

(51) International Patent Classification:
A61B 17/29 (2006.01)(21) International Application Number:
PCT/EP2013/070745(22) International Filing Date:
4 October 2013 (04.10.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12187552.0 6 October 2012 (06.10.2012) EP
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

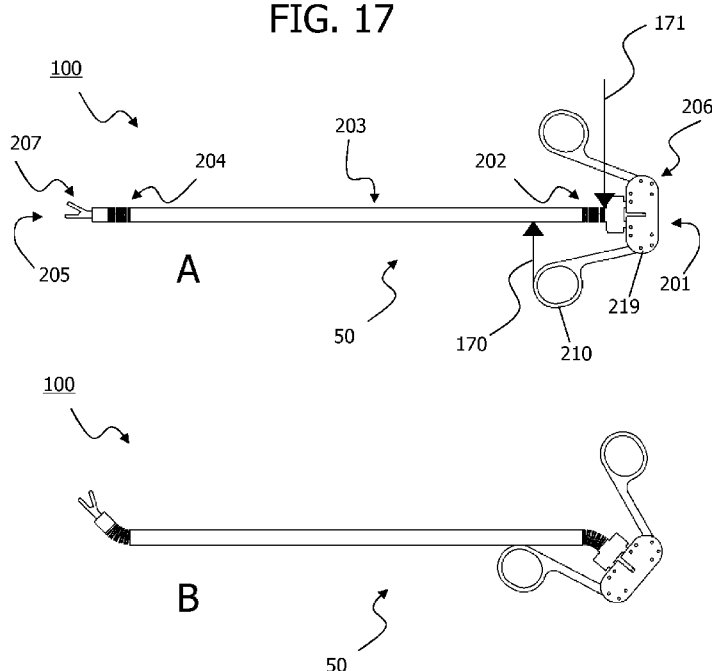
Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

[Continued on next page]

(54) Title: CROSSTALK REDUCING HANDLE FOR SURGICAL ARTICULATED INSTRUMENTS

FIG. 17



(57) Abstract: The present invention relates to a bodily invasive steerable device (100) having a proximal (201) and distal (205) end comprising a steering mechanism (50) having a proximal bending part (202), a distal bending part (204), and an intermediate part (203) disposed between the proximal bending part (202) and the distal bending part (204) configured mechanically to transmit forces applied at the proximal end (201) to the distal end (205). The steering mechanism is configured such that the distal bending part (204) moves responsive to movements of the proximal bending part (202). The device also comprises a handle (206) coupled to the proximal bending part (202) to effect manual bending. The handle (206) comprises at least one grip member (210) that extends distally (205), at least over the proximal terminal end (171) of the proximal bending part (202).



Published:

— with international search report (Art. 21(3))

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

CROSSTALK REDUCING HANDLE FOR SURGICAL ARTICULATED INSTRUMENTS

5 FIELD OF THE INVENTION

The invention relates to a handle for articulated instruments or videoscopes having enhanced control, which can be used in high-precision or medical applications.

BACKGROUND OF THE INVENTION

- 10 Surgery is characterized by a continuous search towards minimal invasiveness. Since the 1980s open surgery is largely replaced by an endoscopic approach in which long instruments are inserted through trocars in a CO₂ extended abdomen. Laparoscopic surgery, known for its validated benefits of shorter hospitalization, less postoperative pain and earlier recovery, is more demanding for the surgeon.
- 15 Precise dissection, suturing and knot tying in minimal access surgery is an advanced skill. Especially when the suture line and the axis of the needle holder are unparallel this skill is difficult to master.
- Recent steps in the evolution towards minimal invasiveness are Single Port Surgery (SPS) and Natural Orifice Transluminal Endoscopic Surgery (NOTES). Both approaches result in a scarless
- 20 healing. In SPS the instruments are inserted through one big trocar through e.g. the umbilicus. NOTES is a surgical technique whereby abdominal operations are performed with an endoscope passed through a natural orifice e.g. mouth through an internal incision in the stomach, bladder or colon. In these procedures surgery is made more challenging by the spatial constraints and the lack of triangulation.
- 25 A disadvantage of endoscopic surgery is reduced dexterity for the surgeon. This is mainly because of the fulcrum effect and the absence of wrist like movements at the tip of the instrument. Awareness of this disadvantage increases as more complex endoscopic procedures and single port surgeries (characterized by sword fighting of the instruments) are performed.
- The fulcrum effect is explained by the long instruments that pivot at the level of the trocar inserted
- 30 in the abdomen. A movement of the handle to the left is translated in a movement to the right at the effector (e.g. a pair of scissors). It is surprising to see how fast surgeons adapt to these inversed movements.
- The lack of wrist-like movements is more difficult to overcome. A state-of-the-art solution is provided by the Da Vinci robot (Intuitive Surgical). In this master slave system all the movements
- 35 of the surgeons' hands at the console are transferred to fluent movements at the instruments' tip. This solution is quite expensive, leading to the development of cheaper hand instruments with an omni-directional articulated tip

Most of the challenge is explained by the reduced dexterity. A conventional rigid laparoscopic instrument offers only 4 degrees of freedom (rotation, up/down angulations, left/right angulations, in/out movements).

To overcome this restriction in movements, various designs for steerable instruments have been developed:

1. In its simplest form an articulated instruments consist of a prebent flexible tube sliding out of a rigid straight tube (uni-directional articulated instruments). This tip can only bend in one direction and cannot withstand an appropriate amount of lateral force. In another solution the instrument tip is operated via gear trains **FIG. 9**.

2. More advanced alternatives are instruments that allow bending movements of the tip in one plane e.g. left to right and vice versa **FIG. 8-10**. Because of the nature of the construction, a mostly stable tip is created. These bi-directional instruments need to be navigated to a point of interest by bending into one direction and then by turning the whole instrument around its own axis. This is not intuitive.

3. True wrist movements are only possible with omni-directional systems **FIG. 11-17**. The omnidirectional articulated instruments consist mainly of a proximal and distal end, a proximal and distal bending part and an intermediate part in between. Movement of the proximal end is transferred to a movement at the distal end.

Examples are described in US Patent Number: 7,410,483 **FIG. 11** and US Patent Number: 8,105,350 **FIG. 15**.

Similar to robotic surgery, omni-directional articulated instruments provide 7 degrees of freedom (axial rotation and deflection of the tip in two planes are added to the 4 DOF of conventional rigid instruments). A combination of up/down and left/right movements at the proximal side allows to reach any point at the distal effector side without the need for a rotation around its own axis.

The increased maneuverability is paid back by a serious decrease in tip stability. To solve this, hybrid solutions such as the Kymerax® system (Terumo) and Jaimy® system (EndoControl) compensate by using strong electrical motors to restore the tip stability. In US Patent Application Pub. No.: US 2011/0004157 an alternative solution to provide an appropriate tip stability is presented. The steering mechanism is based on a tubular structure with longitudinal cuts.

Omni-directional articulated instruments offer, in comparison to robotic systems the advantages of low costs and tactile feedback.

Nevertheless all these omni-directional articulated instruments are prone to crosstalk, a conflict of two different movements **FIG. 21**.

Bending the proximal zone **202**, in order to deflect the distal tip of the instrument **205**, will result in an additional unintended swinging of the whole instrument around its fulcrum point at the level of the trocar **221** in the abdomen **FIG. 21**. The distal tip **205** will move to the opposite direction.

In other words, to adjust the direction of the articulated tip **205**, the orientation of the surgeon hand needs to be changed. This is possible by a rotation of the surgeons' hand around the

surgeons' wrist **FIG. 21**. However this also results in a movement of the proximal bendable part **202** around the surgeons' wrist. The latter will result in a movement of the whole instrument around the fulcrum at the level of the trocar **221** in the abdomen.

The surgeons' hand movements are thus involved in the position of the articulated tip as well as in the direction of the whole instrument.

A prior art solution to overcome the problem of crosstalk is disclosed in US Patent Number: 8,105,350 **FIG. 15**. A "locking" feature **150** to keep the tip of the instrument at a constant angle is used. Once the surgeon has the instrument tip in the desired bent position the angle is locked. Thereafter the instrument is further used as a conventional prebent instrument. This results in a complete loss of intuitive wrist like movements.

A second prior art solution to overcome the problem of crosstalk is the use of thumb-controlled (using a small joystick) instruments **FIG. 12** instead of wrist-controlled instruments **FIG. 11**. This has recently been researched by Linde M. Okken. In Surg Endosc (2012) 26:1977–1985 she advocates that thumb control is more suitable for steerable instruments than wrist control to avoid uncontrolled movements. Mostly an additional "locking" feature is mandatory. The thumb-controlled way of steering an instrument is not intuitive.

The crosstalk is thus the result of a rotation point at the surgeons' wrist **223** laying far proximal from the rotation point at the proximal bending part **222** of the steerable instrument **FIG. 20**.

The longer the distance between the rotation point at the surgeons' wrist **223** and the rotation point at the proximal bending part **222** of the steerable instrument the more crosstalk.

In standard in-line handles the distance is around 260 mm **FIG. 20A**, for a standard pistol grip handle 200mm **FIG. 20B**.

Accordingly, an object of the present invention is to provide an improved endoscopic surgical instrument in which the distance between the rotation point at the surgeons' wrist **223** and the rotation point at the proximal bending part **222** is reduced in order to reduce crosstalk and thus leading to more intuitive movements and enhanced dexterity.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 depicts the prior art configuration of a traditional pistol-grip handle for rigid instruments according to US Patent Application Pub. No.: US 2011/0112366. The ergonomic handle enables a surgeon to use all controls on the instrument, including opening and closing of jaws, rotation and ratcheting them with one hand.

FIG. 2 depicts the prior art configuration of a traditional in-line handle for rigid instruments according to US Patent Application Pub. No.: US 2007/0179524. The handle has a "wishbone" configuration.

FIG. 3 depicts the prior art configuration of a scissor-style handle for rigid instruments according to US Patent Number: 5,234,460. The proximal end of each handle diverges away from the longitudinal axis of the instrument. The proximal ends of the handles are angled downwardly.

FIG. 4 depicts the prior art configuration of a handle for rigid instruments having a distally extending lever mechanism **41** according to US Patent Number: 5,352,223.

FIG. 5 depicts the prior art configuration of a pistol-grip handle for rigid instruments according to US Patent Number: 5,700,275. The index finger rests on a pivoting handle **51**.

5 **FIG. 6** depicts the prior art configuration of a Snowden Spencer instrument according to US Patent Number: 5,470,328. The instrument is designed to be held in a 'pencil grip' or 'Vardon golf grip' position; both of which are natural gripping relationships between the index finger and opposable thumb. The surgical instrument actually becomes an 'extension' of the surgeon's hand.

FIG. 7 depicts the prior art configuration for a rigid laparoscopic instrument with a bendable shaft according to US Patent Number: 5,395,367. A connector element (bendable coupling) **71** is provided for connecting the handle to the shaft so that the orientation of the handle with respect to the shaft can be varied prior to the performance of an operation. The bendable shaft section may take the form of a bellows type spring tube as in common use in drinking straws for children.

15 **FIG. 8** depicts the prior art configuration of a surgical instrument with a bending articulation controlled articulation pivot joint according to US Patent Number: 7,481,824. The handle portion includes a pistol grip **83** toward which a closure trigger **82** is pivotally and proximally drawn by the clinician to cause clamping or closing of the staple applying assembly **87**. A firing trigger **81** is further outboard of the closure trigger and is pivotally drawn by the clinician to cause the stapling of tissue clamped in the staple applying assembly **87**. Lateral movement of push buttons **84,85**
20 support the control of the bending articulation mechanism **86**.

FIG. 9 depicts the prior art configuration of a uni-directional articulated instrument according to US Patent Application Pub. No.: US 2009/0192521. The instrument handle has a number of manipulators and/or operating mechanisms for operating the instrument head and/or effector via gear trains. When actuating the turning knob **92** the motion of rotation thereof is transmitted to the effector **91**. The turning knob is operated by the thumb and index. The handle lever **93** actuates the jaws of the effector **91**. A forward movement of the handle results in an initial upward movement of the tip (90°) followed by a movement towards the shaft and eventually parallel to the shaft (90°).

FIG. 10 depicts the prior art configuration of a handle for a bi-directional articulated instruments according to US Patent Number: 5,766,196. When it is desired to change the position of the bendable section **102** from straight to bent or vice versa, the lever **101** is moved 90 degrees which rotates the rotor to move the control wires.

FIG. 11 depicts the prior art configuration of a traditional in-line handle for omni-directional articulated instruments according to US Patent Number: 7,410,483.

35 **FIG. 12** depicts the prior art configuration of an omni-directional articulated instrument in which the proximal link set **120** is separately manipulated in order to steer distal end tool **122**, similar to a joystick, according to US Patent Number: 7,410,483. Proximal link set **120** is operably

connected to distal link set **121**. The link cables are routed such that link set **120** emerges from the handle itself with the distal-most link of the link set being secured to handle.

FIG. 13 depicts the prior art configuration of a device that not only provides a hand user interface, but an actuation mechanism that allow for close simulation of human hand movements to enhance remote maneuverability, according to US Patent Number: 7,410,483. A plurality of articulating mechanism may also be combined in such a way that a user's finger movement can be remotely mimicked to manipulate an object or body tissue

FIG. 14 depicts the prior art configuration of a traditional in-line handle for an articulated instruments steerable in 4 discrete directions according to US Patent Number: 7,090,689.

FIG. 15 depicts the prior art configuration of a traditional in-line handle for omni-directional articulated instruments according to US Patent Number: 8,105,350. The handle is disposed with a "locking feature" **150**.

FIG. 16 depicts the prior art configuration of a traditional pistol-grip handle for omni-directional articulated instruments according to US Patent Number: 7,833,156. The configuration allows for intra-abdominal triangulation through a single incision.

FIG. 17 depicts the present invention configuration in native (straight, unbent) **A** and bent **B** position. The long arrows **170**, **171** indicate the distal most end **170** of the distally extending grip member **210** (in relation to its pivoting point) and the proximal terminal end **171** of the proximal bending part **202**.

