US 20030220667A1

(19) **United States**
(12) **Patent Application Publication**
(10) **Pub. No.: US 2003/0220667 A1**
van der Burg et al.
(43) **Pub. Date: Nov. 27, 2003**

(54) **METHOD OF CONTAINING EMBOLIC MATERIAL IN THE LEFT ATRIAL APPENDAGE**

(76) Inventors: **Erik J. van der Burg**, Sunnyvale, CA (US); **Dino De Cicco**, San Jose, CA (US); **Andrew G. C. Frazier**, Sunnyvale, CA (US); **Alexander K. Khairkhahan**, Palo Alto, CA (US); **Marc S. Kreidler**, Sunnyvale, CA (US); **Michael D. Lesh**, Mill Valley, CA (US); **Chad C. Roue**, Fremont, CA (US)

Correspondence Address:
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614 (US)

(21) Appl. No.: **10/364,910**

(22) Filed: **Feb. 11, 2003**

Related U.S. Application Data

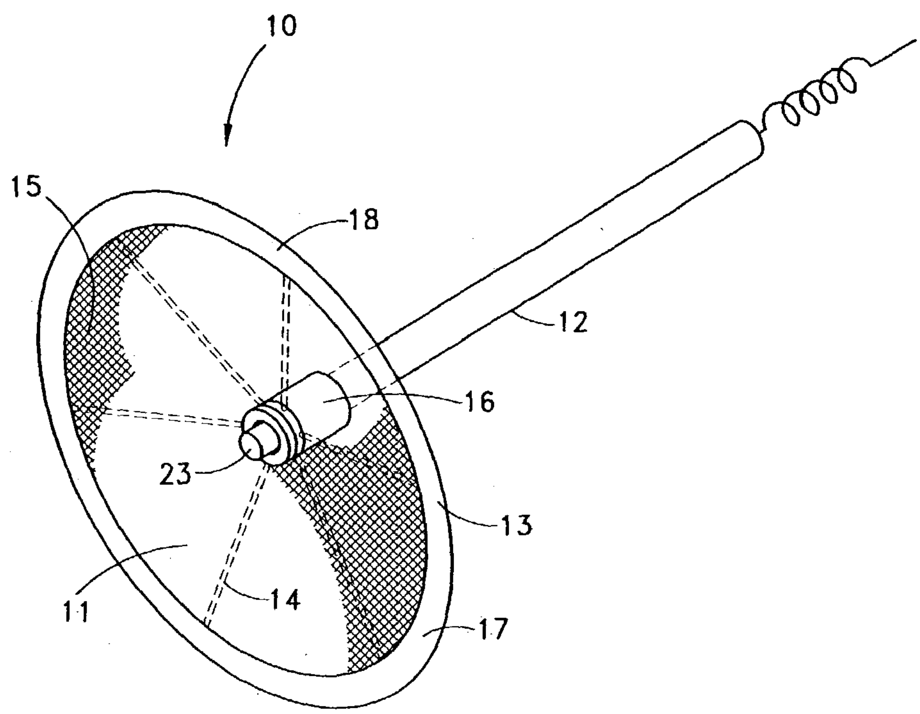
(63) Continuation of application No. 09/435,562, filed on Nov. 8, 1999, which is a continuation-in-part of application No. 09/187,200, filed on Nov. 6, 1998, now Pat. No. 6,152,144.

Publication Classification

(51) **Int. Cl.**^{7} **A61M 29/00**
(52) **U.S. Cl.** **606/200**

(57) **ABSTRACT**

Disclosed are methods and devices for containing embolic material within a left atrial appendage of a patient. The device is deployed such that a barrier substantially obstructs the passage of embolic material from the left atrial appendage. The barrier may be self expandable, and may include a polymeric or wire mesh. The device may additionally include a plurality of tissue engagement members, for engaging tissue.



