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(54) Title: RADIAL INWARD COMPRESSION OF A LUMEN

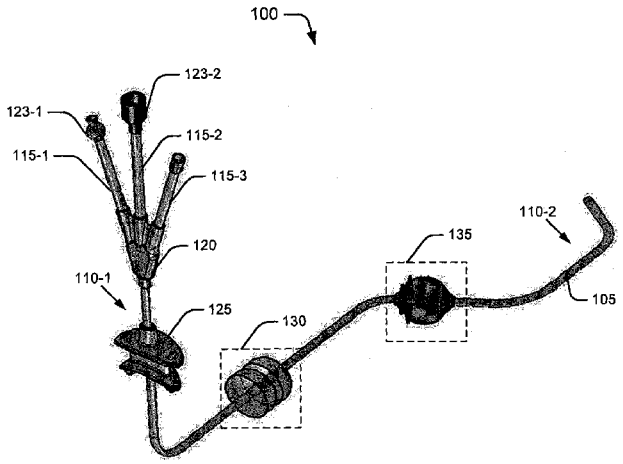

Fig. 1

(57) Abstract: Present subject matter relates to a device (100, 800) to facilitate radial inward compression of a target lumen. The device (100, 800) comprises a tube (105, 705, 805), one or more lumens (202, 710) provided in the tube (105, 705, 805), and a plurality of sealing units (130, 135) integrated into the tube (105, 705, 805) to delineate a segment of the target lumen to be subjected to radial inward compression. The device (100, 800) further includes a primary set of openings (410) provided between two sealing units (130, 135), from amongst the plurality of sealing units (130, 135), to transmit the negative pressure from the lumens (202, 710) to the delineated segment of the target lumen between the two sealing units (130, 135).

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RADIAL INWARD COMPRESSION OF A LUMEN

TECHNICAL FIELD

[0001] The present subject matter relates, in general, to devices and methods used for medical purposes and, in particular, to devices and methods for radial inward compression of a lumen.

BACKGROUND

[0002] Generally, patients suffering from cirrhosis of liver develop portal hypertension where blood flow from intestines and spleen through hepatic portal vein becomes slow and blood pressure in portal vein system increases. Typically, varices develop when most of the normal liver tissue has been replaced by scar tissue. The scar tissue pushes upon the veins in the liver and as a result blood cannot flow normally through the veins. Consequently, pressure inside the liver veins begins to build up and this pressure is then transmitted into other veins located outside the liver. This occurs most frequently in the vessels in the esophagus and stomach, which form a part of the portal circulation. This increased pressure is called portal hypertension. Due to increased pressure, the patients may develop complications, such as esophageal varices, i.e., abnormal dilation of the esophageal vessels. The esophageal varices have thin walls and often rupture, causing bleeding or haemorrhage. Further, the esophageal varices may also lead to bleeding in the esophagus and epigastric bleeding. Upper central region of the abdomen located between costal margins and subcostal plane is referred to as epigastrium region and bleeding in the epigastrium region may be understood as the epigastric bleeding.

[0003] In order to stop the epigastric bleeding, an endoscopy may be performed to identify the source of bleeding. In many situations, it might not be possible to perform the endoscopy and in such situations provisions for certain surgical and endoscopic treatments may have to be made to temporarily tamponade or stabilize the bleeding.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] The detailed description is described with reference to the accompanying figures. In the figures, the left-most digit(s) of a reference number identifies the figure in which the

reference number first appears. The same numbers are used throughout the drawings to reference like features and components.

[0005] Fig. 1 illustrates a device for applying radial inward compression, in accordance with an embodiment of the present subject matter.

[0006] Fig. 2a illustrates a cross sectional view of a multi lumen tube of the device, in accordance with an embodiment of the present subject matter.

[0007] Fig. 2b illustrates a magnified view of a first end of the multi lumen tube of the device, in accordance with an embodiment of the present subject matter.

[0008] Fig. 3 illustrates a positioning unit of the device, in accordance with an embodiment of the present subject matter.

[0009] Fig. 4 illustrates a perspective view of sealing diaphragms of the device, in accordance with an embodiment of the present subject matter.

[0010] Fig. 5 illustrates a perspective view of a mouthpiece of the device, in accordance with an embodiment of the present subject matter.

[0011] Fig. 6 illustrates a perspective view of a manifold connector of the device, in accordance with an embodiment of the present subject matter.

[0012] Fig. 7a and 7b illustrate a tube of the device for applying radial inward compression, in accordance with an embodiment of the present subject matter.

[0013] Fig. 8a-8c illustrate a device for applying radial inward compression, in accordance with an embodiment of the present subject matter.

DETAILED DESCRIPTION

[0014] Method(s) and devices(s) to control internal bleeding, such as epigastric bleeding and for drug elution are described herein. The control may include stabilization or tamponation of the epigastric bleeding.

[0015] In order to tamponade the epigastric bleeding, many devices have been implemented. For example, a balloon tamponade device has been used for emergent control of epigastric bleeding, primarily arising from acute rupture of esophageal varices. Examples of the

balloon tamponade devices include the Sengstaken-Blakemore tube, the Minnesota tube, the Linton tube, and the Esophagogastric tamponade tube. However, most of the tamponade devices rely on vascular compression for arresting and/or stabilizing bleeds. The vascular compression is usually achieved by a combination of balloon inflation and external traction.

[0016] Generally, the devices to control the epigastric bleeding rely on the application of compression on the bleed in order to restrict and ultimately restrain bleeding from varices. Certain tamponade devices are inserted via the nasal cavity into the esophagus and two balloons are inflated to compress the active bleeder thereby controlling the bleeding. However, such devices often have multiple lumens, thereby making them complex. Further, such devices consume considerable time to be deployed effectively. Additionally, application of traction for effective execution of the tamponade function of such devices may be required. Moreover, there have been cases where use of the tamponade devices has led to multiple secondary complications, such as aspiration pneumonitis and mucosal ulcerations or perforations. Furthermore, such tamponade devices may require radiological confirmation with X-ray prior to inflating the balloons. Thus, generally, devices providing the temporary control are often complex and take time to be deployed effectively. Further, certain devices may lead to further complications, such as aspiration pneumonitis and mucosal perforations.

[0017] In an implementation, devices facilitating inward radial compression of a target lumen, such as an esophageal lumen are defined. Such device may be used for a variety of medical applications, for example, controlling internal bleeding, acid reflux, and drug elution. In an example, the device described here is used for controlling epigastric bleeding. In said example, the lower esophageal and/or upper gastric lumen is constricted or compressed by forcing the esophageal lumen to collapse tightly around a central tube instead of applying a radially expansive tamponade. The present subject matter implements localized use of negative pressure for collapsing the lower third of the esophagus on itself. Inward collapse of the esophageal lumen is expected to constrict blood vessels in two ways. Firstly, enforced concentric aggregation of tissue or muscle mass of the esophageal lumen due to the inward collapse results in uniform compressive pressure along the length of the engorged varices embedded in the esophageal lumen wall, thereby constricting them and cutting off the flow. Secondly, when observed from a cross-sectional view of the esophagus, the radially inward collapse decreases the

inner diameter of the lumen, thereby effectively pinching off any active site of bleeding. It will be appreciated that the aforementioned principle may be extended for radial inward compression for any other lumen as well.

[0018] In an embodiment, the device includes a multi-lumen tube with a plurality of sealing units to delineate a segment of the target lumen to be subjected to radial inward compression. For instance, the sealing unit may allow for sealing of the lower one-third portion of the esophagus. In an example, one of the sealing units also functions as positioning unit to position the tube in the target lumen. Further, the device includes multiple suction ports for applying negative pressure between the sealing units. Accordingly, at least one lumen of the tube, from amongst the multiple lumens, is coupled to a source of a negative pressure. Application of the negative pressure between these sealing units causes the lower third portion of the target lumen to collapse around the tube, thereby simultaneously compressing the bleeding vessels and aspirating any residual bleeding. Further, in an example, a primary set of openings may be provided on the tube between two sealing units to transmit the negative pressure from the at least one lumen to the delineated segment of the target lumen between the sealing units.

