

Description

Title of Invention: A SHEATH ASSEMBLY FOR AN ENDOSCOPE

Field Of Invention

- [0001] The present invention relates to endoscopes which provide access for surgical instruments into the gastrointestinal tract for minimally invasive surgery.

Background Of The Invention

- [0002] Some types of endoscope comprise a flexible tube that a clinician may insert into the gastrointestinal (GI) tract through the mouth or anus of a person. The clinician pushes on the part of the endoscope outside the person until the tip of the endoscope comes into proximity of a surgical target in the GI tract. A popular model of such endoscopes contains two instrument channels, each instrument channel having an opening on the tip of the endoscope and another opening on the handle of the endoscope. Surgical instruments can be inserted into the opening on the handle and passed through the instrument channels to operate on surgical targets at the tip of the endoscope.
- [0003] Some clinicians would like to have an endoscope with more than two instrument channels. There are models of endoscope do not have any instrument channel at all and it would be beneficial if these kind of endoscopes could be upgraded instead of replaced. Therefore, it is desirable to be able to expand the functionality of existing endoscopes. Accordingly, it has been proposed to lay a plastic tube along the body of an endoscope to provide an external instrument channel. Adhesive tape is used to wrap around and along the conjoined body of a plastic tube and an endoscope. However, an endoscope become less flexible when bound to a tube over entire length of the endoscope, and inserting the stiffened endoscope is more difficult. Further, handmade modifications are time consuming to make and quality of the modified products is inconsistent.
- [0004] It has been proposed to attach the external instrument channel to the endoscope using discrete attachment points spaced apart along the endoscope, to reduce the stiffening of the endoscope. If two external instrument channels are attached to the endoscope in this way, neighbouring segments of unattached external instrument channels can entwine or twist about each other, due to frequent twisting/torsional motions of the endoscope made by clinicians trying to insert the endoscope deeper. If intertwining happens to an assembly already inserted into the person, it can be very difficult to separate the twisted segments, and the endoscope and any surgical instruments inserted in the external instrument channels will become poorly responsive to further manipulation.

[0005] It has been proposed to use a plastic sheath to cover over assembled endoscopes and external instrument channels. However, it is difficult to pull a plastic sheath over the assembly, as the technician has to push repeatedly on different sections of the sheath to spread the sheath over the assembly, which is time-consuming and increases the risk of infection due to over-handling.

[0006] Therefore, it is desirable to propose methods and/or devices that provide a possibility of adding one or more external instrument channels to an endoscope with minimal loss of flexibility of the endoscope.

[0007] Furthermore, it is also desirable to propose a sheath for an endoscope that that can be used to sheath the endoscope relatively quickly.

Summary of the Invention

[0008] In a first aspect, the invention proposes a sheath assembly for an endoscope, comprising a hollow sheath having a distal end attached over an end-cap and a proximal end attached over an annulus in an end-guard configured for an endoscope to extend through the annulus and the hollow sheath to fit into the end-cap; the sheath folded into a plurality of folds, each of the folds being a circumferential segment of the sheath folded longitudinally over an adjacent circumferential segment of the sheath; wherein the folds are capable of unfolding as the endoscope pushes the end-cap away from the end-guard.

[0009] Therefore, the invention provides a folded sheath that is capable of sheathing over an increasing length of endoscope which is being inserted further into the sheath. This unfolds the distal-most folds of the sheath to lay over the part of the endoscope just passing the end-guard there is no shearing as there is no need to pull the sheath over the endoscope. This provides a possibility of layering the endoscope in a fitting sheath easily.

[0010] Typically, the dimensions of the end-cap allow the end-cap to enter into the GI tract, while the end-guard is too big to enter into the mouth or the anus. Therefore, pushing an endoscope inside the sheath into a person pushes the end-cap further into the person away from the end-guard that cannot enter.

[0011] Optionally, the sheath is folded into a series of telescopic folds. Typically, a telescopic fold comprises a longitudinal segment of the sheath folded along the sheath circumference into extending longitudinally over the next telescopic fold of the sheath. The end-cap is attached to the distal end of the sheath which pulls out and unfolds the distal folds before the proximal folds.

[0012] Preferably, the edge of each telescopic fold extends over the edge of the next telescopic fold. Also preferably, the sheath assembly comprises a plurality of eyelets each attached to an over-extending edge; the plurality of eyelets aligned longitudinally

along the sheath. The aligned eyelets can be inserted with a tubular member inside the sheath, such as an external instrument channel, to restrain movements of the tubular member.

- [0013] In some specific embodiments, it is the edge of the more distal telescopic fold that extends over the edge of the next more proximal telescopic fold. In other embodiments, it is the edge of the more proximal telescopic fold that extends over the edge of the next more distal telescopic fold.
- [0014] Alternatively, the sheath is folded into accordion folds.
- [0015] Generally, it is easier to fold the sheath into telescopic fold, as there are less folding. Also, it is to be certain that the distal folds will unfold first when the sheath is pulled on by the moving end-cap. However, there is a greater amount of sliding between the folds when unfolding the sheath. The accordion fold is harder to make but unfolding accordion folds is smoother than unfolding telescopic folds as there is no sliding between the folds. Also, a sheath folded in accordion fold is more compact.
- [0016] Preferably, the sheath assembly comprises a plurality of eyelets attached to the accordion folds; and the plurality of eyelets aligned longitudinally to the sheath. More preferably, the sheath assembly comprises a second plurality of eyelets attached to the accordion folds; the second plurality of eyelets aligned longitudinally to the sheath; wherein the plurality of eyelets and the second plurality of eyelets are placed apart on the circumference of the sheath.
- [0017] Preferably, the sheath assembly further comprises an inflatable balloon around the end-cap.
- [0018] Preferably, the sheath assembly further comprises at least one external instrument channel extending from the end-cap through the sheath and out of the annulus on the end-guard.
- [0019] More preferably, the sheath assembly comprises two external instrument channels extending from the end-cap through the sheath and out of the annulus on the end-guard; the distal ends of the external instrument channels in a mutually convergent arrangement on the end-cap.
- [0020] As the distal-most folds of the sheath lay over the part of the endoscope just passing the end-guard, there is no need or just little need to pull the sheath over the endoscope; the unfolding part of the sheath just lays itself onto the passing part of the endoscope. This permits the sheath to be fitting to the endoscope and the two (or any number of) external instrument channels to restrain the endoscope and the external instrument channels from being able to stack on and twist one about the other, while permitting the endoscope and the external instrument channels to be able to slide one other the other, to minimise stiffening of the endoscope.

