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(54) **METHODS AND DEVICES CONFIGURED TO PREVENT ASPIRATION**

(71) Applicant: **Emory University**, Atlanta, GA (US)

(72) Inventor: **Anand Jain**, Atlanta, GA (US)

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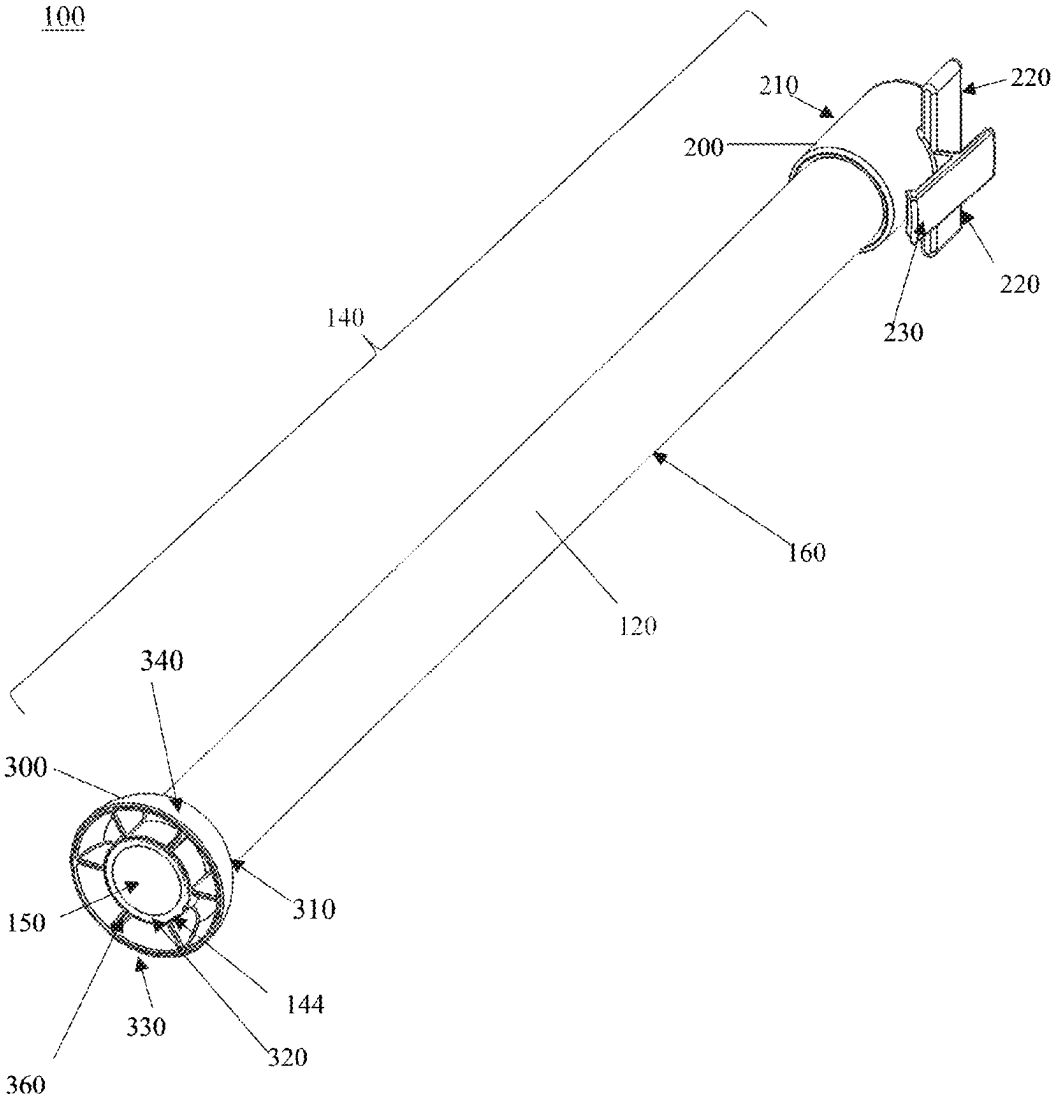
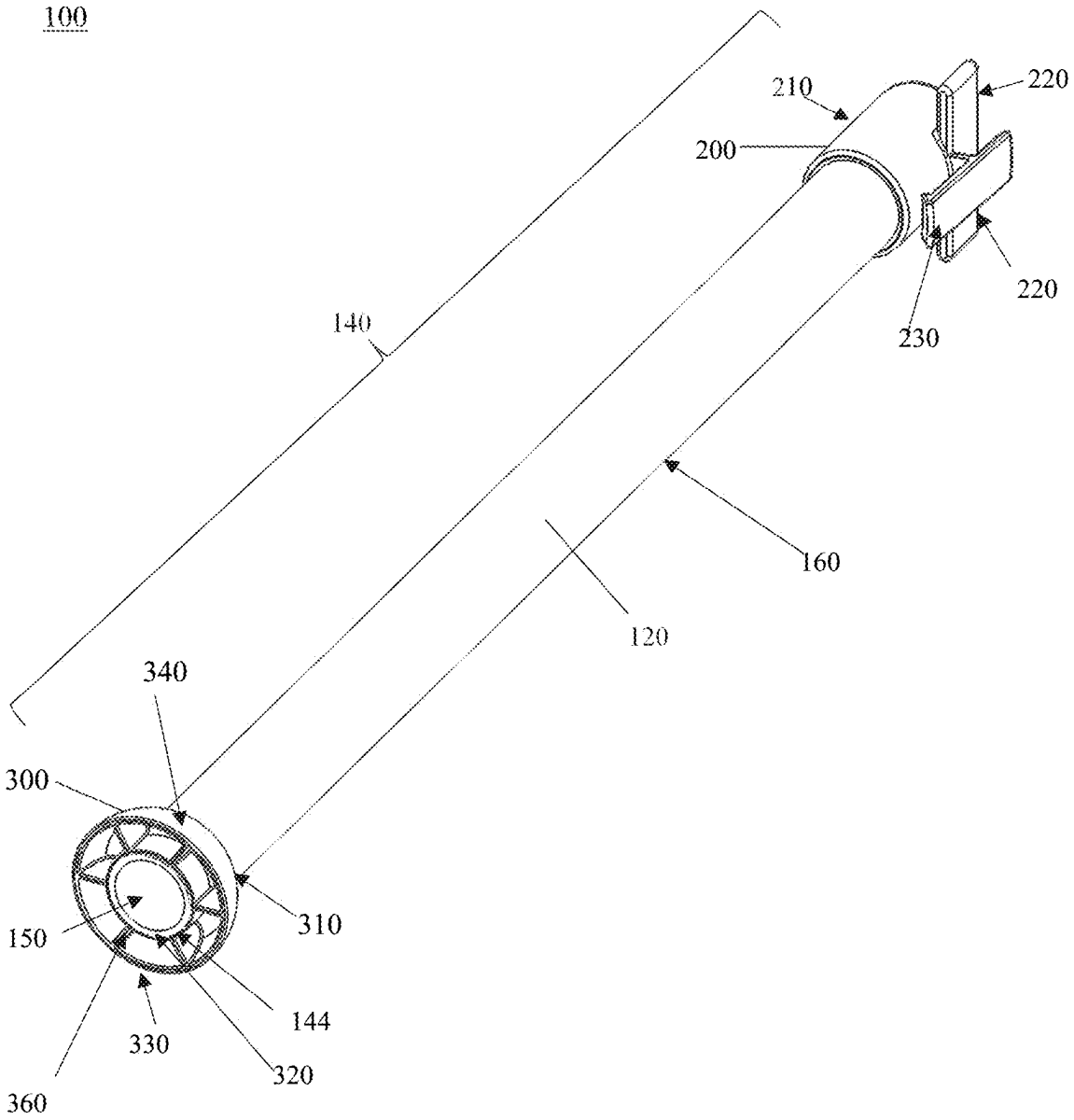
(57) **ABSTRACT**

The present disclosure relates to systems and methods for preventing aspiration. In one implementation, the systems may include devices that can be used during gastrointestinal (GI) endoscopic procedures to prevent pulmonary aspiration and avoid esophageal pinch injury. The device may include a tube including a central lumen disposed along its length. The central lumen may be configured to receive an instrument. The device may include an occluder disposed at an end and including a lumen along its length. The occluder may have an outer surface that extends between a first circumference at its first end and a third circumference at its second end and a lumen that extends between the first circumference and the second circumference at its second end. The occluder may be configured to reversibly collapse to one or more collapsed configurations with respect to the tube. The occluder may be biased to an expanded configuration.

