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Frazier et al.

(10) **Patent No.:** **US 7,713,282 B2**
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(54) **DETACHABLE ATRIAL APPENDAGE
OCCLUSION BALLOON**

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(73) Assignee: **Atritech, Inc.**, Plymouth, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 881 days.

4,007,743 A	2/1977	Blake	
4,309,776 A	1/1982	Berguer	
4,341,218 A	7/1982	U	
4,364,392 A *	12/1982	Strother et al.	606/195
4,545,367 A *	10/1985	Tucci	128/898
4,603,693 A	8/1986	Conta et al.	
4,611,594 A	9/1986	Grayhack et al.	
4,619,246 A	10/1986	Molgaard-Nielsen et al.	
4,638,803 A *	1/1987	Rand	606/192
4,665,906 A	5/1987	Jervis	

(Continued)

(21) Appl. No.: **10/426,130**

FOREIGN PATENT DOCUMENTS

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WO WO 96/40356 12/1996

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(Continued)

Related U.S. Application Data

OTHER PUBLICATIONS

(63) Continuation-in-part of application No. 09/435,562, filed on Nov. 8, 1999, now Pat. No. 7,128,073, which is a continuation-in-part of application No. 09/187,200, filed on Nov. 6, 1998, now Pat. No. 6,152,144.

PCT Search Report from co-pending Application PCT/US02/33808 dated May 20, 2003.

(Continued)

(51) **Int. Cl.**
A61M 29/00 (2006.01)

Primary Examiner—Anhtuan T Nguyen

(52) **U.S. Cl.** **606/200**

Assistant Examiner—Tuan V Nguyen

(58) **Field of Classification Search** 606/190–200;
128/898; 604/96.01–113

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See application file for complete search history.

(57) **ABSTRACT**

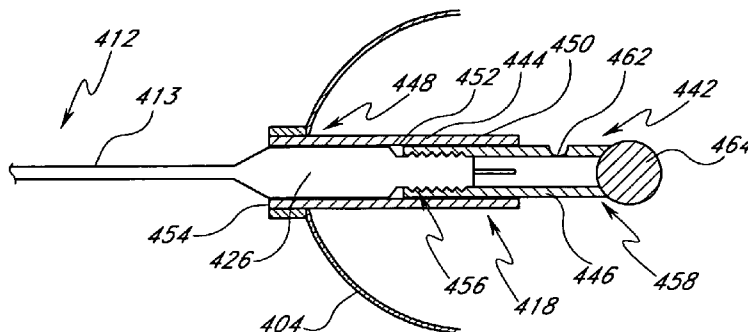
(56) **References Cited**

Disclosed is an adjustable occlusion device for use in a body lumen such as the left atrial appendage. The occlusion device is removably carried by a deployment catheter. The device may be enlarged or reduced to facilitate optimal placement or removal. Methods are also disclosed.

U.S. PATENT DOCUMENTS

3,402,710 A	9/1968	Paleschuck
3,540,431 A	11/1970	Mobin-Uddin
3,638,652 A	2/1972	Kelley
3,844,302 A	10/1974	Klein
3,874,388 A	4/1975	King et al

1 Claim, 18 Drawing Sheets



U.S. PATENT DOCUMENTS							
4,681,588	A	7/1987	Ketharanathan	5,836,968	A	11/1998	Simon et al.
4,710,192	A	12/1987	Liotta et al.	5,843,118	A	12/1998	Sepetka et al.
4,793,348	A	* 12/1988	Palmaz	5,849,005	A	12/1998	Garrison et al.
4,832,055	A	5/1989	Palestrant	5,853,422	A	12/1998	Huebsch et al.
4,917,089	A	4/1990	Sideris	5,865,791	A	2/1999	Wayne et al.
4,921,484	A	5/1990	Hillstead	5,879,366	A	3/1999	Shaw et al.
5,041,090	A	8/1991	Scheglov et al.	5,891,558	A	4/1999	Bell et al.
5,042,707	A	8/1991	Taheri	5,904,680	A	5/1999	Kordis et al.
5,064,435	A	11/1991	Porter	5,906,207	A	5/1999	Shen
5,071,407	A	12/1991	Termin et al.	5,911,734	A	6/1999	Tsugita et al.
5,078,736	A	1/1992	Behl	5,928,260	A	7/1999	Chin et al.
5,098,440	A	3/1992	Hillstead	5,935,145	A	8/1999	Villar et al.
5,108,420	A	4/1992	Marks	5,935,148	A	8/1999	Villar et al.
5,116,360	A	5/1992	Pinchuk et al.	5,951,599	A	9/1999	McCroy
5,122,136	A	6/1992	Guglielmi et al.	5,961,545	A	10/1999	Lentz et al.
5,171,259	A	12/1992	Inoue	5,993,483	A	11/1999	Gianotti
5,176,692	A	* 1/1993	Wilk et al.	6,004,348	A	12/1999	Banas et al.
5,192,301	A	3/1993	Kamiya et al.	6,007,557	A	12/1999	Ambrisco et al.
5,234,458	A	8/1993	Metais	6,013,093	A	1/2000	Nott et al.
5,258,000	A	11/1993	Gianturco	6,024,756	A	2/2000	Huebsch et al.
5,258,042	A	11/1993	Mehta	6,063,070	A	5/2000	Eder
5,284,488	A	2/1994	Sideris	6,076,012	A	6/2000	Swanson et al.
5,304,184	A	4/1994	Hathaway et al.	6,079,414	A	6/2000	Roth
5,306,234	A	4/1994	Johnson	6,080,182	A	6/2000	Shaw et al.
5,334,217	A	8/1994	Das	6,096,053	A	8/2000	Bates
5,350,398	A	9/1994	Pavcnik et al.	6,110,243	A	8/2000	Wnenchak et al.
5,350,399	A	9/1994	Erlebacher et al.	6,124,523	A	9/2000	Banas et al.
5,366,460	A	11/1994	Eberbach	6,132,438	A	10/2000	Fleischman et al.
5,375,612	A	12/1994	Cottenceau et al.	6,135,991	A	10/2000	Muni et al.
5,397,355	A	3/1995	Marin et al.	6,139,573	A	10/2000	Sogard et al.
5,409,444	A	* 4/1995	Kensey et al.	6,152,144	A	* 11/2000	Lesh et al.
5,417,699	A	5/1995	Klein et al.	6,156,055	A	12/2000	Ravenscroft
5,425,744	A	6/1995	Fagan et al.	6,171,329	B1	1/2001	Shaw et al.
5,433,727	A	7/1995	Sideris	6,179,859	B1	1/2001	Bates et al.
5,443,454	A	8/1995	Tanabe et al.	6,214,029	B1	4/2001	Thill et al.
5,443,478	A	8/1995	Purdy	6,231,561	B1	* 5/2001	Frazier et al.
5,451,235	A	9/1995	Lock et al.	6,231,589	B1	5/2001	Wessman et al.
5,464,408	A	11/1995	Duc	6,251,122	B1	6/2001	Tsukernik
5,490,856	A	2/1996	Person et al.	6,258,115	B1	7/2001	Dubrul
5,522,790	A	6/1996	Moll et al.	6,277,138	B1	8/2001	Levinson et al.
5,522,836	A	6/1996	Palermo	6,290,674	B1	9/2001	Roue et al.
5,527,322	A	6/1996	Klein et al.	6,328,727	B1	12/2001	Frazier et al.
5,527,338	A	6/1996	Purdy	6,342,062	B1	1/2002	Suon et al.
5,569,204	A	10/1996	Cramer	6,346,116	B1	2/2002	Brooks et al.
5,614,204	A	3/1997	Cochrum	6,364,895	B1	4/2002	Greenhalgh
5,634,936	A	6/1997	Linden et al.	6,368,338	B1	4/2002	Konya et al.
5,634,942	A	6/1997	Chevillon et al.	6,371,971	B1	4/2002	Tsugita et al.
5,643,282	A	7/1997	Kieturakis	6,375,670	B1	4/2002	Greenhalgh
5,643,292	A	7/1997	Hart	6,391,044	B1	5/2002	Yadav et al.
5,653,690	A	* 8/1997	Booth et al.	6,402,746	B1	6/2002	Wayne et al.
5,669,933	A	9/1997	Simon et al.	6,419,669	B1	7/2002	Frazier et al.
5,693,067	A	12/1997	Purdy	6,440,152	B1	8/2002	Gainor et al.
5,700,285	A	12/1997	Myers et al.	6,443,972	B1	9/2002	Bosma et al.
5,702,421	A	12/1997	Schneidt	6,447,530	B1	9/2002	Ostrovsky et al.
5,709,224	A	1/1998	Behl et al.	6,468,291	B2	10/2002	Bates et al.
5,709,704	A	1/1998	Nott et al.	6,511,496	B1	1/2003	Huter et al.
5,709,707	A	1/1998	Lock et al.	6,517,573	B1	2/2003	Pollock et al.
5,725,552	A	3/1998	Kotula et al.	6,551,303	B1	4/2003	Van Tassel et al.
5,725,568	A	3/1998	Hastings	6,551,344	B2	4/2003	Thill
5,733,294	A	3/1998	Forber et al.	6,558,405	B1	5/2003	McInnes
5,733,302	A	3/1998	Myler et al.	6,562,058	B2	5/2003	Seguin et al.
5,735,290	A	4/1998	Sterman et al.	6,599,308	B2	7/2003	Amplatz
5,749,883	A	5/1998	Halpern	6,652,555	B1	11/2003	VanTassel et al.
5,749,894	A	5/1998	Engelson	6,652,556	B1	11/2003	VanTassel et al.
5,766,219	A	6/1998	Horton	6,689,150	B1	2/2004	VanTassel et al.
5,776,097	A	7/1998	Massoud	6,730,108	B2	5/2004	Van Tassel et al.
5,782,860	A	7/1998	Epstein et al.	6,837,901	B2	1/2005	Rabkin et al.
5,785,679	A	7/1998	Abolfathi et al.	6,855,153	B2	* 2/2005	Saadat
5,800,457	A	9/1998	Gelbfish	6,949,113	B2	9/2005	Van Tassel et al.
5,800,512	A	9/1998	Lentz et al.	6,994,092	B2	* 2/2006	van der Burg et al.
5,830,228	A	11/1998	Knapp et al.	7,011,671	B2	3/2006	Welch
				7,044,134	B2	* 5/2006	Khairkahan et al.
				7,128,073	B1	10/2006	van der Burg et al.

US 7,713,282 B2

2001/0034537	A1	10/2001	Shaw et al.		WO	WO 99/08607	2/1999
2002/0022860	A1*	2/2002	Borillo et al. 606/200		WO	WO 99/44510	10/1999
2002/0035374	A1	3/2002	Borillo et al.		WO	WO 00/16705	3/2000
2002/0062133	A1	5/2002	Gilson et al.		WO	WO 00/27292	5/2000
2002/0138094	A1	9/2002	Borillo et al.		WO	WO 00/67669	11/2000
2002/0138097	A1	9/2002	Ostrovsky et al.		WO	WO 01/15629 A1	3/2001
2003/0023266	A1	1/2003	Borillo et al.		WO	WO 01/30266 A1	5/2001
2003/0057156	A1	3/2003	Peterson et al.		WO	WO 01/30267 A1	5/2001
2003/0181942	A1	9/2003	Sutton et al.		WO	WO 01/30268 A1	5/2001
2003/0220667	A1	11/2003	Van Der Burg et al.		WO	WO 02/15793 A2	2/2002
2004/0098031	A1	5/2004	Van Der Burg et al.		WO	WO 02/24106 A2	3/2002
2005/0004652	A1	1/2005	Van Der Burg et al.		WO	WO 03/032818 A3	4/2003
2005/0113861	A1*	5/2005	Corcoran et al. 606/200				
2005/0203568	A1	9/2005	Van Der Burg et al.				

FOREIGN PATENT DOCUMENTS

WO WO 98/27868 7/1998

OTHER PUBLICATIONS

PCT Search Report from PCT/US99/26325 dated Feb. 15, 2000.

