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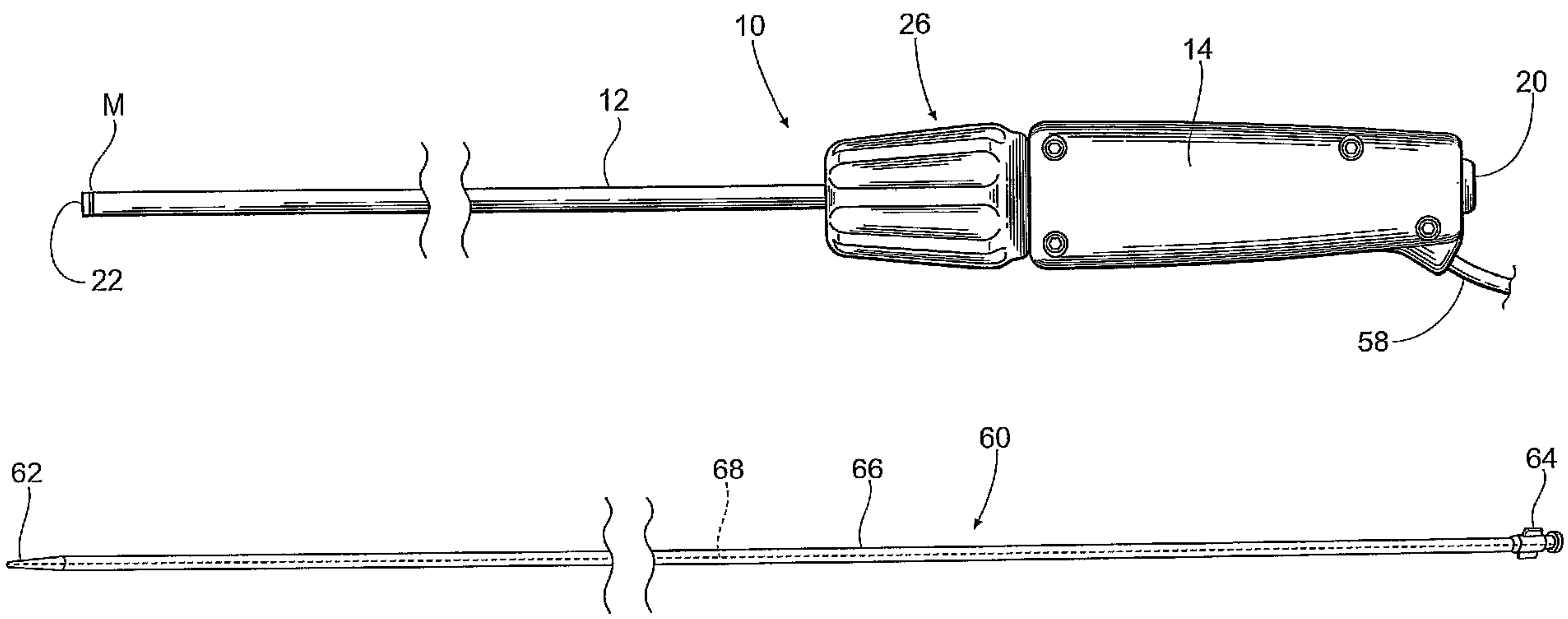
(54) Title: DEVICES, SYSTEM, AND METHODS FOR GUIDING AN OPERATIVE TOOL INTO AN INTERIOR BODY REGION



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(57) Abrégé/Abstract:
A guide device establishes a guide passage through a guide tube, through which an operative tool can be deployed into an interior body region for use. A steering assembly, in use, deflects or bends the distal end region of the guide tube, so that the operative tool can be placed in a desired orientation with respect to tissue. The steering assembly is desirable configured for single handed operation by the clinician. The steering assembly is also desirably configured to provide a mechanical advantage sufficient to translate relatively small increments of clinician control into relatively larger increments of guide tube deflection. In one arrangement, the steering assembly includes a rack and pinion linkage system. In another arrangement, the steering assembly includes a pivoting lever system.

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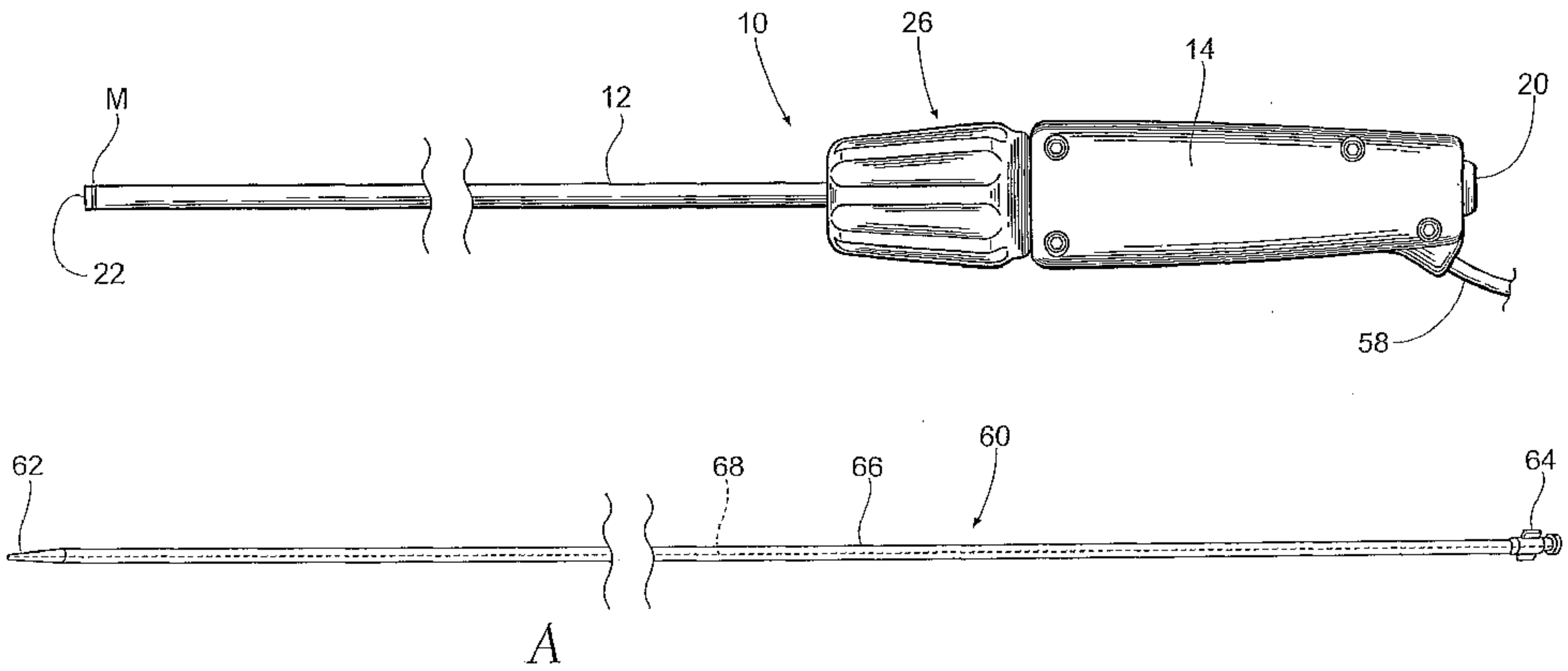

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DEVICES, SYSTEM, AND METHODS FOR GUIDING AN OPERATIVE TOOL INTO AN INTERIOR BODY REGION

Related Applications

This application is a continuation-in-part of co-pending United States Patent Application Serial No. 11/166,411, filed June 24, 2005, entitled "Endovascular Aneurysm Repair System," which is a divisional of United States Patent Application Serial No. 10/271,334, filed October 15, 2002 (now United States Patent No. 6,960,217), which claims the benefit of United States Provisional Patent Application Serial No. 60/333,937, filed November 28, 2001, and entitled "Endovascular Aneurysm Repair System," which are each incorporated herein by reference. This application is also a continuation-in-part of co-pending United States Patent Application Serial No. 10/307,226, filed November 29, 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods" and a continuation-in-part of co-pending United States Patent Application Serial No. 10/669,881, filed September 24, 2003, and entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution," which are each incorporated herein by reference.

Field of the Invention

This invention relates generally to devices, systems, and methods that guide operative tools within a vessel or hollow body organ.

Background of the Invention

In the field of steerable guide systems, there is a need to translate a comfortable rotational manipulation by a physician into an effective distal deflection. There is also a need for a guide system that would provide a mechanical advantage such that a minimal manipulation by a physician would provide a sufficient distal deflection.

Summary of the Invention

The invention provides improved devices, systems, and methods for guiding an operative tool for use within an interior tissue region.

According to one aspect of the invention, a guide device comprises a guide tube that establishes a guide passage through which an operative tool can be deployed into an interior body region for use. The device includes a steering assembly that, in use, deflects or bends the distal end region of the guide tube, so that the operative tool can be placed in a desired orientation with respect to tissue.

The steering assembly is desirable configured for single handed operation by the clinician. The steering assembly is also desirably configured to provide a mechanical advantage sufficient to translate relatively small increments of clinician control into relatively larger increments of guide tube deflection.

In one embodiment, the steering assembly includes a rack and pinion linkage system that translates rotation of an actuator into linear movement of a rack into rotation of a gear train, to apply a tension force to a deflecting component coupled to the distal end region of the guide tube.

In another embodiment, the steering assembly includes a pivoting lever system that translates rotation of an actuator into linear movement of a slider into pivotal movement of a lever arm, to apply a tension force to a deflecting component coupled to the distal end region of the guide tube.

In both embodiments, the tension applied to the deflecting component bends or deflects the distal end region of the guide tube.

In one embodiment, the operative tool applies one or more fasteners to tissue. The steerable guide device makes it possible to accurately orient and maintain the fastening tool with respect to tissue, without the need to place a steering mechanism on-board the fastening tool or without the need to equip the fastening tool with a guide wire lumen.

Brief Description of the Drawings

Fig. 1 is a plane view of a steerable guide device in its straightened, undeflected position.

Fig. 1A is a plan view of a dilator for use with the steerable guide device of Fig.1.

Fig. 2 is a plane view of the steerable guide device shown in Fig. 1 in association with an operative tool.

Fig. 3 is a plane view of the steerable guide system shown in Fig. 1, showing a clinician's hand rotating an actuator knob to operate an associated steering assembly to cause bending or deflection of the distal end region of the device.

Fig. 4 is a plane view of the steerable guide device shown in Fig. 3 in association with an operative tool.

Figs. 5A, 5B, and 5C are plane views of the distal end region of the device shown in Fig. 4, showing the presence of a radiopaque marker that is shaped to provide a different visual image depending upon its orientation, respectively, anteriorly (Fig. 5A), posteriorly (Fig. 5B), or laterally (Fig. 5C).

Fig. 6A is an interior section view of the distal end region of the device shown in Fig. 3, taken generally along line 6A-6A of Fig. 6B.

Fig. 6B is a perspective end view, partially broken away, of the distal end region of the device shown in section in Fig. 6A.

Fig. 6C is a perspective end view, partially broken away, of an alternative embodiment of the distal end region of the device shown in Fig. 6B.

Fig. 6D is a perspective end view, partially broken away, of the distal end region of an alternative embodiment of the device shown in Fig. 6A, and showing multiple control lumens to direct the distal end region in more than one direction.

Fig. 6E is a plane view of the distal end region of the alternative embodiment shown in Fig. 6D, and showing the distal end region having two 90 degree deflections.

Fig. 7 is a plane view, partially diagrammatic, showing the attachment of the guide tube of the device to the handle of the device, and the formation of an interior passage through the handle and guide tube to receive an operative tool.

Fig. 8 is a plane side view, of the device shown in Fig. 1, with the handle broken away and in section to show the components of the steering assembly within the handle; the operation of which bends or deflects the distal end region in the manner shown in Fig. 3.

Fig. 9 is an exploded view, with parts partially broken away and in section, showing the main components of the device, including the components of the steering assembly shown in Fig. 8.

Fig. 10 is a section view taken generally along line 10-10 in Fig. 8.

Fig. 11 is a plane side view, of the device shown in Fig. 3, with the handle broken away and in section to show the operation of the steering assembly within the handle to bends or deflects the distal end region of the device.

Fig. 12 is side plane view of a steerable guide device, with the handle broken away and in section, showing an alternative steering assembly in its neutral position, in which the distal end region of the guide tube is straight and undeflected.

