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(54) **DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE**

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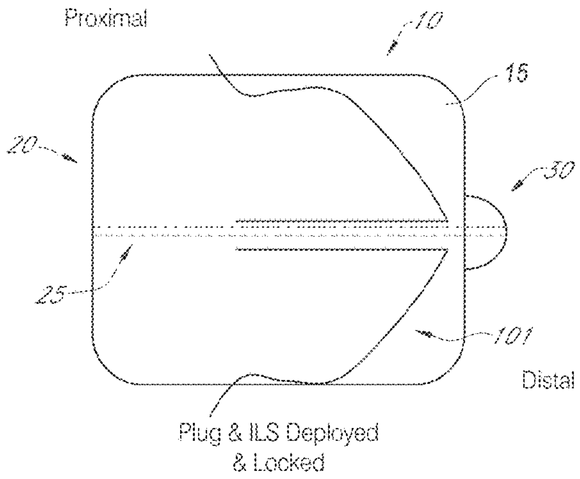
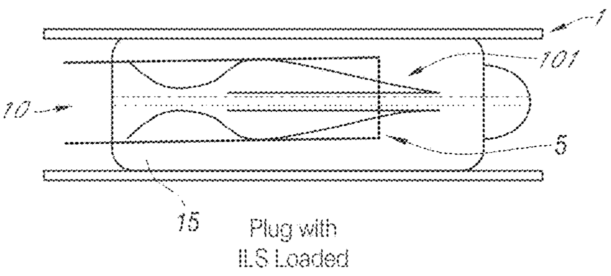
(57) **ABSTRACT**

Devices and methods are described for occluding the left atrial appendage (LAA) to exclude the LAA from blood flow to prevent blood from clotting within the LAA and subsequently embolizing, particularly in patients with atrial fibrillation. An implant is delivered via transcatheter delivery into the LAA. The implant includes a conformable structure comprising a foam body and internal support. The support includes anchors that penetrate the foam body and anchor the implant to the walls of the LAA. The implant provides compliance such that it conforms to the native configuration of the LAA.

19 Claims, 33 Drawing Sheets





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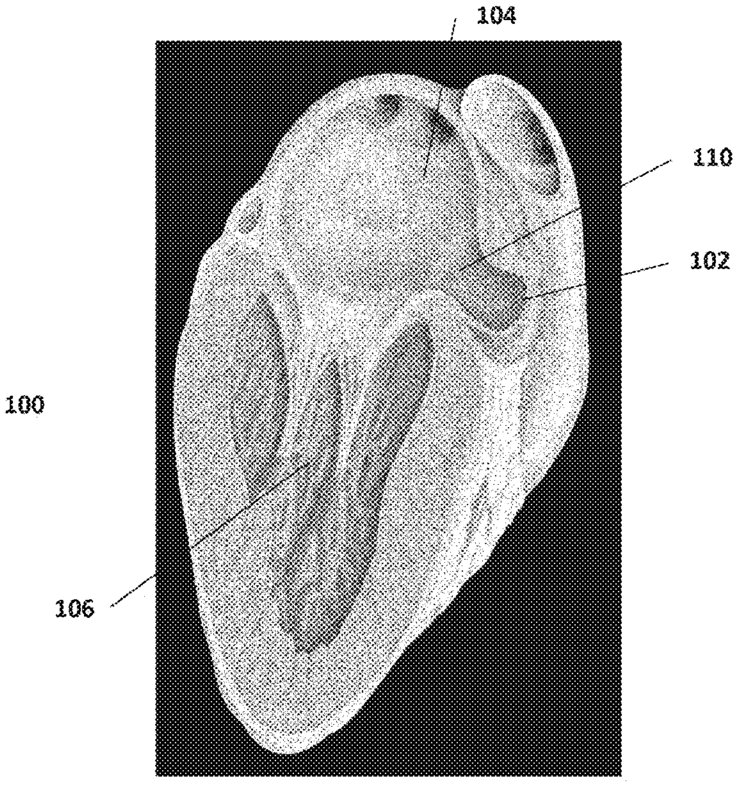


FIG. 1

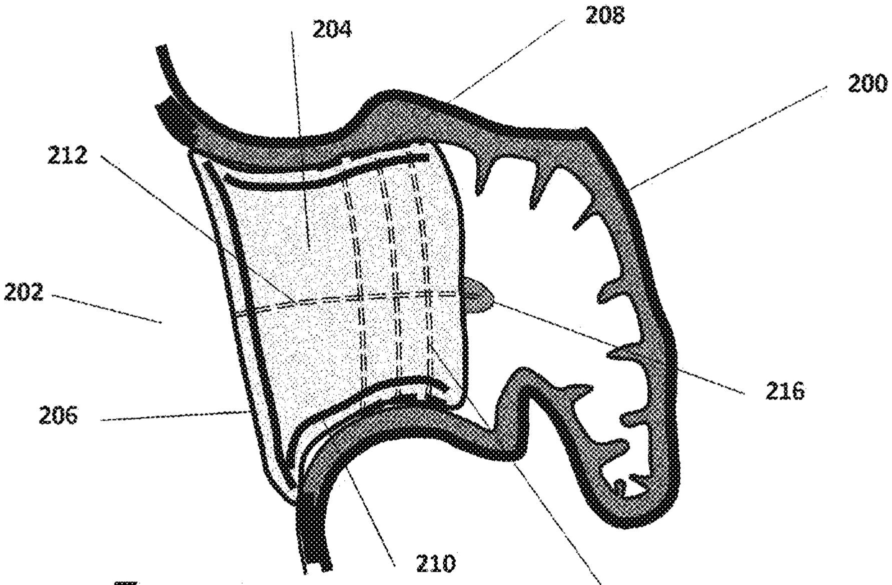
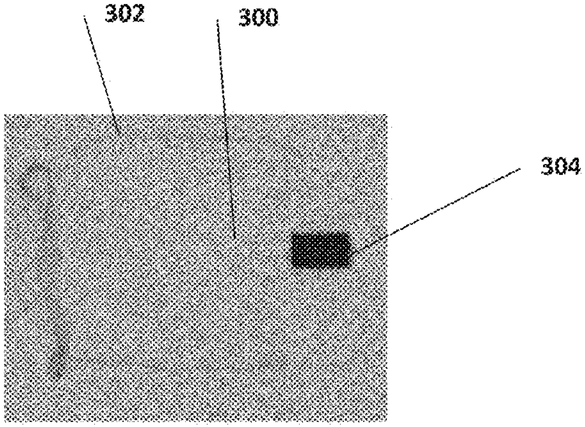


FIG. 2



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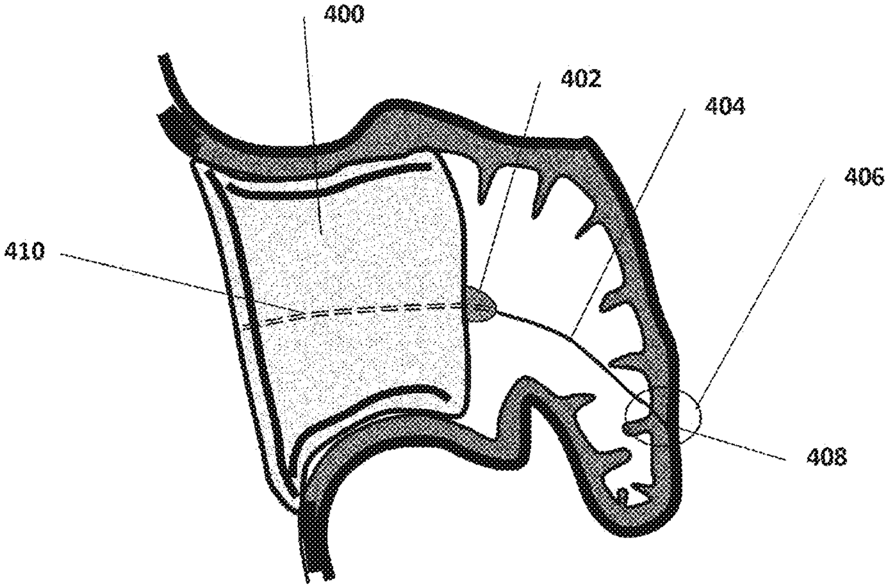

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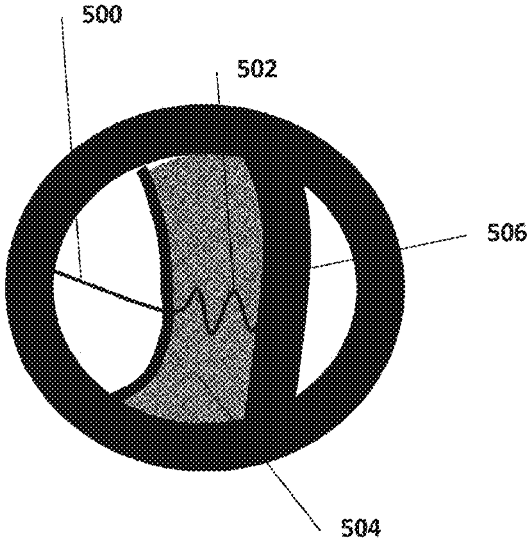


FIG. 5

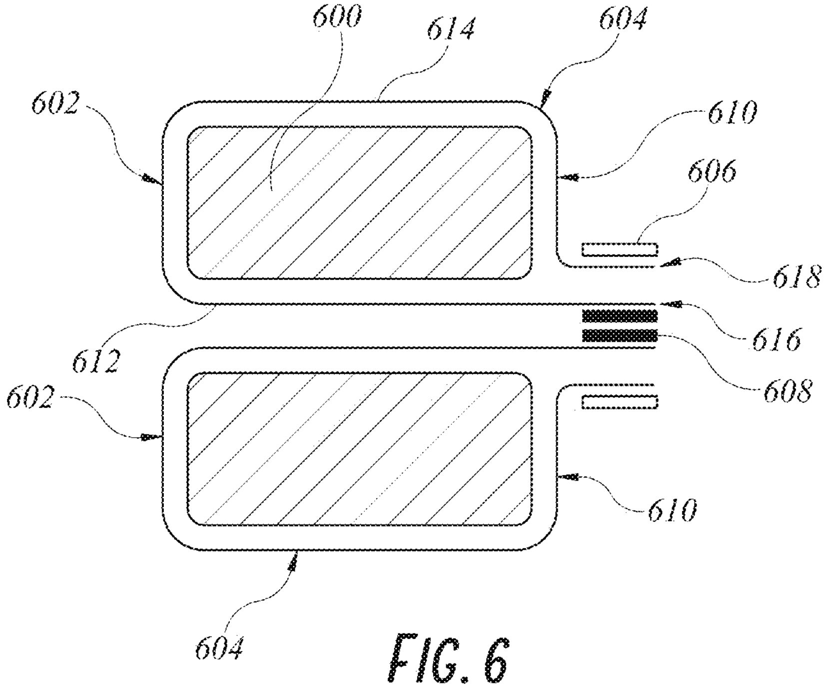


FIG. 6

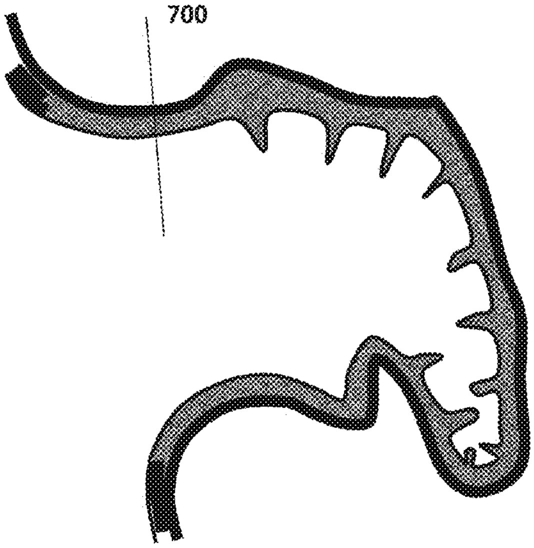
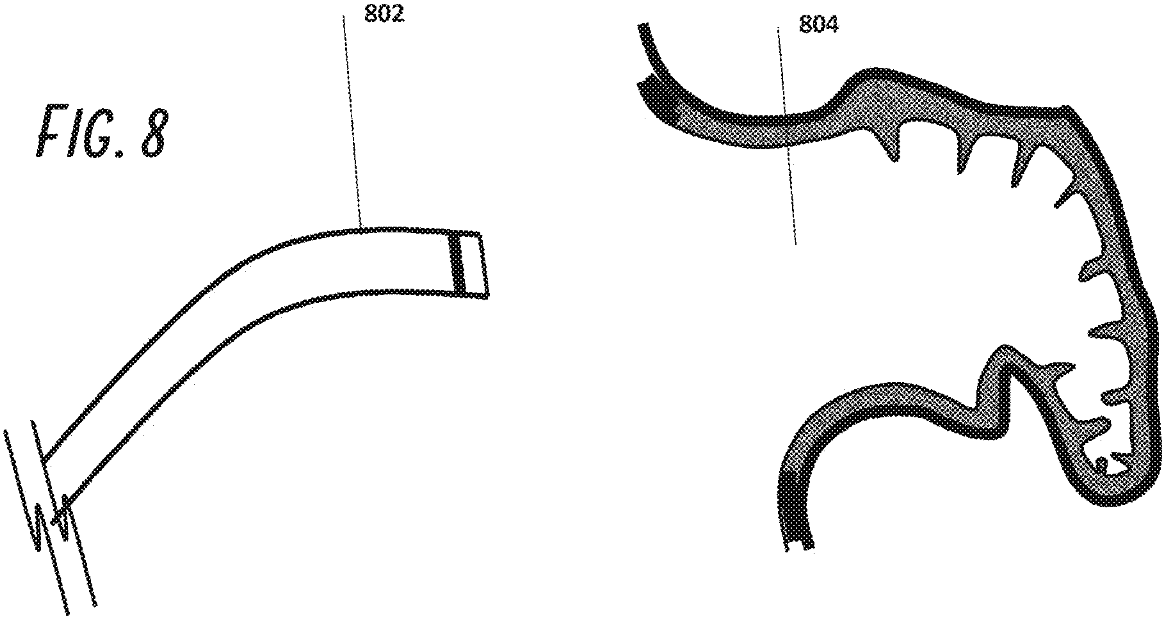


FIG. 7

FIG. 8



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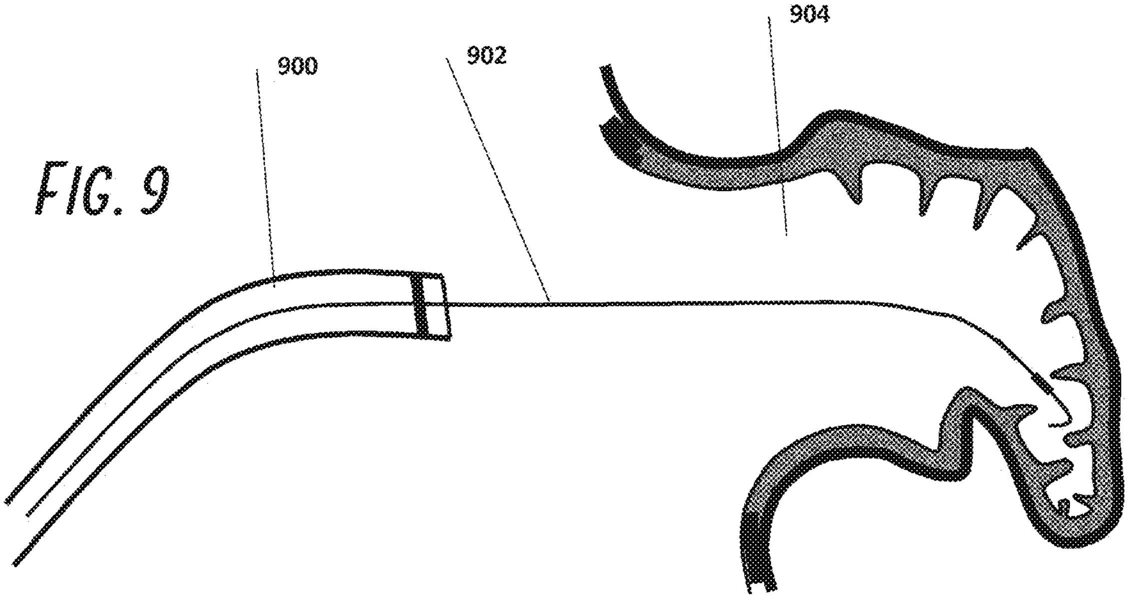

FIG. 10

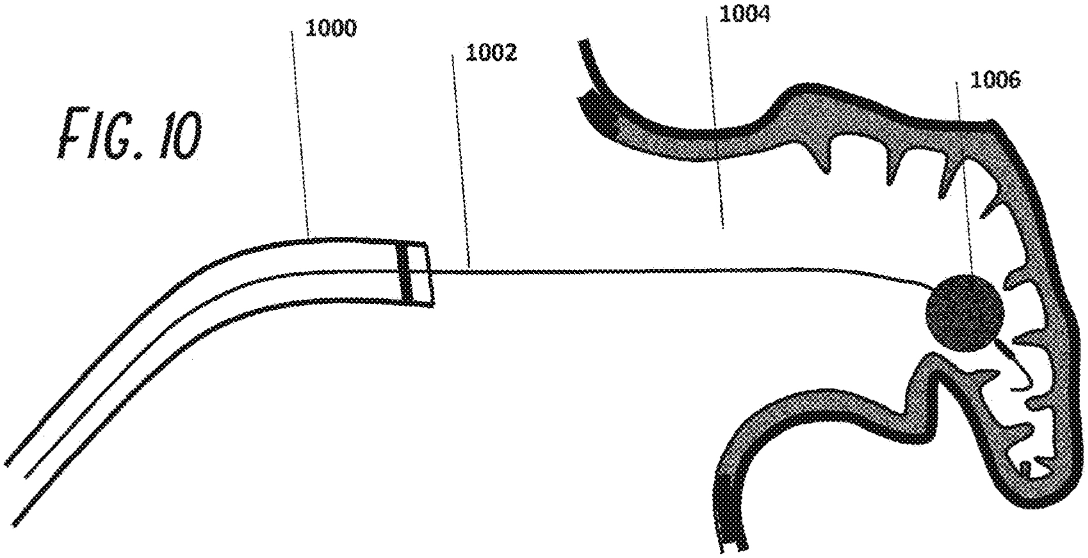

FIG. 11

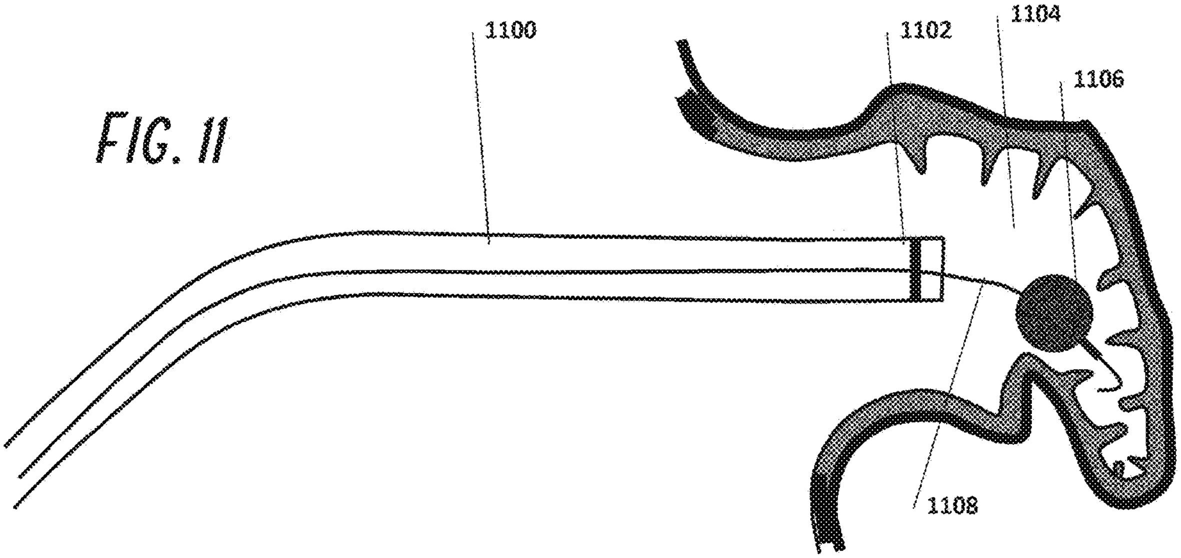

FIG. 12

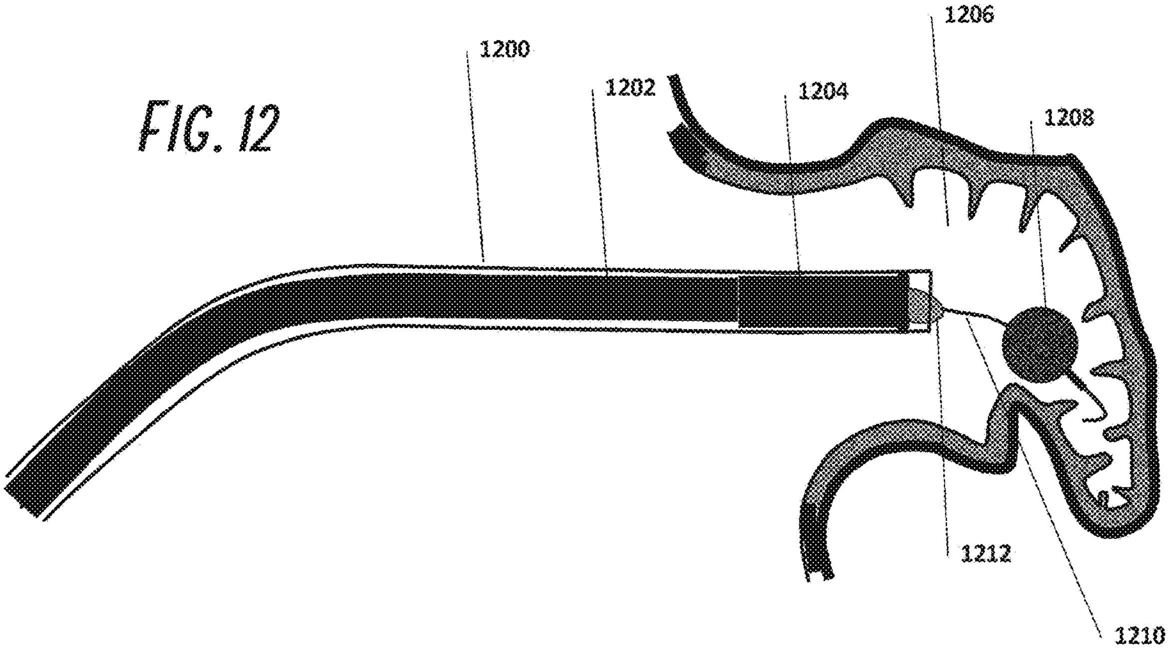
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FIG. 13

