

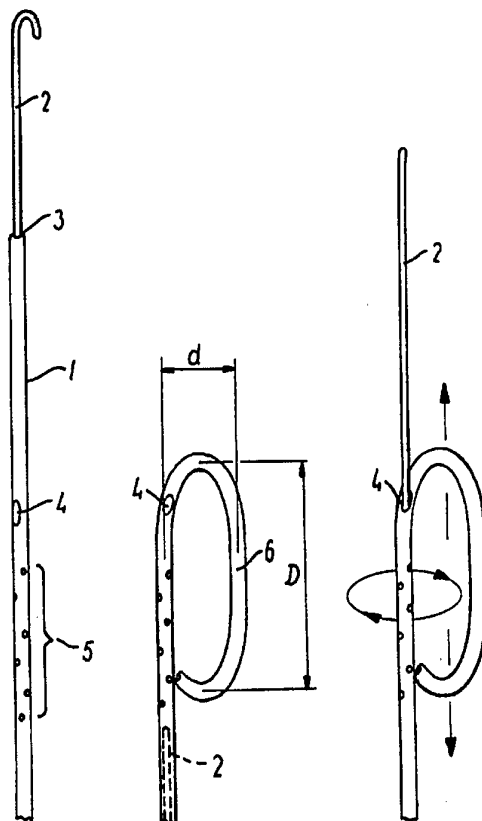


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(54) Title: AN APPARATUS FOR FRAGMENTATION OF A LUNG EMBOLUS**(57) Abstract**

An apparatus for fragmentation of a lung embolus comprises a torsionally stiff or stable catheter (1) and a guide wire (2). A distal end segment of the catheter (1) is provided with a bending which is controllable through the guide wire (2), said bending being on the outer side provided with an opening (4) which is in line with the central axis of the catheter (1), so that the guide wire can be pushed out through the opening. The opening has in a projection on a plane normal to the central axis of the catheter a cross section adapted to the cross section of the guide wire (2).



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AN APPARATUS FOR FRAGMENTATION OF A LUNG EMBOLUS

5 In the industrial countries the third most frequent cause
of death is lung emboli. Ten per cent of the patients with
acute lung emboli die from heart failure. Dissolution by
medicine of the embolus (thrombolysis) takes hours. The
patient often dies before a hemodynamic improvement occurs.
10 Operational removal of the embolus in accordance with the
so-called Tendelenburg operation entails a comparatively
high rate of mortality.

With a combined treatment comprising mechanical
destruction of lung emboli and a subsequent selective
thrombolysis of the resulting fragments it has in some
15 cases already been possible to obtain promising treatment
results. In this case the fragmentation of an embolus took
place by manipulation with diagnostic standard-pulmonalis-
catheters. Such a catheter is advanced by means of a guide
wire past an embolus towards the periphery. When the
20 catheter after the withdrawal of the wire has taken up its
pointed configuration, for instance in form of a so-called
pig tail, the embolus is cut into pieces by the withdrawal
of the catheter. This process admittedly has to be repeated
several times, in order to cause a relatively rough
25 fragmentation of the embolus. By this manoeuvre a lowering
of the pulmonic arterial pressure could be attained, and
consequently the occurrence of a threatening cardiac shock
in the patient with a subsequent death risk could be
avoided.

30 This described fragmentation of pulmonic emboli used
in a few cases is not just fairly complicated and
protracted, but also very rough, as the standard catheters
introduced in that connection do not meet the requirements
made to an apparatus for fragmentation of a lung embolus.

35 However, for the treatment of lung emboli special
apparatuses are already known.

One of these apparatuses known under the name

"Thrombolyseur" is provided with a rotating basket which can be unfolded by centrifugal force for fragmentation of the embolic material. However, a contact between the unshielded basket treads and the wall of the artery can hardly be avoided and may lead to damage of the artery. In an apparatus known under the name "Impeller-Katheter" a rotor (impeller) is present in the centre of a self-expanding, stationary protective basket.

