

MEDICAL DEVICE HAVING ARTICULATION MEMBER AND METHODS OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority from U.S. Provisional Application No. 63/264,668, filed on November 30, 2021, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] The disclosure relates generally to medical devices and related methods of use. For example, the disclosure relates to medical tools and methods related to accessing target sites using scopes and performing medical procedures at the target sites.

BACKGROUND

[0003] In certain medical procedures, it may be necessary to articulate a portion of a medical device, such as a scope (e.g., an endoscope, a duodenoscope, a ureteroscope, etc.). For example, a medical procedure may require accessing a target site via a tortuous path by bending or articulating one or more portions of the scope.

[0004] During an endoscopic procedure, for example, a user inserts a scope into a body lumen of a patient. The user utilizes actuation members on a handle of the endoscope to control the scope during insertion and/or during the procedure. A user may observe torque forces when operating the actuation members as the scope is bent using the actuation members. For example, as a user rotates an actuation member, such as a knob, from a neutral position, the user may observe a greater torque force as the actuation member is rotated further from the neutral position. This force may be related to an amount of material at bending regions on the scope.

In some cases, reducing the material may reduce these forces. However, reduction of material may increase the difficulty of manufacturing the scope and/or may make the scope less robust. This disclosure may solve one or more of these problems or other problems in the art. The scope of the disclosure, however, is defined by the attached claims and not the ability to solve a specific problem.

SUMMARY OF THE DISCLOSURE

[0005] According to an aspect, a medical device includes a handle, a shaft extending from the handle, first and second articulation wires coupled to the handle, and an articulation member at a distal end of the shaft. The articulation member includes a central longitudinal axis within a first bending plane, the first and second articulation wires lie within the first bending plane, the articulation member includes a plurality of links arranged about the central longitudinal axis, a first link of the plurality of links is attached to an adjacent, second link of the plurality of links via a first pair of hinges, a first hinge from the first pair of hinges is arranged on a first side the first bending plane, and a second hinge from the first pair of hinges is located on a second side of the bending plane, opposite the first side.

[0006] The first hinge and the second hinge each may include a body portion having a radially outer surface flush with a radially outer surface of each of the first link and the second link, and the first hinge and the second hinge each may include a protrusion extending from the body portion.

[0007] The protrusion may extend from an inner surface of the body portion toward the central longitudinal axis.

[0008] Each protrusion may define a slot receiving one of the first and second actuation wires, and the slot may be exposed to a lumen of the articulation member.

[0009] The exposed portion of the slot in the first hinge may face the first bending plane, and the exposed portion of the slot in the second hinge may face the first bending plane, and the slot in the first and second hinges may face opposite directions.

[0010] The protrusion may have a generally semi-circular shape in cross-section, and the slot may have a generally semi-circular shape in cross-section.

[0011] The device may further include a first articulation lumen extending through each of the plurality of links, and a second articulation lumen, parallel to the first articulation lumen, extending through each of the plurality of links, where the first articulation lumen may be in communication with the slot in the first hinge, and the second articulation lumen is in communication with the slot in the second hinge.

[0012] Proximal movement or distal movement of each of the first and second articulation wires may be configured to bend the articulation member.

[0013] Each of the first and second articulation wires may be configured to move within a corresponding slot to bend the articulation member.

[0014] The first and second articulation wires may lie in the bending plane when the articulation member is in a neutral position.

[0015] Bending the articulation member in a first direction relative to the first bending plane may cause the first articulation wire to be more exposed from a corresponding slot than the second articulation wire is exposed from a corresponding slot.

[0016] The device may further include a second pair of hinges connecting the second link to an adjacent, third link, the third link being different from the first link, and the second pair of hinges may be radially offset by ninety-degrees relative to the first pair of hinges.

[0017] The device may further include third and fourth articulation wires coupled to the handle and lying within a second bending plane containing the central longitudinal axis, where a first hinge from the second pair of hinges may be arranged on a first side of the second bending plane, and a second hinge from the second pair of hinges may be arranged on a second side of the second bending plane, opposite the first side.

[0018] Each of the pair of second hinges may include a protrusion defining a slot receiving an actuation wire, and the slot of each of the pair of second hinges may be exposed to a lumen of the articulation member.

[0019] The first bending plane may be orthogonal to the second bending plane.

[0020] According to another aspect, an articulation member for a medical device may include a first link, a second link, and a first hinge and a second hinge, the first hinge and the second hinge connecting the first link to the second link and arranged on radially opposite sides of the articulation member, where each of the first hinge and the second hinge includes a slot exposed to a central lumen of the articulation member, and where each slot is configured receive an articulation wire.

[0021] The articulation member may further include a third link adjacent the second link, and a third hinge and a fourth hinge connecting the third link to the second link, where the third hinge and the fourth hinge may be radially offset by ninety-degrees from the first hinge and the second hinge.

[0022] The first link and the second link may define a first bending plane, where the third link and the fourth link may define a second bending plane, and where the second bending plane may be orthogonal to the first bending plane.

[0023] The first link may be positioned on a first side of the first bending plane and the second link may be positioned on a second side of the first bending plane, opposite the first side, and the third link may be positioned on a first side of the second bending plane and the fourth link may be positioned on a second side of the second bending plane, opposite the first side.

[0024] According to another aspect, a method for treating a patient includes advancing a distal end of a shaft to a target site in a patient, where the distal end includes an articulation member having a plurality of links, where adjacent links are connected via a pair of hinges, actuating a first actuator to bend the articulation member relative to a bending plane, where the bending plane includes a central longitudinal axis of the articulation member, and where a first link from the pair of links is positioned on a first side of the bending plane and a second link from the pair of links is positioned on a second side of the bending plane, opposite the first side, where bending the articulation member causes a first articulation wire to be exposed from the first hinge and a second articulation wire to be covered by the second hinge, and performing a medical procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The accompanying drawings, which are incorporated in and constitute a part of this application, illustrate various exemplary embodiments and together with the description, serve to explain the principles of exemplary embodiments.

[0026] FIG. 1 is a schematic of a medical system according to one or more aspects of the disclosure;

[0027] FIGS. 2A and 2B are perspective views of an articulation member of the medical system of FIG. 1;

[0028] FIGS. 3A and 3B are side views of the articulation member of FIGS. 2A and 2B;

[0029] FIGS. 4A and 4B are perspective views of a segment of the articulation member of FIGS. 2A and 2B;

[0030] FIG. 5 is a cross-section of the articulation member taken along the line 5-5 in FIG. 2B; and

[0031] FIG. 6 is a side view of the articulation member of FIGS. 2A and 2B in a bent configuration.

DETAILED DESCRIPTION

[0032] The disclosure is described with reference to exemplary medical systems for performing medical procedures using a scope (e.g., endoscope, ureteroscope, duodenoscope, colonoscope, or the like) on a target site. The devices associated with the medical systems may improve the functionality of the scope by reducing a force felt by an operator or a user, and/or may improve manufacturing of the scopes.

[0033] Reference to any particular device or procedure is provided in this disclosure only for convenience and not intended to limit the disclosure. A person of ordinary skill in the art would recognize that the concepts underlying the disclosed devices and methods may be utilized in any suitable device or procedure. For example, embodiments of the articulation member may be used in any medical device requiring a bending portion, including catheters, sheaths, scopes, and the like, and in any medical procedure, including laparoscopic, endoscopic, bronchoscopic, urologic, cardiovascular, and other procedures. The disclosure may be understood with reference to the following description and the appended drawings, wherein like elements are referred to with the same reference numerals.

[0034] Both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the features, as claimed. As used herein, the terms “comprises,” “comprising,” “having,” “including,” or other variations thereof, are intended to cover a non-exclusive inclusion such that a process, method, article, or apparatus that comprises a list of elements does not include only those elements, but may include other elements not expressly listed or inherent to such a process, method, article, or apparatus.

