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(54) **ESOPHAGEAL STENTS**

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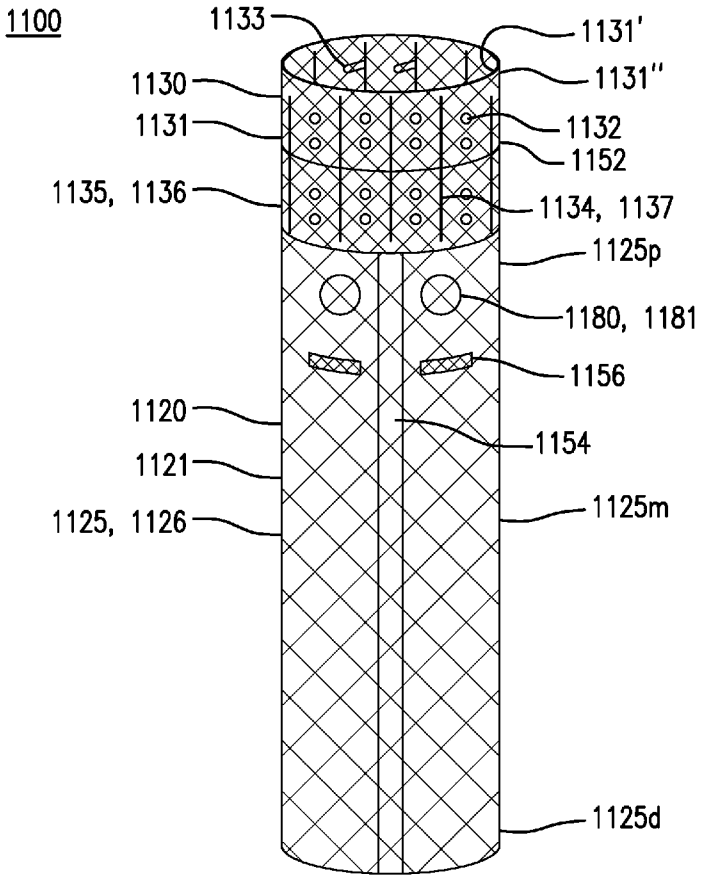
(57) **ABSTRACT**

Luminal devices are described. In one embodiment, a luminal device includes an esophageal stent and an anchoring membrane coupled to the esophageal stent. The anchoring membrane may be configured to be coupled to an esophageal wall with a tissue anchor placed through the anchoring membrane. The anchoring membrane may be configured to be pierced to allow the tissue anchor to be placed through the anchoring membrane.

Methods for attaching a luminal device to the esophageal wall are described. In one embodiment, a method may include forming a bulge in an anchoring membrane of the luminal device and the esophageal wall, piercing the bulge from a first side of the anchoring membrane and a first side of the esophageal wall, placing a second retention element of a tissue anchor on a second side of the esophageal wall; and placing a tension element of the tissue anchor through the anchoring membrane and the esophageal wall. The tension element may be coupled to the second retention element. The method may further include placing a first retention element on the first side of the anchoring membrane. The first retention element may be coupled to the tension element.



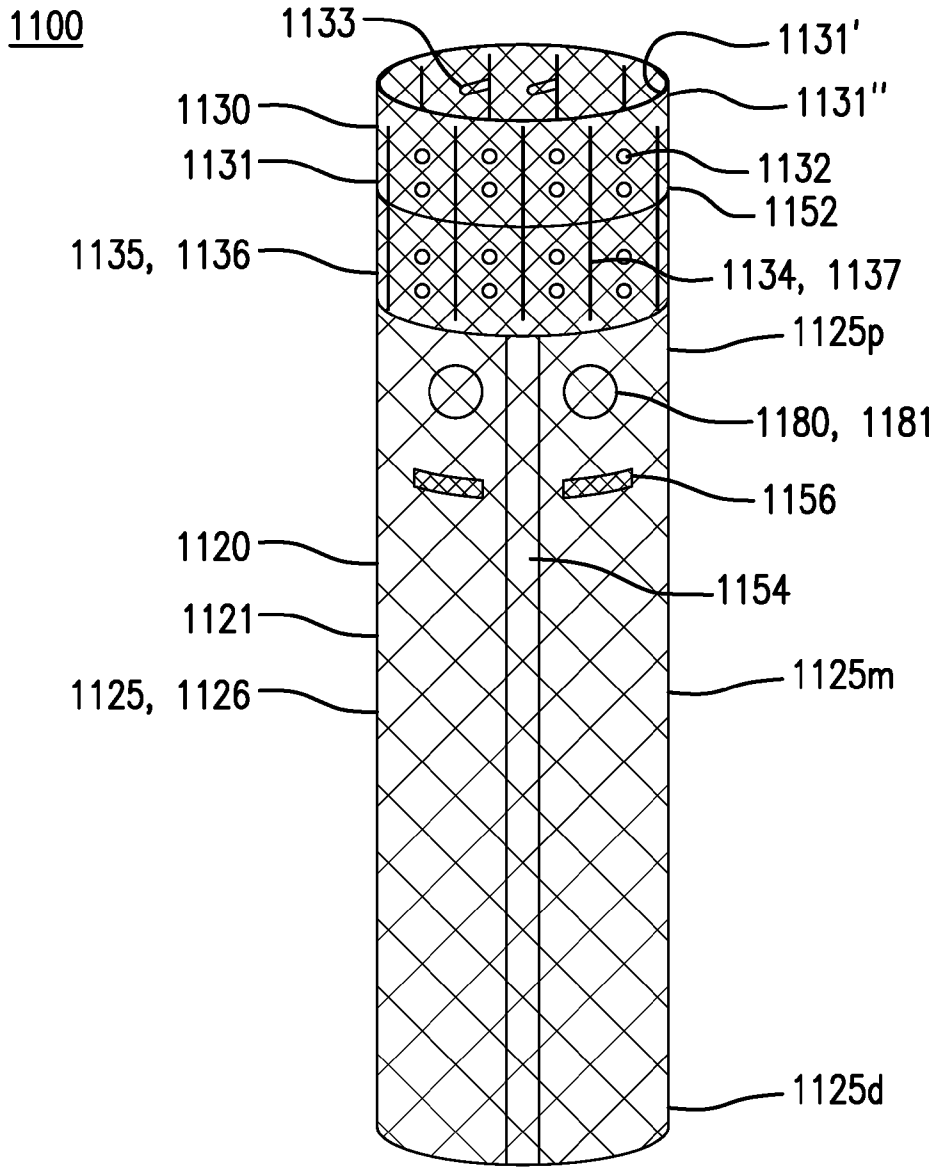

1100
1133
1131'
1130
1131"
1131
1132
1152
1135, 1136
1134, 1137
1125p
1180, 1181
1156
1120
1154
1121
1125m
1125, 1126
1125d

