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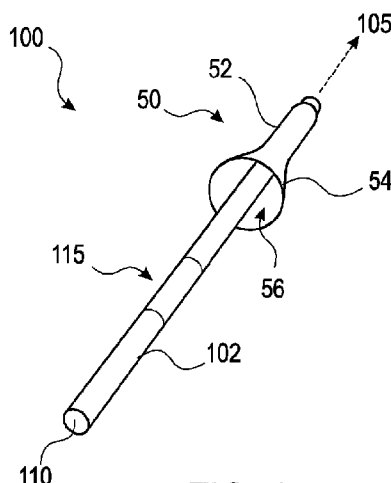


FIG. 1

(57) Abstract: A catheter (100) for retrieving a cardiovascular device from within a blood vessel, the catheter (100) comprising: a retrieval module (115) configured to magnetically engage a cardiovascular device within the blood vessel (10) so as to disengage the cardiovascular device from the blood vessel for retrieval from within the blood vessel (10) using the catheter (100).

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A CATHETER

[0001] This invention relates to a catheter. In particular, a catheter for retrieving a cardiovascular device, such as a heart valve, from within a blood vessel.

5 BACKGROUND

[0002] Valvular Heart Disease relates to diseases which hinder the function of heart valves, such as Aortic Stenosis, in which the aortic valve becomes calcified and narrowed over time, thereby losing its ability to function. Aortic stenosis is common in the elderly. With increasing life expectancy, the prevalence of Aortic Stenosis represents a growing health
10 problem.

[0003] Aortic Stenosis can be treated by either major open heart surgery called surgical aortic valve replacement (SAVR) or, increasingly, a keyhole procedure called transcatheter aortic valve implantation (TAVI). In SAVR, the stenosed aortic valve is excised, and a replacement is sutured in its place. TAVI, by contrast, is a minimally invasive procedure in
15 which a replacement valve is deployed via a catheter and positioned and expanded inside the diseased valve without excising the diseased valve. TAVI was initially developed and approved for use in aortic stenosis patients who were deemed too high risk to be able to survive SAVR. In the last 10 years, however, randomised trials have shown equivalence for TAVI versus SAVR in intermediate risk and even low risk populations. The advantage of
20 TAVI is that, in most cases, the new TAVI valve can be expanded within the diseased valve via a tube inserted in the patient's groin artery, without a requirement for internal surgery and without a general anaesthetic. The risk of this procedure is thus significantly lower. Deployment of the TAVI valve can be via an expandable balloon or a self-expanding system. In both cases, the native diseased valve leaflets are pushed outwards against the aortic wall
25 by the expansion of the TAVI prosthesis from within the native valve.

[0004] An important long-term disadvantage of all surgical bioprosthetic replacement valves is that the leaflets of such devices are inevitably subject to degeneration over time. Thus, the durability of surgical biological valves is, on average, around 7-15 years, although some of these valves are subject to failure much earlier than this (e.g., Trifecta). Given this,
30 the likelihood is that for patients receiving a surgical bioprosthetic valve whose life expectancy is more than a few years, they will need a further procedure to treat the failing aortic prosthesis. At this point, the options would theoretically be: (a) re-do SAVR, or (b) valve-in-valve TAVI. Given the risk of morbidity and mortality associated with re-do SAVR surgery, TAVI valve-in-valve procedure is increasingly becoming the default option.

[0005] Furthermore, being bio-prostheses themselves, TAVI valves are also subject to degeneration and failure over time. Treatment for such cases is also most likely to be TAVI-in-TAVI.

5 [0006] Repeated valve-in-valve TAVI procedures, for example, two, three, or more valve-in-valve TAVI procedures, reduce the effective annular area of the valve orifice each time a new valve “ring” is deployed within the previous valve structure. This shrinking annular area represents a predictable limitation to recurrent treatment of younger patients undergoing bioprosthetic SAVR or *de novo* TAVI. Given the exponential rise globally in the number of patients having these bioprostheses, a solution that prevents shrinking annulus would have
10 a major clinical and economic impact.

[0007] It is known to provide a two part valve assembly with a permanent base part that can be sutured to the aortic wall in open heart surgery, and a replaceable part that can be sutured to the permanent base part. This permits the replaceable part to be removed and replaced by open heart surgery while the permanent base part remains in the aorta.

15 BRIEF SUMMARY OF THE DISCLOSURE

[0008] Viewed from a first aspect, the present invention provides a catheter for retrieving a cardiovascular device, for example a heart valve, from within a blood vessel. The catheter comprises a retrieval module configured to magnetically engage a cardiovascular device within the blood vessel so as to disengage the cardiovascular device from the blood vessel
20 for retrieval from within the blood vessel using the catheter.

[0009] Thus, the present invention provides a device that can reliably and safely remove a cardiovascular device, for example a replacement heart valve component, that is failing due to wear over time.

[0010] In examples, the retrieval module may comprise a ferromagnetic material. During
25 use, the ferromagnetic material may act to disengage the cardiovascular device from the holding member through magnetic attraction. In such examples, the cardiovascular device may comprise a permanent magnet. This advantageously provides a passive retrieval module to disengage the cardiovascular device from the blood vessel. In examples, the retrieval module may comprise one or more permanent magnets.

30 [0011] In other examples, the retrieval module may comprise an electromagnet operable to generate a magnetic force. The magnetic force can act to disengage the cardiovascular device from the blood vessel. In such examples, the cardiovascular device may comprise a ferromagnetic material and/or a permanent magnet. The electromagnet may be operable by a user, for example the electromagnet may be remotely operable, for example by an
35 operator using a switch. The switch may be operatively connected to the retrieval module

via wired or wireless communication means. The electromagnet may be configured to generate a variable magnetic force, for example by operatively connecting the retrieval module to a controlled power source. The retrieval module may be connectable to an external power source.

- 5 **[0012]** Disengagement of the cardiovascular device from the blood vessel may crimp or crush the cardiovascular device.

[0013] The catheter may further comprise one or more gripping elements, for example a barbed member, arranged to secure the disengaged cardiovascular device to the catheter. The one or more gripping elements may secure the disengaged cardiovascular device to
10 the catheter such that the cardiovascular device is removed from the patient with the catheter.

[0014] The catheter may further comprise a sheath slidably connected to the catheter and arranged to receive the disengaged cardiovascular device. The sheath may be configured to at least partially, for example substantially or completely, surround the disengaged
15 cardiovascular device.

[0015] The sheath may be arranged to compress the retrieved cardiovascular device in a radial direction upon receipt of the retrieved cardiovascular device. In some cases, the sheath can crimp or crush the cardiovascular device upon receipt of the cardiovascular device therein. Crimping or crushing the cardiovascular device reduces the size of the
20 cardiovascular device for extraction.

[0016] The sheath may comprise a tapered profile. The sheath may be located at a proximal position along the catheter relative to the retrieval module. Sliding the tapered sheath in a distal direction can cause the cardiovascular device to be crimped or crushed.