[0035] For ease of description, portions of the device and/or its components are referred to as proximal and distal portions. It should be noted that the term “proximal” is intended to refer to portions closer to a user of the device, and the term “distal” is used herein to refer to portions further away from the user. Similarly, extends “distally” indicates that a component extends in a distal direction, and extends “proximally” indicates that a component extends in a proximal direction. Further, as used herein, the terms “about,” “approximately” and “substantially” indicate a range of values within +/- 10% of a stated or implied value. Additionally, terms that indicate the geometric shape of a component/surface include approximate shapes.

[0036] Referring to FIG. 1, a medical system 10 (also referred to herein as a medical device) according to some examples is shown. Medical system 10 includes a flexible shaft 30 (e.g., a catheter) and a handle 20 coupled to a proximal end of flexible shaft 30. Flexible shaft 30 may include a body 40 extending from handle 20, an articulation member 50 extending from a distal end of body 40, and a distal portion 60 extending from a distal end of articulation member 50. Body 40, articulation member 50, and distal portion 60 may be individual members connected together (e.g., via adhesive, rivets, screw threads, or any similar manner) or may be

formed as a single, unitary member. Medical system 10 may include one or more lumens each extending through body 40, articulation member 50, and distal portion 60. Handle 20 may include multiple actuating devices (e.g., actuators) which control articulation of articulation member 50 in multiple directions, and movement of associated components and tools, as will be described herein. Handle 20, body 40, articulation member 50, and distal portion 60 extend along a central longitudinal axis A, which may define a neutral position of articulation member 50.

[0037] With continued reference to FIG. 1, handle 20 may include one or more ports 29a, 29b, 29c for inserting and/or removing tools, fluids, or other materials into and/or from the patient via shaft 30. Port 29b may be used to introduce one or more medical tools through a lumen (e.g., a working channel) of shaft 30. The medical tool may be any tool, such as, but not limited to, a snare, a knife, forceps, an ablation laser, or other suitable tool for performing a medical procedure. A distal opening (not shown) may be disposed in a distal end face of distal portion 60. The lumen, or a different lumen, may also be in communication with an umbilicus (not shown) via port 29a for introducing fluid and/or providing suction to the lumen. In addition, one or more electrical cables may extend from the proximal end of medical system 10 and/or the umbilicus to articulation member 50 and/or distal portion 60 and may provide a user with electrical control over imaging, lighting, and/or other electrical devices or components of medical system 10. Such electrical cables may carry imaging signals from the distal end of flexible shaft 30 proximally to be processed and/or displayed on a display. A third port 29c may provide access to one or more lumens described herein.

[0038] Articulation member 50 is shown in FIGS. 2A and 2B. Articulation member 50 may include a plurality of links 51, including a first link 51a, a second link

51b, a third link 51c, a fourth link 51d, etc. The number of links 51 is not limited.

Adjacent links 51 may be connected via hinges or flexible regions. In some examples, hinges may be "living hinges" including a thin, flexible region formed as a unitary member with adjacent links 51 and including a material of articulation member 50. For example, first link 51a and second link 51b may be connected via a pair of first hinges 60a, 60b. First hinges 60a, 60b may be positioned on radial opposite sides of articulation member 50 from each other, for example 180 degrees from one another about axis A. Second link 51b and third link 51c may be connected by a pair of second hinges 62a, 62b. Second hinges 62a, 62b may be positioned on radial opposite sides of articulation member 50 from each other, for example 180 degrees from one another about axis A. Second hinges 62a, 62b may be radially offset by 90 degrees about axis A from first hinges 60a, 60b. Third link 51c and fourth link 51d may be connected by a pair of hinges 64a, 64b. Third hinges 64a, 64b may be positioned on radial opposite sides of articulation member 50 from each other, for example 180 degrees from one another about axis A.

[0039] The arrangement shown in the Figures may allow articulation member 50 to be deflected from a neutral position along longitudinal axis A in four directions, e.g., up, down, left, and right, each direction being approximately 90 degrees to an adjacent direction. Alternatively, it will be understood that the hinges may all be positioned along articulation member 50 such that articulation member may be deflected in only two directions, e.g., up and down or left and right. For example, articulation member 50 may include hinges that may allow articulation member 50 to bend in only two directions. In other words, articulation member 50 may be formed with hinges 60a, 60b and hinges 64a, 64b, but not hinges 62a, 62b. In this example, links 51b, 51c (and corresponding links 51 that allow articulation member 50 to bend

in the same direction as links 51b, 51c) may be formed as a unitary member and/or may not move relative to each other.

[0040] Articulation member 50, including links 51 and hinges, may be formed as a single, unitary member, e.g., via extrusion molding or three-dimensional (3D) printing. Alternatively, adjacent links 51 of articulation member 50 may be attached via hinges using ultrasonic welding or the like. A material of articulation member 50 may include, for example, plastics that may be flexible at room temperature, such as nylon, polypropylene, polyethylene, polycarbonate, or the like. These materials may provide articulation member 50 sufficient flexibility to navigate a tortuous path while also providing sufficient rigidity to receive medical tools and to remove tissue when performing a medical procedure within the body.

[0041] With continued reference to FIGS. 2A and 2B, each link 51 includes four articulation wire lumens 70. Lumens 70 are equally spaced about each link 51, each lumen 70 being approximately 90 degrees about axis A from adjacent lumens 70. While four lumens 70 are shown, it will be understood that only two lumens 70, equally spaced about each link 51, may be provided. For example, four lumens 70 may allow articulation member 50 to be deflected from a neutral position along longitudinal axis A in four directions (up, down, left, and right), while two lumens 70 may allow articulation member 50 to be deflected in only two directions (up and down, or left, and right). Each link 51 may also include a generally central lumen such that a lumen 56 (e.g., FIGS. 4A and 4B) may be formed through articulation member 50 by the generally central lumen of each link 51. Lumen 56 may be fluidly connected to one or more corresponding lumens of body 40. Lumen 56 may receive one or more medical instruments (e.g., a grasper, a laser fiber, a suction device,

scissors, a scalpel, etc.) such that a medical procedure may be performed on a target tissue, as described herein.

[0042] As shown in FIGS. 2B and 4B, articulation wires 80a, 80b, 80c, and 80d may be disposed in corresponding lumens 70. Each of articulation wires 80a, 80b, 80c, 80d may be connected at a distal end to distal portion 60 and/or a portion of articulation member 50 via adhesive, ultrasonic welding, crimping, or other similar technique. Proximal ends of articulation wires 80a, 80b, 80c, 80d may be connected to articulation control devices 22 or 24. For example, articulation wires 80a, 80c may be connected to control device 22. Rotational movement of control device 22 in a first direction, e.g., a clockwise direction, may cause articulation member 50 to bend in a first direction, e.g., up relative to longitudinal axis A. Rotating control device 22 in a second direction, e.g., a counterclockwise direction, may cause articulation member 50 to move in a second direction, e.g., down relative to longitudinal axis A. Articulation wires 80b, 80d may be attached to control device 24 and rotation of device 24 in a first direction and a second direction, e.g., a clockwise direction and a counterclockwise direction, may cause articulation member 50 to move relative to longitudinal axis A. For example, rotating control device 24 in the first direction may cause articulation member 50 to move right relative to longitudinal axis A. Rotating control device 24 in the second direction may cause articulation member 50 to move left relative to longitudinal axis A.

[0043] One or more bending planes may be defined by a plane perpendicular to the page of FIGS. 3A and 3B and along the longitudinal axis A shown in FIGS. 3A and 3B. Each hinge (e.g., hinge 60a, 60b, etc.) lies in a corresponding bending plane when articulation member 50 is in a straight configuration, as shown in FIG. 3B. FIG. 3A illustrates articulation member 50 as shown in FIG. 3B, but without articulation

wires 80 for ease of understanding. Each of the bending planes may be offset by approximately five degrees in a clockwise direction and/or a counterclockwise direction for each successive set of hinges. This arrangement may cause articulation member 50 to bend along a bending plane located along longitudinal axis A, and actuation wires 80b and 80d, and their corresponding lumens 70, lie in that bending plane when articulation member 50 is in the straight configuration. The arrangement of offset bending planes may also cause articulation member 50 to twist in a helical shape as articulation member 50 bends from its proximal end to its distal end.

