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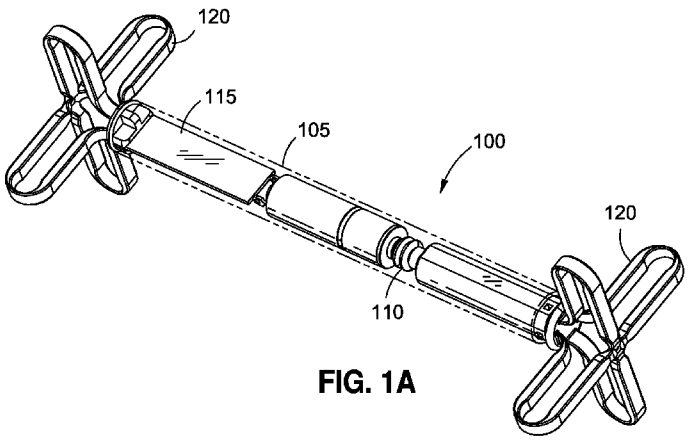

FIG. 1A

(57) Abstract: Transoral obesity treatment devices and related methods for operation thereof are described which occupy space within a stomach and/or stimulate the stomach wall. The transoral obesity treatment devices and related methods are intended to assist a patient in maintaining a healthy body weight. Features of the devices include insertion transorally and without invasive surgery, without associated patient risks of invasive surgery, and without substantial patient discomfort. The life span of these devices may be material-dependent upon long-term survivability within an acidic stomach, but is intended to last one year or longer. The devices have the capacity to vary in size and are desirably self-actuating in that they change shape and/or volume using internal motors or actuators. The changing character of the devices helps prevent the person's stomach from compensating for the implant, such as sometimes happens with static intragastric devices.

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VARIABLE SIZE INTRAGASTRIC IMPLANT DEVICES

RELATED APPLICATIONS

[0001] The present application claims priority under 35 U.S.C. §119 to U.S. Provisional Application No. 61/394,145, filed October 18, 2010, U.S. Provisional Application No. 61/394,592, filed October 19, 2010, and U.S. Provisional Application No. 61/394,685, filed October 19, 2010, the disclosures of which are incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The present invention generally relates to medical implants and uses thereof for treating obesity and/or obesity-related diseases and, more specifically, to transorally-delivered devices designed to occupy space within a stomach and/or stimulate the stomach wall.

BACKGROUND OF THE INVENTION

[0003] Over the last 50 years, obesity has been increasing at an alarming rate and is now recognized by leading government health authorities, such as the Centers for Disease Control (CDC) and National Institutes of Health (NIH), as a disease. In the United States alone, obesity affects more than 60 million individuals and is considered the second leading cause of preventable death. Worldwide, approximately 1.6 billion adults are overweight, and it is estimated that obesity affects at least 400 million adults.

[0004] Obesity is caused by a wide range of factors including genetics, metabolic disorders, physical and psychological issues, lifestyle, and poor nutrition. Millions of obese and overweight individuals first turn to diet, fitness and medication to lose weight; however, these efforts alone are often not enough to keep weight at a level that is optimal for good health. Surgery is another increasingly viable alternative for those with a Body Mass Index (BMI) of greater than 40. In fact, the number of bariatric surgeries in the United States is projected to reach approximately 400,000 annually by 2010.

[0005] Examples of surgical methods and devices used to treat obesity include the The LAP-BAND® (Allergan, Inc., Irvine, CA) gastric band and the LAP-BAND AP® (Allergan, Inc., Irvine, CA). However, surgery might not be an option for every obese individual; for certain patients, non-surgical therapies or minimal-surgery options are more effective or appropriate.

[0006] For example, intragastric balloons may be utilized as non-surgical or minimal-surgery means for treating obesity. One such inflatable intragastric balloon is described in U.S. Pat. No. 5,084,061 and is commercially available as the BioEnterics Intragastric Balloon System (sold under the BIB® System). These devices are designed to provide therapy for moderately obese individuals who need to shed pounds in preparation for surgery, or as part of a dietary or behavioral modification program.

[0007] The BIB® System, for example, comprises a silicone elastomer intragastric balloon that is inserted into the stomach and filled with fluid. Conventionally, the balloons are placed in the stomach in an empty or deflated state and thereafter filled (fully or partially) with a suitable fluid. The balloon occupies space in the stomach, thereby leaving less room available for food and creating a feeling of satiety for the patient. Clinical results with these devices show that for many obese patients, the intragastric balloons significantly help to control appetite and accomplish weight loss.

[0008] Placement of such balloons is temporary, and such balloons are typically removed after about six months. One means of removing the balloon is to deflate it by puncturing the balloon, and either aspirating the contents of the balloon or allowing the fluid to pass into the patient's stomach. Alternatively, if the balloon is left in place beyond its designed lifetime, the acids present in a patient's stomach may erode the balloon to the point where it self-deflates. When this occurs, the deflated balloon may pass naturally through the patient's digestive system and be expelled through the bowel. For instance, McGhan, U.S. Pat. No. 6,733,512, describes a self-deflating intragastric balloon that includes a biodegradable inflation valve. After a certain residence time in the stomach, the valve starts to leak and eventually the balloon deflates and passes though the patient's digestive tract.

[0009] Despite the advances in the design of intragastric balloons, there remains a need for improved transoral obesity treatment devices.

SUMMARY OF THE INVENTION

[0010] Transoral obesity treatment devices generally promote a feeling of satiety in the patient by contacting the insides of the stomach wall, reducing the space in the stomach, or otherwise reducing the amount of food consumed or digested by the patient. The devices have the capacity to vary in size and are desirably self-actuating in that they change shape and/or

volume using internal motors or actuators. The changing character of the devices helps prevent the person's stomach from compensating for the implant, such as sometimes happens with static intragastric devices.

[0011] In addition, transoral obesity treatment devices generally allow for easy and quick placement and removal. Surgery is usually not required or very minimal. In one aspect, the transoral obesity treatment devices are placed in the patient through the mouth, passing the esophagus and reaching the destination, usually in the stomach region. In most instances, the transoral obesity treatment device does not require suturing or stapling to the esophageal or stomach wall, and remains inside the patient's body for a lengthy period of time (e.g., months or years) before removal.

[0012] In one embodiment, the transoral obesity treatment device may be a stomach stimulator, which may fight obesity by stimulating the stomach walls of the patient and occupying space inside the stomach. The stomach stimulator may be an electromechanical device comprising a telescoping body and expandable ends. The ends may be configured to exert a pressure on the inner stomach walls of the patient and, when in the expanded state, prevent the stomach stimulator from entering the patient's intestines. The telescoping body shortens or lengthens the stomach stimulator, either randomly or in accordance with a predefined schedule, such that the patient's body cannot compensate. Studies have shown that obesity may be more effectively reduced when a patient's body cannot compensate to the obesity device.

[0013] In one embodiment, a system for treating obesity by applying a pressure to the patient's stomach comprises a central elongated body having an adjustable length. Two collapsible atraumatic feet on opposite ends of the elongated body are each configured to exert pressure on the patient's stomach when in a deployed position. An actuator within the central elongated body adjusts the length of the body and simultaneously the distance between the atraumatic feet. The two collapsible atraumatic feet may comprise balloon-like structures, or they may comprise an array of living hinges that may be unfolded to an elongated delivery configuration and folded outward to a deployed configuration. In the latter configuration, the array of living hinges are in an X-shape. The actuator may comprise an electronic motor, and further may include a control circuit board having a battery and a memory. The actuator control circuit board further may have a transceiver, and the system further includes a remote control for instructing the motor from outside the patient's body. In one embodiment, the actuator comprises a telescoping screw driven by the motor. Alternatively, the actuator comprises a polymer element that is acid-activated to lengthen in a highly acidic environment, and the central elongated body includes through holes for exposing the polymer element to the stomach

environment. The central elongated body may comprise a series of telescoping tubular members having apertures along their lengths. In one embodiment, the atraumatic feet include uneven external surface stimulation features.

[0014] In the system having the elastic balloon, an aseptic ring may be provided that fits around a portion of the exterior of the body and contact the stomach liquid when the stomach liquid is inside the elastic balloon. The device further may include a control circuit board having a battery and a memory. The control circuit board may also have a transceiver, and the system further includes a remote control for instructing the motor from outside the patient's body. In one embodiment, the elastic balloon includes uneven external surface stimulation features. In another embodiment, the elastic balloon is shaped to encourage rotation within the stomach, such as by being formed in an aggregation of spheres, or having a plurality of outwardly projecting legs terminating in rounded or bulbous feet.

[0015] In yet another embodiment, the transoral obesity treatment device may be a variable size balloon device. The device may include a peristaltic pump for inflating or deflating the balloon. Instead of saline, the pump may fill the balloon with naturally-existing stomach fluid already present in the patient's stomach. The pump may be controlled by a motor sealed off from the acidic stomach fluid. The device may further include an aseptic ring inside the balloon intended to disinfect the stomach fluids retained inside the balloon. In one aspect, the motor may be controlled by an electronic device outside the patient's body.

[0016] Another system disclosed herein for preventing obesity by occupying space inside the patient's stomach comprises an elastic balloon configured to be variably filled with stomach liquid. A body of the implantable device attached to the elastic balloon is configured to inflate and deflate the elastic balloon by transferring stomach liquid into and out of the elastic balloon. A peristaltic pumping device housed within the body of the implantable device transfers the stomach liquid from outside the elastic balloon to inside the elastic balloon in a first mode of operation, and further transfers the stomach liquid from inside the elastic balloon to outside the elastic balloon in a second mode of operation. The body of the implantable device further may house a motor configured to operate the peristaltic pumping device. The motor rotates rollers that are in contact with a pair of flexible tubes that form a conduit between an external opening located outside the elastic balloon and an internal opening located within the inner cavity of the elastic balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The following detailed descriptions are given by way of example, but not intended to limit the scope of the disclosure solely to the specific embodiments described herein, may best be understood in conjunction with the accompanying drawings in which:

[0018] Figure 1A illustrates a perspective view of an elongated stomach stimulator having soft, folded feet and a variable length.

[0019] Figure 1B illustrates a perspective view of the stomach stimulator of Figure 1A in an extended state.

[0020] Figure 1C illustrates a close up view of a portion of the stomach stimulator.

[0021] Figure 1D illustrates a control board for the stomach stimulator.

[0022] Figure 1E illustrates a flow chart for controlling the stomach stimulator of Figure 1A.

[0023] Figure 1F illustrates a close up view of an end portion of a stomach stimulator in a folded state.

[0024] Figure 1G illustrates a close up view of an end portion of a stomach stimulator in a deployed or unfolded state.

[0025] Figure 1H illustrates a close up view of an end portion of a stomach stimulator in a pressuring state.

[0026] Figure 2 illustrates a side view of an intragastric obesity treatment device with a piston in a patient's stomach.

[0027] Figure 3 illustrates a perspective view of an intragastric obesity treatment device with a piston.

[0028] Figure 4 illustrates a sectional view of an intragastric obesity treatment device with a piston and a motor in accordance with an embodiment of the present invention.

[0029] Figure 5A illustrates a perspective view of a balloon device with the balloon inflated.

[0030] Figure 5B illustrates a balloon device with a silver band.

[0031] Figure 5C illustrates a perspective view of a balloon device without the outer balloon shell.

[0032] Figure 5D illustrates a balloon device with the outer body removed.

[0033] Figure 5E illustrates a close up view of the peristaltic pump of the balloon device.

[0034] Figure 5F shows an electronic controller for operating the peristaltic pump of an intragastric balloon device of the three-dimensionally orthogonal intragastric spring device;

[0035] Figure 5G illustrates a flow chart for controlling the balloon device.

[0036] Figures 6 and 7 illustrate intragastric devices that encourage rotational variation.

[0037] Figures 8 and 9 illustrate intragastric devices that both encourage rotational variation and provide additional stomach cavity stimulation.

