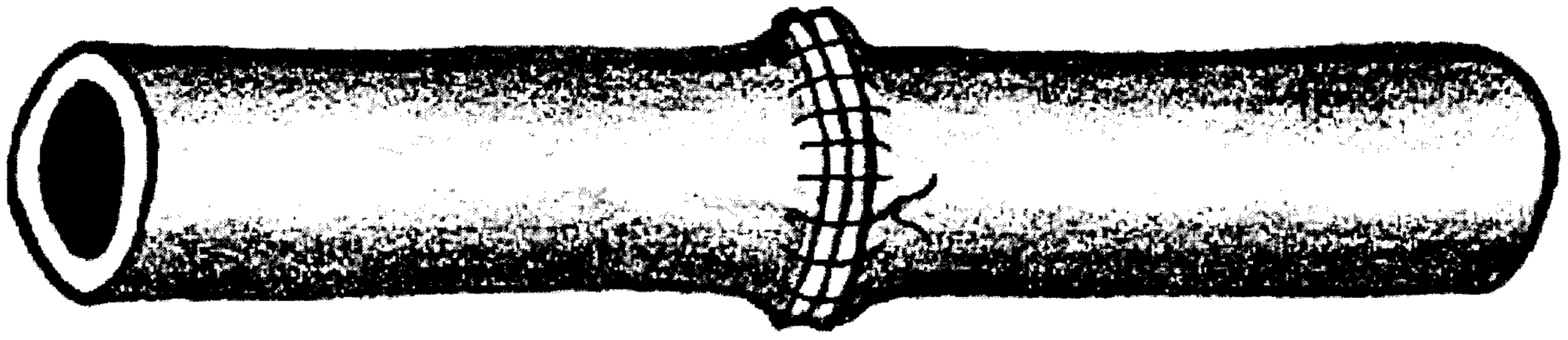


Fig. 1

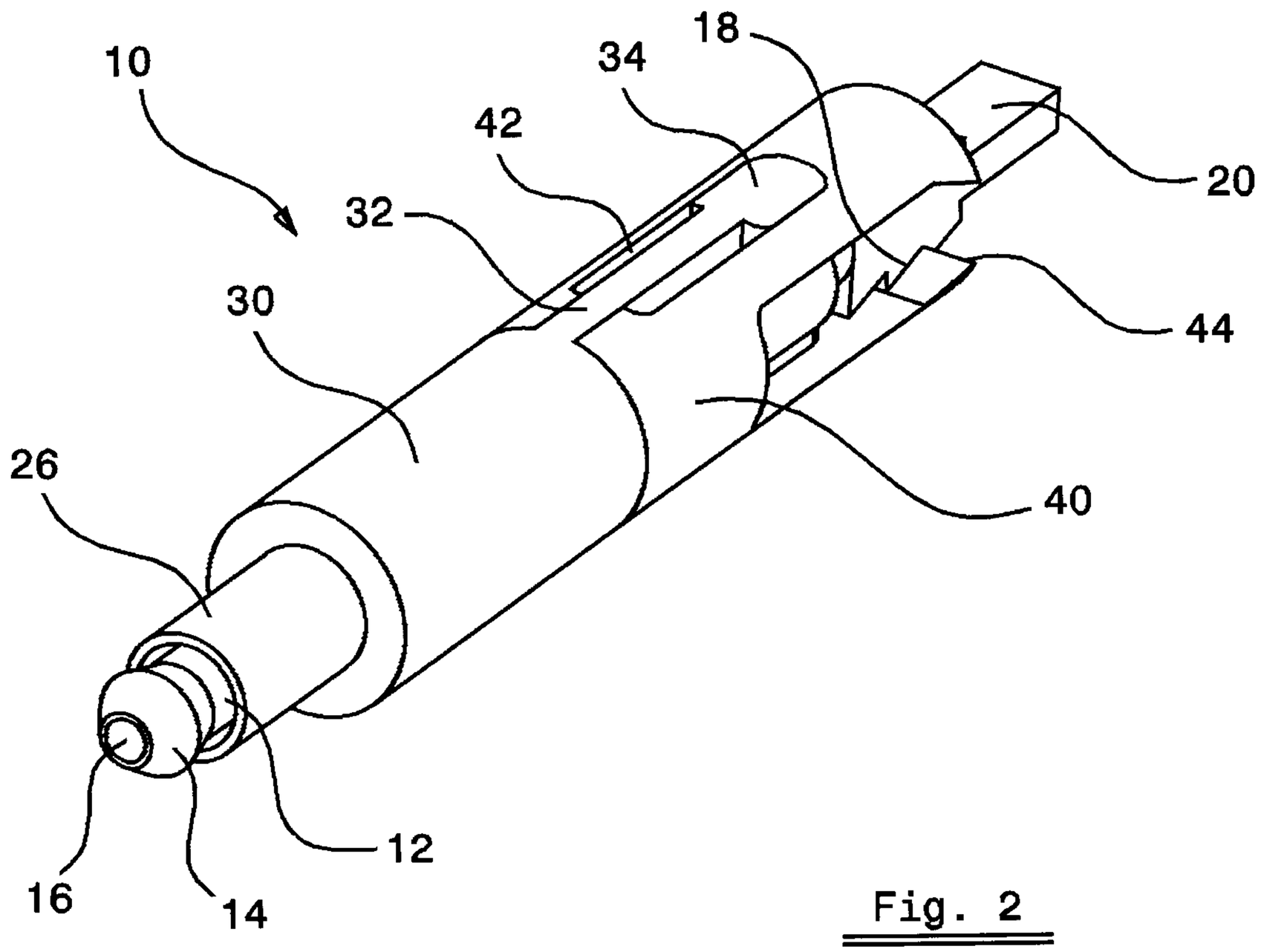



Fig. 2