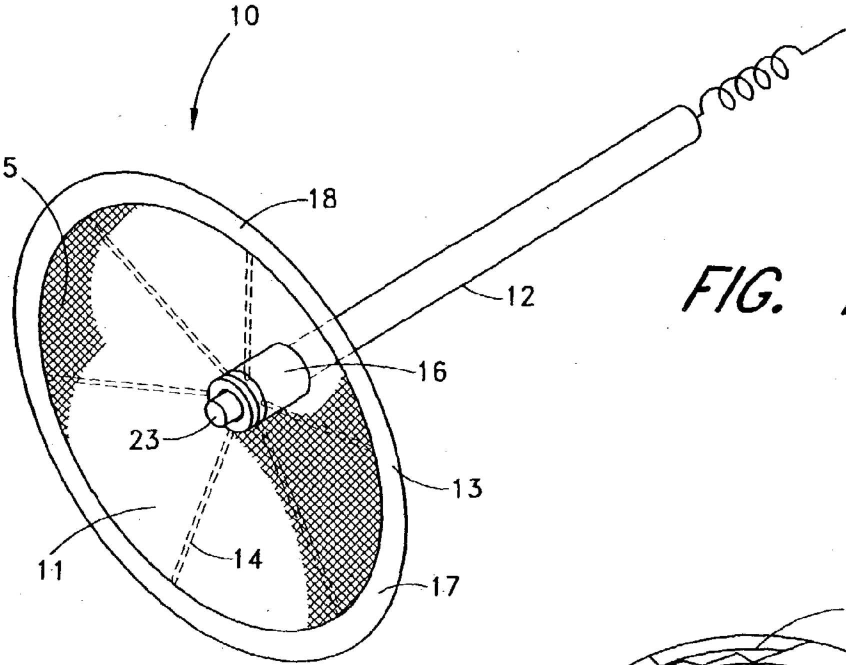


FIG. 1

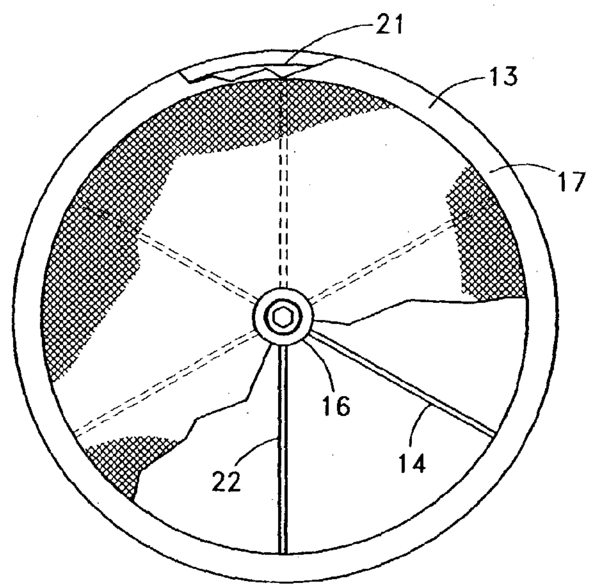


FIG. 2

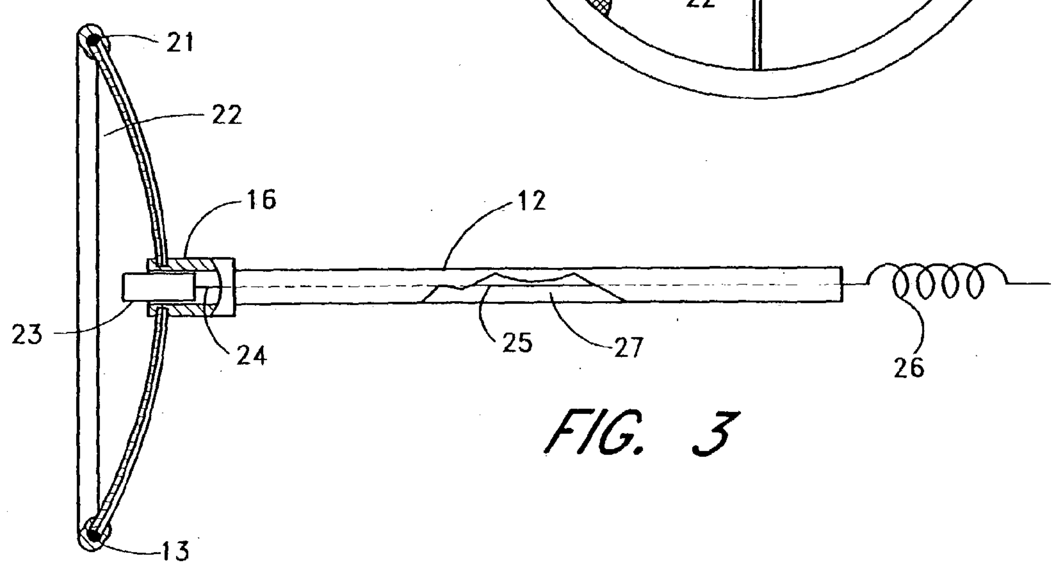


FIG. 3

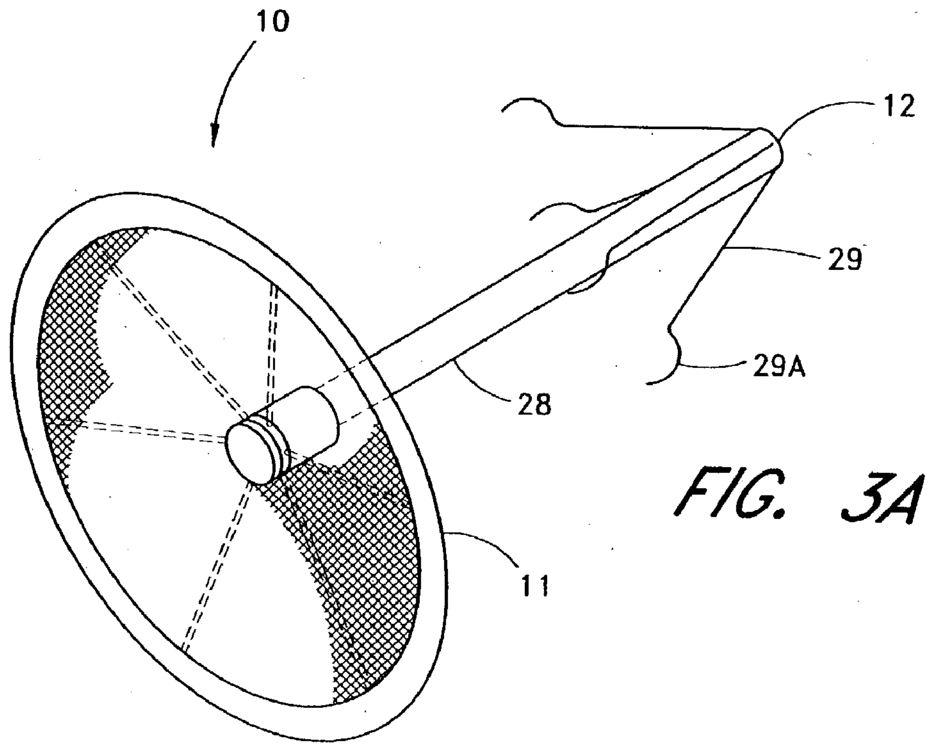


FIG. 3A

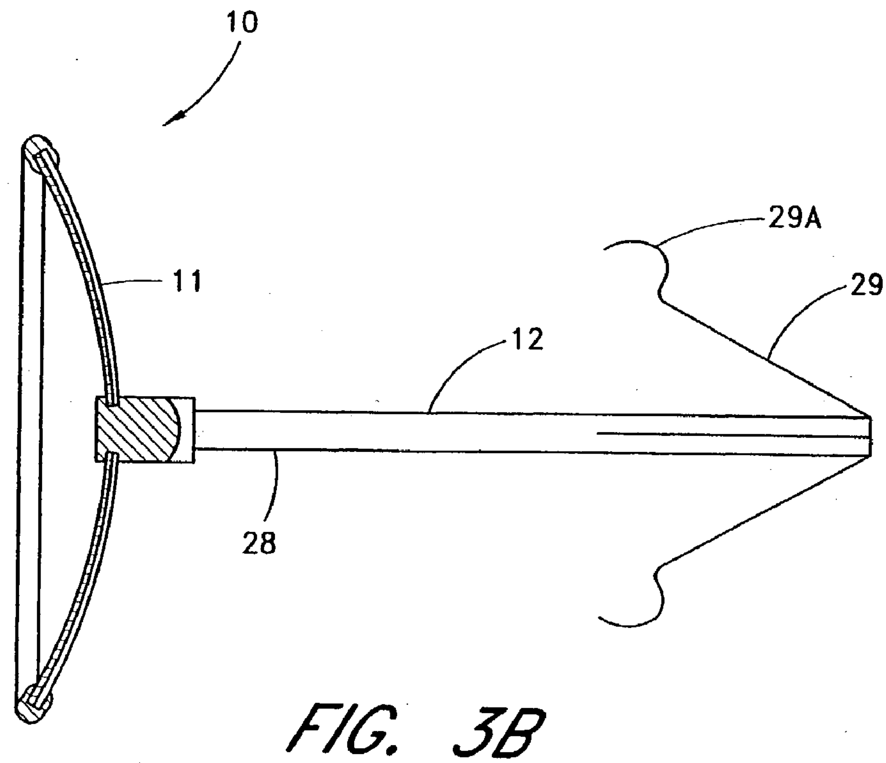


FIG. 3B

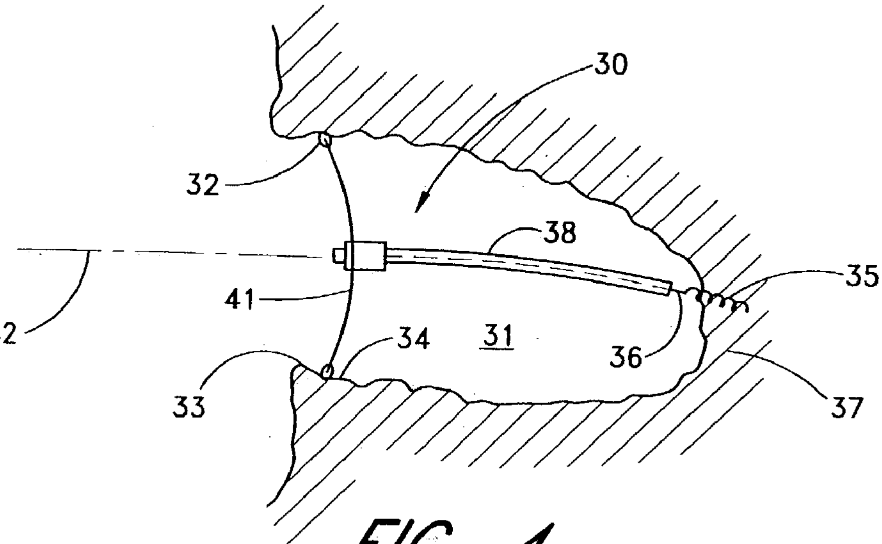


FIG. 4

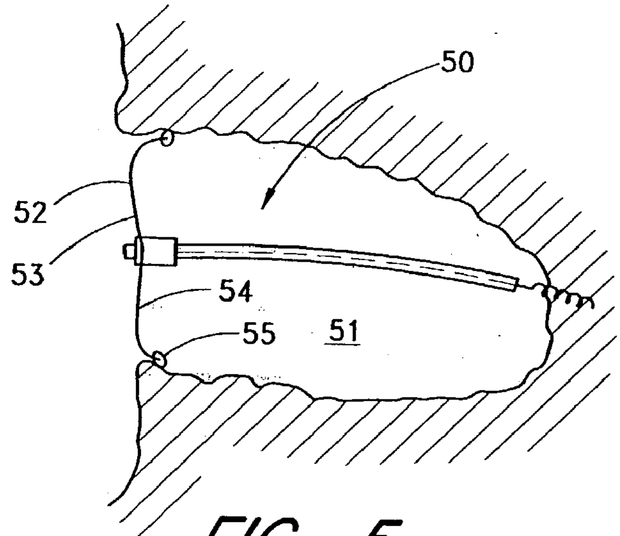


FIG. 5

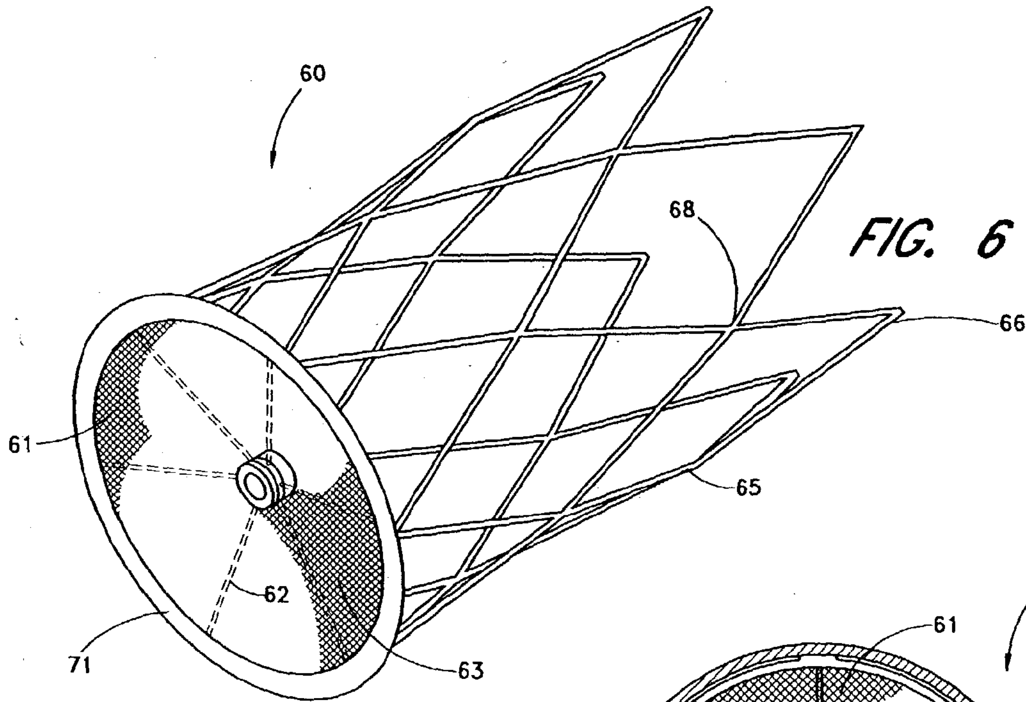


FIG. 6

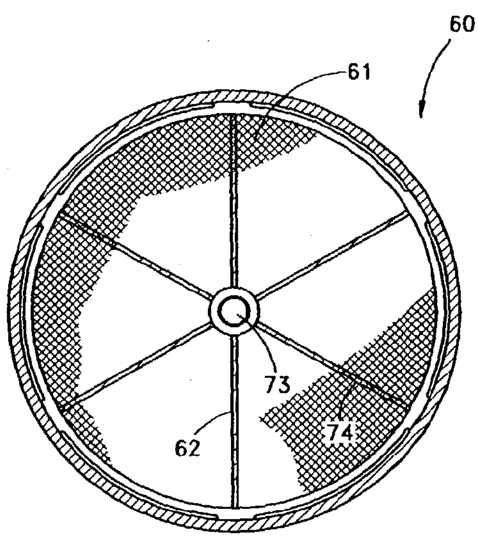


FIG. 8

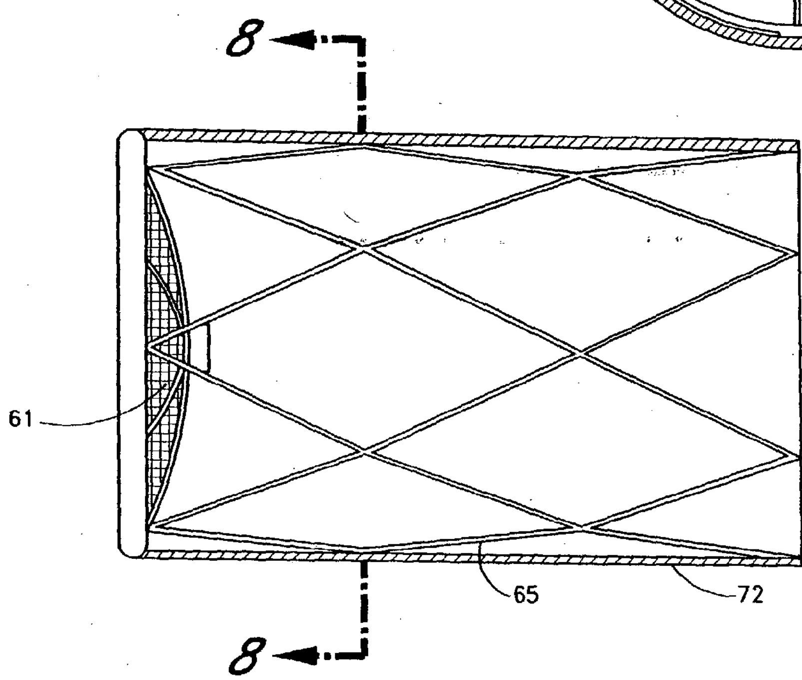


FIG. 7

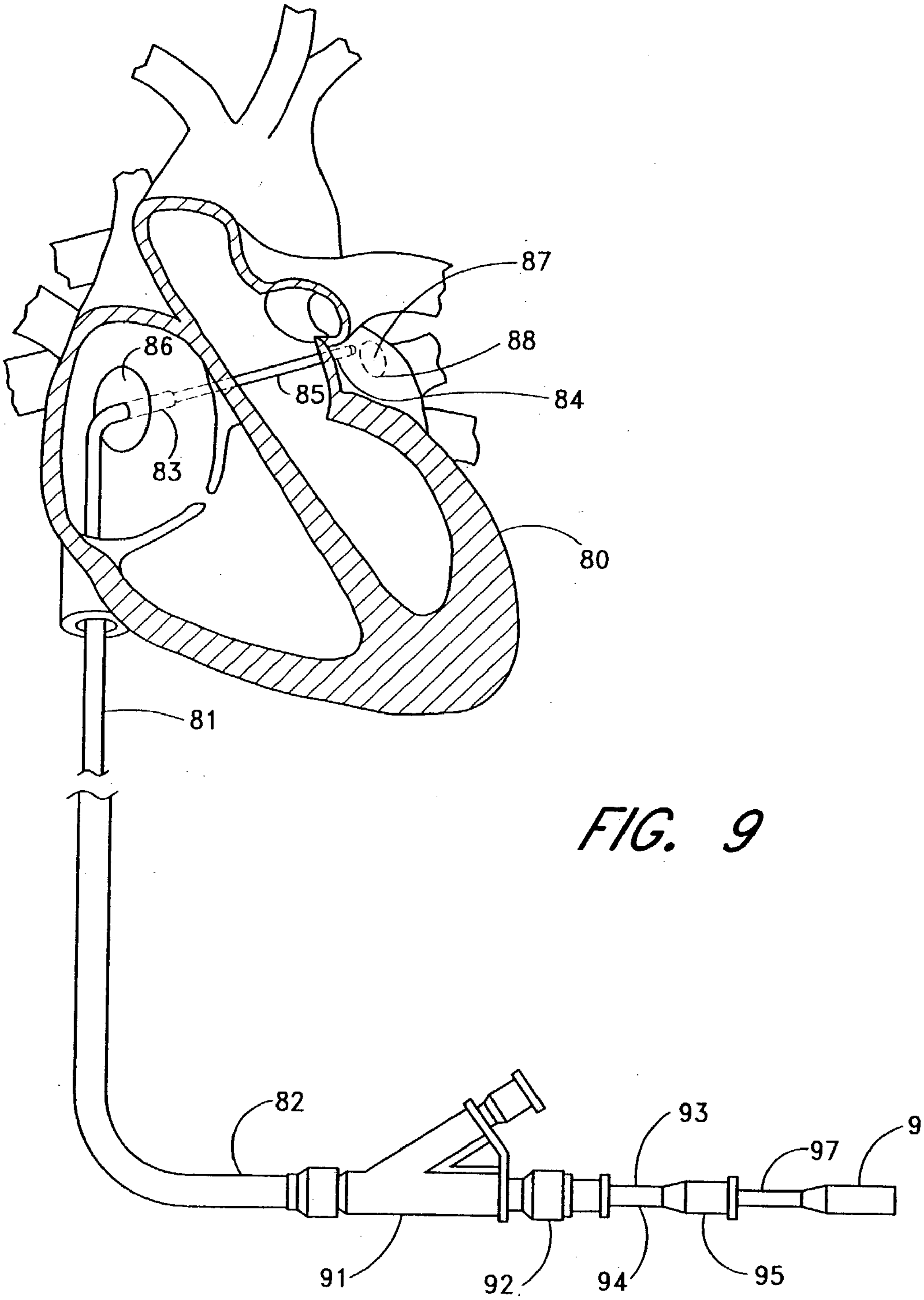


FIG. 9

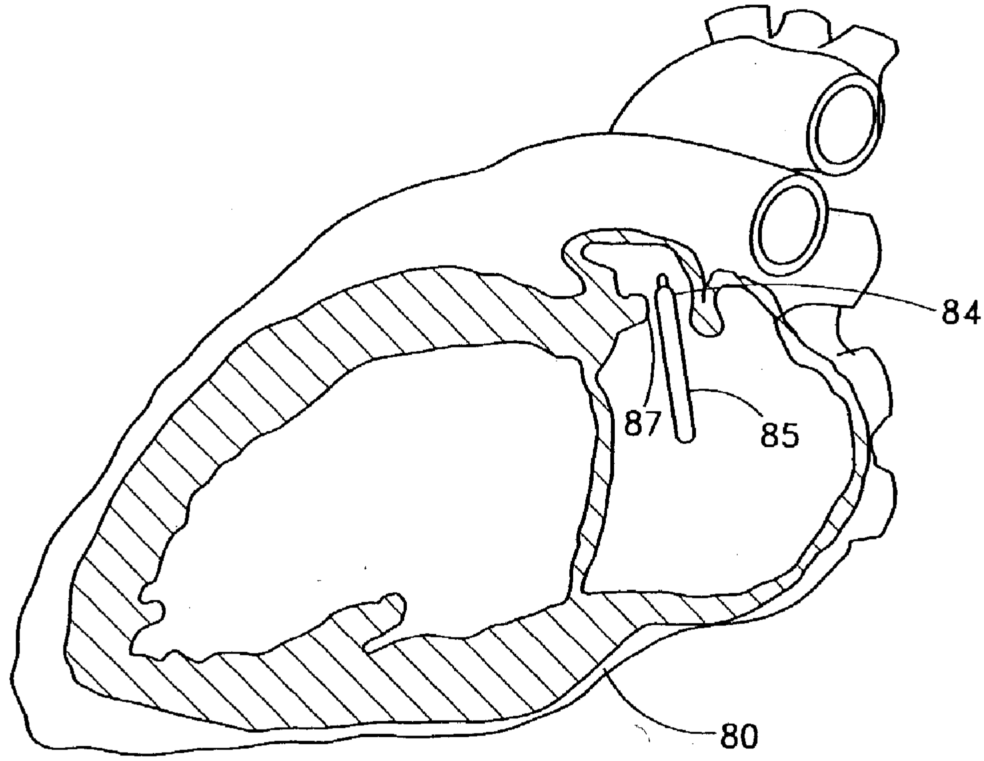


FIG. 10

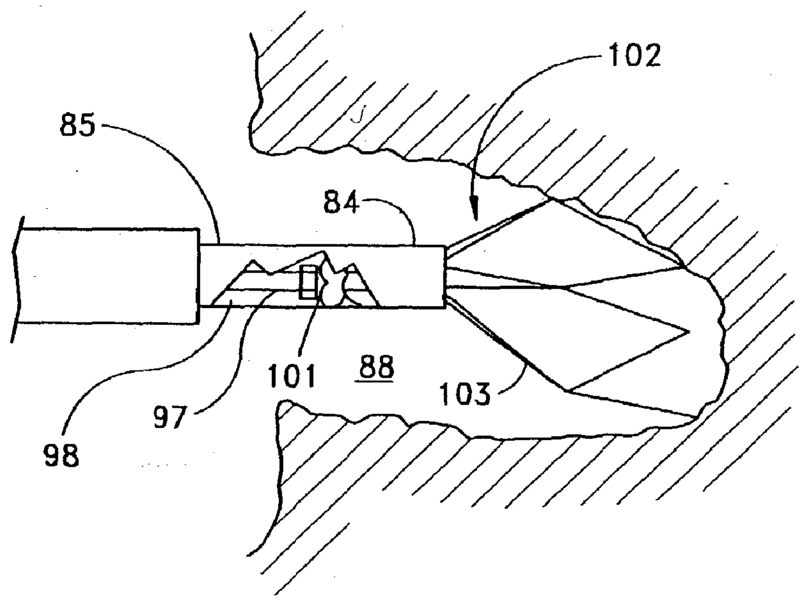


FIG. 11

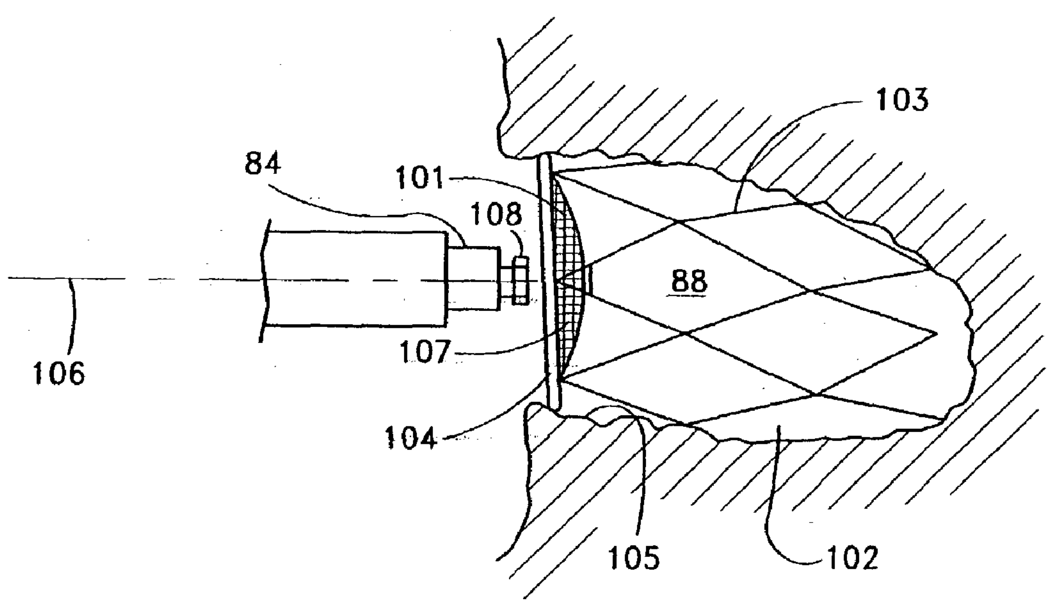


FIG. 12

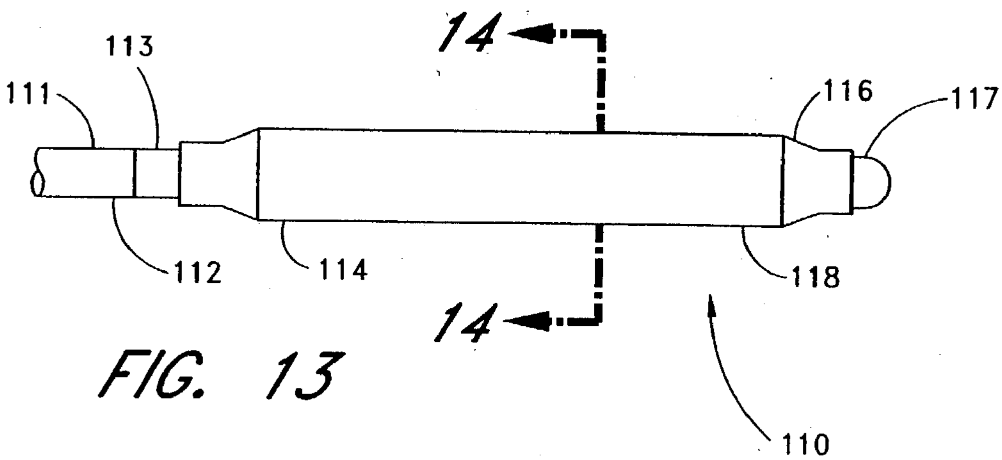


FIG. 13

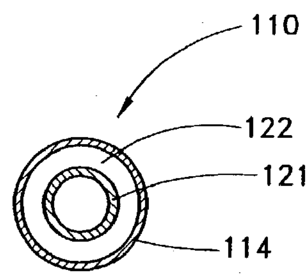


FIG. 14

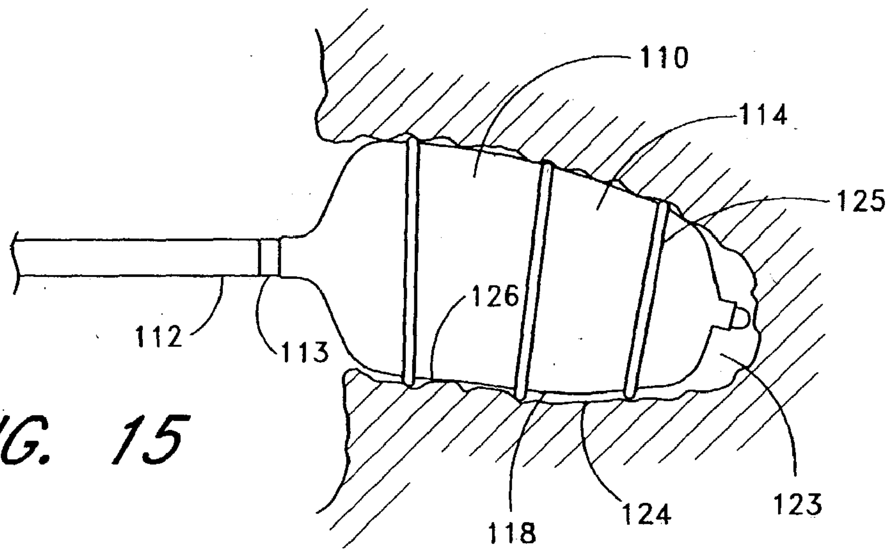

110
114
125
126
112
113
118
124
123

FIG. 15

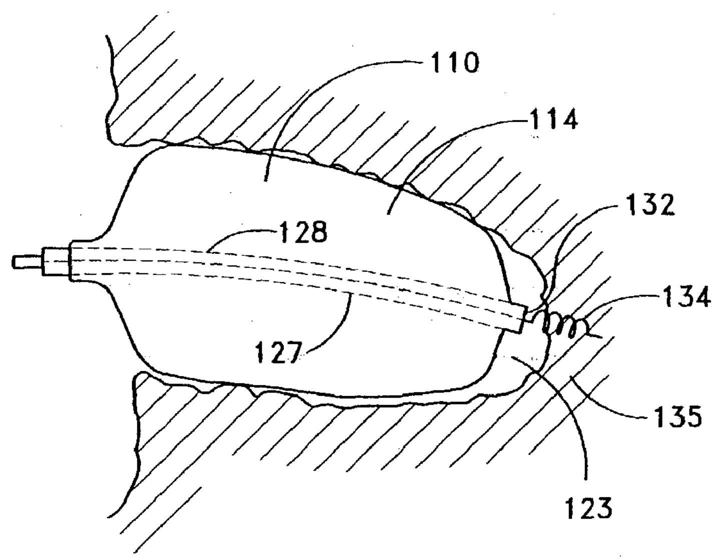

110
114
132
128
134
127
135
123

FIG. 16

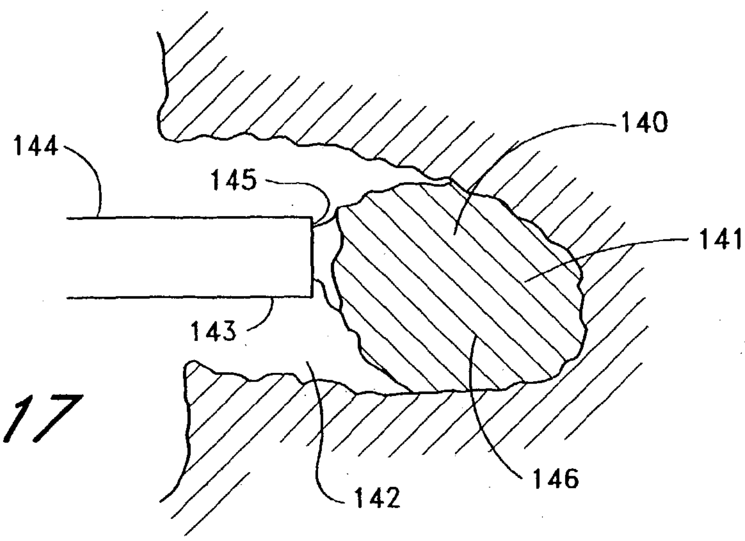


FIG. 17

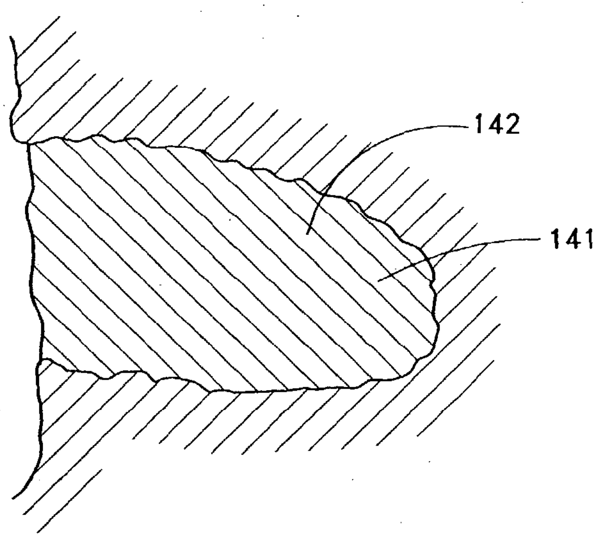


FIG. 18

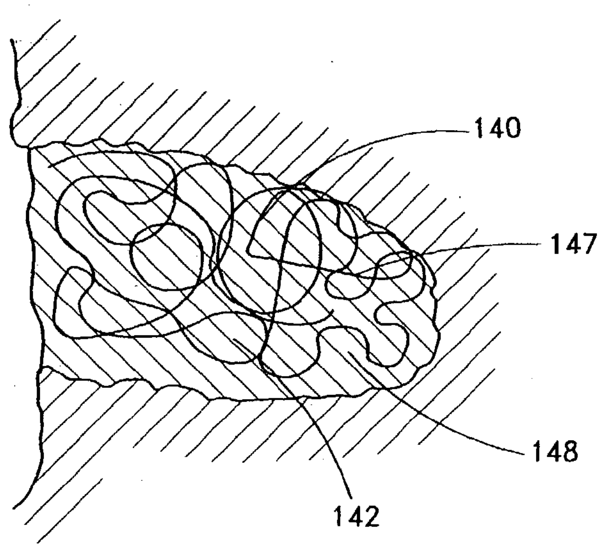


FIG. 19

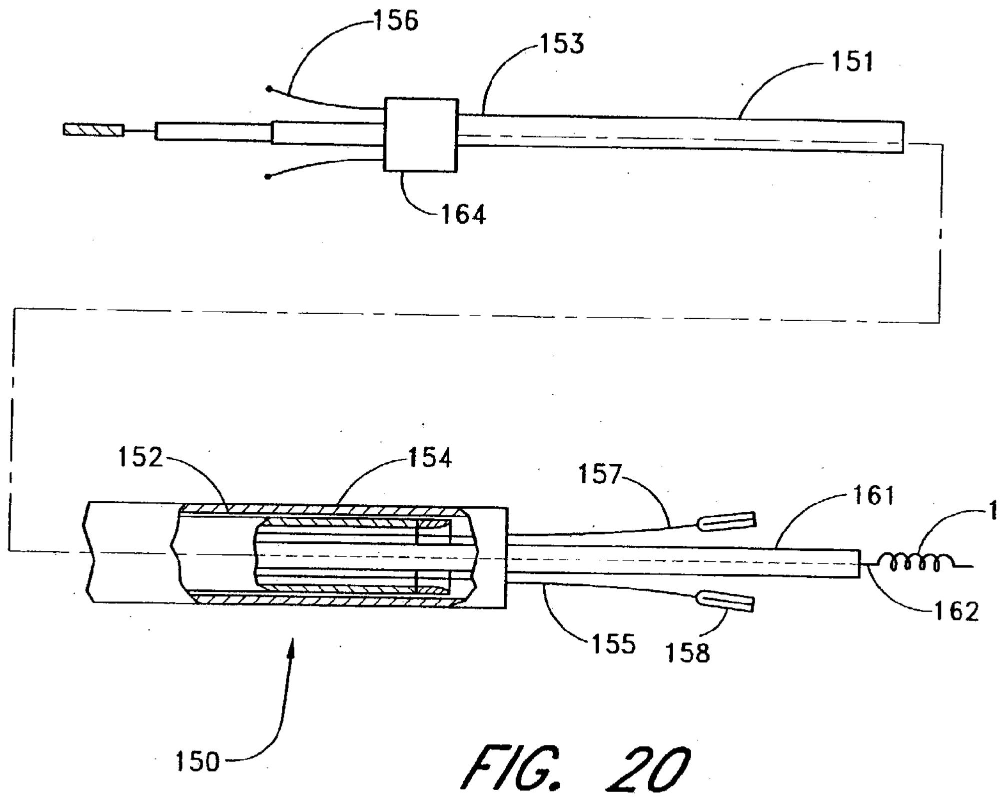


FIG. 20

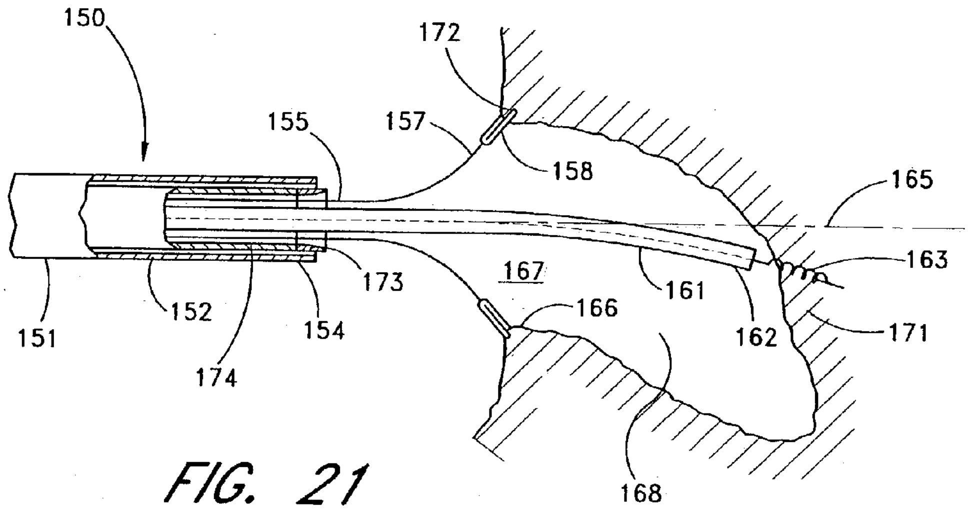

150
172
155
157
158
165
163
167
173
161
166
162
171
151
152
154
174
168

FIG. 21

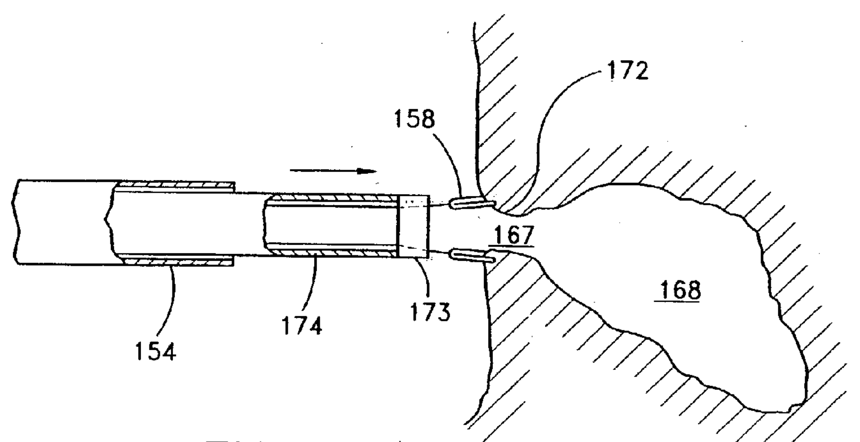

172
158
167
168
154
174
173

FIG. 22

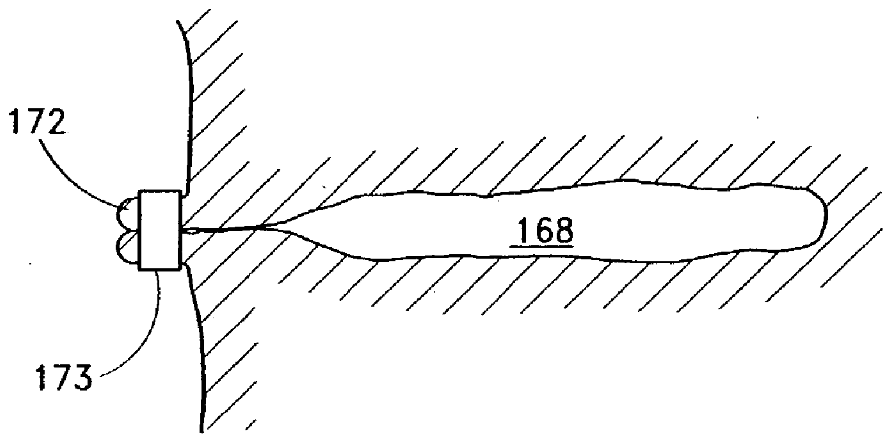


FIG. 23

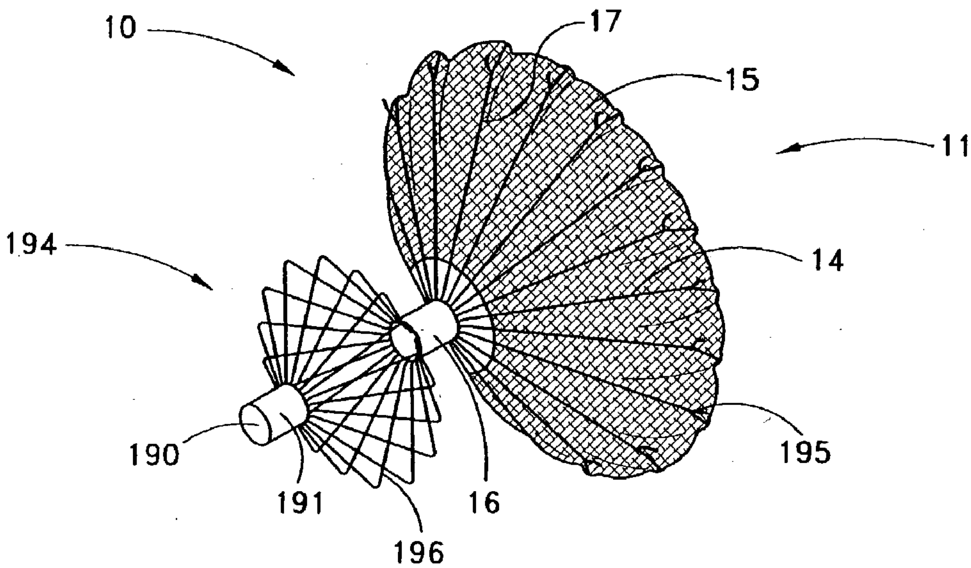

10
17
15
11
194
14
195
190
191
16
196

FIG. 24

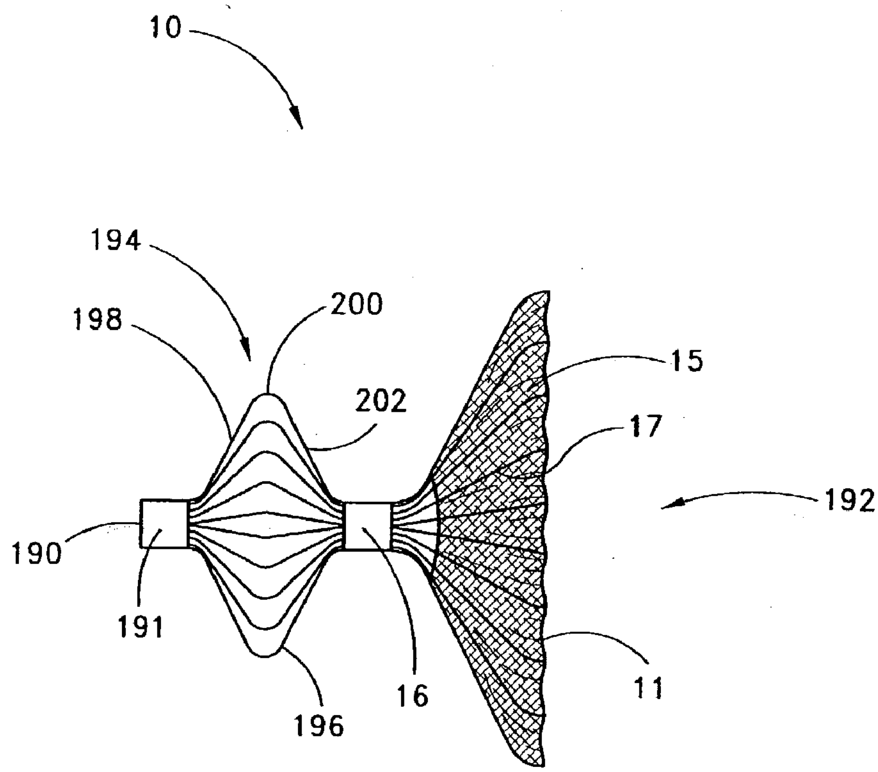

10
194
200
198
202
15
17
192
190
191
16
11
196

FIG. 25

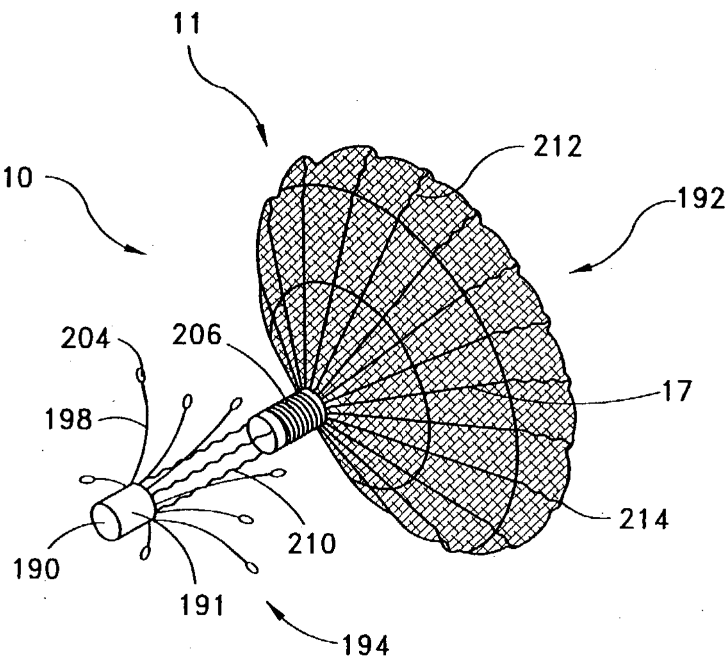

11
10
212
192
204
206
198
17
214
210
190
191
194

FIG. 26

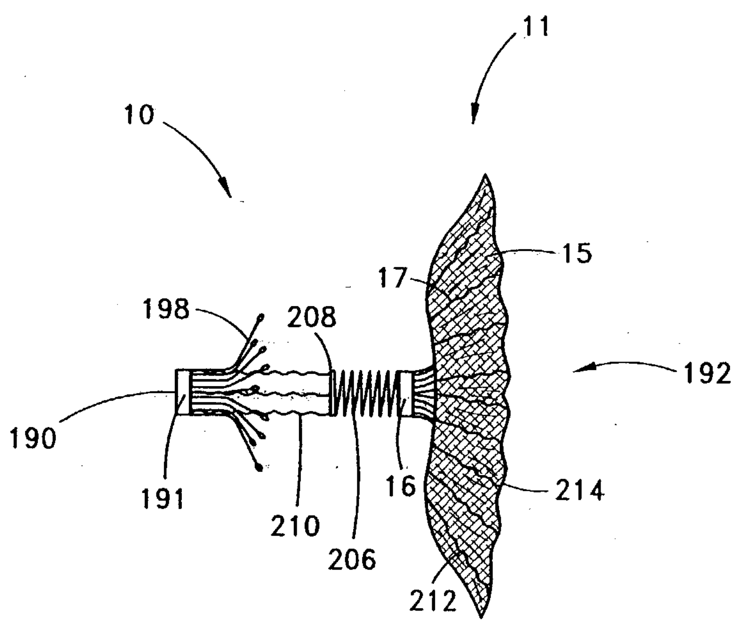

11
10
15
17
198
208
192
190
191
16
214
210
206
212

FIG. 27

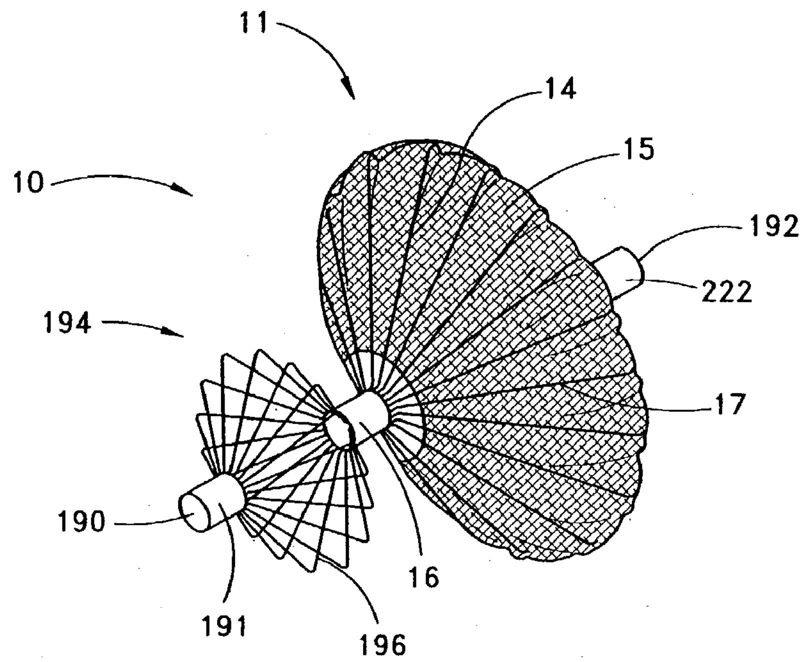

11
14
15
10
192
222
194
17
190
16
191
196

FIG. 28

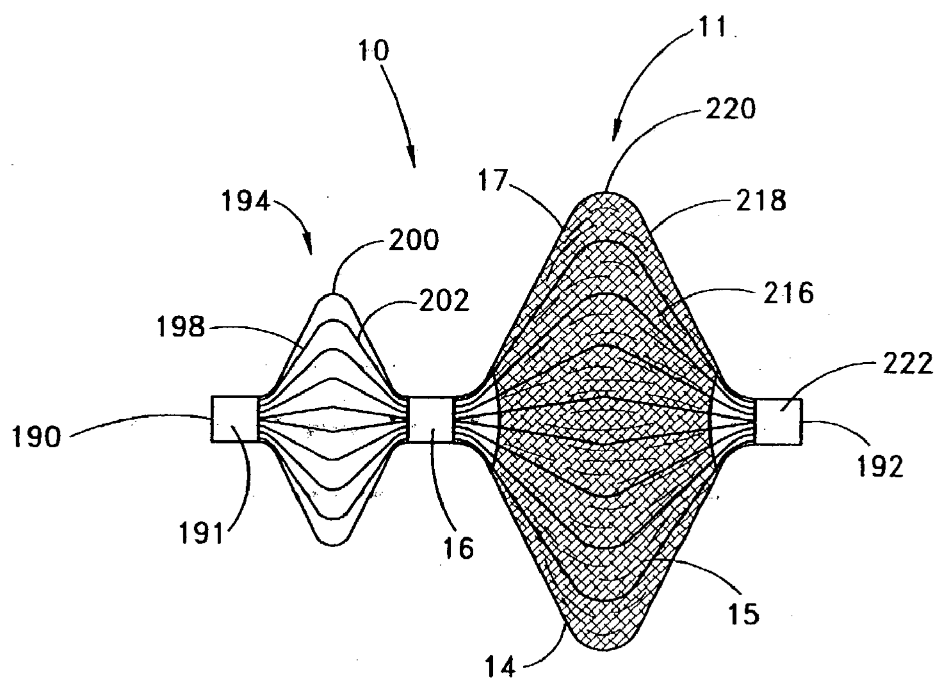

11
10
220
17
218
194
200
202
216
198
222
190
192
191
16
15
14

FIG. 29

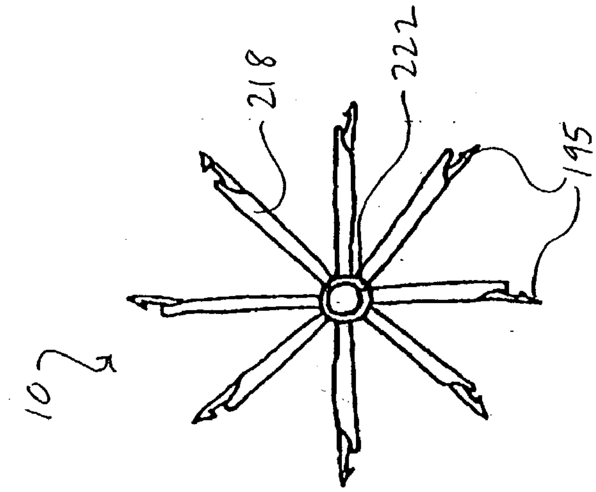


FIG. 31

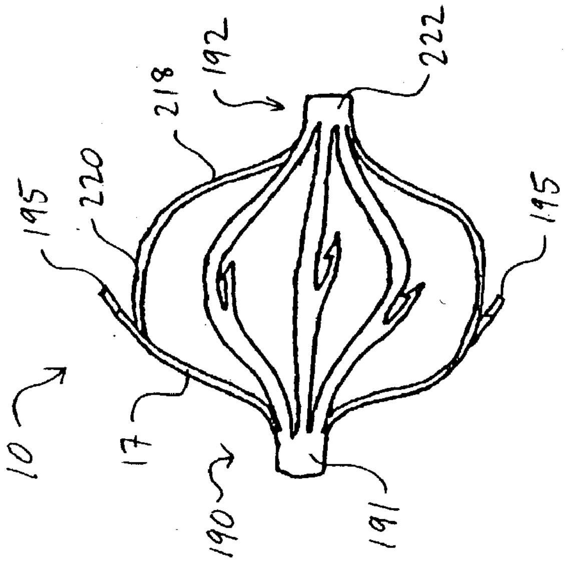


FIG 30A

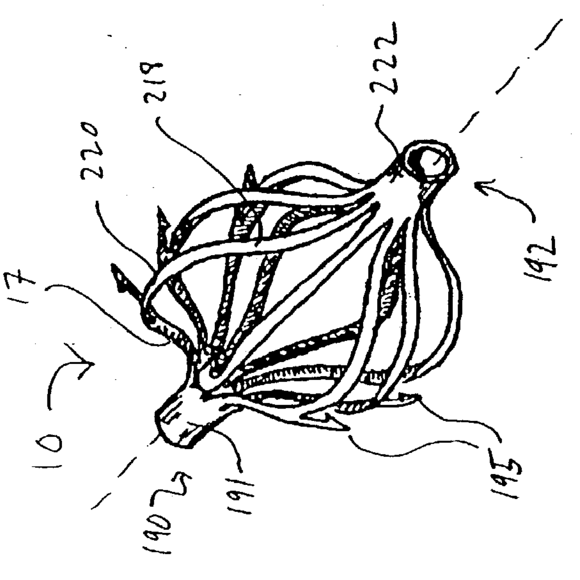


FIG 30

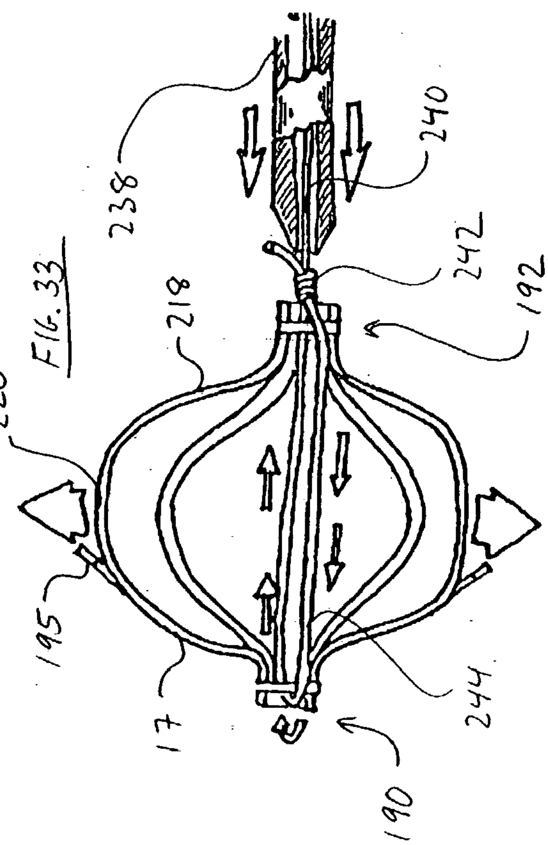

238
240
242
192
218
220
195
17
244
190

FIG. 33

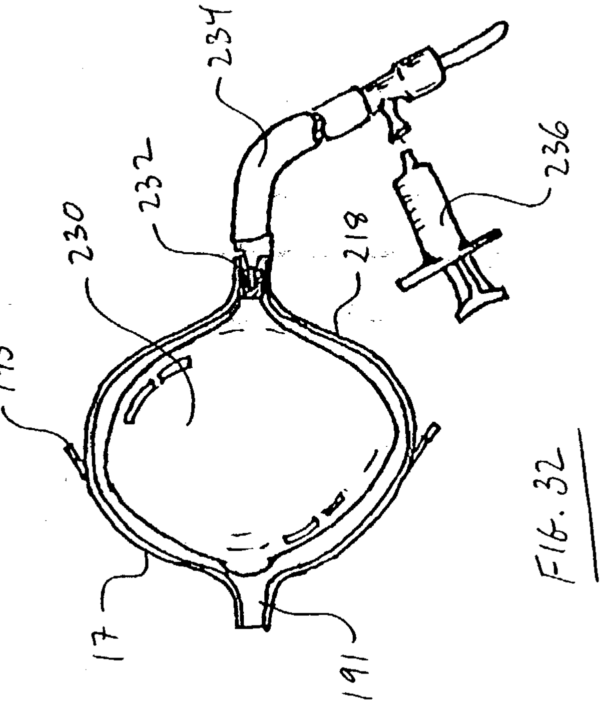

234
232
230
195
218
236
17
191

FIG. 32

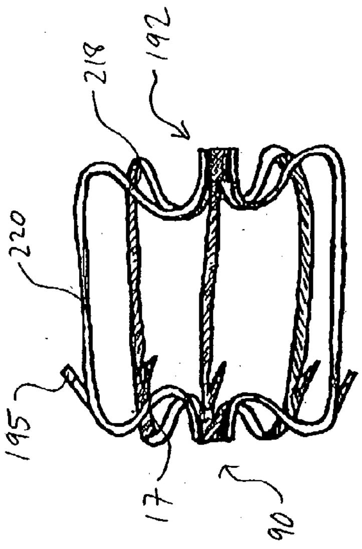


FIG. 35

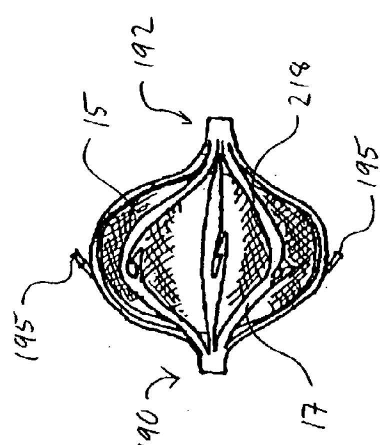


FIG 34B

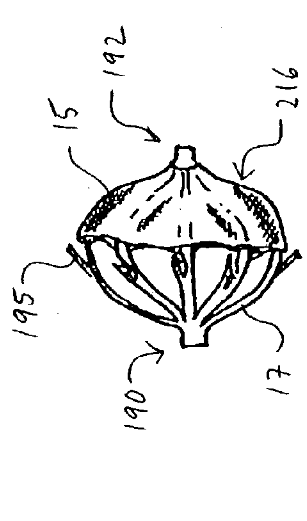


FIG 34A

FIG. 36

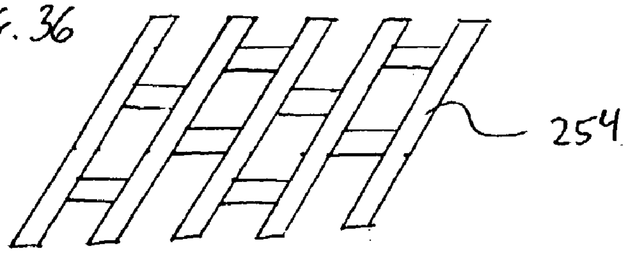


FIG. 37

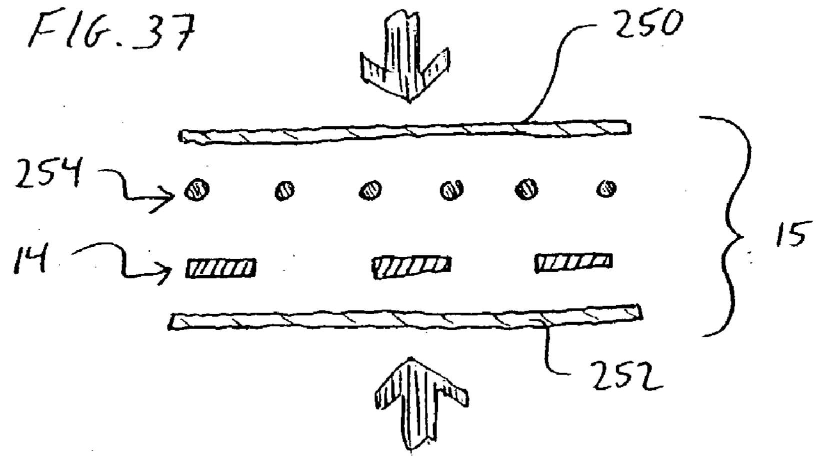


FIG. 38

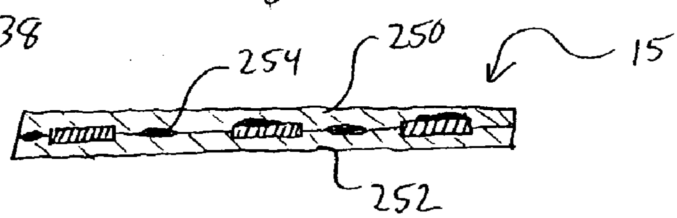
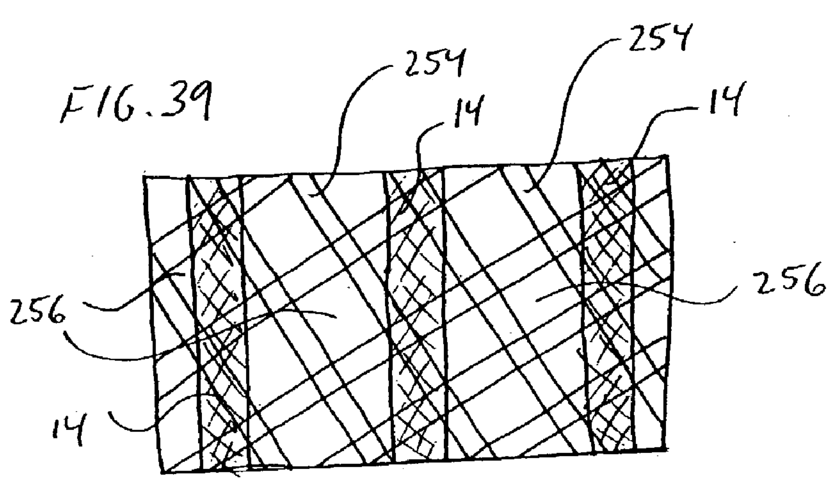


FIG. 39



METHOD OF CONTAINING EMBOLIC MATERIAL IN THE LEFT ATRIAL APPENDAGE

[0001] This is a continuation application of U.S. patent application Ser. No. 09/435,562 filed on Nov. 8, 1999 which is a continuation-in-part of U.S. patent application Ser. No. 09/187,200, filed Nov. 6, 1998, now U.S. Pat. No. 6,152, 144, the disclosures of which are incorporated in their entirety herein by reference.

BACKGROUND OF THE INVENTION

