

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
31 December 2008 (31.12.2008)

PCT

(10) International Publication Number
WO 2009/003049 A2

- (51) International Patent Classification:
A61F 2/94 (2006.01) A61B 18/04 (2006.01)
A61F 2/82 (2006.01)
- (21) International Application Number:
PCT/US2008/068210
- (22) International Filing Date: 25 June 2008 (25.06.2008)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/946,101 25 June 2007 (25.06.2007) US
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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, BR, BW, BY, BZ, CA, CH, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— without international search report and to be republished upon receipt of that report

(54) Title: SELF-EXPANDING PROSTHESIS

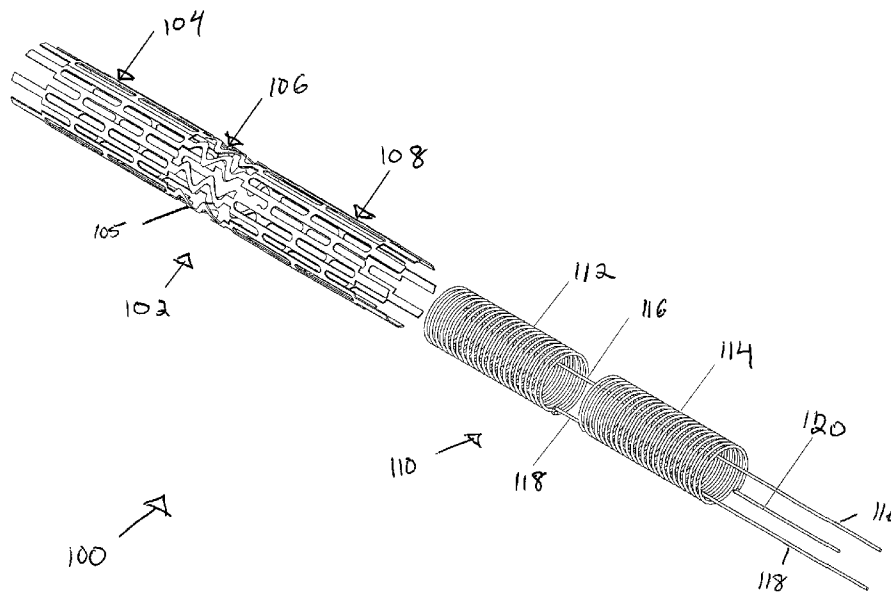


Fig 1

(57) Abstract: In one preferred embodiment, a prosthesis is provided that can be selectively expanded by increasing the temperature of the prosthesis within the patient. The prosthesis is composed of a shape memory material that expands when heated to a temperature greater than an average body temperature, allowing the user to selectively heat and therefore expand the prosthesis at a desired location.



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SELF-EXPANDING PROSTHESIS

RELATED APPLICATIONS

[0001] The present application claims benefit of U.S. Provisional Application Serial No. 60/946,101, filed June 25, 2007 entitled *Self-Expanding Prosthesis*; which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Endoprosthesis devices, more generally referred to as stents, are known in the art for treating a wide range of medical conditions. Generally, an endoprosthesis consists of a cylindrical device that can be expanded from a smaller diameter configuration to a larger diameter configuration. The smaller diameter configuration facilitates advancing the endoprosthesis through an often convoluted lumen of a patient while the expanded diameter configuration presses against the walls of the patient's lumen, often to both anchor the prosthesis and restore the patency of the lumen.

[0003] Many endoprosthesis devices can be classified according to their method of expansion. Some devices are expanded by the exertion of an outwardly directed radial force on an inner surface of the endoprosthesis. For example, the endoprosthesis may be compressed or crimped over a deflated balloon of a balloon catheter. When the endoprosthesis is positioned at a desired target area, the balloon is inflated, expanding the endoprosthesis.

[0004] Other endoprosthesis devices are self-expanding and therefore recover to an expanded position after being compressed. For example, some self-expanding endoprosthesis devices are composed of a shape memory material such as Nitinol (Ni—Ti alloy). The shape memory material allows the device to be compressed within a delivery catheter, yet expand in diameter when released within the lumen of a patient, similar to a spring. For some applications, self-expanding endoprosthesis devices are thought to be superior to balloon expandable devices since self-expanding devices often require less elaborate delivery mechanisms (e.g., no inflatable balloons) and are often less likely to be damaged after deployment (e.g., by being crushed or otherwise

permanently deformed). Examples of prior art shape memory device can be seen in U.S. Pat. No. 4,665,905 to Jervis and U.S. Pat. No. 4,925,445 to Sakamoto et al., the contents of which are hereby incorporated by reference.