[0044] In addition, a bending segment is formed by, or includes, any two adjacent links 51, such as bending segment 52 that includes links 51b, 51c. Bending segment 52 may move relative to its adjacent link 51a via hinges 60a, 60b, and bending segment 52 may move relative to its adjacent link 51d via hinges 64a, 64b.

[0045] Hinge 60a may be positioned above the bending plane and longitudinal axis A and hinge 60b may be positioned below the bending plane and longitudinal axis A in FIG. 3A. The arrangement of hinges and wires allows a pivot point for bending segment 52 relative to link 51a to be located on or near the bending plane and longitudinal axis A. For example, as discussed above, actuating wire 80b extends parallel to longitudinal axis A as shown in FIG. 3B. Actuating wire 80b may allow bending segment 52 to bend relative to link 51a at a point along actuating wire 80b.

[0046] Hinge 64a may be positioned below the bending plane (e.g., a first bending plane) and longitudinal axis A, and hinge 64b may be positioned above the bending plane and longitudinal axis A. The arrangement of hinges and wires allows a pivot point for bending segment 52 relative to link 51d also to be located on or near the bending plane and longitudinal axis A. A second bending plane may be

perpendicular to the first bending plane. For example, hinge 62a may be positioned above the second bending plane and hinge 62b may be positioned below the second bending plane (see. FIG. 2A). Similarly, hinge 66a may be positioned below the second bending plane and hinge 66b may be positioned above the second bending plane (FIG 2B). This may allow articulation joint 50 to bend in directions perpendicular to the first bending plane (e.g., up and down as well as right and left). Links 51a, 51b, 51c, and 51d, and associated hinges 60, may form a bending unit 58 (FIGS. 2A, 2B, and 3A) which may enable articulation member 50 to bend in right, left, up, and down directions as described herein. Multiple bending units 58 may form articulation member 50. For example, articulation member 50 may include any number of bending units 58 connected in series or, alternatively, formed as a unitary member in series, based on a desired and/or necessary length of articulation member 50. This arrangement of hinge locations above or below the bending plane may be selected by the user such that a bias or a twist in bending of articulation member 50 alternates between links to balance each other and deflect in a flat plane or to compound with each other and form a helix, based on an anatomy of the patient and/or a path for accessing a target site.

[0047] FIGS. 4A and 4B show links 51a and 51b and cross-sections of adjacent hinges 62a and 62b. Some or all of the hinges throughout member 50 may have the same or similar structure as hinges 62a and 62b, which will now be described.

[0048] Hinge 62a may include a body portion 62a1 extending generally parallel to longitudinal axis A between link 51b and link 51c. A radially outer surface of body portion 62a1 may be flush with a radially outer surface of articulation member 50. Body portion 62a1 has a width W1 measured perpendicular to axis A

and in line with body portion 62a2, a height H1 measured perpendicular to axis A and perpendicular to width W1, and a length L1 measured parallel to axis A. Width W1 may be approximately 0.020 inches to approximately 0.150 inches. For example, a length of width W1 may be sufficient for body portion 62a1 to encompass a diameter of an articulation wire and to include two walls of sufficient thickness on either side of the articulation wire. Length L1 may be approximately 0.020 inches to approximately 0.200 inches and may depend on the flexibility of the material and the desired bend angle of hinge 62a in each direction. Hinges (e.g., hinge 62a) may include a material capable of flexing at operating temperatures and may include one or more of nylon, polypropylene, polyethylene, or polycarbonate, or any composite thereof. The material may provide a sufficient balance of flexibility to articulation member 50 during bending and may provide sufficient resistance to compression or torsion in operation, as well as rigidity/structural integrity during manufacturing of articulation member 50. A material and/or a size of hinge 62a may be any material suitable to allow hinge 62a to bend or flex. A protrusion 62a2 may extend generally perpendicular from body portion 62a1 toward longitudinal axis A. Protrusion 62a2 may define a generally semi-circular slot 72, which may extend parallel to longitudinal axis A. Additionally, slot 72 may be open to lumen 56 of articulation member 50 (e.g., FIGS. 4A and 4B). It will be understood that slot 72 may be rectangular, or any other suitable shape, in cross-section. A shape of a cross-section of protrusion 62a2 may be similar to that of slot 72, e.g., the shape may be semi-circular. Semi-circular slot 72 may be an extension of a corresponding lumen 70 in links connected by hinge 62a, e.g., link 51b and adjacent link 51c (not shown in FIGs. 4A and 4B). Slot 72 may receive articulation wire 80a such that a portion of

articulation wire 80a may be exposed from slot 72, as shown in FIG. 4B. Wire 80a is therefore exposed to lumen 56 that extends through member 50.

[0049] Hinge 62b may have a similar design as hinge 62a. For example, a body portion 62b2 may extend generally parallel to longitudinal axis A. Body portion 62b1 and body portion 62b2 may have dimensions similar to those of body portions 62a1 and 62a2 based on a desired articulation of articulation member 50 in a direction perpendicular to hinges 60a, 60b, which may provide sufficient rigidity to articulation member 50 during bending and/or during manufacturing of articulation member 50. Each of a width, a height, and a length of body portions 62b1 or 62b2 may be the same and/or may be different from width W1, length L1, and height H1, respectively, of body portions 62a1 or 62a2. If width, height, and length of each body portion are different dimensions, a user may feel a different amount of torque when articulating articulation member 50 in different directions. A protrusion 62b2 may extend generally perpendicular from body portion 62b2 toward longitudinal axis A. A generally semi-circular slot 74 may be formed in protrusion 62b2 and may extend parallel to longitudinal axis A. Additionally, slot 74 may be open to lumen 56 of articulation member 50 (e.g., FIGS. 4A and 4B). As with slot 72, the cross-sectional shape of slot 74 is not limited. A shape cross-section of protrusion 62b2 may be similar to that of slot 74, e.g., the shape may be semi-circular. Slot 74 may receive wire 80c such that a portion of wire 80c is exposed, as shown in FIG. 4B. The reduced size of protrusions 62a2 and 62b2, relative to sizes of conventional hinges, may reduce an amount of material of hinges 62a and 62b. This may reduce the force necessary to bend articulation member 50 at hinges 62a and 62b, which may reduce an amount of torque necessary to be applied at control devices 22 and/or 24. In this manner, the force necessary to bend articulation member 50 may be reduced, which

may reduce fatigue and/or pain by a user. While not shown, all hinges, e.g., hinges 60a, 60b, may be similar in cross-section to hinges 62a, 62b. For example, the slots in each hinge may face different directions, but may all be open to lumen 56 of articulation member 50.

[0050] A cross-section of articulation member 50 taken along line 5-5 in FIG. 2B is shown in FIG. 5. The cross-section illustrates body portion 62a1 of hinge 62a and body portion 62b1 of hinge 62b, which connect links 51b and 51c. Gaps 82 and 84 are between links 51c and 51d. Gaps 82 and 84 are in regions between links 51c and 51d that are not filled by hinges 64a, 64b which connect links 51c and 51d. Each gaps 82, 84 may be rectangular in cross-section and have a partial annular shape. Two gaps, e.g., gap 82 and gap 84, may be formed between adjacent links 51, e.g., links 51c and 51d, in the regions not filled by hinges. Alternatively, gaps 82, 84 may be V-shaped, U-shaped, or Y-shaped. Gaps 82, 84 may be variable across a length of articulation member 50 which may elicit specific bending behavior and/or may allow procedural access to a target site. For example, changing a size and/or a position of the gaps may change a bend radius and/or an amount of articulation of articulation member 50 in the up/down and/or the left/right directions.

