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Published:
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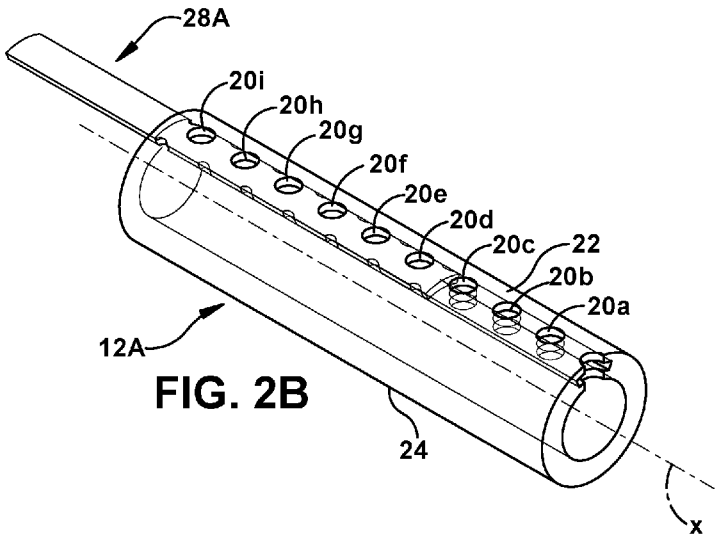


FIG. 2B

(57) Abstract: Systems and method for peripheral cannulation are provided. Systems include cannulas defining fenestrations that can be exposed or occluded by a cover slip to selectively expose fenestrations to blood flow in an artery or vein.

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SYSTEMS AND METHODS FOR PERIPHERAL VASCULAR CANNULATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Application No. 62/407,766, filed on October 13, 2016, the entirety of which is incorporated by reference herein.

TECHNICAL FIELD

[0002] The present invention relates to systems and methods for peripheral arterial and venous cannulation.

BACKGROUND

[0003] Percutaneous arterial and venous cannulation is used in a wide variety of medical procedures. For example, peripheral arterial and venous cannulation is often required for short, intermediate and long term circulatory support in patients with cardiopulmonary compromise. Extracorporeal Membrane Oxygenation (ECMO) is a form of partial cardiopulmonary bypass used for long-term support of respiratory and/or cardiac function. ECMO is primarily indicated for patients with such severe ventilation and/or oxygenation problems that they are unlikely to survive conventional mechanical ventilation. ECMO often involves shunting blood around the heart and lungs through an extracorporeal blood circuit and membrane oxygenator. Roller or centrifugal heart-lung bypass pumps are used to circulate blood through the ECMO circuit. Treatment courses can be as short as a few days or as long as a month or more.

[0004] There are different forms of ECMO such as venoarterial (VA), venovenous (VV) and arterio-venous (AV). VA ECMO takes deoxygenated blood from a central vein or the right atrium, pumps it past the oxygenator, and then returns the oxygenated blood, under pressure, to the arterial side of the circulation (typically to the aorta). This form of ECMO partially supports the cardiac output as the flow through the ECMO circuit is in addition to the normal cardiac output. Typically, patients with cardiac insufficiency require VA-ECMO. In the case of VA ECMO, an approximately 20F (6-7 mm internal diameter) arterial cannula is placed in the femoral artery, for example, but such arteries are typically much smaller, particularly in children or other smaller patients.

[0005] VV-ECMO takes blood from a large vein and returns oxygenated blood back to a large vein. Typically patient with respiratory insufficiency not amendable to ventilator support require VV-ECMO. In VV ECMO, either two large cannulas are placed in two separate extremity veins or a single dual lumen cannula is placed in one extremity. These cannulas remove blood from central circulation and return oxygenated blood to the right atrium. Often a 31F (10mm internal diameter) cannula is placed in the internal jugular vein or the subclavian vein.

[0006] Due to the large size of the cannulas used in ECMO, the venous drainage in the extremity or head and neck region where a cannula is placed is significantly impaired. Many patients develop venous stasis, thrombosis, and edema in the extremity. Intracranial venous hypertension has been well described in the case of internal jugular vein cannulation, especially in children. On the arterial side, if a femoral artery is cannulated, the blood is often returned into the abdominal aorta and there is no perfusion to the leg on the side of cannulation. This can lead to drastic ischemic complications. Presently, if arterial cannulation is required for more than a few hours, a second smaller cannula is placed in the femoral artery for antegrade perfusion.

[0007] Accordingly, a need exists for a cannula that provides adequate proximal venous drainage and distal arterial perfusion during peripheral cannulation procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is flow chart depicting components of a system according to an embodiment of the present disclosure.

[0009] FIG. 2A is an exploded view of a cannula with a coverslip inserted into a channel thereof according to an embodiment of the present disclosure.

[0010] FIG. 2B is a perspective view of the cannula of FIG. 2A with the coverslip of FIG. 2B inserted into a channel of the cannula.

[0011] FIG. 3 is a perspective view of a cannula with a cover slip inserted into a channel thereof according to another embodiment of the present disclosure.

[0012] FIG. 4 is a flow chart depicting steps of a method of using an embodiment of a system of the present disclosure in a cannulation procedure.