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210
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200
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230
140
160
120
340
300
310
150
144
330
320
360

FIG. 1

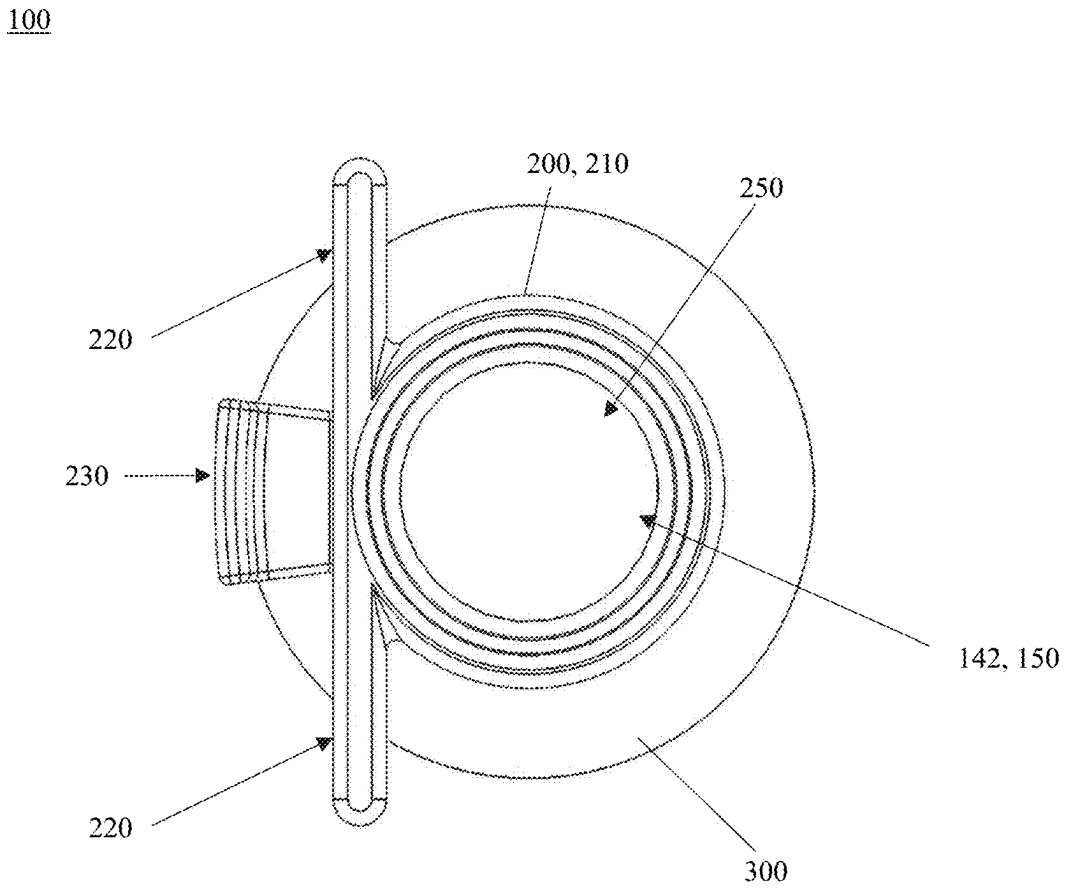
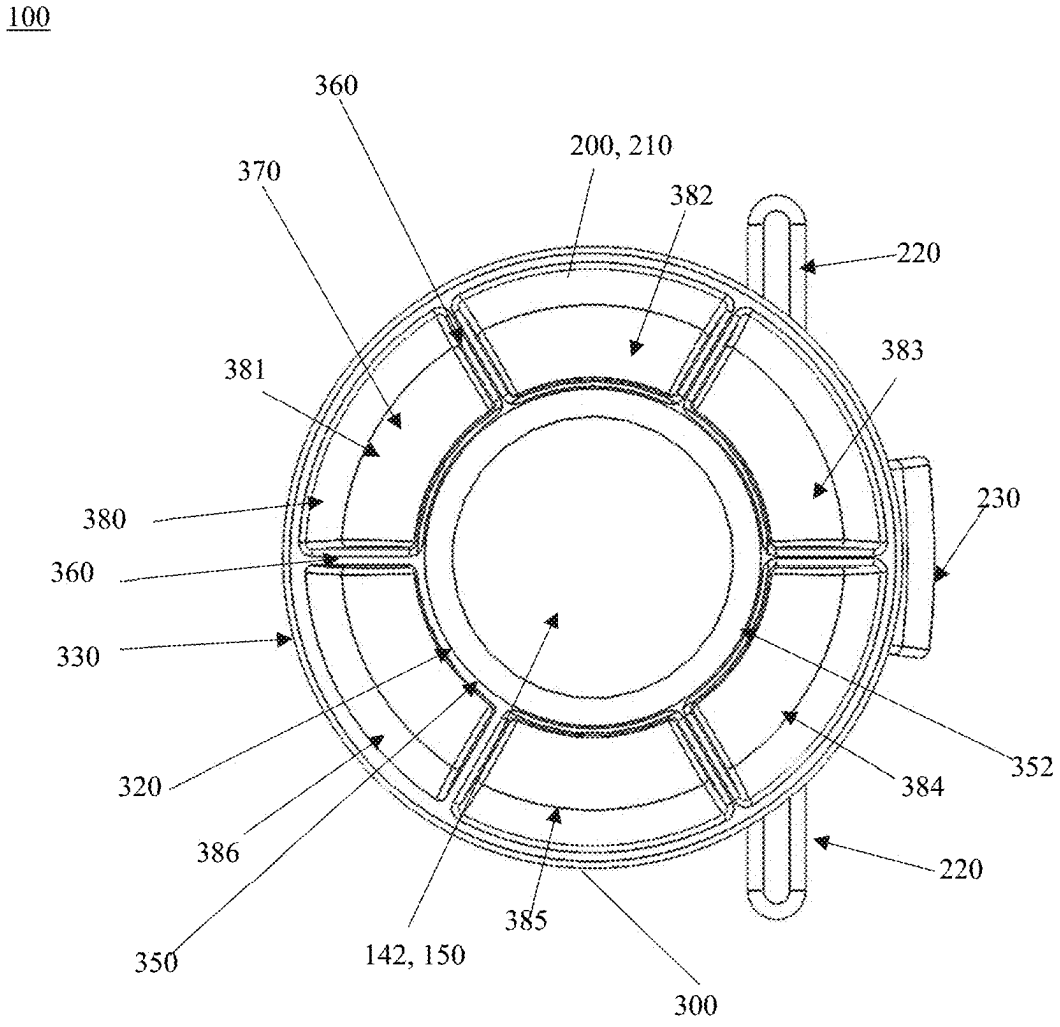


FIG. 2


100
360
200, 210
370
382
220
381
383
230
380
360
330
320
352
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386
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385
350
142, 150
300

