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(54) Benævnelse: **MODULÆR GREBSENHED TIL ET STYRBART KATETER**

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DESCRIPTION

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to steerable catheters, and more particularly to a modular handle assembly for supporting and controlling a steerable catheter.

2. Description of the Prior Art

[0002] This section provides background information related to the present disclosure which is not necessarily prior art.

[0003] A modular handle assembly in accordance with the pre-characterizing portion of claim 1 is disclosed in WO 2014/093457. Other handle assemblies for steerable catheters are disclosed in DE 27 52 325 A1, US 2006/100640 A1 and EP 1 532 999 A2.

[0004] Cathethers (i.e., catheters or sheaths) that have flexible tubular bodies with deflectable distal ends and control handles for controlling distal end deflection are used for many non-invasive medical producers. The distal portion of the catheter body is selectively deformed into a variety of curved configurations using an actuator on the control handle which remains outside the patient's body. The actuator is commonly internally linked to the distal portion of the catheter body by at least one deflection wire. Some catheter bodies employ a single deflection wire, which is pulled (i.e., placed in tension) by the actuator in order to cause the distal portion of the catheter body to deform. Other catheter bodies having at least two deflection wires, where the displacement of one wire (i.e., placing one wire in tension) with the other wire going slack (i.e., the wire does carry a tensile load). In such catheters, where the deflection wires are not adapted to carry compressive loads (i.e., the deflection wires are only meant to be placed in tension), the deflection wires are commonly called pull or tension wires.

[0005] Although the prior art control handles are capable of controlling distal end deflection of catheter bodies, they have several drawbacks. For example, the prior art control handles are often excessively bulky and oftentimes expensive. Additionally, the prior art control handles often have a mechanical component that requires a significant effort to operate on the part of the user, and once a desired distal end deflection has been reached, the control handles typically require the operator to actuate a locking mechanism to maintain the catheter at the desired deflection. Further, the prior art control handles can not be easily modified, and thus are specifically designed to work with a specific steerable catheter design. Finally, the prior art control handles often subject the deflection wires to a tortious path to steer a distal end of the

catheter.

[0006] Accordingly, there remains a need in the art for an improved control handle for use with a steerable catheter.

SUMMARY OF THE DISCLOSURE

[0007] This section provides a general summary of the disclosure and is not intended to be a comprehensive disclosure of its full scope, aspects, objectives, and/or all of its features.

[0008] A modular handle assembly for supporting and controlling a steerable catheter includes a handle portion which extends along an axis for being secured about a portion of the steerable catheter. The module handle assembly includes at least one barrel rotatably connected to the handle portion for rotation about the axis and at least one actuation screw shaft disposed within the handle portion and extending through said barrel for connection with a deflection wire of the steerable catheter. The module handle assembly further includes at least one pinion gear disposed radially between the actuation screw shaft and the barrel and threadedly interconnecting the actuation screw shaft and said barrel for translating rotational movement of said barrel about the axis into axial movement of said actuation screw shaft to provide for movement of said deflection wire to curl the steerable catheter.

[0009] As will be described in more detail below, the subject modular handle assembly provides for equal or better steering performance of steerable catheters using less overall parts and a simpler design than the prior art handle assemblies. Accordingly, the subject modular handle assembly provides for a lower cost solution to steering a catheter. Additionally, the subject modular handle assembly is easily customizable to achieve two or four direction deflection of the distal end of the steerable catheter, and even customizable for use with a variety of different steerable catheter designs. Thus, the subject modular handle provides for increased flexibility and modularity over the prior art handle assemblies.

[0010] Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Other advantages of the present invention will be readily appreciated, as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Figure 1 is a perspective assembled view of a modular handle assembly constructed in accordance with the principles of the present disclosure;

Figure 2 is an exploded view of the assembled modular handle assembly illustrated in Figure 1;

Figure 2A is an magnified end view of a screw shaft of Figure 2 illustrating a projection extending radially from the screw shaft and which defines a niche for receiving a deflection wire of a steerable catheter;

Figure 2B is a magnified view of a first connector of Figure 2 illustrating a plurality of passageways which extend axially therethrough;

Figure 3 is a perspective assembled view of a second embodiment of the modular handle assembly constructed in accordance with the principles of the present disclosure; and

Figure 4 is an exploded view of the assembled modular handle assembly illustrated in Figure 4.

DETAILED DESCRIPTION OF THE ENABLING EMBODIMENTS

[0012] Example embodiments will now be described more fully with reference to the accompanying drawings. The example embodiments are provided so that this disclosure will be thorough and fully convey the scope to those skilled in the art. Numerous specific details are set forth such as examples of specific components, devices, mechanisms, assemblies, and methods to provide a thorough understanding of various embodiments of the present disclosure. It will be apparent to those skilled in the art that specific details need not be employed, that example embodiments may be embodied in many different forms, and that neither should be construed to limit the scope of the disclosure. With this in mind, the present disclosure is generally directed to a module handle assembly for supporting and controlling a steerable catheter.

[0013] Referring to the Figures, wherein like numerals indicate corresponding parts throughout the several views, a modular handle assembly **20**, **220** for supporting and controlling a steerable catheter **22** that has a tubular, flexible elongated body **24** that extends to a distal tip **26.** At least one deflection wire **28** extends from the distal tip **26** of the steerable catheter **22** and through the body **24** for curling the distal tip **26** in response to movement of the deflection wires **28.**

[0014] The modular handle assembly **20**, **220** includes a rear handle portion **30**, generally indicated, that has a shell **34** and a skirt **36** for being disposed about and secured to the body **24** of the steerable catheter **22.** The rear handle portion **30** has a hoop shaped cross-section that defines an inner wall **38** surrounding a hollow. However, the rear handle portion **30** could have other shapes including, but not limited to, a square shaped cross-section without departing from the scope of the subject disclosure. The rear handle portion **30** extends along

an axis **A** from a first end **40** to a second end **42**, and the shell **34** is tapered radially inwardly from the first end **40** to the skirt **36.**

[0015] As best shown in Figures 2 and 4, the rear handle portion **30** further includes a pair of rear handle halves **44** that are mirror images with one another and which mate along a plane **P** that extends diametrically across the rear handle portion **30** through the axis **A.** A mechanical attachment **48**, such as tabs, slots, nuts, bolts, or the like, removeably attaches the rear handle halves **44** to one another at the plane **P.** The construction of the modular handle assembly **20**, **220** having two rear handle halves **44** advantageously provides for ease in manufacturing and assembly of the modular handle as the rear handle halves **44** can be molded separately. In addition, the two rear handle halves **44** provide for increased flexible modularity of the handle assembly as components internal to the rear handle portion **30** can easily be installed while the rear handle halves **44** are disconnected from one another.