- [0021] Typically, the sheath assembly comprises two eyelets attached to the inner surface of the sheath and spaced apart on the circumference of the sheath; the two external instrument channels each extending through a different one of the two eyelets; the eyelets being attached to the inner surface of the sheath at a distance from the end-cap; wherein the distance (when the sheath is unfolded) is less than or equal to half the length of bending section of an endoscope or the distance is less than or equal 10cm. The purpose of these eyelets is not so much for separating the external instrument channels but for ensuring the distal end of the external instrument channels do not swivel about the end-cap. Most bending section is about 18 to 20 cm, and a 10 cm distance between the end cap and the position of the eyelet is likely to be somewhat in the midway of most bending section.
- [0022] In a further aspect, the invention proposes a method of sheathing an endoscope, comprising the steps of providing a hollow sheath folded into in plurality of folds, each of the folds being a circumferential segment of the sheath folded longitudinally over an adjacent circumferential segment of the sheath; inserting an endoscope through the proximal end of the sheath; ; pushing more of the endoscope into the sheath and pushing the distal end of the sheath further away from the proximal end of the sheath to unfold the sheath; wherein the fold of the sheath being unfolded is laid onto a part of the endoscope passing the unfolding the fold of the sheath.
- [0023] Although, an end-cap is provided at the distal end of the sheath in most of the described embodiments, other kinds of attachments between the distal end of the sheath and the tip of the endoscope is possible and this step of a method does not have to be limited to an end-cap is provided at the distal end of the sheath.
- [0024] Typically, pushing the distal end of the sheath further away comprises the step of pushing the distal end of the sheath into the gastrointestinal tract of a person.
- [0025] Preferably, the method further comprises the step of: providing at least a tube attached to the distal end of the sheath; wherein the fold of the sheath being unfolded is laid onto a part of the endoscope and the at least one tube passing the unfolding fold of the sheath.
- [0026] Such the method of laying or layering of the unfolding fold or segment of the sheath against or onto the passing part of the endoscope relieves the need of pulling the sheath over the endoscope (and any such tube attached to the distal end of the sheath) allows the sheath to be more fitting over the sheathed contents than prior art that requires the sheath to be pulled over the endoscope to sheath the endoscope.
- [0027] Brief Description Of The Figures
- [0028] 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 arrangements 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.

- [0029] Figure 1 is an illustration of a robotic endoscopic surgical system;
- [0030] Figure 2 is a photograph of an endoscope useable in the system of Figure 1; Figure 3 is a photograph of a surgical instrument that can be inserted into the endoscope of Figure 2;
- [0031] Figure 4 is an illustration of steerable arms extending out of the tip of an endoscope such as that shown in Figure 2;
- [0032] Figure 5 is an illustration of how the endoscope of Figure 2 is mounted on a positioning cart in the system of Figure 1;
- [0033] Figure 6 is a schematic illustration of a sheath assembly for expanding the function of an endoscope such as that shown in Figure 2;
- [0034] Figure 7 is another schematic illustration of the sheath assembly shown in Figure 6;
- [0035] Figure 8 is another schematic illustration of the sheath assembly shown in Figure 6;
- [0036] Figure 9 is a series of schematic drawings showing the sheath assembly in use;
- [0037] Figure 10 is an illustration of a variation of the sheath assembly of Figure 6;
- [0038] Figure 11 is an illustration of a sheath assembly with an inflated;
- [0039] Figure 12 is an illustration of the balloon of Figure 11 in the front view;
- [0040] Figure 13 is a photograph of an endoscope fitted into a sheath assembly prototype;
- [0041] Figure 14 is the negative image of the boxed portion of in Figure 13;
- [0042] Figure 15 is photograph of the assembly in Figure 13 stripped into components;
- [0043] Figure 16 is a schematic illustration of a variation of the sheath assembly;
- [0044] Figure 17 is a schematic illustration of a variation of the sheath assembly;
- [0045] Figure 18 is a schematic illustration of a variation of the sheath assembly;
- [0046] Figure 19 is a schematic illustration of a variation of the sheath assembly;
- [0047] Figure 20 is a schematic illustration of a variation of the sheath assembly;
- [0048] Figure 21 is a schematic illustration of a variation of the sheath assembly;
- [0049] Figure 22 is a schematic illustration of a variation of the sheath assembly;
- [0050] Figure 23 is a schematic illustration of a variation of the sheath assembly;
- [0051] Figure 24 is an illustration of one of the simplest variations of the sheath assembly;
- [0052] Figure 25 is an illustration of another simplest variation of the sheath assembly;
- [0053] Figure 26 is an illustration of a preferred feature in the end-cap of the sheath assembly;
- [0054] Figure 27 is an illustration of a preferred feature in the end-cap;
- [0055] Figure 28 is an illustration of another preferred feature in the end-cap;
- [0056] Figure 29 is an illustration of a variation of the end-guard; and
- [0057] Figure 30 is an illustration of a prototype of the end-guard.
- [0058] Detailed Description Of Specific Embodiments