[0017] The catheter may comprise displacement means for moving at least part of the
25 retrieval module in a radial direction. The radial direction may be a radially outward direction. This advantageously allows the retrieval module to be brought into closer proximity with the cardiovascular component within the blood vessel to facilitate the disengagement of the cardiovascular device and the blood vessel. In examples, the radial displacement of the retrieval module can facilitate engagement between the retrieval module and the
30 cardiovascular device.

[0018] In examples, the cardiovascular device may be a replacement heart valve component. The magnetic coupling may be configured to disengage the replacement heart valve component from a holding member arranged to hold the replacement heart valve component within the blood vessel.

[0019] The catheter may further comprise a deployment module arranged to deploy a second cardiovascular device within the blood vessel. The second cardiovascular device may thereby be anchored within the blood vessel. The second cardiovascular device may be a replacement heart valve component. The replacement heart valve component may, for example, be a new exchangeable replacement part for replacing the failing exchangeable replacement part.

[0020] The deployment module may be located at a distal position along the catheter relative to the retrieval module.

[0021] The deployment module may comprise an electromagnet operable to generate a magnetic force. The electromagnet may be operable to urge, for example push, a magnetic portion of the second cardiovascular device in a radial direction away from the deployment module, for example to cause engagement of the second cardiovascular device with the blood vessel.

[0022] In such examples, the magnetic portion of the second cardiovascular device may comprise a ferromagnetic material or a permanent magnet. The electromagnet may be operable to hold a self-expanding frame to the deployment module, such that when the electromagnet is deactivated the self-expanding frame will expand into position. Additionally or alternatively, the deployment module may comprise an inflatable bladder. The bladder may be arranged to expand and urge the second cardiovascular device in a radial direction away from the deployment module. The inflatable bladder may be arranged to urge the second cardiovascular device into engagement with a holding member in the blood vessel. The self-expanding frame may be made using additive manufacturing processes.

[0023] The catheter may comprise the second cardiovascular device. The second cardiovascular device may be secured to the deployment module, for example, in a pre-deployed configuration. The catheter, in particular the deployment module, may comprise a second sheath for housing the second cardiovascular device. The second sheath may be slidably connected to the catheter. The second sheath may be arranged to slide along the catheter to expose the second cardiovascular device to the blood vessel.

[0024] Where the second cardiovascular device is a second replacement heart valve, the second replacement heart valve component may comprise a second magnetic portion for engaging with a corresponding magnetic portion of a holding member within the blood vessel.

[0025] Viewed from a further aspect, the present invention provides a kit of parts comprising a catheter as described above and a cardiovascular device for use with the catheter described above.

- [0026]** Further aspects described herein provide a replacement heart valve component for deployment using the catheter and the deployment module described above. In particular, the replacement heart valve component may comprise a magnetic portion, for example a ferromagnetic material or a permanent magnet, arranged such that the deployment module described above can urge the replacement heart valve component away from the catheter and into position. The replacement heart valve may be configured to engage with a holding member in the blood vessel to secure the replacement heart valve to the blood vessel. In other examples, the replacement heart valve may directly engage the blood vessel when deployed.
- [0027]** Further aspects described herein provide a valve implant comprising a holding member configured to be secured, for example sutured, into a patient's aortic root, and a replaceable heart valve component configured to engage the holding member to be held within the blood vessel. The holding member and the replacement heart valve component are magnetically couplable.
- [0028]** Further aspects described herein provide a method of retrieving a cardiovascular device, such as a replacement heart valve component, from within a blood vessel. The method comprises using the catheter described above. The method may also include activating an electromagnet of the catheter to magnetically engage the cardiovascular device so as to disengage the cardiovascular device from the blood vessel.
- [0029]** Further aspects provide an exchangeable cardiovascular device comprising a magnetic portion for magnetically engaging a holding member and/or a retrieval module of a catheter. In examples, the magnetic portion of the exchangeable cardiovascular device is configured to magnetically engage a retrieval module of a catheter so that the retrieval module of the catheter disengages the exchangeable cardiovascular device from the blood vessel. In examples, the exchangeable cardiovascular device may be configured to engage a holding member within the blood vessel, and in such examples the magnetic portion of the exchangeable cardiovascular device may be magnetically couplable to the holding member. In some examples, the magnetic portion of the exchangeable cardiovascular device is configured to magnetically engage a holding member in the blood vessel, and a retrieval module of a catheter for disengaging the exchangeable cardiovascular device from the holding member.
- [0030]** In some cases, the magnetic portion of the exchangeable cardiovascular device comprises one or more permanent magnets or electromagnets. The permanent magnets or electromagnets may be attached to the exchangeable cardiovascular device by chemical adhesive means, for example by a biocompatible epoxy bonding agent. The permanent magnets or electromagnets may additionally or alternatively be welded to the cardiovascular

device. In another example, the permanent magnets or electromagnets may be secured to the exchangeable cardiovascular device between two skirts sutured around the outside and inside of the cardiovascular device. In some cases the cardiovascular device includes a frame, such as a self-expanding frame. The exchangeable cardiovascular device may include one or more magnet housing structures for receiving one or more permanent magnets or electromagnets. The permanent magnets or electromagnets may be secured within the magnet housing structure using a mechanical connection, such as a snap fit connection. In some examples, the exchangeable cardiovascular device includes a magnetic coating to define a magnetic portion. The magnetic coating is preferably applied to specific regions of the cardiovascular device after the frame is manufactured. The magnetic coating may include any of a magnetic powder or a ferromagnetic powder. In some cases, the exchangeable cardiovascular component comprises a replacement valve component having an arrangement of leaflets secured thereto.

[0031] Further aspects provide a holding member for securing an exchangeable cardiovascular component to a blood vessel. In some cases, the exchangeable cardiovascular component is secured to the holding member by an outward radial force exerted by the exchangeable cardiovascular device. In some cases, the holding member secures the exchangeable cardiovascular device via a magnetic coupling, for example via magnetised bands on the holding member. Additionally or alternatively to the magnetised bands, the holding member can include individual magnets for coupling with the exchangeable cardiovascular device. While it is preferable to secure the holding member and the exchangeable cardiovascular device by a magnetic coupling, it would be apparent that this was not essential and that the exchangeable cardiovascular device may be secured to the holding member using mechanical means, such as one or more inter-engaging mechanical elements located on the holding member and/or the exchangeable cardiovascular device. In some cases, the holding member includes an electromagnet to hold the exchangeable cardiovascular device thereto. Including an electromagnet in the holding member provides enhanced anchoring and controllable release of the failing exchangeable component.

[0032] Further aspects provide a replacement heart valve comprising a holding member and an exchangeable cardiovascular device as described above.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] The accompanying drawings are provided to assist in the understanding of the present disclosure, in which:

Figure 1 illustrates an exemplary catheter;

Figure 2 illustrates a cross-sectional view of an aortic root with a part of a replacement heart valve secured thereto;

Figure 3 illustrates an exemplary replacement heart valve;

Figure 4 illustrates a perspective view of an exemplary catheter within an aortic
5 root;

Figure 5 illustrates a perspective view of a further exemplary catheter;

Figures 6A to 6H illustrates an exemplary method of using a catheter according to the present disclosure;

Figure 7 illustrates a further exemplary catheter;

10 Figure 8 illustrates an exemplary retrieval module.

DETAILED DESCRIPTION

[0034] Figure 1 discloses an exemplary catheter 100 having an elongate body 102 extending from a proximal end 105 to a distal end 110 and including a retrieval module 115. In use, the catheter 100 is inserted into a patient's blood vessel with the distal end 110 being
15 passed into the blood vessel and the proximal end 105 being accessible to an operator for controlling the catheter 100.