[0016] A plurality of flanges **50** extend inwardly in spaced and parallel relationship with one another from the inner wall **38** of each of the rear handle halves **44** of the shell **34** for providing structural, rigidity to the rear handle portion **30.** It should be appreciated that any number of flanges **50** could be used to meet specific design needs and they could be oriented in other directions than shown in the Figures. The skirt **36** has a tube shape and extends at the second end **42** axially from the shell **34** for being disposed about and in engagement with a hemo valve **52** for securing the catheter **22** to the rear handle portion **30.** The skirt **36** also could be disposed about and in engagement with the body **24** of the steerable catheter **22.**

[0017] A proximal cap **54** that has a generally hemispherical shape is disposed about the rear handle portion **30.** The proximal cap **54** defines a recess **56** that has a cylindrical shape that extends axially therein. The recess **56** removeably receives the skirt **36** of the rear handle portion **30** to close the hollow of the rear handle portion **30** and to hold the rear handle halves **44** together in addition to the mechanical attachment **48.** It should be appreciated that the recess **56** and skirt **36** could have cross-sections of other shapes including, but not limited to, a square shaped cross section, without departing from the scope of the subject disclosure. The proximal cap **54** further defines an opening **58** that extends therethrough along the axis **A** for surrounding the body **24** of the catheter. The shell **34** further defines an orifice **60** that extends into the hollow adjacent to the skirt **36** at the plane **46** for receiving a hose of a stopcock assembly **61** of the steerable catheter **22.**

[0018] As best shown in Figures 2 and 4, the modular handle assembly **20**, **220** includes a first connector **62** and a second connector **64** each having a generally wheel shape and extending about the axis **A.** The first and second connectors **62**, **64** each have a front face **66**, a rear face **68**, and an outside wall **70** that extends axially between the front face **66** and the rear face **68.** A ring **72** extends radially outwardly from the outside wall **70** of each of the first and second connectors **62**, **64** to axially divide each of the first and second connectors **62**, **64** into a front segment **74** and a rear segment **76.** The first end **40** of the shell **34** is disposed about and is connected to the rear segment **76** of the first connector **62** in axial abutment with the ring **72** of the first connector **62.** The first and second connectors **62**, **64** each further define a central

passageway **78** that extends therethrough along the axis **A** for receiving the body **24** of the catheter. A first barrel **80** is disposed axially between the rings **72** of the first and second connectors **62**, **64** and is rotatably disposed on the rear segment **76** of the second connector **64** and the front segment **74** of the first connector **62.** The first barrel **80** has a generally tube shape to define an inside surface that presents a plurality of axially extending internal teeth **82.** However, the internal teeth **82** could also extend in other directions without departing from the scope of the subject disclosure.

[0019] The modular handle assembly **20**, **220** includes a front handle portion **32** that has a case **86** and a conduit **88** and a hoop shaped cross-section extends along the axis **A** from a first termination **90** to a second termination **92** for being disposed about the body **24** of the steerable catheter **22.** The front handle portion **32** defines a chamber and includes a pair of front handle halves **94** that are mirror images with one another and mate along the plane **46.** The front handle portion **32** also includes a mechanical coupling **96**, such as tabs, slots, nuts, bolts, or the like, for removeably attaching the front handle halves **94** to one another at the plane **46.** As best shown in Figures 1 and 2, in the first enabling embodiment, the second termination **92** of the case **86** is in axial abutment with the ring **72** of the second connector **64** about the front segment **74** of the second connector **64.** Like the rear handle halves **44**, it should be appreciated that the construction of the modular handle assembly **20**, **220** having two front handle halves **94** advantageously provides for ease in manufacturing and assembly **20**, **220** as the front handle halves **94** can be molded separately. In addition, the two front handle halves **94** provide for increased flexible modularity of the handle assembly as components internal to the rear handle portion **30** can easily be installed while the front handle halves **94** are disconnected from one another.

[0020] As best shown in Figures 1 and 3, the case **86** is tapered radially outwardly from the second termination **92** to the conduit **88**, and the conduit **88** has a tube shape which extends at the first termination **90** axially from the case **86.** A crimp pipe **98** that has a generally tube shape is disposed in the conduit **88** for being disposed about and in engagement with the body **24** of the catheter for tightening the front handle portion **32** about the body **24** of the steerable catheter **22.** The crimp pipe **98** has a thickness that can vary based on the diameter of the body **24** of the steerable catheter **22** to ensure that the front handle portion **32** is tightened about the body **24** of the steerable catheter **22.** Put another way, the size of the crimp tube **98** can be adjusted to accommodate a wired range of differently sized catheters 22, and thus provides for improved modularity of the subject handle assembly **20.** It should be appreciated that the crimp pipe **98** could extend axially to other lengths, such as to the central passageway **78** of the first connector **62** to advantageously hold the body **24** of the steerable catheter **22** in place along a further length. It also should further be appreciated that the elongated body **24** of the steerable catheter **22** can be secured to the modular housing assembly **20** at various points along the length of the modular housing assembly **20** advantageously preventing the elongated body **24** of the catheter from twisting or binding up within the modular housing assembly **20** as is known to be a common issue in prior art handle assemblies **20.**

[0021] As further shown in Figures 1 and 3, the modular handle assembly **20**, **220** includes a

distal cap **100** that has a generally hemispherical shape and is disposed about the front handle portion **32.** The distal cap **100** defines a passage **102** that extends axially therethrough to removeably receive the conduit **88** of the front handle portion **32** and to hold the front handle halves **94** in addition to the mechanical coupling **96.** It should be appreciated that an additional crimp pipe **98** could be disposed in the conduit **88** for being positioned about the body **24** of the steerable catheter **22** to ensure that the front handle portion **32** is tightened about the body **24.** Similar to the crimp tube **98**, the passage **102** of the distal cap **100** can be adjusted to accommodate a wide range of differently sized catheters **22**, and thus provide for improved modularity of the subject handle assembly **20.**

[0022] As best shown in Figures 2 and 4, the front face **66** of each of the first and second connectors **62**, **64** defines four channels **104** that extend therein and which are circumferentially and evenly spaced about the central passageway **78.** The second connector **64** additionally includes four legs **106** that extend axially from the rear face **68** of the second connector **64** and are circumferentially and evenly spaced from one another about the central passageway **78**, Each of the four legs **106** are each received by one of the channels **104** of the first connector **62** for connecting the first and second connectors **62**, **64** in axially spaced relationship with one another. It should be appreciated that alternatively, any other number of channels **104** and corresponding legs **106** could be present on the first and second connectors **62**, **64** based on design needs. As further shown in Figures 2 and **4**, the first and second connectors **62**, **64** also define a pair of horizontal outer passageways **108** that extend axially therethrough and which are aligned with one another on opposing sides of the axis **A.** Additionally, the first and second connectors **62**, **64** define a pair of vertical outer passageways **110** that extend axially therethrough and which are aligned with one another on opposing sides of the axis **A** and circumferentially disposed between the horizontal outer passageways **108.**