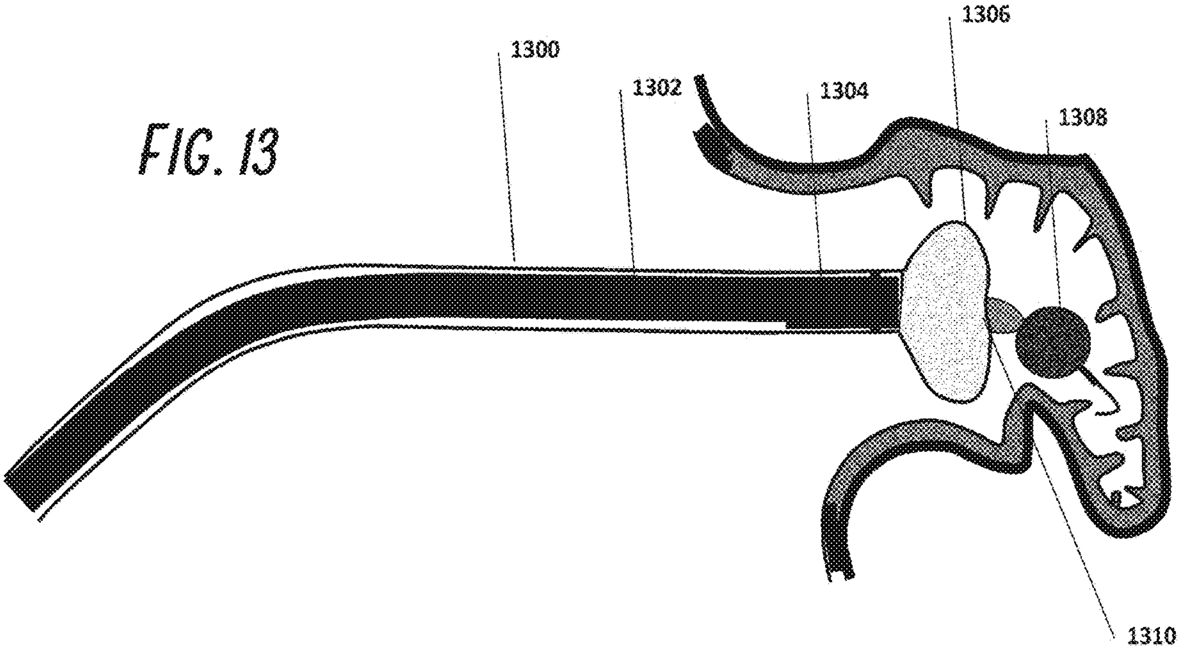
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FIG. 14

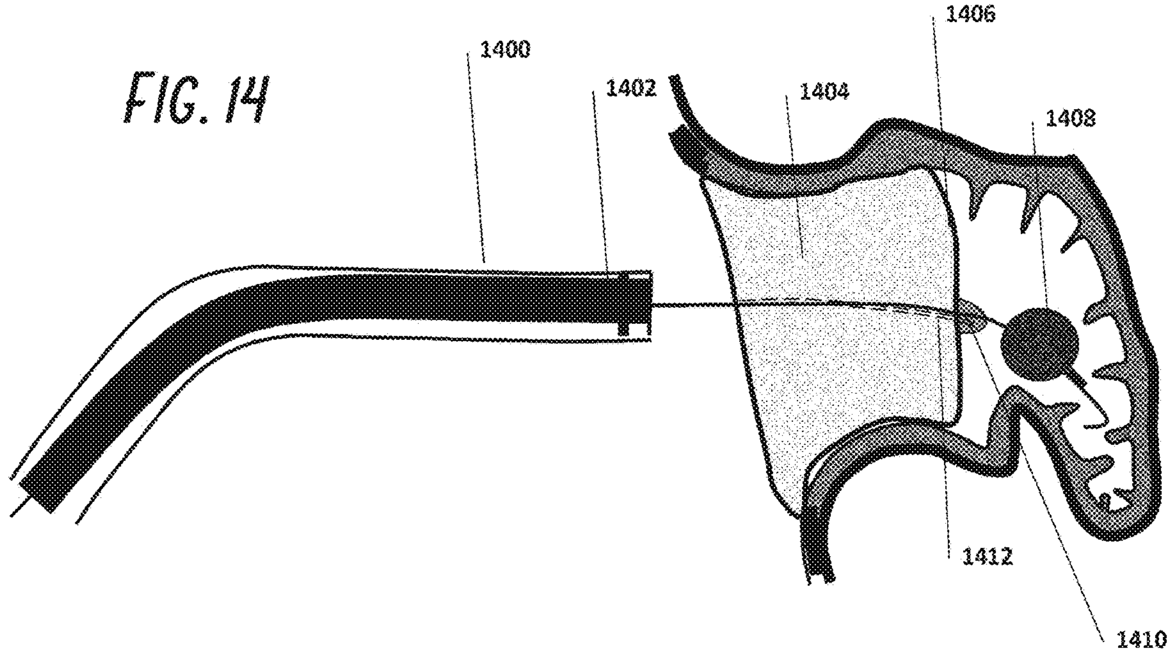
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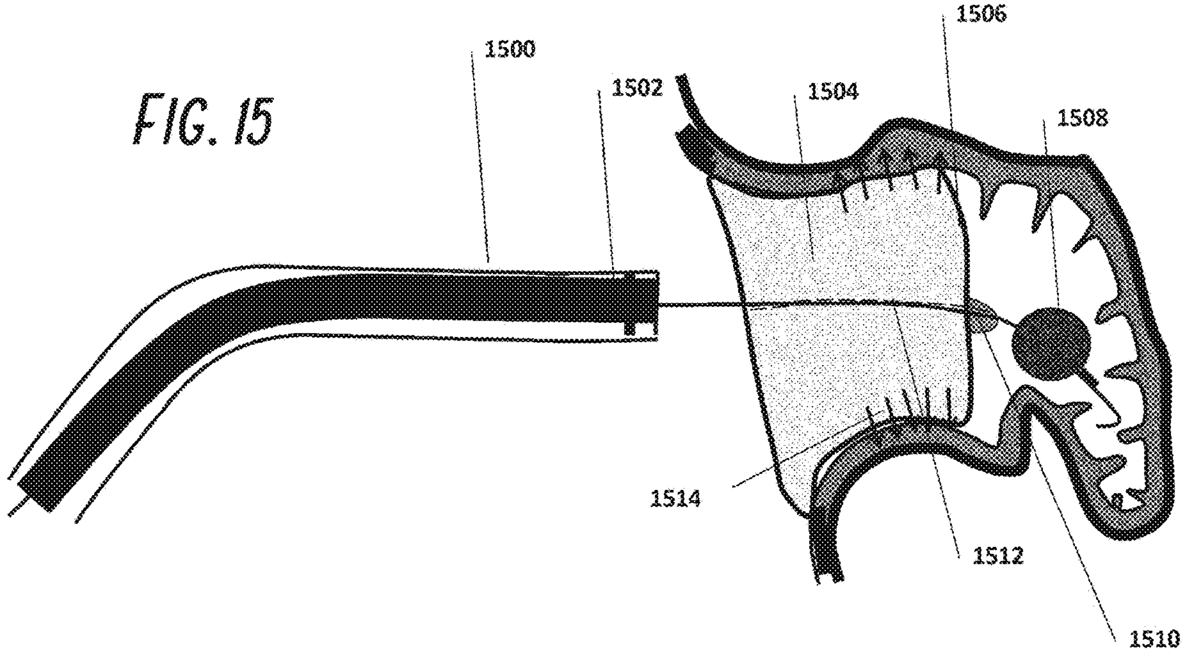
FIG. 15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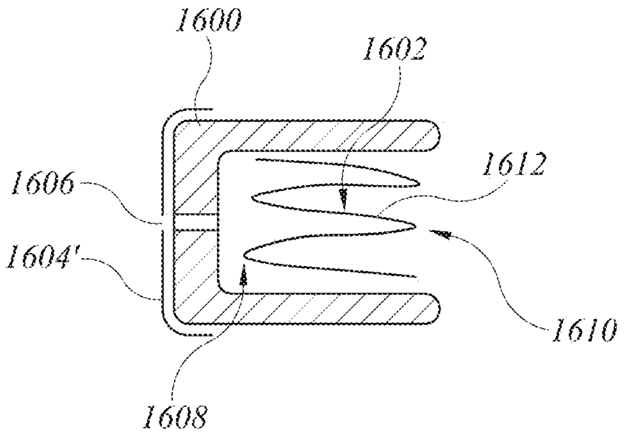


FIG. 16

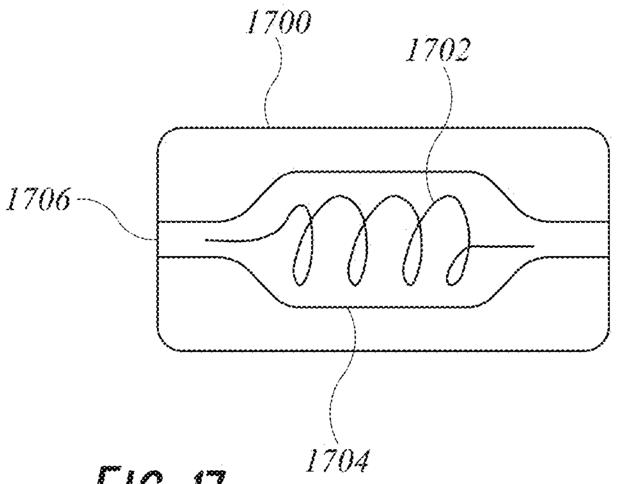


FIG. 17

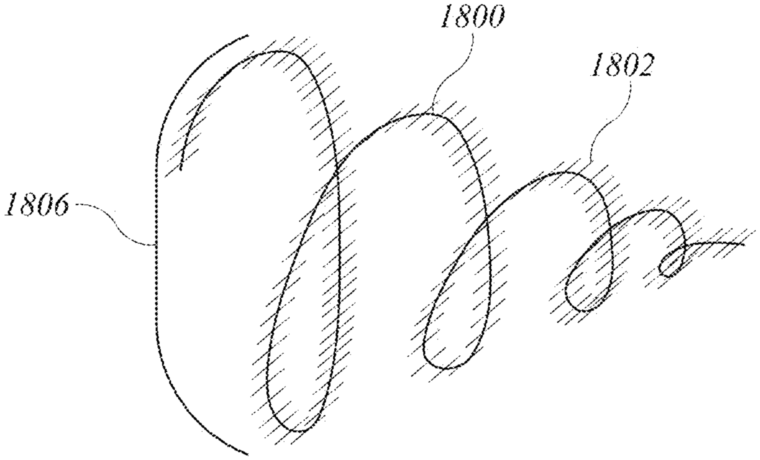


FIG. 18

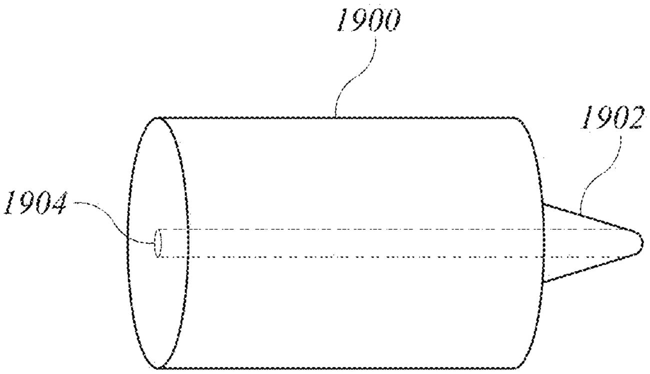


FIG. 19

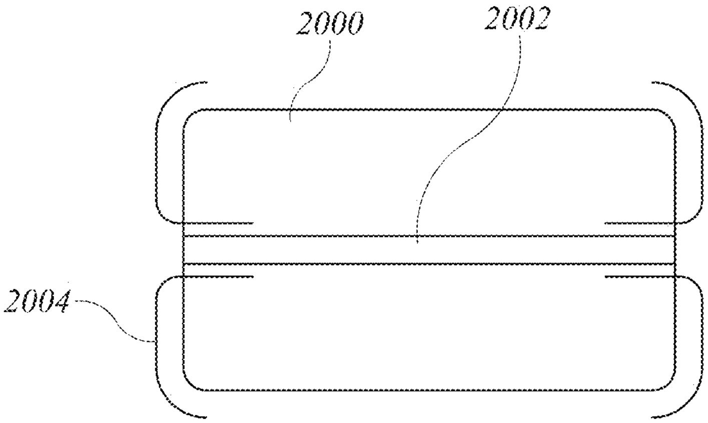


FIG. 20

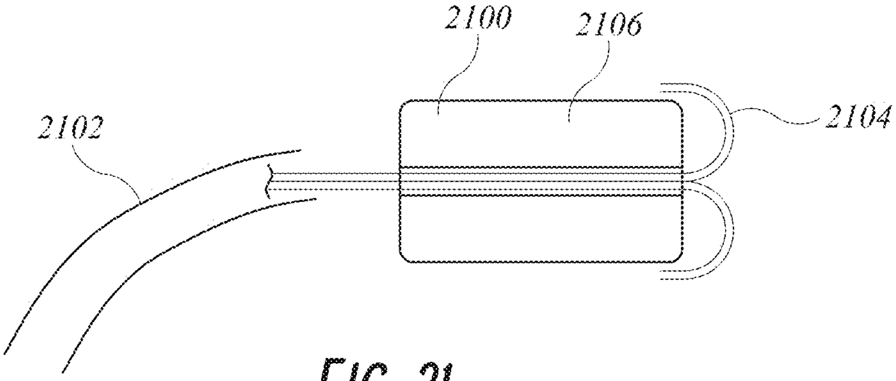


FIG. 21

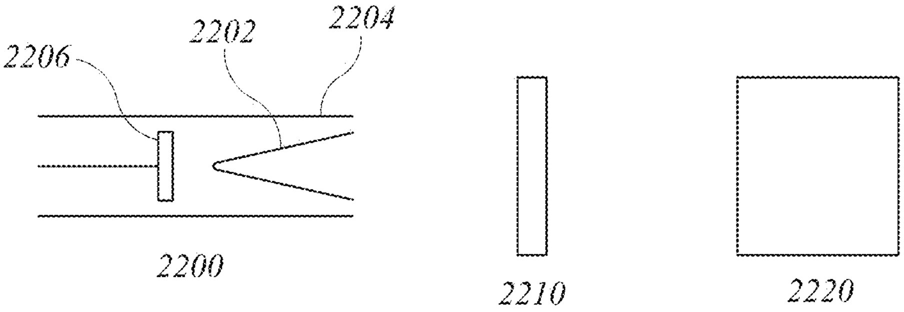


FIG. 22

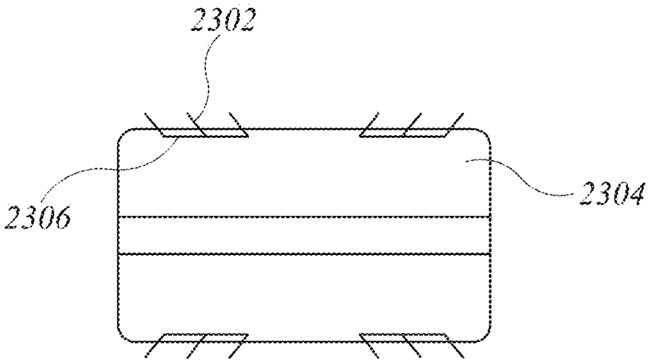


FIG. 23

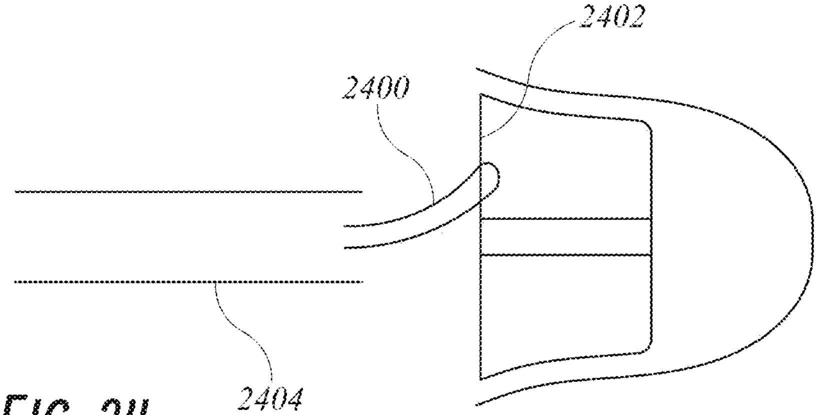


FIG. 24

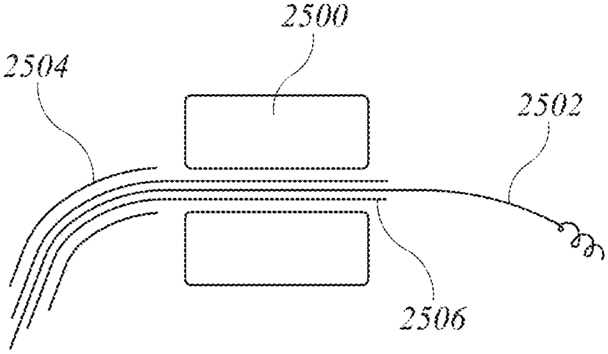


FIG. 25A

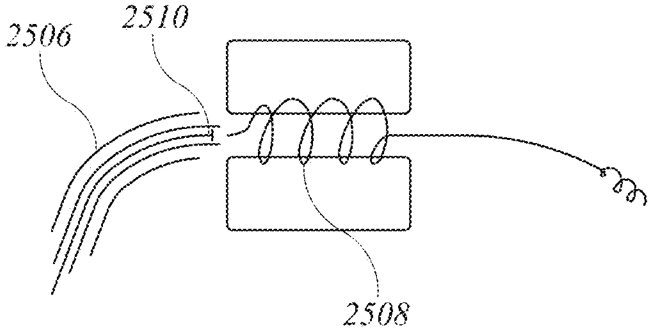


FIG. 25B

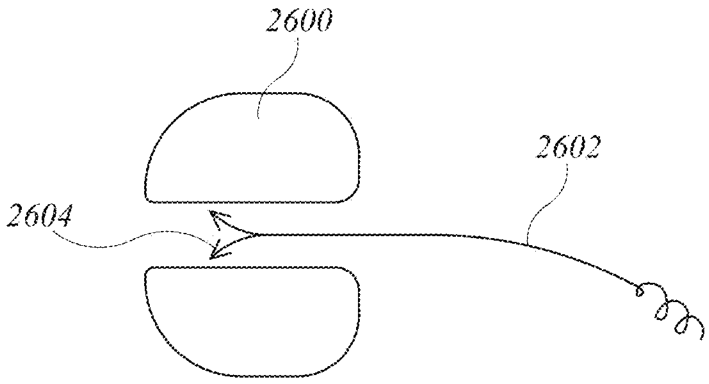


FIG. 26

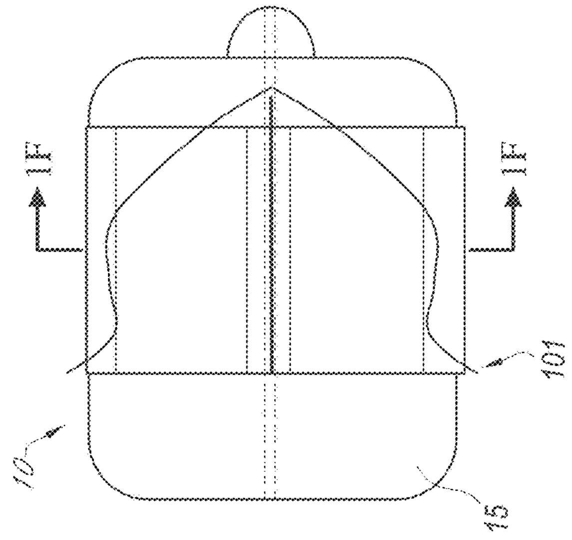


FIG. 27C

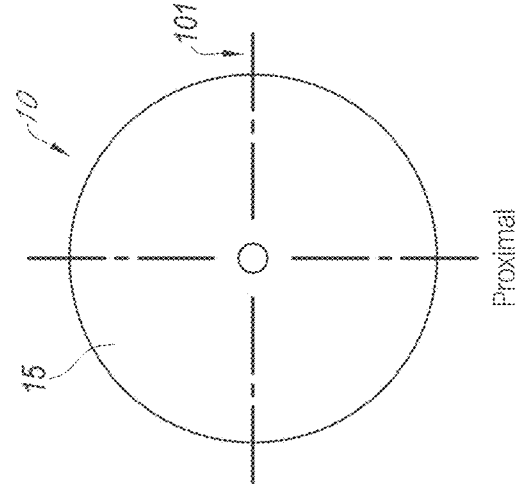


FIG. 27B

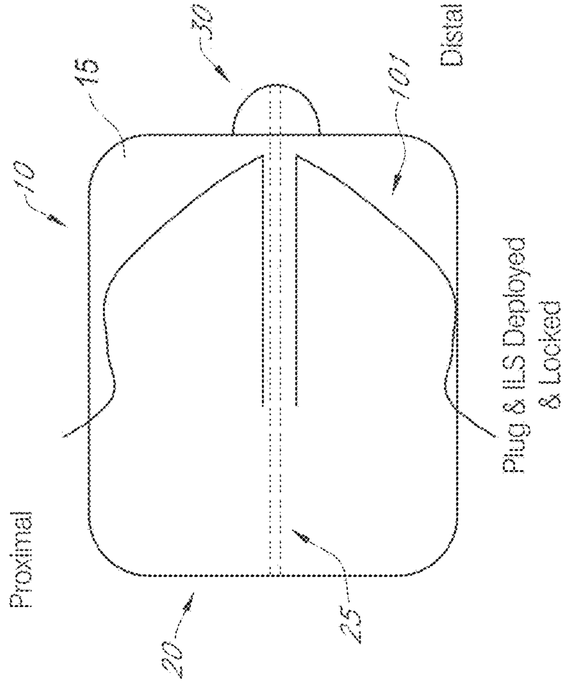
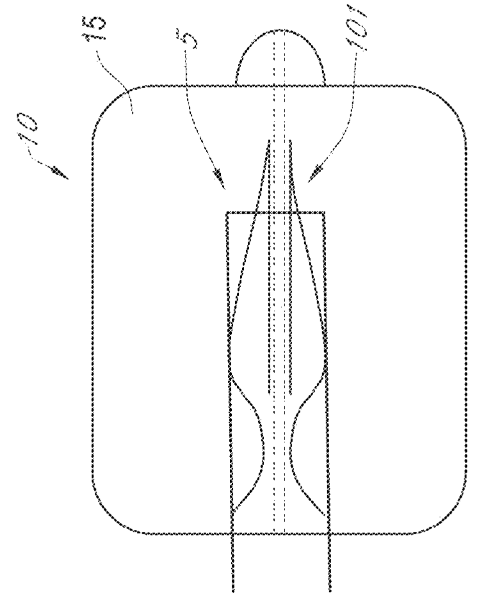


