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(54) MEDICAL DEVICE WITH A DEFLECTABLE SHAFT SECTION AND TENSION CONTROL

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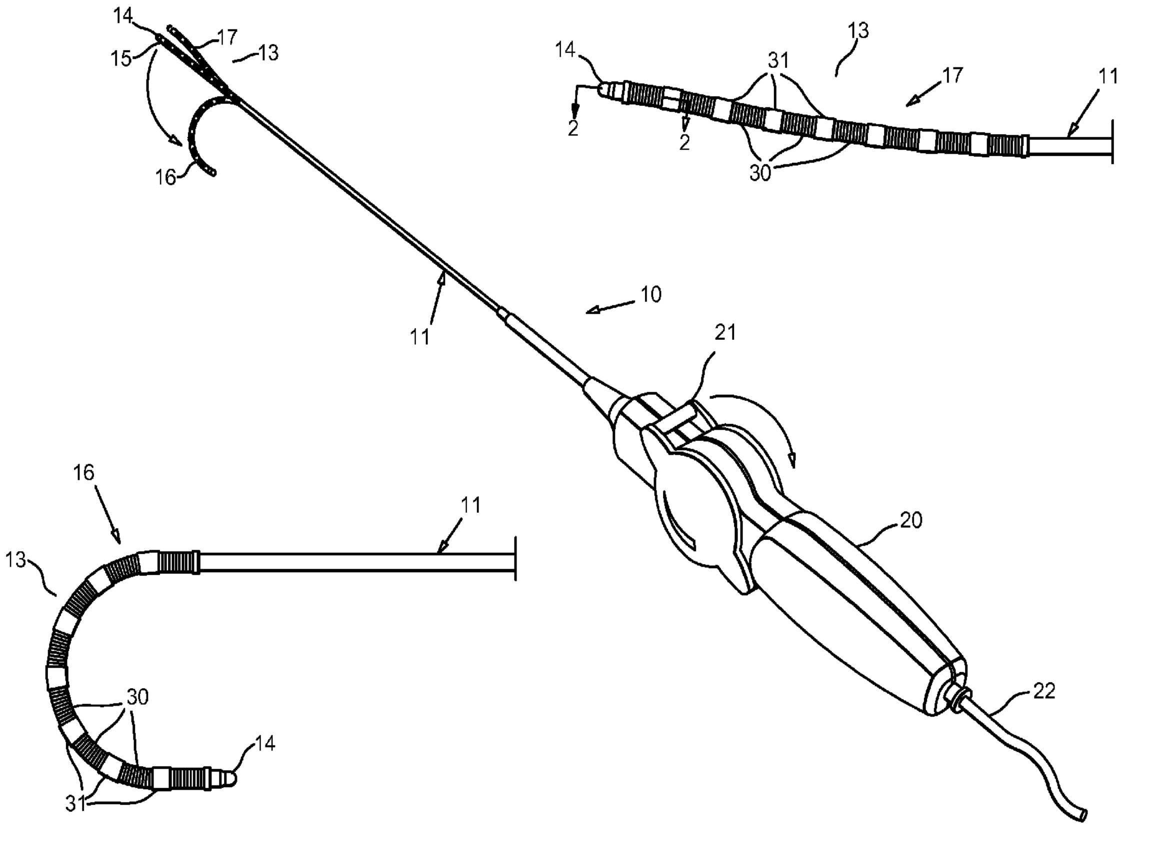
(52) **U.S. Cl.**
USPC **600/301**; 600/146; 600/104; 600/373

(57) **ABSTRACT**

A catheter comprises an elongated shaft having a proximal shaft section and a shapeable shaft section distal to the proximal section, an inner lumen extending within the proximal and shapeable shaft sections; a shaping member slidably disposed within the inner lumen and extends into the shapeable shaft section; a shape memory member adjacent to the shaping member in the inner lumen of the shapeable shaft section, wherein the shaping member and the shape memory member are coupled by a coupling coil; and a handle having an operating lever, wherein the handle receives the proximal shaft section and the shaping member for operating the shapeable shaft section.



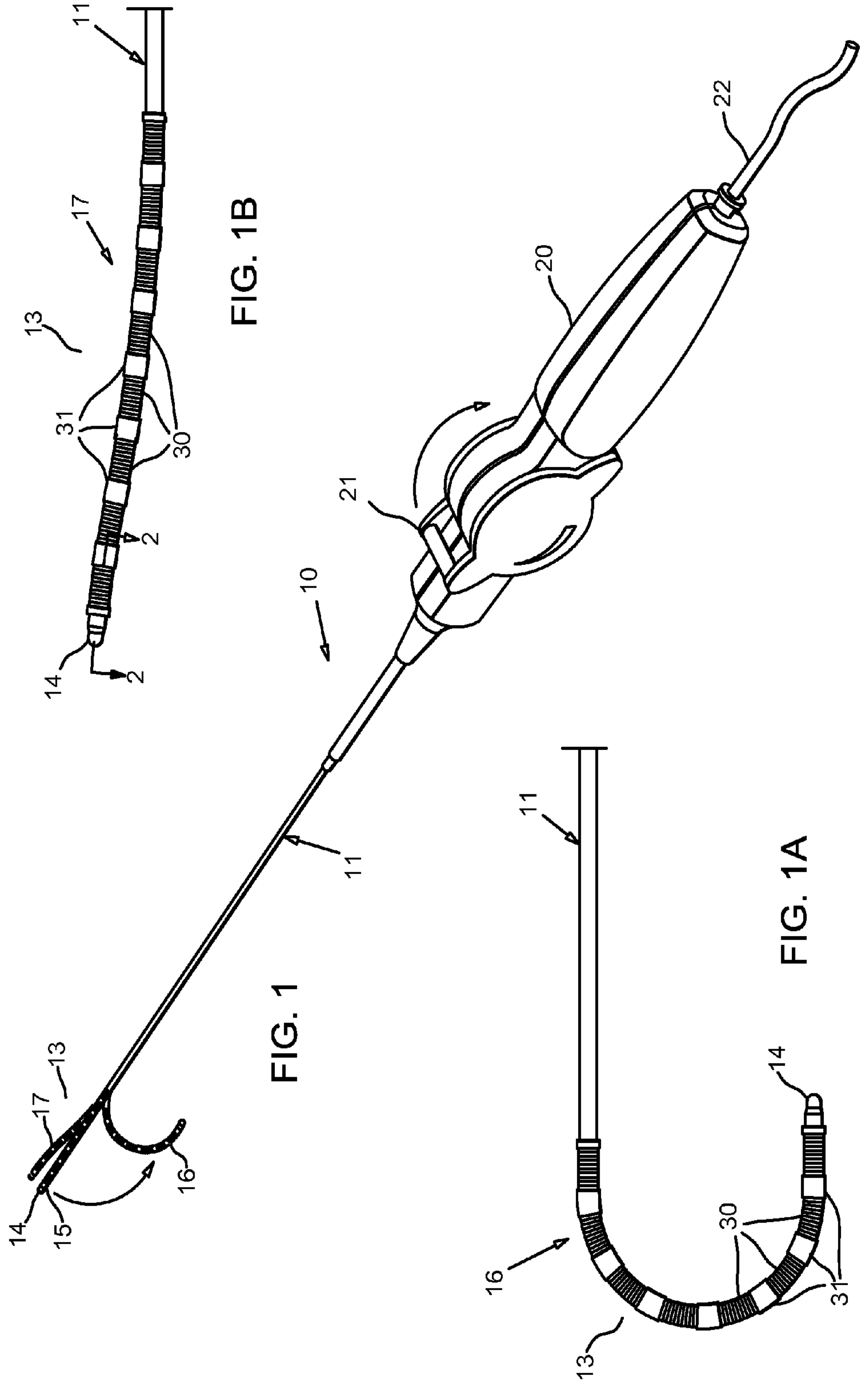


FIG. 1

FIG. 1A

FIG. 1B

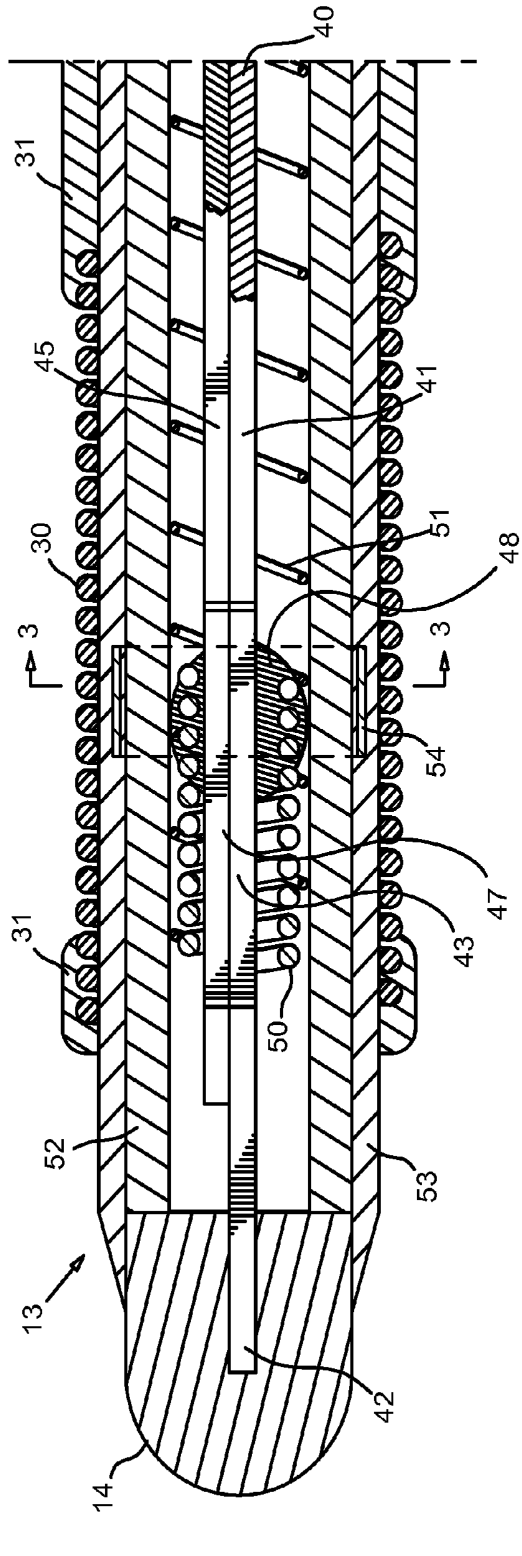

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FIG. 2

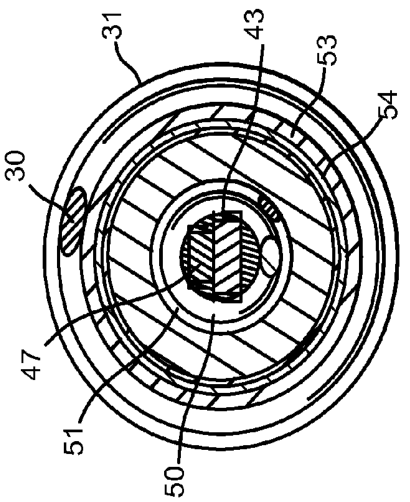
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FIG. 3