[0005] However, delivery systems for self-expanding endoprosthesis devices are not without their drawbacks. For example, one common delivery system includes a catheter having a retractable sheath. The endoprosthesis device is preloaded onto a reduced diameter region on a distal end of the catheter. The retractable sheath is positioned over the device, preventing it from expanding in diameter. When a desired target location is reached by the device, the user retracts the outer sheath, releasing the self-expanding device. However, the self-expanding force can cause the device to spring laterally out of the sheath, sometimes missing the desired target area. Further, the device may tend to become imbedded within the wall of the sheath, resulting in damage to the device or the device becoming stuck. Additional delivery system details can be found in U.S. Pat. Nos. 4,580,568 and 4,732,152, the contents of which are hereby incorporated by reference.

[0006] Accordingly, there is a need for a self-expanding endoprosthesis delivery system which overcomes the disadvantages of the prior art.

OBJECTS AND SUMMARY OF THE INVENTION

[0007] It is an object of the present invention to overcome the disadvantages of the prior art.

[0008] It is another object of the present invention to provide a prosthesis delivery system that can more predictably release a prosthesis within a patient.

[0009] It is another object of the present invention to provide a prosthesis delivery system that reduces unwanted complications during delivery of the prosthesis within the patient.

[0010] The present invention seeks to achieve these objects by providing a prosthesis that can be selectively expanded. In one preferred embodiment, the prosthesis is composed of a shape memory material that expands when heated to a

temperature greater than an average body temperature. When a heater positioned inside of the prosthesis is activated, the shape memory material of the prosthesis expands to a predetermined shape.

[0011] In another preferred embodiment, electrical current is directly supplied to the prosthesis with electrical leads, causing the body of the prosthesis itself to heat up and thereby expand in diameter. Once expanded, the electrical leads are detached from the prosthesis and removed from the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Figure 1 illustrates a disassembled perspective view of a prosthesis deployment system according to a preferred embodiment of the present invention;

[0013] Figure 2 illustrates an assembled perspective view of the prosthesis deployment system of Figure 1;

[0014] Figure 3 illustrates a perspective view of a prosthesis deployment system according to another preferred embodiment of the present invention;

[0015] Figure 4 illustrates a differential scanning calorimetry (DSC) graph of an example shape memory material according to a preferred embodiment of the present invention;

[0016] Figure 5 illustrates a side view of the prosthesis of Figure 1 for use in treating an aneurysm; and

[0017] Figure 6 illustrates a side view of the prosthesis of Figure 1 with a prosthesis coil for use in treating an aneurysm.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Referring to Figures 1 and 2, a prosthesis deployment system 100 is shown according to a preferred embodiment of the present invention. This deployment system 100 includes a prosthesis 102 (e.g., a stent) which can be selectively expanded within a lumen of a patient by activating a heater 110. Due to its composition, the prosthesis 102

expands in diameter when heated to a predetermined temperature and remains expanded at the patient's body temperature. In this respect, the deployment system 100 allows a user to determine when the prosthesis 102 expands in diameter within the patient.

[0019] Preferably, the prosthesis 102 is composed of a shape memory material, such as Nitinol, which changes phases from a Martensitic state to an Austenitic state. In the Martensitic state, the prosthesis 102 maintains ductile properties which can be especially useful when delivering the prosthesis 102 through tortuous vessels within a patient. In the Austenitic state, the prosthesis 102 expands in diameter to a larger predetermined shape while becoming more rigid.

[0020] Referring to Figure 4, a differential scanning calorimetry (DSC) graph is shown of an example shape memory material. The transformation temperature range from the Martensitic state of the shape memory material to the Austenitic state begins with the Active Austenite Start Temperature (A_S) and completes with the Active Austenite Finish Temperature (A_F). Similarly, the transformation temperature range from the Austenitic state to the Martensitic state begins with the Active Martensite Start Temperature (M_S) and completes with the Active Martensite Finish Temperature (M_F). As seen in the Figure, the Austenitic temperature range is generally higher than the Martensitic temperature range.

[0021] Typical self expanding stents of the prior art have an A_F of 37°C or less to ensure that the stent expands when delivered to a desired target location within the patient. However, the prosthesis of a preferred embodiment according to the present invention has an A_S and A_F above 37°C while the M_F and the M_S remain below this temperature. Thus, the prosthesis 102 can be delivered to a target location in its flexible Martensite state, heated to transition to its expanded Austensite state (e.g., a preset shape having a larger diameter), then allowed to cool to 37°C where the prosthesis remains in its expanded Austensite state. In other words, the prosthesis 102 can be selectively expanded by simply heating.

[0022] The desired transition temperatures can, for example, be obtained from either the Ingot Active temperature or via heat treatment.

[0023] Preferably, the A_F is above 37°C and more preferably is within the range of about 40°C and about 55°C. For example, the A_S of the prosthesis material is about 45°C and the A_F is about 55°C.