FIG. 3

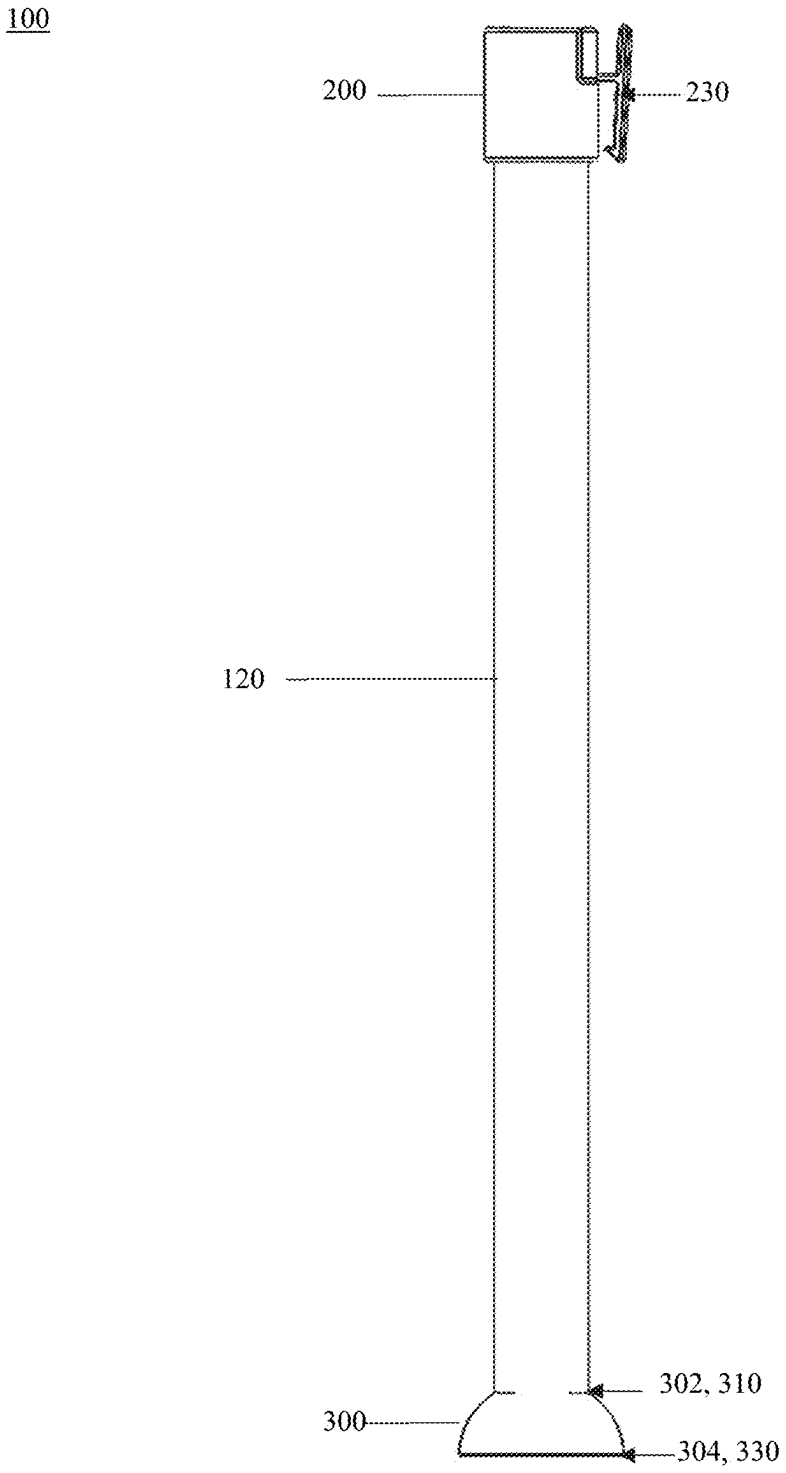

FIG. 4

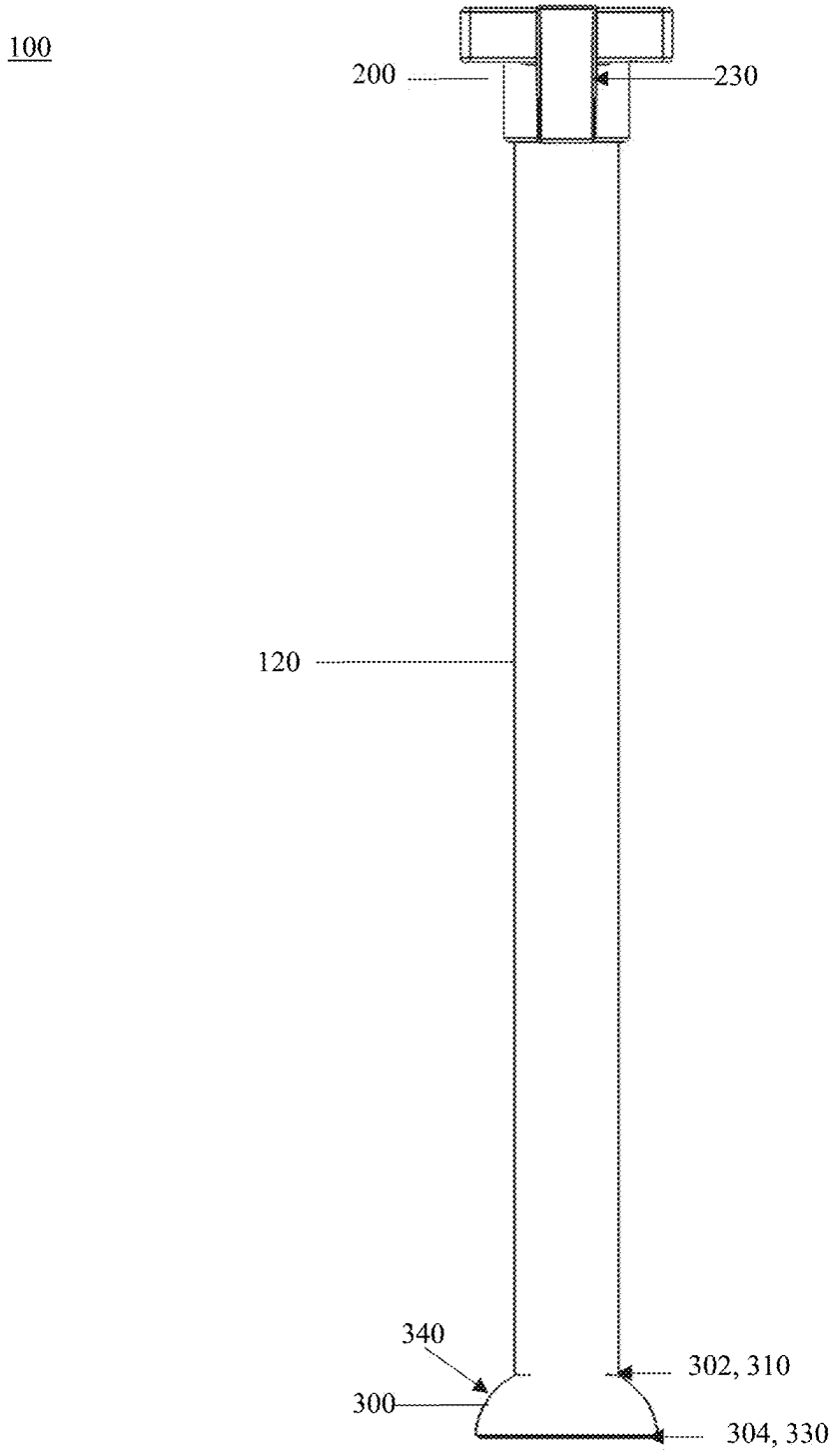

FIG. 5A

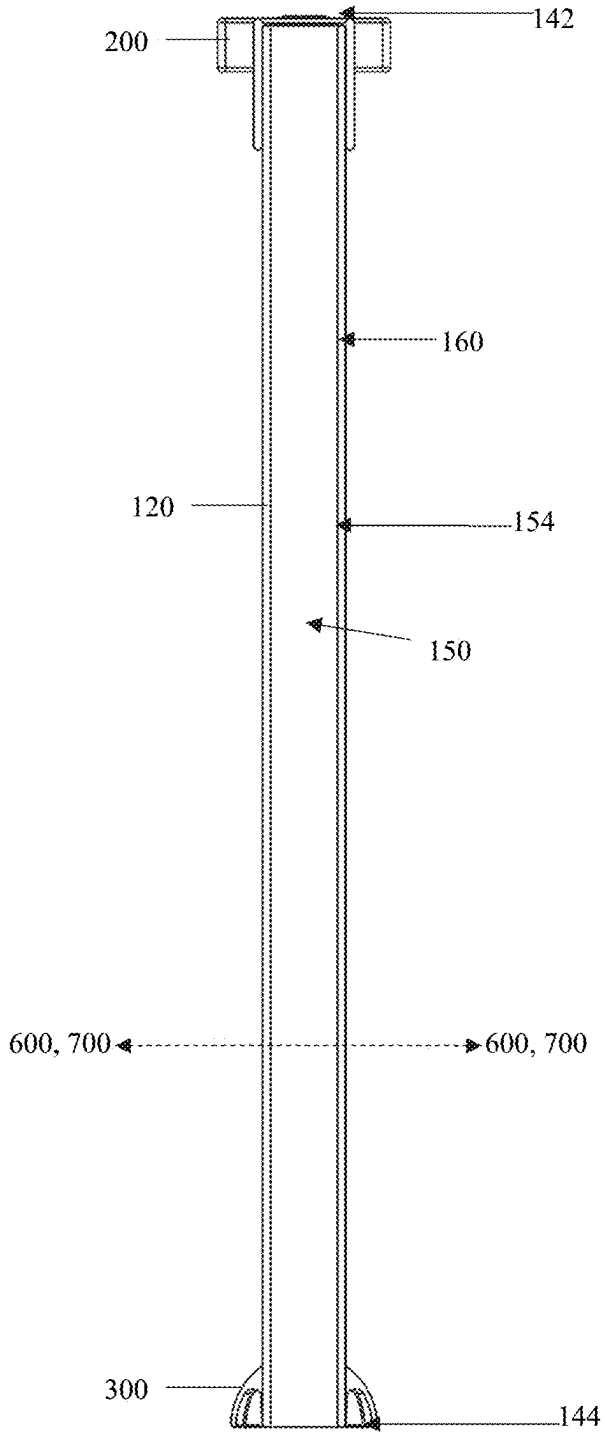

FIG. 5B

600

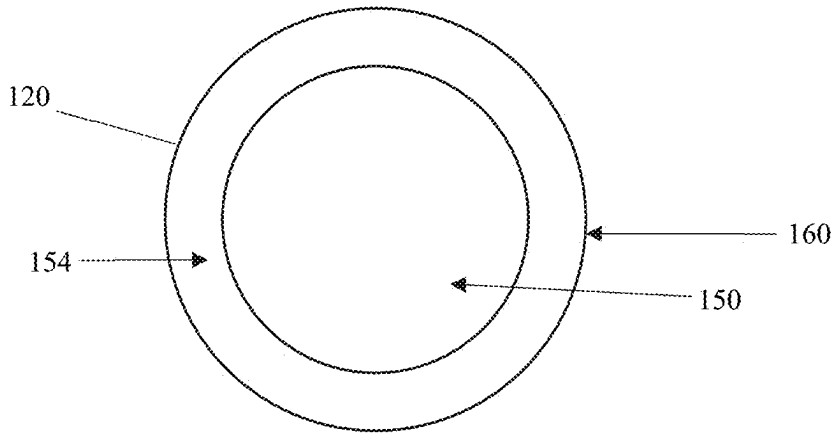

FIG. 6

700

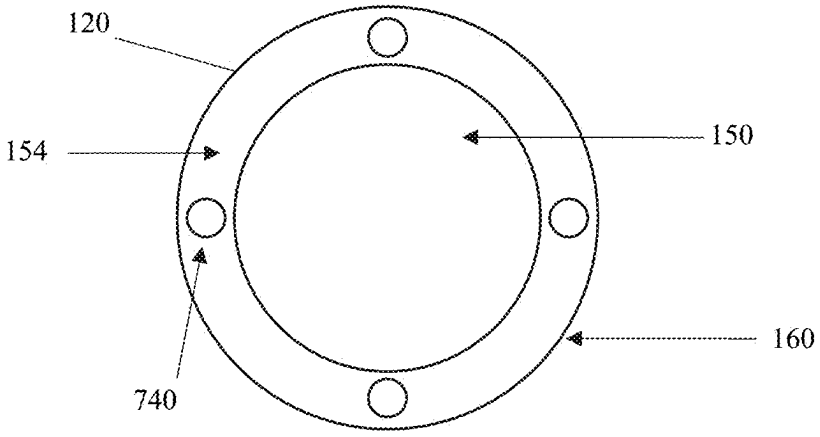

