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CONTROLLED AND PRECISE STENT PLACEMENT AT A CORONARY OSTIUM IN PERCUTANEOUS CORONARY INTERVENTIONS

Abstract

A stent delivery system (**100**) comprises a balloon-inflatable stent (**10**) with a guide wire (**31**) for guiding the stent (**10**) into a target vessel (V**1**) for treating a stenosis (**4**) in the target vessel (V**1**) with the stent (**10**) to be delivered at a predetermined stent position (Xs). An anchor wire (**32**) is provided through an anchor port (**52**) for anchoring the stent (**10**) by entering into a lumen or second vessel (V**2**) branching from the target vessel (V**1**) at a branching position (Xb). The anchor port (**42**) is freely adjustable along a length (ΔX) of the guide wire (**31**) for adjusting the anchor position (Xa) relative to the stent position (Xs), or vice versa. An anchor positioning means (**41**) is connected to the anchor port (**42**) and configured to control said freely adjustable anchor position (Xa) relative to the stent position (Xs), e.g. by pushing and pulling on a hypotube.

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Background/Summary

TECHNICAL FIELD AND BACKGROUND

[0001] The present invention relates to a system for delivering a stent to a stenosis in target vessel adjacent a branching position where the target vessel branches from a lumen or second vessel (carina or bifurcation). The invention also relates to a kit of parts for building such system, and an anchor port assembly for use in a stent delivery system or kit of parts.

[0002] Coronary stenosis is a ubiquitous disease. Since the introduction of percutaneous coronary intervention (PCI) in 1977 by Andreas Grüntzig, both the number of PCI's as well as development of techniques and devices have seen exponential growth. Currently, almost every technical aspect of coronary disease has been addressed including the much awaited successful treatment of chronic total occlusions. The PCI of coronary lesions located at or near a coronary ostium is often pursued and part of mainstream clinical practice, although the procedure can be technically challenging.

[0003] The exact positioning of the (proximal edge of a) coronary stent at a coronary ostium, if pursued, is of great importance. Although more difficult than conventional lesions, the operator is limited to the same palette of PCI techniques, including the limitations of **2**D angiography and patient induced movement resulting. This can result in excessive radiation, contrast dye use and uncontrolled/undesired coronary stent positioning.

[0004] The problem of stent placement can be addressed by the so-called “tail wire” or “Szabo” technique. The tail wire technique uses the most proximal stent strut as an anchor for a second or “anchor” wire to pass through. The anchor wire is positioned in the space in which the stent is not supposed to protrude, usually the aorta or, in case of a bifurcation, the side branch. The anchor prohibits the stent from advancing into the coronary artery, positioning its proximal part exactly at the carina. Although the technique provides more control during stent positioning, which is of great value in stenting at coronary ostia, it also requires stent manipulation and thereby introduces subsequent problems.

[0005] In a previous patent publication WO2019/156560A1, by the present inventor, problems of the traditional “tail wire” technique are alleviated by separating the anchoring possibility from the stent. In particular, this patent publication describes a system for delivering a stent to a predetermined stent position in a target vessel. The stent is wrapped around an inflatable balloon with a guide channel. A guide wire for entering into the target vessel passes through the guide channel for guiding the stent into the target vessel. A part of the inflatable balloon is wrapped by an elastic sleeve. The sleeve also provides an anchor port separate from the stent struts for guiding an anchor wire, e.g. into a branching vessel. Additionally, the sleeve is configured to at least partly prevent or delay the inflating of the inflatable balloon at the wrapped part compared to another part of the inflatable balloon opposite the stent. The anchor port can be connected to an anchor port line configured to remotely control the exit direction of the anchor port.

[0006] While the anchor port in the known system of WO2019/156560A1 has the advantage of preventing damage to the stent by not being directly connected to the stent struts, the present inventor has now recognized disadvantages of the known system. First of all it is recognized that the anchor port is still fixated via the elastic sleeve to the inflatable balloon which is also inside the stent. Essentially, the elastic sleeve wrapped around the balloon forming the anchor port, and the stent wrapped around the same balloon, can thus only be delivered into the patient as a single unit. In practice, the surgeon will typically first insert the main guide wire and anchor wire into

respective branches, before the stent with anchor port is passed along both these wires. Unfortunately, these wires may inadvertently become rotated around each other during delivery. This may become a problem when the stent with the anchor is advanced as a single unit along the rotated wires (passing through the stent balloon and anchor port, respectively) because the fixed position of the anchor port may not allow the wires to easily untangle. So, the entanglement may get further concentrated by being pushed along the wires until they may get stuck. Additionally, it is recognized that, while the anchor port of the known system allows adjusting an angle of the anchor wire exiting the anchor port, the position of the anchor port relative to the stent position is fixed. This may limit the possibility to control the position of the stent with respect to the position of the anchor wire.