DESCRIPTION OF THE DETAILED EMBODIMENTS

[0038] Persons skilled in the art will readily appreciate that various aspects of the disclosure may be realized by any number of methods and devices configured to perform the intended functions. Stated differently, other methods and devices may be incorporated herein to perform the intended functions. It should also be noted that the drawing Figures referred to herein are not all drawn to scale, but may be exaggerated to illustrate various aspects of the invention, and in that regard, the drawing Figures should not be construed as limiting. Finally, although the present disclosure may be described in connection with various medical principles and beliefs, the present disclosure should not be bound by theory.

[0039] By way of example, the present disclosure will reference certain transoral obesity treatment devices. Nevertheless, persons skilled in the art will readily appreciate that certain aspects of the present disclosure advantageously may be applied to one of the numerous varieties of transoral obesity treatment devices other than those disclosed herein.

[0040] In one aspect, these transoral obesity treatment devices described herein are intended to be placed inside the patient, transorally and without invasive surgery, without associated patient risks of invasive surgery and without substantial patient discomfort. Recovery time may be minimal as no extensive tissue healing is required. The life span of these transoral obesity treatment devices may be material-dependent upon long-term survivability within an acidic stomach, but is intended to last one year or longer.

[0041] Figure 1A illustrates a first embodiment of a variable sized transoral obesity treatment device, namely a variable-length stomach stimulator **100**. The stomach stimulator **100** may include a tubular body **105** (shown in phantom to reveal the inner components), two opposite atraumatic feet **120**, a control portion **115**, and O-ring seals **110** to prevent stomach juices (e.g., acids) from reaching and corrupting or destroying the control portion **115**. The stomach stimulator **100** may reduce appetite as the feet **120** contact and pressure the inside of the patient's stomach walls, thereby affecting nerves and causing early feelings of satiety. In one

aspect, the entire stomach stimulator including the feet **120** (in a folded state) may be no larger than 10 millimeters (mm) in diameter, thereby easily passing transorally into the patient's mouth, through the esophagus and into the patient's stomach.

[0042] In one aspect, the stomach stimulator **100** may be configured to telescope to varying lengths. For example, Figure 1B illustrates the stomach stimulator of Figure 1A in an extended position. The extension portion **125** may be a screw-like device that telescopically shortens in the direction of the control portion **115** and telescopically lengthens in the direction away from the control portion **115**. As shown, the extension portion **125** attaches to a shaft portion **130** such that when the extension portion telescopically lengthens, a part of the intermediate portion extends outside the body **105**, thereby "extending" the length of the stomach stimulator **100**. The stomach stimulator **100** has the capacity to vary in length and is desirably self-actuating in that the size change occurs from components within. The term, "self-actuating," however, does not exclude a remote connection to an external controller, as will be described below.

[0043] Figure 1C illustrates a close up view of the extension portion **125** and the dual O-ring seals **110** configured to prevent stomach acid from entering the control portion **115**. The control portion **115** may include an implantable motor and gearhead assembly (not shown) configured to drive the extension portion **125**. In one aspect, the motor and gearhead assembly may be controlled by an electronic controller also housed in the control portion **115**.

[0044] Figure 1D illustrates a control board **160** for the stomach stimulator **100** that includes a processor **165**, physical memory (e.g., a EEPROM, RAM, ROM, etc.) **170**, battery **175** and transceiver **180**. The memory may store data such as a schedule for lengthening or shortening the stimulator **100**. The transceiver **180** may allow the control board **160** to communicate with an external computer and receive commands and send status information such as current length of the stimulator **100**, etc. The control board **160** may further include a sensor **185** configured to detect a current length of the stimulator **100**. The control board **160** desirably controls the motor and gearhead assembly (not shown) to drive the telescoping screw **125** (Fig. 1B) to either lengthen or shorten the stimulator **100**. In one aspect, the schedule may be updated, changed or interrupted by the transceiver receiving a command from an external computer. In another example, the transceiver may receive a new or updated target stimulator length schedule to assist the stomach stimulator **100** in determining when to adjust the length of the extension portion and the target length to adjust it to. By virtue of the transceiver **180**, the stimulator **100** can be controlled externally by hand-held radiofrequency remote controller (not shown). The control board **160** communicates with the remote control unit, and also may contain program information that drives the motor at various random or pre-set distances and at random or preset

intervals, causing one end of the stimulator **100** to telescope in and out. The randomness of the telescoping length provides varying pressure, so the patient's body is not likely to compensate, or to adapt to any one typical stomach size.

[0045] Figure 1E illustrates a flow chart of one example of how the stomach stimulator **100** may function. Initially, when the stomach stimulator **100** is first deployed in the patient's stomach, the stomach stimulator **100** may read a schedule instructing the different lengths that the stimulator may adjust to and at which times at step **S160**. In one example, the schedule may be a daily schedule that the stomach stimulator **100** follows. Alternatively, the schedule may be for a week, month, year and so forth. After the schedule is read in step **S160**, the target length may be determined according to the schedule at step **S165**. At step **S170**, the motor may be driven to achieve the target length. At step **S175**, the stomach stimulator **100** may determine if a trigger to change the length is detected. For example, the trigger may be merely determining that the schedule dictates a changing of the length of the stomach stimulator **100**. Other triggers may include a command from the external computer to change the length of the stomach stimulator **100**. In one aspect, the external computer may issue a "max short" command to have the stomach stimulator **100** shorten itself as much as possible. This command may be advantageous, for instance, when the physician is preparing to remove the stomach stimulator. The stomach stimulator **100** may be configured to override the schedule anytime a command is received from the external computer. In response to the trigger, the stomach stimulator may determine a new target length and drive the motor to achieve the target length. However, if at step **S175** no trigger is detected, the stomach stimulator **100** may maintain its current length until a new trigger is detected to alter the length.

[0046] In one aspect, changing the length of the stomach stimulator **100** may be advantageous to prevent the patient's body from compensating or adapting to the presence of the stomach stimulator **100**. It is thought that if the body is allowed to adapt to the stomach stimulator **100**, weight gain due to body compensation may occur decreasing the effectiveness of the stomach stimulator **100**. Some clinical indications are that patients adapt to introduction of gastrointestinal implants normally within the first few months of surgery, so early weight gain due to compensation will likely be avoided with the randomly changing stimulator **100**. In this sense, by constantly and unpredictably changing the lengths of the stomach stimulator **100**, the patient's body cannot adapt effectively, thus promoting weight loss more effectively. In one alternative, the stomach stimulator may be configured to continuously telescope (e.g., never stopping to maintain a particular length). As the stomach muscles churn their contents, the stomach stimulator **100** will essentially randomly shift the point at which pressure is exerted

from within the stomach, thus helping to prevent physiological compensation by the stomach for the object within.

[0047] In addition, the changing lengths may further have an additional benefit. The pressure exerted by the feet (e.g., feet **120** of Figure 1A) on the inside of the stomach walls may cause early feelings of satiety. The feet **120** are configured to be atraumatic, in that they are soft and pliable. The feet **120** are desirably formed as an array of fingers of a soft polymer, each preferably having thinned regions so as to function like living hinges. More particularly, each of the spokes of the "X" shaped feet **120** has a rectangular cross-section to facilitate bending in one plane, and thinned regions at three points: where it connects to the stimulator **100**, where it connects to the other spokes along an axis of the device, and at a mid-portion which forms the outermost end of each of the spokes in the deployed configuration seen in Figure 1G. Of course other configurations for the atraumatic feet are contemplated, such as rounded pillows, cups, or the like. The feet **120** also may have a radio-opaque additive molded therein so that they can be seen with X-ray, such as during a removal procedure.

[0048] Figure 1F illustrates the feet **120** in an extended or elongated position to allow easier implantation and removal. However, once implanted inside the patient's stomach, the feet may fold to a deployed state as shown in Figure 1G. In this state, the feet point outwards and prevent migration through the pylorus, and then the intestines. In one aspect, the length of the inner end portion **135** and outer end portion **140** may be configured to form an "X" pattern that is larger than the opening of the pylorus. Figure 1H illustrates the feet **120** bending, which may occur when the stomach stimulator **100** is exerting pressure on the stomach walls. Advantageously, even in this pressuring state, the end portion **120** is not able to migrate through the pylorus as the inner portion **140** and the outer portion **135** contact each other and resist the end portion **120** from bending further. In other words, even at the pressuring state, the end **120** is still too large to fit through the pylorus. While shown as three distinct states, the stomach stimulator **100** may be configured to take on any position therebetween.

[0049] In accordance with another embodiment of the present invention, and with reference to Figures 2-4, a gastrointestinal implant, such as an intragastric obesity treatment device **200**, may comprise a piston assembly **205**, such as a telescoping tube, coupled to two atraumatic, pliable end portions, which are shown in the illustrated monument as balloon feet **210, 212**. The piston assembly **205** is configured to bias the balloon feet **210, 212** against the walls of a patient's stomach **202**. As the balloon feet **210, 212** exert pressure against the walls of the stomach **202**, the patient may experience a feeling of satiety, resulting in a reduced desire to eat, and eventually resulting in weight loss. For example, the balloon **212** may exert pressure on the

greater curvature of the stomach, causing the balloon **210** to exert pressure on the cardia. Such cardial pressure may stimulate the release of satiety-inducing hormones, thus reducing meal time food intake. In various embodiments, the shape of the intragastric obesity treatment device **200** appropriately orients the balloon feet **210, 212** within the stomach **202** approximate the greater curvature and the cardia.

[0050] As seen in Figure 3, the piston assembly **205** may comprise a piston **206** disposed within sleeves **207, 208**. The piston **206** is fixed with respect to one of the sleeves **207, 208** and was the other toward or away from the first sleeve, causing the balloon feet **210, 212** similarly to move toward or away from each other. In other embodiments, the piston **206** may slide within both sleeves **207, 208**.

[0051] As seen in the cross-section of Figure 4, a self-actuating lengthener **209** may be disposed within one of the sleeves **207, 208**, for example, within the sleeve **208** (as illustrated in Figure 4), to facilitate moving the piston **206** within the sleeves **207, 208**. Various such devices are contemplated within the scope of the present invention, but, in one embodiment, the self-actuating lengthener **209** may comprise a polymer that is acid-activated. For example, the self-actuating lengthener **209** may comprise a polymer bundle that is capable of expanding up to two times its original length when the polymer bundle is exposed to an acidic environment with a lower pH. Such acid-activated polymers may be referred to as stimuli sensitive polymers, and may comprise polyacrylonitrile (PAN) fibers.

[0052] Such polymers are disclosed in the following documents, all of which are hereby incorporated by reference in their entirety: Anasuya Sahoo, et al., "Effect of copolymer architecture on the response of pH sensitive fibers based on acrylonitrile and acrylic acid," *European Polymer Journal* 43 (2007), 1065-1076. Kiyoung Choe and Kwang J. Kim, "Polyacrylonitrile linear actuators: Chemomechanical and electro-chemomechanical properties," *Sensors and Actuators A* 126 (2006), 165-172. R, Samatham, et al., "Electrospun nanoscale polyacrylonitrile artificial muscle," *Smart Materials and Structures* 15 (2006), N152-N156. B. Tondu, et al., "A pH-activated artificial muscle using the McKibben-type braided structure," *Sensors and Actuators A* 150 (2009), 124-130. Ping An Song, et al., "A pH-sensitive Modified Polyacrylamide Hydrogel," *Chinese Chemical Letters*, Vol. 17, No. 3 (2006) 399-402.

[0053] Although PAN fibers for acid-activated lengthener are discussed herein, it should be understood that various lengthener are contemplated within the scope of the present invention. For example, all lengthener that are capable of being actuated by substances that may exist in the

body, such as stomach juices, enzymes, and/or the like, are within the scope of the present invention. Such substances may be referred to herein as "bodily substances."

[0054] Accordingly, as a patient begins to eat, digestive enzymes along with hydrochloric acid (HCL) are secreted into the stomach **202**, resulting in a lowered pH in the stomach **202**. This lowered pH causes the polymer in the lengthener **209** to expand, which in turn causes the piston assembly **205** to move the balloon feet **210, 212** away from each other to exert pressure on the stomach **202**. The pressure stimulates the release of satiety-inducing hormones, reducing meal time food intake. As the patient stops eating and digestion progresses, the pH levels in the stomach **202** begin to rise, resulting in contraction of the polymer in the lengthener **209**, which causes the balloon feet **210, 212** to move away from the stomach **202** walls.

