US00RE48750E

(19) **United States**

(12) **Reissued Patent**

Piskun et al.

(10) **Patent Number: US RE48,750 E**

(45) **Date of Reissued Patent: Sep. 28, 2021**

(54) **SUBSTAINTIALLY RIGID AND STABLE ENDOLUMINAL SURGICAL SUITE FOR TREATING A GASTROINTESTINAL LESION**

(71) Applicant: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

(72) Inventors: **Gregory Piskun**, Delray Beach, FL (US); **Dan Rottenberg**, Haifa (IL); **Boaz Manash**, Givat-Ada (IL); **Dima Pinhasov**, Qiryat Yam (IL); **Oleg Shikhman**, Trumbull, CT (US)

(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

(21) Appl. No.: **16/531,590**

(22) Filed: **Aug. 5, 2019**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **9,161,746**
Issued: **Oct. 20, 2015**
Appl. No.: **13/726,147**
Filed: **Dec. 23, 2012**

U.S. Applications:

(63) Continuation of application No. 12/970,604, filed on Dec. 16, 2010, now Pat. No. 8,506,479.

(Continued)

(51) **Int. Cl.**

A61B 1/32 (2006.01)
A61B 17/02 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61B 17/0218*** (2013.01); *A61B 1/0051* (2013.01); *A61B 1/00082* (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC ... A61B 1/00085; A61B 1/00087; A61B 1/31; A61B 1/32

(Continued)

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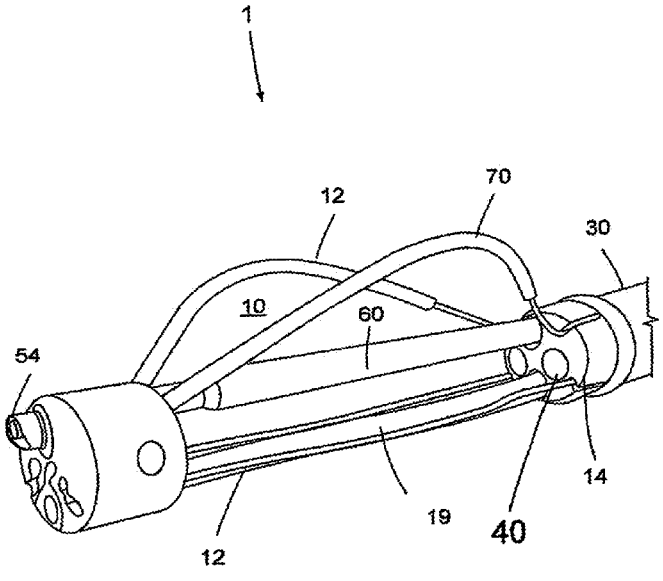
Primary Examiner — Beverly M Flanagan

(74) *Attorney, Agent, or Firm* — Kacvinsky Daisak Bluni PLLC

(57) **ABSTRACT**

Exemplary embodiments of devices and method for affecting at least one anatomical tissue can be provided. A configuration can be provided that includes a structure which is expandable (i) having and/or (ii) forming at least one opening or a working space through which the anatomical tissue(s) is placed in the structure. For example, the structure, prior to being expanding, can have at least one partially rigid portion. In addition, or as an alternative, upon a partial or complete expansion thereof, the structure can be controllable to have a plurality of shapes. Further, the structure can be controllable to provide the working space with multiple shapes and/or multiple sizes.

19 Claims, 15 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 61/287,077, filed on Dec. 16, 2009.

(51) **Int. Cl.**

A61B 1/005	(2006.01)
A61B 1/00	(2006.01)
A61B 1/31	(2006.01)
A61B 1/018	(2006.01)
A61B 17/00	(2006.01)

(52) **U.S. Cl.**

CPC *A61B 1/00085* (2013.01); *A61B 1/00087* (2013.01); *A61B 1/00154* (2013.01); *A61B 1/018* (2013.01); *A61B 1/31* (2013.01); *A61B 1/32* (2013.01); *A61B 17/00234* (2013.01)

(58) **Field of Classification Search**

USPC 600/203–205, 210, 221, 129, 114, 115, 600/106

See application file for complete search history.

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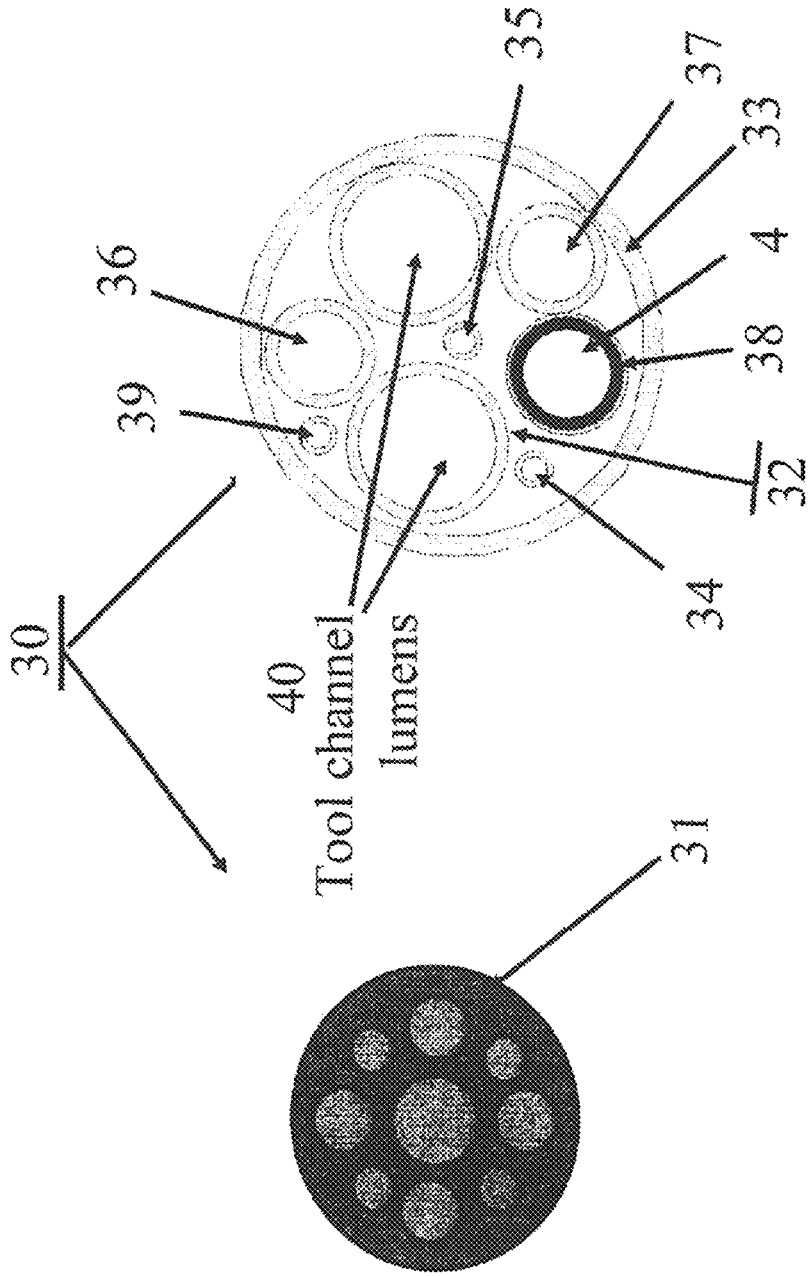

