

A STEERABLE ARM FOR USE IN ENDOSCOPIC SURGICAL PROCEDURES

TECHNICAL FIELD OF THE INVENTION

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The invention relates to the field of endoscopic surgical instruments.

BACKGROUND

10 Gastrointestinal (GI) cancers are the most common cancers worldwide. According to World Health Organization (WHO) cancer statistics, colorectal and gastric cancers are respectively the second and third most common cause of cancer related deaths globally, which amount to 862,000 and 783,000 respectively in 2018. While advanced GI cancers are difficult to cure, 15 early GI cancers carry a significantly better prognosis. The 5-year survival for GI cancers at an early stage is more than 90% worldwide.

Conventional treatment for GI cancers is surgery, which involves resection and anastomosis, and is associated with significant morbidity and mortality 20 rates.

The preferred methods of surgery of the gastrointestinal (GI) tract include directing surgical instruments through the instrument/biopsy channels of an endoscope. A flexible endoscope is inserted through the mouth into the 25 stomach to reach the target location, or from the anus up into the large intestine to reach the target location, with the distal end of the endoscope steered by the surgeon using a control handle on the proximal end of the endoscope. The endoscope has at least one biopsy channel into which a

long, flexible instrument with a surgical tool at the distal tip is inserted from the proximal end of the endoscope. The most commonplace flexible endoscopes are made by Olympus, and have biopsy channel diameters as large as 3.7 mm, but which may be as small as 2.8 mm and lower.

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Medrobotics proposes a semi-robotic robotic endoscope with channels for manual surgical instruments (described in US10016187B2). The diameter of the surgical instrument is assembled from many discrete joints to allow articulation when pulled by a pair of pair of antagonistic wires (two wires on opposite sides pulling in opposite directions). To bend a joint in one direction, one wire must be pulled, while the other wire must be released or pushed. The discrete joints are complex to design and assemble, and necessitate a wide 4-mm thick diameter. Hence, a major disadvantage of this surgical instrument is that it does not fit into the biopsy channel in the commonplace flexible endoscopes.

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Endomaster proposes a similar robotic surgical instrument, which is also assembled from discrete joint-based mechanisms (described in US20210186309A1) that suffer from the same disadvantages.

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Lumendi proposes an endoscopic surgical instrument that comprises a flexible backbone fabricated from a single body of flexible material, e.g. a nickel titanium (nitinol) tube, with unconnected, discrete slots cut into and along the side of the tube (described in US20200305906A1). The straight tube can be bent to either direction by pulling wires affixed to the respective side of the tube. Again, this design requires complex manipulation in pulling on one wire while releasing the opposite wire. Furthermore, this surgical instrument is also

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too thick to be useable with the biopsy channels in commonplace endoscopes and must be used with their proprietary accessory system.

Endotheia proposes a surgical instrument that can be used with the
5 commonplace endoscope, described in US10441371B2. This design
comprises nested concentric nitinol tubes, which are each pre-curved. These
tubes have an overall diameter that is capable of extending through the
biopsy channel in the commonplace endoscope. To bend the surgical
instrument towards a target location, each of the nested tubes is extended to
10 a suitable extent to create the required curvature. There is no need of wires to
bend the tubes. However, the extent to which each curved tubes should
extend requires complex computation, which makes it rather necessary for
software and robotic control, and manual override is implausible even when
the situation might call for it. Furthermore, the lifting force of the thin tubes is
15 too weak for some procedures. Also, the tubes cannot provide a sharp bend,
and the endoscope has to be placed relatively far from the target site in order
for the tubes to extend far enough to provide sufficient curvature. As a result,
the camera on the tip of the endoscope may be too far from the distal end of
the surgical instrument to provide good visualization of the operation; the
20 lateral and vertical reach of the instrument may be limited if the target site is
too near the tip of endoscope.

Therefore, it is desirable to propose a surgical instrument that provides
dexterous tissue manipulation while being suitable for use with commonplace
25 endoscopes, and which provides a possibility of better control to the surgeon.

STATEMENT OF INVENTION

In a first aspect, the invention proposes a steerable arm for use in endoscopic surgical procedures, comprising: a tubular member having a proximal end and
5 a distal end; distal end suitable for being fitted with a surgical end effector; the tubular member being made of a resilient material; a wire extending inside the tubular member from the proximal end; the wire attached to the distal end of the tubular member, and to a side of the tubular member; the tubular member capable of having a curvature lengthwise; wherein the curvature changes
10 when the distal end of the tubular member is pulled on by the wire; and the resilience of the material providing the tubular member with a bias such that the curvature change reverses when the pull on the distal end is released.

Advantageously, the invention provides the possibility that releasing the pull
15 allows the bias to manifest and restores the steerable arm to the shape in the rest state. This makes the second wire in the prior art steerable art redundant. This one-wire approach is easier than the two-wire approach of the prior art that requires additional coordination between pulling one wire and releasing the other, and saves space inside the steerable arm for other components or
20 wires.

The tubular member does not have to be a tube with solid walls, but may be any elongate member, such as a coil of loops, that provides the required features and functions.

25 Preferably, the tubular member has a first side and a second side along the axis of the tubular member; the first side being relatively more compressible than the second side; the second side being relatively less compressible

- compared to the first side; wherein the side of the tubular member that the wire is attached is the first side; and a pull on the wire compresses the first side to change the curvature of the tubular member. Advantageously, the greater compressibility of the first side accommodates the bending and flexing of the second side, allowing the whole steerable arm to bend and flex. The greater compressibility of the first side and the lesser compressibility of the second side can be provided by making the first side and the second side of different materials, or be provided by structural design.
- 10 Preferably, the steerable arm further comprises gaps in the first side to provide the compressibility of the first side; wherein the pull of the wire changes the curvature of the tubular member by bringing gaps closer and bending the second side towards the first side. This feature relates to structurally-provided compressibility, which improves the inherent
- 15 compressibility provided by the material of the tubular member.

Preferably, the steerable arm further comprises wire guides or eyelets inside the tubular member for guiding the translation of the wire.

- 20 Preferably, the tubular member is curved in a rest state, such that there is a concave side and a convex side to the tubular member; and the convex side of the tubular member being the first side. Advantageously, this allows that a single wire can flex the steerable arm from being bent in one direction over to being bent in the opposite direction, to the extent where the compressibility of the first side make this possible, potentially swinging the steerable arm across
- 25 a plane.