[0055] With continued reference to Figures 2-4, and in accordance with various embodiments, the intragastric obesity treatment device **200** comprises holes **215** to allow stomach juices to come into contact with the lengthener **209** so that it may expand and/or contract. Further, the holes **215** may permit the intragastric obesity treatment device **200** to be properly situated within the stomach **202**, such that motion of the stomach juices does not substantially affect the position of the intragastric obesity treatment device **200**, other than by causing the lengthener **209** to move the piston assembly **205** and the balloon feet **210, 212**. For example, the sleeves **207, 208** and/or the piston **206** may be hollow to allow the stomach juices to flow through the holes **215** and through the sleeves **207, 208** and/or the piston **206** to come into contact with the lengthener **209**.

[0056] Further, in accordance with various embodiments, the balloon feet **210, 212** may be configured to cushion the ends of the intragastric obesity treatment device **200** as the ends expand against the stomach **202** walls, to reduce the likelihood of ulceration. Although the balloon feet **210, 212** may be referred to as "balloons," this reference is for descriptive purposes only, and not to limit the structures to balloons *per se*. Rather, the balloon feet **210, 212** are "balloon-like" structures intended to protect the stomach **202** walls, and all such protective structures are contemplated within the scope of the present invention. For example, the balloon feet **210, 212** may comprise compliant structures that expand and contract, such as when the balloon feet **210, 212** are filled after implantation with air, saline, and the like. In other embodiments, the balloon feet **210, 212** may have thicker walls such that they substantially maintain their as-molded shape without inflation. Where the balloon feet **210, 212** maintain their shape, the holes **215** may also be placed in the balloon feet **210, 212** to allow the stomach juices to flow through the balloon feet **210, 212**.

[0057] The flexible nature of the balloon feet **210, 212** and the small diameter of the rigid piston assembly **205** allows for deployment and/or removal of the intragastric obesity treatment device **200** via a guiding tube placed through a patient's mouth, down the patient's esophagus, and into the patient's stomach **202**. The balloon feet **210, 212** are configured to collapse and/or fold down around the piston assembly **205** to allow the intragastric obesity treatment device **200** to be inserted into and/or removed from the stomach **202** via the guiding tube in the esophagus. Alternatively, the intragastric obesity treatment device **200** may be configured to be implanted into or extracted from the stomach **202** without the use of this guiding tube.

[0058] Where the balloon feet **210, 212** are inflatable, a fluid tube may be connected to the intragastric obesity treatment device **200** and deployed down the guiding tube through which the device **200** is inserted into or extracted from the stomach. This fluid tube may be coupled to one or both of the balloon feet **210, 212** (in series or in parallel -- *e.g.*, one of the balloon feet may be connected to the other balloon via internal tubing in the piston assembly **205**) to allow the balloon feet **210, 212** to be filled with air, saline, or other fluid. A syringe may be coupled to the fluid tube outside of the patient's mouth to facilitate filling or draining the balloon feet **210, 212**. After implantation/extraction, both of the tubes are removed from the esophagus, resulting in a minimally invasive implantation/extraction procedure.

[0059] In another embodiment, where the balloon feet **210, 212** may be self supporting (*e.g.*, thick walls may allow the balloon feet to maintain shape without internal pressure from added air/saline), air may be pre-extracted from the balloon feet **210, 212**, creating a partial vacuum to cause the balloon feet **210, 212** to collapse around the piston assembly **205**. In this respect, a portion of the piston assembly **205** adjacent each of the balloon feet **210**, **212** is relatively thin, permitting collapse of the balloon feet therearound to form a substantially consistent delivery/removal diameter. Then, when the intragastric obesity treatment device **200** is implanted in the stomach, the fluid tube may allow the partial vacuum in the balloon feet **210, 212** to be released, causing them to expand to their self-supported shape.

[0060] Regardless of which embodiment of the stomach stimulator **200**, the feet **210**, **212** may be, for example, an acid-resistant plastic or any other appropriate material injected with radio-opaque additive so that they may be seen with an x-ray machine during the removal procedure. In addition, the tubular body **205** may be constructed, for example, out of a polysulphone, polypropylene or an acid-resistant plastic material configured to resist the strong acidity of the stomach juices.

[0061] In another aspect, removal of the stomach stimulator **200** may be easily performed using a standard grabber. Once the ends are folded down and the stomach stimulator **200** is compressed, the entire stomach stimulator **200** may be easily pulled up through the patient's stomach and esophagus and exit the patient's mouth.

[0062] Figure 5A illustrates another embodiment of a transoral obesity treatment device, namely the inflatable balloon device **300**. As shown, the inflatable balloon device **300** is inflated and filled with stomach juices naturally occurring and produced in the patient's body. The inflatable balloon device **300** includes an inflatable layer **305** which spans almost the entire length of body **320**. In one aspect, the top **310** and bottom **350** of the inflatable balloon device **300** might not be maintained within the inflatable layer **305**. At the outer surface of the top **310** is an opening **315**. The opening **315** may be configured to allow peristaltic pump **325** to pull stomach juices into the inflatable layer **305** to fill the balloon or to push out stomach juices from inside the inflatable layer **305** to deflate the balloon. The inflatable balloon device **300** may further include an aseptic band **335**, a barrier **360** and a control portion **330**. By inflating the inflatable balloon device **300** to a volume between 0 milliliters (mL) and 1000 mL (but preferably between 400 mL and 700 mL), the balloon occupies space in the stomach decreasing the amount of space for food, and also stimulates the stomach walls when the inflatable balloon device **300** via inflation and/or migration exerts a pressure on the inner stomach walls. The inflatable balloon device **300** has the capacity to vary in volume and is desirably self-actuating in that the size change occurs from components within. The term, "self-actuating," however, does not exclude a remote connection to an external controller, as will be described below.

[0063] Figure 5B is a deconstructed version of inflatable balloon device **300**. In this view, the inflatable layer **305** forming the "balloon" is removed to better illustrate the various other aspects of the inflatable balloon device **300**. Here, a portion of the body **320** of the inflatable balloon device **300** is covered by an antiseptic band **335**. The band **335** may be a separate piece of metal attached to the body **320**, or may be directly integrated into the body **320** as an exterior layer. The band **335** may be constructed of any material with cleansing, antiseptic qualities. In one example, silver may be used to form the band since silver has natural antiseptic qualities. The function of the band **335** is to passively disinfect the stomach fluid inside the inflatable layer **305**.

[0064] Figures 5C and 5D are further deconstructed versions of the inflatable balloon device of Figure 5B. Here, the antiseptic band **335** is removed to better show the portion of the tubular body **320** otherwise blocked from view by the band **335**. As shown, the body **320** may house a number of components. For example, the body may contain a peristaltic pump **325**, rollers **340**

operating in conjunction with the pump **325**, a barrier portion **360** and a control portion **330**. The tubular body **320** may be attached to a top **310** and bottom **340**. The tubular body **320** may include a hole **345**, and the top **310** may also include a hole **315**. The first hole is located at the top **315** and the second hole **355** is located on the side of the body **345**. The stomach fluid is pumped into and out of the inflatable balloon device **300** via these two holes since one of the holes (e.g., hole **345**) is located inside the inflatable layer **305** and the other hole (e.g., hole **315**) is located outside the inflatable layer **305**. In Figure 5D the tubular body **320** is removed to better show the peristaltic pump and the control board **330**.

[0065] As shown in Figure 5F, the control board **330** may include a processor, physical memory (e.g., a EEPROM, RAM, ROM, etc.), battery and transceiver. The transceiver **338** may allow the control board **330** to communicate with an external computer and receive commands and send status information such as current volume, etc. The control board **330** may further include a sensor **339** configured to detect a current volume of the inflatable balloon device **300**. In one embodiment, all the components of the control board **330** may be coupled to one another. In one embodiment, the control board **330** may further include a motor (not shown) to drive the rollers **340**. Alternatively, the motor may be part of the roller mechanism **340**. Regardless, the processor may drive the rollers **340** to either pump stomach fluid into the inflatable balloon device **300** thereby inflating it to a desirable volume or the processor may drive the rollers **340** to pump stomach fluid out of the inflatable balloon device **300** to deflate it to a desirable volume. More particularly, the processor may control a motor and/or a gearhead, which in turn drives the rollers **340**. The memory may store data such as a schedule for inflating or deflating the balloon. In one aspect, the schedule may be updated, changed or interrupted by the transceiver receiving a command from an external computer.

[0066] Figure 5E is a close up view of the peristaltic pump **325** apparatus. As shown, the peristaltic pump **325** includes an external opening **315** leading out through the top of the inflatable balloon device **300**, and an internal opening **345** leading out to the side of the tubular body **320** and within the inner cavity of the inflatable layer **305**. Rollers **340** of the pump **325** are in contact with flexible tubes **365** and **375** that form a conduit between the external opening **315** and internal opening **345**.

[0067] In operation, the rollers **340** rotate in a clockwise direction, moving stomach fluid in through the inlet opening **345** as shown and through the distal tube **365** to proximal tube **375** and out external opening **315**, thereby deflating the inflatable balloon device **300**. To inflate the inflatable balloon device **300**, the rollers **340** rotate in a counter-clockwise direction pulling fluid in through external opening **315**, down through tube **375**, up through tube **365** and out opening

345, in the opposite direction of the arrows. In this fashion the stomach fluid outside the inflatable layer **305** is moved inside the inflatable layer **305**, thereby expanding the volume inside the inflatable layer **305**.

[0068] The rollers **340** may be controlled according to any of a number of methods. Figure 5G illustrates an example of one such method via a flow chart. Initially, when the inflatable balloon device **300** is first deployed in the patient's stomach, inflatable balloon device **300** may read a schedule instructing the different volumes that inflatable balloon device **300** may adjust to and at which times at step **S360**. In one example, the schedule may be a daily schedule that inflatable balloon device **300** follows. Alternatively, the schedule may be for a week, month, year and so forth. After the schedule is read in step **S360**, the target volume may be determined according to the schedule at step **S365**. At step S**370**, the motor may be driven to achieve the target volume. At step **S375**, inflatable balloon device **300** may determine if a trigger to change the volume is detected. For example, the trigger may be merely determining that the schedule dictates a changing of the volume of the device **300**. Other triggers may include a command from an external computer to change the length of the inflatable balloon device **300**.

[0069] In one aspect, the external computer may issue a "min volume" command to have inflatable balloon device **300** deflate itself as much as possible. This command may be advantageous, for instance, when the physician is preparing to remove inflatable balloon device **300**. The inflatable balloon device **300** may be configured to override the schedule anytime a command is received from the external computer. Referring back to Figure 5F, in response to the trigger, inflatable balloon device **300** may determine a new target volume and drive the pump to achieve the target volume. However, if at step **S375**, no trigger is detected, the inflatable balloon device **300** may maintain its current volume until a new trigger is detected to alter the volume.

[0070] In one aspect, the volume of the balloon might not decrease beyond a certain predetermined threshold to prevent the inflatable balloon device **300** from getting lodged in the patient's pylorus.

[0071] In an alternative embodiment, the top and bottom of the inflatable balloon device **300** may be attached to foldable ends similar to feet **120** of the stomach stimulator as shown in Figures 1E, 1F and 1G. In another alternative, the top and bottom of the inflatable balloon device **300** may widen outwards at the two ends, where the diameter of the top and bottom may be sufficiently large enough such that the inflatable balloon device **300** might not be able to fit through the opening of the pylorus.

[0072] Accordingly, with or without the foldable feet, the diameter of the tubular body **320** may be 10 mm or less, and the control portion housed within the tubular body may be 8 mm or less in width, and configured to fit inside the tubular body **320**.