FIG. 18 shows a schematic view of the present invention configuration. Proximal end **201**, proximal bending part **202**, intermediate part **203**, central longitudinal axis **250** of the intermediate part **203**, distal bending part **204**, distal end **205**, distal end piece **207** that may be an end effector or visualization means, handle **206**, grip member **210** and base element **219**.

FIG. 19 depicts in detail the inside mechanism of the handle transferring the rotational movement of the grip members **210** to a linear motion of the actuating rod **220**.

FIG. 20 shows a schematic overview of the distance between the rotation point at the surgeons' wrist **223** and the rotation point at the proximal bending part **222** of the steerable instrument in a prior art configuration **A and B** and in the present invention configuration **C and D**.

FIG. 21 illustrates the result of crosstalk due to a long distance between the rotation point at the surgeon's wrist and the rotation point at the proximal bending part of the steerable instrument in the prior art configuration of an in-line handle. Bending the proximal part, in order to deflect the tip of the instrument to the left, will result in an additional unintended movement of the whole instrument around its fulcrum point **221** to the right **FIG. 21 B**.

FIG. 22 illustrates the result of crosstalk due to a long distance between the rotation point at the surgeons' wrist and the rotation point at the proximal bending part of the steerable instrument in the prior art configuration of a pistol-grip like handle. Bending the proximal part, in order to deflect the tip of the instrument downwards, will result in an additional unintended movement of the whole instrument around its fulcrum point upwards **FIG. 22 B**.

FIG. 23 illustrates reduced crosstalk thanks to a short distance (60 mm) between the rotation point at the surgeons' wrist and the rotation point at the proximal bending part of the steerable instrument in the present invention configuration.

FIG. 24 illustrates reduced crosstalk thanks to a short distance (30 mm) between the rotation point at the surgeons' wrist and the rotation point at the proximal bending part of the steerable instrument in the present invention configuration.

FIG. 25 illustrates an embodiment with reduced crosstalk. Steering of the distal tip is based on wrist and finger movements allowing very precise surgical procedures.

FIG. 26 depicts the present invention configuration in native straight **A** and bent **B** position. The long arrows indicate the distal most end of the distally extending grip member and the proximal most end of the proximal bending part.

FIGs. 27A to G depict the distal bending part bent in a plurality of different directions relative to a radial axis.

SUMMARY OF THE INVENTION

One embodiment of the invention is bodily-invasive steerable device (100), in particular, an endoscopic device (100) having a proximal (201) and distal (205) end comprising a:

-steering mechanism (50) having a proximal bending part (202), a distal bending part (204), and an intermediate part (203) disposed between the proximal bending part (202) and the distal bending part (204) configured mechanically to transmit forces applied at the proximal end (201) to the distal end (205). The steering mechanism configured such that the distal bending part (204) moves responsive to movements of the proximal bending part (202),

-a handle (206) coupled to the proximal bending part (202) to effect manual bending; wherein the handle (206) comprises at least one grip member (210) that extends distally (205), at least over the proximal terminal end (171) of the proximal bending part (202).

The distal bending part (204) may be configured for movement in at least two different intersecting planes. The proximal bending part (202) may be configured for movement in at least two different intersecting planes. The handle (206) may comprise two grip members (210), one configured to engage a thumb of a hand, the other configured to engage a finger of the same hand, said grip members arranged to maintain an open palm of the hand. There may be two grip members each disposed with ring or annular segment configured to engage a digit, wherein one or both grip members (210) are levers, and the position of the one or both levers is not biased.

Another embodiment of the invention is an endoscopic device(100) as described above wherein the steering mechanism (50) is configured for omni-directional movement of the distal end.

Another embodiment of the invention is an endoscopic device(100) as described above wherein the terminal distal end (170) of at least one grip member (210) in a native straight configuration is at a distance of at least 20 mm from said steering mechanism (50) to prevent collisions with said steering mechanism (50).

Another embodiment of the invention is an endoscopic device(100) as described above wherein the inclination of a plane defined by a grip member (210) relative to the longitudinal axis of the intermediate part (203) of said steering mechanism is between 0° and 75°.

Another embodiment of the invention is an endoscopic device (100) as described above wherein the inclination of a plane defined by a grip member (210) relative to a longitudinal axis of the intermediate part (203) of said steering mechanism is adjustable.

Another embodiment of the invention is an endoscopic device (100) as described above wherein the handle (206) is dismountably fixed to the proximal bending part (202) of said steering mechanism (50).

Another embodiment of the invention is an endoscopic device (100) as described above wherein the handle (206) is rigidly fixed to the proximal bending part (202) of said steering mechanism (50).

Another embodiment of the invention is an endoscopic device (100) as described above wherein the handle (206) is flexibly mounted to the intermediate part (203) of said steering mechanism (50).

Another embodiment of the invention is an endoscopic device (100) as described above wherein the handle (206) comprises a base element (219) for attachment to the proximal bending part (202), and of at least one grip member (210).

Another embodiment of the invention is an endoscopic device (100) as described above wherein the base plate is fixed to proximal bending part of said steering mechanism according an angle between 0° and 85°.

The handle (206) may be lockably rotatable relative to the proximal bending part (202). The device (100) may be further provided with an end effector at the distal end of the distal bending part (204) wherein the steering mechanism (50) is configured such that the end effector is rotationally fixed in relation to the distal bending part (204), and the end effector is rotatable when the distal bending part (204) is in a bent position, by a complementary rotation of the proximal bending part (202). The device (100) may be comprised in an endoscope, videoscope or vascular catheter.

DETAILED DESCRIPTION OF THE INVENTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by one of skill in the art. All publications referenced herein are incorporated by reference thereto. All United States patents and patent applications referenced herein are incorporated by reference herein in their entirety including the drawings.

The terms "distal" and "proximal" are used through the specification, and are terms generally understood in the field to mean towards (proximal) or away (distal) from the surgeon's side of the apparatus. Thus, "proximal" means towards the surgeon's side and, therefore, away from the

patient's side. Conversely, "distal" means towards the patient's side and, therefore, away from the surgeon's side.

Reference is made in the description below to the drawings which exemplify particular
5 embodiments of the invention; they are not at all intended to be limiting. It will be understood that the skilled person may adapt the device and substitute components and features according to the common practices of the skilled artisan.

In addition to use in a laparoscopic procedure, the instrument of the present invention may be
10 used in a variety of other diagnostic or therapeutic procedures including, but not limited to neurosurgery, ophthalmic surgery, ENT surgery, thoracic and cardiac surgery, arthroscopy etc.

The present invention relates to a steerable device. The steerable device is preferably a bodily
invasive medical device. The steerable device may be incorporated into or substantially function
as an endoscope, a videoscope, a catheter, in particular an endovascular catheter.

15 With reference to **FIG. 18**, the steerable device **100** of the invention has a proximal end **201** and a distal **205** end. The steerable device comprises a steering mechanism **50** having a proximal bending part **202**, a distal bending part **204**, and an intermediate part **203** disposed between the proximal bending part **202** and the distal bending part **204**. The proximal bendable part **202** has a
20 proximal **201** end and a distal **205** end, the distal **205** end being adjacent to the intermediate part **203**, and the proximal **201** end being adjacent to the handle **206**. The distal bendable part **204** similarly has a proximal **201** end and a distal **205** end, the proximal **201** end being adjacent to the intermediate part **203**. The distal **205** end of the distal bendable part **204** may be adjacent to a distal end piece **207**. The steering mechanism **50** preferably has a circular transverse profile.

25 The proximal bending part **202** is moved by the user (e.g. the surgeon). The intermediate part **203** is configured mechanically to transmit forces applied at the proximal end **201** to the distal end **205**. The steering mechanism **50** is configured such that the distal bending part **204** moves responsive to movements of the proximal bending part **202**. Movements of the proximal bending
30 part **202** and the distal bending part **204** are relative to the intermediate part **203**. The steerable device further comprises a handle **206** coupled to the proximal bending part **202** to effect manual bending. The handle **206** comprises a grip member **210** that extends distally **205**, at least over the proximal terminal end of the proximal bending part **202**. The steering mechanism may be configured such that a rotation of the intermediate part **203**, (e.g. by rotation of the handle **206**)
35 causes a rotation of the distal bendable part **204** around a central axis of the intermediate part **203**, even when the distal bendable part **204** is bent.

The inventors have found that the configuration provided by the invention reduces the problem of crosstalk in manually actuated steerable devices, in particular of endoscopes. The reason for this crosstalk is the non-coinciding of the rotation point of the proximal bending part **222** and the rotation point of the operator's wrist **223** **FIG. 20**. In most wrist-controlled, omni-directional articulated instruments using pistol-like, wishbone-like or scissor-like handles, the distance between the two rotation points is relatively large, for instance, more than 200 mm.

When a surgeon, trying to deflect the instrument's tip, rotates his/her hand around their wrist, the proximal bendable part will also rotate around this wrist with a radius of about 260 mm **FIG. 21A**. Since the axis of the shaft is determined by the fulcrum point **221** at the level of the trocar in the abdomen and the proximal bendable zone, the whole instrument changes its orientation.

In the present invention this distance can be reduced. Using the configuration in **FIG. 20C**, for instance, the distance can be reduced to around 60 mm, resulting in a significant reduction **FIG. 23** of crosstalk effect exhibited in the prior art **FIG. 21 and 22**. In an alternative embodiment the distance may be reduced to even less than 30 mm **FIG. 20D** resulting in a further reduction still. The effect can be attributable to the handle of which the grip member **210** extends distally over the proximal bending part **202**, more preferably, extends distally over the proximal terminal end of the proximal bending part **202**.

To prevent collisions between the grip member **210** and the proximal bending part **202** or intermediate part **203** of the steering mechanism, the grip member **210** may divert away from the central longitudinal axis of the steering mechanism.

Using the invention, the grip member **210** of the handle is brought to a position distal to the proximal bendable zone. The goal is to bring the rotation point of the proximal bending part **222** and the rotation point of the surgeon's wrist **223** as close together as possible.

An interesting observation is that a very small amount of crosstalk might be advantageous. As can be appreciated from **FIG. 23A to C** the swinging of the whole instrument around the fulcrum over a small angulation has the benefit that the jaws of the distal actuating tip circulate around the same operative spot. It is a compensation for the length of the distal tip. This becomes more clear when comparing with **FIG. 24A to C** an embodiment in which crosstalk is virtually absent. Here it can be appreciated that the jaws of the distal actuating tip overshoots the operative spot.

As mentioned earlier, the handle **206** coupled to the proximal bending part **202**, comprises a grip member **210** that extends in a distal direction over at least over the proximal terminal end of the proximal bending part **202**. In particular, the extension in the distal direction is considered when the proximal bending part **202** is in a neutral (unbent) configuration.

There may be one grip member, or more than one grip member (e.g. 2, 3, 4 or more). When there are two grip members, they may be arranged diametrically around a central longitudinal axis of the proximal bending part **202**.

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A grip member **210** may comprise a member, that is preferably longitudinal, having a proximal and distal end, the proximal end being attached to the proximal bending part. The distal end may comprise a hook, or ring (open or closed, circular or non-circular (e.g. oval)), or annular segment for a thumb or finger, particularly at the terminal end.

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In a preferred configuration, there are two grip members, one for engagement with a thumb, and one for engagement with a finger of the same hand. Preferably, the two grip members **210** are configured such that the handle **206** is gripped with the palm open *i.e.* the handle **206** is gripped by the fingers, and not through clenching with the palm. In such configuration, the grip members **210** may be positioned either side of the proximal bending part **202**, as shown, for instance, in **FIG. 18**. The separation between the two grip members **210** forces the hand into an open position. The palm may be placed over the proximal bending part **204**. Examples of the grip members placed to maintain the open palm configuration is shown in **FIGs. 20C, 20D, 25 A to C**. One or both grip members may be levered, for instance, to control a jaw at the distal end.

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By using an open palm configuration, not only is the position of the handle **206** controlled by the wrist alone allowing more intuitive control (see **FIGs. 23A to C, 24A to C, 25A to C**), but the grip allows the user simultaneously to move the proximal bending part **202** omnidirectionally and operate any levered grip members. When a closed palm is used to grip the handle, by contrast, omnidirectional control of proximal bending part **202** must temporarily be relinquished when a lever is released since grip on the handle must be released at the same time.

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The handle may further comprise a base element **219** to which the grip member **210** is attached, which base element **219** contains a coupling for attachment to the proximal bending part **202**.

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The grip member may be rigidly attached to the base element **219**. Alternatively, the grip member **210** may be pivoted with respect to the base element **219**, to act as a lever actuator for a tool such as a grip tool, disposed at the distal end of the device.

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From **FIG. 17** and **FIG. 18** it can be appreciated that a diverging of the grip member **210** away from the central longitudinal axis of the intermediate part **203** is advantageous. When bending the proximal part **202** in order to steer the distal tip **205**, a collision between the grip member **210** and the intermediate part **203** of the steering mechanism is avoided. It is envisaged that other collision avoiding configurations are possible.

A far lateral positioning of pivot point **215**, when the grip member **210** is pivoted, even with converging levers will have the same positive result. In another embodiment (**FIG. 24**) conflict avoidance between the grip member **210** and intermediate part **203** is achieved by an inclination of the plane defined by grip member **210** relative to the longitudinal axis of the intermediate part of the steering mechanism in a straight position of the distal effector. It can be appreciated from **FIG. 24 B** that a downward movement of the handle until 45 degrees is possible without conflict. Upward movement and left-right movements are completely free of interaction with the intermediate part.

