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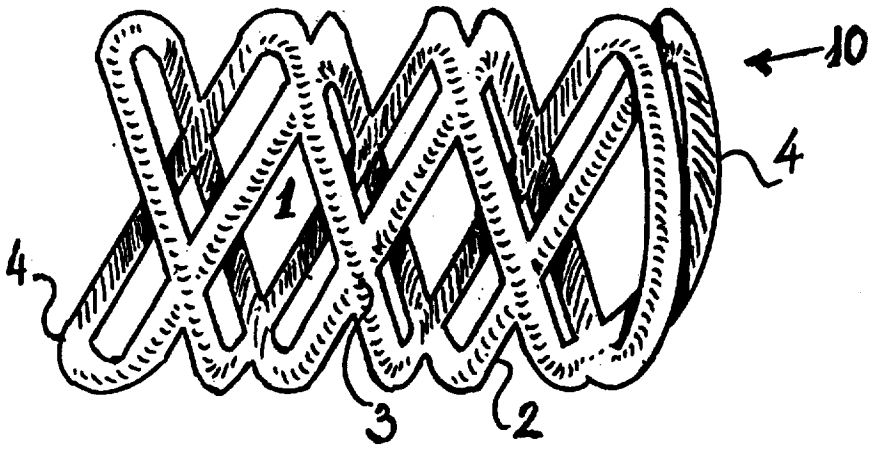

(57) Abstract

Endoluminal stent (10) with tubular network (1) structure to eliminate the narrowing of blood vessels or other luminal passageways of the human body, which stent disposed in the expanded location of the said lumen to stabilize the expanded diameter of it, and in the state disposed in desired location of the blood vessel or the other luminal passageway of the human body the radial force of it is greater than the recoil of the blood vessel, characterized by that the network (1) structure of the stent (10) is made by an endless self-contained monofilament of metal-wire (2), and preferably the stent (10) is made of noble metal, especially gold, or is coated with precious metal, e.g. gold. At the preferred embodiment of the stent according to the present invention the longitudinal size of the network (1) is defined by the general formula [n.k+j].L wherein the "L" is the length of one lead in the helix for any wire filament (2) in the network (1); the "n" is an integral number especially between 5 and 24; the value "k" is 0.125; the value "j" may be 0.06-0.13; and the length of the stent (10) is about any multiple of the one eighth of the "L".

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Endoluminal Stent

The Field of the Invention

The present invention relates to endoluminal stent with tubular network stucture to eliminate the narrowing of blood vessels or other luminal passage ways of the human body, which stent disposed in the expanded location of the said lumen can stabilise the expanded diameter of it.

Prior Art

The known endoluminal grafts or stents are used mainly to treat narrowing of blood vessels. It can be a network structure of metal wire or can be made of metal tube with slots by laser. These products are different by the metal-component and the design of the network. One of the well-known products is the slotted tube stent design of Johnson & Johnson Co, which has less diameter in elongated state, thus it is easy to dispose in the desired location of the lumen, wherein the rhomboidal structure opens and the stent will be shorter, simultaneously its diameter bigger. Some stent types are crimped on a balloon catheter, and in the lumen the stent will be enlarged with help blowing of the balloon, which just after will be removed from the blood vessel. These stent are made of the special tissuefil and metalworking metal „316L Stainless Steel" produced for this purpose and keeps its network shape and size against the pressure of the lumen's wall. Further it is known and used other stents made of resilient material being unstable and tense at elongated state, therefore they dispose it closed in the lumen with help of a protection casing. After removing the said casing the self-expandable stent opens and steps in stabile state. The shape of Medtronic stent's network is a plurality of loops on both directions on a virtual cylindrical surface. The wire helix of Cordis stent includes a main helix line and a second one on it, quasi „modulated" the main line by the second one. Cobalt-steel gives the resilient property to the structure. There are stents made of plastic material, and it is known the use of tantalum-alloy too. We can find stent with network as a combination of right and left directional helix. The Schneider Co produces a stent wherein the network lays between an inner and an outer coaxial catheter, just removing them after the stent is disposed in the desired location. The AVE (Advan-

ced Vascular Engineering.) uses multiple units defined as endless zig-zag line wire cylinders with welded joints one to other. The US.Pat. 5,102 417 and the 5,195 984 describe casing network with rhomboidal or „brick-wall" shape and the segments of it is bonded one to other with linkages on mutual side.