In the application when the tubular member is used in the biopsy channel of an endoscope, the curve in the tubular member advantageously allows the camera on the tip of the endoscope to be positioned closer to the target tissue, as compared to a straight steerable arm of the same length without a curvature. Also, the camera's view is not obscured, as the curvature places the body of the steerable arm away from the centre of the endoscope's view.

Preferably, the tubular member is a tubular coil of spiralling loops; the curvature of the tubular member being such that the edges of the loops on the first side are spaced apart to provide the gaps; and the edge of each of the loops on the second side abutting the edge of each adjacent loop; wherein the first side and the second side are on opposite sides of the tubular member. The abutting edges prevent compression, and provide leverage about which the steerable arm may be flexed.

The advantage of a spiralling loops structure provides the possibility of cutting the steerable arm from a single original tube, which is economical and provides a continuum structure. This also provides the possibility of exploiting the flexibility of the looping structure to flex the steerable arm while relying on the stiffness of the material making up the tubular member to provide the bias. In the embodiments, the loops on the first side are described as ribs that can open apart or close up, while the second side is described as a spine.

Optimally, the loops have different spiral pitches and/or spacing variations along different parts of the steerable arm, in order to provide the different parts with different flexibility.

- 5 Preferably, the distal part is more flexible than the proximal part, advantageously preventing pulling of a wire attached to a more distal part of the steerable arm to cause unintentional deformation of a more proximal part; this allows the bending of the more distal part to be controlled without affecting the bending of other more proximal parts, providing greater control
10 over the steerable arm.

Preferably, the loops are produced by at least one spiralling cut made to a tube.

- 15 Preferably, the steerable arm further comprises at least a slit in the edge of at least one of the loops on the second side. Advantageously, the slit allows some measure of stretch-ability in the spine which increases flexibility.

- Optionally, the tubular member is a tubular coil of spiralling loops; and the
20 steerable arm further comprising two opposite columns of coupling joints each arranged along opposite sides of the tubular member; each of the coupling joints of each column rotatably connecting a respective two adjacent loops; such that the opposite columns of coupling joints providing the second side; the tubular member having an axis located at the centre of the tubular
25 member's cross-section and along its length; and the first side and the second side are orthogonally arranged to each other with respect to the axis of the tubular member.

Preferably, the tubular member is fabricated from a single piece of material; such that the tubular member is a continuum structure. (i.e. remains a monolithic structure). For example, the single piece of material is a single tube. Advantageously, a continuum structure provides the possibility to rely
5 entire only the innate strength and stiffness of the material making up the structure, without additional connections or coupling required to join separate parts.

Optionally, there is an elongate piece of spring attached to the length of the
10 second side; the elongate piece of spring reinforcing the bias by providing additional structural stiffness.

Preferably, the tubular member comprises at least two sections; a respective number of wires extending inside the tubular member from the proximal end;
15 each wire affixed to the distal end of each section, the distal end of the most distal section being the distal end of the tubular member; each section capable of having a curvature lengthwise of the tubular member, such that curvature of each section is changed when the distal end of each section pulled on by the respective wire; wherein the resilience of the material
20 provides the tubular member with a bias such that the curvature change of each section is reversed when the pull on the distal end of the each section is released.

Advantageously, each section can contribute to a different plane of
25 movements which gives better freedom of movement to the distal tip of the steerable arm.

Preferably, the change of curvature of each of the at least two sections lies in a different plane.

5 Preferably, the stiffness of each section is different such that the sections located near the proximal end of the steerable arm are larger in order to reduce the mechanical coupling effect between sections when pulling the wires of different sections.

10 Typically, the steerable arm is placed at the distal end of a transmission tube; the transmission tube having minimal compressibility and extensibility along its axial direction, having high twisting stiffness to provide efficient torque and force transmission including force transmission from the pull wires to the steerable arm and end effector, and containing a channel in which the wire is threaded alongside other necessary components such as electrical
15 connections or surgical functions like suction or tubing for injections; the proximal end of the wires connected to knobs and/or levers for pulling on the wire; such that the curvature changes when the distal end of the tubular member is pulled on by the wire at the proximal end of the transmission tube.

20 In a second aspect, the invention proposes A method of making a hollow tube into a steerable arm for use in an endoscope surgical procedure, comprising the steps of:

- a) providing the hollow tube having a proximal end and a distal end;
25 the distal end suitable for being fitted with a surgical end effector; and the hollow tube being made of a resilient material;
- b) cutting the hollow tube circumferentially and along the length of the tube to make a spiral cut;

the spiral cut producing gaps along at least one side of the tube;

c) inserting a wire into the proximal end of the hollow tube;
and

5 d) attaching the wire to the hollow tube, the attachment being:

- i. on the side of the tube where the gaps are; and
- ii. so distal from the proximal end such that the wire extends over the gaps.

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Cutting a whole, hollow tube to form the steerable arm provides the possibility that the steerable arm has a continuum structure

The method allows a single tube of material to be pre-selected for the
15 diameter of the tube, and tailor make the size of the steerable arm to suit the channel size of the endoscope. In contrast, it is harder in prior art methods which rely on assembling different parts together, to fabricate a small steerable arm.

20 Preferably, the method further comprises the steps of holding the hollow tube in a bent position; and causing the hollow tube to memorise the bend in the rest state through plastic deformation or heat treatment.

Preferably, the method further comprises the steps of cutting the hollow tube
25 in such a way as to leave couplers on each of the loops for coupling with adjacent loops.