[0035] A retrieval sheath 50 is also shown slidably secured to the body 102. The sheath 50 has a neck portion 52 at a proximal end of the retrieval sheath 50 and a conical portion 54 defining an opening 56 for receiving a failing exchangeable part 30 of the replacement
20 heart valve as explained below.

[0036] Figure 2 shows an aortic root 10 where the native diseased valve has been excised and only a lip 12 of the native aortic root remains. Also shown in Figure 2, the native valve is replaced with a replacement heart valve (only part of the replacement heart valve is shown in Figure 2 for clarity). The replacement heart valve is a two-part component with a
25 permanent component 20 and an exchangeable component 30, which is illustrated in Figure 3. The exchangeable component 30 is releasably secured to the permanent component 20. The permanent component 20 is secured within the patient and acts as a holding member that holds the exchangeable component 30 in place, as described below.

[0037] In Figure 2 the permanent component 20 is shown secured to the aortic root 10 in
30 close proximity to the lip 12 of tissue. However, it would be apparent this was not essential. The permanent component 20 has a collar 22 that engages the lip 12 which works with the expansile force of a self-expanding frame of the permanent component 20 to anchor the replacement heart valve within the aortic root 10. The permanent component 20 also defines an inner region 24 against which the exchangeable component 30 is held. While the

permanent component 20 is shown attached to the aortic root 10, in some cases, such as where a patient can't undergo surgery but who would benefit from an exchangeable valve in the future, it may be desirable to implant the permanent component 20 in the aortic annulus using a transcatheter valve-in-valve approach. In this case, the permanent component 20 would be secured to an existing replacement heart valve (not shown).

[0038] In some cases, the permanent component 20 may comprise a frame that can be implanted in the aorta at the aortic root 10. In some cases the permanent component 20 can be a self-expanding frame or a frame that can be expanded by an expanding balloon.

[0039] In some cases, the permanent component 20 can be deployed into a native diseased valve either before or simultaneously with the deployment of the exchangeable component 30 illustrated in Figure 3. Where the permanent component 20 is deployed before the deployment of the exchangeable component 30 this can be achieved using a separate catheter to the one used to deploy the exchangeable component 30. In some cases, the exchangeable component 30 is deployed directly against the native diseased aortic root 10 and anchored thereto by the radially expanding force of a self-expanding frame 32 of the exchangeable component 30. In some cases, the exchangeable component 30 is deployed directly against an existing bio-prosthetic replacement valve and is anchored thereto by the radially expanding force of a self-expanding frame 32 of the exchangeable component 30. Where the existing bio-prosthetic valve is not configured to couple magnetically with the catheter 100, magnetic elements, such as individual magnets or magnetic bands, may be attached to the existing bio-prosthetic valve to enable magnetic coupling with the catheter 100. The existing bio-prosthetic valve may be adapted to include magnetic elements in situ, or prior to implanting the valve. This may be performed using a catheter configured to attach the magnets to the bio-prosthetic valve.

[0040] Figure 4 shows an exemplary replacement heart valve with a permanent component 20 and an exchangeable component 30 secured within the aortic root 10. The permanent component 20 is shown holding the exchangeable component 30 via a magnetic coupling. The magnetic coupling is achieved by magnets 34 secured to the exchangeable component 30 and magnetised bands 26 on the permanent component 20. Additionally or alternatively to the magnetised bands 26, the permanent component 20 can include individual magnets 34 for coupling with the exchangeable component 30. The magnets 34 may be attached to the frame by chemical adhesive means, for example by a biocompatible epoxy bonding agent. The magnets may additionally or alternatively be welded to the frame after manufacture. In another example, the magnets may be held between the frame 32 and two skirts 36A, 36B (see Figure 3) sutured around the outside and inside of the frame 32.

[0041] In some examples, the frame 32 may include magnet housing structures incorporated during an additive manufacturing process. Permanent magnets may then be pushed into the magnet housing structures and secured in position, for example using a mechanical connection such as a snap fit connection.

5 [0042] In some examples, the magnetic regions on the replacement heart valve includes a magnetic coating. The magnetic coating is preferably applied to specific regions on the frame 32 after the frame is manufactured. The magnetic coating may include any of a magnetic powder or a ferromagnetic powder.

[0043] While it is preferable to secure the permanent component 20 and exchangeable
10 component 30 by a magnetic coupling, it would be apparent that this was not essential and that the exchangeable component 30 may be held by the permanent component 20 using mechanical means, such as one or more inter-engaging mechanical elements located on the permanent component 20 and/or the exchangeable component 30, or by the outward radial force exerted by the exchangeable component 30. While the combination of magnets
15 34 and magnetised bands 26 is preferable, it would be apparent that this specific arrangement was not essential to the function of the catheter 100.

[0044] In some cases, the permanent component 20 includes an electromagnet to hold the exchangeable component 30 thereto. Including an electromagnet in the permanent component 20 provides enhanced anchoring and controllable release of the failing
20 exchangeable component 30.

[0045] In other examples, the exchangeable component 30 may be axially restrained by the permanent component 20, for example by opposing lips of the permanent component 20. Accordingly, the exchangeable component 30 may not be attached to the permanent component 20, but is held in place by engagement with the permanent component 20.

25 [0046] As illustrated in Figure 3, the replacement component 30 comprises one or more leaflets 38 secured to the inner skirt 36B. While three leaflets are illustrated, it would be apparent that other arrangements of leaflets could be used depending on the application.

[0047] When the exchangeable component 30 needs to be replaced, for example due to component fatigue over time, the exchangeable component 30 can be retrieved from within
30 the aortic root 10 using a catheter that has been positioned in a minimally invasive manner as shown in Figure 4. The function of the retrieval module 115 is to magnetically engage the exchangeable component 30, such that the exchangeable part 30 is disengaged from the permanent part 20. It would be apparent that the exchangeable part 30 includes a magnetic portion for engaging with the retrieval module 115 when the retrieval module 115 applies a
35 radially inward force to the exchangeable component 30. For example, the exchangeable

component 30 may include any of: a ferromagnetic material, one or more magnets or one or more magnetic portions arranged to engage the retrieval module 115. The exchangeable part 30 can, therefore, be disengaged from the blood vessel wall 10 via the permanent part 20.

- 5 **[0048]** In some cases there is no permanent part 20 and the exchangeable part 30 may be implanted directly against the blood vessel wall 10 and disengaged directly from the blood vessel wall 10.

