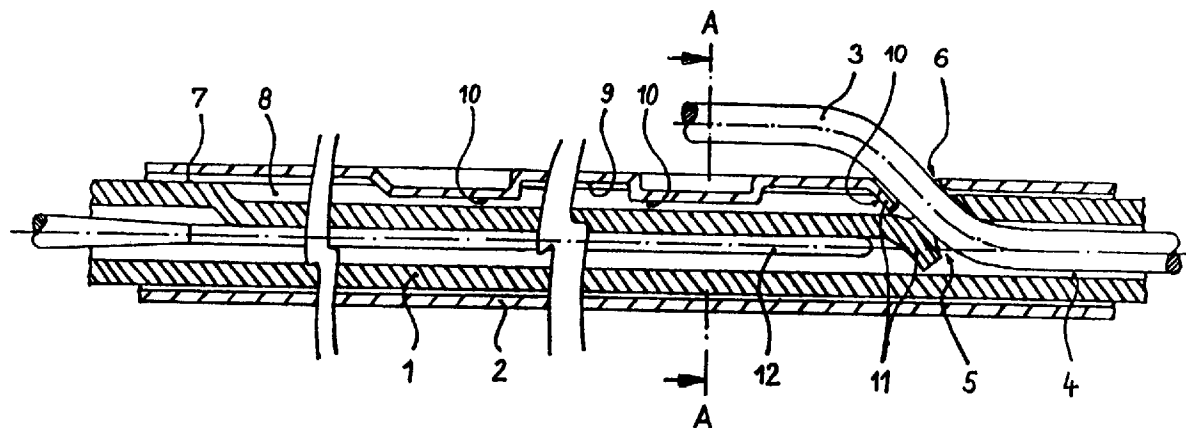




(72) DELALOYE, Stéphane, CH
(71) SCHNEIDER (EUROPE) GmbH, CH
(51) Int.Cl.⁶ A61M 25/01, A61M 25/09
(30) 1997/06/10 (97201746.1) EP
(54) **SYSTEME DE CATHETER**
(54) **CATHETER SYSTEM**



(57) Dans un système de cathéter pour échange rapide via un fil-guide (3) muni d'un cathéter interne flexible allongé (1), ayant une extrémité proximale et une extrémité distale ainsi qu'une lumière pour fil guide (4) et s'étendant depuis un orifice d'insertion sur l'extrémité distale jusqu'à un orifice de passage latéral (5) disposé distalement par rapport à l'extrémité proximale, et d'un cathéter extérieur tubulaire flexible (2), dans lequel le cathéter interne (1), muni d'un orifice de sortie latéral (6) pour le fil guide (3), est placé de façon à pouvoir se déplacer dans le sens de l'axe, un dispositif est fourni qui tient en place le cathéter interne (1) et le cathéter externe (2) et qui empêche la torsion du cathéter externe (2) par rapport au cathéter interne (1). Ainsi, l'orifice de passage (5) et l'orifice de sortie (6) demeurent alignés l'un par rapport à l'autre, et le système de cathéter peut être déplacé simplement le long du fil-guide (3). De surcroît, le cathéter externe (2) peut être facilement déplacé par rapport au cathéter interne (1).

(57) In a catheter system for rapid exchange via a guide wire (3) with a flexible, elongated inner catheter (1), which has a proximal end and a distal end as well as a guide wire lumen (4), which extends from an insertion port on the distal end to a lateral through port (5) distally from the proximal end, and a flexible, tubular outer catheter (2), in which the inner catheter (1) is disposed axially displaceably, and which has a lateral exit port (6) for the guide wire (3), retaining means are provided on the inner catheter (1) and the outer catheter (2), which retaining means prevent twisting of the outer catheter (2) relative to the inner catheter (1). Thus, the through port (5) and the exit port (6) remain aligned with each other and the catheter system can be displaced simply along the guide wire (3). In addition, the outer catheter (2) can be readily displaced relative to the inner catheter (1).