* cited by examiner

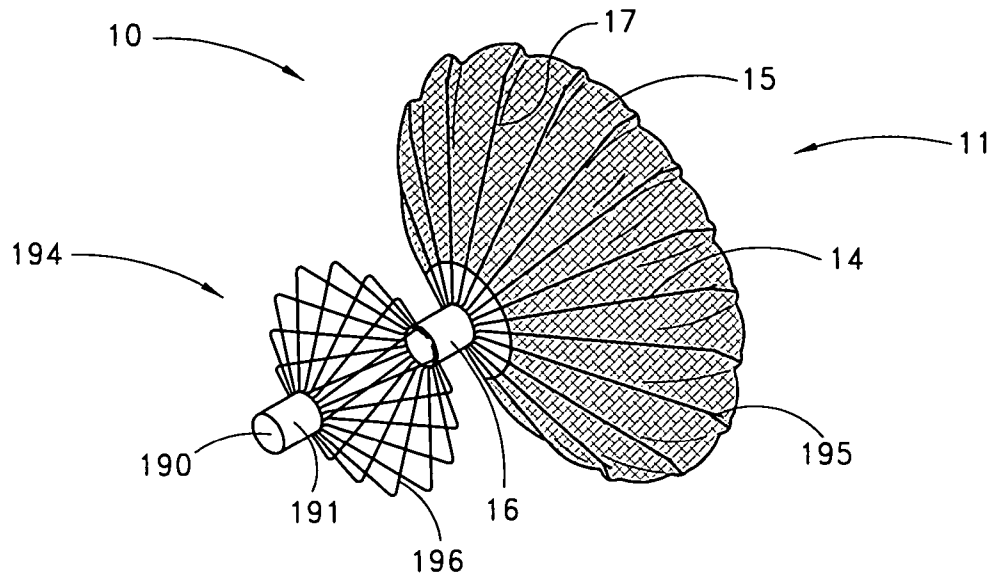


FIG. 1

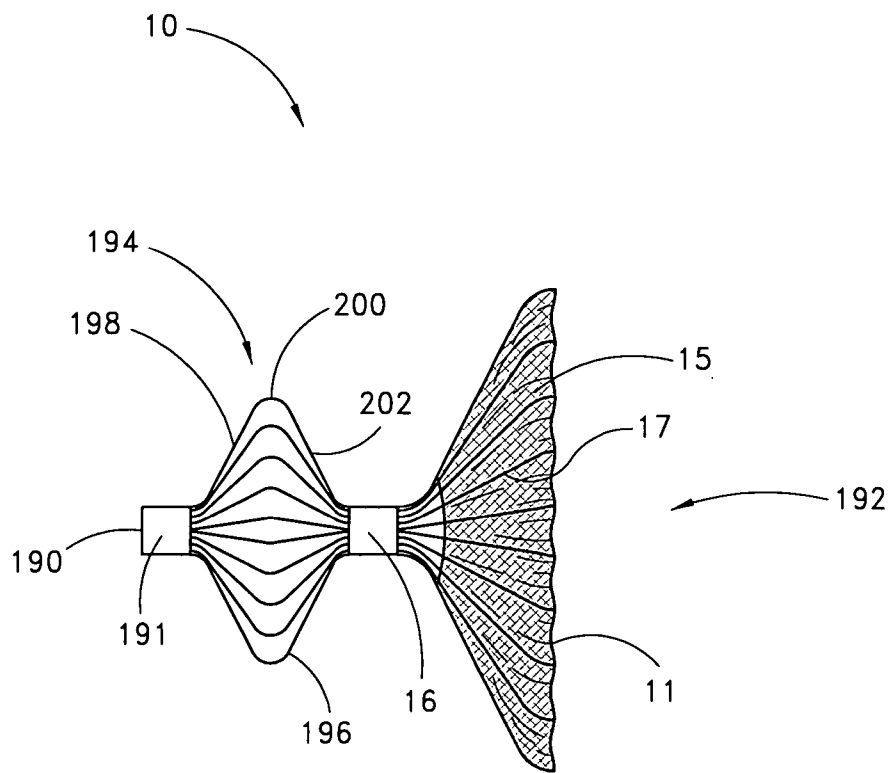


FIG. 2

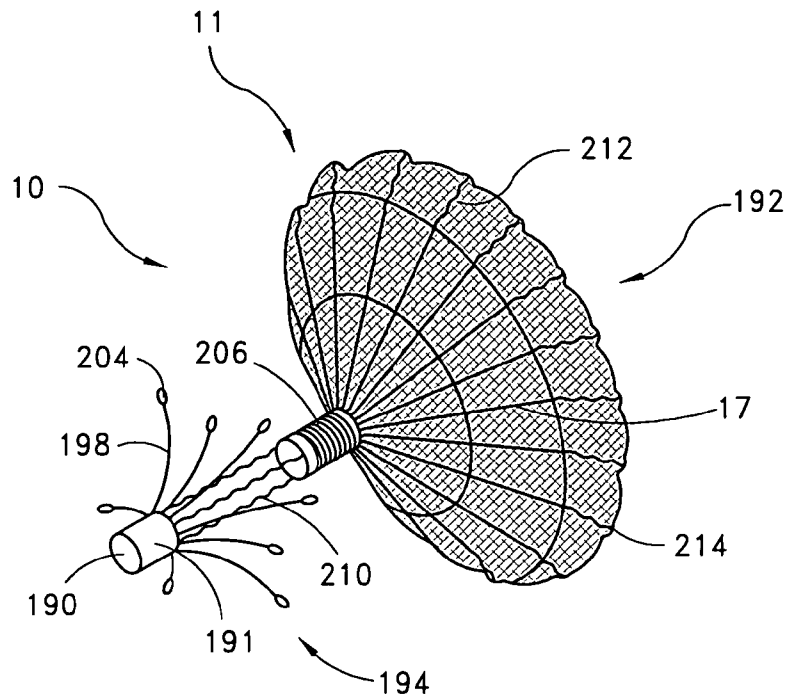


FIG. 3

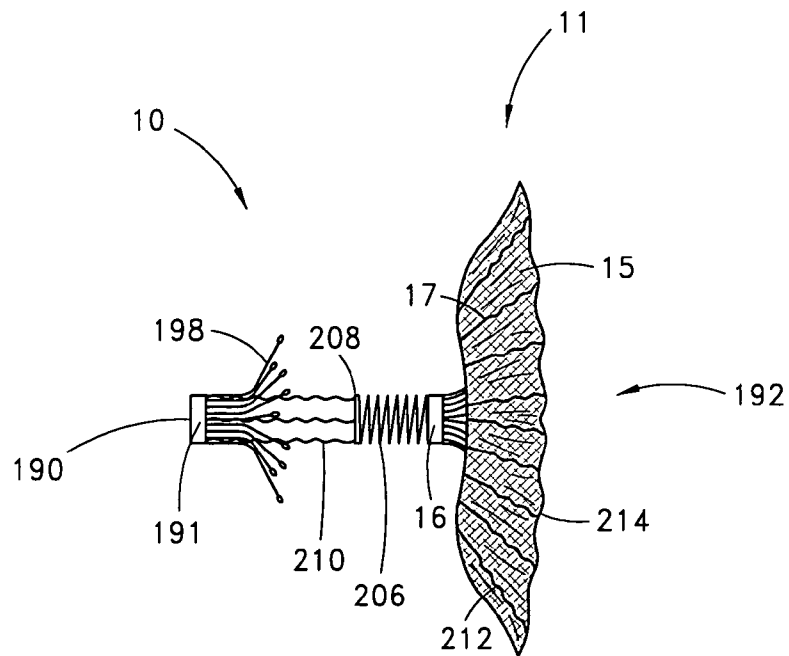


FIG. 4

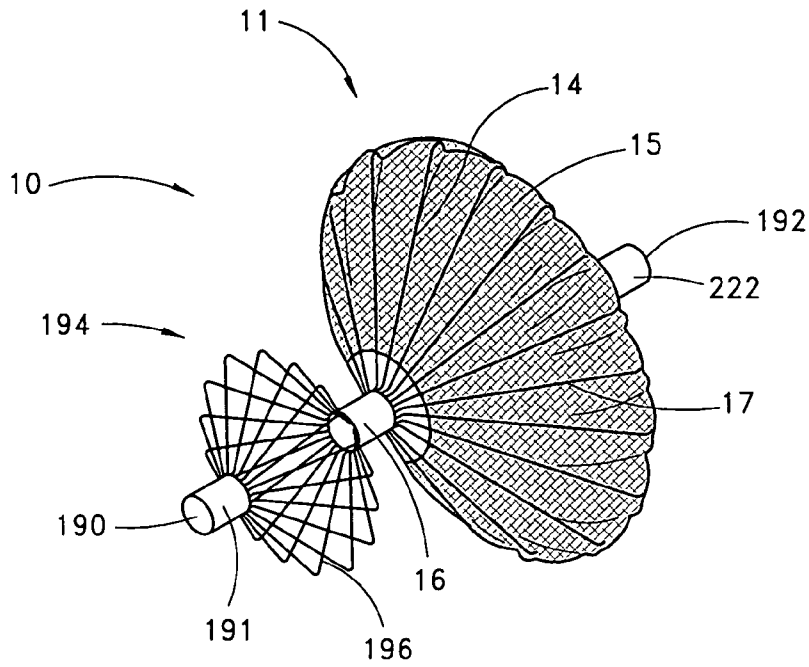


FIG. 5

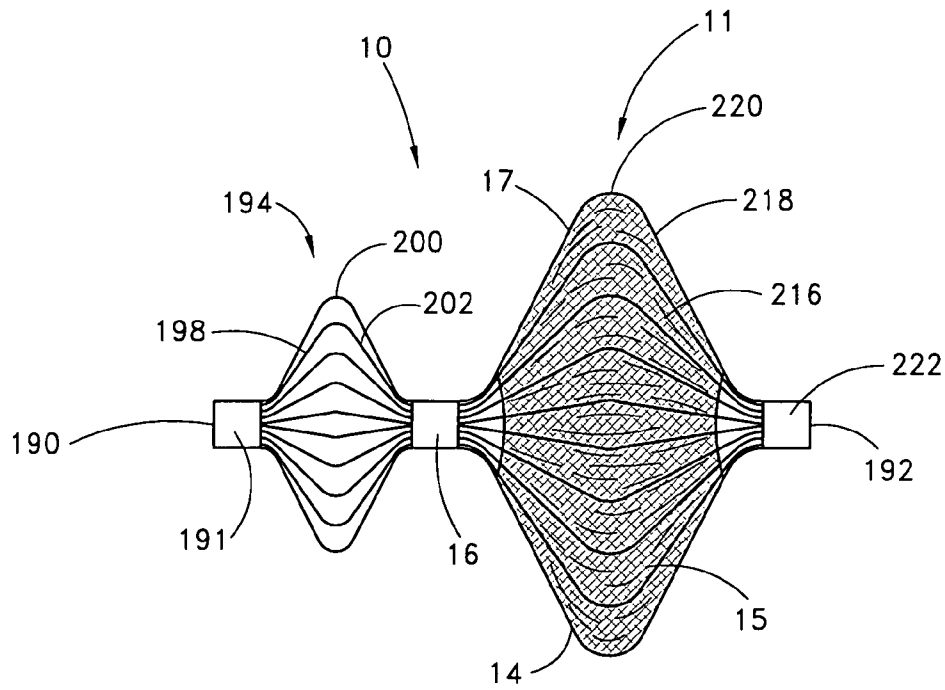


FIG. 6

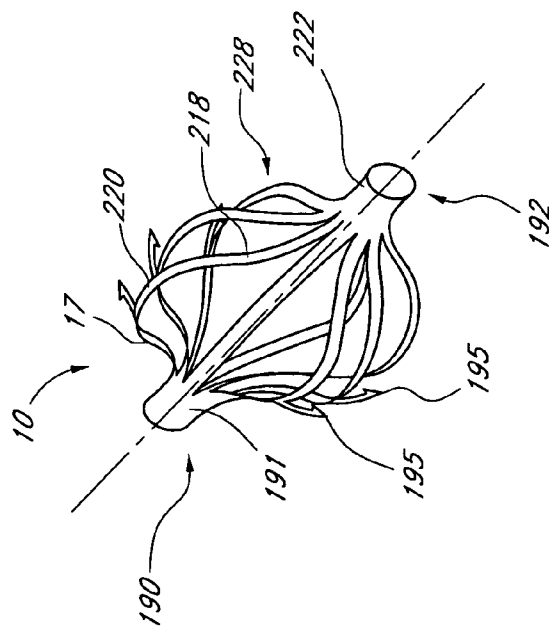
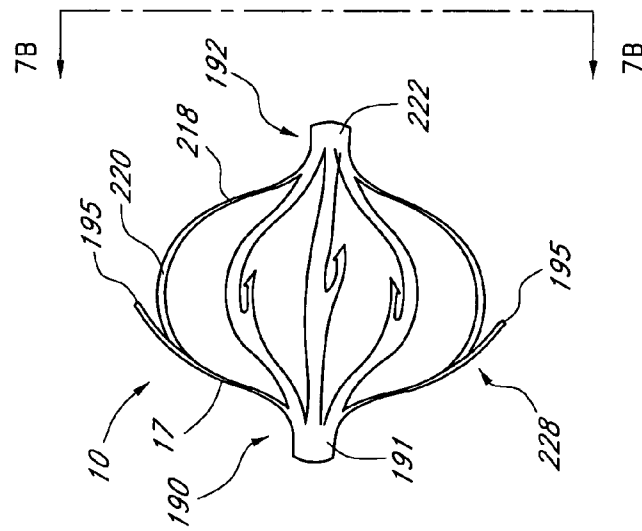
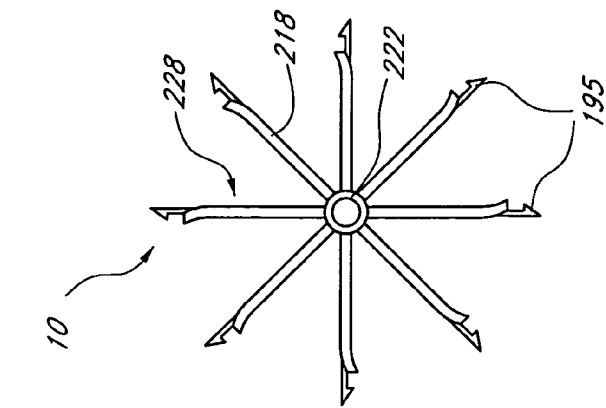