Fig. 1A

Fig. 1

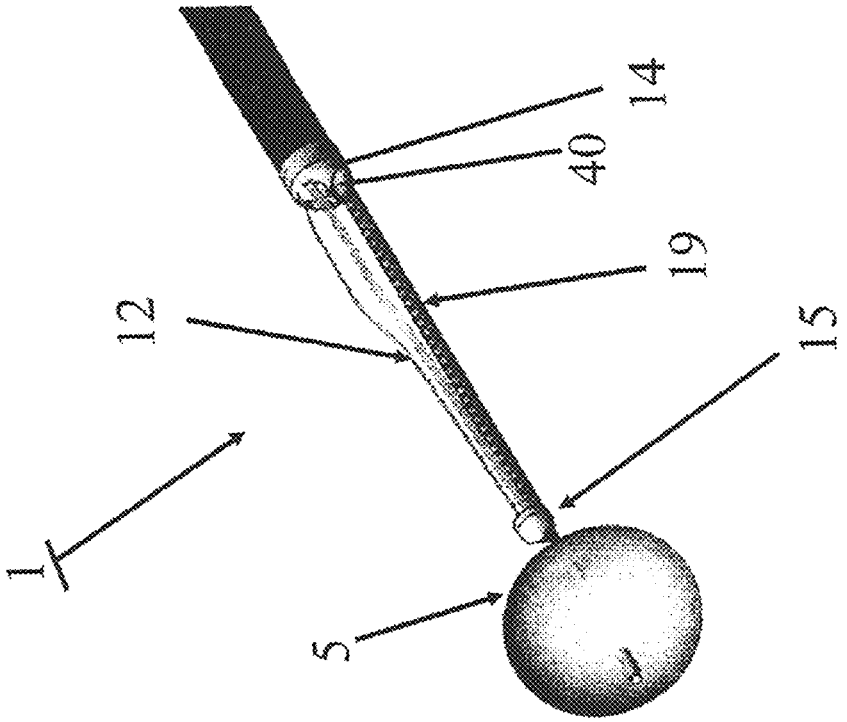

Fig. 2

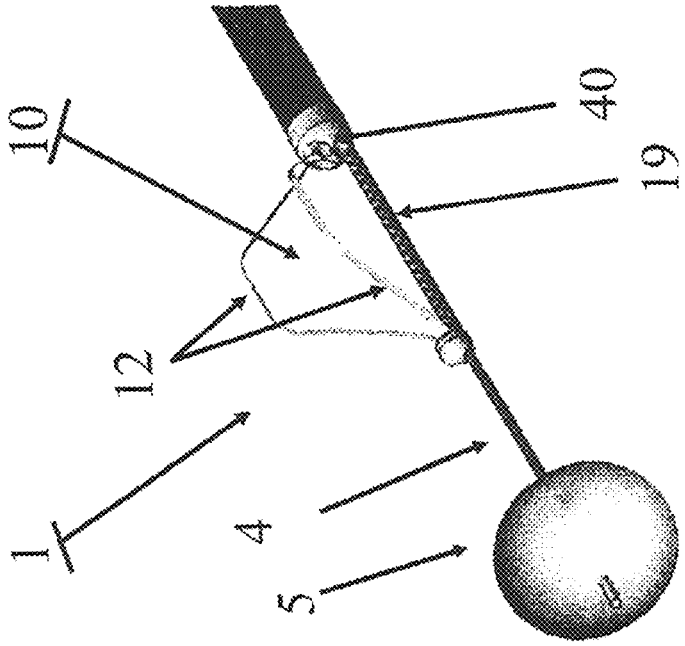

Fig. 2A

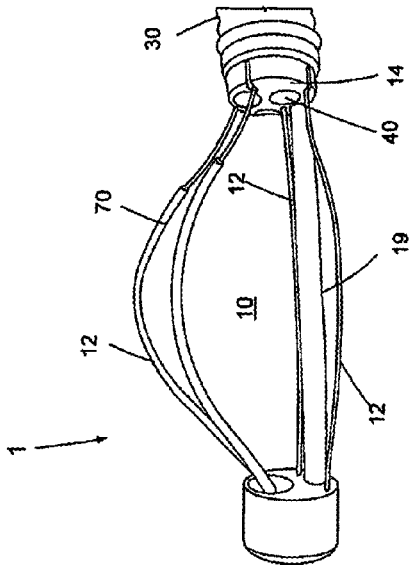

Fig. 2B

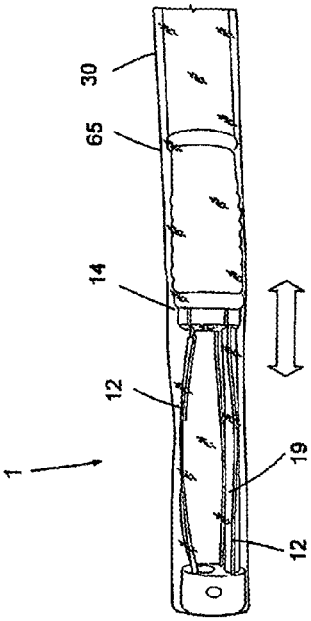

Fig. 2C

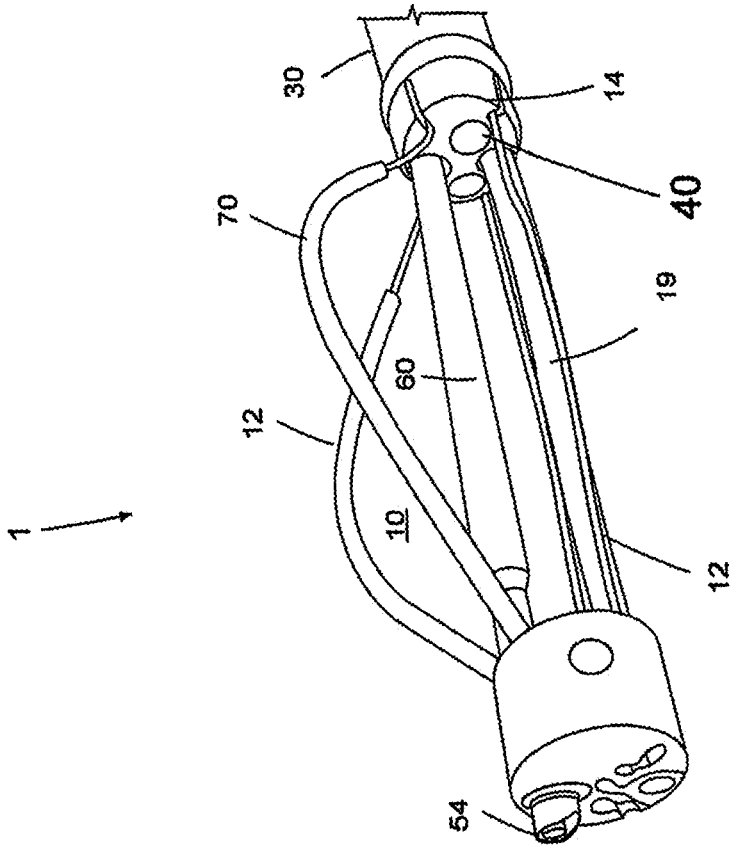

Fig. 2D

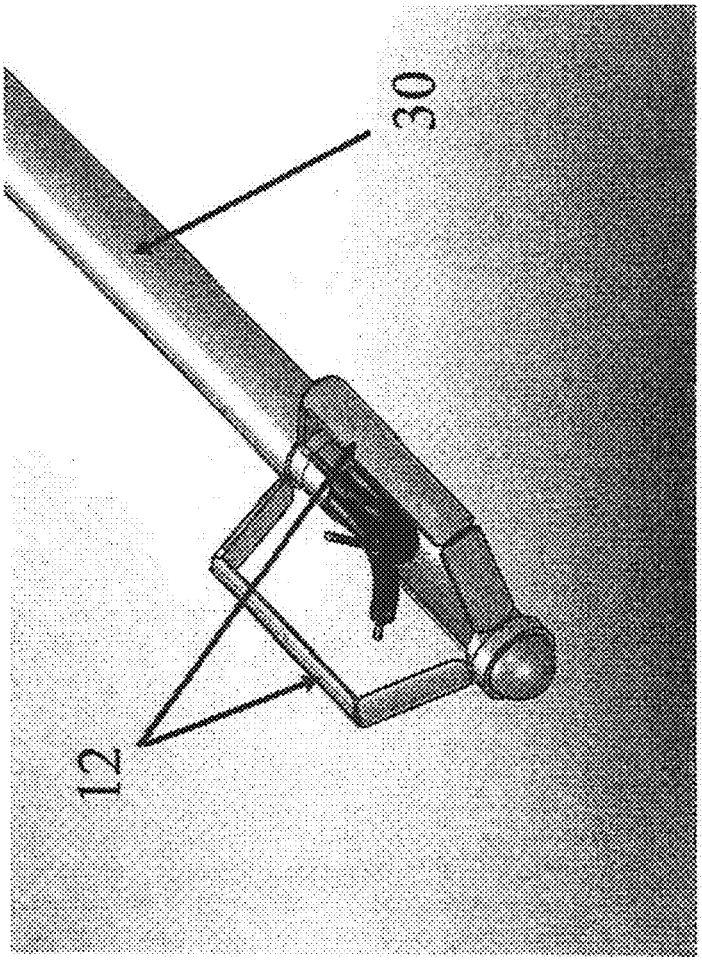

Fig. 3

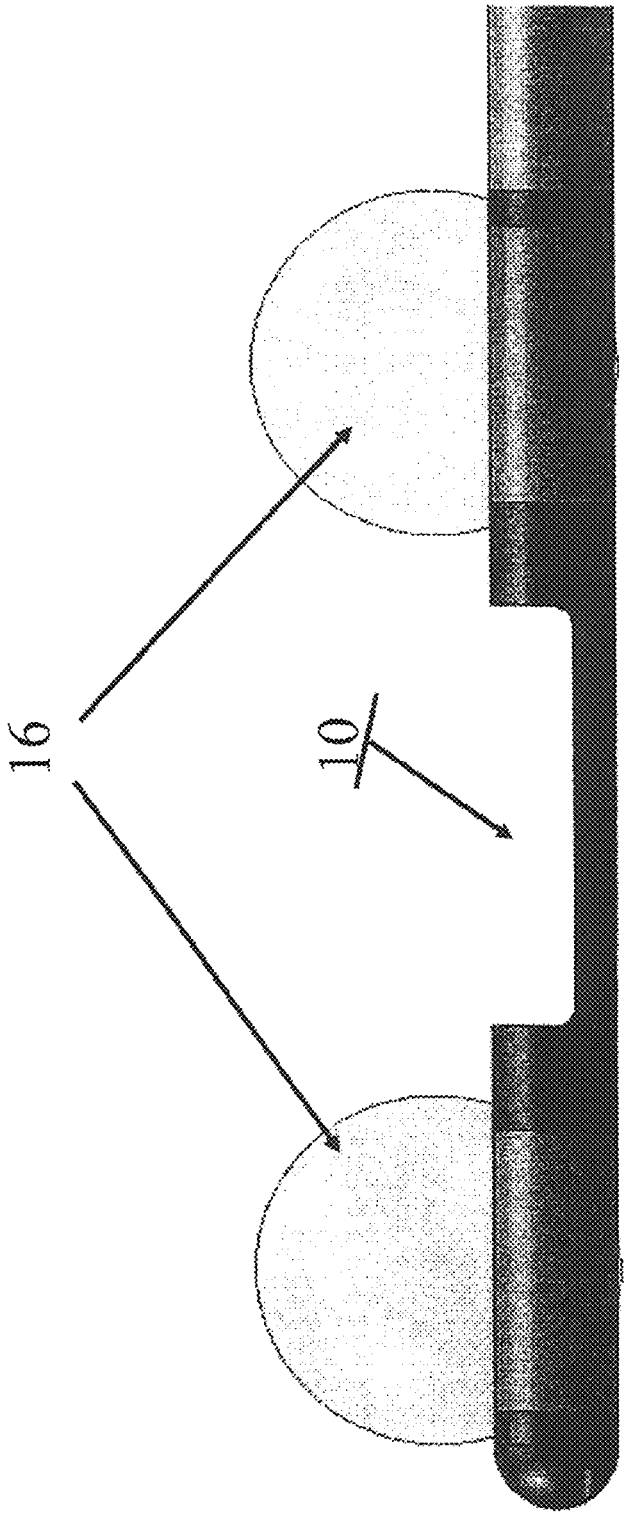

Fig. 4

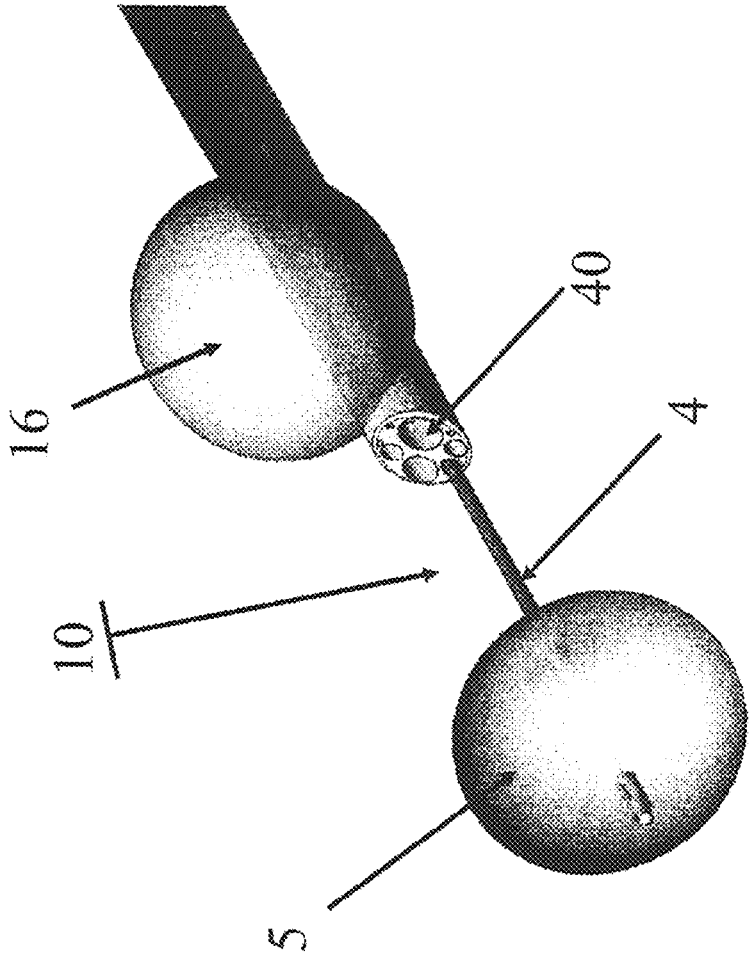

Fig. 5

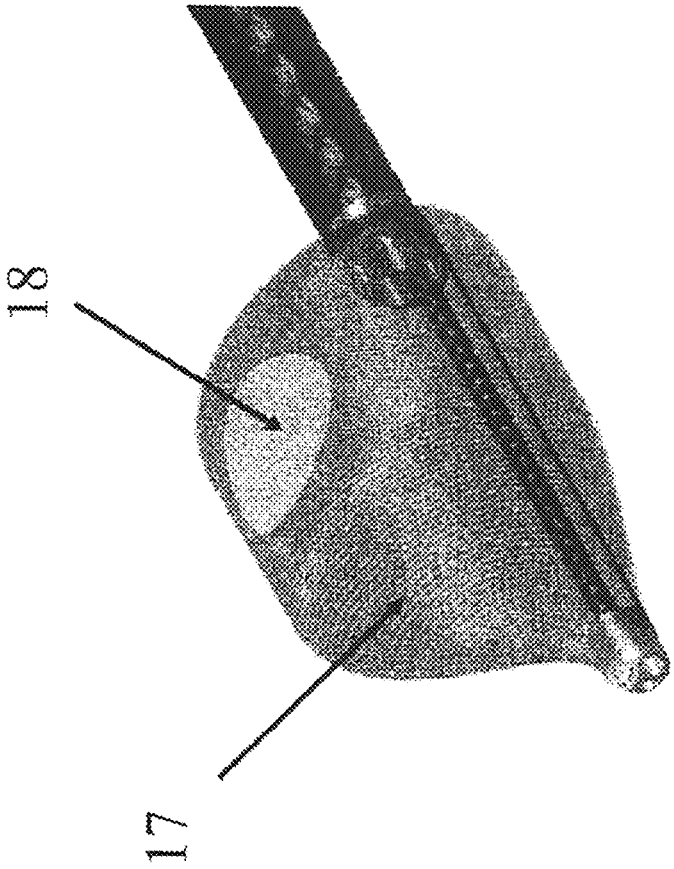

Fig. 6

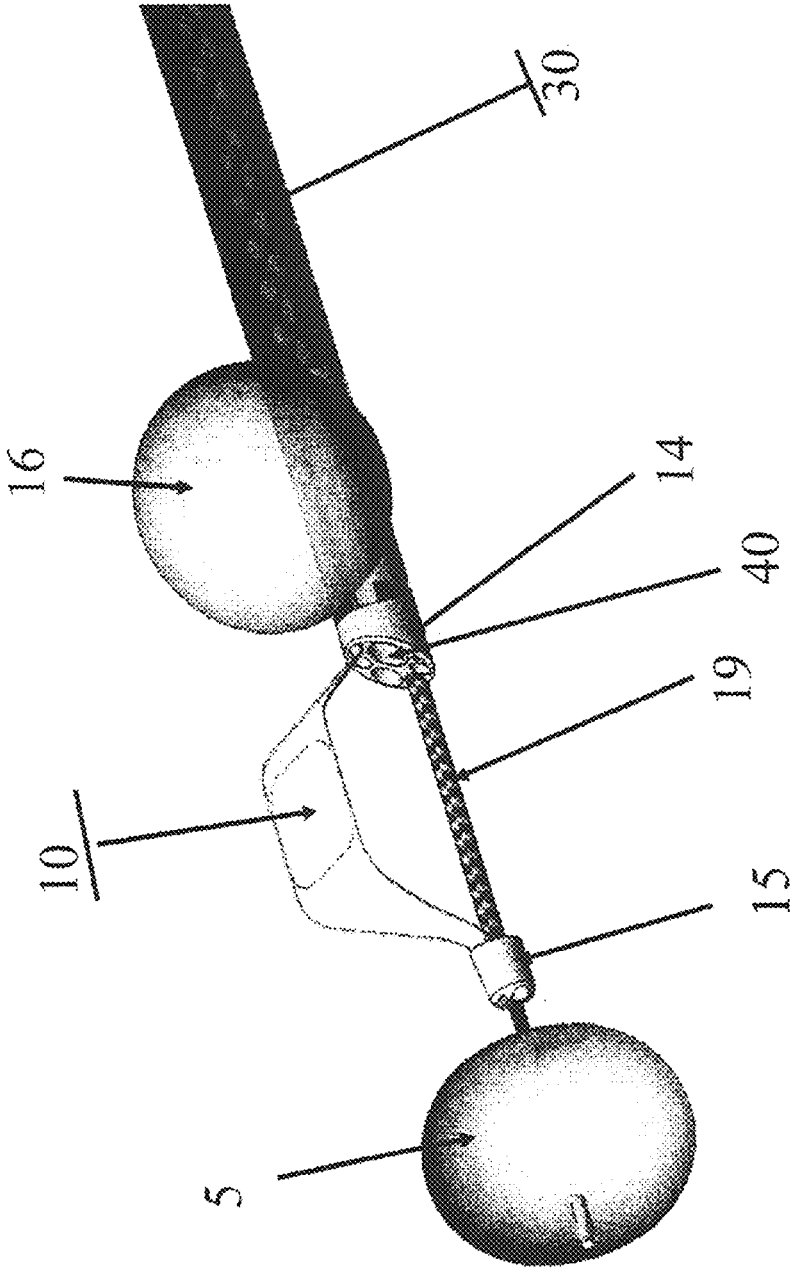

Fig. 7

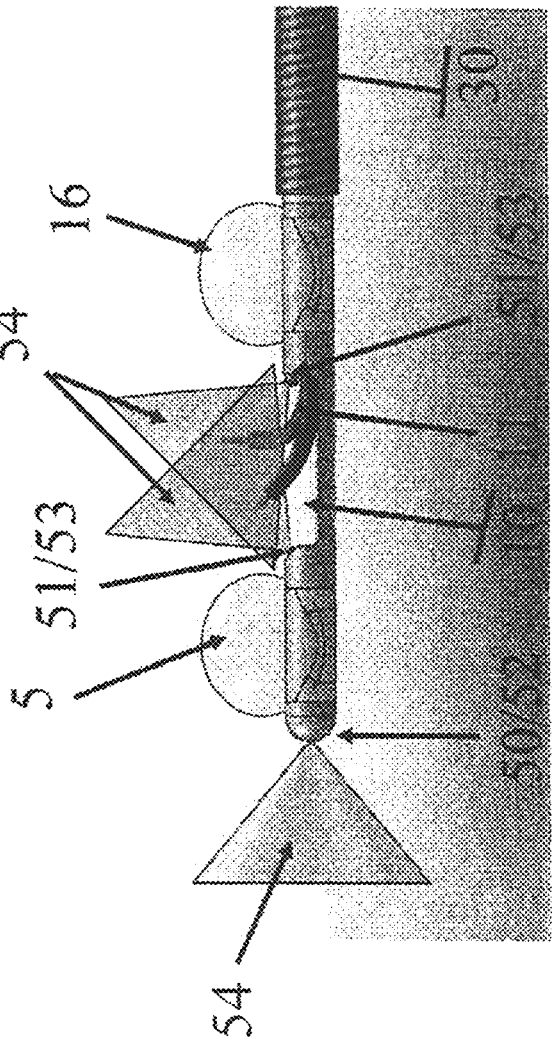

Fig. 8

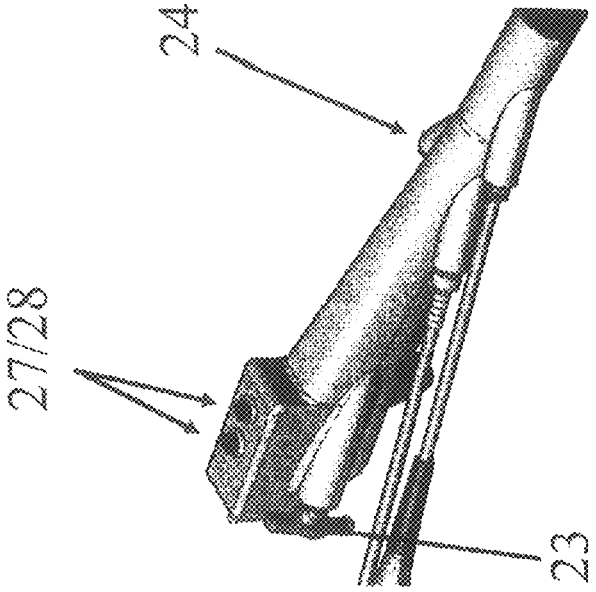

Fig. 9A

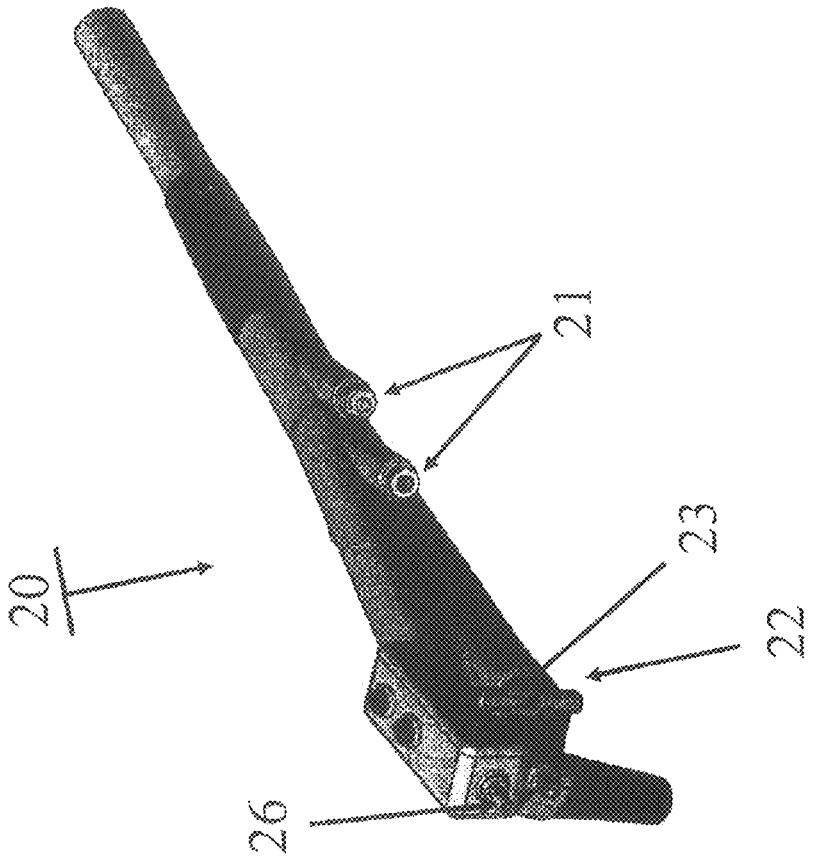

Fig. 9

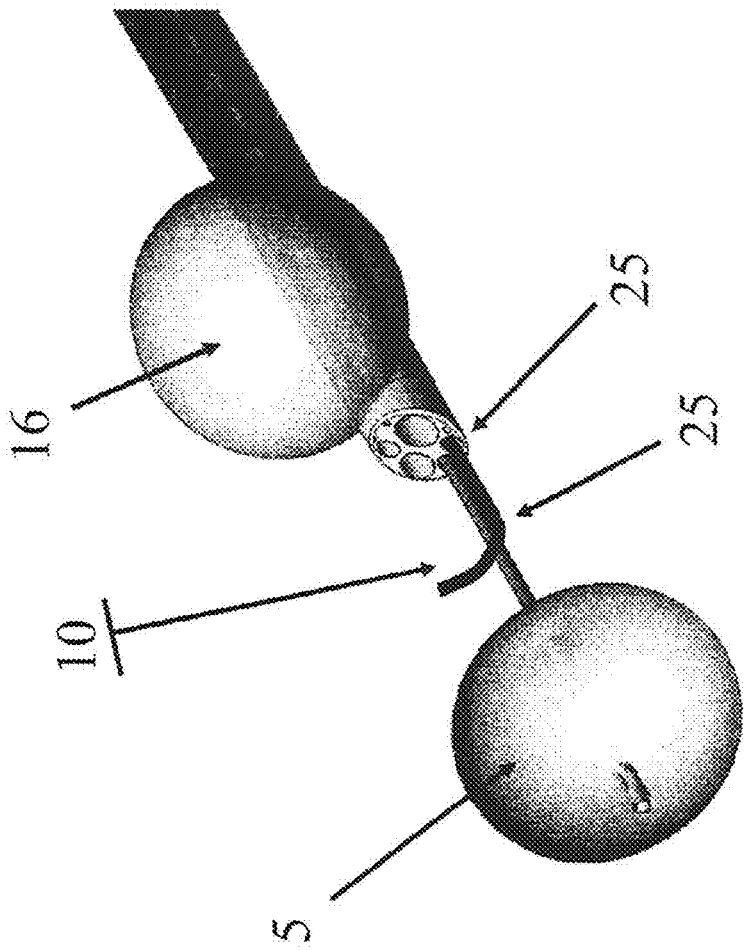

Fig. 10

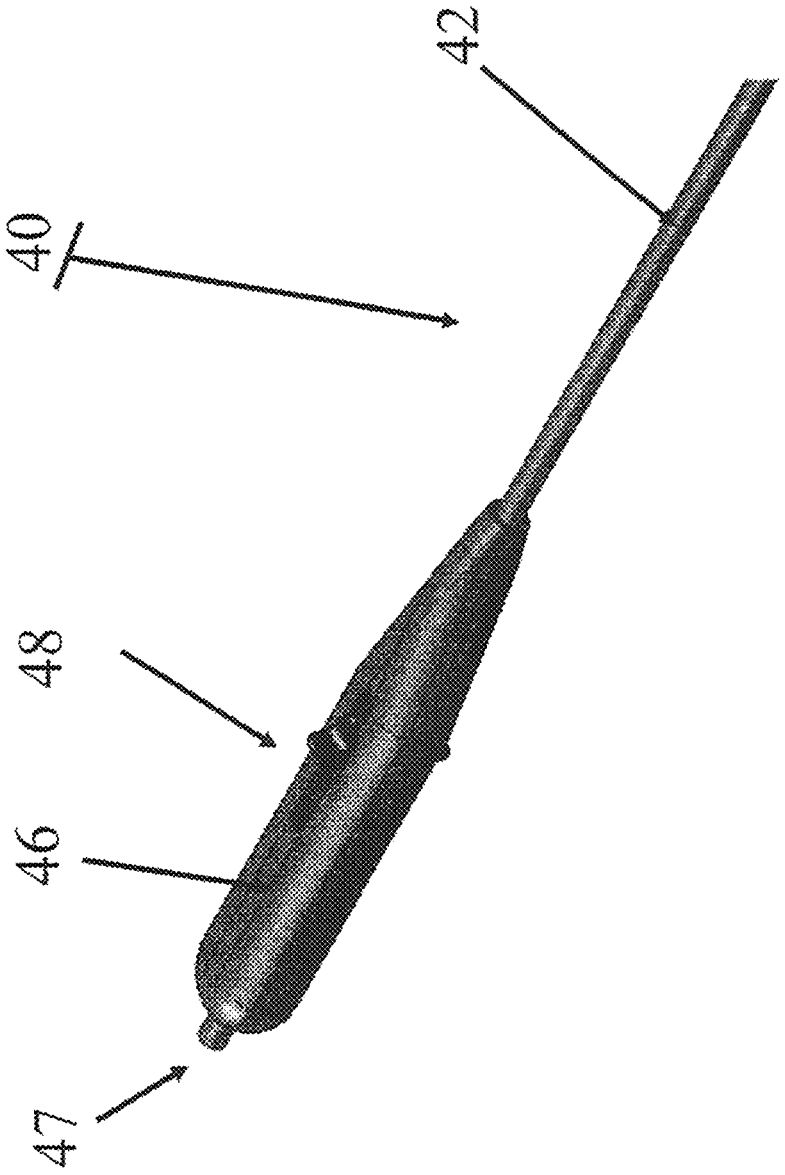

Fig. 11

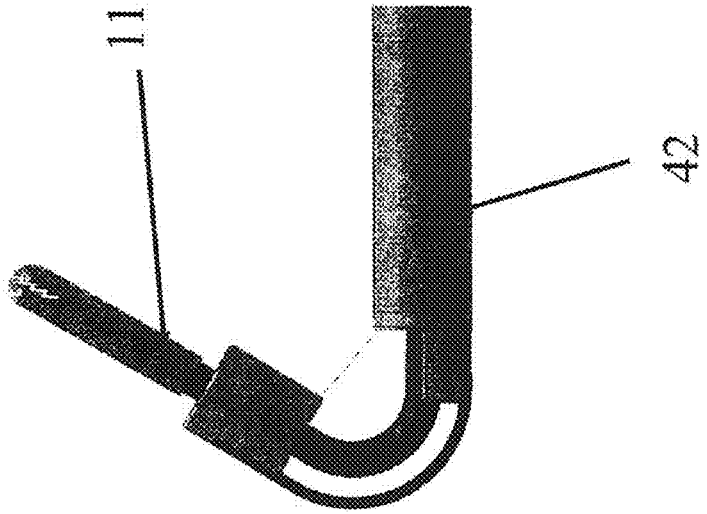

Fig. 12A

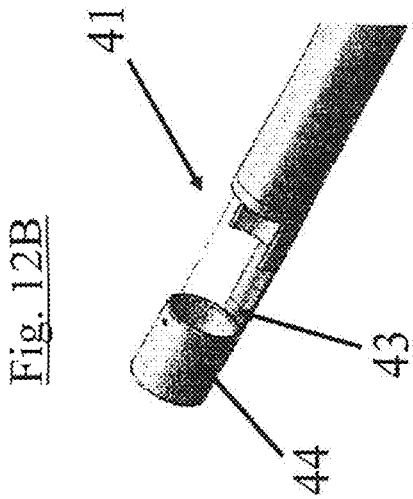

Fig. 12B

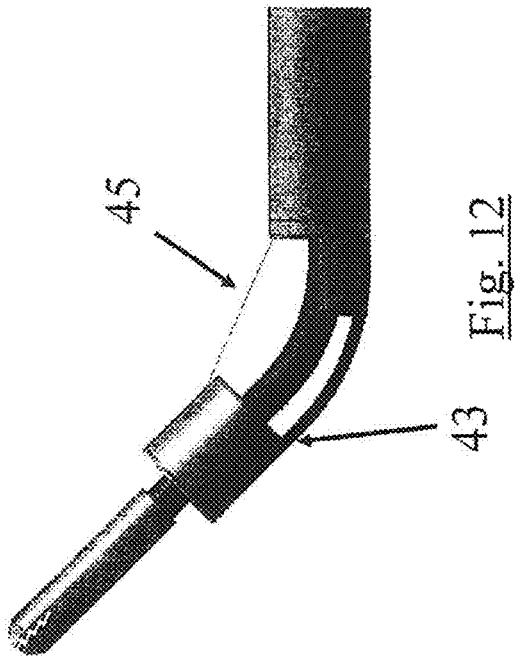

Fig. 12

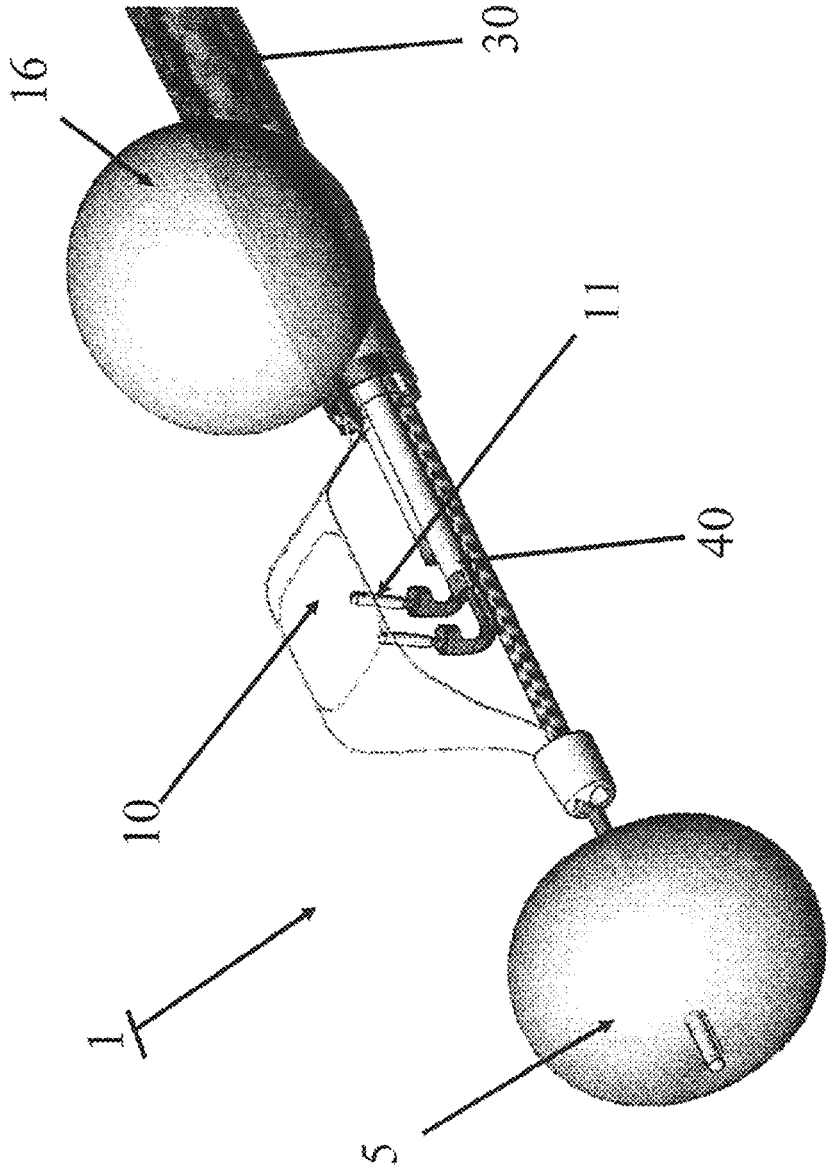

Fig. 13

SUBSTAINTIALLY RIGID AND STABLE ENDOLUMINAL SURGICAL SUITE FOR TREATING A GASTROINTESTINAL LESION

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 12/970,604, filed Dec. 16, 2010, which claims priority from U.S. Provisional Patent Application No. 61/287,077, filed Dec. 16, 2009. The contents of these applications are incorporated by reference in their entirety herein.

FIELD OF THE DISCLOSURE

Exemplary embodiments of the present disclosure relate to arrangements and methods for effecting an endoluminal anatomical structure, and more particularly to arrangements and methods for treatment of gastrointestinal lesions that currently require open abdominal surgery. The exemplary embodiment of at least one of the arrangements can provide an endoluminal colon chamber and a variety of maneuverable operating tools inside that chamber. For example, the exemplary embodiment of such arrangement can function as a miniature operating room inside the colon.

BACKGROUND INFORMATION

Current endoscopic technologies may not facilitate treating colon perforations, large polyps and tumors, and a significant colon bleeding effectively and safely. A gastrointestinal bleeding is a common and potentially life-threatening medical condition, which can complicate any polypectomy (polyp removal), and excision of colonic tumors. A colon perforation can occur when excessive mechanical force or excessive energy is inadvertently applied to a colonic wall. A colon perforation is a life-threatening condition and currently requires major emergency surgery to close the colon perforation and preclude fecal contamination of an abdominal cavity and resulting sepsis.