BRIEF DESCRIPTION OF DRAWINGS

- It will be convenient to further describe the present invention with respect to the accompanying drawings that illustrate possible arrangements of the invention, in which like integers refer to like parts. Other embodiments of the invention are possible, and consequently the particularity of the accompanying drawings is not to be understood as superseding the generality of the preceding description of the invention.
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- 10 Figure 1 shows a prior art for comparative purpose;
Figure 2 shows a prior art for comparative purpose;
Figure 3 shows a device that includes an embodiment of the invention;
Figure 4 shows two of the device of Figure 3 in use with an endoscope;
Figure 5 is a close-up view which shows an embodiment, the view being a
15 part of that shown in Figure 4;
Figure 5a shows the embodiment of Figure 5 fitted with forceps;
Figure 5b shows the embodiment of Figure 5 fitted with electrosurgical knives;
Figure 6 is a photograph taken by the camera of an endoscope of a prototype
corresponding to the embodiment of Figure 5;
20 Figure 7 is an illustration of a more specific embodiment that is found in the
embodiment of Figure 5;
Figure 8 is a schematic illustration of the workings of the embodiment of
Figure 7;
Figure 9 is a schematic illustration of the fabrication of the embodiment of
25 Figure 7;
Figure 10 shows a part of the embodiment of Figure 7;
Figure 11 shows a part of the embodiment of Figure 7;
Figure 12 is an embodiment alternative to that of Figure 7;

- Figure 13 shows alternate views of the embodiment of Figure 12;
Figure 14 is shows alternate views of the embodiment of Figure 12;
Figure 15 shows a variation of the embodiment of Figure 12;
Figure 16 shows an embodiment based on the embodiment of Figure 7;
5 Figure 17 is a schematic illustration of the fabrication of the embodiment of
Figure 16;
Figure 18 is a technical drawing of the embodiment of Figure 16;
Figure 19 is a schematic illustration showing how the embodiment of Figure
16 operates;
10 Figure 20 illustrates the operation of another embodiment;
Figure 21 shows a variation to the embodiment of Figure 20;
Figure 21a shows another variation to the embodiment of Figure 20;
Figure 22 shows a variation to the embodiment of Figure 7;
Figure 23 is a schematic illustration of the fabrication of the embodiment of
15 Figure 22;
Figure 24 shows how the embodiment of Figure 22 operates;
Figure 25 shows a possible feature in the embodiment of Figure 7;
Figure 26 shows variation to the feature Figure 25; and
Figure 27 shows a more general embodiment of the invention
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DESCRIPTION OF EMBODIMENT(S)

- Figure 1 shows a prior art for comparative purpose. The prior art is a steerable
arm that may be used in endoscopic surgery. This steerable arm comprises
25 nested, curved segments that can extend telescopically. The end of the
thinnest segment can extend furthest and is affixed with an end-effector, such
as a pair of forceps or a diathermy knife. Each segment can be extended fully
or partially to contribute the overall bend of the steerable arm in order to reach

a target area. Bending of the steerable arm is not achieved through pulling wires.

Figure 2 illustrates another steerable arm of the prior art. This steerable arm is generally an elongate member 201 that has a series of parts cut out from the lateral sides of the elongate member. Two wires inside the elongate member are affixed to opposite lateral sides at the distal end of the elongate member. To bend the elongate member to one side, one wire has to be pulled while the other wire has to be released, as an agonist-antagonistic wire pair.

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Figure 3 illustrates an embodiment of the present invention, which is a flexible surgical instrument 300 for use with an endoscope 400.

The flexible surgical instrument 300 comprises a transmission tube 307, which makes up the bulk of the length of the flexible surgical instrument 300. The distal end 303 of the transmission tube 307 is installed with a steerable arm 301. In turn, the distal end of the steerable arm 301 is affixed with a surgical end-effector 403 (see insert in Figure 4) that determines the functionality of the flexible surgical instrument 300, such as forceps, diathermy knife, injection needle, suturing tool and so on.

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Figure 4 shows an endoscope 400 inserted with two flexible surgical instruments 300. An endoscope 400 is an optical instrument that is capable of being extended into the gastrointestinal (GI) tract through the mouth or anus, and manoeuvred to reach a target location in the tract to provide a view. An endoscope 400 may comprise a video display connected to its proximal end, and a light source and a camera with a large field of view on the distal end 411. Image transmission from the camera to the video display may be

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provided by an optical fibre system or a sensor chip system.

Endoscopes 400 for GI procedures are typically longer than 1 m. The outer diameter of an endoscope 400 that has two biopsy channels is usually larger than 1.2 cm. The core of the most common GI endoscopes 400 is provided with one or two channels that may have a diameter of 2.8 mm to 3.7 mm, typically called the biopsy channels 405 or instrument channels. A biopsy channel 405 has a channel entrance 413 at the proximal end of the endoscope 400 and a channel exit at the distal end 411 of the endoscope 400.

10 The flexible surgical instrument 300 can be inserted into a biopsy channel 405 through the channel entrance. The endoscope 400 of Figure 4 has two biopsy channels 405, one for each of the two flexible surgical instruments 300.

Figure 5 is a magnified view of the drawing insert in Figure 4 and shows an exemplary arrangement of the camera 501 and the source of light 503 on a cap 401 at the distal end 411 of the endoscope 400. The camera 501 provides a live view of the surgical site, steerable arms 301 and the end-effector 403, to guide the surgeon in manipulating the steerable arms 301.

20 Figure 5a shows a steerable arm 301 the distal end of which is provided with forceps 505 as the end-effector. Figure 5b shows a steerable arm 301 the distal end of which is provided with a diathermy knife 507 as the end-effector. Other end effectors can be installed onto the distal tip of the steerable arm 301 to determine the final functionality of the arm, such as injection needle and suturing tools and so on.

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Figure 6 is a picture that may be taken by the camera 501, showing two steerable arms 301 each affixed with an end-effector 403 and performing a

procedure on tissue. The two steerable arms 301 in Figure 6 are fitted with an outer sheath, which reduces friction when the flexible surgical instrument 300 is inserted into the biopsy channel 405, and to provide electrical insulation.

- 5 In the preferred embodiment, the transmission tube 307 and the steerable arm 301 have an outer diameter of 2.7 mm or less, in order to fit into most biopsy channels 405 provided by commonplace GI endoscopes 400. The length of the transmission tube 307 may vary by design and depends on the length of the endoscope 400 that the flexible surgical instrument 300 is intended to be
10 used with.

The steerable arm 301 can be moved or bent by pulling on wires that are threaded through at least one channel in the transmission tube 307. The distal ends of some of the wires are affixed to different parts inside the steerable
15 arm 301. The distal ends of the remaining wires are connected to the end-effector 403.