Abstract

In a catheter system for rapid exchange via a guide wire (3) with a flexible, elongated inner catheter (1), which has a proximal end and a distal end as well as a
5 guide wire lumen (4), which extends from an insertion port on the distal end to a lateral through port (5) distally from the proximal end, and a flexible, tubular outer catheter (2), in which the inner catheter (1) is disposed axially displaceably, and which has a lateral exit port (6) for the guide wire (3), retaining means are provided
10 on the inner catheter (1) and the outer catheter (2), which retaining means prevent twisting of the outer catheter (2) relative to the inner catheter (1). Thus, the through port (5) and the exit port (6) remain aligned with each other and the catheter system can be displaced simply along the guide wire (3). In addition, the outer catheter (2) can be readily displaced relative to the inner catheter (1).

15 Fig. 1

Pa 96/16 Bath Tub Shaft
PC9891

5 **Description**

The invention relates to a catheter system for rapid exchange via a guide wire with a flexible, elongated inner catheter, which has a proximal end and a distal end as well as a guide wire lumen, which extends from an insertion port on the distal end to
10 a lateral through port distally from the proximal end, and a flexible, tubular outer catheter, inside which the inner catheter is disposed axially displaceably and which has a lateral exit port for the guide wire.

Catheter systems with two catheters disposed one inside the other and displaceable
15 relative to each other have many potential uses in interventions in body cavities, such as in blood vessels, air passages, or the esophagus. Usually, the catheter system is inserted along a pre-positioned guide wire through a body lumen to the desired site for use there.

20 For example, US 4,655,746 discloses a catheter system, in which the inner and outer catheters are designed as balloon catheters, such that a vascular segment bounded by the balloons may be sealed relative to the rest of the vascular system. The distance between the balloons and thus the length of the vascular segment to be sealed may be adjusted by shifting the outer catheter relative to the inner
25 catheter. Via a lumen provided for this, a therapeutic substance is infused into the sealed vascular segment or fluid is aspirated therefrom. The guide wire lumen extends in this catheter system over the entire length of the inner catheter. A catheter exchange with an indwelling guide wire requires either a very long guide wire or the attachment of an extension. Either is very time-consuming and
30 represents an additional strain on the patient. Moreover, a second person must assist during such an intervention, and a large area around the puncture opening must be kept sterile.

- 2 -

To overcome the aforementioned disadvantages, catheter systems have been developed in which the guide wire lumen extends over only a short distal portion, and the guide wire runs for most of its length beside the catheter system to the proximal end. The guide wire protrudes out of the body by only roughly the length of the guide wire lumen, whereby a rapid catheter exchange is possible without attachment of an extension.

From EP 0 505 686 B1, a catheter system of the type mentioned in the introduction is known, in which the inner catheter is designed as a rapidly exchangeable balloon catheter with a premounted stent, whereas the outer catheter serves as a protective sheath during insertion of the stent. The guide wire leaves the catheter system proximally through two mutually aligned ports in the inner and outer catheters. To insert the catheter system, the two ports are at least partially aligned such that the catheter system can move along the guide wire. To expand the stent, the outer catheter is retracted along the inner catheter, whereby the guide wire ports move against each other and the guide wire runs between the openings in an annular lumen between the inner and outer catheter. After successful stent implantation, the outer catheter, which has a slot for this purpose extending from the guide wire port to the distal end of the outer catheter, may first be retracted. Then, the balloon catheter is removed from the body in a known manner along the guide wire. In the manipulation of such a catheter system in the vascular system of a patient, for example, it is possible for the inner and outer catheters to twist against each other, particularly in the distal portion of the catheter system, whereby the mutual position of the guide wire ports changes. During insertion or withdrawal of the catheter system, this results in undesired clamping of the guide wire in the zone of the ports, which significantly hinders rapid and uniform movement of such a catheter system. In addition, the guide wire ports may lose their mutual alignment during displacement of the outer catheter along the inner catheter, and additional frictional forces between the guide wire and the rim of the port may have to be overcome. And finally, during retraction of the outer catheter, the guide wire may be pressed into the slot and become clamped there.