Consequently, many patients who develop large polyps, colon perforation, colon bleeding and other significant colon pathology currently have to undergo a major surgery and endure a significant operative trauma and, typically, painful and prolong recovery. Currently there are no effective and safe devices and methods for replacing major abdominal surgery in case of colon perforation or when large wide-based polyps need to be removed.

Thus, there may be a need to address at least some of the deficiencies described herein above.

U.S. Provisional Patent Application Ser. No. 61/247,605 filed on Oct. 1, 2009 and entitled "Detachable Balloon Catheter" describes exemplary embodiments of device and method for treatment of a gastrointestinal perforation and/or a gastrointestinal bleeding. The exemplary device can include a balloon catheter that can control bleeding by pressing on a bleeding area or/and prevents the gastrointestinal contents trespassing outside a gastrointestinal lumen into a body cavity by blocking an opening in the luminal wall or blocking the colon distal to the perforation. Such exemplary device can be inserted using an endoscope, and can allow a partial or complete withdrawal of an endoscope, while leaving the balloon at the target area. More specifically, the exemplary device and method can facilitate ceasing a colonic bleeding and blocking a colon perforation.

The Minos Megachannel is a large bore flexible reinforced tube, which is designed to be inserted over the standard colonoscope. After the colonoscope is removed, the tube can be used as a passage for insertion of different instruments into the colon.

Further, conventional endoscopes generally have one to two working channels, which likely do not have independent movements from the main body of the endoscope. As a result, when conventional flexible endoscopic instruments are inserted via such channels into the intestinal lumen, an operator can only manipulate these instruments axially (e.g., forward and backward movements), and possibly somewhat rotationally. In addition, since the conventional instruments can only be advanced from the tip of the endoscope towards the target lesion axially and in front of the endoscopic image, the conventional instruments have only limited functionality.

Accordingly, there may be a need to address at least some of the deficiencies described herein above.

SUMMARY OF EXEMPLARY EMBODIMENTS OF THE PRESENT DISCLOSURE

Exemplary embodiments of the present disclosure can address most if not all of the above-described needs by providing device and method for a treatment of, e.g., a gastrointestinal perforation, bleeding, removal of large polyps, and/or other significant endoluminal pathology, for example, colonic pathology.