[0019] In another embodiment, the device may include the tube, a plurality of lumens and a manifold connector provided a first end, the end that is to be kept external to the target lumen. The lumens may extend from the manifold connector to other end, i.e., the end entering the target lumen, of the tube. Further, the device may include a tube extension corresponding to each of lumens and the tube extension may be coupled to the manifold connector. The tube extensions may include a first tube extension, which may be provided with at least one of a luer lock and a balloon-like identifier; and a second tube extension provided with a concentric cap.

[0020] Since, the present subject matter implements a non-specific strategy of radially compressing a flexible target lumen to compress and constrict any bleeding varices; the present subject matter may be used in cases where it may not be possible to pinpoint the specific location of bleeding, for instance, due to unavailability of specialized imaging devices, such as endoscopic devices, in emergency situations or low-resource settings. Moreover, in an example, the one or more components, such as sealing units and tube, of the device may be made of biodegradable material to allow it to internally disintegrate at a controlled rate over time after initial deployment.

[0021] These and other advantages of the present subject matter would be described in greater detail in conjunction with the following figures. While aspects of described systems for controlling the epigastric bleeding can be implemented in any number of different systems, environments, and/or configurations, the embodiments are described in the context of the following exemplary system(s).

[0022] Fig. 1 illustrates a device 100 for facilitating inward radial compression of a lumen, in accordance with an embodiment of the present subject matter. Although the present subject matter has been explained in considerable detail with respect to epigastric bleeding; however it will be understood that the device 100, may be used for other applications as well. For example, the device 100 may be used to control bleeding in the colon.

[0023] The device 100 includes, for example, a tube 105, which may be flexible and may be encased in an elliptical cross-section. The elliptical cross-section allows the tube 105 to bend only about the major axis and aids its insertion into the lumen, such as esophagus by preventing twisting or collapse. The two ends of the tube 105 may be referred to as a first end 110-1 and a second end 110-2. Further, the tube 105, in an example, may be provided with three independent lumens, viz, a first lumen 202-1 (shown in fig. 2a), a second lumen 202-2 (shown in fig. 2a), and a third lumen 202-3 (shown in fig. 2a) all along its length starting from a manifold connector 120 to the second end 110-2. The three lumens 202-1, 202-1, and 202-3 may be collectively referred to as the lumen(s) 202. In an example, the lumens 202 are disposed parallel to each other in the tube 105.

[0024] Further, access to the lumens 202 may be provided via the manifold connector 120. The first end 110-1 may terminate in the manifold connector 120. In an implementation, the manifold connector 120 may include a tube extension 115-1, 115-2, and 115-3, corresponding to each of the lumens 110-1, 110-2, and 110-3 respectively. Each of the three tube extensions 115-1, 115-2, and 115-3, collectively referred to as tube extension (s) 115, may have a differentiated design to facilitate intuitive identification of the lumens 202. For example, the first tube extension 115-1 may be provided with at least one of luer lock terminator with a balloon-like identifier 123-1. The first tube extension 115-1 may be coupled to an independent source of aspiration. Alternatively, the first tube extension 115-1 corresponding to the first lumen 202-1 may be used for balloon inflation. Further, the second tube extension 115-2 may be provided

with a concentric cap 123-2, which may function as a standard connector to connect to any standard vacuum line. The second tube extension 115-2 and thus the second lumen 202-2 may be connected to a negative pressure source, such as, vacuum line, a bellows-type close wound suction pump, hand-operated bulb –type pump, and foot pumps. The third tube extension 115-3 may be left relatively simple and without any specific identifier. The third tube extension 115-3 may be connected to any standard aspiration line. In other examples, the sources to which the tube extensions 115 are connected and thus the lumens 202 may vary based on an end application. Additionally, the number of lumens 202 that are to be provided in the tube 105 may depend on the end application of the device. For example, if the device 100 is used for localized collapse of the lungs, the tube 105 may include only one lumen. In such a case, the lumen 202 may be coupled to a negative pressure source.

[0025] In an example, one end of the manifold connector 120 may be coupled to a mouthpiece 125. The device 100 may be secured to a patient by the mouthpiece 125. The tube 105 may run through the mouthpiece 125 and may connect to a first sealing unit 130. Thus, the first sealing unit 130 may be provided proximal to the first end 110-1 of the tube 105. The first sealing unit 130 may include, for example, a set of circular flexible diaphragms or fins. One end of the first sealing unit 130 may be coupled to the mouthpiece 125 and other end may be coupled to another sealing unit 135 via the tube 105. The another sealing unit 135, hereinafter referred to as the second sealing unit 135, may be provided proximal to the second end 110-2 of the tube 105. The second sealing unit 135 in some embodiments may serve as positioning unit configured to position the device 100 in a target lumen. It will be appreciated that based on an application, more than two sealing units may also be provided.

[0026] In an implementation, to stabilize the epigastric bleeding, the device 100 may be inserted into the esophagus of a patient via an oral route. Prior to insertion, the device may be shielded by a sheath (not shown) that covers the second sealing unit 135 and the sealing unit 130. The sheath may be smooth and may reduce the overall footprint of the device 100 and aid its insertion into the esophagus via the oral route. Furthermore, the elliptical cross-section of the tube 105 pre-disposes it to bend only about the major axis of the ellipse, thereby constraining it from twisting about, in order to facilitate quick insertion. It will be understood that in other implementations, the cross-section of the tube 105 and the configuration of the device 100 may

be tweaked to facilitate insertion through other routes. For example, to facilitate insertion through the nasal route the tube 105 may have configuration similar to that of a Ryle's tube.

[0027] To aid insertion, markings may be provided on the tube 105. The markings may notify a physician regarding the length of the tube that has been or is to be inserted. In an example, about 45 centimeter to about 50 centimeter of the marked length of the tube 105 may be inserted. Once the tube 105 is inserted into the stomach past the lower esophageal sphincter (LES), a flexible sealing component (shown in Fig. 3) of the second sealing unit 135 is deployed inside the stomach. The flexible component may be, for example, a balloon, a diaphragm, or a bellow, which may be flexible enough to conform to shape of a target lumen, for instance, LES. In an example, the flexible component may be sufficient to position the device 100 and provide a seal at the second end 110-2. The flexible component may be deployed via the first lumen 202-1.

[0028] Further, the tube 105 may be gently pulled out, until the flexible component abuts against an upper surface of the stomach and registers the tube 105 just below the LES. Thus, the second sealing unit 135 locates the device 100 around the LES. Additionally, if the sheath is present, it may be removed by externally positioning on or through a special release mechanism. In an implementation, the dimensions of the second sealing unit 135 are small to aid easy insertion of the device 100 in the esophagus. Further, since the second sealing unit 135 is small in size, accidental inflation of the second sealing unit 135 inside the esophagus may not cause any harm, since the second sealing unit 135 in inflated state would only gently expand the esophagus without causing any other trouble. Thus, in present case, an endoscopy during insertion of the device 100 may not be required and further the device may be easily inserted with the aid of visual marking provided on the tube 105. In an example, accurate localization of the device 100 may be confirmed by clinical procedures such as auscultation or the addition of an internal locating beacon, such as a small light source or other electromagnetic signal generator.

[0029] Once the flexible component abuts against the lower surface of the LES, the first sealing unit may open and loosely conform to the inner diameter of the esophagus. Further, the second lumen 202-2 may now be attached to negative pressure source, such as a vacuum pump or a manually-operated bellows pump. Activation of negative pressure creates a pressure differential above and below the first sealing unit, further causing the first sealing unit to

conform and adhere tightly to the esophageal lumen. Simultaneously, the flexible component may be drawn further up into the base of the LES, thereby creating an effective seal for subsequent application of negative pressure.

[0030] As air continues to be drawn out of the sealed section below the first sealing unit, the flexible esophageal lumen collapses on itself, and starts constricting around an outer surface of the tube 105. This radial contraction of the esophageal lumen may in turn compress all associated blood vessels. The inward radial compression may constrict any bleeding blood vessel and stop the active flow of blood, provided that a negative pressure of an adequate magnitude is applied is continuously.