[0051] Cross-sections of articulation wire lumens 70 are also shown in FIG. 5. Articulation wire lumens 70 extend parallel to longitudinal axis A. Articulation wire lumens 70 may be circular in cross-section, or may have any other suitable cross-sectional shape. A distal end of each of articulation wires 80a, 80b, 80c, 80d may be attached at a distal end 54 of articulation member 50 using crimping, adhesive, welding, or other suitable fastening mechanism. Alternatively, or additionally, distal end portion 60 (which may include imaging, lighting, and other structural features, including an end effector) may be attached to distal end 54. In another example,

articulation wires 80a, 80b, 80c, 80d may be attached to distal end portion 60. Actuation of control devices 22 and/or 24 may cause articulation wires 80a, 80b, 80c, 80d to move proximally and distally within corresponding lumens 70 of links 51 and slots between lumens 70. Proximal movement of one or more of articulation wires 80a, 80b, 80c, 80d may cause articulation member 50 to bend from a first position, generally parallel to longitudinal axis A, to a second position, in which articulation member 50 is angled relative to longitudinal axis A, as shown in FIG. 6. Distal movement of one or more of articulation wires 80a, 80b, 80c, 80d may cause articulation member 50 to bend from the second position shown in FIG. 6 to the first position.

[0052] A method of performing a medical procedure using medical system 10 will be described. Distal end 54 of articulation member 50 (and distal end portion 60) may be inserted into the body via an opening (a natural orifice or an incision in the patient). Alternatively, distal end 54 of articulation member 50 may be advanced to the target site via an access catheter previously positioned within the body.

[0053] Once distal end 54 of articulation member 50 (and distal end portion 60) is positioned at the target site, articulation member 50 may be actuated. Alternatively, or additionally, articulation member 50 may be actuated as the distal end 54 is advanced to the target site to, for example, navigate tortuous paths. To actuate articulation member 50, one or both of control members 22, 24 may be actuated. For example, a user may rotate control member 22, which may cause articulation member 50 to move in an up-down direction. Similarly, rotation of control member 24 may cause articulation member 50 to move in a left-right direction. As a user rotates one or both of control members 22, 24, a force felt by the user may be less than a force when using conventional articulation members. For example, as

control members 22, 24 are rotated and articulation member 50 is bent relative to longitudinal axis A (e.g., FIG. 6), the reduced material of hinges 62, 64, 66, etc., may reduce a force necessary to bend articulation member 50.

[0054] Furthermore, slots 72, 74 may alternately expose and/or hide articulation wires 80 as articulation member 50 is bent relative to longitudinal axis A. For example, as articulation member 50 bends in a first direction, hinge 62a may bend to further expose slot 72 and, thus, further expose articulation wire 80a. This bending movement may also cause hinge 62b to bend to close off slot 74, which may hide or prevent articulation wire 80c from being seen (FIG. 6). As articulation member 50 is bent in the opposite direction, slot 72 may close, while further exposing slot 74. Similar movement in a direction orthogonal to hinges 62a, 62b may expose or hide slots in hinges 64. As articulation member bends in a second direction, opposite the first direction, hinge 62a may bend to close of slot 72 and, thus, hide slot 74.

[0055] It will be understood that one or more instruments or tools may be advanced along lumen 56 to perform a medical procedure at the target site. The user may continue to actuate control members 22, 24 to provide access to the target site from different directions, which may aid in performing the medical procedure. Additionally, or alternatively, tissue and/or fluids may be removed from the target site using suction, graspers, or the like. Once the medical procedure is complete, articulation member 50 may be removed from the body.

[0056] It will be understood that articulation member 50 may include any number of links 51. Further, the hinges connecting the links 51 may be positioned around articulation member 50 in any manner.

[0057] Medical system 10 may allow a user to operate a catheter, scope, sheath, or other device having an articulation member using less force than conventional articulation members. In this manner, the user may be able to perform a medical procedure in a more timely and/or cost effective manner, while minimizing harm to a patient. Moreover, medical system 10 may have fewer manufacturing failures, which may result in reduced costs for medical system 10 and/or the medical procedures using the same.

[0058] It will be apparent to those skilled in the art that various modifications and variations can be made to the disclosed device without departing from the scope of the disclosure. Other embodiments of the disclosure will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

CLAIMS

What is claimed is:

1. A medical device comprising:
 - a handle;
 - a shaft extending from the handle;
 - first and second articulation wires coupled to the handle; and
 - an articulation member at a distal end of the shaft, wherein the articulation member includes a central longitudinal axis within a first bending plane,
 - wherein the first and second articulation wires lie within the first bending plane, wherein the articulation member includes a plurality of links arranged about the central longitudinal axis, wherein a first link of the plurality of links is attached to an adjacent, second link of the plurality of links via a first pair of hinges, and wherein a first hinge from the first pair of hinges is arranged on a first side the first bending plane, and a second hinge from the first pair of hinges is located on a second side of the bending plane, opposite the first side.
2. The device according to claim 1, wherein the first hinge and the second hinge each includes a body portion having a radially outer surface flush with a radially outer surface of each of the first link and the second link, and wherein the first hinge and the second hinge each includes a protrusion extending from the body portion.
3. The device according to claim 2, wherein the protrusion extends from an inner surface of the body portion toward the central longitudinal axis.

4. The device according to claim 3, wherein each protrusion defines a slot receiving one of the first and second actuation wires, and wherein the slot is exposed to a lumen of the articulation member.

5. The device according to claim 4, wherein the exposed portion of the slot in the first hinge faces the first bending plane, and wherein the exposed portion of the slot in the second hinge faces the first bending plane, and the slots in the first and second hinges face opposite directions.

6. The device according to claims 4 or 5, wherein the protrusion has a generally semi-circular shape in cross-section, and wherein the slot has a generally semi-circular shape in cross-section.

7. The device according to any of claims 4-6, further comprising:
a first articulation lumen extending through each of the plurality of links; and
a second articulation lumen, parallel to the first articulation lumen, extending through each of the plurality of links,

wherein the first articulation lumen is in communication with the slot in the first hinge, and the second articulation lumen is in communication with the slot in the second hinge.

8. The device according to any of claims 2-7, wherein proximal movement or distal movement of each of the first and second articulation wires is configured to bend the articulation member.

9. The device according to claim 8, wherein each of the first and second articulation wires is configured to move within a corresponding slot to bend the articulation member.

10. The device according to claims 8 or 9, wherein the first and second articulation wires lie in the bending plane when the articulation member is in a neutral position.