The handle **206** may be coupled to the proximal bending part **202** of the steering mechanism by a threaded annular fixation plate **216** (**FIG. 19**) in the base of the handle. The annular fixation plate **216** is connected to the base plate **211**. The cover plate has been omitted in order to have a better understanding of the inside. The proximal end of the push/pull rod **220** is coupled to the grip members **210**, which act as levers, by an intermediate linear sliding plate **212**. In **FIG. 19** this rod is removed from the handle and shifted to the left. The intermediate plate **212** is slidably mounted. It is maintained by bearing plates **213** and **214**. When a surgeon grasps the handles in order to close the jaws of the end effector a rotation of the grip member **210** around pivot point **215** induces a linear proximal ward motion in the intermediate sliding plate **212**. It is commonly understood by one of skill in the art that other mechanisms to translate a pivotal movement of levers to an actuation at the distal tip are known e.g. ball coupling.

Some embodiments may contain only one pivoting grip member (*i.e.* that acts as a lever) and one static grip member. Embodiments that do not require actuation at the tip e.g. a videoscope can be constructed with only one or two grips extending distally from the proximal portion of the proximal bending part **171**.

In one embodiment, there are two grip members, wherein one or both are levers that are biased in an open configuration, using a compliant member. In another embodiment, there are two grip members, wherein one or both grip members are levers and the position of one or both levers is not biased. When one or both grip members are levers and the position of one or both levers is not biased, the surgeon can readily apply force in both the closing and opening actions of the levers. This is particularly suitable when the distal end of the grip member comprise a hook, or ring (open or closed, circular or non-circular (e.g. oval)), or annular segment for a thumb or finger. An electrical, electronic or mechanical switch may be disposed on the handle to control another device. For instance, an electrical push button may control a laser or electrocautery.

The fixation plate may be disposed with a ferrule or rotating ring that allows the push/pull rod and steering mechanism to rotate around its own axis relative to the handle. In this way the jaws of the distal actuator can be rotated.

Optionally, the handle may be provided with a locking mechanism to fix the proximal bending part in a desired position.

- 5 Optionally, the handle may be provided with a ratcheting or self-locking clutch mechanism to fix or prevent opening of a jaw tool at the distal end. A quick-release system may be provided to release the jaws.

10 In another embodiment, the grip member **210** may be a shortened, to allow steering with the tips of the fingers or thumb, as shown for instance in **FIGs. 25A to C**. This allows for finger dexterity. The movements of the proximal part are a result of wrist movements and finger movements. This is especially of interest in very precise procedures such as suturing of micro anastomosis of blood vessels in cardiac surgery.

- 15 In another embodiment, the base element **219** comprises one half of a ball and socket joint, to which the grip member **210** is attached and which couples to the proximal bending part **202**. The other half **203'** of the ball and socket joint is attached to the proximal end of the intermediate part **203**. An example of this configuration is shown in **FIGs. 26A and B**.

- 20 The steerable device may be formed mostly from stainless steel, titanium or injection molded plastic, or a mixture of one or more these. The handle is preferably formed from stainless steel, titanium or injection molded plastic, or a mixture of one or more these.

- 25 The handle **206** may be rotatable, preferably lockably rotatable, relative to the proximal bending part **202**. The handle **206** may be revolute connection, preferably lockable revolute connection, with the proximal bending part **202**. The handle **206** may be rotatable relative to or in revolute connection with the proximal bending part **202** around one axis. This allows the operator to reset the position of an end effector (e.g. a jaw) relative to the handle **206**.

- 30 The handle may further be provided with a disengagable locking mechanism, configured to lock the revolute position of the handle **206** relative to the proximal bending part **202**.. The disengagable locking mechanism may be activated by a button on the handle **206**. The disengagable locking mechanism may comprise a lockable collar.

- 35 The steering mechanism **50** of the invention is preferably an omnidirectional articulated instrument which is known in the art. It has a proximal **201** and distal end **205**, a proximal **202** and distal **204** bending part and an intermediate part **203** in between (**FIG. 18**). Movement of the proximal end **201** is transferred to a movement at the distal end **205**. The resulting directional

movement of the distal end can be inverted, mirrored or otherwise depending on the degree of rotation. In **FIG. 18** the instrument is shown with a break between proximal end and the distal end.

- 5 Omni-directional steering mechanism **50** may bend in any direction (about 360°). Omni-directional steering mechanism **50** may bend in at least 2, 3, 4, 5, 6, 7, 8, 9, 19, 11 or 12 different directions.

10 Omni-directional steering mechanism **50** may be configured to bend the distal bending part **204**, relative to the intermediate part **203**, in any radial direction (e.g. at least 2, 3, 4 5, 6, 7, 8, 9, 10, 11, or 12 or more different radial directions). The radial direction may be with respect to a radial axis **258** (**FIG. 27**). The radial axis **258** may be co-axial with the central longitudinal axis **250** of the intermediate part **203**. The radial axis **258** may be co-axial with a central longitudinal axis **250** of the distal end **205** of the intermediate part **203**. The radial axis **258** may be co-axial with a
15 central longitudinal axis of the distal bending part **204** when adopting a linear form. The radial axis **258** may be co-axial with a central longitudinal axis **256** of the proximal end **201** of the distal bending part **204**.

Examples of different radial directions are depicted in **FIG. 25 A to G**. In **FIG. 25A**, the distal
20 bending part **204**, is unbent, and the projection **254** viewed along the radial axis **258** in the direction of the arrow **252** shows no radial movement of the distal bending part **204**. In **FIG. 25B**, the distal bending part **204** is bent downwards relative to the intermediate part **203**, and the projection **254** viewed along the radial axis **258** in the direction of the arrow **252** shows a radial movement of the distal bending part **204** in the "6h00" direction. In **FIG. 25C**, the distal bending
25 part **204** is bent upwards relative to the intermediate part **203**, and the projection **254** viewed along the radial axis **258** in the direction of the arrow **252** shows a radial movement of the distal bending part **204** in the "12h00" direction. **FIGs. 25D, E and F** each depict radial movement of the distal bending part **204** in the "3h00", "10h30" and "7h30" directions respectively. **FIG. 25G**, shows a superimposition of 8 different directions.

30

The distal bending part **204** may be configured for movement in at least two different intersecting planes. The different planes preferably intersect each other along a common straight line (known as a plane axis herein). The plane axis may be co-axial with a central longitudinal axis **250** of the intermediate part **203**. The plane axis may be co-axial with a central longitudinal axis of the distal
35 end of the intermediate part **203**. The plane axis may be co-axial with a central longitudinal axis of the distal bending part **204** when adopting a linear form. The plane axis may be co-axial with a central longitudinal axis **256** of the proximal end of the distal bending part **204**. The distal bending part **204** may be configured for movement in at least two different planes disposed parallel to and

contacting a central longitudinal axis **250** of the intermediate part **203**. Two planes are preferably perpendicular to each other.

The distal bending part **204** may be configured for movement in at least 2, 3, 4, 5, 6, 7, 8, 9 or 10 different planes. Said planes are preferably arranged in a star configuration. Preferably, the distal bending part **204** is configured for movement in an infinite number of different planes. The movement is relative to a central longitudinal axis **250** the intermediate part **203**.

The distal bending part **204** may be configured for movement, relative to the intermediate part **203**, around x- and y-axes, which axes are perpendicular to each other and also perpendicular with respect to the central longitudinal axis (z-axis) of the intermediate part **203**.

The distal bending part **204** may be configured for pitch and yaw movement, relative to the intermediate part **203**, whereby rotations of the intermediate part **203** represent roll.

The distal bending part **204** may be configured for movement having 2 rotational degrees of freedom that are perpendicular with respect to each other, and perpendicular with respect to the central longitudinal axis of the intermediate part **203**.

Furthermore it may be possible to rotate the distal tip of the instrument about its own axis even in a bent status.

With respect to the proximal bending part, the omni-directional steering mechanism **50** may be configured such that the proximal bending part **202**, is bendable relative to the intermediate part **203**, in any radial direction (e.g. at least 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, or 12 or more different radial directions). The radial direction may be with respect to a radial axis. The radial axis may be co-axial with the central longitudinal axis **250** of the intermediate part **203**. The radial axis may be co-axial with a central longitudinal axis **250** of the proximal end **205** of the intermediate part **203**. The radial axis may be co-axial with a central longitudinal axis of the proximal bending part **202** when adopting a linear form. The radial axis may be co-axial with a central longitudinal axis **256** of the distal end **205** of the proximal bending part **202**. The examples of different radial directions of the distal bending part **204** in FIGs. **25 A** to **G** are applicable to proximal bending part **202**.

The proximal bending part **202** may be configured for movement in at least two different intersecting planes. The different planes preferably intersect each other along a common straight line (known as a plane axis herein). The plane axis may be co-axial with a central longitudinal axis **250** of the intermediate part **203**. The plane axis may be co-axial with a central longitudinal axis of the distal end of the intermediate part **203**. The plane axis may be co-axial with a central longitudinal axis of the proximal bending part **202** when adopting a linear form. The plane axis

may be co-axial with a central longitudinal axis **256** of the distal end of the proximal bending part **202**. The proximal bending part **202** may be configured for movement in at least two different planes disposed parallel to and contacting a central longitudinal axis **250** of the intermediate part **203**. Two planes are preferably perpendicular to each other.

5

The proximal bending part **202** may be configured for movement in at least 2, 3, 4, 5, 6, 7, 8, 9 or 10 different planes. Said planes are preferably arranged in a star configuration. Preferably, the proximal bending part **202** is configured for movement in an infinite number of different planes. The movement is relative to a central longitudinal axis **250** of the intermediate part **203**.

10

The proximal bending part **202** may be configured for movement, relative to the intermediate part **203**, around x- and y-axes, which axes are perpendicular to each other and also perpendicular with respect to the central longitudinal axis (z-axis) of the intermediate part **203**.

15 The proximal bending part **202** may be configured for pitch and yaw movement, relative to the intermediate part **203**, whereby rotations of the intermediate part **203** represent roll.

The proximal bending part **202** may be configured for movement having 2 rotational degrees of freedom that are perpendicular with respect to each other, and perpendicular with respect to the
20 central longitudinal axis of the intermediate part **203**.

A proximal bendable part **202** has the same meaning as is commonly understood by one of skill in the art. For avoidance of doubt, proximal bendable parts based on flexing of wires or strips, gear mechanisms, ball and socket joints, incompressible drive rods, lever mechanisms, tubular
25 member with longitudinal cuts, hydraulically or electrically actuated articulation joints, pivotal joints...etc are covered by the term proximal bendable part. The same applies mutatis mutandis to a distal bendable part **204**.

The device **100** described herein is primarily for laparoscopic or endoscopic procedures.
30 However, it is to be understood that the instrument of the present invention can be used for a wide variety of other procedures, including endovascular procedures, fine mechanical processes etc.

The diameter of the intermediate part **203** may range from about 0.3 mm to about 20 mm or more
35 depending on the application. For endoscopic applications, diameters may range from about 1 mm to about 4 mm for small endoscopic instruments, and about 5 to 20 mm for large endoscopic instruments. For endovascular catheter application, the diameter may range from about 0.3 mm to about 9 mm.

The amplitude of bending motion at the distal bendable part **204** is related in part to the dimensions of the proximal bendable part. Mostly the diameter at the proximal bendable part **202** is larger than the diameter at the distal bendable part **204**. The increase in diameter may be linear from proximal to distal or concentrated over a short conical part located at the proximal side of the instrument.

Overall length of the steering mechanism **50** may vary from 6 cm for small endoscopic applications to 200 cm and more for endovascular catheter applications

The intermediate part **203** in endoscopic surgery may be mostly rigid. However in some situations semi-rigid or flexible configurations may be advantageous. For example, in Single Port Surgery a flexible articulated instruments could be introduced in a prebent guiding tube. This will compensate for the lack of triangulation.

The intermediate part **203** may be straight or (pre)bent.

An end effector or visualization means may be coupled to the distal **205** end of the steering mechanism *i.e.* to the distal terminal end of the distal bending part **204**. Such end effector or visualization is depicted in the figures as a distal end piece **207**. End effectors comprise of, but are not limited to, scissors, graspers, clamps, dissectors, ultrasound visualization devices, energy device using ultrasound, drills, electrocautery tips, staplers, lasers, cameras, stapler clip appliers, needle drivers, suction/irrigation channels etc.

The end effector may be rotatable. Preferably, it is rotatable relative to the distal bending part **204**. The device may further comprise a rotary actuator at the proximal end **201** of the device and the rotatable end effector at the distal end **205** of the device **100**, wherein the steering mechanism **50** is further configured to rotate the end effector responsive to the application of torque to the rotary actuator. The intermediate part **203** may be configured to mechanically transmit the torque applied to the rotary actuator to the rotatable end effector. The rotary actuator may be a turning knob disposed on the handle **206**. The rotary actuator may be the handle configured to rotate relative to the proximal bending part **202**. Using this arrangement, the end effector may be rotated about its own axis when the distal bending part **204** is bent. The rotatable end effector may be implemented using known means, for instance, using a cylindrical transmission cable. Such elements are described also in US 2009/0192521 for instance. The handle may further be provided with a disengagable locking mechanism, configured to fix the revolute position of the rotary actuator and/or the revolute position of the rotatable end effector. The disengagable locking mechanism may be activated by a button on the handle **206**.

The steering mechanism may be configured such that the end effector is rotationally fixed in relation to the distal bending part **204**, and the end effector is rotatable when the distal bending part **204** is in a bent position, by a complementary rotation of the proximal bending part **202**. Such a mechanism does not require a separate rotary actuator described above. In another embodiment (videoscope) the distal end is provided by a visualization means such as a chip on tip camera (2D or 3D) or optical fibers. The handle with fixed grips according the present invention allows intuitive maneuvering of the camera to allow visual inspection of the operative field. Especially in Single Port Surgery it adds to the avoid clashing with the endoscopic instruments.

