



US010667825B2

(12) **United States Patent**
Zhadkevich

(10) **Patent No.:** **US 10,667,825 B2**
(45) **Date of Patent:** **Jun. 2, 2020**

(54) **NONINVASIVE PROTECTION FROM EMBOLI**

(71) Applicant: **ZHADKEVICH MEDICAL, INC.**,
Greenwood, SC (US)

(72) Inventor: **Michael Zhadkevich**, Greenwood, SC
(US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 176 days.

(21) Appl. No.: **15/691,026**

(22) Filed: **Aug. 30, 2017**

(65) **Prior Publication Data**

US 2017/0360452 A1 Dec. 21, 2017

Related U.S. Application Data

(62) Division of application No. 14/703,669, filed on May
4, 2015, now Pat. No. 9,808,260.
(Continued)

(51) **Int. Cl.**
A61B 17/135 (2006.01)
A61B 17/132 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 17/1355** (2013.01); **A61B 17/132**
(2013.01); **A61B 17/135** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 5/00; A61B 5/0002; A61B 5/0004;
A61B 5/02; A61B 5/0205; A61B 5/022;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,271,927 A 2/1942 Saighman
2,571,461 A 10/1951 Livingston
(Continued)

FOREIGN PATENT DOCUMENTS

CN 201 356 600 Y 12/2009
EP 0109627 A1 5/1984
(Continued)

OTHER PUBLICATIONS

European Patent Office; Communication Regarding Extended Euro-
pean Search Report pursuant to Rule 62 EPC; European Application
No. 17190479.0-1122; European Patent Office; pp. 1-7; publisher
European Patent Office; Published Munich Germany; copyright and
dated Jan. 16, 2018; (7 pages).

(Continued)

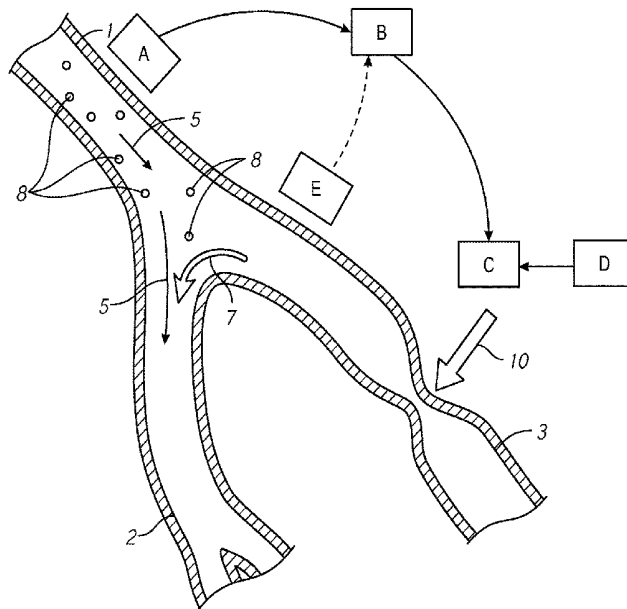
Primary Examiner — Robert A Lynch

(74) *Attorney, Agent, or Firm* — J. Bennett Mullinax,
LLC

(57) **ABSTRACT**

A system for diverting emboli within a patient can include
a device that detects a presence of emboli in a first blood
vessel of a patient. A compression member can be aligned,
with a second blood vessel of the patient when a collar
supporting the compression member is positioned at, least
partially around a portion of the patient. In response to, the
detection device, a controller can actuate the compression
member, when the presence of emboli is detected, from an
unactuated state to an actuated state in which at least a
portion of the compression member (i) is closer to the
second blood vessel than while in the unactuated state and
(ii) compresses and limits blood flow through the second
blood vessel.

13 Claims, 29 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 61/988,217, filed on May 4, 2014.

(51) Int. Cl.

A61B 5/02 (2006.01)

A61B 5/026 (2006.01)

A61B 5/022 (2006.01)

A61H 9/00 (2006.01)

A61H 1/00 (2006.01)

A61B 5/00 (2006.01)

A61B 17/00 (2006.01)

(52) U.S. Cl.

CPC *A61B 17/1325* (2013.01); *A61B 5/02* (2013.01); *A61B 5/022* (2013.01); *A61B 5/026* (2013.01); *A61B 5/02233* (2013.01); *A61B 5/6822* (2013.01); *A61B 2017/00022* (2013.01); *A61H 1/008* (2013.01); *A61H 9/0078* (2013.01); *A61H 2205/04* (2013.01)

(58) Field of Classification Search

CPC *A61B 5/02208*; *A61B 5/02233*; *A61B 5/02405*; *A61B 5/026*; *A61B 5/145*; *A61B 5/4881*; *A61B 5/4845*; *A61B 5/68*; *A61B 5/6801*; *A61B 5/6803*; *A61B 5/6814*; *A61B 5/6822*; *A61B 8/08*; *A61B 8/0808*; *A61B 8/0816*; *A61B 8/52*; *A61B 8/54*; *A61B 8/546*; *A61B 17/132*; *A61B 17/1325*; *A61B 17/135*; *A61B 17/1355*; *A61H 9/0078*; *A61H 1/008*; *A61H 2205/04*

See application file for complete search history.

(56)

References Cited

U.S. PATENT DOCUMENTS

2,676,586 A 4/1954 Coakwell, Jr.
3,587,584 A 6/1971 Bourbon
4,676,232 A 6/1987 Olsson et al.
4,686,085 A 8/1987 Osterholm
4,745,924 A 5/1988 Ruff
5,234,459 A 8/1993 Lee
5,271,409 A 12/1993 Millay
5,312,350 A 5/1994 Jacobs
5,348,015 A 9/1994 Moehring
5,372,575 A 12/1994 Sebastian
5,376,067 A 12/1994 Daneshvar
5,441,051 A 8/1995 Hileman
5,514,079 A 5/1996 Dillon
5,685,321 A 11/1997 Klingenstein
5,741,295 A 4/1998 McEwen
5,792,173 A 8/1998 Breen
6,063,036 A 5/2000 Li
6,238,413 B1 5/2001 Wexler
6,299,629 B1* 10/2001 Gruenfeld *A61B 5/02233*
606/202
6,336,901 B1 1/2002 Itonaga et al.
6,547,736 B1* 4/2003 Moehring *A61B 8/06*
600/441
7,074,177 B2 7/2006 Pickett
7,314,478 B2 1/2008 Hui
7,727,254 B2 6/2010 Pah
7,972,356 B2 7/2011 Boyle et al.
D643,536 S 8/2011 Vivenzio
7,988,104 B1 8/2011 Cook et al.
7,998,104 B2 8/2011 Chang
8,025,674 B2 9/2011 Barbut et al.
8,062,324 B2 11/2011 Shimon et al.
2001/0025643 A1 10/2001 Foley
2003/0167070 A1* 9/2003 McEwen *A61B 17/135*
606/203

2004/0098035 A1 5/2004 Wada
2005/0075531 A1 4/2005 Loeb et al.
2006/0100530 A1 5/2006 Kliot
2006/0241485 A1 10/2006 Hacker
2007/0173886 A1 7/2007 Rouso
2007/0191881 A1 8/2007 Amisar
2008/0154140 A1 6/2008 Chang et al.
2008/0262535 A1 10/2008 Gavriely et al.
2009/0209925 A1 8/2009 Marinello
2009/0287101 A1 11/2009 Ferren
2010/0082060 A1 4/2010 Avitable
2010/0094332 A1 4/2010 Willshaw
2010/0324429 A1* 12/2010 Leschinsky *A61H 9/0078*
600/493
2010/0324589 A1 12/2010 Carpenter et al.
2011/0028934 A1 2/2011 Buckman et al.
2012/0035652 A1 2/2012 McGrimley
2013/0023909 A1* 1/2013 Duhay *A61F 2/01*
606/158
2013/0304111 A1 11/2013 Zhadkevich
2014/0135816 A1 5/2014 Hyde et al.
2014/0236221 A1 8/2014 Zhadkevich
2014/0277101 A1* 9/2014 Smith *A61B 17/1325*
606/202
2015/0018869 A1 1/2015 Benz et al.
2015/0080942 A1 3/2015 Garrison
2015/0313607 A1 11/2015 Zhadkevich
2016/0030001 A1 2/2016 Stein

FOREIGN PATENT DOCUMENTS

EP 0203310 A2 12/1986
EP 0 462 088 A2 12/1991
EP 0934726 A1 8/1999
EP 2662034 A1 11/2013
EP 2796099 A1 10/2014
FR 699349 A 2/1931
FR 719730 A 2/1932
WO WO 98/46144 A1 10/1998
WO WO 99/36028 A1 7/1999
WO WO 2007/074350 A1 7/2007
WO WO 2008/00932 A1 1/2008
WO WO 2008/150966 A1 12/2008
WO WO 2010/141752 A1 12/2010
WO WO 2011/088543 A1 7/2011
WO WO 2014/027347 A1 2/2014
WO WO 2014/037960 A1 3/2014
WO WO 2014/074993 A1 5/2014

OTHER PUBLICATIONS

European Patent Office; Communication Regarding Extended European Search Report pursuant to Rule 62 EPC; European Application No. 17199143.3-1122; European Patent Office; pp. 1-10; publisher European Patent Office; Published Munich Germany; copyright and dated Feb. 14, 2018; (10 pages).

Gabor Erdoes, MD, titled "Letter by Erdoes et al Regarding Article, Cerebral Embolization During Transcatheter Aortic Valve Implantation: A Transcranial Doppler Study," item title "Journal of the American Heart Association"; copyright 2013; p. 590; No. 127; American Heart Association, Inc.; Dallas Texas, USA; parent application (2 pages).

Marie-Christine Guilbert, titled "Arterial trauma during central venous catheter insertion: Case series, review and proposed algorithm," item title "Journal of Vascular Surgery", copyright 2008, pp. 918-925, vol. 48, No. 4, Canadian Society for Vascular Surgery; Montreal, Quebec, Canada; parent application (8 pages).

Philipp Kahlert, "Cerebral Embolization During Transcatheter Aortic Valve Implantation: A Transcranial Doppler Study," Item titled "Journal of the American Heart Association", copyright Aug. 16, 2012; pp. 1245-1255; No. 126; American Heart Association, Inc.; Dallas, Texas, USA; parent application (16 pages).

H. Löffler; Stratum corneum adhesive tape stripping: Influence of anatomical site, application pressure, duration and removal; British Journal of Dermatology; 2004; pp. 746-752; vol. 151; publisher

(56)

References Cited

OTHER PUBLICATIONS

United States Patent and Trademark Office; Published United Kingdom; copyright 2004 British Association of Dermatologists; parent application (8 pages).

United States Patent and Trademark Office; Office Action; U.S. Appl. No. 14/703,669; USPTO; pp. 1-7; publisher United States Patent and Trademark Office; Published Alexandria, Virginia, USA; copyright and dated Jun. 9, 2017; parent application (7 pages).

European Patent Office; Communication Supplementary European Search Report and European Search Opinion, European Application No. 15788567.4/3139840; European Patent Office; pp. 1-7; publisher European Patent Office; Published Munich, Germany; copyright and dated May 12, 2017; parent application (7 pages).

International Search Report and Written Opinion, dated Feb. 11, 2016 in the International application: PCT/US2015/029104, filed May 4, 2015, parent application (6 pages).

United States Patent and Trademark Office; Office Action; U.S. Appl. No. 15/008,276; USPTO; pp. 1-14; publisher United States Patent and Trademark Office; Published Alexandria, Virginia, USA; copyright and dated Jul. 20, 2018; (14 pages).