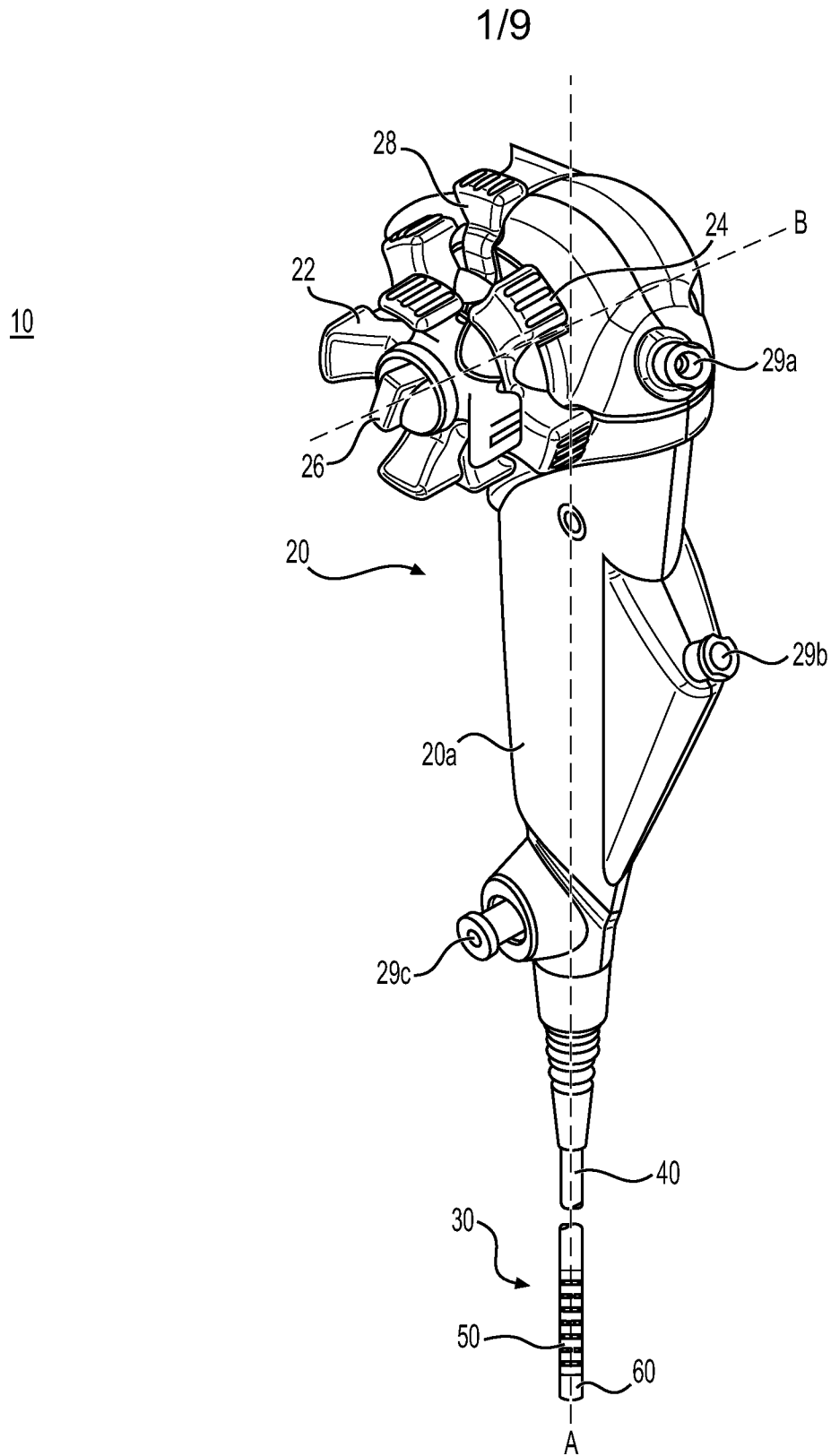
11. The device according to any of the preceding claims, wherein bending the articulation member in a first direction relative to the first bending plane causes the first articulation wire to be more exposed from a corresponding slot than the second articulation wire is exposed from a corresponding slot.

12. The device according to any of the preceding claims, further comprising a second pair of hinges connecting the second link to an adjacent, third link, the third link being different from the first link, and wherein the second pair of hinges are radially offset by ninety-degrees relative to the first pair of hinges.

13. The device according to claim 12, further comprising third and fourth articulation wires coupled to the handle and lying within a second bending plane containing the central longitudinal axis, wherein a first hinge from the second pair of hinges is arranged on a first side of the second bending plane, and wherein a second hinge from the second pair of hinges is arranged on a second side of the second bending plane, opposite the first side.

14. The device according to any of claims 12 or 13, wherein each of the pair of second hinges includes a protrusion defining a slot receiving an actuation wire, and wherein the slot of each of the pair of second hinges is exposed to a lumen of the articulation member.

15. The device according to any of claims 12-14, wherein the first bending plane is orthogonal to the second bending plane.



