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(54) Title: A BENDABLE STRUCTURE AND A METHOD FOR BENDING A STRUCTURE

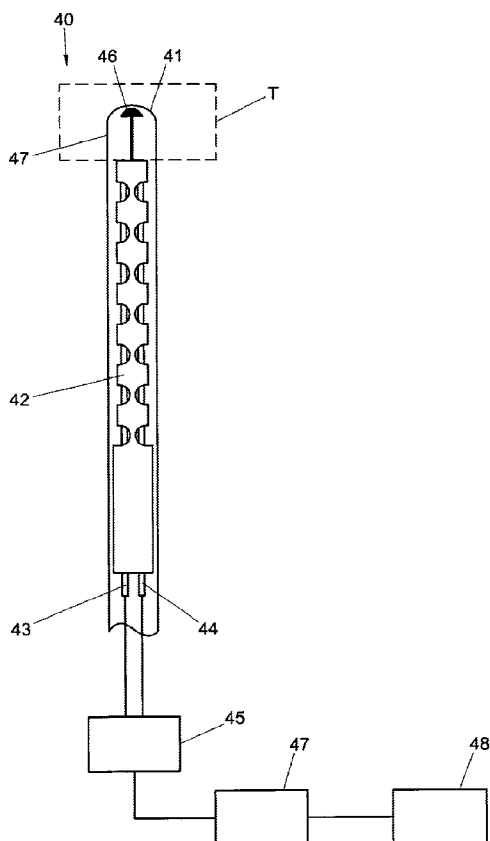


FIG. 3

(57) Abstract: The invention relates to a bendable structure 40 comprising a body 41 conceived to be bent; an actuator 42, 43, 44 for inducing a bending force in the body, wherein the actuator comprises a wire at least partially manufactured from a uni-directional shape memory alloy (SMA) material, said wire being pre-deformed and being arranged in contact with a portion of the body for forming a bridge structure conceived to transfer mechanic energy across the bridge. The bendable structure 40 may relate to a bendable catheter or an endoscope.

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FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,
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Title: A bendable structure and a method for bending a structure

FIELD OF THE INVENTION

The invention relates to a bendable structure. In particular, the invention relates to a bendable medical instrument, like a catheter or an endoscope. The invention further relates to a method of bending a structure.

5

BACKGROUND OF THE INVENTION

An embodiment of a bendable structure is known from Ki-Tae Park et al "An active catheter with integrated circuit for communication and control". In the known bendable structure bending functionality is enabled by providing a tubular body of a catheter with coils fabricated from a shape memory alloy (SMA). SMA materials are known as such in the art and relate to a class of materials which may be deformed in a controlled way, for example, pursuant to heating by application of a current pulse. Details on SMA materials may be found in M. Langelaar and F. van Keulen "Modeling of a shape memory alloy active catheter".

The known bendable structure comprises a plurality of segments manufactured from SMA coils, said segments being consecutively interconnected by links. The SMA coils are pre-deformed having 3% deformation strain. When the SMA actuator is heated above its phase transition temperature by electric current and starts recovering its original shape, the active catheter bends in the direction of the heated SMA actuator. In order to implement bending of the known bendable structure a total of three SMA actuator wires are provided within a body conceived to be bent, these three actuator wires are arranged at vertices of an imaginary triangle fitted into a cross-section of the body.

It is a disadvantage of the known bendable body that bending with poor accuracy can be achieved. Next, the known bendable structure has limited

bending angles. Finally, the known bendable structure cannot be adequately miniaturized due to required use of at least three SMA actuator wires.

SUMMARY OF THE INVENTION

5 It is an object of the invention to provide a bendable structure wherein greater bending accuracy can be reached. Additionally, it is a further object of the invention to provide a bendable structure wherein greater bending angles can be enabled. It is a still further object of the invention to provide a bendable structure having substantially diminished power
10 dissipation into surroundings upon actuation.

To this end the bendable structure according to the invention comprises:

- a body conceived to be bent;
- an actuator for inducing a bending force in the body, wherein the
15 actuator comprises a wire at least partially manufactured from a uni-directional shape memory alloy (SMA) material, which is pre-deformed and is arranged in contact with a portion of the body for forming a bridge structure.