In both the apparatuses described above the rotational body is driven through a flexible shaft positioned in the interior of the catheter by an external drive with 100,000 to 150,000 rpm. Thrombotic material in the lung flow path is caught by the created whirl and mechanically fragmented. The high rotational speed, however, means a high load on the material and makes these apparatuses prone to defects. Due to the complexity of both apparatuses, the risk of an erroneous handling by a not optimally trained operator is considerable.

The object of the present invention is to provide an apparatus for fragmentation of a lung embolus, which apparatus has a simple construction and is easy to handle and which simultaneously allows an effective and untraumatic fragmentation treatment of an embolus.

To meet this object an apparatus according to the invention is characterized by a torsionally stiff or stable catheter and a guide wire, a distal end segment of the catheter being provided with a bending which is controllable through the guide wire, said bending being on the outer side provided with an opening which is in line with the central axis of the catheter, which opening in a projection on a plane normal to the central axis of the catheter has a cross-section adapted to the cross-section of the guide wire.

The torsionally stiff or stable catheter is simple and may quickly by means of the guide wire be placed in the Arteria pulmonalis. The guide wire first extends over the whole length of the catheter and does not allow the distal

catheter end segment to take up a curved form until the guide wire is withdrawn from the area of the catheter end segment. By a renewed advancing of the guide wire, its distal end segment comes out of the opening which is in line with the centre axis of the catheter in the curved area, and the guide wire thus serves as rotational axis for the torsionally stable catheter. After anchoring of the guide wire further away in the pulmonary artery system the catheter is through its proximal end made to rotate by hand or by means of a mechanical drive. By rotation of the bending of the distal catheter end segment within the embolic blockage the embolic material can be fragmented. The fragmentation may also in addition to rotation take place by moving the catheter forwards and backwards over the stationary guide wire used as a guide member. Thereby the thrombotic material is cut into pieces by the bending of the distal catheter end segment passing in quick forwards and backwards movements. On account of the uncomplicated design of the catheter tip and if the usual angiographic precaution measures are taken, no damages to the artery walls are to be expected.

When the catheter end segment occupies its bent configuration, the central axis of the proximal part of the catheter extends out through the opening so that the distal tip of guide wire can catch the opening during advancement of the guide wire. Normally the guide wire tip is rounded or slightly pointed in order to facilitate catching of the opening. With a wire tip shaped in this manner the opening need only be slightly larger than the cross-section of the guide wire extending through the opening, because the guide wire will make the rim of the opening adapt to its own cross-section, once the opening has been caught. It is also possible to make the opening with a suitable overmeasure so that whole or the major portion of the inner lumen of the catheter is exposed by the opening when the distal end segment occupies its bent configuration.

According to a preferred embodiment of the apparatus

according to the invention a free end of the bending points towards the central axis of the catheter, whereby the bending is made into an oval loop.

5 The small diameter of the loop is preferably 7 to 10 mm, and the big diameter of the loop is preferably two to three times as big as the small diameter.

10 In order to be able to use the apparatus according to the invention also for diagnosing a lung embolus, openings are according to a further embodiment of the invention arranged in the distal end segment of the catheter, the cross section of said openings being smaller than the cross section of the guide wire.

15 The lateral openings known per se in catheters prevent also by their preferred orientation parallel to the axis of the guide wire that the guide wire unintentionally penetrates through one of these openings and impedes a proper handling and positioning of the catheter.

20 Through the lateral openings a thrombolyticum may also be injected during the fragmentation process or in connection therewith, which thrombolyticum supports the dissolution of the thrombus medicinally. When the guide wire is positioned a so-called Y - rotation adaptor is connected at the proximal catheter end, handle end or motor end. The adapter does not impede the rotation of the
25 catheter, it seals the guide wire with respect to the proximal adaptor end and it allows injection of the thrombolyticum through a lateral inlet.

30 Finally, according to another embodiment of the invention a thread, one end of which protrudes from the proximal end of the catheter, is passed through the catheter, leaves at the distal end of the catheter, is introduced again in the catheter through an opening and protrudes likewise with its other end from the proximal end of the catheter.

35 By this embodiment the loop formed from the bent distal end segment of the catheter may be stabilized by means of a tightening of the two proximal wire ends, which

improves the cutting effect of the bent segment on an embolus.