- 3 -

WO 94/15549 discloses a likewise rapidly exchangeable catheter system. A self-expanding stent, which is confined in its compressed state between an inner and an outer catheter on the distal end of the catheter system, is released by retracting the outer catheter relative to the inner catheter. The guide wire leaves the catheter system proximally through a lateral port in the inner catheter and a slot in the outer catheter. An elongated depression, in which the guide wire can lie during retraction of the outer catheter, connects proximally to the port in the inner catheter. Thus, the guide wire is gently guided out of the catheter system without sharp bending. The slot in the outer catheter is, however, so narrow that significant frictional forces occur during displacement of the catheter system along the guide wire, and also during retraction of the outer catheter. Moreover, the catheter system suffers from the disadvantage that the slot and the depression reduce the cross-section and thus the kink resistance of the catheter system, in particular when the slot and the depression extend to the proximal end of the catheter system.

Consequently, the object of the invention is to report a catheter system of the type mentioned in the introduction, which is evenly and easily movable along a guide wire and whereby the outer catheter can be retracted simply relative to the inner catheter.

The invention provides a catheter system for rapid exchange via a guide wire with a flexible, elongated inner

- 3a -

catheter, which has a proximal end and a distal end as well as a guide wire lumen, which extends from an insertion port on the distal end to a lateral through port, and a flexible, tubular outer catheter, in which the inner catheter is disposed axially displaceably, and which has a lateral exit port for the guide wire,

characterized in that retaining means are provided on the inner catheter and the outer catheter, which retaining means prevent twisting of the outer catheter relative to the inner catheter, whereby the through port and the exit port remain aligned with each other.

The retaining means, which prevent twisting of the outer catheter relative to the inner catheter, are provided on the inner catheter and the outer catheter, whereby the through port and the exit port remain aligned with each other, the guide wire being provided with a large port area to leave the catheter system. Clamping of the guide wire between the through port and the exit port is thus avoided both during advancing or retraction of the entire catheter system along the guide wire and during displacement of the outer catheter relative to the inner catheter. A catheter system according to the invention thus has improved sliding properties, which facilitate its manipulability in practical use.

- 4 -

In an advantageous embodiment of the invention, the retaining means are formed interlockingly by a depression in the outer wall of the inner catheter and by at least one protrusion on the inner wall of the outer catheter which engages in the
5 depression. Thus, a simple to manufacture twist protection between the inner catheter and the outer catheter is provided, which does not impair axial displacement of the outer and the inner catheter relative to each other. The retaining means are integrated into the catheter system such that it is unnecessary to carry out any enlargement of the profile. Without leaving the scope of patent
10 protection, the depression may alternatively also be made in the outer catheter and the protrusions on the inner catheter; even a hybrid form is conceivable.

In a preferred embodiment of the invention, the depression has an elongated shape with axial alignment. The protection against twisting here also satisfies the
15 additional object of guiding the outer shaft during retraction relative to the inner shaft. In addition, with this measure it is also possible to define a distal and proximal end position of the outer shaft relative to the inner shaft.

The protrusion is, in its axial dimension, preferably small in comparison to the length
20 of the depression. Thus, the length of the depression may remain as small as possible, i.e., roughly in the size range indicated by practical application--i.e., for example, the maximum length of a vascular segment to be sealed by two balloons or the length of the stent used. Moreover, the frictional area between the protrusion and the depression is reduced, which contributes to simple manipulation of a
25 catheter system according to the invention during displacement of the outer catheter.

In an advantageous embodiment of the invention, the through port is disposed on the distal end of the depression. In this arrangement, the guide wire may lie in the
30 depression during retraction of the outer catheter, whereby sharp bending of the guide wire as it leaves the catheter system is avoided. In addition, the guide wire does not take up any cross-sectional space inside the inner catheter in the region of

- 5 -

the depression. Thus, the overall cross-section of the catheter system may be kept small.

5 In a preferred embodiment of the invention, the exit port passes through the protrusion. The protection against twisting and the guidance here are particularly efficient since they directly affect the course of the guide wire, by keeping the exit port and the through port aligned with each other in each catheter position. The design also has advantages in terms of production technology, since the exit port and protrusion can be produced with a single production process.