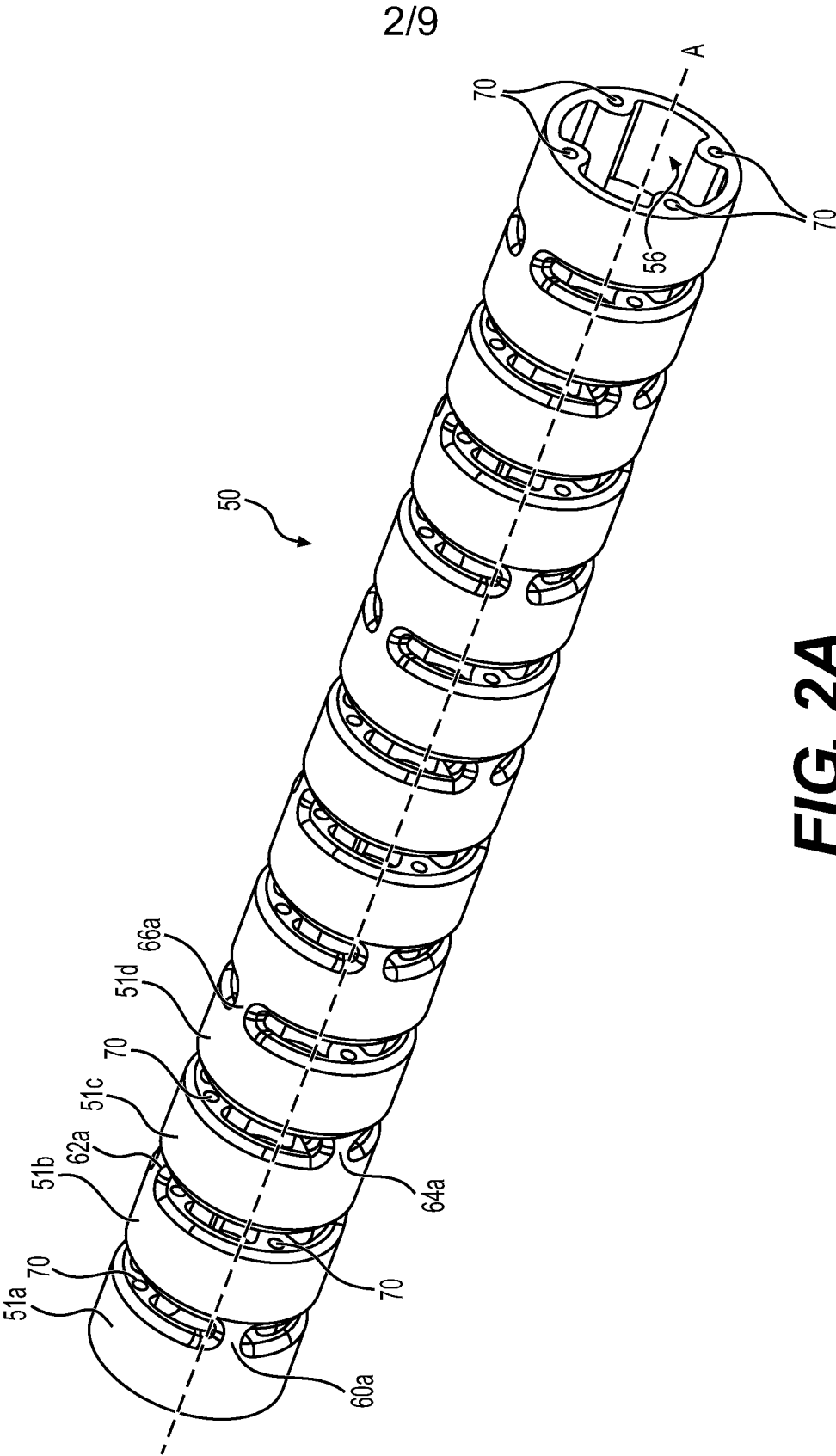


FIG. 2A

3/9

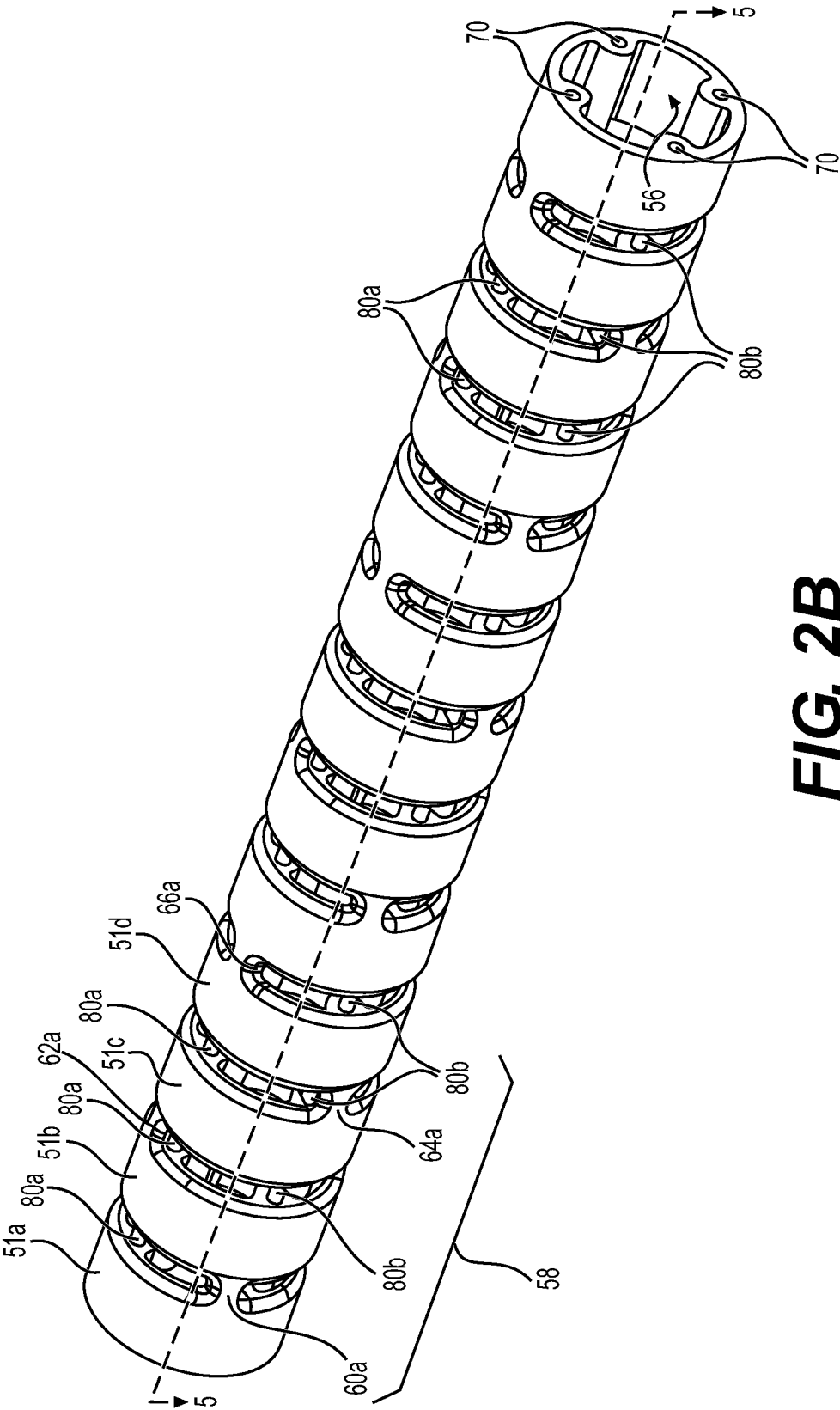


FIG. 2B

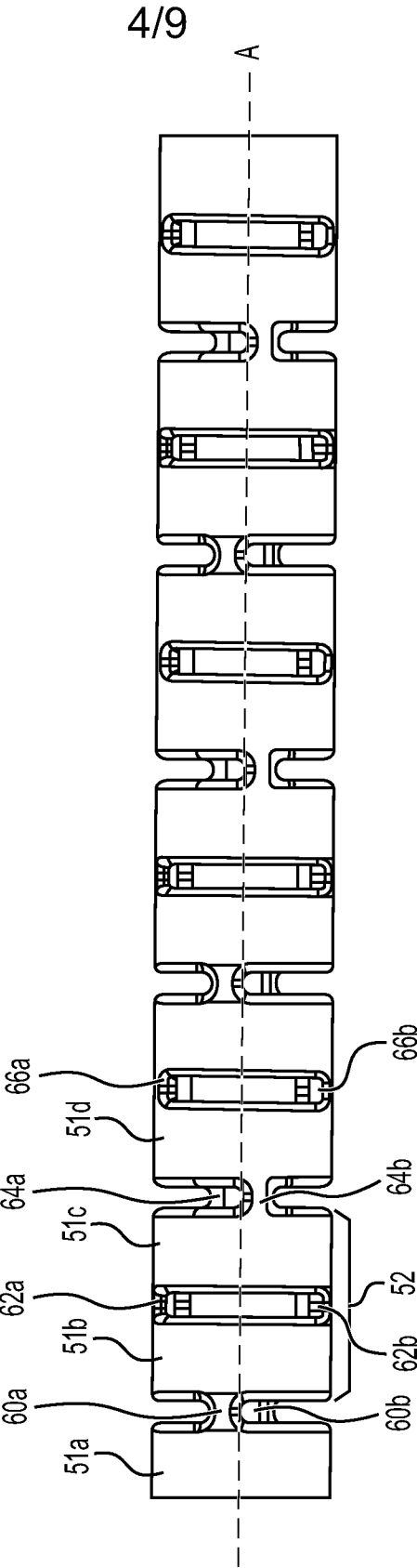
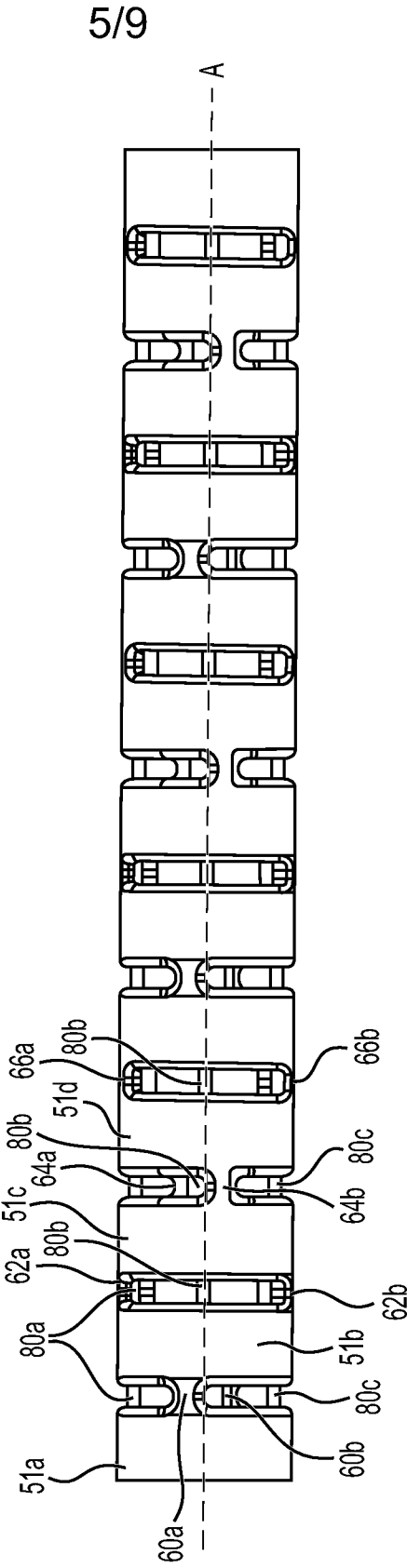