[0049] Thus, when the retrieval module 115 is situated within the exchangeable component 30, an electromagnet within the retrieval module 115 can be activated to
10 generate a sufficiently large magnetic force to disengage the exchangeable component 30 from the permanent component 20. In examples where the permanent component 20 includes an electromagnet, this can be deactivated to release the failing exchangeable component 30. In some cases, the catheter 100 includes displacement means to displace the retrieval module 115 in a radially outward direction to facilitate engagement with the
15 exchangeable component 30. For example, the displacement means may include an inflatable bladder for moving one or more permanent magnets and/or additional electromagnetics in a radially outward direction to help detach the exchangeable component 30 from the wall of the blood vessel. It will be appreciated that reducing the distance between the magnets of the retrieval module 115 and the exchangeable component 30 will increase
20 the force of the magnetic attraction and so provide a larger force to disengage the exchangeable component 30 from the blood vessel 10 and/or permanent component 20.

[0050] The retrieval module 115 may also be operatively connected to a controllable power source (not shown) adapted to provide a variable electrical power to the electromagnet in order to generate a variable level of magnetic force. This advantageously increases the utility
25 of the catheter 100, as a single catheter 100 can be used to disengage exchangeable components 30 of different sizes, and allows the electromagnetic force to be increased if required to disengage the exchangeable component 30.

[0051] The catheter 100 can also include an electrical connector (not shown) for connecting to an external power supply. While an electromagnet is preferable, it would be
30 apparent that this is not essential. In some cases, the retrieval module 115 comprises a ferromagnetic material to provide a magnetic portion so that the retrieval module 115 can function in a passive manner and cause the disengagement of the exchangeable component 30 without requiring external power.

[0052] As shown in Figures 7 and 8, the catheter 100, in particular the retrieval module
35 115, may include magnets and/or electromagnets 140 mounted on a self-expanding frame 130 which can be unsheathed to expand when in close proximity to the permanent

component 20. This frame 130 can then be controllably collapsed, for example by pulling on wires 135 connected to the magnets 140 and/or the frame 130, when magnetic engagement to the exchangeable part 30 is achieved. This causes the exchangeable part 30 to collapse with the self-expanding frame 130. Advantageously, the wire 135 may be a power cable for the electromagnets 140. Thus the wire 135 may act as a tensile element while providing an electrical connection from the electromagnet 140 to the power source (not shown) connected to the proximal end of the catheter 100. This advantageously provides a catheter which, in some cases, can magnetically couple with the exchangeable component 30, but be collapsed to the catheter body 102 using mechanical means alone if necessary. It would be apparent that the retrieval module 115 may collapse the self-expanding frame 130 using magnet forces alternatively or in addition to the mechanical means. The catheter 100 illustrated in Figures 7 and 8 may also include a deployment module 120 having a new exchangeable valve 40 that can be unsheathed in the manner described below.

[0053] The exchangeable component 30 is retained on the catheter 100 after it has been disengaged from the permanent component 20 or blood vessel 10 by the magnet or electromagnet. The exchangeable component 30 may be retained on the catheter 100 by the magnet or electromagnet that acts to hold the exchangeable component 30 on the catheter 100. In examples, the magnet or electromagnet acts to collapse the exchangeable component 30 against the body 102. The retrieval sheath 50 may be slid over the collapsed exchangeable component 30 to cover it and facilitate extraction of the catheter 100 and exchangeable component 30.

[0054] In some examples, the retrieval module 115 includes a gripping element, such as a barbed member (not shown), for gripping the retrieved exchangeable component 30 against the body 102. This provides a further means for retaining the retrieved exchangeable component 30 when retrieving the catheter 100 from the patient.

[0055] Figure 5 illustrates an alternative exemplary catheter with a body 102, a retrieval module 115, a retrieval sheath 50 and a deployment module 120. The functional and structural aspects of the catheter body 102, the retrieval sheath 50 and the retrieval module 115 are the same as those described in relation to the catheter 100 illustrated in Figures 1, 4, 7 and 8.

[0056] The deployment module 120 illustrated in Figure 5 is used to deploy a replacement exchangeable component 40 once the old or failing exchangeable component 30 has been removed from the permanent component 20. The illustrated deployment module 120 also includes a deployment sheath 42 for holding the replacement exchangeable component 40 on the body 102 until it is needed. While a deployment module 120 is advantageous, it is not essential to the function of the retrieval module 115. Similarly, a catheter may be

provided having a deployment module 120 without a retrieval module 115. Thus, the exchangeable component 30 can be deployed using a standard delivery system, or an adapted system when deployed in a coupled configuration with a permanent component 20 as described in the present application.

5 **[0057]** A catheter including both a retrieval module 115 and deployment module 120 advantageously removes the need for performing the steps of removing the catheter 100 with the failing exchangeable component 30 from the patient and then inserting a further catheter with the replacement exchangeable component 40 into the patient, as the replacement exchangeable component 40 is conveyed to the implant site at the same time
10 as the retrieval module 115. It would be apparent it is not necessary to remove the first catheter with the failing exchangeable component 30 before inserting the second catheter with the replacement exchangeable component 40, and that in some cases, it will be advantageous to simultaneously deploy both catheters. For example the two catheters may be deployed through each femoral artery. Once aligned with the permanent component 20,
15 the deployment module 120 preferably deploys the replacement exchangeable component 40 using magnetic means, for example using an electromagnet arranged to exert a radially outward magnetic force on the replacement exchangeable component 40 such that the replacement exchangeable component 40 is urged towards the permanent component 20. The exchangeable component 40 preferably includes an expanding frame 32 which opens
20 and achieves secure engagement with the permanent component 20 so that the permanent component 20 holds the replacement exchangeable component 40 in place. In some cases the replacement exchangeable component 40 includes an array of magnets for engaging with the magnetic bands 26 of the permanent component 20. Thus, the expansion of the replacement exchangeable part 40 can be aided by the magnetic attraction between the
25 magnetic bands 26 on the permanent component and the arrays of magnets on the replacement exchangeable component 40, and the radially outward force of the electromagnet of the deployment module 120. It would be apparent that when the replacement exchangeable component 40 is held by the permanent component 20 by a magnetic coupling, the anchoring forces holding the replacement exchangeable component
30 40 to the permanent component 20 can be used to enhance an anchoring force provided by the contact between the permanent component 20 and the replacement exchangeable component 40. For example, where the replacement exchangeable component 40 is designed to have a larger cross-sectional profile than the permanent component 20, this will provide an interference fit between the permanent component 20 and the replacement
35 exchangeable component 40 which will contribute to the anchoring force that restricts axial movement of the exchangeable component 30 within the aorta.

[0058] In some cases, the deployment module 120 includes an inflatable bladder or balloon (not shown) arranged to urge the replacement exchangeable component 40 towards the permanent component 20 and into engagement with the permanent component 20, such that the replacement exchangeable component 40 is held in place by the permanent component 20. Where an inflatable bladder is used to deploy the replacement exchangeable component 40, the inflatable bladder may be arranged to press the replacement exchangeable component 40 against the permanent component 20 to secure the replacement exchangeable component 40 in position. Where the permanent component 20 and the replacement exchangeable component 40 are held together by a magnetic coupling, it is not necessary for the deployment module 120 to ensure contact between the replacement exchangeable component 40 and the permanent component 20, although this may still be achieved.