FIG. 27A



Plug Deployed

FIG. 27D

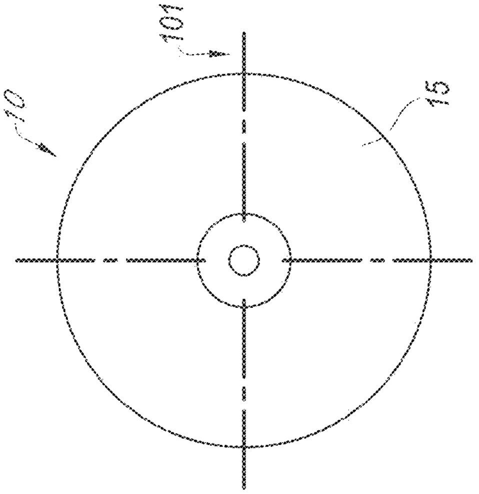


FIG. 27E

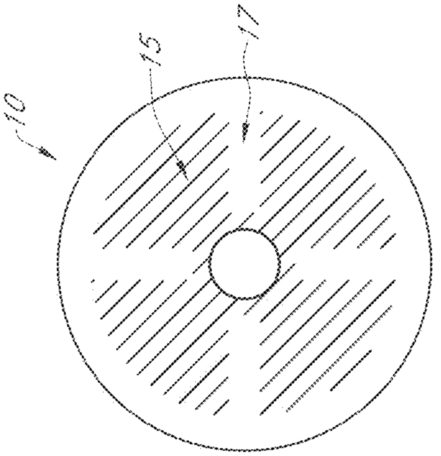
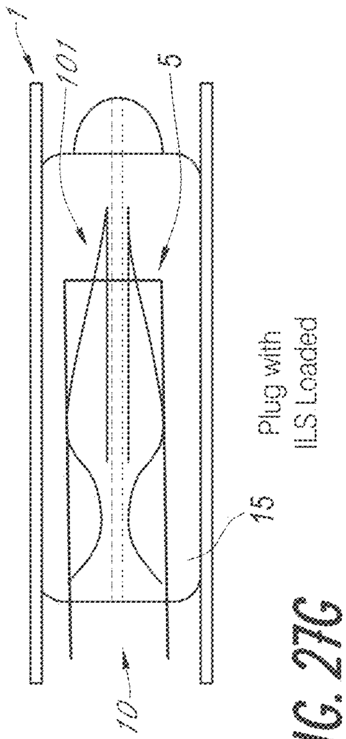