FIG. 7

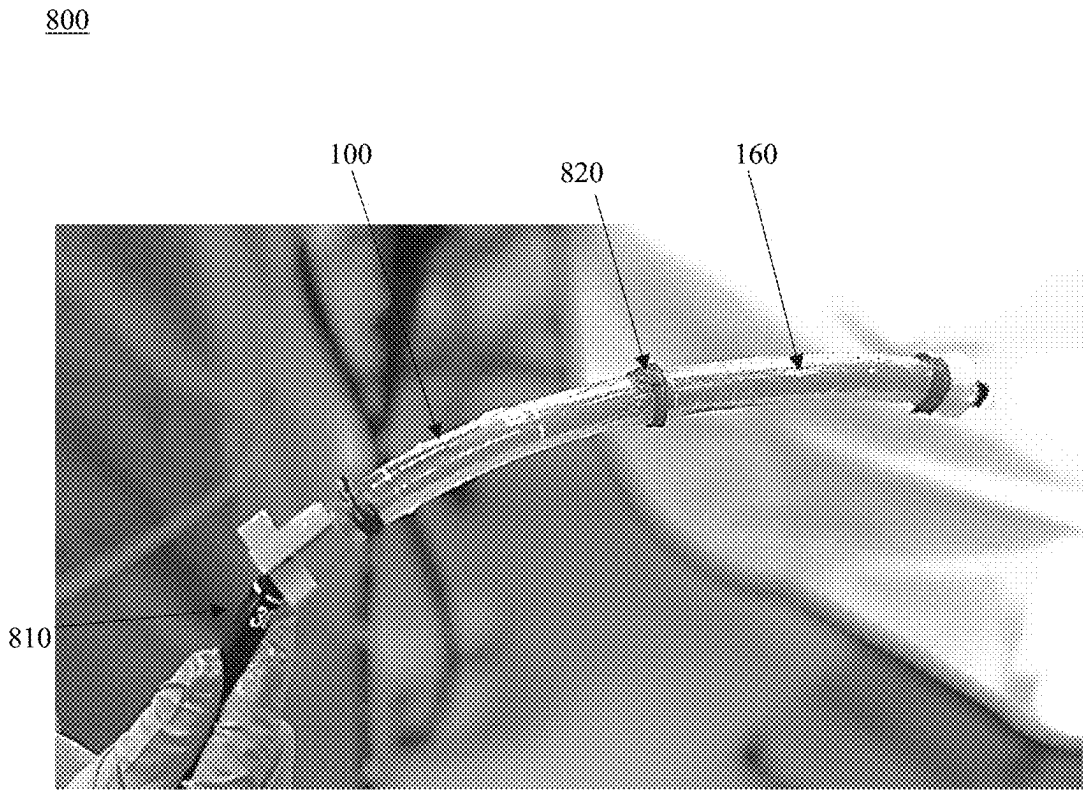

FIG. 8

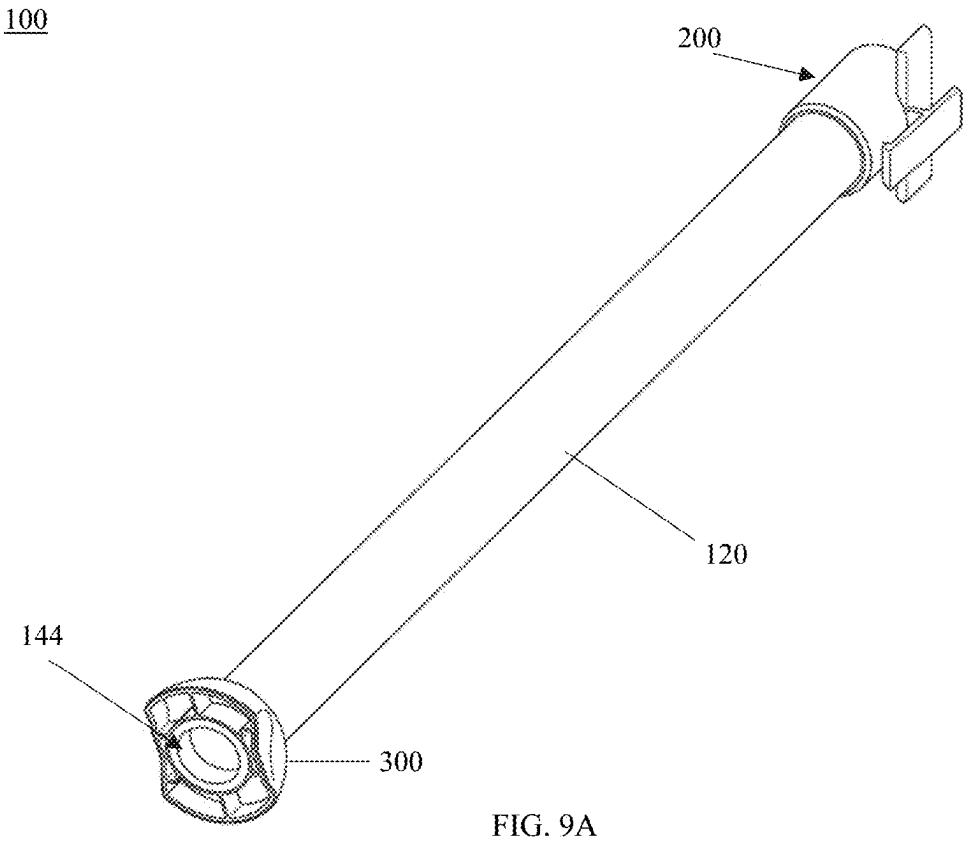
100
200
120
144
300

FIG. 9A

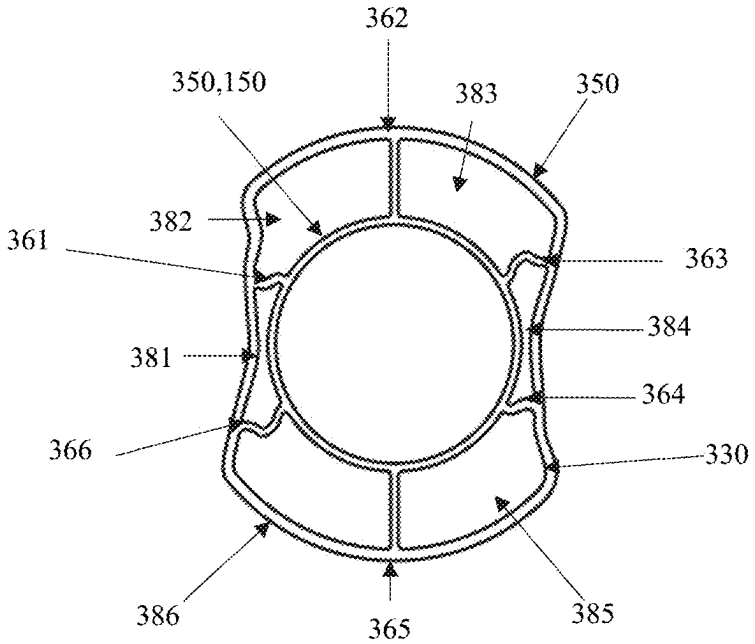
362
350,150
383
350
382
361
363
384
381
364
366
330
386
365
385

