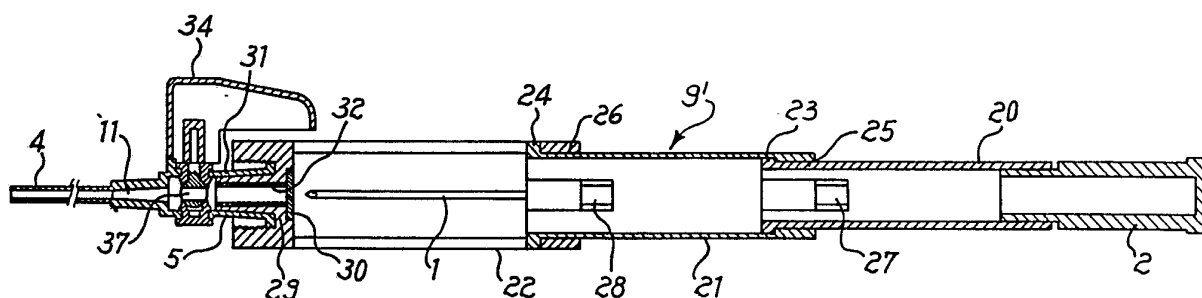




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/EP92/02458 (22) International Filing Date: 28 October 1992 (28.10.92) (30) Priority data: MI91A002897 31 October 1991 (31.10.91) IT (71) Applicant (for all designated States except US): INDUSTRIA PRODOTTI MEDICINALI I.P.M. S.R.L. [IT/IT]; Viale Aldo Moro, 32, I-24054 Calcio (IT). (71)(72) Applicants and Inventors: MASTRONARDI, Pasquale [IT/IT]; Via S.Stefano, 23, I-80127 Napoli (IT). ROSSI, Antonio, Ercole [IT/IT]; Via Giotto, 60, I-81031 Aversa (IT). FRAGANZA, Fiorentino [IT/IT]; Via Libertà, 6, I-81030 Cancellò Arnone (IT).		(74) Agent: MINOJA, Fabrizio; Studio Consulenza Brevettuale, Via Rossini, 8, I-20122 Milano (IT). (81) Designated States: AU, BB, BG, BR, CA, CS, FI, HU, JP, KP, KR, LK, MG, MN, MW, NO, PL, RO, RU, SD, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: NEEDLE CATHETER WITH SAFETY DEVICE**(57) Abstract**

A needle catheter particularly for endovasal use, including a needle-guide or metallic mandrel (1) fitted with an end grip (2), and a catheter (4) with end casing (5). Between the end grip (2) of the metallic needle (1) and the casing (5) of the catheter (4), there is an extensible element (9), (9') acting as a cover for the metallic needle (1) after its extraction and with at least one means of blockage (10), (10'), (33) of interception and/or of needle (1) blockage being foreseen in the casing (5) of the catheter, movable from a position where it does not obstruct the lumen (11) of the catheter, to a position where it occludes the lumen.

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NEEDLE CATHETER WITH SAFETY DEVICE

This invention concerns a needle catheter to be placed in the lumen of a blood vessel, for example for the administration of anaesthetics drugs or drips or for similar uses and equipped with a safety device, in particular against possible injury to the user or to other personell.

A needle catheter consists of a needle-guide or metallic mandrel enclosed in a catheter made of plastic material. In practice, the whole is inserted in the blood vessel like a normal needle and then the metallic needle-guide is extracted, to allow, for example, a drip to be connected to the catheter for administration to the patient.

This type of needle catheter is superseding ordinary metallic needles because of its indisputable advantages among which are: ease of endovasal positioning, greater freedom of movement for the patient who can move his limbs without danger of damaging the blood vessel and longer lasting patency.

However, two major disadvantages must be added to these qualities and these represent a potential danger of transmission of infective pathology.

These disadvantages are connected with the extraction of the needle-guide or metallic mandrel for the connection of the catheter to a drip or other device and the consequent bleeding.

Whereas it is possible to protect oneself from the blood flow by using gloves for example and thereby considerably reducing the risk of contagion, this is

not possible, either during the extraction of the metallic needle or later on, so that it is easy to be pricked and possibly infect oneself because surgical gloves are by no means imperforable.

5 The object of the invention is to eliminate these disadvantages, and in particular the risk of injury to the user or other personell with the metallic needle-guide.

10 This objective is achieved, by the means of the invention, in providing an extending cover element, joining the end grip of the needle-guide to the casing of the catheter, in such a way as to cover the needle when this is withdrawn from the catheter, a means of blocking being provided to fix the metallic needle in
15 the withdrawn position as well as a means of interception to prevent the outflow of blood.

 This extensible cover, best takes the form of telescopic sections or of an elastic element such as a bellows.

20 A flexible lateral branch for joining to a drip or other item can be fixed to the catheter at a point above the said means of interception.

 This means of interception and possibly of blocking can take the form of an adjustable vane in
25 appropriate guides set in the body of the catheter, in such a way as to create a barrier in the lumen of the catheter when it is lowered.

 Alternatively a ball can be set in an appropriate space in the casing of the catheter and which is forced
30 into the lumen thus occluding it.

 Again, a tap can be provided, consisting of a ball

valve or other equivalent means, actioned by an external lever.

The needle once extracted can remain in situ, inside the extensible element which remains attached to the catheter. It is however better to completely remove
5 the needle-guide together with the extensible covering element.

Further features of the invention will be clarified by the detailed description which follows and
10 which is simply an example and therefore not limitative in its application. It is illustrated by the enclosed drawings of which:

Figure 1 represents a lateral schematic view, partly in section, of a needle catheter complete with the safety
15 device according to the invention, in its first form of construction, before retraction of the metallic needle-guide.

Figure 2 is the same view as Figure 1 but with the needle-guide retracted.

20 Figures 3A and 3B are enlarged schematic sections at the point of the adjustable vane which is shown in the open and closed positions respectively.

Figures 4 and 5 show similar views to Figures 1 and 2 and illustrate a second form of construction for the
25 invention.

Figures 6 and 7 again show similar views to Figures 1 and 2 and illustrate a third form of construction for the invention.

Figures 8 and 9 show yet again similar views to Figures
30 1 and 2 and illustrate a fourth form of construction for the invention.

Figure 10 represents a lateral view in section of a fifth and preferred form of construction of the needle catheter according to the invention and before the withdrawal of the metallic needle-guide.

5 Figure 11 represents a view, partly in section and which is at an angle of 90° with respect to that of Figure 10.

Figures 12 and 13 represent similar views to Figures 10 and 11 respectively but with the needle-guide retracted.

