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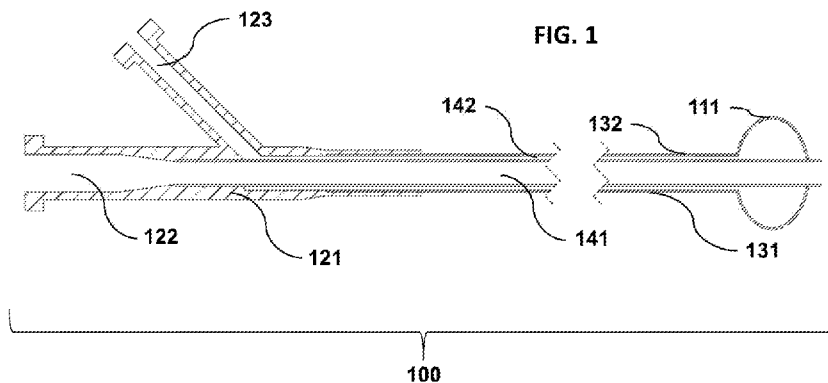
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(54) Title: A METHOD FOR REMOVING FREE FLOATING NON-THERAPEUTIC DRUG PARTICLES RELEASED FROM A DRUG COATED BALLOON CATHETER



(57) Abstract: A method for removing free floating non-therapeutic drug particles released from a drug coated balloon catheter is disclosed.



A METHOD FOR REMOVING FREE FLOATING NON-THERAPEUTIC DRUG PARTICLES RELEASED FROM A DRUG COATED BALLOON CATHETER

Description

FIELD OF THE INVENTION

This invention relates generally to balloon aspiration catheters and drug coated balloon catheters. More specifically, the invention relates to the use of a balloon aspiration catheter to remove free floating non-therapeutic drug particles released from drug coated balloon catheters during treatment in order to mitigate any negative effect these drug particles poses.

BACKGROUND OF THE INVENTION

A meta-analysis published on 6 Dec 2018 in the Journal of the American Heart Association concluded that “There is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs. Further investigations are urgently warranted.” [1]

Although the exact mechanism for the increased mortality rate is not yet known, it is known that paclitaxel for chemotherapy is solvent-based and has a half-life of about six hours, the paclitaxel on medical devices has a half-life of weeks to months. Also, studies have shown that for drug coated balloons, only a small portion of drug is transferred to the vessel walls, while the majority will be released into the bloodstream. The drug transferred to the vessel walls adheres to the vessel walls and aids in preventing restenosis, thus in this article they will henceforth be referred to as therapeutic drug. The drug released into the bloodstream floats around freely as particles and does not aid in preventing restenosis, thus in this article they will be henceforth be referred to as free floating non-therapeutic drug particles.

After studying drug coated balloon catheters in an artificial vascular model, three occasions where the majority of free floating non-therapeutic drug particles are released into the blood stream were identified. The three occasions are during the process of a) tracking the drug coated balloon to a target site; b) inflating and deflating the drug coated balloon to treat a target lesion; c) retrieving the drug coated balloon through the introducer.

a) In the patent “Drug delivery balloon catheter - WO2019009809A1” it was mentioned that during the tracking process, the drug coating on the balloon will be dislodged from the balloon if the drug coated balloon is tracked to the lesion without any form of protection. This dislodgement is caused by the physical contact between the drug coating with the vessel walls and blood. The method described to overcome this issue was to use a protective sheath to protect the drug coating before the drug can reach the target site. Doing so will not only reduce the amount of free floating non-therapeutic drug particles released but also

1. Katsanos, K., Spiliopoulos, S., Kitrou, P., Krokidis, M., & Karnabatidis, D. (2018). Risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg: A systematic review and meta-analysis of randomized controlled trials. *Journal of the American Heart Association*, 7(24), e011245.

increase the amount of drug available on the balloon to transfer to the target lesion, thus, improving the efficacy of the treatment.