10

The through port and the exit port of a catheter system according to the invention are advantageously provided with guiding aids for the distal insertion of the guide wire. The guide wire threaded into the distal end of the catheter system is thus guided during advancement of the catheter system without additional manipulation
15 through the through port and the exit port out of the guide wire lumen. A catheter system according to the invention may thus be inserted quickly and without problems via a pre-positioned guide wire.

Additional advantages of a catheter system according to the invention are revealed
20 through a preferred exemplary embodiment, which is explained in detail with reference to the drawing, in which

Fig. 1 depicts a longitudinal section of the catheter system, and

25 Fig. 2 depicts a cross-section of the catheter system along the intersecting line A-A in Fig. 1.

Fig. 1 and Fig. 2 depict a catheter system according to the invention with a flexible, elongated inner catheter 1 and a flexible, tubular outer catheter 2, which is suitable
30 for rapid exchange via a guide wire 3. For this, the guide wire lumen 4 extends from the insertion port (not shown) on the distal end (not shown) of the inner catheter 1 to a through port 5, which is positioned distally relative to the proximal end (not

- 6 -

shown) of the inner catheter 1. The outer catheter 2 has a lateral exit port 6 for the guide wire 3, from which the guide wire 3 runs in the proximal direction along with the catheter system.

5 The inner catheter 1 has on its outer wall 7 an elongated, axially aligned depression 8, in which protrusions 10 disposed on the inner wall 9 engage. This yields an interlocking protection against twisting between the inner catheter 1 and the outer catheter 2, which keeps the exit port 6 and the through port 5 aligned with each other both during displacement of the entire catheter system along the guide wire 3
10 and also during displacement of the outer catheter 2 relative to the inner catheter 1. Thus, the guide wire 3 is provided in all positions with as large an area as possible for its exit from the catheter system, and the friction between the guide wire 3 and the through port 5 or the exit port 6 is kept low. The manipulation of a catheter system according to the invention is made significantly easier since position-
15 associated frictional resistances do not have to be overcome. For additional ease of manipulation, the through port 5 and the exit port 6 are provided with guide aids 11 which allow the guide wire 3 threaded through the insertion port into the guide wire lumen 4 from the distal end to find its way through the through port 5 and the exit port 6 without additional manipulations during the advancing of the catheter system.

20

The depression 8 and protrusion 10 may, for example, be stamped simply in the inner catheter 1 and outer catheter 2 by thermoforming by means of shaping tools. The guiding aids 11 may likewise be produced without additional expense during the incorporation of the through port 5 and the exit port 6, by forming them from the
25 excess material on the edges of the bore.

In the inner catheter 1 runs a stiffening wire 12 tapering in the distal direction, which contributes to the support of the section in which the depression 8 is disposed.

- 7 -

Reference character list

	1	inner catheter
	2	outer catheter
5	3	guide wire
	4	guide wire lumen
	5	through port
	6	exit port
	7	outer wall
10	8	depression
	9	inner wall
	10	protrusion
	11	guiding aids
	12	stiffening wire

- 8 -

Claims

- 5 1. A catheter system for rapid exchange via a guide wire (3) with a flexible, elongated inner catheter (1), which has a proximal end and a distal end as well as a guide wire lumen (4), which extends from an insertion port on the distal end to a lateral through port (5), and a flexible, tubular outer catheter (2), in which the inner catheter is disposed axially displaceably, and which has a lateral exit
10 port (6) for the guide wire (3),
characterized in that retaining means are provided on the inner catheter (1) and the outer catheter (2), which retaining means prevent twisting of the outer catheter (2) relative to the inner catheter (1), whereby the through port (5) and the exit port (6) remain aligned with each other.
- 15
2. The catheter system according to Claim 1,
characterized in that the retaining means are formed interlockingly by a depression (8) in the outer wall (7) of the inner catheter (2) and by at least one
20 protrusion (10) on the inner wall (9) of the outer catheter (2) engaging in the depression (8).
3. The catheter system according to Claim 2,
characterized in that the depression (8) is elongated with axial alignment.
- 25 4. The catheter system according to Claim 2 or 3,
characterized in that the protrusion (10) is small in its axial dimension compared to the length of the depression (8).
- 30 5. The catheter system according to any one of Claims 2 through 4,
characterized in that the through port (5) is disposed on the distal end of the depression (8).