10 Figure 14 represents an exploded view of the part of the needle catheter illustrated in Figure 12.

Referring firstly to Figures 1 and 2, the needle catheter according to the first construction form of the invention comprises a needle-guide or metallic mandrel (1) fitted with an end grip (2) closed by a threaded plug (3) and a catheter (4) surrounding the needle (1) and provided at the top end with a grip or casing (5) to which a flexible lateral branch may be attached (6) for the connection of a drip for example; the branch may be fitted at its extremity with a threaded plug (7) and with temporary closing of the flow (8) in an intermediate section.

20 Between the casing 5 of the catheter 4, and the grip (2) of the metallic needle (1) an extensible elastic element is disposed, in particular a bellows (9) which can be produced by die-casting with the other elements or be soldered at the respective ends.

An adjustable vane (10) is placed in the casing (5) of the catheter (4) above the bellows (9) and is movable from a raised position to a lowered position in

which it occludes the lumen (11) (Figures 2 and 3B).

The functioning of the needle catheter according to the invention is as follows:

Once it has been inserted into the lumen of the blood vessel (Figure 1) the needle guide or metallic mandrel (1) is retracted and the adjustable vane (10) (Figure 2) is lowered, having the form of an inverted "L", and which, in addition to stopping the blood, blocks the needle-guide (1) which thus remains enclosed in the bellows (9) which is attached to the catheter casing (5). In this way, any possibility of contagion is eliminated, either during use of the needle catheter or during its dismantling.

The other forms of construction of the invention are now described, in using the same reference numbers as used in the construction according to Figures 1 and 2, so as to identify equal or similar parts and in adding an apostrophe to these numbers to distinguish and identify corresponding parts.

The construction illustrated in Figures 4 and 5 differs from that in Figures 1 and 2 only by the fact that the means of blocking the metallic needle (1) consists of a ball (10') contained in a pliable housing (13) (like a tablet blister) which allows the ball to escape by simple downward pressure so that it occludes the catheter lumen as shown in Figure 5.

According to the construction shown in Figures 6 and 7, two adjustable vanes (10) are fitted in the casing (5) of the catheter (4) and the casing (5) is divided into two parts in correspondence with the zone included between the vanes and between which parts

there is a screwed, grooved or similar connection, shown schematically in these Figures and indicated by the reference number (12).

Once the catheter (4) has been placed in the vasal lumen, and the needle (1) has been retracted, both of the vanes (10) are lowered and the opposed part of the casing (5) of the catheter to which the bellows (9) are attached, is released (Figure 7). In this way, the metallic needle (1) which stays fixed in the bellows (9) can be completely removed and disposed of.

The construction illustrated in Figures 8 and 9 corresponds substantially to that of Figures 6 and 7, with the sole difference that in this case, a simpler needle catheter is shown which does not have the flexible lateral connection (6).

For the administration of a drip or for other uses, a small auxiliary tube can be provided with one end screwed or grooved so as to be able to connect with the end of the part of the casing (5) which remains attached to the catheter (4).

The construction illustrated in Figures 10 to 14 differs from those described above principally by the fact that the extensible element, indicated globally by reference number (9'), is of the telescopic type and comprises three tubular elements (20), (21), (22) which insert one inside the other. The most internal element (20) is attached to the grip (2) of the needle (1) whereas the most external element (22) can be fixed to the casing (5) of the catheter (4).

The maximum telescopic extension of the group (9') is determined by the stop pegs (23), (24), protruding

externally from the elements (20), (21) which engage respectively with pegs (25), (26) protruding internally from the elements (21), (22).

5 The blocking of the telescopic group in the condition of maximum extension is assured by elastic stop tongues (27), (28) set in the walls of the elements (20), (21) which bear on the posterior edges of the tubular elements (21), (22) respectively.

10 The most external tubular element (22) can be fixed to the casing (5) of the catheter by a screw thread as is shown on the attached sketch or by other suitable means, for example by a groove. A small holed plate is placed near the front end of element (22) holding internally a rubber stop (30) and extending
15 externally (from the catheter (4)) with a spigot (31) which inserts into the casing (5) of the catheter (4).

The rubber stop (30) made of natural rubber, polystyrol or similar) is penetrated by the needle (1) before use (Figures 10 and 11) and closes up again when
20 the needle is retracted (Figures 12 and 13) to prevent blood from running out.

At least one internal part (32) of the spigot (31) is in spongy material to absorb the few drops of blood which might remain on the outside of the rubber stop
25 (30) when the needle (1) is withdrawn.

A tap consisting of a ball valve (33) and operated by an external lever (34) is foreseen in the casing (5) of the catheter (4). The ball valve (33) is placed between two opposing ferrules (35), (36) and has an
30 internal lumen (37) for the passage of the needle and of any liquid which may be administered to the patient.

When the needle is retracted by turning the lever (34) through 90°, the ball (33) occludes the lumen (11) of the casing (5) of the catheter and any outflow of blood is cut off.

5 Instead of the ball valve tap, another flow deviation means may be used, such as a tap placed inside the casing (5) of the catheter so as to be coaxial with the catheter itself, allowing the flow of liquids or of the metal needle-mandrel in one position
10 and closing the passage when rotated of 90°.

 In using the needle catheter according to this construction, when the needle has been retracted as shown in Figures 12 and 13, the ball valve (33) is closed by rotating the lever (34) through 90° and the
15 telescopic group (9') containing the needle (1) is removed. When this is done, a tube for the administration of a drip or similar is connected to the top of the casing (5) of the catheter (4), and the valve (33) is re-opened by rotating the lever (34).

20 Naturally, even in this case a flexible lateral connection (6) can be made, joined to the casing (5) of the catheter (4) above the ball valve (33). In this case it is possible to leave the telescopic group (9') in situ during use.

25 It is evident that some of the methods introduced in the construction according to Figures 10 to 14, such as, for example, the flow interception valve (33), could also be used in the previously illustrated constructions in substitution of items with the same
30 function and vice versa.

 Figures 10 to 13 also show a cap (38) for the

protection of the catheter (4) before use.

From what has been written above, it is clear the invention fulfils the defined objective in eliminating any risk whatever that the metallic needle guide could prick the user of the needle catheter according to the invention or prick the waste disposal workers. It likewise blocks the flow of blood after the extraction of the metallic needle.