The ends of the wires 309 protruding from the proximal end 305 of the flexible surgical instrument 300 are coupled to an adapter (not illustrated) located
20 outside of the endoscope 400. The adapter comprises knobs, pulleys or levers (not illustrated) to which the ends of the wires are separately connected. Rotation or translation of each knob, pulley or lever causes a pull on the respective wire. Pulling on the proximal end of the wires move or bend the steerable arm 301, or actuate the end-effector 403. The adapter can be
25 operated robotically via electronic components and software to control movements of the steerable arms 301 and the end-effectors 403.

In a surgery, the surgeon inserts the endoscope 400 into the patient's body and navigates the endoscope 400 to the desired location in the GI tract. The wires 309 that extend from the proximal end of the endoscope 400 can be pulled or released by the adapter.

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Figure 7 illustrates the main part of the steerable arm 301, which is a metal tube fashioned into a tubular coil 707 of loops or a spiralling metal ribbon. The steerable arm 301 is bent when at rest, and therefore has a convex side 703 and a concave side 701. On the concave side 701, the edges of the loops are closed up, and each edge abuts the corresponding edge of each adjacent loop, which prevents compression of the loops on the concave side 701. This provides a spine on the concave side 701 of the tubular coil 707. On the convex side 703, the edges of the loops are spaced apart, and this forms ribs that extend from the spine. The edges of the ribs on the concave side 701 are capable of moving closer or further apart from each other, to allow the spine to be flexed. The steerable arm 301 can be flexed to become straightened or, optionally, even bent to the opposite side. However, the metal is a resilient material and provides a bias in the steerable arm 301 to revert to the original shape when the flexing force is removed.

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Figure 8 is a series of schematic illustrations of the articulation of the steerable arm 301. The drawings show the end of the wire 309 for controlling the steerable arm 301 extending through the core of the steerable arm 301 and connected to a rib at or near the distal end of the steerable arm 301. The wire 309 is illustrated as a solid line for clarity but the skilled reader would appreciate that the wire 309 is largely hidden from sight by being inside the steerable arm 301. The distal end of the wire 309 can be secured to the rib via a knot, crimp, or by other means of ensuring the wire 309 remains fixed to the

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rib. The steerable arm can be made of a spiral of loops or can be made from a tube which has sections cut along the side of the tube.

The left-most drawing shows the steerable arm 301 in the rest state, which is bent such that the spine is concave (Figure 8a). The ribs are on the convex side and spread apart to accommodate the bend. When the wire 309 is pulled, some of the ribs are brought closer to each other, and the spine is flexed and straightened (Figure 8b). On pulling the wire 309 further, the ribs are pulled even closer to each other such that the curvature of the steerable arm 301 reverses and now bends away from the original bending direction (Figure 8c). Releasing the pull allows the bias to manifest and restores the steerable arm 301 to the shape in the rest state. It is this bias that makes a second wire to pull the steerable arm back to its original rest state redundant.

Therefore, the steerable arm 301 can be moved from being bent in one direction to being bent in another direction within a plane. This allows the end-effector 403 on the steerable arm 301 to manipulate tissue. This one-wire approach is easier than the two-wire approach of the prior art that requires additional coordination between pulling one wire and releasing the other. Also, the presence of the second wire would take up space within the steerable arm 301.

Figure 9 shows schematically a preferred way in which the steerable arm 301 is made. Firstly, a tube 901 made of a super-elastic material is provided, which has a diameter small enough to be channelled through the biopsy channel 405 of the endoscope 400 that the steerable arm 301 is expected to be used on. Typically, a diameter of 2.7 mm or less is preferred for universal application. The trailing transmission tube 307 may have a similarly small

diameter that is not a concern for channelling through the biopsy channel.

Super-elastic materials are those which have the ability to undergo large deformations and immediately return to its undeformed shape upon removal of the external load, such as nitinol (nickel titanium) and the following alloys:

- 5 Cu–Zn, Cu–Al–Ni, Au–Cd, Au–Cu–Zn, and In–Ti.

The tube 901 is cut spirally and along the length of the tube 901, as shown in Figure 9a, to fabricate the tube 901 into a tubular coil 707. The cut may be made by a precision machining e.g. laser cutting, computer numerical control
10 (CNC) milling or other means. Figure 9 illustrates a laser source 903 used to cut the tube 901.

Other cuts are made into the side of the tube 901 to slice and remove a part 907 of each loop. This provides a gap 905 between every two adjacent loops
15 on that side of the tube 901, which provides the ribs 909 (Figure 9b). The gaps 905 allow the ribs 909 to close in onto each other to accommodate a bend of the spine 911 toward the rib side. Also, the ribs 909 can be moved further apart to accommodate a bend of the spine 911 towards the spine side (Figure 9c). The other side of the tube 901 that forms the spine 911 is cut with
20 minimal gaps 905 between the loops.

It should be noted that a spiral cut is made all around the circumference of the tube 901, including the side of the tube 901 that becomes the spine 911. The edges of the loops on the spine 911 are therefore also cut and separated.
25 However, edge of each loop on the spine side abuts the edge of each adjacent loop. The abutment prevents compression of the spine 911 when the steerable arm 301 is flexed by pulling the wire 309.

Optionally, in other embodiments, the tube 901 can be cut only one side to provide gaps 905 that form the ribs 909, without a spiralling cut that is made all around the circumference, so that the side of the tube 901 that forms the spine 911 is left integral and not cut in any way at all.

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Optionally, the steerable arm 301 is then held into the desired shape and heat-treated or plastically deformed to cause the material to memorise the shape.

10 Figure 10 and Figure 11 are technical drawings of the ribs 909 and the spine 911, without the spine 911 shown bent. The left drawing in Figure 10 shows the exterior image of the steerable arm 301, while the right drawing of Figure 10 is the corresponding cross-sectional view from the direction marked h-h. The left of Figure 11 is the cross-sectional image in the direction j-j, while the
15 right of Figure 11 shows the corresponding outward appearance of the steerable arm 301.

The spiral pattern can be varied to change the spiral pitch (L), spacing variation (M), number of turns, thickness of cut, shape of cut, slot location and
20 size. These parameters can be adjusted to change the profile of the bending, range of motion, and stiffness of the spine 911, and may be selected according to surgical application requirements. Accordingly, the extent and shape of the pre-curvature can be varied to meet different surgical requirements such as a particular angle-of-attack of the instrument end-
25 effector 403.

