Title: STENT FOR BIFURCATION AND A SYSTEM FOR INTRAVASCULAR IMPLANTATION OF THE STENT FOR BIFURCATION

Abstract: The stent for bifurcation 1 is characterized in that it consists of the distal part that has a smaller diameter and of the proximal part that has a greater diameter, connected with connecting struts to form a cell of the stent of an increased surface area. The system for intravascular implantation of the stent for bifurcation 3 is characterized in that, in the distal part of the system 3, there is a profilled balloon 2 marked with three marker bands 6, 7, 8 located on an internal tube 5 of the system for intravascular implantation of the stent for bifurcation. The profilled balloon 2 consists of three inseparable parts: the distal part - that has a smaller diameter, the proximal part - that has a greater diameter and of the middle part. On the profilled balloon 2, the stent for bifurcation 1 is crimped in a detachable manner, in such a way that the cell of the stent of an increased surface area of a stent for bifurcation 1 coincides with the middle part of the profilled balloon 2.
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<td>as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(U))</td>
<td>with international search report (Art. 21(3))</td>
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Stent for bifurcation and a system for intravascular implantation of the stent for bifurcation

Object of the invention is a stent for bifurcation and a system for intravascular implantation of the stent for bifurcation.

The state-of-the art systems for intravascular implantation of stent for bifurcation, utilizing various structural solutions at implantation of the stent, often bring about injuries, especially in bifurcations of arteries. The most frequent problems at implantation of the stent for bifurcation include partial or complete closure of a side branch of artery, contraction of a side branch of artery, dissection at bifurcation of vasculues, a decrease in a cross section of a side branch of artery as a result of covering of lumen with struts of an implanted stent, and occurrence of thrombosis foci.

To avoid such situations, at present either one stent per each branch is implanted by using separate systems for intravascular implantation for each of the implanted stents or one forked stent, mounted on the system, is implanted.

Procedures of intravascular implantation of stents for bifurcation using state-of-the-art methods are extremely complicated to implement and burdened with very high probability of various post-procedural complications in stented arteries. They must be carried out in surgeries provided with very modern equipment. Furthermore, operators carrying out the implantation are required to have high skills and much experience.

Accordingly, there is a demand for new, more effective structural solutions for stents for bifurcation and systems for intravascular implantation of such stents, in order to facilitate implantation at bifurcation place even by less experienced operators and to provide higher safety and efficacy of the procedure.

Aim of the present invention, the object of which is a stent for bifurcation and a system for intravascular implantation of the stent for bifurcation, is to increase efficacy and to facilitate implantation procedure, thus increasing safety of procedure and promoting wide use of dedicated stents for bifurcations.

A system for intravascular implantation of a stent for bifurcation, consisting of a proximal part and a distal part including an external tube, an internal tube, a profilled balloon and a leading tube, according to the invention, is characterized in
that, in the distal part of the system, there is a profilled balloon fastened with the proximal part to the external surface of an external tube and with the distal part to the external surface of an internal tube.

The profilled balloon consists of three inseparable parts: i.e. a distal part - a longer one and of smaller diameter, a proximal part - a shorter one and of greater diameter and a middle part of a specified length, located between the distal part and the proximal part.

Preferably, a ratio of a distal part diameter to a proximal part diameter of the profilled balloon is within the limits of 1.0:1.1 to 1.0:2.0.

Preferably, a length of the middle part of the profilled balloon amounts from 1 to 3 mm.

Preferably, angle θ is within the limits of 15° to 65°.

There are three marker bands, well visible at X-rays, which are fastened on the internal tube of the system for intravascular implantation of the stent for bifurcation, in such a manner that the first marker band coincides with a beginning of long edges of the proximal part of the profilled balloon, the second marker band coincides with a beginning of long edges of the distal part of the profilled balloon, whereas the third marker band coincides with an ending of long edges of the distal part of the profilled balloon.

On the profilled balloon, the stent for bifurcation is appropriately crimped in a detachable manner.

The stent for bifurcation of the invention is characterized in that it consists of two parts: the distal part, a longer one and having smaller diameter, and the proximal part - a shorter one and having greater diameter, which are connected with connecting struts of a specified length, forming a cell of the stent characterized by an increased surface area.