[0059] In some examples, the replacement exchangeable component 40 may comprise a self-expanding frame 32, for example comprising a shape memory material. In such examples the replacement exchangeable component 40 may be held on the deployment module 120 in a collapsed state by an electromagnet of the deployment module 120, and then the electromagnet can be deactivated to release the replacement exchangeable component 40. In particular, once the electromagnet is deactivated the self-expanding frame 32 of the replacement exchangeable component 40 may expand into contact with the permanent component 20 such that the permanent component 20 holds the replacement exchangeable component 40 in position. In such examples the replacement exchangeable component 40 comprises ferromagnetic material or permanent magnets to allow the electromagnet to hold the replacement exchangeable component 40 in the collapsed state.

[0060] In some cases, the catheter 100 may be provided with a deployment module 120 without a replacement exchangeable component 40 secured thereto. Such a device may be part of a kit provided to a cardiologist so that they can select the appropriate size of replacement exchangeable component 40 for attaching to the deployment module 120 in the catheter laboratory.

[0061] It will be appreciated that in some examples there is no permanent component 30, and the deployment module 120 may deploy the replacement exchangeable component 40 into direct contact with the blood vessel 10.

[0062] Figures 6A to 6H illustrate an exemplary method of using the catheter 100.

[0063] As shown in Figures 6A and 6B, a catheter 100 having a retrieval module 115 and deployment module 120 as described above is deployed and guided into position such that the retrieval module 115 is aligned with the failing exchangeable component 30. This process can be aided using an imaging technique such as X-Ray imaging. The catheter 100

is preferably advanced into position on a guidewire through the failing exchangeable component 30 in the aortic root 10. In this position, the replacement exchangeable component 40 is sheathed on the catheter 100, and is located in the left ventricle.

[0064] The next step is to retrieve the failing exchangeable component 30 (Figure 6C).

5 This is achieved through a magnetic engagement between the retrieval module 115 and the failing exchangeable component 30 and the disengagement of the failing exchangeable component 30 and the permanent component 20. Where an electromagnet is used, the failing exchangeable component 30 is disengaged from contact with the permanent component 20 by increasing the magnetic attraction from the electromagnet over and above
10 the outward radial forces on the failing exchangeable component 30. As the failing exchangeable component 30 is disengaged from the permanent component 20, it preferably crimps or collapses as it is pulled towards the retrieval module 115 due to the magnetic force of the retrieval module 115.

[0065] Once the failing exchangeable component 30 has been disengaged from the
15 permanent component 20 and securely held by the retrieval module 115, the failing exchangeable component 30 can be withdrawn from the aortic root 10 into the aorta (Figure 6D). It is preferable to space the deployment module 120 and the retrieval module 115 such that the withdrawal of the retrieval module 115 simultaneously positions the replacement exchangeable component 40 in the correct position within the permanent component 20.

20 **[0066]** With the deployment module 120 positioned within the permanent component 20 (Figures 6E and 6F), the deployment sheath 42 is withdrawn from the replacement exchangeable component 40 and deployed in the manner described above. The replacement exchangeable component 40 may be designed not to make contact with native tissue as this minimises tissue growth onto the replacement exchangeable component 40,
25 which is undesirable.

[0067] With the replacement exchangeable component 40 held in place by the permanent component 20, the failing exchangeable component 30 can be withdrawn into the retrieval sheath 50 to reduce its cross-sectional profile (Figure 6G). The reduced cross-sectional profile allows the failing exchangeable component 30 to be withdrawn through the vascular
30 access sheath (not shown). It would be apparent that it is not necessary for the failing exchangeable component 30 to be fully crimped before it could be withdrawn into the retrieval sheath 50. The tapered profile of the conical portion 54 helps to reduce the cross-sectional profile of the failing exchangeable component 30 as it is withdrawn. In some cases, the failing exchangeable component 30 is crushed during the retrieval process. However,
35 this is not an issue, as the failing exchangeable component 30 is contained within the retrieval sheath 50.

[0068] Once the failing exchangeable component 30 is securely held in the retrieval sheath 50, for example within the neck portion 52 of the retrieval sheath 50, the catheter 100 is removed from the patient (Figure 6H). While the above method includes the deployment of a replacement exchangeable component 40, it would be apparent that the steps in relation to the deployment of the replacement exchangeable component 40 are not essential to the steps in relation to the retrieval of the failing exchangeable component 30. Similarly, if a catheter having only a deployment module 120 is to be used, the steps in relation to retrieving the failing exchangeable component 30 can be omitted.

[0069] As such, the present disclosure provides a method of retrieving a replacement heart valve component from within a blood vessel, including the steps of introducing a catheter 100 having a retrieval module 115 into the blood vessel, positioning the retrieval module 115 within the aortic root 10 to retrieve a failing exchangeable component 30, retrieving the failing exchangeable component 30 by a magnetic engagement between the retrieval module 115 and the failing exchangeable component 30. Withdrawing the catheter from the blood vessel with the failing exchangeable component 30 secured to the retrieval module 115.

[0070] While the catheter 100 has been described in relation to retrieving a replacement heart valve component from within an aortic root 10, it would be apparent the presently described catheter 100 could be used to retrieve components within any of the valves of the heart, such as the mitral valve, the tricuspid valve, or the pulmonary valve. Similarly, while the present disclosure is in relation to retrieving a replacement heart valve component, the magnetic coupling between the catheter and the replacement heart valve component may be used to retrieve any cardiovascular device from within a blood vessel, such as a stent. In particular, the catheter may have a retrieval module configured to magnetically engage a stent within the blood vessel, to disengage the stent from the blood vessel. It would be apparent that the self-expanding frames described herein are similar to those used in stents. The heart valve frame may be considered equivalent to a stent frame, with the skirt and leaflets attached thereto.

[0071] Throughout the description and claims of this specification, the words “comprise” and “contain” and variations of them mean “including but not limited to”, and they are not intended to (and do not) exclude other moieties, additives, components, integers or steps. Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

[0072] Features, integers, characteristics, or groups described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be

applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The invention is not restricted to the details of any foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS

1. A catheter for retrieving a cardiovascular device from within a blood vessel, the catheter comprising:

5 a retrieval module configured to magnetically engage a cardiovascular device within the blood vessel so as to disengage the cardiovascular device from the blood vessel for retrieval from within the blood vessel using the catheter.

2. A catheter according to claim 1, wherein the retrieval module comprises a ferromagnetic material.

10

3. A catheter according to claim 1 or 2, wherein the retrieval module comprises an electromagnet operable to generate a magnetic force.

4. A catheter according to claim 3, wherein the electromagnet is remotely operable.

15

5. A catheter according to claim 3 or claim 4, wherein the electromagnet is configured to generate a variable magnetic force.

6. A catheter according to any of claims 3 to 5, wherein the retrieval module is connectable to an external power source.

20

7. A catheter according to any preceding claim further comprising one or more gripping elements arranged to secure the retrieved cardiovascular device to the catheter.