[0007] There is yet a need for further improvements that can alleviate one or more problems of known stent delivery systems while maintaining at least some of their advantages. In particular, the inventor has recognized issues of guide wire entanglement in the known system and a need to more freely determine an exact position of the stent placement relative to a branching vessel structure while maintaining necessary precision and control over the stent deployment.

SUMMARY

[0008] Aspects of the present invention relate to a system or kit of parts for delivering a stent. In particular the system is configured for delivery of the stent to a predetermined stent position in a target vessel adjacent a branching position where the target vessel branches from a lumen or second vessel. A stent delivery system typically comprises a balloon-inflatable stent which is advanced over a guide wire for entering into the target vessel. A secondary guide wire can be introduced which enters into a side branch or any other adjacent vascular structure such as the aorta. The secondary guide wire is used in conjunction with the present invention, providing an anchor or tail wire, in such manner, that the position of the stent can be moved relative to the branching position. In particular, the anchor wire can pass through an anchor port to fix the position accordingly.

[0009] Contrary to previous solutions, the position of the anchor port, as described herein, is separated from the stent delivery catheter. Furthermore, the anchor port may not only function as a anchoring point for the anchoring guide wire, but may also function as a lumen to advance the stent delivery catheter and accompanying guide wire there through. As a result of the balloon inflators connecting hub that is part of a standard stent delivery catheter, the guide wires, the anchor port assembly as described herein, and the stent delivery catheter typically need to be introduced into the patient in respective order, subsequently. Advantageously, the anchor port is freely adjustable along a length of the guide wire relative to the stent position. Similarly, the stent delivery catheter and anchoring guidewire, both can freely move around each other in an axial manner, preventing guide wire entrapment or entanglement with the struts of the crimped stent. Furthermore, the stent position can also be adjusted with respect to the anchor position (which is determined by the anchor wire relative to the branching position). As will be appreciated, this configuration can provide improved control over the exact stent position while maintaining precision provided by the anchoring relative to the branching position. For example, this may be compared to other solutions, wherein the anchor port is formed by a stent strut (as in the traditional Szabo technique), or fixated relative to the stent such as disclosed in the inventor's above mentioned previous patent publication by connection to a sleeve that is immobile by being wrapped around the balloon and therefore not freely adjustable. Furthermore, as described herein, an anchor positioning means, preferably comprising a hypotube or rigid control wire, is directly or indirectly connected to the anchor port for controlling said freely adjustable position, e.g. by pushing and pulling on the hypotube. This is different from the inventor's above mentioned previous patent publication where the anchor port is optionally connected to an anchor port line but only for adjusting its orientation, not suitable to change relative position with respect to the balloon—at least not by pushing on the wire. Furthermore, because the anchor port of the previous patent publication was essentially fixed to the stent via the elastic sleeve and balloon, it was found that the guide wire and anchor wire may

become entangled. This problem is alleviated because the wires can now freely rotate around each other inside the separate and freely adjustable anchor port. Together, the distinguishing features of the present anchor port assembly alleviate entanglement of wires when advancing the stent, and allow more freedom to adjust the exact position relative to the balloon/stent where the main wire and anchor wire split up into the respective vessels. Further synergetic aspects include providing the anchor port with a radiopaque material that allows the device to be precisely placed. Further aspects may also include the ability to form the anchor port as a widening tubular member which can slide over a proximal part of the balloon and prevent or delay inflation thereof.

[0010] Other or further aspect relate to an anchoring assembly for supplementing a balloon-inflatable stent delivery system. The assembly can, e.g., act as a visual and mechanical aid to position and/or anchor a coronary stent exactly at a coronary ostium, e.g. defined by the so-called “carina”. Also other types of stents may benefit from the assembly. For example, while the precision of the exact positioning in coronary vessels is most challenging, similar techniques can also be applied in other (larger) vessels, such as bifurcations at the renal vessels (arteries and veins), leg vessels, brain vessels, et cetera. As described herein, the device preferably consists of an anchor positioning means which is connected to a ring or tubular extension which may contain a radiopaque material, to define the exact location of an ostium, enabling the operator to aim the desired stent position precisely, in particular by using two separate guidewires in combination, one positioned in the target vessel, the other position in the adjacent structure (e.g. branching vessel). For example, after positioning of both guidewires the ostium can be marked by carefully pushing the tubular extension until resistance is met, mechanically and subsequently visually identifying the carina.

[0011] By providing the anchor port with an opening having a minimum inner diameter that is larger than an outer diameter of the crimped stent before inflation of the balloon, the crimped stent may be allowed to be passed through the opening of the anchor port to the stent position, after the anchor port has been guided along the guide wire and the anchor wire to the anchor position. For example, the anchor port assembly may be used in combination with a relatively small stent, e.g. coronary stent. For a typical size of these and other stents, the assembly may comprise an anchor port formed by a ring or tubular shape, preferably having a minimum inner diameter between one and two millimeter. Also other diameters could be used depending on a size of the crimped stent which may be fitted through the anchor port.