[0031] The continuous application of the negative pressure inside the esophageal lumen also aspirates out any blood oozing out of the bleeder until the compression constricts the flow. Furthermore, the first sealing unit may effectively prevent the backflow of blood up to the esophagus. The continuous application of the negative pressure and prevention of backflow of blood considerably reduces the risk of aspiration pneumonitis.

[0032] In an example, the tubing of both the second lumen 202-2 and the first lumen 202-1 may be clamped externally in order to maintain the negative and positive pressure inside each respective lumen. The device 100 may maintain the inward compression on the esophageal lumen as long as sealing provided by the first sealing unit 130 and the second sealing unit 135 remains intact and the negative pressure is maintained.

[0033] Further, once it is confirmed that there is no active blood aspirate emerging from the collapsed portion of the esophagus, the patient may be clinically monitored to ensure stabilization of vital signs before proceeding to more definitive treatment. The device 100 may then be secured externally by lightly tying the mouthpiece 125 to the head of the patient using flexible bands or straps. Further, the third lumen 202-3 provides gastric access, if required, for suction of gastric contents or supplemental parenteral feeding. Additionally, the third lumen 202-3 may also serve as a dedicated aspiration lumen to extract blood pooled in the stomach.

[0034] In an implementation, to release the device 100 prior to surgical and/or endoscopic intervention, the flexible component may be deflated and the application of negative pressure may be stopped. This in turn may detach the second sealing unit from the esophagus,

thus releasing the negative pressure and allowing the tube 105 to collapse to a short distance into the stomach. After detaching the mouthpiece, the tube may be simply extracted back out of the esophagus.

[0035] Thus, the device 100 may be understood to be based on the principle that a vascular area associated with a flexible lumen may be constricted on application of inward radial force and associated collapse of the flexible lumen. In an implementation, this is achieved by creating a seal over a localized area of the flexible lumen and the subsequent application of negative pressure. In other implementations, the force may be applied by using magnets or radially tightening wires or structures.

[0036] In an embodiment, a device for stabilizing internal bleeding, such as epigastric bleeding includes a tube with multiple lumens. One of the lumens may be coupled to an independent aspiration line to extract blood or gastric debris, another lumen may be connected to a vacuum line to apply negative pressure, and another may also be connected to an aspiration line to inflate a balloon provided on a lower end of the tube. Further, a sealing unit may be provided to seal the lower third portion of the esophagus. As air continues to be drawn out of the sealed section below the sealing unit, the esophageal lumen collapses on itself, and starts constricting around an outer surface of the tube. This radial contraction of the esophageal lumen may in turn compress all associated blood vessels localized in that area. The inward radial compression may constrict any bleeding blood vessel and stop the active flow of blood. Further, the continuous application of the negative pressure inside the esophageal lumen also aspires out any blood oozing out of the bleeder until the compression constricts the flow.

[0037] Fig. 2a illustrates a cross sectional view of the tube 105, according to an embodiment of the present subject matter. As mentioned previously, the tube 105 includes a first lumen 202-1, a second lumen 202-2, and a third lumen 202-3. In an example, the second lumen 202-2 has circular cross-section and is used to apply negative pressure to the esophagus. The first lumen 202-1 and the second lumen 202-2 may have kidney shaped cross section. However, it will be understood that the lumens 202 may have other cross sections as well.

[0038] Fig. 2b illustrates the second end 110-2 of the tube 105, according to an embodiment of the present subject matter. As illustrated, an auxiliary set of openings 205-1, 205-

2, 205-3, and 205-N may be provided on the tube 105, which may be located inside the stomach when the device 100 is deployed. The auxiliary set of openings 205, in an example, may be provided via the third lumen 202-3 for aspiration of gastric contents. Further, the auxiliary set of openings 205 provide redundancy in case one or more suction ports get blocked due to clotted blood, mucus, or other gastric debris. In another example, the auxiliary set of openings 205 may be used for delivering nutrition or drugs to the target lumen following inward radial compression.

[0039] Fig. 3 illustrates the second sealing unit 135 of the device 100, according to an embodiment of the present subject matter. As an example, the second sealing unit 135 may include a flexible component 305 and two sealing components 310-1 and 310-2. The flexible component 305 may be any component that provides for positioning of the tube 105 in a lumen. The flexible component 305 may be capable of conforming to a shape of a target lumen, when deployed. The flexible component 305 may be for example, a balloon or a bellows type structure. The second sealing unit 135 may be provided proximal to at the second end 110-2. As mentioned previously, after the insertion of the tube 105 past LES, the flexible component 305 may be deployed via the first lumen 202-1. After inflation in the stomach, the flexible component 305 abuts against a top part of the fundus, i.e., below LES and serves to temporarily restrain the tube 105 from slipping out of the esophagus. The top surface of the flexible component 305 that abuts against the LES is provided with the two sealing components 310-1 and 310-2. The sealing components 310-1 and 310-2, collectively referred to as sealing components 310, may be provided as concentric diaphragms or circular fins. In an example, the sealing components 310 may have elliptical cross section. Further, the sealing components 310 serve as redundant seals for the flexible component 305 against the lower surface of the LES after the application of negative pressure above the flexible component 305. It will be appreciated that the sealing components 310 may be capable of withstanding a pressure differential before and after its placement along the tube 105, when deployed at the target site. As mentioned previously, the number and configuration of sealing components 310 may vary based on sealing requirements.

[0040] By way of an example and not as limitation, the dimensions of the flexible component 305 may be in a range of about 15 cc to about 25 cc. Further, the flexible component 305 could either be a balloon or a diaphragm similar to the sealing components 310. The flexible

component 305 may have an elliptical cross section, with a major axis of a length of about 20-35 mm, and a minor axis of a length about 10-20 mm. It will be understood that the dimensions of various components of the sealing unit may vary for various applications. For example, in case the sealing units 130 and 135 are used inside a blood vessel, the dimensions of the sealing units 130 and 135 could well be in single digits, for instance, the length may be less than 5m.

[0041] In other embodiments, the second sealing unit 135 may be independent of the sealing component. For instance, the second sealing unit 135 may be a simple diaphragm without any sealing component, or the second sealing unit 135 may be a radio-opaque marker as in a case where device 100 is catheter-based device, as will be explained with reference to Fig. 8a-8c.

[0042] Fig. 4 illustrates a perspective view of the first sealing unit of the device 100, in accordance with an embodiment of the present subject matter. The first sealing unit includes a set of diaphragms or fins 405-1 and 405-2. The diaphragms 405-1 and 405-2 may be flexible and may be collectively referred to as the diaphragms 405. Based on end application, the diaphragms 405 may have a suitable cross-section, for example, circular or elliptical. The first sealing unit helps to seal the lower one-third of the esophagus. The diaphragms 405-1 and 405-2 are designed to loosely conform to inner lumen of the esophagus prior to insertion. Further, the diaphragms 405-1 and 405-2 may be radially compliant in order to maintain an air-tight seal upon the application of negative pressure below them. Two diaphragms 405-1 and 405-2 may be separated by a lateral distance '*l*' along the length of the tube 105, in order to provide redundancy in sealing the esophageal lumen in case one of the diaphragms 405 is broken. It will be understood that more than two diaphragms may also be provided, in case sealing is deemed to be inadequate. Additionally, a primary set of openings 410-1, 410-2,...410-N may be provided between the first sealing unit and the second sealing unit 135 such that they correspond to the lower one-third part of the esophagus. Like the auxiliary set of openings 205, the primary set of openings 410 may provide redundancy in case one or more suction ports is blocked due to clotted blood, mucus or other gastric debris. Further, the primary set of opening 410 may be located in any intermediate area between the first sealing unit and the second sealing unit 135, where inward compression is to be achieved.