[0073] The insertion process for the inflatable balloon device **300** may be as simple as having the patient swallow the inflatable balloon device **300** while the inflatable balloon device **300** is in a deflated state. Alternatively, the inflatable balloon device **300** in a deflated state may be carefully inserted through the mouth of the patient, down the esophagus and into the patient's stomach by using a standard grabber.

[0074] The removal process for the inflatable balloon device **300** may be substantially the reverse of the insertion process. After substantially deflating the inflatable balloon device **300**, a standard grabber may be used to clamp onto one end of the inflatable balloon device **300** and pulled back up through the esophagus and out the patient's mouth.

[0075] Figures 6 and 7 illustrate certain specific features that encourage rotational variation, and may be incorporated into the devices shown herein, in particular to the inflatable balloon device **300** of Figures 5A-5G. In Figure 6, an intragastric obesity treatment device **490** essentially comprises an aggregation of spheres **492**. The overall exterior shape of the device is somewhat spherical, encouraging rotation. However, the outwardly projecting spheres that make up the device contact the stomach wall at different locations as the device rotates. In Figure 7, a device **500** comprises a plurality of outwardly projecting legs **502** terminating in rounded or bulbous feet **504**. Again, the device **500** rotates relatively easily within the stomach, especially upon peristaltic motion, and the separated legs **502** and feet **504** therefore contact the stomach wall at different locations on a constantly changing basis. The devices **490**, **500** of Figures 6 and 7 may also serve to temporarily block the pylorus and slow gastric emptying. These features can be utilized in a device that looks like the device **500**, or can be added to a number of the embodiments described herein, such as the inflatable balloon device **300**.

[0076] Another option for a number of the intragastric devices disclosed herein is to add uneven external surface stimulation features, such as any raised or depressed geometry which act to stimulate certain portions of the stomach walls. Such features may be particularly effective for those embodiments which stimulate the cardia. For instance, Figure 8 illustrates a spherical intragastric device **510** having numerous external bumps **512** projecting outward therefrom. These bumps **512** separately contact the inner walls of the stomach, potentially increasing the stimulation to the surrounding satiety-sensing nerves. Another example of exterior stimulation features is seen in Figure 9, where an intragastric device **520** formed as a sphere features a

multitude of small pins or flagella **522** extending outward therefrom. It should be noted that the two embodiments shown in Figures 8 and 9 rotate freely within the stomach, such as the inflatable balloon device **300**, and that the bumps **512** or flagella **522** may be provided in a non-uniform distribution so as to take advantage of the benefits of the rotational variation described above. That is, a regular array of such exterior features may stimulate the stomach wall more than a smooth surface, but also providing a non-uniform distribution will create different sensations on a constantly changing basis. The bumps **512** or flagella **522** may also be provided on the atraumatic feet **120** of the embodiment in Figures 1A-1H or the balloon feet **210**, **212** of Figures 2-4, to facilitate nerve stimulation.

[0077] An alternative intragastric device may include recesses or dimples extending inward from the surface of the intragastric device, much like the reverse of the outward bumps in Figure 8. For instance, the intragastric device may have a surface comprised of recesses between flat portions. A plurality of such recesses may be equally spaced apart on the outer surface. The recesses may not contact each other, and may be of equal heights and diameters. In addition to being depressed, the recesses may employ a thinner wall. For example, if the flat portions have a wall thickness of 20 millimeters, the recesses may have a wall thickness of 10 millimeters. With a thinner wall, the recesses may be more susceptible to larger strains.

[0078] The implantable devices described herein will be subjected to clinical testing in humans. The devices are intended to treat obesity, which is variously defined by different medical authorities. In general, the terms "overweight" and "obese" are labels for ranges of weight that are greater than what is generally considered healthy for a given height. The terms also identify ranges of weight that have been shown to increase the likelihood of certain diseases and other health problems. Applicants propose implanting the devices as described herein into a clinical survey group of obese patients in order to monitor weight loss.

[0079] The clinical studies will utilize the devices described above in conjunction with the following parameters.

[0080] Materials:

Silicone materials used include 3206 silicone for any shells, inflatable structures, or otherwise flexible hollow structures. Any fill valves will be made from 4850 silicone with 6% $BaSo_4$. Tubular structures or other flexible conduits will be made from silicone rubber as defined by the Food and Drug Administration (FDA) in the Code of Federal Regulations (CFR) Title 21 Section 177.2600.

[0081] Purposes:

the devices are for human implant,

the devices are intended to occupy gastric space while also applying intermittent pressure to various and continually changing areas of the stomach;

the devices are intended to stimulate feelings of satiety, thereby functioning as a treatment for obesity.

[0082] General implant procedures:

The device is intended to be implanted transorally via endoscope into the corpus of the stomach.

Implantation of the medical devices will occur via endoscopy.

Nasal/Respiratory administration of oxygen and isoflurane to be used during surgical procedures to maintain anesthesia as necessary.

[0083] One exemplary implant procedure is listed below.

a) Perform preliminary endoscopy on the patient to examine the GI tract and determine if there are any anatomical anomalies which may affect the procedure and/or outcome of the study.
b) Insert and introducer into the over-tube.
c) Insert a gastroscope through the introducer inlet until the flexible portion of the gastroscope is fully exited the distal end of the introducer.
d) Leading under endoscopic vision, gently navigate the gastroscope, followed by the introducer/over-tube, into the stomach.
e) Remove gastroscope and introducer while keeping the over-tube in place.
f) *OPTIONAL:* Place the insufflation cap on the over-tubes inlet, insert the gastroscope, and navigate back to the stomach cavity.
g) *OPTIONAL:* Insufflate the stomach with air/inert gas to provide greater endoscopic visual working volume.
h) Collapse the gastric implant and insert the lubricated implant into the over-tube, with inflation catheter following if required.
i) Under endoscopic vision, push the gastric implant down the over-tube with gastroscope until visual confirmation of deployment of the device into the stomach can be determined.
j) Remove the guide-wire from the inflation catheter is used.

k) If inflated: Inflate the implant using a standard BioEnterics Intragastric Balloon System ("BIB System") Fill kit.

l) Using 50-60cc increments, inflate the volume to the desired fill volume.

m) Remove the inflation catheter via over-tube.

n) Inspect the gastric implant under endoscopic vision for valve leakage, and any other potential anomalies. Record all observations.

o) Remove the gastroscope from over-tube.

p) Remove the over-tube from the patient.

[0084] End Point Criteria:

- Weight Loss
- Comprehensive Metabolic Panel (CMP)
- HbA1C
- Lipid Panel
- Tissue Samples/Response

[0085] Unless otherwise indicated, all numbers expressing quantities of ingredients, properties such as molecular weight, reaction conditions, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless indicated to the contrary, the numerical parameters set forth in the specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques.

[0086] Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the disclosure are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

[0087] The terms "a," "an," "the" and similar referents used in the context of describing the invention(especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated

herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0088] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other members of the group or other elements found herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0089] Certain embodiments are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0090] Furthermore, references may have been made to patents and printed publications in this specification. Each of the above-cited references and printed publications are individually incorporated herein by reference in their entirety.

[0091] Specific embodiments disclosed herein may be further limited in the claims using "consisting of" or "consisting essentially of" language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the invention so claimed are inherently or expressly described and enabled herein.

[0092] In closing, it is to be understood that the embodiments of the invention disclosed herein are illustrative of the principles of the present invention. Other modifications that may be employed are within the scope of the invention. Thus, by way of example, but not of limitation, alternative configurations of the present invention may be utilized in accordance with the teachings herein. Accordingly, the present invention is not limited to that precisely as shown and described.

WHAT IS CLAIMED IS:

1. A system for an implantable device of a size too large to pass through an opening of a patient's pylorus configured to be placed in a patient's stomach transorally without surgery to treat and prevent obesity by applying a pressure to the patient's stomach, comprising:

a central elongated body having an adjustable length;

two collapsible atraumatic feet on opposite ends of the elongated body, each foot configured to exert pressure on the patient's stomach when in a deployed position; and

an actuator within the central elongated body configured to adjust the length of the body and simultaneously the distance between the atraumatic feet.

2. The system of claim 1, wherein the two collapsible atraumatic feet comprise balloon-like structures.

3. The system of claim 1, wherein the two collapsible atraumatic feet comprise an array of living hinges that may be unfolded to an elongated delivery configuration and folded outward to a deployed configuration.

4. The system of claim 1, wherein the array of living hinges are in an X-shape.

5. The system of claim 1, wherein the actuator comprises an electronic motor.

6. The system of claim 5, wherein the actuator further comprises a control circuit board having a battery and a memory.

7. The system of claim 6, wherein the actuator further comprises a control circuit board having a transceiver, and the system further includes a remote control for instructing the motor from outside the patient's body.

8. The system of claim 5, wherein the actuator further comprises a telescoping screw driven by the motor.

9. The system of claim 1, wherein the actuator comprises a polymer element that is acid-activated to lengthen in a highly acidic environment, and the central elongated body includes through holes for exposing the polymer element to the stomach environment.

10. The system of claim 9, wherein the central elongated body comprises a series of telescoping tubular members having apertures along their lengths.

11. The system of claim 1, wherein the atraumatic feet include uneven external surface stimulation features.

12. A system for an implantable device of a size too large to pass through an opening of a patient's pylorus configured to be placed in a patient's stomach transorally without surgery to treat and prevent obesity by occupying space inside the patient's stomach, comprising:

an elastic balloon configured to be variably filled with stomach liquid; and

a body of the implantable device attached to the elastic balloon, the body configured to inflate and deflate the elastic balloon by transferring stomach liquid into and out of the elastic balloon; and

a peristaltic pumping device housed within the body of the implantable device configured to transfer the stomach liquid from outside the elastic balloon to inside the elastic balloon in a first mode of operation, and further configured to transfer the stomach liquid from inside the elastic balloon to outside the elastic balloon in a second mode of operation.

13. The system of claim 12, wherein the body of the implantable device further houses a motor configured to operate the peristaltic pumping device.

14. The system of claim 13, wherein the motor rotates rollers that are in contact with a pair of flexible tubes that form a conduit between an external opening located outside the elastic balloon and an internal opening located within the inner cavity of the elastic balloon.

15. The system of claim 12, further comprising:

an aseptic ring configured to fit around a portion of the exterior of the body and contact the stomach liquid when the stomach liquid is inside the elastic balloon.

16. The system of claim 12, wherein the device further comprises a control circuit board having a battery and a memory.

17. The system of claim 12, wherein the device further comprises a control circuit board having a transceiver, and the system further includes a remote control for instructing the motor from outside the patient's body.

18. The system of claim 12, wherein the elastic balloon includes uneven external surface stimulation features.

19. The system of claim 12, wherein the elastic balloon includes an aggregation of spheres to encourage rotation within the stomach.

20. The system of claim 12, wherein the elastic balloon includes a plurality of outwardly projecting legs terminating in rounded or bulbous feet that encourage rotation within the stomach.

