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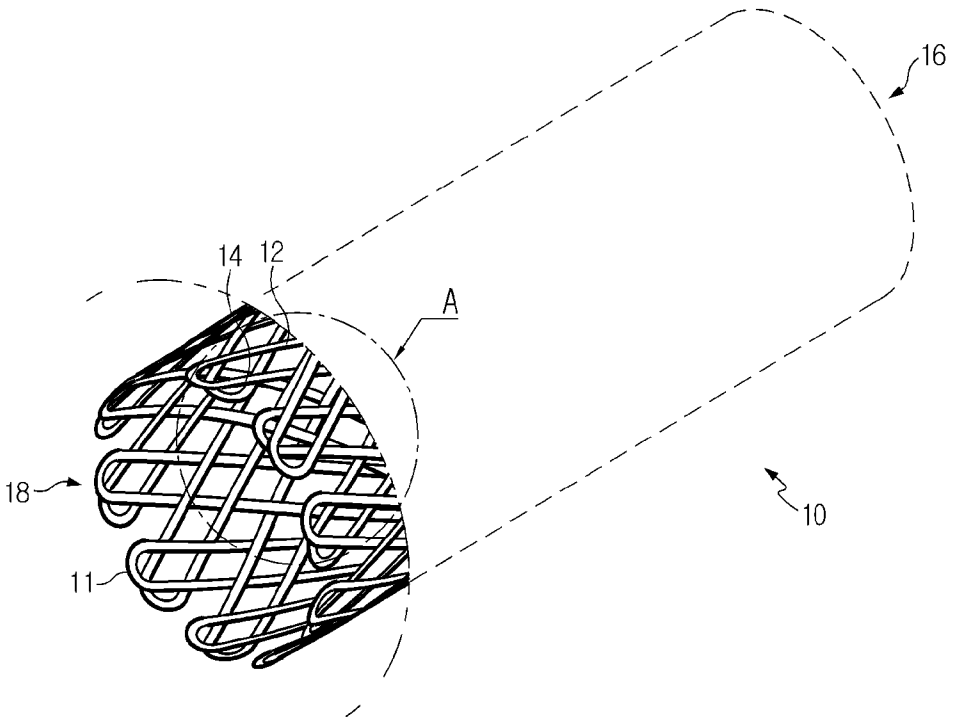
(54) Title: STENT AND FABRICATION METHOD THEREOF



(57) Abstract: Disclosed is a stent having a hollow tubular structure with open ends, formed by weaving alternately a plurality of filaments, each having an elongated closed-loop wire, wherein both ends of the respective filaments are positioned at the open ends.

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Description

STENT AND FABRICATION METHOD THEREOF

Technical Field

[1] The present invention relates to a medical stent for implantation in a patient and a fabrication method thereof, and more particularly to a stent which may be self-expanding and may deliver drugs topically or transport gene therapeutic agents, and a fabrication method thereof.

[2]

Background Art

[3] Expandable medical prostheses, frequently referred to as stents, are well known and commercially available. They are, for example, disclosed in US Patent No. 4,655,771 (Wallsten), US Patent No. 5,061,275 (Wallsten *et al.*) and US Patent No. 5,645,559 (Hachtmann *et al.*). Stents are used within body vessels of humans for a variety of medical applications. For example, the stents include intravascular stents for treating stenoses, stents for maintaining openings in the urinary, biliary, tracheobronchial, oesophageal and renal tracts and inferior vena cava.

[4] Commonly used materials for known stent filaments include Elgiloy and Phynox metal spring alloys. Other metallic materials that can be used for expandable stent filaments are 316 stainless steel, MP35N alloy and superelastic Nitinol nickel-titanium. Another expandable stent has a radiopaque clad composite structure such as shown in U.S. Patent No. 5,630,840 by Mayer. Expandable stents can also be made of a titanium alloy.

[5] For example, EP 1287790 (Schmitt & Lentz) discloses an axially flexible braided stent that is self-expandable due to the elastic memory of the braided polymer fibers. The braided fibers are shaped into a tube at or just below the melting temperature of the polymer, and then longitudinally stretched upon cooling.

[6] Known stents are, however, unproductive since the conventional stents are mainly hand-made. In the case of the conventional stents, it is difficult to ensure uniform characteristics (elasticity and/or self-expandability) over their entire length, for example irregular distances between metallic wires.

[7] Also, conventional stents may be manufactured using a typical braiding apparatus. However, each metal filament has end portions which would be exposed to both ends of the stent, and therefore it is troublesome to weld the exposed end portions - the end portions of the metal filaments - to each other. In particular, it is almost impossible to weld the end portions of a stent composed of a fine filament of which diameter is relatively small.