The invention is based on the insight that a uni-directional SMA
20 wire, when pre-deformed, relaxes during activation (i.e. during heating). In course of relaxation a bending force induced by the relaxing SMA wire can be transferred to another side of the body across the bridge structure. Uni-directional memory material relates to a material which can revert to its original shape, which is defined a-priori. It will be appreciated that the term
25 “uni-directional” may be substituted by a term “one-way”, as both this terms are used in the art for denoting a characteristic of being capable of transiting from the martensitic phase to the austenitic phase, for example, due to heating. Upon heating, energy, stored in the pre-deformed uni-directional SMA wire is released and is not reproducible, unless the energy is stored in a second

element, for example a second uni-directional SMA wire, preferably located opposite to the first SMA wire with respect to the bridge structure.

The bendable structure according to the invention is different from commonly known embodiments utilizing bi-directional SMA materials. Two
5 stripes of bi-directional SMA materials (i.e. "two-way" SMA) may be arranged in a bendable structure, wherein each of the stripes has a different length at a different temperature, corresponding either to the martensitic or the austenitic phase. These two different lengths are reproduced each time the temperature of the SMA stripe is changed. However, energy produced by the SMA stripe
10 during transition from one state to another is not stored in any element of the bendable structure.

There are at least two principal embodiments envisaged for the bridge structure according to an aspect of the invention. First, the body may comprise an elastic hinge, whereas the bridge structure may be formed by the
15 elastic hinge connected to the uni-directional SMA wire. In a particular embodiment, when the elastic flexible hinge is manufactured from a SMA material, the bending force transferred from the uni-directional SMA wire can be stored in an opposite arm of the elastic hinge. This feature is based on the insight that the hinge can be implemented as a spring-like element, in
20 particular when for a material of the flexible hinge a material having pseudo-elastic properties is selected. Advantageously, when such material exhibits austenitic properties at room temperature, it can be brought in the martensitic state by inducing deformation. When a force causing the deformation is relieved, the material will return in its original shape. In general such
25 materials are similar to rubber when transiting from austenitic to martensitic state. It is appreciated that during transition from the martensitic to austenitic phase substantially great forces are relieved. Use of pseudo elastic material is advantageous for reasons of low bending stiffness and large allowable strain (bending angle). Secondly, choosing a uni-directional SMA for

the hinge material is advantageous, due to low bending stiffness, large allowable strain, and the energy that can be stored.

Details on operation of the bridge structure are explained with reference to Figure 1. When the opposite side of the SMA hinge is actuated, the
5 force is transferred back to the uni-directional SMA wire. In this way bending force induced in the bendable structure is being transferred from one side of the bridge to another side of the bridge in accurate way. In addition, this embodiment uses only one actuation uni-directional SMA wire and is, therefore, preferable in situations when the bendable structure has to meet
10 miniaturization requirements, for example for minimal invasive surgery, such as miniature endoscopes. Alternatively, a miniaturized device may be used for industrial applications, for example for purposes of engine or gear inspection.

Secondly, it is possible that the bridge structure comprises a further deformable uni-directional SMA wire joined by a rigid hinge to the pre-
15 deformed wire.

In this case the bridge structure may represent a substantially rigid hinge connected to two deformable SMA wires acting as it arms. It will be appreciated that the term 'rigid' relates to a material of the hinge being substantially non-deformable. Preferably, the hinge material has a Young
20 modulus of more than 1GPa at $T=20^{\circ}\text{C}$. The hinge interconnecting the pre-deformed wire and the further wire forms a mechanical bridge for transferring a bending momentum from one side of the hinge to another thereby causing the body of the bendable structure to bend. It will be appreciated that the bridge has a pre-stored mechanical energy due to the fact that the first uni-
25 directional SMA wire is pre-deformed. In this way, when the electrical current pulse of a suitable duration is applied to the pre-deformed first wire and the material of the wire is heated above a phase transition temperature, the SMA wire create a force on the further deformable SMA wire. In response, the second deformable uni-directional SMA wire will be elongated until
30 equilibrium of forces across the bridge is reached. In this way the mechanical

energy is transferred to the second wire and is stored there. When the second uni-directional SMA wire is being heated above its phase transition temperature by means of electrical current or otherwise, the second wire will be shortening in response and will thereby create a force on the first (now
5 relaxed) uni-directional SMA wire. As a result the first uni-directional SMA wire will be elongated until equilibrium of forces along the bridge is reached. Now, the mechanical energy is being transferred again across the bridge and being stored in the first wire. By repeating alternating heating the first wire and the second wire the controlled bending of the bendable structure is
10 achieved. This phenomenon is explained in more detail with reference to Figure 1.