[0013] FIG. 5A-5C is a schematic illustration of a cover slip being retrieved proximally from a blood vessel to expose the blood vessel to fenestrations of an inner wall of a

cannula according to an embodiment of the present disclosure.

SUMMARY

[0014] The present disclosure relates to systems and methods of vascular cannulation. A system can include a cannula, a cover slip, a medical device, and a connector. In an embodiment, a system comprises a cannula that has a longitudinal axis and comprises an outer wall and an inner wall that defines a lumen. Fenestrations are located along the longitudinal axis, extend through the outer and inner wall, and are in fluid communication with the lumen. The cannula also includes a channel that extends along the longitudinal axis between the inner and outer walls and that is aligned with the fenestrations. The system further includes a cover slip that is slidable within the channel and sized and shaped to occlude the fenestrations. The system also includes a medical device that processes blood and a connector sized and shaped to connect the medical device to the cannula.

[0015] In another embodiment, a system comprises a cannula having a longitudinal axis. The cannula includes an outer tube and an inner tube defining a lumen. Fenestrations are located along the longitudinal axis, extend through the outer and inner tubes, and are in fluid communication with the lumen. A channel extends along the longitudinal axis between the outer and inner tubes and is aligned with the fenestrations. The system further includes a cover slip that is slidable within the channel and is sized and shaped to occlude the fenestrations. The system also includes a medical device that processes blood and a connector sized and shaped to connect the medical device to the cannula.

[0016] In another embodiment, a method that can be used in a cannulation procedure is provided. The method comprises obtaining a cannula having a longitudinal axis and a first and second portion. The cannula comprises an outer wall and an inner wall that defines a lumen. The cannula also includes fenestrations that are located along the longitudinal axis, extend through the outer and inner wall, and are in fluid communication with the lumen. The cannula further includes a channel extending along the longitudinal axis between the inner and outer wall and aligned with the fenestrations. The method further includes inserting the first portion of the cannula inside a peripheral artery or vein. The method also includes sliding a cover slip into the channel. The covers slip is sized and shaped to occlude the fenestrations. The method further includes retrieving proximally the cover slip to a

position such that the fenestrations of the first portion of the cannula are exposed to the peripheral artery or vein while the fenestrations of the second portion are occluded. The method includes connecting the cannula to a medical device that processes blood.

DETAILED DESCRIPTION

[0017] As used herein with respect to a described element, the terms "a," "an," and "the" include at least one or more of the described element unless otherwise indicated. Further, the term "or" and "and" refer to "and/or" unless otherwise indicated. In addition, it will be understood that when an element is referred to as being "over," "on," "attached" to, "connected" to, "coupled" with, "contacting," "in fluid communication with," etc., another element, it can be directly over, on, attached to, connected to, coupled with, contacting, or in fluid communication with the other element or intervening elements may also be present. In contrast, when an element is referred to as being "directly over," "directly on," "directly attached" to, "directly connected" to, "directly coupled" with, "directly contacting," or in "direct fluid communication" with another element, there are no intervening elements present. It will also be appreciated that references to an element that is disposed "adjacent" another element may have portions that overlap or underlie the adjacent element. As used herein, a "patient" is mammal such as, for example, a human being.

[0018] The present disclosure relates to systems and methods of vascular cannulation, such as peripheral vascular cannulation. Referring to FIG. 1, in certain aspects, system **10** is provided that includes cannula **12**, medical device that processes blood **16**, and connector **14** that is sized and shaped to attach cannula **12** to medical device **16**.

[0019] Referring to FIGs. 2A and 2B, in an embodiment, cannula **12A** comprises outer wall **14** and inner wall **16** that defines lumen **18**. Fenestrations **20** are located along longitudinal axis **X**, extend through outer wall **14** and inner wall **16**, and are in fluid communication with lumen **18**. The fenestrations can extend along the entire length of the cannula or a portion less than the entire length. In certain aspects, cannula **12** has first side **22** and opposing second side **24**. First side **22** defines fenestrations **20** and fenestrations **20** do not extend through second side **24** of cannula **12**. Cannula **12** further includes channel **26** that extends along longitudinal axis **X** between outer wall **14** and inner wall **16** and that is aligned with fenestrations

20. In another embodiment, the cannula has an inner tube and a concentric outer tube. For example, referring to FIG. 3, cannula **12B** has an inner tube **34** defining lumen **36** and outer tube **38** disposed about inner tube **32.** Fenestrations **40** are located along longitudinal axis **X** and are in fluid communication with lumen **36**. Cannula **12B** further includes channel **42** that extends along longitudinal axis **X** between outer tube **38** and inner tube **34** and that is aligned with fenestrations **40**.

[0020] In either embodiment, the system further a cover slip **28** slidable within channel **26** of cannula **12** (cover slip **28A**) or channel **42** of cannula **12B** (coverslip **28B**) and sized and shaped to occlude fenestrations **20** and **40** of cannulas **12A** and **12B** respectively. In certain embodiments, the cover slip can have an inner lumen that can receives tubing or other devices that may be used in the medical procedure for which the cannula is used. The cover slip can also include guides to ensure the cover slip is in the proper position in the channel of the cannula. For example, as shown in FIGs. 2A and 2B, cover slip **28A** can include guides at a portion thereof, such as distal portion to ensure cover slip **28A** is in the correct position in relation to the other components of the cannula such as the fenestrations of the cannula. FIG. 2 illustrates cover slip **28A** having detent notches **30** but other types of guides can be used that ensure the cover slip is in the correct position. A cover slip can also include fenestrations that are aligned with the fenestrations of the inner wall or inner tube.