[8] In order to solve the above problems in the prior art, Korean Patent Publication No. 1999-45770 (A Braided Stent) discloses a stent in which beads are welded at ends of filaments constituting a stent body. However, this technique has problems that it is not easy to weld fine particles of beads to ends of the filaments having a fine diameter, and also undesirable exposure of a sharp tip portion of stents due to poor welding of the beads may give adverse affects on blood vessels of the patient.

[9]

Disclosure of Invention

Technical Problem

[10] Accordingly, the present invention is designed to solve the problems of the prior art, and therefore it is an object of the present invention to provide a stent which is formed of a plurality of filaments having a closed-loop shape in order to ensure uniformity of a stent and safety in its use.

[11] Also, it is another object of the present invention to provide a method for fabricating a stent capable of being easily manufactured using a so-called pre-welding technique for braiding a plurality of assembly lines in which the both ends of a guide line are connected to one closed-loop filament, respectively.

[12]

Technical Solution

[13] In order to accomplish the above object, one preferred embodiment of the present invention provides a stent having a hollow tubular structure with open ends, formed by alternately weaving a plurality of filaments, each having an elongated closed-loop wire, wherein both ends of the respective filaments are positioned at the open ends.

[14] Preferably, a plurality of the filaments are divided into two groups of closed loops which are arranged spirally in a longitudinal direction of the tubular structure and alternate with each other in opposite directions.

[15] Preferably, the elongated closed-loop filament has a pair of parallel parts which are substantially in contact with each other.

[16] Preferably, the elongated closed-loop filament has a pair of parallel parts which are spaced from each other at predetermined distances.

[17] Preferably, each of the filaments is made of a biocompatible metal or its alloys.

[18] Preferably, the tubular structure is formed by braiding and/or winding a plurality of closed-loop filaments.

[19] In order to accomplish the above object, another preferred embodiment of the present invention provides a method for fabricating a stent, including: (a) preparing a plurality of filaments having an elongated closed-loop wire; (b) forming a plurality of assembly lines, in each of which at least one closed-loop filament is connected with at

least two guide lines in an alternating fashion; (c) braiding the assembly lines into a tubular structure by providing a plurality of the assembly lines to a braiding device; and (d) removing the guide lines from both ends of the tubular structure composed of the filaments.

[20] Preferably, the method for fabricating a stent according to the present invention further includes: processing a first heat-treatment of the filaments to fix a shape of the closed-loop filaments prior to the step (b); and processing a second heat-treatment of the stent to memorize a shape of the stent next to the step (d).

[21] Preferably, each of the assembly lines has at least two closed-loop wire filaments connected with a guide line so that the at least two closed-loop filaments are positioned alternately with a guide line.

[22] Preferably, the step (a) includes a step of bending both ends of each of the closed-loop wire filaments in advance so as to fix a shape of each of the closed-loop wire filaments.

[23] The stent according to one preferred embodiment of the present invention is formed of right-handed filaments having a closed-loop wire and left-handed filaments having a closed-loop wire, wherein the right-handed filaments are composed of a plurality of elongated wires arranged in right handed helices in their longitudinal direction, and the left-handed filaments are composed of elongated wires arranged in left handed helices in their longitudinal direction and have the same number as that of the right-handed filaments. The left/right-handed filaments are woven to each other in a one-over/one-under pattern to form a tubular structure having both open ends. Accordingly, in the hollow tubular structure with both open ends of the stent according to the present invention, both open ends of each of the closed-loop wire filaments start from one open end of a stent and are helically woven to reach the other end of the stent.

[24] In order to ensure structural stability of a stent to be used, each of the closed-loop wire filaments in the stent is formed in at least one helical turn. The number of helical turns of the closed-loop wire filaments in the stent is preferably determined by desired uses and specifications of the stent. Also, the number of the closed-loop wire filaments may be differently determined by both desired sizes and diameters of the open ends of the stent when the closed-loop wire filaments are expanded and contracted in a radial direction of the stent, and diameters of the wires used for each of the filaments. Accordingly, both the diameters of the wires and the number of the closed-loop wire filaments have an effect on the flexibility of the stent whose filaments are contracted in a radial direction during the expansion of the stent.

[25] Also, the closed-loop filament is preferably made from wires having a round section. Alternatively, the closed-loop filament may be made from wires having a rectangular section, depending on specific applications and uses of the stent.

[26] One way to alternately form closed-loop wire filaments is generally preformed by alternately weaving two groups of closed-loop wire filaments in opposite directions in a one-over/one-under pattern, but the present invention is not limited thereto. It goes w ithout saying that other patterns of forming for the stent, such as a one-over/two-under pattern, a two-over/two-under pattern, etc., may be used herein.