10

*

CLAIMS

1. A bodily-invasive steerable device (100) having a proximal (201) and distal (205) end
5 comprising:
- i) a steering mechanism (50) having
 - a proximal bending part (202),
 - a distal bending part (204), and
 - an intermediate part (203) disposed between the proximal bending part (202)
10 and the distal bending part (204) configured mechanically to transmit forces applied at the proximal end (201) to the distal end (205),the steering mechanism configured such that the distal bending part (204) moves responsive to movements of the proximal bending part (202),
 - ii) a handle (206) coupled to the proximal bending part (202) to effect manual bending;
15 wherein
 - the handle (206) comprises at least one grip member (210) that extends distally (205), at least over the proximal terminal end (171) of the proximal bending part (202), and
 - the distal bending part (204) is configured for movement in at least two different intersecting planes.
- 20
2. The device (100) according to claim 1 wherein proximal bending part (202) is configured for movement in at least two different intersecting planes.
3. The device (100) according to claim 1 or 2, wherein the handle (206) comprises two grip
25 members (210), one configured to engage a thumb of a hand, the other configured to engage a finger of the same hand, said grip members arranged to maintain an open palm of the hand.
4. The device (100) according to any of claims 1 to 3, wherein there are two grip members each disposed with ring or annular segment to engage a digit, wherein one or both grip members
30 (210) are levers, and the position of the one or both levers is not biased.
5. The device (100) according to any of claims 1 to 4 wherein the terminal distal end (170) of at least one grip member (210) in a native straight configuration is at a distance of at least 20 mm from said steering mechanism (50) to prevent collisions with said steering mechanism
35 (50).

6. The device (100) according to any of claims 1 to 5, wherein the inclination of a plane defined by a grip member (210) relative to the longitudinal axis of the intermediate part (203) of said steering mechanism is between 0° and 75°.
- 5 7. The device (100) according to any of claims 1 to 6, wherein the inclination of a plane defined by a grip member (210) relative to a longitudinal axis of the intermediate part (203) of said steering mechanism is adjustable.
8. The device (100) according to any of claims 1 to 7, wherein the handle (206) is dismountably
10 fixed to the proximal bending part (202) of said steering mechanism (50).
9. The device (100) according any of claims 1 to 7, wherein the handle (206) is rigidly fixed to the proximal bending part (202) of said steering mechanism (50).
- 15 10. The device (100) according to any of claims 1 to 9, wherein the handle (206) is flexibly mounted to the intermediate part (203) of said steering mechanism (50).
11. The device (100) according to any of claims 1 to 10, wherein the handle (206) comprises a base element (219) for attachment to the proximal bending part (202), and of at least one grip
20 member (210).
12. The device (100) according to any of claims 1 to 11, wherein the base plate is fixed to proximal bending part of said steering mechanism according an angle between 0° and 85°.
- 25 13. The device (100) according to any of claims 1 to 12, wherein the handle (206) is lockably rotatable relative to the proximal bending part (202).
14. The device (100) according to any of claims 1 to 13, further provided with an end effector at the distal end of the distal bending part (204) wherein the steering mechanism (50) is
30 configured such that the end effector is rotationally fixed in relation to the distal bending part (204), and the end effector is rotatable when the distal bending part (204) is in a bent position, by a complementary rotation of the proximal bending part (202).
15. The device (100) according to any of claims 1 to 14, comprised in an endoscope, videoscope
35 or vascular catheter.

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PRIOR ART

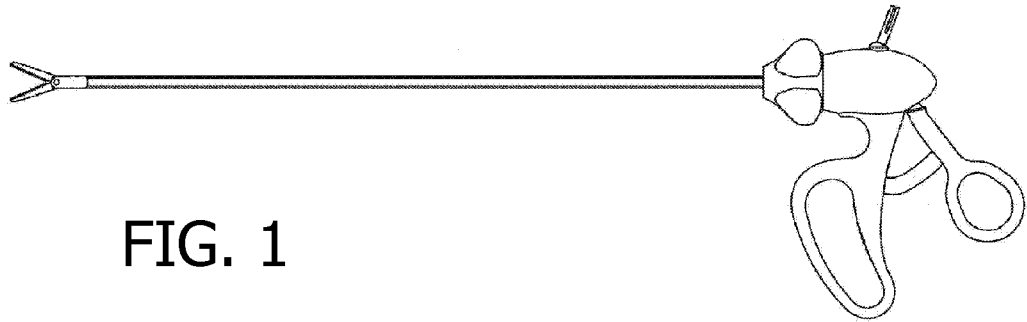


FIG. 1

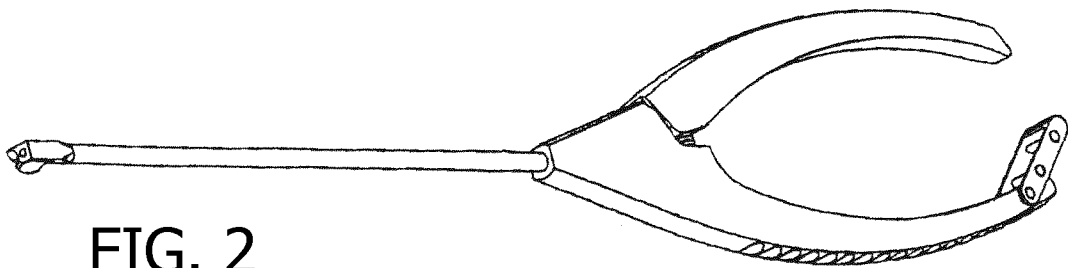


FIG. 2

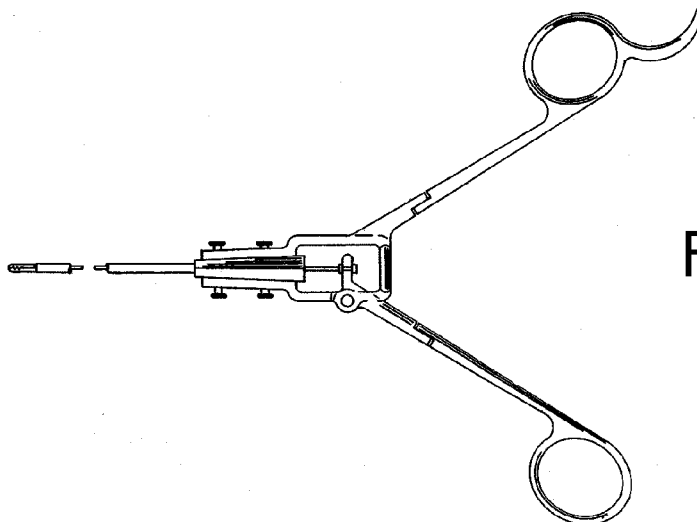
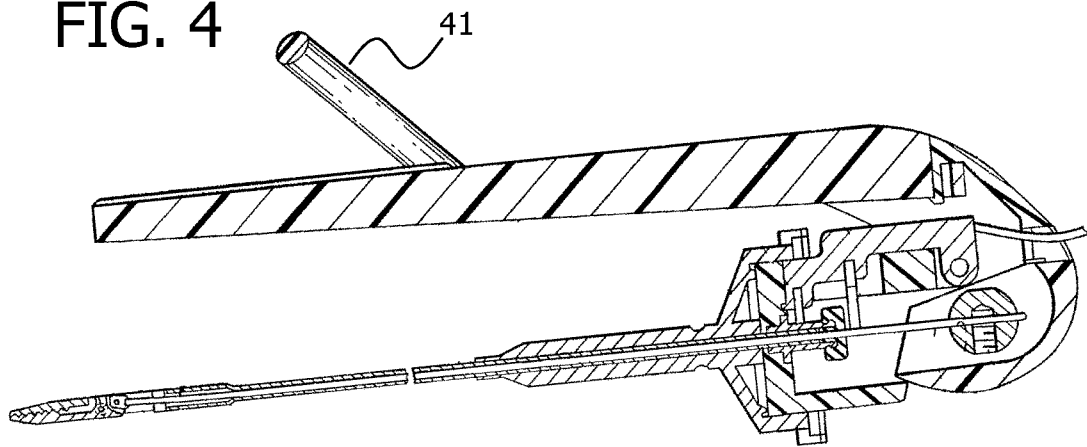


FIG. 3

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PRIOR ART

FIG. 4



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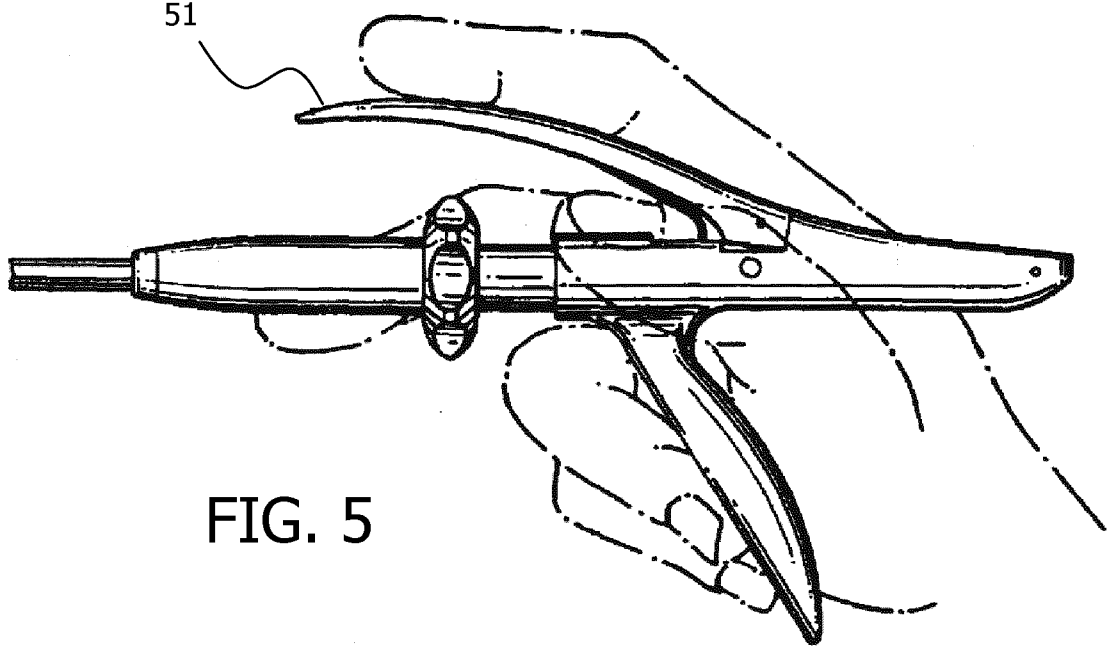