- [0059] Figure 1 shows a robotic endoscopic surgical system comprising suite of medical furniture and robotic devices. The suite is used to support the deployment of a rigid endoscope 201 in the urinary tract of a person, as shown in Figure 1, or a flexible endoscope 201 into a person's gastrointestinal (GI) tract, not shown in Figure 1. Typically, an endoscopic surgery is performed with this system by robotic instruments with end-effectors at the tip of the endoscope.
- [0060] The main parts of the suite include an operation table 101, a positioning cart 103, a control console 105, and a display monitor on the top of a rack 107. The positioning cart 103 is arranged in a straight line with the operation table 101. On the far side and somewhat between the positioning cart 103 and operation table 101 is the rack 107 with a display monitor. On the near side is the control console 105, in which a clinician may sit to control the robotic instruments. This gives an open layout which allows the clinician to observe live-images of the endoscope view on the display monitor while keeping an eye on the person.
- [0061] Figure 2 is a photograph of a flexible endoscope 201 that is suitable for insertion into the GI tract through the mouth or anus. An axially aligned handle 203 on the proximal end of the endoscope 201 has dials 207 for curling a bending section 205 at the distal end of the endoscope 201. A stem 209 extends from the handle 203 for connecting to a video image processor in the rack 107, and to pumps and containers which supply air and water through the endoscope into the person and for collection of fluids suctioned from the GI tract by the endoscope 201.
- [0062] An endoscope 201 surgery begins with a clinician inserting an endoscope 201 into a person on the operation table 101 using manual manipulation techniques. The tip of the endoscope 201 is provided with a light source 403 and a camera 405, which transmit a view of the endoscope's progress in the GI tract to the display monitor. When the tip of the endoscope 201 is in close proximity of the surgical target in the GI tract, the endoscope handle 203 is mounted onto a holder 109 extending from the positioning cart 103, and the endoscope 201 is left to be as stationary as possible.
- [0063] On the endoscope handle 203 are the proximal openings 211 of the two instrument channels, the distal openings being on the endoscope tip. Each of the instrument channels may be inserted with a surgical instrument. With no surgical instrument inserted, the endoscope 201 has no surgical function.
- [0064] Figure 3 is a photograph of a surgical instrument 300. A typical surgical instrument 300 has a transmission tube 301 of 0.5m to 1.8m as the main body. A small robotic arm about 3 cm long called a steerable arm 303 is provided on the distal end of the transmission tube 301. The tip of the steerable arm 303 has an end-effector 401 which is used for performing surgical actions in the person, such as cutting, grasping and suturing. Wires attached on one end to the steerable arm 303 and the end-effector

401 are threaded through the transmission tube 301 and connected on the other end to spools inside a coupler 305 which connects to the positioning cart 103.

- [0065] Figure 4 is an illustration of two steerable arms 303 extending out of instrument channels on the tip of an endoscope, beneath a light source 403 and a camera 405 which are also on the tip of the endoscope 201. Each steerable arm 303 can be seen brandishing an end-effector 401.
- [0066] Figure 5 shows how the endoscope 201 is mounted onto the holder 109. An actuator platform 501 on the top of the positioning cart 103 has receptacles for mating with the couplers of surgical instruments 300.
- [0067] The control console 105 is a modified Dentist Stool, also called a surgical chair. A Dentist Stool is a commonly seen in clinics and are designed for dentists and doctors to sit upon ergonomically and roll across a clinic. An electromagnetic field (EMF) generator on the control console 105 creates an EMF which monitors the coordinates of two EMF-responsive controllers. The EMF generator is about the size of a brick, and the front edge of the seat is the only appropriate mounting place. The EMF is therefore always to the front of the clinician in the control console 105. The actuator platform 501 operates the spooled wires in the coupler 305 to continually re-position the steerable arms 303 and end-effectors 401 according to the coordinates of controllers in the (electromagnetic field) EMF as held and moved by the clinician in the control console 105, operate on the surgical target in the GI tract or urinary tract.
- [0068] Figure 6, Figure 7 and Figure 8 are schematic illustrations of a sheath assembly 700 in different views and configurations. The sheath assembly 700 provides a possibility of sheathing an endoscope 201 effectively and expeditiously.
- [0069] The sheath assembly 700 comprises a sheath 711 made from a hollow column of thin, foldable plastic. The distal end of the sheath closes around and is sealed onto the outer surface of a band that is used as an end-cap 701. The end-cap 701 has an inner bore which has a diameter that is almost as small as the diameter of the endoscope 201. A narrow, radial lip 703 extends over the inner surface of the end-cap and flushed to the distal edge of the end-cap 701. Therefore, the tip of an endoscope may be inserted into the end-cap from the proximal end, to be mounted onto firmly by the end-cap. The endoscope is stopped by the lip from extending over the distal end of the end-cap 701. The lip 703, being narrow, does not obstruct the operation of camera 405, light source 403 and instrument channels on the endoscope tip.
- [0070] On the other hand, the circumference of the opening of the sheath at proximal end is attached to an end-guard 715, and over an annulus in the centre of the end-guard.
- [0071] The dimensions of the end-cap allow the end-cap to enter the mouth or anus and be moved into the GI tract. However, the end-guard has dimensions, shape or size that prevents the end-guard from even moving into the mouth or the anus.

- [0072] Two conduits 705 are integrated onto the outer surface on one side of the end-cap 701, the axes of which are in parallel to the axis of the end-cap 701. Figure 6 has a drawing insert which is encircled in broken lines, showing only the end-cap and the conduits 705 in a side view. Each conduit 705 crimps firmly onto the distal end of a hollow tube but without deforming the inner shape of the hollow tube. The hollow tubes may be used as external instrument channels 707 and, therefore, have a length in excess of the length of the part of a typical endoscope 201 expected to be inserted into a person. One simple guideline is that the external instrument channels 707 have a length similar to or greater than that of the instrument channel in the average or most popular flexible endoscope 201. Furthermore, the internal diameter of the external instrument channels 707 should be similar to the diameter of the instrument channels in most endoscopes 201. In this way, the external instrument channels 707 are compatible almost at once with the length and girth of existing surgical instruments 300, with little chance of size mismatch. In a variation of the embodiment, the end-cap 701 has only one conduit 705 crimping onto an external instrument channel 707 (not illustrated) .
- [0073] Hollow tubes used as external instrument channels 707 preferably have the following characteristics:
- [0074] 1) Low bending resistance which, in the least, is lower the bending resistance of the endoscope 201;
- [0075] 2) Good structural resistance to radial distortion, which prevents buckling when the tube is bending and keeps the instrument channel open; and
- [0076] 3) Smooth internal surface to let a surgical instrument 300 pass through easily and repeatedly during a surgery.
- [0077] An example of a hollow tube possessing the above characteristics is a stainless steel spring-embedded thermoplastic polyurethane tube (spring-embedded tube) . Basically, the spring-embedded tube comprises a “coil spring” coated with plastic and has smooth internal and external surfaces (which addressed point 3) .
- [0078] The edges of the coils on one side of the coil spring are able to spread apart so that the coil spring may bend towards the other side. As there is a large number of coils per unit length of tube, the edges of a number of coils need only move apart just very slightly on the convex side to bend the coil spring towards the concave side. Little or no bending resistance manifests with such a small movement. Therefore, such spring-embedded tubes have bending resistance that is so low, the tubes may be described as floppy. That is, the spring-embedded tubes are capable of bending over in any direction and have practically no structural bias or strength to hold itself up. Therefore, an external instrument channel 707 made of a spring-embedded tube is able to bend along with the endoscope 201 about the folds of the GI tract with little or no resistance.