CLAIMS

1. Needle catheter particularly for endovascular use, including a metallic needle-guide (1), with an end grip (2) and a catheter (4) with related grip or end casing (5) covering the needle (1) and characterized by the fact of having an extensible element (9), (9'), situated between the grip (2) of the needle (1) and the casing (5) of the catheter (4), in such a way as to cover the needle (1) when this is retracted; also by the fact of having a blocking system (10, (10'), (27), (28) for the needle (1) in the retracted position, as well as the means (10), (10'), (33) of intercepting the flow in the lumen (11) of the casing (5) of the catheter (4).
2. Needle catheter according to claim 1, in which the said extensible element (9') consists of a telescopic group including several tubular elements (20), (21), (22) insertable one in the other.
3. Needle catheter according to claim 2, characterized in that the means of blocking the needle in the retracted position consists of elastic stop tongues (27), (28), set in the walls of the tubular elements (20), (21) or (21), (22) and bearing on the ends of the adjacent elements (21), (22) or (20), (21), and in that stop means (23, 24; 25, 26) are provided for limiting the maximum extension of the tubular elements (20, 21, 22).
4. Needle catheter according to claims 2 or 3, characterized in that a rubber stop (30) closure is provided, near the end of the telescopic group (9) and

attached to the casing (5) of the catheter (4), and in that at least a part (32) in spongy material is provided near the rubber stop (30).

5 Needle catheter according to claims 2 to 4 and characterized by the fact that the said telescopic group (9') is fixed to the casing (5) of the catheter (4) in a movable fashion.

6. Needle catheter according to claim 1 and characterized by the fact that the said extensible
10 element (9) is an elastic element such as a bellows.

7. Needle catheter according to any of the preceding claims and characterized by the fact that the said means of intercepting the flow in the lumen (11) of the casing (5) of the catheter (4) and/or of blocking the
15 needle (1) in the retracted position, consists of a tap (33) operated through a lever (34), between a position in which it does not obstruct the lumen (11) and a position where it occludes the lumen.

8. Needle catheter according to any of the claims from
20 1 to 6 and characterized by the fact that the said means of intercepting the flow and blocking the needle (1) consist of an adjustable vane (10) movable from a raised position in which it does not obstruct the lumen (11) of the casing (5) of the catheter, to a lowered
25 position in which it occludes the lumen.

9. Needle catheter according to any of the claims 1 to 6 and characterized by the fact that the said means of interception of the flow and blocking of the needle (1) in the retracted position consist of a ball (10'),
30 contained in a housing (13) in the casing (5) of the catheter (4) and movable into the lumen (11) of the

casing (5) by simple pressure.

10. Needle catheter according to any of the claims 6 to 9 and characterized by the fact that two means of blocking are provided (10), (10'), (33), between which
5 the casing (5) of the catheter (4) is separated into two parts, held together by a screw thread, by grooves or by similar means.

11. Needle catheter according to any of the preceding claims and characterized by the fact that a flexible
10 lateral connection (6) is provided above the said means of interception and/or blocking which are in the casing (5), or a further inlet cone connectable to a syringe or to a drip, using a 3 way valve.

