(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 July 2013 (18.07.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/106146 A1

(51) International Patent Classification:
A61B 17/221 (2006.01)

(21) International Application Number:
PCT/US2012/068482

(22) International Filing Date:
7 December 2012 (07.12.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1200333.1 10 January 2012 (10.01.2012) GB

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: OBJECT CAPTURE DEVICE

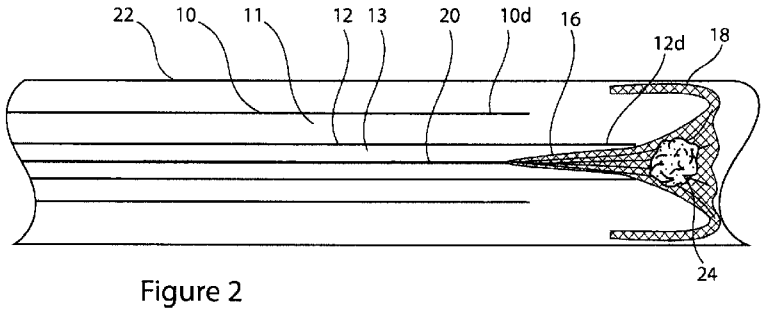


Figure 2

(57) Abstract: Described is a medical device for collecting objects from a body lumen (22). The medical device comprises a catheter (12), a basket (14) which may have a closed first end and an open second end, and an actuator connected to the closed first end of the basket, the catheter and basket being moveable relative to one another between a first configuration and a second configuration so as to draw objects from a body lumen into the basket (14). In the first configuration the closed first end (16) of the basket (14) is inside the catheter (12) and open second end (18) is everted over at least a part of the closed first end (16). The apparatus may be actuated so as to pull the closed first end of the basket further into the catheter (12) and invert the second end (18) of the basket, the second end (18) scraping the sides of the lumen (22) as it inverts, surrounding an object in the lumen (22), and drawing the object into the basket (14).

WO 2013/106146 A1

OBJECT CAPTURE DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of GB Application No. GB 1200333.1, filed on January 10, 2012, entitled "OBJECT CAPTURE DEVICE," the entire contents of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates to an object capture device as well as to a method of capturing objects from a body lumen, particularly for the capture of thrombi in a patient's vasculature.

BACKGROUND ART

[0003] It is known that material may form or build up in vessels of the circulatory system; such material may seriously compromise the health of the patient. For example, thrombi or blood clots may form and may partially or completely occlude a blood vessel, decreasing or even completely cutting off blood flow through the vessel. The thrombus may adhere to the vessel wall or may be dislodged, becoming free floating in the vessel. A free floating thrombus, also known as an embolus, may travel along a vessel and eventually cause a blockage in a distant part of the body, such as the heart or the brain, with potentially lethal consequences.

[0004] Various devices are known for capturing and removing thrombi and other objects from a patient's blood system. Such devices typically involve the use of a plurality of different tools which are deployed in different stages of the capture and removal procedure. For example, a first medical device may be introduced to break the thrombus into pieces so as to prevent it from blocking a vessel. However, breaking the thrombus into pieces can be harmful to the patient as dislodged parts may travel through the circulatory system and eventually block another vessel elsewhere. In order to avoid this, blocking and/or suction means are required to ensure that the dislodged parts are safely collected. For example,

a filter may be positioned distal of the thrombus so as to catch the dislodged parts after the thrombus has been broken up by the first medical device. The material trapped by the filter can remain in place until removed using yet further apparatus such as an aspirator. Various prior art thrombus capturing devices are disclosed in US2010/0249815, US 7,621,870, US 2007/0149996 and US 7,780,696.

DISCLOSURE OF THE INVENTION

[0005] The present invention seeks to provide an improved object capture device and method, particularly for removing objects such as thrombi from a patient's vasculature.

[0006] The preferred embodiment provides a single tool for capturing and removing thrombi. This tool can be used in a single stage, thus facilitating the medical procedure quickly and easily. There is also disclosed a method for capturing and removing thrombi. In particular the invention provides a mechanism for pulling a thrombus away from a vessel wall. The device comprises an object collecting member, hereinafter referred to as a basket.