FIG. 5

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PRIOR ART

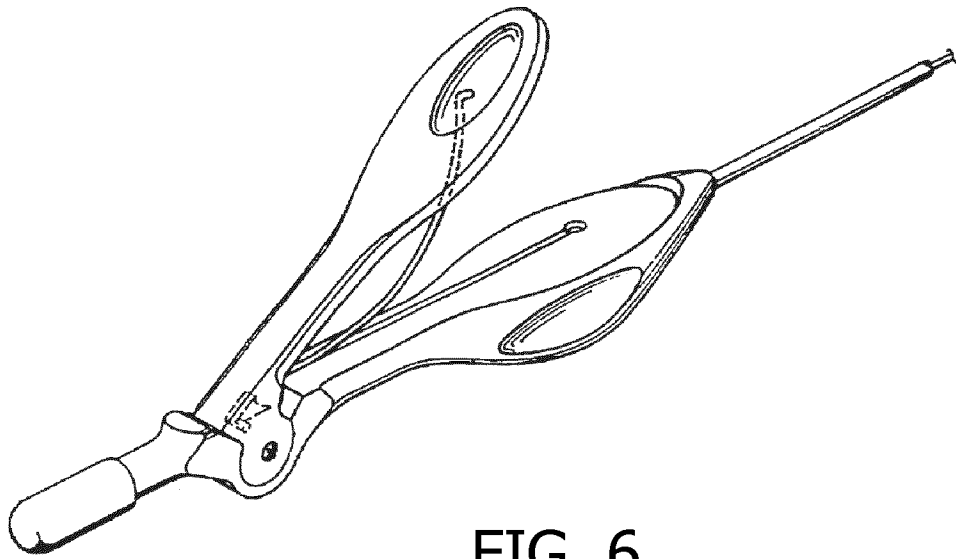


FIG. 6

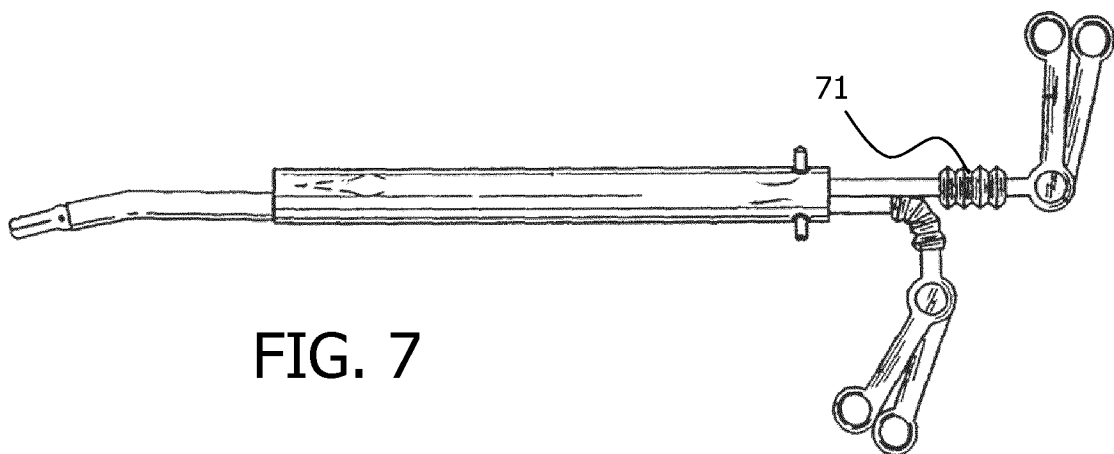
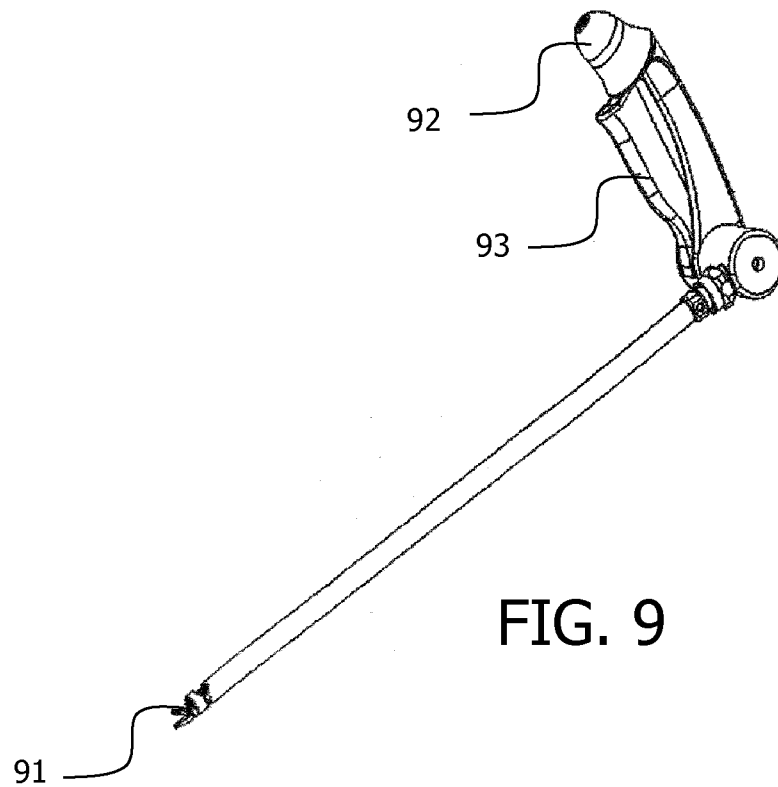
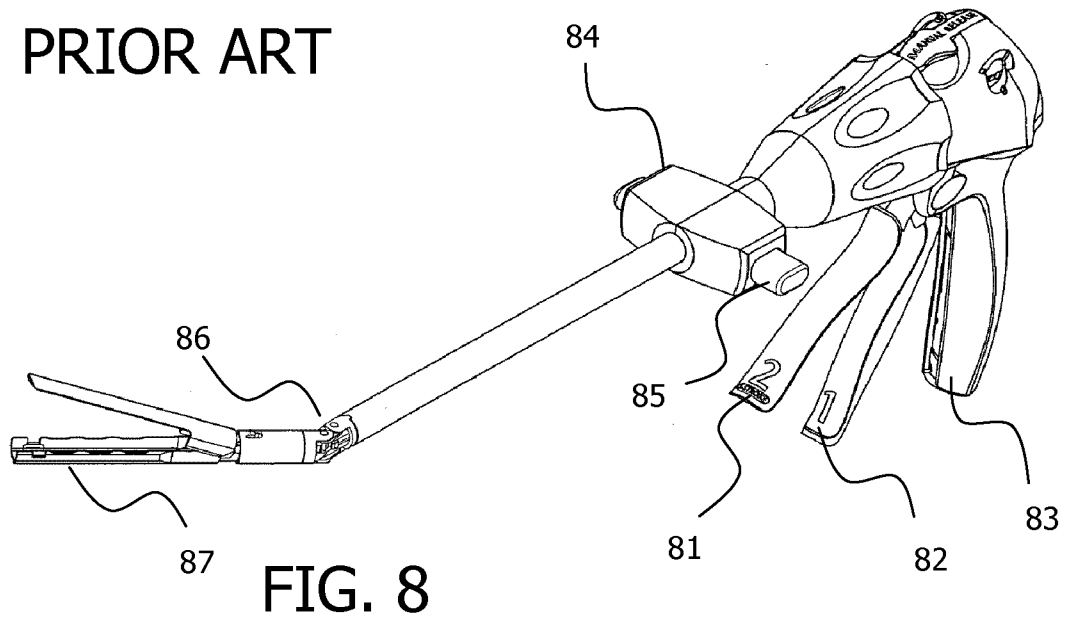


FIG. 7

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PRIOR ART



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PRIOR ART

FIG. 10

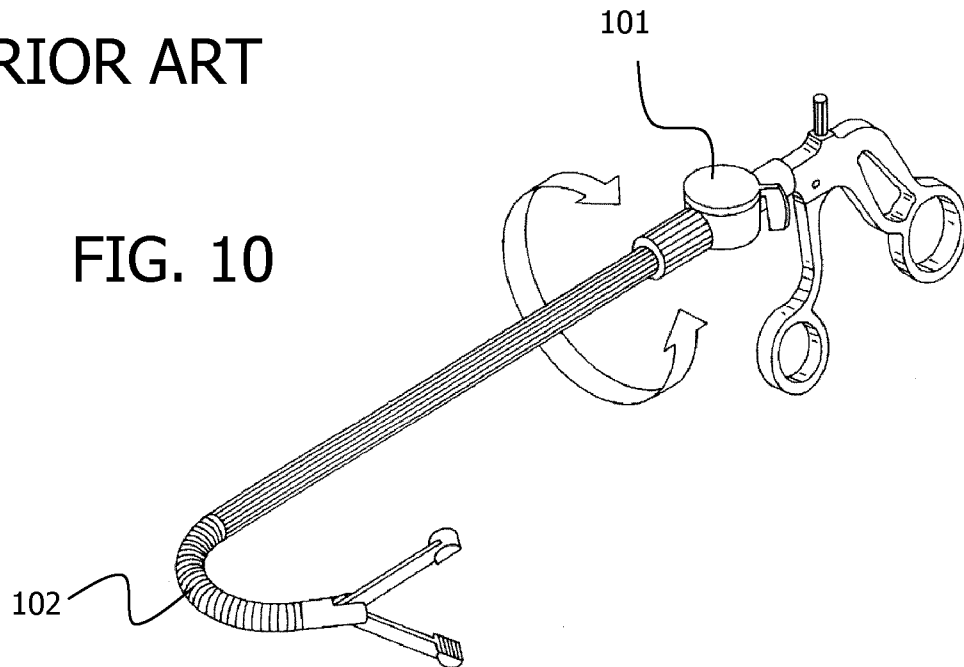
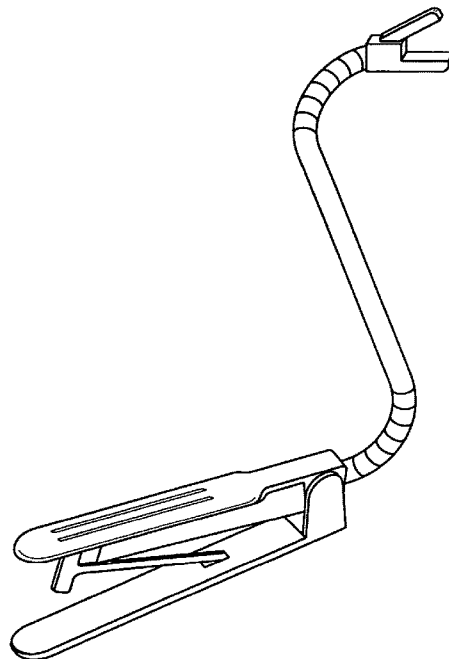


FIG. 11



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PRIOR ART

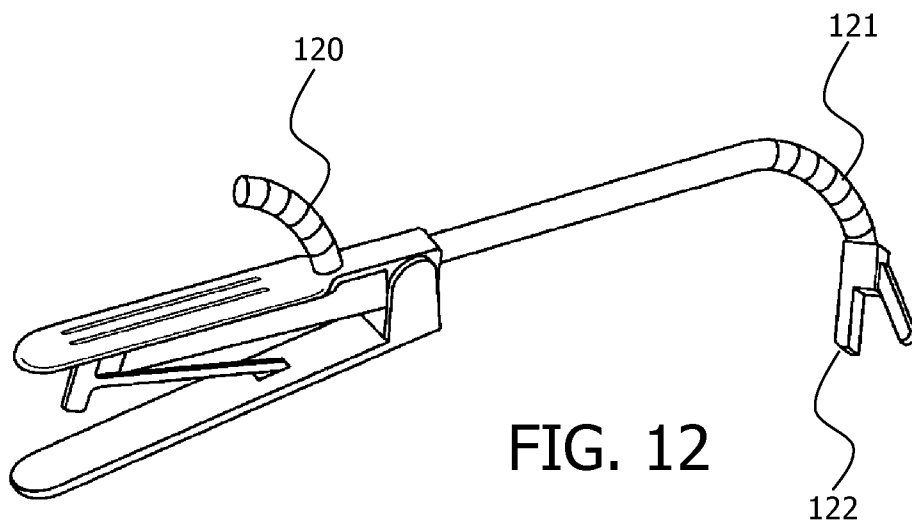


FIG. 12

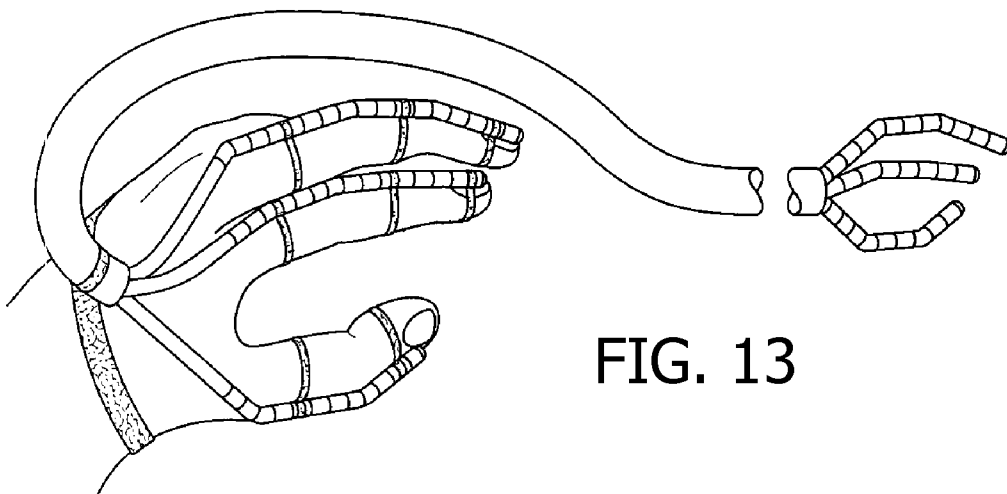


FIG. 13

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PRIOR ART

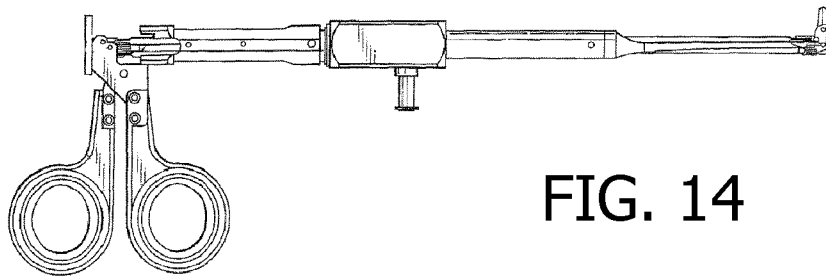
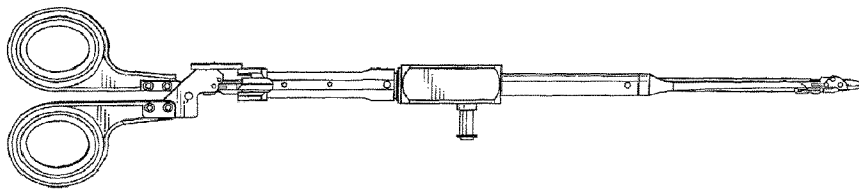