[0043] Fig. 5 illustrates a perspective view of the mouthpiece 125, in accordance with an embodiment of the present subject matter. The mouthpiece 125 may include two flanges, viz., a

first flange 505-1 and a second flange 505-2. The first flange 505-1 may have two projections 510-1 and 510-2, collectively referred to as the projections 510. The projections 510 may have enlarged ends so that they may be gripped between teeth of the patient. Further, the two flanges 505-1 and 505-2 may be connected via a bridge 515, which may be made substantially smaller in size as compared to the flanges 505-1 and 505-2. The bridge 515 may be provided such that a patient may comfortably hold the mouthpiece 125 without hurting his/her lips. Further, the second flange 505-2 may include a slot 520 for securing elastic or flexible bands. The bridge 515 may allow free motion of the lips without compression. Since, the projections 510 allow the patient to hold onto the mouthpiece 125 with their teeth, the pressure from the elastic bands is transmitted via the bridge 515 to the teeth and not the lips. Thus, the mouthpiece 125 may be provided to allow the patient to comfortably hold the device 100 with their teeth. However, in case of a non-compliant or unconscious patient, the mouthpiece 125 may be secured with the help of a flexible band.

[0044] It will be understood that in cases where the device 100 is inserted via nasal routes, the device 100 may not include the mouthpiece 125. In such a case, the device 100 may be secured to the patient using bands or medical tape.

[0045] Fig. 6 illustrates a perspective view of the manifold connector 120, in accordance with an embodiment of the present subject matter. The first end 110-1 of the tube 105 may terminate in the manifold connector 120. The manifold connector 120 provides independent access to the three lumens 202-1, 202-2, and 202-3, which may be connected to a common tube, i.e., tube 105. The manifold connector 120 may include three slots, viz., a first slot 605-1, a second slot 605-2, and a third slot 605-3 for housing the first, the second, and the third lumen 202-1, 202-2, and 202-3, respectively. Thus, based on the requirement, one of the lumens 202 may be activated and the manifold connector 120 provides for separation of the lumens 202 so that they may function independently.

[0046] In an implementation, a method for facilitating radial compression of a flexible lumen is described. The order in which the method is described is not intended to be construed as a limitation, and any number of the described method steps can be combined in any order to implement the methods, or alternate methods.

[0047] The method includes inserting a tube, such as the tube 105 into a target lumen of the patient. The target lumen may be understood as a lumen that is to be constricted for various medical reasons. The tube 105 may be inserted, for example, with the aid of the visual markings provided on the tube 105. Further, the tube 105 may be positioned inside the target lumen by deploying a positioning unit, such as the second sealing unit 135 inside the target lumen. Additionally, in an example, a flexible component of the positioning unit may be further inflated and the sealing components 310 may conform to the target lumen to provide an effective seal. Once, the tube 105 is secured to the target lumen, a sheath covering the various components of a device implementing the said method may be removed. This also serves to deploy the first sealing unit 130 and uncover the second set of openings 410 located in the intermediate area between the first sealing unit 130 and the second sealing unit 135, to delineate the target lumen where inward compression is to be achieved.

[0048] Furthermore, a negative pressure source may be activated to apply negative pressure, which in turn creates a pressure differential before and after a sealing unit, such as the first sealing unit 130. The pressure differential causes the first sealing unit to conform and adhere tightly to the target lumen. As a result, a negative pressure is created in a volume of the target lumen enclosed between the positioning unit and the sealing unit 130. Further, the negative pressure may be increased to evacuate all contents of the target lumen in the volume enclosed between the sealing unit 130 and the positioning unit in order to cause radial inward compression of the target lumen. The continuous application of the negative pressure draws out air from the sealed section, thereby causing the target lumen to collapse on itself to constrict around an outer surface of the tube 105.

[0049] Fig. 7a and 7b illustrate a tube 705 of the device 100, according to an embodiment of the present subject matter. In an example, the tube 705 may include multiple concentric lumens 710-1, 710-2, and 710-3. The concentric lumens may include a first lumen 710-1, a second lumen 710-2, and a third lumen 710-3; and may be collectively referred to as concentric lumen(s) 710. For the purpose of explanation, the lumen 710-1, 710-2, and 710-3 may correspond to lumens 202-1, and 202-2, and 202-3 respectively. In an example, like the first lumen 202-1, a tube extension corresponding to the first lumen 710-1 may also be provided with

a luer lock terminator with a small balloon-like identifier 123-1. Likewise, a tube extension corresponding to the second lumen 710-2 may be provided with the concentric cap 123-2.

[0050] As illustrated, a second concentric lumen 710-2 may be provided around the third lumen 710-3. In an example, the concentric lumens 710 may open up just below the lower end of the diaphragms 405 or just above an upper end of the balloon 305. The outer concentric lumens, such as concentric lumen 710-1 and 710-2 may be designed to terminate and seal around the second lumen 710-3 at the specified locations. In this case, the negative pressure may be applied from the top or the bottom of the sealed area, based on the positioning of the concentric lumens 710, instead of applying the negative pressure along the longitudinal axis. In other words, the suction ports may be located just below the top seal, or just above the bottom seal or the flexible component to provide negative pressure.

[0051] In an implementation, the principle used for the collapse of the target lumen, such as esophageal lumen, as a means of constricting actively bleeding vessels, may be used to constrict the target lumen of a vessel itself, thereby temporarily cutting off flow downstream. For this purpose, a catheter-based system may be employed for intravascular or intra-bronchial use. Such a device may be useful in a number of scenarios. For example, in situations where the target lumen is vascular, temporary restriction of blood flow prior to surgery or clinical procedure in such target vessels that provide blood to an organ or tissue undergoing major surgery may substantially decrease the likelihood of surgical blood loss. A longer-term device deployment in blood vessels feeding tumors may result in tumor shrinkage and possible regression due to choking off their blood supply. A catheter-based, intravascular system may also be used in stabilizing aneurisms, and for evacuating clots from blood vessels. Finally, in cases where the target lumen is an airway, device deployment may cause a controlled local collapse of a downstream section of the lungs, which in turn may be therapeutic for the treatment of pulmonary hypertension.

[0052] An embodiment of such a catheter-based system is illustrated in Fig. 7a-7b. As illustrated, the tube 705 includes two or more catheters 715-1, 715-2, and 715-3, which are concentric about a central axis of the tube 705 instead of being arranged in parallel. The external catheter 715-1 defines the first lumen 710-1, which in turn encases other internal catheter(s) 715-2 and 715-3 of decreasing diameter(s). The internal catheters 715-2 and 715-3 may in turn define

other internal concentric lumens 710-2 and 710-3, respectively. It will be appreciated that the internal diameter of the internal catheter 715-2 will be smaller than that of the external catheter 715-1, and larger than that of the innermost catheter 715-3. Further, the internal catheter 715- 2 and 715-3 may have sufficient clearances to allow for a sliding fit between all three catheters 715. The assembly of the catheters 715-1, 715-2, and 715-3, collectively referred to as catheters 715, encased within each other together form the multi-lumen tube 705. Each of the concentric catheters 715 may be free to traverse a target lumen independently. Furthermore, the internal catheters 715-2 and 715-3 may be free to slide in and out of the target lumen of their preceding external catheter.

[0053] The tube 705 may be terminated and sealed at its second end 110-2 at a suitable distance away from the second sealing unit 135. By way of an example, and not as a limitation, the tube 705 may be terminated at a distance of 10 mm away from a distal edge of the second sealing unit 135. In an example, a radio-opaque marker or other terminal unit may be provided at the second end 110-2, to aid with the visualization of the device 100 during intravascular or intra-bronchial placement. The first end 110-1, or the proximal end, of the tube 705 may be fused with a catheter exchange system like Rapid Exchange ™ similar to that used for deployment of intravenous stents etc or with the manifold 120 as required.

[0054] Fig. 8a, 8b, and 8c illustrate a device 800 for radial inward compression of a target lumen, according to another example of the present subject matter. The device 800 may include a tube 805 and multiple sealing units 130 and 135. The tube 805 may be similar to tube 105 or tube 705. Further, the sealing units 130 and 135 may include one or more sealing members to seal a target area. In an example, the sealing units 130 and 135 may be made of flexible material or special materials, such as shape memory alloys, magnetic material, or a combination of two or more such materials to enable the sealing units 130 and 135 to conform to a shape of a target lumen, when deployed. The conformational change of the sealing units 130 and 135 may be controlled by an independent parameter, such as the local temperature or fluid flow, or the external application of mechanical, electromagnetic, thermal or acoustic energy.