The stiffness, flexibility and resilience of the steerable arm can be adjusted by varying the structure of the gaps and the loops. For example, if the loops are

thicker, the steerable arm has less flexibility and is stiffer. Alternatively, if the loops are narrow, the steerable arm has more flexibility. The size of the gaps between the loops, the width of each gap, the tilt of the gaps (spiral pitch), the closeness of the gaps, all may affect the flexibility and the resilience.

- 5 Generally, the larger the gaps and the greater the density of the loops, the more deformable or flexible the tube. Even in embodiments where the steerable arm is not a coil of loops, but merely a tube with gaps that are sliced into the tube along the side of the tube, the same variations in the gaps can produce similar variation in the flexibility of the tube. Therefore, it is possible to
- 10 produce a steerable arm that is more flexible at the distal end and less flexible at the proximal end, merely by cutting the distal end more finely to have either more fine loops or more cut-out portions, and the proximal end to have less finely cut loops or less cut-out portions. Advantageously, this prevents pulling of a wire attached to a more distal part of the steerable arm to cause
- 15 unintentional deformation of a more proximal part; this allows the distal end not to lose control sensitivity over the proximal end, which makes the steerable arm more dextrous.

- The steerable arm 301 is fabricated from a single body of metal that provides
- 20 a continuum structure. A continuum structure refers to something that is integral and bends in a continuous way by actually deforming the material, rather than by movement between separate but connected joints. In other words, a continuum structure is typically made of a single piece of material. Furthermore, a continuum structure has no sharp folds or folding bends that
- 25 may create high stress concentrations, and a continuum structure may only have gradually curving or straight sides. In this way, the molecular or elemental structure of the material may provide the strength, stiffness and resilience and flexibility to the continuum structure.

The continuum structure avoids having to assemble separate parts into a steerable arm 301, and overcomes the challenge found in prior art wherein steerable instruments require labour-intensive assembly of complex individual parts or interconnecting joints, and which the parts' complexity may have a resultant size too large for use with the biopsy channels 405 of some endoscopes 400. Furthermore, this also reduces manufacturing time, complexity, and costs. In contrast to the embodiment, the prior art steerable arm comprised of individual parts cannot be made to bend in the rest state, as separate parts cannot be heated to retain a memory of a position.

Furthermore, the material used in a continuum structure can give sufficient strength and stiffness to the steerable arm 301 to retract/lift tissue in a surgical setting, while an assembled structure made up of separate parts cannot exploit the strength of the material to do so.

Preferably, eyelets 2201 (see Figure 22) for guiding the wire 309 are provided on the internal surface of the ribs. The eyelets allow axial translation of the wire 309 to facilitate actuation of the spine 911, and also constrain the wire 309 against the internal side of the steerable arm 301. The eyelets may be provided as additional parts fabricated separately and assembled together with the steerable arm.

Figure 12 shows a second embodiment in which coupling joints 1201 are provided between every adjacent rib 909 to prevent the ribs 909 from widening or sliding radially or prevent twisting about the steerable arm long axis. Figure 13 and Figure 14 correspond to Figure 12, except that the version in Figure 12 is shown biased to bend in the rest state.

The coupling joints 1201 can be seen in Figure 13a as provided on opposite sides of the steerable arm 301. The edges of the ribs 909 are spaced apart on the convex side of the bend, as well as on the concave side. Thus, unlike the afore-mentioned embodiments, the spine is not defined by abutting ribs on the concave side. Instead, the spine is defined by the coupling joints 1201 which prevent the ribs 909 from being compressed, and the coupling joints 1201 are arranged in a column along the length of the steerable arm 301 such that the coupling joints 1201 provide the pivots about which the ribs 909 may rotate, and the spine may bend to either side. In other words, the ribs 909 and the spine are orthogonally arranged to each other with respect to the axis of the tube 901.

The coupling joints 1201 minimise bending or twisting outside of the joints' rotational plane, and prevents the loops that form the ribs 909 from loosening and enlarging radially. Generally, the coupling joints 1201 do not provide additional stiffness to the steerable arm 301 for returning to an original shape when the steerable arm 301 is flexed. The resilience and bias is still provided by the choice of material making up the steerable arm 301, and that the steerable arm 301 is a continuum structure.

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A wire 309 (not illustrated in this drawing) extends within the steerable arm 301 and is affixed to an edge of one of the most distal ribs 909, where the edge is on the part of the rib 909 that is on the convex side. Pulling on the wire 309 can articulate the ribs 909 by rotating each rib 909 about the respective coupling joints 1201 and bending the steerable arm 301. Bending simply means changing the curvature of the arm. Bending could mean bending the arm from a straight configuration or straightening the arm from a bent configuration. The edges of the ribs 909 on the convex side of the spine

close up while the edges of the ribs 909 on the concave side open up. Pulling further on the wire 309 reverses the bend such that the steerable arm 301 now bends in the opposite direction (not illustrated). The steerable arm 301 naturally returns to the memorised shape when the pull on the wire 309 is released.

This embodiment is also made by cutting a single tube of nitinol. Pieces of the tube are cut away to create a coil of spaced out spiralling loops, and these loops forms the ribs 909 of the steerable arm 301. However, the cut out leaves behind the shape of a male coupling joint on one side of each rib 909, and the shape of a female coupling joint on the other side of the rib 909. In this case, 'side' does not refer to the lateral sides of the whole tube, but the sides of each rib 909 of the coil. The male coupling joint on the lower side of each rib 909 as shown in the drawing fits into the female coupling joint on the upper side of the adjacent rib. After being cut from the tube, the steerable arm 301 is held in the desired bend with all the coupling joints 1201 mated and heat treated to memorise the bend.

In some variations of this embodiment, both sides of the tube about the spine of coupling joints can be affixed with a wire each, one wire to bend the tube to either side. In these variations, the tube may or may not be pre-curved. Of course, having a pre-curved, resilient tube allows only one wire to flex the tube to be curved towards the opposite side and the original shape restored by the bias provided by the resilience.

Figure 14 shows the male coupling joint 1401 and female coupling joint 1403 separately, unmated, each provided on facing sides of adjacent ribs 909. The male coupling joint 1401 comprises a neck on which is a round head, and is

capable of fitting into the female coupling joint 1403 which comprises a jaw defining a round gap. The rounded jaw is capable of rotating about the round head to allow the ribs 909 to articulate. Note that during fabrication of the continuum structure, the male coupling joint and female coupling joint are
5 already mated, and that Figure 14 is for illustrative purposes only.