[0002] Embolic stroke is the nation's third leading killer for adults, and is a major cause of disability. There are over 700,000 strokes per year in the United States alone. Of these, roughly 100,000 are hemoragic, and 600,000 are ischemic (either due to vessel narrowing or to embolism). The most common cause of embolic stroke emanating from the heart is thrombus formation due to atrial fibrillation. Approximately 80,000 strokes per year are attributable to atrial fibrillation. Atrial fibrillation is an arrhythmia of the heart that results in a rapid and chaotic heartbeat that produces lower cardiac output and irregular and turbulent blood flow in the vascular system. There are over five million people worldwide with atrial fibrillation, with about four hundred thousand new cases reported each year. Atrial fibrillation is associated with a 500 percent greater risk of stroke due to the condition. A patient with atrial fibrillation typically has a significantly decreased quality of life due, in part, to the fear of a stroke, and the pharmaceutical regimen necessary to reduce that risk.

[0003] For patients who develop atrial thrombus from atrial fibrillation, the clot normally occurs in the left atrial appendage (LAA) of the heart. The LAA is a cavity which looks like a small finger or windsock and which is connected to the lateral wall of the left atrium between the mitral valve and the root of the left pulmonary vein. The LAA normally contracts with the rest of the left atrium during a normal heart cycle, thus keeping blood from becoming stagnant therein, but often fails to contract with any vigor in patients experiencing atrial fibrillation due to the discoordinate electrical signals associated with AF. As a result, thrombus formation is predisposed to form in the stagnant blood within the LAA.

[0004] Blackshear and Odell have reported that of the 1288 patients with non-rheumatic atrial fibrillation involved in their study, 221 (17%) had thrombus detected in the left atrium of the heart. Blackshear J L, Odell J A., Appendage Obliteration to Reduce Stroke in Cardiac Surgical Patients With Atrial Fibrillation. Ann Thorac. Surg., 1996.61(2):755-9. Of the patients with atrial thrombus, 201 (91%) had the atrial thrombus located within the left atrial appendage. The foregoing suggests that the elimination or containment of thrombus formed within the LAA of patients with atrial fibrillation would significantly reduce the incidence of stroke in those patients.

[0005] Pharmacological therapies for stroke prevention such as oral or systemic administration of warfarin or the like have been inadequate due to serious side effects of the medications and lack of patient compliance in taking the medication. Invasive surgical or thorascopic techniques have been used to obliterate the LAA, however, many patients are not suitable candidates for such surgical procedures due to a compromised condition or having previously undergone cardiac surgery. In addition, the perceived risks of even a thorascopic surgical procedure often outweigh the potential benefits. See Blackshear and Odell, above. See also Lindsay B D., Obliteration of the Left Atrial Appendage: A Concept Worth Testing, Ann Thorac. Surg., 1996.61(2):515.

[0006] Despite the various efforts in the prior art, there remains a need for a minimally invasive method and associated devices for reducing the risk of thrombus formation in the left atrial appendage.

SUMMARY OF THE INVENTION