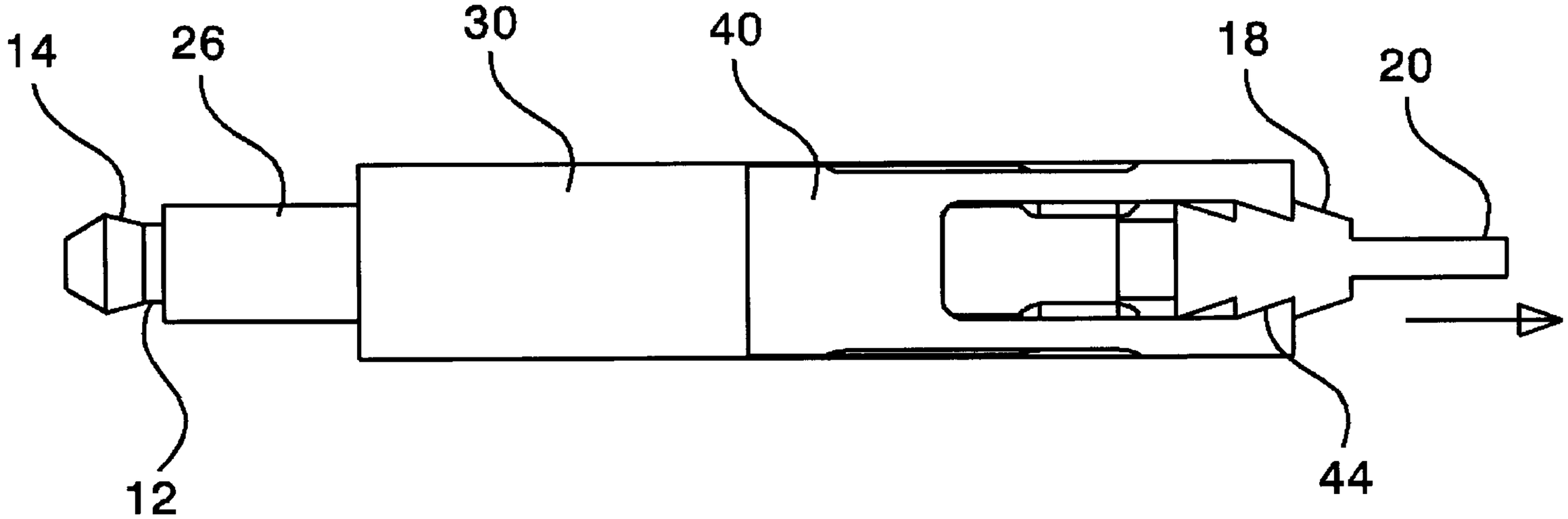



Fig. 3

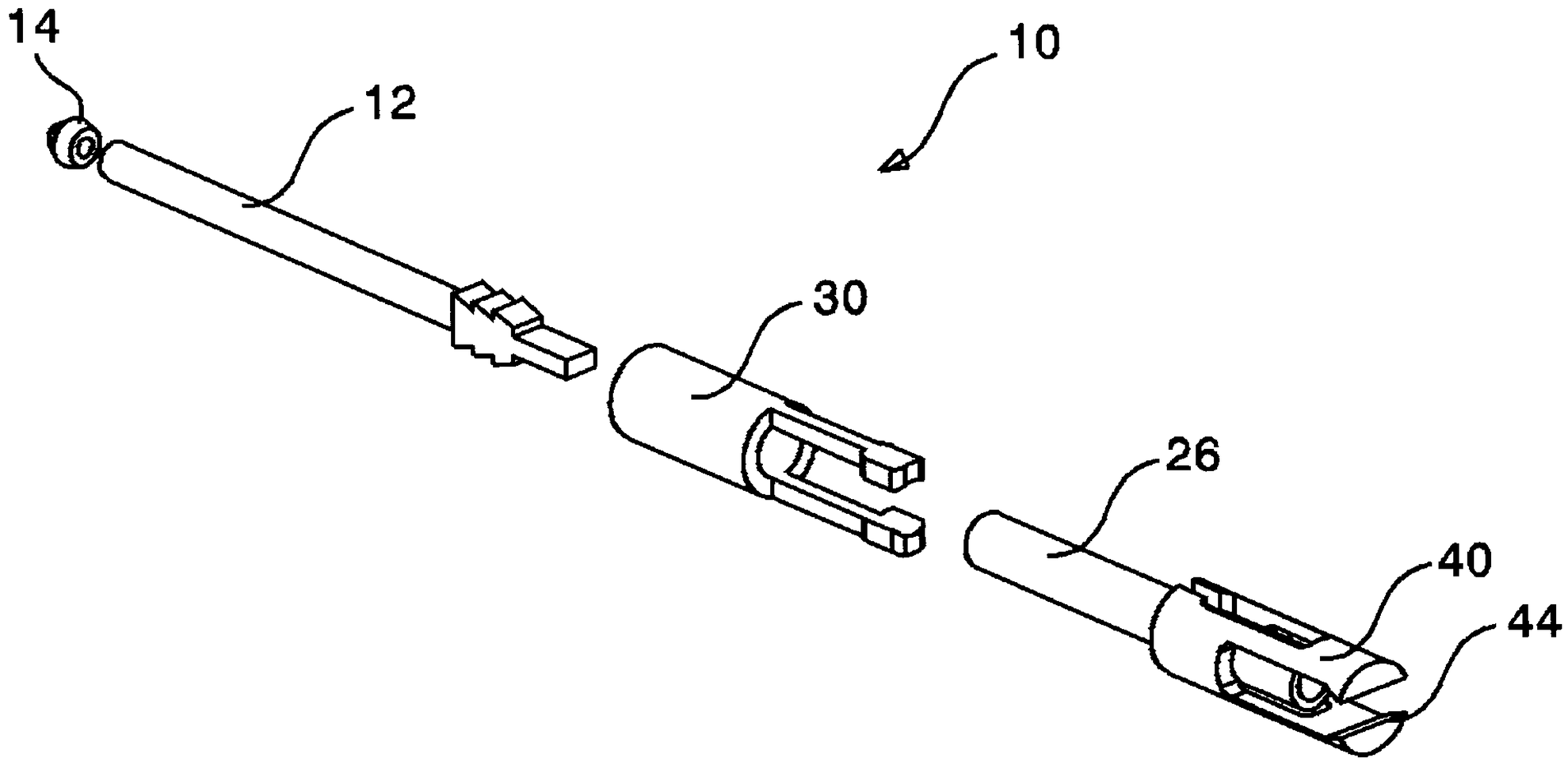



Fig. 4