[27] According to still another preferred embodiment of the present invention, the elongated closed-loop filament preferably has a pair of parallel parts which are substantially in contact with each other. In the stent configured as in the above, each of the closed-loop filaments has two wires overlapped with each other, but end portions of each of the closed-loop filaments form a round loop in the open ends of the stent. Therefore, it is possible to prevent damage of human blood vessels and the like by means of the open ends of the stent which are composed of the round portion of the filaments of the stent.

[28] As a substitute, in the stent according to the preferred embodiment of the present invention, the elongated closed-loop filament preferably has a pair of parallel parts which may be arranged apart from each other at predetermined distances.

[29] According to one preferred embodiment of the present invention, the closed-loop wire filaments in use are made of, for example, metals such as surgical steel, etc., and have a good elasticity which is, for example, similar to alloys such as high cobalt stainless steel, Elgiloy alloys, etc. These materials enable the stent to show a good self-expandability.

[30] According to another preferred embodiment of the present invention, some or all of the filaments are preferably made from shape memory alloys such as Nitinol since, in addition to the self-expandability, mechanical characteristics of the stent should be changed according to temperature.

[31] According to still another preferred embodiment of the present invention, in order to minimize an adverse and undesirable interaction with walls of blood vessels and/or blood flowing through the blood vessels, the closed-loop wire filament preferably has a biocompatible coating composed mainly of polymer materials. Such a coating enables the stent to deliver drug agents.

[32] According to yet another preferred embodiment of the present invention, the stent is preferably manufactured by braiding a plurality of closed-loop wire filaments using a known braiding machine, and the stent may also be hand-made alone or made in combination of the hand-made process and a braiding process.

[33]

Brief Description of the Drawings

[34] The accompanying drawings illustrate preferred embodiments of the present

invention, and technical spirit of the present invention will be more fully described in combination with the following detailed description, so it should be understood that the scope of the present invention is not limited to the accompanying drawings.

[35] FIG. 1 is a perspective view schematically showing a stent according to one preferred embodiment of the present invention.

[36] FIG. 2 is a partial exploded view taken from a section "A" of FIG. 1.

[37] FIG. 3 is a perspective view schematically showing a stent according to another preferred embodiment of the present invention.

[38] FIG. 4 is a partial exploded view taken from a section "B" of FIG. 3.

[39] FIG. 5 is a diagram showing an assembly line in which closed-loop wire filaments are formed and connected to guide lines in order to form a stent according to the preferred embodiment of the present invention.

[40] FIG. 6 is a perspective view schematically showing a method for fabricating a stent according to the preferred embodiment of the present invention.

[41]

Best Mode for Carrying Out the Invention

[42] Hereinafter, preferred embodiments of the present invention will be described in detail referring to the accompanying drawings. Prior to the description, it should be understood that the terms used in the specification and appended claims should not be construed as limited to general and dictionary meanings, but interpreted based on the meanings and concepts corresponding to technical aspects of the present invention on the basis of the principle that the inventor is allowed to define terms appropriately for the best explanation. Therefore, the description proposed herein is just a preferable example for the purpose of illustrations only, not intended to limit the scope of the invention, so it should be understood that other equivalents and modifications could be made thereto without departing from the spirit and scope of the invention.

[43] FIG. 1 is a diagram showing a stent according to one preferred embodiment of the present invention, and FIG. 2 is a perspective view taken from a section "A" of FIG. 1.

[44] Referring to FIGs. 1 and 2, the stent 10 according to the preferred embodiment of the present invention is formed of right-handed filaments 12 having a closed-loop wire and left-handed filaments 14 having a closed-loop wire, wherein the right-handed filaments 12 are composed of a plurality of elongated wires spirally arranged in right handed helices in their longitudinal direction, and the left-handed filaments 14 are composed of elongated wires spirally arranged in left handed helices in their longitudinal direction and have the same number as the right-handed filaments 12. The left/right-handed filaments 12, 14 are woven to each other in a one-over/one-under pattern to form a tubular structure having both open ends 16, 18. The both open ends

16, 18 of each of the closed-loop wire filaments 12, 14 start from one open end of the stent 10 and are helically woven to reach the other end of the stent 10.

[45] The closed-loop filaments 12, 14 used in this embodiment are made of Nitinol wires whose sections are round in shape, and a contact point 3 (see FIG. 5) of the closed-loop filaments 12, 14 is preferably positioned in a substantially central region in a longitudinal direction of the stent 10.

[46] In the stent 10, each of the closed-loop filaments 12, 14 has a pair of wires arranged in parallel with each other, and the parallel wires are substantially spaced apart from each other. Also, end portions 11 of each of the closed-loop filaments in the open ends 16, 18 of the stent 10 are formed with a ring shape.