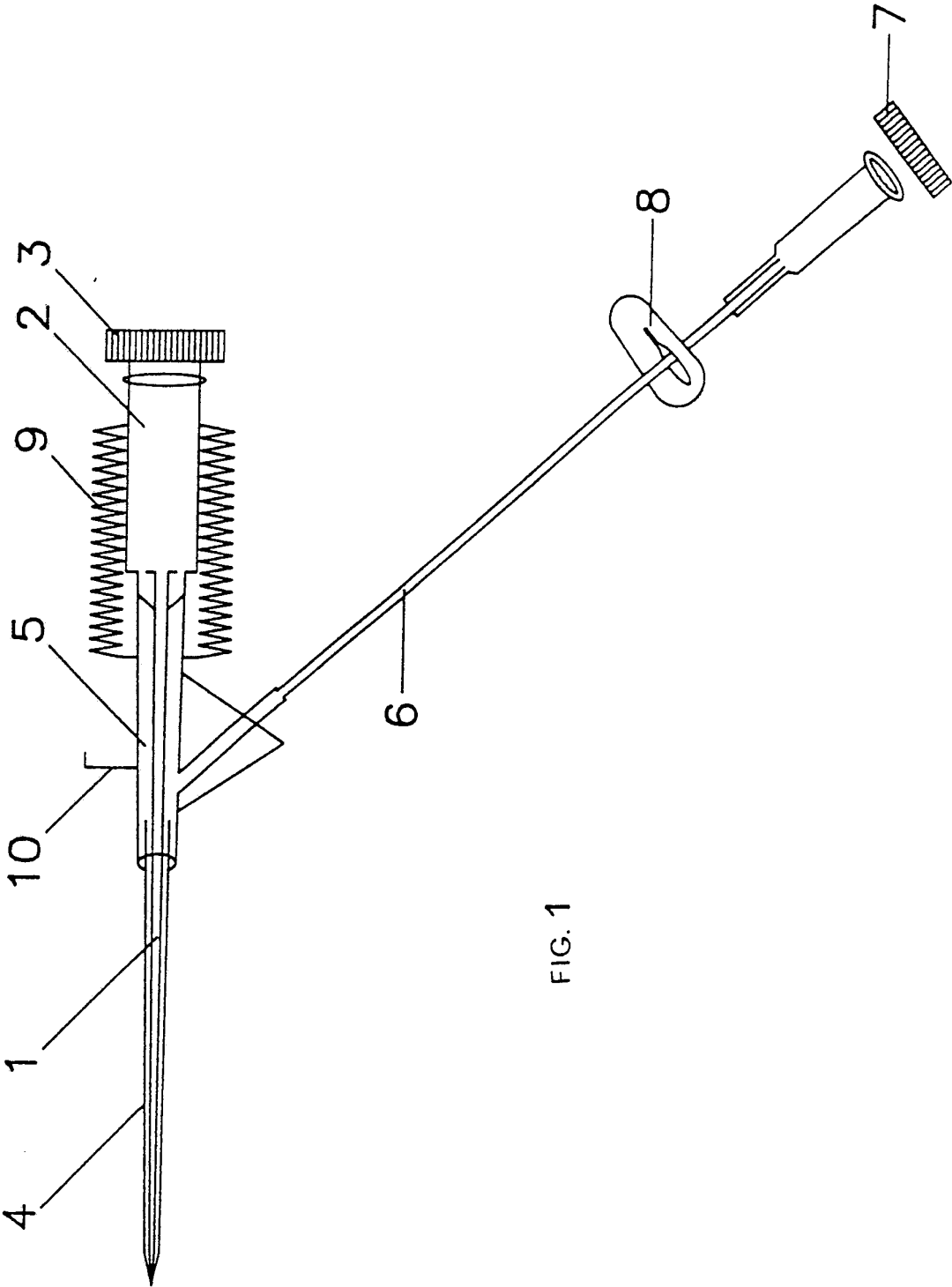
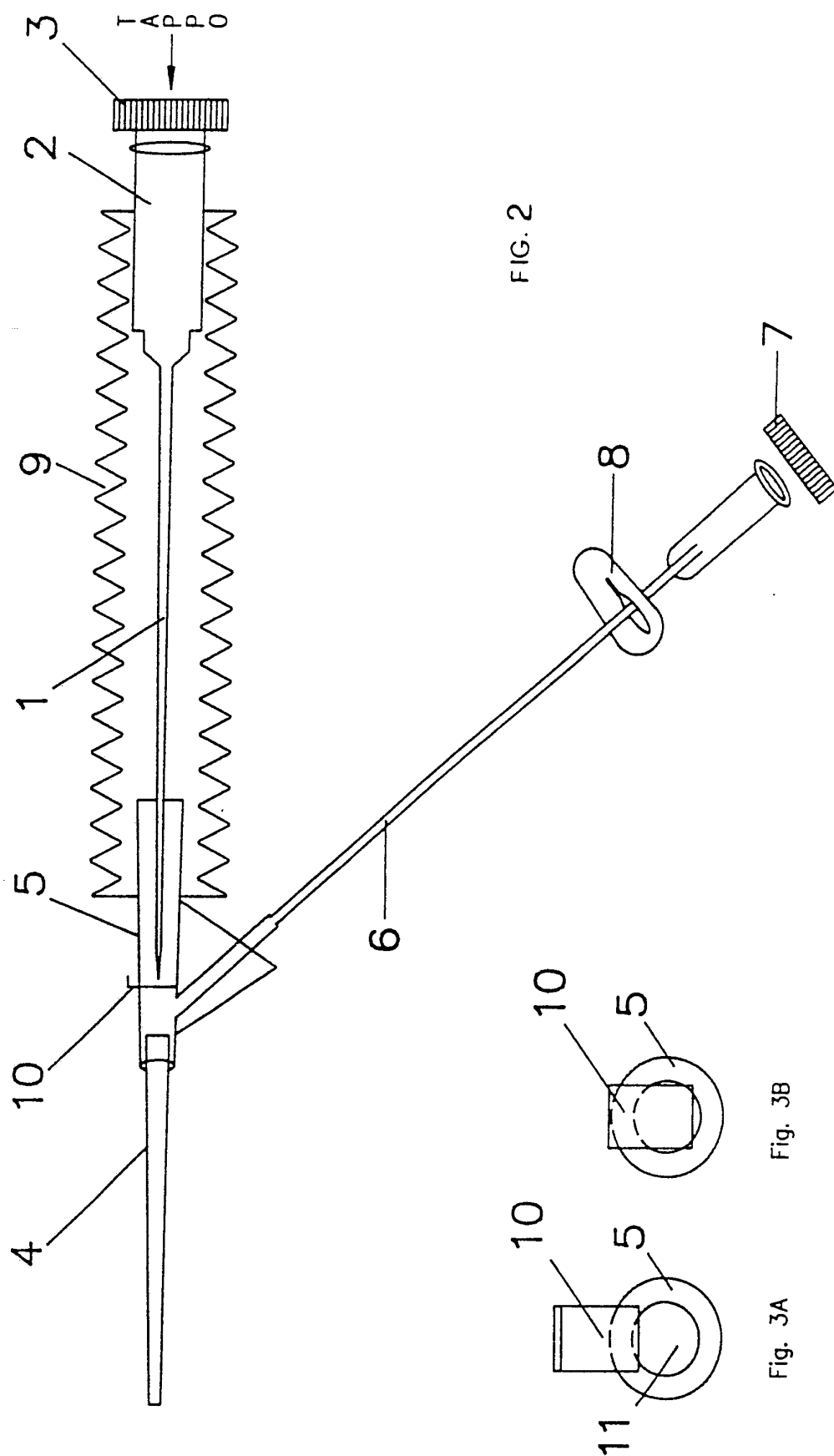


FIG. 1