[0007] According to an aspect of the present invention there is provided a medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and a second configuration in which the first end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted; and wherein, the medical device is operable so as to relatively move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

[0008] The second end may be constrained in the first position and free from attachment or constraint in the second position.

[0009] The actuator may be, for example, a wire, rod or cable, hereinafter referred to as a wire.

[0010] In the second configuration at least part of the second end of the basket may be withdrawn into the catheter.

[0011] According to another aspect of the present invention there is provided a medical device for collecting objects from a body vessel, including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and an actuator connected to the first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted, the second end being free from constraint; and wherein, the medical device is operable so as to release the second end from constraint, and move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

[0012] The basket may be provided with a closed first end and an open second end. By providing a basket having a closed first end, the basket is able to pull, as if sucking, an object such as a thrombus into the basket.

[0013] Preferably the basket is made of spring steel, or shape memory material such as, for example, Nitinol, hereinafter referred to as shape memory material. Where the remembered shape is a generally tubular basket, on release of the second end of the basket the basket may spring radially outwardly and distally of the catheter to surround a thrombus. By providing a rolling basket which rolls outwardly during its deployment so as to position itself between a thrombus and the vessel wall in which the thrombus lies, the basket may surround the thrombus such that when the basket is withdrawn into the catheter the thrombus is withdrawn into the basket.

[0014] The everted portion of the basket may scrape against the vessel wall thus dragging any plaque or thrombus adhered thereto into the basket as the

basket is reverted or inverted by withdrawal of the member into the catheter. As the basket is withdrawn into the catheter a pulling or suction effect is created, pulling an end of the thrombus or other object or material into the basket and pulling the rest of the thrombus through the vessel towards the catheter so that it too can be captured by the basket. The pulling or suction effect may be best achieved when the basket is positioned up against the object in the vessel before pulling the basket into the catheter.

[0015] The actuator may be actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration. The medical device may be operable so as to advance the catheter over the basket and so as to draw the basket into the catheter. Thus the basket may be withdrawn into the catheter and the catheter may be advanced over the basket at the same time. In use the movement between the catheter and the basket may cause objects in a body lumen to be drawn into the basket.

[0016] In the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter. If the thombus is appropriately sized, the basket containing the thrombus may be withdrawn through the catheter lumen and out of the patient.

[0017] The thombus may be broken down in the patient's lumen by a lytic agent, before being removed from the patient. The lytic agent may be delivered to the site of the thrombus through the catheter lumen, or through a lumen external to the catheter, for example though a lumen in an outer sheath.

[0018] The basket can, in the first configuration, have a first end inside the catheter and second end everted over the distal end of the catheter. In the first configuration the second end of the basket may extend radially out of the catheter and be everted over the first end of the basket and over the distal end of the catheter.

[0019] The basket may be made from wire or filamentary material. The basket may be made from braided material such as braided wire. The braiding of the basket may be tight. In other words the wires may be packed closely together, such that the spaces between the wires, if any, are small. The wires may be

tightly braided so as to prevent bodily fluid such as blood from passing through the basket. For example the basket may be similar to that found in a flow diverter. The basket may have an impermeable covering to prevent fluid from passing through the basket.

[0020] The basket may be constructed so as to allow fluid to pass through the closed first end of the basket. For example the basket may comprise apertures through which fluid can pass. However, the closed first end of the basket may prevent captured objects, such as fibres from a thrombus, from passing through.

[0021] The basket may be sized so as to collect a substantially entire thrombus or other object or material. Thombi can be very large. As such the second end of the basket may be, for example from approximately 10 mm to 200mm in length. The medical device may comprise an outer catheter, also known as an outer sheath. The outer sheath may be provided with a proximal and a distal end and a lumen therethrough. The catheter may be disposed within the lumen of the outer catheter, thereby to be configured as an inner catheter. An annular space may be provided between the inner and the outer catheters. Where an outer catheter is provided, the second end of the basket may be located in the annular space between the inner and outer catheters in the first configuration, so as to constrain the second end during delivery.

[0022] The inner and outer catheters may be moveable relative to one another so as to release the second end of the basket from between the outer catheter and the inner catheter. The second end of the basket may be free from constraint in the second configuration. The second end of the basket may be free from attachment in both the first and second configurations.

[0023] The second end may be attached to the catheter in the first configuration. Such attachment may be with ties. The ties may be releasable using a trigger wire, for example.