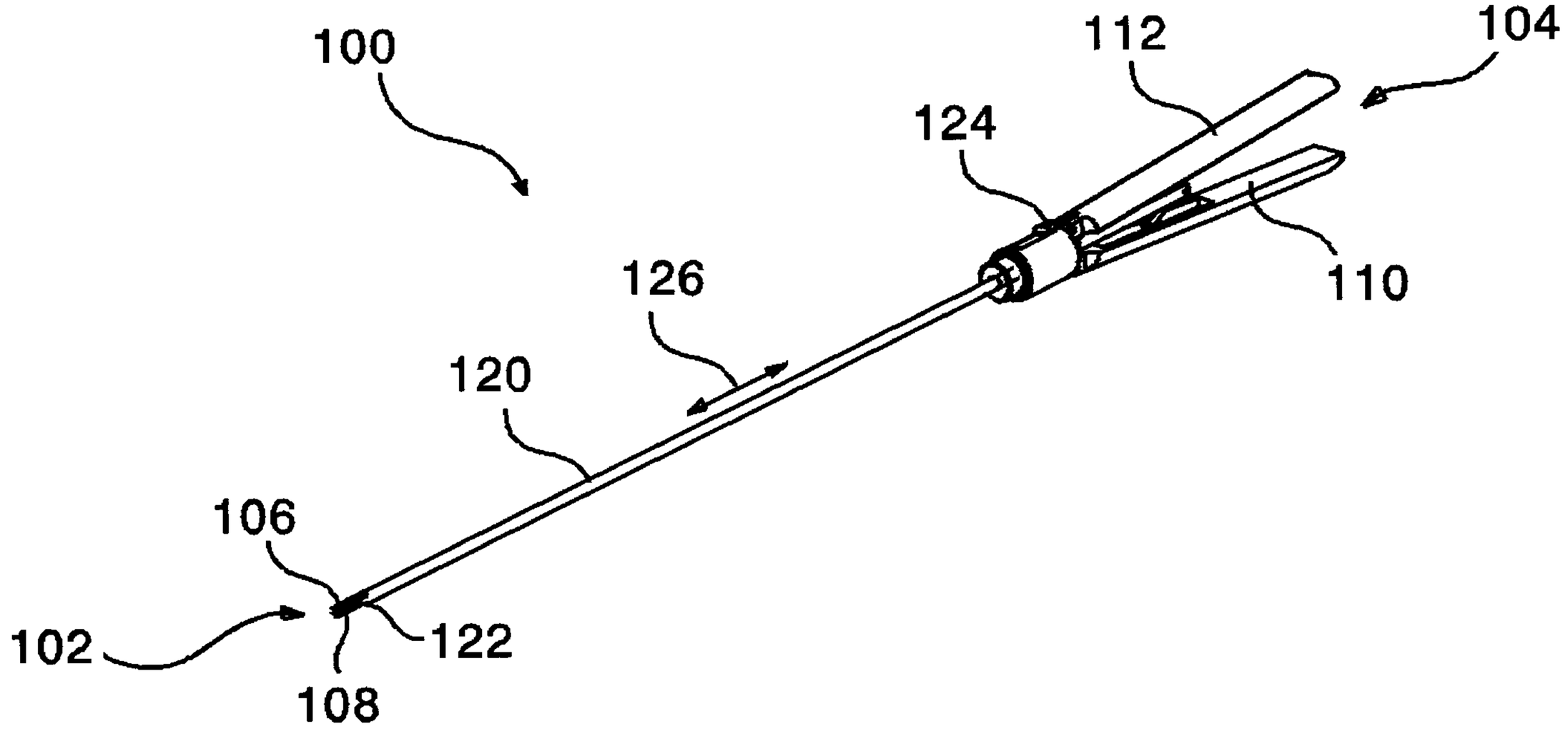



Fig. 5

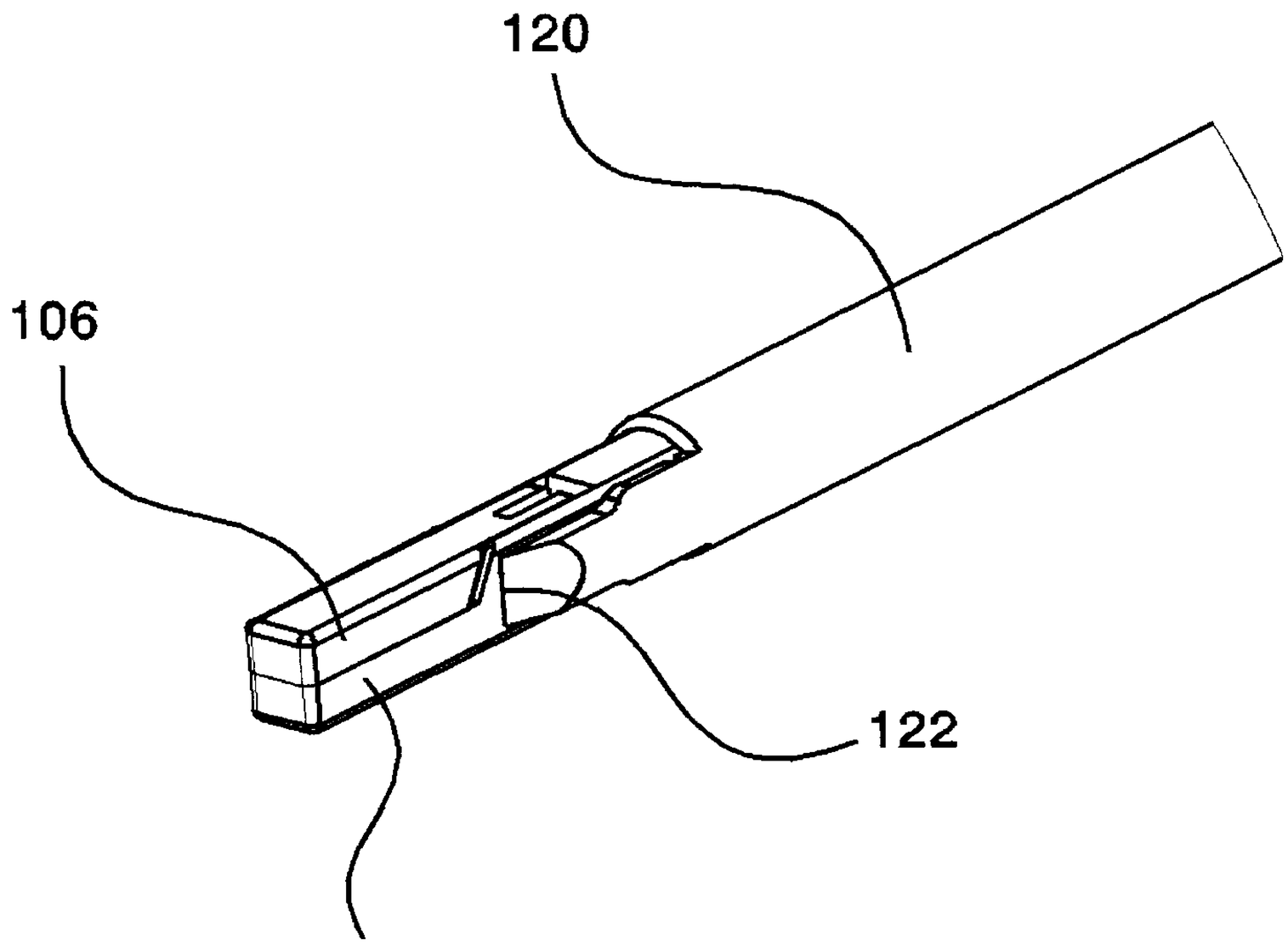



Fig. 6