According to one exemplary embodiment of the present disclosure, the device can function as a miniature operating room inside the lumen, for example, colon, and providing an operator with advanced endoluminal functionalities replicating capabilities of a surgical suite. The exemplary device of the present disclosure can provide such miniature endoluminal operating room, chamber or at least partial enclosure, and the ability to utilize a variety of articulating surgical instruments, which can operate within, at or around the chamber.

According to one exemplary embodiment of the present disclosure, the exemplary arrangement/device can be introduced after a standard diagnostic colonoscopy is performed. An exemplary balloon guide catheter, as described in U.S. Provisional Patent Application Ser. No. 61/247,605, or a large endoluminal channel such as a Minos Megachannel manufactured by, e.g., Minos Inc., can be used to facilitate the insertion of the exemplary device according to the present disclosure.

In another exemplary embodiment of the present disclosure, the arrangement/device can contain a plurality (e.g., three) primary sections, e.g., a handle, a multi-lumenal tube, and an expandable chamber.

It is possible to utilize endoluminal channels and associated articulating endoluminal instruments with the exemplary embodiments of the arrangement/device. To that end, the exemplary arrangement/device can include a multi-lumen tube. The multi-lumen tube can include lumens for at least two special tools or tool-channels, or three or more special tools and/or tools-channels. In addition, the multi-lumen tube can include other channels, which can be used

for, as an example, air, water, vacuum delivery, etc. The exemplary arrangement/device can also include channel for scope and illumination; and lumens for a chamber activation and lumen for a balloon guide catheter as indicated herein.

According to still another exemplary embodiment of the present disclosure, the arrangement/device may also contain a chamber located distally, which can be expanded to different sizes within the colon, thus producing a relatively large working space near the targeted luminal lesion. The exemplary arrangement/device can be structured to manipulate the tools and/or tool-channels in such a way that distal ends of one or more of such tools and/or channels can operate within or at the chamber, and approach the lesion from multiple or even all directions, and using numerous angles. In addition, at least one tool-channel can accommodate a large diameter tool, for example, a special endoscopic stapler.