In the drawing examples of embodiments of the apparatus according to the invention is shown schematically and will be explained in further detail in the following. In the drawing

Fig. 1 shows the distal end segment of the apparatus

- 10 A in unbent condition of the catheter with a guide wire protruding from its end
- B the catheter according to A, but with withdrawn guide wire
- 15 C the catheter according to B, but after advancing of the guide wire,

Fig. 2 shows the proximal end of the apparatus

- 20 A with a handle threaded onto the catheter
- B with an electromotor connected with the catheter,

25 Fig. 3 shows the apparatus according to Figs. 1 A - C with a thread running through the catheter lumen

- A when the catheter is straightened by the guide wire
- 30 B after withdrawal and renewed advancing of the guide wire and tightening of the thread, and

Fig. 4 shows angled catheter tips for facilitating examination of the right ventricle of the heart and the pulmonic artery.

35

The apparatus consists substantially of a torsionally

stiff or stable catheter 1 and a guide wire 2, which forms the rotational axis of the catheter 1, which at its proximal end is provided with a handle or a motor (cf. Fig. 2). Torsionally stiff catheters are well known in the prior art and may e. g. be manufactured by embedding a wire braiding in the catheter wall.

At the introduction in the artery system and during advancing to the right heart atrium the catheter 1 is positioned in the straightened condition on the guide wire 2, shown in Fig. 1. The guide wire protrudes with a portion from the distal end 3 of the catheter 1. When the guide wire is withdrawn, the distal end segment of the catheter 1 enters by elastic restoring forces into the loop configuration 6 shown in Fig. 1 B. This configuration is preferably oval, the small diameter d being from 7 to 10 mm and the big diameter D two or three times as big as d . In this configuration the right part of the heart and the pulmonal artery can be examined without problems. After positioning of the catheter loop 6 in the lung flow path an angiography may be carried out. Contrast agent comes out of lateral openings 5 for contrast agent and causes a regular contrasting of the artery lumen. After location of the embolus the guide wire 2 is pushed through the catheter 1 and leaves the interior of the catheter through an opening 4 positioned in line with the centre axis of the catheter 1, as shown in Fig. 1 C. The catheter loop 6 hereby retains its shape. The guide wire 2 is in order to stabilize the positioning of the catheter 1 pushed past the embolus and towards the periphery, while the loop is placed in the area of the embolus. By means of the handle or the electromotor at the proximal end the catheter 1 with the loop 6 is made to rotate. The guide wire 2 serves in this connection as a stationary rotational axis. The embolus is fragmented by means of the loop 6, as due to the torsional stability of the catheter the movement of rotation exerted thereon is transferred to the loop 6. The opening 4 is dimensioned so that the guidewire can pass through the

opening when the distal end segment is loopshaped. The opening 4 only needs to be slightly larger than the cross-section of the guidewire. When the distal end segment is in the straightened shape, the opening 4 preferably has an oval shape with its major axis extending in parallel with the longitudinal axis of the catheter.

By using a guide wire 2 with a movable core and J-tip with narrow bending, the loop 6 of the catheter 1 may once again become straightened by renewed advancing of the guide wire 2 with resilient distal end segment of the guide wire 2, as the guide wire 2 with resilient narrow bending during advancing follows the course of the central axis of the catheter also in the area of the catheter segment with the opening 4, so that the guide wire tip passes the opening and is moved into the bent distal end segment of the catheter. Then the movable core may be advanced and the distal end segment straightened. Such a handling may be necessitated for a repositioning or for a further peripheral examination with the catheter. By alternatively advancing the guide wire 2 with stiff distal end, it comes out through the opening 4 of the catheter.

During or after fragmentation thrombolyticum may be introduced directly in the embolus through the openings 5 or may be injected in the flow area containing the fragments.

According to Fig. 3 a thin, non-stretch thread 7 is passed through the interior of the catheter and comes out at the distal end of the catheter 1 and returns to the interior of the catheter through an opening 8 and runs back to the proximal end of the catheter 1. If the thread 7 is tightened, the loop 6 according to Fig. 3 B is stabilized by anchoring of the catheter distal end opposite the opening 8.

An angling of a distal end segment of the catheter 1, as shown in Fig. 4, facilitates the examination of the right heart ventricles and the central pulmonal arteries.