- b) When inflating and deflating the drug coated balloon for treatment, the drug coating on the balloon is subjected to a myriad of forces in an attempt to dislodge the drug from the balloon to transfer as much of the drug as possible to the vessel walls. However, in most cases, only a small portion of the dislodged drug will be transferred to the vessel walls as therapeutic drug while the majority of will end up as free floating non-therapeutic drug particles.
- c) To retrieve the drug coated balloon catheter from the patient, the deflated balloon will have to pass through the device used to provide access to the vessel, i.e. an introducer. After inflation and deflation has been performed in the balloon, the deflated balloon will generally have a larger profile. The larger profile is generally larger than the distal opening of the introducer. Therefore, when the deflated balloon is pulled through the introducer, the balloon will scrape against the distal opening of the introducer, leading to the majority of the drug remaining on the balloon to be dislodged as free floating non-therapeutic drug particles.

By removing free floating non-therapeutic drug particles from the body, the total amount of drug introduced into the patient will be significantly reduced, since only the therapeutic drug remains. It is believed that in doing so, the risks such as embolization, mortality, or any other risks associated with free floating non-therapeutic drug particles released from the drug coated balloon during the angioplasty procedure will be reduced.

Aspiration is a common method used to remove particles from the within vessels. Such methods that use an aspiration catheter are described in "Methods for Reducing Distal Embolization", Imran, U.S. Patent Publication 20030055398 published Mar. 20, 2003. The removal of particles through aspiration can be improved by first occluding flow within the vessel to prevent the particles generated from being immediately carried away by flowing blood. A specific example of how an occlusion can be used to improve the efficacy of aspiration to capture particles is described by Rauker and others in "Occlusion Device", U.S. Pat. No. 6,475,185 issued Nov. 5, 2002. The occlusion device includes an elongated tubular shaft having an inflatable balloon disposed near the elongate shaft distal end with a proximal seal of a sufficiently small profile to allow a second catheter to pass over the distal occlusion device while the inflatable balloon remains uninflated. One occlusion device includes an elongated fluid displacement rod within the elongated shaft of the occlusion device, providing both a fluid pressure source and a seal.

Although various systems and methods to remove particles have been described, they mainly focus on the removal of particles generated from the vessel itself in an attempt to prevent distal embolization. Examples include the removal of particles generated from a stenosed lesion during angioplasty using a plain old balloon catheter, stenting or atherectomy. Both the physical properties as well as the source of the aforementioned particles are vastly different from that of free floating non-therapeutic drug particles released from drug coated balloon catheters. Therefore, there is a need for systems and methods tailored to remove free floating non-therapeutic drug particles released from drug coated balloon catheters to reduce the risk posed

by free floating non-therapeutic drug particles such as increased mortality, while at least retaining the efficacy of the drug coated balloon catheter treatment.

SUMMARY OF THE INVENTION

The present invention provides a balloon aspiration catheter and the associated systems and methods to remove free floating non-therapeutic drug particles released from a drug coated balloon catheter

A preferred variation of the inventive balloon aspiration catheter is made up of an inner elongate tubular member having an inner surface, a proximal end, and a distal end. The interior surface of the inner elongate member forms the large lumen in which a drug coated balloon catheter can be tracked through and where aspiration is performed. In this preferred variation, a balloon, preferably but not necessarily compliant, is located at the distal end and is connected to at least one fluid supply lumen that is independent of the large lumen. An outer elongate tubular member that is substantially concentric with the inner elongate tubular member forms an annular lumen between the two for supplying fluid to the balloon. The inner elongate tubular member generally contains a stiffener member situated in its wall to provide kink resistance to the balloon aspiration catheter. The stiffener member may be a coil or a braid. Ancillary features, e.g., radio-opaque marker bands distal of said inflatable member and fluid fittings, are included.

Although the inventive balloon aspiration catheter may be independent from the drug coated balloon catheter, they may be incorporated into one or more devices or kits.

For instance, a device or kit might contain, e.g., a balloon aspiration catheter described above; and a drug coated balloon.