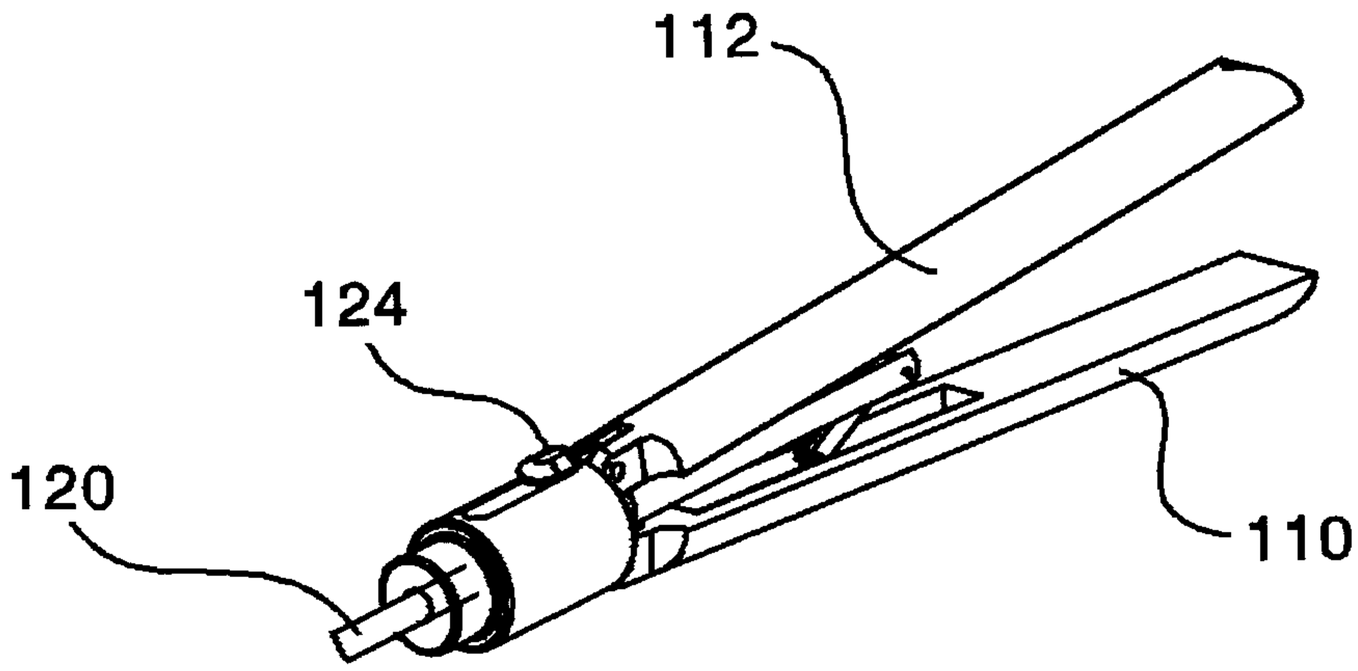



Fig. 7

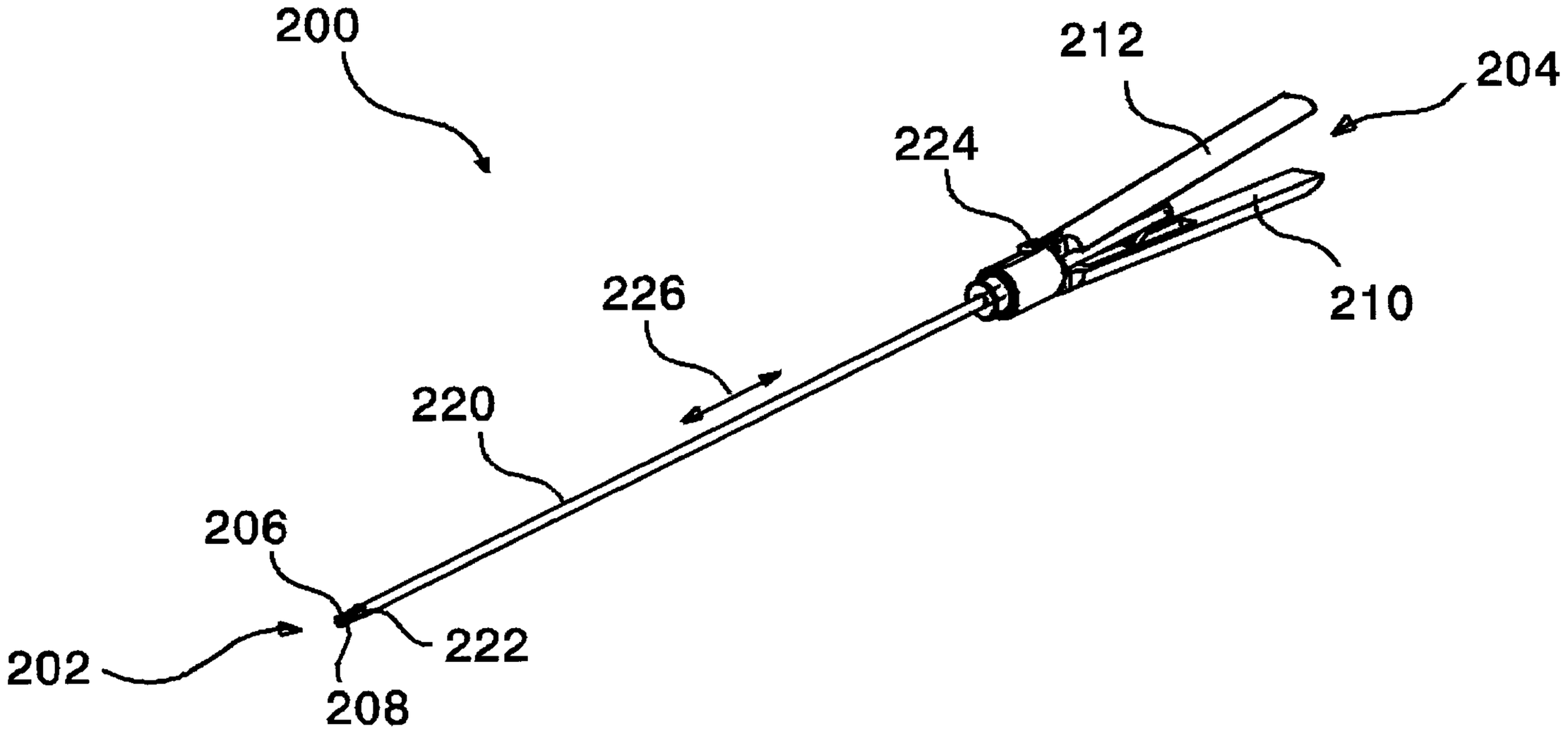



Fig. 8

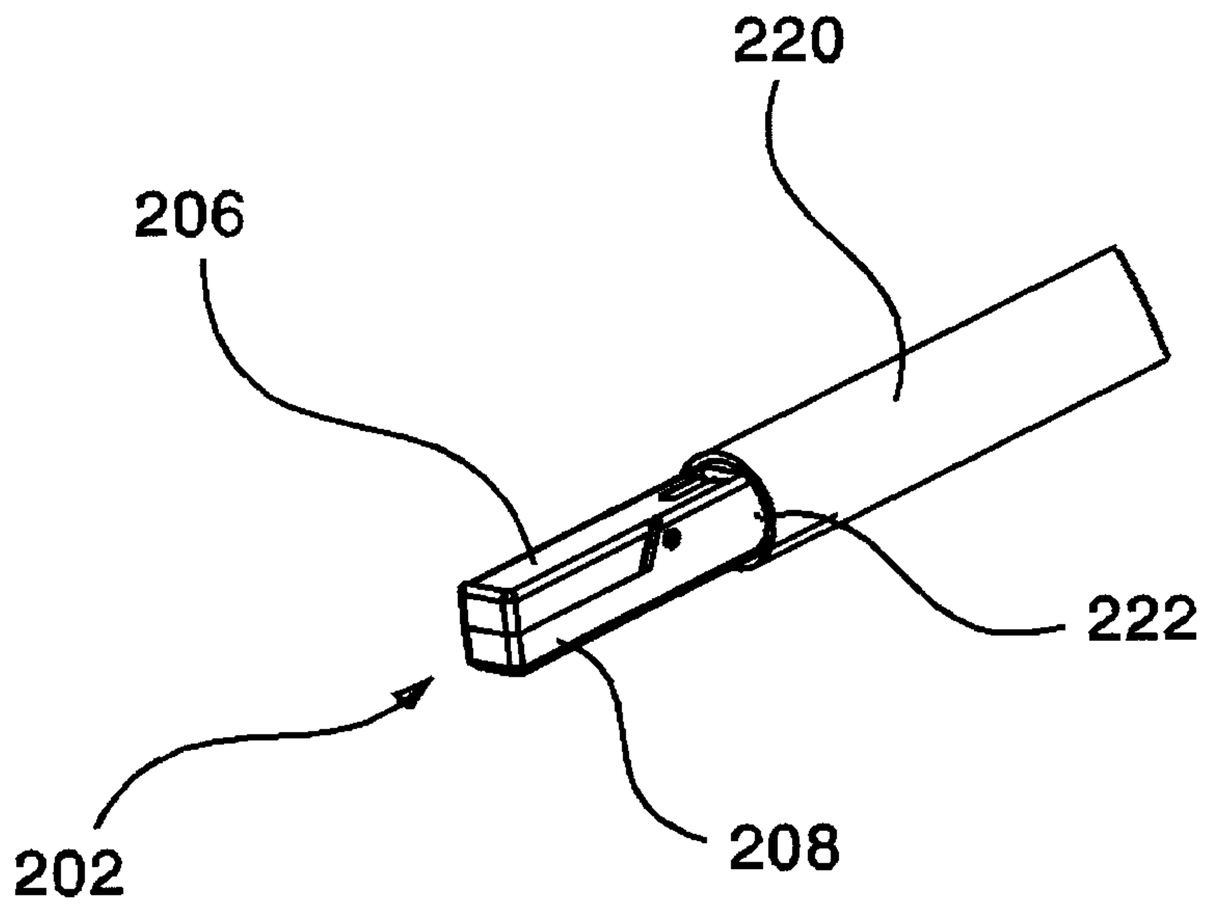



