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(54) **STENT SPACER**

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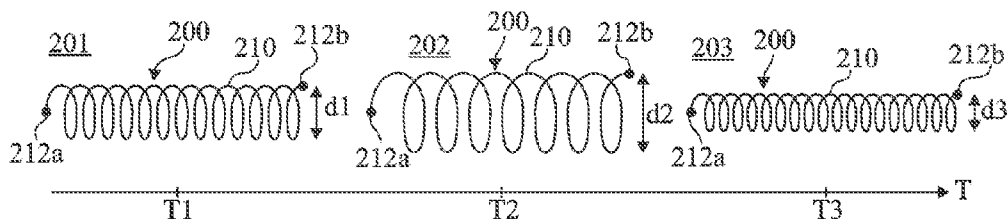
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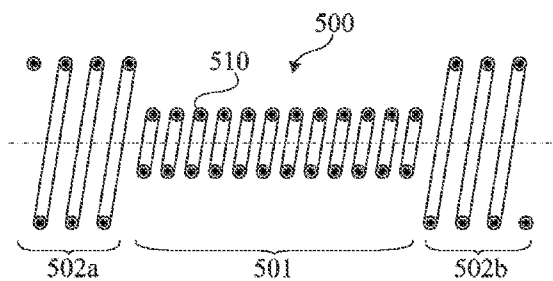
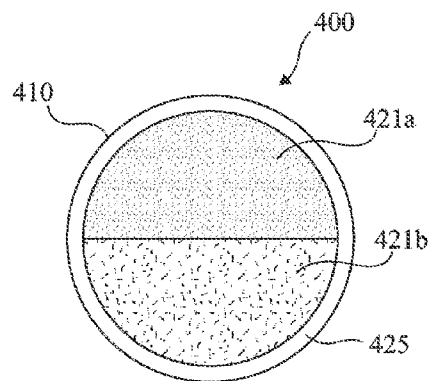
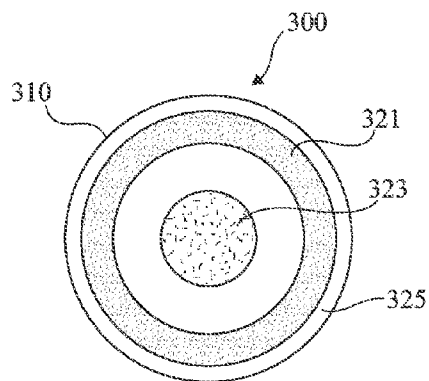
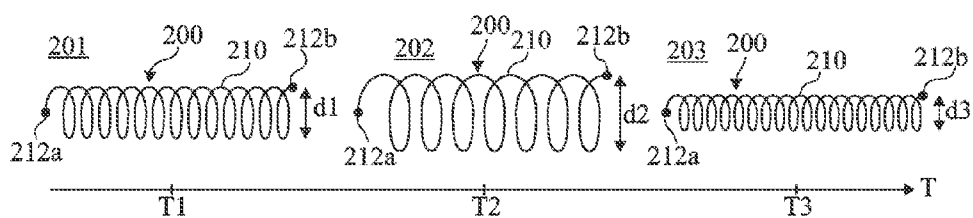
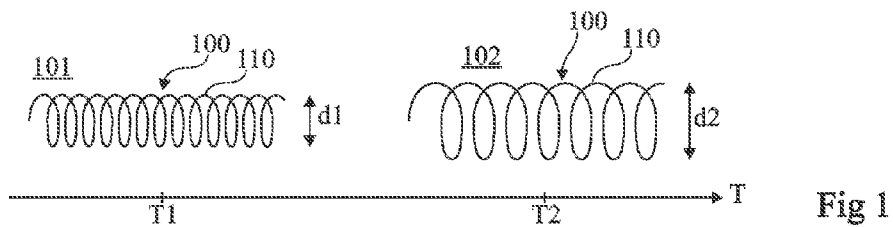
(57) **ABSTRACT**

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A spacer including a first part made from a first shape memory material, and a second part made from a second shape memory material.

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STENT SPACER

[0001] The present patent application claims the priority benefit of French patent application FR13/55935 which is herein incorporated by reference.

BACKGROUND

[0002] The present application generally relates to the field of spacers or extensors, and more particularly aims at the field of vascular or urethral retractors usually called stent in the art.