Another desirable device or kit includes a balloon aspiration catheter described above; a protective sheath i.e. a guiding catheter; and a drug coated balloon catheter;

Another desirable device or kit includes a balloon aspiration catheter described above; and a device in which the drug coated balloon catheter is protected by a sheath;

The balloon aspiration catheter is used to remove free floating non-therapeutic drug particles released from drug coated balloon catheters from a vascular lumen, e.g., in sites as varied as the periphery, or the coronary vessels, by the steps of first tracking the balloon aspiration catheter through the vessel until distal end of the balloon aspiration catheter is positioned proximal to a lesion. The inflation of the balloon on the balloon aspiration catheter is next carried out to occlude antegrade flow in the vessel. After occlusion, the drug coated balloon catheter is then tracked through the large lumen of the balloon aspiration catheter and until the drug coated

balloon is positioned at the target lesion. The tracking of the drug coated balloon through the large lumen of the balloon aspiration catheter to position it the target lesion can cause the release of drug from the drug coating but since antegrade flow has been occluded, the dislodged drug will not flow distally. Treatment of the lesion is then done according to the instructions provided by the drug coated balloon catheter's supplier. The drug coated balloon catheter is then withdrawn from the balloon aspiration catheter and aspiration through the large lumen of the balloon aspiration catheter is conducted to remove the free floating non-therapeutic drug particles released from the drug coated balloon catheter. Finally, the balloon on the balloon aspiration catheter is deflated and the balloon aspiration catheter withdrawn. In this method, aspiration through the large lumen of the balloon aspiration catheter can also be conducted after deflation of the drug coated balloon catheter, prior to its removal. In this method, the drug coated balloon catheter can be a kit or a device which a drug coated balloon catheter is protected by a protective sheath similar but not limited to the one stated in "Drug delivery balloon catheter - WO2019009809A1". The use of said kit or device will allow the drug coating to be completely protected during tracking.

Another aspect of the method comprises first pre-loading the drug coated balloon catheter into the large lumen of the balloon aspiration catheter. The pre-loading step consists of inserting the distal end of the drug coated balloon catheter through the proximal end of the large lumen of the balloon aspiration catheter. The drug coated balloon catheter is then pushed through the large lumen of the balloon aspiration catheter until the distal end of the drug coated balloon catheter is close to the distal end of the balloon aspiration catheter. Said unit of the balloon aspiration catheter and drug coated balloon catheter is then tracked through the vessel and finally positioned such that the drug coated balloon is at a lesion to be treated. While maintaining the position of the drug coated balloon catheter, the balloon aspiration catheter is shifted proximally relative to the drug coated balloon to expose the drug coated balloon. By keeping the balloon aspiration catheter and drug coated balloon catheter as a unit until the drug coated balloon is positioned at the target lesion, the balloon aspiration catheter is able to act as a protective sheath. The inflation of the balloon on the balloon aspiration catheter is then carried out to occlude antegrade flow in the vessel. Treatment of the lesion is then done according to the instructions provided by the drug coated balloon catheter's supplier. The drug coated balloon catheter is then withdrawn from the balloon aspiration catheter. Aspiration through the large lumen of the balloon aspiration catheter is then conducted to remove the free floating non-therapeutic drug particles released from the drug coated balloon catheter. Finally, the balloon on the balloon aspiration catheter is deflated and the balloon aspiration catheter withdrawn. In this method, aspiration through the large lumen of the balloon aspiration catheter can be conducted after deflation of the drug coated balloon catheter, prior to its removal.

Another aspect of the method comprises first pre-loading the drug coated balloon catheter into the large lumen of the balloon aspiration catheter. The pre-loading step consists of inserting the distal end of the drug coated balloon catheter through the proximal end of the large lumen of the balloon aspiration catheter, the drug coated balloon catheter is then pushed through the large lumen of the balloon aspiration catheter until the distal end of the drug coated balloon catheter is close to the distal end of the balloon aspiration catheter. Said unit of the balloon aspiration catheter and drug coated balloon is then tracked through the vessel and finally positioned such that the distal end of the balloon aspiration catheter is proximal to the lesion. By keeping the