8. A catheter according to any preceding claim further comprising a sheath slidably connected to the catheter and arranged to receive the retrieved cardiovascular device.

25

9. A catheter according to claim 8, wherein the sheath is arranged to compress the retrieved cardiovascular device in a radial direction upon receipt of the retrieved cardiovascular device.

30

10. A catheter according to claim 8 or 9, wherein the sheath comprises a tapered profile.

11. A catheter according to any of claims 8 to 10, wherein the sheath is located at a proximal position along the catheter relative to the retrieval module.

5

12. A catheter according to any preceding claim comprising displacement means for moving at least part of the retrieval module in a radially outward direction.

13. A catheter according to any preceding claim, wherein the cardiovascular device is a replacement heart valve component.

10

14. A catheter according to claim 13, wherein the magnetic coupling is configured to disengage the replacement heart valve component from a holding member arranged to hold the replacement heart valve component within the blood vessel.

15

15. A catheter according to any preceding claim further comprising a deployment module arranged to deploy a second cardiovascular device within the blood vessel.

16. A catheter according to claim 15, wherein the deployment module is located at a distal position along the catheter relative to the retrieval module.

20

17. A catheter according to claim 15 or 16, wherein the deployment module comprises an electromagnet operable to generate a magnetic force.

18. A catheter according to claim 17, wherein the electromagnet is operable to urge a magnetic portion of the second cardiovascular device in a radial direction away from the deployment module.

25

19. A catheter according to claim 17 or 18, wherein the electromagnet is operable to hold a self-expanding frame to the deployment module.

30

20. A catheter according to any of claims 15 or 16, wherein the deployment module comprises an inflatable bladder arranged such that inflation of the bladder urges the second cardiovascular device in a radial direction away from the deployment module.

5 21. A catheter according to any of claims 15 to 20 comprising the second cardiovascular device, wherein the second cardiovascular device is secured to the deployment module.

22. A catheter according to any of claims 15 to 21 when dependent on claim 14, wherein the deployment module is configured to deploy the second cardiovascular device into
10 engagement with the holding member so as to secure the second cardiovascular device within the blood vessel.

23. A catheter according to claim 22, wherein the second cardiovascular device is a second replacement heart valve component.

15

24. A catheter according to claim 23, wherein the second replacement heart valve component comprises a second magnetic portion for engaging with a corresponding magnetic portion of the holding member.

20 25. A kit of parts comprising a catheter according to any preceding claim and a cardiovascular device for use with a catheter.

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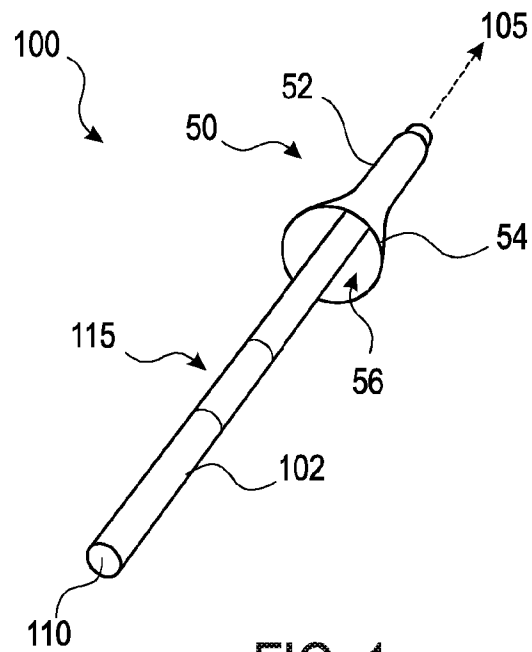


FIG. 1

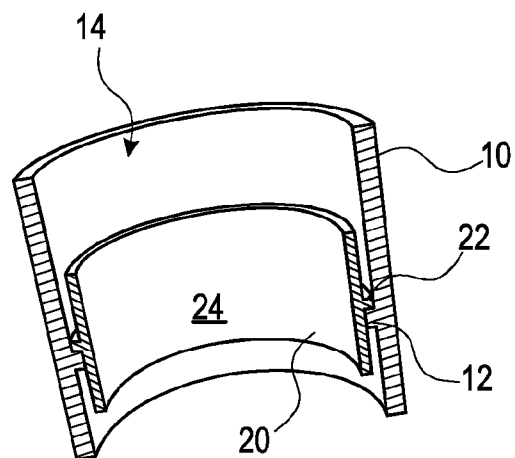


FIG. 2

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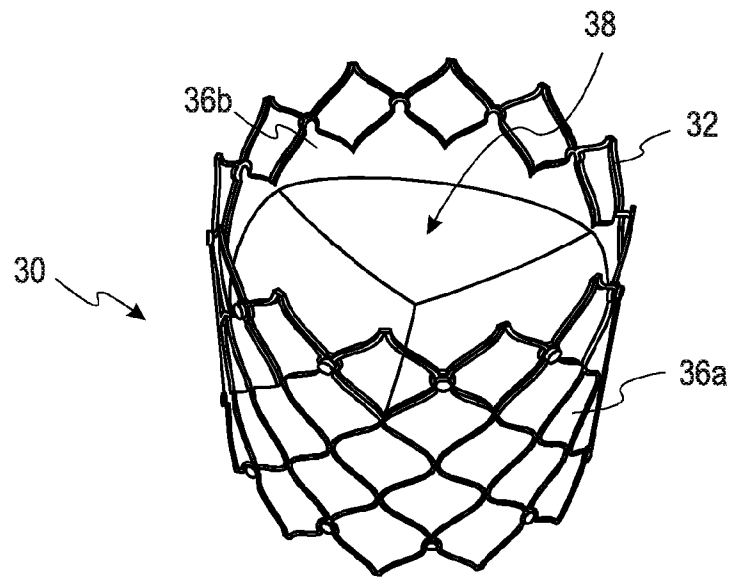