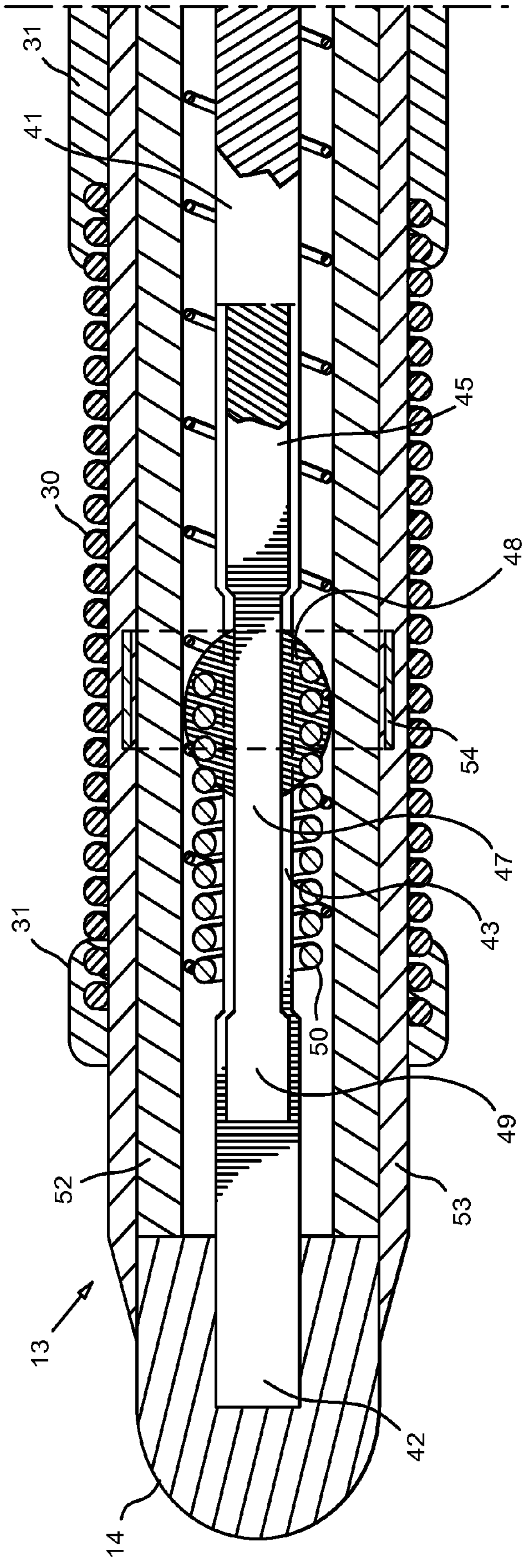

FIG. 4

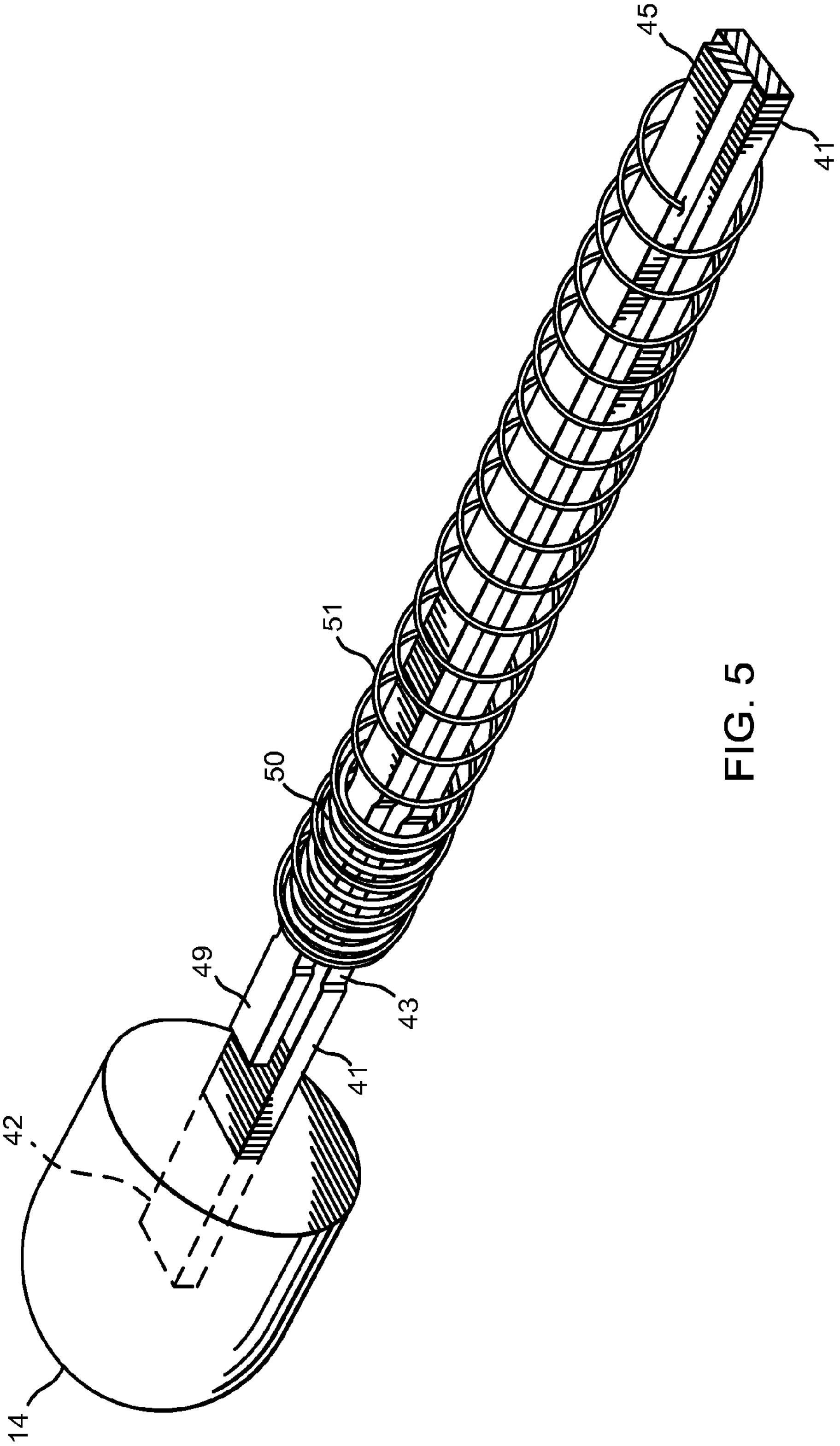

FIG. 5

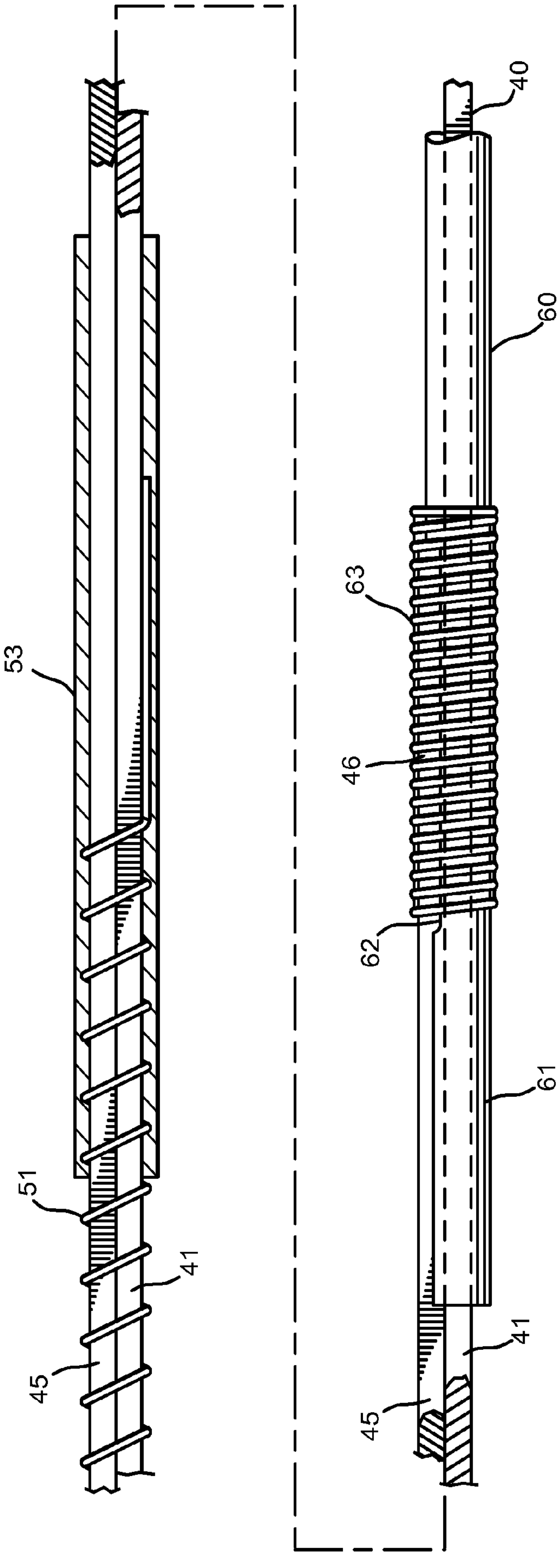

FIG. 6

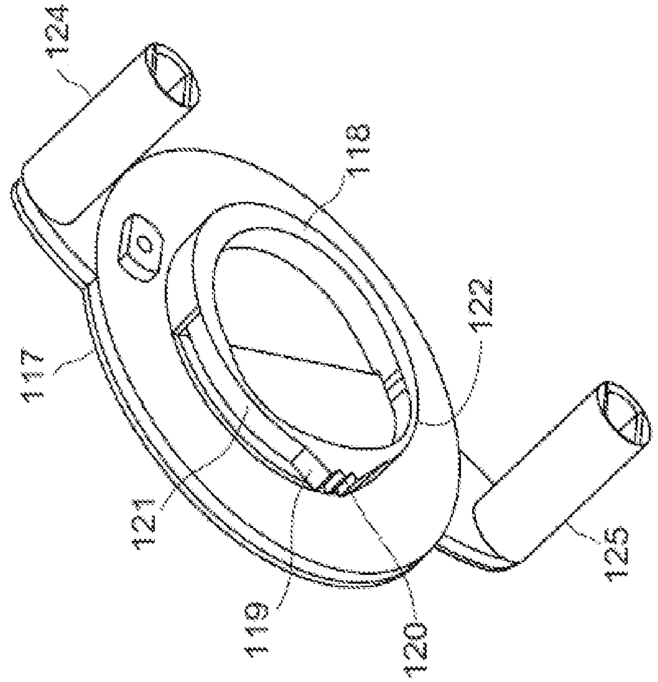

FIG. 7

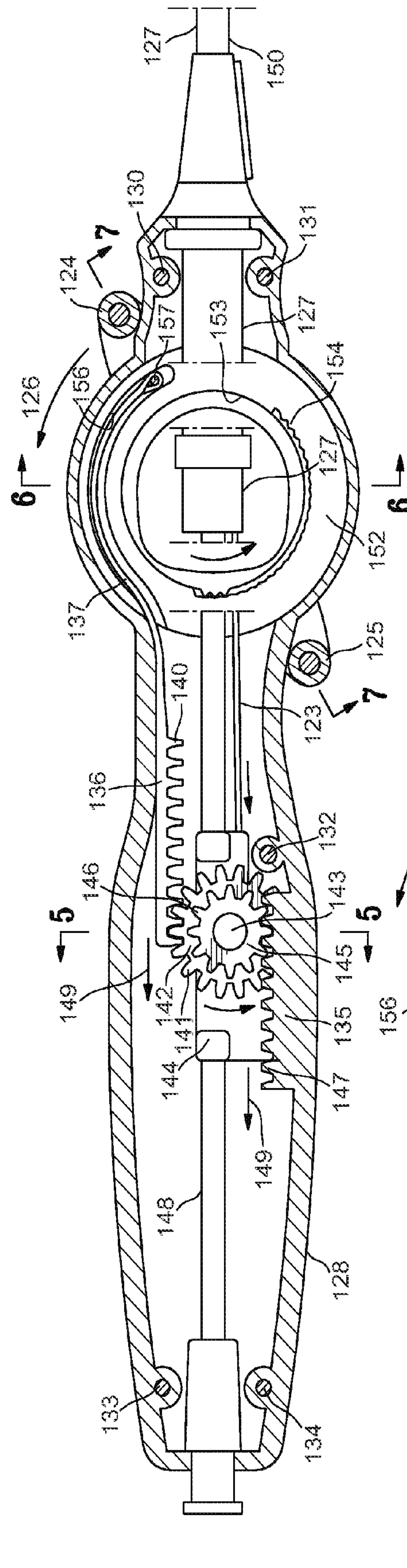
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FIG. 8

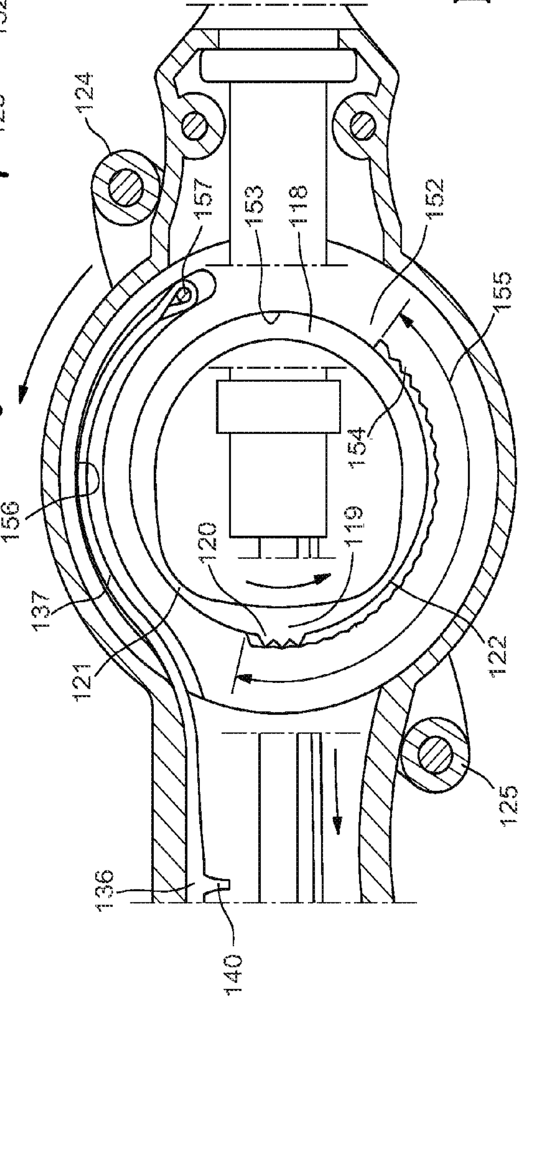