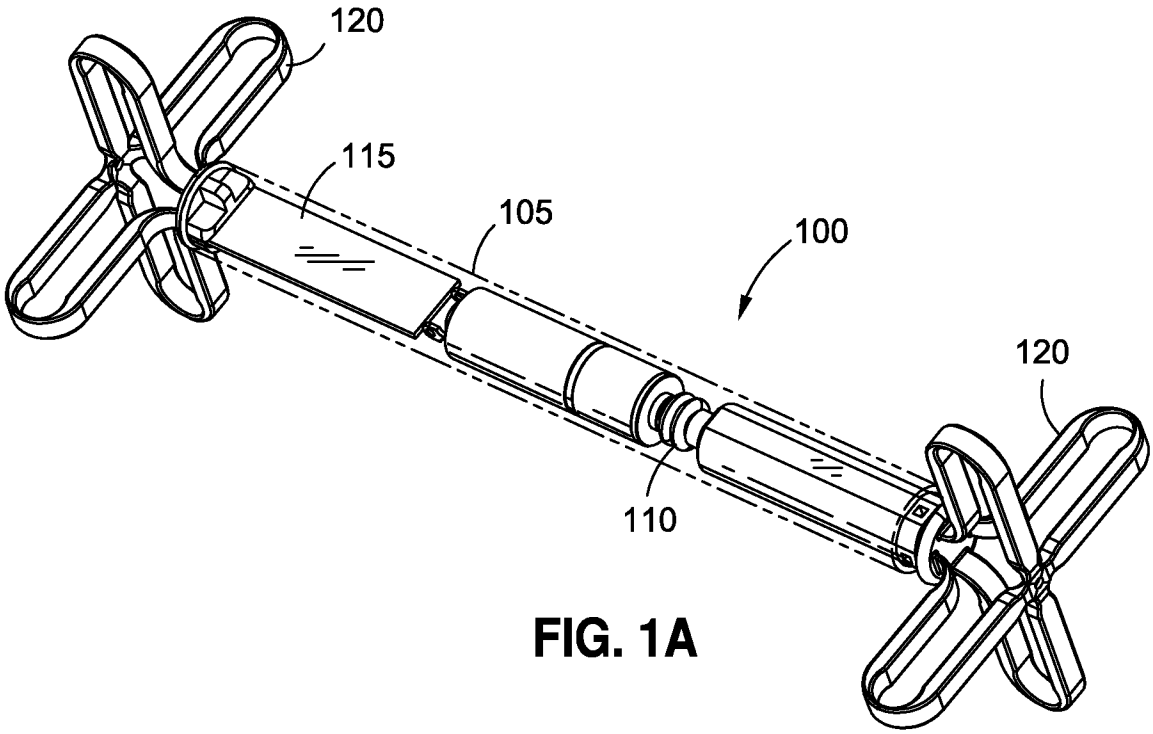

FIG. 1A

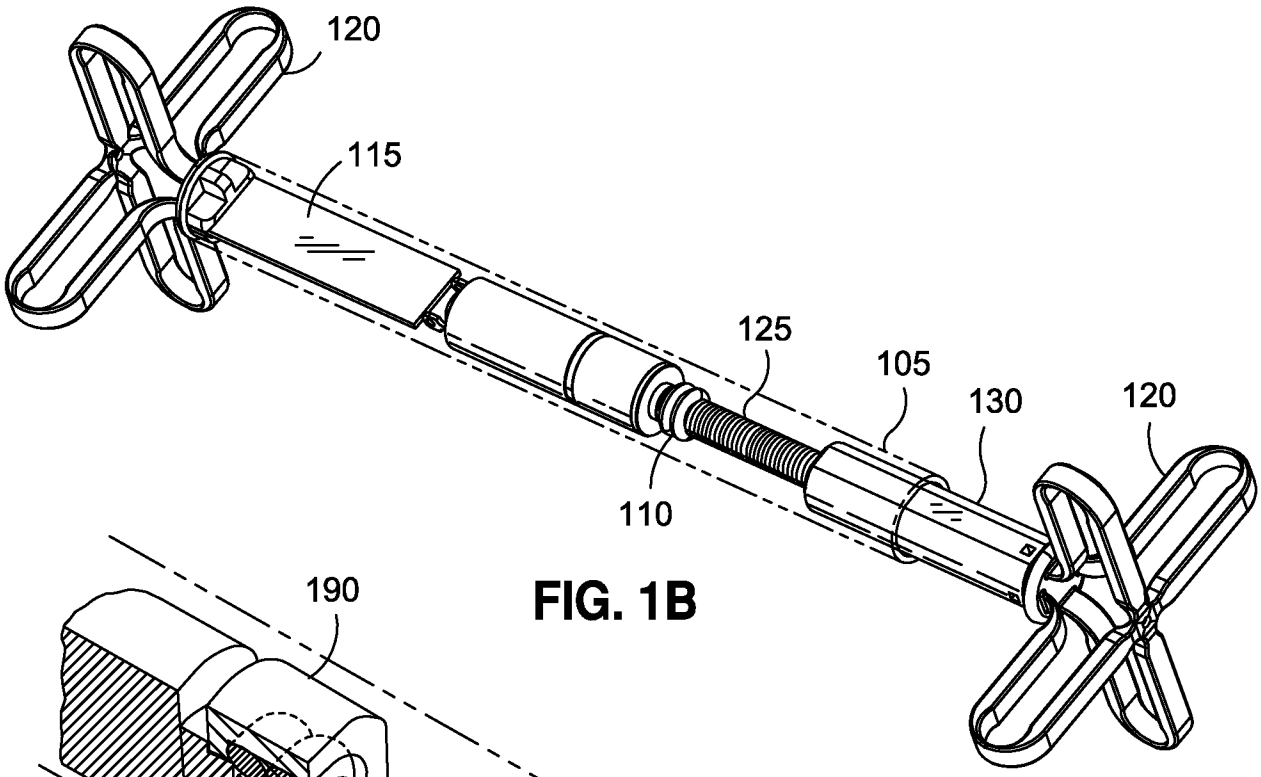

FIG. 1B

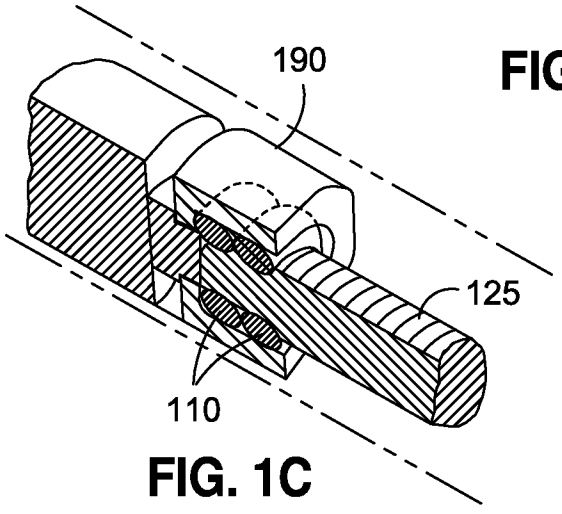

FIG. 1C

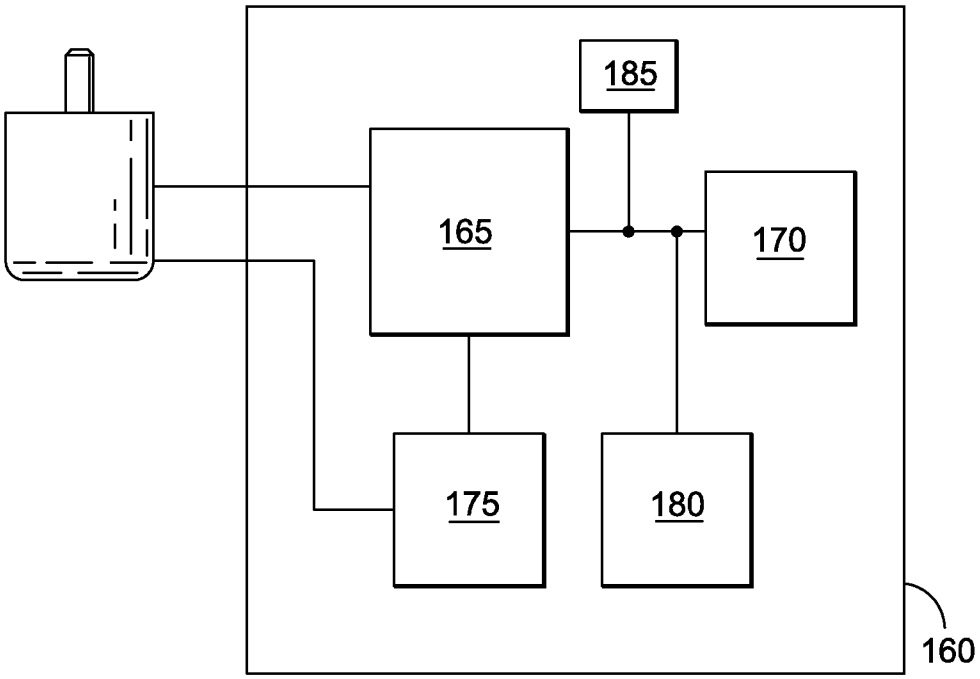

FIG. 1D

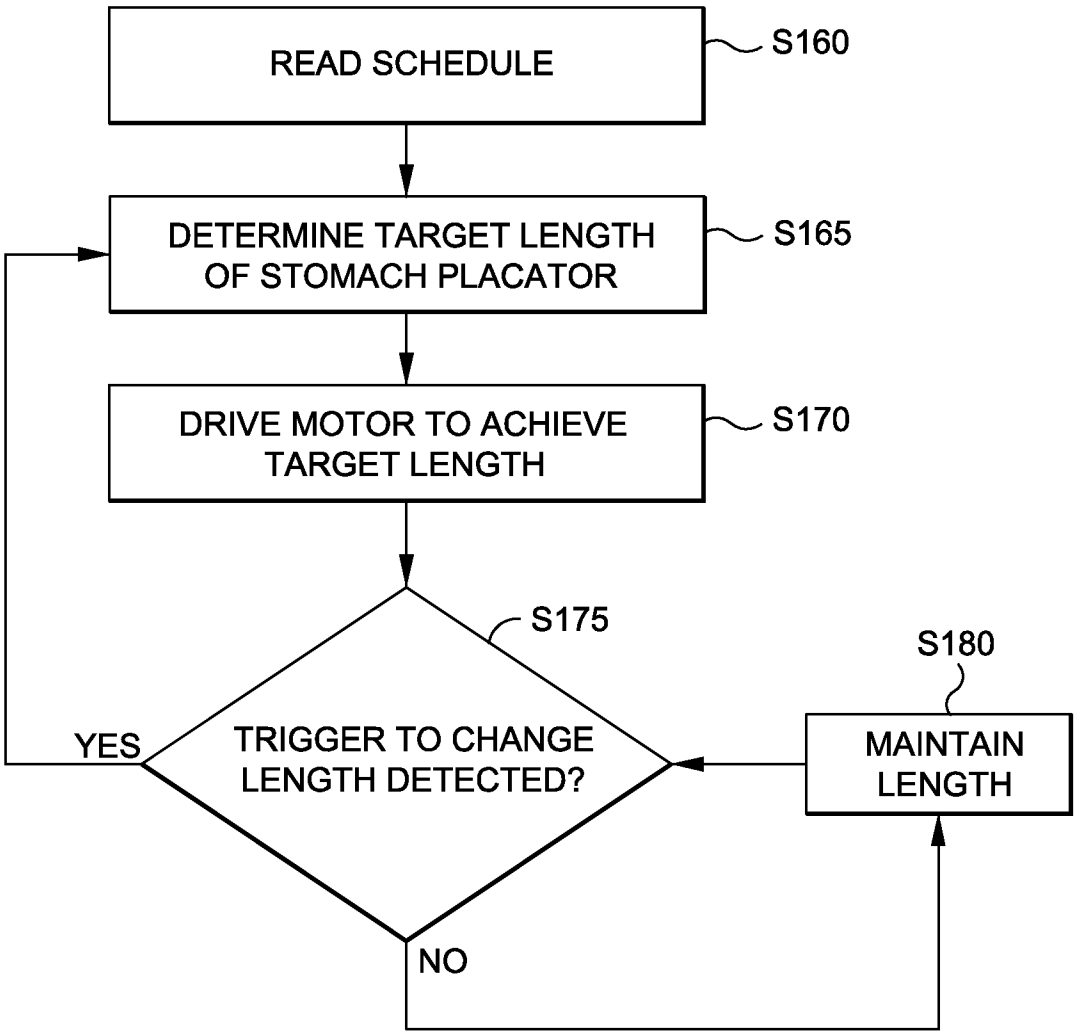
READ SCHEDULE
S160
DETERMINE TARGET LENGTH OF STOMACH PLACATOR
S165
DRIVE MOTOR TO ACHIEVE TARGET LENGTH
S170
S175
TRIGGER TO CHANGE LENGTH DETECTED?
YES
NO
S180
MAINTAIN LENGTH