[0012] By forming the anchor positioning means of a main cord ending in a set of branch cords, interconnecting the main cord with the anchor port at different positions around a perimeter of the opening, the inventor finds that the assembly may be easier to retract, e.g. into a guiding catheter, alleviating a potential issue that the anchor port may get stuck, which is more likely to happen if the tube or ring is only connected only at one position on the perimeter. By forming the branch cords of a resilient material or structure configured to recover its shape after deformation, it may be relatively easy to pass the crimped stent between the branch cords, after which they may recover to be more easily retracted. Similarly, by forming the anchor port of the same or different resilient material, or any structure configured to recover its shape after deformation, it may be relatively easy to pass the crimped stent through the anchor port, while the shape is thereafter recovered to perform the function of the anchoring and/or delaying inflation of the balloon.

[0013] By forming the main cord formed of hypotube or rigid control wire, the anchor position can be more accurately controlled and/or maintained. The individual branch cords may be relatively flexible compared to the main cord, whereas in combination they may provide sufficient rigidity to control and/or maintain the anchor position. The main cord, e.g. formed by a hypotube, or (rigid) control wire, typically has an outer diameter less than that of the anchor port, e.g. less than two millimeter, preferably less than one millimeter, e.g. between 0.2-0.5 mm. To provide sufficient reach inside the body, the main cord typically has a length of at least half meter, preferably at least one meter.

Description

BRIEF DESCRIPTION OF DRAWINGS

[0014] These and other features, aspects, and advantages of the apparatus, systems and methods of the present invention will become better understood from the following description, appended claims, and accompanying drawing wherein:

[0015] FIGS. **1**A and **1**B illustrate delivery and deployment of a stent to treat a stenosis in a target vessel near a bifurcation with a second vessel; and

[0016] FIGS. **2**A-**2**D illustrate use of the stent delivery system, including a preferred sequence of steps for the delivery;

[0017] FIG. **3**A illustrates details of an anchoring assembly for use in a stent delivery system; and

[0018] FIGS. **3**B-**3**D illustrate different anchoring assemblies;

[0019] FIGS. **4**A-**4**D illustrate further aspects of anchoring assemblies.

DESCRIPTION OF EMBODIMENTS

[0020] Terminology used for describing particular embodiments is not intended to be limiting of the invention. As used herein, the singular forms “a”, “an” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. The term “and/or” includes any and all combinations of one or more of the associated listed items. It will be understood that the terms “comprises” and/or “comprising” specify the presence of stated features but do not preclude the presence or addition of one or more other features. It will be further understood that when a particular step of a method is referred to as subsequent to another step, it can directly follow said other step or one or more intermediate steps may be carried out before carrying out the particular step, unless specified otherwise. Likewise it will be understood that when a connection between structures or components is described, this connection may be established directly or through intermediate structures or components unless specified otherwise.

[0021] The invention is described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. In the drawings, the absolute and relative sizes of systems, components, layers, and regions may be exaggerated for clarity. Embodiments may be described with reference to schematic and/or cross-section illustrations of possibly idealized embodiments and intermediate structures of the invention. In the description and drawings, like numbers refer to like elements throughout. Relative terms as well as derivatives thereof should be construed to refer to the orientation as then described or as shown in the drawing under discussion. These relative terms are for convenience of description and do not require that the system be constructed or operated in a particular orientation unless stated otherwise.

[0022] FIGS. **1**A and **1**B illustrates delivery and deployment of a balloon-inflatable stent **10** to treat a stenosis **4** in a target vessel V**1** near a bifurcation with a second vessel V**2**. FIGS. **2**A-**2**D illustrate use of the stent delivery system **100**, including a preferred sequence of steps for the delivery. Also other uses and/or sequences of steps may be envisaged.

[0023] In some embodiments, the system comprises an inflatable balloon **20**. In one embodiment, the stent **10** comprises an extendable frame **11** wrapped around the inflatable balloon **20**. In another or further embodiment, the system comprises a guide wire **31** for entering into the target vessel V**1**. For example, the guide wire **31** may pass through a guide channel **21** inside the stent or balloon for guiding the inflatable balloon **20** with the stent **10** (while crimped) along or with the guide wire **31** into the target vessel V**1**.

[0024] In some embodiments, the system comprises an anchor wire **32** for determining an anchor position Xa relative to a branching position Xb where the target vessel V**1** branches from a lumen or second vessel V**2**. In one embodiment, the system comprises an anchor port **42** in use having the anchor wire **32** passing there through and determining the anchor position Xa relative to the stent position Xs. Typically, the guide wire **31** and anchor wire **32** may be first positioned into the

respective vessels V**1**, V**2**, e.g. as shown in FIGS. **2**A and **2**B; after which the anchor port **42** is guided from outside into the patient over the two wires and then advanced to the carina, e.g. as shown in FIG. **2**C. So it will be understood that the anchor port **42** is preferably unaffixed, i.e. not fixed, to any of the inflatable balloon **20** or the balloon-inflatable stent **10**. Accordingly, the anchor position Xa of the anchor port **42** can be freely adjustable along a length ΔX of the guide wire **31** relative to the stent position Xs of the stent **10**. In a preferred embodiment, an anchor positioning means **41** is provided having a distal end connected to the anchor port **42**. A proximal end of the anchor positioning means **41** is configured to control said freely adjustable anchor position Xa relative to the stent position Xs by pushing and pulling the proximal end. Most preferably, the anchor positioning means **41** comprises a hypotube which is directly or indirectly connected to the anchor port **42** for controlling said freely adjustable anchor position Xa relative to the stent position Xs, e.g. by pushing and pulling on the hypotube **41**.