FIG.1A

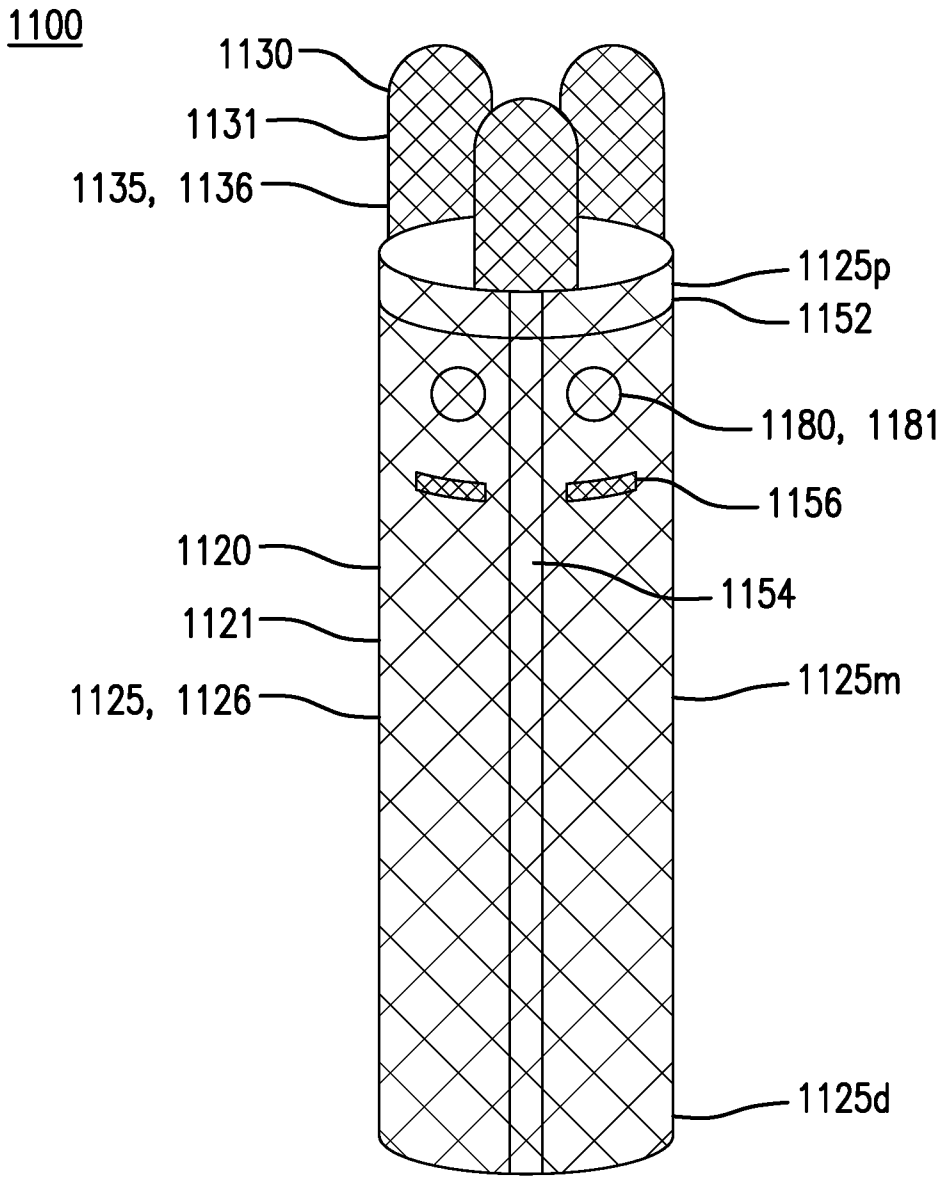

1100
1130
1131
1135, 1136
1125p
1152
1180, 1181
1156
1120
1154
1121
1125m
1125, 1126
1125d

FIG.1B

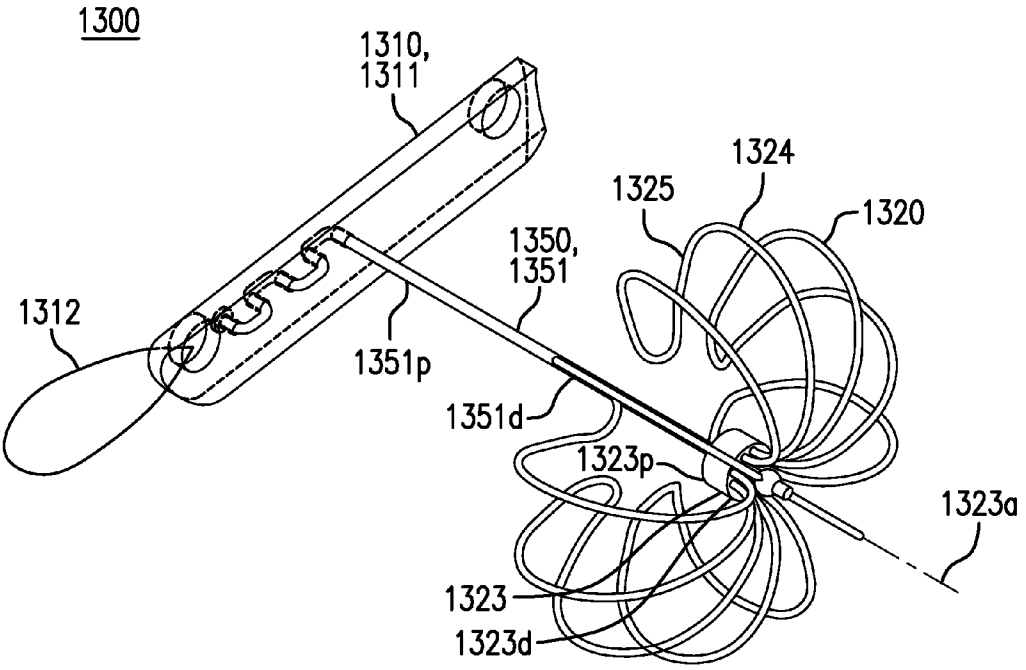

1300
1310,
1311
1324
1325
1320
1350,
1351
1312
1351p
1351d
1323p
1323a
1323
1323d

