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DILATION CATHETER STRUCTURE

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The present invention pertains to dilation catheters of the so-called rapid exchange type with an inflatable balloon and with a lumen for a guide thread.

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These catheters can be used in various operating and surgical procedures and/or for inserting molds, called stents, inside the ducts or lumens of a live body.

A dilation catheter generally comprises a thin and extended tubular element and usually has an inflatable balloon near its distal end, a first lumen for a guide thread and at least a second lumen for the passage of a fluid for inflating the balloon.

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In the prior-art designs, the first and the second lumina of the catheter may be coaxial or not, may be made into a single extruded element, separated by a baffle, or formed by two small tubes of different diameter arranged one inside the other.

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However, the current trend is to create a point for passing the guide thread in the catheter in a zone close to the distal end even though before, above, the inflatable balloon in order to reduce or preferably balance the sliding force of the catheter along the guide thread during the insertion in the body.

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Various embodiments of dilation catheters have already been proposed in order to meet such a requirement.

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In one embodiment, the catheter has a single extruded body, which has two integral lumina (e.g., EP-A-0 712 639) with one lumen for inflating the balloon and another lumen for the guide thread, this second lumen simply having a radial opening for the passage of the guide thread above the balloon.

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According to another embodiment, a first and a second lumen of the catheter (e.g., US-A-5 102 403) are obtained, in a distal section from the front of the balloon of the catheter, by means of a longitudinal deformation of a starting tube which has a single lumen. The deformation is performed along a generating line of the tube and aimed at creating a lumen for the guide thread, which lumen has an opening on one side of the starting tube, which goes deep down to more or less on the axis of the said tube, and which opens at the distal end of same, while the lumen proper of the starting tube opens into the balloon.

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Starting from these premises the object of the present invention is to propose a

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novel dilation catheter structure produced by means of an original configuration and combination of single tubular elements, therefore not in a single piece obtained from extrusion or deformed as taught by the prior art.

5 This object is accomplished with a dilation catheter according to claim 1, and which will be described here in detail below with reference to the attached drawings, in which:

Figure 1 shows a sectional view, before assembly, of parts of the tubes intended to form the catheter; and

10 Figure 2 shows a distal part of the assembled catheter and complete with balloon.

The catheter proposed here comprises a main tube 11, a distal tube 12, a guide tube 13 and a balloon 14.

15 The main tube 11 may be a single piece or comprise many tubular parts which are combined consecutively, perhaps different in terms of material and thickness or rigidity, so that the tube has a different flexibility or softness in various parts along its length.

20 The distal tube 12 is arranged as a continuation of the main tube 11, at the distal end 11' of same and the guide tube 13 is arranged in the distal tube 12. These two additional tubes 12, 13 may be of identical or different materials and thicknesses or rigidities, though different from those of the main tube.

25 As is shown in the drawing, the proximal end 12' of the distal tube 12 is flared so as to fit on the distal end 11' of the main tube and at the same time to enclose the proximal end 13' of the guide tube 13. Moreover, this same end 13' of the guide tube 13 is put on the outside of the distal end 11' of the main tube, on a part 11" which is deflected and inclined towards the axis of the tube itself, or more preferably and for a greater robustness of the resulting unit, the guide tube 13 is made to pass in an opening 11a provided in the main tube as shown in Figure 1.

30 The tubes 11, 12, 13 thus arranged and combined are then fixed to one another by means of a heat-sealing operation. To keep the tubes in shape in their zones to be sealed, and thus preventing their collapse and the blocking of their lumina, two expanders 15 and 16 are inserted into the main tube 11 and in the guide tube 13, respectively, which [expanders] are then extracted once the sealing has been performed.

35 In particular, the sealing is done in order to seal to one another the contact zones of the guide tube with the main tube and the outer distal tube all around the main tube and the guide tube. After this action, the expanders are extracted, and the initial ends of the guide tube and the distal tube are beveled in 17 as shown in the drawing.

40 It should be noted that the guide tube 13 extends beyond the front end of the distal tube 12. The balloon 14 is arranged around the guide tube and has two terminal necks 14', 14', one of which is sealed around the front end of the distal tube, the other is sealed around the distal end of the guide tube.

45 In the catheter thus constructed, the main tube 11 and the distal tube 12 together form a first axial lumen 18, which opens into the balloon 14; the guide tube 13 forms a second lumen 19 which has an opening on one side of the catheter, at the level of the bevel



17, and an axial opening at the front end of the guide tube itself.

The first lumen 18 is used to send an inflation fluid into the balloon, while the second lumen is used for passing a guide thread, which is usually used to facilitate the introduction of the catheter into the duct in question.

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CLAIMS



1. Dilation catheter structure of the rapid exchange type provided with an inflatable balloon and with a lumen for a guide thread, characterized by comprising a said main tube (11), which has a said distal end (11'), a said distal tube (12) and a said guide tube (13), in which the said guide tube (13) extends in the said distal tube, and the said proximal ends (13', 12') of the said guide tube (13) and the said distal tube (12) are joined to one another and at the said distal end of the said main tube (11), and in which the said proximal end (13') of the said guide tube (13) has a said opening on one side of the said main tube (11), and the said proximal end (12') of the said distal tube (12) encloses the said distal end of the said main tube and the said proximal end of the said guide tube tightly and simultaneously.

2. Catheter structure in accordance with claim 1 in which the said distal end of the said main tube (11) has a said part (11"), which is deflected and inclined towards the inside of the said tube, in which the said proximal end (13') of the said guide tube (13) rests on the outside of the said inclined part (11") of the said main tube, and in which the said proximal end (12') of the said distal tube (12) is flared in order to reach both the said distal end of the said main tube and the said proximal end of the said guide tube peripherally.

3. Catheter structure in accordance with claim 1 in which the said distal end of the said main tube (11) has a said lateral opening (11a), in which the said proximal end (13') of the said guide tube (13) extends into the said lateral opening of the said main tube, and in which the said proximal end (12') of the said distal tube (12) is flared in order to peripherally reach both the said distal end of the said main tube and the said proximal end of the said tube.

4. Catheter structure in accordance with claim 2 or 3, in which the said proximal ends of the said guide tube (13) and the said distal tube (12) are joined to one another and to the said distal end of the said main tube by means of heat sealing.

5. Catheter structure in accordance with the above claims, in which the said proximal ends of the said guide and distal tubes are beveled at the said lateral opening of the said guide tube.

6. Catheter structure in accordance with the above claims, in which the said guide tube (13) extends beyond the said front end of the said distal tube (12), and in which the said balloon (14) is arranged between said two tubes, with a said terminal neck fixed to the said guide tube and another said terminal [neck] fixed to the said distal tube.

7. Catheter structure in accordance with the above claims, in which the said main tube (11) and the said distal tube (12) together form a said first lumen for sending an inflation fluid into said balloon, and in which the said guide tube (13) forms a said second lumen for the passage of a said guide thread.

8. Catheter structure in accordance with any of the above claims in which the said main tube comprises one or more tubular sections of identical or different material, thickness and rigidity, and in which the said guide tube and the said distal tube are of materials, thicknesses and rigidities that are identical to or different from one another and with respect to the main tube.