[0025] For example, US 2017/0274179 A1 describes a hypotube construction. As explained in this prior art, a hypotube is typically a long metal tube with micro-engineered features along its length. A hypotube can be used as a component of minimally-invasive catheters, in conjunction with balloons and stents to open up clogged arteries. Typically, the balloon portion of the catheter can be attached to a head of the hypotube. A hypotube may have a reinforcement which may give its liners more support and integrity as the catheters navigate the vasculature to a treatment location. In some instances, a polymer jacket is distributed on an outer diameter of the hypotube to provide a seal and also to minimize any surface roughness imparted by the laser cutting of the hypotube while still providing flexibility. Also other types of hypotube may be used.

[0026] By connecting the anchor port **42**, as described herein, to a hypotube the freely adjustable anchor position Xa relative to the stent position Xs can be more accurately controlled, e.g. by pushing and pulling on the hypotube. Furthermore, the controllable position can be more accurately maintained, in particular when the balloon inflates. Alternatively, or in addition to a hypotube, also other or further relatively rigid and/or incompressible structures can be used such as a rigid, e.g. metal, wire which is not necessarily a tube, e.g. does not have to be hollow.

[0027] In some embodiments, the anchor port **42** is formed by a ring-shaped and/or tubular member connected to the hypotube **41**. In one embodiment, the guide wire **31** passes through the anchor port **42**. For example, a proximal part of the guide wire **31** can be inside a second hypotube connected to the balloon-inflatable stent. In another or further embodiment, each of the guide wire **31** and the anchor wire **32** pass through the same opening of the anchor port **42**, e.g. through the ring or tube forming said anchor port. For example, this provides an easy construction with a single opening to guide both wires (and also the stent). Alternatively there could be separate openings for the respective wires.

[0028] In some embodiments, the anchor port **42** is configured to fit at least part of the inflatable balloon **20** inside. For example, part of the inflatable balloon **20** (before deployment) may fit inside the anchor port **42**, e.g. up to the extendable frame **11**, or further. By fitting part of the balloon **20** inside the anchor port **42**, while the balloon is being inflated, the anchor port **42** can at least partially prevent and/or delay inflation of said part of the balloon. This may be advantageous in further controlling the inflation process, e.g. prevent the stent frame from shifting during inflation, according to the properties of the narrowing or stenosis, which is a common phenomenon during percutaneous interventions and disadvantageous in the treatment of ostial lesions

[0029] In some embodiments, the crimped stent **10**, i.e. undeployed stent frame **11** around the deflated balloon, fits completely inside and/or can be guided through the anchor port **42**, e.g. as shown in FIGS. **2**C and **2**D. This may be advantageous, e.g. if the stent **10** is sent along the guide wire **31** after the position of the anchor port **42** is established. For example, FIG. **1**B illustrates a deployed stent wherein a proximal side **20***p* of the inflated balloon is partially inflated inside the tubular extension forming the anchor port **42**. By preventing or delaying the inflation, it may be prevented, e.g., that the stent frame moves away from the intended position during inflation.