Preferably, a ratio of the distal part diameter to the proximal part diameter of the stent for bifurcation is within the limits of 1.0:1.1 to 1.0:2.0.

Preferably, a distance between the distal part and the proximal part of the stent for bifurcation depends on anathomy of the bifurcation place and amounts from 1 to 3 mm.
Preferably, upon detachable crimping of the stent for bifurcation on the profilled balloon, a cell having an increased surface area of the stent for bifurcation coincides with the middle part of the profilled balloon.

The leading tube is fastened, at at least one point, with its proximal part below the profilled balloon to the external tube of the system.

The leading tube is held in a position also by the proximal part of the stent for bifurcation crimped in a detachable manner on the profilled balloon. The distal part of the leading tube extends beyond the proximal part of the stent and is placed along the distal part of the stent.

The distal part of the leading tube has atraumatic ending of a colour different from that of the remaining part of the leading tube.

The stent for bifurcation and the system for intravascular implantation of the stent for bifurcation of the invention are characterized by relatively simple construction and solutions that facilitate fast, accurate and thus safe implantation of the stent for bifurcation in vessels.

The solutions are as follows:

- Special and profilled construction of the stent for bifurcation allowing for such positioning of the system for intravascular implantation of the stent for bifurcation during implantation such stent for bifurcation that the distal part of the stent for bifurcation is positioned beyond a fork of a vessel in a narrower part of the vessel, the proximal part of the stent for bifurcation is positioned before the fork, and the middle part of the stent, with connecting struts of the stent, forming at the same time a cell of the stent having a special, increased surface area, is positioned exactly at the lumen of the side branch while not disturbing the blood flow through the side branch of the fork.

- Locating three marker bands, well visible at X-rays, on the internal tube to ensure accurate positioning and visibility of the stent for bifurcation during its implantation in vessels.

- The stent for bifurcation crimped in a detachable manner on the profilled balloon in such a way that the cell of an increased surface area of the stent for bifurcation coincides with the middle part of the profilled balloon.
A special shape of the profilled balloon that prevents from shifting the carina tip during implantation of the stent for bifurcation, thereby preventing from blocking blood flow through the side branch of artery.

Designation of the distal end of the leading tube with a different colour from that of its remaining part, a way of its fastening to the external tube of the system for intravascular implantation of the stent for bifurcation, and also fastening of the leading tube through the proximal part of the stent for bifurcation, facilitate introduction and removal of the system for intravascular implantation of the stent for bifurcation from blood vessels upon implanting the stent for bifurcation.

The stent for bifurcation, as an object of the invention in an embodiment, is presented on Fig. 1, which shows a view of the stent for bifurcation with a depicted cell of the stent having an increased surface area 1.4.

The system for intravascular implantation of the stent for bifurcation in an embodiment is presented in a drawing, in which Fig. 2, shows a view of the profilled balloon, Fig. 3 shows a view of the distal part of the system for intravascular implantation of the stent for bifurcation and its location in a fork of artery, being a place of implantation of the stent, Fig. 4 shows arrangement of the stent for bifurcation upon its implanting in an artery and in its main branch.

The stent for bifurcation 1 of the invention consists of the distal part, that is longer and has a smaller diameter 1.1, and the proximal part - that is shorter and has a greater diameter 1.2, connected with connecting struts 1.3 having length L1, forming a cell of the stent of an increased surface area 1.4.

The system for intravascular implantation of the stent for bifurcation of the invention in its distal part 3 consists of the profilled balloon 2 fastened to the system 3 in such a way that the proximal part 2.2 of the profilled balloon 2 is fastened to the external surface of an external tube 4 of the system 3, and the distal part 2.1 of the profilled balloon 2 is fastened to the external surface of the internal tube 5 of the system 3.