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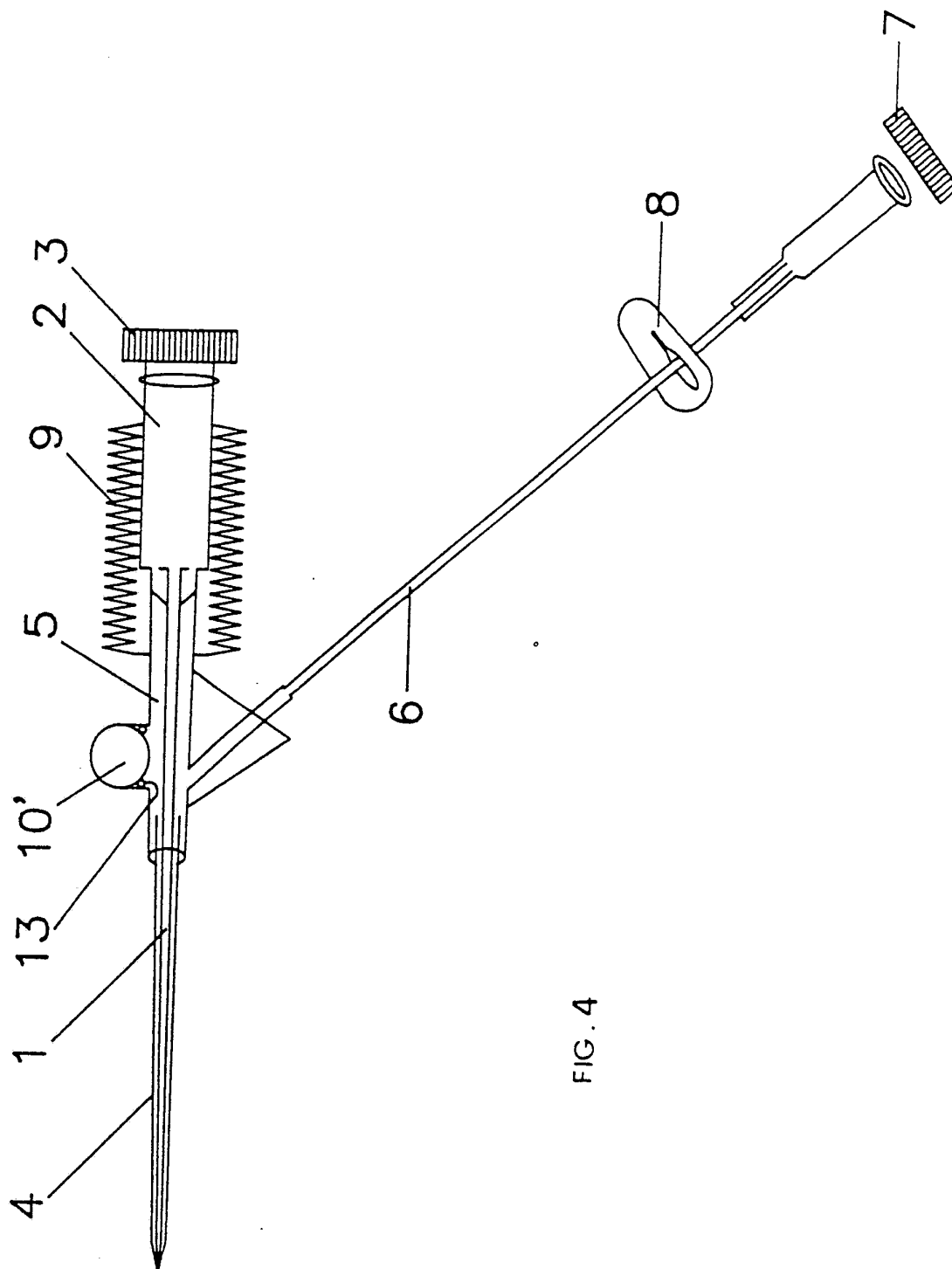