- [0079] Furthermore, the coils of the spring are thin on the edge but relatively wide radially, which gives the coils resistance to radial deformation. Therefore, an external instrument channel 707 provided by a spring-embedded tube does not buckle, crease or fold sharply when bending in the GI tract. The helps to ensures unobstructed passage in the external instrument channel 707 under normal circumstances.
- [0080] With the conduits on the end-cap providing the external instrument channels, the distal end of sheath 711 has to close around and be sealed to the outer surfaces of the end-cap 701 and the conduits 705, preferably in an air-tight manner. The edge of the sheath 711 may be pleated to fit neatly onto the end-cap 701 and the conduits 705 for efficient sealing.
- [0081] Another preferred feature of the embodiment is that the end-cap 701 is placed inside the core of a torus-shaped balloon 709. The balloon 709 is made of a plastic material which may be elastic or inelastic. The balloon 709 is shown deflated and folded against the side of the end-cap 701 in both Figure 6 and Figure 7, and shown inflated in Figure 8.
- [0082] A torus is a three-dimensional shape which is circular in the plan view and has an open vertical core in the centre. Basically, this is the shape of a doughnut, but the balloon preferably has a greater height-to-diameter ratio than a real doughnut.
- [0083] The external surface of the core of the balloon 709 is glued, laminated or otherwise sealed onto every side of the end-cap 701, the conduits 705, any exposed part of the inflation tube 710 on the outer surface of the end-cap, and also the edge of the sheath 711 which is sealed to the end-cap 701.
- [0084] An inflation tube 710 is provided for introducing air into the balloon 709. Typically, the inflation tube 710 is made of silicone or other polymer which is very flexible. The inflation tube 710 has a distal end inserted through the torus core into the balloon 709. The rest of the inflation tube extends between the sealed sheath 711 and end-cap 701 (and conduits 705) , through the hollow of the sheath 711 and out of the annulus in the end-guard 715. Typically, the inflation tube 710 has at least the same length as the external instrument channels 707.
- [0085] Outside the end-guard 715, the proximal end of the inflation tube 710 can be connected to the needle hub of a syringe 1501 for pumping air using the syringe piston into the balloon 709. The balloon is also deflated by drawing air from the inflation tube using the syringe, especially if the balloon is made of non-elastic material which applies no force to deflate the balloon. Preferably, the inflation tube 710 is supplied with a valve near the proximal end. The valve may be opened to allow air passage into or from the balloon 709. The valve can be closed to prevent escape of air from the inflated balloon 709, and to allow the syringe 1501 to be removed from the inflation tube 710. Preferably, a pressure-release valve is provide downstream, between the

valve and the end-guard 715 that allows excessive air in the balloon 709 to be relieved, preventing the balloon 709 inside the person from bursting or injuring the person.

[0086] For brevity and convenience, the two external instrument channels 707 and the inflation tube 710 shall be referred to collectively as the “tubular members” in some of the following paragraphs.

[0087] Therefore, in the pristine condition before use, with the sheath being folded and having a shortened passage length, most of the tubular members can be seen extending out of the annulus of the end-guard from within the folded sheath. However, these tubular members will be drawn back into the annulus when an endoscope penetrates the annulus and the folded sheath, and is inserted into a person mounted on the tip with the end-cap. This unfolds the sheath by the distal-most folds first, and lays the unfolding part of the sheath onto and around the part of the endoscope and tubular members just moving past; there is no need to pull and adjust the sheath over the endoscope and the tubular members.

[0088] Accordingly, the endcap assembly provides a possibility of sheathing the endoscope and the tubular members with fitting or even tight-fitting sheaths easily.

[0089] Figure 9 is a series of drawings which show how an endoscope 201 may be inserted into a person while being sheathed concurrently. The top drawing shows pre- insertion preparation, in which the sheath assembly is about to be mounted onto an endoscope 201. The second drawing shows the endoscope inserting into the annulus and the hollow folded sheath and into the end-cap (not visible in the drawing) .

[0090] With the end-cap of the sheath assembly mounted onto the tip of the endoscope, the endoscope and the sheath assembly are ready to be inserted into the person.

[0091] The sheath assembly is then placed onto the mouth of the person, who will be wearing a mouth guard to keep access through the mouth open. The endoscope is pushed into the annulus and into the mouth guard. The end-cap riding on the tip of the endoscope slowly passes into the throat, the oesophagus and then the stomach. The end-cap pulls along the unfolding sheath.

[0092] As the end-guard is too big to enter into the mouth by design, the end-guard is able to provide resistance against which the end-cap may pull the sheath into unfolding, i.e. usually systematically by the distal-most folds first. The external instrument channels and inflation tube are pulled along by the end-cap to extend into the annulus and the sheath. Thus, the endoscope, external instrument channels and inflation tube that are passing through the end-guard and into the person’s GI tract are sheathed dynamically by the currently unfolding segment of the sheath.

[0093] The sheath assembly is used in the same way in anal insertion of the endoscope. The end-cap mounted onto the tip of the endoscope is pushed into the anal cavity of the person. As the end-guard is unable to enter into the anus by design, the end-cap

moving further into the person and away from the end-guard outside the person pulls the folded sheath into unfolding over the part of endoscope and tubular members just moving into the end-guard.