[0024] As best seen in the disassembled view of Figure 1, the delivery system 100 includes a heater 110 which is composed of a highly resistive material which produces heat when current is passed through it. Figure 2 illustrates an assembled view of the heater 110 positioned inside of the unexpanded prosthesis 100. When the prosthesis 102 is positioned at a desired target location within a patient, the user applies current to the heater 110, causing the heater 110 and therefore the prosthesis 102 to increase in temperature. As the prosthesis 102 reaches its A_F temperature, the prosthesis 102 expands in diameter against the walls of the patient's lumen. Thus, the user can first position the prosthesis 102 at a desired location in the lumen, and then cause the prosthesis 102 to expand. Further, if the user is unsatisfied with the initial position of the prosthesis 102, it may be recaptured prior to expansion and redeployed at a more desirable location.

[0025] In the present preferred embodiment, the prosthesis 102 includes a first section 104 and a second section 108 connected by an intermediate section 106. While the first and second sections 104 and 108 are preferably composed of axially and radially interconnecting segments, the intermediate section 106 includes only axially arranged members 105 which allow each section 104 and 108 to expand independently of the other. Preferably the intermediate section 106 is unitary with and therefore the same material as the first and second sections 104 and 108. However, the intermediate section 106 may also be composed of a different material, such as a polymer, to further facilitate independent expansion of the two sections 104 and 108.

[0026] The heater 110 has matching segments in the form of a first heating coil 112 and a second heating coil 114 that are positioned within sections 104 and 108 respectively. Wires 116 and 118 supply current to the first heating coil 112 while wires 120 and 118 (electrically connected to both coils 112 and 114) provide current to the second heating coil 114. Thus, each coil 112 and 114 can be heated independently of the other which ultimately allows each section 104 and 108 of the prosthesis 102 to be

expanded independently of each other. Further discussion of a similar heating mechanism can be found in U.S. Publication Number 2006/0052815, the contents of which are hereby incorporated by reference.

[0027] Preferably, the heater 110 is provided with enough current to reach a temperature equal to or greater than the transition temperature of the shape memory material of the prosthesis 102. However, it is also preferred that the max temperature and duration of heat be limited so as to prevent or minimize further damage to the patient's lumen. Additionally, the prosthesis 102 may be covered with a thin film such as a heat shrink tubing as to limit the heat exposure to the patient's lumen.

[0028] The independent expansion of sections 104 and 108 of the prosthesis 102 may allow the user to more precisely position the prosthesis 102 at a target location within a patient. For example, once the prosthesis is located at a desired target location, the user may first expand the distal first section 104 to provide an initial anchor point, and then expand the proximal second section 108. Since many prior art self expanding stents tend to shrink in length as they increase in diameter, their final position can be difficult to predict during the delivery. However, by expanding one section 104 or 108 first, the ultimate expanded position of the prosthesis 102 can be deployed to a more predictable position.

[0029] While only two sections 104 and 108 are illustrated in the present preferred embodiment, additional sections are also possible. For example, the prosthesis 102 may have 3 or 4 sections and an equal number of corresponding coils for heating each section of the prosthesis 102.

[0030] In operation, the prosthesis deployment system 100 is used to deploy the prosthesis 102 by initially passing a guidewire into the patient so that a distal end of the guidewire is positioned at a target area. A catheter or microcatheter containing both the heater 110 and the prosthesis 102 is slid over the guidewire until a distal end of the catheter reaches the desired target area of the patient's lumen. Since the prosthesis 102 is in its martensitic state, it remains relatively flexible and therefore can easily pass through tortuous passageways to reach the target area.

[0031] Once the distal end of the catheter reaches the target area, an outer sheath (if present) is retracted to expose the prosthesis 102. If the user is unsatisfied with the position of the prosthesis 102, the prosthesis 102 can optionally be recaptured by the outer sheath (again, if present) and advanced or retracted until a desired position has been achieved. The user then expands the distal first section 104 of the prosthesis 102 by causing the first heater coil 112 to increase in temperature and thereby changing the phase of the first section 104 from Martensitic to Austenitic (i.e. causing the first section 104 to move to its predetermined expanded configuration). Next, the user expands the proximal second section 108 by causing the second heater coil 114 to increase in temperature, thereby changing the phase of the second section 108. Finally, the user may confirm the final position of the prosthesis 102 (e.g., by radio fluoroscopy) and remove the catheter. In some cases, the user may prefer not to expand the proximal second section 108.

[0032] Referring now to Figure 3, another preferred embodiment of a self-heating prosthesis 200 is illustrated according to the present. The self-heating prosthesis 200 is similar to the previously described prosthesis 102, having a first section 202 and a second section 204 connected by an intermediate section 206 which facilitates each of the sections 202 and 204 to expand independently of each other.

[0033] However, the self-heating prosthesis 200 is directly connected to wires 208, 210 and 212, which selectively provide current to increase the temperature of the prosthesis 200. More specifically, wire 212 is connected to a distal end of the first section 202 while wire 208 is connected to the intermediate section 206. When a current passes through these wires 212 and 208, it also passes through the first section 202, thereby increasing its temperature. In this respect, the prosthesis itself acts as a heating element, similar to the previously described heater coils. As with the previously described prosthesis 102, when the first section 202 passes the A_S temperature it begins to expand until it reaches the A_F temperature.