FIG. 3A



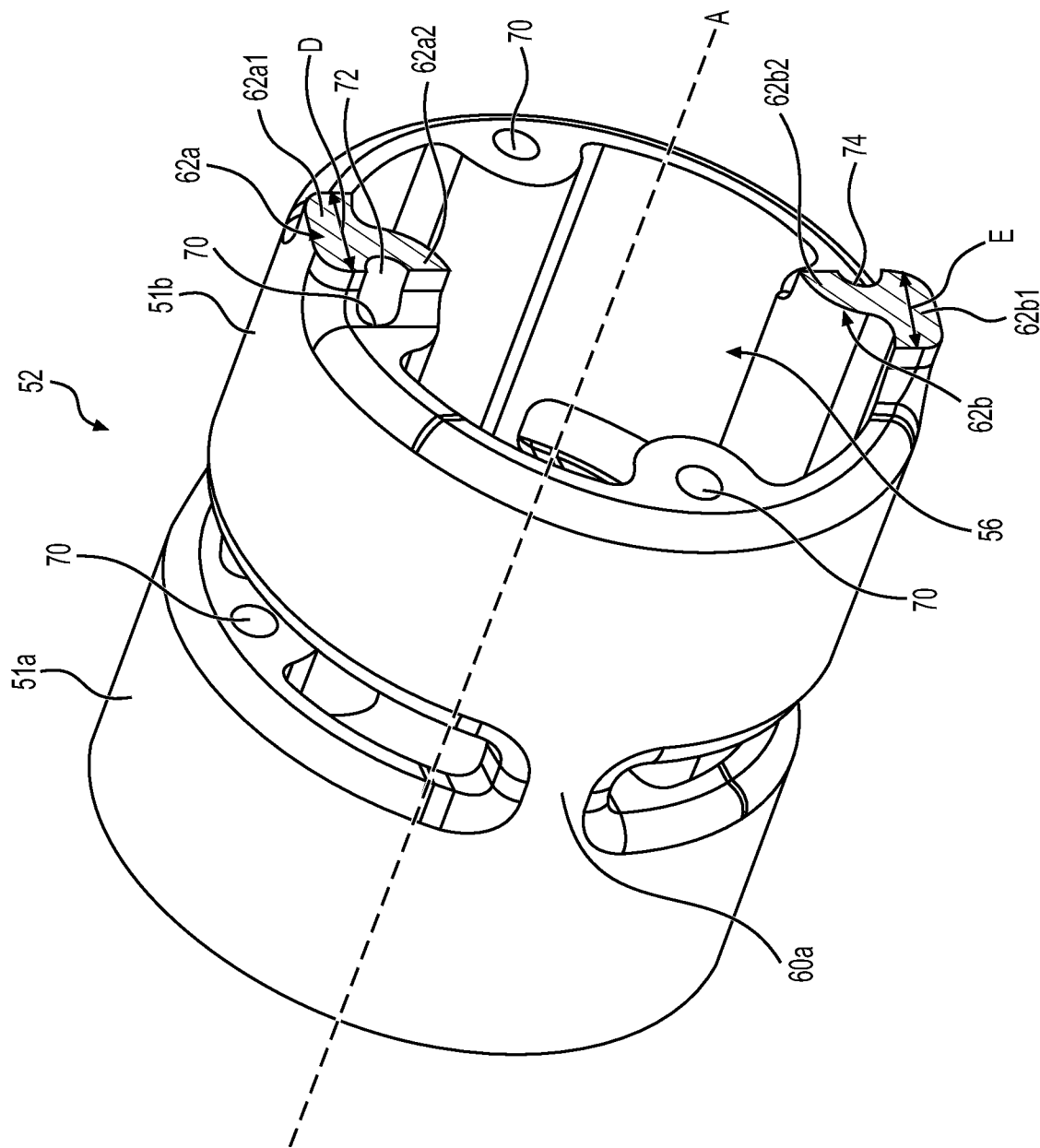


FIG. 4A

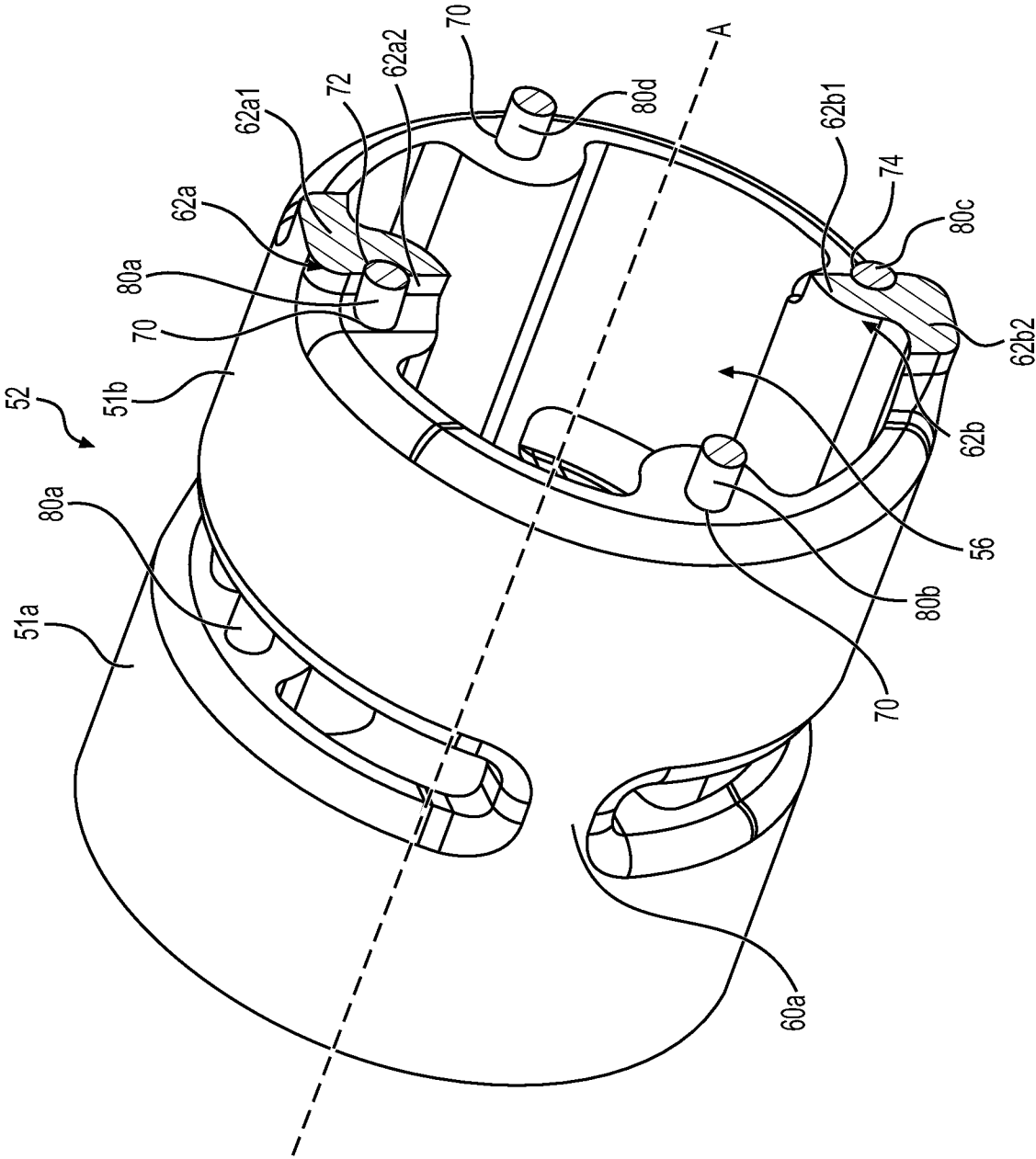


FIG. 4B

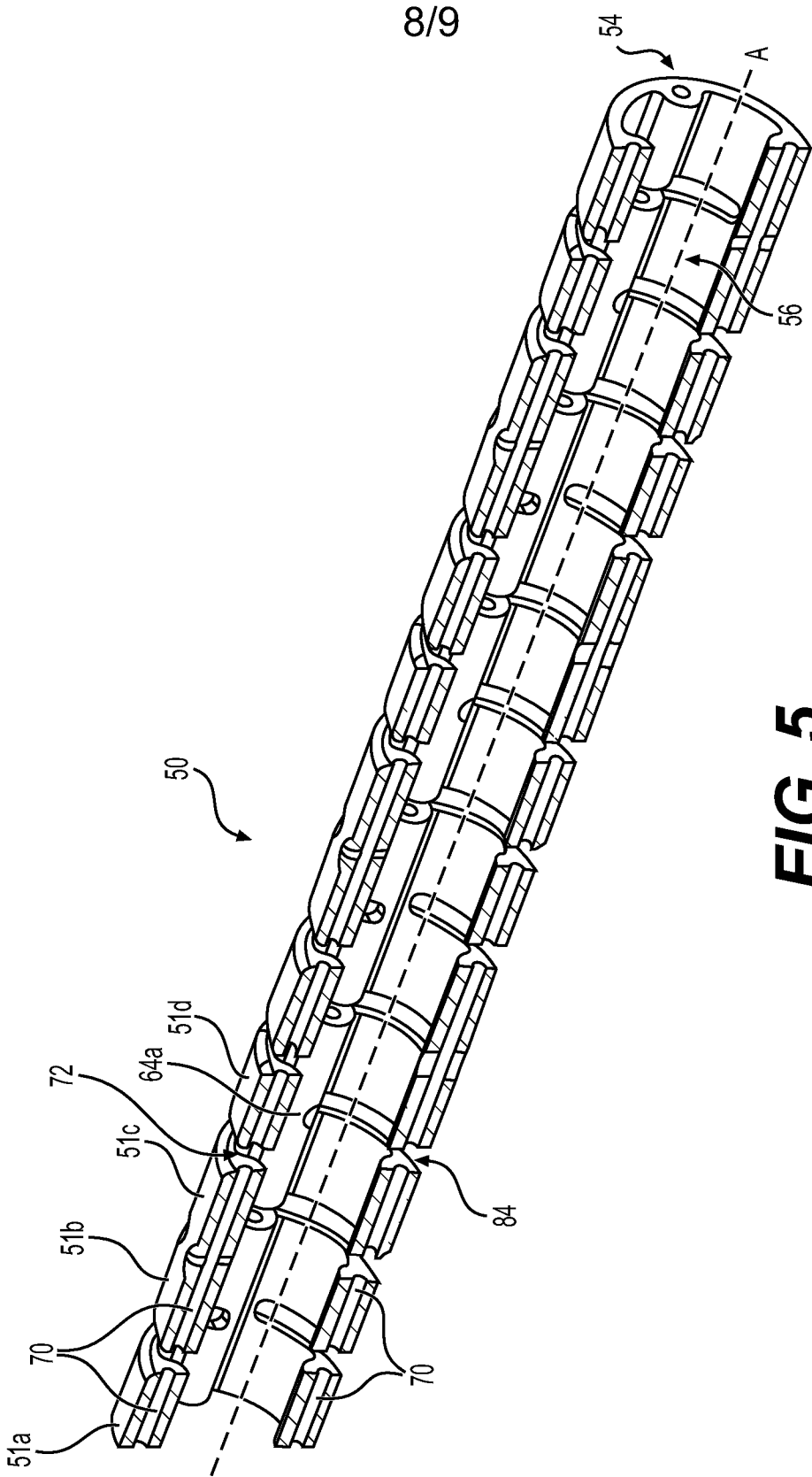


FIG. 5

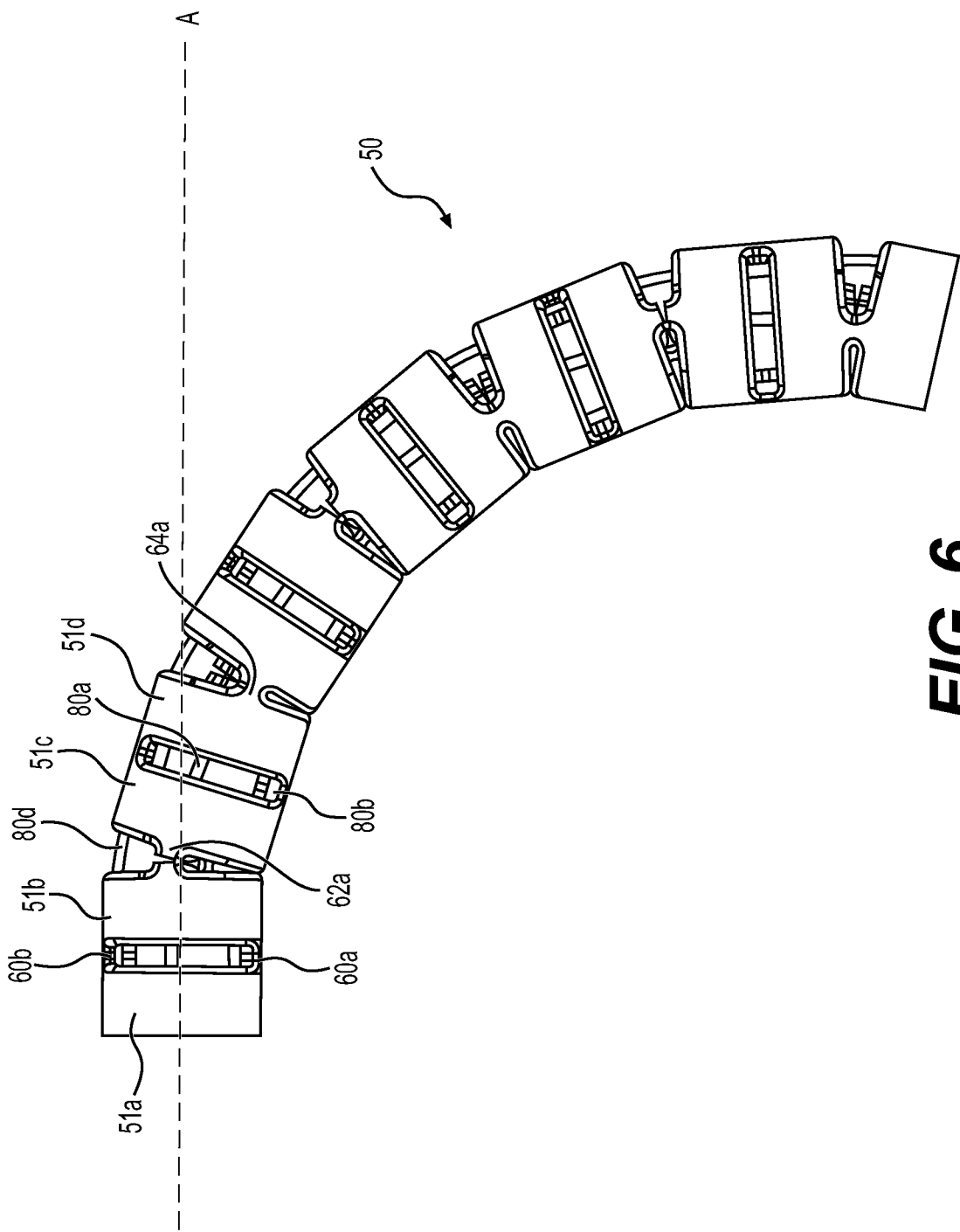


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2022/050822

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B1/008 ADD. A61B1/005		
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		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2019/099061 A1 (ISOBE YOSUKE [JP]) 4 April 2019 (2019-04-04) paragraphs [0020] - [0022], [0030], [0035] figures 1, 2, 4, 10 -----	1-15
X	JP 2010 259479 A (HOYA CORP) 18 November 2010 (2010-11-18) the whole document -----	1-15
X	US 2016/029878 A1 (YAMAZAKI MASAYUKI [JP] ET AL) 4 February 2016 (2016-02-04) paragraphs [0045], [0046], [0050], [0051], [0054] paragraphs [0060], [0061], [0069] - [0071] figures 1, 2, 3 -----	1-15
☐ 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		Date of mailing of the international search report
7 March 2023		15/03/2023
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Neumeyr, Theresa

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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