[0007] There is provided in accordance with one aspect of the present invention, a method of containing embolic material within a left atrial appendage of a patient. The method comprises the steps of providing a containment device comprising a barrier for preventing the escape of embolic material from the left atrial appendage. A delivery catheter is provided, having a proximal end and a distal end. The delivery catheter is advanced through the patient's vasculature to position the containment device within the patient's left atrium. The containment device is deployed such that the barrier substantially obstructs the passage of embolic material from the left atrial appendage. In one implementation of the invention, the barrier comprises a mesh. The barrier may comprise polyethylene. Alternatively, the barrier may comprise a nickel titanium alloy, or other materials disclosed herein. The barrier may comprise a self expandable frame, and may further carry a mesh on the frame. The self expandable frame may comprise a wire mesh.

[0008] In accordance with another aspect of the present invention, there is provided a method of treating the left atrial appendage of a patient. The method comprises the steps of providing a delivery catheter having a proximal end and a distal end, and a self expandable wire structure for acting as a barrier to the passage of embolic material from the left atrial appendage, removably carried by the distal end. The delivery catheter is advanced into the patient's left atrium. The self expandable wire structure is positioned at the left atrial appendage, and the self expandable wire structure is deployed such that it substantially obstructs the passage of embolic material from the left atrial appendage.

[0009] The method may additionally comprise the step of removing thrombotic or fibrotic material from the patient's left atrial appendage prior to deployment of the self expandable wire structure. The deploying step may comprise deploying the self expandable wire structure such that it engages at least a portion of an inner surface of the left atrial appendage. The self expandable wire structure may comprise wire mesh. The self expandable wire structure may comprise a plurality of tissue engagement members, and the method further comprises the step of engaging tissue with the tissue engagement members.

[0010] Further features and advantages of the present invention will become apparent to those of ordinary skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] **FIG. 1** shows a perspective view of an embodiment having features of the invention with an occluding member and a retention member.

[0012] **FIG. 2** shows an end view of the apparatus of **FIG. 1** in partial section.

[0013] **FIG. 3** shows a longitudinal cross-sectional view of the apparatus of **FIGS. 1 and 2**.

[0014] **FIG. 3A** shows a perspective view of an apparatus having features of the invention.

[0015] **FIG. 3B** shows an elevational view in partial section of the apparatus of **FIG. 3A**.

[0016] **FIG. 4** shows an elevational view of an apparatus having features of the invention in a deployed state within a body cavity.

[0017] **FIG. 5** shows an elevational view of an apparatus having features of the invention in a deployed state within a body cavity.

[0018] **FIG. 6** shows a perspective view of an apparatus for sealing off a body cavity having features of the invention.

[0019] **FIG. 7** shows an elevational view in partial section of an apparatus for sealing off a body cavity having features of the invention.