FIG. 7A

FIG. 7B

FIG. 7C

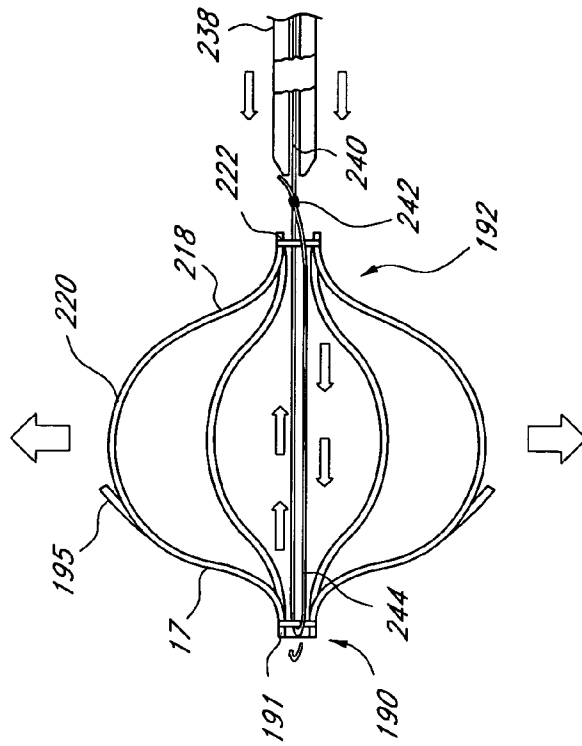


FIG. 9

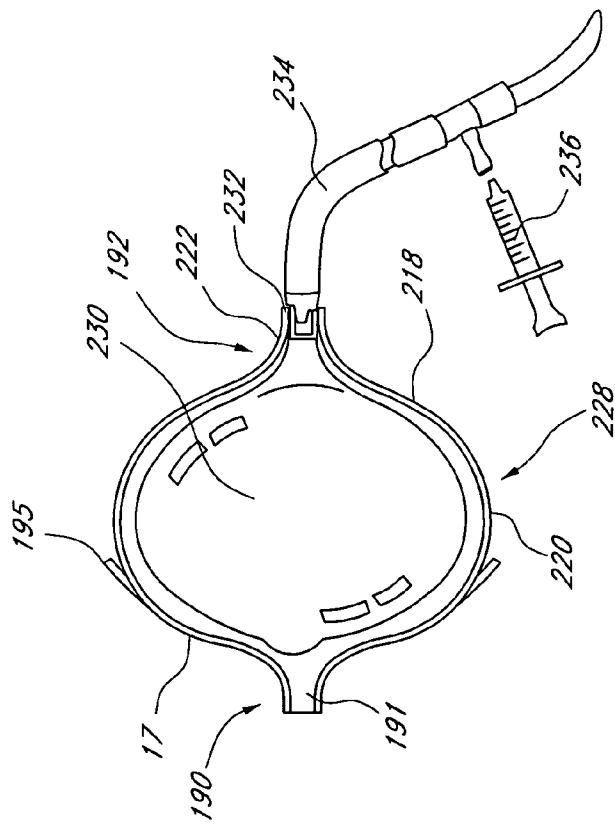


FIG. 8

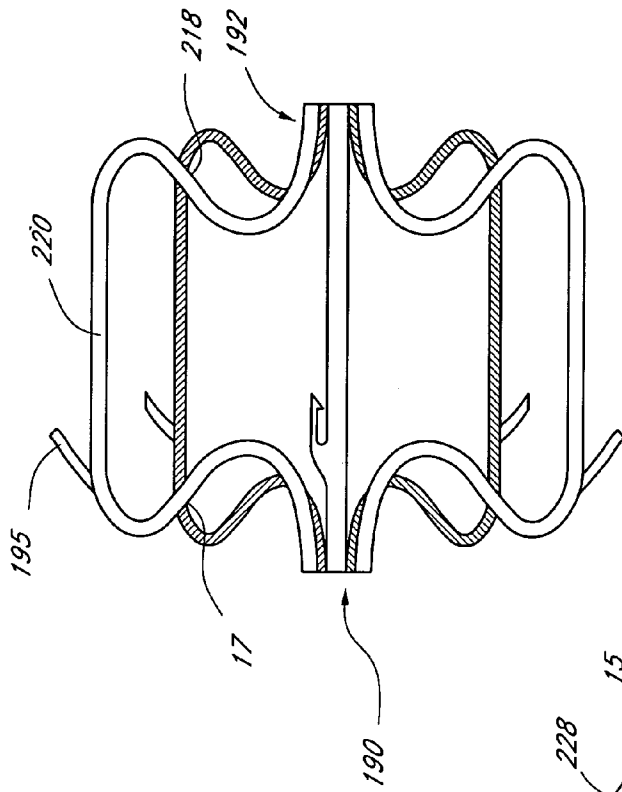


FIG. 12

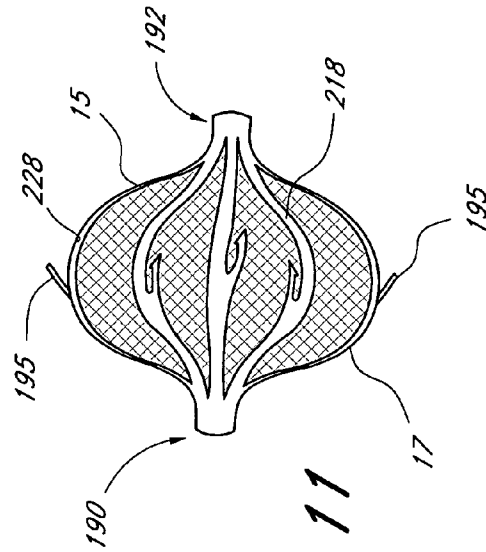


FIG. 11

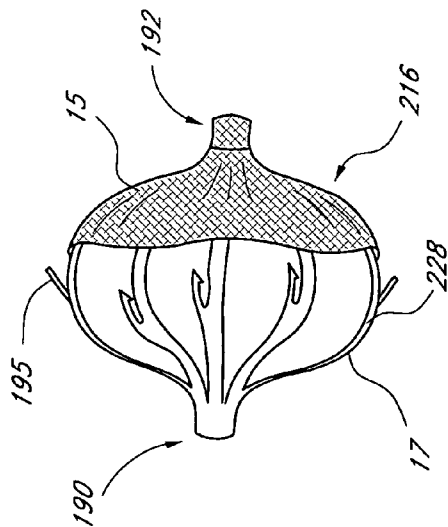
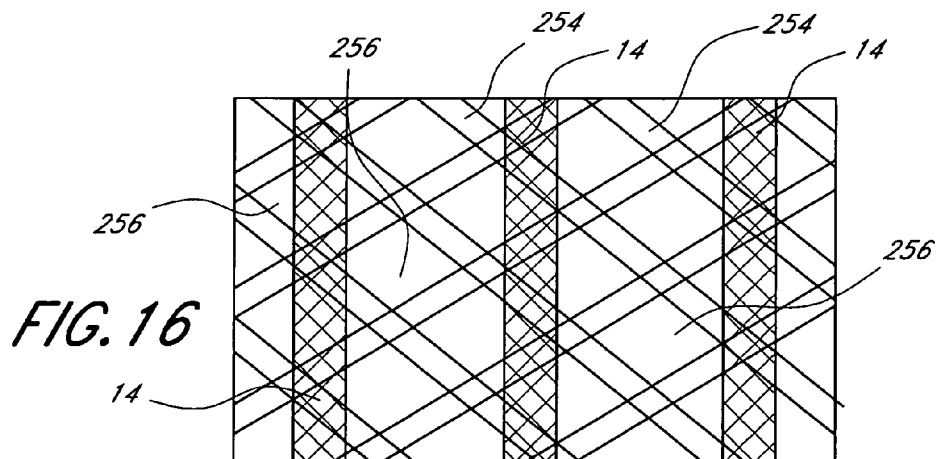
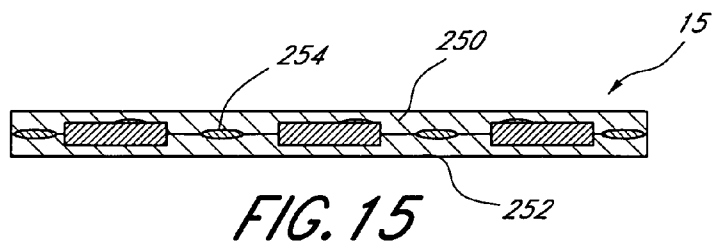
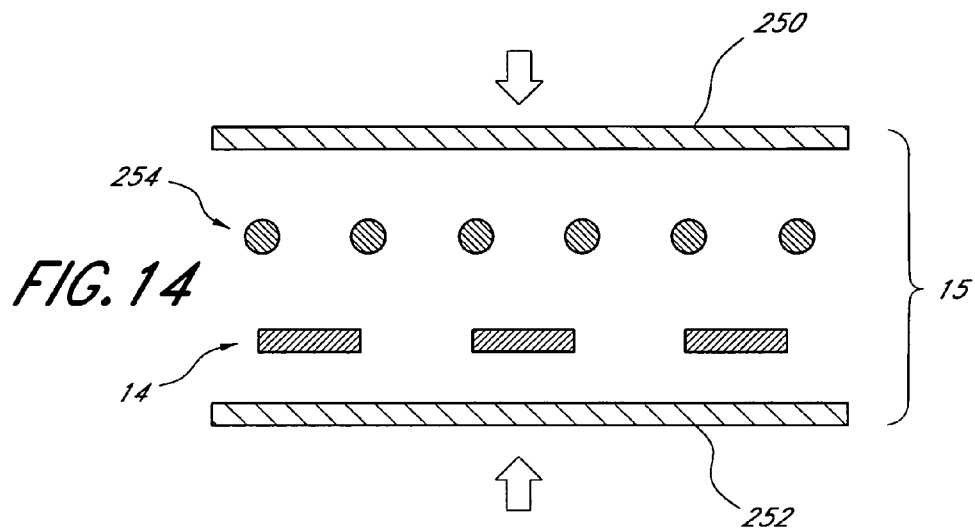
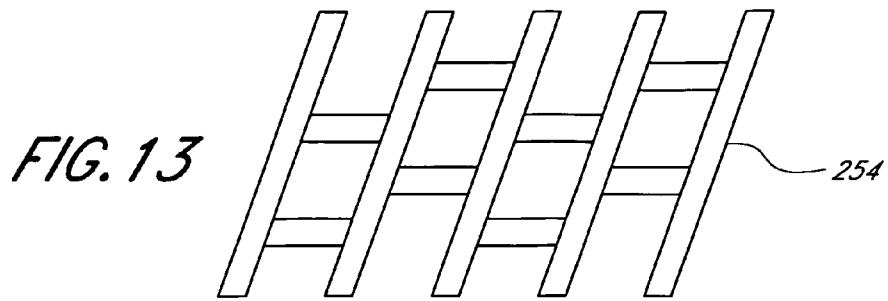