FIG. 9B

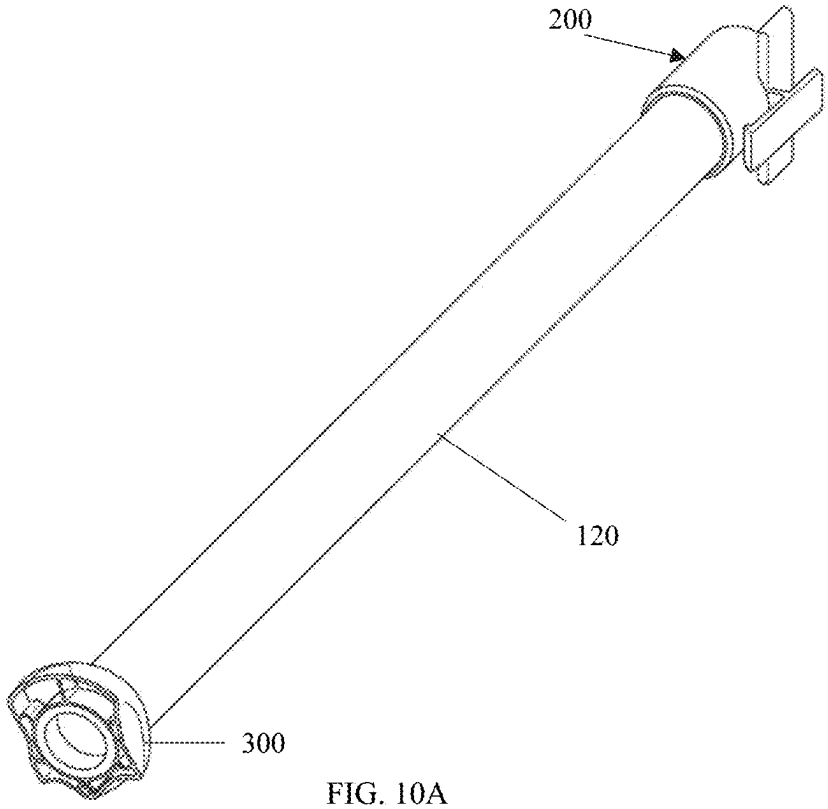

FIG. 10A

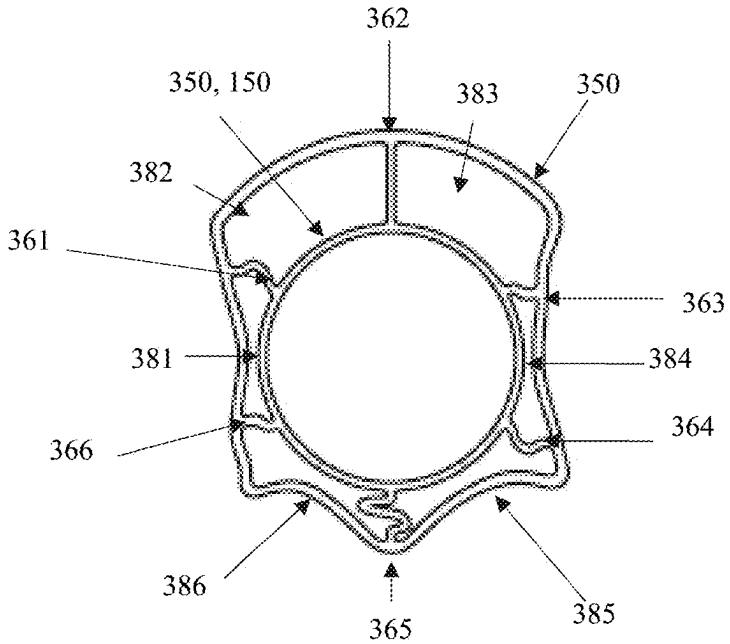

FIG. 10B

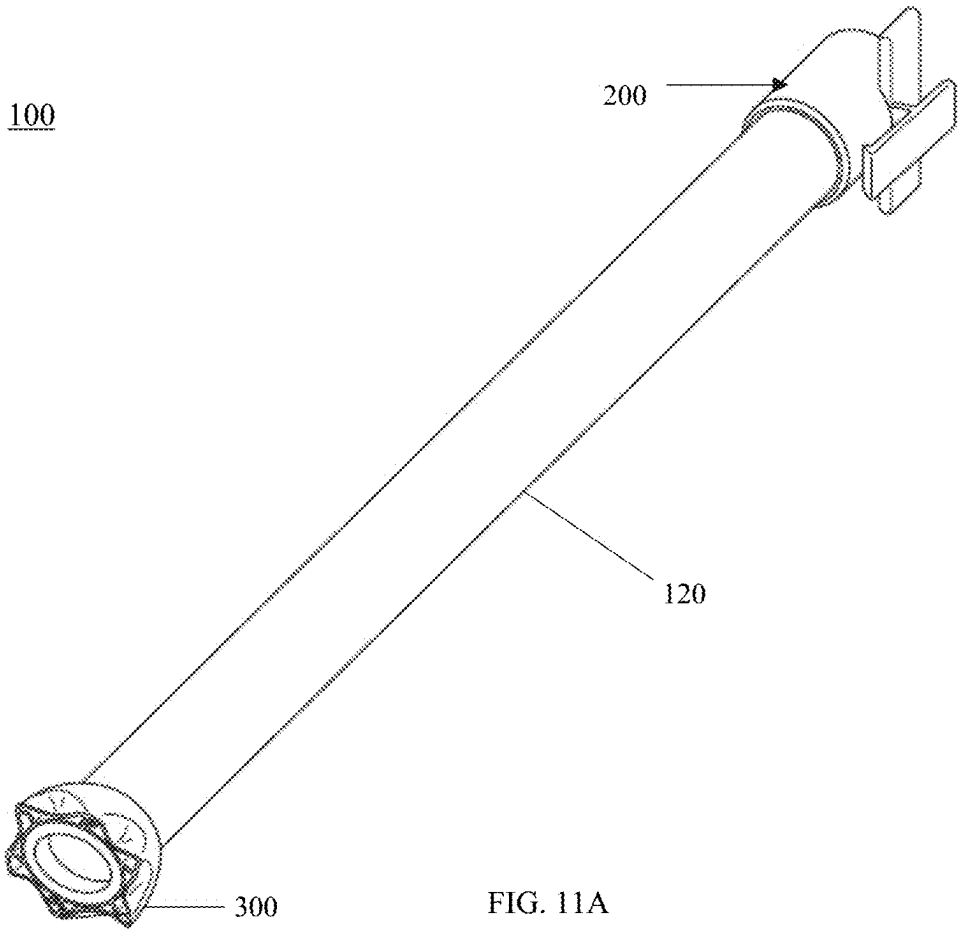

FIG. 11A

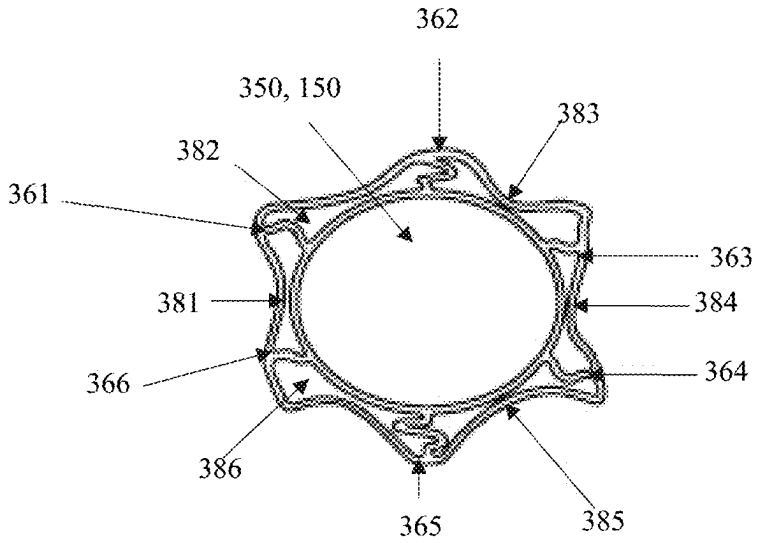

FIG. 11B

METHODS AND DEVICES CONFIGURED TO PREVENT ASPIRATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 63/553,891 filed Feb. 15, 2024. The entirety of this application is hereby incorporated by reference for all purposes.

BACKGROUND

[0002] Upper gastrointestinal (GI) endoscopic procedures are commonly performed to investigate, diagnose, and/or treat conditions affecting the upper part of the digestive system (esophagus, stomach, duodenum). During these procedures, an endoscope is threaded through the mouth and into the digestive system so that a clinician can diagnose and/or treat conditions of the upper part of the digestive system, such as the esophagus, the stomach, and an upper portion of the small intestine (e.g., duodenum). Normally, this procedure is performed and/or attempted to be performed under sedation, for example, using propofol, without general anesthesia. However, this procedure can have a risk of pulmonary aspiration from retained stomach or esophageal continents. This risk can be increased for those patients who have certain conditions (e.g., patients with gastroesophageal reflux disease who have an incompetent lower esophageal sphincter barrier).

[0003] To reduce this risk, endoscopic GI procedures will generally be performed under general anesthesia; thereby increasing the risk of complications associated with the procedure, as well as resource and financial costs. Additionally, during GI endoscopic procedures, patients can be at risk of pharyngeal perforation as a result of a pinch injury. This can occur when the esophageal diameter is larger than the diameter of the endoscope but smaller than a typical overtube. As the overtube advances over the endoscope, pharyngeal or esophageal tissue can involute in between the endoscope and the overtube, and a certain amount of force exerted on the pinched pharyngeal or esophageal tissue can cause it to perforate.