[47] FIG. 3 is a diagram showing a stent according to another embodiment of the present invention, and FIG. 4 is an exploded perspective view taken from a section "B" of FIG. 3.

[48] Referring to FIGs. 3 and 4, the stent according to this embodiment includes both open ends 22, 24, unlike the embodiment described referring to FIGs. 1 and 2, and therefore each of the closed-loop filaments 26 has a pair of wires arranged in parallel with each other, and the parallel wires are in contact with each other in a longitudinal direction. That is to say, ends of each of the filaments 26 in the open ends 22, 24 of the stent 20 do not have a sharp portion but a round portion 28 where the wires are bended.

[49] Referring to FIGs. 5 and 6, a fabrication method of the stent according to the preferred embodiment of the present invention will be described.

[50] FIG. 5 shows a method for forming a closed-loop wire filament which may be used in the stent according to the present invention, and a method for forming an assembly line using the same method.

[51] Referring to FIG. 5, the closed-loop wire filaments 12, 14 are formed by welding both ends 2, 4 of a metal wire 1 having a predetermined length, for example, using a laser bonding, or other general bonding processes. In this case, the ends 2, 4 of the wire 1 are preferably cut obliquely to a longitudinal direction. If the closed-loop wires are formed as described above, contact points 3 are formed on the filaments 12, 14. The contact points 3 are shown in a larger scale than an actual cross-sectional diameter of the wire 1, but a diameter of the contact point 3 is preferably substantially identical to the cross-sectional diameter of the wire 1. A plurality of the closed-loop filaments 12, 14 having a substantially identical length are provided in this manner.

[52] Then, a conventional medical wire 1 has a very high elasticity, and therefore each of the closed-loop filaments 12, 14 is heat-treated to lower inherent elasticity of the medical wire 1 to the extent that its inherent elasticity is not an obstacle to the braiding process (first heat treatment). Here, the heat treatment is preferably performed by the conditions (temperature or time) widely known in the art of the stent.

[53] If the closed-loop filaments 12, 14 are subject to this heat treatment process, the closed-loop filaments 12, 14 may be smoothly braided during a braiding process since the heat treatment prevents them from being entangled or folded due to their elasticity.

[54] As an alternative, both ends of the wire 1 having a constant length may be bended in a round shape, and then the both ends of the wire 1 may be welded. If this method is used, the above-mentioned heat treatment used for fixing a shape of closed-loop filaments may be omitted, and the parallel closed-loop wires may be in close contact with each other.

[55] Next, a plurality of assembly lines 7 are formed, for example, by sequentially connecting guide lines 5 such as threads to both ends of each of the closed-loop filaments 12, 14, wherein the threads includes fiber yarn and cotton yarn which are composed of polyamide, polyester, etc. Here, in the process of connecting the closed-loop filaments 12, 14 to the guide lines 5, a contact point 3 of the closed-loop filaments 12, 14 is preferably positioned as remotely as possible from a point to which the guide line 5 is connected. This is why the connection point 3 is positioned closer to the open ends 16, 18 of the stent 10 as the contact point 3 approaches the guide line 5, and therefore a welding area may be highly damaged by the connection point 3 in use of the stent 10.

[56] FIG. 6 is a diagram schematically showing main parts of a braiding apparatus for manufacturing a stent according to one preferred embodiment of the present invention by employing a plurality of assembly lines.

[57] Referring to FIG. 6, the braiding process is performed using a conventional braiding apparatus 30 provided with standard techniques. That is to say, when ends of each of the assembly lines 7 is connected to a circumferential surface of a mandrel 32 having substantially the same diameter as a stent 10 (before expansion) to be manufactured and a predetermined length, the desired stent 10 is braided onto the circumferential surface of the mandrel 32 with the two groups of the assembly lines moving in a zig-zag manner if a braiding bed (not shown), in which a carrier (not shown) that is unweaved by winding of the other end of the assembly line 7 is installed, is transferred into a predetermined shape and also if the mandrel 32 moves through a winding roller 34.

[58] As described above, a diameter of the stent is determined by a diameter of the mandrel 32, and a density of the stent is determined by the number of the assembly lines 7, cycles of a carrier, a take-up speed of a take-up motor, etc. Also, in the braiding process, an angle formed between two groups of the filaments in the stent may be adjusted by controlling the take-up speed which is engaged with the cycles of the carrier. The angle between the filaments in the stent, which is an important factor that determines a bending property of the stent, should be sustained at more than a

certain level in order to show good performances in blood vessels.