[0030] FIG. **3**A illustrates details of an anchoring assembly **40** for use in a stent delivery system **100**, e.g. as described herein. For example, anchoring assembly **40** can be a stand-alone device used to supplement an existing stent delivery system.
[0031] In some embodiments, the anchor port **42** (e.g. tubular member as shown or other tube or ring-shape) has a (minimum) inner diameter Dmin Dp that is larger than a cumulative outer diameter of the guide wire **31** and the anchor wire **32**, e.g. by at least a factor 1.1, 1.5, 2, or more. For example, the minimum inner diameter Dp is more than twice the outer diameter of each of the guide wire **31** and anchor wire **32**. This allows each of the guide wire **31** and anchor wire **32** to freely slide through the anchor port **42** and/or allows the anchor port **42** to be freely adjustable along said wires. Typically the anchor port **42** is at least larger in diameter than the hypotube **41** used to control its position. In one embodiment, the anchor port **42** has an outer diameter larger than an outer diameter of the hypotube **41**, e.g. by at least a factor two, four, six, eight, ten, or more.
[0032] In some embodiments, the anchor port **42** is formed by a tubular member shaped to slide over a proximal region of the inflatable balloon **20** for at least partially preventing and/or delaying inflation at said proximal region. In one embodiment, the anchor port **42** has an inner diameter Dd, at least at a distal side facing a proximal side of the inflatable balloon **20**, that is larger than an outer diameter Db of the inflatable balloon **20** (before inflation). This allows at least part of the inflatable balloon **20** to be fitted inside the anchor port **42**, as noted above.
[0033] In some embodiments, the anchor port **42** has a minimum inner diameter Dmin that is larger than an outer diameter Ds of the (crimped) stent **10** before inflation of the balloon **20**. This allows to fit the crimped stent **10** inside and pass through the anchor port **42**. In other or further embodiments, the anchor port **42** has a minimum inner diameter Dmin that is (slightly) larger than a cumulative outer diameter of the anchor wire **32** and the (crimped) stent **10** before inflation of the balloon **20**, e.g. larger by a factor between 1.01 and 1.5, preferably between 1.05 (5% larger) and 1.3 (30% larger). This allows to fit the crimped stent **10** inside and pass through the anchor port **42** also when the anchor wire **32** is already passed through the anchor port **42**, e.g. as shown in FIGS. **2**C and **2**D.
[0034] In a typical balloon-inflatable stent for coronary application, before deployment, the outer diameter Ds of the (crimped) stent is typically between one tenth of a millimeter and four millimeter, more commonly between 0.3 and 2 mm. The minimum inner diameter Dmin of the anchor port **42** is preferably slightly larger, e.g. at least one tenth of a millimeter (0.1 mm) larger than the outer diameter Ds of a crimped stent. For example, a thickness of the guide wire **31** and/or anchor wire **32** is typically less than one millimeter, more commonly less than half a millimeter, e.g. 0.3 mm. Accordingly, in one embodiment, the minimum inner diameter Dmin of the anchor port **42** is typically less than half a centimeter, preferably between 0.4 and 2.5 mm, more preferably between one and two millimeter, most preferably between 1.2-1.5 mm, or more, depending on the stent. When deployed, the diameter may increase, e.g. by a factor between 1.5 and 2.5, or more, e.g. between 2 mm up to 5 mm, or more. Typical lengths of the stent (frame) may vary, e.g. between 8 and 40 mm, more commonly between 10 and 30 mm, or between 12 and 20.
[0035] In some embodiments, the system **100** comprises a (coronary) guiding catheter **1** having an inner diameter Dc configured to fit a maximum outer diameter of the anchor port **42** inside for guiding the anchor port **42** through the guiding catheter **1**. For example, the maximum outer diameter of the anchor port **42** is slightly larger than its maximum inner diameter Dd (depending on a thickness of the tube wall or ring). In other or further embodiments, the hypotube **41** is configured to push the anchor port **42** through a guiding catheter **1**, and beyond a distal end of the guiding catheter **1** along the guide wire **31** and/or anchor wire **32**.
[0036] In some embodiments, the anchor port **42** is shaped as a tubular member having a length Lt that is larger than its (minimum and/or maximum) inner diameter Dp, Dd. In a typical balloon-inflatable stent, the inflatable balloon, or at least the part that expands in diameter, extends beyond the edge of the stent frame, e.g. by at least one hundredth of a millimeter, more commonly at least

one tenth of a millimeter, e.g. between 0.1 and 5 mm, or more. In one embodiment, the length Lt of the anchor port **42** is the same or similar to the length of said (inflatable) part of the balloon extending beyond the stent frame, e.g. the same within a factor 1.2, or a factor 1.5, up to a factor two, or more. Accordingly, in one embodiment, the length Lt of the of the anchor port **42** is between 1 and 20 mm, more commonly between 4 and 15 mm, or between 6 and 10 mm, depending on the stent, or any other suitable length. Preferably, there is no continuous closed lumen between the guiding catheter and the anchor port, to prevent high pressure buildup of fluids such as contrast dye, at anchor port's distal end. Alternatively, e.g. as shown in FIG. **3**D, the tubular member could also be embodied as a relatively short tube, e.g. ring.

[0037] In some embodiments, e.g. as shown in FIGS. **3**A and **3**B, the anchor port **42** is formed by an extended tubular member having a proximal end, where the anchor port **42** is connected to the anchor positioning means **41**, and a distal end, opposite the proximal end, wherein the extended tubular member has an (inner) proximal diameter Dp at the proximal end (e.g. determining the minimum diameter Dmin), wherein the diameter increases towards an (inner) distal diameter Dd at said distal end. For example, the increasing diameter may allow a relatively large opening angle between the guide wire **31** and anchor wire **32** exiting the distal end of the tubular member while still substantially preventing or delaying inflation of part of the balloon **20**. For example, the tubular member has a frusto-conical hollow shape. Also other diverging shapes could be used. In other or further embodiments, e.g. as shown in FIG. **3**C, wherein the anchor port **42** is formed by an extended tubular member having an (inner) diameter Dd that increases towards both the distal and proximal ends. For example, the tubular member has a relatively low waist diameter Dw relative to the diameter Dd, Dp at the distal and/or proximal ends, e.g. lower by at least 10%, 20%, up to 50%, or more. In other or further embodiments (not shown), the tubular member could be a straight tube, e.g. with relatively large diameter to allow the large opening angle.