* cited by examiner

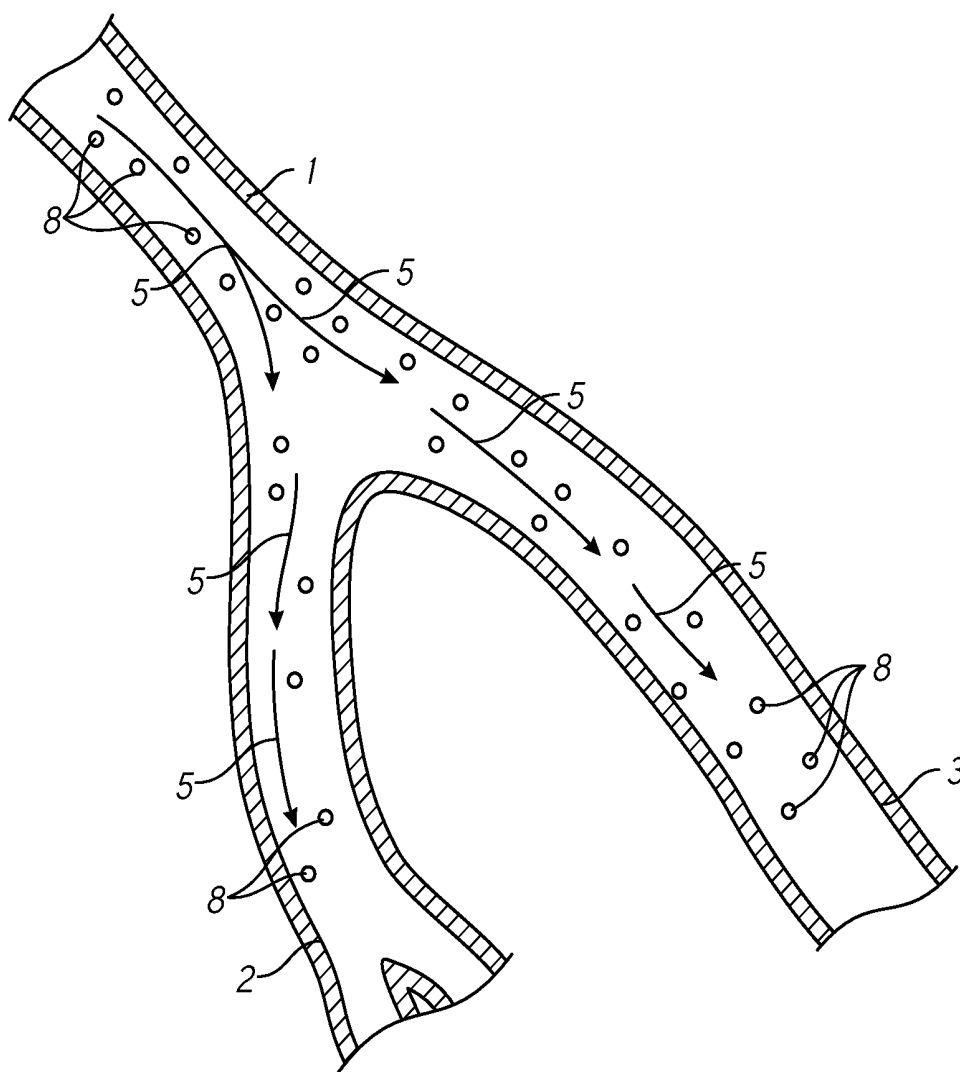


FIG. 1

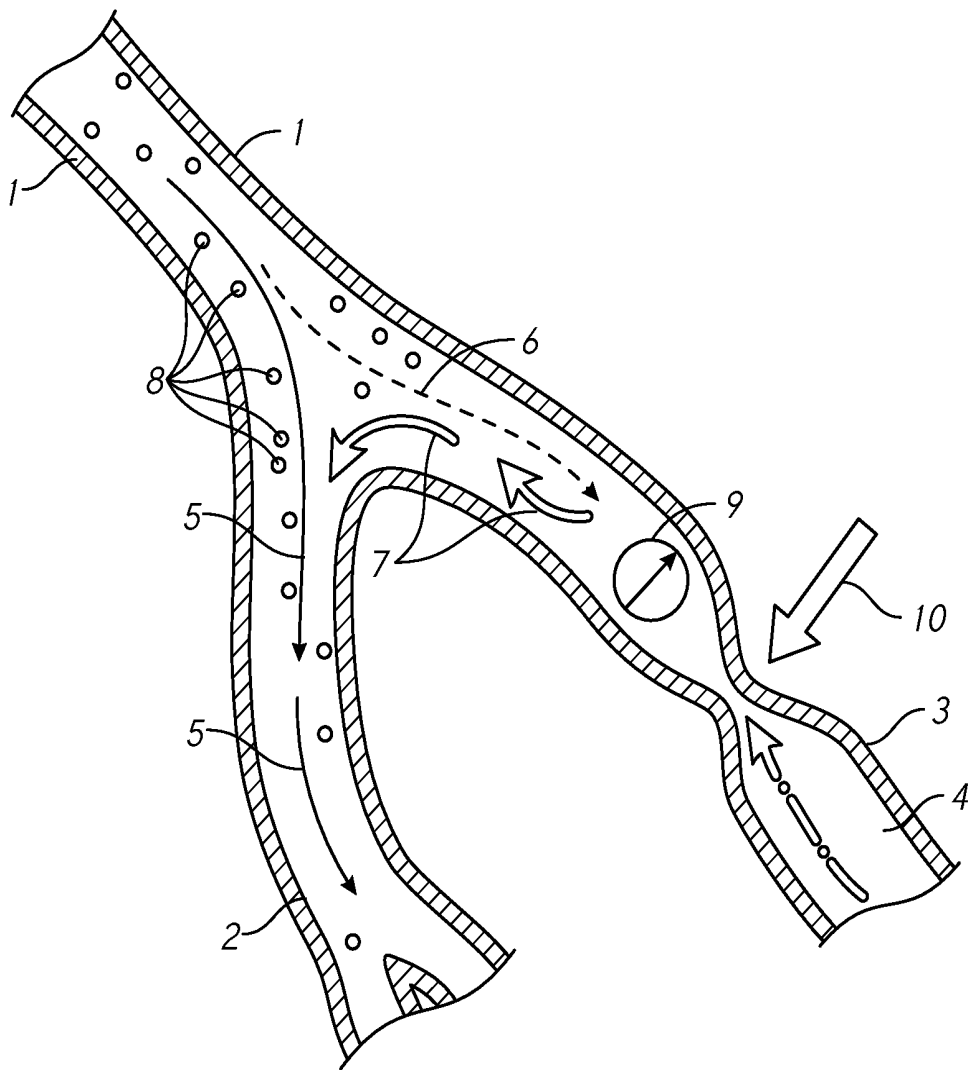


FIG. 2

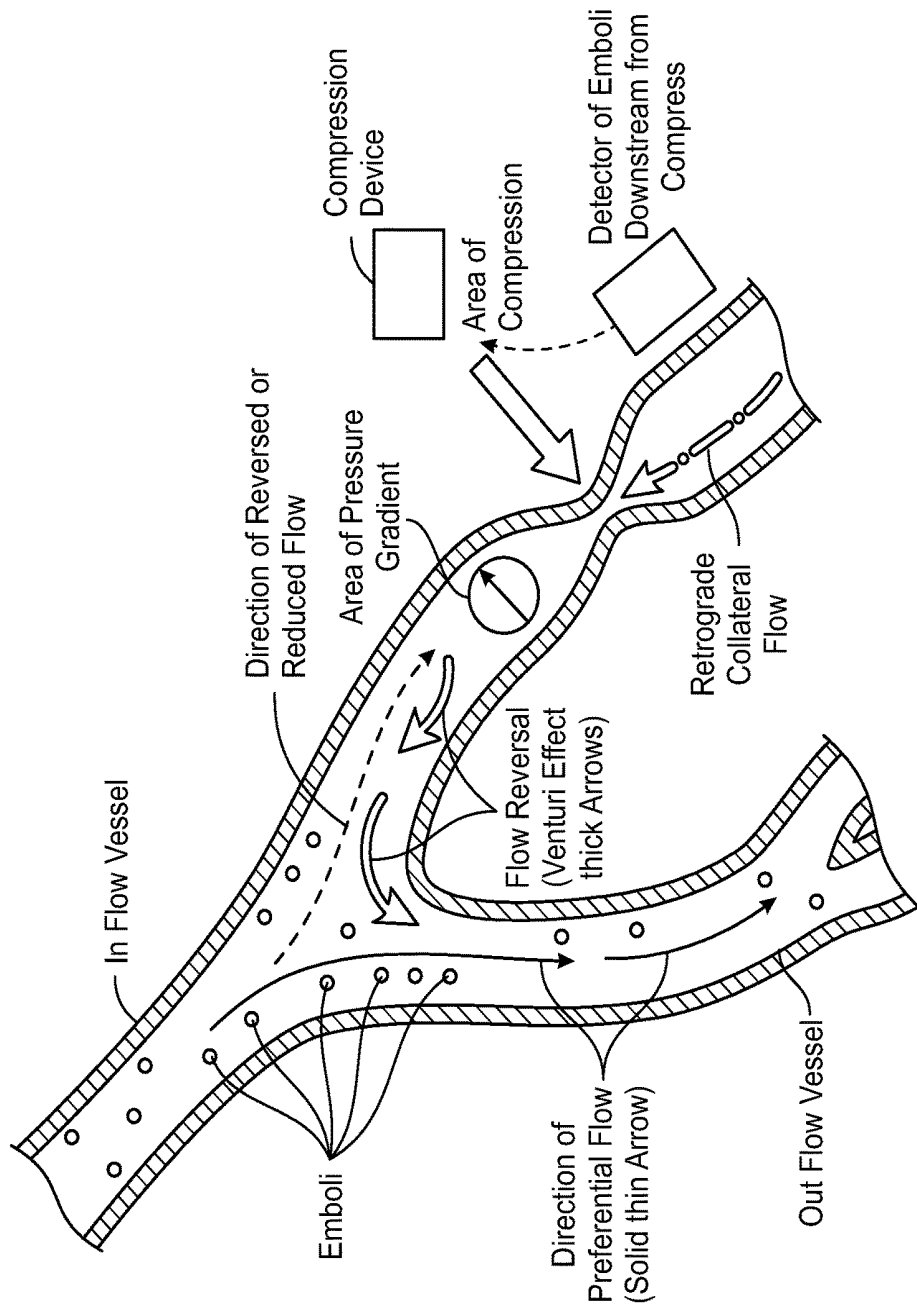


FIG. 3

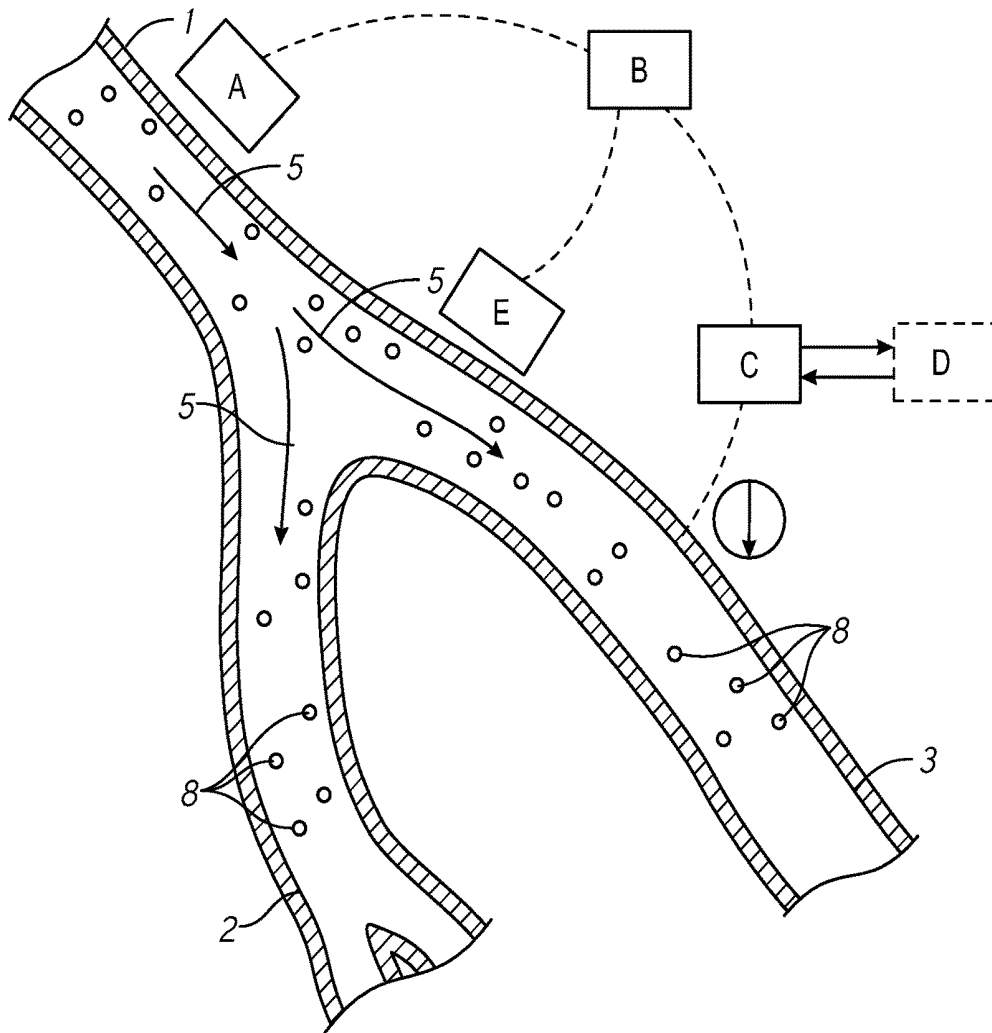


FIG. 4

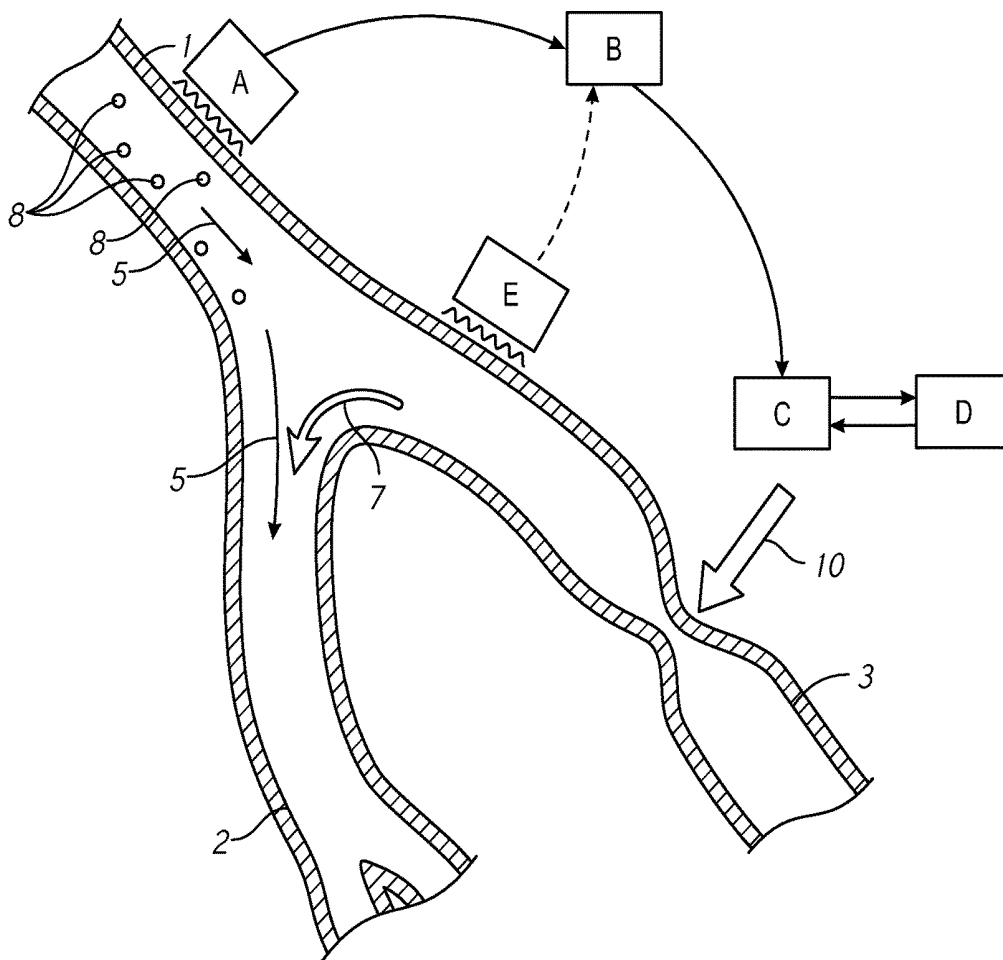


FIG. 5

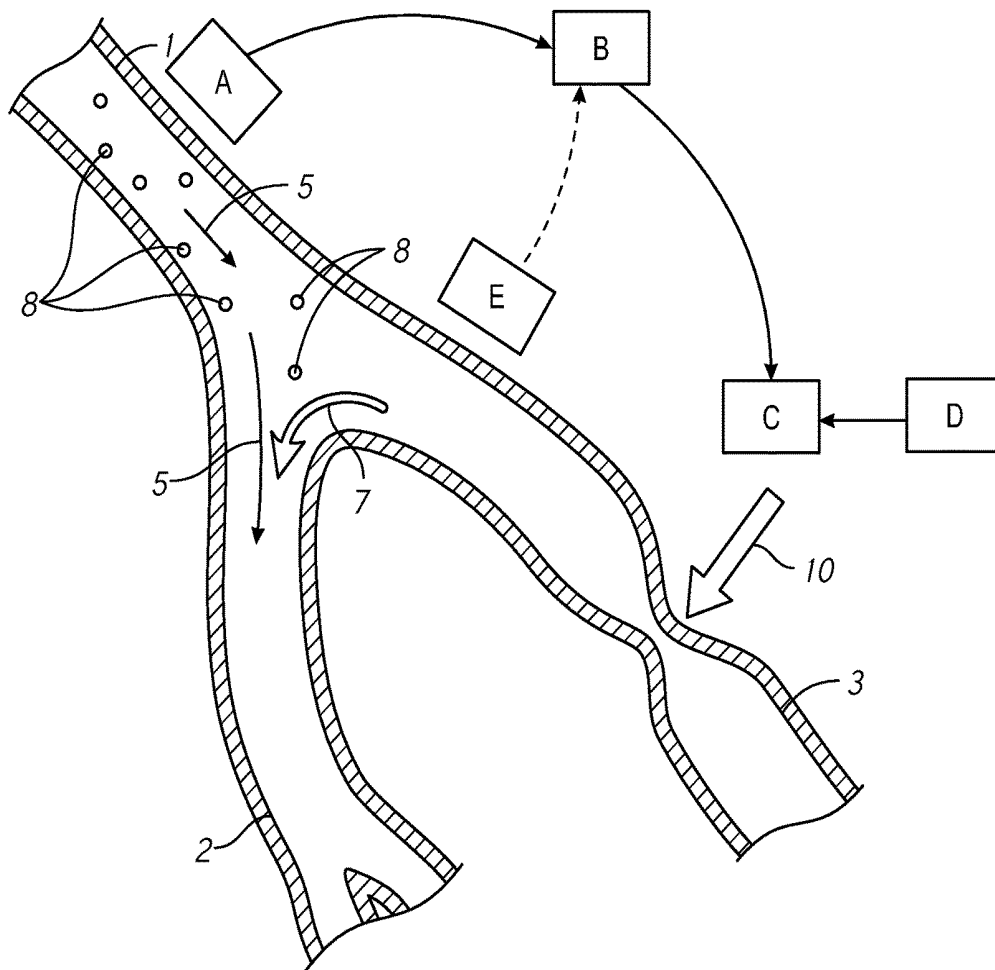


FIG. 6

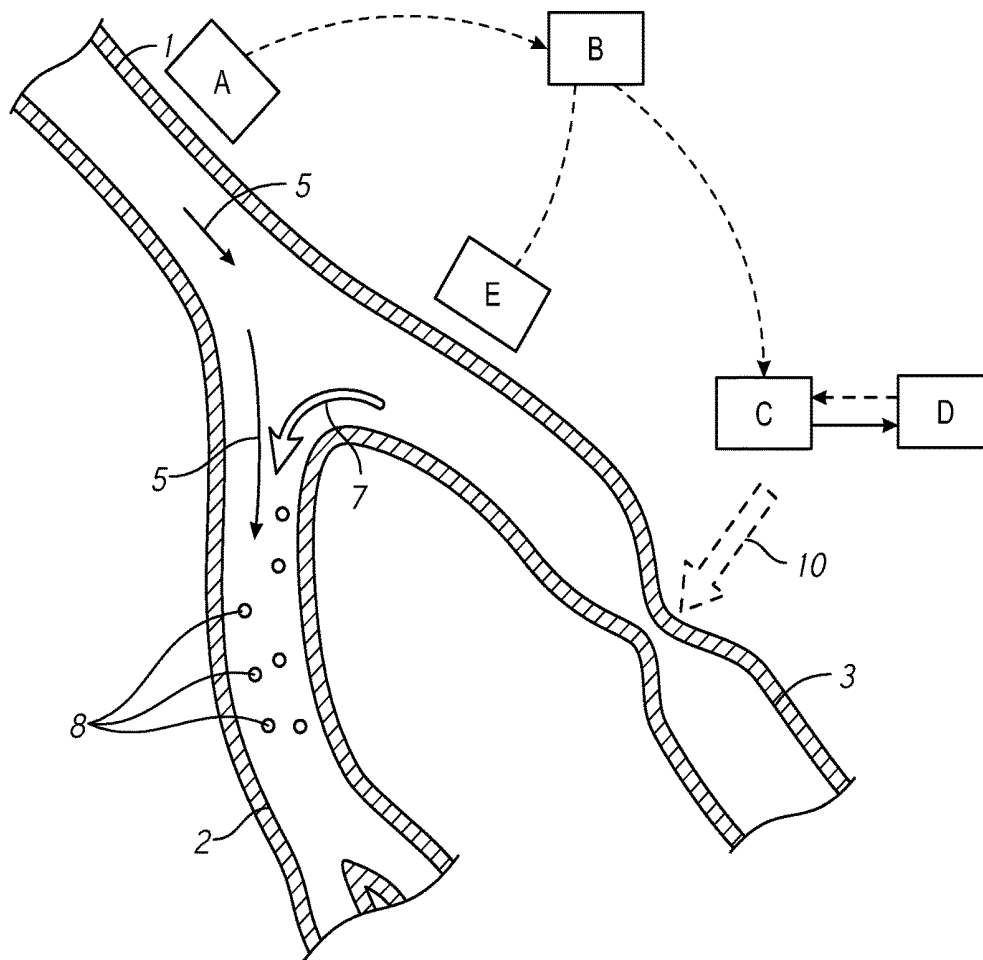


FIG. 7

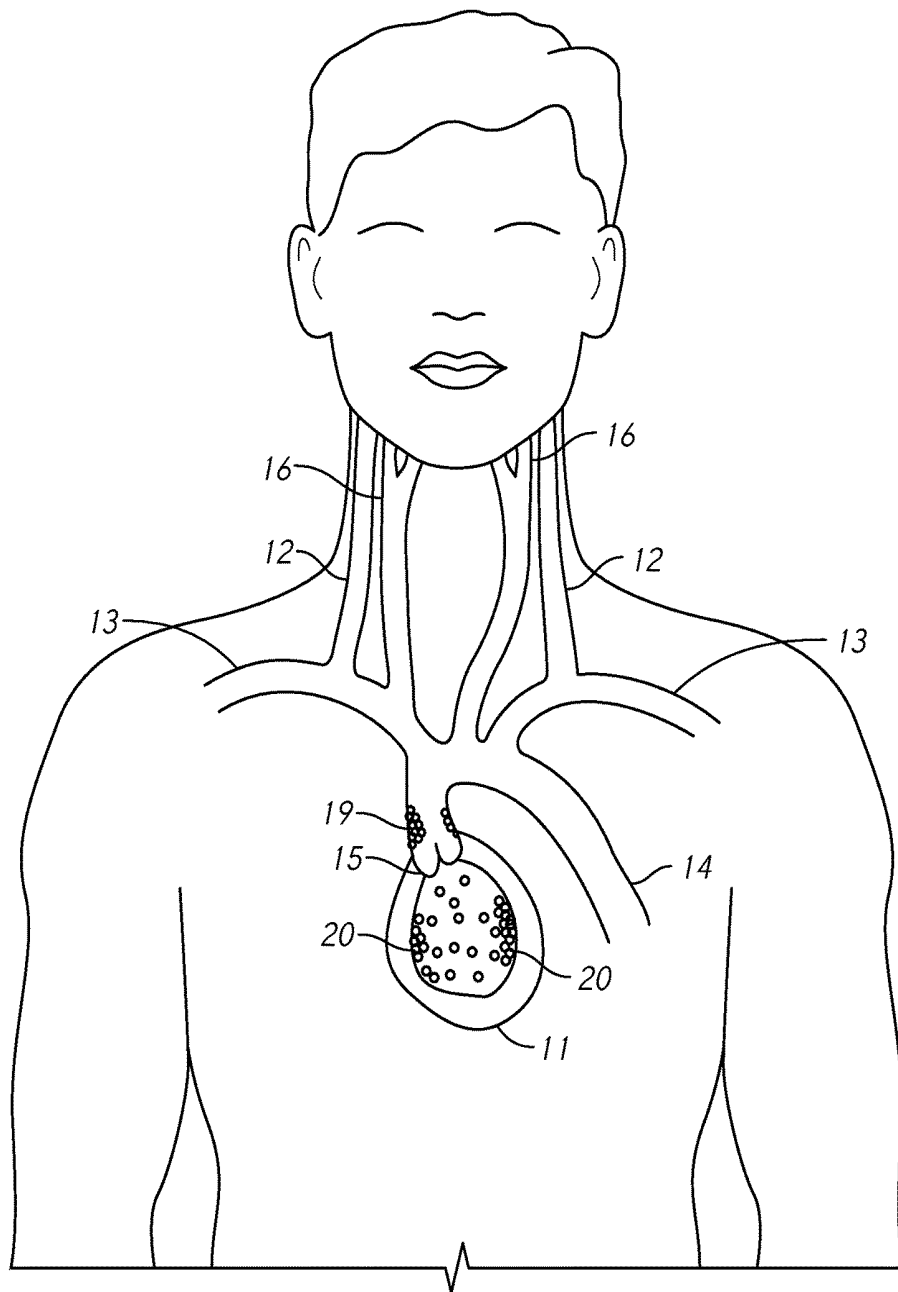


FIG. 8

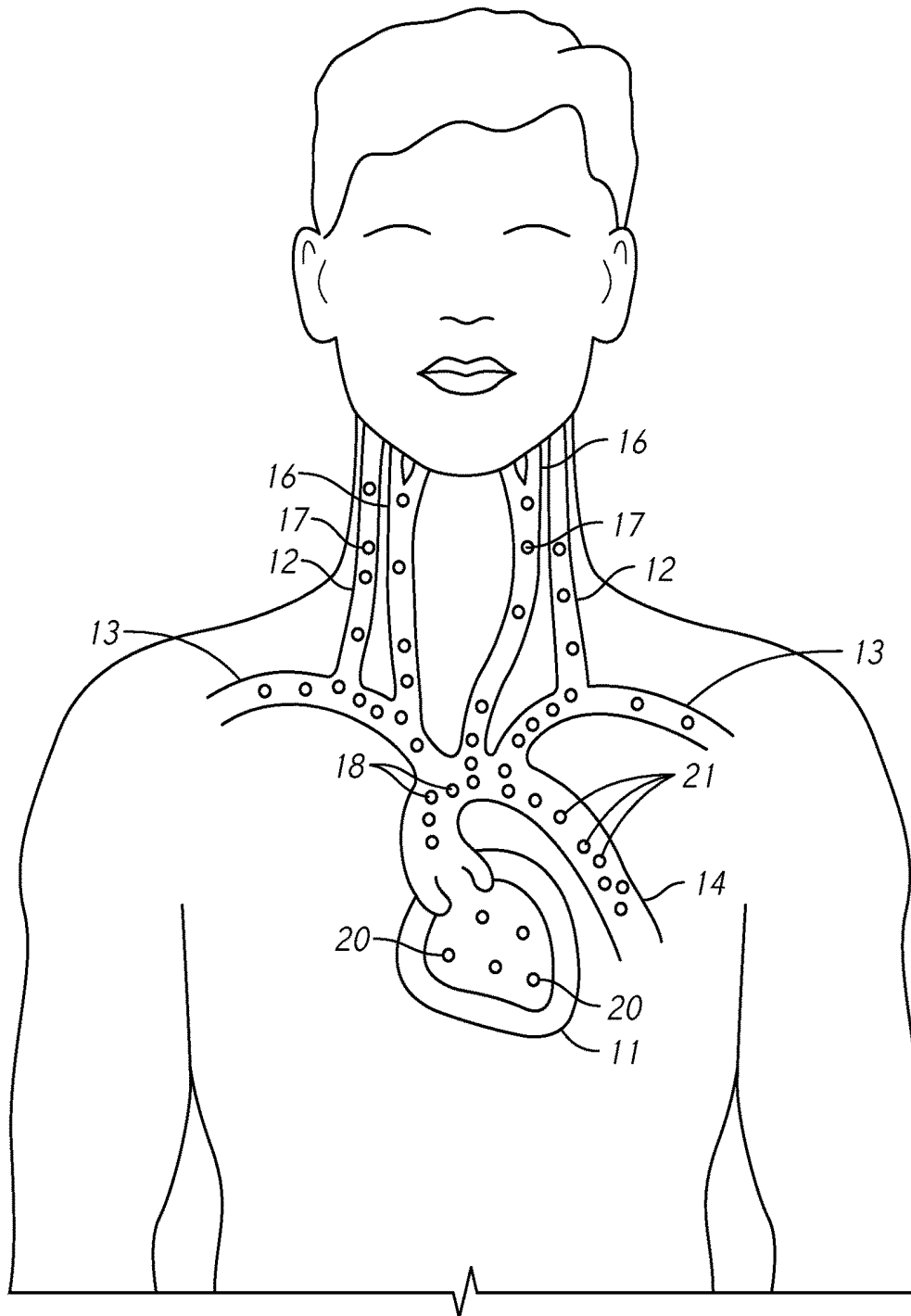