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FIG. 9

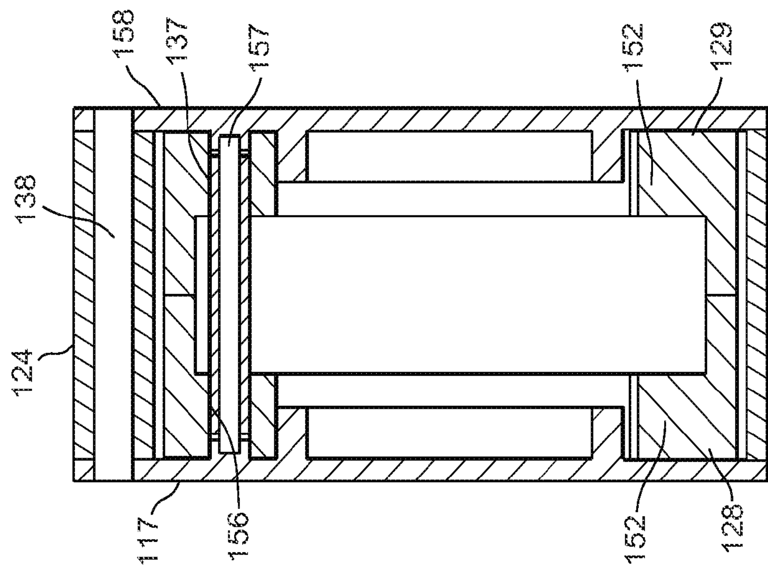

FIG. 12

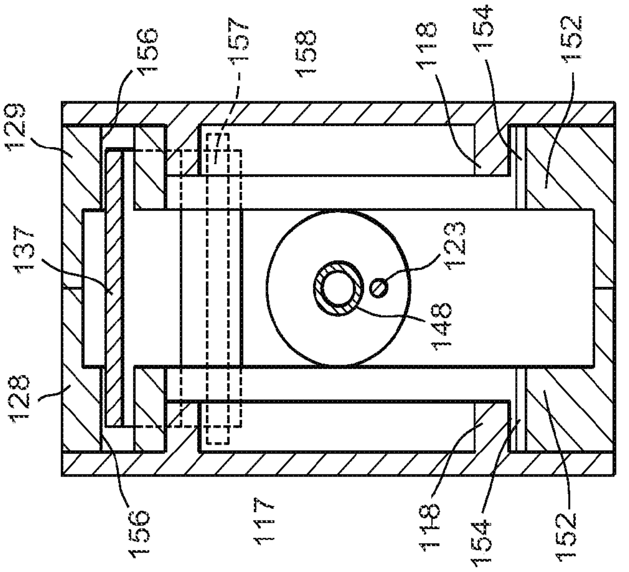

FIG. 11

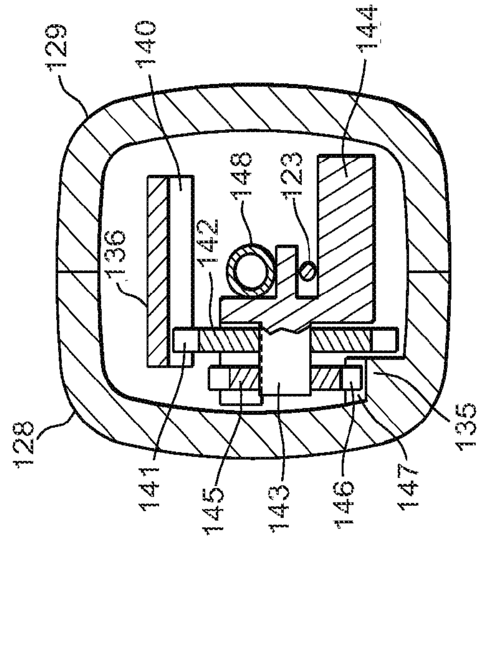

FIG. 10

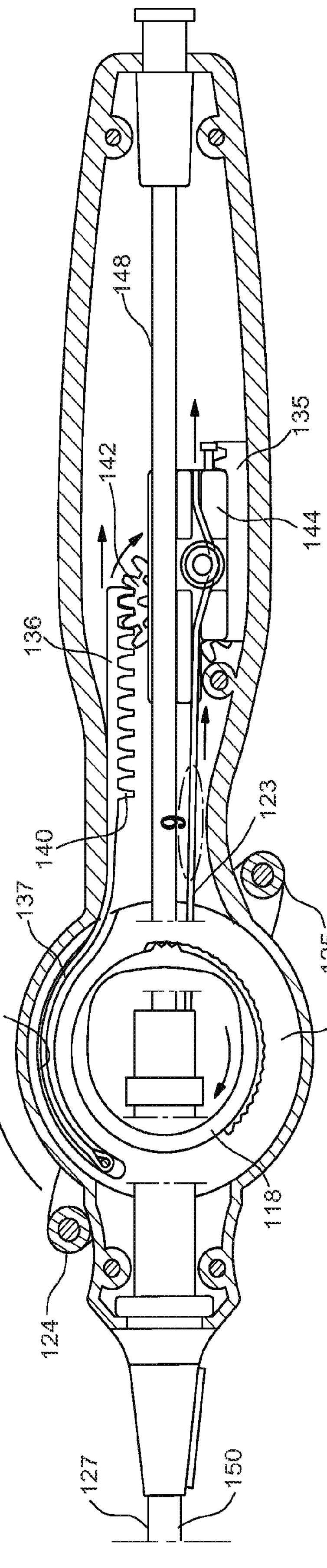
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FIG. 13