[0023] A pair of horizontal actuation screw shafts **112** each extend through one of the horizontal outer passageways **108** of the first and second connector **62**, **64** and into the hollow of the rear handle portion **30.** Each of the horizontal actuation screw shafts **112** includes a projection **114** that extends radially toward the axis **A** from each of the horizontal actuation screw shafts **112** for connection with one of the deflection wires **28.** As best presented in Figure 2A, each of the projections **114** defines a niche **116** that has a T-shape extending therein for receiving one of the deflection wires **28.** The T-shape of the niche **116** advantageously allows the deflection wire **28** to easily be threaded into the niche, and thus improves the assembly and modularity of the subject handle assembly **20.** The deflection wires **28** are held in place by the niche **116** in conjunction with the tension of the deflection wire **28** within the niche **116.** The niche **116** can also be designed with different shapes, such as L-shaped, without departing from the scope of the subject disclosure. A wire crimp **118** is fixedly disposed about each of the deflection wires **28** axially past the niche **116** of the horizontal actuation screw shafts **112** and next adjacent the distal cap **100** for preventing the deflection wire **28** from axially sliding out of the niche **116** during axial movement of the horizontal actuation screw shafts **112.** The wire crimp **118** advantageously allows the deflection wires **28** to slide axially back and forth through their respective niches **116** to a predetermined extent during axial movement of the screw shafts **112**, but will not allow the deflection wires **28** to slide

out of the niche **116.** As a result, the design of the niche **116** prevents the build-up of slack of the deflection wires **28** within the hollow of the rear handle **30.** Put another way, the niche **116** allows for sliding of the deflection wire through the niche **116** when the actuation screws are moving in a distal axial direction, and the crimp **118** facilitates a pulling of the deflection wire when the actuation screws are moving in a proximal axial direction. As a result, the niche **116** and crimp **118** effectuate a tension-only action on the deflection wires **28.**

[0024] As best shown in Figures 2 and 4, each of the horizontal actuation screw shafts **112** has an outer surface that presents a plurality of external threads **120.** A rear pinion gear **122** is disposed about and axially aligned with each one of the horizontal actuation screw shafts **112**, and disposed axially between the first and second connectors **62**, **64.** The rear pinion gear **12** has a generally tube shape to define an internal and external surface. The external surface of the rear pinion gears **122** presents a plurality of axially extending external teeth **84** for mating with the internal teeth **82** of the first barrel **80** for providing for rotational movement of the rear pinion gears **122** in response to rotation of the first barrel **80.** The external teeth **84** could extend in other directions but they should mate with the internal teeth **82** of the first barrel **80.** The internal surface of each of the rear pinion gears **122** presents a plurality of internal threads **124** that are threadedly connected with the external threads **120** of the horizontal actuation screw shaft **112.** An arrangement in this regard provides for axial movement of the horizontal actuation screw shaft **112** relative to the rear pinion gear **122** in response to rotation of the rear pinion gear **122** about the horizontal actuation screw shaft **112** as a result of the first barrel **80** being rotated about the axis **A.** Accordingly, the pinion gears **122** translate rotational movement of the first barrel **80** about the axis **A** into axial movement of the horizontal actuation screw shaft **112** to provide for movement of the deflection wire **28** to curl the distal tip **26** the steerable catheter **22** horizontally.

[0025] In one embodiment, the external threads **120** of each of the horizontal actuation screw shafts **112** extend in opposing directions with one another for providing for axial movement of the horizontal actuation screw shafts **112** in opposite axial directions from one another. Movement in this regard moves the deflection wires **28** in opposite directions from one another to allow the steerable catheter **22** to be curled in two horizontal or directly opposing directions. However, in another embodiment, the external threads **120** of each of the horizontal actuation screw shafts **112** could extend in the same direction with one another for providing for axial movement of the horizontal actuation screw shafts in the same axial direction. The external threads **120** of the horizontal actuation screw shafts **112** and the internal threads **124** of the pinion gears **122** could also be oriented at various pitches to provide for increased or decreased axial movement of the horizontal actuation screw and deflection wire **28** per revolution of the first barrel **80** based on design needs. The interchangeability of the external threads **120** of the horizontal actuation screw shafts **122** provides for increased modularity for the subject handle assembly **20.**

[0026] Thus, as can be understood from the aforementioned disclosure in connection with the Figures, when the external threads **120** of each of the horizontal actuation screw shafts **112** extend in opposing directions with one another, as the first barrel **80** is rotated clockwise

relative to the axis **A**, the internal teeth **82** of the first barrel **80** being meshed with the external teeth **84** of the pinion gears **122**, in conjunction with the internal threads **124** of the pinion gears **122** being threaded with the external threads **120** of the actuation screw shafts **112** cause simultaneous opposed displacement of the horizontal actuation screw shafts **112** longitudinally or axially within the handle assembly **20.** Specifically, because of the meshed and threaded relationship of the first barrel **80**, the pinion gears **122**, and the screw shafts **112**, one of the horizontal actuation screw shafts **112** moves distally within the handle assembly **20** and the other of the horizontal actuation screw shafts **112** moves proximally within the handle assembly **20** when the first barrel **80** is rotated clockwise to relative to the rear handle portion **30** and the front handle portion **32.** Conversely, when the first barrel **80** is rotated in a counterclockwise manner relative to the rear handle portion **30** and the front handle portion **32**, each of the horizontal actuation screw shafts **112** reverse or alternate their axial direction.

[0027] With reference to Figures 2 and 4, when the first barrel **80** is rotated such that the first one of the horizontal actuation screw shafts **112** is urged distally and the other one of the horizontal actuation screw shafts **112** is urged proximally, the distal end **26** of the catheter body **24** is caused to deflect in a first direction. Conversely, when the first barrel **80** is rotated such that the directions of the horizontal actuation screw shafts **112** is reversed, the distal end **26** of the catheter body **24** to deflect in a second direction that is directly opposite to the first direction. Although the actuation screw shafts are described throughout the specification as being horizontal, it should be appreciated that movement of the horizontal actuation screw shafts **112** need not result in horizontal deflection of the catheter **24**, but rather just two movements of the distal end **26** of the catheter body **24** which occur directly opposite to one another. Accordingly, the horizontal actuation screw shafts **112** of the first embodiment the modular handle assembly **20** provide for two (2) direction deflection of the distal end **26** of the catheter body **24.**

[0028] Additionally, the meshed and threaded relationship of the first barrel **80**, the pinion gears **122**, and the screw shafts **112**, provides for a natural means to lock the deflection of the distal end **26** of the catheter body **24** without the need for an additional lock control mechanism as is required in the prior art handle assemblies. Put another way, an operator or user of the modular handle assembly **20** can simply hold the first barrel **80** in place, which prevents the distal end **26** of the catheter body **24** from moving because of the intermeshed and threaded relationship of the first barrel **80**, the pinion gears **122**, and the screw shafts **112.**

[0029] As best shown in Figures 2 and 4, a stop **126** is disposed in the hollow of the rear handle portion **30** axially adjacent to the skirt **36** for limiting axial movement of the horizontal actuation screw shafts **112.** In a preferred arrangement, the stop **126** has a cross shape to define a center and four arms **128** that extend radially outwardly from the center. Two of the arms **128** are each in axial alignment with one of the horizontal actuation screw shafts **112** for limiting the axial movement of the horizontal actuation screw shafts **112.** This advantageously prevents the horizontal actuation screw shafts **112** from axially moving out of the pinion gears **122.** As will be described in more detail below, the other arms **128** of the stop **126** could be used to limit axial movement of additional actuation screw shafts **112**, **130.** However, the

modular handle assembly **20** could omit the stop **126** without departing from the scope of the subject disclosure.