[0034] Additionally, a wire 210 is connected to a proximal end of the second section 204 which allows current to selectively flow between wires 210 and 208, passing through the second section 204. Thus, the temperature of the second section 204

similarly increases, ultimately causing it to pass into an expanded Austenite state. In this respect, the user can control which of the sections 202 or 204 increase in temperature and therefore expand by passing current through either wires 212 and 208 or 210 and 208.

[0035] After both sections 202 and 204 have been expanded, the wires 208, 210 and 212 are disconnected from the prosthesis 200. For example, these wires 208, 210 and 212 may have a heat sensitive connection which becomes disconnected when heated to a predetermined temperature. Alternately, the wires 208, 210 and 212 may have hooks or latching mechanisms that allow selective disconnection and removal by the user.

[0036] While electrical current is preferably used to generate heat and therefore expand the prosthesis according to the present invention, other forms of energy may also be used. For example, RF current may be used. In another example hot liquid may be delivered to the prosthesis. In yet another example, a heat-generating chemical reaction may be used.

[0037] It should be understood that the present invention, including the previously described preferred embodiments, can be used for a variety of treatments, techniques and procedures within a patient's body.

[0038] Figure 5 illustrates one such example treatment for an aneurysm 152 in which the prosthesis 102 is positioned over the opening of the aneurysm 152 in a vessel 150. Once in place, tissue growth of endothelial cells is promoted (e.g., either with the prosthesis 102 alone or with tissue growth promoting agents) which ultimately results in a layer of tissue that closes of the aneurysm 152.

[0039] Figure 6 illustrates a similar example in which an aneurysm 152 is treated with both a prosthetic coil 160 and the prosthesis 102. More specifically, the prosthetic coil 160 is delivered into the aneurysm 152 while the prosthesis 102 is delivered over the opening of the aneurysm 152 to prevent the prosthetic coil 160 from moving into the vessel 150. Additional details regarding the use of the prosthetic coil can be found in the previously incorporated U.S. Publication Number 2006/0052815.

[0040] One preferred embodiment according to the present invention includes a method of expanding a prosthesis within a body comprising providing a prosthesis comprising a shape memory material; delivering the prosthesis to a desired location within a body; increasing a temperature of the prosthesis above a human body temperature to change a phase of the shape memory material, thereby expanding the prosthesis to an expanded state; decreasing the temperature of the prosthesis to the human body temperature while maintaining the expanded state.

[0041] In a further example of this preferred embodiment, the expanding the prosthesis further comprises expanding a diameter of the prosthesis.

[0042] In a further example of this preferred embodiment, the increasing a temperature further comprises changing the phase of the shape memory material from a martensitic state to an austenitic state.

[0043] In a further example of this preferred embodiment, the expanding the prosthesis to an expanded state further comprising: expanding a first segment of the prosthesis; and expanding a second segment of the prosthesis.

[0044] In a further example of this preferred embodiment, the expanding the prosthesis further comprises producing heat adjacent to the prosthesis.

[0045] In a further example of this preferred embodiment, the expanding the prosthesis further comprises producing heat with the prosthesis.

[0046] In a further example of this preferred embodiment, the delivering the prosthesis to a desired location within a body further comprises: locating an aneurysm; and positioning the prosthesis over an opening of the prosthesis.

[0047] In a further example of this preferred embodiment, providing a prosthesis comprising a shape memory material is followed by delivering a prosthetic coil within the aneurysm.

[0048] Another preferred embodiment according to the present invention includes a prosthesis for deploying within a human body comprising a prosthesis body having a

first predetermined shape while in a first phase and a second predetermined shape while in a second phase; wherein a transition from the first phase to the second phase occurs at a temperature above a human body temperature and wherein a transition from the second phase to the first phase occurs at a temperature below the human body temperature.

[0049] In a further example of this preferred embodiment, the prosthesis body comprises a shape memory material.

[0050] In a further example of this preferred embodiment, the first phase is an austenitic state and the second state is a martensitic state.

[0051] In a further example of this preferred embodiment, the prosthesis includes an active austenite start temperature and an active austenite finish temperature above 37°C.

[0052] In a further example of this preferred embodiment, the active austenite finish temperature is within a range of about 40°C and about 55°C.

[0053] In a further example of this preferred embodiment, the prosthesis body further comprises a first segment and a second segment wherein the first segment is independently expandable relative to the second segment.

[0054] In a further example of this preferred embodiment, the prosthesis comprises a tubular shape having an interior diameter; the diameter having a first length during the first predetermined shape and a second, increased length during the second predetermined shape.

[0055] Another preferred embodiment according to the present invention includes a prosthesis delivery system comprising a delivery tool shaped to enter a body; and a prosthesis removably disposed on the delivery tool; the prosthesis including a first shape-memory configuration and a second shape-memory configuration; the prosthesis transitioning from the first shape-memory configuration to the second shape-memory configuration at a temperature above about 37°C; wherein the delivery tool selectively heats the prosthesis within the body.