[0055] For instance, the sealing members may include diaphragms, sealing balloons, or a combination thereof. An example of the sealing units 130 and 135 is illustrated in fig. 8a. In fig. 8a, both the sealing units 130 and 135 are provided by way of diaphragms 810-1, 810-2, 810-3,

and 810-4. In another example, as illustrated in Fig. 8b, both the sealing units 130 and 135 may be provided or sealing balloons 815-1 and 815-2, each sealing balloon serving as a sealing unit 130. In yet another example, as illustrated in Fig, 8c, one of the sealing units, say the first sealing unit 130, is provided by way of diaphragms 810-5 and 810-6; while the second sealing unit 135 may be provided by way of a sealing balloon 815-3.

[0056] Further, each of the sealing units 130 and 135 may be positioned proximal to the second end 110-2 of the tube 805 and may be separated by a predetermined distance, for instance, 10-20 mm to seal the targeted collapsible lumens from both ends. The volume between the two sealing units 130 and 135 may form the area of collapse of the target lumen.

[0057] Referring to the embodiment of multiple catheters, the external catheter 715-1 may be provided with two sealing units, the first sealing unit 130 and the second sealing unit 135. As mentioned before, the sealing units 130 and 135 may be, for example, a balloon, a diaphragm, or a combination of both, which may be flexible enough to conform to shape of the target lumen, such as a vascular lumen or an airway, such as a bronchiole. The sealing units 130 and 135 may be sufficient to position the device 800 and provide a seal in the region between them. The catheters 715 may be configured such that the first sealing unit 130 may be deployed via the first lumen 705-1, while the second sealing unit, 135 may be deployed via the second lumen 705-2. The third lumen, i.e., the innermost lumen, 705-3 may connect to a negative pressure source.

[0058] By way of example and not as limitation, the external diameter of the tube 705 may be in a range of about 4 to about 20 mm, depending upon its use for intra-venous and intra-bronchial applications respectively. Additionally, the external diameter of the fully deployed first sealing unit 130 and the second sealing unit 135 may be in the range of 5-20 mm and the length of the first sealing unit 130 and the second sealing unit 135 may be 15-30 mm. It will be understood that the dimensions of various components of the first and second sealing unit 130 and 135 may vary for various applications.

[0059] For example, for intra-vascular use in distal arteries, the dimensions of the sealing units 130 and 135 could well be in single digits, for instance, both the diameter and the length may be less than 5mm. It will be obvious that in the non-deployed state the sealing units 130 and

135 will be in a collapsed position and will contribute to only a nominal increase in the external diameter of the tube 705. Further, in the deployed state, the external diameter of the sealing units 130 and 135 will conform to and cause a nominal elastic and reversible expansion of the target lumen that produces adequate force for holding the sealing units in place without translating inside the target lumen. For example, if the internal diameter of the target lumen is apriori known to be 10 mm, then the external diameters of the sealing units 130 may be nominally at 11-12 mm after deployment.

[0060] As illustrated in Figure 7b, the primary set of openings 410 may be provided on the innermost catheter 710-3, which may be located inside the vasculature or airway when the device 100 is deployed. The primary set of openings 410 may take the form of perforations through the concentric catheters 715-1 and 715-2, which are external to the innermost catheter 715-3, to provide access to the third lumen 705-3 for providing negative pressure and aspiration of vascular or airway contents. Further, as mentioned before, the primary set of openings 410 provide redundancy in case one or more suction ports get blocked due to clotted blood, mucus, or other debris. The primary set of openings 410 may be located in between the two sealing units 130 along the length of the multi-lumen tube 105 so as to restrict the application of negative pressure through lumen 715-3 to the volume enclosed between the two sealing units 130 and provide a zone of inward radial compression.

[0061] Further, in an example, an additional guide wire (not shown in figures) may be inserted into the innermost lumen 715-3 to provide a temporary increase in its stiffness, so as to assist with its intra-vascular insertion and navigation through a circuitous vascular pathway. In a method for the deployment of such a catheter-based device 800, the guide wire may be first inserted into the target vascular or airway lumen, until such length as is confirmed to be at the desired location inside the target lumen as indicated by visualization of the device 800. The innermost catheter 715-3 may then be slid over the guide wire, following which the other external catheter(s) 715-1 and 715-2 may also be slid into place in the target lumen over the innermost catheter 715-3. Alternatively, the entire multi-lumen assembly, i.e., the tube 705 with three lumens 710 and the catheters 715 may be concurrently slid over the guide wire to the desired location inside the target lumen, such that the sealing units 130 are located on either end of the section of the lumen to be targeted for inward radial collapse.

[0062] Once the location of the sealing units within target lumen is confirmed, the sealing units 130 and 135 may be deployed, thereby creating a temporary seal. Following this, the negative pressure may be activated through lumen 710-3. This will initially result in suction of all contents such as blood, clots or mucus within the target volume enclosed by the sealing agents. As the negative pressure continues to build, the target lumen may undergo inward radial compression. The target lumen may continue to remain in this state of collapse until such time that the negative pressure within the target volume is not relieved or the sealing units 130 and 135 are reverted to their collapsed or un-deployed state.

[0063] In the deployed state, device 800 may prevent the flow of any fluid including blood or air, past the compressed target lumen. Thus, the inward compression will act to constrict fluid flow through the compressed target lumen. In the case of intra-bronchial use, such a constriction of airflow may lead to a localized collapse of all alveoli downstream to the target lumen. This limited lung collapse may provide therapeutic benefit in treating certain respiratory diseases such as localized lung cancer or in controlling pulmonary hypertension.

[0064] If the dimensions of the current embodiment are appropriately scaled up, then the device 100, 800 may also be easily configured for use in intestinal lumens. For example, in an embodiment, such a modified device may be guided to the appropriate target location inside the colon via the instrument port of a conventional endoscope. Once the sealing units 130 and 135 emerge from the distal end of the endoscope, the device 100 may be deployed inside the colon, thereby causing inward radial compression in a region immediately following the distal end of the endoscope.

[0065] Furthermore, in a deployed state inside the colon, the device 100, 800 may be translated along the length of the colon by gently pushing or pulling the endoscope, thereby effectively translating the target volume under radial compression. In this situation, the device 100, 800 may replicate a similar scenario to that of gastric peristalsis, wherein starting from the distal end of the colon, a limited portion, say about 25 mm, of the colon undergoes coordinated inward contraction, which is propagated serially to subsequent sections of the colon along its entire length in the form of peristalsis. This results in the displacement of the internal contents from the distal to the proximal or terminal end of the colon in the form of a bolus. In patients who loose this ability to self generate contractions because of pathology or injury, the result is

the onset of chronic constipation. The device 100, 800, when translated at the end of the endoscope as described above, may then be used to move a bolus or any object located ahead of the collapsed lumen. Thus, the present subject matter may be tweaked to facilitate bowel movements in chronic constipation. A similar scenario is possible when the device is deployed in the esophagus via upper endoscopy or simply through the nasal or oral cavities, to aid in swallowing and movement of food in patients with gastric paralysis, or in controlling the motion of a capsule-based endoscopy.

[0066] In an implementation, the present subject matter is based on the principle that a vascular area associated with the esophageal lumen may be constricted on application of inward radial compression and associated collapse of the esophageal lumen. In an example, this is achieved by creating a seal over a localized area of the esophagus and the subsequent application of negative pressure. However, it will be understood that localized seals and the negative pressure may be created and applied in many other ways apart from those described above.

[0067] Although embodiments for providing radial inward compression of target lumen for multiple medical applications have been described in language specific to structural features and/or methods, it is understood that the invention is not necessarily limited to the specific features or methods described. Rather, the specific features and methods are disclosed as example embodiments for radial inward compression.

I/We claim:

1. A device (100, 800) to facilitate radial inward compression of a target lumen, the device (100, 800) comprising:

a tube (105, 705, 805);

one or more lumens (202, 710) provided in the tube (105, 705, 805);

a plurality of sealing units (130, 135) integrated into the tube (105, 705, 805) to delineate a segment of the target lumen to be subjected to the radial inward compression; and

a primary set of openings (410) provided between two sealing units (130, 135), from the plurality of sealing units (130, 135), to transmit negative pressure from the one or more one lumens (202, 710) to the delineated segment of the target lumen between the two sealing units (130, 135).