These products are expensive, consequently the true requires of market is limited to an smaller group of patient being able to pay the stent. Thus the development costs ratio of total product will be higher especially at the laser technique which is economical only in case of large series production. On the other hand the network of wire may better expand and elongate, but disadvantageously it has many free wire-end which can cause wounds inside of the lumen. An other drawback of the known stent is the bad X-ray contrast which in the insertion of the stent is dangerous for the patient and it makes the work more difficult for the physician.

Disclosure of the Invention

The first object of present invention is to develop an endoluminal stent for stabilising the enlarged state of blood vessel or other endoluminal passageway producing with a quality according to medical requires in lower cost than the known products even in small series production.

A further purpose of the present invention is to eliminate the drawbacks of the known products said in prior art, especially the bad X-ray contrast.

The inventiv step based the present invention is the idea that we may eliminate the dangerous wire-ends and the linkages between the segments applying endless wire filament merely with one welding point on the conjoin of two end of said filament.

It was recognized that may prove the satisfactory radial force against the wall-pressure of blood vessel with help spot welding on a few cross of filament.

Furthermore it was recognized that producing the stent of noble metal or coating it with precious metal the tissuefil property will be better and it gives excellent X-ray contrast against the known wire-metal. In this description the noble or precious metal means always gold, silver or platina.

On the base of the said inventiv recognization the invention is endoluminal stent with tubular network structure to eliminate the narrowing of blood vessels or other luminal passageways of the human body, which stent disposed in the expanded location of

the said lumen to stabilize the expanded diameter of it, and in the state disposed in desired location of the blood vessel or the other luminal passageway of the human body the radial force of it is greater than the recoil of the blood vessel, and may characterized by that the network structure of the stent is made by an endless self contained monofilament of metal-wire.

The said stent especially may characterized by that the 50-100% of the nodel cross of the network the crossing wire filaments are fixed one to other, preferably with help of spot welding.

Also especially the said stent is made of noble metal or it is coated with precious metal.

The longitudinal size of the network in our stent preferably may characterized by the general formula [n.k + j] . L wherein the „L" is the length of one lead in the helix for any wire filament in the network, the „n" is an integral number especially between 5 and 24, the value „k" is 0,125, the value „j" may be 0,06-0,13, so these means that the length of stent is about any multiple of the one eighth of the „L".

An other object is of this invention a stent to eliminate the narrowing of blood vessel or other endoluminal passageway of human body which may characterized in that the stent is made of noble metal, especially of gold, or is coated with precious metal, f.e. with gold.

The invention will be demonstrated detail with help of the drawings but without limiting the claims to the examples of demonstration.

Figures

Figure 1. A view of an preferred embodiment of the stent according to the present invention.

Figure 2. The theoretical schema of the structure of the stent according Fig.1.

The stent 10 includes the wire 2 starting from the lower and upper loops 4 being accordingly the Fig.1. on the left end of the stent 10 and running along a virtual cylinder surface. Both left loop 4 is the start-point of an right-, and an left helix-line which more times cross 3 one the other on the said cylinder surface and finally its unite in the two loops 4 found before an behind on the right end of stent 10. The 50% of the nodel cross 3 of the network 1 the crossing wire filaments 2 are fixed one

to the other with help of spot welding. The wire 2 composes thus the network 1 on the virtual cylinder surface forming an endless self-contained curveline. The said example is a network 1 having two loops 4 on its each end. In the practice we must use more compact network with smaller openings to eliminate surely the invagination of the lumen-wall in the said network openings. To satisfy these requirement the network openings may be at most 2,3 mm, what means a network 1 with at least four loops 4 on both ends further the network 1 is formed by four left-helix and four right-helix wires 2, but all the said wires 2 together create one monofilament. It is used embodiment with five, six or eight loops 4 both end of the network 1.