[0056] A further example of this preferred embodiment comprises at least one heating element disposed on the delivery tool.

[0057] In a further example of this preferred embodiment, the delivery tool selectively delivers electrical current to the prosthesis.

[0058] In a further example of this preferred embodiment, the prosthesis further comprises a plurality of independently expandable regions and wherein the delivery tool further comprises a plurality of individually actuable heaters.

[0059] In a further example of this preferred embodiment, each of the plurality of independently expandable regions is disposed over a corresponding heater of the plurality of individually actuable heaters.

[0060] In another example of a preferred embodiment of the present invention, the prosthesis is tubular. More specifically, the prosthesis material is made from a laser-cut tube or is a tube formed by braided fibers or members.

[0061] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A method of expanding a prosthesis within a body comprising:
providing a prosthesis comprising a shape memory material;
delivering the prosthesis to a desired location within a body;
increasing a temperature of the prosthesis above a human body temperature to change a phase of the shape memory material, thereby expanding said prosthesis to an expanded state;
decreasing said temperature of the prosthesis to the human body temperature while maintaining said expanded state.
2. The method of claim 1, wherein said expanding said prosthesis further comprises expanding a diameter of said prosthesis.
3. The method of claim 1, wherein said increasing a temperature further comprises changing the phase of the shape memory material from a martensitic state to an austenitic state.
4. The method of claim 1, wherein said expanding said prosthesis to an expanded state further comprises: expanding a first segment of said prosthesis; and expanding a second segment of said prosthesis.
5. The method of claim 1, wherein said expanding said prosthesis further comprises producing heat adjacent to said prosthesis.
6. The method of claim 1, wherein said expanding said prosthesis further comprises producing heat with said prosthesis.
7. The method of claim 1, wherein said delivering said prosthesis to a desired location within a body further comprises:
locating an aneurysm; and
positioning said prosthesis over an opening of said aneurysm.

8. The method of claim 1, wherein said providing a prosthesis comprising a shape memory material is followed by delivering a prosthetic coil within said aneurysm.
9. A prosthesis for deploying within a human body, comprising:
 - a prosthesis body having a first predetermined shape while in a first phase and a second predetermined shape while in a second phase;
 - wherein a transition from said first phase to said second phase occurs at a temperature above a human body temperature; and,
 - wherein a transition from said second phase to said first phase occurs at a temperature below said human body temperature.
10. The prosthesis of claim 9, wherein said prosthesis body comprises a shape memory material.
11. The prosthesis of claim 9, wherein said first phase is an austenitic state and said second state is a martensitic state.
12. The prosthesis of claim 9, wherein said prosthesis further comprises an active austenite start temperature and an active austenite finish temperature above 37°C.
13. The prosthesis of claim 12, wherein said active austenite finish temperature is within a range of about 40°C and about 55°C.
14. The prosthesis of claim 9, wherein said prosthesis body further comprises a first segment and a second segment, wherein said first segment is independently expandable relatively to said second segment.
15. The prosthesis of claim 14, wherein said prosthesis further comprises a tubular shape having an interior diameter; said diameter having a first length during said first predetermined shape and a second, increased length during said second predetermined shape.

16. A prosthesis delivery system comprising:
a delivery tool shaped to enter a body; and,
a prosthesis removably disposed on said delivery tool;
said prosthesis including a first shape-memory configuration and a second shape-memory configuration; the prosthesis transitioning from said first shape-memory configuration to said second shape-memory configuration at a temperature above about 37°C;
wherein said delivery tool selectively heats said prosthesis within said body.
17. The prosthesis delivery system of claim 16, further comprising at least one heating element disposed on said delivery tool.
18. The prosthesis delivery system of claim 16, wherein said prosthesis further comprises a plurality of independently expandable regions wherein the delivery tool further comprises a plurality of individually actuatable heaters.
19. The prosthesis delivery system of claim 18, wherein each of said plurality of independently expandable regions are disposed over a corresponding heater of the plurality of individually actuatable heaters.