[59] If the assembly lines 7 are braided in the circumferential surface of the mandrel 32 in this manner, a region of the stent 10 is alternately connected to a region of a braided stent to form a complex braided product, wherein the region of a braided product is formed by entangling guide lines 5 and the region of the stent 10 is formed by closed-loop filaments 12, 14. Accordingly, after the braiding process is completed, a stent 10 having a certain shape may be manufactured by separating the complex braided product from the mandrel 32, followed by removing the region of the braided product, composed of the guide lines 5, from the region of the stent 10 using cutting, burning, melting methods, etc.

[60] Of course, the stent 10, manufactured through the above-mentioned procedure, may be finally heat-treated to memorize an inherent stent shape (second heat treatment). This heat-treatment step may be performed prior to the step of removing a guide line 5, performed at the same time as the removal process, or performed on the finished stent after the process of removing a guide line 5. Also, the heat treatment is preferably performed under the conditions (temperature or time) widely known in the art of the stent.

[61] In this embodiment, a method for continuously fabricating at least two stents from a plurality of assembly lines having guide line-closed-loop filament-guide line units connected thereto, is described. Accordingly, it is apparent that lengths of the fabricated stents 10 may be different if overlapped lengths of the closed-loop filaments 12, 14 are different from each other in one assembly line 7. Also, just one stent 10 may be braided by connecting one guide line 5 to both ends of one closed-loop filament.

[62] The stent according to the present invention has effects, as follows.

[63] First, the stent according to the present invention can prevent a welding area from being damaged since both open ends of the stent are formed in round regions of the ends of the closed-loop filament.

[64] Second, since a closed-loop filament, in which elongated wires are formed into a closed-loop shape in advance, is braided with a guide line (a pre-welding technique), the stent according to the present invention can be easily manufactured, compared to almost all of the conventional techniques in which a stent is welded or bonded at a time point that the stent is nearly completely assembled.

[65] Third, according to the process for providing a closed-loop filament to a conventional braiding apparatus using a guide line, the stent may be mass-produced since it is possible to automatize the braiding process, and also its uniformity in quality may be ensured in comparison to the conventional techniques using the hand-made or post-welding method.

[66] Fourth, it is sufficiently possible to constantly mass-produce a stent having a fine

diameter, which is required in the art.

[67]

Industrial Applicability

[68] The stent according to the present invention can be used as a heat-expandable or apparatus-expandable stent, as well as a self-expandable stent for treating blood vessels within human body.

Claims

[1] A stent having a hollow tubular structure with open ends, formed by weaving alternately a plurality of filaments, each having an elongated closed-loop wire, wherein both ends of the respective filaments are positioned at the open ends.

[2] The stent according to claim 1,
wherein a plurality of the filaments are divided into two groups of closed loops which are arranged spirally in a longitudinal direction of the tubular structure and alternate with each other in opposite directions.

[3] The stent according to claim 1 or 2,
wherein the elongated closed-loop filament has a pair of parallel parts which are substantially in contact with each other.

[4] The stent according to claim 1 or 2,
wherein the elongated closed-loop filament has a pair of parallel parts which are spaced from each other at predetermined distances.

[5] The stent according to claim 1 or 2,
wherein each of the filaments is made of a biocompatible metal or its alloys.

[6] The stent according to claim 1 or 2,
wherein the tubular structure is formed by braiding and/or winding a plurality of closed-loop filaments.

[7] A method for fabricating a stent, including:
(a) preparing a plurality of filaments with an elongated closed-loop wire;
(b) forming a plurality of assembly lines, in each of which at least one closed-loop filament is connected with at least two guide lines in an alternating fashion;
(c) braiding the assembly lines into a tubular structure by providing a plurality of the assembly lines to a braiding device; and
(d) removing the braided guide lines from both ends of the tubular structure composed of the filaments.