Fig. 13 is side plane view of a steerable guide device shown in Fig. 12, with the handle broken away and in section, showing the operation of the alternative steering assembly to bend or deflect the distal end region of the guide tube.

Fig. 14 is a side view of the steerable guide device and associated operative tool, as also generally shown in Fig. 4, with the operative tool shown to be an endovascular fastener oriented by the guide device for the application of a fastener to a prosthesis deployed in a tissue region.

Description of Preferred Embodiments

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention which may be embodied in other specific structures. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

I. OVERVIEW

Fig. 1 shows a steerable guide device 10. The steerable guide device 10 comprises a flexible guide tube 12 carried by a handle 14. The flexible guide tube 12 may be constructed, for example, by extrusion using standard flexible, medical grade plastic materials. Further details of the guide tube 12 will be described later.

The handle 14 may be constructed, for example, from molded plastic. The handle 14 is sized to be conveniently held by a clinician, to introduce the guide tube 12 into an interior body region that has been targeted for treatment.

As used in this disclosure, the term "proximal" refers to the aspect of the device that is, in use, held by the clinician, while the term "distal" refers to the aspect of the device that is, in use, positioned in or toward the body.

The purpose of the guide device 10 is to establish an open path through which an operative tool 16 can be deployed for use. For this purpose (see Fig. 2), the guide device 10 includes an interior guide passage 18. The guide passage 18 extends through an interior portion of the handle 14 continuously into and through the guide tube 12. Entrance into the guide passage 18 is provided by a proximal opening 20 formed in the handle 14. The guide passage 18 terminates at an opening 22 at the distal end of the guide tube 12. Further details of the configuration of the guide passage 18 will be described later.

As Fig. 2 shows, the guide passage 18 is sized and configured so that, in use, the operative tool 16 can be inserted through the proximal opening 20 and advanced through the passage 18 outwardly beyond the distal opening 22. Use of the guide device 10 in this manner facilitates the deployment and positioning of the operative tool 16 that, by construction, may be less flexible and harder to manipulate than the guide tube 12 itself.

The guide tube 12, while flexible, preferable has a plastic memory or bias that normally orients the distal end region of the guide tube 12 in an essentially straight configuration, as shown in Fig. 1. To enable greater control of the orientation of the distal end region of the guide tube 10, the guide device 10 includes a steering assembly 24. In operation, the steering assembly 24 deflects the distal end region of guide tube 12 out of its essentially straight configuration and into a bent or deflected configuration, as shown in Fig. 3.

In its essentially straight configuration, the guide tube 12 is well oriented for deployment into an interior body region, e.g., through an intra-vascular or cannulated access path. During such deployment, the guide tube 12 may be passed over a conventional guide wire, which can be inserted through the interior passage 18. Or alternatively, the guide tube 12 may be used with a dilator 60 (see Fig. 1A) which may be inserted through the interior guide passage 18. The dilator 60 features a tapered nosecone 62 on its distal end, a Luer type connector 64 on its proximal end, and a shaft 66 coupling the nosecone 62 to the Luer connector 64. The dilator 60 desirably includes a guide wire lumen 68 extending throughout the length of the dilator. In use, the tapered nosecone 62 extends past the distal tip or opening 22 of the steerable guide catheter 10 to facilitate access to the intra-vascular or cannulated access path and provide improved tracking onto the guide wire.

Upon deployment of the guide tube 12 to a desired body region (and withdrawal of the guide wire and dilator 60, if used), a clinician can operate the steering assembly 24 to deflect the distal end region of the guide tube 12 in its bent or deflected condition. A radiopaque marker M (see Fig. 3) can be placed on the distal end region to permit fluoroscopic visualization of the orientation of the deflected end region. In its bent or deflected configuration, the distal passage end 22 can be oriented in a desired relationship with a targeted tissue surface in the body region.

Desirably -- as Figs. 5A, 5B, and 5C show -- the radiopaque marker M forms a partial ring (i.e., C-shaped) or comparable shape that changes depending upon orientation, so that the radiopaque image is visually distinct when observed in different orientations, e.g., presenting an upward U-shape when in an anterior orientation (Fig. 5A); or a downward U or "little-N" shape when in a posterior orientation (Fig. 5B); or an edge-on shape when in a lateral orientation (Fig. 5C). It should be appreciated that multiple radiopaque markers can also be used to provide an image which is visually distinct when observed in different orientations.

Desirably (as Fig. 3 shows), the guide tube 12 is placed into its bent or deflected configuration before passage of the operative tool 16 through the passage 18. Once in its bent or deflected configuration, as Fig. 4 shows, the operative tool 16 can be advanced through the passage 18 and guided by the bent configuration into the desired relationship with the tissue surface for use.

The steering assembly 24 holds the distal end of the guide tube 12 in its deflected condition, thereby maintaining the operative tool 16 in its desired relationship during use. The steerable guide tube 12 obviates the need to equip the operative tool 16 with an on-board steering mechanism or a guide wire lumen.

As Figs. 3 and 4 show, the steering assembly 24 is desirable configured for single handed operation by the clinician. The steering assembly 24 is also desirably configured to provide a mechanical advantage sufficient to translate relatively small increments of clinician control into relatively larger increments of guide tube deflection.

As will be described in greater detail later, and as Fig. 3 generally shows, the steering assembly 24 includes an actuator 26 that can be manipulated by the clinician. The actuator 26 is coupled through a linkage system 28 to a deflecting component 30, which is coupled to the distal end region of the guide tube 12.

In general operation, manual force applied by the clinician to the actuator 26 is translated by the linkage system 28 into a pulling force or tension exerted on the deflecting component 30, which deflects or bends the distal end region of the guide tube 12. The linkage system 30 is desirably configured with a mechanical advantage that amplifies relatively small increments of movement of the actuator 26 into relatively larger increments of movement of the deflecting component 30.

Further details of particular embodiments of the guide tube 12 and the steering assembly 24 will now be described.

A. Components of the Guide Tube

Referring to Figs. 6A and 6B, in the illustrated embodiment, the guide tube 12 comprises a main lumen 32, which constitutes a portion of the interior passage 18, already described. The guide tube 12 also includes a control lumen 34. The deflection component 30, previously described, extends through the control lumen 34.

The illustrated embodiment shows one control lumen 34 and one deflection component 30. It should be appreciated that multiple control lumens (and deflection components) can be provided, if desired. As can be seen in Figs. 6D and 6E, multiple control lumens would provide the ability to direct the flexible guide tube 12, (e.g., the distal end region) of the steerable guide 10 in more than one direction. For example, two control lumens 34, 34′ oriented 180 degrees apart (along with two deflection components 30, 30′) would allow the distal end region to be deflected 90 degrees in two directions within one plane. This feature would allow for additional steering control to accurately position the distal opening 22 at the targeted tissue site.

In the illustrated embodiment, the control lumen 34 is also shown to extend outside the main lumen 32. It should be appreciated that the control lumen 34 can extend inside the main lumen 32, or the main lumen 32 and the control lumen 34 can be formed as a composite.

Both the main lumen 32 and the control lumen 34 desirably include a liner 36. Each liner 36 preferably comprises a material with a low coefficient of friction, such as PTFE, although other materials having comparable mechanical properties can be used. The presence of the liner 36 in the main lumen 32 reduces friction to ease the passage of the operative device 18 through the main lumen 32. The presence of the liner 36 in the control lumen 34 reduces friction and this moderates the pulling force or tension necessary to manipulate the deflecting component 30.

The guide tube 12 also desirably includes a reinforcement sheath 38. The reinforcement sheath 38 envelopes both the main lumen 32 and control lumen 34. The reinforcement sheath 38 can have multiple shape configurations, can be made of multiple materials, and can be arranged in multiple patterns. Patterns can range from a simple coil to a complex braid arrangement. The pattern can be uniform or can vary along the length of the catheter tube 12. In the illustrated embodiment, the reinforcement sheath 38 is in the form of a braid made of round wire made, e.g., from stainless steel, titanium, cobalt alloys, polymers, and natural fibers.

The guide tube 12 also desirably includes a tip reinforcing element(s) 40. The reinforcing element 40 is disposed at or near the distal opening 22 of the passage 18, and serves to resist collapse or distortion of the main lumen 32 during deflection as a result of pulling on the deflecting component 30.

In a desired embodiment, (see Fig. 6B), the tip reinforcing element 40 comprises a metallic ring, such as a uniform ring, but other shapes and materials are also contemplated. As seen in Figs. 6A and 6B, the tip reinforcing element 40 is shown disposed over the reinforcement sheath 38. Alternatively, the tip reinforcing element 40 and the reinforcement sheath 38 can comprise a composite structure.

In the desired embodiment, the deflecting component 30 makes a continuous loop completely around the tip reinforcing element 40 and returns back through the control lumen 34 into the handle 14, where it is coupled to the linkage system 28, as will be described in greater detail later. In an alternative embodiment (see Fig. 6C), the deflecting component 30 loops around only a portion of a reinforcing element 41. As shown, the reinforcing element 41 comprises more than one ring (i.e., two or more individual rings) coupled together with at least one coupling element 43. In this configuration, the deflecting component 30 may be looped around one or more coupling element(s) 43.

The guide tube 12 also desirably includes a cover 42. The cover 42 envelopes all of the internal structures heretofore described, forming a composite structure. The cover 42 can be made of different types of material or of a uniform material with different physical characteristics throughout the length of the guide tube 12. The cover 42 can be of uniform thickness, or the thickness can vary along the length of the guide tube 12. In a preferred embodiment, the cover is made of a polymer material of differing hardness. The softest portion is located at the distal portion of the guide tube 12 (near the opening 22) and the stiffer portion is located at the proximal portion of the guide tube 12 (within the handle 14). The cover 42 can also include a material within the polymer which allows the cover 42 to be radiopaque or a material that reduces friction.

The tip reinforcing element 40, 41 and/or reinforcement sheath 38 can also be used as radiopaque markers. Alternatively, or in combination, one or more radiopaque markers M can be attached to the distal end of the catheter assembly 12. The use of radiopaque materials makes it possible to gauge the deflected orientation of the guide tube 12. A given radiopaque marker can made from platinum. Still, other materials (and different shapes) can be used.

As Fig. 7 shows, the guide tube 12 extends into the distal end of the handle 14. A transition shaft 44 is connected at one end to the proximal end of the guide tube 12 (where the cover 42 is stiffer) and at the other end to a sealing element 46 that occupies the proximal-most region of the handle 14. The sealing element 46 includes an interior lumen 48 that comprises an extension of the interior passage 18, and also includes the proximal opening 20. The transition shaft 44 also includes an interior lumen 50 that also forms an extension of the interior passage 18, linking the main lumen 32 of the guide tube 12 in communication with the proximal opening 20. The transition shaft 44 can be an integrated component of the guide tube 12.

The sealing element 46 desirably includes an in-line hemostatic valve assembly 52 at or near the proximal opening 20 of the passage 18. The valve assembly 52 prevents blood or fluid loss by sealing the proximal opening 20 when an operative tool 16 is within the passage 18, as well as when no operative tool 16 is present in the passage 18.

The valve assembly 52 desirably includes a main seal component 54 and a lip seal component 56, which can comprise separate or integrated components. The main seal component 54 seals the proximal opening 20 in the absence of an operative tool 16 in the passage 18. The lip seal component 56 seals upon insertion of the operative tool 16 through the proximal opening 20 into the passage 18.

An infusion valve 58 can also be coupled to the passage 18 through the sealing element 46. In this way, fluid can be conveyed through the passage 18 into the interior body region, e.g., to flush materials from the passage 18 during use.

As described, the guide tube 12 is secured to the handle 14 and does not rotate relative to the handle 14. To rotate the guide tube 12, the clinician must rotate the handle 14.

B. Components of the Steering Assembly

1. The Actuator

It should be appreciated that the actuator 26 of the steering assembly 24 can take many forms, such as a sliding lever or a pistol grip. The actuator 26 can be located at many locations on the handle 14, such as the proximal end, the distal end, or the mid-portion. In the embodiment shown in Figs. 1 to 4, the actuator 26 takes the form of a fluted knob that is rotationally attached to the distal end of the handle 14. The knob 26 is positioned so that it can be rotated by the thumb of the clinician's hand that holds the handle 14. As shown in Fig. 3, the handle 14 may be held in the palm of the hand while the knob 26 is manipulated by the thumb.