The wire 2 is made of the commercial 316L stainless steel or of with treated reinforced gold or of gold coated wire-metal. The proposed diameter of the stent 10 for coronary blood vessel is 3-5 mm made of about 0,2 mm diameter wire 2, for peripheral blood vessels 3-12 mm diameter of stent with about 0,3 mm diameter wire 2. In the case of prostata complaint the stent diameter must be 10-15 mm and the wire diameter 0,3-0,4 mm, further it is proposed for swalling throat (i.e. gullet) 28 mm stent diameter with about 0,5 mm wire diameter. In the above-mentioned cases the stent must supplied at least eight-eight wire 2, except the coronary disease for what is enough four-four left and right helix line to create the network 1.

Using precious metal may apply also the silver or the gold-silver alloy instead of with crystalline treat reinforced gold. For prostate disease it is very advantageous to apply silver or silver-coating because of experimental data prove the disinfecting effect of silver in the urinary tract. Using the gold as coating --- e.g. on 316L wire-metal --- the 316L metal-core forms 0,150-0,195 mm diameter part and it is surrounded with a 2,5-25,0 mm thick noble metal coating.

The lead angle of network 1 may be 45^0-60^0 concerning to the end plane of the structure's virtual cylinder. The length of the stent 10 is the summerized length of the united networks 1. The length of the network 1 is a function of the lead but against it we may define it in a wide range. After our experiences the length of the network 1 must be an integral multiple of the suboctuple lead [„L"] because the three-dimensional monofilament network may best form on this way. The „L" length we can reasonable accept as period-length because inside of this length all wire-segments, starting whether to left or right direction from the loops 4, make a whole spiral-lead.

Practically we set up the length of network 1 to the five times valve of 0,125.L and we unite two above-mentioned network element with monofilament-creating welding. For example we are realizing a 20 mm long stent 10 for a 4 mm inner diameter lumen according to the 20 mm length enlarging balloon available on the market. In this case our network 1 is 8 mm long in enlarged state and 10 mm long in elongated state. To create a two part stent 10 with the above method we achieve the stent-length accordingly the 20 mm long enlarging balloon and this stent 10 is very flexible consequently its two part construction against it length. Generally the network 1 has a length characterized with the formula :

0,125 n L + j.L wherein the „n" is a simple integral preferably in the scale 4 -12, the valve of „j" is in the range 0.06-0,13. Apparently about a suboctuple length-extension is necessary for the back-turning the filament i.e. for the loops-forming (See Fig.2.)

The stent according to present invention is cheaper than the laser slotted network structure and may be produced economically also in smaller series. Compared to the known stents with network structure of wire the products of present invention has no free wire ending and despite it comprises only one welding for that. A number of reinforcing welding may be used additionally. The stent of present invention shows controllable X-ray visibility in the group of known stent, because of the amount and ratio of the noble metal used.

Claims.

1.) Endoluminal stent with tubular network structure to eliminate the narrowing of blood vessels or other luminal passageways of the human body, which stent disposed in the expanded location of the said lumen to stabilize the expanded diameter of it, and in the state disposed in desired location of the blood vessel or the other luminal passageway of the human body the radial force of it is greater than the inwardly wall pressure of the blood vessel, **characterized by that** the network (1) structure of the stent (10) is made by an endless self contained monofilament of metal-wire (2).

2.) The stent accordingly to claim 1 sets forth in that the 50-100% of the nodel cross (3) of the network (1) the crossing wire filaments (2) are fixed one to other, preferably with help of spot welding.

3.) The stent accordingly to claims 1. or 2. set forth in that is made of noble metal or it is coated with precious metal.