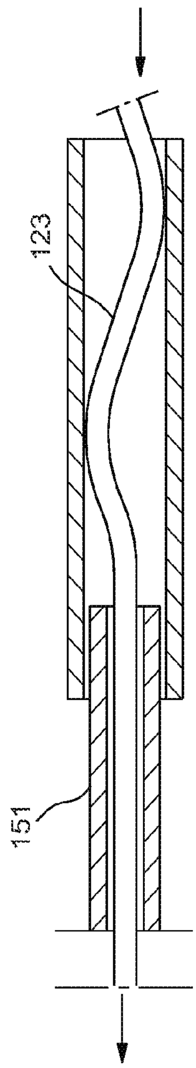
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FIG. 14

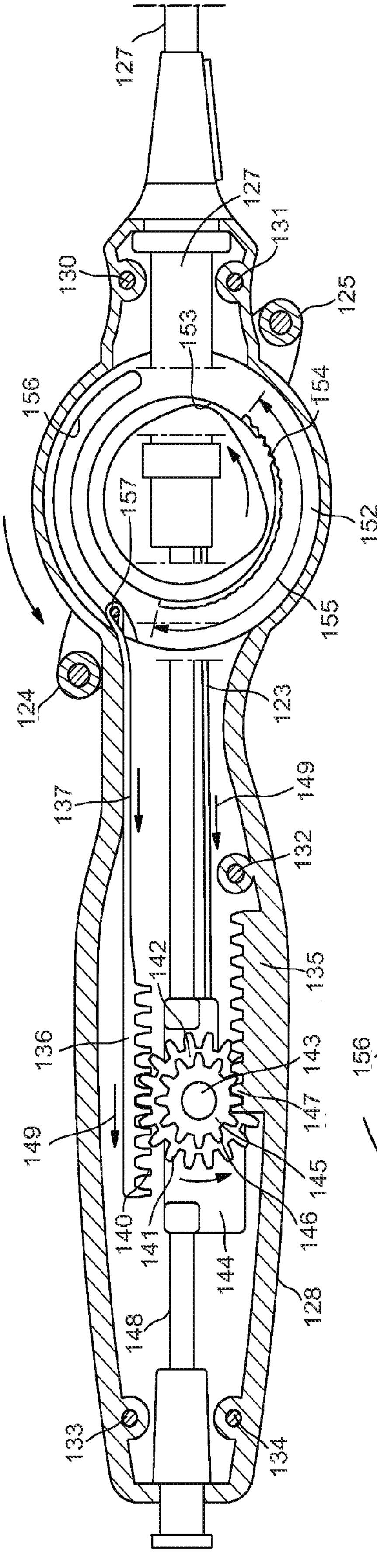
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FIG. 15

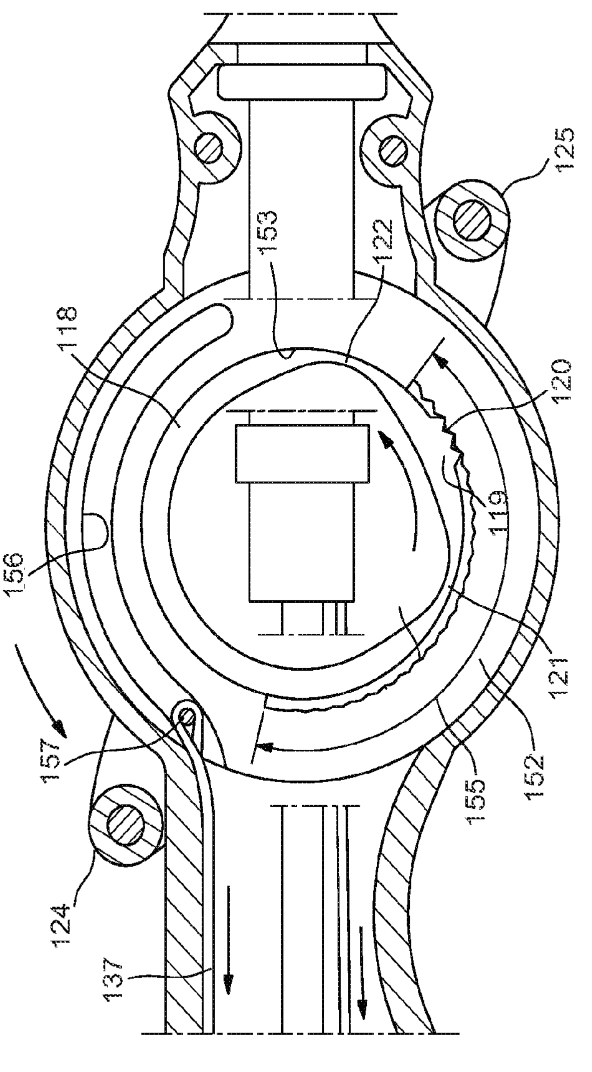
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FIG. 16

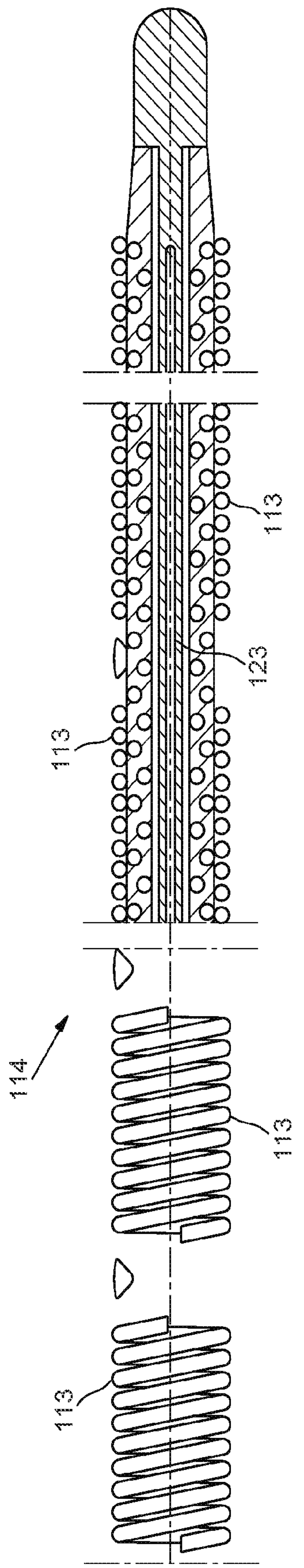

FIG. 17

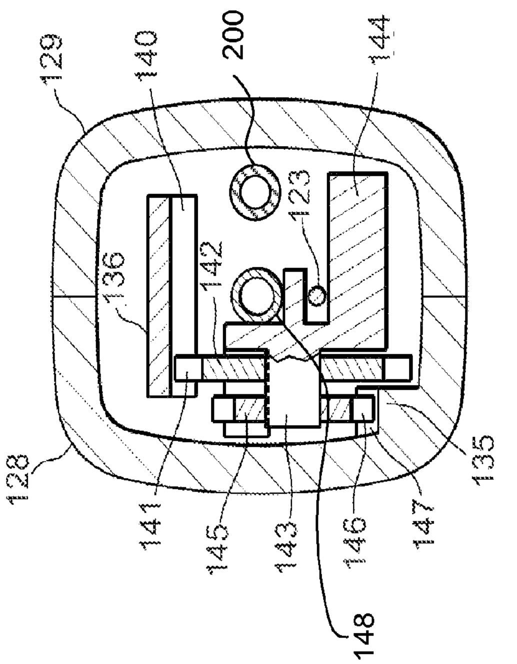

FIG. 18

MEDICAL DEVICE WITH A DEFLECTABLE SHAFT SECTION AND TENSION CONTROL

FIELD OF INVENTION

[0001] The present invention generally relates to medical devices with a deflectable portion, such as catheters, and, in particular to, a catheter having a steerable and deflectable distal shaft portion with tension control of the deflectable distal shaft portion.

BACKGROUND

[0002] The heartbeat of a healthy human occurs as a result of the transfer of electrical signals within the heart. These signals are transmitted through pathways of conductive heart tissue. Unhealthy conductive heart tissue can interfere with the passage of these regular electrical signals. This interference can disturb the normal heartbeat rhythm and cause an abnormal rhythmic condition referred to as "cardiac arrhythmia."

[0003] A widely accepted non-pharmacologic treatment for arrhythmia involves selectively destroying the unhealthy conductive heart tissue with energy such as radio frequency ("RF") energy. In such cases, an RF ablation procedure is performed to eliminate the electrical signal irregularities by desiccating the tissue causing the arrhythmia or interfering with the transmission of such signal irregularities; the dessicated tissue is no longer electrically viable, effectively forming a barricade that prevents the conduction of electrical signal irregularities. Successful ablation of the conductive tissue at the arrhythmia initiation site usually terminates the arrhythmia or at least moderates the heart rhythm to acceptable levels. Such ablation can be performed by an electrophysiological (EP) catheter that is percutaneously introduced into the patient to perform the ablation procedure.

[0004] EP catheters are generally either tip ablation catheters or linear ablation catheters. A tip ablation catheter typically includes a longer (e.g. 4 mm to 8 mm) bullet-shaped tip ablation electrode that is made from platinum-iridium, along with shorter annular sensing electrodes (e.g. 1 mm) that are proximal to the tip. A linear ablation catheter typically includes a plurality of spaced apart electrodes, such as coil electrodes, located at the distal end of the catheter and arranged in a linear array. These electrodes are used for both sensing and energy delivery.

[0005] With respect to EP catheters, RF energy is applied through the electrode(s) to the heart tissue to produce a series of long linear lesions (e.g., via "drag and burn" methods for tip ablation catheters, or via direct placement of the distal linear array of electrodes for linear ablation catheters), that destroy the irregularly electrical-conducting tissue or interfere with the transmission of irregular signals. The cardiac electrophysiologist may choose to ablate the endocardial tissue of the heart, while the surgeon may choose to ablate the epicardial surface of the heart.

[0006] The catheters currently used for endocardial RF ablation procedures are typically flexible at the distal end, and the profile at the distal end is adjustable. Placement of the catheter distal section to achieve good tissue contact is more easily accomplished when the catheter is steerable, shapeable and deflectable.

[0007] Changing the profile of the distal shaft portion of the catheter typically involves the use of a shaping member (e.g., a wire strand) slidably disposed within an inner lumen of the catheter shaft and having its distal end attached to the distal shaft section of the catheter. The proximal end of the shaping member is attached to a lever or other element on the handle of the catheter.