FIG.2A

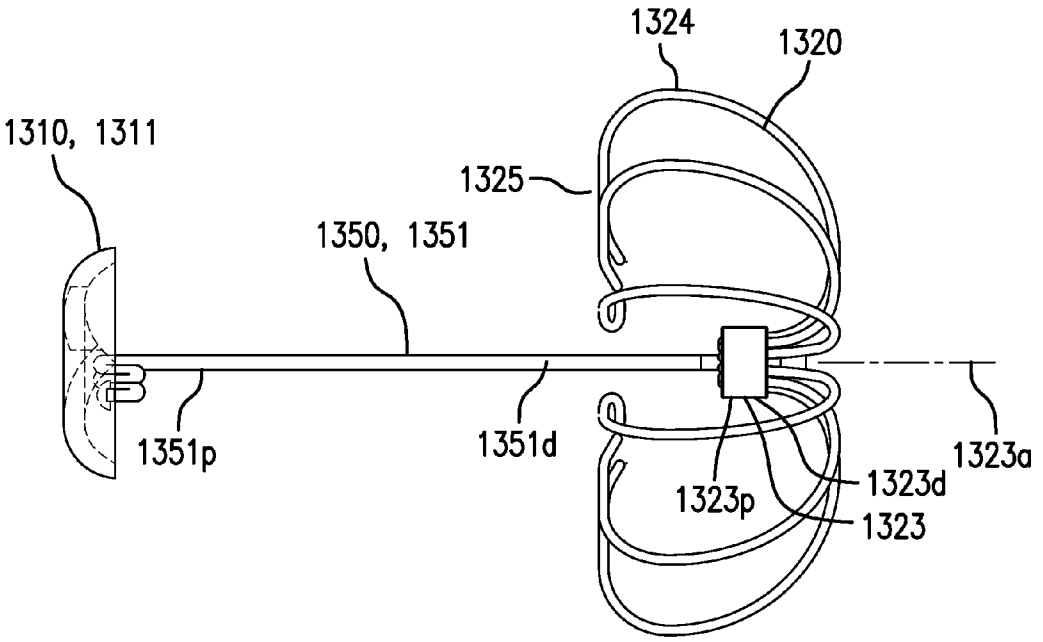

1324
1320
1310, 1311
1325
1350, 1351
1351p
1351d
1323a
1323d
1323p
1323

FIG.2B

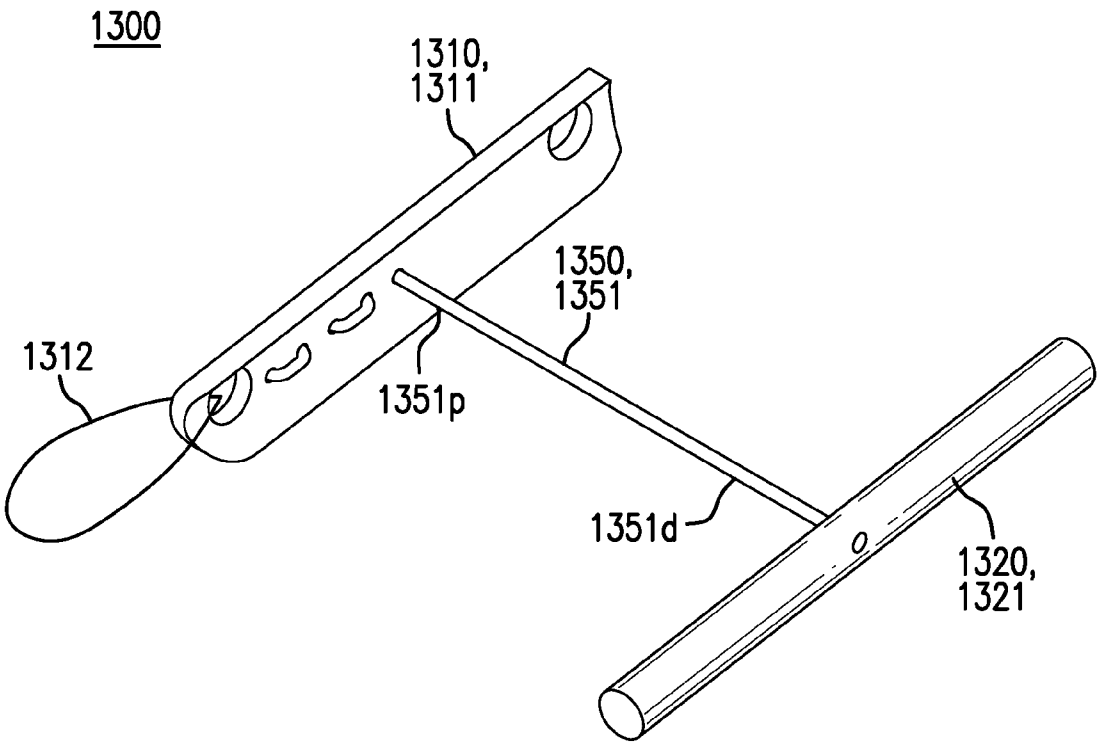


FIG.2C

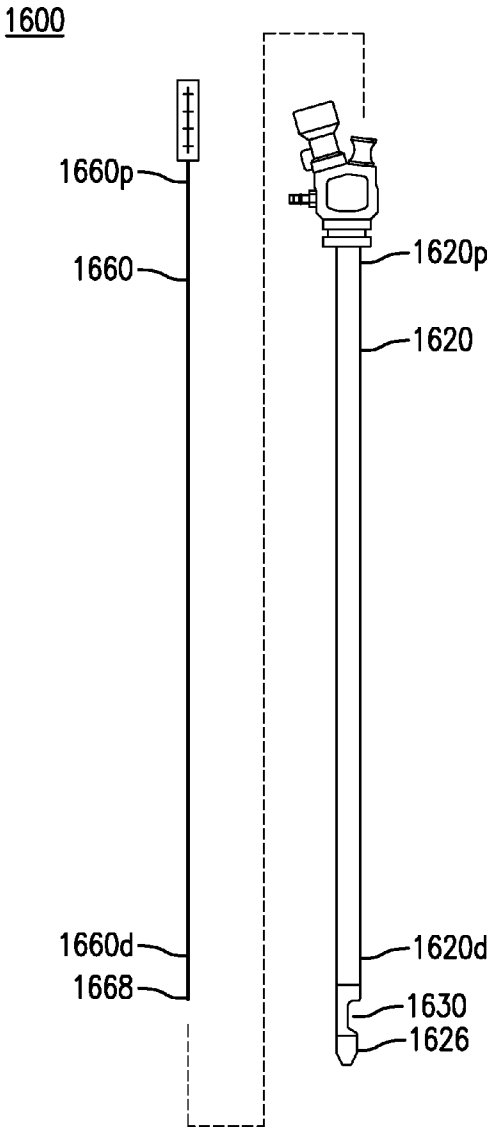

1600
1660p
1660
1660d
1668
1620p
1620
1620d
1630
1626

FIG.3A

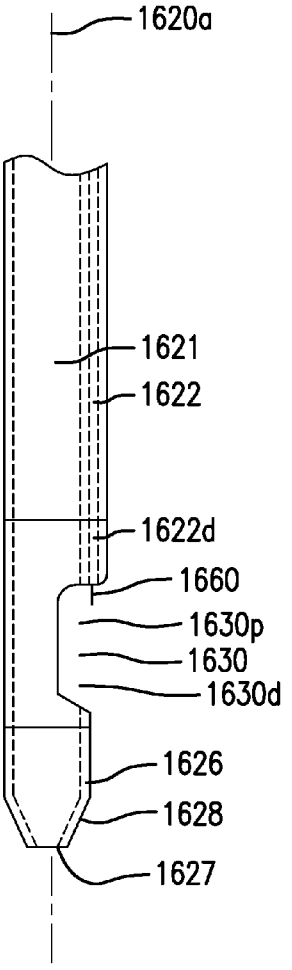

1620a
1621
1622
1622d
1660
1630p
1630
1630d
1626
1628
1627

FIG.3B

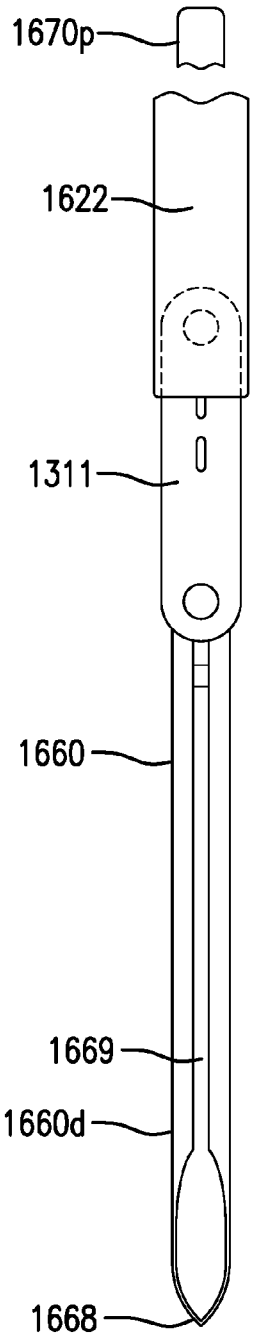

1670p
1622
1311
1660
1669
1660d
1668

FIG.3C

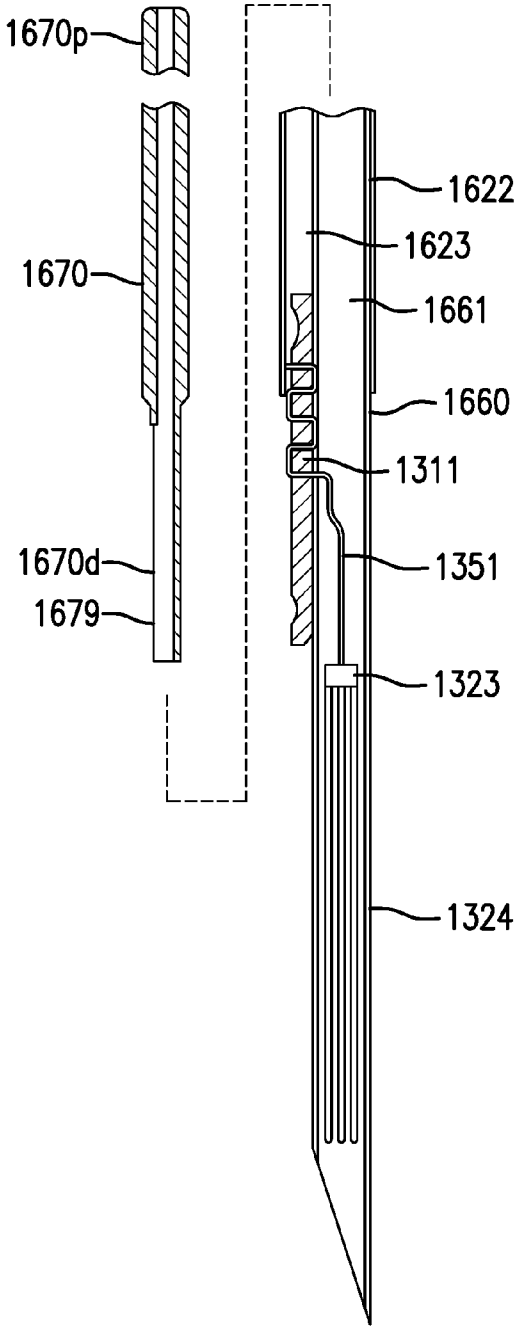

1670p
1670
1670d
1679
1622
1623
1661
1660
1311
1351
1323
1324

FIG.3D

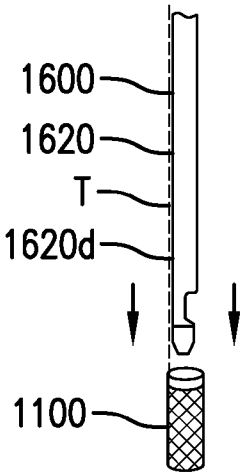


FIG.4A

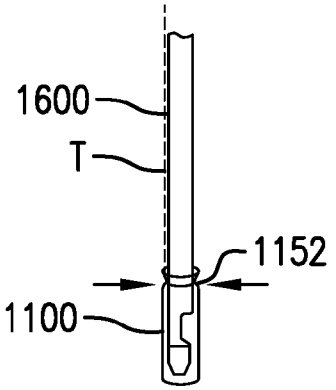


FIG.4B

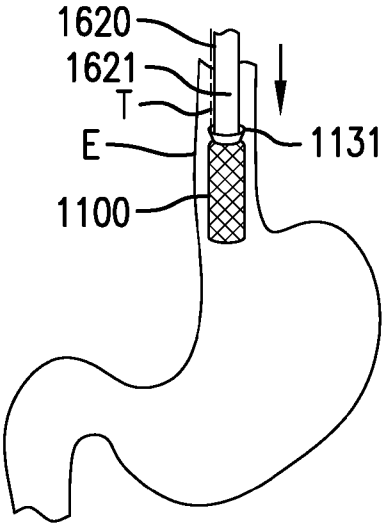


FIG.4C