FIG. 27F



Plug with ILS Loaded

FIG. 27G

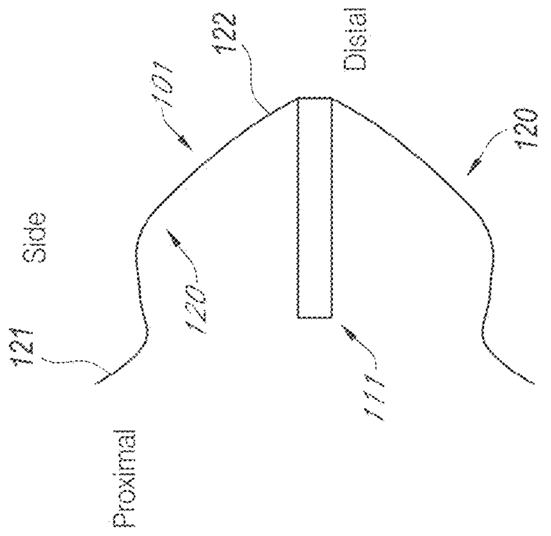


FIG. 28A

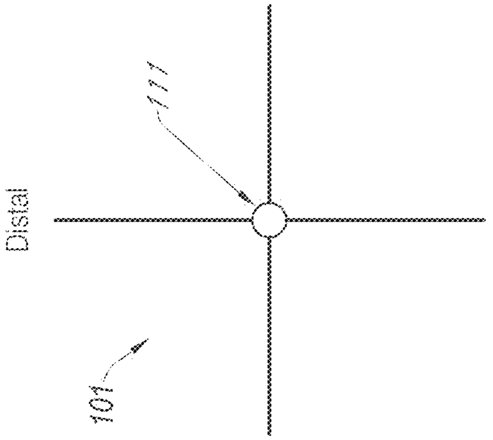


FIG. 28B

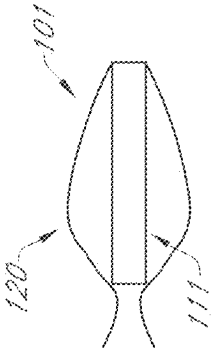


FIG. 28C

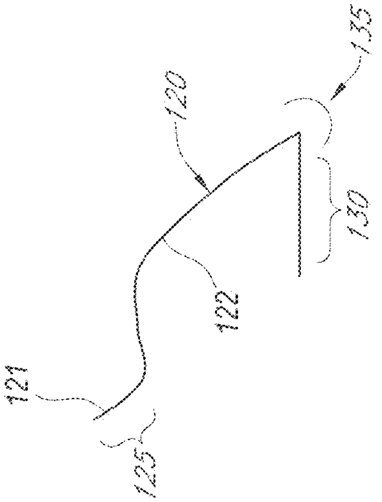


FIG. 28D

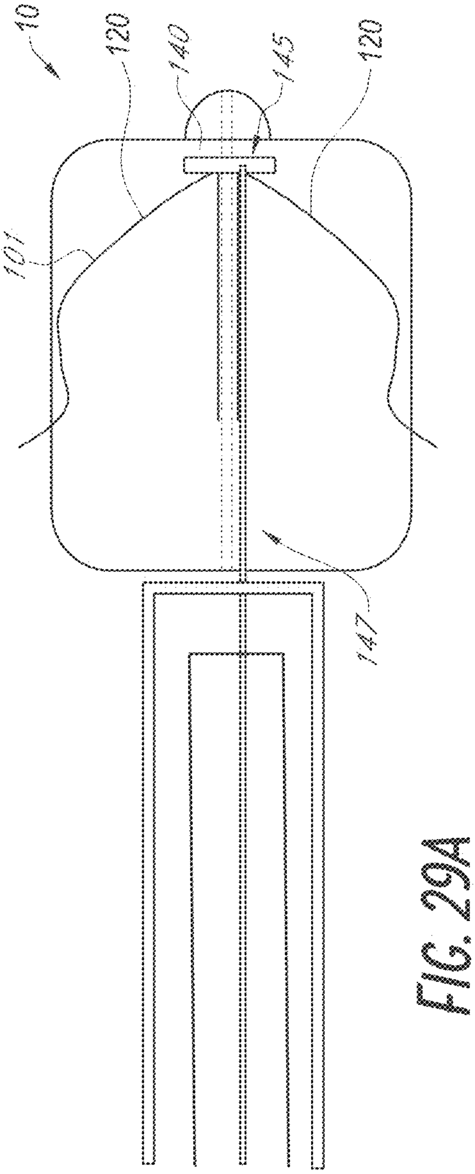


FIG. 29A

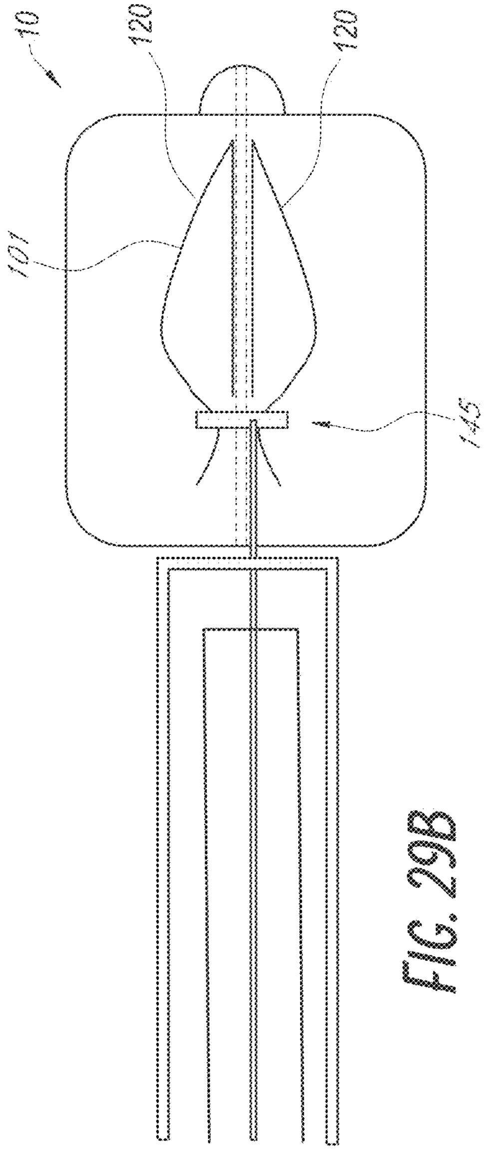


FIG. 29B

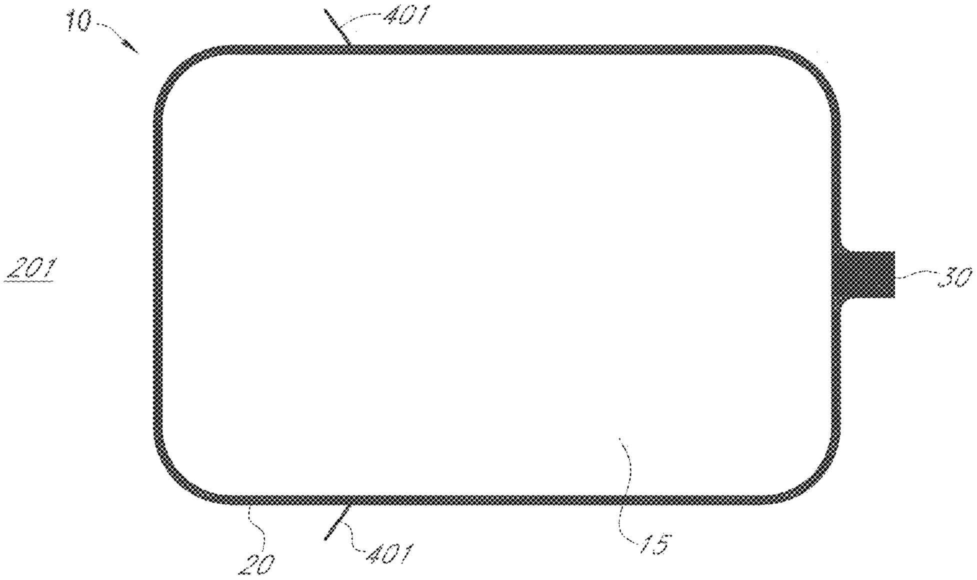


FIG. 30

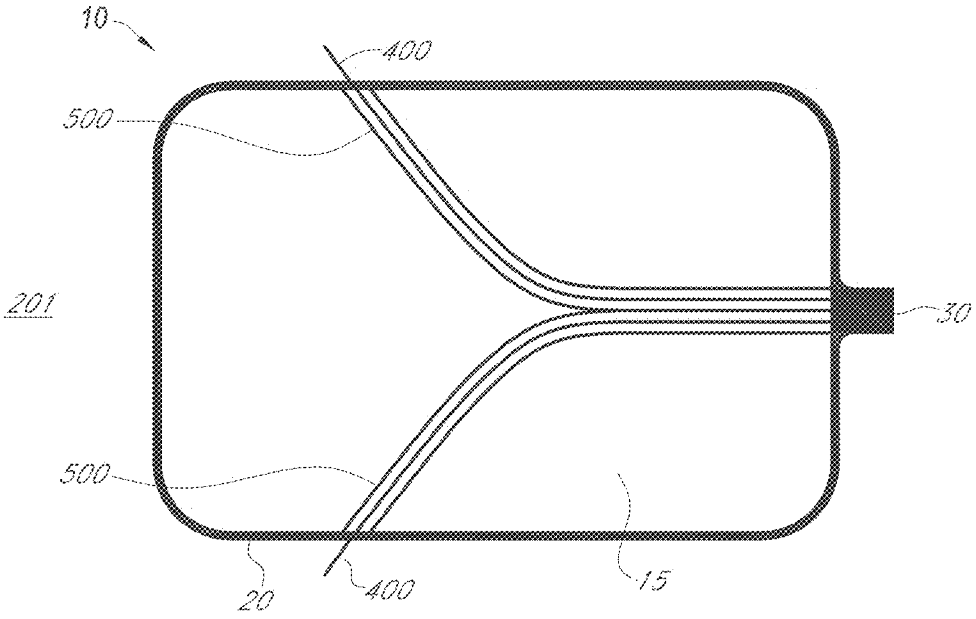


FIG. 31

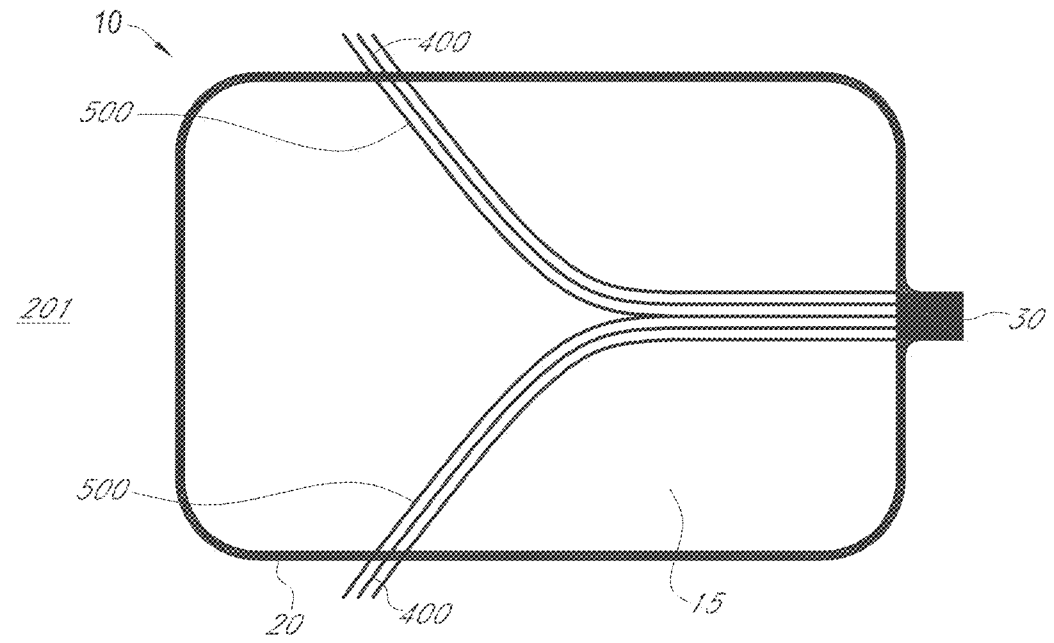


FIG. 32

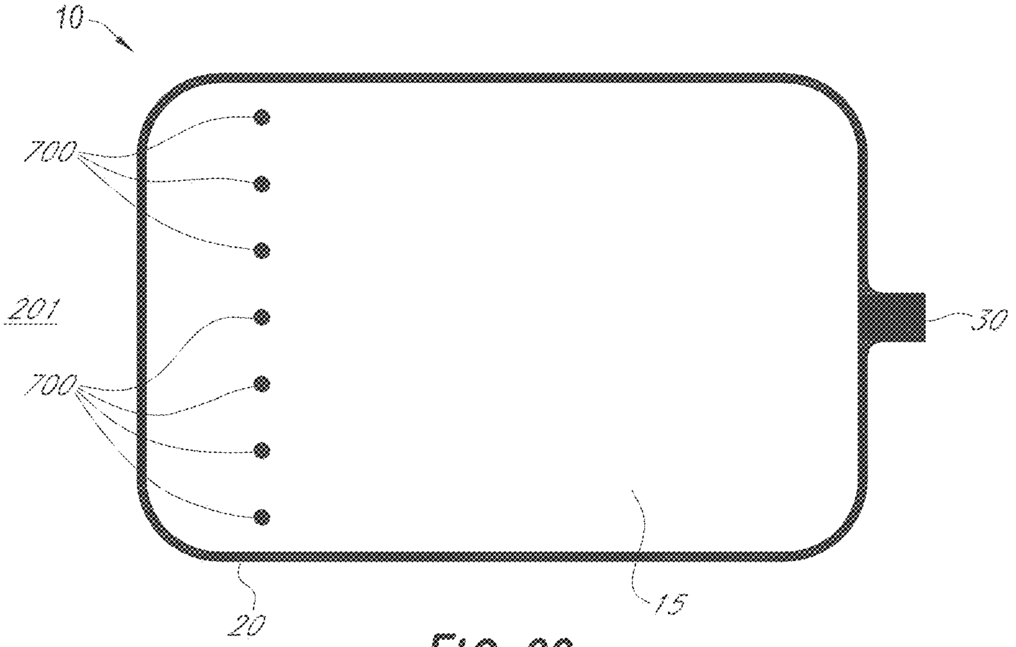


FIG. 33

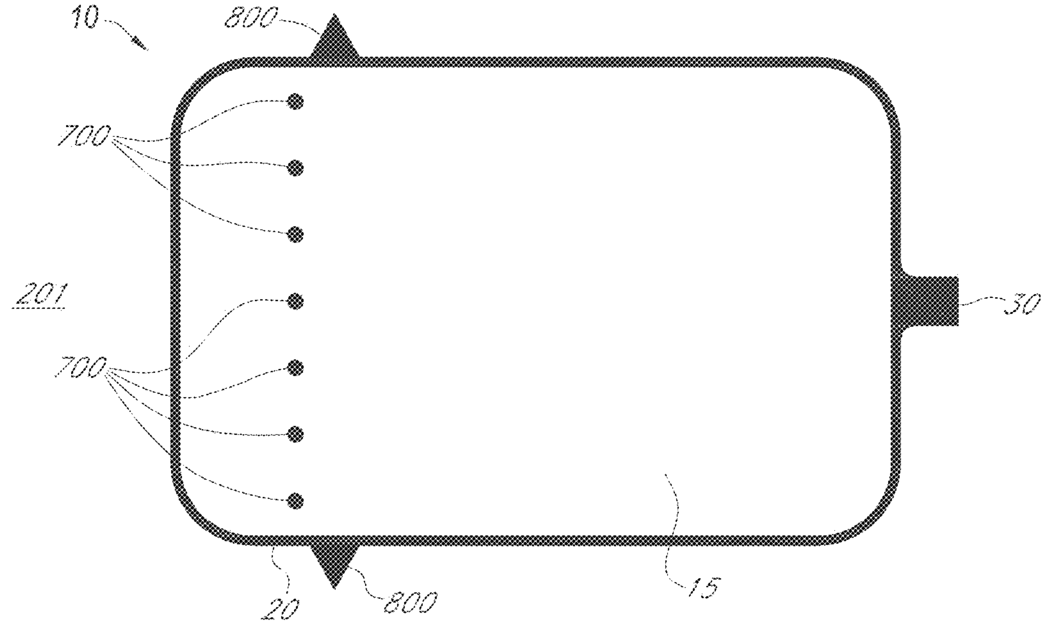


FIG. 34

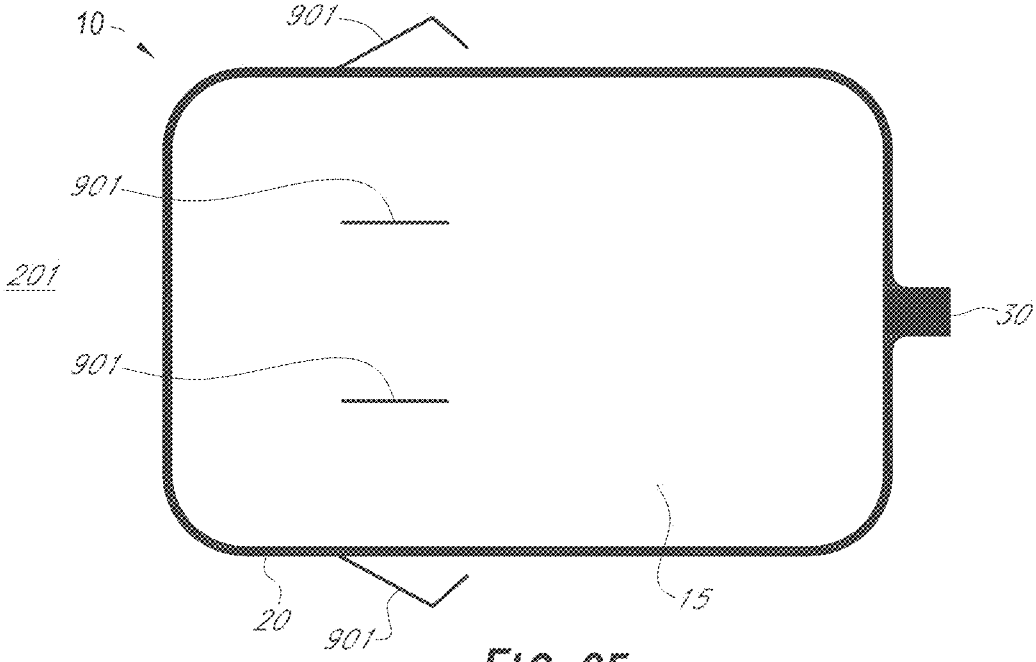


FIG. 35

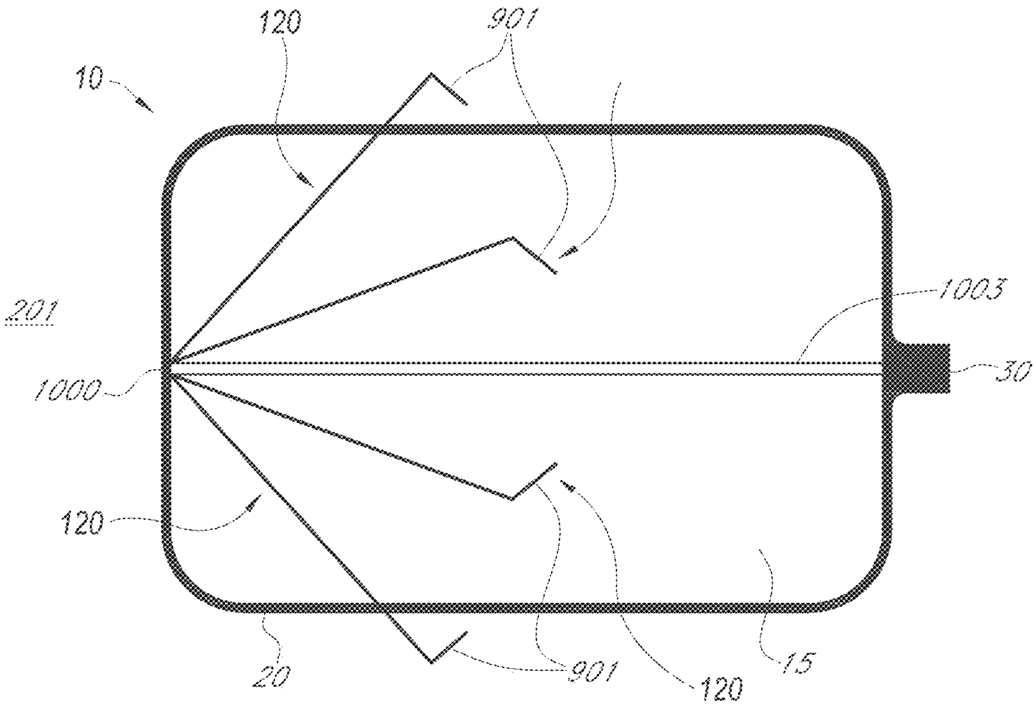


FIG. 36

FIG. 37A

FIG. 37B

FIG. 37C

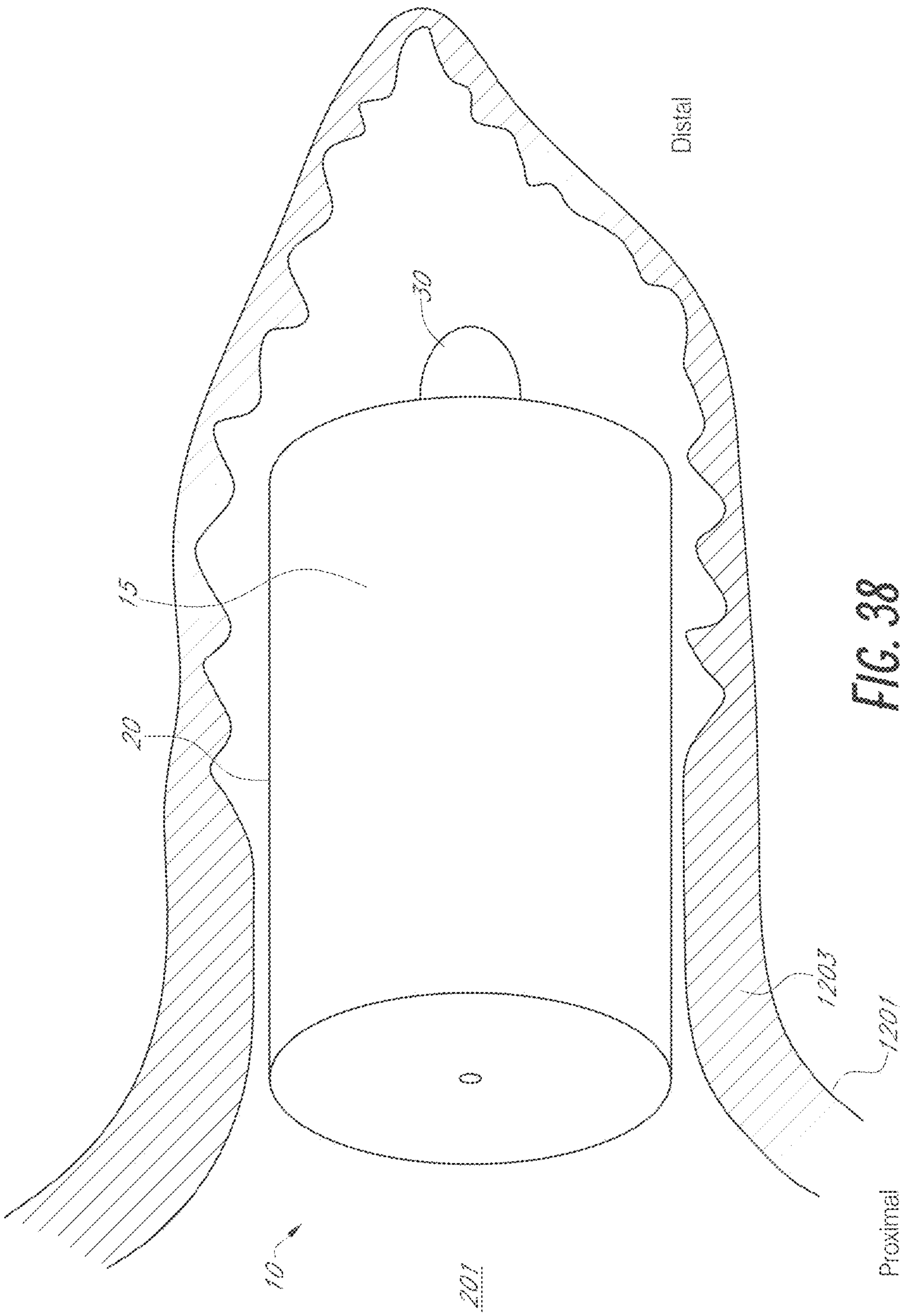


FIG. 38

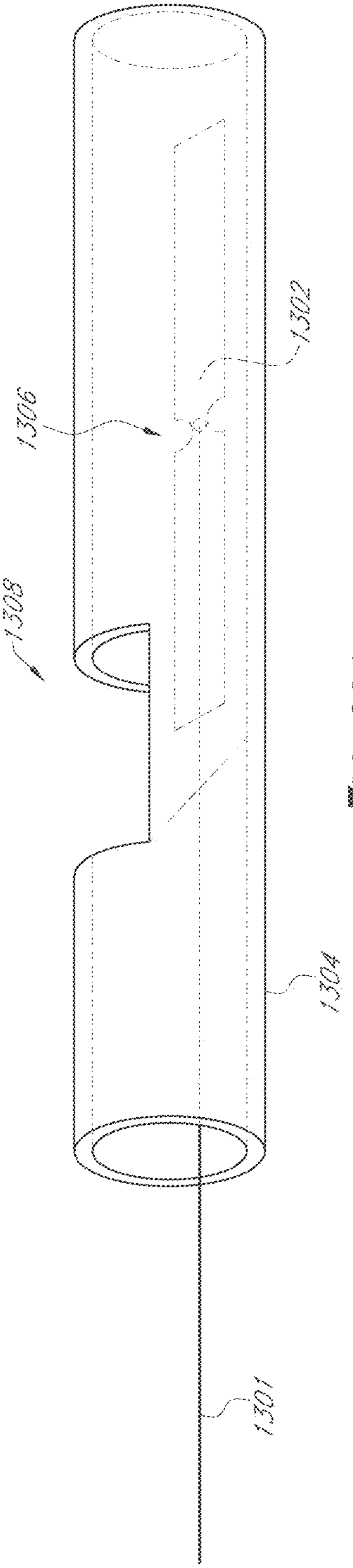


FIG. 39A

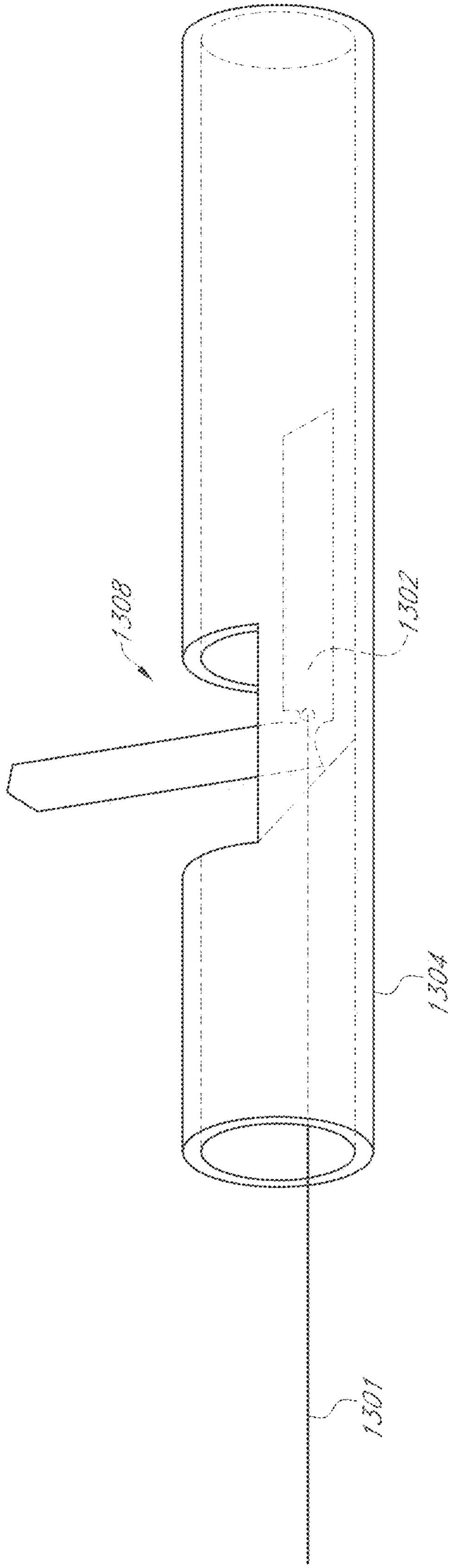


FIG. 39B

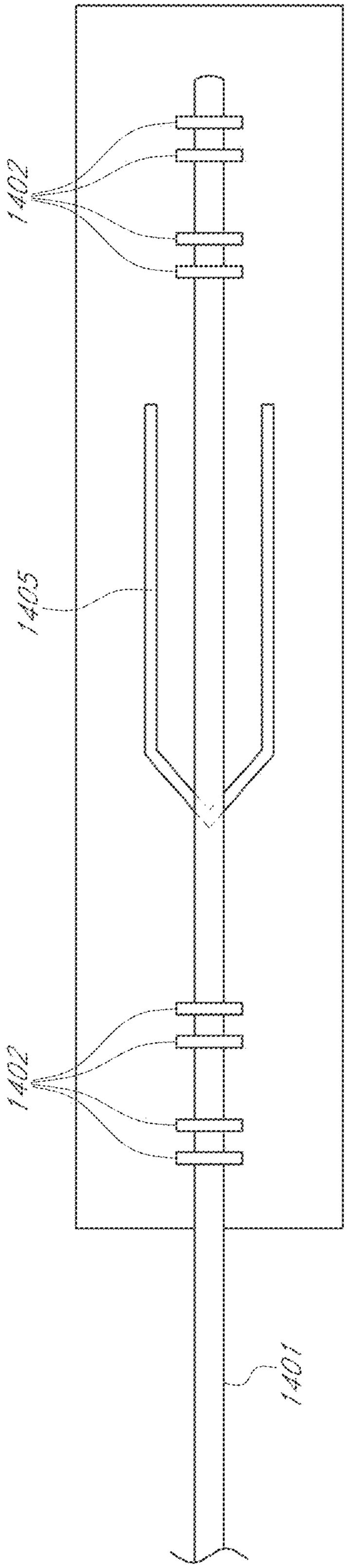


FIG. 40A

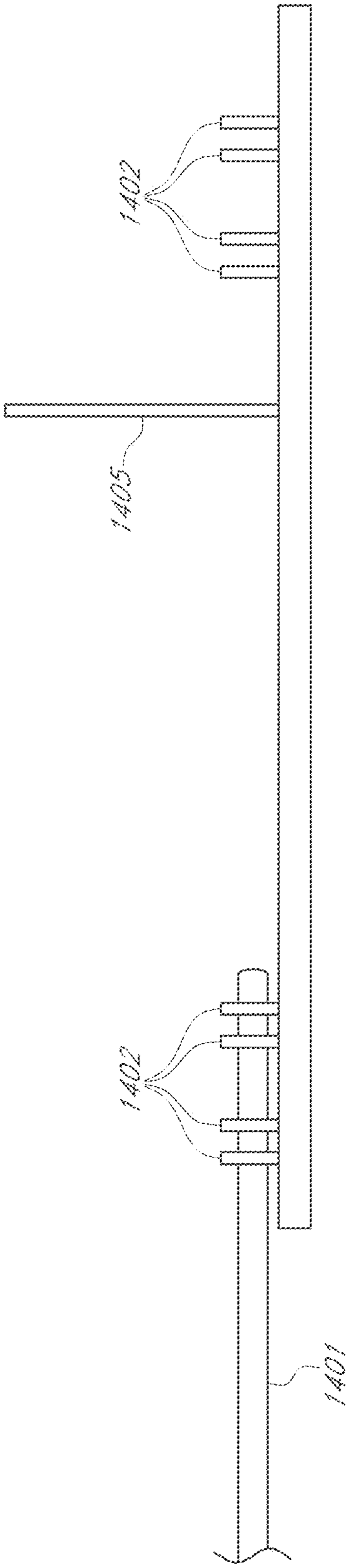


FIG. 40B

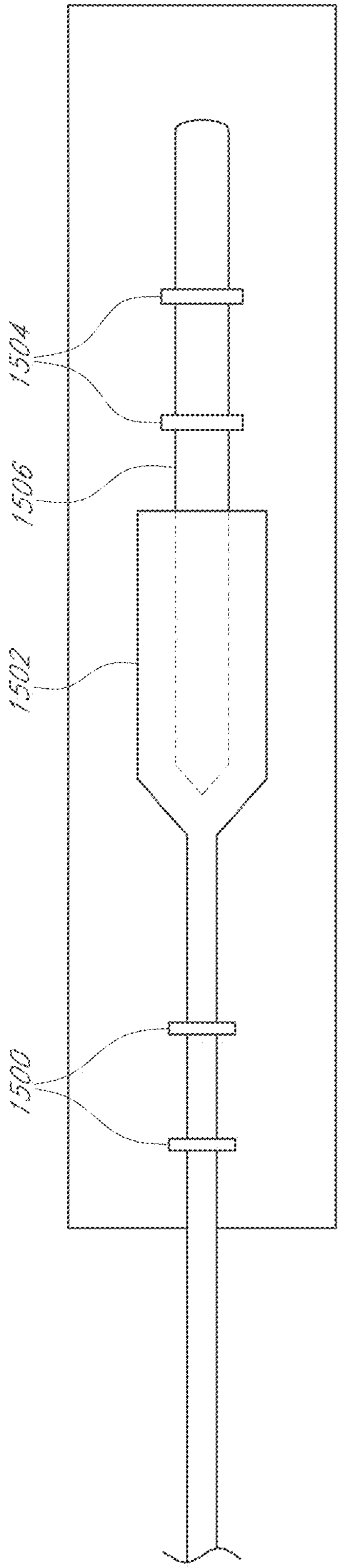


FIG. 41A

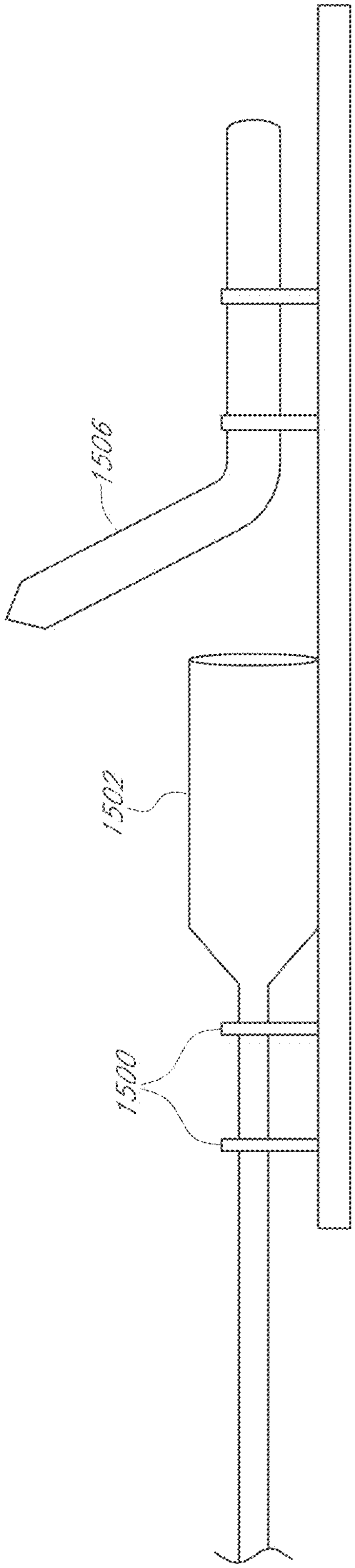


FIG. 41B

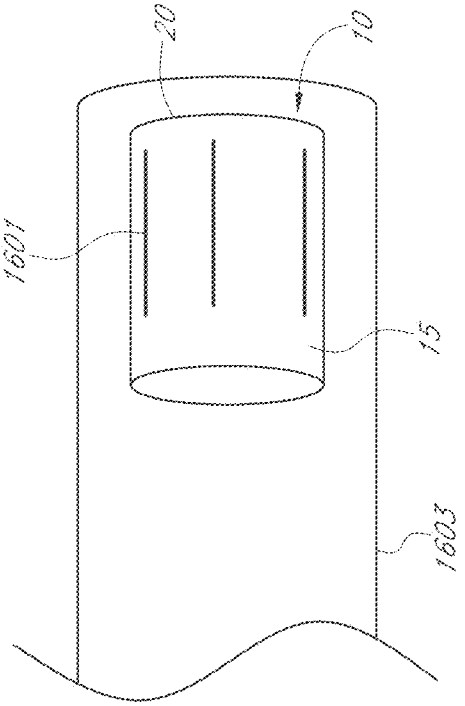


FIG. 42A

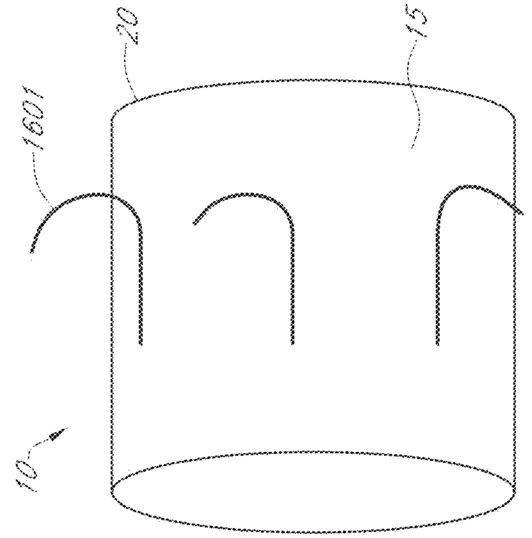


FIG. 42B

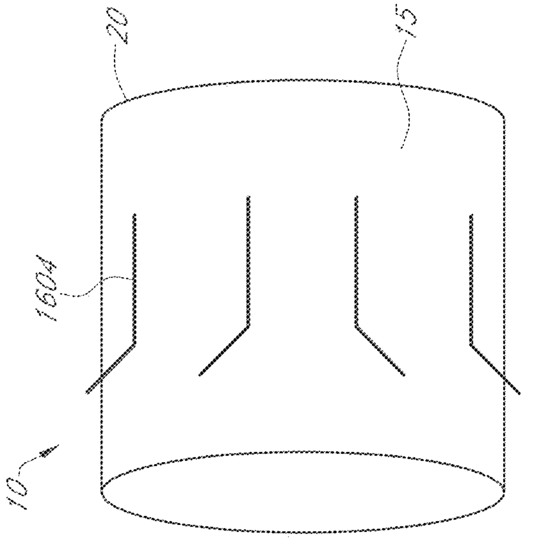


FIG. 42D

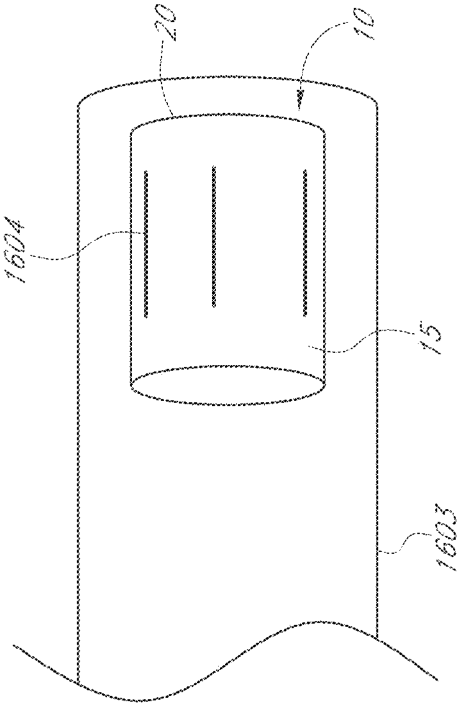


FIG. 42C

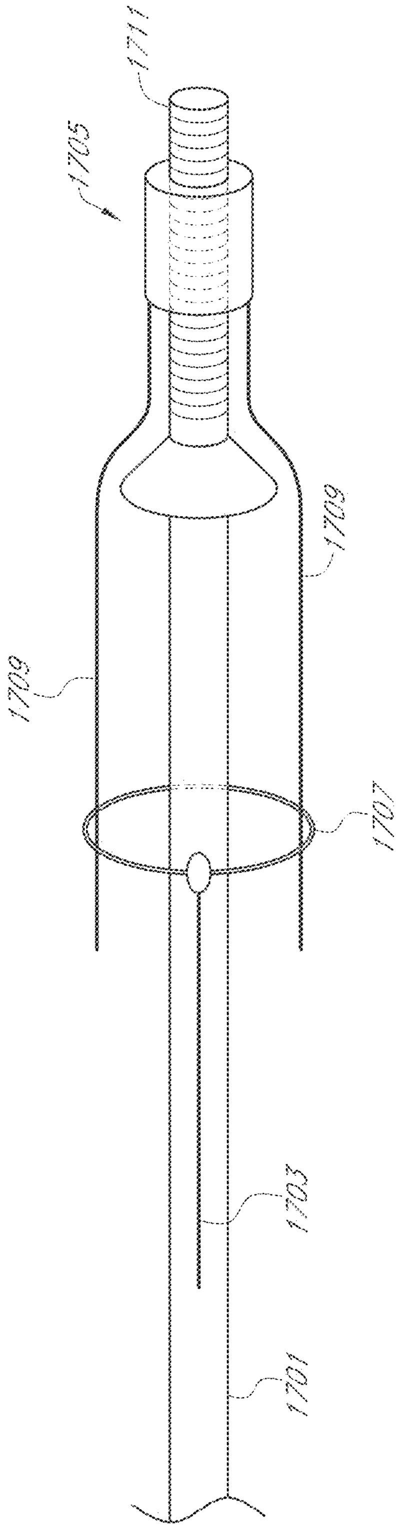


FIG. 43A

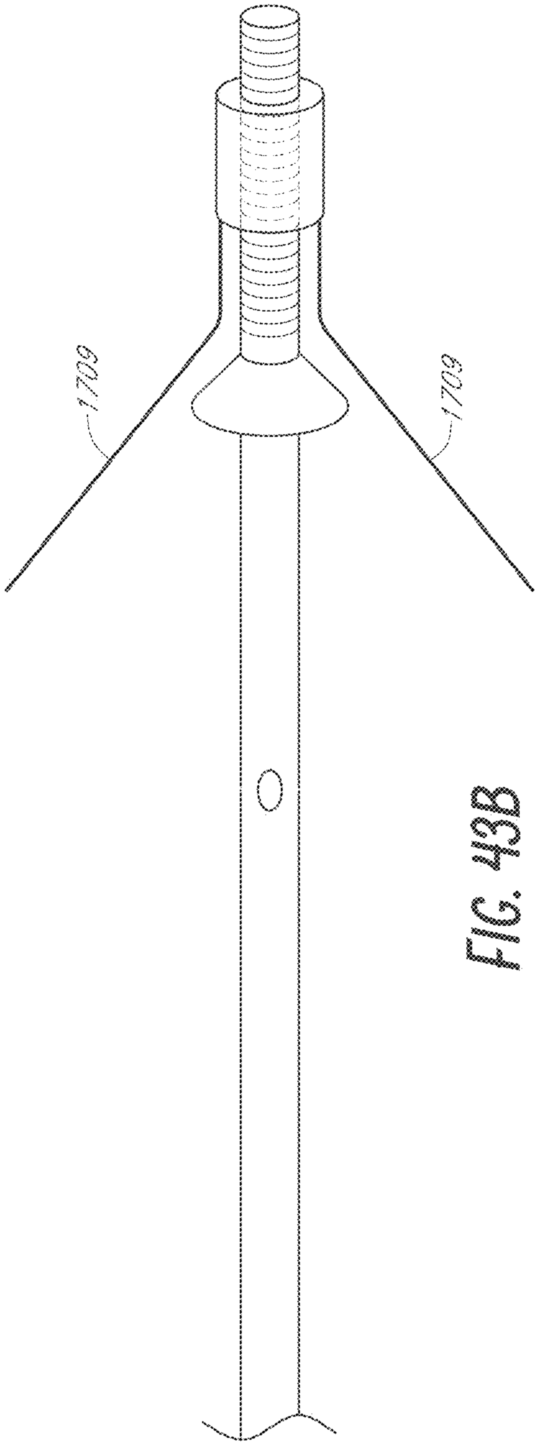


FIG. 43B

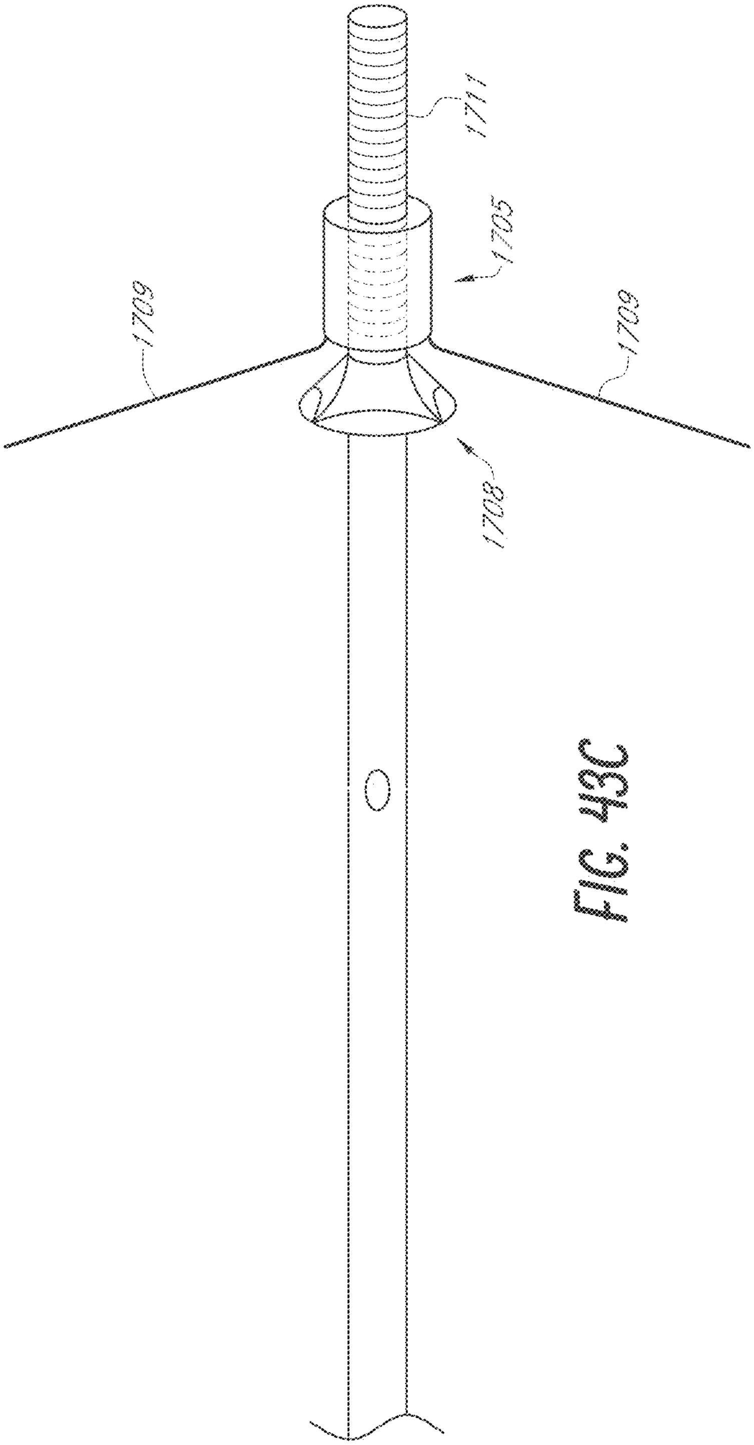


FIG. 43C

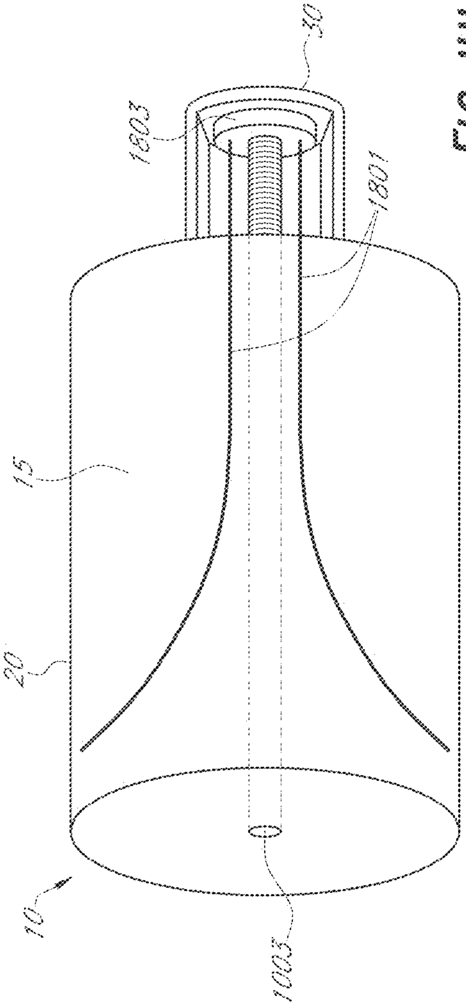


FIG. 44A

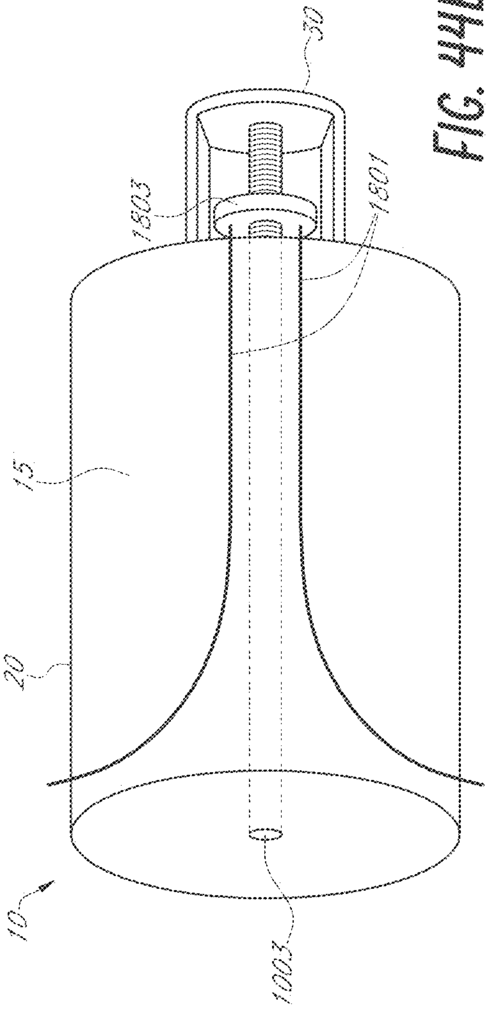


FIG. 44B

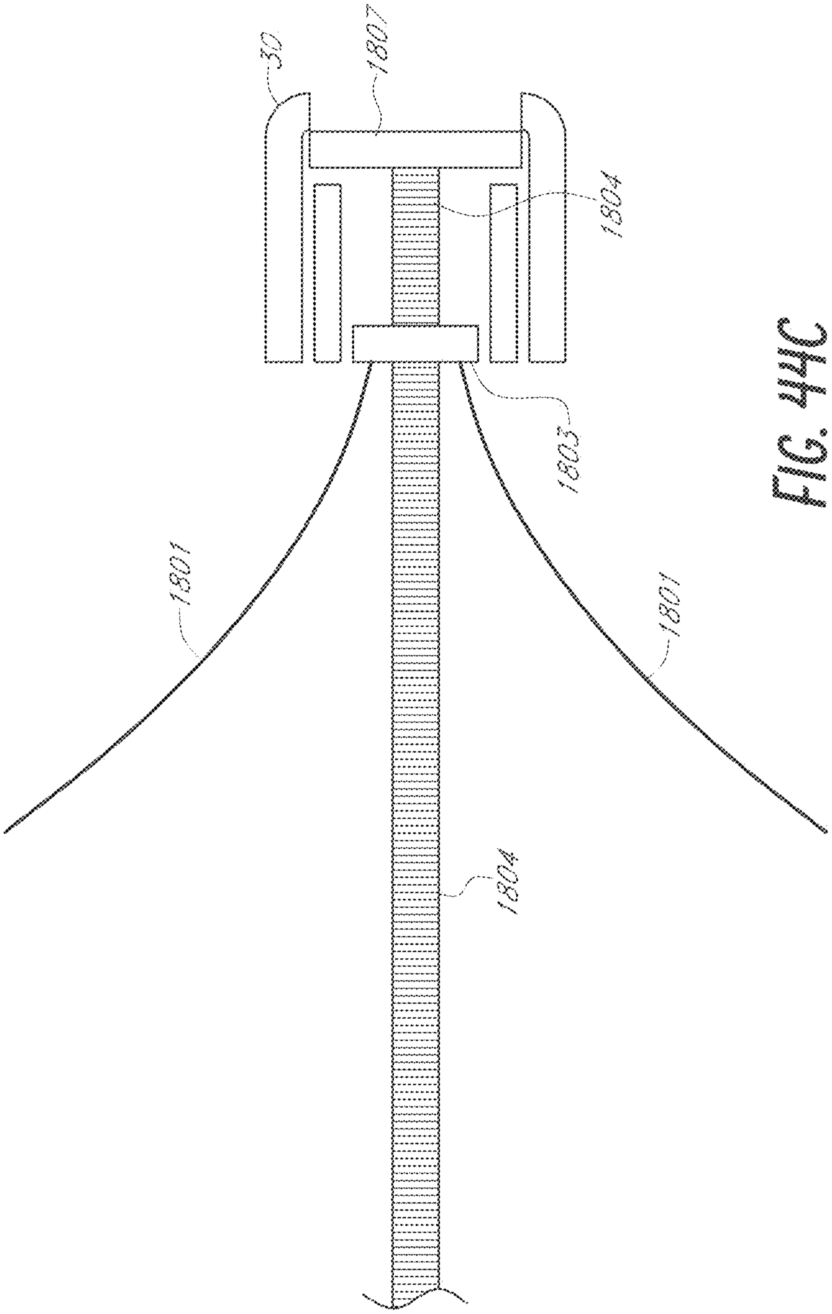


FIG. 44C

DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57. For example, this application is a continuation of U.S. application Ser. No. 16/846,076, entitled "DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE" and filed on Apr. 10, 2020, which is a continuation of U.S. application Ser. No. 15/290,692 entitled "DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE" and filed on Oct. 11, 2016, which is a continuation in part of U.S. application Ser. No. 14/203,187 entitled "DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE" and filed on Mar. 10, 2014, and claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 62/240,124 entitled "DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE" and filed on Oct. 12, 2015, and U.S. application Ser. No. 14/203,187 claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 61/779,802, entitled "LEFT ATRIAL APPENDAGE OCCLUSION DEVICE" and filed on Mar. 13, 2013, the entire disclosure of each of which is incorporated herein by reference for all purposes and forms a part of this specification.

BACKGROUND

Field

This development relates generally to systems, devices and methods for excluding the left atrial appendage (LAA). In particular, systems, devices and methods for excluding the LAA using an expandable foam implant with deployable anchors are described herein.

Description of the Related Art

Atrial fibrillation (Afib) is a condition in which the normal beating of the left atrium (LA) is chaotic and ineffective. The left atrial appendage (LAA) is a blind pouch off the LA. In patients with Afib blood stagnates in the LAA facilitating clot formation. These clots (or clot fragments) have a tendency to embolize or leave the LAA and enter the systemic circulation. A stroke occurs when a clot/clot fragment embolizes and occludes one of the arteries perfusing the brain. Anticoagulants, e.g. Coumadin, have been shown to significantly reduce the stroke risk in Afib patients. These drugs reduce clot formation but also increased bleeding complications including hemorrhagic strokes, subdural hematoma, and bleeding in the gastrointestinal tract.

There are about 8 million people in the US and EU with Afib. About 4.6 million of these patients are at a high risk for stroke and would benefit from anticoagulation. A large portion of these patients cannot take anticoagulants due to an increased bleeding risk, leaving their stroke risk unaddressed. The prevalence of Afib increases with age.

Several devices for occluding the LAA are described in the prior art and each has limitations this invention improves upon. The prior art devices are metal structures which are circular in cross section and are made to expand to fill the LAA ostium. These devices are offered in many sizes and must be closely matched to the highly variable LAA anatomy. This is difficult to do using fluoroscopy and often requires adjunctive imaging in the form of transesophageal echocardiography (TEE), cardiac CT and MRI, all with three dimensional reconstructions. If the device is significantly oversized, the LAA ostium may become overstretched leading to tearing, resulting in bleeding into the pericardial space. If the device is too small, it will not adequately seal the ostium and may be prone to embolization. Even if sized correctly, the device forces the oval LAA ostium to take the round shape of the device, often resulting in residual leakage at the edges due to poor sealing.

Anchoring of these implants in the proper location is described in the prior art devices predominately using an array of radially disposed barbs or hooks that engage into the surrounding cardiac tissue upon expansion of the device. The device must therefore have sufficient spring force or stiffness for the barbs to engage the surrounding tissue. These barbs may lead to leaking of blood through the tissue into the pericardial space which may lead to cardiac tamponade. Furthermore, the geometry of these barbs and hooks prevent repositioning once the implant is fully expanded.

For all of these reasons it would be desirable to have a device which conforms to the oval shape of the LAA, does not require an excessive number of sizes therefore negating the need for extensive pre-procedure imaging, can be easily repositioned after it is fully expanded, then secured in place once the final position has been optimized.

SUMMARY

The embodiments disclosed herein each have several aspects no single one of which is solely responsible for the disclosure's desirable attributes. Without limiting the scope of this disclosure, its more prominent features will now be briefly discussed. After considering this discussion, and particularly after reading the section entitled "Detailed Description," one will understand how the features of the embodiments described herein provide advantages over existing systems, devices and methods.

The following disclosure describes non-limiting examples of some embodiments. For instance, other embodiments of the disclosed systems and methods may or may not include the features described herein. Moreover, disclosed advantages and benefits can apply only to certain embodiments of the invention and should not be used to limit the disclosure.

Devices and methods are described for occluding the left atrial appendage (LAA) to exclude the LAA from blood flow to prevent blood from clotting within the LAA and subsequently embolizing, particularly in patients with atrial fibrillation. A foam implant is delivered via transcatheter delivery into the LAA and anchored using an internal locking system of the implant. The locking system includes deployable anchors that can be deployed after deployment of the foam implant from the delivery catheter and expansion of the foam within the LAA. The implant location can thus be verified before deploying the anchors to secure the implant. The locking system can be reversible to allow retraction of the anchors and repositioning or retrieval of the implant.

The devices and methods allow for occluding the LAA with a foam plug to prevent blood from clotting within the LAA and subsequently embolizing. An implantable device is delivered through a catheter that is tracked over a guide wire through the vascular system. The guide wire lumen within the foam is expandable, to allow for placement of the guide wire, then is self-closing upon removal of the guide wire.

Foams, which can be tubular in shape with a central lumen, are described that are collapsed for delivery and then expand in place within the LAA. The plug is anchored by tissue ingrowth from the left atrium (LA) and LAA into the foam, by independent and/or integrated repositionable anchors, barbs, and/or by distal anchoring elements. For example, independent repositionable anchors are described which deploy through openings in the compressible foam plug and tubular film and can be expanded, re-collapsed, and locked through the central guide wire lumen. Repositionable atraumatic anchor system embodiments are also disclosed which can be independent structures or integral to the foam plug and/or skin. Foam plugs are described that are encapsulated with jackets or skins that can be tubular in shape that are sufficiently strong to enable handling of the plugs without tearing, allow for repositioning and retrieval of the plugs, provide a thromboresistant surface within the LA which will encourage formation of a neointima, assist in the creation of occlusion zones designed to encourage thromboresistance and endothelialization from the blood and adjacent tissue and anchoring zones designed to promote fast and tenacious tissue ingrowth into the compressible implant from the adjacent non-blood tissue, and can assist in closure at the ostium. These jackets or skins can be independent or can be attached to the foam plugs. Retrieval finials can be attached at one or more points to aid in retrieval of an embolized device and to increase radiopacity.