[0008] The profile of the distal shaft section of the catheter shaft can be adjusted from an essentially straight configuration to a deflected or shaped configuration by applying a tensile or compressive force on the proximal portion of the shaping member. When the force is released, the distal shaft section of the catheter tends to spring back to its original or straight configuration due to the structure of the catheter shaft.

[0009] Manual maintenance of the tension or compression during the course of a medical procedure to retain the deflected or shaped distal profile of the catheter is difficult. In some existing steerable catheters, an additional knob is attached to the handle to lock the displacement of the shaping member in tension or compression to hold the distal shaft section in the desired shape. However, this is difficult and inconvenient for the operating physician.

[0010] A steerable catheter is described in U.S. Pat. No. 6,652,506 which has a locking mechanism integrated with the deflection mechanism. However, in the system described, the locking mechanism is disengaged to allow the deflection mechanism to function.

[0011] Thus, there remains a need for a steerable catheter having a deflection mechanism for better contact with the target surface and having an improved lockable steering control mechanism that can be manipulated and locked in a single-handed operation.

SUMMARY OF INVENTION

[0012] Briefly, the present invention generally relates to a catheter comprising an elongated shaft having a proximal shaft section and a shapeable shaft section distal to the proximal section, an inner lumen extending within the proximal and shapeable shaft sections; a shaping member slidably disposed within the inner lumen and extends into the shapeable shaft section; a shape memory member adjacent to the shaping member in the inner lumen of the shapeable shaft section, wherein the shaping member and the shape memory member are coupled by a coupling coil; and a handle having an operating lever, wherein the handle receives the proximal shaft section and the shaping member for operating the shapeable shaft section.

[0013] The present invention is also generally directed to a medical device such as an electrophysiology-type catheter that has an operating handle and a shapeable or deflectable distal shaft section to facilitate placement of the catheter to a desired location within a patient's body. The catheter has a self-locking deflection system which facilitates placing and holding the distal shaft section of the catheter in a desired shape or state of deflection. The steering system can be manipulated by an operator with a single hand to establish a desired distal shaft section shape and lock the distal shaft section in the desired shape with a single operation.

[0014] These and other features of the invention will become more apparent from the following detailed description and the accompanying drawings.

DESCRIPTION OF THE DRAWINGS

[0015] The foregoing and other objects, aspects, and advantages of the invention can be better understood from the following detailed description of the preferred embodiment of the invention when taken in conjunction with the accompanying drawings in which:

[0016] FIG. **1** illustrates an elevational view of a catheter of the present invention having an elongated catheter shaft secured to a handle which has a movable lever for deflecting or shaping the distal shaft portion of the catheter.

[0017] FIGS. **1**A-**1**B illustrate enlarged elevational views of the shapeable shaft section of a catheter of the present invention in curved and extended positions, respectively.

[0018] FIG. **2** illustrates an enlarged longitudinal cross-sectional view of the distal section of a catheter of the present invention.

[0019] FIG. **3** illustrates a transverse cross-sectional view of the distal portion of a catheter of the present invention.

[0020] FIG. **4** illustrates an enlarged longitudinal cross-sectional view of a catheter of the present invention.

[0021] FIG. **5** illustrates an elevational view of the distal portion of the deflection mechanism of a catheter of the present invention, in which the polymeric tubing is not present.

[0022] FIG. **6** illustrates an elevational view of a proximal part of the deflection mechanism of a catheter of the present invention, in which the electrodes and outer sheaths are removed and the polymeric tubing of the elongated shaft is shown.

[0023] FIG. **7** illustrates an exploded view of the side wall of the self-locking deflection system in FIG. **1** to illustrate details of a rotor secured thereto.

[0024] FIG. **8** illustrates a longitudinal cross-sectional view of the handle of a catheter of the present invention.

[0025] FIG. **9** illustrates an enlarged longitudinal cross-sectional view of the distal portion of the handle of a catheter of the present invention.

[0026] FIG. **10** illustrates a transverse cross-sectional view of the handle of a catheter of the present invention.

[0027] FIG. **11** illustrates a transverse cross-sectional view of the handle of a catheter of the present invention.

[0028] FIG. **12** illustrates a transverse cross-sectional view of the handle of a catheter of the present invention.

[0029] FIG. **13** illustrates a longitudinal cross-sectional view of the handle of a catheter of the present invention.

[0030] FIG. **14** illustrates an enlarged longitudinal cross-sectional view of the tubular support member for the shaping member of a catheter of the present invention.

[0031] FIGS. **15** and **16** illustrate longitudinal transverse cross-sectional views of a handle of a catheter the present invention with the operating lever in a proximal position for deflecting the distal shaft section of the catheter.

[0032] FIG. **17** illustrates a longitudinal cross-sectional view of the distal shaft section of a catheter of the present invention which shows details of the shaping member secured within the distal shaft section.

[0033] FIG. **18** illustrates a transverse cross-sectional view of the handle of a catheter of the present invention having an irrigation channel inside the handle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0034] FIG. **1** illustrates an elevational view of a catheter of the present invention having an elongated catheter shaft secured to a handle which has a movable lever for deflecting or shaping the distal shaft portion of the catheter. An elongated catheter device **10** (e.g., an electrophysiology catheter) has an elongated shaft **11**, a proximal shaft section **12** and a shapeable shaft section **13** distal to the proximal shaft section **12** with a non-traumatic distal end or tip **14**. FIG. **1** shows the shapeable shaft section **13** in various positions, including a neutral position **15**, a curved position **16**, and a hyper-extended position **17**. Generally, the catheter **10** has a handle **20**, located proximally from the elongated shaft **11**. The elongated shaft **11** has a plurality of electrodes **30** on the deflectable or shapeable distal shaft section **13**. The proximal shaft portion **12** is secured to the distal end of handle **20**. The operating handle **20** has a self-locking steering control or deflection system that is operated by a lever **21** for deflecting or otherwise shaping the distal shaft section **13**. The lever **21** can be a wheel or dial, where a user can turn the wheel or dial to set the amount of deflection of the shapeable distal shaft section **13**. The operating handle **20** also provides a power source connection **22** for supplying power to the electrodes **30**.

[0035] In other embodiments of the invention, the distal shaft portion **13** of the elongated catheter device **10** can also have temperature sensing elements, such as thermocouples, underneath the electrodes **30**. The temperature sensing elements or thermocouples are preferably spaced from the electrode so as to provide a response time (t_r), which is approximately 3 time constants (3τ) and does not exceed 4 seconds, i.e. $t_r \cong 3\tau \leqq 4$ sec.

[0036] In addition, a pressure sensor can be disposed on the non-traumatic distal end **14**, i.e., the distal tip of the shapeable shaft section **13**. Preferably, there is a pressure sensor disposed on each of the four quadrants of the non-traumatic distal end **14**. The wiring for the electrodes **30**, thermocouples, and/or pressure sensors can be bundled together; the bundled wiring can be routed from the handle **20**, through the inner lumen of the elongated shaft **11**, to the respective electrodes, thermocouples, and/or pressure sensors.

[0037] FIGS. **1**A and **1**B are enlarged perspectives illustrating the shapeable shaft section **13** in the curved position **16** and hyper-extended position **17**, respectively. The catheter device **10** has multiple, preferably coiled electrodes **30** between multiple polymer laminations **31** which overlap and fix the ends of the electrodes **30**. The polymer laminations **31** may be composed of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride ("THV") or another similar insulating polymer material. The atraumatic distal tip **14** may be composed of a gold solder or platinum alloy. The atraumatic distal tip **14** is configured to allow for the advancement of the catheter through body tissue and lumens with minimal harm to tissue the tip contacts.

[0038] FIG. **2** illustrates an enlarged longitudinal cross-sectional view of the distal section of a catheter of the present invention, along line **3**-**3**. In particular, the shapeable shaft section **13** of the elongated shaft **11** of a deflectable catheter **10** is shown. A shaping member **40** can have a flattened distal portion **41** that extends axially within the shapeable shaft section **13**. The shaping member **40** is preferably a wire composed of stainless steel. The shaping member **40** of this embodiment can be controlled by the lever **21** on the operating handle **20** shown in FIG. **1**. The shaping member's distal end **42** is affixed to the atraumatic distal tip **14**.

[0039] The shape memory ribbon **45** can extend axially in the shapeable shaft section **13** and is located adjacent to the shaping member's flattened distal portion **41**. Preferably, the shape memory ribbon **45** is a ribbon formed of a stress-induced martensite (SIM) NiTi alloy. Other shape memory materials may also suffice as well. Note that a shape memory ribbon can also be referred to as a shape memory member.

[0040] FIGS. **2-5** illustrate the manner by which the shaping member's flattened distal portion **41** and the shape memory ribbon **45** are affixed to one another in the shapeable shaft section **13**. Referring to FIG. **4**, the shaping member's flattened distal portion **41** has a notched section **43** proximal to and near the shaping member's distal end **42**. The shape memory ribbon **45** has a corresponding notched distal section **47** proximal to and near the shape memory ribbon's distal end **49**. The notched sections **43** and **47** are affixed to one another by a distal joint coil **50**. Generally, a coupling coil can be used to affix the notched sections **43** and **47**, such that some bowing can occur when the shaping member **40** is pulled or pushed. However, the shaping member **40** and the shape memory ribbon **45** are prevented from completely bowing apart by the coupling coil. A specific embodiment of a coupling coil is the distal joint coil **50**.

[0041] The distal joint coil **50** may be composed of stainless steel. Thus the distal joint coil **50** surrounding the shaping member notched distal section **43** and the shape memory ribbon notched distal section **47** forms a mechanically secure joint. Also a body of solder **48**, shown in FIGS. **2** and **4**, fixes the distal joint coil **50** to the shaping member notched section **43** and the shape memory ribbon notched section **47**. Those skilled in the art may choose to secure the shaping member's flattened distal portion **41** and the shape memory ribbon **45** in an alternative manner as well.

[0042] While not illustrated in the drawings, the shaping member's flattened distal portion **41** preferably has a polytetrafluoroethylene (PTFE) coating, or is surrounded by PTFE tubing. The coating or tubing can act as a lubricant so that the shaping member's flatten section **41**, helical confining wire **51**, and shape memory ribbon **45** can slide with respect to one another, while still occupying a confined space within helical confining wire **51**.