- [0094] The sheath 711 has a function of keeping the tubular members close to the endoscope 201, while allowing the tubular members and the endoscope 201 to slide one over the other. The slide-ability allows the endoscope 201 to move in the GI tract with full manoeuvre-ability.
- [0095] When the endoscope 201 has been pushed into the desired position inside the person, the clinician mounts the handle 203 of the endoscope 201 onto the holder 109 extending from the positioning cart 103 to keep the endoscope 201 stationary. The clinician then inflates the balloon to stabilise the position of the endoscope tip inside the person, by using a large syringe 1501 to push air through the inflation tube 710 into the balloon 709. The inflated balloon 709 stabilizes the position of the tip of the endoscope 201 by pressing against a large surface area of the GI tract gently and to provide traction for insertion and extraction of surgical instruments 300. The inflated balloon also acts as a seal in the oesophagus or colon to prevent air leakage during insufflation.
- [0096] Then, the clinician inserts a surgical instrument with the required end-effector into each of the external instrument channels. Using view provided by the camera, the clinician can see whether the steerable arms of the surgical instruments has extended out of the external instrument channels and are ready for perform surgery. The clinician then connects the couplers of the surgical instruments to the actuator platform of the positioning cart. Subsequently, the clinician sits in the control console 105 and hold the controllers to make surgical movements, guided by a live-display of the situation in the GI tract. The coordinates of the movements of the controllers in the EMF generated by the control console 105 is sent to the actuator to be converted in real-time into movements of the steerable arms and end-effectors.
- [0097] Figure 8 shows the sheath assembly 700 in an operational condition, in which the tip of an endoscope 201 extending through the annulus 713 of the end-guard 715 into the sheath 711, is inserted into the end-cap 701. Figure 8 also shows the balloon 709 is inflated all about the end-cap. The insert in Figure 8 is a torus, which the balloon 709 looks like.
- [0098] Figure 11 shows the balloon 709 inflated around the end-cap 701 on the tip of the endoscope 201. The sheath 711 can be seen attached over the proximal edge of the end-cap 701 and sheath 711 ing over the external instrument channels 707 crimped to conduits 705 at the end-cap 701. Furthermore, Figure 11 shows the inflation tube 710 extending into the balloon 709 on one end and entering between sheath 711 and the surface of the end-cap 701 into the hollow of the sheath 711. Figure 11 shows the

external instrument channels 707 each inserted with a surgical instrument 300, the steerable arm 303 of each surgical instrument 300 can be seen extending from the respective external instrument channel 707, brandishing an end-effector 401.

- [0099] Figure 12 is an illustration of a preferred feature of the balloon 709 in the front view of the end-cap 701, showing the balloon 709 inflated all around the end-cap 701.
- [0100] The core of the torus-shape balloon 709 is eccentric or off-centre with reference to the circumference of balloon 709. This provides the end-cap 701 is lifted above the axis of the GI tract by providing more of the balloon 709 beneath the end-cap 701 than above the end-cap 701, indicated by $y > x$, where x is the distance between the centre of the bore and the top of the balloon 709 as shown, and y is the distance between the centre of the bore to the bottom of the balloon 709. This configuration gives better stability because the likelihood of the endoscope 201 twisting or turning axially out of control is reduced. Note that manipulation techniques for insertion of an endoscope 201 includes “twisting” the endoscope 201 axially and the balloon 709 does not get in the way of this manipulation technique as the balloon 709 is inflated only when the endoscope 201 has reached the target position and here is no further endoscope 201 insertion. Also, the configuration gives the endoscope tip a higher elevation which allows for more room for and direction in which the steerable arms 303 may close in onto the surgical target.
- [0101] Figure 13 is a picture taken of an endoscope 201 dressed in a prototype of the “sheath assembly 700”. Figure 14 is an enlargement of the box in Figure 13, and converted into the negative. Figure 15 is another picture of the same assembly shown in Figure 13 but stripped apart to show the components.
- [0102] Figure 13 does not show a folded sheath 711. Instead, Figure 13 shows a sheath 711 is fully unfolded and drawn over the part of an endoscope 201, two external instrument channels 707 and an inflation tube 710 expected to be inserted into a person. It can be seen that the girth of the sheath 711 is quite fitting to the endoscope 201 and the tubular members within the sheath 711. Accordingly, the sheath 711 provides limited radial space which keeps the tubular members close to each other without preventing all the tubular members from sliding longitudinally over each other, preventing stiffening of the assembly.
- [0103] A white rectangle in solid lines is drawn into Figure 13 over the proximal opening of the sheath 711. The white rectangle represents an end-guard 715, which is not in the original picture. The external instrument channels 707 can be seen extending out from the sheath 711 of the end-guard 715, towards the left of the picture. A surgical instrument 300 is inserted into each external instrument channel 707. The coupler 305 of each surgical instrument 300 can be seen on the left side of Figure 13, with a transmission tube 301 extending out of each coupler 305 into an external instrument

channel 707. The steerable arms 303 on the other end of the transmission tubes 301 extend out of the external instrument channels 707. However, the external instrument channels 707 are blocked from view by the sheath 711 and the balloon 709. A syringe 1501 is shown in the picture connected to the proximal end of the inflation tube 710 extending into the end-guard 715 and sheath 711, to be connected to the balloon 709 at the end-cap 701 (not visible). The balloon 709 is seen semi-inflated around the distal end of the endoscope 201.

[0104] In Figure 15, the sheath assembly 700 is stripped into the components which are placed next to the endoscope 201, i.e. external instrument channels 707 crimped to the conduits 705 of the end-cap, an inflated balloon 709, an inflation tube 710 extending from the balloon 709 to the needle hub of the syringe 1501, an unfolded sheath 711 detached from the end-cap 701. The surgical instruments 300 and the end-guard 715 are not included in Figure 15.

[0105] Variations of Sheath Folding

[0106] In Figure 6, Figure 7 and Figure 8, the sheath is folded in “accordion folds”. That is, the sheath 711 is folded onto itself, alternating between folding inwardly and folding outwardly. An inward fold is made by folding a segment of the sheath 711 to form an outer fold edge extending all around the sheath 711 circumference, and an outward fold is made by folding a segment of the sheath 711 to form an inner edge extending all around the sheath 711 circumference. The inner edges tend to be more creased than the outer edges for accommodating more sheath material on a smaller circumference. An example of suitable sheath material is a thin sheet of plastic such as TPU or polyethylene (PE) that is easily foldable and can be safely used within a person.

[0107] Figure 10 shows a variation of the sheath assembly 700. The top drawing in Figure 10 illustrates the variation in an un-used state. The sheath 711 can be seen folded into “telescopic folds”. A telescopic folding of the sheath 711 is made by folding the sheath into itself and using the circumference as the fold line. Folding the sheath several times like this result in the sheath becoming a plurality of nested sleeves, each smaller sleeve nested in the next larger sleeve.

[0108] Preferably, the sheath 711 is tapered from the proximal end to the distal end. The taper provides each outer fold with a slightly bigger diameter, making it easier to contain the next inner fold. The outermost fold is the proximal end of the sheath 711 and is attached onto the end-guard 715, and the innermost fold is the distal end of the sheath and is attached onto the end-cap 701.