In the illustrated arrangement (best shown in Figs. 8 and 9), the knob 26 includes front and rear thrust bearing surfaces 132 and 134. These thrust bearing surfaces can be integral to the knob component or they can be separate components which are added to the knob 26 to make a complete assembly. Front and rear journals 136 and 138 on the handle 14 support the thrust bearing surfaces 132 and 134, so that the knob 26 can be easily rotated relative to the distal end of the handle 14 by movement of the thumb.

2. The Linkage System

a. Rack and Pinion Gear Assembly

In the illustrated arrangement, the linkage system 28 translates rotational movement of the actuator knob 26 into a linear force direction. To affect this translation (see Figs. 8 and 9), the linkage system 28 includes a female threaded shaft 140 formed within the knob 26, which rotates in common with the knob 26, and a threaded male component 146 that is coupled to a slider 142, which is mounted for linear movement in a channel 144 within the handle 14. It should be appreciated that the thread placement on both of these elements could be reversed. The threads can take any form and/or type, and can be self-locking or non-locking. In a preferred arrangement, the threads on the female threaded shaft 140 and the male threaded component 146 are locking.

The slider 142 is restrained by the channel 144 from twisting or rotating. Coupled to the slider 142, which is kept from twisting or rotating within the channel 144, the threaded component 146 is likewise kept from rotation.

The threaded male component 146 extends from the slider 142 in the direction of the knob 26. The male threads on the component 146 are configured to thread into the female threads of the shaft 140 in response to rotation of knob 26. Rotation of the knob 26 progressively moves the threaded component 146 within the shaft 140. The slider 146 follows, moving in a linear direction within the channel 144 fore (toward the distal end of the handle 14) or aft (toward the proximal end of the handle 14), depending upon the direction the knob 26 is rotated. Aft linear movement of the slider 142 within the channel 144 is halted by a proximal stop 148. This position (i.e., when the slider 142 rests in abutment against the stop 148) (as shown in Fig. 8) will be called in shorthand a "neutral position," because, in this position, the linkage system 28 is configured to apply no force upon the deflecting component 30.

When in the neutral position (as shown in Fig. 8), the male component 146 extends from the slider 142 a distance sufficient to thread a portion of the male component 146 within a portion of female threads of the shaft 140. When in the neutral position, rotation of the knob 26 in a single predetermined direction (in the illustrated embodiment, clockwise from the clinician's view point) (see Fig. 11) advances the component 146 along the shaft 140 and draws the slider 142 in a linear forward direction within the channel 144 (i.e., toward the knob 26). It should be appreciated that the direction for activation could be reversed (i.e., rotating the knob 26 advances the slider 142 in a linear direction away from the knob 26).

The linkage system 28 is configured to translate this linear forward movement of the slider 142 into a tension or pulling force on the deflecting component 30. To affect this translation, the linkage system 28 includes a rack and pinion gear system. More particularly (see Figs. 8 and 9), a rack 150 is coupled to slider 142 for linear movement in common with the slider 142. In the illustrated embodiment, the rack 150 extends in a direction away from the knob 26, into the more proximal region of the handle 14. There (as also shown in Fig. 10), the rack 150 engages a pinion gear 152. The pinion gear 152 is coupled to a main gear 154, which is supported for rotation on a shaft within the handle 14. The main gear 154 is, in turn, coupled through another pinion gear 158 to a pick up reel 56, which is likewise supported for rotation on a shaft within the handle 14. The proximal end of the deflecting component 30 is coupled to the pick up reel 156. The attachment can be accomplished, e.g., by crimping, tying, or adhesion.

Rotation of the pick up reel 156 in a predetermined direction (which, in the illustrated embodiment, is counterclockwise) applies a linear aft pulling force or tension upon the deflecting component 30, thereby bending the distal end region of the catheter tube 12.

In an alternative arrangement (not shown), a spiral cut gear coupled to the knob could engage the rack to move the rack in a linear direction in response to rotation of the knob.

As Fig. 11 best shows, the linkage system 28, as described, translates rotation of the knob 26, which draws the slider 142 toward the knob 26, into linear forward translation of the rack 150. Linear forward translation of the rack 150 is, in turn, translated into rotation of the pinion gear 152 (which, in the illustrated embodiment, is clockwise). Rotation of the pinion gear 152 translates into an opposite rotation (i.e., counterclockwise) of the main gear 154. Rotation of the main gear 154 translates into an opposite rotation (i.e., clockwise) of the pinion gear 158. Rotation of the pinion gear 158 translates into an opposite rotation (i.e., counterclockwise) of the pick up reel 156. Rotation of the pick up reel 156 is, in turn, translated into a linear aft pulling force or tension on the deflecting component 30, to deflect the distal end of the guide tube 12.

The gear ratio of the rack 150 and the main gear 154, as well as the diameter of the main gear 154, are selected, taking into account the size constraints imposed by the handle 14, to provide a desired mechanical advantage. The mechanical advantage amplifies the incremental amount of deflection of the deflection component 30 for a given increment of rotation of the knob 26. Due to the mechanical advantage, the amount of manual, thumb-applied force required to rotate the knob 26 is, to the clinician, normal and without strain. Deflection of the guide tube 14 occurs with comfortable thumb control.

b. Pivot Tensioning System

Figs. 12 and 13 show an alternative arrangement for the steering assembly 24. The alternative arrangement shown in Figs. 12 and 13 shares many of the functional components of the arrangement shown in Fig. 8. Both include the rotary actuator knob 26 that carries the internal female threaded shaft 140, and a slider 142 that carries the threaded male component 146, which threadably engages the threaded shaft 140.

Also as before described, and as shown in Fig. 13, rotation of the actuator knob 26 is translated into linear movement of the slider 142 within the channel 144 inside the handle 14.. In the rack and pinion linkage arrangement shown in Fig. 11, distal movement of the slider 144 (toward the knob 26) serves to apply tension to the deflecting component 30 through the rotation imparted to the take up reel 156 by the lateral movement of the rack 150 attached to the slider 144. In the alternative arrangement shown in Figs. 12 and 13, proximal movement of the slider 142 (away from the knob 26) applies tension to the deflection component 30 through a tension arm 160 that pivots in a proximal direction along the longitudinal axis of the handle 14. The deflecting component 30 is attached to the pivoting tension arm 160 and is placed into tension as a result of the proximal pivoting movement, to bend the distal region of the catheter tube 12, as Fig. 13 shows.

More particularly, the tension arm 160 is mounted on a pin 162 within the housing 14 for pivoting between a first pivot position, leaning distally toward the knob 26 (see Fig. 12) and a second pivot position leaning proximally away from the knob 26 (see Fig. 13). In the first pivot position (Fig. 12), no tension is applied to the deflecting component 30 attached to the tension arm 160. In the second pivot position (Fig. 13), the deflecting component 30 is placed into tension, to bend or deflect the distal end region of the guide tube 12.

When in the first pivot position (Fig. 12), the pivoting tension arm 160 rests against the proximal end of the slider 142. As the knob 26 is rotated in a predetermined direction (which, in the illustrated embodiment (Fig. 13), is counterclockwise from the standpoint of the clinician), the slider 142 is moved in a linear direction away from the knob 26. The slider 142 pushes against the tension arm 160, causing it to pivot about the pin 162 into the second pivot position. Pivoting of the tension element translates into a linear proximal pulling force or tension on the deflecting component 30, to deflect the distal end of the guide tube 12.

Translating the linear movement of the slider 142 into rotational movement of the pivoting tension arm 160 reduces the mechanical force advantage of the overall system, while increasing the amount of deflection of the distal end region per given rotation of the rotary control element.

3. The Deflection Component

The deflecting component 30 extends from the pick up reel 156 or pivoting tension arm 160 and into the control lumen 34 of the guide tube 12. The deflecting component 30 desirably comprises a strong and flexible material, e.g., metallic wire, braided metallic wire, monofilament wire, etc. In a preferred arrangement, the deflecting element 30 comprises a continuous length of braided polymer or natural fiber. The fiber extends from the pick up reel 156 or pivoting tension arm 160, through the control lumen 34, looping completely around the tip reinforcing element 40, as Fig. 6B best shows. From there, the fiber extends back through the control lumen 34 to terminate at the pick up reel 156 or pivoting tension arm 160.

In this arrangement, the deflecting component 30 can be attached to the tip reinforcing element 40 by various methods, such as adhesion, welding techniques, soldering techniques, tying or wrapping the deflection component 30 to the tip reinforcing element 40, or by forming the deflecting component 30 and the tip reinforcing element 40 as a composite structure. In the alternative embodiment shown in Fig. 6C, separate attachment means may not be necessary to connect the deflecting component 30 to the tip reinforcing element 41.

II. USE OF STEERABLE GUIDE DEVICE

Fig. 14 shows the steerable guide device 10 in use to guide an operative tool 16 to a tissue site. In Fig. 14, the operative tool 16 takes the form of a powered device that applies a helical fastener 164. A representative embodiment of an endovascular device that, in use, applies a helical fastener is described in U.S. Patent Application 10/786,465, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ," which is incorporated herein by reference. In use (as Fig. 14 shows), the endovascular fastener device 16 is manipulated through the guide device 10 to apply one or more fasteners 164 to a prosthesis 166 that is deployed to repair diseased and/or damaged sections of a hollow body organ and/or a blood vessel, e.g., to repair an aneurysm in the aorta in the region between the heart and the iliac bifurcation.

In use, the steerable guide device 10 is introduced to the targeted tissue site through a conventional intravascular approach. For example, when the targeted tissue site is in the aorta, the guide device 10 can be introduced through the femoral artery. However, other access sites and methods can be utilized. The guide device 10 is desirably introduced over a guide wire, which extends through the passage 18. The guide wire can comprise the same guide wire over which the prosthesis 166 has been previously introduced, by means of a separately deployed prosthesis introducing tool. Or alternatively, introduction of the steerable guide device 10 can be accomplished through a separate access site.

Upon withdrawal of the prosthesis introducing tool over the guide wire, and under fluoroscopic visualization, the clinician tracks the guide device 10 and dilator 60 over the same guide wire to locate the distal end region of the device 10 at or near the desired location with respect to the prosthesis. The guide wire and dilator 60 can now be withdrawn. Actuating the steering assembly 24 (by rotating the knob 26), and still employing fluoroscopy visualization, the clinician deflects the distal end region of the device 10 -- and rotates the handle 14 to rotate the catheter tube 12, if necessary -- to orient the distal opening 22 of the passage 18 in a desired facing relationship with the site where introduction of a fastener 164 is desired.

The operative tool 16, e.g., the endovascular fastener device, is now inserted through the proximal opening 20 and advanced through the passage 18 until the fastener 164 is located for deployment outside the now-oriented distal opening 22, as Fig. 14 shows. The operative tool 16 can be actuated to apply a fastener 164 to the prosthesis 166. If the operative tool 16 is a single fire device, i.e., it carries only one fastener 164, the operative tool 16 is withdrawn through the passage 18 and a new fastener 164 mounted. The distal end region of the device 10 is reoriented in facing relationship with a new fastening site. The operative tool 16 is inserted back through the passage 18 to apply the second fastener to the new fastening site. This sequence is repeated until a desired number and array of fasteners 164 are applied to the prosthesis 166. At this point, the guide device 10 can be withdrawn.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

We Claim:

1. A guide device comprising

a guide tube defining a guide passage through which an operative tool can be deployed into an interior body region, and

a steering assembly comprising a deflecting element coupled to a distal end region of the guide tube to apply a deflecting force to bend the distal end region, an actuator, and a linkage system coupling the actuator to the deflecting element to apply the deflecting force in response to operation of the actuator, the linkage system including a rack and a gear train coupled to the rack, the linkage system being operative to translate rotation of the actuator into linear movement of the rack into rotation of the gear train to apply the deflecting force to the deflecting component.

2. A device according to claim 1

further including a handle coupled to the guide tube, and

wherein the linkage system is carried within the handle.

3. A system comprising

a guide device as defined in claim 1, and

an operative tool that applies one or more fasteners to tissue.

4. A method comprising

providing a guide device as defined in claim 1,

deploying the guide device into an interior tissue region, and

operating the steering assembly to bend the distal end region of the guide tube.

5. A method comprising

providing a system as defined in claim 3,

deploying the guide device into an interior tissue region, operating the steering assembly to bend the distal end region of the guide tube,

passing the operative tool through the guide device, and

operating the operative tool while residing in the guide device to apply at least one fastener to tissue.