2. The device (100) as claimed in claim 1, wherein the tube (105, 805) has an elliptical cross-section.

3. The device (100) as claimed in claim 1, wherein the one or more one lumens (202) are disposed parallel to each other in the tube (105, 805).

4. The device (100, 800) as claimed in claim 1, wherein the tube (105, 705, 805) comprises an auxiliary set of openings (205) provided on the tube (105, 705, 805), the auxiliary set of openings (205) being provided proximal to a second end (110-2) of the tube (105, 705, 805).

5. The device (100, 800) as claimed in claim 1, wherein the device (100, 800) comprises a manifold connector (120) provided at an first end (110-1) of the tube (105, 705, 805), wherein the one or more lumens (202, 710) extend from the manifold connector (120) to a second end (110-2) of the tube (105, 705, 805).

6. The device (100, 800) as claimed in claim 5, wherein the device (100, 800) comprises a tube extension (115), corresponding to each of the one or more lumens (202, 710), coupled to the manifold connector (120).

7. The device (100, 800) as claimed in claim 6, wherein tube extensions (115) comprise:

a first tube extension (115-1) provided with at least one of a luer lock and a balloon-like identifier (123-1); and

a second tube extension (115-2) provided with a concentric cap (123-2).

8. The device (100, 800) as claimed in claim 1, wherein the device (100, 800) includes a mouthpiece (125) to secure the device (100, 800) to a patient.

9. The device (100, 800) as claimed in claim 1, wherein a sealing unit (135), from among the plurality of the sealing units (130, 135) is provided proximal to a second end (110-2) of the tube (105, 705, 805) to position a portion of the device (100, 800) inside a patient.

10. The device (100, 800) as claimed in claim 1, wherein the sealing unit (135) further comprises a flexible component (305), wherein the flexible component (305) is capable of conforming to a shape of the target lumen, when deployed.

11. The device (100, 800) as claimed in claim 10, wherein the sealing unit (135) further comprises at least one sealing component (310).

12. The device (100, 800) as claimed in claim 1, wherein each of the plurality of the sealing units (130, 135) includes one of a plurality of diaphragm (405, 810), a sealing balloon (305, 815), and a radio opaque marker.

13. The device (100, 800) as claimed in claim 1, wherein the plurality of the sealing units (130, 135) is made at least one of a flexible material, a shape memory alloy, and a magnetic material to enable the plurality of the sealing units (130, 135) to conform to a shape of the target lumen, when deployed.

14. The device (100, 800) as claimed in claim 1, wherein one or more components of the device (100, 800) are made of biodegradable material to allow it to internally disintegrate at a controlled rate over time, after initial deployment.

15. The device (800) as claimed in claim 1, wherein the tube (705, 805) includes a plurality of catheters (715), wherein each catheter (715) in the plurality of catheters (715) is concentric about a central axis of the tube (705, 805).

16. The device (800) as claimed in claim 15, wherein the plurality of catheters (715) include an external catheter (715-1) encasing at least one internal catheter (715-2, 715-3), and wherein the external catheter (715-1) defines a first lumen (710) and the at least one internal catheter (715-2, 715-3) defines an internal concentric lumen (710-2, 710-3).

17. The device (800) as claimed in claim 15, wherein the primary set of openings (410) is provided on an internal catheter (715-3) from amongst the plurality of catheters (715).

18. The device (800) as claimed in claim 15, wherein the device (800) includes an additional guide wire provided in an internal concentric lumen (710-3), from the one or more lumens (710).

19. The device (100, 800) as claimed in claim 1, wherein the device (100, 800) comprises visual markings to provide for insertion of the device (100, 800) in the target lumen.

20. A method for deploying a device (100, 800) facilitating radial inward compression of a target lumen, the method comprising:

inserting a tube (105, 705, 805) into the target lumen;

positioning the tube (105, 705, 805) inside the target lumen by deploying a positioning unit (135) at the target lumen; and

applying negative pressure to a lumen (202, 710) of the tube (105, 705, 805) to create a pressure differential before and after a sealing unit (130) to conform and adhere the sealing unit (130) to the target lumen.

21. The method as claimed in claim 20, wherein the method further comprises increasing the negative pressure to evacuate all contents of the target lumen in the volume enclosed between the sealing unit (130) and the positioning unit (135) in order to cause radial inward compression of the target lumen.

22. The method as claimed in claim 20 further comprises inflating a flexible component (305) of the sealing unit (135) to provide a seal between the sealing unit (130) and the positioning unit (135).

23. A device (100, 800) to facilitate radial inward compression of a target lumen, the device (100, 800) comprising:

a tube (105, 705, 805) having a first end (110-1) and a second end (110-2);

a plurality of lumens (202, 710) provided in the tube (105, 705, 805);

a manifold connector (120) provided at the first end (110-1) of the tube (105, 705, 805), wherein the plurality of lumens (202, 710) extend from the manifold connector (120) to the second end (110-2); and

a tube extension (115), corresponding to each of the plurality of lumens (202, 710), coupled to the manifold connector (120), wherein tube extensions (123) comprise,

a first tube extension (115-1) provided with at least one of a luer lock and a balloon-like identifier (123-1); and

a second tube extension (115-2) provided with a concentric cap (123-2).