DISCUSSION OF THE RELATED ART

[0003] To maintain open and/or enlarge the lumen of certain ducts or vessels of the human body narrowed or obstructed by diseases, it is known to insert into the duct a tubular prosthesis usually called stent. During a phase of positioning the stent in the duct, the stent is in a contracted configuration where its diameter is much smaller than the duct diameter, which enables it to freely displace within the duct. Once the stent has been positioned at the desired location, a step of stent expansion, during which the stent is radially stretched to a diameter of the same order as that of the duct, or even slightly greater than that of the duct, to enlarge the opening of the narrowed area of the duct. The stent may be left in place for the time necessary to treat the causes of the duct narrowing. In many cases, it should however be removed after the treatment.

[0004] A disadvantage of known stents is that their removal is relatively complex and may cause lesions of the duct.

SUMMARY

[0005] An object of an embodiment is to provide a stent overcoming all or part of the disadvantages of known stents.

[0006] An object of an embodiment is to provide a stent simpler to extract from a duct than known stents.

[0007] Thus, an embodiment provides a stent comprising a first portion made of a first shape-memory material, and a second portion made of a second shape-memory material.

[0008] According to an embodiment, the first shape-memory material has a first activation temperature, and the second shape-memory material has a second activation temperature higher than the first temperature.

[0009] According to an embodiment, the first and second portions are arranged so that the stent takes a first configuration when the first material is activated, and a second configuration when the second material is activated.

[0010] According to an embodiment, the first shape-memory material is a superelastic material, and the second shape-memory material memorizes a thermally-activatable shape.

[0011] According to an embodiment, the first and second portions are arranged so that the stent takes a first configuration when the second material is not activated, and a second configuration when the second material is activated.

[0012] According to an embodiment, at least one section of the stent has an approximately generally cylindrical shape having a first diameter in the first configuration and a second diameter smaller than the first diameter in the second configuration.

[0013] According to an embodiment, the first and second portions are part of a same filiform element of generally helical shape.

[0014] According to an embodiment, the filiform element has the shape of a diabolo.

[0015] According to an embodiment, the first portion is a hollow wire, and the second portion is a wire of smaller diameter arranged within the hollow wire.

[0016] According to an embodiment, the first and second portions are separate areas of the cross-section of a same wire.

[0017] According to an embodiment, the first and second shape-memory materials are alloys based on nickel and on titanium.

[0018] According to an embodiment, the stent comprises contact terminals enabling to apply an electric current in the first and/or second portions.

[0019] According to an embodiment, the stent further comprises a silicone coating.

[0020] Another embodiment provides a method of using the above-mentioned stent, comprising a step of positioning the stent in a duct or a cavity in a first configuration at a temperature lower than the activation temperature of the second shape-memory material.

[0021] According to an embodiment, the method further comprises a step of heating the stent to the second temperature, followed by a step of removing the stent from the duct or the cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The foregoing and other features and advantages will be discussed in detail in the following non-limiting description of specific embodiments in connection with the accompanying drawings, among which:

[0023] FIG. 1 schematically shows the operation of an example of a stent;

[0024] FIG. 2 schematically shows the operation of an embodiment of a stent;

[0025] FIG. 3 is a partial cross-section view illustrating in further detail a preferred embodiment of a stent compatible with the operation of FIG. 2;

[0026] FIG. 4 is a partial cross-section view illustrating in further detail another embodiment of a stent compatible with the operation of FIG. 2; and

[0027] FIG. 5 is a cross-section view illustrating an example of the general shape that a stent of the type described in relation with FIGS. 2 to 4 may have.

[0028] For clarity, the same elements have been designated with the same reference numerals in the different drawings. Further, only those elements which are useful to the understanding of the present invention have been shown and will be described. In particular, the tools capable of being used to place and/or remove a stent have neither been described in detail nor shown, the described embodiments being compatible with usual stent placing and removal tools, or the forming of stent placing and removal tools compatible with the described embodiments being within the abilities of those skilled in the art.

DETAILED DESCRIPTION

[0029] It has already been provided to form a stent made of a shape-memory material, that is, a material having the ability of memorizing a shape and, after a deformation, of almost instantaneously returning thereto when its temperature exceeds a transition or activation temperature.

[0030] FIG. 1 schematically shows the operation of a shape-memory stent. Stent 100 of FIG. 1 comprises a con-

tinuous wire **110** of helical shape made of a shape-memory material, for example, a nickel-titanium alloy, having an activation temperature T_2 .