[0024] Where the basket is made of shape memory material, releasing the second end may allow the basket to assume its memory shape.

[0025] According to another aspect of the present invention there is provided a method of collecting objects from a body vessel, including: providing a medical device including a catheter provided with proximal end, a distal end and a lumen therethrough, and an elongate basket provided with a closed first end and

an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are moveable relative to one another between a first configuration and a second configuration, wherein in the first configuration the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and in the second configuration the first end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted; inserting the medical device into a body vessel; and operating the medical device so as to move the catheter and the basket from said first configuration to said second configuration thereby causing objects in a body vessel to be drawn into the basket.

[0026] The method may comprise the step of withdrawing the medical device from the body lumen, the medical device containing objects from the body vessel. In particular the basket may contain objects from the body vessel. The object containing portion of the basket may be contained within the catheter.

[0027] Where the medical device comprises an outer sheath, and where the second of the basket is held between the sheath and the inner catheter, the method may comprise the step of withdrawing the outer sheath so as to release the basket.

[0028] After operating the medical device so as to capture a thrombus or other object or material in the basket, the method may comprise advancing the outer sheath distally relative to the catheter and basket, such that the outer sheath surrounds an object containing portion of the basket, before removing the device from the patient's lumen. In this case the object containing portion of the basket may be contained within the outer sheath. Where the second end of the basket is held in the first position by ties, for example, the method may comprise the step of releasing the ties so as to release the basket.

[0029] The device described may be in the first configuration whilst tracking through the vasculature. On reaching a location proximate to the thrombus or other object, the site of interest, the device may be activated so as to move to the second configuration.

[0030] According to another aspect of the present invention there is provided a method of collecting objects from a body vessel, including: providing a

medical device for collecting objects from a body vessel, the medical device including: a catheter provided with a proximal end, a distal end and a lumen therethrough; an elongate basket provided with a first end and a second end; and a wire connected to the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the second end is at least partially inverted, the second end being free from constraint; inserting the medical device into a body vessel; and operating the medical device so as to release the second end from constraint, and so as to move the catheter and the basket from said first configuration to said second configuration, such that an object in a body vessel is drawn into the basket.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

[0032] Figure 1 shows an embodiment of a medical device for collecting objects from a body lumen, the medical device having a catheter and a basket arranged in a first configuration;

[0033] Figure 2 shows the medical device of Figure 1 after the outer sheath has been withdrawn from around the basket;

[0034] Figure 3 shows the medical device of Figures 1 and 2, the catheter and the basket arranged in the second configuration; and

[0035] Figure 4 shows another embodiment of a medical device for collecting objects from a body lumen.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0036] Referring to Figure 1, there is shown in schematic form an embodiment of a medical device for collecting objects from a body lumen 22. The medical device is shown inside a patient's vessel 22; within which there is also a thrombus 24. The medical device comprises an outer catheter 10 disposed

concentrically around an inner catheter 12, and an object collecting member 14, hereafter called a basket 14.

[0037] The inner 12 and outer 10 catheters are in the form of elongate tubes having proximal (not shown) and distal 10d,12d ends. In use the distal ends 10d,12d of the catheters are positioned proximate the thrombus or object or material to be removed and the proximal ends are outside of the patient. The outer catheter 10 comprises a lumen in which the inner catheter 12 is disposed. The catheters are arranged such that an annular gap 11 is provided between the inner 12 and outer 10 catheters. The inner catheter 12 also comprises a lumen 13, into which the basket 14 may be withdrawn.

[0038] The basket comprises a first end portion 16 and a second end portion 18. The first end portion 16 of the basket 14 is connected to an actuator wire 20. The wire 20 is disposed inside the lumen of the inner catheter 12 and extends through the lumen to an actuating portion of the medical device which in use is external to the patient's body. The first end portion 16 of the basket 14 is, in a first configuration, housed within the lumen of the inner catheter 12. The basket 14 extends, from the first end portion 16, out of the end of the inner catheter 12 and is everted so as to extend backwardly over itself around the inner catheter and inside the outer catheter 10 such that the second end portion 18 of the basket 14 is housed in the annular gap 11 between the inner catheter 12 and the outer catheter 10.