[0030] In a second enabling embodiment, the modular handle assembly **20** includes a third connector **132** which a generally wheel shape and which extends about the axis **A.** As best shown in Figure 4, like the first and second connectors **62**, **64**, the third connector **132** has a front face **66** and a rear face **68** and has an outside wall **70** that extends axially between the front face **66** and the rear face **68.** A ring **72** extends radially outwardly from the outside wall **70** of the third connector **132** to axially divide the third connector **132** into a front segment **74** and a rear segment **76.** The third connector **132** further defines a central passageway **78** that extends therethrough along the axis **A** for receiving the body **24** of the steerable catheter **22.**

[0031] As best shown in Figure 3 and 4, the second enabling embodiment of the modular handle assembly **220** includes a second barrel **134** that is rotatably disposed on the rear segment **76** of the third connector **132** and the front segment **74** of the second connector **64** and axially between the rings **72** of the second and third connectors **64**, **132.** Like the first barrel **80**, the second barrel **134** has a generally tubular shape to define an inside surface that presents a plurality of axially extending internal teeth **82.** The front face **66** of the third connector **132** further defines four channels **104** that extend axially therein and which are circumferentially and evenly spaced about the central passageway **78.** The third connector **132** further includes four legs **106** that extend axially from the rear face **68** of the third connector **132** and which are circumferentially and evenly spaced from one another about the central passageway **78.** Each of the legs **106** are received by one of the channels **104** of the second connector **64** for connecting the second and third connectors **64**, **132** in axially spaced relationship with one another. It should be appreciated that alternatively any other number of channels **104** and corresponding legs **106** could be present on the second and third connectors **64**, **132** based on design needs.

[0032] The third connector **132** further defines a pair of horizontal outer passageways **108** that extend therethrough in parallel and aligned relationship with the axis **A** and which are aligned with one another on opposing sides of the axis **A.** The third connector **132** also defines a pair of vertical outer passageways **110** that extend therethrough in parallel and aligned relationship with the axis **A** and which are aligned with one another on opposing sides of the axis **A** and circumferentially spaced between the horizontal outer passageways **108.** The pair of horizontal actuation screw shafts **112** each further extend through one of the horizontal outer passageways **108** of the third connector **132.** A pair of vertical actuation screw shafts **130** each extend through one of the vertical outer passageways **110** of the first, second and third connectors **62**, **64**, **132** and into the hollow of the rear handle portion **30.** Like the horizontal actuation screw shafts **112**, each of the vertical actuation screw shafts **130** includes a projection **114** that extends radially toward the axis **A** from each of the vertical actuation screw shafts **130** each for connecting with one of additional deflection wires **28.** Additional wire crimps **118** are fixedly disposed about each of the additional deflection wires **28** axially past the niche **116** of the vertical actuation screw shafts **130** and next adjacent toward the distal cap **100** for preventing the deflection wires **28** from axially sliding out of the niche **116** during axial

movement of the vertical actuation screw shafts **130.** The wire crimp **118** advantageously allows the deflection wires **28** to slide axially back and forth through their respective niches **116** to a predetermined extent during axial movement of the vertical actuation screw shafts **130**, but will not allow the deflection wires **28** to slide out of the niche **116.** As a result, the design of the niche **116** prevents the build-up of slack of the deflection wires **28** within the hollow of the rear handle **30.**

[0033] Each of the vertical actuation screw shafts **130** have an outer surface that presents external threads **120**, with the external threads **120** of each of the vertical actuation screw shafts **130** extending in an opposing direction relative to the other. A front pinion gear **136** is disposed about each of the vertical actuation screw shafts **130** and axially between second and third connectors **64**, **132.** Like the rear pinion gears **122**, each of the front pinion gears **136** has a generally tube shape to define an internal surface and an external surface, with the external surface of the front pinion gears **136** presenting a plurality of external teeth **84** for mating with the internal teeth **82** of the second barrel **134** for providing for rotational movement of the front pinion gears **136** in response to rotation of the second barrel **134.** The internal surface of each of the front pinion gears **136** presents internal threads **124** threadedly connected with the external threads **120** of the vertical actuation screw shaft **130.** An arrangement in this regard provides for axial movement of the vertical actuation screw shaft **130** relative to the front pinion gear **136** in response to rotation of the front pinion gear **136** about the vertical actuation screw shaft **130** as a result of second barrel **134** being rotated about the axis **A.** Accordingly, the front pinion gears **136** provide for movement of the deflection wires **28** to curl the distal tip **26** of the elongated body **24** vertically or transversely relative to the movement effectuated by the horizontal actuation screw shafts **112.** Put another way, the front pinion gears **136** translate rotational movement of the second barrel **134** about the axis **A** into axial movement of the vertical actuation screw shaft **130** to provide for movement of the deflection wire **28** to curl the distal tip **26** of the steerable catheter **22** in a direction which is transverse to the movement of the distal tip **26** effectuated by the horizontal actuation screw shafts **112.**

[0034] The external threads **120** of each of the vertical actuation screw shafts **130** extend in opposing directions with one another for providing for axial movement of the vertical actuation screw shafts **130** in opposite axial directions. Movement in this regard moves the deflection wires **28** in opposite directions from one another to allow the steerable catheter **22** to be curled in two vertical or directly opposing directions. However, in another embodiment, the external threads **120** of each of the vertical actuation screw shafts **130** could extend in the same direction with one another for providing for axial movement of the vertical actuation screw shafts **130** in the same axial direction. Like the horizontal actuation screw shafts **112**, the external threads **120** of the vertical actuation screw shafts **130** could advantageously be oriented at various pitches to provide for increased or decreased axial movement of the vertical actuation screw shaft **130** and corresponding deflection wire **28** per revolution of the second barrel **134** based on design needs. The interchangeability of the external threads **120** of the horizontal actuation screw shafts **122** provides for increased modularity for the subject handle assembly **20.** As mentioned above, the other arms **128** of the stop **126** each are in axial alignment with one of the vertical actuation screw shafts **130** for limiting the axial movement of

the vertical actuation screw shafts **130.**

[0035] Thus, as can be understood from the aforementioned disclosure in connection with the Figures, as the second barrel **134** is rotated clockwise relative to the axis **A**, the internal teeth **82** of the second barrel **134** being meshed with the external teeth **84** of the front pinion gears **136**, in conjunction with the internal threads **124** of the front pinion gears **136** being threaded with the external threads **120** of the vertical actuation screw shafts **130** cause simultaneous opposed displacement of the vertical actuation screw shafts **130** longitudinally or axially within the handle assembly **20** when the external threads **120** extend in opposing directions. Specifically, because of the meshed and threaded relationship of the second barrel **134**, the front pinion gears **136**, and the vertical screw shafts **130**, one of the vertical actuation screw shafts **130** moves distally within the handle assembly **20** and the other of the vertical actuation screw shafts **130** moves proximally within the handle assembly **20** when the second barrel **134** is rotated clockwise to relative to the rear handle portion **30** and the front handle portion **32.** Conversely, when the second barrel **134** is rotated in a counterclockwise manner relative to the rear handle portion **30** and the front handle portion **32**, each of the vertical actuation screw shafts **134** reverse or alternate their axial direction.