[0021] System **10** also includes medical device that processes blood **16**. A medical device that processes blood is a medical device that stores, analyzes, samples, collects, pumps, inflows, outflows, or transmits therapeutic agents to blood of a patient. Non-limiting examples of medical devices that process blood include hemodynamic monitoring devices and extracorporeal support (ECS) circuits. ECS circuits include ECMO circuits such as VV-ECMO, VA-ECMO and AV-ECMO circuits. The ECS circuit can also be a cardiopulmonary bypass machine.

[0022] System **10** further includes connector **14** sized and shaped to connect medical device **16** to cannula **12**. Non-limiting examples of connectors include luer-type fittings, clamps, adhesives, clips, or various types of male-female fasteners.

[0023] Certain aspects of the present disclosure provide a method that can be used during a peripheral cannulation procedure such as, for example, an ECMO or cardiopulmonary bypass procedure. Referring to FIG. 4, method **40** includes obtaining a cannula, as described above, having a first portion and a second portion

(step **42**). For example, in an embodiment, the cannula has an outer wall and an inner wall that defines a lumen. Fenestrations extend along the length of the cannula. The fenestrations are in fluid communication with the lumen of the inner wall. The cannula has a channel that extends along the longitudinal axis between the inner and outer wall and that is aligned with the fenestrations of the cannula. The method further includes inserting the first portion of the cannula inside a peripheral artery or vein (step **44**) and positioning the second portion of the cannula outside of the peripheral artery or vein (step **46**). The method includes sliding a cover slip into the channel of the cannula (step **48**). The cover slip is sized and shaped to occlude the fenestrations of the cannula. The method also includes retrieving proximally the cover slip to a position such that the fenestrations of the first portion of the cannula are exposed to the peripheral artery or vein while the fenestrations of the second portion are occluded (step **50**). The method also includes connecting the cannula to a medical device that processes blood (step **52**).

[0024] As schematically shown in FIG. 5A-5C, in use, cover slip **42** can be retrieved proximally to expose any number of fenestrations **44** of cannula **46** to the artery or vein **51**. Since the depth of cannula insertion is different for every patient, the operator can retrieve the cover slip back to the level of insertion into the vessel such that the fenestrations inside the vessel are open while those outside the vessel remain occluded. In embodiments where one side of the inner tube defines the fenestrations, the cover slip can be retrieved back to open any number of fenestrations to the blood vessel lumen towards the side that is being blocked by the cannula itself. In the case of peripheral venous cannulation, features of a cannula as described herein allow drainage of venous blood from the extremity into the cannula and thus into the medical device, such as an ECS circuit. In the case of peripheral arterial cannulation, such features allow perfusion of the artery and extremity distal to the cannulation site as indicated by the arrows.

[0025] Cannulas and methods as disclosed herein can eliminate steps in certain cannulation procedures. For example, if a femoral artery is cannulated and the cannula needs to remain in the artery for more than a couple of hours, a second smaller cannula is placed for antegrade perfusion to prevent ischemic complications. With cannulas as disclosed herein, only one cannula is necessary in the femoral artery as the cover slip and fenestrations allow access to the vessel lumen on the side being blocked by the cannula. Such cannulas can be smaller than those

currently used to achieve the same degree of drainage, decreasing vascular complication rates as well as preventing ischemia without inserting a second reperfusion cannula. Further, the fenestrations of cannulas as disclosed herein provide flexibility regarding the distance the cannula is inserted in the blood vessel. Cannulas as described herein address the problem of inadequate venous drainage at the site of venous cannulation and inadequate antegrade perfusion at the site of arterial cannulation. Such cannulas can prevent stasis, venous thrombosis, improves blood flow and prevent ischemia (without necessarily inserting a second reperfusion cannula). Cannulas as described herein also can be used for longer term and can be smaller than current cannulas to achieve the same degree of drawing, which can decrease vascular complication rates.

[0026] Cannulas as disclosed herein can be used for several different indications. As mentioned above, cannulas can be used for ECMO, cardiopulmonary bypass procedures and other cardiovascular perfusion procedures. Cannulas as disclosed herein can also be used during organ transplant procedures, such as lung transplant procedures. Cannulas can be used for the adult population as well as the pediatric population. Depending on the indication and patient, the cannulas can be implanted for different periods of times and have different sizes. For example, if implanted into the neck, a cannula can be about 50 centimeters (cm). If implanted in the groin, the cannula can be about 100 cm. If used for ECMO, a cannula can be implanted for up to 100 days and for cardiopulmonary bypass cannulation approximately 3 to 4 hours. In terms of sizes, for pediatric procedures, the cannula can have a size of approximately 8 Fr. Such indications and sizes are exemplary and cannulas as disclosed herein can be used for other suitable indications and have other configurations.