Advantageously, the embodiment of Figure 12 combines the benefits of a continuum device (an integral device without any assembly of different parts, providing benefits such as fabrication simplicity, ease of miniaturization,
10 selectable stiffness based on the tube material and/or structure, inherent antagonistic force due to compliance) with the benefits of a joint-based bending segment (such as mechanical constraints to minimize axial compression and out-of-plane bending).

15 Figure 15 shows a variation of the coupling joints with a more simplified design. In this case, the male coupling joint 1401 is simply a small, rounded head without a neck, and the female coupling joint 1403 is a shallow cradle. There is no need for the female couple to claw onto the head of the make coupling joint as the male coupling joint does not have a neck.

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The embodiments described so far can be flexed to bend or be straightened within only one plane of movement. To provide multiple planes of movements, the embodiments can be thought of modularly, and be cut into different sections from the same nitinol tube as different parts of a larger steerable arm
25 301. Accordingly, Figure 16 shows a steerable arm 301 made of a single tube that has been cut such that there are two tubular coils 707 connected in series which are like that of Figure 7. The two tubular coils 707 shares the same axis but are angularly offset such that each part can be bent in a different plane.

Thus, the spine 911 of the top part 1601 of the tube (top as illustrated in the drawing) faces one direction while the spine 911 of the bottom part 1603 faces a different direction. The top part 1601 can be actuated by one wire 309 to bend and move in a first plane, while the bottom part 1603 can be actuated by another wire 309 to bend and move in a second plane. Moving the bottom part 1603 moves the top part 1601 too, as the top part 1601 extends from the bottom part 1603. In combination, this gives the surgeon greater freedom in directing the end-effector 403 on the steerable arm 301.

It should be noted that the meaning of being co-axial in the embodiments do not require the axis to be straight. The axis is curved and continuous along with the bent shapes of the steerable arms 301.

Figure 17 shows the method of fabrication of the steerable arm 301 with multiple sections. Figure 17a illustrates how a spiralling cut is made along and around the whole tube 901 first, and produces a tubular coil 707 of loops. Subsequently, as shown in Figure 17b, a further cut is made into the side of the tubular coil 707 to remove a part of each loop in the top part. This provides the gaps 905 between the loops, forming the ribs 909. Such further cuts are also made to the bottom part of the tube, but to a different side of the tubular coil 707. As a result, the spine 911 of the bottom part and the spine 911 of the top part are on formed on different sides of the tube 901. Therefore, the top part is able to bend in one direction as shown in Figure 17c, while the bottom part is able to bend in a different direction as shown Figure 17d. Figure 18 is a technical drawing of the tube cut to provide a spine 911 in the top part 1601 which in different side to the spine 911 in the bottom part 1603. Finally, the top part 1601 is then held bent into the one desired shape and the bottom part 1603 is held bent into another desired shape, and heat treated (not illustrated)

to memorise the overall shape.

Cutting the tube such that the spine of the top part and the spine of the bottom part bend in the exact opposite directions is just optional, as this means both
5 the top part and the bottom part bend within the same plane albeit in opposite directions. Alternatively, that spine of the top part and the spine of the bottom part are angularly offset along the axis instead.

Figure 19 schematically shows how the embodiment of Figure 16 operates. In
10 the drawing, the upper part 1601 of the steerable arm 301 is made to bend towards the left of the drawing when at rest. The lower part 1603 is made to bend to the right when at rest. As a result, the steerable arm 301 has a shape like an inverse letter S. The curvature of the upper part 1601 of the steerable arm 301 can be reduced by pulling on one wire 309 that extends inside the
15 steerable arm 301, and which is fixed to one of the most distal ribs of the upper part 1601. When pulled further, the curvature can be reversed to be towards the rib-side.

Similarly, the lower part 1603 can be straightened when a wire 309 is pulled. If
20 the wire 309 is pulled on further, the curvature can even be reversed to be towards the rib-side. In this case, the wire 309 extends inside the steerable arm 301 and is fixed to one of the ribs near the distal part of the lower part or, optionally, to the most proximal part of the upper part. This is because the distal part of the lower part 1603 ends where the proximal part of the upper part 1601 starts. Therefore, the most distal rib of the lower part 1603 is the rib
25 just below the spine 911 of the upper part 1601.

When pulling fully on both wires 309, the inverse S shape of the steerable arm 301 is flipped, with all the ribs on both the upper part 1601 and lower part 1603 of the steerable arm 301 closed up.

- 5 Figure 20 shows another embodiment which comprises different parts made up of the earlier embodiments. To fabricate the embodiment in Figure 20, different sections of the same metal tube is cut in a different way such that each section is able to bend in a different plane. A corresponding number of wires is provided inside the channel of the steerable arm 301, each wire 309
10 attached to the distal end of a respective section to control the bending of that section.

Figure 20a on the left of the drawing shows the steerable arm 301 in a rest state. Figure 20b on the right illustrates the different directions in which each
15 part may be moved or bent by action of a respective wire 309.

There are four parts 2001, 2003, 2005, 2007 to the steerable arm 301 in Figure 20. The first, distal part 2001 of the steerable arm 301 is made like the embodiment of Figure 12. Right below this first part is a second part 2003 and
20 third part 2005 which together correspond to the embodiment of Figure 16.

The first part 2001 and the second part 2003 are axially offset such that the first part 2001 is able to bend in a first plane 2009 while the second part 2003 is able to bend in a second plane 2011 that is at an angle to the first plane
25 2009. The second part 2003 and the third part 2005 are also axially offset such that the third part 2005 is able to bend in a third plane 2013 that is at an angle to the second plane 2011. Therefore, the three parts 2001, 2003, 2005

can be moved in different planes 2009, 2011, 2013, and provide three degrees of freedom of motion.

The fourth part 2007, which is below the third part 2005 as illustrated, is a
5 coupler that is fitted to a corresponding coupler on the transmission tube 307 which can be affixed via various methods including welding, adhesive, or mechanically, etc. Preferably, the coupling allows the steerable arm 301 to rotate when the transmission tube is twisted at the proximal end of the endoscope, adding a further degree of movement.