6. A guide device comprising

a guide tube defining a guide passage through which an operative tool can be deployed into an interior body region, and

a steering assembly comprising a deflecting element coupled to a distal end region of the guide tube to apply a deflecting force to bend the distal end region, an actuator, and a linkage system coupling the actuator to the deflecting element to apply the deflecting force in response to operation of the actuator, the linkage system including a slider and a pivoting lever arm coupled to the slider, the linkage system being operative to translate rotation of the actuator into linear movement of the slider into pivotal movement of the lever arm to apply the deflecting force to the deflecting component.

7. A device according to claim 6

further including a handle coupled to the guide tube, and

wherein the linkage system is carried within the handle.

8. A system comprising

a guide device as defined in claim 6, and

an operative tool that applies one or more fasteners to tissue.

9. A method comprising

providing a guide device as defined in claim 6,

deploying the guide device into an interior tissue region, and

operating the steering assembly to bend the distal end region of the guide tube.

10. A method comprising

providing a system as defined in claim 8,

deploying the guide device into an interior tissue region,

operating the steering assembly to bend the distal end region of the guide tube,

passing the operative tool through the guide device, and

operating the operative tool while residing in the guide device to apply at least one fastener to tissue.

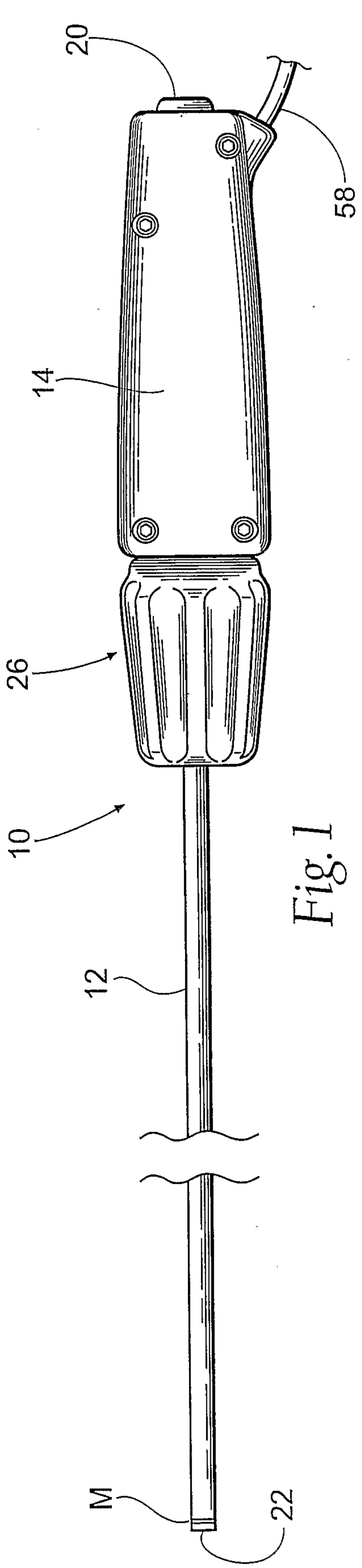

Fig. 1

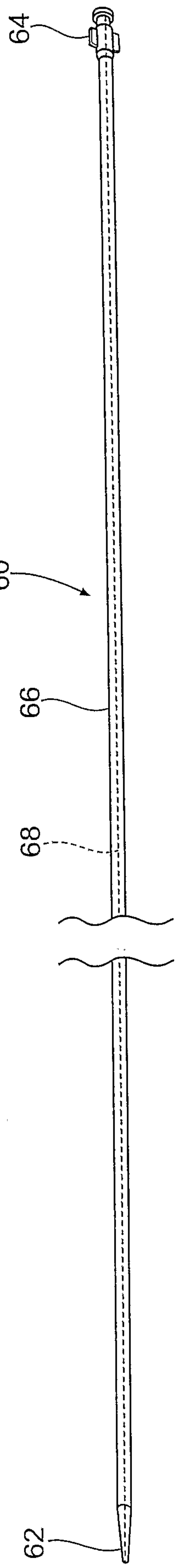

Fig. 1A

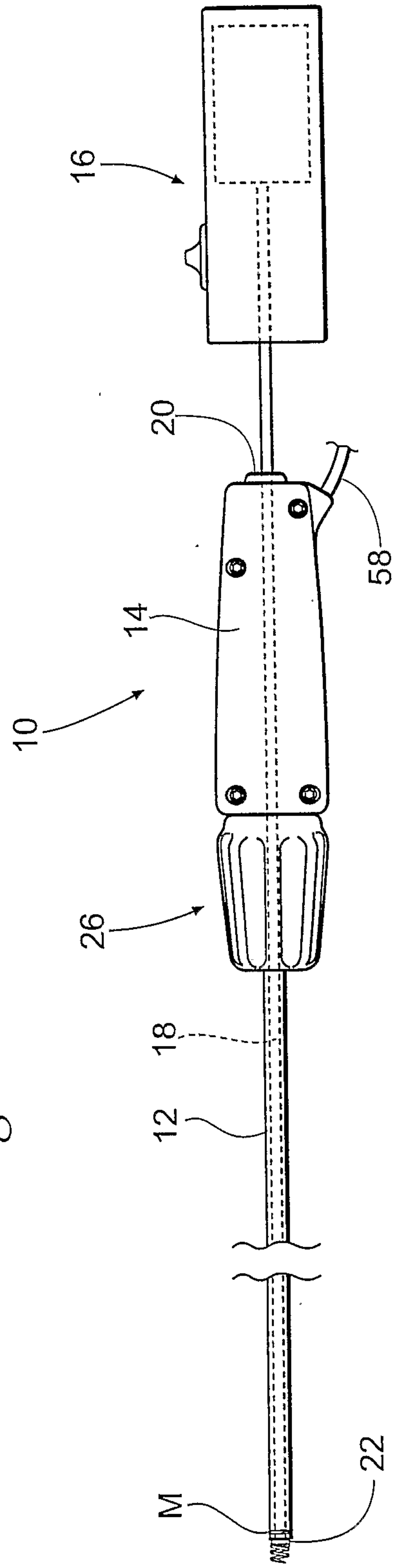

Fig. 2

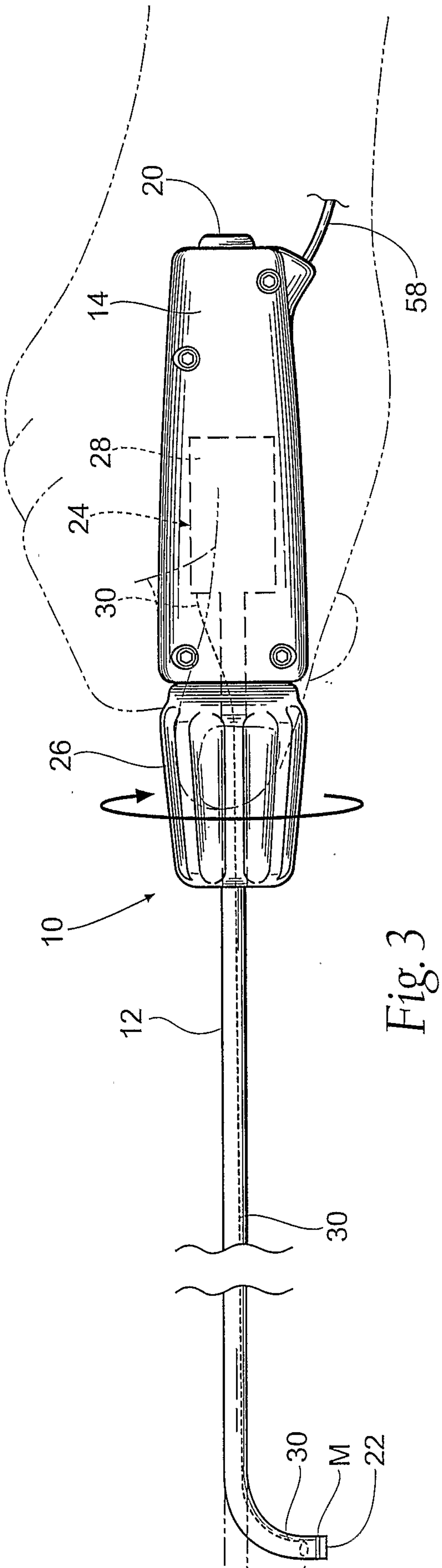

Fig. 3

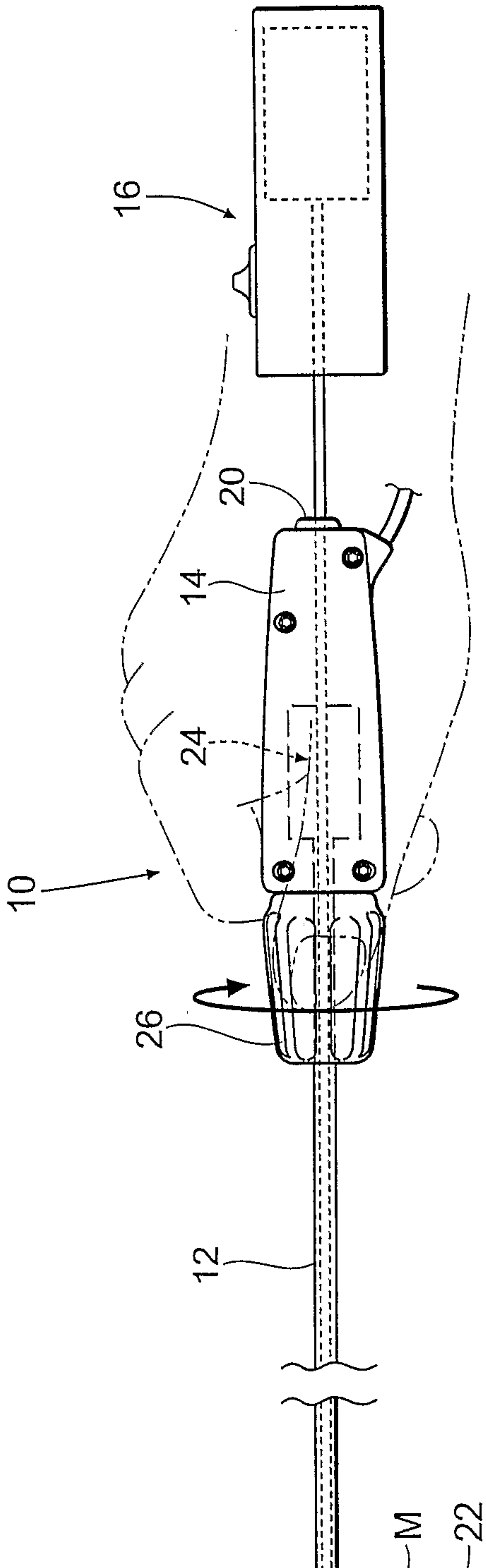

Fig. 4

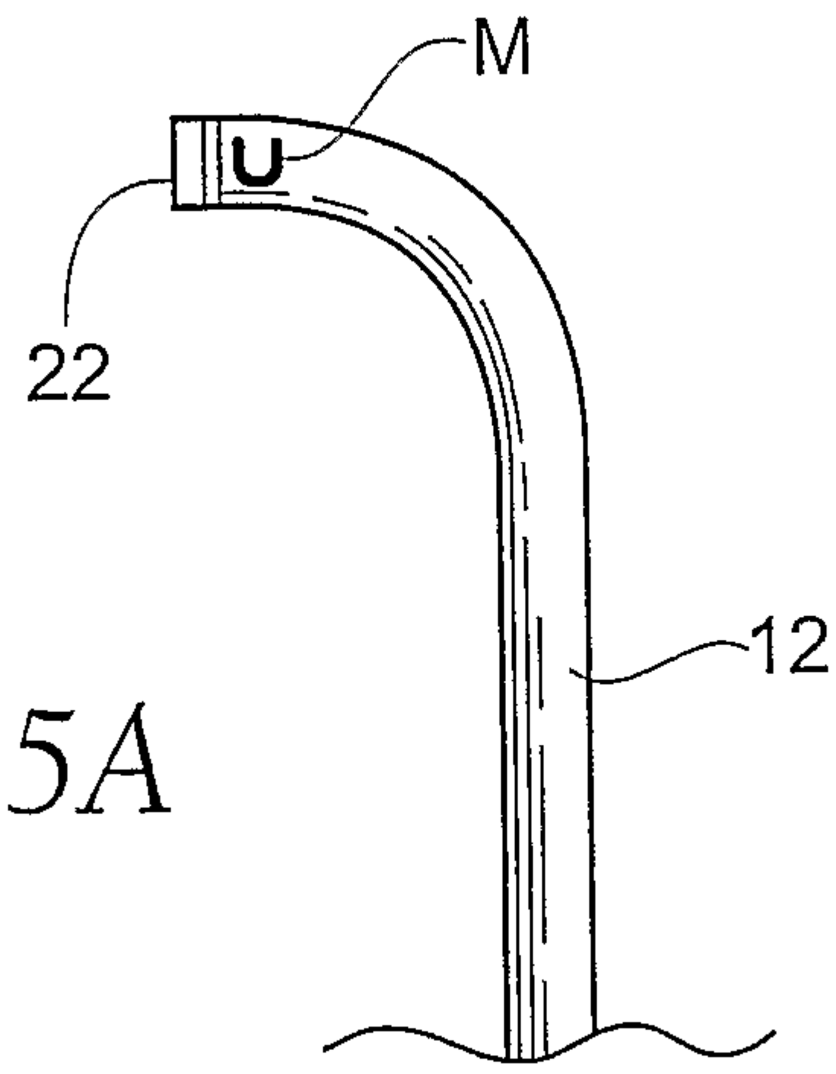

Fig. 5A