FIG. 10



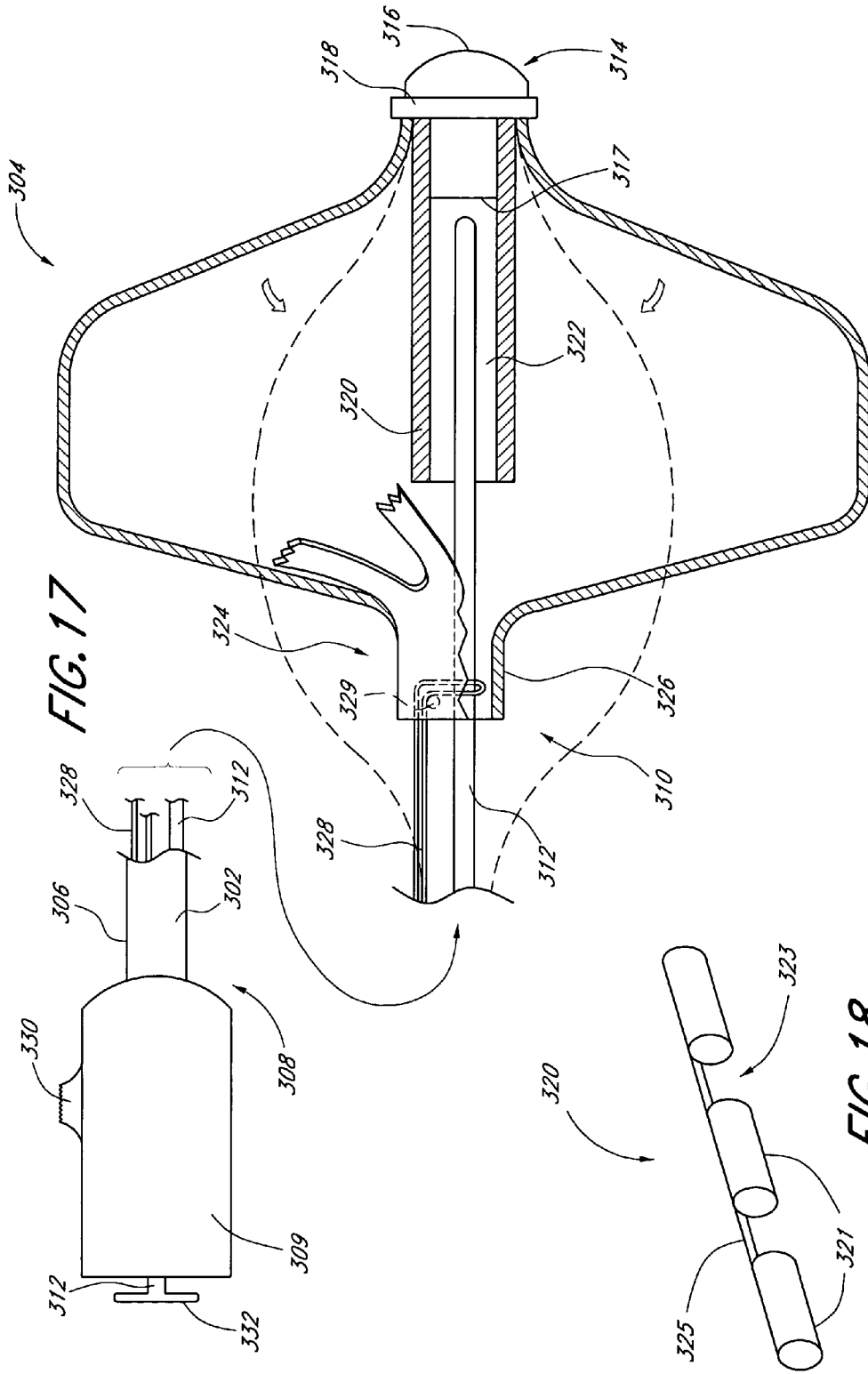


FIG. 17

FIG. 18

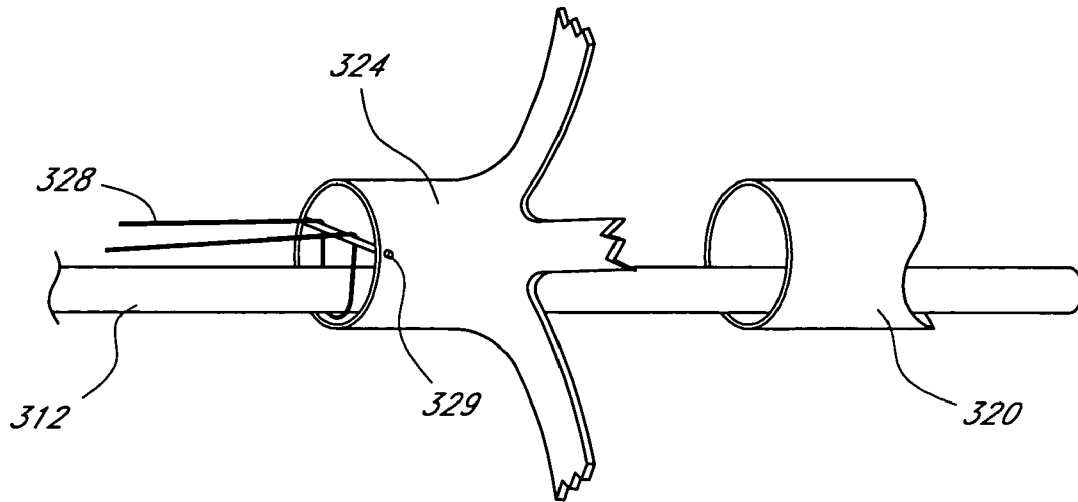


FIG. 17A

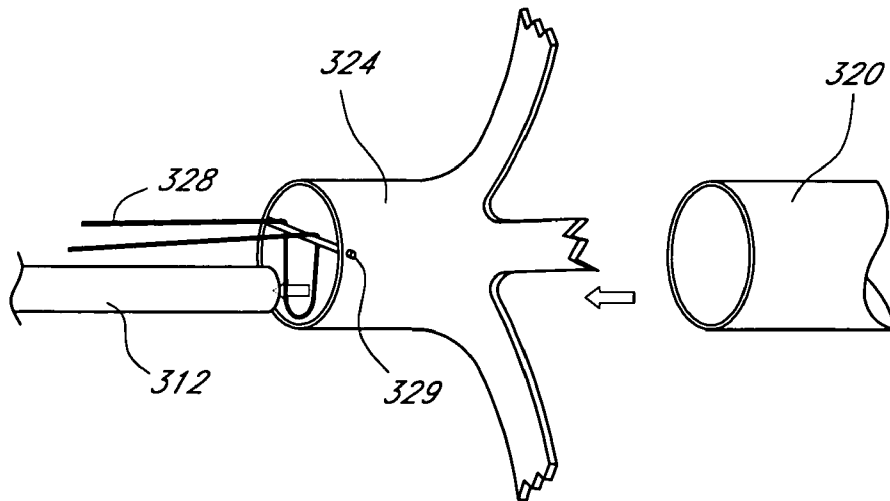


FIG. 17B

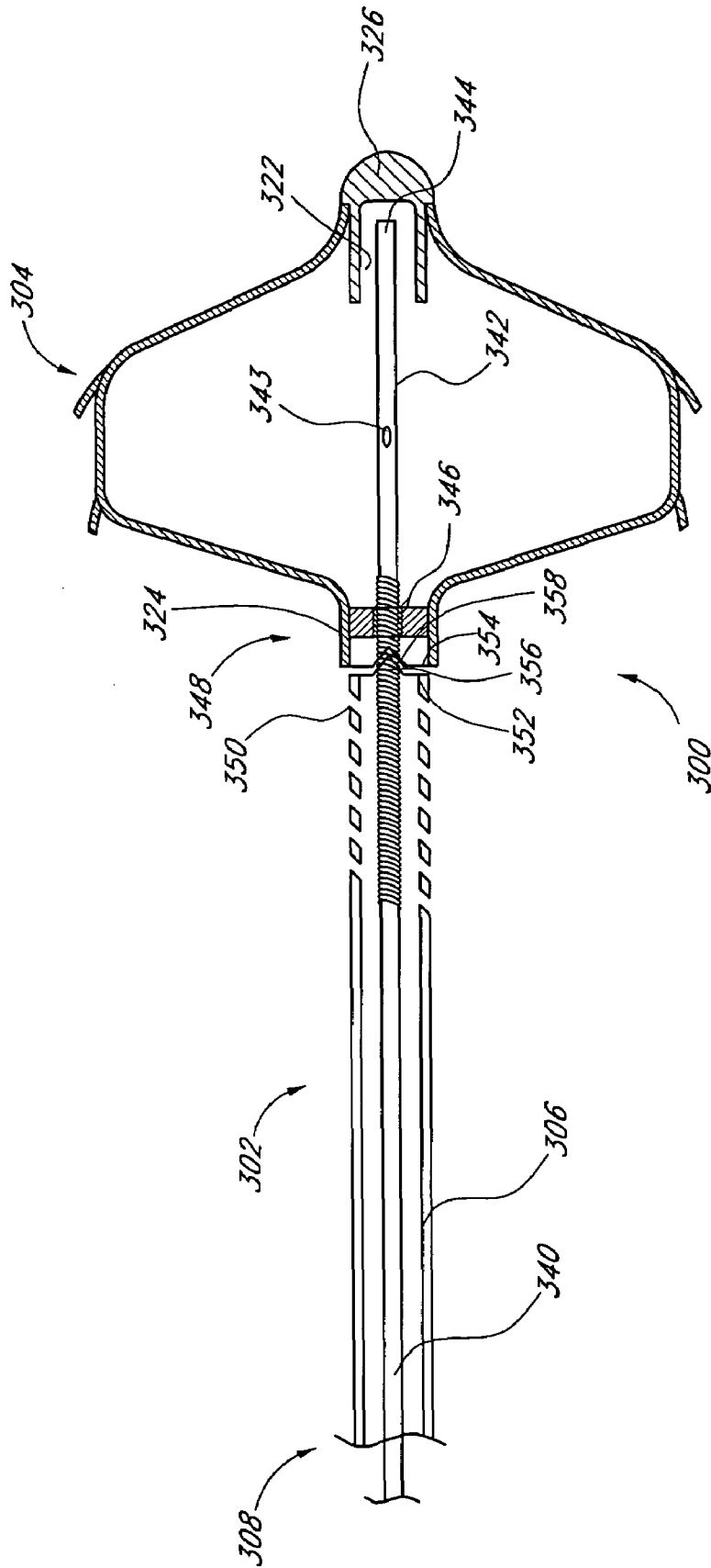


FIG. 19

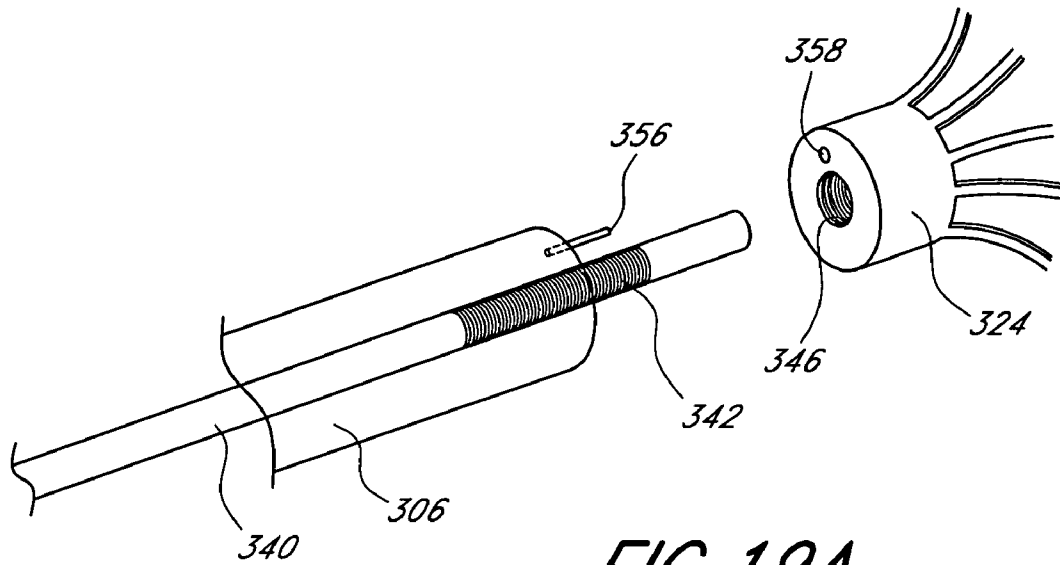


FIG. 19A

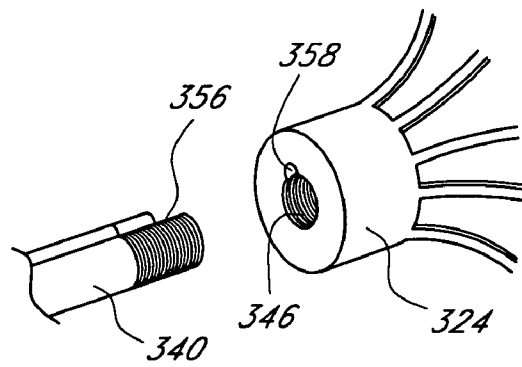


FIG. 19B

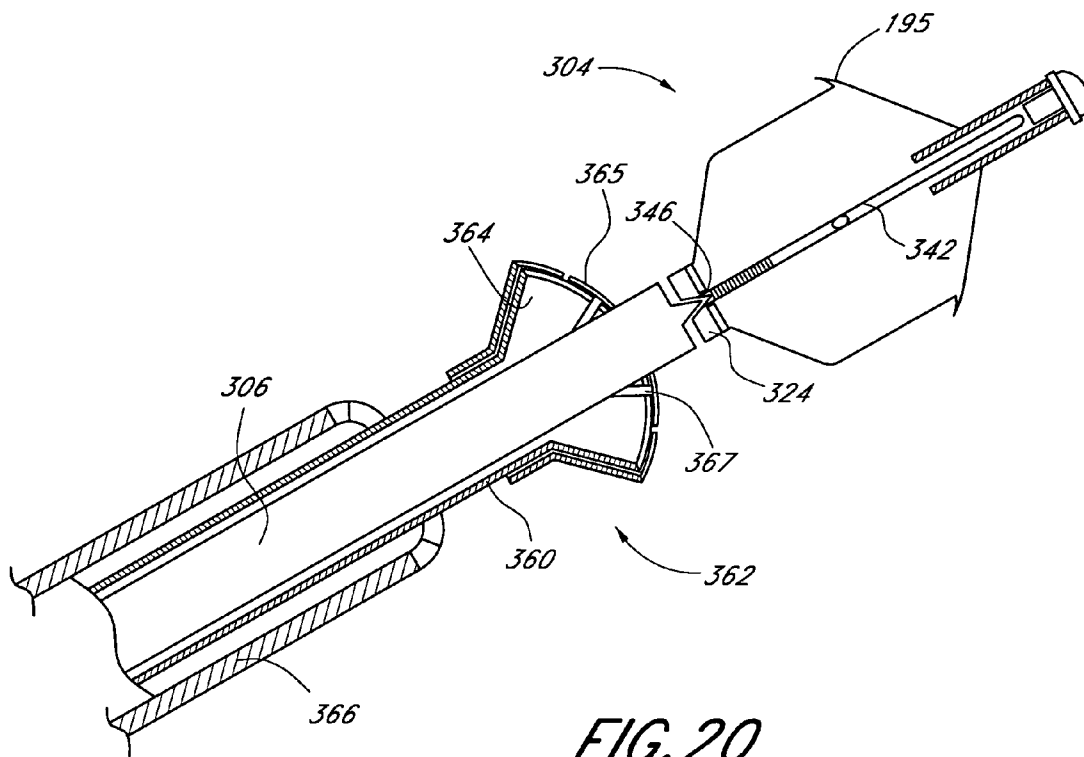


FIG. 20

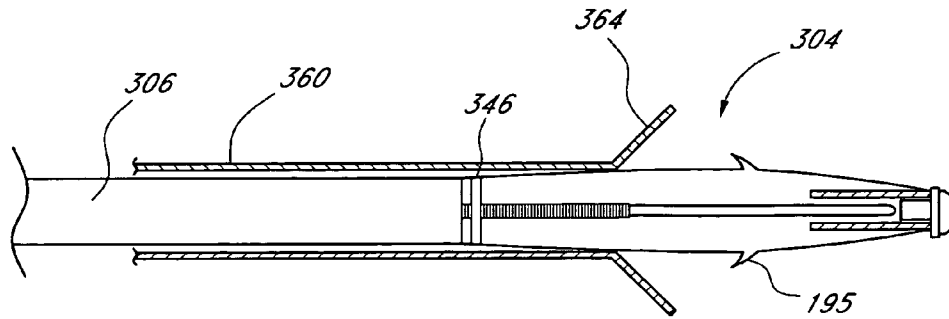


FIG. 20A

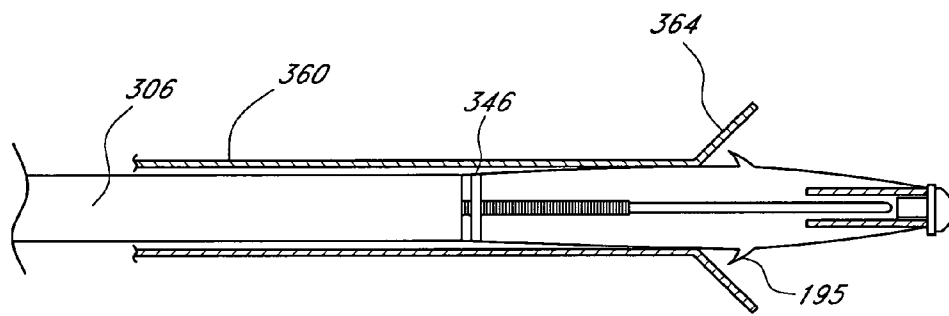


FIG. 20B

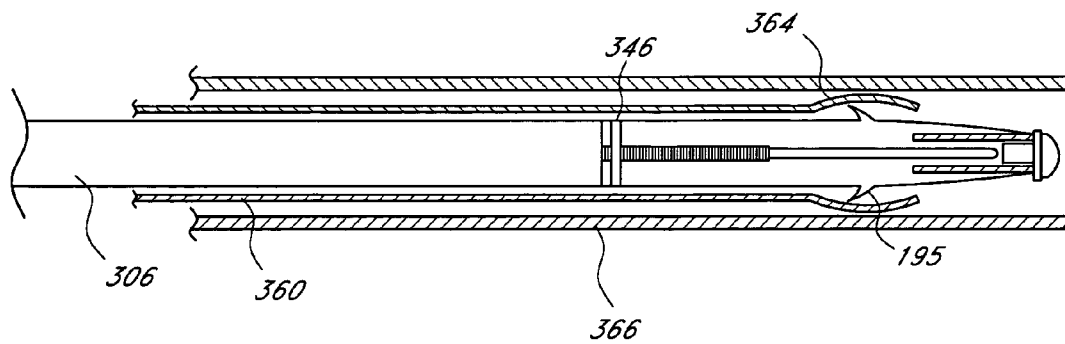


FIG. 20C

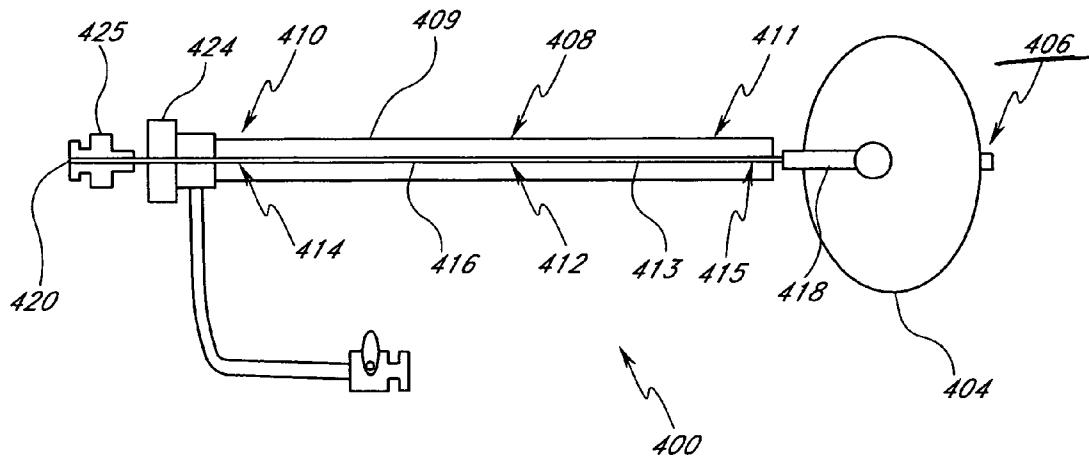


FIG. 21

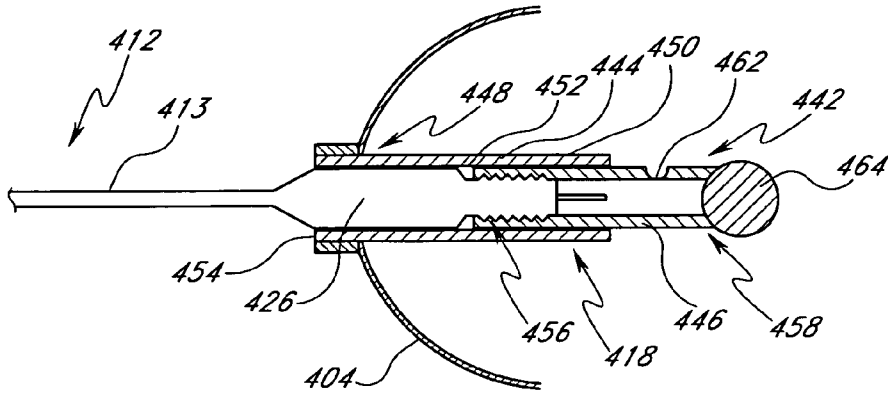


FIG. 22A

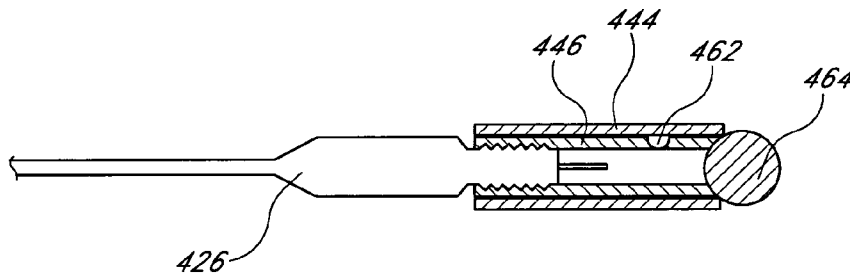


FIG. 22B

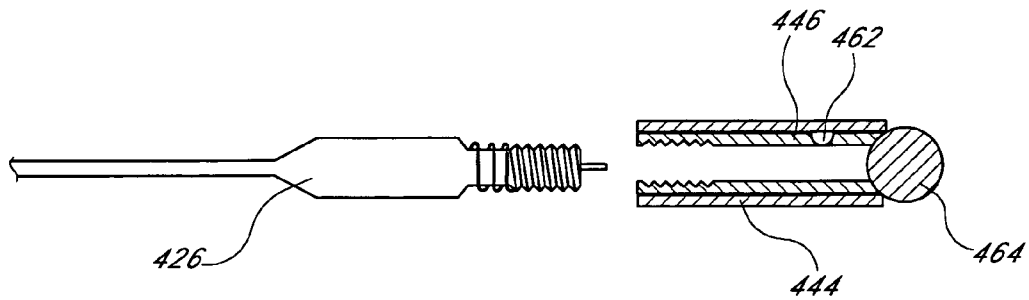


FIG. 22C

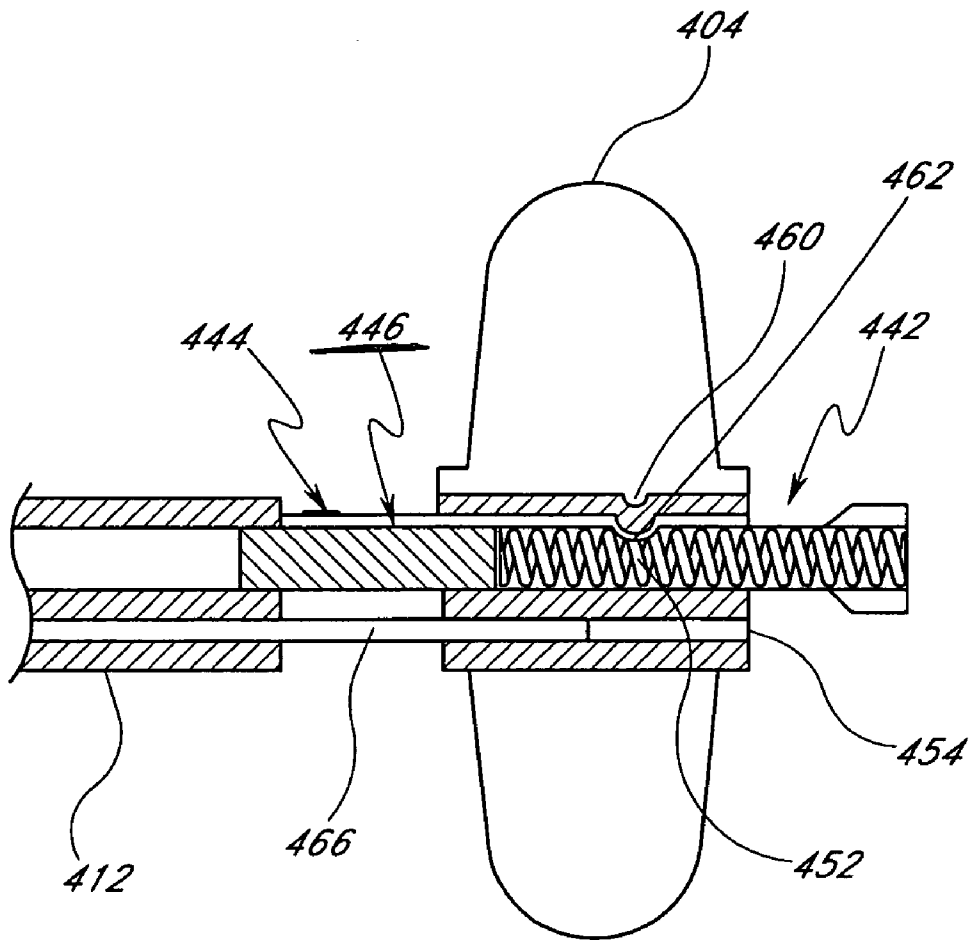


FIG. 23