The profilled balloon 2 consists of three inseparable parts: a distal part - that is longer and has smaller diameter 2.1, proximal - that is shorter and has greater diameter 2.2 and of a middle part 2.3 having a specified length, located between the distal part 2.1 and the proximal part 2.2. Between long edges of
the distal part 2.1 and an edge of the middle part 2.3 of the profilled balloon 2, there is
an angle Θ. The stent for bifurcation 1 is crimped in a detachable manner on the
profilled balloon 2, in such a way that the cell of the stent of an increased surface area
1.4 of the stent for bifurcation 1 coincides with the middle part 2.3 of the profilled
balloon 2. The leading tube 10 is fastened at at least one point 9 to the external tube 4
of the system 3 below the profilled balloon 2, the distal part 11 of the leading tube 10
having an atraumatic ending and colour different from that of the remaining part of
the leading tube 10. The leading tube 10 is held by the proximal part 1.2 of the stent
for bifurcation 1 crimped in a detachable manner on the profilled balloon 2. The distal
part 11 of the leading tube extends beyond the proximal part 1.2 of the stent for
bifurcation 1 and is placed along the distal part 1.1 of the stent for bifurcation 1.

Three marker bands 6, 7, 8, visible at X-rays, are fastened on the internal tube
5 of the system for intravascular implantation of the stent for bifurcation 3 in such a
way that the marker band 6 coincides with a beginning of long edges of the proximal
part 2.2 of the profilled balloon 2, the marker band 7 coincides with a beginning of
long edges of the distal part 2.1 of the profilled balloon 2, whereas the marker band 8
coincides with the ending of the long edges of the distal part 2.1 of the profilled
balloon 2.

The system for intravascular implantation of the stent 3 of the invention is
introduced into body in such a way, that two guide wires are advanced to the
bifurcation site, the first P1 of which is located in a side branch of artery, the second
P2 - in the main branch of artery.

Then, on the guide wires P1 and P2, the system for intravascular implantation
of the stent 3 of the invention is introduced.

The leading tube 10 fastened to the external tube 4 is put onto the first guide
wire P1. The internal tube 5 of the system for intravascular implantation of the stent 3
is put onto the second guide wire P2.

Then, moving on the guide wires P1 and P2 the whole system for intravascular
implantation of the stent 3, while controlling at the same time a position of the three
marker bands 6, 7, 8, at X-rays, the stent for bifurcation 1 is very precisely placed
with the profilled balloon 2 at the bifurcation site: the leading tube 10 on the guide
wire P1 enters a side branch of the artery, and the remaining part of the system 3 is
introduced on the guide P2 into the main branch of the artery.
Such introduction of the system for intravascular implantation of the stent for bifurcation 3 results in that the distal part 1.1 of the stent for bifurcation is situated beyond the bifurcation place of the artery, in the main branch, the proximal part 1.2 of the stent for bifurcation - before the bifurcation place, and the middle part of the stent, including the cell of the stent having a special, increased surface area 1.4, is located in the lumen of the side branch.

Liquid inflation under pressure 6 to 16 arm expanding the profilled balloon 2. Thereby opening of the stent for bifurcation 1. Fully opened stent for bifurcation 1 increasing lumen diameter of the vessel, thus eliminating stenosis.

Upon complete extension of the stent for bifurcation 1 its middle part, including the cell of the stent having a special, increased surface area 1.4, is located exactly in lumen of the side branch, which enables free blood flow through the side branch of artery.

Then, the liquid is removed from the profilled balloon 2, the whole system 3 with an deflated profilled balloon 2 and the leading tube 10 is withdrawn from blood circulation system. At the end, the guide wires P1 and P2 are removed. The opened stent for bifurcation 1 remains in a place where stenosis of artery existed, while preventing vessel from renarrowing.
Claims

1. Stent for bifurcation characterized in that it consists of two parts: the distal part, that has smaller diameter (1.1) and the proximal part that has greater diameter (1.2), connected with connecting struts (1.3) forming a cell of the stent of an increased surface area (1.4).

2. Stent for bifurcation of Claim 1, characterized in that the connecting struts (1.3) having length (Ll) from 1 to 3 mm.

3. Stent for bifurcation of Claim 1 or 2, characterized in that the ratio of a diameter of the distal part (1.1) to a diameter of the proximal part (1.2) of the stent for bifurcation is within the limits of 1.0:1.1 to 1.0:2.0.