- 9 -

6. The catheter system according to any one of Claims 2 through 5,
characterized in that the exit port (6) passes through the protrusion (10).
7. The catheter system according to any one of Claims 1 through 6,
5 characterized in that the through port (5) and the exit port (6) are provided with
guiding aids (11) for the distal insertion of the guide wire (3).

Smart & Biggar
Ottawa, Canada
Solent Agents

1/1

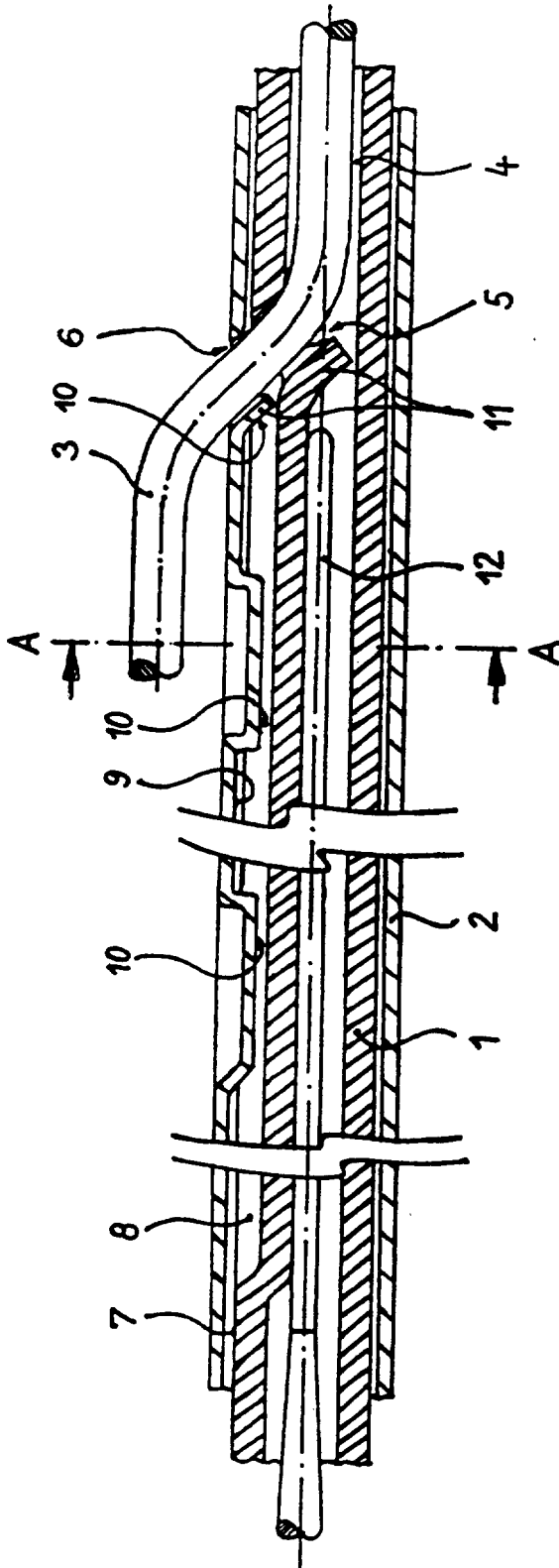


FIG. 1

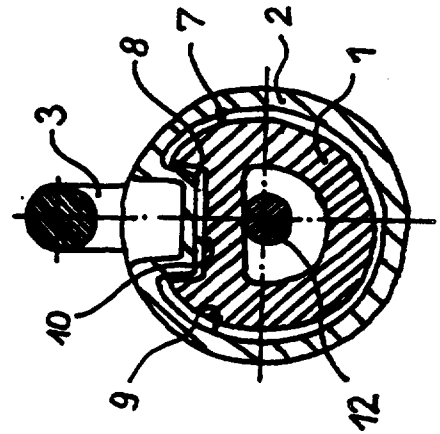


FIG. 2