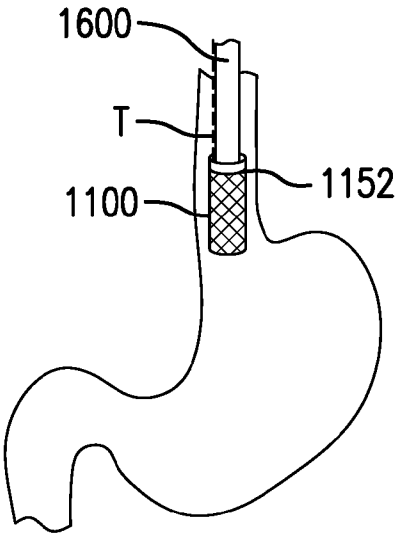


FIG.4D

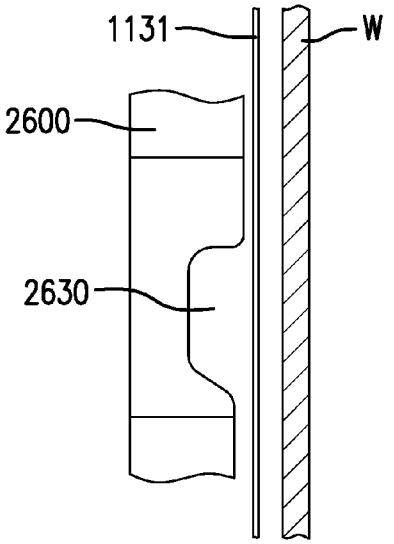


FIG.4E

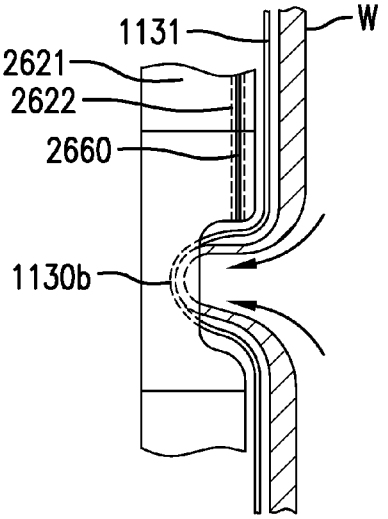


FIG.4F

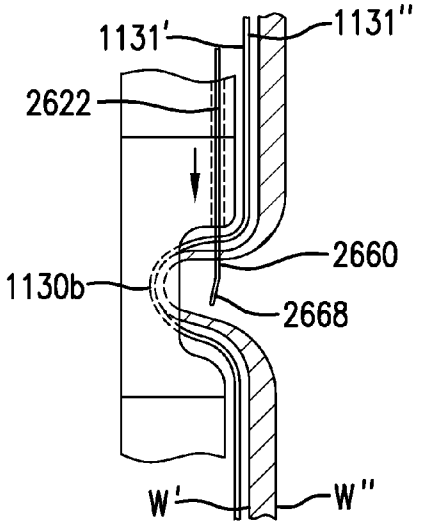


FIG.4G

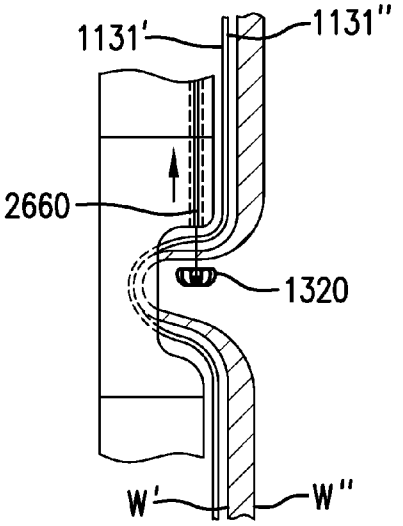


FIG.4H

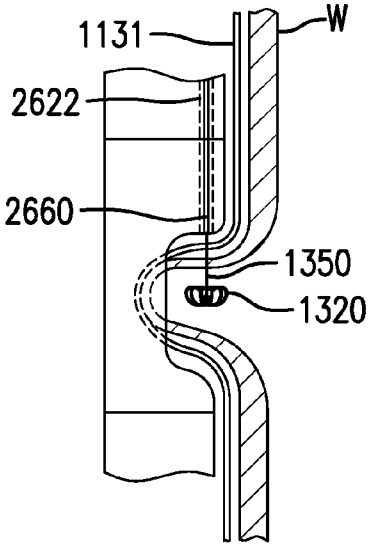


FIG.4I

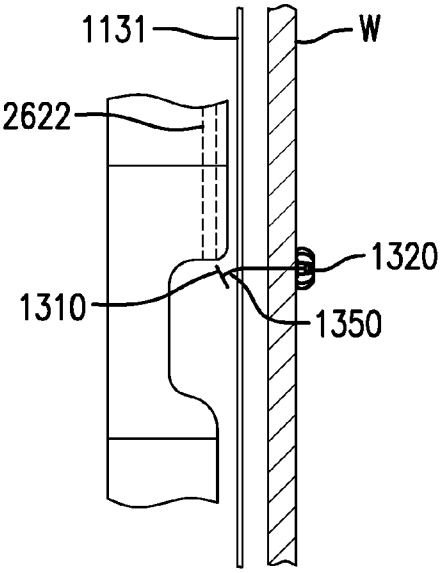


FIG.4J

ESOPHAGEAL STENTS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional application Nos. 62/073,927, filed Oct. 31, 2014, and 62/147,588, filed Apr. 15, 2015. These applications are hereby incorporated by reference in their entireties.

BACKGROUND

[0002] Esophageal stents are used to treat strictures and malignances in the esophagus. Esophageal stents are also used to treat fistulas, perforations, and leaks in the esophagus.