[0020] **FIG. 8** shows a transverse cross-sectional view of the apparatus of **FIG. 7** taken along lines **8-8**.

[0021] **FIG. 9** shows a schematic view of a patient's heart with a transeptal catheter deployed through the septum and a delivery catheter and apparatus for sealing off a body cavity disposed therein.

[0022] **FIG. 10** shows a schematic view of a patient's heart in partial section with a delivery catheter disposed within the opening of the LAA.

[0023] **FIG. 11** shows a magnified view of the delivery catheter distal end and the LAA of a patient of **FIG. 10** with an apparatus for sealing off a body cavity partially deployed within the LAA.

[0024] **FIG. 12** shows the apparatus for sealing off a body cavity of **FIG. 11** fully deployed within a LAA.

[0025] **FIG. 13** shows an elevational view of a device for occluding a body cavity having features of the invention.

[0026] **FIG. 14** shows a transverse cross sectional view of the device for occluding a body cavity of **FIG. 13** taken along lines **14-14**.

[0027] **FIG. 15** shows a device for occluding a body cavity having features of the invention deployed within a LAA.

[0028] **FIG. 16** shows a device for occluding a body cavity having features of the invention deployed within a LAA.

[0029] **FIG. 17** shows a LAA being occluded by a method having features of the invention.

[0030] **FIG. 18** shows a LAA occluded by method having features of the invention.

[0031] **FIG. 19** shows a LAA occluded by method having features of the invention.

[0032] **FIG. 20** is an elevational view of an apparatus for closing an interior body cavity of a patient in partial section having features of the invention.

[0033] **FIG. 21** is a schematic view of an apparatus for closing an interior body cavity of a patient in contact with tissue of a LAA.

[0034] **FIG. 22** is a schematic view of an apparatus for closing an interior body cavity of a patient in contact with tissue of a LAA.

[0035] **FIG. 23** shows a LAA which has been closed by a method having features of the invention.

[0036] **FIG. 24** is a perspective view of an occlusion device in accordance with the present invention.

[0037] **FIG. 25** is a side elevational view of the occlusion device shown in **FIG. 24**.

[0038] **FIG. 26** is a perspective view of an alternate embodiment of the present invention.

[0039] **FIG. 27** is a side elevational view of the embodiment shown in **FIG. 26**.

[0040] **FIG. 28** is a perspective view of a further embodiment of the present invention.

[0041] **FIG. 29** is a side elevational view of the embodiment of **FIG. 28**.

[0042] **FIG. 30** is a perspective view of a further occlusion device in accordance with the present invention.

[0043] **FIG. 31** is an end view taken along the line **31-31** of **FIG. 30**.

[0044] **FIG. 32** is a schematic illustration of an inflatable balloon positioned within the occlusion device of **FIG. 30**.

[0045] **FIG. 33** is a schematic view of a pull string deployment embodiment of the occlusion device of **FIG. 30**.

[0046] **FIGS. 34A and 34B** are side elevational schematic representations of partial and complete barrier layers on the occlusion device of **FIG. 30**.

[0047] **FIG. 35** is a side elevational schematic view of an alternate occlusion device in accordance with the present invention.