[0027] Each of the disclosed aspects and embodiments of the present disclosure may be considered individually or in combination with other aspects, embodiments, and variations of the present disclosure. Further, while certain features of embodiments of the present disclosure may be shown in only certain figures, such features can be incorporated into other embodiments shown in other figures while remaining within the scope of the present disclosure. In addition, unless otherwise specified, none of the steps of the methods of the present disclosure are confined to any particular order of performance.

What is claimed is:

1. A system comprising:

a cannula having a longitudinal axis and comprising:

an outer wall;

an inner wall defining a lumen;

fenestrations located along the longitudinal axis, extending through the outer and inner wall, and in fluid communication with the lumen; and

a channel extending along the longitudinal axis between the outer and inner wall and aligned with the fenestrations;

a cover slip slidable within the channel and sized and shaped to occlude the fenestrations;

a medical device that processes blood; and

a connector sized and shaped to connect the medical device to the cannula.

2. The system of claim 1, wherein the cannula has a first side and an opposing second side, the first side defining the fenestrations, the fenestrations not extending through the second side of the cannula.

3. The system of claim 1, wherein the cover slip comprises a guide at a portion thereof.

4. The system of claim 3, wherein the guide is a dented notch.

5. The system of claim 1, wherein the medical device is a hemodynamic monitoring device.

6. The system of claim 1, wherein the medical device is an extracorporeal support (ECS) circuit.

7. The system of claim 6, wherein the ECS circuit is an extracorporeal membrane oxygenation circuit (ECMO) circuit.

8. The system of claim 7, wherein the ECMO circuit is a veno-venous ECMO (VV-ECMO) circuit, a veno-arterial ECMO (VA-ECMO) or an arterio-venous (AV-ECMO) circuit.

9. The system of claim 6, wherein the ECS circuit is a cardiopulmonary bypass machine.

10. A system comprising:

a cannula having a longitudinal axis and comprising:

an outer tube;

an inner tube defining a lumen;

fenestrations located along the longitudinal axis, extending through the outer and inner tube, and in fluid communication with the lumen; and

a channel extending along the longitudinal axis between the outer and inner tubes and aligned with the fenestrations;

a cover slip slidable within the channel and sized and shaped to occlude the fenestrations;

a medical device that processes blood; and

a connector size and shaped to connect the medical device to the cannula.

11. The system of claim 10, wherein the cannula has a first side and an opposing second side, the first side defining the fenestrations, the fenestrations not extending through the second side of the cannula.

12. The system of claim 10, wherein the medical device is a hemodynamic monitoring device.

13. The system of claim 10, wherein the medical device is an extracorporeal support (ECS) circuit.

14. The system of claim 10, wherein the ECS circuit is a cardiopulmonary bypass machine.

15. A method comprising:

obtaining a cannula having a longitudinal axis and a first and second portion, the cannula comprising:

an outer wall;

an inner wall defining a lumen;

fenestrations located along the longitudinal axis, extending through the outer and inner wall, and in fluid communication with the lumen; and

a channel extending along the longitudinal axis between the outer and inner wall and aligned with the fenestrations;

inserting the first portion of the cannula inside a peripheral artery or vein;

positioning the second portion of the cannula outside of the peripheral artery or vein;

sliding a cover slip into the channel, the cover slip sized and shaped to occlude the fenestrations;

retrieving proximally the cover slip to a position such that the fenestrations of the first portion of the cannula are exposed to the peripheral artery or vein while the fenestrations of the second portion are occluded; and

connecting the cannula to a medical device that processes blood.

16. The method of claim 15, wherein positioning the second portion of the cannula outside of the peripheral artery or vein is positioning the second portion at the level of insertion into the peripheral artery or vein.

