AN ORIENTATION CONTROLLER AND A DISPOSABLE ENDOSCOPE

FIELD OF THE INVENTION

The present invention relates generally to the field of medical instruments, and more specifically, to an orientation controller to be connected to an insertion unit of an endoscopic device having a rotatable bending section, and also to a disposable endoscope.

BACKGROUND OF THE INVENTION

Endoscopes and imaging catheters are widely used in many medical procedures for viewing areas of body organs, cavities, passageways, etc. Generally, such imaging devices include an elongated sheath or similar structure wherein optical fibers are arranged both for transmitting illumination light to the distal end of the sheath to illuminate a viewing field, and for carrying an optical image back to a viewing port or camera. One or more lenses may be positioned on the distal end of the imaging device to focus the optical image received by the instrument, or the illumination cast by the instrument.

As an aid to the early detection of disease, it has become well established that there are major public health benefits from regular endoscopic examinations of internal structures such as alimentary canals and airways, e.g., the esophagus, lungs, colon, uterus, and other organs. A conventional imaging endoscope used for such procedures comprises a flexible tube with a fiber optic light guide that directs illuminating light from an external light source to the distal tip where it exits the endoscope and illuminates the tissue to be examined. Frequently, additional optical components are incorporated to adjust the spread of light exiting the fiber bundle and the distal tip. An objective lens and fiber optic imaging light guide communicating with a camera at the proximal end of the scope, or an imaging camera chip at the distal tip, produce an image that is displayed to the operator (usually a physician). In addition, most endoscopes include one or more working channels, through which medical devices, such as biopsy forceps, snares, fulguration probes, and other tools, may be passed.

In many applications, it is desirable that the distal portion of the imaging device be "steerable", bendable or maneuverable from the proximal end of the device, to facilitate guidance of the device through tortuous or furcated anatomical passageways. Additionally, the ability to bend the device at or near its distal end may enable the operator to visually scan an expanded viewing area by bending or otherwise manipulating the distal end of the device. The ability to maneuver the tip makes it easier to guide the tip of the device properly through the often highly branched and convoluted passageways near organs.

In order to control deflection of the distal tip of an imaging device, many designs have been introduced that incorporate either two opposed control wires to control bending in one plane, or four wires evenly spaced to control bending in two perpendicular planes. These control wires run the length of the device and terminate at the distal end of the steerable region, or at the distal tip. The proximal end of each control wire is functionally connected to a separate drum or spool rotated manually, or by a dedicated electrical or fluid motor for linearly advancing and retracting the control wire in relation to the device. In operation, when one of the control wires is pulled proximally by rotation of the drum or spool, the distal tip of the device bends at the steerable region toward the retracted wire.

Navigating channels in the human body can be very challenging. Some parts of the human anatomy can be difficult to see and are not always oriented in a convenient location relative to the position of the scope or surgical instrument. Occasionally, the anatomy and the degrees of freedom of the instruments can impede or prevent successful navigation. During conventional colonoscopy procedures, a colonoscope advances through the tortuous sigmoid colon until the colonoscope reaches the descending colon. The colonoscope is manipulated to reduce redundancy in the sigmoid colon. When the sigmoid colon has been straightened, the colonoscope typically further advances through the colon. However, this type of procedure is generally difficult to perform, and/or painful for the patient due to stretching of the colon which occurs upon impact between the colonoscope and the wall of the colon as the colonoscope advances, especially during progression of the colonoscope around the bends of the tortuous sigmoid colon. Navigation of the endoscope through complex and tortuous paths is critical to success of the examination with minimum pain, side effects, risk, or sedation to the patient. To this end, modern endoscopes include means for deflecting the distal

tip of the scope to follow the pathway of the structure under examination, with minimum deflection or friction force upon the surrounding tissue. Control cables similar to puppet strings are carried within the endoscope body in order to connect a flexible portion of the distal end to a set of control knobs at the proximal endoscope handle. By manipulating the control knobs, the operator is usually able to steer the endoscope during insertion and direct it to a region of interest, in spite of the limitations of such traditional control systems, which are cumbersome, non-intuitive, and friction-limited. Common problems for operators of traditional endoscopes include their limited flexibility, limited column strength, and limited operator control of stiffness along the scope length.

Conventional endoscopes are generally built of sturdy materials, which decrease the flexibility of the scope and thus decrease patient comfort. Furthermore, conventional endoscopes are complex and fragile instruments that frequently need costly repair as a result of damage during use or during a disinfection procedure. Moreover, many procedures using steerable instruments remain complex. A great deal of skill and patience is often required to correctly orient the instrument in a predetermined position.