5

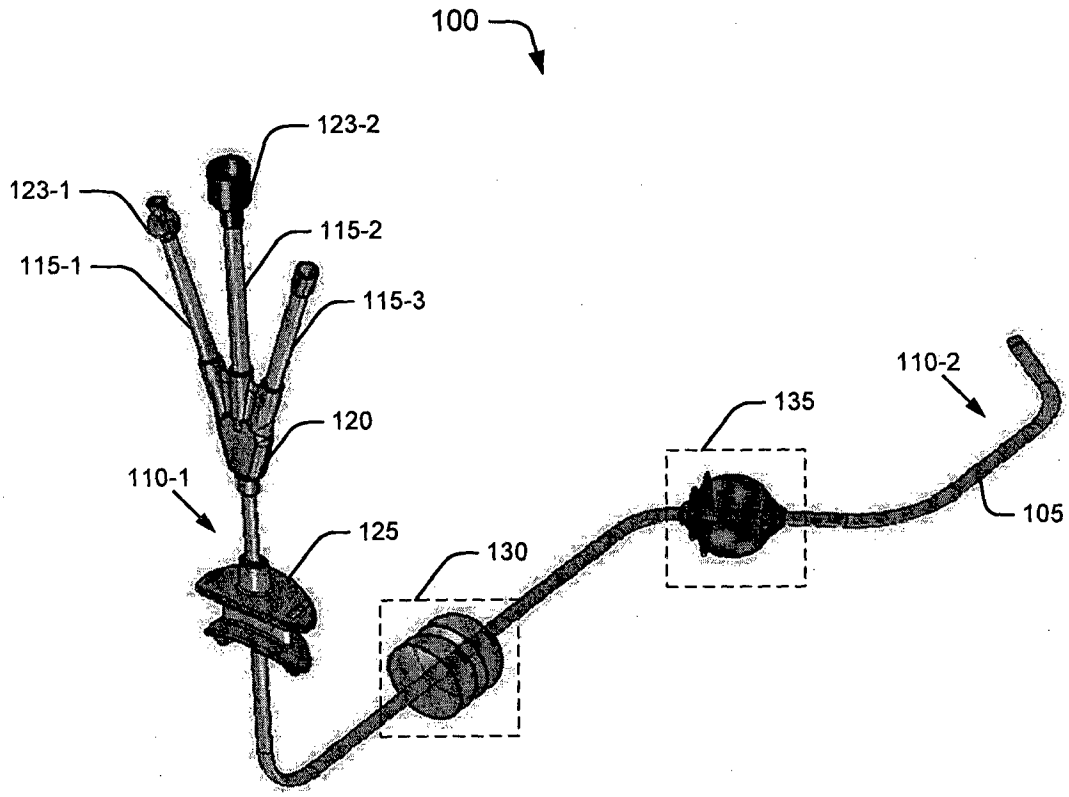


Fig. 1

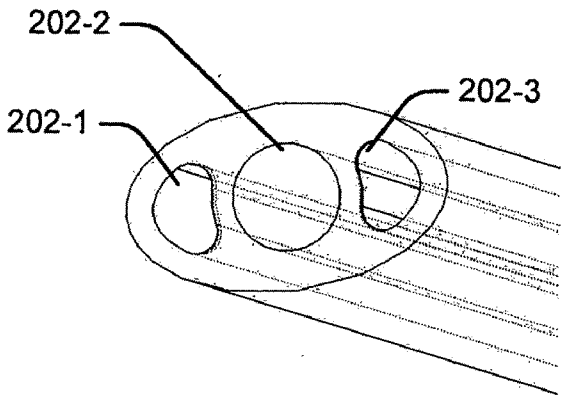


Fig. 2a

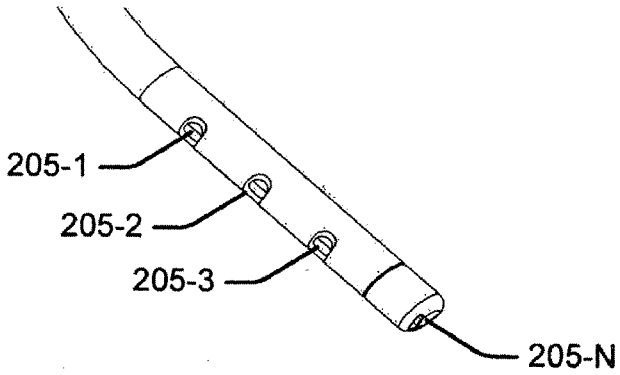


Fig. 2b

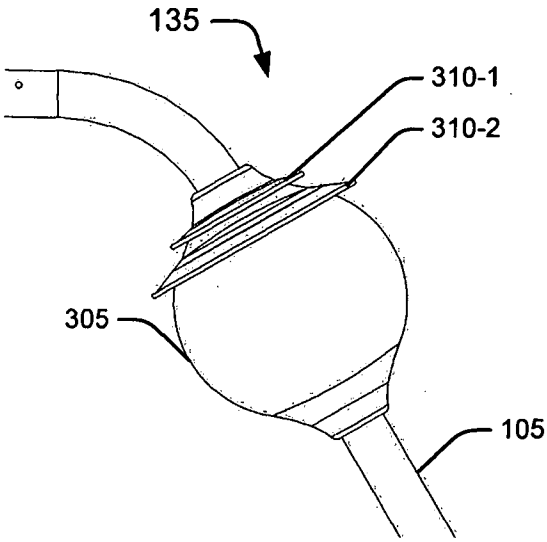


Fig. 3

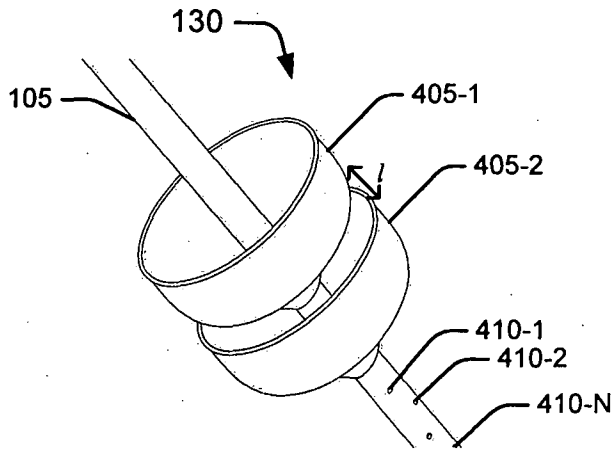


Fig. 4

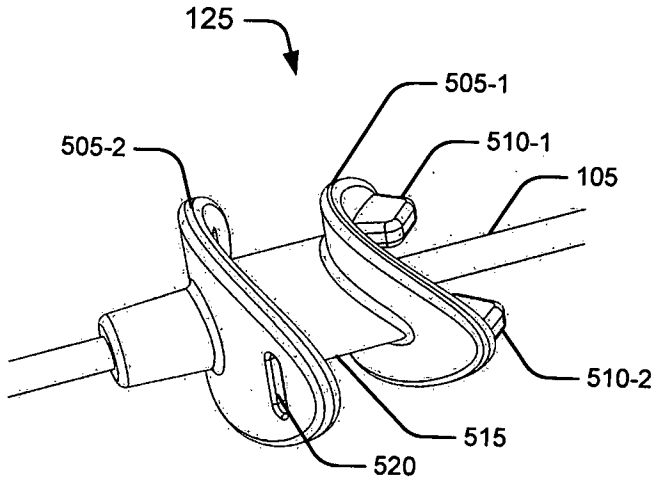


Fig. 5

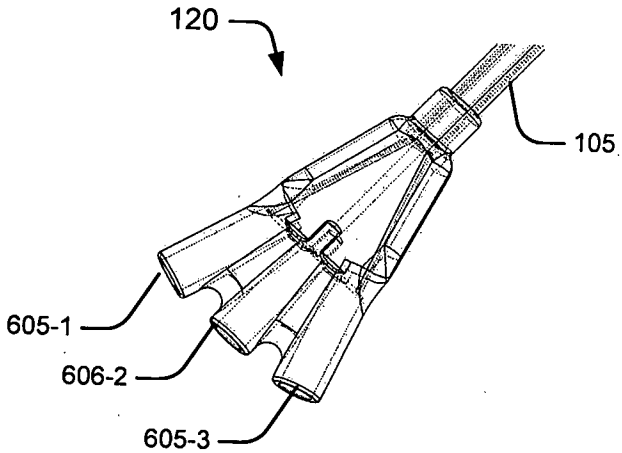


Fig. 6

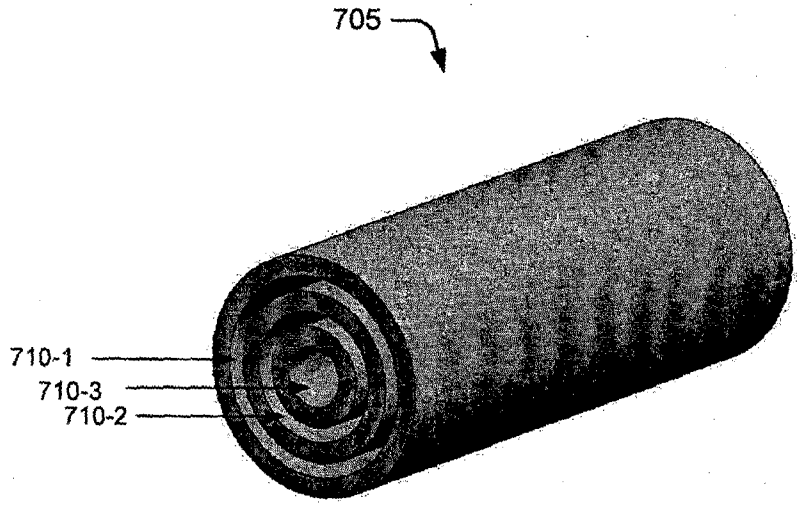