The bendable structure according to the invention has the following advantages. First, due to provision of the bridge structure accurate bending actuation is reached due to good controllability of phase transition of the uni-
15 directional SMA material. In addition, due to use of a uni-directional SMA material a small amount of activation energy is required to bend the bendable structure. Secondly, the activation energy is only applied for a short duration, for example a current pulse of 0.1 – 10 s duration, preferably 5s duration can be used to achieve necessary bending angle. This is advantageous with respect
20 to the prior art where the activation pulse has to be applied continuously leading to a great energy dissipation in surroundings. This may be not acceptable for medical applications wherein heating of surrounding tissue is not allowable.

Preferably, the SMA wire is pre-deformed by elongation by 4-8% of
25 its initial length. This means that for reaching envisaged bending radii of about 10mm for a 1mm diameter, at least 4-8% elongation of the SMA wire is advantageous. It will be appreciated that it is also possible that both SMA wires are pre-deformed for a portion of 4 – 8% range.

In an embodiment of the bendable structure according to the invention the uni-directional shape memory alloy is selected from a group of materials comprising: NiTi, CuZnAl or CuAlNi.

As has been mentioned earlier, uni-directional shape memory
5 property is a functionality of a material to transit to its original shape from a deformed condition after it is heated. This phenomenon is based on a phase transition in the crystal structure during cooling of a rigid, high temperature state (austenitic) to a less rigid lower temperature state (martensitic) and vice versa during heating. This phase transformation is reversible and, therefore,
10 can easily be used for actuation purposes. It will be appreciated that there is another transition possible for the shape memory alloys, namely a transition between the austenitic state and the so-called R-phase. The R-phase corresponds to rhombohedral crystal orientation. It is found that it is preferable to use the transformation between the austenitic phase and the
15 martensitic phase in case smaller bending radii are required. For larger bending radii it is advantageous to use the transformation between the austenitic phase to the R-phase because such transition is linear as a function of temperature and has little hysteresis, which is advantageous for simplifying control of the bending.

20 In a further embodiment of the bendable structure according to the invention the body has a low bending stiffness, which may be implemented when for the material of the hinge a SMA material is selected, in particular a material having pseudo-elastic properties.

This is advantageous, as in this case the body demonstrates
25 substantially no resistance to bending and substantially no backwards recoiling. This further improves bending accuracy.

In a still further embodiment of the bendable structure according to the invention, it further comprises control means for inducing a transition of the shape memory alloy from martensitic phase to austenitic phase or from
30 austenitic phase to R-phase.

Preferably, the control means is arranged to apply a pulse of electrical current of suitable duration and/or amplitude for enabling a transition of the shape memory alloy from martensitic phase to austenitic phase or from austenitic phase to R-phase.

5 The control means may be advantageously arranged to use a pre-calibrated dependency between a desired bending radius of the bendable structure and the duration or amplitude of a current pulse conceived to be applied to the SMA wires for enabling such bending. This feature further improves the bending accuracy. This short term activation (0.1s – 10 s,
10 preferably about 5s) has an advantage of reduced power dissipation on the bendable structure, which is preferable for medical applications due to strict limitation on local heating of tissue.

 In a further embodiment of the bendable structure according to the invention the elastic hinge comprises a plurality of interconnected hinge
15 elements extending in a longitudinal direction of the body.

 This technical feature is based on the insight that by providing a continuous structure having a plurality of interconnected bridge structures the accuracy of the bending is improved. In particular, when the elastic hinge comprises a plurality of interconnected hinge elements having substantially
20 tubular cross-section and provided with recesses, controlled bending with preservation of the shape of the cross-section may be achieved. This is of particular advantage for medical applications. More details on this embodiment will be presented with reference to Figure 2.

 A method for bending a structure according to the invention
25 comprises the steps of:

- selecting for the structure a body arranged with an actuator in contact with the body for transforming a bending force to the body, said actuator comprising a wire at least partially manufactured from a uni-directional shape memory alloy (SMA)

material, said wire being pre-deformed and being arranged in contact with a portion of the body for forming a bridge structure;

- providing actuation signals to the wire thereby bending the structure.