As described above, an endoscope is an instrument used to see inside a body lumen. A conventional medical endoscope includes a flexible tube, a functional control mechanism to direct the position of a distal end of the flexible tube, and a camera. The camera provides images of the internal body cavity to help the medical practitioner position the distal end of the flexible tube and confirm that the end is positioned at an acceptable location. When the endoscope is used in a medical procedure, the flexible tube of an endoscope is generally directed into an internal body cavity of a patient. During its use in the procedure by a medical practitioner, the endoscope may acquire high levels of microbial contamination. Such microbial contamination may include infectious agents or any number of harmful bacterial and viral microorganisms. In some cases, an endoscope used in a medical procedure on one patient is contaminated, improperly or insufficiently disinfected, and is then used in a medical procedure on another patient. In such cases, the health of the second patient is put at risk of microbial transmission or disease.

Medical practitioners work to prevent the spread of infection and disease by following strict procedures to clean and disinfect an endoscope. Unfortunately, most conventional endoscopes (e.g., bronchoscopes, colonoscopes, gastrointestinal

endoscopes, nasopharyngoscopes, sigmoidoscopes, and the like) are heat sensitive and cannot be sterilized. Instead, the endoscopes are cleaned using alternative procedures, and are wiped, or even bathed, in high-level disinfectants.

When endoscopes are made of materials that can be sterilized, the hospital needs to set up a dedicated sterilization chamber and equip it with dedicated sterilization equipment and corresponding operators. The required sterilization procedure limits the frequency of reuse, and still carries the risk of cross infection etc. caused by imperfect sterilization.

In spite of rigid attempts to effectively clean endoscopes, some patients suffer injury, illness, and even death as a result of an endoscope that carries pathogens from one patient to another. In 2010, the ECRI Institute cited endoscopic contamination as one of the top 10 health risks in a document entitled "Top 10 Health Technology Hazards for 2011," Reprinted from Volume 39, Issue 11, November 2012 by the ECRI Institute (www.ecri.org). A seminal work that studied and described the problem of improperly cleaned endoscopes is "Transmission of Infection by Gastrointestinal Endoscopy and Bronchoscopy," from the Annals of Internal Medicine, 1993; 118:117-128 by the American College of Physicians.

Flexible endoscopes in general, and colonoscopes in particular, are difficult to clean and disinfect thoroughly, leading to potential problems of cross-contamination between patients, and between patients and staff. Additionally, such endoscopes often use costly devices such as camera heads, electro-mechanical steering devices, and control electronics modules, which cannot be readily sterilized, and, because of their cost, cannot be discarded after every use.

The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Infection control lapses, due to non-compliance with recommended reprocessing procedures, highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to review reprocessing practices at their facility to ensure they are complying with all steps as directed by the device manufacturers, and have in place appropriate policies and procedures that are consistent with standards and guidelines. Safety communications are published every year to guide hospitals and

health care facilities that utilize colonoscopes to take additional steps to further reduce the risk of infection and increase the safety of these medical devices. They recognize that not all health care facilities can implement one or more of these measures, which require specific resources, training, and expertise. Reprocessing instructions are provided as a detailed, multistep process to clean and disinfect or sterilize reusable devices, and can result in infection transmission if reprocessing instructions are not followed in every step of the process.

GENERAL DESCRIPTION

A traditional endoscope has a semi-flexible shaft i.e. it cannot pass through the body lumen in its original shape because it is not flexible enough. Therefore, the operator needs to perform manipulations with the endoscope to reshape the body lumen to an easier path for the endoscope to maneuver. The main way to reshape the body lumen is by rotating the insertion tube. The rotation of the tube first straightens the tube, in order to deliver the torsion forces to the distal tip, affecting the body lumen in the same way. The novel configuration of the present invention enables to provide navigation of a distal tip by using both deflection of a bending section of the endoscopic device (e.g. using knobs or a joystick) together with rotation of the bending section. The novel orientation controller allows the operator to rotate the bending section from the operator's orientation controller, without rotating the insertion unit. The insertion unit then has the capability to advance through a tortuous body lumen fitting the looped configuration of the body lumen shape, transmitting pushing, and optionally also rotation and bending forces, from one extremity to the other, despite the possible looped condition of the insertion unit. The insertion unit enables to perform intubation of an endoscope by pushing the insertion unit, and is also capable of fully steering and rotating the bending section of an intubation system without rotating the outer elongated shaft structure of the insertion unit itself, and therefore without straightening the body lumen. The present invention thus enables rotating an inner part of an insertion unit of an endoscopic device without changing the entire insertion unit's position inside the body lumen.

According to a broad aspect of the present invention, there is provided an intubation system comprising (a) an insertion unit to be connected to a bending section

of a medical instrument comprising an inner elongated shaft structure being capable of torque transmission around its length axis and an outer elongated shaft structure surrounding the inner elongated shaft structure and having a continuous outer surface, and (b) an orientation controller being attached to the inner elongated shaft, such that when the orientation controller rotates, the bending section turns around itself.