[0038] In some embodiments, the anchor port **42** comprises a rigid material, e.g. compared to a material of the balloon **20**. For example, the balloon is made of rubber or nylon. For example, the material of the anchor port **42** has Young's modulus more than 0.1 GPa, typically more than 1 GPa. In one embodiment, the anchor port **42** comprises a tubular member having a (relatively rigid) mid-section and at least one end section having higher flexibility than the mid-section. For example, by providing one or both end sections with more flexibility, this may facilitate larger angles between the guide wire **31** and anchor wire **32** guided there through while maintaining prevention or delay of inflation of balloon. In other or further embodiments, the anchor port **42** comprises and/or is shaped as a gutter and/or has any other interruption in its circular form. For example, this may prevent potentially harmful pressure buildup of fluids such as contrast dye at anchor ports **42** distal end.

[0039] In some embodiments, the anchor port **42** comprises a radiopaque material **42***r*. The skilled person will understand that a radiopaque material has a relatively high absorbance for X-rays, at least to such a degree that it is normally visible and can be distinguished (e.g. from biological tissue background) in a radiological image of a body. In contrast, a radiolucent or radiotransparent material is essentially transparent to X-rays so that it is normally invisible or barely visible in a radiological image, e.g. having similar X-ray characteristics as tissue background. So by providing the anchor port **42** with a radiopaque material **42***r*, an operator of the system can easily discern a position of the anchor port **42** inside the body using radiological/X-ray imaging. Typically, at least part of the stent, e.g. outer edges, are also provided with a radiopaque material. This allows to determine in a radiographic image where the stent is located. For example, the radiopaque material **42***r* of the anchor port **42** can be the same or similar as the radiopaque material provided on the stent. Providing both the anchor port **42** and stent **10** with respective radiopaque material, allows to determine in a radiographic image where the anchor port **42** is located relative to the stent, which may help further control its deployment.

[0040] In some embodiments, the anchor port **42** has a tubular shape and comprises a radiopaque

material **42***r* disposed (at least or exclusively) at a distal edge of the tubular shape (opposite the anchor positioning means **41**), e.g. forming a radiopaque ring at said distal edge. In this way the exact position of the distal end can be more precisely distinguished, which is the most relevant as it forms the exit port for the different wires and determines a position where inflation of the balloon may be prevented. For example, the rest of the tubular shape, e.g. proximal region, is formed by a radiolucent or radiotransparent material, e.g. at least more transparent to X-rays than the radiopaque material **42***r*.

[0041] As described herein, the anchor positioning means **41** is preferably configured to allow various forms of control over positioning of the anchor port **42**, e.g. allowing the anchor port **42** to be pushed towards the stent/balloon. Preferably, the anchor positioning means comprises a hypotube **41** that is directly or indirectly attached to a proximal edge of the anchor port **42**. Hypotubes are typically manufactured having a diameter between 0.2-5 mm. In some embodiments, the system comprises multiple hypotubes. In one embodiment, the anchor port **42** is connected to a first hypotube **41** and the balloon-inflatable stent **42** is connected to a, separate, second hypotube. In principle, the second hypotube can be the same or similar as the first hypotube. Typically, the second hypotube connected to the stent may be different, e.g. having a larger diameter to accommodate the balloon inflation channel inside. Also the guide wire **31** could be accommodated inside the second hypotube leading to the balloon-inflatable stent.

[0042] For the present purposes, the anchor positioning means **41**, e.g. hypotube (or other rigid control wire), connected directly or indirectly to the anchor port **42** preferably has a relatively low (inner and/or outer) diameter, e.g. less than 2 mm, less than 1 mm, less than 0.5 mm, or even less than 0.3 mm. Typically the hypotube **41** is hollow, although the tube may also be filled if it is used only to manipulate the anchor port **42**. The hypotube has specific advantages of control at minimal thickness, although in principle it could also be substituted for tube and/or wire-like structures, e.g. nitinol, that allow similar manipulation such as pushing and pulling on the anchor port **42**. In one embodiment, the hollow hypotube **41** is additionally used as a guide, e.g. used to guide the anchor wire **32** inside. For example, a proximal end of the hollow hypotube **41** may end inside or close before (proximal) the anchor port **42** so the anchor wire **32** can exit through the anchor port **42**.

[0043] In some embodiments, the hypotube **41** is formed by long tube, e.g. formed of metal or other material, typically having micro-engineered features along its length. For example, the micro-engineered features may include one or more of a continuous or interrupted spiral cut pattern, radial cut pattern, cut holes, et cetera. To facilitate deployment and/or prevent damage, the hypotube **41** may be coated, e.g. with Teflon. Typically, the hypotube **41** has a similar length as the wires **31**,**32** and/or channel leading to the inflatable balloon. For example, the length Lh of the hypotube **41** is at least half a meter, more commonly at least one meter, e.g. between 1.2 and 2.5 meter, or more. Each of the hypotube **41** and anchor port **42** is typically of a medical grade material.