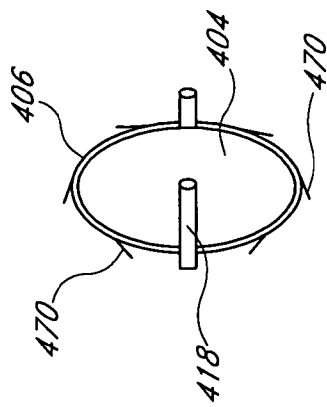


FIG. 24A

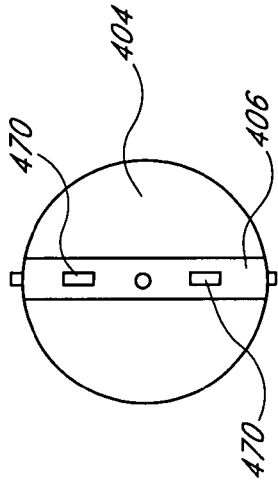


FIG. 24B

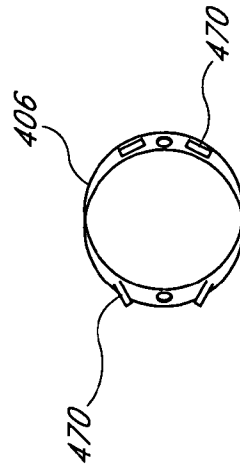


FIG. 24C

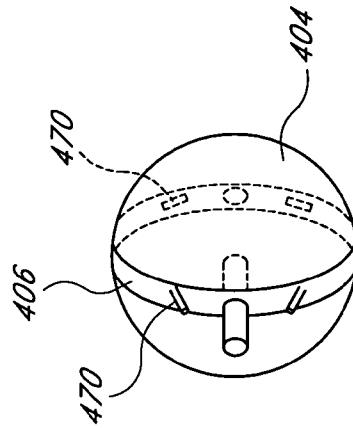


FIG. 24D

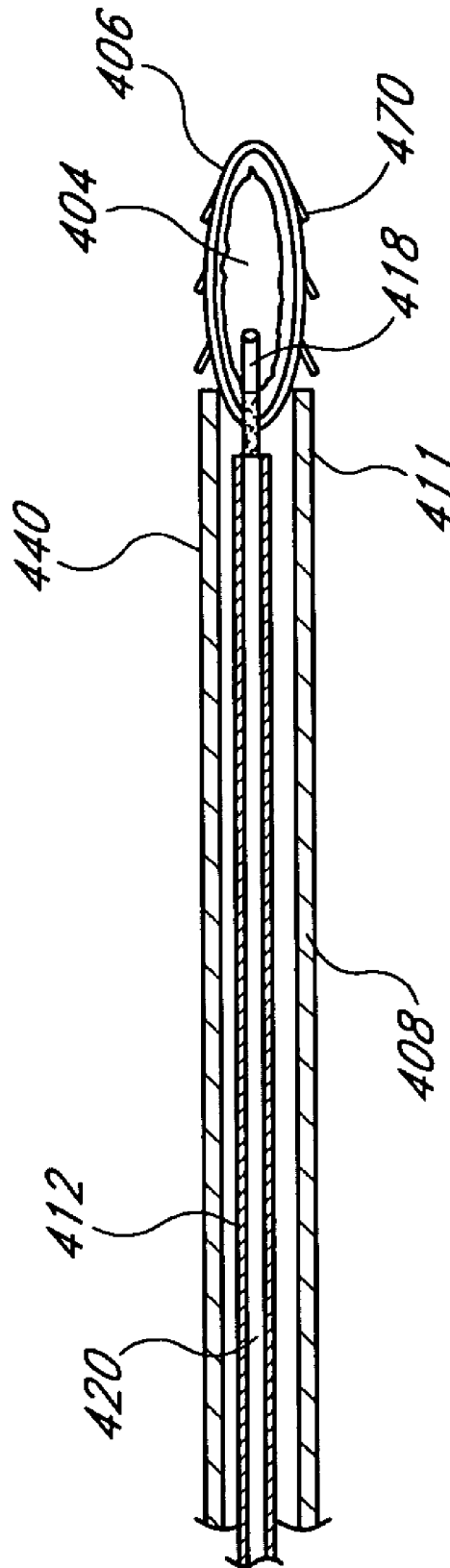


FIG. 25

1

DETACHABLE ATRIAL APPENDAGE OCCLUSION BALLOON

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. application Ser. No. 09/435,562 filed on Nov. 8, 1999, now U.S. Pat. No. 7,128,073 which is a continuation-in-part of U.S. application Ser. No. 09/187,200 filed on Nov. 6, 1998, now U.S. Pat. No. 6,152,144, issued Nov. 28, 2000, the disclosures of which are incorporated in their entirety herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to methods and devices for closing a body lumen or cavity and, in particular, for closing the left atrial appendage.