Fig. 9

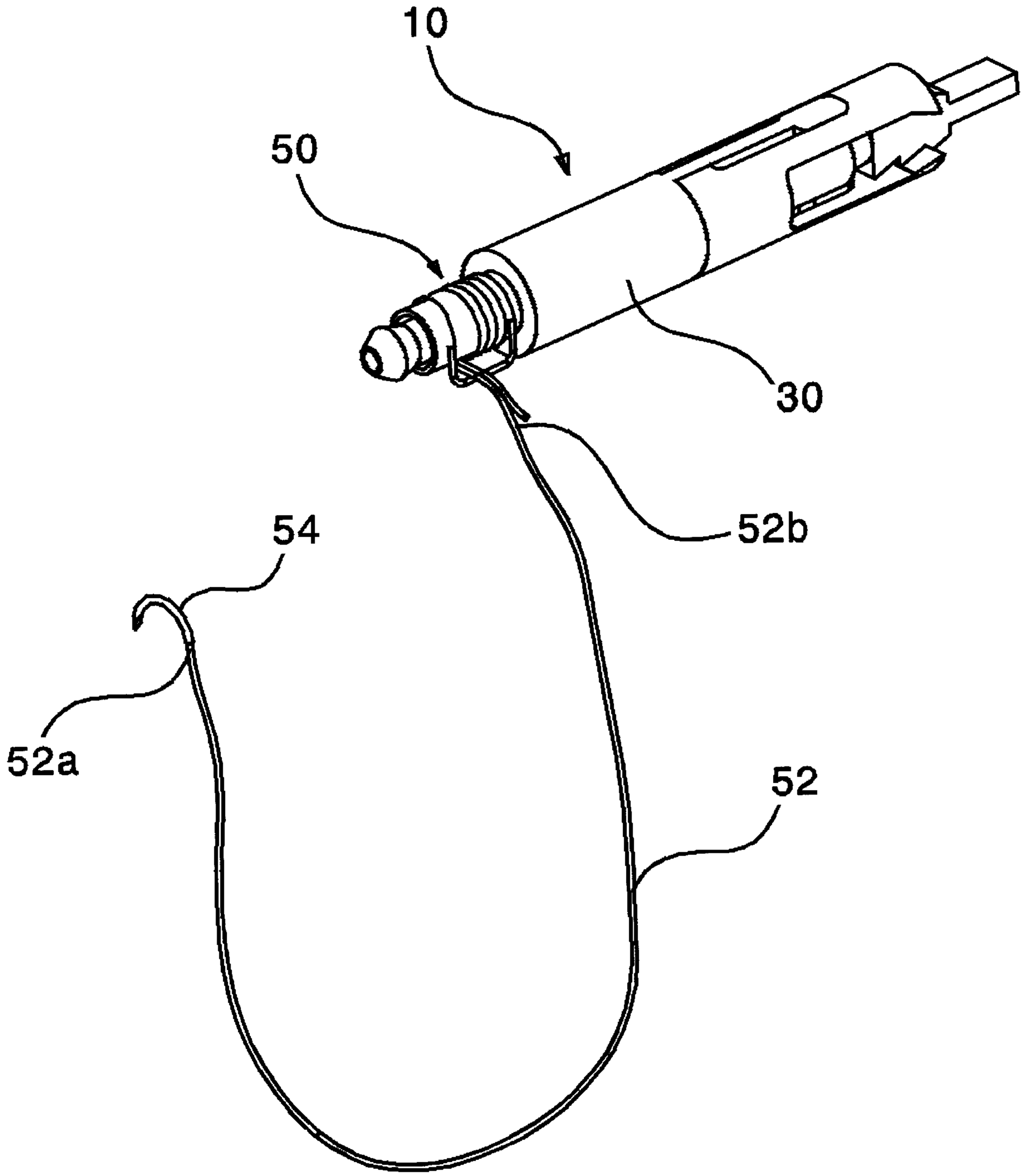



Fig. 10

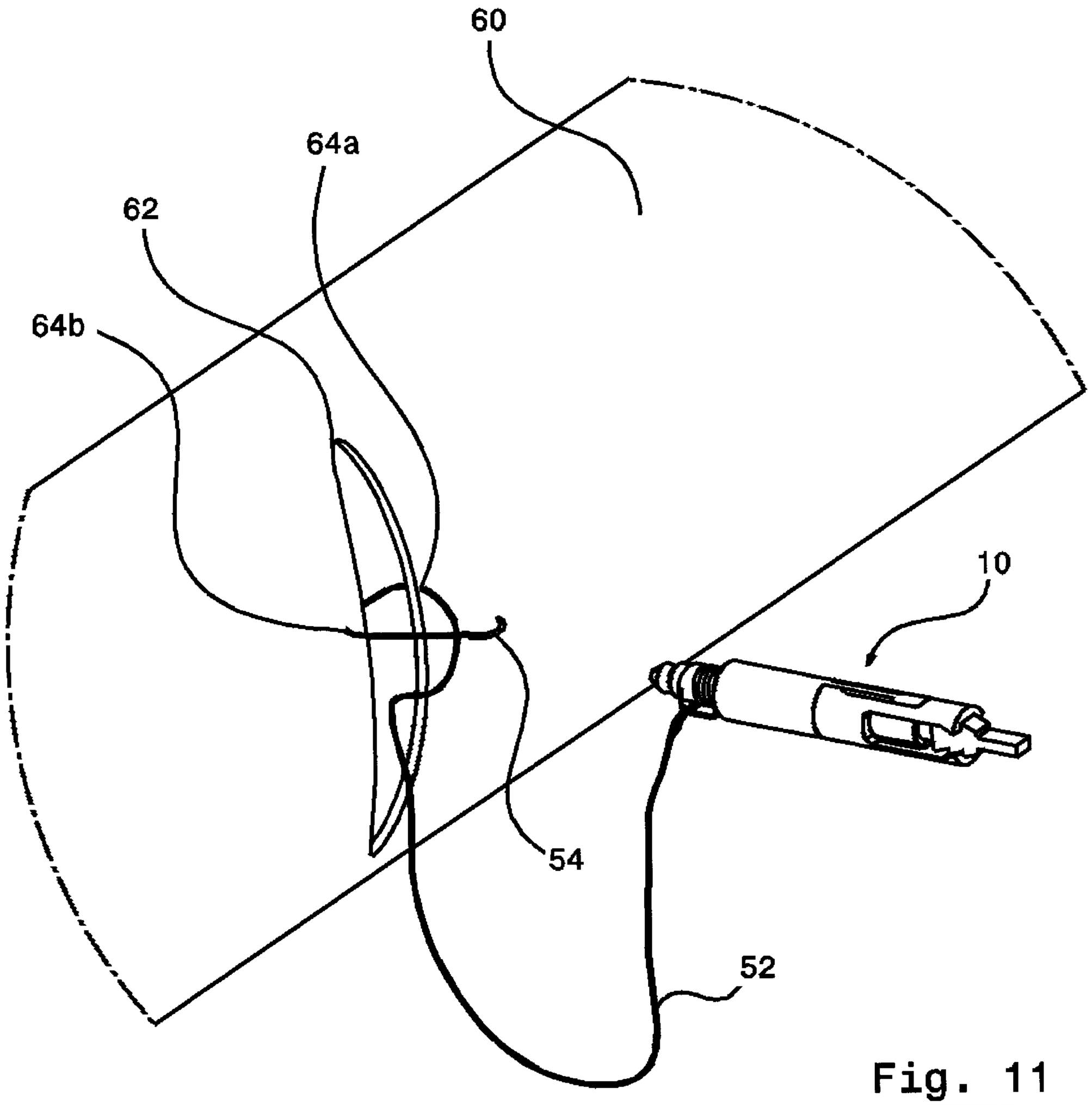