17. The method of claim 15, wherein the medical device is a hemodynamic monitoring device.

18. The method of claim 15, wherein the medical device is an ECS circuit.

19. The method of claim 18, wherein the ECS circuit is an ECMO circuit.

20. The method of claim 18, wherein the ECS circuit is a cardiopulmonary bypass machine.

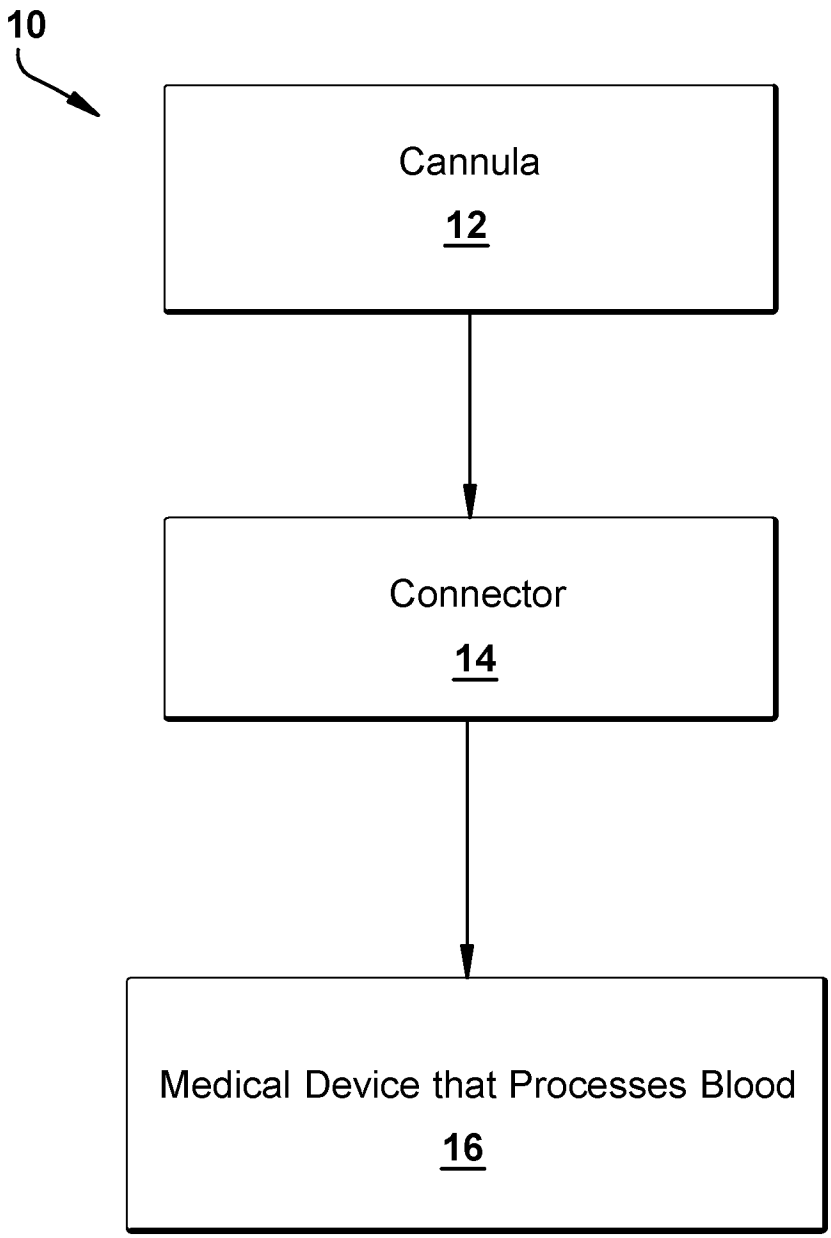

10
Cannula
12
Connector
14
Medical Device that Processes Blood
