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SYSTEM FOR INTRODUCING AND POSITIONING EXPANDABLE STENTS

The present invention pertains to the instruments for the introduction and the positioning of mechanically dilating stent in the ducts or lumina of a live, either human or animal body.

Stents are tubular molds which are made of biocompatible materials and are contracted on their introduction and then they dilate for their stable insertion into the desired duct or lumen. Some types of stents dilate mechanically, and for their insertion they require the use of an expandable element arranged along the introducing instrument and acting inside the stent.

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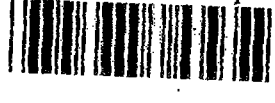
As the instrument for the introduction of mechanically dilating stents, a catheter having an inflatable balloon at its distal end of the type already used may also be used, e.g., for dilating arterial ducts or other lumina in a live body. Therefore, for the introduction operation, the balloon, empty, is wrapped tightly around a corresponding zone of the catheter, and the stent, in its turn, is arranged tightly around the balloon in order to remain fixed there during the introduction into a lumen.

In general then, the catheter, at the balloon, has a radiopaque marker in order to be able to control the position of the catheter and, therefore, that of the balloon in the duct or lumen in question.

However the requirements of a catheter for the simple dilation of ducts or lumina most often are incompatible with those of a catheter for the positioning of a stent, which is why specific catheters would be needed for one or the other operation.

A dilating catheter, for example, for angioplasty procedures, or the like, must have a small diameter, a low coefficient of surface friction, and a highly resistant balloon. On the other hand, a catheter for the positioning of stents must have a remarkable friction, at least at the balloon, be made of a material having a surface that is adapted to the interior of the closed, i.e., contracted stent, and have a diameter of the balloon, when closed, i.e., wrapped around the catheter, that is at least slightly greater than the internal diameter of the closed stent. All this is to

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hold the stent and to prevent its loss during the insertion in a duct or lumen.

Otherwise, a diameter in the zone of the catheter, including the closed balloon wrapped there, that is smaller than the internal diameter of the closed stent that is applied there may cause:

- a so-called overlapping resulting from a corrugation and an overlapping of some parts of the stent with possible deformation of its structure, if the stent is contracted too tightly in order to adhere to such a zone; or

- an improper fixing of the stent with the possibility of losing it during the introduction if the stent, although suitably and correctly closed, does not adhere to the too-small outer surface of the catheter plus closed balloon.

Starting from these representative premises of the state of the art, the object of the present invention is to provide a valid solution to the problems mentioned above and to correspondingly provide an improved catheter structure, which is reliable for a correct arrangement of the stent contracted around the closed balloon and which makes it possible to reduce, if not to eliminate, the possibilities of release and loss of the stent during the phase of introduction into the duct or lumen in which it is inserted.

Another object of the present invention is to propose a catheter structure that can be used advantageously either as a catheter for dilating or a catheter for positioning expandable stents.

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These objects are accomplished with a catheter structure for positioning stents according to claim 1.

In practice, the contracted stent is thus arranged and is held positively between two shoulders, prevented from sliding axially and thus from being lost, and this is independent of the actual diameter of the catheter, of the material with which the balloon is made and of the degree of friction offered by the said balloon.

In addition, the diameter of the catheter portion between shoulders may be adapted by increasing it with the application of a tubular adapter.

Greater details of the present invention, as well as its other aspects and advantages, shall become more evident from the description below with reference to the attached drawings, in which:

Figure 1 shows the partial view of a catheter according to the present invention with wrapped balloon and stent contracted around the balloon between two conical collars;

Figure 2 shows a similar view of the catheter of Figure 1, but with the balloon inflated and the stent dilated;

Figure 3 shows part of a catheter with biconical collars; and

Figures 4 and 5 show views that are similar to those of Figures 1 and 2, but in which the collars are defined by spherical elements.

In the said drawings, the catheter is indicated globally by 11 and has, in the known manner, an inflatable balloon 13 on its distal section 12.

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Two collars 14, which are spaced apart and delimit two annular shoulders 15, one in front of the other, around the catheter, are applied on the catheter part that is within the balloon.

The two collars 14 may preferably be conical, with opposite conicities, as shown in Figures 1 and 2, one towards the distal end 12 of the catheter and the other in the opposite direction, in order to facilitate the introduction and the extraction of the catheter in a duct or lumen of a body. As an alternative, the said collars 14 may be biconical as shown in Figure 3, or spherical as shown in Figures 4 and 5.

The said collars 14 may be made of a radiopaque material in order to form markers which make it possible to find the position of the catheter in the duct or lumen, in which it is inserted.

The distance between the two collars and, therefore, between the annular shoulders 15 is at least slightly greater than the length of a stent 16 to be used and to be inserted with the dilating catheter described.

Therefore, to use this catheter in the positioning of an expandable stent 16, the empty balloon is wrapped tightly on the collars 14 and around the part of the catheter comprised between said collars. The stent 16 is then placed and contracted around the balloon and is held in the space comprised between the two annular shoulders 15 defined by the collars 14 as shown in Figures 1, 2 and 4.

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If the catheter plus the balloon wrapped thereon has a suitable diameter, the contracted stent is adapted to the outer surface of the closed balloon with no overlapping and, moreover, positively held axially between the shoulders 15 and radially within the peripheral outline of the collars.

In the case of a particularly thin catheter, as in the catheters used for angioplasty, and in which the external diameter of the catheter plus the empty balloon wrapped thereon may be much smaller than the internal diameter of the contracted, i.e., closed, stent, without overlapping around the catheter part comprised between the two collars 14, a tubular adapter 17 held between the two shoulders 15 may be applied and so as to artificially increase the diameter of the catheter as shown in the drawings. Therefore, even in this case, the stent may be applied correctly on the catheter without the possibility of loss during the introduction into the duct or lumen in question.

Figures 2 and 5 of the drawings illustrate the condition of expansion of the balloon and of dilation of the stent for the release of same at the time of its insertion.

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CLAIMS

1. Catheter structure for dilating and for positioning stents, comprising a catheter having a inflatable balloon, characterized:

- by two collars (14) fixed around the catheter part inside the said balloon and intended to define two annular shoulders (15) one in front of the other and spaced apart in parallel;

- by a tubular adapter (17) arranged around the said catheter portion between the said collars; and

- in that the said balloon, when empty, is wrapped around the collars with the tubular adapter comprised between same, the shoulders forming bilateral axial closing means for a stent that is arranged and contracted around the empty and wrapped balloon.

2. Catheter structure in accordance with claim 1 in which the collars are conical with opposite conicities, one towards a distal end of the catheter and the other in the opposite direction.

3. Catheter structure in accordance with claim 1 in which the said collars are each biconical.

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4. Catheter structure in accordance with claim 1 in which the said collars are spherical.

5. Catheter structure in accordance with the claims 2-4 in which the said collars are made of a radiopaque material.

6. Catheter structure in accordance with claim 1 in which the tubular adapter (17) is held between the said shoulders and is intended to increase the external diameter of the said catheter.

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