[0039] In this case the distal ends of the catheters are aligned with one another and are positioned such that the basket abuts the thrombus 24. The basket surrounds part of the thrombus when it is moved up against the thrombus, giving it a grip on the thrombus and thus aiding withdrawal/pulling of the thrombus into the basket when the device is used.

[0040] The basket 14 comprises a braided wire basket made of shape memory material, or of spring steel, for example. Such a basket may be flexible so as to fit around thrombi of various shapes and sizes, and so as to be able to be withdrawn into the narrow lumen of the inner catheter. The braiding of the basket is tight, such that the spaces between the wires, if any, are small. It is not necessary for the basket to allow blood or other fluid to pass through it. The thrombus removal process may be carried out very quickly and as such

preventing blood flow through the vessel whilst the procedure is carried out does not harm the patient.

[0041] Figure 2 shows the medical device of Figure 1 after the outer catheter 10 has been withdrawn relative to the inner catheter 12. The outer catheter is provided so as to cover the basket and prevent it from springing open during introduction of the device. Once the outer catheter has been withdrawn the second end portion 18 of the basket 14 is no longer constricted and is able to spring open outwardly. The basket opens until it comes into contact with the internal walls of the vessel, scraping along the sides of the lumen so as to surround the thrombus 24. The second end portion 18 of the basket 14 remains everted, backwards over itself, and contacts the sides of the vessel 22.

[0042] Figure 3 shows the medical device of Figures 1 and 2 in a second configuration, in which the first end portion 16 of the basket 14 and part of the second end portion 18 are withdrawn into the inner catheter 12 such that the basket 14, and the thrombus 24 inside it, is substantially contained within the inner lumen 12. The basket 14 can be from 10 to 200mm long, depending on the length and size of the material/thrombus to be captured. The basket 14 is designed to be long enough to trap the entirety of the thrombus. In particular, the everted second portion 18 of the basket 14 is designed to be long enough to trap the entirety of the thrombus. In one mode movement of the basket 14, from the first configuration shown in Figure 1 to the second configuration shown in Figure 3, is actuated by pulling on the actuating element 20. By pulling back on the actuating element 20 the second end portion 18, the open end of the basket, is pulled into the distal end 12d of the inner catheter 12. This action causes the second end portion 18 of the basket to roll inwardly, thus drawing, as if pulling or sucking, the thrombus into the closing basket. The thrombus is thus trapped bit-by-bit in the basket and withdrawn into the inner catheter 12. As a result of the relative movement between the inner catheter 12 and the basket 14 from the first configuration to the second configuration the thrombus 24 is thus drawn into the inner catheter 12, inside the basket 14.

[0043] Where the thrombus is small enough to be withdrawn through the lumen of the inner catheter continued retraction of the actuating element 20 allows withdrawal of the basket, in which the thrombus is held, through the lumen 13 of the inner catheter 12. The basket 14 containing the thrombus 24 may thus be

completely removed from the patient's vessel through the lumen 13 of the inner catheter 12. As such this embodiment provides a single tool which is used in a single stage to remove the thrombus from a patient's vessel.

[0044] Where the thrombus is too large to be pulled into the lumen of the inner catheter, the outer catheter or sheath may be advanced over the thrombus. In this manner the thrombus can be held within the basket and also within the outer catheter so that it can then be removed from the patient.

[0045] In some instances, instead of pulling back on the actuator wire 20, the inner catheter 12 may be advanced over the basket 14. This movement from the first configuration to the second configuration will have the same effect of withdrawing the basket 14 into the inner catheter 12.

[0046] The apparatus may be operated by advancing the inner catheter 12 over the basket 14 as the actuator wire 20 is basket 14 withdrawn into the catheter 12. A combination of the two movements may be performed together so that as the basket 14 is withdrawn in the catheter 12 the catheter is also advanced over the basket.

[0047] Figure 4 shows another embodiment of a medical device for collecting objects from a body vessel. The medical device comprises an inner catheter 32, and a basket 34 having first 36 and second 38 end portions.

[0048] In this device ties 30 are provided to secure the second end portion 38 of the basket 34 in its everted position around the outside of the inner catheter 32. In this embodiment the outer catheter is not required to secure the basket 34 in its first configuration. Trigger wires (not shown) may be used to release the ties 30 so as to enable the basket to open outwardly as a result of its shape memory characteristics, and to be withdrawn into the inner catheter 32. An outer catheter (not shown) may be provided for use in delivery of the medical device to a location adjacent a thrombus inside a vessel.