[0044] FIGS. **4**A-**4**D illustrate further aspects of anchoring assemblies **40**. In some embodiments, the anchor positioning means **41** comprises a main cord **41***m* ending in a set of branch cords, which interconnect the main cord **41***m* with the anchor port **42**. In one embodiment, e.g. as illustrated in FIGS. **4**A and **4**C, the anchor positioning means **41** comprises two branch cords **41***a*, **41***b*. In another or further embodiment, e.g. as illustrated in FIGS. **4**B and **4**D, the anchor positioning means **41** comprises three branch cords **41***a*, **41***b*.

[0045] In some embodiments, the anchor port **42** comprises a proximal rim **42***p* forming part of an opening through which the anchor wire **32** can be passed. In one embodiment, the branch cords **41***a*, **41***b*, **41***c* are connected to different positions around a circumference of the opening, e.g. proximal rim **42***p*. This may allowing one or more, preferably each, of the guide wire **31**, the anchor wire **32**, and the crimped stent to be passed in between the branch cords **41***a*, **41***b*, **41***c* and though the opening of the anchor port **42**. In principle also, more than three branch cords could be used, e.g. four, but this may start hindering the ability to pass the other parts of the system to be passed there between. So, preferably the number of branch cords is limited to two or three. Most

preferably, the two, three, or more branch cords **41***a*, **41***b*, **41***c* are distributed equidistantly around the circumference of the proximal rim **42***p*. This configuration may on the one hand allow more easily passing other parts of the system as well as forming a structure that can be more easily retracted, e.g. into a guiding catheter or otherwise.

[0046] In some embodiments, the anchor positioning means **41** comprises a hypotube or (rigid) control wire configured to control the freely adjustable anchor position, e.g. relative to the stent position by pushing and pulling on the hypotube. In other or further embodiments, the main cord **41***m* is formed by the hypotube or rigid control wire. In one embodiment, the branch cords **41***a*, **41***b*, **41***c* are formed of a resilient material or structure configured to recover its shape after deformation. In another or further embodiment, the anchor port **42** is formed of a resilient material or structure configured to recover its shape after deformation. Preferably, one or more of the branch cords and/or anchor port comprise or are essentially formed Nitinol. Nitinol (Nickel-Titanium) is a shape-memory alloy that exhibits various properties that make it particularly suitable for the present application, including its shape memory effect, super-elasticity, high corrosion resistance, biocompatibility, high fatigue resistance, low coefficient of friction, high strength-to-weight ratio, et cetera. Of course also other suitable resilient materials may be used. Alternatively, or in addition to using a resilient material, the anchor port **42** may comprises a spring structure forming part of the ring (not shown).

[0047] In some embodiments, e.g. as illustrated in FIGS. **4**A and **4**B, the anchor port **42** is formed by a ring shaped member. In other embodiments, e.g. as illustrated in FIGS. **4**C and **4**D, the anchor port **42** is formed by a tubular-shaped member. Of course, the anchor port **42** (connected to a main cord **41***m* via a set of branch cords **41***a*, **41***b*, **41***c*) can also take any of the shapes as described before with reference to any of FIGS. **3**A-**3**D, providing similar advantages. In a preferred embodiment, e.g. as illustrated in FIGS. **4**C and **4**D, the anchor port **42** comprises a radiopaque material **42***r*. For example, the tubular shape comprises a ring of radiopaque material **42***r* at a distal end of the tube. Similarly, for embodiments wherein the anchor port **42** is formed by a ring shape, e.g. as shown in any of FIGS. **4**A, **4**B, or relatively short tube, e.g. as shown in FIG. **3**D, the entire ring or short tube may comprise or be essentially formed of radiopaque material **42***r*

[0048] In interpreting the appended claims, it should be understood that the word “comprising” does not exclude the presence of other elements or acts than those listed in a given claim; the word “a” or “an” preceding an element does not exclude the presence of a plurality of such elements; any reference signs in the claims do not limit their scope; several “means” may be represented by the same or different item(s) or implemented structure or function; any of the disclosed devices or portions thereof may be combined together or separated into further portions unless specifically stated otherwise. Where one claim refers to another claim, this may indicate synergetic advantage achieved by the combination of their respective features. But the mere fact that certain measures are recited in mutually different claims does not indicate that a combination of these measures cannot also be used to advantage.

Claims

1. A stent delivery system comprising: a balloon-inflatable stent comprising a stent frame wrapped around an inflatable balloon and having a guide wire for guiding the stent into a target vessel for treating a stenosis in the target vessel with the stent to be delivered at a predetermined stent position; an anchor wire for anchoring the stent by entering into a lumen or second vessel branching from the target vessel at a branching position; an anchor port configured to be guided along the guide wire and the anchor wire, both passing there through, and determining an anchor position relative to the stent position, wherein the anchor position of the anchor port is freely adjustable along a length of the guide wire for adjusting the anchor position relative to the stent position, or vice versa; and an anchor positioning means having a distal end connected to the

anchor port, and having a proximal end configured to control said freely adjustable anchor position relative to the stent position by pushing and pulling the proximal end.