The braiding in the catheter wall may preferably

extend to a position just proximal of the opening 4, leaving the bendable distal segment of the catheter free of such braiding. The distal end segment is by well known techniques set in the desired loop shape, and the elastic properties of the segment allows it to be straightened by the guide wire.

It is alternatively possible to let the braiding partially extend into the bendable distal end segment in the area at the inside of the bending in order to strengthen the catheter at the transition from the proximal to the distal side of the opening 4. In this case the braiding extending into the bendable distal end segment may also be preset in the shape of the loop 6.

P A T E N T C L A I M S

1. An apparatus for fragmentation of a lung embolus,
c h a r a c t e r i z e d by a torsionally stiff or stable
5 catheter (1) and a guide wire (2), a distal end segment of
the catheter (1) being provided with a bending which is
controlable through the guide wire (2), said bending being
on the outer side provided with an opening (4) which is in
line with the central axis of the catheter (1), which
10 opening in a projection on a plane normal to the central
axis of the catheter has a cross-section adapted to the
cross-section of the guide wire (2).
2. An apparatus according to claim 1, c h a r a c t e r -
i z e d in that a free end of the bending (6) points
15 towards the central axis of the catheter (1) and that the
bending is made into an oval loop (6).
3. An apparatus according to claim 2, c h a r a c t e r -
i z e d in that the small diameter (d) of the loop (6) is
approximately 7 to 10 mm and the big diameter (D) of the
20 look (6) is two or three times as big as the small diameter
(d).
4. An apparatus according to any of claims 1 to 3,
c h a r a c t e r i z e d in that openings (5) are
arranged in the distal end segment of the catheter (1), the
25 cross section of said openings being smaller than the cross
section of the guide cord (2).
5. An apparatus according to anyone of claims 1 to 4,
c h a r a c t e r i z e d in that a thread (7), one end of
which protrudes from the proximal end of the catheter, is
30 passed through the catheter (1), leaves at the distal end
of the catheter (1), is introduced again in the catheter
(1) through an opening (8) and protrudes likewise with its
other end from the proximal end of the catheter (1).