FIG. 3

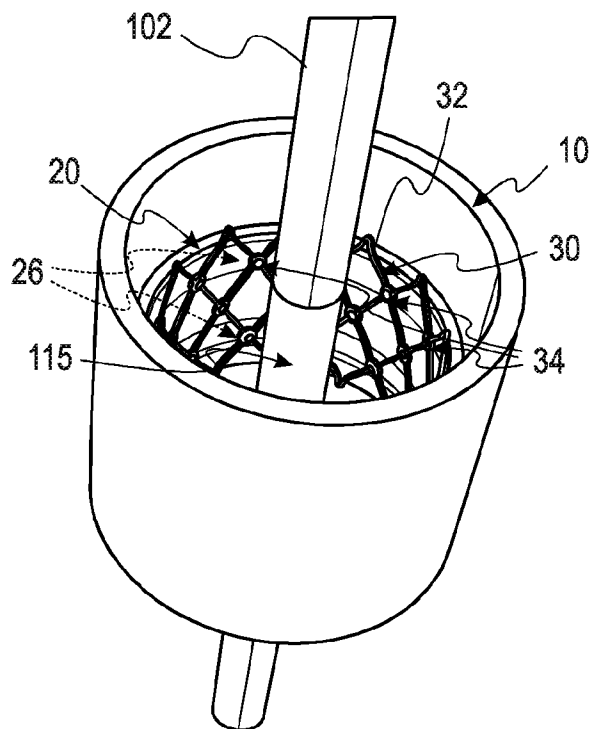


FIG. 4

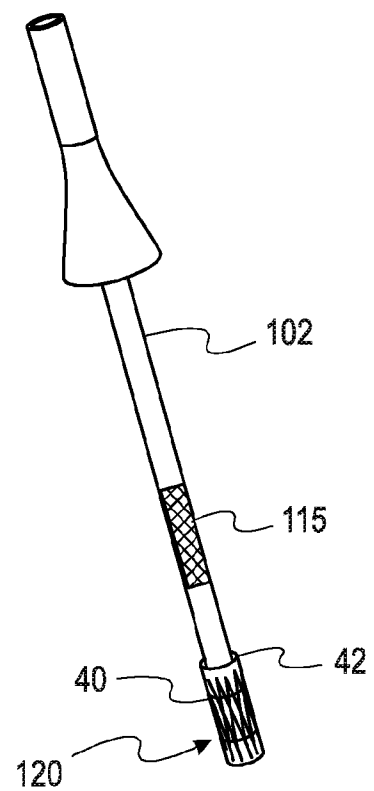


FIG. 5

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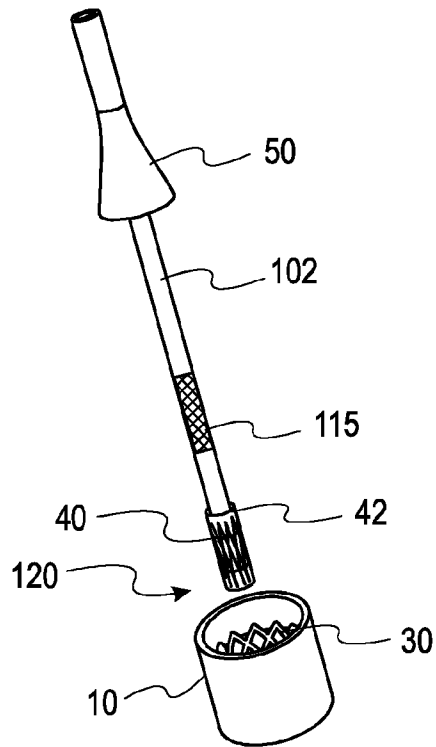


FIG. 6A

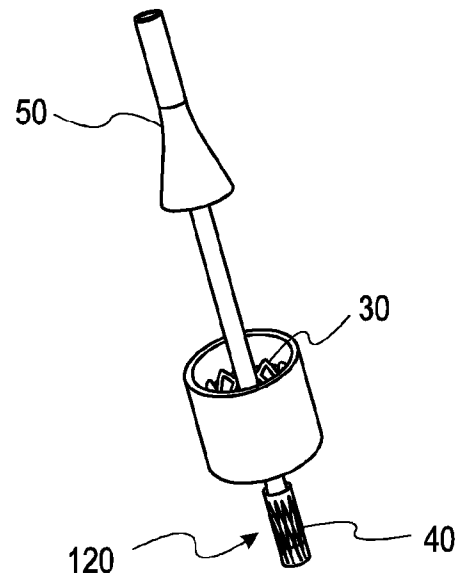


FIG. 6B

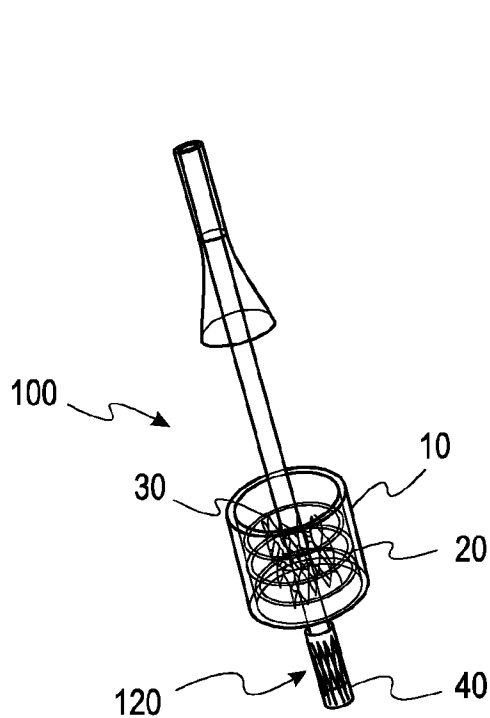


FIG. 6C

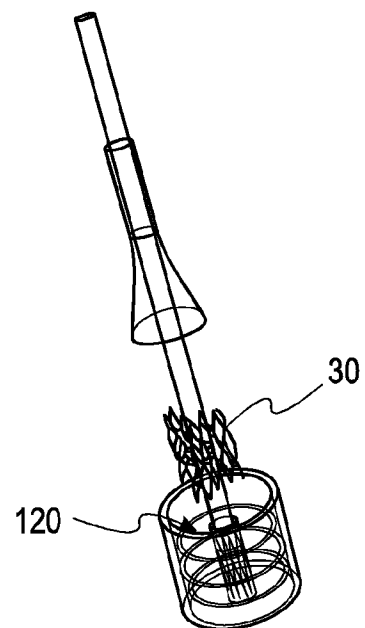


FIG. 6D

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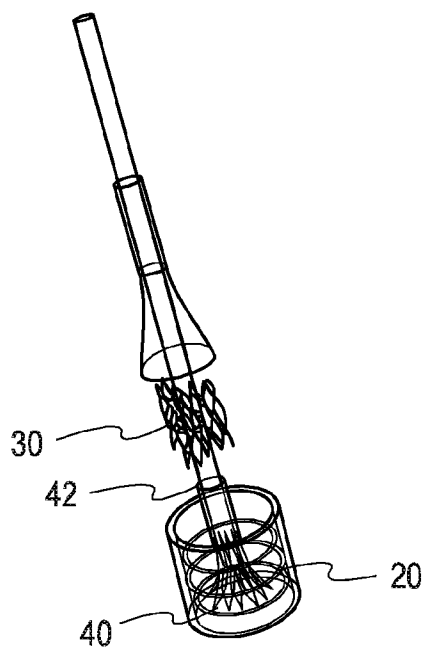