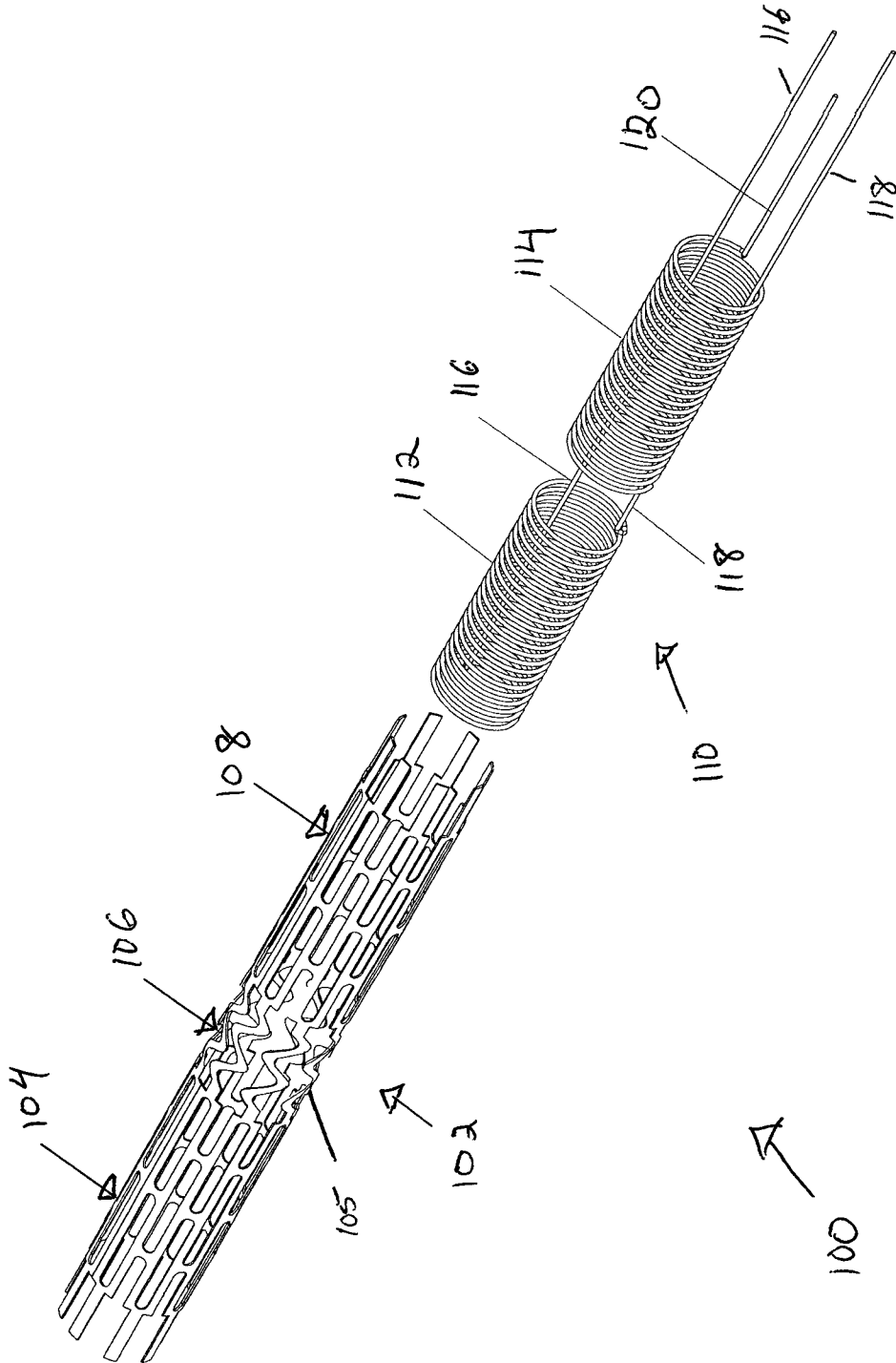


Fig 1

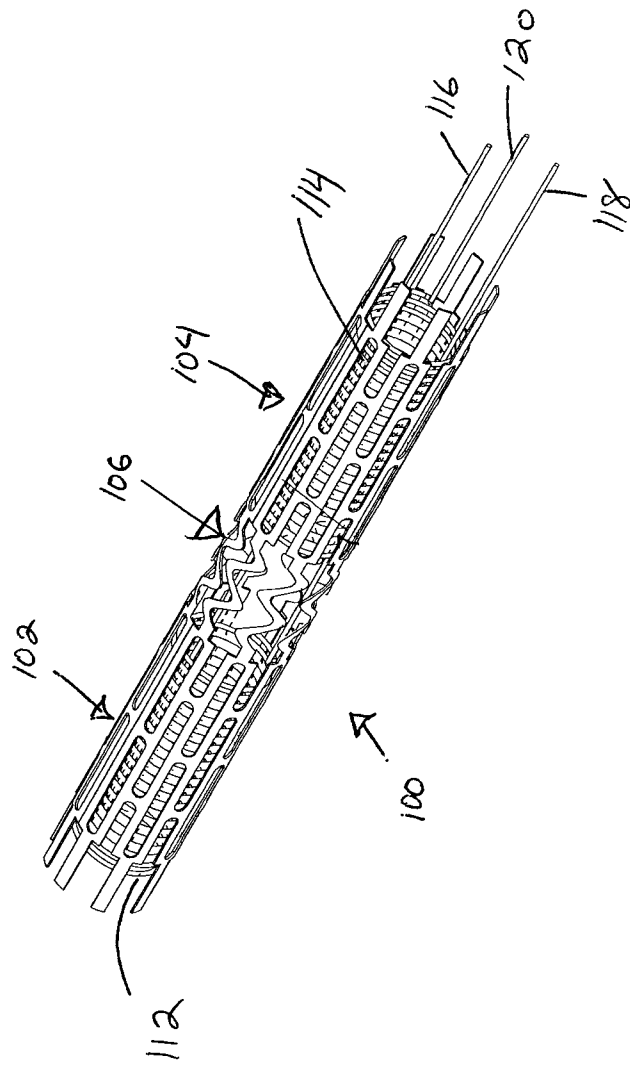


Fig. 2