[0036] With reference to Figure 4, when the second barrel **134** is rotated such that the first one of the vertical actuation screw shafts **130** is urged distally and the other one of the vertical actuation screw shafts **130** is urged proximally, the distal end **26** of the catheter body **24** deflects in a second direction which is transverse to the direction effectuated by the horizontal actuation screw shafts **112.** Conversely, when the second barrel **134** is rotated such that the directions of the vertical actuation screw shafts **130** are reversed, the distal end **26** of the catheter body **24** deflects in the opposite direction. Although the actuation screw shafts are described throughout the specification as being vertical, it should be appreciated that movement of the vertical actuation screw shafts **130** need not result in vertical deflection of the catheter **24**, but rather just movement of the distal end **26** of the catheter body **24** which occurs transverse to the movement effectuated by the horizontal actuation screw shafts **112.** Thus, the second embodiment of the modular handle assembly **20** provides for four (4) direction deflection of the distal end **26** of the catheter body **24.** In addition, as can be understood from the aforementioned disclosure, the subject handle assembly **20** can be easily modified to incorporate the second barrel **134**, the front pinion gears **136**, and the vertical actuation screw shafts **130** to provide the four (4) direction deflection, and thus provides for more flexibility and modularity over the prior art handle assemblies. Further, the subject modular handle assembly **20** achieves the four (4) direction deflection of the distal end **26** of the catheter body **24** using less overall parts and a simpler design than the prior art handle assemblies.

[0037] Due to the modular construction of modular handle assembly **20**, additional barrels **134**, **80**, pinion gears **122**, connectors **132**, **62**, **64** and screw shafts **112**, **130** could be added to the assembly **20** in the same fashion as the second enabling embodiment to provide for movement of the steerable catheter **22** in a wide variety other directions or along different lengths along the body **24** of the steerable catheter **22.**

[0038] The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO2014093457A **[0003]**
- DE2752325A1 **[0003]**
- US2006100640A1 **[0003]**
- EP1532999A2 **[0003]**

PATENTKRAV

1. Modulært grebsenhed (20, 220) til understøttelse og styring af et styrbart kateter (22) med mindst én afbøjningstråd (28), hvilken modulær grebsenhed (20, 220) omfatter;

en grebsdel (30, 32), der strækker sig langs en akse (A) for at blive fastgjort omkring en del af det styrbare kateter (22),

mindst én cylinder (80, 134), der er roterbart forbundet med grebsdelen (30, 32) for rotation omkring aksen (A),

kendetegnet ved, at

mindst ét aktiveringsskrueskaft (112, 130), der er placeret inde i grebsdelen (30, 32) og strækker sig gennem cylinderen (80, 134) til forbindelse med det styrbare kateters (22) afbøjningstråd (28), og

mindst ét tanddrev (122, 136), der gevindforbinder aktiveringsskrueskaftet (112, 130) og cylinderen (80, 134) for overførsel af rotationsbevægelse af cylinderen (80, 134) omkring aksen (A) til aksial bevægelse af aktiveringsskrueskaftet (112, 130) for at tilvejebringe bevægelse af afbøjningstråden (28) for oprulning af det styrbare kateter (22).

2. Modulær grebsenhed (20, 220) ifølge krav 1, der endvidere omfatter:

hvor cylinderen (80, 134) har en indvendig overflade, der har en flerhed af indvendige tænder (82),

tanddrevet (122, 136) har en udvendig overflade, der har en flerhed af udvendige tænder (84), der hver passer sammen med cylinderens (80, 134) indvendige tænder (82) til tilvejebringelse af rotationsbevægelse af tanddrevet (122, 136) som reaktion på rotationen af cylinderen (80, 134) omkring aksen (A),

aktiveringsskrueskaftet (112, 130) har en udvendig overflade, der har en flerhed af udvendige gevind (120), og

tanddrevet (122, 136) har en indvendig overflade, der har en flerhed af indvendige gevind (124), der gevindforbinder aktiveringsskrueskaftets (112, 130) udvendige gevind (120) for overførsel af rotationsbevægelse af tanddrevet (122, 136) til aksial bevægelse af aktiveringsskrueskaftet (112, 130).

3. Modulær grebsenhed (20, 220) ifølge krav 2, hvor det mindst ene aktiveringsskrueskaft indbefatter et par horisontale aktiveringsskrueskafter (112), der er placeret i afstands- og parallelt forhold i forhold til hinanden, således at hvert af dem er forbundet med en tilsvarende

afbøjningstråd (28), og det mindst ene tanddrev indbefatter et par tanddrev (122), der hvert er placeret radialt mellem ét af de horisontale aktiveringsskrueskafter (112) og cylinderen (80) og gevindforbinder det horisontale aktiveringsskrueskaft (112) og cylinderen (80).

4. Modulær grebsenhed (20, 220) ifølge krav 3, hvor de udvendige gevind (120) af hvert af de horisontale aktiveringsskrueskafter (112) strækker sig i modstående retninger af hinanden for at tilvejebringe aksial bevægelse af de horisontale aktiveringsskruer (112) i modstående aksiale retninger.

5. Modulær grebsenhed (20, 220) ifølge krav 3, hvor de udvendige gevind (120) af hvert af de horisontale aktiveringsskrueskafter (112) strækker sig i den samme retning i forhold til hinanden for at tilvejebringe aksial bevægelse af de horisontale aktiveringsskruer (112) i den samme aksiale retning.

6. Modulær grebsenhed (20, 220) ifølge krav 3, hvor de udvendige gevind (120) af hvert af de horisontale aktiveringsskrueskafter (112) er orienteret i forskellige stigninger i forhold til hinanden for at tilvejebringe forskellige hastigheder af aksial bevægelse af de horisontale aktiveringsskrueskafter (112) i forhold til hinanden pr. omdrejning af cylinderen (80).