FIG. 9

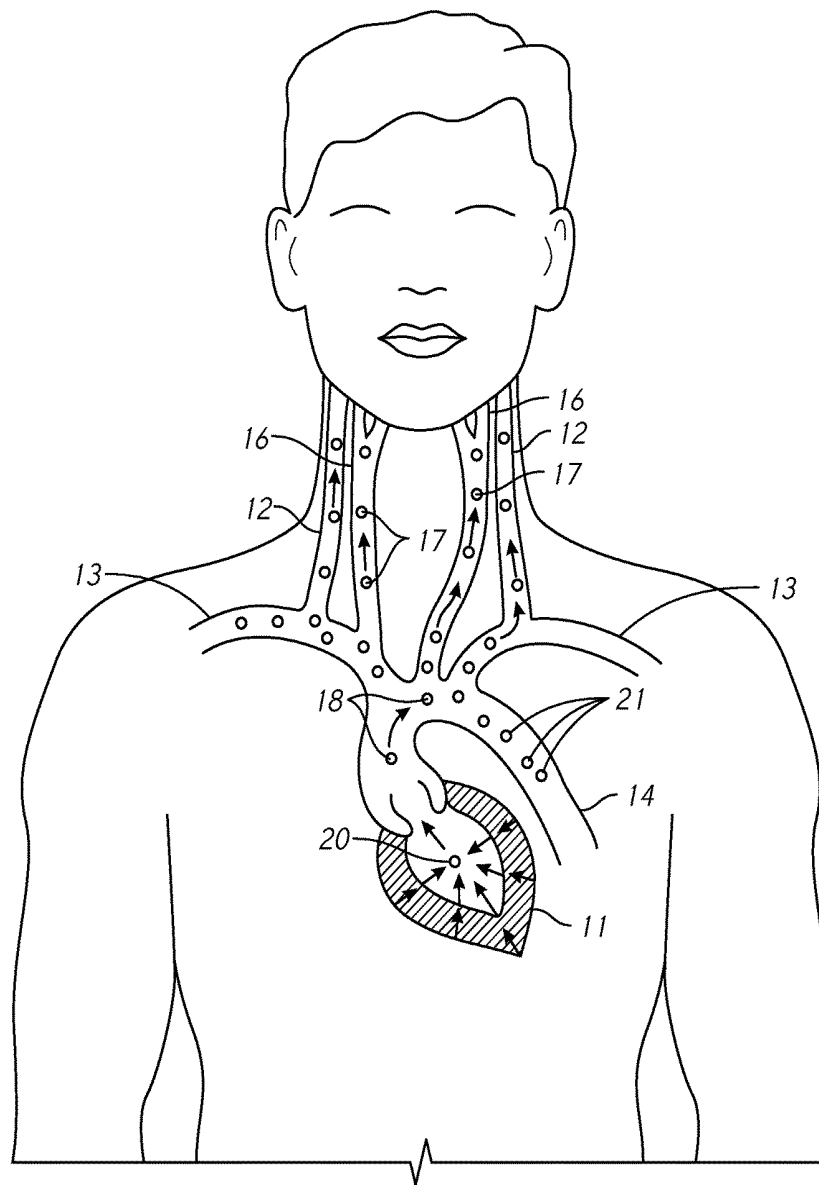


FIG. 10

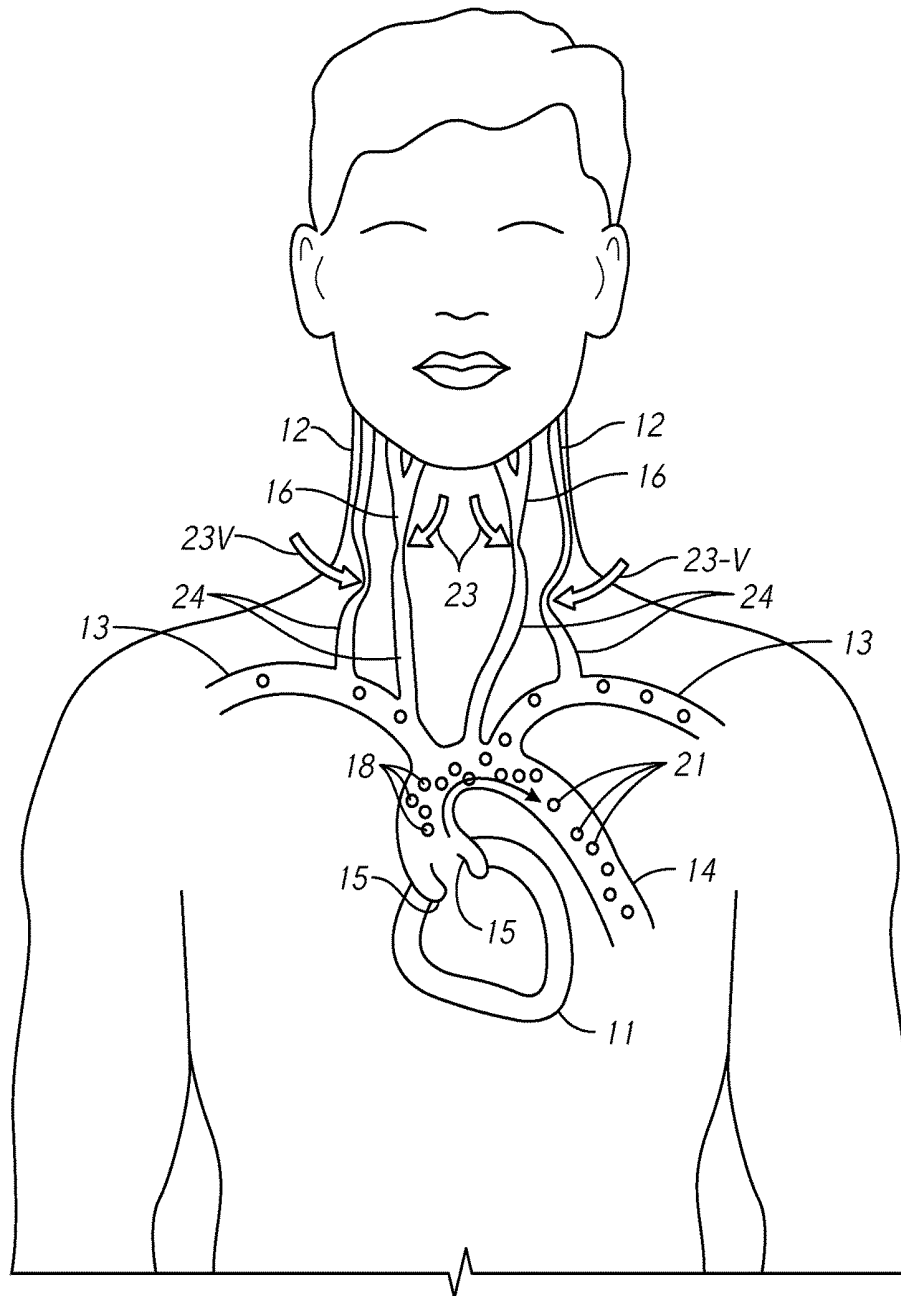


FIG. 11

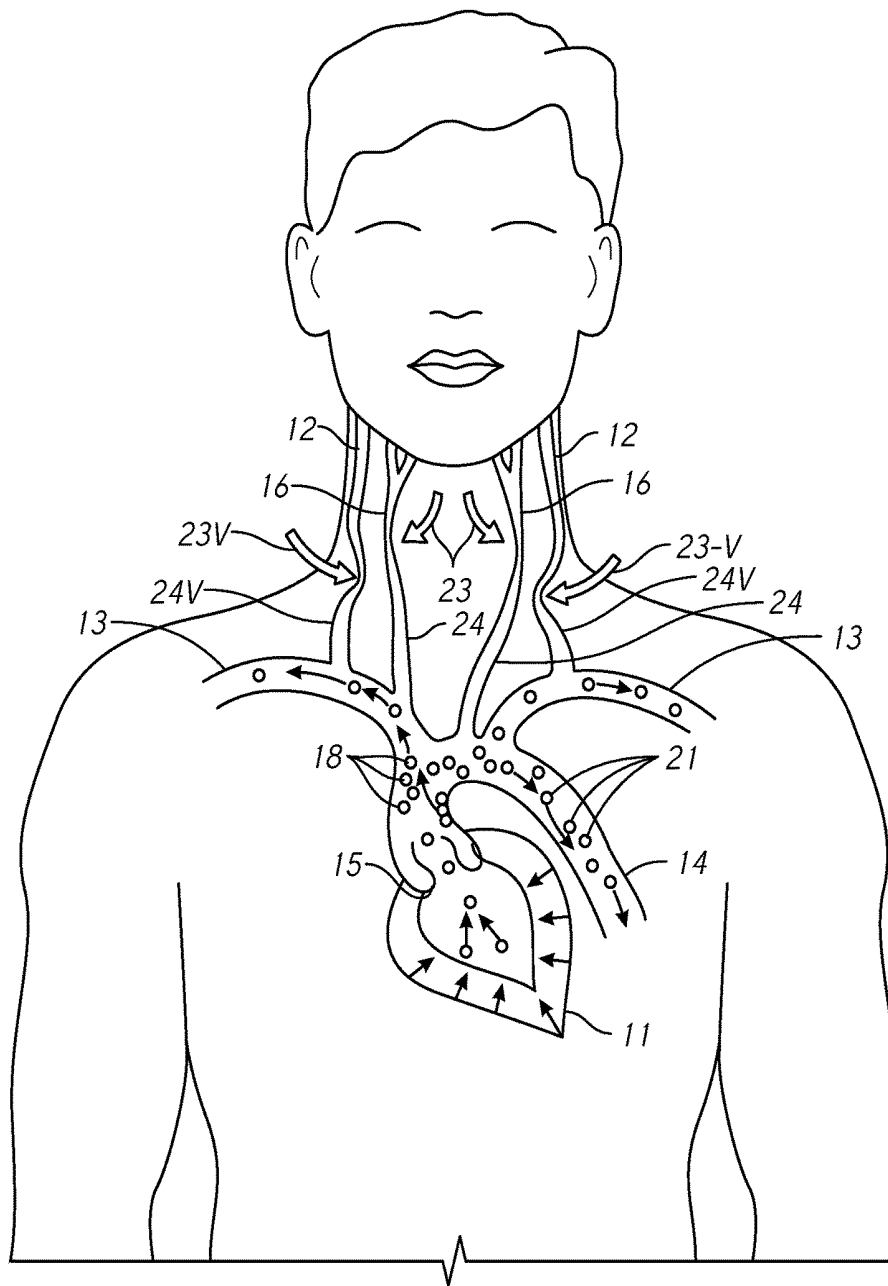


FIG. 12

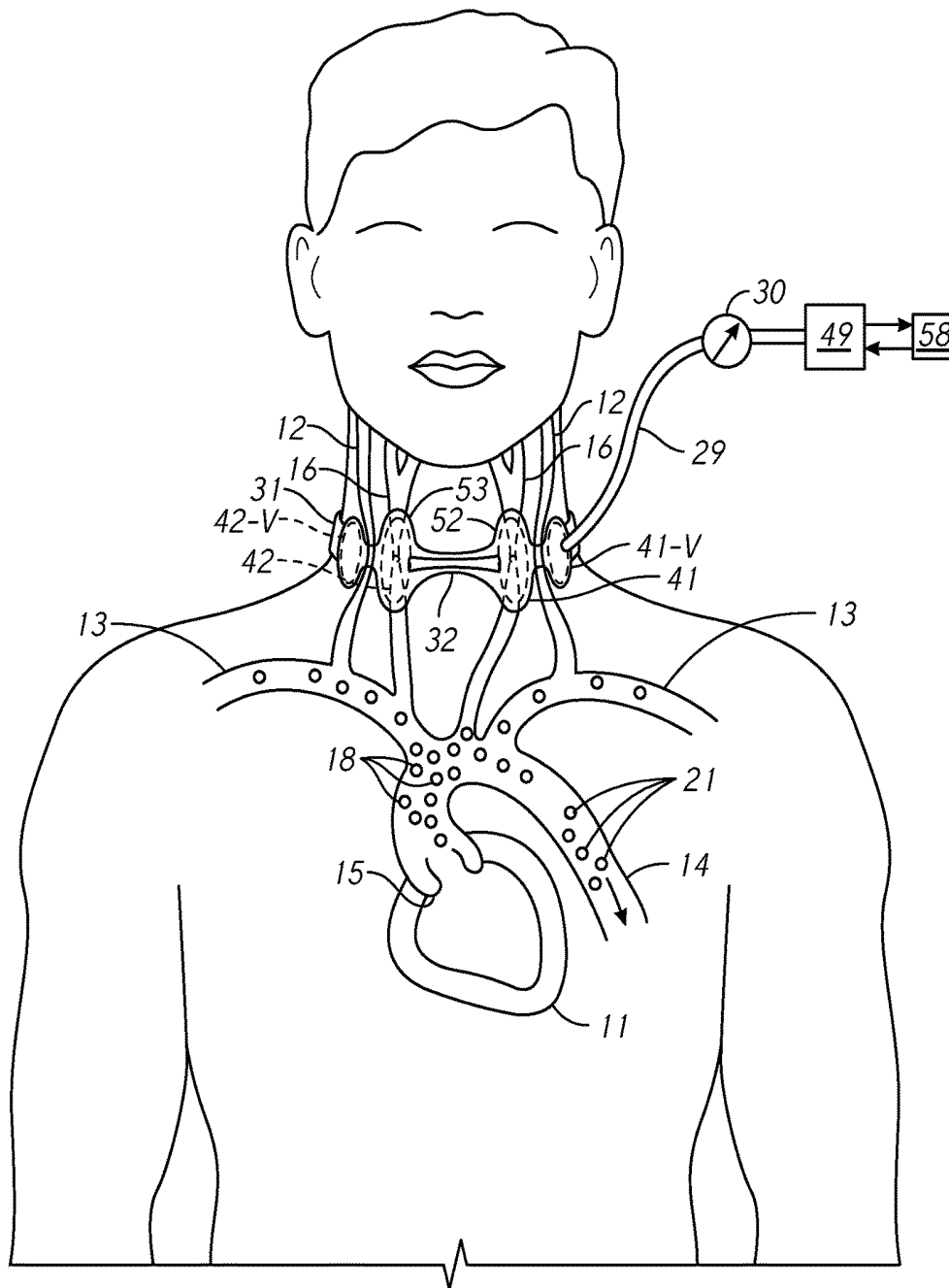


FIG. 13

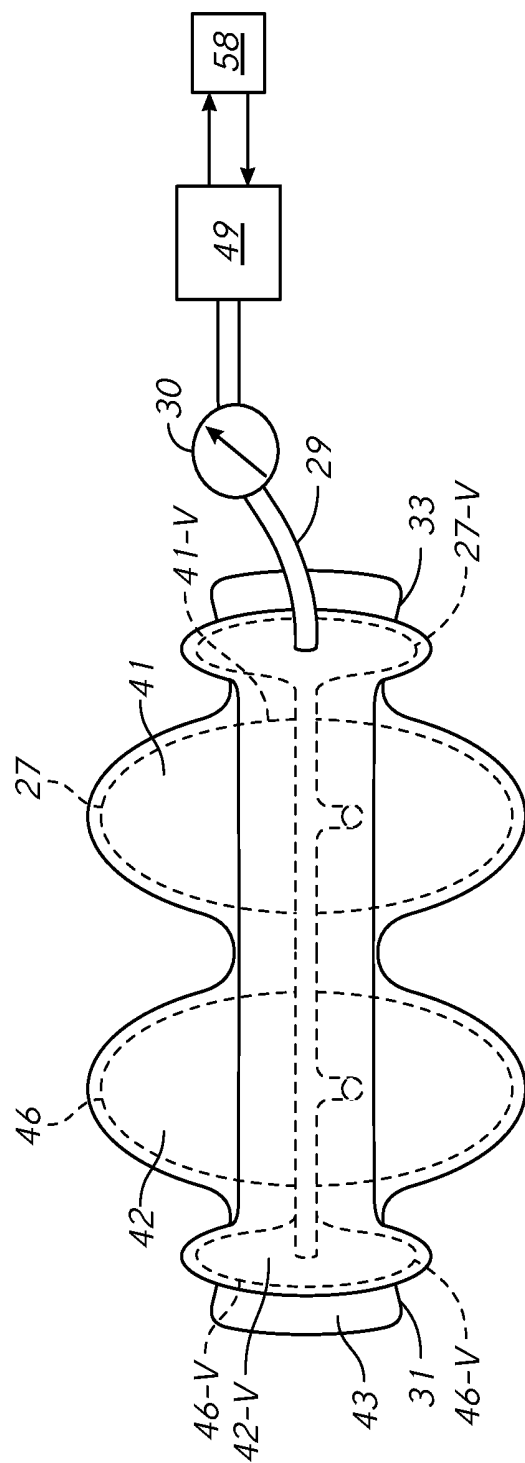


FIG. 14

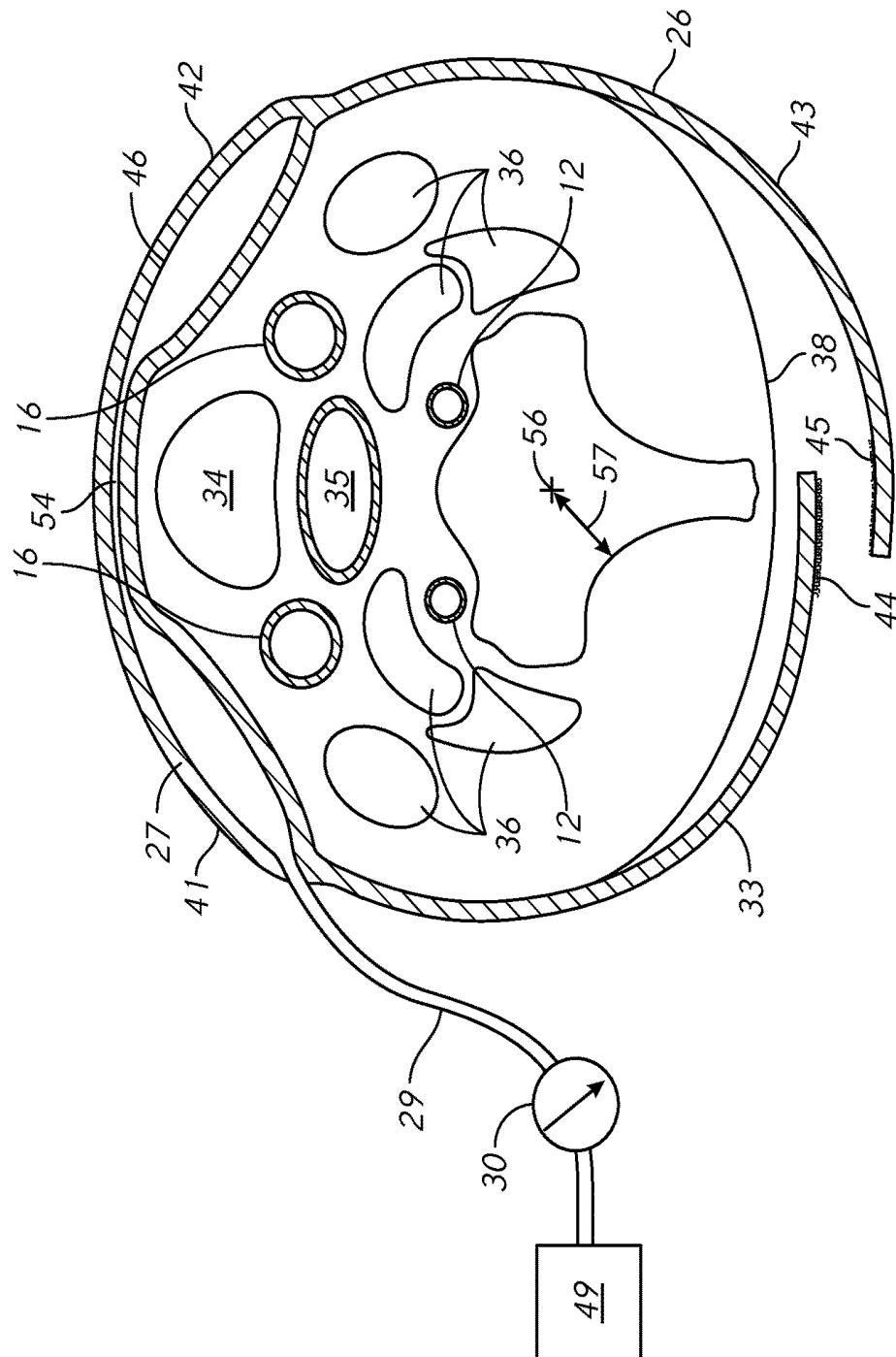


FIG. 15

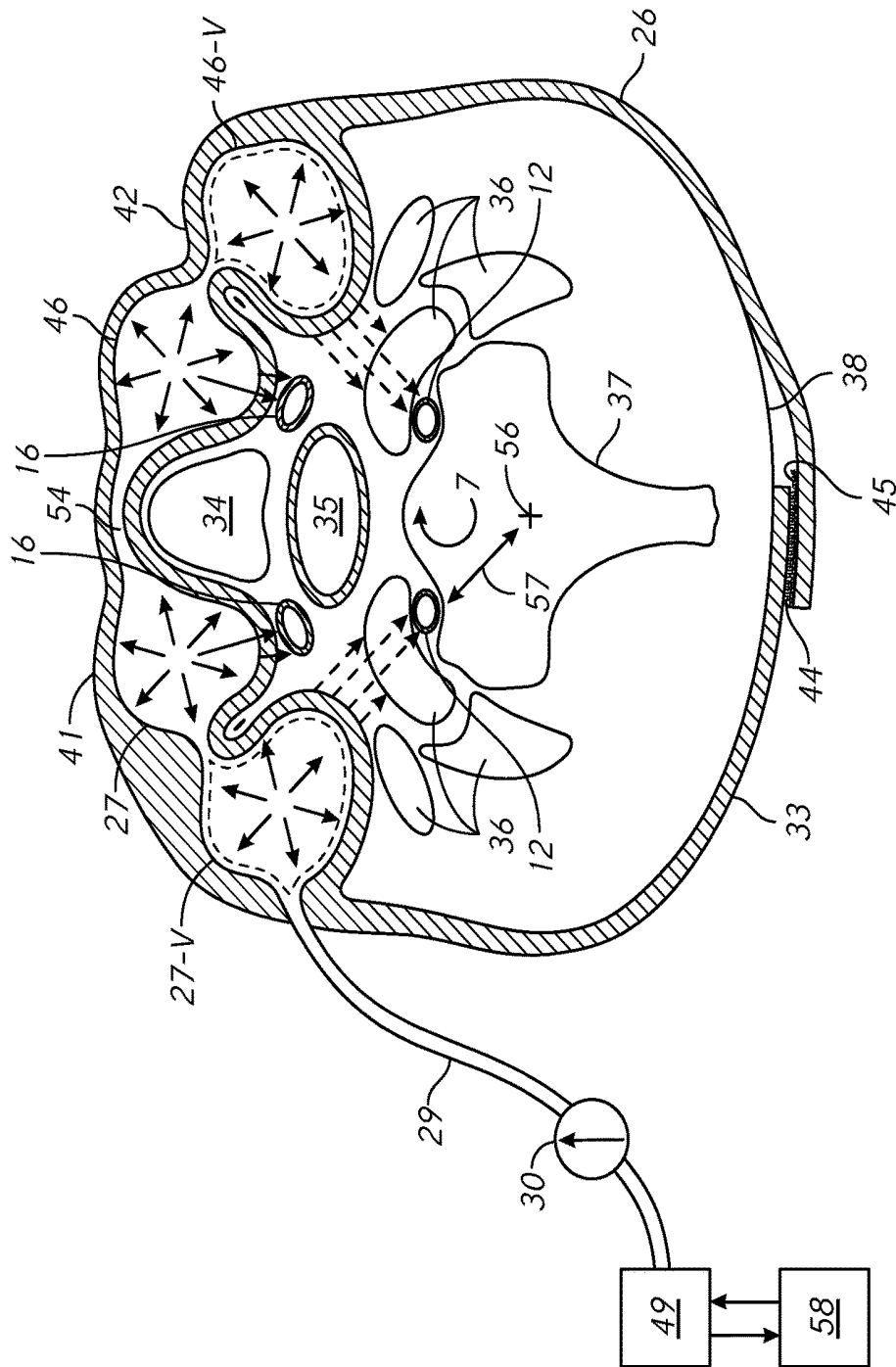


FIG. 16

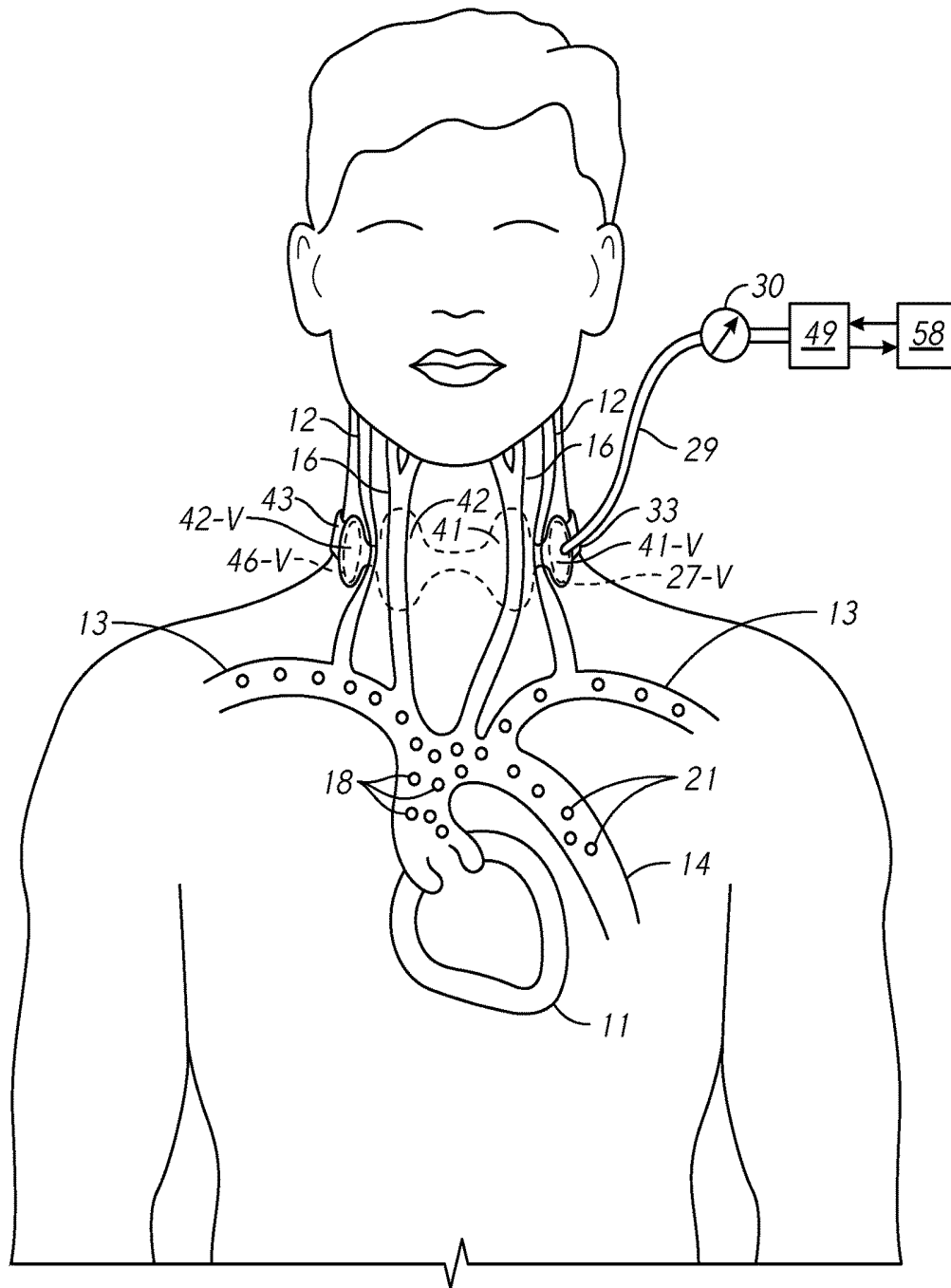


FIG. 17