2. Description of the Related Art

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 hemorrhagic, 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.

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.

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.

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

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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.

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

In accordance with one embodiment of the present invention, an adjustable occlusion device deployment system, for implanting an occlusion device within a tubular structure in the body is provided. The system includes an occlusion device, movable between a reduced cross section and an enlarged cross section, an inflation catheter, releasably attached to the occlusion device, and an anchoring system for the occlusion device.

In one embodiment, the anchoring system comprises an anchoring ribbon. In another embodiment, the anchoring system comprises a plurality of anchoring hooks. In some embodiments, the occlusion device comprises an occluding member, enlargeable from a reduced cross section to an enlarged cross section, and an anchoring member, enlargeable from a reduced cross section to an enlarged cross section. In some embodiments, the system also includes a two-way valve.

In accordance with another embodiment of the present invention, an occlusion device for occluding a tubular body structure is provided. The device includes an occluding member, enlargeable from a reduced cross section to an enlarged cross section, and an anchoring member, enlargeable from a reduced cross section to an enlarged cross section. In some embodiments, the device also includes at least one tissue attachment element on the occluding member. In some embodiments, the tissue attachment element comprises a tissue piercing element.

In accordance with another embodiment of the present invention, an occlusion device implantation system is provided. The system includes an inflation catheter, having an elongate flexible body with a proximal end and a distal end, and a radially expandable implant releasably connected to the distal end of the body.

In accordance with another embodiment of the present invention, a method of implanting a device in the left atrial appendage is provided. The method includes the steps of providing an inflation catheter, having an elongate flexible body with a proximal end and a distal end, and a device removably carried by the distal end, positioning at least a portion of the device in the left atrial appendage, enlarging the device under positive force or pressure, and anchoring the device in the left atrial appendage.

The systems and methods have several features, no single one of which is solely responsible for its desirable attributes. Without limiting the scope as expressed by the claims that follow, its more prominent features will now be discussed briefly. After considering this discussion, and particularly after reading the section entitled "Detailed Description of the Preferred Embodiments" one will understand how the features of the system and methods provide several advantages over traditional systems and methods.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an occlusion device in accordance with the present invention.

FIG. 2 is a side elevational view of the occlusion device shown in FIG. 1.

FIG. 3 is a perspective view of an alternate embodiment of the present invention.

FIG. 4 is a side elevational view of the embodiment shown in FIG. 3.

FIG. 5 is a perspective view of a further embodiment of the present invention.

FIG. 6 is a side elevational view of the embodiment of FIG. 5.

FIG. 7 is a perspective view of a support structure for a further occlusion device in accordance with the present invention.

FIG. 7A is a side elevational view of the device of FIG. 7.

FIG. 7B is an end view taken along the line 7B-7B of FIG. 7A.

FIG. 8 is a schematic illustration of an inflatable balloon positioned within the occlusion device of FIG. 7.

FIG. 9 is a schematic view of a pull string deployment embodiment of the occlusion device of FIG. 7.

FIGS. 10 and 11 are side elevational schematic representations of partial and complete barrier layers on the occlusion device of FIG. 7.

FIG. 12 is a side elevational schematic view of an alternate occlusion device in accordance with the present invention.

FIG. 13 is a schematic view of a bonding layer mesh for use in forming a composite barrier membrane in accordance with the present invention.

FIG. 14 is an exploded cross sectional view of the components of a composite barrier member in accordance with the present invention.

FIG. 15 is a cross sectional view through a composite barrier formed from the components illustrated in FIG. 14.

FIG. 16 is a top plan view of the composite barrier illustrated in FIG. 15.

FIG. 17 is a schematic view of a deployment system in accordance with the present invention.

FIG. 17A is an enlarged view of a releasable lock in an engaged configuration.

FIG. 17B is an enlarged view as in FIG. 17A, with the core axially retracted to release the implant.

FIG. 18 is a perspective view of a flexible guide tube for use in the configurations of FIG. 17 and/or FIG. 19.

FIG. 19 is a schematic view of an alternate deployment system in accordance with the present invention.

FIGS. 19A-19B illustrate a removal sequence for an implanted device in accordance with the present invention.

FIG. 20 is a schematic cross sectional view through the distal end of a retrieval catheter having an occlusion device removably connected thereto.

FIG. 20A is a side elevational schematic view of the system illustrated in FIG. 20, with the occlusion device axially elongated and radially reduced.

FIG. 20B is a side elevational schematic view as in FIG. 20A, with the occlusion device drawn part way into the delivery catheter.

FIG. 20C is a schematic view as in FIG. 20B, with the occlusion device and delivery catheter drawn into a transeptal sheath.

FIG. 21 is a schematic view of an alternate system in accordance with the present invention.

FIGS. 22A-C are an enlarged cross-sectional view of the distal end of the system of FIG. 21.

FIG. 23 is an enlarged cross-sectional view of the distal end of the system of FIG. 21.

FIG. 24A is a cross-sectional view of an implant and anchor element in accordance with the present invention.

FIG. 24B is a side elevational view of the combined implant and anchor element in accordance with the present invention.

FIG. 24C is a perspective view of the anchor element in accordance with the present invention.

FIG. 24D is a perspective view of the combined implant and anchor element in accordance with the present invention.

FIG. 25 is a cross-sectional view of the system including the implant and anchor element in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1 and 2, there is illustrated one embodiment of the occlusion device 10 in accordance with the present invention. Although the present invention will be described primarily in the context of an occlusion device, the present inventors also contemplate omitting the fabric cover or enlarging the pore size to produce implantable filters or other devices which are enlargeable at a remote implantation site.

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.

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. 1 and FIG. 2 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, or a catheter for axially shortening the occlusion member, as is discussed further below.

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.

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 axially facing 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 μ m to about 60 μ m.

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. **13-16**. As illustrated schematically in FIG. **13**, 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.

Referring to FIG. **14**, 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 membrane **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.

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. **15**. 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**.

As illustrated in top plan view in FIG. **16**, 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 or other wall pattern formed by the bonding layer **254**. Preferably, a regular window **256** pattern is produced in the bonding layer **254**.

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.

Referring back to FIGS. **1** and **2**, 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. **1** and **2**, the stabilizer **194** is spaced distally apart from the occluding member **11**.

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 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 distal hub **191** and proximal hub **16** is about 2.5 mm.

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 cavity or 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 or more anchors each.

The illustrated anchor is in the form of a barb, with one on each spoke for extending into tissue at or near the opening of the LAA. Depending upon the embodiment, two or three barbs may alternatively be desired on each spoke. In the single barb embodiment of FIG. **7**, each barb is inclined in a proximal direction. This is to inhibit proximal migration of the implant out of the left atrial appendage. In this context, distal refers to the direction into the left atrial appendage, and proximal refers to the direction from the left atrial appendage into the heart.

Alternatively, one or more barbs may face distally, to inhibit distal migration of the occlusion device deeper into the LAA. Thus the implant may be provided with at least one proximally facing barb and at least one distally facing barb. For example, in an embodiment of the type illustrated in FIG. **12**, discussed below, a proximal plurality of barbs may be inclined in a first direction, and a distal plurality of barbs may be inclined in a second direction, to anchor the implant against both proximal and distal migration.

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, ingrowth surfaces and others which will be apparent to those of skill in the art in view of the disclosure herein.

In use, the occlusion device **10** is preferably positioned within a tubular anatomical structure to be occluded such as

the left atrial appendage. In a left atrial appendage application, 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 minimizes leakage, and provision of the barbs facilitates endothelialization or other cell growth across the occluding member **11**.

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 (pre-stretched) 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. 2, 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.

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 central lumen or other capillary tube or aperture which permits 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.

Modifications to the occlusion device **10** are illustrated in FIGS. 3-4. The occlusion device **10** comprises an occlusion member **11** and a stabilizing member **194** as previously discussed. 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 an 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, three 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 distal 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.

The occlusion device **10** illustrated in FIGS. 3 and 4 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, 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.

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**, which may be provided with a wave pattern as illustrated.

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.

Referring to FIGS. 5 and 6, a further variation on the occlusion device **10** illustrated in FIGS. 1 and 2 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. 1 and 2. The proximal face **216** is formed by providing a proximal spoke **218** which connects at an apex **220** to some or all of the distal spokes **17**. The proximal spoke **218**, and corresponding apex **220** and distal spoke **17** may be an integral structure, such as a single ribbon or wire, or element cut from a tube stock as has been discussed.

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.

Referring to FIGS. 7-12, alternate structures of the occlusion device in accordance with the present invention are 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.

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 ten. In one embodiment, sixteen 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.

Each support **228** comprises a proximal spoke portion **218**, a distal spoke portion **17**, and an apex **220** as has been discussed. Each of the proximal spoke portion **218**, distal spoke portion **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.

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 is inclined in the proximal direction. One or more barbs may also be inclined distally, as is discussed elsewhere herein. 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**.

The occlusion device **10** constructed from the frame illustrated in FIG. 7 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 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, brazing, 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.

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 under positive force following positioning within the tubular anatomical structure, in any of a variety of manners.

For an example of enlarging under positive force, referring to FIG. 8, 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. The balloon **230** may be either left in place within the occlusion device **10**, or deflated and removed by the inflation catheter **234**.

In an alternate embodiment, the supports **228** are radially enlarged such as through the use of a deployment catheter **238**. See FIG. 9. Deployment catheter **238** comprises a lumen for movably receiving a deployment element such as a flexible line **240**. Deployment line **240** extends in a loop **244** formed by an aperture or slip knot **242**. As will be apparent from FIG. 9, proximal retraction on the deployment line **240** while resisting proximal movement of proximal hub **222** such as by using the distal end of the catheter **238** 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.

A variety of alternative structures may be utilized, to open or enlarge the occlusion device **10** under positive force. For example, Referring to FIG. 9, a pullwire **240** may be removably attached to the distal hub **191** or other distal point of attachment on the occlusion device **10**. Proximal retraction of the pullwire **240** while resisting proximal motion of the proximal hub **222** such as by using the distal end of the catheter **238** will cause enlargement of the occlusion device **10** as has been discussed. The pullwire **240** may then be locked with respect to the proximal hub **222** and severed or otherwise detached to enable removal of the deployment catheter **238** and proximal extension of the pullwire **240**. Locking of the pullwire with respect to the proximal hub **222** may be accomplished in any of a variety of ways, such as by using interference fit or friction fit structures, adhesives, a knot or other technique depending upon the desired catheter design.

Referring to FIGS. 10 and 11, 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. 11, or may be provided on the radially outwardly facing surfaces of supports **228**, or both.

A further embodiment of the occlusion device **10** is illustrated in FIG. 12, 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. 12 may also be provided with any of a variety of other features discussed herein, such as a partial or complete

barrier **15**. In addition, the occlusion device **10** illustrated in FIG. **12** may be enlarged using any of the techniques disclosed elsewhere herein.

Referring to FIG. **17**, there is schematically illustrated a further aspect of the present invention. An adjustable implant deployment system **300** comprises generally a catheter **302** for placing a detachable implant **304** within a body cavity or lumen, as has been discussed. The catheter **302** comprises an elongate flexible tubular body **306**, extending between a proximal end **308** and a distal end **310**. The catheter is shown in highly schematic form, for the purpose of illustrating the functional aspects thereof. The catheter body will have a sufficient length and diameter to permit percutaneous entry into the vascular system, and transluminal advancement through the vascular system to the desired deployment site. For example, in an embodiment intended for access at the femoral artery and deployment within the left atrial appendage, the catheter **302** will have a length within the range of from about 50 cm to about 150 cm, and a diameter of generally no more than about 15 French. Further dimensions and physical characteristics of catheters for navigation to particular sites within the body are well understood in the art and will not be further described herein.

The tubular body **306** is further provided with a handle **309** generally on the proximal end **308** of the catheter **302**. The handle **309** permits manipulation of the various aspects of the implant deployment system **300**, as will be discussed below. Handle **309** may be manufactured in any of a variety of ways, typically by injection molding or otherwise forming a hand-piece for single-hand operation, using materials and construction techniques well known in the medical device arts.

The implant **304** may be in the form of any of those described previously herein, as modified below. In general, the implant is movable from a reduced crossing profile to an enlarged crossing profile, such that it may be positioned within a body structure and advanced from its reduced to its enlarged crossing profile to obstruct bloodflow or perform other functions while anchored therein. The implant **304** may be biased in the direction of the enlarged crossing profile, may be neutrally biased or may be biased in the direction of the reduced crossing profile. Any modifications to the device and deployment system to accommodate these various aspects of the implant **304** may be readily accomplished by those of skill in the art in view of the disclosure herein.

In the illustrated embodiment, the distal end **314** of the implant **304** is provided with an implant plug **316**. Implant plug **316** provides a stopping surface **317** for contacting an axially movable core **312**. The core **312** extends axially throughout the length of the catheter body **302**, and is attached at its proximal end to a core control **332** on the handle **309**.