Fig. 11

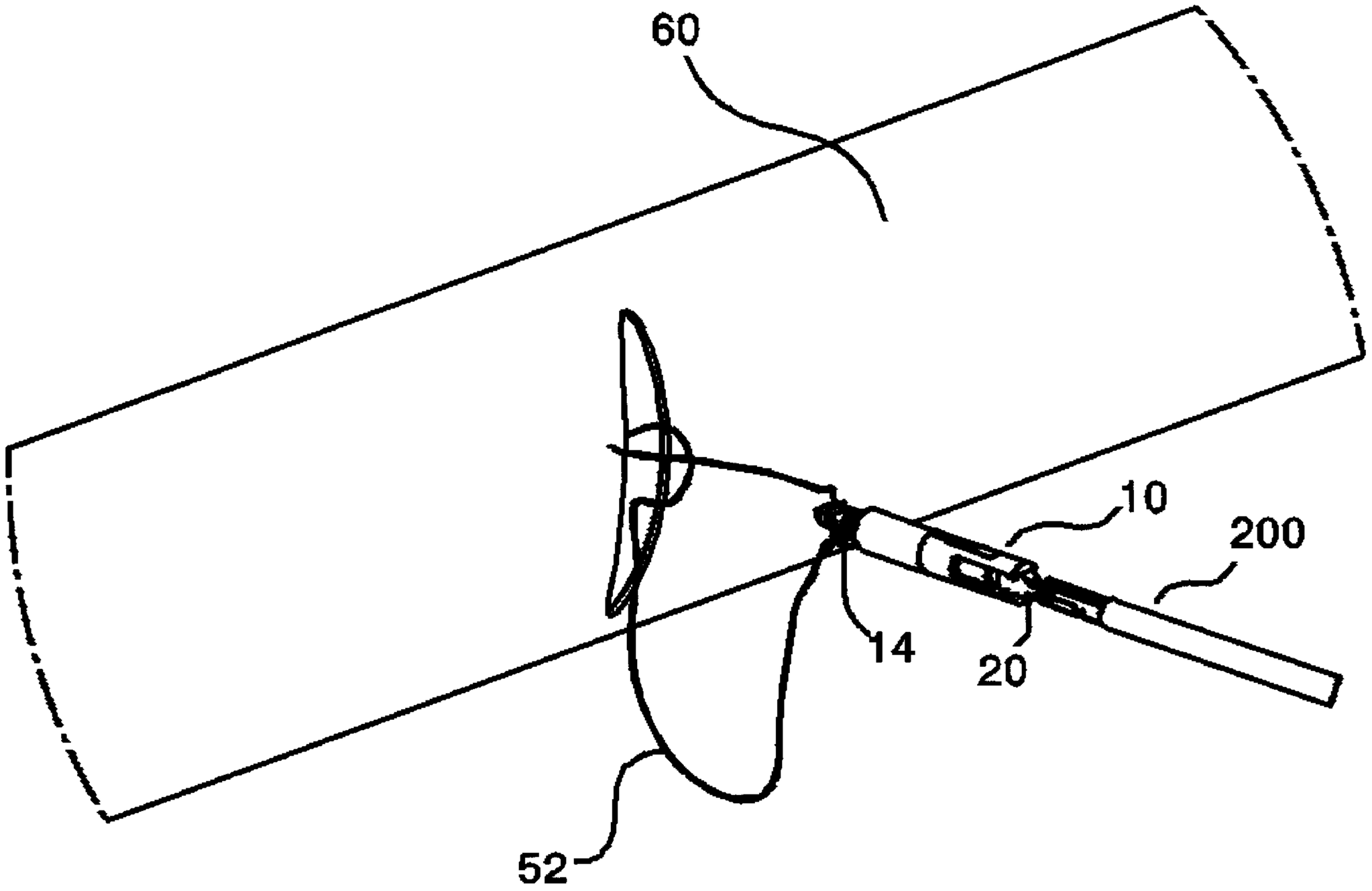



Fig. 12

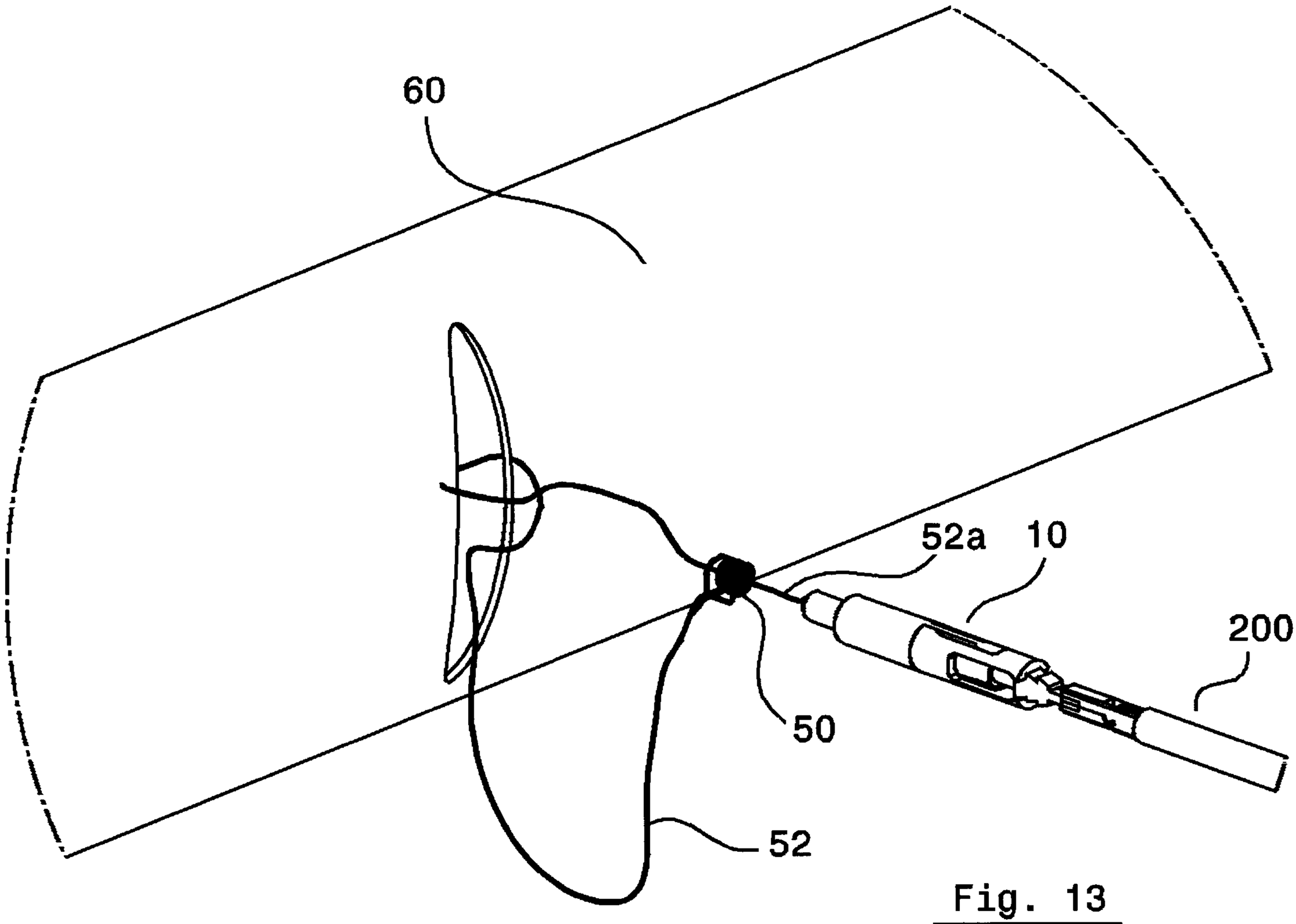