4. System for intravascular implantation of the stent for bifurcation, consisting of the proximal part and the distal part including an external tube, an internal tube and a profilled balloon, characterized in that in the distal part of the system (3), on the internal tube (5) marked with three marker bands (6, 7, 8), visible at X-rays, there is a profilled balloon (2) fastened with the proximal part (2.2) to the external surface of the external tube (4), and with the distal part (2.1) to the external surface of the internal tube (5), the stent for bifurcation (1) being crimped on the profilled balloon (2) in a detachable manner.

5. System of Claim 4, characterized in that the leading tube (10) is fastened with its proximal part at at least one point (9) to an external tube (4) below the profilled balloon (2), the distal part of the leading tube (10) is ended atraumatically and marked with a different colour than that of the remaining part of the leading tube (10).

6. System of Claim 4 or 5, characterized in that the profilled balloon (2) consists of three inseparable parts - the distal part that has smaller diameter (2.1), the proximal part that has greater diameter (2.2) and the middle part (2.3) having length from 1 to 3 mm located between the distal part (2.1) and the proximal part (2.2).

7. System of Claim 4 or 5 or 6, characterized in that the ratio of a diameter of the distal part (2.1) to a diameter of the proximal part (2.2) of the profilled balloon (2) is within the range from 1.0:1.1 to 1.0:2.0.
8. System of any one of Claims 4 to 7, characterized in that there is an angle $\theta$ between the limits from $15^\circ$ to $65^\circ$ between the long edges of the distal part (2.1) of the profilled balloon (2) and the edge of the middle part (2.3) of the profilled balloon (2).

9. System of any one of Claims 4 to 8, characterized in that the leading tube (10) is additionally held by the proximal part (1.2) of the stent for bifurcation (1) crimped in a detachable manner on the profilled balloon (2).

10. System of any one of Claims 4 to 9, characterized in that upon detachable crimping of the stent for bifurcation (1) on the profilled balloon (2), the cell of an increased surface area (1.4) of the stent for bifurcation 1, coincides with the middle part (2.3) of the profilled balloon (2).
### A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/84 A61F2/92

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)

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)

EPO-Internal

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<tr>
<td>X</td>
<td>WO 01/74273 A1 (ADVANCED CARDIOVASCULAR SYSTEM [US]) 11 October 2001 (2001-10-11) page 5, line 18 - page 6, line 28; figure 1</td>
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<td>Y</td>
<td>WO 00/74595 A1 (ADVANCED STENT TECH INC [US]) 14 December 2000 (2000-12-14) page 17, lines 29-30; figures 3-5</td>
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<td>A</td>
<td>EP 1 547 546 A2 (BOSTON SCIENT LTD [BB]) 29 June 2005 (2005-06-29) paragraph [0037]; figures 12b, 12c</td>
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### D

Further documents are listed in the continuation of Box C

* Special categories of cited documents

- **A** document defining the general state of the art which is not considered to be of particular relevance
- **E** earlier document but published on or after the international filing date
- **L** document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- **O** document referring to an oral disclosure, use, exhibition or other means
- **P** document published prior to the international filing date but later than the priority date claimed

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Name and mailing address of the ISA/Authorized officer

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See patent family annex

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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

"E" member of the same patent family
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos. because they relate to subject matter not required to be searched by this Authority, namely

2. Claims Nos. because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically

3. Claims Nos. because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 64(a)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. X As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.

Remark on Protest

☒ The additional search fees were accompanied by the applicant's protest and where applicable, the payment of a protest fee

☒ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation

☐ No protest accompanied the payment of additional search fees
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-3

   A stent for bifurcation comprising a distal part, that has smaller diameter and a proximal part that has greater diameter, wherein said parts connected with connecting struts forming a cell of the stent of an increased surface area.

2. claims: 4-10

   A system for intravascular implantation, comprising an external tube; an internal tube; a profiled balloon; and a stent for bifurcation being crimped on said profiled balloon in a detachable manner, wherein the distal part of the system marked with three marker-bands on the internal tube, and wherein said three marker-bands are visible at X-rays.
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