[0031] Before a phase of inserting the stent into a duct (not shown), the stent is shaped in a configuration **101** where the stent has a generally cylindrical shape of diameter d_1 smaller than the normal diameter of the duct, that is, than the diameter of the duct in the absence of a narrowing due to a disease. The stent is inserted into the duct in configuration **101** and positioned at the desired location, for example, by means of a catheter (not shown).

[0032] Once it has been properly positioned in the duct, the stent is expanded and takes a configuration **102** where the stent has a generally cylindrical shape of diameter d_2 greater than diameter d_1 . If activation temperature T_2 of the shape-memory material is lower than the temperature of the human or animal body having the stent introduced into it, the expansion may be obtained by expelling the stent (in its activated shape) from the catheter, by taking advantage of the super-elasticity specific to shape-memory materials. If temperature T_2 of activation of the shape-memory material is higher than the temperature of the human or animal body having the stent introduced into it, the stent may, once properly positioned in the duct, be heated up to a temperature higher than or equal to temperature T_2 . To achieve this, an aqueous solution heated at a temperature greater than or equal to temperature T_2 may be injected into the duct.

[0033] Diameter d_2 is for example of the same order as the normal diameter of the duct or slightly greater than the normal diameter of the duct, which may enable to enlarge the lumen of the narrowed portion of the duct at the stent level. The shape of the stent in configuration **102** corresponds to the shape memorized by shape-memory wire **110**, or memory shape of the stent. The shape-memory material may be selected to be such that its activation temperature T_2 is greater than the temperature of the human or animal body, for example, in the range from 40 to 45° C., to avoid an unwanted activation of the stent during its insertion into the duct. After its activation, the stent remains in configuration **102** even when its temperature falls back under temperature T_2 , due to the hysteresis properties of the shape-memory material.

[0034] To remove the stent after a disease treatment step, it may be provided to force unwind the helical wire forming it. However, a disadvantage is that the risk of lesion of the duct on removal thereof is relatively high.

[0035] As a variation, to remove the stent, it may be provided to cool it down to a deactivation temperature T_1 , lower than temperature T_2 , at which the shape-memory material remains in the radially stretched shape of configuration **102** but acquires a larger deformability than at the temperature of the human or animal body, thus enabling to remove the stent by unwinding the helical wire while decreasing risks of duct lesion.

[0036] The shape-memory material may be selected to be such that its deactivation temperature T_1 is much lower than the temperature of the human or animal body, for example, in the order of 25° C., to avoid an unwanted deactivation of the stent. To cool down the stent, an aqueous solution at low temperature (lower than or equal to T_1) may be injected in the vicinity of the stent, for example, via a catheter. However, a disadvantage is that the injection of a cold fluid in the vicinity of the stent is a relatively complex operation and may be a problem.

[0037] An object of the described embodiments is to provide a shape-memory stent which overcomes all or part of the above-mentioned disadvantages.

[0038] FIG. 2 schematically shows the operation of an embodiment of a stent **200**. Stent **200** comprises a filiform element **210** shaped according to a substantially helical general configuration, having shape-memory properties.

[0039] Before a phase of inserting the stent into a duct (not shown), the stent is shaped in a configuration **201** where the stent has a generally cylindrical shape of diameter d_1 smaller than the normal diameter of the duct. The stent is inserted into the duct with configuration **201** and positioned at a desired location of the duct, for example, by means of a catheter (not shown).

[0040] Once it has been properly positioned in the duct, the stent is heated up to a temperature higher than or equal to a first temperature T_2 of activation of element **210**. To achieve this, a fluid heated up to a temperature T_2 may be injected into the duct. However, in a preferred embodiment, it is provided to heat the stent by Joule effect by circulating an electric current in element **210**. This provides a heating which is simpler to implement and more efficient than a heating by fluid injection. This further enables to limit risks of burns with respect to a heating by fluid injection. To allow the application of an electric heating current, element **210** may comprise two contact terminals **212a** and **212b** respectively connected to its to ends. The electric heating current is for example provided by a cell or battery coupled to a tool for inserting the stent into the duct. According to the envisaged use, a conductive wire (not shown in the drawings) may be provided to bring one of contact terminals **212a**, **212b** close to the other, to ease the application of the electric heating current.