Fig. 7a

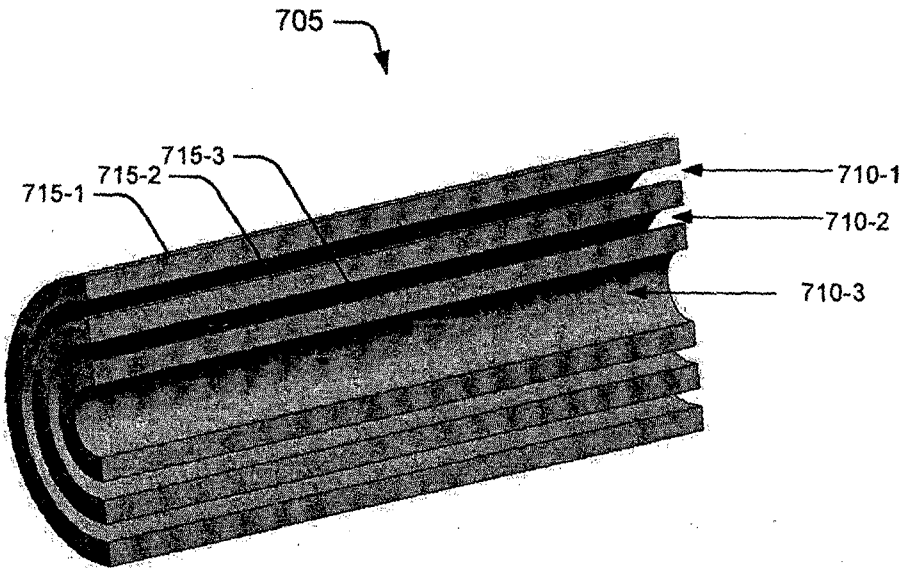


Fig. 7b

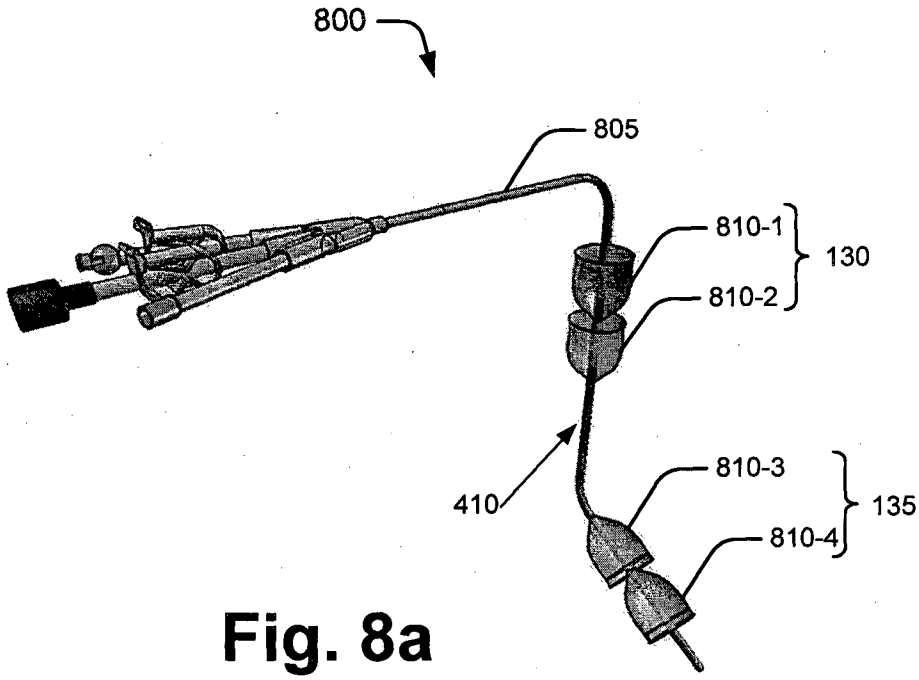
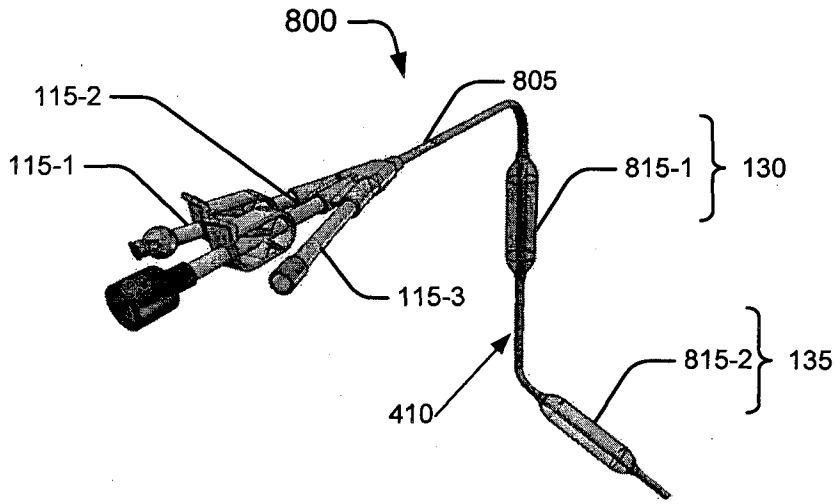

800
805
810-1
130
810-2
410
810-3
135
810-4

Fig. 8a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815-1
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135
410

Fig. 8b

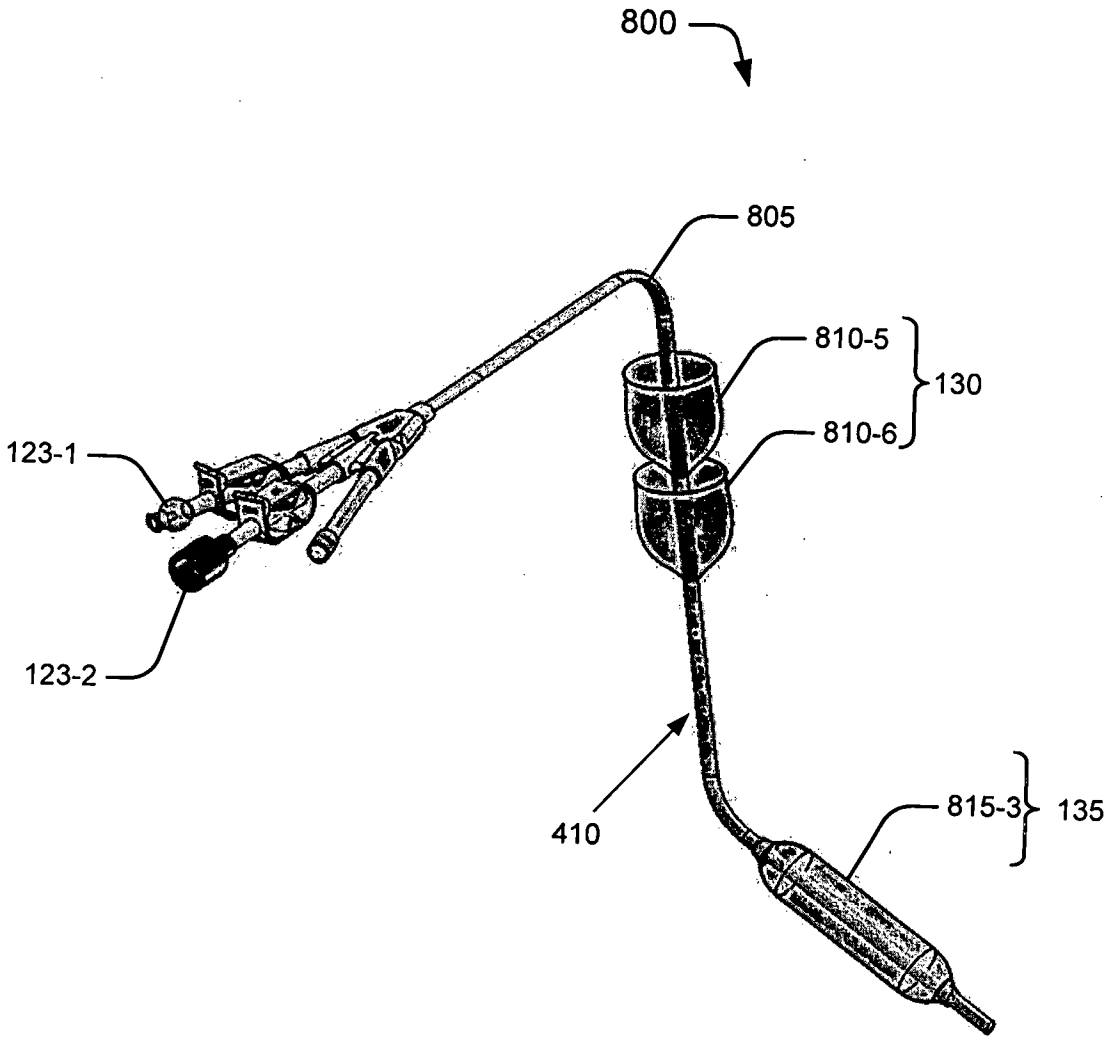

Fig. 8c