[0048] **FIG. 36** is a schematic view of a bonding layer mesh for use in forming a composite barrier membrane in accordance with the present invention.

[0049] **FIG. 37** is an exploded cross sectional view of the components of a composite barrier member in accordance with the present invention.

[0050] **FIG. 38** is a cross sectional view through a composite barrier formed from the components illustrated in **FIG. 37**.

[0051] **FIG. 39** is a top plan view of the composite barrier illustrated in **FIG. 38**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0052] FIGS. **1-3** show an embodiment of an occluding device **10** having features of the invention where an occluding member **11** is secured to a retention member **12** that is arranged to fix the occluding member in a desired position within a body passageway or cavity. The occluding member **11** generally has disc shape with an outer rim **13** around the perimeter of a frame structure **14** which supports a barrier

15. The outer rim **13** can be circular or polygonal, or any other shape that is suitable for conforming to the inside surface of a body cavity. A hub **16** can be located near the center of the occluding member **11** which serves to connect the retention member **12** to the occluding member, in addition to other functions. The outer rim **13** is typically made from a soft polymer material **17** which permits flexibility of the outer rim and facilitates sealing of the outer rim against the inside surface of a body cavity or passageway. The barrier **15** can be a thin mesh or film of material which serves to block the passage of material within an area surrounded by the outer rim **13**. The barrier **15** can be secured to the outer rim **13** along its entire perimeter **18** in order to achieve a complete seal therebetween and can be molded into the outer rim **13** or bonded thereto by a suitable method such as gluing, welding, sewing or other suitable method.

[**0053**] The outer rim **13** is at least partially supported by the frame structure **14** which connects the outer rim and the hub. The frame structure **14** can be made from one or more elements of high strength material such as stainless steel or MP35N, or may preferably be made from shape memory or pseudoelastic alloys such as NiTi, or any of a variety of known structural biodegradable materials (e.g. polyglycolic acid, poly lactic acid, poly-L-lactic acid and derivatives or copolymers such as PLGA). Preferably, the frame structure **14** is made from a material which can be self-expanding from a constrained configuration so that the occluding device **10** can be delivered to the deployment site in a low profile an flexible configuration which facilitates percutaneous delivery.

[**0054**] Preferably a radial hoop **21** is contained within the soft polymer material **17** of the outer rim **13** and serves to maintain the annular shape of the outer rim and facilitate radial expansion of the outer rim from a constrained position or configuration. The radial hoop **21** may be isolated within the soft polymer material **17** of the outer rim **13**, or may be connected to at least some of the elements **22** of the frame structure **14**, in order to have stronger mechanical joint between the outer rim and the frame structure. The radial hoop **21** is shown in a substantially circular configuration, but may also be polygonal or otherwise suitably shared, and may have connections or joints spaced thereon to facilitate contraction or folding of the device for non-invasive delivery.

[**0055**] In addition to connecting the retention member **12** and the occluding member **11**, the hub **16** may serve to house a rotational coupling **23** which is connected to the proximal end **24** of a tissue penetrating shaft **25** within the retention member. The rotational coupling **23** allows the transfer of torque to the tissue penetrating shaft **25** which preferably has a helically shaped extension or distal extremity **26** which is configured to screw into tissue and be mechanically fixed thereto. Longitudinal movement of the tissue penetrating shaft **25** relative to the retention member **12** and hub **16** may be prevented by sizing a lumen **27** of the retention member which contains the tissue penetrating shaft such that the helically shaped extension **26** at the distal end is too large to pass through the lumen and the proximal end **24** of the tissue penetrating shaft is prevented from passing through the lumen by the rotational coupling attached thereto. The rotational coupling **23** may also be configured to be longitudinally captured by the hub **16** but still be rotatably disposed therein.

[**0056**] **FIGS. 3A and 3B** depict an alternative embodiment of an occluding device **10** having an occluding member **11** and a retention member **12**. The retention member **12** has a shaft **28** and radially extending members **29** extending radially from a proximal end of the shaft. The radially extending members **29** serve to anchor the shaft **28** and the occluding member **11** by engaging the tissue surrounding the occluding device. Preferably, the radially extending members are self-expanding from a constricted state and are made of a pseudo elastic alloy such as NiTi, or a high strength material such as stainless steel. Although it is preferable for the radially extending members **29** to be self-expanding from a constricted state, they may also be expanded by use of shape memory properties or a radial outward force as would be provided by an inflatable balloon or the like. The shaft **28** can be a single element or made of multiple elements, and can be made from the same materials as the radially extending members or different materials such as polymers or polymer composites. The radially extending members **29** have a proximally directed bias at their radial extremities **29A** so that the members readily fold down and move easily in a distal direction during insertion of the occluding device **10**, but spring outward and aggressively engage surrounding tissue upon movement in a proximal direction. This configuration of the radially extending members **29** allows easy insertion into a body cavity, but prevents egress of the device **10** in and outward or proximal direction.

[**0057**] **FIG. 4**. depicts an occluding device **30** similar to that depicted in FIGS. **1-3** deployed within the left atrial appendage **31** of a patient. An outer rim or periphery **32** of the occluding device **30** is disposed adjacent the opening **33** of the left atrial appendage **31** in a position which allows for a substantial seal of the outer rim against the inside surface **34** of the LAA. A helically shaped distal extremity **35** of a tissue penetrating shaft **36** has been screwed into the wall tissue of the LAA and is mechanically secured thereto. A retention member **38** maintains the position of an occluding member **41** in a substantially perpendicular orientation with respect to a longitudinal axis of the LAA **42**.

[**0058**] **FIG. 5** depicts an occluding device similar to that depicted in FIGS. **1-4** deployed within a LAA **51** of a patient similar to what is shown in **FIG. 4**. The structure of an occluding member **52** of the embodiment as shown in **FIG. 5** differs from that shown in **FIG. 4** in that a barrier **53** and frame structure **54** of the embodiment of **FIG. 5** protrudes proximally from a plane defined by an outer rim **55**. This configuration may be useful for certain morphologies of patient's LAAs. One object of the invention is to create a smooth surface outside the body passageway or cavity in order to prevent turbulent flow or eddies of blood or other bodily fluid within the cavity or passageway. The alternative configuration of the occluding device **50** shown in **FIG. 5** may be useful in this regard.

[**0059**] **FIG. 6** shows an alternative embodiment of an occluding device **60** which has an occluding member **61**, a frame structure **62**, a barrier **63** and a retention member in the form of an expandable member **65** which has linked elements **66** that are preferably expandable from a constrained configuration. The expandable member **65** is generally cylindrical in shape and can have a series of circumferential linked elements **66** connected by links **68**. Although **FIG. 6** depicts the expandable member **65** as a series of linked elements **66**, those skilled in the art will realize that a similar effect can be achieved with a single wire in a helical configuration or a plurality of wires in a mesh or braided configuration, or any other suitable configuration that can be self-expanding from a constrained configuration or expanding with the application of heat or other form of energy or force. For example, the expandable member **65** may be configured to be deployed by an outward radial force delivered from within the expandable member. An inflatable balloon or the like could be used to exert such a force. The expandable member is preferably secured to an outer rim **71** of the occluding member **61** but may also be secured to the frame structure **62** directly or indirectly. The expandable member **65** can be self-expanding from a constrained configuration as can the occluding member **61** and the frame structure **62** and outer rim **71** thereof. The frame structure **62**, outer rim **71** and barrier **63** may have construction similar to that described above with regard to the similar elements of the embodiments depicted in FIGS. **1-5**.

[**0060**] Referring to **FIG. 7**, the expandable member **65** as shown in **FIG. 6** may also have a sheath **72** disposed around it so as to act as a shield between the expandable member and an inner surface of a patient's body cavity or passageway. The sheath **72** may facilitate the sealing function of the occluding member **61**, but is primarily intended to prevent damage to either tissue on the inside surface of a body cavity or to the linked elements **66** of the expandable member. The sheath **72** may surround all or part of the expandable member **65** and may be made from a variety of suitable biocompatible materials such as Dacron®, Nylon, TFE, PTFE or ePTFE. The sheath **72** may be a weave, braid, film or have any other suitable configuration. Expandable member **65** may also be coated by dipping, spraying, or other suitable process with a friction reducing material such as Teflon®, or with an active compound such as heparin.

[**0061**] **FIG. 8** shows a transverse cross-sectional view of the embodiment of **FIG. 7** taken at lines **8-8**. The frame structure **62** has an axis or hub **73** disposed at approximately the center of the frame structure which serves to connect the various radial elements **74** of the frame structure. The hub **73** can have an independent structure that links the several elements **74** of the frame structure **62** or it may be merely the terminus of the various frame structure elements and have a solid composition. In either structure, the hub **73** preferably allows a constrained configuration of the occluding member **61** to facilitate percutaneous delivery of the occluding device **60**. The hub **73** may also have a lumen disposed therein to allow passage of a guidewire of other guiding member. Preferably, the lumen would have a self sealing valve or gasket which prevents the passage of fluid or embolic material once the guidewire or guiding member is removed from the lumen.

[**0062**] Referring to **FIG. 9, a** schematic view of a patient's heart **80** in partial section shows a trans-septal catheter **81** having a proximal end **82** and a distal end **83**. The distal end **83** of the trans-septal catheter **81** is disposed within a patient's heart **80** with the distal end **84** of a delivery catheter **85** extending from the distal end **83** of the trans-septal catheter. The distal end **83** of the trans-septal catheter **81** has breached the septum **86** of the patient's heart **80** and is disposed adjacent the opening of the patient's LAA **88**. At the proximal end **82** of the trans-septal catheter **81** there is a Luer connector **91** coupled to a hemostasis valve **92** which prevents the egress of blood from a lumen **93** of the trans-septal catheter **81**. The proximal end **94** of the delivery catheter **85** extends proximally from the hemostasis valve **92** and has a Luer connector **95** attached to the proximal extremity thereof. The proximal end **96** of, a plunger **97** extends from the Luer connector **95** of the delivery catheter. The proximal end **94** of the delivery catheter is arranged to allow rotational and axial movement of the plunger **97** while preventing blood or other bodily fluids from leaking between the delivery catheter **85** and the plunger **97**.

[**0063**] Referring to **FIG. 10, a** patient's heart **80** is shown in partial section with the distal end **84** of a delivery catheter **85** disposed within the LAA opening **87**. **FIG. 11** is a magnified view of the LAA **88** shown in **FIG. 10** and the distal end of the delivery catheter **84**, which is shown in partial section, contains a plunger **97** which is slideably disposed within an inner lumen **98** of the delivery catheter **85** and serves to apply axial force in a distal direction on the collapsed occluding member **101** disposed within the delivery catheter so as to force the occluding device **102** from the delivery catheter and deploy it. An occluding device **102** having an expandable member **103** and an occluding member **101** secured thereto is partially deployed and extending from the distal end of the delivery catheter **84** into the patient's LAA **88**. The occluding device **102** can also be guided into the patient's LAA **88** by use of an appropriate guidewire or guiding member.

[**0064**] **FIG. 12** shows the occluding device **102** of **FIG. 11** in a deployed state within the patient's LAA **88**. An outer rim **104** of the occluding member **101** is in substantial sealing contact with the inside surface **105** of the LAA **88**. The expandable member **103** has expanded so as to contact the inside surface **105** of the LAA and secure the occluding device **102** thereto and maintain the occluding member **101** in a substantially perpendicular orientation relative to a longitudinal axis **106** of the LAA **88**. A barrier **107** is disposed within an area bounded by the outer rim **104** and is positioned to prevent the passage or embolic or other material to or from the LAA **88**. The distal end **108** of the plunger **97** is extending from the distal end of the delivery catheter **84** after having pushed the occluding device **102** from the delivery catheter.

[**0065**] Referring to **FIG. 13**, an occluding device **110** having features of the invention is shown. The occluding device **110** has a delivery catheter **111** with a distal end **112**, a detachment mechanism **113** disposed on the distal end of the delivery catheter and an occlusive body or inflatable member **114** detachably secured to the detachment mechanism. The inflatable member **114** has a proximal end **115** and a distal end **116** with the proximal end being attached to the detachment mechanism **113** and the distal end terminating at an end cap **117**. The inflatable member **114** has an outside surface **118** that may contain a fibrosis inducing material such as Dacron® or other similar materials. The inflatable member **114** may be made from a fluid tight film of polymer material which can be either compliant or non-compliant. Preferably the inflatable member **114** is made from silicone, however, any suitable material such as polyethylene, polyurethane or PET can be used.

[0066] The detachment mechanism **113** can be activated by mechanical force or by delivery of thermal or optical energy by a suitable conduit. Alternatively, the inflatable member can be pushed into the LAA from the delivery catheter **111** by an elongate push member without the use of a detachment mechanism. The inflatable member **114** can be filled with a gas, fluid or gel which is injected under pressure through the delivery catheter **114** and into the inflatable member. Suitable fluids to inject would include saline and silicone. The inflatable member **114** may also be filled with a polymer material that can be hardened. Autologus fluid such as blood, or collagen may also be used. A fluid, gel or polymer used to fill the inflatable member may contain contrast agents such as gold, tantalum, bismuth, barium sulfate or the like in order to improve visualization under fluoroscopy or x-ray imaging.

[0067] **FIG. 14** is a transverse cross-sectional view of the occluding device **110** of **FIG. 13** taken along lines **14-14**. An optional inner shaft **121** is shown disposed within the inflatable member **114**, preferably in a concentric arrangement. The inner shaft **121** provides longitudinal axial support to the inflatable member **114** so as to maintain a longitudinal dimension of the inflatable member **114** when it is being inflated and deployed. The inner shaft **121** may be solid or contain one or more lumens that may or may not be in fluid communication with an inner lumen **122** of the inflatable member **114**, and can be used for the passage of a guidewire or guiding member.

[0068] **FIG. 15** depicts an alternative embodiment of an occluding device **110** which consists of an inflatable member **114** similar to the inflatable member of **FIG. 13**, shown substantially deployed, within a patient's LAA **123**. The inflatable member **114** has been at least partially filled with a fluid, gas or gel within the patient's LAA **123** such that the outside surface of the inflatable member **118** is in contact with at least part of the inside surface **124** of the LAA. The inflatable member **114** can have rib members **125** which can mechanically interlock with the trebeculae **126** of the inside surface of the LAA **124** or other surface irregularities of the inside surface of a patient's body cavity or passageway. The rib members **125** form a complete circumference of the inflatable member **114**, but could also form a partial circumference, spiral configuration, or consist of random projections on the surface of the inflatable member **118**. The rib members **125** should extend radially about 1 to about 4 mm from the nominal surface of the inflatable member **114**, and are preferably spaced about 3 to about 8 mm from each other. The rib members **125** may be made from any suitable polymer material, but are preferably made from the same material as the inflatable member, and are integrally molded thereon, or bonded thereto with a heat weld or adhesive bond suitable for bonding flexibly medical polymers. The inflatable member **114** is depicted with the distal end of the delivery catheter **112** and detachment mechanism **113** attached. As an alternative, or in addition to the polymer rib members **125** shown in **FIG. 15**, barbs or hooks could be secured to the outside surface of the inflatable member **114** which are configured to engage the inside surface of a patient's LAA **124**. Preferably, barbs or hooks disposed on the outside surface of the inflatable member and configured to engage the tissue of the inside surface of a patient's LAA **124** would have a proximally directed bias at their radial extremity so that the barbs would fold down and move easily in a distal direction during insertion of the inflatable member **114**, but would spring outward and aggressively engage the tissue of the body cavity upon movement in a proximal direction of the inflatable member.