[0043] FIGS. **2-6** show the helical confining wire **51** extending about the shaping member's flattened distal portion **41** and the shape memory ribbon **45**. The helical confining wire **51** is wrapped around the shaping member **40** and the shape memory ribbon **45** to control the spacing between these two members when the shapeable shaft section **13** is deflected, hyper-extended, or otherwise shaped. Essentially the helical confining wire **51** prevents the shaping member's flattened distal portion **41** and the shape memory ribbon **45** from completely bowing apart when the shaping member **40** is pulled or pushed. This is to ensure improved tissue contact force is applied by the distal electrodes near the distal tip **14**.

[0044] The shaping member **40** and the shape memory ribbon **45** can be spaced apart along the longitude of the shapeable shaft section **13** a predefined distance away from each other; this predefined distance can be set based on an amount of deflection required. The helical confining wire **51** restricts the maximum distance between the shaping member **40** and the shape memory ribbon **45** to the predefined distance. Thereby, the shape memory ribbon **45** provides a spring back force near the distal tip **14** of the shapeable shaft section **13** that is opposite to the movement and/or curvature of the shapeable shaft section **13**. For instance, when the shapeable shaft section **13** is deflected, the shape memory ribbon **45** can slightly curve the shapeable shaft section **13** near the distal tip **14** in opposition to the movement and/or curvature of the shapeable shaft section **13**. In such a manner, improved tissue contact can be provided at the distal electrodes of the shapeable shaft section **13** near the distal tip **14**.

[0045] FIGS. **2-4** illustrate a braiding layer **52** that surrounds the helical confining wire **51**, further confining the movement of the shaping member's flattened distal portion **41** and shape memory ribbon **45**. Alternative ways to control the space between the shaping member's flattened distal portion **41** and the shape memory ribbon **45** include a wire mesh or other structures.

[0046] The helical confining wire **51** and braiding layer **52** can be located within a polymeric tube **53**; the latter being preferably formed of vinylidene fluoride (THV) or equivalent. The coiled electrodes **30** are located about the polymeric tube **53**. FIGS. **2-4** show the most distal of the multiple coiled electrodes **30**. Between the coiled electrodes **30**, also about the polymeric tube **53**, are circumferential bands of polymer electrode end fixing lamination **31**. The lamination **31** may be formed of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride (THV). Located beneath the coiled wire electrodes **30** are thermocouple bands **54** capable of accurate temperature measurements. The bands **54** are preferably spaced from the coiled wire electrodes **30** to provide a 3 tau response time of less than four seconds. The bands **54** may be spaced from coiled electrodes **30** by a suitable polymeric material such as an extruded viscoelastic polymer selected from the group of polyethylene and polypropylene. FIGS. **2-4** only depict the most distal of the multiple thermocouple bands **54**. The thermocouple bands **54** are preferably formed of gold.

[0047] FIG. **5** illustrates an elevational view of the distal portion of the deflection mechanism of a catheter of the present invention, in which the polymeric tubing is not present. The distal shaft section **13** is shown after removing the braiding layer **52**, polymeric tubing **53** and coiled electrodes **30** from view. The shaping member's flattened distal portion **41** and the shape memory ribbon **45** are bound together by a helical confining wire **51**. A mechanically fixed joint formed by the distal joint coil **50** binding the distal shaping member notched section **43** and the distal shape memory ribbon notched portion is also illustrated.

[0048] FIG. **6** illustrates an elevational view of a proximal part of the deflection mechanism of a catheter of the present invention, in which the electrodes and outer sheaths are removed and the polymeric tubing of the elongated shaft is shown. The polymeric tube **53** is cut-away to allow for viewing of the joint formed by the shape memory ribbon proximal end **46** and the hypotube **60**. The shape memory ribbon's proximal end **46** and a recessed section **62** of the hypotube distal portion **61** are configured to form a splice joint. While not illustrated in FIG. **6**, the articulating surfaces of the shape memory ribbon's proximal end **46** and the recessed hypotube section **62** may be additionally secured with a metal adhesive. The shape memory ribbon proximal end **46** may also be secured with adhesive to the interior of the proximal end of the polymeric tube **53**. A hypotube joint coil **63** circumferentially surrounds and further secures the joint formed by shape memory ribbon's proximal end **46** and the hypotube distal portion **61**. The proximal portion of the shaping member **40** extends proximally within the hypotube **60** toward the handle **20**. As discussed previously, the handle **20** controls the pushing and pulling of the shaping member **40**. FIG. **6** represents just one illustration of how the proximal end of the shape memory ribbon **46** is secured. Those skilled in the art may choose to secure the proximal end of the shape memory ribbon **46** in a different manner.

[0049] In one presently preferred embodiment, an EP catheter of the present invention as described above is inserted through an opening in a patient's femoral vein and advanced within the patient's venous system until the shapeable shaft section is within the patient's vena cava. The lever on the operating handle is pulled proximally to put the shapeable shaft section in a circular shape and placed on target tissue. High frequency electrical current is supplied to a plurality of the electrodes on the shapeable shaft section **13** so as to form a continuous lesion in the endocardial surface of the patient's heart in order to terminate arrhythmia in the patient's heart.

[0050] The typical dimensions of an EP catheter of the present invention such as shown in the drawings are as follows:

Catheter Component	Dimension
Distal Tip Outer Diameter	0.052" ± 0.005" (4 F, 1.14 mm)
Electrode Region Outer Diameter	0.074" ± 0.005" (5.6 F, 1.9 mm)
Proximal Shaft Outer Diameter	0.071" ± 0.005" (5.4F, 1.8 mm)
Electrode Length	4 mm ± 0.05 mm
Electrode Spacing	0.6 mm ± 0.5 mm
Thermocouple Band Length	1.75 mm ± 0.25 mm
Electrode Region Length	40 mm ± 5 mm
Working Length of Catheter	110 cm ± 3 cm
Proximal Adapter Length	22 cm ± 3 cm
Distal Tip Length	2 mm ± 1 mm
Curve Dia. of Distal End	1.5 cm to 2.5 cm
Extension of Distal End	0.5 cm minimum

[0051] FIG. **7** illustrates an exploded view of the side wall of the self-locking deflection system shown in FIG. **1**. A side wall **117** of a self-locking deflection system for the catheter device has a rotor **118** that has an engagement member **119**. The engagement member **119** has teeth **120** and is secured to the rotor **118** by a pair of spring members **121** and **122**. Operating levers **124** and **125** are attached to the side wall **117** for rotating the rotor **118**. Either or both of the operating levers **124** and **125** can be used to rotate the rotor **118**. For purposes of clarity, the detailed description may refer to using a single operating lever, however, it is understood that either or both of the operating levers can be used for rotating the rotor **118**.

[0052] FIG. **8** illustrates a longitudinal cross-sectional view of the handle of a catheter of the present invention. FIG. **9** illustrates an enlarged longitudinal cross-sectional view of the distal portion of the handle and FIGS. **10**, **11**, **12** illustrate transverse cross-sectional views of the handle shown in FIG. **8** taken along lines **5-5**, **6-6**, and **7-7**, respectively.

[0053] As shown in FIGS. **8**, **9 10**, **11**, and **12**, a deflecting or shaping member **123** of the catheter device extends from the elongated shaft of the catheter device into the handle. Therein, the shaping member **123** is secured within the handle of the catheter device to the self-locking deflection system. To operate the deflecting or shaping member **123**, the self-locking deflection system is operated by operating levers **124** and **125** which move in the direction shown by arrow **126**. Tensile or compressive forces applied to the proximal portion of shaping member **123** by the operating levers **124** and **125** causes the deflection and/or shaping of the distal shaft portion of the catheter. The shaping member **123** is preferably slidably disposed within tubular support member **127** which provides columnar support thereto.

[0054] The handle for a catheter of the present invention can have two half shells, a left side half shell and a right side half shell. FIGS. **8** and **9** illustrate the interior of the left side half shell. The left side half shell is secured to the right side half shell by a plurality of pins **130-134**. Minor details of the interior have been omitted from FIGS. **8-9** for purposes of clarity. The lower base of left side half shell has a fixed rack **135** and the upper portion of the left side half shell is provided with a flexible rack **136**. The flexible rack **136** has a flexible belt frame **137** which is secured to a pin **157** that passes through the self-locking deflection system. The flexible rack **136** can be made of nylon plastic, metal alloy, or other material. The teeth **140** of the flexible rack **136** engage the teeth **141** of the large gear **142** which is rotatably secured to a post **143**. The post **143** is fixed to a slider **144**. The small gear **145** is rotatably secured to the post **143** and the teeth **146** of the small gear **145** engage the teeth **147** of the fixed rack **135**.

[0055] Movement of the operating lever **124** (and/or operating lever **123**) in the direction of arrow **126** pushes on the flexible lead **137** of the flexible rack **136**, moving it toward the proximal end of handle. Proximal movement of the flexible rack **136** rotates the larger gear **142** fixed to the post **143** which in turn rotates the small gear **145**, which is likewise fixed to the post **143**. The small gear **145** rotates along the fixed rack **135**. The slider **144** is slidably mounted to a tubular member **148** which extends through the handle. When the slider **144** is urged proximally as shown by arrow **149** and rides along tubular member **148**, the proximal end of shaping member **123** which is fixed to the slider **144** (as shown in FIGS. **8** and **13**) is therefore pulled proximally within tubular support member **127**.

[0056] As shown in FIGS. **8**, **9**, **13** and **16**, the self-locking deflection system includes a journal **152** within the housing **20** which is secured to a wall of the self-locking deflection system. The journal **152** has an inner surface **153** which is provided with a plurality of teeth **154** which extend along a length **155** of the inner surface **153**. The teeth **154** increase in height along the length **155**. The rotor **118** (shown in FIG. **7**) slides into the interior of journal **152** and is configured to be slightly larger than the interior of the journal, so that the engagement member **119** and the teeth **120** thereon are pressed against the teeth **154** along the length **155** of the_ inner surface **153**. The springs **121** and **122** of rotor **118** apply constant pressure on the engagement member **119** so that the teeth **120** thereon are always engaging the teeth **154** on the inner surface **153** as the engagement member moves along the length **155**. Thus, as the operating lever **124** is moved by the operator from the forward position as shown in FIGS. **1**, **8**, **13** and **16** to a proximal position as shown in FIGS. **15** and **16**, the operator senses greater resistance to movement because of the gradually increasing height of the teeth **154**. The increased resistance gives the operator an indication of the shape of the distal shaft section **13** of catheter **10** in addition to any indicia that may be provided on the handle or the self-locking deflection system. This increased resistance to movement also ensures that the shaped distal shaft section **13** remains in the desired position when the operator's pressure against the operating lever **124** is removed due to the pressure against the engagement member by springs **121** and **122**.