balloon aspiration catheter and drug coated balloon catheter as a unit for the majority of the tracking process, the balloon aspiration catheter is able to act as a protective sheath during the majority of the tracking process. The inflation of the balloon on the balloon aspiration catheter is then carried out to occlude antegrade flow in the vessel before the drug coated balloon catheter is shifted distally relative to the balloon aspiration catheter to expose the drug coated balloon and until the drug coated balloon is positioned at the target lesion. The tracking of the drug coated balloon outside the balloon aspiration catheter to position it the target lesion can cause the dislodgement of drug from the drug coating but since antegrade flow has been occluded, the dislodged drug will not flow distally. Treatment of the lesion is then done according to the instructions provided by the drug coated balloon catheter's supplier. The drug coated balloon catheter is then withdrawn from the balloon aspiration catheter. Aspiration through the large lumen of the balloon aspiration catheter is then conducted to remove the free floating non-therapeutic drug particles released from the drug coated balloon catheter. Finally, the balloon on the balloon aspiration catheter is deflated and the balloon aspiration catheter withdrawn. In this method, aspiration through the large lumen of the balloon aspiration catheter can be conducted after deflation of the drug coated balloon catheter, prior to its removal. In this method, the drug coated balloon catheter can be a kit or a device which a drug coated balloon catheter is protected by a protective sheath similar but not limited to the one stated in "Drug delivery balloon catheter - WO2019009809A1". The use of said kit or device will allow the drug coating to be completely protected during tracking.

Another aspect of the method comprises first pre-assembling a drug coated balloon catheter, a protective sheath, and a balloon aspiration catheter into one unit. The pre-assembly consists of first inserting the distal end of the drug coated balloon catheter through the proximal end of the protective sheath until the distal end of the drug coated balloon catheter is close to the distal end of the protective sheath. Next, said unit of drug coated balloon catheter and protective sheath is inserted through the proximal end of the large lumen of the balloon aspiration catheter via its distal end and pushed through the large lumen of the balloon aspiration catheter until the proximal end of the drug coated balloon is distal to the distal end of the balloon aspiration catheter. Said unit of the balloon aspiration catheter, protective sheath and drug coated balloon is then tracked through the vessel and finally positioned such that the drug coated balloon catheter is at a lesion to be treated before the inflation of the balloon on the balloon aspiration catheter is carried out to occlude antegrade flow in the vessel. While maintaining the position of the drug coated balloon catheter, the protective sheath is pulled back to exposed the drug coated balloon. Treatment of the lesion is then done according to the instructions provided by the drug coated balloon catheter's supplier and the drug coated balloon catheter and protective sheath is withdrawn from the balloon aspiration catheter as a unit. Aspiration through the large lumen of the balloon aspiration catheter is then conducted to remove the free floating non-therapeutic drug particles released from the drug coated balloon catheter. Finally, the balloon on the balloon aspiration catheter is deflated and the balloon aspiration catheter withdrawn. In this method, aspiration through the large lumen of the balloon aspiration catheter can also be conducted after deflation of the drug coated balloon catheter, prior to its removal. In this method, the drug coated balloon catheter and protective sheath can be a kit or a device. In this method, the drug coated balloon, protective sheath, and balloon aspiration catheter can be incorporated into a single device.

The present invention is illustrated by the accompanying drawings of various embodiments and the detailed description given below. The drawings should not be taken to limit the invention to the specific embodiments, but are for explanation and understanding. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof. The foregoing aspects and other attendant advantages of the present invention will become more readily appreciated by the detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention are illustrated by the accompanying figures, wherein:

FIG. 1 is a longitudinal cross-sectional view of a balloon aspiration catheter having a central lumen and an occlusion balloon;

FIG. 2 shows one method for using a balloon aspiration catheter to remove free floating non-therapeutic drug particles released from a drug coated balloon catheter

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, there is depicted an embodiment of the balloon aspiration catheter of the present invention. Although depicted and described as a two lumen catheter, it should be appreciated that the present invention may also be adapted to catheters having more than two lumen. The manner of adapting the present invention to these various treatments and structures will become readily apparent to those of skill in the art in view of the description which follows.

FIG. 1 shows a balloon aspiration catheter **100** for removal of free floating non-therapeutic drug particles **212**.

The balloon aspiration catheter **100** generally comprises a balloon **111** with a distal and proximal end, a hub **121**, an outer elongate tubular member **131** with a distal and proximal end, and an inner elongate tubular member **132** with a distal end proximal end. The balloon **111** is positioned at the distal end of the catheter **100**. The hub **121** is positioned at the proximal end of the catheter **100**. The distal end of the outer tubular member **131** is coupled to the proximal end of the balloon **111**, while the proximal end of the outer tubular member **131** is coupled to the hub **121**. The inner tubular member **132** is substantially concentric with the outer tubular member **131**. The distal end of the inner tubular member **132** is coupled to the distal end of the balloon **111**, while the proximal end of the inner tubular member **132** is coupled to the hub **121**.