SUMMARY

[0004] Thus, there is a need for an overtube that can successfully reduce the potential for GI fluid to be aspirated into the lungs while allowing for an endoscopic procedure to be performed under sedation without general anesthesia and preventing pharyngeal or esophageal pinch injury.

[0005] The devices disclosed herein relates generally to endoscopic overtubes that can be used during GI endoscopic procedures to prevent pulmonary aspiration and avoid esophageal pinch injury.

[0006] In some examples, the devices may include a device that includes a tube. The tube may have a first end, a second end, and a length there between. The tube may include a central lumen. The device may also include an occluder disposed at the second end of the tube. The occluder may have a first end, a second end, and a length there between. The occluder may include a lumen disposed along the length. The occluder may have a first circumference at the first end, and a second circumference and a third circumference at the second end. The third circumference may be larger than the first circumference and the second circumference. The occluder may have an outer surface extending between the first circumference and the third circumference. In some examples, the occlude may include a lumen extending between the first circumference and the second circumference. The occluder may be configured to reversibly collapse to one or more collapsed configurations with respect to the tube. The occluder may be biased to an expanded configuration.

[0007] In some examples, the device may also include an adapter. The adapter may be disposed at the first end of the tube. In some examples, the adapter may include a clip configured to attached onto an instrument. In some examples, the second circumference may correspond to the central lumen and/or surround the tube.

[0008] In some examples, the methods may include a method of occluding a lumen of a body. The method may include providing the device. The method may include advancing the device over an instrument disposed within a body lumen to a region of interest within the body lumen so that the occluder engages surrounding tissue of the body lumen while the device is advanced until the device reaches the region of interest. In some examples, if the device encounters resistance from the surrounding tissue when advanced along the body lumen towards the region of interest, the occluder may move from the expanded configuration to the one or more of the collapsed configurations. In some examples, when the device is at the region of interest, the occluder may be in a more expanded configuration so as to occlude the body lumen. The method may include performing a procedure with the other device when the occluder is in the more expanded configuration at the region of interest.

[0009] Additional advantages of the disclosure will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the disclosure. The advantages of the disclosure will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the disclosure, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The disclosure can be better understood with the reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis being placed upon illustrating the principles of the disclosure.

[0011] FIG. **1** shows an isometric view of a device according to embodiments.

[0012] FIG. **2** shows a top view of the device shown in FIG. **1**.

[0013] FIG. **3** shows a bottom view of the device shown in FIG. **1**.

[0014] FIG. **4** shows a side view of the device shown in FIG. **1**.

[0015] FIG. **5**A shows a front view of the device shown in FIG. **1**.

[0016] FIG. **5**B shows a cross-sectional view of the device as shown in FIG. **5**A.

[0017] FIG. **6** shows a cross-sectional view of the device shown in FIG. **1** according to embodiments.

[0018] FIG. **7** shows another cross-sectional view of the device shown in FIG. **1** according to embodiments.

[0019] FIG. **8** shows an example of a prototype of the device according to embodiments.

[0020] FIGS. **9**A and **9**B show views of the device shown in FIGS. **1-7** in an example of a collapsed configuration according to embodiments. FIG. **9**A shows an isometric view of the device in the example of the collapsed configuration and FIG. **9**B shows a bottom view of the device shown in FIG. **9**A.

[0021] FIGS. **10**A and **10**B show views of the device shown in FIGS. **1-7** in another example of a collapsed configuration according to embodiments. FIG. **10**A shows an isometric view of the device in the other example of the collapsed configuration and FIG. **10**B shows a bottom view of the device shown in FIG. **10**A.

[0022] FIGS. **11**A and **11**B show views of the device shown in FIGS. **1-7** in another example of a collapsed configuration according to embodiments. FIG. **11**A shows an isometric view of the device in the other example of the collapsed configuration and FIG. **11**B shows a bottom view of the device shown in FIG. **11**A.

DESCRIPTION OF THE EMBODIMENTS

[0023] In the following description, numerous specific details are set forth such as examples of specific components, devices, methods, etc., in order to provide a thorough understanding of embodiments of the disclosure. It will be apparent, however, to one skilled in the art that these specific details need not be employed to practice embodiments of the disclosure. In other instances, well-known materials or methods have not been described in detail in order to avoid unnecessarily obscuring embodiments of the disclosure. While the disclosure is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that there is no intent to limit the disclosure to the particular forms disclosed, but on the contrary, the disclosure is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

[0024] The disclosed embodiments may relate to devices that can be used as an endoscopic overtube that can prevent pulmonary aspiration and avoid esophageal pinch injury, such as, during GI endoscopic procedures. In some embodiments, the device may include an occluder configured to occlude a body lumen in which it is delivered to prevent the outflow of contents, such as those in the stomach. In some examples, when in its expanded configuration, the occluder may be configured to splay the tissue of the body lumen so as to minimize or prevent a pinch injury in that tissue. By way of example, the occluder may be configured to splay the pharyngeal or esophageal tissue during the advancement of the device into the esophagus, such as to minimize the risk of pharyngeal or esophageal pinch injury. In some examples, the occluder may include spaced internal ribs configured to stabilize the occluder and to bias the occluder to its expanded configuration as it is passed through a body lumen, such as the esophagus. In some examples, the occluder may have a diameter wider than the body/tube of the device so that it can be configured to displace/splay the esophageal tissue at the leading edge as the device is advanced, creating a path for the device and minimizing risk of pinch injury. This way, the occluder may have three functions: 1) block refluxate, 2) stabilize position of the tube; and 3) splay the pharyngeal and esophageal tissue during advancement of the device so as to minimize the risk of crimp/pinch injury.

[0025] The devices and methods of the disclosure are described with respect to upper gastrointestinal procedures and esophagus. For example, the disclosed devices and methods can be used with another instrument, such as any gastrointestinal endoscope, and can be configured to prevent aspiration and pinch injury so that a diagnostic or investigational procedure may be performed in the gastrointestinal region without the need of general anesthesia. However, it will be understood that the devices and methods are not limited to this type of gastrointestinal procedure and device. The devices and methods may be used with an endoscope for any gastrointestinal procedure performed within the esophagus or a different body lumen, with an endoscope for a procedure performed in a different body lumen, with another instrument for a different procedure performed in a different body lumen, by itself, or any combination thereof. For example, the devices and methods can be used with a surgical laparoscope, colonoscope, small bowel enteroscope, ureteroscope, hysteroscope, among others, or any combination thereof. By way of another example, the devices and methods may be used with any procedure to improve visualization by displacing areas of tissue within a body lumen to provide a clear path. For example, the devices and methods may be used with an endoscope during a pancreatic necrosectectomy to improve visualization.

[0026] FIGS. **1-11**B show an example of device **100** according to some embodiments. FIGS. **1-11**B shows an example of the device **100** in which the device **100** can act as a flexible overtube. In some embodiments, the device **100** may include a body or tube **120**. In some embodiments, the tube **120** may be configured to surround the sheath or tube of another instrument, such as a GI endoscope.

[0027] In some embodiments, the tube **120** may have a first end **142**, a second end **144**, and a length **140** there between. In some embodiments, the tube **120** may have a central lumen **150** disposed along the length **140**. The central lumen **150** may be configured to receive and surround an insertable portion of an instrument, such as a GI endoscope. In some embodiments, the diameter of the central lumen **150** may be sized so that the instrument, such as a gastrointestinal instrument, such as GI endoscope, can advance/retract through to/from the desired procedural region.

[0028] In some embodiments, the tube **120** may be made of one or more biocompatible materials. For example, the one or more biocompatible materials may be flexible. By way of example, the one or more materials may include but is not limited to polybutylene succinate (PBS), polylactide (PLA), acrylate butadiene styrene (ABS), resin, silicone, among others, or in a combination thereof.

[0029] In some embodiments, the tube **120** may be transparent. In some examples, the tube **120** may be semi-transparent or fully transparent.

[0030] In some embodiments, the tube **120** may have an outer surface **160**. In some embodiments, the tube **120** may include a wall **154** disposed between the central lumen **150** and the outer surface **160**. In some examples, as shown in the cross-section **600** in FIG. **6**, the wall **154** of the tube **120** may be solid. In some examples, as shown in the cross-section **700** shown in FIG. **7**, the wall **154** of the tube **120** may include one or more channels **740** configured to receive and/or deliver one or more instruments, such as probe(s),

suction instrument(s), irrigation instrument(s), among other instrument(s), or any combination thereof.

[0031] In some embodiments, the dimensions (e.g., length, diameter, etc.) and/or other features (i.e., flexibility/stiffness) of the tube **120** may depend on the delivery site and/or instruments to be delivered. For example, the tube **120** may be stiffer, longer, and wider when used as a laparoscopic surgical port where instruments need to be advanced deep into the abdomen.

[0032] In some embodiments, the device **100** may include one or more features (not shown) disposed on the outer surface **160** of the tube **120**. By way of example, the one or more additional features may include but is not limited to one or more of: inflatable balloons, stents, stitching devices, snares, ablation devices, hooks for loop reduction, sensors, medications, biocompatible lubricants, among others, or any combination thereof.