[0069] **FIG. 16** depicts an occluding device **110** consisting of an inflatable member **114** which is shown deployed within a patient's LAA **123**. The embodiment of the inflatable member **114** shown in **FIG. 16** has an optional retention member **127** with a tissue penetrating shaft **128** which has a proximal **131** end and a distal end **132**. A rotational coupling **133** is disposed at the proximal end **131** of the tissue penetrating shaft **128** and a helically shaped extremity **134** is disposed at the distal end of the shaft **132**. The helically shaped distal extremity **134** is shown deployed within and mechanically engaging wall tissue **135** of the LAA so as to secure the inflatable member **114** and maintain its position within the LAA **123** of the patient.

[0070] **FIG. 17** shows an alternative embodiment of an occlusive member **140** consisting of a polymer mass **141** which has been injected or delivered into a patient's LAA **142**. The distal end **143** of a delivery catheter **144** has a lumen **145** therein which extends to a proximal end of the delivery catheter which is in fluid communication with a source of pressurized polymer material. A source of pressurized polymer material **146** can be any type of pump or device capable of forcing a polymer fluid or gel into the proximal end of the delivery catheter with sufficient pressure to force the polymer fluid or gel out the distal end **143** of the delivery catheter **144** and into a patient's body cavity or passageway. The delivery catheter **144** may be positioned by the techniques discussed above, e.g., the Mullins trans-septal approach or any other suitable method. Once the distal end of the delivery catheter **143** is disposed within a desired portion of the patient's LAA **142**, the polymer mass **141** may be injected to fill the cavity to the desired level. The LAA **142** can be completely or partially filled with the polymer mass **141** which can be formulated to harden over time, with heat or remain in a fluid or gel state. The distal end of the delivery catheter can optionally include an expandable member which is used to substantially seal the delivery catheter against the inside surface of the opening of the patient's body cavity during the delivery of polymer material. The expandable member can be an inflatable balloon or the like which are well known in the art.

[0071] Optionally, a retention member **127** having a tissue penetrating shaft **128** or the like, such as shown in **FIG. 16** with regard to the inflatable member **114**, may be deployed within the LAA **142** prior to injection of the polymer mass **141** and captured thereby so as to secure the polymer mass within the LAA. Alternatively, the polymer mass can be used to fill the patient's LAA and surround and secure a deployed device as shown in **FIG. 4** or **5** in the patient's LAA **142**.

[0072] Once a desired amount of polymer mass **141** has been injected into the LAA **142**, as assessed for example by TE Echo imaging, the delivery catheter **144** may be withdrawn and the procedure terminated. Preferably, the entire LAA **142** of a patient is filled with the polymer mass **141** as shown in **FIG. 18** and hardens or gels to maintain its shape. It may be desirable to have the polymer mass **141** retain a soft compressible form after setting or hardening so that it is at least partially compliant with the constrictive pumping action of a heart and resistant to fatigue as a result thereof. A material used to form the polymer mass **141** may contain contrast agents such as gold, platinum, tantalum, bismuth or the like in order to better visualize the deployment of the polymer mass under fluoroscopic or x-ray imaging.

[0073] Another alternative embodiment of an occlusive member **140** can be found in **FIG. 19** which shows an occlusive coil **147** which has been deployed within an LAA **142**. The occlusive coil **147** as shown has assumed a random configuration that is mechanically occluding the LAA **142** and which has induced clot and/or fibrosis formation **148** which further facilitates occlusion of the LAA **142**.

[0074] An apparatus for closing off a body cavity or passageway **150** is shown in **FIG. 20** which has features of the present invention. The apparatus **150** has an elongate shaft **151** with an inner lumen **152** and a proximal end **153** and a distal end **154**. Slideably disposed within the inner lumen **152** of the elongate shaft **151** are at least two elongate members **155** which have proximal ends **156** and distal ends **157** and have tissue attachment members **158** disposed on the distal ends. An optional distal anchor member **161** is also slideably disposed within the inner lumen **152** of the elongate shaft **151** and preferably has a distal end **162** terminating with a helical member **163**. The proximal end **153** of the elongate shaft **151** has a proximal control module **164** which seals the inner lumen **152** of the elongate shaft **151** and allows rotation and translation of the proximal ends **156** of the elongate members **155** and the distal anchor member **161** while maintaining a seal between said members to prevent leakage of bodily fluids therefrom. The proximal control module **164** can optionally be configured to control advancement and retraction of the elongate members **155** and control activation of the tissue attachment members **158**.

[0075] **FIG. 21** shows the apparatus for closing off a body cavity **150** of **FIG. 20** with the distal ends of the elongate members **157** and the tissue attachment members **158** extending distally from the distal end of the elongate shaft **154**. The distal ends of the elongate members **157** are angled or deflected from a longitudinal axis **165** of the elongate shaft **151** so as to engage tissue **166** of the opening **167** of the LAA **168** as shown. The elongate members **155** may be deflected by an abutment or angulation contained in the distal end of the elongate shaft **154**, but are preferably preshaped in an angled configuration which manifests when the distal ends are freed of the constraint of the inner lumen **152** of the elongate shaft an allowed to assume their relaxed preshaped condition. The helical member **163** at the distal end **162** of the distal anchor member **161** is engaged with the wall tissue **171** of the LAA **168** so as to provide an optional anchor that can be used to move the elongate shaft **151** relative to the distal anchor member **161** and give greater control of the longitudinal axial movement of the elongate shaft relative to the LAA opening **167**. The tissue attachment members **158** are shown attached to the annular edge **172** of the LAA opening **167**. Once the tissue attachment members **158** are attached, a closure member or retaining ring **173** may be advanced distally by applying axial force on an elongate push shaft **174** which draws the tissue attachment members **158** and the tissue attached thereto closer together as shown in **FIG. 22**. As the closure member **173** is further advanced distally, the annular edge of the LAA **172** is drawn closed, and eventually, the annular edge of the LAA will be completely closed into a closed state with the closure member **173** surrounding and compressing the tissue of the annular edge as shown in **FIG. 23**. Once a closed state of the LAA is achieved, the tissue attachment members **158** may be detached, and the apparatus for closing off a body cavity **150** withdrawn. One alternative method can have the tissue attachment members **158** drawn together by retracting them proximally into the distal end **154** of the elongate shaft **151** as opposed to distally advancing the closure member **173** with the elongate push shaft **174**. In this way, the annular edge of the LAA **172** can be drawn into a closed state within the distal end **154** of the elongate shaft **151** at which point the annular edge may be fixed in the closed state by a variety of methods including suturing, tissue welding, the application of a suitable biocompatible adhesive, surgical staples or the like.

[0076] Referring to **FIGS. 24 and 25**, there is illustrated an alternate embodiment of the occlusion device **10** in accordance with the present invention. The occlusion device **10** comprises an occluding member **11** comprising a frame **14** and a barrier **15**. In the illustrated embodiment, the frame **14** comprises a plurality of radially outwardly extending spokes **17** each having a length within the range of from about 0.5 cm to about 2 cm from a hub **16**. In one embodiment, the spokes have an axial length of about 1.5 cm. Depending upon the desired introduction crossing profile of the collapsed occlusion device **10**, as well as structural strength requirements in the deployed device, anywhere within the range of from about 3 spokes to about 40 spokes may be utilized. In some embodiments, anywhere from about 12 to about 24 spokes are utilized, and, 18 spokes are utilized in one embodiment.

[0077] The spokes are advanceable from a generally axially extending orientation such as to fit within a tubular introduction catheter to a radially inclined orientation as illustrated in **FIG. 24** and **FIG. 25** following deployment from the catheter. In a self-expandable embodiment, the spokes are biased radially outwardly such that the occlusion member expands to its enlarged, implantation cross-section under its own bias following deployment from the catheter. Alternatively, the occlusion member may be enlarged using any of a variety of enlargement structures such as an inflatable balloon.

[0078] Preferably, the spokes comprise a metal such as stainless steel, Nitinol, Elgiloy, or others which can be determined through routine experimentation by those of skill in the art. Wires having a circular or rectangular cross-section may be utilized depending upon the manufacturing technique. In one embodiment, rectangular cross section spokes are cut such as by known laser cutting techniques from tube stock, a portion of which forms the hub **16**.

[0079] The barrier **15** may comprise any of a variety of materials which facilitate cellular in-growth, such as ePTFE. The suitability of alternate materials for barrier **15** can be determined through routine experimentation by those of skill in the art. The barrier **15** may be provided on either one or both sides of the occlusion member. In one embodiment, the barrier **15** comprises two layers, with one layer on each side of the frame **14**. The two layers may be bonded to each other around the spokes **17** in any of a variety of ways, such as by heat bonding with or without an intermediate bonding layer such as polyethylene or FEP, adhesives, sutures, and other techniques which will be apparent to those of skill in the art in view of the disclosure herein. The barrier **15** preferably has a thickness of no more than about 0.003" and a porosity within the range of from about 5 Pm to about 60 Pm.

[0080] The barrier **15** in one embodiment preferably is securely attached to the frame **14** and retains a sufficient porosity to facilitate cellular ingrowth and/or attachment. One method of manufacturing a suitable composite membrane barrier **15** is illustrated in FIGS. **36-39**. As illustrated schematically in **FIG. 36, a** bonding layer **254** preferably comprises a mesh or other porous structure having an open surface area within the range of from about 10% to about 90%. Preferably, the open surface area of the mesh is within the range of from about 30% to about 60%. The opening or pore size of the bonding layer **254** is preferably within the range of from about 0.005 inches to about 0.050 inches, and, in one embodiment, is about 0.020 inches. The thickness of the bonding layer **254** can be varied widely, and is generally within the range of from about 0.0005 inches to about 0.005 inches. In a preferred embodiment, the bonding layer **254** has a thickness of about 0.001 to about 0.002 inches. One suitable polyethylene bonding mesh is available from Smith and Nephew, under the code SN9.

[0081] Referring to **FIG. 37**, the bonding layer **254** is preferably placed adjacent one or both sides of a spoke or other frame element **14**. The bonding layer **254** and frame **14** layers are then positioned in-between a first membrane **250** and a second membrane **252** to provide a composite membrane stack. The first membrane **250** and second **252** may comprise any of a variety of materials and thicknesses, depending upon the desired functional result. Generally, the membrane has a thickness within the range of from about 0.0005 inches to about 0.010 inches. In one embodiment, the membranes **250** and **252** each have a thickness on the order of from about 0.001 inches to about 0.002 inches, and comprise porous ePTFE, having a porosity within the range of from about 10 microns to about 100 microns.

[0082] The composite stack is heated to a temperature of from about 200° to about 300°, for about 1 minute to about 5 minutes under pressure to provide a finished composite membrane assembly with an embedded frame **14** as illustrated schematically in **FIG. 38**. The final composite membrane has a thickness within the range of from about 0.001 inches to about 0.010 inches, and, preferably, is about 0.002 to about 0.003 inches in thickness. However, the thicknesses and process parameters of the foregoing may be varied considerably, depending upon the materials of the bonding layer **254** the first layer **250** and the second layer **252**.

[0083] As illustrated in top plan view in **FIG. 39**, the resulting finished composite membrane has a plurality of "unbonded" windows or areas **256** suitable for cellular attachment and/or ingrowth. The attachment areas **256** are bounded by the frame **14** struts, and the cross-hatch pattern formed by the bonding layer **254**. In the illustrated embodiment, the filaments of the bonding layer **254** are oriented in a nonparallel relationship with the struts of frame **14**, and, in particular, at an angle within the range of from about 15° to about 85° from the longitudinal axis of the struts. Preferably, a regular window **256** pattern is produced.

[0084] The foregoing procedure allows the bonding mesh to flow into the first and second membranes **250** and **252** and gives the composite membrane **15** greater strength (both tensile and tear strength) than the components without the bonding mesh. The composite allows uniform bonding while maintaining porosity of the membrane **15**, to facilitate tissue attachment. By flowing the thermoplastic bonding layer into the pores of the outer mesh layers **250** and **252**, the composite flexibility is preserved and the overall composite layer thickness can be minimized.

[0085] The occlusion device **10** may be further provided with a bulking element or stabilizer **194**. The stabilizer **194** may be spaced apart along an axis from the occluding member **11**. In the illustrated embodiment, a distal end **190** and a proximal end **192** are identified for reference. The designation proximal or distal is not intended to indicate any particular anatomical orientation or deployment orientation within the deployment catheter. As shown in **FIGS. 24 and 25**, the stabilizer **194** is spaced distally apart from the occluding member **11**.

[0086] For use in the LAA, the occluding member **11** has an expanded diameter within the range of from about 1 cm to about 5 cm, and, in one embodiment, about 3 cm. The axial length of the occluding member **11** in an expanded, unstressed orientation from the distal end **192** to the proximal hub **16** is on the order of about 1 cm. The overall length of the occlusion device **10** from the distal end **192** to the proximal end **190** is within the range of from about 1.5 cm to about 4 cm and, in one embodiment, about 2.5 cm. The axial length of the stabilizer **194** between distal hub **191** and proximal hub **16** is within the range of from about 0.5 cm to about 2 cm, and, in one embodiment, about 1 cm. The expanded diameter of the stabilizer **194** is within the range of from about 0.5 cm to about 2.5 cm, and, in one embodiment, about 1.4 cm. The outside diameter of the disial hub **191** and proximal hub **16** is about 2.5 mm.

[0087] Preferably, the occlusion device **10** is provided with one or more retention structures for retaining the device in the left atrial appendage or other body lumen. In the illustrated embodiment, a plurality of barbs or other anchors **195** are provided, for engaging adjacent tissue to retain the occlusion device **10** in its implanted position and to limit relative movement between the tissue and the occlusion device. The illustrated anchors are provided on one or more of the spokes **17**, or other portion of frame **14**. Preferably, every spoke, every second spoke or every third spoke are provided with one or two anchors each. The illustrated anchor is in the form of a barb, for extending into tissue at or near the opening of the LAA.

[0088] One or more anchors **195** may also be provided on the stabilizer **194**, such that it assists not only in orienting the occlusion device **10** and resisting compression of the LAA, but also in retaining the occlusion device **10** within the LAA. Any of a wide variety of structures may be utilized for anchor **195**, either on the occluding member **11** or the stabilizer **194** or both, such as hooks, barbs, pins, sutures, adhesives and others which will be apparent to those of skill in the art in view of the disclosure herein.

[0089] In use, the occlusion device **10** is preferably positioned within a tubular anatomical structure to be occluded such as the left atrial appendage such that the occluding member **11** is positioned across or near the opening to the LAA and the stabilizer **194** is positioned within the LAA. The stabilizer **194** assists in the proper location and orientation of the occluding member **11**, as well as resists compression of the LAA behind the occluding member **11**. The present inventors have determined that following deployment of an occluding member **11** without a stabilizer **194** or other bulking structure to resist compression of the

LAA, normal operation of the heart may cause compression and resulting volume changes in the LAA, thereby forcing fluid past the occluding member **11** and inhibiting or preventing a complete seal. Provision of a stabilizer **194** dimensioned to prevent the collapse or pumping of the LAA thus minimize leakage, and provision of the barbs facilitates endothelialization or other cell growth across the occluding member **11**.

[**0090**] For this purpose, the stabilizer **194** is preferably movable between a reduced cross-sectional profile for transluminal advancement into the left atrial appendage, and an enlarged cross-sectional orientation as illustrated to fill or to substantially fill a cross-section through the LAA. The stabilizing member may enlarge to a greater cross section than the anatomical cavity, to ensure a tight fit and minimize the likelihood of compression. One convenient construction includes a plurality of elements **196** which are radially outwardly expandable in response to axial compression of a distal hub **191** towards a proximal hub **16**. Elements **196** each comprise a distal segment **198** and a proximal segment **202** connected by a bend **200**. The elements **196** may be provided with a bias in the direction of the radially enlarged orientation as illustrated in **FIG. 25**, or may be radially expanded by applying an expansion force such as an axially compressive force between distal hub **191** and proximal hub **16** or a radial expansion force such as might be applied by an inflatable balloon. Elements **196** may conveniently be formed by laser cutting the same tube stock as utilized to construct the distal hub **191**, proximal hub **16** and frame **14**, as will be apparent to those of skill in the art in view of the disclosure herein. Alternatively, the various components of the occlusion device **10** may be separately fabricated or fabricated in subassemblies and secured together during manufacturing.