The inner surface of the inner tubular member forms the large lumen **141**. The large lumen **141** is accessed from the working port **122** of the hub **121**. The large lumen **141** is used to track a drug coated balloon catheter **211** as well as for aspiration of the free floating non-therapeutic drug particles **212**. An inflation lumen **142** is formed between the inner surface of the outer elongate tubular member **131** and the outer surface of the inner elongate tubular member **132**. The inflation lumen **142** is independent of the large lumen **141** and is accessed from the inflation port **123** of the hub **121** and is in fluid communication with the balloon **111**. The inflation lumen **142** is used to control the inflation and deflation of the balloon **111**.

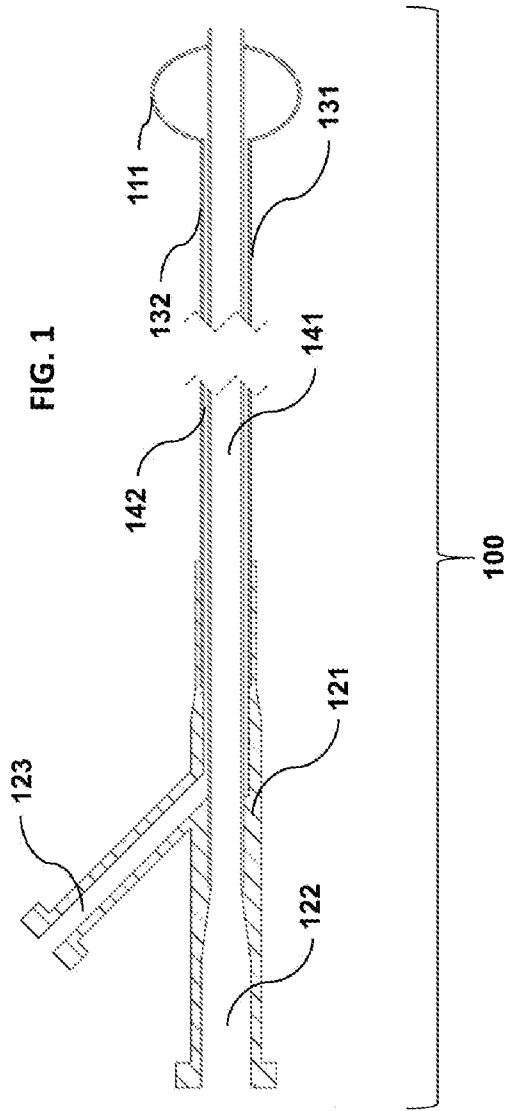
Referring to FIG. 2, there is depicted a method to use the balloon aspiration catheter of the present invention to remove free floating non-therapeutic drug particles released from drug coated balloon catheters. The specific method in FIG. 2 is not intended to limit the invention in any way. Additionally, to the extent that there are variations of the invention that are within the spirit of the disclosure and yet are equivalent to the inventions found in the claims, it is our intent that this patent cover those variations as well.