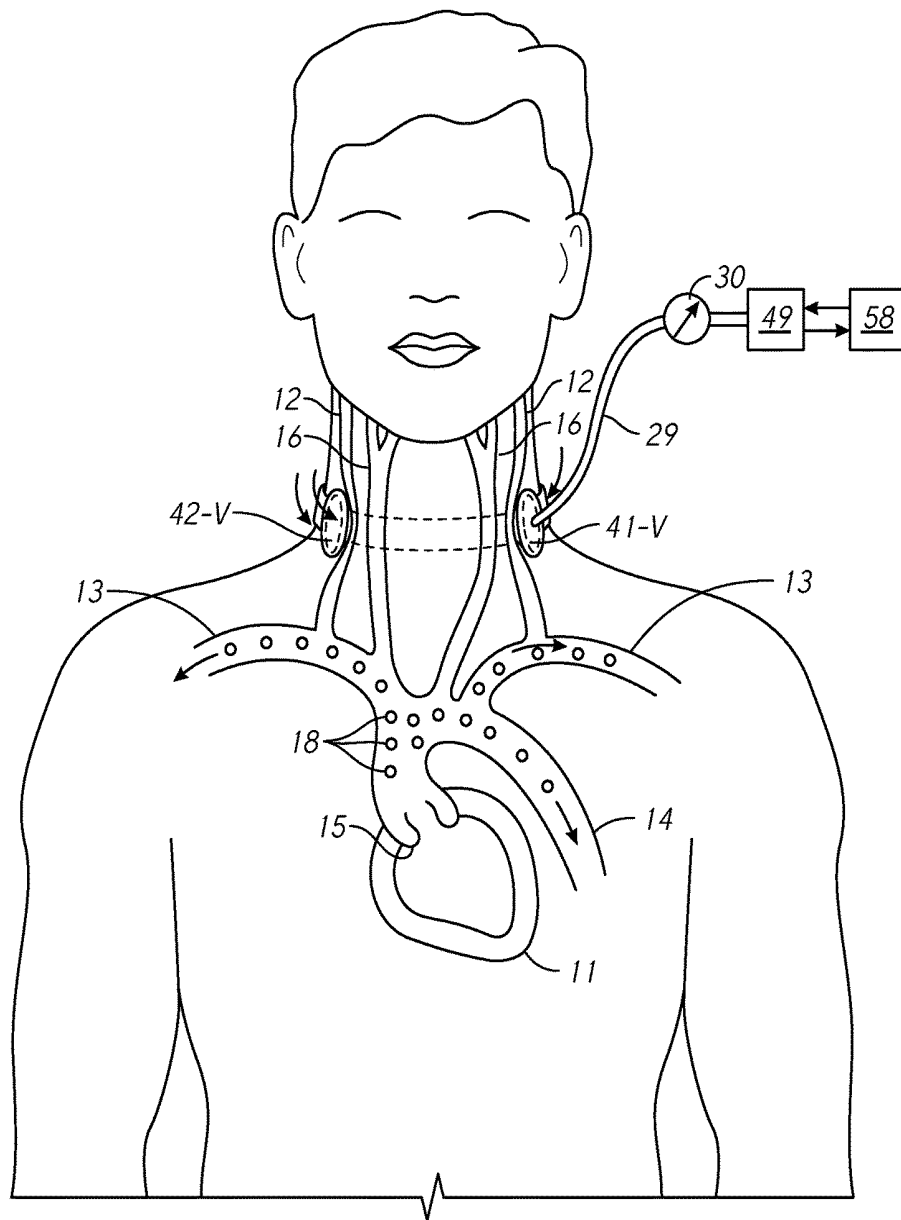


FIG. 18

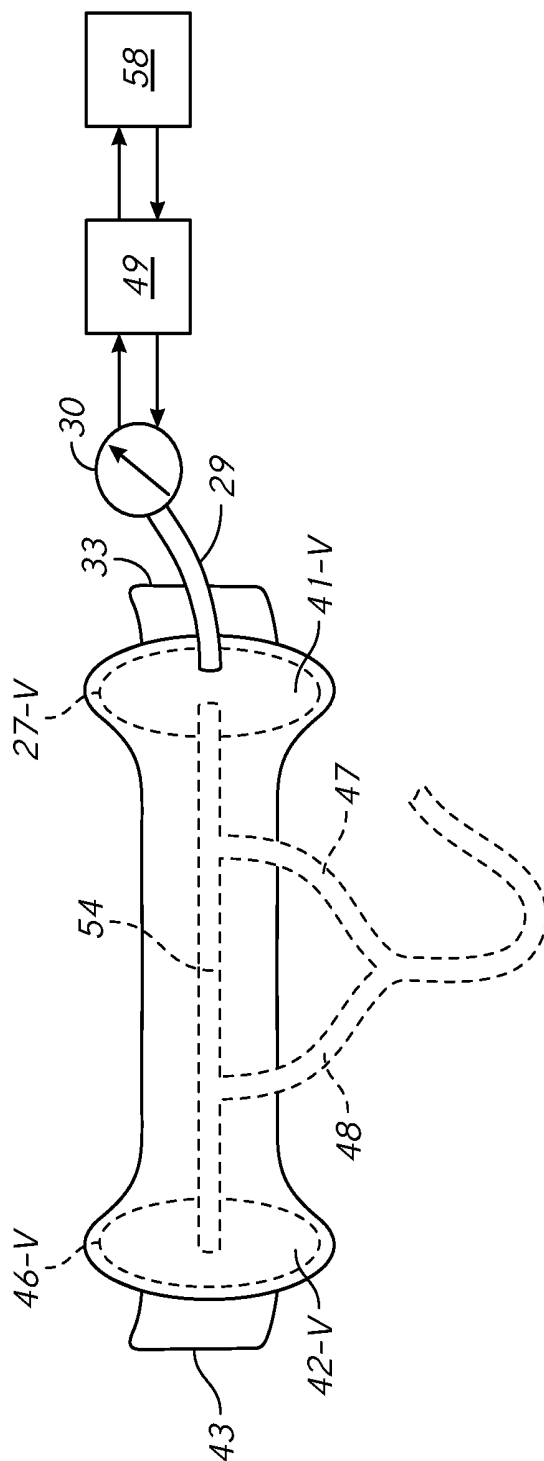


FIG. 19

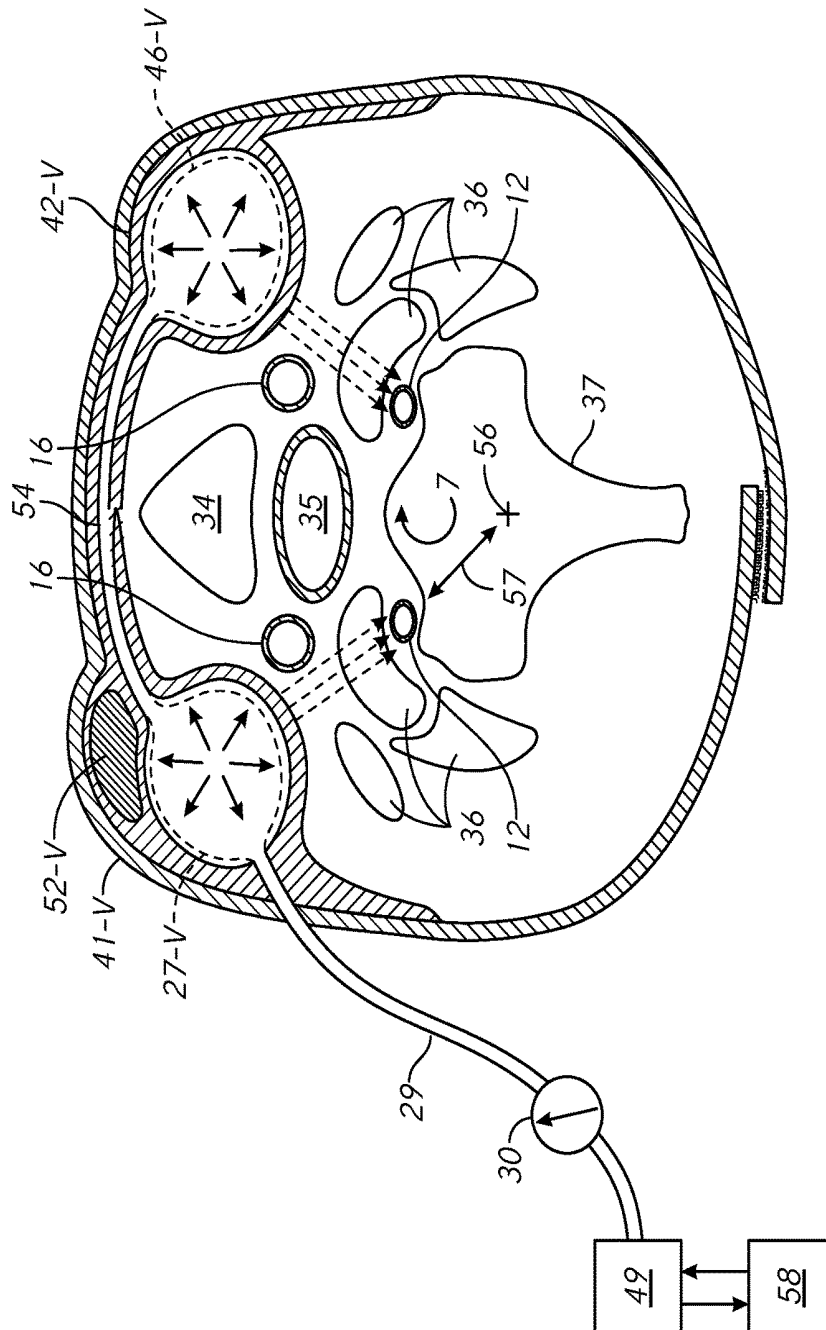


FIG. 20

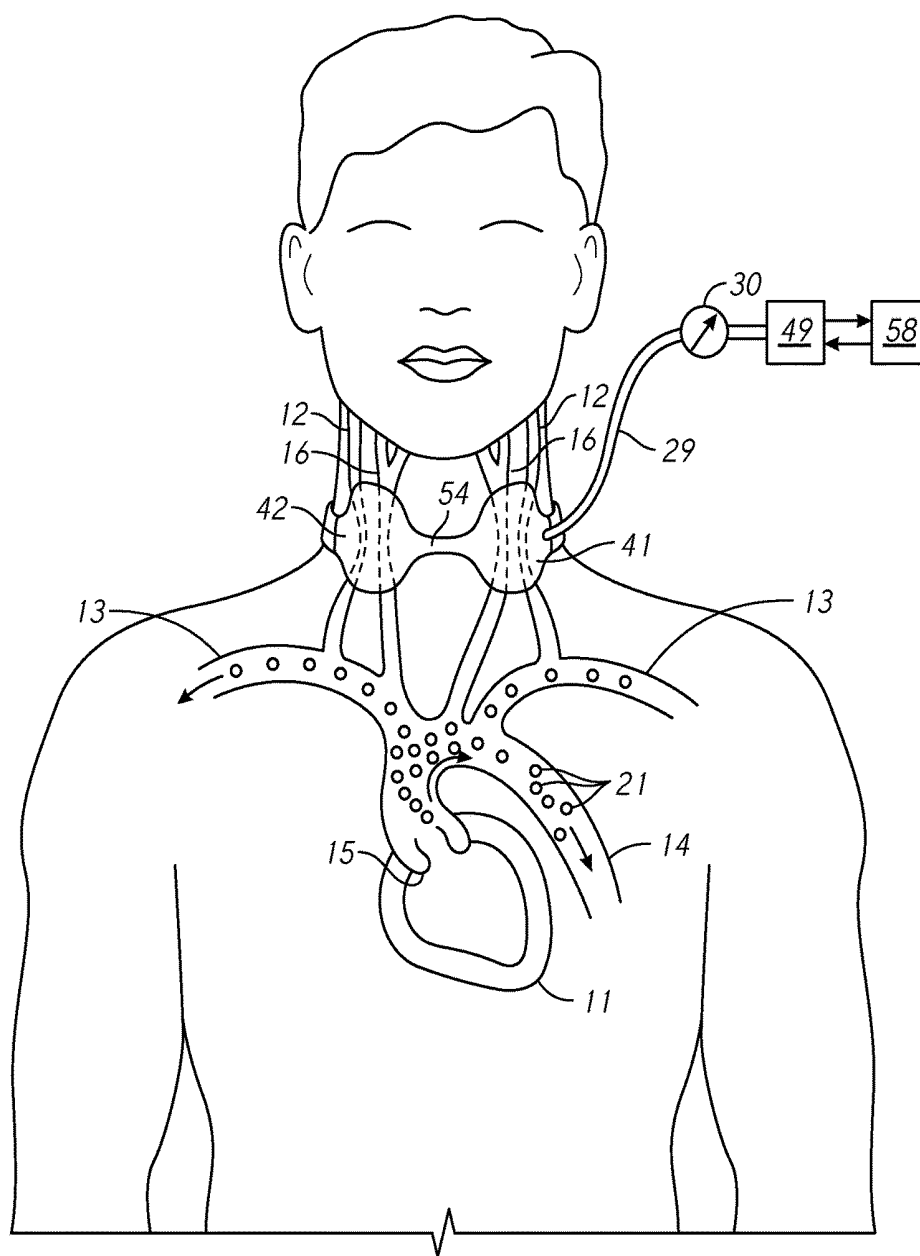


FIG. 21A

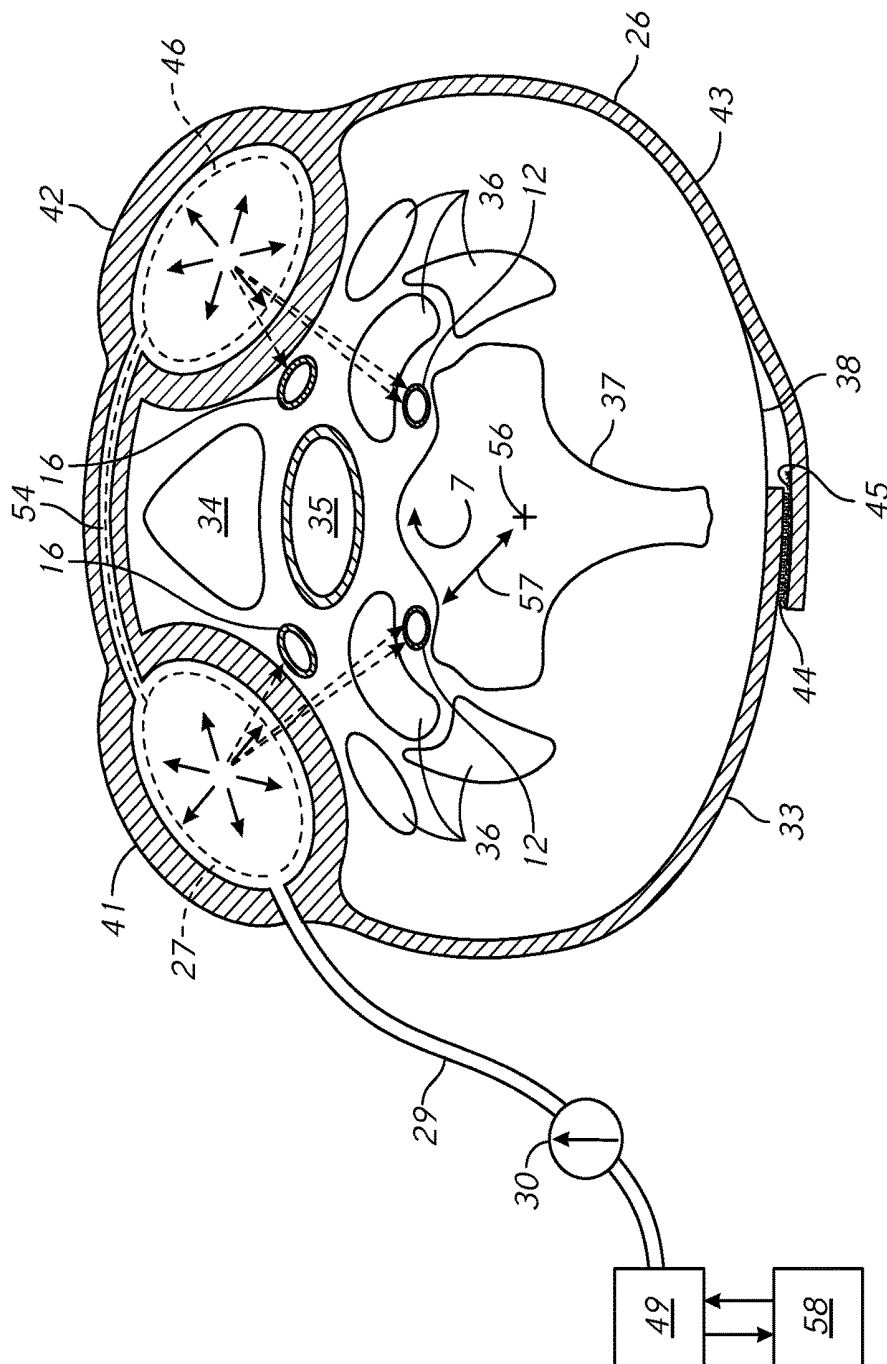


FIG. 21B

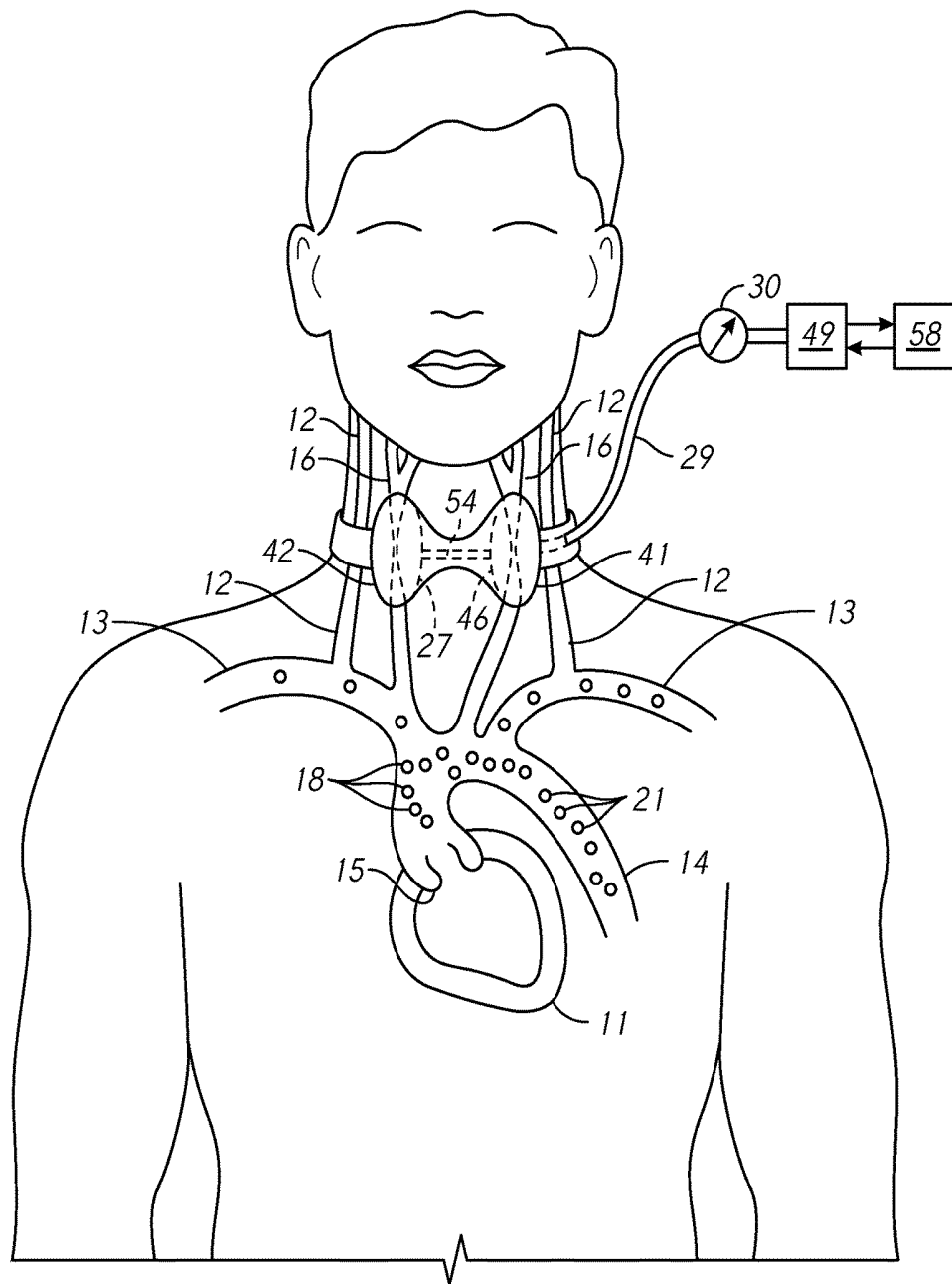


FIG. 22

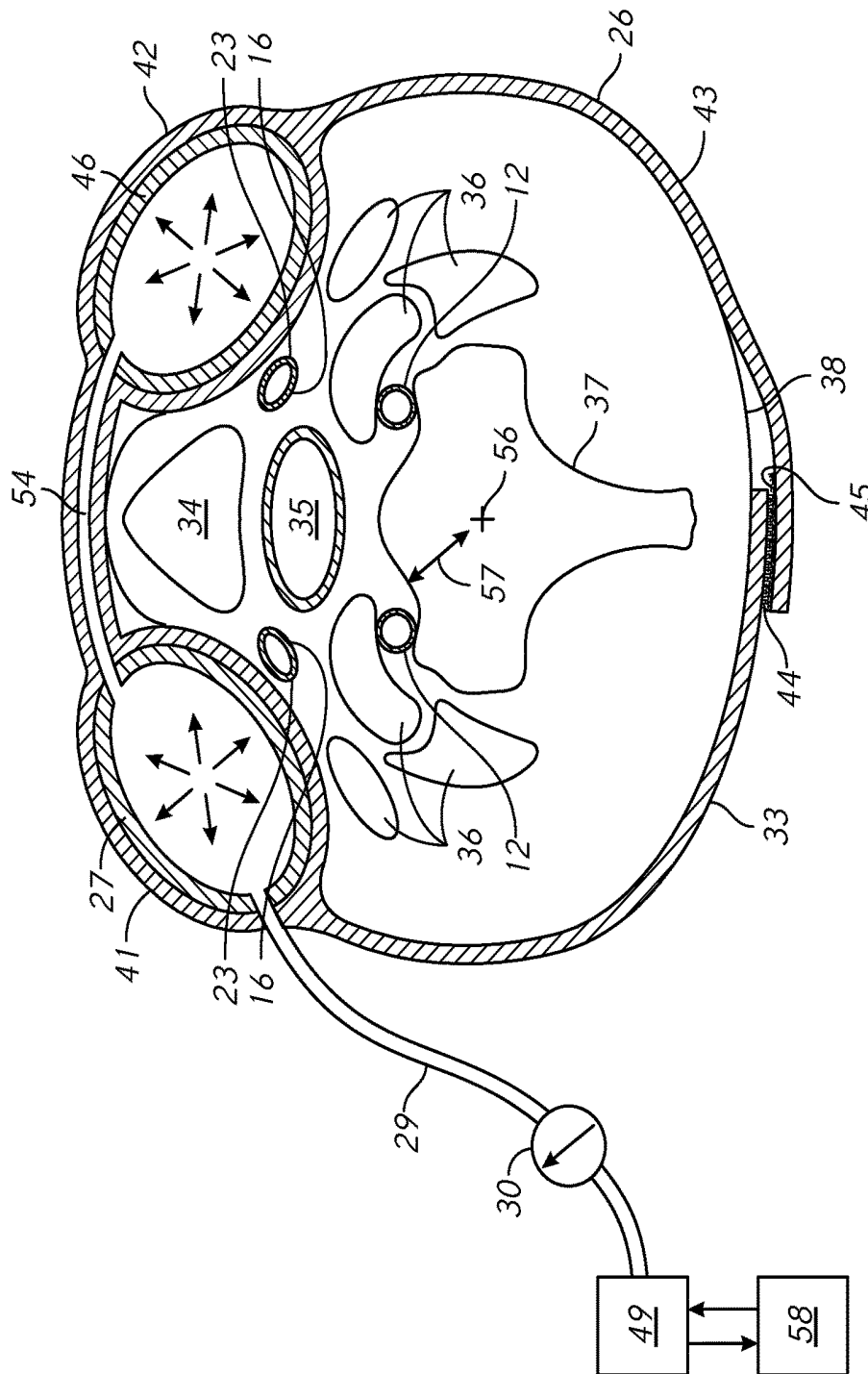
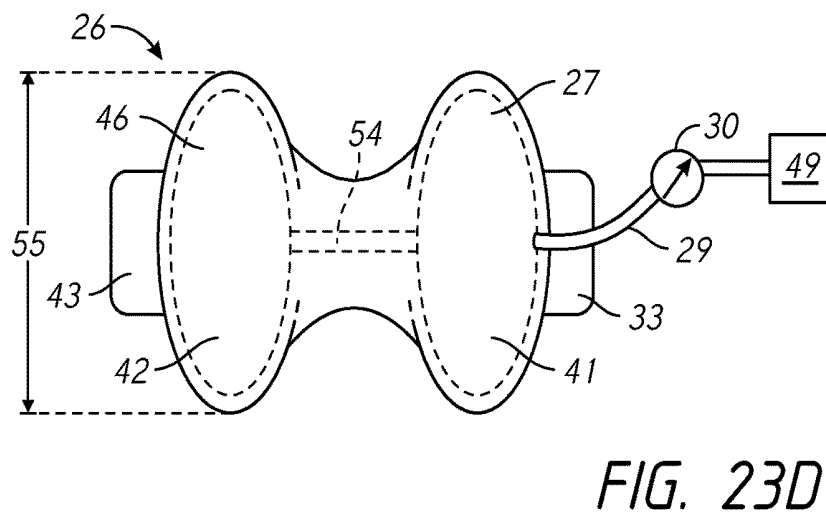
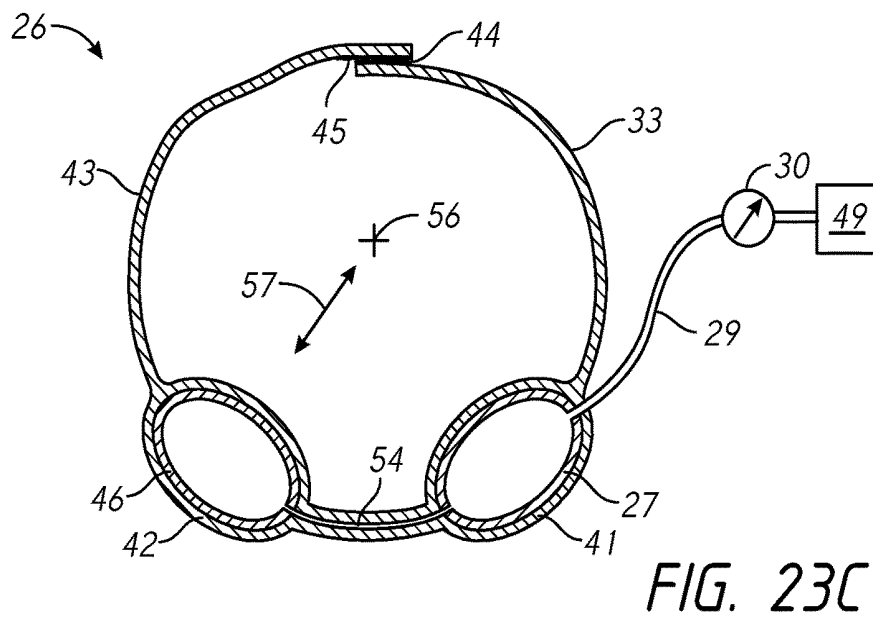
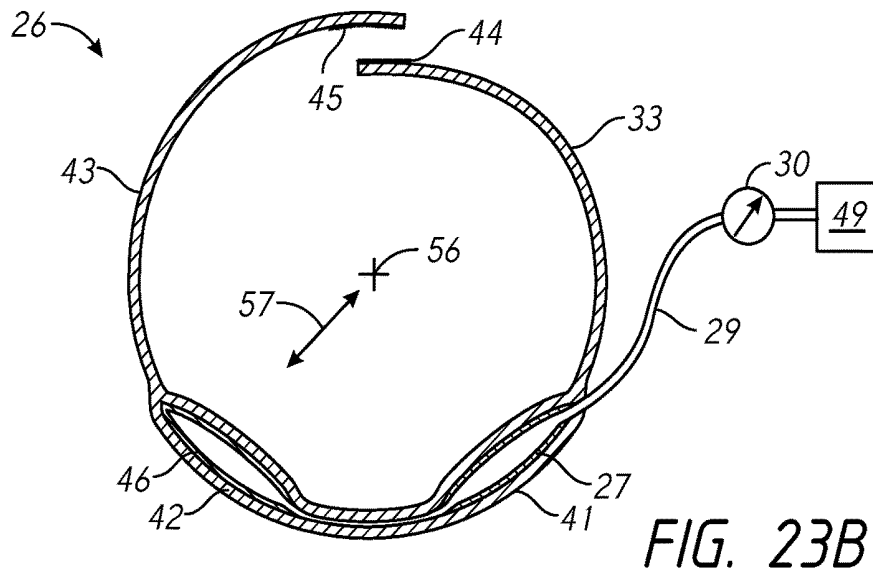