5 In a particular embodiment of the method according to the invention, wherein the bridge structure comprises a further deformable uni-directional SMA wire conceived to interact with the pre-deformed wire, the method comprises the steps of alternatively actuating the wire and the further wire.

10 These and other aspects of the invention will be further discussed with reference to drawings, wherein like reference signs represent like elements. It will be appreciated that the drawings are used for illustrative purposes only and may not be construed for limiting the scope of the appended claims.

15

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 presents a schematic view of a bridge principle used in the bendable structure according to the invention.

Figure 2 presents a schematic view of a hinge comprising a plurality
20 of hinge elements.

Figure 3 presents a schematic view of a medical device comprising the bendable structure according to the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

25 Figure 1 presents a schematic view of a bridge principle used in the bendable structure according to the invention. The bendable structure 10 comprises a body 1, preferably a tubular body being manufactured from an elastic material. The body is provided with actuator comprising a first uni-directional SMA wire 4, a second uni-directional SMA wire 2 and a
30 substantially rigid hinge 3 arranged to mechanically interconnect the first

wire 2 and the second wire 4 for obtaining a bridge. An equivalent mechanical scheme is presented by element 20, illustrating the first wire 24, the second wire 22 and the bridging element 23. The first wire 4 is preferably pre-deformed by at least 4 – 8 % of its length at rest, i.e. before the bendable structure is operable. It is possible that the wire is elongated by at least 4 – 8 % of its length at rest. Due to the fact that the first wire is at least partially manufactured from a suitable uni-directional SMA material, in operation, upon heating above its phase transition temperature, for example by application of a current pulse of a suitable duration and amplitude, it will recover its normal shape, i.e. shorten thereby pulling the portion 3a of the hinge to the left. Due to the fact that the hinge 3 is manufactured from a substantially rigid material, the force applied by the first wire 4 to the portion 3a will be transferred substantially without loss to the portion 3b of the hinge 3. As a result the wire 2 will be elongated until equilibrium of forces is reached. As a result the second SMA wire 2 will store mechanical energy released by the first uni-directional SMA wire during relaxation. When the second wire is heated above its phase transition temperature, the second wire will resume its original length by pulling the portion 3b to the right. As a consequence the first SMA wire 4 will be elongated back to its original deformation condition. Thus, by alternating application of current pulses of suitable amplitude and duration, controlled bending of the body is reached. It will be appreciated that in order to bend the body in one direction at least two SMA wires 2, 4 are required. The hinge is connected to the body 1, which is schematically indicated by arms A, B. It will be appreciated that in practice instead of arms other technical means may be used, like adhesive or the like. Alternatively, the actuator comprising the hinge and the wires may be tightly fitted in the interior of the body 1 so that bending of the actuator is substantially transferred into bending of the body 1. It will be appreciated that for enabling controlled bending of the structure 10 in other directions additional wires may be required.

The hinge element 3 may be preferably manufactured from a tubular structure by means of laser ablation for producing voids having radius R. The absolute dimensions of the hinge 3 and the radius R depend on application. For example, for application in a bendable endoscope, it is possible
 5 that the outer dimension of the body is 0.7 mm, the inner dimension of the body is 0.5 mm L1 is about 0.5 mm, L2 is about 0.1 mm and radius R is about 0.5 mm. In order to determine feasible bending angles for this structure, the following equations are to be considered:

10 $M = F * L$, wherein
 M represents moment applied to a point;
 F represents force acting on a point;
 L represents arm length.

15 $F = A * E * \varepsilon$ (Hook's law)

During actuation of the perforated hinge as shown in Figure 2, the hinge will rotate in direction of the wire which is being actuated. Although the explanations are given with respect to the wires which are elongated and
 20 which shorten under application of the actuation pulse, it is also possible that the wire is shortened a-priori and elongates during application of the actuation pulse.

The rotation of the hinge proceeds until equilibrium of forces across the bridge (see Figure 1 element 20) is reached. In this state a sum of
 25 momenta in the bendable structure is zero, which is given by:

$$\sum M = 0$$

By filling in data pertaining to the geometry of the hinge, one
 30 obtains:

$$F1 * l1 - F2 * l2 - T\psi = 0$$

When the above equation is resolved with respect to the angle ψ , one obtains that the forces equilibrium is maintained for the angle ψ of 7,2
5 degrees. By providing a suitable plurality of the hinge elements 31, 32, ..., N, as shown in Figure 2 a suitable bending angle is obtained. For example, for 30 elements forming the hinge 30 the bending angle of 216 degrees is reached. It is noted that when the body comprises an elastic hinge and the bridge structure is formed by the elastic hinge connected to the wire, in particular,
10 when the elastic hinge is manufactured from a uni-directional SMA material, it is sufficient to use a sole actuating uni-directional SMA per desired bending direction, the elastic hinge acting as the second uni-directional SMA wire.