FIG. 6E

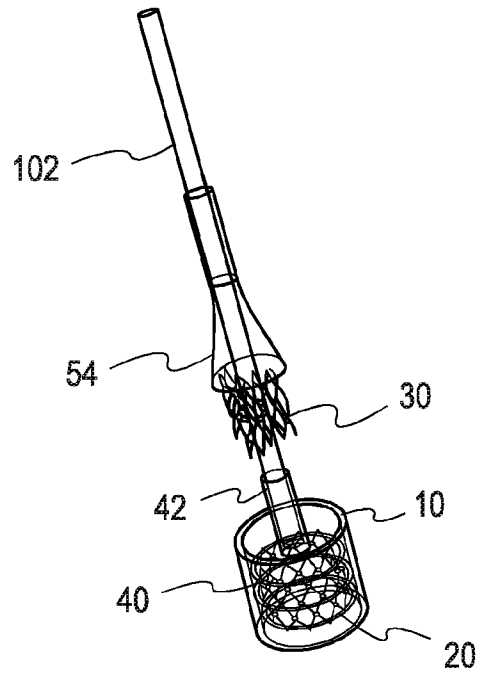


FIG. 6F

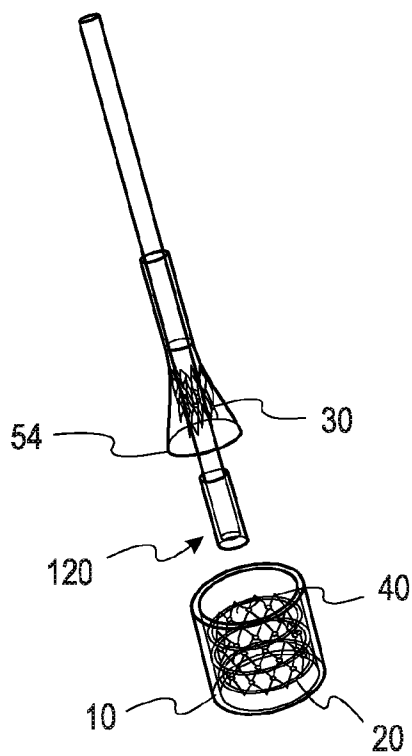


FIG. 6G

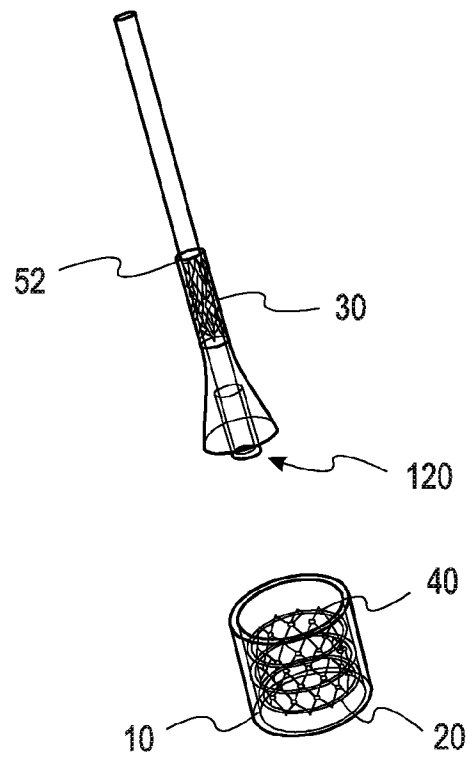


FIG. 6H

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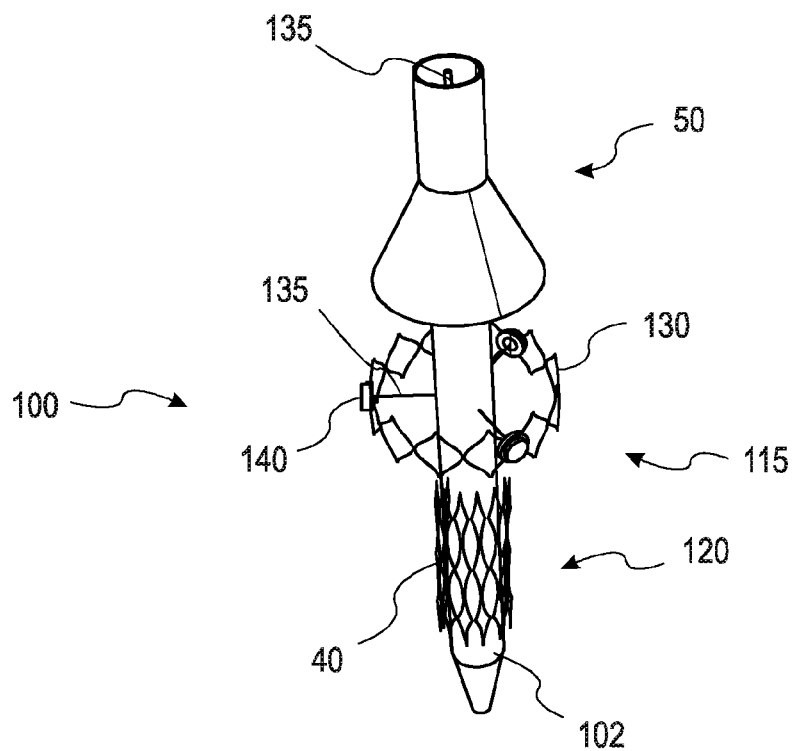


FIG. 7

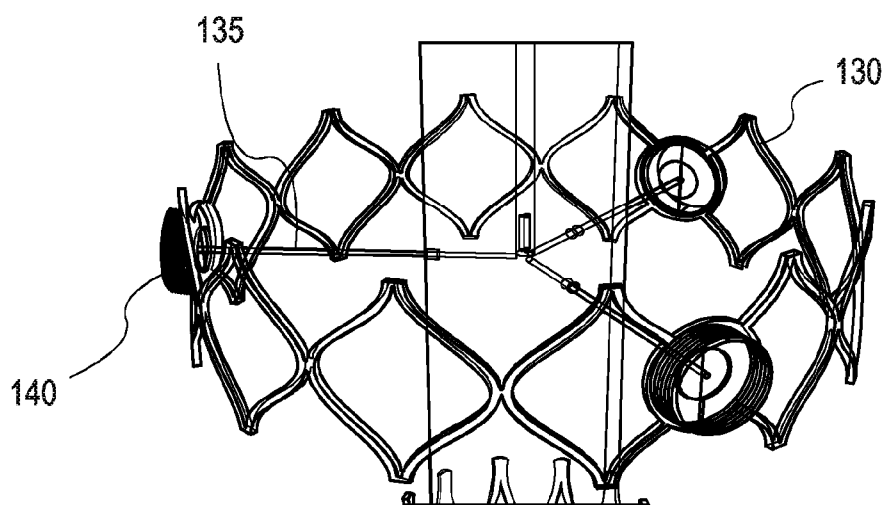


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2022/050562

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F2/24 ADD. A61F2/95		
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) A61F		
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		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/131423 A1 (YACHIA DANIEL [IL] ET AL) 16 June 2005 (2005-06-16)	1-3, 7, 13, 14, 25
Y	paragraphs [0003], [0004], [0024],	4-6
A	[0027]; figures	15-24

X	WO 2020/106827 A1 (EDWARDS LIFESCIENCES CORP [US]) 28 May 2020 (2020-05-28)	1, 7-12, 25
	paragraphs [0106], [0108] - [0110], [0115], [0168] - [0170]; figures 26-38	

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	paragraph [0117]; figure 12C	

X	US 2020/368006 A1 (GALE CAYTLIN [US] ET AL) 26 November 2020 (2020-11-26)	1, 8, 9, 11, 25
	paragraph [0074]; figures	

-/-		
☒ 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 9 May 2022	Date of mailing of the international search report 17/05/2022	
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Neumann, Elisabeth	

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2022/050562

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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