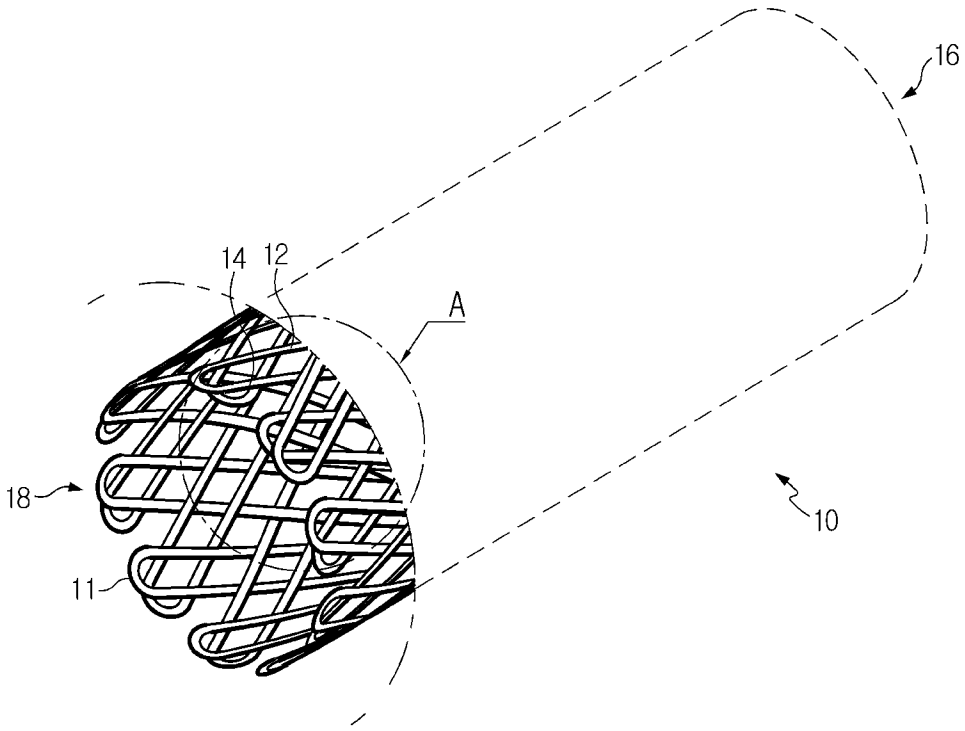
[8] The method for fabricating a stent according to claim 7, further including:
processing a first heat-treatment of the filaments to fix a shape of the closed-loop filaments prior to the step (b); and
processing a second heat-treatment of the stent to memorize a shape of the stent next to the step (d).

[9] The method for fabricating a stent according to claim 7 or 8,
wherein each of the assembly lines has at least two closed-loop wire filaments connected with a guide line so that the at least two closed-loop filaments are positioned alternately with the guide lines.

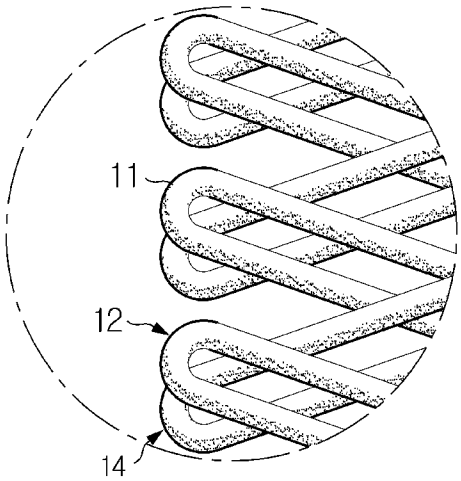
[10] The method for fabricating a stent according to claim 7,

wherein the step (a) further includes a step of bending both ends of each of the closed-loop wire filaments in advance so as to fix a shape of each of the closed-loop wire filaments.

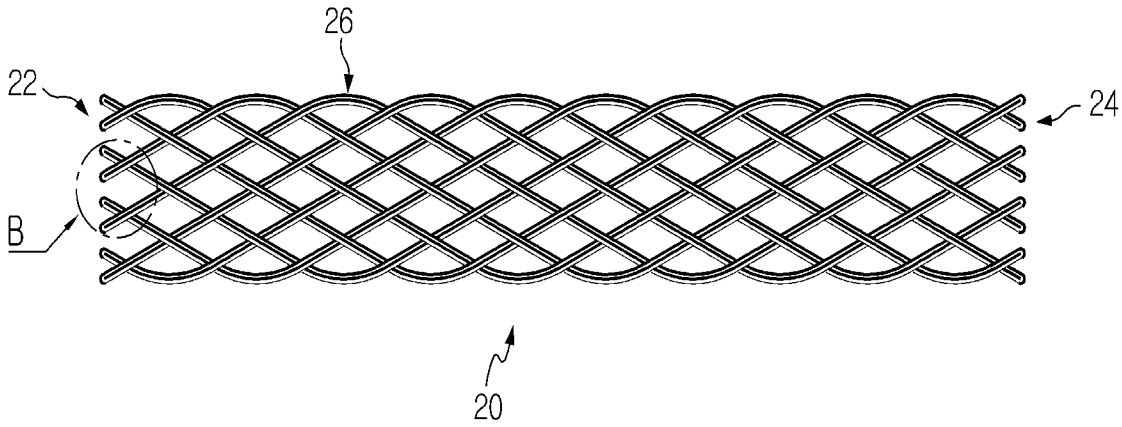
[Fig. 1]