The orientation controller may be an integral part of an endoscopic system (e.g. comprising an image capturing device which is steered to any desired destination to enable to image a body lumen and perform polypectomy), or may be coupled to elements together forming an endoscope. The insertion unit refers hereinafter to the part of an endoscope device connecting between an orientation controller to the bending section of the intubation system and the optical head of the endoscope. The orientation controller of the present invention may be thus connected to any commercially available insertion unit.

According to another broad aspect of the present invention there is provided an orientation controller to be connected to an insertion unit of an endoscopic device having a rotatable bending section. The orientation controller comprises a handle defining an axial direction to be handled by an operator, a rotatable bearing structure connecting between the handle and the insertion unit and being configured and operable to rotate the rotatable bending section of the insertion unit about the axial direction and a mode selector capable of operating the endoscopic device in locked and unlocked operation modes, wherein operation of the locked operation mode blocks the rotatable bearing structure, and operation of the unlocked operation mode allows the operator to rotate the rotatable bending section by rotating the rotatable bearing structure around itself about the axial direction without changing the outer elongated shaft structure's position inside the body lumen. The handle is a static part of the orientation controller.

In some embodiments, operation of the locked operation mode allows the operator to rotate the rotatable bending section by rotating the handle about the axial direction. The present invention thus provides a manually operable mechanical structure (i.e. an orientation controller) being capable of rotating a bending section of an endoscopic device being located within a body lumen. This special configuration enables to transfer a torque from an operator's hand to a bending section of an insertion unit by (1) rotating the handle of the orientation controller being attached to an insertion unit via a rotatable bearing structure, while the rotatable bearing structure is locked or

(2) rotating the rotatable bearing structure, while the rotatable bearing structure is unlocked. Therefore, in the locked mode, the rotatable bearing structure is blocked such that the elongated shaft structure itself does not rotate, forming, together with the handle, a rigid unit.

Alternatively, operation of the locked operation mode prevents the operator from rotating the rotatable bending section, by rotating the handle about the axial direction. This configuration of the locked mode operation may be used for intubation. This locked mode allows to advance with minimal force without straightening the body lumen. In a locked mode, the rotatable bearing structure is not capable of rotating. The locked mode may be used when pushing forces are used to advance the endoscope. Therefore, the locked mode can be used in a navigation mode, when the medical instrument passes through the GI tract.

In an unlocked mode, the handle is disconnected from the insertion unit and the inner elongated shaft is free to move. The mode selector is thus configured to release the rotatable bearing structure. The torque is then transferred by rotating the rotatable bearing structure only, while the rotatable bearing structure is unlocked. More specifically, the unlocked mode disconnects the handle from the rotatable bearing structure such that rotation of the handle does not affect the rotatable bearing structure and enables the rotatable bearing structure that is fixed to the inner elongated shaft structure and to the outer elongated structure, to be free for rotating and transferring the torque directly to the distal tip by itself through the inner elongated shaft structure. The inner elongated shaft structure itself then rotates within the outer elongated shaft structure without affecting the position of the insertion unit.

The unlocked mode in which the rotation of the rotatable bearing structure causes the rotation of the distal tip, can be used especially for polypectomy procedures when the orientation of the medical instrument should be changed. More specifically, in polypectomy processes, the operator needs to navigate the distal tip to examine and remove the polyp. The operator needs to be able to bend the tip in every direction and also rotate the insertion tube in order to get to the right position. In this connection, it should be understood that, typically, the operator would prefer to rotate the device until the polyp is shown in a 6 o'clock direction to the tool exit point. If the polyp is found at the 12 o'clock direction, by using commercially available devices, the operator needs to rotate the tool by 180° to bring the polyp to the desirable location. To this end, the

operator manipulates the device back and forth, to try to keep the desired position, while rotating the tool. This procedure is unsafe and not accurate, losing the precise location of the polyp and consuming time. The novel configuration of the orientation controller solves the above-mentioned problem. This technique enables to rotate the distal tip to an extent being higher than 180° in two directions without affecting the body lumen structure. This unique configuration of the insertion unit of the present invention enables to provide, together with steering capabilities, rotating capabilities leading to an accurate, rapid and safe procedure enabling to target and to treat any precise location of the polyp. As mentioned above, this unique configuration provides the capability to convey the polypectomy tool at any three-dimensional desired location and position. Deflection of the distal tip is necessary to ease intubation, scanning and removal of polyps. The bending section is thus capable of full steering, as well as full rotation around itself, providing accurate imaging and polypectomy.

In some embodiments, the rotatable bearing structure comprises an inner rotatable bearing element being configured for connecting between the inner elongated shaft structure and the handle and an outer rotatable bearing element connected to the outer elongated shaft structure such that the rotatable bearing structure is configured for allowing the inner elongated shaft to rotate inside the outer elongated shaft of the insertion unit.