FIG. 4

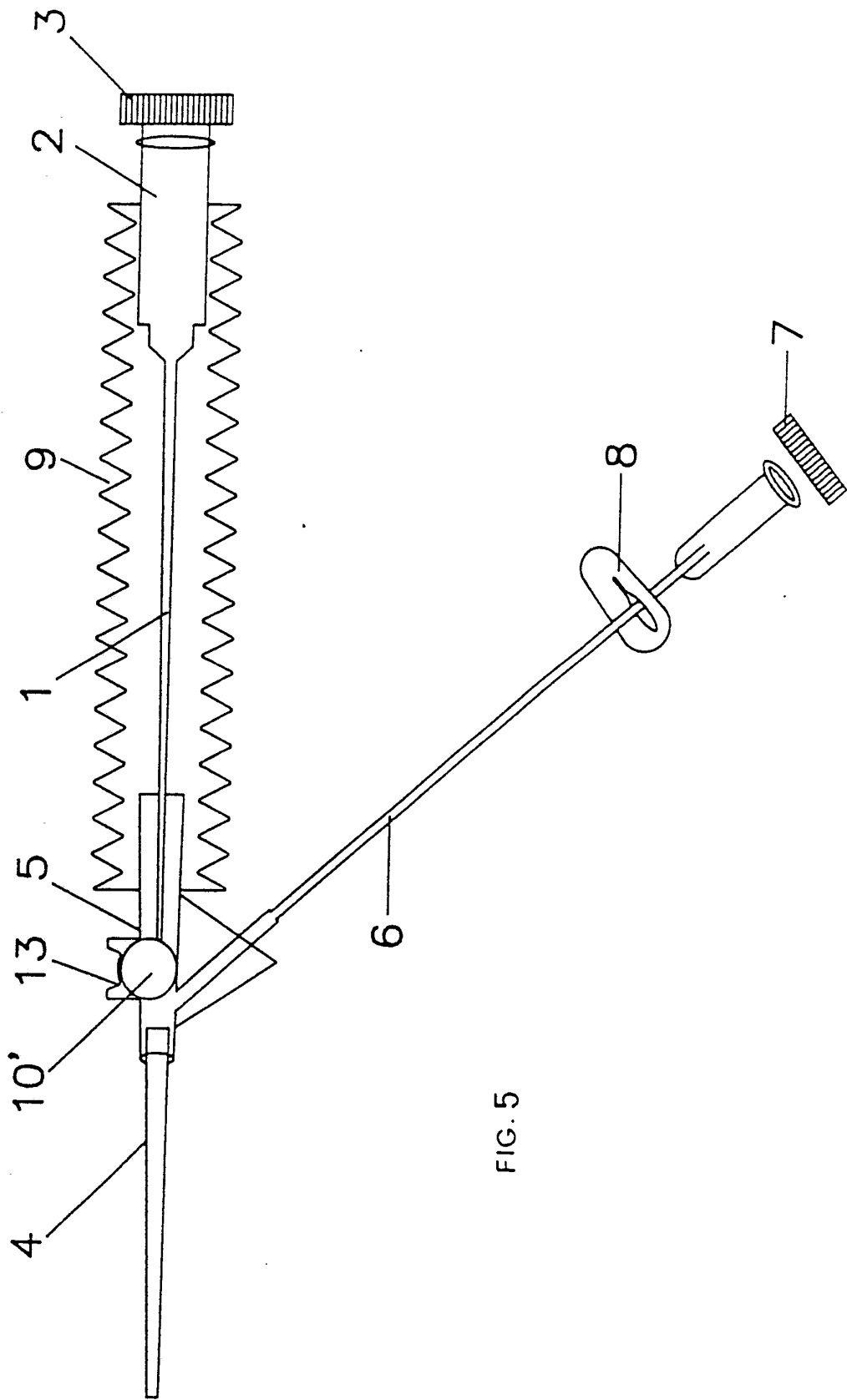


FIG. 5

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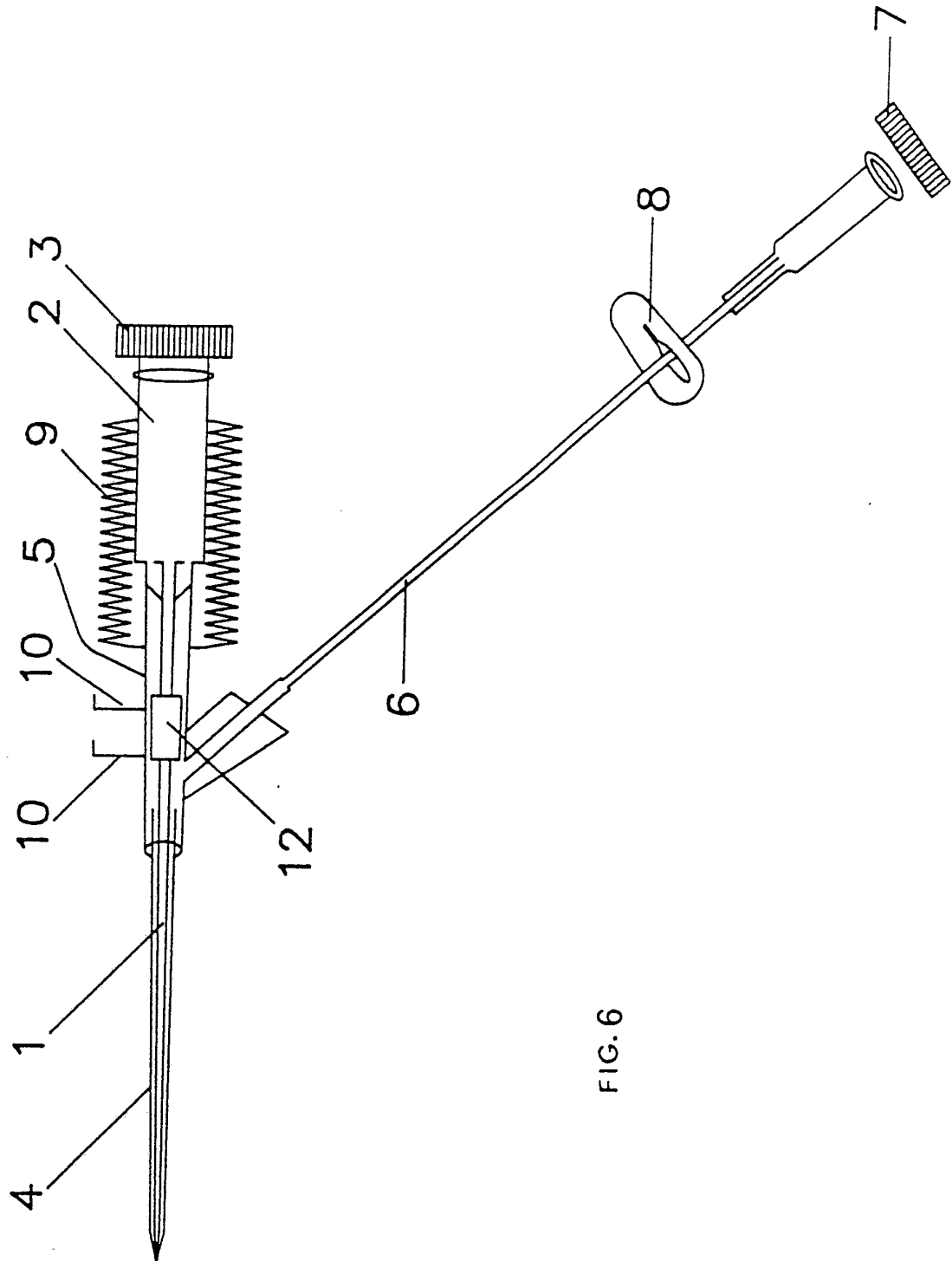


FIG. 6

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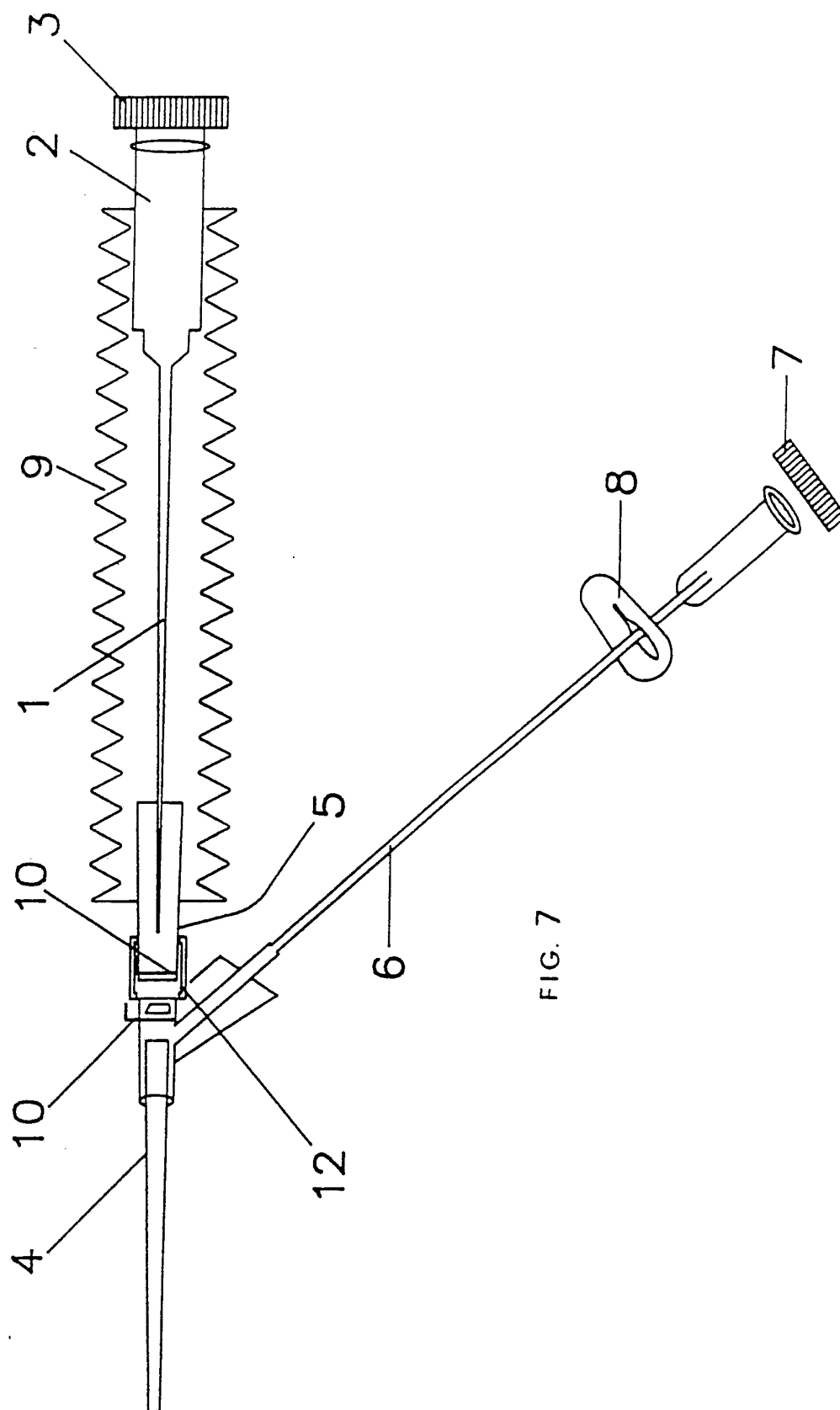