FIG. 1E

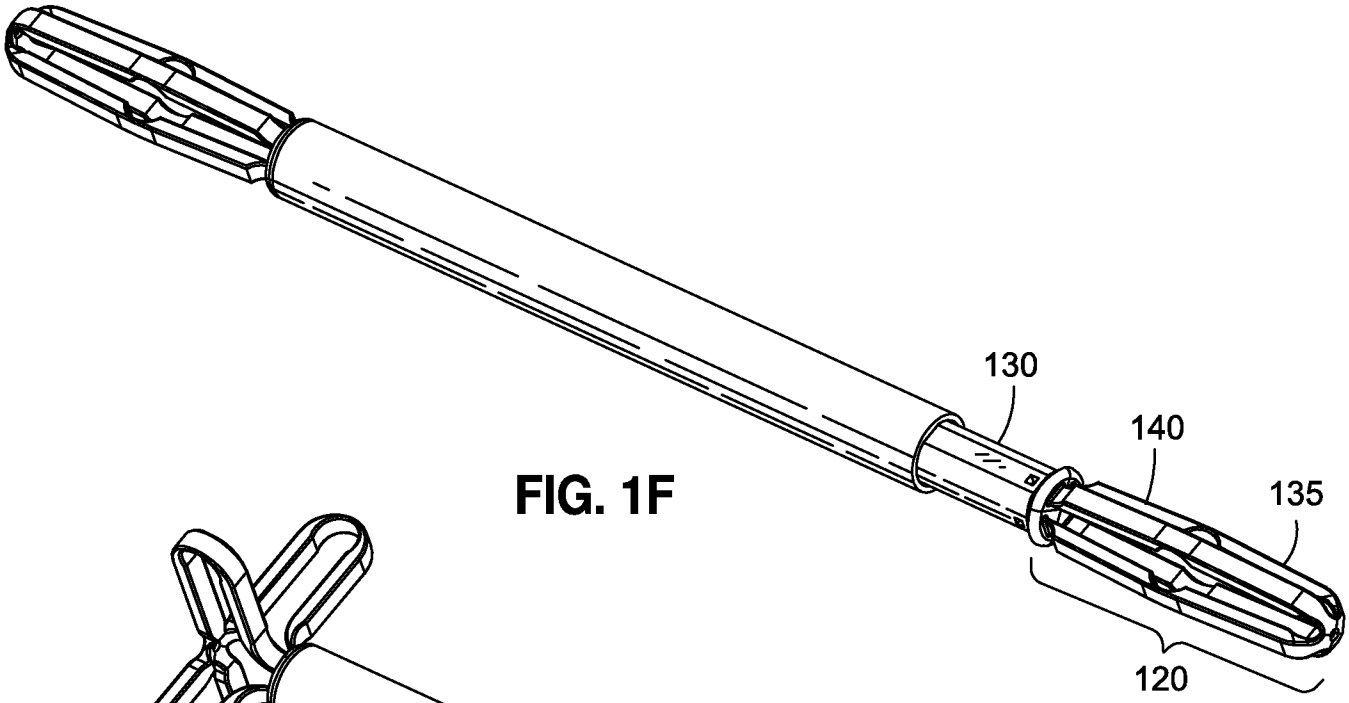

FIG. 1F

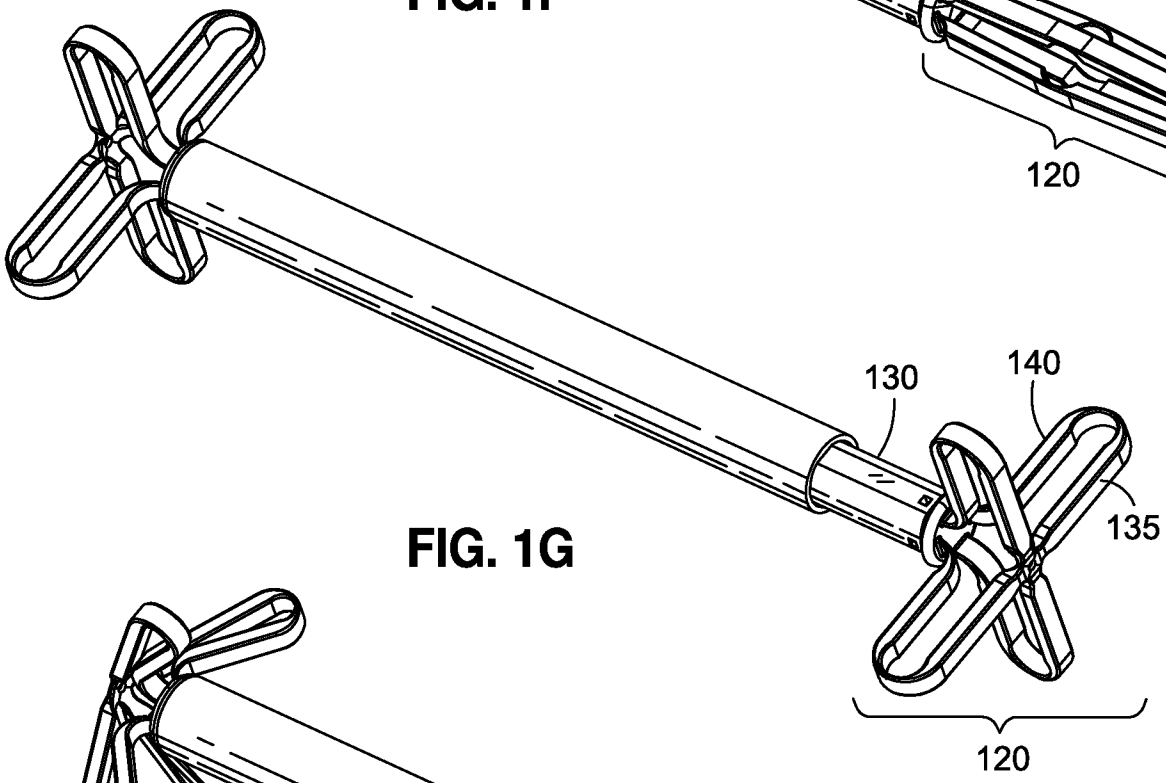

FIG. 1G

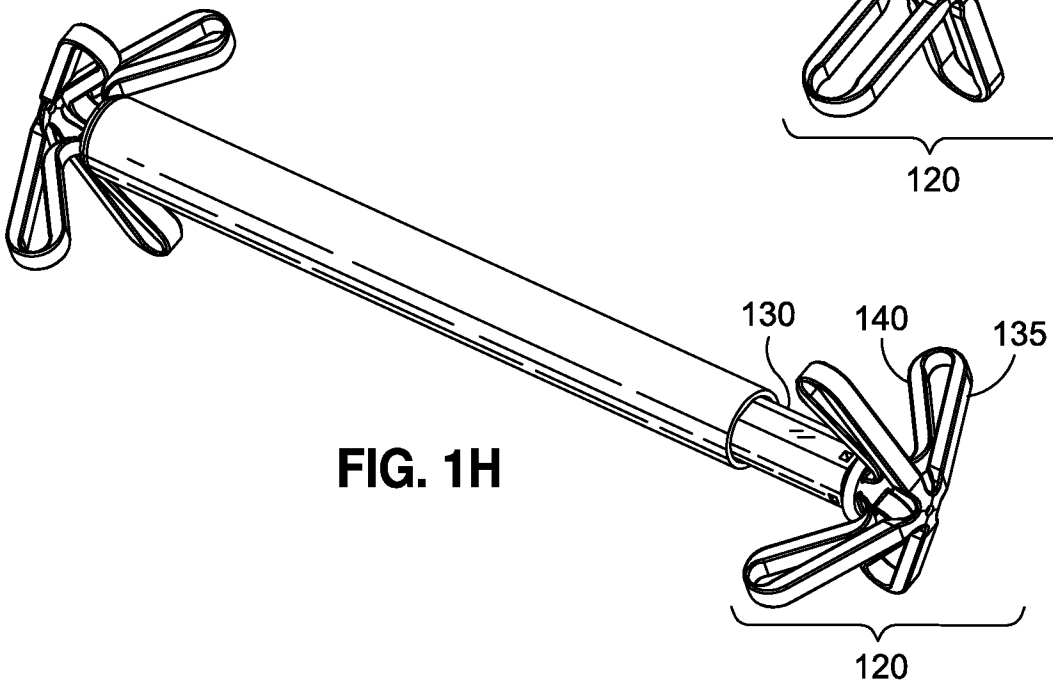

FIG. 1H

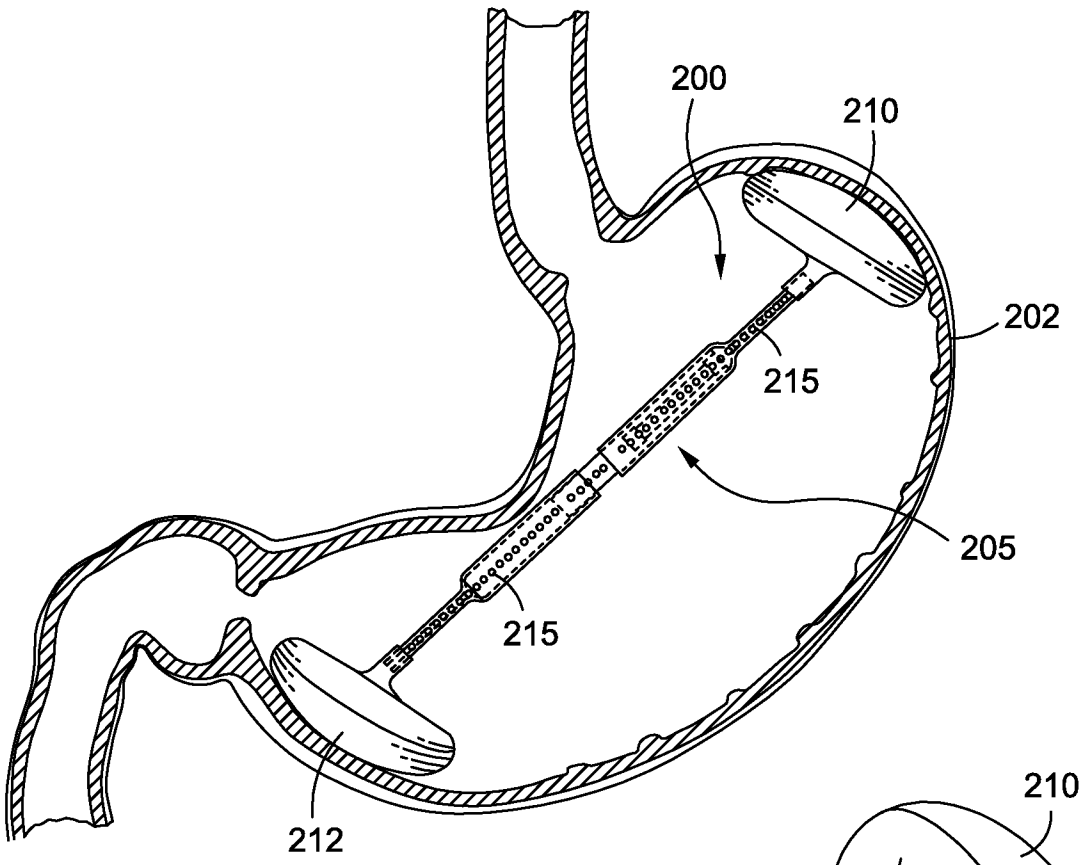

FIG. 2

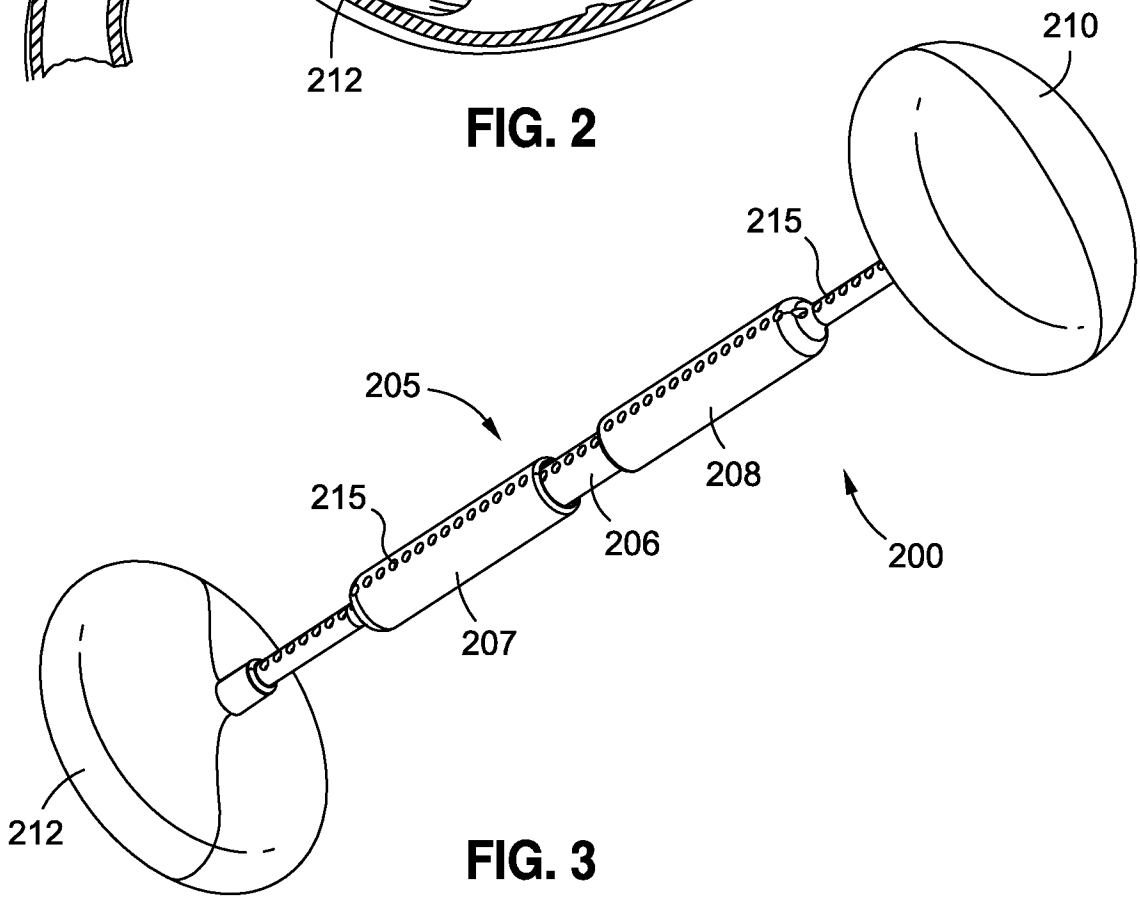

FIG. 3

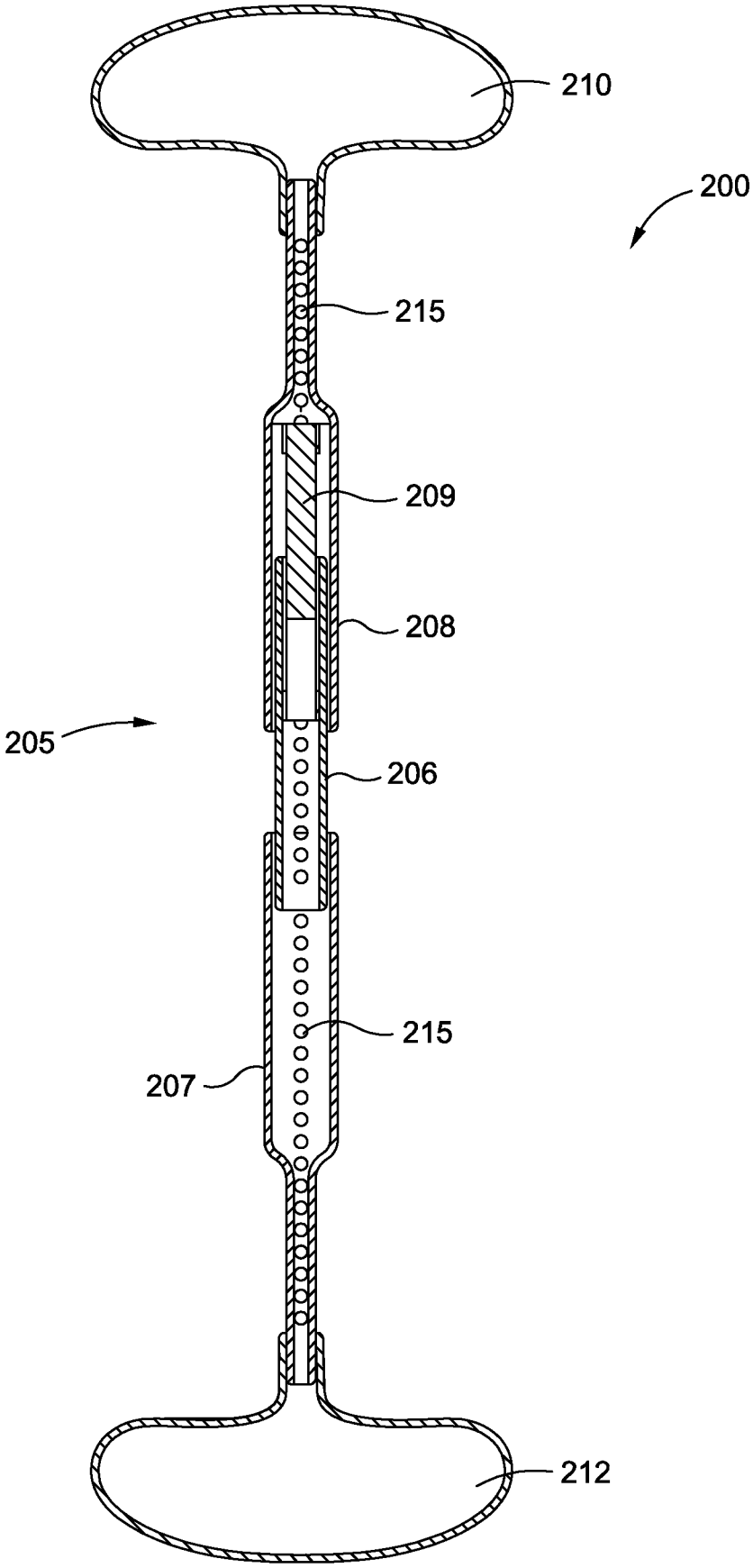

FIG. 4

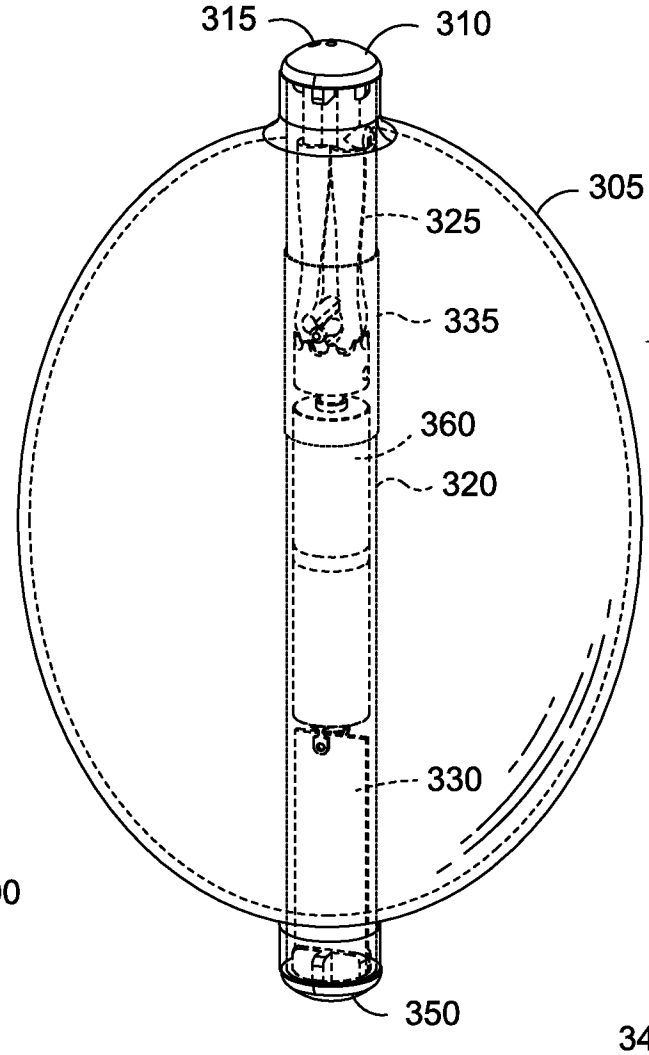