[0041] When the stent reaches temperature T_2 , it takes a configuration **202** where the stent has a generally cylindrical shape of diameter d_2 greater than diameter d_1 . Diameter d_2 is for example of the same order of magnitude as the normal diameter of the duct or slightly greater than the normal diameter of the duct, which may enable to enlarge the lumen of the duct at the stent level. The shape of the stent in configuration **202** corresponds to a first shape memorized by element **210**, or first memory shape of the stent. Element **210** may be selected to be such that its first activation temperature T_2 is higher than the temperature of the human or animal body, for example, in the range from 40 to 45° C., to avoid an unwanted activation of the stent during its insertion into the duct. After its first activation, the stent remains in configuration **202** even when its temperature falls back under temperature T_2 , due to the hysteresis properties of the shape-memory material.

[0042] To remove the stent, it is provided to heat it up to a temperature greater than or equal to a second activation temperature T_3 of element **210**, higher than temperature T_2 . To achieve this, a fluid heated up to a temperature higher than or equal to temperature T_3 may be injected into the duct. However, in a preferred embodiment, it is provided to heat the stent by Joule effect by circulating an electric current in element **210**. The electric heating current is for example supplied by a cell or a battery coupled to a stent extraction tool.

[0043] When the stent reaches temperature T_3 , it contracts to a configuration **203** where the stent has a generally cylindrical shape of diameter d_3 smaller than diameter d_2 . Diameter d_3 is for example of the same order of magnitude as diameter d_1 of configuration **201**, or smaller than diameter d_1 . In any case, diameter d_3 is smaller than the normal diameter of the duct. The shape of the stent in configuration **203**

corresponds to a second shape memorized by element **210**, or second memory shape of the stent. Element **210** may be selected so that its second activation temperature **T3** is significantly higher than temperature **T2**, to avoid an incidental contraction of the stent in configuration **203** when the stent is heated to be deployed in configuration **202**. Temperature **T3** is however preferably selected to be sufficiently low to avoid for the patient to be burnt on removal of the stent. As an example, element **210** is such that its second activation temperature **T3** is in the range from 50 to 60° C. After its second activation, the stent remains in configuration **203** even when its temperature falls back below temperature **T3**, due to the hysteresis properties of the shape-memory material.

[0044] When the stent is in configuration **203**, it may freely circulate in the duct, which enables to smoothly remove it with no risk of lesion of the duct.

[0045] FIG. 3 is a partial cross-section view illustrating in further detail a preferred embodiment of a stent **300** compatible with the operation described in relation with FIG. 2, that is, capable of expanding to a first configuration at a first activation temperature **T2** and of contracting to a second configuration at a second activation temperature **T3** higher than temperature **T2**. As in the example of FIG. 2, stent **300** comprises a filiform element **310** of substantially helical general shape (not shown in FIG. 3), having shape-memory properties. The described embodiments are however not limited to a stent of helical shape, and other shapes may be provided according to the envisaged use. In FIG. 3, only a cross-section of filiform element **310** has been shown.

[0046] Element **310** comprises a hollow wire or tube **321** made of a first shape-memory material and, inside of hollow wire **321**, a solid wire **323** made of a second shape-memory material. Wires **321** and **323** have approximately the same length, which approximately corresponds to the length of unwound element **310**. Wires **321** and **323** are preferably metallic to allow the circulation of an electric current of activation of the stent by Joule effect in element **310**. Wires **321** and **323** may be made mechanically and/or electrically attached to each other at their ends and/or along all or part of their length, for example, by friction, welding, etc.

[0047] As an example, hollow wire **321** is treated to memorize a shape corresponding to configuration **202** of FIG. 2 and to activate at temperature **T2**, and solid wire **323** is treated to memorize another shape corresponding to configuration **203** of FIG. 2 and to activate at temperature **T3**. The treatments applied to wires **321** and **323** to obtain the desired memory shapes and activation temperatures will not be described in detail herein, such treatments being within the abilities of those skilled in the art. As an example, wires **321** and **323** may be made of a same initial material, for example, a same nickel-titanium alloy, after which different thermal treatments may be applied to wires **321** and **323** to modify by different proportions the atom bonds or the atom compositions of the alloy in the two wires to obtain the desired properties.

[0048] In the shown example, element **310** further comprises a sheath **325** coating the outer wall of hollow wire **321**. Sheath **325** is made of a material selected to prevent or to limit possible phenomena of encrustation of the stent in the duct walls, and to ease the extraction of the stent. Sheath **325** is preferably electrically and thermally insulating to decrease electrocution or burning risks for the patient in case of an activation of the stent by application of an electric current in the stent. Sheath **325** is for example made of silicone. It

should be noted that sheath **325** may be replaced or completed with a skirt made of an insulating material, for example, made of silicone, coating the external wall of the generally cylindrical shape defined by the stent.