[0003] An esophageal stent may be held in place by its own outward bias. However, the esophageal stent may migrate out of position, or migrate completely out of the esophagus. An esophageal stent may be held in place by tissue ingrowth portions which allow the esophageal wall to grow into the esophageal stent. However, the esophageal stent subsequently becomes difficult to remove or reposition.

[0004] What is needed is an esophageal stent which reduces the likelihood of migrating out of position. What is needed is an esophageal stent which reduces the likelihood of migrating out of position, and also allows subsequent removal or repositioning.

SUMMARY

[0005] Luminal devices are described. In one embodiment, a luminal device includes an esophageal stent and an anchoring membrane coupled to the esophageal stent. The anchoring membrane may be configured to be coupled to an esophageal wall with a tissue anchor placed through the anchoring membrane. The anchoring membrane may be configured to be pierced to allow the tissue anchor to be placed through the anchoring membrane.

[0006] Methods for attaching a luminal device to the esophageal wall are described. In one embodiment, a method may include forming a bulge in an anchoring membrane of the luminal device and the esophageal wall, piercing the bulge from a first side of the anchoring membrane and a first side of the esophageal wall, placing a second retention element of a tissue anchor on a second side of the esophageal wall; and placing a tension element of the tissue anchor through the anchoring membrane and the esophageal wall. The tension element may be coupled to the second retention element. The method may further include placing a first retention element on the first side of the anchoring membrane. The first retention element may be coupled to the tension element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. **1**A shows one embodiment of luminal device **1100**. FIG. **1**B shows another embodiment of luminal device **1100**.

[0008] FIGS. **2**A-**2**C shows two embodiments of a tissue anchor **1300**.

[0009] FIGS. **3**A-**3**D show one embodiment of an anchor delivery device **1600**.

[0010] FIGS. **4**A-**4**J show one embodiment of a method for delivering a luminal device.

DESCRIPTION

[0011] FIG. **1**A shows one embodiment of a luminal device **1100**. FIG. **1**B shows another embodiment of luminal device **1100**.

[0012] Luminal device **1100** may be configured to treat strictures, malignancies, fistulas, perforations, and leaks in the esophagus.

[0013] Luminal device **1100** may include an esophageal stent **1120**.

[0014] Esophageal stent **1120** may be configured to be placed at least partially in the esophagus. Esophageal stent **1120** may be placed against the esophageal wall. Esophageal stent **1120** may be configured to be placed through a stricture or malignancy in the esophagus. Esophageal stent **1120** may be configured to keep the esophagus at least partially open through a stricture or malignancy in the esophagus. Esophageal stent **1120** may be configured to be placed against a fistula, perforation, or leak in the esophageal wall. Esophageal stent **1120** may be configured to reduce leakage from a fistula, perforation, or leak in the esophageal wall.

[0015] Esophageal stent **1120** may include a scaffold **1125**. Scaffold **1125** may include a proximal portion **1125***p*, a middle portion **1125***m*, and a distal portion **1125***d*.

[0016] Scaffold **1125** may be configured to have an outward bias. Scaffold **1125** may be configured to have an outward bias sufficient to keep the esophagus at least partially open through a stricture or malignancy in the esophagus. Scaffold **1125** may have an outward bias sufficient to keep the esophagus at least 10% open through the stricture or malignancy in the esophagus.

[0017] Scaffold **1125** may have a width that is constant. Scaffold **1125** may have a width greater at proximal portion **1125***p* and/or distal portion **1125***d*.

[0018] Scaffold **1125** may include a braid **1126**. Braid **1126** may be made of plastic, metal, or other suitable material. Braid **1126** may have uniform or varying opening sizes. Scaffold **1125** may include a stent, a mesh, or other suitable structure.

[0019] Esophageal stent **1120** may include a liner **1121**. Liner **1121** may be coupled to scaffold **1125**. Liner **1121** may include two or more layers that sandwich scaffold **1125**, such as by blow molding. Liner **1121** may include a coating formed on scaffold **1125**, such as by dip coating.

[0020] Liner **1121** may be configured to line the esophagus. Liner **1121** may be configured to be placed against a fistula, perforation, or leak in the esophageal wall. Liner **1121** may be configured to reduce leakage from a fistula, perforation, or leak in the esophageal wall.

[0021] Liner **1121** may be made of silicone, polyethylene, polypropylene, a polyurethane such as PELLETHANE, or other suitable material.

[0022] Luminal device **1100** includes an anchor attachment element **1130**.

[0023] Anchor attachment element **1130** may include at least one anchoring membrane **1131**. Anchoring membrane **1131** may include a first side **1131'** and a second side **1131"**. Anchoring membrane **1131** is coupled to esophageal stent **1120**. Anchoring membrane **1131** may be coupled to proximal portion **1125***p*, middle portion **1125***m*, distal portion **1125***d*, or any part of scaffold **1125**. Anchoring membrane **1131** may interrupt scaffold **1125** and/or liner **1121**.

[0024] Anchoring membrane **1131** may be configured to be placed in the esophagus. Anchoring membrane **1131** may be configured to be placed next to a wall of the esophagus.

Anchoring membrane **1131** may be configured to be attached to a tissue anchor. Anchoring membrane **1131** may be configured to be attached to the wall of the esophagus with a tissue anchor placed through anchoring membrane **1131**. Anchoring membrane **1131** may be configured to be pierced to allow a tissue anchor to be placed through anchoring membrane **1131** and attach anchoring membrane **1131** to the wall of the esophagus. Anchoring membrane **1131** may be configured to retain a tissue anchor placed through anchoring membrane **1131**. Anchoring membrane **1131** may be sufficiently strong to prevent a tissue anchor placed through anchoring membrane from pulling through and/or tearing anchoring membrane **1131**.

[0025] Anchoring membrane **1131** may be configured to be collapsible. Anchoring membrane **1131** may be configured to be pulled or collapsed with a vacuum applied to first side **1131'** of anchoring membrane **1131**. Anchoring membrane **1131** may be configured to be pulled or collapsed with a grasper or hook from first side **1131'** of anchoring membrane **1131**. Anchoring membrane **1131** may be configured to be pulled or collapsed toward first side **1131'** of anchoring membrane **1131**.

[0026] Anchoring membrane **1131** may be flexible. Anchoring membrane **1131** may be stretchable and recover without permanent set.

[0027] Anchoring membrane **1131** may include one or more layers. Anchoring membrane **1131** may be made of silicone, polyethylene, polypropylene, a polyurethane such as PELLETHANE, or other suitable material.

[0028] Anchoring membrane **1131** may include one or more perforations **1132** formed in anchoring membrane **1131**.

[0029] Perforations **1132** may be configured to allow at least a portion of a vacuum applied to one side of anchoring membrane **1131** to reach through anchoring membrane **1131**. Perforations **1132** may be configured to allow at least a portion of a vacuum applied to anchoring membrane **1131** to reach a tissue wall placed next to anchoring membrane **1131**. Perforations **1132** may be configured to allow at least a portion of a vacuum applied to first side **1131'** of anchoring membrane **1131** to reach a tissue wall placed next to second side **1131"** of anchoring membrane **1131**.

[0030] Perforations **1132** may include any one or any combination of holes, slits, and other openings of any suitable shape and size.

[0031] Anchoring membrane **1131** may include one or more pulls **1133**. Pulls **1133** may be coupled to anchoring membrane **1131** and/or reinforcement structure **1135**. Pulls **1133** may extend from first side **1131'** of anchoring membrane **1131**.

[0032] Pulls **1133** may be configured to allow anchoring membrane **1131** to be pulled or collapsed. Pulls **1133** may be configured to allow anchoring membrane **1131** to be pulled or collapsed toward first side **1131'** of anchoring membrane **1131**.

[0033] Pulls **1133** may include any one or any combination of loops, tabs, and other suitable structures. Pulls **1133** may be made of a biodegradable material.

[0034] Anchoring membrane **1131** may include one or more creases **1134**. Creases **1134** may be formed by scoring anchoring membrane **1131** and/or forming thinner portions of anchoring membrane **1131**. Creases **1134** may be configured to allow anchoring membrane **1131** to collapse along creases **1134**. Creases **1134** may allow anchoring membrane **1131** ato be more easily and/or predictably pulled or collapsed.