[0057] While the self-locking deflection system is described utilizing an engagement member **119** with teeth **120** which engages the teeth **154** on the inner surface **153** of journal **152**, a variety of biased frictional engagements may be employed. For example, similar results may be obtained with the inner surface **153** of journal **152** having increase coarseness, e.g. sandpaper, or stickiness along the length **155**.

[0058] Moreover, engagement member **119** may be biased by hydraulic pressure, pneumatic pressure, compressible materials, elastic materials, magnetic forces, or by any equivalent means instead of spring members **121** and **122**.

[0059] Referring to FIGS. **8**, **9**, **15**, and **16**, flexible lead **137** of flexible rack **136** is slidably disposed within the groove or raceway **156** formed in the journal **152** and the distal end of flexible lead **137** is secured to a pin **157** that is secured to the rotating side wall **117** and the other accompanying rotating wall. Movement of the operating lever **124** moves the flexible lead **137** and thus flexible rack **136**. The teeth **140** of the flexible rack **136** engage the teeth **141** of large gear **142**, thereby driving the slider **144** proximally along the tubular member **148**. The proximal end of shaping member **123** is secured to the slider **144** so that proximal movement of the slider deflects or otherwise shapes the distal shaft section **13**.

[0060] Usage of the handle **20** and movement of the operating levers **124** or **125** by an operator can be accomplished with a single hand. For example, while the operator is holding the handle in his or her hand, the lever **124** from a forward position to a proximal position with his or her thumb until the desired deflection or shaping of the distal shaft section **13** of the catheter shaft **110** is obtained. The operator may release his or her thumb from the operating lever **124**, thereby holding deflected or shaped configuration of the distal shaft section

[0061] Referring to FIGS. **13** and **14**, the proximal end **150** of tubular support member **127** is secured to a smaller diameter tubular member **151** which extends within the catheter shaft. When the operator pushes lever **124** in the reverse direct, the shaping member **123** is pushed along the inner wall and transits into the smaller tubular member **151**, resulting in a reversing deflection of the distal shaft section **13**.

[0062] FIG. **17** illustrates the deflection shaping member **123** secured to the distal shaft section of the catheter. Generally, a plurality of electrodes **113** is disposed on an exterior **114** of the deflectable or shapeable distal shaft section. The other layers of the distal shaft section are not shown for purposes of clarity.

[0063] FIG. **18** illustrates a transverse cross-sectional view of a handle of the present invention, taken along the lines **5-5**, having an irrigation channel in the interior of the handle. The electrophysiology catheter can include an irrigation system, where the irrigation system provides liquid to the exterior of the shapeable shaft section **13** to irrigate the electrode(s) of the electrophysiology catheter. The liquid can be saline or other solution for medical use. The distal shaft section **13** is provided with outlet openings adjacent to the electrode(s) of the catheter. The fluid can be pumped through the handle via an irrigation channel **200** to the inner lumen of the elongated shaft. Upon reaching the distal shaft section **13**, the fluid can flow from the outlet openings over the exterior of the shapeable shaft section **13** where the electrodes are disposed. Thus, the irrigation system can be useful for controlling the degree of thermal effect surrounding the intended treatment site.

An Embodiment of the Present Invention

[0064] A presently preferred catheter having features of the invention includes an elongated shaft having a proximal and distal ends with a shapeable or deflectable distal shaft section having at least one exposed electrode to perform an electrophysiology function such as sensing, ablating or both. The shapeable shaft section better maintains a profile that allows for contacting the heart surface at the time of ablation.

[0065] The elongated shaft of the catheter has at least one inner lumen extending from the proximal end of the shaft to the distal shaft section and a shaping member having proximal and distal ends extending within the inner lumen. The distal end of the shaping member is secured to the distal shaft section so that when a tensile or compressive force is applied to the shaping member, the distal shaft section will be provided with a desired shape or deflection.

[0066] The shapeable shaft section of a catheter having electrodes is placed inside the chamber of a patient's atrium, preferably in a curved shape, advanced within the patient's heart chamber to engage target tissue. The curved shapeable shaft section of the catheter is then extended into a more linear shape. As the distal catheter section is extended, some of the electrodes make tissue contact sooner than others. The lengths of the shapeable shaft portion which do not contact tissue encounter less resistance and will uncurl or straighten out more that those lengths which engage tissue and encounter a greater resistance. As a result, the shapeable shaft section of the catheter, to a certain extent, takes the shape of the irregular surface terrain of the patient's atrium. This allows for better contact facilitating a better ablated linear lesion over an uneven surface with fewer ablation procedures.

[0067] An elongated medical device embodying features of the invention includes a deflection mechanism that has an elongated shaping member such as a wire that extends through the interior thereof with a flattened distal portion. The distal end of the flattened distal portion is secured, preferably to the distal non-traumatic tip of the medical device. A shape memory member such as a ribbon or strip, preferably a stress induced martensite (SIM) NiTi alloy such as NITINOL, extends adjacent to and co-linear with at least part of the flattened distal portion of the elongated shaping member.

[0068] One or more confining members such as wires or strands extend about the shape memory member and the flattened distal portion of the elongated shaping member to control the spacing between these two members when the shapeable distal section of the device is deflected or otherwise shaped. The one or more confining members may be in the form of a helical coiled wire, a mesh member or be of a braided construction.

[0069] The elongated shaft of the medical device preferably has a stainless steel hypotube with an inner lumen that slidably receives at least part of the elongated shaping member and a proximal portion which extends into the handle of the device. The hypotube extends distally to the shapeable shaft section preferably to a location proximal to the flattened distal portion of the elongated shaping member. A polymeric tube is preferably secured to the distal end of the hypotube and extends therefrom for stress relief and kink resistance. The proximal portion of the shape memory member is secured, preferably by adhesive between the exterior of the distal end of the hypotube and the interior of the proximal end of the polymeric tube and a locking key feature. A coil or wound wire is placed over the locking key feature, fixed by solder, to further enhance the coupling joint. The polymeric tube may be formed of vinylidene fluoride or polyimide.

[0070] The distal end of the shape memory member is secured to the distal end of the flattened portion of the elongated shaping member. Preferably, the distal ends of the shape memory member and the flattened portion of the elongated shaping member have notches so that a wire or ribbon made of suitable material such as stainless steel can be wrapped around both members within the notches thereof to mechanically secure them together. A body of solder may be formed about the notches and wound wire or ribbon to further secure the members together. The distal ends of the one or more wires or strands of the confining member may also be secured within the notches by the solder. NiTi alloys are difficult to solder so the mechanical connection of the wrapped wire and the solder secures the distal end of the NiTi shape memory member to the flattened stainless steel shaping member (e.g., a wire).

[0071] The elongated shaping member and hypotube extend proximally to an operating handle. The handle is provided with a mechanism that pulls and pushes the shaping member which in turn shapes or deflects the shapeable shaft section of the elongated device. The proximal end or portion of the shaping member is secured to a force applying slider or collar that is preferably configured to follow a desired or predefined path within the catheter handle.

[0072] The handle of the steerable device receives the proximal end of the elongated shaft and has a self-locking deflection system to both move the distal shaft section into a desired configuration and hold or lock the distal shaft section in the desired configuration. The self-locking deflection system includes a first friction engaging surface with a first friction characteristic such as plurality of protuberances or teeth and a second friction engaging surface with variable friction characteristics along a length thereof such as a plurality of protuberances or teeth with increased protuberance or tooth height along a length of motion to increase the frictional resistance felt by the operator. The handle has a shaping operating member such as a lever which is directly or indirectly connected to the shaping member and to one of the first or second friction engaging surfaces. The self-locking deflection system has a movable member with one of the friction surfaces and one or more biasing elements which urge the movable member having a friction engaging surface toward the other of the friction engaging surfaces. The biasing element(s), such as springs, are configured so the friction engaging surface on the movable member is always in contact with the other friction engaging surface, even as the movable member is moving so as to control the shape or deflection of the distal shaft section.

[0073] The self-locking deflection system is operated by an operating member or lever which is movably mounted on the handle housing and which is directly or indirectly secured to the slider or collar mounted to a proximal end of the shaping member, and which is secured to a rotating or moving member having one of the friction engaging surfaces with a second set of a plurality of protuberances.

[0074] Preferably, the first and second friction engaging surfaces have undulating surfaces with a plurality of peaks and valleys. With the first of the friction engaging surfaces, the peaks of the undulating surface are about the same height. With the second friction engaging surface, the peaks of the undulating surface have increasing heights along a length of the undulating surface to provide an increase in the resistance between the first and second friction surface as the moving member moves in the moving direction. At least one of the peaks of the first friction engaging surface is always in a valley of the second friction engaging surface and the biasing element(s) ensure contact between the first and second friction engaging surfaces.

[0075] With the present invention, there is preferably no disengagement of the friction engaging surfaces, so the distal shaft section is automatically locked in the desired position. The increased resistance felt by the operator provides that operator with an indication of the shape of the distal shaft section.

[0076] Preferably, an electrophysiology catheter of the present invention includes an irrigation system, where the irrigation system provides liquid to the exterior of the shapeable shaft section for irrigating the electrode(s) of the electrophysiology catheter.

[0077] While the medical device described herein is a EP catheter, a variety of medical devices can be produced or used in accordance with embodiments of this invention, including without limitation, steerable catheters and guide wires, urologic or gynecologic catheters, coronary catheters (both venous and arterial), all in a wide variety of lengths and diameters. Embodiments including the shapeable shaft sections and the operating handle described herein may be used in a variety of medical and surgical procedures.

[0078] Furthermore, while the present invention has been described with reference to certain preferred embodiments or apparatuses, it is to be understood that the present invention is not limited to such specific embodiments or apparatuses. Rather, it is the inventor's contention that the invention be understood and construed in its broadest meaning as reflected by the following claims. Thus, these claims are to be understood as incorporating not only the preferred apparatuses described herein but all those other and further alterations and modifications as would be apparent to those of ordinary skilled in the art.

We claim:

1. A catheter comprising,

an elongated shaft having a proximal shaft section and a shapeable shaft section distal to the proximal section, an inner lumen extending within the proximal and shapeable shaft sections;

a shaping member slidably disposed within the inner lumen and extends into the shapeable shaft section;

a shape memory member adjacent to the shaping member in the inner lumen of the shapeable shaft section, wherein the shaping member and the shape memory member are coupled by a coupling coil; and

a handle having an operating lever, wherein the handle receives the proximal shaft section and the shaping member for operating the shapeable shaft section.