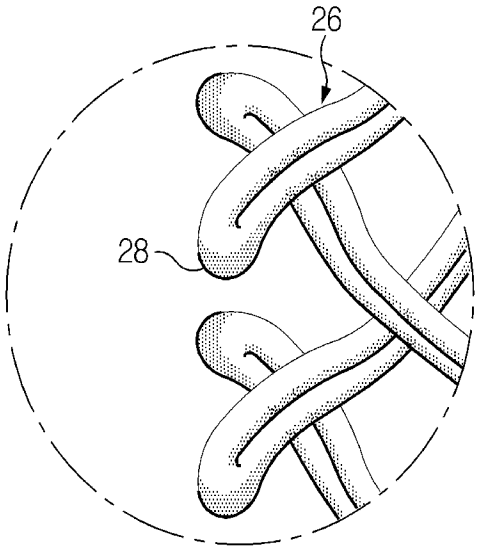
[Fig. 2]



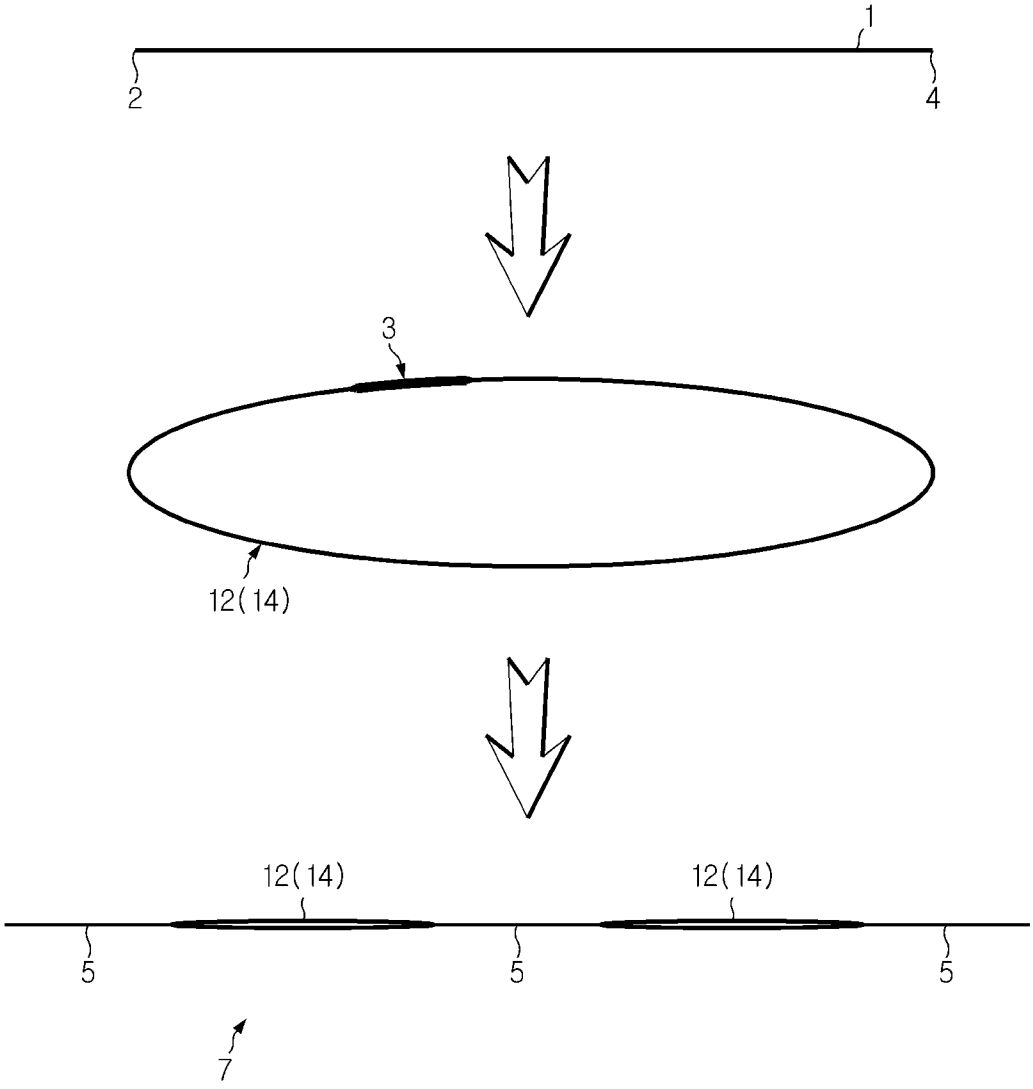
[Fig. 3]