In one aspect, a left atrial appendage occlusion device is described. The device includes an open cell foam body and an internal locking system. The body has a proximal end, a distal end and an outer skin. The proximal end is configured to face a left atrium and the distal end is configured to face the left atrial appendage following implantation in the left atrial appendage. The body can be compressed for delivery within a delivery catheter and can self-expand when removed from the delivery catheter. The internal locking system is coupled with the body and comprises at least one deployable tissue anchor. The deployable anchor is configured to deploy from a constrained configuration within the body to a deployed configuration where a tissue engaging segment of the anchor extends outside the body to secure the body within the left atrial appendage. The deployable anchor is configured to deploy to the deployed configuration after the body expands within the left atrial appendage. The deployable anchor is retractable from the deployed configuration to a retracted configuration within the body.

In some embodiments, the internal locking system further comprises a plurality of the deployable anchors rotatably coupled with the body, wherein the plurality of anchors are configured to rotate to the deployed and retracted configurations. The internal locking system may comprise four of the deployable anchors. In some embodiments, the body further comprises a plurality of axially extending slots corresponding to the plurality of anchors, wherein each of the plurality of anchors is configured to deploy and retract through the corresponding axial slot.

In some embodiments, the internal locking system further comprises a restraint that restrains the anchor in the constrained configuration, and the anchor is deployed from the constrained configuration to the deployed configuration by removing the restraint from the anchor. The restraint may be a sheath that restrains the anchor in the constrained configuration by covering the anchor, wherein the anchor is deployed from the constrained configuration to the deployed configuration by removing the sheath from covering the anchor. The restraint may be a lasso that restrains the anchor in the constrained configuration by surrounding the anchor, and the anchor is deployed from the constrained configuration to the deployed configuration by removing the lasso from surrounding the anchor.

In some embodiments, the internal locking system further comprises a moveable mount coupled with an end of the anchor, and the anchor is deployed from the constrained configuration to the deployed configuration by axially moving the mount.

In some embodiments, the internal locking system further comprises a constraint configured to move over the anchor to cause the anchor to retract. The constraint may be a ring configured to slide over the anchor to cause the anchor to retract.

In some embodiments, the skin comprises ePTFE.

In some embodiments, the device further comprises at least one tissue ingrowth surface on a sidewall of the body.

In some embodiments, the device further comprises a plurality of openings in the skin to permit tissue ingrowth into the open cell foam body. The plurality of openings of the skin may be located in an anchoring region of the device located at least between the proximal and distal ends of the device, and the device may further comprise an occlusion region located at the proximal end of the device and configured to encourage thromboresistance and endothelialization from the blood and adjacent tissue.

In another aspect, a left atrial appendage closure system is described. The system comprises a delivery catheter and a left atrial appendage occlusion device. The delivery catheter comprises an elongate flexible tubular body, having a proximal end and a distal end and at least one lumen extending therethrough. The left atrial appendage occlusion device is configured to be compressed within the delivery catheter and to self-expand upon deployment from the delivery catheter. The device comprises a self-expandable open cell foam body coupled with an internal locking system. The internal locking system comprises a deployable anchor configured to deploy from a constrained configuration to a deployed configuration after the body expands within the left atrial appendage and is configured to retract from the deployed configuration to a retracted position within the body.

In some embodiments, the system further comprises an axially movable deployment control extending through a lumen of the body, for deploying the deployable anchor. The system may further comprise an axially movable deployment control extending through a lumen of the body, for deploying the foam body from the distal end of the closure system. The internal locking system may further comprise a restraint that restrains the anchor in the constrained configuration, and the anchor is actively deployed from the constrained configuration to the deployed configuration by removing the restraint from the anchor using an axially movable deployment control extending through a lumen of the body. The internal locking system may further comprise a moveable mount coupled with an end of the anchor, and the anchor is actively deployed from the constrained configuration to the deployed configuration by axially moving the mount using an axially movable deployment control extending through a lumen of the body.

In another aspect, a method of excluding a left atrial appendage is described. The method comprises advancing a guidewire into the left atrial appendage, advancing a distal end of a delivery catheter over the guidewire and into the left atrial appendage, and deploying a left atrial appendage occlusion device from the distal end of the delivery catheter. The device comprises an expandable foam body coupled with an internal locking system having a deployable anchor, and the body expands within the left atrial appendage upon deploying from the distal end of the delivery catheter. The method further comprises actively deploying the deployable anchor after the body expands within the left atrial appendage. The deployable anchor is configured to retract from the deployed configuration to a retracted position within the body. In some embodiments, the method further comprises retracting the deployable anchor from the deployed configuration to the retracted position.

In another aspect, a left atrial appendage occlusion device is described. The device comprises an expandable foam body and an internal locking system. The body can be compressed for delivery within a delivery catheter and can self-expand when removed from the delivery catheter. The internal locking system is coupled with the body and comprises a deployable anchor configured to deploy from a constrained configuration within the body to a deployed configuration where the anchor extends outside the body to secure the body within the left atrial appendage. The body is configured to expand upon removal from the delivery catheter, and the deployable anchor is configured to deploy to the deployed configuration after the body expands.

In another aspect, a left atrial appendage occlusion device is described. The device comprises an expandable foam body and an internal locking system. The body can be compressed for delivery within a delivery catheter and can self-expand when removed from the delivery catheter. The internal locking system is coupled with the body and comprises a deployable anchor configured to deploy from a constrained configuration within the body to a deployed configuration where the anchor extends outside the body to secure the body within the left atrial appendage. The deployable anchor is configured to retract from the deployed configuration to a retracted configuration within the body such that the body can be repositioned within the left atrial appendage.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of the present disclosure will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. Understanding that these drawings depict only several embodiments in accordance with the disclosure and are not to be considered limiting of its scope, the disclosure will be described with additional specificity and detail through use of the accompanying drawings. In the following detailed description, reference is made to the accompanying drawings, which form a part hereof. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the detailed description, drawings, and claims are not meant to be limiting. Other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the subject matter presented here. It will be readily understood that the aspects of the present disclosure, as generally described herein, and illustrated in the drawing, can be arranged, substituted, combined, and designed in a wide variety of different configurations, all of which are explicitly contemplated and make part of this disclosure.

FIG. **1** shows the anatomy of the left atrium and left atrial appendage.

FIG. **2** shows a left atrial appendage with one foam plug embodiment in place that uses adhesive.

FIG. **3** shows an x-ray image of a foam plug.

FIG. **4** shows a left atrial appendage with foam embodiment and distal anchor in place.

FIG. **5** shows a screw anchor.

FIG. **6** shows a longitudinal cross section of a foam plug embodiment.

FIG. **7** shows an LAA cross section.

FIG. **8** is a schematic illustration of a guide catheter approaching the ostium to the left atrial appendage.

FIG. **9** is an illustration as in FIG. **8**, with a guidewire placed within the left atrial appendage.

FIG. **10** is an illustration as in FIG. **9**, with an inflatable balloon at the distal region of the guidewire positioned within the left atrial appendage.

FIG. **11** is an illustration as in FIG. **10**, with the guide catheter advanced distally along the guidewire and into the left atrial appendage.

FIG. **12** is an illustration as in FIG. **11**, showing the occlusion device and pusher positioned within the guide catheter.

FIG. **13** is an illustration as in FIG. **12**, showing the occlusion device partially deployed exiting the guide catheter.

FIG. **14** is an illustration as in FIG. **13**, with the occlusion device fully deployed within the left atrial appendage.

FIG. **15** is an illustration as in FIG. **14**, showing the deployment of adhesives or other anchoring structures to retain the occlusion device within the left atrial appendage.