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Figure 21 shows a variation of the embodiment of Figure 20. The main section of the steerable arm comprises the embodiment shown in Figure 16, the two ends of which are provide with the embodiment of Figure 12. The proximal end is provided with the coupler to connect the embodiment to the
15 transmission tube. Thus, this steerable arm 301 has four different sections extending from the coupler, and may each bend in a different plane.

In yet another embodiment shown in Figure 21a, the embodiment comprises coupler at the bottom, followed on top by a second section that is made
20 according to the embodiment of Figure 12, which is in turn followed on top by the two-sectional embodiment of Figure 16. The end effector is wielded by the distal end of Figure 16 embodiment. In this embodiment, the two-sectional part is more flexible than the second section because the gaps in the two-section part are bigger. Similarly, the embodiment of Figure 15 has a more
25 flexible distal section that is connected to a less flexible proximal section.

Figure 22 shows a further embodiment, in which the spine 911 in the embodiment of Figure 7 is provided with open slits 2203. The slits 2203 are

not made around the entire circumference of the steerable arm 301, but are only cut into the spine 911 from the side of the steerable arm. Preferably, a slit 2203 is provided by removing a thin piece from the spine 911. The slits 2203 structurally reduces the resistance of the nitinol to allow the spine 911 to
5 straighten up more easily when the wire 309 is pulling on the rib-side, resulting in improved dynamic performance. It should be noted that even in this case, the spine 911 resists compression significantly, despite the slits 2203. Optionally, the distal part of the embodiment can be given more cuts to make the distal part more flexible than the proximal part.

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Figure 23 shows the process of cutting a tube 901 spirally with laser 903 to provide the ribs. The spiralling cut shown in Figure 23a is not made along the entire length of the tube 901 at once. If the spiral is cut at once along the entire length of the tube 901, the resultant tubular coil of loops will be too
15 flimsy to allow slits to be cut into the spine. Instead, only a short section of the tube is spirally cut each time, followed immediately by slicing shallowing into side of the tube that is to become the spine. After that, the next part of the spiral cut is made by continuing from where the first spiral cut has stopped. Figure 23c shows how, after the tube has been satisfactorily cut, the resultant
20 steerable arm 301 is bent into the desired shape and heat treated to memorizes the shape, where the spine is on the concave side and the ribs are on the convex side.

Figure 24 illustrates how the embodiment of Figure 22 operates. Figure 24(a)
25 shows the rest state of the steerable arm 301 of Figure 22. Figure 24(b) shows the steerable arm 301 straightened and the slits open. Figure 24(c) shows the bend being reversed to flex to the opposite side with the slits on the spine more open.

Figure 25 shows a variation of the embodiment of Figure 7, in which the stiffness of the spine 911 is reinforced by affixing the internal surface of the spine with a reinforcing element 2501, such as a stiff but bent piece of metal that conforms to the shape of the spine 911. The reinforcing element helps to restores the shape of the spine 911 quickly when the pull on the most distal rib 909 is released, which improves transmission response time and reduces mechanical hysteresis. The reinforcing element 2501 can be thought of as a spring. The reinforcing element is sufficiently flexible to allow straightening of the spine 911 when actuating the wire 309. The wire is not drawn as following the curve of the steerable arm in this embodiment, to show that is it not necessary in all cases that wire guides are provided to guide the translation of the wire.

15 Different sections of spine 911 in the embodiment of Figure 20 may be provided with such a reinforcing element each.

Figure 26 illustrates yet a further embodiment, wherein the strip of reinforcing element 2501 is not made of a very flexible material but both ends of the reinforcing element are supplied with springs 2601. The springs 2601 are secured to appropriate locations on the inside of the spine 911. The springs 2601 can be stretched when the steerable arm 301 is flexed. However, the springs 2601 reinforce the bias of the steerable arm 301 to restore memorised shape quickly when the pull on the most distal rib 909 is released. This improves transmission response time and reduces mechanical hysteresis, i.e. the effect of the pull of the wire 309 can be seen more readily in the steerable arm 301.

To further improve the responsiveness of the steerable arm 301, all the wires 309 connected to the steerable arms 301 are preferably pre-tensioned. That is, all the wires 309 are pulled taut in anticipation of use so that the sections of the steerable arm 301 are ready to be moved on further pulling of the wires 309. If the wires 309 were not pre-tensioned and hang loose, backlash would occur, resulting in a delay occurring before the steerable arm 301 responds to the wire pulling.

Figure 27 shows a more general embodiment, in which the steerable arm 301 comprises a hollow elongate member 2701 that is more resilient on one side of the axis, marked x, and more rigid on the other side of the axis, marked y. The elongate member is moulded, mould-cast or heat treated to be permanently bent towards the more rigid side when at rest. The material of the hollow elongate member is capable of remaining bent when at rest and yet is resilient enough to be straightened and even bent the other way by application of a suitable force. As with the previous embodiment, the curvature and bias in the bend provides the possibility of using one wire 309 to swing the steerable arm 301 across a plane. The hollow elongate member may be made of two different polymers that are co-extruded such that each polymer forms a side of the hollow elongate member. The convex side in this case can be provided with the more rigid material so that the steerable arm 301 does not shorten when the distal end of the steerable arm 301 is pulled upon by a wire 309. The concave side can be provided with the more expandable material that can stretch to accommodate the flexing of the steerable arm 301.

So far, the afore-described embodiments are described and illustrated to have a wire 309 secured to the side of a bent tube, the side being the furthest away from the spine. This provides better leverage when pulling the ribs close to

bend the spine. However, it is within the contemplation of this description that the wire is secured to the spine side of the bent tube.

Accordingly, the embodiments include a steerable arm 301 for use in an
5 endoscope 400 to manipulate surgical tools, comprising: a tubular member
having a proximal end and a distal end; distal end suitable for being fitted with
a surgical end effector; the tubular member being made of a resilient material;
a wire 309 extending inside the tubular member from the proximal end; the
wire attached to the distal end of the tubular member, and to a side of the
10 tubular member; the tubular member capable of having a curvature
lengthwise; wherein the curvature changes when the distal end of the tubular
member is pulled on by the wire; and the resilience of the material providing
the tubular member with a bias such that the curvature change reverses when
the pull on the distal end is released.