[0109] In the embodiment of Figure 10, the telescopically folded sheath 711 is placed on the proximal side of the end-guard 715, which permits the distal side of the end-guard 715 to be placed adjacent the proximal edge of the end-cap 701. The end-cap 701 is illustrated as having balloon 709 folded against the outer surface of the end-cap.

Two external instrument channels 707 and an inflation tube 710 attached to the end-cap extend from the end-cap 701 through the hollow folded sheath 711 and out of the annulus 713 of the end-guard 715. The bottom drawing shows the end-cap 701 mounted onto the tip of an endoscope 201 that extends into the annulus and through the hollow folded sheath 711. If more of the endoscope 201 presses forward, the end-cap 701 is pushed away from the end-guard 715 by the endoscope 201. The end-cap 701 departing the end-guard 715 pulls on the attached sheath 711 causing the inner telescopic folds to unfold first before outer folds, the unfolding part of the sheath 711 encasing the tubular members and the endoscope 201 passing through the annulus 713 in the end-guard 715. The balloon 709 is shown not inflated. As only the inner most layer of folds of the telescopic folds contact the endoscope, the user can much more easily install the end-cap to the endoscope tip, only having to navigate one edge of the fold to enter the sheath and end-guard. Conversely, the edges of the accordion folds all face inwards, which means that during installation, the endoscope tip must be carefully inserted past each fold, which may not be feasible without a kind of internal guide that creates a clear channel from the proximal end to the distal end of the sheath.

- [0110] Preferably, the length of the sheath 711 is in excess of the length of the typical portion of the endoscope 201 expected to be inserted into a person. Thus, not every fold is unfolded in some situations and the bottom drawing illustrates remaining folds on the proximal side of the end-guard 715.
- [0111] The drawing also shows a gap between the end-guard 715 and the end-cap 701 which can be used for introducing lubrication onto the folds of the sheath 711.
- [0112] As the folded sheath 711 is on the proximal side of the end-guard 715, instead of between the end-guard 715 and the end-cap 701 as in the case of the embodiment of Figure 6, this provides a possibility of closing the annulus 713 in the end-guard 715 with the end-cap 701, using a breakable seal (not illustrated) all about the edge of the annulus 713 and the proximal edge of the end-cap 701. Alternatively, the connection between the end-guard and end-cap could be a snap-on or twist-lock connection which can be disconnected after fitting the endoscope.
- [0113] The reader should note that the type of sheath 711 folding, be it telescopic, accordion or other kinds of folding, is mentioned incidentally here and is an independent feature which has nothing to do with the possibility or enablement of placing the bulk of the folded sheath 711 on the proximal side of the end-guard 715. Also, there are many ways to fold the sheath 711 and this depends on the pliability of the material used for the sheath 711, the thickness of the walls of the sheath 711, the elasticity of the material, the overall shape of the sheath 711 and so on.
- [0114] Figure 16 relates to a variation of the sheath 711, and is a schematic illustration of an unfolded sheath 711 in which there are three series of eyelets 1601 sewn, laminated

or otherwise attached to the internal surface of the sheath 711. The drawing does not illustrate an endoscope to avoid cluttering the drawing. The eyelets 1601 of each series are aligned longitudinally to the sheath 711. Each of the two external instrument channels 707 and the inflation tube 710 is threaded through a different one of the three series of eyelets 1601. The eyelets 1601 restrains segments of any two of the instrument channels and the inflation tube 710 from intertwining or co-twisting by keeping the instrument channels and the inflation tube 710 apart.

[0115] The drawing insert in Figure 16 is view in a radial cross-section of the sheath 711, showing the three series are spread out on internal circumference of the sheath 711. The cross section of the inserted external instrument channel 707 or inflation tube 710 can be seen inside the corresponding eyelet1. The circle in dotted lines in the middle of the sheath 711 indicates the position of an endoscope 201 if one is inserted into the sheath 711, which is the outside of the eyelets 1601. Preferably, the eyelets 1601 have a thin edge so that the eyelets 1601 can be stacked on each other when the sheath 711 is folded, and may be made of a thin piece of wire, plastic rings, flexible plastic, fabric or strings.

[0116] Figure 17 is an illustration of a variation of the sheath, without showing an endoscope, in which eyelets 1601 are attached on the proximal end of each telescopic fold of a sheath 711. Each outer fold extends towards the proximal direction a little further than the edge of the adjacent inner fold. For each eyelet 1601 in the three series of eyelets 1601, every next eyelet 1601 in each series is attached to the proximal edge of an over-extending outer fold adjacent each inner fold. It should be noted that it is not necessary for every fold to be provided with an eyelet1. Of course, the eyelets 1601 could be placed in between the folds but this would prevent inserting the instrument channels and the inflation tube 710 in advance, at factory. Accordingly, as shown in the top drawing in Figure 17, each series of eyelets 1601 are already inserted with the respective one of the instrument channels and the inflation tube 710.

[0117] Figure 18 is an illustration of a variation of the telescopic folding. In this case, it is the distal end of each outer fold that extends over the adjacent, nested, inner fold. Typically, the sheath 711 tapers or becomes narrower from the distal end to the proximal end. The outer-most fold is connected to the end-cap 701 and is drawn to unfold first by an inserted endoscope 201. The eyelets 1601 are provided on the over-extending distal edge of every outer fold. The top left drawing of Figure 18 is a side view of folded sheath 711 and the eyelets 1601 without the end-cap 701, while the top right drawing shows the view of the left drawing in the distal end, where the arrangement of three series of eyelets 1601 can be seen. The bottom drawing shows how the instrument channels and the inflation tube 710 are each inserted into the

eyelets 1601 of the corresponding series. In this embodiment, the folded sheath 711 is between the end-cap 701 and the end-guard 715.