FIG. 14

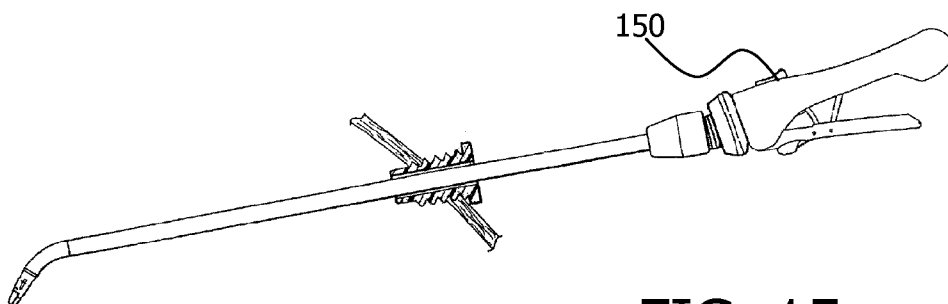


FIG. 15

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PRIOR ART

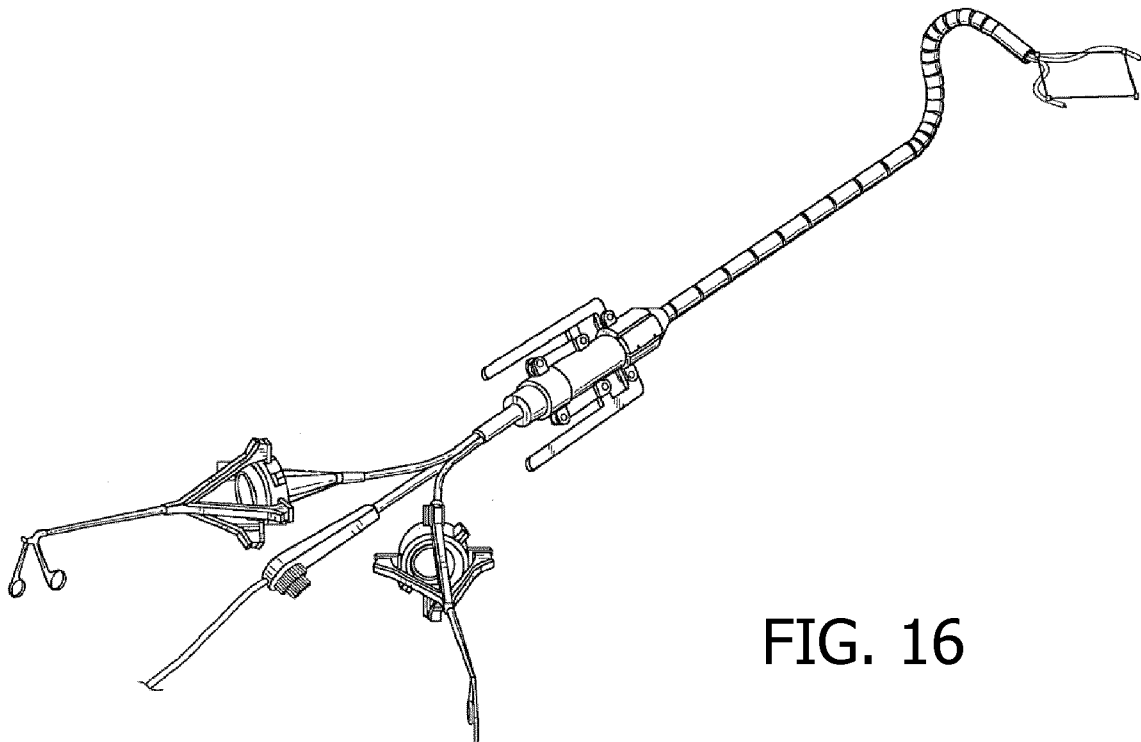


FIG. 16

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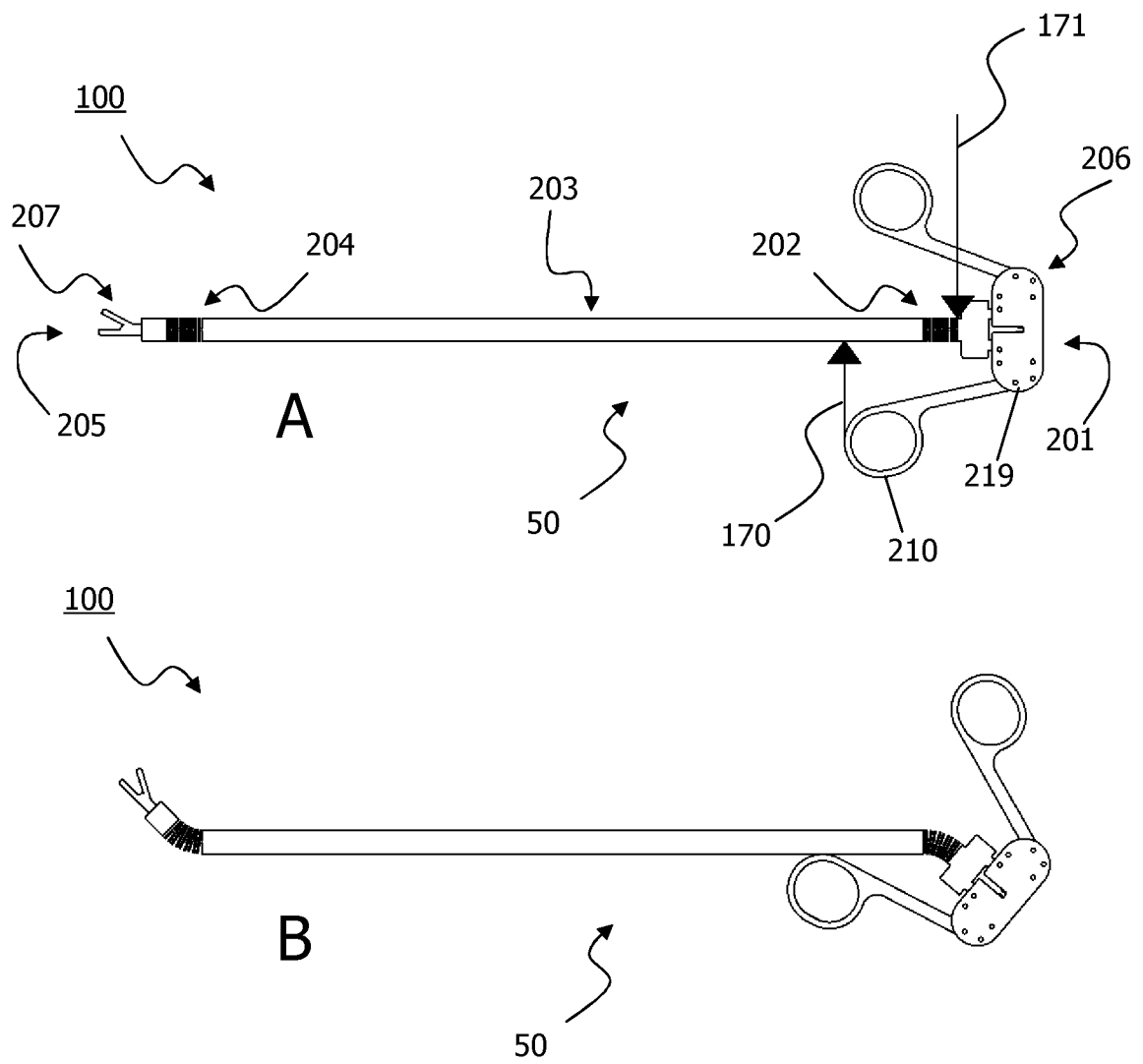


FIG. 17

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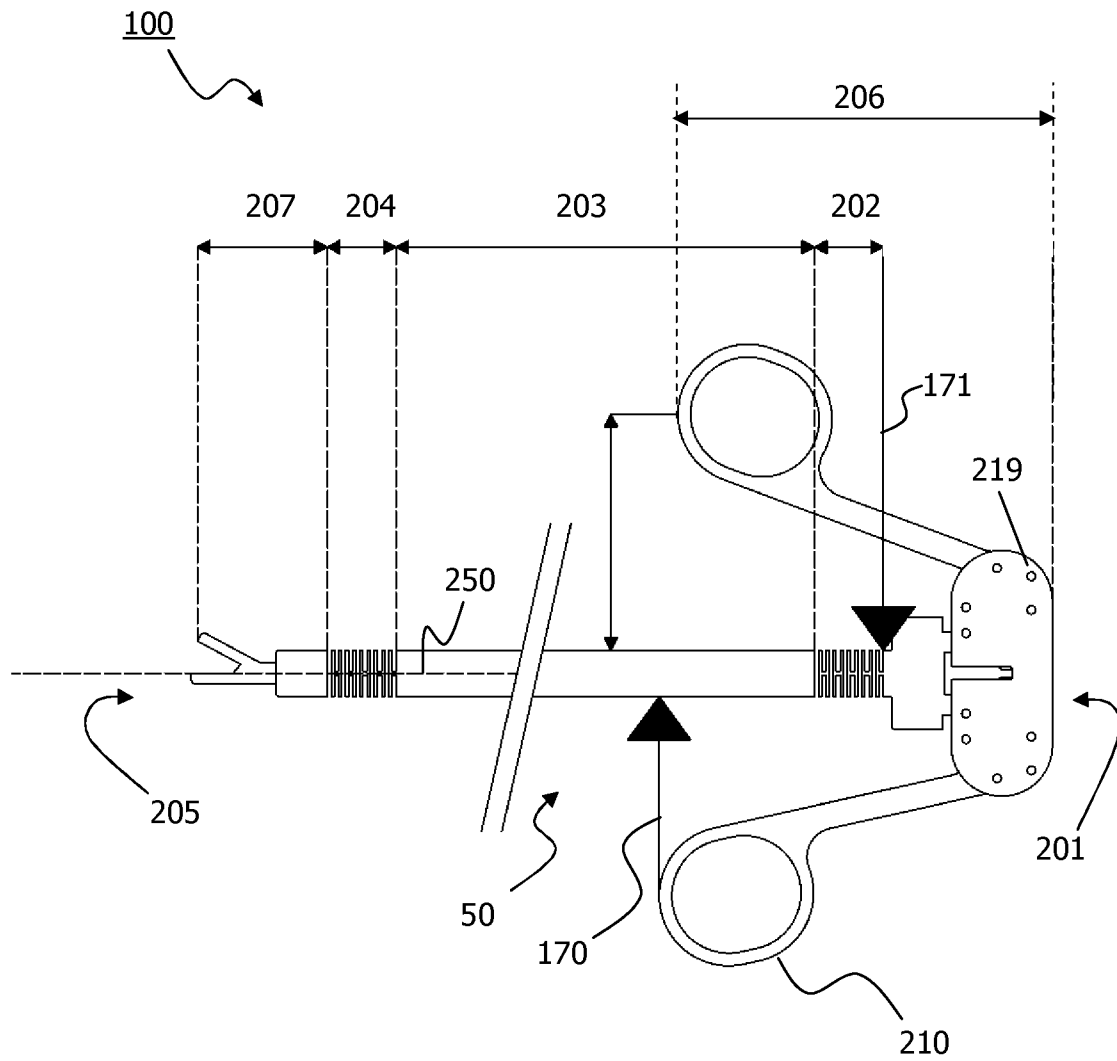


FIG. 18

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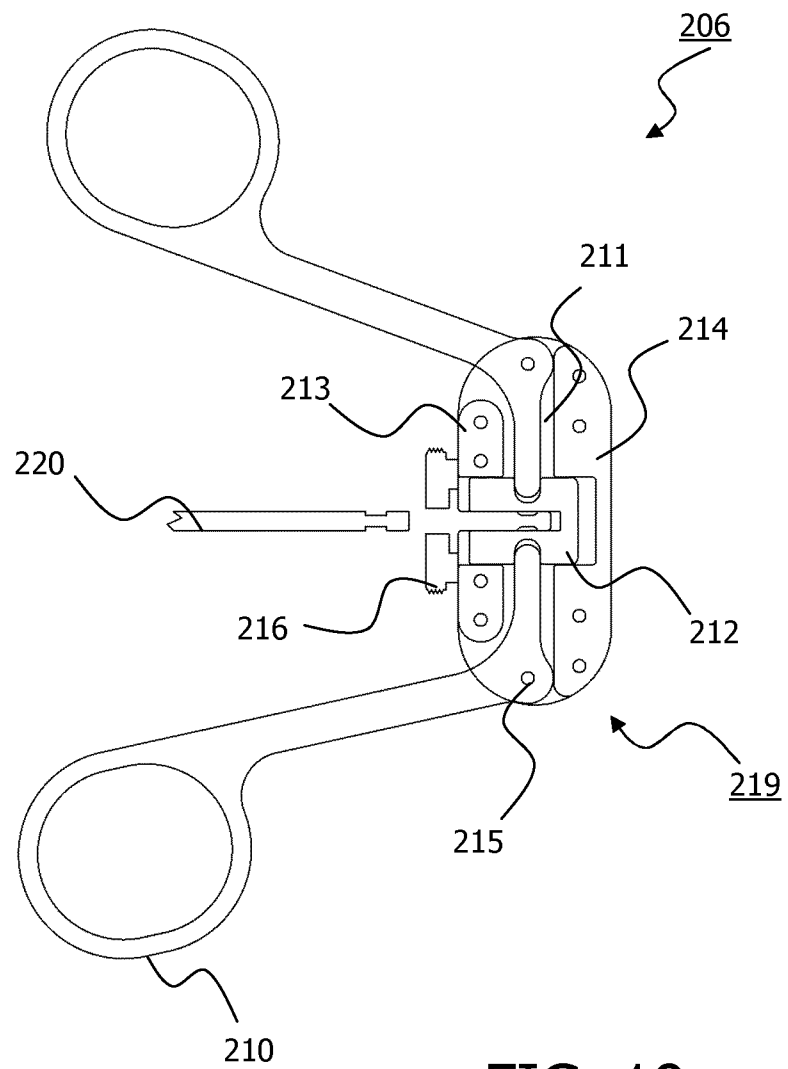
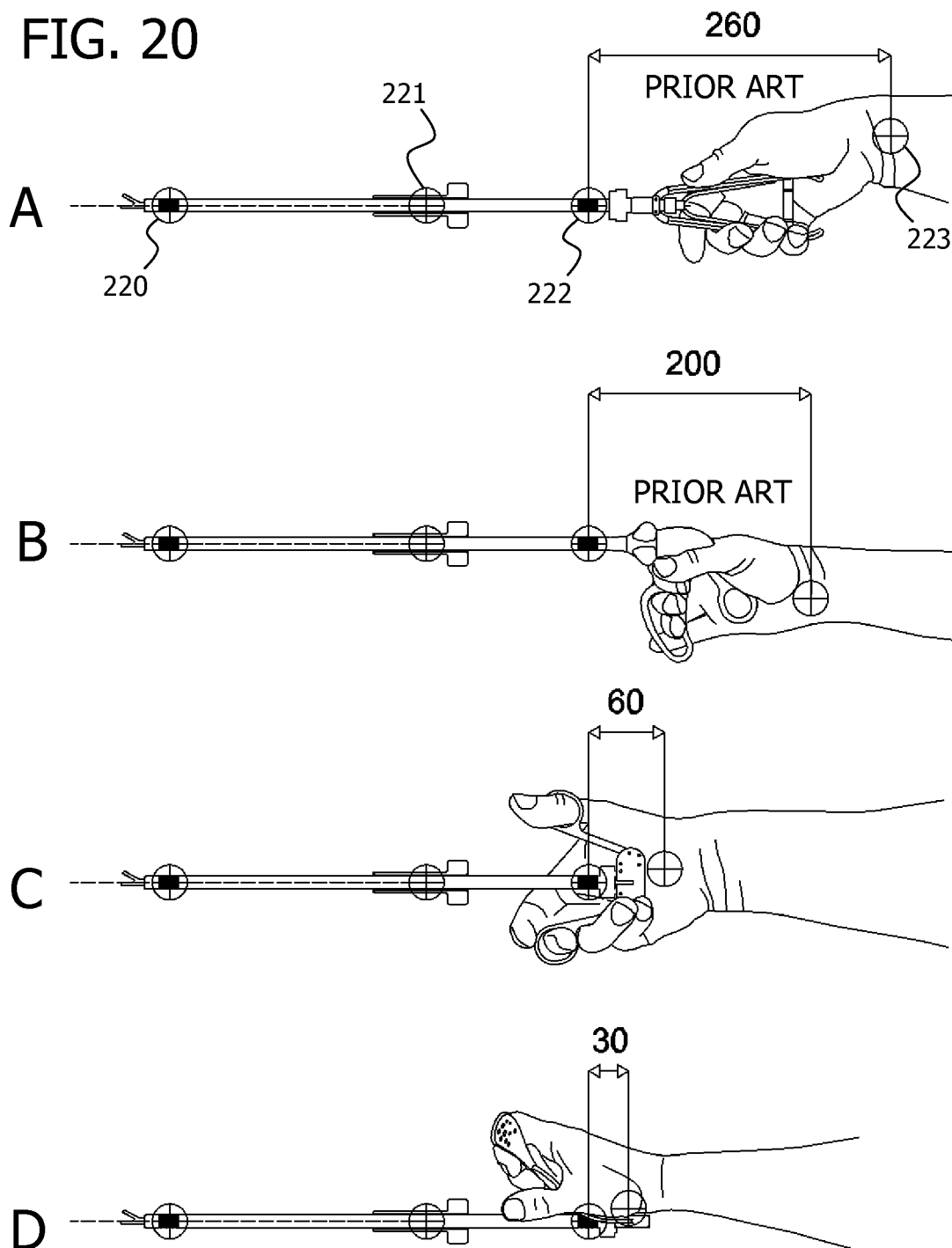