FIG. 7

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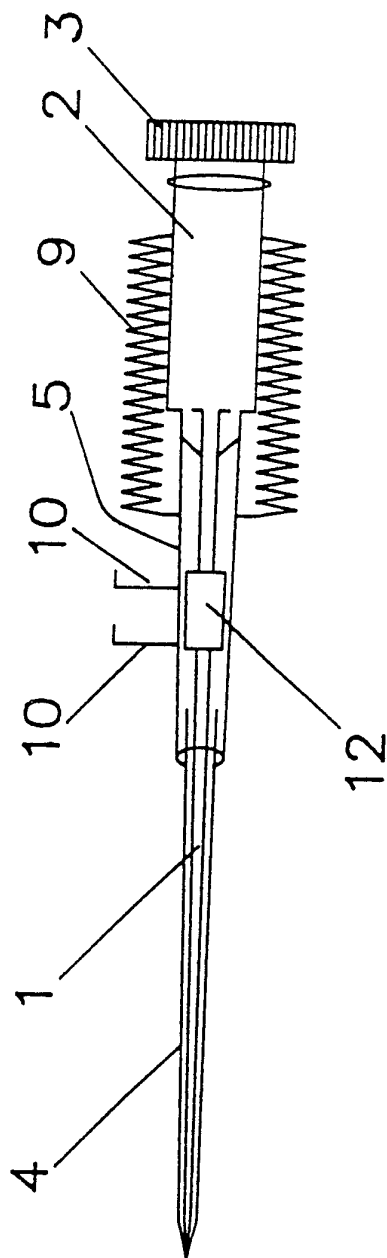
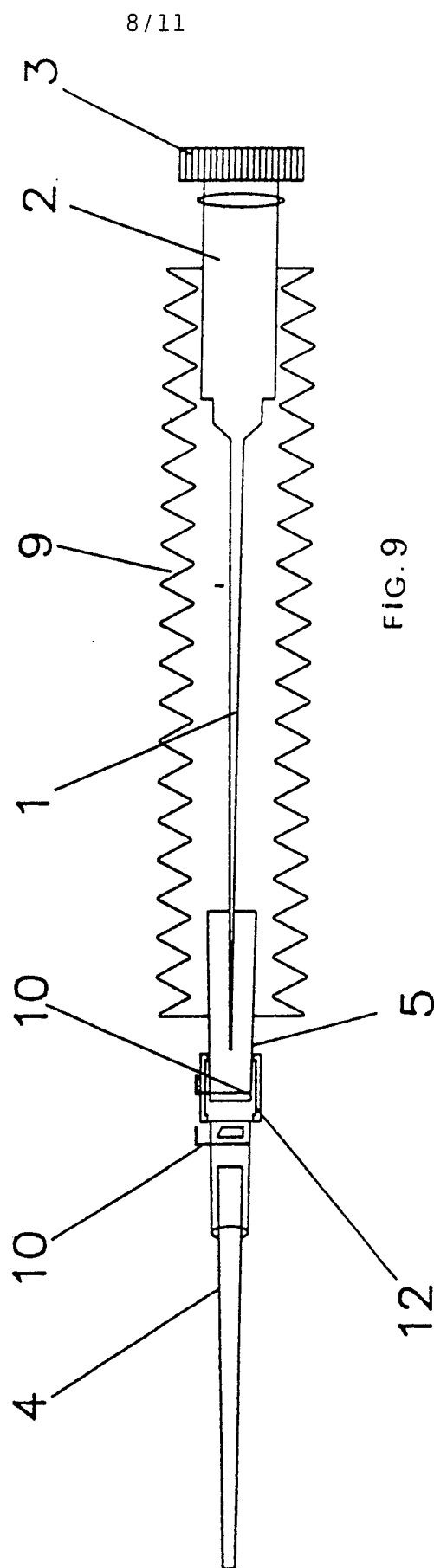


FIG. 8



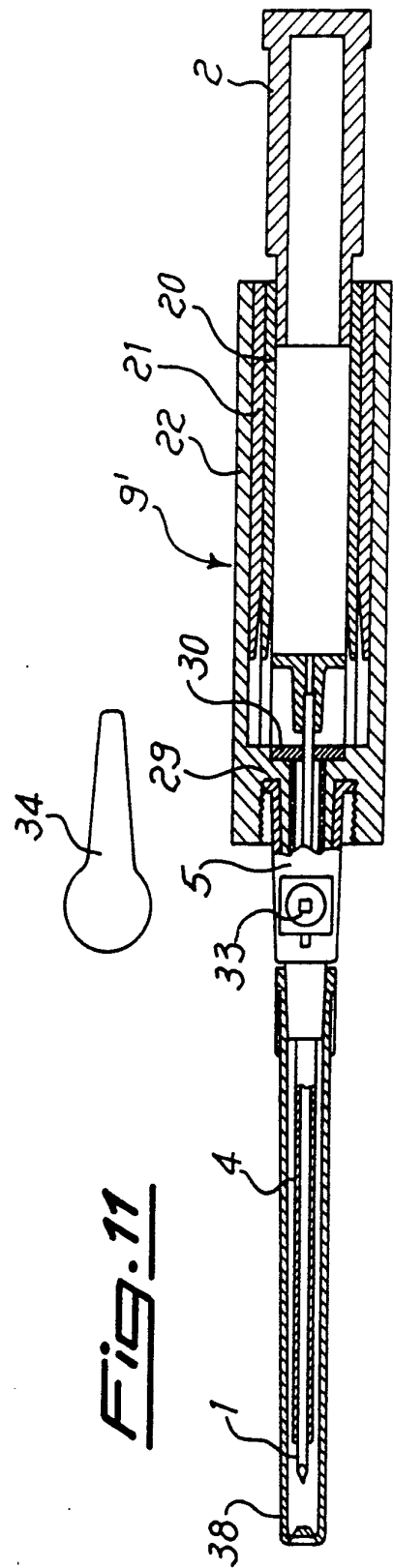
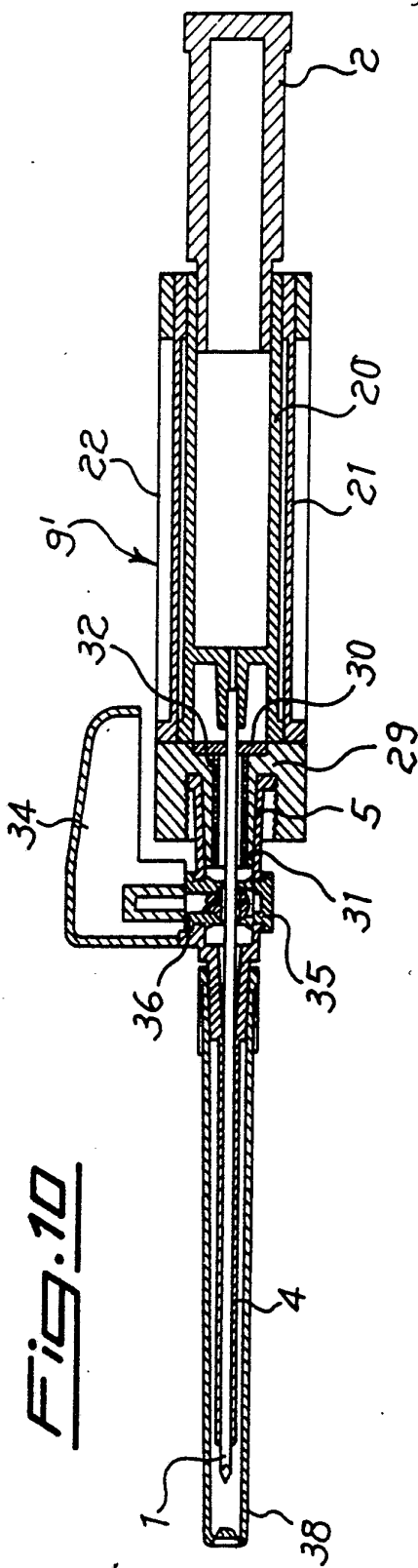