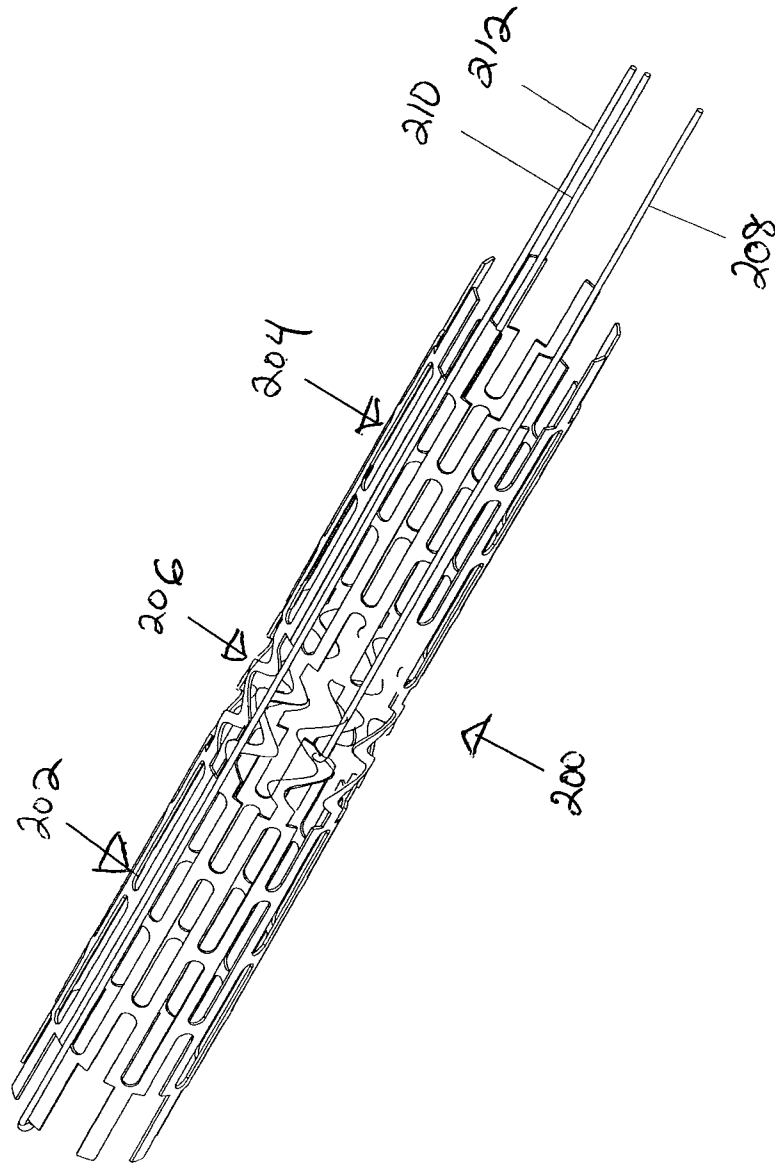


Fig 3

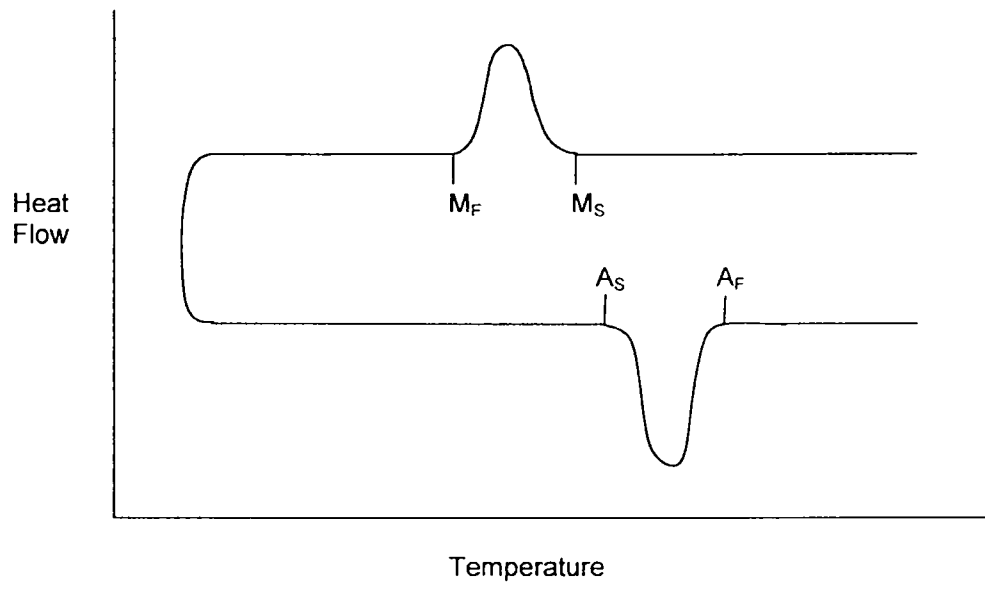


Fig 4