FIG. 23A



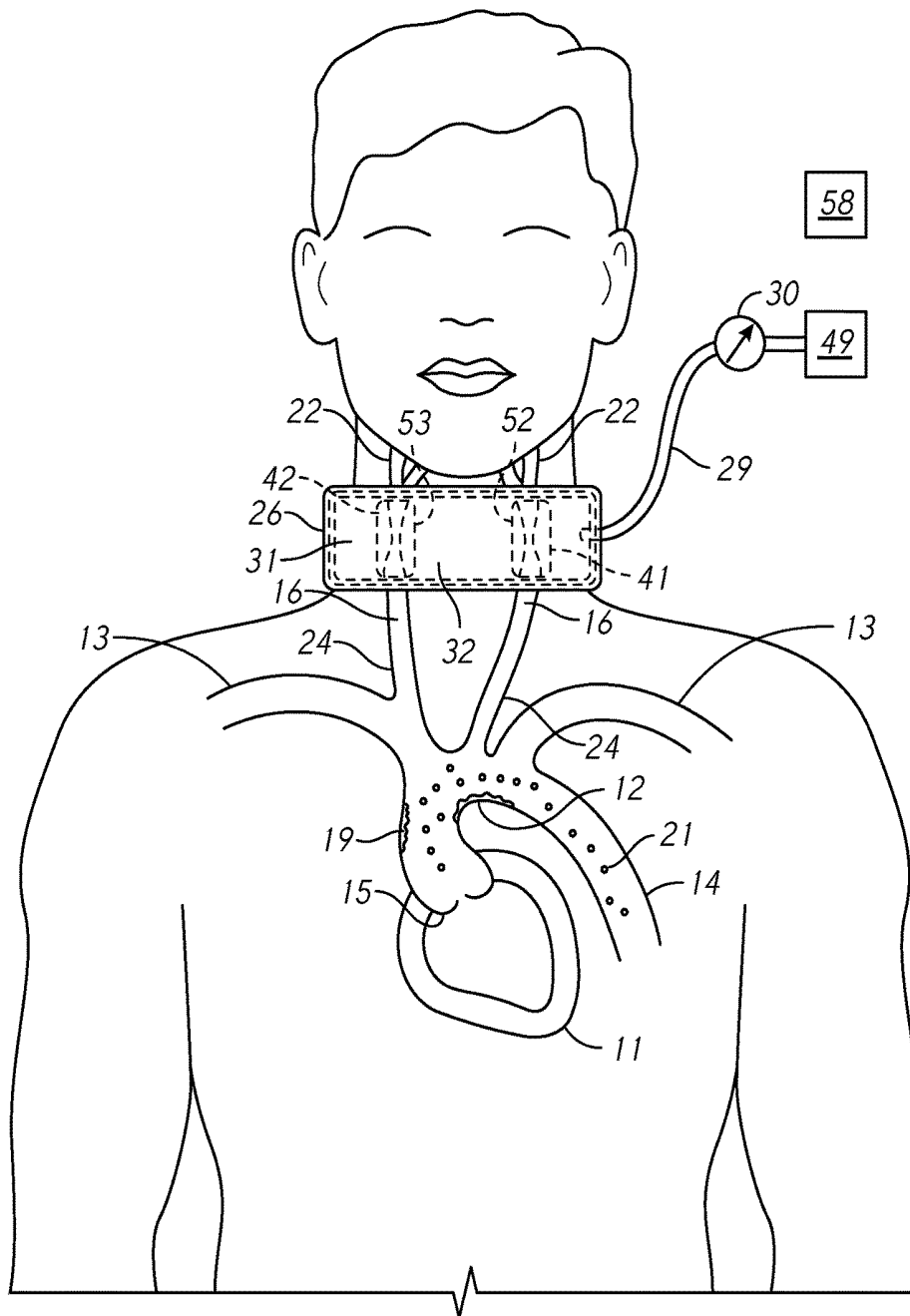
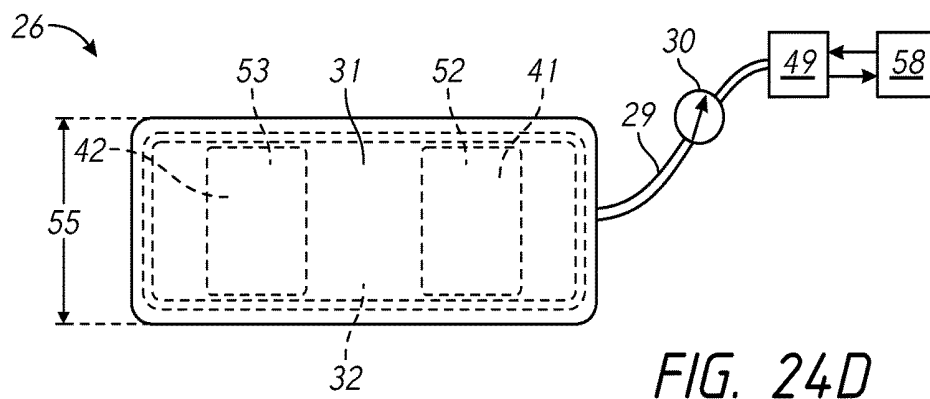
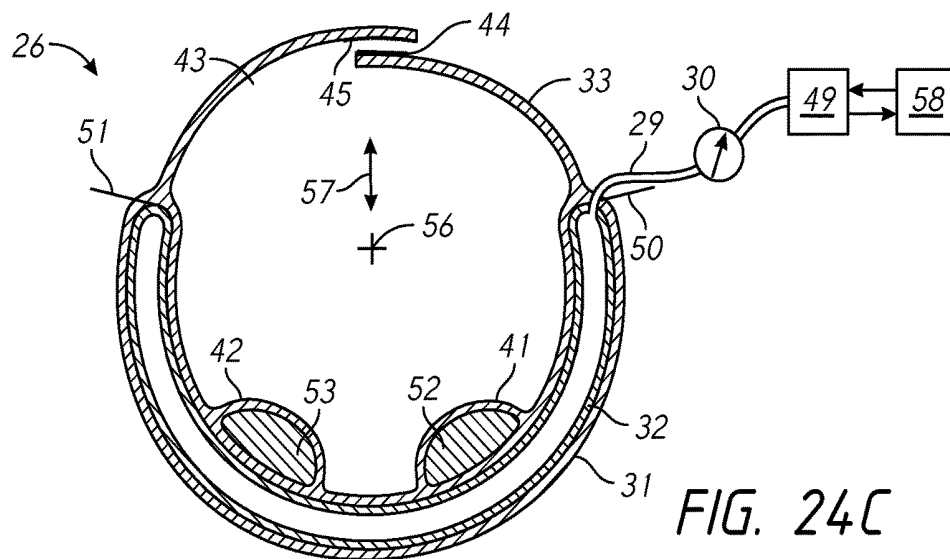
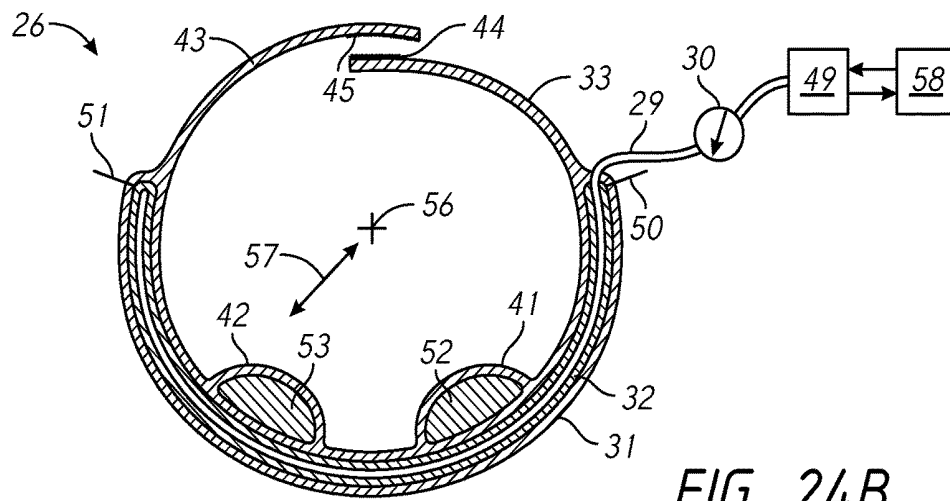
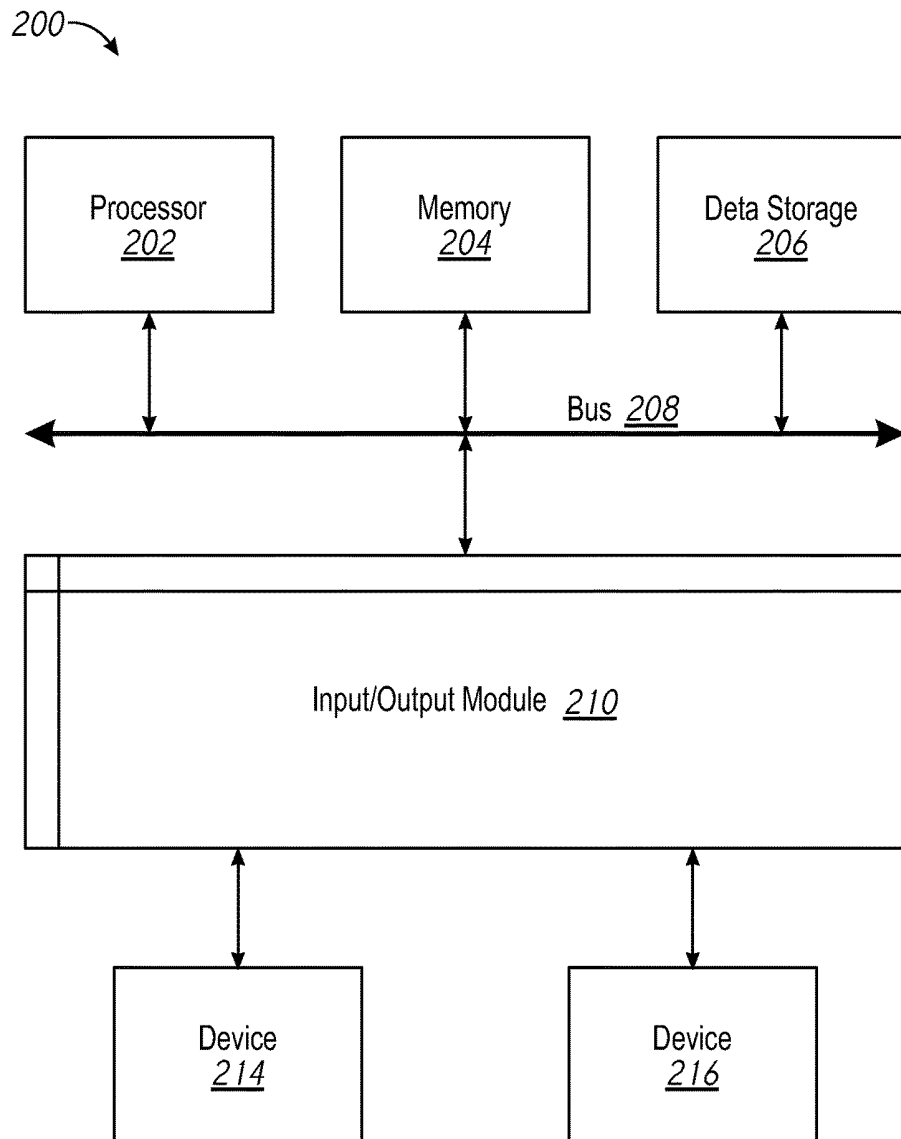
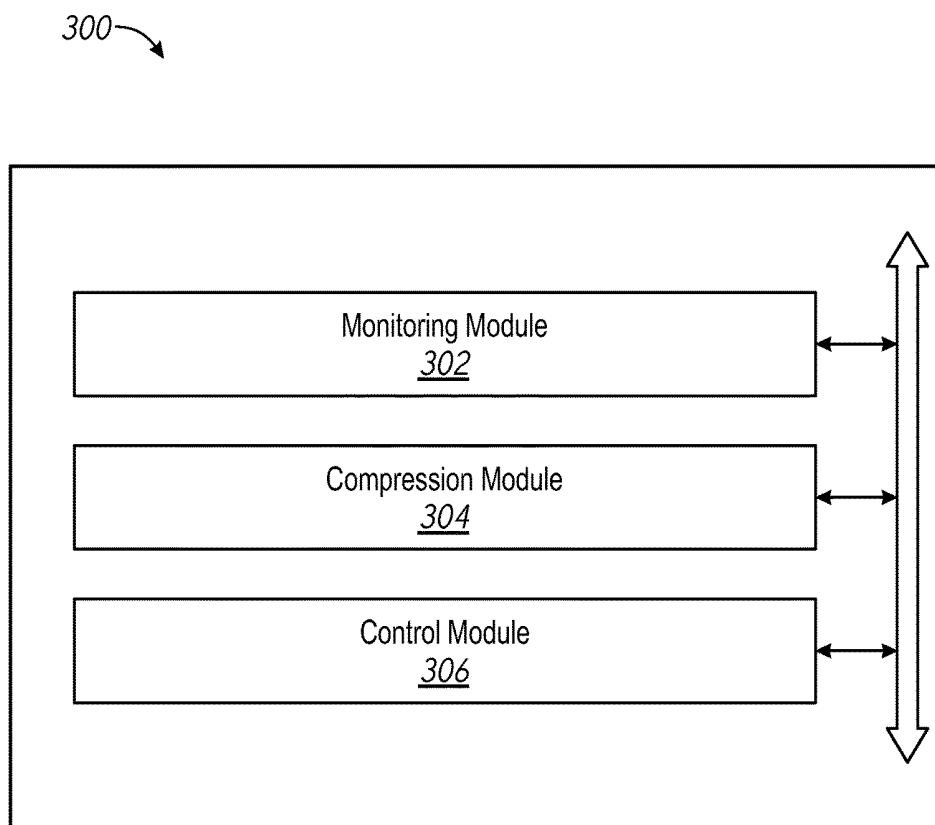


FIG. 24A



*FIG. 25*

*FIG. 26*

1

NONINVASIVE PROTECTION FROM EMBOLI

RELATED APPLICATIONS

The present application is a divisional application and claims the benefit of U.S. application Ser. No. 14/703,669 filed on May 4, 2015 and entitled, "Noninvasive Protection from Emboli" that issued on Nov. 7, 2017 having U.S. Pat. No. 9,808,260. U.S. application Ser. No. 14/703,669 claims priority to U.S. Provisional Patent Application No. 61/988,217, filed May 4, 2014, titled NON-INVASIVE METHOD OF PROTECTION FROM EMBOLI, the entire contents of which, along with the entire contents of U.S. application Ser. No. 14/703,669, are incorporated herein by reference.

FIELD

The subject technology relates to prevention of embolic and ischemic injury (such as ischemia and stroke) as a consequence of emboligenic event and interventions.

BACKGROUND

Arterial embolism, leading to embolic ischemia or stroke, is one of the most dreadful complications of cardiac, aortic and vascular procedures, diagnosed in 1-22% of patients undergoing cardiovascular surgery. Even more frequently, in up to 70% of cases, patients undergoing heart, valve, coronary artery bypass or aortic surgery experience subclinical embolic events. These embolic events lead to cognitive impairment and disability, extremity ischemia and multiple organ failure, having a significant impact on patients' recovery.

The main sources of emboli in this setting reside in the heart, heart valves, thoracic aorta, and great vessels, when these structures are intervened thereon (i.e. when an emboligenic procedure is performed). Even simple cardiac, catheterization with an endovascular catheter can induce microtrauma of the atherosclerotic thoracic aorta leading to formation of embolic particles with subsequent embolic brain, liver, kidney and extremity injury ranging from latent ischemic foci to a massive or even fatal event. Multiple devices are known that attempt to prevent embolization of the carotid arteries during endovascular and cardiac interventions by using different types of filters, deflection devices or endoluminal balloons. These anti-embolic devices, however, have not received wide acceptance in surgery of the heart, heart valves and thoracic aorta due to their complexity and invasive character with the risk of additional trauma to the inner vessel wall resulting in a high risk to benefit ratio. Known devices require insertion of additional hardware into the arterial system or aorta, a procedure that is known by itself to be associated with all classical risks of endovascular intervention, including aortic dissection, bleeding, thrombosis, and arterial embolization. One known intra-aortic filter device that is inserted into the ascending portion of the thoracic aorta via an aortic cannula to capture potential embolic material released from the heart and aortic wall during heart surgery was found to be quite difficult to implement and was reported to be associated with major trauma to aortic wall and acute aortic dissection.

Aside from introducing hardware into the patient and causing the aforementioned problems, intravascular filters are not able to capture embolus smaller than the pore size of the available devices (currently 60-140 μm) resulting in cerebral microembolization. Furthermore, the placement of

2

the filter by itself may produce cerebral emboli. For example, the mere passing of a guide wire into a carotid artery generates approximately 40,000 microemboli, with a significant percentage of small, less than 60 μm , particles that are not retained by standard filters. Therefore, in spite of multiple innovations in the field of anti-embolic devices, the problem of arterial emboli and stroke during cardiovascular surgery is far from being resolved. As such, there remains room for variation and improvement within the art.

SUMMARY

The subject technology is illustrated, for example, according to various aspects described below. Various examples of aspects of the subject technology are described as numbered clauses (1, 2, 3, etc) for convenience. These are provided as examples and do not limit the subject technology. It is noted that any of the dependent clauses may be combined in any combination, and placed into a respective independent clause, e.g., clause 1, 6, 14, or 21. The other clauses can be presented in a similar manner.

Clause 1. A system for diverting emboli within a patient, comprising:

- a detection device configured to detect a presence of emboli in a first blood vessel of a patient;
- a compression member configured to be aligned with a second blood vessel of the patient when a collar supporting the compression member is positioned at least partially around a portion of the patient;
- a controller configured to actuate the compression member, when the presence of emboli is detected, from an unactuated state to an actuated state in which at least a portion of the compression member (i) is closer to the second blood vessel than while in the unactuated state and (ii) compresses and limits blood flow through the second blood vessel.

Clause 2. The system of clause 1, wherein the second blood vessel, is downstream of the first blood vessel.

Clause 3. The system of clause 1, wherein the detection device blood vessel is configured to detect a threshold amount of emboli in the first blood vessel, wherein the controller is configured to actuate the compression member when the detected emboli exceeds, the threshold amount.

Clause 4. The system of clause 1, wherein the detection device comprises a Doppler ultrasound device, a Doppler probe device, an oscillotometry device, an electroencephalography device, a transcranial Doppler device, a pulse indicator device, a cardiac Echo device, a pulse oximeter, or a cerebral oximeter.

Clause 5. The system of clause 1, further comprising a supplemental detection device configured to detect a presence of emboli in a third blood vessel of a patient, upstream of the second blood vessel.

Clause 6. A method for diverting emboli within a patient, comprising:

- detecting a presence of emboli in a first vascular location of a patient;
- when the presence of emboli is detected, actuating a compression member aligned with a second vascular location of the patient when a collar supporting the compression member is positioned at least partially around a portion of the patient, from an unactuated state to an actuated state in which at least a portion of the compression member (i) is closer to the second vascular location than while in the unactuated state and (ii) compresses and limits blood flow through the second vascular location.

Clause 7. The method of clause 6, wherein the second vascular location is downstream of the first vascular location.

Clause 8. The method of clause 6, further comprising: determining whether the detected emboli exceeds a threshold amount;

wherein the compression member is actuated when the detected emboli exceeds the threshold amount.

Clause 9. The method of clause 6, further comprising: determining whether the detected emboli does not exceed a threshold amount;

transitioning the compression member to the unactuated state when the detected emboli does not exceed the threshold amount.

Clause 10. The method of clause 6, further comprising: transitioning the compression member to the unactuated state after the compression member has been actuated for a predetermined time limit.

Clause 11. The method of clause 6, wherein the detecting is by a Doppler ultrasound device, a Doppler probe device, an oscillotometry device, an electroencephalography device, a transcranial Doppler device, or a cerebral oximetry device.

Clause 12. The method of clause 6, wherein the first vascular location is a heart valve, an aorta, a calf vein, a femoral vein, a popliteal vein, an iliofemoral vein, an iliac vein, an inferior vena cava, or a peripheral vein of the patient.

Clause 13. The method of clause 6, wherein the second vascular location is a carotid artery or a vertebral artery of the patient.

Clause 14. A device for diverting emboli from cerebral circulation of a patient, comprising:

a first carotid compression member configured to be aligned with a first carotid artery of the patient radially between the first carotid compression member and a cervical spine of the patient when the device is positioned at least partially around a neck of a patient, the first carotid compression member having an unactuated state and an actuated state in which at least a portion of the first carotid compression member (i) is closer to the first carotid artery than while in the unactuated state and (ii) compresses and limits blood flow through the first carotid artery;

a first vertebral compression member configured to be aligned with a first, vertebral artery of the patient radially between the first vertebral compression member and the cervical spine when the device is positioned at least partially around the neck, the first vertebral compression member having an unactuated state and an actuated state in which at least a portion of the first vertebral compression member (i) is closer to the first vertebral artery than while in the unactuated state and (ii) compresses and limits blood flow through the first vertebral artery.

Clause 15. The device of clause 14, wherein an internal volume of the first carotid compression member and an internal volume of the first vertebral compression member are in fluid communication with each other.

Clause 16. The device of clause 14, wherein first carotid compression member has a maximum height, parallel to a central axis of the device, that is greater than a maximum height of the first vertebral compression member.

Clause 17. The device of clause 14, further comprising: a second carotid compression member configured to be aligned with a second carotid artery of the patient radially between the second carotid compression mem-

ber and the cervical spine when the device is positioned at least partially around the neck, the second carotid compression member having an unactuated state and an actuated state in which at least a portion of the second carotid compression member (i) is closer to the second carotid artery than while in the unactuated state and (ii) compresses and limits blood flow through the second carotid artery;

a second vertebral compression member configured to be aligned with a second vertebral artery of the patient radially between the second vertebral compression member and the cervical spine when the device is positioned at least partially around the neck, the second vertebral compression member having an unactuated state and an actuated state in which at least a portion of the second vertebral compression member (i) is closer to the second vertebral artery than while in the unactuated state and (ii) compresses and limits blood flow through the second vertebral artery.

Clause 18. The device of clause 17, wherein an internal volume of the second carotid compression member and an internal volume of the second vertebral compression member are in fluid communication with each other.

Clause 19. The device of clause 17, wherein an internal volume of the first carotid compression member, an internal volume of the first vertebral compression member, an internal volume of the second carotid compression member, and an internal volume of the second vertebral compression member are in fluid communication with each other.