2. The system according to claim 1, wherein the anchor port has an opening with a minimum inner diameter that is larger than an outer diameter of the crimped stent before inflation of the balloon, allowing the crimped stent to be passed through the opening of the anchor port to the stent position, after the anchor port has been guided along the guide wire and the anchor wire to the anchor position.

3. The system according to claim 2, wherein the anchor positioning means comprises a main cord ending in a set of branch cords, interconnecting the main cord with the anchor port, wherein the anchor port comprises a proximal rim forming part of an opening through which the guide wire, anchor wire, and crimped stent can be passed, wherein the branch cords are connected to different positions around a circumference of the proximal rim, allowing each of the guide wire, the anchor wire, and the crimped stent to be passed in between the branch cords and through the opening of the anchor port.

4. The system according to claim 3, wherein the anchor positioning means comprises a hypotube or rigid control wire configured to control said freely adjustable anchor position relative to the stent position by pushing and pulling on the hypotube or rigid control wire.

5. The system according to claim 4, wherein the main cord is formed by the hypotube or rigid control wire.

6. The system according to claim 3, wherein the branch cords are formed of a resilient material or structure configured to recover its shape after deformation.

7. The system according to claim 1, wherein the anchor port is formed of a resilient material or structure configured to recover its shape after deformation.

8. The system according to claim 7, wherein the anchor port is formed by a ring or tubular-shaped member.

9. The system according to claim 8, wherein the anchor port comprises a spring structure forming part of the ring.

10. The system according to claim 1, wherein the anchor port is unaffixed to any of the inflatable balloon or the balloon-inflatable stent.

11. The system according to claim 1, wherein the anchor port comprises a material that is more rigid than a material forming the balloon.

12. The system according to claim 1, wherein the anchor port has a tubular shape and comprises a radiopaque material disposed exclusively at a distal edge of the tubular shape to form a radiopaque ring at said distal edge.

13. A kit of parts for assembling a stent delivery system, comprising: a balloon-inflatable stent comprising a stent frame configured to be wrapped around an inflatable balloon; a guide wire configured for guiding the stent into a target vessel for treating a stenosis in the target vessel, with the stent to be delivered at a predetermined stent position; an anchor wire for anchoring the stent by entering into a lumen or second vessel branching from the target vessel at a branching position; an anchor port configured to be guided along the guide wire and the anchor wire, both passing therethrough, and determining an anchor position relative to the stent position, wherein the anchor position of the anchor port is freely adjustable along the length of the guide wire for adjusting the anchor position relative to the stent position, or vice versa; and an anchor positioning means having a distal end configured to be connected to the anchor port, and having a proximal end configured to control said freely adjustable anchor position relative to the stent position by pushing and pulling the proximal end.

14. An anchor port assembly for use in the stent delivery system, the anchor port assembly comprising: an anchor port formed by a ring or tubular shape having a minimum inner diameter between one and two millimeter; and an anchor positioning means comprising a main cord having an outer diameter less than two millimeter, preferably less than one millimeter, and a length of at

least one meter, wherein a distal end of the main cord ends in a set of branch cords, interconnecting the main cord with the anchor port, wherein the branch cords are connected to different positions around a circumference of the anchor port.

15. The anchor port assembly according to claim 14, wherein the anchor port is formed of a resilient material or structure configured to recover its shape after deformation; the set of branch cords consists of two or three branch cords formed of a resilient material or structure configured to recover its shape after deformation; and the main cord is formed by a hypotube or rigid control wire having a rigidity and/or thickness larger than one of the branch cords.

16. The anchor port assembly according to claim 14, wherein the anchor port has an opening with a minimum inner diameter that is larger than an outer diameter of a crimped stent before inflation of a balloon, allowing the crimped stent to be passed through the opening of the anchor port after the anchor port has been guided along a guide wire and an anchor wire to an anchor position.

17. The anchor port assembly according to claim 16, wherein the anchor port comprises a proximal rim forming part of the opening through which a guide wire, an anchor wire, and a crimped stent can be passed, wherein the branch cords are connected to different positions around a circumference of the proximal rim, allowing each of the guide wire, the anchor wire, and the crimped stent to be passed between the branch cords and through the opening of the anchor port.

18. The anchor port assembly according to claim 16, wherein the hypotube or rigid control wire is configured to control the anchor position by pushing and pulling on the hypotube or rigid control wire.

19. The anchor port assembly according to claim 14, wherein the anchor port comprises a spring structure forming part of the ring or tubular shape.

20. The anchor port assembly according to claim 14, wherein the anchor port has a tubular shape and comprises a radiopaque material disposed exclusively at a distal edge of the tubular shape to form a radiopaque ring at said distal edge.