FIG. 5A

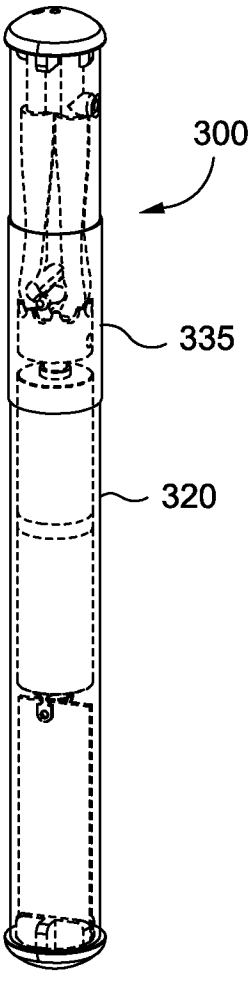

FIG. 5B

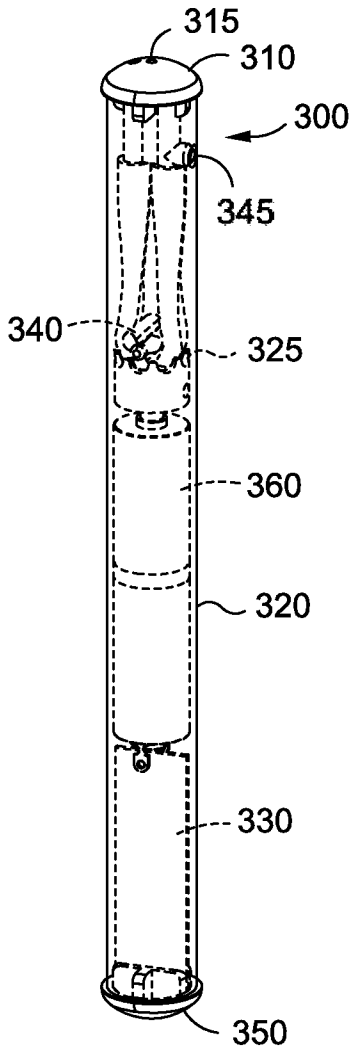

FIG. 5C

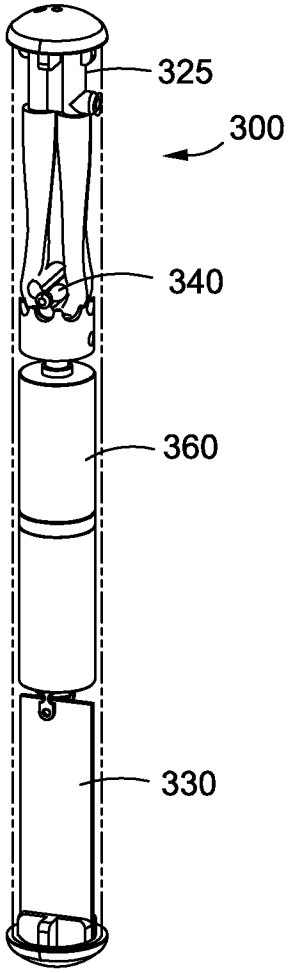

FIG. 5D

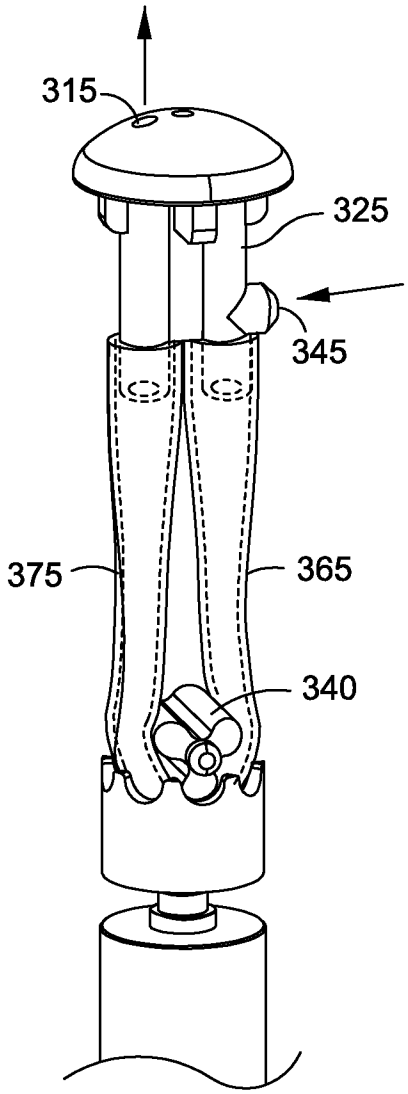

FIG. 5E

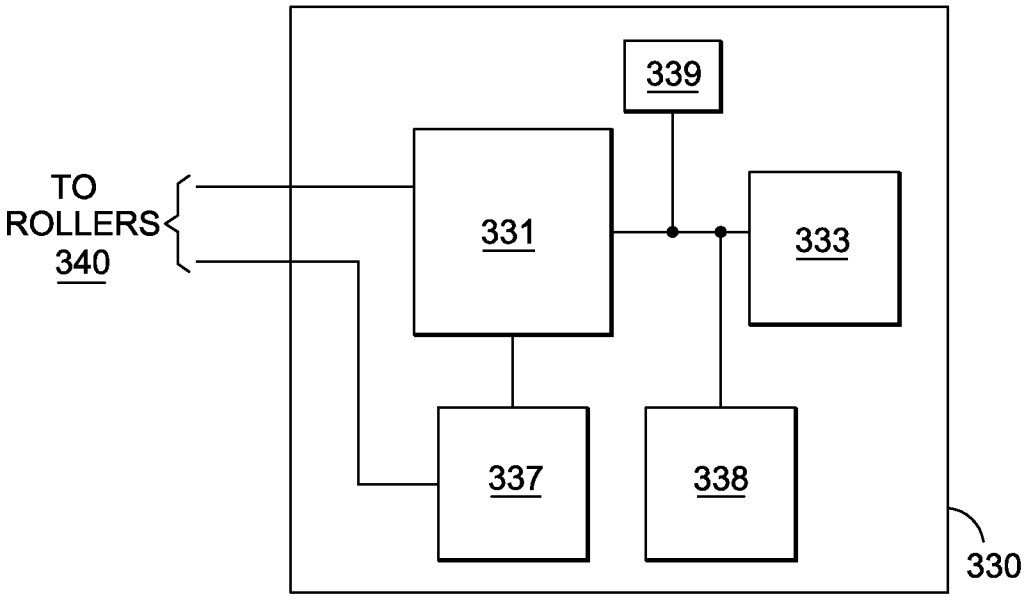

FIG. 5F

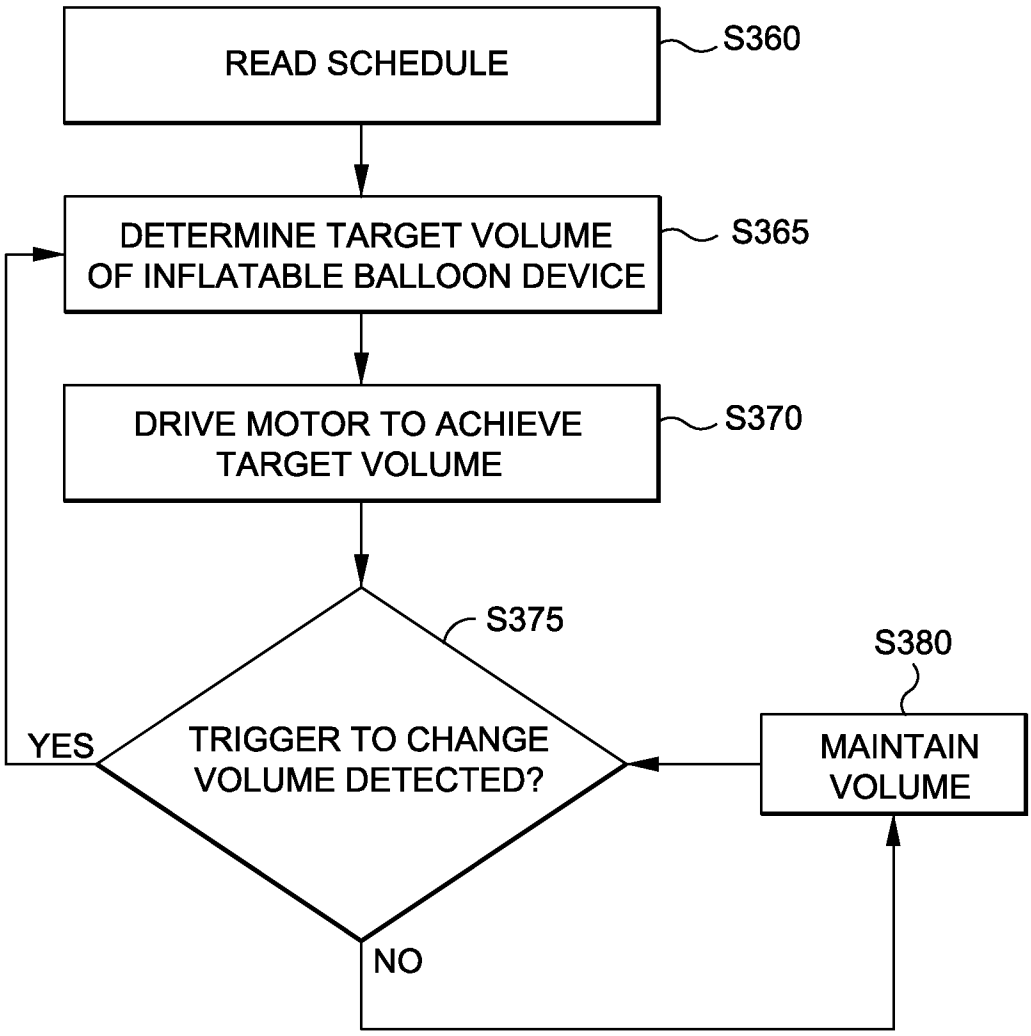
READ SCHEDULE
S360