The core **312** may comprise any of a variety of structures which has sufficient lateral flexibility to permit navigation of the vascular system, and sufficient axial column strength to enable reduction of the implant **304** to its reduced crossing profile. Any of a variety of structures such as hypotube, solid core wire, "bottomed out" coil spring structures, or combinations thereof may be used, depending upon the desired performance of the finished device. In one embodiment, the core **312** comprises stainless steel tubing.

The distal end of core **312** is positioned within a recess or lumen **322** defined by a proximally extending guide tube **320**. In the illustrated embodiment, the guide tube **320** is a section of tubing such as metal hypotube, which is attached at the distal end **314** of the implant and extends proximally within the implant **304**. The guide tube **320** preferably extends a sufficient distance in the proximal direction to inhibit buck-

ling or prolapse of the core **312** when distal pressure is applied to the core control **332** to reduce the profile of the implant **304**. However, the guide tube **320** should not extend proximally a sufficient distance to interfere with the opening of the implant **304**.

As will be appreciated by reference to FIG. **17**, the guide tube **320** may operate as a limit on distal axial advancement of the proximal end **324** of implant **304**. Thus, the guide tube **320** preferably does not extend sufficiently far proximally from the distal end **314** to interfere with optimal opening of the implant **304**. The specific dimensions are therefore relative, and will be optimized to suit a particular intended application. In one embodiment, the implant **304** has an implanted outside diameter within the range of from about 5 mm to about 45 mm, and an axial implanted length within the range of from about 5 mm to about 45 mm. The guide tube **320** has an overall length of about 3 mm to about 35 mm, and an outside diameter of about 0.095 inches.

An alternate guide tube **320** is schematically illustrated in FIG. **18**. In this configuration, the guide tube **320** comprises a plurality of tubular segments **321** spaced apart by an intervening space **323**. This allows increased flexibility of the guide tube **320**, which may be desirable during the implantation step, while retaining the ability of the guide tube **320** to maintain linearity of the core **312** while under axial pressure. Although three segments **321** are illustrated in FIG. **18**, as many as 10 or 20 or more segments **321** may be desirable depending upon the desired flexibility of the resulting implant.

Each adjacent pair of segments **321** may be joined by a hinge element **325** which permits lateral flexibility. In the illustrated embodiment, the hinge element **325** comprises an axially extending strip or spine, which provides column strength along a first side of the guide tube **320**. The guide tube **320** may therefore be curved by compressing a second side of the guide tube **320** which is generally offset from the spine **325** by about 180°. A limit on the amount of curvature may be set by adjusting the axial length of the space **323** between adjacent segments **321**. In an embodiment having axial spines **325**, each axial spine **325** may be rotationally offset from the next adjacent axial spine **325** to enable flexibility of the overall guide tube **320** throughout a 360° angular range of motion.

Alternatively, the flexible hinge point between each adjacent segment **321** may be provided by cutting a spiral groove or plurality of parallel grooves in a tubular element in between what will then become each adjacent pair of segments **321**. In this manner, each tubular element **321** will be separated by an integral spring like structure, which can permit flexibility. As a further alternative, the entire length of the guide tube **320** may comprise a spring. Each of the forgoing embodiments may be readily constructed by laser cutting or other cutting from a piece of tube stock, to produce a one piece guide tube **320**. Alternatively, the guide tube **320** may be assembled from separate components and fabricated together using any of a variety of bonding techniques which are appropriate for the construction material selected for the tube **320**.

Various distal end **314** constructions may be utilized, as will be apparent to those of skill in the art in view of the disclosure herein. In the illustrated embodiment, the distal implant plug **316** extends within the implant **304** and is attached to the distal end of the guide tube **320**. The implant plug **316** may be secured to the guide tube **320** and implant **304** in any of a variety of ways, depending upon the various construction materials. For example, any of a variety of metal bonding techniques such as a welding, brazing, interference fit such as threaded fit or snap fit, may be utilized. Alterna-

tively, any of a variety of bonding techniques for dissimilar materials may be utilized, such as adhesives, and various molding techniques. In one construction, the implant plug 316 comprises a molded polyethylene cap, and is held in place utilizing a distal cross pin 318 which extends through the implant 304, the guide tube 320 and the implant plug 316 to provide a secure fit against axial displacement.

The proximal end 324 of the implant 304 is provided with a releasable lock 326 for attachment to a release element such as pull wire 328. Pull wire 328 extends proximally throughout the length of the tubular body 306 to a proximal pull wire control 330 on the handle 309.

As used herein, the term pull wire is intended to include any of a wide variety of structures which are capable of transmitting axial tension or compression such as a pushing or pulling force with or without rotation from the proximal end 308 to the distal end 310 of the catheter 302. Thus, monofilament or multifilament metal or polymeric rods or wires, woven or braided structures may be utilized. Alternatively, tubular elements such as a concentric tube positioned within the outer tubular body 306 may also be used as will be apparent to those of skill in the art.

In the illustrated embodiment, the pull wire 328 is releasably connected to the proximal end 324 of the implant 304. This permits proximal advancement of the proximal end of the implant 304, which cooperates with a distal retention force provided by the core 312 against the distal end of the implant to axially elongate the implant 304 thereby reducing it from its implanted configuration to its reduced profile for implantation. The proximal end of the pull wire 328 may be connected to any of a variety of pull wire controls 330, including rotational knobs, levers and slider switches, depending upon the design preference.

The proximal end 324 of the implant 304 is thus preferably provided with a releasable lock 326 for attachment of the pullwire 328 to the deployment catheter. In the illustrated embodiment, the releasable lock is formed by advancing the pullwire distally around a cross pin 329, and providing an eye or loop which extends around the core 312. As long as the core 312 is in position within the implant 304, proximal retraction of the pullwire 328 will advance the proximal end 324 of the implant 304 in a proximal direction. See FIG. 17A. However, following deployment, proximal retraction of the core 312 such as by manipulation of the core control 332 will pull the distal end of the core 312 through the loop on the distal end of the pullwire 328. The pullwire 328 may then be freely proximally removed from the implant 304, thereby enabling detachment of the implant 304 from the deployment system 300 within a treatment site. See FIG. 17B.

The implant deployment system 300 thus permits the implant 304 to be maintained in a low crossing profile configuration, to enable transluminal navigation to a deployment site. Following positioning at or about the desired deployment site, proximal retraction of the core 312 enables the implant 304 to radially enlarge under its own bias to fit the surrounding tissue structure. Alternatively, the implant can be enlarged under positive force, such as by inflation of a balloon or by a mechanical mechanism as is discussed elsewhere herein. Once the clinician is satisfied with the position of the implant 304, such as by injection of dye and visualization using conventional techniques, the core 312 is proximally retracted thereby releasing the lock 326 and enabling detachment of the implant 304 from the deployment system 300.

If, however, visualization reveals that the implant 304 is not at the location desired by the clinician, proximal retraction of the pull wire 328 with respect to the core 312 will radially reduce the diameter of the implant 304, thereby enabling

repositioning of the implant 304 at the desired site. Thus, the present invention permits the implant 304 to be enlarged or reduced by the clinician to permit repositioning and/or removal of the implant 304 as may be desired.

In an alternate construction, the implant may be radially enlarged or reduced by rotating a torque element extending throughout the deployment catheter. Referring to FIG. 19, the elongate flexible tubular body 306 of the deployment catheter 302 includes a rotatable torque rod 340 extending axially therethrough. The proximal end of the torque rod 340 may be connected at a proximal manifold to a manual rotation device such as a hand crank, thumb wheel, rotatable knob or the like. Alternatively, the torque rod 340 may be connected to a power driven source of rotational energy such as a motor drive or air turbine.

The distal end of the torque rod 340 is integral with or is connected to a rotatable core 342 which extends axially through the implant 304. A distal end 344 of the rotatable core 342 is positioned within a cavity 322 as has been discussed.

The terms torque rod or torque element are intended to include any of a wide variety of structures which are capable of transmitting a rotational torque throughout the length of a catheter body. For example, solid core elements such as stainless steel, nitinol or other nickel titanium alloys, or polymeric materials may be utilized. In an embodiment intended for implantation over a guide-wire, the torque rod 340 is preferably provided with an axially extending central guidewire lumen. This may be accomplished by constructing the torque rod 340 from a section of hypodermic needle tubing, having an inside diameter of from about 0.001 inches to about 0.005 inches or more greater than the outside diameter of the intended guidewire. Tubular torque rods 340 may also be fabricated or constructed utilizing any of a wide variety of polymeric constructions which include woven or braided reinforcing layers in the wall. Torque transmitting tubes and their methods of construction are well understood in the intracranial access and rotational atherectomy catheter arts, among others, and are not described in greater detail herein. Use of a tubular torque rod 340 also provides a convenient infusion lumen for injection of contrast media within the implant 304, such as through a port 343.

The proximal end 324 of the implant 304 is provided with a threaded aperture 346 through which the core 342 is threadably engaged. As will be appreciated by those of skill in the art in view of the disclosure herein, rotation of the threaded core 342 in a first direction relative to the proximal end 324 of the implant 304 will cause the rotatable core 342 to advance distally. This distal advancement will result in an axial elongation and radial reduction of the implantable device 304. Rotation of the rotatable core 342 in a reverse direction will cause a proximal retraction of the rotatable core 342, thus enabling a radial enlargement and axial shortening of the implantable device 304.

The deployment catheter 302 is further provided with an antirotation lock 348 between a distal end 350 of the tubular body 306 and the proximal end 324 of the implant 304. In general, the rotational lock 348 may be conveniently provided by cooperation between a first surface 352 on the distal end 350 of the deployment catheter 302, which engages a second surface 354 on the proximal end 324 of the implantable device 304, to rotationally link the deployment catheter 302 and the implantable device 304. Any of a variety of complementary surface structures may be provided, such as an axial extension on one of the first and second surfaces for coupling with a corresponding recess on the other of the first and second surfaces. Such extensions and recesses may be positioned laterally offset from the axis of the catheter. Alterna-

tively, they may be provided on the longitudinal axis with any of a variety of axially releasable anti-rotational couplings having at least one flat such as a hexagonal or other multifaceted cross sectional configuration.

As schematically illustrated in FIG. 19, one or more projections 356 on the first surface 352 may engage a corresponding recess 358 on the second surface 354. Any of a variety of alternative complementary surface structures may also be provided, as will be apparent to those of skill in the art in view of the disclosure herein. For example, referring to FIG. 19A, the projection 356 is in the form of an axially extending pin for engaging a complimentary recess 358 on the proximal end 324 of the implant 304. FIG. 19B illustrates an axially extending spline 356 for receipt within a complimentary axially extending recess 358. The various pin, spline and other structures may be reversed between the distal end of tubular body 306 and the proximal end 324 of the implant 304 as will be apparent to those of skill in the art in view of the disclosure herein.

Upon placement of the implantable device 304 at the desired implantation site, the torque rod 340 is rotated in a direction that produces an axial proximal retraction. This allows radial enlargement of the radially outwardly biased implantable device 304 at the implantation site. Continued rotation of the torque rod 340 will cause the threaded core 342 to exit proximally through the threaded aperture 346. At that point, the deployment catheter 302 may be proximally retracted from the patient, leaving the implanted device 304 in place.

By modification of the decoupling mechanism to allow the core 342 to be decoupled from the torque rod 340, the rotatable core 342 may be left within the implantable device 304, as may be desired depending upon the intended deployment mechanism. For example, the distal end of the core 342 may be rotatably locked within the end cap 326, such as by including complimentary radially outwardly or inwardly extending flanges and grooves on the distal end of the core 342 and inside surface of the cavity 322. In this manner, proximal retraction of the core 342 by rotation thereof relative to the implantable device 304 will pull the end cap 326 in a proximal direction under positive force. This may be desirable as a supplement to or instead of a radially enlarging bias built into the implantable device 304.

In the embodiment illustrated in FIG. 19, or any other of the deployment and/or removal catheters described herein, the distal end of the tubular body 306 may be provided with a zone or point of enhanced lateral flexibility. This may be desirable in order allow the implant to seat in the optimal orientation within the left atrial appendage, and not be restrained by a lack of flexibility in the tubular body 306. This may be accomplished in any of a variety of way, such as providing the distal most one or two or three centimeters or more of the tubular body 306 with a spring coil configuration. In this manner, the distal end of the tubular body 306 will be sufficiently flexible to allow the implant 304 to properly seat within the LAA. This distal flex zone on the tubular body 306 may be provided in any of a variety of ways, such as by cutting a spiral slot in the distal end of the tubular body 306 using laser cutting or other cutting techniques. The components within the tubular body 306 such as torque rod 340 may similarly be provided with a zone of enhanced flexibility in the distal region of the tubular body 306.

The implantable device 304 may also be retrieved and removed from the body in accordance with a further aspect of the present invention. One manner of retrieval and removal will be understood in connection with FIGS. 20 through 20c. Referring to FIG. 20, a previously implanted device 304 is

illustrated as releasably coupled to the distal end of the tubular body 306, as has been previously discussed. Coupling may be accomplished by aligning the tubular body 306 with the proximal end 324 of the deployed implant 304, under fluoroscopic visualization, and distally advancing a rotatable core 342 through the threaded aperture 346. Threadable engagement between the rotatable core 342 and aperture 346 may thereafter be achieved, and distal advancement of core 342 will axially elongate and radially reduce the implant 304.

The tubular body 306 is axially moveably positioned within an outer tubular delivery or retrieval catheter 360. Catheter 360 extends from a proximal end (not illustrated) to a distal end 362. The distal end 362 is preferably provided with a flared opening, such as by constructing a plurality of petals 364 for facilitating proximal retraction of the implant 304 as will become apparent. Petals 364 may be constructed in a variety of ways, such as by providing axially extending slits in the distal end 362 of the delivery catheter 360. In this manner, preferably at least about three, and generally at least about four or five or six petals or more will be provided on the distal end 362 of the delivery catheter 360. Petals 364 manufactured in this manner would reside in a first plane, transverse to the longitudinal axis of the delivery catheter 360, if each of such petals 364 were inclined at 90 degrees to the longitudinal axis of the delivery catheter 360.