In some embodiments, the rotatable bearing structure comprises a gear mechanism having an outer wheel configured to block rotation of the rotatable bearing structure upon operation of the mode selector, and an inner wheel configured to be capable of free rotation by the outer wheel and to hold an extremity of the rotatable bending section. The gear mechanism may be configured to allow free rotation between the outer elongated shaft structure and the inner elongated shaft structure. In an unlocked operation mode, rotation of the outer wheel rotates the inner elongated shaft structure inside the outer elongated shaft structure via the inner wheel and thereby rotates a rotatable bending section around itself without changing the outer elongated shaft structure's position inside the body lumen.

In some embodiments, the gear mechanism may further comprise an outer shaft holder configured to hold an extremity of the outer elongated shaft structure, wherein the inner wheel is configured to hold an extremity of the inner elongated shaft structure.

The novel configuration of the orientation controller enables to perform safe procedures. The insertion unit is configured for guiding an endoscope through a body lumen with low danger for the patient.

According to another broad aspect, the present invention provides a novel disposable endoscope having disposable components eliminating the need to sterilize the medical instrument. This requirement involves the use of low-cost material. To fulfill the requirements of mass production techniques, the steering mechanism might be made of injected plastic parts (e.g. injection molded). Moreover, to appropriately steer the device at any desired angle and position, the steerable portion of the tube should be flexible and the steering threads should have the following physical properties: withstanding a high load (e.g. about 20 kg), high abrasion resistance, high suppleness, high flexibility and low spool memory. Steel cables, usually used in steering devices, do not have these required properties. Therefore, there is provided an endoscope comprising a steering mechanism having at least two steering threads that are made of a non-metal material. The steering threads of the present invention may thus be selected to be a thread made of polymer material, such as plastic. For example, steering threads are configured as braided fishing line. The braided line may be made of any one of copolymer, fluorocarbon, and nylon-based monofilaments. However, due to their lack of stretch and slippery surface, threads made of plastic are hard to knot properly. Fastening a non-metal steering thread to a pulley, while withstanding high forces and elongation, is a challenging task. To this end, the present invention provides a novel thread pulling device having a special configuration being aimed at properly holding steering threads being made of non-metal material having the physical properties as defined above.

The steering mechanism is configured for one-handed, either-handed use. The bending section is torque stable, rotatable and steerable. The handle of the endoscopic device (i.e. orientation controller) and the insertion unit are configured for use on a single patient and are disposed of after use in a single medical procedure.

In some embodiments, at least two steering threads are made of a non-metal material.

In some embodiments, the endoscope further comprises a thread pulling device configured and operable for fastening at least two non-metal steering threads. The thread pulling device includes at least one pulley on which the at least two steering

threads are enwrapped. A first pulley may be configured and operable for directing the distal end portion leftwards and rightwards, and a second pulley may be configured and operable for directing the distal end portion downwards and upwards. The pulleys are connected to each other and are operated independently.

In some embodiments, the thread pulling device further comprises a locking mechanism configured and operable to lock the steering mechanism in a locked steered position.

According to another broad aspect of the present invention, there is provided an endoscope comprising a gas release valve configured to control the level of pressure exiting from a gas supply by releasing gas to the environment when the pressure reaches a certain threshold.

BRIEF DESCRIPTION OF THE FIGURES

In order to understand the invention and to see how it may be implemented in practice, preferred embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawing, in which

Fig. 1 schematically illustrates an example of an endoscopic device incorporating an orientation controller according to some embodiments of the present invention;

Fig. 2A schematically illustrates a partial view of an example of an orientation controller according to some embodiments of the present invention;

Fig. 2B schematically illustrates a partial view of another example of an orientation controller according to some embodiments of the present invention;

Figs. 3A-3B schematically illustrate partial cross sectional views of an example of a rotatable bearing structure according to some embodiments of the present invention;

Figs. 4A-4E show different views of examples of a mechanical steering mechanism according to some embodiments of the invention; and

Fig. 5 shows an example of a release valve according to some embodiments of the invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Performing colonoscopy or even polypectomy procedures requires a great deal of skill from the operator to manipulate the distal tip to a desirable position and use a therapeutic tool to perform the procedure. Reference is made to **Fig. 1**, illustrating an example of an endoscopic device **100** incorporating an operator's orientation controller **210** of the present invention. The present invention provides a novel configuration of an orientation controller **210** to be connected to an insertion unit **200** for performing safe procedures. The insertion unit **200** is configured for guiding an endoscope through a body lumen with low danger for the patient. Navigation of a distal tip is possible by using both deflection of a bending section **310** of the endoscopic device **100** (e.g. using knobs or a joystick) together with rotation of the bending section **310**. The novel insertion unit **200** allows the operator to rotate the bending section **310** from the operator's orientation controller **210**, without rotating the outer elongated shaft structure of insertion unit **200** shown in **Fig. 2A** below. Insertion unit **200** connects between an orientation controller **210** (e.g. a grip comprising valves, steering knobs and buttons) located in the handle to the bending section **310** including an optical head. Insertion unit **200** has the capability to advance through a tortuous body lumen fitting the looped configuration of the body lumen shape, transmitting pushing, and optionally also rotation and bending forces from one extremity to the other, despite the possible looped condition of the shaft. The physical properties required for the insertion unit **200** are appropriate flexibility and restoring performance against bending, pushability for transmitting an operational force from the proximal end portion to the distal side, and kink resistance (often called "resistance against sharp bending"). Insertion unit **200** is connected to the bending section **310**.