- [0118] It should be noted that it is not always necessary for the sheath 711 to have a taper just to facilitate telescopic folding, as other factors such as crease-ability or elasticity of the sheath material and so on may also permit telescopic folding.
- [0119] Figure 19 shows how are eyelets 1601 attached to a sheath 711 in accordion folds. As explained, the accordion fold comprises a plurality of alternating inward radial folds, and outward radial folds, away from the axis of the sheath 711. As none of the folds is inserted one into another as in the telescopic folds, the sheath 711 does not need to be tapered. The accordion folding is more compact than the telescopic folding, and is suitable for compact storing and transporting in large numbers. The inner edges of the folds tend to be creased for accommodating excess sheath material fitting into a smaller circumference. Therefore, the sheath 711 can be constructed of any plastic material, such as TPU or polyethylene (PE), that is thin and foldable and preferably easily creased. The drawing on the left shows the distal end of the folded sheath 711 sealed to the proximal edge of the end-cap 701. Two external instrument channels 707 and the inflation tube 710 are shown extending from the end-cap 701 and through the corresponding series eyelets 1601 in the folded sheath 711 and out of the annulus 713 in the end-guard 715. The right drawing shows the sheath 711 unfolded.
- [0120] Figure 20 shows a variation of the folded sheath 711 in which the end-cap is contained or nested inside the inner-most telescopic fold. In this case, the eyelets 1601 are provided on each outer fold extending towards the proximal end, i.e. beyond the inner fold.
- [0121] Generally, the lengths of the folds depend on the thickness of the sheath 711 wall, the material used for the sheath 711 and the angle of the taper of the sheath 711, the positions, diameters and thickness of the eyelets 1601, and the intended length of the endoscope 201 to be sheathed 711.
- [0122] Figure 21 shows a variation of the sheath 711 in which the inflation tube 710 is not threaded through any eyelet 1601, and only the instrument channels are each threaded to a separate series of eyelets 1601. The inflation tube 710 does not require the third series of eyelets 1601 since two series of eyelets 1601 are sufficient to provide three segregated space for three tubular members. Therefore, the inflation tube 710 shares space with an inserted endoscope 201.
- [0123] Figure 22 shows a modified use of the sheath 711 shown in Figure 21, in which the inflation tube 710 is looped around the each eyelet of one series of eyelets.
- [0124] Figure 23 shows a variation of the sheath 711 in which there are three series of eyelets but the eyelets of each series of are spaced apart by a large distance. Furthermore, the positions of the eyelets 1601 along the sheath 711 are staggered between

the three series of eyelets 1601. This allows a smaller number of eyelets 1601 to be provided while yet maximises the effects of the eyelets 1601 in preventing the tubular members from intertwining.

- [0125] Figure 24 shows one of the simplest embodiment which is a folded sheath 711 attached to an end-cap 701 that can be fixed to the tip of an endoscope 201. There is no inflatable balloon 709 and inflation tube, and also no external instrument channels 707 attached to the end-cap 701. The end-cap 701 is just a band, and is not attached with any conduit 705. In Figure 24, the bulk of the folded sheath 711 is placed on the proximal side of the end-guard 715. Other configurations of folding and placement are possible in simple embodiments of just a sheath 711 attached to an end-cap 701 and end-guard 715 on both ends. This embodiment is simply used to sheath 711 over endoscopes 201 without supplying additional functionality. The advantage is in the reduction of contamination on the external surface of the endoscope 201.
- [0126] Figure 25 shows another simple embodiment having only an end-cap 701 with no external instrument channel 707, balloon 709 and inflation tube 710. In this case, the end-cap 701 is nested inside the sheath 711 in telescopic folding. The folded sheath 711 and nested end-cap 701 is placed against the distal side of the end-guard 715.
- [0127] In some variations of the sheath 711, only one eyelet 1601 is provided instead of a series of eyelets 1601 for each of the instrument channels. The single eyelet 1601 is provided on the internal surface of the sheath 711 near the end-cap 701 to limit the extent to which the external instrument channel 707 may twist about the end-cap 701.
- [0128] Variations of the end-cap and end-guard
- [0129] Figure 26 is a schematic illustration of an end-cap 701 having a preferred feature the front view, showing the bore as the apex of a triangular arrangement formed with the two conduits 705 beneath and both sides of the bore as the base. The other components of the sheath assembly 700 are not shown. The conduits 705 are spaced apart along the circumference of the bore, the axes of the conduits 705 and therefore the axes of the instrument channels held in the bore, and the axes of the of the surgical instruments 300 that may be inserted into the instrument channels, forming equal angles a° with reference to the axis of the bore on both sides of a line of symmetry dissecting the axis of the bore. From the plan view which is shown as Figure 27, the conduits 705 are placed on the opposite sides of the axis of the bore at an angle, b° placed so that the steerable arms 303 may converge towards a point in front of the endoscope tip. The angles a° and b° depends on the thickness and circumference of the endoscope 201 which depend in turn on the number of channels and other contents in the endoscope 201. However, for most endoscopes 201 suitable for colonoscopy, the angles a° and b° are typically 15° for the external instrument channels.

- [0130] Figure 28 shows an end-cap 715 having another preferred feature. The end-cap 715 is made of plastic and comprises of a band for capping onto an endoscope tip. However, the band is split into two facing ends across the band, longitudinally. The facing ends on both sides of the split can be closed using a one-way locking mechanism, which comprises a serrated strip provided on one of the facing end, and a crimp having teeth that are pointed against the serrations to prevent release on the other end. An advantage of this feature is that the end-cap 715 may fit well into endoscopes 201 of different brands that have slightly different thicknesses, and can be attached rigidly to the endoscope tip to prevent twisting or displacement of the end-cap without requiring additional adhesive tape. The band has a hood extending towards the distal direction, to prevent intestinal tissue from covering the camera 405.
- [0131] In a variation of the end-guard 715, illustrated schematically and shown as Figure 29, several annuli are provided on the end-guard 715, each annulus 713 having a diameter corresponding to the specific one of the tubular members extending through the end-guard 715, and the annuli are positioned in the end-guard 715 somewhat according to the arrangement of the tubular members at the end-cap 701. The largest annulus 713 which is also the annulus in the top position, according to the orientation shown in Figure 29, is for insertion of the endoscope 201, which then passes through the core of the folded sheath to be fitted by the tip into the end-cap 701. The annulus in the lowest position is for the inflation tube to extend out of the sheath. The two annuli in the same position vertically are each for an external instrument channel to extend out of the sheath.
- [0132] Figure 30 shows a prototype of the end-guard 715 having a corrugated external surface around the cap profile for better grip, and separate annulus 713 for the endoscope 201, the two external instrument channels 707 and the inflation tube 710.
- [0133] Accordingly, the embodiments include a longitudinally folded sheath that is capable of being unfolded to sheath over an endoscope that is inside the sheath and being inserted into a person. In other words, the embodiments include a sheath assembly for an endoscope, comprising a hollow sheath having a distal end attached over an end-cap and a proximal end attached over an annulus in an end-guard configured for an endoscope to extend through the annulus and the hollow sheath to fit into the end-cap; the sheath folded into in plurality of folds, each of the folds being a circumferential segment of the sheath folded longitudinally over an adjacent circumferential segment of the sheath; wherein the folds are capable of unfolding as the endoscope pushes the end-cap away from the end-guard.
- [0134] Using the embodiments include using a method for sheathing an endoscope, comprising the steps of: providing a hollow sheath folded into in plurality of folds, each of the folds being a circumferential segment of the sheath folded longitudinally

over an adjacent circumferential segment of the sheath; inserting an endoscope through the proximal end of the sheath; pushing more of the endoscope into the sheath and pushing the distal end of the sheath further away from the proximal end of the sheath to unfold the sheath; wherein the fold of the sheath being unfolded is laid onto a part of the endoscope passing the unfolding the fold of the sheath.