16

FIG. 1

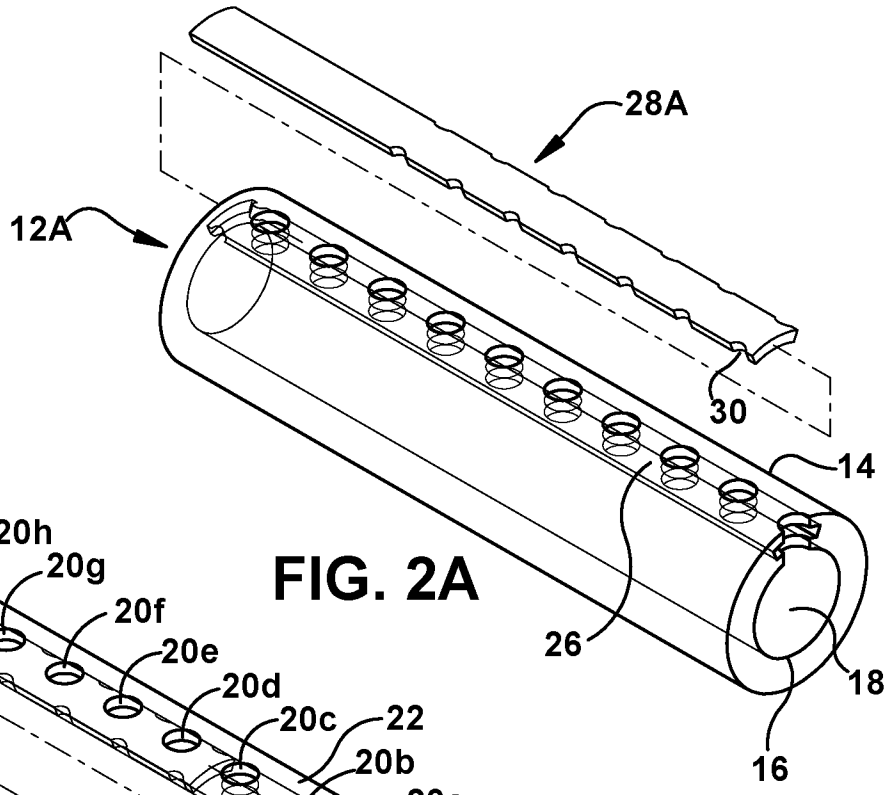


FIG. 2A

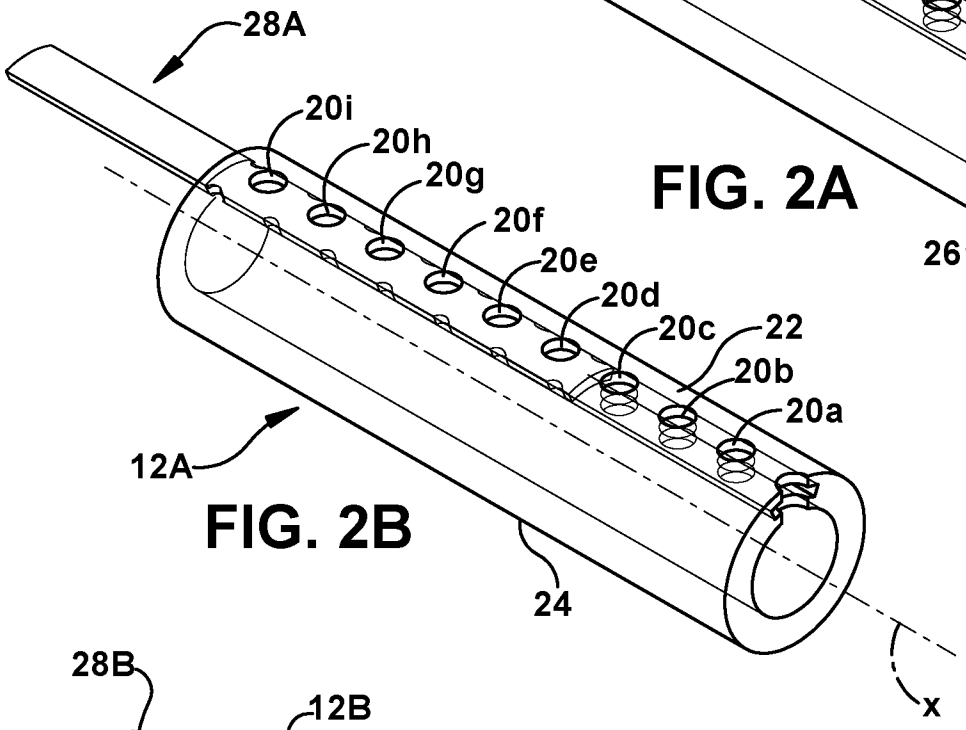


FIG. 2B

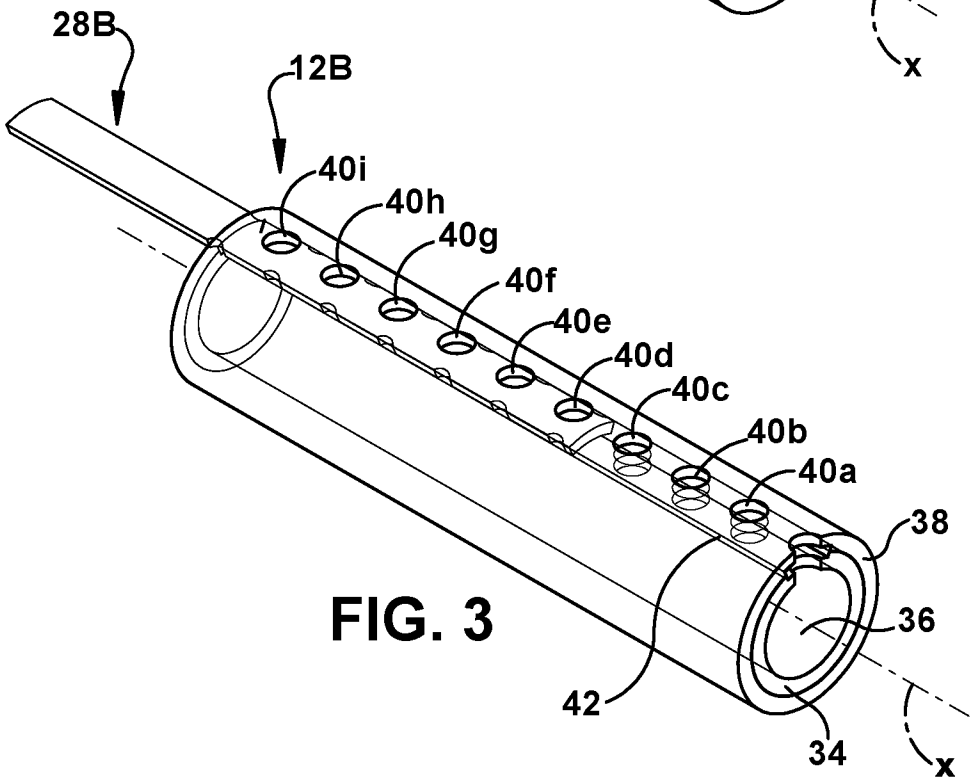


FIG. 3

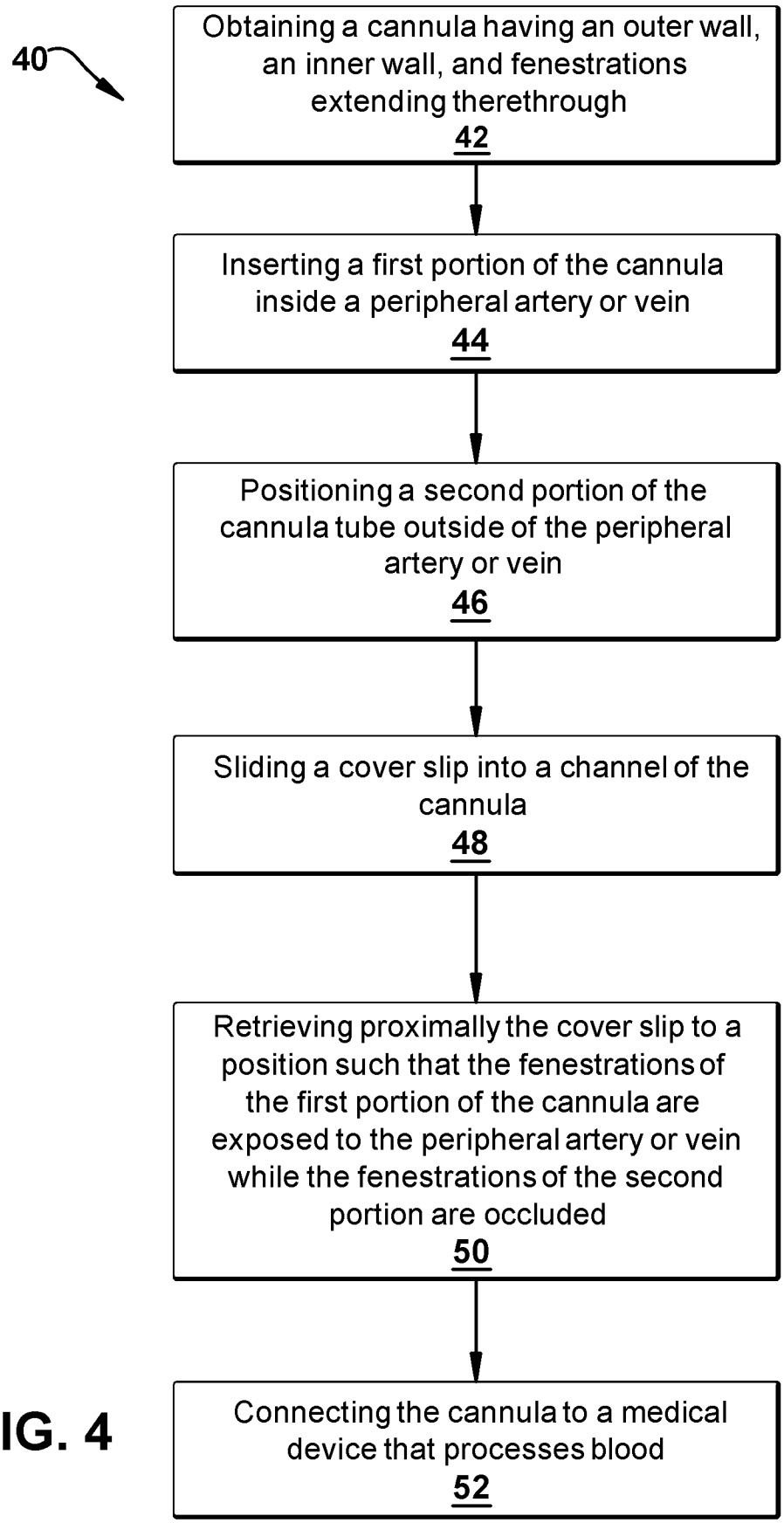

40
Obtaining a cannula having an outer wall, an inner wall, and fenestrations extending therethrough
42
Inserting a first portion of the cannula inside a peripheral artery or vein
44
Positioning a second portion of the cannula tube outside of the peripheral artery or vein
46
Sliding a cover slip into a channel of the cannula
48
Retrieving proximally the cover slip to a position such that the fenestrations of the first portion of the cannula are exposed to the peripheral artery or vein while the fenestrations of the second portion are occluded
50
Connecting the cannula to a medical device that processes blood
52