[0049] An advantage of the embodiment of FIG. 3 is that stent **300** is relatively simple to form.

[0050] FIG. 4 is a partial cross-section view illustrating another embodiment of a stent **400** compatible with the operation described in relation with FIG. 2. As in the example of FIG. 2, stent **400** comprises a filiform element **410** of substantially helical general shape (not shown in FIG. 4), having shape-memory properties. In FIG. 4, only a cross-section of filiform element **410** has been shown.

[0051] Element **410** comprises a wire **421**, for example, a solid wire, having in cross-section two areas **421a** and **421b** made of different shape-memory materials. Areas **421a** and **421b** for example extend along the entire length of wire **421**. The described embodiments are however not limited to this specific case. Wire **421** is preferably metallic to allow the circulation, in element **410**, of an electric current for activating the stent by Joule effect.

[0052] As an example, area **421a** is treated to memorize a shape corresponding to configuration **202** of FIG. 2 and to activate at temperature **T2**, and area **421b** is treated to memorize another shape corresponding to configuration **203** of FIG. 2 and to activate at temperature **T3**.

[0053] As an example, to form wire **421**, it is started from a wire made of a single material, for example, a nickel-titanium alloy, and the entire wire is treated to memorize a first shape and to activate at temperature **T2**. After this first treatment, the wire may be shaped according to a second shape different from the first shape, and locally treated so that only area **421b** of the wire cross-section memorizes the second shape and acquires an activation temperature **T3** higher than temperature **T2**. This local treatment of the wire cross-section is for example performed by means of a laser beam heating a single side of the wire along the entire wire length. Other treatment methods may be envisaged to obtain the desired result. As an example, nickel may be diffused on a single side of the wire. To achieve this, an element having a high nickel content may be placed on a single side of the wire, the assembly being heated at high temperature.

[0054] It should be noted that, although a clear separation of areas **421a** and **421b** has been shown in FIG. 4, in practice, according to the treatment method used, the shape-memory properties of element **410** may gradually vary between areas **421a** and **421b** of wire **421**.

[0055] It should further be understood that the embodiment of FIG. 4 may apply not only to a solid wire **421**, as has just been described, but also to a hollow wire.

[0056] In the shown example, element **410** further comprises a sheath **425**, for example, made of silicone, coating the outer wall of wire **421**.

[0057] FIG. 5 is a cross-section view along a longitudinal plane of a stent **500**, illustrating an example of the general shape that a stent of the type described in relation with FIGS. 2 to 4 may have. As in the example of FIGS. 2 to 4, stent **500** comprises a filiform element **510** of substantially helical general shape. To avoid unwanted migrations of the stent after it has been deployed in a duct, stent **500** has a diabol shape, that is, it comprises a substantially cylindrical central section **501** and, on either side of section **501**, cylindrical sections **502a** and **502b** having diameters greater than the diameter of section **501**. The described embodiments are however not

limited to this specific example. Other stent shapes may be envisaged (widening on a single side, number of different diameters greater than two, etc.).

[0058] An advantage of the embodiments described in relation with FIGS. 2 to 5 is that the described stents may easily be inserted into and extracted from a duct with no risk of lesion of this duct.

[0059] Further, the stent may be inserted and extracted without requiring the injection of a heating or cooling fluid in the vicinity of the stent, which greatly simplifies stent placing and removal operations and avoids risks of burns or contamination for the patient.

[0060] The described embodiments are particularly adapted for a use in the urethra when the urethral canal is narrowed or obstructed by the prostate due to a hypertrophy of the prostate.

[0061] It is thus provided to use a stent of the type described in relation with FIGS. 2 to 5 to increase the lumen of the urethral canal when the latter is narrowed or obstructed due to a hypertrophy of the prostate.

[0062] The described embodiments may however also be used in other canals, ducts, or cavities of the human or animal body.

[0063] In the above-described embodiments, stents are formed from a filiform element (respectively **310** and **410** in FIGS. 3 and 4) comprising, longitudinally, two portions (**321** and **323** in FIGS. 3 and **421a** and **421b** in FIG. 4) made of shape-memory materials treated differently, each portion memorizing a shape of the stent and activating (that is, recovering its memorized shape) when it is heated up to its activation temperature.