15 While there has been described in the foregoing description preferred
embodiments of the present invention, it will be understood by those skilled in
the technology concerned that many variations or modifications in details of
design, construction or operation may be made without departing from the
20 scope of the present invention as claimed.

For example, although loops have been mentioned as cut from a tube, it is
possible that in some embodiments, that the ribs are just an extension from
the spine that are curved, and are attached the spine on one end with the
25 other end freely cantilevering.

For example, the flexible surgical instrument 300 can be adapted to be used
with other kinds of devices that are similar to endoscopes 400, such as trans-

nasal endoscopes 400 or transurethral resectoscopes. Where these devices do not have an inner channel for inserting the flexible surgical instrument 300, an additional sheath can be made which maybe slipped over the device to create a channel for the flexible surgical instrument 300.

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Claims

1. A steerable arm for use in endoscopic surgical procedures, comprising:
 - a tubular member having a proximal end and a distal end;
 - distal end suitable for being fitted with a surgical end effector;
 - the tubular member being made of a resilient material;
 - a wire extending inside the tubular member from the proximal end;
 - the wire attached to the distal end of the tubular member, and to a side of the tubular member;
 - the tubular member capable of having a curvature lengthwise;
 - wherein
 - the curvature changes when the distal end of the tubular member is pulled on by the wire; and
 - the resilience of the material providing the tubular member with a bias such that the curvature change reverses when the pull on the distal end is released.
2. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 1, wherein
 - the tubular member has a first side and a second side along the axis of the tubular member;
 - the first side being relatively more compressible than the second side;
 - the second side being relatively less compressible compared to the first side; wherein
 - the side of the tubular member that the wire is attached is the first side; and

a pull on the wire compresses the first side to change the curvature of the tubular member.

3. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 2, further comprising
gaps in the first side to provide the compressibility of the first side; wherein
the pull of the wire changes the curvature of the tubular member by bringing gaps closer and bending the second side towards the first side.
4. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 3, further comprising
wire guides inside the tubular member for guiding the translation of the wire.
5. A steerable arm for use in endoscopic surgical procedures, as claimed in any one of claim 2, claim 3 or claim 4, wherein
the tubular member is curved in a rest state, such that there is a concave side and a convex side to the tubular member; and
the convex side of the tubular member being the first side.
6. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 5, wherein
the tubular member is a tubular coil of spiralling loops;
the curvature of the tubular member being such that the edges of the loops on the first side are spaced apart to provide the gaps; and

the edge of each of the loops on the second side abutting the edge of each adjacent loop; wherein

the first side and the second side are on opposite sides of the tubular member.

7. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 6, wherein

the loops have different spiral pitches and/or spacing variations along different parts of the steerable arm, in order to provide the different parts with different flexibility.

8. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 6, wherein

the loops are produced by at least one spiral cut made to a tube.

9. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 6, further comprising

at least a slit in the edge of at least one of the loops on the second side.

10. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 3, wherein

the tubular member is a tubular coil of spiralling loops; and

the steerable arm further comprising

two opposite columns of coupling joints each arranged along opposite sides of the tubular member;

each of the coupling joints of each column rotatably connecting a respective two adjacent loops; such that

the opposite columns of coupling joints providing the second side;

the tubular member having an axis located at the centre of the tubular member's cross-section and along its length; and

the first side and the second side are orthogonally arranged to each other with respect to the axis of the tubular member.

11. A steerable arm for use in endoscopic surgical procedures, as claimed in any one of the preceding claims, wherein

the tubular member is fabricated from a single piece of material; such that

the tubular member is a continuum structure.

12. A steerable arm for use in endoscopic surgical procedures, as claimed in any one of the preceding claims, further comprising

an elongate piece of spring attached to the length of the second side;

the elongate piece of spring reinforcing the bias.

13. A steerable arm for use in endoscopic surgical procedures, as claimed in claim 1, wherein

the tubular member comprises at least two sections;

a respective number of wires extending inside the tubular member from the proximal end;

each wire affixed to the distal end of each section, the distal end of the most distal section being the distal end of the tubular member;

each section capable of having a curvature lengthwise of the tubular member, such that curvature of each section is changed when

the distal end of each section is pulled on by the respective wire;
wherein

the resilience of the material providing the tubular member with
a bias such that the curvature change of each section is reversed when
the pull on the distal end of the each section is released.

14. A steerable arm for use in endoscopic surgical procedures, as claimed
in claim 13, wherein

the change of curvature of each of the at least two sections lies
in a different plane.

15. A steerable arm for use in endoscopic surgical procedures, as claimed
in claim 1, wherein

the steerable arm is placed at the distal end of a transmission
tube;

the transmission tube containing a channel in which the wire is
threaded;

the proximal end of the wires connected to knobs and/or levers
for pulling on the wire; such that

the curvature changes when the distal end of the tubular
member is pulled on by the wire at the proximal end of the transmission
tube.

16. A steerable arm for use in endoscopic surgical procedures, as claimed
in claim 1, wherein the surgical end effector is forceps, diathermy knife,
injection needle, suturing tool.

17. A method of making a hollow tube into a steerable arm for use in an endoscope surgical procedure, comprising the steps of:

- a) providing the hollow tube having a proximal end and a distal end;
the distal end suitable for being fitted with a surgical end effector; and the hollow tube being made of a resilient material;
- b) cutting the hollow tube circumferentially and along the length of the tube to make a spiral cut;
the spiral cut producing gaps along at least one side of the tube;
- c) inserting a wire into the proximal end of the hollow tube;
and
- d) attaching the wire to the hollow tube, the attachment being:
 - i. on the side of the tube where the gaps are; and
 - ii. so distal from the proximal end such that the wire extends over the gaps.

18. A method of making a hollow tube into a steerable arm for use in an endoscope surgical procedure as claimed in 17, further comprising the steps of

- holding the hollow tube in a bent position; and
- causing the hollow tube to memorise the bend in the rest state through plastic deformation or heat treatment.

19. A method of making a hollow tube into a steerable arm for use in endoscopic surgical procedures as claimed in claim 17, further comprising the step of:

cutting the hollow tube in such a way as to leave couplers on each of the loops for coupling with adjacent loops.