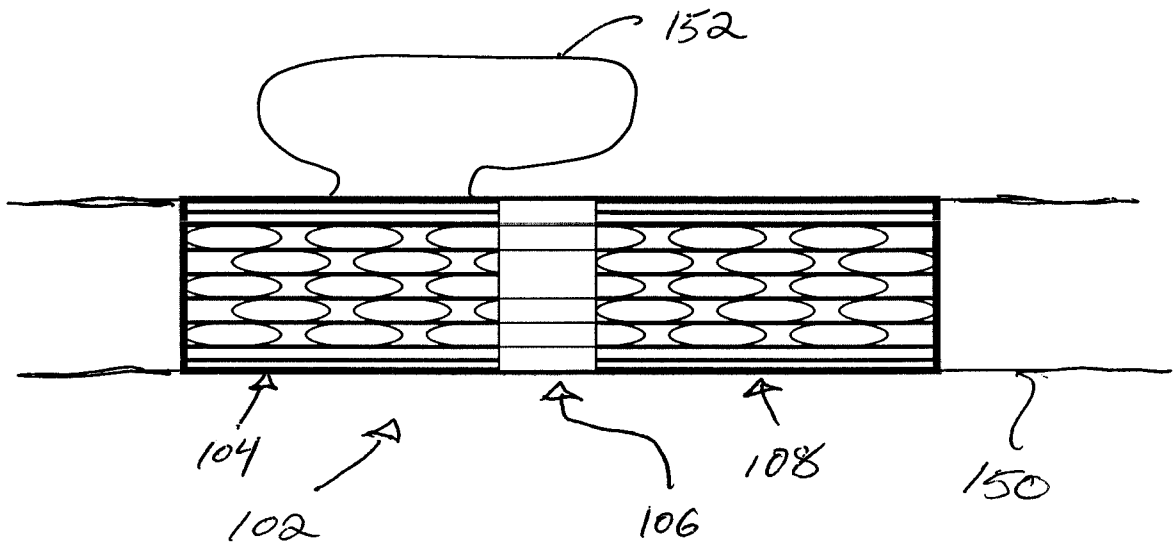


Fig 5

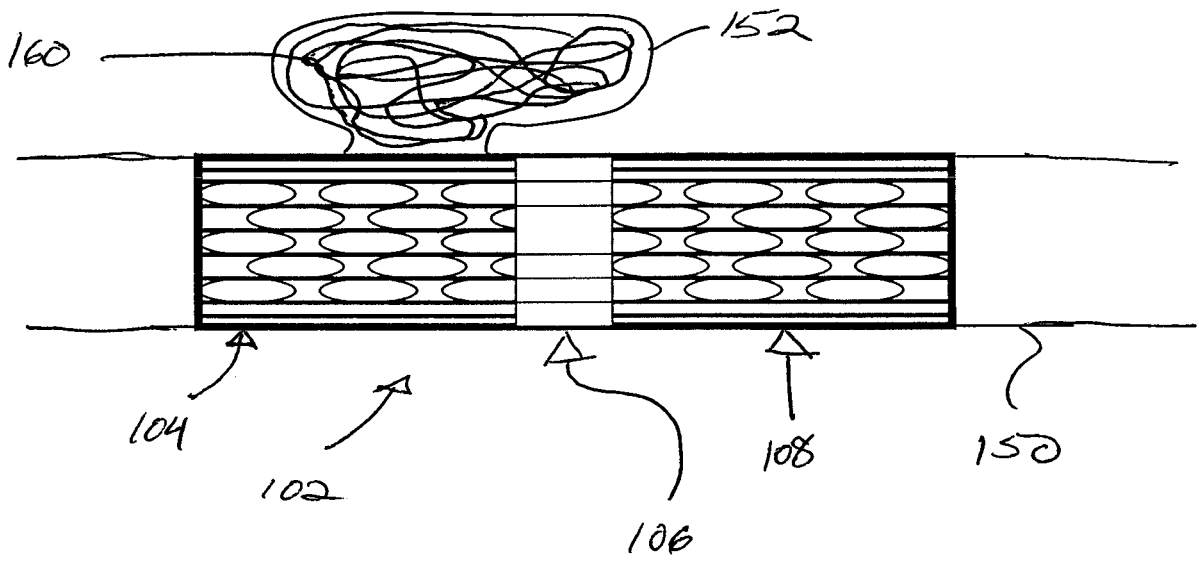


Fig 6