Fig. 12

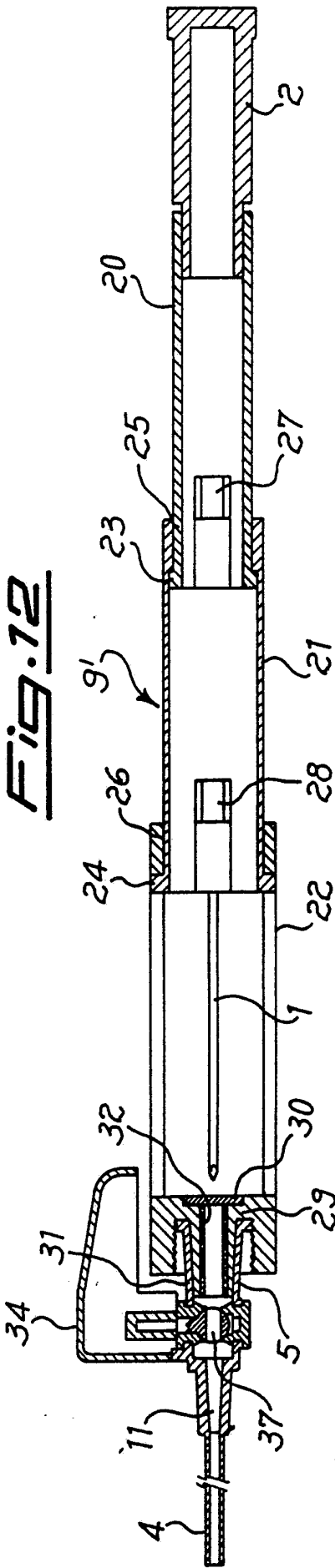
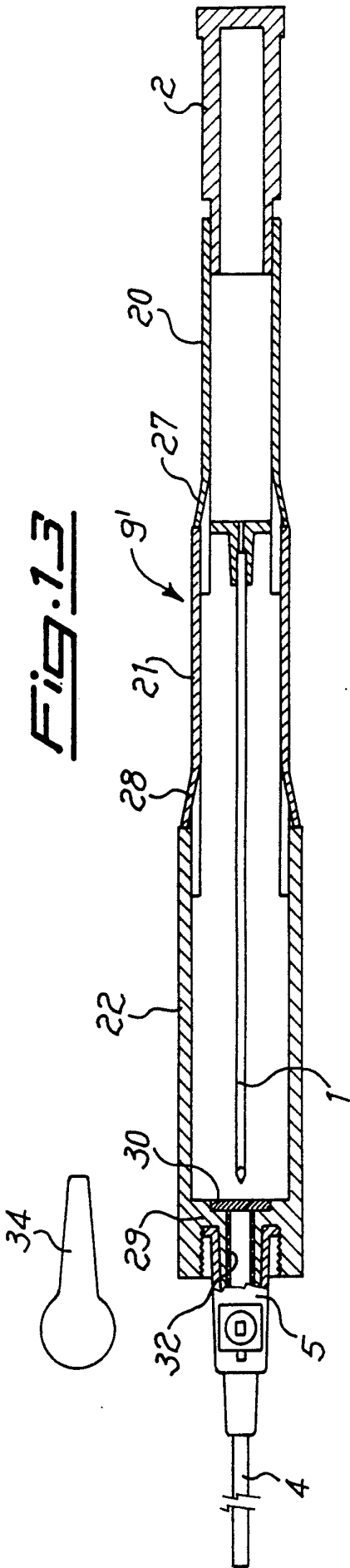


Fig. 13



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Fig. 14

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 92/02458

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M25/06; A61M39/00		
II. FIELDS SEARCHED		
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Classification System	Classification Symbols	
Int.Cl. 5	A61M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	EP,A,0 449 510 (CRITIKON, INC) 2 October 1991 see column 2, line 4 - line 54 see figures 1-5	1, 11
Y	---	6
A	---	10
Y	US,A,4 160 450 (DOHERTY) 10 July 1979 see column 4, line 3 - line 58 see figures 4-7	6
Y	---	1-3, 5, 8
Y	US,A,4 944 728 (CARRELL ET AL.) 31 July 1990 see column 3, line 38 - column 5, line 38 see column 7, line 22 - line 33 see figures 1-5, 9	1-3, 5, 8
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
15 JANUARY 1993	04. 02. 93	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	SCHOENLEBEN J.	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category ^a	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y	EP,A,0 194 886 (CRITIKON LTD) 17 September 1986 see page 15, line 17 - page 18, line 35 see figures 10-15 ---	1-3,5,8
A	DE,A,2 636 812 (LAUBE) 23 February 1978 see page 2, line 1 - page 3, line 11 see figure 1 ---	7
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A	US,A,5 051 109 (SIMON) 24 September 1991 see figures 1-8 ---	1
A	US,A,4 755 170 (GOLDEN) 5 July 1988 see column 1, line 63 - line 66 see column 6, line 56 - column 7, line 11 see figures 8,29,30 -----	4

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

EP 9202458
SA 66709

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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15/01/93

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