FIG. **16** shows a plug occlusive device in longitudinal cross section using metal and foam.

FIG. **17** shows a plug using metal coils and foam.

FIG. **18** shows a plug using a single metal coil.

FIG. **19** shows a plug with a dilating distal tip.

FIG. **20** shows a plug with proximal and distal caps.

FIG. **21** shows a plug adhesive delivery system.

FIG. **22** shows the delivery of an expanding foam system.

FIG. **23** shows a plug with barbs.

FIG. **24** shows a plug with a retrieval suture attachment.

FIGS. **25**A and **25**B show a distal anchoring system.

FIG. **26** shows an alternative distal anchoring system.

FIGS. **27**A-**27**G are various views of an embodiment of a device for occlusion of the left atrial appendage (LAA) with an internal locking system for securing the device.

FIGS. **28**A-**28**D are various views of an embodiment of an internal locking system that may be used with the various devices and plugs described herein for occlusion of the LAA, such as the device of FIGS. **27**A-**27**G.

FIGS. **29**A-**29**B are sequential side views of an unlocking mechanism that may be used with the various devices and plugs described herein for occlusion of the LAA, such as the device of FIGS. **27**A-**27**G.

FIG. **30** is a side view of an embodiment of a device for occlusion of the LAA having flexible anchors.

FIG. **31** is a side view of an embodiment of a device for occlusion of the LAA having flexible anchors, with stiffening tubular members in a pre-deployed configuration.

FIG. **32** is a side view of the device of FIG. **31**, with the stiffening tubular members in a deployed configuration.

FIG. **33** is a side view of an embodiment of a device for occlusion of the LAA having discrete attachments of an outer skin to an internal foam.

FIG. **34** is a side view of an embodiment of a device for occlusion of the LAA including an outer rim.

FIG. **35** is a side view of an embodiment of a device for occlusion of the LAA having anchors with V-tips shown in the deployed configuration.

FIG. **36** is a side view of another embodiment of a device for occlusion of the LAA having anchors with V-tips shown in the deployed configuration.

FIGS. **37**A-**37**C are side views of various embodiments of V-tips that may be used with the anchors described herein.

FIG. **38** is a side view of an embodiment of a device for occlusion of the LAA implanted inside an LAA.

FIGS. **39**A-**39**B are perspective views of an embodiment of a deployable anchor activated by a pull wire and shown, respectively, in the constrained and deployed configuration, that may be used with the various devices for occlusion of the LAA described herein.

FIGS. **40**A-**40**B are perspective views of an embodiment of a deployable anchor activated by a lock wire and shown, respectively, in the constrained and deployed configuration, that may be used with the various devices for occlusion of the LAA described herein.

FIGS. **41**A-**41**B are perspective views of an embodiment of a deployable anchor activated by a sheath and shown, respectively, in the constrained and deployed configuration, that may be used with the various devices for occlusion of the LAA described herein.

FIGS. **42**A-**42**D are various views of embodiments of devices for occlusion of the LAA having external deployable anchors which can be collapsed and expanded by retraction into or out of a sheath or outer catheter.

FIGS. **43**A-**43**C are sequential side views of an embodiment of a device for occlusion of the LAA shown, respectively, constrained by a lasso, deployed, and adjusted with a mount.

FIGS. **44**A-**44**C are side views of an embodiment of a device for occlusion of the LAA having an adjustable two stage anchor system activated by moving a mounting base along a rod.

While the above-identified drawings set forth presently disclosed embodiments, other embodiments are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of the presently disclosed embodiments.

DETAILED DESCRIPTION

The following detailed description is directed to certain specific embodiments of the development. In this description, reference is made to the drawings wherein like parts or steps may be designated with like numerals throughout for clarity. Reference in this specification to "one embodiment," "an embodiment," or "in some embodiments" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the invention. The appearances of the phrases "one embodiment," "an embodiment," or "in some embodiments" in various places in the specification are not necessarily all referring to the same embodiment, nor are separate or alternative embodiments necessarily mutually exclusive of other embodiments. Moreover, various features are described which may be exhibited by some embodiments and not by others. Similarly, various requirements are described which may be requirements for some embodiments but may not be requirements for other embodiments. Reference will now be made in detail to embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

The devices and related methods are described herein in connection with use in occluding, i.e. excluding, a left atrial appendage (LAA). The various figures show various embodiments of LAA occlusion devices, systems and methods for delivery of the LAA occlusion devices, and/or methods of using the device to occlude a LAA. The various systems, devices and methods described herein may include the same features and/or functionalities as other LAA occlusion systems, devices and methods as described, for example, in U.S. application Ser. No. 14/203,187 entitled "DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE" and filed on Mar. 10, 2014, and/or as described in U.S. Provisional Application No. 62/240,124 entitled "DEVICES AND METHODS FOR EXCLUDING THE LEFT ATRIAL APPENDAGE" and filed on Oct. 12, 2015, the entire disclosure of each of which is incorporated herein by reference for all purposes and forms a part of this specification.

The heart **100** is shown in FIG. **1** with the left atrial appendage (LAA) **102** which is a cavity emanating from the left atrium (LA) **104**. The LAA **102** is quite variable in shape in all dimensions. If the heart is not beating normally, a condition called atrial fibrillation, blood within the LAA becomes stagnant which promotes clot formation. If blood clots within the LAA, the clots may pass from the LAA **102** to the LA **104**, to the left ventricle **106** and out of the heart **100** into the aorta. Vessels that bring blood to the brain branch off the aorta. If the clot passes to the brain via these vessels, it may get stuck and occlude a small vessel in the brain which then causes an ischemic stroke. Strokes have severe morbidities associated with them.

The opening of the LAA **102** to the LA **104** is called an ostium **110**. The object of this invention is to occlude the ostium **110** thereby sealing off the LA **104** from the LAA **102**. The ostium **110**, is oval, highly variable and dependent of loading conditions, i.e., left atrial pressure.

One embodiment of the LAA occlusion device is shown in FIG. **2**. The occlusion device or plug **204** is placed within the LAA **200** at its opening to the LA **202**. It is understood that the "plugs" described herein, such as the plug **204**, may have the same or similar features as other implantable "devices" described herein, such as the device **10**, and vice versa. The plug **204** comprises an expandable media such as an open cell foam which enables collapse and expansion of the plug and also to enhance ingrowth of tissue into the foam. The foam plug **204** is at least partially encapsulated within a thin strong layer **206** such as ePTFE (expanded polytetrafluoroethylene), polyolefin or polyester. The layer **206** may be referred to herein as a "skin." Alternatively bioabsorbable materials could be utilized such as PLA, PGA, PCL, PHA, or collagen. This thin encapsulating layer can be oriented or otherwise modified to be elastomeric in at least one direction, such as radially.

The plug may be made of polyurethane, polyolefin, PVA, collagen foams or blends thereof. One suitable material is a polycarbonate-polyurethane urea foam with a pore size of 100-250 um and 90-95% void content. The foam could be non-degradable or use a degradable material such as PLA, PGA, PCL, PHA, and/or collagen. If degradable, the tissue from the LAA will grow into the foam plug and replace the foam over time. The plug **204** may be cylindrical in shape in an unconstrained expansion but may also be conical with its distal end smaller than the proximal end or reversed. It could also be oval in cross section to better match the opening of the LAA.

The foam plug **204** is oversized radially in an unconstrained expansion to fit snuggly into the LAA and may be 5-50 mm in diameter depending on the diameter of the target LAA. The length "L" of the plug is similar to or greater than its diameter "D" such that the L/D ratio is about or greater than about 1.0 or greater than about 1.5 or greater than about 2.0 to maximize its stability. In some embodiments, the length may be less than the diameter such that the L/D ratio is less than 1.0. The compliance of the material is designed such that it pushes on the walls of the LAA with sufficient force to maintain the plug in place but without overly stretching the LAA wall. The foam and/or skin also conforms to the irregular surfaces of the LAA as it expands, to provide a complementary surface structure to the native LAA wall to further enhance anchoring and promote sealing. Thus, while some left atrial appendage occlusion devices in the prior art include a mechanical frame which forces at least some aspect of the left atrial appendage into a circular configuration, the expandable foam implant of the present invention conforms to the native configuration of the left atrial appendage. In one embodiment, the structure of the foam may be fabricated such that squeezing axially on the opposing ends of the foam causes the foam to increase in diameter.

The ePTFE or foam material may be provided with one or two or more radiopaque markers such as radiopaque threads **210** or be filled with or impregnated with a radiopaque filler such as barium sulfate, bismuth subcarbonate, or tungsten which permit the operator to see under x-ray the plug for proper positioning in the anatomy. An x-ray image is shown in FIG. **3** where one cannot see the foam plug **300** but can clearly see the threads **302** and the crimp **304** (discussed below). This thread or ribbon may be made from a radiopaque metallic wire such as platinum or tungsten or a polymer with a radiopaque filler such as barium, bismuth, tantalum, tungsten, titanium or platinum.

The outer ePTFE layer may be formed from a tube with a diameter about the same diameter of the foam plug and a wall thickness between about 0.0001" and about 0.001" thick and serves to allow one to collapse and pull on the plug without tearing the foam material. The ePTFE material also serves as the blood contacting surface facing the left atrium **206** and has pores or nodes such that blood components coagulate on the surface and an intimal or neointimal covering of tissue grows across it and anchors tightly to the material. Pore sizes within the range of from about 4μ to about 110μ, ideally 5-35μ are useful for formation and adherence of a neointima.

The outer covering **206** may be constructed of materials other than ePTFE such as woven fabrics, meshes or perforated films made of FEP, polypropylene, polyethylene, polyester or nylon. The covering should have a low compliance (non-elastic), at least longitudinally, be sufficiently strong as to permit removal of the plug, a low coefficient of friction, and be thromboresistant. The outer covering serves as a matrix to permit plug removal as most foams are not sufficiently strong to resist tearing when pulled. The plug can also be coated with or contain materials to enhance its ultrasonic echogenic profile, thromboresistance, lubricity, and/or to facilitate echocardiographic visualization, promote cellular ingrowth and coverage.

The outer covering has holes in it to permit contact of the LAA tissue with the foam plug to encourage ingrowth of tissue into the foam plug pores. These holes may be 1 to 5 mm in diameter or may also be oval with their long axis aligned with the axis of the foam plug, the length of which may be 80% of the length of the foam plug and the width may be 1-5 mm. The holes may be as large as possible such that the outer covering maintains sufficient strength to transmit the tensile forces required for removal. The holes may be preferentially placed along the device. In one embodiment, holes are placed distally to enhance tissue ingrowth from the LAA wall.

In one implementation of the invention, the implant is provided with proximal and distal end caps of ePTFE, joined together by two or three or four or more axially extending strips of ePTFE. The axially extending strips are spaced apart from each other circumferentially, to provide at least two or three or four or more laterally facing windows through which the open cell foam body will be in direct contact with the tissue wall of the left atrial appendage. This outer covering could be a mesh or netting as well. As shown in FIG. **20**, the covering **2004** is only on the proximal and distal faces of the plug **2000**. They may be glued to the foam plug and then crimped to the center tube **2002**.

The implantable plug **204** or device **10** (as described below) may be anchored and secured in place in the LAA by tissue ingrowth and/or with additional anchoring features. In some embodiments, the plug or device **10** may be anchored by tissue ingrowth alone. In some embodiments, other anchoring means may be implemented. One means of adhering the foam plug in place within the LAA is to use an adhesive, such as a low viscosity cyanoacrylate (1-200 cps). The adhesive is injected into place along the sidewall near the distal end of the foam plug **208**. Holes in the ePTFE covering permit the adhesive to interact between the foam plug **204** and the LAA wall **200**. Injection of the adhesive may be accomplished with several means, one of which is to inject through the catheter into the center lumen **212**. Passages **214** serve to guide the adhesive to the correct location. The distal end of the foam plug must be restricted at that time to prevent the adhesive from exiting the distal crimp **216**. Alternatively, FIG. **21** shows tubes **2104** that are pre-placed through the guide catheter **2102**, through the center lumen of the plug **2106** and bend backwards in the LAA to the distal end of the plug **2100**. These tubes **2104** pass all the way to the proximal end of the guide catheter **2102** where a fitting is attached to permit injection of the adhesive which then exits the small tubes **2104** at the desired location of the plug. These tubes are made of polyethylene, polypropylene or FEP so that the adhesive will not adhere to the tubes. The tubes **2104** are withdrawn after injection through the guide catheter out of the patient.

Other one part adhesives including aqueous cross linking adhesives, polyurethane, PEG, PGA, PLA, polycaprolactone or a lycine-derived urethane may be used. In addition, these adhesives may be made in two components such that one component is adherent to the foam and the second injected in vivo. Also, these two component adhesives may be injected simultaneously to mix in vivo to prevent fouling of injection tubes.

An alternative anchoring means for plug **400** is one or two or more distal anchors as shown in FIG. **4**. Wire **404** is passed through the center lumen **410** into the LAA and attached to the distal wall of the LAA. In this case, a screw wire **408** is threaded into the wall of the LAA **406**. A closer detail of this is seen in FIG. **5** as screw **502** is shown embedded into the LAA wall **504** but not all the way through the epicardial surface **506**.

Additional means of anchoring include the use of a plurality of hooks or barbs or graspers to grab the distal wall and baskets, malecots, distal foam plugs and Nitinol wire birds nests that open within the LAA and push outward on the wall or engage the protrusions of the LAA. It may be desirable to place the plug then engage the anchor as a secondary step. One such embodiment could include a multitude of nitinol wires with a ball or catch welded proximal to the anchor tip. These could be gathered with the delivery catheter then released when the ideal plug position has been confirmed.

A cross section of one embodiment is shown in FIG. **6** with foam plug **600** and the left atrium face **602** and the LAA face **610**. The ePTFE material **604** encapsulates the foam plug **600** and its open ends are connected with an attachment structure such as a wire, suture or tubular crimp **606** over an inner tube **608**. The inner tube **608** may be made of an implant grade stainless steel such as 304 or 316 grades or a cobalt-chromium alloy such as MP35n and the crimp **606** may be made of annealed 304 or 316 stainless steel or a cobalt-chromium alloy such as MP35n. This crimp also serves as an element which can be snared should the device need to be removed.

Referring to FIG. **6**, the tubular ePTFE layer **604** extends along an inner layer **612** which lines the guidewire lumen, and everts out around the left atrial face **602** to form outer layer **614**. A first end **616** of inner layer **612** is disposed concentrically within a second end **618** of outer layer **614**. The first end **616** and second end **618** are clamped between inner tube **608** and outer crimp **606**. In this manner, the implant can be encapsulated in a manner that presents a seamless left atrial face **602**, and preserves the integrity of the guidewire lumen with inner tube **608**.

Placement of the device is shown in FIG. **7** through **15**. To close the left atrial appendage, the left atrium (LA) must first be accessed from the venous system. One approach is to use a Brockenbrough-style needle to puncture the atrial septum to access the LA from the right atrium (RA). The basic needle-puncture technique is performed obtaining venous access typically via the right femoral vein. A Mullins sheath and dilator are then tracked over a 0.025" or 0.032" guide wire previously placed in the superior vena cava (SVC). Fluoroscopic and echocardiographic imaging, such as transesophageal echo (TEE) or intracardiac echo (ICE), are typically utilized. If echo is not utilized, it is common to also place a pigtail catheter in the aortic root to define the location of the aortic valve, a step not necessary when using echo.

Once the Mullins sheath and dilator are in the SVC, the guide wire is removed and a trans-septal needle is placed through the dilator. The needle contains a stylette to prevent skiving off of polymeric material from the dilator lumen as it traverses to the tip. Once the needle is near the dilator tip, the stylette is removed and the needle is connected to a manifold and flushed. The Mullins sheath/dilator set and the needle (positioned within the dilator tip) are retracted into the SVC toward the RA as a unit. As the system is withdrawn down the wall of the SVC into the RA and positioned in the fossa ovale, the preferred puncture location.

Once proper position in the fossa ovale is observed, the needle is advanced across the fossa ovale into the LA. Successful trans-septal puncture can be confirmed by echo, pressure measurement, O_2 saturation and contrast injection. Once the needle position is confirmed to be positioned in the LA, the sheath and dilator can be advanced over it into the LA. In some cases, the user will first pass a guide wire through the needle into the LA and into an upper pulmonary vein (typically the left) prior to crossing. Alternative options include the use of radiofrequency trans-septal needles, which are useful for crossing very thick or hypertrophic septa, or the use of a safety wire placed through the needle and utilized for the initial puncture.

Referring to FIGS. **8** through **15**, a guide catheter **802** is placed through the femoral vein into the right atrium of the heart and across the intra-atrial septum into the left atrium as described above and positioned near the LAA ostium **804**. A guidewire **902** usually of 0.035" diameter is placed through guide catheter **900** and into the LAA **904**. This guidewire **1002** may have attached to its distal end a balloon **1006** which is inflated in the LAA and serves as a bumper to prevent guide catheter **1100** from perforating the wall of the LAA. The guide catheter **1100** is then advanced over the guide wire **1108** into the LAA **1104**. A radiopaque marker **1102** is used to guide catheter placement under fluoroscopy. The foam plug **1204** is then pushed through the guide catheter **1200** with pusher **1202** and is shown exiting the guide catheter **1300** slowly in FIG. **13** until it is fully deployed as shown in FIG. **14**. The foam plug **1404** position may then be adjusted in place using the distal balloon **1408** and the guide catheter **1400**, sliding the foam plug proximally by pulling on the balloon **1408** through shaft **1412** or sliding it distally by pushing guide catheter **1400** distally. The guide wire may also contain a pressure sensor within it such that sealing of the LAA is monitored and confirmation of a sufficient seal is made. Once the user is happy with the placement, the adhesive **1514** may be injected and/or mechanical anchors be deployed anchoring the plug to the wall. The guide wire balloon **1508** is deflated, after which the guide wire is removed. In an alternative embodiment, a binary adhesive system can be used where one component of the binary system is bonded to the outer surface of the skin covering the foam plug. The second component can be injected at the interface between foam plug and the wall of the LAA such that bonding happens only at the interface minimizing the risk of adhesive embolization.

An alternative to pushing the plug through the entire length of the guide catheter is that the plug **1204** may be initially located at the distal end of the guide catheter **1200** as shown in FIG. **12**. The guidewire **1210** passes through the center of the plug **1204** and in this mode, the pusher **1202** only needs to push the plug a short ways to deploy it into the LAA.

For alternative anchors, they may be deployed, the shafts disconnected and removed. Disconnection mechanisms may be any of several types, such as threaded, electrolytic detachment, or others known in the art. In some embodiments, a suture attachment may be implemented, for example as described with respect to FIG. **24**.

Alternative plug concepts include a combination of foam and metal implant as shown in FIG. **16**. The foam **1600** is designed to provide ingrowth of tissue and also to provide a cushion of the metal stent **1602** onto the tissue of the LAA. The proximal face **1604'** of the plug is covered in ePTFE, polyester or another thromboresistant tissue scaffold material to facilitate sealing with the desired pore size to encourage overgrowth. Stent **1602** could be made of Nitinol to enable it to pack into a 10, 12, 14, 16, 18 or 20 F delivery catheter and expand to its desired diameter. It could be braided, laser cut or wire formed. Any of a variety of stent wall patterns may be utilized, depending upon the desired performance. The stent may be a balloon expandable stent, or self-expandable stent as are understood in the art. In the illustrated embodiment, a self-expandable stent **1602** comprises a plurality of proximal apexes **1608** and distal apexes **1610** connected by a plurality of zig zag struts **1612**. A hole **1606** allows passage of the guidewire for delivery. This design may be advantageous in that the expansion force exerted by the plug on the LAA can be controlled separately from the foam characteristics. Also, it may be easier to pack this concept into a smaller geometry. For example, the plug can be packed into a smaller geometry by reducing the amount of foam that must be compressed into the delivery catheter while maintaining sufficient dilation force.

Alternatively, the foam plug may be constructed of 2 foams. One denser core to provide force, for example radial force, and an outer softer foam to engage the tissue irregularities. The softer foam could also be located on the proximal and/or distal ends to facilitate retrieval.

Another means of adding stiffness to the foam plug is shown in FIG. **17** where a cavity **1704** in the foam plug **1700** is made and a coil of wire **1702** may be advanced from the guide catheter at the proximal end **1706** into the cavity **1704**. As the wire enters the cavity, it expands to its predetermined size and exerts force on the foam radially outwards. The type and amount of wire may be determined in vivo using x-ray guidance to examine the radial expansion of the foam into the LAA.

Instead of wires as shown in FIG. **17**, a balloon may be passed into the foam and inflated to provide radial force while the outer foam serves to engage the tissue irregularities and tissue ingrowth. Following inflation, the balloon may be detached from a deployment catheter and the deployment catheter withdrawn. The balloon is preferably provided with a valve, to prevent the escape of inflation media. Inflation media may be any of a variety of media which is convertible between a first, flowable state and a second, hardened state such as by cross linking or polymerization in situ.

Another LAA plug is shown in FIG. **18** as a spring like implant wire **1800** that is covered with foam **1802** to encourage ingrowth. The proximal face of the implant is covered with a sheet of ePTFE or other tissue scaffolding material. This implant may be stretched out for delivery and released in place.

Rather than using a foam, a low porosity outer bag without perforations could be placed in the LAA and then filled with a substance to provide the radial expansion. This substance may be a hydrogel, cellulose or polyvinylacetate.

Rather than requiring the use of a separate dilation device to cross the septum, the distal crimp element **1902** may be formed in a tapered manner such that it extends from the distal end of the catheter **1200** and serves as a dilating tip to dilate the opening in the septum as the catheter is advanced. See FIG. **19**.

An alternative plug design uses a foam such as cellulose sponge material that is compacted and dehydrated such that it can be packed into the guide catheter. This foam material **2202** may be packed into the guide catheter as shown in FIG. **22**. The foam plug **2202** is then advanced from the distal end of the guide catheter **2204** with a plunger **2206** into the LAA. The plug exits the guide catheter and opens to a disc shape **2210**. As the foam absorbs fluid in the blood, its length expands to form a cylinder **2220** filling the LAA. Expansion ratios for compressed cellulose materials may be as high as 17:1, expanded to compressed length.

It may be advantageous to use small barbs **2302** in FIG. **23** to further engage the plug **2204** into the LAA. Barbs may be unidirectional or bidirectional to resist movement in either the proximal or distal direction. These barbs are embedded into the foam plug and may be 0.1 to 1 mm in height. It may be desirable to place the plug then engage the barbs as a secondary step. One such embodiment could include a multitude of nitinol barb wires with a ball or catch welded proximal to the barb tip. These could be gathered with the delivery catheter within a sleeve or suture then released when the ideal plug position has been confirmed.

One means of removing a device that is not functioning properly is to releasably attach a retrieval suture **2400** to the implant, such as to the proximal cap **2402** which also passes proximally throughout the entire length of the guide catheter **2404** in FIG. **24**. If the device is to be removed, pulling on both ends of the suture **2400** will pull the outer covering into the guide catheter **2404** which can then be removed from the patient. If the device is properly placed, the suture **2400** may be cut and removed leaving the plug in place.

