980338-4
IPOS copy

This Sheet Has Been Replaced



# *DILATING CATHETER FOR THE INTRODUCTION OF EXPANDABLE STENTS*

The present invention pertains to the instruments for the introduction and the mechanical dilation of stents 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 upon their introduction and then they dilate for their insertion into the desired duct or lumen. Some types of stents dilate mechanically, and they require for their insertion the use of an expandable element arranged along the introducing instrument and dilatable inside the stent.

As the instrument for the introduction of mechanically dilating stents, a



THIS SHEET HAS BEEN REPLACED

catheter having an inflatable balloon at its distal end of the type already used may be used, e.g., for the dilation of 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.

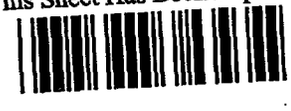
However the requirements of a catheter for the simple dilation of ducts or lumina most often are incompatible with those of a catheter for the positioning of a stent, which is why specific catheters would be needed for one or the other operation.

A dilating catheter, for example, for angioplasty procedures, or the like, must have a small diameter, a highly resistant balloon, and a low coefficient of surface friction. On the other hand a catheter for positioning stents must have a remarkable friction at least at the balloon, must be made of a material with a moldable surface that is adapted to the interior of the closed, i.e., contracted stent, and must have a diameter of the balloon, when closed around the catheter, at least slightly greater than the internal diameter of the closed stent. All this is to interfere with the stent and to hold it, preventing its loss during the insertion in a duct or lumen.

In other words, the surface slipperiness of the balloon may be a cause of a loss of the stent.



This Sheet Has Been Replaced



THIS SHEET HAS BEEN REPLACED

In addition, 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 make it adhere to such a zone; or

- an improper fixation of the stent with the possibility still of losing it during the introduction if the stent, although suitably and correctly closed, does not adhere to the 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 a dilating catheter improved at the level of the inflatable balloon, so that this constitutes a valid, positive grip to interfere with and to hold the stent that is applied there from inside, so as to prevent the loss of the latter during the introduction phase without, however, having an effect on the dilatability of the balloon when the stent is expanded and released.

This object is accomplished with a dilating catheter according to claim 1.

In practice, the outer surface of the balloon is roughened with a material coating having a higher coefficient of friction and through a deformation or an embossing of the wall of the said balloon for an increase in the friction and/or diameter of the balloon, and so that the stent is in a better anchoring position when



This Sheet Has Been Replaced



THIS SHEET HAS BEEN REPLACED

it is in its contracted position around the balloon.

Greater details of the present invention will become more evident from the description given below with reference to the attached drawings, in which:

Figure 1 shows a part of a catheter with balloon modified according to the present invention and with a stent contracted around the empty balloon;

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

Figure 3 shows another way of roughening the outer surface of the balloon.

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.

According to the present invention and according to a first embodiment as shown in Figures 1 and 2, a layer 14 of a material having a high coefficient of friction or of roughening of this surface is coated on the outer surface of the balloon, for at least a section of its length. The material for the formation of this surface layer 14 may be a silicone, gel, or other biocompatible product that is chemically bound by vulcanization or by another suitable method with the material that forms the balloon. Therefore, the coated layer 14 contributes to an increase in the external diameter of the balloon for its greater interference with the inside of a stent 15, which is tight around it, and moreover, increases the surface friction of the balloon in order to better hold the stent against the longitudinal sliding and therefore against the loss during the introduction in a duct or lumen.



This Sheet Has Been Replaced

THIS SHEET HAS BEEN REPLACED

A similar result can be achieved without the coating of a material on the outer surface of the balloon but by means of a deformation or corrugation of the wall of the said balloon, e.g., by means of knurling or embossing 16 as shown in Figure 3.

Figure 1 shows the condition of the balloon, which is empty and is wrapped around the catheter, and the stent, which is contracted around the same, while Figures 2 and 3 show the condition of expansion of the balloon and the dilation of the stent for the release of same, when the balloon has an outer coated layer and a corrugated wall, respectively.



This Sheet Has Been Replaced



THIS SHEET HAS BEEN REPLACED



CLAIMS

1. Dilating catheter for introducing and inserting expandable stestents comprising a inflatable balloon, which is applied on a distal section of the catheter and which can be wrapped, if empty, on the said section in order to be applied there around a contracted stent, characterized in that the outer surface of the cal balloon is roughened by means of a supply of material or a deformation in order to offer greater interference and grip to the stent contrac= ted tightly sround it.

2. Dilating chateter in accordance with claim 1 in which a layer (14) of material having a high coefficent of friction, which is chemically bound by vulcanization or another method with the surface of the said balloon to be coated, is applied to the outer surface of the balloon.

3. Dilating catheter in accordance with claim 2, in which the layer of material increases the external diameter and the surface friction of the balloon, and the material may be a silicone, a gel or another biocompatible product.

4. Dilating catheter in accordance with claim 1, in which the wall of the balloon is deformed in order to have corrugations, knurling, or embossing for interfering with the stent applied thereto.

This Sheet Has Been Replaced



THIS SHEET HAS BEEN REPLACED