[0135] 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 scope of the present invention as claimed.

[0136] For example, where circumference has been used to describe the radial cross section of the sheath, it is possible that the sheath is oval, or rhombic in the radial cross-section, and folding of such sheaths in accordion or telescopic folds of segments over segments of the sheaths along the longitudinal direction are made in the same way as in the described embodiments.

Claims

- [Claim 1] A sheath assembly for an endoscope, comprising
a hollow sheath having a distal end attached over an end-cap and a proximal end attached over an annulus in an end-guard configured for an endoscope to extend through the annulus and the hollow sheath to fit into the end-cap;
the sheath folded into in plurality of folds, each of the folds being a circumferential segment of the sheath folded longitudinally over an adjacent circumferential segment of the sheath; wherein
the folds are capable of unfolding as the endoscope pushes the end-cap away from the end-guard.
- [Claim 2] A sheath assembly for an endoscope as claimed in claim 1, wherein the dimensions of the end-cap allow the end-cap to enter into the gastrointestinal tract of a person while the dimensions of the end-guard prevents the end-guard from entering the mouth or anus of the person.
- [Claim 3] A sheath assembly for an endoscope as claimed in claim 1 or claim 2, wherein
the sheath is folded into a series of telescopic folds.
- [Claim 4] A sheath assembly for an endoscope as claimed in claim 3, wherein a telescopic fold comprises a longitudinal segment of the sheath folded along the sheath circumference into extending longitudinally over the next telescopic fold of the sheath.
- [Claim 5] A sheath assembly for an endoscope as claimed in claim 4, wherein the edge of each telescopic fold extends over the edge of the next telescopic fold.
- [Claim 6] A sheath assembly for an endoscope as claimed in claim 5, comprising a plurality of eyelets inside the sheath, each eyelet attached to an over-extending edge of the next telescopic fold; wherein
the plurality of eyelets is aligned longitudinally on the sheath.
- [Claim 7] A sheath assembly for an endoscope as claimed in claim 6, comprising a second plurality of eyelets, each eyelet attached to an over-extending edge;
the second plurality of eyelets being aligned longitudinally on the sheath; wherein
the plurality of eyelets and the second plurality of eyelets are placed apart on the circumference of the sheath.

- [Claim 8] A sheath assembly for an endoscope as claimed in claim 1 or claim 2, wherein
the sheath is folded into accordion folds.
- [Claim 9] A sheath assembly for an endoscope as claimed in claim 8, comprising
a plurality of eyelets attached to the accordion folds; and
the plurality of eyelets aligned longitudinally to the sheath.
- [Claim 10] A sheath assembly for an endoscope as claimed in claim 9, comprising
a second plurality of eyelets attached to the accordion folds;
the second plurality of eyelets aligned longitudinally to the sheath;
wherein
the plurality of eyelets and the second plurality of eyelets are placed
apart on the circumference of the sheath.
- [Claim 11] A sheath assembly for an endoscope as claimed in claim 1 or claim 2,
further comprising
an inflatable balloon around the end-cap.
- [Claim 12] A sheath assembly for an endoscope as claimed in claim 11, wherein
the end-cap is eccentrically placed in the balloon.
- [Claim 13] A sheath assembly for an endoscope as claimed in claim 1 or claim 2,
comprising
at least one external instrument channel extending from the end-cap
through the sheath and out of the annulus on the end-guard.
- [Claim 14] A sheath assembly for an endoscope as claimed in claim 13, further
comprising
two external instrument channels extending from the end-cap through
the sheath and out of the annulus on the end-guard.
- [Claim 15] A sheath assembly for an endoscope as claimed in claim 14, further
comprising
the distal ends of the external instrument channels in a mutually
convergent arrangement on the end-cap.
- [Claim 16] A sheath assembly for an endoscope as claimed in claim 15,
comprising
two eyelets attached to the inner surface of the sheath and spaced apart
on the circumference of the sheath;
the two external instrument channels each extending through a different
one of the two eyelets;
the eyelets being attached to the inner surface of the sheath at a distance
from the end-cap.

- [Claim 17] A sheath assembly for an endoscope as claimed in claim 15, comprising two eyelets attached to the inner surface of the sheath and spaced apart on the circumference of the sheath;
the two external instrument channels each extending through a different one of the two eyelets;
the eyelets being attached to the inner surface of the sheath at a distance from the end-cap; wherein the distance is less than or equal to half the length of bending section of an endoscope or the distance is less than or equal 10cm.
- [Claim 18] A method for sheathing an endoscope, comprising the steps of:
providing a hollow sheath folded into in plurality of folds, each of the folds being a circumferential segment of the sheath folded longitudinally over an adjacent circumferential segment of the sheath;
inserting an endoscope through the proximal end of the sheath;
pushing more of the endoscope into the sheath and pushing the distal end of the sheath further away from the proximal end of the sheath to unfold the sheath; wherein
the fold of the sheath being unfolded is laid onto a part of the endoscope passing the unfolding the fold of the sheath.
- [Claim 19] A method for sheathing an endoscope as claimed in claim 18, wherein pushing the distal end of the sheath further away comprises the step of pushing the distal end of the sheath into the gastrointestinal tract of a person.
- [Claim 20] A method for sheathing an endoscope as claimed in claim 19, further comprising the step of:
providing at least a tube attached to the distal end of the sheath;
wherein
the fold of the sheath being unfolded is laid onto a part of the endoscope and the at least one tube passing the unfolding the fold of the sheath.