[0033] In some embodiments, the device **100** may include an adapter **200** disposed at the first end **142** and an occluder **300** disposed at the second end **144**. In some embodiments, the adapter **200** and the occluder **300** may partially surround the tube **120** and/or have an opening that corresponds to the central lumen **150**.

[0034] In some examples, the adapter **200** may be disposed on the outer surface **160** of the tube **120** and may have an opening **250** that corresponds to the central lumen **150**. In some embodiments, the adapter **200** may have an anchoring member **230** configured to anchor to another instrument or device, such as a bite guard. For example, the anchoring member **230** may be configured to clip onto a bite guard. In some examples, the anchoring member **230** may include a set of wings **220** disposed on opposing sides.

[0035] In some embodiments, the adapter **200** may be made of one or more biocompatible materials. By way of example, the one or more materials may include but is not limited to polybutylene succinate (PBS), polylactide (PLA), acrylate butadiene styrene (ABS), resin, silicone, among others, or in a combination thereof.

[0036] In some examples, the device **100** may have an alternative adapter or no adapter. For example, the geometry and shape of the adapter **200** may depend on the site of the procedure and/or instrument or device to which to be anchored. By way of example, the adapter **200** may have a different-shaped anchoring member. For example, the adapter **200** may have a different anchoring member **230** configured to anchor to an instrument or device.

[0037] In some embodiments, the occluder **300** may have a first end **302**, a second end **304**, and a length there between. In some examples, the occluder **300** may be configured to move between an expanded configuration with respect to the tube **120** shown in FIGS. **1-7** and one or more collapsed configurations with respect to the tube **120**, for example, as shown in FIGS. **9A-11B**. In some examples, the occluder **300** shown in FIGS. **1-7** may be biased to the expanded position as shown in FIGS. **1-7** so that the expanded configuration is the default configuration. In this example, the occluder **300** may be configured to collapse from the expanded configuration to a collapsed configuration upon application of force and/or resistance, for example, by surrounding body lumen. For example, one or more sections of the occluder **300** may be configured to reversibly collapse with respect to the tube **120** when advanced through a body lumen having a circumference that is smaller than the occluder **300**. This way, the occluder **300** may easily and reversibly conform to the patient's anatomy by enabling displacement of the surrounding tissue laterally and distally, such as to allow smooth advancement of the device **100** and minimize tissue trauma. FIGS. **9A-11B** show examples of the device **100** in collapsed configurations.

[0038] In some embodiments, the occluder **300** may have a first circumference **310** disposed at the first end **302**, and a second circumference **320** and a third circumference **330** disposed at the second end **304**. The third circumference **330** may correspond to an outer circumference and the second circumference **320** may correspond to an inner circumference at the second end **304**. In some examples, the third circumference **330** may be larger than the first circumference **310** and the second circumference **320**. In some embodiments, the occluder **300** may include a central lumen **350** that extends between the first circumference **310** and the second circumference **320**. The central lumen **350** may correspond to the inner surface of the occluder **300**. In some examples, the occluder **330** may include at least one opening **352** disposed at the second end **304** that interfaces with the central lumen **350**.

[0039] In some examples, the occluder **300** may at least partially surround the outer surface **160** of the tube **120**. For example, at least a portion of the tube **120** may be disposed within the central lumen **350**, for example, as shown in FIGS. **3-5B**. In some examples, the second end **304** of the occluder **300** may align with the second end **144** of the tube **120** so that the opening **352** corresponds to and interfaces with the central lumen **150**. In other examples, the occluder **300** may be integrated with the tube **120**.

[0040] In some embodiments, the occluder **300** may have an outer surface **340** extending between the first circumference **310** and the third circumference **330**. In some examples, the outer surface **340** of the occluder **300** may flair (taper) between the first circumference **310** to the third circumference **330** when in the expanded configuration.

[0041] In some embodiments, the occluder **300** may include a plurality of ribs **360** spaced disposed so as to extend along the length between the second circumference **320** and the third circumference **330**. In some embodiments, the plurality of ribs **360** may be spaced apart with respect to the central lumen **350** by an empty space **370** between each set of ribs **360** and the third circumference **330** and the second circumference **320**. In some embodiments, the plurality of ribs **360** may be evenly spaced with respect to the second circumference **320** and the third circumference **330** of the occluder **300**. In some embodiments, the dimensions of the plurality of the ribs **360** may be substantially the same. The plurality of ribs **360** may include any number of ribs and is not limited to the six ribs (the **361**, **362**, **363**, **364**, **365**, and **366**) shown.

[0042] In some embodiments, the occluder **300** may include a plurality of sections **380**. In some examples, each section **380** may correspond to the empty space **370** defined by a set of ribs **360**, the second circumference **320**, and the third circumference **330**. In some examples, the sections **380** may have substantially the same dimensions, as shown. In other examples, the sections **380** may have different dimensions.

[0043] In some embodiments, the occluder **300** may include six sections **380** as shown in FIGS. **1-7** and **9A-11B**. For example, the sections **380** may include a first section **381** defined by the set of ribs **361** and **366**; a second section **382** defined by the set of ribs **361** and **362**; a third section **383**

defined by the set of ribs **362** and **363**; a fourth section **384** defined by the set of ribs **363** and **364**; a fifth section **385** defined by a set of ribs **364** and **365**; and a six section **386** defined by a set of ribs **365** and **366**. In some embodiments, the occluder **300** may include more or less sections **380**.

[0044] When in the default, expanded configuration, for example, as shown in FIGS. **1-7**, the ribs **360** of the occluder **300** may be elongated so that they extend between the second circumference **320** and the third circumference **330**. In this configuration, the outer surface **340** may be separated by the inner surface/central lumen **350** by the ribs **360** so that the outer surface **340** flairs between the first circumference **310** to the third circumference **330**. For example, as shown in FIGS. **1-7**, when the occluder **300** is in an expanded configuration, the ribs **360** may be substantially straight between the second circumference **320** and the third circumference **330**.

[0045] When in a collapsed configuration, at least a portion of the outer surface **340** of the occluder **300** may be pressed towards or against the inner surface/central lumen **350**. In the collapsed configuration, one or more ribs **360** may be bent between the second circumference **320**/outer surface **340** and the third circumference **330**/central lumen **350** causing the respective section(s) including the one or more bent rib(s) **360** to at least partially collapse. When one or more ribs **360** of a section bends, it may cause at least a portion of the outer surface **340** of the respective section(s) **380** to move towards the inner surface/central lumen **350** causing that section(s) to at least partially collapse. This can result in at least the outer surface **340** of the occluder to change shape. In some examples, depending on the outside force, a portion of the inner surface/central lumen **350** and the corresponding section **380** and the corresponding portion of the tube **120** may also collapse causing the occluder **300**, including the inner surface/central lumen **350**, and corresponding portion of the tube **120** to change shape.

[0046] FIGS. **9**A-**11**B show examples of the device **100** with the occluder **300** shown in FIGS. **1-7** in different collapsed configurations. FIGS. **9**A-**10**B show examples of the occluder **300** in partially collapsed configurations and FIGS. **11**A and B show examples of the occluder in a mostly collapsed configuration. These examples are nonlimiting and the occluder **300** can be configured to be in a different collapsed configuration depending on the resistance during delivery.

[0047] FIGS. **9**A and B show an example of the occluder **300** in a collapsed configuration. In this example, the ribs **361**, **363**, **364**, and **366** are bent resulting in at least partial collapse of all sections **381**, **382**, **384**, **385**, and **386** and a change in shape of the occluder **300** from the change in shape of the outer surface **340**/third circumference **330**. In some examples, the state of collapse of the corresponding section **380** may depend on whether one or both ribs of that section are bent. By way of example, as shown, the sections **381** and **384** for which both corresponding ribs (ribs **361** and **366** for the first section **381**; and ribs **363** and **364** for the fourth section **384**) are bent can be more collapsed than the other sections **381**, **385**, and **386**.

[0048] FIGS. **10**A and B show another example of the occluder **300** in a collapsed configuration. In this example, more of the ribs **360** are bent so that more sections are mostly collapsed. By way of example, the ribs **361**, **363**, **364**, **365**, and **366** are bent resulting in at least partial collapse of all sections **381-386** and a change in shape of the occluder **300** from the change in shape of the outer surface **340**/third circumference **330**. As shown, the sections **381**, **384**, **385**, and **386** for which both corresponding ribs are bent can be more collapsed than the other sections **382** and **383**.

[0049] FIGS. **11**A and B show another example of the occluder **300** in a collapsed configuration. In this example, all of the ribs **360** are bent so that all sections are mostly collapsed. By way of example, all of the ribs **361-366** are bent resulting in the mostly collapse of all sections **380** and a change in shape of the occluder **300** from the change in shape of the outer surface **340**/third circumference **330**. As shown, the sections **381-386** for which both corresponding ribs are mostly collapsed. In this example, the mostly collapse of one or more sections **360** can also result in the change of shape of the inner surface/central lumen **350** and the tube **120** at the end **144**.

[0050] In some embodiments, the occluder **300** may be made of one or more biocompatible materials. In some examples, the occluder **300** may be semi-flexible or flexible.