In a further exemplary embodiment of the present disclosure, the arrangement/device can further contain a control handle, e.g., at or about its proximal end. The handle can be provided in a similar way and/or shape as handles of other endoscopes', while including further more ports, such as, e.g., tool-channels ports, a balloon guide catheter port, a special lever to control the opening and closing of the device chamber, etc.

According to a still further exemplary embodiment of the present disclosure, the arrangement/device can include and/or utilize particular tools or tool-channels. For example, the distal ends of the particular tools and/or tool-channels can be operated in all directions and within all degrees of freedom using the actuating mechanisms, which can be controlled at or about the proximal ends of the device. The exemplary instruments/tools (e.g., grasper(s), scissor(s), dissector(s), others), which can be inserted in the special tools or tool-channels, may be manipulated (e.g., rotated, moved axially forward and backward, bent at the distal end at any desired angles) by manipulating the tool-channels.

In a further exemplary embodiment of the present disclosure, the arrangement/device can facilitate a lateral and/or multi-directional movements of the instruments/tools, in addition to the axial and rotational movements thereof. Since the exemplary tool-channels can be manipulated independently from the main endoscope and other tool-channels, the instruments/tools can approach the lesion from the different and possibly limitless directions. For example, when the endoscopic instruments/tools approach the lesion from the sides in relation to the main longitudinal axis and, hence, without blocking the endoscopic image, a so-called and well-known in laparoscopy "tri-angulation" can be achieved. The tri-angulation can be a preferable technique for achieving the endoscopic arrangement's/device's improved functionality and safety. Such exemplary methodology can mimic the functionality of well-established surgical operating room environments. The exemplary tool-channels can be advanced in the lumen from the working ports of the multi-lumen tube and/or be at least partially pre-fixed to the element(s) of the associated expandable chamber. The exemplary tool-channels can also be advanced directly into the body lumen (e.g., an intestinal lumen), into the chamber space, and/or initially advanced along the element(s) of the chamber and then further into the body lumen or into the chamber space.

As an alternative according to yet another exemplary embodiment of the present disclosure, the arrangement/device, alternatively to the tool-channels or in combination with the tool-channels, can use conventional and/or articulating instruments/tools with at least two degree of freedom.