Reference is made to **Fig. 2A** illustrating an example of the configuration of an orientation controller **210**, according to some embodiments of the present invention. The orientation controller **210** is configured to be connected to an insertion unit **200** of an endoscopic device having a rotatable and steering bending section. The insertion unit may be formed of a unit made of an elongated shaft as illustrated in **Fig. 1**. In some embodiments, the inner elongated shaft structure may be implemented by an elongated torsion shaft **30C** surrounded by the outer hollow elongated shaft structure **10**. In this context, in the specification and in the claims, "torsion shaft" refers to a rotatable flexible non-hollow cable having a non-continuous surface driven by gearing linked to

the output of the orientation controller **210**. The non-continuous property of the inner elongated shaft structure enables to transmit pushing and rotation forces along the length of the insertion tube **200**. When the operator turns orientation controller **210** in both rotational directions **R**, orientation controller **210** turns the torsion shaft **30C** in both rotational directions **r**. This shaft can transfer a great amount of torsion and remain very flexible. In this connection, it should be understood that since torsion shaft **30C** is not hollow, a plurality of channels may be accommodated between the outer structure **10** and the torsion shaft **30C** as will be illustrated further below. Moreover, torsion shaft **30C** is capable of transmitting torque even if it is wrapped around itself, because of the loops naturally formed by the colon.

As illustrated above, controller **210** comprises a handle **42** defining an axial direction **A** to be handled by an operator, a rotatable bearing structure **44** connecting between handle **42** and the torsion shaft **30C** and the outer elongated shaft structure **10** and is configured and operable to rotate the bending section about the axial direction **A** and a mode selector **48** capable of allowing the operator to rotate the bending section by rotating the handle **42** or by rotating the rotatable bearing structure **44**. A mode selector **48** is capable of operating the endoscopic device in two operative modes: one locked mode being capable of blocking the rotatable bearing structure, and one unlocked mode capable of allowing the operator to rotate the bending section by rotating the rotatable bearing structure **44** about the axial direction **A**. In the unlocked mode, the rotation of handle **42** does not affect the rotatable bending structure **44** (i.e. the handle **42** is disconnected from the rotatable bearing structure **44**). The two modes may be actioned by translationally displacing mode selector **48** along **L** direction.

Reference is made to **Fig. 2B** illustrating an example of the configuration of an orientation controller **210**, according to some embodiments of the present invention. The orientation controller **210** is configured to be connected to an insertion unit **200** of an endoscopic device having a rotatable and steering bending section. The insertion unit may be formed by a unit made of an elongated shaft as illustrated in **Fig. 1**. Controller **210** comprises a handle **42** to be handled by an operator, a rotatable bearing structure **44** being capable of rotating around itself (illustrated in the figure by two elements **44A** and **44B**) connecting between handle **42** and the insertion unit **200** and being configured and operable to rotate the bending section, and a mode selector **48** capable of operating the endoscopic device in the two operative modes.

In some embodiments of the present invention, insertion unit **200** comprises an inner elongated shaft structure **30** surrounded by an outer elongated shaft structure **10**. Inner elongated shaft structure **30** has thus a diameter smaller than outer elongated shaft structure **30**. Moreover, the inner elongated shaft structure **30** and the outer elongated shaft structure **10** form together an integrated insertion unit **200** connecting at its extremities via a rotatable bearing structure **44** at one side of the orientation controller **210**.

The inner elongated shaft **30**, connected to the orientation controller **210** at one edge and to the bending section at the other, is able to transfer rotation of the orientation controller **210** directly to the distal tip through the insertion unit **200**, without affecting the position of the insertion unit **200**. The outer elongated shaft structure is flexible and is not capable of transferring torsion. In the locked mode, the rotatable bearing structure **44** is blocked, forming a rigid unit with the handle **42**, such that any rotation of the handle **42** could not rotate the distal tip/bending section because the outer elongated shaft does not have the capability to transfer torsion.

In this configuration, rotatable bearing structure **44** comprises a inner rotatable bearing element **44A** connecting between the inner elongated shaft structure **30** and the handle **42** and an outer rotatable bearing element **44B** connected to the outer elongated shaft structure **10** such that the inner rotation bearing element **44A** can rotate within the outer rotatable bearing element **44B**.