[0064] It should however be noted that expression “shape-memory material” designates not only materials capable of memorizing a shape and of returning thereto when their temperature exceeds a so-called activation temperature, but also materials capable of being treated to acquire so-called superelasticity properties in a range of temperatures of use. The shape-memory materials treated in superelasticity have no specific activation temperature, but are capable of reversibly undergoing a significant deformation under the effect of stress in the considered temperature range.

[0065] As an alternative embodiment, it may be provided, in the above-described embodiments, to form one of the two shape-memory portions of the stent (for example, portion **321** in FIG. 3 and portion **421a** in FIG. 4) with a shape-memory material treated to acquire superelastic properties at the temperature of the human or animal body into which the stent is intended to be inserted. The superelasticity of the first material may be taken advantage of during the stent insertion phase, and the shape memorized by the second material may be exploited on removal of the stent.

[0066] In this case, the stent for example has the following operation:

[0067] On insertion thereof into a duct, the stent is stressed to a configuration corresponding to configuration **201** of FIG. 2 (superelastic deformation), for example, by means of a tool, for example, a catheter, comprising hooks enabling to apply the desired stress.

[0068] Once the stent has been properly positioned in the duct, the stress is released, and the stent relaxes, like a spring, to return to a shape corresponding to configuration **202** of FIG. 2 (reversibility of the superelastic deformation).

[0069] To remove the stent, it is provided to heat it up to a temperature higher than or equal to the activation temperature

of the second shape-memory material (portion **323** of the stent in FIG. 3 or portion **421b** of the stent in FIG. 4). The stent then contracts to a configuration corresponding to configuration **203** of FIG. 2, which enables to remove it.

[0070] Thus, the placing of the stent may be performed without heating and the stent removal comprises a heating step.

[0071] Specific embodiments have been described. Various alterations, modifications, and improvements will readily occur to those skilled in the art.

[0072] In particular, the described embodiments are not limited to the specific stent structures described in relation with FIGS. 2 to 5. It will be within the abilities of those skilled in the art to adapt the provided solution to other stent types, for example, stents using a meshing rather than a simple filiform element, or stent comprising a helical band rather than a helical wire.

[0073] More generally, it will be within the abilities of those skilled in the art to adapt the provided solution to all types of stents, in the medical field or in other fields.

[0074] Further, the described embodiments are not limited to the case where the shape-memory materials are nickel-titanium alloys. Other shape-memory materials may be used, such as for example certain alloys based on copper and/or on aluminum and/or on nickel and/or on zinc, a titanium/nickel alloy, etc.

[0075] Further, the described embodiments are not limited to a double shape-memory stent. Based on the teachings of the present disclosure, it will also be within the abilities of those skilled in the art to form stents where a number of memory shapes greater than two is memorized.

1. A stent comprising a filiform element made of a shape-memory metal alloy, this element comprising, in cross-section, first and second portions having different shape-memory properties.

2. The stent of claim 1, wherein the first portion has a first activation temperature, and the second portion has a second activation temperature higher than the first temperature.

3. The stent of claim 2, wherein the first and second portions are arranged so that the stent takes a first configuration when the first portion is activated, and a second configuration when the second portion is activated.

4. The stent of claim 1, wherein the first portion has superelasticity properties and the second portion memorizes a thermally activatable shape.

5. The stent of claim 4, wherein the first and second portions are arranged so that the stent takes a first configuration when the second portion is not activated, and a second configuration when the second portion is activated.

6. The stent of claim 3, wherein at least one section of the stent has an approximately generally cylindrical shape having a first diameter in the first configuration and a second diameter smaller than the first diameter in the second configuration.

7. The stent of claim 1, wherein the filiform element has a generally helical shape.

8. The stent of claim 7, wherein said element has the shape of a diabolo.

9. The stent of claim 1, wherein the first portion is a hollow wire, and wherein the second portion is a wire of smaller diameter arranged within the hollow wire.

10. The stent of claim 1, wherein the first (**421a**) and second (**421b**) portions are different areas of the cross-section of a same wire.

11. The stent of claim 1, wherein said shape-memory alloy is an alloy based on nickel and titanium.

12. The stent of claim 1, wherein said filiform element comprises at its ends contact terminals enabling to circulate an electric current in the first and/or second portions.

13. The stent of claim 1, further comprising a silicone coating.

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