In addition, according to a further exemplary embodiment of the present disclosure, a method can be provided for using the exemplary arrangement/device in the body lumen (e.g., colon). For example, using such exemplary method, it is possible to perform a standard colonoscopy and identify a lesion that may not be treated using standard endoscopy and techniques. A balloon guide catheter can be inserted, the balloon inflated and the standard colonoscope (the balloon catheter and inflated balloon are left in place) removed. The balloon guide catheter can be used as a guide-wire to facilitate the insertion of the exemplary arrangement/device. The exemplary arrangement/device can be inserted over the balloon guide catheter, e.g., until the chamber is in the proximity to the lesion. The chamber can be deployed and adjusted to certain dimensions. It is possible to readjust the chamber during the procedure, as needed. Further, an operative area can be cleaned with a provided suction catheter. Further, a proximal balloon, a distal balloon or both proximal and distal balloons can be inflated for the treatment area isolation. Tool-channels can be inserted, followed by or in conjunction with an insertion of the instruments/tools into the tool-channels. It is also possible to manipulate the tool-channels to optimize and facilitate the instruments'/tools' approach to the lesion. Further, a procedure can be performed, for example, closing a colonic perforation, removing a large colon polyp or tumor, stopping a bleeding, closing diverticuli, removing an appendix, treating other body luminal lesions.

Further, exemplary embodiments of devices and method for affecting at least one anatomical tissue can be provided. A configuration can be provided that includes a structure which is expandable (i) having and/or (ii) forming at least one opening or a working space through which the anatomical tissue(s) is placed in the structure. For example, the structure, prior to being expanding, can have at least one partially rigid portion. In addition, or as an alternative, upon a partial or complete expansion thereof, the structure can be controllable to have a plurality of shapes. Further, the structure can be controllable to provide the working space with multiple shapes and/or multiple sizes.

According to yet another exemplary embodiment of the present disclosure. prior to the structure being expanded, the structure can have at least one partially rigid portion that is expandable to form a non-cylindrically-shaped working area which can be asymmetrical. Further, an endoscopic arrangement can be included that is structured to be provided in the working area, and that can include a further configuration that facilitates an articulation of a tip portion of the endoscopic arrangement within the working area. The further configuration can include a mechanical bending arm which can facilitate the tip portion to be moved within the working area so as to facilitate a visualization of at least one object in the working area. An arrangement can also be provided which is coupled to the structure, and which can provide (i) at least one lumen and/or (ii) at least one instrument there through to reach the working area. For example, a distance between a tip of the arrangement and a distal portion of the structure that is farthest away from the arrangement can be controllable to adjust a shape and/or a size of the working area.

In still another exemplary embodiment of the present disclosure, upon a complete or partial expansion of the structure, the structure can be controllable to have a plurality of shapes. In addition, the structure can be controllable to provide the working space with multiple shapes and/or multiple sizes. The structure can have an expanded portion and an unexpanded portion, and form an axes of extension

of the device, a first distance to a highest point of the expanded portion can be different than a distance to an non-expanded portion. For example, the first distance can be greater than the second distance. The structure can be controllable to adjust the first distance, while maintaining the second distance approximately the same. Further, in an non-expanded state, the configuration can be controllable to provide an articulation thereof in a plurality of directions.

According to a further exemplary embodiment of the present disclosure, a first arrangement can be provided at a distance from the configuration and the anatomical structure(s). In addition, a second arrangement can be provided between the first arrangement and the configuration, and can have at least one lumen that is connected to the first arrangement. Further, a third arrangement can be provided which may be structured to move through the lumen at or near the anatomical structure(s), and which can be configured to be provided in the structure. The lumen(s) can comprise a multi-channel tube, and the structure can be structured to be movable through the multi-channel tube and rigidly connected thereto so as to limit or reduce a movement of the structure with respect to the multi-channel tube. At least one movable camera and an illumination arrangement can be provided within or near the configuration, and movable through the multi-channel tube. At least one movable vacuum catheter and/or irrigation catheter can be provided within or near the structure, and movable through the multi-channel tube.

In one exemplary embodiment, the lumen(s) can comprise a tube channel and/or a tool channel, which is/are movable therein. The tool channel can be axially movable, rotatable, and/or bendable, and can include at least one wire which is configured to bend the tool channel. A distal end of the tool channel can be configured to reach any point inside or near the structure. The tool channel can include at least one wire which can be usable to bend the tube or the tool channel at least in one direction and in at least at one angle which is between 0 and 180 degrees. For example, a distance between the working channel and the structure can be controllable by moving at least one wire in the working channel toward and/or away from the structure. An endoscope can be provided within or near the configuration, and movable through the multi-channel tube to reach the working space. The endoscope can include an image sensor provided on a flexible shaft to visualize at least one portion of the tissue(s).

According to yet a further exemplary embodiment of the present disclosure, the structure can have at least one flexible strip or at least one wire and/or two or more flexible strips or wires. At least one of the strips or wires can have a pre-formed shape to provide the desired geometry of the working space. In addition, at least one balloon can be provided or two or more balloons. At least one of the balloons can be an asymmetric shape and/or a symmetric shape. The balloon(s) can be positioned proximal to the structure. According to one exemplary variant, a first balloon and a second balloon can be provided, where the first balloon is provided distally in relation to the structure, and the second balloon is provided proximally in relation to the structure. The structure can be composed of wires and/or a mesh. Such wires/mesh, prior to being expanded, can have (i) at least one partially rigid portion, (ii) upon a partial or complete expansion thereof, can be controllable to have a plurality of shapes, and/or (iii) can be controllable to provide the working space multiple shapes and/or multiple sizes.

These and other objects, features and advantages of the exemplary embodiment of the present disclosure will become apparent upon reading the following detailed description of the exemplary embodiments of the present disclosure, when taken in conjunction with the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Further objects, features and advantages of the present invention will become apparent from the following detailed description taken in conjunction with the accompanying figures showing illustrative embodiments of the present disclosure, in which:

FIGS. **1** and **1**A, are schematic cross-sectional illustrations of an exemplary embodiment of an arrangement/device comprising a multi-lumen extrusion tube, and multiple tubes inside one large tube in accordance with the present disclosure;

FIG. **2** is a perspective view of an exemplary embodiment of the arrangement/device according to the present disclosure comprising which includes a nitinol strips chamber in an position;

FIG. **2**A is a perspective illustration of the arrangement/device of FIG. **2** with the chamber formed by flexible strips in an open position;

FIG. **2**B is a side view of the arrangement/device of FIG. **2** with the chamber formed by flexible strips in another position;

FIG. **2**C is a side view of the arrangement/device of FIG. **2** with an overtube covering the chamber that is in the closed position according to an exemplary embodiment of the present disclosure;

FIG. **2**D is a side view illustration of the arrangement/device of FIG. **2** with a scope that is provided in one of the working channels and facilitating a field of view therefor according to another exemplary embodiment of the present disclosure;

FIG. **3** is a perspective view of another exemplary embodiment of the arrangement/device according to the present disclosure which includes the chamber made from two metal strips;

FIG. **4** is a side cross-sectional view of an exemplary embodiment of the arrangement/device according to the present disclosure which includes the chamber made from two asymmetric balloons;

FIG. **5** is a perspective view of another exemplary of another exemplary embodiment of the arrangement/device according to the present disclosure which includes the chamber made from one asymmetric balloon together with the balloon guide catheter;

FIG. **6** is a perspective view of another exemplary of still another exemplary embodiment of the arrangement/device according to the present disclosure which includes the chamber made from metal wires braid;

FIG. **7** is a perspective view of a further exemplary of yet another exemplary embodiment of the arrangement/device according to the present disclosure which includes the nitinol strips chamber with two blocking balloons at both sides;

FIG. **8** is a side view of another exemplary of yet a further exemplary embodiment of the arrangement/device according to the present disclosure which includes the chamber with cameras;

FIG. **9** is a right side perspective view of a further exemplary embodiment of the arrangement/device according to the present disclosure which includes a particular handle;

FIG. **9**A is a left side perspective view the exemplary arrangement/device of FIG. **9**;

FIG. **10** is a perspective view of yet another exemplary of yet another exemplary embodiment of the arrangement/device according to the present disclosure which includes a vacuum catheter;

FIG. **11** is a perspective view of yet another exemplary of another exemplary embodiment of the arrangement/device according to the present disclosure which includes a tool-channel;

FIGS. **12**, **12**A and **12**B are different illustrations of a preferred embodiment of still another exemplary of the arrangement/device according to the present disclosure which includes a tool-channel elevator with FIG. **12** showing the device in a first bent position, FIG. **12**A showing the device in a second bent position, and FIG. **12**B showing the device in a non-bent position; and

FIG. **13** a perspective view of yet another exemplary of another exemplary embodiment of the arrangement/device according to the present disclosure which includes the tool-channels inside the chamber thereof.

Throughout the figures, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components or portions of the illustrated embodiments. Moreover, while the subject disclosure will now be described in detail with reference to the figures, it is done so in connection with the illustrative embodiments. It is intended that changes and modifications can be made to the described exemplary embodiments without departing from the true scope and spirit of the subject disclosure as defined by the appended claims.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

According to one exemplary embodiment of the present disclosure, a device, an arrangement and a method can be provided for treatment of, e.g., conditions associated with body lumen(s) or/and cavities, for example, gastro-intestinal conditions, including but not limited to a gastrointestinal perforation, bleeding, large polyps or/and tumors, diverticuli, appendix, and others.

The exemplary embodiments of the arrangement/device according to the present disclosure can provide various functions, which may be the same and/or similar to the surgical functions provided in the surgical operating room, therefore, thus representing a miniature operating room within a lumen (e.g., of a body), such as, e.g., colon and allowing to replace a major surgery, e.g., an open abdominal surgery.

For example, as shown in FIGS. **2** and **2**A, the exemplary embodiment of the arrangement/device **1** according to the present disclosure can provide an endoluminal chamber which can also be at least partial enclosure, such as, e.g., an endoluminal colon or an intra-colon chamber/enclosure, and include various maneuverable operating instruments and/or tools **11** within the chamber **10**. The exemplary arrangement/device **1** can be inserted after one or more relevant lesions is/are identified, e.g., during standard colonoscopy. A particular balloon guide catheter **4**, e.g., such as described in U.S. Provisional Patent Application Ser. No. 61/247,605 filed on Oct. 1, 2009, or Mega-channel such as Minos Inc. Mega-channel, can be used to facilitate an insertion of the exemplary arrangement/device **1**.