In this configuration, orientation controller **210** is thus configured and operable to selectively connect the handle **42** to the inner elongated shaft structure **30** without the outer elongated shaft structure **10** or together with the outer elongated shaft structure **10**. Orientation controller **210** is configured to allow free rotation in the two directions (clockwise or counterclockwise).

In some embodiments, mode selector **48** is capable of allowing the operator to decide if the rotation of the bending section (**310** of **Fig. 1**) is made by moving the handle **42** (in a locked mode), or if the rotation of the bending section (**310** of **Fig. 1**) is made by moving only the inner elongated shaft structure itself **30** (in an unlocked mode). In one operative locked mode, this may be implemented by blocking the rotatable bearing structure **44**. In the second operative unlocked mode, in which the rotation is made by moving only the inner elongated shaft structure **30**, the rotatable bearing structure **44** is released from the handle **14** such that the inner elongated shaft

structure **30** is free to move alone and can rotate. For example, mode selector **48** may comprise an outer wheel **840**. Upon activation of mode selector **48** (e.g. displacement towards the bending section) outer wheel **840** can be immobilized and cannot rotate, blocking the rotatable bearing structure **44**. Upon deactivation of mode selector **48** (e.g. displacement in the direction opposite to the bending section), outer wheel **840** can be released and can rotate, releasing the rotatable bearing structure **44** such that the inner elongated shaft structure **30** is free to move alone and rotate.

Reference is made to **Fig. 3A** illustrating an example of a rotatable bearing structure **44** incorporating a gear mechanism **800** according to some embodiments of the present invention. Gear mechanism **800** comprises an inner wheel **830** configured to hold an extremity of the inner elongated shaft structure (e.g. torsion shaft **30C** of **Fig. 2B**) and an outer wheel **840** configured to rotate the inner wheel **830** while mode selector **48** is in unlocked mode. More specifically, outer wheel **840** may activate inner wheel **830** of the gear mechanism of the rotatable bearing structure **44** rotating the inner elongated shaft structure **30** within the outer elongated shaft structure **10** without changing the outer elongated shaft structure's position inside the body lumen. Activation (e.g. displacement) of the mode selector **48** to locked mode, blocks the outer wheel **840** which cannot rotate. Rotatable bearing structure **44** comprises an outer shaft holder **810** configured to hold an extremity of the outer elongated shaft structure. Gear mechanism **800** is configured to allow free rotation between the outer elongated shaft structure and the inner elongated shaft structure.

In some embodiments, rotatable bearing structure **44** comprises *inter alia* an indentation **842** for accommodating the handle portion of the orientation controller, and a gear holder **820** configured for accommodating a plurality of channels running through the length of the insertion unit **200** from the handle straight to the outer elongated shaft structure. Inner wheel **830** is configured to move freely inside the gear holder **820** for example, due to an inner bearing **832** and by rotation of the outer wheel **840**. The gear mechanism is configured and operable to transfer a small movement of rotation from the operator hand to a larger movement of the bending section, and therefore achieve more range and less delay.

Reference is made to **Fig. 3B** illustrating another cross sectional view of the rotatable bearing structure **44** incorporating a gear mechanism **800** according to some embodiments of the present invention. Gear mechanism **800** comprises an inner wheel

830 configured to hold an extremity of the inner elongated shaft structure **30**. The outer wheel is configured to block the rotation of the rotatable bearing structure **44** upon displacement of the mode selector **48**. As described above, mode selector **48** is capable of allowing the operator to decide whether to use the gear mechanism **800** or not. This may be implemented by blocking, in one locked operative mode, an outer wheel **840** of the gear mechanism **800** such that the outer wheel **800** is immobilized and cannot rotate. For example, displacement of the mode selector **48** blocks the outer wheel **800** which cannot rotate. In the second unlocked operative mode in which the gear mechanism **800** is used, the operator can rotate the outer wheel **840** in both rotational directions **R**. The rotation of the outer wheel **840** can rotate the bending section in the ratio of the gear. The mode selector **48** may be configured as a knob selectively operating the two locked and unlocked operative modes. The transmission ratio of the gear can be calculated from the diameter's wheels, as follows:

Gear's transmission ratio = outer wheel radius / inner wheel radius.

For sake of illustration only, the figure shows a plurality of channels **400** running through the length of the insertion unit **200** from the handle straight to the outer elongated shaft structure. However, the plurality of channels **400** are not a part of the present invention. Reference is made to **Fig. 4A**, exemplifying a perspective view of a thread pulling device **300** such as mechanical knobs according to some embodiments of the present invention. In this configuration, the thread pulling device **300** comprises two pulleys **16** and **24** being operated by two controller wheels **16A** and **24A** respectively. The pulleys **16** and **24** are configured for separating the control of the steering, such that one pulley is configured and operable for directing the optical head leftwards and rightwards, while the second pulley is configured and operable for directing the optical head upwards and downwards. Pulley **16** is configured and operable for steering the optical head in the left and right directions, while pulley **24** is configured and operable for steering the optical head in the up and down directions. This novel configuration enables to provide full control of the steering device. The controller wheels **16A** and **24A** can be rotated clockwise and counterclockwise by the user in order to pull the steering threads. This action rotates the optical head to the desired direction. Each pulley holds two steering threads being configured for moving the optical head in opposite directions (i.e. left and right, or up and down). In this way, while one of the

threads is being pulled, the other thread is released from tension. The pulleys **16** and **24** operate in the same manner, but for different directions.