FIG. 4

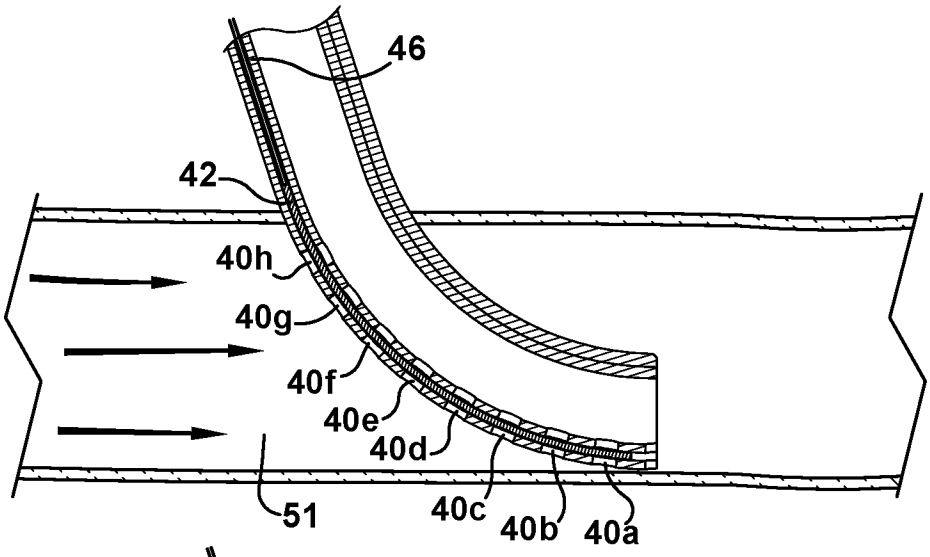


FIG. 5A

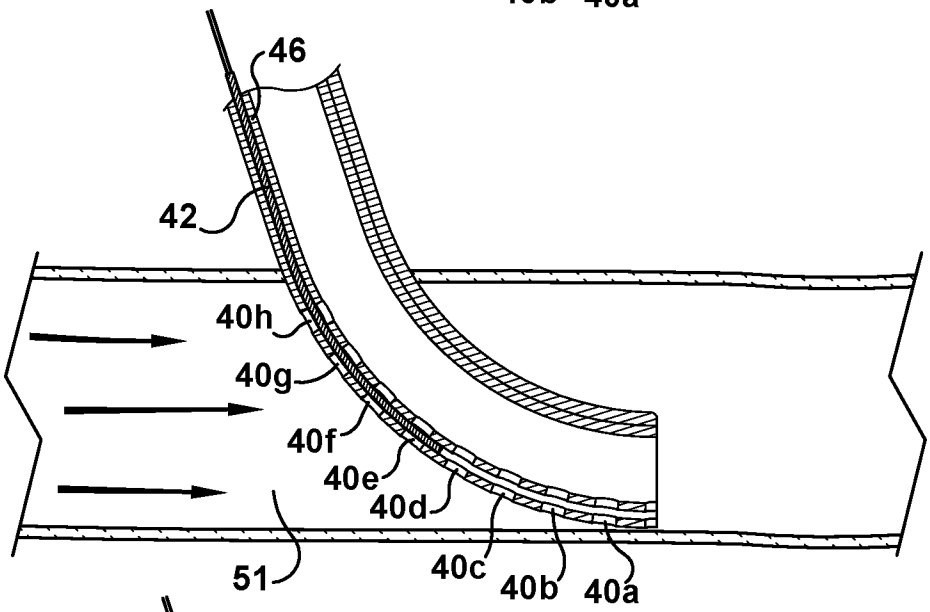


FIG. 5B

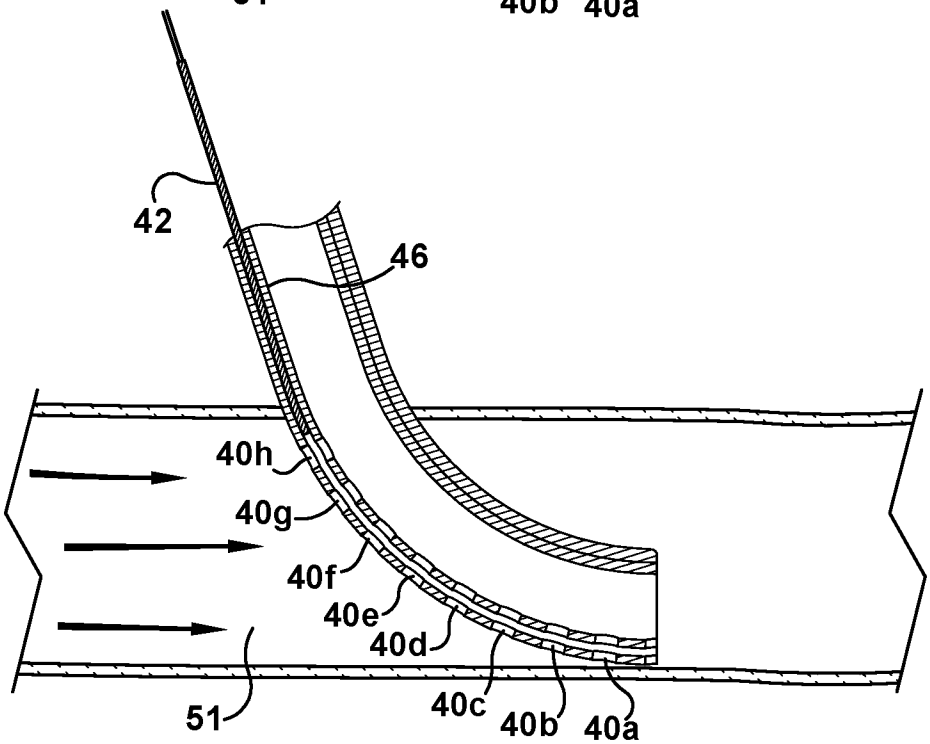


FIG. 5C

INTERNATIONAL SEARCH REPORT

WO 2018/071254

International application No
PCT/UPCT/US2017/055228

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/36 A61M25/00
ADD.

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)
A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 643 712 A (KULIK YAROSLAV P [SU] ET AL) 17 February 1987 (1987-02-17) abstract; figures column 3, lines 10-66	1-14
A	FR 2 964 877 A1 (RAHIL MOHAMED AMINE [FR]) 23 March 2012 (2012-03-23) abstract; figures page 1, line 38 - page 2, line 39	1-14
A	US 2014/276331 A1 (BIAN XIAOMING [CN] ET AL) 18 September 2014 (2014-09-18) abstract; figures paragraphs [0014] - [0019]	1-14

☐ 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

"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

Date of the actual completion of the international search	Date of mailing of the international search report
13 December 2017	19/12/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kaden, Malte

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/055228

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. [X] Claims Nos.: 15-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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.:
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:

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 an 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.:

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/055228

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