[0051] In some embodiments, the one or more biocompatible materials may have flexible properties. By way of example, the one or more materials may include but is not limited to polybutylene succinate (PBS), polylactide (PLA), acrylate butadiene styrene (ABS), resin, silicone, among others, or in a combination thereof.

[0052] In some examples, the outer surface **340** of the occluder **300** may have a different hardness/stiffness than the central lumen **350** of the occluder **300**. For example, the outer surface **340** may be more flexible than the wall/inner surface of the central lumen **350** of the occluder **300**.

[0053] In some examples, the occluder **300** may be more flexible than the tube **120**. By way of example the occluder **300** may have a hardness of about 10-20 A; and the tube **120** may have a stiffness of about 40-60 A. In some examples, the occluder **300** may be about 10 A and the tube may be about 50 A.

[0054] In some embodiments, the occluder **300** may be transparent. In some examples, the occluder **300** may be semi-transparent or transparent.

[0055] In some examples, as shown in an example **800** shown in FIG. **8**, the device **100** may be disposed on an endoscope tube **810** before the advancement into a patient's esophagus. In some embodiments, the device **100** may include one or more sets of imaging markers **820** disposed on the outer surface **160** of the tube **120**. For example, the one or more sets of imaging markers **820** can be set at a number of different distances, including but not limited to 5 cm, 10 cm, 15 cm, 20 cm, and/or 25 cm.

[0056] In some examples, the disclosed devices may be used in a procedure to redirect/block retrograde contents whilst maintaining an open central lumen to facilitate passage of an instrument, such as an endoscope or other instrument. For example, for a gastrointestinal procedure, after the patient is prepared for the procedure by providing access to the esophagus, such as inserting a mouthguard with a bit block opening the airway, an instrument, such as endoscope may be positioned to the desired location. After which, the disclosed device **100** may be inserted into a mouth of a patient advanced over an instrument, such as an endoscope, through the esophagus in anterograde motion until positioned at a desired location and the anchoring member **230** of the adapter **200** interfaces with the bite block clip provided at the patient's mouth. When initially inserted into the pharynx, the occluder **300** may be in one or more

collapsed configurations due to the resistance. For example, any resistance during the device's advancement may cause one or more of the ribs **360** to bend so that one or more of the sections **380** collapses toward the central lumen **350** resulting in one or more of the collapsed configurations. During advancement into the esophagus, the occluder **300** of the device **100** may move to the expanded configuration or a less collapsed configuration (i.e., a more expanded configuration) so that the outer surface **340** engages the surrounding tissue. By way of example, the device **100** may move from a collapsed configuration shown in FIGS. **11**A and B to a less collapsed/more expanded configuration shown in FIGS. **10**A and B or FIGS. **9**A and B or the expanded configuration shown in FIGS. **1-7**.

[0057] The stiffness profile, shape, and structure of the occluder **300** can enable displacement of the surrounding tissue laterally and distally such as to allow smooth advancement of the device **100** and minimize tissue trauma. After the device **100** is advanced to the desired position and the anchoring member **230** interfaces with the complimentary bite block of the mouth guard, the instrument, such the endoscope or other instrument, can be advanced freely further into the esophagus to the site to conduct the procedure. After the procedure is completed, the disclosed device **100** can be removed whilst the endoscope is still in place or after endoscope has been removed.

[0058] While the disclosure has been described in detail with reference to exemplary embodiments, those skilled in the art will appreciate that various modifications and substitutions may be made thereto without departing from the spirit and scope of the disclosure as set forth in the appended claims. For example, elements and/or features of different exemplary embodiments may be combined with each other and/or substituted for each other within the scope of this disclosure and the appended claims.

What is claimed is:

1. A device, comprising:
- a tube having a first end, a second end, and a length there between;
- the tube including a central lumen disposed along the length, the central lumen configured to receive an instrument; and
- an occluder disposed at the second end;
- the occluder having a first end, a second end, and a length there between;
- the occluder including a lumen along the length;
- the occluder having a first circumference at the first end;
- the occluder having a second circumference and a third circumference at the second end;
- the third circumference being larger than the first circumference and the second circumference;
- the occluder having an outer surface extending between the first circumference and the third circumference; and a lumen extending between the first circumference and the second circumference;
- the occluder being configured to reversibly collapse to one or more collapsed configurations with respect to the tube; and
- the occluder being biased to an expanded configuration.

2. The device according to claim **1**, further comprising:
- a plurality of ribs disposed along the length of the occluder;
- wherein each rib extends between the second circumference and the third circumference; and
- a plurality of sections, each section being defined by (i) a set of ribs of the plurality of ribs and (ii) the second circumference and the third circumference.

3. The device according to claim **2**, wherein:
- the plurality of ribs is spaced apart with respect to the lumen by an empty space; and
- each empty space corresponding to a section.

4. The device according to claim **3**, wherein:
- in the expanded configuration, the plurality of ribs are elongated between the second circumference and the third circumference; and
- in the one or more collapsed configurations, one or more of the plurality of the ribs are bent between the second circumference and the third circumference so that one or more sections defined by the one or more of the plurality of the ribs collapse towards the lumen of the occluder;
- in the one or more collapsed configurations, the outer surface disposed in that section is pushed towards the lumen of the occluder.

5. The device according to claim **4**, wherein:
- the tube is made of one or more materials and the occluder is made of one or more materials; and
- the one or more materials of the occluder is more flexible than the one or more materials of the tube.

6. The device according to claim **1**, further comprising:
- an adapter disposed at the first end.

7. The device according to claim **6**, wherein:
- the adapter is disposed on an outer surface of the tube; and
- the adapter includes an anchor member configured to engage another device.

8. The device according to claim **6**, wherein the other device is a mouthguard.

9. The device according to claim **1**, wherein:
- one or more surface features is disposed on the outer surface of the tube.

10. The device according to claim **9**, wherein:
- the one or more surface features includes one or more of inflatable balloons, stents, stitching devices, snares, ablation devices, hooks for loop reduction, sensors, medications, and/or biocompatible lubricants.

11. The device according to claim **1**, wherein:
- the tube includes an outer surface; and
- the tube includes a wall between the lumen and the outer surface, the wall including one or more additional internal channels configured for one or more instruments.

12. The device according to claim **11**, wherein the one or more instruments includes one or more probes, a suction instrument, an irrigation instrument, and/or another instrument.

13. The device according to claim **1**, wherein the central lumen is configured to receive an endoscope.

14. A method of occluding a lumen of a body, comprising:
- providing a device including:
  - a tube having a first end, a second end, and a length there between;
  - the tube including a central lumen disposed along the length, the central lumen configured to receive an instrument; and
  - an occluder disposed at the second end;
  - the occluder having a first end, a second end, and a length there between;
  - the occluder including a lumen along the length;

the occluder having a first circumference at the first end;

the occluder having a second circumference and a third circumference at the second end;

the third circumference being larger than the first circumference and the second circumference;

the occluder having an outer surface extending between the first circumference and the third circumference; and a lumen extending between the first circumference and the second circumference; and

the occluder being configured to reversibly collapse to one or more collapse configurations with respect to the tube; and

the occluder being biased to an expanded configuration;

advancing the device over an instrument disposed within a body lumen to a region of interest within the body lumen so that the occluder engages surrounding tissue of the body lumen while the device is advanced until it reaches the region of interest;

wherein if the device encounters resistance from the surrounding tissue when advanced along the body lumen towards the region of interest, the occluder moves from the expanded configuration to the one or more of the collapsed configurations; and

wherein when the device is at the region of interest, the occluder is in a more expanded configuration so as to occlude the body lumen; and

performing a procedure with the other device when the occluder is in the more expanded configuration at the region of interest.

15. The method according to claim **14**, wherein the device further includes:

a plurality of ribs disposed along the length of the occluder;

wherein each rib extends between the second circumference and the third circumference; and

a plurality of sections, each section being defined by (i) a set of ribs of the plurality of ribs and (ii) the second circumference and the third circumference.

16. The method according to claim **15**, wherein the device further includes:

the plurality of ribs is spaced apart with respect to the lumen by an empty space; and

each empty space corresponding to a section.

17. The method according to claim **16**, wherein:

in the expanded configuration, the plurality of ribs are elongated between the second circumference and the third circumference; and

in the one or more collapsed configurations, one or more of the plurality of ribs are bent between the second circumference and the third circumference so that one or more sections defined by the one or more of the plurality of the ribs collapse towards the lumen of the occluder;

in the one or more collapsed configurations, the outer surface disposed in that section is pushed towards the lumen of the occluder.

18. The method according to claim **16**, wherein:

the tube is made of one or more materials and the occluder is made of one or more materials; and

the one or more materials of the occluder is more flexible than the one or more materials of the tube.

19. The method according to claim **16**, further comprising:

an adapter disposed at the first end;

wherein the adapter is disposed on an outer surface of the tube; and

wherein the adapter includes an anchor member configured to engage another device.

20. The method according to claim **19**, wherein:

the other device is a mouthguard;

the instrument is an endoscope; and

the body lumen is an esophagus.

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