4.) The stent accordingly to any of the claims 1.-3. set forth in that the longitudinal size of the network (1) is defined by the general formula [n.k + j] . L wherein the „L" is the length of one lead in the helix for any wire filament (2) in the network (1); the „n" is an integral number especially between 5 and 24; the value „k" is 0,125; the value „j" may be 0,06-0,13; and the length of the stent (10) is about any multiple of the one eighth of the „L".

5.) Stent to eliminate the narrowing of blood vessel or other endoluminal passageway of human body **characterized by that** the stent (10) is made of noble metal, especially of gold, or is coated with precious metal, f.e. with gold.

AMENDED CLAIMS

[received by the International Bureau on 22 December 1997 (22.12.97); original claims 1 and 5 amended; remaining claims unchanged (1 page)]

1.) Endoluminal stent with tubular network structure to eliminate the narrowing of blood vessels or other luminal passageways of the human body, which stent disposed in the expanded location of the said lumen to stabilize the expanded diameter of it, and in the state disposed in desired location of the blood vessel or the other luminal passageway of the human body the radial force of it is greater than the inwardly wall pressure of the blood vessel, **characterized by that** the network (1) structure of the stent (10) having double helix line with mutual opposite direction each to another is made by an endless self contained monofilament of metal-wire (2).

2.) The stent accordingly to claim 1 sets forth in that the 50-100% of the nodel cross (3) of the network (1) the crossing wire filaments (2) are fixed one to other, preferably with help of spot welding.

3.) The stent accordingly to claims 1. or 2. set forth in that is made of noble metal or it is coated with precious metal.

4.) The stent accordingly to any of the claims 1.-3. set forth in that the longitudinal size of the network (1) is defined by the general formula [n.k + j] . L wherein the „L" is the length of one lead in the helix for any wire filament (2) in the network (1); the „n" is an integral number especially between 5 and 24; the value „k" is 0,125; the value „j" may be 0,06-0,13; and the length of the stent (10) is about any multiple of the one eighth of the „L".

5.) Stent to eliminate the narrowing of blood vessel or other endoluminal passageway of human body **characterized by that** the stent (10) is made of crystalline treated reinforced-gold, or it is coated with the same.

Statement under Article 19

The difference between the original and the new claim 1 is the text written below, and it is an insert in the 9.line of the unchanged text of the original claim 1 between the „...the stent(10)" and „is made by..." :

„ having double helix line with mutual opposite direction each to another".

The difference between the original and the new claim 5 is in the characterising part of the claim, where the new text is: „ the stent (10) is made of *crystalline treated reinforced-gold*, or it is coated with *the same*." instead of the old text: „the stent (10) is made of noble metal, especially of gold, or is coated with precious metal, f.e. with gold."

Both changing are based on the priority document and the original international filing.

The USP 5,354,308 description may not consider to be interfering matter with the present invention, because the formerly is composed of individual cell shape frames welded on long straight portions [6] each to others, where two wire run together parallel. The cited structure is quite different comparing to the double helix structure of the present invention having neither two-wire segments, nor long straight portions.

The other document considered to be relevant, the USP 4,969,458, although relates a device made of gold as an „low memory metal", but the gold is suitable for a stent only after the method of the present invention, i.e. after the crystalline treated reinforced state. This is the main difference between the formerly and the present technical solution.