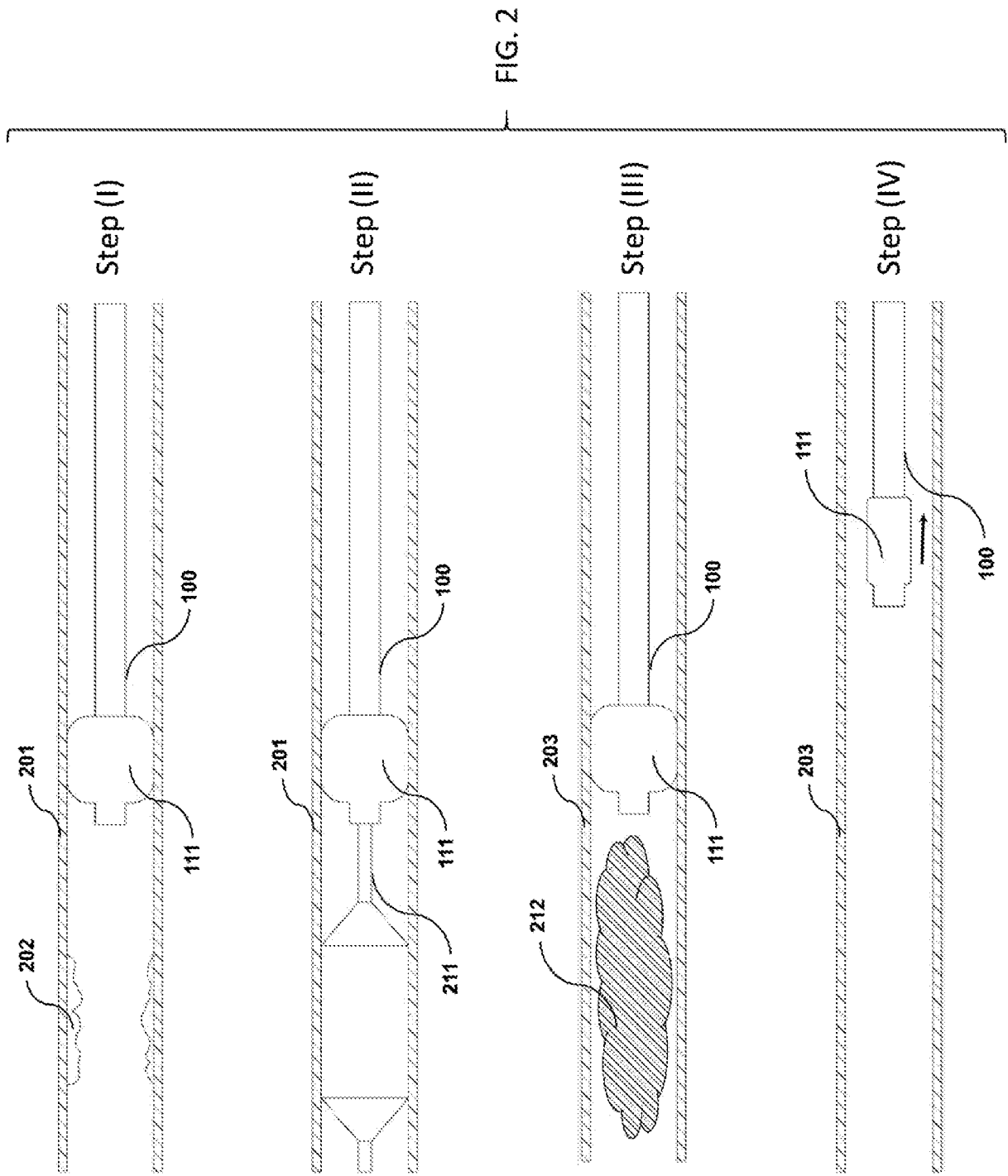
FIG. 2 shows a four-step method for utilizing the balloon aspiration catheter **100** in a vessel for removal of free floating non-therapeutic drug particles **212** released from a drug coated balloon catheter **211**.

In Step (I), the balloon aspiration catheter **100** is placed in the stenosed vessel **201**. The balloon **111** is then inflated close to a target lesion **202**. Inflation of balloon **111** prevents blood from carrying the free floating non-therapeutic drug particles close to a target lesion **202** distally which will prevent their removal. In Step (II), the drug coated balloon catheter **211** is advanced through the large lumen **141** to reach target lesion **202** and treatment of the target lesion **202** in the stenosed vessel **201** is conducted using the drug coated balloon catheter **211**. After treatment, the drug coated balloon catheter **211** is withdrawn from the treated vessel **203**, leaving behind the free floating non-therapeutic drug particles **212** released from the drug coated balloon catheter **211**. In Step (III), aspiration is carried out through the large lumen **141** to remove the free floating non-therapeutic drug particles **212** from the treated vessel **203**. In step (IV), the balloon **111** is deflated and the balloon aspiration catheter is withdrawn from the treated vessel **203**.