7. Modulær grebsenhed (220) ifølge krav 2, der endvidere omfatter:
hvor det mindst ene aktiveringsskrueskaft indbefatter et par horisontale aktiveringsskrueskafter (112) og et par vertikale aktiveringsskrueskafter (130), der er placeret i afstands- og parallelt forhold i forhold til hinanden, således at hvert af dem er forbundet med en tilsvarende afbøjningstråd (28),
det mindst ene tanddrev indbefatter et par bagtanddrev (122) og et par fronttanddrev (136),
den mindst ene cylinder indbefatter en første cylinder (80) og en anden cylinder (134), der er aksialt adskilt fra hinanden,
bagtanddrevene (122), der hvert er placeret radialt mellem ét af de horisontale aktiveringsskrueskafter (112) og den første cylinder (80) og gevindforbinder de horisontale aktiveringsskrueskafter (112) og den første cylinder (80), og
fronttanddrevene (136), der hvert er placeret radialt mellem ét af de vertikale aktiveringsskrueskafter (130) og den anden cylinder (134) og gevindforbinder de vertikale aktiveringsskrueskafter (130) og den anden cylinder (134).

8. Modulær grebsenhed (220) ifølge krav 7, hvor de udvendige gevind (120) af hvert af de horisontale aktiveringsskrueskafter (112) strækker sig i modstående retninger i forhold til hinanden for at tilvejebringe aksial bevægelse af de horisontale aktiveringsskruer (112) i modstående aksiale retninger for at bevæge afbøjningstrådene (28) i modstående retninger i forhold til hinanden for at gøre det muligt for det styrbare kateter (22) at blive oprullet i to modstående horisontale retninger, og de udvendige gevind (120) af hvert af de vertikale aktiveringsskrueskafter (130) strækker sig i modstående retninger i forhold til hinanden for at tilvejebringe aksial bevægelse af de vertikale aktiveringsskruer (130) i modstående aksiale retninger for at bevæge afbøjningstrådene (28) i modstående retninger i forhold til hinanden for at gøre det muligt for det styrbare kateter (22) at blive oprullet i to modstående vertikale retninger.

9. Modulær grebsenhed (20, 220) ifølge krav 1, der endvidere omfatter;
en første konnektor (62) og en anden konnektor (64), der hver er generelt hjulformet og strækker sig omkring aksen (A) og hver har en frontflade (66) og en bagflade (68) og hver har en udvendig væg (70), der strækker sig aksialt mellem frontfladen (66) og bagfladen (68);
en ring (72), der strækker sig radialt udefter fra den udvendige væg (70) af hver af de første og anden konnektorer (62, 64) for aksialt at opdele hver af de første og anden konnektorer (62, 64) i et frontsegment (74) og et bagsegment (76); og
hvor cylinderen (80, 134) er aksialt placeret mellem ringene (72) af de første og anden konnektorer (62, 64) og roterbart placeret på bagsegmentet (76) af den anden konnektor (64) og frontsegmentet (74) af den første konnektor (62).

10. Modulær grebsenhed (20, 220) ifølge krav 9, hvor de første og anden konnektorer (62, 64) hver definerer en central passage (78), der strækker sig derigennem langs aksen (A) for modtagelse af det styrbare kateter (22).

11. Modulær grebsenhed (20, 220) ifølge krav 10, hvor frontfladen (66) af hver af de første og anden konnektorer (62, 64) definerer mindst én kanal (104), der strækker sig deri adskilt fra den centrale passage (78), og hvor den anden konnektor (64) indbefatter mindst ét ben (106), der modtages af kanalen (104) af den første konnektor (62), der forbinder de første og anden konnektorer (62, 64) i aksialt adskilt forhold med hinanden.

12. Modulær grebsenhed (20, 220) ifølge krav 11, hvor de første og anden konnektorer (62, 64) hver definerer mindst én udvendig passage (108, 110), der strækker sig derigennem, og hvor aktiveringsskrueskaftet (112, 130) strækker sig gennem de udvendige passager (108, 110) af de første og anden konnektorer (62, 64).

13. Modulær grebsenhed (22, 220) ifølge krav 1, hvor aktiveringsskrueskaftet (112, 130) indbefatter et fremspring (114), der strækker sig radialt mod aksen (A) til forbindelse med afbøjningstråden (28).

14. Modulær grebsenhed (20, 220) ifølge krav 13, hvor hvert af fremspringene definerer en niche (116), der har en T-form, der strækker sig deri for aftagelig modtagelse af afbøjningstråden (28) for at forbinde forbindelsestråden (28) med aktiveringsskrueskaftet (112, 130) og for at gøre det muligt for afbøjningstråden (28) at glide inde i nichen (116) under aksial distal bevægelse af aktiveringsskrueskaftet (112, 130).

15. Modulær grebsenhed (20, 220) ifølge krav 14, der endvidere omfatter en trådfastklemningsanordning (118), der er fast placeret omkring afbøjningstråden (28) aksialt proksimalt for nichen (116) af de horisontale aktiveringsskrueskafter (112, 130) og direkte stødende op til en distal hætte (100) til at forhindre afbøjningstråden (28) i aksialt at glide ud af nichen (116) under aksial proksimal bevægelse af aktiveringsskrueskaftet (112, 130).