[**0091**] As a post implantation step for any of the occlusion devices disclosed herein, a radiopaque dye or other visualizable media may be introduced on one side or the other of the occlusion device, to permit visualization of any escaped blood or other fluid past the occlusion device. For example, in the context of a left atrial appendage application, the occlusion device may be provided with a capillary tube or aperture which permit introduction of a visualizable dye from the deployment catheter through the occlusion device and into the entrapped space on the distal side of the occlusion device. Alternatively, dye may be introduced into the entrapped space distal to the occlusion device such as by advancing a small gauge needle from the deployment catheter through the barrier **15** on the occlusion device, to introduce dye.

[**0092**] A further embodiment of the occlusion device **10** is illustrated in FIGS. **26**-**27**. The occlusion device **10** comprises an occlusion member **11** and a stabilizing member **194** as in the previous embodiment. In the present embodiment, however, each of the distal segments **198** inclines radially outwardly in the proximal direction and terminates in a proximal end **204**. The proximal end **204** may be provided with atraumatic configuration, for pressing against, but not penetrating, the wall of the left atrial appendage or other tubular body structure. Three or more distal segments **198** are preferably provided, and generally anywhere within the range of from about 6 to about 20 distal segments **198** may be used. In one embodiment, 9 distal segments **198** are provided. In this embodiment, 3 of the distal segments **198** have an axial length of about 5 mm, and 6 of the distal segments **198** have an axial length of about 1 cm. Staggering the lengths of the proximal segments **198** may axially elongate the zone in the left atrial appendage against which the proximal ends **204** provide anchoring support for the occlusion device.

[**0093**] The occlusion device **10** illustrated in **FIGS. 26 and 27** is additionally provided with a hinge **206** to allow the longitudinal axis of the occlusion member **11** to be angularly oriented with respect to the longitudinal axis of the stabilizing member **194**. In the illustrated embodiment, the hinge **206** is a helical coil, although any of a variety of hinge structures can be utilized. The illustrated embodiment may be conveniently formed by laser cutting a helical slot through a section of the tube from which the principal structural components of the occlusion device **10** are formed. At the distal end of the hinge **206**, an annular band **208** connects the hinge **206** to a plurality of axially extending struts **210**. In the illustrated embodiment **210**, three axial struts **210** are provided, spaced equilaterally around the circumference of the body. Axial struts **210** may be formed from a portion of the wall of the original tube stock, which portion is left in its original axial orientation following formation of the distal segments **198** such as by laser cutting from the tubular wall.

[**0094**] The occlusion member **11** is provided with a proximal zone **212** on each of the spokes **17**. Proximal zone **212** has an enhanced degree of flexibility, to accommodate the fit between the occlusion member **11** and the wall of the left atrial appendage. Proximal section **212** may be formed by reducing the cross sectional area of each of the spokes **17**, or by increasing the length of each spoke by making a wave pattern as illustrated.

[**0095**] Each of the spokes **17** terminates in a proximal point **214**. Proximal point **214** may be contained within layers of the barrier **15**, or may extend through or beyond the barrier **15** such as to engage adjacent tissue and assist in retaining the occlusion device **10** at the deployment site.

[**0096**] Referring to **FIGS. 28 and 29**, a further variation on the occlusion device **10** illustrated in **FIGS. 24 and 25** is provided. The occlusion device **10** is provided with a proximal face **216** on the occlusion member **11**, instead of the open and proximally concave face on the embodiment of **FIGS. 24 and 25**. The proximal face **216** is formed by providing a proximal spoke **218** which connects at an apex **220** to each distal spoke **17**. Proximal spokes **218** are each attached to a hub **222** at the proximal end **192** of the occlusion device **10**. The barrier **15** may surround either the proximal face or the distal face or both on the occlusion member **11**. In general, provision of a proximal spoke **218** connected by an apex **220** to a distal spoke **17** provides a greater radial force than a distal spoke **17** alone, which will provide an increased resistance to compression if the occlusion member **11** is positioned with the LAA.

[**0097**] Referring to FIGS. **30**-**35**, an alternate embodiment of the occlusion device in accordance with the present invention is illustrated. In general, the occlusion device **10** comprises an occluding member but does not include a distinct stabilizing member as has been illustrated in connection with previous embodiments. Any of the embodiments previously disclosed herein may also be constructed using the occluding member only, and omitting the stabilizing member as will be apparent to those of skill in the art in view of the disclosure herein.

[0098] The occluding device **10** comprises a proximal end **192**, a distal end **190**, and a longitudinal axis extending therebetween. A plurality of supports **228** extend between a proximal hub **222** and a distal hub **191**. At least two or three supports **228** are provided, and preferably at least about six. In one embodiment, eight supports **228** are provided. However, the precise number of supports **228** can be modified, depending upon the desired physical properties of the occlusion device **10** as will be apparent to those of skill in the art in view of the disclosure herein, without departing from the present invention.

[0099] Each support **228** comprises a proximal spoke portion **218**, a distal spoke portion **217**, and an apex **220** as has been discussed. However, each of the proximal spoke **218**, distal spoke **17** and apex **220** may be a region on an integral support **228**, such as a continuous rib or frame member which extends in a generally curved configuration as illustrated with a concavity facing towards the longitudinal axis of the occlusion device **10**. Thus, no distinct point or hinge at apex **220** is necessarily provided as is disclosed in previous embodiments, which include a hinged connection between proximal spoke **218** and distal spoke **17**.

[0100] At least some of the supports **228**, and, preferably, each support **228**, is provided with one or two or more barbs **195**. In the illustrated configuration, the occlusion device **10** is in its enlarged orientation, such as for occluding a left atrial appendage or other body cavity or lumen. In this orientation, each of the barbs **195** projects generally radially outwardly from the longitudinal axis, and are inclined in the proximal direction. In an embodiment where the barbs **195** and corresponding support **228** are cut from a single ribbon, sheet or tube stock, the barb **195** will incline radially outwardly at approximately a tangent to the curve formed by the support **228**.

[0101] The occlusion device **10** illustrated in **FIG. 30** may be constructed in any of a variety of ways, as will become apparent to those of skill in the art in view of the disclosure herein. In one preferred method, the occlusion device **10** is constructed by laser cutting a piece of tube stock to provide a plurality of axially extending slots in-between adjacent supports **228**. Similarly, each barb **195** can be laser cut from the corresponding support **228** or space in-between adjacent supports **228**. The generally axially extending slots which separate adjacent supports **228** end a sufficient distance from each of the proximal end **192** and distal end **190** to leave a proximal hub **222** and a distal hub **191** to which each of the supports **228** will attach. In this manner, an integral cage structure may be formed. Alternatively, each of the components of the cage structure may be separately formed and attached together such as through soldering, heat bonding, adhesives, and other fastening techniques which are known in the art. A further method of manufacturing the occlusion device **10** is to laser cut a slot pattern on a flat sheet of appropriate material, such as a flexible metal or polymer, as has been discussed in connection with previous embodiments. The flat sheet may thereafter be rolled about an axis and opposing edges bonded together to form a tubular structure.

[0102] The apex portion **220** which carries the barb **195** may be advanced from a low profile orientation in which each of the supports **228** extend generally parallel to the longitudinal axis, to an implanted orientation as illustrated, in which the apex **220** and the barb **195** are positioned radially outwardly from the longitudinal axis. The support **228** may be biased towards the enlarged orientation, or may be advanced to the enlarged orientation following positioning within the tubular anatomical structure, in any of a variety of manners. For example, referring to **FIG. 32**, an inflatable balloon **230** is positioned within the occlusion device **10**. Inflatable balloon **230** is connected by way of a removable coupling **232** to an inflation catheter **234**. Inflation catheter **234** is provided with an inflation lumen for providing communication between an inflation media source **236** outside of the patient and the balloon **230**. Following positioning within the target body lumen, the balloon **230** is inflated, thereby engaging barbs **195** with the surrounding tissue. The inflation catheter **234** is thereafter removed, by decoupling the removable coupling **232**, and the inflation catheter **234** is thereafter removed.

[0103] In an alternate embodiment, the supports **228** are radially enlarged such as through the use of a deployment catheter **238**. Deployment catheter **238** comprises a lumen for movably receiving a deployment line **240**. Deployment line **240** extends in a loop **244** formed by a slip knot **242**. As will be apparent from **FIG. 33**, proximal retraction on the deployment line **240** will cause the distal hub **191** to be drawn towards the proximal hub **222**, thereby radially enlarging the cross-sectional area of the occlusion device **10**. Depending upon the material utilized for the occlusion device **10**, the supports **228** will retain the radially enlarged orientation by elastic deformation, or may be retained in the enlarged orientation such as by securing the slip knot **242** immovably to the deployment line **240** at the fully radially enlarged orientation. This may be accomplished in any of a variety of ways, using additional knots, clips, adhesives, or other techniques known in the art.

[0104] Referring to **FIGS. 34A and 34B**, the occlusion device **10** may be provided with a barrier **15** such as a mesh or fabric as has been previously discussed. Barrier **15** may be provided on only one hemisphere such as proximal face **216**, or may be carried by the entire occlusion device **10** from proximal end **192** to distal end **190**. The barrier may be secured to the radially inwardly facing surface of the supports **228**, as illustrated in **FIG. 34**B, or may be provided on the radially outwardly facing surfaces of supports **228**, or both.

[0105] A further embodiment of the occlusion device **10** is illustrated in **FIG. 35**, in which the apex **220** is elongated in an axial direction to provide additional contact area between the occlusion device **10** and the wall of the tubular structure. In this embodiment, one or two or three or more anchors **195** may be provided on each support **228**, depending upon the desired clinical performance. The occlusion device **10** illustrated in **FIG. 35** may also be provided with any of a variety of other features discussed herein, such as a partial or complete barrier **15** covering. In addition, the occlusion device **10** illustrated in **FIG. 35** may be enlarged using any of the techniques disclosed elsewhere herein.

[0106] While particular forms of the invention have been described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed:

1. A method of containing embolic material within a left atrial appendage of a patient, comprising:

a) providing a containment device comprising a barrier for preventing the escape of embolic material from the left atrial appendage;

b) providing a delivery catheter having a proximal end and a distal end;

c) advancing the delivery catheter through the patient's vasculature to position the containment device within the patient's left atrium; and

d) deploying the containment device such that the barrier substantially obstructs the passage of embolic material from the left atrial appendage.

2. A method of containing embolic material as in claim 1, wherein the barrier comprises a mesh.

3. A method of containing embolic material as in claim 1, wherein the barrier comprises polyethylene.

4. A method of containing embolic material as in claim 2, wherein the mesh comprises polyethylene.

5. A method of containing embolic material as in claim 1, wherein the barrier comprises a polymer film.

6. A method of containing embolic material as in claim 1, wherein the barrier comprises a polymer mesh.

7. A method of containing embolic material as in claim 1, wherein the barrier comprises a nickel titanium alloy.

8. A method of containing embolic material as in claim 1, wherein the barrier comprises stainless steel.

9. A method of containing embolic material as in claim 1, wherein the barrier comprises ePTFE.

10. A method of containing embolic material as in claim 1, wherein the barrier comprises Dacron.

11. A method of containing embolic material as in claim 1, where the barrier comprises nylon.

12. A method of containing embolic material as in claim 1, wherein the barrier has a pore size of no greater than about 0.04 inches.

13. A method of containing embolic material as in claim 1, further comprising the step of removing thrombotic or fibrotic material from the patient's left atrial appendage prior to deployment of the containment device.

14. A method of containing embolic material as in claim 13, wherein the thrombotic or fibrotic material is removed from the patient's left atrial appendage by aspiration through an aspiration lumen of a catheter having a port in the distal end thereof in fluid communication with the aspiration lumen which is operatively connected at its proximal end to a vacuum source.

15. A method of containing embolic material as in claim 1, wherein the containment device comprises an expandable member configured to engage an inside surface of the left atrial appendage and the containment device is at least partially deployed by expanding the expandable member within the left atrial appendage so as to engage at least a portion of an inner surface of the left atrial appendage.

16. A method of containing embolic material as in claim 1, wherein the barrier comprises a self expandable frame.

17. A method of containing embolic material as in claim 16, further comprising a mesh on the frame.

18. A method of containing embolic material as in claim 17, wherein the mesh comprises a polymer selected from the group consisting of Dacron, Nylon, TFE, PTFE, ePTFE, polyethylene and polyurethane.

19. A method of containing embolic material as in claim 1, wherein the containment device is self expandable.

20. A method of containing embolic material as in claim 1, wherein the containment device comprises a self expandable wire structure.

21. A method of containing embolic material as in claim 1, wherein the advancing step comprises advancing the delivery catheter through the femoral vein.

22. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises wire mesh.

23. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises braided wire.

24. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises wire coil.

25. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises shape memory material.

26. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises pseudoelastic alloy.

27. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises nickel titanium alloy.

28. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises stainless steel.

29. A method of containing embolic material as in claim 20, wherein the self expandable wire structure comprises composite material.

30. A method of treating the left atrial appendage of a patient, comprising the steps of:

providing a delivery catheter having a proximal end and a distal end, and a self expandable wire structure for acting as a barrier to the passage of embolic material from the left atrial appendage, removeably carried by the distal end;

advancing the delivery catheter into the patient's left atrium;

positioning the self expandable wire structure at the left atrial appendage; and

deploying the self expandable wire structure such that it substantially obstructs the passage of embolic material from the left atrial appendage.

31. The method of claim 30, further comprising the step of removing thrombotic or fibrotic material from the patient's left atrial appendage prior to deployment of the self expandable wire structure.

32. The method of claim 31, wherein the thrombotic or fibrotic material is removed from the patient's left atrial appendage by aspiration through an aspiration lumen of a catheter having a port in the distal end thereof in fluid communication with the aspiration lumen which is operatively connected at its proximal end to a vacuum source.

33. The method of claim 30, wherein the deploying step comprises deploying the self expandable wire structure such that it engages at least a portion of an inner surface of the left atrial appendage.

34. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises wire mesh.

35. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises braided wire.

36. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises wire coil.

37. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises shape memory material.

38. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises pseudoelastic alloy.

39. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises nickel titanium alloy.

40. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises stainless steel.

41. A method of treating the left atrial appendage as in claim 30, wherein the self expandable wire structure comprises composite material.

42. A method as in claim 30, further comprising a barrier on the wire structure.

43. A method as in claim 42, wherein the barrier comprises a polymer selected from the group consisting of Dacron, Nylon, TFE, PTFE, ePTFE, polyethylene and polyurethane.

44. A method as in claim 43, wherein the barrier has a pore size of up to about 0.04 inches.

45. A method as in claim 30, wherein the advancing step comprises advancing the delivery catheter through the right femoral vein.

46. A method as in claim 30, wherein the advancing step comprises advancing the delivery catheter to the left atrial appendage intraoperatively.

47. A method as in claim 30, wherein the self expandable wire structure comprises a plurality of tissue engagement members, and the method further comprises the step of engaging tissue with the tissue engagement members.

48. A method as in claim 1, wherein the containment device comprises a plurality of tissue engagement members, and the method further comprises the step of engaging tissue with the tissue engagement members.

* * * * *