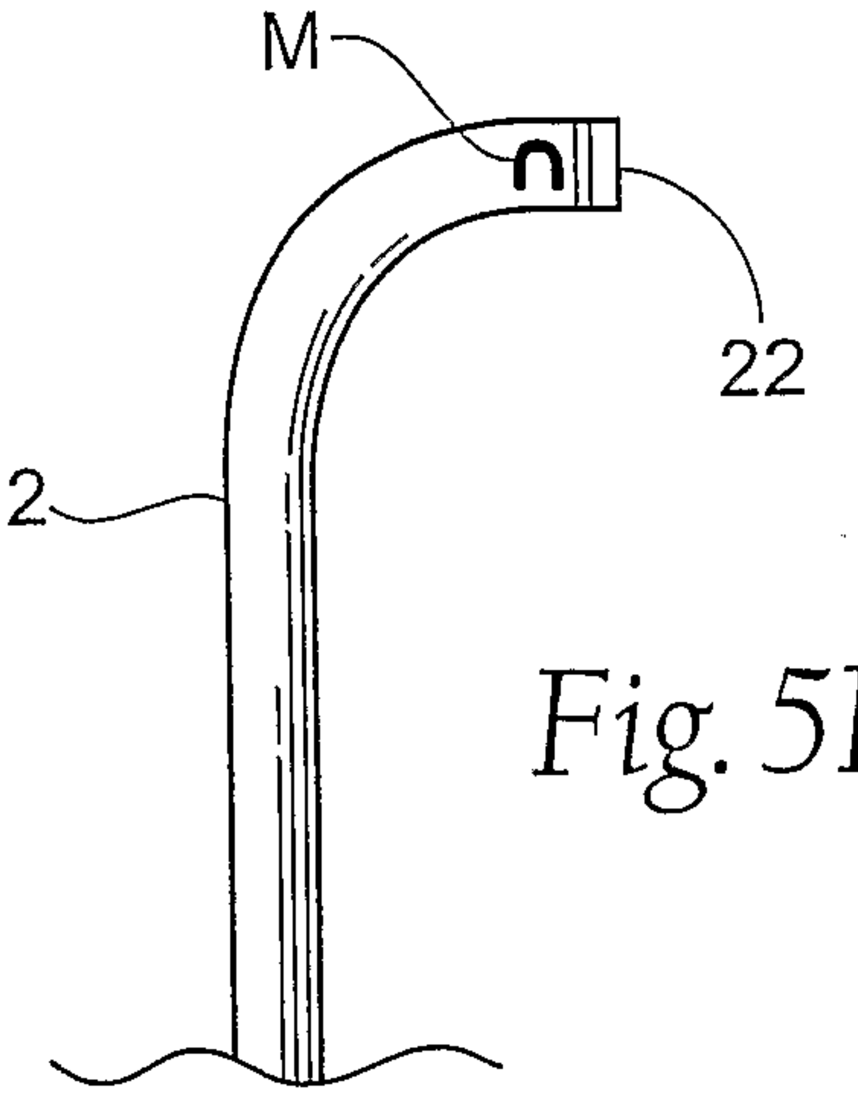

Fig. 5B

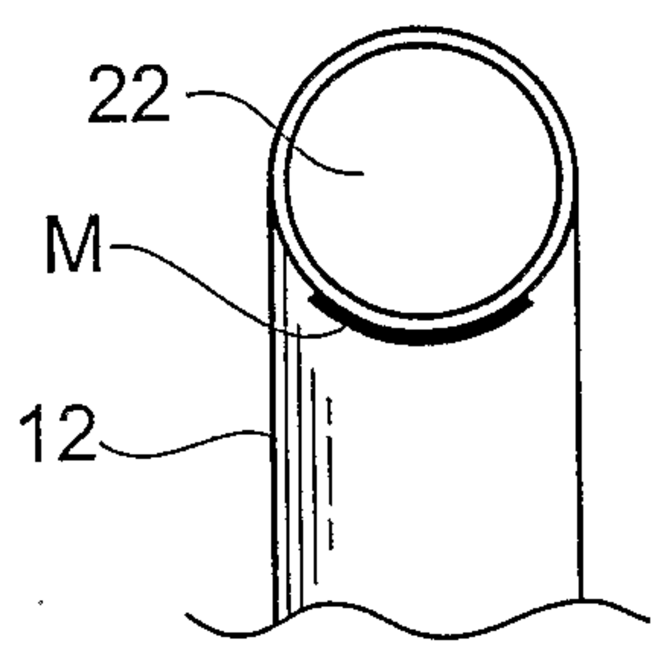

Fig. 5C

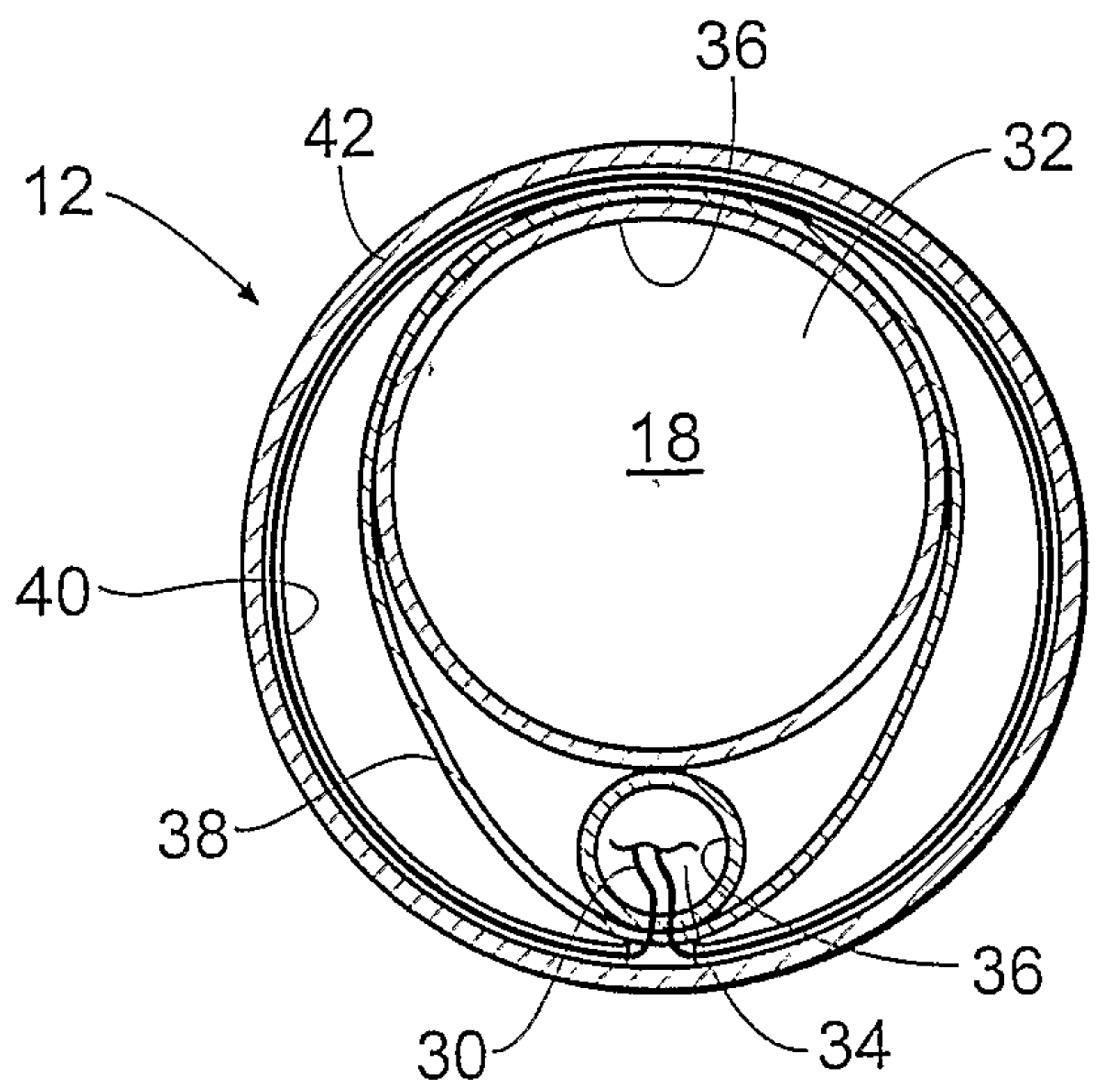

Fig. 6A

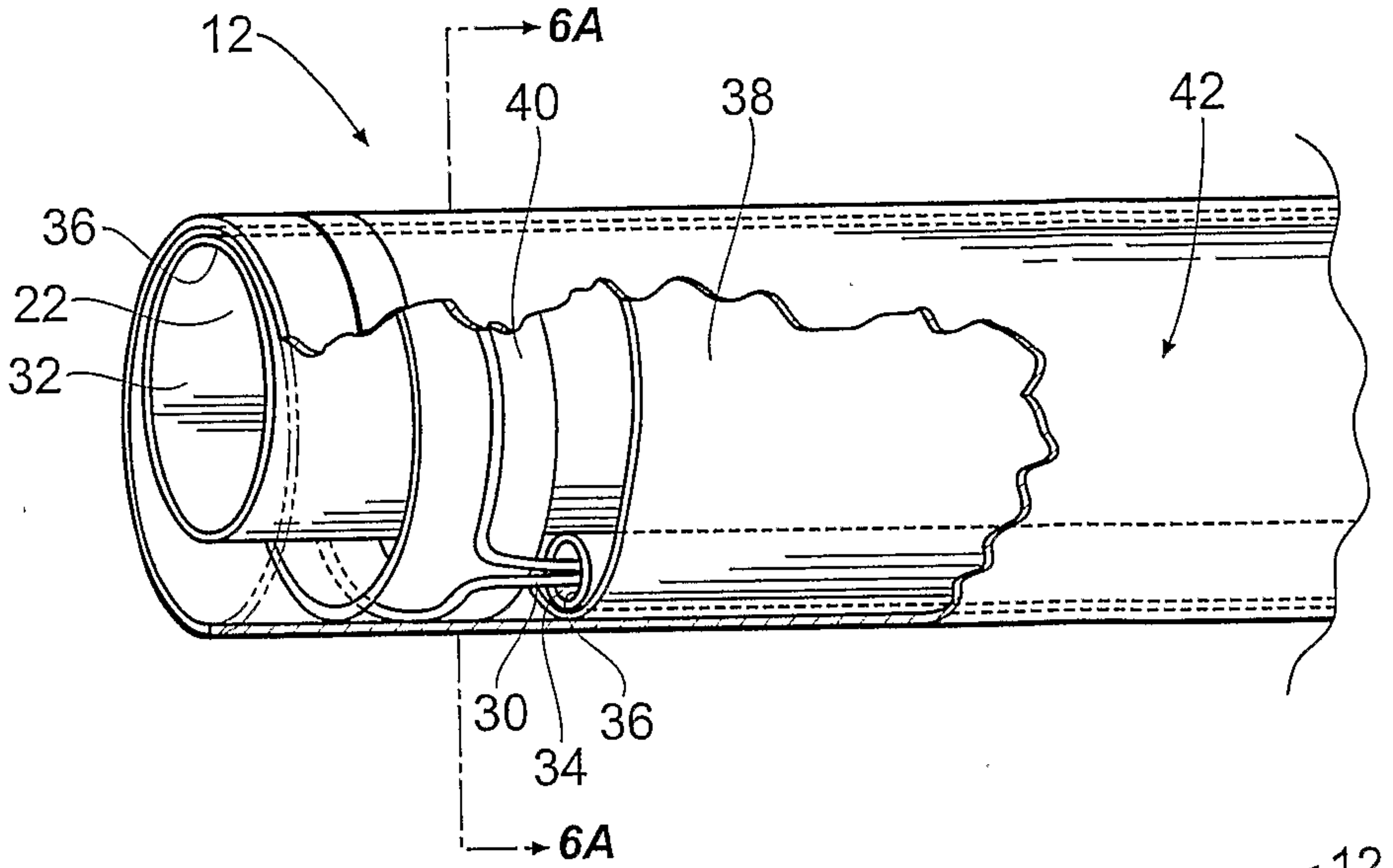

Fig. 6B

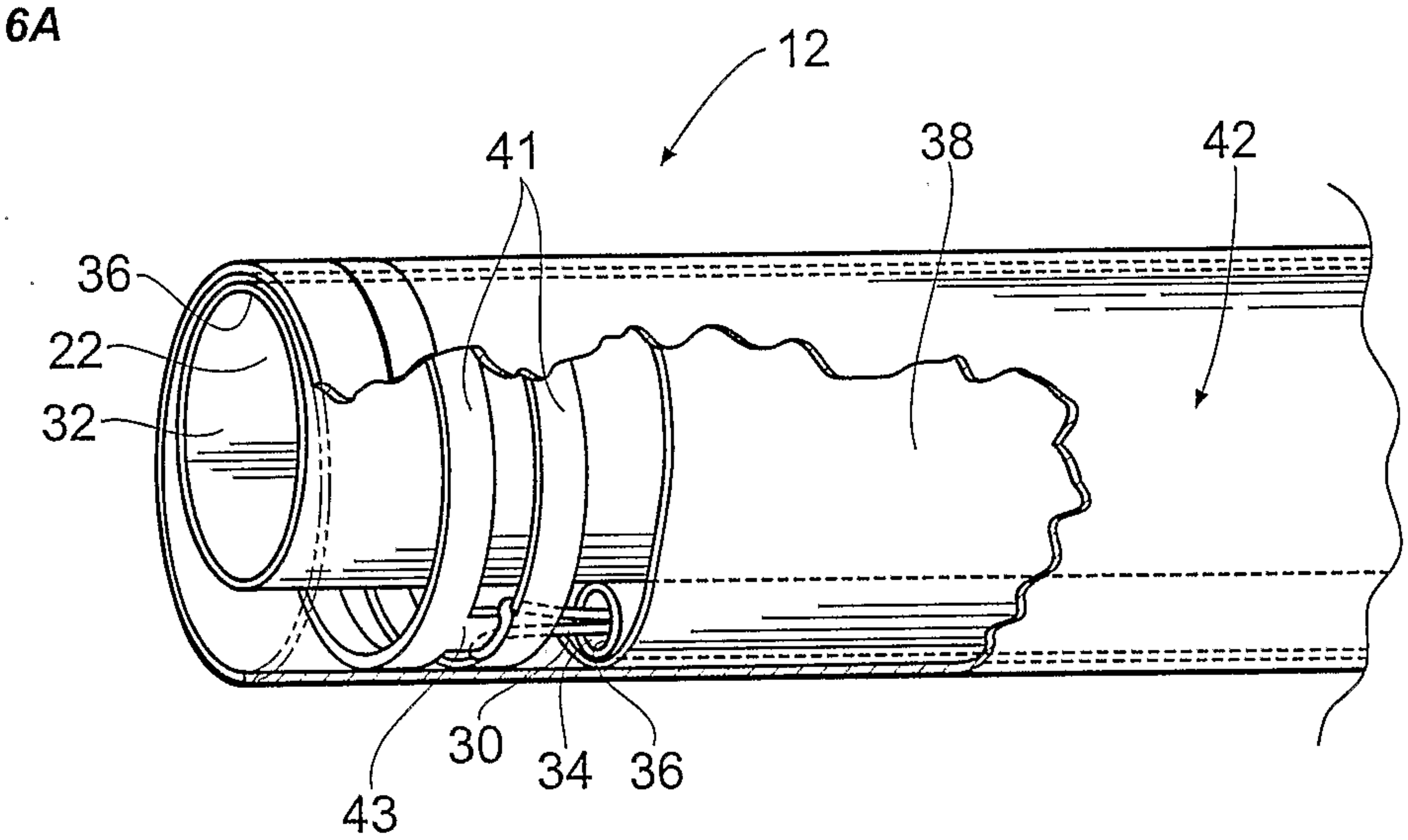

Fig. 6C

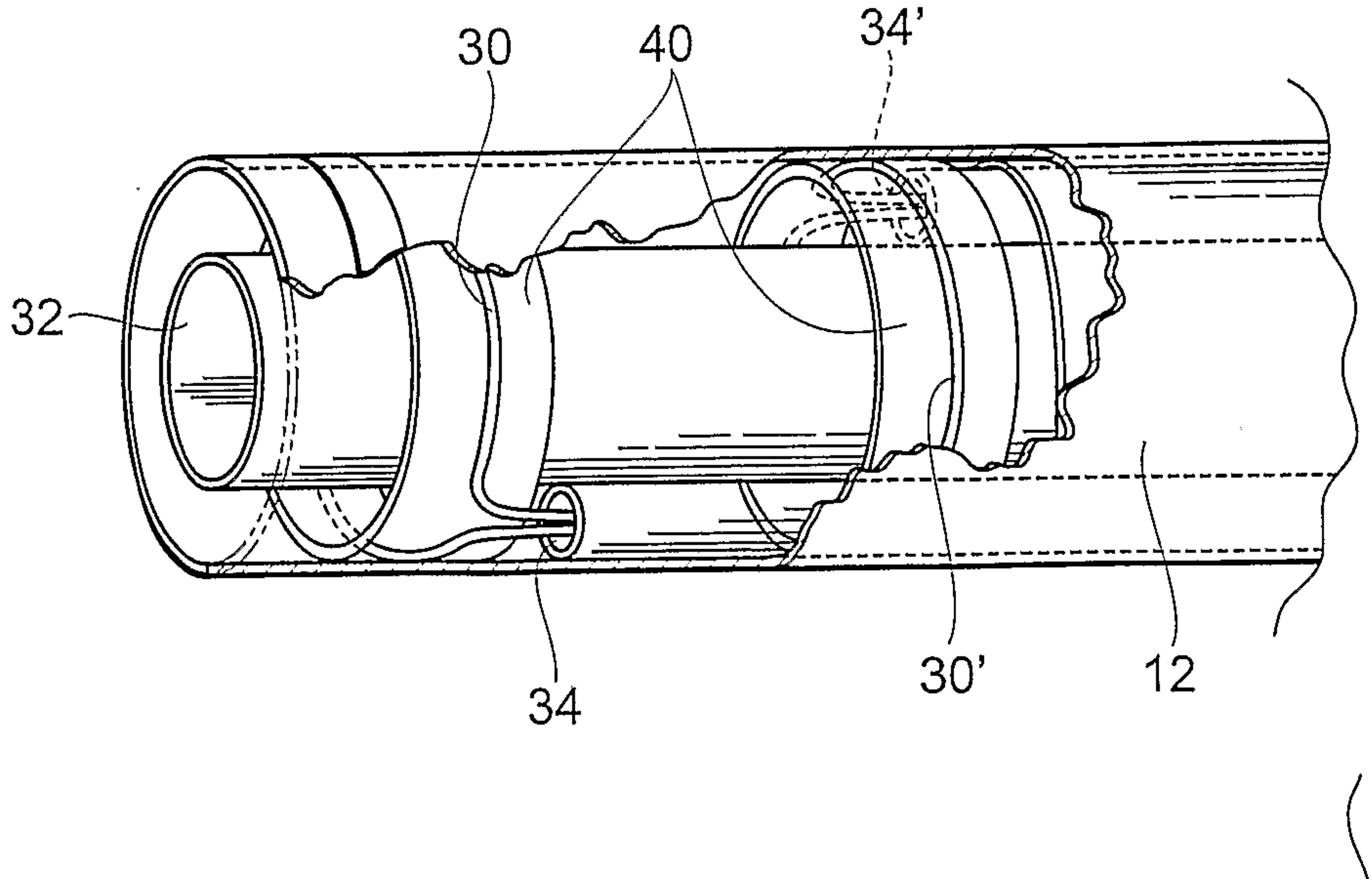

Fig. 6D

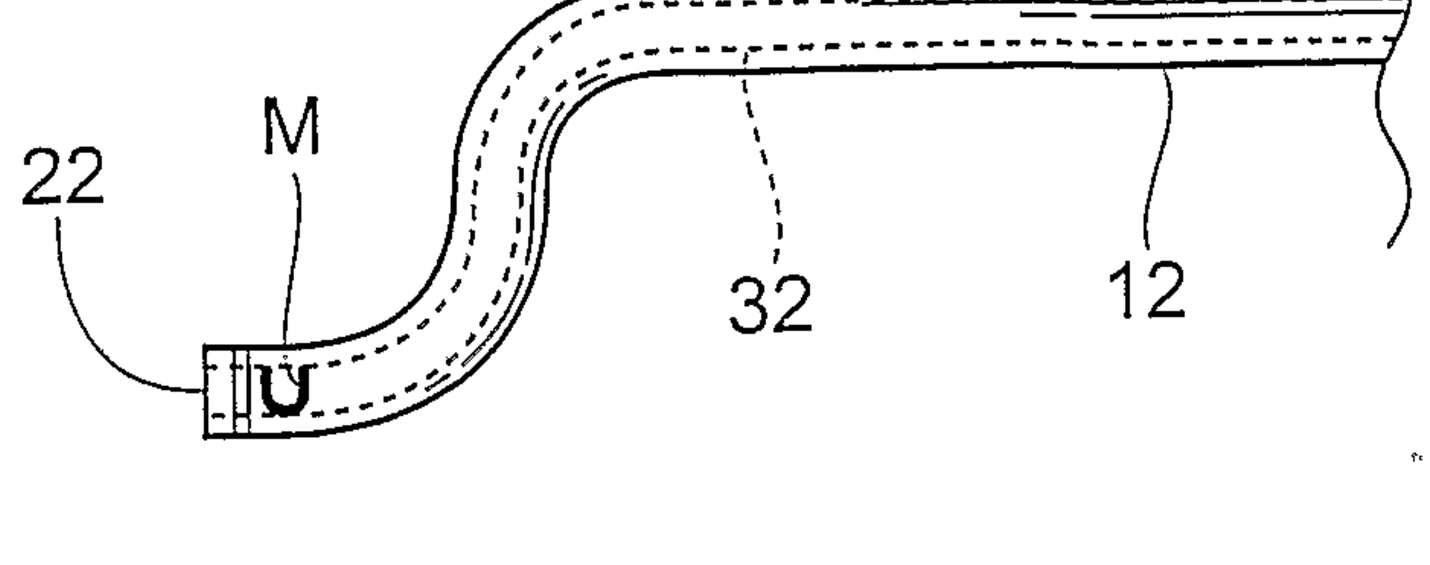

Fig. 6E

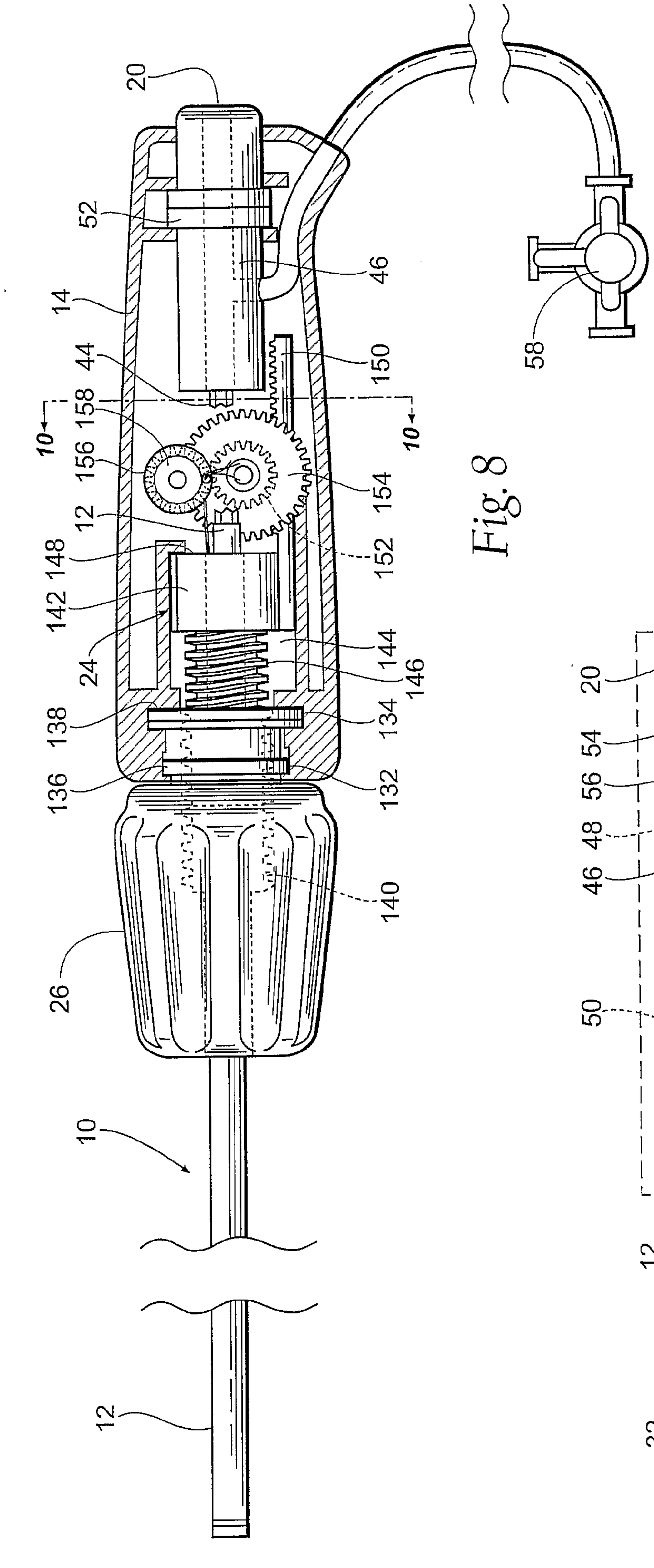
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Fig. 8

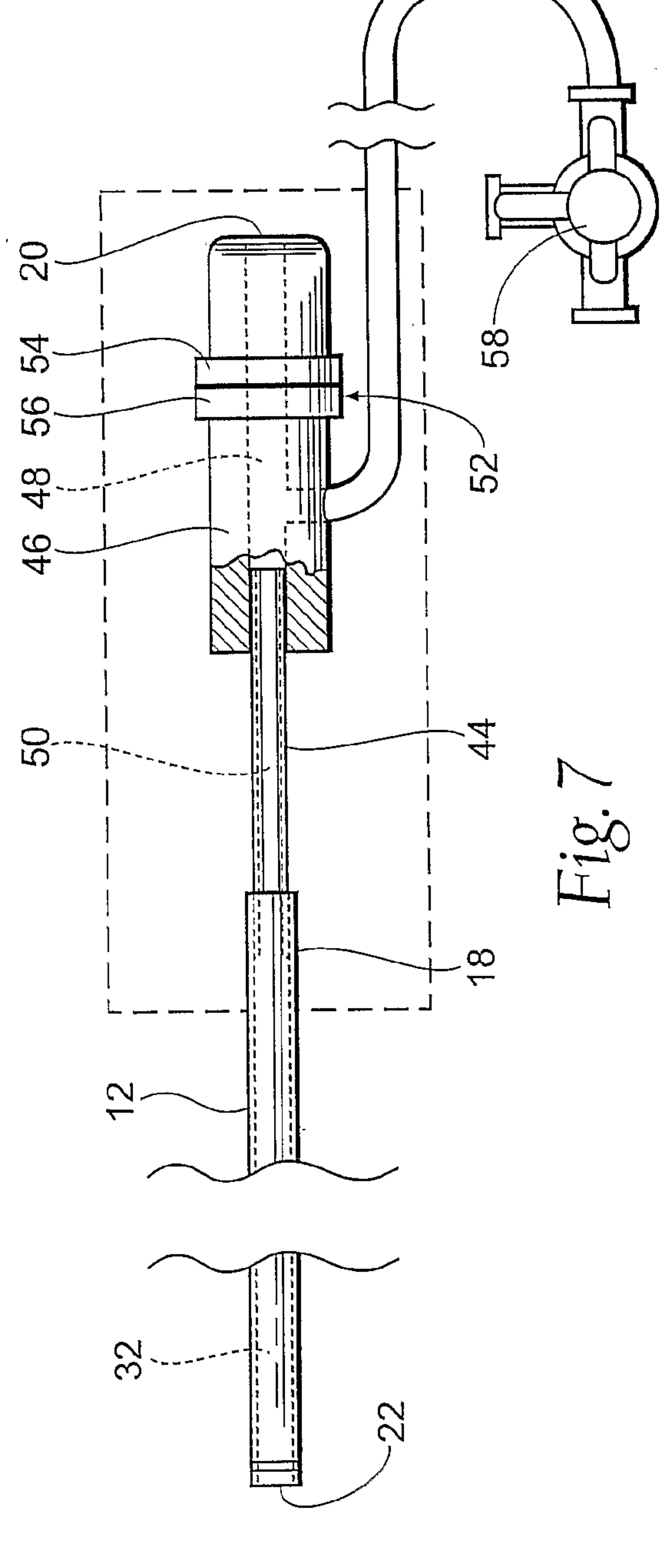
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Fig. 7

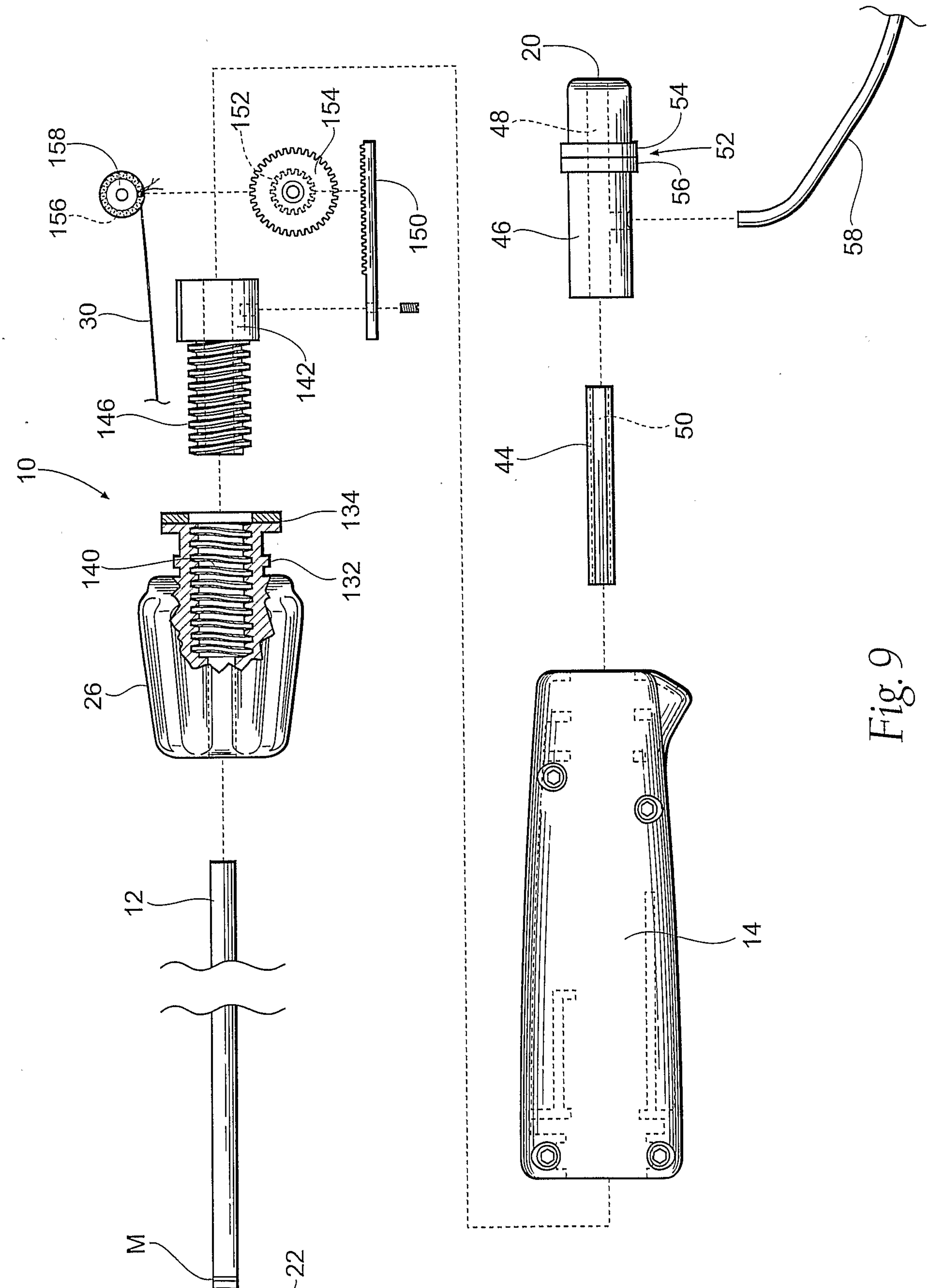
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Fig. 9