DRAWINGS

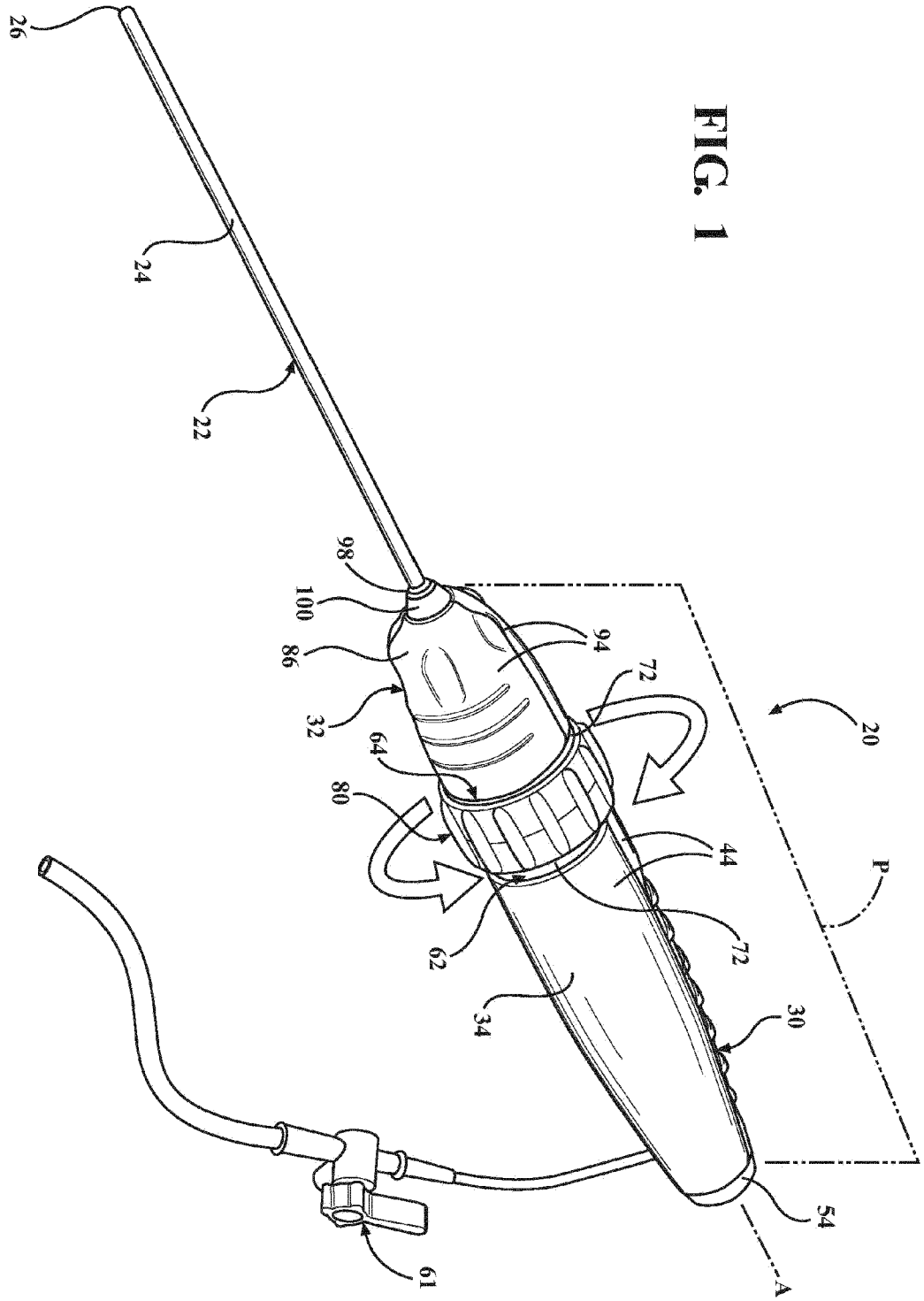

FIG. 1

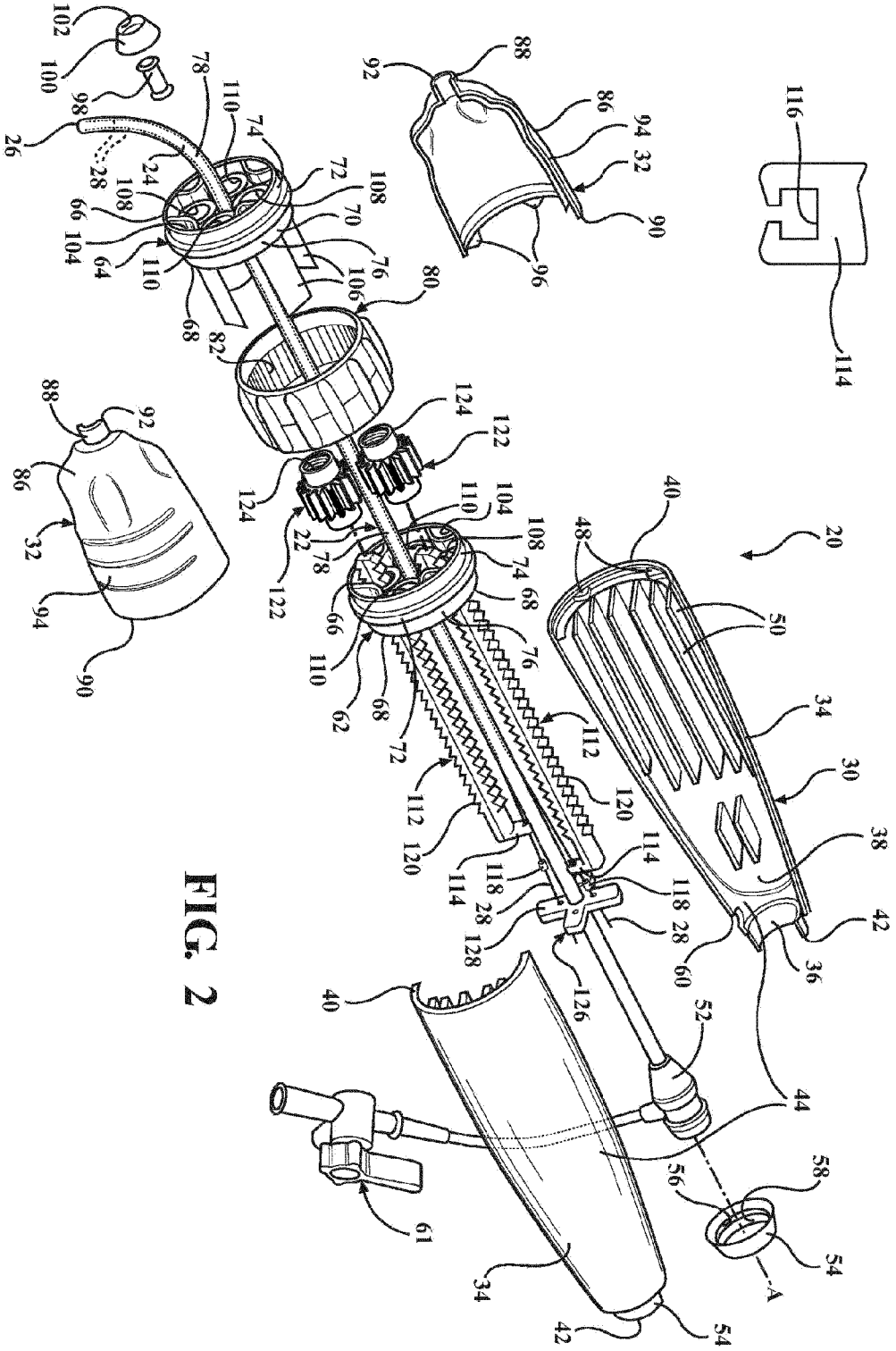

FIG. 2

FIG. 2A

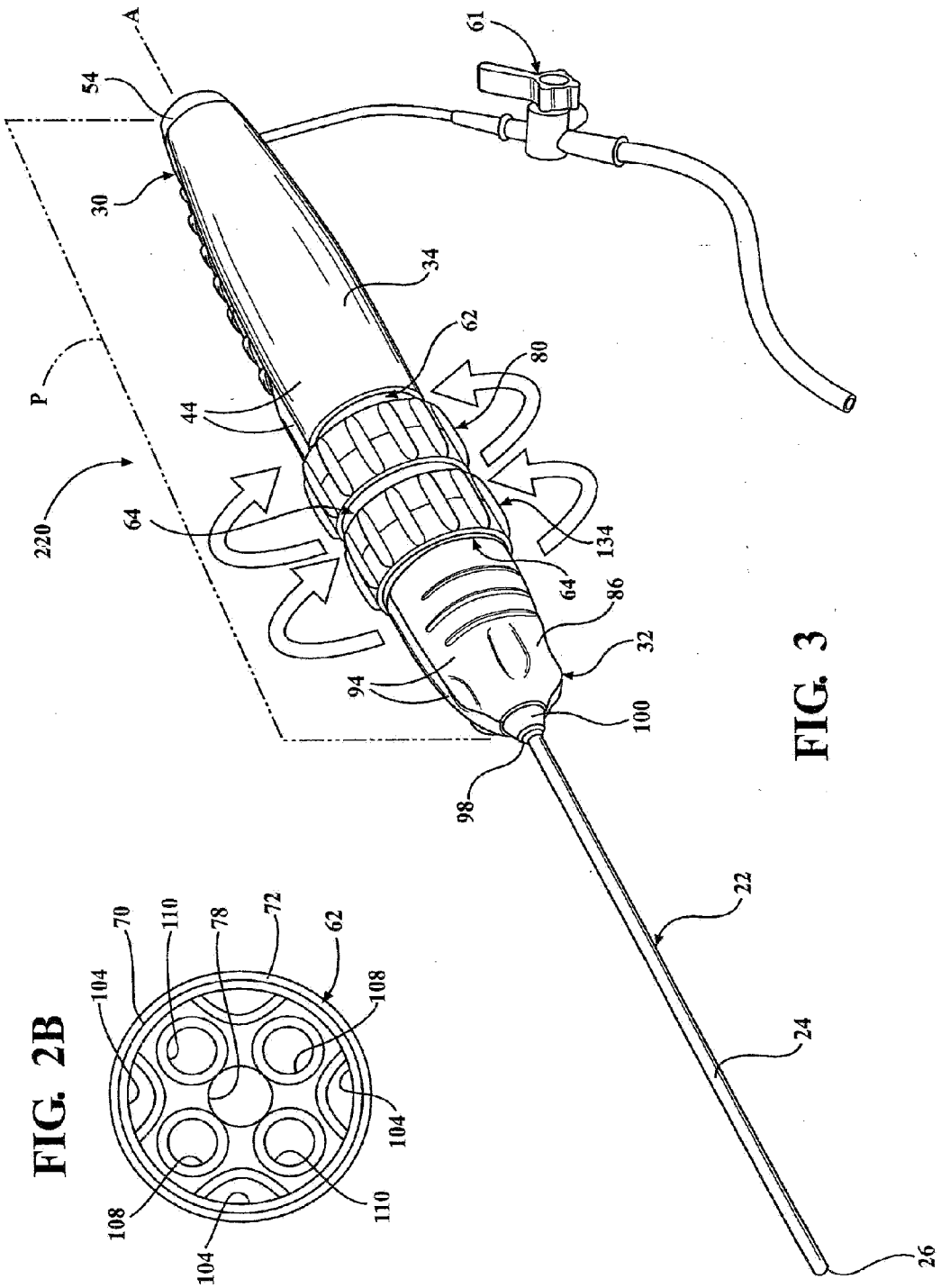
A
54