Figure 3 presents a schematic view of a medical device comprising the bendable structure according to the invention. The bendable structure 40
15 may relate to a bendable catheter or an endoscope. The catheter may be suitable to be maneuvered in a body's conduit, for example in a blood vessel or in a urinary tract. Below, example of the bendable structure implemented in a miniature endoscope will be given. It will be appreciated that a skilled artisan can employ the same teaching in application to catheters or any other suitable equipment requiring remote controlled bending.
20

Endoscope 40 may comprise an outer tubular body 41, whereto a flexible hinge 42 arranged with uni-directional SMA wires 43, 44 is attached. It is also possible that the endoscope 40 comprises a suitable lumen occupying only a portion of the internal volume, the hinge 42 together with the wires 43,
25 44, being arranged in the lumen. Preferably, the tubular body 41 has a diameter in the range of 0.5 – 10 mm, preferably in the range of 0.5 – 2 mm.

The uni-directional SMA wires may be actuated by means of application of a pulse of electrical current for heating the uni-directional SMA wire above its phase transition temperature. It is noted that either a transition
30 of a suitable SMA material from martensitic phase to austenitic phase or from

austenitic phase to R-phase is envisaged. In order to actuate the wires 43, 44 the endoscope 45 comprises a control unit, which is arranged to deliver the current pulse with required characteristics to the first wire 43 or to the second wire 45.

5 In a medical field, it is advantageous that a protrusion of the endoscope 40 in the human or animal body is being monitored in real-time. Preferably, such monitoring is arranged to prove a three-dimensional tracking of a position of the endoscope. Advantageously, the control unit 45 is arranged to receive the positional information on the endoscope together with imaging
10 data on the area wherein the endoscope, in particular its tip portion T is dwelling. The bending angle can also be monitored using a strain sensor or optical fiber.

 In accordance with the imaging data the control unit 45 or a suitable data analysis unit 47 arranged in communication with a suitable imaging unit
15 48 calculates the angle with which the tip portion T of the endoscope is to be bent prior to further insertion. It will be appreciated that the same procedure can be followed when an inspection endoscopy is performed, for example when the endoscope is positioned within an organ, or a cavity and is moved around to enable a wide view for the optical means 46. The optical means 46 is
20 arranged in connection with an external device (not shown) for further processing of the data. Such connection is preferably implemented using optical fiber.

 Preferably, the uni-directional SMA wires 43, 44 are arranged with a flattened cross-section. This has an advantage that less space is occupied by
25 the wires 43, 44. This feature is of particular advantage for catheters conceived to be used in cardiac arteries, because miniaturization of cardiac devices plays a crucial role with respect to induced ischemia.

 It will be appreciated that while specific embodiments of the invention have been described above, that the invention may be practiced
30 otherwise than as described. In addition, isolated features discussed with

reference to different figures may be combined. Although the bendable structure is explained with reference to endoscope other applications are contemplated, including other optical devices, for example for industrial application, catheters, or the like.

Claims

1. A bendable structure comprising:
 - a body conceived to be bent;
 - an actuator for inducing a bending force in the body, wherein the actuator comprises a wire at least partially manufactured from a uni-directional shape memory alloy (SMA) material, which is pre-deformed and is arranged in contact with a portion of the body for forming a bridge structure.
2. A bendable structure according to claim 1, wherein the body comprises an elastic hinge, the bridge structure being formed by the elastic hinge connected to the wire.
3. A bendable structure according to claim 2, wherein the body comprises a plurality of interconnected hinges extending in a longitudinal direction of the body.
4. A bendable structure according to claim 2 or 3, wherein the body comprises SMA material.
5. A bendable structure according to claim 1, wherein the bridge structure comprises a further deformable uni-directional SMA wire joined by a rigid hinge to the pre-deformed uni-directional SMA wire.
6. A bendable structure according to claim 5, wherein the uni-directional SMA material is selected from a group of materials consisting of: NiTi, CuZnAl or CuAlNi.