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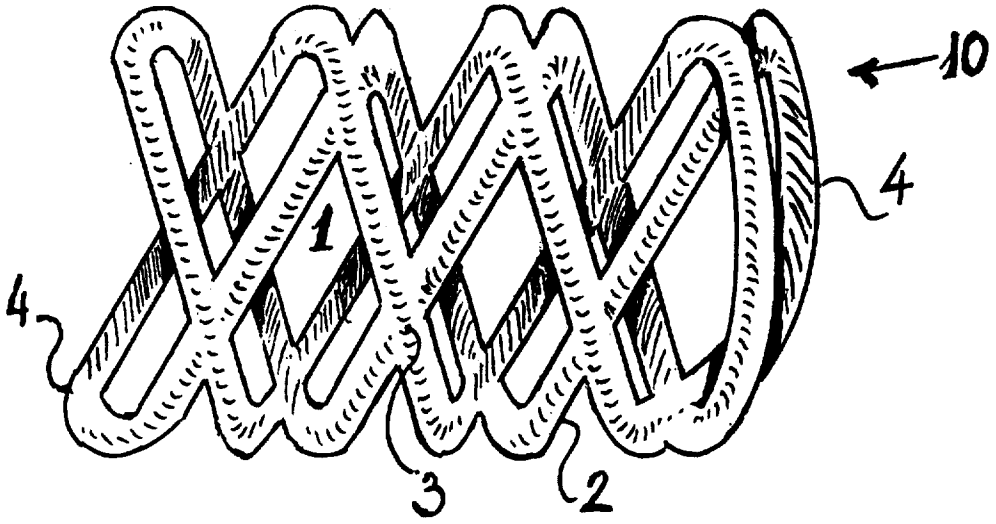

FIG. 1

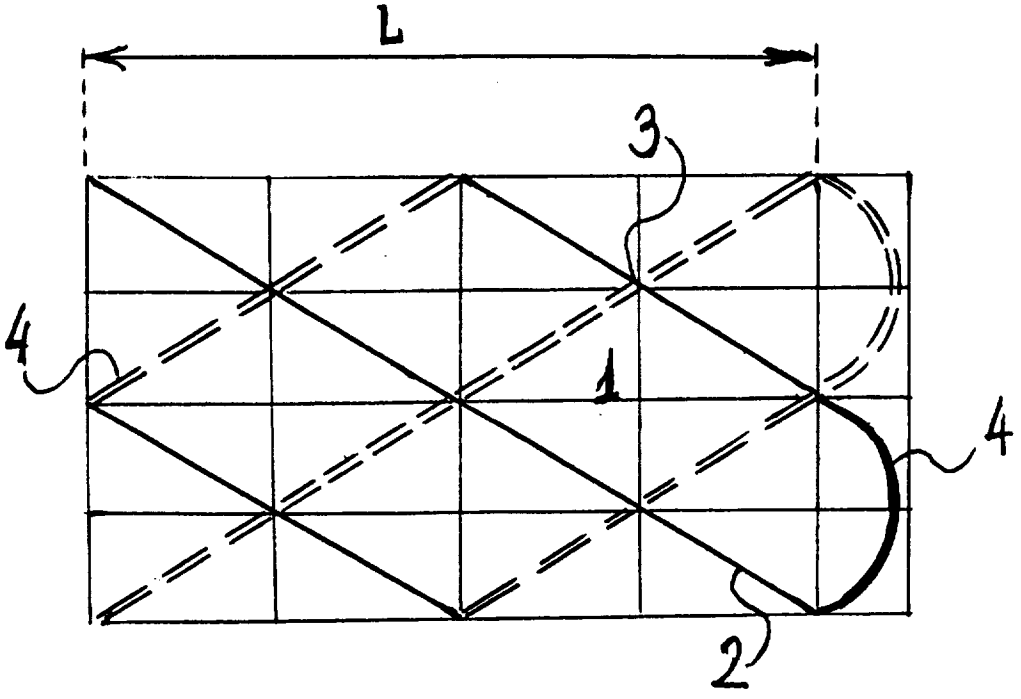

FIG. 2

INTERNATIONAL SEARCH REPORT

Internat Application No
PCT/HU 97/00042

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

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)
IPC 6 A61F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 354 308 A (SIMON ET AL.) 11 October 1994 see column 3, line 4 - line 15; figure 1	1,2
X A	US 4 969 458 A (WIKTOR) 13 November 1990 see abstract	5 3
A	GB 1 205 743 A (NATIONAL RESEARCH DEVELOPMENT) 16 September 1970 see page 1, line 96 - page 2, line 6; figure 1	1
A	WO 95 28895 A (WILLY RÜSCH AG) 2 November 1995 see page 10, line 8 - line 11	2
A	WO 92 09246 A (NUMED) 11 June 1992 see abstract	3

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

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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