30
61
34
62
80
P
44
220
64
134
64
86
32
94
100
98
22
24
26

FIG. 3

70
110
78
72
62
104
108
104
108
110
104

FIG. 2B

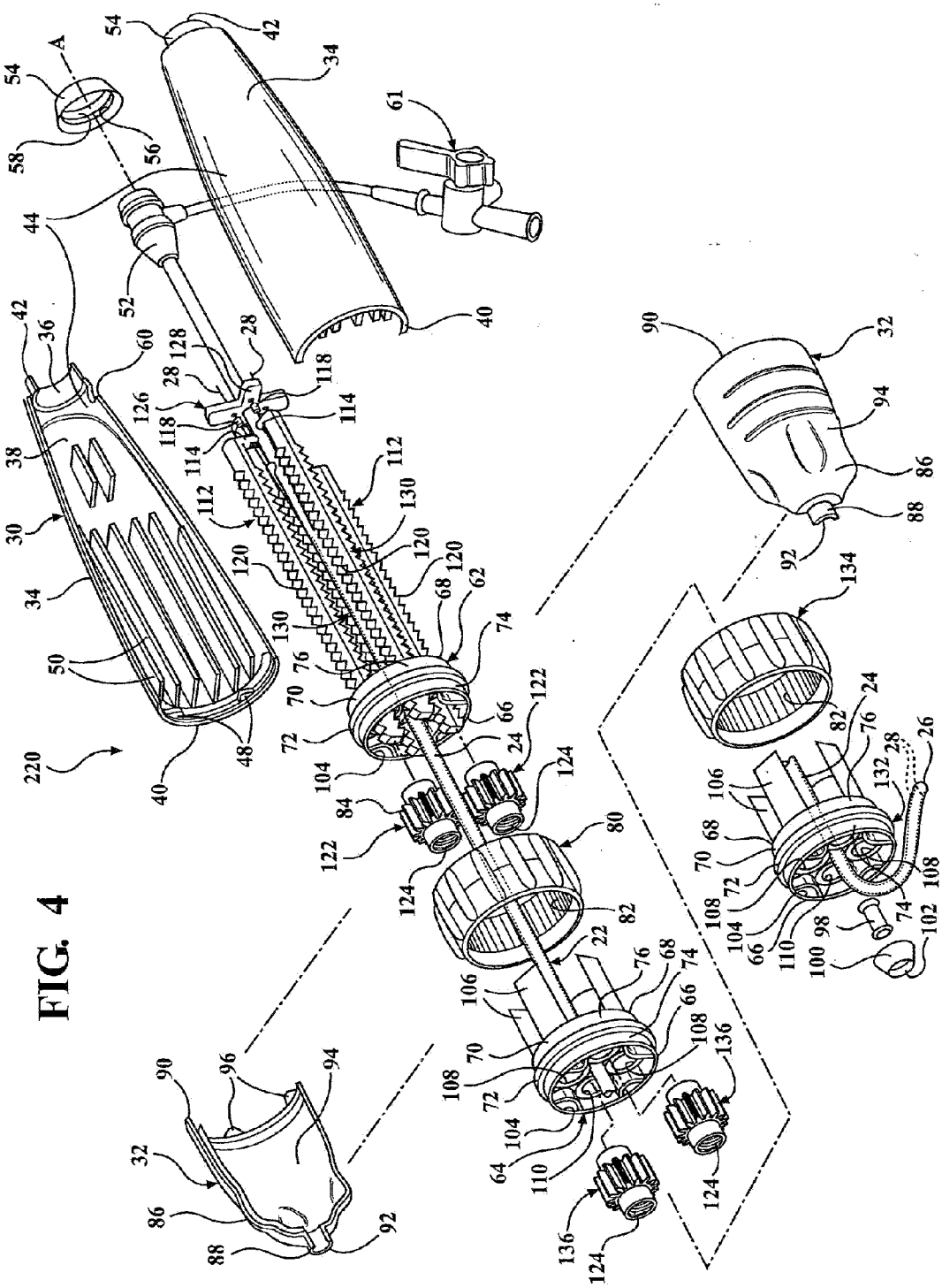

FIG. 4