DETERMINE TARGET VOLUME OF INFLATABLE BALLOON DEVICE
S365
DRIVE MOTOR TO ACHIEVE TARGET VOLUME
S370
S375
TRIGGER TO CHANGE VOLUME DETECTED?
YES
NO
S380
MAINTAIN VOLUME

FIG. 5G

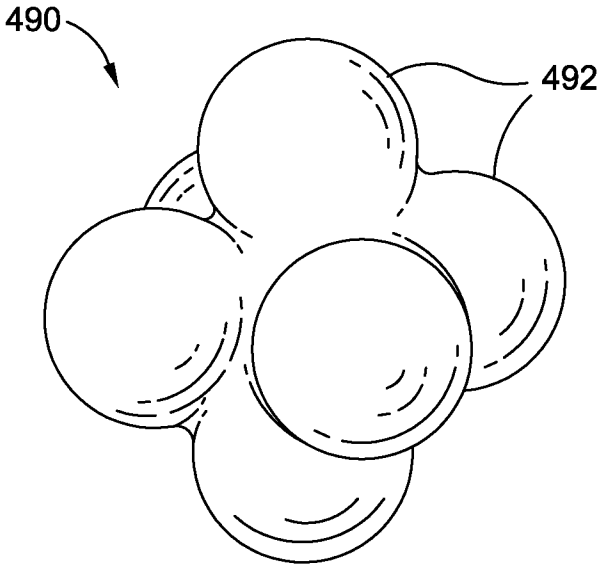

FIG. 6

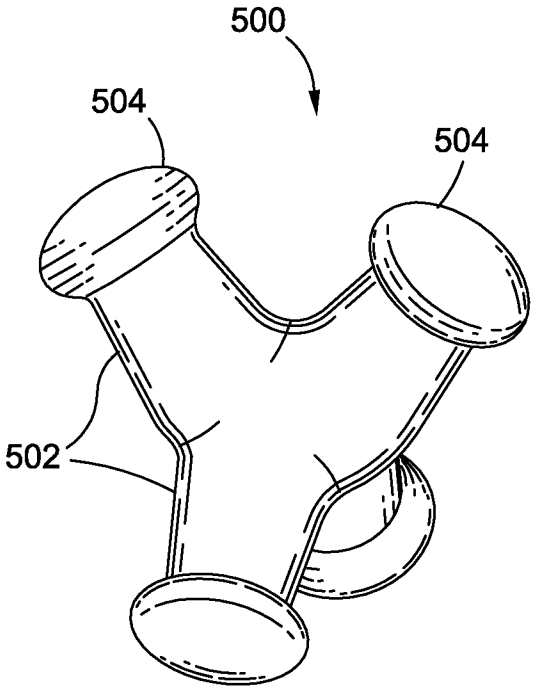

FIG. 7

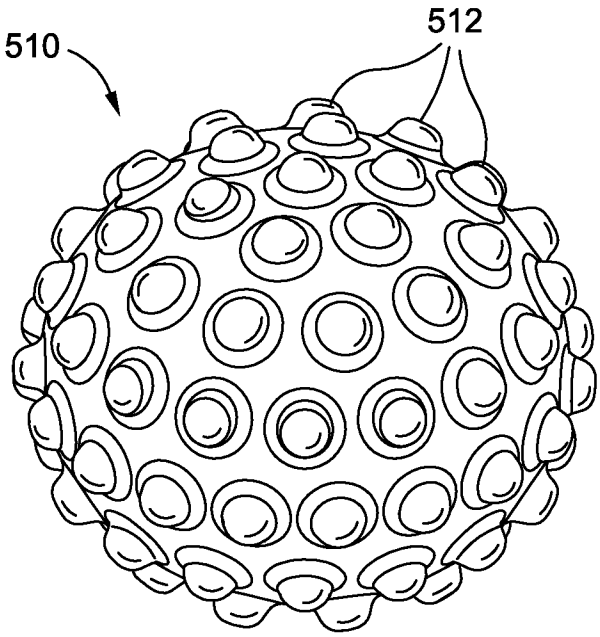

FIG. 8

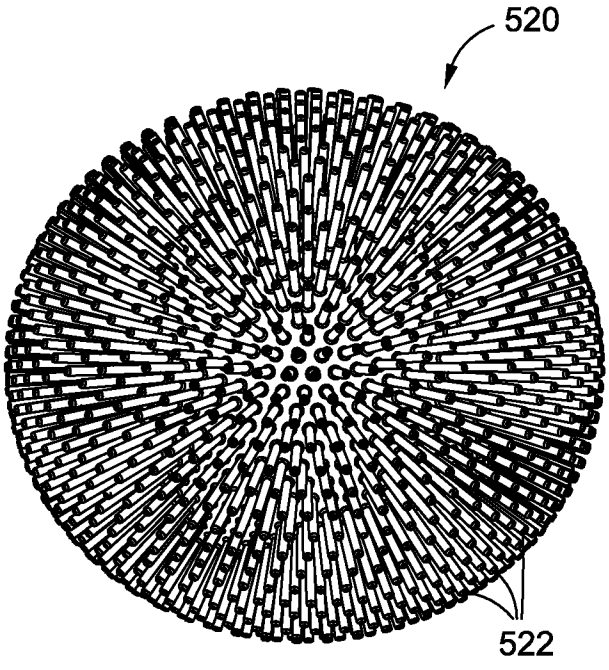

FIG. 9