In one application of the invention, a second layer of petals 365 are provided, which would lie in a second, adjacent plane if the petals 365 were inclined at 90 degrees to the longitudinal axis of the delivery catheter 360. Preferably, the second plane of petals 365 is rotationally offset from the first plane of petals 364, such that the second petals 365 cover the spaces 367 formed between each adjacent pair of petals 365. The use of two or more layers of staggered petals 364 and 365 has been found to be useful in retrieving implants 304, particularly when the implant 304 carries a plurality of tissue anchors 195.

The petals 364 and 365 may be manufactured from any of a variety of polymer materials useful in constructing medical device components such as the delivery catheter 360. This includes, for example, polyethylene, PET, PEEK, PEBAX, and others well known in the art. The second petals 365 may be constructed in any of a variety of ways. In one convenient construction, a section of tubing which concentrically fits over the delivery catheter 360 is provided with a plurality of axially extending slots in the same manner as discussed above. The tubing with a slotted distal end may be concentrically positioned on the catheter 360, and rotated such that the space between adjacent petals 365 is offset from the space between adjacent petals 364. The hub of the petals 365 may thereafter be bonded to the catheter 360, such as by heat shrinking, adhesives, or other bonding techniques known in the art.

The removal sequence will be further understood by reference to FIGS. 20a through 20c. Referring to FIG. 20a, the radially reduced implant 304 is proximally retracted part way into the delivery catheter 360. This can be accomplished by proximally retracting the tubular body 306 and/or distally advancing the catheter 360. As illustrated in FIG. 20b, the tubular body 306 having the implant 304 attached thereto is proximally retracted a sufficient distance to position the tissue anchors 195 within the petals 364. The entire assembly of the tubular body 306, within the delivery catheter 360 may then be proximally retracted within the transeptal sheath 366 or other tubular body as illustrated in FIG. 20c. The collapsed petals 364 allow this to occur while preventing engagement of the tissue anchors 195 with the distal end of the transeptal sheath 366 or body tissue. The entire assembly having the

implantable device **304** contained therein may thereafter be proximally withdrawn from or repositioned within the patient.

In accordance with an embodiment of the present invention, an occlusion device implantation system **400** having a detachable implant **404** and anchoring device **406** is provided. With reference to FIG. **21**, the system **400** comprises a deployment catheter **408**, having an elongate tubular flexible body **409** with a proximal end **410** and a distal end **411**. An inflation catheter **412** is also provided having an elongate flexible body **413** with a proximal end **414** and a distal end **415**. Inflation catheter extends within tubular body **409** of deployment catheter **408**. The inflation catheter may include a rotatable core **416** and a radially expandable implant **404** is releasably connected to the distal end of the body **413**. Inflatable implant **404** is connected by way of a removable coupling **418** to inflation catheter **412**. Inflation catheter **412** is provided with an inflation lumen **420** for providing communication between an inflation media source **422** outside of the patient and the implant **404**.

The tubular body **409** is further provided with a handle **424** generally on the proximal end **410** of the catheter **408**. The tubular body **413** is also further provided with a handle **425** generally on the proximal end of the catheter **412**. The handles **424**, **425** permits manipulation of the various aspects of the implant deployment system **400**, as will be discussed below. Handles **424**, **425** may be manufactured in any of a variety of ways, typically by injection molding or otherwise forming a handpiece for single-hand operation, using materials and construction techniques well known in the medical device arts.

The implantation system **400** is shown in highly schematic form, for the purpose of illustrating the functional aspects thereof. The catheter body will have a sufficient length and diameter to permit percutaneous entry into the vascular system, and transluminal advancement through the vascular system to the desired deployment site. For example, in an embodiment intended for access at the femoral artery and deployment within the left atrial appendage, the catheter **408** will have a length within the range of from about 50 cm to about 150 cm, and a diameter of generally no more than about 15 French. Further dimensions and physical characteristics of catheters for navigation to particular sites within the body are well understood in the art and will not be further described herein.

With reference to FIGS. **22A-C** and **23**, the distal end of inflation catheter **412** is shown in detail. The elongate flexible tubular body **413** of the inflation catheter **412** includes a rotatable torque rod **426** extending through the deployment catheter **408**. The proximal end of the torque rod **426** may be connected at a proximal manifold to a manual rotation device such as a hand crank, thumb wheel, rotatable knob or the like. Alternatively, the torque rod **426** may be connected to a power driven source of rotational energy such as a motor drive or air turbine. The distal end of the torque rod **426** extends axially through the implant **404** and connects to removable coupling **418**.

The terms torque rod or torque element are intended to include any of a wide variety of structures which are capable of transmitting a rotational torque throughout the length of a catheter body. For example, solid core elements such as stainless steel, nitinol or other nickel titanium alloys, or polymeric materials may be utilized. In an embodiment intended for implantation over a guide-wire, the torque rod **426** is preferably provided with an axially extending central guidewire lumen. This may be accomplished by constructing the torque rod **426** from a section of hypodermic needle tubing, having

an inside diameter of from about 0.001 inches to about 0.005 inches or more greater than the outside diameter of the intended guidewire. Tubular torque rods **340** may also be fabricated or constructed utilizing any of a wide variety of polymeric constructions which include woven or braided reinforcing layers in the wall. Torque transmitting tubes and their methods of construction are well understood in the intracranial access and rotational atherectomy catheter arts, among others, and are not described in greater detail herein. Use of a tubular torque rod **426** also provides a convenient infusion lumen for injection of contrast media within the implant **404**, such as through a port **420**.

With reference to FIGS. **22A-C**, coupling **418** preferably comprises a two-way valve **442** for inflating and deflating implant **404**. The two-way valve **442** includes a first tubular body **444** and a second tubular body **446**. The first tubular body **444** has a proximal end **448** and a distal end **450** and preferably comprises a single lumen **452**. Tubular body **446** can move longitudinally within the first lumen **452** of tubular body **444**. The second tubular body **446** has a proximal end **456** and a distal end **458**. A skive **462** is preferably provided on the tubular body **446** for inflation and deflation. A safety stop **464** is also positioned at the distal end **458** of tubular body **446**. The inner diameter of the second tubular body is tapered to match the screw on the distal end of the torque shaft **426**.

Referring to FIG. **23**, an alternative embodiment of the distal end of inflation catheter **412** is shown. The first tubular body **444** has a proximal end and a distal end and preferably comprises two lumens **452** and **454**. Tubular body **446** can move longitudinally within the lumen **454** of tubular body **444**. A skive **462** is preferably provided on the tubular body **446**. Initially, the tubular body **442** is positioned inside the first tubular body **444**, so the skives **460**, **462** are aligned.

The implant **404** is preferably bonded on the tubing; however, any other known means for attaching a balloon to tubing may be used as known to those of skill in the art. The torque rod **426** is positioned inside the first lumen **452** of the tubing and can move freely within the tubing preferably in both the radial and longitudinal directions. The implant **404** and inflation catheter **412** are connected by screwing the distal tip of the torque rod **426** into tubular body **446**. The inflation catheter also preferably has two lumens which are complementary to the lumens of tubing **444**.

The two-way valve is locked and sealed by pulling back on torque rod **426** after inflating the implant **404**. The catheter **412** is detached from the implant **404** and removable coupling **418** by twisting the torque rod **426**.

A pin **466** is preferably provided within the second lumen of the catheter at its distal tip and also engages the second lumen **454** of the tubing of the coupling **418**. The pin **466** stops the implant **404** from turning during detachment. After the implant is inflated to a desired diameter, by pulling on the rotatable core **416** while holding the delivery catheter **408** against the balloon, the tubing **446** is pulled inside the tubing **444** and the skive **460** is sealed by the plastic tubing **444**. The implant **404** can be detached by unscrewing the torque rod **426** from the delivery catheter.

In other embodiments, the complimentary cross sections can be other shapes, such as a triangle, square, hexagon, ellipse, circle with one or more complimentary intruding and extruding pins, splines, flanges, grooves or other structures disclosed elsewhere herein, or any other regular or irregular polygon that allows the rotatable core **416** to apply a rotational torque to the implant **404**.

In general, the implant is movable from a reduced crossing profile to an enlarged crossing profile, such that it may be

positioned within a body structure and advanced from its reduced to its enlarged crossing profile to obstruct bloodflow or perform other functions while anchored therein. The implant **404** may be biased in the direction of the enlarged crossing profile, may be neutrally biased or may be biased in the direction of the reduced crossing profile. Any modifications to the device and deployment system to accommodate these various aspects of the implant **404** may be readily accomplished by those of skill in the art in view of the disclosure herein.

Throughout this application the applicants have used the terms implant and occlusion device. One of ordinary skill in the art will appreciate that all of the disclosures herein are applicable to a wide variety of structures that include both implants that may or may not also be occlusion devices. Routine experimentation will demonstrate those limited circumstances under which certain disclosures and combinations thereof are not beneficial.

Any of a variety of balloon materials may be used, ranging in physical properties from latex for a highly compliant, low pressure system to PET for a noncompliant high pressure and consequently high radial force system for implant **404**, as is understood in the balloon angioplasty arts.

Implant **404** is preferably provided with a tissue anchor as shown in FIGS. **24A-D**. The tissue anchor **406** comprises a retention structure for retaining or anchoring the implant in the patient's body. The tissue anchor in the illustrated embodiment comprises a tubular body having an axial length of about 5 inches, and a 0.003 in. wall thickness. The ribbon is preferably laser cut and formed into a circular shaped collar. One or preferably, a plurality of hooks, are laser cut on the ribbon. The collar is then mounted on the balloon. Two or more barbs **470** may be provided by laser cutting a pattern in the wall of the tube, and bending each barb such that it is biased radially outwardly as illustrated.

Alternatively, one or more barbs may face distally, to inhibit distal migration of the occlusion device deeper into the LAA. Thus the implant may be provided with at least one proximally facing barb and at least one distally facing barb. For example, in an embodiment of the type illustrated in FIG. **24C**, discussed below, a proximal plurality of barbs may be inclined in a first direction, and a distal plurality of barbs may be inclined in a second direction, to anchor the implant against both proximal and distal migration.

The tissue anchor may be made from any of a variety of biocompatible metals such as stainless steel, Nickel Titanium, Nitinol, Elgiloy or others known in the art. Polymeric anchors such as HDPE, nylon, PTFE or others may alternatively be used.

The anchoring element is designed to easily collapse over the balloon to be pulled inside the delivery catheter.

With reference to FIG. **25**, a delivery catheter is shown including detachable implant **404** and anchoring element **406**. Implant **404** is shown in a deflated position. The implant deployment system **400** thus permits the implant **404** to be maintained in a low crossing profile configuration, to enable transluminal navigation to a deployment site.

As will be appreciated by reference to FIG. **25**, the guide tube **440** of catheter **408** may operate as a limit on distal axial advancement of the proximal end of implant **404**. Thus, the guide tube **440** preferably does not extend sufficiently far proximally from the distal end **411** to interfere with optimal opening of the implant **404**. The specific dimensions are therefore relative, and will be optimized to suit a particular intended application.

Following positioning within the target body lumen, the implant **404** is inflated, thereby engaging barbs **470** with the surrounding tissue. The inflation catheter **412** is thereafter removed, by decoupling the removable coupling **418** as previously discussed.

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 is:

1. A method of implanting a device in the left atrial appendage, comprising:

providing an inflation catheter having an elongate flexible body with a proximal end and a distal end, and a balloon releasably attached to the distal end;

said inflation catheter having a first inner tubular body and a second inner tubular body, the first inner tubular body being moveable with respect to the second inner tubular body between a first sealed position and a second inflation position, wherein said movement exposes or seals an inflation lumen provide on one of the tubular bodies within said balloon and wherein the inflation catheter is releasably attached to one of the tubular bodies, and axial movement of the inflation catheter moves the first inner tubular body relative to the second inner tubular body, thereby forming a two way valve that can be used for both inflation and deflation of said balloon, by operating the valve located within said balloon;

said balloon including a spherical stop to limit motion of said valve and define said second position;

said balloon has a proximal end and a distal end, and further comprises a plurality of anchors each of said plurality of anchors arranged in multiple circumferential rows along an outer surface of the balloon, that deploy with positive force thus displacing tissue in contact with said balloon and said anchors, some of said anchors pointing distally and some of said anchors pointing proximally;

positioning at least a portion of the balloon in the left atrial appendage;

inflating the balloon so that the balloon securely engages an inner surface of the left atrial appendage to displace the tissue in the LAA proximate the ostium of the LAA, thereby trapping the balloon in the LAA; and

releasing the balloon from the distal end of the inflation catheter, with the balloon remaining securely engaged with the inner surface of the left atrial appendage.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,713,282 B2
APPLICATION NO. : 10/426130
DATED : May 11, 2010
INVENTOR(S) : Frazier et al.

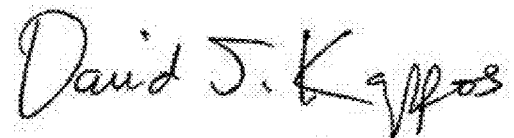
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Pg, Item (75) Inventors:

After the third inventor listed, Erik J. van der Burg, delete "Sunnyvale, CA" and insert therefor -- Los Gatos, CA --.

Signed and Sealed this
Fifth Day of July, 2011

A handwritten signature in black ink that reads "David J. Kappos". The signature is written in a cursive, slightly slanted style.

David J. Kappos
Director of the United States Patent and Trademark Office