7. A bendable structure according to any preceding claim, wherein the body has a low bending stiffness.
- 5 8. A bendable structure according to any preceding claim, further comprising control means for inducing a transition of the shape memory alloy from martensitic phase to austenitic phase or from austenitic phase to R-phase.
- 10 9. A bendable structure according to claim 8, wherein the control means is arranged for controlling of the uni-directional shape memory alloy by application of a current pulse of a short duration.
10. A bendable structure according to any preceding claim, wherein the
15 bridge structure is formed as a carrier of the body.
11. A bendable structure according to any preceding claim, wherein the body is tubular, having a diameter in the range of 0.5 – 10 mm, preferably in the range of 0.5 – 2 mm.
20
12. A bendable structure according to any preceding claim, wherein the body forms part of an optical device.
13. A bendable structure according to claim 12, wherein the optical
25 device is an endoscope.
14. A bendable structure according to any preceding claim 1 - 11, wherein the body forms part of a catheter.

15. A bendable structure according to any preceding claim, wherein the wire and the further wire have a flattened cross-section.
16. A bendable structure according to any preceding claim, wherein the
5 deformable wire is pre-deformed by elongation by 4 – 8 % of its initial length.
17. A bendable structure according to any preceding claim 6 - 16, wherein the wire and the further wire are pre-deformed.
- 10 18. A method for bending a structure comprising the steps of:
- selecting for the structure a body arranged with an actuator in contact with the body for transforming a bending force to the body, said actuator comprising a wire at least partially
15 manufactured from a uni-directional shape memory alloy (SMA) material, said wire being pre-deformed and being arranged in contact with a portion of the body for forming a bridge structure;
 - providing actuation signals to the wire thereby bending the structure.
- 20 19. A method according to claim 18, wherein the bridge structure comprises a further deformable uni-directional SMA wire conceived to interact with the pre-deformed wire, the method comprising the steps of alternatively actuating the wire and the further wire.

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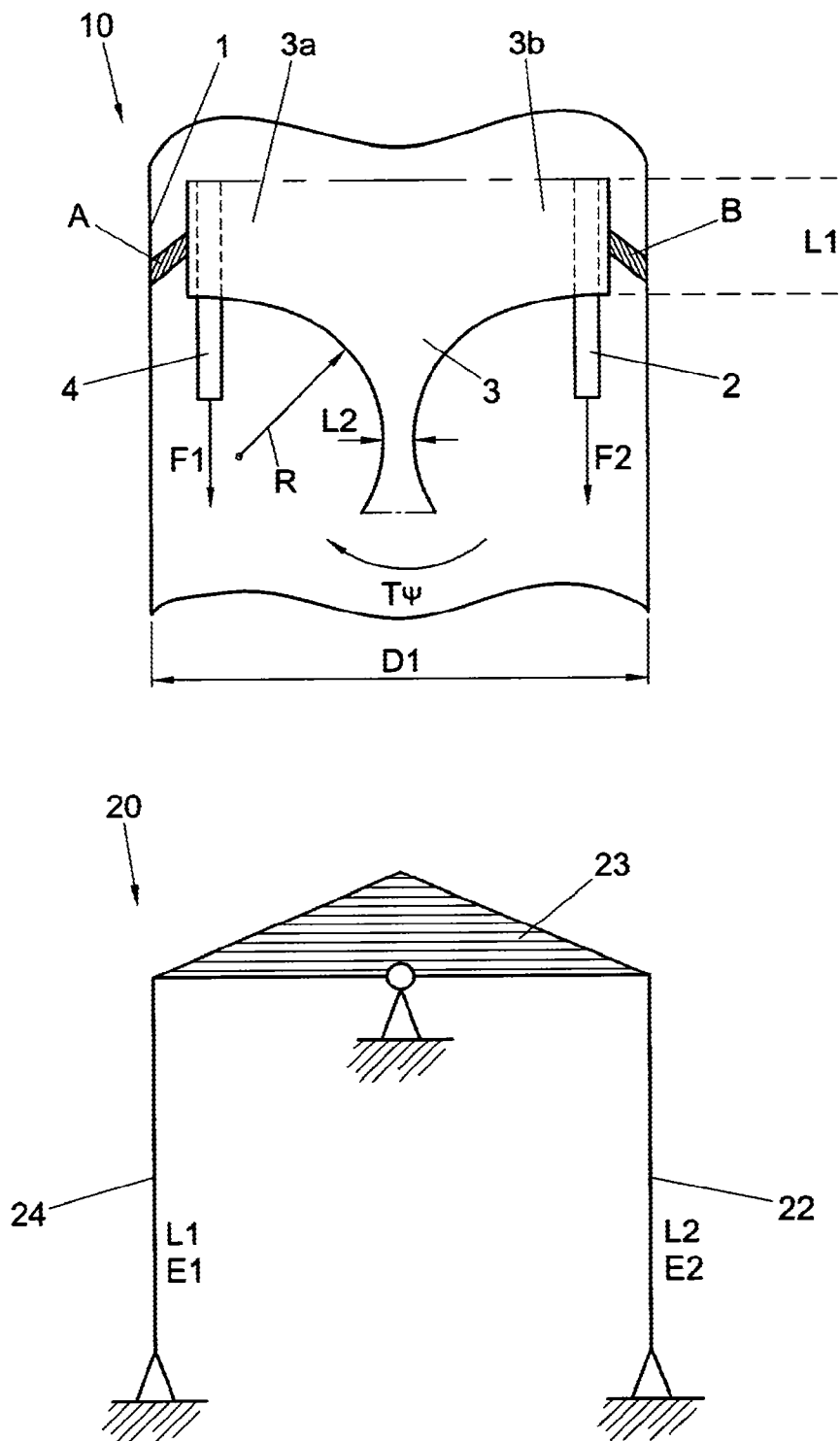