[0049] It is to be understood that the different features of the various embodiments described herein can be combined together.

[0050] The disclosures in GB application number 1200333, from which this application claims priority, and in the abstract accompanying this application, are incorporated herein by reference.

CLAIMS

1. A medical device for collecting objects from a body vessel, including:

a catheter provided with a proximal end, a distal end and a lumen therethrough;

an elongate basket provided with a closed first end and an open second end; and

an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter;

wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over at least part of the first end of the basket, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted; and

wherein, the medical device is operable so as to move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

2. A medical device according to claim 1, wherein the basket is made of shape memory material.

3. A medical device according to any preceding claim, wherein the basket is made of wire or filamentary material.

4. A medical device according to claim 3, wherein the basket is made of braided wire or filamentary material.

5. A medical device according to claim 4, wherein the wire or filamentary material is tightly braided so as to prevent fluid from passing through the basket.

6. A medical device according to any preceding claim, wherein the basket has an impermeable covering.

7. A medical device according to any preceding claim, wherein the actuator is a wire.

8. A medical device according to any preceding claim, wherein the basket comprises apertures sized to allow fluid to pass through the closed first end of the basket but prevent the captured objects from passing therethrough.

9. A medical device according to any preceding claim, wherein the actuator is actuatable so as to draw the basket into the catheter and so move the catheter and the basket from said first configuration to said second configuration.

10. A medical device according to any preceding claim wherein, the medical device is operable so as to advance the catheter over the basket and so move the catheter and the basket from said first configuration to said second configuration.

11. A medical device according to any preceding claim, wherein in the second configuration the first end and substantially the whole of the second end of the basket may be withdrawn into the catheter.

12. A medical device according to any preceding claim, wherein the basket is from 10 to 200mm in length.

13. A medical device according to any preceding claim, wherein the second end is constrained in the first position and free from constraint in the second position.

14. A medical device according to any preceding claim including an outer sheath provided with a proximal and a distal end and a lumen therethrough, wherein the catheter is disposed within the lumen of the outer sheath, thereby to be configured as an inner catheter, an annular space being provided between the inner catheter and the outer sheath, and wherein in said first configuration the second end of the basket is located in the annular space between the inner catheter and outer sheath.

15. A medical device according to claim 14 wherein the second end of the basket is free from attachment and wherein the inner catheter and outer sheath are moveable relative to one another so as to release the second end of the basket from between the outer sheath and the inner catheter.

16. A medical device for collecting objects from a body vessel, including:

a catheter provided with a proximal end, a distal end and a lumen therethrough;

an elongate basket provided with a first end and a second end; and

an actuator connected to the first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter;

wherein the catheter and the basket are movable relative to one another between a first configuration in which the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, the second end being constrained in position, and a second configuration in which the first end is withdrawn into the catheter and the everted second end is at least partially inverted, the second end being free from constraint; and

wherein, the medical device is operable so as to release the second end from constraint, and move the catheter and the basket from said first configuration to said second configuration, said movement in use causing objects in a body vessel to be drawn into the basket.

17. A medical device according to claim 16, wherein the first end of the basket is closed and the second end open.

18. A medical device according to any of claims 16 and 17, wherein the basket is made of shape memory material, said material having a memory shape, and wherein releasing the second end portion allows the basket to assume its memory shape.

19. A method of collecting objects from a body vessel, including:

providing a medical device including a catheter provided with proximal end, a distal end and a lumen therethrough, and an elongate basket provided with a

closed first end and an open second end; and an actuator connected to the closed first end of the basket and extending through the lumen of the catheter to the proximal end of the catheter; wherein the catheter and the basket are moveable relative to one another between a first configuration and a second configuration, wherein in the first configuration the first end of the basket is located within the distal end of the catheter and the second end of the basket extends radially out of the catheter and is everted over the first end of the basket, and in the second configuration the first end and at least part of the second end of the basket is withdrawn into the catheter and the everted second end is at least partially inverted;

inserting the medical device into a body vessel; and

operating the medical device so as to move the catheter and the basket from said first configuration to said second configuration thereby causing objects in a body vessel to be drawn into the basket.