Deployment of the occlusion device has been discussed primarily in the context of a transvascular access. However, implants of the present invention may alternatively be deployed via direct surgical access, or various minimally invasive access pathways (e.g. jugular vein). For example, the area overlying the xiphoid and adjacent costal cartilage may be prepared and draped using standard techniques. A local anesthetic may be administered and skin incision may be made, typically about 2 cm in length. The percutaneous penetration passes beneath the costal cartilage, and a sheath may be introduced into the pericardial space. The pericardial space may be irrigated with saline, preferably with a saline-lidocaine solution to provide additional anesthesia and reduce the risk of irritating the heart. The occlusion device may thereafter be introduced through the sheath, and through an access pathway created through the wall of the LAA. Closure of the wall and access pathway may thereafter be accomplished using techniques understood in the art.

Depending upon the desired clinical performance, any of the LAA occlusion devices of the present invention may be provided with a drug or other bioactive agent, which may be injected via the deployment catheter, or impregnated within the open cell foam or coated on the implant. The bioactive agent may be eluted or otherwise released from the implant into the adjacent tissue over a delivery time period appropriate for the particular agent as is understood in the art. Useful bioactive agents can include those that modulate thrombosis, those that encourage cellular ingrowth, throughgrowth, and endothelialization, and potentially those that resist infection. For example, agents that may promote endothelial, smooth muscle, fibroblast, and/or other cellular growth into the implant including collagen (Type I or II), heparin, a combination of collagen and heparin, extracellular matrix (ECM), fibronectin, laminin, vitronectin, peptides or other biological molecules that serve as chemoattractants, molecules MCP-1, VEGF, FGF-2 and TGF-beta, recombinant human growth factors, and/or plasma treatment with various gases.

Anti-thrombotics can typically be separated into anticoagulants and antiplatelet agents. Anti-Coagulants include inhibitors of factor(s) within the coagulation cascade an include heparin, heparin fragments and fractions as well as inhibitors of thrombin including hirudin, hirudin derivatives, dabigatran, argatroban and bivalrudin and Factor X inhibitors such as low molecular weight heparin, rivaroxaban, apixaban.

Antiplatelet agents include GP 2b/3a inhibitors such as epifibitide, and abciximab, ADP Receptor agonists (P2/Y12) including thienopyridines such as ticlopidine, clopidogrel, prasugrel and tacagrelor and aspirin. Other agents include lytic agents, including urokinase and streptokinase, their homologs, analogs, fragments, derivatives and pharmaceutical salts thereof and prostaglandin inhibitors.

Antibiotic agents can include, but are not limited to penicillins, cephalosportins, vancomycins, aminoglycosides, quinolonges, polymyxins, erythromycins, tetracyclines, chloraphenicols, clindamycins, lincomycins, sulfonamides, their homologs, analogs, derivatives, pharmaceutical salts and combinations thereof.

Biologic agents as outlined above maybe be added to the implant **204** and may be injected through the delivery catheter into the space between the proximal cap **206** and the foam plug **204**. This may serve as a reservoir to minimize thrombus formation during the initial implantation and reduce the need for systemic anticoagulation following device implantation.

An electronic pressure sensor may be embedded into the proximal end of the foam plug which may be used to transmit LA pressure to a remote receiver outside the body for the monitoring of LA pressure which is useful to monitor cardiac function. In addition, a cardiac pacer or defibrillator may be embedded into the foam plug and attached electrically to the distal anchor. A drug delivery reservoir may be embedded with connection to the LA for controlled delivery of biologic agents as outlined above.

Another means of anchoring is shown in FIG. **25**A where the foam plug **2500** is placed in the LAA. The distal screw lead **2502** is advanced and screwed into the LAA wall. Guide **2506** is pulled proximally as shown in FIG. **25**B. When this guide **2506** is pulled back, the screw lead wire, made of Nitinol, bunches up into a "birds nest" **2508** or forms a coil inside the foam plug **2500**. The screw lead wire **2502** is pushed distally from the guide catheter **2504** with a pusher **2510** and continues to bunch up into the foam. The catheter system **2504**, **2506** and **2510** are then removed.

Another means of anchoring the distal anchor element to the foam is shown in FIG. **26**. Two barbed leads **2604** are attached to anchor **2602** such that when advanced into place in the foam plug **2600**, the barbs **2604** dig into the foam plug.

FIGS. **27**A-**27**G are various views of an embodiment of a device **10** for occlusion of the left atrial appendage (LAA). The device **10** may include the same or similar features as other devices for occlusion of the LAA described herein, such as the plug **204**, and vice versa. The device **10** includes an internal locking system **101** for securing the device **10** within the LAA. In some embodiments, the device **10** may not include the internal locking system **101** or other anchoring features, for example the device **10** may be anchored by tissue ingrowth alone. The occlusion device **10** comprises an expandable media such as an open cell foam body **15**, for example a plug. The body **15** enables collapse and expansion of the device **10** and also enhances ingrowth of tissue into the foam.

The body **15** of the device **10** shown in FIG. **27**A through FIG. **27**F is in its expanded configuration. The body **15** is in a compressed configuration in FIG. **27**G. The device **10** includes the foam body **15**, a skin **20**, a central lumen **25**, a finial **30**, and a dynamic internal locking system **101** which anchors the device **10** within the LAA. FIG. **27**A is a side cross-section view of the device **10** showing the body **15** and the internal locking system **101** in a deployed configuration. FIG. **27**B is an end view of the proximal end of the device **10** showing the body **15** and the internal locking system **101** in a deployed configuration. FIG. **27**C is a side view of the device **10** showing the body **15** and the internal locking system **101** in a deployed configuration. FIG. **27**D is a side cross-section view of the device **10** showing the body **15** in a deployed configuration and the internal locking system **101** in a constrained configuration. FIG. **27**E is an end view of the distal end of the device **10** showing the body **15** and the internal locking system **101** in a deployed configuration. FIG. **27**F is a cross-section view of the device **10** taken along the line **1**F-**1**F as shown in FIG. **27**C. FIG. **27**G shows the body **15** and internal locking system **101** loaded and compressed within a delivery sheath **1**. The device **10** may be delivered via a delivery catheter in the configuration shown in FIG. **27**G. The body **15** of the device **10** may then expand with the internal locking system **101** still constrained, as shown in FIG. **27**D. The internal locking system **101** may then deploy into the deployed configuration as shown in FIG. **27**A.

FIG. **27**G shows the body **15** and internal locking system **101** loaded and compressed within an embodiment of a delivery sheath **1**. In some embodiments, the delivery sheath **1** may be an outer delivery catheter. The body **15** and internal locking system **101** are loaded and compressed within a delivery catheter **5**. The device **10** may be entirely or partially inside the delivery catheter **5**. In some embodiments, the delivery catheter **5** may be an inner delivery catheter. The device **10** may be loaded and compressed with the delivery catheter **5** inside of the delivery sheath **1**. Removing the delivery sheath **1**, for example by retracting the delivery sheath **1** in the proximal direction, may allow the body **15** of the device **10** to expand. The body **15** expands while the internal locking system **101** is still constrained, for example by the delivery catheter **5**. FIG. **27**D shows the body **15** in its deployed state, with the internal locking system **101** in a constrained configuration within the delivery catheter **5**. This demonstrates the first step in the deployment process, specifically placement of the device **10** within the LAA where the body **15** is expanded and the internal locking system **101** is constrained and thus the anchors are not deployed. The second step of the deployment process is shown in FIG. **27**A where the internal locking system **101** has been deployed through the body **15**. In some embodiments, this second step is reversible to retract the anchors, for example if placement of the device **10** within the LAA is unacceptable. The internal locking system **101**, for example an anchoring component or system as further described herein, is deployed from within the body **15** to deploy at least one and in some implementations at least 2 or 4 or 6 or more anchors of the internal locking system **101** outside the body **15** to engage adjacent anatomy of the LAA.

The internal locking system **101** may be controllably deployed a period of time after the body **15** expands. For instance, the location, orientation, etc. of the device **10** may be verified with various imaging techniques such as by fluoroscopy with injection of contrast media via the central lumen before the internal locking system **101** is deployed and the anchors secure the device **10** within the LAA. In some embodiments, even after deployment of the internal locking system **101** and anchors thereof, the anchors may be retracted to a position within the body **15** for repositioning, and/or retrieval of the device **10** from, within the LAA.

FIG. **27**F shows an embodiment of the device having slots **17**. The slots **17** are formed within the foam body **15**. For instance, material of the foam body **15** may be removed to facilitate deployment of the internal locking system **101**, such as outward expansion of anchors to engage the tissue.

The device **10** may have any or all of the same or similar features and/or functionalities as the other plugs described herein, for example the plug **204**, etc. For example, the device **10** is at least partially encapsulated within the skin **20**. In some embodiments, the skin **20** may cover the proximal end of the body **15**. The skin **20** may be a thin, strong outer layer. The skin **20** may be a thin, encapsulating layer. The skin **20** may be fabricated from ePTFE (expanded polytetrafluoroethylene), polyolefin, polyester, other suitable materials, or combinations thereof. In some embodiments, the skin **20** may be fabricated from bioabsorbable materials, for example polylactic acid (PLA), Polyglycolic acid (PGA), ploycaprolactone (PCL), PHA, collagen, other suitable bioabsorbable materials, or combinations thereof. The skin **20** can be oriented or otherwise modified to be elastomeric in at least one direction, such as radially.

The body **15** may be made of polyurethane, polyolefin, PVA, collagen foams or blends thereof. One suitable material is a polycarbonate-polyurethane urea foam with a pore size of 100-250 um and 90-95% void content. The body **15** may be non-degradable or use a degradable material such as PLA, PGA, PCL, PHA, and/or collagen. If degradable, the tissue from the LAA will grow into the foam body **15** and replace the foam over time. The body **15** may be cylindrical in shape in an unconstrained expansion but may also be conical with its distal end smaller than the proximal end, or vice versa. The body **15** may also be oval in cross section to better match the opening of the LAA.

The device **10** is oversized radially in an unconstrained expansion to fit snuggly into the LAA. The device **10** may be 5-50 millimeters (mm) and generally at least about 10 mm or 15 mm in diameter in its unconstrained configuration, for example depending on the diameter of the target LAA. The length "L" of the device **10** may be less than, similar to or greater than its diameter "D" such that the L/D ratio is less than 1.0, about or greater than about 1.0, greater than about 1.5, or greater than about 2.0. The L/D ratio may be greater than 1.0 to maximize its stability. However, in some embodiments, the L/D ratio may be less than 1.0, for example, from about 0.2 to about 0.9, or from about 0.3 to about 0.8, or from about 0.4 to about 0.6. The compliance of the material of the device **10** is designed such that it pushes on the walls of the LAA with sufficient force to maintain the plug in place but without overly stretching the LAA wall. The foam body **15** and/or skin **20** also conforms to the irregular surfaces of the LAA as it expands, to provide a complementary surface structure to the native LAA wall to further enhance anchoring and promote sealing. Thus, the expandable foam body **15** conforms to the native irregular configuration of the LAA. In some embodiments, the structure of the foam body **15** may be fabricated such that axial compression on the opposing ends of the body **15** such as by proximal retraction of a pull wire or inner concentric tube causes the foam to increase in diameter.

The body **15** and/or skin **20**, for example the foam material and/or ePTFE, may be provided with one, two or more radiopaque markers, such as radiopaque threads **210** (see FIG. **2**) or filled with or impregnated with a radiopaque filler such as barium sulfate, bismuth subcarbonate, or tungsten, which permit the operator to visualize under x-ray the device **10** for proper positioning in the anatomy. Visualization of the device **10** may be used to verify the position of the device **10** before deployment of anchors to secure the device **10** in place.

The skin **20**, such as an outer ePTFE layer, may have a thickness between about 0.0001 inches and about 0.0030 inches. In some embodiments, the thickness of the skin **20** may be between about 0.0003 inches and about 0.0020 inches. In some embodiments, the thickness of the skin **20** may be between about 0.0005 inches and about 0.0015 inches. The thickness of the skin **20** may be uniform, for example the same or approximately the same no matter where the thickness is measured. In some embodiments, the thickness of the skin **20** may be non-uniform, for example the thickness may be different in different portions of the skin **20**.

The skin **20**, such as an outer ePTFE layer, may also serve as the blood contacting surface on the proximal end of the device **10** facing the left atrium. The skin **20** may have pores or nodes such that blood components coagulate on the surface and an intimal or neointimal covering of tissue grows across it and anchors tightly to the skin material. Pore sizes may be within the range of from about 4μ to about 110μ. In some embodiments, the pore sizes are within the range of from about 30μ to about 90μ. In some embodiments, the pore sizes are within the range of from about 30μ to about 60μ. Such ranges of pore sizes are useful for formation and adherence of a neointima. In some embodiments, the skin **20**, such as an outer ePTFE layer, may be formed from a tube with a diameter about the same diameter of the foam body **15**. and allows one to collapse and pull on the body **15** without tearing the foam material.

The skin **20** may be constructed of materials other than ePTFE such as woven fabrics, meshes or perforated films made of FEP, polypropylene, polyethylene, polyester or nylon. The skin **20** may have a low compliance (e.g. non-elastic), for instance a low compliance longitudinally, may be sufficiently strong as to permit removal of the plug, may have a low coefficient of friction, and/or may be thromboresistant. The skin **20** serves as a matrix to permit plug removal as most foams are not sufficiently strong to resist tearing when pulled. The body **15** can also be coated with or contain materials to enhance its ultrasonic echogenic profile, thromboresistance, lubricity, and/or to facilitate echocardiographic visualization, promote cellular ingrowth and coverage.

The skin **20** may include holes to permit contact of the LAA tissue with the foam body **15**. Exposure of the foam body **15** to the LAA or other tissue has benefits for example encouraging ingrowth of tissue into the foam plug pores and/or increasing friction to hold the body **15** in place. These holes may be 1 to 5 mm in diameter or may also be oval with their long axis aligned with the axis of the foam plug, the length of which may be 80% of the length of the foam plug and the width may be 1-5 mm. The holes may be as large as possible such that the outer covering maintains sufficient strength to transmit the tensile forces required for removal. The holes may be preferentially placed along the device **10**. In some embodiments, the holes are placed distally to enhance tissue ingrowth from the distal LAA wall.

In some embodiments, the device **10** includes an occlusion region and anchoring region. The proximal portion of the device **10** facing the left atrium after the device is implanted in the LAA may include the occlusion region. The occlusion region may be a blood contacting surface on the proximal end of the device **10** that is thromboresistant while promoting formation of a neointima at the occlusion region. The occlusion zone encourages thromboresistance and endothelialization from the blood and adjacent tissue. The anchoring zone promotes fast and tenacious tissue ingrowth into the device **10** from the adjacent non-blood tissue. The anchoring zone may be lateral surfaces of the device **10** that interface with tissue adjacent and/or within the LAA. The anchoring zone can also include the distal end of the device **10** that faces the distal wall of the LAA after implantation.

FIGS. **28**A-**28**D are various views of an embodiment of an internal locking system **101** that may be used with the device **10**. In some embodiments, multiple internal locking systems **101** may be used with the device **10**. FIG. **28**A is a side view of the internal locking system shown in a deployed configuration. FIG. **28**B is an end view of a distal end of the internal locking system **101** in a deployed configuration. FIG. **28**C is a side view of the internal locking system

201101 in a constrained configuration. FIG. **28**D is a side view of an embodiment of an anchor **120** of the internal locking system **101**.

Any of a variety of structures may be utilized as the dynamic internal locking system **101** with the device **10**. In general, at least about two or four or six or more tissue anchors **120** may be actively or passively advanced from the implantable device **10** into adjacent tissue surrounding the implantation site. Following deployment of the device **10** and expansion of the body **15**, a tissue engaging segment **121** of the tissue anchor **120** will extend beyond the skin by at least about one, and in some implementations at least about two or four 4 mm or more. The tissue engaging segment **121** is carried by a support segment **122** of the tissue anchor **120** which extends through the foam body **15**, and may be attached to a deployment control such as a pull wire, push wire, tubular support or other control structure depending upon the desired configuration.

The locking system **101** discussed primarily herein is a passive deployment construction. Removal of a constraint allows the tissue anchors **120** to laterally self expand to deploy into adjacent tissue. Self expansion may be accomplished by constructing the tissue anchor **120** using nitinol, Elgiloy, stainless steel or other shape memory or spring bias materials. The constraint may be removed by proximal retraction or distal advance until the tissue anchors **120** are no longer engaged by the constraint, depending upon the construction of the locking system **101**.

Alternatively, tissue anchors **120** may be deployed actively such as by distal advance, proximal retraction or rotation of a control, or inflation of a balloon positioned within the device **10** to actively drive the anchors **120** through the skin **20** or corresponding apertures on the skin **20** and into tissue. For example, a plurality of support segment **122**, such as struts, may be joined at a distal end to a central hub **111**, and incline radially outwardly in the proximal direction. Proximal retraction of the hub **111** will cause the tissue engaging segment **121** to advance along its axis beyond the skin **20** and into the adjacent tissue. The inclination angle of the support segment **122**, for example the struts, may be reversed, in another construction, such that distal advance of the hub **111** will deploy the tissue engaging segments **121** beyond the skin **20**. Proximal or distal advance of the hub **111** may be accomplished by proximal or distal advance of a control such as a control wire or inner tube releasably engaged with the hub **111**.

Depending upon the desired clinical performance, the tissue anchors **120** may be retractable, such as by axial distal or proximal movement of the control depending upon the inclination angle of the anchors **120**. In the embodiment primarily illustrated herein, re-sheathing the anchors **120** may be accomplished by advancing the tubular constraint along the ramped surface of the tissue anchor **120** to move the anchor **120** radially inwardly towards the central longitudinal axis of the device **10**. In the case of an anchor **120** which deploys by advance along its own longitudinal axis, the anchor **120** may be retracted by advancing the control in the opposite direction from the direction advanced to deploy the anchors **120**.

Referring to FIGS. **28**A-**28**D, the internal locking system **101** includes a central tubular element or hub **111** and anchors **120**. The anchors **120** may be arms, segments, or other members extending from the hub **111**. Each anchor **120** may comprise a tissue engaging segment **121** and a support segment **122** which extends to the hub **111** or other control. The internal locking system **101** has a single central tubular hub **111** and a multitude of the anchors **120**. As shown, there are four anchors **120**. There may be two, three, four, five, six, seven, eight, or more anchors **120**. The anchor **120** may be rotatably, hingedly, or otherwise moveably coupled with the hub **111**. The anchor **120** may thus move relative to the hub **111**, for example after being released from a restraint holding the anchor **120** in a constrained configuration to deploy into a deployed configuration. As further example, the anchor **120** may move from the deployed configuration to a retracted position, as further described herein. The anchor **120** may be curvilinear as shown, for example to allow the anchor **120** to take the geometry shown in FIG. **28**A when unconstrained.

The illustrated anchor **120** may have a distal region **130**, a hinge region **135**, and/or a proximal region **125**. The distal region **130** interacts with the hub element **111**. The hinge region **135** and the curvilinear geometry as shown allow the end of the proximal region **125** to extend beyond the body **15**, for example beyond a sidewall of the body **15**. The proximal region **125** includes a tissue engaging segment **121** configured to engage adjacent tissue. The tissue engaging segment **121** may be the entire proximal region **125** or a portion thereof, for example the tip, etc. The proximal region **125** may thus include a sharpened tissue engaging segment **121**, a shaped tissue engaging segment **121**, an angled tissue engaging segment **121**, a thickness configured for tissue engagement, and/or other suitable features. In some embodiments, the proximal region **125** may retract back within the body **15**, as further described herein. In the embodiment shown, the anchor **120** and central tube **111** are distinct elements which are affixed to one another as shown. In other embodiments, the anchor **120** and tube **111** are a single, integral unit.

The internal locking system **101** is made from biocompatible metallic wire such as Nitinol, implant grade stainless steel such as 304 or 316, or cobalt-chromium based alloys such as MP35N or Elgiloy. In some embodiments, the internal locking system **101** may be cut from a single tubular piece of metal fabricated via machining or laser cutting followed by a secondary forming or annealing step using similar materials.

The internal locking system **101** may be in a constrained configuration as the device **10** is placed in position in the LAA and the body **15** expands therein. Then, in a secondary step, the internal locking system **101** locks or otherwise secures the device **10** in the LAA by engaging the anchors **120**. If the position is not considered optimal, or if the device **10** otherwise needs to be repositioned within and/or removed from the LAA, the internal locking system **101** and anchors **120** thereof can be unlocked and the device **10** repositioned and/or removed.

FIGS. **29**A-**29**B are sequential side views of an axially movable loop type unlocking mechanism that may be used with the device **10** to release the tissue anchors. FIG. **29**A is a side cross-section view of the device **10** showing the tissue anchors of internal locking system **101** in a deployed configuration. FIG. **29**B is a side cross-section view of the device **10** showing the tissue anchors in a retracted configuration. An embodiment of an unlocking system **140** is shown. The unlocking system **140** includes a ring **145**. The ring **145** may be moved over the anchors **120** to move the anchors **120** to retracted configurations. The ring **145** may be moved by a pull rod **147**. The ring **145** may be releasably attached to the pull rod **147**. The pull rod **147** may extend through a catheter to engage the ring **145**. The unlocking system **140** may be utilized if, after the internal locking system **101** is deployed, it is desirable to unlock the device **10** from within the LAA in order to reposition and/or remove the device **10**.

In the illustrated construction, deployment of the tissue anchors by distal advance of the restraint enables reversible deployment, so that subsequent proximal retraction of the restraint will retract the tissue anchors. Alternatively, proximal retraction of the restraint to release the tissue anchors will irreversibly release the tissue anchors.

FIG. **30** is a side view of an embodiment of the device **10** having flexible anchors **401**. The device **10** shown in FIG. **30** may have the same or similar features and/or functionalities as the other devices for excluding the LAA described herein, and vice versa. The device **10** may be in the configuration shown in FIG. **30** adjacent to or within a left atrium (LA) **201**. The device **10** in FIG. **30** includes the expandable body **15**, such as an open cell foam body, which enables collapse and expansion of the device **10**, and at least partially encased within the skin **20**, which may be a thin, strong layer fabricated from ePTFE (expanded polytetrafluoroethylene), polyolefin, or polyester which assists with healing, anchoring, and retrieval. The device **10** may also be deployed, and, if desired, repositioned and/or retrieved, or the device **10** may be permanently fixated within the LAA by engaging an anchoring system, such as the internal locking system **101**, as described herein. The anchors **401**, which may be metallic, may be fabricated from Nitinol. The anchors **401** may be small diameter Nitinol wire approximately 0.001 inches to approximately 0.010 inches in diameter. In some embodiments, the anchors **401** may be approximately 0.0005 inches to approximately 0.020 inches in diameter. The anchors **401** may be deployed upon expansion of the body **15**. For example, the anchors **401** may self-deploy upon deployment of the device **10** from a delivery catheter. The anchors **401** may be relatively short and extremely flexible. The anchors **401** may be unable to penetrate the tissue or cause any anchoring immediately after deployment of the device **10**.

FIG. **31** is a side view of an embodiment of a device **10** for occlusion of the LAA having anchors **401** with tubes **500**. The device **10** may be positioned adjacent to or within the left atrium (LA) **201**. The anchors **401** may be flexible anchors, or in some embodiments the anchors **410** may be relatively stiffer, as further described. The tubes **500** may be stationary or moveable tubes, as further described. In some embodiments the tubes **500** are hypotubes. The tubes **500** may be stainless steel, polyamide, or other suitable materials. The tubes **500** may surround a corresponding anchor **401**, as further described.