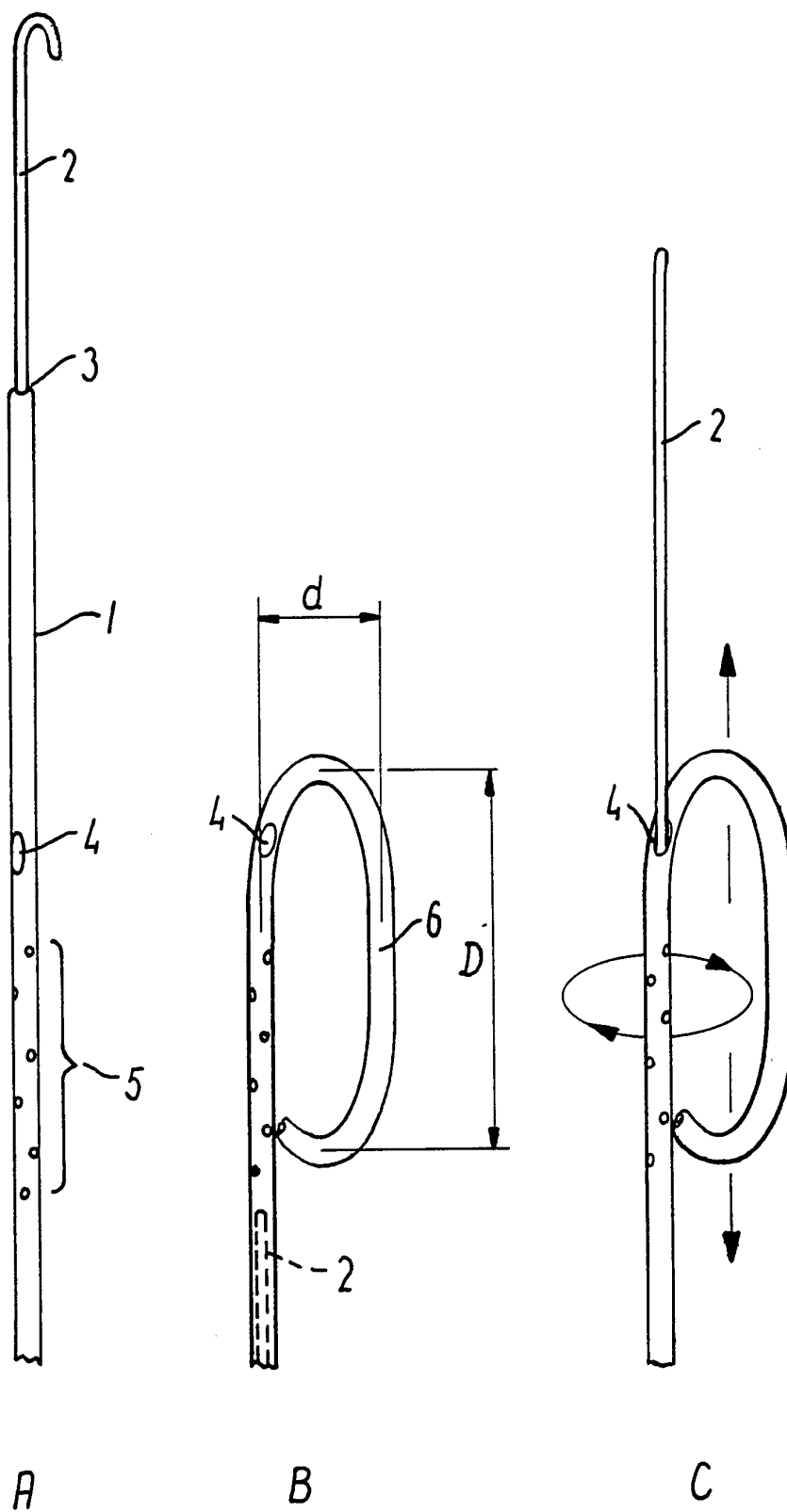
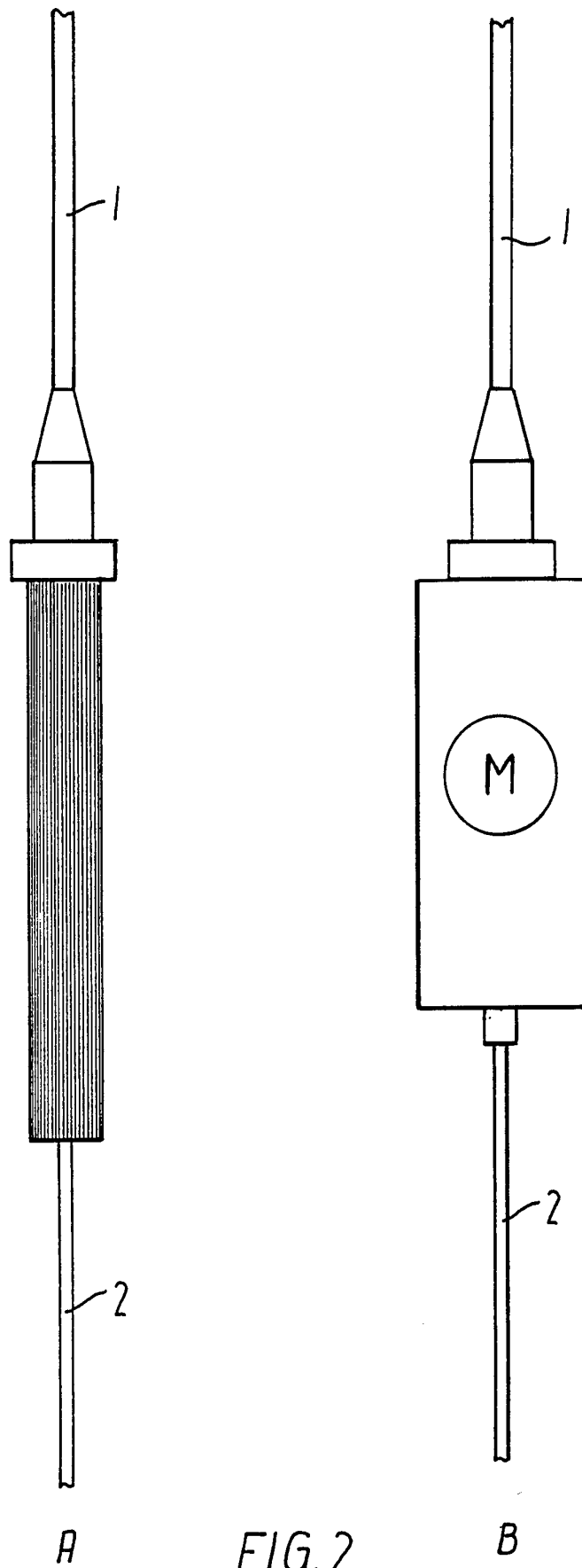