According to certain exemplary embodiments of the present disclosure, the arrangement/device **1** can be a particularly-designed endoscope, such as, e.g., a colonoscope. As shown in FIGS. **9** and **9**A, according to certain exemplary embodiments, the arrangement/device **1** can include, e.g., an exemplary handle **20** (see FIGS. **9** and **9**A), an exemplary multi-lumen tube **30** (see FIGS. **1**, **1**A, **3**, **7**, **8** and **13**), and an exemplary expandable chamber **10** (see FIGS. **5**, **7**, **10** and **13**). In addition, the arrangement/device **1** can include standard and particular exemplary instruments/tools **11** (see FIGS. **8**, **12** and **13**) and/or exemplary tool channels (see FIG. **13**).

As indicated herein above, the exemplary arrangement/device **1** can include the multi-lumen tube **30**. Such exemplary multi-lumen tube **30** can be made from a single extrusion polymer tube **31** having multiple lumens {see FIG. **1**}, and/or made in a standard endoscopic equipment configuration using a collection of single or multi-lumen tubes **32** of different sizes that are enclosed by a single, large, flexible tube **33** (see FIG. **1**A). External and internal tubes can be simple polymer tubes and/or reinforced tubes or braided tubes, as known in the art. The external tube **33** can have a diameter that is large enough to contain all inner tubes **32** provided for the exemplary arrangement/device **1**. The exemplary multi-lumen tube **30** can include at least one lumen, and, e.g., possibly 2 to 4 or more lumens for 2 to 4 or more exemplary instruments/tools **11** and/or tool-channels **40**, and possibly additional lumens, for example, for a air insufflation **34**, water irrigation **35**, vacuum **36**, lumen for wiring and/or fibers for cameras and illumination **37**, lumen for a balloon guide catheter **4**, lumen for chamber expansion control **38**, and/or lumen for proximal balloon inflation **39**, as shown in the exemplary embodiment of FIG. **1**A.

For example, according to particular exemplary embodiments of the present disclosure, the arrangement/device **1** can contain a distal chamber **10** that can be expanded to different sizes inside the colon, thus likely creating relatively large or sufficient working space near the lesion to be treated. The exemplary chamber **10** can provide a space for manipulations of multiple tools and/or tool-channels in such a way that several tools can approach the lesion from all sides and directions, as shown in, e.g., FIGS. **3**, **7**, **8** and **13**. The exemplary multi-lumen tube **30**, e.g., having a diameter between 10 mm to 40 mm, can accommodate at least one tool-channel, which can in turn accommodate, e.g., a non-standard instrument, for example, an endoscopic stapler, both having a sufficient size for a particular purposes thereof.

According to one exemplary embodiment of the present disclosure, the exemplary chamber **10** can be constructed from at least one, and possibly two or more flexible metal strips, fibers or wires **12**, which can be made from a flexible material, such as, e.g., Nitinol, as shown in FIGS. **2**, **2**D and **3**. These exemplary strips, fibers or wires can be composed of other materials as well, including but not limited to surgical plastic or other materials. The exemplary strips, fibers or wires **12** can be substantially straightened (or slightly-to-moderately bent as needed during steering the device through the lumen) when the chamber **10** (providing a working space) is in non-deployed position (see FIGS. **2** and **2**C), and are substantially bent when actuated by a control lever **23** in the handle **20**, hence, enlarging the chamber **10** and creating a larger working space inside the colon, as shown in FIGS. **2**A, **2**B, **2**D and **3**. For example, pushing or pulling the exemplary strips, fibers or strips **12** can be performed with a tube **19** that can slide in the lumen **38** by pulling and/or pushing the tube **19** proximal end lever **23** in the handle **20**, as shown in FIGS. **2**, **2**D, **3**, **9** and **9**A. Further, the guide catheter **4** can be inserted inside the tube **19**. The exemplary strips **12** can be covered by a soft polymer cover to avoid possible inner colon tissue damage.

According to an exemplary embodiment of the present disclosure, as shown in FIGS. **2**-**2**D, the chamber **10** it can be deflected by pulling on the exemplary strips, fibers or wires **12**, or the chamber **10** can be opened when the exemplary strips, fibers or wires **12** are pushed forward from the handle **30**. In thus manner, the exemplary strips, fibers or wires **12** increase working space with in the chamber **30** to facilitate the anatomical structure to be pulled into the chamber **10** by other instruments/tools **11** being manipulated from the handle **30**, as described in further details herein, and shown in, e.g., in FIG. **8**.

Further, as shown in FIGS. **2**B and **2**D, the exemplary strips, fibers or wires **12** can be covered with a protective cover portions **70** so as to reduce damage being caused by the exemplary strips, fibers or wires **12** when they are actuated to expand the chamber **10** (i.e., which causes the exemplary strips, fibers or wires **12** to push on the surrounding tissue). As shown in FIG. **2**C, the arrangement/device **1** can also include an overtube **65** which can be pushed forward toward the front of the arrangement/device **1** so as to cover the collapsed chamber **10** (e.g., to facilitate insertion and removal and containing the specimen), and pulled back to prepare for the chamber **10** for its expansion. FIG. **2**D shows an illustration of the arrangement/device **1** of FIG. **2** with a scope **60** (including a camera and at least one light illuminating source) that is provided in one of the working channels **40** and facilitating a field of view **54** for positioning and propelling the exemplary arrangement/device **1**.

When the instrument **1** reaches the desired position within the body, the scope **60** can be retracted inside the chamber **10**, e.g., via the working channel **40** to facilitate visualization inside and/or near the chamber **10**. According to another exemplary embodiment of the present disclosure, an articulating scope (which can perform similar functions as that of the scope **60**) can be provided through one or more of the working channels **40** into the chamber **10**. Such articulating scope can be configured to illuminate and/or provide images of the anatomical structure and tools inside and/or near the chamber **10**. The articulating scope can have a distal portion that can rotate in 360 degrees and bend to provide an end part thereof so as to illuminate and visualize any portion of the anatomical structure and the tools inside and/or near the chamber **10** at any angle.

In another exemplary embodiment of the present disclosure, as shown in FIG. **7**, the strips **12** can be proximally connected to a first cap **14**, which can be made from a solid material. The first cap **14** can have multiple holes for most or all lumens **32**. The strips **12** can also be distally connected to a second cap **15** which can be smaller in diameter than the first cap **14**, to facilitate a passage of large specimens, for example, polyps into the area of the chamber **10**. The distal second cap **15** can include a hole for insertion of the balloon guide catheter **4**. Alternatively or in addition, the exemplary chamber **10** can be made from two asymmetrical balloons **5**, **16**, as shown in the exemplary embodiment of FIG. **4**. For example, the balloons **5**, **16** can create space for the chamber **10** and the exemplary instruments/tools **11** when inflated. Alternatively or in addition, the exemplary chamber **10** can be provided using the proximal balloon **16** and the distal balloon **5**, being connected to one another via their attachment to the balloon guide catheter **4**, as shown in FIG. **5**. Further alternatively or in addition, the exemplary chamber **10** can be provided by a braided metal wire net **17** having an opening **18** at desired location, as shown in FIG. **6**.

In another exemplary embodiment of the present disclosure, at least one, and possibly two or more balloons can be used with the chamber **10** that is made from strips **12** made from a bendable material (e.g., metal). The exemplary balloon(s) **5**, **16** can assist in blocking and/or isolating the chamber **10** from the rest of the colon, hence, minimizing and/or preventing the inflow and outflow of liquids and solids from and/or to the chamber **10**, while the exemplary strips **12** can provide a substantially rigid and stable working space and facilitate treatment of the lesion. For example, as shown in FIG. **7**, the first symmetric or asymmetric balloon **16** can be provided in proximal to the chamber **10** or the position of the strips **12**. The second balloon **5** can be provided at the position that is distal to the strips **12**. Alternatively, the second balloon **5** that can be connected to the guide catheter **4**.

According to still another exemplary embodiment of the present disclosure, the arrangement/device **1** can include at least one camera and an illumination apparatus to provide sufficient light to the area of interest. For example, camera or cameras and illuminating component can be movable or fixed in the arrangement/device **1**, for example, to the chamber **10**. In one exemplary embodiment shown in FIG. **2**D, the scope/front camera **50** can be used to facilitate the insertion of the arrangement/device **1** into the colon. Referring to FIG. **8**, e.g., at least one, two or more additional and possibly fixed cameras **51** can be positioned so to facilitate image capture at a location of the lesion. Exemplary field views **54** of the cameras **51** can overlap, and such overlap may facilitate visualization if one or more instruments/tools blocks or adversely affects view of one of the cameras. For example, illumination can be provided by a variety of ways, e.g., by LEDs **52**, **53**. Exemplary front LEDs **52** can be used for the front camera **50**, and in-chamber LEDs **53** can be used for the illumination in or at the chamber **10**. Alternatively or in addition, a conventional flexible endoscope, having distal bendable section, can be used instead of or together with the fixed camera(s) **51** and illumination via the LEDs **52**, **53**.

As shown in FIGS. **9** and **9**A, the exemplary arrangement/device **1** according to a further exemplary embodiment of the present disclosure can include a control handle **20** at or about its proximal end. The exemplary handle **20** can have similar shape and configuration with respect to other conventional endoscope's handles, while likely having additional channel ports and actuators than standard endoscope. For example, the ports in the handle **20** can include at least one, and possibly 2-4 or even more ports for the tool-channels **21**, balloon guide catheter port **22** and particular lever **23** to control the opening and closing of the chamber **10**. Additional ports can include, but not limited to, a luer port **24** for a proximal balloon inflation, and a port **26** of a vacuum catheter **25** or an irrigation catheter. The handle **20** can include switches **27**, **28** for air insufflations, water irrigation and vacuum activation, as well as switch (not shown) for switching camera(s) between frontal and inner locations.

As illustrated in FIG. **10**, the exemplary arrangement/device **1** according to a still further exemplary embodiment of the present disclosure can include a vacuum catheter with a bent tip **25**, inserted in a vacuum lumen **36** through a vacuum port **26**. The vacuum catheter can operate as a standalone (as describe herein), and/or may be inserted into tool channel **40** and deflect. Further, the vacuum catheter can be manipulated to reach all or most areas inside and around the chamber **10**, hence, providing an access for elimination of liquids and solids from and around the chamber **10**. In another exemplary embodiment of the present disclosure, the chamber **10** can include bendable and steerable section, which can be actuated at the lever **23**, which when pulled,

the instrument **1** is articulated, and when pushed, the chamber **10** is opened (or increased in size). Thus, movements of the exemplary arrangement/device **1** in the colon can be facilitated. According to a further exemplary embodiment, a locking mechanism can be provided which can, e.g., rotate one or more times (e.g., counterclockwise or counter-clockwise) to lock the lever **23**.

