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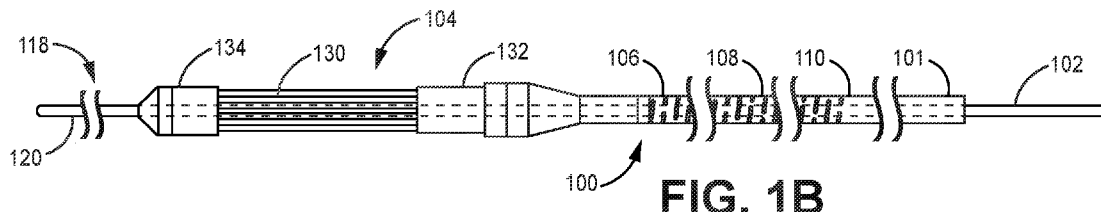
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(54) Title: AN EMBOLIC PROTECTION DEVICE DESIGNED IN PARTICULAR FOR TORTUOUS BLOOD VESSELS,
ESPECIALLY CEREBRAL VESSELS



(57) Abstract: An embolic protection device with a flexible fiber-based filter element is described associated with an integrated guide structure. The integrated guide structure comprises a corewire within a hypotube having an uncut proximal section and a distal section having laser cuts through the hypotube wall. A corewire extends through the hypotube with a low friction channel, which can have a friction reducing coil between the corewire and at least a portion of the hypotube. A torque coupler restricts rotation of the corewire while allowing at least some sliding of the corewire within the hypotube that provides for actuating the filter element and for curving the laser cut hypotube. Torque coupler designs provide connection to the laser cut hypotube. The fiber bundle has an initial undeployed configuration with the fibers aligned and a deployed configuration with the fibers bent.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/32720

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61F 2/01 (2024.01)

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y — A	US 2018/0303498 A1 (Medtronic, Inc.) 25 October 2018 (25.10.2018), entire document	1 — 2-5
Y — A	US 5,972,019 A (Engelson et al.) 26 October 1999 (26.10.1999), entire document, especially Fig. 15B; col 15, ln 3	1 — 2-5
A	US 2006/0006649 A1 (Galdonik et al.) 12 January 2006 (12.01.2006), entire document	2-5
A	US 2020/0101267 A1 (MIVI Neuroscience, Inc.) 02 April 2020 (02.04.2020), entire document	1-5
A	US 10,463,386 B2 (MIVI Neuroscience, Inc.) 05 November 2019 (05.11.2019), entire document	1-5
A	US 2020/0046389 A1 (MIVI Neuroscience, Inc.) 13 February 2020 (13.02.2020), entire document, especially Fig. 1B and 1D	1-5

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/32720

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.: 6-16, 22-31, 35-38, 43-45, 50-54, 59-65
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-5, directed to an embolic protection device with a flexible fiber-based filter element comprising a friction reducing coil between a corewire and a portion of a distal section of a hypotube and a torque coupler restricting rotation of the corewire and the hypotube while allowing some sliding of the corewire within the hypotube.

Group II: Claims 17-21, directed to an embolic protection device with a flexible fiber-based filter element comprising a stake having a non-circular central lumen shaped to engaged a non-circular cross section of a corewire to prevent relative motion of the stake and the corewire without limiting sliding of the corewire to the stake, wherein the stake is secured with the hypotube.

--- See Continuation Box ---

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

Box III - Unity of Invention

Group III: Claims 32-34, directed to an embolic protection device with a flexible fiber-based filter element comprising a distal tip comprising a distal coil secured with a second attachment element of a fiber bundle and/or to a corewire, wherein a first attachment element of the fiber bundle comprises a first marker band having laser cut walls and is formed from highly radiopaque metal.

Group IV: Claims 39-42 and 46-49, directed to an embolic protection device with a flexible fiber-based filter element and method for delivering an embolic protection device comprising a friction reducing structure or a mechanical element having a low friction channel located between a corewire and a portion of a distal section of a hypotube, wherein advancing the corewire within the hypotube in a distal direction results in curving of the hypotube along the distal section.