Fig. 11

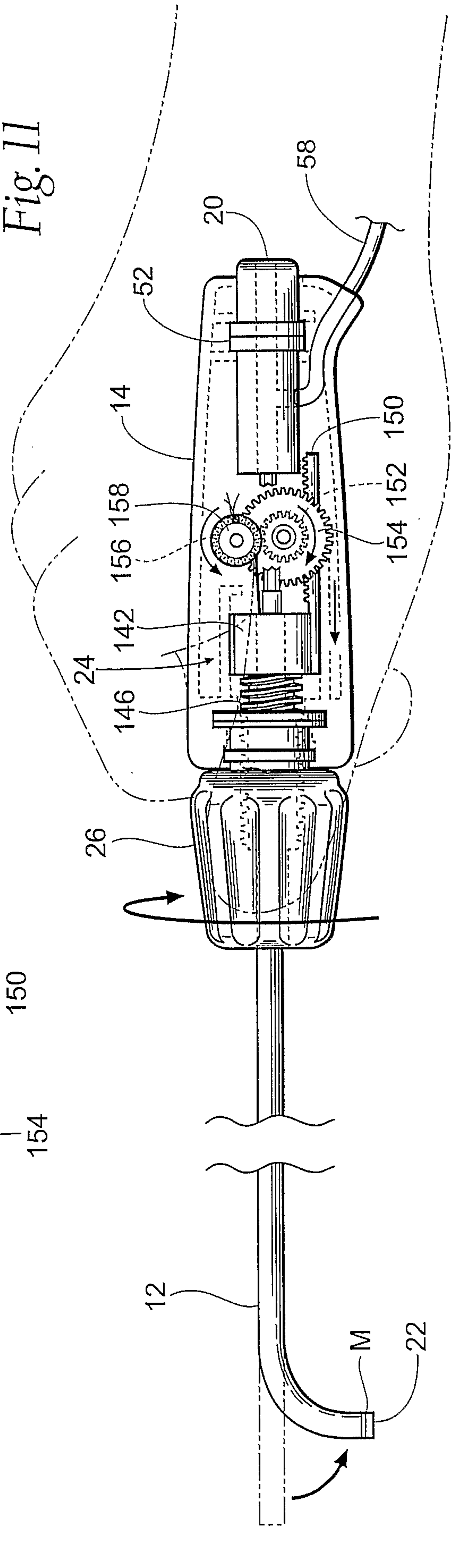
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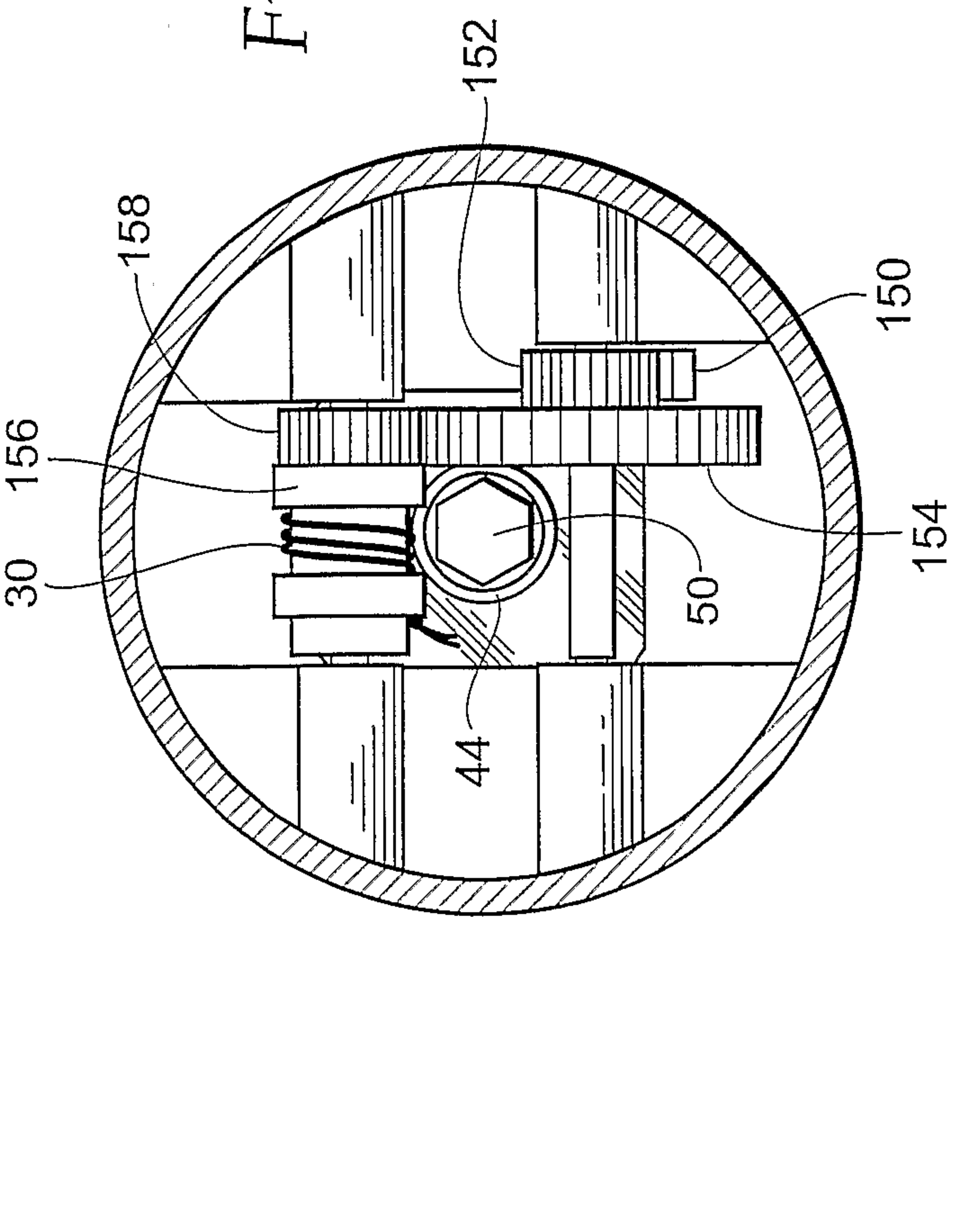
Fig. 10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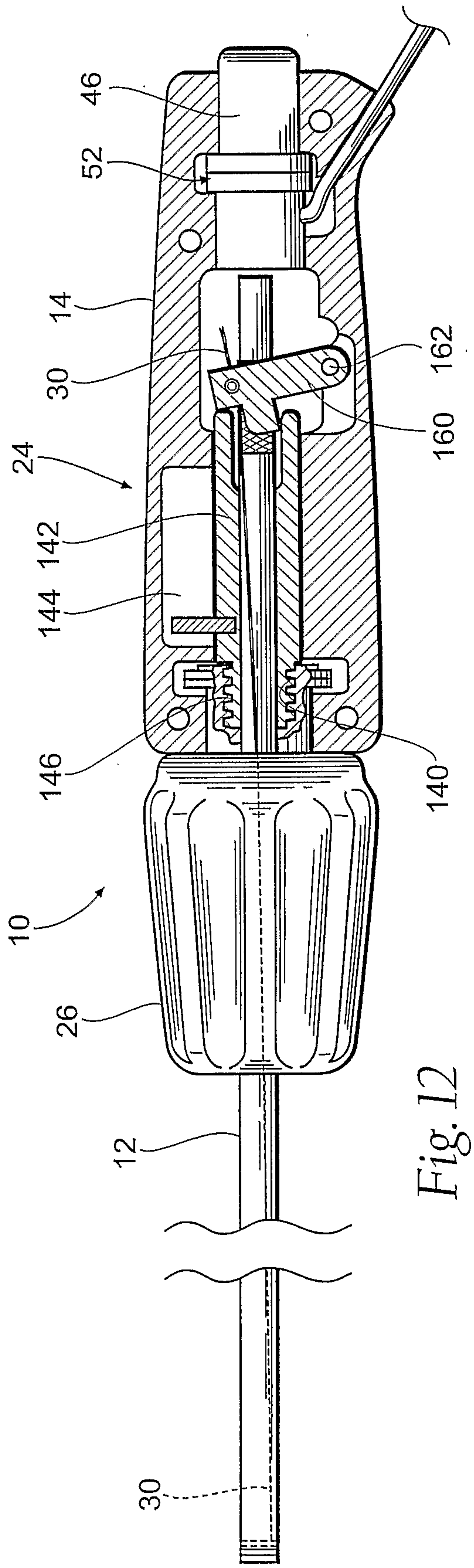
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Fig. 12

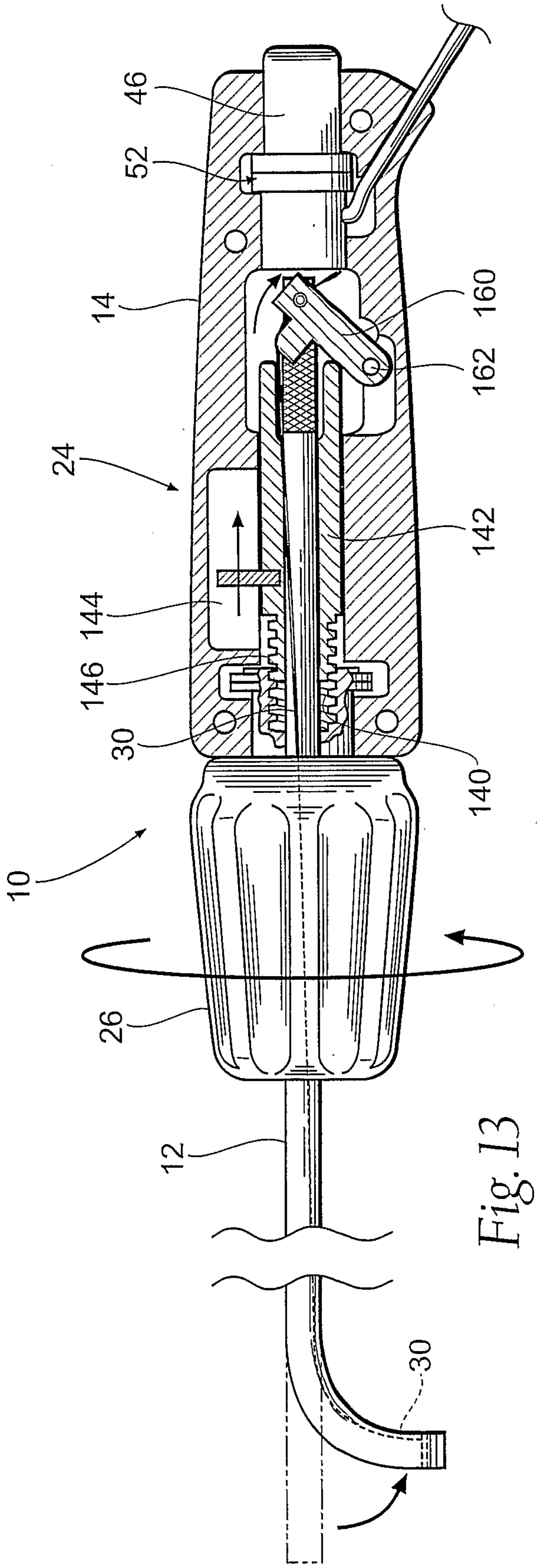
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Fig. 13

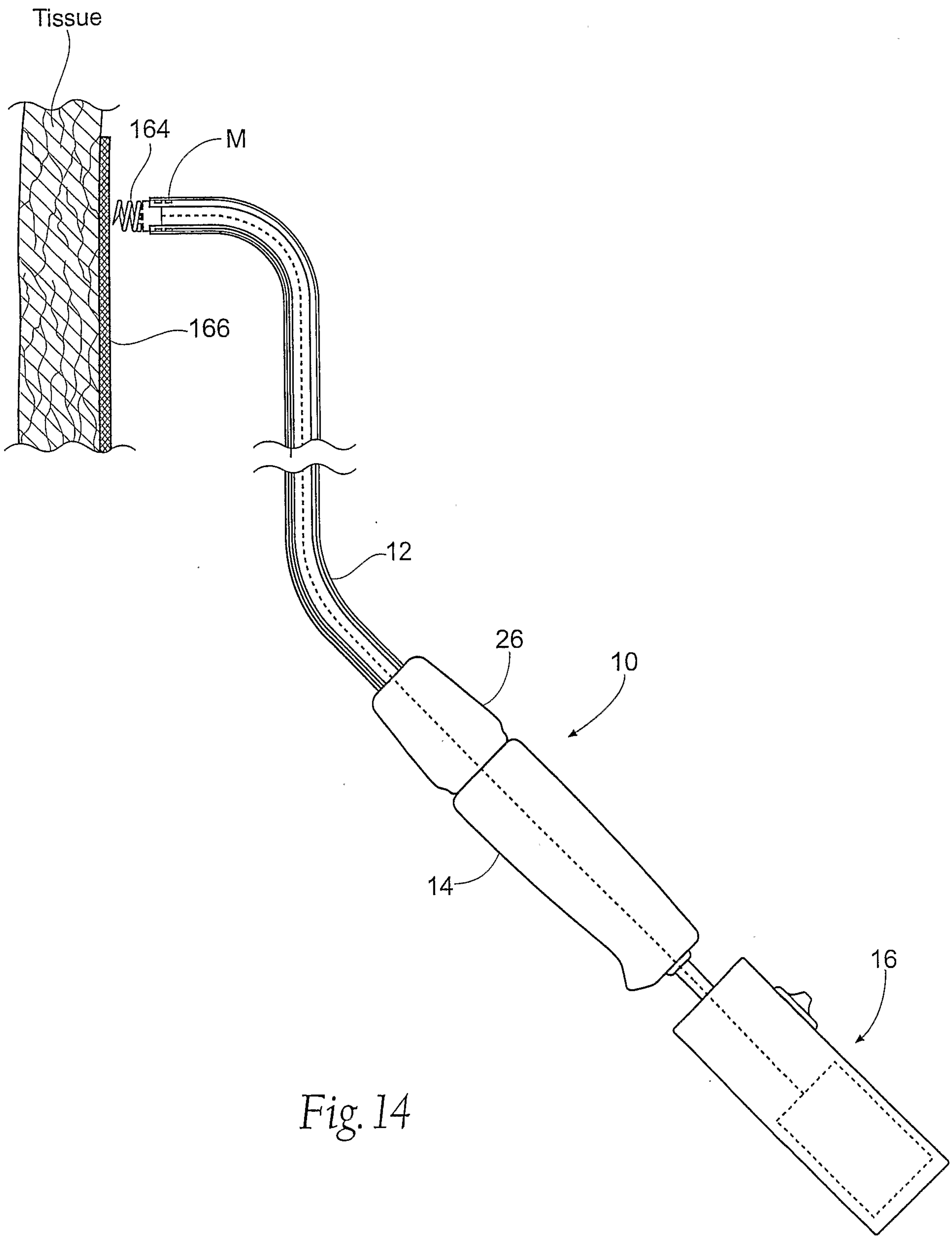

Fig. 14

A