According to still another exemplary embodiment of the present disclosure, the exemplary arrangement/device **1** can include the instruments/tools **11** and/or tool-channels **40**, as shown in FIG. **11**. When the exemplary instruments/tools **11** are inserted in the tool channels **40**, distal ends **41** thereof change the position(s) and/or shapes of the instruments/tools **11**, for example, rotated, axially moved, bent at desired angles, whenever the position and shape of the associated tools channels **40** are changed, as shown in FIGS. **12** and **12**A (compare to FIG. **12**B). The tool channels **40** can be actuated and manipulated at or about proximal end of the exemplary arrangement/device of the present disclosure. The described maneuverability of the tool-channels **40**, for example, their distal ends **41** provide and/or facilitate multidirectional and multiangular approach to the target lesion. For example, the tool-channels **40** can include at least one, and preferably two, three or more lumen tubes **42**, which can be made of polymer, possibly having high torque-ability, low friction, connected at or about their distal ends to an additional section **41**, which can have "elevators" **43**. The exemplary polymer tube(s) **42** can be reinforced with other materials to change its/their structural or/and functional properties. The elevator **43** can be a flexible bendable section, made, e.g., from a laser cut nitinol tube **44**, and/or actuated, e.g., bent, using one or two metal wires **45**. The instruments/tools **11** can be inserted in the first (e.g., relatively large) lumen of the tube **42**, and the wire **45** can be inserted in the second (e.g., relatively small) lumen of the tube **42**.

As shown in FIG. **13**, the ability of the tool-channel tubes **42** to move, independently or simultaneously, axially (e.g., pushing, pulling directions), rotate and bend using the elevator **43**, facilitates the instruments/tools **11** or/and the tool-channels **40** in reaching any point within and around the chamber **10**, and can provide possibly an unlimited range of instrumental freedom within the working space. For example, as shown in FIG. **11**, the tool channel **40** can include one or more handles **46** connected to the tube **42** at or about a proximal side of the tube **42**, and can be used for a manipulation of the elevator **43**, and utilize a port **47** for an insertion of the exemplary instrument/tool. **11**. The exemplary tool-channel handle **46** can include a slider or knob **48** which can be used to actuate, e.g., pull and release a wire **45**, as shown in FIG. **12**. Any standard tool(s) can be used with the exemplary tool-channel(s) **40**. Alternatively or in addition, articulating tools having maneuverable distal ends, e.g., with at least two degrees of freedom, can be used.

According to yet a further exemplary embodiment of the present disclosure, a method for implementing the exemplary arrangement/device **1** according to the present disclosure can be provided. Such exemplary method can be utilized as follows:

i. Perform a standard colonoscopy and identifying a lesion that may not be treated using standard endoscopy and techniques.

ii. Insert a balloon guide catheter, inflating the balloon and removing the standard colonoscope (the balloon catheter and inflated balloon are left in place). The balloon guide catheter can be used as a guide-wire to facilitate the insertion of the exemplary arrangement/device **1**.

iii. Insert the exemplary arrangement/device **1** over the balloon guide catheter, until the chamber is in the proximity to the lesion.

iv. Deploy and adjust the chamber **10** of the exemplary arrangement/device **1** to preferred dimensions. Readjust the chamber **10** during the procedure as needed.

v. Clean an operative area with a provided suction catheter. If desired, inflate a proximal balloon, a distal balloon or both proximal and distal balloons for the treatment area isolation.

vi. Insert the tool-channels.

vii. Insert the instruments/tools into the tool-channels. Manipulate the tool-channels to optimize and facilitate the instruments/tools approach to the lesion.

viii. Perform a procedure, e.g., closing a colonic perforation, removing a large colon polyp or tumor, stopping a bleeding, closing diverticuli, removing an appendix, treating other body luminal lesions.

The foregoing merely illustrates the principles of the present disclosure. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. For example, more than one of the described exemplary arrangements, radiations and/or systems can be implemented to implement the exemplary embodiments of the present disclosure. It will thus be appreciated that those skilled in the art will be able to devise numerous systems, arrangements and methods which, although not explicitly shown or described herein, embody the principles of the present disclosure and are thus within the spirit and scope of the present disclosure. In addition, to the extent that the prior art knowledge has not been explicitly incorporated by reference herein above, it is explicitly being incorporated herein in its entirety. All publications referenced herein above are incorporated herein by reference in their entireties.

What is claimed is:

1. An endoscopic surgical system for accessing a target tissue structure comprising**[**:**]**:

an endoscopic device having a handle at a first portion, a longitudinal axis, a chamber at a second portion and first and second lumens extending through the device, the chamber having a proximal end portion and a distal end portion, each of the lumens having an opening to the proximal end portion of the chamber for access to the proximal end portion of the chamber, the chamber *comprising a plurality of members* movable from a first collapsed position for insertion to an expanded position to increase a working space adjacent the target tissue structure*, wherein the plurality of members are connected at a distal end to a cap*;

a first tube having a distal tip and movable within the first lumen to orient a first instrument through the first tube and into the chamber, the first tube controllable at the proximal end for movement within the first lumen, the proximal end portion of the chamber configured to allow for passage of a distal portion of the first tube; *and*

a second tube having a distal tip and movable within the second lumen to orient a second instrument through the second tube and into the chamber, the second tube controllable at a proximal end for movement within the second lumen, the proximal portion of the chamber configured to allow for passage of a distal portion of the second tube; **[**and**]**

the first and second tubes **[**movable**]** *being independently manipulable axially and rotatably* to orient the first and

second instruments to achieve triangulation within the increased working space formed by the chamber; *and*

the chamber expandable to increase the working space adjacent the target tissue structure by moving the target tissue structure laterally with respect to the longitudinal axis of the device such that a distance between the distal tip of the first and second tubes and the target tissue structure within the increased working space is increased such that first and second instruments inserted through the respective first and second tubes have an increased space to maneuver within the chamber and to act on the target tissue structure within the increased working space formed by the chamber.

[2. The endoscopic device of claim **1**, wherein the chamber comprises a plurality of members movable between collapsed and expanded positions.**]**

[3. The endoscopic device of claim **2**, further comprising a cover positioned over the plurality of members of the chamber to protect the body lumen during insertion.**]**

4. An endoscopic device of claim **[2]** *1*, wherein a transverse arc intersecting all of the plurality of members of the chamber extends around less than full circumference of a circle.

5. The endoscopic device of claim **[2]** *1*, wherein the plurality of members are connected at a proximal end to a cap.

[6. The endoscopic device of claim **2**, wherein the plurality of members are connected at a distal end to a cap.**]**

7. The endoscopic surgical system of claim **[2]** *1*, wherein the members are covered with a protective cover portion.

8. The endoscopic device of claim **1**, wherein the chamber is movable in a lateral direction to only one side of a longitudinal axis of the device.

9. The endoscopic surgical system of claim **1**, wherein the endoscopic device has a third lumen, and further comprising an endoscope receivable with the third lumen for visualizing the tissue structure within the chamber.

10. The endoscopic surgical system of claim **9**, wherein the endoscope is an articulating endoscope such that a tip of the endoscope is movable laterally within the chamber.

11. The endoscopic surgical system of claim **1**, wherein the first and second tubes are movable axially from a position wherein distal tips are outside the chamber to a position wherein the distal tips are inside the chamber, and the distal tips bendable within the increased working space formed by the chamber to provide angular access to the target tissue structure thereby enabling triangulation for performance of a surgical procedure on the target tissue structure.

12. The endoscopic surgical system of claim **1**, wherein the chamber is expanded within a colon of a patient.

13. The endoscopic surgical system of claim **1**, wherein the first and second tubes are independently manipulable from the proximal end.

14. The endoscopic surgical system of claim **1**, wherein the chamber includes a side opening for the target tissue structure.

15. The endoscopic surgical system of claim **14**, wherein the chamber includes flexible elements and the side opening is between the flexible elements.

16. The endoscopic surgical system of claim **1**, wherein the chamber is adjustable to provide the working space with multiple sizes.

17. The endoscopic surgical system of claim **1**, wherein the chamber in the expanded position is non-cylindrically shaped and asymmetrical.

18. The endoscopic surgical system of claim **1**, wherein the chamber has a partially rigid portion.

19. The endoscopic surgical system of claim **1**, wherein the first and second tubes are bendable at a distal end by a wire.

20. The endoscopic surgical system of claim **1**, wherein the endosopic device has first and second working ports and the first tube is inserted through the first working port and the second tube is inserted through the second working port.

21. The endoscopic surgical system of claim **1**, wherein the chamber includes a plurality of strips of metal.

22. An endoscopic surgical system for accessing a target tissue structure comprising:

an endoscopic device having a handle at a first portion, a longitudinal axis, a chamber at a second portion and first and second lumens extending through the device, the chamber having a proximal end portion and a distal end portion, each of the lumens having an opening to the proximal end portion of the chamber for access to the proximal end portion of the chamber, the chamber movable from a first collapsed position for insertion to an expanded position to increase a working space adjacent the target tissue structure;

a first tube having a distal tip and movable within the first lumen to orient a first instrument through the first tube and into the chamber, the first tube controllable at the proximal end for movement within the first lumen, the proximal end portion of the chamber configured to allow for passage of a distal portion of the first tube; and

a second tube having a distal tip and movable within the second lumen to orient a second instrument through the second tube and into the chamber, the second tube controllable at a proximal end for movement within the second lumen, the proximal portion of the chamber configured to allow for passage of a distal portion of the second tube;

the first and second tubes being independently manipulable axially and rotatably to orient the first and second instruments to achieve triangulation within the increased working space formed by the chamber; and

the chamber expandable to increase the working space adjacent the target tissue structure by moving the target tissue structure laterally with respect to the longitudinal axis of the device such that a distance between the distal tip of the first and second tubes and the target tissue structure within the increased working space is increased such that first and second instruments inserted through the respective first and second tubes have an increased space to maneuver within the chamber and to act on the target tissue structure within the increased working space formed by the chamber;

wherein the endoscopic device has a third lumen, and further comprising an endoscope receivable with the third lumen for visualizing the tissue structure within the chamber; and

wherein the endoscope is an articulating endoscope such that a tip of the endoscope is movable laterally within the chamber.

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