FIG. 1

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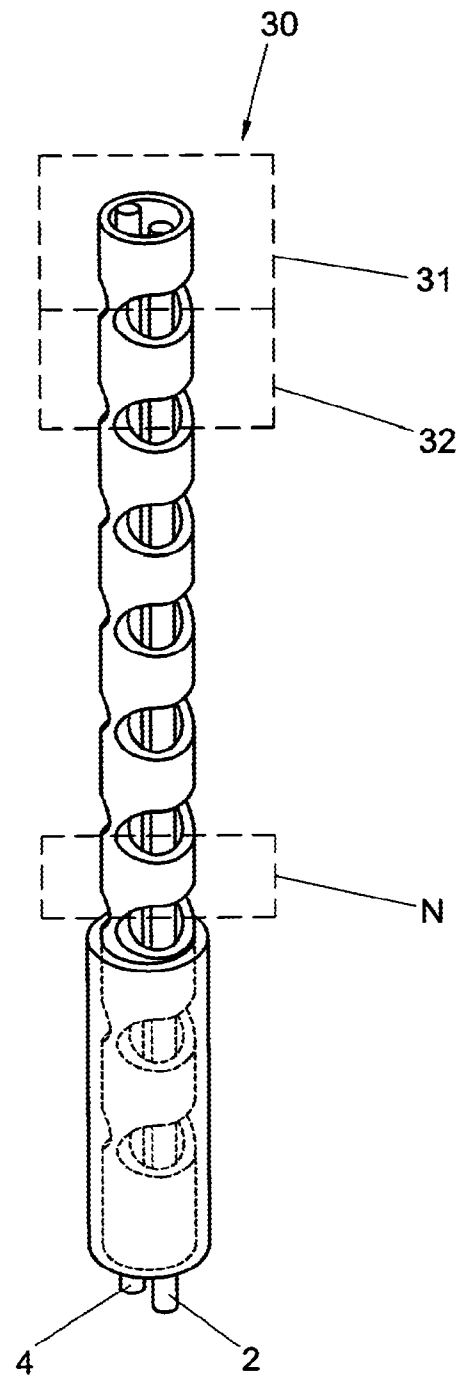