[0035] Anchor attachment element **1130** may include a reinforcement structure **1135**. Reinforcement structure **1135** may be coupled to anchoring membrane **1131**.

[0036] Reinforcement structure **1135** may be configured to reinforce anchoring membrane **1131**. Reinforcement structure **1135** may be configured to retain a tissue anchor placed through reinforcement structure **1135**. Reinforcement structure **1135** may be configured to reduce the likelihood of a tissue anchor placed through anchoring membrane **1131** pulling through and/or tearing anchoring membrane **1131**.

[0037] Reinforcement structure **1135** may include a braid **1136**. Braid **1136** may have uniform or varying opening sizes. Braid **1136** may be made of plastic, metal, or other suitable material. Reinforcement structure **1135** may include a stent, mesh, or other suitable structure.

[0038] Reinforcement structure **1135** may be coupled between two layers of anchoring membrane **1131**. Reinforcement structure **1135** may be coupled between two layers of anchoring membrane **1131** blow molded to sandwich reinforcement structure **1135**. Reinforcement structure **1135** may provide a substrate on which at least a portion of anchoring membrane **1131** is formed, such as by dip coating, spray coating, or other suitable methods.

[0039] Reinforcement structure **1135** may include one or more creases **1137**. Creases **1137** may be formed by scoring reinforcement structure **1135** and/or forming thinner portions of reinforcement structure **1135**. Creases **1137** may be configured to allow reinforcement structure **1135** to collapse along creases **1137**. Creases **1137** may allow reinforcement structure **1135** ato be more easily and/or predictably pulled or collapsed.

[0040] Liner **1121** and anchoring membrane **1131** may have the same or different properties. Liner **1121** and anchoring membrane **1131** may be made of the same or different materials and/or thicknesses.

[0041] Scaffold **1125** and reinforcement structure **1135** may have the same or different properties. Scaffold **1125** and reinforcement structure **1135** may be made of the same or different materials and/or thicknesses. Scaffold **1125** may overlap with reinforcement structure **1135**.

[0042] Any combination of liner **1121**, anchoring membrane **1131**, scaffold **1125**, and reinforcement structure **1135** may be formed as one or more pieces. For example, anchoring membrane **1131** and reinforcement structure **1135** may be formed as a single piece.

[0043] Esophageal stent **1120** and anchoring membrane **1131** may have the same or different widths.

[0044] Esophageal stent **1120** may have a length of approximately 20 mm to 150 mm. Anchoring membrane **1131** may have a length of approximately 10 mm to 40 mm. Esophageal stent **1120** and anchoring membrane **1131** may have widths of approximately 15 mm to 35mm.

[0045] Luminal device **1100** may include one or more drawstrings **1152**. Drawstrings **1152** may be coupled to esophageal stent **1120** and/or anchoring membrane **1131**. Drawstrings **1152** may be at least partially coupled around esophageal stent **1120** and/or anchoring membrane **1131**. Drawstrings **1152** may be configured to reduce a width of esophageal stent **1120** and/or anchoring membrane **1131** for delivery and/or removal of luminal device **1100**. Drawstrings **1152** may be removable or non-removable. One or more

drawstrings **1152** may include a loose portion forming a loop **1152'** which may facilitate grasping drawstring **1152**.

[0046] Luminal device **1100** may include at least one stiffening member **1154**. Stiffening member **1154** may be coupled along at least a portion of a length of luminal device **1100**. Stiffening member **1154** may be configured to reduce the likelihood of esophageal stent **1120** and/or anchoring membrane **1131** inverting. Stiffening member **1154** may be bonded to esophageal stent **1120** and/or anchoring membrane **1131**. Stiffening member **1154** may be elongate. Stiffening member **1154** be made of metal, plastic, or other suitable material. Stiffening member **1154** may be radiopaque.

[0047] Luminal device **1100** may include one or more radiopaque markers **1156**. Radiopaque markers **1156** may be coupled to esophageal stent **1120** and/or anchoring membrane **1131**. Radiopaque markers **1156** may be configured to facilitate delivery of luminal device **1100**.

[0048] Luminal device **1100** may include one or more tissue ingrowth elements **1180**. Tissue ingrowth elements **1180** may be configured to allow the esophageal wall to grow into esophageal stent **1120** and/or anchoring membrane **1131**.

[0049] Tissue ingrowth elements **1180** may include one or more holes **1181** formed in esophageal stent **1120** and/or anchoring membrane **1131**. Holes **1181** may be configured to allow tissue ingrowth. Tissue ingrowth elements **1180** may include exposed portions of scaffold **1125**. Tissue ingrowth elements **1180** may include exposed portions of reinforcement structure **1135**.

[0050] Luminal device **1100** may include a tissue anchor **1300**. Luminal device **1100** may include any of the tissue anchors described in U.S. patent application nos. VALENTX 028A1 and VALENTX 028A2, filed Oct. 31, 2015, and U.S. patent application publication nos. 2009/0012541 and 2015/0018745, each of which are incorporated by reference.

[0051] FIGS. **2**A-**2**C show embodiments of a tissue anchor **1300**. FIGS. **2**A-**2**B show perspective and side views, respectively, of one embodiment of tissue anchor **1300**. FIG. **2**C shows another embodiment of tissue anchor **1300**.

[0052] Tissue anchor **1300** may be configured to attach a device to a tissue wall. Tissue anchor **1300** may be configured to attach a luminal device to the esophageal wall.

[0053] Tissue anchor **1300** may include a first retention element **1310**. First retention element **1310** may be configured to be placed on a first side of an anchoring membrane of a luminal device. First retention element **1310** may be configured to be placed on a proximal side of an anchoring membrane of a luminal device.

[0054] First retention element **1310** may include a T-tag **1311**. T-tag **1311** may include a longitudinal cylindrical segment, such as one-third or one-fourth of a cylindrical tube cut lengthwise. T-tag **1311** may be configured to fit between the outside of a delivery needle and an inside of a catheter lumen. T-tag **1311** may be configured to fit in a gap between a delivery needle and a catheter lumen. T-tag **1311** may include a pull **1312** to facilitate removal. First retention element **1310** may include a button or other suitable device.

[0055] Tissue anchor **1300** includes a second retention element **1320**. Second retention element **1320** may be configured to be placed on a second side of a tissue wall. Second retention element **1320** may be configured to be placed on a distal side of a tissue wall.

[0056] Second retention element **1320** may include a hub **1323**. Hub **1323** may include a proximal portion **1323***p*, a distal portion **1323***d*, and a longitudinal axis **1323***a*.

[0057] Second retention element **1320** may include one or more petals **1324**. Petals **1324** may be coupled to hub **1323**. Petals **1324** may extend from distal portion **1323***d* of hub **1323**. Petals **1324** may be configured to be collapsed inside a delivery needle. Petals **1324** may be coupled to hub **1323** by being at least partially inserted into opening **1324**. Petals **1324** may be coupled to hub **1323** with any one or any combination of an adhesive, solder, weld, compression fit, and other suitable methods. Petals **1324** may be formed of lengths of wire. Hub **1323** and petals **1324** may be formed as one or more pieces.

[0058] Petals **1324** may include a contact portion **1325**. Contact portion **1325** may be configured to be substantially perpendicular to longitudinal axis **1323***a* of hub **1323**. Contact portion **1325** may be configured to be proximal to proximal portion **1323***p* of hub **1323**.

[0059] Alternatively, second retention element **1320** may include a T-tag **1321**, as shown in FIG. **2**C. T-tag **1321** may be configured to be loaded in a delivery needle. Second retention element **1320** may include any of the retention elements described in U.S. patent application nos. VALENTX 028A1 and VALENTX 028A2, filed Oct. 31, 2015, and U.S. patent application publication nos. 2009/0012541 and 2015/0018745, each of which are incorporated by reference.