Fig. 13

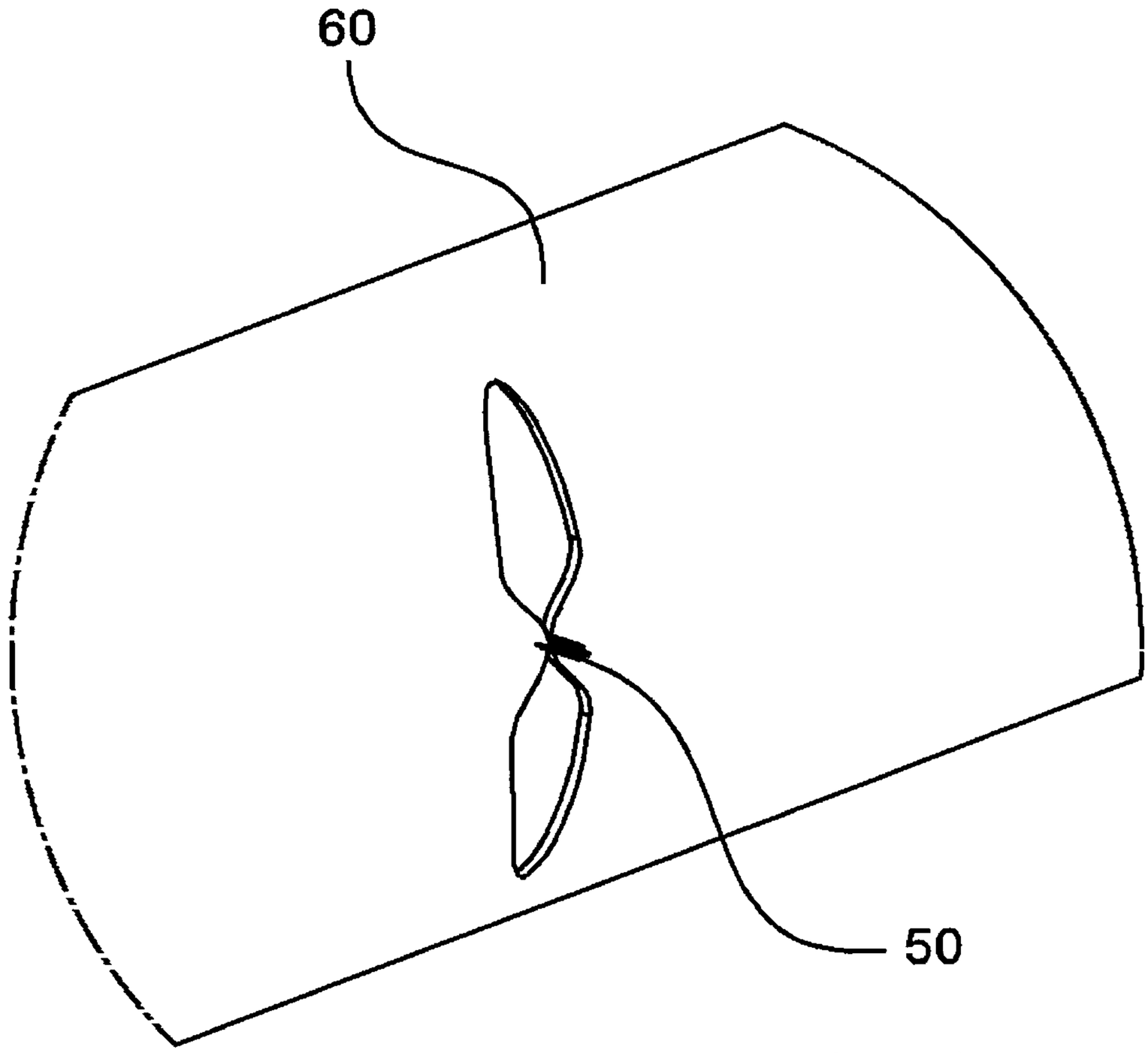



Fig. 14

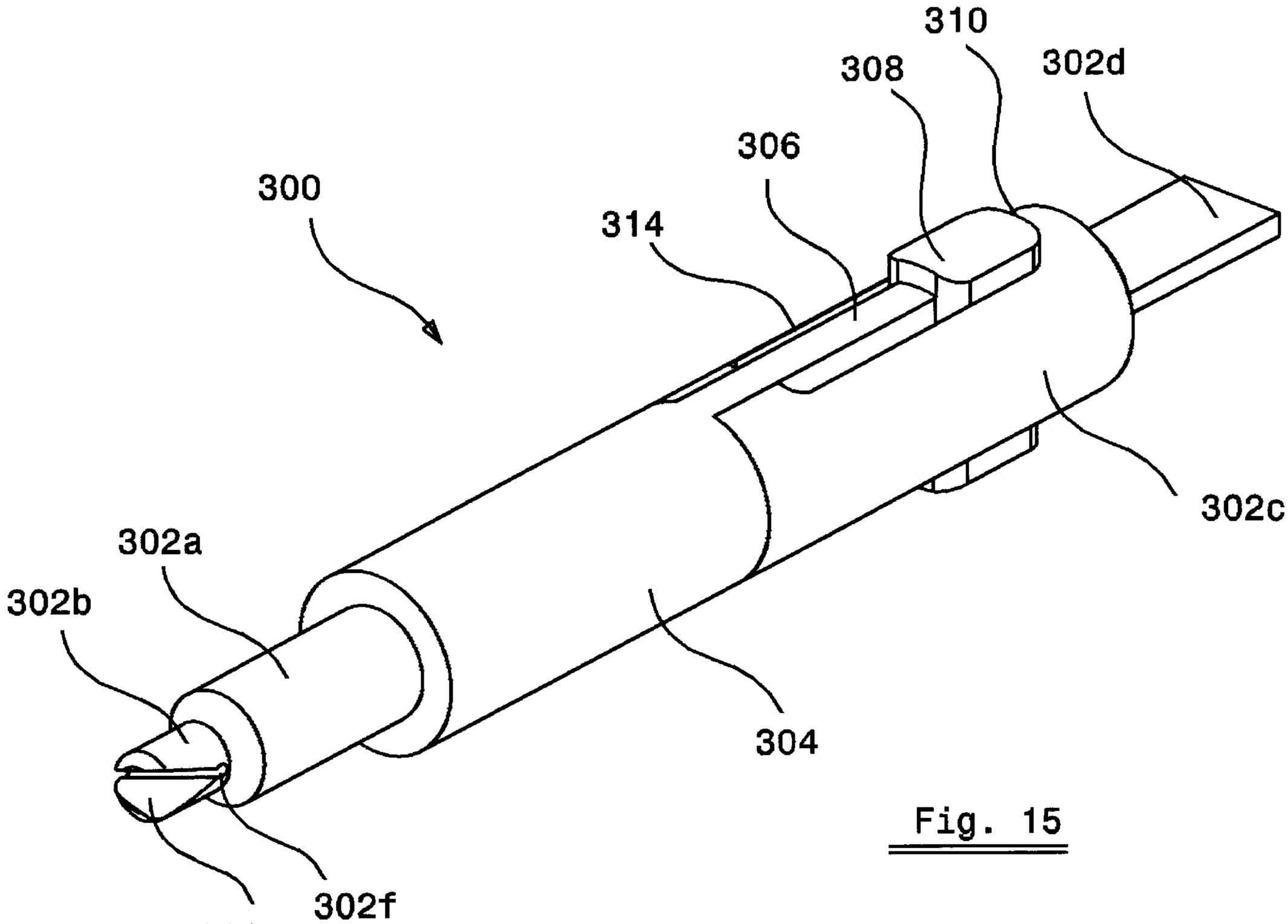