In some embodiments, the thread pulling device **300** also comprises a locking mechanism **22**, configured to lock the steering mechanism in the desired locked position. The pulleys **16** and **24** are thus configured for orienting the steering thread **14** at any desired position and tension, and, when the desired position is reached, locking mechanism **22** is configured for locking the steering mechanism at a specific steered position, and locking the optical head at a specific position. The locking capability of the steering mechanism of the present invention enables to provide an accurate inspection of any desired region within the body lumen. The locking mechanism **22** locks the pulleys **16** and **24** but still allows a very fine movement of the controller wheels (e.g. knobs) **24A** and **16A** for a very fine steering for the removal of polyp stage. More specifically, locking mechanism **22** has two operative modes. In normal operation (e.g. free mode), the screw of the locking mechanism **22** does not come into contact with the pulleys **16** and **24**. The screw is turned to lock the pulleys **16** and **24**. The screw presses the pulleys **16** and **24**, creates a friction force on the pulleys **16** and **24** and locks them to move. In order to rotate them and overcome the friction, a large force should be applied on the knobs **24A** and **16A**, providing a very fine movement of the controller wheels (e.g. knobs) **24A** and **16A** for a very fine steering for the removal of polyp stage. The operator may then decide whether to increase the resolution of the image of the specific region of interest, while the steering mechanism is locked in the optimal locked position.

The pulleys **16** and **24** are connected to each other (e.g. by using bearings) in a way that each pulley can operate without affecting the other pulley. In this way, the thread pulling device **300** allows 360° optical head control. In this connection, reference is made to **Fig. 4B** exemplifying a cross-sectional view of the thread pulling device **300**. Bearing **28** connects between the pulleys **16** and **24** to enable rotation of each pulley independently.

More specifically, as exemplified in **Fig. 4C**, one end/extremity of the non-metal steering threads **14A** and **14B** is threaded to fastening points **18A** and **18B** respectively, knotting the ends of the non-metal steering threads **14A** and **14B** to prevent threads **14A** and **14B** from becoming detached from the wheel **20**. The fastening points **18A** and **18B** are configured as two openings in the tension wheel **20** through which the extremity of

each steering thread passes through respectively. The extremity of the steering threads **14A** and **14B** are connected to a pulley **16** that is rotated to bend the bending section, and the steering threads **14A** and **14B** are enwrapped around the pulley **16**. Each thread **14A** and **14B** is enwrapped a few loops around a respective slot **20A** and **20B** in the wheel **20**. The threads **14A** and **14B** are threaded via two holes (not shown) located on the pulley **16**. In order to lock the threads **14A** and **14B**, wheel **20** is inserted into pulley **16**. As described above, each steering thread **14A** and **14B**, is enwrapped around its respective slot **20A** and **20B** by turning the tension wheel **20** within the pulley **16** using a motion controller **26** as exemplified in **Fig. 4D** below. The other extremity of the steering threads **14A** and **14B** is connected to one of an outermost spaced-apart element or the tube's distal end. This novel configuration in which the thread connection is implemented by wrapping the non-metal thread a few loops around the tension wheel **20** tightly and locking the steering threads **14A** and **14B** due to the insertion of wheel **20** into pulley **16** solves the problem mentioned above of fastening a non-metal thread to a pulley.

This novel configuration provides a basting of the steering thread around the pulley, fastening the steering thread to the pulley while allowing a fine movement of the controller wheels (e.g. knobs) **24A** and **16A** for a fine steering for the removal of polyp stage. In this connection, it should be noted that the thread cannot be fixed to the tension wheel by using an adhesive material, since the surface of the thread is too small to withstand shearing stress. For example, the diameter of the thread may be in the range of about 0.1-0.5mm.

Moreover, this configuration provides an accurate tension on the thread, preventing slack of the thread that may be achieved by the teeth of the tension wheel. It should be understood that the more teeth the tension wheel **20** has around it, the more accurate the locking position of the wheel **20** within the pulley **16**, thus facilitating better prevention of slack of the thread.

Reference is made to **Fig. 4D** exemplifying a partial view of the rear side of the thread pulling device **300** being in a locked position according to some embodiments of the present invention. In this specific and non-limiting example, the threaded wheel **20** is secured within the pulley **16** in a locked position upon activation of the operator of a motion controller **26** (e.g. jig). In the locked position, the tension wheel **20** is pushed towards the pulley **16** until the locking teeth of the threaded wheel **20** insert their final

position. Engagement of the teeth of the wheel within the pulley prevents the tension wheel from rotating.