FIG. 1



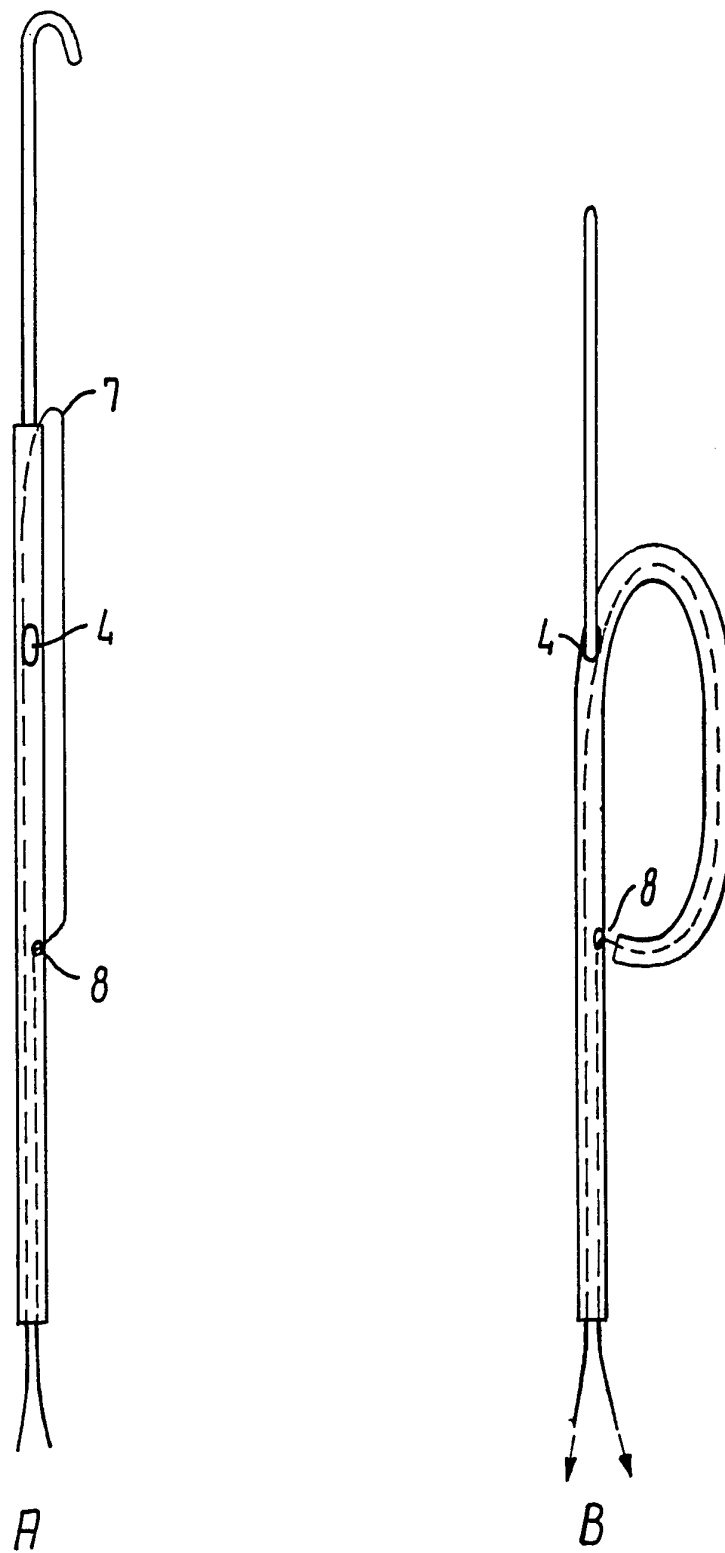


FIG. 3

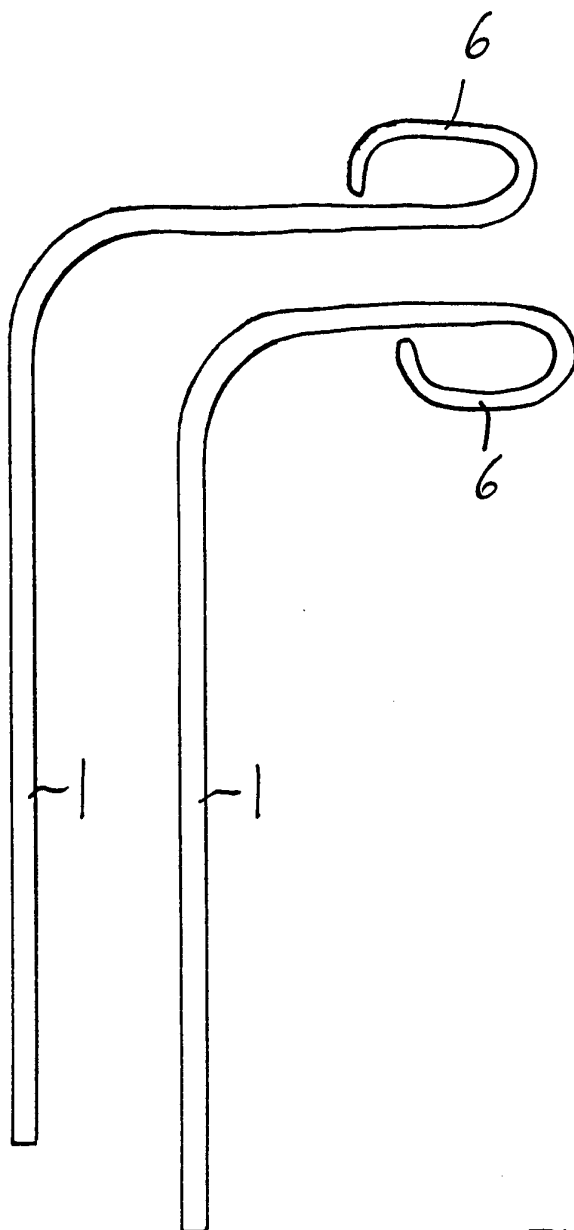


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 95/00248

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9313820 A1 (BROWN, STEPHEN), 22 July 1993 (22.07.93) --	1
A	EP 0123175 A1 (KORTH, KNUT), 31 October 1984 (31.10.84) --	1,5
A	DE 688834 C (LUDWIG ZEISS), 2 March 1940 (02.03.40) --	1,5
A	DE 3309052 A1 (SCHLAMMINGER, LUDWIG), 20 Sept 1984 (20.09.84), claim 2 --	4

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9203098 A1 (WILLIAM COOK EUROPE A/S), 5 March 1992 (05.03.92) --	
A	US 3119392 A (KARL-LUDWIG ZEISS), 28 January 1963 (28.01.63) --	
A	US 5201741 A (DULEBOHN), 13 April 1993 (13.04.93) -- -----	

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/10/95

International application No.

PCT/DK 95/00248

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 9313820	22/07/93	AU-A- 3262693 GB-A- 2277271 GB-D- 9413452	03/08/93 26/10/94 00/00/00
EP-A1- 0123175	31/10/84	DE-A- 3313895 DE-A- 3408661	25/10/84 24/10/85
DE- C- 688834	02/03/40	NONE	
DE-A1- 3309052	20/09/84	NONE	
WO-A1- 9203098	05/03/92	AU-A- 8427191 DE-A, C- 4025825 EP-A, B- 0543862 ES-T- 2061264 US-A- 5330484	17/03/92 20/02/92 02/06/93 01/12/94 19/07/94
US-A- 3119392	28/01/63	NONE	
US-A- 5201741	13/04/93	NONE	