Clause 20. The device of clause 17, wherein second carotid compression member has a maximum height, parallel to a central axis of the device, that is greater than a maximum height of the second vertebral compression member.

Clause 21. A method of diverting emboli from cerebral circulation of a patient, comprising:

while a device is positioned around a neck of a patient, expanding a first carotid compression member of the device toward a first carotid artery of the patient to compress and limit blood flow through the first carotid artery;

while the device is positioned around the neck, expanding a first vertebral compression member of the device toward a first vertebral artery of the patient to compress and limit blood flow through the first, vertebral artery.

Clause 22. The method of clause 21, wherein expanding the first carotid compression member comprises radially advancing a portion of the first carotid compression member toward a cervical spine of the patient.

Clause 23. The method of clause 21, wherein expanding the first vertebral compression member comprises radially advancing a portion of the first vertebral compression member toward a cervical spine of the patient.

Clause 24. The method of clause 21, further comprising: while the device is positioned around the neck, expanding a second carotid compression member of the device toward a second carotid artery of the patient to compress and limit blood flow through the second carotid artery;

while the device is positioned around the neck, expanding a second vertebral compression member of the device toward a second vertebral artery of the patient to compress and limit blood flow through the second vertebral artery.

Clause 25. The method of clause 24, wherein expanding the second carotid compression member comprises radially

advancing a portion of the second carotid compression member toward a cervical spine of the patient.

Clause 26. The method of clause 24, wherein expanding the second vertebral compression member comprises radially advancing a portion of the second vertebral compression member toward a cervical spine of the patient.

Additional features and advantages of the subject technology will be set forth in the description below, and in part will be apparent from the description, or may be learned by practice of the subject technology. The advantages of the subject technology will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the subject technology as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are included to provide further understanding of the subject technology and are incorporated in and constitute a part of this description, illustrate aspects of the subject technology and, together with the specification, serve to explain principles of the subject, technology.

FIG. 1 is a view of the blood vessel with the blood carrying emboli. The blood vessel branches into the vessels carrying blood to different areas and organs.

FIG. 2 is a view of the blood vessel, containing emboli, where an external compression of its branch, carrying blood to an organ (such as brain) will divert potential emboli to another vessel.

FIG. 3 is a schematic representation of the method of protection from vascular emboli with an option of an automated external compression of an artery carrying blood to an organ.

FIG. 4 represents a mechanism of detection of embolic particles upstream from the organ to be protected with an automated feedback signaling system that is able to trigger the process of arterial compression to limit the entry of emboligenic particles into this organ.

FIGS. 5 and 6 show compression of an artery, triggered by detection of the embolic particles in the afferent vessel, with subsequent diversion of emboli into the less important blood vessel.

FIG. 7 shows release of arterial compression once embolic particles are diverted away from the organ to be protected on the basis of the negative feedback mechanism, triggered by disappearance of embolic particles in the afferent vascular pathway.

FIG. 8 is a front view of a patient with embolic particles in the heart and, ascending thoracic aorta with a potential for propagation into both carotid arteries and other vessels with the source of emboli being diseased aorta, aortic valve and the heart.

FIG. 9 is a front view of a patient with the release of embolic particles arising in the heart, aortic valve and aorta, into the systemic circulation, including both carotid and vertebral arteries, and descending thoracic aorta.

FIG. 10 shows accentuation of the process of arterial embolization during cardiac contraction (systole).

FIG. 11 is a front view of a patient with external compression of both carotid and vertebral arteries that leads to temporary interruption of the cerebral arterial inflow, protecting the brain from potential emboli.

FIG. 12 is a front view of a patient with external compression of both carotid and vertebral arteries during cardiac contraction.

FIG. 13 is a front view of a patient with external compression of carotid and/or vertebral arteries by virtue of an external compression device and mechanism, actuated by certain physiological parameters.

FIG. 14 is a schematic view of the device for carotid and vertebral compression, depicted on FIG. 13.

FIG. 15 is a cross-sectional view of a neck of a patient and a device attached thereto in an unactuated state.

FIG. 16 is a cross-sectional view of a neck of a patient and a device attached thereto in an actuated state.

FIG. 17 is a front view of a patient with a compression device in accordance with another exemplary embodiment, leading to selective compression of vertebral arteries.

FIG. 18 is a front view of a patient with a compression device for vertebral arteries in accordance with yet another exemplary embodiment.

FIG. 19 is a schematic view of the device for vertebral compression, similar to the one depicted on FIG. 18, but carrying features of an additional exemplary embodiment.

FIG. 20 is a cross-sectional view of a neck of a patient and a device of FIGS. 18 and 19 for selective compression of vertebral arteries attached thereto in an actuated state with an option of restrictive pad at the external surface of the compression member.

FIG. 21A is a front view of a patient with a compression device in accordance with another exemplary embodiment.

FIG. 21 B is a cross-sectional view of a neck of a patient and a device of FIG. 21A attached thereto in an actuated state when both carotid and vertebral arteries are compressed.

FIG. 22 is a front view of a patient with another embodiment of the compression device, designed for selective compression of carotid arteries.

FIG. 23A is a cross-sectional view of a neck of a patient and a device of FIG. 22 attached thereto in an actuated state with selective compression of carotid, but not vertebral arteries.

FIG. 23B is a cross-sectional view of the device of FIG. 23A in a unactuated state.

FIG. 23C is a cross-sectional view of the device of FIG. 23A in an actuated state.

FIG. 23D is a schematic view of the device of FIGS. 23A, 23B and 23C.

FIG. 24A is a front view of patient with yet another embodiment of the anti-embolic compression device.

FIG. 24B is a cross-sectional view of the device of FIG. 24A in a partially unactuated state.

FIG. 24C is a cross-sectional view of the device of FIG. 24A in a fully actuated state.

FIG. 24D is a schematic view of the device of FIG. 24A.

FIG. 25 is a block diagram illustrating a system of the subject technology.

FIG. 26 is an exemplary diagram illustrating modules implementing methods of the subject technology.

DETAILED DESCRIPTION

In the following detailed description, specific details are set forth to provide an understanding of the subject technology. It will be apparent, however, to one ordinarily skilled in the art that the subject technology may be practiced without some of these specific details. In other

instances, well-known structures and techniques have not been shown in detail so as not to obscure the subject technology.

The subject technology relates to prevention of emboli and ischemic injury (such as ischemia and stroke) as a consequence of emboligenic event and interventions, e.g., on the heart, heart valves, coronary arteries and aorta. More particularly, the subject technology relates to an external compression method and device that induce temporary non-invasive external compression of the blood vessels supplying the organs at risk for embolic damage. The device can be actuated at the moment of emboligenic intervention and may be triggered and deactivated on demand and automatically on the basis of patient's physiological parameters and detection of emboligenic particles.

Reference will now be made in detail to embodiments of the subject technology, one or more examples of which are illustrated in the drawings. Each example is provided by way of explanation of the subject technology, and not meant as a limitation of the subject technology. For example, features illustrated or described as part of one embodiment can be used with another embodiment to yield still a third embodiment. It is intended that the present subject technology include these and other modifications and variations.

It is to be understood that the ranges mentioned herein include all ranges located within the prescribed range. As such, all ranges mentioned herein include all sub-ranges included in the mentioned ranges. For instance, a range from 100-200 also includes ranges from 110-150, 170-190, and 153-162. Further, all limits mentioned herein include all other limits included in the mentioned limits. For instance, a limit of up to 7 also includes a limit of up to 5, up to 3, and up to 4.5.

The subject technology provides for a method of preventing arterial embolization by diverting emboli from the circulation to be protected, such as cerebral circulation, arm circulation, leg circulation or else.

With reference to FIG. 1, a schematic view of a branching vessel such as an aortic arch is shown in which emboli 8 are transferred from the more proximal arterial trunk 1, such as an ascending aorta, into more distal branches 2 and 3, such as carotid 16, vertebral 12, subclavian 13 arteries causing ischemic injury to the organ they supply (such as stroke in the case of embolization of cerebral arteries).

FIG. 1 shows a hypothetical blood vessel 1 branching into the blood vessels 2 and 3. The antegrade flow 5 in the vessel 1 carries blood, containing emboligenic particles 8 to different areas in the human body, including the organ more vulnerable to ischemic injury (such as brain)—via the blood vessel 3, and less vulnerable (such as soft tissues)—via blood vessel 2. As shown on FIG. 1 the emboli 8 entering vessel 1 will follow the path of branching into the vessels 2 and 3 and will enter both vessels 2 and 3 proportionally to the magnitude of flow through these vessels. The more flow would occur via the blood vessel 2, the more emboli will enter the organ to be protected (such as brain) leading to serious ischemic injury (such as stroke).

FIGS. 2-7 show the disclosed method of diverging emboli 8 from important structures such as brain by exerting external pressure 10 on the blood vessel 3 (such as carotid, or vertebral artery) to create an area of the pressure gradient 9 leading to limitation of the blood flow 5 carrying emboli 8 to the compressed blood vessel 3. Such compression will lead to flow reversal 7 diverting emboli 8 into other less important vessel 2. Acceleration of flow via the blood vessel 2 while the blood vessel 3 is compressed will lead to a Venturi effect providing additional force 7 deflecting the

emboli 8 from the vessel 3 into the vessel 2. In order to avoid prolonged limitation of flow to the most important area of the human body (such as brain) the time of the protective compression of the blood vessel 2 should be brief. This goal is achieved by a disclosed method of vascular compression “on demand”, i.e. at the brief periods of time when the emboligenic particles are released. As shown on FIGS. 3-7 the detectors of emboli “A” and/or “E” can be placed over the source of emboli (such as heart, heart valve, aorta, etc.) or the blood vessels 1 and 3, carrying said emboli to the target organ (such as brain). The appearance of emboli in said areas when detected as echogenic signal or as another physiological parameter(s), reflecting cardiac ejection and systole (such as EKG, arterial Doppler, pulse oximetry, arterial waveform etc.) will be recorded by monitor “B” and will actuate the compression mechanism “C” that would temporarily compress the blood vessel 3 leading to limitation, interruption and/or reversal of the flow to the organ to be protected. Detection can occur during and be sensitive to flight of emboli or other debris in transit within a blood vessel. The length of compression and its intensity will be recorded by monitoring system “D” with a capacity of overruling the act of compression if its length or intensity exceed the safe limit. Thus, a positive and, negative feedback mechanisms will be assured with a potential for an automated auto-regulatory function of such a device.

Once the emboli 8 disappear from the inflow vessel 1 and/or deflected from the blood vessel 3 into the blood vessel 2, the detectors “A” and/or “E” will signal such events to the device “B”, that in turn will provide negative feedback to the device “C” thus interrupting the act of compression 10 and restoring circulation via the blood vessel 3 to the organ to be protected (such as brain). Considering the fact that the majority of embolic events leading to the organ damage and stroke in cardiovascular procedures are very short, this method and system appear to be feasible and reliable, thus providing anti-embolic protection at the moments of surgery when the risk of embolism is maximal, while restoring circulation to such organs when the risk of embolism is minimal. The process of vascular compression alternating with vascular release can be repeated on multiple occasions throughout the course of cardiovascular procedure or a cardiac cycle.

The emboli 8 (FIG. 1) may be fragments of atherosclerotic plaque 19 (FIGS. 8, 9) of the ascending thoracic aorta that become dislodged during surgical or catheter manipulations on the aorta. Also shown in FIGS. 8 and 9 is calcification of the aortic valve 15 and intra-cardiac embolic particles 20 of the heart 11 that can also be the origin of emboli 17 eventually present in any artery such as the carotid artery 16 or vertebral artery 12. The intra-cardiac emboli 20 may include air, gas, thrombi and atherosclerotic materials. Although all of the various emboli in the heart 11, aorta and aortic valve 15 need not be present in all instances, they are all shown in FIGS. 8 and 9 for sake of example. Trauma to the heart 11, aortic valve 15 and aortic structures during placement and removal of items such as an aortic clamps, guidewires, catheters, balloons and electrophysiological instruments, along with manipulations such coronary artery bypass grafting, aortic and mitral valve replacement, catheter ablation, endovascular grafting of the aorta, percutaneous implantation of the aortic or mitral valves, endovascular manipulations on the aorta, aortic branches and the heart 11 may give rise to the presence of emboli 17 in the carotid arteries 16, vertebral arteries 12, and subclavian arteries 13. Critical moments of the aforementioned procedures (for example during the aortic cross clamp

manipulation, aortic valvuloplasty or valve implantation, coronary interventions, and endovascular procedures on the aorta) may cause emboli 17 to form and cause stroke and are referred to as emboligenic events.

The method and system described can be also applied for prevention of venous and pulmonary artery emboli. In this case the detection of the moving venous thrombus/embolus traveling from the peripheral vein toward the heart and pulmonary artery may initiate the measures for prevention of embolism by virtue of compression of the veins on its path, and signaling and initiating of other measures of prophylaxis of pulmonary embolism if necessary (such as deployment of the embolic trap or starting thrombolytic therapy).

A device similar to the embodiments depicted in FIGS. 13-24 may be placed around the part of the body containing the target vessel that is noninvasive and can include a vascular compression member(s) 27 and/or 27-V applied to the area of the artery at a certain angle (ranging from 0 to 90) to the axis of the artery. The device may comprise a transverse vascular compression member 32. The members 27, 27-V and 32 can be converted from an unactuated state to an actuated state in which the members 27, 27-V and 32 create an area of compression 23 and 23-V at the target arteries such as carotid (16), vertebral (12), subclavian (13) or femoral or any other hypothetical vessel 2 to limit blood flow therethrough into the circulation to be protected such as cerebral or any other circulation. Emboli 8, 17, 18, 20 that are formed in the patient secondary to emboligenic intervention are diverted into a descending aorta 14 and other less important vascular structures.

As shown in FIG. 9 the emboligenic particles 18 and 20, formed in the heart 11, aortic valve 15 and aorta may enter the carotid arteries 16 and vertebral arteries 12, thus becoming cerebral emboli 17 leading to obstruction of cerebral circulation and stroke. As shown on FIG. 10, the degree of embolization may significantly increase at the time of cardiac contraction (systole) when intra-cardiac (20) and aortic (18) particles are forcefully ejected into the systemic circulation, leading to a massive entry of emboli 17 into the carotid 16 and vertebral 13 arteries. With respect to our method of anti-embolic protection disclosed above it seems to be feasible to protect cerebral circulation by applying temporary pressure on the carotid and, if needed, vertebral arteries for the brief period of time when the risk of embolization is maximal (FIG. 11). Using detectors of potential emboligenic particles and emboli in the heart (by ECHO), aorta and its branches (as assessed by Doppler ultrasound) with timely signaling and immediate initiation of the protective compression of the target blood vessels such as carotid, arteries 16 and/or vertebral arteries 12 will lead to temporary limitation of the blood inflow such as carotid and/or vertebral flow, thus protecting the organ, such as brain, from embolic load. Upon creation of the areas of vascular compression 23 (carotid) and 23-V (vertebral), a relative pressure gradient and a "no-flow" or "low-flow" condition is produced in the proximal segments of the compressed arteries such as carotid 16 and vertebral 12 arteries that prevents emboli 18 from entering the circulation to be protected such as cerebral circulation. The proximal carotid 16 and vertebral 12 arteries are areas of said arteries upstream from the areas of compression 23 and 23-V that have interrupted or diminished blood flow due to the compression. Potential cerebral vascular emboli such as emboli 18 are diverted into the more distal vessels such as descending aorta 14 and are illustrated, as emboli 21. The thin arrow at the level of aortic arch on FIG. 11 shows preferential direction of the blood flow that carries potential emboli such

as cerebral emboli 17 into the descending aorta 14 when the areas of compression 23 and 23-V are created. To protect the brain from an augmented embolic load at the time of cardiac systole (FIGS. 12 and 13) we disclose a method of carotid 16 and/or vertebral 12 compression synchronized with systolic phase of cardiac activity. The compression system 49 (box C on FIG. 7) is actuated and deactuated by the device 58 (Box B) depending on the phase, of cardiac activity. Thus, the timing of the vascular compression 23 and 23-V in order to limit the inflow of emboli 17 can be triggered by electrophysiological, hemodynamic and/or pulse-oximetric indices of cardiac contraction, received and processed by the detector 58. On the other hand, the deactuation of the compression in order to restore arterial perfusion to the brain may be triggered by the same indices, but in the phase of cardiac relaxation.

FIGS. 13-16 disclose an exemplary embodiment that can selectively limit flow to either carotid 16 or vertebral arteries 12, or if necessary, limit flow to all or any combination of these vessels. Said device can be used to create the areas of compression 23 and 23-V as previously described to deflect emboli 18 and 20 from the target arteries such as carotid arteries 16 and vertebral arteries 13. The goal of this compression is to prevent the entry of emboli in the circulation to be protected such as cerebral circulation. The device can be positioned on the neck of the patient so that a pair of straps 33 and 43 extend around the neck 38 of the patient and are secured to one another via hooks 44 and loops 45 that form a hook and loop type arrangement. However, it is to be understood that other mechanisms of securing the straps 33 and 43 to one another are possible and that the disclosed arrangement is only one exemplary embodiment. Securement of the hooks 44 and loops 45 causes the device 26 to be retained onto the body part such as the neck 38 of the patient. This retention may be loose so that the device 26 has some room to give on the body part such as the neck 38, or the retention may be of a tightness that firmly secures the device into the body part such as the neck 38 and prevents same from moving or twisting. The compression device may be a neck collar 26, combination of compression elements, bars, levers, pads, inserts and screws to provide compression of the target vessel in accordance with various exemplary embodiments. In other arrangements the compression device 26 may be a strap that lays on the front of the body part to be protected such as the neck 38 of the patient, or may, be made of multiple components that are not directly attached to one another but are positioned proximate to the neck 38 of the patient. The device 26 may include two semi-oval halves that may be positioned around body part of the patient such as the neck 38 or extremity of the patient in accordance with one exemplary embodiment. The device 26 need not be circular in shape. Even if the device 26 is not circular in shape it may still have a central axis 56 (FIG. 23A) as the central axis 56 can be located at the center of the vessel and the body part to be protected such as a carotid artery and the neck 38 of the patient and thus may still be a central axis 56 of the device 26.

With reference in particular to FIGS. 23B, 23C and 23D, a pair of insertion pockets 41 and 42 are present on the device 26 and may be sealed at their tops and bottoms with respect to the vertical direction 55. As used herein, the vertical direction 55 may be the direction of the device 26 that is parallel to the direction of extension of the central axis 56. Strap 33 may extend from the first insertion pocket 41, and strap may extend from the second insertion pocket 42. The first insertion pocket 41 forms a cavity into which a first vascular compression member 27 is located. Member 27 is

shown in a relaxed or unactuated state in FIG. 23 and may be made of a flexible material that can be stretched or otherwise deformed. The material making up member 27 can be nonporous such that member 27 is capable of being filled with gas or liquid that enables the member 27 to expand and at the same time hold the gas or liquid therein. The pocket 41 may be made of a material that is different than the material making up, member 27.

The second insertion, pocket 42 forms a cavity into which the second vascular compression member 46 is retained. Member 46 may be configured in a manner similar to member 27 and a repeat of this information is not necessary. Member 46 may be completely sealed or connected to an opening that leads into connecting tube 54. Member 46 is in an unactuated state in FIG. 23B. Similarly, for compression of vertebral arteries 13 two insertion pockets 41-V and 42-V may be created. Said pockets may contain compression members 27-V and 46-V and other components to facilitate arterial compression as described in previous paragraphs. If necessary, only vertebral compression members can be actuated (FIG. 17). The specific anatomic location of the vertebral compression members is disclosed and should correspond to the level of the C5-C7 vertebra in order to assure adequate compression of the vertebral arteries 13 against the body of C-7 (FIGS. 16 and 20). In other embodiments, however, only the carotid (FIGS. 22 and 23A) or, conversely, only vertebral (FIGS. 18-20) compression members could be present. Other arrangements and combinations of compression members are possible in order to achieve selective compression of any combination of the carotid and vertebral arteries. Some of these embodiments are shown on FIGS. 17-23.

A pressure or compression source 49 is included and is placed into communication with the first vascular compression member 27 by the way of tubing 29 that extends through a port of member 27. A manometer 30 may be included in, the device 26 at some point between the member 27 and the pressure/compression source 49 in order to monitor and measure pressure in the system. A detector of emboli and/or EKG, pulse oximeter, arterial waveform monitor 58 can be bundled with the pressure source 49 to assure an option of initiation of the vascular compression once the potential emboli are ejected or anticipated. FIGS. 23C and 23D illustrate the device 26 once the pressure/compression source 49 is activated in order to cause the device 26 to be pressurized. The pressure source 49 may be a pump that injects air, gas or liquid, such as water, through the pressure tubing 29. Injection of air or otherwise increasing the pressure causes the first vascular compression member 27 to expand. Due to fluid communication through the connecting tube 54, the second vascular compression member 46 will likewise expand and the two members 27 and 46 may expand at the same rate to the same size. Expansion may be in the radial direction 57 such that the expandable members 27 and 46 expand towards the central axis 56 and away from the central axis 56. In some exemplary embodiments, the members 27 and 46 may expand in the radial direction 57 towards the central axis 56 but not in the radial direction 57 away from the central axis 56. This arrangement may be accomplished by making portions of the compression members 27 and 46, for example the portions facing away from the central axis 56 in the radial direction 57, such that they cannot expand while the portion facing towards the central axis 56 are in fact expandable. Said arrangements can be also applied to the vertebral compression elements 41-V, 42-V, 46-V and 27-V and their repetition of them is not necessary.

The compression members 27 and 46 as well as 27-V and 46-V may be inflated to a pressure level that is just above the level of the patient's arterial pressure to achieve temporary limitation or interruption of the arterial blood flow. The arteries to be protected such as both the left and right carotid arteries 16, left and right vertebral arteries 12, and if needed, femoral and brachial arteries can be compressed at the same time or separately and in any combination.

Additionally or alternatively, the insertion pockets 41, 42 and 41-V, 42-V could have portions that are made of different materials so that the parts facing the central axis 56 in the radial direction 57 are expandable while the parts facing away from the central axis 56 in the radial direction 57 are not expandable. The compression members 27, 27-V and 46, 46-V are elongated in the vertical direction 55, which is the same direction as the central axis 56. However, it may be the case that upon expansion of the expandable members 27, 27-V and 46, 46-V from the =actuated to the actuated states the expandable members 27, 27-V and 46, 46-V do not expand in the vertical direction 55. Moreover the compression members may not be expandable at all and may exert compression into the underlying vascular structure by virtue of tightening of their attachment apparatus or external straps.

The exemplary embodiment of the device 26 in FIGS. 23A-23D does not include a transverse vascular compression member 32 but instead includes only two compression members 46 that can be expandable. The device 26 may be placed onto the patient so that the first longitudinal compression member 27 overlays the artery to be protected such as a carotid artery 16, or both carotid and vertebral artery 12 (FIGS. 21A and 21B) such that the artery is located between the central axis 56 and the member 27 in the radial direction 57. However, other arteries such as subclavian, or femoral and brachial artery can be compressed in a similar manner. If needed second vascular compression member 46 and 46-V may be laid on top of the other artery such as carotid artery 16 and vertebral artery 12, such that the second artery is likewise between the member 46 and 46-V and the central axis 56 in the radial direction 57. Expansion forces of the expandable members 27 and 46 and 27-V, 46-V or the outer compression forces on non-expandable or partially expandable members 27, 27-V and 46, 46-V may be imparted onto the target arteries such as carotid arteries 16 and vertebral arteries 12 so that they are compressed thus forming the areas of compression 23 and 23-V as previously discussed. The pressure at the compression members 27, 27-V and 46, 46-V may be set so as to exceed the patient's systemic pressure to achieve adequate compression of the carotid arteries 16 and vertebral arteries 12 to have a transient "no-flow" or "low-flow" effect. In some arrangements the pressure of the members 27, 27-V, 32 and/or 46, 46-V may exceed the patient's systemic pressure by 10-20 mm Hg, or up to 30 mm Hg and even higher in accordance with certain exemplary embodiments. Once the emboligenic part of the procedure is completed, the pressure in members 27 and 46 may be released in order to establish adequate arterial flow, such as carotid, brachial or femoral arterial flow. The release of pressure can also be triggered by disappearance of embolic particles in the heart chambers (as detected by cardiac ECHO), aorta (as detected by arterial Doppler), carotid and cerebral arteries (as detected by carotid Doppler ultrasound and transcranial Doppler) and by the indices of cardiac relaxation (diastole) as reflected by EKG, pulse oximetry, arterial pressure waveform and other indices.