Group V: Claims 55-58, directed to a method for assembling an integrated guide structure.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features:

Group I requires the special technical features [a friction reducing] coil [between the corewire and at least a portion of the hypotube distal section].

Group II requires the special technical features a stake having a central lumen with a non-circular cross section along the inner diameter, wherein the non-circular cross section of the inner diameter is shaped to engage [the non-circular cross section of the tip section of the corewire], wherein the stake is interfaced with the corewire [to prevent relative rotation of] the stake and [the corewire without limiting sliding of the corewire relative to] the stake, and wherein the stake is secured with [the hypotube] to [resist relative rotation] of the stake and [the hypotube].

Group III requires the special technical features wherein relative movement of [the corewire] and [the hypotube] can transition the filter cartridge from a low profile delivery conformation to a deployer filtering conformation; and [a distal tip] comprising a distal coil [secured with the second attachment element and/or to the corewire], wherein [the first attachment element] comprises a first marker band having laser cut walls over at least a portion of its length, wherein the first marker band is formed from a highly radiopaque metal.

Group IV requires the special technical features [a friction reducing] structure comprising a polymer associated with the hypotube or a mechanical element having a low friction channel, [located between the corewire and a portion of the hypotube distal section]; and wherein advancing [the corewire within the hypotube] in a distal direction with [the fiber bundle in an undeployed configuration] results in curving of [the hypotube] along [the distal section].

Group V requires the special technical features a method for assembling an integrated guide structure comprising: assembling components of the integrated guide structure, wherein the components comprise [a hypotube having laser cuts along at least a portion of the length of the hypotube that extend through the wall of the hypotube, a corewire extending through a central lumen of the hypotube], and a central element with a central hole through which at least a portion of [the corewire] extends through and an outer surface that fits within [the central lumen of the hypotube]; and reflowing a thermoplastic elastomer jacket over the exterior of [the laser cut hypotube], wherein thermoplastic elastomer extends through holes through [the hypotube] to engage the exterior of the central element to resist movement of the central element without restricting at least some movement of [the corewire within the lumen of the hypotube].

--- See Continuation Box ---

Box III - Unity of Invention

Common Technical Features:

Groups I-V share the technical features an embolic protection device with a flexible fiber-based filter element comprising: a corewire having a proximal section with a first diameter, a distal section having a second diameter less than the first diameter, and a tip section having a non-circular cross section over at least a portion of its length; a hypotube with a proximal section free of laser cuts and a distal section having laser cuts through the wall of the hypotube, wherein the corewire extends through the hypotube with the proximal end and the distal end of the corewire extending from respective ends of the hypotube; a friction reducing element between the corewire and at least a portion of the hypotube distal section; a torque coupler restricting rotation of the corewire and the hypotube at the torque coupler while allowing at least some sliding of the corewire within the hypotube; a fiber bundle comprising a bundle of fibers each having a first end and a second end, a first attachment element, and a second attachment element, wherein the first attachment element secures the first end of the polymer fibers and the second attachment element secures the second end of the fibers, wherein the first attachment element is secured to the distal section of the hypotube, wherein the fiber bundle has an initial undeployed configuration with the fibers aligned and a deployed configuration with the fibers bent and the corewire in a proximal position relative to the hypotube in the undeployed configuration; a distal tip secured with the second attachment element and/or to the corewire. However, these technical features are not unifying features because they are anticipated by US 2018/0303498 A1 to Medtronic, Inc (hereinafter 'Medtronic'). Medtronic teaches an embolic protection device with a flexible fiber-based filter element (see 100 with 104, Fig. 1A; fiber-based device 100 comprising... a fiber cartridge 104, para [0062]; upon deployment... the fibers flare outward to form a filtration matrix across the diameter of the vessel, para [0081]; the fiber cartridge can be used as an embolism protection device, para [0125]) comprising: a corewire (106, Fig. 1A-B; corewire 106, para [0062]) having a proximal section with a first diameter (see diameter of the left section of 106, Fig. 1B), a distal section having a second diameter less than the first diameter (130, Fig. 1B; distal segment 130 is tapered, para [0063]), and a tip section having a non-circular cross section over at least a portion of its length (132, Fig. 1B; distal tip 132 is flattened along a portion, para [0063]); a hypotube (108 and 110, Fig. 1A; first resilient element 110 extends from the distal end of overtube 108, para [0062]) with a proximal section free of laser cuts (see smooth 108, Fig. 1A; see smooth and analogous 150, Fig. 2B; overtube 150, para [0066]) and a distal section having laser cuts through the wall of the hypotube (see 110 with line, Fig. 1A; see 140 with similar lines showing cuts, Fig. 2B; as shown in Fig. 2B, resilient member 140 is cut into overtube 150 such that they are integral members of the structure, para [0066]), wherein the corewire extends through the hypotube with the proximal end and the distal end of the corewire extending from respective ends of the hypotube (see 112 past the distal end of 106/110, Fig. 1A; corewire 106 extends through a central lumen of overtube 108 with the distal end and the proximal end of the corewire extending from the overtube. First resilient element 110 covers a portion of corewire 106... second resilient element 112 is secured to corewire 106 at or near the distal end of the device, para [0062]); a friction reducing element between the corewire and at least a portion of the hypotube distal section (the surface of the corewire and the inner surface of the overtube can be coated with a friction reducing agent, para [0072]; reasonably assuming a friction reducing agents on the inner surface of the overtube or on the surface of the corewire is between the corewire and the hypotube); a torque coupler restricting rotation of the corewire and the hypotube at the torque coupler while allowing at least some sliding of the corewire within the hypotube (114 and 116, Fig. 1A-1B, 3A and 4A; torque couplers 114, 116 have appropriate structure to rotationally couple 106 with 108 and 110, para [0062]; torque couplers... provide desired longitudinal motion of the integrated guiding device, para [0051]); a fiber bundle (104, Fig. 1A; 178, Fig. 8A-B; Fiber cartridge 104, para [0062]; a fiber-based device similar to 100 of Fig. 1A... fiber cartridge 178, para [0088]) comprising a bundle of fibers (188, Fig. 8A; fiber-based element 188, para [0088]) each having a first end (see left end of 188 coupled to 184, Fig. 8A-B) and a second end (see right end of 188 coupled to 186, Fig. 8A-B), a first attachment element (184, Fig. 8A; proximal bonded end 184, para [0088]), and a second attachment element (186, Fig. 8A-B; distal bonded end 186, para [0088]), wherein the first attachment element secures the first end of the polymer fibers (the ends of the fibers can be melt bonded to secure bonded ends, para [0083]) and the second attachment element secures the second end of the fibers (the ends of the fibers can be melt bonded to secure bonded ends, para [0083]), wherein the first attachment element is secured to the distal section of the hypotube (see 184 secured to 176, Fig. 8A-B; proximal resilient member 176, para [0088]), wherein the fiber bundle has an initial undeployed configuration with the fibers aligned (see configuration of 178 with 188 aligned in Fig. 8A; Fig. 8A is a side view of a filter device with a fiber cartridge in a delivery configuration, para [0028]) and a deployed configuration with the fibers bent (see configuration of 178 with 188 bent in Fig. 8B; Fig. 8B is a side view of a filter device in a flared configuration, para [0029]) and the corewire in a proximal position relative to the hypotube in the undeployed configuration (corewire is pulled in a proximal direction relative to overtube to deploy the fiber cartridge, para [0100]; reasonably assuming the corewire is in a position proximal to the overtube prior to being pulled away proximally from the overtube during the fiber cartridge deployment since the corewire extends from the proximal end of the overtube (para [0062])); a distal tip secured with the second attachment element and/or to the corewire (112, Fig. 1A; second resilient element 112 is secured to the corewire 106 at or near the distal end of the device, para [0062]). Groups I-V share no further features with each other.

Accordingly, the inventions listed as Groups I-V above lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature providing contribution over prior art.