Fig. 4E exemplifies an enlarged cross-sectional view of the threaded wheel **20** engaged within the pulley **16** in a locked position. The threaded wheel **20** comprises two locking trenches **20A** and **20B** located at two opposite sides of the threaded wheel **20**. In this novel configuration, the threaded wheel **20** has a first locking trench **20A** configured as a fastener having groove-like configuration securing the threaded wheel **20** within the pulley **16** having snap-like configuration, and a second locking point **20B** having the same configuration as **20A**. The use of injection plastic elements, as described above, aimed at reducing the cost of the steering mechanism and rendering the steering mechanism disposable, enables the fastening of the elements, one to each other, by using snaps. This technique provides easy, simple, low-cost integration of locking parts for fastening tension wheel **20** into pulley **16**.

Reference is made to **Fig. 5**, illustrating a release valve being configured to control the level of pressure exiting from a gas supply by releasing gas to the environment when the pressure reaches a certain threshold. Release valve **200** may be integrated within the handle of the endoscope and may be configured as a cavity **208** (e.g. valve housing) connected to a gas supply via a gas channel and is sealed at one end by a cover **202**. Cover **202** is placed on top of a spring **204** on top of which a ball **206** is placed. Ball **206** is pressed against cavity **208** using spring **204** to seal the gas channel. The gas channel may be connected to cavity **208** via a tube (e.g. PVC) such that the pressure built up in the gas channel (i.e. the pressure in the colon) is also applied on a part of the ball surface. Whilst the force *(Fpressure)* acting on the ball **206** from the gas pressure remains lower than the force of the spring (*Fspring)* acting on the ball **206** from the spring **204**, the valve is closed such that the gas channel is sealed from the environment. If the pressure on the ball surface reaches a certain threshold and the force *Fpressure* acting on the ball **206** from the gas pressure becomes higher than the force *Fspring* acting on the ball **206** from the spring **204**, a movement of the ball **206** towards valve cover **202** occurs, opening the valve and allowing venting of gas to the environment. The spring is selected to match the required release pressure.

CLAIMS:

1. An orientation controller to be connected to an insertion unit of an endoscopic device having a rotatable bending section; said controller comprises:

a handle defining an axial direction to be handled by an operator;

a rotatable bearing structure connecting between the handle and the insertion unit; wherein said rotatable bearing structure is configured and operable to rotate the rotatable bending section of the insertion unit about the axial direction; and

a mode selector capable of operating the endoscopic device in having a locked mode and unlocked operation modes, wherein operation of the locked operation mode blocks the rotatable bearing structure, and operation of the unlocked mode allows the operator to rotate the rotatable bending section by rotating the rotatable bearing structure about the axial direction;

wherein, when the insertion unit comprises an inner elongated shaft structure and an outer elongated shaft structure surrounding the inner elongated shaft structure; said rotatable bearing structure comprises an inner rotatable bearing element being configured for holding the inner elongated shaft structure, and an outer rotatable bearing element connected to the outer elongated shaft structure such that the inner rotation bearing element is capable of rotating within the outer rotatable bearing element, thereby rotating in the unlocked operation mode the rotatable bending section around itself without changing the outer elongated shaft structure's position inside the body lumen.

2. The orientation controller of claim 1, wherein in the unlocked mode in which the rotation is made by rotating the rotatable bearing structure, said mode selector is configured to release the rotatable bearing structure.

3. The orientation controller of claim 1, wherein said rotatable bearing structure comprises a gear mechanism, wherein said outer rotatable bearing element comprises an outer wheel configured to block rotation of rotatable bearing structure upon operation of said mode selector, and said inner rotatable bearing element comprises an inner wheel configured to be capable of free rotation by the outer wheel and to hold an extremity of the rotatable bending

section, such that in a locked operation mode, rotation of the orientation controller rotates said inner elongated shaft structure inside said outer elongated shaft structure, and in an unlocked mode, rotation of the outer wheel rotates the inner elongated shaft structure via the inner wheel inside the outer elongated shaft structure.

4. The orientation controller of claim 3, wherein said gear mechanism is configured to allow free rotation between the outer elongated shaft structure and the inner elongated shaft structure; said gear mechanism further comprises an outer shaft holder configured to hold an extremity of the outer elongated shaft structure, wherein said inner wheel is configured to hold an extremity of the inner elongated shaft structure.

5. An intubation system comprising an insertion unit to be connected to a bending section of a medical instrument and an orientation controller as defined in claim 1.

6. The intubation system of claim 5, wherein said insertion unit comprises an inner elongated shaft structure being capable of torque transmission around its length axis and an outer elongated shaft structure surrounding the inner elongated shaft structure and having a continuous outer surface.