An automated self-regulating compression-relaxation mechanism or system is thus possible, allowing for real-time

monitoring and anti-embolic protection during cardiovascular interventions. Such mechanism or system would include the elements A, B, C, D and E as depicted in FIGS. 1-6 with a feature of a fully automated vascular compression-relaxation depending on the embolic load and the phase of cardiac cycle.

Another exemplary embodiment of the device 26 is illustrated in FIGS. 24A-24D. The device 26 in this exemplary embodiment also functions to compress the carotid arteries 16 to create the areas of compression 23. The device 26 includes a first insertion pocket 41 and a second insertion pocket 42 but lacks first and second vascular compression members 27 and 46. Instead a first compression member 52 is located within the first insertion pocket 41, and a second compression member 53 is located within the second insertion pocket 42. The compression members 52 and 53 are not expandable but may be made of a material, such as foam, that can be compressed and then can subsequently expand back into its original shape. The compression members 52 and 53 may alternatively be made of a material that does not exhibit any give upon the application of forces thereto that would be encountered in a procedure of the type described herein. The compression members 52 and 53 may be elongated in the vertical direction 55 and may have a convex shape that faces the central axis 56. The shape of the compression members 52 and 53 at their surfaces that face away from the central axis 56 in the radial direction 57 may be different than those that face towards the central axis 56.

The device 26 may include a transverse carotid compression section 31 that is located outward from the compression members 52 and 53 in the radial direction 57 from the central axis 56. A transverse carotid expandable member 32 may be held by the section 31 and can have an arc length about the central axis 56 that extends beyond both of the compression members 52 and 53. The transverse carotid expandable member 32 has a height in the vertical direction 55 that is the same as, larger or smaller than the height of the compression members 52 and 53 in the vertical direction 55. The member 32 is made of a material that will hold air, gas or liquid such that it can be expanded upon the application of fluid thereto. The member 32 has a single port that is in fluid communication with the pressure tubing 29. Application of pressure to the member 32 will cause the member 32 to expand as shown for example in FIGS. 24C and 24D. In other embodiments, the compression members 52 and 53 can be removed and not present so that only the expandable member 32 is present to compress the carotid arteries 16.

The transverse carotid compression section 31 can be arranged so that all of it is expandable or so that only a portion of it expands as the member 32 expands. Boundary lines 50 and 51 may demarcate areas of the transverse carotid compression section 31 that can expand from those that cannot expand. For example, the portion of section 31 radially outward from the boundary lines 50 and 51 may not be capable of expansion while the portions of section 31 radially inward from boundary lines 50 and 51 are capable of stretching and thus expanding or contracting. This arrangement may cause expansion only, or primarily, in the radially inward direction upon expansion of the expandable member 32. In other embodiments, the section 31 is made of the same material and exhibits expansibility such that it generally expands in all directions equally. The expandable member 32 may be arranged so that it does not lengthen in the vertical direction 55 upon expansion, or in some arrangements only minimally expands in the vertical direction 55 when actuated.

Placement of the device 26 onto the patient may result in the first compression member 52 overlaying the target artery such as carotid artery 16 femoral or brachial artery so that the artery to be compressed is between compression member 52 and the central axis 56 in the radial direction 57. The second compression member 52 will be arranged so that it overlays the second carotid artery 16 causing it to be between the second compression member 52 and the central axis 56 in the radial direction 57. The expandable members 27, 32 and 46 may be located at the neck 38, upper chest, shoulder, lower abdomen or an extremity of the patient such that they are secured to the neck 38 or extremity or otherwise proximate. The compression members 27, 32 and 46 need not be in direct contact with the body part of the patient such as the neck 38, chest, abdomen or extremity but only located near them. Application of pressure via the pressure source 49 causes the transverse compression member 32 that may be expandable to exert pressure in the radial direction 57. This inward radial pressure causes the compression members 52 and 53 to move inwards and be urged against the target vessels such as carotid arteries 16, femoral, brachial or other compressible arteries. The positioning and configuration of the members 52 and 53 function to impart compressive forces onto the arteries to be compressed such as carotid arteries 16, femoral, brachial or other arteries when the device 26 is pressurized thus resulting in the creation of the areas of compression 23. The other components of the device 26 may be made as those previously described and a repeat of this information is not necessary.

Although described as lacking first and second longitudinal vascular compression members 27 and 46, an alternative arrangement may be made in which these members 27 and 46 are present. In such an arrangement, the expandable members 27 and 46 may expand in order to press the compression members 52 and 53 towards the arteries to be compressed such as carotid arteries 16, femoral, brachial or other compressible arteries.

Moreover, it can also be arranged for compression of the vertebral arteries 12, or both vertebral 12 and carotid 16 arteries by adding additional compression members in the same arrangement as described above.

An alternative exemplary embodiment of the device 26 would be the one in which both a pair of longitudinal vascular compression members 27 and 46 are present along with a transverse vascular compression member 32. A pair of compression members 52 and 53 may be missing from this embodiment, or they may be present in certain arrangements. This exemplary embodiment may include additional pressure tube lines 47 and 48 that are separate from pressure tubing 29 that actuates the transverse vascular compression member such as carotid compression member 32. Pressure tube lines 47 and 48 provide pressure to, the first and second longitudinal vascular compression members 27 and 46 so that these members 27 and 46 can be actuated at different rates, amounts, and/or times than compression member 32. This flexibility provides selective pressure adjustments between the transverse vascular compression member 32 and longitudinal vascular compression members such as carotid members 27 and 46. This feature will provide an option to decrease or completely eliminate the degree of circumferential compression of the body part such as the neck 38 or extremity when selective inflation of the longitudinal vascular compression members is adequate. Conversely, if inflation of longitudinal compression members such as carotid members 27 and 46 does not lead to sufficient reduction of the arterial flow, an additional inflation of the transverse vascular compression member such as carotid

member 32 would allow one to achieve the desired effect by combining the effect of pressure created in all of the members described.

The preferred method, of an arterial compression in this case, for example—compression of the carotid and vertebral arteries, will be an initial inflation of longitudinal members 27 and 46, followed by inflation of member 32 when necessary. The degree of interruption of the arterial flow in this and other embodiments can be checked by the data of arterial Doppler, distal pulsation and oximetry as well as other techniques of assessment of distal perfusion. The other components of the device 26 are the same as those previously disclosed with respect to other embodiments and a repeat of this information is not necessary.

An alternative exemplary embodiment of the device 26 that is being disclosed is similar to that previously disclosed with respect to FIGS. 23 and 24 and a repeat of the features and functionality that are similar between the two need not be repeated. The pressurization of the members 27, 32 and 46 are different in that the second pressure tube 47 feeds into the first longitudinal vascular compression member 27, and in that the third pressure tube 48 supplies the second longitudinal vascular compression member 46 to allow the members 27 and 46 to be pressurized independently from one another. In this regard, one can apply more or less pressure to member 27 than member 46 so that compression of the arteries, such as carotid arteries 16 or femoral and brachial arteries can be more precisely controlled. The transverse vascular compression member 32 is supplied by pressure tubing 29 and is independent from the expansion of members 27 and 46 such that it can be pressurized to a greater or lesser extent than members 27 and 46. The manometer 30 may be capable of measuring pressures in all of the lines 29, 47 and 48 so that their individual pressures can be monitored. In use, one may adjust the pressures in members 27 and 46 first, then subsequently if needed one may apply pressure into member 32 to cause its actuation so that adequate compression of the carotid arteries 16 is realized.

The ports for the pressure lines 47 and 48 may be located at the bottom of the expandable members 27 and 46 in the vertical direction 55. However, the ports for pressure lines 47 and 48 need not be in the disclosed locations in accordance with other exemplary embodiments and may be above the transverse carotid compression section 31 or at the same location as the section 31 in the vertical direction 55 in other exemplary embodiments. The insertion pockets 41 and 42 although described as being sealed may have an opening into which the expandable members 27 and 46 may be removed and into which first and/or second compression members 52 and 53 may be inserted so that the device 26 can function with the compression members 52 and 53 and transverse carotid expandable member 32 as previously discussed.

The arrangement of the device 26 in this case includes a pair of longitudinal vascular compression members 27 and 46 along with a transverse vascular compression member 32. The circumferential distance about the central axis 56 may be the circumferential distance about the neck 38 or extremity of the patient when the device 26 is worn by a patient and thus these two terms can be interchangeable when discussing the arc length of the member 32. In other exemplary embodiments, the arc length of the member 32 may be from 50-65% (180 degrees-234 degrees) about the circumference of the body part of the patient, from 25%-50% (90 degrees-180 degrees) about the circumference of the body part patient, or from 15%-25% (54 degrees-90

degrees) about the circumference of the body part of the patient. In yet other exemplary embodiments, the member 32 may extend 360 degrees completely about the body part of the patient.

The longitudinal vascular compression member such as carotid compression members 27 and 46 are closer to the central axis 56 in the radial direction 57 than the transverse compression member 32 is to the central axis 56. Comparison of FIG. 6C and, using a device for compression of the carotid arteries as an example, demonstrates that the lengths of the members 27, 32 and 46 do not increase in the vertical direction 55, or in the arc length direction, upon moving from the actuated orientation to the actuated orientation or only slightly expand in these directions upon actuation. The majority of the expansion may be in the radial direction 57 either towards the central axis 56 or away from the central axis 56 or a combination of the two. In other arrangements, however, expansion of the members 27, 32 and 46 may result in equal expansion in all directions. As previously stated, various, components of the device 26 may be arranged and function in a manner similar to those as previously discussed and a repeat of this information is not necessary.

FIGS. 15, 16, 20, 21B, and 23A demonstrate the method of use and the effect of inflation of the vascular compression device such as device 26 and its different embodiments resulting in external compression of carotid arteries 16 and/or vertebral arteries 12 leading to transient interruption of carotid and/or vertebral flow. These figures demonstrate the anatomic relationship of the device 26 to carotid arteries 16, vertebral arteries 12 and surrounding structures 34, 35, 36, 37 and 40 of the neck 38. The carotid arteries 16 are bordered by neck muscles 36, esophagus 35, trachea 34 and fat tissues 40. These structures provide a protective cushion, minimizing the risk of the carotid and vertebral artery injury during external compression. In fact, an external compression of arteries 16 and 12 in this setting would lead to significantly lower risk of injury to carotid intima than intravascular carotid occlusion with the balloon or umbrella devices used for cerebral protection in patients undergoing carotid stenting. The longitudinal carotid (42, 46) and/or vertebral (42-V, 46-V) expandable members are positioned along the course of both carotid arteries 16 and/or vertebral arteries 12 on the neck 38. Similar considerations are applicable to protective compression of all other compressible arteries such as femoral and brachial arteries and the repeat description of identical processes is not necessary.

The exemplary embodiment of the device 26 may be any one of those previously disclosed that lacks a transverse carotid expandable member 32. However, it is to be understood that this is just one example and that other devices 26 that include member 32 can function in a similar manner to the device 26 disclosed in FIGS. 8A and 8B. As shown in FIGS. 15, 16, 20, 21B, and 23 longitudinal vascular compression members are placed along the course the target arteries such as carotid and/or vertebral artery, or brachial and femoral artery, or any other combination of compressible vessels. The lumen of the target arteries such as carotid or vertebral arteries is compressed between the vascular compression members anteriorly (outward in the radial direction 57) and the cervical spine 37 (or brachial and femoral bones in the case of the arteries of the extremities) posteriorly (inward in the radial direction 57). Actuation of the members 27 and 46 and/or 27-V, 46-V cause the members to move radially inward and compress fat tissue 40 that is immediately adjacent the device 26. In the case of the carotid artery compression the vascular compression mem-

bers 27 and 46 are shown moving in the radial direction 57 inward of portions of the trachea 34 and neck muscles 36 so that portions of the vascular compression members 27 and 46 are closer to the central axis 56 in the radial direction 57 than portions of the trachea 34 and neck muscles 36. Full expansion of the vascular compression members 27 and 46 may result in inward radial movement so that they are not radially closer to the axis 56 than any portion of the esophagus 35. However, other embodiments are possible in which at least some portion of the vascular compression members 27 and 46 are closer to the central axis 56 than a portion of the esophagus 35. Actuation of the compression members 27-V and 46-V achieve similar compression of the vertebral arteries against the cervical spine, that would be most efficient at the level of C5-C7 vertebrae.

The soft tissues such as the fat tissues 40, neck muscles 36, esophagus 35 and trachea 34 around carotid arteries 16 provide a smooth cushion assuring adequate protection against carotid trauma. Same considerations will hold true in the case of compression of the arteries of upper and lower extremities and the repetition of them is not necessary. In the case of protection of both carotid arteries, the actuation of the members 27, 46 and/or 27-V, 46-V causes the areas of compression to restrict blood flow through the carotid arteries 16 and/or vertebral arteries 12 which leads to transient limitation or interruption of cerebral flow. The trachea 34 and esophagus 35 are not closed or restricted upon actuation of the expandable members 27 and 46 due to the placement and specific configuration of said expandable members. The fact that in most cases this maneuver is performed while the patient is intubated and sedated makes the risk of compression of trachea minimal. Performing the same procedure on the ambulatory basis, however, or while the patient is not intubated, may prove to be hazardous. However, in some arrangements some degree of restriction of the trachea 34 and/or esophagus 35 may occur and is considered acceptable in the setting of general anesthesia with endotracheal intubation and mechanical ventilation. It is advisable, however, to obtain Duplex scan in all patients planned for this procedure to rule out significant atherosclerotic disease of these vessels, especially if carotid arteries 16 are compressed. The mere presence of carotid artery disease in these patients should be considered a contraindication to carotid compression due to increased risk of carotid atherosclerotic plaque injury leading per se to distal cerebral embolization and stroke i.e. defeating the purpose of such a procedure.

The divergence of potential distal emboli such as cerebral emboli 17, 18 and prevention of ischemic organ injury such as stroke can be achieved by a noninvasive safe method that involves external compression of the vessel, such as carotid, vertebral or some other arteries and veins, carrying said emboli. The method and device 26 disclosed do not require puncture of the skin or vessels and do not necessitate the use of endovascular devices. The device 26 and disclosed method allow for the divergence of emboli such as, carotid and, vertebral emboli 17 and 18 of all sizes, including those microscopic particles that are too small to be trapped with, the known intravascular filters.

Various types of mechanisms capable of compressing the carotid arteries 16, vertebral arteries 12 and other vessels can be included in the device 26 in addition to or alternatively to those previously discussed. For example, the device 26 can be supplied with different vascular compression mechanisms, including different forms and shapes of longitudinal or transverse bladders, cuffs, compression pads or inserts with the same effect of vascular compression to the point of transient limitation or interruption of blood flow. The fluid

provided to pressurize the expandable components of the device 26 from the pressure source 49 may be a liquid, substance in some embodiments. Fluid that is a liquid may be used in the device 26 to effect pressurization and more uniform constriction of the carotid arteries 16 than gas or air fluid because liquid is more non-compressible at the operating range of pressures. Liquid fluid in the members 27, 32 and 46 may more directly transmit pressure to the carotid area than gas or air fluid.

Further, although shown as employing a single pressure source 49, it is to be understood that multiple pressure sources of different types may be used. For instance, the transverse carotid expandable member 32 may be pressurized by a first pressure source 49 such as a pump, tightening or direct compressing mechanism while a second source of pressure of similar types is included in the device 26 to provide pressure to the two longitudinal vascular compression members 27 and 46.

A monitoring system 58 may be included with the device 26 to assure a safe, adequate, easily manageable and controllable compression of carotid, vertebral and other vessels. The monitoring system 58 may comprise Doppler ultrasound, Doppler probe, oscillotonometer, electroencephalography, transcranial Doppler, cerebral oximetry and/or other techniques. The device 26 may be actuated to such a degree that, the one, two or more areas of vascular compression formed completely stop the flow of blood into the distal artery such as carotid artery 22, or to an extent that partial flow of blood passes through the areas of compression 23 and into the distal artery such as carotid artery 22.

The device 26 provided is a noninvasive and precise apparatus with an option of assessing a degree and an effectiveness of an interruption of the arterial flow by the optional inclusion of a monitoring system 58. The device 26 assures a uniform, and reproducible interruption or limitation of the arterial flow bilaterally minimizing the risk of trauma to the artery compressed such as carotid and vertebral artery and subsequent distal emboli, such as cerebral emboli 17. An alarm system 59 can be included in the device 26 that is triggered by excessive or lengthy compression of the target artery, such as carotid arteries 16, brachial or femoral arteries. The alarm system 59 may be a part of the monitoring system 58 or may be a different component that is not part of the monitoring system 58. The alarm system 59 may thus measure the time of compression, and the magnitude of compression. Constant monitoring of arterial, such as carotid 16, brachial or femoral and systemic arterial and device 26 pressures with pressure in the device 26 exceeding only slightly the pressure in the arterial system may be conducted to ensure safe operation and use of the disclosed device 26. The device 26 provides a noninvasive compression apparatus that does not require the insertion of intra-vascular devices.

A method for reducing or totally preventing cerebral emboli will now be discussed. A brief compression of arteries to be protected from emboli, such as carotid arteries 16 and vertebral arteries 12 by way of a device 26 may be performed first to assure adequate position of the device leading to reduction or interruption of flow or pulse through said artery as assessed by carotid Doppler, a pressure gauge, percutaneous cerebral oximetry or transcranial Doppler.

Once an adequate position of the device 26 is confirmed, the pressure in the vascular compression components (27, 32, 46 and/or 27-V, 32-V, 46-V) is released and the apparatus 26 is ready for use. The device 26 is inflated to the pressure exceeding patient's systemic pressure just before proceeding with the emboligenic part of the procedure. Adequate com-

pression of the target arteries such as carotid arteries 16 will lead to divergence of blood and emboli away from the vessels to be protected and toward more distal less important arteries, thus decreasing the risk of deadly complications, such as stroke.

The pressure in the device 26, and thus to the vascular compression components 27, 32, 46 and/or 27-V, 32-V, 46-V is released after the emboligenic procedure is completed after a full washout of potential emboli 20, 18 from the heart 11, thoracic aorta and all other potential sources. The pressurization of the device 26 and its different compartments can be repeated any time and on multiple occasions when the emboligenic intervention is contemplated.

Should the physician or physician's assistant forget to release arterial compression timely, an alarm would go off and the pressure would be released spontaneously to avoid undue interruption of the arterial flow. The alarm and deflation could be overridden by the physician when clinically indicated. The alarm may be sounded by the alarm system 59, and the deflation may be activated by the pressure source 49 and/or the alarm system 59 and/or the monitoring system 58.

The central axis 56 may be present even when the device 26 is not configured with straps 33, 43 to form a generally circular member when viewed from the top as for example in FIG. 6A. In some embodiments of the device 26, a circular member is not formed when viewed from the top by the straps 33, 43. For instance, the straps 33, 43 may be missing such that the section 31 is attached to sides of a bed or otherwise secured so that the device 26 is located at the neck 38 of the patient. In such instances, the central axis 56 is still present. The central axis 56 may be located at a location within the neck 38 of the patient, for examples shown with reference to FIGS. 8A and 8B. This location may be at the spinal column 37 of the patient, or may be at the center of the neck 38 of the patient. It is to be understood that various embodiments of the device 26 exist in which the device 26 does not wrap completely around the neck 38 of the patient but instead only wraps around a portion of the neck 38 of the patient less than 360 degrees fully about the neck of the patient.

The apparatus and methods discussed herein are not limited to the detection and compression of any particular vessels or combination of vessels, but can include any number of different types of vessels. For example, in some aspects, vessels can include arteries or veins. In some aspects, the vessels can be suprathoracic vessels (e.g., vessels in the neck or above), intrathoracic vessels (e.g., vessels in the thorax), subthoracic vessels (e.g., vessels in the abdominal area or below), lateral thoracic vessels (e.g., vessels to the sides of the thorax such as vessels in the shoulder area and beyond), or other types of vessels and/or branches thereof.

In some aspects, the detection and compression systems disclosed herein can be applied to superthoracic vessels. The suprathoracic vessels can comprise at least one of intracranial vessels, cerebral arteries, and/or any branches thereof. For example, the suprathoracic vessels can comprise at least one of a common carotid artery, an internal carotid artery, an external carotid artery, a middle meningeal artery, superficial temporal arteries, an occipital artery, a Lacrimal (ophthalmic) artery, an accessory meningeal artery, an anterior ethmoidal artery, a posterior ethmoidal artery, a maxillary artery, a posterior auricular artery, an ascending pharyngeal artery, a vertebral artery, a left middle meningeal artery, a posterior cerebral artery, a superior cerebellar artery, a basilar artery, a left internal acoustic (labyrinthine) artery, an

anterior inferior cerebellar artery, a left ascending pharyngeal artery, a posterior inferior cerebellar artery, a deep cervical artery, a highest intercostal artery, a costocervical trunk, a subclavian artery, a middle cerebral artery, an anterior cerebral artery, an anterior communicating artery, an ophthalmic artery, a posterior communicating artery, a facial artery, a lingual artery, a superior laryngeal artery, a superior thyroid artery, an ascending cervical artery, an inferior thyroid artery, a thyrocervical trunk, an internal thoracic artery, and/or any branches thereof. The suprathoracic vessels can also comprise at least one of a medial orbitofrontal artery, a recurrent artery (of Heubner), medial and lateral lenticulostriate arteries, a lateral orbitofrontal artery, an ascending frontal (candelabra) artery, an anterior choroidal artery, pontine arteries, an internal acoustic (labyrinthine) artery, an anterior spinal artery, a posterior spinal artery, a posterior medial choroidal artery, a posterior lateral choroidal artery, and/or branches thereof. The suprathoracic vessels can also comprise at least one of perforating arteries, a hypothalamic artery, lenticulostriate arteries, a superior hypophyseal artery, an inferior hypophyseal artery, an anterior thalamostriate artery, a posterior thalamo striate artery, and/or branches thereof. The suprathoracic vessels can also comprise at least one of a precentral (pre-Rolandic) and central (Rolandic) arteries, anterior and posterior parietal arteries, an angular artery, temporal arteries (anterior, middle and posterior), a paracentral artery, a pericallosal artery, a callosomarginal artery, a frontopolar artery, a precuneal artery, a parietooccipital artery, a calcarine artery, an inferior vermian artery, and/or branches thereof.

In some aspects, the suprathoracic vessels can also comprise at least one of diploic veins, an emissary vein, a cerebral vein, a middle meningeal vein, superficial temporal veins, a frontal diploic vein, an anterior temporal diploic vein, a parietal emissary vein, a posterior temporal diploic vein, an occipital emissary vein, an occipital diploic vein, a mastoid emissary vein, a superior cerebral vein, efferent hypophyseal veins, infundibulum (pituitary stalk) and long hypophyseal portal veins, and/or branches thereof.

The intrathoracic vessels can comprise the aorta or branches thereof. For example, the intrathoracic vessels can comprise at least one of an ascending aorta, a descending aorta, an arch of the aorta, and/or branches thereof. The descending aorta can comprise at least one of a thoracic aorta, an abdominal aorta, and/or any branches thereof. The intrathoracic vessels can also comprise at least one of a subclavian artery, an internal thoracic artery, a pericardiophrenic artery, a right pulmonary artery, a right coronary artery, a brachiocephalic trunk, a pulmonary trunk, a left pulmonary artery, an anterior interventricular artery, and/or branches thereof. The intrathoracic vessels can also comprise at least one of an inferior thyroid artery, a thyrocervical trunk, a vertebral artery, a right bronchial artery, a superior left bronchial artery, an inferior left bronchial artery, aortic esophageal arteries, and/or branches thereof.

In some aspects, the intrathoracic vessels can also comprise at least one of a right internal jugular vein, a right brachiocephalic vein, a subclavian vein, an internal thoracic vein, a pericardiophrenic vein, a superior vena cava, a right superior pulmonary vein, a left brachiocephalic vein, a left internal jugular vein, a left superior pulmonary vein, an inferior thyroid vein, an external jugular vein, a vertebral vein, a right highest intercostal vein, a 6th right intercostal vein, an azygos vein, an inferior vena cava, a left highest intercostal vein, an accessory hemiazygos vein, a hemiazygos vein, and/or branches thereof.