FIG. 19

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FIG. 20



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PRIOR ART

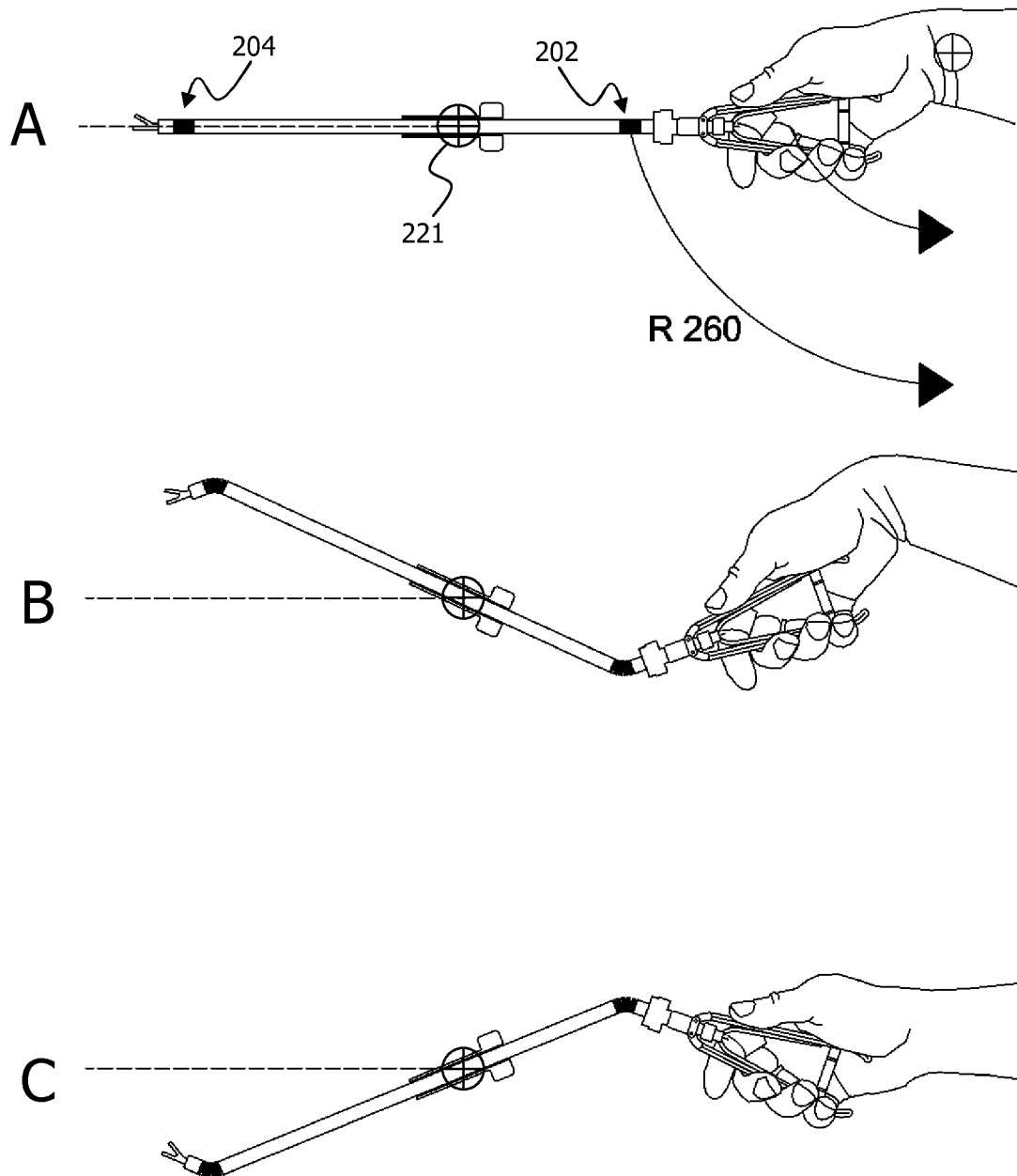


FIG. 21

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PRIOR ART

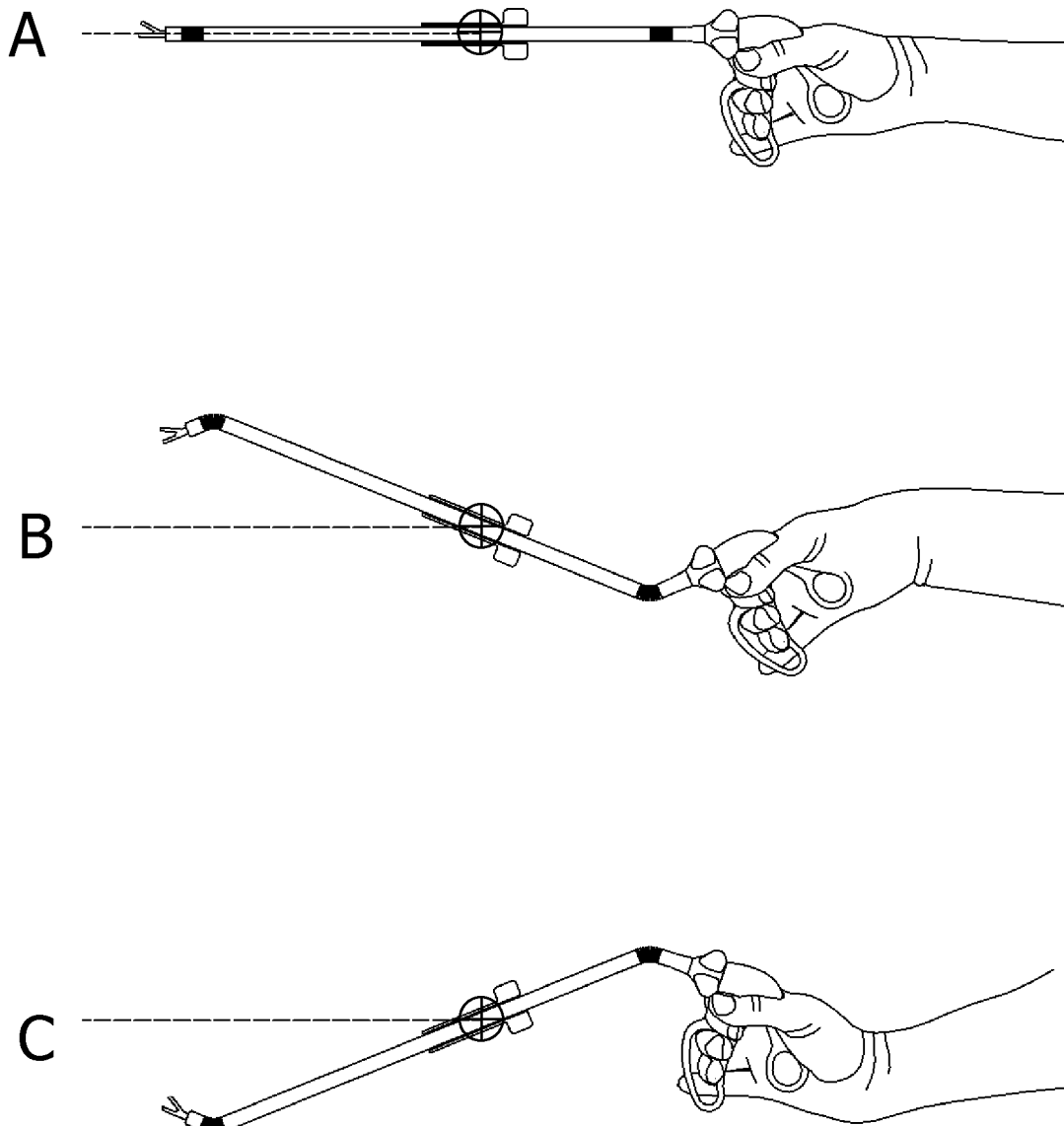


FIG. 22

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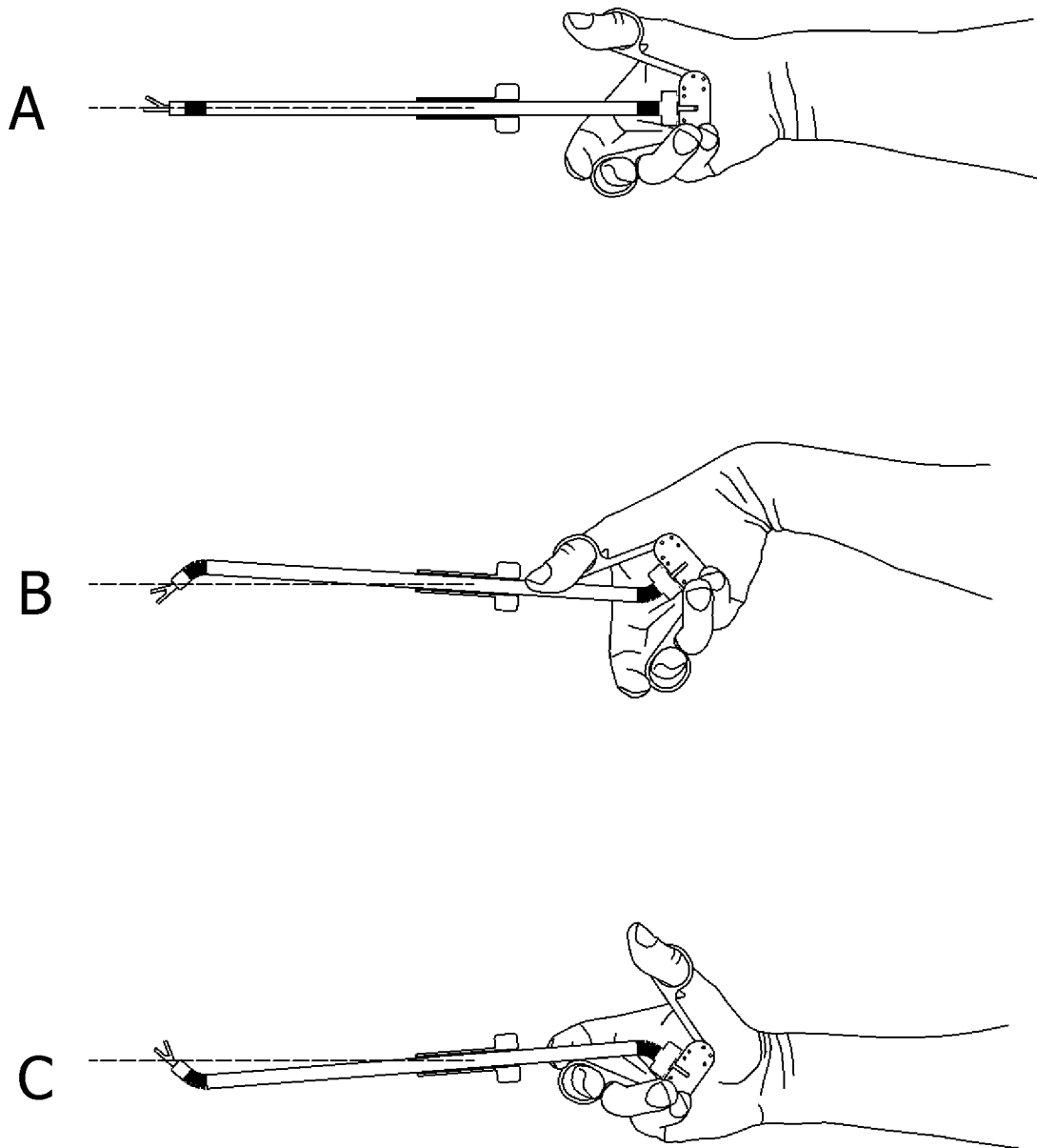