In some embodiments, the anchors **401** may be fixed such that they do not move axially. For example, the anchors **401** may have a portion, such as a tissue engaging segment **121**, of a fixed length extending outside the body **15**. The portion of the anchors **401** extending outside the body **15** may be bent when compressed within a delivery catheter and/or sheath, and these portions of the anchors **401** may then straighten out to the configuration shown in FIGS. **31** and **32** after deployment of the body **15**. The fixed length portion of the anchors **401** extending beyond the body **15** may be from about 1 mm to about 5 mm, or from about 1.5 mm to about 4 mm, or from about 2 mm to about 3 mm. This length of exposed anchor **401** outside the body **15** may be effectively shortened by deployment of a corresponding tube **500**, as further described. Deployment of the corresponding tube **500** about the corresponding anchor **400** may shorten the effective length of exposed anchor **401**, i.e. the length of the anchor **401** extending beyond the end of the tube **500** after deployment of the tube **500**, from about 0.5 mm to about 1 mm. These are merely examples of different lengths of the anchor **401** and other suitable lengths may be implemented.

In some embodiments, the anchors **401** may be moveable axially. For example, the anchors **401** may not deploy or otherwise extend outside the body **15** immediately upon expansion of the body **15**. Following acceptable positioning of the device **10** within the LAA, the flexible anchors **401** may then be advanced through a corresponding tube **500**. The anchors **401** may move axially in any suitable manner, including those described elsewhere herein. The anchor **401** may be moved through the tube **500** either before or after the tube **500** has been moved and deployed outside the body **15**, as described below.

In some embodiments, the tubes **500** are moveable and deploy outside the body **15**. The tubes **500** may be moveable in embodiments having either fixed or moveable anchors **401**. The tubes **500** may be pre-loaded over corresponding wire anchors **401** as shown in FIG. **31**, for example one tube **500** per anchor **401**. The tube **500** may then be moved over the corresponding anchor **401** as shown in FIG. **32**. The tube **500** may straighten the anchor **401** and add mechanical integrity. The tube **500** may also act as a perforation protector to prevent the anchor **401** from puncturing through the wall of the LAA. Movement of the tube **500** over the corresponding anchor **401** may shorten the exposed length of the anchor **401**, as described. This may provide for a stiffer tissue engaging segment of the anchor **401** due to the shortened exposed length.

In some embodiments, the tubes **500** extend from the delivery catheter to or near the outer surface of the body **15** but do not extend outside the body **15**. Instead, the tubes **500** just guide the anchor **401**, for example around the curve, and support the wire **401** right up to tissue penetration. The tubes **500** may set the launch angle so the anchor **401** does not buckle and hits the tissue at the right angle. In this embodiment, the anchor **401** may have relatively more stiffness than in the embodiments where the anchors **401** are relatively flexible, in order to provide a more secure anchoring of the device **10** to the tissue. It is understood the tube **500** may provide this guiding function to the corresponding anchor in any of the embodiments described herein having moveable anchors, such as the moveable anchors **401**, the anchors **120**, etc.

The flexible anchors **401** and/or the external stiffening tube **500** may be made from biocompatible metallic materials such as Nitinol, implant grade stainless steel such as 304V or 316LVM, cobalt-chromium based alloys such as MP35N or Elgiloy, other suitable materials, or combinations thereof. The anchor **401** length can vary from 0.1 mm to 5 mm in length with an external stiffening tube **500** that covers from 10% to 90% of the exposed length of the anchor **401**.

The skin **20** at least partially surrounds the body **15** and portions of the skin **20** may or may not be attached to the body **15**. The various devices **10** described herein may have the body **15** at least partially encased within the skin **20**, which may be fabricated from a material such as ePTFE (expanded polytetrafluoroethylene), polyolefin, or polyester which assists with healing, anchoring, and retrieval. FIG. **33** is a side view of an embodiment of a device **10** for occlusion of the LAA having discrete points of attachment **700** of the skin **20** to the internal foam body **15**. For clarity, the points of attachment **700** are shown as dots in the figures. It is understood the points of attachment **700** may not be visible from outside the device **10**, for example the skin **20** may be bonded to the body **15** at the points of attachment **700**, etc. In some embodiments, in addition or alternatively to bonding, the skin **20** may be secured for example with sutures to the body **15** at the points of attachment **700**, and thus some or all of the points of attachment **700** may be visible from outside the device **10**. The device **10** may be in the configuration shown in FIG. **33** adjacent to or within the left atrium (LA) **201**. The skin **20** may be attached to the body **15** at the various separate points of attachment **700**. As shown in FIG. **33**, the skin **20** can be partially attached, with portions thereof not attached at all, to the body **15**. This may allow, for example, the skin **20** to move during expansion of the body **15** that occurs after deployment of the device **10** from the delivery catheter. The skin **20** may, in some embodiments, be attached at points of attachment **700** located near the proximal side of the device **10**, for example to help promote closure of the ostium of the LAA, such as with a rim **800** as described below. The skin **20** may, for example, be tacked in place in one or more points of attachment **700** near the proximal face so that any bunching of the skin **20** that occurs during implantation occurs near the ostium but within the LAA. This can be achieved using sutures, adhesive bonding, heat bonding, other suitable approaches, or combinations thereof.

The selective location of the points of attachment **700** may facilitate with formation of a circumferential rim **800** of the skin **20**. The rim **800** is shown schematically in FIG. **34** as a triangular rim for clarity. It is understood the rim **800** may be a variety of different shapes depending on the configuration of the device **10**, the shape of the LAA, etc. Further, the rim **800** may extend completely or partially around the device **10**. The rim **800** may surround the ostium of the LAA. The formation of the rim **800** may help to completely seal the entrance to the LAA around the device **10** and thereby prevent leakage. The attachment points **700** between the skin **20** and the body **15** can prevent irregular bunching of the fabric and instead guide any excess material to form the sealing rim **800** around or near the proximal face of the device **10**, as shown in FIG. **34**. The rim **800** may form upon expansion of the body **15** after deployment from the delivery catheter, as described herein. Alternatively the attachment points **700** can be designed so as to prevent any bunching at all of the fabric and provide a smooth surface, such as a smooth proximal surface.

FIGS. **35-36** are side views of embodiments of the device **10** having anchors **120** with V-tips **901** shown in the deployed configuration. The V-tips may be located in the proximal region **125** and/or may form all or part of the tissue engaging segment **121** of the anchor **120**, as described herein. The V-tips **901** form a V-shaped point. The V-tips **901** are generally in the shape of a "V" or an otherwise angled, segmented shape. The V-tips **901** may be sharp barbs or hooks. The V-tips **901** may be formed from wire or laser-cut tubing or other suitable methods. As shown in FIG. **35**, one or more of the V-tips **901** are attached to the body **15** encased in the skin **20**. The V-tips **901** can be attached to the body **15** and/or to the skin **20**. In some embodiments, the V-tips **901** are ends of anchors **1000**. For example, the V-tips **901** may be part of the anchors **1000** that are within the body **15** and skin **20**, as shown in FIG. **36**. The distal ends of the V-tips **901** may be free to slide along and collapse or expand. The distal ends of the V-tips **901** may be attached to the body **15**, skin **20**, and/or the anchors **1000** to allow the V-tips **901** to collapse and retract. During retrieval into a catheter or sheath, the V-tips **901** can flatten out when engaging the inner diameter of the catheter or sheath. The V-tips **901** can be formed from Nitinol, implant grade stainless steel such as 304 or 316, cobalt-chromium based alloys such as MP35N or Elgiloy, other suitable materials, or combinations thereof. The V-tips **901** may then recover their pre-set shape after deployment or re-deployment.

FIGS. **37**A-**37**C are side views of various embodiments of V-tips that may be used with the anchors described herein. FIG. **37**A is a side view of an embodiment of the V-tip **901**. The V-tip **901** includes two angled segments. The segments may form the angle in a free state. The angle may be various angular amounts. In some embodiments, the angle formed by the V-tip **901** is no more than about 170°, 160°, 150°, 140°, 130°, 120°, 110°, 100°, 90°, 80°, 70°, 60°, or any smaller, greater or intermediate angular amount. FIG. **37**B is a side view of an embodiment of a wave V-tip **1101**. The wave V-tip **1101** may include a curved segment and an angled straight segment. FIG. **37**C is a side view of an embodiment of a two-wave V-tip **1103**. The two-wave V-tip **1103** may include two curved segments. The curved segments may promote engagement of the tip with the inner wall of the LAA. The end of the various V-tips may be smooth and rounded or sharp to promote tissue penetration. In some embodiments, all of the V-tips may have the same shape. In some embodiments, some of the V-tips may have a first shape and other V-tips may have a second shape different from the first shape. In some embodiments, some of the V-tips may be attached to the skin **20** and or body **15**. In some embodiments, some of the V-tips may be attached to the anchors **1000**.

FIG. **38** is a side view of an embodiment of a device **10** for occlusion of the LAA implanted inside an LAA **1201**. The device **10** includes a body **15** with a skin **20** and finial **30** placed within the LAA **1201**. The LAA includes a thicker proximal portion **1203** closer to the ostium. The internal locking system **101**, for example anchors thereof, may be configured to engage with the thicker proximal portion **1203** of the LAA. The various anchors, V-tips etc. described herein for the various embodiments of the device **10** may be used to secure the anchors in the thicker proximal portion **1203**. In some embodiments, the device **10** may be deployed from the catheter such that the body **15** expands. The location, orientation, etc. of the expanded body **15** within the LAA may be verified, for example by imaging, as described herein. The location, orientation, etc. of the expanded body **15** within the LAA may be verified to ensure engagement of the internal locking system **101**, for example anchors thereof, with the thicker proximal portion **1203**. Then, the internal locking system **101**, for example anchors thereof, may be deployed to engage the thicker proximal portion **1203**. If after deployment of the internal locking system **101**, for example anchors thereof, it is determined that the anchors did not engage with the thicker proximal portion **1203**, the anchors may be retracted, as described herein, in order to reposition and/or retrieve the device **10**.

In some embodiments, the internal locking system **101**, for example anchors thereof, may be preloaded surface elements releasably constrained or otherwise locked down in a collapsed or constrained position or configuration. The internal locking system **101**, for example anchors thereof, may be constrained using a restraint. The restraint may be a dissolvable polymer, a lasso, or wires that can be retracted to release the anchors. The restraint may be similar to a deadbolt. Other anchoring concepts include Velcro integral to the ePTFE, electrically orientable/ratcheting anchoring elements, unidirectional Gecko tape, or wires pre-attached to the finial **30**. In some embodiments, the body **15** with skin **20** may be secured within the LAA by texturing the body **15** and exposing the body **15** to the tissue through holes in the skin **20** to increase the friction with the cardiac surface to a high enough level to prevent implant migration.

FIGS. **39**A-**39**B are perspective views of an embodiment of a deployable anchor **1302** activated by a pull wire **1301** and shown, respectively, in the constrained and deployed configuration, that may be used with the various devices **10** for occlusion of the LAA described herein. A two-stage anchoring system allows deployment of the anchors **1302** after implantation and expansion of the body **15**. This embodiment incorporates one or more hinged anchors **1302**. The anchors **1302**, which be a barb or other anchoring element, may lie flat during delivery and during deployment of the body **15**. Next, when pulled or pushed, the anchors **1302** bend at a hinge **1306** and extend outward from the surface of the body **15** and into the LAA tissue. The anchors **1302** may bend at the hinge **1306** using a hollow constraining element **1304** which can be a thin, metallic, round or rectangular box such as a round or rectangular shaped tube, and the pull wire **1301**, for example a sliding element, which can be a wire or suture. The pull wire **1301** is attached to the proximal end of the anchor **1302** and extends back through the delivery catheter or sheath. When the pull wire **1301** is retracted, the anchor **1302** slides back though a slot **1308** in the tube **1304** and bends at the preformed hinge **1306**. A portion of the anchor **1302** then extends out through the slot **1308**.

FIGS. **40**A-**40**B are perspective views of an embodiment of a deployable anchor **1405** activated by a lock wire **1401** and shown, respectively, in the constrained and deployed configuration, that may be used with the various devices **10** for occlusion of the LAA described herein. The anchor **1405**, which be a barb or other anchoring element, may be formed from wire or a flat sheet of Nitinol or other shape memory material and heat set to be in an expanded configuration. One or more of the anchors **1405** can be placed along the skin **20** or otherwise along an external surface of the body **15**. One or more corresponding guides **1402**, such as loops, may be located along the skin **20** or the body **15**. The guides **1402** may be located on both sides of the anchor **1405**, as shown. The guides **1402** on a first side of the anchor **1405** may fix the anchors **1405** in place. The guides **1402** on a second, opposite side of the anchor **1405** may act as a guide for the lock wire **1401**, which may be a restraining wire, suture, etc. The lock wire **1401** may be used to constrain the anchors **1405** in a constrained configuration, for example in the flat position as shown in FIG. **40**A. When the lock wire **1401** is retracted, the anchors **1405** deploy, as shown in FIG. **40**B. The anchors **1405** may extend perpendicular to the body **15**, or at an angle.

FIGS. **41**A-**41**B are perspective views of an embodiment of a deployable anchor **1506** activated by a sheath **1502** and shown, respectively, in the constrained and deployed configuration, that may be used with the various devices for occlusion of the LAA described herein. The anchor **1506**, which be a barb or other anchoring element, may be formed from wire or a flat sheet of Nitinol or other shape memory material and heat set to be in an expanded configuration.

One or more of the anchors **1506** may be placed along the skin **20** or otherwise along an external surface of the body **15**. One or more corresponding guides **1500** and locking loops **1504** may be located along the skin **20** or the body **15**. The guides **1500** may be located on a first side of the anchor **1506** and the locking loops **1504** may be located on a second, opposite side of the anchor **1506**, as shown. The anchors **1506** are held in the constrained or restrained configuration or position by a sheath cover **1502**. The sheath cover **1502** may be tubular or rectangular in shape. The sheath cover **1502** constrains the anchors **1506**. The sheath cover **1502** may constrain the anchors **1506** in a flat position as shown in FIG. **41**A. When the sheath cover **1502** is retracted, the anchors **1506** deploy, as shown in FIG. **41**B. The anchors **1506** may extend at an angle to the body **15**, or perpendicularly.

FIGS. **42**A-**42**D are various views of embodiments of devices **10** for occlusion of the LAA having external deployable anchors **1601**, **1604** which can be collapsed and expanded by retraction into or out of a sheath or outer catheter. FIG. **42**A is a side view of the device **10** having anchors **1601** constrained by a delivery sheath **1603**. FIG. **42**B is a side view of the device **10** unconstrained by the delivery sheath **1603** with the anchors **1601** deployed. FIG. **42**C is a side view of the device **10** having anchors **1604** constrained by the delivery sheath **1603**. FIG. **42**D is a side view of the device **10** unconstrained by the delivery sheath **1603** with the anchors **1604** deployed. The body **15** with skin **20** can contain the anchors **1601** or **1604** which are fixed to the surface of the skin **20** and are unconstrained and therefore expanded in a free state, as shown in FIGS. **42**B and **42**D. The delivery sheath **1603**, such as a catheter, may be used to constrain the anchors **1601** or **1604**. The anchors **1601** or **1604** may then expand when the body **15** is unconstrained by the delivery sheath **1603**, for example when the when the body **15** is released from the delivery sheath **1603**. The anchors **1601** may deploy into a curved shape as shown in FIG. **42**B. The anchors **1604** may deploy into an angled shape as shown in FIG. **42**D. The anchors **1603** or **1604** after deployment may point toward either the proximal or distal side of the body **15**.

FIGS. **43**A-**43**C are sequential side views of an embodiment of a device **10** for occlusion of the LAA shown, respectively, constrained by a lasso **1707**, deployed, and adjusted with a mount **1705**. One or more anchors **1709** may be pre-mounted within the body **15** and attached distally to the mount **1705**. The mount **1705** may be a ring-like member having an opening extending therethrough. The mount **1705** is positioned over a **1701**rod **1711**. The mount **1705** can move, for example slide, over the **1701**rod **1711** in the proximal direction. In some embodiments, the mount **1705** may be pulled proximally, for example by a pull wire. In some embodiments, the mount **1705** may move when the **1701**rod **1711** is rotated. In some embodiments, the mount **1705** and/or **1701**rod **1711** may be threaded. Movement of the mount **1705** causes the anchor **1705** to move. The device may include a tapered cone **1708**. The cone **1708** may be attached to the end of the rod **1711**. The mount **1705** may be moved toward the cone **1708** to adjust the height of the anchors **1709**. Thus, the anchors **1709** are angled more in FIG. **17**C relative to FIG. **17**B. The anchor **1709** may move through the body **15** and into the tissue. The anchors **1709** may be adjusted to increase or decrease the amount of tissue penetration, for example by moving the mount **1705** as described. For retrieval, this process can be reversed. In some embodiments, the lasso **1707**, attached to a wire **1703**, may extend, for example thread, through the threaded **1701**rod **1711** and be placed around the anchors **1709** to retract the anchors **1709** back into the body **15**. In some embodiments, the lasso **1707** may be used to initially constrain the anchors **1709** and then retract to allow the anchors **1709** to deploy.

FIGS. **44**A-**44**C are side views of an embodiment of a device **10** for occlusion of the LAA having an adjustable two stage anchor system with anchors **1801** activated by moving a mount **1803** along a rod **1804**. The anchors **1801** may be internal grappling hook type structures placed within the body **15** and skin **20**. The anchors **1801** may be introduced through a central lumen **1003** that extends through the body

15, as shown in FIG. **43**A. The anchors **1801** may then travel through the body **15** and skin **20** to engage tissue, as shown in FIG. **43**B. The anchors **1801** may be adjusted to increase or decrease the amount of tissue penetration. The anchors **1801** are attached at distal ends to the moveable mount **1803**. The mount **1803** is prevented from rotating, for example the mount **1803** may be notched to prevent rotation of the mount **1803** within the finial **30**, as shown in FIG. **43**C. The mount **1803** is threaded onto the threaded rod **1804** that can be rotated clockwise or counter clockwise to change the linear position of the mount **1803**. The distal end of the rod **1804** may couple with a cap **1807**. The cap **1807** may rotate with the rotation of the rod **1804**. The mount **1803** may move proximally causing the anchors **1801** to extend past the surface of the body **15** and skin **20** as shown in FIG. **43**B. The mount **1803** may move distally to pull the anchors **1801** back within or under the surface of the skin **20**. The depth of penetration of the anchors **1801** may be controlled, for example to account for the non-circular cross-section of the LAA. In some embodiments, the anchors **1801** may be deployed individually. Another option is to deploy the anchors **1801** distal to the body **15** with skin **20** and control the stiffness of the anchors **1801** such that they apply a reasonably uniform penetrating force to the tissue at contact.

Various modifications to the implementations described in this disclosure will be readily apparent to those skilled in the art, and the generic principles defined herein can be applied to other implementations without departing from the spirit or scope of this disclosure. Thus, the disclosure is not intended to be limited to the implementations shown herein, but is to be accorded the widest scope consistent with the claims, the principles and the novel features disclosed herein. The word "example" is used exclusively herein to mean "serving as an example, instance, or illustration." Any implementation described herein as "example" is not necessarily to be construed as preferred or advantageous over other implementations, unless otherwise stated.

Certain features that are described in this specification in the context of separate implementations also can be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation also can be implemented in multiple implementations separately or in any suitable sub-combination. Moreover, although features can be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination can be directed to a sub-combination or variation of a sub-combination.

Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. Additionally, other implementations are within the scope of the following claims. In some cases, the actions recited in the claims can be performed in a different order and still achieve desirable results.

It will be understood by those within the art that, in general, terms used herein are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.). It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases "at least one" and "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to embodiments containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an" (e.g., "a" and/or "an" should typically be interpreted to mean "at least one" or "one or more"); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should typically be interpreted to mean at least the recited number (e.g., the bare recitation of "two recitations," without other modifiers, typically means at least two recitations, or two or more recitations). Furthermore, in those instances where a convention analogous to "at least one of A, B, and C, etc." is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., "a system having at least one of A, B, and C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). In those instances where a convention analogous to "at least one of A, B, or C, etc." is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., "a system having at least one of A, B, or C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or "B" or "A and B."

What is claimed is:

1. A left atrial appendage occlusion device, comprising:

an expandable foam body having a proximal face and a sidewall extending distally from the proximal face, wherein the foam body can be compressed for delivery within a delivery catheter and can self-expand when removed from the delivery catheter; and

a central hub within the foam body and at least one deployable tissue anchor coupled with the hub, the at least one deployable tissue anchor comprising a tissue engaging segment terminating in a tissue engaging tip, the at least one deployable tissue anchor configured to deploy from a constrained configuration within the foam body to a deployed configuration in which the at least one deployable tissue anchor extends outside the foam body to position the tissue engaging tip of the at least one deployable tissue anchor outside the foam body to secure the device within the left atria appendage, wherein the at least one deployable tissue anchor penetrates the foam body in the deployed configuration.

2. The left atrial appendage occlusion device of claim **1**, wherein the at least one deployable tissue anchor is coupled to the hub via a support segment.

3. The left atrial appendage occlusion device of claim **1**, wherein the at least one deployable tissue anchor is configured to extend perpendicularly relative to the foam body in the deployed configuration.

4. The left atrial appendage occlusion device of claim **1**, wherein the at least one deployable tissue anchor includes a curved segment.

5. The left atrial appendage occlusion device of claim **4**, wherein the tissue engaging segment is in the shape of a hook.

6. The left atrial appendage occlusion device of claim **1**, wherein the tissue engaging segment comprises an angled tissue engaging segment.

7. The left atrial appendage occlusion device of claim **6**, wherein the tissue engaging tip is configured to point proximally in the deployed configuration.

8. The left atrial appendage occlusion device of claim **1**, wherein the at least one deployable tissue anchor is configured to advance along a longitudinal axis of the at least one deployable tissue anchor from the constrained position to the deployed position.

9. The left atrial appendage occlusion device of claim **1**, wherein the at least one deployable tissue anchor comprises a plurality of deployable tissue anchors coupled by a respective plurality of support segments with the hub.

10. The left atrial appendage occlusion device of claim **9**, wherein the respective plurality of the support segments comprises a plurality of struts.

11. The left atrial appendage occlusion device of claim **1**, wherein the tissue engaging segment in the deployed configuration extends beyond the foam body by at least about 1 mm.

12. The left atrial appendage occlusion device of claim **1**, wherein the foam body comprises an open cell foam body having a pore size of 100-250 um and a 90-95% void content.

13. The left atrial appendage occlusion device of claim **1**, wherein the proximal face comprises an occlusion region comprising a blood contacting surface that is thromboresistant.

14. The left atrial appendage occlusion device of claim **1**, wherein the tissue engaging segment extends along an axis and the tissue engaging tip is configured to advance along the axis from the constrained position to the deployed position.

15. The left atrial appendage occlusion device of claim **1**, wherein the at least one deployable tissue anchor is rotatably coupled with the hub.

16. The left atrial appendage occlusion device of claim **1**, wherein the foam body comprises a skin.

17. The left atrial appendage occlusion device of claim **16**, wherein the skin comprises expanded polytetrafluoroethylene (ePTFE).

18. The left atrial appendage occlusion device of claim **16**, wherein the skin comprises a plurality of holes.

19. The left atrial appendage occlusion device of claim **1**, wherein the at least one deployable tissue anchor extends through slots in the foam body in the deployed configuration.

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