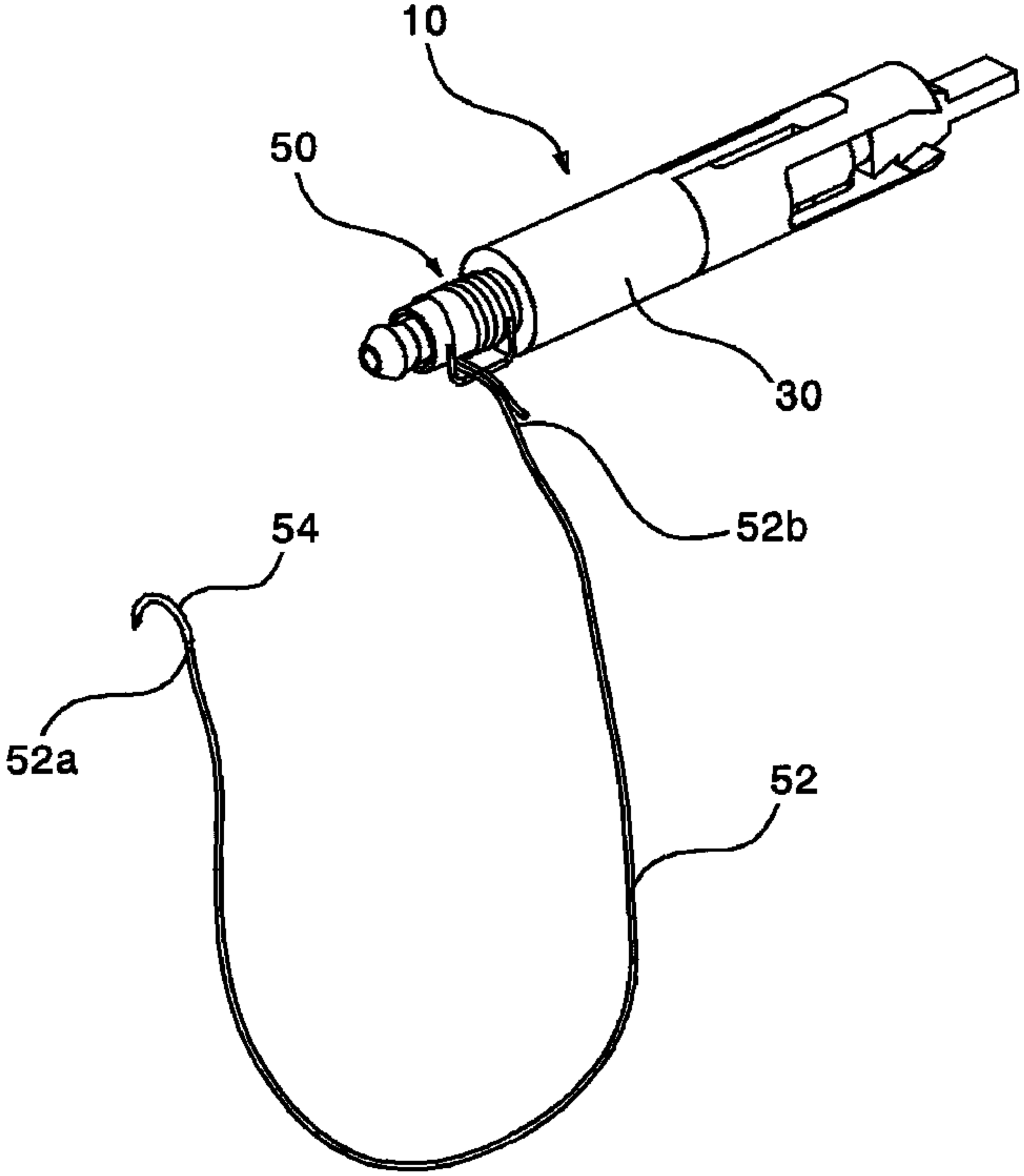



Fig. 15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