Claims

1. A method for removing free floating non-therapeutic drug particles released from a drug coated balloon catheter, comprising:
 - a. Providing a balloon aspiration catheter, the balloon aspiration catheter including a large lumen that runs through the entire length of the catheter and an occlusion balloon located at the distal end of the catheter
 - b. Providing a drug coated balloon catheter, the drug coated balloon catheter including an angioplasty balloon located at the distal end of the catheter, whereby a drug coating is on the surface of the angioplasty balloon
 - c. Introducing the balloon aspiration catheter into a blood vessel and positioning the occlusion balloon close to a target lesion
 - d. Advancing the drug coated balloon catheter through the large lumen and positioning the angioplasty balloon at the target lesion
 - e. Treating the target lesion with the drug coated balloon catheter, thereby releasing the drug coating
 - f. Aspirating through the large lumen to remove the free floating non-therapeutic drug particles
2. The method of claim 1, wherein the occlusion balloon is inflated to occlude the blood vessel before the angioplasty balloon is deflated
3. A method for removing free floating non-therapeutic drug particles released from a drug coated balloon catheter, comprising:
 - a. Providing a balloon aspiration catheter, the balloon aspiration catheter including a large lumen that runs through the entire length of the catheter and an occlusion balloon located at the distal end of the catheter
 - b. Providing a drug coated balloon catheter, the drug coated balloon catheter including an angioplasty balloon located at the distal end of the catheter, whereby a drug coating is on the surface of the angioplasty balloon
 - c. Introducing the drug coated balloon catheter into the large lumen until the angioplasty balloon is housed within the large lumen
 - d. Introducing the unit comprising the drug coated balloon catheter and the balloon aspiration catheter into a blood vessel
 - e. Positioning the angioplasty balloon and the occlusion balloon at the target lesion and close to the target lesion respectively
 - f. Treating the target lesion with the drug coated balloon catheter, thereby releasing the drug coating
 - g. Aspirating through the large lumen to remove the free floating non-therapeutic drug particles
4. The method of claim 3, wherein the occlusion balloon is inflated to occlude the blood vessel before the angioplasty balloon is deflated





INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2020/082258

A. CLASSIFICATION OF SUBJECT MATTER		
A61M 25/10(2013.01)i; A61M 25/01(2006.01)i; A61M 31/00(2006.01)i; A61L 29/08(2006.01)i; A61L 29/16(2006.01)i		
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; A61L		
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) DWPI, VEN, CNABS, CNTXT, CNKI, WANFANG, ISI WEB OF SCIENCE, ELSEVIER SCIENCE DIRECT, GOOGLE scholar, baidu scholar: balloon, catheter, drug, coat+, particl+, aspiration, angioplasty, float+		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019009809 A1 (VASCUROS MEDICAL SHANGHAI CO LTD) 10 January 2019 (2019-01-10) claims 1-6, description page 4 lines 10-25	1-4
X	WO 2018093329 A1 (SHANGHAI MAIKE MEDICAL TECHNOLOGY CO LTD et al.) 24 May 2018 (2018-05-24) claims 1-3, description page 3 lines 27-37, abstract	1-4
X	WO 2019024726 A1 (HANGZHOU WEIQIANG MEDICAL TECHNOLOGY CO LTD et al.) 07 February 2019 (2019-02-07) claims 1-2, description page 1 lines 21-29, page 3 lines 14-21, abstract	1-4
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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 23 June 2020		Date of mailing of the international search report 06 July 2020
Name and mailing address of the ISA/CN National Intellectual Property Administration, PRC 6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088 China		Authorized officer DOU,Bojian
Facsimile No. (86-10)62019451		Telephone No. 62411125

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.: **1-4**
because they relate to subject matter not required to be searched by this Authority, namely:
 - [1] The subject matter of claims 1-4, which encompasses a method of treatment of the human/animal body, is not required to be searched by this Authority under Rule 39.1 (iv) PCT. Regardless, the search has been carried out and based on use of the balloon aspiration catheter and the drug coated balloon catheter for the manufacture of a medicament for the therapeutic application.
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).

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/CN2020/082258

Patent document cited in search report			Publication date (day/month/year)	Patent family member(s)			Publication date (day/month/year)
WO	2019009809	A1	10 January 2019	None			
WO	2018093329	A1	24 May 2018	CN	109414571	A	01 March 2019
WO	2019024726	A1	07 February 2019	CN	109381783	A	26 February 2019
				CN	208448410	U	01 February 2019