In some aspects, the subthoracic vessels can comprise at least one of renal arteries, inferior phrenic arteries, a celiac trunk with common hepatic, left gastric and splenic arteries, superior suprarenal arteries, a middle suprarenal artery, an inferior suprarenal artery, a right renal artery, a subcostal artery, 1st to 4th right lumbar arteries, common iliac arteries, an iliolumbar artery, an internal iliac artery, lateral sacral arteries, an external iliac artery, a testicular (ovarian) artery, an ascending branch of deep circumflex iliac artery, a superficial circumflex iliac artery, an inferior epigastric artery, a superficial epigastric artery, a femoral artery, a ductus deferens and testicular artery, a superficial external pudendal artery, a deep external pudendal artery, and/or branches thereof. The subthoracic vessels can also comprise at least one of a superior mesenteric artery, a left renal artery, an abdominal aorta, an inferior mesenteric artery, colic arteries, sigmoid arteries, a superior rectal artery, 5th lumbar arteries, a middle sacral artery, a superior gluteal artery, umbilical and superior vesical arteries, an obturator artery, an inferior vesical artery to ductus deferens, a middle rectal artery, an internal pudendal artery, an inferior gluteal artery, a cremasteric, pubic (obturator anastomotic) branches of inferior epigastric artery, a left colic artery, rectal arteries, and/or branches thereof.

In some aspects, the lateral thoracic vessels can comprise at least one of humeral arteries, a transverse cervical artery, a suprascapular artery, a dorsal scapular artery, and/or branches thereof. The lateral thoracic vessels can also comprise at least one of an anterior circumflex humeral artery, a posterior circumflex humeral artery, a subscapular artery, a circumflex scapular artery, a brachial artery, a thoracodorsal artery, a lateral thoracic artery, an inferior thyroid artery, a thyrocervical trunk, a subclavian artery, a superior thoracic artery, a thoracoacromial artery, and/or branches thereof.

In some aspects, vessels can include other portions of the vasculature, such as the heart or chambers of the heart. In some aspects, the detection and compression systems disclosed herein can be applied to the heart or chambers of the heart, such as the right atrium, the left atrium, the right ventricle, and/or the left ventricle. For example, detection of emboli can be performed within or near one or more chambers of the heart.

In some aspects, a vessel in which detection is performed is, different from a vessel in which compression is performed. For example, detection is performed in a first vessel and compression is performed in a second vessel. The second vessel can be downstream of the first vessel.

In some aspects, a vessel in which detection is performed is the same as a vessel in which compression is performed. For example, detection is performed in a vessel at a first location and compression is performed in the vessel at a second location. The second location can be downstream of the first location.

FIG. 25 is a block diagram illustrating an exemplary computer system 200 with which a system (e.g., monitoring module/system and/or detection module/system) of the subject technology can be implemented. In certain embodiments, the computer system 200 may be implemented using hardware or a combination of software and hardware, either in a dedicated server, or integrated into another entity, or distributed across multiple entities.

The computer system 200 includes a bus 208 or other communication mechanism for communicating information, and a processor 202 coupled with the bus 208 for processing information. By way of example, the computer system 200 may be implemented with one or more processors 202. The processor 202 may be a general-purpose microprocessor, a

microcontroller, a Digital Signal Processor (DSP), an Application Specific Integrated Circuit (ASIC), a Field Programmable Gate Array (FPGA), a Programmable Logic Device (PLD), a controller, a state machine, gated logic, discrete hardware components, and/or any other suitable entity that can perform calculations or other manipulations of information.

The computer system 200 can include, in addition to hardware, code that creates an execution environment for the computer program in question, e.g., code that constitutes processor firmware, a protocol stack, a database management system, an operating system, or a combination of one or more of them stored in an included memory 204, such as a Random Access Memory (RAM), a flash memory, a Read Only Memory (ROM), a Programmable Read-Only Memory (PROM), an Erasable PROM (EPROM), registers, a hard disk, a removable disk, a CD-ROM, a DVD, and/or any other suitable storage device, coupled to the bus 208 for storing information and instructions to be executed by the processor 202. The processor 202 and the memory 204 can be supplemented by, or incorporated in, special purpose logic circuitry.

The instructions may be stored in the memory 204 and implemented in one or more computer program products, i.e., one or more modules of computer program instructions encoded on a computer readable medium for execution by, or to control the operation of, the computer system 200, and according to any method well known to those of skill in the art, including, but not limited to, computer languages such as data-oriented languages (e.g., SQL, dBase), system languages (e.g., C, Objective-C, C++, Assembly), architectural languages (e.g., Java, .NET), and/or application languages (e.g., PHP, Ruby, Perl, Python). Instructions may also be implemented in computer languages such as array languages, aspect-oriented languages, assembly languages, authoring languages, command line interface languages, compiled languages, concurrent languages, curly-bracket languages, dataflow languages, data-structured languages, declarative languages, esoteric languages, extension languages, fourth-generation languages, functional languages, interactive mode languages, interpreted languages, iterative languages, list-based languages, little languages, logic-based languages, machine languages, macro languages, metaprogramming languages, multiparadigm languages, numerical analysis, non-English-based languages, object-oriented class-based languages, object-oriented prototype-based languages, off-side rule languages, procedural languages, reflective languages, rule-based languages, scripting languages, stack-based languages, synchronous languages, syntax handling languages, visual languages, wirth languages, and/or xml-based languages. The memory 204 may also be used for storing temporary variable or other intermediate information during execution of instructions to be executed by the processor 202.

A computer program as discussed herein does not necessarily correspond to a file in a file system. A program can be stored in a portion of a file that holds other programs or data (e.g., one or more scripts stored in a markup language document), in a single file dedicated to the program in question, or in multiple coordinated files (e.g., files that store one or more modules, subprograms, or portions of code). A computer program can be deployed to be executed on one computer or on multiple computers that are located at one site or distributed across multiple sites and interconnected by a communication network. The processes and logic flows described in this specification can be performed by one or

more programmable processors executing one or more computer programs to perform functions by operating on input data and generating output.

The computer system **200** further includes a data storage device **206** such as a magnetic disk or optical disk, coupled to the bus **208** for storing information and instructions. The computer system **200** may be coupled via an input/output module **210** to various devices (e.g., devices **214** and **216**). The input/output module **210** can be any input/output module. Exemplary input/output modules **210** include data ports (e.g., USB ports), audio ports, and/or video ports. In some embodiments, the input/output module **210** includes a communications module. Exemplary communications modules include networking interface cards, such as Ethernet cards, modems, and routers. In certain aspects, the input/output module **210** is configured to connect to a plurality of devices, such as an input device **214** and/or an output device **216**. Exemplary input devices **214** include a keyboard and/or a pointing device (e.g., a mouse or a trackball) by which a user can provide input to the computer system **200**. Other kinds of input devices **214** can be used to provide for interaction with a user as well, such as a tactile input device, visual input device, audio input device, and/or brain-computer interface device. For example, feedback provided to the user can be any form of sensory feedback (e.g., visual feedback, auditory feedback, and/or tactile feedback), and input from the user can be received in any form, including acoustic, speech, tactile, and/or brain wave input. Exemplary output devices **216** include display devices, such as a cathode ray tube (CRT) or liquid crystal display (LCD) monitor, for displaying information to the user.

According to certain embodiments, the computer system **200** can, operate in response to the processor **202** executing one or more sequences of one or more instructions contained in the memory **204**. Such instructions may be read into the memory **204** from another machine-readable medium, such as the data storage device **206**. Execution of the sequences of instructions contained in the memory **204** causes the processor **202** to perform the process steps described herein. One or more processors in a multi-processing arrangement may also be employed to execute the sequences of instructions contained in, the memory **204**. In some embodiments, hard-wired circuitry may be used in place of or in combination with software instructions to implement various aspects of the present disclosure. Thus, aspects of the present disclosure are not limited to any specific combination of hardware circuitry and software.

Various aspects of the subject matter described in this specification can be implemented in a computing system that includes a back end component (e.g., a data server), or that includes a middleware component (e.g., an application server), or that includes a front end component (e.g., a client computer having a graphical user interface and/or a Web browser through which a user can interact with an implementation of the subject matter, described in, this specification), or any combination of one or more such back end, middleware, or front end components. The components of the system **200** can be interconnected by any form or medium of digital data communication (e.g., a communication network). Examples of communication networks include a local area network and a wide area network.

The term “machine-readable storage medium” or “computer readable medium” as used herein refers to any medium or media that participates in providing instructions to the processor **202** for execution. Such a medium may take many forms, including, but not limited to, non-volatile media, volatile media, and transmission media. Non-volatile media

include, for example, optical or magnetic disks, such as the data storage device **206**. Volatile media include dynamic memory, such as the memory **204**. Transmission media include coaxial cables, copper wire, and fiber optics, including the wires that comprise the bus **208**. Common forms of machine-readable media include, for example, floppy disk, a flexible disk, hard disk, magnetic tape, any other magnetic medium, a CD-ROM, DVD, any other optical medium, punch cards, paper tape, any other physical medium with patterns of holes, a RAM, a PROM, an EPROM, a FLASH EPROM, any other memory chip or cartridge, or any other medium from which a computer can read. The machine-readable storage medium can be a machine-readable storage device, a machine-readable storage substrate, a memory device, a composition of matter effecting a machine-readable propagated signal, or a combination of one or more of them.

As used herein, a “processor” can include one or more processors, and a “module” can include one or more modules.

In an aspect of the subject technology, a machine-readable medium is a computer-readable medium encoded or stored with instructions and is a computing element, which defines structural and functional relationships between the instructions and the rest of the system, which permit the instructions’ functionality to be realized. Instructions may be executable, for example, by a system or by a processor of the system. Instructions can be, for example, a computer program including code. A machine-readable medium may comprise one or more media.

FIG. **26** illustrates an example of a system **300** for diverting emboli within a patient, in accordance with various embodiments of the subject technology. The system **300** is an example of an implementation of a system for diverting emboli within a patient. The system **300** comprises monitoring module **302**, compression module **304**, and control module **306**. Although the system **300** is shown as having these modules, the system **300** may have other suitable configurations. The modules of the system **300** may be in communication with one another. In some embodiments, the modules may be implemented in software (e.g., subroutines and code). For example, the modules may be stored in the memory **204** and/or data storage **206**, and executed by the processor **202**. In some aspects, some or all of the modules may be implemented in hardware (e.g., an Application Specific Integrated Circuit (ASIC), a Field Programmable Gate Array (FPGA), a Programmable Logic Device (PLD), a controller, a state machine, gated logic, discrete hardware components, or any other suitable devices) and/or a combination of both. Additional features and functions of these modules according to various aspects of the subject technology are further described in the present disclosure.

As used herein, the word “module” refers to logic embodied in hardware or firmware, or to a collection of software instructions, possibly having entry and exit points, written in a programming language, such as, for example C++. A software module may be compiled and linked into an executable program, installed in a dynamic link library, or may be written in an interpretive language such as BASIC. It will be appreciated that software modules may be callable from other modules or from themselves, and/or may be invoked in response to detected events or interrupts. Software instructions may be embedded in firmware, such as an EPROM or EEPROM. It will be further appreciated that hardware modules may be comprised of connected logic units, such as gates and flip-flops, and/or may be comprised of programmable units, such as programmable gate arrays or

processors. The modules described herein are preferably implemented as software modules, but may be represented in hardware or firmware.

It is contemplated that the modules may be integrated into a fewer number of modules. One module may also be separated into multiple modules. The described modules may be implemented as hardware, software, firmware or any combination thereof. Additionally, the described modules may reside at different locations connected through a wired or wireless network, or the Internet.

In general, it will be appreciated that the processors can include, by way of example, computers, program logic, or other substrate configurations representing data and instructions, which operate as described herein. In other embodiments, the processors can include controller circuitry, processor circuitry, processors, general purpose single-chip or multi-chip microprocessors, digital signal processors, embedded microprocessors, microcontrollers and the like.

Furthermore, it will be appreciated that in one embodiment, the program logic may advantageously be implemented as one or more components. The components may advantageously be configured to execute on one or more processors. The components include, but are not limited to, software or hardware components, modules such as software modules, object-oriented software components, class components and task components, processes methods, functions, attributes, procedures, subroutines, segments of program code, drivers, firmware, microcode, circuitry, data, databases, data structures, tables, arrays, and variables.

A phrase such as “an aspect” does not imply that such aspect is essential to the subject technology or that such aspect applies to all configurations of the subject technology. A disclosure relating to an aspect may apply to all configurations, or one or more configurations. An aspect may provide one or more examples of the disclosure. A phrase such as “an aspect” may refer to one or more aspects and vice versa. A phrase such as “an embodiment” does not imply that such embodiment is essential to the subject technology or that such embodiment applies to all configurations of the subject technology. A disclosure relating to an embodiment may apply to all embodiments, or one or more embodiments. An embodiment may provide one or more examples of the disclosure. A phrase such as “an embodiment” may refer to one or more embodiments and vice versa. A phrase such as “a configuration” does not imply that such configuration is essential to the subject technology or that such configuration applies to all configurations of the subject technology. A disclosure relating to a configuration may apply to all configurations, or one or more configurations. A configuration may provide one or more examples of the disclosure. A phrase such as “a configuration” may refer to one or more configurations and vice versa.

The foregoing description is provided to enable a person skilled in the art to practice the various, configurations described herein. While the subject technology has been particularly described with reference to the various figures and configurations, it should be understood that these are for illustration purposes only and should not be taken as limiting the scope of the subject technology.

There may be many other ways to implement the subject technology. Various functions and elements described herein may be partitioned differently from those shown without departing from the scope of the subject technology. Various modifications to these configurations will be readily apparent to those skilled in the art, and generic principles defined herein may be applied to other configurations. Thus, many changes and modifications may be made to the subject

technology, by one having ordinary skill in the art, without departing from the scope of the subject technology.

It is understood that the specific order or hierarchy of steps in the processes disclosed is an illustration of exemplary approaches. Based upon design preferences, it is understood that the specific order or hierarchy of steps in the processes may be rearranged. Some of the steps may be performed simultaneously. The accompanying method claims present elements of the various steps in a sample order, and are not meant to be limited to the specific order or hierarchy presented.

As used herein, the phrase “at least one of” preceding a series of items, with the term “and” or “or” to separate any of the items, modifies the list as a whole, rather than each member of the list (i.e., each item). The phrase “at least one of” does not require selection of at least one of each item listed; rather, the phrase allows a meaning that includes at least one of any one of the items, and/or at least one of any combination of the items, and/or at least one of each of the items. By way of example, the phrases “at least one of A, B, and C” or “at least one of A, B, or C” each refer to only A, only B, or only C; any combination of A, B, and C; and/or at least one of each of A, B, and C.

Terms such as “top,” “bottom,” “front,” “rear” and the like as used in this disclosure should be understood as referring to an arbitrary frame of reference, rather than to the ordinary gravitational frame of reference. Thus, a top surface, a bottom surface, a front surface, and a rear surface may extend upwardly, downwardly, diagonally, or horizontally in a gravitational frame of reference.

Furthermore, to the extent that the term “include,” “have,” or the like is used in the description or the claims, such term is intended to be inclusive in a manner similar to the term “comprise” as “comprise” is interpreted when employed as a transitional word in a claim.

The word “exemplary” is used herein to mean “serving as an example, instance, or illustration.” Any embodiment described herein as “exemplary” is not necessarily to be construed as preferred or advantageous over other embodiments.

A reference to an element in the singular is not intended to mean “one and only one” unless specifically stated, but rather “one or more.” Pronouns in the masculine (e.g., his) include the feminine and neuter gender (e.g., her and its) and vice versa. The term “some” refers to one or more. Underlined and/or italicized headings and subheadings are used for convenience only, do not limit the subject technology, and are not referred to in connection with the interpretation of the description of the subject technology. All structural and functional equivalents to the elements of the various configurations described throughout this disclosure that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference and intended to be encompassed by the subject technology. Moreover, nothing disclosed herein is intended to be dedicated to the public regardless of whether such disclosure is explicitly recited in the above description.

While certain aspects and embodiments of the subject technology have been described, these have been presented by way of example only, and are not intended to limit the scope of the subject technology. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms without departing from the spirit thereof. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the subject technology.

What is claimed is:

1. A system for diverting emboli within a patient, comprising:

a detection device configured to detect a presence of emboli in a first blood vessel of a patient;

a compression member configured to be aligned with a second blood vessel of the patient when a collar supporting the compression member is positioned at least partially around a portion of the patient;

a controller configured to actuate the compression member, when the presence of emboli is detected from an unactuated state to an actuated state in which at least a portion of the compression member (i) is closer to the second blood vessel than while in the unactuated state and (ii) compresses and limits blood flow through the second blood vessel;

wherein compressive force applied in the actuated state by the compression member to the second blood vessel exceeds an arterial pressure of the patient.

2. The system of claim 1, wherein the second blood vessel is downstream of the first blood vessel.

3. The system of claim 1, wherein the detection device is configured to detect a threshold amount of emboli in the first blood vessel, wherein the controller is configured to actuate the compression member when the detected emboli exceeds the threshold amount.

4. The system of claim 1, wherein the detection device comprises a Doppler ultrasound device, a Doppler probe device, an oscillotonometry device, an electroencephalography device, a transcranial Doppler device, a pulse indicator device, a cardiac Echo device, a pulse oximeter, or a cerebral oximeter.

5. The system of claim 1, further comprising a supplemental detection device configured to detect a presence of emboli in a third blood vessel of a patient, upstream of the second blood vessel.

6. The system of claim 1, wherein the controller is configured for synchronizing the application of compressive force by the compression member with a systolic phase of cardiac activity by monitoring a phase of cardiac activity and by actuating the compression member to cause the compression member to apply compressive force when the systolic phase of cardiac activity is detected, and to cause the compression member to release compressive force when a diastolic phase of cardiac activity is detected.

7. A device for diverting emboli from cerebral circulation of a patient, comprising:

a first carotid compression member configured to be aligned with a first carotid artery of the patient radially between the first carotid compression member and a cervical spine of the patient when the device is positioned at least partially around a neck of a patient, the first carotid compression member having an unactuated state and an actuated state in which at least a portion of the first carotid compression member (i) is closer to the first carotid artery than while in the unactuated state and (ii) compresses and limits blood flow through the first carotid artery;

a compression source that applies fluid to actuate the first carotid compression member; and

a monitoring system that monitors an arterial pressure of the patient and communicates with the compression source to cause the first carotid compression member to apply pressure based upon the measured arterial pressure of the patient so as to be above the measured arterial pressure of the patient;

wherein the monitoring system is configured for synchronizing the application of pressure by the first carotid compression member with a systolic phase of cardiac activity by monitoring the phase of cardiac activity and by communicating with the compression source to cause the first carotid compression member to apply pressure when the systolic phase of cardiac activity is detected, and to cause the first carotid compression member to release pressure when a diastolic phase of cardiac activity is detected.

8. The device of claim 7, further comprising:

a first vertebral compression member configured to be aligned with a first vertebral artery of the patient radially between the first vertebral compression member and the cervical spine when the device is positioned at least partially around the neck, the first vertebral compression member having an unactuated state and an actuated state in which at least a portion of the first vertebral compression member (i) is closer to the first vertebral artery than while in the unactuated state and (ii) compresses and limits blood flow through the first vertebral artery;

wherein an internal volume of the first carotid compression member and an internal volume of the first vertebral compression member are in fluid communication with each other;

wherein the compression source applies fluid to actuate the first vertebral compression member; and

wherein the monitoring system monitors the arterial pressure of the patient and communicates with the compression source to cause the first vertebral compression member to apply pressure based upon the measured arterial pressure of the patient so as to be above the measured arterial pressure of the patient.

9. A device for diverting emboli from cerebral circulation of a patient, comprising:

a first carotid compression member configured to be aligned with a first carotid artery of the patient radially between the first carotid compression member and a cervical spine of the patient when the device is positioned at least partially around a neck of a patient, the first carotid compression member having an unactuated state and an actuated state in which at least a portion of the first carotid compression member (i) is closer to the first carotid artery than while in the unactuated state and (ii) compresses and limits blood flow through the first carotid artery;

a compression source that applies fluid to actuate the first carotid compression member; and

a monitoring system that monitors an arterial pressure of the patient and communicates with the compression source to cause the first carotid compression member to apply pressure based upon the measured arterial pressure of the patient so as to be above the measured arterial pressure of the patient;

a first vertebral compression member configured to be aligned with a first vertebral artery of the patient radially between the first vertebral compression member and the cervical spine when the device is positioned at least partially around the neck, the first vertebral compression member having an unactuated state and an actuated state in which at least a portion of the first vertebral compression member (i) is closer to the first vertebral artery than while in the unactuated state and (ii) compresses and limits blood flow through the first vertebral artery;

29

wherein an internal volume of the first carotid compression member and an internal volume of the first vertebral compression member are in fluid communication with each other;

wherein the compression source applies fluid to actuate the first vertebral compression member; and

wherein the monitoring system monitors the arterial pressure of the patient and communicates with the compression source to cause the first vertebral compression member to apply pressure based upon the measured arterial pressure of the patient so as to be above the measured arterial pressure of the patient;

wherein the first carotid compression member has a maximum height, parallel to a central axis of the device, that is greater than a maximum height of the first vertebral compression member.

10. A device for diverting emboli from cerebral circulation of a patient, comprising:

a first carotid compression member configured to be aligned with a first carotid artery of the patient radially between the first carotid compression member and a cervical spine of the patient when the device is positioned at least partially around a neck of a patient, the first carotid compression member having an unactuated state and an actuated state in which at least a portion of the first carotid compression member (1) is closer to the first carotid artery than while in the unactuated state and (ii) compresses and limits blood flow through the first carotid artery;

a first vertebral compression member configured to be aligned with a first vertebral artery of the patient radially between the first vertebral compression member and the cervical spine when the device is positioned at least partially around the neck, the first vertebral compression member having an unactuated state and an actuated state in which at least a portion of the first vertebral compression member (i) is closer to the first vertebral artery than while in the unactuated state and (ii) compresses and limits blood flow through the first vertebral artery;

30

a second carotid compression member configured to be aligned with a second carotid artery of the patient radially between the second carotid compression member and the cervical spine when the device is positioned at least partially around the neck, the second carotid compression member having an unactuated state and an actuated state in which at least a portion of the second carotid compression member (i) is closer to the second carotid artery than while in the unactuated state and (ii) compresses and limits blood flow through the second carotid artery;

a second vertebral compression member configured to be aligned with a second vertebral artery of the patient radially between the second vertebral compression member and the cervical spine when the device is positioned at least partially around the neck, the second vertebral compression member having an unactuated state and an actuated state in which at least a portion of the second vertebral compression member (i) is closer to the second vertebral artery than while in the unactuated state and (ii) compresses and limits blood flow through the second vertebral artery.

11. The device of claim 10, wherein an internal volume of the second carotid compression member and an internal volume of the second vertebral compression member are in fluid communication with each other.

12. The device of claim 10, wherein an internal volume of the first carotid compression member, an internal volume of the first vertebral compression member, an internal volume of the second carotid compression member, and an internal volume of the second vertebral compression member are in fluid communication with each other.

13. The device of claim 10, wherein the second carotid compression member has a maximum height, parallel to a central axis of the device, that is greater than a maximum height of the second vertebral compression member.

* * * * *

专利名称(译)	栓塞的无创保护		
公开(公告)号	US10667825	公开(公告)日	2020-06-02
申请号	US15/691026	申请日	2017-08-30
[标]申请(专利权)人(译)	ZHADKEVICH医疗		
当前申请(专利权)人(译)	ZHADKEVICH MEDICAL , INC.		
[标]发明人	ZHADKEVICH MICHAEL		
发明人	ZHADKEVICH, MICHAEL		
IPC分类号	A61B17/135 A61B5/026 A61B5/022 A61B5/02 A61B17/132 A61H9/00 A61B17/00 A61B5/00 A61H1/00		
CPC分类号	A61B17/1355 A61B17/1325 A61B17/132 A61B17/135 A61H9/0078 A61H2205/04 A61B2017/00022 A61B5/02233 A61H1/008 A61B5/026 A61B5/02 A61B5/6822 A61B5/022		
优先权	61/988217 2014-05-04 US		
其他公开文献	US20170360452A1		
外部链接	Espacenet		

摘要(译)

用于在患者体内转移栓子的系统可以包括检测患者的第一血管中栓子的存在的装置。当支撑压缩构件的套环至少部分地围绕患者的一部分定位时，压缩构件可以与患者的第二血管对准。响应于该检测装置，当检测到栓塞的存在时，控制器可致动压缩构件从未致动状态到致动状态，在该致动状态中，至少一部分压缩构件 (i) 更靠近第二构件。(ii) 压缩和限制流过第二血管的血流。