FIG. 2

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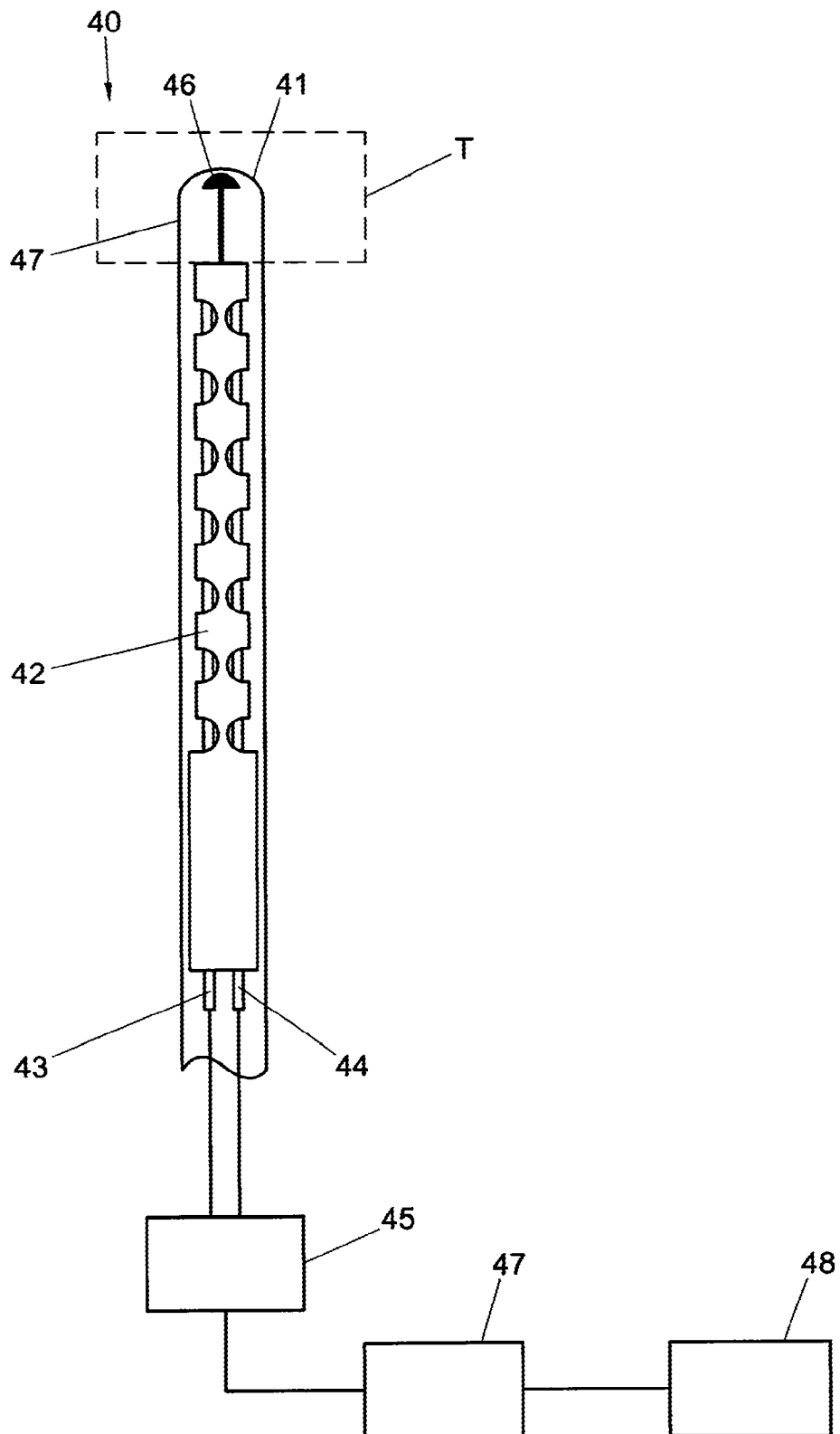


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No

PCT/NL2008/050811

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B1/005

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, 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 5 679 216 A (TAKAYAMA SHUICHI [JP] ET AL) 21 October 1997 (1997-10-21)	1,4,5,7, 9,10, 12-14, 18,19
Y	abstract column 5, line 30 - column 7, line 28 column 13, line 43 - column 15, line 5 -----	2-4,6,8, 11,14-17
Y	US 4 753 223 A (BREMER PAUL W [US]) 28 June 1988 (1988-06-28) the whole document -----	1-19
Y	US 5 897 488 A (UEDA YASUHIRO [JP]) 27 April 1999 (1999-04-27) column 9, line 46 - column 10, line 67 ----- -/--	1-3,5-7, 9,10,12, 13,18,19

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

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- *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.
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Date of the actual completion of the international search

3 March 2009

Date of mailing of the international search report

11/03/2009

Name and mailing address of the ISA/

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Rivera Pons, Carlos

INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/154261 A1 (OHLIN ROBERT M [US] ET AL) 14 July 2005 (2005-07-14) the whole document -----	1,18
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