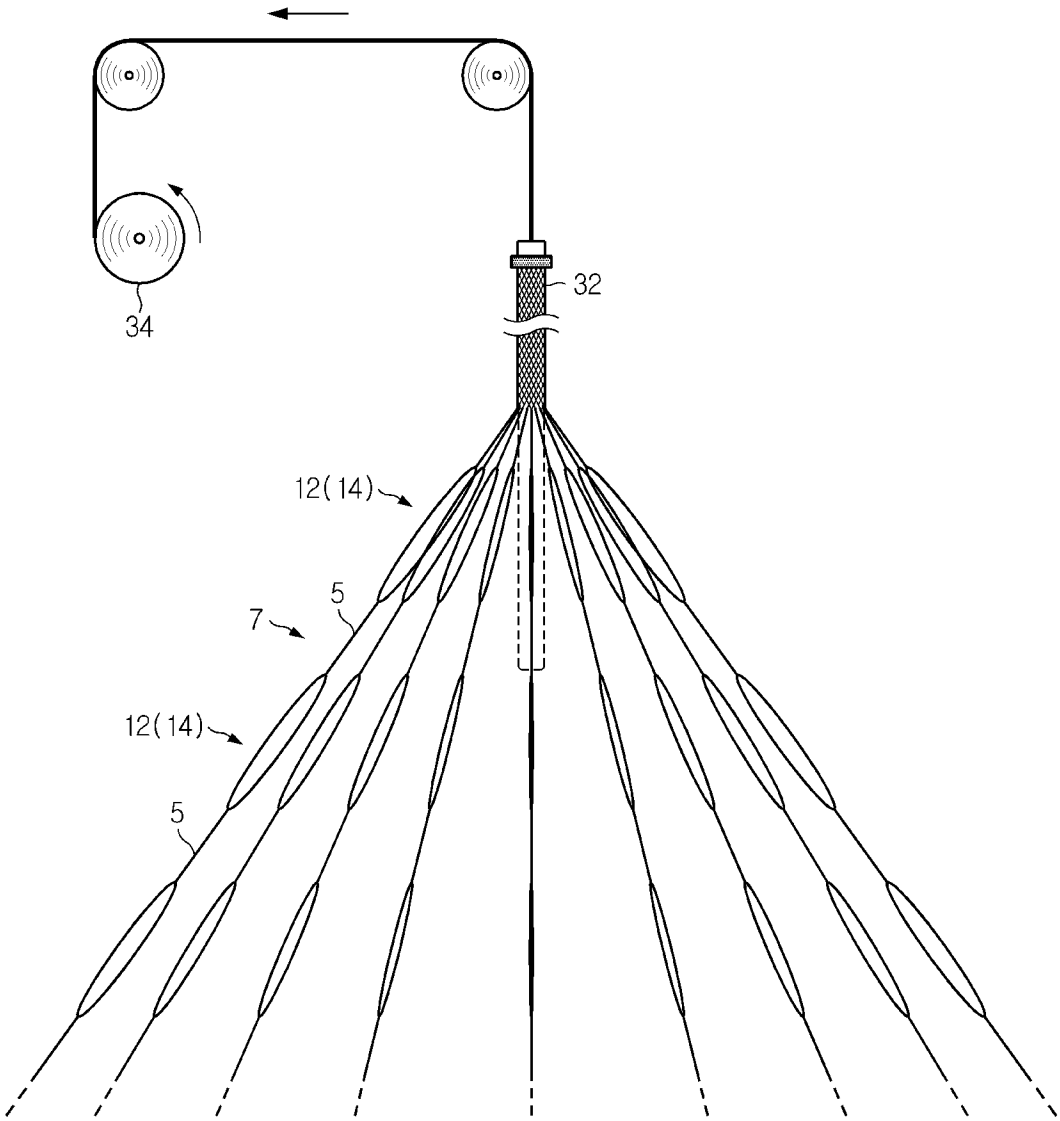
[Fig. 4]



[Fig. 5]



[Fig. 6]



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2007/000930

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/82(2006.01)i

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)
IPC8 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility Models since 1975
Japanese Utility models and applications for Utility Models since 1975

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
KIPASS(KIPO internal), DELPHION, "stent, closed-loop, braid*, and similar terms"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/0149473 A1 (PAUL F. CHOUINARD et al.) 07 August 2003 See the whole document.	1 - 10
A	US 2001/0029398 A1 (BALKRISHNA S. JADHAV) 11 October 2001 See the whole document.	1 - 10
A	EP 1440672 A1 (MEDTRONIC VASCULAR Inc.) 28 July 2004 See the whole document.	1 - 10
A	WO 97/16133 A1 (BIOCOMPATIBLES LIMITED) 09 May 1997 See the whole document.	1 - 10

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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