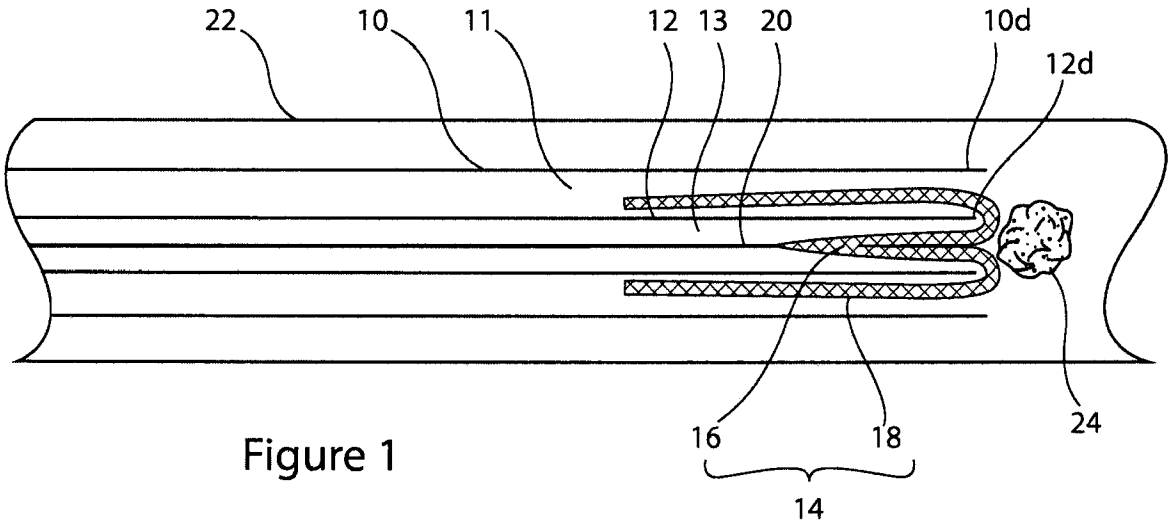


Figure 1

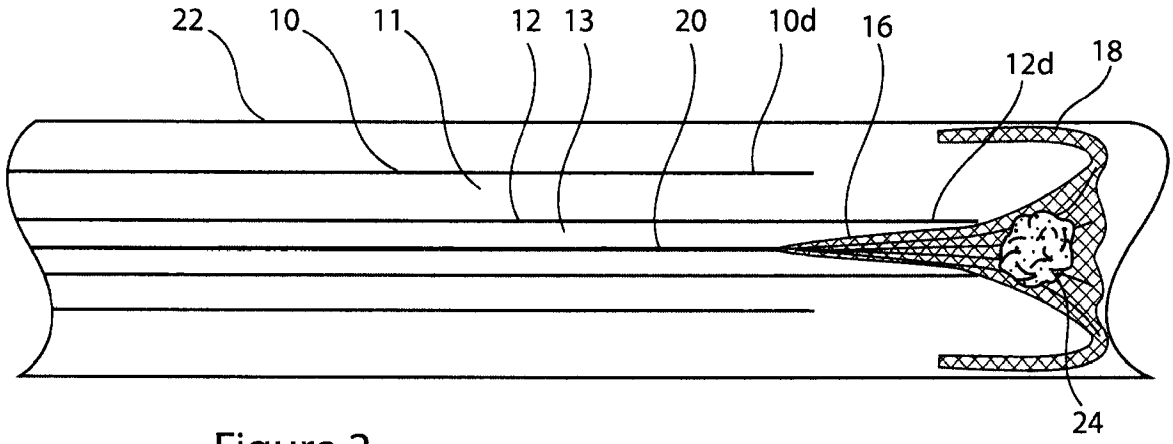


Figure 2

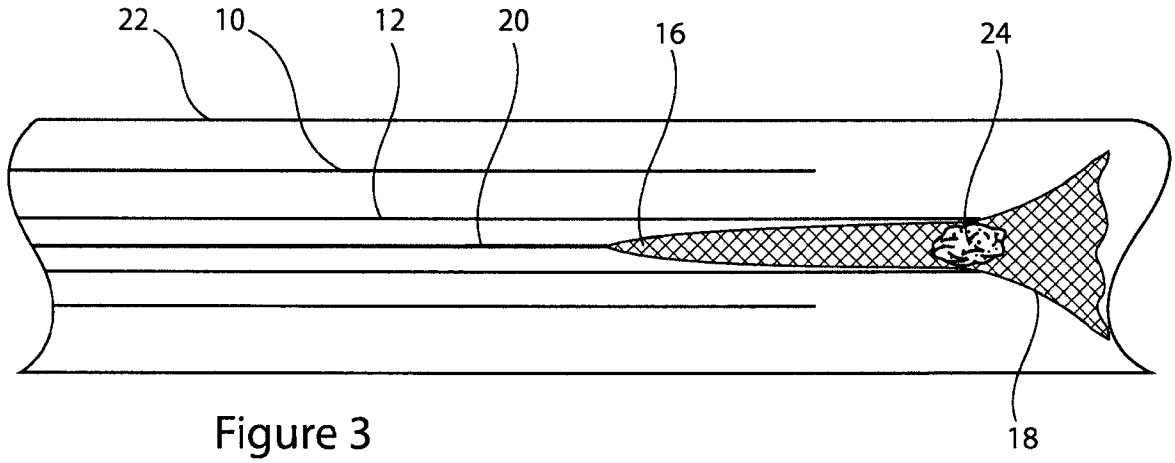


Figure 3

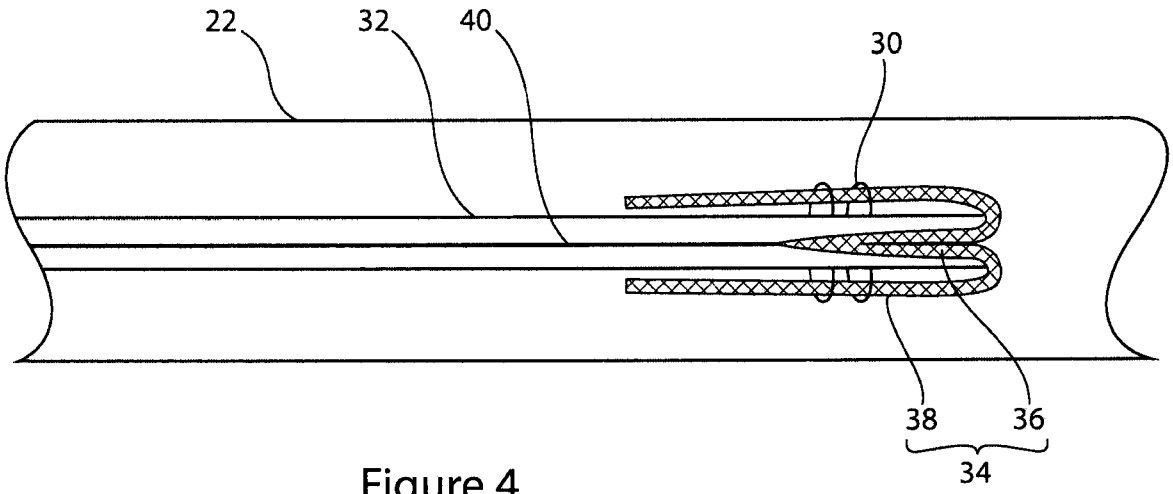


Figure 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/068482

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221
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)
A61B

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 2010/030256 A1 (DUBRUL WILLIAM R [US] ET AL) 4 February 2010 (2010-02-04) paragraph [0178]; figures 29-34	1,16
A	US 2010/249815 A1 (JANTZEN ALEXANDRA E [US] ET AL) 30 September 2010 (2010-09-30) cited in the application paragraph [0026]; figures 1, 2	1,16
A	US 2010/137846 A1 (DESAI RUPESH [US] ET AL) 3 June 2010 (2010-06-03) paragraph [0027] - paragraph [0032]; figures 1-5a	1,16
A	US 2007/213765 A1 (ADAMS DANIEL O [US] ET AL) 13 September 2007 (2007-09-13) paragraph [0083]; figures 13a,b	1,16

☐ 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
5 March 2013	12/03/2013

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	Moers, Roelof

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/068482

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.: 19
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/US2012/068482

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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