[0060] Tissue anchor **1300** includes a tension element **1350**. Tension element **1350** may be configured to couple first retention element **1310** and second retention element **1320**. Tension element **1350** may be configured to placed through an anchoring membrane and a tissue wall.

[0061] Tension element **1350** may include a suture **1351**. Suture **1351** may have a proximal portion **1351***p* and a distal portion **1351***d*. Proximal portion **1351***p* of suture **1351** may be coupled to first retention element **1310**. Proximal portion **1351***p* of suture **1351** may be coupled to T-tag **1311**, such as with an adhesive and/or a knot. Distal portion **1351***d* of suture **1351** may be coupled to second retention element **1320**. Distal portion **1351***d* of suture **1351** may be coupled to hub **1323** of second retention element **1320**. Tension element **1350** may include a wire, a stent, or other suitable device. Tension element **1350** may be made of a polymer or other suitable material.

[0062] Alternatively, tissue anchor **1300** may include no first retention element **1310**, and proximal portion **1351***p* of suture **1351** may be coupled to a luminal device.

[0063] FIGS. **3**A-**3**D show one embodiment of an anchor delivery device **1600**. FIG. **3**A shows a perspective view of anchor delivery device **1600**. FIG. **3**B shows an enlarged view of an anchoring cavity **1630** of anchor delivery device **1600**. FIG. **3**C shows an enlarged view of a delivery needle **1660**. FIG. **3**D shows a cross-sectional view of delivery needle **1660**. FIGS. **3**C-**3**D show delivery needle **1660** loaded with a tissue anchor **1300**. FIGS. **3**C-**3**D show delivery needle **1660** advanced out of a secondary lumen **1622** of a catheter **1620**.

[0064] Anchor delivery device **1600** may be configured to place tissue anchors through a device and a tissue wall. Anchor delivery device **1600** may be configured to place tissue anchors through an esophageal stent and an esophageal wall.

[0065] Anchor delivery device **1600** may include a catheter **1620**. Catheter **1620** may include a proximal portion **1620***p*, a distal portion **1620***d*, and a longitudinal axis **1620***a*.

[0066] Catheter **1620** may include a primary lumen **1621**. Primary lumen **1621** may be configured to accommodate an endoscope or other instrument.

[0067] Catheter **1620** may include at least one secondary lumen **1622**. Secondary lumen **1622** may be formed in a wall of catheter **1620**. Secondary lumen **1622** may include a proximal portion **1622***p* and a distal portion **1622***d*. Secondary lumen **1622** may be configured to accommodate a delivery needle.

[0068] Distal portion **1622***d* of secondary lumen **1622** may be angled and/or curved inward toward longitudinal axis **1620***a* of catheter **1620**. Distal portion **1622***d* of secondary lumen **1622** may be angled and/or curved inward toward longitudinal axis **1620***a* from approximately 0 degrees to 10 degrees.

[0069] Catheter **1620** may have a width of approximately 10 mm to 20 mm.

[0070] Anchor delivery device **1600** may include an anchoring cavity **1630** formed in catheter **1620**. Anchoring cavity **1630** may include a proximal side **1630***p* and a distal side **1630***d*. Anchoring cavity **1630** may be at or near distal portion **1620***d* of catheter **1620**. Anchoring cavity **1630** may be proximal to tip **1626**. Anchoring cavity **1630** may be in communication with primary lumen **1621** and secondary lumen **1622**.

[0071] Anchoring cavity **1630** may be configured to draw in a portion of an anchoring membrane. Anchoring cavity **1630** may be configured to draw in a portion of an anchoring membrane and a tissue wall.

[0072] Anchoring cavity **1630** may cut completely through distal portion **1622***d* of secondary lumen **1622**. Distal portion **1622***d* of secondary lumen **1622** may be positioned at a proximal side **1630***p* of anchoring cavity **1630**.

[0073] Anchoring cavity **1630** may have a length of approximately 10 mm to 40 mm. Anchoring cavity **1630** may have a width of approximately 10 mm to 20 mm.

[0074] Anchor delivery device **1600** may include a delivery needle **1660**. Delivery needle **1660** may include a proximal portion **1660***p* and a distal portion **1660***d*. Delivery needle **1660** may be slidably disposed within secondary lumen **1622**. Delivery needle **1660** may be configured to be advanced out of and withdrawn into secondary lumen **1622**.

[0075] Delivery needle **1660** may include a needle lumen **1661**. Needle lumen **1661** may be configured to be loaded with a second retention element of a tissue anchor in a collapsed or delivery configuration. Needle lumen **1661** may also be configured to be loaded with a first retention element and/or a second retention element of a tissue anchor in a collapsed or delivery configuration. Needle lumen **1661** may also be configured to be loaded with a therapeutic agent. Therapeutic agent may include any one or any combination of a phospholipid gel, hyaluronic acid, and other agents.

[0076] Delivery needle **1660** may include a tip **1668**. Tip **1668** may be coupled to distal portion **1660***d* of delivery needle **1660**. Tip **1668** may be configured to pierce an anchoring membrane. Tip **1668** may be configured to pierce a tissue wall. Tip **1668** may be sharp.

[0077] Delivery needle **1660** may include a slot **1669**. Slot **1669** may be formed longitudinally at distal portion **1660***d* of delivery needle **1660**. Slot **1669** may be configured to allow a tension element of a tissue anchor to pass through so that a second retention element of a tissue anchor may be loaded inside of needle lumen **1661** and a first retention element of a tissue element may be loaded outside of needle lumen **1661**.

[0078] Distal portion **1660***d* of delivery needle **1660** may be angled and/or curved inward toward longitudinal axis **1620***a* of catheter **1620**. Distal portion **1660***d* of delivery needle **1660** may be angled and/or curved inward toward longitudinal axis **1620***a* from approximately 0 degrees to 10 degrees. This may reduce the likelihood of contacting bodily parts on the other side of a tissue wall.

[0079] Delivery needle **1660** and secondary lumen **1622** may be configured to define a gap **1623** when delivery needle **1660** is slidably disposed within secondary lumen **1622**. Delivery needle **1660** and secondary lumen **1622** may have sizes selected to define a gap **1623** when delivery needle **1660** is slidably disposed within secondary lumen **1622**. Gap **1623** may be configured to be loaded with a proximal delivery element of a tissue anchor. Gap **1623** may be configured to be loaded with a proximal delivery element such as a T-tag that is thin and elongate. Gap **1623** may be configured to be loaded with proximal delivery element such as a T-tag such as T-tag **1311** of tissue anchor **1300**.

[0080] Anchor delivery device **1600** may include a pushrod **1670**. Pushrod **1670** may include a proximal portion **1670***p* and a distal portion **1670***d*. Pushrod **1670** may be slidably disposed within needle lumen **1661**.

[0081] Pushrod **1670** may be configured to push a second retention element of a tissue anchor out of needle lumen **1661** of delivery needle **1660**. Pushrod **1670** may be configured to push a first retention element of a tissue anchor out of needle lumen **1661**.

[0082] Pushrod **1670** may include a channel **1679**. Channel **1679** may be formed longitudinally at distal portion **1670***d* of pushrod **1670**. Channel **1679** may be configured to allow a tension element of a tissue anchor to pass through. Channel **1679** may be aligned with slot **1669** of delivery needle **1660**.

[0083] FIGS. **4**A-**4**J show one embodiment of a method for delivering a luminal device. Although delivery of luminal device **1000** is shown as an example, the method may also be used to deliver other luminal devices and esophageal stents.

[0084] FIG. **4**A shows loading luminal device **1100** onto anchor delivery device **1600**. Distal portion **1620***d* of catheter **1620** is inserted into the lumen of luminal device **1100**.

[0085] FIG. **4**B shows coupling luminal device **1100** to anchor delivery device **1600**. Drawstring **1152** may be cinched to couple luminal device **1100** to anchor delivery device **1600**.