FIG. 23

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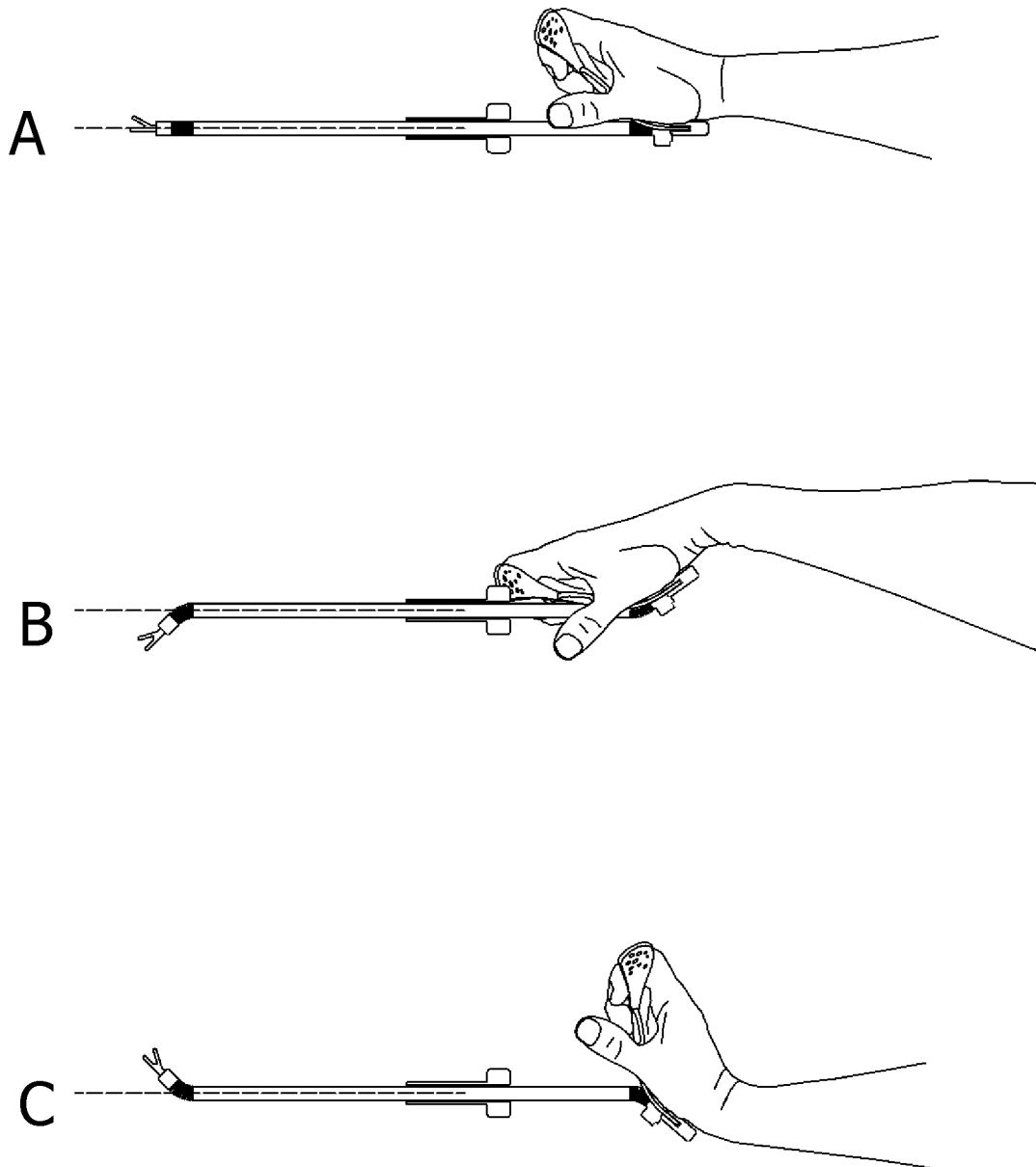


FIG. 24

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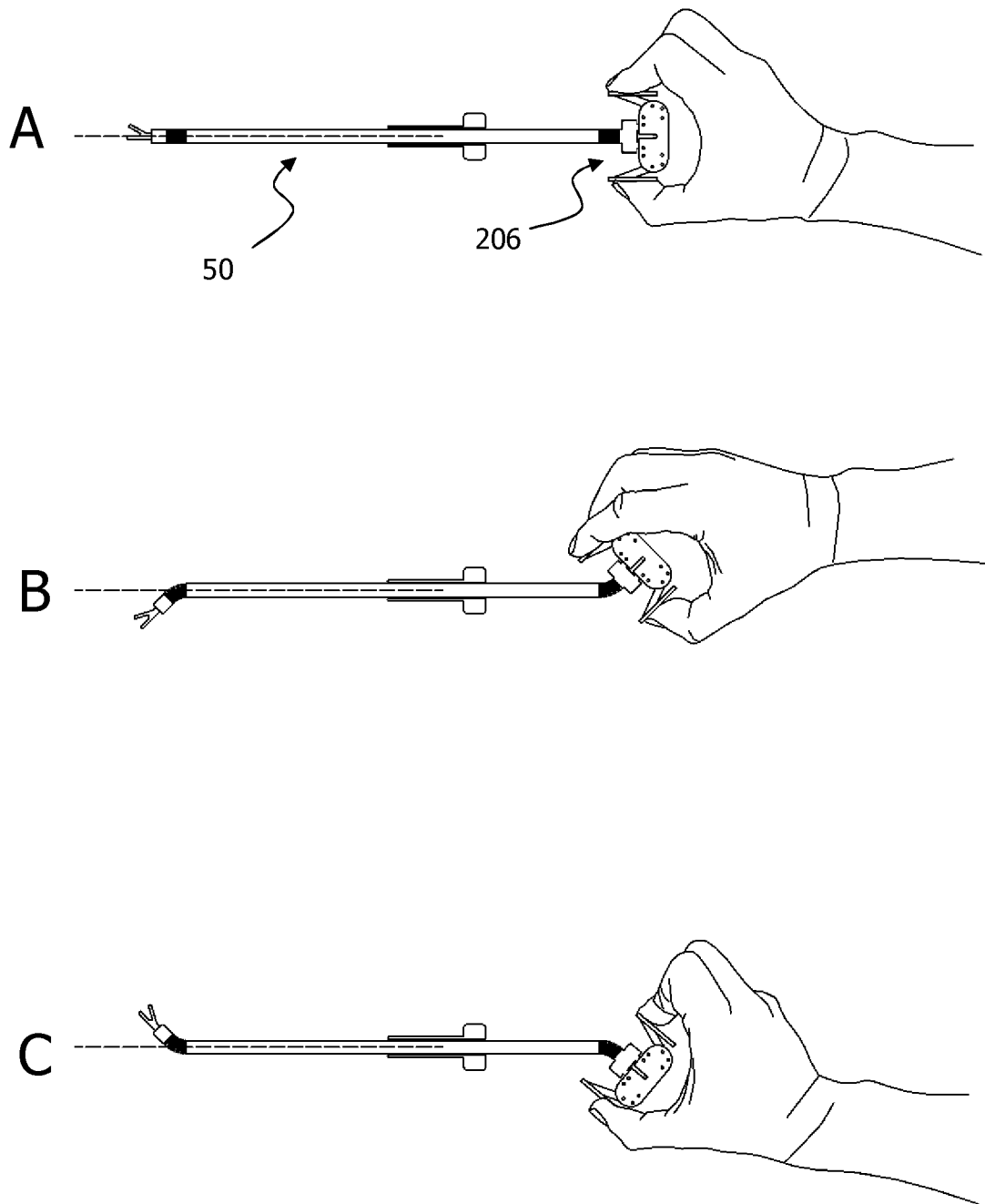


FIG. 25

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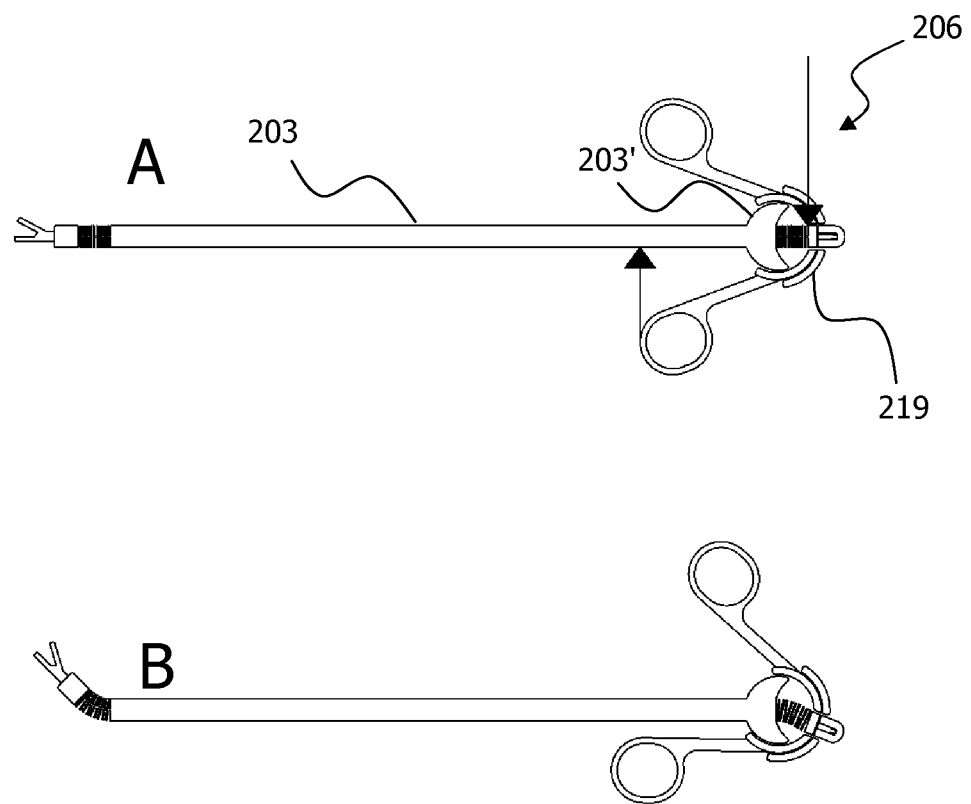


FIG. 26

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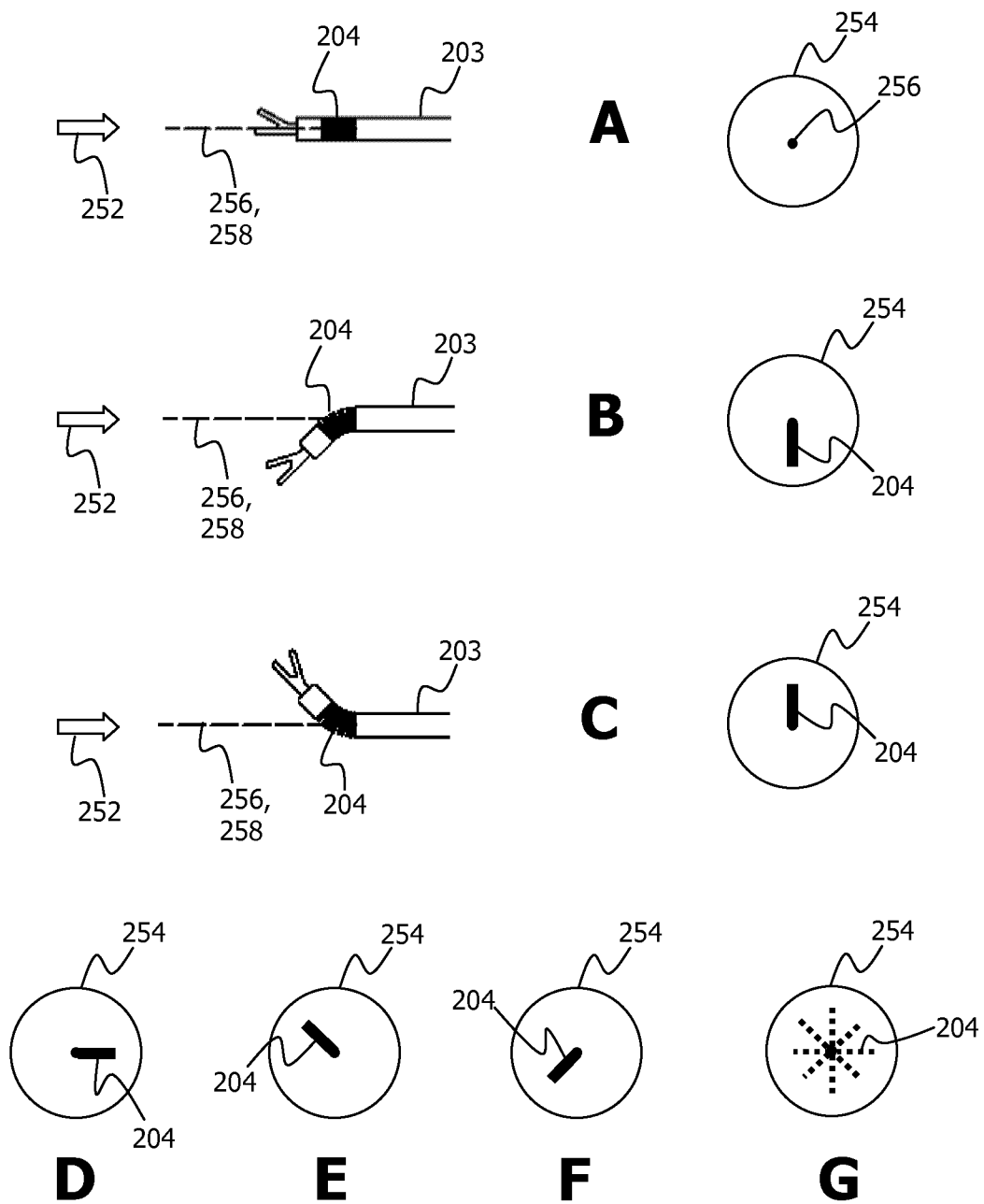


FIG. 27

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2013/070745

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/29

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/109898 A1 (SCHWARZ KNUT M [DE] ET AL) 12 June 2003 (2003-06-12)	1-12,15
A	figures 6-11 paragraph [0071]	14
X	GB 2 421 912 A (BLACKER ANTHONY [GB]) 12 July 2006 (2006-07-12)	1-11
Y	figures 4-8	12,13,15
Y	WO 2010/002904 A1 (EDWARDS LIFESCIENCES CORP [US]; JAKOUBEK FRANZ [DE]; BROSTOFF DANIEL []) 7 January 2010 (2010-01-07) figure 1	12,13,15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

5 February 2014

Date of mailing of the international search report

21/02/2014

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2013/070745

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