2. The catheter of claim **1** wherein a helical confining wire is disposed around the shaping member and the shape memory member to prevent the shaping member and the shape memory member from completely bowing apart when the shaping member is pulled or pushed.

3. The catheter of claim **2** wherein the helical confining wire defines a maximum distance between the shaping member and the shape memory member.

4. The catheter of claim **1** wherein a wire mesh is disposed around the shaping member and the shape memory member to prevent the shaping member and the shape memory member from completely bowing apart when the shaping member is pulled or pushed.

5. The catheter of claim **4** wherein the wire mesh defines a maximum distance between the shaping member and the shape memory member.

6. The catheter of claim **1** wherein the shapeable shaft section has a curvature and wherein the shape memory member provides a spring back force at the distal end of the shapeable shaft section that is opposite to the curvature of the shapeable shaft section.

7. The catheter of claim **1** wherein the shaping member has a flattened distal portion and wherein the flattened distal portion of the shaping member and the distal portion of the shape memory member each has a notched section and the coupling coil is wrapped around the notched sections of the elongated shaping member and the shape memory member.

8. The catheter of claim **1** further comprising a self-locking deflection system that comprises,

a rotor which is movably mounted within the handle, which has an engagement member secured thereto having a second friction engaging surface, which has at least one biasing element which urges the engagement member toward a first friction engaging surface so as to engage the second friction engaging surface with the first friction engaging surface; and

one of the first and the second friction engaging surfaces having increased frictional resistance to motion in a moving direction as the engagement member moves in the moving direction so as to hold the rotor in position upon release of pressure on the operating lever and to hold the elongated shaping member in a deflected position.

9. The catheter of claim **8** wherein the handle includes a rotatable wall on the exterior of the handle to which the operating lever is secured, and wherein the rotor is secured to an interior of the rotatable wall.

10. The catheter of claim **9** wherein the handle includes a flexible rack in the interior of the handle having a plurality of teeth and a flexible tail movably mounted within the handle.

11. The catheter of claim **10** wherein the handle includes a pin that passes through the rotatable wall, having one end secured to the operating lever and another end secured to the flexible tail of the flexible rack so that movement of the operating lever will cause movement of the flexible rack.

12. The catheter of claim **11** wherein the handle includes a slider secured to the proximal end of the shaping member and a gear assembly secured to the slider having a first gear engaging the flexible rack such that movement of the flexible rack will cause movement of the shaping member.

13. The catheter of claim **12** wherein the first gear of the gear assembly is mounted to a post rotatably secured to the slider.

14. The catheter of claim **13** wherein the gear assembly comprises a second gear mounted to the post rotatably secured to the slider and a second rack secured to the interior of the handle that is configured to receive teeth of the second gear.

15. The catheter of claim **1** wherein the catheter is an electrophysiology catheter having at least one electrode disposed on the exterior of the shapeable shaft section.

16. The catheter of claim **15** further comprising at least one temperature sensing element disposed adjacent to the at least one electrode.

17. The catheter of claim **1** further comprising at least one pressure sensor disposed on a distal tip of the shapeable shaft section.

18. The catheter of claim **1** is a linear ablation catheter.

19. The catheter of claim **1** is a tip ablation catheter.

20. The catheter of claim **1** further comprising an irrigation system, wherein the irrigation system provides liquid to the exterior of the shapeable shaft section to irrigate the at least one electrode.

21. An electrophysiology catheter comprising,

an elongated shaft having a proximal shaft section and a shapeable shaft section distal to the proximal section, an inner lumen extending within the proximal and shapeable shaft sections;

at least one electrode disposed on the exterior of the shapeable shaft section;

a shaping member slidably disposed within the inner lumen and extends into the shapeable shaft section;

a shape memory member adjacent to the shaping member in the inner lumen of the shapeable shaft section, wherein the shaping member and the shape memory member are coupled by a coupling coil, wherein the shaping member has a flattened distal portion and wherein the flattened distal portion of the shaping member and the distal portion of the shape memory member each has a notched section and the coupling coil is wrapped around the notched sections of the elongated shaping member and the shape memory member;

a handle having an operating lever, wherein the handle receives the proximal shaft section and the shaping member for operating the shapeable shaft section; and

a self-locking deflection system that comprises

a rotor which is movably mounted within the handle, which has an engagement member secured thereto having a second friction engaging surface, which has at least one biasing element which urges the engagement member toward a first friction engaging surface so as to engage the second friction engaging surface with the first friction engaging surface; and

one of the first and the second friction engaging surfaces having increased frictional resistance to motion in a moving direction as the engagement member moves in the moving direction so as to hold the rotor in position upon release of pressure on the operating lever and to hold the elongated shaping member in a deflected position;

wherein a helical confining wire is wrapped around the shaping member and the shape memory member to prevent the shaping member and the shape memory member from completely bowing apart when the shaping member is pulled or pushed and wherein the helical confining wire defines a maximum distance between the shaping member and the shape memory member.

22. The electrophysiology catheter of claim **21** wherein the handle includes a rotatable wall on the exterior of the handle to which an operating lever is secured, wherein the rotor is secured to an interior of the rotatable wall, wherein the handle includes a flexible rack in the interior of the handle having a plurality of teeth and a flexible tail movably mounted within the handle, wherein the handle includes a pin that passes through the rotatable wall, having one end secured to the operating lever and another end secured to the flexible tail of the flexible rack so that movement of the operating lever will cause movement of the flexible rack, wherein the handle includes a slider secured to the proximal end of the shaping member and a gear assembly secured to the slider having a first gear engaging the flexible rack such that movement of the flexible rack will cause movement of the shaping member, wherein the first gear of the gear assembly is mounted to a post rotatably secured to the slider, and wherein the gear assembly comprises a second gear mounted to the post rotatably secured to the slider and a rack secured to the interior of the handle that is configured to receive teeth of the second gear.

23. The catheter of claim **21** further comprising at least one temperature sensing element disposed adjacent to the at least one electrode, at least one pressure sensor disposed on a distal tip of the shapeable shaft section and an irrigation system, wherein the irrigation system provides liquid to the exterior of the shapeable shaft section to irrigate the at least one electrode.

24. An electrophysiology catheter comprising, an elongated shaft having a proximal shaft section and a shapeable shaft section distal to the proximal section, an inner lumen extending within the proximal and shapeable shaft sections;

at least one electrode disposed on the exterior of the shapeable shaft section;

at least one temperature sensing element disposed adjacent to the at least one electrode;

at least one pressure sensor disposed on a distal tip of the shapeable shaft section;

an irrigation system, wherein the irrigation system provides liquid to the exterior of the shapeable shaft section to irrigate the at least one electrode;

a shaping member slidably disposed within the inner lumen and extends into the shapeable shaft section;

a shape memory member adjacent to the shaping member in the inner lumen of the shapeable shaft section, wherein the shaping member and the shape memory member are coupled by a coupling coil, wherein the shaping member has a flattened distal portion, wherein the flattened distal portion of the shaping member and the distal portion of the shape memory member each has a notched section and the coupling coil is wrapped around the notched sections of the elongated shaping member and the shape memory member, wherein the shapeable shaft section has a curvature, and wherein the shape memory member provides a spring back force at the distal end of the shapeable shaft section that is opposite to the curvature of the shapeable shaft section;

a handle having an operating lever, wherein the handle receives the proximal shaft section and the shaping member for operating the shapeable shaft section; and

a self-locking deflection system that comprises

a rotor which is movably mounted within the handle, which has an engagement member secured thereto having a second friction engaging surface, which has at least one biasing element which urges the engagement member toward a first friction engaging surface so as to engage the second friction engaging surface with the first friction engaging surface; and

one of the first and the second friction engaging surfaces having increased frictional resistance to motion in a moving direction as the engagement member moves in the moving direction so as to hold the rotor in position upon release of pressure on the operating lever and to hold the elongated shaping member in a deflected position;

wherein a helical confining wire is wrapped around the shaping member and the shape memory member to prevent the shaping member and the shape memory member from completely bowing apart when the shaping member is pulled or pushed, wherein the helical confining wire defines a maximum distance between the shaping member and the shape memory member, wherein the handle includes a rotatable wall on the exterior of the handle to which an operating lever is secured, wherein the rotor is secured to an interior of the rotatable wall, wherein the handle includes a flexible rack in the interior of the handle having a plurality of teeth and a flexible tail movably mounted within the handle, wherein the handle includes a pin that passes through the rotatable wall, having one end secured to the operating lever and another end secured to the flexible tail of the flexible rack so that movement of the operating lever will cause movement of the flexible rack, wherein the handle includes a slider secured to the proximal end of the shaping member and a gear assembly secured to the slider having a first gear engaging the flexible rack such that movement of the flexible rack will cause movement of the shaping member, wherein the first gear of the gear assembly is mounted to a post rotatably secured to the slider, and wherein the gear assembly comprises a second gear mounted to the post rotatably secured to the slider and a rack secured to the interior of the handle that is configured to receive teeth of the second gear.

* * * * *

patsnap

专利名称(译)	具有可偏转轴部分和张力控制的医疗设备		
公开(公告)号	US20130204096A1	公开(公告)日	2013-08-08
申请号	US13/366034	申请日	2012-02-03
[标]申请(专利权)人(译)	文森特wenchung Ku 陈ERICķÿ		
申请(专利权)人(译)	KU，VINCENT WENCHUNG 陈，ERIC K.Y.		
当前申请(专利权)人(译)	睿兴有限公司		
[标]发明人	KU VINCENT WENCHUNG CHAN ERIC K Y		
发明人	KU, VINCENT WENCHUNG CHAN, ERIC K.Y.		
IPC分类号	A61B5/00 A61B5/04 A61B1/00		
CPC分类号	A61B1/00 A61B5/00 A61B5/04 A61B1/00066 A61B1/0058 A61M2025/0002 A61M25/0133 A61M25/0136 A61M25/0138 A61M25/0144 A61M25/00		
外部链接	Espacenet USPTO		

摘要(译)

导管包括细长轴，细长轴具有近端轴部分和远离近端部分的可成形轴部分，内腔在近端和可成形轴部分内延伸;成形构件可滑动地设置在内腔内并延伸到可成形的轴部分中;形状记忆构件，邻近可成形轴部分的内腔中的成形构件，其中成形构件和形状记忆构件通过耦合线圈连接;手柄具有操作杆，其中手柄接收近端轴部分和成形构件，用于操作可成形轴部分。