[0086] FIG. **4**C shows positioning luminal device **1100** at an attachment point. Catheter **1620** is advanced into the esophagus E to position anchoring membrane **1131** of luminal device **1100** in the esophagus E. An endoscope may be used in primary lumen **1621** to guide catheter **1620**. A tether T may be used to adjust the position of luminal device **1100** and/or control drawstring **1152**. Tissue marks made previously by tissue marking device **1400** may be used as a guide.

[0087] FIG. **4**D shows releasing luminal device **1100** from anchor delivery device **1600**. Drawstring **1152** may be uncinched to release luminal device **1100** from anchor delivery device **1600**.

[0088] FIG. **4**E shows positioning anchoring cavity **1630** of anchor delivery device **1600** next to anchoring membrane **1131** and the tissue wall W.

[0089] FIG. **4**F shows forming a bulge **1130***b* in anchoring membrane **1131** and the tissue wall W. Delivery needle **1660** is retracted completely within secondary lumen **1622**. A vacuum may be applied to anchoring cavity **1630** to draw anchoring membrane **1131** and the tissue wall W into anchoring cavity **1630** to form bulge **1130***b*. The vacuum may be approximately 50 mmHg to 500 mmHg.

[0090] Alternatively, anchoring membrane **1131** and tissue wall W may be pulled into anchoring cavity **1630** by a grasper or other suitable device to form bulge **1130***b*. Alternatively, anchoring membrane **1131** and the tissue wall W may be allowed to enter anchoring cavity **1630** without assistance, such as from muscle activity of the tissue wall W, to form bulge **1130***b*.

[0091] FIG. **4**G shows piercing bulge **1130***b* from first a side **1131'** of anchoring membrane **1131** and a first side W' of the tissue wall W. Delivery needle **1660** may be advanced a set distance out of secondary lumen **1622** of catheter **1620**. Delivery needle **1660** may be advanced through bulge **1130***b* to position tip **1668** of delivery needle **1660** on a second side W" of the tissue wall W.

[0092] Delivery needle **1660** may be advanced in a direction substantially parallel to longitudinal axis **1620***a* of catheter. Delivery needle **1660** may be advanced in a direction substantially parallel to the tissue wall W other than bulge **1130***b*. Delivery needle **1660** may be advanced in a direction approximately 0 degrees to 10 degrees from parallel toward longitudinal axis **1620***a* of catheter. Delivery needle **1660** may be advanced in a direction approximately 0 degrees to 10 degrees from parallel away from the tissue wall W other than bulge **1130***b*.

[0093] FIG. **4**H shows placing second retention element **1320** of tissue anchor **1300** on a second side W" of the tissue wall W. Delivery needle **1660** may be pulled back over pushrod **1670** to release second retention element **1320** from needle lumen **1661**. Alternatively, pushrod **1670** may be advanced a set distance through delivery needle **1660** to release second retention element **1320** from needle lumen **1661**. A therapeutic agent may also be released from needle lumen **1661**. Second retention element **1320** expands.

[0094] FIG. **41** shows placing tension element **1350** of tissue anchor **1300** through anchoring membrane **1131** and the tissue wall W. Delivery needle **1660** and pushrod **1670** may be pulled back through the tissue wall W and pulled back through anchoring membrane **1131** to place tension element **1350** through the tissue wall W and anchoring membrane **1131**.

[0095] FIG. **4**J shows placing first retention element **1310** of tissue anchor **1300** on first side **1131'** of anchoring membrane **1131**. Bulge **1130***b* may be released. Vacuum applied to anchoring cavity **1630** may be stopped. First retention element **1310** is placed on first side **1131'** of anchoring membrane **1131**. First retention element **1310** may be pulled out of secondary lumen **1622** of catheter **1620** by tension element **1350**.

[0096] Alternatively, delivery needle **1660** may be advanced through bulge **1130***b* at both proximal side **1630***p* and distal side **1630***d* of anchoring cavity **1630**, to position tip **1668** of delivery needle **1660** back on first side **1131'** of anchoring membrane **1131**. Second retention element **1320** may be placed on first side **1131'** of anchoring membrane **1131**, tension element **1350** may be placed through anchoring membrane **1131** and the tissue wall W at two points, and first retention element **1310** may also be placed on first side **1131'** of anchoring membrane **1131**.

[0097] Alternatively, delivery needle **1660** may be advanced only partially through bulge **1130***b* at proximal side **1630***p* of anchoring cavity **1630**. Delivery needle **1660** may be advanced through anchoring membrane **1131** and only partially through the tissue wall W, to position tip **1668** of delivery needle **1660** within the tissue wall W, such as between layers of the tissue wall W. Second retention element **1320** may be placed within the tissue wall W, tension element **1350** may be placed through anchoring membrane **1131** and part of the thickness of tissue wall W, and first retention element **1310** may be placed on first side **1131'** of anchoring membrane **1131**.

[0098] Anchor delivery device **1600** may be rotated within luminal device **1100** to deliver one or more additional tissue anchors. Delivery needle **1660** may be removed from secondary lumen **1622** to be reloaded with another tissue anchor, or exchanged for another delivery needle **1660** that has already been loaded.

[0099] While the foregoing has been with reference to particular embodiments of the invention, it will be appreciated by those skilled in the art that changes in these embodiments may be made without departing from the principles and spirit of the invention.

What is claimed is:

1. A luminal device, comprising:
an esophageal stent; and
an anchoring membrane coupled to the esophageal stent, the anchoring membrane configured to be attached to an esophageal wall with a tissue anchor placed through the anchoring membrane.

2. The luminal device of claim **1**, wherein the anchoring membrane is configured to be pierced to allow the tissue anchor to be placed through the anchoring membrane.

3. The luminal device of claim **1**, wherein the anchoring membrane is configured to retain a tissue anchor placed through the anchoring membrane.

4. The luminal device of claim **1**, further comprising:
a braid coupled to the anchoring membrane, the braid configured to reinforce the anchoring membrane.

5. The luminal device of claim **1**, wherein the anchoring membrane is collapsible.

6. The luminal device of claim **1**, further comprising:
one or more perforations formed in the anchoring membrane, the perforations configured to allow a vacuum to reach through the anchoring membrane.

7. The luminal device of claim **1**, further comprising:
one or more pulls coupled to the anchoring membrane, the pulls configured to allow the anchoring membrane to be pulled.

8. The luminal device of claim **1**, further comprising:
one or more creases formed in the anchoring membrane, the creases configured to allow the anchoring membrane to collapse along the creases.

9. A luminal device, comprising:
an esophageal stent; and
an anchor retaining means coupled to the esophageal stent, the anchor attachment means configured to be attached to a wall of an esophagus with a tissue anchor placed through the anchor retaining means.

10. The luminal device of claim **9**, further comprising:
a reinforcement means coupled to the anchor retaining means, the reinforcement means configured to reinforce the anchor retaining means.

11. A method for attaching a luminal device to an esophageal wall, the method comprising:
forming a bulge in an anchoring membrane of the luminal device and the esophageal wall;
piercing the bulge from a first side of the anchoring membrane and a first side of the esophageal wall;

placing a second retention element of a tissue anchor on a second side of the esophageal wall; and

placing a tension element of the tissue anchor through the anchoring membrane and the esophageal wall, the tension element coupled to the second retention element.

12. The method of claim **11**, wherein forming a bulge includes drawing the anchoring membrane and the esophageal wall with a vacuum.

13. The method of claim **11**, wherein forming a bulge includes pulling the anchoring membrane and the esophageal wall with a grasper.

14. The method of claim **11**, wherein piercing the bulge includes advancing a delivery needle through the bulge to position a tip of the delivery needle on a second side of the esophageal wall.

15. The method of claim **14**, wherein advancing a delivery needle includes advancing a delivery needle in a direction between 0 degrees and 10 degrees from parallel to the esophageal wall other than the bulge.

16. The method of claim **11**, wherein placing a second retention element includes pushing the second retention element out of a lumen of the delivery needle.

17. The method of claim **16**, wherein placing a tension element includes pulling the delivery needle back through the bulge.

18. The method of claim **11**, further comprising:

placing a first retention element on the first side of the anchoring membrane, the first retention element coupled to the tension element.

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